CZECH TECNICAL UNIVERSITY IN PRAGUE
FACULTY OF BIOMEDICAL ENGINEERING
Department of Biomedical Technology

Design of a modular, powered, elbow joint brace

MASTER'S THESIS

Study programme: Biomedical and Clinical Technology
Study branch: Biomedical Engineering

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Diploma thesis assignment

(Master project thesis assignment)

Student: **Kevin Bancud**

Study branch: Biomedical Engineering (CEMACUBE)

Title: **Design of modular powered elbow joint brace**

Title in Czech: Návrh modulární ortézy loketního kloubu vybavené aktuátorem

Instructions for processing:

Create design and select actuator of powered elbow joint brace. SolidWorks software will be used for design of elements and tests of powered brace. Modules of brace will be used for measurement of kinematics of elbow joint. The elbow joint brace will be designed to overcome muscle spasticity of patient during the rehabilitation process. Determine the muscle forces applied to the components and overcome by the actuator. Specify structural characteristics of components and actuators for different age groups and different types of disease. Design modular structure with regard to different age groups and diseases. Verify the strength of elements of modules and the entire construction in the SolidWorks software by finite element analysis.

References:

[1] Michelle M. Lusardi, Orthotics and Prosthetics in Rehabilitation, ed. 2nd, Butterworth-Heinemann, 2006, ISBN 10: 0750674792

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[4] AK Agarwal , Essentials of Prosthetics and Orthotics , ed. 1st, Jaypee Brothers Medical Publishers (p) Ltd., 2013, ISBN 10: 9350904373

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In Kladno, 19.02.2018

Declaration

I hereby declare that I have completed this thesis with the topic: Design of modular, powered, elbow joint brace independently and I have attached a full list of used references and citations.

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Abstract

Spasticity and contractures are secondary to most neurological and orthopaedic pathologies. The most conservative method of management of spasticity and contractures is passive stretching exercises. However, human therapy may not be accessible to most patients. Robotic rehabilitation aims to provide a solution to this problem.

While there have been a lot of development in the field of robotic rehabilitation, only a few have reached successful clinical use. Even fewer are fully portable, which is a requirement to greatly improve the accessibility of the treatment.

This project details the design of a powered orthosis especially designed for managing spasticity and contractures. The device is fully portable, allowing the patient to undergo repeated-passive-dynamic exercises outside the hospital environment. The design of the device is modular to make it adaptable to different anatomies and pathologies. The device is also fitted with electrogoniometers and torque sensors to record kinematics, and EMG sensors to record neuromuscular response of the patient, improving the insight of the clinicians to the rehabilitation of the patient, as well as providing data for further scientific investigations. The mechanical integrity of the device elements is simulated and verified using finite element analysis.

Keywords

orthosis, rehabilitation, spasticity, contracture, elbow-wrist orthosis

Abstrakt

Spasticita a svalová kontrakce jsou nejčastějšími komplikacemi při neurologických a ortopedických poruchách. Nejkonzervativnější metodou léčby spasticity a kontrakce jsou zpravidla pasivní protahovací cvičení. Tyto terapie však často nejsou dostupné pro velkou část pacientů. Robotická rehabilitace proto cílí na nalezení řešení právě pro tento problém.

Ačkoliv na poli robotické rehabilitace bylo dosaženo značného pokroku, pouze několik aplikací bylo úspěšných v běžném klinickém použití. Výrazně méně využitelných aplikací je navíc přenosných, což je jednou z podmínek dosažení zvýšené dostupnosti léčby.

Tato práce popisuje návrh elektricky poháněné ortézy navržené přímo na léčení spasticity a svalové kontrakce. Toto zařízení je plně přenosné a umožňuje tak pacientovi podstoupit opakované pasivní dynamické cvičení i mimo prostory rehabilitačního centra. Navržené zařízení je modulární a je tedy adaptabilní různým anatomiím a poruchám. Zařízení je také vybaveno elektrogoniometry a snímači kroutícího momentu pro snímání kinematiky a EMG senzory pro zaznamenávání neuromuskulární odezvy pacienta, čímž se zlepší informovanost lékařů o stavu pacienta a získají se data přínosná pro další vědecké výzkumy. Mechanická integrita dílů zařízení je simulována a otestována pomocí metody konečných prvků.

Klíčová slova

ortéza, rehabilitace, spasticita, svalová kontrakce, loketní zápěstí ortézy

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1. Introduction

Neurological pathologies and orthopaedic disorders often lead to locomotor system abnormalities, joint complications, and limb problems [1]. Neurological pathologies, such as Duchenne's muscular dystrophy and neuropathies lead to muscle weakness due to the progressive muscle degeneration. Patients with cerebral palsy and stroke survivors commonly suffer from imbalance between antagonist muscles or spasticity due to brain damage or immature development of the brain. Patients suffering from osteoarthritis or rheumatoid arthritis who experience severe pain during movement prevent them from mobilizing their joint through the whole range of motion, thus making them at risk of developing contractures which compounds to the challenge during rehabilitation. Spasticity, the velocity-dependent increase in tonic stretch reflexes, and contractures, the physical shortening of the muscles, tendons, or ligaments, if not treated, can result to the complete immobilization of limbs.

Spasticity and contractures often require several treatment approaches [1] [6] [8] [9]. Available interventions include passive stretching, orthotic intervention, pharmacological approaches, and orthopaedic surgery. Long term repeated passive stretching is the most conservative approach. This may require frequent visits to physical therapists. However, considering the usual patient condition having limited mobility, this may not be convenient. In addition to this, the projected demographics of countries such as China, Japan, and Scandinavian countries, age-related disabilities may overwhelm the foreseen shortage of working age individuals [2].

As such, robotic devices are constantly being developed to provide a part of the rehabilitative requirements of the patients. Robotic devices have the potential to reduce the dependence of patients to human therapists. These devices also provide the advantage of high repeatability, which human therapists may not be completely capable of.

Despite these potentials and the numerous developments in the field, only a few of these devices have been used clinically, especially for the upper limbs [3]. A review of the other devices showed room for improvement, specifically for the purpose of spasticity and contracture management.

Majority of the robotic devices for the upper limb are not completely portable, limiting its use to the laboratory or a hospital setting. On the other hand, the portable devices have low output torques, and will not be suitable for patients with severe spasticity and contractures.

This work describes the design of a powered upper limb orthosis specifically directed towards treatment and management of spasticity and contracture due to neuromuscular or orthopaedic pathologies. The device is also designed to be adaptable to different anatomies, minimizing the number of customized components. In addition to these, the orthosis is fitted with devices that measure the kinematics and neuromuscular response of the patient during the exercises, improving the insight of the clinicians to the rehabilitation of the patient, as well as providing data for further scientific investigations.

The start of the design process is an extensive review of pathologies and current technologies in powered orthosis to discover the user needs and define the requirements of the device. Requirements such as the torque loads and anthropometry are considered. Several designs were made before arriving to the final design, which was verified to meet the requirements set in the beginning of the design process. Finally, the final device was simulated using finite element method to ensure that the device can carry the expected loading during normal use and will not fail over the span of five years.

2. Review of Related Literature

2.1. Pathologies and Role of Orthosis in Rehabilitation

There is a multitude of pathologies that can benefit from orthotic devices for rehabilitation. Neurological pathologies and orthopaedic disorders often lead to locomotor system abnormalities, joint complications, and limb problems [1]. Houlden et al. (2007) provided a review of neurological pathologies, management, and rehabilitation in the article "Neurology and Orthopaedics".

Depending on the type of injury or disease, the following symptoms can be observed [1]:

- Functional deficiencies
- Gait and posture abnormalities
- Deformity
- Muscle weakness
- Spasticity and contractures
- Sensory problems
- Autonomic function deficiencies

Orthoses are commonly prescribed for managing deformities, muscle weakness, spasticity, and contractures.

Contracture is the physical shortening of the muscles, tendons, or ligaments. Contracture can also occur in joint capsules. Physical shortening of other soft tissues such as fascia, nerves, blood vessels, and skin is secondary to muscle contracture [4].

Limb contracture is a common effect of neuromuscular diseases. A known factor to the development of contractures is the decreased mobility of a limb [5]. With unbalanced weak muscles, deformities occur because one group of muscles is weaker than its antagonist group. If not corrected, a permanent contracture can occur.

Spasticity is another common complication of neurological pathologies. Spasticity is a condition where certain muscles are continuously contracted [6], or a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neuron syndrome [7]. Long periods of untreated spasticity can lead to the development of joint contractures [8].

Neuromuscular disorders such as Duchenne's and Becker's muscular dystrophy (DMD and BMD) cause a progressive degeneration of the skeletal muscle and associated weaknesses. Peripheral neuropathy is a result of damage to the peripheral nerves, causing weakness, numbness, and pain usually in the hands and feet. Cerebral palsy is a group of disorders that result from non-progressive brain damage during early development, with associated problems such as ataxia, dystonia, athetosis, weakness and spasticity [1]. Thirty percent of patients who suffered from stroke experience upper motor neuron syndromes that may cause both positive and negative signs [9]. Positive signs are involuntary muscle overactivity such as spasticity, and negative signs are impaired voluntary movement and motor control.

Non-neuromuscular causes of contractures are also not uncommon. People with orthopaedic pathologies that prevent the use of a limb throughout the normal range of motion, such as severe osteoarthritis or rheumatoid arthritis are at risk of deformities due to contracture.

In conclusion, the main role of orthoses in the management of neuromuscular and orthopaedic pathologies is to prevent contractures and maintain range of motion.

2.2. Management Techniques for Spasticity and Contracture

Spasticity and contracture treatment is important because the increased tone and the decreased mobility may interfere with the physical functioning of the patient [10] [11].

Spasticity and contracture management is multidisciplinary [1] [8] [10] [11]. Available interventions include passive stretching, orthotic intervention, pharmacological approaches, and orthopaedic surgery.

Passive stretching and orthotic intervention are the most conservative approach in maintaining mobility in the presence of positive and negative signs of upper motor neuron syndromes and contractures secondary to orthopaedic pathologies. Passive stretching and orthotic intervention should be started as early as possible to maintain ambulation for as long as possible and maintain range of motion. For neuromuscular diseases such as DMD, the goal is to correct any contractures while the patient is still ambulatory [1]. Most peripheral neuropathies are untreatable, rehabilitative practice is important in long-term management [12].

Continuous motion has been reported to be more effective than holds in decreasing the stiffness of the ankle joint [13] [14]. However, passive stretching is laborious and require access to a therapist. In a study by Wu et al. (2006), dynamic-repeated-passive stretching of the ankle joint using a constant speed electrically powered device in stroke patients presented significant reduction in spasticity and improved gait performance [15].

Motor-driven devices have consistently shown good results in the effectiveness in treating spasticity [16] [17]. Unfortunately, there are no significant research done with regards to the effects of rehabilitation of the elbow [18]. This may be because contractures of the arm and hand are perceived as effects of the static positioning of the arms on wheelchair armrests when lower limb mobility is lost [19], as such, most academic effort is put into lower limb rehabilitation.

Nevertheless, upper limb contractures are just as important to treat as reduced range of motion may impede personal care and hygiene.

In conclusion, it is known that there is a gap in evidence regarding the orthotic management of elbow joint rehabilitation. It is also worth investigating the effect of dynamic-repeated-passive stretching in reducing spasticity and contractures in the elbow joint, as a positive effect was reported with spastic ankle joints.

2.3.Orthotic Devices

An orthosis is a mechanical device applied to the body to support a body segment, correct anatomical alignment, protect a body part, or assist motion to improve body function (American Academy of Orthopedic Surgeons, 1985).

Orthotic devices can be classified based on the joints which they affect or its function. Functional classification of conventional orthoses is usually separated between structural or functional, structural being static to hold a joint rigidly and functional being flexible or articulated to maintain alignment of joints during dynamic functioning [20].

In spasticity and contracture management, structural splinting such as night orthoses is commonly prescribed to force the joint into correct alignment and prevent contractures due to immobilization [1] [8].

An alternative orthotic approach is to provide rehabilitative exercises using externally powered and controlled orthotics. The important advantages of these systems over manual rehabilitation methods are reliability, repeatability, and reduced dependence on therapists.

To provide the frequent dynamic-repeated-passive exercises as concluded in Section 2.2, the device should be externally powered and portable to eliminate the dependence to therapists and rehabilitation can be done at home. It should also be able to overcome spastic forces, and to a certain degree, contracture forces.

Islam et al. made a comprehensive review of robotic rehabilitation equipment for the upper extremity [3]. They categorized the developed devices based on five criteria:

- end effector or exoskeleton type,
- purpose (rehabilitation, power assistance or both)
- type of actuation
- training mode (unilateral or bilateral)
- portability

Out of the 77 reviewed devices, only four are completely portable [21] [22] [23] [24]. Three of which provide torques of less than 8 Nm for gravity support, which is insufficient to overcome spasticity [21] [22] [23]. RUPERT IV [24] has a maximum elbow torque of 15 Nm, sufficient only to overcome mild spasticity [25].

In conclusion, it was found that there is room for improvement in the effort to provide accessible robotic rehabilitation devices. Completely portable devices that can be used outside the clinical setting could benefit from a device with larger output torques to overcome severe spasticity. Another improvement that can be added to the current designs would be adaptability to different anatomies and pathologies with minimal customized parts.

2.4. Anthropometric Data

The beginning of any design process for products intended to cater to more than one individual is the objective knowledge of the range of the human's size, shape, and mechanical capacities. Hence, gathering of anthropometric data is needed to succeed in the design of the orthosis.

To design an orthosis that is adaptable to different anatomies, the sizing must be based on data from a sample representative of the population. An independent assessment of the geometry of the upper limb is not within the scope of the project, as such, existing published data will be used to support the design process. It will be assumed that the overall geometry of the upper arm can be adequately represented by the available data.

There are multiple anthropometric studies that could support the orthosis design process. Comprehensive and relevant databases utilized for the design of the orthosis are NHANES Anthropometric Reference Data for Children and Adults, ANSUR, and CPSC Anthropometric Data of Children.

United States National Health Examination Survey (NHANES) [26] records anthropometric data as a measure of the general health of the population. The report contains a combined 4-year dataset from 2007-2010 from a sample of 20,015 persons. The reports include weighted population means, standard errors of the means, and selected percentiles of body measurement values. Measurements are also reported in subgroups of sex, age, as well as race and ethnicity in adults. The limitation of this report is that only the measurements at selected percentiles are reported, as such, there is a limitation to the information that can be extracted.

The 2012 Anthropometric Survey of U.S. Army Personnel (ANSUR) [27] is a comprehensive anthropometric survey of the U.S. Army to acquire a large body of data from males and females to support design and engineering needs of the U.S. Army. The study obtained 93 directly measured dimensions and 41 derived dimensions from a sample composed of 4,082 men and 1,986 women measured between 2010 and 2012. The report also provides the raw data to the public, and additional information can be processed from the data set. However, it is also not perfect because the study only represents healthy adults.

The Anthropometry of Infants, Children, and Youths to Age 18 for Product Safety Design [28] is a study of the United States Consumer Product Safety Commission (CPSC) to create a database to support the design of children's furniture. The study contains 41 measurements obtained from 4000 infants and children representative of the US population in 1977. Although the study is outdated, it is the most comprehensive found so far and thus, will be used in the design.

Important measurements for the upper arm orthosis are the upper arm length, forearm length, wrist to hand length, arm circumference, forearm circumference, and wrist circumference. To be able to design a properly fitting orthosis, it is also beneficial to see the correlations between related dimensions, such as forearm length to forearm circumference of each sample, and not just the measurements in percentiles of each individual dimension, to see the shape of the segments and give us an insight on the required design of the orthosis to indeed be adaptable. In this regard, the ANSUR data set is significant because the raw data can be processed to show us information about the required shape of the orthosis. As such, this is used as a starting point for the design.

The male and female data were combined because there is no intent to develop sex-specific designs. The following plots were created:

- Arm length to bicep circumference
- Forearm length to forearm circumference
- Forearm length to wrist circumference

The means of each parameter ± 2x standard deviations were computed for each dimension and added to the plot forming a box within which 95% of the population was located. Linear regression was performed, and the standard error was computed. The regression line and standard error bands were added to the scatter plots. The areas enclosed by the ± 2 standard deviation box and standard error bounds represent the target population for the design. The plots are shown in Figure 1,Figure 2, and Figure 3.

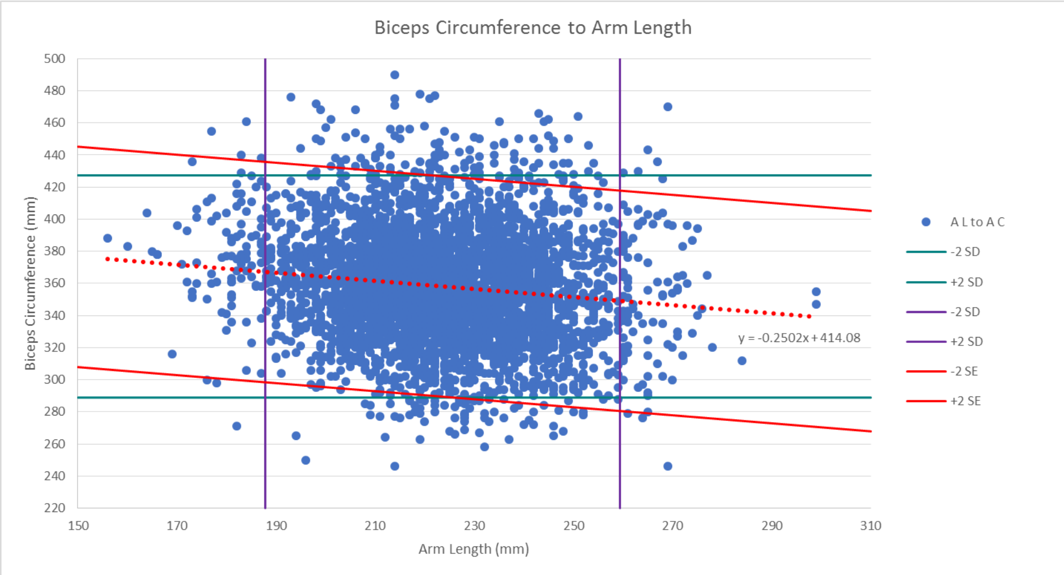


Figure 1: Biceps circumference versus arm length.

Table 1: Standard deviation and standard error of bicep circumference and arm length.

	Standard deviation	Standard error
Bicep circumference	34.6181	34.3315
Arm length	17.8961	

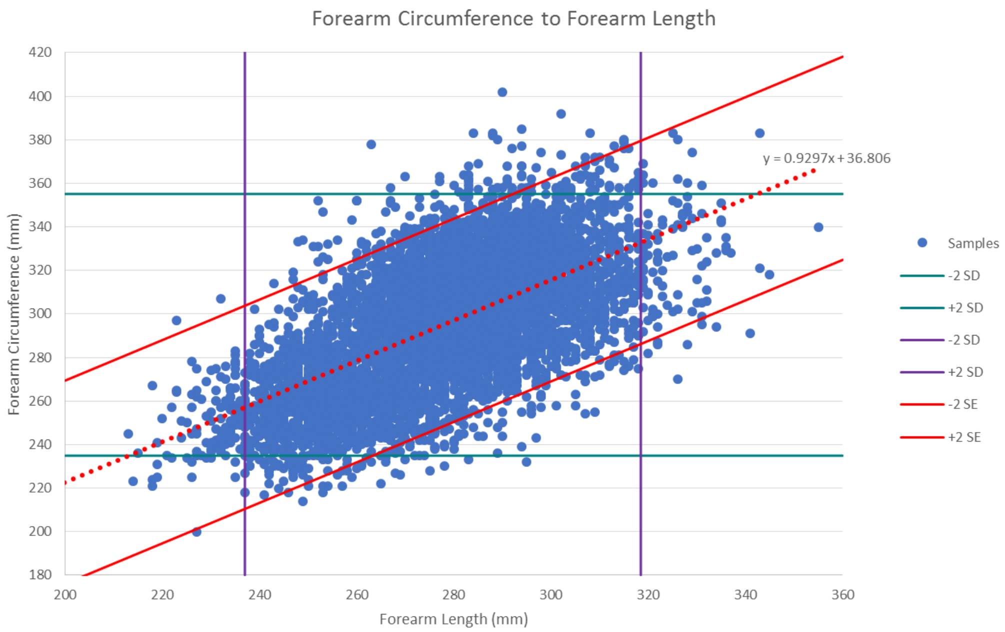


Figure 2: Forearm circumference versus forearm length.

Table 2: Forearm circumference and forearm length standard deviation and standard error.

	Standard deviation	Standard error
Forearm circumference	30.0497	23.3331
Forearm length	20.3691	

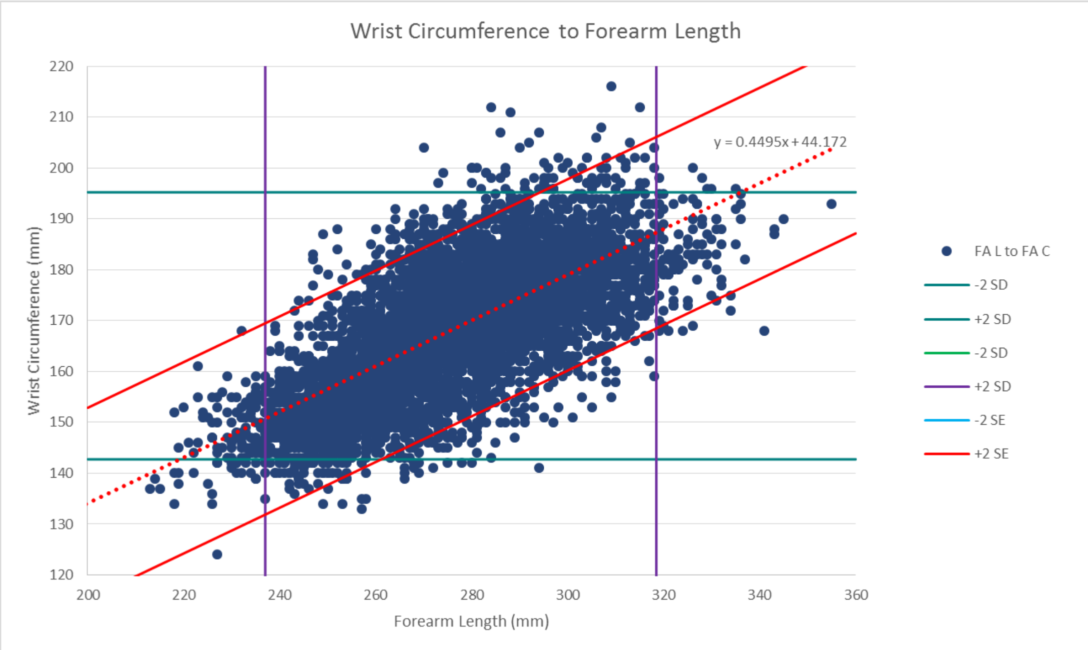


Figure 3: Wrist circumference versus forearm length.

Table 3: Wrist circumference and forearm length standard deviation and standard error.

	Standard deviation	Standard error
Wrist circumference	13.1245	9.40436
Forearm length	20.3691	

2.5. Loads

Designing a mechanically sound device requires knowledge of the loading that the device is intended to carry in normal conditions.

The device to be designed is intended to do passive exercises, so resistance from voluntary muscle contractions are not expected. In the intended use of the device, the following loads and resistances are expected:

- The inertia of the limb and device for acceleration

- Counteracting gravity
- Passive stiffness of the soft tissues
- Spasticity and contracture

2.5.1. Passive Stiffness, Spasticity, and Contracture

Published literature on the stiffness and strengths of elbow FE, forearm PS, and wrist FE were reviewed.

Kumar et al. (2006) [25] reported passive stiffness of the elbow joint for different levels of spasticity. Forces were reported, torques were not calculated, and the point of application was not standardized [29], so an approximation of the point of application of 260mm from the elbow joint was assumed from the illustration provided in the literature. The maximum torques derived from these assumptions are summarized in Table 4.

Table 4: Passive elbow joint stiffness for the non-spastic and severely spastic elbow joint. Force reported by Kumar et al. converted to torque

Level of Spasticity	Maximum Force, N (Kumar 2006)	Maximum Torque, Nm (95% confidence)
Non-spastic	8.9 (0.8)	3.1
Severely Spastic	37.9 (3.1)	13.1

Pasternak et al. (2007) [30] reported maximum active flexion and extension torques of the elbow joint for both spastic and non-spastic limbs.

Table 5: Maximum torques of active flexion of the elbow of spastic and non-spastic limbs as reported by Pasternak et al. [30]

Limb	Maximum Torque, Nm
Non-Spastic	50.1
Spastic	37.4

Maximum torques during active contraction and passive stretching of the wrist FE and forearm PS are presented by Turk (2008) [31], Formica (2012) [32], Matsuoka (2006) [33], and O'Sullivan (2005) [34]. However, there is a lack of data on passive wrist FE and forearm PS torques of spastic limbs. An assumption was made from the data of Pasternak (2007) and Kumar (2006) that the ratio between the passive stretch torque of a spastic limb and the active contraction of the non-spastic limb can be applied to the wrist FE and forearm PS.

$$ratio = \frac{50.1}{13.1} = 0.26$$

As such, passive stretching torques of spastic limbs will be assumed as 30% of the maximum active contraction torques.

Table 6 shows the summary of joint torque values that can be used in the design of the orthosis.

Table 6: Summary of biomechanical torque values to be used in the design of the orthosis

Motion	Passive Stiffness, Non-Spastic (Nm)	Active Contraction, Non-Spastic (Nm)	Passive Stiffness, Spastic (Nm)
Elbow FE	3.1	50.1 [30]	13.1
Wrist FE	1.4 [32]	20 [31]	6
Forearm PS	0.4 [32]	15.6 [33], [34]	4.7

2.5.2. Counteracting Gravity

To counteract gravity, it is necessary to determine the mass and centre of mass of each segment. The centre of mass and segment masses were estimated from anthropometric data [35], where the segment masses are estimated as a fraction of the total body mass, and the centre of mass is a ratio of the total segment length.

The body weights are taken from NHANES [26] as the 95th percentile of males over 20 years of age. The segment lengths are taken from ANSUR [27] as the 95th percentile of males and females.

The torques are calculated for each motion, except the forearm PS, where the motion is not expected to be affected by gravity.

$$T = mgr \tag{1}$$

where:

T = torque

m = mass

g = acceleration due to gravity (9.8 m/s^2)

r = distance of the center of mass to joint

The torque requirement for the orthosis weight is estimated using SolidWorks mass properties.

The summary of the torque requirement is shown in Table 7.

Table 7: Required joint torques to counteract gravity

Motion	Torque to counteract limb weight (Nm)	Torque to counteract orthosis weight (Nm)
Elbow FE	5.2	1.92
Wrist FE	0.7	0.02
Forearm PS	0	0

2.5.3. Inertia of the limb and device for acceleration

The orthosis also needs to be able to provide enough torque to accelerate the limb and the device to achieve the required motion.

To get the torque required to accelerate the limb and the device, it necessary to find the peak angular acceleration that the limb needs to undergo. To do this, the angular position function must be defined, from which, the second derivative will be taken to get the angular acceleration function. The peak angular acceleration will then be used to calculate the torque required, using equation (2):

$$T = I_j \alpha \qquad (2)$$

where:

T = torque

I_j = moment of inertia about the joint axis

α = angular acceleration

The angular position function is generated from an assumption of 10 cycles of flexion-extension per minute, based on a consultation with Dr Vojtěch Havlas as a reasonable motion for rehabilitation. The function will be assumed to be sinusoidal to allow accelerations and decelerations during the cycle.

Using these assumptions, the angular position function is generated, shown in Equation (3) and plotted in Figure 4.

$$\theta = 90 \sin\left(\frac{\pi}{3} t\right) + 90 \tag{3}$$

where:

θ = angular position (flexion angle)

t = time in seconds

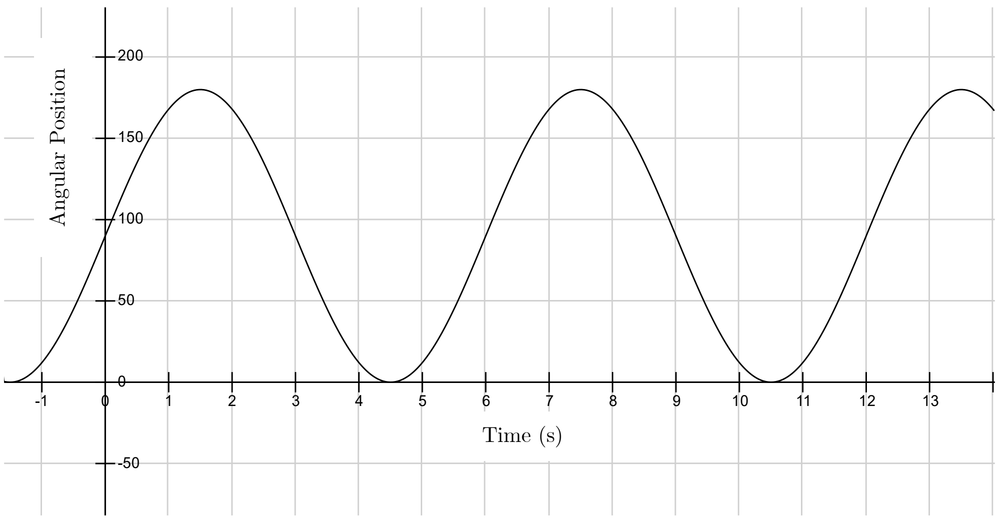


Figure 4: Flexion angle of the limb with respect to time

The angular acceleration is obtained as the second derivative of the angular position.

$$\alpha = -10\pi^2 \sin\left(\frac{\pi}{3}t\right) \tag{4}$$

The peak accelerations happen at:

$$\frac{d\alpha}{dt} = 0 = \frac{d}{dt}\left(-10\pi^2 \sin\left(\frac{\pi}{3}t\right)\right) = -\frac{10}{3}\pi^3 \cos\left(\frac{\pi}{3}t\right) \tag{5}$$

$$t = 1.5\text{s and } 4.5\text{s} \tag{6}$$

Substituting (6) to (4) gives us the peak angular acceleration values of

$$\alpha = \pm 98.7°/s^2 \text{ or } \pm 1.7 \text{ rad/s}^2 \tag{7}$$

Zatsiorsky (1983) provided anthropometric estimates of the moment of inertia about the axis of the centre of mass of each segment as a function of the body weight and stature [36].

Since the axis of rotation is the joint axis, the parallel axis theorem, shown in Equation (8), is used to find the moment of inertia about the joint axis from the moment of inertia from the centre of mass

$$I_j = I_{cm} + md^2 \tag{8}$$

where:

I_j = moment of inertia about the joint axis

I_{cm} = moment of inertia about the center of mass

m = segment mass

d = distance between the center of mass and the joint axis

The moment of inertia about the joint axis from equation (8) and the angular acceleration from equation (7) are inputted to equation (2) to get the torque required to move the limb to the required motion profile.

The torque requirement for the orthosis acceleration is estimated using SolidWorks mass properties.

The torques to produce the required motion profile are summarized in Table 8.

Table 8: Required joint torques to produce the required motion profile.

Motion	Torque for Limb Acceleration (Nm)	Torque for Orthosis Acceleration (Nm)
Elbow FE	0.28	0.10
Wrist FE	0.02	0.01
Forearm PS	0.01	0.01

2.5.4. Summary of Loads

The effective torque loads are computed by summing the torque loads for the limb and the orthosis from Table 7 and Table 8 to the corresponding motions in Table 6. The effective torques are summarized in Table 9.

Table 9: Summary of the torque requirement of the orthosis in different joint motions and patient condition

Motion	Passive Stiffness, Non-Spastic (Nm)	Active Contraction, Non-Spastic (Nm)	Passive Stiffness, Spastic (Nm)
Elbow FE	10.6	57.6	20.6
Wrist FE	2.15	20.75	6.75
Forearm PS	0.42	15.62	4.72

2.6. Sensors

The device will incorporate several measuring devices in the design. The data that will be recorded will primarily be used for analysis of the patients' recovery, especially when the device is used outside the supervision of the clinicians, to provide suitable medical intervention based on the current state of the patient. The recorded data will also open new opportunities for scientific research, given that scientific studies on upper limb rehabilitation using orthotics is not yet well established [18].

2.6.1. Kinematics Measurement

Kinematics is the most important parameter that needs to be measured in the powered orthosis being designed. This parameter, specifically the position of the limb, will serve as the feedback mechanism to the actuator. It will also be used to record the range of motion of the joints, and together with the other sensors, providing insight into the progress of patient rehabilitation. Knowing the angular speeds and accelerations will also provide additional data that can be used for scientific purposes.

A device that can be implemented in a portable orthosis is a potentiometer. A potentiometer is an analogue device that utilizes the motion to drive a moving contact in a variable resistor divider. The variation in the resistance in the circuit will translate to a variable voltage, and when calibrated with the angular position, can be a viable device for measuring the kinematics.

A rotary encoder is an electromechanical device that converts angular position or motion into an analogue or digital signal. The role of an encoder is similar to a potentiometer. However, the mechanism of sensing is different. Optical encoders, the most common type of encoder, move a code disk with light permeable windows, and photoelectric receptors convert these into digital pulses.

Gyroscopes, usually paired with accelerometers, are devices that can measure the absolute position, speed, and acceleration of a body with respect to the ground. Using them in pairs can provide relative position, speed, and acceleration, for example, between two body segments.

Electrogoniometers use strain gauges to measure angles between two bodies.

Potentiometers and rotary encoders have similar functions. In the foreseen use of the sensors, these devices may need to be installed in-line with the hinge connecting the two segments from which the relative motion will be measured. Between the potentiometer and the encoder, the encoder may be more suitable as the mechanical nature of the potentiometer may limit the device life.

Gyro-accelerometers and electrogoniometers, unlike potentiometers and encoders, must be placed away from the joint line. An advantage of this feature is it allows the measuring device to be placed close to the limb, thus reducing the error in motion sensing that can be brought about by compliance of the limb and/or the device. Electrogionometer is more favourable over gyro-accelerometers because it is cheaper and has a smaller package.

Electrogoniometer is seen to be a suitable device for the orthosis based on the advantage of positioning.

2.6.2. Torque Measurement

Torque sensors will be used to measure spastic forces or passive stiffness during the passive stretching exercises. It will also serve as a safety mechanism to stop the exercises when the torque readings exceed the expected values.

Torque measurement methods can be separated into two categories, direct or indirect. Direct methods involve measurement of torque in the drivetrain. A common method of direct method is measurement of the strains on a component that carries the torque, and the strain measurement is calibrated to show torque values. Indirect methods involve measurement of other parameters that are related to the torque. These related parameters could be the electric motor's power consumption or inertial measurement of the moving body.

The direct method has an advantage of higher measurement accuracy and the possibility to measure higher rotational speeds. Indirect methods normally have larger errors, therefore large measurement uncertainties, due to factors such as transmission inefficiencies and calibration difficulties.

Based on the purpose of the orthosis, accuracy will be the priority, as such, direct methods will be used in the design.

2.6.3. Neuromuscular Response Measurement

Resistance to passive movement can be a combination of changes in biomechanical properties, such as contracture, and spasticity. To further study the rehabilitation of joints, these two sources of resistances should be distinguished to determine if the stiffness is purely biomechanical, neural, or a combination of both [25].

As such, electromyography (EMG) will be part of the sensors to be included in the system. Muscle contraction follows when electrical signals reach the muscles to produce an action potential. EMG is a technique that measures muscle activity by sensing and recording these action potentials using electrodes. These electrodes can either be surface or subcutaneous electrodes. Surface EMG record the electrical signals from the surface of the skin. Subcutaneous electrodes allow penetration of the electrode into the muscle.

Subcutaneous EMG allows precise measurement of muscle activation, as opposed to surface EMG, where adjacent muscle activations can be detected by a single electrode. However, since the device to be designed is intended to be used outside the supervision of a clinician, subcutaneous EMG measurements will be difficult to implement. As such, surface EMG will be used.

Ideally, activation of the muscles during elbow FE, wrist FE, and forearm PS are intended to be recorded. EMG electrodes are placed over the biceps brachii and triceps brachii for the elbow FE. For wrist FE, electrodes should be placed over the extensor carpi radialis and flexor carpi radialis [37]. Unfortunately, pronator and supinator muscles of the forearm are deep, as such will not be accessible for surface EMG measurement.

2.6.4. Temperature Measurement

The device will be fitted with a Peltier module designed by the FBMI Biomechanics and Assistive Technology to aid in the cooling of the device. The cooling will be provided to components in direct contact with the patient to eliminate discomfort while the device is worn.

A temperature sensor will be placed on the device as close as possible to the patient's skin to provide feedback to the Peltier module.

The 4 most common types of temperature sensors [38] are the following:

- Negative Temperature Coefficient (NTC) Thermistor
- Resistance Temperature Detector (RTD)
- Thermocouple
- Semiconductor-based sensors

NTC thermistors are relatively cheap and provide a fast response with high accuracy (0.05 to 1.5°C). Standard NTC thermistors' operating range is within -50 to 150°C.

RTD's have high accuracies (0.1 to 1°C) and wider operating ranges (-200 to 600°C). However, it is also the most expensive among the temperature sensors.

Thermocouples generally have a low accuracy (0.5 to 5°C) but with the widest temperature range (-200 to 1750°C)

Semiconductor-based sensors are placed on integrated circuits. They have the lowest accuracy (1-5°C), slowest responsiveness (5 to 60 s) and narrowest temperature range (-70 to 150°C).

NTC thermistor is the best option because of the cost, accuracy, and its operating range covers the requirements.

2.7. Actuator and Power source

Veale and Xie (2016) and Redlarski et al. (2012) did reviews in the current and emerging actuator technologies that are being used or developed for orthoses and exoskeletons.

Technologies, paired actuator and power source, that were reviewed are the following:

- Electric – Rotary motor
- Electric – Linear motor
- Hydraulic – Electrohydraulic actuator
- Hydraulic – Portable double acting cylinder
- Pneumatic – Double acting cylinder
- Pneumatic – Antagonist Pneumatic Muscle Actuator Pair

Other emerging technologies were also reviewed, such as shape memory actuators, dielectric elastomer actuators, carbon nanotube actuators, etc. While the emerging actuator technologies show promise in solving shortcomings of the current technologies, these will not be considered in this design because there are still a lot of fundamental limitations, such as efficiency and manufacturability, that require further development to be successfully applied to portable orthoses.

The advantages of each of the traditional technologies over each other are clear [39]. Electric actuators have high power to weight ratio, easy to control, and battery powered; hydraulic actuators are silent, can have high backdriveability and high specific power; pneumatic actuators have inherent compliance and high force output.

However, a significant limitation regarding the application to a portable, powered orthosis of the hydraulic and pneumatic actuators is its power source. Hydraulic and pneumatic actuators rely on pressure supplies. While developments in this field are available, this adds additional weight to the whole system, decreasing its effective specific power. As such, electric actuators will be used.

2.8. Chapter Conclusion

Based on the review of the pathologies, the state-of-the-art in elbow joint rehabilitation devices, requirements, and available technologies that will support the orthosis design process, a device concept was created based on the unmet needs of the medical practitioners and patients.

The proposed device is a powered elbow-wrist orthosis that will provide dynamic-repeated-passive motion exercises for the elbow and wrist joints. The device will be indicated for patients that could benefit from such exercises, such as patients with orthopaedic and neuromuscular pathologies that cause spasticity or contracture.

The device should also measure kinematics using electrogoniometers, torques using in-line torque sensors, and neuromuscular response using EMG sensors, throughout the exercise program. The data on kinematic and neuromuscular response should be useable for improvement of the treatment strategies by providing feedback on the patient rate of recovery, as well as for scientific purposes.

The device should be portable, and use should not restrict the user to a certain location. The device should cater to a wide range of anatomies, age groups, and pathologies using the anthropometric data available while minimizing the number of personalized components.

The device should be battery powered, use electric motors as actuators, to be able to provide suitable exercise motions through the safe range of motion to overcome resistances from severe spasticity or contractures.

3. Design Considerations

After the device concept was created, the design requirements that will drive the design process were formulated. This was done to create a general idea of what the device is supposed to accomplish and provide a basis for validating the design if it delivers the specified performance requirements.

3.1. Product Characterization

To be able to create an effective and safe design of the orthosis, the device needs to be sufficiently characterised. The international standard ISO 14971:2007 “Application of Risk Management to Medical Devices” [40] Annex C was used as guidance for this process. The following questions were derived from the aforementioned standard.

1. *What is the intended use and how is the medical device to be used?*

   The device is indicated for patients with neuromuscular and orthopaedic pathologies that could benefit from dynamic-repeated-passive motion exercises for the elbow and wrist joints. The primary use of the device will be the prevention or therapeutic intervention for contractures due to paresis, muscle imbalance or spasticity from neuromuscular disorders such as stroke or cerebral palsy, or orthopaedic rehabilitation after joint replacement surgeries or reconstruction after traumatic injuries.

The intended use will be to provide dynamic-repeated-passive motion exercises for the elbow and wrist joints. The motion to be performed, as per the recommendations of Dr Vojtěch Havlas, will be the flexion-extension of the elbow joint and pronation-supination and flexion-extension of the wrist joint.

The device is also intended to record data that will provide insight on the recovery of the patient for improved interventions, as well as for scientific purposes. Data to be recorded are joint angles and accelerations, neuromuscular response, joint torques, and temperature.

2. *Is the medical device intended to be implanted?*

   The medical device is not intended to be implanted.

3. *Is the medical device intended to be in contact with the patient or other persons?*

   The device will be in contact with the patient. There will be a surface contact with the skin of the patient. The maximum period of contact will be thirty minutes per day, daily.

4. *What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?*

   The components of the medical device will be mostly metal, plastics, and textile. The components that will be in contact with the patient shall be made of biocompatible materials for short duration contact with the skin.

5. *Is energy delivered to or extracted from the patient?*

   During the intended use of the device, the device will deliver mechanical energy to provide passive motions to the elbow and wrist joints of the patient. The device will extract minute electrical energy during sensing of the neuromuscular response of the patient during the exercises delivered.

6. *Are substances delivered to or extracted from the patient?*

No substances are delivered nor extracted from the patient.

7. *Are biological materials processed by the medical device for subsequent re-use, transfusion, or transplantation?*

   No biological materials are to be processed by the medical device.

8. *Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?*

   No parts are required to be sterilized.

9. *Is the medical device intended to be routinely cleaned and disinfected by the user?*

   Fabric padding should be routinely cleaned by regular laundry process.

10. *Is the medical device intended to modify the patient environment?*

    The device will provide cooling to the surfaces touching the skin of the patient to eliminate discomfort. A temperature sensor will provide feedback to control the cooling to comfortable levels.

11. *Are measurements taken?*

    Measurements of kinematics, neuromuscular response, joint torques, and temperature will be measured.

12. *Is the medical device interpretative?*

    The neuromuscular response will be processed by the device.

13. *Is the medical device intended for use in conjunction with other medical devices, medicines, or other medical technologies?*

    While no other external devices will be required for the proper use of the device, off-the-shelf medical devices will be built-in to the system. These built-in devices are the measurement devices stated in number 11.

14. *Are there unwanted outputs of energy or substances?*

    Noise and vibration can be produced by the actuators during normal use. Electromagnetic noise can also be produced by the electric motor.

15. *Is the medical device susceptible to environmental influences?*

    Some components of the device could produce electromagnetic noise.

16. *Does the medical device influence the environment?*

    Some components of the device could produce electromagnetic noise.

17. *Are there essential consumables or accessories associated with the medical device?*

    Batteries that power the device are required.

18. *Is maintenance or calibration necessary?*

    Maintenance is required on the bearings. Calibration is required for the measuring devices stated in number 11.

19. *Does the medical device contain software?*

    The medical device contains software. The software will be pre-installed and will not be modifiable by the user.

20. *Does the medical device have a restricted shelf-life?*

    The medical device does not have a restricted shelf-life.

21. *Are there any delayed or long-term use effects?*

    Mechanical fatigue of components is possible. Wear on the bearings is definite. Straps and paddings are subject to wear-and-tear. Batteries also have finite charge-discharge cycles.

22. *To what mechanical forces will the medical device be subjected?*

    The device will be required to support inertial forces of the arm during the passive motion exercises. The device will also need to overcome forces due to spasticity.

23. *What determines the lifetime of the medical device?*

    The lifetime of the medical device will be dependent on the mechanical failure of the parts that are not user replaceable such as mechanical linkages. A reasonable lifetime is 5 years.

24. *Is the medical device intended for single use?*

    The device is intended for multiple uses.

25. *Is safe decommissioning or disposal of the medical device necessary?*

    The batteries should be decommissioned by battery recycling facilities.

26. *Does installation or use of the medical device require special training or special skills?*

    No.

27. *How will information for safe use be provided?*

    User manuals should be provided if the device will be commercialized. However, at the prototype stage, the device should be operated by trained personnel only.

28. *Will new manufacturing processes need to be established or introduced?*

    No.

29. *Is successful application of the medical device critically dependent on human factors such as the user interface?*

    Yes. However, the control system is not yet included in the scope of this project.

30. *Does the medical device use an alarm system?*

    An alarm system is to be set for unexpected torque loads to protect from excessive force introduced to the patient.

31. *In what ways might the medical device be deliberately misused?*

    The device might be used as a resistive exercise device.

32. *Does the device hold data critical to patient care?*

    The device holds the program for the rehabilitation exercises designed for the patient. The unauthorized modification can lead to excessive forces being introduced to the patient.

33. *Is the medical device intended to be mobile or portable?*

    The device should be portable and should be operable without location restriction.

3.2.Design Inputs

The design inputs were formulated as the starting point of the design process. The design inputs are the user needs to be translated into engineering requirements. The design inputs established the basis of the design process and the requirements for the verification of the design.

The creation of the design inputs was guided by the US FDA Design Control Guidance. [41] Based on the Product Characterization from section 3.1, the following design inputs were created:

3.2.1. Indications

3.2.1.1. The device shall be indicated for rehabilitation from orthopaedic and neuromuscular pathologies that could benefit from dynamic-repeated-passive motion exercises.

3.2.1.2. The device shall be indicated for the elbow and wrist joint.

3.2.2. Functional and Performance Requirements

3.2.2.1. The device shall be able to perform dynamic-repeated-passive motion exercises for the elbow and wrist joints. The following motions shall be produced:

Table 10: Normal range of motion of the elbow, wrist, and forearm [42]

Motion	Range of Motion (degrees)
Elbow Flexion	140-150
Elbow Extension	0
Wrist Flexion	60-80
Wrist Extension	60-75
Forearm Pronation	76-84
Forearm Supination	80

3.2.2.2. The device shall record kinematics of the joints throughout the exercises. The following measurements shall be recorded:

- Angular Position
- Angular Speed
- Angular Acceleration

3.2.2.3. The device shall be capable of providing torque to overcoming muscle spasticity and inertial forces during rehabilitation exercises determined in Table 9.

3.2.2.4. The device shall provide measurement accuracy within ±2° (benchmarked to common biomechanical research equipment [43] [44])

3.2.2.5. The device shall measure EMG and joint reaction torques during the exercises.

3.2.2.6. Electrical noise from the motor shall not cause interference with other functions of the device.

3.2.2.7. The specifications of the batteries shall be specified.

3.2.2.8. The mechanical components shall have sufficient fatigue strength for 150,000 cycles.

The cycle count is based on an estimation of 5-year useful life, 200 days per year, 15 minutes per day, and 10 cycles per minute.

3.2.2.9. Maintenance procedures shall be specified for bearings, straps and paddings, and batteries.

3.2.3. Form Requirements

3.2.3.1. The device shall not prevent the patient from ambulation.

3.2.3.2. The device weight shall not exceed 4kg.

3.2.3.3. Sizing shall accommodate 90% of the target population.

3.2.3.4. The paddings shall be detachable and be cleanable by users using regular laundry processes.

3.2.3.5. The device shall have provisions for off-the-shelf EMG, torque, and angular kinematic measurement devices.

3.2.4. Safety Requirements

3.2.4.1. The parts contacting the patient body should be biocompatible for short duration skin contact.

3.2.4.2. The device shall have a safety mechanism against over-extension/flexion of joints during passive stretching.

3.2.4.3. The device shall have an alarm system/safety stop for a high resistance torque that can be set by the medical practitioner.

3.2.4.4. The device shall have the capability of setting the range of motion and speed for the exercises.

3.2.4.5. The required software shall come pre-installed, and no installation shall be required from the user

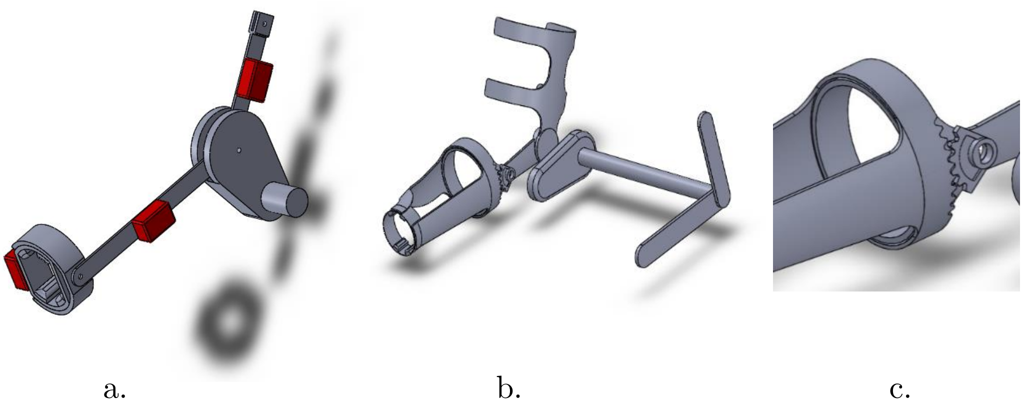
3.2.4.6. The user shall not be able to modify the software.

3.2.4.7. The patient shall not be able to modify the exercise program. Only the medical practitioner shall have authority to modify the exercise program.

4. Design Process

This section outlines the evolution of the design from rough design to the final design specifications. This section will detail the rationale behind each design stage, the feedback from design reviews, and the design changes that come as a result.

4.1. Version 01



a. b. c.

Figure 5: a. Draft with accelerometer positions; b. Version 01 of the design; c. The mechanism for pronation and supination of the forearm

- A design for manual actuation using levers was conceptualized
- The mechanism for pronation-supination positioned at the mid area of the forearm
- Moulded upper arm and forearm segments are conceptualized
- The position of accelerometers for data gathering proposed

Figure 5 shows the first draft version of the design. This draft proposes to use XSens MTi-series accelerometers that are currently available in the Biomechanics and Prosthetics Laboratory to provide the kinematic information required. Figure 5.a shows the three accelerometers positioned to provide the required data on the kinematics of the elbow flexion-extension and forearm pronation-supination. One accelerometer on the upper arm to be used as a reference, one accelerometer on the forearm to provide data on the elbow flexion-extension kinematics, and one accelerometer for the pronation-supination of the forearm.

The upper arm and forearm segments are to be moulded. The mechanism for pronation and supination of the forearm was placed in the middle portion of the forearm as shown in Figure 5.b and Figure 5.c. The mechanism proposed was a solid circular track guided with bearings where the forearm piece will rotate. This will ensure that the centre of rotation of the forearm piece can be maintained during operation. The rotation will be controlled by the actuator through a curved rack and pinion mechanism.

The actuator will both control the flexion-extension of the elbow and pronation-supination of the forearm. The actuator can either be an automated actuator or a manual actuator using levers

This design entails multiple sizing of the forearm piece, as the centre of rotation needs to be aligned with the centre of rotation of the forearm. Otherwise there will be eccentric forces acting on the forearm. The multiple sizing is demonstrated in Figure 6.

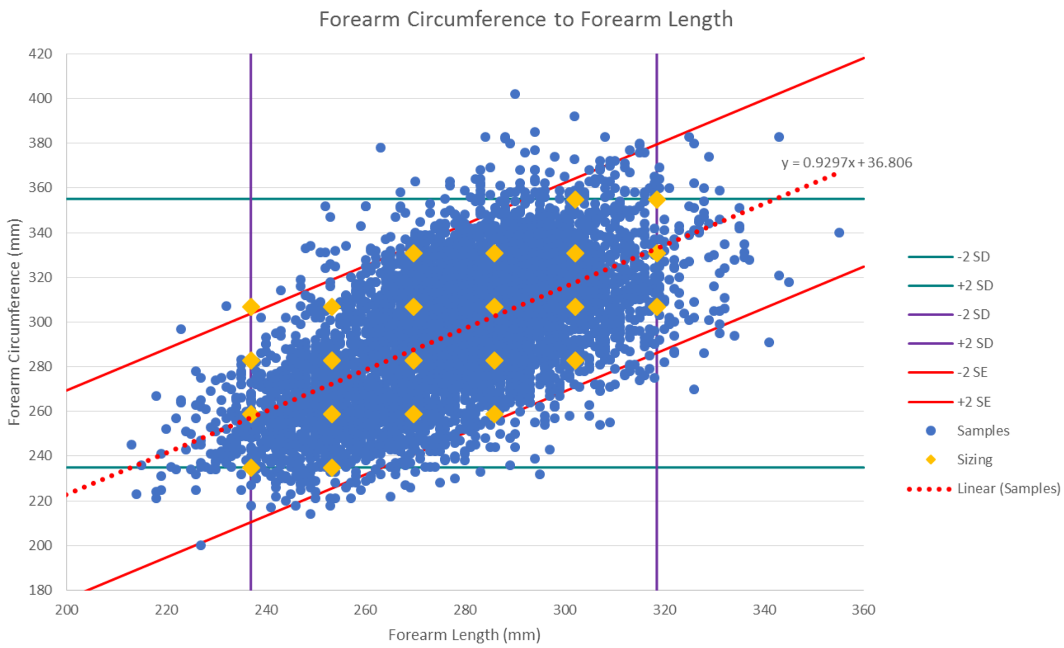


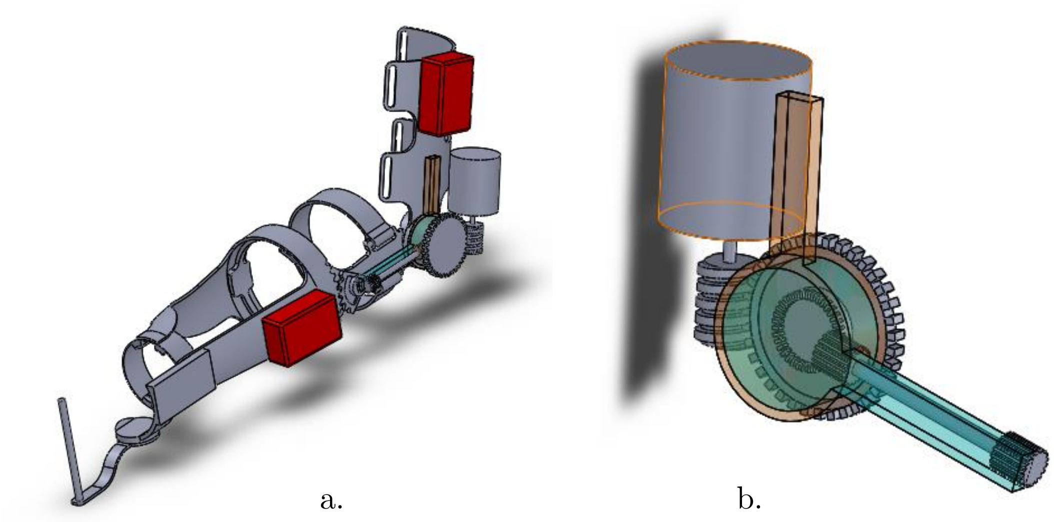
Figure 6: Forearm circumference versus forearm length with sizing.

Design Review

Attendees: Kevin Bancud, Patrik Kutilek

The design was approved by Prof. Kutilek and the design process proceeds.

4.2. Version 02



a. b.

Figure 7: a. Version 02 of the design; b. Concept of the automated actuation with worm gear drive.

- Wrist flexion-extension function was added
- The concept of the automated actuation with worm gear was conceptualized

Figure 7 shows the first revision of the orthosis design. The concept of the automated actuation was modelled here. The actuator is a DC brushless motor which will control both elbow flexion-extension and forearm flexion-extension. The power transfer will be accomplished using a worm drive. The worm drive was selected because of its high mechanical advantage, high reduction ratio, and limited backdriveability.

A single motor is used to control the flexion-extension of the elbow and the pronation-supination of the forearm. The worm gear can be directly connected to the forearm, controlling the elbow flexion-extension. A crown gear is attached to the worm gear, which will then drive a shaft that will transfer power to the forearm piece, producing the pronation-supination motion. A selector needs to be designed to switch between the two actions.

Wrist flexion-extension was also added to the functionality of the device. It was done as an improvement from the initial design requirement. The actuation of this function is not yet defined, whether it can be powered by the same motor or a separate actuator needs to be added.

Design Review

Attendees: Kevin Bancud, Patrik Kutilek, Vojtěch Havlas

A formal design review was conducted at this stage. The design was presented to the medical consultant, Dr Vojtěch Havlas. Record of the review is attached in Appendix 11.1.

4.3.Version 03

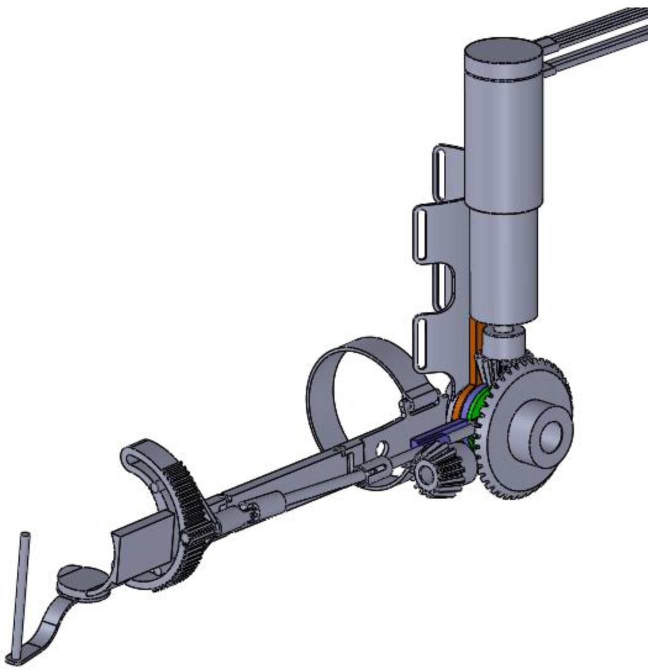


Figure 8: Version 03 of the design.

- The mechanism for pronation-supination was transferred to the wrist area from the mid-forearm.
- The sensor for kinematics measurement was changed to an electrogoniometer instead of accelerometers.

- The actuator was sufficiently sized based on the 25 Nm torque and 10rpm requirement. (Based on continuous running specifications)
- Bevel gear drive selected.

Figure 8 shows the third version of the orthosis. A major design change was driven by the previous design review, where Dr Havlas recommended a significant reduction in the number of sizes. This brought about the idea of moving the mechanism for pronation-supination from the mid-forearm to the wrist area. This was done because the variability of the wrist diameter within the population is smaller than that of the forearm diameter as can be observed in Figure 2 and Figure 3 and summarized in Table 2 and Table 3. This allowed the reduction in the number of sizes that need to be provided to cater to the target population while meeting the requirement of maintaining the centre of rotation of the forearm aligned with the orthosis centre of rotation during pronation-supination.

The motor with a reduction gearhead and bevel gear drive was selected over the previous worm drive concept. The change was brought about by the spatial constraint, and the high reduction ratio required. The bevel gear drive also provided better efficiencies.

The sensor for kinematics was also re-evaluated. Electrogoniometers were used instead of accelerometers because electrogoniometers could provide the required data with smaller package size and lower cost.

Design Review

Attendees: Kevin Bancud, Patrik Kutilek

The design was approved by Prof. Kutilek and the design process proceeds.

4.4. Version 04

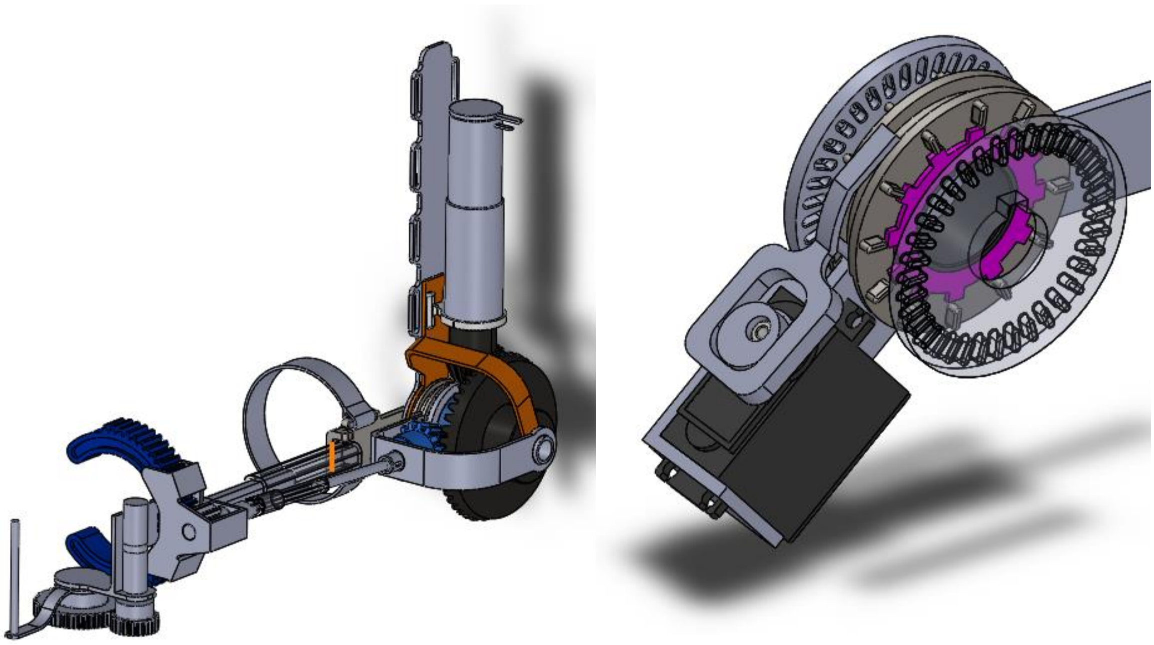


Figure 9: Left: Version 04 of the device. Right: Switching mechanism between elbow FE and forearm PS.

- The actuator was re-evaluated and resized.
- The gears are suitably sized, and the material is selected based on the forces.
- Switching mechanism between elbow flexion-extension and forearm pronation-supination is designed.
- Adjustable forearm length designed.
- The mechanism in the wrist area is conceptualized.
- Wrist flexion-extension motion is provided by a separate actuator.

Figure 9 shows the fourth version of the device. Optimization of the device was started during this stage. As a part of the optimization, re-evaluation of the motor was done to reduce the overall weight of the device. Instead of sizing the motor based on the continuous running regime, the required torque and speed were taken from the intermittent operation regime. Greater power can be extracted from the motor if ran intermittently, allowing a smaller motor to be used to achieve the requirements.

The length adjustment was also designed at this point. The length adjustment was provided by telescoping beam and shaft connecting the wrist member to the forearm member.

The switching mechanism allows switching between elbow flexion-extension and forearm pronation-supination. The mechanism is a positive engagement clutch mechanism actuated by a servo motor.

Design Review

Attendees: Kevin Bancud, Patrik Kutilek

The design was approved by Prof. Kutilek and the design process proceeds.

4.5. Version 05

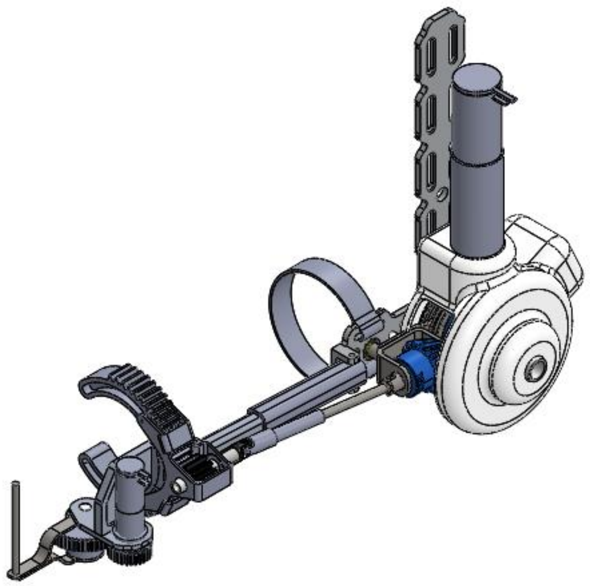


Figure 10: Version 05 of the device.

- Components were optimized to minimize material and weight.
- A gearbox was designed around the actuator mechanism, instead of simple supports.

Figure 10 shows the fifth and final version of the device.

Simulations were done for static loading and fatigue loading. Also, redesign for overloaded components and optimization for overdesigned components were done. Major changes include a material change from AISI 304 stainless steel to 6061 T6 aluminium to decrease weight.

Another major change was the design of a gearbox around the actuator gears instead of the previously designed simple supports because of the excessive deformation during operation. The excessive deformation will cause misalignment of the gears that can cause excessive wear or jumping of gear teeth. The gearbox is made from cast aluminium. Moulded ABS plastic was considered as a possible material for the gearbox. However, the rigidity achieved with aluminium is better with an equivalent weight.

Design Review

Attendees: Kevin Bancud, Patrik Kutilek

The addition of a cooling mechanism (Peltier module) that is already designed by the laboratory is suggested. Otherwise, the design is approved.

5. Final Design Specifications

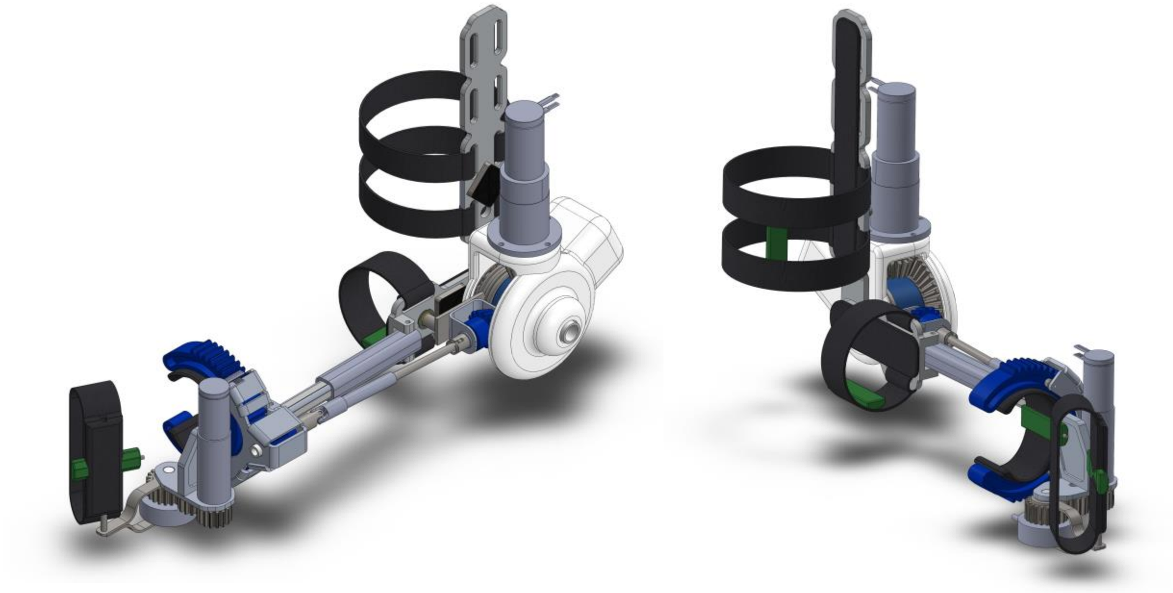


Figure 11: Final design.

The following section describes the final device after the design process.

5.1. Main Device Features

5.1.1. Function

The device is capable of providing automated dynamic-repeated-passive motion exercises for the elbow and wrist joints. It can provide elbow joint flexion-extension, forearm pronation-supination, and wrist flexion-extension.

The device is indicated for the following:

- Neuromuscular Disorders
  - Duchenne's Muscular Dystrophy (DMD)
  - Becker's Muscular Dystrophy (BMD)
  - Peripheral neuropathy
  - Hereditary neuropathy

    - Cerebral palsy
    - Stroke
- Orthopaedic Rehabilitation
    - Rehabilitation after trauma reconstruction
    - Rehabilitation after joint replacement

The device is powered by a portable 24-volt lithium ion battery and actuator system, allowing unrestricted ambulation to the patient during the exercise session.

The device is capable of measuring:

- reaction torques during elbow flexion-extension and wrist flexion-extension,
- joint angles during elbow flexion-extension, wrist flexion-extension, and forearm pronation-supination,
- EMG from biceps brachii, triceps brachii, extensor carpi radialis, flexor carpi radialis.

5.1.2. Anatomic Adaptability

The model is designed to fit 90% of the adult population. This adaptability is achieved by the following design features:

- Adjustable straps that can accommodate 99% of the population's arm and forearm diameters,
- three upper arm strap position options that can accommodate 99% of the population's upper arm lengths,
- three telescoping forearm beams to cater to 95% of the population's forearm lengths,
- and five wrist paddings to cater to 95% of the population's wrist diameters.

The device is capable of performing dynamic-repeated-passive motion exercises to patients with the most severe spastic arms. The device is capable of producing 25 Nm of torque for elbow flexion-extension, 8.5 Nm of torque for wrist flexion-extension, and 6 Nm of torque for forearm pronation-supination.

5.2. Mechanism Description

5.2.1. Anatomic Adaptability

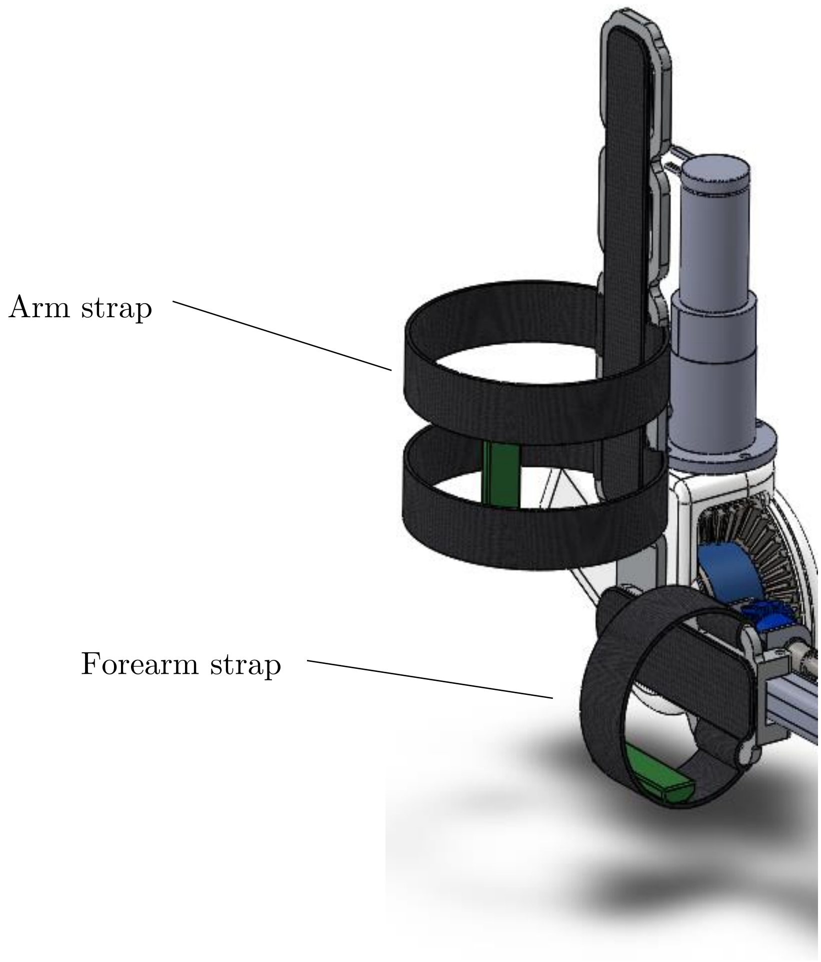


Figure 12: Forearm and upper arm are constrained using Velcro straps.

The upper arm straps are Velcro straps that allow adjustments of the fit around the upper arm. The positioning options are designed such that the most distal arm strap will clear the largest forearm in the population. The second distal arm strap position is designed to clear the axilla of the shortest arm. For longer arm lengths, the second distal arm strap can be moved as far proximally as possible without irritating the patient's axilla.

The forearm strap is located such that it will clear the patient's cubital fossa.

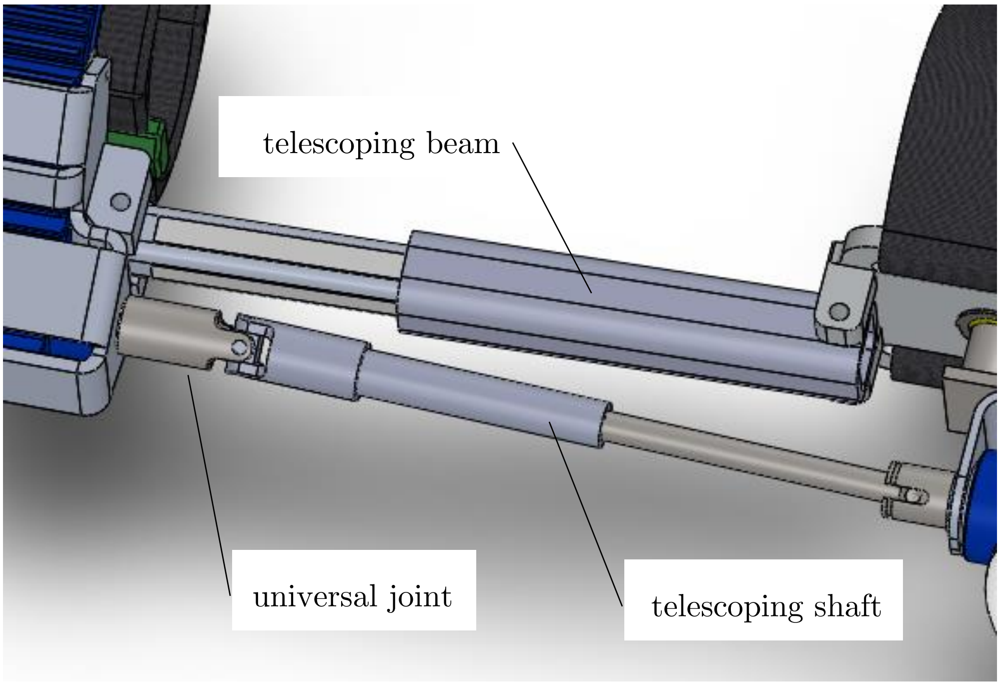


Figure 13: Telescoping beam and shaft provide a wide range of forearm lengths.

The forearm beam is telescoping to accommodate a wide range of forearm lengths. The telescoping forearm beam utilizes pre-fabricated telescoping tubings from Alcobra Metals, which has clearances and tolerances to provide both smooth telescoping motion and constraint. The internal beam is covered with 0.25mm UHMW tape to provide a bearing surface between the tubes.

The telescoping beam is pin-connected to the wrist assembly and the forearm base (KBP-001). This allows the wrist assembly to self-align with the pronation-supination centre of rotation of the forearm.

The pin-connected telescoping beam design requires the shaft that drives the wrist pronation-supination to be telescoping and self-aligning to allow transfer of torque from the motor to the wrist assembly. As such, the shaft is designed to be telescoping and connected using universal joints. The universal joints are bought off-the-shelf.

The wrist paddings are interchangeable, with 5 different sizes for adults covering 95% of the wrist sizes in the population

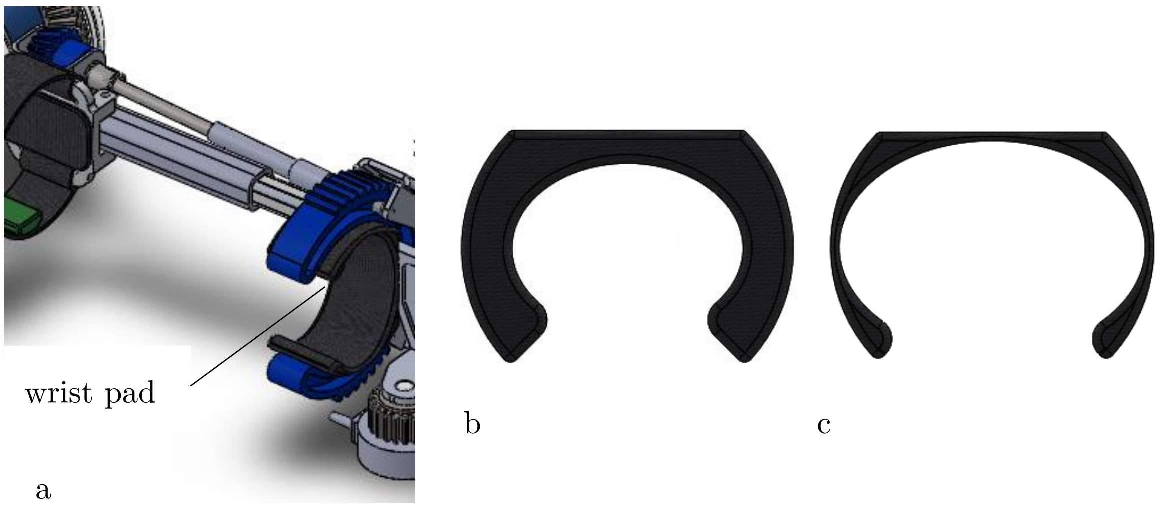


Figure 14: a. Interchangeable wrist pad; b. Size 1 (smallest) wrist pad; c. Size 5 (largest) wrist pad.

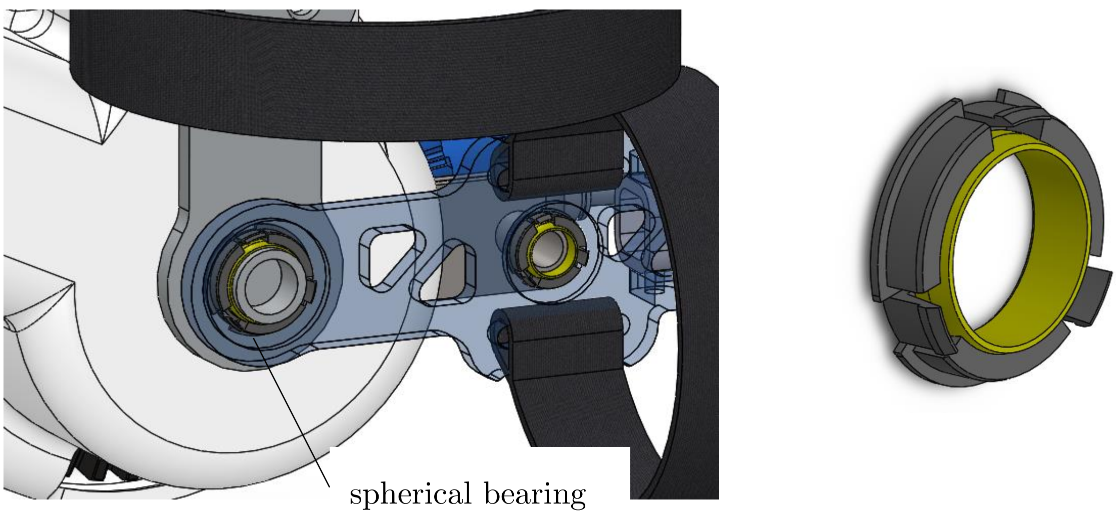


Figure 15: Spherical bearings allow misalignment between the forearm and upper arm attachments.

The connection along the elbow joint is a spherical bearing (Figure 15). This allows misalignment between the Base FA (KBP-001) and Base UA (KBP-002). This provides for different shapes of the patient forearm while still allowing efficient transfer of torque along the axis of the joint.

5.2.2. Modularity

The device can be separated into four different modules, as shown in Figure 16. Modules have different specifications and sizes, and thus be capable of interchangeability depending on the patient requirements.

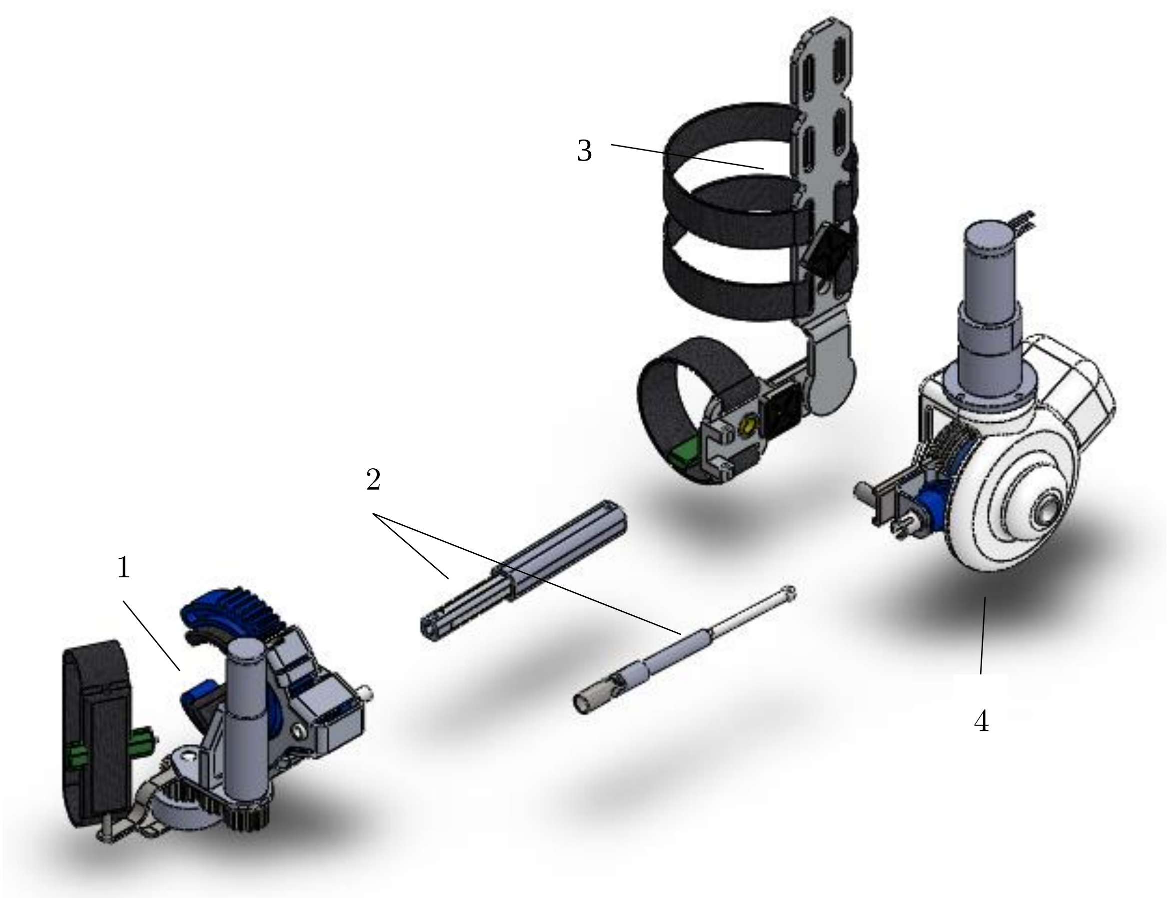


Figure 16: Four modules of the device. (1) wrist base; (2) telescoping beam and shaft; (3) elbow base; (4) main actuator

5.2.3. Actuator Options

As found out in section 2.5, different levels of spasticity have different mechanical requirements. The elbow torques expected from patients with severe spasticity are twice as much as with patients without spasticity. As such, a smaller actuator will suffice for patients without spasticity. This actuator will also be applicable for children. The gearbox material is changed from 6061-T6 Aluminum to ABS plastic, and the gears are changed from steel to MC901 nylon. The two elbow joint actuators are shown in Figure 17.

Non-spastic wrist FE torques are only 32% of the torques of severely spastic wrist joints. As such, the motor required only needs 32% of the power as well. The two wrist components are shown in Figure 18.

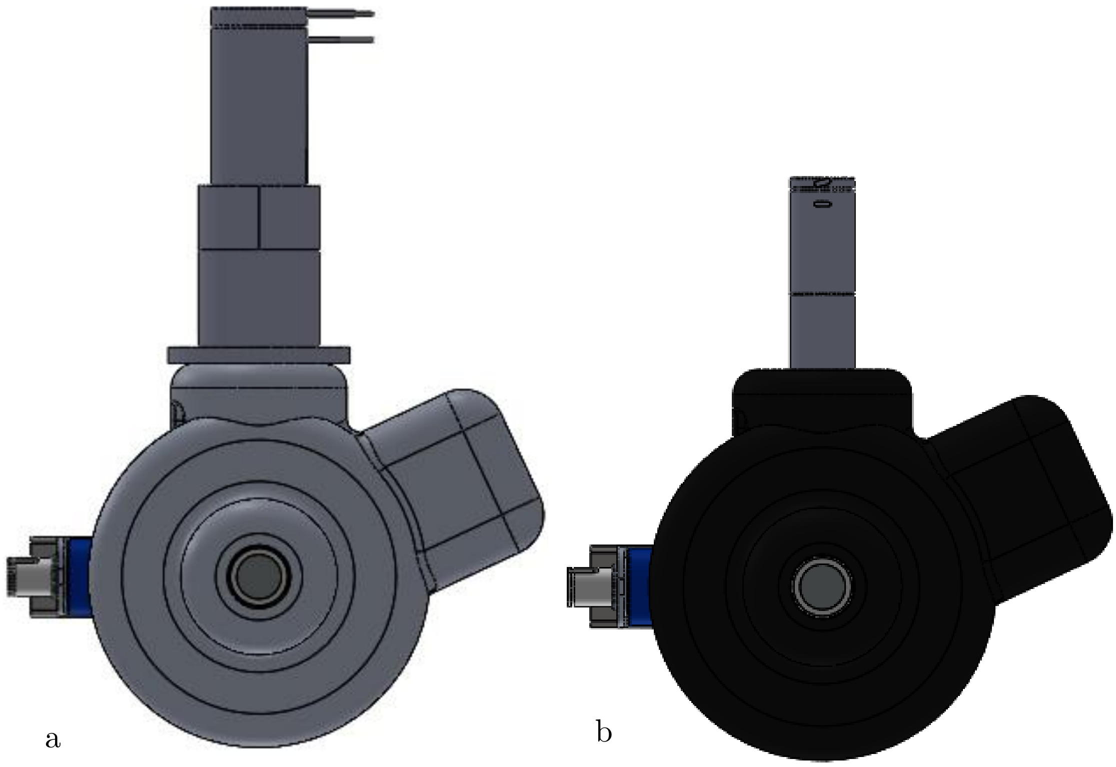


Figure 17: Two options for the elbow actuator. a. 25 Nm elbow actuator for severely spastic patients; b. 12 Nm elbow actuator for children and non-spastic patients.

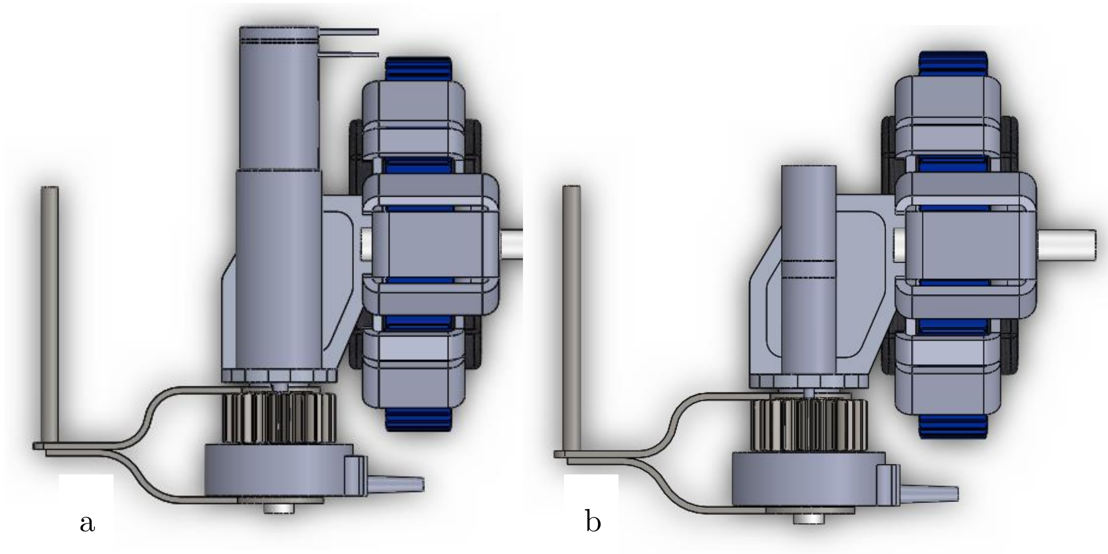


Figure 18: Two options for the wrist actuator. a. 8.5 Nm wrist actuator for severely spastic patients; b. 2.5 Nm wrist actuator for children and non-spastic patients.

5.2.4. Elbow FE/Wrist PS Selector

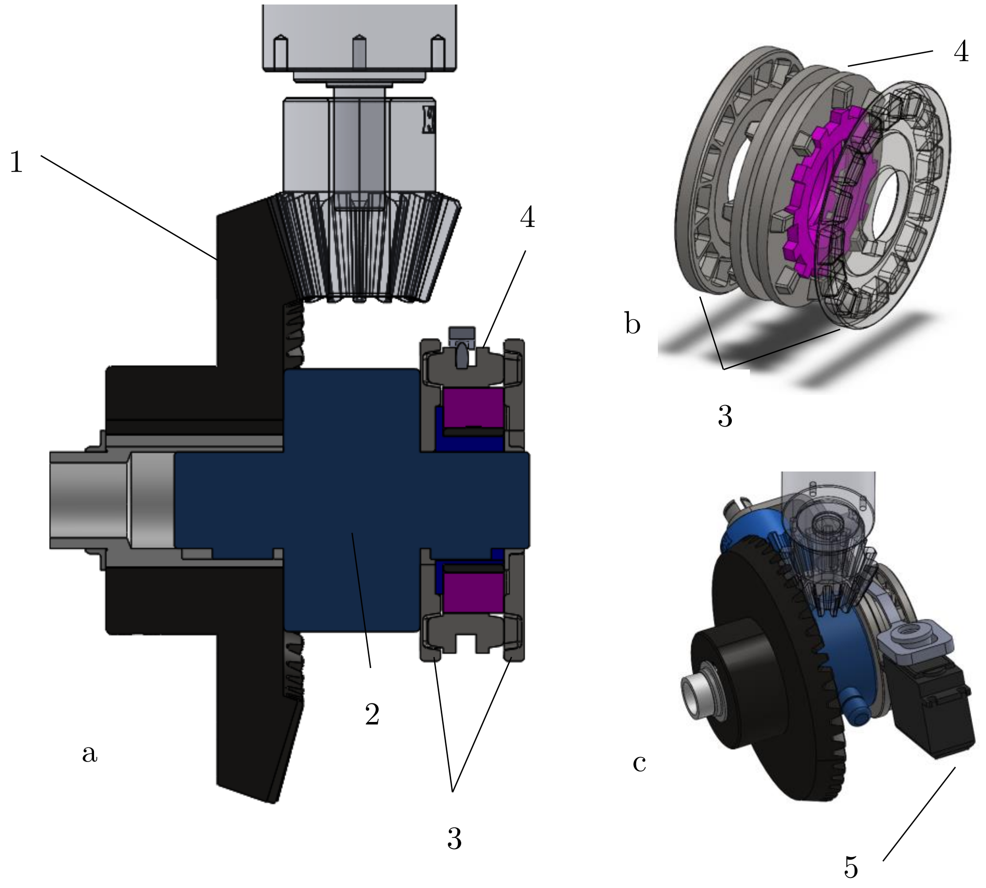


Figure 19: Device elbow FE and forearm PS selector parts. (1) bevel gear, (2) torque transducer, (3) engagement plates, (4) selector plate, (5) servo. a. Cross section view of the selector mechanism; b. Positive engagement clutch mechanism; c. Servo motor actuates the selector

Elbow flexion-extension and forearm pronation-supination motion are controlled by a single motor. The motor transfers the torque using a bevel drive to the shaft adapter. The shaft adapter is rigidly connected to the torque transducer. An engagement plate with recesses is rigidly connected to the torque transducer. Another engagement plate on the opposite side freely rotates along the shaft of the transducer. The selector plate with protrusions slides along a spline to positively engage on either selector plate. The mechanism is shown in Figure 19.

If the selector engages on the first selector plate, the forearm connects with the torque sensor and the main bevel gear, producing elbow flexion-extension.

If the selector engages on the second selector plate, the forearm locks with the upper arm. The main bevel gear produces rotation to the forearm bevel gear, producing wrist pronation-supination.

The selector is actuated by a servo motor connected to a cam and mounted on the gearbox. The cam actuates a lever that slides the selector to engage to either selector plate.

The selector protrusions have negative draft angles. This feature allows the selector to release engagement from the selector plate more easily even with torque load.

5.2.5. Elbow Flexion-Extension

Elbow flexion-extension is provided by engaging the selector, locking the forearm with the main bevel gear and the torque transducer. With this, the motion of the main bevel gear is transferred to the torque transducer shaft, which is then transferred to the forearm, producing the required flexion and extension. The torque transducer measures the resistance torque during the motion.

5.2.6. Wrist Pronation-Supination

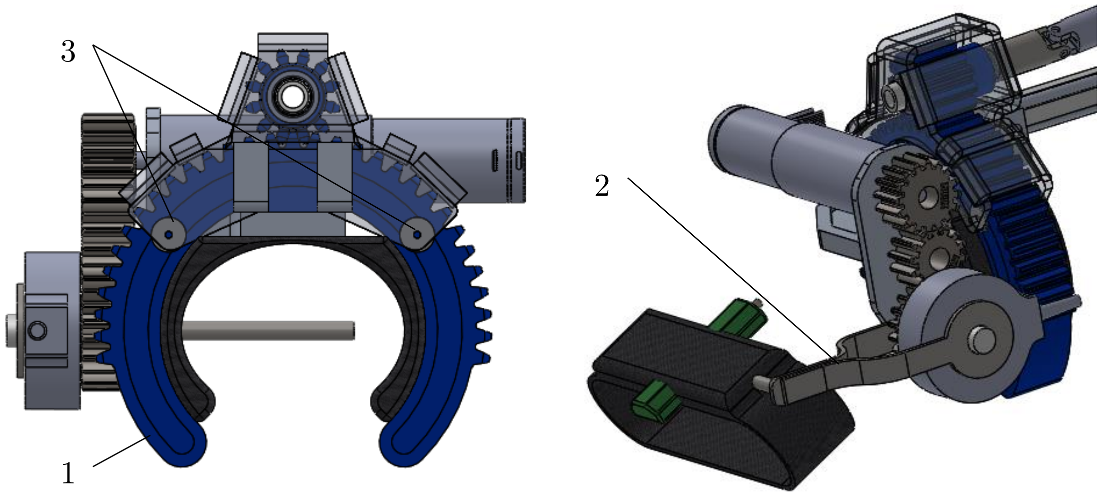


Figure 20: Wrist pronation-supination mechanism. (1) wrist gear, (2) hand bar, (3) bearings.

The wrist pronation-supination motion is provided by the same motor that drives the elbow flexion-extension. The selector locks the forearm with the upper arm, allowing the main bevel gear to transfer the torque to the shaft to the wrist.

The wrist gear, together with the hand bar and wrap, transfers the torque to the hand to produce the forearm pronation-supination motion. The wrist gear's rotation is guided by two bearings with a radial distance of 45mm and 104° apart. These dimensions were computed to allow the force transferred by the pinion to produce an equivalent force on the wrist gear directed tangentially, with the centre of rotation located on the centre of the wrist gear.

5.2.7. Wrist Flexion-Extension

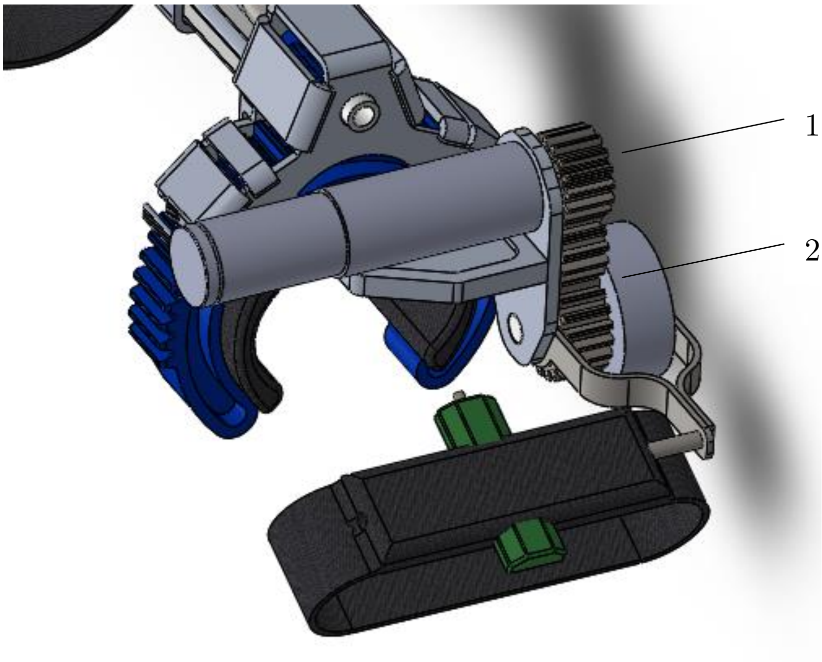


Figure 21: Wrist flexion-extension mechanism. (1) spur gear, (2) torque sensor.

Wrist flexion-extension motion is provided by a separate motor (Figure 21). A spur gear drive transfers the torque to the hand bar. The spur gear is directly connected to a torque sensor that measures resistance torque during the motion.

5.3.Performance Specifications

5.3.1. Maximum Range of Motion

Wrist Extension – 60°

Wrist Flexion – 80°

Forearm Pronation-Supination - ±80°

Elbow Extension – 0°

Elbow Flexion – 140°

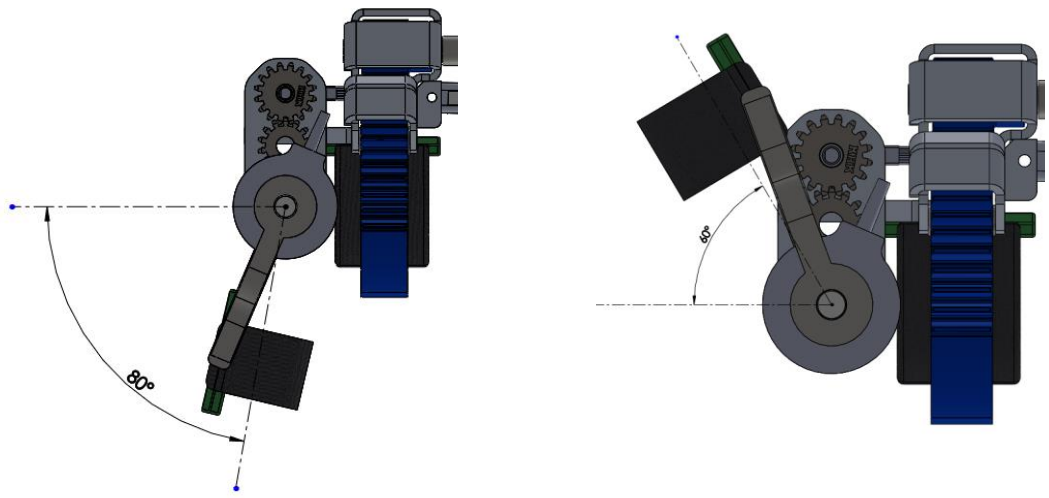


Figure 22: a. 80° wrist flexion; b. 60° wrist extension.

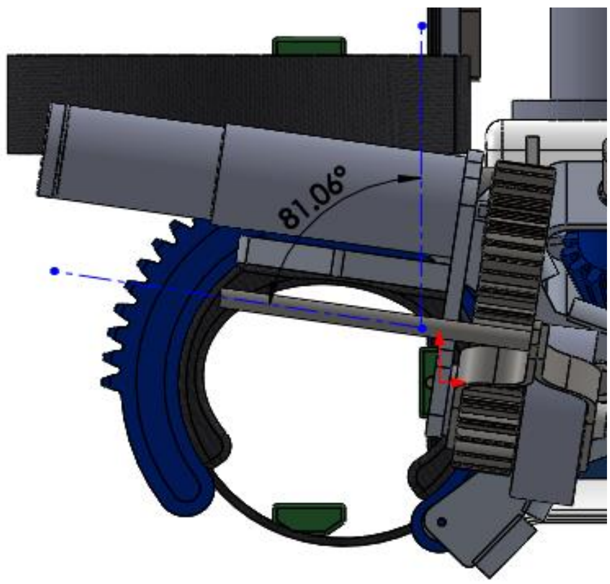


Figure 23: ±81° forearm pronation-supination.

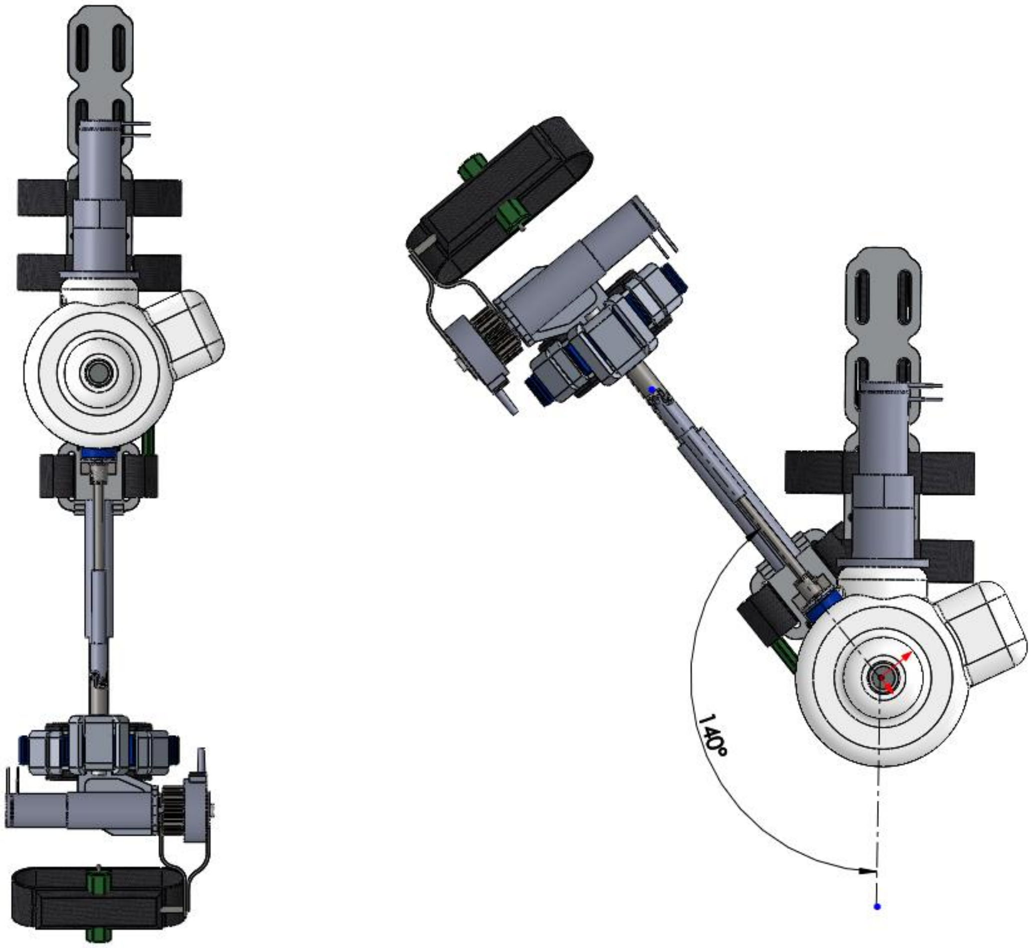


Figure 24: 0° elbow extension and 140° elbow flexion.

5.3.2. Batteries

Battery to be used will be 24-volt lithium ion battery pack with at least 2Ah of capacity and 2A of peak discharge current. With this battery capacity, the device can be used for three to four 15-minute exercise sessions before requiring recharging.

5.3.3. Device Weight

The total device weight is approximately 3.2 kg.

5.3.4. Padding Material

Paddings are made from EVA foam with Lycra lining. All padding materials are attached to the orthosis using Velcro and can be removed for cleaning.

6. Stock Component Sizing and Selection

6.1. Section Introduction

One of the main principles of the device design is using as much stock components as possible, minimizing the number of customized parts. This will allow faster prototyping, will reduce the cost for low volume production and will have available data on the performance characteristics of the components.

The main consideration for choosing the components are its mechanical strength in handling the loads and the geometry that is suitable for the general design of the device. The components are also chosen such that it can be available from any stock component supplier or manufacturer, as long as the critical specifications during selection are met.

6.2. Primary Actuator

The selection of the motor was based on the following design constraints:

- Peak output torque on the elbow shall at least be 25 Nm
- Peak output angular speed at peak torque on the elbow shall be 60 deg/sec (10 rpm or 1.08 rad/s)

The requirements were based on the elbow FE because the power requirements for this joint is significantly higher than that of the forearm PS. The power will then be verified for sufficiency for the forearm PS.

The motor selection was based on the assortment of brushless DC servomotors of Micromo (Florida, USA). The company was chosen because of their wide range of brushless DC motors, a wide range of off-the-shelf compatible reduction gearheads, and FDA compliant verification and validation processes.

The power requirement was computed from the peak output torque and angular velocity requirement:

$$P = T \times \omega \tag{9}$$

wherein:

P: Power (W)

T: Torque (Nm)

ω: angular velocity (rad/sec)

The power requirement calculated was 27 W.

For the motor to be a suitable candidate with good power to weight ratio, the operating point of the motor at 27 W should be in the intermittent operation region. This is because the motor will be reversing and will operate in periods of 10 to 20 minutes at a time with normal use, thus not requiring it to be in the continuous operation region.

A suitable motor found was the Faulhaber 3056 B FMM brushless DC motor. The power and the torque-speed curves are shown in Figure 25 below.

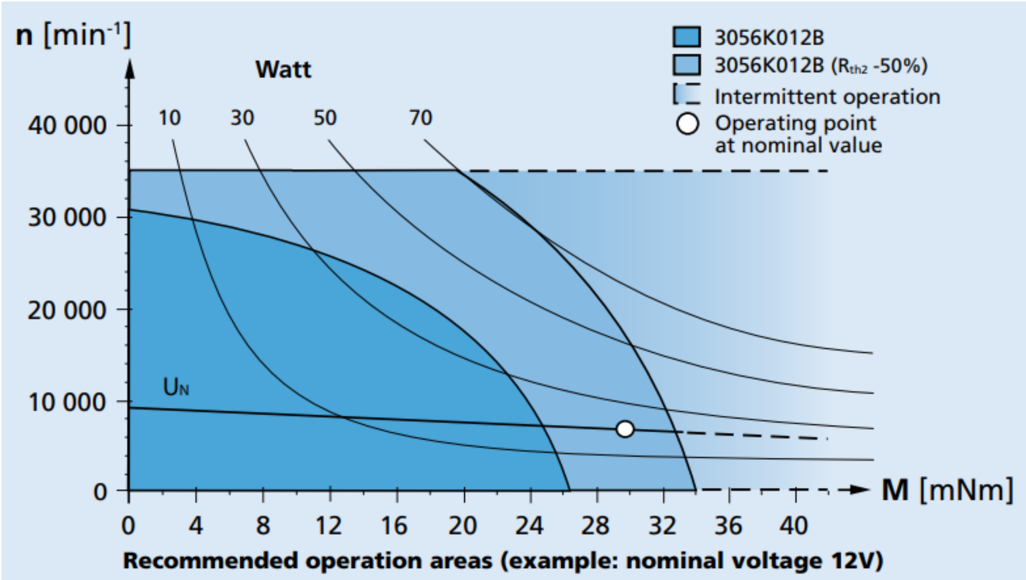


Figure 25: Power and torque-speed curves of Faulhaber 3056 B FMM brushless DC motor.

The operating voltage was initially chosen to be 24 V. The motor no-load speed and stall torque were taken from the product specifications (0).

No load speed at 24V ($n_{no\ load}$): 8100 rpm

Stall torque at 24V (T_{stall}): 104 mNm

With the available information, the torque and speed at the operating point can be obtained.

The torque-speed line equation is:

$$n = -\frac{n_{no\ load}}{T_{stall}} T + n_{no\ load} \tag{10}$$

wherin:

n = angular speed (rpm)

T = torque (mNm)

$n_{no\ load}$ = no load speed (rpm)

T_{stall} = stall torque (mNm)

The operating point angular speed and torque at 24V and 27 W can be computed by equating equations (9) and (10) and solving for n and T. This gives us:

$$n = 6152 \text{ rpm}$$

$$T = 25 \text{ mNm}$$

These values give us the parameters needed to select the required reduction gearhead and bevel gear sizes.

6.3. Bevel Drive

The selection of the gears was based on the stock gear catalogue of KHK Gears (Saitama-ken, Japan). However, any equivalent stock gear from a different supplier will suffice.

The main parameter that drove the bevel drive selection was the output torque. The bevel gear characteristics to be decided were the gear ratio, main bevel gear diameter, module, and material. The gear ratio defines the mechanical advantage, increasing the output torque. The main bevel gear diameter defines the magnitude of the transmitted force that the gear needs to receive to provide the required output torque. The module is descriptive of the tooth size, where a higher module gear has larger teeth, and in turn, can carry a larger transmitted force. The gear material also determines the strength of the gear teeth.

The KHK gear catalogue (11.3) shows the allowable torque that stock gears can bear. During the selection, it became apparent that a large main bevel gear and a large module were needed to provide the required 25 Nm output torque without damaging the gears. As such, further information was used to reduce the size of the gears.

It is known that the allowable torques published in the catalogues are based on continuous running regimes and high speeds. In the required application, the gears will be undergoing an intermittent operation at very low speeds. As such, the allowable torque that the gears can carry in the desired application will be greater than the catalogue value.

The American Gear Manufacturer's Association (AGMA) identified several factors that affect the strength of bevel gears [45]. Relevant to the low speed and intermittent operation expected in the device are the Dynamic Factor (K_v) and Cycle Factor (K_l). The dynamic factor makes the allowance for the effect of gear tooth quality related to the speed and load, and the increase in stress that follows [45]. The cycle factor provides the allowance for the number of load cycles that the gear undergoes throughout its useful life [45]. Considering these factors, the allowable load was recomputed using KHK Gear's Strength Calculation of Gear tool.

Bevel Gears (SB) [SB2-4515] Strength Calculation (Output)

[Calculation result]

--- Bending Strength [JGMA403-01] ---	
Allowable Tangential Force(N)	686.8718
Allowable torque(N·m)	26.0220
Allowable power (kW)	0.0273

Figure 26: Allowable torque and power for KHK steel straight bevel gear using the "Strength Calculation of Gear" tool. Module 2.0, 45-tooth gear, 15-tooth pinion.

[Operating condition input value]

Rotating Speed	[10.0] rpm
Number of repetitions	[Approx.100,000]
Direction of Load	[Bidirectional]
Dimension Factor of Root Stress	[1.25]
Kinematic Viscosity of Lubricant	[ISO VG 100] cSt
Method of Gear shaft Support	[Bearing on Both Ends]
Relative Factor	[1.5]

[Various factors values]

--- Bending Strength [JGMA403-01] ---	
Standard Value of Tooth Profile Factor	2.2862
Radial Tooth Profile Factor	2.4009
Load Distribution Factor	0.6428
Helix Angle Factor	1.0000
Cutter Diameter Effect Factor	1.1500
Life Factor	1.2000
Dimension Factor of Root Stress	1.0000
Tooth Flank Load Distribution	1.4000
Overload Factor [notes]	1.0000
Dimension Factor of Root Stress	1.2500
Relative Factor	1.5000
Allowable Bending Stress at Root	12.6667

[notes] JIS grade 3

--- Surface Durability [JGMA404-01] ---	
Material Factor	60.6037
Life Factor	1.3000
Lubricant Factor	1.0000
Surface Roughness Factor	0.7673
Sliding Speed Factor	0.9000
Hardness Ratio Factor	1.0000
Dimension Factor of Root Stress	1.0000
Zone Factor	2.4946
Contact Ration Factor	1.0000
Helix Angle Factor	1.0000
Flank Load Distribution	1.4400
Overload Factor [notes]	1.0000
Dimension Factor of Root Stress	1.2500
Relative Factor	1.5000
Allowable Herts Stress	49.0000

Figure 27: Input parameters used in KHK "Strength Calculation of Gear" tool.

Re-calculation shows that KHK's steel straight bevel gear with 2.0 module, 45-tooth gear, and 15-tooth pinion is sufficient to provide 25 Nm of output torque for elbow FE.

6.4. Reduction Gearhead

The reduction gearheads compatible for the Faulhaber 3056 B FMM brushless DC motor have different output torque capacities and different reduction ratios.

The selected bevel gear drive has a reduction ratio of 3:1. The input torque of the bevel drive should be around 8.3 Nm, and the input speed should be around 30 rpm.

Among all the compatible gearheads, only the Series 38/1 S Planetary gearhead meets the 8.3 Nm torque requirement, with the catalogue intermittent torque specified is at least 15 Nm (11.4).

To get the required reduction ratio of the gearhead, the operating point angular velocity calculated from section 6.1 (6152 rpm) divided by the effective reduction ratio of the gearhead and bevel drive should result to the required output angular velocity of 10 rpm.

The following table shows the output torques and angular velocities using the different gearhead reduction ratios that are closest to the requirements.

Table 11: Output RPM and torques of the gearhead reduction ratios within the required range.

Gearhead Ratio	Bevel Ratio	Output RPM	Output Torque
159:1	3:1	12.9	24.99 Nm
246:1	3:1	8.33	52.98 Nm

Using the torque-speed curve formulated in (10), the output RPM at 25 Nm of resistance torque were calculated.

Table 12: Output RPM of the gearheads at 25 Nm of resistance torque.

Gearhead Ratio	Resistance Torque	Output RPM
159:1	25 Nm	12.9
246:1	25 Nm	8.33

Based on these results, it was decided that the gearhead reduction ratio to be used is 159:1 because at 24V and 25 Nm of resistance, the output RPM is higher than required. To produce a lower RPM, a slightly lower voltage can be provided by the controller.

6.5. Universal Joint

The universal joint selection requirements are the torque to be transmitted, the maximum operating angle, and the shaft diameter.

The torque to be transmitted is computed from the forearm PS resistance and the reduction ratio of the wrist spur gear drive. The wrist spur gear drive reduction ratio is 4.58:1 from section 6.6. The forearm PS resistance is 6Nm from 2.5.4. The transmitted torque is 1.31 Nm.

The maximum operating angle is measured from the 3D model, which is measured at less than 9°

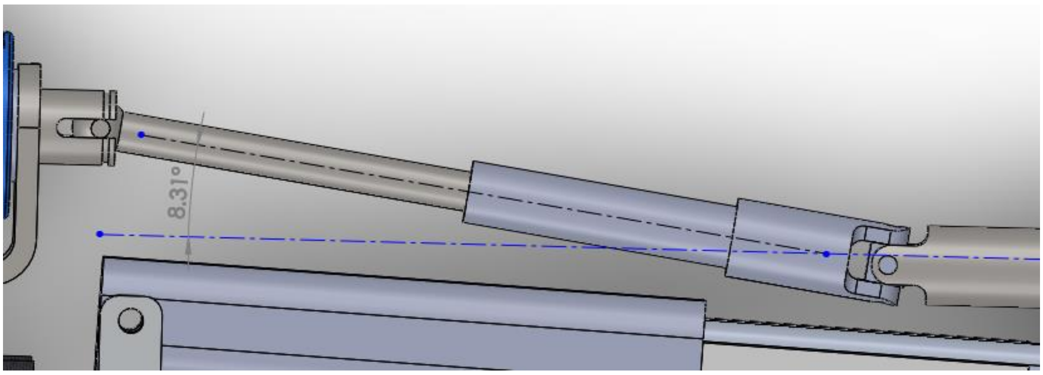


Figure 28: Operating angle of the universal joint.

The shaft diameter is approximately 9mm.

The universal joint was chosen from the McMaster-Carr Supply company catalogue. However, any off-the-shelf universal joints that can meet the requirements can be used. A pin and block, machinable bore, ½", single U-joint (PN 6443K12). The chosen part is oversized for the torque requirement with a torque capacity of 51 in.-lbs. (5.76 Nm) at 10° operating angle, but fit well with the geometric requirements of the mating components.

6.6. Forearm PS Spur Gear Drive

The forearm PS spur gear drive sizing is driven by the wrist size and the forearm PS resistance torque.

The forearm PS resistance torque is at 6 Nm from section 2.5.4. The wrist size is taken from the 95th percentile of the wrist diameters from section 2.4.

The relatively low torque and large diameter allow selection of plastic gears from the KHK Plastic Spur Gear catalogue (11.5). Using the torque requirement and approximation of the size, a module 2, 48-tooth, MC901 spur gear can be selected.

Geometric dimensions during 3D modelling required a larger spur gear, leading to the selection of module 2, 55-tooth, MC901 spur gear (PN PSA2-55). The purchased part will then be machined to final specifications.

The pinion selected is a KHK Steel Spur gear from the catalogue (0) since a plastic spur is not capable of carrying the required torque. The module 2, 12-tooth, S45C spur gear (PN SS2-12) was selected.

6.7. Wrist FE Actuator, Reduction Gearhead, and Spur Gear Drive

The wrist FE actuator selection follows the same selection process as used in the primary actuator detailed in sections 6.1 and 6.3 with the following requirements:

- Peak output torque on the wrist shall at least be 20 Nm
- Peak output angular speed at peak torque on the wrist shall be 60 deg/sec (10 rpm or 1.08 rad/s)

The selected actuator is the Faulhaber 2444 B FMM brushless DC motor (11.8). The reduction gearhead is the Faulhaber Series 26/1S (11.9) with a reduction ratio of 1526:1. The spur gear drive is KHK S45C steel (0) 21 tooth and 16 tooth, 1.5 module, spur gears, with a 14 tooth idler gear.

6.8. Torque Sensor – Elbow FE

The torque sensor for the elbow FE was selected based on the torque capacity and geometry. The torque capacity requirement is 25Nm with a small axial dimension.

The choices were the Interface Force Measurement Solutions TS21 (Arizona, USA) and ATI Industrial Automation Mini85 (North Carolina, USA). Both sensors have short axial dimensions and meet the torque requirements.

Table 13: Selection of possible torque sensors for elbow FE

	Interface TS21	ATI Mini85
Torque	1-100 Nm	1-80 Nm
Axial Dimension	27 mm	30 mm
Attachment	Shaft interface	Screws

The Interface TS21 was selected based on its shorter axial length and the shaft interface which was also utilized as the main shaft of the gearbox.

Figure 29: Interface Force Measurement Solutions TS21 miniature shaft style reaction torque transducer. (https://www.interfaceforce.com/)

6.9. Torque Sensor – Wrist FE

The torque sensor for the wrist FE was selected based on the torque capacity and geometry. The torque capacity requirement is 8.5 Nm with a small axial dimension.

The ATI Industrial Automation Mini45 (North Carolina, USA) was selected based on its 20 Nm capacity and geometry that fits the design.

Figure 30: ATI Industrial Automation Mini45 torque transducer (http://www.ati-ia.com)

6.10. Electrogoniometer

The electrogoniometer and torsiometer for the flexion angle measurement selected were from Biometrics Ltd. The devices have small packages and flexible installation requirements, thus easily incorporated in the design. The sensors have $\pm 2°$ accuracy, meeting the design requirement.

6.11. Bearings

The mechanical bearings are sourced from Igus. Since the loads and speeds allow the use of plastic bearings, these were chosen over metal ball bearings allowing a lighter and smaller device.

Figure 31: igus plastic bearings used in the orthosis design: a. sleeve bearing; b. thrust washer; c. self-aligning bearing.

6.12. Chapter Conclusion

The stock components selected meet the design requirements of the device. The design of the device is based on the specifications of the stock components from the manufacturers/suppliers specified. For prototyping, the said components can be purchased from the selected manufacturers.

It is not limited, however, to these manufacturers since the components can be sourced from different manufacturers. Equivalent components can be used, as long as the specifications are met. It should be understood, however, that minor modifications to the design, such as connectors, may be needed to accommodate components from other manufacturers as minor details may be different.

Table 14: Summary of off-the-shelf devices incorporated in the design.

Item	Section Reference
Faulhaber 3056 B FMM	6.2
Faulhaber Series 38/1 S 159:1 Planetary Gearhead	6.4
KHK US SB2-1545	6.3
KHK US SB2-4515	6.3
KHK US PB2-4515	6.6
Universal Joint (McMaster PN 6443K12)	6.5
KHK US PS2-55	6.6
KHK US PS2-12	6.6
KHK US SS1.5-16	6.7
KHK US SS1.5-14	6.7
KHK US SS1.5-21	6.7
Faulhaber Series 26/1 S 1526:1 Planetary Gearhead	6.7
Faulhaber 2444 B FMM	6.7
ATI Mini45	6.9
Interface TS21	6.8
Biometrics Wrist Electrogoniometer (SG75)	6.10
Biometrics Elbow Electrogoniometer (SG110)	6.10
Biometrics Forearm Torsiometer (Q150)	6.10

7. Simulation

7.1. Introduction

Not all of the device components were possible to be sourced stock from manufacturers. As such, other components are custom made for the device.

Unlike the stock components which have rated capacities, custom components need to be simulated to verify that the designs can carry the loads that they will encounter during normal use.

Finite element method is used to verify the strength of the components. The mechanical simulations were performed using Dassault Systemes SolidWorks Simulation 2015 (Massachusetts, USA).

The foreseeable failure mechanisms can be due to static or fatigue failure. Static failure will happen if any part of the component experiences stresses that exceed the yield strength of the material. The basic requirement is that the maximum stress should not exceed the material yield strength. However, the more important parameter that is checked is the minimum factor of safety, which is the ratio of the material yield strength to the working stress. As the minimum requirement, minimum factor of safety in the parts should be at least 1.3.

Fatigue failure happens when components fail at stresses levels lower than the yield strength due to repeatedly applied loads. The important parameter that is checked is the damage percentage, which shows how much of the component life is spent during the life cycle of the device. The minimum requirement is that the damage percentage obtained after the device lifecycle should be less than 80%.

Static studies were based on the highest loads that the device is designed to handle, summarized in Table 15 below.

Table 15. Maximum design loads for each motion of the device.

Motion	Load
Elbow FE	25 Nm
Wrist FE	8.5 Nm
Forearm PS	6 Nm

Fatigue studies were performed at 150,000 fully reversing cycles of the highest load in Table 15. The cycle count was based on the predicted use with the following parameters:

- 10 cycles per minute
- 15 minutes per exercise session
- 150 days per year of use
- 5 years of useful life

The study summaries of two parts are written in this document to demonstrate briefly how the study was done and the corresponding results. Full reports of all parts and assemblies are included in the accompanying CD as digital copies. A summary of the factors of safety and percentage of damage after 150,000 cycles is shown in section 7.4.

7.2. KBP-001 Base FA

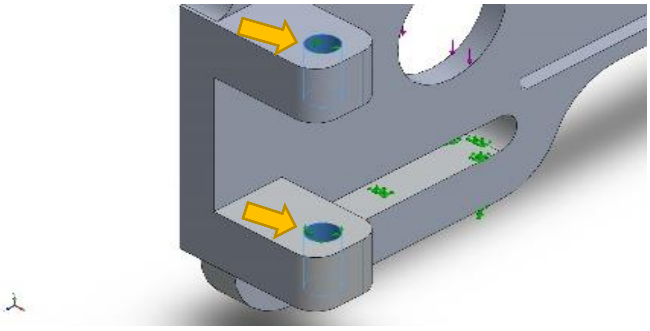
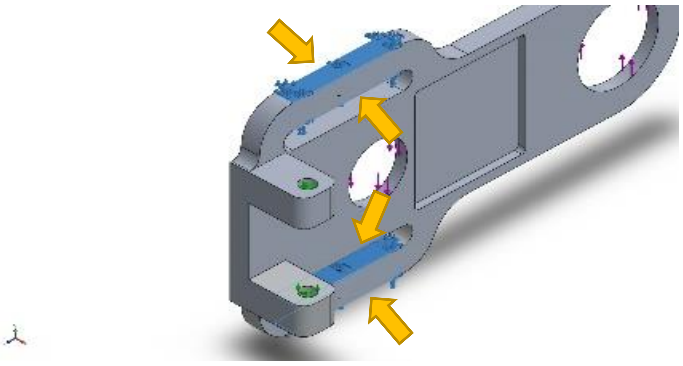
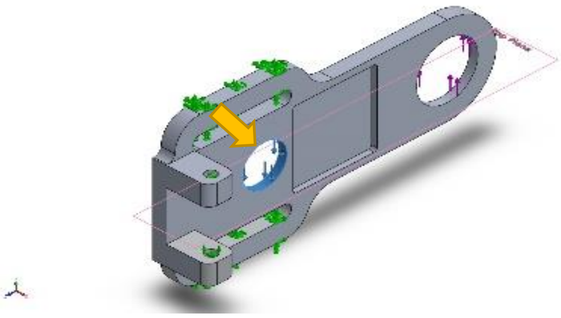
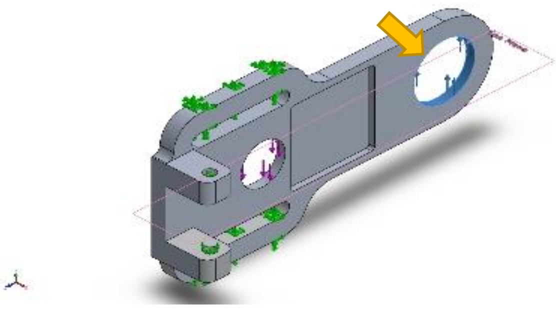
7.2.1. Material

The part is made of 6061-T6 Aluminum. 6061-T6 Aluminum is a high-grade structural aluminium, also commonly used in medical devices. The yield strength is 275 MPa. The S-n curve is shown in Appendix 11.10.

7.2.2. Loads and Fixtures

Loads and fixtures were set up based on a loading where the part will be supported by the pins and the forearm strap, while a 25 Nm torque is transmitted to the part by the actuator on the two bearings.

Table 16. Fixtures and loads applied to KBP-001.

Fixture/Load Type	Image
Fixed Hinge	
Fixed Geometry	
Force: 384 N	
Force: 384 N	

7.2.3. Static Study Results

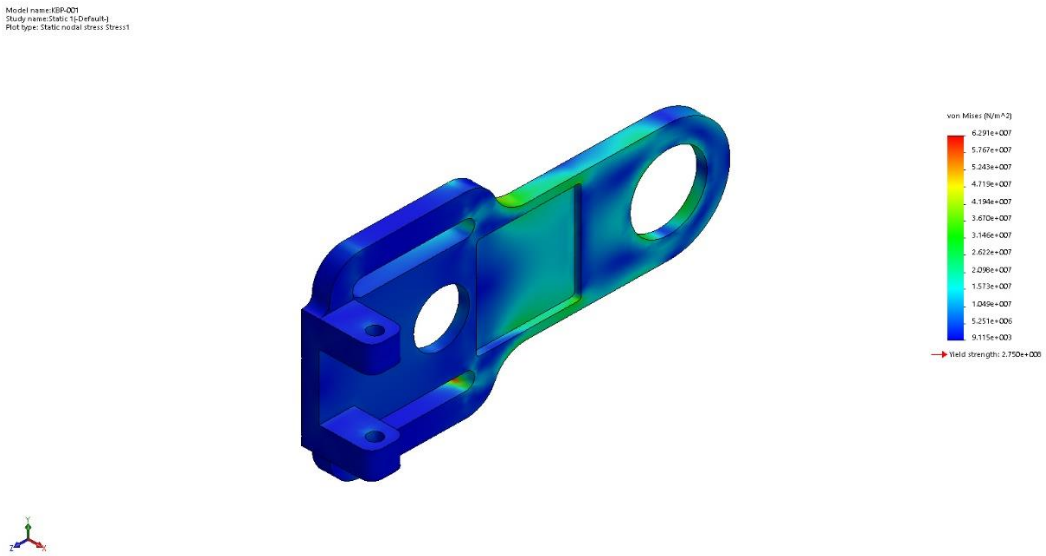


Figure 32: von Mises stress plot of KBP-001.

Minimum Factor of Safety : 4.4

Maximum Deflection: 0.062 mm

7.2.4. Fatigue Study Results

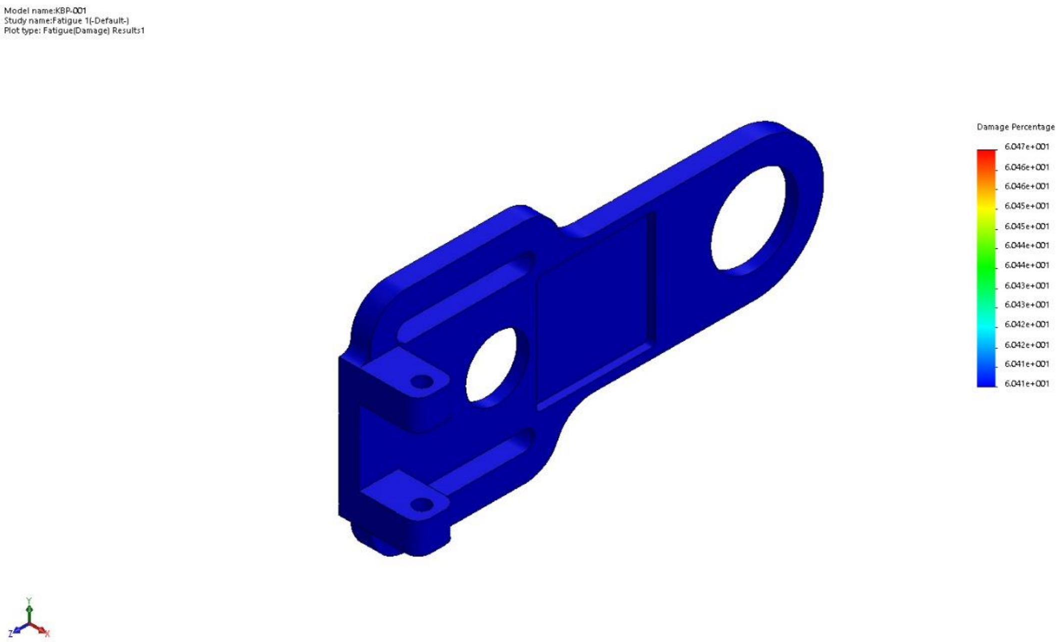


Figure 33: Damage plot of KBP-001.

Damage Percentage: 60% damage over 150,000 cycles

7.3. KBS-003 Forearm Spline

7.3.1. Material

KBP-029 Forearm Plate

The material of the forearm plate is AISI 304 Stainless Steel. 304 stainless steel is a common type of stainless steel, also normally used in surgical devices. It has a yield strength of 207 MPa. The S-n curve is shown in Appendix 11.1

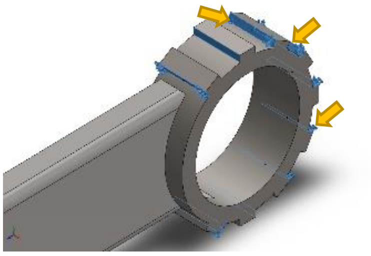
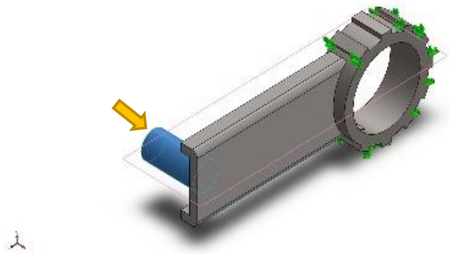
KBP-030 Forearm Spline

The material of the forearm spline is AISI 440C Stainless Steel, tempered at 371°C, with a yield strength of 1,666 MPa. 440C stainless steel is usually used in high strength applications such as shafts. The S-n curve is shown in Appendix 11.2.

7.3.2. Loads and Fixtures

The part transfers the 25 Nm torque from the main bevel gear to the arm. Loads and fixtures were set up based on a loading where the outside spline is rotated, and the forearm plate transfers the force to the forearm.

Table 17. Fixtures and loads applied to KBP-002.

Fixture/Load Type	Image
Fixed Hinge	
Force: 384 N	

7.3.3. Static Study Results

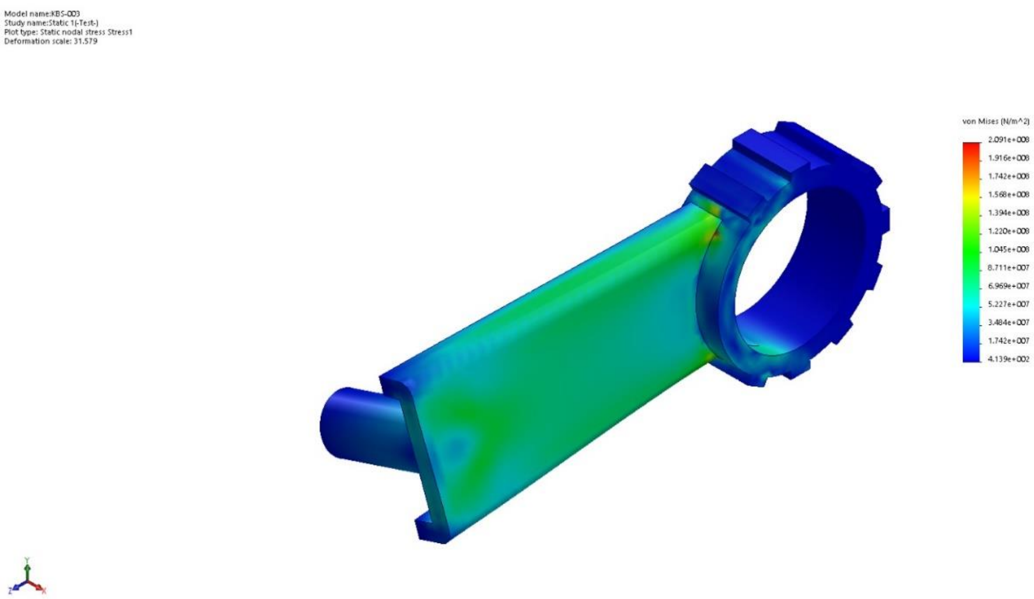


Figure 34: von Mises stress plot of KBS-003.

Minimum Factor of Safety: 1.41

Maximum Deflection: 0.29 mm

7.3.4. Fatigue Study Results

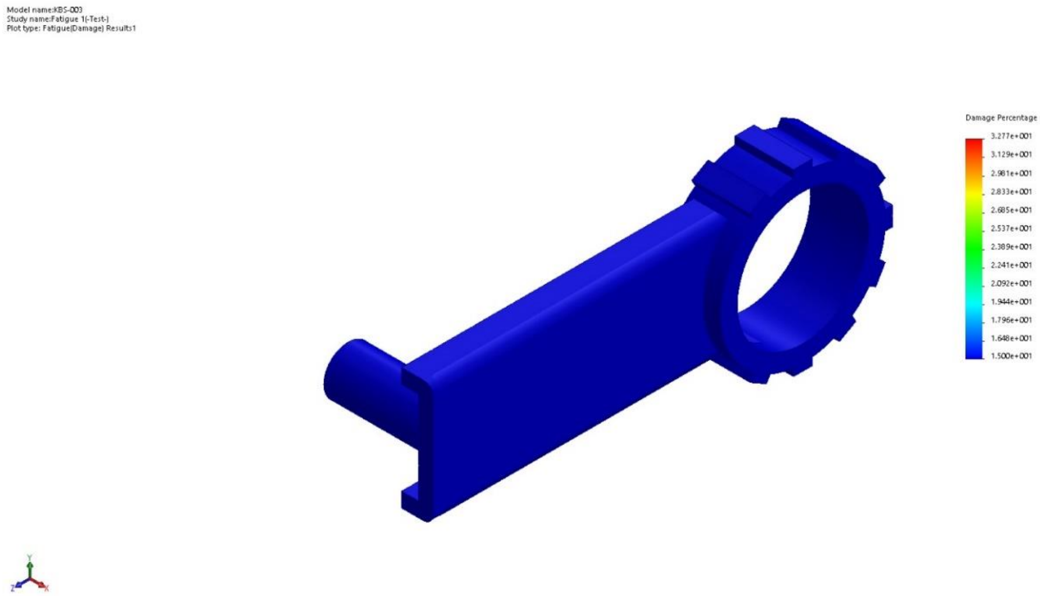


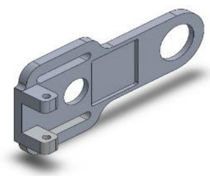
Figure 35: Damage plot of KBP-002.

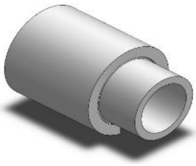
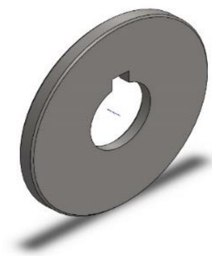
Damage Percentage: 32.8% damage over 150,000 cycles

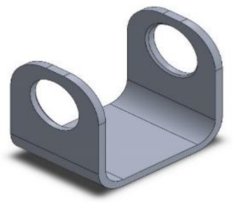
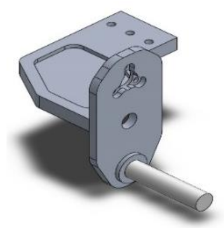
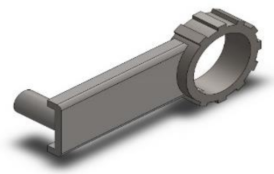
7.4. Summary

The table below summarizes the factor of safety and damage percentage after 150,000 cycles of all custom parts and sub-assemblies in the device.

Table 18: Factor of safety and damage percentage at 150,000 cycles of all custom parts.

Part number/ description	Image	Factor of Safety	Percentage of damage after 150,000 cycles
KBP-001/ Base FA		4.4	60%

KBP-002/ Base UA		4.0	0.2%
KBP-004/ Shaft Adapter		11.7	15%
KBP-005/ Actuator FA U Joint Shaft		10.6	15%
KBP-006/ U Joint Link		8.5	31.9%
KBP-007/ U Joint Link Sleeve		31.8	15%
KBP-008/ Wrist U Joint Shaft		45.5	15%
KBP-015/ Engagement Plate		2.7	15%

KBP-016/ Selector		4.3	15%
KBP-018/ FA Bevel Box		6.4	0.2%
KBS-001/ Wrist Carrier Sub-Assembly		1.9	79.95%
KBS-002/ Wrist Plate		2.1	34%
KBS-003/ Forearm Spline		1.4	33%
KBS-004/ Telescoping Beam		5.0	0.2%

8. Conclusion

8.1. Discussion

The main goal of the project is to develop a powered orthosis that is designed to be used in the management of spasticity and contracture of the upper limb with passive-repeated-dynamic exercises while recording measurements of the kinematics and neuromuscular response of the joints and muscles. In addition, the device should also cater to different anatomies and pathologies.

These requirements were met by conducting a literature review and engineering analysis to find the torque loads during flexion and extension of the elbow, flexion and extension of the wrist, and pronation and supination of the forearm with different levels of spasticity. A review of anthropometric data was also done to provide a basis on the sizing of the device. The literature review and review of industry standards shaped the list of design requirements that were used in the design process.

Off-the-shelf parts were selected based on their specifications and ratings. Customized parts were simulated using the SolidWorks Simulation software applying loads each component will experience during normal use, and over the course of the 5-year usable life.

The result of the design process is a modular orthosis, with four modules: the elbow base, main actuator, telescoping beam and shaft, and wrist base. These modules can have different sizes for different anatomies and pathologies and can be interchanged based on the requirements of the patient.

8.2. Fulfilling the Objectives of the Thesis

1. *Modules of the brace will be used for measurement of the kinematics of the elbow joint.*
    - The designed device is fitted with torque sensors and electrogoniometers to measure the resistance torques and kinematics

during the exercises. In addition to the elbow flexion-extension, the device also meets the requirements for the wrist flexion-extension and forearm pronation-supination.

2. *The elbow joint brace will be designed to overcome spasticity of the patient during the rehabilitation process. Determine the muscle forces applied to the components and to be overcome by the actuator. Specify structural characteristics of components and actuators for different age groups and different types of disease.*
    - The joint resistance torques with no spasticity and with severe spasticity were determined by a review of the literature. These forces were used as the basis of the design, selection of components and actuators, and the simulation of the device.
3. *Design modular structure based on different age groups and diseases.*
    - The resulting design consists of four separate modules with different sizes that can be interchanged based on the specific requirement of the patients.
4. *Verify the strength of elements of modules and the entire construction in the SolidWorks software by finite element analysis.*
    - The components and assemblies were simulated using SolidWorks Simulation. The components and assemblies underwent static testing to ensure that the device does not fail and has enough margin for safety when expected maximum loads during normal use are applied, and fatigue testing was done to ensure that the device will not fail over the expected life of five years.

8.3. Perspective of Continuing Work

The project was concluded with complete mechanical design of the powered orthosis with the selection of suitable components. The next step is to manufacture a prototype and perform a physical test to validate the design.

The device requires a control system to control the device. The control system should also meet the design requirements set during the initiation of the project. It should provide sufficient robustness to ensure the safety of the device.

Lastly, the design of the device has a potential to be adapted to become an assistive device. The components were designed with a sufficient safety margin and can be suitable to carry loads when performing activities of daily living and fitted with EMG sensors which can be used as a platform for assistive rehabilitation. Additional backdriveability using series elastic mechanisms can be added to make the device fully fit for assistive rehabilitation.

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10. Abbreviations

FE – flexion-extension

PS – pronation-supination

DRP – dynamic-repeated-passive

RPM – resistance to passive movement

EMG – electromyography

ROM – range of motion

MAS – Modified Ashworth scale

11. Appendices

11.1. Design Review

1. Is passive stretching enough? Will providing resistive exercises be beneficial?
    a. Primary function of the orthosis is for immobilization of the joint. For an active brace (with an actuator) progressive stretching is the main purpose.
    b. Resistive exercises can be a positive addition. If it does not make the device too complicated, then it is good to have it. If it will make it too complicated, then it is acceptable not to have it.
2. What feedback from patients can be usable?
    a. EMG is a good addition, could be good for measurement of reactions to stretching or to find sources of resistance.
3. What exercises should be done?
    a. Elbow – Flexion/extension
    b. Wrist – Pronation/supination, flexion/extension. Radial/ulnar deviation is not important.
4. Frequency of exercises
    a. Decision can be made later
5. Sizing
    a. Proposed sizing for the forearm has 20 sizes for adults and another 20 for children. This is deemed as too many by the consultant.
    b. The consultant proposed that an acceptable number of sizes is 6 to 10 for adults.
    c. For children, the age range of targeted is proposed to be from 6 or 8 years old up (instead of from 2 years of age)
6. Safety
    a. Safe range of motion can be determined by the clinician during consultation. It can be done by slowly extending or flexing the joint

and determining the pain free region. The safe speed can be determined in a similar way. As such, the device should have a provision for adjustment of the range of motion and speed that is accessible to the clinician.

b. The patient may be allowed to modify the range of motion and speed, but should be limited.

FAULHABER

Brushless DC-Servomotors — 33 mNm

2 Pole Technology — 71 W

Series 3056 ... B

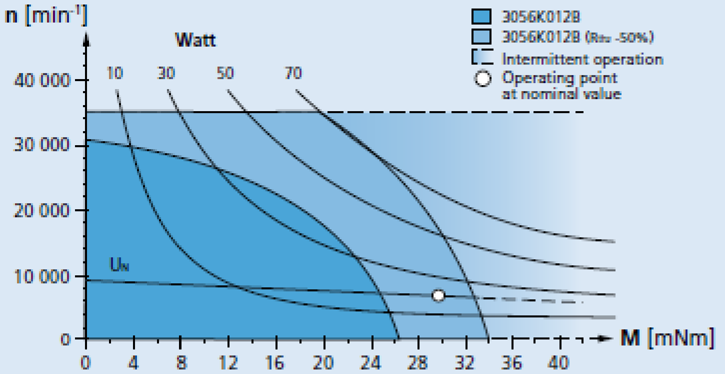
	Values at 22°C and nominal voltage	3056 K		012 B	024 B	036 B	048 B	
1	Nominal voltage	U_N		12	24	36	48	V
2	Terminal resistance, phase-phase	R		1,5	6,4	12,3	23,6	Ω
3	Efficiency, max.	η_{max}		76	77	77	76	%
4	No-load speed	n_0		8 800	8 100	8 900	8 900	min⁻¹
5	No-load current, typ. (with shaft ø 4 mm)	I_0		0,128	0,057	0,044	0,033	A
6	Stall torque	M_H		102	104	111	103	mNm
7	Friction torque, static	C_0		0,81	0,81	0,81	0,81	mNm
8	Friction torque, dynamic	C_v		$9{,}5\cdot10^{-5}$	$9{,}5\cdot10^{-5}$	$9{,}5\cdot10^{-5}$	$9{,}5\cdot10^{-5}$	mNm/min⁻¹
9	Speed constant	k_n		742	343	251	188	min⁻¹/V
10	Back-EMF constant	k_E		1,35	2,91	3,99	5,32	mV/min⁻¹
11	Torque constant	k_M		12,9	27,8	38,1	50,8	mNm/A
12	Current constant	k_I		0,078	0,036	0,026	0,02	A/mNm
13	Slope of n-M curve	$\Delta n/\Delta M$		87	79	81	87	min⁻¹/mNm
14	Terminal inductance, phase-phase	L		160	740	1 400	2 600	µH
15	Mechanical time constant	τ_m		13,6	12,4	12,7	13,7	ms
16	Rotor inertia	J		15	15	15	15	gcm²
17	Angular acceleration	α_{max}		68	69	74	68	·10³rad/s²
18	Thermal resistance	R_{th1} / R_{th2}	2,2 / 7,9					K/W
19	Thermal time constant	τ_{w1} / τ_{w2}	11,7 / 650					s
20	Operating temperature range:							
	– motor		-30 ... +125					°C
	– winding, max. permissible		+125					°C
21	Shaft bearings		ball bearings, preloaded					
22	Shaft load max.:							
	– with shaft diameter		4					mm
	– radial at 3 000 min⁻¹ (5 mm from mounting flange)		75					N
	– axial at 3 000 min⁻¹ (push only)		18					N
	– axial at standstill (push only)		62					N
23	Shaft play:							
	– radial	≤	0,015					mm
	– axial	=	0					mm
24	Housing material		aluminium, black anodized					
25	Mass		192					g
26	Direction of rotation		electronically reversible					
27	Speed up to	n_{max}	35 000					min⁻¹
28	Number of pole pairs		1					
29	Hall sensors		digital					
30	Magnet material		SmCo					
	Rated values for continuous operation							
31	Rated torque	M_N		28,5	30	29,4	28,3	mNm
32	Rated current (thermal limit)	I_N		2,4	1,17	0,838	0,605	A
33	Rated speed	n_N		5 340	4 820	5 600	5 450	min⁻¹

Note: Rated values are calculated with nominal voltage and at a 22°C ambient temperature. The R_{th2} value has been reduced by 25%.

Note:
The diagram indicates the recommended speed in relation to the available torque at the output shaft for a given ambient temperature of 22°C.

The diagram shows the motor in a completely insulated as well as thermally coupled condition (R_{th2} 50% reduced).

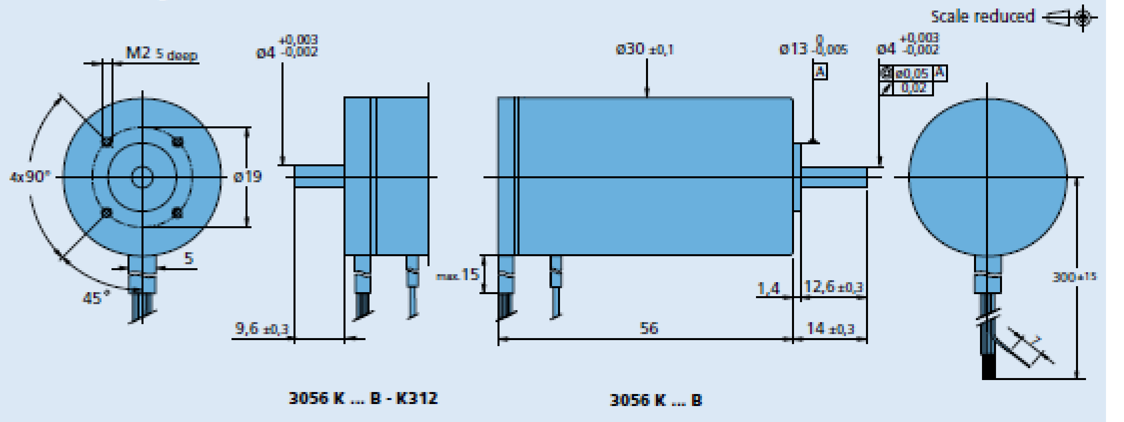
The nominal voltage (U_N) curve shows the operating point at nominal voltage in the insulated and thermally coupled condition. Any points of operation above the curve at nominal voltage will require a higher operating voltage. Any points below the nominal voltage curve will require less voltage.



Recommended operation areas (example: nominal voltage 12V)

For notes on technical data and lifetime performance refer to "Technical Information".
Edition 2017

Dimensional drawing



Option, cable and connection information

Example product designation: **3056K012B-K1155**

Option	Type	Description
K1155	Controller combination	Analog Hall sensors for combination with Motion Controller MCBL
K1026	Sensorless	Motor without Hall sensors
K1555	Lead wires length	Single lead wires 750 mm long in PTFE
K1838	Encoder combination	Motor with rear end shaft for combination with Encoder IE3
K312	Encoder combination	Motor with rear end shaft for combination with Encoder HEDS/HEDL/HEDM
K179	Bearing lubrication	For vacuum of 10^{-5} Pa @ 22°C

Connection

Function	Colour
Phase C	yellow
Phase B	orange
Phase A	brown
GND	black
U_{DD} (+5V)	red
Hall sensor C	grey
Hall sensor B	blue
Hall sensor A	green

Standard cable

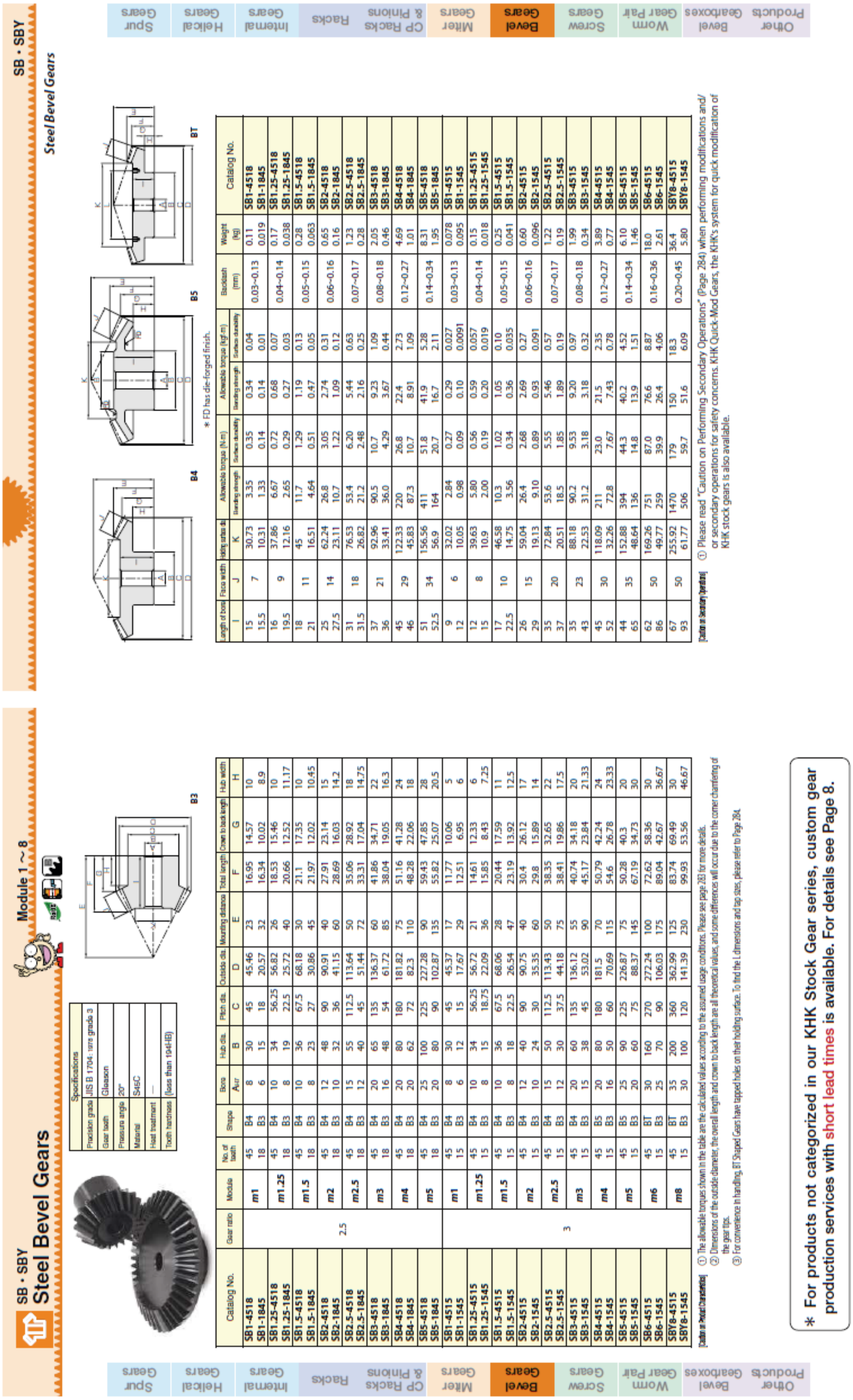
Single wires, material PTFE
AWG 20: Phase A/B/C
AWG 26: Hall A/B/C, U_{DD}, GND

Product combination

Precision Gearheads / Lead Screws	Encoders	Drive Electronics	Cables / Accessories
30/1	HEDS 5500	SC 2402	MBZ
30/1 S	IE3-1024	SC 2804	To view our large range of accessory parts, please refer to the "Accessories" chapter.
38/1	IE3-1024 L	SC 5004	
38/1 S	HEDL 5540	SC 5008	
38/2		MC 5004	
38/2 S		MC 5005	
		MCBL 3002	
		MCBL 3003	
		MCBL 3006	

For notes on technical data and lifetime performance refer to "Technical Information".
Edition 2017

11.3. KHK Steel Bevel Gears



SB · SBY

Steel Bevel Gears

Module 1 ~ 8

Specifications	
Precision grade	JIS B 1704: 1978 grade 3
Gear teeth	Gleason
Pressure angle	20°
Material	S45C
Heat treatment	—
Tooth hardness	(less than 194HB)

Catalog No.	Gear ratio	Module	No. of teeth	Shape	Bore A_{H7}	Hub dia. B	Pitch dia. C	Outside dia. D	Mounting distance E	Total length F	Crown to back length G	Hub width H
SB1-4518	2.5	m1	45	B4	8	30	45	45.46	23	16.95	14.57	10
SB1-1845			18	B3	6	15	18	20.57	32	16.34	10.02	8.9
SB1.25-4518		m1.25	45	B4	10	34	56.25	56.82	26	18.53	15.46	10
SB1.25-1845			18	B3	8	19	22.5	25.72	40	20.66	12.52	11.17
SB1.5-4518		m1.5	45	B4	10	36	67.5	68.18	30	21.1	17.35	10
SB1.5-1845			18	B3	8	23	27	30.86	45	21.97	12.02	10.45
SB2-4518		m2	45	B4	12	48	90	90.91	40	27.91	23.14	15
SB2-1845			18	B3	10	32	36	41.15	60	28.69	16.03	14.2
SB2.5-4518		m2.5	45	B4	15	55	112.5	113.64	50	35.06	28.92	18
SB2.5-1845			18	B3	12	40	45	51.44	72	33.31	17.04	14.75
SB3-4518		m3	45	B4	20	65	135	136.37	60	41.86	34.71	22
SB3-1845			18	B3	16	48	54	61.72	85	38.04	19.05	16.3
SB4-4518		m4	45	B4	20	80	180	181.82	75	51.16	41.28	24
SB4-1845			18	B3	20	62	72	82.3	110	48.28	22.06	18
SB5-4518		m5	45	B4	25	100	225	227.28	90	59.43	47.85	28
SB5-1845			18	B3	20	80	90	102.87	135	55.82	25.07	20.5
SB1-4515	3	m1	45	B4	8	30	45	45.37	17	11.77	10.06	5
SB1-1545			15	B3	6	12	15	17.67	29	12.51	6.95	6
SB1.25-4515		m1.25	45	B4	10	34	56.25	56.72	21	14.61	12.33	6
SB1.25-1545			15	B3	8	15	18.75	22.09	36	15.85	8.43	7.25
SB1.5-4515		m1.5	45	B4	10	36	67.5	68.06	28	20.44	17.59	11
SB1.5-1545			15	B3	8	18	22.5	26.54	47	23.19	13.92	12.5
SB2-4515		m2	45	B4	12	40	90	90.75	40	30.4	26.12	17
SB2-1545			15	B3	10	24	30	35.35	60	29.8	15.89	14
SB2.5-4515		m2.5	45	B4	15	50	112.5	113.43	50	38.35	32.65	22
SB2.5-1545			15	B3	12	30	37.5	44.18	75	38.41	19.86	17.5
SB3-4515		m3	45	B4	20	60	135	136.12	55	40.74	34.18	20
SB3-1545			15	B3	15	38	45	53.02	90	45.17	23.84	21.33
SB4-4515		m4	45	B5	20	80	180	181.5	70	50.79	42.24	24
SB4-1545			15	B3	16	50	60	70.69	115	54.6	26.78	23.33
SB5-4515		m5	45	B5	25	90	225	226.87	75	50.28	40.3	20
SB5-1545			15	B3	20	60	75	88.37	145	67.19	34.73	30
SB6-4515		m6	45	BT	30	160	270	272.24	100	72.62	58.36	30
SB6-1545			15	B3	25	70	90	106.03	175	89.04	42.67	36.67
SBY8-4515		m8	45	BT	35	200	360	362.99	125	83.74	69.49	30
SBY8-1545			15	B3	30	100	120	141.39	230	99.93	53.56	46.67

[Caution on Product Characteristics] ① The allowable torques shown in the table are the calculated values according to the assumed usage conditions. Please see page 283 for more details.
② Dimensions of the outside diameter, the overall length and crown to back length are all theoretical values, and some differences will occur due to the corner chamfering of the gear tips.
③ For convenience in handling, BT Shaped Gears have tapped holes on their holding surface. To find the L dimensions and tap sizes, please refer to Page 284.

∗ For products not categorized in our KHK Stock Gear series, custom gear production services with short lead times is available. For details see Page 8.

SB · SBY

Steel Bevel Gears

∗ FD has die-forged finish.

Length of bore I	Face width J	Holding surface dia. K	Allowable torque (N·m) Bending strength	Allowable torque (N·m) Surface durability	Allowable torque (kgf·m) Bending strength	Allowable torque (kgf·m) Surface durability	Backlash (mm)	Weight (kg)	Catalog No.
15	7	30.73	3.35	0.35	0.34	0.04	0.03~0.13	0.11	SB1-4518
15.5		10.31	1.33	0.14	0.14	0.01		0.019	SB1-1845
16	9	37.86	6.67	0.72	0.68	0.07	0.04~0.14	0.17	SB1.25-4518
19.5		12.16	2.65	0.29	0.27	0.03		0.038	SB1.25-1845
18	11	45	11.7	1.29	1.19	0.13	0.05~0.15	0.28	SB1.5-4518
21		16.51	4.64	0.51	0.47	0.05		0.063	SB1.5-1845
25	14	62.24	26.8	3.05	2.74	0.31	0.06~0.16	0.65	SB2-4518
27.5		23.11	10.7	1.22	1.09	0.12		0.16	SB2-1845
31	18	76.53	53.4	6.20	5.44	0.63	0.07~0.17	1.23	SB2.5-4518
31.5		26.82	21.2	2.48	2.16	0.25		0.28	SB2.5-1845
37	21	92.96	90.5	10.7	9.23	1.09	0.08~0.18	2.05	SB3-4518
36		33.41	36.0	4.29	3.67	0.44		0.46	SB3-1845
45	29	122.33	220	26.8	22.4	2.73	0.12~0.27	4.69	SB4-4518
46		45.83	87.3	10.7	8.91	1.09		1.01	SB4-1845
51	34	156.56	411	51.8	41.9	5.28	0.14~0.34	8.31	SB5-4518
52.5		56.9	164	20.7	16.7	2.11		1.95	SB5-1845
9	6	32.02	2.84	0.27	0.29	0.027	0.03~0.13	0.078	SB1-4515
12		10.05	0.98	0.09	0.10	0.0091		0.095	SB1-1545
12	8	39.63	5.80	0.56	0.59	0.057	0.04~0.14	0.15	SB1.25-4515
15		10.9	2.00	0.19	0.20	0.019		0.018	SB1.25-1545
17	10	46.58	10.3	1.02	1.05	0.10	0.05~0.15	0.25	SB1.5-4515
22.5		14.75	3.56	0.34	0.36	0.035		0.041	SB1.5-1545
26	15	59.04	26.4	2.68	2.69	0.27	0.06~0.16	0.60	SB2-4515
29		19.13	9.10	0.89	0.93	0.091		0.096	SB2-1545
35	20	72.84	53.6	5.55	5.46	0.57	0.07~0.17	1.22	SB2.5-4515
37		20.51	18.5	1.85	1.89	0.19		0.19	SB2.5-1545
35	23	88.18	90.2	9.53	9.20	0.97	0.08~0.18	1.99	SB3-4515
43		22.53	31.2	3.18	3.18	0.32		0.34	SB3-1545
45	30	118.09	211	23.0	21.5	2.35	0.12~0.27	3.89	SB4-4515
52		32.26	72.8	7.67	7.43	0.78		0.77	SB4-1545
44	35	152.88	394	44.3	40.2	4.52	0.14~0.34	6.10	SB5-4515
65		48.64	136	14.8	13.9	1.51		1.46	SB5-1545
62	50	169.26	751	87.0	76.6	8.87	0.16~0.36	18.0	SB6-4515
86		49.77	259	39.9	26.4	4.06		2.61	SB6-1545
67	50	255.92	1470	179	150	18.3	0.20~0.45	36.4	SBY8-4515
93		61.77	506	59.7	51.6	6.09		5.80	SBY8-1545

[Caution on Secondary Operations] ① Please read "Caution on Performing Secondary Operations" (Page 284) when performing modifications and/or secondary operations for safety concerns. KHK Quick-Mod Gears, the KHK's system for quick modification of KHK stock gears is also available.

Spur Gears | Helical Gears | Internal Gears | Racks | CP Racks & Pinions | Miter Gears | Bevel Gears | Screw Gears | Worm Gear Pair | Bevel Gearboxes | Other Products

FAULHABER

Planetary Gearheads

10 Nm

For combination with
DC-Micromotors
Brushless DC-Motors

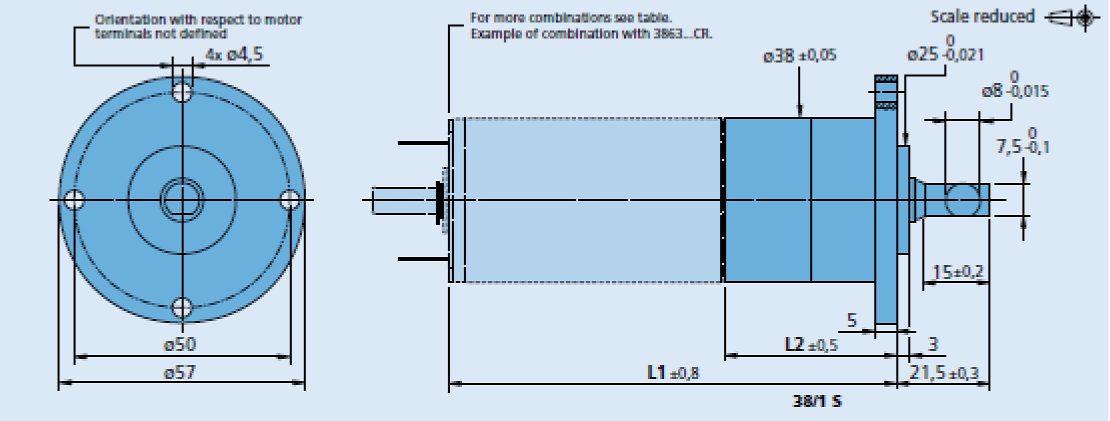
Series 38/1 S

	38/1 S
Housing material	metal
Geartrain material	steel
Recommended max. input speed for:	
– continuous operation	4 000 min⁻¹
Backlash, at no-load	≤ 1 °
Bearings on output shaft	ball bearings, preloaded
Shaft load, max.:	
– radial (10 mm from mounting face)	≤ 300 N
– axial	≤ 300 N
Shaft press fit force, max.	≤ 350 N
Shaft play	
– radial (10 mm from mounting face)	≤ 0,03 mm
– axial	≤ 0,15 mm
Operating temperature range	- 20 ... + 125 °C

Specifications						
Number of gear stages			2	3	4	5
Continuous torque		Nm	10	10	10	10
Intermittent torque		Nm	15	15	15	15
Mass without motor, ca.		g	215	268	320	375
Efficiency, max.		%	80	70	60	55
Direction of rotation, drive to output			=	=	=	=
Reduction ratio [1]			14:1	43:1	134:1	415:1
(rounded)				66:1	159:1	592:1
					246:1	989:1
						1 526:1
L2 [mm] = length without motor [2]			40,1	47,9	55,7	63,5
L1 [mm] = length with motor	3242G...CR		81,3	89,1	96,9	104,7
	3257G...CR		96,3	104,1	111,9	119,7
	3272G...CR		111,3	119,1	126,9	134,7
	3863A...CR		99,1	106,9	114,7	122,5
	3890A...CR		125,1	132,9	140,7	148,5
	3056K...B		96,1	103,9	111,7	119,5
	3242G...BX4		83,5	91,3	99,1	106,9
	3268G...BX4		109,5	117,3	125,1	132,9
	3274G...BP4		114,1	121,9	129,7	137,5
	3564K...B		104,1	111,9	119,7	127,5

[1] The reduction ratios are rounded, the exact values are available on request or at www.faulhaber.com.
[2] L2 - 0,8 mm, in combination with 3242G...CR, 3257G...CR, 3272G...CR, 3242G...BX4 and 3268G...BX4.
L2 - 5 mm, in combination with 3863A...CR and 3890A...CR.

Note: The gearheads as S-type have all steel gears and heavy duty lubricant for extended lifetime performance.



For notes on technical data and lifetime performance refer to "Technical Information".
Edition 2017

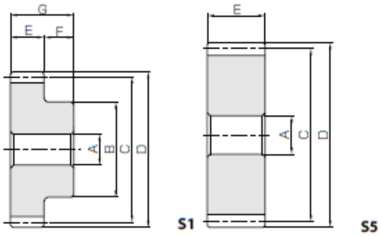
PS • PSA

Plastic Spur Gears

Module 2

Specifications	
Precision grade	JIS grade N9 (JIS B1702-1: 1998) * JIS grade 5 (JIS B1702: 1976)
Gear teeth	Standard full depth
Pressure angle	20°
Material	MC901
Heat treatment	—
Tooth hardness	(115 ～ 120HRR)
Face width (E)	20
Hub width (F)	10 (Shape S1)
Total length (G)	30 (Shape S1)
Screw offset (J)	5 (Shape S1)

* The precision grade of J Series products is equivalent to the value shown in the table.



Catalog No.	No. of teeth	Shape	Bore	Hub dia.	Pitch dia.	Outside dia.	Allowable torque (N·m)	Allowable torque (kgf·m)	Backlash	Weight
			A_{H7}	B	C	D	Bending strength	Bending strength	(mm)	(kg)
PS2-12	12			18	24	28	2.25	0.23		0.011
PS2-13	13			20	26	30	2.59	0.26		0.013
PS2-14	14			20	28	32	2.96	0.30		0.015
PS2-15	15			24	30	34	3.29	0.34		0.019
PS2-16	16			26	32	36	3.63	0.37		0.022
PS2-18	18			30	36	40	4.24	0.43	0~0.42	0.029
PS2-20	20	S1	10	32	40	44	4.91	0.50		0.036
PS2-22	22			35	44	48	5.55	0.57		0.044
PS2-24	24			38	48	52	6.19	0.63		0.052
PS2-25	25			40	50	54	6.54	0.67		0.057
PS2-26	26			42	52	56	6.90	0.70		0.063
PS2-28	28			45	56	60	7.54	0.77		0.073
PS2-30	30			50	60	64	8.20	0.84		0.086
PSA2-32	32				64	68	8.91	0.91		0.075
PSA2-35	35				70	74	10.0	1.02	0~0.44	0.089
PSA2-36	36				72	76	10.4	1.06		0.094
PSA2-40	40				80	84	11.9	1.21		0.12
PSA2-45	45				90	94	13.7	1.40		0.15
PSA2-48	48				96	100	14.9	1.52		0.17
PSA2-50	50				100	104	15.7	1.60		0.18
PSA2-55	55				110	114	17.5	1.78		0.22
PSA2-60	60	S5	12	—	120	124	19.3	1.97		0.26
PSA2-65	65				130	134	21.1	2.15		0.31
PSA2-70	70				140	144	23.0	2.34		0.36
PSA2-75	75				150	154	24.9	2.54	0~0.46	0.41
PSA2-80	80				160	164	26.7	2.72		0.47
PSA2-85	85				170	174	28.5	2.91		0.53
PSA2-90	90				180	184	30.4	3.10		0.59
PSA2-95	95				190	194	32.3	3.29		0.66
PSA2-100	100				200	204	34.2	3.48		0.73

[Caution on Product Characteristics]
① Significant variations in temperature or humidity can cause dimensional changes in plastic gears (MC Nylon gears), including bore size (H8 when produced), tooth diameter, and backlash. Please see the section "Design of Plastic Gears" in separate technical reference book. (Page 101).
② The allowable torques shown in the table are calculated values according to the assumed usage conditions. Please see Page 31 for more details.
③ Without lubrication, using plastic gears in pairs may generate heat and dilation. It is recommended to mate them with steel gears.
④ The backlash values shown in the table are the theoretical values for the backlash in the normal direction of a pair of identical gears in mesh.

[Caution on Secondary Operations]
①Please read "Caution on Performing Secondary Operations" (Page 32) when performing modifications and/or secondary operations for safety concerns. KHK Quick-Mod Gears, the KHK's system for quick modification of KHK stock gears is also available.
②Plastic gears are susceptible to the effects of temperature and moisture. Dimensional changes may occur while performing secondary operations and during post-machining operations.

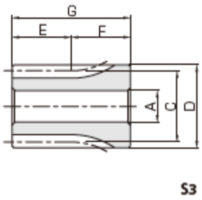
* In regards to MC Nylon gears, other materials are available for plastic gears, including Ultra High Molecular Weight Polyethylene (UHMW-PE), which has excellent abrasion resistance. Poly Ether Ether Ketone (PEEK) also has quality properties. A single piece order is acceptable and will be produced as a custom-made gear. For details on quotations and orders please see Page 8.

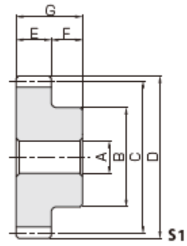
11.6. KHK Steel Spur Gears

SS
Steel Spur Gears

Module 1.5

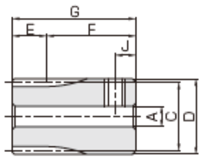
Specifications	
Precision grade	JIS grade N8 (JIS B1702-1: 1998) JIS grade 4 (JIS B1702: 1976)
Gear teeth	Standard full depth
Pressure angle	20°
Material	S45C
Heat treatment	—
Tooth hardness	(less than 194HB)
Surface treatment	Black oxide coating



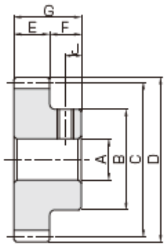


Catalog No.	Module	No. of teeth	Shape	Bore	Hub dia.	Pitch dia.	Outside dia.	Face width	Hub width	Total length	Web thickness	Web O.D.	Keyway
				A_{H7}	B	C	D	E	F	G	H	I	Width×Depth
SS1.5-12 **SS1.5-12A**	*m*1.5	12	S3 S3T	8 6	21	18	21	15	15	30	—	—	— —
SS1.5-13 **SS1.5-13A**		13	S3 S3T	8 6	22.5	19.5	22.5	15	15	30	—	—	— —
SS1.5-14 **SS1.5-14A** **SS1.5-14B**		14	S1 S1T S1T	8 6 8	16	21	24	15	10	25	—	—	— — —
SS1.5-15 **SS1.5-15A** **SS1.5-15B**		15	S1 S1T S1T	8 6 8	18	22.5	25.5	15	10	25	—	—	— — —
SS1.5-16 **SS1.5-16A** **SS1.5-16B**		16	S1 S1T S1T	8 6 8	20	24	27	15	10	25	—	—	— — —
SS1.5-17 **SS1.5-17A**		17	S1 S1T	8 8	21	25.5	28.5	15	10	25	—	—	— —
SS1.5-18 **SS1.5-18A** **SS1.5-18B**		18	S1 S1T S1K	8 8 10	22	27	30	15	10	25	—	—	— — 4 x 1.8
SS1.5-19 **SS1.5-19A**		19	S1 S1T	8 8	23	28.5	31.5	15	10	25	—	—	— —
SS1.5-20 **SS1.5-20A** **SS1.5-20B** **SS1.5-20C**		20	S1 S1T S1T S1K	8 6 8 10	24	30	33	15	10	25	—	—	— — — 4 x 1.8
SS1.5-21 **SS1.5-21A** **SS1.5-21B**		21	S1 S1T S1K	8 8 10	25	31.5	34.5	15	10	25	—	—	— — 4 x 1.8
SS1.5-22 **SS1.5-22A**		22	S1 S1K	8 10	26	33	36	15	10	25	—	—	— 4 x 1.8
SS1.5-23 **SS1.5-23A**		23	S1 S1K	8 10	27	34.5	37.5	15	10	25	—	—	— 4 x 1.8
SS1.5-24 **SS1.5-24A** **SS1.5-24B** **SS1.5-24C**		24	S1 S1T S1K S1K	8 8 10 12	28	36	39	15	10	25	—	—	— — 4 x 1.8 4 x 1.8
SS1.5-25 **SS1.5-25A** **SS1.5-25B** **SS1.5-25C**		25	S1 S1T S1K S1K	8 8 10 12	30	37.5	40.5	15	10	25	—	—	— — 4 x 1.8 4 x 1.8
SS1.5-26 **SS1.5-26A**		26	S1 S1K	10 12	32	39	42	15	10	25	—	—	— 4 x 1.8
SS1.5-27 **SS1.5-27A**		27	S1 S1K	10 12	34	40.5	43.5	15	10	25	—	—	— 4 x 1.8
SS1.5-28 **SS1.5-28A**		28	S1 S1K	10 12	36	42	45	15	10	25	—	—	— 4 x 1.8
SS1.5-29 **SS1.5-29A**		29	S1 S1K	10 12	37	43.5	46.5	15	10	25	—	—	— 4 x 1.8
SS1.5-30 **SS1.5-30A** **SS1.5-30B** **SS1.5-30C** **SS1.5-30D**		30	S1 S1K S1K S1K S1K	10 10 12 15 16	38	45	48	15	10	25	—	—	— 4 x 1.8 4 x 1.8 5 x 2.3 5 x 2.3
SS1.5-32 **SS1.5-32A** **SS1.5-32B** **SS1.5-32C** **SS1.5-32D**		32	S1 S1K S1K S1K S1K	10 10 12 15 16	40 38 38 38 38	48	51	15	10	25	—	—	— 4 x 1.8 4 x 1.8 5 x 2.3 5 x 2.3
SS1.5-34 **SS1.5-34A**		34	S1 S1K	10 12	40 38	51	54	15	10	25	—	—	— 4 x 1.8
SS1.5-35 **SS1.5-35A**		35	S1 S1K	10 12	42 40	52.5	55.5	15	10	25	—	—	— 4 x 1.8
SS1.5-36 **SS1.5-36A**		36	S1 S1K	10 12	45 40	54	57	15	10	25	—	—	— 4 x 1.8
SS1.5-38 **SS1.5-38A**		38	S1 S1K	12 15	45 40	57	60	15	10	25	—	—	— 5 x 2.3
SS1.5-40 **SS1.5-40A** **SS1.5-40B** **SS1.5-40C**		40	S1 S1K S1K S1K	12 12 15 16	45 40 40 40	60	63	15	10	25	—	—	— 4 x 1.8 5 x 2.3 5 x 2.3

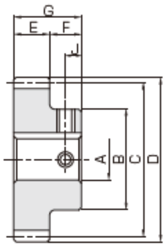
Steel Spur Gears



S3T



S1T



S1K

Set Screw		Allowable torque (N·m)		Allowable torque (kgf·m)		Backlash	Weight	Catalog No.
Size	J	Bending strength	Surface durability	Bending strength	Surface durability	(mm)	(kg)	
— M4	— 4	6.86	0.36	0.70	0.037	0.10~0.22	0.059 0.063	**SS1.5-12 SS1.5-12A**
— M4	— 4	8.84	0.44	0.90	0.045	0.10~0.22	0.070 0.075	**SS1.5-13 SS1.5-13A**
— M4 M5	— 5 5	11.1	0.52	1.13	0.053	0.10~0.22	0.047 0.051 0.046	**SS1.5-14 SS1.5-14A SS1.5-14B**
— M4 M5	— 5 5	12.5	0.60	1.27	0.062	0.10~0.22	0.057 0.061 0.056	**SS1.5-15 SS1.5-15A SS1.5-15B**
— M4 M5	— 5 5	13.8	0.70	1.41	0.071	0.10~0.22	0.068 0.072 0.067	**SS1.5-16 SS1.5-16A SS1.5-16B**
— M5	— 5	15.2	0.80	1.55	0.082	0.10~0.22	0.077 0.077	**SS1.5-17 SS1.5-17A**
— M5 M4	— 5 5	16.6	0.91	1.69	0.093	0.10~0.22	0.087 0.086 0.080	**SS1.5-18 SS1.5-18A SS1.5-18B**
— M5	— 5	18.0	1.03	1.83	0.11	0.10~0.22	0.098 0.097	**SS1.5-19 SS1.5-19A**
— M4 M5 M4	— 5 5 5	19.4	1.15	1.98	0.12	0.10~0.22	0.11 0.11 0.11 0.10	**SS1.5-20 SS1.5-20A SS1.5-20B SS1.5-20C**
— M5 M4	— 5 5	20.8	1.29	2.12	0.13	0.12~0.26	0.12 0.12 0.11	**SS1.5-21 SS1.5-21A SS1.5-21B**
— M4	— 5	22.3	1.43	2.27	0.15	0.12~0.26	0.13 0.12	**SS1.5-22 SS1.5-22A**
— M4	— 5	23.7	1.58	2.42	0.16	0.12~0.26	0.15 0.14	**SS1.5-23 SS1.5-23A**
— M5 M4 M4	— 5 5 5	25.2	1.73	2.57	0.18	0.12~0.26	0.16 0.16 0.15 0.14	**SS1.5-24 SS1.5-24A SS1.5-24B SS1.5-24C**
— M5 M4 M4	— 5 5 5	26.7	1.90	2.72	0.19	0.12~0.26	0.18 0.17 0.17 0.16	**SS1.5-25 SS1.5-25A SS1.5-25B SS1.5-25C**
— M4	— 5	28.2	2.06	2.87	0.21	0.12~0.26	0.19 0.18	**SS1.5-26 SS1.5-26A**
— M4	— 5	29.7	2.23	3.03	0.23	0.12~0.26	0.21 0.20	**SS1.5-27 SS1.5-27A**
— M4	— 5	31.2	2.41	3.18	0.25	0.12~0.26	0.23 0.22	**SS1.5-28 SS1.5-28A**
— M4	— 5	32.7	2.60	3.34	0.26	0.12~0.26	0.24 0.23	**SS1.5-29 SS1.5-29A**
— M4 M4 M4 M4	— 5 5 5 5	34.2	2.79	3.49	0.28	0.12~0.26	0.26 0.26 0.25 0.24 0.23	**SS1.5-30 SS1.5-30A SS1.5-30B SS1.5-30C SS1.5-30D**
— M4 M4 M4 M4	— 5 5 5 5	37.3	3.19	3.80	0.33	0.12~0.26	0.30 0.28 0.28 0.26 0.26	**SS1.5-32 SS1.5-32A SS1.5-32B SS1.5-32C SS1.5-32D**
— M4	— 5	40.4	3.63	4.12	0.37	0.12~0.26	0.32 0.30	**SS1.5-34 SS1.5-34A**
— M4	— 5	41.9	3.85	4.28	0.39	0.12~0.26	0.35 0.33	**SS1.5-35 SS1.5-35A**
— M4	— 5	43.5	4.09	4.43	0.42	0.12~0.26	0.38 0.34	**SS1.5-36 SS1.5-36A**
— M4	— 5	46.6	4.58	4.75	0.47	0.12~0.26	0.40 0.36	**SS1.5-38 SS1.5-38A**
— M4 M4 M4	— 5 5 5	49.8	5.10	5.07	0.52	0.12~0.26	0.44 0.41 0.39 0.39	**SS1.5-40 SS1.5-40A SS1.5-40B SS1.5-40C**

[Caution on Product Characteristics]

① The key groove used is a JIS B 1301 normal type (Js9) and a set screw is included for products with a tapped hole.

② The allowable torques shown in the table are calculated values according to the assumed usage conditions. Please see Page 31 for more details.

③ The backlash values shown in the table are the theoretical values for the backlash in the normal direction of a pair of identical gears in mesh.

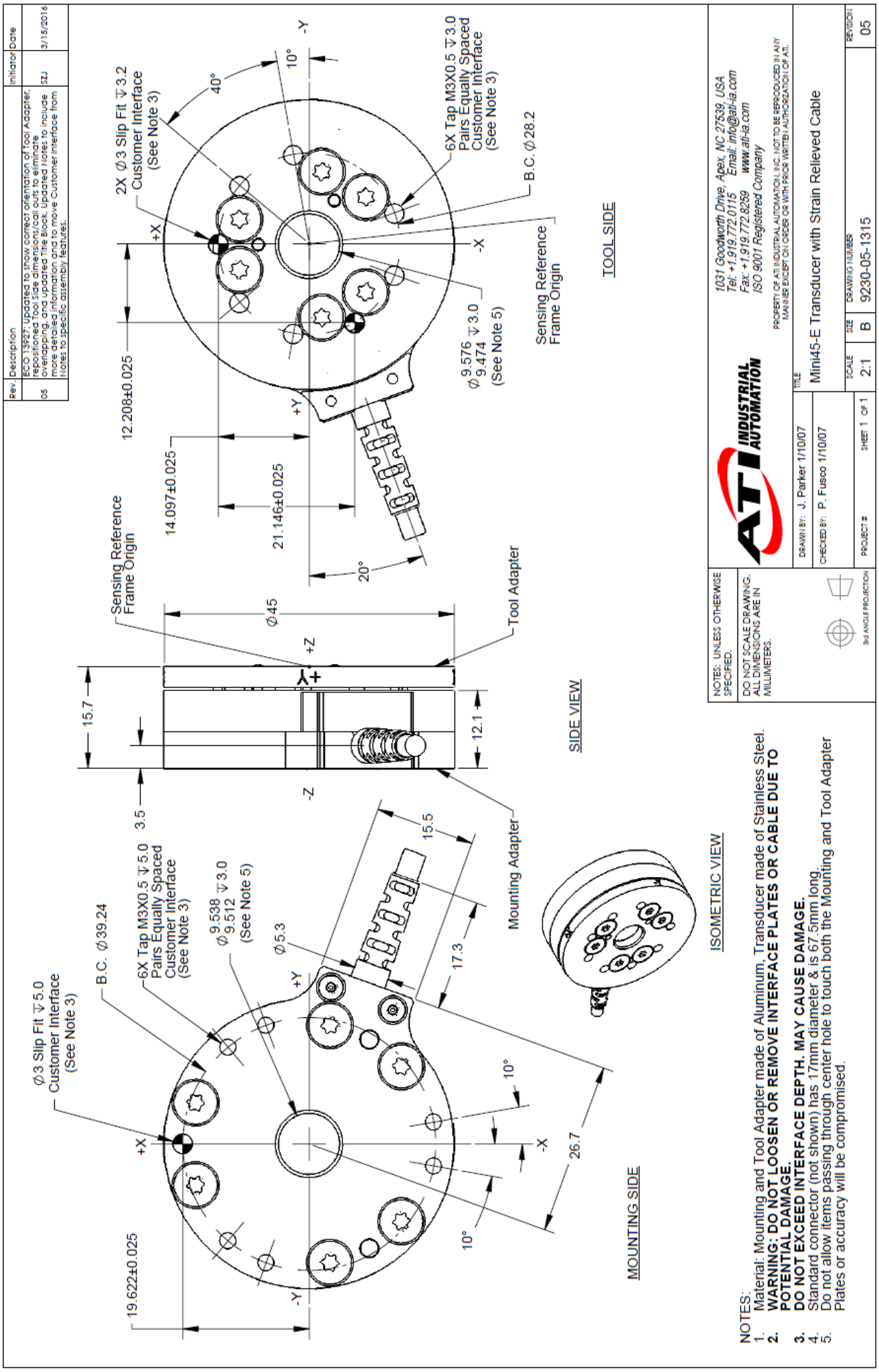
④ When using S3T and S1T set screws for fastening gears to a shaft, only use this method for applications with light load usage. For secure fastening, please use dowel pins in combination.

[Caution on Secondary Operations]

① Please read "Caution on Performing Secondary Operations" (Page 32) when performing modifications and/or secondary operations for safety concerns. KHK Quick-Mod Gears, the KHK system for quick modification of KHK stock gears, is also available.

② Avoid performing secondary operations that narrow the tooth width as it affects precision and strength.

11.7. ATI Mini45 Drawing



11.8. Faulhaber 2444 B FMM Data Sheet

FAULHABER

Brushless DC-Servomotors

2 Pole Technology

18 mNm

51 W

Series 2444 ... B

	Values at 22°C and nominal voltage	2444 S		024 B	048 B	
1	Nominal voltage	U_N		24	48	V
2	Terminal resistance, phase-phase	R		2	8,54	Ω
3	Efficiency, max.	η_{max}		79	78	%
4	No-load speed	n_0		22 200	21 600	min^{-1}
5	No-load current, typ. (with shaft ø 3 mm)	I_0		0,159	0,076	A
6	Stall torque	M_H		123	118,5	mNm
7	Friction torque, static	C_0		0,746	0,746	mNm
8	Friction torque, dynamic	C_v		$3{,}87 \cdot 10^{-5}$	$3{,}87 \cdot 10^{-5}$	mNm/min^{-1}
9	Speed constant	k_n		927	450	min^{-1}/V
10	Back-EMF constant	k_E		1,08	2,22	mV/min^{-1}
11	Torque constant	k_M		10,3	21,2	mNm/A
12	Current constant	k_I		0,097	0,047	A/mNm
13	Slope of n-M curve	$\Delta n/\Delta M$		180	181	min^{-1}/mNm
14	Terminal inductance, phase-phase	L		175	740	µH
15	Mechanical time constant	τ_m		10,8	10,8	ms
16	Rotor inertia	J		5,7	5,7	gcm^2
17	Angular acceleration	α_{max}		216	208	$\cdot 10^3 rad/s^2$
18	Thermal resistance	R_{th1} / R_{th2}	2,4 / 11,6			K/W
19	Thermal time constant	τ_{w1} / τ_{w2}	9,6 / 470			s
20	Operating temperature range:					
	– motor		-30 ... +125			°C
	– winding, max. permissible		+125			°C
21	Shaft bearings		ball bearings, preloaded			
22	Shaft load max.:					
	– with shaft diameter		3			mm
	– radial at 3 000 min^{-1} (5 mm from mounting flange)		31			N
	– axial at 3 000 min^{-1} (push only)		16			N
	– axial at standstill (push only)		57			N
23	Shaft play:					
	– radial	≤	0,015			mm
	– axial	=	0			mm
24	Housing material		aluminium, black anodized			
25	Mass		98			g
26	Direction of rotation		electronically reversible			
27	Speed up to	n_{max}	45 000			min^{-1}
28	Number of pole pairs		1			
29	Hall sensors		digital			
30	Magnet material		SmCo			

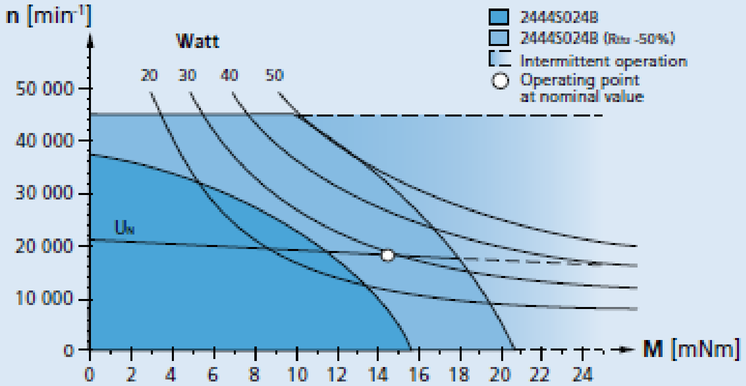
	Rated values for continuous operation			024 B	048 B	
31	Rated torque	M_N		14,2	14,3	mNm
32	Rated current (thermal limit)	I_N		1,58	0,772	A
33	Rated speed	n_N		18 800	18 100	min^{-1}

Note: Rated values are calculated with nominal voltage and at a 22°C ambient temperature. The R_{th2} value has been reduced by 25%.

Note:
The diagram indicates the recommended speed in relation to the available torque at the output shaft for a given ambient temperature of 22°C.

The diagram shows the motor in a completely insulated as well as thermally coupled condition (R_{th2} 50% reduced).

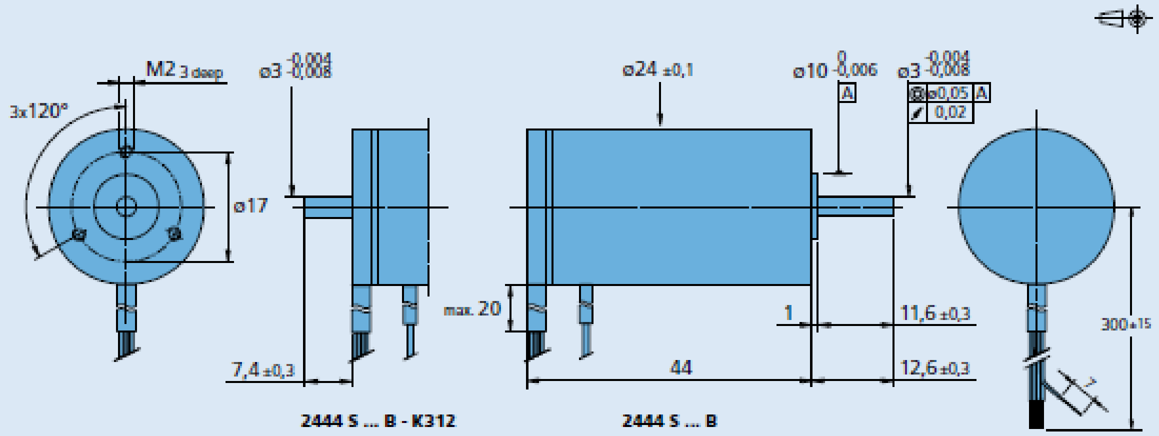
The nominal voltage (U_N) curve shows the operating point at nominal voltage in the insulated and thermally coupled condition. Any points of operation above the curve at nominal voltage will require a higher operating voltage. Any points below the nominal voltage curve will require less voltage.



Recommended operation areas (example: nominal voltage 24V)

For notes on technical data and lifetime performance refer to "Technical Information".
Edition 2017

Dimensional drawing



2444 S ... B - K312 **2444 S ... B**

Option, cable and connection information

Example product designation: **2444S024B-K1155**

Option	Type	Description
K1155	Controller combination	Analog Hall sensors for combination with Motion Controller MCBL
K1026	Sensorless	Motor without Hall sensors
K1555	Lead wires length	Single lead wires 750 mm long in PTFE
K903	Lead wires length	Single lead wires 1000 mm long in PTFE
K1838	Encoder combination	Motor with rear end shaft for combination with Encoder IE3
K313	Encoder combination	Motor with rear end shaft for combination with Encoder IE2
K312	Encoder combination	Motor with rear end shaft for combination with Encoder HEDS/HEDL/HEDM
K179	Bearing lubrication	For vacuum of 10^{-5} Pa @ 22°C

Connection

Function	Colour
Phase C	yellow
Phase B	orange
Phase A	brown
GND	black
U_{DD} (+5V)	red
Hall sensor C	grey
Hall sensor B	blue
Hall sensor A	green

Standard cable
Single wires, material PTFE
AWG 24: Phase A/B/C
AWG 26: Hall A/B/C, U_{DD}, GND

Product combination

Precision Gearheads / Lead Screws	Encoders	Drive Electronics	Cables / Accessories
22/7	HEDS 5500	SC 2402	MBZ
23/1	IE3-1024	SC 2804	
26/1	IE3-1024 L	SC 5004	To view our large range of accessory parts, please refer to the "Accessories" chapter.
26/1 S	HEDL 5540	SC 5008	
30/1		MC 5004	
30/1 S		MC 5005	
		MCBL 3002	
		MCBL 3003	
		MCBL 3006	

For notes on technical data and lifetime performance refer to "Technical Information".
Edition 2017

11.9. Faulhaber Series 26/1S Planetary Gearhead

FAULHABER

Planetary Gearheads

3,5 Nm

For combination with
DC-Micromotors
Brushless DC-Motors
Stepper Motors

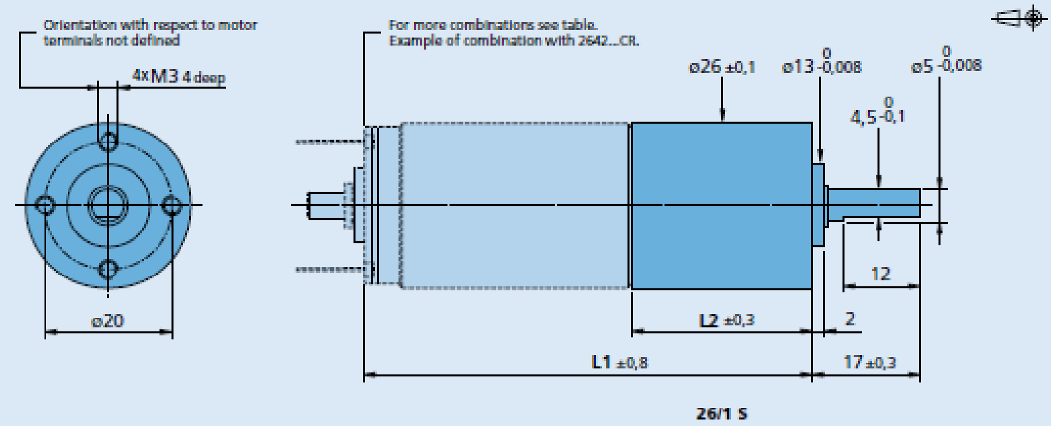
Series 26/1 S

	26/1 S
Housing material	steel
Geartrain material	steel
Recommended max. input speed for:	
– continuous operation	4 000 min⁻¹
Backlash, at no-load	≤ 1 °
Bearings on output shaft	ball bearings, preloaded
Shaft load, max.:	
– radial (10 mm from mounting face)	≤ 150 N
– axial	≤ 100 N
Shaft press fit force, max.	≤ 150 N
Shaft play	
– radial (10 mm from mounting face)	≤ 0,03 mm
– axial	≤ 0,1 mm
Operating temperature range	- 30 ... + 100 °C

Specifications						
Number of gear stages			2	3	4	5
Continuous torque		Nm	3,5	3,5	3,5	3,5
Intermittent torque		Nm	4,5	4,5	4,5	4,5
Mass without motor, ca.		g	116	139	162	185
Efficiency, max.		%	80	70	60	55
Direction of rotation, drive to output			=	=	=	=
Reduction ratio [1]			9,7:1	43:1	134:1	415:1
(rounded)			14:1	66:1	159:1	592:1
			23:1	86:1	246:1	989:1
						1 526:1
L2 [mm] = length without motor			36,4	44,4	52,4	60,5
L1 [mm] = length with motor	2342S...CR		78,4	86,4	94,4	102,5
	2642W...CR		78,4	86,4	94,4	102,5
	2642W...CXR		78,4	86,4	94,4	102,5
	2657W...CR		93,4	101,4	109,4	117,5
	2657W...CXR		93,4	101,4	109,4	117,5
	2668W...CR		104,4	112,4	120,4	128,5
	2444S...B		80,4	88,4	96,4	104,5
	AM2224-R3...-30		67,3	75,3	83,3	91,4

[1] The reduction ratios are rounded, the exact values are available on request or at www.faulhaber.com.

Note: The gearheads as S-type have all steel gears and heavy duty lubricant for extended lifetime performance.



For notes on technical data and lifetime performance refer to "Technical Information".
Edition 2017

11.10. Aluminum 6061-T6 S-N Curve

MMPDS-09
1 April 2014

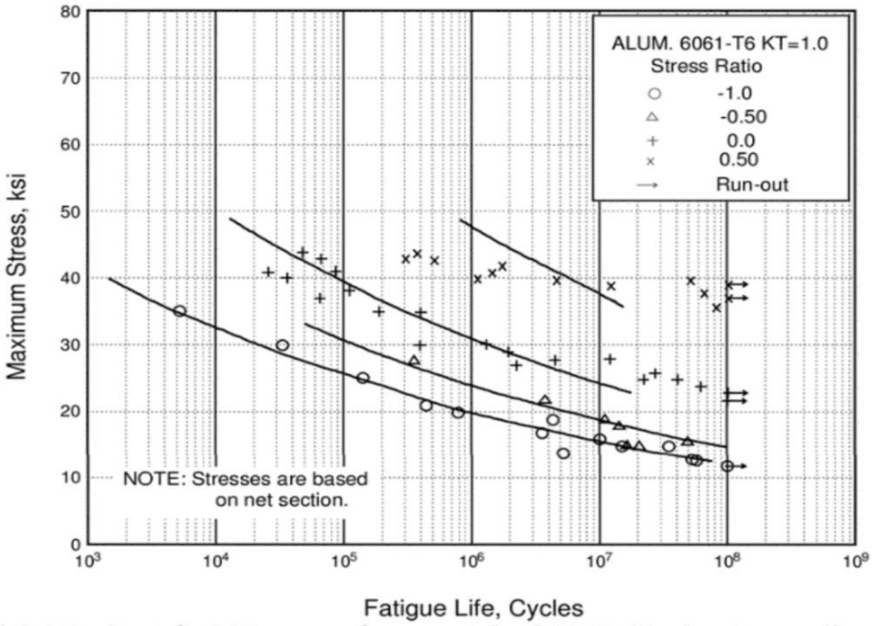
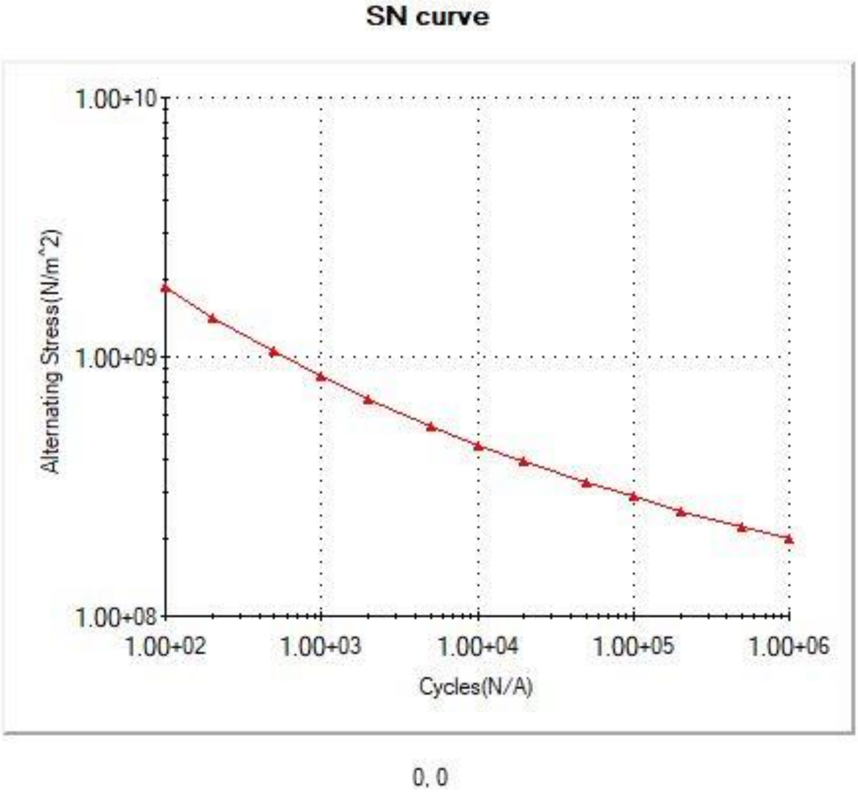
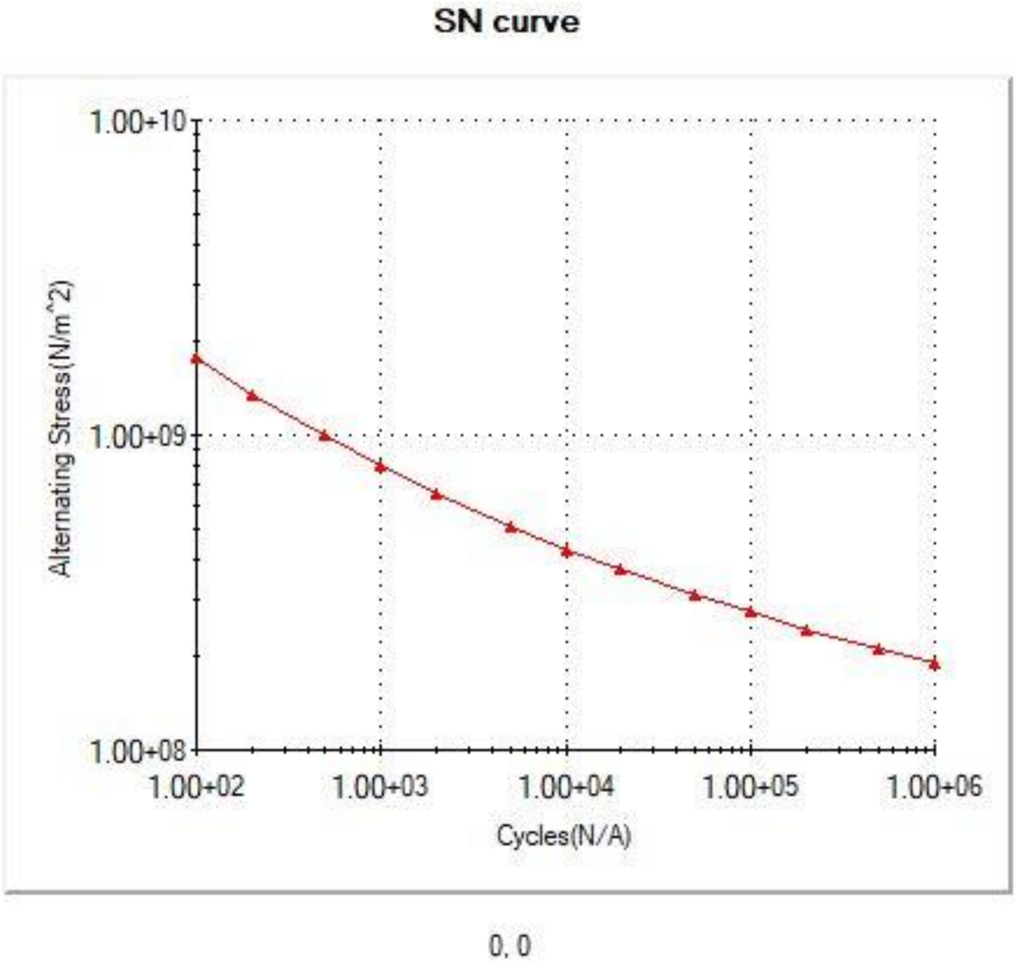


Figure 3.6.2.2.8. Best-fit S/N curves for unnotched 6061-T6 aluminum alloy, various wrought products, longitudinal direction.

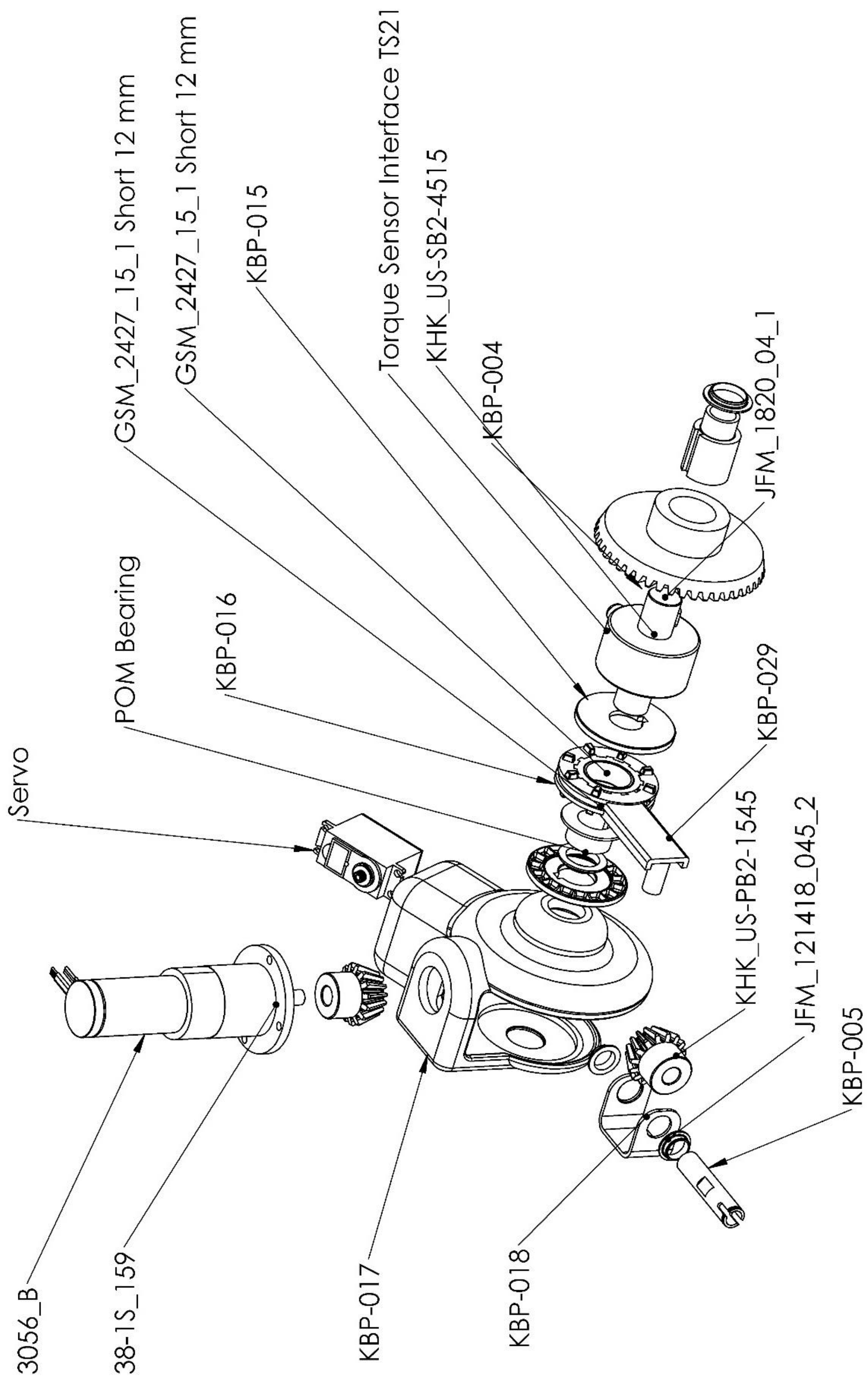
11.1. AISI 304 Stainless Steel S-N Curve



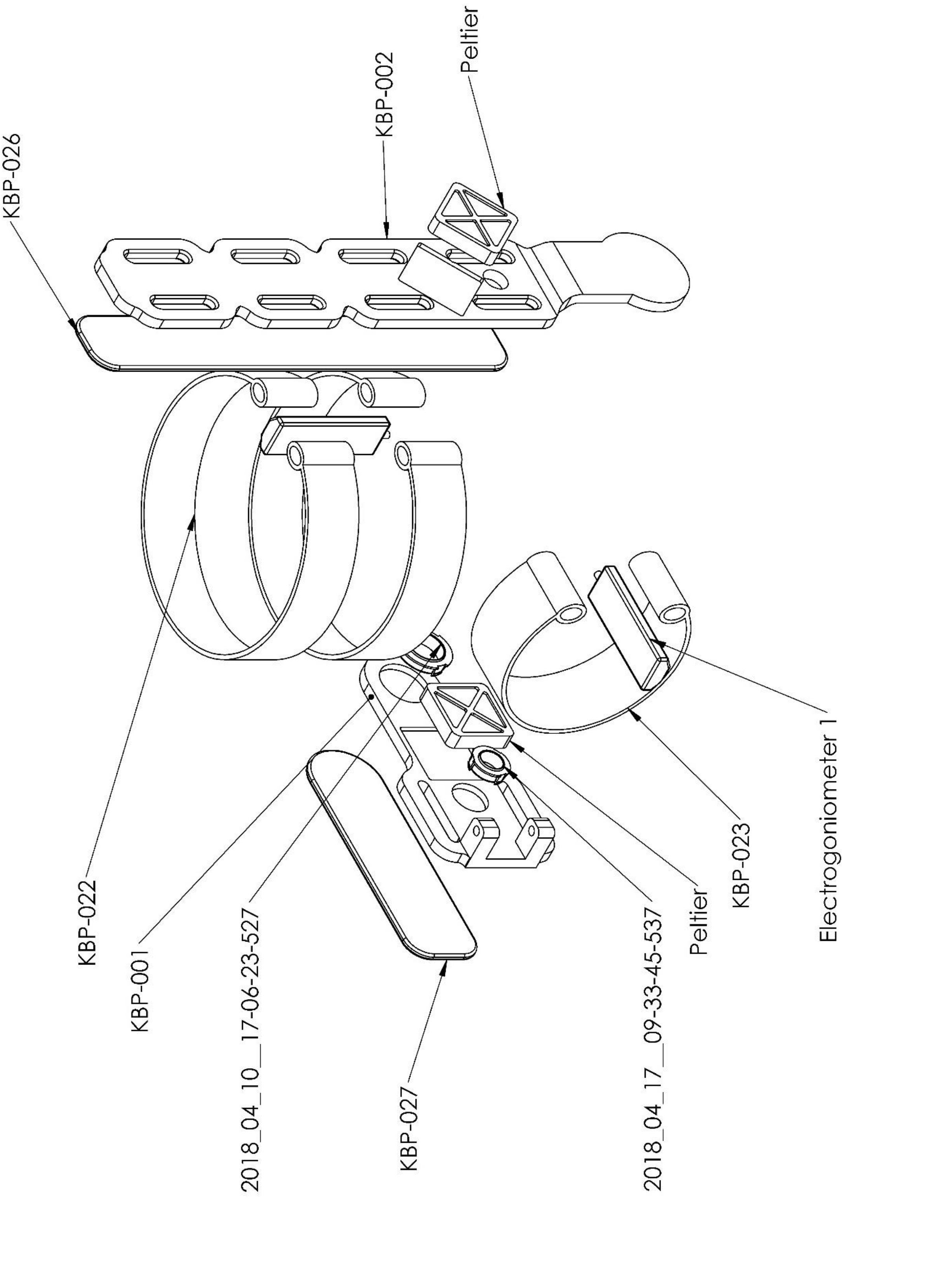
11.2. AISI 440C Stainless Steel S-N Curve



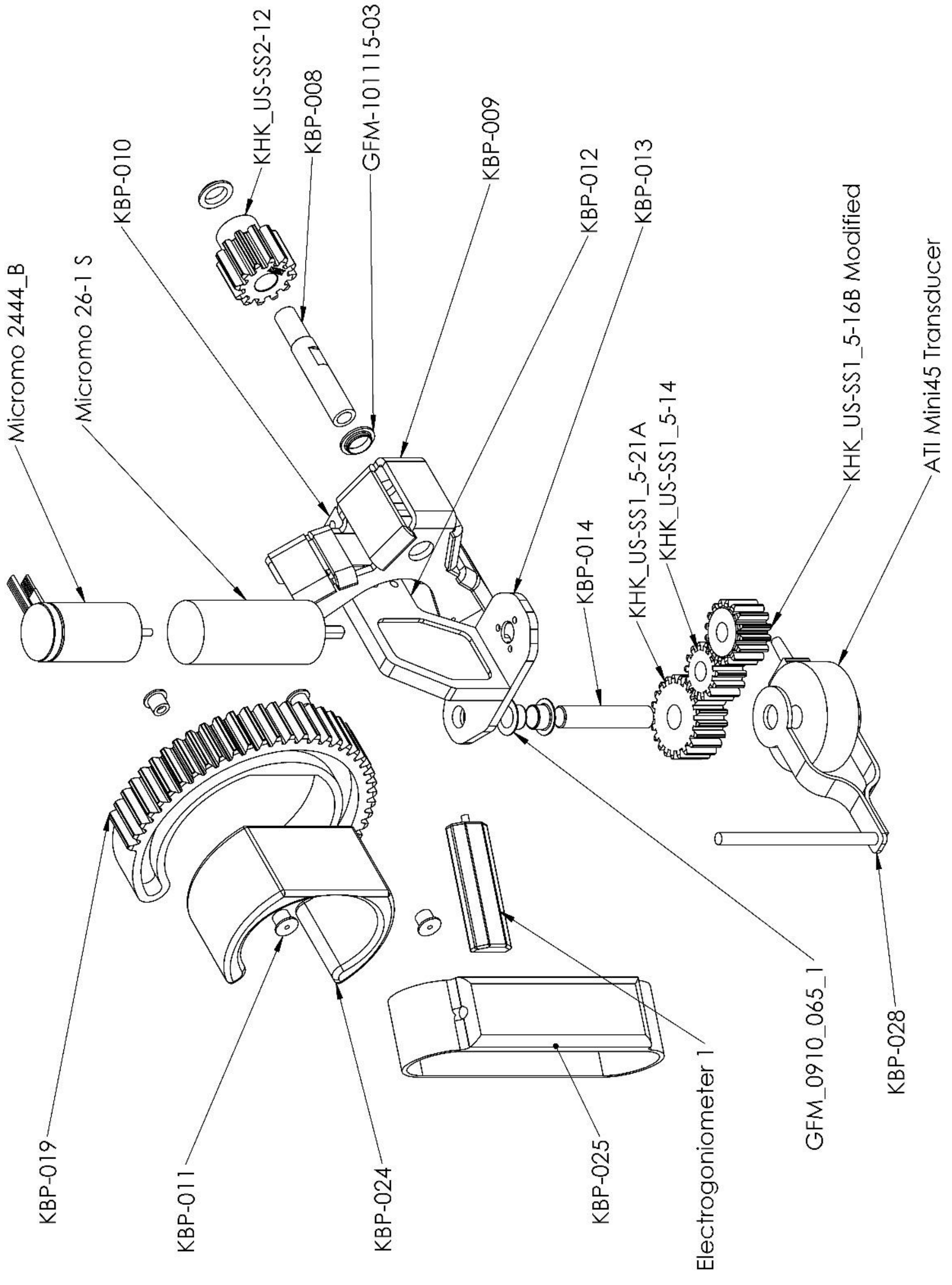
11.3. Actuator Exploded View



11.4. Elbow Base Exploded View



11.5. Wrist Base Exploded View



11.6. Telescoping Beam and Shaft Exploded View