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Analysing the data developed by simulation cases in health care for further service development

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The aim of the thesis was to describe the role and implementation of simulations in the multi-professional product development process. The simulations are utilized further product development at Dyme Solutions Oy, a software company in Pori. In addition, the purpose of this project was to study how the outcomes of the simulations can be the help of developing simulation teaching at Satakunta University of Applied Science (SAMK) and find out how a health care prototype, Florie, can be utilised in health care use.

The research of the thesis was carried out as a mixed-methods approach both quantitative and qualitative. The data was collected by measuring load cell data during simulations (quantitative) and thematic interview (qualitative) with developer. The first phase of the study was arranged simulation with the help of identified simulated cases related on the part of the Degree Programme in Nursing at Satakunta University of Applied Sciences (SAMK) and development ideas from the client for the further design of the prototype and product development process. In the second phase of the study, feedback was collected with the questions of the semi-structured interview that addressed themes such as the simulations and the role of simulations in product development. The data consist of answers to this semi-structured interview and was analyzed using qualitative content analysis.

According to the results of the thesis, simulations of the health care prototype are important for further product development and risk management. The results of this research show that simulations play a major role in product development and especially at the beginning of the product development process, where the possibilities of a product can be identified and, on the other hand, existing ideas can be refined into product entities. Another significant result identified during this thesis was that the simulations could be more widely used as part of nursing studies, and the simulations could be utilized in collaboration with companies to achieve broader multi-professional product development processes.

Key words
Welfare technology, simulations, product development, prototype, service design

CONTENTS

1 INTRODUCTION

The simulations aim to understand how the prototype works in different simulations and whether the simulations can identify critical issues for product development. Simulations and computational modelling play a key role in traditional engineering disciplines to support product development and evaluation. In addition, simulations are a very cost-efficiency way to test a new product in the industry and manufacturing field. According to Mourtzis (2019, p. 2) research, simulation in the manufacturing field's design and operation will also offer time, quality, safety, and productivity efficiency, as shown in the picture below (Figure 1).

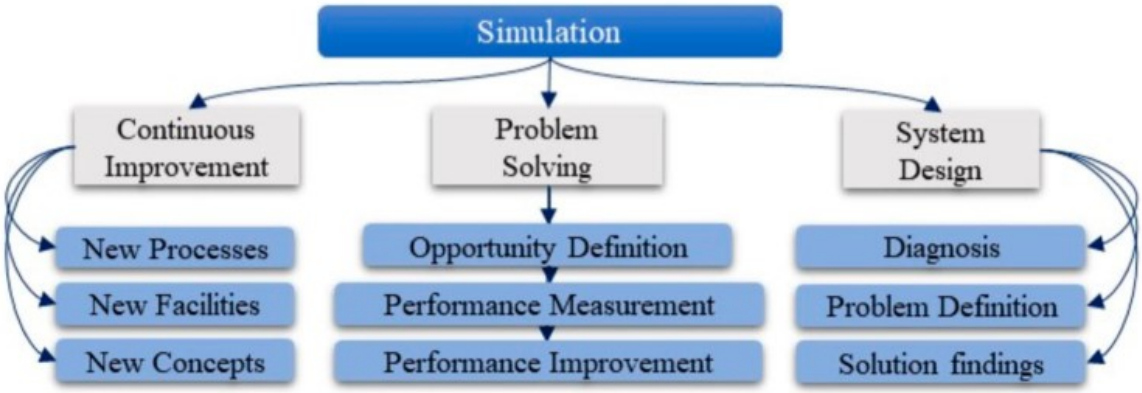


Figure 1. Simulation for design and operation of manufacturing systems (Mourtzis, 2019, p. 2)

In general, simulation offers a practical methodology to investigate and understand complex manufacturing systems, such as aerospace and electronics (Mourtzis, 2019, p. 2). Simulations can also be of significant benefit in the product development of a healthcare product. With the help of simulations, there are many possibilities to develop the product, such as decreasing costs or minimising harm to a patient. (Madani et al., 2017, p. 9.) In medical education, simulations have a long history in the simulation of the clinical treatment environment. Simulations can offer a powerful technique for reflection, learning, abstraction, conceptualisation and connections to actual events. Today, the benefits of simulations are also being identified to improve

healthcare systems and processes in the healthcare sector by testing new healthcare approaches before they are implemented in real life. (Lamé & Dixon-Woods 2020, p. 87.)

This research is focusing to interface between product development and health care prototype simulations. The work begins with a background of the identified simulation cases, and in addition, a simulation plan is prepared. The simulation plan is used to perform three different simulations, which are presented in Chapter 4. The work examines the measurement results in Chapter 5. In the Chapter 6, results from the simulations and thematic interviews are considered and discussed in relation to the findings of the earlier studies. The answers to research questions are finalized in the discussion chapter. The final Chapter 7 compiles a summary of the work, reviewing its success and its challenges and usefulness for further product development. Product testing and product development are an integral part of overall health device development to verify the product's performance, effectiveness, and safety following the requirements. Medical product development is a continuous process with multiple feedback steps and overlapped validations. With the help of clinical tests, product development can consider definitions of safety and reliability. (Mathews et al., 2019, p. 4.)

2 PURPOSE, OUTCOMES AND RESEARCH QUESTIONS

This master thesis collaborated with the software development company Dyme Solutions Oy and Satakunta University of Applied Sciences. The purpose of this master thesis was to describe the role and implementation of simulations in the multi-professional product development process with the help of simulating, designing, and analysing three different simulation cases directly related to patient weight monitoring. These three pre-set cases are also part of the Degree Programme in Nursing at Satakunta University of Applied Sciences (SAMK). The results of the simulations are utilized further product development at Dyme Solutions Oy to find out how a Florie-type device can be utilised in healthcare use. In addition, the outcomes of the simulations are the help of developing simulation teaching at SAMK.

This study involved a health care prototype, Florie, created by Dyme Solutions' Oy, a software company in Pori, and it is also linked to further health care service use at Dyme Solutions Oy. The prototype was developed to gather weight data with the help of sensors placed under the feet of the bed and store and visualise it with Florie's cloud service (Dyme Solution Oy, 2021).

The advantage of these simulations is identifying the benefits of simulation in product development at Dyme Solutions Oy and creating an operating model for utilising nursing simulations in product development. Simulated data was generated with a SparkFun Electronics strain gauge load cells TAS606 sensor. A strain gauge is a device that measures the change in electrical resistance when a force is applied. SparkFun Electronics is an electronics retailer in Niwot, Colorado, United States. It manufactures and sells microcontroller development boards and breakout boards. (SparkFun, 2020.)

According to the World Health Organization (WHO), the current approach to estimate device safety is to evaluate device possible safety problems and harms. Another approach linked more substantial to device product development is clinical effectiveness. Clinical effectiveness is a strong indicator of device performance. However, like WHO (2003, p. 3) and medical device regulation (MDR 2017/745) also

propose in their publication, it is easier to measure a device's performance objectively and quantify performance rather than analyse the device’s clinical effectiveness.

According to the design and development approach, the study focuses on the usability, functionality, and meaningfulness of products' future needs (Ellis & Levy 2010, p. 115). This thesis also presents the study's methodology, simulation cases, designed simulation plan and data collection process, and summary results.

2.1 Research questions

The research questions are:

1. How suitable is the current prototype version of Florie for the simulated cases?

2. How can the acquired simulation data be utilised in the product and service development phase of Florie cloud service?

3 BACKGROUND

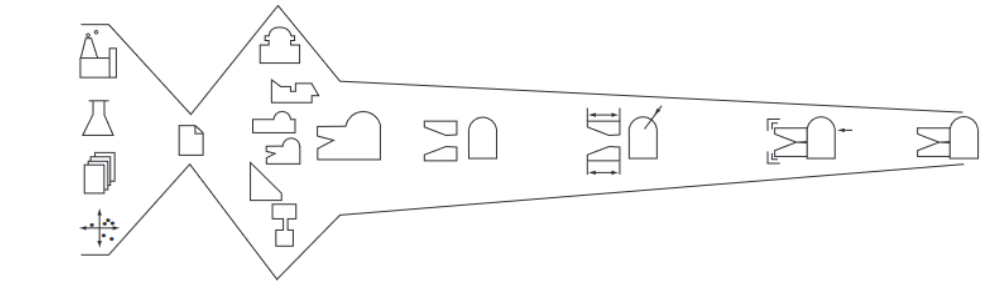
The concept of this study is to focus on the healthcare product of the concept level phase. Therefore, all testing will also be done during the concept development phase.

3.1 Product design and development

Product development is a wide range of different activities and opportunities. The role of product development is one of the essential things in a company's operations, especially when developing a product that will operate in an industry where the lifespan of products can be very short. Product development strives for a technically excellent and cost-effective entity by considering product quality and cost objectives. (Ulrich et al., 2020, p. 2.)

Ulrich et al. (2020, p. 3) raise five specific dimensions from the investor point of view, which are crucial for successful product development: product quality, product cost, development time, development cost and development capability. These all factors are strongly linked to economic product development success and performance criteria, which comes from members of the development team, stakeholders in the enterprise and other parties related to the product's ecologically resources.

Ulrich et al. (2020, p. 12, 57) present that a well-defined development process offers good quality, precise coordination and planning, efficient management, and improvement. These steps are included in the six phases generic product development process (Figure 2). Product development starts with an idea of a new product and, in the end, reach the product in sale. Thus, product development could be a very different process in every organisation.



Planning	Concept Development	System-Level Design	Detail Design	Testing and Refinement	Production Ramp-Up
Marketing					
• Articulate market opportunity. • Define market segments.	• Collect customer needs. • Identify lead users. • Benchmark competitive products.	• Develop plan for product options and extended product family.	• Develop marketing plan.	• Develop promotion and launch materials. • Facilitate field testing.	• Place early production with key customers.
Design					
• Consider product platform and architecture. • Assess new technologies.	• Investigate feasibility of product concepts. • Develop industrial design concepts. • Build and test experimental prototypes.	• Develop product architecture. • Define major subsystems and interfaces. • Refine industrial design. • Preliminary component engineering.	• Define part geometry. • Choose materials. • Assign tolerances. • Complete industrial design control documentation.	• Test overall performance, reliability, and durability. • Obtain regulatory approvals. • Assess environmental impact. • Implement design changes.	• Evaluate early production output.
Manufacturing					
• Identify production constraints. • Set supply chain strategy.	• Estimate manufacturing cost. • Assess production feasibility.	• Identify suppliers for key components. • Perform make-buy analysis. • Define final assembly scheme.	• Define piece-part production processes. • Design tooling. • Define quality assurance processes. • Begin procurement of long-lead tooling.	• Facilitate supplier ramp-up. • Refine fabrication and assembly processes. • Train workforce. • Refine quality assurance processes.	• Begin full operation of production system.
Other Functions					
• Research: Demonstrate available technologies. • Finance: Provide planning goals. • Project Management: Allocate project resources.	• Finance: Facilitate economic analysis. • Legal: Investigate patent issues.	• Finance: Facilitate make-buy analysis. • Service: Identify service issues.		• Sales: Develop sales plan.	• Project Management: Conduct postproject review.

Figure 2. The generic product development process (Ulrich et al., 2020, p. 14)

As Figure 2 shows, the process begins with a planning phase, when many ideas are "on the table", and it generates input for the concept development phase. During the concept development phase, many specific questions must develop and identify. The concept is an early sketch about a future product and can be noticed as the primary point-like shape, material, or color. Product conception helps to understand the future design challenges of a product and, on the other hand, to potentially innovate new uses and thus find entirely new product options for the future — the actual design phase focuses more on the product and its functions, materials, tolerances, and other

technical functions. Next, early prototypes are built-in in the test and refinement phase. This phase helps determine product accuracy and whether the product will work as designed. The last phase, production ramp-up, is when the product is launched and becomes available for widespread distribution. (Ulrich et al., 2020, p. 15.)

Especially product concept development phase usually needs a lot of coordination and time because there are many open questions, and many activities are involved during that phase. For example, Ulrich et al. (2020, p. 16) describe how new information could cause one step back action during the concept development phase (Figure 3).

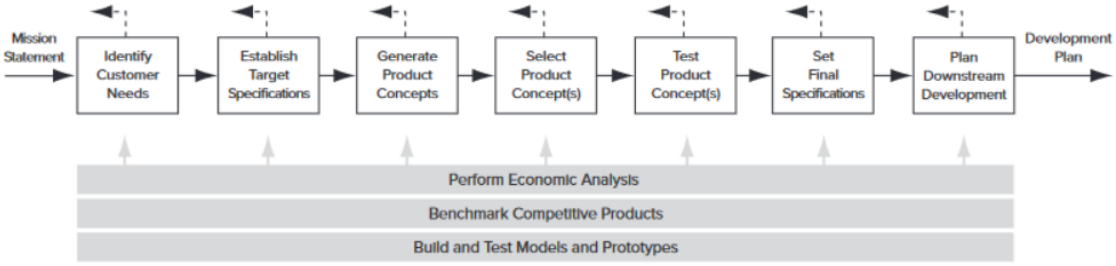


Figure 3. Many front-end activities comprising the concept development phase (Ulrich et al., 2020, p. 16)

Quick-build products are a very efficient way to repeat the spiral product development process (Figure 4). This process benefits are flexible and responsive development process, which offers data from every cycle and helps design products for the next cycle. (Ulrich et al.,2020, p. 21.)

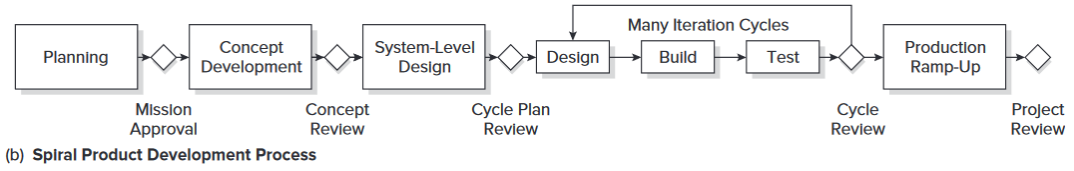


Figure 4. Spiral Product Development diagram (Ulrich et al., 2020, p. 23)

Simulations will support design and development research work as an investigation methodology. Lamé & Dixon-Woods (2020, p. 92) describe how simulations as an investigative methodology can offer a safer environment to test new technology and improve health care products without causing risks to actual patients.

According to Sääski and Riitahuhta (2007, p. 2), the main objective is to improve product development effectiveness when using simulations. Prototype simulations allow developers to improve product development methods and identify possible problems in the product development process. Simulation-based product development can also improve the process if the simulations are integrated into the whole product lifecycle.

Concept level (prototype) testing is used to gather information on improving the product for future use. Ulrich and Eppinger (2020, p. 172) point out that tests can also refine demand forecasts before production and service launch.

The simulations aim to describe the phenomenon under study or the system's essential features using the theoretical model. Therefore, simulations are emphasised, especially when modelling dangerous scenarios potentially harmful to the environment or people. (Potyondi 2013, p. 10.)

3.2 Health care product definition and legislation

WHO (2017) defines devices, medicines, vaccines, procedures, and system development that solve any health problem or improve quality of life as a health care technology. The Healthcare product field is vast, and the regulations are very tight. In the European Union (EU), medical and in vitro diagnostic medical devices are regulated by a European Union framework. These two Regulations, namely, Regulation (EU) 2017/745 relating to medical devices (MDR) and Regulation (EU) 2017/746 relating to in vitro diagnostic medical devices (IVDR), entered into force in April 2017. The Regulations are intended to increase clinical safety and guarantee fair access to the market for manufacturers of medical devices and software. The regulation relating to medical devices prioritises patient safety and increases transparency in the device compliance process. (MDR 2017/745, 8 §.)

A prototype is used for testing during the master thesis, and therefore, no other position is taken on regulations and laws during simulations. However, it is good to understand that if the end products fit the definition of health care products, they must comply

with the medical device EU-regulation (MDR 2017/745) and new national legislation about The Medical Devices Act (719/2021) in Finland. Ståhlberg (2015, p. 52) states in his study, that one of the essential issues in product development is identifying the regulatory environment in which it operates, thus giving the company a clear competitive advantage. For example, if the product is a medical device, the first stage of the product development process must consider the European Parliament's classification of the device according to, among other things, the duration of use and contact with the body.

As Ståhlberg points out (2015, p. 52), product categories define the needs of product requirements, and thus the product developer and manufacturer must be aware of the device's ability to meet the requirements set for it, in which case product development must consider the use of lower product categories. However, Stålberg comments that the device can still be sold, for example, in a hospital environment and does not automatically mean that the device should be registered as a healthcare device, but that the device can still be subject to the exact safety requirements as healthcare devices.

3.3 Florie

Florie is a cloud service prototype developed by Dyme Solution Oy that measures and monitors weight changes. Ravn et al. (2016, p. 5) state two main understandings of the word prototype found in product development literature. A prototype can mean a more extensive product development that takes place during product design, in which case only an attempt is made to gain an understanding of the model, or a prototype can be a more advanced design model that tests the reliability and functionality of the product before the actual production phase.

3.3.1 Mock-up

A physical mock-up, like Florie, is a very early phased prototype, a scale or full-size model of a design, to test and simulate design ideas early in the product and development phase. According to Peavey et al. (2012, p. 140), a physical mock-up is

fast to test and support the product's operation and future concept and technical functionality (Table 1).

Table 1. Physical Mock-up part of basic benefits and challenges of simulation and mock-up types (Peavey, E et al., 2012, p. 140)

Type	Benefits	Challenges
Physical Mock-Up	• Provides rapid user feedback • Fosters user, owner buy-in • Test impact of design decisions • Useful for education and training • Offers some flexibility to test design alternatives • Evaluates usability, positioning, mobility, room dimensions, layout, finishes, colour, specific furnishing, equipment, materials, etc. • Useful as a live laboratory to test real patient numbers	• Cost of construction materials and labor • Space for construction (depending on detail) • Transport of users to mock-up

Ulrich et al. (2020, p. 297) defines prototype as follows: A prototype approximates a product to one or more dimensions of interest. Prototypes can be classified into two dimensions. The degree of the first dimension is where the prototype is physical rather than analytical. Here physical means prototype created by the development team for testing and experimentation and analytical is a nontangible, usually mathematical, or visual product for analyzing a not built product. The second dimension is the comprehensive degree. Such a prototype already has most of the features of the product. Physical prototypes that differ from the comprehensive prototype are concrete objects created to iterate the product. Outcomes of interest to the product development and design team have been built as an object for testing and experimentation. Examples of physical prototypes are models that look and feel like a product, concept prototypes used to test an idea quickly, and experimental hardware used to test the functionality of a product. (Ulrich et al., 2020, p. 304.)

3.3.2 Data

Florie's data is stored in a data-driven cloud service, from which it can be monitored and analysed as required (Figure 5). With the help of the data, professionals can plan the necessary measures related to the treatment or, for example, identify possible diseases. (Dyme Solution Oy, 2021.)

Figure 5. Florie cloud service (Dyme Solutions Oy, 2021)

The data processed by Florie are collected from four weight sensors (Figure 6). The sensors can be placed, for example, under a mattress or, as in this thesis, the sensors were placed under the wheels of a hospital bed using separate 3D printed adapters designed for simulations. In addition, the data generated by the device can be read

Figure 6. Florie prototype set-up (Leppänen, 2021)

directly from the user interface connected to the cloud service or, as in this thesis, the excel data produced by the device can also be used for analysis.

3.4 Spark Fun´s TAS606 as the load cell in health care

In the healthcare industry, weighing and monitoring are already becoming more important, especially now in the middle of the pandemic healthcare also needs technologies that can remotely monitor. COVID-19 pandemic has shown that monitoring patients remotely or wirelessly improves treatment and helps prevent the spread of the virus. (Siwicki, 2020.) Therefore, new modern wireless interfaces and enhanced semiconductors and electronic circuit devices have become vital in designing new medical devices. The design of the devices must aim for clear communication between the patient and the device used and be useful in the work of the healthcare professional. The use of force feedback is one way to monitor these requirements, for example, during surgery, or with the help of an assistive living outside of the hospital or during medical training with interactive cardiopulmonary resuscitation manikins. (Lowe, 2019.)

A load cell is a physical element (or transducer if you want to be technical) that can translate pressure (force) into an electrical signal (Sparkfun, 2021). It converts a force such as tension, compression, pressure, or torque into an electrical signal that can be measured and standardised. As the force applied to the load cell increases, the electrical signal changes proportionally. The most common types of load cells used are strain gauges, pneumatic, and hydraulic (Wikipedia, 2021.) Disc load cell (sometimes called a strain gauge) can translate up to a whopping 200kg of pressure (force) into an electrical signal. Load cell (Figure 7) can measure the electrical resistance that changes in response to, and proportional to, the strain (e.g., pressure or force) applied to the disc. (Sparkfun, 2021).

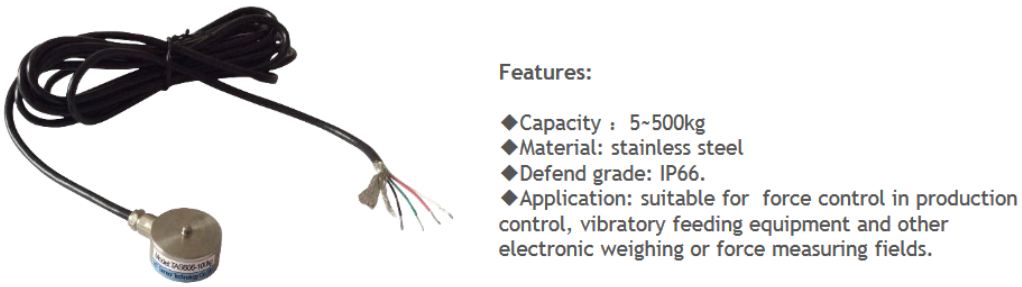


Figure 7. TAS606 Miniature compression type force sensor (Sparkfun, 2021)

3.5 Identified Use Cases

To evaluate Florie's additional value and use in the care context, weight-measurement related use cases were identified by SAMK care professionals. Three pre-set healthcare cases (Figure 8) are directly linked to weight changes: premature baby nutrition, heart failure and position treatment. The pre-set cases were chosen because cases were identified as essential by health care professionals (SAMK nursing professionals), and the changes in weight changes or weight compositions that occurs in cases can be simulated under laboratory conditions.

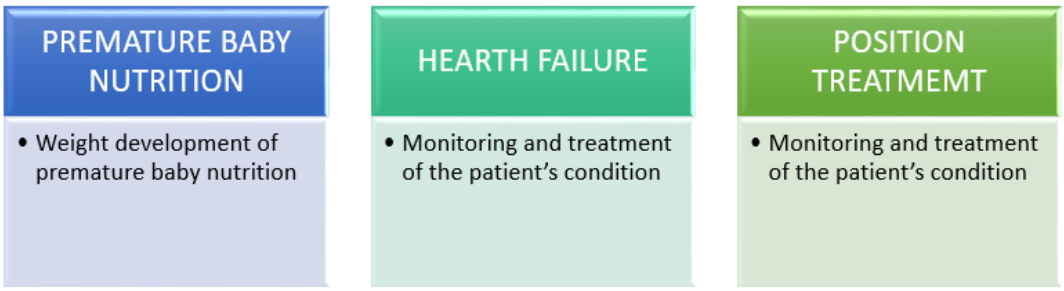


Figure 8. Pre-set simulation cases (Leppänen, 2021)

3.5.1 Premature baby nutrition

Babies born at less than 37 weeks gestation (premature) have different nutritional needs than babies born at full term (after 38 weeks). Premature babies will often stay in the neonatal intensive care unit (NICU). They are watched closely to make sure they are getting the right balance of fluids and nutrition. (MedlinePlus, 2020.)

3.5.2 Heart failure

Tarnanen, K et al. (2018) describe that heart failure is a condition in which the heart cannot pump blood efficiently enough. About 90% of cases are found to be due to coronary artery disease, high blood pressure, or valve defect. Heart failure affects 1-2% of the total population. The incidence increases sharply with age: about 10% of those over the age of 70 have heart failure.

Suspicion of heart failure may arise if the patient begins to gain weight abruptly. Sudden weight gain can indicate fluid accumulation in the body, and therefore weight monitoring in heart failure cases should also be considered. (Tarnanen et al. 2018.)

3.5.3 Position treatment

In long-term care and nursing wards, special attention is paid to preventing pressure ulcers by changing the patient's position often enough. The basic rule is that pressure points should be changed every couple of hours. Thus, one of the essential rules for treating pressure points is that pressure points should be changed every couple of hours, such as turning a person from side to side, which changes the weight distribution on the skin. (Lumio, 2021.)

A pressure ulcer is a localised injury to the skin and/or underlying tissue, usually over a bony prominence due to pressure or pressure combined with shear. Several contributing or confounding factors are also associated with pressure ulcers; these factors' significance is yet to be elucidated. (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel, 2019.)

4 METHODOLOGY

4.1 Design and development research

This research strategy is design and development research. Design and development research is a practical way to test and validate theory in practice. Ellis & Levy (2010, p. 108) present (Figure 9) that design and development research targets building a bridge between conceptualisation and evaluation cycle.

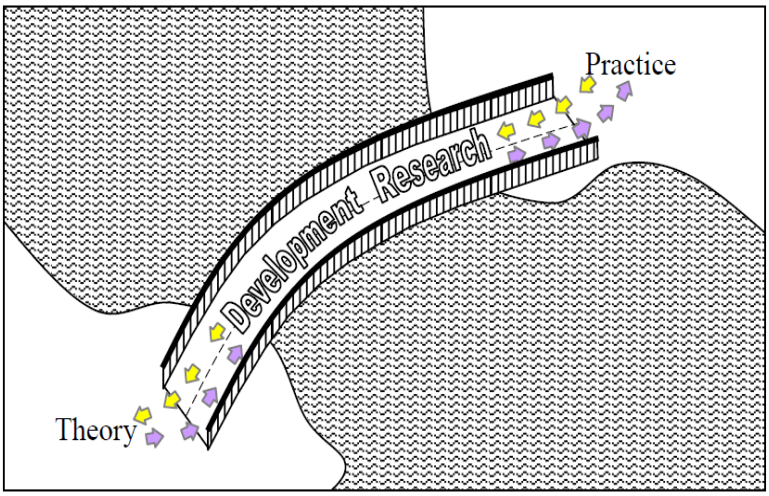


Figure 9. Design and development research framework (Ellis & Levy, 2010, p. 109)

In this study, design and development research is adapted especially for the product testing and development phase. Ellis & Levy (2010, p. 109, 111) have defined the 6-phase design and development research approach (Figure 10).

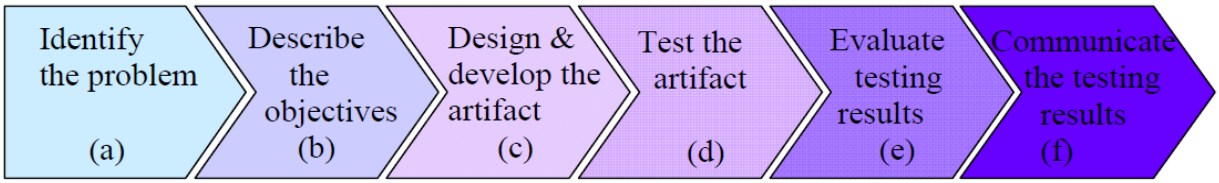


Figure 10. The 6-phase design and development research approach (Ellis & Levy, 2010, p. 111)

It is essential to understand the differences between design and development research and product development. Product development aim is to develop a product for commercial use without research context. The research target is addressing knowledge

of the problem, building upon existing literature, and making an original contribution to the body of knowledge.

In the concept phase of product design, a product description is created, which estimates the product's cost, performance, reliability, and, for example, safety. Furthermore, the simulations make it possible to utilise test data and validate the maturity of the product before the actual release of the product. (Bhuiyan, 2011, p. 748.) Therefore, the simulations of this thesis and the simulation report formed from it provided valuable data specifically for the further development of the product and clarified the more detailed product structure and purpose.

4.2 Approach and data collection

The mixed-methods approach is used in the thesis as both quantitative and qualitative data is used in the research. The data is collected by measuring load cell data during simulations (quantitative) and thematic interviews (qualitative) with the developer specialists from Dyme Solution. Combining qualitative and quantitative data provide a more diverse understanding of the study's subject than a qualitative or quantitative research method alone (Doyle et al., 2009, p. 178). Although the research questions are qualitative, the quantitative data provide how the simulations support further service and product development. Quantitative data provide an overview of sensors functionality to pre-set cases in the study, and qualitative data made it possible to open questions about how to physical mock-up health care product simulations support more detailed product development. According to Vilkka (2007, p. 49), quantitative analysis is suitable for studies when numerically describing something and measuring its changes and how much one thing affects another. Data will be collected from the signal information obtained based on the simulations; the aim is to identify the data that significantly affect the pre-set example cases' weight monitoring and are directly connected to service development. The sensors' measured values will be read from the Florie application's cloud service (Dyme Solutions Oy, 2021) and collected to excel format.

The qualitative part of this study's approach was to understand simulation data results and those further used for product and service development and prototype simulations as a part of the development process (Alasuutari 2011, p. 34). Produced data from the simulations were presented to the developers. After showing the results, thematic interviews, a conversational interview method was arranged for developers to assess the significance of the simulations in the product development phase and how simulation-based product development can set the boundary conditions for further development.

4.2.1 Simulations and laboratory measurements

Peavey et al. (2012, p. 135) present several mock-ups and simulation models for design decision making (Figure 11). In this study, a physical mock-up is used to build up immediate feedback from prototype simulation cases. During simulations, the researcher can easily modify mock-ups to gather and investigate different data from prototype use. In this study, a physical mock-up is built to capture situations that can occur, especially in a patient's behaviour (Pietroforte & Tombesi 2010, p. 95). This is because a patient's behaviour can be challenging to forecast, and the researcher can manually adjust the simulation environment to detect more realistic situations.

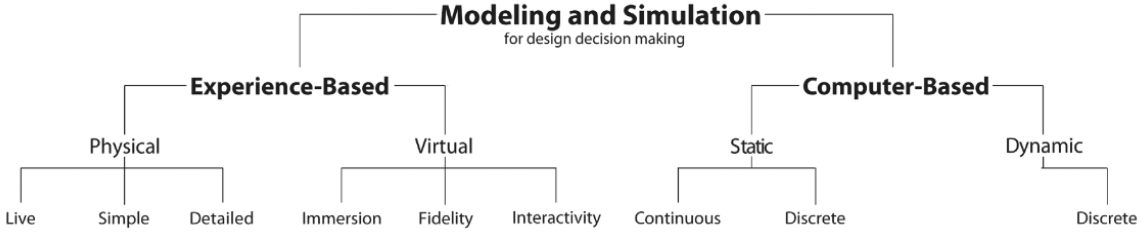


Figure 11. A simplified diagram of the simulation and mock-up types discussed in this article as options available for informing design decision making (Peavey et al., 2012, p. 135)

The simulations were performed on the 8th – 9th of April 2021 in the nursing class of Satakunta University of Applied Sciences. The functionality of the equipment and the condition of the tools was ensured on the 8th of April. Dyme Solutions presented the prototype of Florie before simulations.

On the 9th of April, the simulations were held 9:00 – 14:00. At the simulation, there were two participants: a simulator (thesis author) and a SAMK project employee with nursing expertise. With her help, it was ensured that during the simulations, treatment situations would be simulated correctly. Simulations were started from case 1 and then continued from cases 3 and 2.

The simulation used Dyme Solution's Florie cloud service software, the researcher's own mobile phone and laptop, four Spark Fun's TAS606 sensors and realistic nursing dolls; one of adult size and one of baby size and two realistic hospital beds; one regular size and one baby size (Appendix 1).

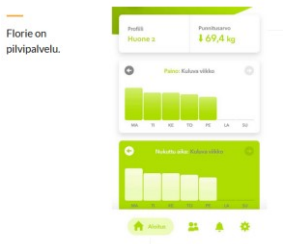
During the simulations, the basic idea was to observe and study the electrical resistance changes on each TAS606 sensor when adding extra weight in the bed to infer possible bodyweight changes or changes of weight distribution - sensors placed on the simulation's room hospital bed's legs with unique mounting base (Figure 12).

Figure 12. 3D printed adapter for the sensor (Leppänen, 2021)

When the person is lying in bed, the bodyweight distribution changes, and it causes each loadcell's resistance to adjust accordingly. Sensor data will be collected to the Florie cloud service.

Before performing the simulations, a simulation plan was created that defined what would be simulated and with what accuracy the simulation would be performed and how the results will be used. The tools required for the simulations were defined in the first section of the simulation plan (Table 2).

Table 2. The equipment required during the simulations (Leppänen, 2021)

Tools/Things	**Responsible person**	**Nb!**
Load cells (4 pcs) SparkFun TAS606	Dyme	
Stands (slides) for sensors (8 pcs) • for normal hospital bed (4 pcs) • for baby hospital bed (4 pcs)	SAMK	
Nursing doll 2 pcs; • one adult • one baby	SAMK	
Hospital bed 2 pcs; • one normal hospital bed (Merivaara Futura PLUS) • one baby hospital bed	SAMK	
Laptop / Tablet	Henna	
Mobilephone (+stand)	Henna	
Scale	SAMK	
Weights (rice bags) • CASE1: 5 x 20g bags filled with rice • CASE2: 10 x 200g bags filled with rice • CASE3: no need for extra weights	Henna	
Simulation assistance	SAMK	
Florie cloud service	Dyme	

The necessary preliminary information and objectives are defined in the third part of the simulation plan (Table 3).

Table 3. Information and objectives for the simulation (Leppänen, 2021)

INFORMATION AND OBJECTIVES FOR THE SIMULATION	
PREPARATION PHASE	
Basic knowledge of simulated situations→ • what to observe? • how much weight needs to be added?	Preliminary plan: APPENDIX1, APPENDIX2, APPENDIX3
The authenticity of the simulated situation→ • doll and doll positioning / turning (weight distribution on the bed) • necessary weighing	
The most important roles known to perform the simulation → • the division of roles is clear before the start of the simulation	Simulation plan
Necessary tools available and ready	Simulation plan
Aim of observing and recording (as well as videotaping) situations that may need to be studied in the simulation report	Simulation plan
SIMULATION PHASE	
Chronological and systematic execution of the simulation	Simulation plan
Data collection	Florie cloud service
Videotaping	Mobile phone
PRE-SET SIMULATION CASES	
Premature Baby Nutrition	Appendix 1
Hearth Failure	Appendix 2
Position Treatment	Appendix 3

Finally, the last section contains roles and responsibilities (Table 4) and monitoring risks and problems (Table 5).

Table 4. Roles and Responsibilities of the simulation (Leppänen, 2021)

ROLES AND RESPONSIBILITIES OF THE SIMULATION			
Actor	**Role**	**Responsibilities**	**Additional considerations**
Henna Leppänen	Simulator	Arranging and performing the entire simulation	
Dyme Solution Oy	Supplier of the product to be simulated	Product installation and instructions for using the software/confirmation of operation / possible participation in the simulation	
Nursing student	Supports simulations	Supports the simulator and gives a view on how to perform the simulations	
SAMK	Simulation facilities	Required spaces + equipment	
Henna Leppänen	Simulator	Arranging and performing the entire simulation	
Dyme Solution Oy	Supplier of the product to be simulated	Product installation and instructions for using the software/confirmation of operation / possible participation in the simulation	

Table 5. Risks and problem management (Leppänen, 2021)

RISKS AND PROBLEM MANAGEMENT	
Possible exceptions and problems	**Appropriate corrective action**
Schedule	Clear timetable (APPENDIX 4)
Workload	Division of roles defined (see division of roles and responsibilities)
Pressure sensors do not work	Testing with a software company before simulations
Weight changes are not shown in the program	The number of weights required to get a response
One of the sensors is broken	Testing with the software company before simulations
Remember to simulate everything needed	Simulation definitions (APPENDIX1, APPENDIX2, APPENDIX3)
How to control the simulation	Division of roles (see division of roles and responsibilities)

Recording date	**Risk description**	**Probability**	**Effect**	**Mitigation plan**
19.3.2021	Timetable	2	3	Clear timetable
19.3.2021	Workload	2	3	Clear division of roles
19.3.2021	Weight sensors	2	2	New simulation
19.3.2021	Weight changes	3	2	New simulation
19.3.2021	Simulation	3	2	New simulation
5.4.2021	Illness	2	3	New simulation

The simulation plan also included preliminary data for each case to be simulated, and these cases will be presented next.

Case 1, Baby Nutrition

Before the simulation, the instruments used (baby and extra weights) were weighed to know the exact weights for each device participating in the simulation. Then, the sensors were installed under the feet of a nursing crib using separate 3D-printed adapters.

Weights of a baby and additional weights were used to monitor weight changes (Figure 13).

Figure 13. Weights of 20 grams (Leppänen, 2021)

Five of these weights were reserved to simulate weight changes over five days period corresponding to a preterm growth rate of 15g/kg/day as determined by the intensive care unit. Each "daily" weight gain was reviewed and verified by Florie's service.
Weight increases were made in the abdominal area of the baby doll (Figure 14) according to the computational plan (Table 6).

Figure 14. Weight gain point (Leppänen, 2021)

Table 6. Computational plan case baby nutrition (Leppänen, 2021)

Day	**Weight**
First addition (according to day 1 situation):	Baby weight on day 1 (1,270g) / 1000g * 15g = 19g ➔ increase rounded to 20g
Second addition (according to day 2 situation):	Baby weight on day 2 (1,290g) / 1000g * 15g = 19.35 g ➔ increase rounded to 20g
Third addition (according to day 3 situation):	Baby weight on day 3 (1,310g) / 1000g * 15g = 19.65g ➔ increase rounded to 20g
Fourth addition (according to the day 4 situation):	Baby weight on day 4 (1330g) / 1000g * 15g = 19.95 g ➔ increase rounded to 20g
Fifth addition (according to day 5 situation):	Baby weight on day 5 (1,350g) / 1000g * 15g = 20.25 g ➔ increase rounded to 20g

Case 2, Heart failure

A manikin was used in the simulation. The sensors were installed under the feet of a nursing home hospital bed (Merivaara Futura PLUS) using separate 3D printed adapters (Figure 15). A manikin and bags filled with rice weighing 200g were used to monitor weight changes.

Figure 15. Merivaara hospital bed and 3D printed adapter with TAS606 sensor (Leppänen, 2021)

Weight increases were made in the lower extremities and the upper abdominal area, where fluid accumulation in the body was simulated and adjusted as closely as possible in the case of heart failure according to the simulation plan (Figure 16).

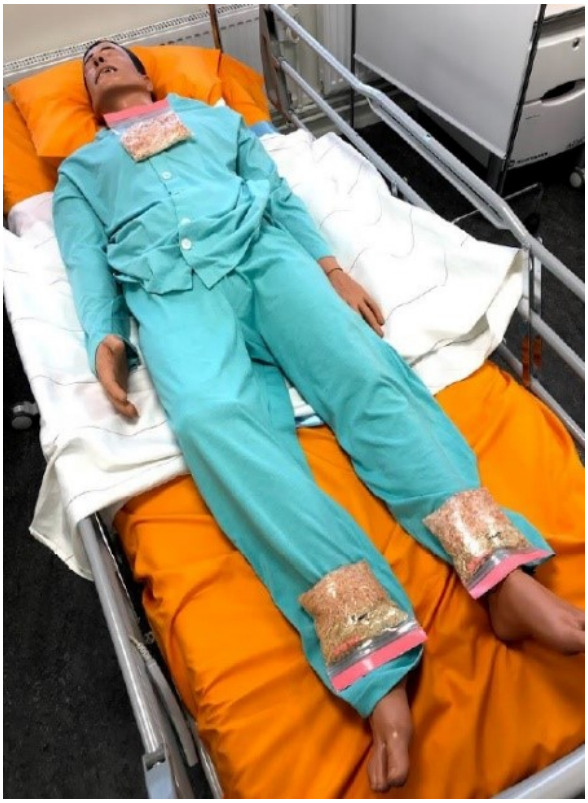


Figure 16. Weight increases in the lower extremities as well as in the upper abdominal area (Leppänen, 2021)

Weight increases were made in the lower limbs and upper abdomen according to the computational plan (Table 7).

Table 7. Computational plan case hearth failure (Leppänen, 2021)

Day	**Weight**
First addition (according to day 1 situation):	Right and left lower limbs: ➔ right: 200g ➔ left: 200 g
Second addition (according to day 2 situation):	Upper abdomen: 200g
Third addition (according to day 3 situation):	Right and left lower limbs: ➔ right: 200g + 200g ➔ left: 200g
Fourth addition (according to the day 4 situation):	Upper abdomen: 200g
Fifth addition (according to day 5 situation):	Right and left lower limbs: ➔ right: 200g ➔ left: 200g + 200g

Case 3, Position treatment

The sensors were installed under the feet of a hospital bed in the nursing class (Merivaara Futura PLUS) using separate 3D-printed adapters. An adult mannikin and only the mannikin's weight were used to monitor weight changes. Weight changes on the mattress are simulated by moving the doll to different positions.

An attempt was made to simulate situations corresponding to correct movement in bed, such as:

- The distribution of weight changes at different points of the bed (edges, ends).

Pillows or similar devices were used to support the position (Figure 17):

- The 30-degree recommendation for the lateral position was taken into account. Perpendicular side effects of 90 degrees should be avoided in bed patients due to an increased risk of pressure ulcers. Therefore, the

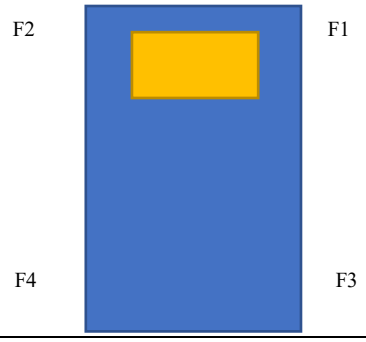
position of the bed patient is supported to a lateral part of about 30 degrees using pads, whereby the pressure at the pelvis is evened out over the widest possible area. (Juutilainen & Hietanen 2012, p. 319.)

- Each posture change was reviewed and verified (recorded) by Florie.

Figure 17. Position support with pillows (Leppänen, 2021)

During the simulations, a measurement report (Table 8) was kept, in which all measurements made during the simulations were recorded with a timestamp so that later, in the analysis phase, it was possible to go back to each measurement time to find the related functions of the specific timestamp. In addition, other observations that emerged, such as additional spikes in the measurement data or other simulation-related disturbances, were also recorded in the measurement report.

Table 8. Example of the measurement report (Leppänen, 2021)

Timestamp	**Action**	**Additional notes**
9:15	Simulate a day 1 situation: The baby wakes up and moves	Rocking the baby on the bed/sensors respond to changes in weight distribution that can be seen on Florie
9:18	Simulating baby care: Changing a diaper/diaper with a bed. General movement.	The sensors respond a lot.
9:19	Simulate a mother's visit to a baby. Baby off the bed, stroking the bed .	The sensors respond a lot.
9:21	Add 20g of extra weight to the baby's abdominal area (picture in the report).	An increase of 20 grams mimics the need for daily weight gain according to a preset plan. Measurement point 1 in the simulation report.
9:25	Add 20g of extra weight to the baby's abdominal area (picture in the report).	An increase of 20 grams mimics the need for daily weight gain according to a preset plan. Measurement point 2 in the simulation report.
9:26	Add 20g of extra weight to the baby's abdominal area (picture in report).	An increase of 20 grams mimics the need for daily weight gain according to a preset plan. Measurement point 3 in the simulation report.
9:28	Add 20g of extra weight to the baby's abdominal area (picture in report).	An increase of 20 grams mimics the need for daily weight gain according to a preset plan. Measurement point 4 in the simulation report.
9:29	Add 20g of extra weight to the baby's abdominal area (picture in report).	An increase of 20 grams mimics the need for daily weight gain according to a preset plan. Measurement point 5 in the simulation report.
9:32	Some spike in the data in sensor F1, in others no change. No information on what caused the peak.	
9:35	External vibration was tested (distance approx. 0.5m) → no great effect on the sensors	
9:36	The bed is shaken (slightly).	
9:39	2kg extra weight on the bed.	The scale changes substantially in the application.
	More information: The simulation followed the simulation plan. Position the sensors in the legs of the bed as shown. F1: value_a F2: value_b F3: value_c F4: value_d	

The data from the simulations were obtained in .csv format and further analysed using Microsoft Excel. The measurement data were collected from the obtained data with the help of important measurement moments, and the measurement results were analysed concerning the case to be measured (Appendix 3). Each example of the cases was different, and the measured data had to be processed as required by the example case.

Each case set specific attributes for analysis that needed to be looked at from the data. The data itself was the same format for each example case (Figure 18); however, through the interpretation of the data and the excel analysis performed on it, it was possible to define different information from the data (Figure 18). The results of the simulation report are presented in Chapter 5.

Figure 18. Collected sensor data in excel and excel analysis (Leppänen, 2021)

4.2.2 Thematic interview and content analysis

It was important for the thesis assignment company that the research provided comprehensive information related to the operation of the prototype device and its suitability in three example cases, and at the same time produce data for future further development. The second part of the study was carried out qualitatively to find out the importance of simulations in this case and at the same time to form a better understanding of the importance of simulations in the further development of the product. The success of the simulations and their application to the further development of the product is easier and more valuable to describe verbally than just statistically. A deeper understanding of the importance of simulations enables more

comprehensive product development and more efficient design (Mourtzis, 2019, p. 2). The flexibility of qualitative research provides answers to precisely these questions, and for this reason, a semi-structured thematic interview was chosen as one of the data collection methods. A thematic interview is an intermediate form of an open and a form interview, in which the themes of the discussion are structured in advance. (Valli & Aarnos, 2018, p. 24.)

Valli and Aarnos (2018, pp. 27-28) raise three different factors in favour of thematic interviews: the opportunity for the interviewee to express their views, the sharing of their own experiences and participation in scientific research, and the good experiences gained from it.

During the preparation of the interview framework for this thesis, the previous product development literature, and the role of simulations in product development were examined. The answers of the interview were not tied to the answer options and the interviewee was allowed to answer in his own words. The interview highlighted the interviewee's own experience and definitions of the intended use of the simulated product and the success of the simulations. The interviewee was also one of the facilitators of the simulations and the interviewee understood the purpose and thematic areas of the interview. (Hirsjärvi & Hurme, 2008, p. 47-48, 60, 66-67.)

The interview requires good contact with the interviewee, which is why the interviewee's workplace was chosen as the place of the interview (Hirsjärvi & Hurme, 2008, p. 73-74). In the interview situation, the questions act as a checklist and, if necessary, a discussion facilitator. The choice of questions in this study was based on simulations and the utilisation of data obtained from them. The themes of the interview framework were divided into two parts according to the conceptual framework, i.e., the simulations themselves and the utilisation of simulations in further development. Within the themes and preprepared questions, the intention was to ask in-depth questions improvising depending on the course of the discussion. Therefore, the interview body was made as short and flexible as possible to obtain authentic and relevant responses. (Valli & Aarnos, 2018, p. 38.)

In qualitative studies, the sample size is always one significant factor. However, it is also possible for the researcher to choose their material at their discretion in qualitative studies. The discretionary term arises from the fact that a researcher can choose a research subject at his or her own discretion so that it is nevertheless justified from the point of view of the research. In this case, the aim is not to generalise the results but rather to understand the phenomenon or find new perspectives. (Vilkka, 2007, p. 58.)

One person was selected for the discretionary sample size in this study because the interviewee was already chosen at the thesis assignment time. The person selected for the interview also acts as one of the designers and developers of the product, and in that case, his own motivation to discuss the results of the simulations helped to achieve the results of this study.

In qualitative analysis, the material is often considered a whole, but in such a way that it is possible to distinguish between the reduction of observations and the solution of the main task. The material was listened to through several times and, at the same time further delved into the knowledge base of the topic. After listening to the material, it was transcribed. Literation refers to writing interviews cleanly. It is a good idea to do the transcription as soon as possible after the interviews. A successful and appropriate transcription method is essential for successful analysis. According to Hyvärinen et al. (2017, pp. 367-368), spelling can be performed at different levels of accuracy depending on the research questions and the method of analysis. From the saved file, the text is a transcripted word for word. During transcription, repetitions were ignored, and unnecessary filler words were left out.

After transcription, it was possible to summarise the findings of the interview material into themes and group them into an analysis framework. Thus, thematising was chosen as the method of analysis, which is the basic method of qualitative research that aims to outline key themes (Tuomi & Sarajärvi, 2018, p. 79; Hirsijärvi & Hurme, 2008, p. 173). With the help of thematising, it was possible to create a unified whole from the material, which was included in the final analysis framework. The analysis framework was theoretical in which existing theory was identified but guided by the research data.

5 SIMULATION, LABORATORY MEASUREMENT RESULTS AND THEMATIC INTERVIEW RESULTS

The aim of the thesis was to find answers on how simulation data can be utilised in the product and service development phase of the Florie cloud service and how nursing simulations can be further utilised in the design of prototype product and service development. Answers to the research questions of the thesis were sought with the help of a simulation event organised at Satakunta University of Applied Sciences Pori and an expert interview conducted at Dyme Solution Oy. The simulations and interviews were conducted during spring and summer 2021.

5.1 Simulation

The simulation was conducted on the 8th – 9th of April 2021 in the nursing class of Satakunta University of Applied Sciences. The functionality of the equipment and the condition of the tools was ensured on the 8th of April with the help of a designed simulation plan as well as a specialist from Dyme Solution Oy. The total duration of the simulations was approximately 180 minutes. Before starting the simulations, all simulated equipment was checked, and the needed tools were confirmed. The simulation plan and nursing student assisted of the simulations ensured that all critical steps related to the identified use cases were considered.

A particularly valuable outcome of the simulations was the construction of a simulation measurement report and simulation report. A great help in this was the nursing student, whose knowledge and skills could be used during the simulations. Because the simulations were not performed in the hospital environment, it was important to get information from the nursing student about how the patient is being treated in each situation and how the patient and nurse might behave. During the simulations, a reflection on the functionality of the device was conducted together with the nursing student. The following questions arose during the simulations: What worked well or as expected when using the device? What were the errors and problems

using the device? What are the strengths of the device? This reflection was written out the simulation report and its results are discussed in the following section 5.2.

5.2 Laboratory measurement

The data from each identified use case was stored in the Florie cloud service, from where it was collected in .csv format in Excel for further analysis. Results are opened here in each case alone.

Case 1, Baby Nutrition

The graph was formed from the calculated measurement moments, and the data average graph (Figure 19) added a linear trend line to predict the future behavior of the variable based on the data, if the trend continues similarly. It can be seen from the graph that the average of the sensors increases with each measurement moment, which indicates an increase in the child's weight concerning the previous measurement moment as well as the total weight.

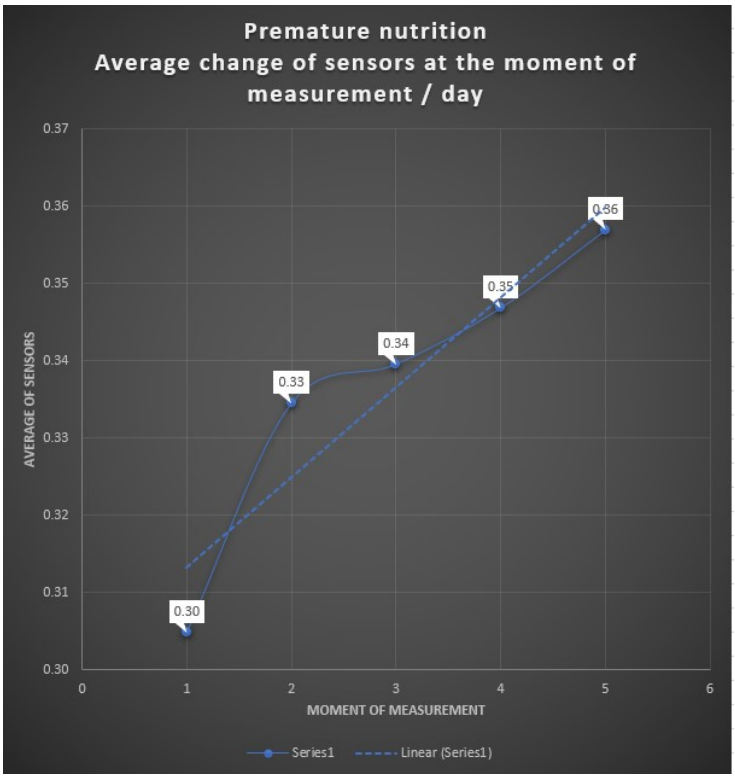


Figure 19. Average change of sensor data case baby nutrition (Leppänen, 2021)

However, in this example, the weight increases are so small that the change is minimal from value 0,30 to 0,36 but still interpretable from the sensor data.

This example case was used to produce data that required exact precision, and considering the results obtained in the simulation, it is conceivable that these results are helpful when trying to understand how a prototype device works with such small weight changes, and these interpreters can also be used for further product design.

Case 2, Heart failure

The graph was formed from the calculated measurement moments, and a linear trend line was added to the mean change graph (Figure 20) to predict the future behavior of the variable based on the data, if the trend continues similarly.

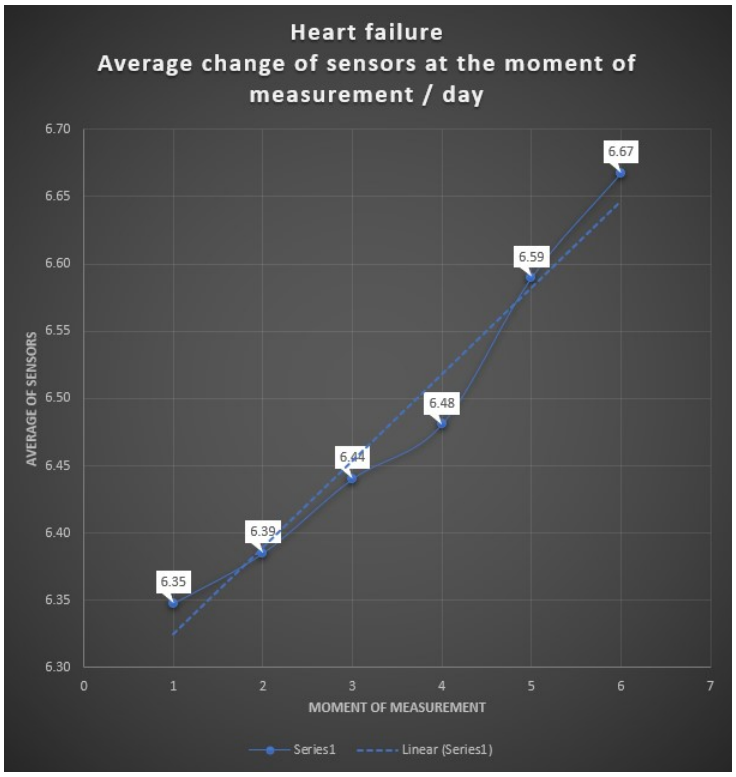


Figure 20. Average change of sensor data case heart failure (Leppänen, 2021)

It can be seen from the graph that the average of the sensors increases with each measurement moment from the value of 6,35 to value 6,67, which indicates an increase in weight relative to the previous measurement moment as well as the total weight. A

bar graph was also formed from the data, to which the averages of all sensors at the time of measurement were introduced (Figure 21).

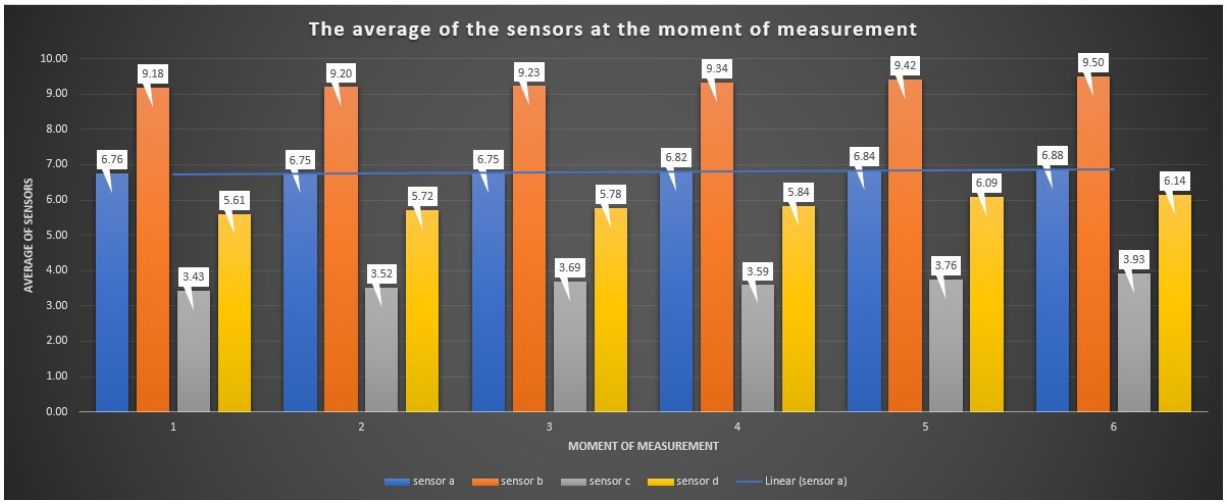


Figure 21. The average value of sensors at the time of measurement (Leppänen, 2021)

It can be seen from the bar graph that in the initial situation, the average of sensors a and b at the top of the bed is greater than the value of sensors c and d at the foot end. The weight can be said to increase steadily according to the simulation plan, but for example, the accumulation of fluid in the feet (sensors c and d) can by no means be observed explicitly from this data because the average change of each sensor at each measurement time is very close to the average of the previous measurement.

The obtained results indicate that these results are helpful when trying to understand how a prototype device works with these changes, and these interpreters can also be used for further product design.

Case 3, Position treatment

From the measurement results, each measurement moment must be considered as its own to interpret whether the weight distribution is detectable from the data:

Measurement time 1 = patient lying on his back in bed (baseline). The sensor values are distributed as shown in the bar graph (Figure 22) at measurement 1.

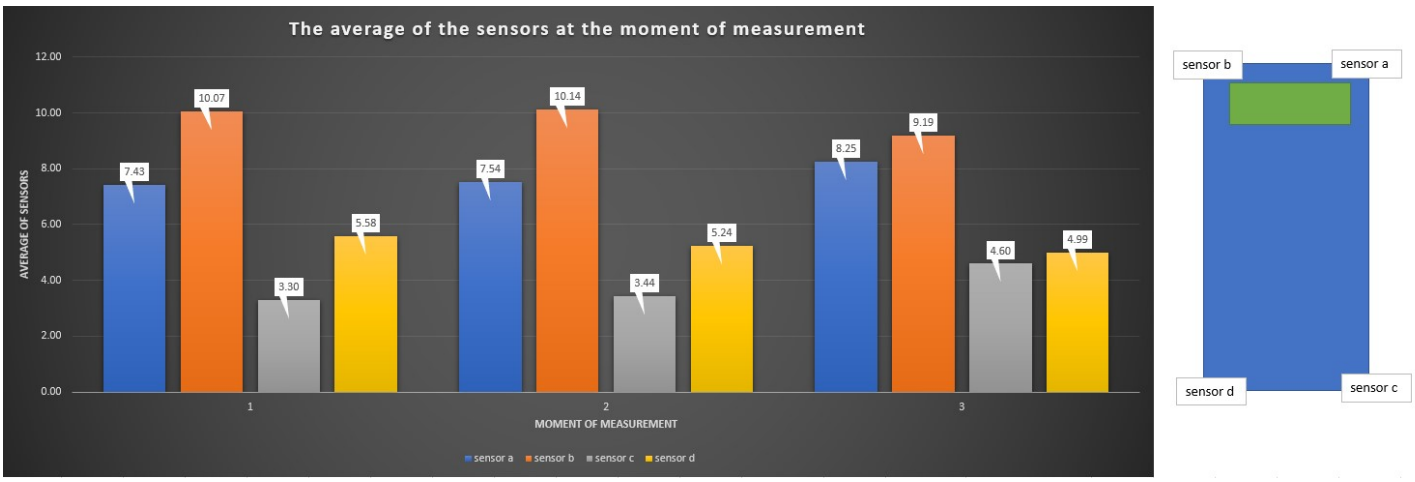


Figure 22. The average value of sensors at the time of measurement (Leppänen, 2021)

Measurement time 2 = The patient's legs are raised on the pad/heels raised. However, the average of the sensors shows a momentary change in the sensor data; the average of the sensors returns to the level of the initial situation (Figure 22) as indicated at the time of measurement 2. Thus, lifting the legs does not indicate that the weight was distributed differently than measurement time 1. Presumably, the sensors are located too far apart relative to the position of the manikin on the mattress for such a change to be interpreted from the sensor values.

Measurement time 3 = The position is changed to the side position on the right side of the bed (Figure 23). A change from the previous measurement moment is detected in each sensor. The sensor values now more accurately indicate the weight distribution on the mattress. The value of sensors b and d becomes smaller than the values of the previous measurement moment, and the value of sensors a and c increases from the last moment measurement (Figure 22).

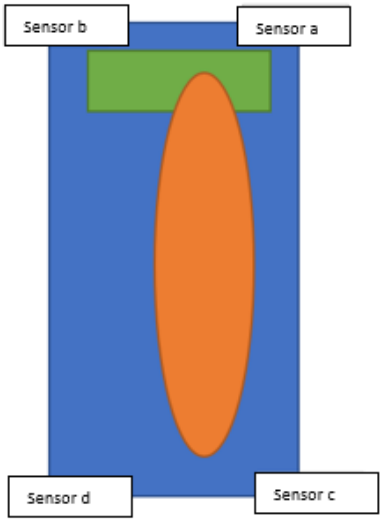


Figure 23. Lateral position on the right side of the bed (Leppänen, 2021)

Sensor data can be used to detect changes in weight distribution; however, the detection of weight distribution is not accurate enough to interpret which point of the patient's weight is more in contact with the mattress (pressure ulcer formation). The obtained results indicate that these results are helpful when trying to understand how a prototype device works with these changes, and these interpreters can also be used for further product design.

5.3 Interview

The thematic interview was conducted on the 18th of June at the Dyme Solutions Oy. The presentation of the results of the simulations and the total duration of the interview was approximately 90 minutes. Before starting the interview, the interviewee was asked permission to record the conversation. The interview was conducted without interruption, and the discussion also progressed beyond the preliminary topics. The implementation of the interview was successful, and the discussion provided a diversity of information. Referring to the research tasks, five different main themes emerged from the data (Figure 24):

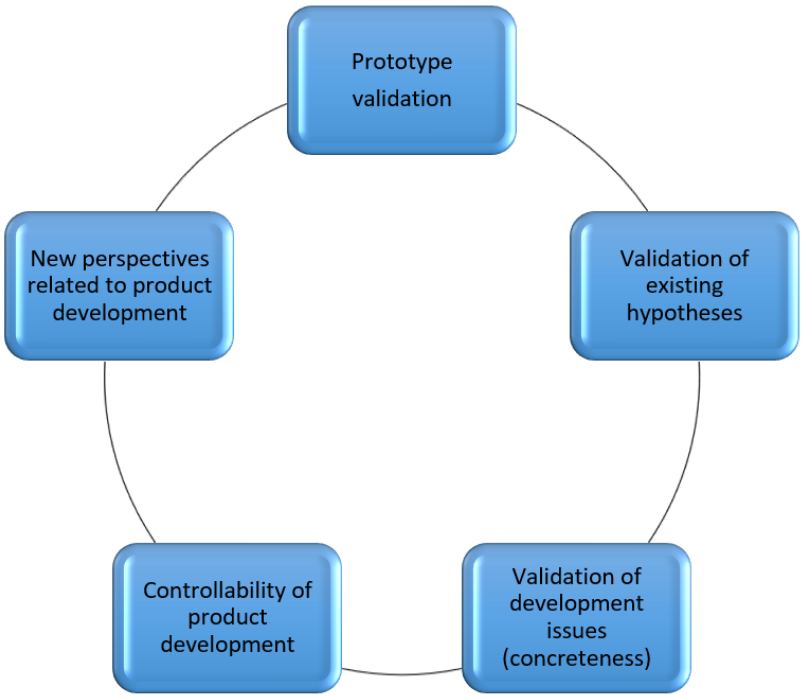


Figure 24. Themes formed by the results of the interview (Leppänen, 2021)

5.3.1 Validation of existing hypotheses

Theme 1 of the interview was about the importance of simulations in defining prototype hypotheses. A prototype manufactured by the product development team was used to test the hypotheses during the simulations. The challenge for companies that are constantly innovating can be how to develop a product that is of interest to customers and how to develop a ready-made solution from a hypothetical product. During the interview, the interviewee stated that "At the beginning of this study, product development had some hypotheses about a prototype's behaviors' before the simulations…" The interviewee continued that "…simulations strengthened faith in the product and provided new ideas for further product development."

5.3.2 Validation of development issues (concreteness)

The concreteness of the simulations was reviewed through interview questions of Theme 2, i.e. "Do the simulations facilitate the formation of the meaning of the

product?". The importance of the simulations was found to be very important for the further development of the product, especially because the three pre-defined example cases provided a concrete way to verify the functioning of the prototype at an early stage. The interviewee stated that "during the simulations, as well as the data related to the outcome of the simulations, issues related to the development of the sensors and concrete requirements became clearer."

5.3.3 Controllability of product development

Theme 3 of the interview was about developing a technological product that contains intelligence and is intended to be a healthcare product when a certain kind of controllability and precision are needed. Therefore, especially from the point of view of product design, it is essential to manage vital things to develop the product further. The interviewee agreed that "in the early stages of prototype development, it is essential to see if the product fits the goals at all just to make big changes in the beginning.". For this reason, the data obtained from the simulations means a lot to which further development of the product is to be taken.

5.3.4 New perspectives related to product development

Concerning the new perspectives, the interviewee believed that the simulations produced information that helped to "add new angles to the box." According to the interviewee, the simulations provided an expanded perspective on how or where the device could be helpful or where or how it should not be used. Before the simulations and the pre-set cases performed in the simulations, there was no information on how the product would behave in these situations, so the added value brought by the simulations was perceived as an excellent addition to product development.

5.3.5 Prototype validation

Theme 5 of the prototype validation was built on based on the previous four themes. The interviewee said that "Simulations provided a much better understanding of user

interface and sensor development”. The interviewee also thought that "Initial type testing is an important part of seeing whether a prototype is fit for purpose at all or whether major changes need to be made in the beginning."

Concerning quality assurance and risk management, simulations of a product in the prototype stage could also be used to validate product safety and failures. In general, product safety arises at the design stage. Before placing a product on the market, the manufacturer must assess the intended use of the product at different stages of its life cycle and consider the different user needs. (Lamé & Dixon-Woods, 2020, p. 89.)

6 DISCUSSION

With the help of the data obtained from the simulations and the analysis framework produced from the interview, five key topics can be raised, which were essentially related to the product's further development and support a spiral product development process. In addition, new and even refreshing perspectives were found on the actual research problem, i.e., using simulation data in the product development process. Because data from the simulations was available for a limited period, the simulation model's validity can only be assessed in this situation in the observation area. Furthermore, the measurement data accumulated very little concerning what should be simulated in this type of case, so it is not possible to make a clear interpretation of it: Is there a clear dependence between the averages? Would a more extended period of data (enormous amounts of data) better determine these dependencies?

Based on the results of case 1, it would be necessary to perform more detailed tests over a much more extended period and in the hospital environment to consider deviations that cannot be considered in this test (e.g., treatment measures, different movements during the day). In addition, even when the weight changes to be monitored are very small (15-20g), other weight changes occurring during the day may distort the result of the measurements and give an erroneous impression of a continuous increase in weight. From the measurement results of case 2, it is not possible to see, for example, exactly where the weight of the parts accumulates, which would be essential data in this case. However, the weight was increased unevenly in the simulation by adding 400g to the chest area throughout the simulation and 1600g to the legs so that it was evenly distributed between 800g and 800g on both the right and left legs. For this reason, it could have been thought that the weight distribution for sensors a and b and sensors c and d could have been better interpreted from the data, but this was not noticeable.

The sensor data from case 3 can be used to detect changes in weight distribution. However, the detection of weight distribution is not accurate enough to interpret which point of the patient's weight is more in contact with the mattress (pressure ulcer

formation). If more sensors were placed directly under the mattress, the weight changes could be more noticeable. However, the four sensors used in the simulation under the feet indicate that the position has changed, which in a sense already indicates that movement has taken place. Therefore, the measurement results have mainly examined whether the sensors react to the mattress's weight distribution (dummy transfers) to be interpreted from the sensor data. Based on simulation results, more testing and development is needed. Although there were clear variations in weight from the measurement results, the data was still so rough that more measurements and possibly more sensors were needed to obtain more accurate data for the weight distribution use of the product. However, the simulations showed that the current prototype is already suitable for indicating whether the patient is in bed and even for noticing where the patient's weight on the bed changes. At this level, it would already be possible to use the prototype to example case 3, but other example cases need longer testing periods and more accurate data.

According to the study, testing the hypothesis confirmed where the further development of the product should be adjusted. In addition, the three example cases in the testing generated measurable results that were used to construct the direction of the product, which in turn helped refine the product hypotheses. Testing the prototype creates concreteness and savings in software development. In particular, the study highlighted the benefits of concretising the prototype in the sense that the simulations and the data generated from the simulations provided a clear indication of how to steer the prototype in the right direction, anticipate errors and identify potential future problems, and estimate development costs. (Ulrich et al., 2020, p. 304.)

Particularly crucial during this thesis was that data was explicitly obtained on how the product would work in an end-user environment. Thus, data acquisition through simulations is valuable, especially when there is no existing knowledge base for a possible operation in the end-user environment. The simulation data can also react very early to developing a compliant product, thus better responding to regulatory requirements, user needs, safety, and quality. The study showed that the simulations also provide accurate data if product would fail and lead to a product failure. No accurate risk analysis was performed during this thesis, but the simulations created an

opportunity for the company to conduct its risk analysis for the further development of the product, and the results raised issues that should be considered in the design of healthcare products. With the help of risk management, the company receives operational benefits that can be used to identify or reduce disruptions even before they occur and to use the data obtained from simulations in suggestions for improvement. (Healthcare Failure Mode and Effect Analysis, 2021, p. 3.)

Katsaliaki and Mustafe (2011) point out that simulations are applied to many health issues, and the field of simulation has developed a lot in recent decades. However, according to my research and the focus of Katsalia's and Mustafee's research, simulation techniques can be used to provide better accuracy, cost-effectiveness and risk management through health care future planning and development. Like Bhuiyan's (2011, p. 764 - 765) research and this study shows, in the development phase, when the desired prototype data is available, data can be used to be able to agilely iterate whether a product is going in the right direction and prove the product is following the required target. Ulrich, Eppinger, and Yang (2010, p. 173) also emphasise that testing is a stage mastered throughout the project. In this study, prototype simulation helped identify future uses in concretising and testing business ideas. Furthermore, with the information and data from the simulations, it is also possible to communicate and explain the issue to stakeholders, such as gathering new ideas, refining existing development ideas, and providing concrete discussions for possible discussions with funders. (Ulrich et al., 2020, p. 300.)

One of the essential outcomes of this study was that the simulations were used to perform controlled and pre-defined tests from which specific expected results could be compared with the results obtained. In addition, a pre-defined simulation plan created a manageable way for the study to investigate pre-set case studies and helped analyse the results from the simulations. This study showed that one significant factor in the success of the simulations was a simulation plan. Without a plan, simulations may not yield similar benefits. Lamé & Dixon-Woods (2020, p. 87) state in their review that quality can be measured precisely through pre-set quality criteria, which in this thesis were promoted by e.g., availability, reliability, safety, and findings of boundary conditions related to simulations and simulation plan.

The study put emphasis on achieving new perspectives through simulation. Satakunta University of Applied Sciences' nursing simulation facilities made it possible to utilise product testing in its natural environment without the risk situations contained in the hospital environment. Furthermore, when the prototype was tested in the natural environment, many issues relevant to product development emerged that would have been missing or ignored if the product had not been simulated at such an early stage. Thus, the importance of simulations in supporting product development is a valuable addition to the entire product development process. Mandanin et al. (2017, p. 8-9) study admit that the importance of simulations in the industry should also be considered on the healthcare side. The role of simulations and their usefulness, especially in the field of innovation processes, is excellent. The simulations provide much information based on which strategic decisions can be made for the further development of the product. The data analysis from the simulations obtained during the thesis revealed critical data for further design. This was confirmed during the simulation phase when validating the possible use of the product during identified health care cases. Mandani et al. also demonstrated that simulated environments could provide an effective means to assess the actual needs of the subject and use the data from the simulations for possible removal of potential development as desired and a second time to minimise costs and possible deployment. Very typical of successful product development of available products, high quality, development costs and product development capability (Ulrich, Eppinger and Yang, 2010, p. 3).

Gheng et al. (2014, p. 1092) state in their study that simulation-based training effectively improves the knowledge and skills of health care professionals. This research showed that studying and testing the introduction of new medical technology is much more risk-free and more ethically acceptable through a simulation environment than in a hospital situation. The results of this research are consistent with Gheng et al. study that showed that one value area where simulations can play a significant role could be in the training of multiple end-users. Looking at the results from the simulations concerning Ulrich et al. (2020) process model of the Generic Product Development process can be stated that during the detail design phase, many boundary conditions are created before the tests, which are verified in the simulation and testing phase. When designing the simulations during research, a nursing student

was used to identify the parameters needed in the simulations and consider the further development of the product; it could also be possible to include expert-specific working life results in the simulations, which could be needed for the further use. With the help of nursing students, views and boundary conditions could be achieved at a very early stage of product development that would be essential for the further development of the product in launching the product on the market. For example, the health care students would have the necessary vision to define, even at a very early stage, needs that would only become apparent in the regular stage of product development when the product is already in its natural environment of use. Producing such added value together with students and professionals in the field would further increase the importance of simulations in the healthcare product development phase.

7 CONCLUSION

Based on the outcomes of the thesis, the simulations were seen to improve the further design of the product in the prototype phase and highlight important design and development boundary conditions. Furthermore, the simulations aimed to bring out new perspectives and go through different ways of working on how the product development work could be carried out in cooperation with Satakunta University of Applied Sciences, especially concerning simulations.

As the research results showed that the simulations provided a much clearer picture for the further development of the product and especially for the possible operation of the product in future operating environments and cases, one further research task could be to investigate the possibilities of the Simulation model and its use in the future use in Degree Programme in Nursing at Satakunta University of Applied Sciences (SAMK).

Another research task could be to explore how simulations could also be implemented to develop prototype devices in the healthcare sector collaborating with the private sector actors and students. Is it possible, for example, to organise a course that invents the innovation and testing of a product in the prototype stage explicitly? Can students ’skills be extended to the design side of simulation situations that could support the testing prototypes of the private sector.

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VERSIO 1.4

8.4.2021

FLORIE

CASE: FLORIE

SIMULOINTISUUNNITELMA

Luottamuksellinen

SISÄLLYSLUETTELO

Luottamuksellinen

SIMULOINTISUUNNITELMA

KOHDERYHMÄ(T)

Asiakas: Dyme Solutions Oy

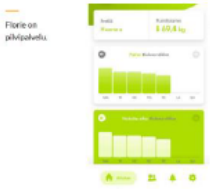
Kohde: Dyme Solutions Oy:n Florie pilvipalvelun kehitys.

Asiakas: Satakunnan ammattikorkeakoulu, Pori

Kohde: Satakunnan AMKn hyvinvointi- ja sairaanhoitopuolen simulointiopetus.

SIMULAATIOSSA TARVITTAVAT VÄLINEET/ASIAT

Välineet/Asiat	Vastuuhenkilö	Huom.
Painosensorit (4kpl) ○ **SparkFun TAS606**	Dyme	
Jalustat (kelkat) sensoreille (8kpl) ○ **normaali sairaalasänky (4kpl)** ○ **vauvan sairaalasänky (4kpl)**	SAMK	
Hoitonukke 2kpl; ○ **yksi aikuinen** ○ **yksi vauva**	SAMK	
Sänky 2kpl; ○ **yksi normaali sairaalasänky (Merivaara Futura PLUS)** ○ **yksi vauvan sairaalasänky**	SAMK	
Läppäri / Tabletti	Henna	
Matkapuhelin (+ jalusta kuvaamiseen)	Henna	
Vaaka	SAMK	

Välineet/Asiat	Vastuuhenkilö	Huom.
Painot (riisipussit) **CASE1: 5 x 20g painavia riisillä täytettyjä pusseja** **CASE2: 10 x 200g painavia riisillä täytettyjä pusseja** **CASE3: ei tarvetta lisäpainoille**	Henna	
Simulointiapu	SAMK	
Florie pilvipalvelu	Dyme	

SIMULAATIOSSA TARVITTAVAT ENNAKKOTIEDOT JA TAVOITTEET

VALMISTAUTUMISVAIHE

- perustiedot simuloitavista tilanteista selvillä →
  - mitä pitää tarkkailla?
  - miten paljon painoa on lisättävä (alustava suunnitelma: LIITE1, LIITE2, LIITE3)
- simuloitavan tilanteen aitous →
  - nukke ja nuken sijoittaminen/kääntely (painonjakautuminen sängyllä)
  - tarvittavat punnitukset
- oleellisimmat roolit tiedossa simulaation suorittamista varten →
  - roolijako selvillä ennen simulaation alkua (sisältyy simulaatiosuunnitelmaan)
- tarvittavat välineet saatavilla ja valmiina
  - sisältyy simulaatiosuunnitelmaan
- tavoitteena havainnoida ja kirjata (sekä videoida) tilanteita, joihin mahdollisesti on syvennyttävä simulaatioraportissa
  - sisältyy simulaatiosuunnitelmaan

SIMULOINTIVAIHE

- simuloinnin kronologinen ja systemaattinen suorittaminen
  - sisältyy simulaatiosuunnitelmaan
- datan kerääminen
  - Florie pilvipalvelu: data kerätään Florie pilvipalveluun, jota
- videointi
  - kännykkä

PRE-SET SIMULATION CASES

- Premature Baby Nutrition
- Hearth Failure

- Position Treatment

CASE	Ennakkotiedot	Tavoitteet	Lisähuomioita
Premature Baby Nutrition	kts. liite1	kts. liite1	
Hearth Failure	kts. liite2	kts. liite2	
Position Treatment	kts. liite3	kts. liite3	

SIMULOINNIN ROOLIT JA VASTUUALUEET

Toimija	Rooli	Vastuut	Lisähuomioita
Henna Leppänen	Simuloija	Koko simuloinnin järjestäminen ja suoritus	
Dyme Solution Oy	Simuloitavan tuotteen toimittaja	Tuotteen asennus ja ohjelmistojen käytön opastus / toiminnan varmistaminen /mahdollinen osallistuminen simulaatioon	
Sairaanhoitaja opiskelija	Tukee simulaatioita	Tukee simuloijaa ja antaa oman näkemyksensä simulointien suorittamisesta	
SAMK	Simulaatiotila	Tarvittavat tilat + välineet	

RISKEJÄ JA ONGELMIEN HALLINTA

MAHDOLLISET POIKKEUKSET JA ONGELMAT

- Aikataulu
- Työmäärä
- Painosensorit eivät toimi
- Painon muutokset eivät näy ohjelmassa
- Jokin antureista on rikki
- Muistetaanko simuloida kaikki tarvittava
- Miten simulaatiota ohjataan

SOPIVAT KORJAAVAT TOIMENPITEET

- Aikataulu →Selkeä laadittu aikataulu (LIITE4)
- Työmäärä → Roolijako määritelty (kts. roolijako ja vastuualueet)
- Painosensorit eivät toimi → testaus ohjelmistoyrityksen kanssa ennen simulointeja
- Painon muutokset eivät näy ohjelmassa → tarvittava määrä painoja, jotta saadaan vastetta
- Jokin antureista on rikki → testaus ohjelmistoyrityksen kanssa ennen simulointeja
- Muistetaanko simuloida kaikki tarvittava →simuloinnin määrittelyt (LIITE1, LIITE2, LIITE3)
- Miten simulaatiota ohjataan → Roolijako (kts. roolijako ja vastuualueet)

RISKIEN JA ONGELMIEN SEURANTA

Tallennuspäivämäärä	Riskin kuvaus	Todennäköisyys	Vaikutus	Lieventämissuunnitelma
19.3.2021	Aikataulu	2	3	Selkeä aikataulu
19.3.2021	Työmäärä	2	3	Selkä roolijako
19.3.2021	Painosensorit	2	2	Uusi simulaatio
19.3.2021	Painonmuutokset	3	2	Uusi simulaatio
19.3.2021	Simulaatio	3	2	Uusi simulaatio
5.4.2021	Sairastuminen	2	3	Uusi simulaatio

LIITE1

CASE 1: Keskosen ravitsemus (Premature Baby Nutrition)

Ennakkotiedot

Ravitsemus

Keskosen ravitsemushoidossa on tavoitteena saavuttaa sama kasvunopeus kuin kohdun sisällä kasvavan, normaaliaikaisena syntyvän lapsen. Tällaisen kasvutahdin saavuttaminen sulkee pois ravintoaineiden puutostiloja ja mahdollistaa paremmat neurokognitiiviset lähtökohdat. (Schneider& Garcia-Rodenas, 2017).

Alkuvaiheessa on hyvin tärkeässä roolissa suonensisäinen eli parenteraalinen ravitsemus. Parenteriaalisella ravitsemuksella pyritään tarjoamaan samat ravintoainemäärät kuin kohdussa kasvavalle sikiöllekin. (Merras-Salmio, Tuokkola, Strengell & Ashorn, 2014). Yleissuositukseen perustuvat nestemäärät inkubaattorissa olevalle keskoselle on esitetty taulukossa 1.

Taulukko 1. Nestehoidon yleissuositus inkubaattorissa olevalle keskoselle (Luukkonen & Saarela 2019)

Paino (g)	Suonensisäinen vesimäärä (ml/kg/vrk)	
	1.–3. vrk	4.–7. vrk
500–800	80–120(–150)	120–140(–180)
801–1 000	70–110(–130)	130–140(–160)
1 001–1 500	60–90(–120)	120–130(–150)
1 501–2 000	60–90(–110)	100–130
Yli 2 000	60–80	100–130

Kasvu

Ennenaikaisen lapsen kasvua seurataan vastasyntyneiden teho-osastolla, jossa lapsen paino mitataan joka päivä. On hyvin tavallista, että lapset menettävät hieman painoaan ensimmäisten päivien aikana. Suurin osa keskosista rupeaa tavallisesti kasvattamaan painoaan muutamien päivien sisällä syntymästä. (MedlinePlus, 2019). Kasvunopeuden mittaaminen tulisi suorittaa aina samalla kaavalla joka viikko, jotta pystytään seuraamaan jokaisen keskosen yksilöityä painonkehitystä. (Greer, F.R. & Olsen, I.E. 2013).

Vastasyntyneiden teho-osastolla on määritelty keskimääräiseksi kasvunopeudeksi 15g / kg /päivä. Kuitenkin viimeaikaiset tutkimukset ovat osoittaneet, että nämä tavoitearvot eivät ota huomioon kasvunopeuden muutoksia tarpeeksi tarkasti. (Greer, F.R. & Olsen, I.E. 2013). Tässä simulaatiossa käytämme kuitenkin vain yleistä määrittelyä (15g) painonmuutosten tarkkailuun, koska tarkoitus on simuloida anturien soveltuvuutta itse tapaukseen eikä ottaa kantaa yksilöllisiin painonvaihteluihin tai kasvunopeuteen.

LIITE1

Tavoitteet ja suorittaminen

Simulaatio

- Simulaatiossa käytettävät välineet punnitaan ennen simulaation alkua, jotta tiedetään tarkat painot kullekin simulaatioon osallistuvalle välineelle.
    - Lasketaan painon lisäystarve per simuloitu ”päivä” vauvanuken painon mukaan (= **15g / kg /pvä**; lisäystarve pyöristetään laskennallisesti seuraavaan tai edeltävään 5 gramman tarkkuuteen ennalta määritellyn laskennan mukaan kts. alla)

- Anturit asennetaan hoitotyöluokassa olevan vauvan sängyn jalkojen alle erillisiä 3D-tulostettuja adaptereja käyttäen.

- Painon muutosten tarkkailuun käytetään vauva nukkea + **20g** painavia painoja. Näitä painoja on varattuna 5 kappaletta, jotta pystytään simuloimaan painon muutoksia viiden päivän ajanjaksolta, joka vastaa teho-osastolla määriteltyä keskosen kasvunopeutta **15g / kg /pvä.**

- Jokainen ”päiväkohtainen” painonlisäys tarkastetaan ja varmistetaan (tallennetaan) Florie palvelusta.

- Painon lisäykset tehdään vauvanuken vatsan alueelle seuraavan suunnitelman mukaan:

    - Vatsan alue yhteensä **5 x 20g**

        - Ensimmäinen lisäys (mukaillen päivä 1 tilannetta):
            - vauvan paino päivänä 1 (1 270g) / 1000g * 15g = 19 g → lisäys pyöristettynä **20g**

        - Toinen lisäys (mukaillen päivä 2 tilannetta):
            - vauvan paino päivänä 2 (1 290g) / 1000g * 15g = 19,35 g → lisäys pyöristettynä **20g**

        - Kolmas lisäys (mukaillen päivä 3 tilannetta):
            - vauvan paino päivänä 3 (1 310g) / 1000g * 15g = 19,65 g → lisäys pyöristettynä **20g**

        - Neljän lisäys (mukaillen päivä 4 tilannetta):
            - vauvan paino päivänä 4 (1 330g) / 1000g * 15g = 19,95 g → lisäys pyöristettynä **20g**

        - Viides lisäys (mukaillen päivä 5 tilannetta):
            - vauvan paino päivänä 5 (1 350g) / 1000g * 15g = 20,25 g → lisäys pyöristettynä **20g**

- Simulaatio videoidaan myöhempää editointia ja tapauksen läpikäyntiä varten.

LIITE1

Lähteet

Luukkonen, P. & Saarela, T. 2019. Nestehoidon toteutus ja seuranta. Vastasyntyneiden akuuttihoito. Viitattu 15.3.2021. https://www-terveysportti-fi.lillukka.samk.fi/dtk/aho/koti

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LIITE2

CASE 2: Sydämen vajaatoiminta (Hearth Failure)

Ennakkotiedot

Sydämen vajaatoiminta on eri syistä johtuva sairaustila, jossa sydän ei pysty normaalisti hoitamaan tehtäväänsä eli veren pumppaamista elimistöön. Sydämen vajaatoiminta on useimmiten sydämen vasemman kammion sairaus. Siinä pääasiallinen oire on hengenahdistus ja voimattomuus ruumiillisen rasituksen yhteydessä. Ahdistus aiheutuu verentungoksesta keuhkoissa, sillä sydän ei jaksa pumpata keuhkoista tulevaa verta riittävästi eteenpäin. Tämän seurauksena elimistöön kertyy ylimääräistä nestettä, paino nousee ja syntyy turvotuksia. Sydämen oikean puolen vajaatoiminnassa tyypillinen oire ovat turvotukset etenkin nilkoissa ja säärissä, lopulta myös ylävatsalla. Ne johtuvat nesteen kertymisestä kudoksiin. (Kettunen, R. 2020).

Vajaatoiminnan vaikeutumisen merkkejä ovat painon nousu (jopa useita kiloja viikossa), turvotuksien lisääntyminen, hengityksen vaikeutuminen, yskä ja sykkeen nousu. (Kettunen, R. 2020).

Vaikeassa sydämen vajaatoiminnassa painon seuranta päivittäin on tärkeää. Voinnin tasaannuttua tai kun oireita ei enää ole, riittää punnitus kahdesti viikossa. (Terveyskylä).

Nesteen kertyminen nopeasti noin viiden päivän sisällä ja useamman kilon painonnousu (yli 2kg/vko; kts. taulukko 1) tarkoittavat, että sydämen vajaatoiminta on pahenemassa ja lääkitystä täytyy säätää. (Käypähoitosuositus.)

Taulukko 1. Sydämen vajaatoiminnan yhteydessä tavattavia oireita ja löydöksiä (Käypähoitosuositus).

Oireet	Tavalliset	Harvinaisemmat
	Hengenahdistus	Yöllinen yskä
	Ortopnea	Hengityksen vinkuminen
	Yöllinen hengenahdistus	Painon nousu (yli 2 kg/viikko)
	Heikentynyt rasituksen sieto	Ruokahalun menetys
	Väsymys, pitkittynyt palautuminen	Sekavuus (vanhukset)
	Nilkkaturvotus	Masennus
		Tykyttely
		Huimaus, pyörtyminen

Tässä simulaatiossa käytämme simulaation pohjana tilannetta sydämen vajaatoiminnan pahenemisesta, eli simuloidaan painon nousua viiden päivän aikajänteellä ja kahden kilogramman painon nousulla taulukkoa 1 mukaillen.

Tavoitteet ja suorittaminen

Simulaatio

- Simulaatiossa käytettävät välineet punnitaan ennen simulaation alkua, jotta tiedetään tarkat painot kullekin simulaatioon osallistuvalle välineelle.

LIITE2

- Anturit asennetaan hoitotyöluokassa olevan sairaalasängyn jalkojen alle erillisiä 3D-tulostettuja adaptereja käyttäen.

- Painon muutosten tarkkailuun käytetään aikuista nukkea + **200g** painavia painoja. Näitä painoja on varattuna **10 kappaletta**, jotta pystytään simuloimaan painon muutoksia **2000 grammaan** asti.
    - Painon lisäykset tehdään lisäämällä painoja tasaisesti erillisen suunnitelman mukaan (kts. alla), jotta täytetään Taulukossa 1 esitetty 2 kilogrammaa viidessä päivässä määritelmä.
    - Simulaatiossa toteutetaan painon nousu 200 gramman lisäyksin, jotta saavutetaan kahden kilon raja-arvo ja voidaan nähdä selkeä muutos painon nousussa.
    - Jokainen ”päiväkohtainen” painonlisäys tarkastetaan ja varmistetaan (tallennetaan) Florie palvelusta.
    - Painon lisäykset tehdään alaraajoihin sekä myös ylävatsan alueelle, jotta simuloidaan ja mukaillaan mahdollisimman tarkkaan nesteen kertymistä kehossa sydämenvajaatoiminta tapauksessa seuraavan suunnitelman mukaan:
        - Oikea-alaraaja: **4 x 200g**
        - Vasen-alaraaja: **4 x 200g**
        - Ylävatsa: **2 x 200g**
            - Ensimmäinen lisäys (mukaillen päivä 1 tilannetta):
                - Oikea- ja vasenalaraaja:
                    - oikea: **200g**
                    - vasen: **200g**
            - Toinen lisäys (mukaillen päivä 2 tilannetta):
                - Ylävatsa: **200g**
            - Kolmas lisäys (mukaillen päivä 3 tilannetta):
                - Oikea- ja vasenalaraaja:
                    - oikea: **200g + 200g**
                    - vasen: **200g**
            - Neljän lisäys (mukaillen päivä 4 tilannetta):
                - Ylävatsa: **200g**
            - Viides lisäys (mukaillen päivä 5 tilannetta):
                - Oikea- ja vasenalaraaja:
                    - oikea: **200g**
                    - vasen: **200g + 200g**

- Simulaatio videoidaan myöhempää editointia ja tapauksen läpikäyntiä varten.

LIITE2

Lähteet

Kettunen, R. 2020. Sydämen vajaatoiminta. Lääkärikirja Duodecim. Helsinki: Kustannus Oy Duodecim. Referred 26.3.2021 https://www.terveyskirjasto.fi/dlk00084/sydamen-vajaatoiminta?q=syd%C3%A4men%20vajaatoiminta

Terveyskylä. Painon, verenpaineen ja sykkeen seuranta. https://www.terveyskyla.fi/sydansairaudet/tietoa-syd%C3%A4nsairauksista/syd%C3%A4men-vajaatoiminta/omahoito/painon-verenpaineen-ja-sykkeen-seuranta

LIITE3

CASE 3: Asentohoito (Position Treatment)

Ennakkotiedot

Painehaavojen synty

Painehaavat eli makuuhaavat syntyvät erityisesti vuodepotilaille, jotka joutuvat makaamaan pidempiä aikoja eivätkä pysty itse kääntymään vuoteessa. Syntyyn vaikuttaa ratkaisevasti kudosten puutteellinen verenkierto, ja siinä mielessä ne muistuttavat säärihaavaa. Myös teho-osastoilla hoidossa olevat saavat herkästi makuuhaavoja. Siten vaikeita sairauksia potevat ja hyvin iäkkäät sekä selkäydinvaurion saaneet ovat erityisen suuressa riskissä. Pitkäaikaista hoitoa tai hoivaa saavista noin joka kymmenennellä on painehaava. (Lumio, 2019).

Painehaava syntyy sellaiselle ihoalueelle, jossa luu painaa ihoa ja estää sen normaalia verenkiertoa. Tavallisimmin painehaavat syntyvät lonkkiin, alaselkään, pakaroihin tai kantapäihin. Yleensä painehaavan syntymiseen tarvitaan usean päivän makuulla olo, mutta joskus se voi syntyä vakavasti sairaille muutamassa tunnissakin. Ensin iholla nähdään painekohdassa punoitus, sitten kudoksiin tulee turvotusta, ja lopuksi iho rikkoutuu. Painehaava on useimmiten ainakin jonkin verran kivulias. Pidemmälle edetessään ihorikosta kehittyy vaikeasti hoidettava kraaterimainen syvä haava, johon vielä tulee usein bakteeri-infektio. (Lumio, 2019).

Pitkäaikaishoidon ja hoivan vuodeosastoilla kiinnitetään erityistä huomiota painehaavojen syntymisen estämiseen vaihtamalla potilaan asentoa riittävän usein. Nyrkkisääntö on, että painekohtia tulisi vaihtaa parin tunnin välein (esimerkiksi kyljeltä toiselle). Tämä vaatii kovasti työtä, jos henkilö ei pysty itse kääntymään. Kotona potilasta hoitavalle se on vielä työläämpää. (Lumio, 2019).

Mobilisaatio

Kaikkien painehaavariskissä olevien tai jo painehaavan saaneiden potilaidenasentoa on muutettava, ellei sille ole vasta-aiheita. Asennonmuutoksilla vähennetään kehon helposti vahingoittuviin alueisiin kohdistuvan paineen kestoa ja voimakkuutta ja vaikutetaan hyvinvointiin, hygieniaan, arvokkuuteen ja toimintakykyyn. (Haesler, 2014).

Potilaan asentoa tulee muuttaa siten, että kudoksiin kohdistuva paine vähenee tai jakautuu uudelleen. Valittaessa potilaalle asentoa on tärkeää arvioida, että kudoksiin kohdistuva paine todellakin vähenee tai jakautuu uudelleen. (Haesler, 2014).

Vuodepotilaan kohdalla asentohoito toteutetaan tyynyjä hyödyntäen kallistaen potilasta oikealle tai vasemmalle kyljelle 30 asteen kulmassa. Puoli-istuvaa asentoa ja 90 asteen kylkiasentoa tulisi välttää, koska ne lisäävät kudosten painetta merkittävästi. Jos esimerkiksi hengityksen helpottamiseksi tai aspiraation välttämiseksi on välttämätöntä käyttää puoli-istuvaa asentoa, suositellaan 30 asteen kohoasentoa. (Painehaavan ehkäisy ja tunnistaminen aikuispotilaan hoitotyössä: Hoitotyön suositus 2015.)

Ihon venytyksen ehkäisemiseksi potilas tuetaan siten, ettei hän liu'u vuoteessa. Kantapäät tulisi tukea irti makuualustasta ja polvet 5-10 asteen koukistukseen. (Painehaavan ehkäisy ja tunnistaminen aikuispotilaan hoitotyössä: Hoitotyön suositus 2015.)

LIITE3

Tavoitteet ja suorittaminen

Simulaatio

- Simulaatiossa käytettävät välineet punnitaan ennen simulaation alkua, jotta tiedetään tarkat painot kullekin simulaatioon osallistuvalle välineelle.
- Anturit asennetaan hoitotyöluokassa olevan sairaalasängyn jalkojen alle erillisiä 3D-tulostettuja adaptereja käyttäen.
- Painon muutosten tarkkailuun käytetään aikuista nukkea ja pelkästään nuken omaa painoa.
    - painon muutokset patjalla simuloidaan siirtämällä nukkea eri asentoihin.
    - Pyritään simuloimaan tilanteita, jotka vastaavat oikeaa liikkumista sängyssä, kuten:
        - painon muutosten jakautumista sängyn eri kohdissa (laidoilla, päädyissä...)
        - käytetään apuna tyynyjä tms. asennon tukemiseen varattuja välineitä
    - Otetaan huomioon **30 asteen** suositus kylkiasennosta.
    - Jokainen asennonmuutos tarkastetaan ja varmistetaan (tallennetaan) Florie palvelusta.
- Simulaatio videoidaan myöhempää editointia ja tapauksen läpikäyntiä varten.

Lähteet

Lumio, J. 2012. Painehaavat eli makuuhaavat. Lääkärikirja Duodecim. Helsinki: Kustannus Oy Duodecim. Referred 19.3.2021 http://www.terveyskirjasto.fi/terveyskirjasto/tk.koti?p_artikkeli=dlk00313

Haesler, E. 2014. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide. Cambridge Media: Osborne Park, Australia. Referred 19.3.2021.

Painehaavan ehkäisy ja tunnistaminen aikuispotilaan hoitotyössä 2015. Hoitosuositus. Hoitotyön tutkimussäätiö. Verkkodokumentti. https://www.hotus.fi/wp-content/uploads/2019/03/painehaava-hs.pdf Luettu 19.3.2021.

9.4.2021

CASE: FLORIE

MITTAUSPÖYTÄKIRJA

CASE 1: Keskosen ravitsemus (Premature Baby Nutrition)

Aikaleima	Tapahtuma	Lisähuomioita
9:15	Simuloidaan päivä 1 tilannetta: Vauva herää ja liikkuu	Heilutetaan vauvaa sängyllä / anturit reagoivat painon jakauman muutoksiin, joka on nähtävissä Florie palvelussa
9:18	Simuloidaan vauvan hoitoa: Vaipan vaihto/vaippa pedillä. Yleistä liikuttelua.	Anturit reagoivat paljon.
9:19	Simuloidaan äidin käyntiä vauvan luona. Vauva pois pediltä, silittelyä pedillä.	Anturit reagoivat paljon.
9:21	Lisätään 20g lisäpainoa vauvan vatsan alueelle (kuva raportissa).	20 gramman lisäys jäljittelee vuorokauden painon lisäys tarvetta esiasetetun suunnitelman mukaan. Mittauspiste 1 simulointiraportissa.
9:25	Lisätään 20g lisäpainoa vauvan vatsan alueelle (kuva raportissa).	20 gramman lisäys jäljittelee vuorokauden painon lisäys tarvetta esiasetetun suunnitelman mukaan. Mittauspiste 2 simulointiraportissa.
9:26	Lisätään 20g lisäpainoa vauvan vatsan alueelle (kuva raportissa).	20 gramman lisäys jäljittelee vuorokauden painon lisäys tarvetta esiasetetun suunnitelman mukaan. Mittauspiste 3 simulointiraportissa.
9:28	Lisätään 20g lisäpainoa vauvan vatsan alueelle (kuva raportissa).	20 gramman lisäys jäljittelee vuorokauden painon lisäys tarvetta esiasetetun suunnitelman mukaan. Mittauspiste 4 simulointiraportissa.
9:29	Lisätään 20g lisäpainoa vauvan vatsan alueelle (kuva raportissa).	20 gramman lisäys jäljittelee vuorokauden painon lisäys tarvetta esiasetetun suunnitelman mukaan. Mittauspiste 5 simulointiraportissa.
9:32	Jokin piikki datassa anturissa F1, muissa ei muutosta. Ei tietoa mikä aiheutti piikin.	
9:35	Testattiin ulkoista tärinää (etäisyyttä n. 0.5m) → ei suurta vaikutusta antureihin	
9:36	Sänkyä tärisytetään (kevyesti).	
9:39	2kg lisäpaino sängylle.	Mitta-asteikko muuttuu oleellisesti sovelluksessa.

Lisätietoja:

Simuloinnissa noudatettiin simulointisuunnitelmaa.

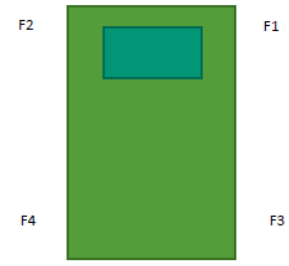
Anturien sijoitus sängyn jaloissa kuvan mukaisesti.

F1 anturi anturidatassa: **value_a**

F1 anturi anturidatassa: **value_b**

F1 anturi anturidatassa: **value_c**

F1 anturi anturidatassa: **value_d**



CASE 2: Sydämen vajaatoiminta (Hearth Failure)

Aikaleima	Tapahtuma	Lisähuomioita
11:35	Lähtötilanne / lähtotaso.	Nuken pituus 165cm.
11:36	Painon lisäys alaraajoihin suunnitelman mukaan.	400 gramman lisäys. Mittauspiste 1 simulointiraportissa. F4/F3 antureissa muutosta.
11:37	F3 anturissa piikki, vaikka mitään ei tehty.	
11:41	Painon lisäys ylävatsalle suunnitelman mukaan.	200 gramman lisäys. Mittauspiste 2 simulointiraportissa. F2/F1 antureissa muutosta.
11:45	Painon lisäys alaraajoihin suunnitelman mukaan.	600 gramman lisäys. Mittauspiste 3 simulointiraportissa. F4 anturissa selkeä ero F3 anturin muutokseen, koska painoa on eri määrä raajoissa.
11:50	Painon lisäys ylävatsalle suunnitelman mukaan.	200 gramman lisäys. Mittauspiste 4 simulointiraportissa. F1 ja F2 anturit reagoi.
11:54	Painon lisäys alaraajoihin suunnitelman mukaan.	600 gramman lisäys. Mittauspiste 5 simulointiraportissa. F4 ja F3 anturit reagoi.
11:22	Ylimääräinen testaus: Nukke kylkiasennossa sängyn reunassa oikealla.	

Lisätietoja:

Simuloinnissa noudatettiin simulointisuunnitelmaa.

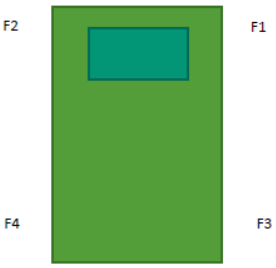
Anturien sijoitus sängyn jaloissa kuvan mukaisesti.

F1 anturi anturidatassa: **value_a**

F1 anturi anturidatassa: **value_b**

F1 anturi anturidatassa: **value_c**

F1 anturi anturidatassa: **value_d**



CASE 3: Asentohoito (Position Treatment)

Aikaleima	Tapahtuma	Lisähuomioita
11:03	Lähtötilanne selin makuulla (ei tyynyä yms.)	Nuken pituus 165cm.
11:06	Jalat tyynylle / kantapäät koholle tyynyn avulla.	F3/F4 anturit reagoivat. Nähtävissä painonjakauman muutos jalkopäässä. Mittauspiste 1 simulointiraportissa.
11:13	Asentoa vaihdetaan.	
11:14	Kylkiasento tuettuna suunnitelman mukaisesti.	Mittauspiste 2 simulointiraportissa. F2/F1 antureissa muutosta.

Lisätietoja:

Simuloinnissa noudatettiin simulointisuunnitelmaa.

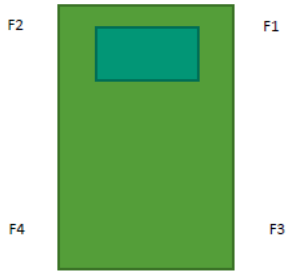
Anturien sijoitus sängyn jaloissa kuvan mukaisesti.

F1 anturi anturidatassa: **value_a**

F1 anturi anturidatassa: **value_b**

F1 anturi anturidatassa: **value_c**

F1 anturi anturidatassa: **value_d**



Luottamuksellinen
VERSIO 1.1
11.6.2021

CASE: FLORIE

SIMULOINTIRAPORTTI

SISÄLLYSLUETTELO

Luottamuksellinen

Luottamuksellinen

SIMULOINTIRAPORTTI

YHTEENVETO

Asiakas: Dyme Solutions Oy

Kohde: Dyme Solutions Oy:n Florie pilvipalvelun kehitys.

Asiakas: Satakunnan ammattikorkeakoulu, Pori

Kohde: Satakunnan AMKn hyvinvointi- ja sairaanhoitopuolen simulointiopetus.

Simuloinnit suoritettiin 8.4 -9.4.2021 Satakunnan Ammattikorkeakoulun hoitotyönluokassa.

8.4.2021 varmistettiin laitteiden toimivuus ja simuloinneissa tarvittavien välineiden ja asioiden kunnossa oleminen.

9.4.2021 järjestettiin itse simuloinnit. Simuloinneissa oli mukana simuloija (opinnäytetyön tekijä) sekä SAMKin projektityöntekijä, jolla osaaminen hoitotyön alalta. Hänen avullaan varmistettiin, että simulointien aikana tullaan simuloimaan hoitotilanteita oikein.

Simuloinnit aloitettiin tapauksesta 1 ja sen jälkeen jatkettiin tapauksesta 3 ja 2.

SIMULAATIO (CASE 1: KESKOSEN RAVITSEMUS)

SIMULAATIO

- Simulaatiossa käytettävät välineet (vauva ja lisäpainot) punnittiin ennen simulaation alkua, jotta tiedettiin tarkat painot kullekin simulaatioon osallistuvalle välineelle.
- Anturit asennettiin hoitotyöluokassa olevan vauvan sängyn jalkojen alle erillisiä 3D-tulostettuja adaptereja käyttäen (Kuva 1).

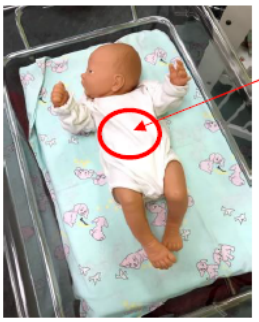
KUVA 1: 3D-TULOSTETTU ADAPTERI JA ANTURI LAPSEN SAIRAALASÄNGYN JALAN ALLA

Luottamuksellinen

- Painon muutosten tarkkailuun käytettiin vauvanukkea + **20 g** painavia painoja (Kuva 2). Näitä painoja oli varattuna 5 kappaletta, joilla pystyttiin simuloimaan painon muutoksia viiden päivän ajanjaksolta, joka vastaa teho-osastolla määriteltyä keskosen kasvunopeutta **15 g / kg /pvä.**

KUVA 2: 20G PAINAVAT PAINOT

- Jokainen "päiväkohtainen" painonlisäys tarkistettiin ja varmistettiin Florie palvelusta.



KUVA 3: VAUVANUKKE JA PAINON LISÄYSKOHTA

Painon lisäykset tehtiin vauvanuken vatsan alueelle (Kuva 3) seuraavan laskennallisen suunnitelman mukaan:

- Vatsan alue yhteensä **5 x 20 g**
- Ensimmäinen lisäys (mukaillen päivä 1 tilannetta):
  - vauvan paino päivänä 1 (1270 g) / 1000 g * 15 g = 19 g → lisäys pyöristettynä **20 g**
- Toinen lisäys (mukaillen päivä 2 tilannetta):
  - vauvan paino päivänä 2 (1290 g) / 1000 g * 15 g = 19,35 g → lisäys pyöristettynä **20 g**
- Kolmas lisäys (mukaillen päivä 3 tilannetta):
  - vauvan paino päivänä 3 (1310 g) / 1000 g * 15 g = 19,65 g → lisäys pyöristettynä **20 g**
- Neljän lisäys (mukaillen päivä 4 tilannetta):
  - vauvan paino päivänä 4 (1330 g) / 1000 g * 15 g = 19,95 g → lisäys pyöristettynä **20 g**
- Viides lisäys (mukaillen päivä 5 tilannetta):
  - vauvan paino päivänä 5 (1350 g) / 1000 g * 15 g = 20,25 g → lisäys pyöristettynä **20 g**

DATAN KERÄÄMINEN, TULKINTA JA ANALYSOINTI

DATAN KERÄÄMINEN

Mittausjärjestelmään kuului neljä kappaletta SparkFun TAS606 tyyppisiä painosensoreita (Kuva 4), jotka muuttavat niihin vaikuttavan kuorman sähköisiksi signaaleiksi. Mittaus tapahtuu anturin sisällä sijaitsevien venymäliuskojen (joustavia piirilevyjen) avulla. Kun venymäliuskaa rasitetaan, liuskan sähköinen vastus muuttuu suhteessa kuormitukseen.

KUVA 4. TAS606-PAINESENORI

Mittausjärjestelmä keräsi dataa .csv muotoon viiden sekunnin aikavälein (Kuva 5).

	A	B
1	timestamp,value_a,value_b,value_c,value_d	
2	2021-04-09T05:45:12.570Z,0,0,0,0	
3	2021-04-09T05:55:59.654Z,0,0,0,0	
4	2021-04-09T05:56:04.891Z,0,0,0,0	
5	2021-04-09T05:56:10.481Z,0,0,0,0	
6	2021-04-09T05:56:15.377Z,0,0,0,0	
7	2021-04-09T05:56:20.309Z,0,0,0,0	
8	2021-04-09T05:56:25.166Z,0.06,0.02,-0.01,0.01	
9	2021-04-09T05:56:29.938Z,0.11,0.03,-0.01,0.02	
10	2021-04-09T05:56:35.059Z,0.1,0.02,-0.01,0.02	

KUVA 5: ANTURIDATA .CSV MUODOSSA

Data tuotiin jatkoanalysointia varten Exceliin, jossa siitä oli mahdollista lähteä tutkimaan Case 1:seen liittyviä merkitseviä asioita simulointisuunnitelman ja mittauspöytäkirjan avulla.

Case 1 koskevaa dataa oli tallennettuna aikavälillä 8:56 - 9:34 viiden sekunnin välein.

Dataa muokattiin niin, että siitä laskettiin yhteen kaikkien anturien antama 5 sekunnin välinen arvo mittaushetkeä ennen ja jaettiin se tallennushetkien lukumäärällä n (=295), josta saatiin antureista saatavien arvojen keskiarvo (Kuva 6).

$$\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n}$$

Kaikki anturit	anturi a,b,c,d
keskiarvo	0,30
keskihajonta	0,20

KUVA 6: CASE 1 MITTAUSHETKI 1 ANTURIDATAN KESKIARVO

Luottamuksellinen

Datasta laskettiin myös anturiarvojen keskihajonta (Kuva 7), joka kuvaa sitä, kuinka lähellä mittausarvot ovat keskimäärin toisiaan.

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n}}$$

Kaikki anturit	anturi a,b,c,d
keskiarvo	0,30
keskihajonta	0,20

KUVA 7: MITTAUSHETKI 1 ANTURIDATAN KESKIHAJONTA

Datasta muodostettiin viisi joukkoa (=mittaushetkeä) ja jokaiselle joukolle laskettiin sekä keskiarvo, että keskihajonta ja näistä muodostettiin kuvaaja (

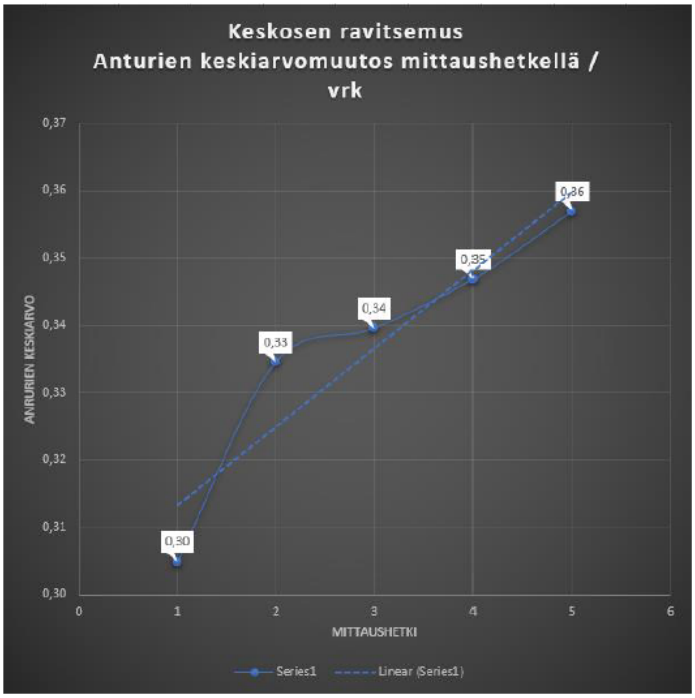
Kuva 8).

DATAN TULKINTA

Kuvaaja muodostettiin lasketuista mittaushetkistä ja keskiarvomuutoskuvaajaan (

Kuva 8) lisättiin lineaarinen trendiviiva ennustamaan aineiston pohjalta tulevaa muuttujan käyttäytymistä, olettaen että kehitys jatkuu samanlaisena.

Kuvaajasta voidaan nähdä, että anturien keskiarvo nousee jokaisella mittaushetkellä, joka indikoi lapsen painon nousua suhteessa edelliseen mittaushetkeen sekä kokonaispainoon. Kuitenkin tässä esimerkissä painon lisäykset ovat niin pieniä, että muutos on erittäin pieni, mutta kuitenkin silti tulkittavissa anturidatasta.



KUVA 8 : ANTURIDATAN KESKIARVOMUUTOSKUVAAJA

11.6 SIMULOINTIRAPORTTI

Luottamuksellinen

Keskiarvon ja keskihajonnan avulla saadaan laskettua variaatiokerroin (Kuva 9), joka määrittelee havaintoarvojen suhteellisen hajonnan prosentteina. Variaatiokerroin (%) osoittaa kuinka monta prosenttia havaintoarvojen keskihajonta on havaintoarvojen keskiarvosta.

$$cv = \sigma \; / \; \bar{x}$$

Mittaushetki	Anturien arvo		
	keskiarvo	keskihajonta	Variaatiokerroin (%)
1	0,30	0,20	65,9
2	0,33	0,28	84,3
3	0,34	0,28	82,7
4	0,35	0,28	80,4
5	0,36	0,28	77,7

KUVA 9: CASE 1 VARIAATIOKERROIN

DATAN ANALYSOINTI

Koska havaintoaineistoa on käytettävissä rajatulta aikajaksolta, mallin pätevyyttä voidaan arvioida tässä tilanteessa vain havaintoalueella.

Mittausdataa kertyi vain hyvin vähän suhteessa siihen, mitä tämän tyyppisessä tapauksessa pitäisi päästä simuloimaan, joten ei voida tehdä selkeää tulkintaa siitä:

- Onko keskiarvojen välillä selkeää riippuvuutta → pidempi ajanjakso (suurempi datan määrä) voisi tuottaa parempaa dataa näiden riippuvuuksien määrittelyyn.

Mittaustuloksissa on tutkittu pääasiassa sitä, reagoivatko anturit painon lisäyksiin ja etenkin tässä tapauksessa hyvin pieniin (15-20g) lisäyksiin siten, että se on vielä tulkittavissa anturidatasta.

Jatkoanalysointia varten olisi tarpeen tehdä tarkempia testejä huomattavasti pidemmällä aikavälillä sekä oikeassa ympäristössä, jotta voidaan ottaa huomioon myös sellaiset poikkeamat, mitä ei tässä testissä osata ottaa huomioon (hoitotoimenpiteet, erilaiset liikuttelut vuorokauden aikana...).

Myös seurattavien painonmuutosten ollessa hyvin pieniä (15-20g) voi vuorokauden aikana tapahtuvat muut painonmuutokset osaltaan vääristää mittausten lopputulosta ja antaa virheellisen vaikutelman painon jatkuvasta noususta. Mittauksessa pyrittiin kuitenkin aiheuttamaan jonkin verran poikkeamia heiluttelemalla sänkyä ja jättämällä sängylle hetkeksi painoa.

SIMULAATIO (CASE 2: SYDÄMEN VAJAATOIMINTA)

SIMULAATIO

- Simulaatiossa käytettiin hoitonukkea.
- Anturit asennettiin hoitotyöluokassa olevan sairaalasängyn (Merivaara Futura PLUS) jalkojen alle erillisiä 3D-tulostettuja adaptereja käyttäen (**Virhe. Viitteen lähdettä ei löytynyt.**).
- Painon muutosten tarkkailuun käytettiin hoitonukkea ja **200g** painavia riisillä täytettyjä pusseja (Kuva 11). Näitä painoja varattuna 10 kappaletta.
- Painon lisäykset tehtiin alaraajoihin sekä ylävatsan alueelle, jolla simuloitiin ja

KUVA 10: MERIVAARA SAIRAALASÄNKY JA 3D TULOSTETTU ADAPTERI

oli

Luottamuksellinen

mukailtiin mahdollisimman tarkkaan nesteen kertymistä kehossa sydämenvajaatoiminta tapauksessa simulointisuunnitelman mukaan (Kuva 11).

- Jokainen ”päiväkohtainen” painonlisäys tarkistettiin ja varmistettiin Florie palvelusta.

KUVA 11:200G LISÄPAINOT JA PAINONLISÄYS KOHDAT

- Painon lisäykset tehtiin alaraajoihin sekä ylävatsan alueelle seuraavan suunnitelman mukaan:

  - Oikea-alaraaja: **4 x 200g**
  - Vasen-alaraaja: **4 x 200g**
  - Ylävatsa: **2 x 200g**

    - Ensimmäinen lisäys (mukaillen päivä 1 tilannetta):
      - Oikea- ja vasenalaraaja:
        - oikea: **200g**
        - vasen: **200g**
    - Toinen lisäys (mukaillen päivä 2 tilannetta):
      - Ylävatsa: **200g**
    - Kolmas lisäys (mukaillen päivä 3 tilannetta):
      - Oikea- ja vasenalaraaja:
        - oikea: **200g + 200g**
        - vasen: **200g**
    - Neljän lisäys (mukaillen päivä 4 tilannetta):
      - Ylävatsa: **200g**
    - Viides lisäys (mukaillen päivä 5 tilannetta):
      - Oikea- ja vasenalaraaja:
        - oikea: **200g**
        - vasen: **200g + 200g**

DATAN KERÄÄMINEN, TULKINTA JA ANALYSOINTI

DATAN KERÄÄMINEN

Mittausjärjestelmään kuului neljä kappaletta SparkFun TAS606 tyyppisiä painosensoreita (Kuva 4), jotka muuttavat niihin vaikuttavan kuorman sähköisiksi signaaleiksi. Mittaus tapahtuu anturin sisällä sijaitsevien venymäliuskojen (joustavia piirilevyjen) avulla. Kun venymäliuskaa rasitetaan, liuskan sähköinen vastus muuttuu suhteessa kuormitukseen.

Mittausjärjestelmä keräsi dataa .csv muotoon viiden sekunnin aikavälein (Kuva 5).

Data tuotiin jatkoanalysointia varten Exceliin, jossa siitä oli mahdollista lähteä tutkimaan Case 2:seen liittyviä merkitseviä asioita simulointisuunnitelman ja mittauspöytäkirjan avulla.

Case 2 koskevaa dataa oli tallennettuna aikavälillä 11:35 - 11:55 viiden sekunnin välein.

Dataa muokattiin niin, että siitä laskettiin yhteen kaikkien anturien antama 5 sekunnin välinen arvo mittaushetkeä ennen ja jaettiin se tallennushetkien lukumäärällä n (=241), josta saatiin antureista saatavien arvojen keskiarvo (Kuva 12).

$$\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n}$$

Kaikki anturit	anturi
keskiarvo	6,35
keskihajonta	1,87

KUVA 12: CASE 2 MITTAUSHETI 1 ANTURIDATAN KESKIARVO

Datasta laskettiin myös anturiarvojen keskihajonta (Kuva 13), joka kuvaa sitä, kuinka lähellä mittausarvot ovat keskimäärin toisiaan.

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n}}$$

Kaikki anturit	anturi
keskiarvo	6,35
keskihajonta	1,87

KUVA 13: MITTAUSHETKI 1 ANTURIDATAN KESKIHAJONTA

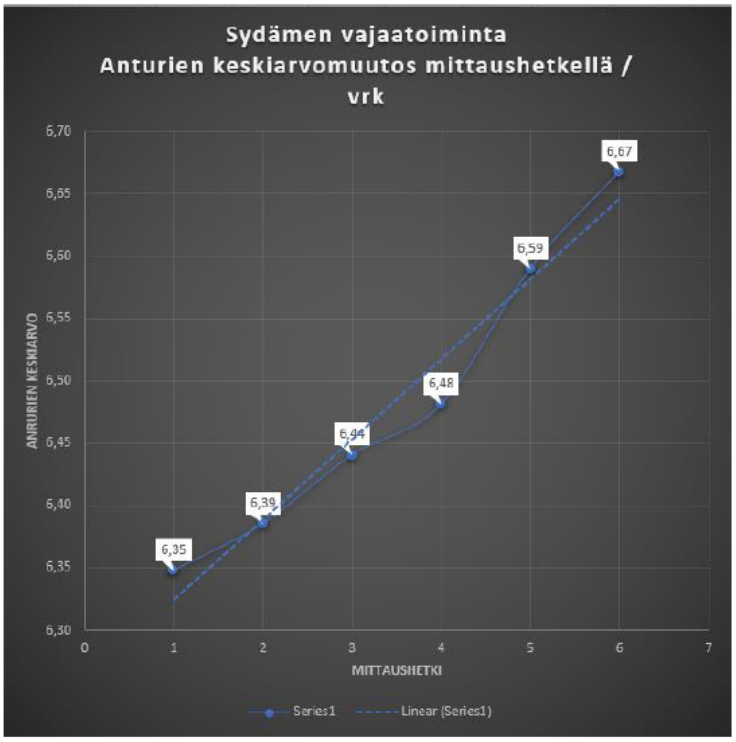
Datasta muodostettiin kuusi joukkoa (=mittaushetkeä) ja jokaiselle joukolle laskettiin sekä keskiarvo, että keskihajonta ja näistä muodostettiin kuvaaja (Kuva 14).

DATAN TULKINTA

Kuvaaja muodostettiin lasketuista mittaushetkistä ja keskiarvomuutoskuvaajaan (Kuva 14) lisättiin lineaarinen trendiviiva ennustamaan aineiston pohjalta tulevaa muuttujan käyttäytymistä, olettaen että kehitys jatkuu samanlaisena.

Kuvaajasta voidaan nähdä, että anturien keskiarvo nousee jokaisella mittaushetkellä, joka indikoi painon nousua suhteessa edelliseen mittaushetkeen sekä kokonaispainoon.

Luottamuksellinen



KUVA 14: ANTURIDATAN KESKIARVOMUUTOSKUVAAJA

Keskiarvon ja keskihajonnan avulla saadaan laskettua variaatiokerroin (Kuva 15), joka määrittelee havaintoarvojen suhteellisen hajonnan prosentteina. Variaatiokerroin (%) osoittaa kuinka monta prosenttia havaintoarvojen keskihajonta on havaintoarvojen keskiarvosta.

$$cv = \sigma \; / \; \bar{x}$$

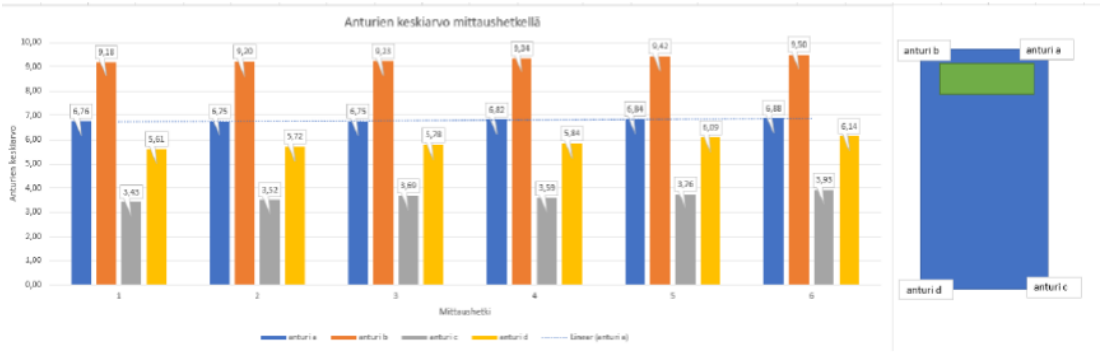
Mittaushetki	Anturien arvo		
	keskiarvo	keskihajonta	Variaatiokerroin (%)
1	6,35	1,87	29,4
2	6,39	1,84	28,8
3	6,44	1,83	28,4
4	6,48	1,85	28,6
5	6,59	1,82	27,5
6	6,67	1,78	26,7

KUVA 15: CASE 2 VARIAATIOKERROIN

Datasta muodostettiin myös pylväsdiagrammi, jonne tuotiin kaikkien anturien keskiarvot mittaushetkillä (Kuva 16). Pylväsdiagrammista on nähtävillä, että lähtötilanteessa anturi a:n ja b:n keskiarvo on suurempi kuin jalkopäädyssä sijaitsevien anturien c ja d arvo.

11.6 SIMULOINTIRAPORTTI

Luottamuksellinen



KUVA 16: ANTURIEN KESKIARVO MITTAUSHETKELLÄ

DATAN ANALYSOINTI

Koska havaintoaineistoa on käytettävissä rajatulta aikajaksolta, mallin pätevyyttä voidaan arvioida tässä tilanteessa vain havaintoalueella.

Mittausdataa kertyi vain hyvin vähän suhteessa siihen, mitä tämän tyyppisessä tapauksessa pitäisi päästä simuloimaan, joten ei voida tehdä selkeää tulkintaa siitä:

- Onko keskiarvojen välillä selkeää riippuvuutta → pidempi ajanjakso (suurempi datan määrä) voisi tuottaa parempaa dataa näiden riippuvuuksien määrittelyyn.

Mittaustuloksissa on tutkittu pääasiassa sitä, reagoivatko anturit painon lisäyksiin siten, että se on tulkittavissa anturidatasta.

Mittaustuloksista ei voida selkeästi havaita esimerkiksi juuri sitä, minne osiin paino erityisesti kertyy, joka tässä casessa olisi tärkeää dataa.

Painon voidaan sanoa tasaisesti kasvavan, mutta esimerkiksi nesteen kerääntymistä jalkoihin (anturit c ja d) ei voida tästä datasta mitenkään erityisesti todeta, koska jokaisen anturin keskiarvo muutos on jokaisella mittaushetkellä hyvin lähellä edellisen mittauksen keskiarvoa.

Painoa kuitenkin lisättiin simuloinnissa epätasaisesti siten, että rinnan alueelle lisättiin koko simuloinnin aikana yhteensä 400g ja jalkoihin 1600kg siten, että se jakautui sekä oikealle että vasemmalle jalalle tasan 800g ja 800g. Tästä syystä olisi voinut ajatella, että datasta olisi voinut olla tulkittavissa paremmin painon jakautuminen antureille a ja b sekä antureille c ja d, tätä kuitenkaan ei selkeästi ollut havaittavissa.

SIMULAATIO (CASE 3: ASENTOHOITO)

SIMULAATIO

- Anturit asennettiin hoitotyöluokassa olevan sairaalasängyn (Merivaara Futura PLUS) jalkojen alle erillisiä 3D-tulostettuja adaptereja käyttäen (Kuva 17**Virhe. Viitteen lähdettä ei löytynyt.**).
- Painon muutosten tarkkailuun käytettiin aikuista nukkea ja pelkästään nuken omaa painoa.
    - painon muutokset patjalla simuloidaan siirtämällä nukkea eri asentoihin.
    - Pyrittiin simuloimaan tilanteita, jotka vastaavat oikeaa liikkumista sängyssä, kuten:
        - painon muutosten jakautumista sängyn eri kohdissa (laidoilla, päädyissä...).
        - käytettiin apuna tyynyjä tms. asennon tukemiseen varattuja välineitä (Kuva 17).

- Otettiin huomioon **30 asteen** suositus kylkiasennosta.

- Jokainen asennonmuutos tarkistettiin ja varmistettiin (tallennettiin) Florie palvelusta.

KUVA 17: ASENNON TUKEMINEN TYYNYILLÄ

DATAN KERÄÄMINEN, TULKINTA JA ANALYSOINTI

DATAN KERÄÄMINEN

Mittausjärjestelmään kuului neljä kappaletta SparkFun TAS606 tyyppisiä painosensoreita (Kuva 4), jotka muuttavat niihin vaikuttavan kuorman sähköisiksi signaaleiksi. Mittaus tapahtuu anturin sisällä sijaitsevien venymäliuskojen (joustavia piirilevyjen) avulla. Kun venymäliuskaa rasitetaan liuskan sähköinen vastus muuttuu suhteessa kuormitukseen.

Mittausjärjestelmä keräsi dataa .csv muotoon viiden sekunnin aikavälein (Kuva 5).

Data tuotiin jatkoanalysointia varten Exceliin, jossa siitä oli mahdollista lähteä tutkimaan Case 3:seen liittyviä merkitseviä asioita simulointisuunnitelman ja mittauspöytäkirjan avulla.

Case 3 koskevaa dataa oli tallennettuna aikavälillä 11:03 - 11:29 viiden sekunnin välein.

Dataa muokattiin niin, että siitä laskettiin yhteen kaikkien anturien antama 5 sekunnin välinen arvo mittaushetkeä ennen ja jaettiin se tallennushetkien lukumäärällä n (=316), josta saatiin antureista saatavien arvojen keskiarvo (Kuva 18).

$$\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n}$$

Kaikki anturit	anturi a,b,c,
keskiarvo	6,59
keskihajonta	2,48

KUVA 18: CASE 3 MITTAUSHETKI 1 ANTURIDATAN KESKIARVO

Datasta laskettiin myös anturiarvojen keskihajonta (Kuva 19), joka kuvaa sitä, kuinka lähellä mittausarvot ovat keskimäärin toisiaan.

KUVA 19: MITTAUSHETKI 1 ANTURIDATAN KESKIHAJONTA

11.6 SIMULOINTIRAPORTTI

Luottamuksellinen

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n}}$$

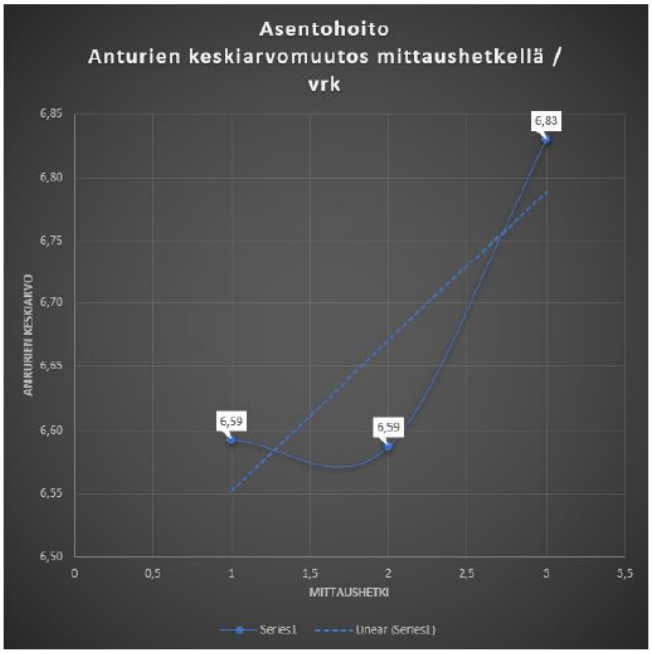
Kaikki anturit	anturi a,b,c,
keskiarvo	6,59
keskihajonta	2,48

Datasta muodostettiin kolme joukkoa (=mittaushetkeä) ja jokaiselle joukolle laskettiin sekä keskiarvo, että keskihajonta ja näistä muodostettiin kuvaaja (Kuva 14).

DATAN TULKINTA

Kuvaaja muodostettiin lasketuista mittaushetkistä ja keskiarvomuutoskuvaajaan (Kuva 20) lisättiin lineaarinen trendiviiva ennustamaan aineiston pohjalta tulevaa muuttujan käyttäytymistä, olettaen että kehitys jatkuu samanlaisena.

Kuvaajasta voidaan nähdä, että anturien keskiarvo nousee jokaisella mittaushetkellä, joka indikoi painon nousua suhteessa edelliseen mittaushetkeen sekä kokonaispainoon.



KUVA 20: ANTURIDATAN KESKIARVOMUUTOSKUVAAJA

Keskiarvon ja keskihajonnan avulla saadaan laskettua variaatiokerroin (Kuva 21), joka määrittelee havaintoarvojen suhteellisen hajonnan prosentteina. Variaatiokerroin (%) osoittaa kuinka monta prosenttia havaintoarvojen keskihajonta on havaintoarvojen keskiarvosta.

11.6 SIMULOINTIRAPORTTI

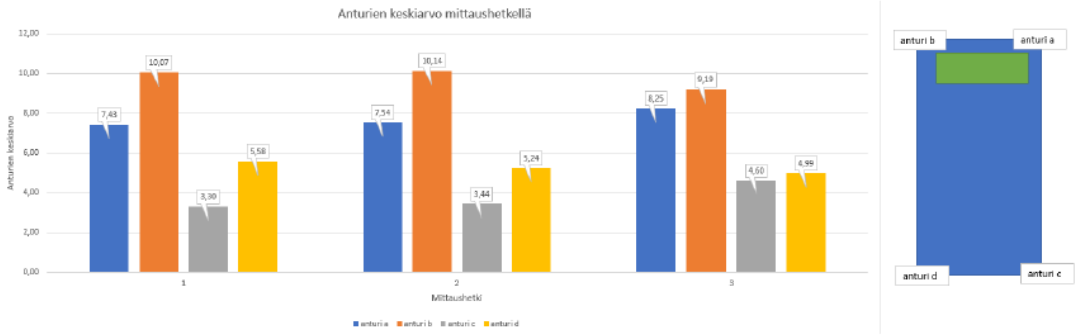
Luottamuksellinen

$$cv = \sigma \; / \; \bar{x}$$

Mittaushetki	Anturien arvo		
	keskiarvo	keskihajonta	Variaatiokerroin (%)
1	6,59	2,48	37,7
2	6,59	2,51	38,1
3	6,83	3,16	46,2

KUVA 21: CASE 3 VARIAATIOKERROIN

Datasta muodostettiin myös pylväsdiagrammi, jonne tuotiin kaikkien anturien keskiarvot mittaushetkillä (Kuva 22). Pylväsdiagrammista on nähtävillä, että lähtötilanteessa anturi a:n ja b:n keskiarvo on suurempi kuin jalkopäädyssä sijaitsevien anturien c ja d arvo.



KUVA 22:ANTURIEN KESKIARVO MITTAUSHETKELLÄ

DATAN ANALYSOINTI

Koska havaintoaineistoa on käytettävissä rajatulta aikajaksolta, mallin pätevyyttä voidaan arvioida tässä tilanteessa vain havaintoalueella.

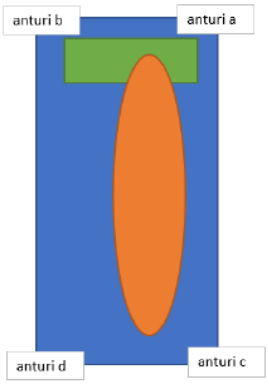
Mittaustuloksissa on tutkittu pääasiassa sitä, reagoivatko anturit painon jakautumiseen (nuken siirtoihin) patjalla siten, että se on tulkittavissa anturidatasta.

Mittaustuloksista täytyy tarkastella kukin mittaushetki omanaan, jotta voidaan tulkita, onko painon jakautuminen havaittavissa datasta:

Mittaushetki 1 = Potilas makaa selinmakuulla sängyllä (lähtötilanne). Anturien arvot jakautuneet pylväsdiagrammin (Kuva 22) mittaushetki 1 osoittamalla tavalla.

Mittaushetki 2 = Potilaan jalat nostetaan tyynylle / kantapäät koholle. Anturien keskiarvossa havaittavissa anturidatassa hetkellistä muutosta, anturien keskiarvo palaa kuitenkin lähtötilanteen tasalle (Kuva 22) mittaushetki 2 osoittamalla tavalla. Jalkojen nosto ei siis tuota indikaatiota siitä, että paino olisi jakautunut eri tavalla kuin mittaushetkellä 1. Oletettavasti anturit sijaitsevat liian kaukana toisistaan suhteessa nuken sijaintiin patjalla, että tällainen muutos olisi tulkittavissa anturien arvoista.

Mittaushetki 3 = Asentoa vaihdetaan kylkiasentoon sängyn oikeaan reunaan (Kuva 23). Havaitaan jokaisessa anturissa muutosta edelliseen mittaushetkeen. Anturien arvot indikoivat nyt tarkemmin painon jakaumaa patjalla. Antureiden b ja d arvo muuttuu pienemmäksi edellisen mittaushetken arvoista ja antureiden a ja c arvo taas kasvaa edellisestä mittaushetkestä (Kuva 22).



KUVA 23: KYLKIASENTO SÄNGYN OIKEASSA REUNASSA

Anturidatan avulla on havaittavissa painonjakautumisen muutoksia, kuitenkin painon jakautumisen havaitseminen ei ole niin tarkkaa, että voitaisiin tulkita mikä kohta potilaan painosta on kosketuksissa enemmän patjaan (painehaavan synty).

Jos antureita olisi sijoitettuna suoraan esimerkiksi patjan alle määrällisesti enemmän voisi painon muutokset olla paremmin havaittavissa. Simuloinnissa käytetyt neljä anturia jalkojen alla indikoi kuitenkin sen, että asento on muuttunut, joka jo tietyssä mielessä kertoo sen, että liikkumista on tapahtunut.

Teemahaastattelu Dyme Solution Oy (18.6.2021)

Haastattelututkimus ohjelmisto- ja tuotekehitys yritykselle

Taustatiedot:

Prototyyppivaiheessa oleva Florie sovellus, jonka käyttöä/jatkokehitystä simuloidaan kolmen eri tapauksen kautta.

TEEMA 1: Simuloinnit

- Ratkaisivatko simuloinnit jotain olemassa olevia haasteita? Entä toiko simuloinnin esiin paremmin käyttäjien tarpeita?
- Helpottivatko simuloinnit tuotteen merkityksen muotoutumiseen?
- Antoivatko simuloinnit käyttöön liittyvää dataa ympäristön vaikutuksista ja vaatimuksista?

TEEMA 2: SIMULOINNIT JA TUOTEKEHITYS

- Simulaatioista saatavan datan merkitys tuotekehitysvaiheessa?
- Kuinka simulointipohjainen tuotekehitys integroituu jatkokehitykseen tuotteen ja palvelun suunnittelusta?
- Kuinka simulointipohjaista tuotekehitystä voidaan käyttää tulevan jatkokehityksen rajaehtojen asettamiseen?
- Kuinka simulointitietoja voidaan hyödyntää terveydenhuollon tuotteiden ja palvelujen kehittämisvaiheessa?

TEEMOITTELU haastattelun pohjalta Dyme Solution Oy (18.6.2021)

TEEMA 1: SIMULOINNIT

Simuloinnin validoi olemassa olevia hypoteeseja.

Lujitti uskoa tuotteesta ja antoi uusia ideoita.

Kolme hyvää esimerkkiä, jotka ovat konkreettisia.

Esimerkiksi anturin kehittämiseen liittyviä asioita tuli hyvin ilmi sekä käyttöliittymän suunnitteluun. Saatiin konkretiaa.

TEEMA 2: SIMULOINNIT JA TUOTEKEHITYS

Ohjaa hyvin tuotekehitystä. Rautaan liittyvät asiat erityisesti.

Mutta hyviä ideoita myös softapuolelle.

Alkuvaiheessa hyvin tärkeä osa nähdä soveltuuko prototyyppi ollenkaan tavoitteisiin vai onko heti alussa tehtävä isojakin muutoksia.

Mitään ei jäänyt pois. ”Laatikon reunukset” eivät ainakaan kaventuneet.

Uusia kulmia ”laatikkoon”.

Nämä simuloinnit eivä tässä vaiheessa vielä tuottaneet tarpeeksi dataa, mutta ehdottomasti simuloinneilla on iso merkitys myös terveydenhuollon palvelujen kehittämisvaiheessa.

Voidaan selvittää onko esim. tuotteen tarkkuus riittävä.