Appendix

Master of Science Thesis

The design and development of a Low Field MRI scanner
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Biomedical Engineering | Integrated Product Design
Delft University of Technology

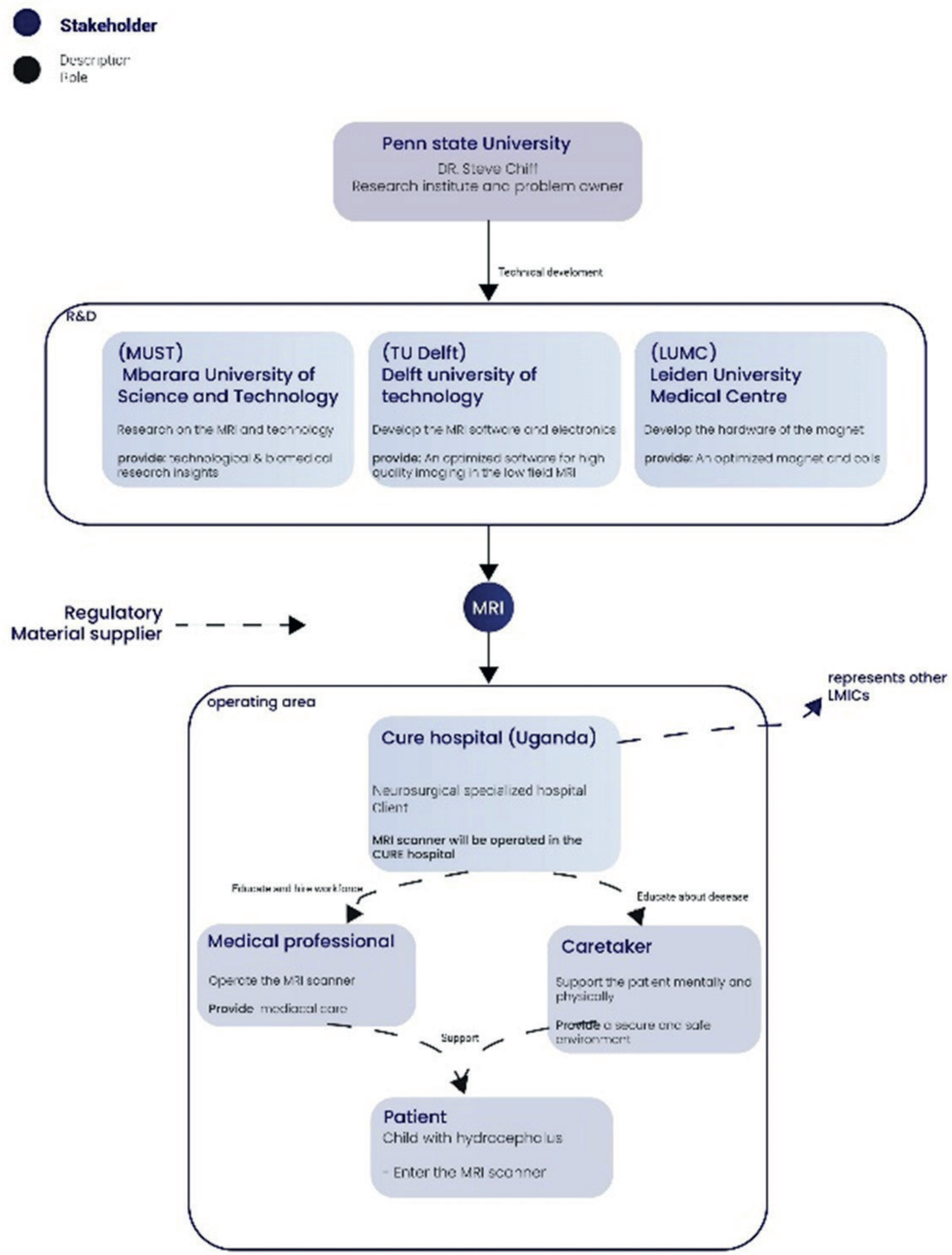
Table of Content

Organizational

Organizational -stakeholders

0. Brief

Figure 1 illustrates the project stakeholder structure of the development of the low field MRI scanner. As can be seen, the project initiative is led by Dr Schiff from the Penn state University. The R&D of the low field MRI scanner Is done by three parties: TU Delft, LUMC and MUST. Once the device is developed it will operate in the Cure Children's Hospital in Uganda, where it will be used by MRI technicians, interact with the patient and caretaker.



DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

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

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

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STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy". Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name: GIESKES 4651
initials: M.T.B. given name: Maite
student number: 4341260
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):
IDE master(s): ★ IPD ◯ DfI ◯ SPD
2nd non-IDE master: Biomedical Engineering - Track 2
individual programme: - - (give date of approval)
honours programme: ◯ Honours Programme Master
specialisation / annotation: ★ Medisign
◯ Tech. in Sustainable Design
★ Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: J.C. Diehl dept. / section: IDE/SDE/DfS
** mentor: Stefan Persaud dept. / section: IDE/SDE/DfS
2nd mentor: Martin van Gijzen ,
organisation: EWI
city: country:

comments (optional):
Double degree.
IDE IPD
3ME Biomechanical Engineering--Supervisor Prof. Jenny Dankelman

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

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

APPROVAL PROJECT BRIEF
To be filled in by the chair of the supervisory team.

chair J.C. Diehl date 08 - 12 - 2020 signature jdiehl Digitally signed by jdiehl Date: 2020.12.08 22:49:24 +01'00'

CHECK STUDY PROGRESS
To be filled in by the SSC E&SA (Shared Service Center, 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: 31 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 31 EC

List of electives obtained before the third semester without approval of the BoE

★ YES all 1st year master courses passed

NO missing 1st year master courses are:

name C. van der Bunt date 15 - 01 - 2021 signature C. van der Bunt Digitally signed by C. van der Bunt Date: 2021.01.15 09:54:10 +01'00'

FORMAL APPROVAL GRADUATION PROJECT
To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: ★ APPROVED NOT APPROVED

Procedure: ★ APPROVED NOT APPROVED

- new version approved, also for Medisign and Entrepreneurship

comments

name Monique von Morgen date 02 - 02 - 2021 signature

TU Delft

Personal Project Brief - IDE Master Graduation

User-centred and sustainable low field MRI scanner for Africa project title

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

start date 02 - 11 - 2020 05 - 07 - 2020 end date

INTRODUCTION **
Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Medical devices serve as the foundation of prevention, diagnostics, treatment of disease and rehabilitation [1]. The gap of the current development of health technologies between High-Income Countries (HIC) and Low and Middle-Income Countries(LMIC) contributes to the global burden of disease and the discrepancy in the distribution and accessibility of medical devices. Therefore the WHO has focused on the need to bridge the gap in access and availability to medical technologies in especially SubSaharan African and Southern Asian countries[4]. According to the WHO, around 70% of medical devices present in low-middle income countries (LMIC) are designed for use in the high-income countries while the majority of the medical devices donated to low-income countries do not function[5]. The MRI scanner is only available for only 10% of the world population, leaving people in Low-middle income countries untreated/undiagnosed. Therefore the research group is introducing a frugal innovation-based MRI scanner specifically to scan children with hydrocephalus. Hydrocephalus is a medical condition where fluid accumulated in the ventricle of the brain of a prenatal. Ultrasound is the most commonly used diagnose procedure during pregnancy. However, The treatment for this condition involves the implant of a shunt which drains away from the fluid into the abdominal cavity. Better detection procedures for hydrocephalus using lowcost ultrasound or MRI would prepare doctors better for surgery[5].

This one-purpose MRI scanner has the advantage to lower the technical specific costs and be therefore available for LMIC.
The implementation and adaptation of medical devices in an LMIC context is not a self-evident process. It is the result of implementation decisions of healthcare providers, the design of the device and the interconnected contextual effects of the device on the environment (use, repair, maintainability). However, little research has been documented by engineers and medical device developers about the feasibility, challenges and opportunities facing these settings [6].

The developing of the frugal innovation MRI scanner involves implementation of the technology, but should also involve the adaptation of the device in the context (people and environment) and sustainability and durability of the device in order to succeed.
Therefore the following stakeholders (figure 1.) pursue to design a low cost MRI scanner for imaging of pediatric hydrocephalus in sub-Saharan Africa based on a Halbach array.

The idea of this project to develop a prototype of a frugal MRI scanner was developed by the group of Dr Steven Schiff from Penn State University in the United States. This device will operate at the Cure Children's Hospital of Uganda in Mbale. This project has been established in collaboration with the LUMC and the TU Delft who jointly develop the technology of the MRI scanner. In 2019 a conceptual minimum viable product was designed, which served as a conceptual proof of principle of the integrated device in context. The final goal of this project is to develop the MRI scanner-prototype for local use in LMIC around the globe and eventually to further develop this for remote settings in HIC.

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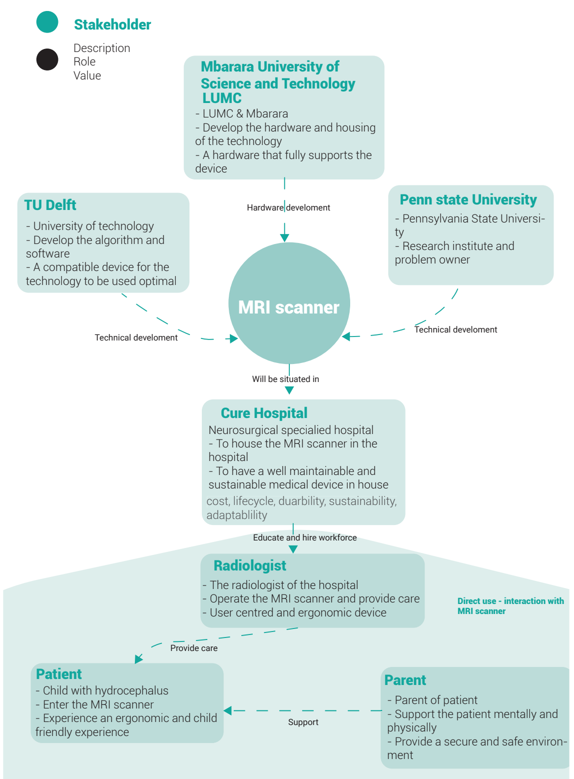

image / figure 1: Staekholder map

TO PLACE YOUR IMAGE IN THIS AREA:
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- CLICK AREA TO PLACE IMAGE / FIGURE

PLEASE NOTE:
- IMAGE WILL SCALE TO FIT AUTOMATICALLY
- NATIVE IMAGE RATIO IS 16:10
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image / figure 2:

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

Determining the correct alignment of the head and the positioning of the head in the centre of the bore is a challenge for the doctor as the bore is designed to be as small as close to the head as possible, which does not leave place for alignment. Furthermore different methods for positioning should be user friendly for the doctor and patient and not intervene with the imaging quality. Furthermore, the integration of the subsystems develop problems with the ergonomics of the patient. The technical requirements and the human factors for the patient can be improved.
Currently, there are only two ventilation holes in the closed MRI scanner, which provides cooling for the human body, but is not optimal for a Ugandan hospital setting. Because the temperature inside the device should stay constant and the temperature of the human body highly affects image quality, a solution should be designed that provides a ventilation system that does not interfere with the technology. All these cases should lead to an integration of the technology and the product layout should facilitate local maintainability and repairability. Currently, the product layout of the design is not optimized. Solutions such as modular design for components can be researched.
Thus the main goal will be to design a sustainable solution: To provide a novel solution integrated design to position the patient in an ergonomic way, that provides good quality images and facilitates the local repair and maintenance of this part. The focus will be on the further development of the head coil assembly, the shield and the integration of these systems on the bed carriage in a human-centred way with the local repair and maintainability in mind.Design a system that; provides accurate alignment of the head in the MRI scanner, without interference with the magnet
- Provides an ergonomic position for the patient, without excessive noise production by producing a constant temperature - provides user-friendly and intuitive operation of the hardware for the radiologist by providing an improved product architecture and use cues - has a perceived user-friendly interface - can be easily integrated into the current hospital - cost-effective to produce and maintain
The end result is a prototype that is ready to be tested in the hospital environment.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

This project aims to develop the design of the LF-MRI scanner into an embodiment design with an improved usability for a sustainable use and maintain in LMIC.

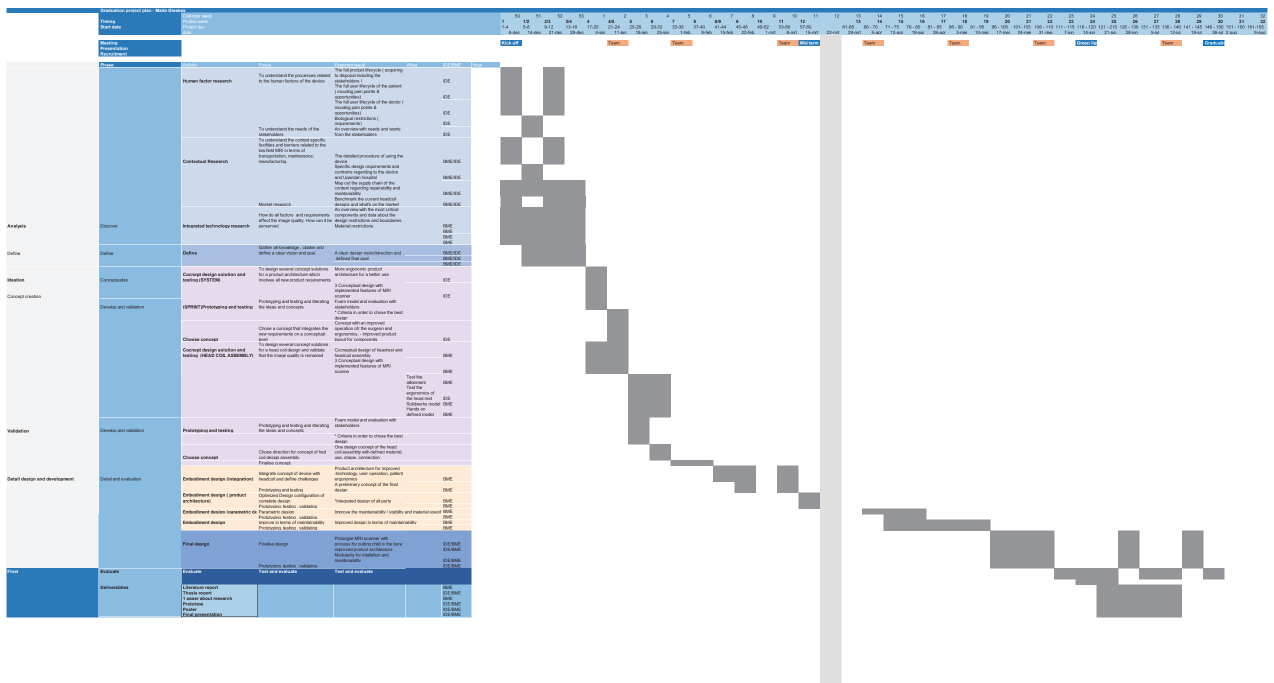
The end goal of this project is an iteration on the minimum viable product that focusses on the implementation of human factors and its technological improvement within the device. A prototype that focusses on the implementation of missing crucial features for the use of the MRI scanner.
- Head coil assembly : Alignment of the head
- Eventually, this will consist of the whole integral system
In order to deliver the full integration of the device, goals have been set for the prototype. Goals and the deliverables:
- Feasibility studies to validate the integration of user requirements
- Feasibility studies to validate the technical functioning of the integral system
- Incorporate essential technological performance and human factors aspects in the device while taking into account the hospital environment with its local maintainability requirements and reduce technical risk.
The outcomes will be integrated into an alpha prototype which includes the aspects mentioned above with as goal to be provided for the clinical tests in the Ugandan hospital environment. During the project, the system is divided into several subsystems, which each have their separate requirements and are linked by interfaces chosen in the design process. In the project, it will be clearly documented if the scope of development work concerns the whole system or a subsystem alone. Eventually the research team is pursuing to start a startup out of this device. Market opportunities and a business model will be researched and delivered.

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and 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 activities.

start date 2 - 11 - 2020

5 - 7 - 2020 end date



The project will be divided into four stages based on the Double Diamond model (Design Council, 2004). There will be more focus on the deliver phase of the double diamond model due to the literature study that has been done prior to the start of this project and due to the aim to deliver a novel prototype for clinical test settings. It is important to already involve the stakeholders in the begining phase when defining the requirements.

o Phase I: DISCOVER: This phase is all about gathering information about the context and the usability of the product in the context. The diagnosis process and the culture and health system of Uganda.

o Phase II: DEFINE: In this phase it is all about trying to make sense of all insights and interpret the meaning. All information gathered in Phase I will be used to (re)frame fundamental opportunities or directions to tackle ad develop ideas upon.

o Phase III: DEVELOP: In this phase it will be about the development of solutions or concepts through ideation, prototyping, testing and iterating. In co-creation (creative sessions with design students and other stakeholders can be generated. Within the develop phase the focus will lay on a lean working method where small ideas will directly be build, tested and improved. These design sprints will be continiously implemented within the design process.

o Phase IV: DELIVER: In this phase, the designed solution(s) will be detailed and refined. The small itterations from the design sprints will be at a level where the intergrated design will be a fully functioning 1:1 prototype. Besides that the focus is on coming up with guidelines to implement the solution(s) in the actual context/system. This phase ends with a thorough reflection on the project and recommendations for further development.

I plan to work on the thesis for 4 days a week until the midterm persentation and for 5 days a week after the midterm. The meeting with the mentor will be scheduled once a week, and the meeting with the chair once every four weeks. Additionaly there is a meeting with the research group every two weeks.

Initials & Name M.T.B. GIESKES 4651 Student number 4341260

Title of Project User-centred and sustainable low field MRI scanner for Africa

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

During my master, I have created a great interest in creating a positive impact through design for the once which value can potentially be enhanced the most. This aspect I have greatly found in design for medical devices and therefore I have put more interest in the track medising in order to learn more about this challenging field of designing. Furthermore, I have a great interest in implementing my knowledge to help others that are less fortunate in order to make medical devices more accessible to all. I have found my passion for using my expertise to design for the context of Africa.

My ambitions for this project are:.

1. Getting in depth knowledge on how to design a human centered complex medical device that is intuitive to use.
2. Getting in depth knowledge on the how to design a complex medical device more sustainable with the focus on local maintainability and repairability.
3. Getting in depth knowledge about sustainable production and material choices for a non-western country.
4. Experiencing the gains a well as the difficulties during designing for a different culture.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Annotation: EITH Health Innovation and Entrepreneurship (TPM)

Initials & Name M.T.B. GIESKES 4651 Student number 4341260

Title of Project User-centred and sustainable low field MRI scanner for Africa

A. List of Requirements

1. Main requirements

LMIC specific requirements

Through literature research, the LMIC specific requirements have been derived that give insight on the accessibility of medical technology (and specific MRI scanners) and opportunities to conduct requirements
The primary barriers that inhibit the MRI scanners in LMICs, is due to the lack of availability that is mostly nurtured by the lack of financial recourses. Supply, use, use for more cycles, dispose of.

Available
Cost for purchase, ownership, and maintenance

- *to be able to purchase the MRI scanner,*
- *to be able to pay the treatment cost*
- *to be able to maintain the product for more life cycles*

1. **The MRI scanner must be affordable to purchase**
(The main barrier to the availability of medical devices in LMIC is due to lack of funds.)

a. **The device must be affordable and not cost more than competing models** ($50,000 Hyperfine 64mT)

b. **Low in cost of ownership**
(W*hen the healthcare facility acquires the medical device, the patient would have to pay the cost per treatment. To keep the cost of treatment affordable for the patients to afford.)*

c. **Low in cost of maintenance**
For the device to be able to be used not only once, but multiple life cycles, the product must be able to be repaired and maintained in Uganda.

2. Long lasting products - design for sustainability

a) The device must be designed to last at least 5 years without additional repair.
(Accessibility in LMIC can be increased by allowing a better repair and manufacturability. However, since this is highly dependent of the infrastructure, which is not yet fully developed, it is beneficial to focus on the longer lasting of the device
This means that the device must be able to withstand the contextual challenges and not be fragile)

a) The device must be robust
b) The head immobilization system must be able to withstand an opening and closing of the headrest for 100 patients a day
c) The moving parts within the medical device must be decreased.
d) The device must be designed to have minimized failure rates in the system and the corresponding modes of failure.
e) The device must be able to be maintained with minimum number of required tools and supporting equipment

Durability in challenging environment

f) The material of the MRI scanner must be able to be operational in the context's temperature and humidity for 5 years in normal use.
g) Able to operate at temperatures between 10 and45C and 0–90% relative humidity
h) The device must be resistant against high ambient dust in rural operation theatres and a possible drop of water on the exterior (IP54)

3. Repair and maintenance - design for repair and maintenance

a) The device must be locally maintainable
b) The device should be designed to have a reduced number of part and assemblies including redundant components
c) The most regularly replaced components must be easy to access
d) The medical device should allow fault detection, localization, and isolation in the quickest possible time.
e) The system must provide adequate labelling, engraving, and marking of parts and critical points for the identification of defects.
f) The device must allow showing the status of an item to be determined (operable, inoperable, or degraded)
g) The Repair/Replacement of functional units within the medical device must be able to be quick to restore

h) Easy and quick opening/fastening of mating parts or components.
i) The medical device must label components for quick mating of parts
j) The medical device should allow availability of troubleshooting and maintenance procedures, checklists, and instruction documentation
k) The medical device should be able to maintain by using generic parts that are easy to access

4. Spare parts and consumables
Medical devices must be designed with repair and maintenance in mind. this includes the accessibility of the spare parts.

a) Parts within the medical device must be standardized and facilitate interchangeability between mating components
b) Maintenance tasks of the medical device should be able to be done with standard hand tools available.
c) The device must be able to facilitate quick removal and replacements with minimum tools
d) Spare parts needed for the maintenance of the medical device must be available at an affordable price
e) The medical device must be designed by considering the accessibility of only standardized parts to provide cost-effective repair and maintenance

Accessible

- understandable
- able to be distributed
- accessible for population
- accessible in looks for the procurer
- accessible in ergonomics for user

5. Accessible for population

a) The device must be able to be transported over muddy, unpaved, and poor pathways
b) The device must be as space efficient as possible
c) The device must be compatible with the power requirements of the context
d) The medical device should allow a hazardous-free environment for maintenance work which requires no proximity of high voltage lines, not gaseous leakages, moderate temperature changes.
e) The device must be able to withstand eruptive power supply
f) A backup power supply is required to stabilize the power supply and keep the equipment functioning during a power blackout.
g) Casing made from 100% non-absorbent material

6. Accessible for users

a) The maintenance tasks of the medical device should be designed to the skill and motivation level of an average technician. Tasks should be such that no more than two technicians are required for accomplishment.
b) Design user cues to guide the repair of the machine right away
c) The medical device must be able to be operated by personnel with limited training
d) The device must be able to be well understood by an MRI technician
e) The medical device must match the knowledge level of the basic trained personnel
f) The medical device should be understandable for the MRI technician with minimal training.

7. Acceptable

- acceptable for the user (create trust)

a) The aesthetics of the device must trigger a feeling of trust with the procurers
b) The visual identity of the MRI scanner must allow the patient to be comfortable
Since lack of training and proper manuals are still a barrier to the proper functioning of medical devices, which can obstruct the use of equipment. Therefore, medical devices should be supplied with instructions.

MRI scanner specific requirements

User-specific requirements

8. Installation

a. The device must contain a handle and wheels to be able to be portable
b. The device must be able to be assemble locally with standard tools and local equipment

c. The device must be able to be portable with 4 people (max. 200kg)
d. The device must be able to fit though a standard door(width) (max. 720 mm).

9. General
a) The aesthetics of the device must trigger a feeling of trust with the procurers
b) The aesthetics of the device must make the baby feel calm (less intimidating).
c) A system that is understandable and usable for people with minimal training
d) The device must provide guidance to the MRI technician
e) Provides a comfortable situation for the patient
f) The personnel must be able to see and monitor the infant during scanning

10. Use by MRI technician
a) The MRI technician must be able to operate and align the head of the patient in a maximum of 5 steps.
b) The medical technician must be able to see directly or indirectly the state of the child
c) The patient must be monitored (heartbeat, breathing, saturation)

11. Use by Patient

a) The medical device should prevent the patient from moving during the entire imaging sequence
b) Enables correct positioning and aligning of the child on the bed
c) The child must be able to lay still for 10-15 minutes (without sedation)
d) The device must prevent and restrict any sudden movement of the limbs and head of the patient
e) When the parents sit at the head of the bed the children will tilt their head, this must be prevented. This prevention is done with a double mirror in the head coil so that the patient can see the mother

Comfort
f) The device must eliminate physical discomfort on the body of the patient
g) The device must enable the patient to remain a correct static posture-
h) The bed must support the natural curvatures of the spine, paediatric patients to not have a double S shape, but rather a C shape.
i) The device must contain a handle or wheels to be able to be portable

13. Repair
a) All components that require frequent repair or replacement must have visual feedback
b) The measurement areas need to be well visible
c) Tools and replacement objects and components need to be standardized

14. Dispose
a) (Parts that interact with the patient must be made clear from bacterial and fluids after each use to prevent infection) The device must be as easy cleanable as possible after each participant

Technical specific requirements

15. System requirements
a) The system must be able to operate at temperatures between 10 and45C and 0–90% relative humidity
b) Casing made from 100% non-absorbent material
c) No ferromagnetic or metals can enter the bore of the magnet or may be in a proximity of 100mm of the bore opening.
d) The device must be resistant against high ambient dust in rural operation theatres and a possible drop of water on the exterior (IP54)
e) The bed system must be attached and detached on the magnet table
f) The electronic components must run from standard power outlets and ultimately battery/solar/diesel-powered.
g) The temperature inside the magnet should stay stable (drift less than 1 degree per hour)

h) No tensile force is allowed at the electronics especially not at the soldering part and the circuit of the head coil
i) The transferring forces from the patient to the bore to the magnets must be as minimal as possible
j) The device must restrict movement of the patient inside of the MRI scanner
k) Non sedative MRI scanner requires a head stabilizing product so that the child can be contained
l) A cooling fan inside the electronics casing is required.
m) The housing must be impact resistant
n) Casing made from 100% non-absorbent material
o) The system must be able to operate at temperatures between 10 and45C and 0–90% relative humidity
p) "The device must be resistant against high ambient dust in rural operation theatres and a possible drop
q) of water on the exterior (IP54"
r) The bed system must be attached and detached on the magnet table
s) A simple air fan cooling is required
t) The housing must be impact resistant

Component specific

16. bed system
a) The bed system must provide support for neck, shoulder and under knee area The device must avoid high pressure (>15mmHg) on areas with low subcutaneous fat, such as the tailbone, the occiput area,
b) The subject needs to be aligned in the middle of the bore in a sphere of 220 mm +/- 1 cm Diameter
c) The RF coil should be concentric with the magnets bore
d) No ferromagnetic or metals can enter the bore of the magnet or may be in a proximity of 100mm of the bore opening.
e) The bed system must provide support for neck, shoulder
f) The blanket must not restrict airflow for breathing
g) The bed must be able to fit taller children (1.4m) and smaller children (80cm)
h) The bed system must be attached and detached on the magnet system
i) The bed framework needs to be stiff enough to withstand the patient's weight (16kg(body) + 5kg (head))
j) The bed framework needs to be accessible for the MRI technician to clean
k) The bed must be fixated on the head coil once slid inside
l) Once the bed is slid inside the bore, there must be a lock to prevent unexpected movement during scanning
m) The bed framework that enters the bore must be non-ferromagnetic

17. bed mattress
a) The bed is the most consumable part, which requires the most frequent replacement. The bed must be made of durable materials.
b) To mattress hardness must be made from polyurethane foam medium hardness (around ILD value 50s)
c) The mattress must be easily replaceable
d) The head must be positioned in an angle of 15 degrees
e) No pressure above 32 mmHg must be measured on the body of the patient.
f) The mattress must allow the patient to lay in a correct posture in a supine position.
g) Head against the headrest, Trunk slumped and uncrossed feet
h) The headrest must have a donut shape to prevent pressure on the occiput area.
i) The mattress must be at least 80cm length by 25 cm width
j) The mattress must be put on a hard material that holds the concave shape and is attached to the sliding mechanism
k) The slides must be integrated and fixated in the framework
l) The metallic bits on the bed framework need to be covered
m) The mattress must have a concave shape for the body to comfortably lay on it.
n) The mattress must be at least 80cm length by 25 cm width

18. Head immobilization
a) The head immobilization device must allow a maximal movement of 3 mm in 6DOF .
b) The head immobilization device must fit on a headrest of 250 mm X 150 mm
c) The head immobilization device must be cleanable after each use
d) The head immobilization device must be comfortable
e) The immobilization device must be soft on the head of the patient.
f) The immobilization must be as compact as possible
g) The immobilization device must immobilize the head by providing cushions on both sides
h) The pressure from the head immobilization on the cranial section of the infant must not be more than 7,5 mm Hg or approximately 1kPa
i) A minimal stiffness of 5,7 Nm stiffness is required for a system that prevents translation in the x and y plane and rotation of the head through the sternocleidomastoid muscle of more than 3 mm
j) The immobilization device must prevent pitch with a lower strap that fixates the mandible

k) The immobilization device must prevent roll by providing a fixated headrest combined with a head strap
l) No external pressure must be applied on the areas with low subcutaneous fat to prevent pressure ulcers: The occiput area must be free from pressure the areas with the lowest subcutaneous fat allow the least amount of pressure on these areas which are the occipital area of the skull.
m) Rotation and bending of the upper spinal area must be limited: Through application of pressure on the parietal areas of the skull
n) The head neck and thorax must be fixed to prevent junctional angulation.
o) The immobilization should not solely support the shoulders to prevent the effect of mobile shoulders.
p) No pressure must be applied on the upper jaw

19. Double mirror

a) The mirror must allow the patient to see the care-take who is situated outside the MRI scanner
b) The Mirror must allow enough space of placement of the child inside the bore.

20. Head coil

a) The product must allow the different head circumference of the child to be adapted.
b) The headcoil must be lightweight
c) The headcoil must be easy to maintain
d) The headcoil must cover over the eyes to be able to image the entire brain
e) 1The headcoil must be able to receive and transmit RF pulses to and from the magnet
f) The head of the patient must fit as close as possible inside the headcoil
g) The headcoil must restrict movement of the head with cushions
h) Once the MRI technician has positioned the child, the headcoil must be attached to the bed system
i) Once the scanning is done the head coil needs to be able to be detached from the bed system with only one gesture.
j) The MRI device must be able to be maintainable locally
k) The product must allow the vomit to be cleaned easily
l) The headcoil needs to rest on the bed
m) The headcoil needs an electical conncection between the headcoil and the magnet
n) The headrest must be a maximum of 150mm * 250mm*
o) The headrest must support the head
p) The headrest must be comfortable for the patient
q) The items that interact with the patients, must be easy to replace or easy to clean
r) The head coil must be easily replaceable The headcoil must be easy to change for a different head size
s) The head coil must be cheaply producible so you can have multiple.
t) The wire connection must be earthed for safety
u) The head coil needs an electrical connection between the head coil and the magnet

21. Swaddle technique

a) The patient acts like an antenna, so something must help with active shielding. Appropriate conductive materials should be included to make sure the person is shielded
b) The blanket must restrict movement of the limbs of the patient and increase comfort through the posture and temperature of the patient.
c) The blanket needs to be tucked tightly around the body. By applying pressure of 100Pa(10 kg/1m^2)
d) The swaddle blanket must be easy cleanable ; Dirt must be washable from the blanket by wiping with water and a cloth
e) The swaddle blanket must be immediately installed correctly by the MRI technician
f) The swaddle blanket must cancel the noise by creating a cage of faraday with aluminium inside the blanket
g) Only the limbs and the upper body of the patient must be able to be swaddled
h) The blanked must prevent bodily temperature fluctuation of more than 3 degrees Celsius in 10 minutes.
i) No direct contact between the skin of the patient and the conductive part of the blanket may occur.
j) The blanket must be connected to the same ground as the aluminium shield around the magnet.
k) The aluminium maze must not be bigger than 10 * 10 mm and 3 mm thick.
l) The blanket must make sure that the swaddling of the patient only can occur in one way
m) The blanket must be made of a textile with a soft material

22. Guiding rail

a) The translation system that moves the head inside the bore must use as minimal space as possible (A lot of effort has been made to make the bore as large as possible. So, if the concept leaves out 1 or 2 cm in empty space, this is not desired)
b) The weight of 16 kg homogenic distribution must be able to be supported on the rails
c) Since the magnet system may not carry load, no force may be exerted on the magnet system (Push force 200N with two hands)
d) The translating mechanism must take at least as volume as possible.

23. Electronics

a) The preferred and most easy way to maintain the device is to make the electronics modular.
b) A shielding is required to reduce the noise dure to the inhomogeneity of the permanent magnet. The frequency must at least 2mHz (between 1 and 20)
c) The repair and maintenance must be able to be done by a technician with minimal training
d) The two capacitors as the most fragile part need to be designed in a robust way. Furthermore, the ability to calibrate the head coil needs to be more user friendly.
e) The conductive housing must be connected to the same contact point as the head coil
f) The MOSFET must be able to be replaced
g) The cool block must be accessible for repair - it is not possible to troubleshoot on component level, only on unit level. The print is connected on a cool block, and this can be mounted as complete unit
h) The airflow must not be restricted inside the closet of the electronics
i) Sound damping and a S pipe should allow the airflow in the closet while dampening the noise
j) The RF amplifier requires its own power supply of 60V
k) The electronic modules must be designed in a robust way
l) The ventilator must be well protected from sand by making it dust proof.
m) For troubleshooting it is important that the technician has visual feedback

24. Magnet system
a). Only ferromagnetic materials can be used
b). The transferring forces from the patient to the bore to the magnets must be as minimal as possible
c). The temperature of the magnet need to stay contstant

25. Bore
a) The head of the patient needs to be exactly in the middle and concentric of the magnet

A. List of Requirements

2. Validation

The entire list of requirement with its validation can be found at the end of the document. It includes 215 requirements for each component. Only the relevant components are evaluated for validation.

Figure 1. Image of the list of requirements and validation starting at page 169. Ref. page 159 for the readable version

3.6.1	The subject needs to be aligned in the middle of the bore in a sphere of 220 mm +/- 1 cm Diameter	Tom O reilly	Bed/ headcoil and magnet	The brain can only be imaged inside the field of View of 225 x225X300mm	Positioning of the headrest is always at a point where the head coil will be in the field of view, for smaller and larger children.	verified	Experiment testing	Requirement met : For both the largest and smallest head coil, the patients head is in the middle of the field of view
3.6.2	No ferromagnetic or metals can enter the bore of the magnet or may be in a proximity of 100mm of the bore opening.	Oreilly,2022	Bed/ headcoil and magnet	magnetic materials may interfere with the magnetic field, causing noise.	No feromagnetic materials enter the bore	verified	Experiment testing	Requirement met : No metalic components are inserted inside the bore. For the blanket, and the slidin mechanism, this part has been devided into two parts. A part that can enter inside the bore, and a part that does not enter inside the bore
3.6.3	The bed system must provide support for neck, shoulder and under knee area The device must avoid high pressure (>15mmHg) on areas with low subcutaneous fat, such as the tailbone, the occipt area, the shoulder is	Roaf, R. "The Causation and Prevention of Bed Sores." Bed Sore Biomechanics, 1976, pp. 5–9. Crossref, https://doi.org/10.1007/978-1-349-02492-6_2.	Bed mattress	This allows a good positioning , mininising muscle strain and discomfort	soft mattress with concave shape and supports on critical areas	verified	final prototyping	Requirement met : The ciritcal areas of the patient are supported
3.6.4	The RF coil should be concentric with the magnets bore	Oreilly,2021	Bed mattress	The magnetic field is strongest in the centre of the FoV	Fixed positioning and laignment of parts	verified	final prototyping	Requirement met : For both the largest and smallest head coil, the patients head is in the middle of the field of view and at the centre of the bore
3.6.5	The bed system must provide support for neck, shoulder	Vink,2018	Mattress	This allows a good positioning , mininising muscle strain and discomfort	Neck rests	verified	final prototyping	Requirement met : The ciritcal areas of the patient are supported
3.6.6	The bed must be able to fit taller children (1.2m) and smaller children (80cm)	Mockup making and testing, Cure hospital	Bed mattress	Children between 0 and 4 years old must be able to fit in the bed. Children of 4 years old are averag 1.02 m	A large bed of 100cm length with 30 cm width : The mattress must be at least 80cm length by 25 cm width	verified	final prototyping	Requirement met : The bed system is 1.2m long so all children up to 4 years old (P95) fit inside the bore. Also space is left to prepare the childer on the table top, without needing to move the child
3.6.7	The bed system must be attached and detached on the magnet system	User test	Docking system	When installing and disassembling the MRI system, the magnet must be alligned with the bed system	Alignment method : Docking system	verified	final prototyping	Requirement met : a docking system has been provided to allign the magnet system with the bed system
3.6.8	The bed framework needs to be stiff enough to withstand the patient's weight (16kg(body) + 5kg (head))	calculations	Bed framework	The bed framework should not deform and should be robust for it to be durable, but also to maintain the same measurement data during each scanning.	Sitff 35mm aluminum framework	verified	final prototyping	Requirement met : an alluminum framework of 35mm is provided with nough stiffness to prevent deflection during use
3.6.9	The bed framework needs to be accessible for the MRI technician to clean	Co-creation session Wouter and Tom	Bed framework	The procedure of scanning can involve fluids from the patient. This needs to be cleaned thoroughly after every scanning. So this should be easy accecible	The Bed is composed of modlar parts which allows easy assembly and disassembly	verified	final prototyping	Requirement met: Only easy to clean surfaces are povided such as the Trespa and PVC. All corners are prevented and only smooth surfaces are implemented
3.6.10	The bed must be fixated on the head coil once slid inside				Form fit of the headcoil on the the tabletop and on the headrest of the matress	verified	final prototyping	Requirement partially met, room for optimization: the sliding mechanism allows enough friction to position the bed on a fixed position. However, once the childe abruptly moves, there is a small chance that the bed also moves. Since there is no mechanical stop.
3.6.11	The bed framework that e	Co-creation session Wouter and Tom	Bed framework	Ferromagnetic elements are not allowed to enter the bore.	No feromagnetic materials enter the bore	verified	final prototyping	Requirement met : the bed framework will not enter the bore. Solely the mattress, mattress holder and tabletop will enter the bore.
3.6.12	Once the bed is slid inside	Testing	Bed assembly - A locking system can also be done by a ball pin that falls in a hole by gravity		A locking system can also be done by a ball pin that falls in a hole by gravity	verified	final prototyping	Requirement met
	3.7 Bed Mattress					verified		
3.7.1	The bed is the most consumable part, which requires the most frequent replacement. The bed must be made of durable materials.	Cure Hospital	Bed mattress	1. The bed is the most consumable part, whic hrequires the most frequent replacement. Approximately 2000 kids per year will be scanner, which is around 10 scans a day minimal		verified	Experiment testing	Requirement partially met, room for optimization: The choice has been made for an off the shelf matress that is widely available inside the context. The effect of this matress on the durability of the bed system has not been verified
3.7.2	To mattress hardness must be made from polyurethane foam medium hardness (around ILD value 50s)	Experiment	Bed mattress	This is the most comfortable mattress hardness as described in literature		verified	Experiment testing	Requirement met :Medium matress which is widely available is used for the making of the mattress

B. Methodology

1. Interview Methodology

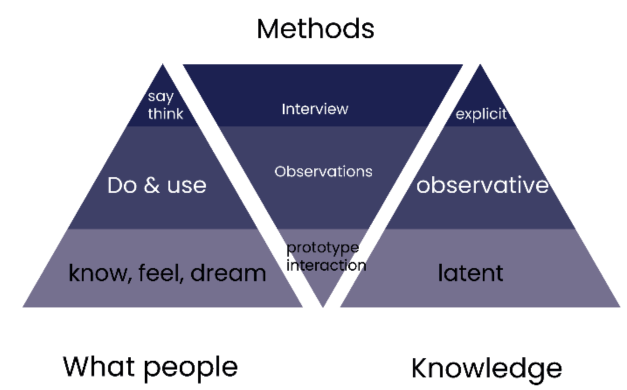


Figure2. stakeholder involvement methodology

Interview Methodology

Stakeholder involvement in the early phases of medical device design is a crucial factor in the understanding of user and context-specific requirements, besides the acceptance and validation of the product. Design processes that promote early and frequent engagement with stakeholders may increase the impact of medical devices aimed at addressing global health challenges by improving the uptake and sustained use of such devices. Prototypes are tools that can be leveraged to engage stakeholders during front-end design to define the problem, elicit requirements, and obtain feedback on early design concepts.
[Coulentianos,2020]. The consulted professionals are experts in their field and were specifically asked for their experience from their expertise, to make sure that the information is reliable. Most experts have experience in both LMIC and HICs, so the difference was specifically discussed.

Approach

A minimal 60-minute systematic interview and discussion was prepared with the experts. The interviews were performed as guided interviews based on a set of prepared questions. The second phase of the interview referred to the specific low field MRI scanner and possible solutions based on proposed ideas and the mock-up. As a discussion,
A set of questions can be found in Appendix B.2 with the transcript of the interviews. Interviews were recorded when agreed.
The goal of the interview was likewise to involve the experts to gain knowledge, to trigger a discussion about decisions and the reasoning behind decisions, to validate assumptions and decisions, to gain advice and to trigger creative sessions where the interviewee becomes a participant in a brainstorm session and can express the value of their expertise in the product.
The gained data and knowledge were analysed and put in excel to differentiate and highlight frequently mentioned values and to determine whether there was a correlation in the experience of the experts in the different LMICs.
The Low Field MRI scanner is designed with the specific context of the CURE hospital. This hospital can be seen as the beachhead market. With the other LMIC contexts and hospitals in mind so that the device can be implemented in other less resourceful hospitals as well.

Asking the right questions

Besides asking the right questions it has been of importance to involve the stakeholders in their thinking and doing. Therefore, prototypes were used to initiate discussion. In each design phase, stakeholders and experts were involved.
The importance to make assumptions explicit and verifying the intended users was required to prevent westernized bias in the design of the product.

	Organization / Individual	Sector	Specialization	Region/Context	Method
Research	**Context**				
Dr. L. Gieskes	Radiologist	Medical device operator	Mammography Radiologist	Congo/ French Caribbean / France	Video interview with the observation
[redacted]	Radiologist	Medical device operator	Intervention Radiologist	The Netherlands / Suriname	Video interview
PhD Emmanuel Ahishakiye	PhD researcher LF MRI scanner	Researcher in Uganda for Low Field MRI	Electrical Engineer	Uganda	Interview Sent photos of context
Dr. Johnes Obungoloch	Biomedical engineer/ Researcher/ Head of MUST	Medical device maintenance / institutional	BMET, maintenance & repair, context	Uganda / HIC	Video Interview Ideation relevance discussion
Marjolijn Heslinga	Philips Manager Point of Care medical devices	Medical device design in LMIC	Manager, strategy	The Netherlands, Low-Middle income countries	Video Interview (design for lmic context)
Edith Mbabazi	CURE Hospital	paediatric nurse	Operation of medical equipment in LMICs	Uganda	Interview (context, hydrocephalus, workload)
	Comfort				
Dr. Steven Schiff, MD, PhD	Penn State University	Surgery MRI scanner use for paediatrics with hydrocephalus	Neurosurgeon specialized in hydrocephalus. Director of the Center for Neural Engineering;	HIC/ Uganda	Interviews, discussion about concept, validation
Dr. Niek van der Aa	Paediatric Neurosurgeon	Medical device operator	Neurosurgeon	Utrecht Medisch Centrum	Interview
"Uppon request"	Paediatric Nurse	Human Factors (child care)	Paediatric Nurse	Belgium	Interview
[redacted]	Senior MBB Radiologic laborant	Patient care in MRI, Operating MRI device	MRI Technician	Holland Proton Centre, Delft	Observation in MRI scanner, Interview
Lara Janssen	Philips Usability Designer	Medical device - human factors research	Human factors , usability designer	The Netherlands	Interview
Teddy Heerbaart	Philips Usability design MRI	Medical device UX design	Medical device designer	The Netherlands	Interview
Brian Kaaya Nsubuga	CURE Hospital	Research & It Technician	CT scan analysis of children with hydrocephalus	Uganda	CT scan children with hydrocepahlus data analysis

	Technology				
Wouter Teeuwisse	Head of technology and safety Radiologie - Technology of Low Field MRI scanner	MRI scanners (their technology, Usability and children	Technology operation and safety of Radiology & children in MRI scanners	LUMC, The Netherlands	Interview Observation at MRI device
Andrew Webb	Head of research team LUMC	Research	MRI technology, LF MRI device	LUMC	Interview
Tom O'Reilly	LF MRI Magnet engineer	Research	PhD low field Magnet design	LUMC, Uganda for field work	Interview Observation Brainstorm session creative discussion Comfort test
Bart de Vos	LF MRI Magnet engineer	Research	PhD low field Magnet design	LUMC	Interview Observation Brainstorm session creative discussion Comfort test
Dr. Ronald Mulondo	MRI technician	Operation, maintenance MRI scanner	Head of MRI equipment Cure Hospital	Uganda	Interview, co-creation session
	Repair and Maintanance				
Ger de Kok	Siemens MRI Repair and maintenance	MRI technical repair	Repair engineer MRI & CT	Suriname, The netherlands,	Interview, concept review on usability
Danny de Gans	DEMO - Electronics Device manufacturer of LF MRI	MRI technical repair of electronics	Device manufacturer	TU Delft, The Netherlands	Interview - Concept review on feasability
	Experimental Design				
R.Happee	TU Delft 3ME BMD	Introduced biomechanical human models for impact and comfort	Human interaction with vehicles focussing on safety, comfort and acceptance.	TU Delft, The Netherlands	Consultation - experiment setup
Ir. M Smulders	PhD: sleeping and seating comfort in transit	Ergonomics Usability design	Comfort	TU Delft, The Netherlands	Experiment focus and setup (bed & immobilizer)
	Specific final concept design				
All of the above					Validation if the requirements were correcly implemented inside the envisioned concept

B. Methodology

2. Transcription of interviews

Interview Context: Cure Hospital

Objective:
To validate the assumptions made
To trigger discussion on the made decisions
To trigger discussion on the values of the stakeholders (MRI technician and patient) and the envisioned concept.

Method
The meeting is subdivided in three parts

1. **Present research and findings based on assumptions - Discuss afterwards**
2. **General questions based on the healthcare systems and the things I've read from the literature**
3. **Present the envisioned concept and provide questions.**

From the perspective of the end-user, it is correct

Age of the child and head size
Most head sizes coming to the hospital range between 50 cm and 60 cm. The age that is most occurring is around 3 months and below. The P95 head size that has come in in the past has been 66 cm.

Choice which head size and age
The choice for the design of which age range depends on the relevance for the hospital and other hospitals around. The need for it (what is the alternatives for these children) and the possibility to grow.
Most of the children coming to the CURE hospital are young children. However, this is mostly the result of awareness and early referral. People are getting to know more and more about hydrocephalus, and therefore the early symptoms are recognized earlier and treated within the 3 months in the hospital. However, in other LMIC countries, the age could be higher due to the lack of awareness and lower popularity of the research on hydrocephalus.

The children that are difficult to position and scan are mostly older children up to three months that are more movable. For this age range, it is a huge challenge to keep them calm and therefore they need to sedate them because they have no other choice.

You can subdivide the patients into 2 categories. The children that come in for the first time and need surgery
1. They are younger and their head-sized are larger. They encounter more pressure in the heads because they haven't had surgery yet.
2 . The second category is the older children that have had surgery already and need to come back to the hospital for revision. These children are more movable and very difficult to keep calm

For both categories, patient comfort is very important since a negative experience for the first younger category will be remembered, and all the following scanning procedures will be challenging.
For the second category that is getting follow up frequently, this has the same effect.

The oldest children that are scanned nowadays are up to 7 to 8 years old and they have already had surgery. This group is part of a study that is ongoing from 2012 and is part of a comparative study that is following the children and the development of hydrocephalus in the children.

conclusion/ Insight
The choice for the device should be able to treat the children of 3 months but is specially designed as a solution for the children that are difficult to comfort and keep still in the MRI scanner. So, the children of 6 months to 5 years old. The anatomy can range from a few cm to 1 year old.

The biggest challenge in imaging is keeping the patient still. In the developed world they can acquire fast scanning for this purpose to decrease the scanning time. However, for the low recourse settings, this is not a possibility. This is a big challenge since children really jump and scream, and those are the ones that need to be sedated.
In developed settings, the room of the MRI scanner is made comfortable and user friendly, however, this is not a possibility for low recourse settings since the MRI scanner will not always operate in the same room for the low field MRI scanner. The time and place recourses are limited, so it is important that the child feels somewhat calm when already approaching the device. The last recourse is sedating.

Conclusion
So the device must have a friendly look for the child to perceive the MRI scanner as approachable and friendly.

In the CURE hospital the treatment is not paid by the patient, so this does not occur for the CURE hospital, but for other public hospitals it is crucial.
However, time is an important factor during scanning. Time is valuable since you want to spend the less time as the doctor has a line of patients waiting. Furthermore, the caretaker who is with the patient often leaves a family at home which needs also care or day-to-day job for financial income. The longer the treatment lasts, the bigger the effect for the caretaker's family and the doctor.

1. **Values of the stakeholder**

1.4 What is the workflow of the MRI technician
a. Patient is received - they come with the request form with the required body part.
b. The technician explains to the relative what is going to happen.
c. Position the child on the machine - In a way that can require the imaging
d. Minimize sedation because this interferes with the physiology of the body. So, you try as much as possible to reduce movement. Once the patient has been positioned. Then the patient can go back.

The CT scan provides accessories, the straps go around the head, the chest, and the limbs. You try to minimize the movement as much as possible, and you try to involve the patient and you try to involve the caretaker.

1.6 What is the ideal MRI from the perspective of the MRI technician? (looks, performance, features)
1. Imaging modality,
2. ease of use is important,
3. the shorter the acquisition time the better.
4. How easy it is to clean.(A patient might come and is bleeding, so that is also important to be able to clean)

1.7 What is the ideal MRI scanner from the perspective of the patient?
- Be able to see the parent
- Have a comfortable bed
- Spend as little time on that bed as possible
- The shorter the acquisition time, the better.
- The less scary is the better. If your MRI is closed like a tube, they would be less recusant to go in.
- How silent it is might also be nice, they do not get anxious.

1.9 Are there any difficulties when operating the MRI scanner? for the MRI technician
At the end of the day, it's still coming back to your ability to keep the child still. That is important. Keeping the child in one position and is the most challenging.

Cleaning

The equipment is cleaned by using a damp cloth and water. Except if you must clean blood, then you must clean with a more effective liquid. In the era of COVID the equipment is required to be cleaned after each patient. Otherwise, this is done each morning of the day.
PPE is required when cleaning or processing equipment and instruments, to protect against splashing, spraying or aerosols.

4. Interactive session where I will present my concept (which was still designed based on the assumptions I had)
back from DR Ronnie :
Most things that are required are implemented in the concept, so I think it's quite solid.
The concept involves well all the needs of the stakeholder. A nice feature it that the patient can see the mother through the double mirror while scanning in the bore. In this way the caretaker and the MRI technician can involve the caretakes which is in an important factor to keel the patient calm.

Feedback from Edith
Swaddling technique is a nice feature to implement in the patient's bed. They use it a lot in the CURE hospital to keep the child warm since the scanning is mostly done in air-conditioned rooms and you need to prevent the heat loss of the infant.

Read in literature and need to validate if it is relevant for Uganda
Comfort

1. How important is parental involvement before, during and after the scanning?
2. What are the methods to keep restrict a child from the movement? (feeding?) and does this always work or their challenge?
3. A variety of methods are used in Dutch hospitals to comfort a child prior to MRI scanning, could you state for each of them if this would be an option?

Methods	Why I think it would / would not work	Cure Hospitals perspective Would this work in Ugandan hospitals, and why?
1. Relaxation methods	By explaining the child to breathe in a certain way or use mediation methods the child is supposed to keep calm. However, the child is **not instructible and time = money that the patient needs to pay themselves** so there is not much time prior to the diagnostics	No, Too timely
Communication	Explaining to the child what will happen and instructing it to stay still would be possible for a child above 6 years old. However, under 6 years old a child is not instructible.	Small children are not instructible
Visual feedback	Distracting the child and what she/he sees inside the head coil, so it is not claustrophobic.	Seeing the mother can actually help
Prone positioning	By placing the head of the child downwards instead of upwards this could work beneficial to keep the child still	Never heard of it
Systemic de-sensitization	By systemic desensitization the child is introduced by toys or positive images prior to the diagnostic in combination with the MRI scanner Positive toy + MRI scanner = Positive experience However, there is not much time to familiarize the patient with the MRI scanner prior to diagnostics because of the cost of the nurse that needs to be there.	Would be nice, but we have not so much resources
Music	Using music to calm the child so that it will stay still could work	Either the baby wants to sleep and the music is disturbing or you would not hear it due to the
Anxiolytics	The child is already sick and sensitive so providing drugs is not desired	
Imaginative visualisation	Visualising	

The methods that I think could work in a Ugandan context is **visual feedback.** When the patient can see a distraction or indirectly his mother through a double mirror this could calm the patient and promote it to keep still besides strapping it. However, I don't know if children with hydrocephalus are able to see properly and look upwards inside the head coil.
Prone positioning
Music
Swaddling technique
Swaddling technique is used well in Uganda.
Blankets from any material are used. A cloth that can go around. And the kangaroo method (skin to skin) has also

proven to be beneficial for some of the CT.
The room is very cold, so most of the time you use an infant and they put it into the swaddle.
In imaging. I think you want to make the patient as comfortable as possible. The bed needs to be warm and make something for the baby to sleep. Maximizes the comfort in the room. Increase the size of the bed. Furthermore, the most important for the MRI scanner, is that it is solid and robust.

Interview Context MRI expert

Dr. Obungoloch is a lecturer in the Department of Biomedical Engineering at Mbarara University of Science and Technology (MUST). He has broad experience working with medical technologies. He has expertise in installation, maintenance and repair of medical equipment and he was previously the head of the equipment repair workshop at (MUST).

What is the type of MRI scanner that is used inside of the device?
Halbach array
The construction of the MRI device in Leiden and the one in Uganda seems to be the same, the bore size is different . However, the direction is the

What is the desired MRI scanner?
Modular assembly would help for installation, repair, and maintenance. In the dream this system would be mounted on trucks and be driven around. A design that considers this type of mobility would be preferred.

As I am considering doctors and medical users of MRI. What helps is coming up with a design. And asking them to make changes until they see something.

A good option for co-creation would be to already design something and present this to the users because , when asking them they do not know what could be different or improved but when presenting it to them this can trigger a reaction.

Are the children sedated?
1. It is not advised to sedate them. But the children are claustrophobic. They cannot follow instructions. So that is why sometimes they end up sedating them. But preferably you would not want this.
Req. It is desired that the patient can lay comfortably and still in such a way that sedation is not needed.

What is the exact procedure
Pre diagnostics
1. The process is explained to the caretaker of the child.
2. The caretaker puts the child on the bed
3. The caretaker straps their hand
Most of the children are ill and young so they are unable to follow instructions. So, they need to strap their hands so that they don't touch their hands and face. They should not be able to roll around. So, a strap might be advisable.
4. Also some of the doctors say need to sedate them. A lot of MRI systems might take 5 minutes to perform. And they slide in, and the imaging starts.

Diagnosing
The caretaker needs to be in the room for the child.
The MRI technologist might also be within the same room because it is a system that is low field, so it is possible to be in proximity of the device.
5.The person operating the device is the MRI technologist.
The images are taken by the doctor. But if the child is ill then it might be accompanied by medical personnel(nurse). You need to maintain the care of the child.
Req: The MRI scanner must be accessible for both the doctor to see the screen and the caretaker to access the patient.

It seems that in every hospital there is someone else that operates the device, is that correct?
That is correct, due to limited expertise and limited personnel in many hospitals they do not have the right trained personnel to operate this device.
Req: The MRI scanner must be able to be operated by personnel with lower training levels

Do some things require the help of more hands?
Installation
It is possible that some things require help. If this system is succeeding the preparation of the imaging is done by a trained MRI technician or an engineer need to be close by to monitor the process and need to see the technical failures

that are taking. This will especially be at the start of implementing the device during installation.
Placing of the head coil
The placing of the head coils the medical personnel might struggle. In the beginning they might need technical personnel to assist. Also, they need mobile assisting. The orientation might change, a change of orientation might change the magnetic field, so a recalibration of the system is required with a new head coil.
Req: For the installation the maintenance needs to be placed in such a way that the general technician can repair and maintain the electronics of the MRI

What are the values and specific needs of the stakeholders?
MRI Technician: Needs access to the operation without obstructing something. Access to the electronic components of the device or maybe replacement of head coils. You might find 2 or 3 different calibrations might be different. When replacing this this should be done without obstructing the radiologist.
Patient : The patient wants a comfortable position during the procedure. This is obstructed by the coil that might cause claustrophobia with the child.
Caretaker: Needs to be able to have access to the child. And be able to call the child when necessary.
Radiologist : want to be able to see the position of the patient and he needs to monitor the screen, so the operation needs to see the patient and operation needs to be easy

Stakeholder map

Repair and maintenance in Uganda
The biggest problem is the expertise
In terms of the equipment , access to spare parts and tools and testing devices. You might not be able to determine what is wrong with the device and access to the tools and spare parts.
The specifications should be few, so you don't confuse it with another. And of course, the recourse is there. The money to acquire this is not there. The other challenge is also the workload. If there is one, he should be doing a lot of things. There is a high workload. There is not a lot of maintenance.

Workload and the access to parts are a huge challenge that restrict the repair and maintenance of the MRI scanner.
Req: The components must not be very specific but widely available.
The MRI scanner needs to be as easy to repair as possible.

The low field envisioned it would need a lot of maintenance.
The Halbach system maintenance is not that much however you still have amplifiers which are electronic components, and it is not telling how an electronic device is failed. And the power bank . One of the challenges is that the power is not regulated so there is not a lot of fluctuation in the power.

Req: The electronic components need to be able to withstand power fluctuations

Who does this maintenance?
The hospitals have a BME in the team, but they are not specialised. They could be one or 2 people and they are expected to maintain everything. So, you find that they have a little bit of knowledge of everything, but they might not have an in-depth knowledge of everything. So, they might like additional support. Training would be well suited, but as it is now, they do not have very high skill or knowledge to repair them .

However, that also might depend on the cost, so those modular components are also very expensive. It is better to modularity replace rather than easily fix it.
Req: The preferred and most easy way to maintain the device is to make the electronics modular.
The repair and maintenance must be able to be done by a technician with minimal training

Context
Our recommendation is that the room is specifically set for the device.
3m * 3m is adequate

Human factors
1. little power and low cost
2. Is portable and easy to repair and modular.

Operating the device
Not many people are trained to operate the device, but after a bit of training people start to understand the device. However, this takes a long time. The factor that makes it difficult to understand is due to the high amount of moving parts and in the long run it can become confusing. Understanding all the components is difficult.
What component breaks the most often
The part that breaks the most is the amplifiers. The RF amplifiers because they must work with high frequencies. and take up high power.

Head coil
The head coil is not fragile because it's just a coil.
However within the coil you have a fragile part which is the 2 capacitors.
They have 2 capacitors that can fail. What we have found is that the parameters of the capacitors can drift. Tomorrow when you test the same frequency there is a drift in the capacitor and it makes tuning a little bit difficult. The high-fidelity ones are difficult.
When it is constructed, you must do the calibration

The two capacitors as the most fragile part need to be designed in a robust way. Furthermore, the ability to calibrate the head coil needs to be more user friendly.

Interview Context, tech, human: Radiologist (HIC & LMIC)

Dr. Leon Gieskes (radiologist, Congo, France, Martinique)

1. **Personal Introduction**

I am radiology of the old generation which means that I am all-round educated to do everything. Personally, I am more focussed on diagnosing for breast cancer, also with the MRI scanner and echography. I also do interventional radiology and all sorts of radiology treatments for different body parts. Within radiology, you have different disciplines, interventional radiology, especially for the limbs, neuroradiology.

Insight
The radiology from the older generation is more generally and overall educated which means that they can do different things. Nowadays the radiologists are specified in one specific body parts/organs. So, the ones that treat hydrocephalus, only do that.

Res: What is the profile of the user?

Req:

2. Hydrocephalus
Hydrocephalus is not the biggest case in Africa, and not the case where an MRI is most needed.
Process
With hydrocephalus, the role of the radiologist is to control the child. In the condition of hydrocephalus, the child has a drain which is a tube on the level of the thorax; ventriculoperitoneal. This allows the treatment of hydrocephalus.
Normally the hydrocephalus would be detected with X-ray, but since the MRI is available, people prefer to use the MRI scanner. However, it is only for people with enough wealth to do so.
Insight
What is important to consider with an MRI scanner for children is that they need to lay still and they can be claustrophobic

Req:
1. The child must be able to lay still for 10-15 minutes (without sedation)
2. The device should facilitate that the child will not become claustrophobic

Nowadays the permanent magnets are only used for bones, but a permanent MRI could be interesting for further development in ambulances for the diagnosing when there is a stroke. Sometimes there is a clog in an artery, so the position of this clog needs to be defined as soon as possible (before arriving at the hospital). Only in the case of the diagnostics of the head, such a device would be of high importance.

3. Accessibility in LMIC
In the Congo, there are 15-18 million inhabitants. There are exactly 5 MRIs in Kinshasa. They need more, but MRI is expensive. The people who have the money will seek treatment abroad, so they are not specifically in need of this device. The device is low accessible because it is difficult to buy it, due to the financial barriers.
For other LMIC it is important that the MRI scanner will be useful and accessible to the population. In HIC there is social security which means that there is a systemic structure such as a health assurance that pays for the cost of the treatment. In LMIC there is not such a system, so the patient needs to pay for the costs themself. They have a great advantage if the MRI scan lowers in cost. When in LMIC or remote areas something breaks, the technician needs to fly over from the big city, and the tools and parts need to come from a different country. So, it is very important that it is maintainable locally otherwise it is not even a benefit to buying a low-cost device.

Insight
An MRI scanner is hardly available in LMIC countries.
Because the patient is the stakeholder that pays for the treatment, a low-cost device has a high positive impact on the device.
It is very important that it is maintainable locally otherwise it is not even a benefit to buying a low-cost device.

Req:
3. The MRI scanner for LMIC must be cost-efficient
4.The MRI device must be able to be maintainable locally

4. **Operation/ process**
To operate an MRI you need a minimum of 2 people. There needs to be a manipulator. It is he who lights up and examines the head. The radiologist interprets the scan to see if there is something going on in the scan. The manipulator is there at the same time. He operates through a protocol list. It is necessary are examined and the doctor makes the examination. It happens that the manipulator. For babies, there is a problem. Normally you can't move during an MRI. If you move the exam that will affect the imaging. For a baby, he must be put to sleep. So, it means that if it is installed. The baby is narcotic. We give him hydro chlorate. It is possible that they will do the same in Africa. It won't surprise me that they do. But normally in limited areas, they will not use narcotics.

Insight
The MRI scanner is operated by two MRI technicians and the radiologist is the one that is interpreting the imaging in a different area. Because there are two MRI technicians this will allow the operation of the device and the interaction with the patient. The technician is the person that operates the device and guides the patient.

Process
1. The patient is briefed about the procedure
2. The patient must take out all
3. The MRI system for the operator is turned on
4. The patient is asked questions by the MRI operator
5. The patient is placed on the bed and secured
6.Check if the patient is well secured and placed
7. See which sequence needs to be put on for which disease (each situation has its own sequence) on the computer of the device

Requirement
5.The device must allow the operation for the MRI technician and the Interpretation for the radiologist.

5. **Interaction between the device and (patient/ MRI technician /**
The interaction with the device is mostly between the MRI technician instead of with the radiologist. This radiologist works with a mouse on the computer of the MRI scanner. This works very easily for him. The radiologist has 3 screens in front of him: with images of the axial, sagittal or frontal plane and a screen with the RIS. It has a great advantage that it has as fewer buttons as possible.
There is no major inconvenience that can be found on the device because the technicians operate with two people, this eases the task. However, fragile features on the device are highly inconvenient because this breaks down easily and is not easy to repair.

Insight
The MRI technician mainly operates the device with the mouse and needs as least buttons as possible.

Fragile features on the device are not convenient because this can be break easily. When something is blocked, it is really blocked until someone with the correct knowledge comes AND the spare parts from abroad.

Important complications with the patient-device interaction that occur are that fact that the patient needs to sit still, and claustrophobic patients can have a hard time and need to be sedated. A scan can take a minimum of 10 minutes to 15 minutes while an Xray can be done in 5 minutes

Requirements:
6. The device must be robust (and not have fragile features) for it not to break
7. The device must be able to maintain and repair locally

6. **Procurement**
The radiologist has a huge influence on which MRI scanner they would buy. Especially when you are a private institute. The important factors when buying an MRI scanner depends on the small details. The most important is 1. the price. 2. The size of the machine, the bigger the machine, the more space you will need to reserve and 3. If it is possible to maintain it immediately (for HIC/developed countries this highly depends on the brand and the service they offer). The maintenance is very important

because an MRI scanner often gets out of service because something is broken. The time that an MRI scanner is out of service is lost money, so immediate maintenance is very crucial. When you have a breakdown, and you stay a week out of service it's financially not capable. So, the maintenance needs to be fast, in the terms of that spare parts are easy to get and no specific tools are used, it is understandable for a regular technician, this would be very beneficial. Nowadays the technician can find everything on the internet and provide maintenance for this.

Insight

In small clinics, the radiologist has a big influence on the purchase and choice of the MRI scanner.

The most important factors that matter when buying an MRI scanner are:
1. the price
2. The size of the machine, the bigger the machine, the more space you will need to reserve which is not beneficial in small hospitals/clinics
3. If it is possible to maintain it immediately (for HIC/developed countries this highly depends on the brand and the service, they offer). The maintenance is very important because an MRI scanner often gets out of service because something is broken. The time that an MRI scanner is out of service is lost money, so immediate maintenance is very crucial. When you have a breakdown, and you stay a week out of service it's financially not desired.

Requirement
8. The device must be low-cost
9. The size of the machine must be as minimal as possible

Donation
Even if it is a device that we use well. It will work a little, but as soon as there is a failure it cannot work. So local maintenance is very important. In France they change their MRI every 5 years, the software and the hardware are no longer the same. You can't do the right things. I no longer agree with the used equipment system.

Insight
It is soon outdated and not workable after a while, so it is not a fitting option.

Interview Human factors: Neonatology

Dr. Niek van de Aa (Neonatologist – hydrocephalus, The Netherlands, UMC)

Children doctor for neonatal children with brain damage I also work in the intensive care unit for children with brain damage

MRI scan for hydrocephalus

Babies met hydrocephalus do not have a different head shape, but a bigger head shape. The skull circumference follows a different growth curve, so the total circumference of the skull is bigger.
The increase of the skull circumference is the last sign of the stages of hydrocephalus. The baby has fontanels which is under pressure. This will grow due to the tension.
The behaviour of the child can be that the child is quieter or more movable. The sunset phenomenon can occur which results in the children to become quieter and vomit.

The product must allow the vomit to be cleaned easily
The product must allow the different head circumference of the child to be adapted.

Procedure

The MRI scanner is operated by physician assistants and the most neonatologist do not see the MRI scanner unless there is something wrong.

Really small children are put in a special MRI incubator which is strictly designed for the smallest children to be diagnosed in an MRI scanner.

The reason why they use such a special device is due to :
- It is comfortable for babies so that the vulnerable neonatal(which can weight 500 grams)
- can be transported without being moved a lot.

The MRI incubator have all the required monitoring equipment so that the MRI technician is all prepared before entering the MRI room. The monitoring equipment involves
- heart monitoring
- Blood saturation monitoring
- Breathing equipment

Wish: Ideally, the patient must be monitored while being inside of the MRI scanner with the vital data (heart rhythm, blood saturation etc)

Challenges in Makin MRI scans
Premature babies
For the category of babies and premature children, it is difficult. Children under 28 weeks, pregnant mother between 40 and 30 weeks. They are scanned for the first times after 5 weeks.
Children that are born on time
Children that are born in time are scanned in the first weeks after birth. If not elaborate damage is present, the first scan is after 3 months.

Children between 0,5 year and - 6 years
Those children are not instructible and can be put at sleep in a difficult way. In western countries they are sedated otherwise there is no way to make a proper scan.

Children between 6 years old (girls) and 7 years (boys)
can be prepared for the procedure and are instructible.

Ways of keeping the child still/ comfortable

1. The young children are packed and will enter the scanner and get sleep medication which makes them sleepy. You can give them mild sleep medication for older children which brings them in a calm state.

2. The anaesthetist ventilates the child through the breathing tube, which brings the children in deep sleep. This method is always successful.

3. The child is distracted with a video that is visible in the head coil through a double mirror

4. A pre-heated vacuum mattress is used to keep the child still. Arms are fixated, which makes that the children are more comfortable

When the parents sit at the head of the bed the children will tilt their head, this must be prevented. This prevention is done with a double mirror in the head coil so that the patient can see the mother

The ideal MRI scanner for your children

To get the child as comfortable as possible for good imaging, the child is in a state of sleep. In some centres, there is a big-time slot booked of 2 hours to feed the children and get them asleep.

The technician does not need to physically see the patient, the guiding medial should have sight on the child. This can be direct or indirect. The MRI scanner needs a saturation meter to monitor or breathing monitoring devices, heartbeat monitoring devices.
In between the scans you can hear what happens inside the device so you can have a sense of what happens inside and if the child is comfortable. The temperature must be comfortable, and the patient must get as less a possible loudness and senses.

The medical technician must be able to see directly or indirectly the state of the child
The patient must be monitored (heartbeat, breathing, saturation)
The patient must have a least gesture as possible as preparation for the scanning
The MRI technician must have at least as possible gestures as preparation for the scanning

Comfort score for MRI
This is a validated score for the MRI scanner

Interview Context: MRI Repair and maintenance in LMIC

Interview Ger de Kok
objective: To find out what is the most important thing to consider when improving a low field MRI scanner for a better repair and Maintenance

Ger de Kok is an employee at Siemens Healthcare and provides service and maintenance on the MRI scanners worldwide. Most work is done on MRI scanners with superconducting magnets, however, Ger also has all the technical knowledge about the MRI scanner and what makes maintenance easy.

Currently
Most hospitals have MRI scanners of 1.5 T superconducting magnets, which is the standard. Due to the standardization of screws and parts, there is not a big difference in the needed tools for maintaining different MRI scanners in different hospitals and countries. It is important that most of the components and tools are standardized to ease it for the technician.

Permanent magnets
A challenge that occurs with the use of the permanent magnet is that this magnet reacts with the environment. There needs to be made sure that there is not inhomogeneity from everything around the magnet. Therefore, the shield is of high importance. This can be done with several materials and in various ways such as chicken wire. It is important that it should fit the frequency of these magnets. With a permanent magnet, this would be approximately 2mHz.

Req: A shielding is necessary of approximately 2mHz.

Problems that can occur within the design of the Low field MRI scanner involve
- Contact problems in the homogeneity which are related to the design of the shim

- How to arrange the gradient and cool this. For superconducting purposes, this can be done with water, however, with a permanent magnet, air cooling is necessary.
- A lot of things will dust out and require a good filter system. Even a vacuum cleaner filter might be good enough.

Req: A filtering system is necessary for dusting out

Due to the cost, it is recommended to minimize the nonferromagnetic materials since they can increase in cost a lot. Materials that can be used are RVs and aluminium bronze as a construction material.
Most of the coils are screwed on with aluminium bronze.
The birdcage can be made from copper thread, and you need to see what the maximum thickness of the used copper thread is.

What to consider when repairing and maintenance
Repairing an MRI scanner requires a lot of training and is a very specialized occupation. For a context in an LMIC, it could be the case that the first few technicians obtain a training, but after a year when that person leaves and his job is replaced by someone else, you will have the same problem of undertrained staff.
It is important that all the components that require feedback are made very visual. Making it visual helps the technician to give information about the state of something and can give feedback on the operation and placement or status of things. It is important that measurement areas are well visible. Furthermore, the tools and replacement objects need to be standardized.

Req: All components that require feedback need a visual indication.
Req: Measurement areas must be made visible.
Req: The MRI scanner must be compatible with standardized tools and replacement objects.

Troubleshooting
Ideally, the system follows that actions that happen inside the MRI scanner and “watches” along with the technician. When something breaks down a smart system needs to visually “tell” the technician who component has problems or what the state is of the components.

Head coil
The RF coil must be permanently connected on the gradient because this the component that breaks the easiest.

First to consider the Maintainability design principles.

What is maintenance and how to design for a maintainable

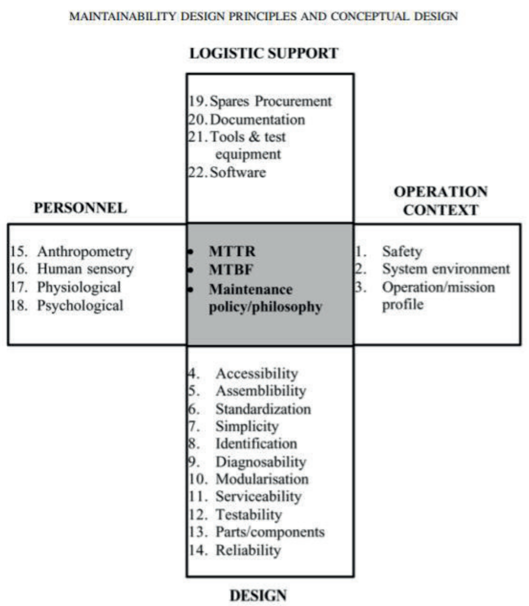


Fig. 3 Maintainability elements cross

Requirements

1. A minimum number of parts should be used
2. Use of standard components must be done to the maximum extent possible
3. Functional sharing
4. Adequate labelling of parts , adjustment points, access doors, safety, lubrication areas, connectors and cables should be present
5. Easy access for visual and manipulate tasks should be present
6. For assembly parts, there should be a minimum, quick-release and standard feature be implemented.
7. Cables connections and fasteners should be standardized.
8. Minimum of soldering and welding joints
9. Minimal servicing requirements should be present. Preferably wear-resistant, self-lubricating, longevity lubricant and surface coating materials should be used.
10. The characteristic should allow the status of an item to be determined (operable, degraded)
11. The weight must be no more than 200 kg.
12. Maintenance task should be designed to the skill, motivation, and moral level of the average technician. Tasks should be designed so that no more than two technicians are required.
13. Appropriate manuals for clear cut maintenance, instructions and check-ups are necessary. (Tjiparuro,2004)

Tjiparuro Z, Thompson G. Review of maintainability design principles and their application to conceptual design. *Proceedings of the Institution of Mechanical Engineers, Part E: Journal of Process Mechanical Engineering*. 2004;218(2):103-113. doi:10.1243/095440804774134280

Interview – Concept presentation/validation Dr Schiff

Objective :
To gain insight into contextual, human factors and technological restrictions considering the first design of the bed system of the MRI scanner

Interview and concept presentation
Dr Schiff

Feedback from Dr. Schiff
The concept is well-considered and covers most of the needed features and elements. Required from the stakeholder's perspective. What is important to include is that there is an importance of the device to be eventually built and assembled in the country, so material availability is very important.

Make sure that the red African dust will not pile up in the system.
For the current system, it will be very difficult to image, with a head only system. The head must be operatable in the field of view.

The person acts as an antenna and the conductive cloths help with shielding. Appropriate conductive materials should be included to make sure that the person is shielded. The loop of current in the mattress inside of the ground leakage
The mattress might have a function as shielding.

Head immobilization
The children have very thin skin on their heads so take this into account. Furthermore, the children can be very malnourished, so the children must be very comfortable and sleepy.
The immobilization needs to be super soft

The swaddling feature is very nice, for children it also works to put them into bean bags.

The future prospect of the Leiden version would ideally be for it to be a modular MRI scanner that travers around in a truck. Therefore, temperature control is very important.

Head circumference
In terms of typical HC on children with hydrocephalus, I usually figure that the median adult HC is a target that will permit most infants even with severe hydrocephalus to get into an infant-sized scanner like the Leiden unit. So, if one targets 55 cm, and if the head were a sphere, then you want at least a 15 cm diameter FOV, given that you need room to access the head of a subject. So … at least a bore diameter of 22-25 cm seems like the minimum size to capture most of these children. As a research device, you don't need a universal device, which would be much larger than anything we are working on (some of the children have very large heads if they are untreated).

We can, of course, try to get a distribution of head sizes from the CURE database, but this may end up requiring some manual chart reviews, and you should probably want to limit the ages of interest and of course the type of hydrocephalus (PIH, NPIH, SB, etc).

3.Observation

1. Problem research:
Observation of patient laying inside current(V3 2020) low field MRI scanner

1. Objective
While laying inside the low field MRI scanner, the researcher mentiones that even though he is very used to laying inside, the main cause of discomfort and cause for moving is the pain occurring in its neck and head. Therefore an observation is planned of the patient laying inside the low field MRI scanner to determine points for improvement.
Methodology
Interview and observation session
During the observation of the entire procedure with the functional prototype of the MRI scanner(20 min), the researcher entered the bore of the MRI scanner.

Result
Bodily pressure points
The subject felt a lot of tension after laying inside of the bore for 20 minutes. In the figure below the points where muscle tension is felt are indicated. An important point is in proximity to the head. When pressure occurs on this point, participants can feel a lot of pain which is very uncomfortable and is only increasing and becomes unbearable during the scan. This pain can already occur after 5 minutes of scanning. To prevent this, cushions are used to provide a soft surface for the body to lay on. However, this is not desired, as the cushions become dirty, can get lost and are not positioned correctly.

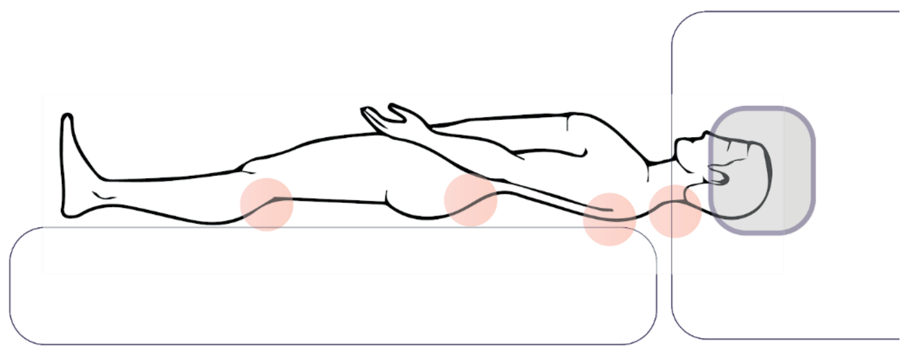


Figure 3 Schematic overview of patient laying inside MRI scanner with red critical points

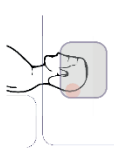


Figure 4 Schematic overview of patient's head inside MRI scanner

Comfort scale **4 out of 10**

Psychologic state:
The participant is asked questions about how calm and anxious he felt. The participant has expressed that in the beginning, he felt a little bit anxious as he is a researcher and fully aware of the dangers and risks of such a system. But in general, he felt calm and expressed that if he was laying comfortable, he would be able to sleep. This can also be since this participant is a researcher and developer of this specific system and has lied multiple times in the MRI scanner.
The environment was very hot and not comfortable. Furthermore, the sound of the system was not too loud.

2. Observation – Experience research

Visit at the Holland Proto therapy Centre
2 hours inside an MRI scanner for the scan of right knee and heart

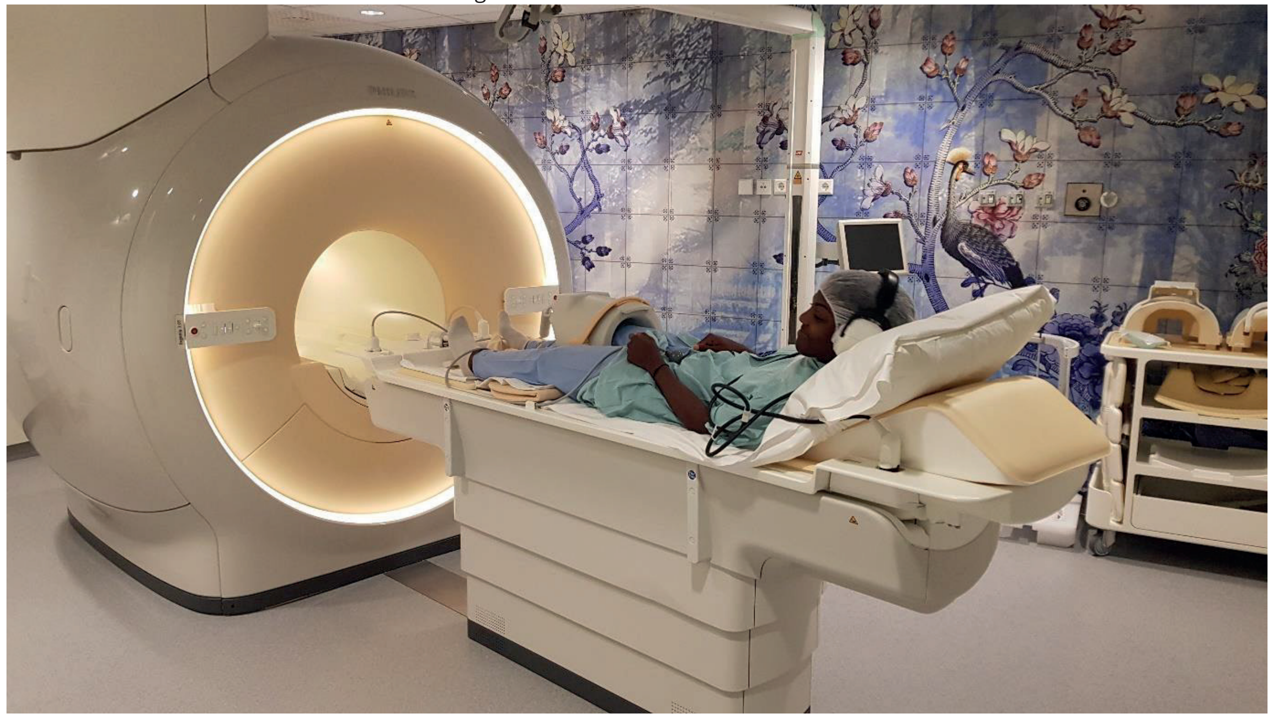


Figure 5 Researcher inside MRI scanner for knee imaging

- Procedure
  - Patient Journey task
    1. Enter the centre
    2. Get informed consent with the researcher and the nurse
    3. Go to the second room to change
    4. Change into medical gown
    5. Remove metallic objects
    6. Prepare with monitoring devices (cardiac, oxygen)
    7. Position self on the bed
    8. Nurse positions all the accessories on the participant
    9. Nurse aligned the subject correctly in the middle of the coil

10. nurse makes sure if the patient is comfortable and ok
11. Nurse explains all the options for when the participant is uncomfortable, and all the emergency exit buttons
12. Nurse puts blanket on the participant for the temperature
13. Nurse slides the bed inside
14. Nurse makes sure the subject is in the middle of the bore
15. Scanning starts
16. Nurse checks in if the subject is always comfortable
    - Thoughts and feelings
      - Despite that everything is done to make you feel comfortable, through cushions and light, eventually after 10 minutes everything that has pressure on you will feel uncomfortable, Posture : under your spine, shoulders, top of head, earplugs
      - Environment: cold at some points

- **What made you feel comfortable**
  Despite the fact that the environment and the equipment is designed to make the subject feel at ease as much as possible. It is the nurse and the researcher that make me feel comfortable.
- So it is of high importance that the nurse and the mother are at ease and can freely talk to the patient
- **What made you feel uncomfortable**
- Entering the bore was very scary. Even though I knew what it was all about and what it was, it was still a cold and narrow environment

- It was nice that the researcher could talk to me
- It was nice that it had an open end and light
- It was comfortable and reassuring to be able to see the end of the tunnel, so you know you are not inserted in a coffin.
- What made me feel uncomfortable was that the environment was very cold
- Also, after a while, the comfortable position starts to hurt and becomes very uncomfortable.

Findings

- Light is nice
- Open environment is nice
- Sandbags are used to immobilize subjects
- Once the head is positioned , it is difficult to move
- If a mirror should be placed, it is comfortable to make the patient look forward, and not backwards or up

Discover

Background research to define product requirements

C. User research

D. Context

E. Technology research

C. User

1. Stakeholder map

	Level	Stakeholder	Role	Characteristics
ning	Regulatory	Ministery of health	Decision maker	Responsible, but not pro-active. Mostly overseeing regulatory requirements
ning	Operational	Public hospital	Future procurer of the device	Not much funds
ning	Operational	Private for provit hospital	Future procurer of the device	Not much funds
ning	Operational	Private not for profit hospital	Purchase the device , use and house the device	Rely on funds and donations. Provide free treatment
astructure		Supervisor	Train the personel	
astructure	Manufacturer	Product packager		
astructure		Safety officer		
astructure	Transporter	Trucker loader	Load MRI scanner in truck	Without heavy of advanced euipment the truck is loaded
astructure		Truck driver	Transport MRI scanner in truck	The MRI scanner is transported on wobbly roads
astructure	Implementer	Quality control officer / Safety officer		
rect use	Maintanance	Repairer	Provide maintanance and repair on the	To repair the MRI scanner when there is a troubleshoot , Order the necessary parts
ct use	Patient	Patient 0-4	Main patient	Needs help when laying still
ct use	Caretaker	Nurse	Take care of the patient when the parent is not there or when the patient is severly sick	Provides care based on his/her training for medical nurse (sedation etc.) Not trained to calm babies Has a very high work load
ct use		Parent	Calm the child, communicate with the child trhoughout the process and take care of the child	Has no training at all and is only present to support the child physically and especially mentally
ct use	Doctor	Doctor	To interpret the images	Highly trained for medical issues, but not for technical devices
ct use	Medical Technicia	Medical Technician	To operate the MRI scanner	Is trained to operate and maintain the MRI device, but has very high working lo
of life	State governemen	Product recycle planner	Arrange logistics of recycling	Not present in country
of life	State governemen	Post production recycle	Recycle materials	Not present in country

Values	Needs	Problems/Challenge	Priority
Wellbeing of the population, Be able to fullfiill mandate of ¶	Cheap and good quality product	Financial funds and ongoing	low
Wellbeing of the patients, provide as adequate care as poss	Time and cost effective device	Financial funds, trained personel	
Wellbeing of the patients, provide as adequate care as poss	Time and cost effective device	Financial funds, trained personel	
Good quality device	Good quality device		
Has a high workload and might be in a different district.	Clean manual, device with standardize parts, understand	That the product is modular and easy t	
Wants to become better	A (physically and emotionaly) comfortable treatment wh	The child can become claust	Very High
1. Care for the child. 2. Wants to be respected and use good functioning products 3.		Has a high workload and is not trained t	
1. Take care of the child (Wellbeing of the patient)	Accessibility for interaction with the child	May be standing in the way	
1. The wellbeing of the child. Must be able to see the imagi	Accesibility for seeing the image and the child at the same time		
A easy to use and to maintain device. No fragile parts	The needs of the medical technician are that the device i	The main problems and cha	Very High

2. Literature research : Patient with hydrocephalus

2. Literature research : Patient with hydrocephalus
Objective : To define what the patient characteristics are
Methodology: Literature research

1. Cause

Cerebrospinal fluid is saltwater with nutrients made inside the ventricles which flows around the brain and spinal cord to cushion them. This fluid is afterwards absorbed into the bloodstream where after new fresh CSF is newly produced. The two types of hydrocephalus that can occur are obstructive hydrocephalus(flow of CSF is blocked) and communicating hydrocephalus (not enough CSF absorbed in the bloodstream). (Noncommunicating) Obstructive hydrocephalus is a condition that indicates noncommunicating hydrocephalus where the flow of the CSF is blocked along one or more of the ventricles. Communicating hydrocephalus occurs when the flow of the CSF is blocked after is exists in the ventricles. The CSF can still flow between the ventricles which remain open.

2. Diagnosis methods

MRI is mostly used for more detailed assessment since it can detect the flow. Hydrocephalus can be diagnosed before birth with prenatal ultrasound only from the third trimester of pregnancy. In this case, a diagnostic imaging technique produces high frequency sound waves to create images of the blood vessels, tissues, and organs.
After birth, the diagnosis can be made through several examinations by the doctor. CT scanning is a method that can scan acute as well as chronic hydrocephalus, therefore it is the typical imaging method, especially in emergency settings. This can only be done up till 12-18 months when the anterior fontanelles close.
After this stage the CT scan can no longer penetrate the skull.
Diagnostic tests can be performed include:

•Ultrasound
Benefit: It is cheap, and an image can be created to determine the size of the ventricles in the womb and neonates. It is best used as a screening or surveillance test for follow up.
Drawback: It can be challenging to visualize details. It is limited in its role for evaluation
since ultrasound is only possible when the anterior fontanelle is still open since ultrasound
cannot penetrate through bone.

•Magnetic Resonance Imaging (MRI)
Benefit: No radiation is needed to image the patient. It shows more particularities than a CT scan.
Drawback: It is expensive, so the availability of the device is minimal.

•Computed tomography (CT) scan
Benefit: Shows detailed images of any body part including bones, muscles fat and organisms. Except for the enlarged ventricles, the eventual cause of the hydrocephalus can be determined.
It is a quick method that can provide high quality images. They can also show movement
of the body part such as flowing blood in vessels. Patients do not need to be sedated because the procedure is fast. No need for metal screening, which makes it useful for emergency setting.
Drawbacks: The drawback of diagnosing with the repeated use of CT, there is risk in exposure of ionizing radiations. Repeated exposure due to multiple examinations may have harmful effects on the developing brain and associated lifetime oncological risk.

Prior to surgery, the diagnostic of the disease is crucial to detect the location of the excess fluid in the ventricles. This can be done through prenatal ultrasound from the third trimester of pregnancy. After birth, the diagnosis may be confirmed through ultrasound up until 12- 18 months when the anterior fontanelles close. After this period, the ultrasound can no longer penetrate the skull and several alternative examinations can be proceeded to diagnose hydrocephalus such as CT scanning or MRI scanning. CT scanning is a method that can scan acute as well as chronic hydrocephalus, therefore it is the typical imaging method, especially in emergency settings. The Low Field MRI scanner can distinguish between CSF, white matter, and gray matter, which is specific enough to provide a diagnosis of hydrocephalus. The MRI scanning method is a preferred technique to CT scanning, ultrasound and cisternography due to its appropriateness with the context and use of diagnosing infants with hydrocephalus. Due to its lack of exposure risk of ionizing radiation it is preferred to CT scanning. Repeated exposure due to multiple examinations may have a harm full effect on the developing brain and associated lifetime oncological risk.

3. Treatment process

Treatment
The goal of the treatment is to reduce the pressure in the baby head and to drain the cerebral spinal fluid (CSF) [37]. Surgical treatment for hydrocephalus can restore and maintain healthy cerebrospinal fluid levels in the brain. This includes one of the two surgical options.

- Ventriculoperitoneal Shunt (VPS) is placement of a shunt into the brain to drain the excess fluid into a cavity in the body to redirect the fluid to be absorbed.
- Endoscopic third ventriculostomy (EVT) is a procedure a hole is made in the lower part of the ventricle to divers the CSF and relieve the pressure.

Imaging technologies play a crucial role in understanding the hydrodynamics of CSF flow, pathological processes, and abnormalities. The comparative analysis between the imaging techniques (ultrasound, CT and MRI) is illustrated in Appendix E.

MR Imaging
Prior to surgery, the diagnostic of the disease aids in detecting the location of the excess fluid in the ventricles.
MRI can provide the opportunity to evaluate the causal disease and to assess the effects of hydrocephalus on the developing brain. Imaging is necessary for disease recognition, shunt infection, shunt malfunction. The MRI is the current modality for

assessing paediatric hydrocephalus. MRI is used for

- Surveillance of ventricular size
- Identification of the underlying aetiology
- Assessment of ETV patency
- Assessment of parenchymal changes
- Pericerebral spaces

Radiological features of hydrocephalus
The common structural detectable characteristics of hydrocephalus are (Figure 5.3)

Detectable characteristics of hydrocephalus in MRI

1. Narrowing of ventricular angle
2. Upward bowing and thinning of the corpus callosum
3. Hyperintense on MRI (hypodense on CT) areas in the periventricular white matter, suggestive features of acute hydrocephalus
4. Effacement of cortical sulci [38]

[6, 4]Enlargement of ventricles (Evans index > 0,3) out of proportion of the size of SAS (cortical Sulci is proportionately narrowed), ballooning of the frontal and posterior ventricular horns
[2]Dilatation of temporal (frontal) ventricular horns of the lateral ventricles
[1]Dilatation of the (anterior and posterior) third ventricle recesses
[4,5] Reduced mamillopontine distance

To allow the low field MRI scanner to provide qualitative images that are able to detect the features mentioned above, the patient 's brain must lay still inside the narrow field of view.

4 After treatment

Hydrocephalus can affect the brain and the child's development based on the severity of the hydrocephalus. The key to treating hydrocephalus is early detection, proper treatment, and infection prevention. Therefore, regular medical evaluations are crucial to ensure proper shunt function. The medical team and the parents collaborate to provide good development for the baby.

Monitoring
Hydrocephalus is a neurological condition that requires lifelong vigilance due to developments in the brain. Patients treated with a VPS are monitored with frequent follow-ups as shunts may malfunction or cause infections. Follow up with a paediatric neurologist is done at least every six months until the age of six, and yearly after six years with brain MRI.

2. What are the patients' characteristics

Behavioural characteristics

Babies met hydrocephalus do not have a different head shape, but a bigger head shape. The skull circumference follows a steeper growth curve, so the total circumference of the skull is bigger. The increase of the skull circumference is the last sign of the stages of hydrocephalus. The baby has fontanels which is under pressure. This will grow due to the tension. The behaviour of the child can be that the child is quieter or more movable. The sunset phenomenon can occur which results in the children to become quieter and vomit more than a healthy child [84].
Behaviour of children inside the MRI scanner It is important that a child remains still inside of the magnet for a qualitative good outcome of the scan. In clinical settings four categories can be defined for the approach on how to remain a child still based on their age.

Children that are born on time
Children that are born in time are scanned in the first weeks after birth. If not elaborate damage is present, the first scan is after 3 months.
Children between 0,5 year and 6 years
Those children are not instructible and can be put at sleep in a difficult way. In western countries they are sedated otherwise there is no way to make a proper scan. Many commercial alternatives have made approaches and methods to provide this.

Children between 6years old(girls)and 7 years(boys)
They can be prepared for the procedure and are instructible and can be familiarized with a
training mock-up.[84]

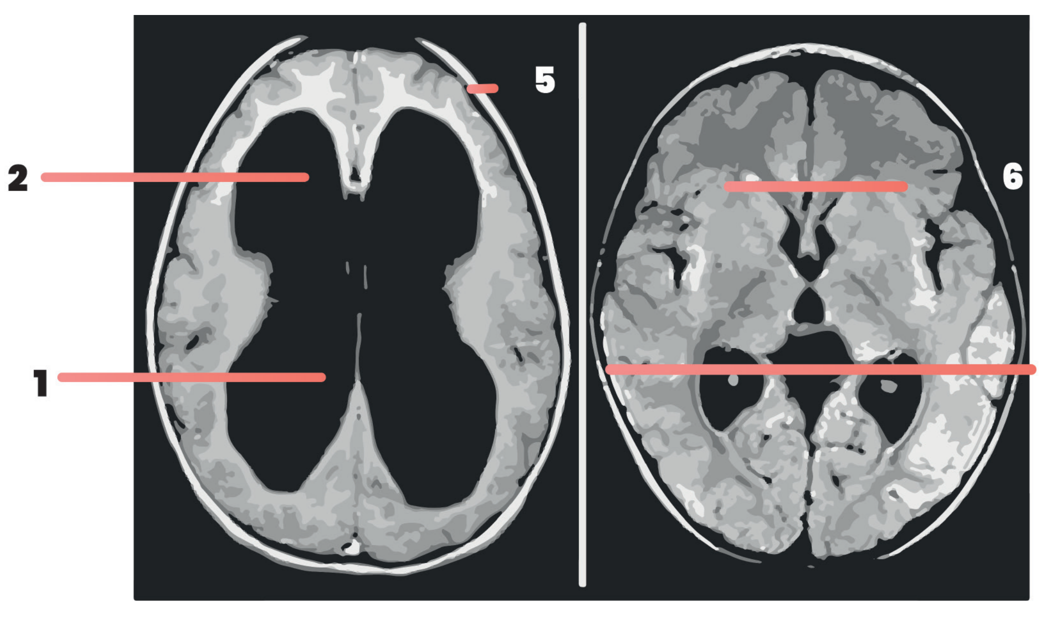


Figure 5.3 Detectable characteristics of hydrocephalus in MR Imaging left patient, right healthy CSF flow

3. Persona

Figure 6,7,8 below illustrates the persona of the patient, MRI technician and radiologist.

Mukisa

Age	0-2 | 2-6 | 6-8 years old
Health condition	Pediatric hydrocephalus
Biology characteristics	Maximum head size of 26 cm Head shape: More round than oval with irregularities
Hobbies	Play
Daily occupation	Be with mother

Mukisa's situation

Mukisa is born with pediatric hydrocephalus and needs to be monitored in the hospital routinely. For this treatment she needs to travel a long time as she begins her journey towards a healthy life.

CHARACTERISTICS

- Very sick and needs care at all times

NEEDS

- Needs her caretakers
- Needs someone to secure her
- To feel loved and supported by family
- Help getting everyday things done

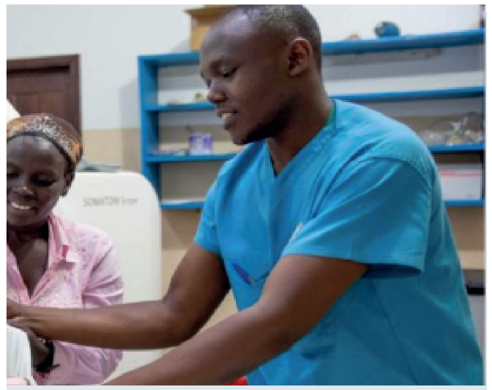
GOALS

- wants to become healthy
- Needs someone to secure her

PAINT POINTS

- Fully dependent on others
- Can not follow directions yet
- Needs someone to secure her

Figure 6 Persona patient



Richard

Age 30 years old
Health condition Healthy
Daily occupation Nurse at CURE hospital

Ochieng situation

Richard is a nurse at CURE hospital. Often the nurses don't have the equipment they need to provide care. Additional to this, there are not a lot of trained nurses in rural hospital which makes the workload very high.
Nurses are yearly rotated so they don't have the chance to familiarize much.

CHARACTERISTICS

- Has has training, but not periodic
- Works hard

NEEDS

- Good functioning equipment
- Trainnig and instructions
- Safe workplace

GOALS

- wants to learn and become a better nurse
- Calm the worries families
- Needs someone to secure her

PAINT POINTS

- High workload
- Not much time to get training
-

Figure 7 Persona MRI Technician

Manuel

Age 50 years old
Health condition Healthy
Daily occupation Radiologue at CURE hospital

Manuels' situation

Manuel is a radiologist in the CURE hosptial in Uganda. As one of the few highly trained doctors he performs the most imaging diagnsotics. Due to the lack of trained personel, he has a very high workload and is only consulted when really needed.
His involvement in procurement is high due to his high influence.

CHARACTERISTICS

- values good quality products that works well and is well usable

NEEDS

- Good functioning equipment
- Trainnig and instructions
- Safe workplace
- A good imaging that is well interpretable

GOALS

- Perform a good imaging
- Needs someone to secure her

PAINT POINTS

- High workload
-

Figure 8 Persona MRI Radiologist

4. Research :Patient bodily characteristics

Objective : To define the bodily characteristics of the patients spine as part of the ergonomics research.
Methodology: 1d, 2D and 3D antrophometrics

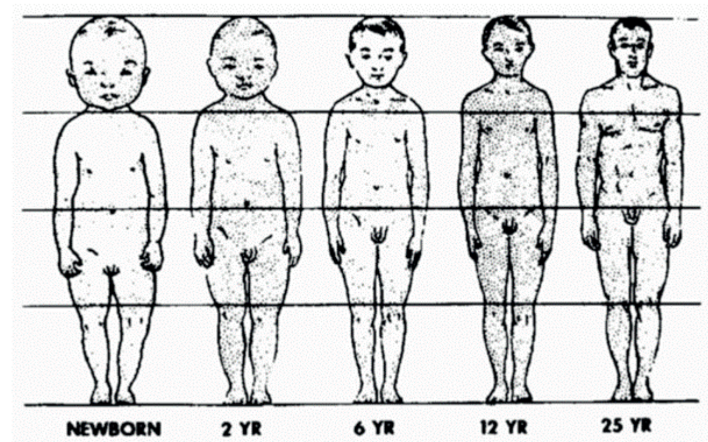


Figure 9 Bodily proportions of human body

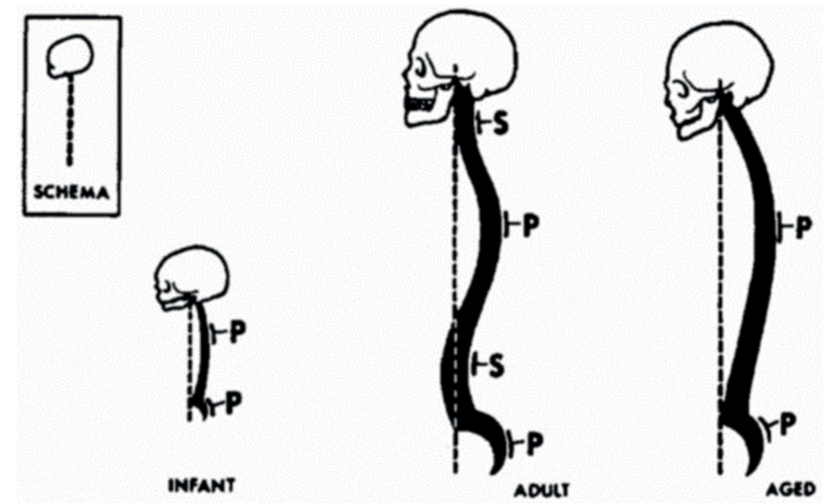


Figure 10 Shape of spine development from infant to aged

Baby spine

At birth, the spinal column comprises 40% of the total length of the infant - identical to the adult. However, the average length of the spinal column in the newborns is just 24 cm or 9.6 inches. The spinal column grows 50% in length during the baby's first year of life. Over the following 4 years the spine will continue to grow another 15 cm reaching a length of 51 cm or 20.4 inches.

Size
Dimensions and data from the CT scans of the Cure hospital have been analysed to determine the mean of the head size, the average age of the most occurring children and the largest occurring head size diagnosed inside the hospital. With this information the range of the to be diagnosed children has been made.
With the knowledge of the proportions and size, 3D models have been made(DINED,2007) and 3D printed that help with understanding the problem, and with conceptualization.

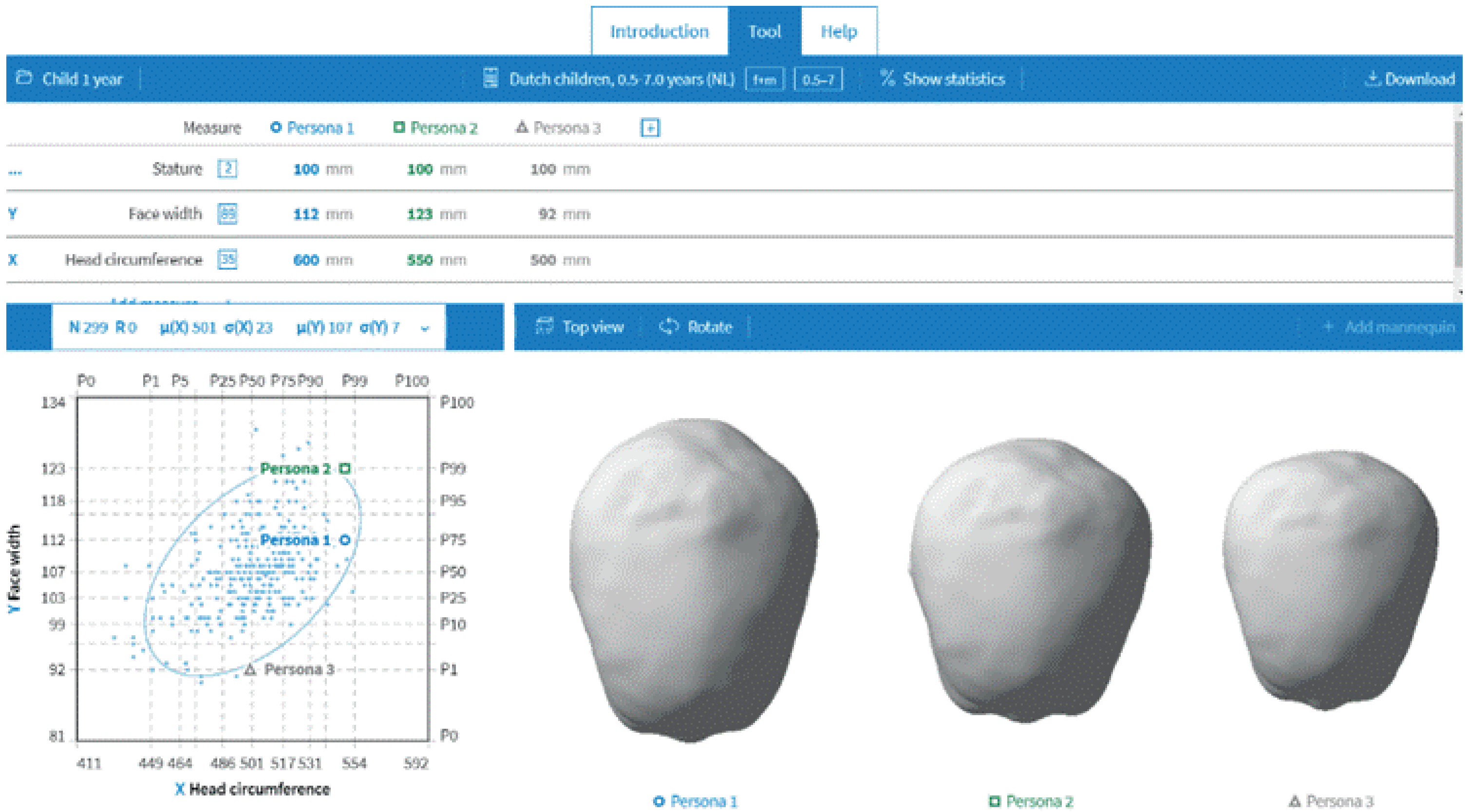


Figure 11 Data acquisition from DINED (top of patients head)

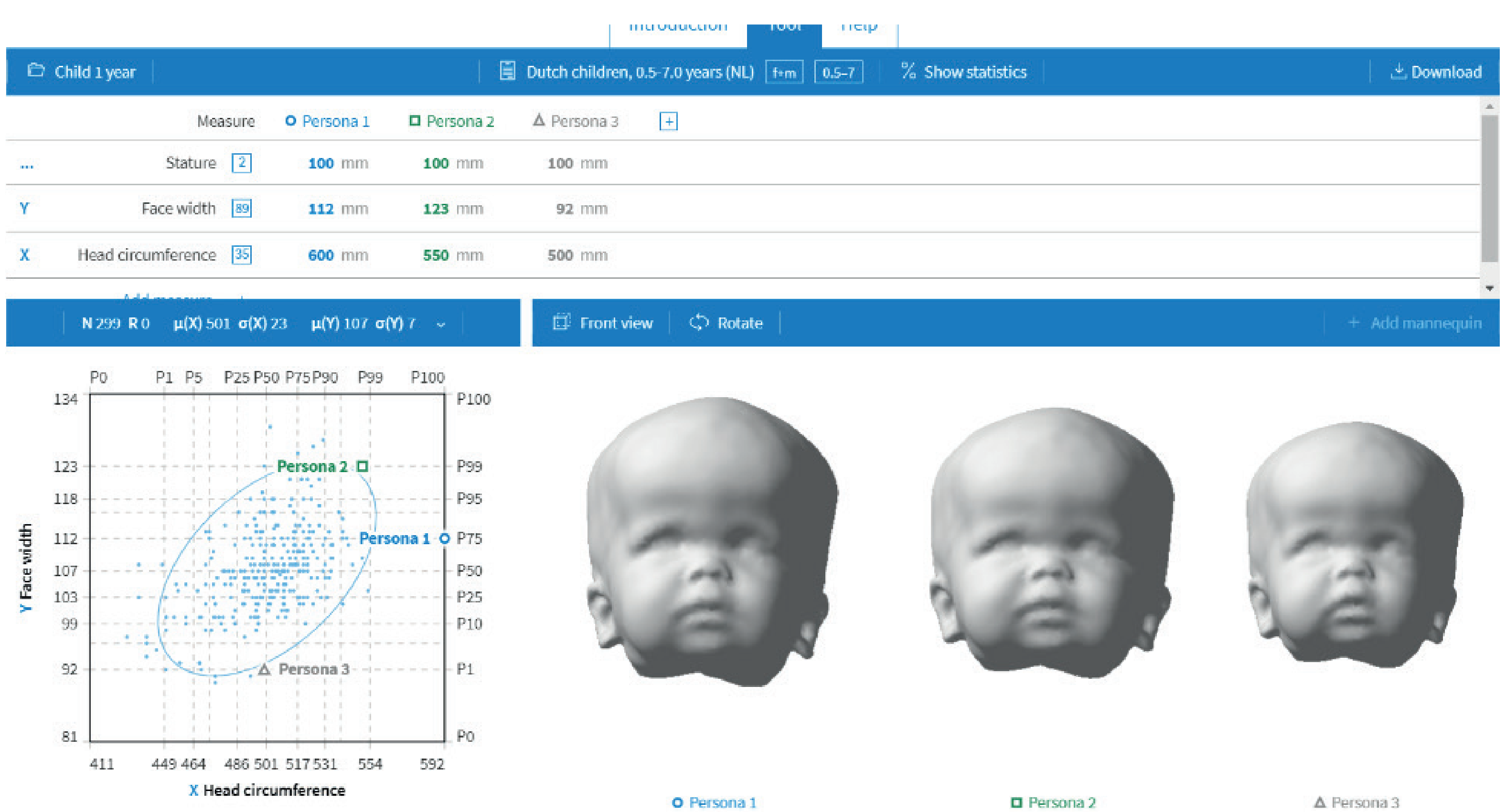


Figure 12 Data acquisition of patients head DINED (en profil)

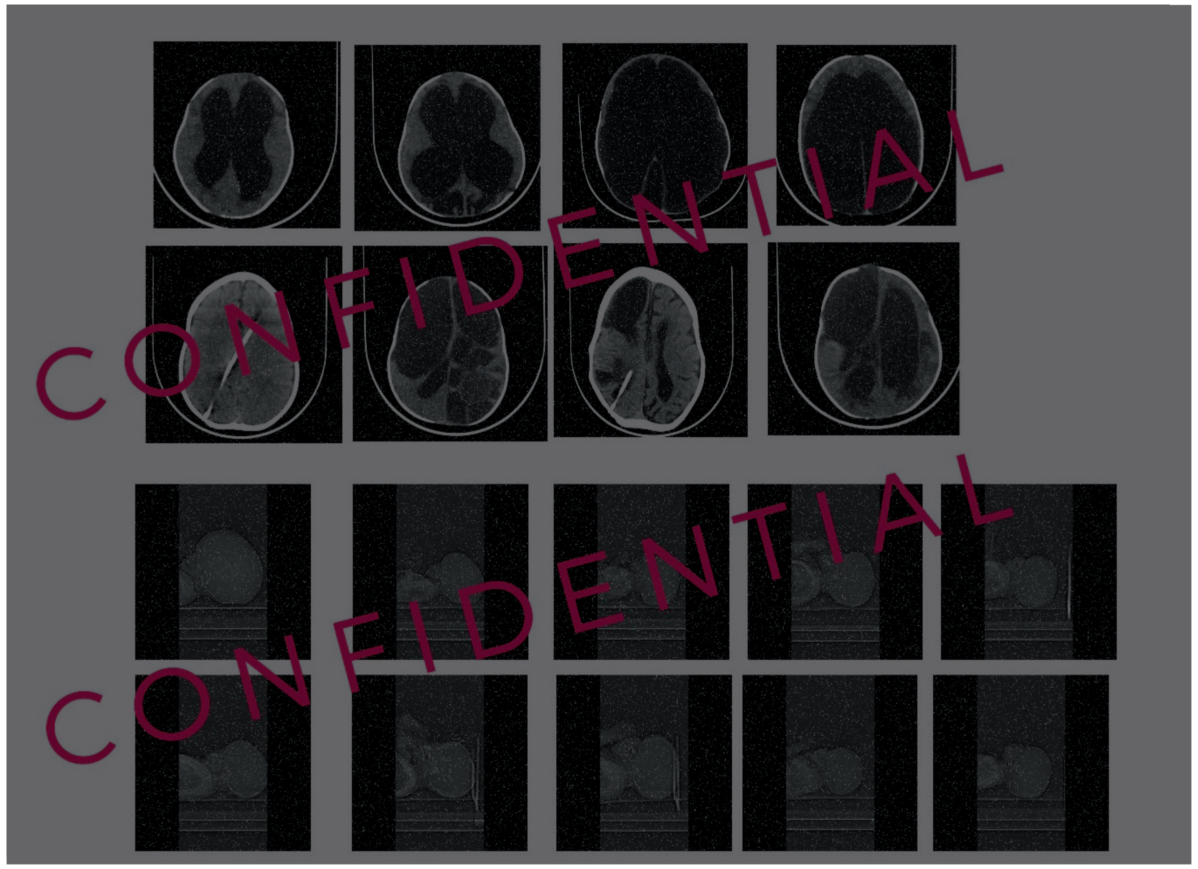
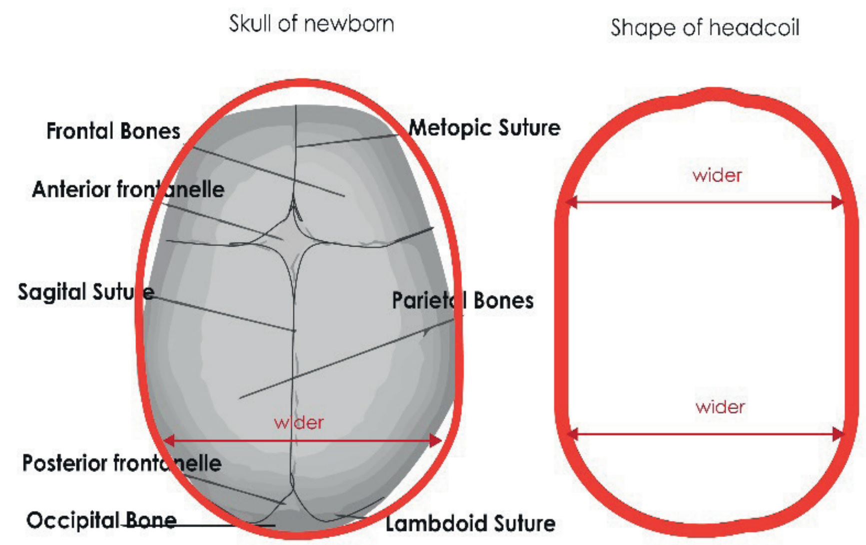


Figure 12 BLurred - CT Scans of patients with hydrocephalus CURE hospital

Shape

The data from the CT scans were analysed to see what the characteristics were of the head shape of a patient with hydrocephalus. The circumference and the side view were analysed. This image is only visible for supervisor – other data is highly confidential and will not be demonstrated.
The head shape is specific, but It has some similarities.
Overall the head is mainly convex shaped, with the top of the head and the
The neck is more concave shaped with bulging on the front of the head and on the occiput area.



As can be seen in figure 13, the parietal bones of the infant's head are wider at a lower angle. Therefore, the designed head coil shape is not completely elliptical, but an ellipse with a wider part at 1/8th of the length of the shape.

Figure 13 Top view of average infant head shape (left) and designed head coil shape)

Anatomy Research
The important data for the design of the head coil has been retrieved from data out of HICs. There is a minimal difference in the data from children from African and Caucasian descent. Therefore, the data from DINED and other anthropometrics could be used.

Children with hydrocephalus
No different growth curve but just a steeper growth curve.
Per patients there can be a lot of variety in the dimensions, the age, and physical conditions.
The mean of the patients coming in for treatment are around 50-60 cm with a mean of 55 cm circumference. The values of the head are used as sources to be used when designing the head coil.

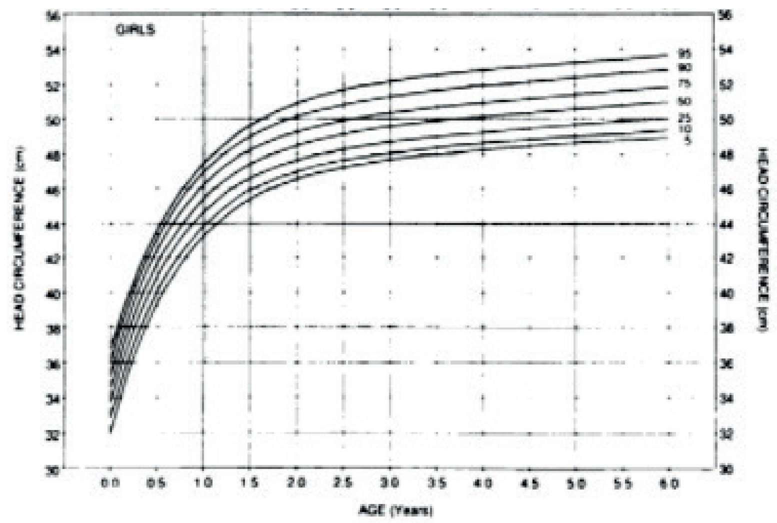


Fig 4. Selected percentiles for smoothed head circumference values of girls from birth to 6 years.

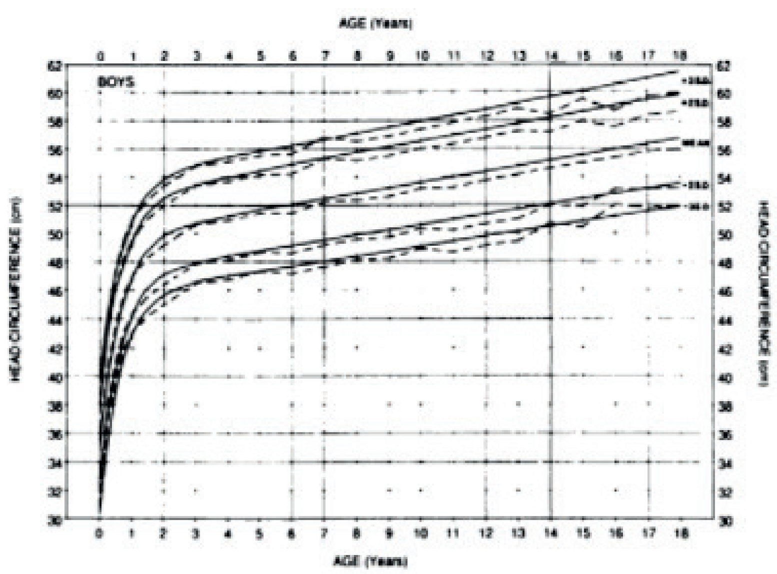


Fig 5. Smoothed means (±2 SD and ±3 SD) from head

Figure 14 growth curve of infants head cirfumerence (Roche, 1987)

Data interpretation
In this graph the growth curve of paediatric patients with hydrocephalus can be found. (Roche AF, Mukherjee D, Guo SM, Moore WM. Head circumference reference data: birth to 18 years. Paediatrics. 1987 May;79(5):706-12. PMID: 3575026.)

The head coil will be designed for children with the range of age between
3 months and 4 years old
this is a body length of 50 cm - 100 cm
and from 9 kg - 15 kg

5. Research 3D mock-up

Objective : To define the patients characteristics in relation to the low field MRI scanner. Proportions, dimensions and are defined.
Methodology: 3D body scanning

Body of child between 0-4 years old.
Because no data was known about the bodily dimensions and proportions/curvatures of children between 0-4 years old. A 3D scan was made of a child of 4 years old.

Method
Eventually a 3D model was CNC milled to be able to analyse the bodily proportions and to use the model during the conceptualization phase.

Figure 14 3D scanning of infant of 4 years old

D. Context

1. Literature research - context

Medical devices in LMIC

Background
Healthcare technology is one of six crucial fundamental components of an effective health care system as identified by the World Health Organization (WHO) [27]. The WHO has set goals to improve the accessibility of good healthcare to every individual worldwide with medical technology [27].The medical device industry is one of the most dynamic sectors of the economy with an estimated worldwide revenue of 210 billion dollar in 2008 which is only growing worldwide [28]. While most of the medical device manufacturers are situated and produced in and for high recourse settings, LMIC only spend 11% of the healthcare spending with 84% of the world population [29]. Despite the growth of this industry and the pursue to provide high-quality healthcare for all, Low to middle income countries mostly lack in this high-quality healthcare.

Current state of medical devices in LMIC
Currently, a large proportion of the basic medical equipment is not available, broken, or unusable. An extensive study of inventory reports reported that 40 % of the medical devices present in hospitals is not usable[3][30]. compared to high income countries, where only 1% of the equipment is out of commission [17]. Of the devices in use 35% was not functioning due to equipment breaks and the in scarce capacity to repair
Donations
Consequently, these areas rely on donations which make up around 80% of their supply of medical devices [18]. These donations are given with the good intent to strengthen health systems and improve the populations wellbeing, however a large amount is observed to be out of service [31], because they often do not meet the WHO guidelines or the local needs, and therefore fail early. The effect of these unused medical equipment is hundreds of millions of dollars of waste.

Mismatch
Most medical devices are designed for industrialized countries with an abundance of recourses. They are produced by ompanies from high income countries, for high income markets. The technology is mostly designed for environments with a high spending on health,m reliable energy supply and many trained professionals [32]. Besides the high cost price, the other main reason for the low availability of MRI scanners in LMICs is the complexity of operating an MR system. As can be seen with donated medical devices from western countries, the donated equipment might have the good functionality, but only 10-30 per cent becomes operational. This is because the market and does not fit the context of the LMICs, because of the mismatch in the suitability indicators. These suitability indicators address issues in the characteristic of the medical device in relation to the appropriate setting, the assured quality and safety, the ease of use and maintenance and the affordable characteristic[33] [14].

3.4. Barriers and challenges
There are certain barriers that are unique for the low recourse settings. These are addressed as follows.

3.4.1. Barriers
The phases and its corresponding barriers can be found in table
1.Contextual challenges
Medical equipment which is known to be effective in High recourse settings but fail in low resource settings can be due to different contextual and environmental barriers. The introduction of donated medical devices but also manufactured devices specially for Low-income countries must take these barriers into account and provide product features the address and overcome these barriers

Cost
The main reason why there is a lack of medical devices in LMIC countries and the cause of the introduction of donations, is due to the high cost of purchase together with the operating cost of the medical devices. Additional to this, disposable parts are paid by the patients on top of the treatment costs, which results in financial challenges for the patient [38].

Environmental conditions
The contextual differences from HICs such as higher temperatures, eruptive power supplies and dust. in LMIC demand different requirements from the device. The technical infrastructure of the receiving hospital is not considered, burdens such as unstable electricity, drastic environmental change [31]. The device must withstand this challenging environment to sustain [39].

Power cuts
In low¬-middle income countries the medical equipment is designed for environments that have reliable electricity. Many countries have a generator to provide electricity during power cuts from the unstable electricity network. For the equipment it means that the device needs to be able to withstand such conditions, as well as the fact that voltage peaks can occur that may cause damage to the device. Many areas in LMIC deal with an inconsistent power supply. This can cause power surges and drops which can potentially damage the equipment. Therefore, it is crucial to consider including a backup power supply stabilized to keep the equipment's continuing during blackouts.

Lack of recourse availability (human/parts)
A reoccurring problem defined in literature has been the lack of spare parts due to budget problems or outdated technology. Donated equipment is mostly delivered with a lacking manual, which makes it impossible for the technician to identify which part is needed [22]. The implementation of repair recourse and spare parts that are readily available also increases the accessibility and durability of the device [23]. Besides the challenge of operating the medical equipment, also the maintenance provides challenges. Replacement costs are high and spare parts are mostly scares. Therefore, it is important that products in this context are designed by considered the accessibility of only standardized parts to provide cost¬-effective repair and maintenance.

As a result many medical devices are deployed in LMIC without enough thought of the conse¬quences, which has as an effect the early end of life of a medical device due to lack of maintenance. This is a problem caused by the lack of experts that are equipped to maintain the devices and the lack of spare parts and exclusive tools needed for the repair and maintenance. A reoccurring problem defined in literature has been the lack of spare parts due to budget problems or outdated technology. Donated equipment is mostly delivered with a lacking manual, which makes it impossible for the technician to identify which part is needed [22]. The implementation of repair recourse and spare parts that are readily available also increases the accessibility and durability of the device [23].

Expertise and training
The safety and treatment outcome of medical devices is directly linked to the operators' skills and how the equipment is managed [14]. This has been perceived to be a continuous case. The one¬time training provided by the manufacturer has often shown to be not sufficient in developing countries. There is a need for frequently training of new staff [40]. Furthermore, the lack of health personnel and proper training forms a problem for the implementa¬tion of the Low Field MRI system [36]. Therefore, it is important to consider the user interaction with the product when designing the embodiment of the device to provide an as intuitive experience as possible to minimize hazard by human error. A" brain leak" also occurs when medical staff is educated but pursues its career elsewhere. The gained knowledge is not transmitted to the other personnel while the investment costs for education and training for the hospital in the low recourse setting was high.

Lack of Biomedical engineering supports
In many cases, users were not trained properly for the use and handling of the equipment which could avoid breakdowns. Technicians with minimal training were scarce. Not only the human recourse was not fully adaptable to the equipment which led that the maintenance and repair could not be handled properly [41] [42] due to lack of knowledge, no formal training. Whenever a medical device is in use, there will be a moment that maintenance or repair needs to be provided to ensure the durability of the device. According to research these factors has been defined as the key element to the safety and sustainability of certain medical equipment. Many Low resource settings lack individuals with expertise in clinical and engineering to ensure timely maintenance and repair [22]. This adds up to the unreliability of the medical equipment and leads to potential hazards and risks to patient safety. Other categories consist of provider related factors, such as the skills and the state of the healthcare providers, patient¬ related factors such as the patient's attitude, and policy governance barriers, that mostly affect the delivery of care [43].

How can we solve this?
By addressing the barriers that hinder the introduction, diffusion, and operability of the device itis important that the implemented medical device can withstand the environmental challenges and is aligned with the values, needs and expertise of the local staff. Further it needs to bring perspective so that it can be used sustainable and not only be implemented in the country without a future perspective. The focus on repair and maintenance/ increasing the use cycle of the medical device is an important factor.

Robust
Considering the setting of the devices, it will most likely operate in an area highly dependent on recourses available on site. Robustness is an important requirement to be able to withstand external forces and environmental influences. Since the field homogeneity can be affected by change in the magnet's magnetization direction, volume, or temperature. Falling or collision damage can reduce the total magnetization of the damage. It is thus of high importance that the embodiment of the device is robust to protect the inner technological setup of the MRI. [44].
1. There is a lack of financial funds that result in the inability for LMIC to purchase medical devices.
1.1 The patients fund their own treatment and every additional time in the hospital increases their treat¬ment cost.
2. Low recourse areas are frequently impacted by power cuts and are dependent on their unreliable power supply.
3. The medical devices are operated in low maintained hospital infras¬tructure, sometimes without an air conditioning and a lot of dust which is not good for the equipment.
3.1 There is a lack of spare parts
3.2 LMICs there is a lack of maintenance recourses
4. There is a scarce of trained medical professionals in hospitals in LMICs.
4.1 Due to the lack of personnel, the trained personnel have a high workload.

System requirements
1. medical device must be cost effective for the hospital to purchase the medical devices
1.1 The medical devices must be cost effective in ownership and not be more expen¬sive than the competition with the same performance 2. The medical device must be able to withstand power eruption
2.2 A backup power supply is required to stabilize the power supply and keep the equipment functioning during a power blackout.
2.3. The medical device must be able to withstand the environmental conditions such as high temperature, high humidity.
3. The medical device must be designed by considered the accessibility of only standardized parts to provide cost-effective repair and maintenance
4. The medical device must match the knowledge level of the basic trained personnel

3.6. DEPESTE Analysis

3.6.1 Demographic trends
The demographics of Uganda in terms of the local education, employment and big changes that impact the business, or the product involved in the lack of trained medical personnel. Traditional births at home are still common in Uganda since the health centers might be too distant, the cost of transportation and medicines are high. [45]. In the past decade, Uganda has been experiencing an 'orphan¬ crisis' where mothers abandon their children that are affected by physical or mental disabilities due to the inability to pay for treatment and stigmatization of their community [45]

Lack of trained personnel
This lack of educated citizens results in a lack of highly educated people that can fulfil the role as medical staff required to equip the hospital in secondary care. When the hospital is contracted with a European medical device, it often provides a service contract with training for use. However, due to the high cost, many medical equipment is donated which does not include this service contract with training. Therefore, much equipment is unusable and when it breaks down it is difficult to repair.

Results in lack of maintenance
The lack of trained personnel created a lack of personnel in the entire journey mapping of the product. The product cannot easily/ directly be maintained, operated, and repaired. This creates a great workload for medical and technical personnel, which results in the skipping of periodical maintenance due to time limitations. When repair is necessary. Either a trained technician needs to be hired from a less rural place (the city) when this person finds time in their schedule or the locally available technician is notable to repair due to the lack of specialized tools, expertise in the problem, or spare parts.

Electricity
The access to electricity is critical for the functioning of any medical device and especially an MRI scanner. Data on the availability and access of electricity on health care facilities are rarely collected. Therefore, mainly data from field research and systematic reviews have been consulted for data. Interviews, paper, and field reports noted that the use of solar power in health facilities was common. 15% of the hospitals rely on a combination of central and solar sources, and this amount was growing in popularity.

However, the reliability of the electrical supply was questionable since electricity outrages during the day were common. When such an electricity outrage occurs, a second generator is used for the use of essential medical apparatus such as oxygen devices

1.2 Healthcare infrastructure
In the Uganda Second National Health Policy 2010, infrastructure is described as "buildings, plants, equipment (medical devices, other equipment for health facilities and IT equipment), transport and health care waste management" [46]. The working group in the Ministry of Health (MOH), Uganda, describes health infrastructure as "composed of buildings, medical and hospital equipment, communi¬cation systems and equipment and ambulance and transportation facilities" [46]. The Ugandan physical healthcare infrastructure recognizes an expansion throughout the years, which has gradually led to an increase of access to modern health care services, especially in the lower-level facilities. The govern¬ment has offered more primary health services. this combined with the fact that the public government hospitals have decreased, has led to secondary health services to be out of reach for most Ugandans due to the high costs in private hospitals. Poor distribution of infrastructure, therefore, brings about inequity of financial resources and access to services [3].
Provision of water, environmental cleanliness, and health care waste management withing Health¬care facilities is hindered by structural and performance limitations.

1.3 Institutional factors
National inventory only for high-cost technologies (such as MRI, CT, or PET scanners). Despite the need for innovation in these settings there are limitations to adoption and implementation of the medical devices.

1.4 Rules and regulations
The National Drug Authority (NDA) regulates, imports, and exports the supply of medical devices in Uganda. These medical devices are regulated under a ministerial decree ADM.140/323/01 of 20th July 2020 and statutory Instrument no 77 of the Surgical Instruments and appliances Regulation 2019. The low field MRI scanner can be classified in the classification Class B [47].
Importing separate parts required approval with a certificate or signed agreement. This import puts restraints on the specific materials where a Pre¬Export Verification of conformity (PVOC) is necessary[48].

Research Ugandan healthcare

Objective
To understand the Ugandan healthcare system and context specific characteristics that have an influ¬ence in the procurement, use and disposal of the medical device.

Research questions
What are the social, cultural, economic characteristics of the environment where the LF MRI scanner will operate? What are the challenges that might be faced?

Method
Literature research Shadowing Interview with previous teams that have been in the field Observation DEPESTE analysis Literature research has been conducted conform the DEPESTE analysis, which researches six factors to give a good overview of the macro-economic environment: Demographic, economic, social cultural, technological, ecological, political juridical. Furthermore, it is crucial for the design of a medical device in a different culture to do research in¬field and not only on desk. However due to the COVID restrictions personal contact and travel restrictions occurred. Therefore, reviews from previous groups that have been to the field have been analysed and people from the field have been interviewed. Based on the outcome of the literature study, a framework was conducted that served as guidance for the acquiring of knowledge of important factors. The behaviour and culture of the people will be further discussing in chapter 2

Outcome
An overview is presented of the current Ugandan healthcare system and the important factors that influence the introduction, procurement, and use of the low field MRI scanner.

Economy and environment
In April 2001, the African Union countries met and pledged to set a target of allocating at least 15% of their annual budget to improve the health sector and urged donor countries to scale up support, but this target was not met[49]. Uganda spent 7% of its budget on health, compared with the 15% the government committed to under the Abuja declaration[49].
A ministry of finance report published last year said the institute was severely understaffed, and used old, inefficient medical equipment that could put patients' lives in danger. A great portion of the Ugandan population live below the poverty line, with less than $2USD to spend per day, health insurances and hospital treatments can rarely be afforded [50]. Therefore, the financial possibilities are the main challenge that hinder the improvement and accessibility of healthcare. Many medical treatments in public hospitals are financed either by pay as you go system where the patient pays their own treatment directly[51].

Environment
Uganda has a tropical climate with temperatures ranging from 25¬-29 degrees Celsius on average [52]. Within the hospital this can also occur when a proper air conditioning system is not present or not properly functioning. Furthermore, the hot environment is also dusty which can pose problems for equipment which is not properly stored[53]

Technology trends
The WHO estimates that a large proportion up to 70% of equipment lies idle because it is donated and not maintained well. The existing maintenance and service facilities range from non-existing to minimal trained technician that is responsible for the maintenance and repair of all the technical equipment in the hospital. Service contracts become therefore more common[54]. Currently the CT scanner is the mostly used medical diagnostic device of Uganda since the MRI scanner is not in use yet. 3.7. Ugandan Healthcare system
The Ministry of Health (MoH) in Uganda oversees managing the referral and regional hospitals and indirectly the public hospital. The decision of all medical policies and regulations lay the MoH's responsibility[46]. Within the MoH several advisory boards can be defined.
•National advisory Committee on Medical Equipment
•National Drug authority
•Uganda National Bureau of standards
•Ugandan revenue authority

Hospitals
The healthcare system in Uganda can be subdivided in three types of hospitals
1. Public hospitals
2. Private for-profit hospitals (PFP)
3. Private not for profit hospitals (PNFP)
4. Public Hospitals

1. Public Hospitals

The public hospitals can be further divided into seven levels which are fully funded by the government (Figure 3.1).
1. National referral hospitals: The country counts two top institutions which are Mulago Hospital(general) and Butabika hospital (mental health). The focus of these institutions is to provide specialized healthcare, training and conducting research.
2.Regional referral hospitals : Regional referral hospitals are supervised by the ministry of health.
3.General hospital: There are 139 General Hospitals, and their management is decentralised. The care carried out in GHs is preventive, promotive outpatient curative, maternity, inpatient, emer¬gency surgery and blood transfusion and laboratory services
4.Health centre IV: District hospitals serve each county of Uganda. It includes services that can be found at health centre III and any type of patient including a theatre to carry out the emergency operation.
5.Health centre III: Present in every sub¬county in Uganda. Provided with a functional laboratory
6.Health centre II: Present in each part of the country to treat common diseases such as malaria and pneumonia.
Besides the listed categories Uganda is also supported by Village Health teams in remote areas. All districts in Uganda had at least a hospital or a level IV primary care facility. A third (32%) of the districts in Uganda did not have a hospital.

2. Private not For Profit hospitals

Private not for profit hospitals mostly treat patients with an insurance coverage or with donations.
CURE Children's Hospital
The CURE hospital can be categorized as a Private not¬fort-profit¬hospital (PNFP)which generally revolve around religion and wellbeing/treating of neighbors which is the reason why donors are a high recourse of income. The PNFP¬hospitals generally revolve around religion and rely on donors. CURE hospital in Mbale, Uganda is a good example of this. They are currently the

leading facility in Uganda for treating Hy¬drocephalus and are a partner for clinical trials during the development of the machine. It is Africa's leading hospital for the treatment of these conditions with an average treat of 1200 cases per year [45]. Most Ugandan hospitals are dedicated to maternity help. Often hospitals and medical studies work closely together.

3. Private For-Profit Hospitals

The private for-profit hospitals are founded by religious organizations and financially supported by international donors outside of the country. Access to those funds promote the access of medical equipment and staff.

Payment

The customer that procures the MRI device is in this case the healthcare facility. These facilities have limited opportunity to charge their patients. For diagnostic scans, the patients are charged the cost price. In cases of the conventional 3Tesla MRI scanner, this can still be too much for many patients to pay. An increased lifespan of the device keeps the cost price low as this is taken over longer time and the operating time is longer. In this way the charging of a patient would be more affordable. PNFP¬ hospitals are not dependent on cash flow coming from the government or patients, but donations from wealthier patients and organizations. In this way they can provide their services for free, which makes the machine more appealing for them. When a hospital buys a device, it is expected that the user training is already included in the bid.
Majority of the hospitals have no extra budget for training.

Medical staff

The under¬staffing of medical services is a huge problem for especially public hospitals. According to Eng. Sitra Mulepo, only doctors up from regional hospitals are properly trained for working with MRI and other imaging devices
. • Nurses rotate each year
If the nurses meet the machine, they must know how to use it properly or at least in a non¬damaging way. Because of the rotating system however it is important to offer trainings periodically, to ensure the long lifespan of the machine [55].

Educational

The level of medical knowledge of the employees in Ugandan hospitals depends on the facility and type of hospital. In regional hospitals, the required MRI knowledge was present among the medical staff. however, in general hospitals this is debatable. This can be due to the educational system and the lack of supply which does not allow medical students to have access to MRI scanners for apprenticeship [55].
Finally, mostly nurses and intern doctors will be using the machine instead of doctors [55].

The production

The production of medical devices is not facilitated by a Ugandan company or institution yet. However, the possibilities for distribution are present. Production facilities are nonexistent or of low quality, so a local production might not be suitable.
Challenge Healthcare system in LMIC.
Most healthcare systems in Sub-Saharan countries in LMICs cannot rely on progression from their healthcare system due to unstable infrastructure and governmental structures and systems. For in¬stance the Ugandan Healthcare system is ranked among the bottom of the world according to the World Health Organization (WHO,2017), due to misalignment of incentives, lack of coordination which promotes the inefficient diffusion of recourses. This affects the cost, outcome of care and eventually the population who are not able to get access to medical devices and thus have a higher hist for chronic illness. This hinders the access and delivery of quality healthcare.

Key insights

1. Patients mostly require paying their treatments themselves, so time is money.
1.1. Except for private hospitals, these pay for the treatments
2.Equipment is transported over muddy, unpaved, and poor pathways
3.Space in hospitals is scarce
4.Pests are present in all hospital environments 5. Heat and humidity are a problem in rooms that are not air conditioned
6. The most prevalent type of hydrocephalus caused in LMIC is due to infections
7. Hospital staff has a high workload and therefore no time for maintenance

System requirements

1.The device must be able to handle power outbreaks
2. The device must be made in such a way that the most fragile parts are easy to repair
3. The device must be as minimal as space efficient as possible.

2. Contextual characteristics of Uganda

The contextual characteristics of Uganda have been researched with help of the framework specifically designed to investigate the context of a low recourse setting with as goal to design a product for this context. Aranda-Jan, Clara & Jagtap, Santosh & Moultrie, James. (2016). Towards A Framework for Holistic Contextual Design for Low-Resource Settings. International Journal of Design. 10. 43-63. 10.17863/CAM.7254.

	2	Availability and accessibility of physical infrastructure	What is the conduction of the infrastructure for the provision of healthcare services?	Lack of public hospitals which increase the disavailability of medical care	http://speed.musph.ac.ug/wp-content/uploads/2019/03/Chapter-11.pdf	Fieldwork needed: Explore and evaluate specific situation of the healthcare system.
	3	Safety of transportation options	What are the characteristics of public mobility in the country?	Mainly transportation by truck of bus on wobbly unhardened roads.		Fieldwork needed: to learn about people's daily transportation options
	4	Access to water services	12.1% (7/58) of HCFs had limited and basic WASH service resp	Mostly no access to water or clean water	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7682765/	
PE		Geographical and Environmental Factors				
	5	**Community/facility remoteness**	What is the average distance from the household to the health facility? How accessible is the community? How far it is from an urban area?	Within each 5 km there needs to be a HCF	World Bank, 2010: http://www.infrastructureafrica.org/system/files/	Fieldwork needed: Specific characteristics of geographic accessibility of facility and community
	6	**Local temperature**	What are the characteristics of the temperature? (yearly averages)	Given its relatively humid climate, temperatures nationally are reasonably constant, ranging from a dry season maximum of 25°C to a wet season maximum of 31°C. Affected by altitude, position and the interplay between the ITCZ and meso-scales, the annual precipitation range is 400mm to 2200mm.	Uganda%20Country%20Report.pdf	Fieldwork needed: Specific characteristics of temperature and humidity. Investigate how they affect the equipment functionality.
	7	**Local humidity**	What are the humidity conditions?		https://journeysbydesign.com/destinations/uganda/when-to-go#:~:text=Given%20its%20relatively%20humid%20climate,range%20is%20400mm%20to%202200mm.	
PE		Institutional Factors				
	8	Reliance on donated equipment	What percentage of medical devices in healthcare facilities come from donations?	The World Health Organization estimates that "a large proportion (up to 70 percent) of equipment lies idle." Another study pegged a lower, still troubling figure of 38 percent		Fieldwork needed: Understand how donation of equipment occurs for a specific facility, how partnerships work, country's donations guidelines.
	9	Availability of maintenance and service facilities	Are there existing maintenance and service facilities for medical equipment?		WHO, 2014: http://www.who.int/medical_devices/countries/tza.pdf	Fieldwork needed: Understand technology management and practices in healthcare facilities.
	10	Level of government involvement	What is the level of government involvement in management and procurement of medical technologies?	Hospitals within the public sector will depend on the government to purchase technologies.		Fieldwork: Understand how procurement systems work for the different triers of service provision. Explore the level of government involvement in all the different levels and types of care.
	11	Skills and training level of providers (Clinical Knowledge)	What is the quality of clinical training of healthcare providers?			
			Are users trained to use medical equipment?			Fieldwork needed: Understand users
	12	Levels of Corruption	How does the country ranks in terms of procurement? What is the impact of corruption on the procurement of medical equipment?		World Bank, 2006: http://www1.worldbank.org/publicsector/anticorrupt/Corruption%20WP_78.pdf	Fieldwork needed: Explore how corruption affects and influences procurement of medical technologies
	13	**Availability of financing and funding**	What is the budget for procuring and operating medical devices in Uganda?	Uganda spent 7% of its budget on health, compared with the 15% the government committed to under the Abuja declaration.		Fieldwork needed: Explore the different types of care providers and how they fund procurement and operations (i.e. consumable and staff) of medical equipment
	14	Appropriateness of specifications and tendering processes	Does the country have a procurement system with technical specifications for devices?		WHO, 2014: http://www.who.int/medical_devices/countries/tza.pdf	Fieldwork needed: For defining potential business model, it is important to understand the procurement system.
	15	Awareness of sterilisation and cleaning protocols				
	16	Availability of biomedical and technical staff	What is the existing availability of technical staff to maintain and repair the devices?	It is not possible to know availability of technical staff. However, in policy document from a Churchbased hospital in Uganda it is mentioned that maintenance of equipment should be provided by qualified staff.		Fieldwork needed: Identified where and how technical staff is trained. Explore the qualifications and training received by technical staff.
	17	Level of technical skills/knowledge	What is level and quality of the technical staff?			
	18	Presence of nonwestern medical/ clinical practices	How acceptable are alternative medical practices in the country?			Fieldwork needed: Explore how alternative medicines may influence the use and adoption of medical devices.
SS		**Economic Factors**				

can be translated back to the high-end MRI scanners [27].

5.3. Contextual challenges

Power cuts
Many areas in LMIC deal with an inconsistent power supply. This can cause power surges and drops which can potentially damage the equipment. Therefore, it is crucial to consider including a back-up power supply stabilized to keep the equipment's continuing during blackouts [28]. Most of the CT and MRI scanner include generator and back-up batteries as a back-up power supply.

Robust
Considering the setting of the devices, it will most likely operate in an area highly dependent on recourses available on site. Robustness is an important requirement to be able to withstand external forces and environmental influences. Since the field homogeneity can be affected by change in the magnet's magnetisation direction, volume, or temperature . Falling or collision damage can reduce the total magnetisation of the damage. It is thus of high importance that the embodiment of the device is robust to protect the inner technological setup of the MRI. Since the direction for the magnetization differs for each magnet, neighbouring magnets will likely align themselves in the same direction and produce a force on the casting they are int. With a great force, the casing might break which will destroy the model [29].

Safety
Even though the MRI scanner is seen as one of the safest medical procedures available [30], it is of great importance that the area inside and surrounding the MRI is free of any metallic objects. Any metallic object will be pulled inside the scanner, including metallic implants or heat up due to induction. Even though the advantage of a low field MRI scanner is the low magnetic force, and thus the less risk on magnetic attraction for metallic objects, there are still safety regulations that must be considered. Considering that the LF-MRI scanner will be used in low resource settings where there will not be a separate room for MRI, there remain safety barriers for approximating the scanner. As defined by the ASTM, the surrounding of an MRI should not exceed 5 Gauss (0,5mT) to "prevent harm to those fitted with medical implants that may be affected by the static magnetic field". Measures could be taken such as shielding measures, where the scanner is placed inside a Faraday Cage, or the area around the scanner is demarcated as non-accessible such as in figure 10 [31].

6. Discussion and conclusion
MRI scanners are preserved as one of the safes diagnostic medical procedures. Due to the increasing development in the magnet technology, both high field MRI scanners are being developed as low field MRI scanners. Despite the improvements in the magnet, RF, and gradient technology a constrain remains present for LF-MRI devices in terms of the SNR. This can be optimized for better imaging by various techniques mentioned in this paper. The clinical relevance of the low-fields MRI is tremendous and is developing towards advances in image reconstruction. The system is characterized with high nonlinearity and non-homogeneity. The ability to obtain distortion-free images even in the presence of non/less-linear gradients could allow the use of, for example, mono polar gradients that are suitable for some of the magnet designs used in low-field and portable MRI. As can be seen in this report the advantages of a low field MRI scanner are present, especially for low recourse settings in LMIC. Firstly, due to the technical ability of producing a high-quality image with a low magnetic field. Second is the potential to have a much more sustainable system than superconducting magnet-based system in the terms that it requires in-expensive repair and replacement. Thirdly the requirements for space, power, and cooling are reduced [32]. Considered the contextual and socioeconomical challenges the relevance needs to be assessed per specific case, as it brings many factors with it within the hardware design.

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2. Introduce the low field MRI scanner LMICs

2.1 Introduction
The aim of the introduction of the low field MRI scanner, has been defined to increase the accessibility of MRI scanning through the introduction of a Cost-effective, sustainable and frugal technology-based product.

Considerable factors are distinguishable within the definition of this goal which are:
1) Increase of accessibility of MR Imaging through the introduction of cost-effective product through frugal technology
2) Provide the sustainability of the product by introducing the ability for local manufacturing and production

Two questions arise: What factors need to be considered for the successful implementation of a medical device in a LMIC and What factors are important to keep the product available in a LMIC.
For a successful introduction and use of the low field MRI scanner in Uganda, both design for innovation and Design for LMICs must be considered.

6.2 Design for innovation
Design innovation is a paramount for the successful implementation of a product, which relies on a products' feasibility, viability, and desirability [112]. Once a design innovation is successful in its introduction and therefore fulfils the requirements for its feasibility, desirability, and viability, this does not guarantee a successful introduction for medical products in LMICs.

6.2.1 The three lenses of innovation
It can be argued that design innovation plays a crucial role in the success of a product within the context and the competitive strategy of the company. The new product development requires compromises on both the end-user's point of view, the innovators perspective, and the technological innovation. According to the three lenses of design innovation and human centred design [21], an innovation may be successful and valuable if three conditions are met ; desirability, feasibility, and viability [11].

They light the potential of the product innovation.
- Desirability
  The product is designed conform the users and stakeholders needs.
- Feasibility
  The product has the technological possibility to be made and function properly.
- Viability
  The product has an economic growth potential in the market.

6.3 Design for LMIC
To ensure that the product remains operable after it gets obsolete(or after the first use cycle), the challenging context needs to be considered in which the lf MRI scanner operates. Therefore design methods addressing design for LMIcs are important.
The accessibility is not solely achieved due to the successful introduction of the MRI scanner, but must also sustain for a longer period in time.
Since a large number of the medical devices in LMICs are obsolete due to the fact the equipment is predominantly designed by designers in HIC for the context of HIC. According to the WHO, around 70% of medical devices present in Low-Middle income countries (LMIC) are designed for use in the high-income countries, while most of the medical devices donated to low-income countries are not functioning [4]. Therefore it is important to take into consideration different factors during the design process.

6.3.1 Challenge design for LMIC
The main reason for the lack of availability of medical devices in LMICs besides the financial burden, is the inability of the device to operate in a challenging context. Medical devices for high income countries are designed by a stepwise process based on directives set out by regulatory bodies. However, their guidelines and representations are focussed on HIC and may not deliver successful products for Bottom of the Pyramid (BOP) markets. Because of the different sets of characteristics, challenges and needs in LMIC, engineers should have an all-encompassing approach on the design of medical technology for LMIC. By laying emphasis on the use and context, one can uncover the values and priorities to design a user-centred medical device.

6.3.2 Proposed Approach
The relation between the successful introduction and use of a medical device in LMICs and the concerning design methodology is crucial and has proven to be the key stone for a successful implementation of medical devices in LMICS.
Previous research has failed to address the importance of combining cost-effective, frugal technology with socio-economic, cultural, and infrastructural factors to get useful design requirements. Additionally, the approach in involving stakeholders, understanding the context, and implementing this for a better design has not been thoroughly understood in research.
Therefore, the following methods are introduced in de the design process to ensure the successful introduction and use of a medical device in a LMIC.

6.3.3 Factors to implement from design for LMIC
For the low field MRI scanner to be successful at its purpose, it needs to conform to the principles of design for innovation but also specific principles which focus on design for LMICs to be able to keep using the product.
The success of a medical device is highly linked to the feasibility, viability, and desirability of the designed concept. However, to secure the right fit for the context, stakeholder involvement is necessary to prevent western bias since the low field MRI scanner is designed in a HIC. Design processes that promote early and frequent engagement with stakeholders may increase the impact of medical devices aimed at addressing global health challenges by improving the uptake and sustained use of such devices [10].

The outcomes of these principles serve as the design principles of the thesis, which are the fundamental principles that are applied to form the basis of a qualitative product. Design principles define and communicate the key characteristics of the system. " Design principles articulate the fundamental goals that all decisions can be measured against and thereby keep the pieces of a project moving towards an integrated whole." [10]

6.3.4 Methods that allow design for LMIC

Frugal innovation, sustainable development and human centred design are the design principles that are used in literature and focus specifically on the design for LMICs. Frugal technology focusses on the implementation of the technology in a resource low setting (feasibility inside context) [12], [13], sustainable development focusses on the durable sustaining of the product inside the context (material viability inside context))[18],[21], and user centred design focusses on the socio-cultural and user associated factors regarding the use of the product (desirability inside context[22] .

6.3.4.1 Frugal technology
What is frugal innovation ?
Frugal technology arises from the need of emerging markets to receive qualitative technology as a solution for the rise in need of functioning technology. The design of the low field MRI scanner is based on the principle to deliver high quality products, that are affordable and optimized in performance. Eventually it aims to deliver a better care for lower cost [113] [13].
As can be derived from analysis of Weyrauch [112], frugal technology is focused on the optimization of the functioning for a lower resource setting.
Why is frugal innovation relevant ?
Introduction and use of technology in resource-poor settings raises several issues that need to be addressed and solved. The main reason why the medical devices are not able to adapt is due to the high cost and limited access to maintenance facilities [12]. A greater focus on frugal technology offers truly global promise. Novel technologies are being created in LMICs that might help mitigate escalating health-care costs in high-income countries.

Downside of frugal innovation
Positive developments towards an innovate, more accessible and low-cost MRI system has been done which allows more accessibility for those systems in LMICs. However, the majority of frugal products mainly focus on making the technology cost-effective to overcome resource constrains, but not focus on the possible services, infrastructure, beliefs, and cultural habits of the context to make the technology fit the context. Initiative that involve the complete life cycle with respect to design, production, fabrication, end-of-life, and maintenance need to be considered

6.3.4.2 Sustainable development
What is sustainable development and why is it relevant
However, challenges arose as it is not sufficient for a technology to be sophisticated, inexpensive, and effective for it to be a successful implementation in LMIC due to additional obstacles [15], [16]. It also needs to function safely in the challenging conditions which can be found in LMIC, but most essentially, it needs to so in a sustainable way [17]. Current medical device development has been lacking in the thorough understanding of crucial factors which result in quickly obsolete medical devices due to an unreliable system which does not allow for instance maintenance.
The strives of sustainable development in products, involves a balance of economical social and ecological goals to be fulfilled [18].

The concept/definition of sustainability is often a subject of discussion in literature. In this case sustainability highlights the shaping of human systems and produces this in a way that the ability of the earth's ecosystems assimilates. It stresses the need for creating resilient systems regarding ecology, economy, and society while respecting the limits of ecological capacity and capability [19]. Therefore, taking the sustainability and the entire equipment life cycle into consideration is essential for the device to survive in the context.
Therefore, it is of importance to consider all elements that involve the context, during the design of medical device specific for the LMIC context for the product to last longer, be maintainable and disposable. Sustainable development is development that meets the needs of the present, without compromising the ability of future generations. This means that devices should be designed with the finiteness of the resources in mind [21].

6.3.4.3 User centred design
An additional challenge arises ; one of the main reason for the failure of medical equipment is due to the incorrect assumptions which lead from incorrect and superficial interpretation of contextual factors. To secure the right fit for the context, stakeholder involvement is necessary to prevent western bias since the low field MRI scanner is designed in a HIC. To prevent making wrong assumptions and to research the incentives well, human centred design approaches are recommended [22].

Efforts need to be made to ensure that the technology is acceptable to and will be adopted by users. It is important that during the procurement process, not only cost-effectiveness evidence is presented, but also a value- based evidence which involves a diverse range of stakeholders [23].

6.4 Discussion
Medical devices in LMICs have mostly only been designed to overcome the first burden which is the financial barrier, which allows the medical device to be introduced inside the country with low resources. As stated earlier, the success of a medical device has proven to be not solely dependent on the ability to make the technology fit for the environment, but also a

contextual and user fit.
During the design of the sustainable low field MRI scanner, both " the three lenses of design innovation" [21] and methods for design for LMICs are relevant for the successful implantation and use of the MRI scanner in context. It is argued how future innovations in low resource settings will concern ways to make the system cheaper and more efficient with frugal innovation, rather than qualitatively better and a long term fit for the context.
Different strategies have been researched and implemented in studies for the successful and durable implementation of medical devices in LMIC.
Those strategies can be subdivided into different themes within the design process of the hardware(1) which involves the consideration of stakeholders, environments, and infrastructure(3) and the end-of life(3).

6.4.1 Frugal innovation
All the discussed factors can be attributed to the principles of frugal innovation. A combined literature review categorized all design principles and concluded the following. Frugal innovation includes various attributes that contribute to the fit of the technology inside the context, such as (functional, lower cost of purchase, reducing cost of ownership, minimise use of materials, user friendly and easy to use, robust, high in value and quality, scalable and sustainable [113].
In the resource-constrained market, customers are demanding affordable, high quality products that are environmentally friendly, socially inclusive.

6.5 Methods to include in the design process
Involvement of stakeholders during the design process has been proved to be of high benefit for the applicability of the design [24].

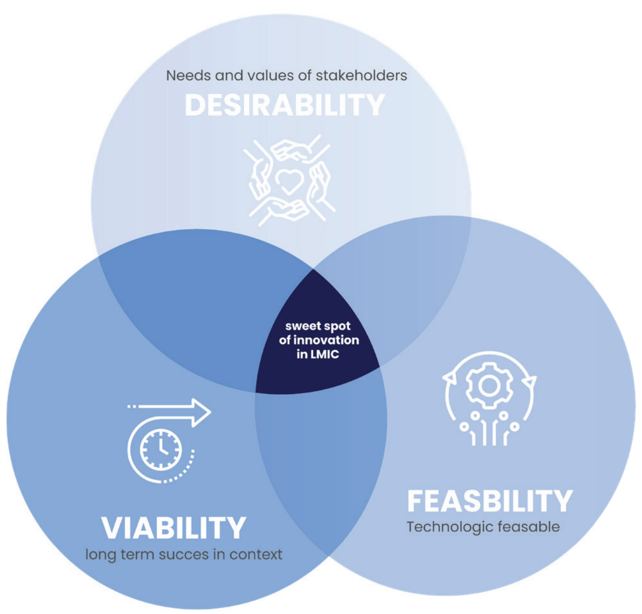


Figure 15 Combination of design for LMIC with three lenses of innovation

User-centred design approach for the design approach prove to have higher success rates than technical sophistication[25].
This can be done by;
1. Co-creative design processes that involve local stakeholders,
By assembling a multi-disciplinary team including users when possible is the best way to co-create, design, and evaluate the design.

2.Creation of series of prototypes to get critical feedback from end-users while also learning and improving the product in terms of its functionality. Rapid-prototyping is a human-centred design skill due to its ability to involve the stakeholders. With the prototypes quick feedback and validation loops can be generated.

All methods have been implemented during the design of the low field MRI scanner to secure successful introduction of medical equipment in LMICs.

MRI scan instead of other methods
This can be done through prenatal ultrasound from the third trimester of pregnancy. After birth, the diagnosis may be confirmed through ultrasound up until 12- 18 months, when the anterior fontanelles close. After this period, the ultrasound can no longer penetrate the skull, and several alternative examinations can be proceeded to diagnose hydrocephalus, such as CT scanning or MRI scanning. CT scanning is a method that can scan acute and chronic hydrocephalus; therefore, it is the typical imaging method, especially in emergency settings. The Low Field MRI scanner can distinguish between CSF, white matter, and grey matter, which is specific enough to diagnose hydrocephalus. The MRI scanning method is preferred to CT scanning, ultrasound and cisternography due to its appropriateness with the context and use of diagnosing infants with hydrocephalus.

E. Technology

1. Research Basic principles of MRI

Objective
To define the working principle of the Low Field MRI scanner

Research questions
1. What are the fundamental principles of conventional MRI
2. What are the fundamental principles of a low field MRI

Method
A literature study has been performed to point out the main discrepancies between conventional of MRI magnetic resonance and Low field magnetic resonance. The Low field MRI scanner prototype has been analyzed thoroughly on its components, functionality, and main challenges. The entire literature review can be found in Appendix B.

Outcome

The result is a broad overview and discussion about the technology of the low field MRI scanner

Magnetic Resonance Imaging (MRI) is a widely used diagnostic medical procedure in clinical applications. However, due to the generally high cost, this leads to a low availability of the technology in low recourse settings. In these areas, the need for affordable and appropriate medical technologies continues to rise, while the challenges such as irregular energy supply, limited technical expertise and poor infrastructures remains. To decrease the cost of an MRI, a novel approach can be used where the superconducting magnet is replaced by permanent Halbach arrays. In this case a low-field MRI is created to meet specific imaging needs within low recourse settings and specifically low to middle income countries. The reduction in field strength does not only have an advantage in the cost of the MRI, but also presents benefits in the increased sustainability and safety by reducing costs in both materials and manufacturing, lowering power requirements, eliminating the need for specialized equipment siting, and simplifying the technical aspects of troubleshooting, operation, and repair[1].

1. Introduction
Magnetic Resonance Imaging (MRI) is a non-invasive imaging technique that is used to produce three dimensional anatomical images for diagnosis, disease detection and treatment monitoring [1-2]. It is based on the phenomenon of Nuclear magnetic resonance (NMR) and has been developed in the past decades into one of the safest medical diagnostic procedures. However, the MRI scanners are only available for 10 percent of the world population, mainly due to the high cost which is a result of the high field magnetization. In traditional scanners the high magnetic field are widely used which result in images of excellent quality. However, their cost, size and infrastructure make it inaccessible for lower recourse settings [3]. As the demand for MRI scanners keep growing, an alternative low-cost MRI scanner is in development. This essay is focusing on the Lowfield MRI scanner developed by researchers at Delft University of Technology and Leiden Medical Centre. To make it cost effective and a fit to the context of Low to Middle Income Countries (LMIC), the new scanner needs to be affordable and maintainable for this setting. The goal is to make the scanner appropriate for treatment of children with hydrocephalus, which is a severe case in LMIC [4].

2. Fundamental principle MRI scanner

Characterisation of atoms
The proton has several properties that are identified, namely the atomic mass(mp= 1.67 * 10^−27kg), the positive electric charge (qp = 1.6 * 10^−19 C) and spin (S = +/ 1/2). The spin is a quantum mechanical property of a proton which is a measure of the intrinsic angular momentum of a sphere rotating on is axis. The spin contributes to the protons intrinsic magnetic moment, which allows the proton to behave like a bar magnet. The second property that is resulted from spin, besides the angular momentum, is the intrinsic magnetic moment. The spin quantum number (u = hS y) with a constant (y), named the gyromagnetic ratio. This influential element is the empirical constant of the proton.

NMR phenomenon
The presence of a magnetic field affects the spinning of the proton. Figure 4.1 illustrates the following process. Once a spinning particle enters a magnetic field, it will accomplish the following: First, the Nuclei will align with the direction of the external magnetic field. Because the field is in the lower energy state, the spinning particle is most likely to align parallel to the field. This is because both nuclei and tops have angular momentum. Secondly, the magnetic fields produce a torque perpendicular to the orientation of the angular momentum, which results in precession. Precession is the change in the direction of the axis of the spinning particle. Therefore, when an external magnetic field is applied, the precession of the proton will occur in the direction of this magnetic field. The angular precession frequency ώ (in Hz) is proportional to the strength of the magnetic field. The Larmor frequency ώ = γ B0 describes this relation where γ is the gyromagnetic ratio in rad* rad * s-1 T1 and B0 is the strength of the external magnetic field. The Larmor equation indicates the precise frequency of electromagnetic radiation sent into the tissue to excite hydrogen nuclei [50].

The different types of magnets are described below.

Permanent magnets are composed of ferromagnetic earth alloys and run a permanent magnetic field. The magnet is always "on". The main advantage is the low running cost. Besides the great advantage, they also have a few disadvantages comparing to superconductive magnets, which are the high weight, and the lower field strength and uniformity.

Resistive magnets are electromagnets, which are air- or solid-cored coils of wire. The advantage is that they can be instantly shut off in an emergency and they are cheap to run and purchase, but they produce a significant amount of heat and power. Besides this, neither the field strength nor uniformity is as good as the superconducting magnets.

Superconducting magnets are used for most of the MRI systems on the market. A superconducting magnet is an electromagnet made with superconducting wire with a nihil resistance if the temperature is kept close to 0_C. The coil temperature must be kept below the superconductive temperature for the current to continue flowing through the coil. This is achieved by immersing the wire in liquid helium. To operate and maintain a system with such a superconductive magnet, significant high costs are involved.

3. Development of MRI scanner
The first MRI scanners produces had field strengths on the order of 0.1-0.5 Tesla by using electromagnets and permanent magnets. Lower field strengths (0.2-1T) MRI systems had a great importance in the development of the current MRI systems around 1980. The most important advancements were present in the design of the hardware and the magnet which resulted in improved field strengths and decreased magnetic footprint . Further developments in the magnet design and technology, superconducting magnets of 1.5 T and 3T became available which are not the most used field strengths for clinical research. Although being the most imaging diagnostic device among other technologies, only around one tenth of the world population has access to an MRI scanner, which makes the access of MRI scanners scares in Low to middle income countries[13]. According to research of Marques [32], there are two main factors responsible for this phenomenon. (1) The costs involved for the installation and maintenance and (2) The complexity of operating an MR system. The cost of an MRI is estimated on around 1 million euro per Tesla for only the purchase [14-15]. The high cost is caused by the high requirements of the superconducting magnet, which carries a significant portion of the cost. When developing the older MRI systems, the cost increased as the innovation and renewable systems improved, which makes that due to the improvements in mainly hardware, the price kept increasing, which contributes to an imbalance in the accessibility of the MRI scanner. A solution to reduce the cost would be to replace the costly superconductive magnet with a lower cost system. Designing a lower field MRI is a big challenge is because the researchers must use a small, weak magnet. The result is that the images have much lower signal intensity. In this way the main cost will be reduces, and an additional advantage would be that patients with implants would be able to be placed in an MRI scanner [16].

4.Components
Gradient design
Gradient amplifiers are necessary to amplify the pulses that are sent to the gradient coils. Gradient coils are loops of wire or thin conductive sheets that can be found inside the bore of an MRI scanner and alter the B field. Three sets of gradient coils(x,y,z) allow the variations of the main magnetic field (B0). The functionality of the gradient coils does not differ from the conventional MRI scanner.
The gradient amplifier is a open-sourced producible part designed by DEMO, with the aim to be as easy to repair and replace as possible. The part is operating at 60W on average, requiring 12V and 12V power supply.

Gradient coils are loops of wire or thin conductive sheets that can be found inside the bore of an MRI scanner and alter the B field. Most MRI systems use three sets of gradient coils, one for each direction X, Y and Z. Three sets of gradient coils allow the variations of the main magnetic field (B0). The variation in the magnetic field are used to localize the image slices as well as to phase encoding and frequent encoding. The set of gradient coils for the z axis are Helmholtz pairs, and for the x and y axes, paired saddle coils. Through introduction of the gradient magnetic field in three spatial planes, the relocation of the received signal that is allowed.

- It has the capacity to image directional along X,Y,Z axis by changing precessional frequencies.
- Localizes the rf signal in the space
- Produce 3D images of tissue
- RF coils – sends and receive RF signals to and from tissue

A RF signal is generated in a uniform magnetic field by placing a sample or body inside the homoge¬neous magnetic field, where after a 90° RF pulse at the precise Larmor frequency is generated. The transverse magnetization vector that results from this, induces a signal in a receiver coil (antenna)that is proportional to the number of precessing protons. In order to localize spatially the source of sig¬nal within a volume, the homogeneous magnetic field of is intentionally varied in a predictable manner. This produces a gradient of magnetic field strength along each axis[61].

- **RF coil**

RF coils transmit and receive signals as the patient is positioned in the MRI scanner. The stronger the RF pulse generated by the RF transmit coil, the farther the magnetization will tilt or flip. In the lower strength range of low-field MRI, the noise is caused by the losses in the RF coil, while in the higher range, the noise contribution from the body becomes significant. Receive arrays are implemented in many low-field systems to ensure that coil noise does not dominate. This results in SNR ratio improvement in the periphery of the image. Another benefit of implementing multiple receive elements is that it enables fast scanning times through sparse sampling of k-space, the Fourier transform of the MR image.

For brain imaging the subject is placed into a 3D printed Rf coil, with solenoids used as the transmit/receive coil. On the coil, non-magnetic capacitors are spaced evenly to avoid self-resonance. Important for the subject to be imaged is that it needs to be placed on the area of the field of view (FoV) with the highest magnetic field strength. It is necessary that the subject is place predominantly in proximity of the isocentre, as in-homogeneity causes distortion, shading, and other issues in the imaging. It is therefore important that the subject is aligned in the isocentre of the bore, within the field of view of 220mm to provide a high-quality image [58].

Rf Transmitter coil
The radiofrequency transmitter is the generator if radiofrequency current which is delivered to the trans¬mitting coil. The created signal from the transmitter is used to excite protons in the imaging field [63] (figure 4.1).

RF receiver oil
The receiver coils detect the electromagnetic radiation produced by the process of relaxation inside the subject as a result of the transmitted electromagnetic field. The oscillating net magnetic flux is amplified, quantified, and filtered after being detected from the excited spin system when a current is generated.

Spectrometer
The processing of the system is regulated by the spectrometer, by regulating pulses from the gradient in RF amplifier, by processing received signals and communicating this to the computer. During the intended scanning sequence of 10 minutes, an average of 40W is used.

Additional components
The components of the current prototype (September2020) The components of the current prototype (September2020) have been analysed for their function according to the system. The full system can be seen in the functional analysis. The elaborated functional analysis is discussed in Appendix E. The entire system is placed into a Faraday cage to minimize the environmental noise. This system is constructed of 2-mm thick aluminium sheets and 32 X 32 mm aluminium extrusion profiles.

- **Desktop computer and monitor**

The function of the desktop and monitor is to process the data to construct the images. The interface and user guide are provided by the monitor. Within this desktop, a digital user interface is required to allow the operator to select the relevant MRI sequence, run the test, and read out the MR images.

- **Power source**

To achieve the desired spatial resolution (3 mm,) high currents are not necessary, so the maximum voltage (15 V) is chosen such that simple air fan and heat sink cooling can be used.

- **Shielding4.4 Challenges**

Since the body can act as an effective antenna, the body is placed under a conductive fabric (Holland Shielding Systems, Dordrecht Netherlands) to prevent additional noise. This sheet is connected to the same ground as the Faraday cage.
The imaging process can be seen in 8.8. The process is subdivided in what happens on the hardware side and what happens on the software side.

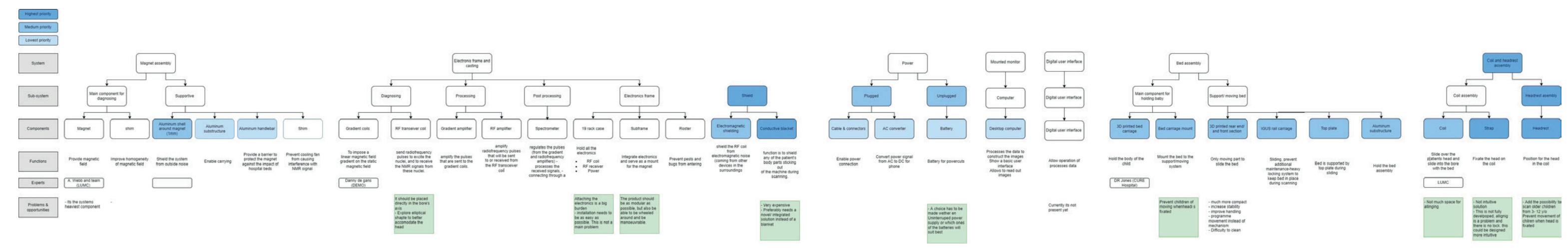
5. Possible improvements
Positive developments towards an innovate, more accessible and low-cost MRI system has been done which allows more accessibility for those systems in LMICs. However, for implementation of such a system, not only the technology needs to be considered, but also the contextual, human factors and the complete life cycle with respect to design, production, fabrication, end-of-life, and maintenance. This section discusses the essential factors besides the technology that needs to be able to implement a LF-MRI system in LMIC countries. Solely exploiting the ability to make the technology is insufficient for it to enhance the medical care of those who need it. Socioeconomic status, context and human-product interaction are aspects that have major impact on the success of the product and the effect it has on people's lives, so it should be including factors for the when assessing the use and relevance of this technology for LMIC.

5.1. System
The developments in the improvements of the low-field technology are broad and include different methods such as standard linear gradient encoding for image formation, standard transmit and receive methods, gradient-less MR system, ultralow-field measurements combined with squid detection, Over Hauser-enhanced MRI, fast field cycling approaches and the use of specialized contrast agents. Besides technical improvements, a lot of other improvements can be made in the low-field MRI system. Although the lower field MRI systems present a decreased quality image than the high-field image systems, the outcomes for patient care are not worsened. Improvements within the technology are bound to the implementations of readout strategies and image reconstruction. In low fields, the T2 relaxation times can be made longer which increases the SNR. Within the technology a few aspects need careful tuning to obtain the sufficient quality. Considering the cylindrical geometry of the Halbach configuration, it is necessary to obtain a reliable z-gradient coil with a sufficient coil efficiency and linear region. This can be optimized by including gradient power minimization, because this will improve the power supply requirements which is important for a LMIC context. Considering the implementation of conductive sheets instead of wires for the gradient coils may be feasible for bulk production [21].

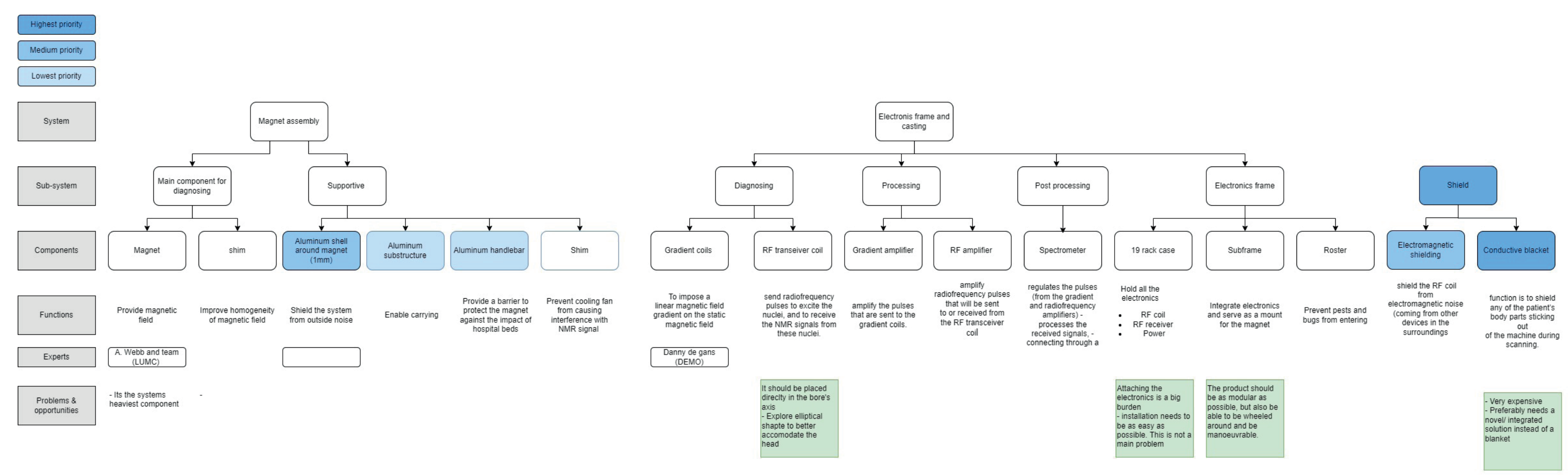
5.2. Human factors
Besides the high-cost price, the other main reason for the low availability of MRI scanners in LMICs is the complexity of operating an MR system. As can be seen with donated medical devices from western countries, the donated equipment might have the good functionality, but only 10-30 per cent becomes operational. This is because the market and does not fit the context of the LMICs, because of the mismatch in the suitability indicators. These suitability indicators address issues in the characteristic of the medical device in relation to the appropriate setting, the assured quality and safety, the ease of use and maintenance and the affordable characteristic [35-36]. Furthermore, the lack of health personnel and proper training forms a problem for the implementation of the Low Field MRI system [26]. Therefore, it is important to consider the user interaction with the product when designing the embodiment of the device to provide an as intuitive experience as possible to minimize hazard by human error.
Besides the challenge of operating the medical equipment, also the maintenance provides challenges. Replacement costs are high and spare parts are mostly scares. Therefore, it is important that products in this context are designed by considered the accessibility of only standardized parts to provide cost-effective repair and maintenance. To conclude, all things considered from the MRI practitioners' perspective, patients, and the technology the main challenge is that MRI scans take a long time and often need to be repeated due to patient moving. Operating and re-sitting the scanners is time consuming and costly. A simplified workflow that suits the operating practitioners for a low-field MRI promises a positive human experience, technological advantage, and economical benefit. These benefits such as a low power use

2. Functional Analysis weakness and opportunities

A functional analysis has been made with as goal to investigate the function of each component , the challenges, and opportunities.



Function analysis complete overview



Zoomed in left side

Figure 16. function analysis

Functional Analysis and breakdown past.
Before our involvement in the project, the MRI scanner has been conceptualized in a graduation project by F.v Doessum. This conceptualized product is a further iteration of the technical development of the MRI scanner. It involves the implementation of the technology, the ergonomics, and components for a safe operation. The components are classified according to their system: Power, Embodiment, .

3. Functional Analysis

5.1 Components

The identified components are

1. **Technical components**
   1.1 Bore
   1.2 Housing
   1.3 RF receiver
   1.4 RD transmitter,
   1.5 Gradient coils
   1.6 Magnet
   1.7 RF amplifier
   1.8 Gradient amplifiers
   1.9 Spectrometer
   1.10 Desktop computer and monitor
   1.11 Digital user interface
   1.12 Electromagnetic shielding
   1.13 Conductive blanket
   1.14 Cables and connectors
   1.15 UPD (uninterruptible power supply)
   Computer

1. **Embodiment of components**
   1. **Magnet subassembly**
      1. Shield
      2. Aluminium handlebar

      provide a barrier to protect the magnet against the impact of hospital beds
      Ample space for people to lift

3. Cooling in the rear

Prevent cooling fan from causing interference with the NRM signal
Electronics case

2.2 Electronics subassembly
2.2.1 Rack cases
Hold all electronics
2.2.1 Subframe
Integrate electronics and serve as mount for the magnet

3. Bed and coil assembly
Bed assembly
2.3.1 3D printed rear end
2.3.2. Aluminium middle section
2.3.3. 3D printed front section
2.3.4 3D printed bed carriage mount
IGUS rail carriage
Sliding, prevent additional maintenance-heavy locking system to keep bed in place during scanning
Allow of load that is “more than sufficient” for carrying and infant
Top plate
The bed is supported by top plate during sliding
- Load is countered on 3 points which reduce stress on the 3D printed material.
-Aluminium safety rails
- Attachment strap
- Headrest
- RF coil
Bed-carriage mount IGUS rail
- Aluminium substructure
- Attachment to magnet
Coil and headrest asset analysis

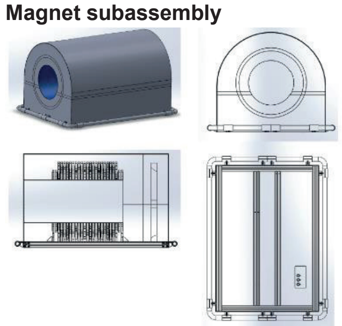
The primary function and secondary function of the components can be seen in table 1.

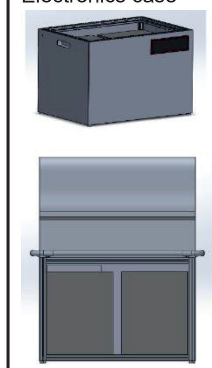
Subsystem	Component	Function	Comment (+/-)	Specs
1. Technical	1.1 Bore	Act as a smooth cylinder to safely insert the patient	*The bore is not a component* • Alignment of the bore with the bed is crucial *1) include a proper alignment tool into the design that ensures accurate alignment during installation, even on crooked floors or 2) increase the margins between the components so that accurate alignment is less of an issue and blockage does not occur when the bed is misaligned. Some alignment tool and bed attachment already exist in the current design, however, need further detailing. Moreover, it is also advised to explore solution 2, as accurate alignment may not always be possible.*	The version 3.0 is made from a PMMA tube with an outside diameter of 300 mm, with a wall thickness of 4 mm gives an inner diameter of 292 mm. Its current length is 488 mm (with the magnet's isocentre at 244 mm).
	1.2 Housing	Serves as connecting part for the inner electromagnetic shielding and gradient coils		
	1.3 RF receiver			
	1.4 RFRF transmitter,			

	1.5 Gradient coils	The gradient coils' function is to impose a linear magnetic field gradient on the static magnetic field	The coils are made of copper wire and are connected to the outside diameter of the bore cylinder. They have a thickness of approximately 3 mm.	
	1.6 Magnet	Provide a static homogenous magnetic field	Arranged in Halbach array which increases the strength	circular PMMA rings that have been laser cut to fit 3125 small neodymium magnets (12x12x12 mm). 100 kg
				(isocentre 60mT)
				Field of View 200 mm (100 mm in each direction from the isocentre
		shims: improve homogeneity of magnetic field	238 magnets	
	1.7 RF amplifier	The RF amplifier's (figure 5) main function is to amplify radiofrequency pulses that will be sent to or received from the RF transceiver coil.		• Sending pulsed of 1KW/millisecond • Power during scanning 10W
	Sub rack	To hold the RF amplifier and cooling fans		• 355 x 267 x 427 sub - rack
	RF transceiver coil	The radiofrequency transceiver's function is to send radiofrequency pulses to excite the nuclei, and to receive the NMR signals from these nuclei.	It should be placed concentrically with the bore's axis, with its centre located at the isocentre of the magnetic field.	• maximum diameter is 250 mm
			O: Future development may explore elliptical shapes to better accommodate the head.	
	Gradient coil	Impose a liner magnetic field gradient on the static magnetic field		
	1.8 Gradient amplifiers	The gradient amplifiers (figure 6) amplify the pulses that are		60 W and require 12V power supplies Built in 19"sub-rack

		sent to the gradient coils.		
	Sub rack	Hold the gradient amplifier and cool the system	Hold the gradient amplifier	295x133x427 mm
	1.9 Spectrometer	The spectrometer functions as the system's brains. It regulates the pulses (from the gradient and radiofrequency amplifiers) - processes the received signals, - connecting through a USB-connection to the computer.	Magritte Kea console	
	1.10 Desktop computer and monitor	A desktop computer processes the data to construct the images. The monitor shows a basic user interface and allows to read out images.	Touch screen on adjustable mount	The current desktop computer equips a quad-core CPU, 16 GB of RAM and a mid-range GPU
	1.11 Digital user interface			
	1.12Electromagnetic shielding : 3mm aluminium sheet	The function of electromagnetic (EM) shielding is to shield the RF coil from electromagnetic noise (coming from other devices in the surroundings) that can negatively affect the image quality.		
	1.13 Conductive blanket	The conductive blanket's function is to shield any of the patient's body parts sticking out of the machine during scanning. These body parts can act as an antenna to income	Very expensive	

		electromagnetic signals; to increase SNR, they are currently shielded from all sides by the conductive blanket.		
	1.14 Cables and connectors			
	1.15 UPD (uninterruptible power supply)	To deliver at least 1kW power pulses for 15 minutes of imaging for all components		
	1.15 Power supply	Currently, power comes from a wall plug at 230v, 50 Hz.	No backup power is installed	

Subsystem	Component	Function	Comment (+/-)	Specs
Magnet subassembly 				
	Shim	shims: improve homogeneity of magnetic field		
	Aluminium sheet	Shield the system from the outside electromagnetic noise	heaviest component	3mm thick aluminium sheet > due to stiffness
	Aluminium substructure	*Enable carrying*		40 x 40 mm aluminium extrusion profiles
	Aluminium handlebar	*provide a barrier to protect the magnet against the impact of hospital beds*		
		Ample space for people to lift		

	Mesh shield	*Cooling in the rear Prevent cooling fan from causing interference with the NRM signal*	In case of the air conditioning is not present	0.5 mm mesh shield
Electronics case 	Rack cases	*Hold all the electronics*	• Magnet • RF coil • RF receiver • Power O: optimize it in size	D: 565 x 570 x 430 mm Thomann.de 8U rack 19"inch rack case 12U (1U = 45.45 mm)
	Subframe	*Integrate electronics and serve as a mount for the magnet*	30 kg	
	Roster	*Prevent pests and bugs from entering*		
Power	Uninterruptible power supply			at least deliver short 1 kW power pulses and an average of 110 W during at least 15 minutes of imaging.
Bed subassembly (30 kg)	3D printed rear end	Slide the patient in and out of the bore	Only moving part > dust resistant follows the diameter of the bed • difficult to clean	20x20 mm aluminium extrusion profiles
	Aluminium middle section			
	3D printed front section			
	3D printed bed carriage mount			
	IGUS rail carriage	*Sliding, prevent additional maintenance-heavy locking system to keep bed in place during scanning*		

		Allow of load that is "more than sufficient" for carrying and infant		
	top plate	*Bed is supported by top plate during sliding*		20 mm thick HDPE
		The load is countered on 3 points which reduce stress on the 3D printed material.		
coil & headrest assembly	coil	Slide over the p[patients head and slide into the bore with the bed	It is a challenging problem, because there is not much space for the operator and aligning is difficult	250 mm inner diameter
	strap	Fixate the head in the coil		
	Headrest	Position for the head in coil	Attached to the coil because the dimension is dependent on coil size	
	Bed		Ensured proper alignment and stability by a fixation on handlebars	

	Empty space below the bed	shelving and store MRI necessities		

4. Functional analysis – Mock-up creation and review

Objective
To evaluate the current state of the low field MRI scanner, define all challenges and investigate the most prominent challenges.

Method

A mock-up was built with the correct 1:1 dimension to get familiar with the dimensions, ergonomics, and usability of the low field MRI scanner.
The Mock-up also served as prototype for stakeholder involvement during zoom meetings and sessions.
A greater understanding of the concept, the problem and the procedure is gained.
Result

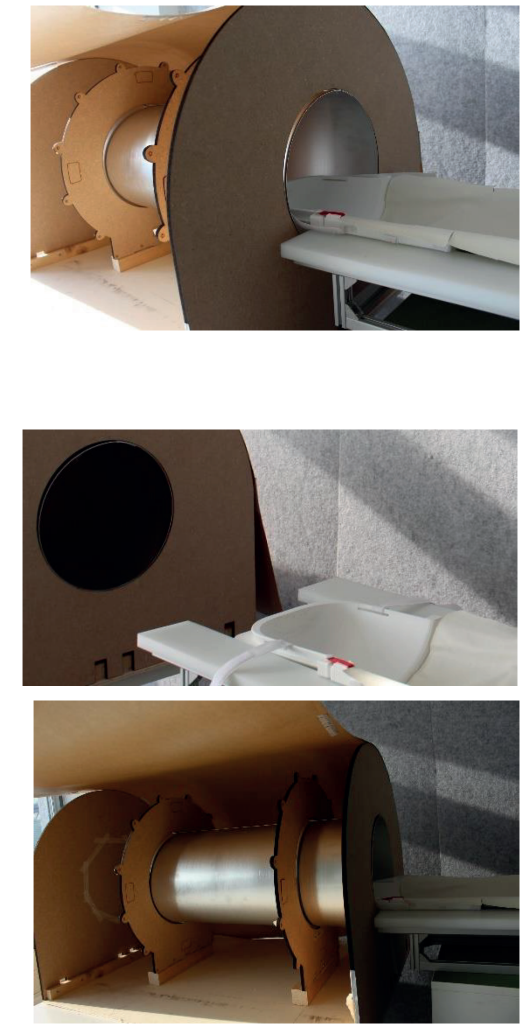
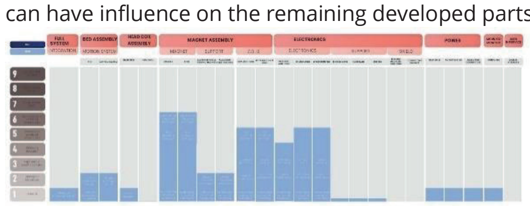


Figure 17. Mockup of MRI scanner

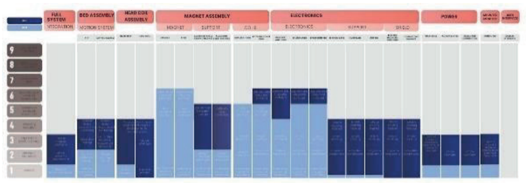
5. Technology Readiness Level

TRL
As can be seen in Figure 1. all systems and subsystems of the low field MRI scanner have been identified. The horizontal row subdivides he subsystems to the parts of the product, while the column illustrates the levels of the Technology readiness level. Two colours can be identified in the introduction of the TRL levels which are light blue for the start of the project and dark blue to indicate the TRL level as the envisioned goal for the graduation project.

Current TRL
The magnet system is the system that has been the most developed, until TRL level 5. However as can be seen the magnet system is still under development, which results that not every requirement is fixed and changesets in the parts can have influence on the remaining developed parts.



Envisioned TRL
For the low Field MRI scanner to be used in the CURE hospital in Uganda, the subsystems of the product must be developed. As can be seen the bed system and the supports for the magnet and electronics are underdeveloped. Furthermore, a first iteration has been made for the visual look of the entire concept.



The envisioned TRL of the product can be seen in figure 2. As can be seen the full system will go from a conceptualized product to a proof of concept where the subsystems are integrated and validated through functional prototypes. This involves the support and connection system of the electronics, power, magnet assembly and be assembly.
The part that has the most influence on the immobilization of the patient is the part that is in direct interaction with the patient, which is the bed assembly in combination of the head coil assembly. All parts that are influenced by the design of the bed assembly will be considered during the design
The product

The goal of the entire product is to:
To design a sustainable LF MRI scanner that provides high-quality imaging through an improved user experience

The requirements for the product are :
The device must allow the operation for the MRI technician and the Interpretation for the radiologist.
The MRI scanner must be able to be operated by personnel with lower training levels
The product must be low cost for the local patient to be able to afford this
For the installation, the maintenance needs to be placed in such a way that the general technician can repair and maintain the
The device must facilitate monitoring of the patient while being inside of the MRI scanner
The device must facilitate direct or indirect following of the patient for the MRI technician

The device must be portable (what is portable?)
The device must look friendly
The operation of The device must be intuitive and understandable for The nurses that change routinely
The patient must have a least gesture as possible as preparation for the scanning

However, some challenges occur that need to be solved to facilitate the requirements of this device.

The final development goal of the "product" will be until the whole system demo.
Therefore, the phases will be passed
Research: what type of interaction is required on the device and what elements the system requires to facilitate this
Concept of technology: A concept will be designed with all the elements implemented as the envisioned product will be
Experimental proof of concept: A 1:1 mock-up will be made to test this interaction and proof the concept
Laboratory simulation: The detailed bed system assembly needs to be implemented inside of the full system.

Magnet
The magnet configuration is out of scope and will not be further developed within this thesis. This will be done by the LUMC

Shim
The research will be conducted on what the best way is to facilitate the required interaction for the shim

The aluminium shell around the magnet
needs to be minimized in size and contribute to a more friendly look of the entire design.
1. Research how the friendliness of the product contributes to the aluminium shell of the design without creating more noise

Electronics
The current electronics will be researched if this is the correct way

1. Research: Research what are the required electronics needed and what is the most fragile
Research how good maintenance and replacement is best implemented in the electronics
2. Concept of technology will implement all this into the design of the complete system and how this can be framed

Challenges :
How can the parts be replaced easily? / What are the factors needed for an easy replacement?
The active ventilation might hinder the imaging
RF transceiver coil must be as close to the subject as possible,
Every head size is different, but an optimal shape is crucial

Electromagnetic shielding

Conductive blanket
The goal is to provide a noise reduction without the conductive blanket to have a more open design.

1. Research: Research how the conductive blanket can contribute to a more interactive and better user experience
2. Concept of technology: A conceptualisation is made of the researched conductive blanket and is integrated in the design
3. An experimental proof of concept is made
4. Simulations are done to prove that the required goal is achieved.

Challenge
The conductive blanket reduces the noise; however, it contributes to a difficult airflow inside of the bore for the patient and a dark and hot environment where no interaction with the caretaker is possible.

Power

The goal is the provide a power source that can overcome the power fluctuations
An additional power source might be necessary, but the cost must not be too high, and it must be locally available

Research :
Research will be done on what is the best power source for the device

Computer
The goal of the computer is to visualise the imaging to the doctor

The challenge is that the doctor might be in the way and must see the patient while also seeing the baby
Bed assembly
The bed assembly needs to hold the patient comfortably
Requirements
The child must be able to lay still for 10-15 minutes without sedation
The patient must be able to lay comfortably in the bed
The head and shoulders of the patients need to be able to be inserted inside the bore
The product must allow the vomit to be cleaned easily

The challenges are
Movement must be minimized while the patient must lay comfortably
The child of 2 years old and the child of 8 years old need to be able to lay comfortably in the same bed.
The head and shoulder size of the range of children entering the bore is very different
No rigid edges must be implemented for cleaning, but also the functional sliding must be optimal

1. Research: Research will be conducted to decide on the best way to place the patient of different ages comfortably in one bed.
2. The concept will investigate the materials that need to be used in the MRI scanner
3. Experimental proof of concept: A prototype will be made to secure the smooth functional working of the bed and if the patient really gets to be calmer.

Motion system of the bed

The motion system must provide guidance of the bed system inside of the bore

Requirements
Must slide the bed smoothly
Must not obtain ferromagnetic components

Challenges
Must facilitate good/smooth sliding without the use of metals
Must facilitate smooth sliding with the weight of a child on the bed

Bed system
The bed system must provide an ergonomic platform for the patient to lie on

Requirements
Must provide support for the pressure and stress points of the patient
Must provide a restriction for the movement of the patient

Challenges
The materials must be well cleanable
The ergonomics must be for either a specific body or "one size fits all" (would this still be relevant economically wise)
TRL
1. Research: What are the main variables and values of these parameters
2. Concept: What different ways allow this goal to be achieved.
3. The experimental proof of concept: Prototype the concept and test this on its ergonomic
4. Laboratory simulation: Test the shape with a simulation to check if this does indeed
5. Validation in a simulated environment: Test the head coil inside the working MRI scanner
6. Demonstrated in a simulated environment:

Head Coil

The goal is to design an ergonomic head coil that improves the interaction of the patient and caretaker

Requirements
The MRI technician must be able to intuitively position and align the patient without additional instructions
The subject must be able to be placed in a range of 25 cm inside of the bore
The head coil must be lightweight
The head coil must be easy to maintain

The head coil must be easy to change for a different head size

The challenges are
Must facilitate the comfort of the patient
The head of the patient can variate a lot

Research: What is the best way to keep the patient comfortably physically and mentally
Research what is the best way to fit the patient head coil on different patient head sizes?
Concept of technology: Conceptualize the new head coil and integrate the design into the complete system

Define

Background research to define product requirements

F. Product challenges

G.

H.

F. All prodcut challenges

1. Product challenges

Objective: To investigate all challenges in the user, context, technology, and prior product development.
The most crucial challenge that needs to be solved has been chosen.

Method: The challenges have been researched and potential opportunity areas have been defined. These have been evaluated on their potential desirability feasibility and viability with experts.
Result:
Figure

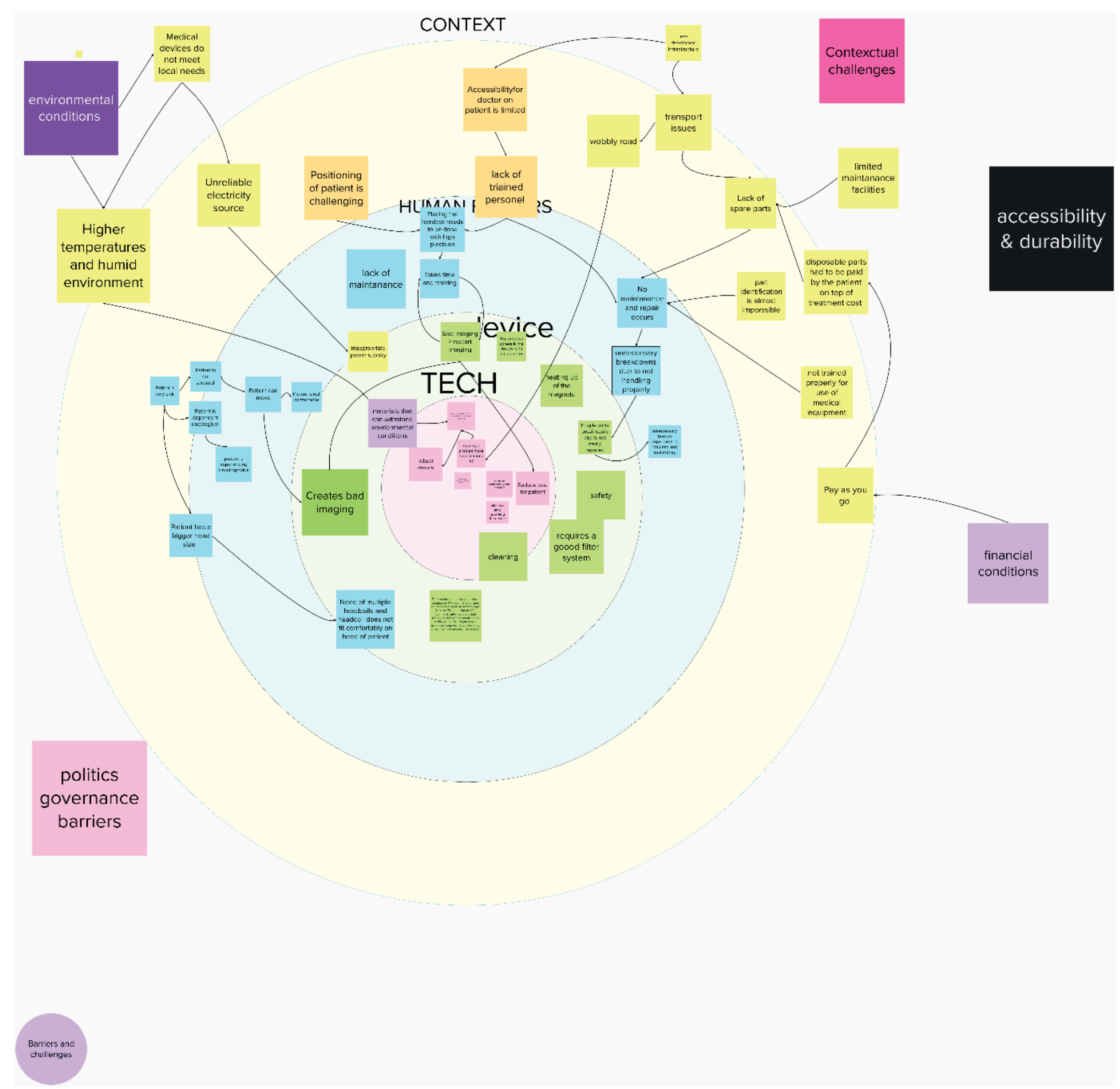


Figure 18. Mindmap of all challenges within the product

Technology	Context	User	Product development
Motion distrorts the imaging	The MRI scanner is not fitted and designed for full repair and maintanance inside the context.	The most challenging part of the imagnig is calming the child	The MRI scanner needs to be as cost-effective as possible, while being able to be manufactured locally while maintaining a high quality and usability.
The RF coil needs to be at close proximity of the head of the patients. This can range in different sizes and shapes		The head of the patient has paper-thin skin and is very fragile	The bore of the MRI scanner is 300mm which can only allow the entrance of children up to 4 years old inside the bore
The imaging field of the MRI scanner is 225*225, but the most homogenous B0field is in the middle of the MRI scanner, So ideally the patients head must fall within this field		The MRI technicians have a challenging and high workload due to the lack of other personnel and the lack of knowledge of complex equipment	Features for safe and ergonomic use are not developed
The low field magnet has a lower homogeneity			Sticky drawer effect of the RF coil in the bore
Using permanent magnets require a shielding around the patient to prevent an antenna effect from the body			sliding mechanism of bed inside bore is not developed
Using permanent magnets result in temperature dependency			Patient is not able to lay comfortable and still in the bed
The electronics heat up inside the 19" rack and need filtration while preventing red dust to enter.			
The shielding blanket obstructs the air flow			
The low SNR of the lf MRI decreases the image quality			

The most prominent challenges, and the challenges that affects both, technology, the user, and the product development is the fact that motion caused by the patient causes motion distortion, which results In a time consuming and costly repetitive scan
Therefore it is crucial to solve this challenge.

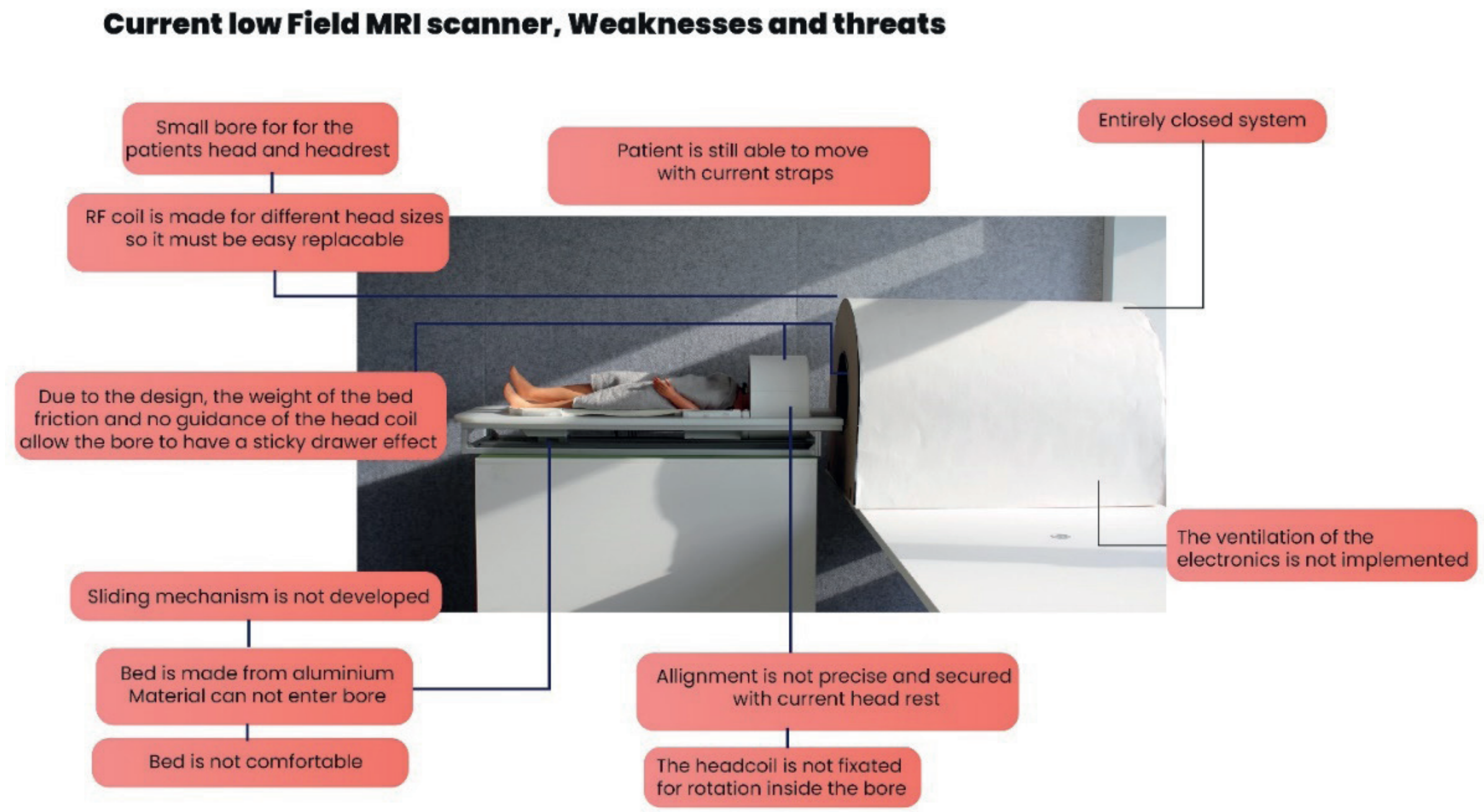


Figure 19. Challenges occuring in product

Figure 20. Main challenges

6.1 Challenges

6.1.1. Flexible coil

One of the main challenges for the lower field MRI is the lower signal-to-noise ratio (SNR) caused by the lower field strength. This drastically influences the image quality and determines whether an image is appropriate or not. The radiofrequency coil must be in proximity of the head for qualitative images to increase the signal. However, due to the large un-informalities and great dimension range in the anatomy, different brain parts are not imaged well, such as the cerebellum. Currently, the head coil is stiff and rigid. The shape is fixed to be round or oval. Coils are at a specific range in a fixed pattern to provide the best imaging. This makes it not able to shape the coil on the body.

Figure 6.1 Flexible coil

6.1.2. Movement

Since the children do not get sedated prior to an MR scan, they are prone to move. As a result, motion inside the MRI scanner causes motion distortion. Mainly, low fields are by conditions that are optimal to retrieve an adequate qualitative image. The system has a resolution of 3*2*2mm, which is the allowable motion. According to the Cure Hospital's MRI technicians, keeping the child calm is the most challenging task. A time-consuming and essential part of the procedure is effortful and demanding.

6.1.3. Sustainability

Considering the context characteristic challenges and the low field MRI scanner aims to increase the availability of these high technological advancements in LMICs, it is essential to consider how multiple life cycles are promoted within the product. As said in multiple interviews, once a product turns obsolete, the product is not usable anymore due to the lack of parts. This can occur within a few months.

6.2 Solution direction

6.2.1 Opportunity 1 - SNR

A promising opportunity to increase this SNR is by introducing flexible coils (Figure 6.1). The proximity of the receive coil to the anatomy of interest contributes to improved signal reception with decreased noise. This improvement of the coil results in improving the patient and technologist' experience. Furthermore, it increases the potential for accelerated imaging, improving the SNR. In addition, flexible coils can contribute to increased SNR by positioning the coil elements closer to the anatomy of interest, increasing image quality, and potentially allowing faster scan times. Finally, multi-element receive coils increase achievable acceleration factors for parallel imaging, enabling reduced scan times and, as a result, faster, more accessible scan sessions.
The patient comfort and the SNR can be increased by introducing the technique of flexible coils in the production of head coils. In this case, there is no need for different sizes of coils for different ranges of head-sized due to the flexible coil combination.
This can be fulfilled through screen-printed flexible coils that have been inkjet printed on flexible surfaces. This approach avoids the bulky characteristics of conventional head coils.
The receiver coils should maintain an overlap between the neighbouring coil elements to minimise mutual inductance while covering the entire occipital and temporal visual cortex. As a result, the coils are not fixed in their pattern and cause them to be flexible and adapt to the patients' different shapes and sizes. In addition, mounting the coils on a close-fitting head cap maintains proximity between the subject and the receive arrays. As a result, this may increase the SNR [67].

6.2.2 Opportunity 2 - Movement

The movement has been identified as one of the main challenges that harm imaging. A solution could be found in patient-centred care, where the patients' values are taken into consideration during the design process. Making the MRI scanner a better fit for the patient by reducing the factors that trigger the movement would be again throughout the entire procedure. Repetitive scans and traumatic experiences would be prevented. Improving the comfort of the patient would induce the triggers for movement. The interaction between mother and child has been found as the primary interaction during the scanning procedure.

6.2.3 Opportunity 3 - Sustainability

Focus on the repair and maintenance of the Low Field MRI scanner could be an opportunity to increase the life cycle of the LF MRI scanner.
Troubleshooting within MRI scanners is the most challenging part of conventional MRI scanning experiences maintenance because the lack of spare parts could lead to an opportunity for a system where troubleshooting would be made approachable and parts available or accessible.

6.3 Assessment - the choice

6.3.1. Opportunity 1

Opportunity 1 might not suit the low field MRI due to the complexity of achieving an accurate result. This is due to the resonant structure of the flexible coils. An antenna is an electrically resonant structure.
A strong magnetic field has a higher frequency. When the structure is changed, the coil is stretched, which results in an adjustment in the tuning circuit. This can be done to a certain extent. This means that with every change of shape of the head and thus the coil, the tuning of the system needs to be altered.
SNR - Besides the proximity of the coil to the subject, the thickness of the wire affects the SNR. The thicker the wire, the smaller the resistance [R]. The wires on the foil printed coils are thin and thus contribute to a larger resistance. Moreover, the way of printing the coil on the surface is fragile. The problem is valid, desirable to solve, and has a great prospect. However, the technology is not yet at an advanced stage to contribute directly to the improvement and development of the Low Field MRI scanner. A hardware improvement in the increase in the achievable resolution and SNR increases the sensitivity to motion, which is still a problem.

6.3.2. Opportunity 2

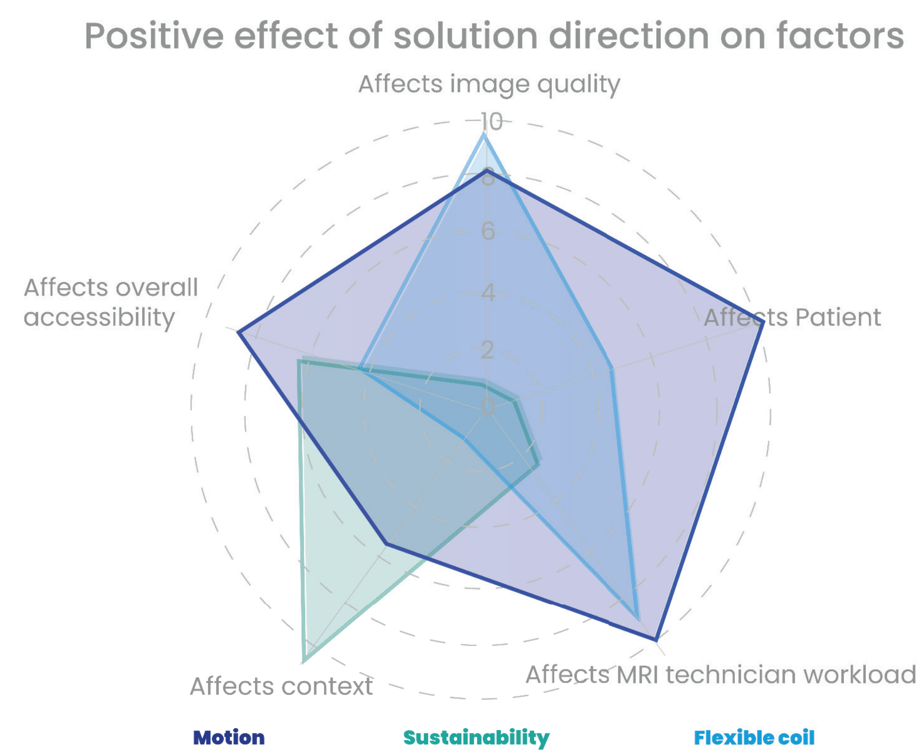
According to the interviews, literature studies, and co-creation sessions, the challenge of the movement of the patient has been identified as the main challenge that needs immediate attention prior to imaging. This is a challenge that has a direct relation to the context (which does not allow the patients to be sedated and do not have the resources to keep a child still), the technology of the low field MRI that does not allow a movement more than 3 mm and the human that has a specific condition, where comfort and ergonomics play a prominent role in its behaviour inside the MRI scanner. The effect will have a significant impact on the imaging outcome and will eventually allow more children will be able to be scanned within the MRI scanner.

6.3.3. Opportunity 3

Challenge 3 is a combined challenge of all small challenges that consider the product development of the Low Field MRI scanner and the user functionality within the product. Unfortunately, the product development is not at a stage where detailed troubleshooting implementation can be designed. Therefore this opportunity might be valuable at a later stage.

6.3.4 Conclusion

Possible solutions such as flexible head coils to increase the SNR or temperature regulated components would have a minor effect on the quality improvement. However, when looking at the entire process, the main challenge is to keep the un-sedated child still, which is the most critical problem that allows the product to function accordingly. It is most beneficial for the patient when solving this problem since a patient-centred environment is created during the scanning. It benefits the MRI technician by easing the most challenging task comforting the patient, and directly leads to better clinical outcomes (Figure 6.2).



G. design driver, vision direction

1. Design direction

The most relevant key challenges based on insights

1. There is no available immobilization for patients with hydrocephalus.

Good quality imaging requires the patient to keep settled and not to move more than 3 mm. However, an un-sedated infant is prone to move due to discomfort and not instruct able enough to prevent moving. Therefore it is crucial to provide an environment where the patient is able to reduce the triggers for motion, which is discomfort and trigger that factors that will keep the patient settled, which is comfort.(At the stage of ultimate comfort the patient may fall asleep.) Current immobilization devices are not suitable for children with hydrocephalus. and only available as expensive and advanced options with additional accessories not available in LMICs.

MRI technicians perspective
2. Keeping the child still is the most time consuming and challenging part of the workflow of an MRI technician

MRI technicians are trained to provide the technical support for MR Imaging and the guiding the patient through the produce of such. During the installation, keeping the child as still as possible is the most time consuming and challenging task due to the not inscrutable infants and disturbed state of minds of the patients. Limited support of workflow in the installation of patient

Patient
3. The patient must be calm in a disturbing environment

The patient in the age category of 0-4 years old is heavily relying on its caretakers. From the moment the patient is prepared for the scanning, it is separated from the caretaker and in this case increasing discomfort. The placement of the infant in an unknown , noisy cold and dark object is not calming nor securing for the patient.

Context
4. High financial barrier for the purchase and cost of ownership of an MRI scanner

The main barrier that reduce the availability of MRI scanners in low resource settings is not only the financial barrier to purchase the device, but especially the cost of ownership is an important factor to consider in procuring such a device. Medical experts in LMICs have mentioned that the purchase of a device that can not be maintained is counterproductive.

5. Difficult repair and maintenance

The MRI scanner is a maintenance intensive device which requires regular checks in order for it to function properly. An additional barrier for the availability of medical devices in LMICs is the lacking of spare parts and maintenance resources (human and tools). There is no accessibility in repair tool and maintenance tools.

Solution area
The most desirable opportunity areas from the design vision has been combined to define the most crucial solution area that is defined as an opportunity statement for an initial design assignment.

6. Low-tech and non invasive patient-centred and sustainable The design guides that have been leading in the principles for the design.

For a success full product with a qualitative outcome and a future perspective it is of importance that the MRI scanner is designed to be patient-centred and sustainable in a way that it is designed as robust as possible for a longer life time.
The envisioned MRI scanner should be a low-tech solution that is as robust as possible in order to be maintained easily and have a longer life cycle. Every additional electronics that is not necessary is an extra risk that is prone to break.

2. Define the product vision

Comfort can influence the patients next experience in a positive and negative way. That is why the bed design is focused on preventing discomfort and promoting comfort to the user by looking at reducing the physical discomfort and promoting the psychological comfort.

The method ViP is used to create a vision for the product that not only solves the present problems, but also sets the product in the society with a certain value. The user centred perspective and systematic approach of ViP promotes to an all embracive and comprehensive vision for the product with a novel future perspective which is especially important in LMIC where the quickly changing contextual factors have great influence in the working and sustaining of the product.

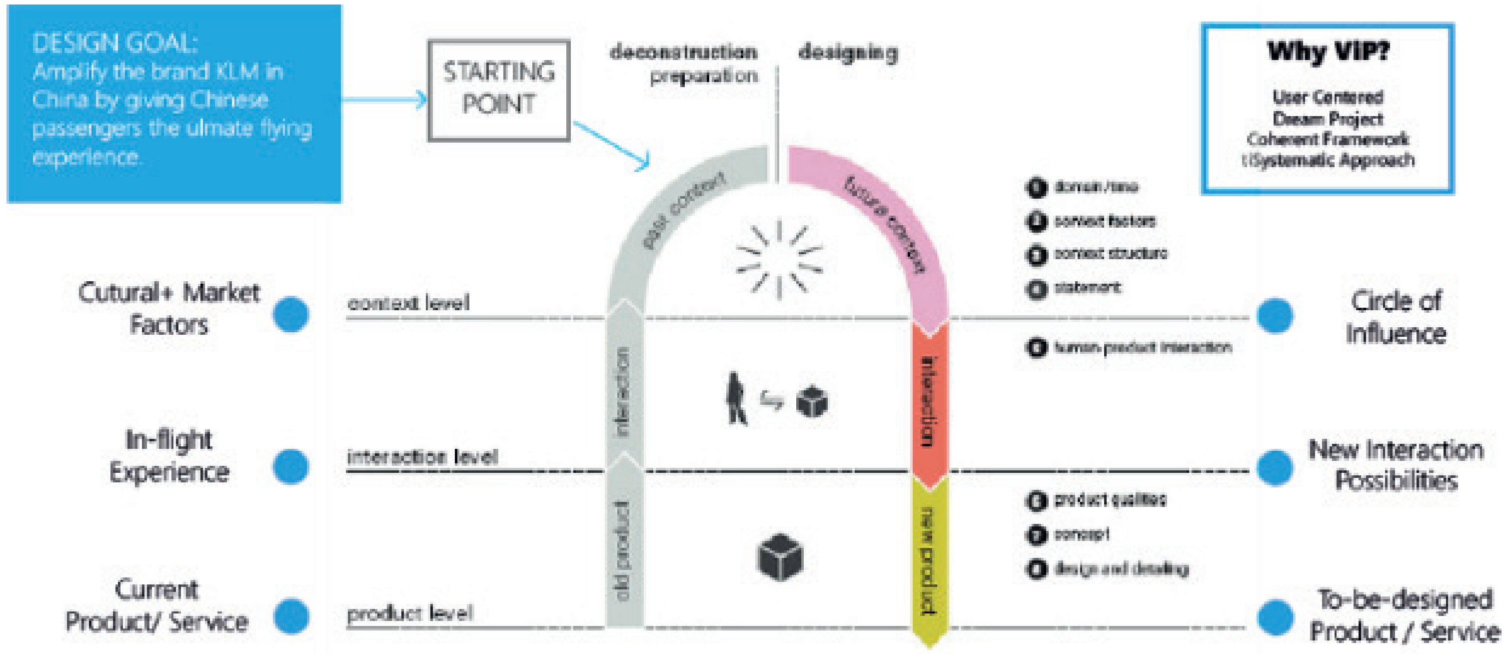


Figure 19. ViP

1. Domain/ time
The domain wherefore we will design is for 10 years, with an expansion in all LMIC and not only Uganda
2. Contextual factors that have great influence in this can be subdivided in
• environmental factors
• system/market factors
The most important that drive the product are the fact that
o The cost of the device must conform to the country's abilities
o Due to low education, there are not much trained medical workers which makes the workload of the current medical workers high
Also, the technical workers are scarce and are not able to provide the needed maintenance and due to lack of recourses the maintaining of the device

Background
The current interaction between the patient, MRI technician and caretaker is defined according to the main key insights.
1. Frugal innovation is focused on making the a device approachable by declining the amount of complex and costly features in a product. As a result most of these products have an appearance that is technological oriented, which can be perceived as unfamiliar and scary for the patient.
2. Caretakers and MRI technician may be anxious during the scanning of the child. This may have influence on the psychological comfort of the patients.
3. The newly trained personnel, gets to use a new technology, with a many procedures involved. Positioning the patient is a time-consuming task without any a standard protocol, during their already high workload.

16.1.2 Objective
The goal is the define the future envisioned interaction of the stakeholders and the product.

16.1.3 Method
Through the design method Vision in Product (ViP) developed at

the TU Delft, the underlying vision of the concept for the future is created. A vision of the relationship between the user and product is defined, where after this vision is served as a fundamental for the future design vision. The ViP method is future oriented, interaction centred and context-driven.
First, the key insights and challenges from the discover phase have been outlied where after the challenges have been translated into opportunity areas.
In order to envision the interaction, an analogy is made from the current and future interaction.

Finding
Design vision
Current interaction vs. future interaction

As can be seen in the Patient journey mapping, the current interaction involves three important stakeholders namely, the MRI technician, the patient and the caretaker.

Analogy
The interaction between the MRI technician, the patient and the product can be envisioned just like an amateur trying to fix a leak. The MRI technician somewhat knows what to do, but while performing the task, trying to calm the patient adds another level of complexity. Uncertainty and stress increases while doing a precision task.

What are the current design drivers?

1. Human product interaction

Current interaction
The current interaction between the MRI technician- product and patient

Just like an amateur dad trying to fix a leak. You don't really know where it comes from, but you're trying to solve it without really knowing which things you need to touch, and time runs, and you are getting stressed while needing to do a precision alignment task.

Figure 20. Person struggling with fixing the sink

Desired interaction with MRI tech and patient

•securing
•quick
•product guides you through the process
•you have more time for interaction with the child

Figure 21. Parent & child interaction

The current interaction between the patient and the product

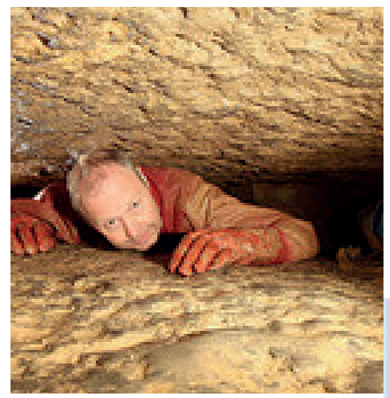


Figure 22. Anxious and closed in feelings

Interaction you want for the child

- warm
- securing

Figure 23. comfortable interaction

images from:
20: https://www.healthline.com/health/baby/your-newborns-stomach-size-is-smaller-than-you-think
21:https://www.familyservicesnew.org/news/8-ways-to-strengthen-a-parent-child-relationship/
22: https://www.familyadventureproject.org/duisburg-walking-roller-coaster/
23: https://www.homedeal.nl/loodgieter/loodgieter-kosten/

Product qualities
Core Vision
Sustainable MRI scanner that comforts the patient and secures the caregivers. A relying system that guides you through the process and supports the state of mind

- A cost effective & modular MRI scanner that provides high quality imaging by providing an optimal comfortable patient experience and secure work field

For hydrocephalus patients and their parents, The low field sustainable MRI scanner is a diagnostic medical device that provides high quality imaging by maximizing the patient experience unlike high field MRI scanners that are of high cost and do not sustain in LMIC, this product provides a sustainable solution for LMIC to diagnose diseases

My goal is
To design a product system that demonstrates a minimum viable prototype and increases the human experience of diagnostic MRI scanners.

Design drivers
- Sustainable MRI scanner - The true value of a low-cost MRI scanner lays in one that works and keeps working and fits in the right context (so design for easy replacement)
- Human centred : Improving the stakeholder experience has a direct (intuitive design)
- Design for low cost - but a novel and professional solution (performance and looks vs cost)

Vision Interaction
positioning the patient in the MRI scanner must be like placing a child in a car seatbelt
- You know with one look how it works
- The product guides you through it
- You don't need a lot of adjustment
- The patient is placed in one gesture comfortably and safe
- Once every handling is done, the patient and the caretaker is feeling safe and secure

Worldview:
Humanizing robust technology more to increase an understanding and create trust so that the handling can be secure

Statement:
I want the patients to be comfortable in their healing process just like they are comfortable in their mother's womb for a better patient outcome.

3. Solution Direction

The phase Develop discusses the development of the concept where all insights and fundamentals from the phases Discover and Define have been implemented. This chapter discusses the rationale behind the defined concept.

11.1 Analysis Solution direction

Design of medical devices for paediatrics is an extremely challenging field, The engineers are restricted by high and narrow technological requirements for a patient that is not so responsive, instructable and highly depended and influenced by its surrounding (MRI technician and caretaker). Figure 11.4 illustrates the narrow solution field, which needs to compromise between a low field MRI scanner that is optimizes to meet the users values, or optimized to meet all technological requirement either optimized for the use by MRI technicians.

As can be seen in chapter Technology and Chapter User (value promotion), the values, needs and requirements from each party may have a negative effect for the codependent factors.

When researching alternatives that mainly focus on solely one factor, the other factor is neglected which results in an outbalanced product that is either not easy to use, functioning or conform the patients comfort.

Design a product that meets the needs and values of the medical personnel as the patient without compromising of the technical requirements for better patient outcomes.

The final design of the low field MRI scanner must meet the sweet spot that compromises all values of the stakeholders. The middle of the circle is care beneficial for the technology, the patient, the caretaker.

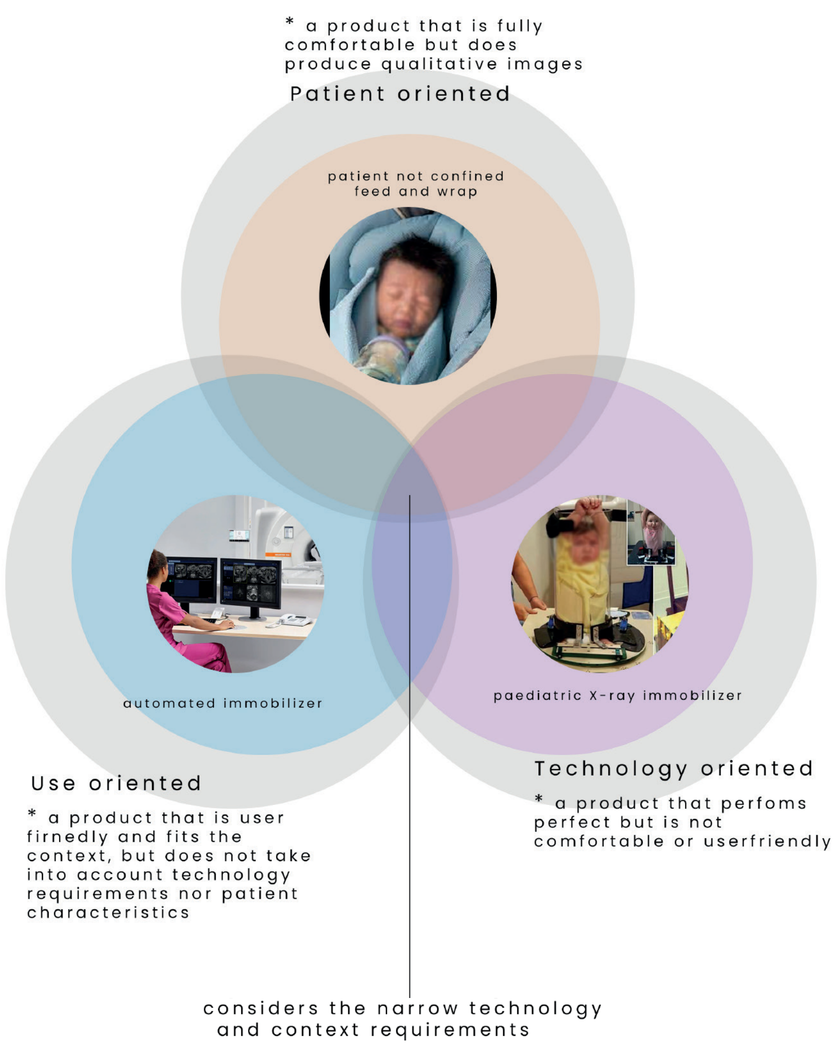


Figure 11.1 Solution direction of a non sedative MRI

3. Research: Concept solution directions

Concept direction
The concept directions created are based on the ability of the device to be fulfilled the design drivers in an extent from perspective of the important stakeholders (the decision maker, the operational user, and the treated user). There is a trade-off for the optimal concept of the design for the MRI technician who values a highly technical and qualitative good MRI scanner, from the perspective of the patient who wants to sit there as comfortable and minimal time as possible and from the decision maker who wants an as cost-effective solution with a great added value for the hospital.

The MRI technician values
- Quality and innovation.

The MRI technician values a good interaction with the patient and caretakes, while being able to perform the imagine without doubt or struggle. Ideally the MRI technician does not need to comfort the patient, because no discomfort is triggered.

User
- Comfortable experience. Optimal situation you would maximize the space inside the bore, but this is not possible due to the technology. The image quality that MRI technician is aiming for will not be achieved in this way.

Technology
- The ideal concept direction for the technology is a product where the patient is laying completely still. A fully enclosed system so that no noise from the body can interfere the imaging. However, this option is highly uncomfortable.

Different concept direction

1. One size fit all (but module for growing children)

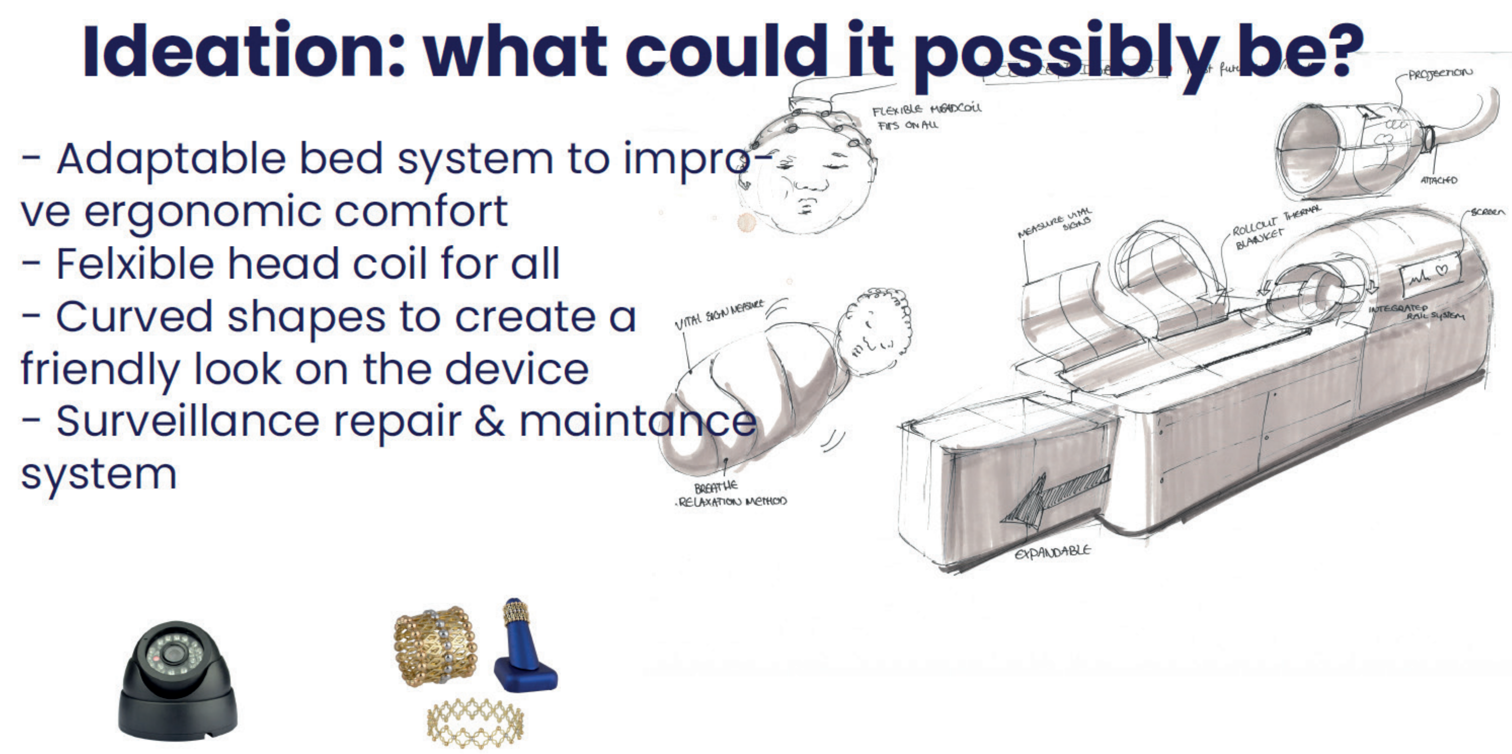


Figure 24. Solution direction 1

2. Modular (interchangeable head coil)
A system that is fixed for a certain group of age 0-4 years old. The Head coil can be interchangeable, and a shielding blanket can be attached. All accessorized can be added depending on the need of the patient. This concept is more focussed on the patients' comfort; however, it is not ideal for the MRI technician because they must do more actions to make the MRI a fit for the patient.

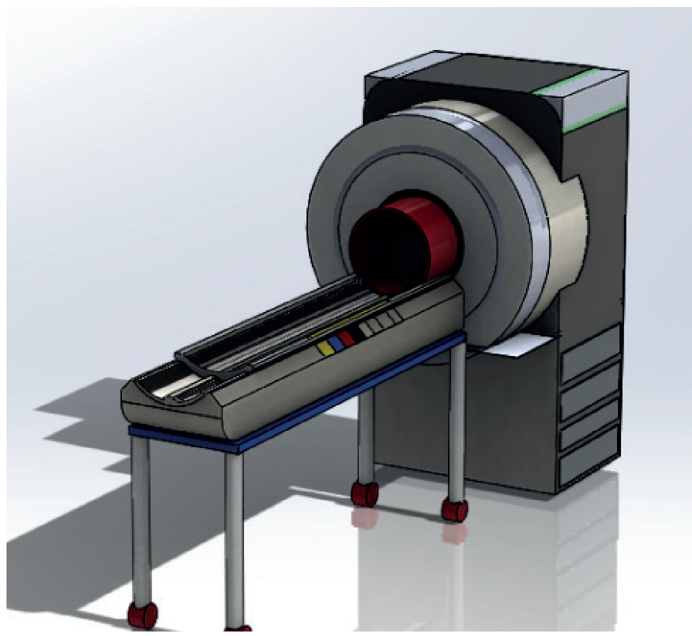


Figure 25. Solution direction 2

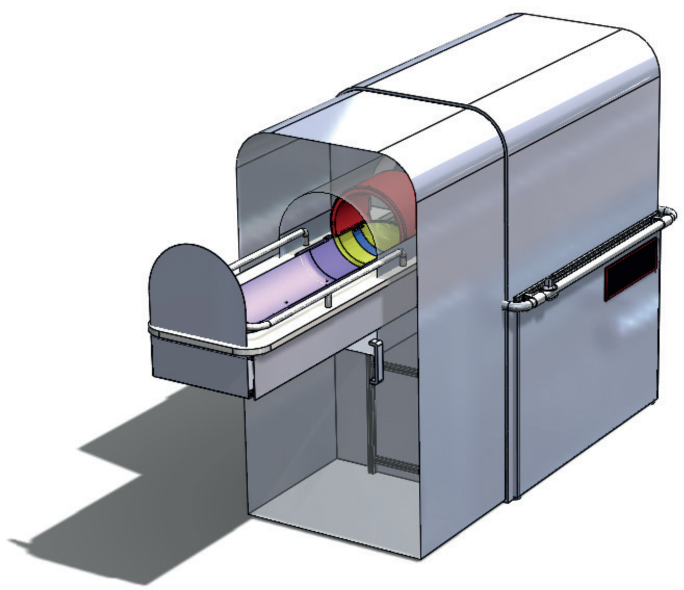


Figure 26. Solution direction 3

3. Ideal for technology (an enclosed system (no shielding needed)) Where the patient is inserted.

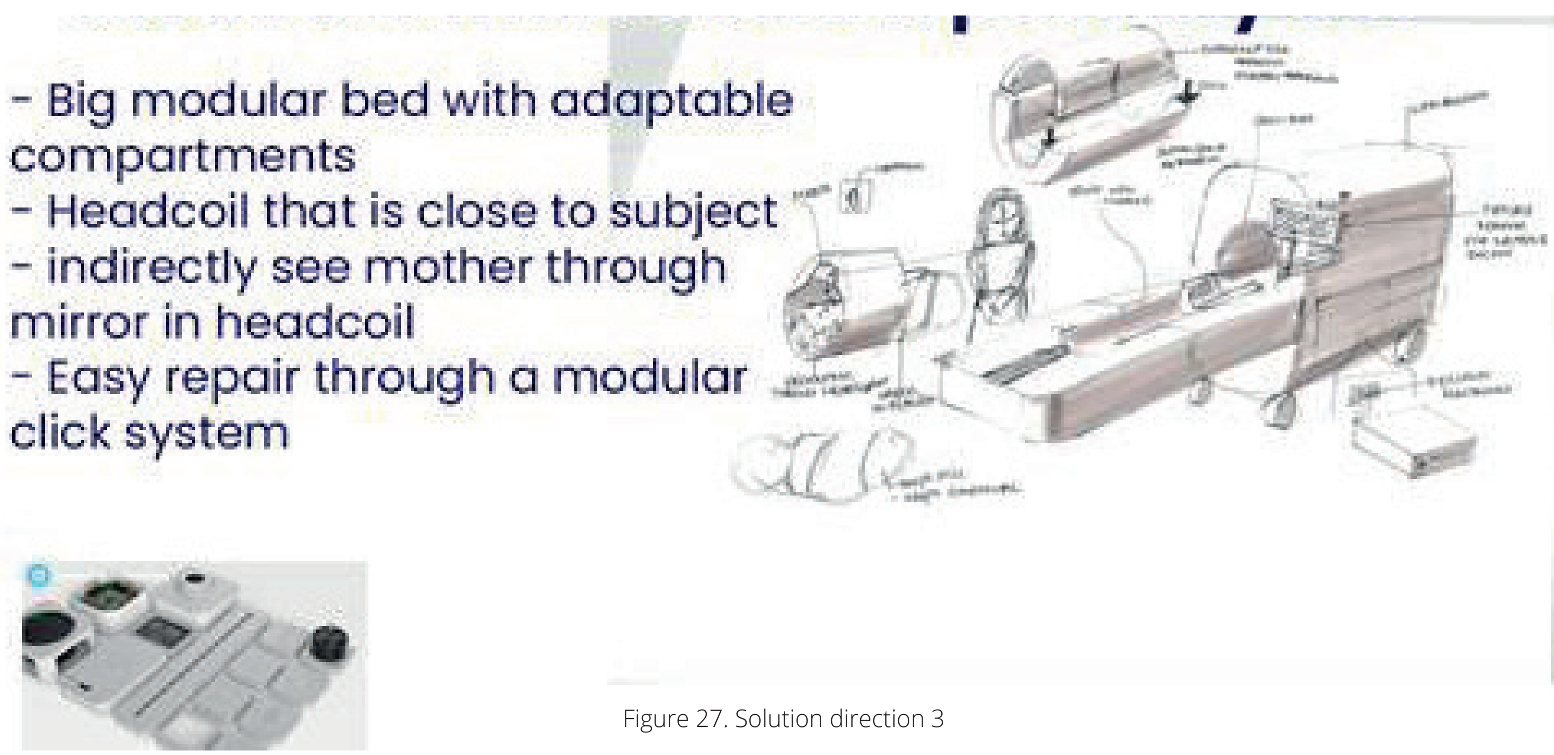


Figure 27. Solution direction 3

Choice of concept
Unique in this approach is that it is designed for paediatric patients, but it can grow , because infants all need a different approach. Unique in children is that they grow physically and mentally. So, the solution is appropriate for all ages in the user group, without excluding.
Moreover, it is good for all head sizes.

Concept direction decision

Feasibility	**Concept 1**	**Concept 2**	**Concept 3**
Technologic Achievable	One size fit all is an ideal situation for the comfort of the patient to meet the ideal technological requirements, however the technology has not reached this level of possibility yet. 6/10	The idea of modular compartments being attached to the product suits the technological requirements; However, this is more work for the MRI technician. However, it is achievable. 9/10	The idea of a shield over the patient has not been done yet, However this has the least possibility of additional noise 8/10
Fit with lower field MRI scanner	This is not a possibility yet with the low field MRI scanner . In a future scenario this would be ideal. **3/10**	Possible 8/10	Ideal situation 9/10
Desirability			
Desirable for MRI technician	The ability of a head coil that fits on all heads would ideally be to ease the workload of the MRI technician. However, each dimension requires its own sequence. Therefore, it is as much work as introducing multiple head coils. 6/10	A little bit more work. However, the patient is still visible for the MRI technician 6/10	It is less work for the MRI technician; however, the patient is not visible at all. A camera or additional technology should be added to be able to monitor the child inside the scanner. 7/10
Comfortable for patient	A flexible head coil is comfortable for the patient, because it is made exactly at its physical characteristics 10/10	The idea is somewhat comfortable for the patient because it is implementing a head coil that fits the head of the patient. 7/10	The patient is completely separated from the caretaker and the patient and laying inside an enclosed compartment. This is not ideal for the patient. 2/10
Viability			
Innovativeness	An innovative technology and idea. However, it is not so feasible yet.	Less innovative that (1) but, more achievable	Not seen yet in the MRI industry.
Low risk	When considering the safety and implementing electronics safety design, the idea is at low risk.	Moderate risk when no safety in electronics is applied. Or when liquids reach the electronics in the blanket. However, this must be prevented prior to use.	Least risk.
Future perspective	**5/10**	**5/10**	**5/10**
Overall			

Develop

Background research to define product requirements

H. Conceptualization

Objective: A multidisciplinary brainstorm session has been performed with design students, medical students, mechanical students, and healthcare professionals to ideate on the challenges defined for the subfunctions. Creation of mutliple solutions for the challenges occuring in each part.

Methodology:
an online brainstorm session has been designed that allowed co-working and iteration of the individually derived ideas. How tops have been de leading methodologies to ideate whereafter a discussion per idea was performed.
Eventually the ideas have been clustered and analysed.

Methodology:
Through a brainstorm session with 10 design students, mechanical engineering students, clinical technologist and nurses various ideas have been developed.
The brainstorm session was a combination of the 5-method, how can you and brainwriting,

Result
Ideation for each of the subcomponents has led to morphological charts that have been the foundation to the development of all components.

Main functions
Possibilities of a different product architecture have been researched; however, the technology requires several features to be present and thus the system is fixed with the

- The insertion of the patient's head inside the bore

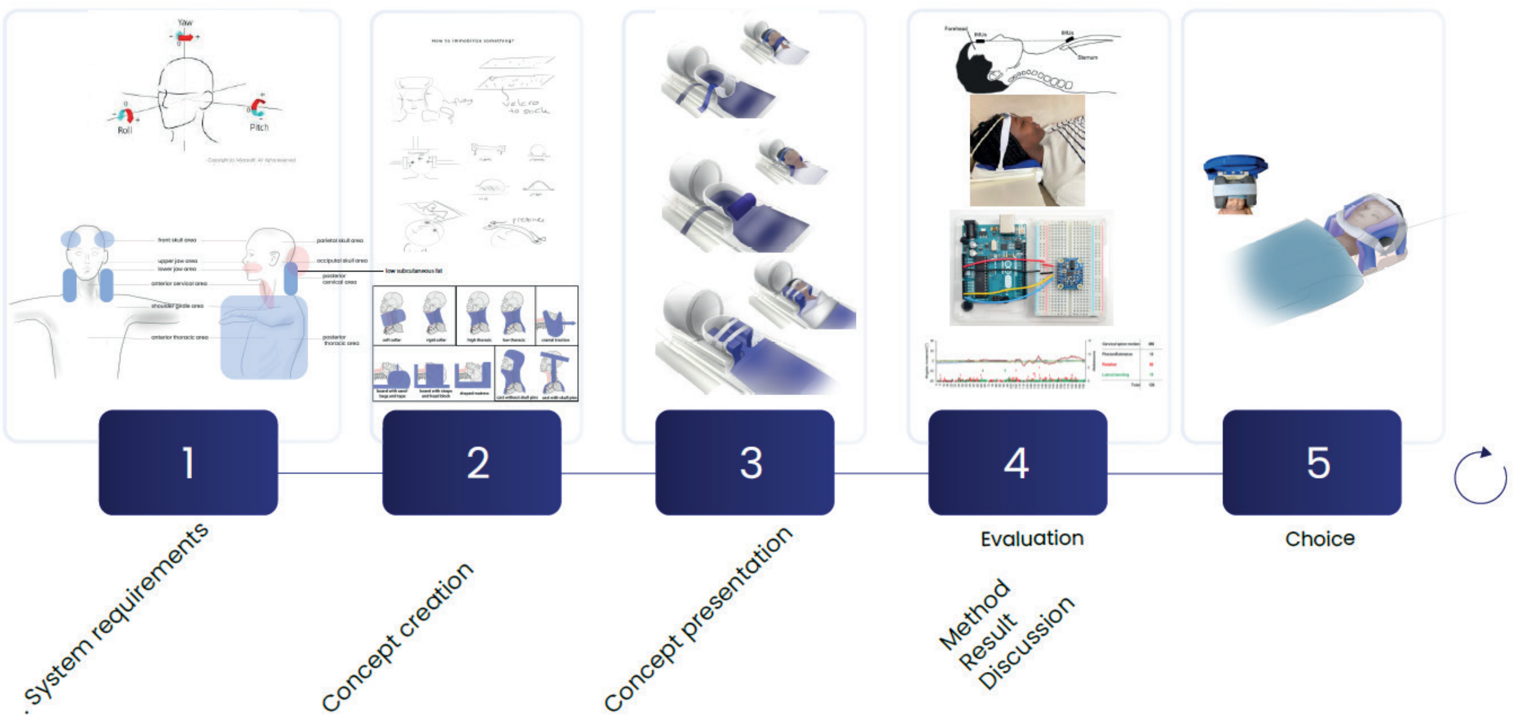
The design challenges - Translated into sub-functions

1. Provide a bed system for children of 30 cm - 1 meter
2. Provide a modular coil for different head size
3. Provide a trustworthy look for the MRI scanner
4. Facilitate easy repair/ replacement
5. Provide monitoring for vital signs
6. Facilitate interaction between mother and patient
7. Facilitate interaction between patient and MRI tech
8. Facilitate interaction between doctor and imaging
9. Accessible positioning of electronics
10. Maximize physical comfort
11. Minimize psychological stress
12. To Provide visual feedback (time/mother)
13. To provide a versatile combination of what the device could look like or what it would possibly be, the challenges have been a source for ideation and different solutions have been selected to be used as input for the morphological chart.

I. Concept methodology

Concept design methodology
The design methodology for the defining of the concepts have been based on gathering knowledge, create restrictions, brainstorm, and design with different perspectives (students and experts), create, test, and iterate

During the concept development phase, the concept has been developed based on
1. Dimensional concept
2. functional concept
3. Usability concept
4. Concept taken manufacturability and materialization into account
5. Fully integrated concept

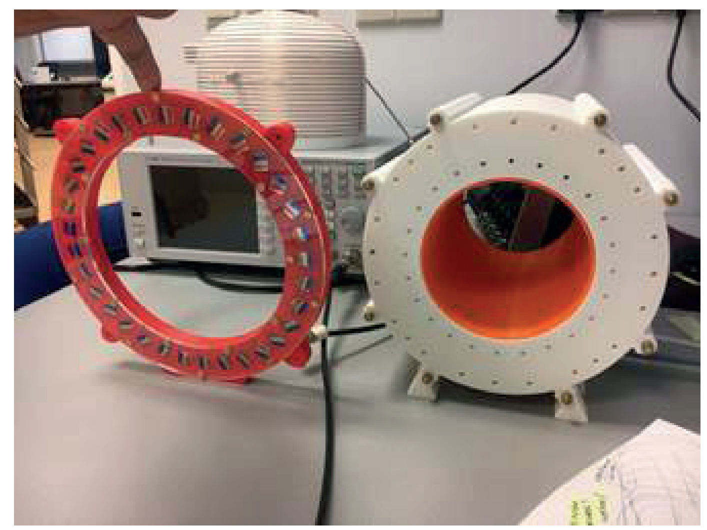


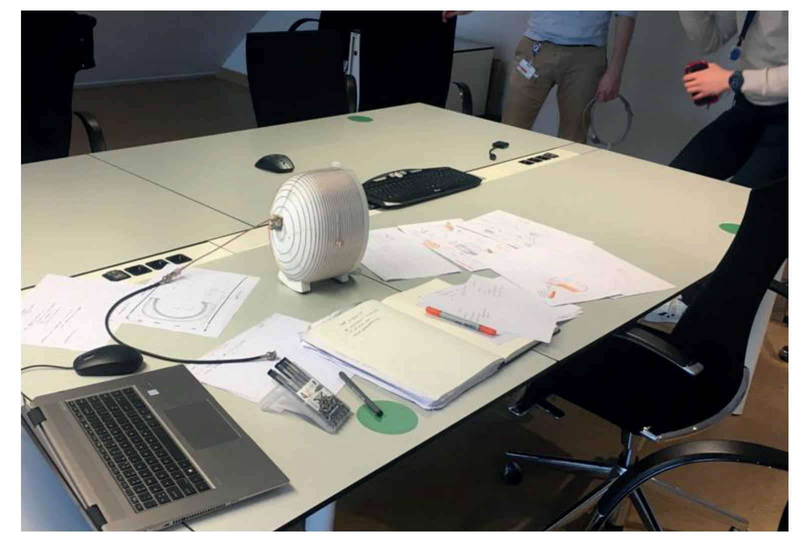
I2. Co-creation session

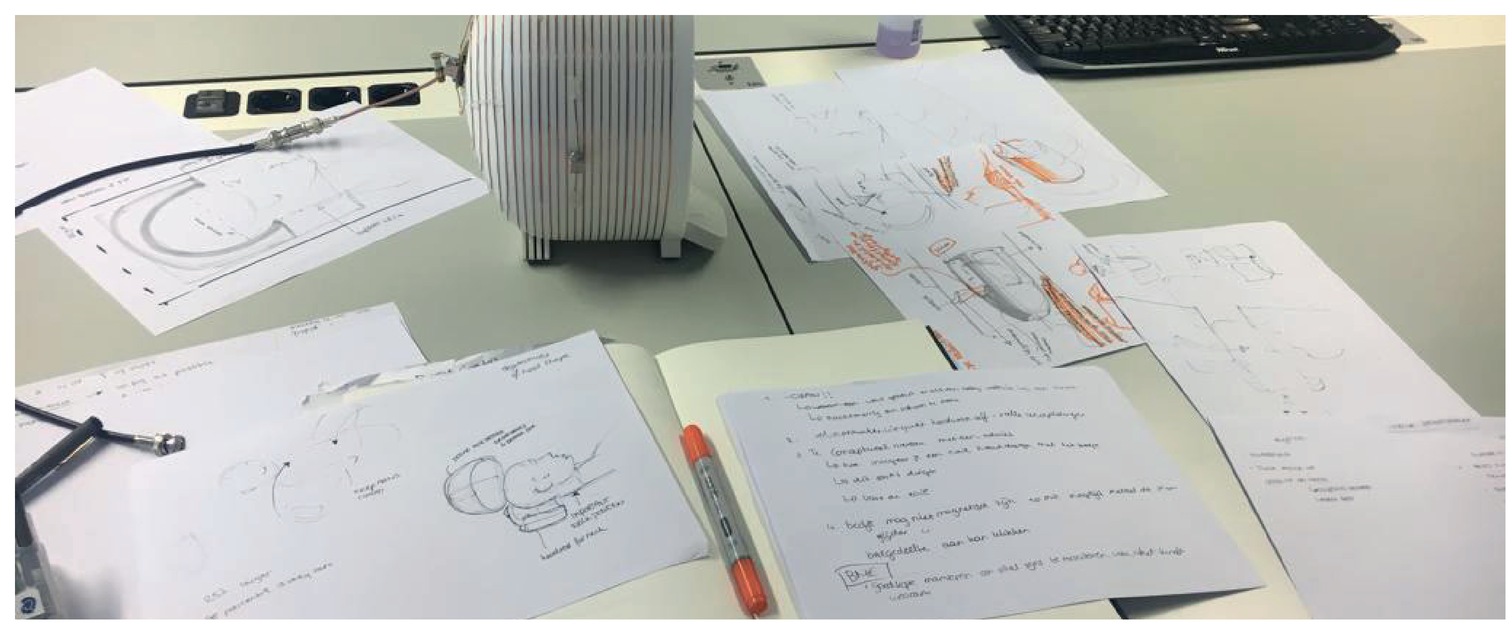
Objective :
The co-creation session has been the start of the development phase. The objective of the co-creation session has been to dive more into detail on potential solutions for the technical sub-problems.
Co-creation sessions have been organized with the technical team,

Methodology
Due to the social distancing rules, and covid measurements limitations were present in the movement freedom of the co-creation session.
Provided were a presentation about the technical challenges, and an interactive Solidworks model on a touch board screen which could be moved and adjusted.
Furthermore, drawing utilities (paper, marker, and mock-up) have been provided on the table to tackle each technical problem and to provide a discussion.

Result
This resulted in the different concept direction for the design of the low field MRI scanner.







I.3 Concept review

Concept review 3.
A cocnept review was done with the technical team of the LUMC inorder to have a critical perspective on the feasibility of the concept.

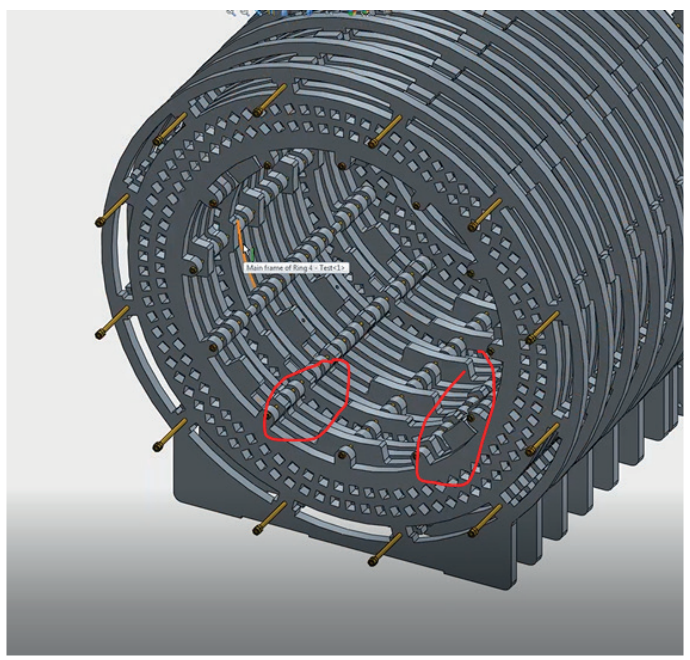
Concept choice

Hard requirement: Use minimal space of the guiding rail
A lot of effort has been made to make the bore as large as possible. So, if the concept leaves out 1 or 2 cm in (empty) space, this is not desired

Requirement: Deformation and relaxation
Over time the bridge will deform. This ensures that the position of the head will not always be the same, perhaps also during the measurement. The movement of the child will cause it to deform the head during the measurement.

Choice of concept 1. just a guiding rail over the bore
As few forces as possible on the magnet, but the only forces acting on the magnet are the weight of the main coil and the patient's head. This is manageable.

Design
Decrease force load on bore

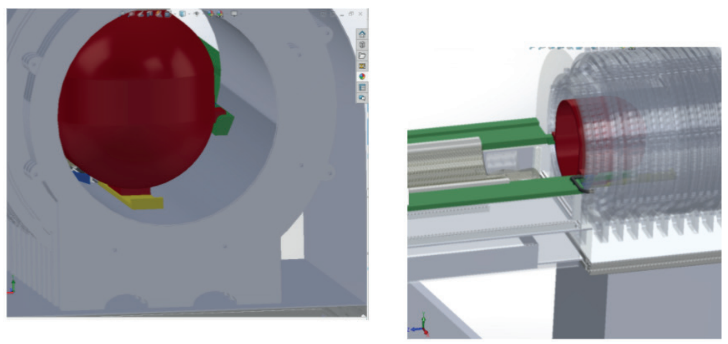


Furthermore, extra efforts have been made inside the design of the magnet to transfer the forces acting on the magnets to make it as minimal as possible
The green element

Will also reduce the force acting on the bore, because the force is lifted by the green element.

Green element
-Reduces rotation in X and Y-axis, but also makes sure that the

Rail & force on magnet - option 1

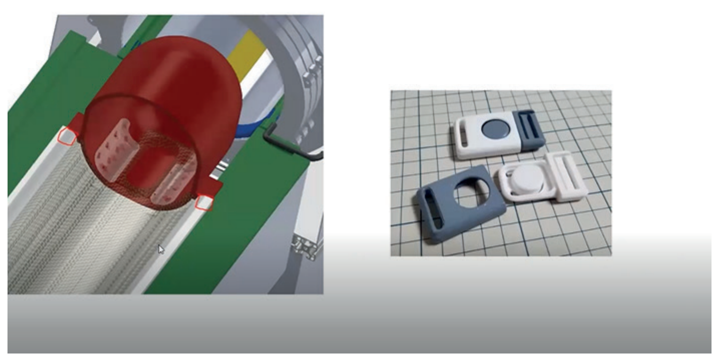


head coil remains stable and can slide along one single surface.
- Makes sure to reduce the force acting on the magnet

The connection between head coil and bed

Attach head coil with bed system when the MRI technician is done with positioning child in bed. Once this is done the bed can be slid inside the bore and out the bore with a fixed connection. Once the scanning is done, the connection can be released by only pressing on the button.

Bed & connection on headcoil



This concept has the benefit of only needing two hands for attaching and releasing.

The head coil
The head coil is 3D printed and has a lot of form design freedom. An integrated buckle system can be integrated.

Thermoforming
- Method is known and widely used in the LMIC
- Materials have the good mechanical properties
, les form freedom

Wire Connection
it must all be earthed for safety

Head coil - plug-in housing - electronics

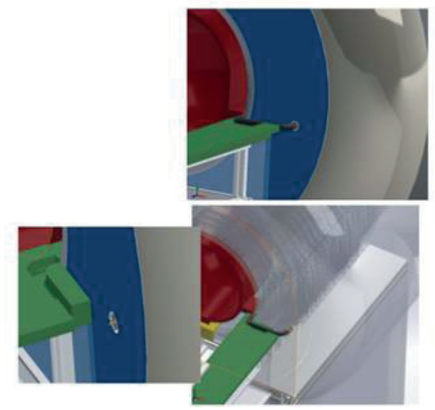
Connection

wires:

Headcoil to housing

Bed to housing

blanket to housing



The head coil is attached by a wire and plugged inside of the magnet housing. This relates to the electronics situated in the 19" rack.

Bed to housing
And blanket to housing
It must be connected to the same contact point as the head coil. inside the housing.
The wire framework attached to the thermoformed mattress has contact with the aluminium framework. This has the benefit that the current can go through aluminium framework and
However this must be tested, since it is possible that the framework will have too much resistance.

Housing Requirements
- Impact resistance
- Durability after disinfection
- Manufacturability

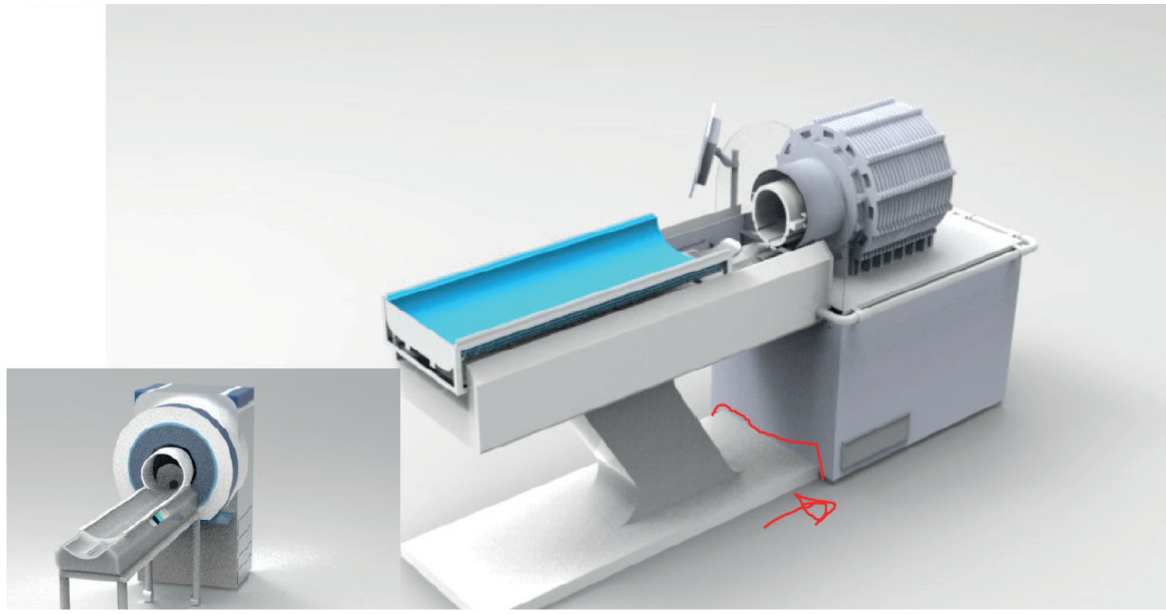
Challenge: once the bed is slide inside the bore. There will be an opening of 30 cm before the bed. It is not beneficial that the opening remains open due to the red dust that will accumulate in the sliding mechanism. This must be closed off.

Elastic material
More layers that move and slide over each other.

Next step
-Once the bed is slid inside the bore. there must be a lock to

prevent unexpected movement during the scanning. A locking system can be also done by a ball pin that falls in a hole/ use gravity

Concept review #4.



1. Bed fixed or detached (full system)

The connection between both systems must be simple and stupid. You need to make sure that if you alight both systems, that the system is aligned and fixed in the x/y direction.
You cannot assume the floor is completely straight. -- For now, we should assume that the floor is completely straight.

2. Bed alignment (full system) - This system needs to be as stable as possible
The bed and magnet could be attached or not attached. There are different reasons why they would detach the magnet and the bore
1. For a mobile system,
2. For a system with high magnetization that needs a safety procedure where the patient can be reanimated directly in the bed while moving the bed out of the room
3. When you cannot go around the bed so easily (your space of freedom is restricted)

Disadvantages
• Any movement on the x / y plane is translated to the magnet. This is highly not recommended as it could disturb the imaging.
•
•
So therefore, it is highly recommended that the bed is fixed.

For making the bed fixed to the magnet this has some advantages
1. This is advantageous when the MRI technician can walk around the bed freely

• The bed only needs to be "docked" into the magnet frame during the installation and not after the installation anymore.
• The movement from the MRI technician or the mother around the bed will not be translated to the magnet or the alignment

the disadvantages are that there will need to be a connection system between the
- Conductive blanket and the magnet
- The head coil and the bed
- and the bed frame and the bed

The two-bed system can be fixed with a latch

The magnet and bed can be aligned with guide pins that stick in the bed once it is put in the correct position.

3. Bed stiffness (bed framework/ full system t.o.v. magnet)

requirement
You don't want to put any force on the magnet

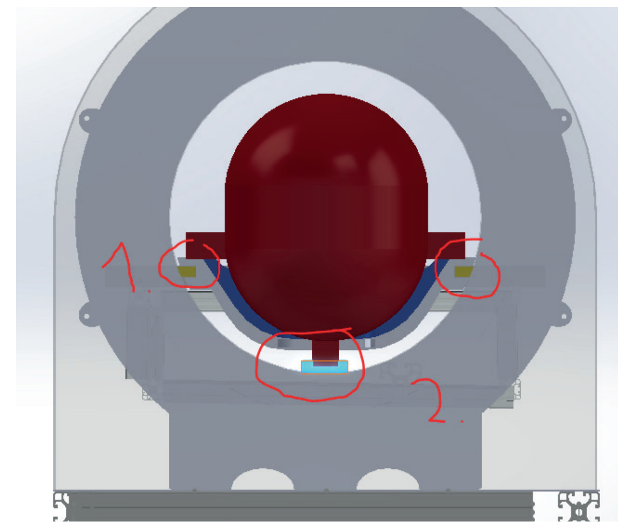
The weight of 16 kg + a water head must be able to be supported on the rails

Once the bed is slid into the magnet and there is a weight in the bed, the forces acted on the guides and rails need to be very stiff. so, it does not bend.
When the bed and the magnet are often detached this problem occurs frequently, while when the bed is not detached. the fixation can be made as sturdy as possible.

4. Head coil fixed on the bed
The head coil is the component that is most prone to break. This head coil needs to be attached to the magnet. so, the setup of the head coil must be very rigid.

Now the head coil is resting on the pieces on the bore. This is not needed of the head coil is positioned on the bed, this prevents any force to be transferred inside the bore to the magnet.

Fixing the coil on the x axis by :
Fixing the coil on the y- axis by :
Fixing the coil on the z- axis by



Preventing the bed to rotate by.

Find a way to fix the head coil on the bed and slide the bed as a whole system inside the coil.

Important is
- There needs to be an electrical connection between the head coil and the magnet.
This can be done with a groove in the table to position the electrical cable.
Through the groove the cable can be kept in place as the cable is the most fragile part.
This must not move too much.
• in This way the head coil can also be replaced easily

5. Material for the bed framework
Requirements
• Easy to clean
• Stiff enough for the patients to be put on (how much weight(incl. head size))
• non-metallic for inside the bore
• metallic must be sealed/covered to prevent current to pass through the body

Why not metallic
- for safety reasons this can be

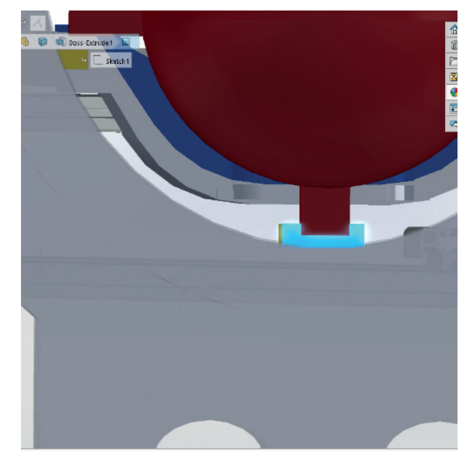
6. Sliding system bed into the bore
The bed is sliding into the bore on a rail system. Now the rail is sliding on a "U" form

It would be better to prevent the rails sliding on a U form due to the risk of someone bumping on the bed and this force in x-y plane guiding all the way to the magnet. Any force on the magnet is not wanted. so, it is best to make this just a flat plane where the head coil and bed can slide on.

It is best to remove the sides and let the head coil (red) just slide on the device

Slide
+ For cleaning this could be a good option, because you will just wipe it off.
- You will need a very sturdy connection between head coil and bed

Wheels
+ slide very easily
+ not necessarily need metallic parts
- red Ugandan dust will not be easily cleanable on wheels
- Wear easily and wear out



7. Bed electronics detachment

6. Bed cleaning
Make sure that if there is spillage of fluid, that it absolutely does not get in the holes
The filling absolutely does not get in the magnet
Make sure what it does
What material

7. Bed material
mattress
Bed is the most consumable part
-So it requires to be able to be replaceable easily
Approximately 2000 kids per year will be scanned, which is around 10 scans a day minimal. So, this part must be easy to replace as possible.

From a foam like material

Foam
And as cheap as possible. It needs to be done with a foam like material and a sheet from pvc.

Fluids and 10 scans a day.
If some kid pees of vomit this needs to be incorporated. as well.
The it out and

Mattress cover with sheet polyethylene- PU _ - PVC the function of this is to keep all the fluids
Thinking of fluids coming in places where it must not go.
Make sure that if there are fluids, or when a kid pees, that the thing can be built.

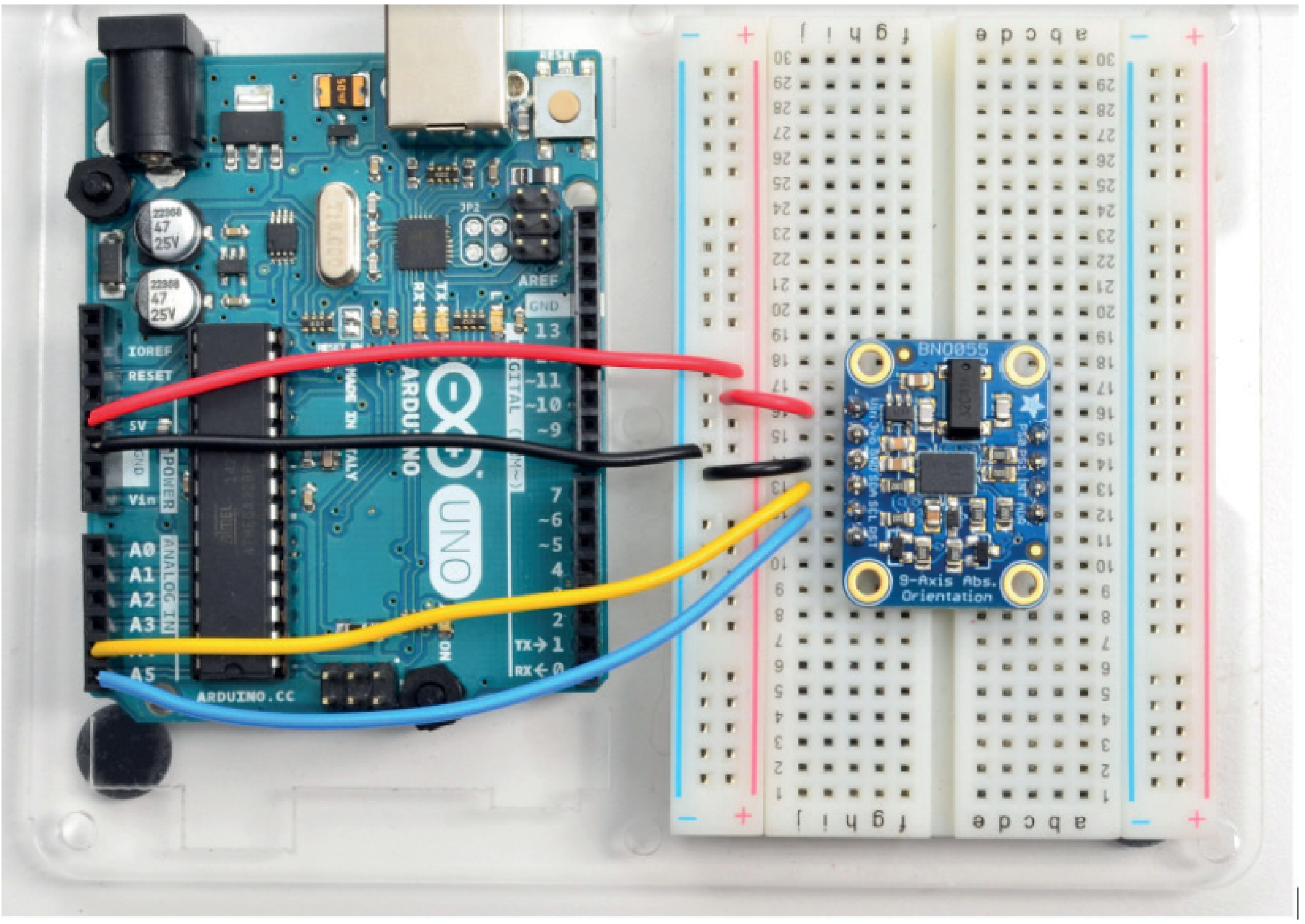
Mattress Needs stiffness - solution - foam

We need to see what is easy to get

8. Bed manufacturability

Bed frame
Requirements: Metallic bits on the frame need to be covered
Safety - for the safety the subject cannot make an electrical connection
aluminium must be covered (If the patient also gets monitored with ECG, the patient will make a circuit with the blanket and the rest of the apparatus, which will allow the product to be

I.4 Immobilisation experiment apparatus



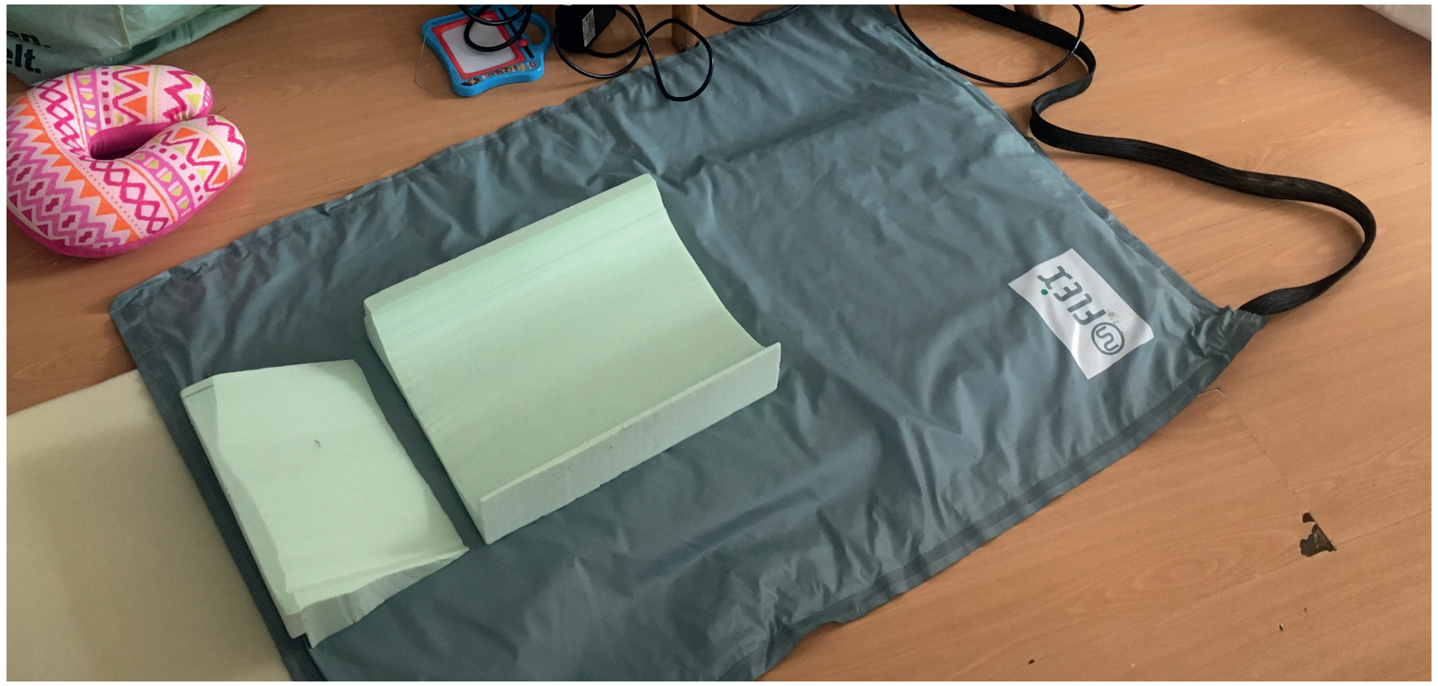
Materials and methods

Apparatus
The apparatus is a accelerometer and gyroscope ADAfruits BNO055 , which is a wired absolute orientation sensor with 9DOF, able to detect the 3D orientation in space. It includes a accelerometer, gyroscope and magnetometer for the needed accuracy. THe sensor is attached to an arduino uno, which is connected to the code on the the laptop.

The BNO055 can output the following sensor data:

Absolute Orientation (Euler Vector, 100Hz)
Three axis orientation data based on a 360° sphere
Absolute Orientation (Quaterion, 100Hz)
Four point quaternion output for more accurate data manipulation
Angular Velocity Vector (100Hz)
Three axis of 'rotation speed' in rad/s
Acceleration Vector (100Hz)
Three axis of acceleration (gravity + linear motion) in m/s^2
Magnetic Field Strength Vector (20Hz)
Three axis of magnetic field sensing in micro Tesla (uT)
Linear Acceleration Vector (100Hz)
Three axis of linear acceleration data (acceleration minus gravity) in m/s^2
Gravity Vector (100Hz)
Three axis of gravitational acceleration (minus any movement) in m/s^2
Temperature (1Hz)
Ambient temperature in degrees celsius

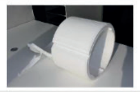
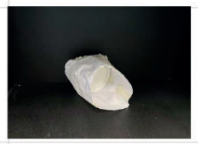
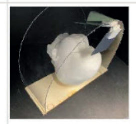
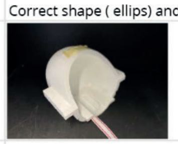
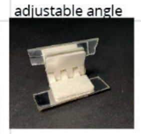
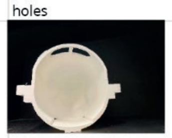
I.5 Comfort experiment apparatus



J: Prototype developing overview map

As can be seen in table "Concept design iterations map", the multiple improvements were made in Solidworks and prototyped solely prior to the integration of all the parts.

Concept design Itterations map

Itterations	Dimensional desing	Matress holder	Head coil design	Headrest	Head immobilizer	Mirror	Conductive blanket
Start point (original design)		Not present			Not present	Not present	
Start point (original design)	Dimensions were not correct	Not present	Open RF coil is not functional, not correct dimension, not according technological requirements	Large cup shape, not convenient for egher large or small heads	Not present	Not present	Off-shelf conductive blanket, very expensive and attached with tape. No air flow
Dimensional design							
							
	+ Good height and dimension for the headrest - (Too large bed, cannot enter inside bore)	+ Correct shape, (-) too large dimension	Paper mockup model Correct circumference	Shape too small for the largest dimension headcoil, edges will hurt in head	Double strapped immobilizer with head blocks	Patient inside double mirror, concept check and validation. Mirror too big	Integrated conductive blanket that is integrated in swaddle blanket. With good airflow and use
Functional design							
	Correct dimensional height, framework from aluminum, tabletop not good materials yet	+ Correct dimension and shape. - Not correct material yet	Correct shape (ellips) and guidin	Wide enough for largest headcircumference, but too large for smallest head. Shape should only support the	Single strapped immobilizer with sot cushion which exert pressure on head	Double mirror clamp. Fixed angle, should be adjustable angle	
							
Usability design	*Correct material, height, dimension, configuration and usability*		Headcoil shape correct, but should be over eyes for wired coils	Correct head rest shape and dimension, prevent pressure on occiput area	Topology optimized rigid head immobilizer in size small and large	Double mirror adjustable clamp (-) the mirror edges should be covered for safety	
							
			Head coil correct shape with eye holes	Minimal headrest sliding inside headcoil, fits in largest headcoil and smallest headcoil	Final shape/base of immobilizer after pressure experiement. Correct shape. Add cushions	Adjustable double mirror with cover over mirror area and mount to attach on the bore	
Manufacturing design							
		+ Correct dimension and shape. - Not correct material yet	Head coil correct shape for head with eye holes and positioning guides for the coil	Headrest integrated with immobilizer	Correct immobilization devices Strapps to immobilize		
							
Final prototype					User friendly off the shelf straps		

L. Dimensionnel design

Objective: To define the minimum and maximum dimension of the entire system and the most crucial parts.= (head coil and headrest)

System dimensions

The system dimensions are based on the height of the MRI technicians, their reach width, and the minimal height of the critical components (the magnet). The MRI technician must be able to reach the bed and work on it. The magnet will be placed on top of the electronics. Since the electronics will be placed inside off-the-shelf cabins, they determine the height of the other components.

angle (°)	comfortable n	comfortable σ	comfortable P5	comfortable $\bar{x}$	comfortable p95	maximum n	maximum σ	maximum P5	maximum $\bar{x}$	maximum P95
90						49	6	194	204	214
75	34	6	181	191	202	60	8	188	204	216
60	49	11	129	147	164	60	9	164	184	198
45						60	11	125	149	165
30						53	12	89	110	128
15						27	13	53	73	91

All values shown in the table below were measured from the *heel* at the specified angle. All values are in *cm*.

Horizontal Distance (x): 68 cm

Vertical Distance (y): 161,5 cm

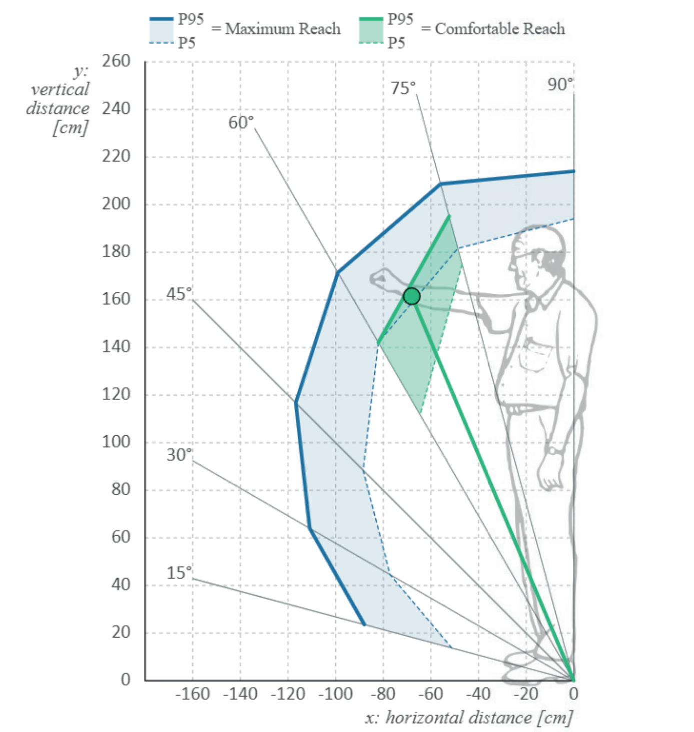
Distance from Heel (r): 175.2 cm

Height of bed

The function of the Bed is to

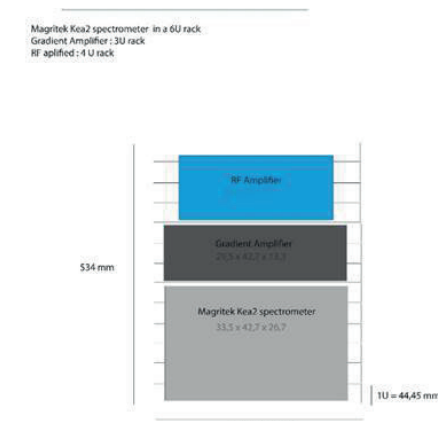
- Keep the patient comfortable in the bed
- Support the body of the patient
- Keep the body of the child still
- The bed must allow the head of the patient to be concentrically aligned in the centre of the bore
- slide inside the bore with ease of (20 kg) on the bed
- stop on the correct alignment

The challenges that are encountered within this are that the MRI technician must keep the patient still. The MRI technician must align the bed of the patient easily without a lot of gestures. Furthermore, there is not much space inside the bore for the correct alignment of the patient.



Main product layout
based on the P50 of woman so they can bend over the bed.
The reach of P50 of woman is 791 mm

Electronics
The RF Amplifier, manufactured by DEMO Delft (335 X 427 X 267mm) fits exactly in a 6U rack. https://uk.farnell.com/schroff/24563-444/subrack-shielded-6u-360mm-84hp/dp/1455807
The Gradient Amplifier fits exactly in a 3U rack (295 X 427 X 133) https://uk.farnell.com/schroff/24563-133/subrack-3u-295mm-84hp/dp/1455788



Dimension of head coil

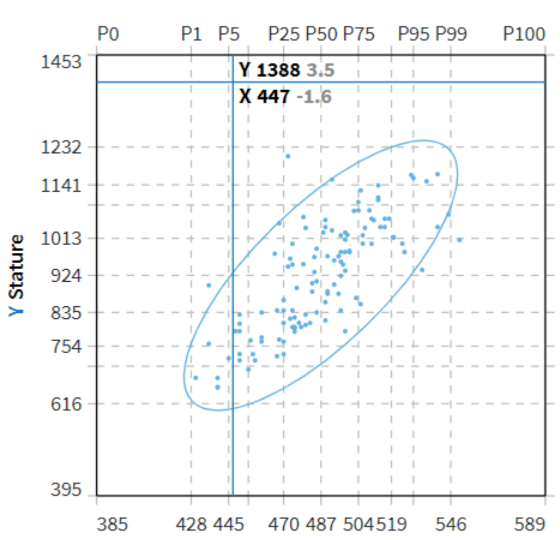
The function of the head coil is
- Embody the coils
- The centre of the RF coil needs to be positioned in the centre of the bore
- Be detached for other sizes coil
- Allow the patient to see the caretaker
- slide inside the bore without "schranken"
- The centre of the patient's head needs to be positioned in the centre of the RF coil
- Immobilize the head
- Support the neck
- Allow for the MRI technician to slide the head coil over the head easily.

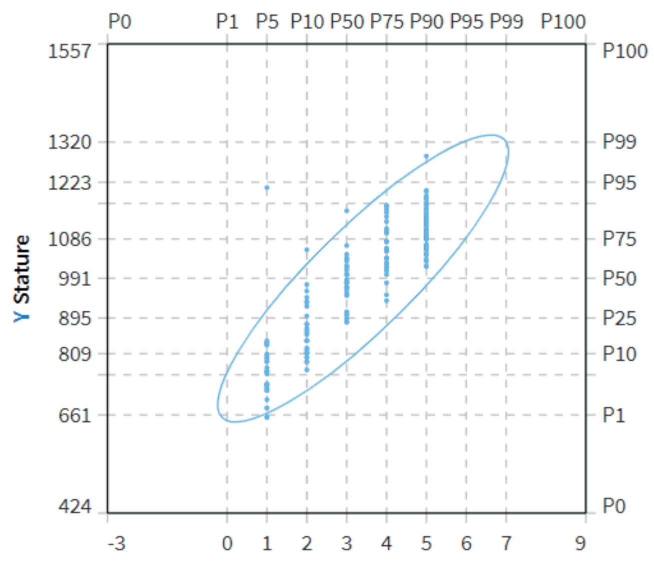
The challenge with this is that the bore is 290mm and a maximum size of the head with hydrocephalus can have a maximum 65 cm diameter (207mm) (average 55 cm = 175mm) which leaves only (290-207)/2= 41,5 mm on both side of the head. This is not much space for the MRI technician to place the bore, but also not much space for the mirrors to be placed.

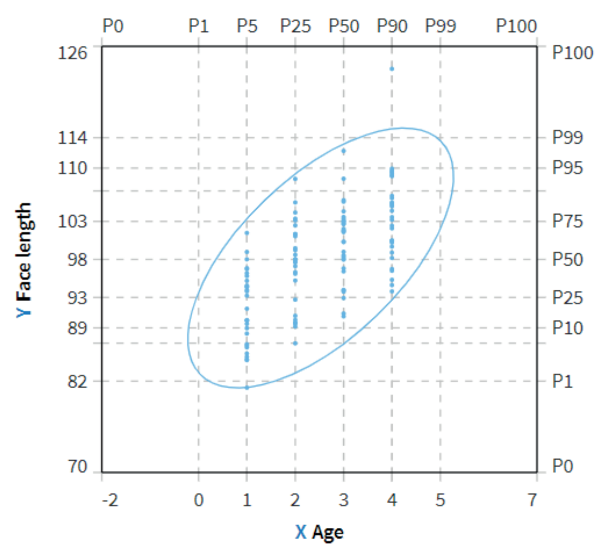
Head coil
Head circumference
The maximum head circumference of children with hydrocephalus that has occurred in the CURE hospital is 65cm circumference P99. The P5 is 50 cm and P95 is 60 cm(20 cm head circumference). The mean head circumference of the head is 55cm.

Age 1-2 mean: 70 cm
Age 2-3 mean : 81 cm
age 3-4 mean : 91 cm
age 4-5 mean: 103 cm
age 5 up : 110 cm
Sd = 5 cm per age

Headsize
DINED







Category	Age	P (min)	P (max)	Mean	Sd	Needed for
Head breadth	1-2 mixed	P25 (127 mm)	134 P75			breadth of head coil
Head depth	1-2 mixed			470 mm	20 mm	Length of head coil

Head size :
The head diameter of a child with hydrocephalus can be up to 204 mm (P95) the average size is around 170,5mm. The bore has a diameter of 292 mm, so not much space is left inside of the bore. The surrounding space left will be 4 cm on each side of the thread with the larges head circumference.

5different head coils
There is a discrepancy of 10 cm between the minimum and maximum size.

I will design for the mean head size of 55 cm.
Face length 123 cm for a head circumference of 55 cm

M. Component Design

Appendix M consists of the concept design of all the components.
The following parts have been designed parallel.
1. Body Mattress
2. Head coil
3. Head Immobilizer
4.Head rest
5. Mirror
6. Blanket

M.1 Body Mattress

The body mattress was a result of literature research, pressure matt experiments, optimization through prototypes.
2. Requirements

The position of the bed has relation to the shape ,while the comfort of the mattress is more related to the hardness of the mattress and the provided supports.

Due to the dimensional restrictions of the bed that needs to enter the bore, the bed is already restricted in its width, length, and slight concave shape.

Once the patient is positioned supine, the safest method is to provide constant surveillance.
The respiratory of the patient is more at risk than in upright position due to the shift of the diaphragm cephalad, which is compressing the adjacent lung tissue. This leads to a decrease in the functional residual capacity and in a sedated situation even more. Therefore, a proper positioning of the head and neck is required by resting the head of a low-profile circular headrest, which is slightly more inclined than the shoulders.

Requirement	Rationale	Source	note	Technical requirements
Posture				
The head must be positioned slightly inclined				The head must be positioned in an angle of 15 degrees
The headrest must have a surface area where the occipital area will not	The occiput area is the most area which is the most prone to experience pain due to the small surface area and large force exerted on this area.	Roaf R. (1976) The Causation and Prevention of Bed Sores. In: Kenedi R.M., Cowden J.M. (eds) Bed Sore Biomechanics. Strathclyde Bioengineering Seminars. Palgrave, London. https://doi.org/10.1007/978-1-349-02492-6_2	Solution could increase the surface area or reduce the force excreted on this area	No pressure above 32 mmHg must be measured on the body of the patient.
The patient must be able to be positioned supine on the mattress	The head will enter the head coil in a supine position			The mattress must allow the patient to lay in a correct posture in a supine position.
The patient must lay in a comfortable position		Kamp et al 2011		Head against the headrest, Trunk slumped and uncrossed feet

Requirement	Rationale	Source	note	Technical requirements
Mattress characteristics				
Head must be rested on a "donut" headrest	The donut headrest facilitates that there is no pressure on the occipital area of the head, which removes the stress and pressure on the most critical area.	Experiment derived that concept 2 was best for the head area		The headrest must have a donut shape to prevent pressure on the occiput area.
The body must lay on a slight concave area	Increase of surface area that interfaces with the mattress, which distributes the pressure.	Experiment concluded that concept 3 was best for the body area.		The mattress must have a concave shape for the body to lay on it.
Neck support is required	A neck support is required to elevate the shoulders and support the eight if the head	Experiment concluded that concept 2 was best for the pressure distribution of the head and neck		A neck support is required.
The mattress must be able to hold children with hydrocephalus up to 4 years old	The maximum shoulder width that can enter the bore is 28 cm, this is a child of 4 years old.	(DINED,2007)		The mattress must be at least 1.20 m by 30 cm
The bed must be able to be slide inside the bore	The head must enter the bore and exit once imaging has been provided.	Patient Journey Map		The mattress must be put on a hard material that holds the concave shape and is attached to the sliding mechanism
The mattress framework should allow the slider to be attached	The mattress framework will slide through the slider inside the bore	Patient Journey Map		The slides must be integrated and fixated in the framework
The bed must be fixated on the head coil once slid inside	Movement of the head coil during the procedure must be prevented	Patient Journey Map		The bed must be fixated on the head coil once slid inside
The bed must be able to be unfixed from the head coil with one gesture		Patient Journey Map		The bed must be able to be unfixed from the head coil with one gesture

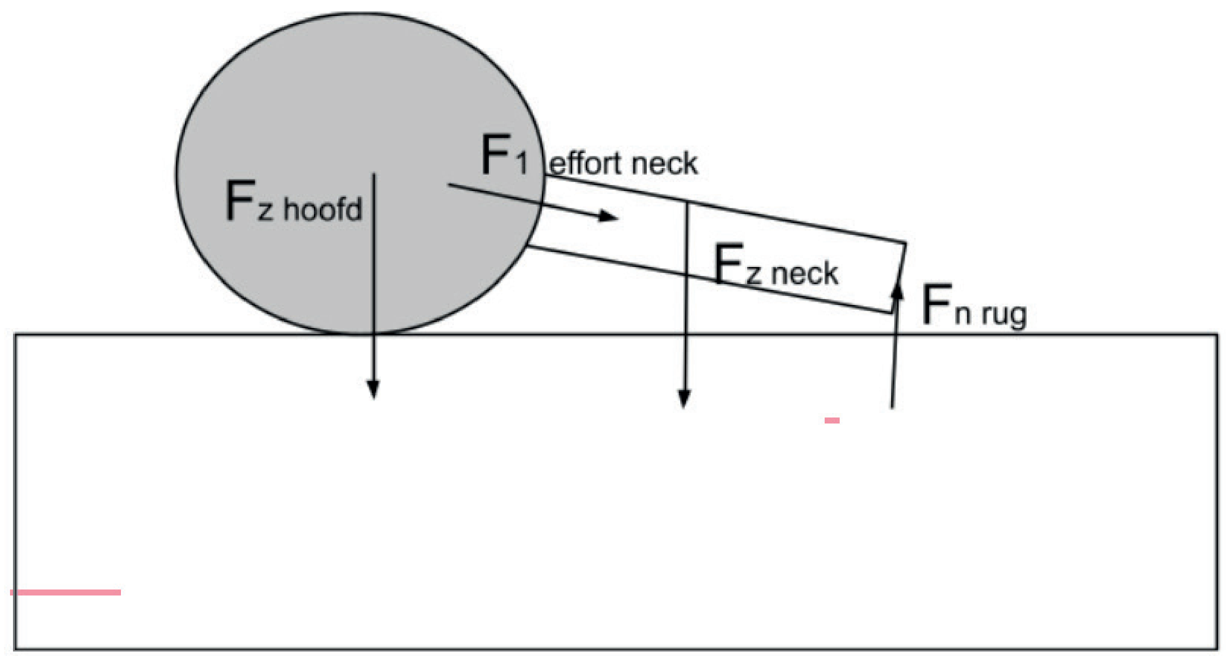
M.2 Mattress holder and Headrest

The headrest is part of the Mattress holder. Due to the importance of the support of the head of the patient, the headrest has been looked specifically into.

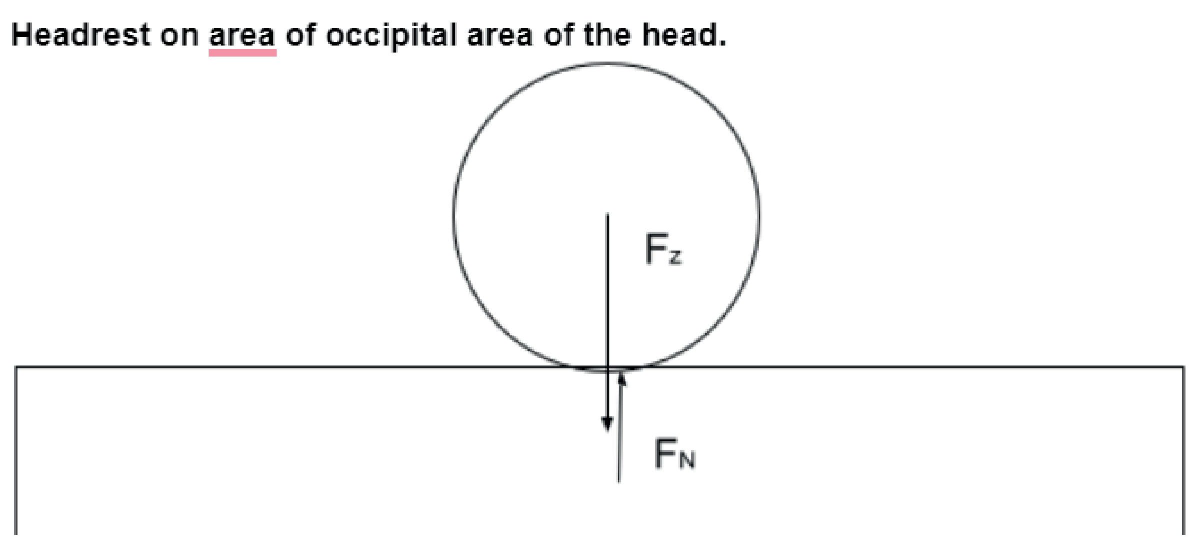
It is known that children acquire pressure ulcers in different locations than do adults; thus, they need a support surface that reduces pressure where they most need it, at the occiput. A child's head is much larger in proportion to the rest of his or her body surface area, which places the occipital region at risk for skin breakdown.

Requirement	Rationale	Source	note	Technical requirements
Human factors				
The cranial side must not be put pressure on	In areas with low subcutaneous fat that nerves are close to the skin. Pressure for a certain amount of time can cause a tense pain. Additionally, the children with hydrocephalus have a paper-thin skin, so this part of their body is more sensitive than others			The pressure on the occipital area of the head must be as evenly distributed as possible.
The neck area must be supported and support the head.	The head of a child can weight up to 4,5 -7 kg based on the severeness of the hydrocephalus. The neck muscle of a child that are responsible for the stabilization and support of the neck area are the sternocleidomastoid and the By six months the child will have strong enough muscles to support their head. However, this is the case with a healthy child. With children with hydrocephalus the muscles can only support a minimal amount of the .No studies have been done on the neck muscle effort of children with hydrocephalus.	Testing		The neck area must be supported.
The spine must have an as uniform pressure distribution as possible. The peak pressure must not be higher than 32 mmHg	Posture: In a supine position the children must be able to lay comfortably for 10 minutes The areas with the lowest subcutaneous fat are prone to have the occipital area in the head, the shoulder area, and the coccyx area. thirty-two mm Hg is often quoted as the ideal interface pressure for support surfaces to prevent pressure ulcers. This number was originally deter-mined in the late 19th century when Starling and other cardiovascular physiologists were develop-ing our understanding of the cardiovascular system dynamics.	Krouskop TA, Garber SL, Reddy NP,Noble PC. A synthesis of the factors that contribute to pressure sore formation. In: Ghista DG, Frankel HL, editors. Spinal cord injury medical engineering. Springfield: C.C.Thomas Publisher; 1986. p. 247-67		Pressure not higher than 32 mmHg
The mattress holder must hold the mattress in its concave shape	The round shape is the most volume efficient and stiff shape to enter the bore.	Experimental setup Components to be developed		The framework must hold the mattress in its concave shape

Headrest on area of occipital area of the head



Side view of head and neck



FBD of occiput area on headrest. The point N is exposed to all forces from Fz head.

Problem

- Since the average size of the head of the patient (55 cm) is as big as the head size of an adult, the weight of an adult's head size is considered (4,5-5Kg)
- This results in a Fz of approximately 50Newton on an area of 1 cm^2. This results in a pressure of 5 kPa (kilogram/ square cm). The threshold of an adult to feel pain is 1,25 kPa.

Pressure algometry has been shown to be a valid and reliable measurement of PPT in cranio-cervical muscles [1,2,3]. Pain perception studies in headache patients measuring muscle tenderness, including PPT, have found that the threshold for an adult to feel pain on the head is around 1,25 kPa.

- Therefore, it is important that the pressure distribution in this area is as uniform as possible.

Requirement :

- should have a pressure lower than 32 mmHg (for adults).

Working principles

The reduction of pressure on the occiput area can be done by

1. decreasing the pressure(force) felt on this area
2. increasing the surface area
3. Making the area feel soft

Solution direction

Head support

The use of a contoured head pillow surface increases the surface area on where the load of the head is positioned. Due to the sensitive skin a soft surface is introduced.

Neck area support

The muscles that are responsible for the stabilization of the head and neck area are the sternocleidomastoid, and other great and small neck muscles.

- Unilateral contraction produces lateral flexion of the neck on the same (ipsilateral) side and lateral rotation of the head to the opposite (contralateral) side.
- Bilateral contraction of the sternocleidomastoid muscles produces flexion of the neck, drawing the head towards the chest. When the head and neck are fixed, the sternocleidomastoid can also elevate the sternum and clavicle and thereby expand the thoracic cavity during forced inspiration.
- Deep cervical flexors. These muscles, also called the longus capitus and longus colli, are located along the front of the cervical spine and help stabilize the neck. When weakened, the deep cervical flexors lengthen as the chin tilts away from the neck, often called "chin poking."
- Erector spinae (lower cervical and upper thoracic).These are extensor muscles attached to the back of the lower cervical spine and upper thoracic spine. The erector spinae play a key role in rotating and straightening the spine. When the erector spinae muscles lengthen and lose strength, they are less capable of keeping the neck and upper back from hunching forward.

- Shoulder blade retractors. The middle trapezius and rhomboid muscles in the upper back help bring the scapulae (shoulder blades) backward to keep the shoulders back and chest open in

Spine support

Up to four years old the spine of an infant still has a C-shape. For and optimal posture of the child the C chape must be able to lay comfortably on the surface area. However, the bed can encompass children up to 3-4 years old depending on their shoulder width. The s-shaped spine is fully developed with healthy adults from 18 years old. The c-shaped spine develops in a s-shaped spine from 4 years old.

Therefore, it is important that the surface area on the back is as large as possible.

Concepts
Based on the support principles the following concepts with additional supports on an anatomical area have been designed

Concept	Head	Neck	Spine
0	Nothing	nothing	nothing
1	Donut head	support	normal mattress
2	Soft gel like material	soft support	tailbone support mattress
3	increase surface area (cap around head) / tiled area)	no support	soft mattress with c shape

Validation
Through an experiment with the concepts, the validation of the best combination of supports can be derived. The objective of the experiment is to define
1.Which support surface or combination of surfaces would provide the lowest interface pressures under the bony prominences of the children?

Result

Based on the experiment result, the best combination for the lowers pressure is as following.

Concept	Head	Neck	Spine
1	Donut head	neck support	standard crib mattress
2	Soft gel like material	soft material in the neck area	soft material
3	inlay on the sides/ tilted area		soft matters with c shape

The combination of those 3 elements provides the best combination for the patients to use

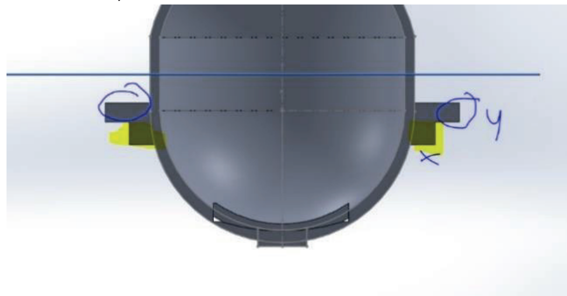
Final concept
Concave shape - spine
To increase the surface area of the spine on the surface a slightly concaved shape is introduced. This additionally allows the bed to slide into the round bore.

In a supine position, movement should be discouraged. By limiting the movement space by elevating the area around the body the movement of limbs of the child will be discouraged.
The concave surface would enable the baby to be positioned on its place.

In addition, elements that eliminate the neck rotation preference and direct pressure on the prominent side of the occipital are encouraged by elevating the coccyx part of the baby. A half round shape will promote the securing of the head.

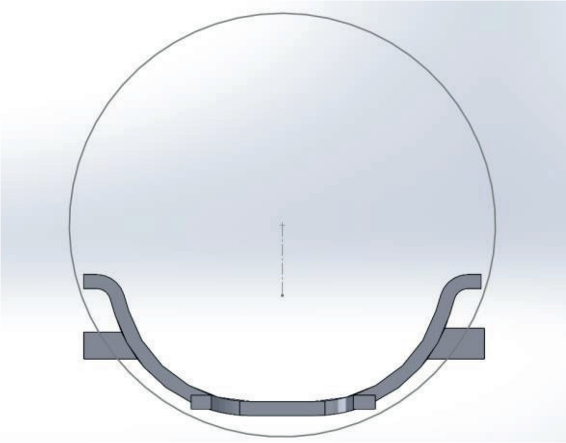
The chosen foam is dense enough to maintain its form under the weight of the infant yet is soft enough to remain comfortable during use. The infant's head rests in a concave space allowing without pain. The neck is supported in an anatomically correct
position by a semi-circular shape in the foam layers.

Headrest dimension
The maximum width of the headrest must be 110 mm.
The reason therefore is that the headrest is the part that remains the same despite the bigger head of diameter of the head coil. Since the head coil must be at as proximity of the head as possible, the sides must not be too big for a head of 50 cm.
Therefore, the headrest is based on the dimensions of the smallest head of 50 cm diameter

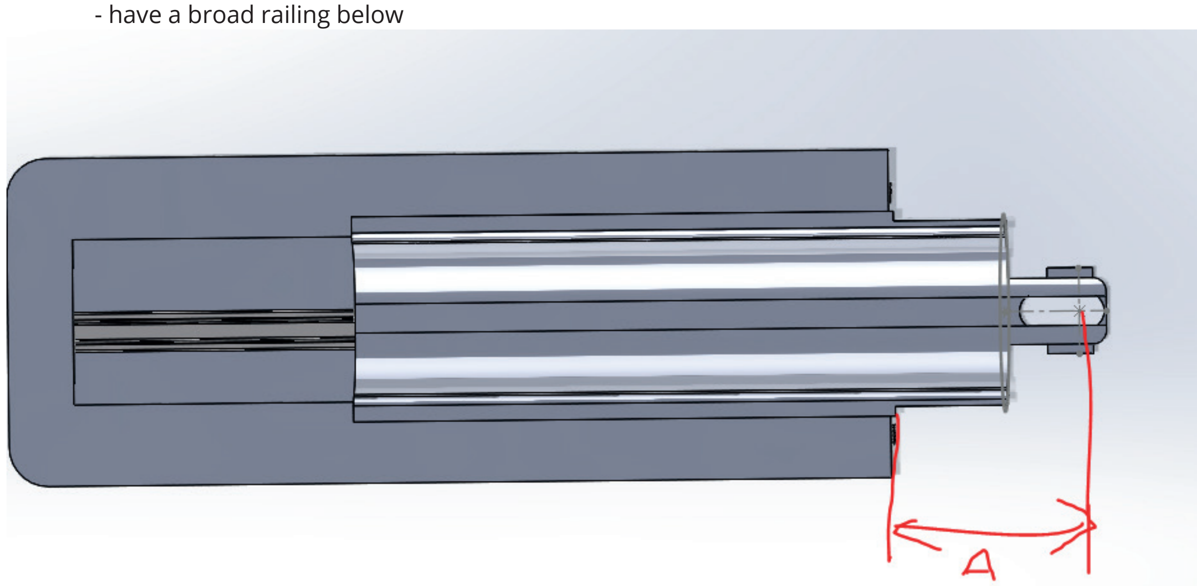


The sides are made 250 mm to be clamped between the tabletop for the x direction (yellow) and the top part for the y part

Mattress holder
Optimal shape to embody the children with the largest shoulders (larger range of target group, means more children can be scanned within 30 cm) with minimal space loss, which is most stiff and comfortable.



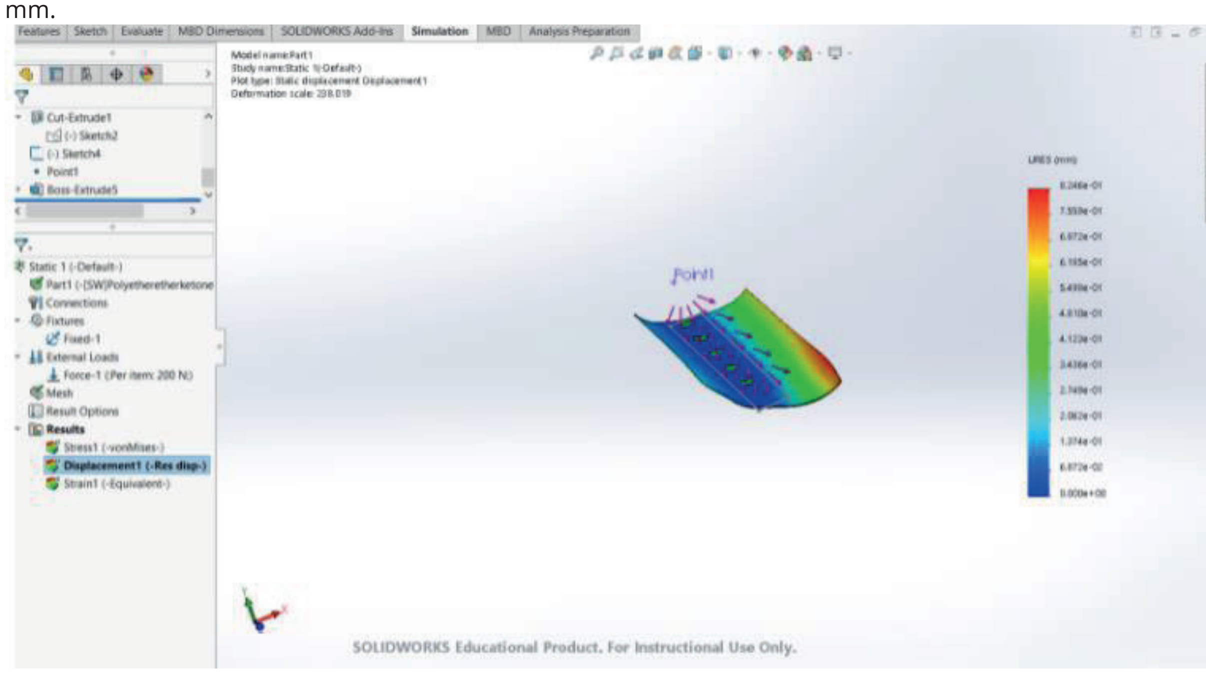
Round - use the space optimal inside the bore
flat part - lay optimal inside the brow with your back straight
- have a broad railing below



A is the distance between the middle of the head and the middle of the bore. This must be 25 cm for the MRI to be able to make a good image of the head.
Once the bed is positioned inside the bore, the additional 15mm work as a stop for the bed to be not inserted more inside.

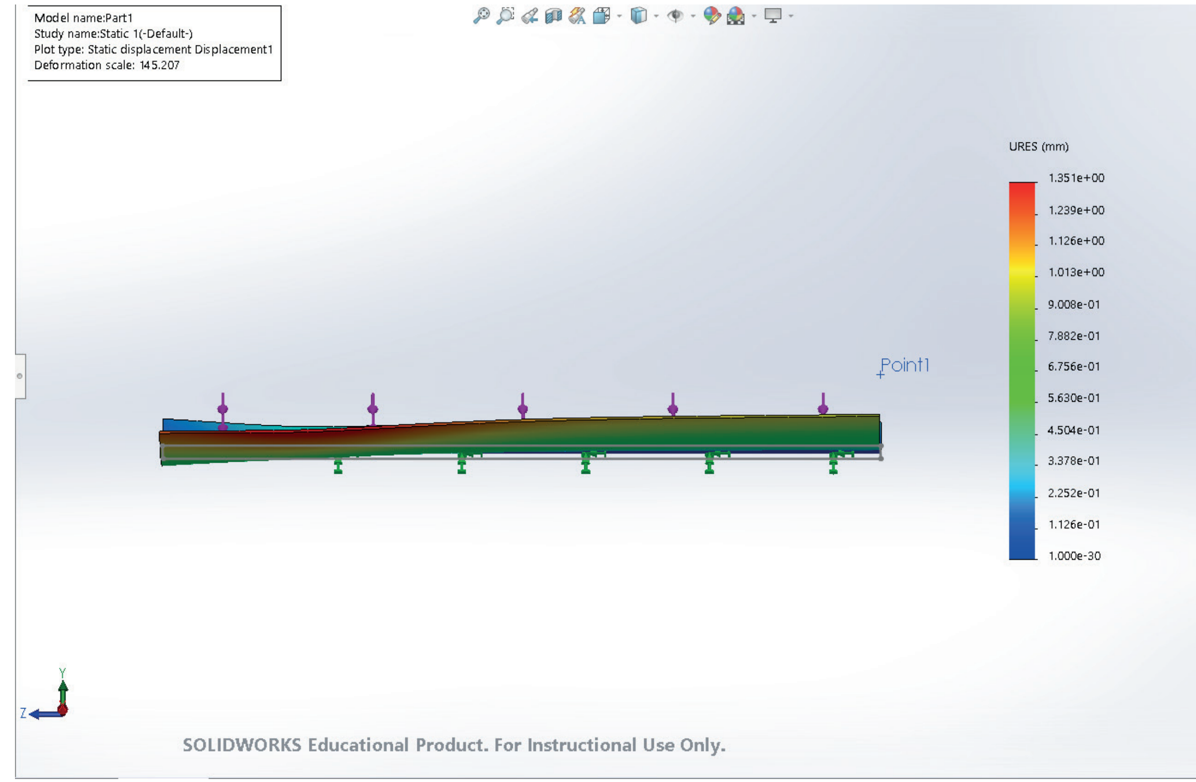
Forces acting on the mattress
Research question: Is the thermoformed holder stiff enough?
Method: Simple FEM analysis is done to assess whether the thermoformed mattress holder of 4mm will be stiff enough to hold the patient on the floating sliding railing system without too much deflection.

With a simplified model the deflection with PEEK and a material thickness of 4 mm will be maximum of 0,8 mm.



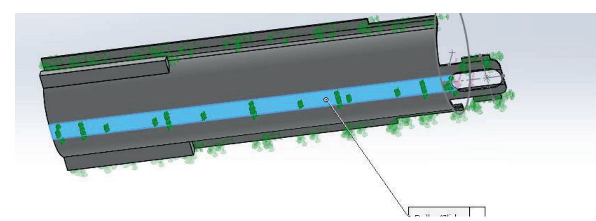
For the material ABS, which is suitable for thermoforming, the maximum deflection is

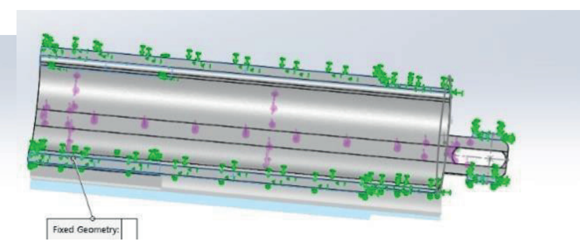
1.35 mm which is suitable.



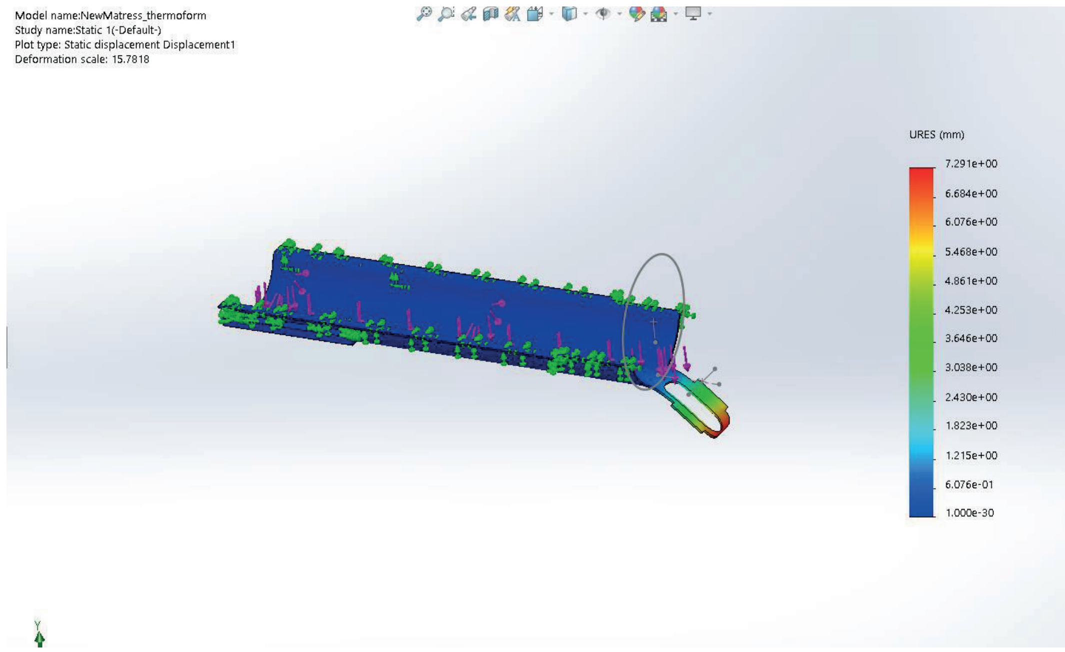
Both PEEK and ABS have an acceptable deflection. However, the mechanical characteristics and cost of PEEK prove to be more suitable for the purpose of the matress holder.

Bottom - held by roller slide system





it is fixed on the green points



As can be seen the maximum deflection of 7 mm will be at the top of the headrest. However, the headrest is held on its place by the head coil, which is rested on the tabletop. This allows the most fragile part of the system to be fixated without deflection.

M.3 Head coil

Coil close to subject
It is important for the coil to be as close to the patients head as possible to provide the best quality image. No active cooling for the gradient coils was used.

Size
Due to the broad discrepancy in the dimension of the heads of children with hydrocephalus, it would not be possible to make one size of the head coil fit for all. Therefor the choice is made to be able to use 4 or 5 head coils for each range of head size. Due to the SD being from 50 cm - 60 cm (10/5) the diameter of each head coil increases with 2cm starting at 50cm.

Shape
For brain imaging the head coil must follow the shape of the human what, which is a slight tangled elliptical shape.

Requirement	Rationale	Source	note	Technical requirements
Mattress characteristics				
The head coil should allow proximity between subject and the receive array .	To maintain a maximal SNR	(O'Reilly, 2020)		The receiver coils must be at proximity of the anatomy of interest.
The head coil must cover the entire brain, which means that it needs to overlap over the eyes and on the occipital area.	For a full brain image, the entire brain must fall inside the field of view.	Experiment concluded that concept 3 was best for the body area.		The mattress must have a concave shape for the body to lay on it.
The head coil must be able to be connected in an easy way	The head coil must be connected to the mattress to be slide inside the bore	User test		
The head coil must be able to be disconnected easily	The head coil must be connected to the mattress to be slide inside the bore	User test		
The head coil must allow the patient to look through the to see the mirror	The patient can look through the eye slots inside the mirror to interact with the caretaker and keep calm	User test		
Ease of use				
The head coil must be able to be easily replaced	Each head circumference range has its own head coil. This may be replaced several times in a day.	Interview Cure hospital		Through standardized connections which are directly visible, the head coil must be able to be replaced.
The head coil must be able to house the headrest				
The head coil must be able to be cleaned				No 90-degree angles or holes where bacteria can accumulate must be present.

M.4 Immobilizer

Based on what is the concept made?
The requirements come from the research of Holla, on how to make the best immobilization as possible. This resulted in 3 different concept designs which were eventually evaluated through an experiment with 7 adult participants. With the result of the best functional concept, the final design of the head immobilizer has been made, by taking into consideration the
1. Mechanical stiffness
2. The materials
3. The dimension - from adult to head with hydrocephalus
4. the integration with the other concept (head coil and headrest)

Background

At the end of the background, we have the ideal shape of the immobilizer for the optimal functionality. After having investigated the ideal shape for the functionality. The concepts are optimized on their usability, their volume/mechanical stiffness and their cleanability.

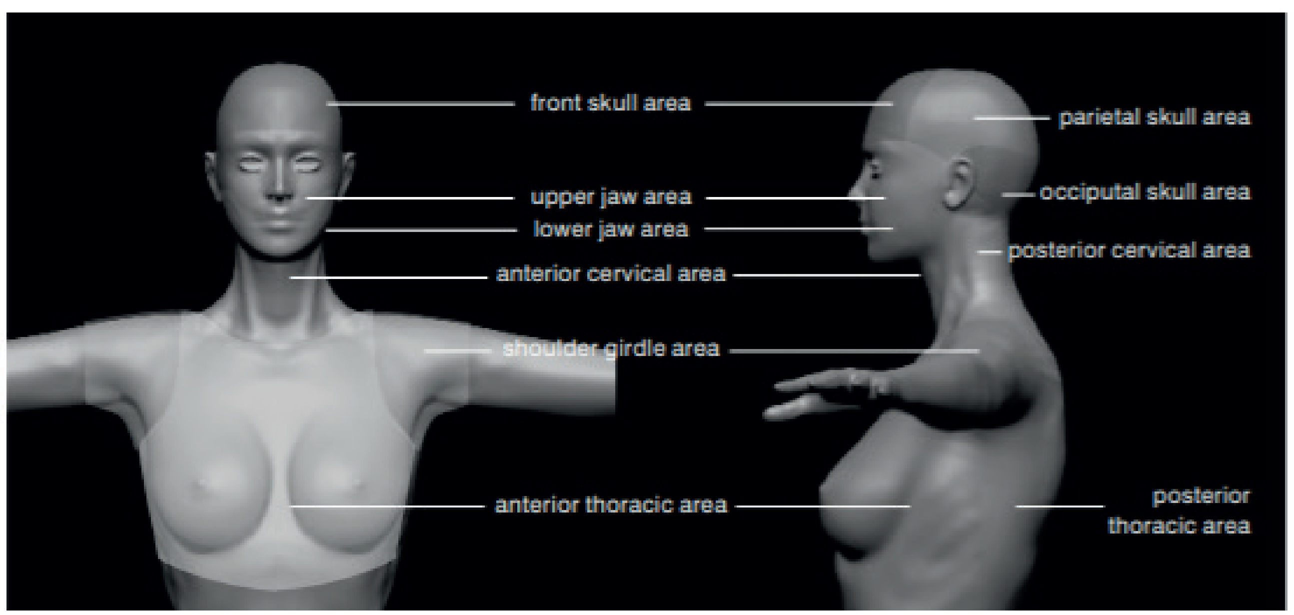
A. Anatomical requirements
Through a literature study, current head and spine immobilizations have been evaluated and the product requirements to achieve a functional immobilization have been extracted. The study was performed to evaluate prospectively the ability of current spine-immobilization devices to achieve MRI scanning positioning of the cervical spine of paediatric hydrocephalus patients.

Normal motion
The normal motion of the head and anatomical structures restricting cervical movement are presented.
Normal motion of the head a cervical spine is created by movement of the first seven cervical vertebrae (C1-C7). Together with the neck muscles they allow flexion, extension, rotation, and lateral bending of the head in relation to the body \cite{Hola}.
Each form of motion is facilitated by a part in the bony spinal channel. The intervertebral motion can be subdivided in different chain parts, responsible for each its own movement.
• Atlanto-occipital (C0-C1) is responsible for flexion and extension - little rotation occurs at this level (7)
• Atlanto-axial joint (C1-C2) allows more than 50% of the rotation of the cervical spine(8)
• Lower cervical levels (C2-C7) allow lateral bending
The result of the motion happens in the sagittal plane (flexion - extension of 122 degrees) - yaw
coronal plane 88 degrees
axial plane 144 degrees.

Restriction of motion

1. The limiting factors of motion are due to the muscle tension, the bony structure, and intervertebral ligaments. Restriction of the bony structures and limiting the muscle rotations are the most effective ways.
Biomechanical principle of an external cervical immobilization device.
The head can be subdivided in the head, neck, and spine area. Pressures on areas of the anatomical zones of the head are needed to achieve a proper external immobilization of the spine, however this must be done according to some requirements and with care. Anatomical areas of the body are needing support and fixation for immobilization

Figure 1.3 Areas for external pressure to achieve immobilization of the cervical spine.



How to achieve the optimal support while immobilizing the patient
To reduce the pain, support is advice in the spinal pathology.

Positioning of the head in relation to the body
Especially for patient with a decreased muscle strength in the neck such as children, external supports can be of great help to position the head.

Supporting the head.
The anatomical zones of the head are separated into the occiput, parietal bone, frontal bone, upper jaw, and lower jaw. The occipital area has little subcutaneous fat, which enable pressure forces from external zones to reach the skull base. The downside of the limited amount of subcutaneous fat is that pressure ulcers on the skin can develop with an increased time in the same position.

Upward pressure on the lower jaw will result in a reduced ability to open the mouth.

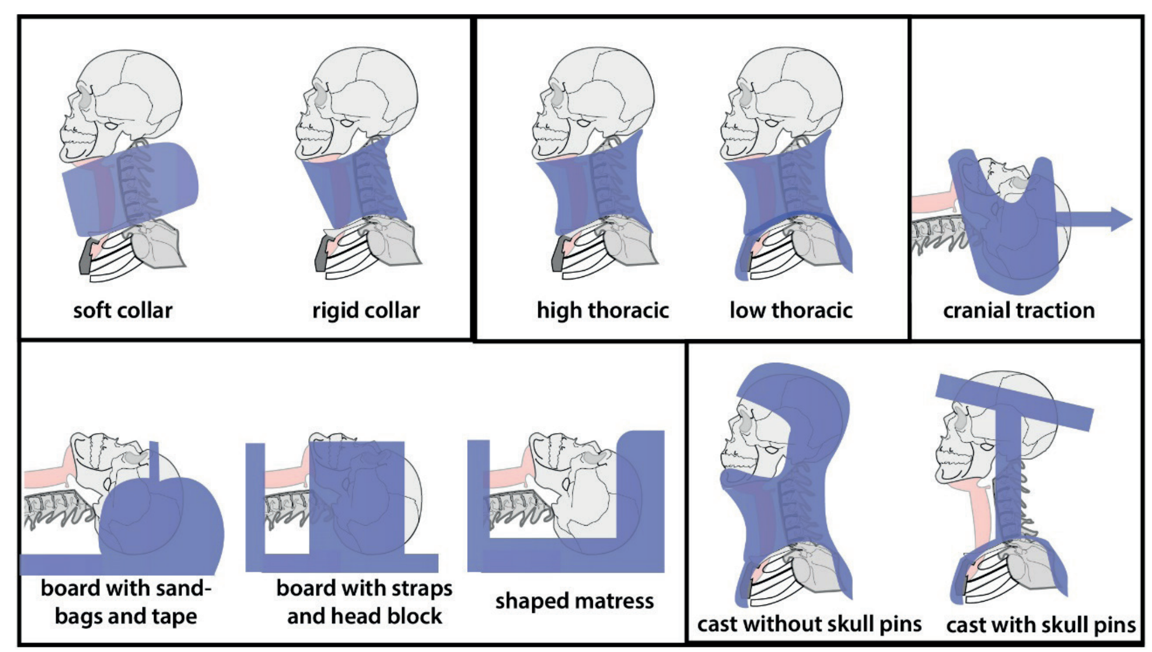
Support on areas of the neck
The areas of the neck can be subdivided in two areas, the frontal and back area. Pressure on the front area of the neck should be avoided, due to the soft tissue and vital structures of the body that will be restricted. It is important to keep this area straight and not flexed or extended to prevent obstruction of the vital areas. Pressure on the back of the neck is preferred as it is rigid due to the cervical spine.

Support on areas of the thorax
The Thoracic zone can be split into the anterior and posterior thoracic area. The subcutaneous fat layer at the sternum is relatively thin, which can also be a sensitive point for external pressure pain

Requirements
1. Requirement: No external pressure must be applied on the areas with low subcutaneous fat to prevent pressure ulcers: The occiput area must be free from pressure
the areas with the lowest subcutaneous fat allow the least amount of pressure on these areas which are the occipital area of the skull. Application of pressure can have as a result that the skull is directly held for immobi¬lization, however the downside is that pressure ulcers and pain can easily develop
2. Requirement: Rotation and bending of the upper spinal area must be limiter: Through application of pressure on the parietal areas of the skull
3. The head neck and thorax must be fixed to prevent junctional angulation.
4. The immobilization should not solely support the shoulders to prevent the effect of mobile shoulders.
5. The immobilization should not solely support the shoulders to prevent the effect of mobile shoulders.
6. No pressure must be applied on the upper jaw
Problems with current immobilizers
Current immobilizers are rigid, uncomfortable, and too big to fit inside the head coil of the low field MRI scanner. Other immobilizers that are specially designed for brain imaging required either automatic vacuum, which is not widely available in LMIC or either required a large workload from the MRI technician.

Design of concepts based on classification
Research from Holla identified 4 different types specific for cervical spine immobilization. This principle is based on the application of pressure on or through the skin in anatomical zones. The patients in the MRI scanner do not specifically need to immobilize the cervical spine but need to immobilize the head.
Based on the functionality and the ability to restrict motion of the head the following three directions have been chosen

From the external immobilization methods, the most effective ones(from literature) that limit movement in all directions (pitch, roll, yaw) have been selected. Which are
1. High thoracic



Type	Category	Note	
A. Cervical devices	Soft collar	Ability to reduce the range of motion was poor in all directions (Holla,2019)	
A. Cervical devices	Rigid collar		
B Cervico-thoracis devices	High thoracic	Also immobilizes the thorax in a minimal way. By immobilizing the thorax, more of the head will be immobilized	With minimal volume, a high thoracic device exerts pressure on anatomical points to be able to not be able to contract of flex those muscles which lead to immobilization
B Cervico-thoracis devices	Low thoracic	Also immobilizes the thorax	
C. Cranial devices	Cranial traction	Excerpts traction force on the cranium. For hydrocephalus patients this is not desired due to the sensitivity of the skin and head.	
D. Cranio-thoracic devices for non-ambulatory patients	Board with sandbags and tape		
D. Cranio-thoracic devices for non-ambulatory patients	Board with straps and head blocks	Immobilizes and fixates the head by tightening on a rigid device. However, the board below the thorax is not necessary for Hydrocephalus patients. Restricted spine movement to nearly all directions (Holla,2020)	Cranio-thoracic device- Rigid headblock with straps.
D. Cranio-thoracic devices for non-ambulatory patients	Shaped mattress	Immobilizes the head by fixating soft material around the head which is tightened. However, the board below the thorax is not necessary.	Cranio-thoracic device- Soft head tightener with straps. Exert pressure on the head to tighten and immobilize.
D. Cranio-thoracic devices for ambulatory patients	Cast/vest without skull pins	The entire skull and thorax are immobilized with a cast. This is time consuming and dimension dependent	
D. Cranio-thoracic devices for ambulatory patients	Vest connected with skull pins	External immobilization which is invasive	

There are different classifications of external immobilization devices based on anatomical support areas. Research from Holla identified 4 different types specific for cervical spine immobilization. The patients in the MRI scanner do not specifically need to immobilize the cervical spine but need to immobilize the head.
Therefore, two categories are dismissed, which have a reduced functionality and would not suit the context of insertion inside the bore. The chosen categories which are the fundamental principles for the conceptualization of the head immobilizer are:

1. Headblock
2. Tightness/ mattress
3. Low rigid collar

B Mechanical Reuirements

A simplified free body diagram has been made to determine the minimal stiffness that the head immobilizer requires to prevent translation and rotation in a rested situation.

1. What is the minimal stiffness that the system requires to prevent a translation in x and y plane?
2. What is the minimal stiffness that the system requires to prevent rotation of the head?

In this case the situation is sketched of a head of patient with hydrocephalus in a rested state. The immobilizer must be able to immobilize the largest and smallest heads of the patients. Therefor the largest head (5 kg, P95) is taken as initiation in this calculation.

The immobilization device will be fixated inside the head coil. As the head of the patient needs to be at the closest proximity of the head coil as possible to be immobilized, the immobilizer itself must have the smallest volume as possible, while being stiff enough to not deform elastically or plastically while the head is moving.

Situation

A situation is sketched to simulate the scenario of the patient moving its head.

1. **Rest**

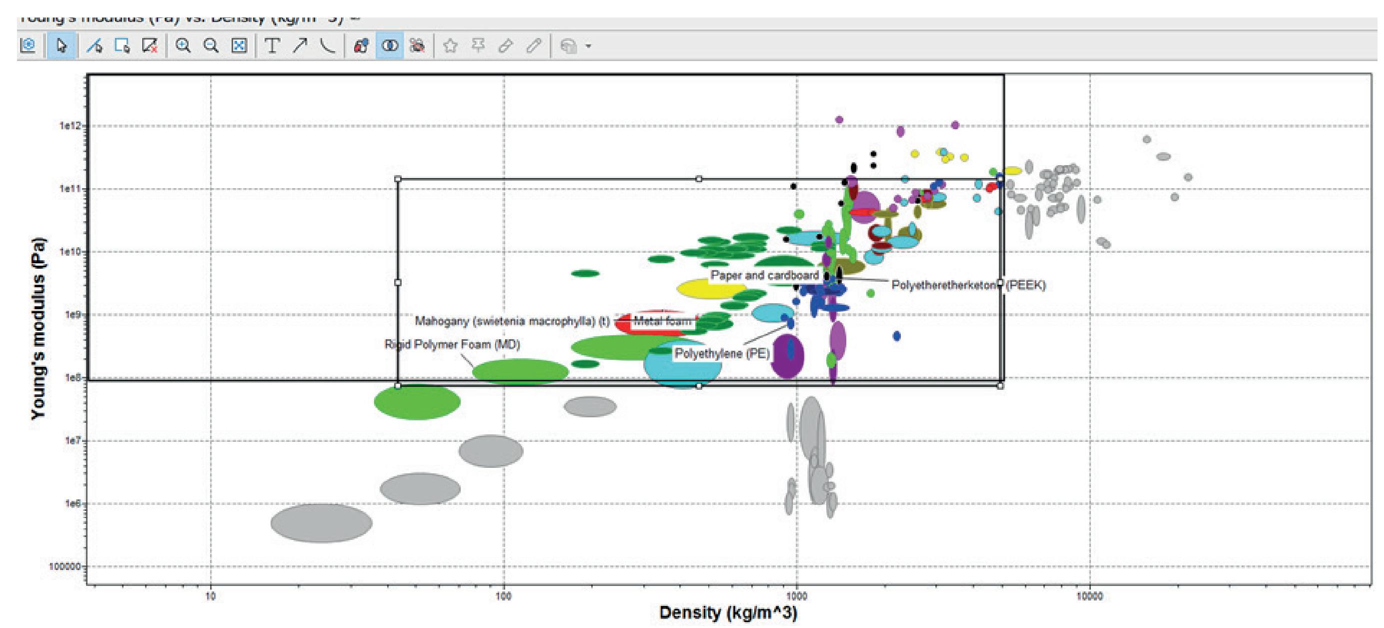
In rest the head of the patient is situated on point A. This point (A) can be seen as a ball and socket system. A normal force and friction force is acted upon this point.

2. **Movement from neck**

Once the patient exerts a force from the neck to the side to roll its head around the z axis, the head will move.

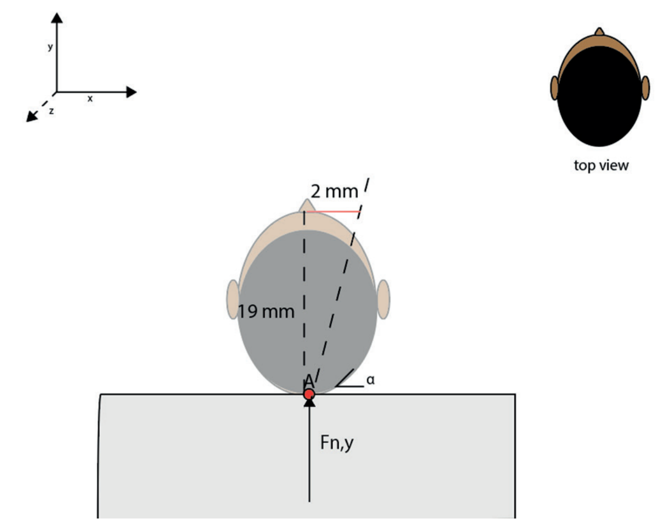
3. **System must prevent movement**

The system must prevent the force acted upon point B to cause a maximum movement/deflection of 3 mm. Therefore, the FBD is simplified to figure 19.5. The required stiffened of the system is calculated through a simplified calculation.



Material

Angle Alpha can be calculated with $\tan^{-1}$ (2mm/190mm) = 0,6 degrees.
So, a maximum rotation of 0,6 degrees is allowed. Through the calculation of the moment of inertia (I_{zz}=(b*h)3/12) and of a uniformly distributed load on a cantilever beam (y=((Pa^2)/(6*E*I))*3x-a) with a maximum force of 50N and a minimum force of 5N, the E modulus of the material may be between 0,9 GPa - 9,8 GPa. This allows the material of the immobilizer may be in the range of thermoplastics and metals as can be seen in figure 19.5 This also excludes stiff materials such as ceramics and unnecessary stiff materials such as aluminium but can include materials such as reinforced cardboard.



Yaw
In a resting state the head is positioned supine on the mattress. The only forces that press on the occipital area are the Fz of the head itself.
Once the patient starts to move, a momentum of 5,7Nm is created that rotates along the occiput area. The system eventually will need to be able to prevent this momentum of 5,7Nm, which is the stiffness of the system.
2. 5,7 Nm = the stiffness required.

Pitch
The pitch movement (flexion of the head towards the chest) is produced by the sternocleidomastoid and the major neck muscles. Rotation and abduction of the head is also facilitated by these muscles. During the pitch movement the head and neck is resting on the pillow and pivoted around the Fulcrum and apex, facilitated by the small neck muscles and the semispinalis extension.

The stiffness[N/m] of the system is calculated by calculating the impact of the head on the system. The impact [force in N] on the system with a 1 second movement is 5,7N (F = net Momentum/net time). With a maximum motion and thus deformation of 2mm the stiffness of the product is required to be 2850 N/m.

Requirement	**Rationale**	**Source**	**note**	**Technical requirements**
The immobilization must be able to keep a head in the X and Y direction	The head must not move for more than 2 mm	The sternocleidomastoid causes the rotation of the neck in the head. With as pivot point the fulcrum.		What is the stiffness of the system - How much newton is this? approximately 6Nm
The pressure from the head immobilization on the cranial section of the infant must not be more than 7,5 mm Hg or approximately 1kPa	A higher force will cause pain or in the longer run deformation in the skull of the smaller infant. Once the fontanels are closed, the children can handle a higher force. for pain and deformation)	No literature could be found about the maximum required pressure of the head of cranium. *Based on anecdotal feedback from clinicians, estimated pressure of a helmet on the apex region of the infants' skull was assumed to be 7.5 mm Hg or 0.145 PSI (or 999.915 Pa). It should be noted that clinicians estimated pressures using a force sensor applied to a human's head with approximately the same force as helmet contact.*		Pressure not higher than 1 kPa
The immobilization must restrict the normal rotation of the head (which is 4Nm)				
The immobilization device must be cost-effective compared to the competitors	Due to the purpose of the immobilization device is to be handled in a context for LMIC, the price of the part must not be too expensive			

Immobilization

1. **Requirements**

Since the patient is not sedated and prone to move, the head will have to be immobilized in the x, y and z translation and rotation. The rotational motion will be denoted as pitch roll and yaw. Due to the spatial resolution of 3mm the maximal acceptable motion is 3mm, a movement larger than the spatial resolution will distort the imaging. Movement in the frontal and sagittal plane is detected.

Anatomy
For the immobilization it is important that several anatomic points are fixed by putting pressure on it or preventing the flexion and extension of muscles.

Requirement	Rationale	Source	note	Technical requirements
Immobilization				
The immobilization device must prevent translation of the head in x, y, and z direction with 3mm	The spatial resolution of the system allows movement not bigger than 3 mm	O'Reilly 2021		The immobilization device must prevent the head to translate the
The immobilization device must prevent rotation (pitch yaw and roll) for more than 3 mm	The immobilization device must prevent translation of the head in x, y, and z direction with 3mm	O'Reilly 2021		
Comfort				
The immobilization must be soft	The children have very thin skin (paper like skin on the head	Interview with Dr. Schiff 07-05-2021		Between 0 and 32 mmHg pressure
	The children must be very comfortable for them to be calm. Children with hydrocephalus have an increased intracranial pressure	Meeting with Tom		
The immobilization must be as compact as possible	The Head coil must be as close to the subject as possible and therefore the immobilization system must not take too much space between the head coil and the head of the subject	Mock-up making and experimentation testing		The immobilization must not be more than 3 cm thick
Must be able to be cleaned properly with water and disinfectant	Multiple sick patients will have to use the same product	Mock-up making	Look up good to be cleaned materials	soft on this inside and good cleanable on the outside
The material must be MRI compatible and not made of metallic fixtures	The MRI scanner does not allow ferromagnetic materials to be inserted inside the bore.			
Must fixate on the back of the neck and from the shoulder to the jaw area				

Several studies describe an increase of intracranial pressure due to rigid collars[MG1] [1]

The results of this proof of principle study demonstrate that the addition of a rigid collar to head blocks does not provide any extra immobilization of the cervical spine and is therefore considered unnecessary. Furthermore, this study showed that a rigid collar reduces the ability to open the mouth and clear the airway. In view of this and other known adverse effects of a rigid collar (increased motion at the level of the high cervical spine, increased intracranial pressures, pressure sores of the skin, increased pain and discomfort, poor quality of radiographs and a false sense of immobilization), the combination of a rigid collar and head blocks should be reconsidered

Product features

The system consists of three main parts: 1 a central head holder
2. A fixation strap
3 fixation adjustable pillows.
Each part is designed to satisfy a purpose.
To minimize the noise in the imaging of the device, all the components are in the non-magnetic area.

Usage:
The installation of the head is as follows: First the back of the head is positioned in the donut area of the head coil. Secondly the pillows are adjusted to provide a tight fir around the patient's head. Finally, the straps are tightened on the forehead of the patient and secondly the mandible to the patient with a diagonal strap. This is done to prevent the head from translation and rotation. Eventually the head coil is slid over the head of the patient. The detailed part of the mechanism is described in the following paragraph.

Central holder
The head holder is designed to prevent posture error in transverse directions. It helps to support the weight of the head and prevents repositioning during the scanning.

Prevent translation
The translation of the head is prevented by resting the head on a headrest which is fixated on the head coil. This prevents unwanted sliding of the head coil and thus translation.

Immobilization
Based on the immobilization experiment the optimal product features have been designed to provide the optimal immobilization to prevent pitch yaw and roll.
Rotation of the head is prevented through the pillows that provide pressure against the movement.
The pitch movement is prevented by the double strap around the head and around the mandible.
The adjustable pillow is designed to fit on all possible head shapes. This improves the comfort of the patient.

Prevent unwanted sliding
The head coil and the bed can only move when the bed is moved inside the bore.

Materialization
Based on the ideal usage, the material requirements are defined. It is desired that this part will be reusable and thus able to be washed and robust instead of being disposable. A disposable part will increase the cost of the procedure significantly and result in a lot of waste.

Only foam is comfortable, but this is not as robust and durable as the combination of thermoplastic with a washable material that is inserted with foam.
The material must be waterproof

polyesters and bi-density polyurethane foam (PE-HD) due to its rigidity and ability to enter the MRI scanner. It can be overlayed with PVC which is well cleanable.

The base plate integrated in the 3D printed headrest. The straps are made of woven polypropylene. and attached with a Velcro strap.

Component research
Comfort

What are the factors that bring discomfort?

Factors that cause discomfort
Anxiety upon being positioned within the bore
Inability to move
Lengths of the procedure
Size of the scanner
Feeling of being closed in

The most prone is the inability to move, which is influenced by sight and the feeling of being closed-in. The factors 3-5 cannot be influenced within the low field MRI, so the most crucial is to investigate minimising the feeling of anxiety and stress upon positioning in the bore (by providing MRI technicians with an intuitive use), improving the perception of the device from the patient's perspective and reducing the inability to move by physical ergonomic and increasing patient vision.

Research M.5 Mirror design

Research Mirror - Experiment

Objective

The objective of this experiment is to define the effect of a mirror within a patient interaction with a patient and an MRI scanner. Furthermore, the mirror experiment is to validate the calculated required angle of the positioned mirror.
- Emphasis on the solution direction
- Validate calculations

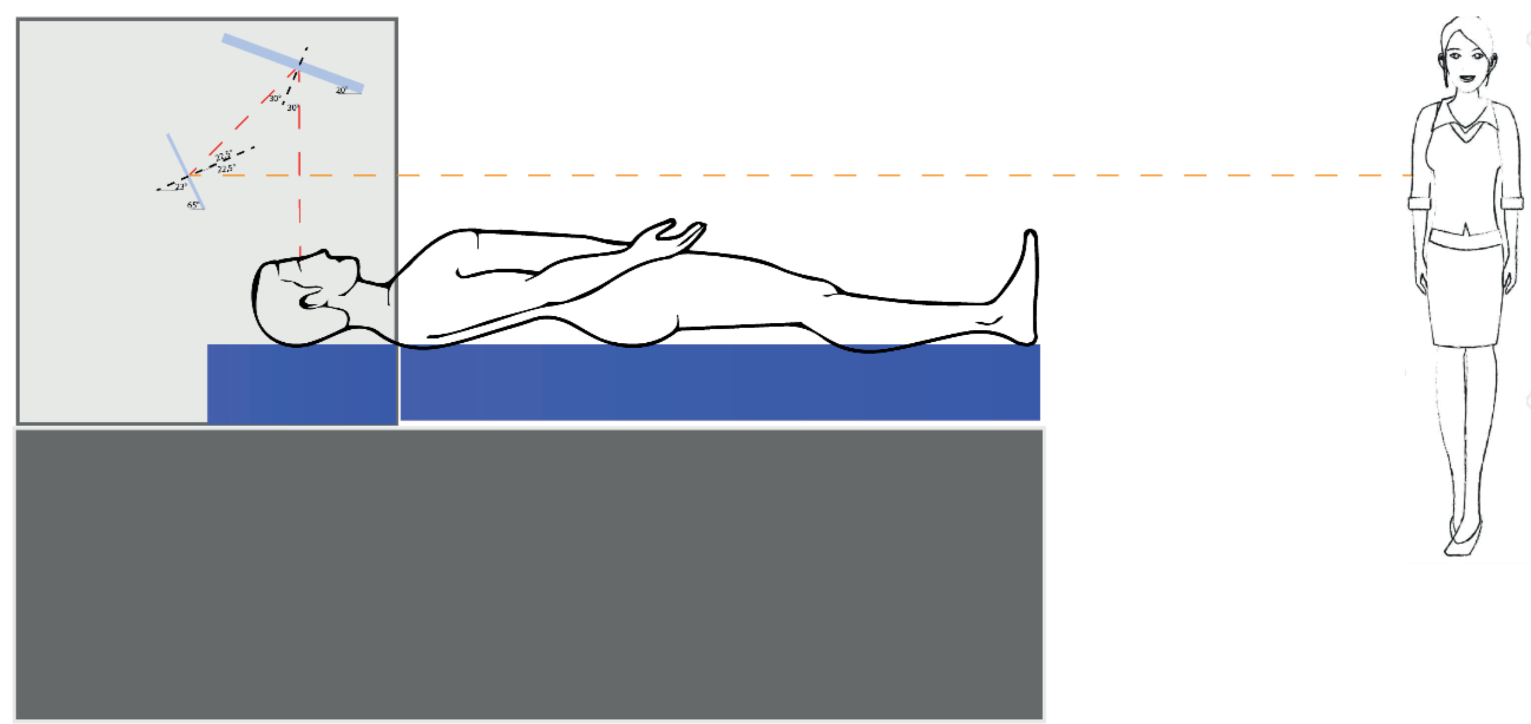
Interaction with parent, what is needed for it
To find out what angle the mirrors need to be
To find out what distance the parent needs to be
What effect will the environment have on the vision of the patient?

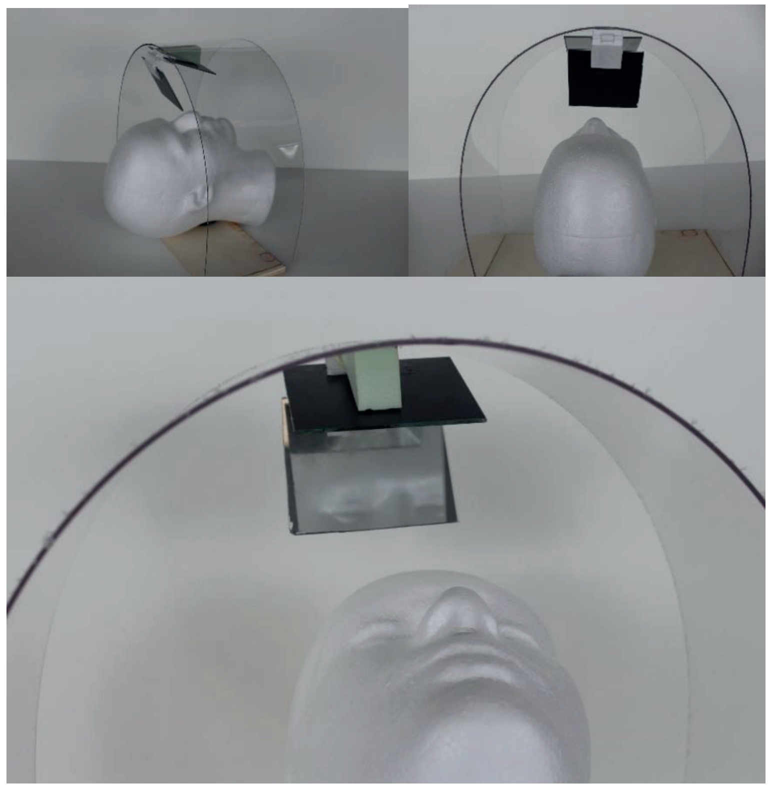
Method

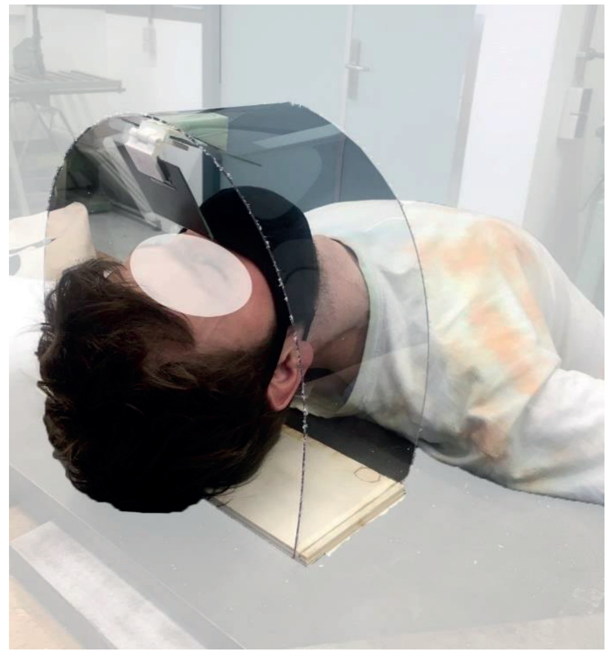
The method used to research the objective was by first calculating the desired interaction between the patient and caretaker while considering their position and field of view within the system.

Literature study
Mock-up making
The test setup used allowed the

Result

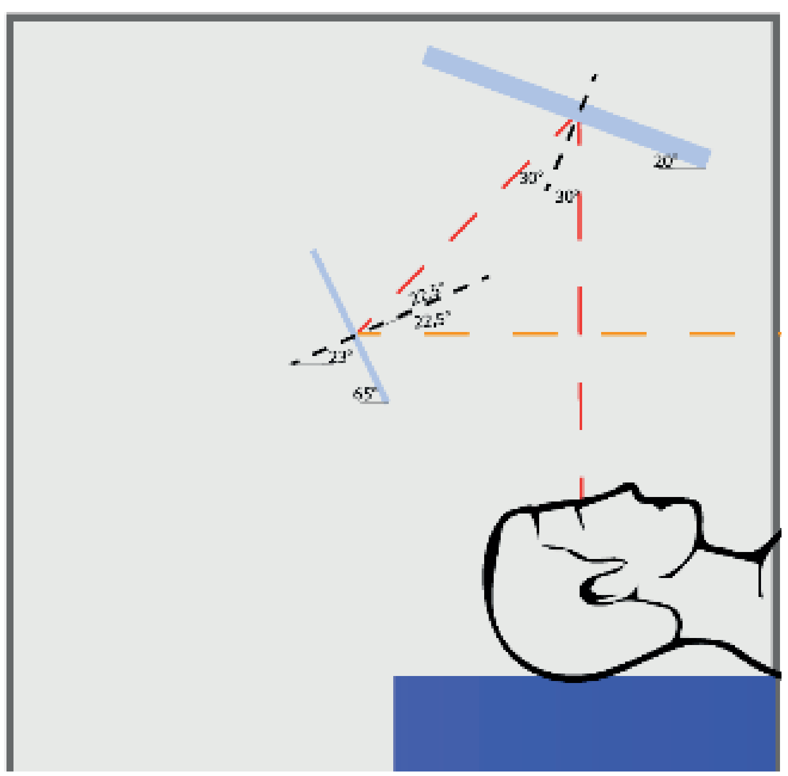






The calculated angles were prototyped in a small mock-up and tested with a participant.

Conclusion
Design
As can be seen, there is a lot of room on the sides with an oval head. So, the shape of the head. It is best to position the mirror on the bore and not in the head coil with a limited amount of space.
There is a lot of space on the sides which are usable for the hands
Interaction
The participant noted that through the mirror the other participant could be seen well. During the procedure the eyes were enlarged visible and the state of mind of the participant could be read.



Research M. 6 Blanket design

Conductive blanket *(Swaddle technique)*

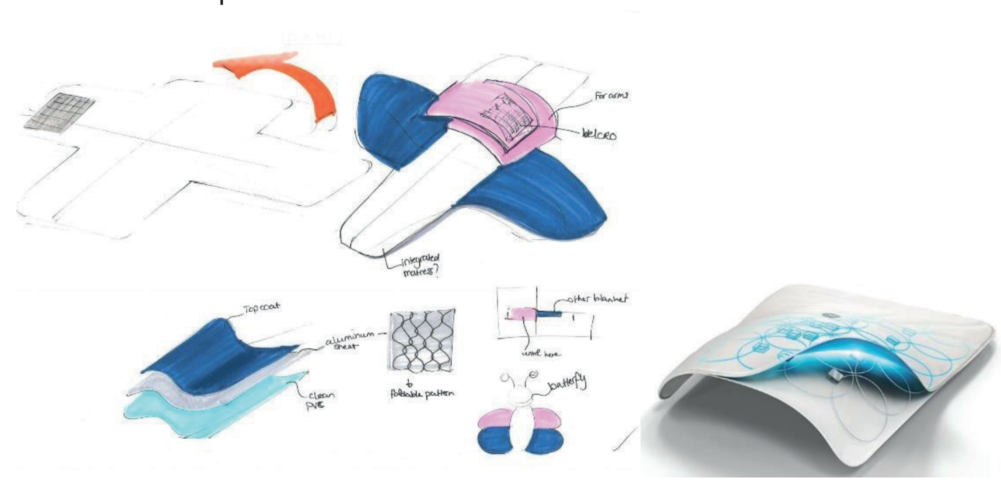
Requirement	reasoning	Source	note	Technical requirements
Swaddle				
The blanket must swaddle the patient	Infants remind swaddling to their previous warm and secure womb/lap of the mother. Being wrapped in cotton cloth of muslin feels like being surrounded and restricted by the amniotic sac in the uterus. This calms down infants and help them fall asleep easily. For small children swaddling promotes deep sleep and immobilizes the patient. For larger children swaddling allows the hands of the children to sit still.	Research opportunity area		
The blanket must keep the upper extremities of the patient in place	The "burrito roll technique is the best way to swaddle a patient.	Brown, TL . Paediatric variations of nursing interventions. In: Hockenberry, MJ, Wilson, D, eds. Wong's Essentials of Paediatric Nursing. 8th ed. St Louis, MO: Mosby-Yearbook, Inc; 2009:687-753.		The blanket needs to be tucked tightly around the body. By applying pressure of 100Pa(10 kg/1m^2)
The blanked must leave the face and neck area uncovered.	The bottom of the cloth must leave the abdomen enough space for the legs to move.			Only the limbs must be able to be swaddled
The blanket must keep the patient within the same bodily temperature (+/- 3-degree fluctuation)	The child must not warm up or cool down too much for comfortability purposes and the prevention of drifting.			The blanked must prevent bodily temperature fluctuation of more than 3 degrees Celsius in 10 minutes.
The infant must be positioned supine while swaddling	For a correct imaging of the brain, the head must fit in the head coil in a supine position			The blanket must indicate a clear visual positioning of the patient
Cage of Faraday				
The maze inside the blanket must be made of non-magnetic materials	Ferromagnetic materials can be used for the shielding of magnetization. Good ferromagnetic materials are Aluminium, copper, chicken wire	Yek, Suen. "How to build a faraday cage on the cheap for wireless TCP/IP fingerprinting." *2nd Australian Computer,*		Aluminium, copper, chicken wire are materials that can be considered for the cage of Faraday

		Network, and Information Forensics Conference. 2005.		
The blanket must be grounded	The excess charges will be neutralized as the ground connection creates an equipotential bonding between the outside and the inside of the cage	Yek, Suen. "How to build a faraday cage on the cheap for wireless TCP/IP fingerprinting." *2nd Australian Computer, Network, and Information Forensics Conference*. 2005.		The blanket must be connected to the electronics to be grounded.
No direct contact between the skin and the conductive part of the blanket may occur	Potential hazard of electrocution may occur when the body is connected to the circuit	Yek, Suen. "How to build a faraday cage on the cheap for wireless TCP/IP fingerprinting." 2nd Australian Computer, Network, and Information Forensics Conference. 2005.		No direct contact between the skin of the patient and the conductive part of the blanket may occur.
The blanket must be connected to the same ground as the aluminium shield around the magnet.	For safety reasons the blanket must be grounded since it relates to the current of the MRI scanner.	Yek, Suen. "How to build a faraday cage on the cheap for wireless TCP/IP fingerprinting." *2nd Australian Computer, Network, and Information Forensics Conference*. 2005.		The blanket must be connected to the same ground as the aluminium shield around the magnet.
The aluminium crates must only be implemented in the part of the blanket that does not enter the bore	(aluminium is ferromagnetic)	O'Reilly Siemens MRI maintenance		The maze of the aluminium grid must not be bigger than 10 * 10 mm and 3 mm thick.
Ease of use				
The blanket must be easily washable with water and a cloth	The main cleaning technique in between the patients is by wiping the equipment with water and a cloth	Edith (Cure hospital)		Dirt must be washable from the blanket by wiping with water and a cloth
The blanket must feel comfortable on the skin	The patients have sensitive skin	Interview Dr Schiff, 2021		The blanket must be made of a textile with a soft material
The blanket must be easy for the MRI technician to install		Mock-up user test	Without any instruction the MRI technician must be able to install the blanket	The blanket must be able to be installed by one person without disassembling the MRI scanner

The swaddling must not obstruct the respiratory of the patient	When the swaddle technique is operated by inexperienced personnel, this may obstruct the respiratory of the patient. Therefore, the product layout must make sure that the swaddling can only occur in one way			The blanket must make sure that the swaddling of the patient only can occur in one way

Design

1. Blanket shape



During use of the classic burrito roll technique downsides occur such as the
- needing to roll the patient over the blanket multiple times
- No way to tuck the blanket
- Need to align the patient well

Only the essentials are excluded from this method, - the way to tuck in the hands on the torso the cleanability after each use

- Therefore, this shape is designed in a double T-shape with Velcro. Velcro makes sure that the MRI technician only needs one gesture to secure the blanket with the right pressure. The possibility of loosening the swaddled patient is reduced to its minimal due to the Velcro. Also, this allows the MRI technician to only use the blanket is one possible way.
- **Positioning - also for older children**

By positioning the patient supine inside the shape, the part A is for the back. The upper limbs are tucked with the upper secured wings, whereas the lower wings are for the lower limbs. For prenatal patients there is a possibility to completely tuck in the child, which is not a necessity for older children.

Looks are approachable for the patient (looks like a butterfly)
The blanket is designed by consisting of three layers,
1) a cleanable layer which keeps the patient on temperature
2) Aluminium grid, which functionates as a cage of faraday to reduce the noise)
3) a cleanable layer which prevent direct contact of the aluminium with the patient.

The connection between the layers must be watertight.
Furthermore, this part is only implemented in the part where the legs are out of the MRI scanner.

Material
Price and availability have made the final decision of the blanket being made of PVC.
Materials that are comfortable and washable. (non-absorbent)

- Nontoxicity
- Nonallergenic response
- The ability to be sterilized
- Mechanical properties
- Strength
- Elasticity
- Durability

2. *Surgical drapes and cover clothes*: - These are used to cover patients or to cover working areas around patients. It should be completely impermeable to bacterial and absorbent to body perspiration and secretion from wound.

Product application	*Fibre type*	*Fabric type*
Surgical clothing gowns	Cotton, Polyester, Viscose rayon, Polypropylene	Nonwoven, Woven
Caps masks	Viscose rayon, Polyester, Viscose, Glass	Nonwoven Nonwoven
Surgical covers Drapes cloth	Polyester, Polyethylene Polyester, Polyethylene	Nonwoven or Woven Nonwoven or Woven
Beddings, Blankets, Sheets Pillow covers	Cotton, Polyester Cotton Cotton	Woven, Knitted Woven Woven

Connection

The blanket will relate to the 32-pin connection. This is a standardized part which is also widely used in the automotive industry and in Uganda.


32 pin connection

Manufacturability
All materials are widely available in Uganda, and manufacturable. If the product gets obsolete, it can be replaced or repaired easily. The component which is most prone to break is the electrical connection, which is widely available.

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Appendix N: Framework Design

Requirement	reasoning	Source	note	Technical requirements
The framework must be able to slide on the guides inside of the bore	The bed must be translated from outside the bore towards inside the bore	Patient journey mapping		The framework must be able to slide on the guides inside of the bore with a mechanism.
The framework must be able to hold 300N	The weight of the patient, the mattress must be held on the framework without breaking			The framework must be able to hold 300N without breaking deflection of 3mm.

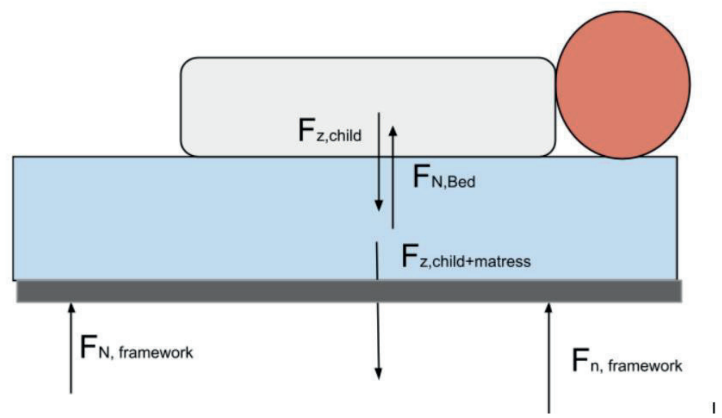
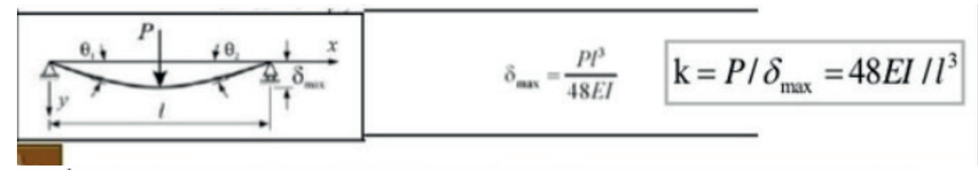
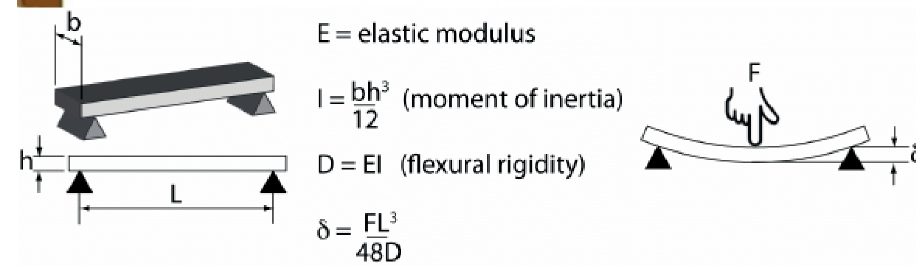


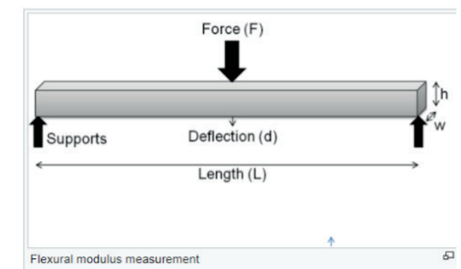
Figure N1. A simplified F of the forces acted on the framework

What is the force that the framework must be able to hold?
Calculation
Weight child: 18 kg + (20% safety norm) = 22 kg
F_z child = 9,81 * 22 = 215,82 N
F_N, bed = 215,82 N
Average weight of foam density mattress (6 kg) + weight of head coil (2kg) = 8 kg *9,81 = 78,48N
F_z child + F_z mattress & coil = 215m82+78,48 = **294,30 N**
Result: 295N





In mechanics, the **flexural modulus** or **bending modulus**[1] is an intensive property that is computed as the ratio of stress to strain in flexural deformation, or the tendency for a material to resist bending. It is determined from the slope of a stress-strain curve produced by a flexural test (such as the ASTM D790), and uses units of force per area.[2] The flexural modulus defined using the 3-point bend test assumes a linear stress strain response.[3]



Flexural modulus measurement

For a 3-point test of a rectangular beam behaving as an isotropic linear material, where *w* and *h* are the width and height of the beam, *I* is the second moment of area of the beam's cross-section, *L* is the distance between the two outer supports, and *d* is the deflection due to the load *F* applied at the middle of the beam, the flexural modulus:[4]

$$E_{\text{bend}} = \frac{L^3F}{4wh^3d}$$

From elastic beam theory

$$d = \frac{L^3F}{48IE}$$

and for rectangular beam

$$I = \frac{1}{12}wh^3$$

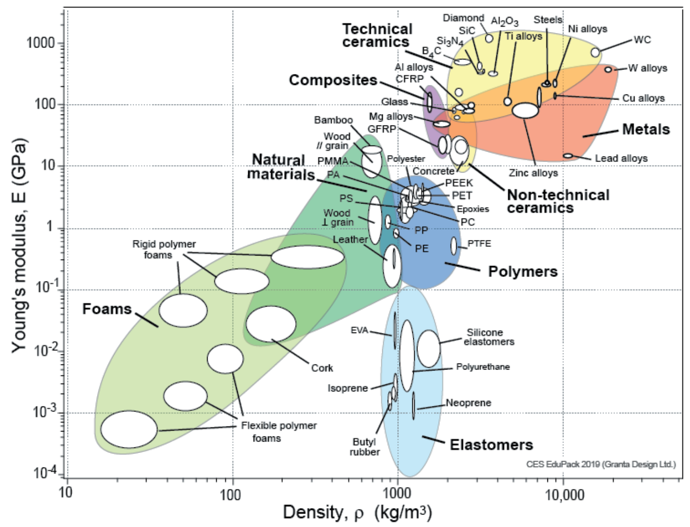
thus $E_{\text{bend}} = E$ (Elastic modulus)

Ideally, flexural or bending modulus of elasticity is equivalent to the tensile modulus (Young's modulus) or compressive modulus of elasticity. In reality, these values may be different, especially for polymers which are often viscoelastic (time dependent) materials.[3] Equivalence of the flexural modulus with Young's modulus also assumes equivalent compressive and tensile moduli as bend specimens have both tensile and compressive strain. Polymers in particular often have drastically different compressive and tensile moduli for the same material.[5]

What is the possible material for the framework with a and a maximum bending
Framework stiffness?
Hight = 20 mm
width = 300 mm
length = 1200mm

Ebend = (L^3*F)/(4*w*h^3*d)
Ebend = 1,2^3 *294 / (4 * 0,3*0,01^3)*4
1728/ 0,0000048= 360 000 000 Nm/ 3,6 GPa

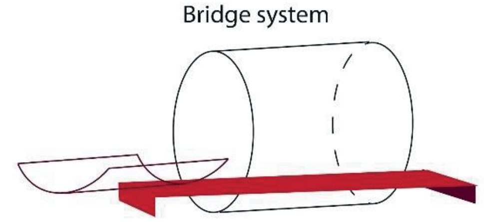
Strength = 3*F*L/(d^2*b*2) = 624.000 Pa = 0,6 MPa
dikte van 1 cm = 15.600.000 Pa dus 15,6 MPa

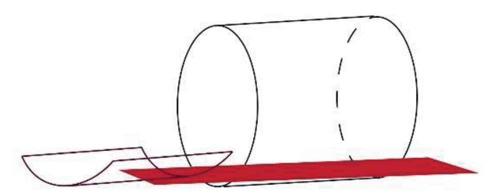


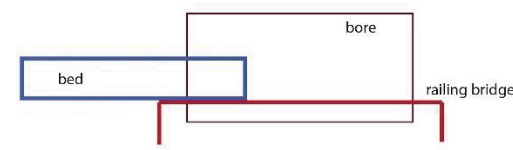
Appendix O Rails and framework

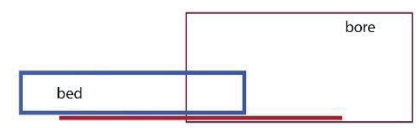
Requirements
Since the magnet system may not carry load, no force may be exerted on the magnet system
The translating mechanism must take as least as volume as possible.

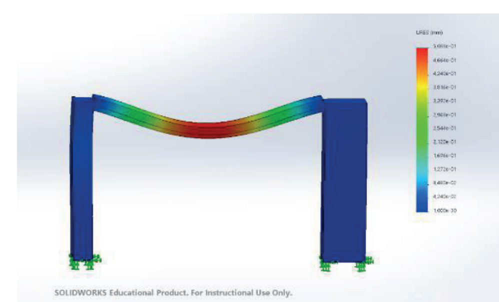
The possible forces that can be exerted on the magnet are the forces from the bed on the bore. To prevent these multiple systems have been considered. The concept which exerts the least force on the magnet system has been implemented

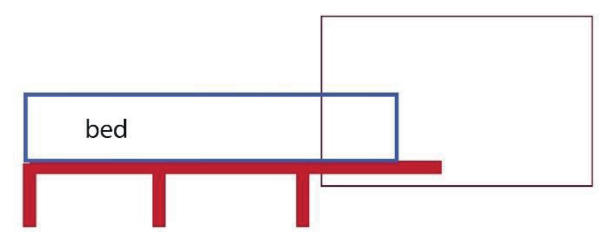












Both the bridge system and the floating system do not exert the forced from the bed nor the railing system to press on the bore (cylinder). The bridge system required the bore to be open, which is not possible. However, the load of 200N (a child) on the rail will cause a maximum deformation in the middle of the rail of 0,5 mm
A load of 400N (the whole bed) on the rail will cause a maximum deformation in the middle of the rail of 1 mm

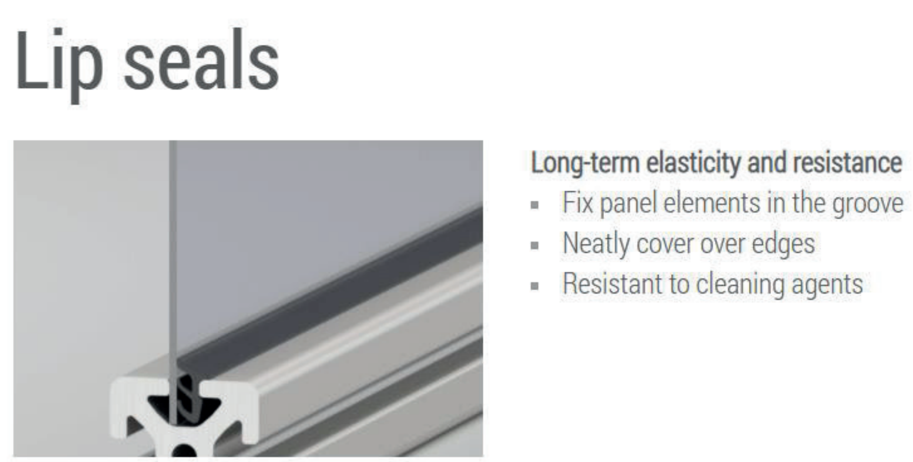
The floating system requires a very stiff framework for the bed to not deflect and exert forces on the railing system. The choice is made for the floating system, due to the feasible requirements.

Aluminium profile

An aluminium profile has been chosen to build up the framework of the bed.
It is important that the parts are well replaceable. Therefore, standardized parts have been chosen for the framework of the bed.
It offers enough stiffness and quality for the product to be robust and durable enough. Furthermore, the magnet of the MRI scanner is built up through aluminium profiles. The additional benefit is that the modules can be ordered when the MRI scanner needs an upgrade (such as accessories or a bar for vital monitoring) which is likely in this stage of the scanner.
This is widely available, and the manufacturers can quickly repair and replace the parts since it is a standardized part

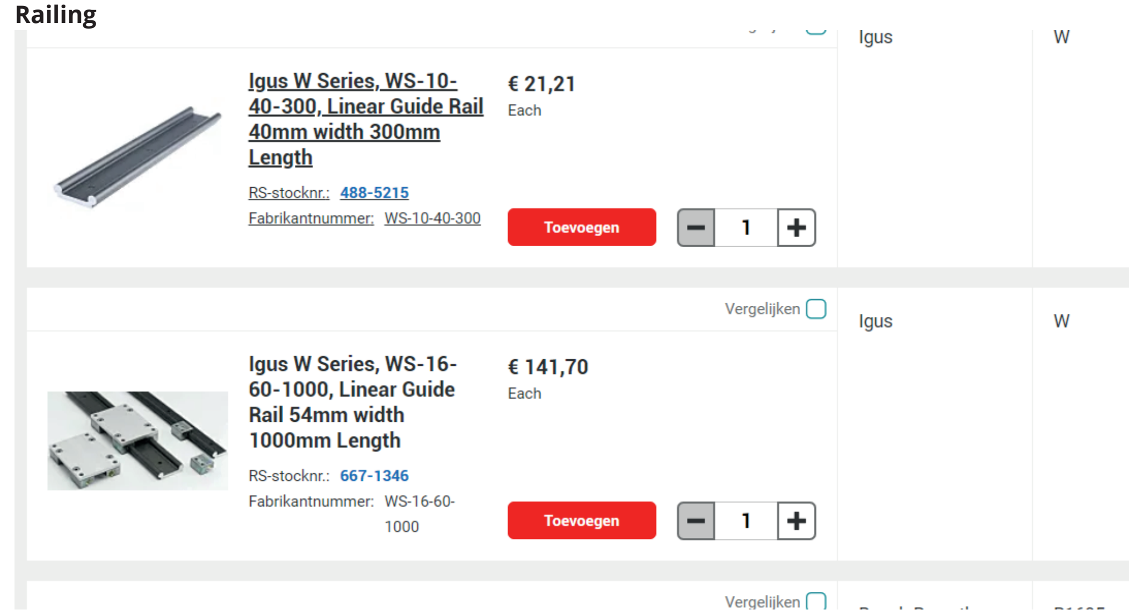
Thickness of the aluminium parts (*provide stiffness on the product)*
The bed must be able to hold the child and the bed framework. This is approximately 25 kg (child) 20 kg(bed and mattress) * SF 1,5 = 67,5 kg = 662 N.
The framework must hold 662.5N without deforming.

Therefore, a framework with 40mm*40 aluminium profiles have been chosen . The 20x20 structure bends when leaning on it.



Lip seals(*Make sure the magnets and moving components are free from dust)*
The lip seals make sure that no moving components will be in contact with the red dust.

Railing



choice of igus rail

Option:
Linear guide
Radial or compressive loads
Linear guides are designed to hold at least 300N for the bed and the patient. The linear guides are subjected to rotational loads. This is beneficial since this increases the stiffness o the system. This prevents the system to rotate through the pitch(rocking back and forth), yaw(side to side along the axis of travel) and roll (tilt or rocking side to side due to radial load) movements.

The static load rating C0 is the maximum allowable load at any moment on the system due to the plastic deformation of the rolling element inside of the guide element. The dynamic load rating Can be read out as a benchmark for the durability of the system under a particular load, and thus the expected life of a system since it is a measurement of fatigue.
Because linear guides have more components and bearings, it is also more prone to be exposed to fatigue through the temperatures, impact loads and lubrication inside of the environment.

Round rail
The choice has been made for an igus linear guide, which is one of the most basic linear guides on the market. Motion occurs along one range of axis. Most versatile and cheap options that need no lubrication. Linear ball bearing has more noise when moving.
This is chosen due to their durability, quiet, light resistant, corrosion resistant dirt-resistant, free of lubrication so clean.
In is inserted of polymer linear liner.
They can exert some friction; This can work for benefit during the use of
No oil is needed. The plastic wire damped vibration.

Guides are quiet. No need for oil of
The guides run without lubrication.

Polymer bushings are good
Negative - increase play while aging. However, they have an expected life. When they do fail , the polymer bushings will work fine, but have more play.
Maintenance free dry-tech polymers
Immune against dust and dirt. Because there are no moving parts, there is no noise.

Appendix P
Embodiment design

1. design for manufacturability / producability

DFM/A is used to not just make sure a part can be made, but make sure that the part can be made reliably to the engineer's original specification, with minimized tooling costs, low part costs, quick cycle speeds, and insignificant scrap rates.

1. Principles which are different in LMICs

Trade of whether to buy or manufacture locally.
The advantage of buying is
- You do not have any investment cost,

- It is already produced and designed,
- Once the product is obsolete you just order it.

Disadvantage of buying is

1. Sometimes you will need to order it from abroad, which takes a lot of time
2. With takes a lot of effort and money
3. The product is not exactly a specific fit for your design

Advantage of manufacturing is

1. You can design the specific shape that is required
2. Once the investment is done for a manufacturing machine, the product can always be replaced and repaired due to the limitless availability.
3. Create job possibilities

Disadvantage of local manufacturing

1. Requires a lot of planning and financial resources

Down the line, it is better do buy something that is widely available. Once something needs to be ordered from a specific web shop in a specific country, it may seem like it is accessible/available. But in the current circumstances in LMIC this situation is far from optimal and requires more effort than manufacturing itself. If the manufacturing and investment costs are low enough, it is considerable to manufacture it locally.

Design for manufacturing principles
1. minimize part count.
The MRI scanner has been designed by using fewer parts, which decreases cost and improves efficiency from manufacturing to logistics. The assembly difficulty is reduced by reducing the overall number of parts, which minimizes tooling costs as well.

2. Use standard components
By reducing the number of custom-made parts and replacing them with standard off-the-shelf components the lead time is lowered, and the sourcing is simplified. The most standardized parts come from the automotive industry in Uganda.
3. Design multi-functional parts

Single parts that serve multiple purposes facilitate the secondary functioning in limiting the necessity of a second part, the aligning and assembling. Such as the blanket that regulates the temperature, immobilizes the patient, and cancels the noise.
4. design parts for use across product lines
5. determine acceptable fit and finish range
Painting and polishing increase the manufacturing costs and may not be required for the quality of the parts. By determining which dimensions are critical, only the most important tolerances are taken into consideration.

6. facilitate handling
Parts should be able to be assembled only in one correct duration. Asymmetry helps as an external guiding feature to avoid failures as a part can only be assembled in one way.
7. design for fixturing
8. design for ease of alignment
Variations in part dimension and accuracy that needs alignment need to be prevented to prevent error. Tapers, chamfers, and radius sizes are used to provide for an ease of alignment.

The bed

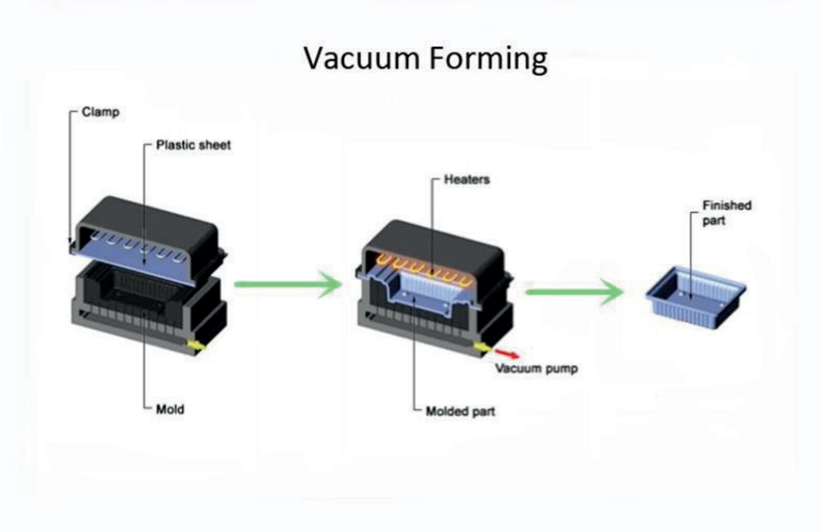
- Product that is prone to replace often, The mattress is a standard object, place it in a specific designed framework.

1. Design (adhere to design guidelines of the chosen core manufacturing process)
Trade-offs among manufacturability and a trustworthy aesthetic of the MRI dominate this review.

The system relies upon the MRI scanner headrest as a base plate that holds the head. This enters the head coil, while being strapped by the immobilization system.

The immobilization device and the headrest have been parallel been improved

2. Manufacturing process



Vacuum forming is the ideal manufacturing method for the mattress holder, due to the cost-effective process to produce low volume, large sized parts. No costly equipment and tooling are necessary to produce the large parts due to the low-cost moulds and ease of manufacturing large quantities.

Material are HIPS, PVC, ABS, PP PC, PEEK

The control for draft is created by the coefficient of thermal expansion of the plastic. As the part is held in the mould it is cooled below the set temperature. This temperature change can be anywhere from 100 to 300 degrees ºF (37 - 149°C) depending on the resin. This change in temperature combined with the coefficient of thermal expansion will cause the part to shrink. Draft also allows for better material distribution by opening a corner area to allow clearance for a plug assist to distribute material.

insert
Moulded in inserts is one of the most cost-effective ways of installing fasteners because the moulding process does all the work. The only added cost is for the insert. The part will take just as long to form whether there is an insert in it or not. The sheet acts as the bond that locks in the fastener. There is no need for glue or sonic welding of the insert. The use of bonded PVC blocks with a brass insert can also be prepared. The cost of the PVC, the labour to bond it in place, the cost of the adhesive, the labour to machine the block to the correct height and add a hole for the fastener or insert, all are substantial

3. Material choice

The choice of the material (a thermoplastic, **ABS+PMMA, ABS**) was made after analysis of the available materials and evaluation of the desirable properties. For the MRI scanner it is important that comfort, lack of photon build-up characteristics, smoothness of inner lining, fineness of moulding detail and ease of manufacturing and use are of importance.
Important trade-offs among the ease of use, moulding detail, structural strength, solidification and colling processes were important factors.

The headrest
The headrest must be attached to the mattress framework.

The mattress

Off the shelf
PVC cover good to clean

Head coil & immobilization device

The design freedom and the rapid manufacturing process, the ability to provide complex shapes is and the lack of needing investment cost allow the head coil and immobilization device to be manufactured through FDM. Since these are parts that are widely use inside the product and need frequent change due to the change of anatomy (4 sizes of head coils). Also, they are prone to break, so a quick replacement is necessary since the lack of the head coil would mean a non-operatable MRI scanner which is costly.

Immobilization device

The immobilization device is a 3D printed frame which is bendable and rigid enough to support the head. The head will be fixated by double straps that are tightened around the forehead nd the mandible of the patient. These stars are made of tight woven PP and secured with Velcro to minimize the workload of the MRI technician and to minimize the volume of the product, which is very important.

Over the 3D frame there is a layer of soft embedding cushion material. Over this cushion material there is a material that is soft and well cleanable

Appendix R Paediatric aesthetics for medical devices

Medical device for paediatrics patients

1. Trade-off between approachability and professional looks
2. Trade of between approachable and professional look and cost/manufacturability

https://www.medicalexpo.com/cat/pediatrics-N.html

As can be seen in the collage made from paediatric medical devices targeted to the youngest patients there has been made use of excessive bright colours. Recognizable shapes (animals, playful objects) and soft materials.

However, these product features will not be applicable for the design of a comfortable MRI scanner since, this will make the device look playful, but also childish. This diminishes the professionalism of the product, which will allow the MRI technician as the procurers to not take the device and its effectivity seriously.
Therefore, the design needs to be approachable, but professional.

- Within professional-looking medical devices, some features can be defined.
  The use of soft rounding's
  The use of soft materials, that are well cleanable
  The use of bright colours in a way that helps the use of the product.

Appearance of the MRI scanner

The aesthetics of the MRI scanner is primarily based on 'form follows function'. The interaction between the patient, MRI technician and caretaker is designed in a way that the MRI technician can have uninterrupted surveillance on the patient while operating the system and facilitating the interaction between the caretaker and patient. The positioning of the bed of the MRI scanner provides a comfortable position for the patient, while also being able to see its caretaker and being scanned at the same time. All electronics are placed in the housing and cabin of the housing to provide the least noise for the best imaging quality while providing the most space-efficient product lay-out.

Secondly, the aesthetic appearance was because patients, do not trust the big MRI scanners they will enter. Therefore, the product should be perceived as reliable and trustworthy.

Stakeholder importance
The MRI scanner is a product that has not only interaction with the patient, but with various key stakeholders within its equipment journey. The looks of the MRI scanner determine the perception of quality, functionality and has a predominant influence on the availability of the MRI scanner and the imaging outcome. The key stakeholders that are influenced by the appearance of the MRI scanner are the procurer, the MRI technician, the patient, and the caretaker. All the key stakeholders have different

priorities. The aesthetic feature of medical devices has a unique influence on paediatric patients as they become increasingly independent from parents and caretakes as they grow.

Patient
The patient is the most important stakeholder within this scenario. The appearance of the equipment is influencing the perception of the device and in the psychological comfort of the patient. As the current MRI scanner is now not harmonic and trust

Earlier research has shown that the patient needs a product that they can trust and that can comfort their mood. When looking at paediatric products, they show the same visual identity and mood.
- Round shapes
- colourful
- transparency though the visual effect

However, the other stakeholders have a high benefit on showing that the product is of high quality. The paediatric looks of the device might have a controversy effect

Procurer
For the procurer, it is important that the device shows trust and quality, as this is a factor that is of high priority in LMICs. A Qualitative product must look professional

MRI technician
According to interviews with medical technicians in LMICs, wanting to be considered professional and qualitative good is highly reliant on the equipment they work with. It does not only need to look qualitative good, but also functional as according to provide a convenient workflow. Trustworthiness, professionality, and quality are key for the MRI technician.
A professional and qualitative look is achieved by
- using materials that are robust, buttons that are big and highly visible
- Neutral colours
- Trustworthy: by providing an open view through the product lay-out.

The stakeholders and their requirements can be categorized in the meat, macro, and micro levels of product aesthetics design.

micro - details
The product needs to
- indicate the MRI technician how to slide the bed inside the bore
- Provide an intuitive process to align the head inside the head coil and immobilize the patient
- Have a well-balanced look of unity and details that indicate the user

macro - see the product as the whole
- The MRI scanner need a professional appearance to ensure the MRI technician and caretaker that they can rely on the product
- The MRI scanner needs to look robust so that the MRI technician , procurer, and basic technician can trust that the product will do its job and is not too fragile to break.
- design the characteristic to stand out to have a novelty
- Have a trustworthy look for the patient to be able to feel comfortable around the product instead of feeling suspicious.

meta - require scenario to get people to understand the product, fit into the whole system/market
- The product must look qualitative well and professional for the procurer to be convinced to buy the product.

Overall aesthetics
Other diagnostic devices were compared and analysed for their aesthetics.
By analysing the unity and variety of the product, the originality and typicality of the product could be assessed. The current MRI scanner has a mand-made look using different manufacturing processes and materials. By using 3D printing, bent sheet metal and wood, this causes to have an un-harmonic look.

Just like the medical devices in industry, a more unified look is achieved by presenting a whole shape, with rounded edges. A repetition of elements and details on the products create rhythm which contributes to the overall harmony of the product.
Additional features such a parting lines and colours aid in understanding the function and use of the product

As analysed, smooth surfaces, soft curves and a white colour help portray an appearance of cleanliness, which aids to communicate the importance of keeping the device sterile and clean.
By finding the right balance between typical and novel, a product can emerge that is able to be memorable and secure.
The LF MRI scanner has a unique form that helps it stand out, leaning toward the user to help show the chamber opens to facilitate sample manipulation. By having form, colour, and part lines that help communicate function to the user, this will make the product not only better aesthetically but also make it more user friendly.

Final friendly collage

- open > transparency
- colourful accents
- round shapes
- white and neutral colours
- integrated features

Deliver

Background research to define product requirements

Busines case

3. Context research

4. Technology research

5. Human Factors research

Implementation of LF MRI Scanner in Low and Middle income countries

MOT 9611 Health innovation and entrepreneurship
MTB Gieskes
4341260

Business case

An evaluation of the current linear-revenue model for the introduction of the Low Field MRI scanner in LMIC

Content

1. Introduction

Main thesis work

Around one-tenth of the world population has access to an MRI scanner, which makes the access of MRI scanners scarce in Low to middle income countries [5]. According to research of Marques [6], there are two main factors responsible for this phenomenon. (1) The high costs involved for the procurement, installation, and maintenance and (2) the complexity of operating an MR system. Therefore, the research group is introducing the low field MRI scanner. A cost-efficient, sustainable, frugal innovation-based, specifically to scan children with hydrocephalus, to increase the availability of MRI scanning in the world [7]. Through the implementation of permanent magnets, the MRI scanner can reduce its cost to be purchasable for Low-income countries.

The thesis project is focused on the development of a comfortable bed system for the low field MRI scanner.
MRI scanner is defined as a high performance/ high risk device where the maintenance is performed by specialised technicians through a service contract (Enderle, 2012) . LMICs have reported a shortage in these trained BMETs (Mullaly, 2003). However, since the medical devices in LMIC are maintained by BMETs with shorter training, or by untrained BMETS it can be beneficial to combine both approaches for the design of a high-risk device that can be repaired fairly easily by a moderately trained expert such as an BMET in a LMIC [5] .

The research group aims to increase the accessibility of the low Field MRI scanner through sales of the MRI scanner to hospitals as a start-up. Therefore, a new entrepreneurial venture project within an established organization has been the focus of this research.
Problem statement related to commercialization
The goal of the low field MRI scanner is to increase the accessibility of healthcare in low to middle income countries. Due to the lack of financial resources, the research team has provided an MRI scanner with 1/7th of the cost of a conventional MRI scanner. The aim of the research team is to sell the low field MRI scanners as a start-up to hospitals in low resource settings. However, questions arise such as Is this linear business model viable for a context with low financial resources and would a sustainable business model not be more suitable regarding the need of repair and maintenance within the MRI scanner?

Objective and deliverable

The objective of the thesis is to evaluate the viability of the current envisioned business model by the research group – soon to be start-up-.

The deliverable will be a value proposition, the current business model, an evaluation, and the proposed business model specifically for Low-middle income countries.

Research approach and framework

The research approach for the main thesis project was performed through the double diamond method. This method consists of 4 stages where the first stage (Discover) is to investigate the field. Here the main stakeholders and the contextual framework is defined. The second stage (Define) is to define the design challenge. The third stage (Develop) aims to explore design solutions and design for it and the fourth stage (Deliver) Is to test and deliver a final conceptual model of the solution.

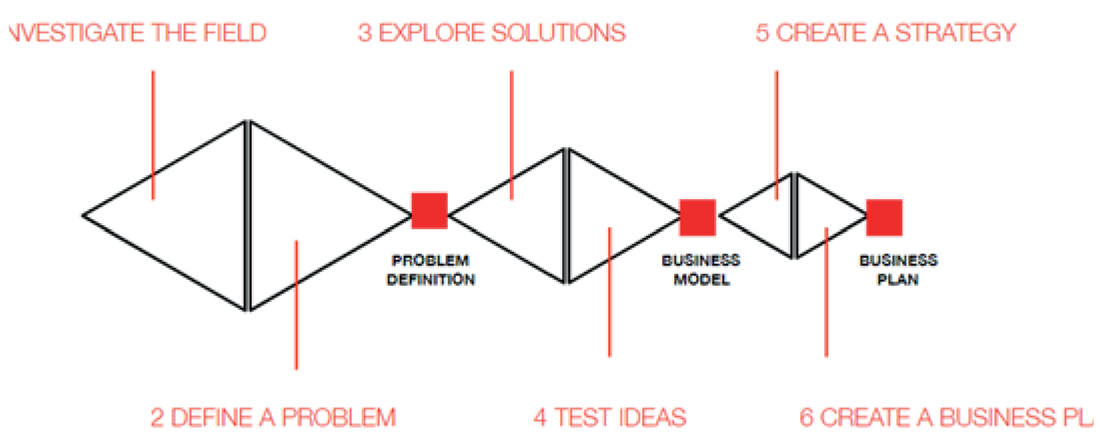
As result of the double diamond method, a conceptual model is introduced that focusses on solving the problems and values of the users (see value proposition). Eventually two diamonds are added which consist of creating a s strategy through a business model prior to creating a business plan.
The current business plan of the company is evaluated on its viability and laid against the contextual challenges occurring in the specific context.
A new business plan is introduced and proposed to the company of interest. Trough interview and discussion the opportunities and challenges from the business model are tweaked and a final business model is delivered.

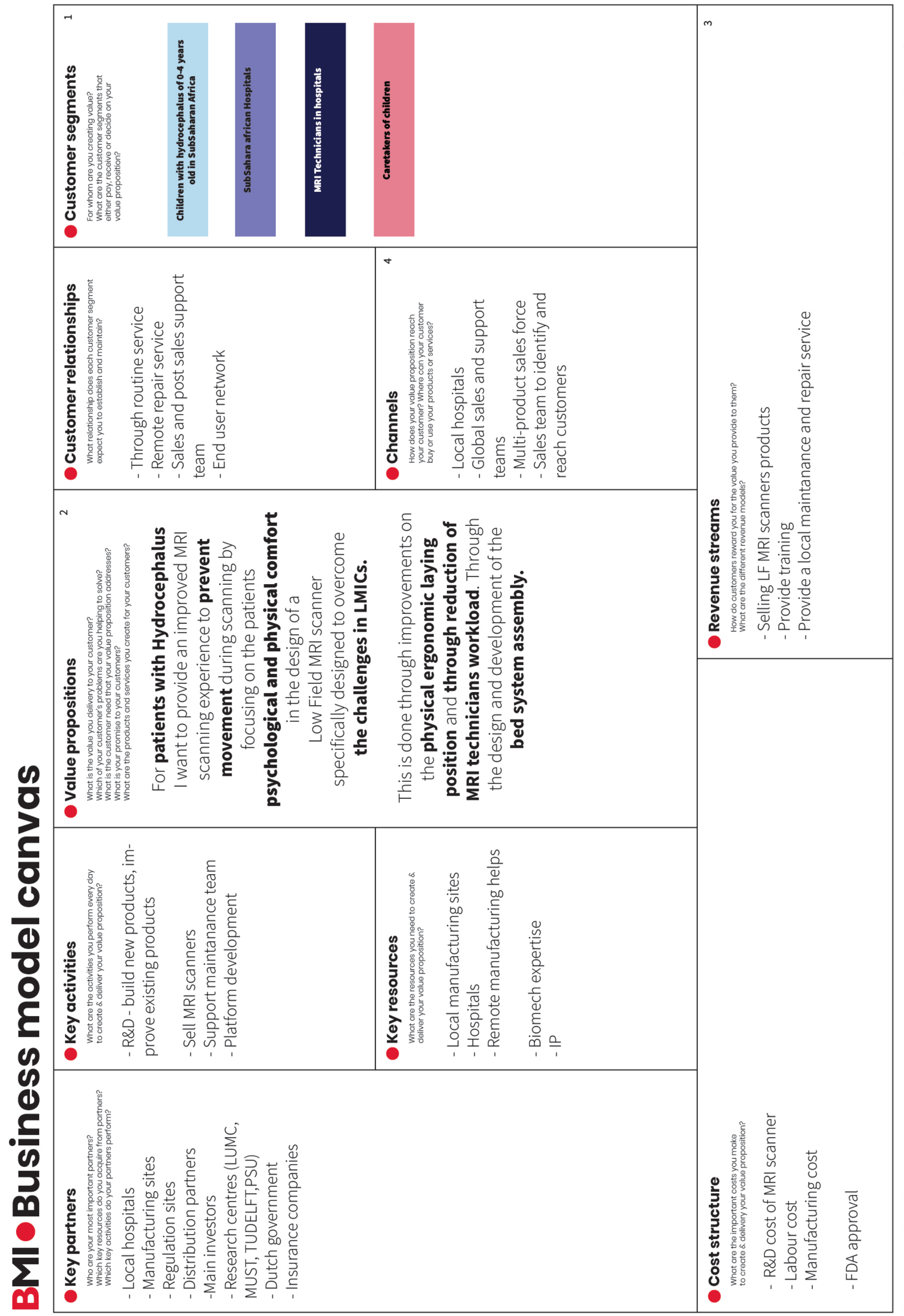
Main research question and sub questions

1. What is the current business model
How linear is the product? (Focused on, production, use , dispose)
2. What would the circular opportunity be?
3. What are the major challenges and barriers for the implementation of the lifelong business model?
4. What is the feasibility of the business model?

Methodology

The providing of high-quality healthcare as defined by the WHO is strongly linked to the context it is operating in. To create a system which optimises healthcare in the context by consistently delivering care that improves or maintains health outcomes, by being valued and trusted by all people, and by responding to the population's needs the intrinsic values motivation and opportunities need to be understood [12]. Therefore, extensive user and context research has been done to define the main stakeholders and their values. Based on the contextual framework, different business models have been researched and a circular business model has been implemented.





2. Business model Canvas

1.Value proposition
Lower cost - increased accessibility
The main value the low field MRI brings to the customers is visible in different ways. The most important value is the reduction of cost for the procurement of the low field MRI scanner in Low-Middle income countries. Since the lack of financial resources is the main barrier of the lacking if MRI scanners in lower resource settings, the low field MRI scanner provides a solution by using a permanent magnet (for a magnetic field of 50mT) instead of the super-conductive magnet (1.5T and above). This solution allows the cost of approximately 1.5 million dollars per Tesla to be reduced to approximately 50.000 dollars for the entire device.

User benefits
Secondly, the use of an MRI scanner is beneficial compared to the use of CT and X-rays due to the lack of radiation, which is a great risk for small children. Furthermore, the low field MRI scanner is specifically designed to improve the scanning experience to prevent movement during scanning by focussing on the patients' comfort. By improving the patient's comfort, the patient is less prone to move which indirectly improves the time efficiency of the MRI scanner by preventing unnecessary and costly repetitive scans done by the MRI technician. This results in the increase of access to healthcare for more people.

LMIC benefits
In addition the aim is to provide the ability to locally repair and maintain the low field MRI scanner, with the certainty of availability of spare parts, open-source software updates. This will increase availability in low resource settings.

The cost of the maintenance can be reduced by providing maintenance and usage training along the purchase of the device. Cost will be reduced by the hospital when the hospital is able to troubleshoot themselves.

Impact
The medical device has a direct impact on the current health care system by providing a lower cost imaging device which is acquirable for hospitals. This will allow the clinical centres to diagnose hydrocephalus and be able to provide surgery.
Furthermore, the patient centred design of the MRI scanner allows the patient to have an improved experience, which adds to the follow-up feelings. An anxious feeling during the first scanning has a negative effect for the follow-up meetings.
With the reduction of acquisition time and scanning time, the cost of one diagnosis is reduced. Due to the fact that patients pay the medical costs themselves, a shorter diagnostics time results in a more accessible treatment for potential patients.

2. Costumer Segment
The main costumer segment for the low field MRI scanner will be private and public hospitals in Low resource settings. This is addressing a B2B (business to business) market, with a product that lasts at least 5 years.
However for the calculation of Total addressable market (TAM), Serviceable available market (SAM), Serviceable obtainable market (SOM), the total of the hospitals in Uganda will be taken into account of 3772 public hospitals. The SOM is estimated by taking 10% of the total adressable public hospitals in Uganda in the first year. This will be around 37 operatable MRI scanners for a LMIC.

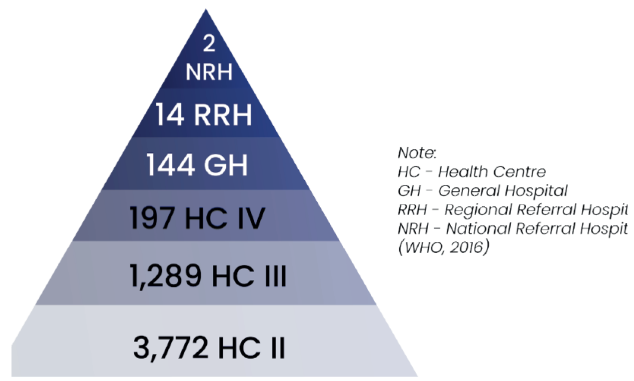


Figure 1. Public hospitals in Uganda (WHO ,2016)

Once the product has developed into a qualitative, reliable system the market can be broadened to hospitals in Sub-Saharan Africa, hospitals in LMICs and eventually small clinics in HICs.
In the future the product has developed further and has reached an adequate quality to enlarge the bore and use the low field MRI scanner for small clinics in HIC.

3. Key partners
•Research centres:
o Leiden University Medical Centre (LUMC), Netherlands
o University of Technology Delft, (TUDelft), Netherlands
o Penn State University (PSU), USA
o Mbarara University of Technology (MUST) , Uganda

•Subsidies
o Dutch government

•Local hospital
o Cure hospital, Uganda
•Ministry of Health Uganda
•Producing companies
•Insurance companies
•Production companies
•Distributing partners

4.Channel
In order to make sure the equipment will be procured in governmental hospitals, it is necessary the National Advisory Committee On Medical Equipment (NACME) advises the ministry about the low field MRI scanner. Since most of the Ugandan hospitals are governmental, this is a large share of the equipment in the country.
Furthermore the UNBS and NDA are responsible for the approval and certifications of the equipment in the country.

5.Key Activities
The key activities necessary to be executed to ensure the value proposition to be met for the stakeholders are listed below.

The entire life cycle of the product (from idea to end of life) needs to be considered. After the R&D the responsibility of the MRI scanner is held over to the procurer.

Within the R&D the activities are

- Development
- Clinical Trials
- Patenting
- Production

Furthermore other activities are
- Certification
- Training
- Distribution
- Maintenance
- Marketing

To ensure client value and a community build-up, a platform development is necessary.

6. Key resources
The key resources of the company will be intellectual property of some parts. Furthermore, the main production will be outsourced and open source. However, moulds of the thermoforming parts will be part of the physical resources.

7. Cost structure
The main costs are a result of the R&D cost, labour cost and regulations and FDA approval. After the procurement stage, marketing and continuous labour for the maintenance will remain the largest cost.

8. Revenue streams
The top three revenue streams will be from the selling of the MRI scanner. Furthermore, the maintenance service will be a top revenue. The cash flow is required to maintain the business and to grow the business. The incomes are mainly achieved by selling the MRI scanners. This includes the maintenance and training service. The different revenue streams are: - One-time fee through asset sale when the MRI scanner is purchased.

2.2 Local production or importing
Following the research of minor Frugal Innovation, the choice has been made for local production of the MRI scanner in the country. This allows the standards and certifications to be acquire locally. During the design and development, the parts have been designed to not meet a high production tolerance. Therefore, it is possible

Figure 2. Render of low field MRI scanner

Figure 3. Cure hospital in Uganda

to produce the majority of the parts locally without needing of high advanced equipment or high investment costs.

3. Evaluation of current business model

The goal of the introduction of the low field MRI scanner is to increase the accessibility of healthcare to people in LMICs. However, to maintain to do this, the business should also have a sustainable business model in order to provide such a product or service.

3.1 Linear business model

The current business model follows a linear approach where the MRI scanner is designed, purchased, (re-)used and disposed. This linear approach has a negative effect for the environment as the highly finite supplies of resources are disposed and release toxic waste, while parts and components still can maintain their value. In a HIC, such a revenue model relies on marketing and sales of new iterations of the product. Due to the lack of financial resources in LMICs, such a business model would only be sustainable with financial aid from governments and subsidies, donations, and insurance companies.

The one-purchase business model makes the entire revenue model relying on the sales of the product. Revenue streams are not viable when the main barrier remains the financial resources in LMICs.
This linear approach is not sustainable and therefore needs to be reconsidered by a business model where the materials maintain their quality and continue to be useful.
Furthermore, a reconsideration of a circular model also introduces the possibility to have a continuous cash-flow.

Customer relation

The MRI scanner is marketed with the focus of fulfilling the customers' needs by sales of the product. This offers the user a high-quality product, however once the users have reached their goal. The relationship with the customer is ended.
A lot of attention is made in gaining potential customers and marketing, but no effort is put in maintaining the relationship with this customer. When considering a circular financial model, the customers may maintain the relationship though the contractual service.

3.2 Sustainable business models contribute to long-term financial viability

Long lasting product and business model

The most significant difference between 'sell more, sell faster' and Long Life and Access design strategies is the (planned) lifetime of the products. 'Sell more, sell faster' aims to replace products as soon as possible, whereas Long Life & Access focus on durability and long-lasting products. This includes using cheaper material (low costs) versus high quality materials and robust structure (long use). Long Life & Access try to make components repairable by making parts replaceable. In those models' loops are closed, especially the tiniest loops (re-use and maintenance) are favourably used to extend a product's lifetime. The low field MRI scanner has a great potential to be introduced in a long life and access business model. The design-characteristics have great potential due to the offer of a qualitative, long lasting, modular product which is designed to be maintained regularly.

4. New Business model Canvas

A proposition for a more durable and viable business model flows a low income country would be to investigate to opportunities for a circular economy model. This aims to keep products, components and materials at their highest utility and value always. It increases business growth by engaging and retaining customers through a circular business model and it provides new growth opportunities by making use of residual value of products and components.

The saving cost is increased by lowering the BOM cost, through re-use of products and components. The obsolete components will remain inside the company and maintain its value or down cycle for other parts. Cost is decreased by stimulation of market availability through usage of recycled plastics.

New opportunity

The long life and access business model will take form in terms of a new revenue model with additional plans. From purchase only to lease the product. The company will not solely sell the product, but they will also offer a service for the use of the low field MRI scanner. This includes all additional maintenance, repair and upgrade of the product. A monthly plan to get access to software updates for a low monthly fee. They will not only pay for the product, but for the routinely maintenance, which allows a longer use of the product.

This also forces the customer to return the product to the manufacturer so the company can refurbish the components in the product (nothing gets thrown away but replaced and the replaced items stay at the company).

Fit for LMIC

Such a long-lasting strategy could be viable for LMIC, since it does not require a high investment cost from the procuring hospital. Challenges arise during the introduction of circular business model by trying to maintaining a constant cash flow. The cash flow is dependent on the incoming patients which is not a constant factor. Furthermore, the cash flow for the producing company requires a high investment for the first stages. Due to the small but steady amount of cash income, the break-even point is reached later in time. Profit might also be less relevant in the first stages of introduction.
Besides the financial benefits and challenges, the offered maintenance service can be provided by training local technicians. Community building will expand the accessibility of such a service.

Potential fit of long life and access models and LMIC

A positive consequence of Long Life and Access models is the shift of responsibility for product repair and disposal from consumer to manufacturer. The earlier the product fails, the higher the costs will be for the manufacturer, because of repairing costs. This means the product will probably last longer and a maintenance service is provided by the company. Both are advantageous for the customer. The using comfort is higher because of reliance on a durable product and on repair after failing. The customer also feels more appreciated by the company because of the services they receive. This is an example on how this shift in responsibility makes the needs of the customer identical to the needs of the manufacturer, which leads to a stronger relationship between customer and manufacturer. This could translate into a positive effect on the sales as the manufacturer is so involved with its customers.

Acceptance

Going from owning a product to having access to a product, may not always be well received by the customer. A Long Life and Access model obviously will lead to less waste, because instead of throwing out the whole product once it's broken, just the parts will get replaced. The customer relationship will be promoted through post-transactional processes. Through the service minded process, the customers are helped with potential problems and questions. Through digitalization, the customer can always rely on the service of the company.

Customer relation

This innovation will improve the experience of the customer in a way that the customer will pay for a scanning experience. The customer will pay a monthly fee where they pay for the product, the service and maintenance and a hardware upgrade after couple of years. The company will get their main revenue from the monthly fee the user is paying. In this way the user will not have to worry about a product getting broken anymore.

What would the system require that doesn't currently exist?

To ensure continuous accessibility to maintenance, a community of service and trained technicians that are locally available should be present. This could be achieved by providing basic training with local technicians through the open-source platform which can be accessed through the plan. In this way there is always a local technician available can repair the product.

The partnerships need to be sustained for this to work well. Challenges could occur in the costs for keeping the products functioning. The company will not receive high amounts of money at once but will now get a more constant flow of revenue. This change together with the new logistics of refurbishments could be causing some challenges, especially In LMICs where logistics already a great barrier for the accessibility is.
Other challenges that may persist would be :

- The collaboration between the different parties
- Insurance of products
- Shifting from a product oriented to a service-oriented company
- The logistics behind the leasing system

Growth potential

Once the product proves its quality, the development can continue in growing for the HIC, which pay a small amount of the purchase for the low field MRI scanner in LMIC.

5. Conclusion

The low field MRI scanner adds value to the current healthcare system in LMICs by improving the diagnosability of hydrocephalus. This improvement is mainly done by providing a low cost system to overcome the finanical burnder of procuring such a system. The system is envisioned to be sold to healthcare systems. However, in order to provide a sustianable business, a stable revenue model is required which need to sel as much as possible. This revenue model might be sustainable for high income countries, but might present challenges in an environment with financial difficulties. Therefore a suitable revenue system and needs to be presented in order to have a sustaining(long lasting) business model that can offer the patients a functioning MRI scanner when needed.

Additionally, the main concern of the low field MRI scanner for a sustained use, is the lacking of reliable maintanance system.

The gap between the revenue system and maintanance system can be closed by the opportunity of a sustainable and circular business model.

The circular business model can be presented as a lease model, which offers the use of the system for a small periodically contribution. This contribution offers the use of the system, but also the maintanance , repair and disposal of the system. In this case the expensive materials persist inside of the use cycle, and product obselence can be prevented by timely service.

In contrast to the lineair business model, the circular business model asks a small amount of money to hospitals in low income countries. This may increase the number of hospitals egible to offer this specific care in the hospitals.

List of requirements (Design Traceability Matrix)

Subject	Low field MRI scanner
Project Code	LF.MRI
Date created	01.12.2020
Date last saved	27.02.2022
Author last saved	Maite
Revision	R00

requirement known, value known
requirement known, value unknown
requirement unknown, value unknown

Requirement met
Requirement partially met, room for optimization
Requirement not validated , partly met
Requirement not met

	1. General requirements						Features					Design Verification			
	(user needs, intended use, and others)	(document, background)	Type/ System / Assembly		Rating	Features	Possible specification for	V&V	Design Input		Design V&V	(output meeting input)			Rationale for justification of design Output (if not matching design input)
ID	General requirement(s)	Source	Part of system	Rationale			What features facilitate this			Ref		Assumption or verified?	Validation Method	Acceptance criteria	Validation Rationale
	1. General requirements														
1.1	The device must be affordable and not cost more than competing models ($50,000 Hyperfine 64mT)	(Malkin, 2007)	system design and material choice	Financial barriers are are one of the most prominent barries for the lack of medical device accessibility on LMIC			permanent magnet. No need to do repetitive scans due to comfortable design					Assumption	Not validated		Requirement partially met, room for optimization: The entire MRI system is designed to be as robust as possible, with low cost components. However the cost could not be estimated.
1.2	Low in cost of ownership	(Malkin, 2007) , insight interview L. Gieskes	system design and material choice	(When the healthcare facility acquires the medical device, the patient would have to pay the cost per treatment. To keep the cost of treatment affordable for the patients to afford.)			Robuse and local low cost materials are used					Assumption	Not validated		Requirement partially met, room for optimization
1.3	Low in cost of maintenance	(Malkin, 2007) , insight interview L. Gieskes	local maintanance	For the device to be able to be used not only once, but multiple life cycles, the product must be able to be repaired and maintained in Uganda.			Robuse and local materials are used					Assumption	Not validated		Requirement partially met, room for optimization
	Long lasting products - design for sustainability														Requirement partially met, room for optimization
1.5	Product must be designed to last at least 5 years long	Interview Dr Johnes O.	Full system	(Accessibility in LMIC can be increased by allowing a better repair and manufacturability. However, since this is highly dependent of the infrastructure, which is not yet fully developed, it is beneficial to focus on the longer lasting of the device			Component design and integration: No fragile components, Translating and moving mechanisms have been reduced. Electronics have been reduced to the minimin					Assumption	Designed to meet requirements, however not tested.		Requirement met : 1.The device is designed to be robust 3.The moving parts are limited 5.The is maintainable with minimum number of required tools and supporting equipment. Standardized equipment is only needed
1.6	The device must be robust	Interview Dr Johnes O. L.Gieskes interview,		To increase the durability of the device and decrease the chance of obsolete parts due to fragility, the robustness of the device is required.								Assumption	Final prototype testing		Requirement met
1.7	The head immobilization system must be able to withstand an opening and closing of the headrest for 100 patients a day	User test , Cure hosptial	Head coil and immobiliser	Aproxiamately 100 scans a day are acquired.			durable mateirals					Assumption	Final prototype testing		Requirement not validated , partly met : the head immobiliser is designed with durability in mind. However, the ability to perfom is not tested nor evaluated
1.8	The moving parts within the medical device must be decreased.	Ger de Kok (SIEMENS maintanace)	Entire system	The parts that move are prone to break and should therefore be decreased			minimal use of moving parts						Final prototype testing		Requirement met
1.9	The device must be designed to have minimized failure rates in the system and the corresponding modes of failure.	Ger de Kok (SIEMENS maintanace)	Entire system	not designed for											Requirement met
1.10	The device must be able to be maintained with minimum number of required tools and supporting equipment	Ger de Kok (SIEMENS maintanace) (Malkin,2007)	Entire system	A barrier that prihibits the accessibility of medical devices in LMICs is the lack of spare parts and tools. By providing the ability to locally repair the device, the part will not have to be obsolete.			standardized parts (screws) and off the shelf components (matress)					Assumption	Final prototype buidling		Requirement met :The assembly is able to be done with locally acquirable materials, production methods of off the shelf parts
1.11	**Durability in challenging environment**														Requirement met
1.12	Parts within the medical device must be standardized and facilitate interchanebility between mating components	(Barlow ,2018)	Connections	The assembly of parts is eased when the mating of parts are taken into consideration in the design process									Final prototype buidling		Requirement met :The assembly is able to be done with locally acquirable materials, production methods of off the shelf parts
1.13	**Repair and maintenance - design for repair and maintenance**														Requirement met
1.14	a) The device must be locally maintainable	(Barlow ,2018)	used parts and materials	The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)					Assumption	-		Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.15	The device should be designed to have a reduced number of part and assemblies including redundant components	(Barlow ,2018)	used parts and materials	The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)					Assumption			Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.16	The medical device must label components for quick mating of parts	(Barlow ,2018)	used parts and materials	The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)					Assumption			Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.17	b) The medical device should allow availability of troubleshooting and maintenance procedures, checklists, and instruction documentation	(Barlow ,2018)	used parts and materials	The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)					Assumption			Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.18	The medical device should be able to maintain by using generic parts that are easy to access	(Barlow ,2018)	used parts and materials	The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)					Assumption			Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.19	**Spare parts and consumables**	(Barlow ,2018)		The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)					Assumption			Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.

1.2	Medical devices must be designed with repair and maintenance in mind. this includes the accessibility of the spare parts.	(Barlow ,2018)		The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)				Assumption			Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.21	a) Parts within the medical device must be standardized and facilitate interchangeability between mating components	(Barlow ,2018)		The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)				Assumption			Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.22	b) Maintenance tasks of the medical device should be able to be done with standard hand tools available.	(Barlow ,2018)		The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)				Assumption			Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.23	c) The device must be able to facilitate quick removal and replacements with minimum tools	(Barlow ,2018)		The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)							Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.24	d) Spare parts needed for the maintenance of the medical device must be available at an affordable price	(Barlow ,2018)		The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)							Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.25	e) The medical device must be designed by considering the accessibility of only standardized parts to provide cost-effective repair and maintenance	(Barlow ,2018)		The medical device is not usable anymore once it gts obsolete due to the lack of personel, maintaninbility faiclities and parts			standardized parts (screws) and off the shelf components (matress)							Requirement not validated , partly met: The device is designed for local maintainability and repair. However this is not tested on site yet.
1.26	**Accessible for population**													
1.27	The device must be affordable and not cost more than competing models ($50 000)	Market research	Full system	The main barrier to the availability of medical devices in LMIC is due to lack of funds. The Hyperfine cost $50 000 for a 64mT portable MRI system			Cost effective magnet system:The components are designed to be cost-effective to purchase, durable or locally manufacturable.				Assumption	Cost analyis		The all designed systems have been designed to be met by implementeing cost effective components, the use of durable materials, the use of robust materials.
1.28	For the device to be able to be used not only once, but multiple life cycles, the product must be able to be repaired and maintained in Uganda.	Market research	Full system	Furthermore, when the healthcare facility acquires the medical device, the patient would have to pay the cost per treatment. To keep the cost of treatment affordable for the patients to afford			Stardardized tool for the framework and the embodiment					Final prototyping		During the final prototyping, only standardized tool are used to manufacture the prototyping.
	Accessible for users													
1.3	a) The maintenance tasks of the medical device should be designed to the skill and motivation level of an average technician. Tasks should be such that no more than two technicians are required for accomplishment.	Interview Cure hospital		Most MRI scanners in LMICs are obsolete due to the lack of knowledge of repair. Most skilled mri repairers are not availabile in remote areas. So the job must be able to be done locally			Stardardized tool for the framework and the embodiment. Easy assembly which can be done by any personnell					The skill level of a MRI technician from a LMIC has not been researched thorioughly. Interviews from skilled MRI technicians in LMICs have been made and insights have been implemented in the design		Requirement not validated , partly met : The design consist of usecues that help the MRI technician guide through the process. However no test have been performed to validate if the design is according to the skill level of the MRI technicians.
1.31	b) Design user cues to guide the repair of the machine right away	User test		Most MRI scanners in LMICs are obsolete due to the lack of knowledge of repair. Most skilled mri repairers are not availabile in remote areas. So the job must be able to be done locally			Stardardized tool for the framework and the embodiment. Easy assembly which can be done by any personnell					The skill level of a MRI technician from a LMIC has not been researched thorioughly. Interviews from skilled MRI technicians in LMICs have been made and insights have been implemented in the design		Requirement not validated , partly met : The design consist of usecues that help the MRI technician guide through the process. However no test have been performed to validate if the design is according to the skill level of the MRI technicians.
1.32	e) The medical device must match the knowledge level of the basic trained personnel	Interview Cure hospitla		Most MRI scanners in LMICs are obsolete due to the lack of knowledge of repair. Most skilled mri repairers are not availabile in remote areas. So the job must be able to be done locally			Stardardized tool for the framework and the embodiment. Easy assembly which can be done by any personnell					The skill level of a MRI technician from a LMIC has not been researched thorioughly. Interviews from skilled MRI technicians in LMICs have been made and insights have been implemented in the design		Requirement not validated , partly met : The design consist of usecues that help the MRI technician guide through the process. However no test have been performed to validate if the design is according to the skill level of the MRI technicians.
	2. Use requirements													
	8. Installation													
2.1	The device must contain a handle or wheels to be able to be portable	User test	Bed system and magnet system	For an increased portability, the bed and magnet system need to contain handles for carrying and wheels for pushin			Not inserted				assumption	Not met		Requirement not met
2.2	For the installation the maintenance needs to be placed in such a way that the general technician can repair and maintain the MRI scannr	L. Gieskes 2020 (Hospital Clinic St Marie), Danny de Gans 2021(DEMO), Ger de Kok 2020 (SIEMENS)	Connections	Full system design and integration of parts: he device should be designed to have a reduced number of part and assemblies including redundant components			Modular parts and off the shelf standardized parts				Validated	Prototyping		Requirement met: The prototype of the bed assembly could be produced by using standardized tools (or replaced by standardized tools)
2.3	The device must be able to be portable with 4 people (max. 200kg)		Material choise, amount of components	The flooring of the hospital ward is not very strong. Furthermore, the personell must carry the MRI scanner into its position							Validated	Calculation solidworks materials		Requirement not validated , partly met: the Magnet system weight 70 kg, and the aluminum bed system weight approximately 35 kg.
2.4	The device must be able to fit though a standard door(width) (max. 720 mm).	Interview Dr Johnes O.	Width of the MRI system								Validated	Measurement of prototype	max 720 mm	Requirement met: the width of the bed system is 35 cm.
2.5	**9. General**													
2.6	The aesthetics of the device must trigger a feeling of trust with the procurers	Aesthetics research, Interview Dr. Johnes	Embodiment design of system.	The procurer value a qualitative and professional look on the product.			White casing around the framwork. No cables showing				Assumption	not validated		Requirement not validated , partly met : The device is designed to have professional look. However this is not tested nor verified
2.7	The aesthetics of the device must make the baby feel calm (less intimidating).	Aesthetics research, ViP	Embodiment design of system.	The look of the device can frighten the patient			The white and rounded surface. Soft and shiny finishing.				Assumption			Requirement not validated , partly met : The device is designed to have professional look. However this is not tested nor verified

2.8	c) A system that is understandable and usable for people with minimal training	Interview Cure hospital	Use cues	The MRI technicians with minimal training must be allowed to provide care without hesitation or doubt	An intuitive workflow where the normal workflow of the MRI technician is not disrupted. Furthermore all the parts that required holding or gestures have an additional colour or indicative shape		Assumption	User test with final prototype and trained technician		Requirement partially met, room for optimization: Tested with a trained MRI technician and not with a basic trained technician. The requirement is met. However some gestures require extra instruction, such as the swaddle blanket
2.9	f) The personnel must be able to see and monitor the infant during scanning	Interview Cure hospital	Device architecture	No additional camera is added for seeing the patient. Therefore the MRI technician needs to be able to monitor the patient by own sight and vital monitoring	The double mirror and the ability to stand next to the bed		Validated	Final prototyping and user test		Requirement met: The MRI technician is able to see the patient while scanning.
3	**10. Use by MRI technician**									
3.1	a) The MRI technician must be able to operate and align the head of the patient in a maximum of 5 steps.	User testing and observation	Bed system	The current installation of the patient requires multiple steps (12+) . To have a significant improvement in the workload a decrease of steps is provided.	All the accesoires are attached to the bed system		Validated	Final prototyping and user test		Requirement met: Only 5 steps are required to instal the patient. Once positioning the patient in the bed, the MRI tehcnician only needs to sexure everything. Alingment and comforting is not necessary anymore.
3.2	d) The patient must be able to be monitored (heartbeat, breathing, saturation)	Cure Hospital	Additions on bed system	The patients get monitored for their vital signs	not designed		Assumption	out of scope		Requirement not met
3.3	**. Use by Patient**									
3.4	a) The medical device should prevent the patient from moving during the entire imaging sequence for (2 mm , 10 min)	(Oreilly,2020)	bed system	movement causes distortion. 2 mm is that spatial resolution	Comfort is promoted to minimise discomfort - head immobiliser minimised the additional movement		Assumption	comfort is subjective and can hardly be validated or tested.		Requirement met: The comfort is promoted through promotion of physical comfort and psychological comfort. Head immobiliser minimises the additional movement.
3.5	b) Enables correct positioning and aligning of the child on the bed	User test	bed system	to easen the task of the MRI technician	The bed usecues	Colour indications on the part s	Validated	final prototyping		Requirement met: The bed usecues allow the MRI technician to position the patient on the exact good position of the bed.
3.6	d) The device must prevent and restrict any sudden movement of the limbs and head of the patient	Observation	bed system	Movement of the limbs can cause the head to move	Swaddle blanket, head immobiliser		Validated	final prototyping		Requirement met: the swaddle blanket prevents movement of the upper and lowe limbs
3.7	**Comfort**		bed system							
3.8	f) The device must eliminate physical discomfort on the body of the patient	(Zhang,1996)	bed system	Discomfort is the largers reason for the patient to move. To prevent discomfort the patient is positioned in a comfortable evironment	Concave bed, swaddle blanket, double mirror,		Validated	final prototyping		Requirement met: The concvave bed support the shoulders and the doughnut area of the head rest support the neck
3.9	g) The device must enable the patient to remain a correct static posture-	(Zhang,1996)	bed system	a bad static posture provides muscle strain	concave bed and neck support		Validated	experiement with infants of 0-6 years old		Requirement met: The concvave bed support the shoulders and the doughnut area of the head rest support the neck
4	h) The bed must support the natural curvatures of the spine, paediatric patients to not have a double S shape, but rather a C shape.	Comfort research	bed system	a bad static posture provides muscle strain	concave bed and neck support		Validated	experiement with infants of 0-6 years old		Requirement met: The concvave bed support the shoulders and the doughnut area of the head rest support the neck
4.1	b) The device should facilitate patient caretaker interaction in the diagnostic process	Comfort research	bed system	double mirror			Validated	final prototyping		Requirement partially met, room for optimization: the double mirror facilitates the interaction between patient and caretaker. However, this effect is not vlaidaed with end users
4.2	**13. Repair**									
4.3	a) All components that require frequent repair or replacement must have visual feedback	Ger de Kok (Siemens maintanace)	Electornics	The electronics should indicate to the MRI tehcnician when a component is obsolete and when this is in need of maintanance	modula design of device					Requirement not validated , partly met
4.4	b) The measurement areas need to be well visible	Ger de Kok (Siemens maintanace)	MRI system	The electronics should indicate to the MRI tehcnician when a component is obsolete and when this is in need of maintanance	modular design of device					Requirement not validated , partly met
4.5	Tools and replacement objects and components need to be standardized	Ger de Kok (Siemens maintanace)	MRI system	The electronics should indicate to the MRI tehcnician when a component is obsolete and when this is in need of maintanance	modular design of device					Requirement not validated , partly met
	3. Functional requirements						Validated			
	3.1 Total system									
3.1.1	a)The system must be able to operate at temperatures between 10 and45C and 0–90% relative humidity	Research barriers and failure of medical devices in LMIC	Magnet system	For its durability	chosen materials and the implementation of a inner and outer framework		Assumption	reuirement met by design but not tested nor validated		Requirement not validated , partly met
3.1.2	b)Casing made from 100% non-absorbent material	Research barriers and failure of medical devices in LMIC	Embodiment design of system.	For its durability			Assumption			Requirement not met
3.1.3	c)No ferromagnetic or metals can enter the bore of the magnet or may be in a proximity of 100mm of the bore opening.	(O'Reily, 20200	magnet system and bed system	This may distrort the imaging and the magnet			Validated	Final user testing with prototype and with magnet		Requirement met : During the final test where the bed system prototype was paired with the magnet system, the bed system was checked on magnetic components

3.1.4	d)The device must be resistant against high ambient dust in rural operation theatres and a possible drop of water on the exterior (IP54)	Research barriers and failure of medical devices in LMIC	entire system	The mechanics and the magnet system are the most critical parts and decrease in durability once the system is in cotact with dust and humid			seal of rubbers and trespa. Double framework						Assumption	reuirement met by design but not tested nor validated		Requirement not validated , partly met . The double framework allows as much as dust and humid to stay out of the inner framework with the critical components.
3.1.5	e)The bed system must be attached and detached on the magnet table	Co-creation session, concept review	bed system	to insure easy installation provided by the tehcnicians			docking system with latch						Validated	Final user testing with prototype and with magnet		Requirement met
3.1.6	f)The electronic components must run from standard power outlets and ultimately battery/solar/diesel-powered.	Co-creation session, concept review	electronics	To keep operating during power outlets									Assumption	reuirement met by design but not tested nor validated		Requirement not validated , partly met
3.1.7	g)The temperature inside the magnet should stay stable (drift less than 1 degree per hour)	(O'reilly,2020)	magnet system	causes noise									Assumption	reuirement met by design but not tested nor validated		Requirement not validated , partly met
3.1.8	h)No tensile force is allowed at the electronics especially not at the soldering part and the circuit of the head coil	Co-creation session, concept review	magnet system	Forces on the magnet cause distrotion of damage the magnet			sliding mechanism and table top						Validated	Final user testing with prototype and with magnet		Requirement met: No force or weight from the patient is exertd on the magnet due to the table op design and railing system
3.1.9	i)The transferring forces from the patient to the bore to the magnets must be as minimal as possible	Co-creation session, concept review	magnet systrm	Forces on the magnet cause distrotion of damage the magnet			sliding mechanism						Validated	Final user testing with prototype and with magnet		Requirement met: No force or weight from the patient is exertd on the magnet due to the table op design and railing system
3.1.10	j)The device must restrict movement of the patient inside of the MRI scanner	Co-creation session, concept review	magnet sysdem	Forces on the magnet cause distrotion of damage the magnet			head immobiliser							Experiement	3 mm in 3 DOF	Requirement met
3.1.11	k)Non sedative MRI scanner requires a head stabilizing product so that the child can be contained	Comfort research	magnet syssem	The motion of the child head must be restricted			head immobiliser							Experiement	4 mm in 3 DOF	Requirement met
3.1.12	l)A cooling fan inside the electronics casing is required.	Co-creation session LUMC	cooling	the magnet and the electronics need to have the same temperature									Assumption	reuirement met by design but not tested nor validated		Requirement not validated , partly met
3.1.16	The system must be able to operate at temperatures between 10 and45C and 0–90% relative humidity	38], [1], [21], [31],[46]	Casing	Climate in Uganda nad environmental characteristics of the hospital ward.												
3.1.17	The device must be resistant against high ambient dust in ruraloperation theaters and a possible drop of wateron the exterior (IP54	38], [1], [21], [31],[46]	casing	The context it operates in has a lot of red dust			The context it operates in has a lot of red dust						assumption	Not validated		Requirement not validated , partly met
3.1.18	The bed system must be attached and detached on the magnet table		A docking system for the bed that goes inside the rack. Furthermore there are clamps that are attachable and detachebal	The connection between the both systems must be simple and stupid. Both systems must be well lalligned and fixed in the x and y direction.			A docking system for the bed that goes inside the rack. Furthermore there are clamps that are attachable and detachebal									
3.1.19	A simple air fan cooling is required	O'reilly, Teeuwisse W, 2021	A simple air fan inside the system	Because we do not need very high currents to achieve the desired spatial resolution (~3 mm,) high currents are not nec-essary, and the maximum voltage (15 V) is chosen such that simple air-fan and heatsink cooling can be used.			A simple air fan inside the system									
3.1.20	The housing must be imapct resistant		magnet sysmum													
	3.2 Sub system system : Magnet subassembly															
3.2.1	No magnetic materials may be used															Requirement met
3.2.2	The tranfering forces from the patient to the bore to the magnets must be as minimal as possible	Interview Tom O'reily	Rails system in the bore				Rails system in the bore									Requirement met:Forces acting on the magnet are highly not desired and distort the immaging.
3.2.3	The temperature of the magnet need to stay contstant															Requirement not met
	3.3 Sub system system : Bore															
3.3	**The head of the patient needs to be exaclty in the middle and cocentric of the magnet**	Oreilly(2020)	Bore and Magnet	The best homogeneity of the magnet is in the middle of the bore inside the field of view.			The head and shoulders of the patients need to be able to be inserted inside the bore							testing , prototpying		Requirement met: The positioning of the tabletop provides a fixed position of the head coil. Which is always in the field of view.
	3.4 Sub system system : Headcoil															

3.4.1	a) The product must allow the different head circumference of the child to be adapted.	Ideally according to all radiologists and MRI technician	Head coil assembly	The maximum head cicumference of children with hydrocephalus that has occured in the CURE hospital is 65cm circumference P99. The P5 is 50 cm and P95 is 60 cm(20 cm headcircumference). The mean head circumference of the head is 55cm.		Verivied			Requirement met : 5 Headcoils are provideed to be fitted on the most frequently occruing head sizes
3.4.2	The headcoil must be lightweight	Experience test inside MRI scanner	Headcoil			Verivied	Measurement	under 4kg	Requirement met: the 3D prnted headcoil with wires is approximately 1.5kg (print density 20%)
3.4.3	The headcoil must be easy to maintain	Observation and user testing	Headcoil			assumption			Requirement not validated , partly met
3.4.4	The headcoil must cover over the eyes to be able to image the entire brain	Oreilly(2020)	Headcoil	The headcoil needs to cover over the eyes to be able to image the entire brain.	Headcoil over the eyes, and the opening in front of the eyes so that the patient can see	Verified	Comparision of head coil cover with anatomical images of paitent with hydrocephalus		Requirement met : the headcoil has the shape to cover the entire brain for proper imaging
3.4.5	The headcoil must be able to receive and transmit RF pulses to and from the magnet	Oreilly(2020)	Headcoil			Verified	Testing at LUMC		Requirement met
3.4.6	The head of the patient must fit as close as possible inside the headcoil	Oreilly(2020)	Headcoil			Verified	Mockup buidling		Requirement met: The head coil fits tightly against the head of each patient due to the 5 different sizes and the minimal volume of the head rest and immobiliser
3.4.7	The headcoil must restrict movement of the head with cushions	Experiment	Headcoil			Verified	Experiement		Requirement met
3.4.8	Once the MRI technician has positioned the child, the headcoil must be attached to the bed system	Observation mockup testing	Headcoil	The head coil needs to rest its weight on the bed nd not on the bore. This prevents any force to be transferred inside the bore to the magnet.		Verified	Mockup buidling	Can it be done or not?	Requirement met : a small button attachement allows the attachement of the headcoil to the mattress
3.4.9	Once the scanning is done the head coil needs to be able to be detached from the bed system with only one gesture.	Observation mockup testing	Headcoil			Verified	Mockup buidling	Can it be done or not?	Requirement met : a small button attachement allows the attachement of the headcoil to the mattress
3.4.10	he MRI device must be able to be maintainable locally	Interview with Dr. L.Gieskes (Interview insights)	Headcoil				Mockup buidling		Requirement not validated , partly met: The local maintainability of this part is ensured by the ability to 3D print the head coil and ability to buy the electrical components
3.4.11	The product must allow the vomit to be cleaned easily	Interview Neonatalog Niek van de r AA	Bed assembly system - Smooth curves in the bed assembly	During the treatment of patients with hydrocephalus, liquids can be excerted which need to be cleaned after each patient. This happens 10 times a day, so this must be a easy actions for the MRI technician	Smooth curves in the bed assembly		/		Requirement not met 3D Printing does not allow good cleaning
3.4.12	The headcoil needs an electical conncection between the headcoil and the magnet	Co-creation session	Headcoil - Groove inside the table where the wires can be guided trhough	The headcoil needs to be connected to the magnet. This can be done with a groove in the table to position the electircal cable. Through the groove the cable can be kept in place as the cable is the most fragile part. In this way the headcoil can also be replaced easily	Groove inside the table where the wires can be guided trhough		Mockup buidling		Requirement met
3.4.13	The headrest must be a maximum of 150mm * 250mm*	Testing with mockups	Headrest - The headrest is designed as compact as possible while being able to support the head		The headrest is designed as compact as possible while being able to support the head		Mockup buidling		Requirement met: The maximum of the head coil dimension is 150 width by 250 length
3.4.14	The headrest must support the head		Headrest	The headrest must be able to support a head of 5Kg of hydrocephalus.	The headrest: The headrest must be able to support a head of 5Kg of hydrocephalus		Mockup buidling		Requirement met: the headrest fits tightly inside the head coil
3.4.15	The headrest must be comfortable for the patient		Headrest - The cushions on the headrest	The headrest is the part that is in direct contact with the fragile skin on the head of the patient	The cushions on the headrest				Requirement not validated , partly met : the head immobiliser is comfortable for the patient, not the head rest.
3.4.16	The items that interact with the patients, must be easy to replace or easy to clean	MRI technician interview	headcoil	the head coil is replaced often, so this must not be a gesture that takes much time	Plugin system				Requirement not validated , partly met
3.4.17	The head coil must be easily replaceable The headcoil must be easy to change for a different head size	MRI technician interview	headcoil	the head coil is replaced often, so this must not be a gesture that takes much time					Requirement partially met, room for optimization
3.4.18	The head coil must be cheaply producible so you can have multiple.	Webb	headcoil	This is the part that is most used and consumed			Research on available production and material cost		Requirement met : 3D Printing
3.4.19	The wire connection must be earthed for safety	Oreilly(2020)	headcoil	safety					Requirement not validated , partly met
	3.5 Electronics								
3.5.1	*a)A shielding is required to reduce the noise dure to the inhomogeneity of the permanent magnet. The frequency must at least 2mHz (between 1 and 20)*								Requirement partially met, room for optimization: The maze of the aluminum grid is approximately 10 * 10mm. This should allow the necessary Mhz.
3.5.2	The device should be designed to have a reduced number of parts and assemblies including redundant components.	An increased number of parts increase the risk of those parts to damage	Electronics						Requirement partially met, room for optimization

3.5.3	Make the most regularly-replaced components easy to acces	Danny de Gans (DEMO)	Resistors in Electronics													Requirement partially met, room for optimization
3.5.4	Design user cues to guide the repair of the machine the right way	Danny de Gans (DEMO)	Resistors in Electronics													Requirement not validated , partly met
3.5.5	The medical device should provide easy access for visual and manipulative tasks, i.e., for inspection, adjustment, repair.	Danny de Gans (DEMO)	Electronics and buttons to Spectrometer													Requirement not validated , partly met
3.5.6	The medical device should allow fault detection, localization and isolation in the quickest possible time.	Danny de Gans (DEMO)	Electronics													Requirement not validated , partly met
3.5.7	The system must provide adequate labeling, engraving and marking of parts and critical points for identification of defect.	Danny de Gans (DEMO)	Electronics													Requirement not validated , partly met
3.5.8	The medical device should allow a hazardous-free envirnoment for maintanance work which requires no proximit of high voltage lines, not gaseous leakages, moderate temperature changes etc.	(Vasan, 2020)	Assembly and installation										assumption	Not validated		Requirement not validated , partly met
3.5.9	1. The conductive housing must be connected to the same contact point as the head coil	Tom and Wouter (LUMC) -	Bed assembly -	A wire that connect the headcoil and the conductive blanket with the power source			A wire that connect the headcoil and the conductive blanket with the power source :The wire framework attached to the thermoformed mattress is has contact with the aluminum framework. This has a benefit that the current can go through the aluminum framework and However this must be tested, since it is possible that the framework will have toom much resistance						verified	testnig		Requirement not validated , partly met
3.5.10	The preferred and most easy way to maintain the device is to make the electronics modular.	Danny de Gans (DEMO)	Electronics - -	Workload and the access to parts are a huge challenge that restrict the repair and maintenance of the MRI scanner.			Workload and the access to parts are a huge challenge that restrict the repair and maintenance of the MRI scanner.						assumption	Not validated		Requirement not validated , partly met
3.5.11	The repair and maintenance must be able to be done by a technician with minimal training	Danny de Gans (DEMO)	Electronics - -	Workload and the access to parts are a huge challenge that restrict the repair and maintenance of the MRI scanner.			Workload and the access to parts are a huge challenge that restrict the repair and maintenance of the MRI scanner.						assumption	Not validated		Requirement not validated , partly met
3.5.12	The two capacitors as the most fragile part need to be designed in a robust way. Furthermore the ability to callibrate the headcoil needs to be more user friendly	Danny de Gans (DEMO)	Electronics - -	Workload and the access to parts are a huge challenge that restrict the repair and maintenance of the MRI scanner.			Workload and the access to parts are a huge challenge that restrict the repair and maintenance of the MRI scanner.						assumption	Not validated		Requirement not validated , partly met
3.5.13	1. The conductive housing must be connected to the same contact point as the head coil	Danny de Gans (DEMO)	Electronics										assumption	Not validated		Requirement not validated , partly met
3.5.14	2. The MOSFET must be able to be replaced	Danny de Gans (DEMO)	Electronics										assumption	Not validated		Requirement not validated , partly met
3.5.15	3. The coolblock must be accessible for repair - it is not possible to troubleshoot on component level, only on unit level. The print is connected on a coolblock and this can be mounted as complete unit	Danny de Gans (DEMO)	Electronics										assumption	Not validated		Requirement not validated , partly met
3.5.16	1. The airflow must not be restricted inside the closet of the electronics	Danny de Gans (DEMO)	Electronics	- If the airflow is restricted, the temperature inside the 9"rack will rise, which is not desired			If the airflow is restricted, the temperature inside the 9"rack will rise, which is not desired						assumption	Not validated		Requirement not validated , partly met

3.5.17	2. Sound damping and a S pipe should allow the airflow in the closet while dampening the noise	Danny de Gans (DEMO)	Electronics 9" rack -	The electronics make a lot of noise, to reduce this noise a sound dampeing system is required, while not restricting the air flow.	The electronics make a lot of noise, to reduce this noise a sound dampeing system is required, while not restricting the air flow.	assumption	Not validated	Requirement not validated , partly met
3.5.18	3. The RF amplifier requires its own power supply of 60V	Danny de Gans (DEMO)				assumption	Not validated	Requirement not validated , partly met
3.5.19	4. The electronic modules must be designed in a robust way	Danny de Gans (DEMO)		The modules can be easily detached to be replaced without aditional practice	The modules can be easily detached to be replaced without aditional practices	assumption	Not validated	Requirement not validated , partly met
3.5.20	5. The ventilator must be well protected from sand by making it dust proof.	Danny de Gans (DEMO)		The context it operates in has a lot of red dust	The context it operates in has a lot of red dust	assumption	Not validated	Requirement not validated , partly met
3.5.21	1. All components that require frequent repair or replacement must have visual feedback	Siemens Maintanance MRI		Visuals of the electornics- Visual icons and led lights that show trouble shooting	Visual icons and led lights that show trouble shooting: It is important that all the components that require feedback are made very visual. Making it visual helps the technician to give information about the state of something and is able to give feedback on the operation and placement or status of things.	assumption	Not validated	Requirement not validated , partly met
3.5.22	The two capacitors as the most fragile part need to be designed in a robust way. Furthermore the ability to callibrate the headcoil needs to be more user friendly.	Intervie with DR Johnes Obungoloch (interview insights)	Electronics					
3.5.23	The temperatureinside the magnet should stay stable (drift less than 1 degree per hour)					assumption	Not validated	Requirement not validated , partly met
	3.6 Bed subassembly					assumption	Not validated	Requirement not validated , partly met
3.6.1	The subject needs to be aligned in the middle of the bore in a sphere of 220 mm +/- 1 cm Diameter	Tom O reilly	Bed/ headcoil and magnet	The brain can only be imaged inside the field of View of 225 x225X300mm	Positioning of the headrest is always at a point where the head coil will be in the field of view, for smaller and larger children.	verified	Experiment testing	Requirement met : For both the largest and smallest head coil, the patients head is in the middle of the field of view
3.6.2	No ferromagnetic or metals can enter the bore of the magnet or may be in a proximity of 100mm of the bore opening.	Oreilly,2022	Bed/ headcoil and magnet	magnetic materials may interfere with the magnetic field, causing noise.	No feromagnetic materials enter the bore	verified	Experiment testing	Requirement met : No metalic components are inserted inside the bore. For the blanket, and the slidin mechanism, this part has been devided into two parts. A part that can enter inside the bore, and a part that does not enter inside the bore
3.6.3	The bed system must provide support for neck, shoulder and under knee area The device must avoid high pressure (>15mmHg) on areas with low subcutaneous fat, such as the tailbone, the occiput area, the shoulder is	Roaf, R. "The Causation and Prevention of Bed Sores." Bed Sore Biomechanics, 1976, pp. 5–9. Crossref, https://doi.org/10.1007/978-1-349-02492-6_2.	Bed mattress	This allows a good positioning , mininising muscle strain and discomfort	soft mattress with concave shape and supports on critical areas	verified	final prototyping	Requirement met : The ciritcal areas of the patient are supported
3.6.4	The RF coil should be concentric with the magnets bore	Oreilly,2021	Bed mattress	The magnetic field is strongest in the centre of the FoV	Fixed positioning and laignment of parts	verified	final prototyping	Requirement met : For both the largest and smallest head coil, the patients head is in the middle of the field of view and at the centre of the bore
3.6.5	The bed system must provide support for neck, shoulder	Vink,2018	Mattress	This allows a good positioning , mininising muscle strain and discomfort	Neck rests	verified	final prototyping	Requirement met : The ciritcal areas of the patient are supported
3.6.6	The bed must be able to fit taller children (1.2m) and smaller children (80cm)	Mockup making and testing, Cure hospital	Bed mattress	Children between 0 and 4 years old must be able to fit in the bed. Children of 4 years old are averag 1.02 m	A large bed of 100cm length with 30 cm width : The mattress must be at least 80cm length by 25 cm width	verified	final prototyping	Requirement met : The bed system is 1.2m long so all children up to 4 years old (P95) fit inside the bore. Also space is left to prepare the childer on the table top, without needing to move the child
3.6.7	The bed system must be attached and detached on the magnet system	User test	Docking system	When installing and disassembling the MRI system, the magnet must be alligned with the bed system	Alignment method : Docking system	verified	final prototyping	Requirement met : a docking system has been provided to allign the magnet system with the bed system
3.6.8	The bed framework needs to be stiff enough to withstand the patient's weight (16kg(body) + 5kg (head))	calculations	Bed framework	The bed framework should not deform and should be robust for it to be durable, but also to maintain the same measurement data during each scanning.	Sitff 35mm aluminum framework	verified	final prototyping	Requirement met : an alluminum framework of 35mm is provided with nough stiffness to prevent deflection during use
3.6.9	The bed framework needs to be accessible for the MRI technician to clean	Co-creation session Wouter and Tom	Bed framework	The procedure of scanning can involve fluids from the patient. This needs to be cleaned thoroughly after every scanning. So this should be easy accecible	The Bed is composed of modlar parts which allows easy assembly and disassembly	verified	final prototyping	Requirement met: Only easy to clean surfaces are povided such as the Trespa and PVC. All corners are prevented and only smooth surfaces are implemented
3.6.10	The bed must be fixated on the head coil once slid inside				Form fit of the headcoil on the the tabletop and on the headrest of the matress	verified	final prototyping	Requirement partially met, room for optimization: the sliding mechanism allows enough friction to position the bed on a fixed position. However, once the childe abruptly moves, there is a small chance that the bed also moves. Since there is no mechanical stop.
3.6.11	The bed framework that e	Co-creation session Wouter and Tom	Bed framework	Ferromagnetic elements are not allowed to enter the bore.	No feromagnetic materials enter the bore	verified	final prototyping	Requirement met : the bed framework will not enter the bore. Solely the mattress, mattress holder and tabletop will enter the bore.
3.6.12	Once the bed is slid inside	Testing	Bed assembly - A locking system can also be done by a ball pin that falls in a hole by gravity		A locking system can also be done by a ball pin that falls in a hole by gravity	verified	final prototyping	Requirement met
	3.7 Bed Mattress					verified		
3.7.1	The bed is the most consumable part, which requires the most frequent replacement. The bed must be made of durable materials.	Cure Hospital	Bed mattress	1. The bed is the most consumable part, whic hrequires the most frequent replacement. Approximately 2000 kids per year will be scanner, which is around 10 scans a day minimal		verified	Experiment testing	Requirement partially met, room for optimization: The choice has been made for an off the shelf matress that is widely available inside the context. The effect of this matress on the durability of the bed system has not been verified
3.7.2	To mattress hardness must be made from polyurethane foam medium hardness (around ILD value 50s)	Experiment	Bed mattress	This is the most comfortable mattress hardness as described in literature		verified	Experiment testing	Requirement met :Medium matress which is widely available is used for the making of the mattress

3.7.3	The head must be positioned in an angle of 15 degrees	Experiment	Bed mattress	According to the test, the head positioned in an angle of 15 degrees provides the leas pressure on the occiput area, while providing a good air flow for the lungs.									verified			Requirement partially met, room for optimization: the design has been made for this requirement. However, no final testing has been done to validate the effect of 15 degree on the final product.
3.7.4	No pressure above 32 mmHg must be measured on the body of the patient.	Krouskop TA, Garber SL, Reddy NP,Noble PC. A syn-thesis of the factors that contribute to pressure soreformation.	Matress	thirty-two mm Hg is often quoted as the ideal interface pressure for support surfaces to prevent pressure ulcers.									verified			Requirement met : a concave shaped mattress allows a pressure distribution on the patients body
3.7.5	The mattress must allow the patient to lay in a correct posture in a supine position.	Comfort literature research	Bed mattress	The optimal position prevents strain in muscles and pressure on areas which can be perceivedas discomfortable			Head against the headrest, Trunk slumped and uncrossed feet						verified			Requirement met : Head against the headrest, Trunk slumped and uncrossed feet als provided on the bed mattress. The swaddle blanket prevents movement of this position into another position
3.7.6	The headrest must have a donut shape to prevent pressure on the occiput area.	[Australian Wound Management Association, Australian Wound Management Association Clinical Practice Guidelines for the Prediction and Prevention of Pressure Ulcers. Cambridge: Cambridge Publising, 1 ed., 8 2001.]	Head area	The donut shape allows the pressure on the occipital area to be evenly distributed and prevent peak pressure on the head.									verified			Requirement met : the doughnut shape provides the least pressure on the head of the patient
3.7.7	The mattress must be put on a hard material that holds the concave shape and is attached to the sliding mechanism	Mockup building and testing	mattress holder	The mattres can not hold its shape without a harder material beneath. Furthermore it can not									verified			Requirement met : The mattress holder is introduced
3.7.8	The slides must be integrated and fixated in the framework	Mockup building and testing	sliding mechanism and framework	To be able to slide the bed inside the bore									verified			Requirement met : A sliding mechanism specially designed for the insertion of this mattress holder inside a magnetic system is provided
3.7.9	The metallic bits on the bed framework need to be covered	Co-creation session Wouter and Tom	Bed framework	The body is also conductive, and if a the bed framework is metallic, this may conduct current when there is a leak. The body will be electrocuted if the bed is not grounded, which is very dangerous.									verified			Requirement not validated , partly met : the metallic bits must be covered for all parts that are interaction with the patient and magnet system (blanket, headcoil), This was out f the scope
3.7.10	The mattress must have a concave shape for the body to comfortably lay on it.	Mockup building and testing	Matress framework - The concave shape of the framework	The round shape is the most volume efficient and stiff shape to enter the bore.			The concave shape of the framework						verified			Requirement met : The convaved bed shape is provided for a volume efficient and comfortable position
		3.8 *Head immobilization*														
3.8.1	1. The head immobilization device must allow a maximal movemen of 3 mm in 6DOF .	Andrew Webb	head immobiliser	The allowable movement must not be bigger than the voxel size ,which determines the spatial resolution of 3x2x2mm			The head immobiliser						Assumption		Move not more thant 3 mm in directions pitch, yaw , roll	Requirement partially met, room for optimization: all separated featue of the head immobiliser contribute to a minimisation of movement. However , the exact amount of immobilisation has not been tested together as a hole.
3.8.2	2. The head immobilization device must fit on a headrest of 250 mm X 150 mm	Mockup building	head immobiliser	The Head immobiliser must fit on the headrest of the mattress holder, which slides inside the headcoil. This must take as minimal as space as possible.			The flat part of the head immobiliser						Validated	Final prototyping testing	Maximum dimension of 250mm x 150mm	Requirement met The head immobilisation has the maximum size of the head rest. Therefore it can fit exaclty on the head rest and be immobilised on it.
3.8.3	3. The head immobilization device must be cleanable after each use	Cure Hospital	Surface of head immobiliser	The head immobiliser is a part that all children will use, so this must be clean.			The PVC cover of the cushions						Validated	Final prototyping testing		Requirement met: the device can be cleaned due to the non water absorbant materials
3.8.4	4. The head immobilization device must be comfortable	Cure Hospital	Cushion	The head of the patient with hydrocephalus is very fragile. The patients have paper-like skin. This requires the patients to be layd on tha soft surface			The cushion allow a soft interface for the patient						Assumption			Requirement not validated , partly met :The device has been designed in order to meet the comfort regulations where pressure on ciritcal areas is prevented. However, this comfort is not validated
3.8.5	5. The immobilization device must be very soft on the head of the patient.	Dr Steve Schiff	head immobilization device - cushions inside the device	The head of the patient with hydrocephalus is very fragile. The patients have paper-like skin. This requires the patients to be layd on tha soft surface			cushions inside the device		The children have very thin skin on their head. So th children must be very comfortable in order to participate well. Therefore the area of the head needs to be very soft.				Assumption			Requirement not validated , partly met : The device is made with cushions. However the part could not be tested ith the fragile patient. PVC is a material that is well cleanable, however it is not so soft for the skin.
3.8.6	The immobilization must be as compact as possible	Mockup making and experimentation testing	Immobilization	The device must not take over much space inside the bore, because this space must be used efficient for the head of the patient.			The immobilization must not be more than 3 cm thick		The Head coil must be as close to the subject as possible and therefore the immobilization system must not take too much space between the head coil and the head of the subject				verified	Prototype making		Requirement met :The head immobiliser can fit inside the headcoil with the head immbilised inside of it, and fixated on the head rest. The cushions however take much place. Tis can be minimised.
3.8.7	Must be able to be cleaned properly with water and disinfectant	Mockup making and experimentation testing	Immobilization	The Cure hospital cleans their parts after each use with water and a cloth. At the end of the day the parts are cleaned with desinfectant			Material which is soft on the inside and good cleanable on the outside : Ppe		Multiple sick patients will have to use the same product				verified			Requirement met :Through application of PVC as surface material the head immobiliser can be cleaned.

3.8.8	The pressure from the head immobilization on the cranial section of the infant must not be more than 7,5 mm Hg or approximately 1kPa		Doughnut shape	Not literature could be found about the maximum required pressure of the head of cranium. Based on anecdotal feedback from clinicians, estimated pressure of a helmet on the apex region of the infants' skull was assumed to be 7.5 mm Hg or 0.145 PSI (or 999.915 Pa). It should be noted that clinicians estimated pressures using a force sensor applied to a human's head with approximately the same force as helmet contact.			The design of the head rest allows a uniformal pressure distribution of thehead on the part		A higher force will cause pain or in the longer run deformation in the skull of the smaller infant. Once the fronatels are closed, the children can handle a higher force. for pain and deformation)				verified	Pressure mat experiemt		Requirement met : The pressure of the head immobiliser on the cranial section is a maximum of 5 mmHg.
3.8.9	A minimalstiffness of 5,7 Nm stiffness is required for a system that prevents translation in the x and y plane androtation of the head through the sternocleidomasteoid muscle of more than 2 mm	Calculation	White rigid part of the head immobiliser	The sternocleidomasteoid causes the rotation of the neck in the head. With as pivot point the fulcrum.			The rigid part of the head immobiliser allows the head rest to be stiff enough to prevent the rotational force of the head on the immobiliser.						Verified	Final prototyping making		Requirement met :The stiffness of the system is met by providing a rigid frame , made of PLA that holds the cushions in place.
3.8.10	The head immobilizer must prevent flexion, lateral bendin and rotation of the head (pitch,roll and yaw)	Experiment	Head immobiliser	The head of the patient is fixated for translation on the head coil, however the patient can still rotate its head.			The rigid materials beneath the cushion allows for a stiff form of the head immobiliser, which will not deform after a lot of use.		The 3D printed part of the head immobiliser				Verified	Final prototyping making		Requirement met :The head immobiliser prevents the movement of pitch, roll and yaw
3.8.11	The head immobilization system must be able to withstand an opening and closing of the head coil for 100 patients a day	Interview Cure hospitak	Head immobilization and headrest	A maximum of 100 patients a day will be using the product. Therefore the head immobiliser must be able to handle this type of wear.			Make the headrest of stiff material		The headrest is manufactured fromsheet PU, a durable and stiff parts				Verified	Final prototyping making		The matress holder and this the headrest is made from PU and the matress is covered by PVC
3.8.12	a) The immobilization device must prevent pitch with a lower strap that fixates the mandible	Immobilisation experiment	headstrap on lower jaw										Verified	Final prototyping making		Requirement met :The movement pitch is prevented by fixating the mandible of the head
3.8.13	b) The immobilization device must prevent roll by providing a fixated headrest combined with a head strap	Immobilisation experiment	headstrap on both forehead and mandible										Verified	Final prototyping making		Requirement met :The movement roll is prevented throug the application of the head strap in combination with cushions
3.8.14	c) Requirement: No external pressure must be applied on the areas with low subcutaneous fat to prevent pressure ulcers: The occiput area must be free from pressure	Holla, 2019	Doughnut shape	a) : The occiput area must be free from pressure the areas with the lowest subcutaneous fat allow the least amount of pressure on these areas which are the occipital area of the skull. pplication of pressure can have as a result that the skull is directly held for immobi-lization, however the downside is that pressure ulcers and pain can easily develop			The doughnut shape allows the pressure to be distributed and not on the occipital area						Verified	final prototype testing		Requirement met : No pressure i applied on the occipital area
3.8.15	d) Rotation and bending of the upper spinal area must be limited: Through application of pressure on the parietal areas of the skull	Holla, 2019	Cushions of immobiliser				Through application of pressure on the parietal areas of the skull		Head immobiliser				Verified	final prototype testing	Pressure on the parietal area of the head results in immobilisatio n of the head.	Requirement met
3.8.16	e) The head neck and thorax must be fixed to prevent junctional angulation.	Holla, 2019	fixation on head and neck by head strap	This motion can cause movement in the head that can be detected									Assumption	not validated		Requirement partially met, room for optimization: This is not tests
3.8.17	f) The immobilization should not solely support the shoulders to prevent the effect of mobile shoulders.	Holla, 2019											Assumption	final prototype testing	The shoulders are allowed to move, as long as the head does not move more than 2 mm	Requirement partially met, room for optimization: The immobilisation of the shoulders is only met by preventing the head movement and by immobilising the arms by swaddling. No attention has been put on the shoulder area
3.8.18	h) No pressure must be applied on the upper jaw	Holla, 2019	straps of immobilisation				No straps on upper jaw						Verified	Final prorotype esting	The upper jaw must be free prom	Requirement met : No pressure is applied on the upper jaw. The airflow is not restricted
	3.9 Double Mirror															
3.9.1	The mirror must allow the patient to see the care-take who is situated outside the MRI scanner	Cure Hospital	Bore and mirror	The double mirror provides parental interaction between the patient and caretaker who is sitting outside. This visual connection is relaxing for the patient and increases the size in the bore which minimizes claustrophobic feelings.			The double mirror allows the patient to see outside		Double mirror				verified	Mockup building with participant	When the patient can see the parent at 1.5 m distance while laying in a supine position	Requirement met
3.9.2	b)The Mirror must allow enough space of placement of the child inside the bore.	Mockup building	Bore and mirror	Once the child with the largest head size is inserted inside the bore, not place is left for a mirror			Therefore the mirror is foldable, to allow insertion of all head coil sizes inside the bore, without obstruction		Hinge				verified	Mockup building with participant	When the largest head coil can be inserted	Requirement met
	3.10 Swaddle Blanket															
3.10.1	a) The patient acts like an antenna, so something must help with active shielding. Appropriate conductive materials should be included to make sure the person is shielded	LUMC	Blanket				Aluminum inside of the blanket		Aluminum layer						Could not be tested with MRI scanner	Requirement partially met, room for optimization

3.10.2	b) The blanket must restrict movement of the limbs of the patient and increase comfort through the posture and temperature of the patient.	Cure and Dr Schiff	Blanket		Velcor to tighten the blanket around the body	Velcro				Requirement met
3.10.3	c) The blanket needs to be tucked tightly around the body. By applying pressure of 100Pa(10 kg/1m^2)	Testing	Blanket		Velcor to tighten the blanket around the body					Requirement met : The Velco allows the body of the patient to be tucked and secured inside of the blanket
3.10.4	d) The swaddle blanket must be easily cleanable ; Dirt must be washable from the blanket by wiping with water and a cloth	Edith (Cure Hosital)	Blanket		PVC layer on the outside of the blanket					Requirement met : PVC layer allows well washable surface that is resitant against chemicals and water repelant
3.10.5	e) The swaddle blanket must be immediately installed correctly by the MRI technician	Wouter LUMC	Blanket		Visual indicators on the blanket		verified	Prototype user testing		Requirement partially met, room for optimization. The MRI technician is able to operate on the system by directly positioning the blanket, however it needs help, so this could be optimized
3.10.6	f) The swaddle blanket must cancel the noise by creating a cage of faraday with aluminium inside the blanket	LUMC	Blanket		Aluminum inside of the blanket		verified	Prototype user testing		Requirement partially met, room for optimization. However it is not tested with the magnet and a human
3.10.7	g) Only the limbs and the upper body of the patient must be able to be swaddled	LUMC & (Holla ,2019)	Blanket	Movement of the upper limbs can provoke movement of the head. This must be minimised	blanket made out of two halves an upper half for the upper limbs without a cage, anda lower half which does not entre the bore with aluminum		verified	Prototype user testing		Requirement met : The blanket cosists of two halves for the upper part and the lower part
3.10.8	h) The blanked must prevent bodily temperature fluctuation of more than 3 degrees Celsius in 10 minutes.	comfort testing/ observation	Blanket	The patient can be cold inside the MRI scanner inside an airconditioned room	n/a		Assumption			Requirement not met
3.10.9	k) No direct contact between the skin of the patient and the conductive part of the blanket may occur.	LUMC	Blanket	aluminum must be covered (If the patient also gets monitored with ECG, the patient will make a circuit with the blanket and the the rest of the aparatus, which will allow the product to be grounded	The blanket consist of 3 layers which are each sealed		Verified			Requirement not validated , partly met
3.10.10	l) The blanket must be connected to the same ground as the aluminium shield around the magnet.	LUMC	Blanket		the blanket is connected with a wire that goes trhough the bed toward the magnet system	Wire from blanket to magnet	Verified			Requirement partially met, room for optimization
3.10.11	m) The aluminium maze must not be bigger than 10 * 10 mm and 3 mm thick.	Ger de Kok Siemens MRI maintanance	Blanket		the aluminum maze is 5*5 mm	Aluminum layer inside the blanket	Verified	Canno be verified		Requirement not validated , partly met
3.10.12	o) The blanket must make sure that the swaddling of the patient only can occur in one way	Mockup making and experimentation testing	Blanket		The alumiun is preshaped and a child can only enter in one way	Aluminum layer inside the blanket	Verified	Mockup making		Requirement met
3.10.13	p) The blanket must be made of a textile with a soft material	Dr Schiff	Blanket		N/a		N/a	N/a		Requirement not met
			4 Guiding Rail							
4.1	1. The translation system that moves the head inside the bore must use as minimal space as possible (A lot of effort has been made to make the bore as large as possible. So if the concpet leaves out 1 or 2 cm in empty space, this is not desired)	Cocreation session	Guiding rail	A lot of effort is made to maximize the bore diameter, the use of effective space for something non essential is not desired.	guiding rail wich are slides	The head of the patient must be as close as possible to the head coil for a good imaging. Not much space is left for operating and aligning of the headcoil and the patients head. (A lot of effort has been made to make the bore as large as possible. So if the concpet leaves out 1 or 2 cm in empty space, this is not desired)	verified			Requirement partially met, room for optimization: Not all options have been assessed for to optimal use of space.
4.2	2. The weight of 16 kg norminal distribution must be able to be supported on the rails	DINDE (2007)	Guiding rail			The bed is for children with hydrocephalus of up to 4 years old. The P95 of children of 4 years old is 16 kg. The rails must hold this weight without too much deformation	verified			Requirement met : The bed can carry and slide up to 1KN
4.3	The rails must be able to slide the bed, and framework smoothly inside and outside of the bore (push force 200 N with two hands	Mockup making and experimentation testing	Guiding rail	The MRI technician must exert more than is comfortable to push	Igus rails which have minimal friction	The friction that the rails need to withstand is the weight of the patietn, bed, framework and rails itself which is approxiametly 300N	Verified	Material and part choice		Requirement met :The guiding rail is chosen for its minimal wear and resistance and optimal lubrication without the need of lubricant
4.4	Since the magnet system may not carry load, no force may be exerted on the magnet system	Cocreation session	Magnet System	Load on the magnet might distort the image	Table top	All load is carryd by the table top and the guiding rail	Verified	Prototype making		Requirement met : No load is exerted on the magnet due to the design of the table to which carries the load of the head rest. The mattress holder which does not deform and allows the guiding rail to carry the load.
4.5	The translating mechanism must take at least as volume as possible.	Mockup making and experimentation testing	Bore, magnet system and guiding rail	The 30 cm diameter of the bore allows entrance of the head of the patient, the head coil, and the mirror, which does not leave much space for the guiding rail and the MRI technician to insert the head.	Shape of the bed	The translating system is only present under the matress inside th bed system and not inside the bore.	Verified	Prototype making		Requirement met

Master of Science Thesis

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