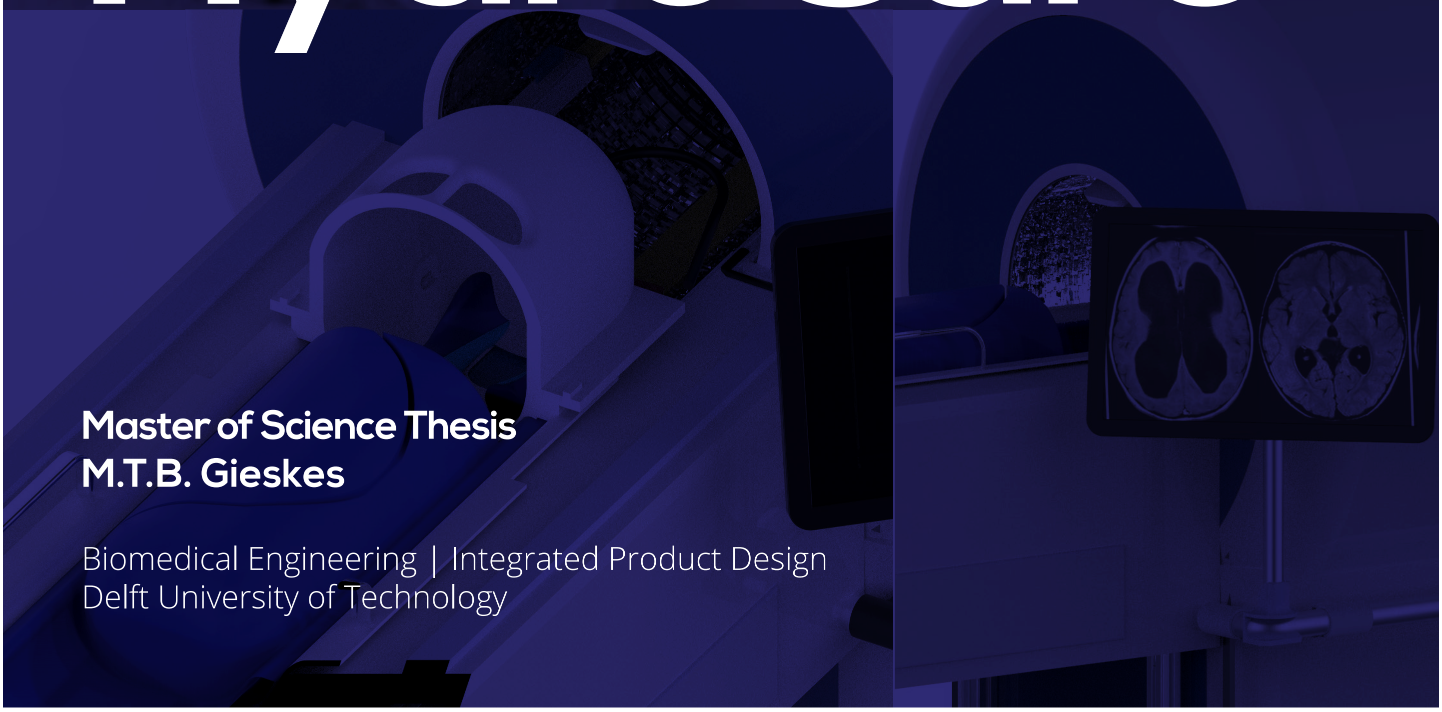
The design and development of a human centred and sustainable low field MRI scanner for Uganda

HydroCare



Master of Science Thesis
M.T.B. Gieskes

Biomedical Engineering | Integrated Product Design
Delft University of Technology

The design and development of a human centred and sustainable low field MRI scanner for Uganda

Master thesis in fulfilment of the requirements for
the degree of Master of Science in the fields of

Master Integrated Product Design
Medesign specialization
Faculty of Industrial Design Engineering
Delft University of Technology

Master BioMedical Engineering
Medical Devices and Bioelectronics
Faculty of Mechanical, Maritime and Materials Engineering
Delft University of Technology

Graduation committee

Jan-Carel Diehl	*Chair Industrial Design Engineering*
Jenny Dankelman	*Chair BioMechanical Engineering*
Stefan Persaud	*Mentor Industrial Design Engineering*
Daniel Robertson	*Mentor BioMechanical Engineering*

March 2022

Preface

This master thesis has been written to fulfil the graduation requirements of the Individual Double Master's Degree of the masters BioMedical Engineering and Integrated Product Design at the Delft University of Technology.

The basis for this research originated from my passion.
With great passion, dedication and ambition I put my heart in providing a positive impact for the people who need this the most by designing medical devices that increase peoples life quality. I have the empathy to create a user-centred design that means something to people and is disruptive, innovative and technically challenging in its function.

The project focussed on the design and development of the low field MRI scanner for sub-Saharan African countries. In particular, the optimization of the bed system for a comfortable use for patients with hydrocephalus between 0-4 years old. Conducting extensive investigation has allowed me to full-fill the research objective.

Writing a thesis during a global pandemic is a challenging time which requires much resilience, perseverance, and support. Throughout the writing of this thesis, I have received a great deal of support and assistance. I would like to thank my supervisors for their guidance during the process.

I would first like to thank my supervisors from Biomedical Engineering, Jenny Dankelman and Integrated product design, Jan-Carel Diehl whose expertise was invaluable in formulating the research questions and methodology. Your insightful feedback pushed me to sharpen my thinking and brought my work to a higher level.

I would like to thank my Industrial Design mentor for the great insights and inspiration throughout the process. I would also like to thank my Biomedical Engineering mentor, Daniel Robertson, for aiding me in keeping focussed and structured.
A special thanks to Martin van Gijzen, for enabling this unique opportunity to participate in this project.

Throughout the graduation project, the suggestion co-creation and aid from the fellow research teams have been invaluable.
I wish to thank Dr. Schiff, the team at Leiden University Medical Centre and the Cure Hospital for the valuable co-creation sessions and discussions.

Finally, I take this opportunity to express my gratitude to my family for their love, unfailing encouragement and support.
This thesis has been the fruit of perseverance and faith. I hope to motivate my siblings and the children from Glory and Salvation Church that have supported me throughout the design and experiment process. Ultimately I thank God, for by this strength, grace and love, He allowed me to carry out this work.

I hope you enjoy reading.

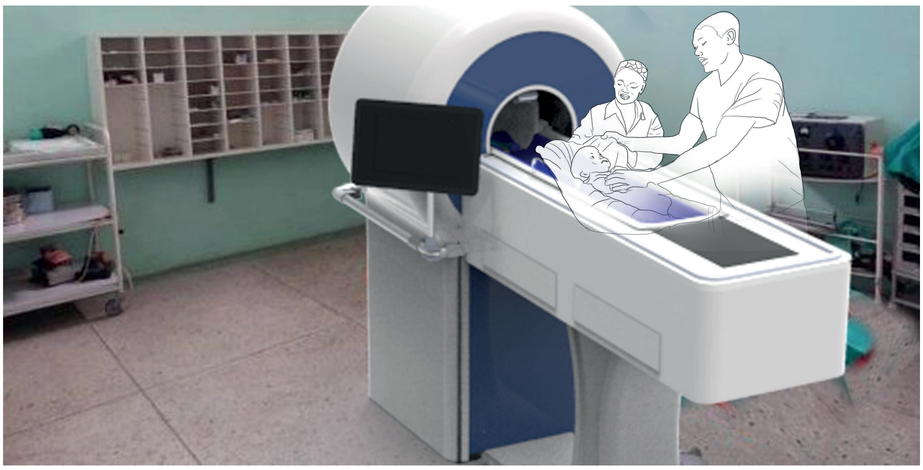
Abstract

In sub-Saharan Africa, more than 100,000 infants develop hydrocephalus yearly. Due to the lack of diagnostic tools, many of those children are poorly treated and not diagnosed.
Magnetic Resonance Imaging(MRI) is the most preferred medical diagnostic technology for the diagnosis and treatment of diseases such as hydrocephalus. Yet, it is currently out of reach for 70 per cent of the world's population due to their high price and complexity in functioning. In Low-middle income countries such as Uganda, MRI scanners are not available due to the financial, infrastructural and maintenance barriers.
Therefore the research team of Penn state university, Leiden University Medical Centre and Delft university of Technology, has joint forces to develop a low-cost, sustainable and portable MRI scanner operating at a lower field (50mT).
Such technology has the potential to meet clinical needs at point of care or in low and middle-income countries.

For a successful and safe implementation of the low field MRI scanner in LMICs, the device requires to function conform to safety, quality norms and adequately address the contextual challenges within sub-Saharan Africa. This requires the low field MRI scanner to be equipped with all necessary functionalities to function and sustain for the brain imaging of infants with hydrocephalus.
An additional complexity arises during the brain imaging besides the functionality of the technology, the fit with the context, which is the human factors.
Accurate brain imaging relies on a settled child lying in the MRI scanner to be able to acquire of the necessary sequences for qualitative images. Infants in low resource settings are not sedated and prone to move due to discomfort. This may lead to an incomplete or unsuccessful scan, costly follow-up reschedule scans with the additional inconvenience of an anxious caretaker. Significant motion during the scanning can mislead or inhibit interpretation, leading to diagnostic errors.
Therefore, this project aims to develop a human centred bed system of the low field MRI scanner that allows immobilization of the patient through the design of a comfortable bed system that is inexpensive, safe and of sufficient quality to diagnose hydrocephalus.
Through an iterative design process based on the double diamond method, a concept for the comfortable MRI system was designed. Stakeholder involvement, prototyping and validation through experimenting lead as the main design inputs for further improvements of the functionality, comfort and usability of the concept.

This resulted in a concept of a complete MRI system that integrates the comfortable bed system in a sustainable MRI system, while addresses the contextual challenges. This MRI system enables an ergonomic and safe operation, facilitates safe and comfortable insertion and removal of the patient from the machine, and allows mothers and operators to remain close and in visual contact with the patient.

A functional system of the bed, divided into the mattress, head immobilizer, mattress holder, double mirror and swaddle blanket, has been developed en optimized for a local production and assembly. With the combination of these systems in an integrated design, MR imaging can be provided by MRI technicians with limited knowledge and reduction of human workload Through the introduction of the low field MRI scanner the accessibility of MR Imaging in low resource setting will increase clinical outcome and support the treatment of hydrocephalus.



HydroCare, 2022

Table of Content

Reading Guide

Chapter Overview

Research chapters feature the same structure of
Background - Introduction to the background of the chapter
Methods and Approach - A description of the performed research and design activities
Findings - A presentation of the research and its influence for the final design
Key insights - A summary of each chapters key insights or highlights are presented in the last page of each chapter in a blue box.

● IDE ● BME ● TPM

Chapter 1 - General Introduction ● ●
This chapter provides an overview of the most relevant aspects leading to the problem definition, its scope, assignment and final design and design approach.

A. Discover

Chapter 2 - MRI scanner in LMIC ● ●
This chapter provides insight in the starting point of the project with the main elements of the Low field MRI scanner inside the context. It gives insight on what the project and product must involve to be successful in its purpose.

Chapter 3 - Human factors research ● ●
This chapter starts the Discovery phase and explores all background and specific physical information relating to the patient to ensure the desirability of the device.

Chapter 4 - Technology research ● ●
This chapter explores all relevant background research necessary to create design requirements. To ensure the feasibility of the device.

Chapter 5 - Context research ● ●
This chapter explores all relevant factors necessary to understand the MRI scanner operating inside the field with as result to create design requirements to ensure the viability of the device.

B. Define

Chapter 6 - Challenges ●
This chapter links the Discover phase with the Define phase by presenting the most relevant key findings and challenges are assessed to define the most relevant and urgent problem to solve for the current patients and context while developing the LF MRI.

Chapter 7 - Problem definition ● ●
This chapter introduces the problem definition and all limitations, source and physiological effects of the problem.

Chapter 8 - Design goal ●
This chapter introduces the specific aim we design for, its scope and solution direction. This chapter introduces the develop phase and materializes the design drivers mentioned chapter 10. The concept is first introduced.

Chapter 9 - List of requirements ● ●
This chapter summarizes all requirements defined in chapter 2-5.It finalises the Define phase by summarizing the list of requirements, solution direction into a vision for the concept.

C. Develop

Chapter 10 - Component research ●
This chapter outlines the rationale behind the concept solution. Insights from literature, design and experiment research is discussed.

Chapter 11 - Component design ● ●
This chapter presents the design fundamental and main component designs. An experiment for validation is done to define the best concept.

Chapter 12 - Final design ● ●
This chapter finalises the develop phase by presenting the final concept. First a general overview of the MRI system is provided and later more detail by means of renders and technical details.

D. Deliver

Chapter 13 - Prototype ● ●
This chapter provides insight in the prototyping building phase and the main gathered insights.

Chapter 14 - Business case - TPM ●
This chapter evaluates the viability of the device through a business model canvas. A more sustainable proposition is made.

Chapter 15 - Evaluate ● ●
This chapter evaluates the product on its desirability, viability and feasibility.

Chapter 16 - Discussion ● ●
The final chapter will present the final discussion about this project and draw conclusions about the main research questions and their answers, future continuation and general limitations.

List of abbreviations

LUMC	Leiden University Medical Centre - LUMC
LMIC	Low - Middle income country - LMIC
HIC	High income country - HIC
LRS	Low resource setting - LRS
CSF	Cerebrospinal fluid (CSF)
LF	Low Field - LF
MRI	Magnetic Resonance Imaging - MRI
MoH	Ministry of Health
NMR	Nuclear magnetic resonance - NMR
Fov	Field of View - Fov
BOP	Bottom of the Pyramid - BOP
SNR	Signal to noise Ratio- SNR

1. Introduction

1.1 Background

Medical devices serve as the foundation of prevention, diagnostics, treatment of disease, and rehabilitation [1]. Medical technology and innovation in medical devices play a crucial role in enabling access to healthcare in the right place. Despite the major advances in this field in the past decades, disparities in healthcare persists and particularly in those Low and Middle-Income countries that have limited access to current medical technology [2].

The differences in the 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 World Health Organization (WHO) has focused on the need to bridge the gap in access and availability to medical technologies in LMICs such as countries within Sub-Saharan Africa and South Asia. [3].

Especially medical technologies with a higher financial responsibility for the procurement and use are lacking in availability, such as the MRI scanner. Despite being the most commonly used diagnostic imaging device, only approximately 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. The cost of an MRI is estimated at around 1 million Euro per Tesla for only the purchase [6].

Due to the financial and contextual barriers that hinder the introduction and implementation of medical technologies in low resource countries, there is a lack of MRI scanners in LMICs.

This causes easily treatable diseases to persist, such as hydrocephalus in Sub Saharan Africa. Hydrocephalus is a severe medical condition where accumulated fluid in the ventricle of the brain of a prenatal causes swelling and an enlarged head size. To support and prepare the treatment through brain surgery, brain imaging is needed. In the Cure hospital in Uganda, this is done through Magnetic resonance imaging (MRI).

1.2 Project initiative

1.2.1. Project stakeholders

To increase the accessibility of MRI scanners in LMICs a cost-efficient, sustainable, frugal innovation-based low-field MRI scanner is introduced [7]. This is a research initiative led by Dr Steven J Schiff (Penn State University), Dr. Johnes Obungoloch (Mbarara University of Science and Technology) and LUMC/TU Delft. This device will operate at the Cure Children's Hospital of Uganda in Mbale.

1.2.2. Frugal innovation Low field MRI scanner

The development of the frugal innovation MRI scanner involves the implementation of the technology, but should also involve the sustainability and durability of the devices as well as take into context how the MRI scanner will benefit the people and their community. All of these factors should be taken into consideration in order for the device to succeed in its purpose. This one-purpose MRI scanner has the advantage to lower the technical specific costs and is therefore available for LMICs. Through the implementation of permanent magnets in a Halbach array, the scanner can be produced at a lower cost, which is advantageous. As a result, the lower field MRI scanner operates at a magnetic field strength of 50mT. Advances in permanent magnet design, RF coil architecture, gradient performance, and image processing algorithms allow high quality images in lower field imaging [6].

Nonetheless, these recent advances in hardware and computational technology have created an accessibility in financing the MRI scanner but must compromise in parts specific developments such as comfort. This ultimately results in design specific challenges that need to be resolved for the low field MRI scanner to be functionable in a safe and usable manner.

1.3 Problem statement

Qualitative imaging requires the patient to be motionless. Movement caused by discomfort from the patient may cause motion artefacts, which result in unnecessary, repetitive and costly scanning by the persistently stressed MRI technician and anxious patients and caretakers. Discomfort is the main cause of movement in infants. Therefore, comfort must be prioritised in order for the patient to remain as motionless as is possible. Patient comfort is an important factor of a successful magnetic resonance (MR) examination, and improvements in the patient's MR scanning experience can contribute to improved image quality, diagnostic accuracy, and efficiency in the radiology department, and therefore reduced cost [8].

1.4 Purpose of thesis

1.4.1. Aim

Therefore, the goal of this project is to provide a comfortable MRI scanning experience to limit motion during the brain imaging of hydrocephalus patients between 0-4 years old in the low field MRI scanner. This project includes design and development of a functional and comfortable MRI bed system which can be integrated in the full low field MRI and which meets the contextual requirements needed for use by LMICs. This thesis discusses the design and development of a minimum viable product that focuses on the implementation of a comfortable bed system assembly, which is integrated in the design of a durable low field MRI scanner.

1.4.2. Objectives

The objective of the thesis has been defined through three phases.

The primary objective of the project was to define the challenge which was most important, valuable and urgent to solve within the development of the LF MRI scanner. This challenges has been defined to be the motion during scanning. Eventually the essence was to define what factors and components were necessary to contribute in the solution of this problem. Finally, this thesis addresses both the challenges addressing the product development of the bed system, and the integration of this system in the complete design of the LF MRI scanner.

The design, development, and implementation of these physics and engineering approaches are reviewed to improve patient comfort. As can be seen in the objective, a broader scope is included where the entire MRI scanner is designed on a concept level. Eventually the factors and parts that contribute to a more comfortable experience for the patient, caretaker and MRI technician are further research and developed.

Design goal

Considering the limitations, requirements and opportunities of the scope, solution space and research questions, the following design assignments was provided:

" To design and develop a functional prototype that limits motion during brain imaging by improving the physical and psychological comfort inside the bed system of the low field MRI scanner."

1.5 Assignment and scope

The technological development of the magnet system of the MRI scanner has been fulfilled by the Leiden University Medical Centre (LUMC), which has reached the technical demonstration level (TRL 3) [9]. The magnet system has been developed into a functional prototype. However, essential features, which are required for a safe and usable use of the MRI system, are lacking. Prior to this project, extensive background research, has led to a provisional concept of what the MRI system could feature. This experimental setup was only designed to validate the design vision and could not be used to provide validation of the usability and patient comfort in the envisioned context. Therefore, the next step in the development process has been to provide an extensive conceptualization of the full MRI system and the development of the bed system towards embodiment design.

Scope

This thesis will focus on the design of the component with the most influence on the physical and psychological features of patient comfort. Eventually the design of the bed system must be integrated in the design of the entire low field MRI scanner. The connections and concept design for the entire MRI scanner will be provided.

The design of medical devices for successful implementation and adaptation in an LMIC 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 the introduction of medical equipment in low resource settings [7]. Facing the socio-economic challenges of the low resource setting, it is crucial for the low field MRI scanner to provide long term value in the context. Therefore the design research is subdivided into context, technology and human.

1.6 Method and approach

Approach
The project approach is carried out using the double diamond process (Figure 1.1), subdivided into four phases; discover, define, develop, and deliver. The following sections will describe the methodology and outcomes of these phases briefly.
The Discover and Define phase serve to research the most prominent challenges to solve such a problem statement. In the first two phases, insights are gathered that define the system requirements.
The research objectives have been approached by first analysing the weaknesses and threats within the LF MRI scanner to define the significant challenge that needs to be solved. Next, various product opportunities have been defined by analysing all factors that might influence the outcome. Eventually, the Develop and Deliver phase focus more on the concept definition and development. Finally, the bed system needs to be addressed for the design and development of several components within this product are set out. Each phase and research combines observations, interviews, trial and testing, backed up by literature research. The stakeholder involvement within every phase increases ideation, validation, and discussion of concepts or gaining background knowledge. A patient-centred approach is used, which includes the involvement of local stakeholders during each phase of the design process. During the design process, the involvement of stakeholders, such as surgeons and MRI experts from Uganda, was implemented to ensure that the correct desirability, feasibility, and viability of the design were placed into the correct context. Expert involvement methods can be found in appendix B.

Discover
The goal of the discover phase has been to gain an understanding of the topic. Literature research on the prevalence of hydrocephalus, the challenges of medical devices in LMICs, the Ugandan healthcare system, and the diagnostic procedure has been performed. Furthermore, the theoretical knowledge has been validated through interviews with experts from the field and multiple observations inside a 3T MRI scanner and the low field MRI scanner have been performed. This helps to understand the areas of opportunity, based on the key insights, which help define the most prominent and crucial challenges to focus on for the further development of the MRI scanner.

Define
During the define phase, all gathered insights are formulated into measurable evidence-based requirements which facilitate the ideation phase. The goal of the define phase is to gather the relevant problems, define the scope, and create the problem statement. Eventually the list of requirements is deployed, which defines the main functionality, envisioned concept, interactions, and usability.

Develop
The goal of the develop phase is to develop the concept of the low field MRI scanner, based on the gathered insights from the discovery phase, which are the conform requirements of the define phase. The development of the scanner has been subdivided into two parts which involve ;
1) the conceptualization and environment of the entire MRI scanner. This is the result of the implementation of the main contextual and socio-economic requirements.
2) The challenges of the parts inside the MRI scanner are designed parallel. Through ideation, co-creation sessions, conceptualization, mock-up, makings, experimenting, and validation, a concept of a part could be developed. Eventually part 1 & 2 are integrated inside the embodiment design and the final concept has been delivered.

Deliver
During the deliver phase (convergence), the final concept is integrated, the business plan is developed and with the final functional prototype, the list of requirements is evaluated. Finally the prototype is evaluated with neurosurgeons, MRI technicians and MRI manufacturers to evaluate its desirability and feasibility.

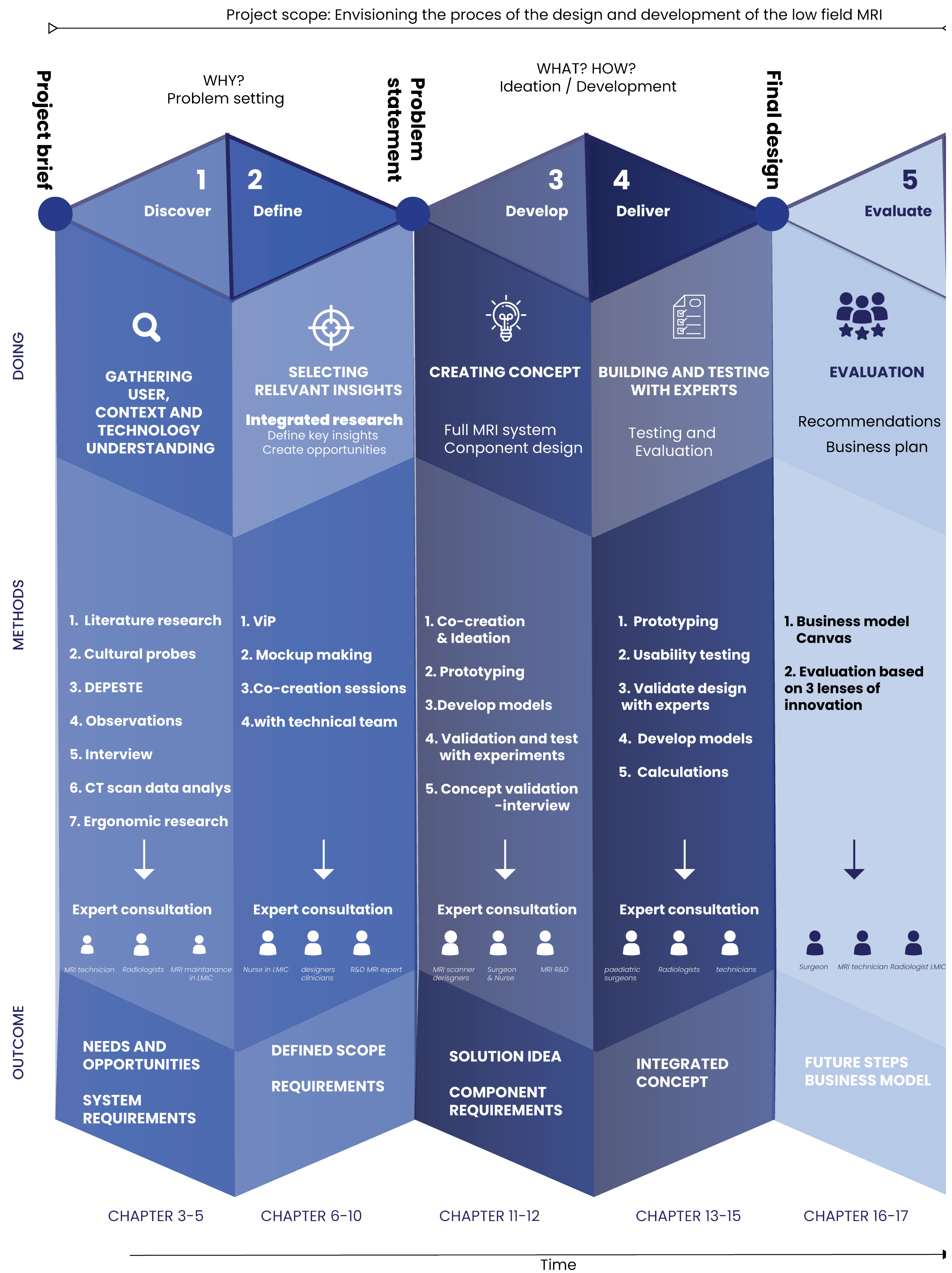


Figure 1.1. Double diamond method

1.7. Report outline

Figure 1.2 zooms in on the second part of the double diamond and illustrates the structure of the concept design of the bed. First, a concept vision is derived from the system requirements (pink). Secondly, the specific parts from the sub-systems (purple) within this concept vision have been conceptualized and developed parallel. Eventually, the sub-parts have been reintegrated together inside the full MRI scanner (blue).

Figure 1.3 illustrates a simplified component structure of the MRI bed system. As can be seen the design of the parts have been performed parallel and are interdependent. The integration of all system comes together in phase Define where the to assist the reader, a reoccurring visual is introduced.

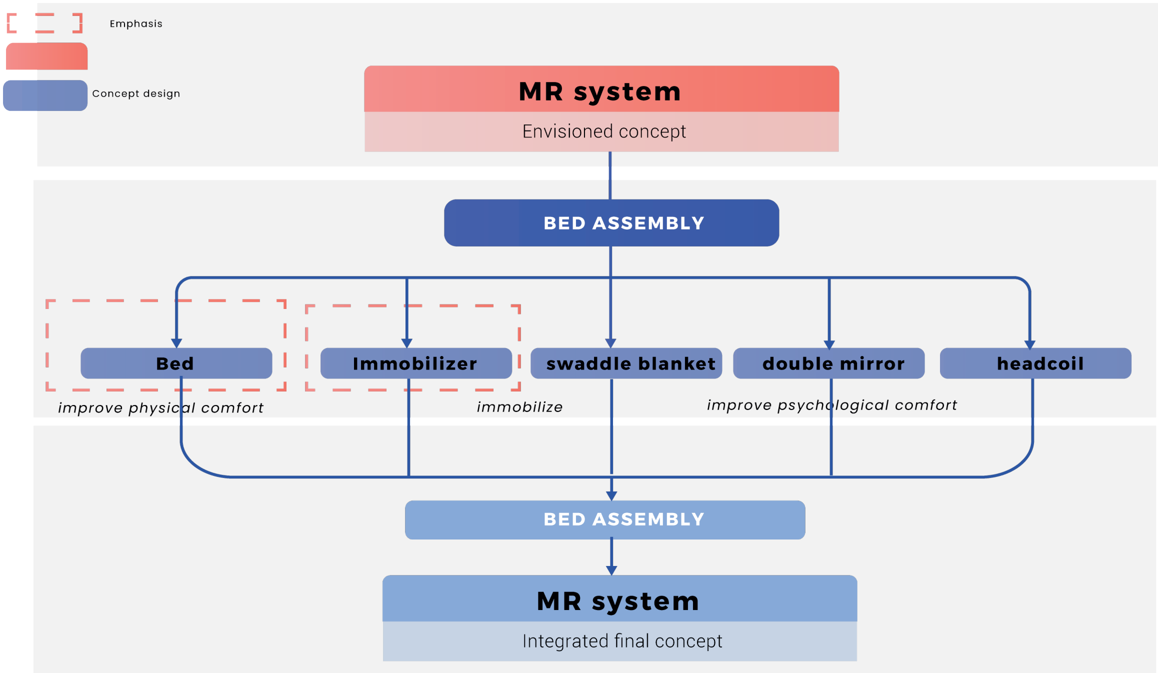


Figure 1.2: Structure conceptualization methodology

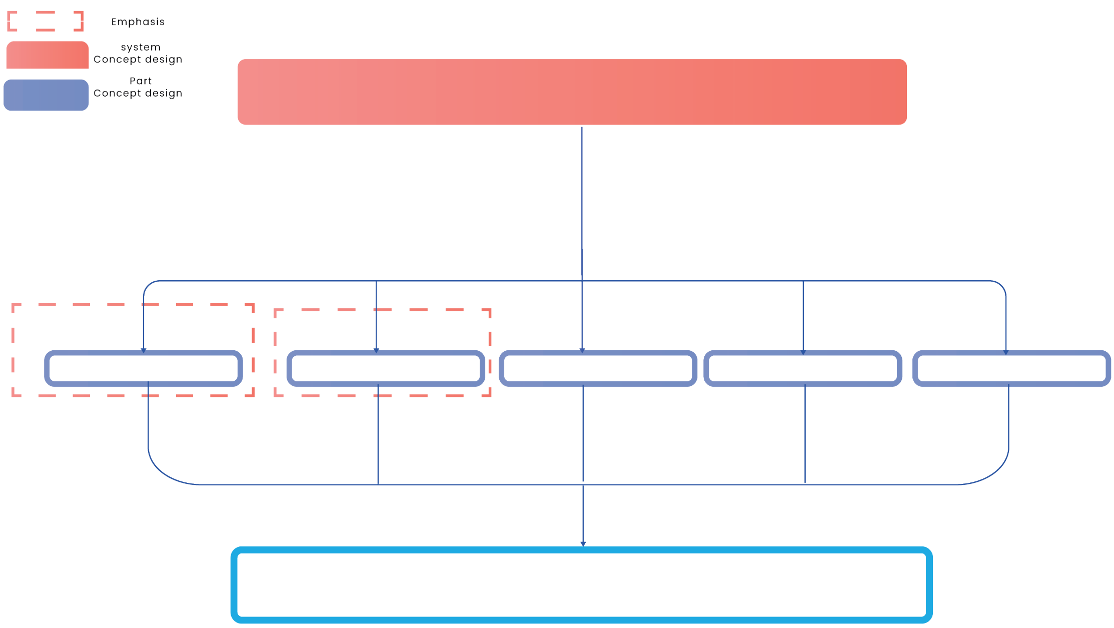


Figure 1.3: Structure of report- reoccurring visual

Discover

Background research to define product requirements

2. Introduce the low field MRI

3. Context research

4. Technology research

5. Human Factors research

2. Introduce the low field MRI

This chapter sheds light into the starting point of the graduation project. Prior to designing, the added value of the Low Field MRI scanner were assessed and evaluated against the proposed design process. What do we need for a successful MRI scanner and how do we need to guide the design process to achieve this?

2.1 Additional value of the LF MRI

The product owners aim to increase the accessibility of MR diagnostics for the treatment of hydrocephalus.
Therefore, many patients need to have access to this device. Magnetic Resonance Imaging (MRI) scanners are one of the safest and highly sophisticated diagnostic devices that use strong magnetic fields to produce anatomical images.
However, due to the high prices and complexity of use and maintenance of the MRI scanner, most of the world has limited to no access to this device for diagnostics, for e.g. hydrocephalus. In response to the need for less costly, less complex medical technologies in LMIC, the low field MRI scanner is designed as a low-cost MR device thanks to the lower magnetic field and appurtenant less complex maintenance.
The low field MRI scanner is the proposed primary diagnostic device for the imaging of brain imaging for resource-low settings for the introduction in the Cure Children's Hospital of Uganda in Mbale.

The Cure hospital is one of Africa's most outstanding paediatric hospitals for brain surgery and treatment of neurological conditions. It provides the most advanced neurosurgical treatments in East Africa by annually performing 1,448 surgeries specified in paediatric neurosurgery, currently the leading facility for treating Hydrocephalus [65]. Considering that an estimated 85% of these surgeries need brain imaging, four patients a day would need the low field MRI scanner. However, even though the Cure hospital is one of Africa's most advanced hospitals, it still endures the challenges present in LMICs. Therefore, the Low Field MRI scanner will be operated in the Cure hospital first and will be expanding its purpose in other hospitals and clinics in LMICs.

In the CURE Children's hospital in Uganda, children with hydrocephalus are scanned by using ultrasonography (US) and computed tomography (CT) [32]. However, complexities occur during the imaging with the US due to the blockage of ultrasound waves by the skull. Therefore this technique is solely used in prenatal cases. CT scanning exerts high doses of radiation, which can be damaging for paediatric patients. Therefore this should be avoided. Magnetic Resonance Imaging (MRI) is beneficial for examining hydrocephalus in children. However, this equipment is not present in the Cure hospital yet.

Opportunities and threats
The introduction of the LF MRI scanner would have both advantages and disadvantages compared to the high field MRI scanners (Figure 2.1). The lower field (50mT) produces lower-quality images. Nevertheless, they should provide diagnostically helpful information for imaging hydrocephalus. In many cases, the decreased image quality does not translate into worsened patient outcomes. The main attractive strengths of low-field systems is their reduced footprint, which could take MRI to the point of care, similar to ultrasound. This increases accessibility in LMICs.

This report outlines the design and development of the low field MRI scanner into a safe and usable consumer product.
The current prototype of the low field MRI scanner focuses on technological advances in permanent magnet design, RF coil architecture, gradient performance, and image processing algorithms developed to improve the lower field strengths [6].

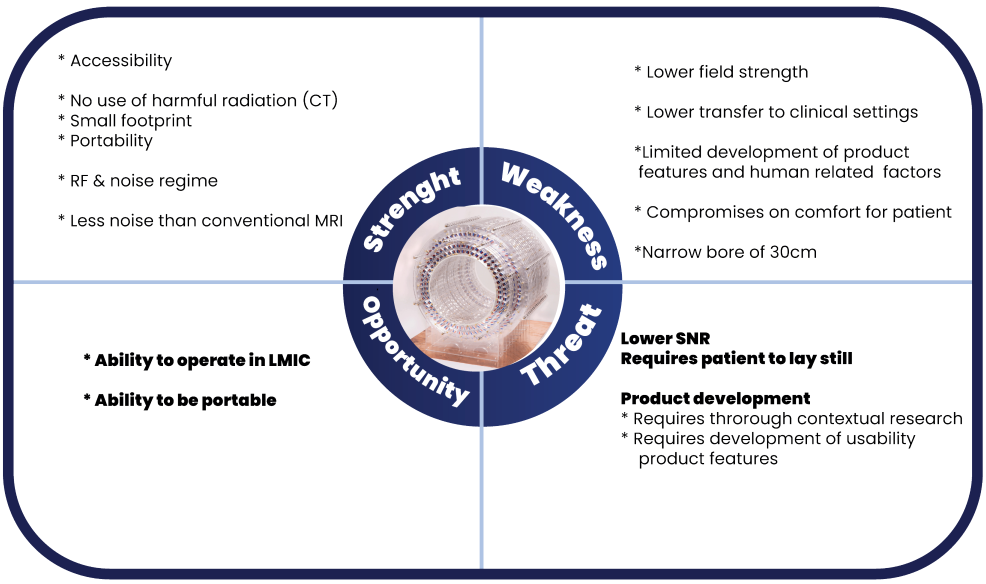


Figure 2.1 SWOT- analysis of the low field MRI scanner in a LMIC

However, to increase the access of the LF MRI scanner, a safe and easy to use operation for a complete MRI system is needed. The improvement allows better accessibility for those systems in LMICs than conventional MRI. However, most frugal products mainly focus on making the technology cost-effective to overcome resource constraints but do not focus on the possible services, infrastructure, beliefs, and cultural habits of the context to make the technology fit the context.

Therefore, to provide qualitative images (Technology research), the development of the further prototype into a consumer product needs to include research about the bed system, the use of patient (Human factors research) and the ability to sustain inside the low resource context (Context research). Additional to the challenging factors that might influence the product design and development, the patient must be immobilised. Accordingly, this report will address the process of the design and development of a safe bed system integrated with a low field MRI scanner that covers the contextual, human, and technological factors. Therefore the principles that address general design for product innovation and design for LMICs will be addressed.

2.2 Product innovation in LMIC

The increase of accessibility of the innovation low resource settings depend on their acceptability [112]. Therefore research on the implementation of a frugal innovation needs, along with research on how this frugal innovation can be successfully sustained, must be done. Two questions arise: What factors need to be considered to implement a medical device in a LMIC successfully?
What factors are essential to keep the product available in a LMIC?

2.2.1 Design for product innovation

Design innovation is paramount for successful product implementation, which relies on feasibility, viability, and desirability [112]. However, once a design innovation is successful in its introduction and fulfils the feasibility, desirability, and viability requirements, this does not guarantee the sustaining of a medical device in LMICs.

Design for product innovation: The three lenses of innovation
Design innovation plays a crucial role in the success of a product within the context and the company's competitive strategy. The new product development requires compromises from both the 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 by meeting the conditions of desirability (*The product considers the needs of users and stakeholders)*, feasibility (*The product has the technological possibility to be made and function properly)*, and viability (*The product has an economic growth potential in the market)* [11] (Figure 2.2).

2.2.2 Design for LMIC

To ensure that the product remains operable after getting obsolete, the challenging context needs to be considered. In addition, the introduction and use of technology in resource-poor settings raise several issues that need to be addressed and solved [12]. Therefore, design methods addressing design for LMIcs are essential. The accessibility is not solely achieved by introducing a sophisticated, inexpensive technology due to additional obstacles [15], [16].

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 focused on HIC and may not deliver successful products for Bottom of the Pyramid (BOP) markets[4]. Because of the different sets of characteristics, challenges, and needs in LMIC, engineers should have an all-encompassing approach to medical technology design for LMIC. By emphasising the use and context, one can uncover the values and priorities to design a user-centred medical device. For a successful implementation, the product additional needs to operate safely, it needs to do so in a sustainable way [17].

2.3 Proposed Approach

A combination of the design for product innovation and design for LMIC is proposed.

2.3.1 Factors to implement from design for LMIC

Previous medical devices for LMICs have failed to address the importance of combining cost-effective, frugal technology with socio-economic, cultural, and infrastructural factors to get applicable design requirements. By implementing an approach that involves stakeholders, understanding the context, and implementing their insights for a better design, this results in . durable implementation of medical devices in LMIC.
Eventually, it aims to deliver better care at a lower cost [113] [13]. Therefore, the following strategies are introduced in the design process to ensure the successful introduction and use of a medical device in a LMIC. The outcomes of these strategies serve as the design principles of the thesis. These principles are applied to form the basis of a qualitative product [10].

2.3.2 Principles to combine product innovation & Design for LMIC

1. Sustainable development - ensure viable use

The strives for sustainable development in products involves a balance of economic, social and ecological goals to be fulfilled [18]. 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 sustainability and the entire equipment life cycle into consideration is essential for the device to survive in the context.

During the design of medical devices, specifically for the LMIC context for the product to last longer, be maintainable and disposable. Sustainable development is a development that meets the needs of the present without compromising the ability of future generations. Therefore, devices should be designed with the finiteness of the resources in mind by considering the entire product life cycle[21].

2. Frugal innovation - Ensure feasibility

All the discussed factors attribute to the principles of frugal innovation. In addition, frugal innovation includes various attributes that contribute to the fit of the technology inside the context, such as (functional, lower cost of purchase, reducing the cost of ownership, minimise the use of materials, user-friendly and easy to use, robust, high in value and quality, scalable and sustainable [113]. Moreover, in the resource-constrained market, customers demand affordable, high-quality, environmentally friendly and socially inclusive products.

3. Human-centred design - Ensure desirability

The success of a medical device attributes to the feasibility, viability, and desirability of the designed concept. Efforts need to ensure that the technology is acceptable to and are adopted by users. Cost-effectiveness evidence must be presented during the procurement process, and value-based evidence involves a diverse range of stakeholders [23]. However, to secure the right fit for the context, stakeholder involvement is necessary to secure the right fit and prevent western bias since the low field MRI scanner is designed in a HIC. Therefore, human-centred design approaches are recommended to prevent making wrong assumptions and to research the incentives well [22].

A user-centred design approach proves to have higher success rates than technical sophistication[25].
Design processes that promote early and frequent engagement with stakeholders may increase the impact of medical devices to address global health challenges by improving the uptake and sustained use of such devices [10].

Co-creative design processes that involve local stakeholders, Assembling a multi-disciplinary team, including users, is the best way to co-create, design, and evaluate the design.
Stakeholder involvement is done by creating a series of prototypes to get critical feedback from end-users while also learning and improving its functionality.

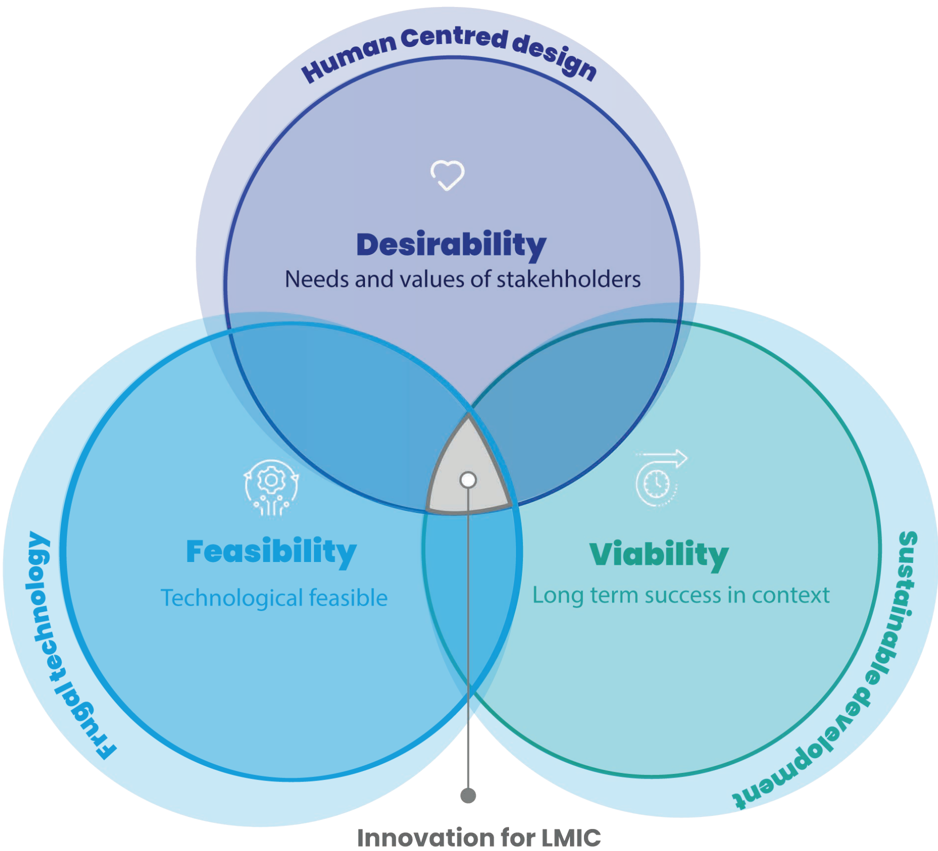


Figure 2.2 Combination of design for LMIC with three lenses of innovation

3. Context

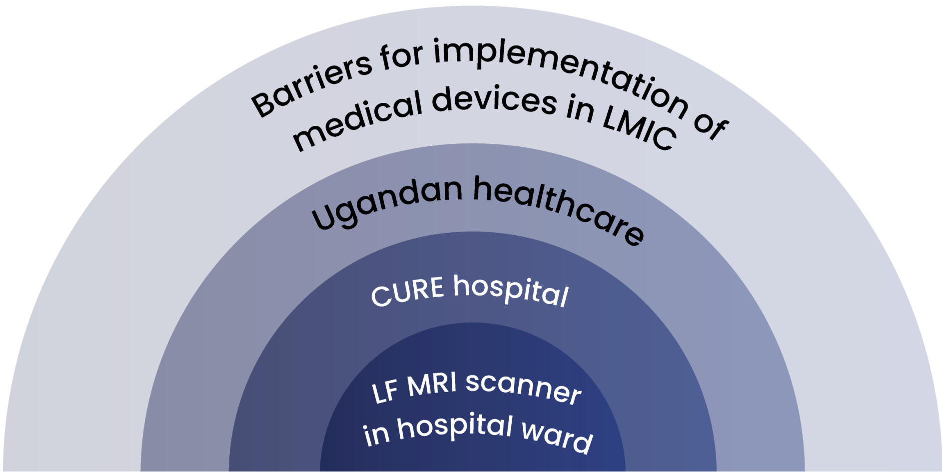


Figure 3.1 Context scope

Introduction
This chapter gives insight in the challenges occurring regarding the envisioned context of the low field MRI scanner. Within this research, the context is scoped into the location and environmental characteristics of the LMIC and Ugandan hospitals. First, the broader scope of the MRI scanner inside an LMIC will be discussed to outline the main challenges of implementing a complex medical device inside the context. The second section is researched in the Ugandan healthcare context, specifically the Ugandan hospital. Finally, the specific challenges concerning the use during the patient journey are addressed.

Objective
- To define the most crucial characteristics of the context and work environment of the Low Field MRI scanner.
- To define the contextual requirements for financially high medical equipment such as an MRI scanner in an LMIC.

Method
The primary research method to better understand the context was through context mapping and **DEPESTE analysis,** which does not solely involve literature research to get a superficial insight but to understand the values, drivers, and way of thinking through interviews observations. The lack of literature in this specific field required alternative resource methods. The complete literature research can be found in Appendix D.

Interviews
have been done with experts and stakeholders, which can be reviewed in Appendix B.1. The findings are discussed as visualised in Figure 3.1 in three layers. The layers' fundamentals, challenges, and influence on their design are discussed. The meta-level discusses the contextual factors of a low resource setting that influence the product's operation, design, and end-of-life. The macro-level discusses the structure and organisational elements of the healthcare system and the factors in Uganda. The micro-level analyses the interactions between the stakeholders and how this influences the final design of the LF MRI scanner.

Observation (Appendix B.3)
Observations of the entire diagnostic process of imaging for patients with hydrocephalus through video have been the primary source for the patient journey mapping. Through observation as a patient (inside MRI scanner) and as an observer (next to MRI technician) of the diagnostic process in a clinical MRI scanner (Philips Achieva 3.0T (TX)) at the Holland Proton Therapy Centre, the patient journey was detailed with values, feelings, and thoughts.
As a result, contextual requirements were defined for designing the concept of the system.

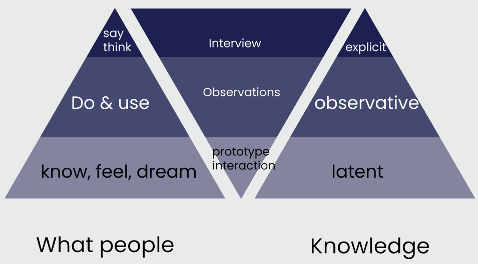


Figure 3.2 Methodology for gathering insight

3.1 Barriers for introduction of medical device in LMIC and Cure hospital

Designing medical devices for a LMIC presents unique challenges. These challenges act as barriers to the availability of the MRI scanner in LMICs. For the device to succeed, designing to overcome this barrier is necessary. Therefore, medical devices must be explicitly designed for their context, not just imported.
The most prominent barriers that hinder the diffusion and availability of the MRI scanner in LMICs are described in this section. The Low Field MRI scanner is cost-effective to overcome the financial barrier of procuring a medical device in a low resource setting. However, this is one of the many barriers present. Therefore, for the Low Field MRI scanner to be purchased and used for a longer time and more use cycles, it is of necessity to consider the main contextual barriers that hinder the availability of MRI scanners in LMICs. This is categorized in financial, resources and environmental conditions. The findings from LMICs are the result from literature study and the findings from the Cure hospital are the result from interviews with radiologist, nurses and medical technicians.

The low field MRI scanner is designed to operate inside the Cure Hospital in Uganda. Unfortunately, the majority of the healthcare systems in LMICs cannot rely on progression from their healthcare system due to unstable infrastructure, governmental structures and systems. For instance, 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 inefficiently promotes the diffusion of resources. This affects the cost, outcome of care and eventually, the population who cannot obtain medical devices and thus have a higher risk for adverse medical outcomes. Furthermore, this hinders the access and delivery of quality healthcare. Below the barrier occurring in LMICs, the specific situation for the Cure hospital will lead to the system requirement.

3.1.1 Lack of financial funds

The main reason for the lack of medical devices in LMIC countries and the cause of the introduction of donations is the high purchase and the operating cost of the medical devices. Additionally, the patients pay disposable parts on top of the treatment costs, resulting in financial challenges [61].
Furthermore, radiologists mentioned that it is necessary to make the product cost-effective to procure, but especially the cost of ownership must be cost-effective [ref. Appendix B.2]. " Solely providing a cheap MRI scanner is not enough. It is important to make the cost of ownership also cost-effective. No one benefits from a product that is broken after two months, which no one can afford to maintain or repair." (Radiologist, LMICs&HIC)

Cure Hospital
The Cure hospital is as a private hospital (PNFP) not dependent on financial resources from the patients. This way, they can provide their services for free, which is exceptional. The majority of the hospitals where this device will be operable is a Public hospital. In these hospitals, the Ministry of Health (MoH) oversees managing the medical policy regulations and the financial responsibility of the equipment in hospitals. The hospitals are dependent on cash flow from the government and paying patients. The patients are left to themselves to finance the cost of the treatment. For diagnostic scans, the patients are charged the equipment cost and procedure price. Therefore, to allow a public hospital in a LMIC to procure the MRI scanner, the cost must be lower than a conventional MRI system.

Therefore, it is necessary consider the price of the purchase, use , maintenance and the durability of the device to keep the price as low as possible for the patient. Furthermore an increased lifespan of the device keeps the cost price low as this is taken over a longer time. In this way, procedure would be more affordable.

3.1.2 Lack of maintenance and repair

The lack of resource availability in either human or material resources is a reoccurring problem defined in various literature [3],[4],[61],[62]. The WHO estimates that a large proportion up to 70% of equipment is obsolete because the equipment is not maintained well. The existing maintenance and service facilities are either non-existing or spare parts are lacking.
Initiatives to support and regulate multiple life cycles and the end of life of medical equipment is not present. The maintenance is vital due to MRI scanner often goes out of service because something is broken. An MRI scanner that is out of service is lost money, so immediate maintenance is crucial.
According MRI maintenance operators[43],[44], not much

Figure 3.3 Cure hospital

maintenance is done for MRI scanners in LMICs. Imaging equipment is often purchased with a service contract, but once this contract is over, the operation of the equipment stops as soon as a part goes obsolete. Once a part of the product is broken, the equipment remains obsolete for longer, wasting costly operating hours and space. The most challenging part is troubleshooting and acquiring replacing parts. Although Uganda does not have many trained MRI maintenance professionals, the essential technicians who currently repair medical equipment are highly skilled.

Cure
Medical equipment maintenance is supported by generally trained technicians, with a wide availability locally. However, the infrastructure does not allow serviceable maintenance, which allows transportation of the parts. Furthermore, disposal or end of life assessment for recycling is not present.
The production of medical devices is not facilitated by a Ugandan company or institution yet. However, the possibilities for distribution are present. Therefore, the potential must be used by allowing local production of the low field MRI. This myst ben done be designing the device with locally available materials from available production methods. This increases the ability to provide local maintenance and repair.

3.1.3 Lack of material resource availability

The most important unique design barriers for medical devices in the developing world hospital are spare parts and required consumables [63]. Unfortunately, once the equipment has been used for its first life cycle, no spare parts or other consumables are available in the LMIC. However, the implementation of repair resources and readily available spare parts increases the accessibility and durability of the device [64]. Therefore, products in this context must be designed by considering the accessibility of only standardised parts to provide cost-effective repair and maintenance. Therefore, the LF MRI must be designed so that spare parts are easy to obtain, and no specific tools are used, it is understandable for a regular technician.

3.1.4 Lack of human resource availability

Human resources
The safety and treatment outcome of medical devices is directly linked to the operators' skills and how the equipment is managed [12]. This has been perceived to be a continuous case. The one-time training provided by the manufacturer has often been revealed to be insufficient in developing countries. There is a need for frequent training of new staff [62]. Furthermore, the lack of personnel and proper training form a problem for implementing the Low Field MRI system [15]. Therefore, it is crucial to consider the user interaction with the product when designing the embodiment of the device to provide an as intuitive experience as possible to minimise the hazard of human error. A" brain leak" occurs when the medical staff is educated but pursues its career elsewhere. The gained knowledge is not transmitted to the other personnel while the investment cost for education and training for the hospital in the low resource setting was high.

Cure Hospital
Nurses rotate each year. When the nurses encounter the machine, they must know how to use it properly without damaging it. Because of the rotating system, training is offered periodically to ensure the long lifespan of the machine [66]. Nevertheless, variabilities in individual staff's training and experience levels can impact imaging outcomes. Due to the under-staffing of trained professionals, primarily nurses and intern doctors will be using the machine instead of doctors[66]. Therefore , the MRI scanner must be understandable for a basic trained personnel. Furthermore it must not increase the current workload of the MRI technician.

The majority of the hospitals have no extra budget for the training of medical staff. The under-staffing of medical services is a considerable problem, especially in public hospitals. The level of medical knowledge of the employees in Ugandan hospitals depends on the facility and type of hospital. Currently, only doctors from regional hospitals, are appropriately trained for working with MRI and other imaging devices and hospitals in general regions are left behind. This is due to the educational system and the lack of supply that does not allow medical students to have MRI scanners for apprenticeship[55]. Therefore it is important that with the supply of the MRI scanner, a training service is included which is suitable for the skill level of the personnel.

3.1.5 Challenging environmental condition

For the product to sustain itself, it is necessary to consider environmental and infrastructural conditions. The contextual differences between HICs and LMIC, such as higher temperature, eruptive power supplies, and dust in LMICs, demand different requirements from the device. Often these are not considered since the technical infrastructure of the receiving hospital is not considered during the design of the medical device. For example, red dust is a problem in many hospitals in Uganda [34]. This dust penetrates all corners and voids of equipment. It should be avoided that the red dust penetrated the moving parts.
Many areas in LMIC deal with an inconsistent power supply. This can cause power surges and drops, potentially damaging the equipment.

"Solely providing a cheap MRI scanner is not enough. It is important to make the cost of ownership also cost-effective. No one benefits from a product that is broken after two months, which no one can afford to maintain or repair."
L. Gieskes - Radiologist in HIC & LMIC

3.2 Stakeholders

3.2.1 Product journey

The equipment journey (Figure 3.5) illustrates the proceeding of the MRI scanner post engineering. The main stakeholders within the phases have been defined, which are the patient, the MRI technician, the caretaker and the radiologist doctor.

Figure 3.4 context research methodology

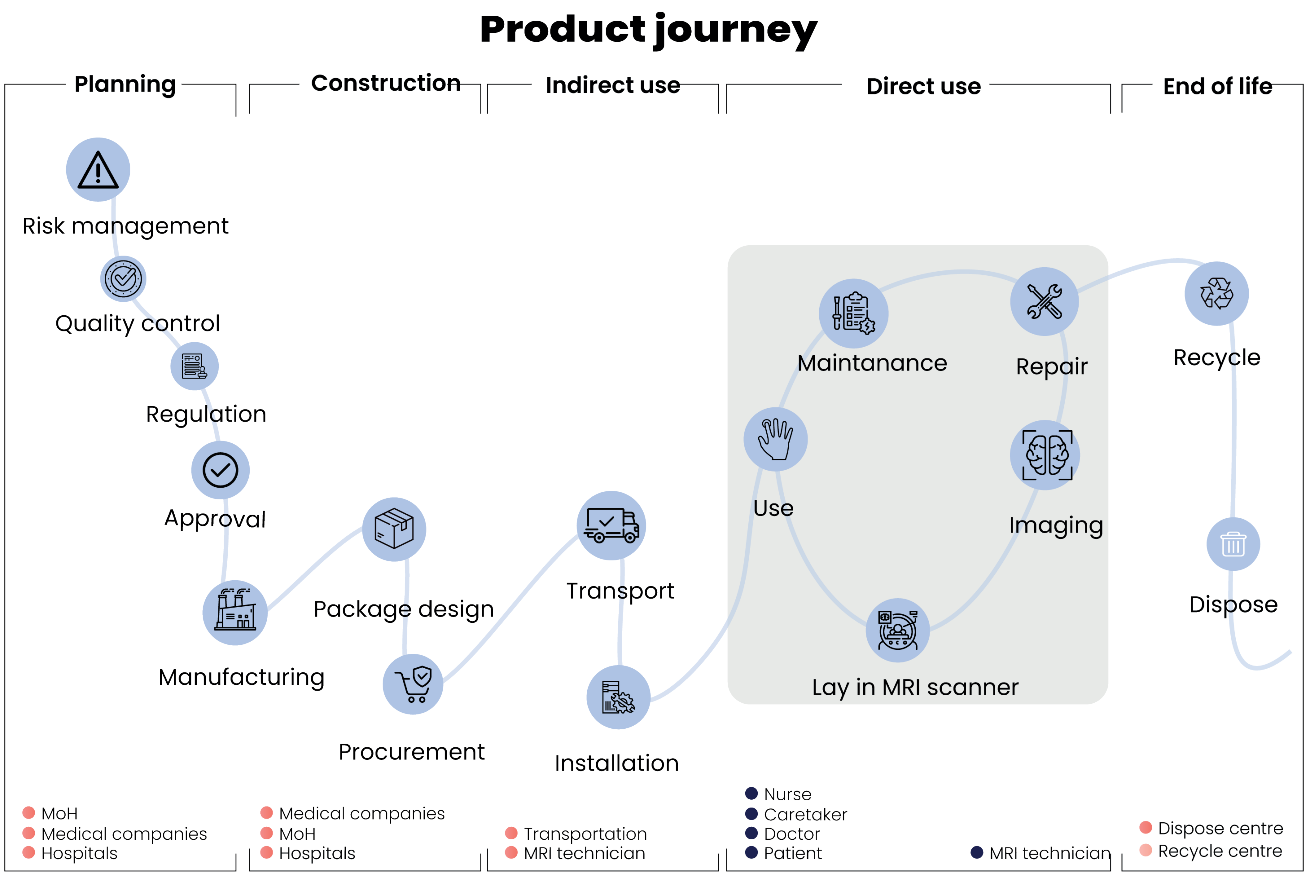


Figure 3.5. Equipment journey map

3.2.2 Stakeholders

Based on the literature research and interviews with different stakeholders, insights of types behaviours and objections of users are gained (Appendix C1). According to the stakeholder (influence/ interest) map(Figure 3.6), three types of users directly influence the product: the patient, the caretaker, and the nurse/MRI technician.

Needs and values of patient

− Children with hydrocephalus are characterised by a less energised attitude while being more movable. The children that come in for the first time are severely ill. The sunset phenomenon can occur, which results in the infant becoming quieter and vomiting more than a healthy child [45]. It is not uncommon for bodily fluids to be excreted during the procedure. Furthermore, the child is heavily dependent on its caretaker, making it challenging to separate prior to an MRI treatment.

+ Being close to its caretaker is essential for the patient to remain calm or be consoled.

Needs and values of MRI technician

The MRI technician is the person that is trained to operate the MRI scanner to guide the patient and caretaker through the process. This may also be a nurse due to a lack of personnel. MRI technologists have the daily challenge of achieving best-quality, first-time-right scans. In addition, communication and comfort are critical components for both patients and care providers.

− Patients are often anxious, which increases the pressure on technologists to get the exam done effectively because a restless patient can mean redoing the exam. However, staff often have little time to interact with patients because their workload can be relentless [4].

+ The cues that patients sense from their care team can impact the experience overall. Primitive equipment designs may be perceived as lesser quality and are rejected despite the lower cost [3].

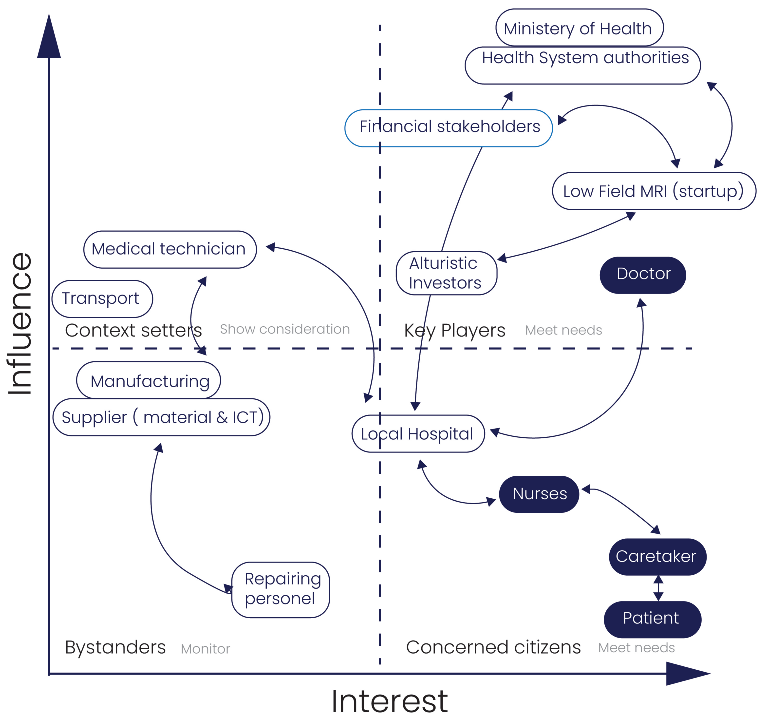


Figure 3.6. Stakeholder influence/interest map

Needs and values of Radiologist

The MRI physician may be the radiologist or the surgeon educated to treat the patient and interpret the MR scanning images.

− In a low resource hospital, highly trained staff is scarce, which makes the workload of the MRI physician significantly high.

+ Medical professionals have great interest and influence in MRI scanners. In small clinics, they have a significant influence on the procurement of the MRI scanner. What the medical professional values in the procurement of an MRI scanner in an LMIC besides the quality is;

1. The price
2. The usability
3. The size of the machine
4. The possibility to maintain it immediately. (For HICs this highly depends on the brand and the service that is offered). Furthermore, doctors are interested in new devices and improved user and patient friendliness [39]. Distrust for equipment originated from LMICs is common. A Western look of the device is more valued according to the professionals, it demonstrates" professionalism" and" quality" [46].

Needs and values of Caretaker

+ The caretaker values safe and personalised care for its child. Keeping close to the patient is important.

" The most challenging procedure during the scanning is keeping the child calm and still" -

Edith Mbabazi - Cure Hospital

3.3 Patient journey mapping

The mapping of the user's values, thoughts, and feelings is visualised in a patient journey map (Figure 3.7) to better understand. This map visualises the entire treatment procedure from entering the hospital to surgery from the perspective of the main stakeholders: the patient, the MRI technician, and the caretaker. The patient journey is the reslt of interviews and observations inside the lof field MRI scanner and a 1.5T MRI scanner.

1. Pre-diagnostic

Prior to the patient's entrance inside the bore of the MRI scanner, it is required to prepare the patient. This involves stripping the infant from metallic parts and calming the patient since motion will distort the imaging. However, comforting is the most challenging and time-consuming task and requires the support of the caretaker. This step is crucial to minimise movement that would cause blurring of the images. After the calming of the patient and placement on the bed, the patients head must be aligned correctly in the middle of the bore. Positioning is a specific task that requires multiple gestures, such as looking, aligning, and strapping. Multiple people might be needed to calm and align the patient. The head is strapped, but this only provides limited and temporary securing. A conductive blanket is provided on top of the patient to minimise noise and close the cage of Faraday. However, this blanket obstructs the airflow of the patient.
From the caretaker's perspective, these are challenging tasks that require high expertise in working with children.

The Cure hospital is a specialised private children hospital with trained personnel. However, the product must be not simply operational in a specialised children's hospital but also inside other hospitals in low-income countries. These settings do have not the privilege of highly trained personnel.

2. Scanning

During the diagnostic procedure, the patient is entered inside the bore while the nurse or medical technician proceeds on the monitor and sets the sequence. For a single shot MRI scan, the patient will remain motionless for 3 minutes and is not sedated. With a complete MRI, this procedure may take 10 - 30 minutes During the diagnosis, infants tend to move frequently. Feelings of claustrophobia occur within the child, which causes the child to cry or make unexpected movements. Important risk factors that may cause the aborting of an MRI scan are when the patient moves, cries, vomits, increases heart rate.

3. Post-scanning

After the brain image is done, the patient is removed from the bore and given to the caretakers. The images are assessed, and surgery is planned. Follow-up imaging is necessary to monitor the development of the disease.
The device must be cleaned after each patient and maintained routinely to use the MRI scanner for more than one life cycle.
For cleaning during the same day after patients use, the MRI technicians at the Cure hospital use a regular cloth with water. After the regular cleaning, the device gets sterilised with disinfectant or hydrogen peroxide [43].

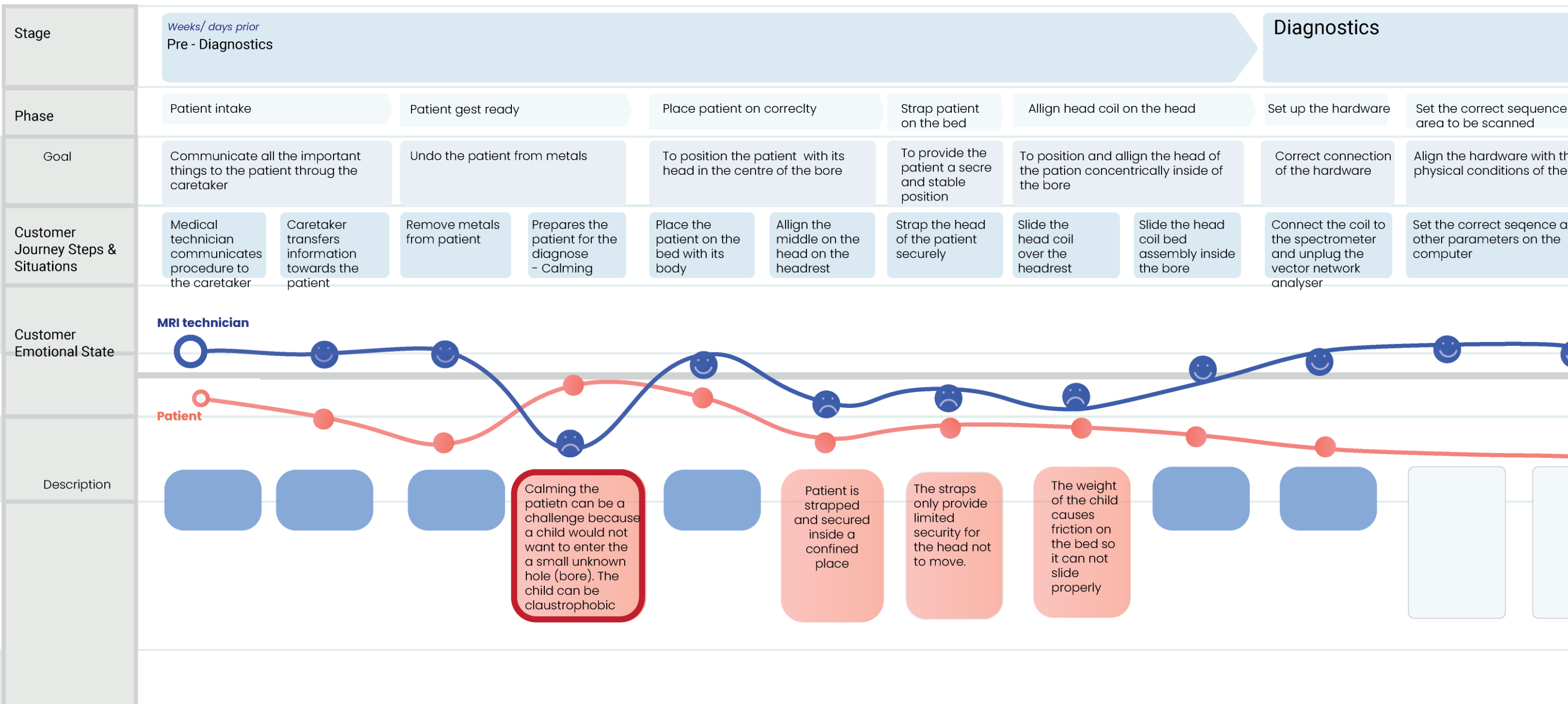


Figure 3.7 Patient journey mapping

Conclusion

Main challenge

The main challenge occurring during the procedure is that the patient is prone to moving and the MRI technician has difficulty calming the patient. For the MRI technician the most challenging part is the calming of the patient. Therefore the MRI scanner must aid with this task.

This movement is caused by discomfort during the procedure. As can be seen in the PJM the negative experience for the patient starts once the patient is removed from the caretaker. Furthermore the in-bore experience is very negative and brightened by positive interaction with the MRI technician and caretaker. Therefore this experience must be improved for a better imaging.

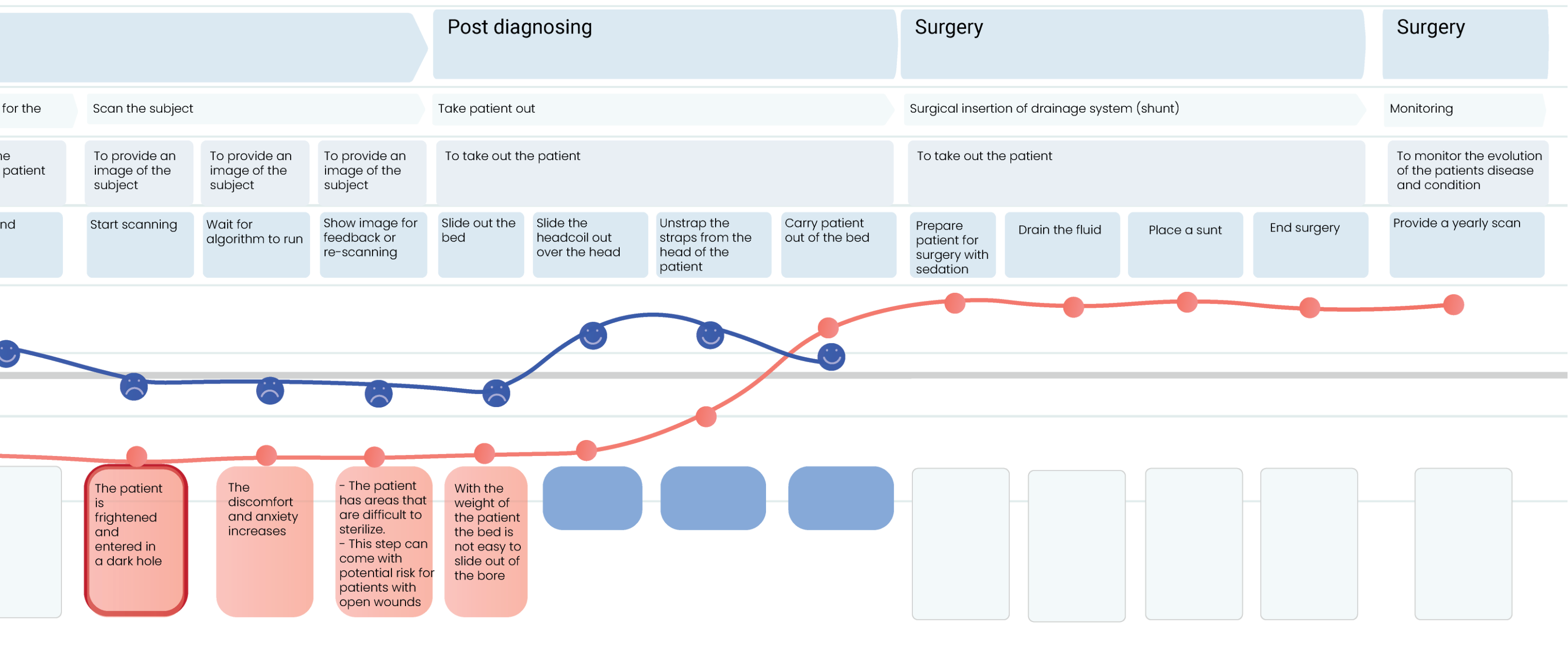
Two types of patients can be defined. First, the patients undergo the scanning for the first time. This is the majority of the occurring patients, with a mean average of 3 months old. They have not had treatment yet and are severely ill.

The other type of patients is the older infants that are reoccurring often to get monitored. This group of patients is more movable and harder to get still, with an average of 4 years old. For the patient that undergoes the scanning the first time, the perception of the MRI scanner is essential. The unfamiliar looking device might trigger anxiety in the infant. The first experience is highly determinant on following procedures, especially with frequent follow-up. The first experience will determine the willingness to continue the scan and participate in the follow-up.

The emotion of the MRI technician and caretaker additionally have an effect on how comfortable the patient feels. Infants encounter the first signals of stress when they are detached from the caretaker and must enter the small narrow tube of an unknown and cold product. The look of the MRI scanner can contribute to a sense of fear. A relaxed setting and friendly appearance of the device decreases the nervosity of the patient. Patient comfort is priority in a good quality image.

Requirement

The LF MRI must have an additional value for the main stakeholders, which are the patient, MRI technician and caretaker. They all value a system they can trust and promotes interaction with the patient.



3.4 Key insights

For the MRI system to operate in the challenging context of a LMIC the following requirements must be considered. An overview of the key insights from this chapter can be seen bellow. *The complete list can be found in Appendix A*

Key insights	System requirements
Context	
1. The main barrier to the availability of medical devices in LMIC is due to lack of financial funds.	1.1 The MRI scanner must be cost effective to purchase
2. Solely making the equipment cost-effective for purchase is not enough. The equipment must also be cost-effective in the total life cycle. The patients fund their own treatment and every additional time in the hospital increases their treatment cost.	2.1 The medical devices must be cost effective in ownership and not be more expensive than the competition with the same performance
3. The lack of maintenance tools and parts, challenges the ability to maintain the MRI scanner locally.	3.1 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
4. Accessibility in LMIC can be increased by allowing a better repair and manufacturability. However since this is highly depended of the infrastructure which is not yet fully developed, focus on the longer lasting of the device. This means that the device must be able to withstand the contextual challenges and be robust.	4.1 The medical device must be designed by taking into account the accessibility of only standardized parts in order to provide cost-effective repair and maintenance
5. In LMICs power cuts and an unstable electricity network are common. Therefore it is crucial to consider including a backup power supply stabilized to keep the equipment's continuing during blackouts.	51. The MRI scanner must be able to overcome the environmental challenges 5.2 A backup power supply is required to stabilize the power supply and keep the equipment functioning during a power blackout.
Usage	
6. A lack of human resource availability is a challenge in low resource settings. Therefore the trained personnel rotates routinely between different departments and has not much time in learning the equipment.	6.1 A system that is understandable and usable for people with minimal training
7. Due to the scarce of trained personnel, there is a high workload. Sometimes even other nurses have to fill in for to operate the MRI scanner.	
8. There is a lack of maintenance personnel in hospitals in LRS, due to this the MRI scanner will be obsolete as soon as the first repair needs to be done.	8.1 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.

Key insights

System requirements

Interaction

9. Comforting the child is the most challenging task for the MRI technician

10. Motion, crying and vomiting brings distortion in the MRI which causes the scanning to be aborted.

11. If the patient is not settled for the time of the scan, a repeated scan is required.

12. It is common that both patients, parents and the MRI technician/nurse are nervous.

13. The patient is dependent and attached on its caretaker. During an MRI procedure, caretaker and patient are separated, which is not beneficial for the comfort of the patient.. The child is not sedated, so calming the child is the most challenging task for the MRI technician.

9.1. The product must aid the MRI technician in calming the patient
9.2 The MRI scanner must allow interaction between caretaker and child

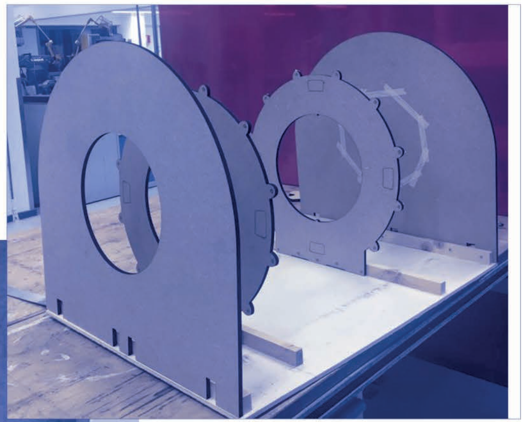
10. The MRI scanner must immobilize the patient as well as possible

13.1 The device must allow a secure work flow of the MRI technician to minimize nervousness
13.2 The MRI technician must be at a comfortable and calm state of mind

13.3 The device must have a “child-friendly” look for the patient

13.4 The MRI scanner must have a professional look for the MRI technician and procurer.

4.Technology



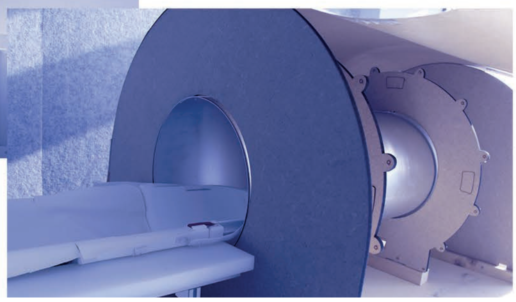


Figure 4.1 Mock-up building to understand the challenges within the technology

Introduction
This chapter gives insight in the fundamental principles of the MRI scanner technology. The differences between a conventional and the low field MRI scanner are discussed to give insights in the main challenges occurring during the product development.

Background
The acute condition hydrocephalus treatment requires early detection and diagnosis prior to treatment. This early detection is achieved through diagnosis with the MRI scanner.
The low field MRI scanner is a medical device that operates based on the fundamentals of Magnetic resonance Imaging while compensating for different functionalities such as less power. These improvements for the technology create trade-offs when introducing the patient inside the challenging context.

Assessing MRI from a clinical perspective shows many advantages, such as that the conventional MRI scanner is one of the safest ways of diagnosing internal tissue due to the absence of ionising radiation. In addition, the patient is not exposed to potential harm. Another advantage is that the images created by MRI technology are precise and definite. Therefore, a medical professional can diagnose tissue by only analysing the image derived from the MRI scanner, which decreases the potential for other diagnostic procedures the patients need to undergo.

Besides the many advantages the MRI scanner presents, the disadvantages are a source for improvement. Since MRI scanning systems reflect hydrogen atom signals, soft tissue is mainly scanned. From a human interaction perspective, inserting a body part inside the coil causes patients to feel uncomfortable and claustrophobic. Furthermore, the patients must lie motionless for the system to operate accurately and have minimal distortion in the measurements. The most significant disadvantages are the expenses of the operation and the maintenance of an MRI system.

Objective
The technological research aims to give insight into the fundamental working principles of Magnetic Resonance Imaging. Furthermore, it describes how the low field MRI scanner functions based on the present components. The ultimate goal is to define the most significant challenges within the hardware development of the LF MRI. Appendix E describes the extensive research.

Method
I did literature research (appendix E), interviews(Appendix B.2), co-creation sessions (Appendix B.2, I.2), trial and testing and mock-up building as methodologies to define the challenges within the technology and the hardware design of the product. (Figure 4.1)

Interview and co-creation sessions
The most challenging problems are defined through interviews and co-creation sessions about the technology with the technical MRI research & development team of the LUMC, the manufacturers of the electronics at DEMO, and researchers from the industry.

Trial testing and mock-up building
Several mock-ups were made, which served as a form of visualising the challenges and communication tools for the online co-creation sessions.

4.1 Working principle of MRI

The fundamental principles of Magnetic Resonance imaging (MRI) are briefly discussed in this section. Magnetic Resonance Imaging (MRI) is a non-invasive imaging technique that is used to produce three-dimensional anatomical images. MRI provides anatomical details and functional information that can help in characterizing hydrocephalus [47]. Conventional MRI technology is based on the physics of nuclear magnetic resonance (NMR) where a selection of atom nuclei with magnetic properties distributes various energy levels. These are defined by the orientation of their magnetic moments relating to the external magnetic field [48].

4.1.1 Fundamental principles of MRI

The magnetic field and magnetisation are discussed to understand the essentials adequately.
A magnetic field is a physical phenomenon caused by a charged particle in motion, which results in an exerted force on particles. A magnetic field is typically characterised as a vector field, which describes the distributed magnetic force. A charged particle causes this magnetic force in motion. The behaviour of the charged particle changes when becoming magnetised after entering a magnetic field. The magnetic field can be described as vector *B,* which describes the direction and magnitude in Tesla (T) and the behaviour is described by the magnetisation *M* in Am^{-1} [49].

Subatomic particles

The atom comprises three subatomic particles: the proton, neutron, and electron. An atomic nucleus with an unpaired proton/neutron or both demonstrates the ability to absorb and re-emit radio-frequency energy when placed in a magnetic field. The hydrogen nucleus has the most potent nuclear magnetic dipole moment of an atom compared to other atomic nuclei found in the human body. Hydrogen atoms are naturally abundant in the biological organism (in water and fat) and are present in nearly every organ in the body. Therefore, it is extensively used to be detected in clinical and research MRI. They generate a macroscopic polarisation detected by antennas close to the subject examined.

4.1.2 MR Imaging

In short, MRI is the technique of separating a tissue sample into individual volume elements, called voxels. Additionally, producing images based on the signal from the nucleus in each voxel [51],[50].
Inside MRI scanners, this phenomenon occurs to make an image eventually. When a body is placed inside an MRI scanner, a solid homogeneous magnetic field creates a uniform alignment of the proton's axes with the magnetic vector oriented along the axis of the MRI scanner. Usually, the field strengths are between 0.5 and 1.5 Tesla. The magnetic vector is deflected due to additional energy (radio wave frequency) that causes resonating of the hydrogen nuclei. A series of gradient electric coils alter the radio waves, which depend on the magnetic field strength B_0 [47] .

The MRI sends a radio frequency (RF) pulse into the body that tilts the nuclei out of alignment with the magnetic field. After that, the RF wave is turned off. This results in the precession of the nuclei, which exerts an RF signal that the scanner detects. Different tissues relax at different rates during the RF excitation period (Figure 4.3).
An RF signal generates in a uniform magnetic field by placing a sample or body inside the homogeneous magnetic field, where after a 90° RF pulse at the precise Larmor frequency is generated. The transverse magnetisation vector that results from this induces a signal in a receiver coil (antenna) proportional to the number of precessing protons. In order to localise the source of signal within a volume spatially, the homogeneous magnetic field is intentionally varied predictably. This produces a gradient of magnetic field strength along each axis[61].

The magnetisation will decay at the moment; the T2 relaxation is described as the process by which the transverse components of magnetisation decay or diphase and return to the resting state. Finally, the nuclei's axial spin will realign its magnetic field in the resting state, which depends on the T relaxation. The MR signal depends on the rate of magnetic flux change that represents the precession frequency signal and the induced nuclear magnetisation. The two-scale linearly with the magnetic field strength means that the MR signal has a quadratic dependence on the magnetic field strength. Eventually, the MR images are composed of a combination of four major factors: (1) spin density (water density/hydrogen density/proton density), (2) T1 relaxation time, (3) T2 relaxation time, (4) flow of protons within an imaging volume [52]. By measuring the change in net magnetisation, the relaxation time is calculated, which indicates the sort of tissue that is detected.

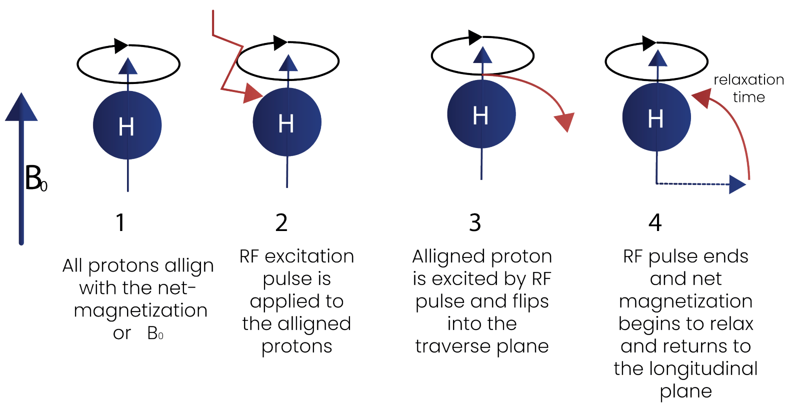


Figure 4.2 Process of magnetization inside MRI

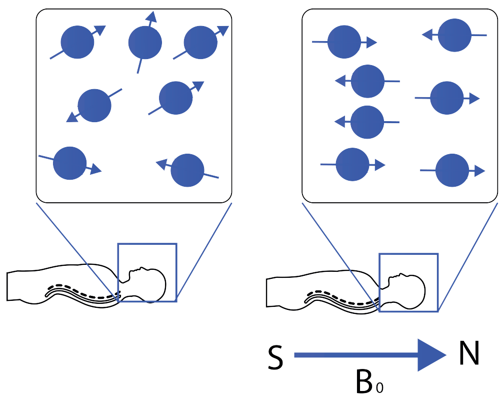


Figure 4.3 Realignment of nuclei inside a MRI scanner

4.2 Hardware design of MR system

4.2.1 Essential components of conventional MRI system

Most conventional MRI systems in clinical applications are equipped with multiple sensors, computers, and accessories to make the operation more convenient and improve human product interaction. However, to acquire high-quality images, solely essential components are vital. The primary function of the MRI is to describe the process of measuring and exciting MR signals while dividing the tissue sample into individual voxels [50]. Therefore, an MRI system requires essential elements to achieve this, which will be discussed in the subsections of this chapter. For more detailed information about the function of the components, consult Appendix E1-5.

The following components are necessary for MR imaging (Fig 4.4).

1. A magnet that produces a uniform magnetic field
2. Radiofrequency (RF) transmitter coil
3. RF receiver coils
4. Magnetic gradients

Magnet

The magnet is the most significant component of the MRI device. Three types of magnets are distinguished: permanent, resistive and superconductive, whereas the last one is most frequent for modern MRI scanners. A high magnetic field is created in superconductive magnets, which is essential to obtain a stronger signal and, thus, a better image. The magnetic field is produced by passing a current through multiple coils inside the superconductive solenoid [10].
The most homogeneous location of the magnetic field is the isocentre, the centre of the magnetic field. Therefore, the subject must be placed predominantly in the proximity of the isocentre, as in-homogeneity causes distortion, shading and other issues in the imaging.
The superconductive magnet in most conventional MRI scanners generates a large magnetic field (1.5-3T). Maintaining this sizeable magnetic field requires high energy, and this is accomplished using involves trying to reduce the resistance in the wires to almost zero. Maintaining a constant temperature of the superconductive magnet requires cooling with liquid helium. Helium absorbs latent heat from superconducting magnets, and it evaporates by cooling the magnets. Unfortunately, cooling the magnet is expensive (around 1M$ per Tesla) and inaccessible for most low resource settings.

4.2.2 Difference with low field MRI

The high cost limits the accessibility for MRI scanners in low-resource settings, even though interest in these areas is growing [53]. These low resource settings cannot meet the requirements of the essential components of the widely used MRI scanners. The context comes with additional challenges, including the financial barrier, high power and fast switches, and transportation to different locations. Therefore, a possibility to propose an MR system for low resource settings is to eliminate the costly superconducting magnet and design a scanner based on a permanent magnet in a Halbach array [54] [55].

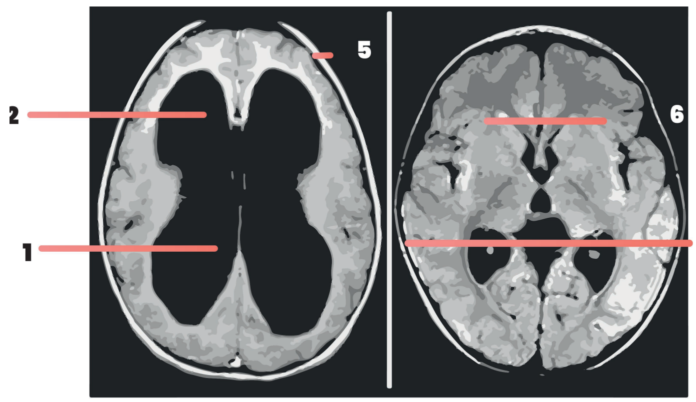


Figure 4.5 Detectable characteristics of hydrocephalus in MR Imaging left patient, right healthy CSF flow (details in Appendix C.2)

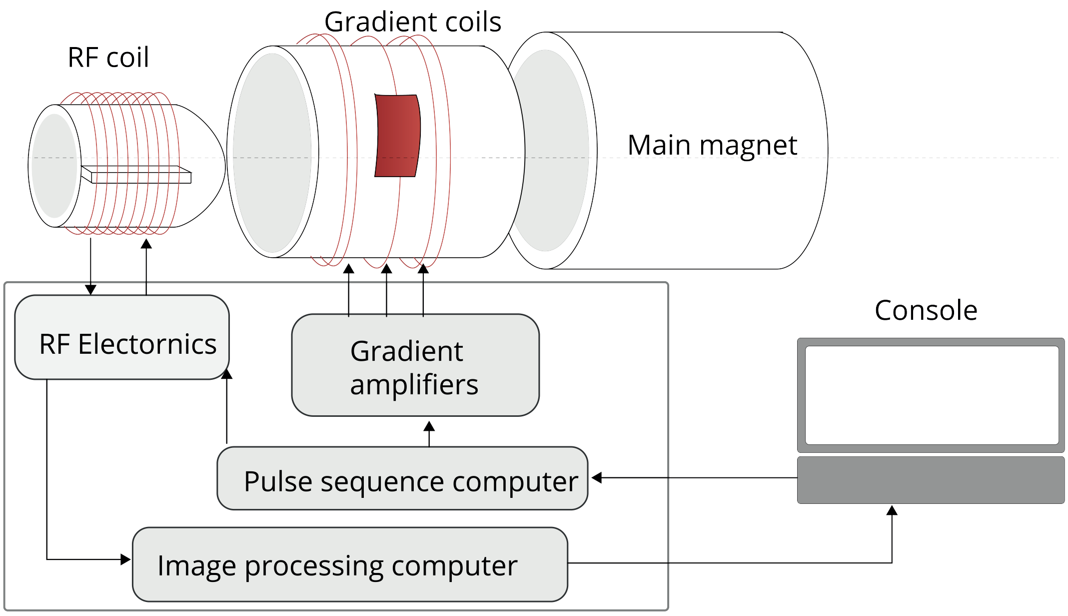


Figure 4.4. Basic components of an MRI scanner

4.3 Low field MRI and essential components

4.3.1 Working principle

In this section, the working principle of a low-field MRI is discussed based on the function of the components. The main difference between the low field MRI scanner and conventional MRI scanners are the magnet, Halbach array and homogeneity. In contrast to a conventional MRI system, a low-field MRI system generates a magnetic field in the order of milli-Tesla with a resistive magnet. Therefore, there are several possibilities to create an LF-MRI system.

Permanent magnet in Halbach array

A technology method to induce a low field MRI suitable for low resource context is by using permanent magnets in a Halbach array. Instead of visualising the body's internal structure by measuring a voltage signal induced by time variations. The low-field homogeneous Halbach MR scanner performs based on transverse-oriented gradients fields. The method is based on cylindrical arranged small-sized permanent magnets which generate uniform magnetic fields. This allows an MRI system with relatively low-weight permanent magnets [56]. Halbach array systems are beneficial due to their low power requirements. However, it is challenging to generate uniform magnetic fields in large-bore sized systems [54]. Eventually, this results in a functioning Low Field MRI scanner with a magnetisation of 50mT.

Homogeneity

Lower homogeneity is a characteristic of low field MRI systems. This homogeneity is optimal within the field of view (Figure 4.6-4.7) and decays when departing from the centre. Ferromagnetic materials may influence the field homogeneity at the proximity of the magnet. As a result, the magnetic field strength decreases to 1% of its strength at 50mm from the magnet Figure 4.4 illustrates the measured magnetic field and decrease of B_0 inside the FoV.

Therefore it is essential for the patients head to be placed inside the FoV of 225*225*300m. For patients that experience claustrophobia, the narrow FoV may present additional challenges to remain still.

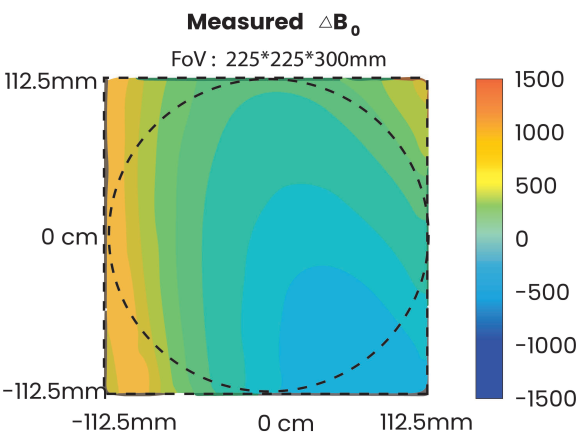
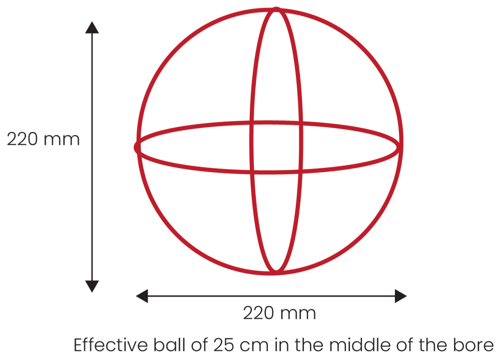


Figure 4.6. Field of view and homogeneity of lf MRI



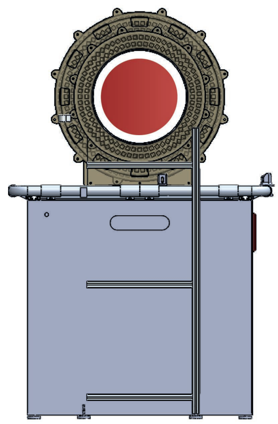


Figure 4.7. Field of view in magnet

Technology

4.3.2 Main components

According to the system, the components of the current prototype (September 2020) are analysed for their function. The functional analysis illustrates the entire system in Appendix E. These components and their requirements must be taken into consideration during the design phase.

Magnet system

Magnet

The essential function of the magnet is to provide a static homogeneous magnetic field. The 23-ring Halbach array magnet of N48 neodymium boron iron resulted in the operation at 50mT. The imaging requires 10 minutes with a spatial resolution of 3mm x2mm x 2mm.The magnet includes shims to improve the magnet's homogeneity. Shims consist of an extra set of magnets inside the diameter to improve the homogeneity of the magnetic field. The total weight of the magnet assembly is 75 kg.

Halbach cylinder

The Halbach generates a field that is as uniform as possible. However, due to limitations in the device's dimensions, this uniformity is attained by a quadrupole [58]. Figure 4.8 illustrates (a) Two layers of magnets in each Halbach array layer. (b) A side view of the Halbach array optimised for homogeneity by varying the diameter of each ring. Each ring is constructed separately using PMMA holders and fixed together using threaded brass rods.

Bore

The primary function of the bore is to provide a smooth cylinder to facilitate the insertion of the patient the subject into the magnetic field. In addition, it serves as the connecting component for the inner electromagnetic shielding and the gradient coils. The diameter results from optimisation between the highest possible B0 homogeneity and additional shimming. The array has a bore of 300 mm and a length of 500 mm [59]

Gradient design

Gradient amplifiers are necessary to amplify the pulses sent to the gradient coils. Gradient coils are loops of wire or thin conductive sheets found inside the bore of an MRI scanner and alter the magnetic field. Three sets of gradient coils(x,y,z) allow the variations of the main magnetic field (B_0). The functionality of the gradient coils does not differ from the conventional MRI scanner. The gradient amplifier is an open-sourced, producible part designed by DEMO to be as easy to repair and replace as possible. The part operates at 60W on average, requiring 12V and 12V power supplies.

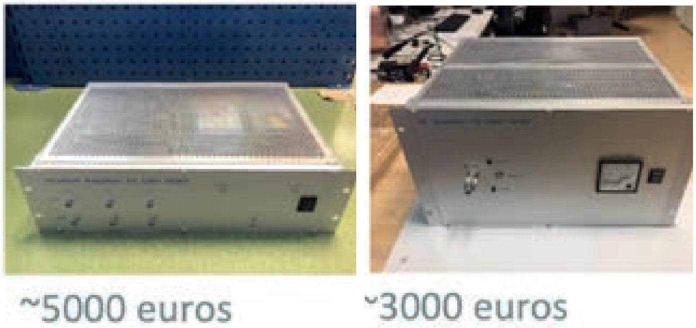


Figure 4.9 Image of the current gradient/ RF amplifier

RF coil

The radiofrequency transmitter is the radiofrequency current generator for the transmitting coil. The created signal from the transmitter excites protons in the imaging field [63] (Figure 4.2). The radiofrequency transmitter is the current generator for transmitting coil. The created signal from the transmitter is used to excite protons in the imaging field [63] (Figure 4.2).
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 magnetisation 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.

The subject is placed into a 3D printed Rf coil for brain imaging, with solenoids used as the transmit/receive coil. On the coil, non-magnetic capacitors are spaced evenly to avoid self-resonance. The subject must be placed predominantly in the proximity of the isocentre, as in-homogeneity causes distortion, shading, and other issues in the imaging. It is, therefore, consequential for the patient's head to be aligned in the isocentre of the bore within the FoV (225mm) [58].

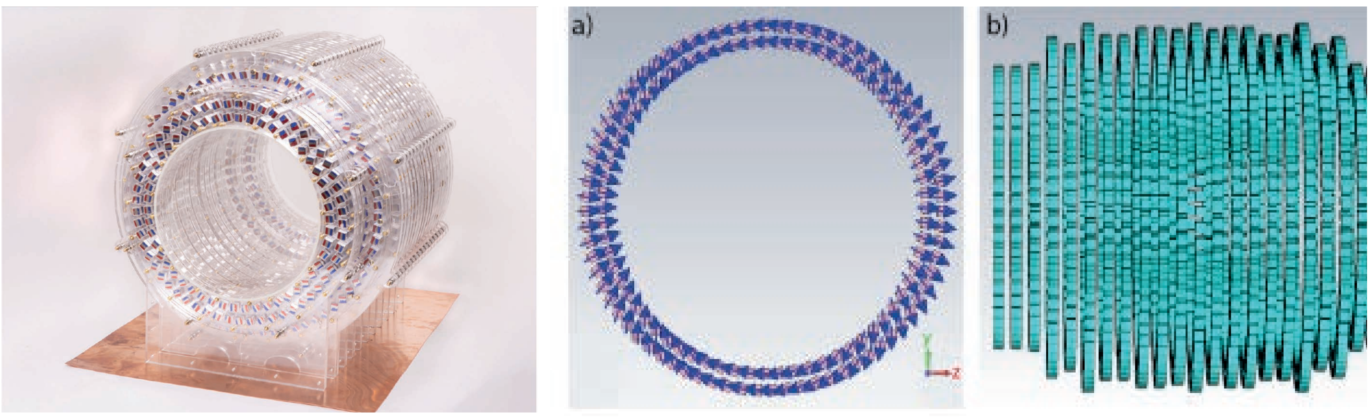


Figure 4.8 Permanent magnet in a Halbach array (LUMC) [54]
Photograph of the constructed magnet array, consisting of 2948 individual magnet elements. The rings are held together using threaded brass rods, with nuts and washers acting as spacers between individual rings.

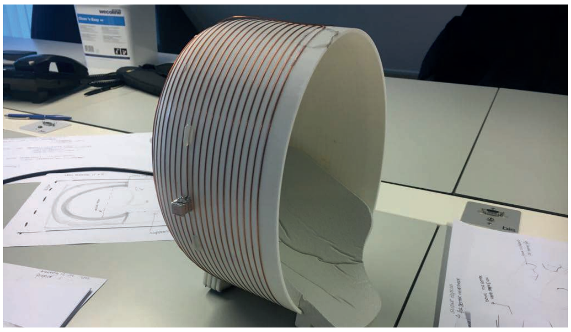


Figure 4.10 Image of the current head coil (RF coil)

Figure 4.11 Image of person being scanned inside the low field MRI (right) under the conductive shield (left)

Additional components

The entire system is placed into a Faraday cage to minimise environmental noise. This system comprises 2-mm thick aluminium sheets and 32 X 32 mm aluminium extrusion profiles.

Electronics system

Spectrometer

The system's processing is regulated by the spectrometer. The spectrometer regulates pulses from the gradient towards the RF amplifier. Furthermore it processes and receives signals which is communicated to the computer. The intended scanning sequence of 10 minutes requires an average of 40W.

Desktop computer and monitor

The function of the desktop and monitor is to process the data to construct the images. In addition, the monitor provides the interface and user guide. A digital user interface is required within this desktop to allow the operator to select the relevant MRI sequence, run the test, and read out the MR images.

Power source

High currents are not necessary to achieve the desired spatial resolution (3 mm), so the maximum voltage (15 V) is chosen such that an uncomplicated air fan and heat sink cooling are used.

Shielding

Since the body acts as an effective antenna, the body is placed under a conductive fabric (Holland Shielding Systems, Dordrecht Netherlands) (Figure 4.11) to prevent additional noise. This sheet is connected to the same ground as the Faraday cage.

Assessement function analysis and TRL

Based on the Technology Readiness Level (TRL), the product lay-out and its components are explained. The TRL is a method developed for estimating the maturity of technologies[9]. TRLs are based on a scale of levels from 1 to 9, with level 9 being the most mature technology and 1 being a basic technology research. With help of the technology readiness level, the current phase of the project is and final phase is defined and the main challenges are outlined. The entire technology readiness level assessment can be seen in Appendix E.

Having presented all the components. The function analysis and the TRL can be introduced. The function analysis represents all the functional components of the low field MRI scanner product in relation to each other. These are subdivided in system, sub system and components. Figure 4.12 illustrates the maturity level of the MRI scanner's current subsystems.

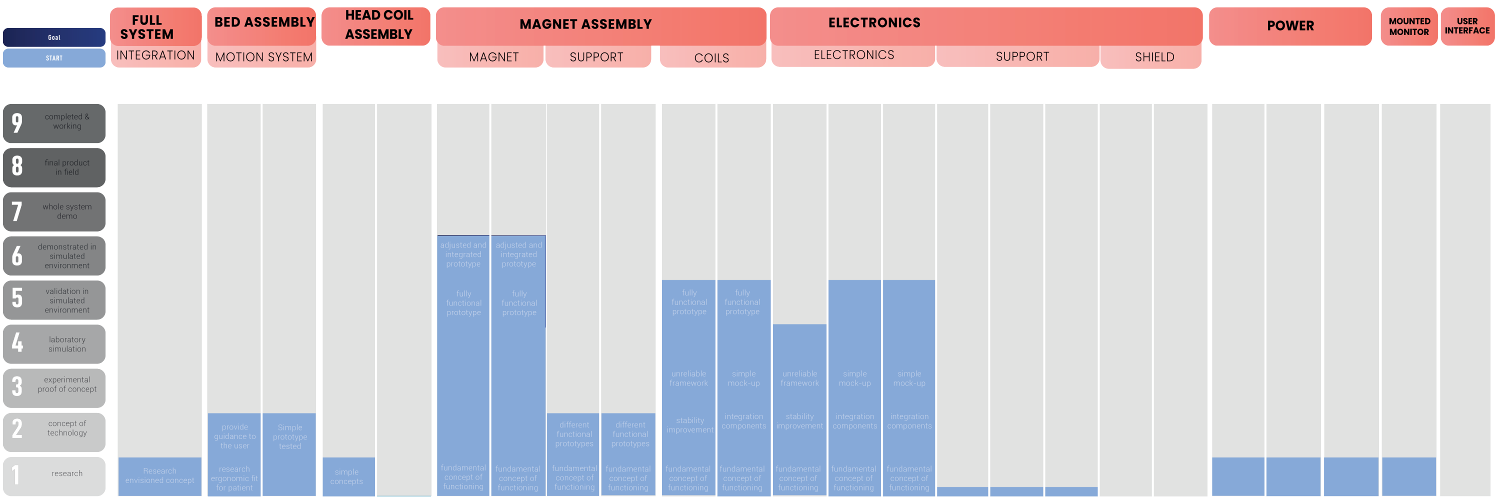


Figure 4.12 Current Technology readyness level.

4.3.3 Challenges within the product

The advantage of the lower magnetic field equally presents challenges. These challenges affect the imaging negatively. The challenges can be found in the technology of the magnet system or the development of the product. The complete overview of the challenges within the LF MRI scanner is described in Appendix F.

Product level
The magnet subsystem is the most developed and has reached level 6 (Technology demonstration) to provide a completely usable and safe system, ready to be used in clinical tests. In addition, the technology is extensively tested, and the concept is demonstrated in a suitable test environment. However, other subsystems such as the bed have only reached TRL 2 with a conceptual proof of concept and no defined components yet.

To provide a functional MRI scanner, the magnet system needs to be developed and all human and safety-related components. However, the level of development of the entire system has not reached a phase yet where it can be used safely. In addition, usability features, functional mechanics, and the ergonomics of the users have not been considered yet

Challenges occurring due to lower field
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 implement readout strategies and image reconstruction. A few aspects need careful tuning within the technology to obtain sufficient quality. Considering the cylindrical geometry of the Halbach configuration, it is necessary to obtain a reliable z-gradient coil with sufficient coil efficiency and linear region. This can be optimised by including gradient power minimisation because this will improve the power supply requirements, which is essential for an LMIC context. [58] . The main challenge is the quality of the imaging. These are affected by the lower homogeneity, the imaging field, the noise and the temperature.

Lower homogeneity
The image quality is affected over a large field of views. This is caused due to the less homogeneous characteristic of permanent and resistive magnets than superconducting magnets. This may limit the ability to perform specific pulse sequences.

Size of field of view
Due to the lower homogeneity, the field of view of the MRI scanner is also smaller than conventional MRI scanners. The bore diameter goes from approximately 70cm to 30 cm diameter. The effective area in where the magnetic field is most potent is the iso-centre, which can be visualised as a sphere of a field of view of D220 mm. Therefore, the subject must be aligned in the middle of the bore.

Noise
Another effect of the lower homogeneity is the sensitiveness to noise. The noise refers to any interference or signal from the background during the scan.

Signal to noise
One of the main issues is a large amount of noise contaminating the images since the field strength is approximately proportional to the signal to noise (SNR). Therefore, with reduced field strength, a reduced signal will be the result causing a lower image quality. There are a few methods on how to reduce this noise. The main problem with low field MRI scanners is that the RF signals generated by nuclear magnetic resonance are weak, which results in a poor signal to noise ratio. This SNR in the low field limit is proportional to the 7/4th power of B_0 [60]. Although, in general, regression methods are used to reduce noise and improve image quality; some factors that can impact the SNR include the following:

1. Type of sequence.
2. Use of surface coils.
3. Size of the field of view.
4. Size of the matrix.
5. Slice thickness.

Factors 1,3 and 5 are influenced during the sequencing and processing, while factors 2 and 4 are influenced by the hardware parts of the low field MRI scanner. Therefore during the development, all efforts have to be made to prevent additional noise and increase the SNR.

Coil
The closer the head coil to the body, the better the imaging Regardless of coil type, the coil size and its distance from the object imaged are critical determinants of coil sensitivity (and hence signal-to-noise ratio). The penetration depth for reception from a simple loop RF surface coil is typically only about 50-75% of the coil's diameter. Based on this underlying physics, the current trend for MR signal detection is to use large arrays of small loop coils located on or close to the patient. This overburdens for patients with hydrocephalus. A well-fitting coil specifically for patients with hydrocephalus is needed.

Temperature
One of the disadvantages of using permanent magnets is the temperature dependency of the magnetic field. The gradient system produces heat, which can cause a drift in the magnetic field. The temperature inside the system must stay stable within an imaging session of one hour. Stable means that it drifts less than 1 degree per hour preferably. However, this is not a severe problem since the scans take less than one hour. Preferably, airflow around the body should be included to remove the hot air.

4.4 Key insights

An overview of the key insights from this chapter can be seen bellow. The entire list can be found in Appendix A

Key insights

1. The field of view of the low field MRI scanner is a sphere of 225 mm by 225mm at the centre of the bore (250 mm from the opening). The magnetic field is highest at the centre

2 The Low Field MRI system is designed with readily available commercial inexpensive permanent magnets in a Hallbach array

3. The diameter of the bore is 300mm, which allows the shoulder of a patient of 26 cm to enter the bore.

The spatial resolution of the system is 2*2*3 mm

4. Lower field strength results in a lower signal-to-noise ratio (SNR)

5. The RF amplifier and gradient amplifier contain heat sinks and require an air fan cooling

6. The field of view is 225 mm where the subject needs to be placed in.

7. For a high quality image the RF head coil must be as close to the subject as possible.

8. For a high quality image the subject must be in the middle of the bore , where the magnetic field is the strongest.

System requirements

1. The head of 50-60 cm circumference must be able to be aligned to concentrically inside the bore in the middle of the bore (220 mm +/- 1 cm from the opening).

2. The patients brain must not move more than 3 mm within the imaging sequence

3.The RF coil must be concentric with the bore

4.No ferromagnetic or metals can enter the bore of the magnet or may be in a proximity of 100mm of the bore opening.

5.No metal (ferro or non-ferro) objects may be used within 40 mm surrounding the radiofrequency transceiver coil

6.No ferromagnetic or metals can enter the bore of the magnet or may be in a proximity of 100mm of the bore opening.

7. The electronic components must run from standard power outlets and ultimately battery/solar/diesel powered.

8. The temperature inside the magnet should stay stable (drift less than 1 degree per hour)

9. A shielding is required to reduce the noise due to the inhomogeneity of the permanent magnet. The frequency needs to be at least 2mHz.

5. Human factors

Figure 5.1 Data analysis of head of Infant with Hydrocephalus with CT scans [65]

Introduction
This chapter gives insight on the disease, hydrocephalus, its cause, prevalence in Uganda and the physical characteristics. The background research serves as the main insight for the creation of the system requirements.

Background
The low field MRI scanner aims to increase the accessibility of costly medical equipment for patients with hydrocephalus in sub-Saharan Africa. This chapter outlines the human factors that influence the design of the MRI scanner. The result of the investigation is system requirements. The investigation of human factors aids to define user requirements to make the use of the scanner more ergonomic, efficient, effective, and safe [26]. Human factors draw upon parts of the design's anatomical, physiological, social, and physical factors.

Objective
This chapter provides an overview of the most critical characteristics of the patient's disease. Hereafter, the characteristics that influence the device are translated into system requirements.

Method
1.Literature research (Appendix C.2)
Prior to the analysis, extensive literature research was performed on the prevalence, aetiology, and treatment of hydrocephalus. As mentioned, patient-centred design requires the involvement and participation of the user.

2. Interviews (Appendix B.2)
Missing knowledge about the specific cases in Sub-Saharan Africa was consulted through interviews with the Cure Hospital's clinical nurse, surgeon, and occupational manager. Through interviews with MRI technicians, radiologists, and paediatric neurosurgeons from Uganda, the behaviour, cultural and biological characteristics are investigated and identified to outline the most prominent values and concerns of the patients with hydrocephalus and its most critical stakeholders.
3. Data analysis (Appendix C.4)
Most research about the development and growth of the symptoms are from High-income countries. Studies that address the development and growth of infants with hydrocephalus in high-income countries are monitored and diagnosed in earlier stages of life due to accessible medical technologies. Not much specific data and research is known about the specific development of the head of infants with hydrocephalus in LMIC. However, it is not specifically relevant to use this data and directly translate it to design an MRI scanner in LMIC since key differences are present. Ergonomic research was conducted by analysing fundamentals through literature and detailed research on the target group through quantitative interviews. CT scans from infants with hydrocephalus at the Cure hospital were analysed to define the anatomical characteristics of the disease.

5.1 Disease hydrocephalus

5.1.1 What is hydrocephalus?

Hydrocephalus is a central nervous system disorder resulting from excessive cerebrospinal fluid (CSF) accumulation in the brain's ventricles. The case can only be treated with neurosurgical treatment through brain imaging. Excessive CSF, produced through filtration of water through the capillary walls, accumulate in the ventricles deep in the brain. In healthy situations, the CSF situated in the CSF spaces flows through the ventricles and flows into the brain and spinal column, where it is absorbed by blood vessels on the brain's surface. The CSF plays a crucial role in brain function by keeping the brain buoyant, cushioning the brain to prevent injury, removing waste products, and maintaining a constant pressure within the brain [27]. On the other hand, the excess CSF may increase the size of the ventricles and cause pressure on the brain [28] (Figure 5.2).

5.1.2 Cause

The leading cause of hydrocephalus is an imbalance between the volume of the produced CSF and the amount that is absorbed through the bloodstream. The two types of causes of hydrocephalus that can occur are non-communicating (obstructive) and communicating hydrocephalus. Obstructive hydrocephalus is a condition that indicates non-communicating hydrocephalus where the flow of the CSF is blocked along with one or more of the ventricles. Communicating hydrocephalus occurs when the flow of the CSF is blocked after it occurs in the ventricles. The CSF can still flow between the ventricles, which remain open; however, not enough CSF is absorbed in the bloodstream [27]. Infant hydrocephalus can be present at birth (congenital) or acquired later in life. When it is present at birth, it is often caused by congenital aqueductal stenosis, while it can also be caused after birth due to premature birth, infections, tumours, or bleeding inside the brain.

5.1.3 Aetiology

The aetiology and occurrence of paediatric hydrocephalus vary throughout the world. In High-income countries, most cases of neonatal hydrocephalus have a congenital cause. While in Low-middle income countries, the most seen aetiologies of hydrocephalus are acquired [29][30]. Infant hydrocephalus is estimated to occur with more than 100 000 new cases each year in sub-Saharan Africa (SSA) [31]. In Uganda, around 1000 to 2000 infants are affected yearly [32]. Post-infectious hydrocephalus (PIH) accounted for 60% of all cases of infant hydrocephalus in Uganda, with most remaining cases being congenital in nature [32]. The two leading causes for post-infectious hydrocephalus are delivery in an unhygienic environment without assistance [33] and satellite-derived rainfalls [34]. When left untreated, the mortality rate for infants is up to 50%, making the disease critical enough to emphasise treatment[35]. Treatment and early diagnosis significantly improve the outcome for hydrocephalus, with 89%-95% survival [36].

5.2 Treatment process

5.2.1 Treatment

The goal of the treatment is to reduce the pressure in the infant's 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.1 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.

5.2.2 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.

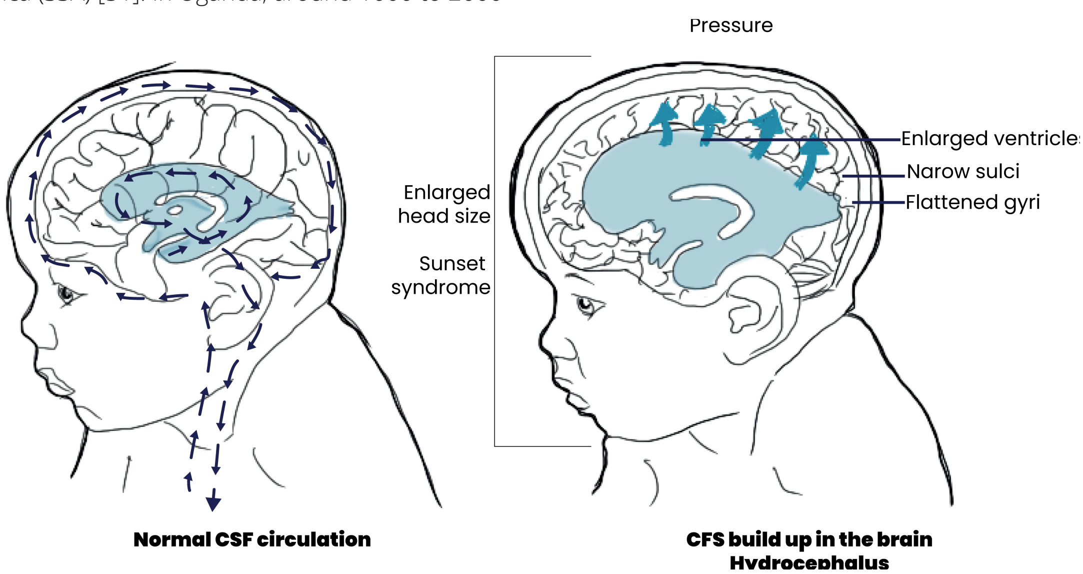


Figure 5.2 Healthy CSF circulation (left) and infant with hydrocepalus (right)

5.3 Patient characteristic

5.3.1 Symptoms

The anatomical characteristics of the patient are outlined in this section. Further research can be found in Appendix C2.
The disease affects brain development and the patient's physical anatomy, which is crucial to consider during the design of the low field MRI scanner. The head of the patient must fit inside the head coil within the boundaries of the field of view.

Hydrocephalus symptoms
Because excessive CSF may interfere with healthy brain development, the result may lead to ependymal damage, microstructural white matter alteration, altered cerebral blood flow and metabolism, cortical gliosis, capillary compression, and axonal damage.
The direct symptoms that can be physically observed within a patient are:

- A bulging fontanelle (soft spot on top of the head)
- Increased head circumference
- Seizures

5.3.2 Physical characteristic

Physical ergonomics of patients may influence the procedure of MRI scanning. For example, the increased head circumference and the body dimension determine the patient position and product layout.

Anatomy of the head/what is important for it to be scanned
Ideally, the Cure hospital would treat as broad age-group as possible. However, the restricted system dimensions do not allow the insertion of larger body parts. In the Cure hospital, infants are treated from birth to +/- 8 years old. The oldest children belong to the group that returns for monitoring after surgery. Currently, the most scanned patients are children up to 3 months old. This is due to the organisational infrastructural factors and acceptance of medical treatment in the LMIC country. Due to the malnourishment of the children, their bodily characteristics may not align with research data of healthy children. Therefore, the infant's age may not directly indicate the age limit of the target group. Bodily dimensions and behaviour may be a better indicator (Figure 5.3).

Age
The age of the child that can enter the bore of the MRI scanner strongly depends on the maximum diameter of the MRI scanner. The smaller the bore, the fewer people can enter the bore with an increased head circumference. Furthermore, the radio frequency coil requires to be at the subject's proximity for a high signal to noise ratio (SNR), which improves image quality. Therefore, it is of high importance that the head of the patient can fit around the head with hydrocephalus. Currently, mostly adult head coils are used; however, the infant head shape differs significantly from that of the adult [41]. The head circumference ranges from 50 to 60 cm and the corresponding shoulder breadth for the age of 0 to approximately five years old is 26,8 cm (mean) [42] (Figure 5.4

The P95 head circumference occurring at Cure is 66 cm [43]. Ideally, hydrocephalus is diagnosed in the earliest life stages. However, due to the lack of education and awareness, the cases of hydrocephalus in the Cure hospital are older children. Besides the head circumference, the head shape and proportions are essential indicators.

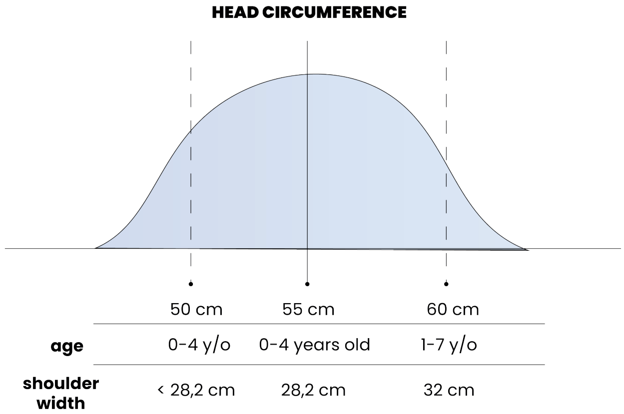


Figure 5.4 Distribution of occurring head circumference in the Cure hospital)

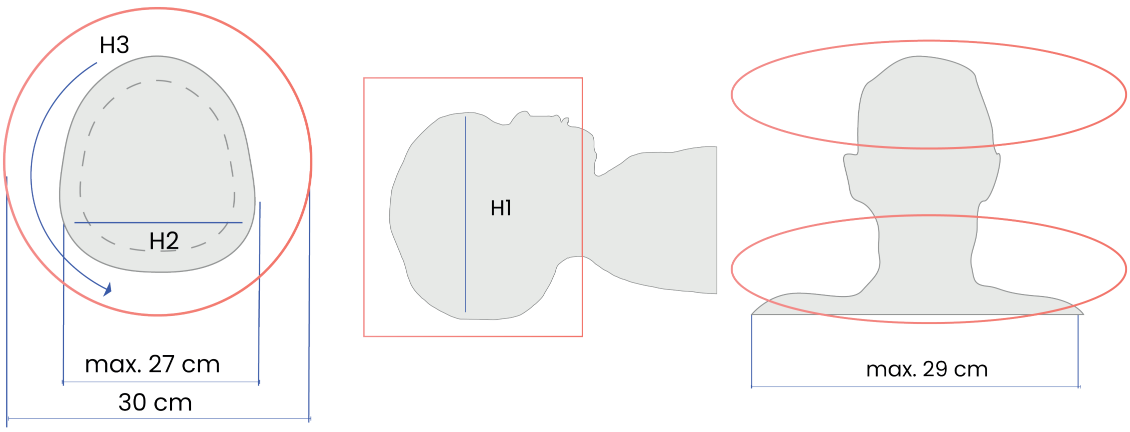
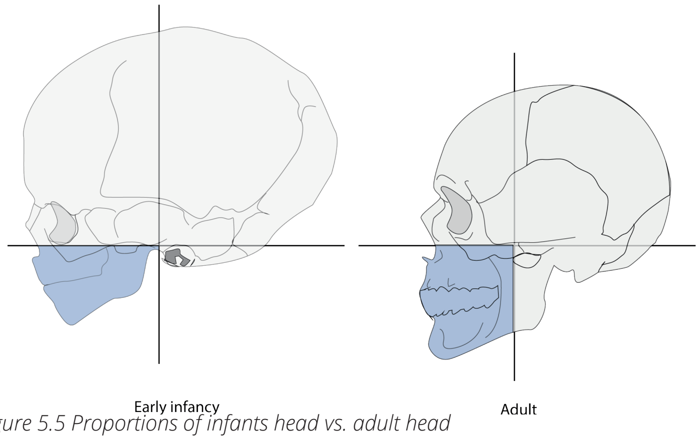


Figure 5.3 Important dimensions of child with hydrocephalus considered



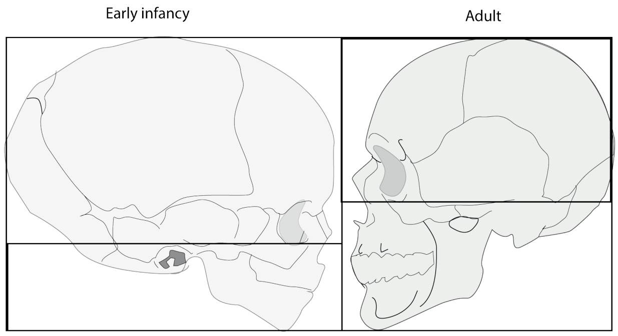


Figure 5.5 Proportions of infants head vs. adult head

Proportions

Anatomical differences in the infant and adult's heads are important to consider. The child's head is proportionally larger than an adult's [44] (Figure 5.6). In the facial profile, the average infant's forehead is high and bulged due to the size of the brain's frontal lobe. In newborns and infants, the face is tucked below the massive brain case, having a facial portion with a face to cranium ratio of 1:8 compared to an adult 1:2, This effect is exaggerated with infants with hydrocephalus, together with a larger head mass. Additional a weaker cervical spine musculature and weaker neck supporting structures redirect the emphasis on a good head support for the bed design (Figure 5.5).

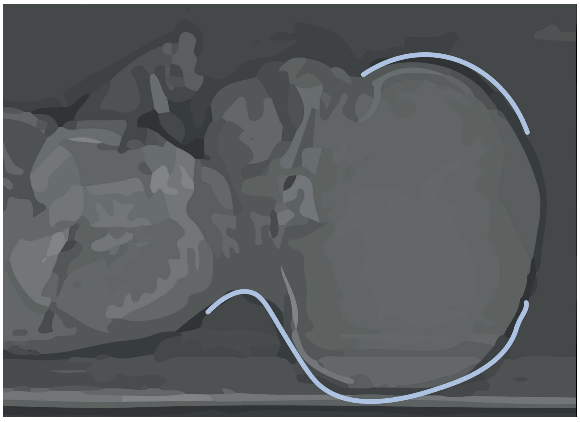


Figure 5.6 Blurred CT scan Hydrocephalus patient Cure Hospital 2020

The head size and shape

Infants with hydrocephalus are characterised through their enlarged head (cephalomegaly), accompanied by paper-thin and fragile skin. The head size of a paediatric patient with hydrocephalus has the same facial proportions as an infant, however, with a larger frontal, parietal, and occipital bone [34]. In older infants, the facial abnormalities are less evident than in younger infants. An infant's head shape differs significantly from an adult head since the cranium is more elongated than a child's. There is no standard characterised head shape for an infant with hydrocephalus due to the uncontrolled growth of CSF volume. This growth results in an irregular shape, including bulging at the soft spots. No significant differences have been found in western and sub-Saharan head shapes [92]. The unconventional head shapes need to be taken into account during the design of the head coil (Figure 5.6 - 5.9).

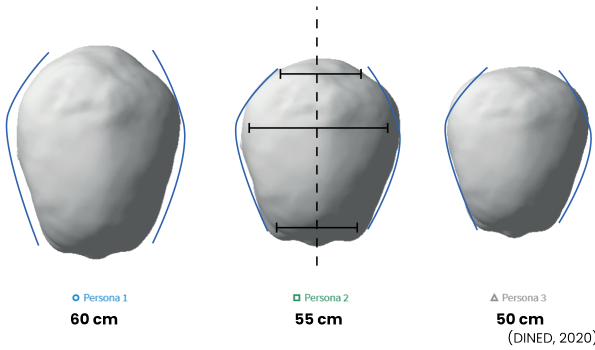


Figure 5.8 3D modelled heads of children with hydrocephalus (DINED)

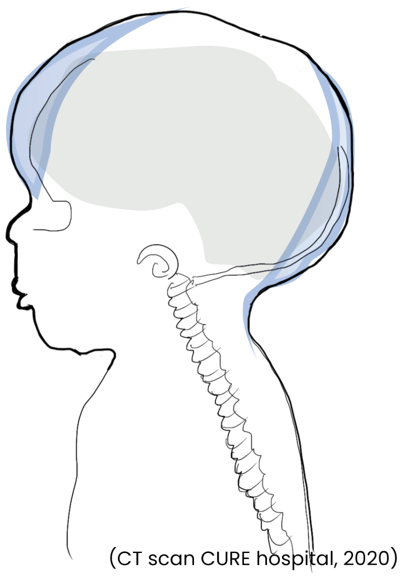


Figure 5.7 Important head shape characteristics to consider (blue)

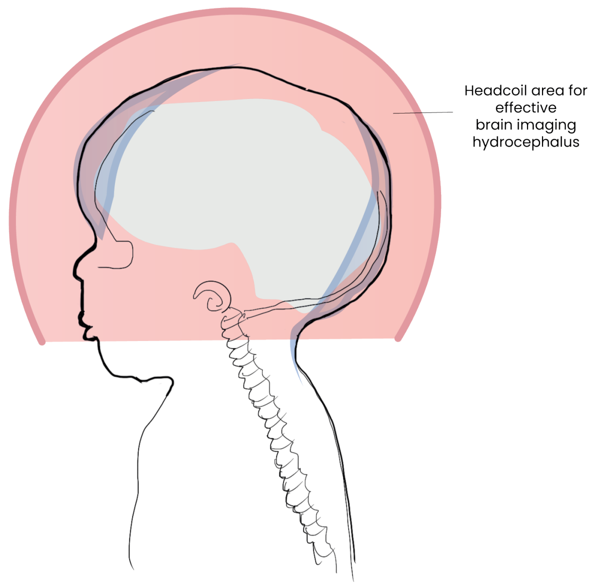


Figure 5.9 head coil must cover red areas of patient

5.4 Key insights

An overview of the key insights from this chapter can be seen bellow. The main system requirements that have been derived can seen bellow. The complete list can be found in Appendix A

Key insights

1. The main cause of infant hydrocephalus in Sub-saharan Africa is acquired due to unhygienic delivery of complex delivery without any assistance.
2. Other alternatives for MRI scanning are the CT scan, which is cheap and fast. So it the LF MRI scanner needs to be able to compete against the CT scanner and ultrasound. Except for the enlarged ventricles. The MRI scanner must have an added benefit over the usage of CT scan, since the CT scan is quicker but exposes the infant to radiation.
3. The main physical characteristic of the patient with hydrocephalus is the enlarged head, which endures high pressure and has very fragile skin.
4. The infants treated at the Cure hospital are from 3 months old up to 8 years old.
5. Half- yearly follow-up is needed after brain surgery which required periodically assessment in the MRI scanner. This increases the cost for a patient that needs to pay for the treatment himself. Therefore it is of high importance that an MRI diagnostic is as low cost as possible. Furthermore, reoccurring diagnosis can be traumatic if the first experience with the MRI scanner was discomfortable and with anxiety.
6. The head circumference of a patient with hydrocephalus treated at the Cure hospital range from 50cm - 60 cm, with the median/mean at 55 cm
7. The head of a patient with hydrocephalus has a bulging head which is not uniform

System requirements

1. The system must provide correct positioning and aligning of the child on the bed
2. The head coil must fit around the head of patients with hydrocephalus (50-60 cm diameter) at proximity of maximal 3 cm.
3. The head coil must fit the multiple non-uniformal head shapes of patients with hydrocephalus
4. Discomfort inside the bore must be prevented for the patient.
5. The system must provide an adequate support for the patients neck and head.

Define

Definition on problem statement and design goal

6. Define the key challenge

7. Problem definition

8. Design goal

9. List of requirements

6. Define key challenge

Figure 6.1 Image of caretaker, MRI technician and patient with hydrocephalus in CT scan at Cure hospital [62]

Introduction
This chapter wraps up the Discover phase, in which the insights from this phase are gathered, analysed, and prioritised to formulate the opportunity as a design challenge. Insights are gathered from literature, observations, and interviews (Appendix F). This chapter aims to outline why the patient motion is the most prominent and relevant challenge, and requires a design solution.

Background
The most prominent challenges and their solution direction are discussed in this section. All device-related challenges can be found in Appendix E4. Finally, Appendix F discusses the entire map of challenges defined inside the low field MRI scanner.

Method
The key challenge has priority to solve now and affects the goal of the low field MRI scanner drastically. Furthermore, it must be solvable in the current stage of the technology (Feasible) and especially from a future perspective (viable). The perspective of practitioners, MRI technicians, procurers of MRI scanners from LMICs, and the Low Field MRI technology developers were collected to define the crucial challenges. These insights were gathered by 1) performing a semi-structured interview (appendix B) 2) providing a co-creative discussion on the potential opportunities. Design potential solutions and provide a feedback discussion to foresee potential failure. Eventually, the possible opportunities of these critical challenges were assessed on their viability, feasibility, and desirability.

Interview
Professionals and experts from the expert map (Appendix B) have been consulted to discuss the viability, feasibility and desirability of the opportunity and the severity of the problem regarding technological, human , and contextual factors.

From analysis to insight
The critical insight gathered from the Discover phase have been analysed together inside a patient journey map. Furthermore, the effect of each insight in correlation to the user, technology, context in the present and future scenario has been evaluated.

6.1 Challenges

The top three main challenges that require priority to solve are the image quality, the movement of the patient and the sustainability of the entire MRI system. The entire analysis of the challenge, solution direction and assessment can be found in appendix F.3.

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.

A promising opportunity to increase this SNR is by introducing flexible coils (Figure 6.2). 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. However, this technology is not mature enough to implement currently as possible solution direction.

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.

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.

6.1.3. 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.
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..

Figure 6.2 Flexible coil

6.1.4 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 6.3).

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.

Compared to the other challenges within the system, the movement had significant effect on the image quality, the workflow of the MRI technician, the patient experience and thus the following scanning procedures. Eventually the most economic value would be derived by solving the movement problem. this is a challenges that can be done immediately with the current technology. Focusing on the patient movement is desirable for the patient, MRI technician and procurer, it is doable with the current technology and contributes to a sustainable MRI scanner .

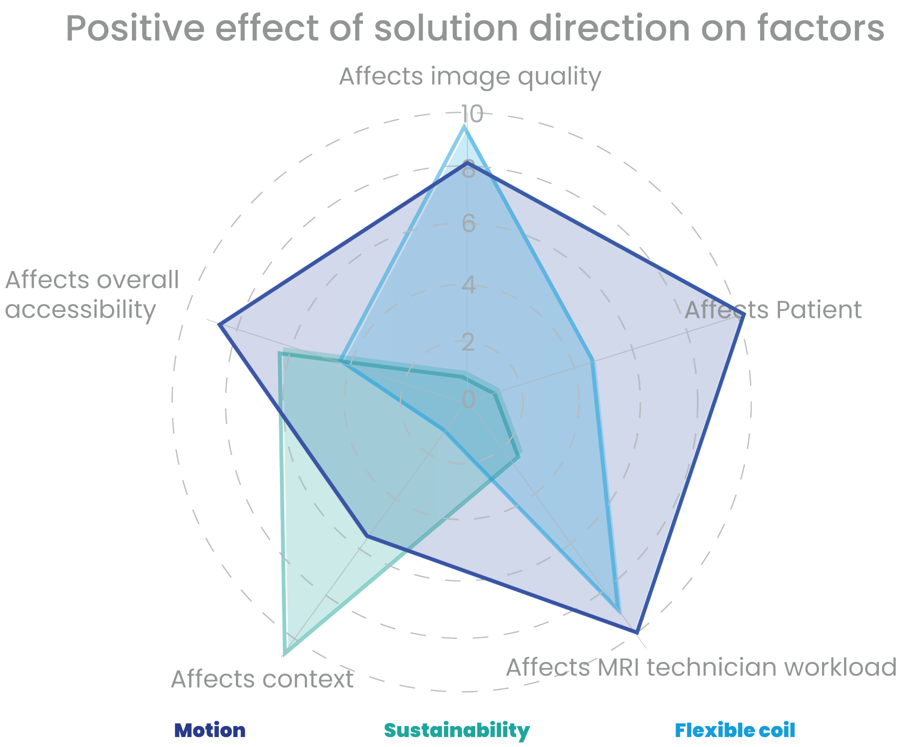


Figure 6.3 Evaluation of effect solution directions on operating area

7. Problem definition

7.1 Problem statement

Successful paediatric brain MRI scanning requires a motionless infant lying inside the scanner to acquire the necessary sequences and good-quality images. Children frequently move in MRI systems, which lead to incomplete or unsuccessful scans through motion artefacts. The motion artefact may confound or avert interpretation from the radiologist, leading to errors within the diagnosis and a prologues process before the surgery.

Once motion artefacts occur, a costly scan must be rescheduled, and inconvenience for the patient is repeated. The use of sedation medication to assist a settled infant for MRI scanning is controversial [68]. Children that require brain imaging in a low resource setting are mostly not subjected to sedation due to the adverse effects on the development of the brain. Computational processing is not adequate for minimising the effects, so prevention of the movements up to the spatial resolution (3mm) is crucial. Non-repetitive motion, larger that the spatial resolution (3mm) can not be corrected through preprocessing and must therefore be prevented.

Due to the low resources of the hospitals in low resource settings and the fragile characteristic of children with hydrocephalus, sedation is discouraged and therefore, an alternative is needed to minimize movement by the patient.

Patient comfort is crucial to delivering integrated longitudinal care and beneficial patient outcomes in MR imaging. Ensuring a comfortable environment is fundamental to the acquisition of high-quality diagnostic images. Research has revealed a strong correlation between a positive patient experience, clinical effectiveness, and patient safety. Therefore, a patient-centric approach in MRI services is crucial[87]. Patient-centric care focuses on physical comfort as well as emotional well-being.

The goal is to minimise movement and maximise patient comfort.

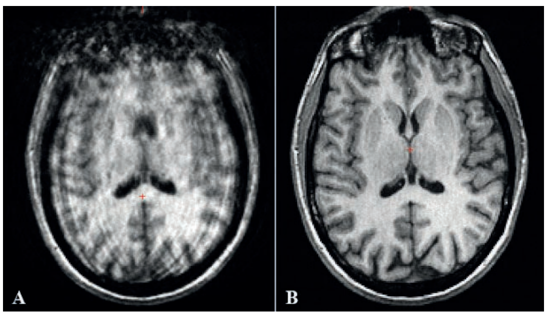


Figure 7.1 Brain imaging with motion artifact (left) no artifact (right)

7.2 Understanding the problem

7.2.1 Whom does the problem affect?

According to researchers at the University of Wisconsin-Madison, between 10 to 15% of all MRI scans need to be redone due to excessive movement during the scan [71] for adults, while the percentage of scans for young children may be higher. In addition, studies prove that one in five MR studies require a repeated scan due to patient motion [69]. These reactions are costly because of non-recoverable staff and equipment time, which effectively reduces the cost-effective effect benefit of the lower field MRI.

The cause for this frequent movement is the lack of understanding of instructions and discomfort. Typically, patients subjected to an MR scan are instructed to remain as motionless as possible prior to the scan.

However, the targeted group of patients is 0-4 years old with hydrocephalus and not instructable. Anxiety-related reactions during MRI have been reported to occur up to 37% [114][78], and up to 15% of patients have claustrophobia during an MRI scan [70]. It is essential to recognise that patients are vulnerable and have little knowledge of expectations. Additionally, they experience stress and anxiety, which can influence their ability to lay still in an enclosed space.

Thus, ensuring a comfortable environment is fundamental to acquiring high-quality diagnostic images. In addition, patient comfort is crucial to delivering longitudinally integrated care for patient outcomes in the MR imaging industry.

7.2.2 Why does the problem occur?

To understand the source of the motion, the child's behaviour is researched. Moreover, the bodily ergonomics that cause this motion are investigated to provide a complete overview of the problem's source and pinpoint the factors that can help inhibit this motion. The cause of this motion can have various origins. However, the most prominent ones are discomfort caused by physical discomfort and psychological malaise. Figure 7.2 illustrates the patient laying inside the bore, experiencing pressure on the head. An extensive research can be found in Chapter 10

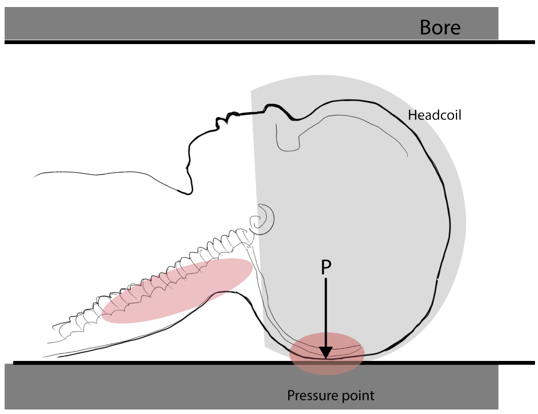


Figure 7.2 Patient inside bore with critical pressure points.

7.2.3 What are the current solutions and their limitation?

Motion artefact
One of the most common artefacts within MRI imaging is a motion artefact. The motion artefact can cause ghost images or diffuse the image noise in the phase-encoding direction. One of the differences between frequency-encoding sampling and phase-encoding sampling is that frequency-encoding sampling occurs during a single echo(milliseconds). At the same time, the second phase encoding takes several seconds to minutes, which allows all k-space lines to undergo the Fourier analysis.

There has not been a single methodological solution to the motion problem in MRI.
This type of motion can either be 1)corrected, 2)the artefact can be reduced or 3) the motion can be prevented.

1. Correction

Motion correction can only occur with the implicit assumption that the subject remains motionless during the acquisition of the slices to acquire the image.
The motion of the volume is assumed to occur within milliseconds of the acquisition of the last slice. Only predictable motion can be corrected, unlike non-periodic and rapid movements, which are a more frequent problem during the acquisition of less cooperative subjects such as infants[74]. The physiological motions that the infant may produce are of too slow duration to affect the frequency-encoded sampling but may have an effect in the phase-encoding direction. This has resulted in periodic movements, such as cardiac movements, pulsation, and breathing can cause ghost images but can be corrected during prepossessing, while non-periodic movements such as a sudden movement of the head of the infant may diffuse image noise. The first stage of pre-processing is often motion correction.

Limitation of processing
In pre-processing for motion, it is vital to ensure that when voxel activation is compared at different times, the compassion is done over the same brain area. MRI with a sequential k-space ordering is insensitive to slow continuous motion, like swallowing. Therefore, small movements such as breathing are not a problem, but uncontrolled movement such as tilting the head or scratching the face is not recommended.

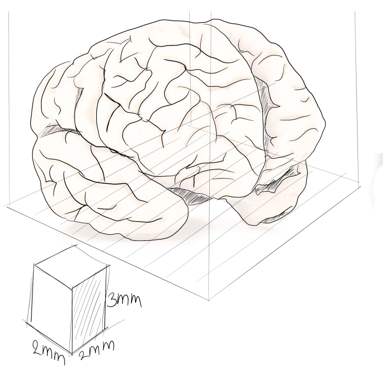


*Figure 7.3 Brain imaging and voxel of 2*2*3mm*

2. Motion prevention

Motion prevention allows the non-periodic motion to be hindered. This is the most effective method of suppressing motion artefacts [76].
Currently, the following methods may manage motion prevention:
1. Constrain the patient's head'
2. Provide explicit instructions to lie as still as possible
3. Ensure the patient comfort prior to and during scanning.
4. Minimise scanning time

In some cases, a mock-up miniature scanner is used for training patients to reduce anxiety. This alternative is not cost-effective nor functional effective for the target group. The patients are too young and therefore not instructible. Therefore, it is crucial to prevent the movement with movement constrain methods. Other ways to constrain such as; padding (soft padding, expandable foam, vacuum bags), hammocks, a bite bar and contours provide a higher workload. Nevertheless, those methods are not easy to use and readily accessible [86].
Generally, in MR imaging, the prevention of the motion is preferred by comforting the patient.

7.2.4 What is the specific motion that must be prevented?
Rigid body motion, or 'bulk motion', includes one-dimensional translation (requiring a single parameter for its mathematical representation), multi-dimensional translation (requiring several parameters), or completely unconstrained rigid motion (requiring six parameters) (Figure 7.4).
In this case, the head motion comprises six degrees of freedom, comprising three translations and three rotations. During the scanning sequencing of 10 minutes inside the bore, the moment of immobility must occur within the milliseconds of the image sequencing. This immobilisation must be within the spatial resolution, which is 3 mm. The hand and legs may move more than 3 mm if the head does not move [77]

7.3 Prevention strategies and how we focus on comfort

7.3.1 Motion prevention strategies

Motion for brain imaging in paediatric patients is a widely occurring problem. The reported incidence of premature termination or failure of the MRI examination due to claustrophobic reactions ranges between 0.5% and 14.5% [115].
Hence, much effort has been devoted to developing various effective motion-prevention strategies.

1. Initiatives in the market

Clinical settings in HICs mostly rely on resourceful strategies to prevent motion. The most occurring is sedation. However, majority of diagnostics in LMICs take place without sedation. Sedation is not recommended and is only an option if no alternative is present[66] [45]. Various studies demonstrated that sedation and anaesthesia lengthen the hospital stay and increase costs due to the additional advanced monitoring equipment, highly trained staff, access to inpatient facilities, and additional time in the scanner or preparation room [72]. In addition, commonly used sedatives had neurotoxic effects on the developing brain of children under the age of 3.
Due to the high risk of sedation with premature patients, this is only administered by a highly skilled doctor (interview Dr Schiff Appendix B.2)[73] and are therefore not suitable for low resource settings.

2. Low resource initiatives

Low Resource settings do not rely on those strategies due to the lack of availability, the lack of medical resources or the potential harm for premature patients with hydrocephalus.
The lack of medical resources, the lack of trained personnel and the potential harm for premature infants with hydrocephalus urge hospitals in low resource settings to rely on non-sedative, low-maintenance, minimal time-consuming alternatives to prevent motion.
In these cases, the caretaker plays a crucial role in calming the under-age patient who is heavily relying on its caretaker. 90-95% of neonatal brain MRI's can be obtained without motion with proper non-sedated techniques[72].

Patients from six years old can follow instructions on motionless scanning and practice. The youngest patients up to 1-year-old are comforted through feed and wrap; however, this strategy is time-consuming and may not be effective when the child wakes up in the noisy MRI scanner. For the age group between 2 and 6 years, no effective strategy is present and is currently comforted through the high involvement of the caretaker[45].

From alternative solution research (Appendix G), the current strategies to successfully and comfortably prevent motion in HIC rely on expensive, timely products and require high maintenance (e.g. pneumatics). In low resource settings, the prevention of motion is highly promoted by maximising comfort by involving the caretaker. However, this strategy is time-consuming and requires much effort from the MRI technician and the caretaker.
Therefore a necessity exists that provides motionless positioning of the patient through comforting the patient supported by the presence of the caretaker.

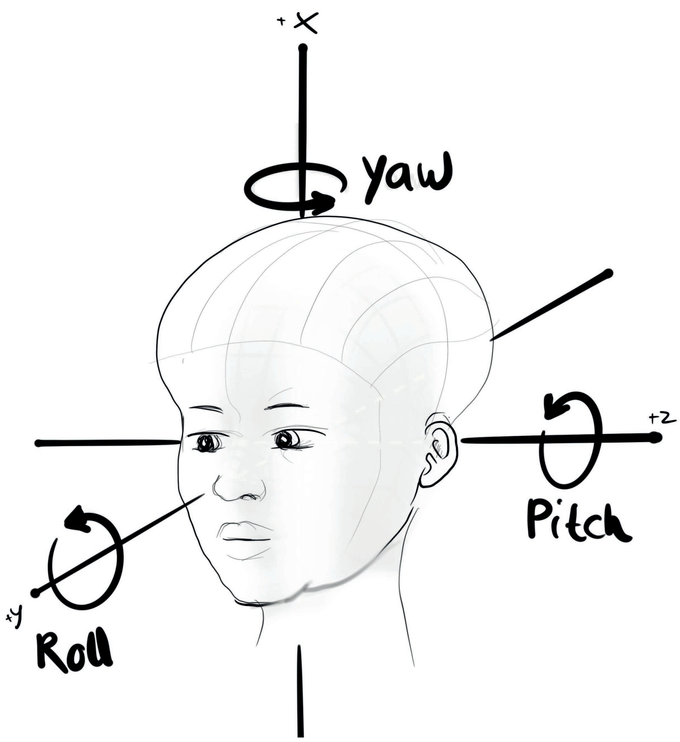


Figure 7.4 DOF motion, translation and rotation in each axis

8. Design goal

This chapter wraps up the define phase, where the insights from the Discover phase are analysed, and the problem definition is established. (Appendix G can be consulted for the entire design process). Key insights are redefined into opportunities that the product must fulfil. This is redefined together in the design goal.

8.1 Product features

8.1.1 Design statement

Based on the problem statement, the design statement was defined as follows:

' For patients between 0 and 4 years old with hydrocephalus, I want to provide an improved MRI scanning experience to **prevent** *patient* **movement** *during scanning by focusing on the* **patient comfort,** *which results in the* **reduction of workload** *of the MRI technician through the design and improvement of the* **bed system assembly.***"*

The research questions are:

1. How can movement inside an MRI scanner best be prevented with as minimal resources as possible?
2. What are the main factors that influence the psychological comfort of the patient and how can it be reduced in the design of the bed system?
3. How can the MRI technicians workload be reduced?

8.1.2 Product features

The main opportunity for the solution direction is defined in this section. The integration between the key insights, the problem definition, the design drivers and the problem statement resulted in several opportunity directions and concept visions. Appendix G1 and G2 discuss the entire value proposition (fig. 8.2) and concept direction iteration. The most essential factors that must be implemented in the redesign of the LF MRI scanner is as following:

- A low field MRI scanner that minimizes motion through the comfort
- A low field MRI scanner that is easy to use
- An MRI scanner that is suitable for LMICs

Immobiliser

Challenge:

- Good quality imaging requires the patient to keep settled and not move more than 3 mm. However, an non-sedated infant is prone to move due to discomfort and not instructing enough to prevent moving. Therefore it is crucial to provide an environment where the patient can reduce the triggers for motion, which is discomfort and trigger factors that will keep the patient settled, which is comfort. Unfortunately, current immobilisation devices are not suitable for children with hydrocephalus. And only available as expensive and advanced options with additional accessories not available in LMICs.

Design solution

- Therefore an additional suitable head stabilizing product needs to be designed.

Human-centred : A device that supports the patient and MRI technician

Challenge:

MR imaging can be stress inducing for both the patient as the MRI technician.

- The patient must be calm in a disturbing environment; therefore, the physical comfort of the patient must be promoted as well as the psychological comfort.
- Keeping the child calm and still is the most time consuming and challenging task for the MRI technician due to the not inscrutable infants and discomfort.

Design solution

It is crucial to promote personnel efficiency and confidence, which is a critical part of providing a positive patient experience. Patient-centric imaging in MR has improved healthcare outcomes (better imaging) and patient experience. Both patient and MRI technicians are essential in this scenario since their state of mind are highly influenced.

- By focusing on the patient's concern, its experience is improved for the current diagnostic and the follow-up. In addition, enhancing immobilization by improving comfort directly influences the image quality.
- Workload can be reduced by providing an intuitive work procedure or positioning, scanning and processing. This allows the technician to perform routine MR exams with confidence. Decreased outcome variabilities due to the additional immobilization aid result in high-quality imaging and enhances the patient experience. The personnel may worry less about the equipment and has more time to focus on the patient.

Design for sustainability

Challenge:

- A barrier to the availability of medical devices in LMICs is the lack of spare parts and maintenance resources. Design solution

The device must be maintained using standardised tooling and locally producible parts. The project brief defined that the low Field MRI system is designed to operate as a sustainable MRI scanner, which is defined utilizing two factors.

- A long-lasting product through robust parts. Sustainability means that the product will last multiple use cycles by making the components durable and robust. As a result, fragile parts or moving components are avoided.
- Local maintenance and manufacturability. Once the component is obsolete, it requires repair or maintenance. By allowing the LF MRI scanner to be locally manufactured, the availability of spare parts, materials and components is assured. The focus is more on making the device long-lasting and durable by providing robust elements.

8.2 Scope

The role of patient comfort during brain-scanning has a significant effect on the child's movement and thus on the image quality and diagnostics outcome. However, This research aims to develop a system that facilitates non-sedated brain scanning for infants of 0-4 years old with hydrocephalus in the low field MRI scanner.

Based on the function analysis, the parts from the Low Field MRI scanner have been defined (Appendix E.3-5).
The TRL envisions the functional parts of the RMI system and their maturity of developmen. The scope of the design assignment is defined based on the TRL seen in Figure 8.1. The light blue parts illustrates the TRL of the initial system, while the dark blue parts illustrate the final goal of parts' development. The complete system starts from a conceptualised product (light blue). The starting point has been the prototype of the Low Field MRI scanner 3.0. The magnet system and the electronics are fully defined on the part level and functionality; however, this system lacks user-related functions such as a bed, interface, and embodiment.

The final goal is to achieve a redefined proof of concept with integrated subsystems that allow immobilisation of the patient.
The part that has the most influence on the patient's immobilisation is the part that is in direct interaction with the patient, which is the bed assembly, excluding the head coil assembly. However, the head coil design highly influences the dimensions, comfort and functionality of the redefined bed systems. Therefore, the head coil is only considered an abstract shape where the electronics and wire design is left out of scope. All parts that are influenced by the design of the bed assembly will be considered during the design.

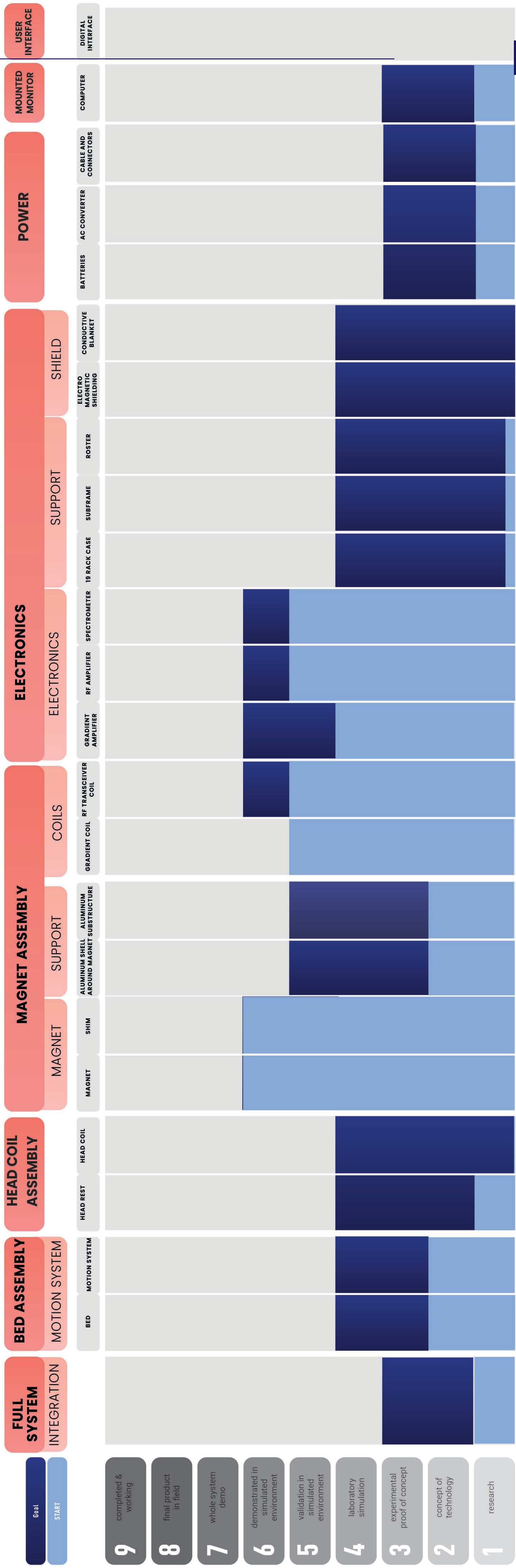
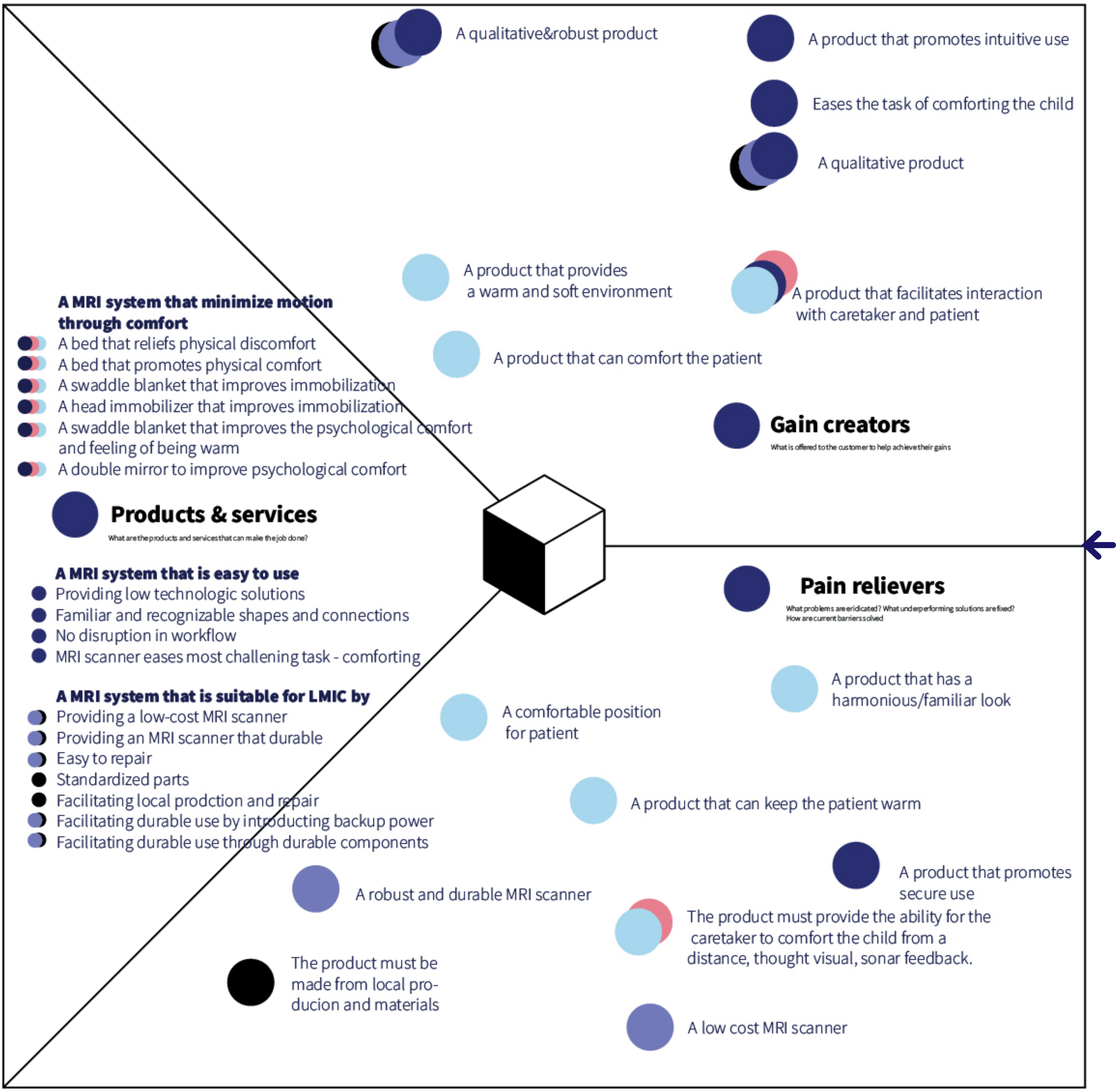


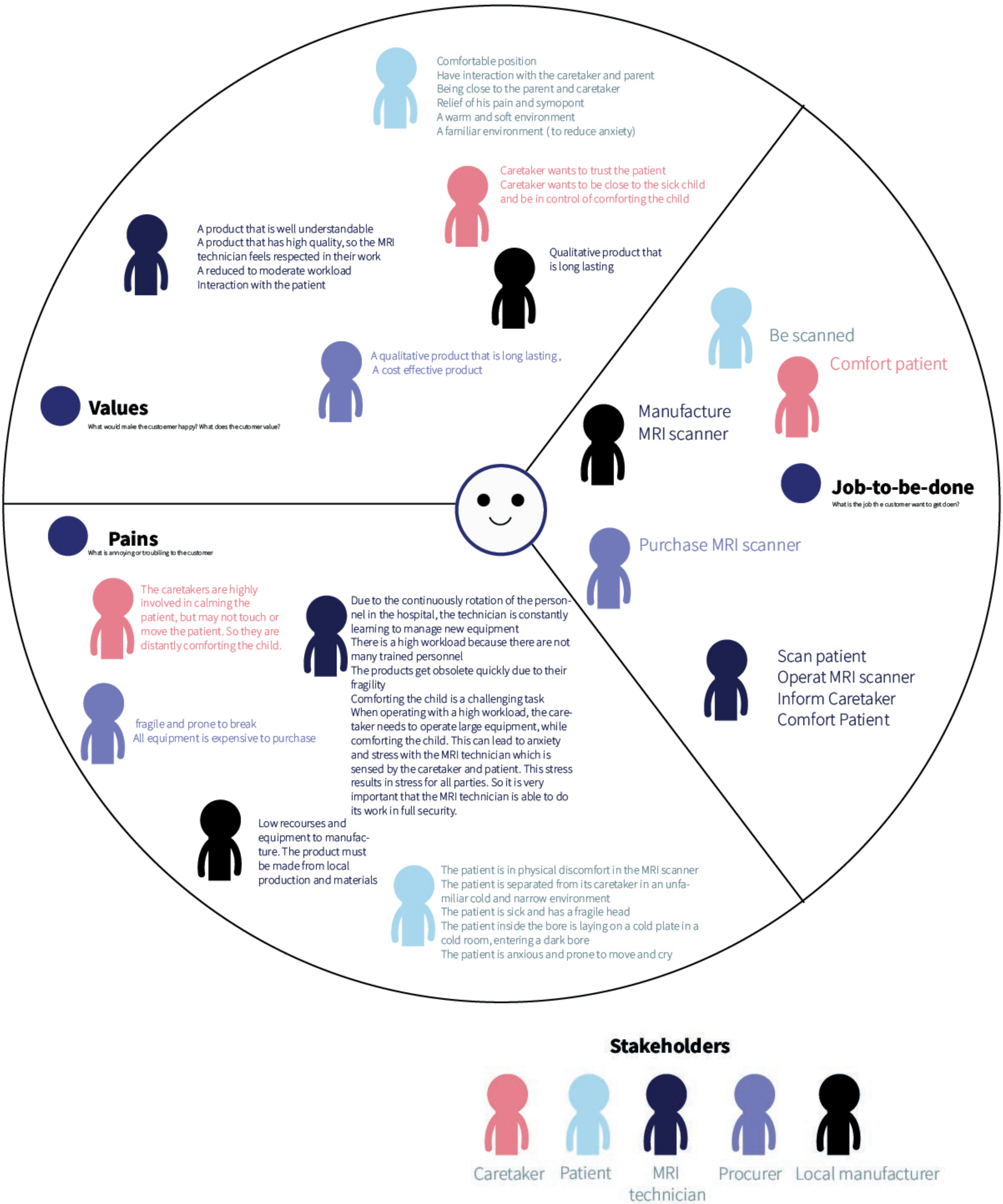
Figure 8.1 TRL of envisioned concept

Value Proposition



The value proposition summarises the values of all main stakeholders and illustrates how this is translated into product features. It is a tool which can help ensure that a product or service is positioned around what the customer values and needs. The left hand side visualises the values and pains of the most important stakeholders. The right hand side visualises the product features and its fit to the user. The fit is achieved due to that the products and services offered as part of the value proposition address the most significant pains and gains from the customer profile.

Figure 8.2 Value proposition


Comfortable position
Have interaction with the caretaker and parent
Being close to the parent and caretaker
Relief of his pain and symopont
A warm and soft environment
A familiar environment (to reduce anxiety)
Caretaker wants to trust the patient
Caretaker wants to be close to the sick child and be in control of comforting the child
A product that is well understandable
A product that has high quality, so the MRI technician feels respected in their work
A reduced to moderate workload
Interaction with the patient
Qualitative product that is long lasting
A qualitative product that is long lasting,
A cost effective product
Values
What would make the custoemer happy? What does the cutomer value?
Be scanned
Comfort patient
Manufacture MRI scanner
Job-to-be-done
What is the job the customer want to get doen?
Purchase MRI scanner
Scan patient
Operat MRI scanner
Inform Caretaker
Comfort Patient
Pains
What is annoying or troubiling to the customer
The caretakers are highly involved in calming the patient, but may not touch or move the patient. So they are distantly comforting the child.
Due to the continuously rotation of the personnel in the hospital, the technician is constantly learning to manage new equipment
There is a high workload because there are not many trained personnel
The products get obsolete quickly due to their fragility
Comforting the child is a challenging task
When operating with a high workload, the caretaker needs to operate large equipment, while comforting the child. This can lead to anxiety and stress with the MRI technician which is sensed by the caretaker and patient. This stress results in stress for all parties. So it is very important that the MRI technician is able to do its work in full security.
fragile and prone to break
All equipment is expensive to purchase
Low recourses and equipment to manufacture. The product must be made from local production and materials
The patient is in physical discomfort in the MRI scanner
The patient is separated from its caretaker in an unfamiliar cold and narrow environment
The patient is sick and has a fragile head
The patient inside the bore is laying on a cold plate in a cold room, entering a dark bore
The patient is anxious and prone to move and cry
Stakeholders
Caretaker
Patient
MRI technician
Procurer
Local manufacturer

9. List of requirements

To provide a low-cost Field MRI scanner that is more accessible than conventional MRI scanners, a sustainable and user-centred MRI scanner that is comfortable for the patient and guiding for the MRI technician is developed. Besides the human factors functional and context requirements defined during the discovery phase, other requirements need to be considered regarding the product's safety, durability, and affordability. A functional, safe, and comfortable MRI scanner is defined through a combination of literature and the framework of [90]. The following chapter aims to outlay the main requirements for designing and developing a user-centred LF MRI scanner. The entire list of requirements can be found in Appendix A.

9.1 Device specific requirements

The device-specific requirements are subdivided into the functionalities of the full MRI scanner as a system and part-specific requirements. The main requirements are stated in this section. The entire list of requirements can be consulted in Appendix A. The category functionality refers to the working technology performance, clinical performance, usability. The usability is based on the Usage efficiency, Ease of use, compatibility based on Park, Kim, and Shin [90].

9.1.1 Functionality

The magnetic field of 50mT with a bore of 30 cm is enough to have a spatial resolution of 3*2*2mm. This requires the subject to be positioned at the epicentre of the bore within a sphere of 250mm, which is the field of view. Therefore, the patient must be fixed with its head during the sequences and not move for more than 3 mm.

9.1.2 Usability

A basic trained MRI technician must use the device. In addition, the product must allow the basic trained technician to walk through the procedure with the help of use cues.

9.1.3 Comfort

Physical comfort influences the mobility of the patient. For prime comfort and minimum discomfort, the patient's posture, the interface pressure Therefore supports are necessary under the most critical anatomical areas, and a medium mattress hardness is required.

The psychological comfort of the patient must be maintained by providing methods that allow the patient to be in a resting state of mind. Through parental interaction within the MRI scanner, the caretaker must interact with the patient.

9.2 Part specific

9.2.1 Bed

Patients from 0 to 4 years old with a head circumference of 50 to 60 cm can enter the bore. This target group is based on the shoulder width of 26 that can enter the bore. However, since multiple children are malnourished, treating an older child with a shoulder width of 26 cm can occur. Their body length will be taller than a 4-year-old. Therefore, the length of the bed must be a minimum of 100cm for the children to lay inside the bed.

Pressure distribution

Areas that can promote pressure ulcer growth and discomfort due to nerve oppression in areas with subcutaneous fat should be avoided. This means that the occipital area, the shoulder area, and the lower spine area should have a distributed pressure on the mattress and avoid a peak pressure of higher than 55 mm Hg.

Use

The MRI technician is responsible for correctly positioning the patient on the bed. Even though the MRI scanner is to be designed as compact as possible, the MRI scanner needs a minimum of 200mm on the bed to install the patient. Moreover, no additional staff must be needed for the installation and comforting of the patient. An Adequate manual is needed to operate the installation and imaging process. Since the nurses rotate routinely between departments, and the workflow is high, not much time is available for training staff. Consequently, a concise step by step guide for the imaging processing is needed to instruct the nurses about the basics of the equipment used. Within the design of the MRI scanner, the feature may require additional use-cues to provide intuitive guidance to the nurses.

9.2.2 Head coil

The head of the patient must be in proximity of the coil. The RF coil must be concentric with the magnet's bore. Because the coil is rigid, this will not be applicable for the range of 50-60 cm. Therefore, multiple head coil sizes are introduced to cover most of the head circumferences. Five head sizes must be covered and placed concentrically inside the middle of the bore. The head coil must cover the full areas of the brain, from the frontal lobe to the cerebellum.

9.2.3 Head immobilizer

General

The lower field MRI scanner operating at 50 mT has a spatial resolution limited to 3×2×2 mm3, equivalent to 1μl volume for each spatially resolved element or "voxel". Therefore, the immobilization of the MRI system must prevent the patient from moving its head more than 3 mm, while preventing discomfort at the patient.

Ergonomics

The anatomical areas in patients with hydrocephalus are specific in shape, sensitivity, and size. The head coil must be elliptical to be in proximity of the head. Furthermore, neck support is needed.

9.3 LMIC specific requirements

9.3.1 Affordability

Due to the high purchasing and maintenance cost of the MRI scanner, the device has low accessibility in low resource settings. One of the main barriers that hinder the introduction of equipment in LMICs is the financial barriers, according to Malkin [3]. By making the MRI scanner affordable for the setting by tailoring its functionality and minimizing additional features, the total cost of the MRI scanner could be limited to not exceed €50.000. To allow the hospital's affordability and market competence, the maintenance per year must not exceed €70.000 per year. Low cost but compatible mechanical materials and design features that limit the cost need to be considered during the design.

9.3.2 Spare parts

The lack of spare parts and consumables and the financial barriers, has been defined as the main design-related barrier to the accessibility of health care technologies in LMICs. As researched in [3], spare parts and consumables are hard to acquire in low-resource settings, complicating the need for maintenance and repair. Therefore, it is necessary for the Designing medical devices for low-resource settings requires considering relying on sub-standard facilities for use and maintenance. In addition, the used parts and tools must be standardized and online available to allow accessibility to acquire the parts for maintenance and repair.

9.3.3 Cleaning compatibility

In LMICs, cleaning and disinfection are performed with frugal manual methods such as boiling water [91] or mild chemicals. Therefore, the material and design appropriate for this cleaning method must be designed. Currently, the medical imaging equipment in the Cure hospital in Uganda is cleaned with water and hydrogen peroxide.
Red dust is a hurdle in Uganda. To prevent this to enter the critical components (the magnet system in the motion systems), these areas must be covered double. The first layer is dust-free, and the second layer is for impact and surface dirt.

Cleaning
To use the product for multiple life cycles, the product must be cleaned, sterilized, and maintained. The design of certain parts of the product requires a specific shape, cover, or features to facilitate this. The medical product is a type 3 product that does not need to enter the body. Only surfaces that interact with the body need to be disinfected, which are the head coil and the mattress.

9.4 Overview of requirements

The entire list of requirements with rationale can be found in Appendix A

N0	Main requirement
	Main Product requirements
P.1	The device must be able to provide a comfortable position for the patient
P.2	The MRI scanner must provide a non-sedating solution to immobilize the patients head with 3 mm in the rotation and translation in 3 axis (x,y,z)
P.3	The MRI scanner must promote the physical and psychological comfort of the patient
P.4	The MRI scanner must ease the workflow of MRI technicians compared to conventional imaging devices.
P.5	The MRI technician must be able to install the patient solely and safely
P.6	The dimension of the MRI scanner must not exceed 90 cm *3m due to the limited space in a hospital ward.
P.7	The product should enable easy and low-cost installation
P.8	The product should prevent heat-loss of the patient
P.9	The product should be resistive to dust and water-non-absorbent
P.10	The product should allow intuitive operation of the workflow (not obstruct)

9.4 Overview of requirements

The entire list of requirements with rationale can be found in Appendix A.

N0	Main requirement
	Main User requirements
U.1	The head coil must encompass the entire brain of the patient, which means that it must overlap the eyes and the upper spinal area (C2).
U.2	The caretaker must be in close interaction with the patient before and after the diagnosing.
U.3	The MRI scanner must be able to scan patients with head circumference between 50 and 60 cm and 30 cm to 1.20m body length
N0	**Main requirement**
	Main Context requirements
C.1	The LF MRi scanner must be cost-effective in purchase (<€50.000) and in cost of ownership.
C.2	The LF MRI scanner must be able to be assembled and produced locally
C.3	The LF MRI scanner must match the knowledge level of basic trained personnel
C.4	Potential spare parts should easily be attainable
C.5	The device requires taking into account relying on sub-standard facilities for use and maintenance.
C.6	The device must be repairable with commonly available tools.
C.7	Cleaning of the device should be attainable with basic cleaning equipment.
	Main Technologic requirements
T.1	The head coil must be at proximity of the subject of interest
T.2	The head of 50 - 60 cm circumference must be able to be aligned concentrically inside the bore at distance of 250mm from the opening.
T.3	No ferromagnetic materials may enter the bore or may be at proximity of 100mm of the bore opening
T.4	The electronic component must run from standard power outlets and be ultimately battery,solar,diesel powered.
T.5	The temperature inside the magnet must stay stable (drift less than 1 degree per hour)
T.6	No forces higher than 10N may be exerted on the magnet.
T.7	No environmental dust or liquids must be able to enter inside the magnet system.
T.8	The RF could should be connected with the magnet

9.5 Design drivers

The system requirements can be categorised and be described in design drives. The design drivers capture in a tangible way what features of the envisioned design. What should the product include for a introduction, acceptance, and use of the LF MRI device inside LMIC system requirements.

Low cost
From the contextual challenges, it became prevalent that it is crucial to keep the low field MRI scanner as cost-effective as possible, even after use. The use of specifically designed consumables or production processes needs to be taken into consideration during the design process. Cost effective design solution must be chosen to keep the cost of purchase as low as possible.

Design for sustainability

The uncontrolled context increases the challenge of the complex device to be used during multiple life cycles. Therefore it is crucial to consider the durability of the device so that it can sustain and can function long term in the context. Therefore design solutions will be introduced that have a positive impact on the durability of the device, such as using basic and standard components that are regularly used in the context to facilitate local repair and manufacturability. Easily replaceable electronics. The use of basic and standardized tools.

Patient Human/centred design

By involving the stakeholders earlier in the design process, the needs of the key players are met and the experience of these stakeholders are improved. This is visible in the product by ensuring and improving operator usability and ensuring increased patient comfort. The MRI scanner focuses on patient centric care, which is a care that encourages active collaboration between the patient, providers and caretakers to design a human centred device that meets the needs, values of the stakeholders. The focus lays on physical comfort as well as emotional well-being which results in a better qualitative care outcome.

Develop

Component research

→

10. Component research

Introduction
This chapter discusses the component research based on literature, experiments and observations. The influence of a range of factors on patient comfort has been investigated to determine the most effective design concept to be integrated into a proof-of-concept prototype of a sustainable and patient-centred low field MRI scanner bed. The most significant factors have been identified through qualitative research, interviews, and experiments to measure different concepts' effectiveness. The factors that are important to implement for a comfortable bed system is discussed, designed and evaluated. For the patient to be immobilized, both comfort and an active immobilisation device are necessary. First the concept of comfort is discussed, subdivided in physical and psychological comfort. The background research lead to component requirements, which are used in Chapter 11 for the deisng.

Objective
The objective is to understand the factors that cause discomfort to the patient while lying inside the lower field MRI scanner. Furthermore how this can be implemented in the bed design. The result is the concept rationale for the concept design.

After defining the fundamental for comfort design and immobilisation, the necessary features that need to be implemented in the concept are designed.

2. To improve physical comfort
How can physical comfort be improved by minimising discomfort through improving the correct posture when lying inside the MRI scanner?

3. Improve psychological comfort
What are the factors that improve the psychological comfort of children in MRI scanners?

4. Immobilise
How can a head immobiliser be designed which is comfortable, easy to replace?

Method
Anthropometric data research (1D, 2D, 3D) information about comfort design was gathered through literature research. This knowledge was fundamental to the concepts of the different parts. The concepts have been defined hereafter through conceptualisation and brainstorming (Appendix I.3).

10.1 Fundamentals of comfort design

10.1.1 Framework to design for comfort

The lack of comfort and presence of discomfort is the leading cause of the movement of children in the MRI scanners. Understanding what factors influence comfort allows to minimise the discomfort and design and improve the increased comfort factors. However, once comfort is achieved, the patient can still move and be immobilised. Therefore section 10.3 focuses on the immobilisation methodology.
The patient encounters discomfort due to the narrow bore and unergonomic position. Comfort can only be introduced once the discomfort is minimised [81].

Discomfort can be defined as an unpleasant state of the human body in reaction to its physical environment (Vink and Hallbeck 2012) [80]. Discomfort and comfort are two independent factors that are influenced by different underlying factors, according to Zhang et al.(1996) [81].
The discomfort inside the bore is associated with feelings of pain, soreness, numbness, and stiffness of the muscles. These feelings are caused by the physical constraints of the bed design of the interface of the human body.
Discomfort is closely related to biomechanical factors such as fatigue of muscles, while the concept of comfort is mainly related to the aspect of the state of mind. Therefore, it is crucial to reduce the discomfort before increasing comfort. Comfort is associated with feelings of relaxation and a calm state of mind.
Comfort is a sense of physical or psychological ease, often characterised as a lack of hardship that can only exist in the interaction between a human and a product within a context [80]. This can be influenced by an aesthetic impression, the interaction with the caretaker, and the scanning duration[82].

Models to predict and assess comfort
According to the model of Helander and Zhang(1997), the theoretical model of comfort and discomfort distinguishes the underlying factors in three levels; 1) the human, 2) the context of diagnosis, and 3) the subject the patient has the most interaction with, the bed (Figure 10.1)[81].

1) Human level; the physical characteristics, anthropometry, expectations, and its behavioural characteristics.
2) Contextual level; the diagnosis site, temperature and the physical environment influence the discomfort.
3) Subject level (bed); additional supports, aesthetic design, and the ease of functioning influence the comfort level [82].
A conceptual model of Hiemstra [82] has been used to explain the interaction between the three different levels and comfort and discomfort. The underlying factors of the bed design that influence the discomfort are; posture, movement and interface pressure. This has all been combined in one visual explaining these relations (Figure 10.1).
When designing for comfort, the most critical indicators are the anthropometrics of the patients and the factors indicated by Hiemsta [87].
Therefore, to increase comfort, the focus is set on improving the bed design and the physical comfort rather than improving the experience (with adjustments in the noise, smell, climate, vibrations and light) since they have a minor effect on the Low resource setting.
During the design, comfort is subdivided into physical and psychological, as Zhang [81] distinguished.

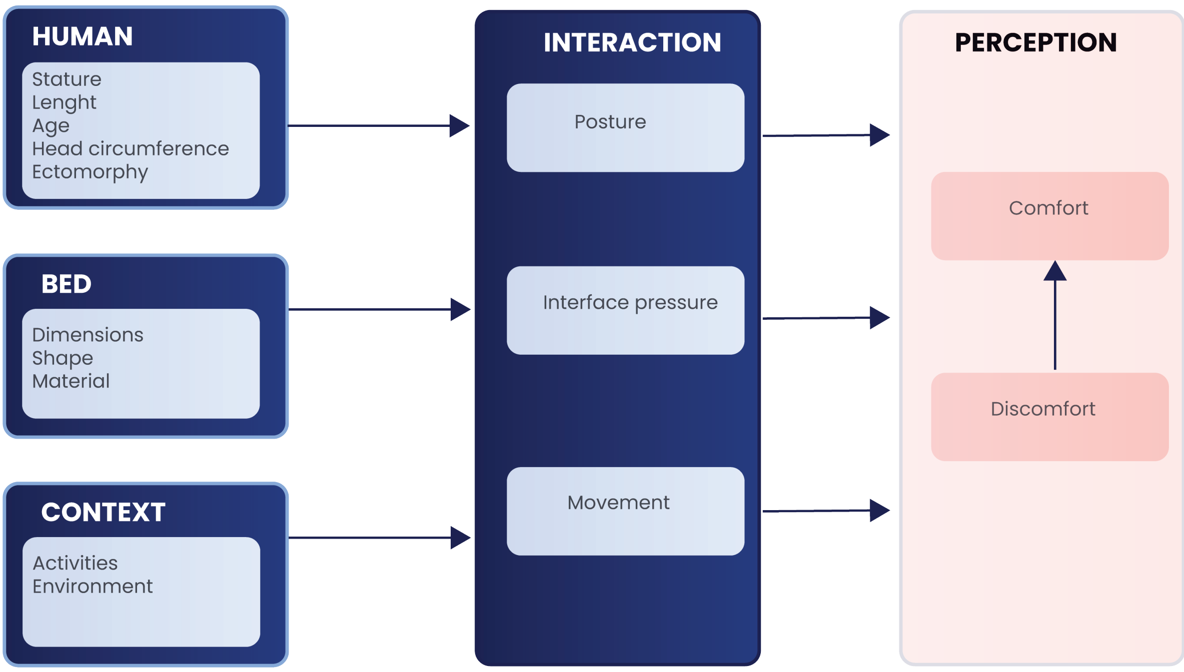


Figure 10.1 Framework define and design comfort (zhang et. al. 1996)

10.1.2 *Psychological comfort*

Anxiety and psychological discomfort are reported to affect the MRI procedure outcome adversely. For example, 19% mentioned that regularly disrupted scanning is due to motion artefacts or increased heart rate[100]. The loss of control, fear, feeling of being closed in, and pain during the procedure contributes to these feelings.

Effective methods in industry

Studies that evaluate the effectiveness to reduce psychological discomfort and anxiety have outlined the following methods. Among others ; prone positioning [102], system desensitisation [103], music [104], anxiolytics [105] and imaginative visualisation [106]. These methods have been translated into products or protocols used in clinical settings. Studies that have focused on improving comfort to reduce motion for paediatric MR Imaging involved the methods; swaddling, feeding, feed and wrap, sleep manipulation, change of physical environment, play therapy with a mock-up MRI and parental communication before, during and after the procedure.

Behavioural training has led to high success rates for immobilising non-sedated children [107]. However, these behavioural trainings, such as systemic desensitisation, occur prior to scanning and require significantly more time. Due to the lack of costly time and trained personnel in the LMICs, this method is excessively resource-demanding for the context. Furthermore, communication has been proven to be the most effective method to reduce stress and anxiety in adults. For infants from 8 years old, this has a beneficial but minor effect. However, communication is not practical for the target group of children between 0 and 4 years old since it requires instructable and conscious children. In LRS there is not much time for training with an MRI scanner. Currently, no optimal method is suitable for an LRS that covers the range for children of 0-4 years old.

The following methods have been analysed against the context state and have been proposed to MRI technicians in LMICs. Promising methods that allow psychological comfort in a low resource area are - parental involvement, light, visual feedback. The effectiveness is age-depending.

Effective methods for LMIC

The psychological factors that influence the patient' comfort are; the interaction with the MRI technician/parents, the environment, and the perception of the product.

1. Improved parental interaction

The most effective comforting method for the youngest children was through parental interaction. On the other hand, visual feedback has been the most effective method for children around four years old during MRI scanning[108]. Parental interaction includes touch, smell, or eye contact. The creation of a child - family-friendly MRI environment where the parents are involved as collaborators helps with the reduction of discomfort with children [108].Calm children react less to negative stimulation than children who are already upset for other reasons [118]. Consequently, procedures require less time and less staff [109]. Parental involvement during the MR Imaging is thus essential to improve the comfort of a paediatric patient. However, the patient is nearly isolated once inserted in the bore. The lower field of the MRI scanner does allow the MRI technician and caretakers to be present around the machine. However, they cannot enter or obstruct the imaging by movement or intervention.

2. Improved interaction with MRI technician

Promoted interaction between the technician and the patient has been proven effective for patients undergoing MRI examination on safety and comfort needs. This must be facilitated to improve the psychological status of patients and improve the quality of examination safety [118].

3. Improved perception of the product

The perception of the MRI scanner for the child influences the amount of anxiety of the patient. For example, the paediatric patient may perceive the unknown and narrow technical product as scary. Other environmental conditions such as the decrease of body temperature during the scanning of the child, the mechanical ticking noise and the dark environment inside the bore contribute to discomfort.

Based on the criteria that the method should not take additional time besides the scheduled procedure time and not change the physical environment of the hospital the swaddle technique is chosen. The swaddle technique is the best method to be introduced to promote a comfortable position in the combination of a parental interaction through a double mirror.

What needs to be implemented into the design for the promotion of physiological comfort;

- Parental interaction
- Visual feedback
- Comfortable temperature
- Trustworthy perception of MRI scanner by patient

This is a combination of methods proven effective in minimising psychological discomfort and immobilising paediatric patients in MRI scanners.

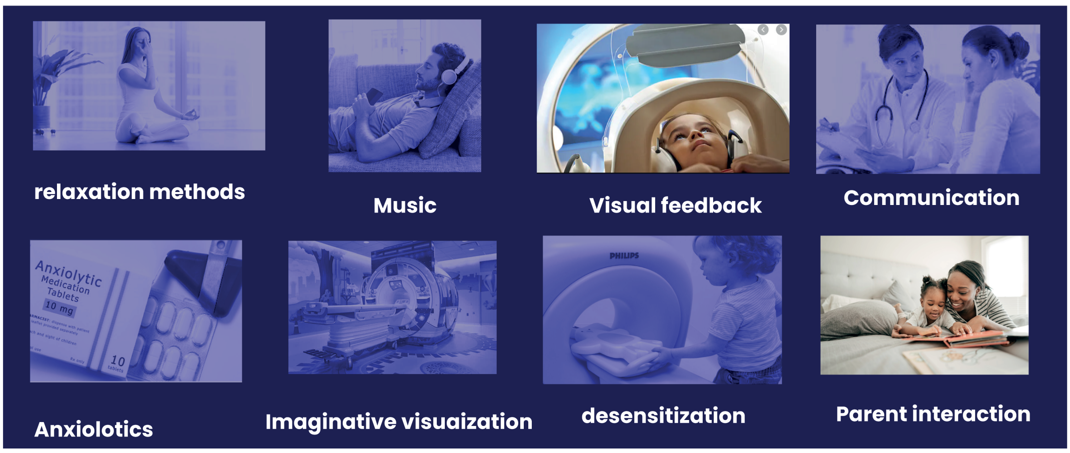


Figure 10.2 Factors that improve the psychological comfort

Component research

10.1.2 Physical comfort

Causes of discomfort

The physical factor influencing discomfort is the interaction between the body and the product. In this section, this cause of discomfort is analysed.

The cause of discomfort was based on the anthropometry of Ugandan children between 0-4 years old, according to the observation and experience inside of the bore (Appendix B.3). Patients with hydrocephalus are ill and encounter pressure in their heads. Especially before surgery, the effects of the disease significantly influence their behaviour and experience.

While lying motionless on the bed, pain can be experienced in certain areas because of bad posture and pressure on critical areas. These phenomenons ant is physiological cause is described. Discomfort can be subdivided according to duration and activity[84]. According to this definition and the situation of the infant being diagnosed, short-term discomfort is being sketched.

Poor Posture

The body position is dependent on the angle of specific joints and anatomical body parts relative to each other. A distinction will be made on the position of the head thorax, the thoracic-pelvic area, and the limbs. During lying inside the LF MRI scanner, a poor static posture results in ligament and muscle tension in the neck and legs. The patient is lying supine with the head in a head coil and the arms and legs medial to the body. Additionally, The unergonomic position challenges the ability to breathe and swallow.

The key to a good posture is the positioning of the spine. In adults, the spine has three natural curves that are ideally supported. In an underdeveloped spine, such as a child, the natural curve only occurs under the neck and the lower back. Therefore, support on the neck and legs help for a better posture. Reducing these types of pain can be done by allocating the pressure points and providing support.

Pressure

The pressure points occur primarily in places with a low level of subcutaneous fat (Figure 10.3a), primarily on the occipital area. Pain or headaches at the base of the skull are often the results of tight muscles in the back of the neck due to tension, stress, or fatigue.

According to Treaster and Marras (1987) [85], the subcutaneous body fat and muscles influence the resulting pressure distribution. An increase of subcutaneous body fat increases the cushioning effect. Therefore, the zones most prone to elevate peak pressure levels and pain are those with lower subcutaneous fat, such as the back of the head, the tail bone and the shoulder area. Figure 10.3a illustrates the pressure distribution of an infant of 20 months on a flat mattress with a pressure mat.

The head is an anatomical area with increased weight, but while lying in the immobilization device, a minimal area is supported on, namely, the occipital area. This area has low subcutaneous fat and is thus more prone and riskier to develop pressure ulcers. Contact with a hard surface may create pressure over an area that can inhibit blood flow or increase nerve irritation, such as in the occipital area.

Once the weight of the body of the patient pushes down on its skeletal structure and is distributed through a small volume of soft tissue located between bony prominence and supporting surfaces, potential harmful pressure may occur. Once the time of such an event is increased, the pressure can develop discomfort feelings, pain, pressure ulcers and if time remains the result can be an ischemic injury.

Pressure on critical areas causes pain

The pain experienced during the scanning procedure is a moderate and constant pressure that hurts. This appears the most in the area where the headrest is pressing on the head. An increased time worsens the pain into the piercing. Piercing pain is caused by the receptors (nociceptors) on the skin. The receptors present in the skin are sensitive to mechanical impact. This anomaly is caused by trigeminal or occipital nerve branches (Figure 10.3b). Nociceptors get triggered, and this unpleasant stimulation can be perceived as pain. When the period increases, the body posture becomes more critical since the unfavourable position increases the tension in the muscles. The pain resolves after relieving or preventing pressure by avoiding the cause [83].

Physiological effects

Pressure in living tissue causes deformation of the tissue surface. If a specific limit value is exceeded, it leads to a restriction in blood flow. This is the case when placing too large support under the knee area. An external pressure of 6-12 mmHg (0,08-0,16 N/cm2) can cause a blockage of the venous outflow. A pressure collapse can occur from pressure of 32 mmHg (0.42 N/cm2). The pain stimuli can already be triggered by lower external pressure combined with a longer duration of time. In this care, the release of toxic substances causes pain stimuli [86], [111].

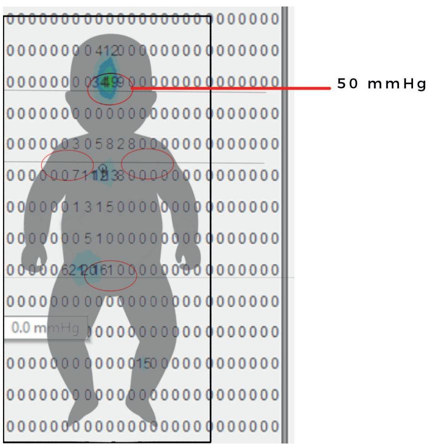


Figure 10.3a Pressure distribution of patient 15months on flat bed

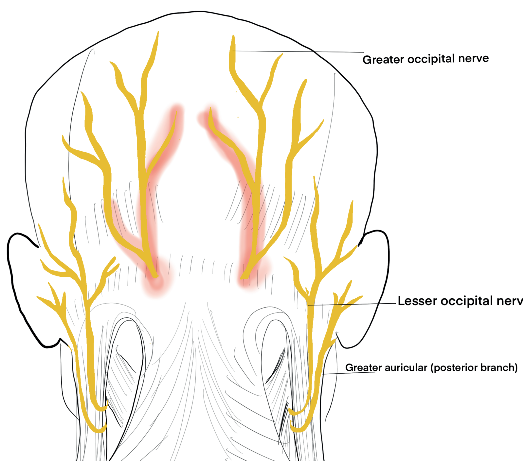


Figure 10.3b Back of head, pressured nerves

Comfort requirements

The literature presents numerous approaches and concrete models that illustrate the connection between the discomfort and the pressure load on the interface between the person and the surface (bed) (Kamijo et al. 1983). Shen and Galer (1993) . The goal of designing a bed with an optimal load distribution is to reduce discomfort. According to Hiemstra, the following characteristics of the human-bed interaction influence the design of an optimal bed. The patient comfort is dependent on the arrangement of the bed geometry, the strain in the shoulders and the time and efforts to reach this posture. Therefore actions will be made to design the bed for a good posture and reduced pain caused by pressure.

Pressure
There is an association between the shape of the bed design and the interface pressure. Different shapes lead to different pressure distributions (Chen et al., 2007). When the design follows the contour of the human body, a larger contact area and a lower average pressure is found.

The shape of the bed
As stated earlier, the bed design that followed the contour of the body shape and provided support led to a better pressure distribution which is beneficial for the average and peak pressure on areas with low subcutaneous fat (Kamp 2012). Too-large support below the knee will pressure the patient's knee, resulting in blood flow restriction to the legs. Mergl. She concluded that the comfort is rated high when an ideal pressure distribution is under the legs and buttocks.

Headrest
The headrest needs side support and neck support for relaxing and sleeping. In addition, the neck needs to be supported to keep the spine in the correct position. Furthermore, the maximum exerted pressure in the head area may not exceed 54 mmHg.

Material and support of the bed
Even though different material hardness per anatomical area might be preferred and beneficial, such as, E.g., firmer foam on the hips, as this is heavy (at least for adults) and sags in the supine position. Sensitive areas such as the shoulder area should be soft (Lips Vink, 2017). The same is one at the lower end of the thigh and the popliteal fossa (Zenk, 2004, Mergl, 2006, Hartung, 2006) because these are sensitive and can cut large veins here (Smulders, 2016). Soft and supportive contact in the neck is desired due to the excessive pressure on the head (Franz, 2012). These suggestions are not well accessible due to the manufacturability complexity of different material hardness. Furthermore, material hardness has a more significant influence on more prolonged periods. Therefore, medium hardness is preferred when considering one type of hardness for the entire bed.

10.1 Key insight
The patient comfort is dependent on the arrangement of the bed geometry, the strain in the shoulders and the time and efforts to reach this posture.
- Good position requires supports of the neck and back
- Pressure on the back of the head can cause pain. Therefore, no pressure higher than 32 mmHg is allowed.

Component requirements:
What needs to be implemented into the design is the promotion of physical comfort through

- Normal pressure distribution on body areas / critical areas
- Correct posture which follows the spinal curve
- Support on neck

10.2 Fundamentals immobilisation

Once the discomfort is minimised by providing a comfortable bed and an environment where the patient can be at ease, the patient can still voluntarily move to re-position. This movement needs to be minimised. The main challenge is to immobilise the head for a maximum movement of 3 mm in 6 DOF for 10 minutes.
The cervical immobilisation of the patient depends on the method of external immobilisation. Scientific evidence has shown the effectiveness of different immobilisation methods that restrict the movement of the head [97]. The fundamental anatomical and biomechanical requirements for the immobilisation of the head is defined.

10.2.1 Anatomical requirements

The biomechanical principle of the immobilisation technique of the cervical spine and the head can be done either internally or externally. In internal immobilisations, the device is placed under the skin, which is thus an invasive method and thus falls out of scope. Therefore, only external immobilisation methods will be considered. This principle is based on applying pressure on or through the skin in anatomical zones. When the different support areas are connected, they can limit the movement of the participant's spine, neck, and head. Indirect immobilisation with support on anatomical areas of the head, neck, and thorax is necessary due to the challenge of achieving a good grip on the skull base and the first thoracic vertebrae.

The body can be separated into occipital, frontal, parietal, and upper jaw zones. The areas with the lowest subcutaneous fat allow the slightest pressure on these areas, which are the occipital area of the skull.

Regular motion
The regular motion of the head and anatomical structures restricting cervical movement are presented. The motion of the head and cervical spine is created by the 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 concerning the body [97]. The bony spinal channel facilitates each form of motion. The inter-vertebral motion can be subdivided into different chain parts responsible for each movement.

- Atlanto-occipital (C0-C1) is responsible for flexion and extension - slight rotation occurs at this level (7)
- Atlanta-acial joint (C1-C2) allows more than 50 degrees
- Lower cervical levels (C2-C7) allow lateral bending

The motion happens in the sagittal plane (flexion-extension of 122 degrees) - coronal yaw plane 88 degrees axial plane 144 degrees.

Restriction of motion
The limiting factors of motion are muscle tension, bony structure, and inter-vertebral ligaments. Restriction of the bony structures and limiting the muscle rotations are the most effective ways.

Biomechanical principle of an external cervical immobilisation device
Application of pressure can result in the skull being directly held for immobilisation; however, the downside is that pressure ulcers and pain can quickly develop.

Supporting the head
Especially for patients with decreased muscle strength in the neck, such as children, external supports can help position the head. In addition, pressures on areas of the head are needed to achieve a proper external immobilisation of the spine.

The anatomical zones of the head are separated into the occipital, parietal bone, frontal bone, upper jaw, and lower jaw. The occipital area has little subcutaneous fat, enabling 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 increased time in the same position.
To limit rotation and bending of the upper spinal area, the parietal areas of the skull, pressure can be applied to immobilise due to their relatively large area.
However, this must be done with care due to the low subcutaneous fat volume.
Pressure on the frontal area of the skull can be put to limit the flexion of the spine. However, setting pressure on the upper jaw will obstruct access to both nose and mouth[116], [117], which is impractical once this area needs to be clear for possible intubation or air mask. In addition, upward pressure on the lower jaw will result in a reduced ability to open the mouth, which can be beneficial to minimise motion (Figure 10.4).

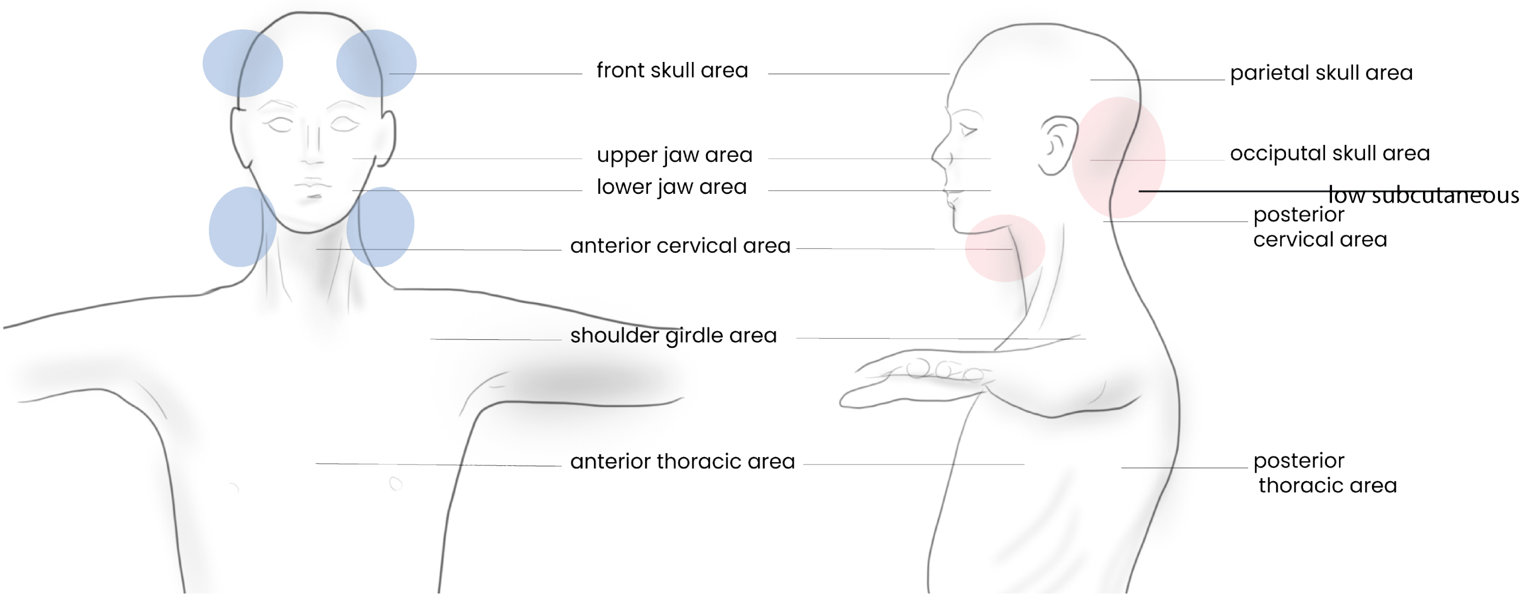


Figure 10.4 Areas that are recommended to fixate on (left) and not recommended (right) for immobilization (Holla,2017)

Support on areas of the neck
The neck area can be subdivided into the frontal and back areas. Pressure on the front area of the neck is discouraged due to obstruction of the vital structures on the soft area. The back of the neck area is covered with muscles, skin, and the spine, so local pressure can be applied in this area. When applying pressure to the spinal area, caution needs to be given to prevent junctional angulation, which is a phenomenon that allows motion at the two ends of the fixated spine. The head, neck, and thorax need to be fixated to prevent this.

Support on areas of the thorax
The Thoracic zone can be split into the anterior and posterior thoracic areas. The subcutaneous fat layer at the sternum is relatively thin, also a sensitive point for external pressure pain. From a biomechanical point of view, the thoracic zone is a good fixation area for external immobilisation of the spine. Due to the mobility of the shoulders, the immobilisation device should not solely rest on the shoulder girdles since the stability can differ based on whether the shoulders are elevated or depressed.

10.2.2 Mechanical Requirements
Considering that the specific anatomical characteristics of the target group that will be scanned will have an enlarged head circumference, which also means an enlarged head weight for the underdeveloped neck muscles and ligaments. The head must be well supported with the product. Additionally, the product must avoid that the user can exert a certain amount of force to rotate, flex or extend the neck muscles that result in movement.
The stiffness of the system has been calculated with the help of a free body diagram and bio-mechanical characteristics of the head-neck system of a child with hydrocephalus. 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 sternocleidomasteoid muscle of more than 3 mm. When the head exerts a force of 5-50N on the head immobilizer, 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. Therefore unnecessarily stiff materials such as ceramics are excluded, but may include materials such as reinforced cardboard.
The entire calculation can be found in Appendix M3.

10.2.3 Immobilisation devices
Problems with current immobilisers
Current immobilisers are rigid, uncomfortable, and too large to fit inside the head coil of the low field MRI scanner. Other immobilisers specially designed for brain imaging require either an automatic vacuum, which is not widely available in LMIC or requires a significant workload from the MRI technician.

Design of concept based on classification
Research from Holla identified 4 different types specific for cervical spine immobilization (Figure 10.5). 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, 2. Rigid head blocks, 3. Shaped mattress (Figure 10.6)

Component Requirements
Fundamentals for the design of the head immobilizer

1. No external pressure must be applied on the areas with low subcutaneous fat to prevent pressure ulcers: The occipital area must be free from pressure
2. The areas with the lowest subcutaneous fat allow the slightest pressure on these areas, which are the occipital area of the skull. Application of pressure can have a result that the skull being directly held for immobilisation; however, the downside is that pressure ulcers and pain can quickly develop
3. Rotation and bending of the upper spinal area must be limiter: Through the application of pressure on the parietal areas of the skull
4. The head, neck and thorax must be fixed to prevent junctional angulation.
5. The immobilisation should not solely support the shoulders to prevent the effect of mobile shoulders.
6. The immobilisation should not solely support the shoulders to prevent the effect of mobile shoulders.
7. No pressure must be applied on the upper jaw

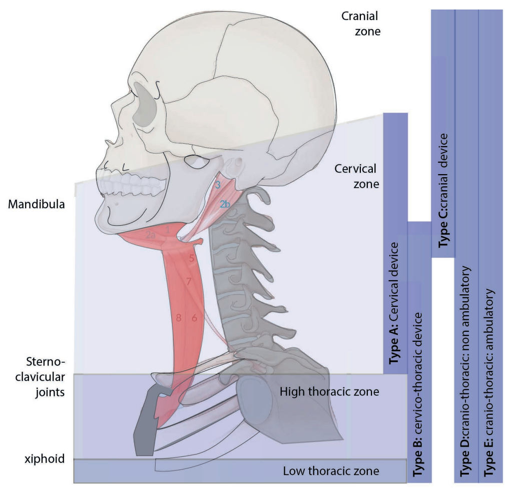


Figure 10.5 Categories to immobilize (modified ;Holla, 2017)

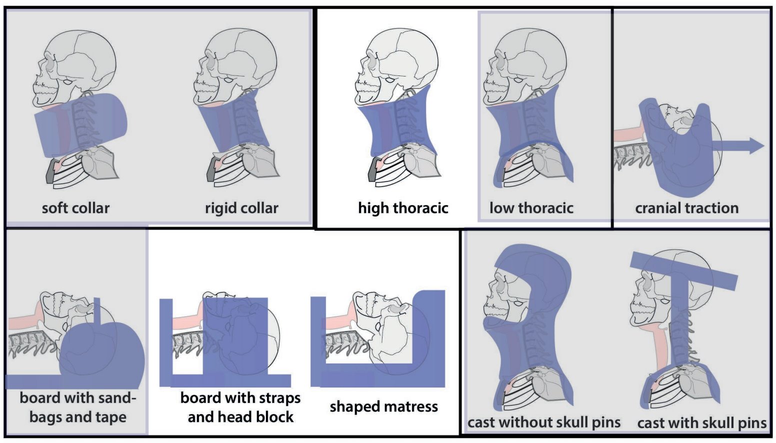


Figure 10.6 Chosen categories to immobilize (modified ;Holla, 2017)

11. Component design

1.

Challenge;
We want to promote parental interaction, but the parent may not obstruct the imaging or touch the child.

Opportunity
Visual feedback

Design solution
Double mirror that enters the bore, so that the patient can see the caretaker.

2.

Challenge;
We want to minimise the pain and discomfort of the patient with minimal extra cost and maintenance.

Opportunity
Pressure distributive surface and support.

Design solution
Comfortable bed design.

3.

Challenge;
We want to minimise the ability to move the head in a way that minimal volume is used and maximal comfort..

Opportunity
Head immobiliser integrated in the bed system.

Design solution
Compact functional head immobiliser.

Figure 11.a Collage of zoom brainstorm session

Introduction
This chapter discusses the component design of the bed system. Based on the previously determined fundamentals for comfort and fundamentals for immobilisation, the design process is initiated. The necessary components are designed and defined. Design for comfort and the immobilisation is presented, evaluated and conceptualised. Finally the chapter closes with one final conceptual design per component.
The concepts have been defined hereafter through conceptualisation and brainstorming (Appendix I.3).

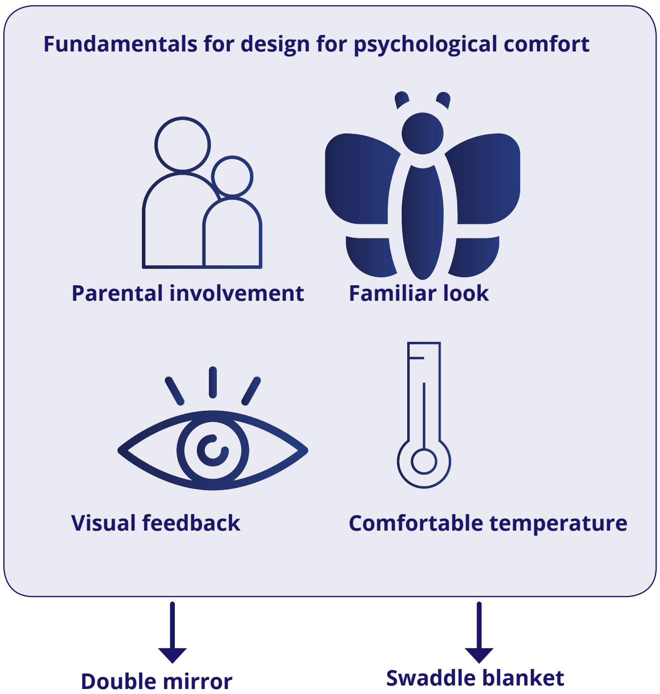
Based on the findings from chapter 10, we can define that the bed system is in need of components that promote the physical comfort and the psychological comfort to minimise motion.
Through an online co-creation session and brainstorm sessions with the following challenges, resulted in the definition of the swaddle blanket, the double mirror, the head immobiliser, the pressure distributive bed.

11.1 Comfort design

11.1.1 Psychological comfort design

To improve the psychological comfort of the patient the best way possible to implement parental involvement and visual feedback in the product features. The entire design process and requirements can be found in appendix M5 (mirror) and M6 (blanket).

Through brainstorm sessions, multiple features were ideate and conceptualised. Then, through a systematic review, the possibilities were evaluated on their feasibility and desirability in the clinical team from Uganda.
Through experiments with mock-ups, the concept has been conceptualised and validated through iterations. 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. Appendix M.5. discusses the entire design process and list of requirements of the double mirror.
The same for the swaddle blanket can be found in Appendix M.6.
For an improved psychological comfort it is important that the following factors are present in the design through.



Swaddle blanket
Infants remind swaddling to their previous warm and secure womb/lap of the mother. Being wrapped in cotton cloth of muslin feels similar to 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.

Double mirror
Calculations have been made to evaluate the maximum dimension of the double mirror inside the narrow bore with consideration of its possible field of view. To validate the calculations, a mockup has been made Figure 11.c.

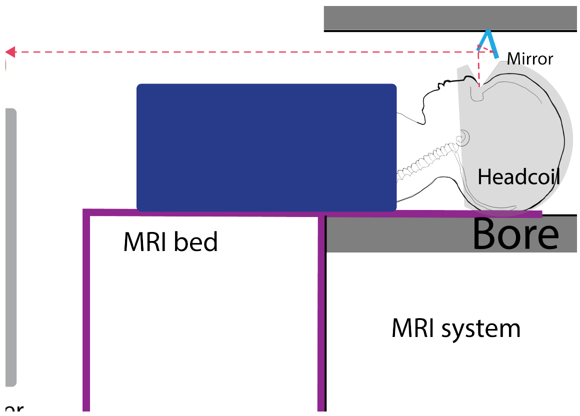


Figure 11.b concept of double mirror

Figure 11.c. Mockup of double mirror with participant to test correct angle

Figure 11.d Ugandan women swaddling infants

11.1.2 Physical comfort design

A brief process towards the design of the bed component is discussed in this section. The product must promote physical comfort, which is most influenced by the bed design. Physical comfort is dependent on the patient's posture to prevent muscle tension and pressure point of the skin. Eventually, an improvement in comfort will decrease discomfort and a decrease in motion from the patient. First, the mattress shape design is defined through literature requirements. The concepts have been tested through experiments with patients. The entire list of requirements and design process can be found in Appendix M.1)

Design objective

To provide the optimal configuration for the bed to provide an even distribution

Method

With the help of the flowchart [82] that illustrates the process of a comfortable seat design, a translation has been done for the comfortable bed design. The model consists of three phases, determine, define, and design.

1.A Determine the area of use
1.B Determine the duration
1.C Determine the activities
2.A Define the body dimensions
2.B Define the body movements
2.C Define the body supports
3.A Design of the bed dimensions
3.B Design the adjust-ability
3.C Design the bed elements

Achieve physical comfort by providing correct posture, pressure distribution

1. A-C. The use, duration and activities for the child in the bed is minimal. For 10 minutes the patient must be able to lay still.
2A. Data acquisition
Anthropometric variables of the infant in interface with the bed greatly influence the comfort of the patient.
The anthropometric variables such as weight, gender, age, percentage of subcutaneous fat, and ectomorphic index greatly influence the interface variables such as contact area, force, mean pressure, peak pressure, and pressure. The following anthropometric measurements were taken Stature, weight, head circumference, head width, and face length [82]. The anthropomorphic data of the human can variate within age, ethnicity, and gender. Proportions between different body dimensions also widely differ within different ethnicities [92].
However, due to the lack of anthropomorphic data of Ugandan infants, an estimation is made based on the 25th percentile of the Dutch children and 3D CT scan measurements. Because a Dutch database is used (DINED 2004), the data is more representative for P5-P05 of the world population [82].
The data acquired for the design of the bed and head coil assembly has been done based on anthropocentric database, the CT scan data from the Cure hospital, data from growth hydrocephalus growth curves and dimensions from a 3D scan of a human infant of 4 years old. The disadvantage of the anthropometric database is that it is restricted to certain bodily sizes and ages from different populations. First the different dimensions were evaluated, selected, and implemented in a design
2B. -The ideal posture has been defined. This led to starting point for the design of the bed. The best posture according to literature is; head against headrest, trunk slumped, uncrossed feet (Kamp et al. 2011). For all concepts this posture has been designed.
2C. -In order to gather knowledge about the ideal posture, three concepts have been designed based on literature. (Figure 11.1)
3. A-C - Three concepts of bed configurations have been according to the literature insights for physical comfortable designs.

- Normal pressure distribution on body areas / critical areas
- Correct posture which follows the spinal curve
- Support on neck

Figure 11.2 indicates the considered ideas for the concept development of concept 1,2,3 used in the experiment.

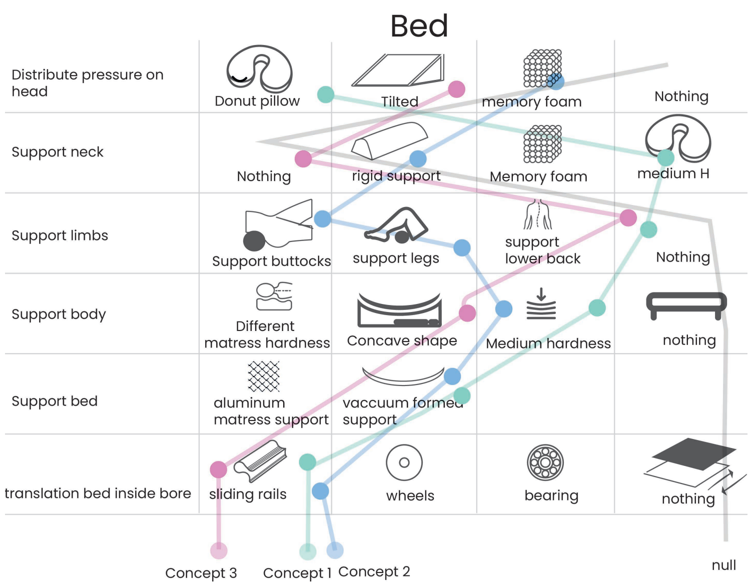


Figure 11.1 Morphological chart bed (step.2-AC)

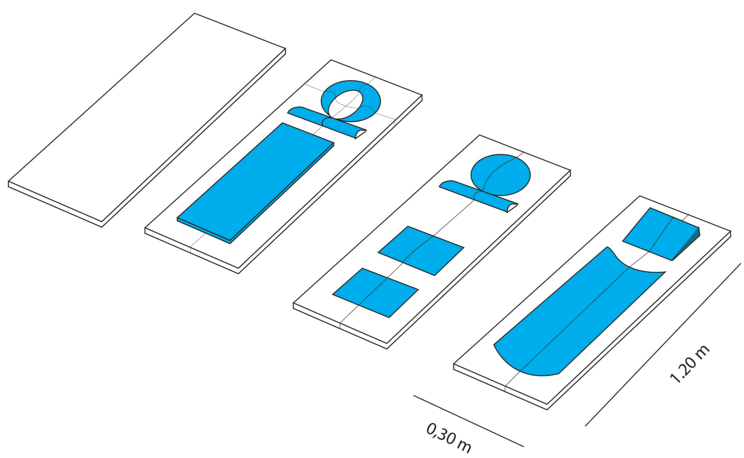


Figure 11.2 Three configurations of bed concept

11.2 Bed functionality evaluation

The three concepts have been designed based on the requirements retrieved from the literature—however, all literature specifics data and requirements for adults. Since the bed will be for paediatric patients and the body distributions of infants are different from adult patients, a separate experiment was done due to lacking literature about comfort in paediatric patients. An experiment has been performed with participants of 0-4 years old to evaluate the functionality of the three designed concepts.

1. Introduction

1.1 Research topic

The study's main objective is to determine the most optimized configuration of supports on the bed of the MRI scanner to decrease the peak pressure points at critical anatomical points, to test the subjective rating of comfort under each condition simultaneously and thus, to eventually the comfort of the patients. Several factors influence the comfort of the patient. One of the main factors is the bed the patient is lying on, as it is the largest contact area between the human body and the device. Therefore, improving this interface can positively impact the patient's comfort during the scanning procedure. Therefore, this experiment aims to collect experimental data that determines the influence of the height and shape of different supports on the sensitive areas of the human body. Furthermore, this experiment collects data to improve and iterate on the main research question: What is the best design for a comfortable bed that immobilizes the head of a 4-year-old infant while maintaining the comfort of the patient.
To characterize the role of the interface pressure distribution on the anatomical points, the maximum and minimum pressure were detected. Additionally, the total stressed area and the area of distribution on different concepts of mattresses was estimated.
Additionally, a subjective questionnaire about the comfort of the concepts was used to explore the role of pressure distribution on the subjective feeling of comfort.

Approach

To find an answer to the research question, an experiment is performed by measuring the maximal peak pressure force exerted on different body parts with different supports.

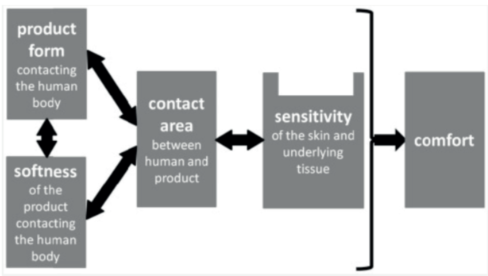


Figure 11.3 Comfort research approach [93].

According to the comfort model of Zhang [81], comfort can be improved by providing a uniform contact area of the product. Research by Buckle [93] approached the study of comfort by assessing different mattress hardnesses (Figure 11.3). However, it is argued that no significant difference is measured with the different hardness of the mattress for the comfort ratings and peak body contact pressures when considering a time shorter than 30 minutes, which is the case when lying in the low field MRI scanner. Furthermore, studies have concluded that mattresses with medium hardness (elastic modulus) are most comfortable[94]. Therefore no variations in mattress hardness are used as the reference surface.
Participants of 4 years old test three configurations of supports.
The participants lay on the mattress for the maximum scan time of 3 minutes while remaining still. The pressure is measured and readout digitally. By determining the area encountering the most pressure on the body, measures can be taken to minimize this high-pressure area and thus discomfort. Furthermore, with the acquired data, an optimized bed design can be developed where the bed will be optimized on the variable of the position and shape of the supports.

Pressure measurement

Literature relating to the evaluation of comfort on mattresses with the use of pressure measurements at body locations are limited to studies undertaken on plain and rigid surfaces, mostly due to the technological limitations of ancient pressure measurement equipment. Due to the development in pressure measurement technologies, more variations and positions are possible. For this experiment, a body pressure mat with 48 by 48 sensors is placed over different configurations on an MRI bed configuration as illustrated in Figure 11.4 and a body pressure mat over a plank. The body pressure distribution is measured on the cushions and headrest separately. The position is placed with reference to the correct posture in the low field MRI scanner designed by LMIC.
3 different kinds of configurations are prepared. Characteristics of the configurations are illustrated in Figure 11.4. The features of the cushions are determined by subjective experimentation, which leads to a hypothesis.

Subjective ratings

During the contact pressure measurement, subjects are asked to rate the comfort level on a 1-3 scale. Some are not approachable because the subjects are 0-4 years old.

2. Materials and Methods

2.1 Participants

Participants aged 0-4 years old were recruited from local communities. Informed consent forms were signed by their parents prior to the experiment, where after the parent participated in the entire experimental process. Moreover, the experiment was performed in the participant's home. The height and weight of the participants were obtained and varied from 89 cm to 100 cm. Figure 11.5 illustrates the participant data.

2.2 Instrument

This experiment used one mattress with three different support configurations (concepts) and a body pressure distribution measurement system. In addition, an experimental setup of the mattress with the pressure mat was made to assure the position of the mat, mattress and supports.
Illustration 11.6 illustrates the setup of the experiment. The experimental instrument was the BodiTrak UT4010-7000 pressure system, which functions on the software FSA 4.1. The system has an array (sensor matrix) of 32 x 16, the size of 675 mm X 959 mm * 3 mm and the pressure range is 0- 100 mmHg PSI with512 sensors. However, due to the sensor's deprecated technology, the system is not as accurate to read out exact data from the pressure measurement. Therefore, the model can be seen as a comparison between different concepts with relatively accurate data.

Participant profiles N=5

Group	No. Of samples	Age (months		Height (cm)		Weight(kg)	
		Average	SD	Average	SD	Average	SD
6 < x < 12 months	0	0	0			0	0
12 < x < 24 months	5	20	0.75	103.2		8.26	0
23 < x <36 months	1	36	0	93		15	0
Total	6	22.66667	0.6	69		9.383333	0

Figure 11.5 Participant data

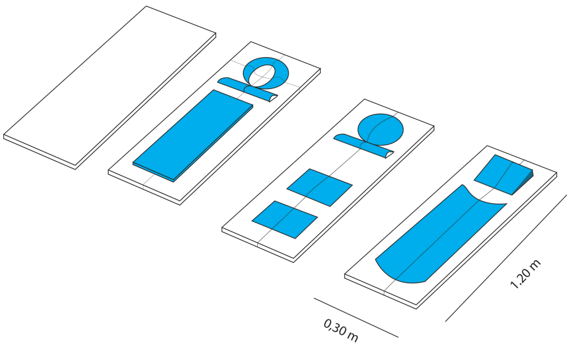


Figure 11.4 Experiment setup

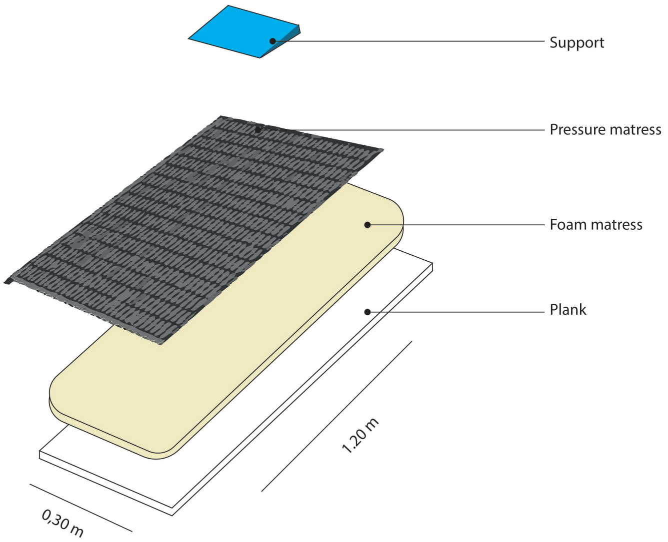


Figure 11.6 Experiment setup

2.3 Procedures

The test was conducted on a flat horizontal surface in the child's home. The subjects wore tight-fitting clothing without shoes. A pressure mattress was placed under the mattress, where after all different configurations of supports were positioned on top of the pressure mattress. On top of the supports, the infants were laid in a supine position. The infants were kept still and relaxed by their caregivers. After one support configuration was measured and captured by the software, the participant was asked about the comfort of the position in the questionnaire. Then, the setup was changed to the following configuration. During the re-positioning, marks were placed to make sure the position of the head of the participant was in the same position.

3. Experimental design and model

3.1 Experimental procedure

The experiments were performed after oral informed consent was given to every participant after a written informed consent form was signed. The room temperature was maintained at 25 degrees during the entire experiment. Subjects were given detailed instructions on the procedure of the experiment. The distribution area of pressure at different parts of the body while lying supine was measured on the mattress.

A pressure sensor mat was placed under the concept mattresses and the subjects laid on the mattress (figure 11.4). The infants were awake and kept calm and relaxed during the experiment by their caretakers. The pressure mat was first calibrated according to the subject's weight and then recorded data for 2 minutes at the sampling rate of 8f/s. The examined surface was changed after lying in a supine position for 2 minutes.

This procedure was routinely performed with the following three concepts. After each concept, the participant was asked to fill in a questionnaire about the comfort level.

Reference surface

Reference surface with support in orientation 1 - 3

Reference surface with soft mattress with support in orientation 1-3

The study is undertaken by taking the comfort setup and bringing to the participants in their comfortable setting. 1.

The study is undertaken by taking the comfort setup and bringing to the participants in their comfortable setting.

The subjects are measured and weighted.

The sensor mat is placed on the mattress and switched on

The instrument was set to measure the peak readings

The subject is asked to lie on the mattress and put the head in the head area

To ensure reproducibly, the sensors from the sensor matt are positioned directly under each anatomical site as following 1) Under the head 2) Under the shoulder

3) Under the hip 4) Under the knee 5) Under the ankle

All subjects in the statistical analysis finished the test of the four different mattresses and the corresponding questionnaire.

3.2 Collected data

In each test, the maximum pressure, the average pressure, contact area, maximum pressure gradient and average pressure gradient were measured in mmHg (1mmHg= 0.13kPa = 0.013N/cm^2)

3.3 Variables and treatment

Dependent variable: Peak pressure

The maximum pressure is the most critical data that will be retrieved from this experiment. Focus is put on the pressure that occurs on the sensitive areas of the human body in relation to the different supports.

Independent variables

The independent variables are the surface area of the support. This surface area is varied through the design of different supports. For example, in Concept 1, only the head is supported while leaving out the In Concept 2, the head and the neck are supported. In Concept 3, the head, neck and body are supported with an as large as possible surface area. The configuration of the supports differs based on their compactness and comfort.

3.4 Nuisance
A nuisance in the data would be possible since the surface area of the body part with the support depends on the anatomical dimension of the infant. Each anatomical body part will have different interfaces with the support.

4. Results

In the case of the reference surface, the following maximum values of pressure were recorded in the position of the head, the neck, the back, and the buttocks. An example of the data for a single participant can be seen in Figure 11.7.

4.1 Most critical area; Infant body pressure
As can be seen, the maximum pressure is measured on the head area when lying in a supine position without any support. The pressure value is not distributed uniformly from the distribution mattress image, but a peak pressure occurs in the occipital area. The maximum recorded pressure was 55 mmHg for a contact area of 30 mm^2.
The software registers the number of active sensors, which indicates the amount of surface contact between the body and the support. From the point of view of ergonomics, the greater the number of active sensors, the greater the surface contact and hence the greater the distribution of the force.

4.2 Interface pressure / pressure distribution
The surface area of the concepts was estimated and plotted in Figure 11.8. The estimation of the surface area depends on the interface with the participant's body and the support. This estimation is made by measuring the supports and estimating the touching surface of the human body with the supports. The interface with the highest mean to peak pressure implies that this surface has the most homogeneous pressure distribution.
Furthermore, the experiment results revealed that the body pressure in younger significantly has higher maximum pressure in the head area than the older subjects due to the weight. This effect is increased in children with hydrocephalus.
Therefore, for those younger subjects, it is crucial to have head support that distributes the pressure on the head well. The three different concepts increase in surface area for the infant to lay on in a supine position. As shown in 11.8 the least pressure is measured in the concepts with the largest surface area, and the largest pressure is measured in the concept with the smallest surface area.

Maximum peak pressures pressure per concept of participant 1

	conc.0	conc.1	conc.2	conc.3
head	55	13	5	10
neck	2	3	0	0
back	12	2	6	1
buttocks	14	16	20	2
s. area	60	130	150	800
max. pressure	55	16.2	19.8	10.3

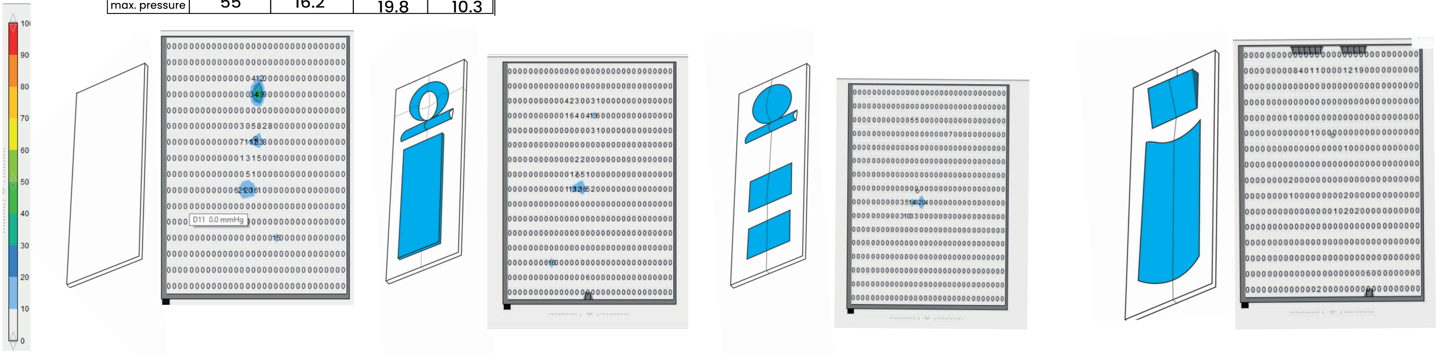


Figure 11.7 Maximum of peak pressures pressure per concept per area of participant 1

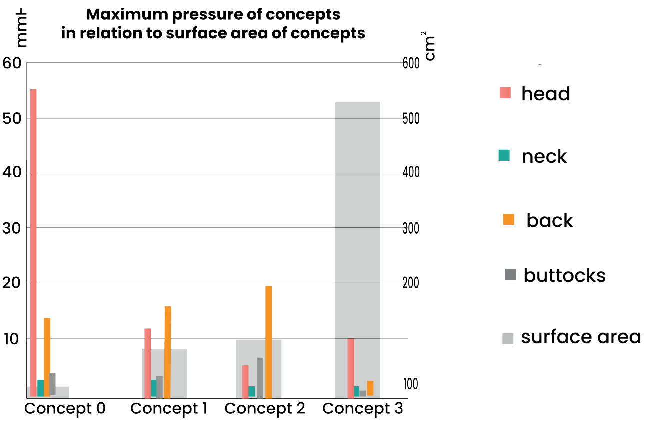


Figure 11.8 Maximum pressure per concept

Infant body pressure distribution
The four essential body parts, head, neck, back and buttocks, were allocated, and the pressure average values of all participants have been plotted in Figure 11.9. In contrast to adult participants that lay in a supine position, not the buttocks but the head area is the area that is exposed to the maximum pressure. Because infants have different body weights and spinal curves than adults, the pressure distribution differs. Therefore, each part requires additional support.

4.3 Relationship between maximum pressure and concept
When a child is lying supine on a mattress, the head is exposed to the highest pressure of 43,4 mmHg average, which is much higher than the value prescribed as comfortable 32 mmHg [111]. It is noted that once the head is elevated on a cushion, the spine and buttocks of the participant is more exposed to the maximum level of pressure of the body part.
From the adjusted concepts, the head is exposed to less pressure in concept 2, while the rest of the body is exposed to less pressure in concept 3.
From the sole data, it can be derived that concept 1 has the lowest maximum pressure for the youngest children for the head area, while concept 2 has the lowest pressure for both young and older children.

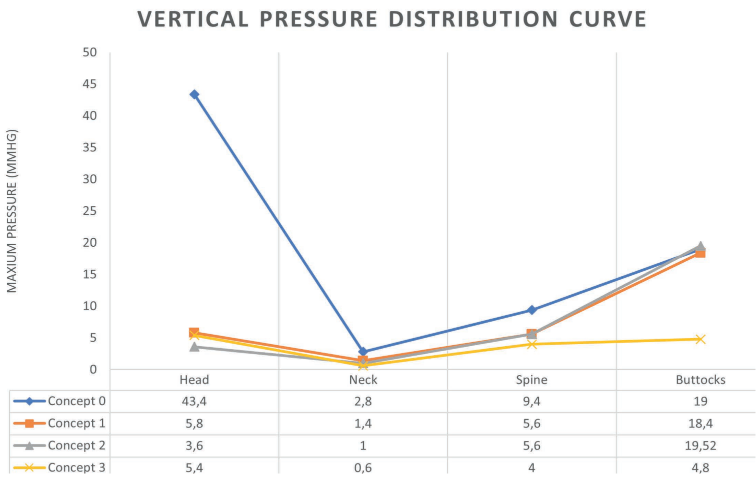


Figure 11.9 Average Peak pressure per anatomical area per concept

5. Disussion

5.1 Limitations of the study

It is argued that mattresses with a medium hardness are most comfortable in pressure distribution. Therefore, this was used during the experiment as a base; however, the supports had a different pressure hardness which is not considered when measuring the maximum pressure.

Furthermore, the data of the experiments could only be used as a comparison between the different concepts since the technology seemed outdated and was not given the exact value of the maximum pressure. No correlation could be measured due to the lack of participants and data. Due to the lack of participants, no proper correlation in the age differences related to the proper design of child restraint systems could be emphasized. The surface area was estimated and not measured, which could influence the pressure distribution and thus choose the best concept with the highest surface area. The difference in the anatomy of the target group plays a significant influence in determining the surface area.

5.2 Subjective comfort rating

The subjective comfort rating for participants between 0 and 36 months is challenging due to the inability to understand and a broad number of factors that can influence the participant's comfort level. The initial method to ask the participants to picture whether they liked it or not did work as the children were reliant on the parent and awaited the parent to respond before replying. Therefore, the method is adjusted by observing anatomical factors and the child's facial expression.

Only extreme discomfort and comfort could be observed by laughing or crying during positioning. All participants expressed extreme discomfort with lying on the headrest of concept 3. With observation, it could be determined that the chin was tilted towards the chest, which obstructs breathing and flexes the neck muscles too much (Appendix B.3). Furthermore, the headrest of Concept 3 was made from HDPE foam type 2 without any soft support.

The pressure in the buttocks was relatively low but increased as the head was elevated. However, the elevated pressure is still in a considerable range that is safe and comfortable for the patient.

Furthermore, the limitations of this study were the small sample size and lack of subjective evaluation from the infant participants. Subjective evaluation in this study was challenging since the infants of 0-4 years old were too young to understand, and multiple factors may have influenced their perception.

5.3 Interpretation of results

Ergonomic principles and dimensional constraints make the mattress need to provide the largest area of contact. The forces produced by the bodyweight will be spread over the area of contact. This results in a lower pressure per area contact of the body part with the surface, which results in a more comfortable experience.

It is necessary to highlight the comparative nature of the measurements. The results cannot be taken in interpreted solely due to the lack of sensitivity of the apparatus and the variety of factors influencing the measurements. Such as the temperature of the environment mood of the participant. Nonetheless, this study serves as a good tool for designing a mattress that needs to prevent discomfort in critical areas.

The head of an infant

The results illustrate that the most critical area is exposed to the highest pressure when no support has been applied to the head (the occipital area), contrary to research that indicated that the buttocks are the most critical part [95]. This is due to the differences in the adult anatomy and the infant anatomy in the supine position. A child's head is approximately 25% of its total body length, while in adults, this is 1/7. In addition, the spine of children up to 4 years old is more shaped as a C-shape, while adult spines are more s-shaped, with a more developed tailbone.

By having a child's head proportionately larger than the adult head (Young,1966), the higher the centre of gravity and head mass in younger children, the combination of this with weaker neck support structures may indicate that the head must be well supported. This is the case with children with hydrocephalus that have an increased head circumference and paper-thin skin with low subcutaneous fat [96].

Result: best concept for head

According to the results, the concept that exposes the infant head to the lowest maximum pressure is concept 2, as soft memory foam like a cushion. This concept shapes the head and allows the participant to lay comfortably on the cushion.

Despite concept 2 having the lowest average for the concepts, concept 1 has the lowest individual maximum pressure measurements, ranging from 1-5 mmHg with an outlier of 13 mmHg in the first measurement. Considering the requirement that the head support design must allow all head shapes and ages with comfortable support, concept 1 is the best design for this.

Result best concept for neck

The lowest measured maximum pressure occurred when the neck was supported instead of unsupported on the mattress. Therefore, support under the neck area is recommended to elevate the shoulders and support the head's weight. No significant difference was measured with the different neck supports.

Result best concept for body

Body pressure distribution is most reasonable when most body parts are supported. This is the case with concept 3, which has a slight concave circumference. The concave shape additionally helps to position the child in one position and make sure that the child cannot roll over in the bed.

5.4 Assessment of concept based on other requirements

The objective of this study was to determine the most comfortable lying position for the infant in a supine position for the LF-MRI scanner. Besides the patient's comfort, a few determinants are essential to decide. The bed will need to be manufactured, assembled, used, and cleaned in a low resource setting. Requirements determined in the last chapter are considered when choosing the best combination of products.

To determine the concept, the influencing factors should be taken into consideration.

Important to note is that the bed will need to be usable for all ages between 0-4, so despite looking at results that have good average pressure but a negative result for one group, this option will be eliminated.

Challenges

Besides the pressure challenges, the bed must fulfil several factors

1. The space of the bed, the mechanics and the
2. The stiffness of the bed
3. The cleanness
4. Done by a manufacturing production method

6. Conclusion
Important factors will be implemented in the final design:
Component requirements

The experiment has resulted in a final configuration of the best elements from the concepts for each body zone.

Head
Together with the bodily measurement and contact criteria regarding the manufacturability of and usage of the system, a choice has been made between the different concepts. The head is best supported with a doughnut-shaped cushion. For ergonomic and comfort purposes, the occipital area is not put pressure on by providing a hole on this area in the cushion. Because this head support needs to enter the head coil, which has the requirement of being as close to the head of the subject as possible, the maximum size of the cushion is 120 mm by 10 mm. This is the dimension that allows enough support with minimal volume.

Neck
This doughnut shape automatically provides support under the neck for the patient to have a comfortable neck posture during the scanning.

Body
The body is supported on a mattress that is concave shaped. The shoulders and buttocks are supported in this way. The concave shape has the additional benefit of preventing the child from moving and rolling out of its position. Additional features are required to provide the full functionality of the bed for the child.

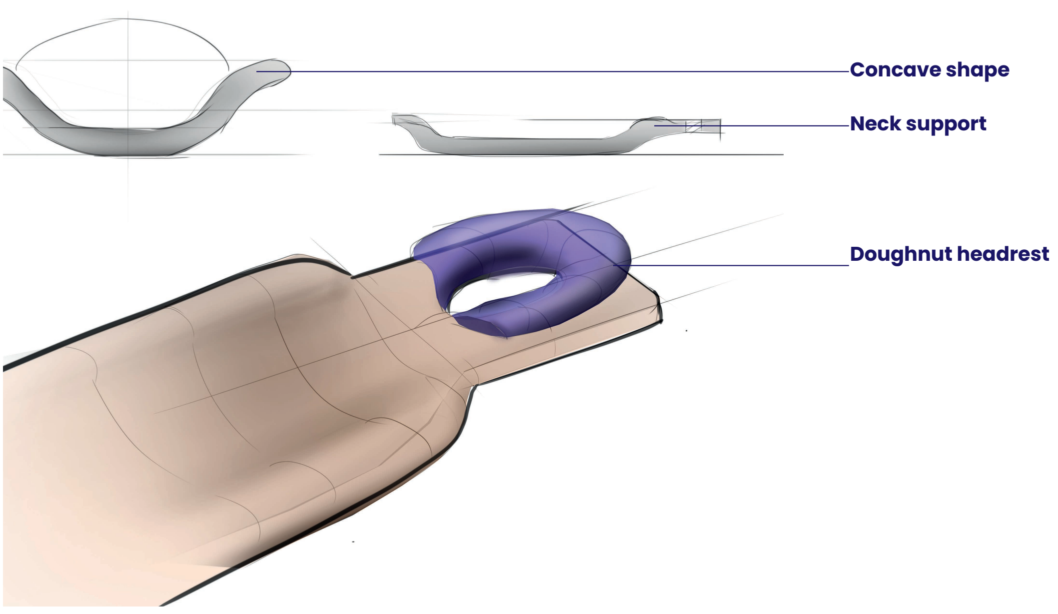


Figure 11.10 Final concept bed concept

11.3 Head immobiliser design

11.3.1 Immobilisation design requirements

Objective
What is the best way to immobilise the head considering the comfort and fixation requirements for the critical areas in the head?1. High thoracic, 2. Rigid head blocks, 3. Shaped mattress have been defined to be effective in literature for the immobilisation of heads. However, to determine the best design for the immobilisation of the head in specificity, yaw, pitch and roll for 3 mm, three concepts have been designed and tested.

Method
Through a brainstorming session (Appendix I.3) with medical students, industrial design students, and mechanical eng.students different concepts were defined. Eventually, the design was optimised on its functionality. Through testing and experiment,s the evaluation of the three different concepts is permitted. This is done by comparing the rate of immobilisation with the help of the sensors. After having investigated the ideal shape for the functionality. The concepts are optimised on their usability, volume/ mechanical stiffness, and cleanliness. In addition, a comparative evaluation was performed of the immobilisation devices. The study was performed to evaluate prospectively the ability of current spine immobilisation devices to achieve MRI scanning positioning of the cervical spine of paediatric hydrocephalus patients.
The entire design process can be found in Appendix M.4.

11.3.2 Concept design

Concept 1
The concept is based on the restriction of movement by an obstruction in the direction of movement through pressure and tension. Concept 1 is based on immobilising the rotation of the head by fixating the cervical zone and the neck through the immobilisation device, using rigid materials, straps, and two types of pillows (Figure 11.12).
Concept1 is a headrest that clamps the head of the participant between two rigid structures. This restricts translation and allows fixation of the head in the x and y planes. Straps allow the forehead to be fixed on the headrest on the sides. The benefit of such a system is that it provides maximum immobilisation by looking individually at each translation and preventing this.
The downside of this method is that the concept depends on how close the structures are to the head of the participant. Due to its universal nature and the fact that participants' heads vary, this can have a negative result for the device's functionality in terms of restricting movement in larger as smaller heads.

Concept 2
The immobilisation concept 1 is based on obstructing the movement by pressure from a soft material on the subject (Figure 11.13). In this way, the movement is obstructed in the translation in x, y, and z.
The head block is unable to rotate the head due to the restriction in movement caused by movement blocking. The immobilisation concept 2 is a headrest with soft immobilisation cushions on both sides of the head. In addition, two straps around the forehead and the chin prevent the movement and roll up and down. The head is clamped and fixed inside the headrest by the cushions.
The movement is obstructed due to the head being squeezed in the soft cushions, which minimises the ability to move the head and increases the friction between the surface and the head. The straps allow the forehead to be fixed and stabilised inside the headrest.
The benefit of such a concept is that it is a complete soft headrest that immobilises the head of the patient with minimal additional elements. The downside of this concept is that it takes much volume due to the cushions. Furthermore, the straps must avoid too much pressure on the subjects' heads.

Concept 3
Concept 3 is a rigid immobilisation system around the neck, based on fixating the cervicothoracic zone to fixate the cervical area, neck area and thorax area to prevent movement(Figure 11.14).It is based on restriction of movement by preventing the movement to occur from the source (contraction and relaxation of the neck muscles). The structure is fixated on the neck and prevents the chin from moving up and down. In addition, a completely rigid system is provided by resting on the shoulders and torso.
Due to the rigid materials that press on specific anatomical points in the product, the concept is dependent on body specific dimensions. A head immobiliser for patients from 0-4 years old needs to provide more flexibility in the dimension.

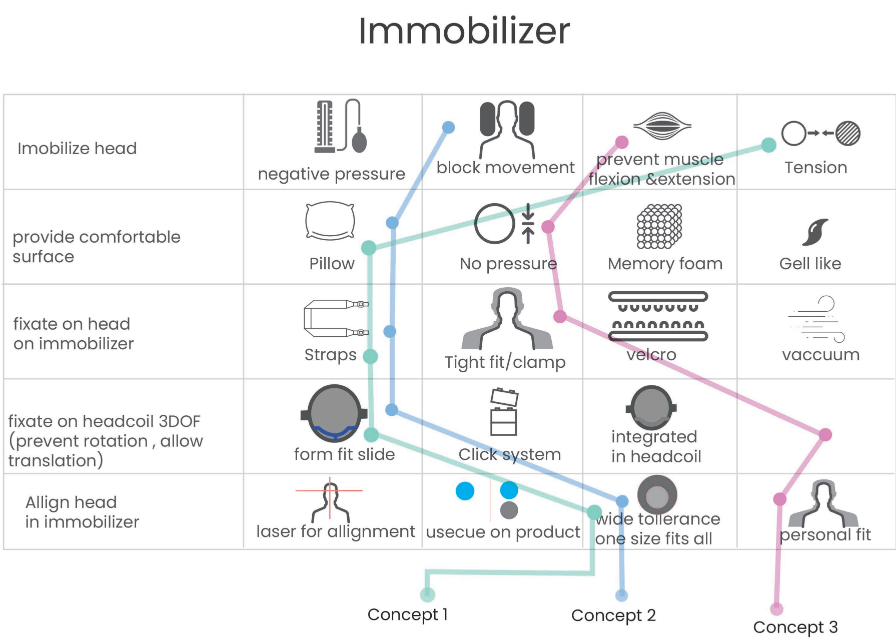


Figure 11.11 Morphological chart head immobilizer for the creation of concept 1,2,3

Component design

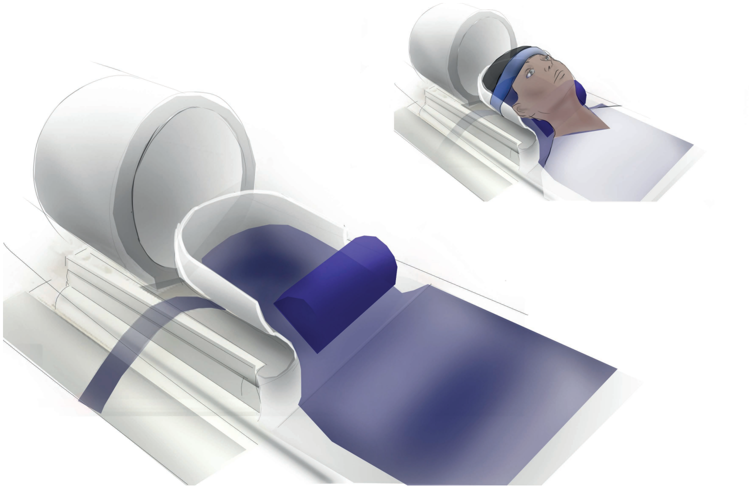


Figure 11.12 a Concept 1

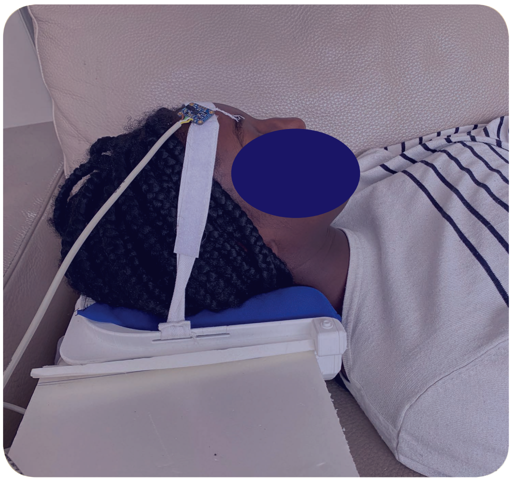


Figure 11.12 b Concept 1 Prototype

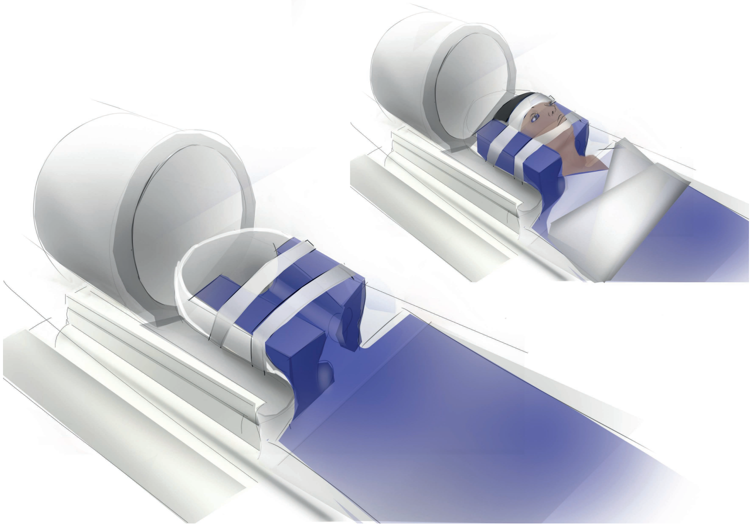


Figure 11.13 a Concept 2

Figure11.13b Concept 2 Prototype

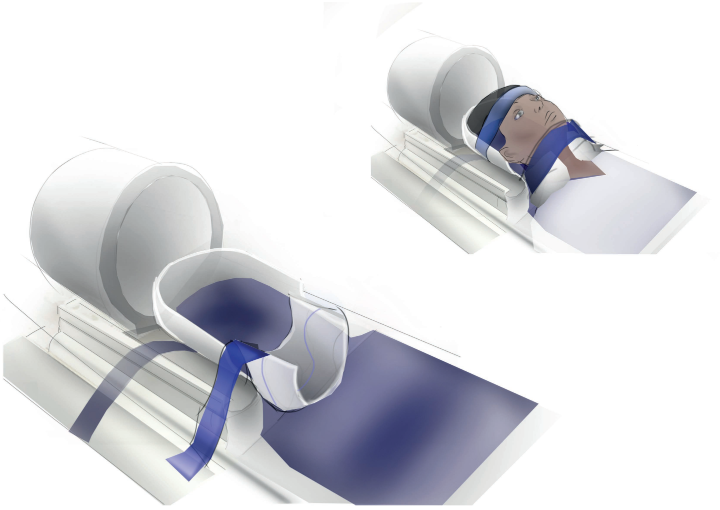


Figure 11.14 a Concept 3

Figure11.14b Concept 3 Prototype

11.4 Evaluation

An experiment has been performed to evaluate the functionality of the three designed concepts.

Experiment
This study is a biomechanical analysis of various immobilisation methods for scanning the head of a child with hydrocephalus.

1. Introduction

1.1 Research topic
The study's main objective is to evaluate the different immobilisation methods through the designed immobilisation devices, which result in the maximum immobilisation of the head. Furthermore, which immobilisation method provides the best head immobilisation that restricts the movements, pitch, roll and yaw.

2.2 Approach
A motion analysis is performed in previous studies to demonstrate the immobilisation, which is achieved by the device. The results of the different devices are compared to each other to define the best immobilisation system based on the restricted movements. The variable measurement of this experiment is the ability to perform movements from the task (pitch, roll, yawn) while being fixed inside the device. The results of the three devices will be compared to each other to determine the best immobilisation method. The devices are designed based on the fixation of specific anatomical points and the use of flexible or rigid materials. Eventually, after assessing the functionality of the immobilisation, the design is evaluated on the user and system requirements, such as operation, installation, compactness, and comfort.

2. Materials and methods
2.1 Participants
The immobilisation device will be used for children with hydrocephalus of 0-4 years old. Howe er, the concept cannot be tested with children due to the inability to follow tasks. Therefore, participants aged 15 -25 have been recruited to participate in the experiment. The experiment's aim can be tested with adult heads capable of assessing the ability to move the head and can follow up tasks such as yaw, pitch, and roll the head. These have been prototyped in three different concepts (1,2,3).

2.2 Apparatus
The apparatus is a wired absolute orientation sensor with 9DOF (ADAfruits BNO055), which can detect the 3D orientation in space. It includes an accelerometer, gyroscope, and magnetometer for the needed accuracy. The sensor is attached to an Arduino Uno, which is connected to the code on the laptop.
The needed output data from the sensor is as following: Absolute Orientation (Euler Vector, 100Hz) Three axis orientation data based on a 360° sphere The used data output is the absolute orientation. The three concepts are fixated on the surface.

2.3 Experimental setup
An experimental setup can be seen in Figure 11.15. The participant is placed on a hospital bed with a fixed position for the concept on the head-end. The concepts are fixed on the concept rest to ensure the minimal movement of the headrest.

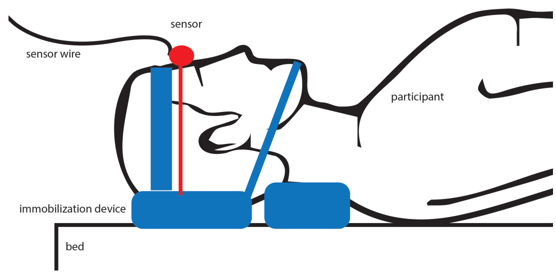


Figure 11.15 Experimental setup

3. Method
3.1 Variables
Dependent variable
The most critical data that will be retrieved from this experiment is the absolute orientation of the forehead during the task concerning the different immobilisation techniques. Eventually, the displacement is calculated from this data.

3.2 Nuisance
The expected nuisance can be a result of: orientation or equipment.
Orientation
Due to the variability of the sensor's starting position (on the participant's forehead), nuisance can occur. By calibrating the sensor for each participant and by providing a stable and rigid concept setup where each participant is lying supine on an assigned position on the same hospital bed with the concept fixed on its position, the variability can be minimised.
The concept is made to withstand muscle contraction and flexion of the neck, resulting in pitch, yaw, and roll under normal circumstances without exerting extra force. Therefore, the stiffness of the concept is made based on 5N. However, the range of participants is between 15 and 25 years old, male and female. So the adult may be able to rotate their head easier, which may result in a displacement of the head compared to a younger participant.
Equipment
The sensitivity of the sensor might be biased since the participant has to move according to its own "normal" speed, which might be different for each participant.
Fitting of Concept on participant
The ability of the participant to perform the task depends on the fitting of the concept on its head. A well-fitted concept might perform better in immobilising the head than a concept that fits loose. Therefore, three different sizes were provided for the most rigid concept (concept 3) based on the neck lengths (S,M,L).

3.3 Experimental design and model
A series of measurements was designed to retrieve data on the immobilisation ability of different immobilisation techniques. The retrieved data come from the absolute orientation measurements, which are for the displacement of the head of the subject. The condition matrix can be seen in Figure 11.16.

Condition matrix

	Task:yaw	Task: roll	Task: pitch
Concept A	EC 1.1	EC 1.2	EC 1.3
Concept B	EC 2.1	EC 2.2	EC 2.3
Concept C	EC 3.1	EC 3.2	EC 3.3

Figure 11.16 Condition matrix

3.4 Experimental protocol
The IMU sensor was first calibrated prior to measurement. This procedure was routinely performed with the designed three concepts.
The concept is fixed on the bed with a holder to disable the x, y, and z-axis translation. After this step, the participant is lateral to its head on the immobilisation device and installed as instructed.
Finally, the participant lies supine on a hospital bed with the immobilisation system (A, B, C) on its head. Then the tasks are performed, and measurements are carried out as described before.
The participants were positioned on the immobilisation device, which used an accelerometer that provided the movement's measurements.
After installation of the head, the sensor is placed on the head of the participant in such a way that the electronics are not hindering the movement or measurements.
After installation, the participant is asked to perform motion tasks at the same speed (approximately 45 degrees/second). The immobilisation device should be able to restrict this movement.
The speed of the head is controlled by facilitating a laser light with a velocity of 45 degrees/second, which had to be followed by the participant's head.

1. Movement sidewards (rotation along the z-axis)(yaw right and yaw left)
2. Movement of chin downwards (rotation along the x-axis) (pitch down and pitch up)
3. Movement chin sidewards (rotation along the y-axis) (roll right and roll up)

The location of the anatomical point on the sensor is compared to the location during the task. The net displacement from the isocentre of the participants heads relative to its position after and during the task is determined. Through the digital measurement of the accelerometer, 9-DOF can be determined along the isocentre.

The used techniques to assess the motion of the head in those studies range from real-time simulation with laser alignment in an MRI scanner [98], manual optical assessment based on high definition cameras with the help of a grid and accelerometers [99]. From the determined assessment techniques, the simulation method and a motion sensor are the most accurate to assess the motion of the head in an immobilisation device. Due to the inability to simulate a child with hydrocephalus's exact behaviour and motion, the participants are provided with strict tasks and restricted in other movements than the head. The procedure setup was designed to provide the same simulated environment for each participant by using marks on anatomical points and positioning marks on the apparatus. The anatomical points were determined for each participant relative to the immobilisation device as isocentre.

Displacement and rotation in the x, y and z-axis are measured by using an accelerometer with a sensitivity of 1mm, which is attached to the cranium of the participant. This anatomical point is the area in the device which is essential to stay immobilised. Any other movement in any other limb will be measured with the accelerometer.
The immobilisation of the three different concepts is evaluated by determining the ability to perform the assigned tasks through flexion, extension, rotation, and lateral bending of the cs. This is evaluated by providing endpoints at the start and beginning of the movement, recorded by a wired sensor 9-DOF IMU BNO055, attached on a breadboard and Arduino. The IMU sensor is attached to the forehead of the participant. The Arduino synchronises the data every microsecond to measure the movement while the participant is lying inside the concept.

3.5 Outcome measures
The measurements are the active range of motion (AROM) of the flexion(pith), lateral flexion(roll), and rotation(yaw) of the head. This movement was recorded with an Adafruit BNO055 Absolute Orientation Sensor, capable of sensing 9-DOF of absolute 3D orientation, linear acceleration, and 3D angular velocity. One sensor was applied to the forehead of the participant. From those locations, a net displacement of the isocentre in the patient relative to its position at the initial simulation was determined (change in the average coordinates of the 5-6 anatomical points at any week relative to the first). Although this would have detected a net displacement of the patient, rotation of patient position alone about the original centre would have been noticed.

3.6 Data processing and analysing
Experiment
The values of the absolute orientation during the tasks are read out. Since only the orientation is measured with the IMU sensor in three degrees of freedom, this does not reveal the displacement. The displacement is calculated by subtracting the maximum-minimum measurement.
During movement, three different phases can be distinguished: the standing phase, the movement, the acceleration, and the stopping of the movement. For functional imaging, the total displacement is most important, so the total displacement of each task is calculated through the maximum and minimum value of the absolute orientation points relative to their original locations and (b) determination of the displacement of the centre of mass of all anatomic points for each patient relative to the centre of mass on each patient's original film.
From all measurements, the maximum displacement per concept is the most essential. All data is processed by using MATLAB, Excel and Python.

Table of contstants	Constants
Number of concepts	3
Time of task	2 seconds
Number of tasks	6

Table 11.17 Table of constants

Component design

Statistics (data processing and analysing)

The data is recorded and pre-processed by filtering out the noise. The maximum displacement from each concept and participant is derived and plotted in Figure 11.18 During movement, three different phases can be distinguished: the standing phase, the movement, acceleration, and the stopping of the movement. However, for qualitative imaging, the total displacement is most important, so the total displacement of each task is calculated through the maximum and minimum values of the absolute orientation. The functional requirement stated that the movement of the head should not be more than 3 mm. However, the measured data from the sensor is Degree in Euler. Therefore, to evaluate the data, the amount of rotation that should not be able to be exceeded is calculated, which is 1.7 degrees maximum not to overcome the restriction of 3 mm.

4. Results

Data ranges from 0,62 minimum to 40 degrees maximum in Euler angle measurement(angle).

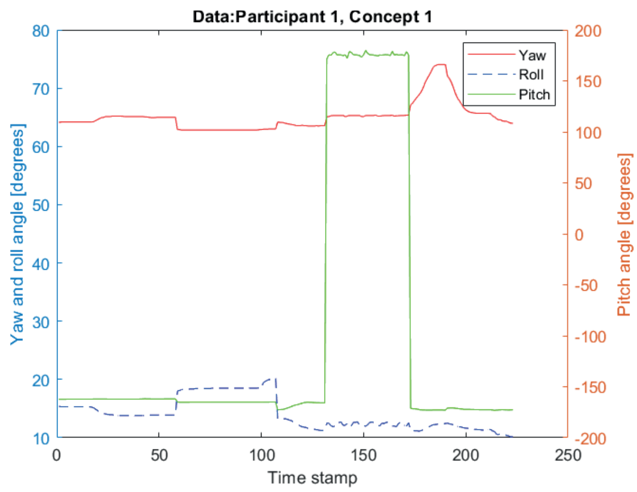


Figure 11.18 raw data from one participant

Comparison functional immobilization

(average) Maximum displacement per concept

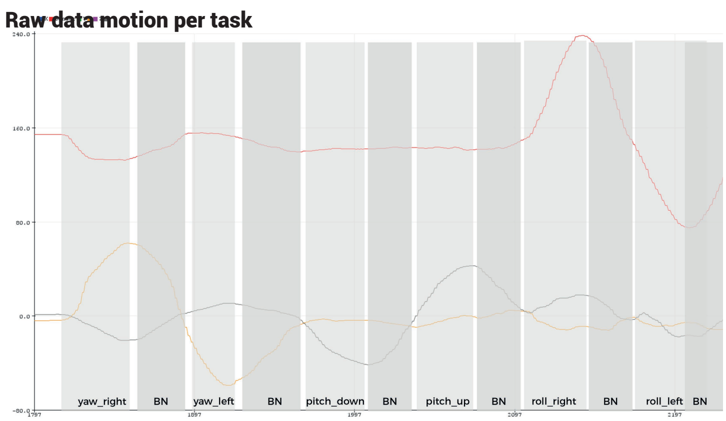


Figure 11.19 Euler orientation of movement in x,y,z direction

Figure 11.19 illustrates the Euler orientation of a random participant while performing the tasks. The measured data from the sensor indicate that yellow = yaw, grey = pitch, and red = roll. During the movement of pitch, yaw, and roll, the head does not solely move around one axis but also slightly around another axis. However, only the measurement from the task will be derived during analysing and evaluation for this experiment. The lighter grey columns illustrate the measurement per task, yaw, pitch, and roll, while the dark grey column illustrates the task where the participant turns back to the start point (Back to Normal).

Movement difference

As explained in the "data analysis" section, the maximum difference in movement is the essential data from the measurements since the requirement is to minimise the movement up to 3 mm as much as possible during one task.

Immobilization device vs. no immobilization device

Difference in use of an immobilization concept and no immobilization concept Without the use of an immobilization device, the participant can move its head freely. As can be seen in Figure 11.21, all devices restrict the movement of the participant.

	concept 1	concept 2	concept 3	No device
yaw	3.36	3.30	3.50	13.81
roll	4.20	2.38	4.71	4.90
pitch	15.89	6.19	9.35	25.37

Table 11.21 maximum ROM in degrees per concept per task

The most immobilization

As is illustrated in table4 the concepts are beneficial in restricting one particular movement compared to the other concepts. The immobilization devices from concept 1-3 improve the fixation of the head with by a factor 1,5 times to 4 times.

In case of the different tasks, yaw, pitch roll the concepts all perform differently for immobilising on specific movements.

Pitch

From all tasks, the pitch movement allows the largest motion. As shown in Table 11.22, the pitch movement is best restricted by concept 2, which allows a rotation of approximately 6.19 degrees. The feature that allows concept 2 to restrict the pitch movement the most is the double strap around the forehead (to prevent pitch down) and around the chin (to prevent pitch up).

Yaw

Furthermore, the maximum motion for yaw is approximately the same for all concepts; however, concept 2 allows more rotation restriction by 3.3 degrees.

Roll

The movement roll is a movement that has the smallest range of movement of 4,9 degrees (No immobilisation device) and 2,38 degrees (concept 2). Additional application of cushions reduced the motion by a factor of 2 by using a pillow under the neck and an additional strap. This limited the lateral bending of the neck.

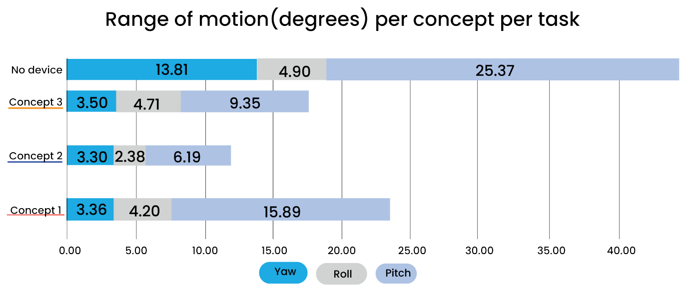


Figure11.22 maximum range of motion per concept per task

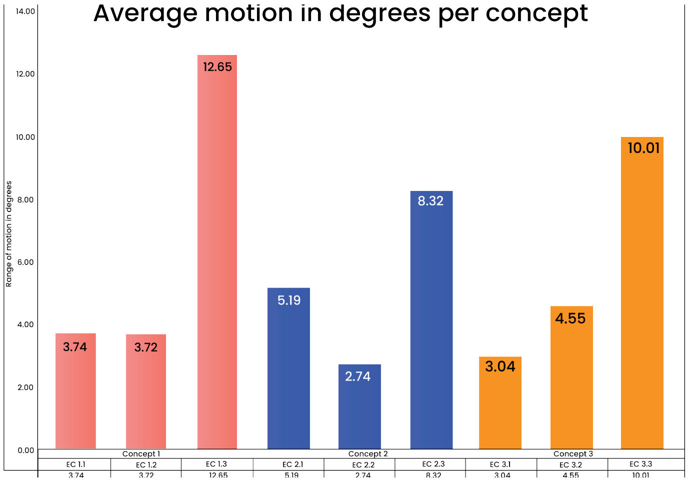


Figure 11.23 maximum range of motion per concept per task

5. Discussion

5.1 Evaluation

Best immobilization system

To assess which concept is best to use, not only the functional requirements need to be taken into consideration. Furthermore, the user and LMIC specific requirements influence the successful implementation and use of the product.

Functional requirement

The concept's functionality is assessed by performing a task by the user and assessing the movement per direction. To analyse various immobilisation techniques for patient scanning , the motion of participants was recorded. The displacement for each concept was calculated for each participant. The immobilisation device should not allow movement of the head of more than 3 mm.

No immobilization device vs. immobilization device

Each participant was asked to perform a movement task without the immobilisation device and the three concepts of the immobilisation device. This is done to compare the functionality and the ability to immobilise. As can be seen in the results, the immobilisation device helps immobilise the head compared to not having an immobilisation device significantly.

Per concept

Concept 1 restricts the yaw movement in both directions but is less effective for rolling up and down because nothing is restructuring this movement. Furthermore, the roll movement in both directions is restricted due to the cushions that press on the head.

Concept 2

Concept 2 performs well to prevent roll up and down compared to the other concepts. This is due to the band around the chin that restricts the movement. Finally, Concept 2 is performing best in terms of restricting the overall movement of the participant compared to all other techniques. Using a chin strap and a forehead strap was more effective in movement restriction than the concept without head straps.

Concept 3

Concept 3 is based on thoracic fixation. A thoracic fixation was most effective when immobilising the motion; pitch. This feature was most effective when restricting motion, such as lateral bending. However, this concept was highly person and dimension-dependent for the tight fit of the product in order to function as envisioned. Therefore, a thoracic fixation is only adequate if it conforms to the patient's dimension by making it custom made or adaptable.

5.2 Final functional evaluation

Best concept for yaw

Concept 1 prevents the movement of yaw, right and left, due to the strap on top of the head that prevents the head from moving sideways. To prevent yaw concept 1 works as well as concept 2 due to the straps. In concept 3, this movement is only prevented because the rigid material prevents translation and rotation.

Best concept to immobilize pitch

Concept 2 functionaries are best to prevent pitch compared to the other concepts since the straps around the chin prevent the chin from tilting up and down.

Best concept to immobilize roll

To prevent roll, concept 3 provides the best support. However, if it is not correctly positioned, which frequently happens when the device's size does not conform to the head size, the immobilisation function does not work at all.

Best overall concept

The concept that functions best to immobilise movement and thus immobilise for translation, pitch, yaw, and roll is the concept that fits best on the head of all participants and prevents yaw and pitch with straps. This is concept 1 with additional chin straps to prevent pitch correctly.

5.3 Assess user requirements

Besides the fact that the immobilisation device must function as required, the device must equally conform to the user and LMIC requirements to be usable and implementable in the entire bed system of the LF MRI scanner. So, only a functional assessment is not sufficient to evaluate which concept will be the best. Therefore, the concept is assessed based on the following requirements: The immobilisation device will be integrated into the bed assembly and is the product that the MRI technician is interacting with the most frequently. This device will enter the head coil that needs to be as close to the subject as possible.

1. The device must be as compact as possible

The device must not be larger than 15 cm X 25 cm X 20 cm for it to fit inside the head coil. The device must be minimal in weight.

2. The device must be easy to use

Since the MRI technician is the person that needs to place the head of the patient in the immobilisation device and align the head correctly, this procedure must not take too many actions and must be as intuitive as possible The device must be directly understandable.

3. The device must be usable for different sizes of patients with hydrocephalus

Patients with hydrocephalus have a large range of head size.

4. The device must be comfortable for the patient

Since the main reason for movement is physical discomfort and pain, the immobilisation device must be as comfortable as possible Since the device must hold the fragile head of a patient with hydrocephalus, the device must not press on specific areas.

5. Material

Locally producible or manufactured in sub-Saharan Africa No magnetic materials

6. Cost effective

The purchase, maintenance and repair of the component must be as low as possible

Assessment

2. During the experiment, the time needed for correct alignment

and positioning of the patients head has been timed.
3. The device is placed on participants with different head sizes
4. The participants were asked in a formative assessment what they found about the comfort level of the device
5. The used materials were assessed on whether they could be locally procured, produced, or replaced by a locally available material in Uganda.
6. The production cost is estimated

Harris profile of 3 concepts

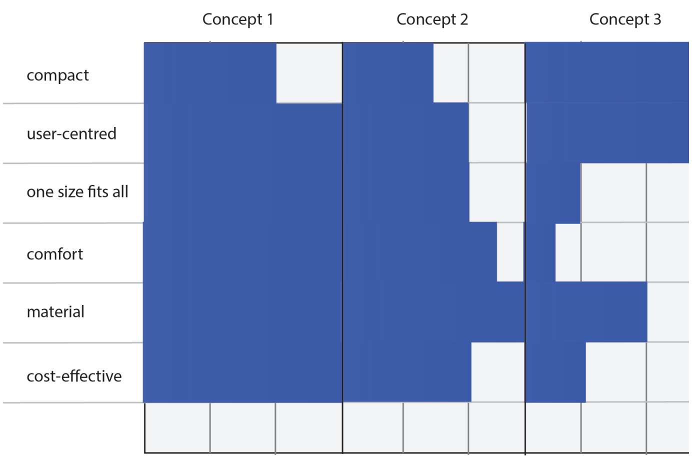


Figure 11.24 Assessment based on Harris Profile

Compact
Weight and size are important for the device's ability to fin inside the head coil. The most sizable concepts are respectively concept 2 (25 cm 15 cm 20 cm), concept 1(20 cm 15 cm 15 cm), and concept 3(11 cm 20 cm 9 cm). Concept 3 has had an optimisation in volume and stiffness and is thus as small as possible. However, since concepts 2 and 3 use flexible material, these concepts can be made smaller.

Intuitive design
The concepts with the minor attachments are the ones that are understood best. Concepts 1 and 3are designed as a fixed shape that needs to be encompassed by the subject. Once the orientation of Concept 3 is understood. It is straightforward to understand how to place the device on the neck of the patient. Conversely, concept 2 needs to be secured on the patient's head with straps and wedged in the device's borders.

Usable for different patients
Fit for all
The ability for the MRI technician to understand and use the product easy is likewise considered within the whole proves of scanning multiple patients a day. The head of a child with hydrocephalus can reveal different types of malformations, dimensions, and shapes. Concept 3 does not score too well on its ability to be fitted for a wide range of head circumferences. The concept is highly dimension dependent. The ability to make the device adaptable exists. However, this elongated the time and effort of installation for the MRI technician.

Comfort
According to the test results, the participants have assessed Concept 1 as the most comfortable due to the soft cushions. The best functioning immobilisation device is a combination of Concept 1 and Concept 2, where the cushions provide a tight-fitting, and the straps around the forehead and chin prevent the movement from pitch and yaw. Concept 3 was tested as the least favourite due to the rigid material that pressed on areas on the head with low subcutaneous fat. Despite this being the most effective way to immobilise and fixate the subject, this is again the most uncomfortable method. Adding a softer material around this will decrease the device's functionality due to play.

Material
Since the MRI system does not allow ferromagnetic materials inside the bore, the design of such an immobilisation device is restricted to plastics textiles, and Regarding the costs of the LF MRI scanner, the materials are chosen to be under 10 € per 1 cm2 volume. Therefore, 3D printing was the best option for concept 3. Furthermore, the cleanability can be better attained with the rigid material of Concept 3 than the soft materials from concepts 1 and 2. The choice of plastic material was made from evaluating the desired mechanical properties (right stiffness), the avoidance of ferromagnetic materials and the available materials for manufacturing in LMICs. Comfort, ease of use, availability, cleanability were essential criteria.

Overall evaluation
An overall assessment can be made by considering the functional and other requirements. Concept 1 is best in the overall assessment.

6. Conclusion
An overall assessment can be made by considering the functional and other requirements. Concept 1 is best in the overall assessment. In this study, various concepts of immobilisation techniques to immobilise the head during patient scanning in the LF MRI scanner while performing natural neck movements have been evaluated with the help of head motion with an IMU sensor. The results of the patient movement analysis indicate that an immobilisation device can effectively use to restrain the motion of the head. Furthermore, the results suggest that head motion can be most effectively immobilised by combining Concept 1 and concept 2. This results in double straps that fixate the mandible and frontal area and head blocks.

Component requirements
Factors that will be implemented in the final design

A combination of head blocks with soft cushions enables tightening of the blocks around the head to be strapped on the forehead and the yaw. The results of this proof of principle study demonstrate that adding a rigid collar to head blocks does not provide any extra immobilisation of the cervical spine and is therefore considered unnecessary. Furthermore, this study demonstrated that a rigid collar reduces the ability to open the mouth and clear the airway.

Given 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 immobilisation), the combination of a rigid collar and head blocks should be reconsidered.

Immobilization is mostly performed with a spine board. However It is not applicable for the implementation in the Low Field MRI scanner, due to the major downside of it being too robust, other downsides such as restriction in respiration, pressure ulcers, pain, and discomfort occur[99]. Therefore, the head will be supported through a headrest that enters in the head coil and is fixated on the bed system assembly.

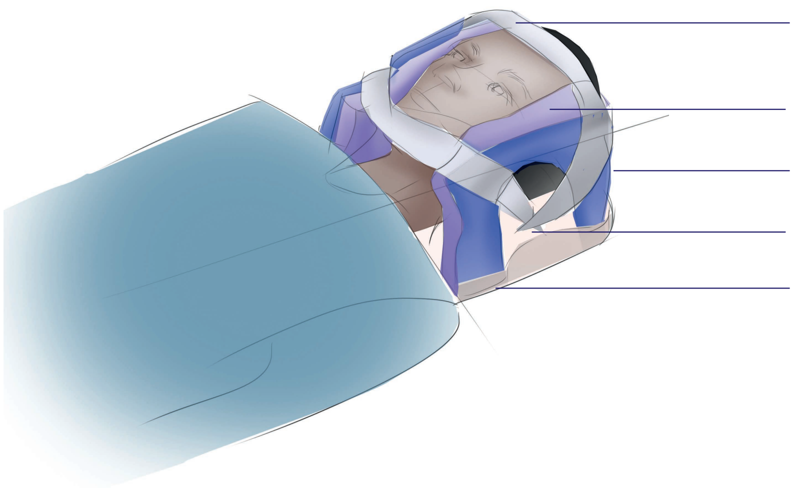


Figure 11.25 concept design of head immobilizer

Component design

11.5 Patient ergonomics

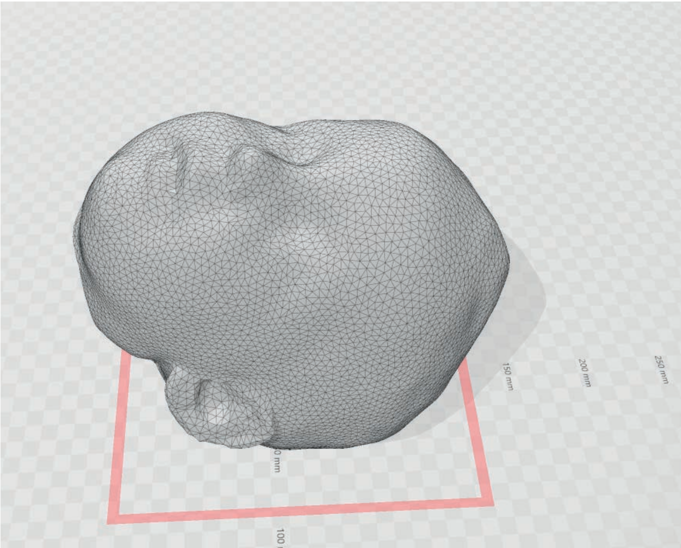


Figure 11.25 3D modelled head of child with hydrocephalus (DINED, goto 2019)

Figure 11.26 3D printed head of child with hydrocephalus P50 and P95 (DINED, goto 2019)

Head shape & dimension analysis
The head of the infant with hydrocephalus is the most fragile part of the body, but also the part that requires a lot of care for adequate imaging. When applying multiple components on the patients head (such as a head immobiliser and head coil), the ergonomy of the patients head is increasingly important.

Through interviews, CT scan analysis and 3D analysis, the characteristics of the head of a patient with hydrocephalus has been defined (Chapter 5).
To define the dimensions of the head coil, the head immobiliser and the head cushions, an additional analysis has been done which defined the more important characteristics of the head shape. Dimensions of the CT scan data from the Cure hospital were analysed and a 3D model of the P5, P50 and P95 of the patients head were computed and 3D printed.

Due to the widened parietal area of patients with hydrocephalus, this part has been made wider in design of the head coil shapes. Additionally, the pressure points of the head immobiliser are likewise on the parietal area. Through application of cushions on this area, the rigid part of the head coil is not pressed on this area. The circular head coil is redesigned into a oval head coil with widened upper and lower parts (figure 11.27)

11.6 Head coil design

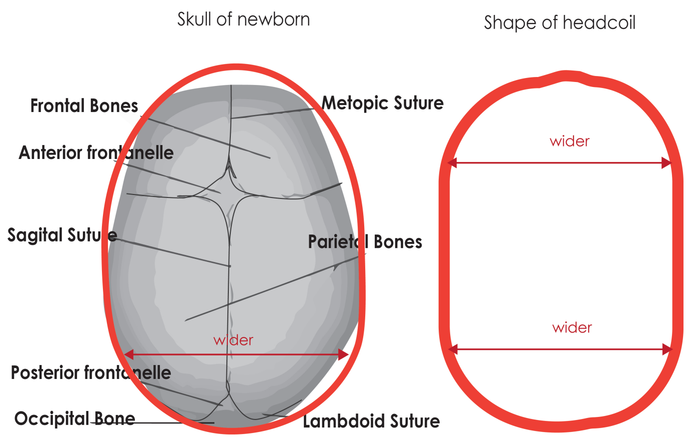


Figure 11.27 top view of head shape of patient with hc, new coil shape

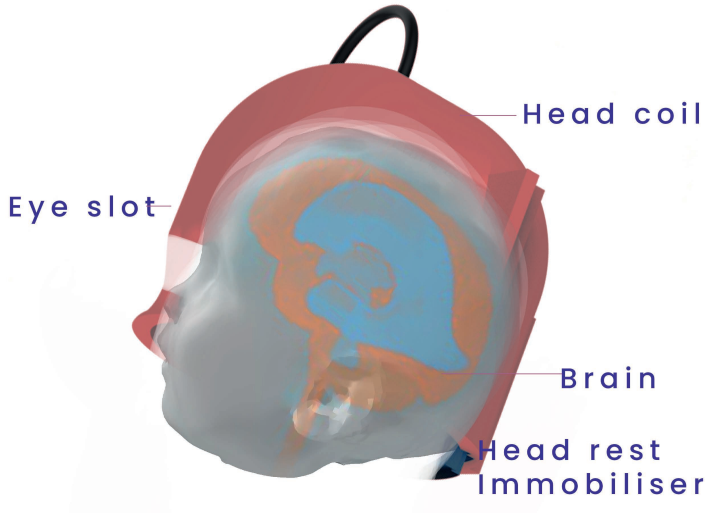


Figure 11.28 head coil over important areas of brain

The head coil is not part of the bed system assembly, but the magnet system and is therefore not in the scope of the design. However, the bed system and the head coil are codependent and greatly influence each other. Therefore the influence of the current bed system assembly on the head coil is discussed in this chapter. Only the main design requirements are discussed in a conceptual model. The electronics and material specification are left out of scope.

1 Functionality
For the imaging of the brain, a head coil is used as a radio-frequency coil. The coil is used to transmit and receive RF pulses that tilts the proton out of alignment and receives the signal that the proton emit. A large solenoid with copper wires around the circumference of the cranium is used to create a magnetic field. The solenoid was segmented by using non-magnetic capacitors to avoid self-resonance.

21.2. Requirements
The head coil is placed concentrically within the bore of the magnet. It is important for the coil to be as close to the patients head as possible to provide the best quality image.
The most critical requirements that follow from the functional requirement and the ergonomic requirement are the following:

Size
Due to the broad discrepancy in the dimensions of the heads of children with hydrocephalus, it would not be possible to make one size of the head coil fit for all. Therefore, 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.

Functionality
The head coil must be at proximity of the cranium The head coil must be attached to the Magnet system The copper wired must be at an even distance from each other

Placement
The head coil must allow to cover the full areas of the brain, from the frontal lobe to the cerebellum. The head coil must allow the patient to look through the head coil to see the mirror The head coil must be able to easily be replaced. The head coil must be able to house the headrest The head coil must be able to be cleaned The head coil must be connected to the magnet A neutral posture while the head is being immobilized inside the head coil must be facilitated. The immobilization must be inside the head coil The head coil must be placed in the isocentre of the magnet (250 mm inside the bore) The head coil must be of an elliptical shape to be able to be at proximity of the head. No active cooling for the gradient coils was used.

Use
The head coil must be able to be replaced for use of circumferences The head coil must be able to be connected to the bed system assembly The head coil must be able to be translated from outside the bore to inside the bore.

Placement
The head coil must cover the entire brain, which means that it needs to overlap over the eyes and on the occipital area. The head coil must allow the patient to look through the head coil to see the mirror The head coil must be able to replaced easily.

Objective
The main objective for the design of the head coil was to provide a head coil where the redesign of the head immobilizer and bed can be connected to the magnet system through the head coil. The design and improvement of the head coil does not fall within the scope. Therefore, only advises that follow from the ergonomic and comfort research are implemented in the current design of the head coil. Further implementations and iterations have been let behind consideration due to the strict requirements.

Method
Design process
The design process of the head coil was in close collaboration with the technical team of the LUMC through co-creation sessions due to the strict functional requirements and complexity of the head coil. At each phase mock-ups were created to define the correct dimensions, shape, and connections specifically for an infant with a head with hydrocephalus. Anatomical 3D models were used for evaluation.

Concept development

→

12. Concept development

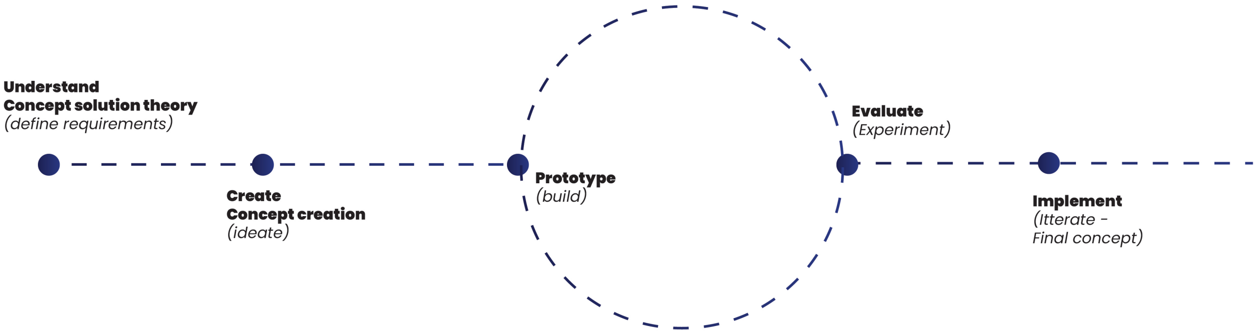


Figure 12.1 Concept design process

Introduction

Background
The chapter concept development concludes the concept research and presents the final concept in three phases (Figure 12.2). Firstly, The development chapter discusses the concept development of the entire MRI scanner (1). This part addresses the challenges concerning minimal space and the most efficient product layout. Secondly, the individual components (2) that address the materialisation of the main challenges –immobilising the patient through maximising comfort- are presented. Finally, all separate components are integrated inside the defined product layout (1). The conceptualisation phase follows a process where the challenge is explained through background, the design method is explained, the concept(s) is presented, whereas the functionality of this process is evaluated through a performance experiment. The concept is optimised for ergonomics, usability, and materialisation through several mock-up and prototype reactions. This entire process can be seen in Appendix I-P.

Objective
The aim is to design an MRI scanner that increases the availability of brain imaging in low resource settings by providing a cost-effective solution. Furthermore, the MRI system must allow multiple use cycles in the challenging context.
Therefore, the first objective is to define the concept of the MRI. Eventually, the parts of the MRI scanner are defined and conceptualised. Furthermore the design research is implemented inside the concept design which answers the following questions
2. How can the researched fundamentals for comfort design be implemented in the low field MRI scanner?
3.How can the researched fundamentals for head immobilisation be implemented in the low field MRI scanner?
How can the optimised parts be integrated into a full MRI scanner without compromising the image quality by considering the MRI scanner's technical requirements?
All questions have considered the design drivers and requirements for context, human comfort and MRI compatibility.

Method
The used design method for the conceptualisation phase includes various forms of stakeholder involvement to broaden the perspective, check the possibilities of ideas, and validate a concept's desirability, viability, and feasibility.

The full MRI scanner was first designed as an envisioned concept, which would serve this goal. The question on how this comfort will be achieved, how this workload will be minimised and how the long-term durability of the MRI scanner will be guaranteed is visible in the design of the specific parts.

1. These parts have been designed through brainstorming organised co-creation sessions with medical, mechanical, and design students and professionals. 2. The parts have been conceptualised and tested through experiments with participants. By making a mock-up of the concept, the concept's functionality could be tested and validated through experiments with participants. 3. The results from the experiments serve as the foundation for the conceptualisation of the idea. 4. Eventually, the concept parts have been put together into an embodiment design and prototype of an entire MRI system.
The visual (Figure 12.1) is reoccurring to guide through the concept.

Function analysis

The focus within the conceptualisation is to optimise the comfortable experience of the patient and MRI technician. This is done by designing for the part that has the most interaction with the body. This is by focusing on the immobilisation and the bed system. Within the bed system, several parts can be defined, which are;

- Bed
- Mattress holder
- Mattress
- Head immobiliser
- Swaddle blanket
- Double mirror
- Sliding mechanism
- Framework

Figure 12.2 illustrates an overview of the MRI system and components from the bed assembly based on the functional analsysis. As can be seen, the swaddle blanket is part of the electronics as well as part of the bed assembly.

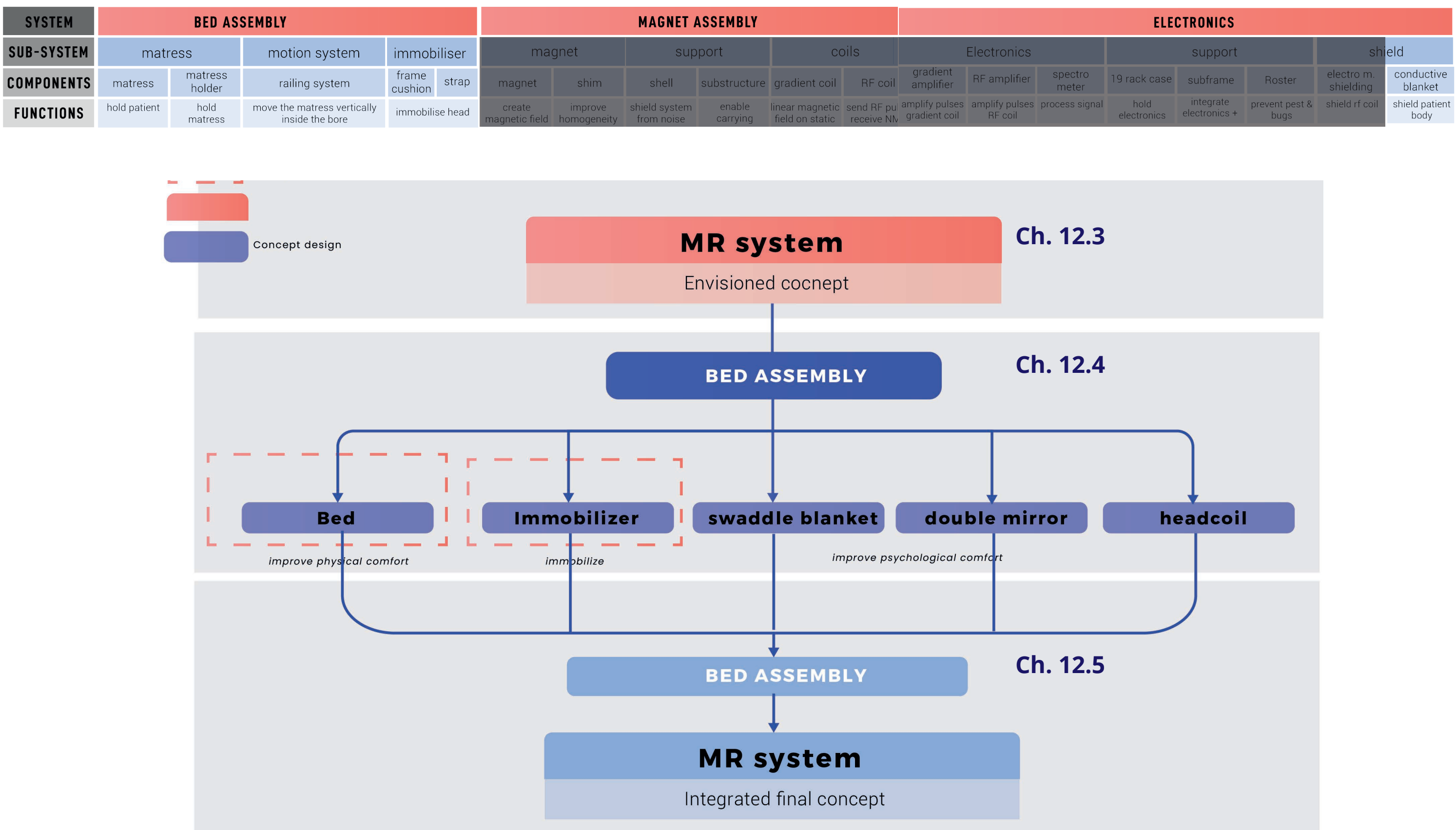


Figure 12.2 Concept development phases and function analysis

12.1 Concept presentation

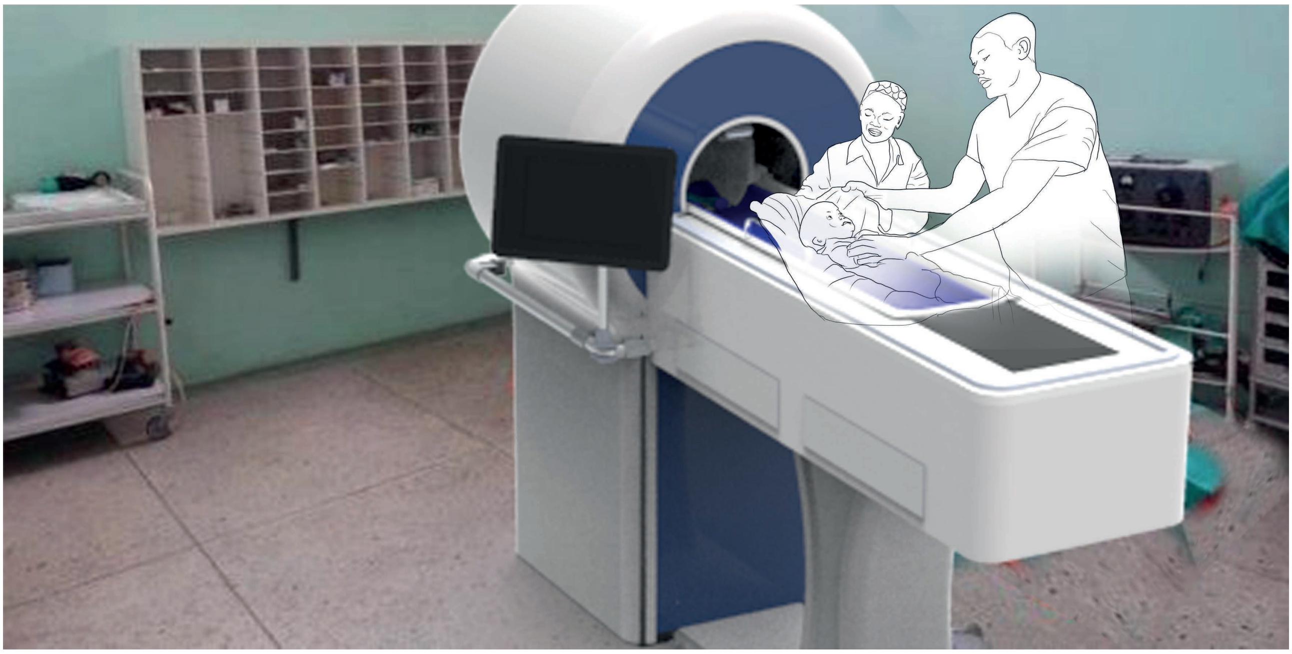
The HydroCare

The “HydroCare” was designed to meet to following criteria:

Provide brain imaging for patients head with hydrocephalus with a head circumference of 50-60 cm, safely and comfortably support patients up to 20 kg and 1.20m in a supine position with not more than 3 mm of deflection. Minimal torque forces must occur on the system. The bed system must ensure the patient is safely restrained from motion with a maximum of 3 mm in 6 DOF. During the immobilisation, no strain must occur on the neck or spine.

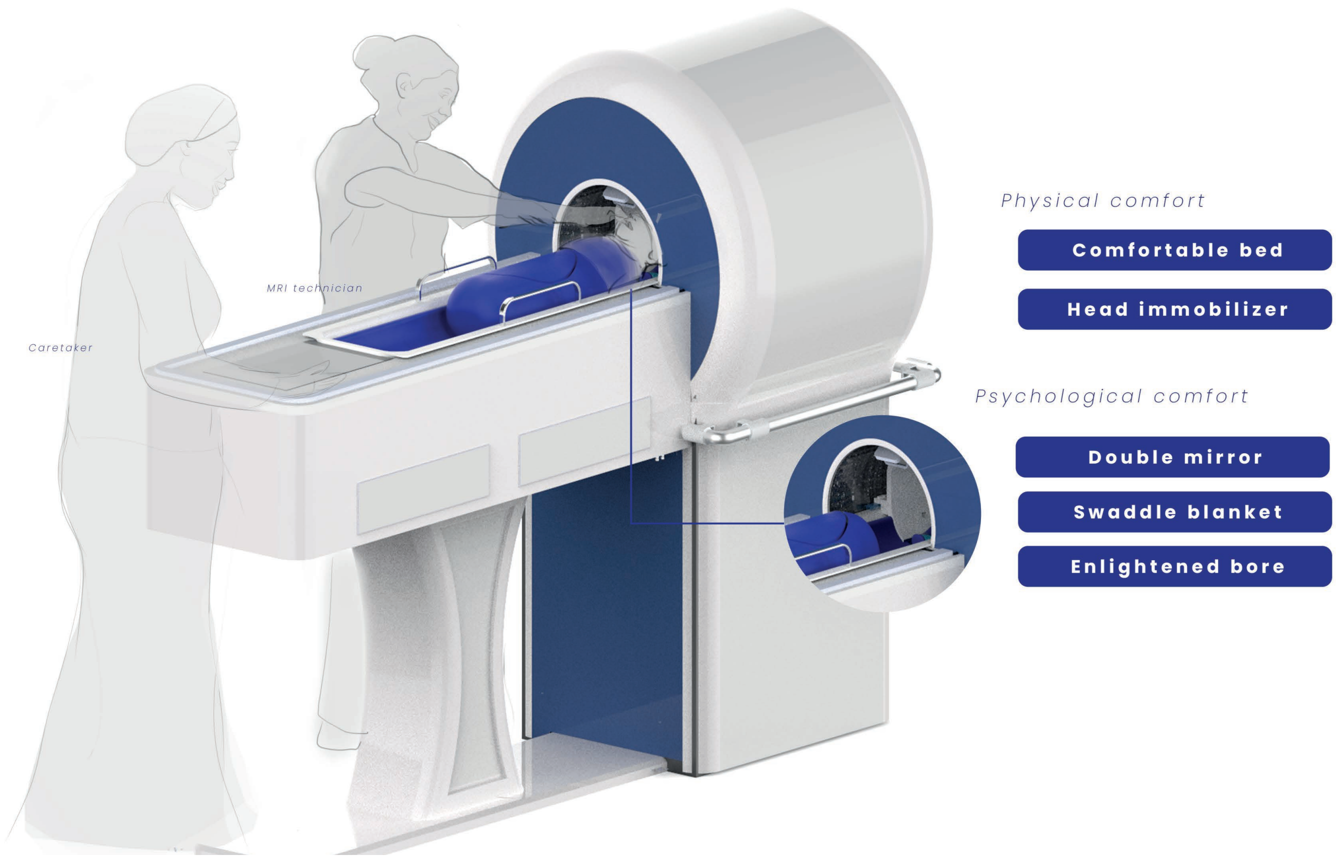
Additionally, the bed system must be compatible with the 50mT magnet system.
This adds more design constraints; The head immobiliser must be compact enough to insert a 30cm bore and be entirely constructed from MRI-compatible materials.
The MRI bed and sliding systems were optimised to maximise the space available for the patient head and the MRI technician to operate. In addition, the MRI bed system and the sliding system were optimised to provide a comfortable and compact concave shape and a doughnut cushion with neck support. This facilitates even loading across the patient surface, minimising pressure points. Moreover, the LF system was designed to have as large a field of visibility as possible while they were being imaged to minimise claustrophobia.
To meet the compatibility and facilities in LMICs, it was decided that the device would be manually assembled and installed by operators and technicians in low resource settings with standard tooling.
To ensure compatibility with the magnet system and the mechanical restrictions, the technical team of the LUMC was involved during multiple co-creation sessions.
Several experts were consulted during the preliminary design, conceptualisation, and evaluation phases to ensure patient and technician friendliness, including radiologists, MRI technicians, neurosurgeons, and paediatric nurses.
For the final design, clinical researchers, radiologists, and MRI human factors researchers were consulted. Based on their advice, the final design has been adjusted to validate and make recommendations.

12.1 Concept presentation



For hydrocephalus patients between 0 and 4 years old
Use of minimal technology and movable parts to prevent quick obsolete parts

Swaddle and double mirror allow the patient to be comfortable
Remove discomfort through the improvements in the bed
MRI technician can see the patient



12.1 Concept presentation

Patient_centric
- *Comforts patient*
- *Guides the MRI technician, through usecues*

Optimal imaging
- *Perfect fit for all head sizes with 5 head coils*
- *Headcoil with optimal shape for comfort*

MRI Compatible

- *Durable and robust components*

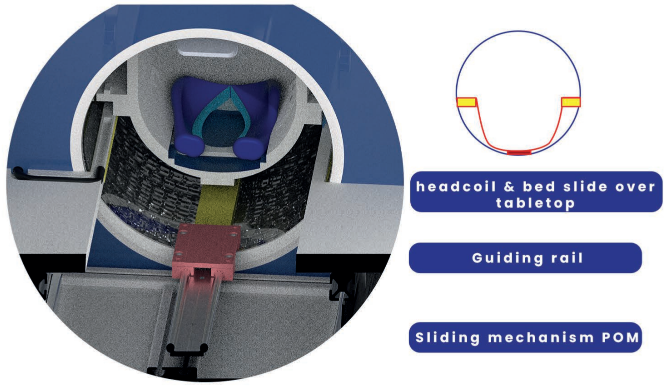
Aluminum framework and sliding mechanism combined with

LMIC compatible

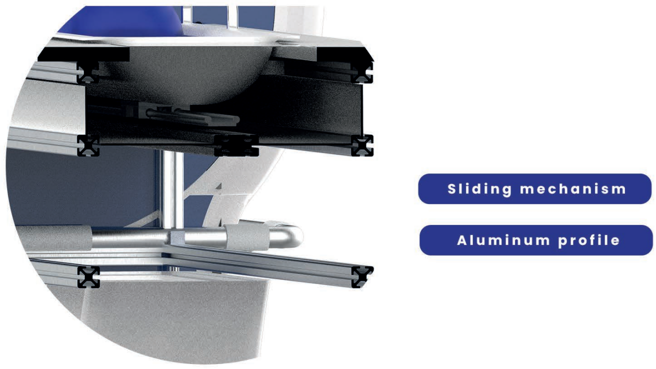
- *Widely accessible parts*
- *Easy maintenance through modular design*

Easy to Repair and Maintain
Use of standardized parts

Space efficient sliding mechanism
Aluminum profile & Igus slides



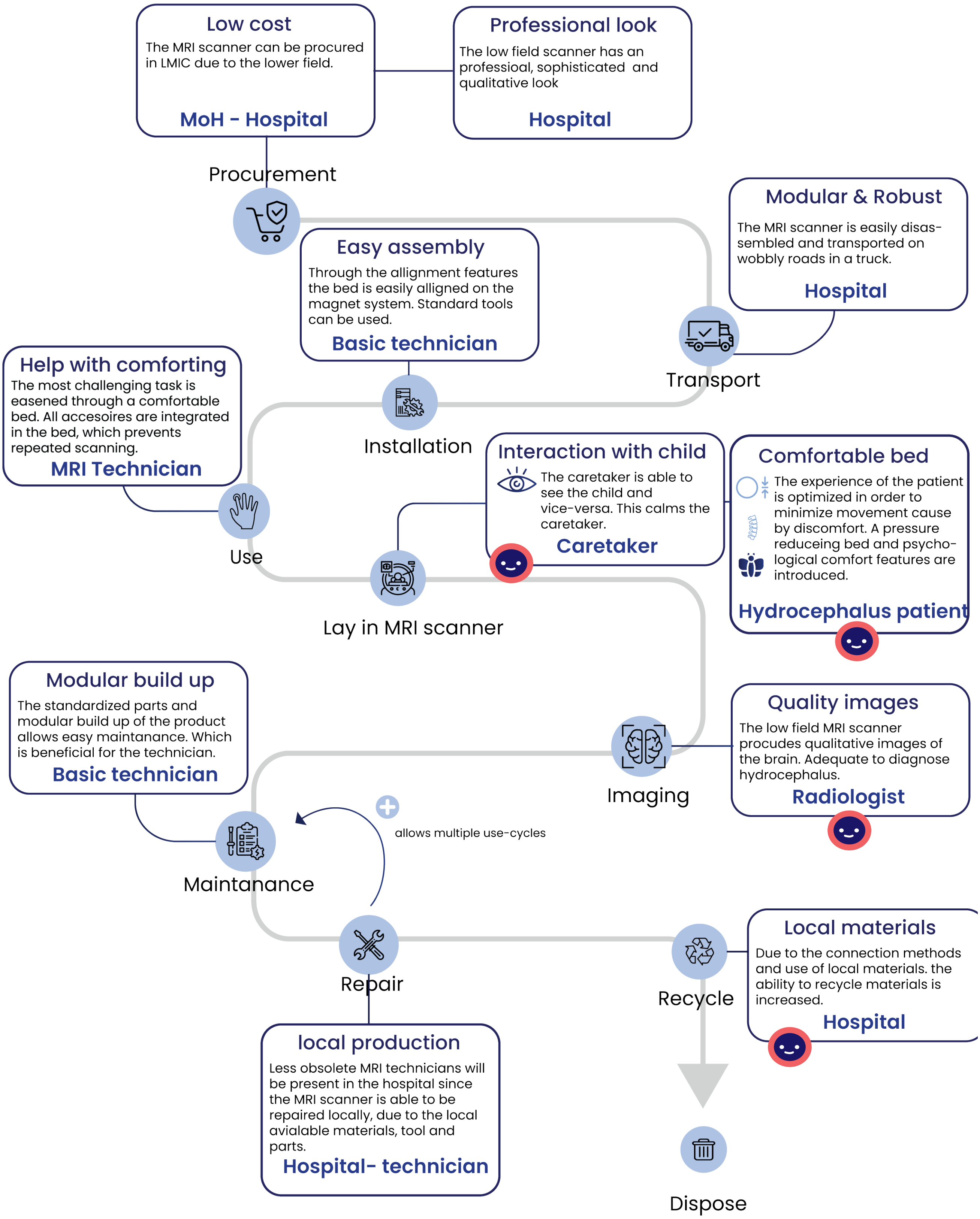
Modular installation
Use of standardized parts and tooling



12.2 Concept validation

This section illustrates the additional benefit and value of the product for the involved stakeholders in the all life cycle phases. The additional values have been a result of the interviews and co-creation sessions with the Cure hospital Uganda, Surgeons, MRI technicians in LMICs and MRI designers from industry.

The values have been connected to the stakeholders in the product life cycle. As illustrated, the product design contributes to beneficial outcomes throughout the entire process.



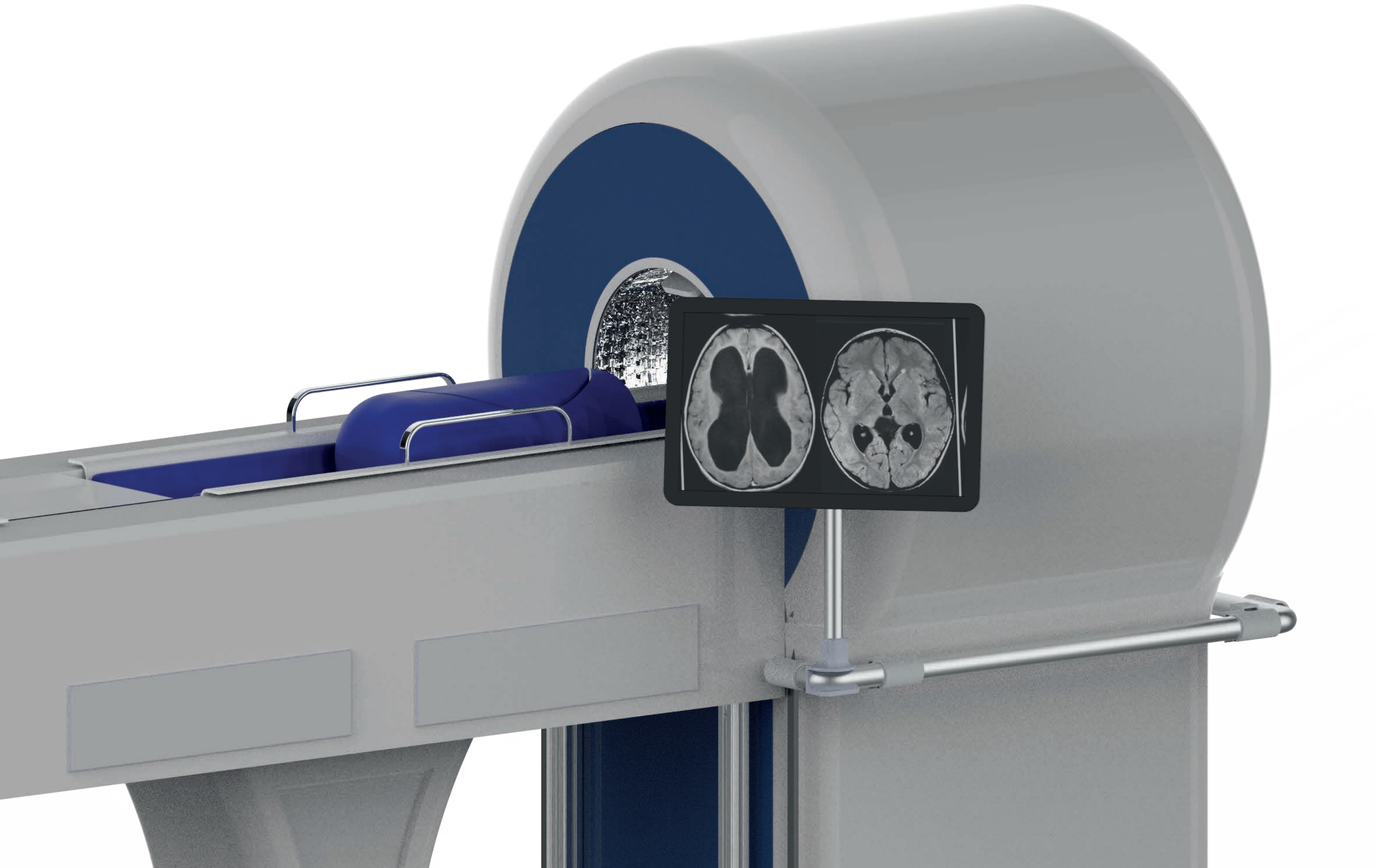
12.2 Concept validation

"The ability to see the parent from inside of the bore is a great additional benefit, which can really help with comforting"
MRI technician (interview Ap.B)

"Children love to be swaddles and will be comforted by it"
Neurosurgeon (interview Ap.B)

"All necessary components are inside to secure a safe device for MRI imaging"
Radiologist (interview Ap.B)

"The ability for the device to be maintained locally with basic tooling is a good opportunity"
Head MUST (interview Ap.B)



12.3 Entire MRI system design

12.3.1. Product layout and dimension

The entire system design is developed to ensure compatibility with the other systems of the low field MRI scanner.
The concept of the MRI scanner is developed by first defining the most crucial dimensions based on the critical components. Therefore, the parts and architecture of the product have been defined prior to the development of critical parts of the bed system assembly.

Design for a good fit with personnel and context

The ergonomic work conditions impact the human factors on human performances [40].
The maximum dimension of the system is defined based on the magnet and underlying electronics. The dimension of the system must be a maximal of 3x2m to fit inside of an average hospital room since no special place will be provided. In addition, the design needs to be compact enough to be transported through a standard door inside award of approximately 10m2 [66].
The minimum height of all the electronics to be fitted inside a 12U 19" rack is D: 565 x 570 x 430 mm. With the magnet on top, the minimum height of the head coil is defined by the position of the magnet isocentre at this point. Through several mock-ups, the product layout of the device has been defined. A height of 90cm is appropriate for the MRI technician to work while keeping an active standing position. The layout of the several MRI parts (imaging, installing, observing) has been defined so that the MRI technician can oversee the patient, the screen for imaging, and the caretaker all from one position and at the reach with P50 of Ugandan adults (Figure 12.4). This height allows the MRI technician to prepare the patient on the bed, which reduces time.

Design for large target group children as possible

The age of the infants being scanned inside the Low Field scanner is based on the technical restriction of the bore size of 30 cm and the most occurring head diameter, which is between 50 and 60 cm 50th percentile 55 cm circumference. Therefore, for the bed design, the body dimensions are essential. However, there is a large variability in the body length and proportions between newborns and infants of 4 years old. Therefore, the bed is designed to fit patients of 0 to 4 yeas old.
The most adjust-ability is needed for the dimensions with the most significant variation, such as the head circumference. In addition, different head coils are provided to ensure a good fit for the variability of head sizes.

Design for optimal fit with components - Design for alignment

The head must be aligned concentrically inside the bore to be captured inside the spherical field of view of 225 mm. A fixed position of the bed sliding inside ensures the headrest always falls inside the field of view. The fixed position and height of the bed allow the headrest to remain at one fixed position while all (50-60cm) head circumferences fit inside the field of view. The headrest is designed for the smallest head coil and head circumference to fall inside the field of view. For the smallest head size, a space of 10 cm is left above the face, while the entire head falls inside the field of view. The remaining space above the head is 4 cm for the largest head (Figure 12.3).

12.3.2. Usability

Assembly and installation of the bed have been designed through the design methodology poka-yoke, which focuses on designing parts that fit into each other fool-proof. Through behaviour-shaping constraints, incorrect operation and positioning by the user are prevented. Through use cues, the product can only be aligned and positioned in one way. This is advantageous because less time is spent on training nurses, and mistakes are detected as they occur.

12.3.3 Design for manufacturability

Parts prone to break

The electronics and the moving components have been defined as the most fragile parts and prone to break. At the same time, the bed and the head coil have been defined as the most-used components and must be wear-resistant. Furthermore, the parts prone to break have been designed to be modular to facilitate easy component replacement. In contrast, the most consumable parts have been optimised on their durability.

Local repair and maintainability

The electronics are developed to use standardised parts when possible, allowing local replacement and maintainability. As a result, the MRI system can be repaired and maintained with simple care tools and components.
The most challenging factor in repair and maintenance is the troubleshooting. It is not possible to troubleshoot on a component level. However, it is possible to troubleshoot on a cool block unit. By allowing troubleshooting on a cool block level, the components on the specific modules can be repaired once a component weakens or loses signal. Therefore each electronic module is connected to the interface and can alert the MRI technician once a module on a cool block is defect.

The vision of the electronics design

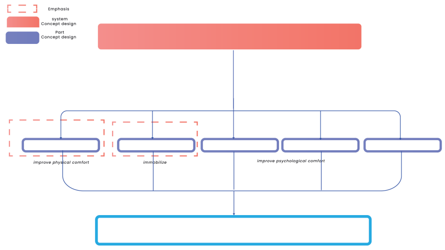
The system is an open-source project, which signifies that all the information and data are openly available for other parties to reproduce the device in detail. Therefore, the architecture and design of electronics have been designed to allow easy assembly and sub-assembly. This is done by positioning the electronics in a modular way to promote replacing a component without disassembling the surrounding system.

Custom designed parts

Some parts will require a specific shape or mechanical standard that cannot be acquired on the standardised market. The bed and the head coil will be locally manufactured with the tooling and machinery available within LMICs. The design of these parts includes additive manufacturing, welding, and thermoforming.

Further, define the concept.
The following chapters discuss how the concepts achieve the goal of improving physical and psychological comfort through the concept design of the following components:

- The head immobiliser
- The bed
- The swaddle blankets
- The double mirror
- The head coil



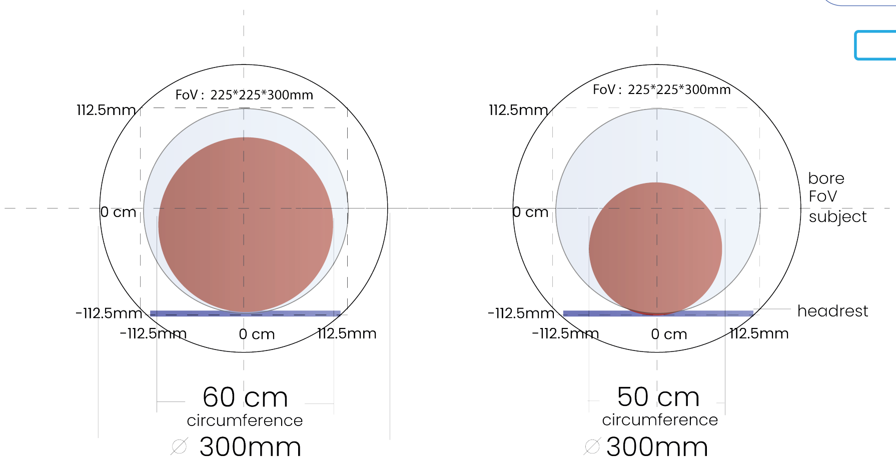


Figure 12.3 Field of view with patient inside of bore

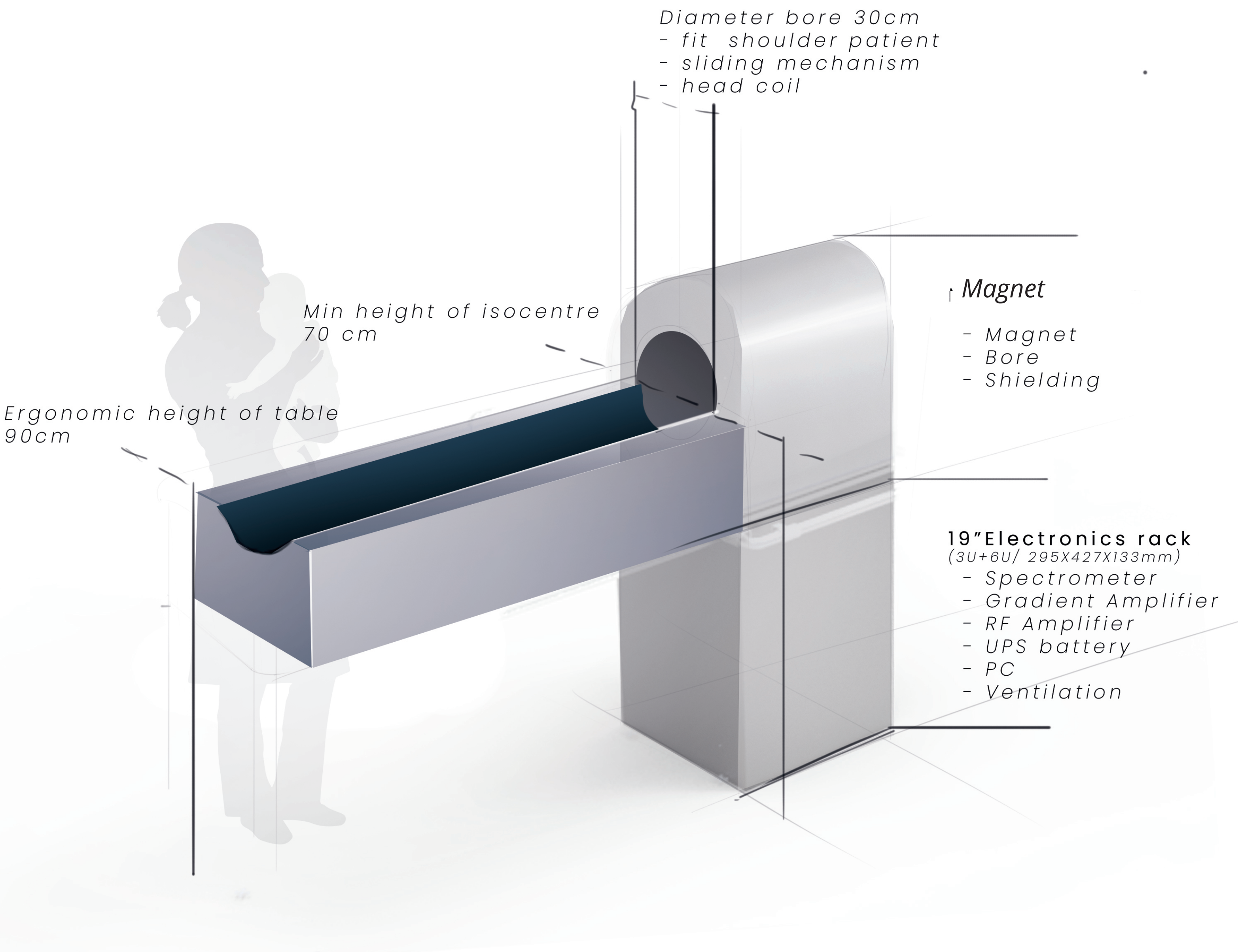
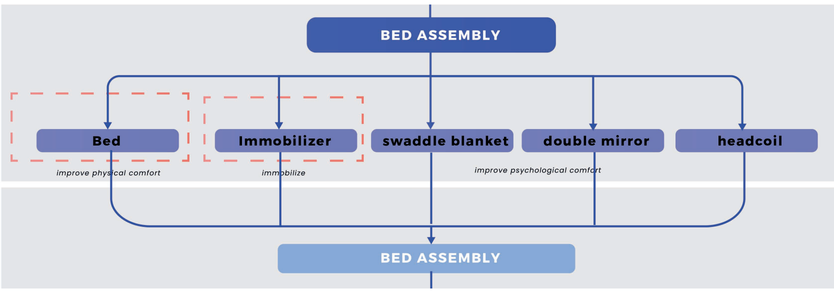


Figure 12.4 Product layout and architecture

12.4 Component final design

This section summarizes the component design part by presenting the final design of each component of the bed system. Figure 12.5 illustrates an overview of the designed components. All calculations can be found in Appendix H- P for each component.



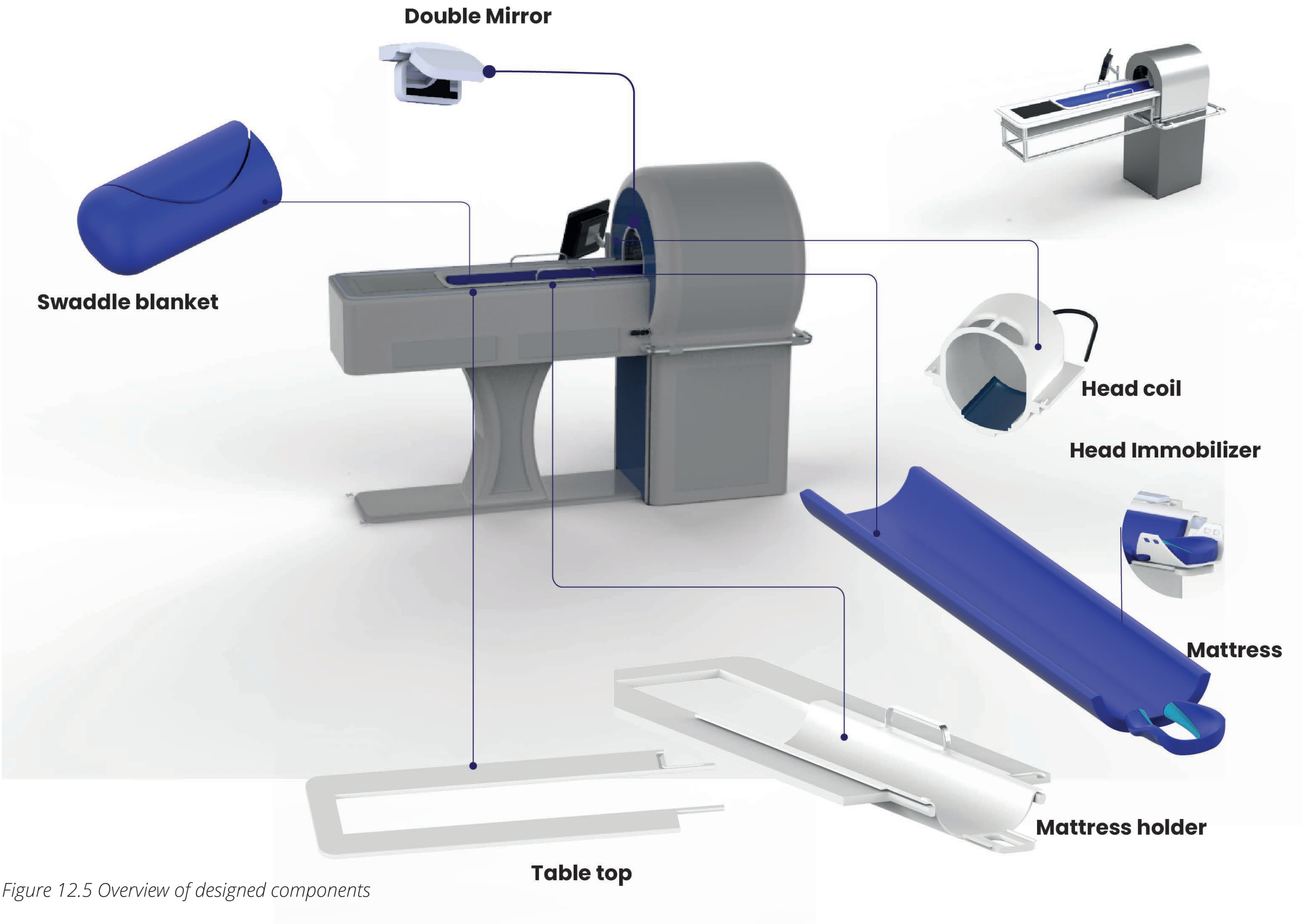
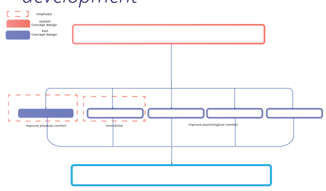


Figure 12.5 Overview of designed components



12.4.1 Final design bed mattress

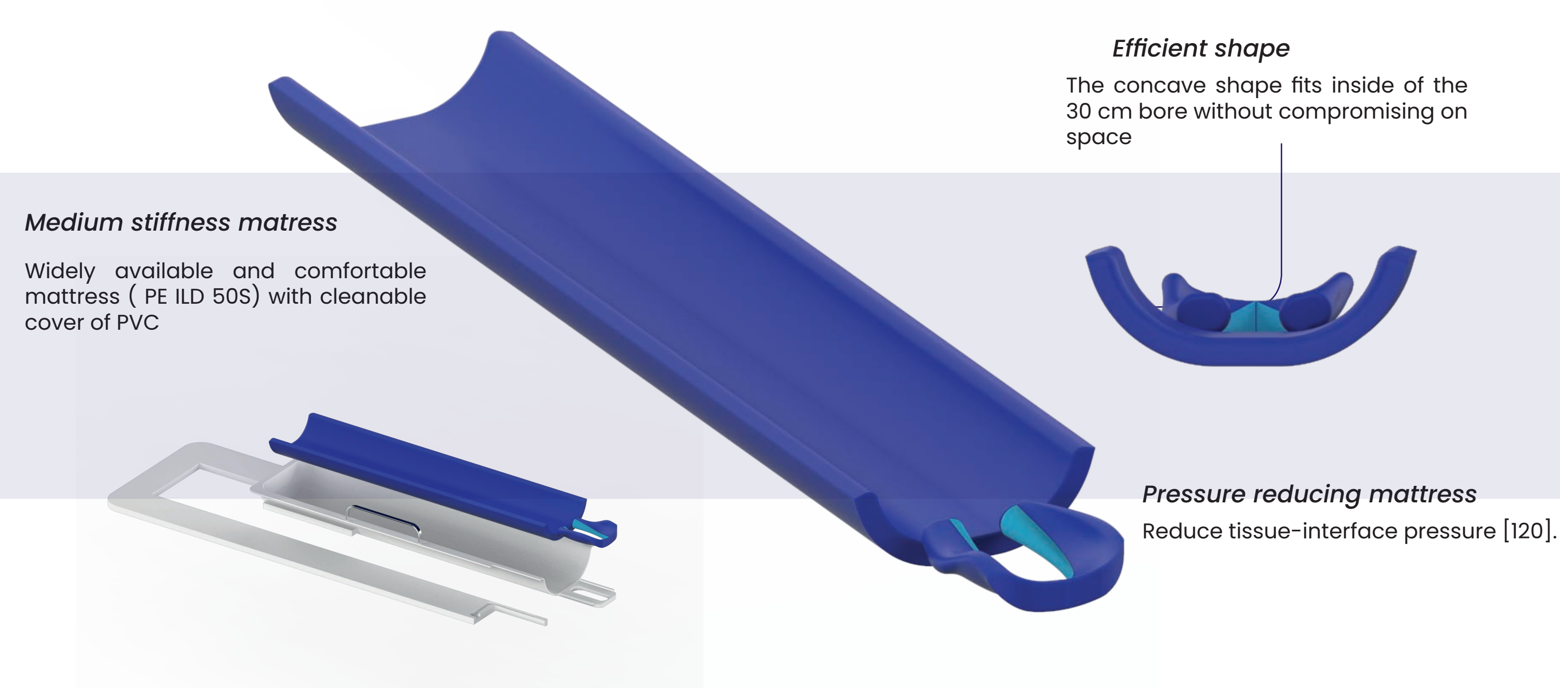


Figure 12.6 Mattress

Functionality
The function of the mattress is to provide a comfortable lying position for the patient. In contrast to the mattress in the preliminary support, which only for the body but caused discomfort and possible pressure ulcers, which cause the child to move.

Challenges
The main requirements for the bed are to be comfortable for the patient with hydrocephalus, well cleanable for MRI technicians after each use, and of minimal volume for insertion inside of the bore. The comfortable bed depends on the proper posture of the child in a supine position while the head is immobilised inside of the head coil. Discomfort must be prevented by allowing evenly distributed pressure on the body and critical areas such as the head.
An additional challenge during supine positioning is the risk of a decrease in functional residual capacity in anxious children (paradoxical breathing). Correctly positioning the head and neck is required by resting the head on a low-profile circular headrest, slightly more inclined than the shoulders.

Design
Due to the successful application of the concept research fundamentals, an optimised ergonomy is promoted, and discomfort is prevented. Due to the increased body weight in the head of paediatric patients, this is the area with the highest pressure, followed by the sacrum area for the minor patients and the shoulder area. A pressure-reducing mattress has been designed to conform to the body contours, thus increasing the area of the body, supporting its weight and avoiding local point pressures [120], [121]. To support the head, the head is positioned at a slight angle of 15 degrees for proper positioning and minimal interface pressure. A slight concave shape in the bed and mattress increases the surface area interface with the bed and the shoulders, causing a lower pressure in this area. The doughnut shape avoids pressure on the occipital area. The rest of the head has a distributed pressure of maximum pressure of 15mmHg, which is below the critical rate.

Volume
Due to the bed's dimensional restrictions that need to enter the bore, the bed is already restricted in its width, length, and slightly concave shape. The most optimal shape that provides the best use of space while allowing the largest area for the body to lay on while proving the most stiffness is the slightly concave shape. The shape follows the rounding of the bore, which makes sure that the shoulders can lay on the mattress. Furthermore, it helps with the minimal space.

Materialisation
The mattress is the most consumable part of the system since this part has the most interaction with the patient.
Due to the local production and repair requirement, the concepts considering optimal hardness for the different anatomical body parts were excluded. This would require a specific manufacturing process to produce the mattress, which would not be possible. Instead of an optimal hardness for the support of each anatomical body part, a standardised widely available medium hardness of polyurethane (PE ILd 50s) is therefore used. The standardised mattress is purchased as an off the shelf product and shaped in the concave shape by the PVC cover and the mattress holder. PVC is water-resistant for possible leakage of fluids and well cleanable. Once this is sewn in the correct pattern, the concave shape will be quickly provided.

12.4.2 Final mattress holder

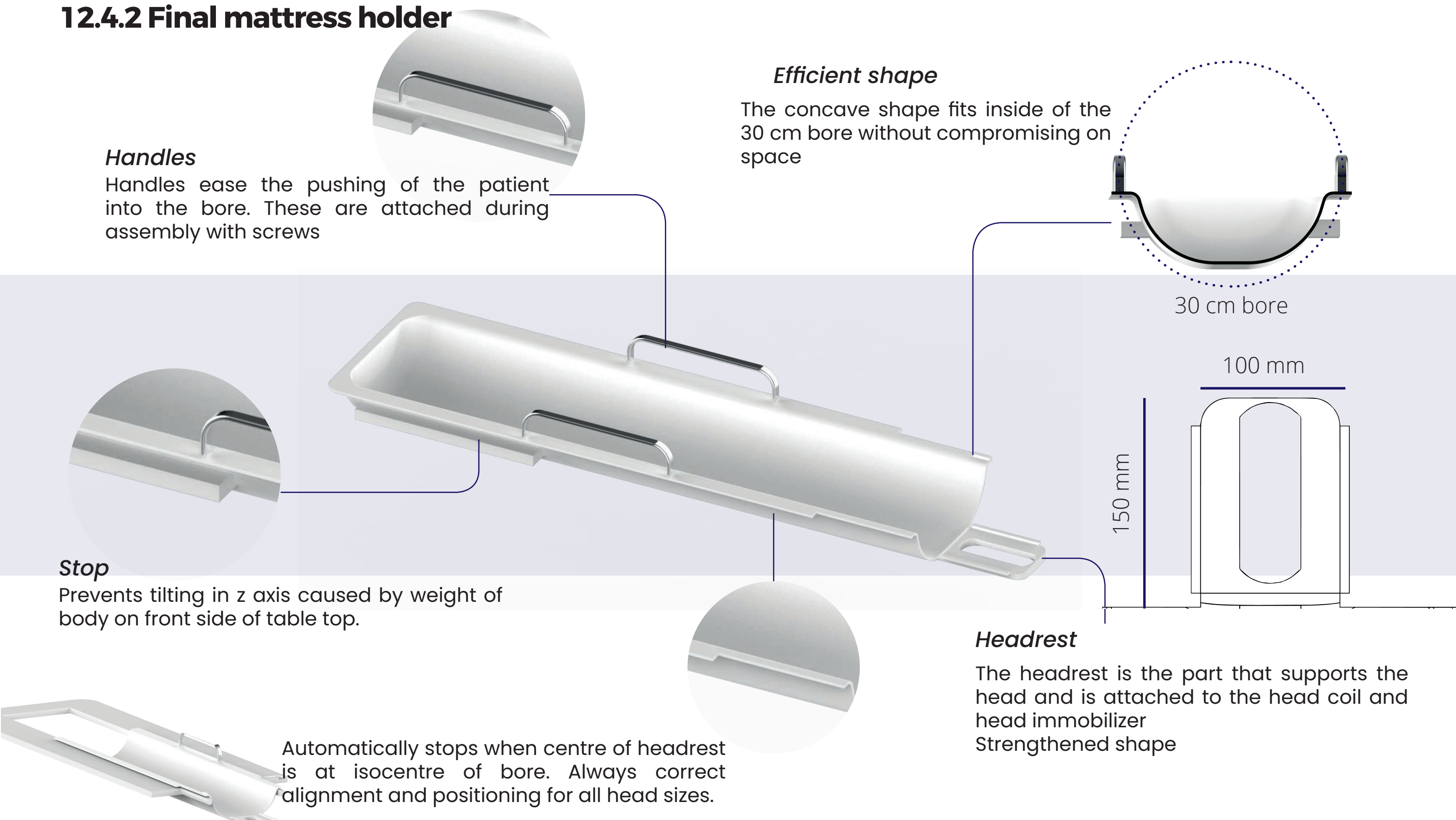


Figure 12.7 Mattress holder

Functionality
The mattress holder is the part that supports and keeps in shape the mattress. Furthermore, it allows translation of the patient inside the narrow bore. The part supporting the head of the patient requires more attention due to the additional function to support the fragile head of the infant while being fixated on the head coil.

Challenge
The main challenges with this part are the multiple interaction points. The head coil must be close to the patient's head on all sides. Because the patients head is lying on the mattress, this part must be of minimal volume to still provide the proximity of the head coil. Additionally, this minimal volume still needs to remain stiff enough with minimal deflection (3mm) and carry the enlarged head (up till 50N). This all needs to be done to allow ease of use for the MRI technician. The total assessment and calculations can be found in appendix M.2.

Design
Shape
Arc-shaped contour adapts to baby's head shape while providing optimum head and ergonomic neck support. Improved shape to avoid pressure on the occipital area of the head The concave shape ensures both the patient's comfort and the ability to insert the largest possible shoulder width with minimal space occupation for the sliding mechanism and other equipment. In addition, the volume inside the bore is optimally used to access the patient and access the patient from the MRI technician.

The head part of the mattress holder is a locked dimension that needs to be fixated in variable-sized head coils. This is done by providing all sizes of the head coils with insertion slots of the same size. Therefore, the headrest has a dimension of 150 mm * 100 mm.

Stiffness
The mattress holder must be able to hold 294,30 N, which includes the maximum weight of the patient, the mattress and a safety factor of 20%. With a minimum deflection of 3 mm (allowable movement), the minimum E-modulus of the material should be at least. 15,6 MPa. Due to the shape, the stiffness of the headrest is a little less stiff. Therefore, ribs in this part ensure robustness and increase the stiffness in this area.

Use
To ensure an easy operation for the MRI technician, the positioning of the patient is eased through the mattress holder design. With one gesture, the head coil can slide over the head of the patient, and no alignment is necessary. In addition, the stops provide a fixed translation for the bed insertion inside the bore. Therefore, no mechanic stop is necessary.

Materialization
Since the mattress is the most consumable product with a specific shape, the purchase is impossible, and local manufacturing must provide the availability. Since the patient may vomit or exert other liquids, it is essential for the material not to be absorbent. The shape has no specific tolerance requirements, which is beneficial, so the product can be designed less costly since tight tolerance requirements increase cost and require specific manufacturing possibilities. PEEK has high chemical resistance, abrasion resistance, low moisture absorption, and a low coefficient of friction. Thermoforming provides a suitable manufacturing process for this part and is widely available in Uganda.

12.4.3 Final head immobiliser

Based on the experiment, the best functioning immobilizer has been defined and conceptualized. The entire list of requirements and design process can be found in Appendix M.4.

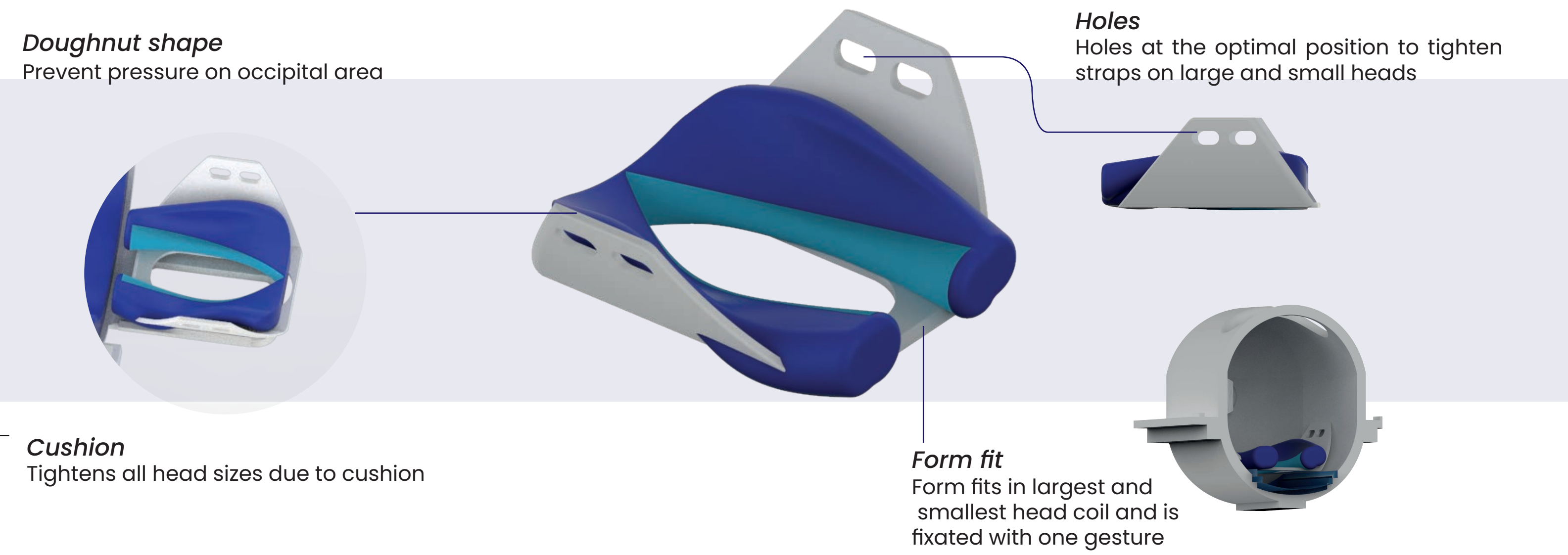
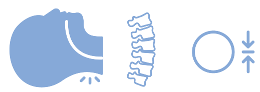


Figure 12.8 Head immobiliser



Function
The head immobiliser is a new part inside the bed system that restricts the head area of the patient. The head immobiliser is further developed based on the literature, use and context requirements (Time needed to apply and remove the immobiliser, skin contact pressure, dimension and weight usability, restriction of spinal movement, cleanability).

Challenge
The head immobiliser is designed to overcome the main challenge of immobilising the paediatric patient with various head sizes in a comfortable way.
Immobilisation
Based on the immobilisation experiment, the optimal product features have been designed to provide the optimal immobilisation 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 the mandible. The adjustable pillow is designed to fit 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.

Design
The system consists of three main parts:

1. A central head holder - To secure on mattress holder
2. A fixation strap - To secure the head
3. Fixation adjustable pillows - To tighten the head

The immobilisation 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 to be immobilised, the immobiliser itself must have the smallest volume possible while being stiff enough to not deform elastically or plastically while the head is moving.

Usage
The installation of the head is as follows: First, the back of the head is positioned in the doughnut area of the head coil. Secondly, the pillows are adjusted to provide a tight fit around the patients 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. In addition, it helps to support the head's weight and prevents repositioning during the scanning.
Prevent translation
The translation of the head is prevented by resting the head on a headrest that is fixated on the head coil. This prevents unwanted sliding of the head coil and thus translation.

Materialisation
Based on the ideal usage, the material requirements are defined. It is desired that this part will be reusable and thus be washed and robust instead of being disposable. A disposable part will significantly increase the cost of the procedure and result in waste. Only foam is comfortable, but this is not as robust and durable as the combination of thermoplastic with a washable material inserted with foam. In addition, the material must be waterproof to allow cleaning when the patient exerts bodily fluids.
The choice has been made for the widely available bi-density polyurethane foam (PE-HD) due to its rigidity and ability to enter the MRI scanner. In addition, it can be covered with PVC, which is well cleanable. The straps are made of woven polypropylene and attached with a Velcro strap. The central holder is made of PEEK, just like the mattress holder. This part is well thermoformed with a pressure mould.

Component development

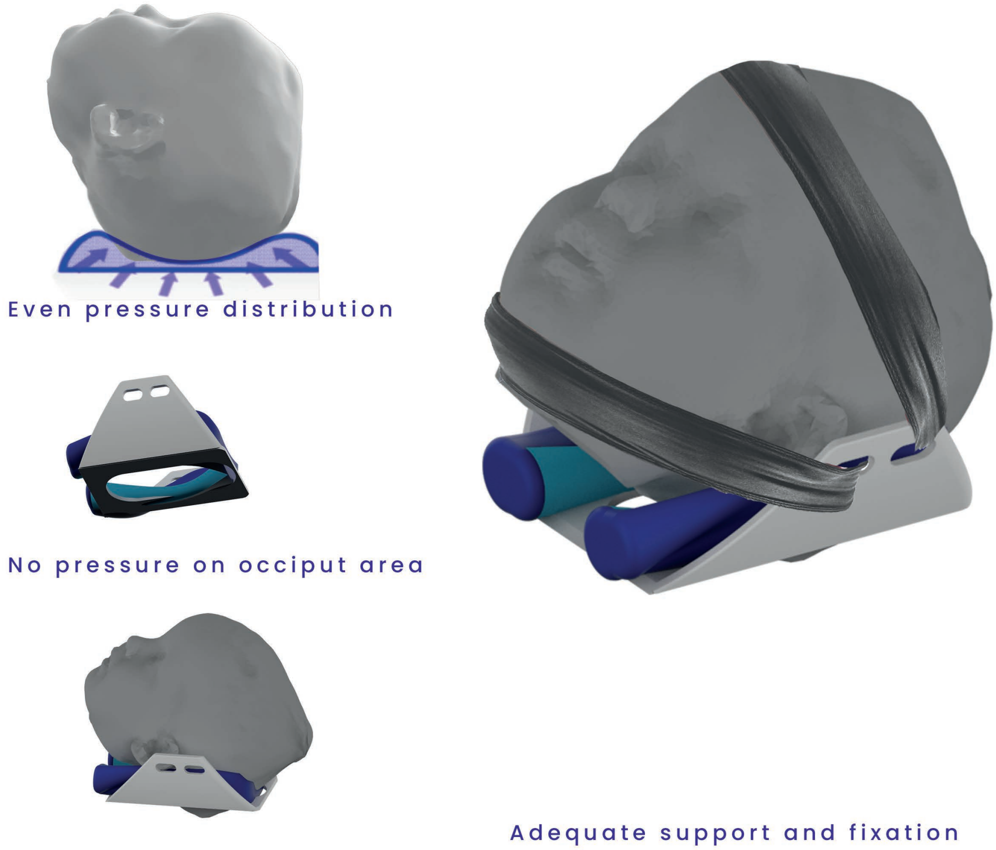


Figure 12.9 Overview of head immobiliser on patients head

Overview

The head coil and immobiliser provide a comfortable fit for head sizes between 50 cm and 60 cm. The pressure distribution on the occipital are is evenly distributed which prevents peak pressure at the critical points. Furthermore, the neck is supported through the doughnut cushion. Additionally, the shoulders are supported by the concave shape,which allows the patient to have ergonomic supine posture, which prevents muscle strain.

These design features stimulate the physical comfort of the child . as a result, the infant is not triggered to move and lay still.
Furthermore, the head immobiliser allows the head to be positioned correctly inside the head coil. Through the use of the cushions, the fragile skin and head bulging of the patients head are supported.

The minimal volume of the head immobiliser, allows the head of the patient to be close to the head coil, which increases the signal to noise ratio and thus the imaging quality. This minimisation of the head immobiliser has a significant beneficial effect on the effective space inside the head coil. The volume of the head immobiliser takes up only 8% of the total space inside the head coil instead of 20% (cushions and pneumatics) with off the shelf immobilisers. Therefore the head coil can be closer to the head, but also more space is left inside the bore, which minimises the feeling of being closed in.

12.4.4 Final double mirror

Figure 12.9 Double mirror

Functionality
The psychological comfort of the patient is improved through the double mirror. The double mirror facilitates the interaction between the patient and caretaker through visual feedback. It is a method that is widely used in MRI scanning to comfort the psychological state of the patient. Through a double mirror, the mother is seen in a correct position toward the child instead of upside-down, which increases parental involvement.

Challenge
Due to the accommodation of the head coil in the bore of 30cm, there is not much space inside the bore is left. The patient's head, the bed, and the MRI technician's hand need to be inserted. Therefore the three smallest head coil sizes facilitate the use of the mirror. This mirror can be adjustable if needed. The largest head coil size is too close to the surface of the bore, which does not allow the required angle of the mirror to be positioned inside of the bore.

Main requirements
1. The mirror must allow the patient to see the care-take who is situated outside the MRI scanner
2. The Mirror allows enough space for the child's placement inside the bore.

Design
The main advantage of the double mirror is the limitation of the feeling of claustrophobia through enlargement of the visual space inside the bore.
The mirror is designed to provide visual feedback to the patient while being scanned. The mirror is placed inside the bore for the patient to look at it. The mirror can easily be folded out after the subject has been placed inside the narrow bore. The focusing of the mirror is not needed since set angles are pre-calculated. In this way, the mirror enables an unrestricted view of the foot end of the scanner, where the caretaker is placed. Light is necessary inside the bore to be able to see appropriately.

Materialization
A 3D printed holder is designed to hold the mirror sticker. These mirrors are easily accessible in Uganda. Furthermore, the mirror holder is designed so that it does not consist of ferromagnetic. The hinge is 3D printed and adjustable. The mirror is connected with brass connectors in the bore. The material of the mirror is made of mirror film, which is easily processable and durable.

12.4.5 Final swaddle blanket

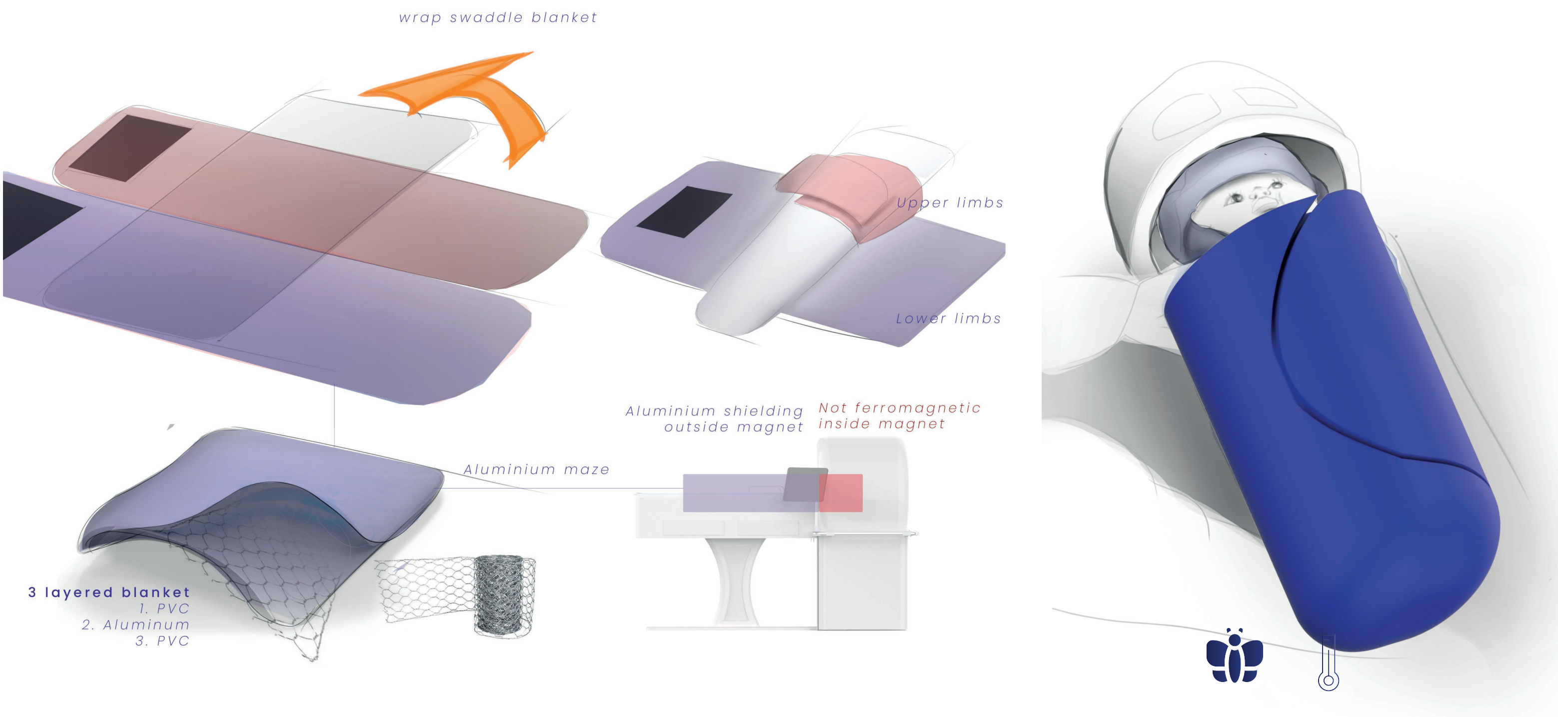


Figure 12.10 Swaddle blanket

Functionality
Psychological comfort is promoted through the swaddle blanket. The swaddle blanket is designed as a multi-functional blanket wrapped around the patient during the MRI scanner. The functionality is three-fold: to promote comfort through the swaddling position, shield the patient from noise, and immobilise the patient's limbs while swaddling. This blanket replaces the previous shielding that obstructed the ariflow and was expensive (€10.000 p.p).

1.Swaddle to comfort
Swaddling is a widely used technique in subSaharan Africa and comfort children.
While swaddling the patient, the child is lying in a comfortable position which promotes rest. Furthermore, body warmth is remained constant, which induces a natural sleep or a calm state of mind. Finally, the blanket will prevent bodily heat loss of more than 3 degrees in 10 minutes, an assumable variable when considering the patient wearing no clothing in a cold environment.

2. Cover for RF shielding as a cage of Faraday
Besides comfort, the swaddle blanket functions as a cage of Faraday to cancel the noise from the environment. When the head is scanned inside the bore, depending on the dimension of the child, parts of the body will extend out of the bore. As a result, the body has the unique characteristic of acting as an effective antenna, attracting more noise. This is undesirable for an effective scanning procedure. Therefore, it is necessary to create a Faraday shield around the body to prevent this "antenna effect".

3. Tighten to immobilize
The swaddle technique is used to reduce motion artefacts by reducing the patient's motion. When applying the burrito roll technique, all blankets secure the tucking of the limbs on both sides of the body. Usually, this would include the lower half of the body to secure the legs; however, this is unnecessary. By only tightening the upper half, the infant's feet are easily accessible for placing cardiorespiratory monitoring equipment during swaddling.

Challenge
The main challenge of the blanket is to secure an adequate functioning of the Cage of Faraday feature close to the magnet while cancelling out the noise and immobilising the patient correctly. To create a cage of Faraday from the blanket, no direct contact between the skin and the conductive blanket may appear to be effective. The blanket must be connected to the same ground as the aluminium shield around the magnet, while the part inserting the magnet must be MRI-compatible.

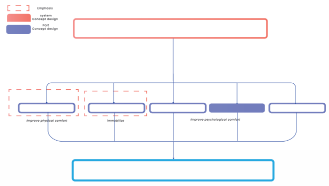
Design
Shape
The blanket is designed as a double T shape on top of each other. On the horizontal part, the body is laid. The double T shape allows a separation of the blankets' dual functioning. The upper T shape immobilises the aluminium grid and is thus MRI compatible. The lower T shape covers the legs of the patient and is embedded with the aluminium grid that provides shielding. This shape allows comfort, shielding and immobilisation of children of all sizes. In addition, it is easy to use due to the preshaped swaddle technique and is easily cleanable. Velcro makes sure that the MRI technician only needs one gesture to secure the blanket with the correct pressure. The possibility of loosening the swaddled patient is reduced to a minimum due to the Velcro. Moreover, this allows the MRI technician only to use the blanket in one possible way.

Figure 12.11 Prototype swaddle blanket

Material
The blanket is designed by consisting of three layers—the shielding material, covered by cleanable layers of fabric.
The three main types of shielding used for MRIs are copper, steel, and aluminium. Due to aluminium's wide availability and low cost, it is a suitable material for RF shielding in LMIC.
A maze of 10*10 mm is sufficient. The connection between the layers is made watertight to prevent fluid on the parts. Furthermore, this part is only implemented where the legs are out of the MRI scanner. The blanket will be connected with the 32 pin connection. This standardised part is also widely used in the automotive industry and Uganda.

Besides the functional requirements, the material must likewise convey the medical requirements of the MRI scanner.
The material selection of the blanket is based on the non-toxicity, non-allergic response, ability to be sterilised, mechanical properties, strength, elasticity and durability. In addition, widely used materials for blankets and clothes that need the same level of cleanability and comfort have been assessed. Price and availability have made the final decision of PVC's outer layer. The inner layer of the bottom part is an aluminium grid. The aluminium grid is an off the shelf chicken maze, which is widely available and cost-effective.

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



12.4.6 Final head coil

Figure 12.13 Head coil

Design
The head coil is constructed as a 3D printed helmet, made of PLA, using Fused Deposition Modelling (FDM) and consists of an inner part, which has the wired coils embedded in this layer, topped by the outer part that works as a protection for the wires and volume to support and slide the head coil on the bore. With 40 windings of 1-mm diameter copper wire. The inner layer has a thickness of 3 mm to ensure maximal strength with minimal distance between the coil and the subject of interest. In this way, the higher receive signal sensitivity is maximised.

Head shape
The coil geometry is chosen such that the receiver coils maintain the critical overlap between neighbouring coil elements, thus minimising mutual inductance while covering the entire occipitotemporal visual cortex, with very high SNR in the cortex. Furthermore, the coils are mounted on a close-fitting former [22] to maintain proximity between the subject and the receive array. The head coil is modelled after an average-sized child with hydrocephalus in Uganda. This research has been done by analysing the CT scans of the head of children with hydrocephalus.

Eye slots
The head coil consists of 2 eye windows that allow the patient to see through the head coil while having full brain coverage and not obstructing the wiring pattern that needs to be at a uniform distance from each other.

Form fit for the headrest
The head coil is slid over the head and fixed through a fit with the headrest. In this way, no additional connection is required, which allows the head to be in proximity of the head coil.

Ease of use
The head coil is slid over the head while the patient is lying on the bed, with its head in the immobiliser. Once the head coil is slid over the head, it is fixated with a connection system that allows easy connection and disconnection of the head coil on the bed-system.

Connection and disconnection of the head coil to the bore
The head coil must be connected to the magnet. The most accessible and convenient way is by applying a connection wire from the magnet to the head coil. This connection is made by plugging in and out the wire.

Sliding mechanism
The head coil can slide along the magnet through the extended tabletop. The sides of the head coil fit precisely between the sides.

Component development

12.5 Integrated design

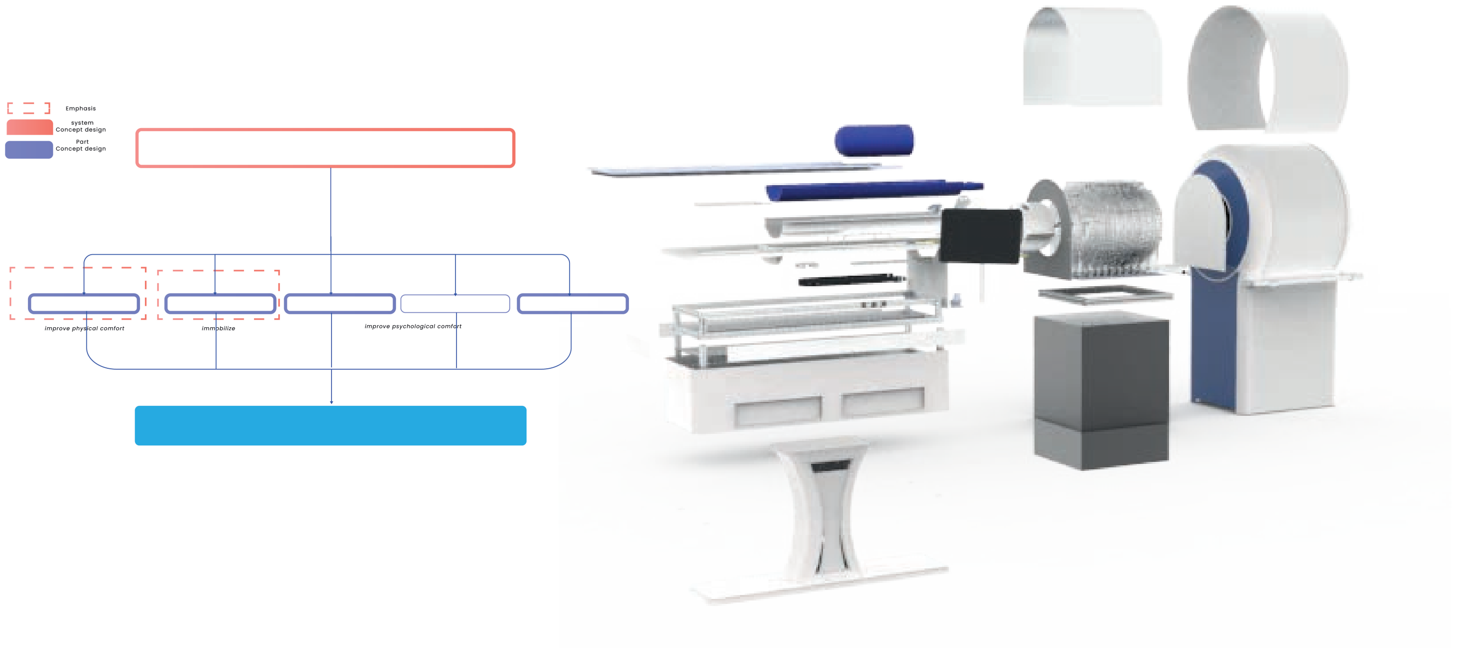


Figure 12.15 System overview and exploded view of entire system

Introduction

This section discusses the integration of all separate components of Ch.12.4 into the entire system design of the MRI scanner of Ch. 12.3. A final concept will be presented. The connection between these parts and how it influences the workflow is discussed in this chapter. Based on the intended use, the best functional principle is chosen. This principle is based on sliding the bed inside the bore with as least force as possible for the head coil to slide and connect to the magnet with as least as activities while considering the possible behaviour of the infant.

12.5.1 Integration Challenges

Alignment
Correct alignment of the magnet and bed systems is crucial for a qualitative image and patient comfort during the scan. The magnetic field is highest at the centre of the bore. Therefore, poor alignment can cause a shift in the imaging and an extra step in processing the image.

Tolerances
One of the main challenges when developing a medical device for LMICs is the correct fit of the manufacturing and its functionality. Low resource settings mostly rely on local manufacturing facilities that produce large equipment with outdated machines. Due to the limited field of view and an extensive range of head circumference that needs to fit inside the MRI scanner, the system's tolerances are considered. This sets the standard of production. The two allowable overall tolerances influencing the image quality depend on the field of view in the x,y, and z-axis.
The x and y tolerance depends on the positioning of the bed system's height, and the z tolerance depends on the insertion of the head inside the bore.
The effective field of view of 225mm in the x and y direction has been chosen to provide the MRI system with a fixed height of the bed(Figure 12.3). The tabletop is set at a height that ensures that the smallest head circumference and the most prominent head circumference fit inside the field of view. In addition, the z distance is enabled by allowing a fixed travel for the middle of the headrest. In this way, the bed will always have a travel of 25 cm towards the bore.

System
The influence on the integration of the systems results in the possibility of building up all systems on a fixed and rigid framework that is not deflecting for more than 3 mm. The moving part, which is the sliding system, must also be a rigid system requiring manufacturing methods. Other components of the system are not as influential on the tolerances. The tolerances are in the range of 3> mm, which allows the systems to be built up from manufacturing principles that manual tooling and production principles. Furthermore, the magnet system requires the bed assembly to be stiff enough to prevent forces from exerting on the magnet. Minor forces, for example, the weight of the head or sideways forces from bumping against the bed, cause damage to the magnet.

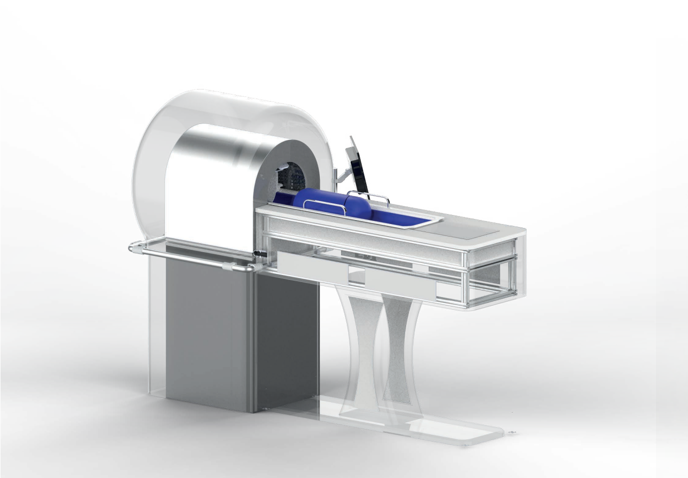


Figure 12.16. Entire system with transparent outer laye17

Figure 12.8. Entire system with transparent inner layer

12.5.2 Integration design solutions

The internal and outer framework

The MRI scanner is built up of two separate layers, a framework and an embodiment. The framework ensures the alignment, tolerances and fixation of the critical systems such as the magnet and the electronics.
The outer layer, the embodiment, separates the inner layer from outer environmental and human risks, such as the red dust that penetrates everywhere and the patient's vomit. This ensures the durability of the critical components and the most prone components to break and replace by allowing the inner framework to be sealed with water and dust-resistant sealing strips. The entire design process can be found in Appendix N.

Aluminium framework

Essential for the components is that it is easily reachable when needing to replace parts efficiently, and the tooling is widely available due to the standardisation of parts. Therefore, it is chosen to place the MR electronics in 19" racks attached to the MRI system secured on the framework. To make sure that the system is able to hold the weight of the patient, any additional leaning forces from the MRI technician and a safety factor, an aluminium profile of 32mm is chosen. Appendix N describes the calculations and the FEM analysis.
This is a low effort and durable option to build up the framework.

The framework must hold 662.5N without deforming. Therefore, a framework with 35mm*35 aluminium profiles has been chosen. The 20x20 structure bends when leaning on it.
The outer layer ensures impact resistance for the inner components, an easily cleanable outer surface and a child friendly and professional appearance of the MRI scanner.
The outer layer consists of all the workflow-friendly features which facilitate the installation of the MRI scanner inside the ward in the hospital. The film between the bed and the framework allows the inner part of the sliding system to be shielded from the environment when the bed is slid inside the system.

Modularity

The advantage of the aluminium profiles is that they are standardised parts that can be retrieved everywhere. However, this may come at a higher cost than the average equipment. As an alternative, the same effect (aesthetically and in stiffness) can be achieved by using square aluminium profiles and welding them together. Again, this is a low-cost alternative.

Installation of magnet system to the bed system

The gap at the bottom of the magnet system ensures the alignment of the bed system to the magnet system, similar to a conventional MRI scanner. Adjustable footings on each site facilitate the adjustment on the floor as the floor may not be entirely flat. The alignment is fixated and attached with a hook latch. The latch hook allows the bed system to be secured on the MRI system and tightly fixated. This fixation allows the system is not able to move in any direction.

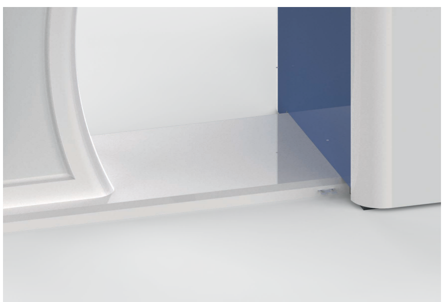


Figure 12.18 Docking of bed in magnet system

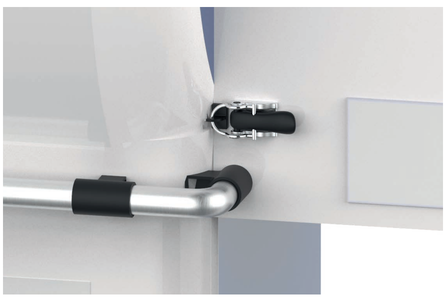


Figure 12.19 Attachment of bed on magnet system

Figure 12.20 Aluminium modular profiles

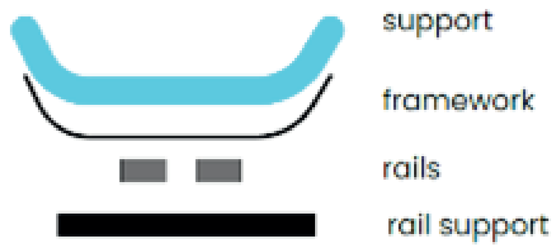


Figure 12.21 Sliding mechanism

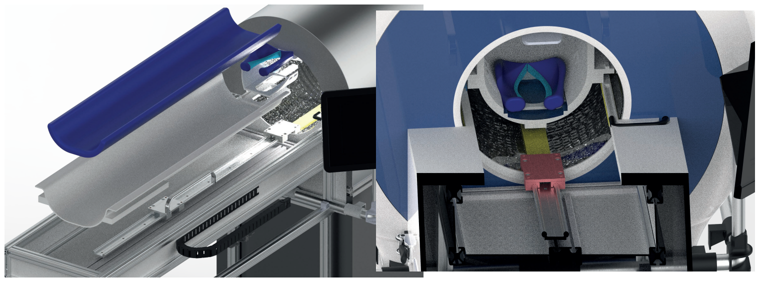


Figure 12.22 Exploded view of table top and sliding mechanism

Sliding mechanism

The sliding mechanism is designed to slide the bed system inside the bore with as minimal volume as possible, while being stiff enough to prevent deflection and force transfer of the bed to the magnet. The bed is slid inside the Magnet system through the tabletop and the sliding mechanism under the tabletop. The Trespa of the tabletop is a rigid, stiff and durable material that is water persistent. This is suitable for a widely exposed to impact, humid chemicals, but still needs to look clean and representable after years.

The mattress holder rests on the table top and is fixed to prevent rotation and translation in x and y direction. Only translation inside the bore is possible. To prevent a large amount of friction, the table top is made out of a low friction and wear material. The tabletop allows fixation in x,y translation and rotation (x,y,z) of the bed and head coil in each way. This provides a system where the bed and head coil can only move in one way. The bed is inserted inside the bore by a sliding mechanism based on a standardised IGUS railing.
To ensure that no forces are exerted on the magnet and that forces from the MRI technician during the procedures such as sideways bumping into the bed system are not transferred to the magnet, a system is designed to ensure smooth sliding of the bed system while being rigid.
the choice has been made to use simple IGUS rails (Figure 12.11)
The system may not contain any ferromagnetic metals. Therefore a sliding system that is built upon the aluminium framework will provide the required stiffness and movement the system requires. The friction from the sliding mechanism allows a fixed position for the bed when slid.

The mattress holder is positioned on an IGUS railing which slides on the aluminium railing system. This component choice was made based on the applied forces, durability, wear, and hazardous situations. The part of the bed that does not enter the bore is entirely produced out of aluminium with a low resistant part sliding on the rail, while plastics entirely manufactures the part that does enter the bore. This sliding system is low in lubrication compared to rolling and bearing systems and easy to clean the sliding components. The system has been optimised based on simulation, prototyping, and testing.

Wire management and connection

Most electronics from the electronics system are situated in a 19" rack. However, the head coil and blanket are parts of the electronics system that must be connected and grounded. Therefore, the following design decisions provide a safe and usable connection.

Connection of electronics of the head coil at the tabletop This allows the MRI technician to easily change the head coils after each use while setting the sequence in the computer.
2. The blanket is connected to the magnet to close the circuit. No connection is made between the body and the conductive materials for safety purposes. The wires are guided under the table towards the electronics system in the rack.
An uninterrupted power supply (UPS) is used to protect the system from data loss during power outages. Therefore all electronics is connected to the UPS and not directly to the power outlet. The electronics are housed inside of a 19" rack. The RF Amplifier, manufactured by DEMO Delft (335 X 427 X 267mm), fits precisely in a 6U rack. The Gradient Amplifier fits precisely in a 3U rack (295 X 427 X 133). RF Amplifier fits inside a 6U rack.

Figure 12.23 Electronic attachment components

12.6 Use based on working principle

This section explains the final design and optimised system of the LF MRI scanner. The product consists of five systems, together responsible for its functionality as structured in Figure 8 - function analysis in chapter 8. The main goal of creating a qualitative sharp image of the sample, is most influenced by the positioning of the patient which is lying on the bed system. The positioning of the bed system is and the joint configuration of all the five parts together (Figure 21.3 and 21.4) For specific configuration requirements see appendix A.

Based on the use of the system, the integration of all concepts and parts are discussed.

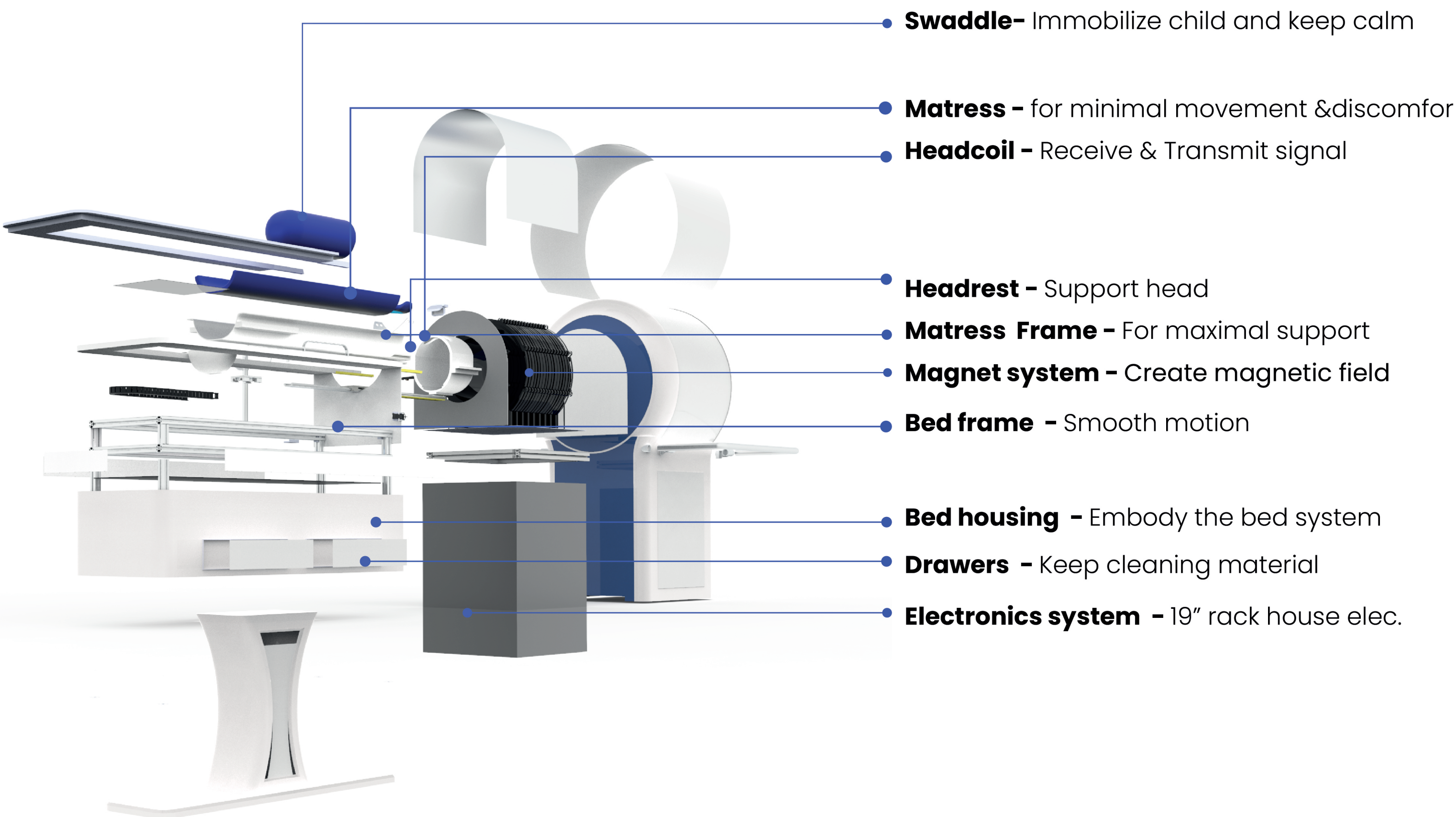
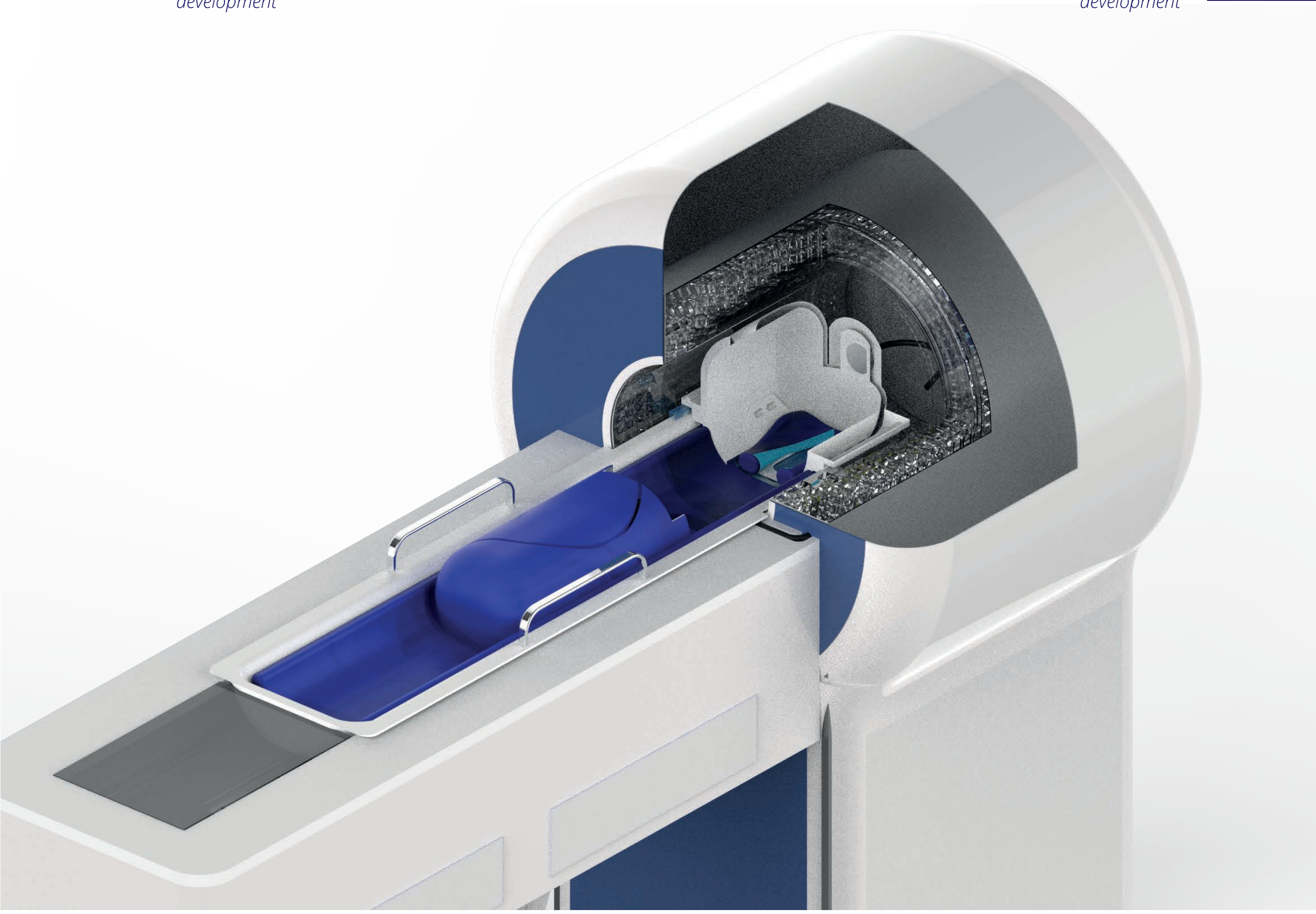
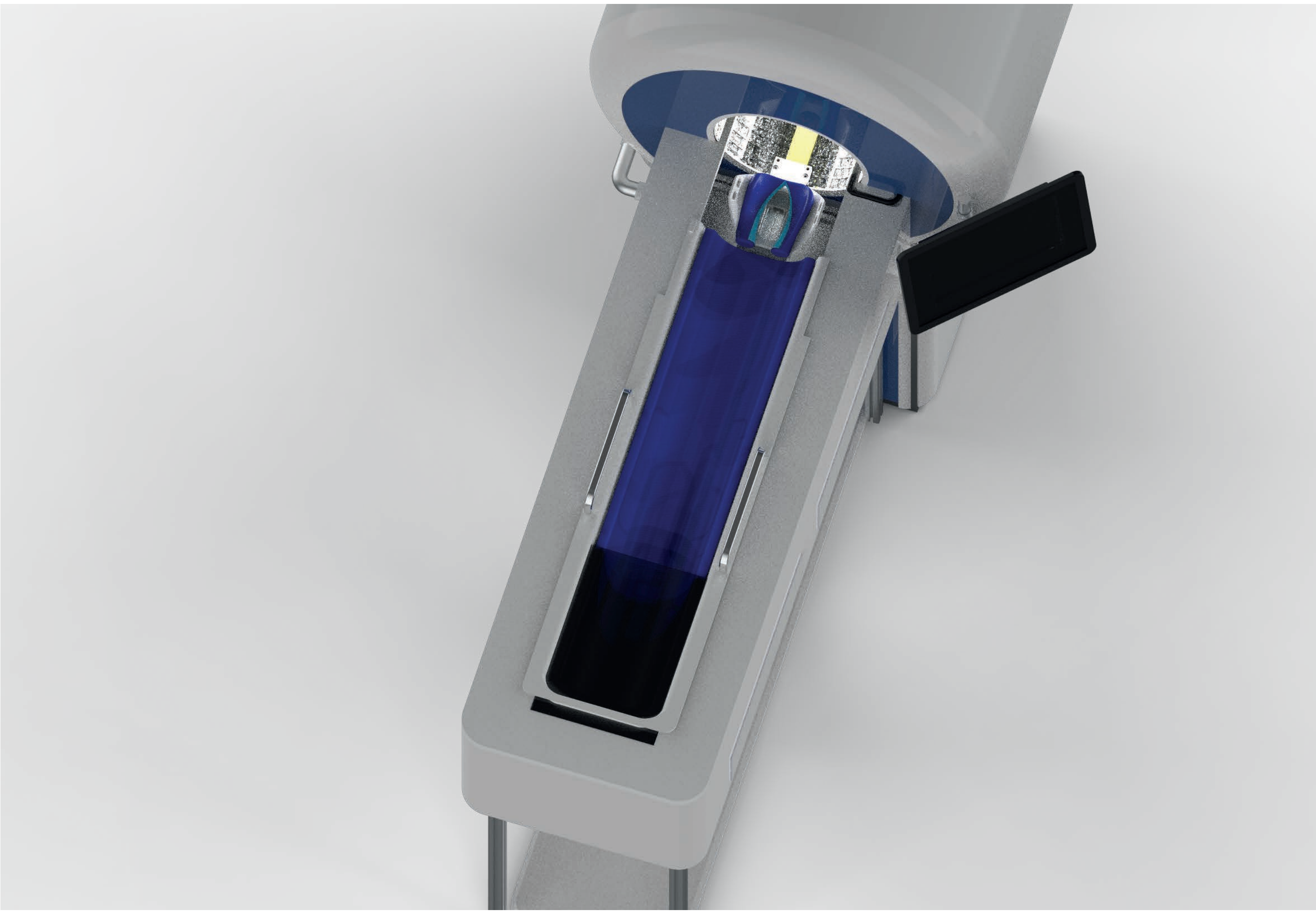


Figure 12.24 Exploded view



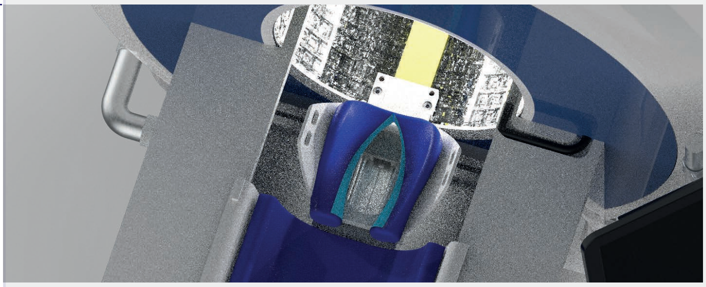


12.6 Use based on working principle

Action

1. Patient positioning

To begin, the brain imaging is prepared for imaging by positioning the patient correctly on the bed. The patient is put on the bed with its head on the headrest. This allows immediate alignment in the correct position.

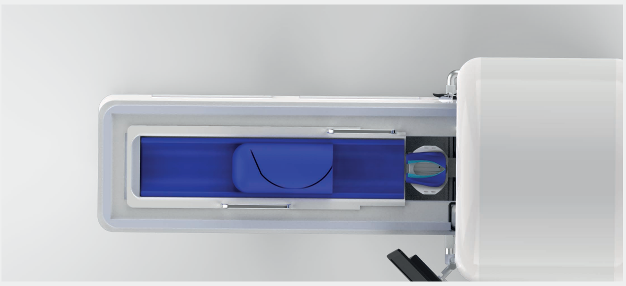


Component

Headrest with doughnut coil, makes sure that the head is positioned on the cushion.
The soft cushion allows all sized to be able to be secured

2. Equipment positioning

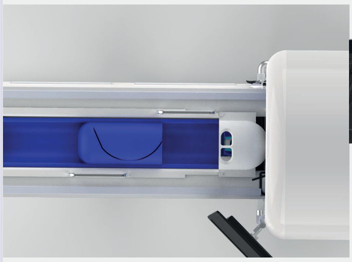
The bottom limbs from the abdomen to the legs is covered by the bottom part of the swaddle blanket. This shields the body parts that do not enter the magnet, while immobilising these parts. The upper part is secured tighter with Velcro.

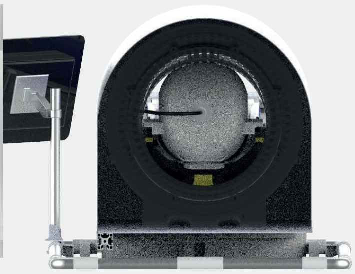


The body is immobilized by the swaddle blanket.

3. Coil Positioning

Due to the extra space of the worktable, the MRI technician is able to prepare and install the head of the patient in the head immobilizer prior to scanner. Once the head immobilizer is set, the head coil is slid over the head and the mirror is set on the correct angle.



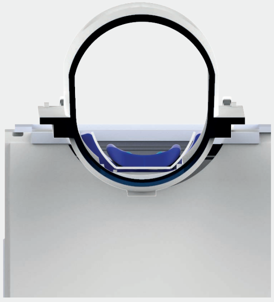


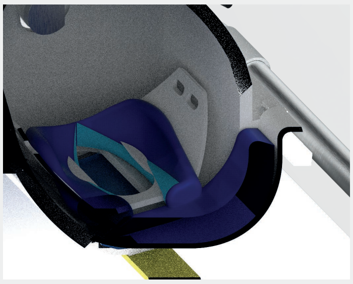
The head coil slides over the worktable which is made out of trespa. A hard material that is durable, UV and chemical resistant.
The head coil has indents that allow smooth sliding over the table top. Furthermore it can not move any other way

Largest head coil and smallest head coil fit inside the bore

4. Positioning of body

The head coil is slid over the head of the patient

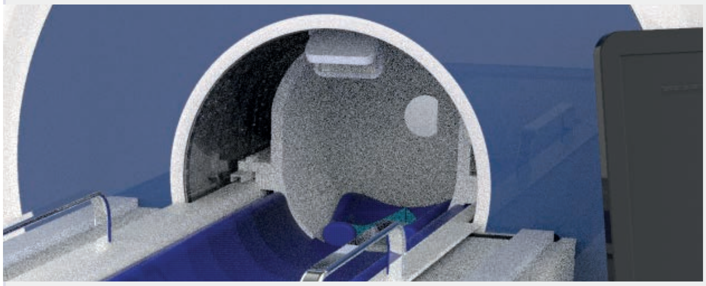




The head coil and the headrest fit exactly into each other due to the form fit. Simply sliding the head coil over the head of the patient makes it possible to secure the head coil

5. Fixation of mirror

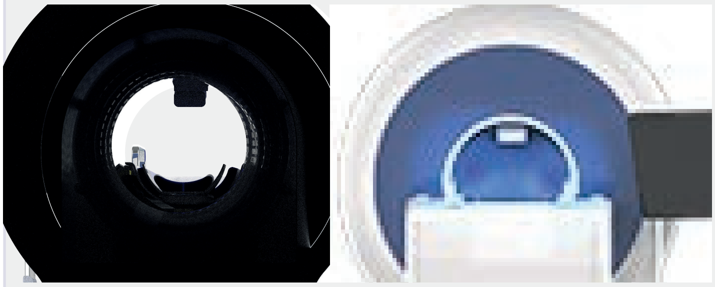
The mirror is fixed and positioned and the light is turned on. Due to the minimal space of the head coil design and the sliding system, the bore has enough space for the MRI technician to operate.



Double mirror

6. Turn on light

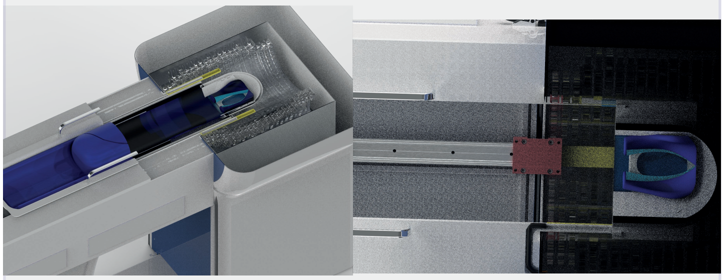
The light is turned on for the patient to see the mother through the double mirror, so the patient continues to have visual feedback and parental interaction without the parent needing to touch the patient. .



Light

7.Sliding of bed inside bore

The head coil is slid inside the bore at a fixed distance due to the stops implemented inside the product. This eases the alignment task and removes the necessity to measure the distance of the subject to the middle of the bore and the need to lock the product.



- The handle facilitates the sliding.
- The mattress holder functions as a support for the mattress while also being a natural stop for the bed system be slid inside the bore.
- The transition and sliding mechanism of the bed system into the magnet system is facilitated due to the thermoplastic guide which slides

The IGUS rails of rubber may enter the bore, but the IGUS rails of metal may not enter the bore.

Inside the bed it slides over the rails and inside the bore it slides over the plastic element that serves as guide.

8. Imaging

The monitor allows the MRI technician to see the images

12.7 User experience

This section discusses the visual identity of the MRI scanner.

The product experiences have been taken into consideration from both the perspective of the MRI technician and the patient. The MRI scanner is designed for functionality, therefore the most aesthetics are based on form follows function and empathy. However, through the appearance research the product identity is defined. Appendix R discusses the entire aesthetics research.

By enhancing the procedure of the MRI technician, the critical steps and timespan necessary for each diagnosis can be reduced. The design is focussed on being approachable and comfortable for the user, while evoking a feeling of confidence and professionalism for the MRI technician. For more acceptance of the new device in Uganda, a professional reliable and yet approachable look and feel is necessary. The product appearance has an influence on the patient.
The stakeholders and their requirements can be categorized in the meta, macro and micro levels of product aesthetics design.

Micro – Detail (interact with the product)
The product must indicate the MRI technician to slide the bed inside the bore, and provide an intuitive process to align the head inside the head coil.
By using a well-balanced look of unity and details that indicate the user. The following features improve the intuitive interaction of the product

- Form indications on the head coil for positioning
- Colour indications on the mattress for positioning
- Handle to drag
- Monitor for procedure

Macro- see the product as whole
The MRI scanner needs to have a trustworthy look for the patient to be able to feel comfortable around the product instead of feeling suspicious. The features improve the perception of the MRI scanner for the child is visible in the product identity.

Meta- professional and understandable product that fits in the whole system/market
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. The MRI scanner need a professional appearance to ensure the MRI technician and caretaker that they can rely on the product.
Product identity
The macro and meta levels are visual in the product identity. By analysing diagnostic devices in the market, specific professional medical devices and medical devices for children a uniform product language could be derived.
Unity and harmony is important for a professional look.
The current MRI scanner has a man-made look through the use of different manufacturing processes and materials. By using 3D printing, bent sheet metal and wood, this causes to have an un-harmonic look.

- Openness, transparency
- Colourful accents
- Round shapes
- White and neutral colours
- Integrated features

Figure 12.25 Visual identity of MRI scanner

12.8 Materials and manufacturing

In this section, the main decisions regarding the material, manufacturing process and cost will be explained briefly for each component. To provide a low field MRI scanner that is affordable and accessible, local manufacturing or purchasing is preferred rather than production in a HIC for shipping. Local production is essential to bridge the gap to the access of medical devices [110]. All design considerations can be found in Appendix P.

Manufacturing in LMIC
Local production may not be suitable for every LMIC, therefore a specific study must be done to measure the viability for local production. By taking into account the regional clinical, regulatory requirements and the infrastructural challenges , an evaluation for the correct production technology can be made. However, this does not lie within the scope of the research.
An estimation is made for the production based on local facilities, the mechanical requirements and its feasibility.
In LRS settings, the key challenges with local production lie in the outsources poor quality components; off-the-shelf components are used to allow low volume production; and there is variation in quality provided by local suppliers of outsourced materials. Ideally the choice for local production is made by both locally sourced and imported components and materials.

LF MRI scanner
There are several parts for the low Field MRI scanner that are preferably manufactured locally rather than purchased.
Design for manufacturing principles have been applied to ensure that the part can be made reliably to mechanical requirements, with minimal tooling cost, low parts cost. In the product the principles are visible by – the minimization of parts through the design of multi-functional parts, such as the headrest/immobilization. The use of standard components, such as the electronics rack and aluminium framework, the design for facilitative handling by asymmetrically designing components and the design for ease of alignment.
The electronics and magnet system have been designed to be assembled locally. This is facilitate though open source. The focus has been laid on analysis for production methods for the bed system considering a batch size of 50 pieces.
 The mattress is the part that is prone to wear and thus prone for replacement. Therefore it is chosen to but an off the shelf mattress, and modification it to the correct measurements. A PVC cover is chosen for cleaning the surfaces due to its water resistant and chemical resistant characteristics.

Mattress holder
Vacuum forming is the ideal manufacturing method for the mattress holder, due to the cost-effective process for the production of low volume, large sized parts. No costly equipment and tooling is necessary to produce the large parts due to the low cost moulds and ease of manufacturing large quantities.
The choice of the material (a thermoplastic, PEEK) 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.
Trade-offs among the ease of use, moulding detail, structural strength, solidification and cooling processes were important factors. The mould costs for thermoforming compared to, for example, injection moulding, are relative low. The complexity and material of the mould can cause a significant difference in price. Therefore the mattress holder is designed to be pressed out of a single mould, where-after post-processing offered to additional detail.

Head coil and head immobilizer
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 (5 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-operable MRI scanner which is costly.

Head immobilizer
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 and 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.
Further components such as the tooling and connection parts, the sliding mechanism, framework and straps are purchased
Trespa is used to seal the inner aluminium framework from the embodiment.

Evaluation
The durability of a material is based on its tensile strength, young modulus, yield strength and hardness and its effect during the user scenario. The choice of FDM as production method is questionable due to its decrease in strength. A watertight product might be an issue for cleaning. PLA is not resistant to scrubbing with a soft brush, and lukewarm water with detergent. PP, PC PEEK and aluminium on the other hand is.

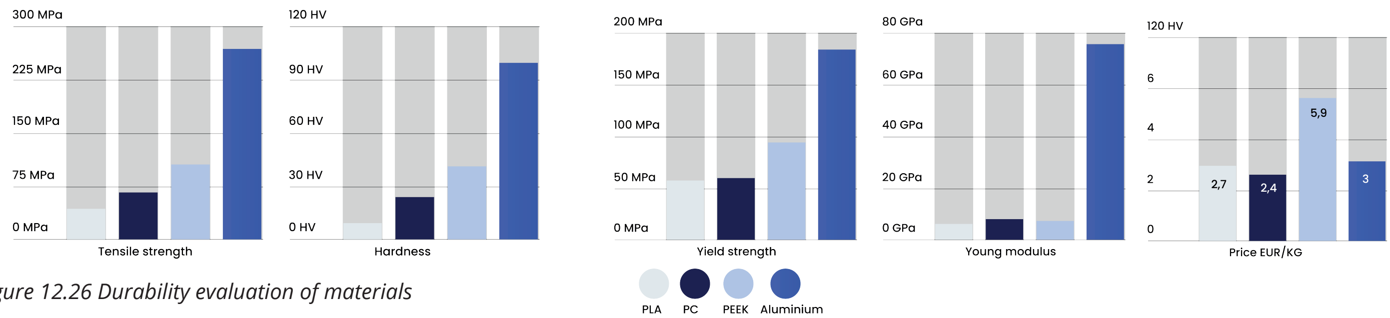


Figure 12.26 Durability evaluation of materials

Deliver

13. Prototpe
14. Business case

13. Prototype

This chapter discusses the prototype building phase. The final result was the functional prototype which captures the essential functional features and underlying principles (Loughborough, 2017). A functional prototype captures both function and appearance of the intended design, though it may be created with different techniques and even different scales from the final design. The final appearance is taken to account on a limited level. The goal of the functional prototype serves as a tool to represent and evaluate the envisioned functionality And user experience. The added value of prototyping and gaining insights during prototyping are discussed as manufacturing evaluations of the concept. An overview of the iterations can be found in Appendix J.

Prototyping is introduced early in the design process to have better stakeholder involvement and to learn from every improvement to deliver a more desirable and feasible product. Stakeholder involvement through prototyping has proven to result in a better designed medical device with a long-lasting life cycle, especially in LMICs [10]. During front-end designs, the stakeholders are engaged to define the problem, elicit requirements, and obtain feedback on early design concepts. The insights gathered from the iterations rounds and the stakeholder meetings resulted in a final prototype.

The final prototype combined separate mock-ups from the parts concept design phase. Developing and researching the functionality of the low field MRI scanner requires high expertise due to the specific boundaries of lower field magnetization. However, this expertise is only necessary during the R&D phase so that the prototyping and manufacturing phases can be done effortlessly.
Prototyping has been done using standardized tools available in LMICs with non-advanced manufacturing methods. For a sophisticated and qualitative finishing, an additional skill was required from the manufacturer. So the overall product can be prototyped, manufactured, and assembled locally; however, the finishing depends highly on the manufacturer's skill. The design is made so that the functionality is not highly dependent on specific tolerances. The electrical parts that are highly specific will be imported from here.

Figure 13.1 Final prototype of bed system with functional magnet system

13.2 Comparision prototype 1 vs. redesign

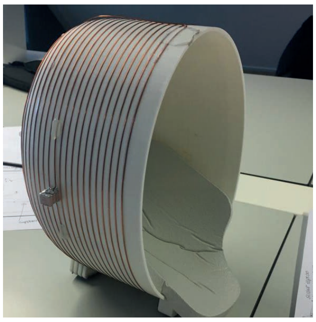


Figure 13.2 Iinitial head coil

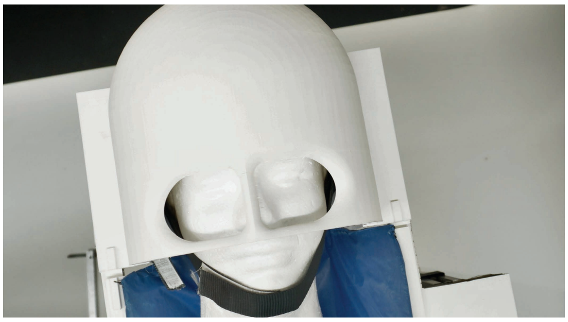


Figure 13.3 Final head coil design

Figure 13.4 Shielding blanket

Figure 13.5 Swaddle blanket

No designed sliding mechanism

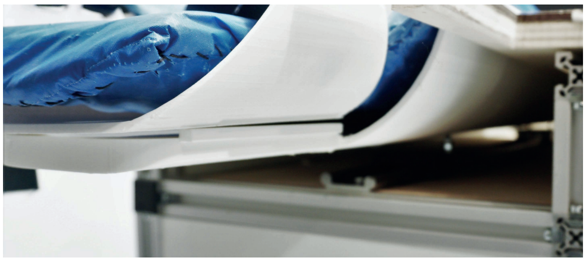


Figure 13.6 sliding mechanism

No designed head immobiliser

Figure 13.7 Head immobiliser

Off shelf hospital bed

Figure 13.8 Concave bed

14. Business case

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

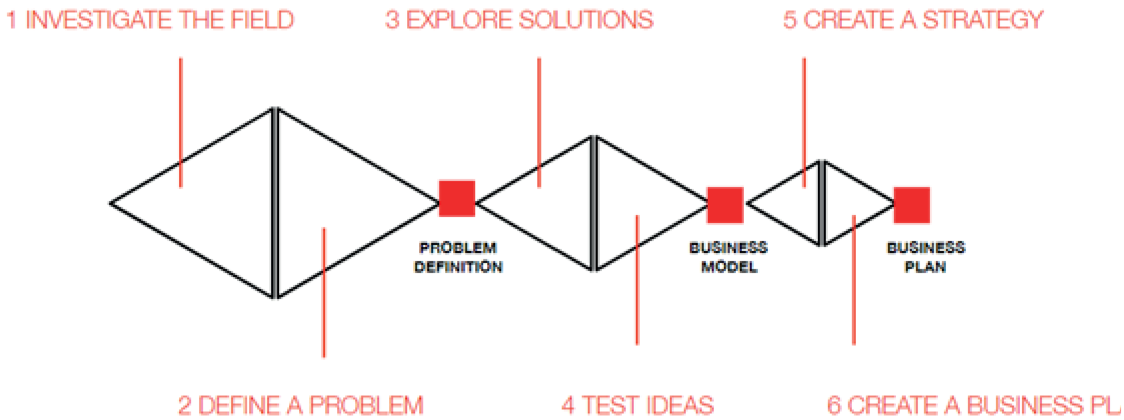


Figure 14.1 Design process including business model

Introduction - Only for TPM Annotation
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 fig 8.1). 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.
Appendix S includes the full Business Model analysis.

BMI • Business model canvas

Key partners

Who are your most important partners?
Which key resources do you acquire from partners?
Which key activities do your partners perform?

- Local hospitals
- Manufacturing sites
- Regulation sites
- Distribution partners
- Main investors
- Research centres (LUMC, MUST, TUDELFT,PSU)
- Dutch government
- Insurance companies

Key activities

What are the activities you perform every day to create & deliver your value proposition?

- R&D - build new products, improve existing products

- Sell MRI scanners
- Support maintanance team
- Platform development

Key resources

What are the resources you need to create & deliver your value proposition?

- Local manufacturing sites
- Hospitals
- Remote manufacturing helps

- Biomech expertise
- IP

Value propositions

2

What is the value you delivery to your customer?
Which of your customer's problems are you helping to solve?
What is the customer need that your value proposition addresses?
What is your promise to your customers?
What are the products and services you create for your customers?

For **patients with Hydrocephalus** I want to provide an improved MRI scanning experience to **prevent movement** during scanning by focusing on the patients **psychological and physical comfort** in the design of a Low Field MRI scanner specifically designed to overcome **the challenges in LMICs.**

This is done through improvements on the **physical ergonomic laying position** and **through reduction of MRI technicians workload**. Through the design and development of the **bed system assembly.**

Customer relationships

What relationship does each customer segment expect you to establish and maintain?

- Through routine service
- Remote repair service
- Sales and post sales support team
- End user network

Channels

4

How does your value proposition reach your customer? Where can your customer buy or use your products or services?

- Local hospitals
- Global sales and support teams
- Multi-product sales force
- Sales team to identify and reach customers

Customer segments

1

For whom are you creating value?
What are the customer segments that either pay, receive or decide on your value proposition?

Children with hydrocephalus of 0-4 years old in SubSaharan Africa

SubSahara african Hospitals

MRI Technicians in hospitals

Caretakers of children

Cost structure

What are the important costs you make to create & delivery your value proposition?

- R&D cost of MRI scanner
- Labour cost
- Manufacturing cost

- FDA approval

Revenue streams

3

How do customers reward you for the value you provide to them?
What are the different revenue models?

- Selling LF MRI scanners products
- Provide training
- Provide a local maintanance and repair service

Brought to you by Business Models Inc

www.businessmodelgeneration.com

Figure 14.2 Business Modell Canvas of curren low field MRI scanner

Evaluation of current business model

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

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 harms the environment as the highly finite supplies of resources are disposed of 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 product iterations. Due to the lack of financial resources in LMICs, such a business model would only be sustainable with government aid and subsidies, donations, and insurance companies.

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

Customer relation

The MRI scanner is marketed to fulfil the customers' needs through product sales. However, this offers the user a high-quality product once the users have reached their goal.

After that, the relationship with the customer is ended. Much attention is put into gaining potential customers and marketing, but no effort is put into maintaining the relationship with this customer. When considering a circular financial model, the customers may maintain the relationship through the contractual service.

Sustainable business models contribute to long-term financial viability

Long-lasting product and business model

The most remarkable difference between 'sell more, sell faster, and Long Life and Access design strategies are the products' (planned) lifetime. '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 (prolonged use). Long Life & Access try to make components repairable by making parts replaceable. 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 designed to be maintained regularly.

New Business model Canvas

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

The savings cost is increased by re-using products and by lowering the manufacturing of additional materials. The obsolete components will remain inside the company and maintain their value or down cycle for other parts. Cost is decreased by stimulation of market availability through recycled materials. such as the magnets..

New opportunity

The long life and access business model will form 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 to use 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 pay not only for the product but also for the routine maintenance, which allows more extended 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. However, challenges arise during the introduction of the circular business model by trying to maintain 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 cash income, the break-even point is reached later. Therefore, profit might also be less relevant in the first stages of introduction. Besides the financial benefits and challenges, training local technicians can provide maintenance services. Nevertheless, again, 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 for the manufacturer because of repair costs. This means the product will probably last longer, and the company provides maintenance service. 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 their services. This is an example of how this shift in responsibility makes the customer's needs identical to the manufacturer's needs, leading 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 is broken, just the parts will get replaced. In addition, the customer relationship will be promoted through post-transactional processes. Through the service feature, the customers are helped with potential problems and questions. Through digitalization, the customer can always rely on the company's service.

Customer relation
This innovation will improve the customer's experience in a way that the customer will pay for a scanning experience. The customer will pay a monthly fee for the product, the service and maintenance and a hardware upgrade after a couple of years. The company will get their primary 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 access to maintenance, a community of service and trained locally available technicians should be present. This could be achieved by providing essential 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 who can repair the product.

The partnerships need to be sustained for this to work well. Challenges could occur in the costs for keeping the functioning of the product. 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 an excellent barrier to accessibility is.

Other challenges that may occur are:

1)The collaboration between the different parties Insurance of products
2) Shifting from a product-oriented to a service-oriented company
3)The logistics behind the leasing system
Once the product proves its quality, the development can continue growing for the HIC, which pays a small amount of the purchase for the low field MRI scanner in LMIC.

Evaluate

15. Evaluation
16. Discussion & Conclusion

15.Evaluation

The evaluation of the concept is supported by 1) the list of requirements and 2) the evaluation based on its viability, feasibility, and desirability for the context. The product is designed to meet the functional requirements. However, due to the lack of resources, a functional evaluation of how well the final design performs is lacking. Therefore, the primary evaluation of the functionality and usability has been through a review with experts. Furthermore, expert meetings and simulated user tests have evaluated the concepts' viability, feasibility, and desirability.

15.1 Validation based on the list of requirements

Based on the list of requirements, the main requirements have been validated and met. Appendix A.2 demonstrates an overview of the main requirements and whether they have been met.

x = requirement is met
~= requirement is partially met
N/a requirement is not met

N0	Main requirement	
	Main Product requirements	
P.1	The device must be able to provide a comfortable position for the patient	x
P.2	The MRI scanner must provide a non-sedating solution to immobilize the patients head with 3 mm in the rotation and translation in 3 axis (x,y,z)	x
P.3	The MRI scanner must promote the physical and psychological comfort of the patient	x
P.4	The MRI scanner must ease the workflow of MRI technicians compared to conventional imaging devices.	x
P.5	The MRI technician must be able to install the patient solely and safely	x
P.6	The dimension of the MRI scanner must not exceed 90 cm *3m due to the limited space in a hospital ward.	x
P.7	The product should enable easy and low-cost installation	~
P.8	The product should prevent heat-loss of the patient	~
P.9	The product should be resistive to dust and water-non-absorbent	~
P.10	The product should allow intuitive operation of the workflow (not obstruct)	x
	Main User requirements	
U.1	The head coil must encompass the entire brain of the patient, which means that it must overlap the eyes and the upper spinal area (C2).	x
U.2	The caretaker must be in close interaction with the patient before and after the diagnosing.	x
U.3	The MRI scanner must be able to scan patients with head circumference between 50 and 60 cm and 30 cm to 1.20m body length	x

N0	Main requirement	
	Main Context requirements	
C.1	The LF MRi scanner must be cost-effective in purchase (<€50.000) and in cost of ownership.	~
C.2	The LF MRI scanner must be able to be assembled and produced locally	~
C.3	The LF MRI scanner must match the knowledge level of basic trained personnel	N/A
C.4	Potential spare parts should easily be attainable	x
C.5	The device requires taking into account relying on sub-standard facilities for use and maintenance.	
C.6	The device must be repairable with commonly available tools.	x
C.7	Cleaning of the device should be attainable with basic cleaning equipment.	~
	Main Technologic requirements	
T.1	The head coil must be at proximity of the subject of interest	x
T.2	The head of 50 - 60 cm circumference must be able to be aligned concentrically inside the bore at distance of 250mm from the opening.	x
T.3	No ferromagnetic materials may enter the bore or may be at proximity of 100mm of the bore opening	x
T.4	The electronic component must run from standard power outlets and be ultimately battery,solar,diesel powered.	x
T.5	The temperature inside the magnet must stay stable (drift less than 1 degree per hour)	x
T.6	No forces higher than 10N may be exerted on the magnet.	~
T.7	No environmental dust or liquids must be able to enter inside the magnet system.	x
T.8	The RF could should be connected with the magnet	x

15.2 Prototype and stakeholder validation

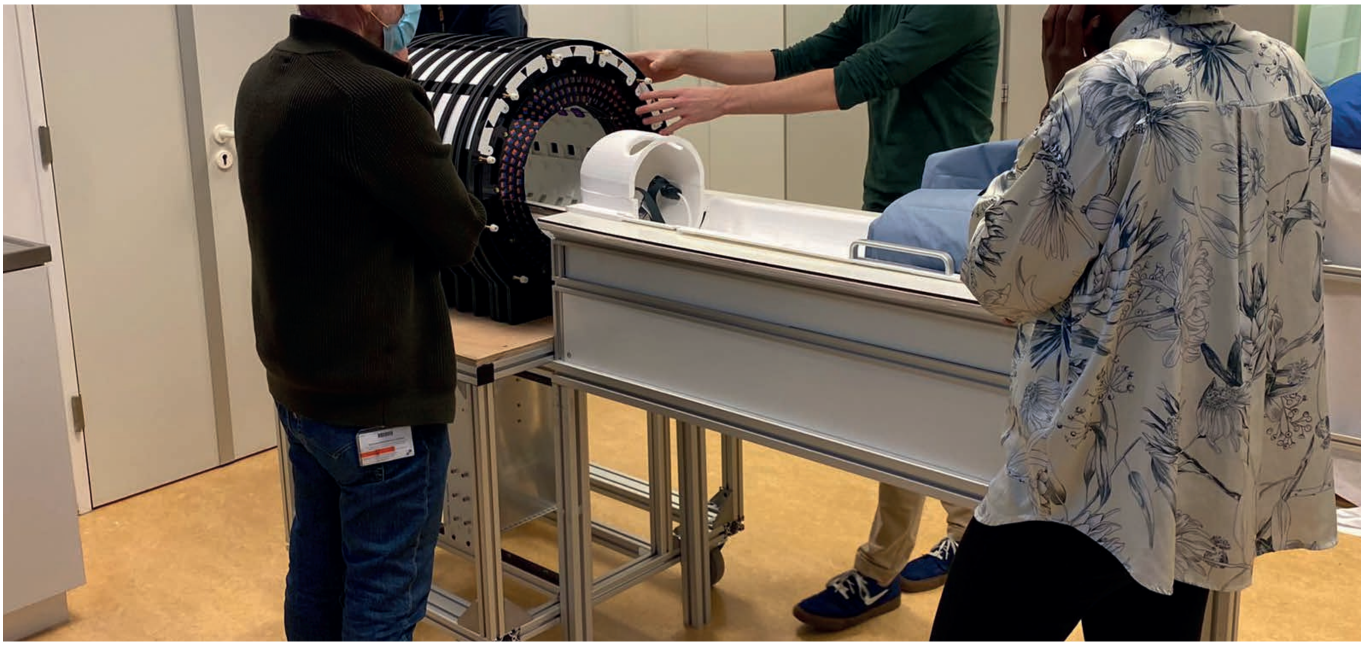


Figure 15.1 Usability testing of prototype with MRI usability expert & technical expert

Method
The validation of the concept was performed through usability testing with the prototype (online and in real life). In addition, the concept's desirability, feasibility, and viability are validated through interviews, concept discussion, usability testing, and prototype demonstration. The desirability can be subdivided into the patient and the MRI technician's desirability. Both have been tested through the presentation and simulation of the prototype.

16.2.1 Validation – patient desirability and viability

Based on a concept review with Dr Schiff, neurosurgeon, and expert in treating paediatric patients with severe brain conditions(also in Uganda), the final concept is reviewed on its fit for the context, desirability with children with hydrocephalus and business prospect. The concept review had the format of a concept presentation and user scenario with the prototype, followed by a structured discussion on all designed points.

The objective of the validation meeting was to define whether the concept would be acceptable for the envisioned stakeholders (patient with hydrocephalus, MRI technician) and fulfil the desired outcomes.

Patient Desirability
Overall the concept contributes to a safe and comfortable operation for the patient to be scanned.
The concept includes all necessary features and components to support the MRI technician in operating the device, especially providing comfort assistance.
The focus on comforting non-sedated children of the ages 0-4 years old is a significant benefit due to the lack of functioning alternatives.
The design output to improve psychological comfort has a great prospect of working well, especially since the current solutions are not precisely focussed on the context and the variety in age.
The design output that aims to improve physical comfort is a bit questionable, based on the experience of prior equipment that confines the head of the patient.

Product strengths
The parts in the concept that will have a beneficial effect are the swaddling effect of the blanket. The children love to be swaddled, which will significantly affect their comfort. Furthermore, children get hysterical in a confined space, so introducing the double mirror to enlarge the space and see the parent will significantly affect the patient's mood. This could develop further by introducing a monitoring system that allows the MRI technician to see the face of the patient. Unfortunately, cameras and other technologies are not compatible with low field MRI scanning.

The concave nature of the bed and the additional supports will have a significant effect on the patient's position and safety.

Weaknesses and opportunities
Questionable features are the confining holder and the straps of the head immobiliser. Experiences have proven that children do not like their heads to be confined. This is also the case with the head coil, which is close to the head. However, the constrain boundaries and design boundaries have been set due to the technological requirements. A non-constraining head coil and head immobiliser would be preferable; however, this would only be feasible in the future once the technology has improved.

Viability
The product features allow great value for the patient, the MRI technician and the society. However, for a viability analysis, the sustained value for the society must be evaluated, which requires a suitable business plan. Currently, the misconception is made that lowering the cost of the medical device to become procurable increases accessibility and acceptability. In one way, it does; however, the added value and the position of such a device inside the infrastructure is of more significant influence. Its desirability and increase of value in the community may indicate how viable a product will be.

An accurate value evaluation can be performed by considering the labour, transport, infrastructure, and maintenance cost besides purchase.
For example, the low field MRI scanner has a significant advantage over high-cost imaging devices due to the low cost. Furthermore, the advantage of the CT scanner is the lack of dangerous radiation. However, the low field MRI scanner is a small value high margin equipment. Moreover, it requires highly trained personnel to make the low field since it is highly specific. In this case cost of personnel increases the purchase cost if labour is considered.
Therefore, when investigating further the health economics of the low field MRI scanner operating in LMICs, it can be seen that the business model is not profitable for the entrepreneurs.
Therefore, a more circular business model and sustainable revenue stream are potential. However, it requires much research on health economics, which includes the total life cycle cost.
Furthermore, the viability may also be increased with awareness of the disease and its treatment.
A lot is done to prevent hydrocephalus and bring awareness inside the LMIC to ensure that people get treatment. Further research needs to be done to assess the actual value for society and economic viability.

Figure 15.2 Usability testing of prototype with model

Figure 15.3 Swaddling

Figure 15.3 Bed system

15.2.2 Validation – patient MRI desirability and feasibility

Based on a live prototype and usability review with the MRI researcher C.J. Gorter Center for High Field MRI, PhD and designer of low field MRI magnet system, and Professor of C.J.Gorter MRI Centre, the final concept is reviewed on its fit for with the magnet system that is designed at the LUMC and its ease of use. The concept review had the format of a concept presentation and a feasibility discussion about the technology, and a user test.

The objective of the validation meeting was to The MRI scanner's desirability is tested by introducing an MRI technician to use the product. The technological feasibility consist of a review of the designed system in relation to the estimated effect on the image quality. The experts are consulted to evaluate whether the introduced feature will not interfere with the low field MRI.

General evaluation

The design of the concept covers all necessary points and creates a good solution for the narrow requirements from the technology while it does not compromise on the comfort for the child and additional effort for the MRI technician. Furthermore, the parts that add to a good comfort, such as the mattress's concave shape, are well producible locally. The additional benefit of the mattress's shape is the use of minimal volume once inserted inside the bore.

Product Feasibility
Strengths

Very important is that the force on the magnet is minimised.
By the tabletop design that allows the head coil to slide over it and is directly positioned at the correct height, no forces are exerted on the magnet system. In addition, the choice of not using a bridge system that connects the sliding system of the bed and the head coil is beneficial to minimise the transfer of forces and ease the docking and alignment.
This tabletop design offers the necessary support for the tabletop and the head coil without transferring forces on the bore.
The alignment of the head coil and the tabletop offer a good height and correct dimension to operate on the tabletop, while the table is exactly outlined in the correct position.

Limitations and opportunities

Questions arise if the sliding mechanism is necessary and can be supported by a rolling system on the tabletop since the sliding of the mattress holder offers enough friction for a lubrication-free translation of the bed. However, the sliding mechanism offers additional durability to the system and is enclosed inside the Trespa box, which keeps dust and humidity out.

Head immobilizer
The head immobiliser must be supported thoroughly on a system due to the possibility of the child that may lift its head. The head immobiliser can be fixated on the mattress.

Swaddle blanket
An outstanding concept includes three features (immobilising, comforting, shielding) and replaces the current expensive and uncomfortable shield. The blanket aluminium grid inside the blanket must be connected to ensure technical feasibility. The swaddle blanket needs to be at a certain distance from the RF coil. To make sure the swaddle blanket remains outside of the bore.

Desirability for MRI technician
Strengths

The usability will not obstruct the workflow of the MRI technician. The significant difference will be that the MRI technician will have more attention for the patient than the device.

Comfortable workload
The table height is very comfortable, and you have an overall view of the patient and the monitor while working on this height.
The MRI scanner provides a shift from focussing on the equipment to focussing more on the patient. The patient can be prepared by providing all accessories on the bed, and the scanning can start directly. The advantage is that the MRI technician is more focused on the patient while operating. In addition, the drawer beneath the bed is a comfortable positioning.

However, the low field MRI scanner is a device that can only function under precise boundaries, so the ability of the MRI scanner to "guide the MRI technician" as stated in the design vision is influenced by the interface and user experience design. Therefore, the UX and interface design can greatly influence the device.

Opportunities
Installation
For the bed to function accordingly, it is necessary to align with the magnet. The bed does not need to be flush with the ground but be parallel to the magnet. The MRI technician or the person who operates it needs to check this. Additional use cues can be implemented to ensure that the MRI technician correctly aligns the tabletop to the magnet system.

Figure 15.4 Double mirror

Figure 15.5 Sliding system of mattress, immobiliser and head coil. Fixed with form fit

Figure 15.6 Bed system fits exactly in magnet system

15.2.3 Overall desirability,viability and feasibility

1. Can it be done ? Feasibility

The final design has proven to minimise the head movement in 6DOF and decreased the movement by 68%. However, it was impossible to do a full assessment to see if the head did not move more than 3 mm. In addition, due to the lack of prototyping skills and materials, the prototype was not made precisely as it was designed.

Overall feasibility

The technical feasibility of the concept is much doable considering the implemented technology, which is relatively frugal, the production methods and materials. However, more research could be done within the production methods to achieve better tolerances and perhaps the implementation of more automated technology to ease the task of the MRI technician. Furthermore, the technology has been kept as low as possible. The noise-cancelling feature of the swaddle blanket must be evaluated and tested how thick the aluminium grates must be and how finite the grid must be to offer a The effect of the implemented concepts must be evaluated during clinical trials to assess the cancellation or produced noise within the concept.

2. Does it bring value? Desirability

Evaluation of the concepts' desirability is essential to assess the added value of the concept for the MRI technician, the patient with hydrocephalus and the caretaker. The concept is designed by considering the values and needs of the stakeholders; however, to what extent the concept meets the values and needs is not measured but estimated through understanding and interpreting through interviews and biomechanical pressure.

Overall desirability

To understand whether the concept can be assessed as desirable for the patient, involving patients with hydrocephalus during the experimenting and data collection is necessary. Through pressure measurements with the concept and healthy children, a rough simulation has proved the minimisation of discomfort through the distribution of load on the critical anatomical areas of the patient However, patients with hydrocephalus experience a slightly different load on their bodies due to the enlarged ventricles in the head. Therefore, a subjective rating is combined with an objective pressure measurement to assess comfort. However, the subjective rating did not result in valuable data since the target group of 0-4 years old is not responsive to questionnaires.

The aesthetics of the MRI scanner have been made intimidating while remaining the professional" look" by providing soft curves with a sleek surface. In addition, by implementing the light inside the bore, the patient's state of mind is eased.

The target of success for the MRI technician could be that the MRI technician can perform the process of scanning in less time and effort than previously, with less training and The MRI technician may be tasked with more procedures prior to the scanning, such as swaddling the patient and adjusting the mirror for the patient. However, the patient is calmer due to the different procedures, allowing the patient to remain settled and not move. This prevents repetitive scanning, effort to keep the patient still and thus a quicker scanning time, which is beneficial for the patient, MRI technician and the hospital who can plan more patients in the 1-time slot.

Finally, the procurer of the hospital is not only able to purchase an MRI scanner but also to maintain it and repair it locally. This has an added value because the cost of ownership of the MRI scanner is one of the barriers to why the accessibility of the MRI scanner is low. Furthermore, the equipment can be used in different wards inside the hospital, so no ward must be specially reserved and preserved for the equipment.

3. Will it sustain? Viability

Through the assembly of a multi-disciplinary team and by defining a specific future vision and goals, the future success of the MRI scanner can be developed and supported. The product's viability is based on how much value the concept provides the user and the resource through the business plan.

Overall viability

A proper estimation can be made by assessing the business model, estimating manufacturing cost, how money can be made from it, and when it will be profitable in the future through market research in Uganda and other Sub Saharan countries.

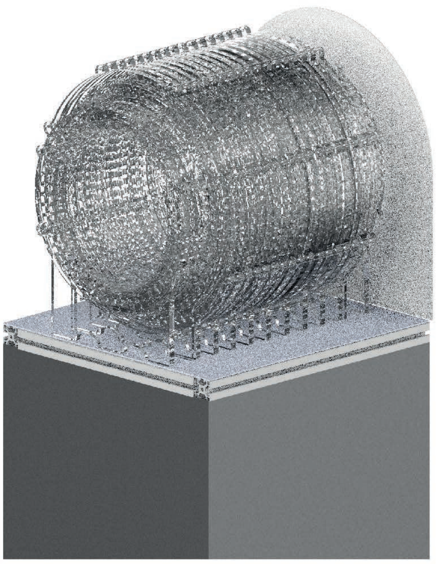
Figure 15.7 Patient with hydrocephalus in Cure hospital [65]

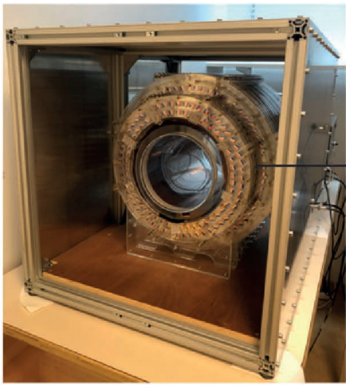
Figure 15.8 Low Field MRI scanner sustains in hospital in LMIC

Evaluation

Goal evaluation

System specific improvements





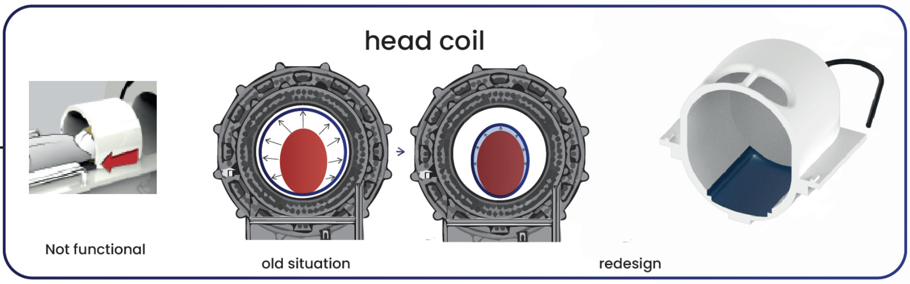
Prototype

Version 3 low field MRI scanner

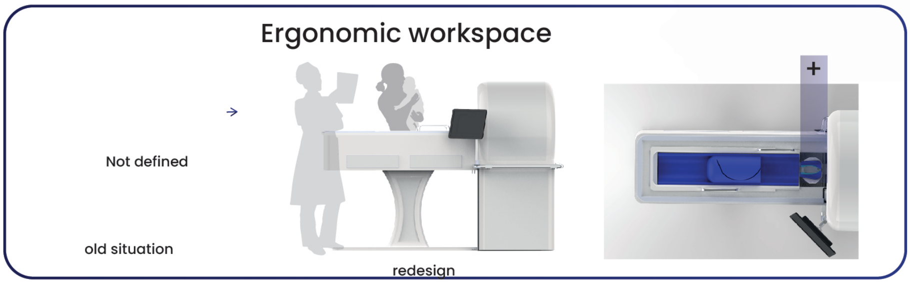
Prototype

HydroCare, low field MRI

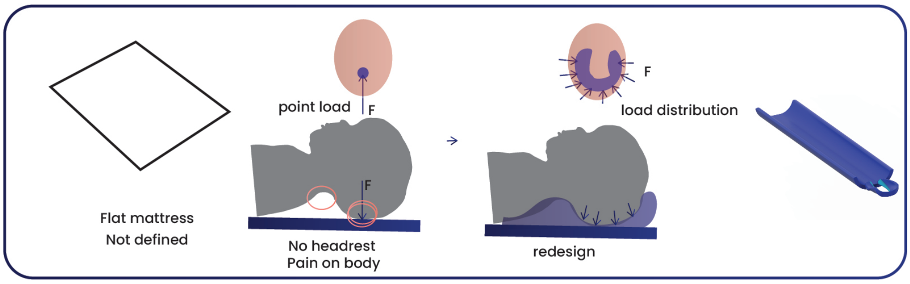
Part specific improvements



Oval shaped head coil
Increased SNR through
- the larger effective size in the bore (300mm)
- Closer proximity of RF coil to head
- Better ergonomic fit



Headcoil placement
Positioning of patient
- work heigh of 90 cm
- Improvement of workspace of 0 cm to 30 cm space



Head rest + concave bed
- Reduce of pressure on head
from 54mmHg to 4 mmHg

Head immobilizer
- Reduce movement with 80%

Swaddle
- Comfort child
- Does not obstruct airflow
- Cage of Faraday

Double mirror
- Increases FoV of patient
- Connects caretaker with patient

system/mechanism

inner and outer frame
System

16.Discussion & Conclusion

16.1. Discussion

Reflection on design challenge

The design goal has been to design and develop a user-centred and sustainable low field MRI scanner that improves the scanning experience for hydrocephalus patients between 0-4 years old by improving the comfort comfortable and reducing the workflow of the MRI technician.
Focussed is to immobilise by comforting the child. The most considerable movement can be prevented when the child is laid comfortable. After this movement is prevented, a head immobiliser is introduced to ensure the heads immobilisation.

1) Although the bed design system has been designed with the anatomy, physical characteristics, behavioural characteristics, values and pinpoints of hydrocephalus patients in mind, the comfort is very challenging to assess, especially for non-responsive patients of a young age. However, the design has optimally met the physical and psychological needs for the patient to be comfortable. The outcomes were evaluated with experts.
2) The ability to reduce the workload for the MRI technician has been approached from a conceptual perspective rather than looking at the process-specific tasks. The introduction of a system that comforts the patient replaces this challenging task for the MRI technician to interact with the patient. This eventually results in an improved patient outcome. In addition, by integrating all additional parts inside the bed instead of adding accessories, sorting out the proper support is eased. It might seem that the overall workload has increased with the additional blanket. However, the beneficial outcome of the patient lying comfortable and motionless results in eliminating reoccurring MRI scans caused by motion.

The design was set out to develop a conceptual design that meets level 3 of the TRL. The new design successfully integrates all necessary parts, evaluates the ability of manufacturability in Uganda and accomplishes the lacking features required for safe and effective use of the low field MRI scanner.

Limitations
A detailed overview of how to install and manufacture the parts is essential to evaluate the local manufacturability of the equipment. However, this part is missing due to the lack of data from context. In addition, the evaluation of how the concept is translated to different head sizes and body-sized sizes would be valuable. A cost overview and material simulation inside of the context should be made.

Strengths
The manufacturing and installation have been designed to meet its specific requirement to be performed with basic tooling. This has been party validated during the prototype building, where minimal non-advanced equipment was available. Furthermore, much effort has been made during the magnet system design to increase the space inside of the bore. The implemented mattress holder shape combined with the sliding mechanism saves space inside the bore. Due to this, the MRI scanner is available to larger children due to the larger space inside the bore. A well overall trade-off has been made between the technical restrictions, the stakeholder desires and the challenging contextual requirements. The LUMC has mentioned incorporating the design of the bed system in the final design of the low field MRI scanner.

Relevance for design context
Overall, by implementing these solutions in the design of the low field, the availability and accessibility of good quality healthcare in LMICs are improved. In addition, the number of children that can be scanned is increased by the more extended durability of the device and lower workload of the MRI technician. As a result, it contributes to the decrease of hydrocephalus in LMICs.

16.2 Recommendation

Installation
Considering op placing wheels
The ability to carry the prototype has been tested during the usability test at the LUMC. It was possible to carry the bed assembly with two people; however, wheels should ease the task.

Alignment
Alignment is an essential factor for the proper functioning of the MRI scanner. Since the magnet system and the bed system are two separate parts docked together, an alignment system should be considered, which eases the task for the bed to be aligned with the magnet. This can be done by providing a stroke going from the aluminium profile on the bed assembly going to the magnet assembly. This alignment system should be visible for the one installing. Otherwise, all imaging will be misplaced.

Certification and regulation
Additional rules and requirements for certification and regulation need to be considered prior to the delivery of the device.

Material selection
The material selection for the parts should consider locally used chemicals and a durability test. For example, the head coil is the most prone to break in available MRI scanners, requiring frequent replacement and repair. Therefore, the manufacturing method and material choice is 3D printed of PLA. However, material durability and washability are not considered within this selection. Initiatives exist that allow PLA of 3D printed parts to be suitable for medical use in LMICs. However, an improved material selection could be PPE due to the device's local manufacturing and wash-ability purposes. However, the durability of the PPE depends highly on its washability and the way of printing. This is out of the scope and a factor that needs to be researched further.

Parts
Sliding mechanism
When the bed is slid inside the bore, the end of the bed is covered with a fold-able sheet to prevent dirt and humidity from entering the sliding mechanism. However, this part is not watertight or durable. Therefore, an alternative should be considered.

Fixation of position
Once the patient is slid inside the bore and correctly positioned, the bed must be fixated to prevent shifting of the bed position during a sudden patient movement. This can be done by providing a notch that would fall into place due to gravity when the correct position of the bed is achieved.

Head immobilizer
The head immobiliser has proven to be the best option of all concepts to prevent head movement. However, since the comfort rate for paediatric patients is not assessed, estimation is done during the design of the parts. According to the paediatric neurosurgeon, straps are not child-friendly. Straps are parts over the head that may cause discomfort to the patient. Other immobilising alternatives such as pneumatics currently offer the needed comfort with the necessary immobilisation. However, this alternative is high in maintenance and thus unsuitable for LRS. Pneumatic component costs are low, but maintenance and operating costs can be high. Currently, no adequate solution offers optimal patient comfort, low cost, and low maintenance in a non-confining way.

Head coil
Confined spaces, such as the head coil over the head of the patient, can cause discomfort with the patient. An alternative for open RF coil solutions exists; however, the technology needs more years of research before achieving this.

Wireless head coil
To prevent the wires of the head coil from obstructing the workplace of the MRI technician while positioning the head of the patient, a wireless head coil could be a possibility.

Double mirror
By enlarging the visual space through a dome-shaped mirror, the reflection mirror and the field of view could be broadened. Currently, the space of the mirror is narrow.

Swaddle blanket
Since scientific research in the swaddle technique is preliminary and scarce, observations have served as the most prominent research methodology, besides the pressure and the tightness of the blanket around the infant's body.
The length of the swaddle blanket could be too oversized for a younger patient, which would require the blanket to be wrapped around the patient multiple times. Multiple blanket sizes or an adjustable blanket could be implemented as a solution. Furthermore, the aluminium grid contributes to the preformed shape of the blanket when opened up. This requires four hands to position the patient. An additional Velcro strap can be added to secure the blanket before positioning the child.
In this way, the patient can be positioned by one MRI technician. Essential factors also include the mother's breathing that is calming the child. The temperature and the scent of the mother and the shape of the back of the mother.
These factors could be implemented in an updated version of the blanket.

16.3 Conclusion

This chapter will conclude the study by summarising the key research findings concerning the research aims and questions and discussing the value and contribution. It will also review the study's limitations and propose opportunities for future research.

This study aimed to investigate three primary factors, which were ;

- The main challenge that was most important, valuable, and urgent to solve was the development of the LF MRI scanner.
- To define what factors and components were necessary to contribute to the solution of this problem.
- To address the challenges concerning the product development of the bed system and the integration in the complete design of the LF MRI scanner.

This thesis defined that motion of the child was the most crucial challenge to solve within the current development phase of the low field MRI scanner. The solution's added value has a significant effect on the clinical outcome, the patient experience, and the accessibility of MR Imaging in LMICs. Without the addressing of this challenge, brain imaging could not be possible.

Based on literate research, and stakeholder involvement with prototyping, it can be concluded that patient experience is best promoted when comfort is considered when designing for paediatric patients. Furthermore, the results indicate that the main factors contributing to the patient's immobilisation are suitable for implementation in a low resource setting are; a pressure distributive concave mattress, a head-immobiliser, a double mirror, and a swaddle blanket.

Further findings show that for integrating the product components into the entire system of the MRI scanner for a low resource setting, it is essential to consider modularity, standardised parts and local production.

The strength of this research is the high involvement of stakeholders, experts and users throughout the research and design procedure. Researcher bias is minimised by involving stakeholders and experts in each phase of the design cycle. As a result, minimal assumptions were made, and most design implementations have been verified with experts, validated by users and tested with prototypes and user testing.

The lack of access to research equipment leads to a comparative comfort measurement. Furthermore, the sample size of the experiments was too small to determine a significant effect. Furthermore comfort is highly subjective and can not be validated by solely experimenting and measurements.

The design of the bed successfully improves the patients' experience and minimises, therefore, the workload of the MRI technician. As a result, the procedure can be done by essential trained personnel. From a technical perspective, the design of the bed system safes spaces inside the bore while maintaining an excellent qualitative image.

17. Bibliography

[1] World Health Organization. "Medical Devices". Who. Int, 2022, https://www.who.int/health-topics/medical-devices Retrieved on February 2021

[2] P. Labarre, "Engineering global health," IEEE Pulse, vol. 2, pp. 18–25, 1 2011.

[3] R. A. Malkin, "Barriers for medical devices for the developing world," Expert Rev. Med. Devices, vol. 4, no. 6, pp. 759–763, 2007.

[4] A. Vasan and J. Friend, "Medical Devices for Low- and Middle-Income Countries: A Review and Directions for Development," Journal of Medical Devices, 2020.

[5] "Health equipment - Magnetic resonance imaging (MRI) units - OECD Data," 2020.

[6] J. P. Marques, F. F. Simonis, and A. G. Webb, "Low MRI: An MR physics perspective,"
Journal of Magnetic Resonance Imaging, vol. 49, pp. 1528–1542, 6 2019.

[7] J. Obungoloch, J. R. Harper, S. Consevage, I. M. Savukov, . Thomas Neuberger,
S. Tadigadapa, magnetic resonance imaging system for infant hydrocephalus," Magnetic Resonance Materials in Physics, Biology and Medicine, vol. 31, pp. 665–676, 2018.

[8] M. C. Nemery and J. B. Mortensen, "Patient comfort leads to first-time-right imaging," Philips Gield Strength ISMRM, 2015.

[9] M. Héder, "From NASA to EU: the evolution of the TRL scale in Public Sector Innovation," The Innovation Journal: The Public Sector Innovation Journal, vol. 22, no. 2, p. 3, 2017.

[10] L. Wroblewski, Designing Web Interfaces . Wiley: Rosenfeld Media, 2008.

[11] K. Ma and Z. Qi, "A human-centred design of general-purpose unmanned electric vehicle chassis for agriculture task payload," Journal of Computing and Information Science in Engineering, vol. 17, 9 2017.

[12] World Health Organization, "Medical Devices: Managing the Mismatch : an Outcome of the Priority Medical ... -," 2010.

[13] N. Radjou, J. Prabhu, and P. Polman, Frugal Innovation: How to do more with less :. Economist Books, 2015.

[14] Breene, R Timothy S et al. "The chief strategy officer." Harvard business review vol. 85,10. 84-93, 164, 2007.

[15] R. A. Malkin, "Technologies for clinically relevant physiological measurements in developing countries," 8 2007.

[16] R. A. Malkin, "Design of health care technologies for the developing world," 2007.

[17] R. Neighbour and R. Eltringham, "The reality of designing appropriate 'Low cost' medical products for developing countries and their unintended consequences," in IET Conference Publications, vol. 2014, Institution of Engineering and Technology, 2014.

[18] F. A. Vollenbroek, "Sustainable development and the challenge of innovation," Journal of Cleaner Production, vol. 10, pp. 215–223, 6 2002.

[19] M. Arnold, "Fostering sustainability by linking co-creation and relationship management concepts," Journal of Cleaner production, 2015.

[20] P. Rathore, S. Kota, and A. Chakrabarti, "Sustainability through remanufacturing in India: A case study on mobile handsets," Journal of Cleaner Production, vol. 19, no. 15, pp. 1709–1722, 2011.

[21] R. W. Kates, T. M. Parris, and A. A. Leiserowitz, "What is sustainable development? Goals, indicators, values, and practice," Environment, vol. 47, pp. 8–21, 4 2005.

[22] T. Barlow, Design for Maintainability in Developing Communities-A Case Study on the Uros Islands BYU ScholarsArchive Citation. PhD thesis, Brigham Young University, Brigham, 2018.

[23] P. Howitt, A. Darzi, G. Z. Yang, H. Ashrafian, R. Atun, , "Technologies for global health," 8 2012.

[24] R. M. Oosting, J. Dankelman, L. S. Wauben, J. Madete, and R. S. Groen, "Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide," in GHTC 2018 - IEEE Global Humanitarian Technology Conference, Proceedings, Institute of Electrical and Electronics Engineers Inc., 1 2019.

[25] B. Ploss, T. S. Douglas, M. Glucksberg, E. E. Kaufmann, R. A. Malkin, J. McGrath,
T. Mkandawire, M. Oden, A. Osuntoki, A. Rollins, K. Sienko, R. T. Ssekitoleko, and W. Reichert, "Part II: U.S.—Sub-Saharan Africa Educational Partnerships for Medical Device Design," 11 2017.

[26] P. Carayon, "Human factors of complex sociotechnical systems," Applied Ergonomics, vol. 37, pp. 525–535, 7 2006.

[27] . M. Larson, D. E., Mayo Clinic Familiy Health book, vol. 6th ed. New York: W. Morrow., 1990. Print.

[28] R. Farb and . Rovira, "Hydrocephalus and CSF Disorders," in Diseases of the Brain, Head and Neck, Spine, ch. 2, pp. 11–24, IDKD Springer Serie, 2020.

[29] K. T. Kahle, A. V. Kulkarni, D. D. Limbrick, and B. C. Warf, "Hydrocephalus in children," The Lancet, vol. 387, pp. 788–799, 2 2016.

[30] P. Krishnan, C. Raybaud, S. Palasamudram, and M. Shroff, "Neuroimaging in Paediatric Hydrocephalus," 10 2019.

[31] M. M. Santos, D. K. Rubagumya, I. Dominic, A. Brighton, S. Colombe, P. O'Donnell, M. R. Zubkov, and R. Härtl, "Infant hydrocephalus in sub-Saharan Africa: the reality on the Tanzanian side of the lake," Journal of neurosurgery. Paediatrics, vol. 20, pp. 423–431, 11 2017.

[32] B. C. Warf, "Paediatric hydrocephalus in east Africa: Prevalence, causes, treatments, and strategies for the future," World Neurosurgery, vol. 73, no. 4, pp. 296–300, 2010.

[33] B. C. Warf, "Hydrocephalus associated with neural tube defects: Characteristics, management, and outcome in sub-Saharan Africa," Child's Nervous System, vol. 27, pp. 1589–1594, 10 2011.

[34] S. J. Schiff, S. L. Ranjeva, T. D. Sauer, and B. C. Warf, "Rainfall drives hydrocephalus in East Africa: Clinical article," Journal of Neurosurgery: Paediatrics, vol. 10, pp. 161–167, 9 2012.

[35] "Hydrocephalus Fact Sheet | National Institute of Neurological Disorders and Stroke." Hydrocephalus Fact Sheet, 15 Nov. 2021, www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Hydrocephalus-Fact-Sheet#3125_9.

[36] M. Gmeiner, H. Wagner, C. Zacherl, P. Polanski, C. Auer, W. J. van Ouwerkerk, and K. Holl, "Long-term mortality rates in paediatric hydrocephalus-a retrospective single-center study," Child's nervous system : ChNS : official journal of the International Society for Paediatric Neurosurgery, vol. 33, pp. 101–109, 1 2017.

[37] Z. Wright, T. W. Larrew, and R. Eskandari, "Paediatric hydrocephalus: Current state of diagnosis and treatment," Paediatrics in Review, vol. 37, pp. 478–488, 11 2016.

[38] A. Dinçer and M. M. Özek, "Radiologic evaluation of paediatric hydrocephalus," Child's nervous system : ChNS : official journal of the International Society for Paediatric Neurosurgery, vol. 27, pp. 1543–1562, 10 2011.

[39] F. Van Doesum, M. I. Bakker, M. F. Client, and M. B. Van Gijzen, "MRI FOR AFRICA THE DESIGN OF AN MRI FOR THE DIAGNOSIS OF INFANT HYDROCEPHALUS IN UGANDAN HOSPITALS," Delft University of Technology, Delft, 2020.

[40] M. I. Abubakar and Q. Wang, "Key human factors and their effects on human centred assembly performance," International Journal of Industrial Ergonomics, vol. 69, pp. 48–57, 1 2019.

[41] D. F. Huelke, "An Overview of Anatomical Considerations of Infants and Children in the Adult World of Automobile Safety Design," Annual Proceedings / Association for the Advancement of Automotive Medicine, vol. 42, p. 93, 1998.

[42] A. Talebian, B. Soltani, A. Moravveji, L. Salamati, and M. Davami, "A study on causes and types of abnormal increase in infants' head circumference in kashan/iran.," Iranian journal of child neurology, vol. 7, no. 3, pp. 28–33, 2013.

[43] E. Mbabazi (Director of Research), "Interview Cure Hospital," 2021.

[44] "Determination of Centers of Gravity of Children, Sitting and Standing - John J. Swearingen, Joseph W. Young - Google Boeken."

[45] N. Dr. Van Der Aa, "Interview," 2020.

[46] L. Dr. Gieskes, "Interview," 2020.

[47] J. Y. M. Lee and E. A. Morris, "Breast Magnetic Resonance Imaging: Historical Overview," in
Breast MRI, pp. 3–6, Springer-Verlag, 12 2005.

[48] P. Dais and A. Spyros, "Nuclear Magnetic Resonance," in Chemical Analysis of Food: Techniques and Applications, pp. 91–115, Elsevier Inc., 1 2012.

[49] E. Furlani, Permanent Magnet and Electromechanical Devices -Materials,Analysis and Applications. . Academic Press Series in Electromagnetism, 1st edition ed., 8 2001.

[50] "Magnetic Resonance Imaging (MRI)." Magnetic

Resonance Imaging, www.nibib.nih.gov/science-education/science-topics/magnetic-resonance-imaging-mri. Accessed 10 Feb. 2021.

[51] A. Berger. “Magnetic resonance imaging.” BMJ (Clinical research ed.) vol. 324,7328 (2002): 35. doi:10.1136/bmj.324.7328.35

[52] K. R. Maravilla and W. A. Cohen, “Normal Anatomy and Variants,” in MRI Atlas Orthopedics and Neurosurgery The Spine, pp. 1–10, Springer Berlin Heidelberg, 4 2007.

[53] M. Sarracanie, C. D. Lapierre, N. Salameh, D. E. Waddington, T. Witzel, and M. S. Rosen, “Low-Cost High-Performance MRI,” Scientific Reports 2015 5:1, vol. 5, pp. 1–9, 10 2015.

[54] C. Zimmerman Cooley, M. W. Haskell, S. F. Cauley, C. Sappo, C. D. Lapierre, C. G. Ha, J. P. Stockmann, and L. L. Wald, “Design of sparse halbach magnet arrays for portable MRI using a genetic algorithm,” IEEE Transactions on Magnetics, vol. 54, 10 2017.

[55] K. van Schuylenbergh and R. Puers, Inductive Powering Basic Theory and Applica-tion to Biomedical Systems, 41 Analog Circuits and Signal Processing, 41–76. Springer Netherlands, 2009.

[56] K. Halbach, “Design of permanent multipole magnets with oriented rare earth cobalt material,” Nuclear Instruments and Methods, vol. 169, pp. 1–10, 2 1980.

[57] M. L. de Leeuw den Bouter, M. B. van Gijzen, and R. F. Remis, “Conjugate gradient variants for-regularized image reconstruction in low-field MRI,” SN Applied Sciences, vol. 1, pp. 1–15, 12 2019.

[58] B. De Vos, P. Fuchs, T. O’Reilly, A. Webb, and R. Remis, “Gradient Coil Design and Realization for a Halbach-Based MRI System,” IEEE Transactions on Magnetics, vol. 56, 3 2020.

[59] T. O’Reilly, W. M. Teeuwisse, D. d. Gans, K. Koolstra, and A. G. Webb, “In vivo 3D brain and extremity MRI at 50 mT using a permanent magnet Halbach array,” Magnetic Resonance in Medicine, vol. 85, pp. 495–505, 1 2021.

[60] Pickup, L et al. “A preliminary ergonomic analysis of the MRI work system environment: Implications and recommendations for safety and design.” Radiography (London, England : 1995) vol. 25,4 (2019): 339-345. doi:10.1016/j.radi.2019.04.001

[61] R. M. Oosting, L. S. G. L. Wauben, J. K. Madete, R. S. Groen, and J. Dankelman, “Availability, procurement, training, usage, maintenance and complications of electrosurgical units and laparoscopic equipment in 12 African countries,” BJS Open, vol. 4, pp. 326–331, 4 2020.

[62] N. Barnea-Goraly, “High success rates of sedation-free brain MRI scanning in young children using simple subject preparation protocols with and without a commercial mock scanner-the Diabetes Research in Children Network (DirecNet) experience,” Paediatric Radiology, vol. 44, pp. 181–186, 2 2014.

[63] R. A. Malkin and C. Whittle, “Biomedical Equipment Technician Capacity Building Using a Unique Evidence-Based Curriculum Improves Healthcare,” Journal of Clinical Engineering, vol. 39, pp. 37–44, 1 2014.

[64] M. A. Rosen, B. H. Lee, J. B. Sampson, R. Koka, A. M. Chima, O. U. Ogbuagu, M. K. Marx, T. B. Kamara, M. Koroma, and E. V. Jackson, “Failure mode and effects analysis applied to the maintenance and repair of anesthetic equipment in an austere medical environment,” International Journal for Quality in Health Care, vol. 26, no. 4, 2014.

[65] https:\/\/cure.org\/author\/debbie-stowell\/#author. “Uganda | CURE International Mbale Pediatric Neurosurgery”. CURE International, 31 januari 2021, cure.org/hospitals/uganda.

[66] J. Dr. Obungoloch, “Interview,” 2020.

[67] A, Haouimi. “Signal-to-Noise Ratio (MRI).” Radiology Reference Article | Radiopaedia.Org, 14 May 2021, radiopaedia.org/articles/signal-to-noise-ratio-mri.

[68] T. Ibrahim, K. Few, R. Greenwood, C. Smith, P. Malcolm, G. Johnson, P. Lally, S. Thayyil, and P. Clarke, “‘Feed and wrap’ or sedate and immobilise for neonatal brain MRI?,” Archives of Disease in Childhood - Fetal and Neonatal Edition, vol. 100, pp. F465–F466, 9 2015.

[69] M. Dewey, T. Schink, and C. F. Dewey, “Claustrophobia during magnetic resonance imaging: cohort study in over 55,000 patients,” Journal of magnetic resonance imaging : JMRI, vol. 26, pp. 1322–1327, 11 2007.

[70] E. Iwan, J. Yang, J. Enders, A. E. Napp, M. Rief, and M. Dewey, “Patient preferences for development in MRI scanner design: a survey of claustrophobic patients in a randomized study,” European Radiology, vol. 31, pp. 1325–1335, 3 2021.

[71] S. Kecskemeti, A. Samsonov, J. Velikina, A. S. Field, P. Turski, H. Rowley, “Robust motion correction strategy for structural MRI in unsedated children demonstrated with three-dimensional radial MPnRAGE,” Radiology, vol. 289, pp. 509–516, 11 2018.

[72] A. D. Edwards and O. J. Arthurs, “Paediatric MRI under sedation: Is it necessary? What is the evidence for the alternatives?” 11 2011.

[73] Dr. Janet Woodcock, “FDA Statement from Dr. Janet

Woodcock, director of FDA's Center for Drug Evaluation and Research, on new safety information on anesthesia use in young children and pregnant women | FDA."

[74] J. L. Andersson, M. S. Graham, I. Drobnjak, H. Zhang, N. Filippini, and M. Bastiani, "Towards a comprehensive framework for movement and distortion correction of diffusion MR images: Within volume movement," NeuroImage, vol. 152, pp. 450–466, 5 2017.

[75] L. Erasmus, D. Hurter, M. Naude, H. Kritzinger, and S. Acho, "A short overview of MRI artefacts," South African Journal of Radiology, vol. 8, p. 13, 6 2004.

[76] M. Zaitsev, J. Maclaren, and M. Herbst, "Motion Artefacts in MRI: a Complex Problem with Many Partial Solutions," Journal of magnetic resonance imaging : JMRI, vol. 42, p. 887, 10 2015.

[77] A. G. Webb and T. H. Oosterkamp, "The Measurement of an NMR Signal with Halbach Arrays Progressing Towards Low-Budget MRI Using Permanent,", Leiden University Medical Centre (LUMC), 2019.

[78] Brennan, SusanC, et al. "ANXIETY AND PANIC DURING MAGNETIC RESONANCE SCANS." The Lancet, vol. 332, no. 8609, 1988, p. 512. Crossref, https://doi.org/10.1016/s0140-6736(88)90159-6.

[79] F. JA and H. K, "Emotional Distress during Magnetic Resonance Imaging," New England Journal of Medicine, vol. 320, pp. 467–468, 2 1989.

[80] P. Vink and S. Hallbeck, "Editorial: comfort and discomfort studies demonstrate the need for a new model," Applied ergonomics, vol. 43, no. 2, pp. 271–276, 2012.

[81] L. Zhang, M. G. Helander, and C. G. Drury, "Identifying Factors of Comfort and Discomfort in Sitting:," https://doi.org/10.1518/001872096778701962, vol. 38, pp. 377–389, 11 2016.

[82] S. Hiemstra-van Mastrigt, Comfortable passenger seats: Recommendations for design and research. Delft: Delft university of Technology, final published ed., 2015.

[83] P. Blake and R. Burstein, "Emerging evidence of occipital nerve compression in unremitting head and neck pain," Journal of Headache and Pain, vol. 20, 7 2019.

[84] M. Kolich, "A conceptual framework proposed to formalize the scientific investigation of automobile seat comfort," Applied Ergonomics, vol. 39, pp. 15–27, 1 2008.

[85] D. Treaster and W. S. Marras, "Measurement of Seat Pressure Distributions:," Human Factors: The Journal of the Human Factors and Ergonomics Society, vol. 29, pp. 563–575, 11 2016.

[86] 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.

[87] J. Bouwens, Design Considerations for Airplane Passenger Comfort. Delft: Delft university of Technology, final published ed., 2018.

[88] J. B. Andre, B. W. Bresnahan, M. Mossa-Basha, M. N. Hoff, C. Patrick Smith, Y. Anzai, and W. A. Cohen, "Toward quantifying the prevalence, severity, and cost associated with patient motion during clinical MR examinations," Journal of the American College of Radiology, vol. 12, pp. 689–695, 7 2015.

[89] A. M. Mathur, J. J. Neil, R. C. McKinstry, and T. E. Inder, "Transport, monitoring, and successful brain MR imaging in unsedated neonates," 3 2008.

[90] J. Park, E. Kim, and K. Shin, "Developing an Evaluation Framework for Selecting Optimal Medical Devices," Journal of Open Innovation:Technology, Market, and Complexity, 2019.

[91] V. Danesi, L. Cristofolini, S. Stea, F. Traina, A. Beraudi, L. Tersi, M. Harman, and M. Viceconti, "Re-use of explanted osteosynthesis devices: A reliable and inexpensive reprocessing protocol," Injury, vol. 42, pp. 1101–1106, 10 2011.

[92] Molenbroek, "Regional differences in capacities of the elderly, relevant to man-product interaction," Contemporary Ergonomics, pp. 62–67, 1996.

[93] P. Buckle and A. Fernandes, "Mattress evaluation-assessment of contact pressure, comfort and discomfort," Applied Ergonomics, vol. 29, pp. 35–39, 2 1998.

[94] L. Li, "Study on effect of elasticity on the mattress comfort with objective and subjective methods," in 2011 2nd International Conference on Mechanic Automation and Control Engineering, MACE 2011 - Proceedings, pp. 5289–5291, 2011.

[95] P. Vink and D. Lips, "Sensitivity of the human back and buttocks: The missing link in comfort seat design," Applied Ergonomics, vol. 58, pp. 287–292, 1 2017.

[96] D. F. Huelke, "An Overview of Anatomical Considerations of Infants and Children in the Adult World of Automobile Safety Design," Annual Proceedings / Association for the Advancement of Automotive Medicine, vol. 42, p. 93, 1998.

[97] M. Holla, New perspective on external immobilization of the cervical spine. PhD thesis, Radboud Universiteit Nijmegen, Nijmegen, 2017.

[98] A. F. Thornton, R. K. Ten Haken, A. Gerhardsson, and M.

Correll, "Three-dimensional motion analysis of an improved head immobilization system for simulation, CT, MRI, and PET imaging," Radiotherapy and Oncology, vol. 20, pp. 224–228, 4 1991.

[99] P. Christian Nolte, D. Deniz Uzun, D. Häske, J. Weerts, M. Münzberg, A. Rittmann, "Analysis of cervical spine immobilization during patient transport in emergency medical services," Springer-Verlag GmbH German, 2019.

[100] V. Tischler, T. Calton, M. Williams, and A. Cheetham, "Patient anxiety in magnetic resonance imaging centres: Is further intervention needed?," Radiography, vol. 14, pp. 265–266, 8 2008.

[101] S. J. Grey, G. Price, and A. Mathews, "Reduction of anxiety during MR imaging: A controlled trial," Magnetic Resonance Imaging, vol. 18, pp. 351–355, 4 2000.

[102] H. Hricak and E. G. Amparo, "Body MRI: Alleviation of claustrophobia by prone positioning," Radiology, vol. 152, p. 819, 9 1984.

[103] E. A. Klonoff, J. W. Janata, and B. Kaufman, "The use of systematic desensitization to overcome resistance to magnetic resonance imaging (MRI) scanning," Journal of Behavior Therapy and Experimental Psychiatry, vol. 17, pp. 189–192, 9 1986.

[104] K. J. Slifer, K. Penn-Jones, M. F. Cataldo, R. T. Conner, and E. A. Zerhouni, "Music enhances patients' comfort during MR imaging [2]," 1 1991.

[105] D. S. Klein, "Prevention of claustrophobia induced by MR imaging: Use of alprazolam [1]," 1 1991.

[106] F. Fernández-Gutiérrez, S. Martínez, M. A. Rube, . "Comparative ergonomic workflow and user experience analysis of MRI versus fluoroscopy-guided vascular interventions: an iliac angioplasty exemplar case study," Int J CARS, 2015.

[107] N. Barnea-Goraly, S. A. Weinzimer, K. J. Ruedy, \"High success rates of sedation-free brain MRI scanning in young children using simple subject preparation protocols with and without a commercial mock scanner-the Diabetes Research in Children Network (DirecNet) experience," Paediatric Radiology, vol. 44, pp. 181–186, 2 2014.

[108] C. W. Nordahl, T. J. Simon, C. Zierhut, M. Solomon, S. J. Rogers, and D. G. Amaral, "Brief report: Methods for acquiring structural MRI data in very young children with autism without the use of sedation," Journal of Autism and Developmental Disorders, vol. 38, pp. 1581–1590, 9 2008.

[109] B. K. Stephens, M. E. Barkey, and H. R. Hall, "Techniques to comfort children during stressful procedures.," Accident and emergency nursing, vol. 7, pp. 226–236, 10 1999.

[110] World Health Organization,WHO press, "Local Production and Technology Transfer to Increase Access to Medical Devices Addressing the barriers and challenges in low- and middle-income countries", 2012.

[111] 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.

[112] Council, Design. "Design for innovation." London: Design Council. Retrieved April 27 (2011): 2012.

[113] Weyrauch, Timo, and Cornelius Herstatt. "What Is Frugal Innovation? Three Defining Criteria." Journal of Frugal Innovation, vol. 2, no. 1, 2016. Crossref, https://doi.org/10.1186/s40669-016-0005-y.

[114] Quirk ME, Letendre AJ, Ciottone RA, Lingley JF. Anxiety in patients undergoing MR imaging. Radiology 1989;170:463–466.

[115] McIsaac HK, Thordarson DS, Shafran R, Rachman S, Poole G. Claustrophobia and the magnetic resonance imaging procedure. J Behav Med 1998;21:255–268.

[116] Penning L, Wilmink JT. Rotation of the cervical spine. A CT study in normal subjects. Spine (Phila Pa 1976). 1987;12(8):732-8

[117] Bogduk N, Mercer S. Biomechanics of the cervical spine. I: Normal kinematics. Clin Biomech (Bristol, Avon). 2000;15(9):633-48

[118] Yu, Yan. " Effects of Dual-Perspective Nursing Intervention Based on Safety and Comfort Needs on Psychological Status and Safety Quality of MRI Patients." Proceedings of Anticancer Research. 4. 10.26689/par.v4i4.1397. 2020

[119] Korner, Anneliese F., and Evelyn B. Thoman. "The relative efficacy of contact and vestibular-proprioceptive stimulation in soothing neonates." Child development (1972): 443-453.

[120] Stewart, T.R . "The decubitus ulcer in eliniealpractice". (pp. 145-168). Berlin: Springer. 1997.

[121] Weaver, V, and J Jester. "A clinical tool: updated readings on tissue interface pressures." Ostomy/wound management vol. 40,5 (1994): 34-6, 38, 40 .