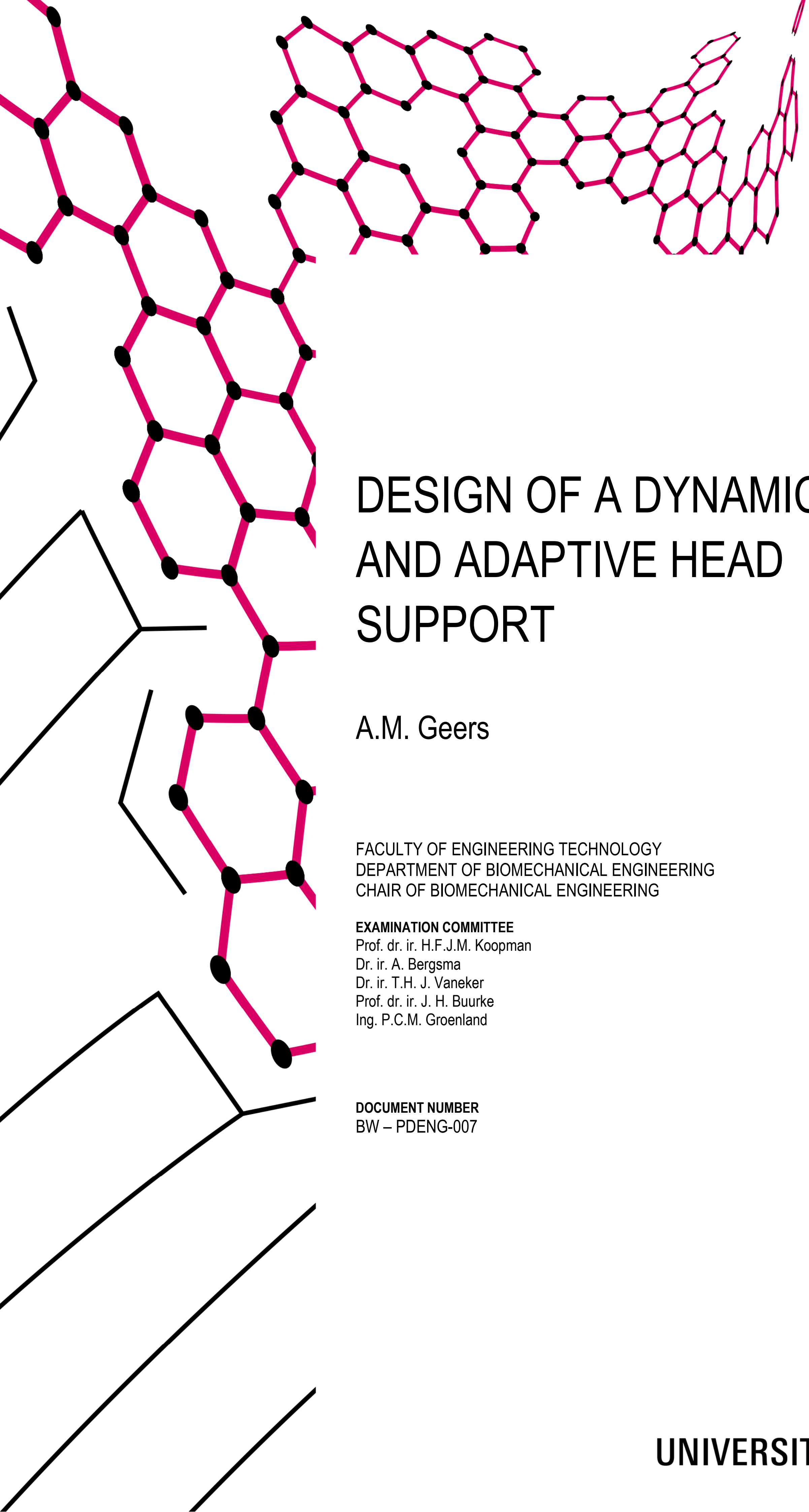

DESIGN OF A DYNAMIC AND ADAPTIVE HEAD SUPPORT

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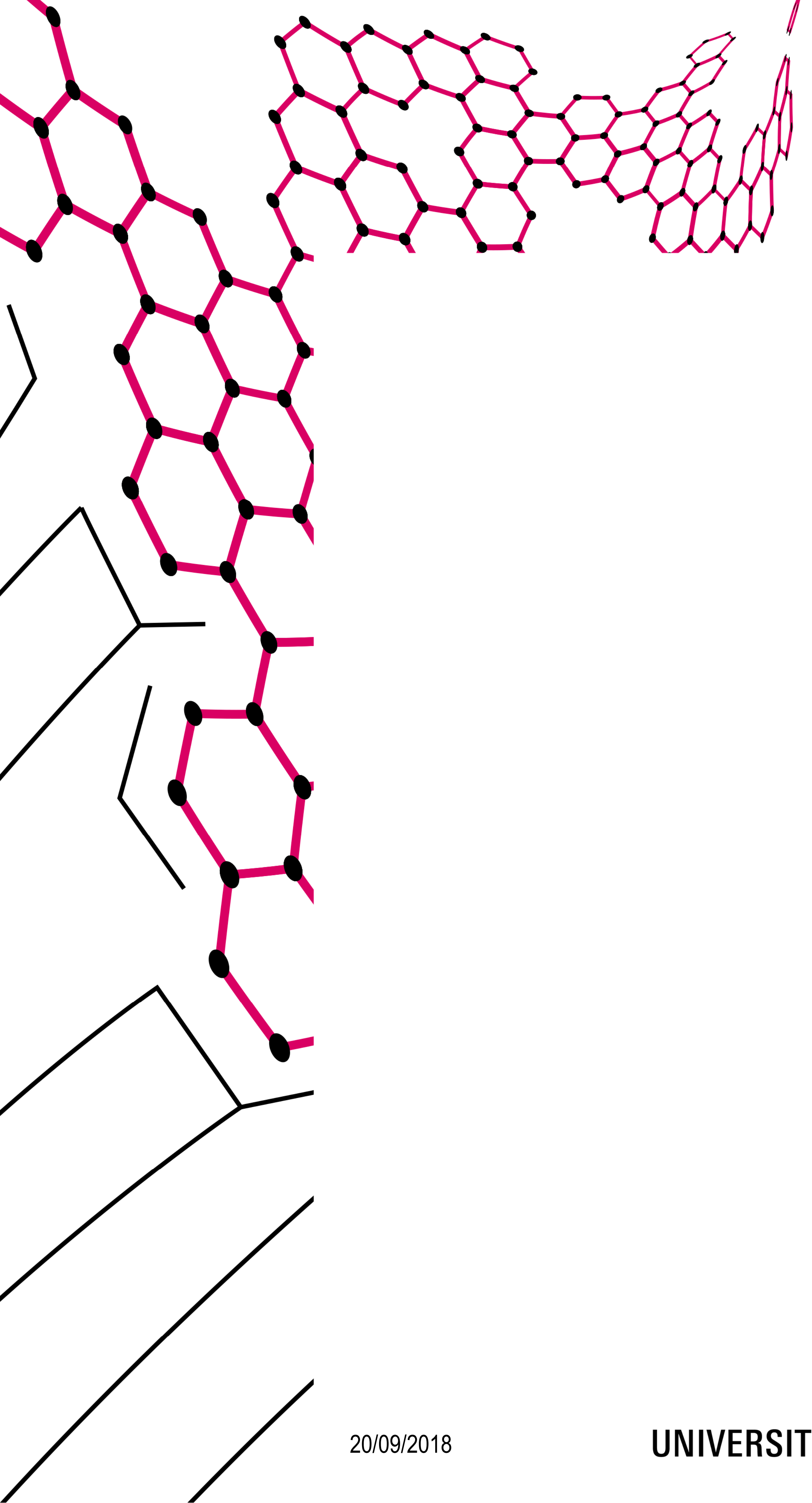

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DESIGN OF A DYNAMIC AND ADAPTIVE
HEAD SUPPORT

PDEng Thesis

to obtain the degree of

Professional Doctorate in Engineering (PDEng) at the University of Twente,
on the authority of the rector magnificus,

prof. dr. T.T.M. Palstra,

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born on 8 August 1988
in Delft, The Netherlands

Summary

For people with severe muscle weakness or paresis in the trunk and neck muscles, adequate head support is required. Although several assistive devices exist that can support a person’s head position, there is an absence of devices that are capable to support head movements in a natural and safe way. The large individual variation between users requires an individual match between user and assistive device.

Existing solutions to stabilize the head are mainly static, meaning that the head can only be stabilized in one position. Some systems offer freedom of movement but do not provide support to the head. Additionally, some systems can be configured to allow a certain level of adaptability to the user. However, if head support systems are adjustable, mostly they are systems which enable the caregiver to manually change the head support to another position. There is no opportunity for adjustment by the user.

It can be concluded that there is a need for assistive devices that provide dynamic adjustability by combining changes in position of the trunk and head with continuous stabilization. The main objectives of this project are to characterize this need for support, and to develop a first proof-of-concept of a dynamic and adaptive head support.

This report explores the use of new control methods, implementing position control on an actuated head support system. The presented system can steer the head support position in 3D (including orientation) in a more efficient and natural way. Additionally, the system can autonomously adapt the head support position according to the back seat angle of the electric wheelchair. Thus, it is a first step in the development of a new generation of dynamic and adaptive head supports that are intelligent enough to autonomously personalize their behavior to the user.

This PDEng project is done in collaboration with the company Focal Meditech B.V. and is part of the TTW research project Symbionics.

Samenvatting

Adequate hoofdondersteuning is noodzakelijk voor personen met een ernstige zwakte of verlamming van de romp- en/of de nekspieren. Alhoewel er verschillende hulpmiddelen bestaan die het hoofd van een persoon kunnen ondersteunen, is er een gebrek aan hulpmiddelen die in staat zijn hoofdbewegingen op een natuurlijke en veilige manier te ondersteunen. De grote individuele variatie tussen gebruikers vereist een individuele match tussen gebruiker en hulpmiddel.

De bestaande oplossingen die het hoofd stabilizeren zijn over het algemeen statisch en kunnen het hoofd enkel in één positie stabilizeren. Sommige systemen bieden bewegingsvrijheid maar ondersteunen het hoofd niet. Andere systemen kunnen zo aangepast worden dat zij een zeker niveau van flexibiliteit naar de bewegingen van de gebruiker bieden. Echter, in de meeste gevallen dat systemen aanpasbaar zijn, moeten deze bediend worden door de mantelzorger of hulpverlener. Er is geen mogelijkheid voor de eindgebruiker om het systeem zelf aan te passen.

Er kan geconcludeerd worden dat er een behoefte is aan hulpmiddelen die dynamische aanpasbaarheid bieden door veranderingen in de posities van de romp en het hoofd te combineren met voortdurende stabilizatie. De belangrijkste doelen in dit project zijn om deze ondersteuningsbehoefte verder te karakteriseren, en om een eerste proof-of-concept te ontwikkelen van een dynamische en adaptieve hoofdsteun.

Dit rapport verkent het gebruik van nieuwe besturingsmethodes, door positieregeling te implementeren in een geactueerd hoofdondersteuningssysteem. Het gepresenteerde systeem kan op een meer efficiënte en natuurlijke manier de hoofdsteunpositie in 3D aansturen (inclusief de oriëntatie). Ook is het systeem zelf in staat om de hoofdsteunpositie aan te passen aan de hoek van de rugleuning van de elektrische rolstoel. Het prototype kan gezien worden als een eerste stap in de ontwikkeling van een nieuwe generatie dynamische en adaptieve hoofdsteunen die intelligent genoeg zijn om autonoom hun gedrag aan de gebruiker aan te passen.

Dit PDEng project is uitgevoerd in samenwerking met Focal Meditech B.V. en maakt deel uit van het TTW project Symbionics.

Contents

1 Introduction

In today's aging population, it is inevitable that existing healthcare systems will come under increasing pressure in the traditional delivery of care. Costs are increasing while the number of human caregivers will decrease over time. The application of technology, including robotics, is generally seen as part of the solution. Rehabilitation- and assistive robotics are two subdomains of healthcare robotics. Robotic systems can provide the support and exercise needed to increase mobility among persons with reduced physical function. There is already some early stage deployment of such systems [1]. In fact, recent healthcare robotics also offer functionalities that humans are not able to provide [2]. Furthermore, ongoing changes in the living conditions of disabled persons due to de-institutionalization and the need to live longer at home require the deployment of robotic solutions [3].

While assistive technology has enabled users to live more independent lives, often there are still mismatches between the needs of users and the capabilities of assistive devices. These mismatches limit the potential of assistive devices, and can lead to suboptimal use or even discontinuation of use. The large individual variation between users shows the need to make the match between user and assistive device on an individual level [4]. One of the progress points for the medium term mentioned in the Robotics 2020 Multi-Annual Roadmap for robots that are able to assist mobility and manipulation, is that such assistive robotic devices should be able to interface naturally with people and guarantee safety and operability in natural environments [1].

This project focuses on developing wheelchair mounted head supports for the severely disabled wheelchair users who need advanced body support.

An essential part of the sitting posture is the positioning of the head and neck for users of electric wheelchairs. A suitable head position is a basic condition for the user during daily activities. It provides a stable frame of reference for vision, eating and breathing [5]. Additionally, it gives the user the opportunity to engage in social interaction and communication, and making eye contact. Unfortunately, many wheelchair users experience limitations in stabilizing and positioning of the head. When a user has incorrect positioning of the head for an extended period, this can have severe consequences. The user can experience pain and stiffness in the head and neck. It impairs the social interaction with other people and may lead to swallowing disorders and malnutrition [6]. Over time, incorrect positioning can lead to posture deformities and limitations in the head mobility [7].

Wheelchair mounted head supports are often used to compensate for weakness or paresis in the neck muscles, keeping the head upright or in the desired position. Alternatively, head supports are used to compensate for a limited head balance and poor control of head movements.

Depending on the condition of the user, the head support is used occasionally, frequently or continuously. Severely disabled persons are commonly confined to continuous use during daytime.

The use of head supports is not restricted to specific medical conditions. Common user groups of the current electronic headrest adjustment system are persons with progressive neuromuscular disorders like Duchenne Muscular Dystrophy (DMD) and Spinal Muscular Atrophy (SMA), persons with progressive neurological disorders like Amyotrophic Lateral Sclerosis (ALS) and Multiple Sclerosis (MS), persons suffering from a Spinal Cord Injury (SCI) and persons with severe orthopedic disorders.

During different daily activities such as resting, reading and taking part in social interaction [8], physiologically different head support positions are required. Besides voluntary posture changes, there are also involuntary changes that need to be accounted for. Gradual changes in seating posture caused by gravity during the day change the optimal head support position. Unfortunately, this optimal position is in general not achieved.

Although involuntary body changes in a seated position are small, it is known that small changes in head position with respect to the head support already have a large effect on experienced comfort and fatigue. A suboptimal head support position will lead to pain, diminished activity performance and lowered quality of life. Additionally, head support users having complex needs often use head movements to control various types of assistive technology, e.g. by pressing buttons. Also from this demand, optimal support is required.

However, existing head support systems mainly provide static support, and are designed to fixate the head. Most static head supports are mechanically fixed to the wheelchair, or settings can only be changed by another person, typically the caregiver (Appendix A, [9]). There is no opportunity for adjustment by the user.

Therefore, users with these head supports either are not supported in various postures or only supported after asking someone else. As a result, they may be unable to perform some activities and often experience symptoms such as pain, stiffness in the neck and fatigue. Additionally, with only static support, there is no effective use of the remaining muscle function and therefore no potential delay in functional deterioration, as has been indicated for the upper extremity, [4] [10]. Especially in the case of severely disabled persons for whom these muscles might be part of one of the last muscle groups which can still be controlled, it seems undesirable to fixate the head.

In recent years, a more advanced type of head support was developed by Focal Meditech BV, the electrically adjustable Papillon (see Figure 1). This head support offers users the opportunity to adjust the position in several directions, and is a combination of a static head support (Papillon) and an actuated adjustment system. Currently it is the only system available on the market which enables users to independently change the head support position.

Figure 1: Electrically adjustable Papillon (Focal Meditech B.V.)

The electrically adjustable Papillon provides suitable support of the head in different static positions by direct positioning of the head support, but it does not offer optimal dynamic support between the different static positions. The head support position is adjusted in one direction at a time, therefore inflicting a movement pattern on the user which is not according to the biomechanics of the head and neck system. There is no intelligence in the head support to personalize the behavior of the device to the user or to the requirements from his environment. Therefore, the user needs to adapt to the behavior of the head support, while the system is not adapting to the user.

1.1 Project goals

Although devices exist that can support a person’s head position in different positions, there is an absence of devices on the market capable of supporting head movements in a natural and safe way. In this context, the application of assistive robotic devices that augment head movement potentially provides solutions.

Little is known about how adequate support of head movements should be achieved, and a large variation between users is expected. Therefore, research is needed on the personalized interaction between user and assistive robotic device [4].

The current study aims to present a proof-of-concept of an actuated dynamic and adaptive head support system. This report explores the use of new control methods, implementing position control on an actuated Papillon system. The presented system can steer the head support position in 3D (including orientation) in a more efficient and natural way. Additionally, the system can autonomously adapt the head support position according to the back seat angle of the electric wheelchair. Thus, it is a first step in the development of a new generation of dynamic and adaptive head supports that are intelligent enough to autonomously personalize their behavior to the user.

2 Design approach

2.1 Project description

Focal Meditech B.V., the company involved in this project, has a strong interest to further develop and produce a new generation of head support systems. One of the main aims of the TTW Symbionics project, of which this PDEng is part, is the development of assistive devices which can adapt to the user. Within this PDEng project, the focus is on developing an actuated dynamic and adaptive head support system attached to the wheelchair.

In order to identify how the head support could optimally assist the user and adapt to the user given his or her needs, several background studies were performed, including a review of the state-of-the-art in head support systems (Appendix A), a stakeholder analysis (Appendix B) and interviews with end users (Appendix C, summarized below). The findings from these studies were used to concretize the design objectives and system requirements.

User interviews

Three users with SMA were interviewed about how they use their current head support, what limitations they experience with their head support, and about their ideas for improvement of the head support. From their feedback it can be concluded that existing adjustment mechanisms are mainly used to change posture between daily activities. The possibility to adjust position is strongly valued by the users with an electrically adjustable system, but motions should appear and feel more natural and the adjustment should be more efficient, considering factors such as usability, speed and safety. Moreover, it is considered essential that the user can ultimately customize the position of the head support his- or herself, as conditions vary every day. It is important that an individual match is made between user and device, implementing user specific limits which also can be customized over time.

Design objectives

Taking into account the characteristics of the system we are redesigning, the main design questions are:

- How can the head support control be made more efficient?
- How can the head support be controlled with more natural appearing motions?
- How can the head support system autonomously adapt to changing posture?

Figure 2 shows a function analysis system technique (FAST) diagram which summarizes what functionalities the system should include. The system should stabilize the head for different user postures and should move the head according the user's intention, taking into account the biomechanics of the human head-neck system and specific mobility limitations of the end user.

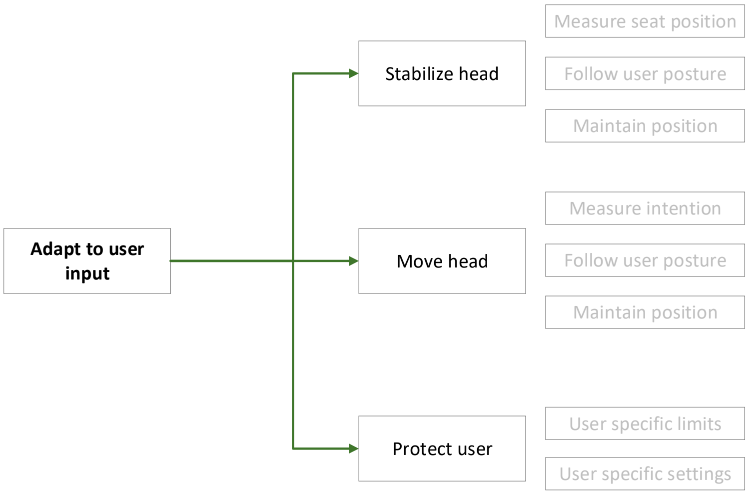

Figure 2: FAST diagram describing 'how?' from left to right and 'why?' from right to left.

2.2 Requirements

Requirements engineering and management techniques were used in order to analyse the needs and the requirements at different levels (e.g. stakeholder, system, system elements) [10]. The evaluation of the proof-of-concept prototype, corresponding approximately with a technology readiness level (TRL) of 3, focuses on the requirements at the system element level. With this evaluation, the functionality of the system existing of different technological components will be assessed at a basic level. Requirements and needs at the higher levels (e.g. stakeholder, system) need to be assessed in a later stage of development. The complete list of requirements can be found in Appendix D.

Table 1 shows an overview of the system requirements at system element level which will be assessed with the prototype. One of the main goals is to implement parallel steering of multiple degrees of freedom to increase the efficiency of the repositioning. With respect to the range of motion, it is important to consider how much of the user’s range of motion according biomechanical head movements can be achieved with the current range of motion of the head support system.

To ensure the safety of the end user, motion limits should be adhered to. Finally, how well the control system is able to perform (e.g. delay, overshoot) is not only important from safety perspective, but also an essential factor in determining user experience and comfort level.

Table 1: System requirements at system elements level

Level	Requirement description
System elements	**Head support** 1. *Range of motion* 1.1. The system should be able to adjust the head position in the same range of motion as an electrically adjustable Papillon with similar adjustment mechanisms; 1.2. During the steering of the head support via joystick, the motions of the three different translational degree-of-freedoms (DOFs) should occur in parallel and not sequentially; 1.3. During the automatic adjustment of the head support position within the sagittal plane, motion in the two translational DOFs (e.g. forward-backward, up-down) should occur in parallel and not sequentially; 1.4. The system (including all adjustment mechanisms) should support approximately 100° of head flexion and extension [11]; 2. *Safety* 2.1. The device needs to be equipped with at least one emergency stop which is activated by an unambiguous emergency command and which functions in all different control modes; 2.2. The maximum angular velocity of the head due to movement of the head support should be 30 °/s [12], [13]; 2.3. When reaching user specific range of motion limits, the system should stop gradually, with a maximum deceleration of 20 m/s^2 [14]; 2.4. Moving parts should be covered in accordance with NEN-EN 349+A1, taking into account a minimum gap of 25 mm for the covers, to avoid crushing of fingers [15]; **User interface** 3. *User input* 3.1. The number of control modes should be kept as low as possible, to keep the end user interface as simple as possible; 3.2. The re-positioning and re-orientation of the head support via joystick/TUI should be possible in a maximum of two steps;

Level	Requirement description
System elements	3.3. It should be possible to specify a user specific range of motion, which is smaller than or equivalent to the system’s range of motion; 3.4. Pre-programmed motion curves in the sagittal plane should be customizable to each user; 4. *Control* 4.1. The delay between user input and motion output should not exceed 0,1 seconds [16]; 4.2. It is not allowed to have a control overshoot during positioning which can be observed by the user; 4.3. The movements of the head support should be smooth, meaning that no significant vibrations can be observed by the user when the wheelchair is standing still and the head support is adjusted; 4.4. The system should be able to measure back seat tilt with respect to the lower cushion within a range of 90° to 125°.

3 Final design

The head support system discussed in this report is based on an electrically adjustable Papillon head support system from Focal Meditech B.V. (The Netherlands). In this configuration, the system has four degrees of freedom: the system can be adjusted in the translational directions up-down, left-right, forward-backward, and has an additional rotational degree of freedom around the pitch axis (flexion-extension). A standard Papillon cushion is attached to the adjustment system.

The original electrical adjustable head support system has undergone a mechanical redesign. Additional sensors have been added in order to accommodate the new control platform and steering methods which have been developed within this project. The complete system has been mounted on a Quicky Puma 4 electrical wheelchair (Sunrise Medical, United Kingdom) for testing purposes. Figure 3 shows a picture of the setup mounted on the wheelchair, and a more detailed picture of the system mounted on the base frame which was earlier used in the design process.

Figure 4 shows a schematic overview of the components and their functionality in the system, as well as the interaction with the end user. Within Section 3.1, the mechanical design of the sensors and actuators is discussed. Section 3.2 discusses the communication of these sensors within the system. Subsequently, Section 3.3 discusses the design of the Simulink model. Finally, Section 3.4 includes the different user interface concepts (steering modes) which have been developed in this project.

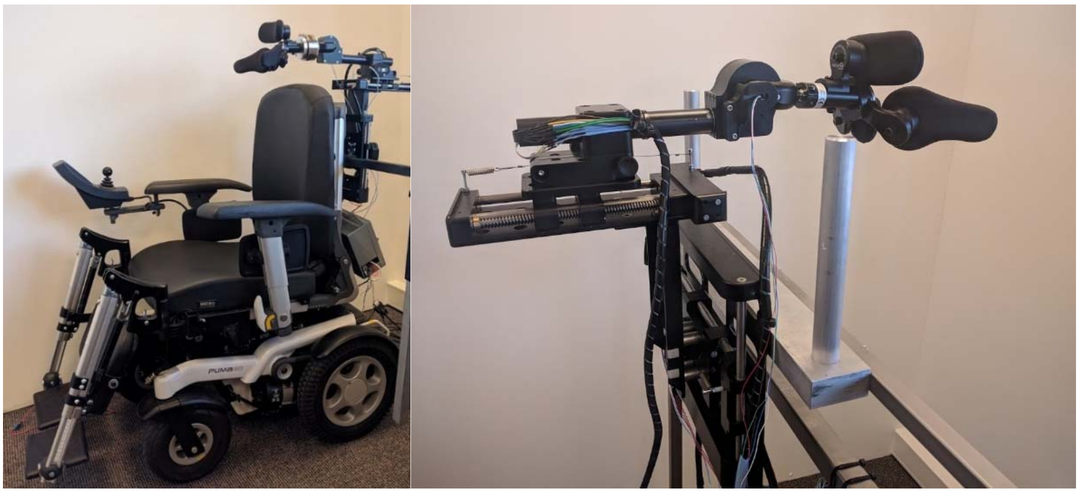

Figure 3: Prototype of head support mounted on Quicky Puma 4 wheelchair (left) Head support system mounted on frame as used during early stage testing (right).

3.1 Sensors and actuation

Actuators

For the actuation of the different degrees of freedom (DOF), each of the joints has its individual motor, resulting in a total of four motors. Faulhaber brushless DC-servomotors 2232 BX4 were selected for the prototype including planetary gearheads of series 22F (Faulhaber, Germany). The transmission ratios for the gearheads were respectively 14:1 for the translational directions (DOF1-3) and 100:1 for the orientation (DOF4). A higher transmission ratio was needed for the last degree of freedom because of the mechanical design of the system (e.g. DOF4 requiring high initial forces to start moving).

Position measurements

To determine the angular positions of the motors, magnetic encoders of series IE3-1024 were used (Faulhaber, Germany). EPOS4 motor controllers (Maxon Motor, Switzerland) were used to receive and send data to the motors.

Complementary to the incremental motor encoders, absolute encoders were designed which could provide an independent measurement of the joint position over the complete range of the joints.

Magnetic encoders were used from the Maxon series 16 EASY, 1024 pulses (Maxon Motor, Switzerland). For the translational directions, this encoder was used in a custom made linear position sensor which translates together with the joint (DOF1-3), see Figure 6 (right). The absolute linear displacement is converted via a reel and small gear wheels (gear ratio 1:3) to a relative angular position measured by the encoder.

For the orientation, the magnetic encoder directly measures the angle of DOF4. The measurements from the absolute encoders are used during the initialisation of the system and as verification of the end effector position.

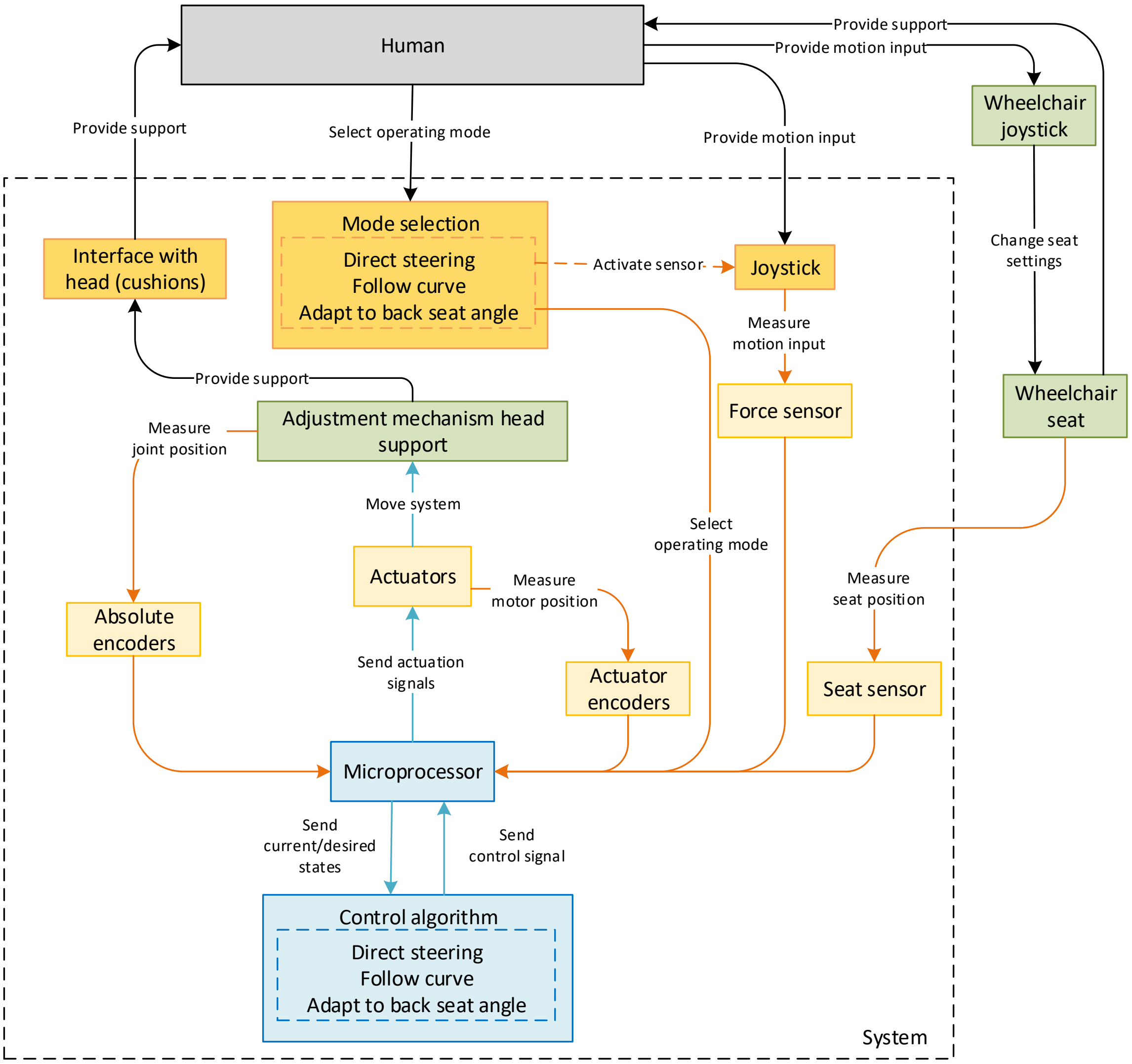

Figure 4: Schematic overview of components and their functions. Labeled arrows indicate the interaction between the different component blocks. Color coding is used for the different component blocks: yellow blocks - sensors; orange blocks - interface with the end user; blue blocks - signal acquisition and software; green blocks - external components and the actuated part of the system. The system boundary indicates the components which are considered part of the design.

User interface

For the user interface, the six DOF load cell ATI F/T Gamma (ATI Industrial Automation, United States) is configured to be used as a joystick. Basically, forces exerted on the force sensor serve as input to the system, isolating the forces F_x, F_y and F_z as inputs for the system for the translational directions (left-right, forward-backward, up-down respectively). The torque M_z serves as input for the orientation. Figure 5 gives an impression of the direction of these forces with respect to the joystick input.

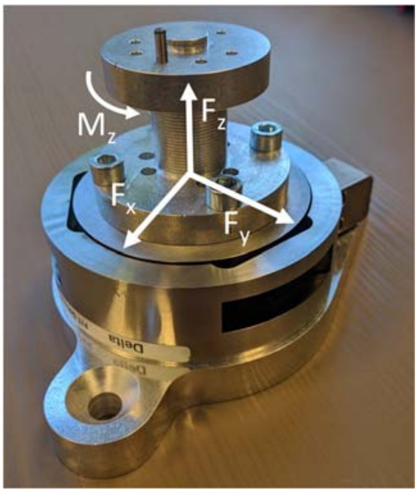

Figure 5: Direction of forces F_x, F_y , F_z and torque M_z with respect to joystick input. F_y corresponds with wheelchair driving direction.

Wheelchair
Similar to the absolute encoders used to measure joint position, a single angular position sensor is placed on the back seat frame of the wheelchair to measure the back seat angle to the wheelchair seat cushion, see Figure 6 (left). This angular position sensor also makes use of a magnetic encoder from Maxon series 16 EASY, 1024 pulses (Maxon Motor, Switzerland), which directly measures the angle.

The wheelchair back seat angle is controlled by the wheelchair control system, by means of the wheelchair control joystick. This control is independent from the head support system.

Figure 6: Picture of wheelchair back seat absolute encoder measuring the angle of the back seat to the seat cushion (left). Picture of joint position absolute encoder (DOF3) measuring forward-backward translation (right).

3.2 Signal acquisition

Figure 7 summarizes the setup of the system for the signal acquisition of the different sensors. A xPC Target computer and a custom made Simulink model (MathWorks Inc., USA) are used to control the head support in this stage of the project. The xPC Target communicates with the host PC via TCP/IP. The protocols for sending and receiving the signals as implemented in the Simulink model are based on earlier work within the R&D department of Focal Meditech B.V.. For the force sensor, an analog-to-digital conversion is performed with a sampling frequency of 500 Hz. The absolute encoder data (joint positions and back seat angle) is sent via serial input (RS485). The EPOS4 motor controllers communicate via CAN protocols with the xPC.

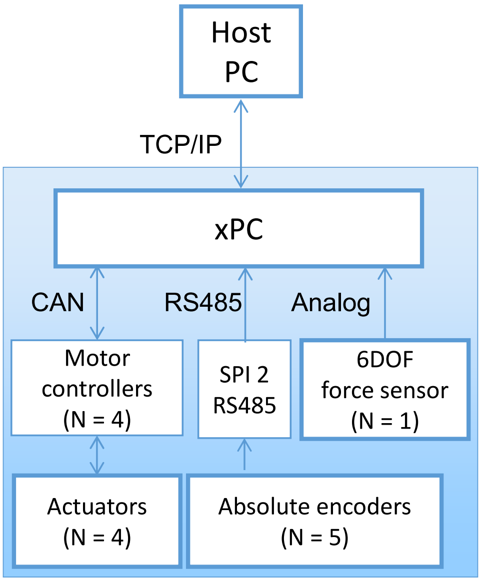

Figure 7: Signal acquisition of the different sensors and actuators. The sensors and actuators communicate with xPC using protocols as indicated in this schematic. Numbers indicate the amount of components for each block (sensor/actuators).

3.3 Model

Figure 8 presents a schematic overview of the usage of the input from the sensors within the Simulink model. Data signals from the motors and absolute encoders are obtained from the head support system (indicated by the plant $P(s)$) and converted using their respective gear ratios (R_1 and R_2), resulting in joint position measurements q_{abs} and q_{inc}. The position measurement q_{inc}, which is based on the incremental motor encoders, uses the initial values from q_{abs} to initialize.

The joint position measurement q_{inc} is used in the forward kinematics, but a safety check is implemented for the different DOFs. This check entails the constant monitoring of the differences between q_{abs} and q_{inc} to verify that the output from the motor encoders corresponds with the actual position measured by the absolute encoders.

The end effector position p_{meas} is obtained from the forward kinematics. This position corresponds to the attachment point of the cushions (frame *e* in Figure 9). The end effector orientation r_{meas} can be directly obtained from the joint position of q_4, as this is already the angle of the end effector to the horizontal.

With respect to the user input, the data from the force sensor is further processed. After obtaining the forces and moment F_x, F_y, F_z and M_z, the signals are thresholded and saturation limits are applied. Subsequently, the processed signals (indicated by F/T_{thres}) are converted to velocities which are used as input to the steering mode block. Depending on the mode this conversion is done differently. The reference position p_{ref} and reference orientation r_{ref} are determined within the steering mode block. Inverse kinematics are then used to come to the desired joint velocities. Subsequently, the motor velocity set points are obtained using the inverse of the gear ratio's, and sent back to the head support adjustment system $P(s)$.

Additionally, also an enable button (e.g. dead man switch) is included in the experimental setup for safety reasons. This enable button guarantees that the system only moves the head support in case the end user actively enables the system.

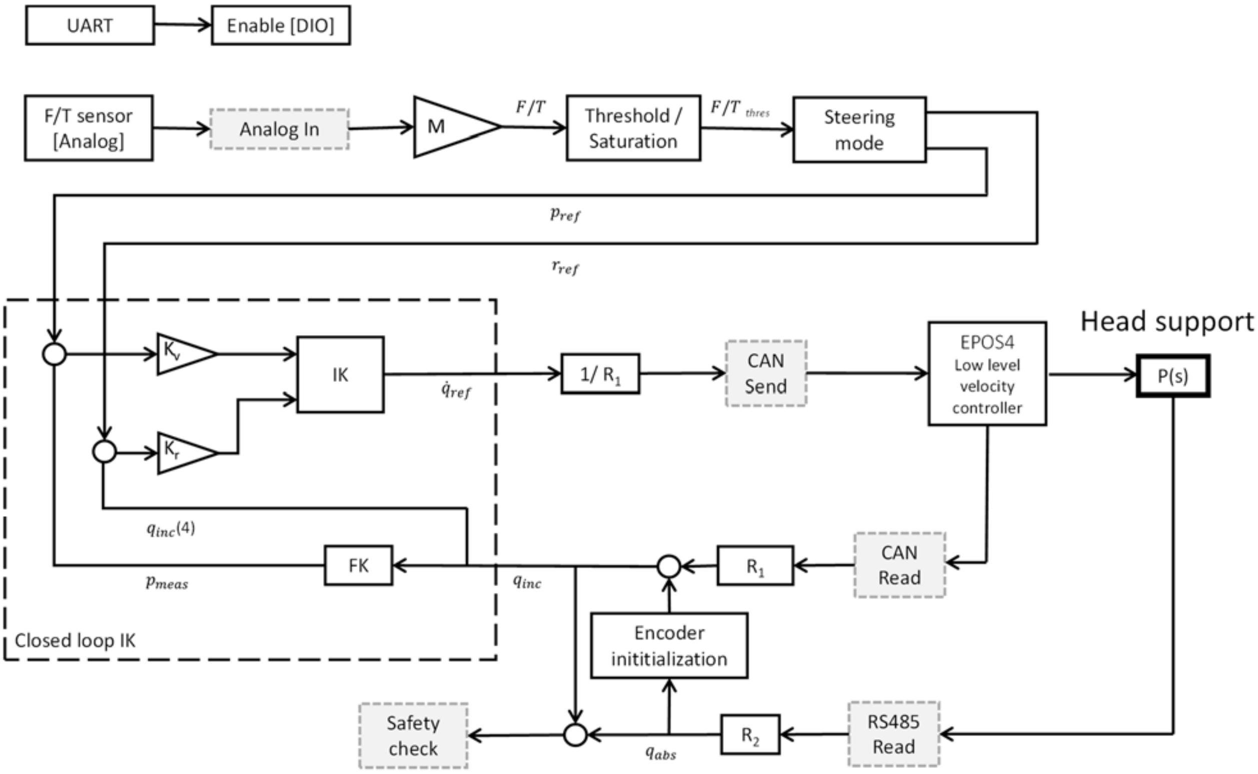

Figure 8: Schematic overview of model showing how the input from the different sensors is used within the Simulink model. The plant P(s) indicates the head support adjustment system. The F/T force sensor provides the input to the kinematic model via the steering mode block in which a reference position and a reference orientation are calculated. Measurements from the incremental and absolute encoders (q_{inc} and q_{abs} respectively) are used in the forward kinematics (FK) and inverse kinematics (IK). An enable button is included in the experimental setup for safety reasons.

Kinematic model

Within the system, it is desirable to control the orientation separately. As the rotational joint is the last degree of freedom, this joint determines the final position coordinates of the end effector. To decouple the rotation from the translation, the location of the rotation point of DOF4 (frame number 4 in Figure 9) is used as intermediate end effector for the translation.

For a given reference position of the end effector, the intermediate reference position can be calculated for the translations using the orientation and length of the last joint. With this intermediate reference and the location of frame number 4, the position error can be calculated which in turn can be used to determine the translational end effector velocity. The angular velocity for the end effector can be calculated using the error between the reference angle and the angle of the last joint. Both controllers are proportional controllers. Using inverse kinematics, individual joint velocities are obtained.

Limits

For the end effector, a user range of motion has been set for the reference position p_{ref} and the reference orientation r_{ref}. Joint position limits as imposed by the mechanical setup of the adjustment system are set for the different joints. Velocity limits have been implemented on the motors, to ensure end user safety but also considering the mechanical limits of the actuators (maximal rpm).

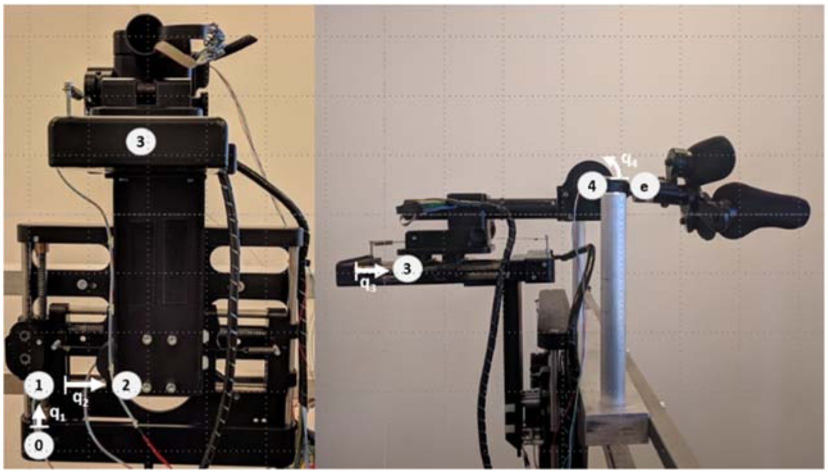

Figure 9: Approximate location of frames and joints as used in the kinematic model. The numbers indicate the frames (with *e* indicating the end effector frame). The arrows show the direction of positive motion (translation and rotation respectively) for q_1 to q_4. The system is shown at a random position and orientation.

3.4 User interface concepts

The system can be steered by the joystick in several ways. Two main steering mode concepts have been developed:

(i) Direct steering of the end effector in 3D
(ii) Curve following

The curve following mode also includes additional re-initialization of the system in case the back seat angle of the wheelchair is changed.

3.4.1 Direct steering mode

The direct steering mode couples the processed forces F_x, F_y, F_z with respectively right-left, forward-backward and up-down translations. Providing torsion input to the system (M_z) changes the orientation of the system. As the joystick inputs can be applied simultaneously, this results in parallel movement of the joints and therefore an end effector moving in 3D space (including orientation). Besides steering with all degrees of freedom active, it is also possible to only steer the translations or only steer the orientation.

The processed forces are converted to velocities following below equations. Basically, the forces relate linearly to the end effector velocities in *x*, *y*, *z* direction while the torsion relates linearly to the angular velocity of the last joint. The maximum force and moment correspond to the saturation limit values, while the maximum velocities (linear and angular) are parameters set in the Simulink model.

$$\dot{p}_{ref} = \frac{F_{thres}}{F_{max}} v_{max} \qquad \dot{r}_{ref} = \frac{M_{z,thres}}{M_{z,max}} \omega_{max}$$

$$p_{ref} = p_{ref} + \dot{p}_{ref} \cdot \Delta t \qquad r_{ref} = r_{ref} + \dot{r}_{ref} \cdot \Delta t$$

3.4.2 Curve following mode

The curve following mode is based on the concept dynamic head support can be provided using more natural motion patterns. In this case, the system delivers support according to the flexion-extension motion of the head. Only one processed force input (F_y) is used to steer the head support along the flexion-extension curve, with the force input now corresponding to the angular velocity.

With respect to the shape of the flexion-extension curve, in [17] it is suggested that an important part of the flexion-extension rotation comes from the upper cervical spine (C0/C1 and C1/C2). Therefore, the initial assumption was that roughly a single rotation point could be found for the motion, resulting in a circle-like motion curve.

Preliminary results from a study performed with healthy children and young adults (age between 6.3 and 20.9 years) by Peeters et al. [18] within the Symbionics project partly support this assumption. The maximum range of motion for flexion-extension was measured for 25 healthy subjects using markers. For several subjects, a circle with user specific radius and rotation center could be successfully matched with kinematic data of the head. Figure 10 shows an example result for one of the subjects with a successful match.

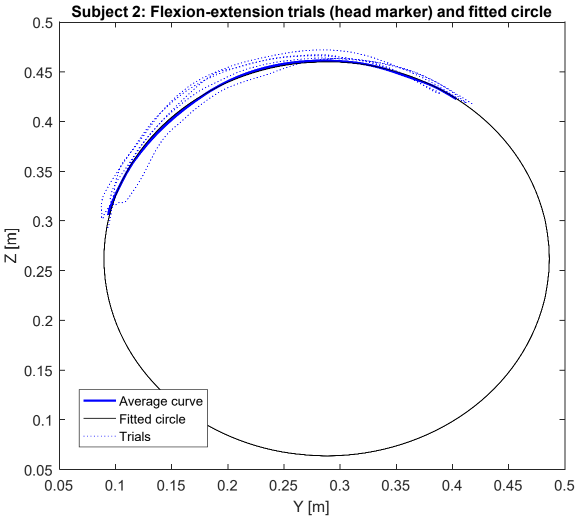

Figure 10: Example results from [18]**, circle fit to flexion-extension motion of 20-year old healthy subject. Results are plotted in the global frame for a marker mounted on the head, including five repetitions (from/towards neutral line), the averaged motion and the circle fit.**

A similar study was recently performed within the aHead project [19]. The aHead project, executed by Roessingh Research and Development, Roessingh Rehabilitation Centre and Focal Meditech B.V., includes a study with 18 healthy adult participants for which the range of motion was measured for respectively flexion-extension, rotation and lateroflexion of the head. Results show that for all subjects the head movements in flexion-extension within a range of 40° from the neutral axis could be closely matched to a circle.

Observations can be made about factors potentially causing the difference in observations between the two studies. One important factor is variation in age. Preliminary analysis of the data of [18] indicated that in general the subjects of older age matched the circle fit more closely. Large variations between repetitions were more often observed for the younger children. Additionally, a larger range of motion was considered for the circle fit compared to [19]. In the study of aHead it was also concluded that with a larger range of motion (e.g. >40°), there was more deviation from the circle fits and motions could not be matched over the complete range.

Nevertheless, for the proof-of-concept prototype it was assumed reasonable to implement a motion curve for p_{ref} based on a circle. A limited range of motion is considered. Additionally, the system will most likely mainly used by young adults and older subjects. For the orientation r_{ref}, a linear motion was deemed appropriate (e.g. positive to negative angle) in backward-forward direction. It is continuously monitored whether p_{ref} stays on the defined circle and a re-initialization is performed in case the end effector deviates too much. Figure 11 shows an impression of how the system is moving along the circle, supporting part of the flexion-extension motion of the head.

Figure 11: Example motion, curve following mode for two different positions on the curve

3.4.3 Adaptation to back seat angle

To reduce the need for repositioning of the head support after the user changes posture, automatic adaptation of the system to the back seat angle is included within the curve following mode. This is necessary because for different positions of the seat (e.g. passive, active, semi-passive posture of the user), the head support position should be located differently with respect to the wheelchair seat. A main cause of this shift is because the rotation point of the wheelchair seat and the rotation point of the user at the hip are not the same. Therefore, in a different posture, the flexion and extension of the head should follow a different curve.

The back seat angle of the wheelchair seat is continuously monitored by an encoder mounted on the backseat, and an additional re-initialization is implemented in the system, adjusting the location of the center of the circle. The radius of the circle is kept the same. The position changes were mapped in a case study (N=1), to illustrate the concept. For different back seat angles (with the head support in neutral position), the circle was manually adjusted until the head was supported correctly. This resulted in a mapping of the curve between 95° and 125°with an interval of 10° (angle of the back seat to the seat cushion). Beyond this range, the curve was outside the workspace of the system (e.g. joint limits were reached). As an approximation, linear fits were implemented between 95° and 105° and 105° and 125°, interpolating between those values. When the system is active, a re-initialization is started in case a change of back seat angle (>1°) is detected by the wheelchair encoder. Figure 12 gives an impression of the head support position with different back seat angles.

Figure 12: Example motion, curve following mode with head support adaptation for two different back seat angles

4 Results

To evaluate the requirements at the system element level, several tests have been performed with the prototype. The test results are included in Section 4.1. Subsequently, the discussion in Section 4.2 shows the adherence of these results to the system requirements set previously (Section 2.2). This section also discusses the techno-economic feasibility and the impact of the developed system.

4.1 Evaluation

The results presented in this section have been generated during tests with the researcher sitting in the wheelchair and operating the joystick (resulting in an arbitrary input). An exception to this are the results that include step inputs, as the figures currently presented are in unloaded conditions.

4.1.1 Direct steering mode

To illustrate the functionality of the mode, Figure 13 shows an example of the direct steering mode with the joystick. With arbitrary force inputs for the different translational directions (bottom graph), this results in the overall end effector motion as shown in the upper graph. There is parallel movement of the different translational directions. As can be observed from the plot, the force inputs have a linear relation with the end effector velocities, therefore a larger force results in a steeper slope.

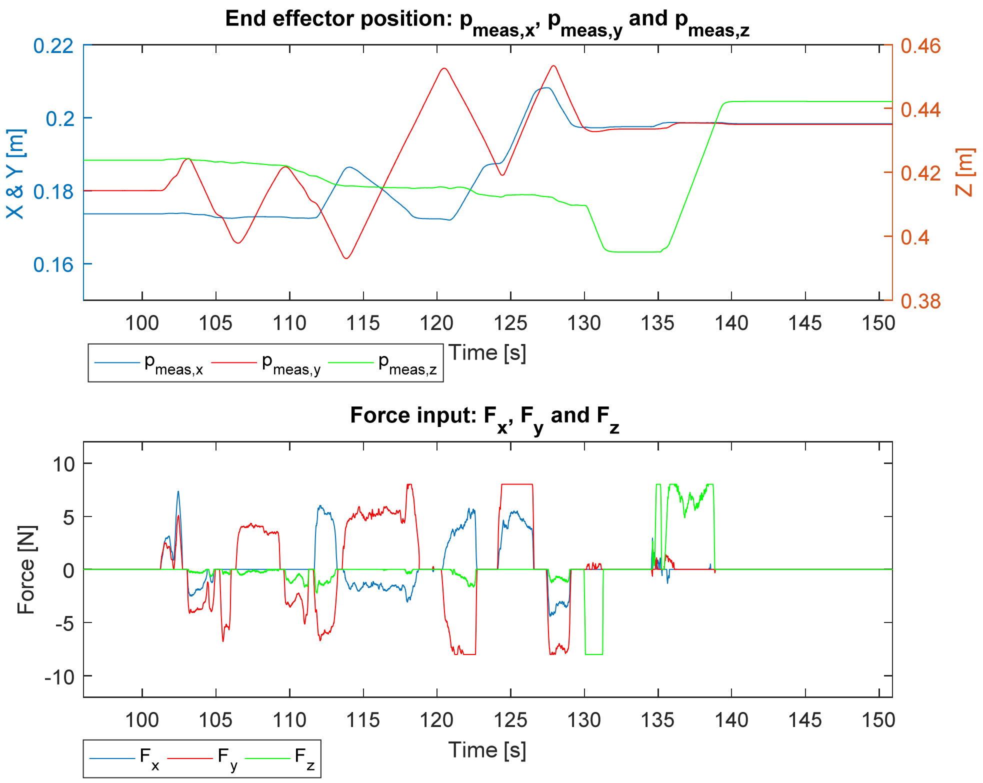

Figure 13: End effector position and force input, translational DOFs. F_x, F_y and F_z (below) correspond to linear end effector velocities, resulting in a change in end effector position in x-, y- and z-direction (upper). The presented results were made with the prototype configuration without mounted force sensor between head support cushions and adjustment system.

Likewise, Figure 14 shows this for the orientation with an arbitrary moment input M_z. For this test, no other input was applied (e.g. no motion in the translational directions). The linear relation between the moment input and angular velocity can be observed from the graph.

The current maximum linear velocity with respect to the implemented motor velocity set point limits of DOF1-3 is 0.02 m/s. The current maximum angular velocity with respect to the implemented motor velocity set point limit of DOF4 is 3 °/s.

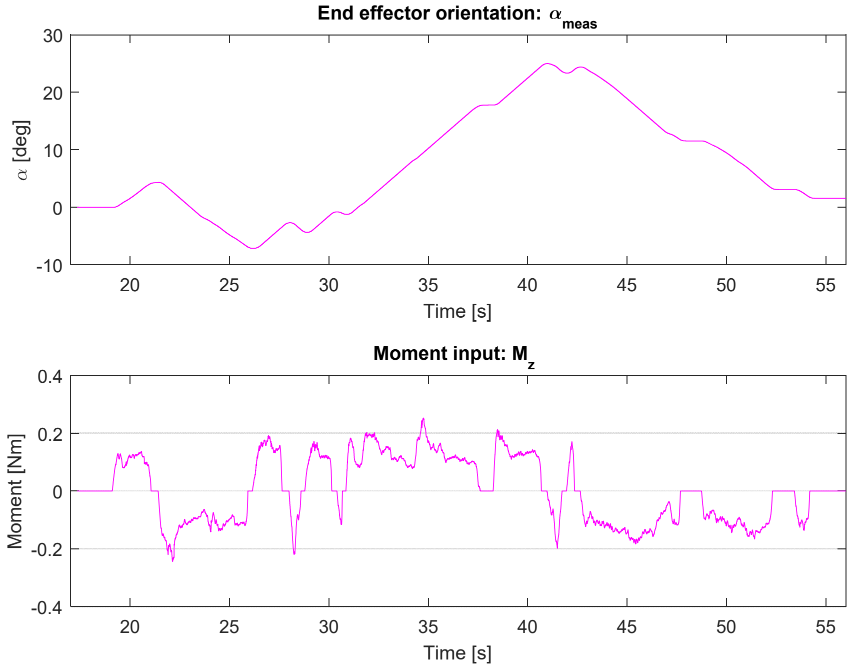

Figure 14: End effector orientation (above) and moment input (below). Moment input M_z corresponds to positive and negative angular velocity, resulting in a change of end effector orientation.

To further evaluate the performance of the system, step inputs were applied for the translational directions. These step inputs of 25 mm were applied respectively individually and in combination for the different directions,. Figure 15 shows the results (including references) for the individual directions *Y* and *Z* and the combination *Y,Z*. This experiment can be repeated for direction *X* and the other combinations.

It can be observed that for the individual directions (blue line and red line) there is no overshoot with respect to the reference lines. Also, there is minimal movement in the other direction (<1 mm). For the simultaneous step inputs for *Y* and *Z*, no overshoot can be observed in y-direction, however for the z-direction there is a small overshoot present (~0.6 mm). In all cases there is no correction by means of a change in orientation, which is as expected since the translational directions and orientation should be fully decoupled. Additionally, although the system in itself is quite slow (maximum translational velocity 0.02 m/s), it can be observed that the system already starts moving in response to the step input within 0.1 seconds.

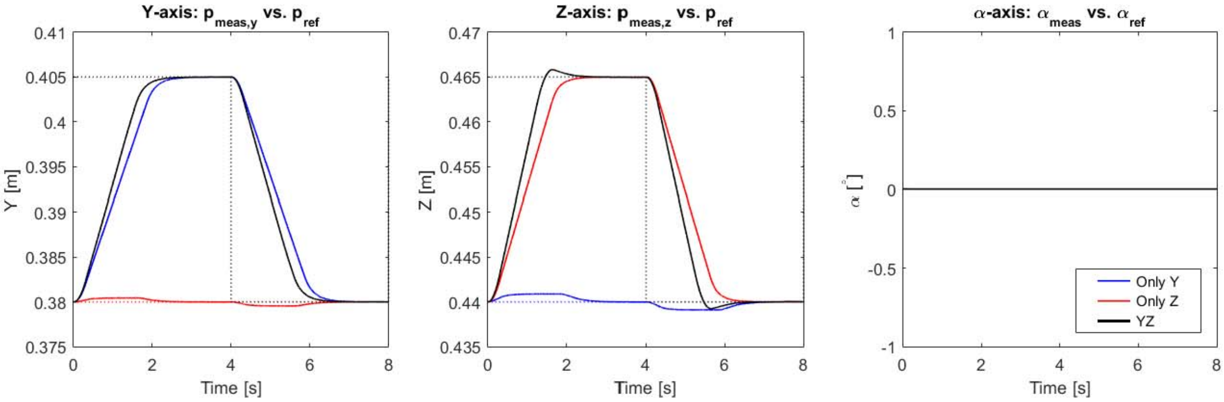

Figure 15: Step input on translational directions (Y and Z) and their combinations. From left to right are respectively plotted measured position and reference position in y-direction, in z-direction and around the rotation axis.

A similar experiment was done for the orientation (Figure 16) to evaluate the performance. A step input from 0° to 8.6° was applied for DOF4 (right). On the left and middle graph, the resulting motions in y- and z-direction and their references are plotted for the intermediate end effector (e.g. frame 4 in Figure 9).

There is mainly a component in z-direction present for this rotation. The intermediate references for *Y* and *Z* are correctly followed with no overshoot. A minimal overshoot is present for the measured angle (~0.1°).

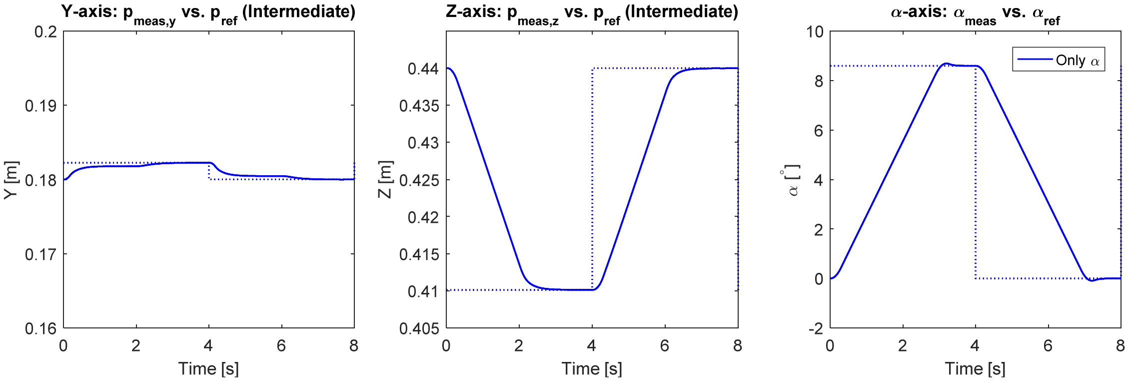

Figure 16: Step input on orientation. From left to right are respectively plotted measured position and reference position in y-direction, in z-direction for the intermediate end effector and around the rotation axis for the actual end effector.

4.1.2 Curve following mode

Figure 17 shows an example of the curve following mode to illustrate the functionality. Arbitrary force input for F_y is applied by the joystick (right), resulting in a combined movement in y- and z-direction and a change in orientation. Figure 18 shows the resulting measured position in the *Y,Z*-plane together with the reference position. The circle fit on which the reference position is based is indicated by the triangles. The system is able to follow the reference position, however it can be observed that this reference position deviates from the curve fit (in this example ~3 mm at most).

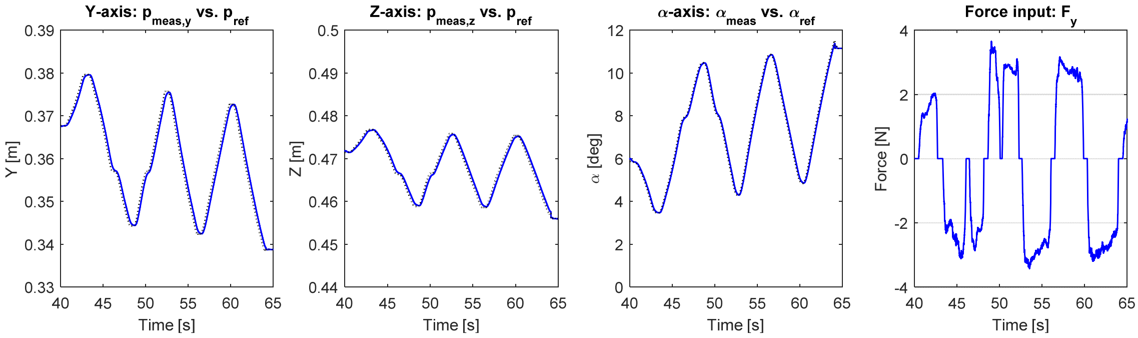

Figure 17: Curve following mode: end effector position in y- and z- direction, end effector orientation and moment input

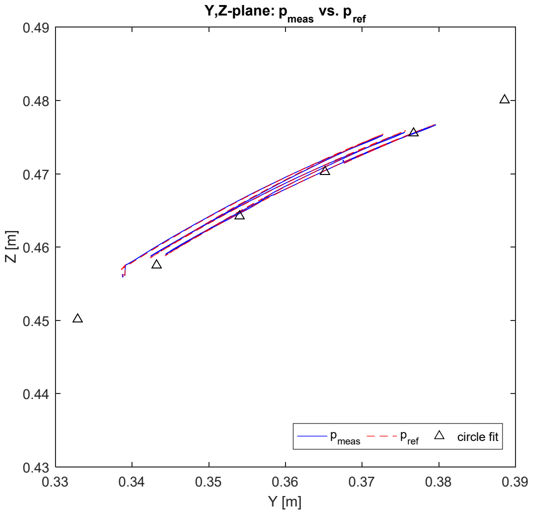

Figure 18: Curve following mode: measured and reference position of the end effector plotted in the Y,Z-plane together with implemented curve based on circle fit

Respecting the position limits of the end effector (e.g. [0.31, 0.43] for Y and [0.39, 0.54] for Z), the maximum range which can be traveled over the circle (for this back seat angle of 95°) is approximately 40°. In practice, this will be lower because of the re-initialization of the system.

4.1.3 Adaptation to back seat angle

Figure 19 shows an example of a trial where the back seat angle of the wheelchair was arbitrarily varied by the wheelchair control joystick within the defined range (95°-125°, left). At four angles (respectively 96°, 104°, 111° and 121°), arbitrary input was also given by the force input joystick to illustrate the end effector positions on the different curves. The back seat encoder is able to measure within the range of 95° to 125°. Table 2 shows an overview of the maximum system range of motion, showing decreasing range of motion with increasing back seat angle.

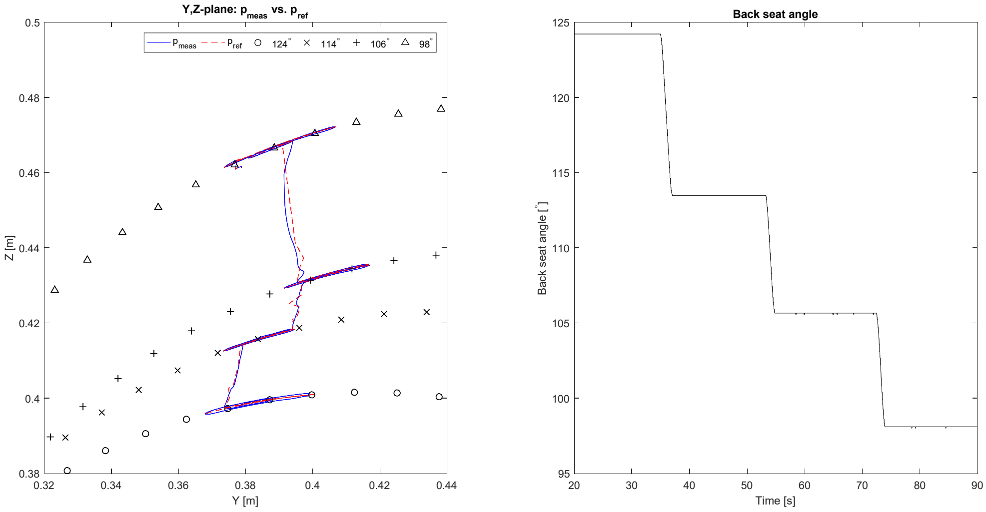

Figure 19: Measured end effector- and reference position, circle fit in the Y,Z-plane with the coordinate system relative to the wheelchair (left) for different back seat angles over time (right)

Table 2: Overview of estimated maximum angle ranges for different back seat angles

Back seat angle [°]	Maximum angle range [°]
95	39
105	34
125	22

4.2 Discussion

4.2.1 Functionality

The results from the previous paragraphs are evaluated based on the requirements presented in Section 2.2 (with the numbers in brackets referring to the numbers in Table 1).

Range of motion

The system is able to use the complete mechanical workspace of the electrically adjustable Papillon (1.1). The redesign has not led to restrictions in the joint limits. Position control has been successfully implemented on the system. For both steering methods (direct and curve following), the different degree of freedom motions occur in parallel when input is provided (1.2, 1.3).

However, considering the current steering concepts the workspace of the current system is limited. When looking at the total range of the flexion-extension motion as dictated by the current curve fit, due to the joint limits this range is 39° at neutral back seat position (95°) and decreases with increasing back seat angle. Clearly, the current requirement of 100° flexion-extension motion is not met (1.4) [11].

From this perspective, a redesign of the joint configuration is needed. However, in this regard it is advised to perform further research on the exact workspace desired by the end users considering their daily activities and occurring postures. The current requirement is based on healthy adults, while end users of the head support often have a limited head mobility. Thus, limiting the requirement to a smaller range of motion might be appropriate. This is also important considering the optimal usage of space by future designs.

Safety

In the current setup, across all the different control modes an enable button in included, meaning that the user needs to actively enable the system before movement is allowed. Hence, an emergency stop occurs whenever the user releases the button. Thus, the requirement of (2.1) is met for the current prototype. In future stand-alone versions, an emergency stop needs to be incorporated in the user interface.

The maximum linear velocity of 0.02 m/s and the maximum angular velocity of 3°/s of the end effector result in a maximum angular velocity of the head which is well below the angular velocity limit of 30 °/s as stated in (2.2). It needs further consideration whether these low velocities are desirable from the perspective of the user, or that higher velocities are desired for the repositioning. The maximum deceleration which is currently obtained from above step responses, which is assumed to be representative, is well below the maximum limit of 20 m/s^2 as stated in the requirements (2.3).

Except for the addition of the encoders, the outside of the electrically adjustable system has not undergone a redesign. Hence, it can be assumed that with respect to crushing hazards (2.4), like the original head support system, the standard NEN-EN 349+A1 is adhered to.

User input

A separate user interface still needs to be designed that allows the user specific settings to be easily adapted to the user, or if necessary, over time. Currently, a preliminary version of a user interface is implemented in the Simulink model. In general, the user interface needs further attention before it is possible to evaluate the individual requirements on a functional level (3.1).

Using the joystick as user interface, two different steering methods have been developed: the curve following mode and the direct steering mode. For the curve following mode, only one input is required to adjust the position and orientation of the head support. For the direct steering mode, it is also possible to perform parallel steering of the orientation and position. Hence, the head support can be repositioned and re-orientated within two steps (3.2). With respect to the currently used joystick, it is important to note that it needs to be redesigned, as users with limited hand function are most likely not able to use this joystick because of the relatively high forces required. In the future, also other user interfaces need to be evaluated together with the system, to also accommodate users without a remaining hand function.

Although it is currently possible to specify a user specific range of motion (3.3), this range of motion should be developed further. The current version of the user range of motion is simple (e.g. box-shaped). This is most likely acceptable for healthy end users, at least for the current velocities the system is operating on. However, for the end users with actual limitations in mobility this is probably not the case.

Likewise, it is also possible to customize the pre-programmed motion curves in the sagittal plane to the user (3.4), but further development is needed. Within the smaller range of motion currently available, the flexion-extension curve follows a circle. The circle is assumed to be representative of the movement within a limited range from the neutral position (~40°) for healthy participants [19] and therefore deemed appropriate at this stage of the project. If the workspace is expanded however, further validation of this assumption is needed. More complex descriptions for the motion curve should also be considered, taking into account possible combinations of motions end users will make (for example pure flexion-extension combined with translations). Especially when end users with varying disabilities are involved, it will be necessary to create a motion curve which is completely user specific.

Control

As stated previously, how well the control system is able to perform is not only important from safety perspective, but also an essential factor in determining user experience and comfort level. With respect to the delay between user input and motion output, the system starts moving within the maximum allowed delay time of 0.1 seconds [16] and therefore the requirement of (4.1) is met.

For the individual translation directions tested, no overshoot is present with respect to step inputs, and only minimal movement occurs in the other direction. In case translations occur in parallel, minimal overshoots may be observed (for the presented test results observed in Z-direction). The size of the overshoot observed is <2.5% of the step input value. Likewise, for the orientation only a minimal overshoot is present (<1.5% of step input value). This performance is deemed acceptable in this stage of the project (4.2). No clear overshoots were observed by the researcher during repositioning trials in the wheelchair.

For the curve following mode, the system is able to follow the reference position, but deviations occur from the curve fit. Further optimization of the reference position calculated is needed to obtain a closer match between the reference and the curve, leading to smoother motions (4.3).

The system can successfully follow different curves based on the changing back seat angle (4.4). Stable results are obtained within the back seat tilt range of 95° (minimum angle possible for this wheelchair) to 125°. Considering wheelchair seat position in relation to posture adaptation, it is advisable to expand the measurements of the wheelchair seat position with measurements of the angle of the wheelchair seat cushion to the wheelchair and the angle of the wheelchair to the earth. These seat settings might influence the head motions of the end user.

General remarks

Overall, the developed prototype is a promising proof-of-concept, as most of the requirements at the system element level can be met. For the requirements which are not yet met, improvement or re-assessment is needed. Nevertheless, it is important to realise that in general the system is not yet at a mature level (TRL 3). Hence, before it is fully ready to be (clinically) tested in a laboratory setting (TRL4) or relevant environment (TRL 5 and higher), further development is necessary. Ultimately, the system needs to evolve from an experimental setup (xPC) to an embedded design (HLC) which can be controlled by an independent user interface.

Above all, the safety of the end user is the most important design criteria, especially when testing with disabled end users. To identify other remaining safety issues within the current design, it is important to perform an in-depth risk analysis to ensure that single failures within the system will always result in a safe situation for the end user. Sensor failure needs to be considered. For example, the measurement on the back seat of the wheelchair is now performed by only one sensor (e.g. encoder mounted on the back seat). This could be expanded to multiple sensors (creating a redundant setup) to prevent unwanted re-initialization of the system due to single sensor failure. With increasing autonomous behavior of the system, this becomes more essential, also with respect to control.

In addition to the functional improvements listed in the paragraphs above, all other requirements and needs at higher levels as discussed in Appendix D need to be assessed properly. Other important system criteria such as design for reliability and maintenance need more attention during the next steps of development.

4.2.2 Techno-economic feasibility

Focal Meditech B.V. is highly interested in further developing and producing a new generation of head support systems. Based on personal communications with the CEO and senior R&D staff, it is expected that there is potential market demand for several hundreds of advanced systems in the first years in a market that is still considered immature.

However, before market implementation is realized, extensive clinical trials and other research projects studying the effects of the usage of the device are required to prove its clinical significance. Proof that the system compared to other solutions significantly improves the end user's quality of life will be essential for the embedding of the system. Currently, if lower cost devices are available which are already considered sufficient, the government and health insurance companies will choose to finance these solutions.

In case these challenges can be overcome, the company's existing network can be used for market implementation. In its final and CE certified versions, it is expected by Focal Meditech B.V. that at first the company can sell and distribute a new generation of head support systems in the home markets Benelux and Germany through own sales networks. Distribution in other countries can take place through its distributors. Uptake outside the home markets is expected in Scandinavia, Australia and New Zealand, where early adoption of advanced assistive technology is high. Another possible sales channel could be the manufacturing and sale of systems as original equipment manufacturer to electronic wheelchair manufacturers. The company has well established contacts with leading manufacturers in this domain.

4.2.3 Impact

As discussed in the introduction, implementation of advanced assistive robotic devices can help decrease pressure on the traditional healthcare system and support the social trends to live longer at home. Additionally, if the capabilities of the head support system can be closely matched to the needs of the user on an individual level, it is expected that the assistive device will be used more extensively, enabling the user to live a more independent life.

The presented system can steer the head support position in 3D (including orientation) in a more efficient and natural way. Additionally, the system can autonomously adapt the head support position according to the back seat angle of the electric wheelchair. Thus, it is a first step in the development of a new generation of dynamic and adaptive head supports that are intelligent enough to autonomously personalize their behavior to the user.

5 Conclusions and future work

5.1 Main conclusions

In this report, a proof of concept of an actuated dynamic and head support system was developed. Referring back to the main design questions (Chapter 2):

- How can the head support control be made more efficient?
- How can the head support be controlled with more natural appearing motions?
- How can the head support system autonomously adapt to changing posture?

Position control was implemented on an actuated Papillon system, resulting in a system that can steer the head support position in 3D (including orientation) in a more efficient way, as parallel steering of the different degrees of freedom is now possible. Additionally, a steering method was developed in which the head supports follows natural head motion curves. Finally, a first version of adaptation to changing posture was implemented in the system. The system is now able to autonomously adapt the head support position to the configuration of the electric wheelchair back seat.

The system is able to meet the majority of the requirements on system element level. Although further development is needed before it is fully ready to be clinically tested, it provides a promising first step in the development of a new generation of dynamic and adaptive head supports that are intelligent enough to autonomously personalize their behavior to the user.

5.2 Future work

More research should be done on the movement strategies end users use to balance and move the head. Subsequently, these desired strategies need to be combined with certain dynamic responses delivered by the head support system. An important factor in this will be the mapping of the interaction between head and head support, therefore further work is needed on sensor solutions which monitor the user’s posture and intention.

It needs to be further established how adaptability and autonomous control behavior should be combined in future prototypes. Additional forms of adaptability need to be considered, such as adaptability to the user’s condition (e.g. changes in level of disability or fatigue), as well as adaptability to various user tasks and various environments (e.g. wheelchair at stand-still or in motion). The further integration of the head support system with the electric wheelchair system and the possible interaction with other commonly used wheelchair-mounted assistive devices need to be carefully considered.

In addition to the position control currently implemented in the system, more advanced control methods need to be considered. An example of this is to consider assist-as-needed principles to challenge the user to maximally deploy remaining capacities. In case shared control between the user and the controller is implemented, validation of the control methods in simulation is needed to ensure the stability of the coupled human-device system. Relevant usage scenarios should be taken into account.

Results from the aHead project as performed by Roessingh Centrum voor Revalidatie, Roessingh Research and Development and Focal Meditech B.V., are expected to complement the results from the PDEng project. The aHead project aims to perform initial research, within a clinical setting, on the users’ needs and wishes and the feasibility of possible input methods for the next generation of head supports. Current research focuses on characterizing head motions in space for healthy subjects. In order to identify the desired dynamic behavior of head support systems, subsequent research will focus on characterizing head motions in space for disabled end users, and quantifying the physiological effects of a head support when imposing movement on the head.

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Appendices

A. State-of-the-art

Wheelchair mounted body support for the disabled user has already been subject of study for a long time. For example, [20] describes various solutions to improve body position for children with general palsy (1974). Similarly, [21] describes a spinal support system mounted to the wheelchair frame which was designed to avoid the development of scoliosis and contractures for patients with muscular dystrophy (1975).

Currently, still many head supports are static and fixed to the wheelchair. There is no opportunity for adjustment, therefore users with these head supports are only supported for one particular posture and head support position. As a result, they may be unable to perform some activities and often experience symptoms such as pain, stiffness in the neck and fatigue. Several systems do offer the possibility to adjust the position of the head support by an external person such as the caregiver. Although this makes switching to a different head support position possible, the user is not independent. Examples of static head supports are [22], [23] and [24].

Besides the fixed head supports, other systems that are available on the market aim to fixate the user in the chair to directly correct their posture. One of these systems is the i2i head and neck support system from Stealth Products [25]. In [5] it was suggested that the usage of this system for children with cerebral palsy related diseases improved the quality of the posture, preventing posture deformities. However possible negative side effects of long term fixation were not considered.

Figure 20: Examples of static head supports. Shown respectively from left to right are the S.O.F.T. Single/Double (Whitmyer) [23], the Multi-Axis Offset Headrest Hardware (Therafin) [24] and the i2i Upper Torso System (Stealth Products) [25]

There are also some systems on the market which offer suspended head support. One currently available is the HeadPod from Siesta Systems [26]. Work from [27] suggested that it can be beneficial for children with cerebral palsy to use the device. It is however not the first design which makes use of a suspending principle, see for example the patent [28] (1991).

An example of a commercially available support which actually allows motion is the Axion Rotary Interface mounting from Symmetric Designs [29] in combination with a headrest. This combination provides physical support but allows rotation in the horizontal plane. No research has been done about the effects on postural stability. As the device is not actuated, it is uncertain how much effort is needed by the user to rotate. Additionally, the Helios biomechanical head support of Helios Anatomic offers a combination of static support and allowed motion [30]. Other devices which allow head support (and body support) motions are dynamic wheelchairs for children with spasticity (for example [31], [32]).

Figure 21: Examples of head supports allowing head motion. Shown respectively from left to right are the Axion Rotary Interface mounting with headrest (Symmetric Designs) [29], the HeadPod (Siesta Systems) [26] and the Helios biomechanical head support (Helios Anatomic) [30].

Recent research projects focus on the development of passive head supports using compliant mechanisms. For example, the prototype of [33] from Delft University of Technology provides passive support for the flexion-extension of the head. Within the Symbionics project, a head orthosis is currently being developed which statically balances the head by gravity compensation, allowing flexion-extension as well as rotational motion [34].

Overall, it can be concluded that although devices exist that can support a person's head position in different positions, there still is an absence of devices that are capable to support head movements in a natural and safe way, providing head support which is both dynamic and adaptive to the user.

B. Stakeholders

B.1 Consortium

The initial stakeholders of the PDEng project are Focal Meditech B.V. and the University of Twente. Additionally, the project is part of the TTW research project Symbionics.

Focal Meditech B.V. is one of the leading manufacturers of head support systems for persons with severe physical disabilities worldwide. In the early nineties, the company started importing a three-piece modular head support system from Whitmyer Biomechanix. During the last 25 years considerable experience was gained in the assessment, advice and supply of such head supports. Gradually, development and manufacturing of electronic headrest adjustment systems was started (available in versions from one up to five axes). Additionally, various dedicated mechanical systems were developed, e.g. for spastic persons or for wheelchair head steering. Due to the lack of further innovation at Whitmyer Biomechanix, Focal Meditech B.V. started five years ago the development of its own patented three-piece modular headrest system Papillon in various versions. The Papillon system is sold in numerous countries.

The Biomechanical Engineering Group (BME) has key expertise in human motor control and biomechanics and design of biomechatronic orthotic and prosthetic systems for supporting and training the impaired human motor system. These biomechatronic systems are developed and clinically evaluated with people with stroke, spinal cord injury, Duchenne and amputation in collaboration with leading national and international rehabilitation and neurology departments, including Roessingh Research and Development.

The main aim of the project is to create assistive devices that are able to adapt automatically to the user and to the environment, depending on the task. Scientific challenges lie in understanding how the individual adapts (human adaptation), how the mechanical properties of the assistive device should shift in order to support this optimally (mechanical adaptation), how the control of the device can be made task and intention dependent (adaptive control) and how these three aspects interact. A user-centered design approach is followed within the project, as end-users have a central role in defining the requirements and priorities for developing the assistive devices [5].

B.2 Stakeholder analysis

To further illustrate the context in which the system will function, in the next section the stakeholders involved in the project are briefly presented together with their expected goals, using the methodology from [35]. Providing a second point of view, a mapping of the socio-technical system is provided using the methodology from [36]. Subsequently challenges and impacts with respect to the design and stakeholders are discussed.

B.2.1 Stakeholder goals

System under development		
Stakeholder	Project-specific description	Stakeholder goals
Normal operator	End users (patients) using an electric wheelchair	• To achieve independence during their daily activities • To appear natural in their movements (e.g. blending in in society)
Operational supporters	Caregivers of the end users (providing assistance) Customer helpdesk (Focal)	• To reduce the time spent on support processes
Maintenance operator	Focal Meditech B.V. staff: Consultants Assembly R&D	• To minimize time spent on maintenance • Standardization of maintenance processes (R&D).

Immediate context		
Functional beneficiary	End users Caregivers of the end users	- To achieve independence during their daily activities - To appear natural in their movements (e.g. blending in in society) - To reduce the time spent on support processes
Stakeholders responsible for interfacing systems	Manufacturers of electric wheelchair and other assistive devices Suppliers	- System under development minimally interferes with the electrical wheelchair and other systems present - To minimize time spent on additional support
Wider context		
Political beneficiary	Focal Meditech B.V.	- To show innovative capacity of the project - Valorisation of academic knowledge
Financial beneficiary		- To expand existing product line - To increase sales
Negative stakeholders	Parties responsible for financing of the device (e.g. government/health insurance)	- To provide the most cost effective solution which is considered adequate in serving the end user's needs (See also Section B.2.3)
Regulator	Inspectie voor de Gezondheidszorg MDR	- System under development and company processes comply to existing standards

B.2.2 Socio-technical system map

In Figure 22, a socio-technical system map is constructed for the head support system to summarize the societal function of the design and its surrounding networks. Within the next sections, the elements in the socio-technical system are briefly highlighted.

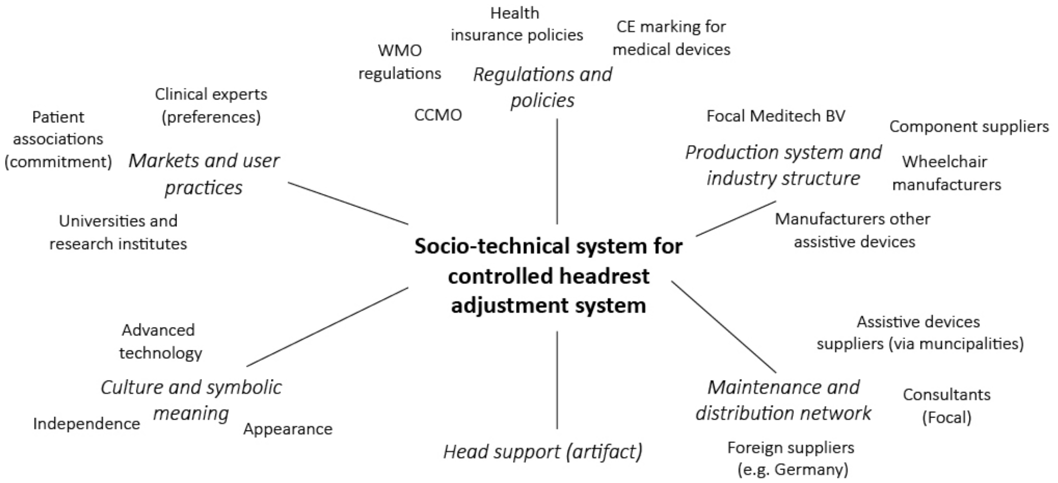


Figure 22: Socio-technical system for controlled headrest adjustment system

With respect to the production system and industry structure, the majority of the components will be manufactured by Focal Meditech B.V.. Only certain components will be procured from other suppliers. The assembly of the device and the assembly on the electric wheelchair will be done internally as well. Obviously, there is a dependency on the wheelchair manufacturers for this, as well as possible suppliers of other assistive devices.

Additionally, it is essential that the design and the procedures within the company comply with the standards as prescribed for medical devices (Medical Device Regulation, MDR), in order to be able to start the implementation of the device. Further development and evaluation of the device is needed for this.

As stated previously, before the end user is able to obtain the device, agreement from a clinical expert is needed and financing needs to be available (via WMO or health insurance). The municipality (via WMO) and health insurance companies have agreements with assistive device suppliers. Focal Meditech B.V. is then asked by such a supplier to deliver the system to the customer. Consultants of Focal Meditech B.V. also perform the maintenance. For export to other countries, foreign suppliers are involved.

Hence, the awareness about, and commitment to the device of clinical experts and end users (e.g. patient associations) is very important. As a means to achieve this, it is essential that in already an early stage of the implementation collaboration with universities and research institutes is secured. This with the aim to show the clinical significance of the device, for example by performing clinical tests with patients. These tests need to comply to the regulations set for experiments with human subjects (e.g. CCMO).

Finally, the perception of the device within society is also important. For the end users, it is very important that it supports their independence (e.g. that they are able to act independently) and that it does not reflect negatively on their appearance (e.g. the desire to not look handicapped).

B.2.3 Challenging elements and stakeholders

For the design to be societally embedded, one of the main challenges will be to prove its relevance and clinical significance: e.g. the usage of the device has significant benefits for the end users. For example, ideally you would like to conclude that the head support enables patients with a progressive muscle disease to move their head for a longer time. For this, extensive clinical trials and other research is needed, studying the effects of the usage of the device. This in turn will help to convince clinical experts of the necessity to select the device for the end user.

If clinical significance is proven, this will also have a direct impact on the financing structures for the device. This financing structure is in fact the main challenge which needs to be addressed before the design can become societally embedded. Taking into account that the government and also the health insurance companies actually intent to decrease the amount of money spent on health care, they will be reluctant to finance a device such as the dynamically adjustable head support, if lower cost devices considered already sufficient are available. Hence, proof that the device compared to other solutions significantly improves the end user’s quality of life will be very valuable.

B.2.4 External stakeholders affected by design

The designated end users of the device, the patients in the electric wheelchairs, are the ones who directly will experience the impact of the design. As explained before, the design aims to result in-increased independence for the end user and a higher user satisfaction. The clinical experts will not directly use the device, however they may consider the device as an additional solution for supporting the patient.

If the design can serve as a new benchmark within the market of head supports and assistive devices, this has consequences for the possible competitors: they also need to innovate to be able to be competitive. This potentially has consequences for the classification within the MDR.

C. User interviews

C.1 Method

This study was done in order to generate some first user input with respect to current usage of the head support, current limitations of the system and ideas for the future. This section highlights the most important findings with respect to the research.

Semi structured interviews were done with the help of beforehand prepared questions. The prepared questions were used as guideline, adapted where deemed appropriate during the conversation. Handwritten notes were taken by the interviewer and afterwards typed out. The question list used can be found on the next page.

A description letter was provided beforehand, to inform potential subjects. After agreement from the subjects, two subjects were interviewed via telephone and one subject was visited at home. Two subjects had head supports from Focal and one subject had a standard head support. This deviation was done to obtain an opinion without having the Papillon system as a reference.

C.2 Subject descriptions

Subject 1 (phone call), female, 28 years, SMA type I/II. On her wheelchair she has an electrically adjustable Papillon with forward-backward, high-low and left right adjustment mechanisms and a head band. She has been using this support for approximately 1.5 years, before a static Papillon was mounted on her wheelchair. She describes her head mobility as still present but more limited than before due to the progression of the disease. Due to limited muscle force certain head positions are hard to obtain and maintain.

Subject 2 (phone call), female, 34 years, SMA. She has a standard head support (from the wheelchair itself). She will receive an electrically adjustable Papillon in the future. She indicates that her head mobility especially in turning the head is limited, and she has limited muscle force.

Subject 3 (home visit), male, 24 years. Diagnosis SMA type 2. On his regular wheelchair he has an electrically adjustable Papillon with forward-backward, high-low and pivoting adjustment mechanisms, plus a head band. On his sporting wheelchair he has a static Papillon and a head band. He is a long-time user of the Papillon system, starting with a static Papillon when it became available. He describes his head mobility as very limited and only very slight rotation is possible.

C.3 Results

Usage

Subject 1

S1 uses the head support regularly during the day. In general, she sits without head support within her wheelchair and only occasionally uses the head support to rest her head. One of the exceptions to this is during transport with the car, then she uses the head support continuously. Also during head postures which are hard to maintain for a longer time she uses the head support, for example looking up. At the end of the day, when she is more tired, she uses the head support more.

As a result, she only uses the adjustment systems occasionally, for example to set in a position to look up (or rest) or a position suited for transport. For short moments of support she indicates it is not necessary to adjust the exact head position, even though she has a slightly different posture. However she deems the systems as beneficial as she is now able to adjust the head support position herself, without help of caregivers. The adjustment mechanism she uses most is forward-backward.

With respect to the head band, basically she does not use it as she did not like the experience.

In general, she is quite satisfied with the head support and the adjustment systems as she experiences it as reliable. The only remark is that the system is quite slow. In the occasions she now uses the head support (see above), she indicates that it enables her to do those activities.

The main point she experiences problems is the position of the cushions with respect to each other: due to unplanned actions (e.g. patient hoist getting stuck) these cushions shift with respect to each other, and the only way to compensate this completely is to have an expert re-configure the cushions. This is quite inconvenient. If the cushions are configured correctly, she experiences the head support as comfortable, however in case she suffers from irritated muscles in the back of her neck, the cushions are too rigid.

Subject 2

Note: this section details current usage of the head support and envisioned usage of the Papillon system. S2 uses her current standard head support only very occasionally. In the future (also due to the progression of the disease) she expects to use the head support more frequently. For example in the car she needs more support and expects to use a head band as well. Also during regular use she expects to use the support every now and then to rest, or maybe to watch TV.

With respect to the adjustments, she expects to use it for instance before transport, but also for posture adjustment. Changing position of the head helps with fatigue/pain symptoms.

Subject 3

For S3 the head support is paramount during daily activities. This subject uses the head support continuously; at this moment it is not possible for him to sit without the support of the headrest. Also the adjustment systems he uses very regularly (‘almost subconsciously’) to optimize his head position for a wide range of reasons.

Overall, he indicates that the adjustments enable him to do certain activities. For example, for reading and watching TV he has particular positions in mind. For eating, he also sets the head support in a particular way – noting that he also uses a different position to help with swallowing, using the pivoting. For transport in the car he also sets the head support in a standard position. With respect to the adjustment over the day, in the beginning of the morning, he sets his head support position in a certain way, correcting during the day for posture adjustments and sliding down in the chair. Comparing the experiences between his regular wheelchair with an adjustable Papillon system and his sporting wheelchair with a static Papillon system, he states that the adjustment system significantly improves comfort, and reduces pain and fatigue symptoms.

The system he uses most and over the widest range is the up-down adjustment system, with small corrections in forward-backward and pivoting. In daily usage, the complete ranges are not used. Only for high-low adjustments he sometimes uses the complete range (and indicates that it could be larger), for the other directions only part of the complete range is met.

In general, he is very satisfied with the system. The only activity where he perhaps would like more support of the system is during driving, especially over wobbly roads as his head tends to lose contact sometimes with the head support during these occasions. Therefore, when this occurs he wears his headband. However, he indicates that he tries to limit the usage of the head band as much as possible as it is not comfortable and is not aesthetically pleasing.

Future

Subject 1

It is very important for S1 to have control over the position of the head support herself. This is also the main safety issue she indicates, with every automated or adaptive behavior, she would like to be able to overrule this motion. Initially she is skeptical about steering the head with the remaining muscle force.

She indicates there could be some improvement if there is a modus in which the head support follows the head automatically; the current approach of configuring the head position is quite cumbersome. For her, a solution to the problem indicated about the position of the cushions, would also be an improvement.

Subject 2

For S2, the ideal head support would be very small and inconspicuous. She deems the head support and especially the head adjustment mechanism as quite big. She thinks this inconspicuousness is not only important for appearance, but also for the ways of moving the system. Also it is very important that the system enables her to do as much as possible herself. Thinking freely she would like a head support which is also able to assist her with stretching her head, as this is something which now she needs to ask other people. If it is possible to set user specific limits/workspaces together with experts, she does not really have safety concerns with respect to this. With respect to a head support which follows the head automatically, she is positive and thinks this would be quite convenient and fast. She deems it important that it is also possible to turn this modus off, as you not always want to move.

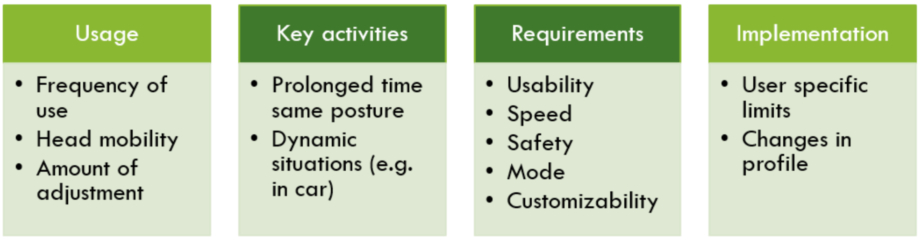
Subject 3

It is very important for S3 to have control over the position of the head support himself. Since no day is the same and the variety in adjustments is large, he stresses that having only preprogrammed positions would not suffice at all. If it would be possible to combine the different directions and steer the head support in the correct direction with one command, this would be an improvement. However, it is needed to keep the same positioning accuracy and range of motion.

Thinking freely about the ideal head support, he mentions a head support which is more like an artificial neck, a support which is able to take over the supporting function in the neck. In case this system is used in an earlier stage of the disease, you can keep moving and therefore keep head mobility. The steering of the support would be without any external command: the system is able to follow whatever direction and position you want to go. However, this system should be able to stay rigid in certain situations, as the reflexes in the neck do. An example of this would be during driving – you want to compensate for the high frequent vibrations, but enable the user to look around.
With respect to this, the main safety issue he mentions is the issue of the system being able to distinguish between the different situations (with different sensor inputs) such that no incorrect movements are initiated by the head support.

C.4 Summary

Figure 23 summarizes the findings from the user interviews. From the feedback it can be concluded that with respect to the intended use of the system, existing adjustment mechanisms are mainly used to change posture between daily activities. The possibility to adjust position is strongly valued by the users with an electrically adjustable system, but motions should appear and feel more natural and the adjustment should be more efficient, considering factors such as usability, speed and safety. Moreover, it is considered essential that the user can ultimately customize the position of the head support his- or herself, as conditions vary every day. It is important that an individual match is made between user and device, implementing user specific limits which also can be customized over time.



Usage	Key activities	Requirements	Implementation
• Frequency of use • Head mobility • Amount of adjustment	• Prolonged time same posture • Dynamic situations (e.g. in car)	• Usability • Speed • Safety • Mode • Customizability	• User specific limits • Changes in profile

Figure 23: Summary of user interview results

D. System requirements and specifications

In Section D.1 to Section D.3, respectively the needs at different levels, system requirements and stakeholder wishes are summarized [10] . Within this report, evaluation of the prototype (proof-of-concept, corresponding approximately with a technology readiness level of 3) focuses on the requirements at the system element level. The functionality of the system existing of different technological components will be assessed at a basic level. Requirements and needs at higher levels need to be assessed in a later stage.

D.1 Needs at different levels

Needs view		Needs description
Enterprise	Enterprise strategies	- Demonstrate innovative capacity of company; - Prove product portfolio has a scientific foundation; - Leading position in market wheelchair based head support solutions.
Business management	Business needs	- Strengthen relationships with research institutes and universities; - Secure innovative capacity of company by continuous R&D activities; - Translate scientific results to (tangible) enhancement of existing products and new products.
Business operations	Stakeholder needs	**Company (Focal Meditech)** - Expand scientific knowledge; - Product acceptance by other parties, by compliance with commonly accepted system standards and validated research; - Compliance with medical device directives; - Expansion of head supports product line; **End user** - Improvement quality of life; **Clinical expert** - Compliance with commonly accepted system standards and directives; **Supplier to end user (e.g. Medipoint)** - Cost effective solution; - Life cycle of device fits within business processes supplier; **Government (WMO regulation)** - Cost effective solution; - Compliance with commonly accepted system standards and directives.
System 1)	System needs	- The system needs to be adjustable to individual user needs; - The device needs to be safe; - The device needs to be reliable; - The device needs to be available when the user is using the wheelchair; - The system needs to appear as inconspicuous as possible; - The device needs to be comfortable to use; - Integration of appropriate maintenance and support processes.

Needs view		Needs description
System elements	System element needs	**Head support system** - The device should be able to steer the head support position in response to user input via joystick (or similar TUI); - The device should be able to adjust the head support position in response to seat position changes (stage 2); - It should be possible to adapt the system to the user’s needs over time, in terms of configuration, motion and motion limits; - Within a specified range of motion, the device should be able to adjust the head position in response to user input; - The resulting motions of the head should appear natural; - The delay between user input and response should be within acceptable limits; **User interface** - The user interface needs to be easy-to-use; - The user interface of the device needs to be tuneable to different users; - The device control system needs to be tuneable to different users; **Maintenance and support processes** - Maintenance time including the wheelchair (e.g. wheelchair unavailable to user) needs to be minimized.

[1)] System’ is defined here as the designed product (head support system) and additional maintenance and support processes.

D.2 System requirements

Level	Requirement description
System	- The system has to take an electrically adjustable Papillon system as the basis for the design, including forward-backward, up-down and left-right linear adjustment mechanisms as well as a rotational mechanism in flexion-extension; - The software of the system should also be compatible with electrically adjustable Papillon systems composed of less degrees of freedom, e.g. not all adjustment mechanisms; - Within the software of the system, it should be possible to adapt the user specific profile over time, including the sensitivity to user input, the range of motion, the motion curve and velocity limits; *Safety* - The user should be able to overrule automatic adjustments at all times; - The device should provide support passively, meaning that no actuators are active when in static mode; - The system needs to be available on standby for the user for 16 hours/day, taking into account the power supply of the wheelchair; - The system should initially be designed for users with muscular weakness, with still limited functioning of the hand (maximum Brooke scale 5) [37]; in order to steer the head support via joystick/TUI; - With respect to size, the system should not exceed the footprint of an electrically adjustable Papillon including the same degrees of freedom; - The system should comply to the protection against ingress of liquids test as described in ISO 7176-9:2009, section 8.6 [38]; - The mean time between failures of individual system components should be above two years;

Level	Requirement description
System elements	**Head support** *Range of motion* - The system should be able to adjust the head position in the same range of motion as an electrically adjustable Papillon with similar adjustment mechanisms; - During the steering of the head support via joystick, the motions of the three different translational degree-of-freedoms (DOFs) should occur in parallel and not sequentially; - During the automatic adjustment of the head support position within the sagittal plane, motion in the two translational DOFs (e.g. forward-backward, up-down) should occur in parallel and not sequentially; - The system (including all adjustment mechanisms) should support approximately 100° of head flexion and extension [11]; *Safety* - The device needs to be equipped with at least one emergency stop which is activated by an unambiguous emergency command and which functions in all different control modes; - The maximum angular velocity of the head due to movement of the head support should be 30 °/s [12], [13]; - When reaching user specific range of motion limits, the system should stop gradually, with a maximum deceleration of 20 m/s^2 [14]; - Moving parts should be covered in accordance with NEN-EN 349+A1, taking into account a minimum gap of 25 mm for the covers, to avoid crushing of fingers [15]; **User interface** *User input* - The number of control modes should be kept as low as possible, to keep the end user interface as simple as possible; - The re-positioning and re-orientation of the head support via joystick/TUI should be possible in a maximum of two steps; - It should be possible to specify a user specific range of motion, which is smaller than or equivalent to the system's range of motion; - Pre-programmed motion curves in the sagittal plane should be customizable to each user; *Control* - The delay between user input and motion output should not exceed 0,1 seconds [16]; - It is not allowed to have a control overshoot during positioning which can be observed by the user; - The movements of the head support should be smooth, meaning that no significant vibrations can be observed by the user when the wheelchair is standing still and the head support is adjusted; - The system should be able to measure backrest tilt with respect to the lower cushion within a range of 90° to 125°.

D.3 Stakeholder wishes

Level	Requirement description
Stakeholders	**Company (Focal Meditech)** - The head support should comply to the Medical Device Regulation 2017/745; - The impact on current assembling and maintenance processes as in place at Focal should be kept as low as possible. - Production and customization costs for one head support system should be below €7000; - For assembling, disassembling and maintenance processes, no tools other than the other tools currently available within Focal should be required; - Critical parts with respect to maintenance should be easily available within Focal, following current Focal procedures regarding logistics. **End user** - In a preliminary evaluation study consisting of five healthy users, evaluating user satisfaction by means of the QUEST scale, there should be a significant overall rating increase comparing the final prototype and the benchmark product; - At most, limited additional training should be required by the user to be able to use the system.

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