CHALMERS

Development of a Non-Invasive Blood Pressure Measurement Device for Cardiopulmonary Exercise Testing

Master's Thesis in Biomedical Engineering

ANNA HEED
JULIA PETERSSON

DEPARTMENT OF ELECTRICAL ENGINEERING
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg 2026
www.chalmers.se

Master's thesis 2026

Development of a Non-Invasive Blood Pressure Measurement Device for Cardiopulmonary Exercise Testing

ANNA HEED
JULIA PETERSSON

CHALMERS

Department of Electrical Engineering
Chalmers University of Technology
Gothenburg 2026

Development of a Non-Invasive Blood Pressure Measurement Device for Cardiopulmonary Exercise Testing

ANNA HEED
JULIA PETERSSON

Supervisors: Jacob Lidman & Selena van der Horst, Sahlgrenska University Hospital
Examiner: Stefan Candefjord, Department of Electrical Engineering

Master's Thesis 2026
Department of Electrical Engineering
Chalmers University of Technology
SE-412 96 Gothenburg
Telephone +46 31 772 1000

Cover: An illustrative image of a Non-Invasive Blood Pressure Measurement Device for Cardiopulmonary Exercise Testing (Created with Canva AI 2.0, 2026).

Trypeset in LaTeX
Gothenburg 2026

Development of a Non-Invasive Blood Pressure Measurement Device for Cardiopulmonary Exercise Testing
ANNA HEED
JULIA PETERSSON
Department of Electrical Engineering
Chalmers University of Technology

Abstract

In this thesis the conceptual development and prototyping of a non-invasive blood pressure (NIBP) measurement device intended for use during cardiopulmonary exercise testing (CPET) at Sahlgrenska University Hospital (SU) is presented. Reliable blood pressure (BP) monitoring during exercise is essential for both patient safety and clinical decision making, but existing methods are challenged by limited usability and reliance on outdated equipment. The aim of the project was to identify clinical and regulatory requirements, develop a conceptual design and prototype solution. This while simultaneously initiating technical documentation in accordance with the Medical Device Regulation (MDR). The project included literature studies, interviews with healthcare professionals, regulatory analysis and iterative prototyping. User and product requirements were established based on clinical needs and relevant standards. Four prototype iterations were developed and evaluated with respect to controllability, inflation and deflation performance, leakage and usability. The results demonstrated that a mechanically controlled system using hospital compressed air can provide rapid and controllable cuff inflation and deflation suitable for CPET environments. Clinical feedback highlighted the importance of usability and compatibility with existing workflows. The project also identified key regulatory considerations related to in-house manufacturing under the MDR. In conclusion, the study demonstrates the feasibility of developing an in-house NIBP device adapted for CPET and provides a foundation for further technical development and future clinical evaluation.

Keywords: Cardiopulmonary Exercise Testing (CPET), Non-Invasive Blood Pressure Monitoring, Medical Device Development, Medical Device Regulation (MDR), Biomedical Engineering, Risk Management, Prototype Development

Acknowledgments

We would like to express our sincere gratitude to everyone who contributed to and supported this master's thesis project. First, we would like to thank our supervisors, Jacob Lidman and Selena van der Horst, for their continuous guidance, valuable feedback and support throughout the project. Their expertise and engagement have been highly appreciated and essential during the project. They have helped guide us through both technical and practical challenges during the thesis work. We are also grateful to the staff at Sahlgrenska University Hospital, including Sahlgrenska, Östra and The Queen Silvia Children's Hospital, for welcoming us and giving us valuable insight into the clinical environment. In particular, we would like to thank the departments of Clinical Physiology for their cooperation and valuable input during our visits. A special thanks goes to the Biomedical Engineering department at Sahlgrenska for providing us with a workspace and a supportive, welcoming environment throughout the entire project. We also appreciate the opportunity to work at the Biomedical Engineering department at Östra. Finally, we would like to thank our examiner, Stefan Candefjord, for his support and valuable perspectives throughout the project. His feedback and encouragement have contributed positively to both the development and the overall direction of the work.

Anna Heed & Julia Petersson, Gothenburg, May 2026

List of Abbreviations

Below is the list of abbreviations that have been used throughout this thesis listed in alphabetical order:

AI	Artificial Intelligence
BMA	Biomedical Analyst
BMAs	Biomedical Analysts
BP	Blood Pressure
CPET	Cardiopulmonary Exercise Testing
CFR	Code of Federal Regulations
DBP	Diastolic Blood Pressure
DCP	Department of Clinical Physiology
EES	European Economic Area
EU	European Union
FDA	Food and Drug Administration
GSPRs	General Safety and Performance Requirements
IBP	Invasive Blood Pressure
IFU	Instructions for Use
MDR	Medical Device Regulation
MedDO	Medical Devices Ordinance
MT	Department of Biomedical Engineering
NIBP	Non-invasive Blood Pressure
PMA	Pre-Market Approval
PMS	Post Market Surveillance
PR	Product Requirement
PRs	Product Requirements
QMS	Quality Management Systems
QSCH	Queen Silvia's Children Hospital
SBP	Systolic Blood Pressure
SS	Sahlgrenska Hospital
SU	Sahlgrenska University Hospital
U.S.	United States of America
UR	User Requirement
URs	User Requirements
ÖS	Östra Hospital

Contents

List of Figures

List of Tables

1
Introduction

Cardiopulmonary exercise testing (CPET) plays an important role in the diagnosis, evaluation and clinical decision-making of cardiopulmonary diseases [1]. These conditions often become apparent during physical activity rather than at rest, making exercise based assessment essential. During CPET, the cardiovascular, respiratory and metabolic responses are similar to those observed during surgical stress, which is why the test is also widely used in preoperative evaluation [2]. Patients undergoing CPET are commonly investigated due to suspected or established cardiovascular disease but also patients with lung problems [3].

An important part of CPET is the repeated monitoring of physiological parameters to ensure patient safety. Among these parameters, blood pressure (BP) measurement is especially important [4]. Reliable BP monitoring during exercise are primarly designed for resting conditions [5], [4]. Nevertheless, accurate BP assessment during exercise is essential for patient safety and clinical evaluation, since abnormal BP responses may indicate underlying cardiovascular pathology and help maintain a safe testing environment [6]. A decrease in systolic blood pressure (SBP) during exercise is considered pathological and may indicate serious cardiovascular disease [7].

Cardiovascular diseases affect up to one in three individuals and remain the leading cause of death in Sweden [8].
Consequently, there is a growing clinical need for reliable BP monitoring systems that can function accurately during exercise testing such as CPET.

1.1 BP physiology

BP is a vital physiological parameter used to assess the function of the cardiovascular system and an individual's overall health [4]. Elevated BP, referred to as hypertension, is associated with an increased risk of several diseases [9], [10]. Blood circulation supplies organs with oxygen, nutrients and other essential substances. Therefore, it is important that blood flows at an appropriate and regulated pressure to avoid damage to the vessel walls. If the BP increases, the heart must work harder to maintain adequate circulation throughout the body, which puts extra strain on the heart over time [11].

BP is not constant but varies throughout the day [12]. It is lowest during nighttime, increases in the morning and during the day and decreases again in the evening.

Physical activity also influences BP. During aerobic exercise, SBP typically increases [13]. In individuals with hypertension, this increase occurs more rapidly and to a greater extent compared to individuals with normal BP. When the physical activity is over, BP decreases again [13].

1.2 Different types of BP measurements

BP can be measured using several methods, which differ in terms of accuracy, invasiveness and suitability for different clinical settings [14]. Among these methods, invasive BP (IBP) monitoring is considered the reference standard [15], [16]. The method involves insertion of a catheter into an artery connected to a pressure transducer, enabling BP measurements for every heartbeat [15], [17]. It provides a high level of accuracy, making it the most accurate way of measuring arterial pressure [16]. On the other hand, the method carries risks such as infection in the arteries, making it unsuitable for CPET and exercise stress test [15], [18].

One of the most common ways of measuring BP is the auscultatory method. This is a non-invasive blood pressure (NIBP) measurement method, involving an inflatable cuff placed around the upper arm [10]. In a cuff-based measurement, the cuff pressure is gradually increased until blood flow in the brachial artery is temporarily stopped. The pressure is then slowly released while blood flow is monitored using a stethoscope. This is done by listening for the characteristic Korotkoff sounds, which occur when blood passes through the previously compressed artery during cuff deflation, creating vibrations that can be detected using a stethoscope. The first detectable Korotkoff sound appears when the cuff pressure has decreased to the level of the SBP and blood flow begins to return. As the cuff pressure is further reduced, the sounds eventually disappear, which indicates the diastolic blood pressure (DBP) [10]. The auscultatory method is widely considered a reliable NIBP measurements reference method and typically shows small mean differences, around ± 5 mmHg, compared to invasive measurements, although variability in individual readings can be considerably higher [19], [16].

Another cuff-based method is the oscillometric technique, which provides automated NIBP measurements [20], [14]. During cuff deflation, pressure oscillations are generated as the arterial blood flow gradually returns and causes variations in the cuff pressure [14]. These oscillations are detected by the device and analyzed using algorithms to estimate mean BP, SBP and DBP. This method is commonly used in ambulatory monitoring, where BP is recorded at predefined intervals over a 24-hour period [20], [14]. Its applications also extend to hospital environments, as well as home-based measurements that allow individuals to monitor their own BP [21]. Compared to invasive measurements, oscillometric methods show small average differences but can deviate by as much as 20–30 mmHg, indicating considerable variability in individual readings [19].

In addition, several cuff-less NIBP devices are currently available, for example smart watches [20]. Still, further development and clinical validation are required before

such devices can be reliably implemented in clinical practice, mainly due to limitations in measurement accuracy [20], [22]. This reduced reliability is even more clear during physical activity, as motion artifacts can further decrease measurement performance [20].

1.3 CPET

CPET is widely used in clinical practice to monitor and evaluate the responses of the cardiovascular and respiratory systems, as well as metabolic function, during physical activity [23], [24]. More generally, such monitoring is also relevant for exercise stress test, where cardiovascular responses to physical stress are assessed. Repeated and reliable monitoring of physiological parameters, including BP, is critical for accurate interpretation of test results and for patient safety [24], [25]. SBP is commonly measured during CPET as part of cardiovascular monitoring, since abnormal SBP responses during exercise may indicate impaired cardiovascular function, and a drop in SBP is a criterion for terminating the test [26], [27].

CPET can be used on a variety of patient groups, such as individuals with heart failure, lung disease, ischemic heart disease, congenital heart disease, dyspnea of unknown cause and high-level athletes [28]. CPET is used for diagnostic evaluation, risk stratification, therapeutic assessment and exercise prescription for both patients and athletes. Since CPET represents a more advanced form of exercise testing, solutions that function reliably in this setting are also expected to be applicable during conventional exercise stress testing [18].

Despite the clinical importance of BP monitoring during CPET, current NIBP measurement methods used during the CPET remain limited in terms of standardization and clinical validation [29]. Most existing NIBP measurement methods are based on techniques developed for resting conditions, where minimal movement is required and their performance is therefore challenged in exercise settings due to artifacts related to motion [30]. Improving BP measurement during CPET could enhance patient safety and support more reliable clinical decision-making and interpretation of test results [26], [29], [31]. Nevertheless, current evidence gaps indicate a need for further research and technological development in this area [31].

1.4 Purpose

The purpose of this master's thesis is to design, conceptually develop and prototype a non-invasive BP measurement device suitable for use during CPET, according to user requirements (URs) and regulatory constraints.

1.5 Objectives

1. Identify the user requirements (URs) for the non-invasive BP measurement device for CPET.
2. Determine the product requirements (PRs) of the non-invasive BP measurement device for CPET, based on URs and regulatory constraints.
3. A conceptual design of a device that meets the user and PRs will be made. Furthermore, the conceptual design will be prototyped and iteratively modified to meet more of the PRs.
4. Initiate the development of the Technical Documentation in accordance with Medical Device Regulation (MDR).

1.6 Limitations

Market analysis
This master's thesis is in the early stage of developing a non-invasive product for measuring BP. A comprehensive market analysis will not be conducted in the scope of this project [18]. Instead, the work will rely on previously conducted market analysis performed by the MT at SU.

Clinical trials
This project does not include clinical trials or patient testing. The developed prototype will not be assessed under intended clinical conditions, instead the validation performed within this thesis is limited to non-clinical methods. Demonstrating sufficient clinical evidence of safety and performance is essential for regulatory compliance. However, if a clinical trial is required to meet regulatory constraints, it will be outside the scope of this thesis and thus considered future work.

Interviews
URs will be derived from interviews with healthcare professionals working at the DCP at SU. Interviews with patients who undergo CPET will not be done to get their opinions about the product. The interviews will focus on gathering the preferences and specific needs to this clinical environment when a CPET is performed and not gathering the patients opinion after performed test.

Target patients
The project and the solution will mainly focus on BP measurements on adults who are doing a CPET. The possibility of also adapting the product for children will be considered. Depending on its complexity, decisions will be made regarding any adaptation. However, it is not the main focus of the project.

Development of doppler device
This project only focuses on the development of a BP measurement system which

does not include the development of a doppler device for detecting Korotkoff sounds, as this is considered outside the scope of the project.

Future implementation cite
Finally, the scope of the project is limited for developing a solution for the needs of the DCP at SU. The work does not aim to develop a product that will be used worldwide. Large scale manufacturing and implementation in different healthcare systems are therefore outside the scope of this master's thesis.

2
Background

In this section the regulatory framework applicable to general medical devices are introduced. This regulatory framework includes the MDR and the most relevant standards applicable to a NIBP device for CPET.

2.1 NIBP device for CPET at Sahlgrenska University Hospital

Reliable NIBP measurement during CPET is essential for patient safety and clinical decision making [32]. At SU, several departments conduct CPET using different methods and devices for NIBP monitoring [33], [34], [35]. In this section, the current practices at the Department of Clinical Physiology (DCP) units across the hospital, including Sahlgrenska Hospital (SS), Östra Hospital (ÖS) and Queen Silvia Children's Hospital (QSCH), are discussed. Furthermore, it examines the limitations of existing equipment. The findings underscore the need for a robust, clinically validated solution tailored to the workflow of the DCP.

At all DCPs, both a bicycle ergometer and a treadmill are available for performing CPET [33], [34], [35]. The preferred method is to use the bicycle ergometer, although a treadmill is used in cases where the patient has difficulty cycling. A common feature across all departments is that the CPET procedure is conducted by a Biomedical Analyst (BMA), who is responsible for measuring BP, monitoring additional physiological parameters and guiding the patient throughout the test. A physician is also present during the test to oversee physiological parameters and assess the patient's clinical status, together with the BMA.

BP measurements are obtained at multiple stages and locations within the testing room [33], [34], [35]. Initially, measurements are taken with the patient lying on a bed. Subsequent measurements are performed during exercise, typically on a bicycle ergometer, and then repeated on the bed following completion of the exercise phase. The different DCP use different measurement methods even though they all are measuring the BP during CPET.

2.1.1 DCP at SS

At the DCP at SS, BP during CPET is measured using an inflatable cuff in combination with either a stethoscope or a doppler device [33]. The cuff is positioned on the patient's upper arm and is automatically inflated to a predefined pressure of 240 mmHg when a foot pedal is activated. If required, additional manual inflation can be applied, and finally, the pressure in the cuff is released manually.

The cuff inflation is facilitated by an in-house developed device [36]. This system uses compressed respiratory air supplied through the hospital's wall outlets at an approximate pressure of 5 bar. Both the bed, bicycle and treadmill are equipped with manometers that are relatively large for monitoring pressure inside the cuff.

The current cuff inflation device is outdated and presents several challenges. Due to its age and in-house design, replacement of components is difficult, as many parts are no longer commercially available [36]. Furthermore, the lack of technical documentation complicates maintenance and repair efforts, increasing the risk of prolonged downtime and limiting serviceability.

2.1.2 DCP at ÖS

The current method used at ÖS is based on an automatic inflation system that is entirely mechanical and does not require electricity [37]. The inflation system is connected to the hospital's compressed respiratory air through the wall outlet. The BMA controls the applied pressure using a manual control rotary knob [34]. This allows the BMA to regulate both the rate at which the pressure increases in the cuff and the rate at which it decreases. This can be done both quickly and slowly, depending on what is preferred. The wheel also controls the amount of pressure applied to the cuff, meaning the BMA can choose whether a higher pressure is needed or if a lower pressure is sufficient. The automatic inflation system is limited to a maximum cuff pressure of 300 mmHg, preventing the pressure from being increased beyond this level. The bed, bicycle and treadmill are all equipped with relatively large manometers for monitoring cuff pressure.

In some rooms, only one device is available, while others are equipped with two. When only one device is present, it must be moved between the bed and the bicycle (or treadmill) depending on the type of measurement being performed. This transfer can be difficult due to the short connecting cable [34].

To detect and assess BP the BMAs primarily use a doppler probe placed at the wrist, although a stethoscope can also be used as an alternative [34]. A major limitation of the current box that regulates the pressure method is that it is no longer commercially available [37]. This creates a significant risk if the equipment fails or becomes damaged, because then it may not be possible to replace it. In such cases, measurements would need to be performed manually, which could have a negative impact on the ergonomics and working conditions of healthcare staff.

2.1.3 DCP at QSCH

The DCP at QSCH also perform CPET and workflow tests [35]. Here, ages range from 6 to 18 years. BP measurement in children differs from adults due to variations in arm circumference and physiological BP ranges. Patient comfort is also an important consideration, as children may be more sensitive to discomfort caused by cuff inflation. Currently, all BP measurements during these tests are performed manually, where the BMA inflates the cuff by hand. This method generally functions well. However, in cases where very high cuff pressures are required, sometimes up to 300 mmHg, the manual inflation can become physically demanding for the operator. Even though, in most cases, the required pressure is lower and this work environment issue is therefore relatively uncommon. The deflation of the cuff is also done manually.

The pressure is measured using a manometer attached directly to the cuff [35]. This means that the manometer is positioned on the patient's arm during cycling and may therefore be affected by movement of the arm and varying levels of muscle tension. According to the BMAs at DCP at QSCH, the needle of the manometer can move back and forth during exercise, making the pressure more difficult to read. However, it is unclear whether this movement is caused by actual variations in cuff pressure, movement of the arm, muscle activity or a combination of these factors. In addition, the small size and position of the manometer further contribute to the difficulty of reading the pressure during the test. A potential improvement suggested by the BMAs was to use a larger external manometer positioned separately from the patient's arm [35].

2.1.4 Market analysis

The Department of Biomedical Engineering (MT) at SU has conducted a market analysis to identify potential replacements for the existing BP measurement equipment used at the DCP at both SS and ÖS [18], [36], [37]. As part of this evaluation, an automatic BP device intended for use during CPET and exercise stress test was borrowed and a test setup was conducted by the DCP at SS together with MT. The device was assessed during an exercise stress test session in which an MT employee served as the test subject. The cuff of the new device was placed on one upper arm, while a reference device was placed on the other arm to enable direct comparison.

The results demonstrated that the new device produced highly inaccurate measurements [36]. In addition, its operation was considered impractical for CPET since the user was required to activate a filter function once the BP exceeded a certain threshold. Although, the expected BP prior to each measurement was uncertain, it was difficult to determine whether activation of the filter was necessary. This made the device unnecessarily complex to operate. As a result, the device demanded too much attention from the operator, diverting focus away from the test subject and the overall monitoring process.

As previously described, all three DCPs currently have the option to use a doppler device in combination with their respective cuff inflation systems [33], [34], [35], [36],

[37]. A limitation is that the doppler device in use relies on a flat-headed probe that is no longer available on the market. Although pen-style probes are available as alternatives, they are not compatible with the CPET workflow and therefore not an appropriate replacement [33], [34], [35], [36], [37], [38].

2.2 MDR

The regulations for medical devices, known as the EU Regulation 2017/745 on Medical Devices (MDR), were adopted in May 2017 and came into effect on May 26, 2021 [39], [40]. The purpose of introducing these updated regulations was to establish a regulatory framework that is transparent, sustainable and robust. The MDR aims to ensure a high level of patient safety while also supporting innovation and the development of new medical technologies [41].

The previous regulatory framework for medical devices in the European Union (EU) was developed in the 1990s [41]. Since then, significant advances have occurred in both technology and scientific research. The earlier regulations contained several weaknesses, which led to incidents that reduced the trust in the safety of medical devices among patients, consumers and healthcare professionals. In response to these challenges, the European Commission proposed two new regulations in 2012 to replace the existing three directives. These proposals later formed the basis of the MDR and the updated regulations strengthen the control and oversight of medical devices, aiming to create a safer and more effective regulatory system. At the same time, they are designed to continue supporting innovation in the development of new products. Consequently, the MDR represents an important update to the regulatory framework, reflecting technological progress while further enhancing patient safety [41].

2.2.1 Different risk classes

There are four main risk classes for medical devices: I, IIa, IIb, and III. The classification is determined based on the intended use of the device and the level of its risk associated with it [42]. Class I devices can be further categorized into sterile devices (Is), devices with a measuring function (Im) and reusable surgical instruments (Ir). These are not separate classes but rather subcategories within Class I, reflecting specific characteristics that may influence conformity assessment procedures [43]. The assigned risk class determines the regulatory requirements and procedures that the manufacturer must follow to demonstrate compliance with applicable regulations. Classification must be carried out in accordance with Annex VIII which contains 22 different rules and is an essential part of the technical documentation. If a product is intended to be used in combination with other devices, each device must be classified separately. In cases where a device may fall under multiple classification rules, the strictest applicable rule determines the final classification. Consequently, the device is assigned to the higher risk class [43].

According to Annex VIII MDR, products within risk Class I are typically characterized as non invasive, intended for use during a short term and having no biological or chemical impact on the human body [44]. Examples of Class I devices include stethoscopes and non-invasive electrodes [42]. Class IIa devices are associated with a moderate level of risk and may include both non invasive and invasive products [44]. In the case of invasive products, they are generally intended for use during a short term and have a limited impact on the body. A key aspect of this class is that the devices do not cause an immediate life threatening risk. Examples of Class IIa devices include electronic blood pressure measuring equipment and diagnostic ultrasound [42].

In contrast, Class IIb devices represent a higher level of risk or increased functional complexity [44]. This includes, for instance, invasive products used for longer durations or products that changes the biological or chemical composition of the body. Active devices may also fall into Class IIb if they deliver energy in a potentially hazardous way or are used to monitor vital physiological functions. Due to their intended use and level of interaction with the body, these devices may involve increased risks. In many cases, they also incorporate more advanced technological features. An example of a Class IIb device are ventilators [42]. Class III devices represent the highest risk category [44]. Examples include implants used in the heart or central nervous system, as well as products that are absorbed by the body. Due to their high level of invasiveness and significant interaction with the body, failure of Class III devices is associated with a high risk of serious injury or death [44].

Differences in regulatory requirements between the risk classes are substantial [43]. For Class I devices, manufacturers can often perform conformity assessment themselves through self certification and the involvement of a notified body (NB) is not required [44]. Additionally, the need for clinical data is limited. For Class IIa devices, a NB must be involved to review the technical documentation and the QMS. Clinical evaluation is required, although it is not as extensive as for higher risk classes.

For Class IIb devices, the requirements become more stringent [44]. The NB performs a more detailed review, and there is a greater need for clinical evidence, risk management and detailed technical documentation. The assessment of design and performance is also more comprehensive. Class III devices are subject to the most demanding regulatory requirements. These devices require a full conformity assessment by a NB and typically involve extensive clinical investigations. In addition, comprehensive risk analysis, detailed documentation and strict post-market surveillance are required to ensure ongoing safety and performance after the product has been placed on the market [44].

2.2.2 CE marking

A CE mark indicates that a medical device complies with the applicable regulatory requirements and may be placed on the market [45]. It also confirms that risk management procedures are implemented and continuously monitored throughout the product lifecycle. For certain Class I devices (Is, Im, and Ir) and for all higher

risk classes (IIa, IIb, and III), certification by a NB is required. The manufacturer is responsible for selecting a NB, which then assesses the product and issues a conformity assessment certificate. For the higher risk devices, the NB performs a more comprehensive assessment compared for the one in Class I, which includes the QMS and the technical documentation of the manufacturer.

As part of the QMS assessment, the NB evaluates the manufacturer's overall processes, including how products are designed and manufactured, how risks are systematically identified and managed and how deviations are handled [45]. In contrast, the technical documentation focuses on a specific device and verifies that all relevant requirements are fulfilled, including device description, design specifications, risk analysis, clinical evaluation and evidence of safety and performance. Although these assessments address different levels, there is some overlap, particularly in areas such as risk management and clinical evaluation, where both the process and its implementation must be demonstrated.

Even though a conformity assessment certificate is issued by a NB, it does not automatically result in CE marking [45]. The manufacturer remains fully responsible for ensuring that the product complies with all applicable regulatory requirements [45]. After this, the manufacturer must draw up an EU Declaration of Conformity, confirming that the manufacturer follows all applicable requirements and that the product has been correctly CE-marked as a medical device [44]. The product must then be registered in EUDAMED, which is the European database for medical devices. Finally, post-market surveillance must be carried out throughout the entire lifecycle of the product to ensure continued safety and performance [44].

2.2.3 In-house manufactured medical devices

In-house manufacturing of medical devices allows healthcare institutions to address specific clinical needs when suitable solutions are not available on the market [44], [46], [47]. This enables the development of devices adapted to specific healthcare environments while ensuring that requirements regarding safety and performance are maintained. In-house manufactured medical devices must comply with the MDR [47], [39], [44], [46]. The regulation says that in-house manufactured devices are devices that are designed and manufactured to be used exclusively within the healthcare institution where they are developed. A healthcare institution is only permitted to manufacture a medical device in-house if no equivalent product is available on the market that meets the same intended use. This implies that existing market solutions do not sufficiently address the clinical need, which must be clearly justified and documented [47], [44], [46].

In-house manufacturing also includes situations where a device is used outside its originally intended purpose [44]. Use outside the intended purpose shift responsibility to the user and require appropriate risk assessment. In such cases, the device is modified or adapted through an in-house manufacturing process in order to align the product with its modified intended use. Therefore, when a

device is adapted for an alternative use through in-house manufacturing, whether it is a completely new device or an existing device repurposed for a different intended use, the healthcare institution assumes full responsibility for the safety, performance and regulatory compliance of the device [44]. A large part of MDR is not applicable to in-house manufacturing but the products level of safety, quality and performance should still be at the same level as that of a CE-marked medical device [47], [46]. From Figure 2.1, it is clear that both in-house devices and other medical devices are regulated under the MDR. Even though, in-house devices are not required to fulfill the exact same requirements as CE-marked products. Despite these differences, both types of devices require risk management as an ongoing process throughout the entire development phase and even after the declaration. A list of requirements that needs to be followed for in-house devices are given in Table 2.1, but overall the rules to follow is stated in Annex I in MDR [46].

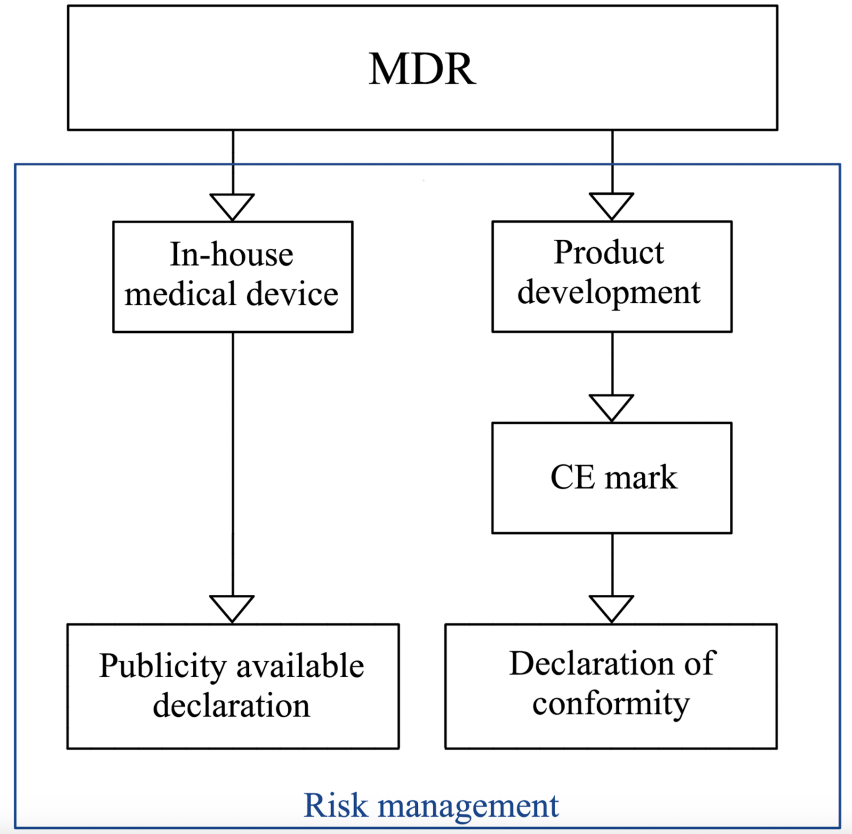


Figure 2.1: Schematic overview of the differences between in-house medical devices and CE-marked products within the MDR framework.

There are several MDR requirements that do not apply to in-house devices [48], [44]. Since these devices are manufactured and used exclusively within the same health institution, requirements associated with placing a medical device on the EU market are not applicable [44], [48]. This includes obligations related to commercial distribution, market availability, CE marking, conformity assessment procedures involving a NB and registration in EUDAMED. Overall, these exemptions simplify

the regulatory process for healthcare institutions developing devices for internal clinical use while still requiring compliance with relevant safety and performance standards [44].

Furthermore, in the documentation it needs to be justified whether the in-house manufactured device meets the General Safety and Performance Requirements (GSPRs) that is mentioned in Annex I of the MDR [44]. If any of the requirements are not fulfilled, the documentation must include a justification explaining why compliance could not be achieved.

Table 2.1: Summary of MDR-related requirements that apply to in-house manufactured devices [46].

Rules to follow for in-house devices	**More detailed description**
Needs to comply with relevant GSPRs in Annex I of the MDR	Examples include risk management, design and manufacturing processes, performance and product-related information. These requirements are specified in Chapters I–III of Annex I.
Manufacture and use of the device are limited to the healthcare unit where it was developed	According to HSLF-FS 2021:32, healthcare institutions manufacturing in-house medical devices must report the healthcare provider's organisation number to the Swedish Health and Social Care Inspectorate (IVO) [49]. This means that the healthcare provider is defined at organisational level, which in this case refers to Västra Götalandsregionen (VGR), and thus that devices manufactured at SU may only be used within VGR.
An appropriate QMS must be in place	Covers responsibilities for management, manufacturing, risk management, monitoring and handling deviations, including communication with authorities.
Documentation describing manufacturing, processes, and design/performance must be available	Documentation shall be sufficiently detailed to allow authorities to verify compliance with Annex I requirements.
Device traceability and labelling must be ensured	Ensures identification of the device throughout its lifecycle and compliance with labelling requirements.
Risk–benefit documentation must be updated	Includes continuous reporting, evaluation and implementation of necessary actions.
Risk management	Documentation describing how different risks have been managed and how they should be managed in the future.
Justification that the need cannot be met by an equivalent product on the market	A comparable CE-marked product may already be commercially available. Therefore, it must be clearly demonstrated that the specific need is not adequately covered.
Documentation must be updated when changes are made	Ensures continued compliance with all applicable requirements after modifications.

2.3 Limitations of MDR and proposed regulatory revisions

The MDR came into effect on 26 May 2021, as previously mentioned in the section about MDR [50]. These regulations included stricter requirements for the manufacturing of medical devices, while also introducing a more reliable system to ensure the quality, safety and performance of the products within the EU market. They also aimed to ensure that conformity assessments are made in a consistent way.

In 2024, the European Commission conducted an evaluation of the MDR [50], [51]. The results highlighted several challenges, particularly reduced product availability and barriers to innovation, which may negatively affect the competitiveness of EU companies. Consequently, this may lead to indirect negative impacts on healthcare quality and patient safety. These limitations have also been observed in clinical practice by staff at SU [18]. One challenge is that medical devices intended for smaller or more specialized markets may become less economically feasible to develop, as increased regulatory requirements can lead to higher development costs and administrative burden in relation to the expected market size [52], [53]. Furthermore, staff at SU report that even minor improvements to a product's use or application require extensive processes to implement [18]. As a result, the potential benefits of such changes may not be fully achieved, as implementation requires significant time and resources. The administrative requirements are important and include, among other things, detailed risk analyses. In some cases, this leads to delays in implementing necessary improvements, which may affect patient safety if beneficial changes are not introduced in time. A similar challenge can be seen in the in-house manufacturing of medical devices. The development of new products is complex and time-consuming, which may delay access to improved solutions and thereby negatively affect patients during the development phase [18].

2.4 Counterparts to MDR

Regulatory frameworks for medical devices vary across different regions, reflecting differences in regulatory structures and approaches to ensuring patient safety [54]. Understanding these differences is essential when considering market access, as regulatory requirements influence development timelines, costs and the level of evidence required for approval.

Although Switzerland is located in Europe, it is not a member of the European Union (EU) or the European Economic Area (EES) and is therefore not directly subject to the MDR [55]. Instead, Switzerland has established its own regulatory framework, the Medical Devices Ordinance (MedDO), which is largely aligned with the MDR [56]. While conformity is demonstrated according to MedDO rather than directly under the MDR, the regulation incorporates many MDR requirements and can therefore be regarded as a Swiss-adapted implementation of the European

framework [56].

A more substantial difference can be observed when comparing the European regulatory framework (MDR and MedDO) with that of the United States of America (U.S.). In the U.S., medical devices are regulated by the Food and Drug Administration (FDA). More specifically it is regulated under FDA's Title 21 of the Code of Federal Regulations (CFR), where specific parts apply to medical devices [57]. One fundamental difference between the frameworks lies in their classification systems, the FDA categorizes devices into three risk classes, which from the lowest to the highest risk class is Class I, II and III, this can be compared to the MDR that classifies into four risk classes [58]. In addition, the level of required clinical evidence varies more significantly across risk classes within the FDA system, particularly less clinical evidence is needed for devices with lower risk in this system.

Another key distinction concerns the regulatory structure and approval process [58]. In the EU, independent NBs (NB) are responsible for assessing conformity and reviewing technical documentation before a device can obtain CE marking. In contrast, the FDA acts as a centralized authority that directly evaluates and clears or approves medical devices. Differences are also evident in post-market surveillance (PMS), where the MDR follows a proactive and continuous approach, that includes periodic safety update reports, while the FDA system is generally more reactive and focuses on adverse event reporting and recalls. Furthermore, compliance with the MDR is generally associated with longer time-to-market, partly due to more extensive documentation and stricter requirements for clinical evaluation [59]. The cost of achieving regulatory compliance is also typically higher under the MDR, particularly for devices with lower risk, due to the broader scope of requirements [60]. In contrast, for devices with higher risk, the costs may exceed those associated with MDR compliance.

Medical devices can enter the U.S. market through the FDA by different regulatory pathways [61]. The pathways differ in the requirements on the medical device, more specifically they differ in the demand for clinical evidence and level of innovation of the device. The most common regulatory FDA pathway is 510(k), followed by the pathways premarket approval (PMA) and De Novo [62], [63]. Medical devices that can demonstrate substantial equivalence to a legally marketed existing devices may qualify for the 510(k) pathway. This pathway generally enables faster market access, as it typically requires less extensive clinical evidence compared to other regulatory routes [59], [64]. A comparable concept, where clinical evaluation could be supported by data from an equivalent device, was previously used under the Medical Device Directive (MDD) [65], [44]. With the transition to the MDR, the conditions for using equivalence became more restrictive, requiring stronger justification and more comprehensive clinical evidence to demonstrate device safety and performance. Devices classified as Class III, which are considered high-risk, typically require Premarket Approval (PMA), a more rigorous process involving comprehensive evaluation of safety and effectiveness, this often includes clinical investigations [66]. For novel medical devices without a legally marketed existing devices and where the devices is classified as a Class I or Class II, the De Novo pathway is the route to

access the market [67].

Overall, the MDR framework tends to require more comprehensive documentation and a higher level of regulatory expertise [68]. Compared to the FDA system, the MDR involves more extensive requirements related to technical documentation, clinical evaluation and PMS.

2.5 Standards

A standard is a widely accepted solution to a recurring problem that ensures consistency, quality, compatibility and efficient communication between stakeholders [69]. It is a document that specifies requirements and standardized methods of working within a specific area [70]. Standards can exist at different levels. International standards are typically developed by organizations such as ISO or IEC, while European standards are referred to as EN. At the national level, standards are published with country specific prefixes and in Sweden, these are designated as SS [70].

When a standard is harmonised, it has been formally linked to a specific regulation, such as the MDR [70]. The relationship between the standard and the regulation is clarified in annexes, where similarities and differences are outlined. Compliance with a harmonised standard provides a evidence of conformity with the relevant regulatory requirements covered by that standard. Even though, harmonised standards do not necessarily cover all applicable requirements. Therefore, it remains the responsibility of the manufacturer to ensure full compliance with the regulation. An example of this is the QMS standard ISO 13485. Although it is harmonised, it does not address all requirements of the MDR in the area, meaning that additional measures may be required to achieve full regulatory compliance [70].

In the development of new medical devices, such as BP measurement systems, relevant standards serve as important guidance, particularly in areas such as risk management, usability, electrical safety and quality management [71]. Some of the most relevant standards are presented below.

2.5.1 ISO 14971:2019 – Risk management

Risk management is an essential part of medical device development since it helps ensure that devices can be used safely [72]. Risk management for medical devices is conducted according to the international standard ISO 14971, which describes a systematic framework for identifying hazards, estimating and evaluating risks and implementing appropriate risk control measures throughout the device life cycle [72]. The objective of this structured process is to ensure that medical devices achieve an acceptable level of safety while maintaining their intended clinical performance [73]. Implementing such a systematic risk management approach is widely recognized as an essential requirement for safe and effective medical device development [73].

The risk analysis process typically begins with identifying hazards related to the device, its intended use and possible misuse [74], [75]. These hazards may include, for example, incorrect pressure readings, electrical faults or inaccurate use, depending on the device design and the intended use. After hazards have been identified, the associated risks are assessed by analysing both the likelihood that harm may occur and the severity of potential consequences. If the estimated risk is considered unacceptable, appropriate mitigation strategies must be implemented to reduce the risk to an acceptable level [72]. In addition to the principles described in ISO 14971, the MDR further emphasizes that risks should be reduced as far as possible and that any remaining residual risks must be acceptable in relation to the expected clinical benefits of the device [44]. In situations where a risk cannot be further reduced without negatively affecting the performance of the device, a benefit–risk analysis should be performed [72]. This evaluation examines whether the expected clinical benefits of the device outweigh the remaining residual risks. Benefit–risk assessments therefore support decisions regarding the acceptability of residual risks and whether the device can be considered sufficiently safe for its intended use.

The risk mitigation strategies include design changes, protective mechanisms or information provided to users about potential risks [72]. According to ISO 14971, risk control measures should be implemented following a prioritized hierarchy. One or several risk control measures may be necessary depending on what is applicable to the specific hazard. First, inherently safe design solutions should be considered in order to eliminate or reduce risks directly through the design of the device. If this is not sufficient, protective measures such as safety mechanisms or alarms may be implemented to further reduce the risk. As a final step, saftey information, including warnings or Instructions for Use (IFU), may be provided to inform users about any remaining risks [72]. The standard also emphasizes the importance of verifying and validating that implemented risk control measures are effective. Because new hazards may arise as the design evolves, risk management is considered an iterative process. This process continues throughout the development and evaluation stages of medical devices and throughout the entire lifetime of the device [74], [75]. During this iterative risk management process it is essential to ensure continuous documentation and traceability in order to get regulatory approval [72].

Overall, the application of ISO 14971 contributes to a systematic and proactive approach to safety, ensuring that risks are minimized as far as possible and that the device can be considered safe for its intended use [72]. In practice, risk management according to ISO 14971 is closely integrated with other standards addressing different aspects of medical device development.

2.5.2 SS-EN 62366-1:2015 - Usability engineering

This standard focuses on usability engineering to ensure that medical devices are safe, effective and user friendly [76]. The standard is particularly important as medical devices are increasingly used by users who are not specialists, for example patients, which places higher demands on intuitive design and user safety. The technical

report IEC TR 62366-2 provides guidance on how to apply usability engineering principles in practice. This includes methods for identifying usability related hazards and conducting formative and summative evaluations of user interfaces [77]. In total, usability engineering is a critical aspect of medical device development, as it directly impacts both patient safety and device effectiveness.

2.5.3 SS-EN ISO 13485:2016 - Quality management systems

This standard defines requirements for quality management systems (QMS) for organizations that develop, manufacture or distribute medical devices [78]. It focuses on meeting regulatory requirements and applies to the entire life cycle of the device. This includes design, development, production and use. The standard ensures that companies have appropriate documentation and that appropriate processes are established.
It includes requirements for management responsibility, document control and process validation. These help ensure that products are safe and meet regulatory standards. The standard also requires procedures for monitoring and measuring equipment. For example, sensors used to measure BP must be regularly calibrated to ensure accurate readings. Test equipment used during development must also be checked and verified to ensure reliable results, which includes calibration and validation of software. The main goal is to create a structured QMS. This helps ensure continuous compliance and improves patient safety.

3
Methods

This section outlines the methodology used to achieve the objectives of the thesis. It describes the processes for background research, requirement specification, conceptual design, prototyping and evaluation, together with the risk analysis performed throughout the project.

3.1 Background research and requirement specification

A literature review was conducted to establish the theoretical and clinical background relevant to this thesis. Searches were performed in databases such as PubMed and Google Scholar using keywords related to CPET, BP monitoring during exercise and different NIBP measurement methods. The results of the literature review provided an important foundation for the direction of the project and helped identify the key steps required for further development. However, the literature review was also an ongoing process throughout the project. As new findings related to the proposed solution and regulatory requirements emerged, additional information and relevant knowledge needed to be continuously identified and incorporated into the work.

To identify clinical needs and current limitations, interviews with clinicians working with CPET at the DCP at SU were conducted. The interviews focused on current practices for BP measurement during CPET, including strengths and shortcomings of the existing equipment, as well as clinical expectations regarding measurement performance and sampling frequency of SBP. The results formed the basis for the formulation of URs.

A set of interview questions related to the current solution and potential improvements was prepared. Interviews were carried out at SS, ÖS and QSCH with healthcare professionals involved in CPET procedures. The authors contacted the section managers at the three DCPs, who were responsible for selecting suitable participants for the interviews. During the interviews, participants were encouraged to describe current workflows during CPET, including strengths and shortcomings of the existing equipment, as well as clinical expectations regarding measurement performance and sampling frequency of SBP. The collected information from the interviews was used to identify clinical needs and formulate user requirements. The interview questions are provided in Appendix A.

Additionally, a regulatory analysis was performed to identify the applicable regulatory framework for the intended device, including relevant requirements from the MDR and applicable standards. This regulatory analysis was discussed with the supervisors Jacob Lidman and Selena van der Horst, as they have expertise in the field of in-house manufacturing under the MDR. Regulatory considerations were incorporated to ensure compliance with relevant laws and guidelines. As part of the regulatory considerations, a risk analysis was conducted, which included risk identification, assessment and mitigation. The analysis was initially performed by the authors and subsequently refined through discussions with supervisors and representatives from the DCP. The reason for this was to include as many different risks as possible in order to be able to highlight and minimize them. The risk analysis was performed iteratively alongside other project activities and was continuously refined in response to the evolving development of the prototype.

Based on the URs and identified regulatory constraints, PRs were derived. These requirements will primarily be measurable, enabling verification through testing in later stages of development.

3.2 Conceptual design, prototyping and evaluation

Based on the established PRs, a conceptual design of the device was developed to ensure that the proposed solution aligned with the PRs. This conceptual design included a schematic description of the system architecture and its main components, thereby providing a clear foundation for implementation. In addition, previously used systems as well as systems currently in operation were reviewed in order to gain insight and inspiration for the conceptual design process. The development process was further supported through consultations with domain experts, including the master thesis supervisors with experience in MDR, standards and previous in-house manufacturing and additional engineers from MT at SU.

Following this, the conceptual design was translated into a prototype in order to demonstrate feasibility and enable practical evaluation. A significant amount of time was devoted to compiling a comprehensive list of components required for the intended prototype. This process was followed by discussions with the supervisors to determine which components were already available at the department and which needed to be purchased. Based on this, an initial prototype was assembled using available components, allowing for early functional testing and evaluation of the conceptual design. Subsequently, additional components, were purchased, as no equivalent products were available within the MT. This enabled further development and refinement of the prototype.

The prototype was then presented to the DCP at SS, where the functionality was demonstrated by the authors and tested by a BMA. This provided valuable user feedback regarding which features should be retained and which aspects could be improved in future iterations. Finally, the prototype was tested and iteratively refined, allowing its performance to be improved and its compliance with the PRs to

be strengthened over successive development cycles.

3.2.1 Overview of prototypes

A preliminary component list indicated that no additional components were required for prototype 1, as suitable parts were available within the department. The prototype was therefore assembled using existing components and the iterations of the following prototypes were made by purchase single components from the component list to improve the previous prototypes. An overview of the developed prototypes and their components is presented in Table 3.1.

Table 3.1: Overview of developed prototypes and their components.

Prototype No.	Components	Manufacturer	Article no.
1	Donated pressure regulator	IMI Norgren	R07-100-RNAA
	T-port ball valve	Unknown	Unknown
	Cuff	GE Healthcare	2752
	Manometer	Unknown	Unknown
2	Donated pressure regulator	IMI Norgren	R07-100-RNAA
	L-port ball valve	Syveco	77910984
	Cuff	GE Healthcare	2752
	Manometer	Unknown	Unknown
3	Donated pressure regulator	IMI Norgren	R07-100-RNAA
	Cuff	GE Healthcare	2752
	Manometer	Unknown	Unknown
4	Self-bleeding pressure regulator	IMI Norgren	11-818-999
	Pressure relief valve	IMI Norgren	V72G-2GK-NMN
	Cuff	GE Healthcare	2752
	Manometer	Unknown	Unknown

3.2.2 Feasibility test on prototype no. 1

The prototype consisted of a donated pressure regulator (from another device that did not need it anymore), a cuff, a manometer and a T-port ball valve used for controlling airflow, the setup can be seen in Figure 3.1. The regulator output pressure range was evaluated, and the manometer readings were compared to a calibrated reference manometer.

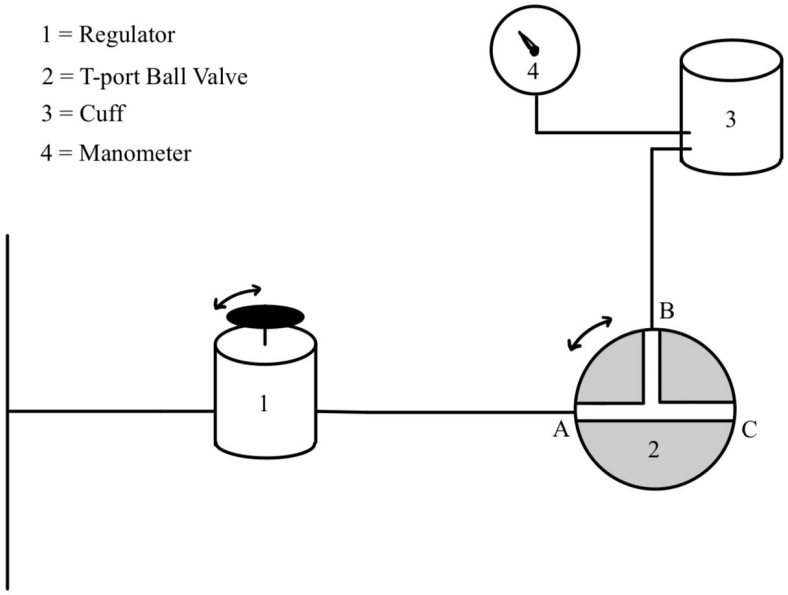
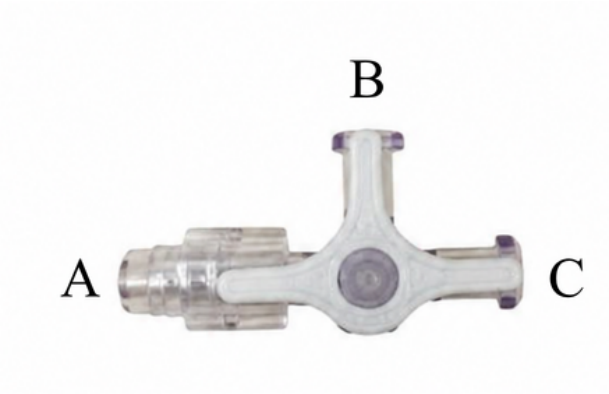
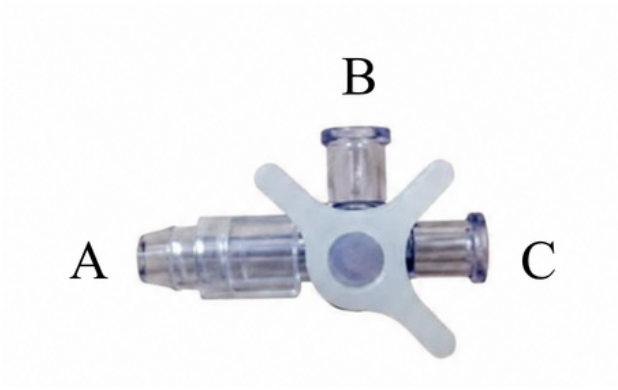


Figure 3.1: Schematic representation of prototype no. 1. The respiratory air wall outlet is shown on the left and is connected to the components indicated accordingly. The bidirectional arrows indicates the rotational adjustment used to control airflow.

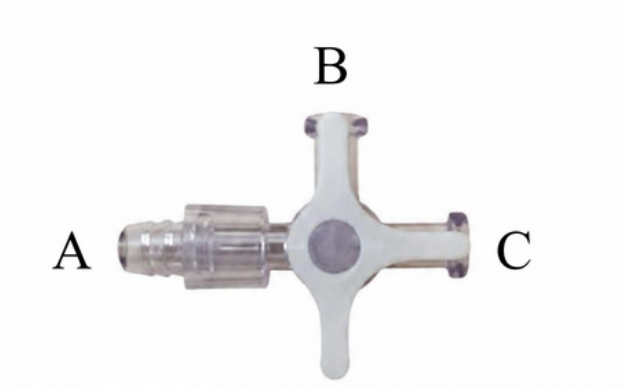
During testing, the cuff was inflated and deflated by manually adjusting the regulator and the T-port ball valve. Since the valve has three ports, one port was manually blocked to create an L-shaped flow path, ensuring that airflow occurred only between two selected ports at a time. The regulator was set to a maximum pressure of 300 mmHg for all tests. For cuff inflation, the valve was positioned to allow airflow from the inlet (port A) to the cuff (port B), while the outlet (port C) was blocked, shown in Figure 3.4, where the T-port functioned as an L-port. For deflation, the valve was rotated 90° clockwise to redirect the airflow from the cuff (port B) to the outlet (port C), while the inlet (port A) was blocked, as demonstrated in Figure 3.2. This allowed air to exit the cuff in a controlled manner. The different valve configurations and flow paths are illustrated in Figures 3.1 and 3.4, where the rotational adjustment of the valve determines the direction of airflow.



(a) T-port inlet position.



(b) T-port in-between position.



(c) T-port out position.

Figure 3.2: Comparison of T-port configurations.

In cases where residual air remained in the cuff, an expansion volume was used instead of the cuff to enable more controlled testing conditions, this applies for all tests where a cuff was used if the same issue occurred. The performance of inflation and deflation was evaluated in terms of response time and controllability.

3.2.3 Feasibility test on prototype no. 2

The second prototype consisted of the same components as the first one, except the T-port that was replaced with an L-port ball valve instead, as demonstrated in Figure 3.3. The valve was manually operated using its handle to switch between inflation and deflation modes, as seen schematically in Figure 3.4 and physically in Figure 3.5. The purpose of replacing the previously used T-port valve with an L-port valve was to improve usability by providing a larger handle and to prevent configurations where more than two ports are open simultaneously. The system was tested by inflating the cuff to the desired pressure using the regulator, followed by manual adjustment of the L-port valve to initiate deflation. The performance was evaluated in terms of inflation time, deflation behaviour and controllability of pressure release.

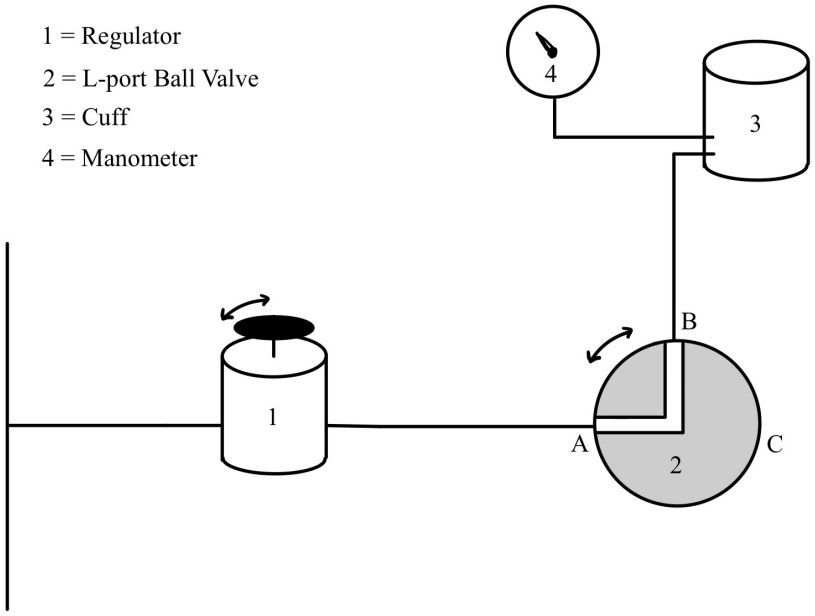


Figure 3.3: Schematic representation of prototype no. 2. The respiratory air wall outlet is shown on the left and is connected to the components indicated accordingly. The bidirectional arrows indicates the rotational adjustment used to control airflow.

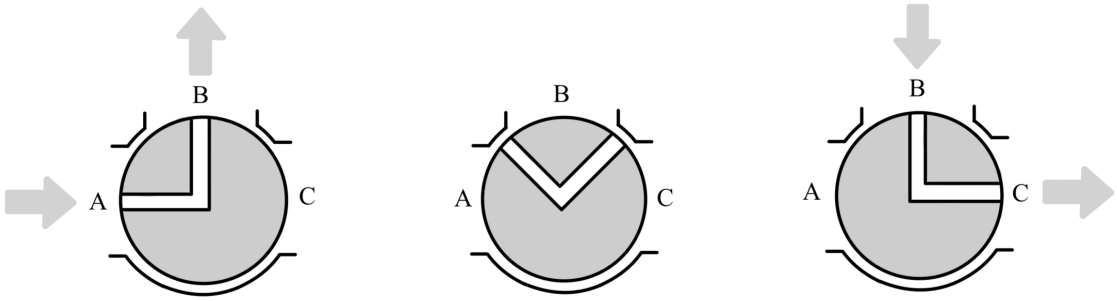


Figure 3.4: Different modes and an in-between position for the L-port ball valve used in prototype no. 2.

(a) Inlet position.

(b) In-between position.

(c) Outlet position.

Figure 3.5: L-port ball valve in different positions.

3.2.4 Leakage test and regulator identification on prototype no. 3

The third prototype consisted of the same components as the second prototype but the L-port ball valve was removed and was not replaced by any other component, as illustrated in Figure 3.6.

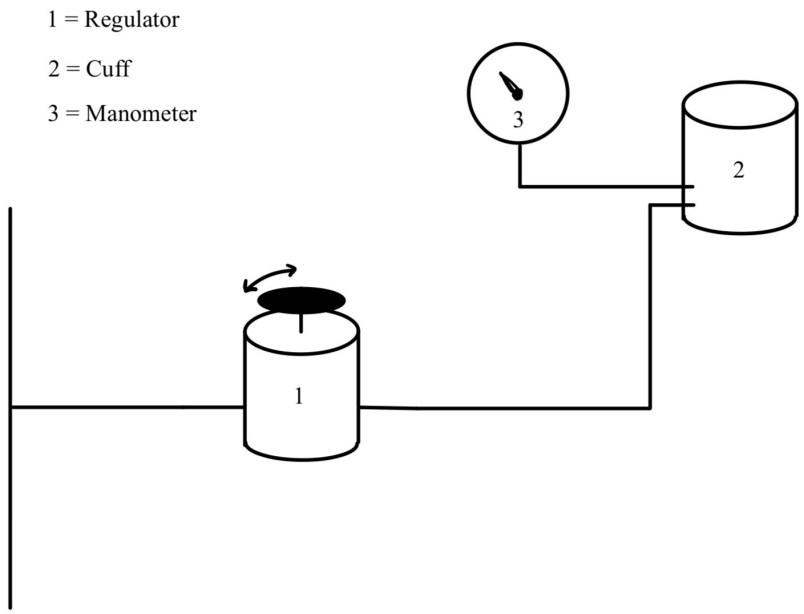


Figure 3.6: Schematic representation of prototype no. 3. The respiratory air wall outlet is shown on the left and is connected to the components indicated accordingly. A bidirectional arrow indicates the rotational adjustment used to control airflow.

It was conducted leakage test and regulator identification on prototype no. 3 to evaluate whether the donated pressure regulator exhibits a self-relieving function when the outlet pressure is decreased. A leak detection spray was applied to the regulator during operation to identify potential air leakage and to observe any air release during pressure adjustment. The regulator was further inspected visually to identify possible exhaust paths. In addition, leak detection spray was also applied to all connections in the system to assess potential leakage points. To quantify system leakage, additional testing was performed using an expansion volume, instead of a cuff, connected to the system together with a calibrated manometer. The pressure decay over time was measured to estimate the leakage rate.

3.2.5 Effect of tubing length on inflation and deflation time on prototype no. 3

Two configurations with different tubing lengths between the regulator and the cuff were evaluated in terms of inflation and deflation time. The total tubing length for the short configuration was 57 cm, while the long configuration had a total length

of 436 cm. For each configuration, the cuff was inflated by adjusting the regulator as quickly as possible until a pressure of 300 mmHg was reached. Immediately thereafter, the regulator was adjusted to release the pressure as quickly as possible. The total time required for inflation and subsequent deflation was measured using a stopwatch. The timing was initiated simultaneously with the regulator adjustment. It should be noted that minor timing inaccuracies may be present due to human reaction time.

Additional tests were conducted using a flow meter with a maximum flow rate of 15 L/min, placed in the system during deflation. The purpose of this test was to determine the flow rate of the system in order to establish the flow requirements before purchasing the safety relief valve.

3.2.6 Feedback from SS on prototype no. 3

A feedback session was conducted with a BMA and a physician at the DCP at SS to evaluate the usability, ergonomics and safety of the developed prototype. Prototype 3 was presented and demonstrated, and the L-port valve was also introduced as an alternative solution. During the session, the functionality of the prototype was demonstrated by the authors, after this the BMA tested the device in the demonstrated way. The evaluation was based on observations, functionality testing and open discussion. The session focused on aspects such as control of cuff inflation and deflation, user interaction with the control mechanism, device placement in the clinical environment and safety considerations. The feedback obtained from this session was used to guide further development of the prototype.

3.2.7 Feasibility test on prototype no. 4

Prototype no. 4 consisted of a new regulator, a pressure relief valve, a cuff and a manometer, as shown in Figure 3.7. All components were integrated and tested. Some connectors and tubing had to be replaced to ensure compatibility with the new components. Resistance of the rotary knob attached to the regulator was evaluated, along with the ability to inflate and deflate the cuff. The fastest inflation and deflation times were measured. In addition, the ability to release the pressure with varying velocity was tested. Furthermore, it was examined whether the pressure could be maintained at a steady level or if it decreased over time. For this purpose, the pressure was increased to 300 mmHg, held for 15 seconds, and then released.

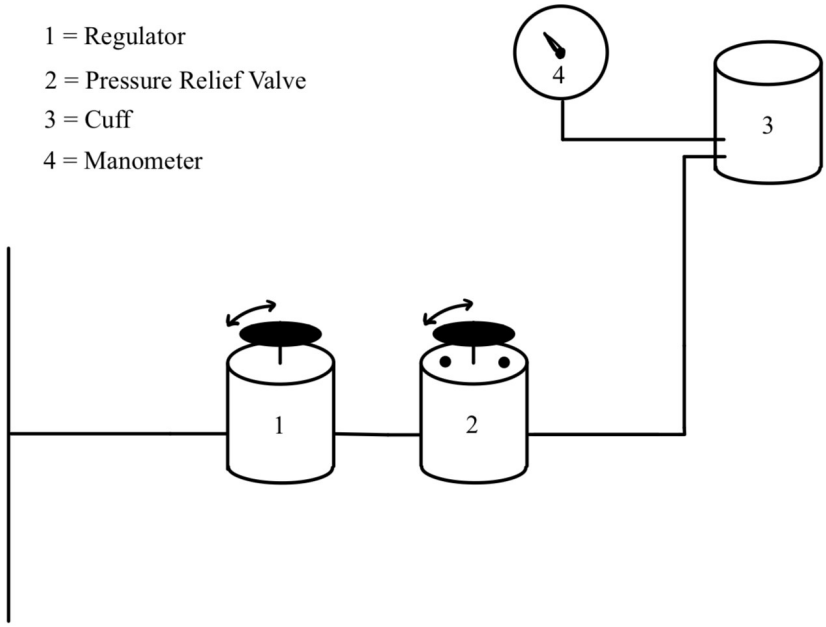


Figure 3.7: Schematic representation of prototype no. 4. The respiratory air wall outlet is shown on the left and is connected to the components indicated accordingly. The bidirectional arrows indicates the rotational adjustment used to control airflow. The dots on the pressure relief valve represents the airflow outlet valves.

To evaluate the function of the pressure relief valve, it was connected according to the manufacturer's instructions. However, after installation, a third port remained open. As the instructions did not provide information regarding this connection, and after consultation with the manufacturer, it was decided to cover this third port with the hand of one of the authors. The relief valve was then set to its lowest release level ($0.3\,\text{bar} \approx 225\,\text{mmHg}$). The pressure was subsequently increased beyond this threshold to assess whether the valve functioned correctly.

3.2.8 Feedback from SS on prototype no. 4

A feedback session was conducted with clinical staff from the DCP at SS to evaluate prototype no. 4. The session included two BMAs and a physician. The prototype was first demonstrated by the authors, after which the participants were allowed to interact with the device. The evaluation focused on usability, ergonomics and functionality of the pressure regulation mechanism, with particular focus on control of cuff inflation and deflation. The feedback was collected through observations, hands-on testing and open discussion during the session. The purpose was to identify strengths, limitations and areas for improvement to guide further development of the prototype.

3.3 Risk analysis

The risk analysis was conducted as a continuous process throughout the entire project. Initiating the process early and running it in parallel with the development phase facilitated the identification of potential risks and their mitigation through design decisions. The first step in the risk analysis was to review the GSPRs in Annex I of the MDR and determine whether each requirement was applicable or not. This was conducted together with supervisor Jacob Lidman, Biomedical Engineer with expertise in the field of in-house manufacturing under the MDR. Only the first column was assessed, stating if the requirement is applicable or not. Thereafter, a risk analysis was performed according to the risk management requirements included in Annex II of the MDR, where hazards associated with the device were identified and documented, also together with Jacob Lidman. Each identified hazard was then linked to one or more hazardous situations. As a single hazard can lead to multiple hazardous situations, the same hazard may appear more than once in different contexts. These hazardous situations may, in turn, lead to harm, which can vary depending on the specific circumstances.

After identifying the risks, the risk assessment phase was initiated. In this stage, each hazardous situation was linked to its potential harm. This was conducted together with Jacob Lidman, a physician and a BMA from DCP at SS. The harm was then assigned a risk value based on its severity and the likelihood of occurrence, this was derived from the scale shown in the Appendix F. Based on this risk value, a decision was made on whether the risk was acceptable or required further mitigation.

If risk reduction was necessary, appropriate measures were determined, this was done together with supervisors. These included eliminating the risk through design, implementing protective measures or providing information to the user. In some cases, all three approaches were required, while in others, one or two were sufficient. The selected measures were documented, along with a description of how their effectiveness would be verified. Subsequently, a document was created containing several test cases outlining how the verification and validation should be conducted in situations where testing was required.

3.4 Use of artificial intelligence (AI)

In this report, AI has not been used to generate substantial parts of the text or any analytical content. AI-based language models have been used to make minor language improvements during the final stages of the writing process. The cover page image was generated using Canva AI 2.0. Apart from these limited uses, all text, analysis and images have been produced by the authors.

4
Result

This section presents the results obtained throughout the project, including findings from interviews, the defined intended purpose of the device and the outcomes of the risk management process. Furthermore, the derived user and product requirements are presented, followed by the evaluation of the developed prototypes. Together, these results provide the basis for assessing the feasibility and performance of the proposed solution.

4.1 Result from interviews

The full interview results are presented in the Appendix B, whereas a summary of the key findings is provided in this section. From the interviews, it became clear that there is a need for updated BP measurement methods. The three different departments (DCP at SS, ÖS and QSCH) had varying experiences with different methods. At SS, a foot pedal was used to inflate the cuff pressure up to 240 mmHg. Beyond this level, a traditional manual hand pump was used to reach the desired pressure. Deflation was performed manually using the same hand pump, with a rotary knob located on the side of the pump. At ÖS, a Low-Pressure Automatic Tourniquet was used, equipped with a rotary knob to adjust the pressure in the cuff. Both inflation and deflation were controlled using this mechanism. Both SS and ÖS used a larger manometer (approximately 10 cm in diameter) to read the pressure.

At the DCP at QSCH, a traditional manual BP device was available for both inflation and deflation. The manometer associated with this device was the only one available and was approximately 5 cm in diameter. The staff considered this too small and expressed a preference for a larger, externally positioned manometer rather than one attached to the patient's arm. Patient BP at QSCH varies considerably. Some patients do not exceed 150 mmHg, while others may require pressures up to 280 mmHg. All three DCPs agreed that having the ability to select the target BP for each measurement would be beneficial, as not all measurements require pressures of 240 mmHg or higher. This is particularly relevant at QSCH, since the patients are children they generally exhibit lower BP, compared to the other DCPs. In particular, the staff emphasized that younger patients should not be exposed to unnecessarily high cuff pressures, as this may negatively affect their performance and cause distraction during the test.

All three DCPs had access to both a stethoscope and a doppler and it was up to

the BMA to determine which method was most appropriate for each measurement. Nevertheless, the ability to use a stethoscope was considered essential. They also agreed that having reserves of the existing doppler would be beneficial, particularly to ensure easy replacement if it breaks. This is especially important in cases where BP is difficult to detected using a stethoscope. The new doppler procured by SU was considered insufficient for measuring BP during CPET, mainly because it could not be properly secured around the wrist, since the probe is pen shaped rather than flat-headed.

One point raised by the DCP at SS was the preference for a pedal system, as it allows the hands to remain free. They also suggested that having two different pedals, one for lower pressure and one for higher pressure, could reduce the need for manual pumping and therefore be better for the work environment and ergonomics of employees. Nevertheless, they also emphasized that manual pumping provides tactile feedback that can give the observer valuable information about the patient. However, this feedback does not come from increased resistance as the pressure rises. Rather, it is based on the observer's familiarity with the pumping process and their expectation of how it should feel.

All three DCPs highlighted the importance of being able to release the cuff pressure at a controlled and adjustable rate. A totally automatic release was considered too slow, which is problematic during CPET, partly because repeated measurements may need to be taken within 15 seconds after the start from the previous measurement if a drop in BP is detected. This is a consequence of that these patients are often severely ill, requiring rapid clinical decision making. BP is typically measured every two minutes, but more frequently if needed. It must be possible to initiate a new measurement immediately after completing the previous one. If BP drops by 5-10 mmHg between two measurements, a new measurement is taken immediately. If the BP continues to decrease, this becomes a criterion for stopping the test. Therefore, 5 mmHg is the minimally required accuracy. Another stopping criterion is a drop in BP greater than 15 mmHg at one measurement. Additionally, if BP exceeds 280 mmHg, this is also a stopping criterion. However, in some cases, depending on the physician's assessment of the patient's condition, the test may continue briefly. When BP reaches 300 mmHg, the examination is always terminated.

CPET is most commonly conducted using a cycle ergometer, although all DCPs are equipped with a treadmill for patients who are unable to perform cycling exercise. Furthermore, BP measurements must be possible in both arms, as certain conditions may prevent measurement in the right arm, which is typically used as the standard site.

4.2 Intended purpose

The intended purpose of the device is to regulate air pressure in an inflatable cuff placed on the patient's upper arm during cardiopulmonary exercise testing (CPET) or exercise stress testing. The device enables controlled pressurization and

depressurization of the cuff to facilitate non-invasive blood pressure measurements.

The device is intended to be used by trained healthcare professionals, such as biomedical analysts (BMAs), for clinical assessment and decision-making. It is designed for transient, non-invasive use on intact skin in a clinical environment, specifically at the Departments of Clinical Physiology at Sahlgrenska University Hospital.

The device does not perform automated blood pressure measurement, signal acquisition or interpretation of physiological data but only provides controlled pressure regulation to support manual auscultatory measurements.

4.2.1 Intended user

The primary intended users are healthcare professionals who operate the device and interact with its functions during CPET. The patient is considered a secondary user, as they are directly affected by the device during use but do not actively operate it. It is essential that both user groups can interact with the device in a safe, effective and user friendly way.

4.3 Risk management

The complete risk management documentation is presented in the appendices, where the GSPR assessment based on Annex I of the MDR is presented in Appendix C and the risk analysis is presented in Appendix D. Selected parts are also presented in this section. Risk management is an ongoing process throughout the device lifecycle and the documentation therefore represents the current stage of development. Consequently, some sections of the risk analysis remain incomplete and will be updated as the device development and verification process continues.

Table 4.1: Risk analysis overview.

Step 1 – Risk Identification			Step 2 – Risk Evaluation				
Risk ID	**Hazard**	**Hazardous situation**	**Harm**	**Severity**	**Probability**	**Risk**	**Need further analysis?**
R03	Cuff inflates with excessive pressure	No pressure relief valve or damaged pressure relief valve	Compression injury, nerve damage. Unlikely with 4–5 bar. Cuff releases from patient.	3	2	6	Yes – mitigate risk
R04	Cuff inflates with excessive pressure	Incorrectly adjusted pressure regulator	Compression injury	3	2	6	Yes – mitigate risk
R05	Cuff inflates with insufficient pressure	Incorrectly adjusted pressure regulator	No BP measurement, leading to switch to manual measurement or continued test without BP measurement. Stress for users. Possibly terminating test.	2	2	4	Yes – mitigate risk
R07	BP cannot be measured	power outage	No BP measurement, leads to switch to manual measurement or continued test without BP measurement. Stress for users. Possibly terminating test.	2	2	4	Yes – mitigate risk
R14	Inaccurate BP measurement or no BP measurement	Broken stethoscope	No BP measurement, leads to switch to manual measurement or continued test without BP measurement. Stress for users. Possibly terminating test.	2	1	2	No – Accept risk
R25	Risk of infection	Cuff cannot be disinfected adequately	Infection	4	3	12	Yes – mitigate risk

Table 4.2: Risk control measures overview.

Step 3 – Risk Control							
Risk ID	**Design**	**Protect**	**Info**	**Risk control measure**	**Responsible**	**Owner**	**Verification**
R03	Yes			Multiple safety functions. For example double valves, valves + regulator. Control or warning system?	Jacob, Selena		Documentation on pressure relief valve and regulator. Pressure test.
R04				Possibly prevent regulator to be set to excessive pressure levels? Otherwise, warning?	Jacob, Selena		
R05	Yes			Warning? Possibility to inflate cuff manually.	Jacob, Selena		Product design document.
R07	Yes			Device is purely mechanic and thus does not require electricity	Jacob, Selena		Product design document.
R14			Yes	Stethoscope shall be available in CPET room. Stethoscope is not included with the device. Primary user determines if back-up is necessary			Product design document.
R25	Yes			Only use cuffs that are CE-marked for multiple use and that can be adequately disinfected.			IFU - refer to that CE-marked cuffs should be used.

In Table 4.1 and 4.2 the risk analysis for risk 3, 4, 5, 7, 14 and 25 are presented. As illustrated in step 3 of Table 4.2, under the section Verification of Risk Control, the risk control verification process may, in certain cases, require different types of tests to verify that the implemented measures are effective and that the risks are adequately managed. These tests are described in more detail in the individual test cases presented in Appendix E.

4.4 User requirements

The URs represent the user needs that the medical device must fulfil in order to be safe, effective and usable within its intended use environment. They describe what the user requires from the device, rather than how the device should be designed. The identified URs were divided into primary and secondary requirements. Primary URs represent the primary user needs, i.e. the needs from the healthcare professional, that are necessary for the device to fulfil its intended purpose. Secondary URs represent the secondary user needs, i.e. the needs from the patient. The resulting

primary and secondary URs derived from the interviews are presented in Table 4.3 and Table 4.4.

Table 4.3: Primary URs for a NIBP device for CPET at SU.

UR ID	Primary user requirement (UR)
01	Healthcare professionals need to be able to quickly measure the patient's BP during the test, within 15 seconds.
02	Healthcare professionals need to be able to adjust the pressure in the cuff in a precise way.
03	Healthcare professionals need to be able to easily use the device after reading the user manual.
04	Operation of the device should not require excessive attention from healthcare professionals.
05	Healthcare professionals need to trust the device.
06	Healthcare professionals should be able to use the device on patients at the DCP at SU.
07	Healthcare professionals need to be able to easily clean relevant parts of the device between patients.
08	Healthcare professionals need to be able to easily use the device within existing CPET workflows.
09	Healthcare professionals need to be able to easily read the SBP and DBP.
10	Healthcare professionals should be able to operate the device from different positions.
11	Healthcare professionals should be able to distinguish Korotkoff sounds.
12	Healthcare professionals need to be able to rapidly repeat measurements when needed.

Table 4.4: Secondary URs for a NIBP device for CPET at SU.

UR ID	Secondary user requirement (UR)
13	The patient should be able to perform the exercise test without being significantly restricted by the device.
14	The patient should not experience more discomfort than necessary during use of the device.

4.5 Product requirements

The PRs represent the verifiable requirements that the device must fulfill in order to ensure safety, effectiveness and compliance with its intended purpose in accordance

with the MDR. These requirements, presented in Table 4.5, are derived from URs and regulatory constraints.

Table 4.5: PRs for a NIBP device for CPET at SU.

PR ID	Product requirement (PR)
01	The pressure should be easy to adjust during CPET.
02	The cuff needs to be able to reach the pressure determined by healthcare professionals within 4 s.
03	The cuff needs to be able to hold the pressure for 10 s without a pressure drop $> 2\%$.
04	The cuff needs to be able to release the pressure by healthcare professionals within 4 s.
05	The cuff should be able to reach a pressure of 300 mmHg.
06	The cuff should not be able to reach a pressure over 300 mmHg.
07	The cuff must be reusable and easy and quick to clean.
08	The cuff should remain secure during CPET.
09	In case of initial failure, no one shall be harmed.
10	Regular calibration and maintenance of the device must be feasible.
11	The device must have a large (at least 10 cm in diameter) and easily readable manometer.
12	The device must be easy to position and secure during movement.
13	The device must be compact and suitable for use at the DCP at SU.
14	The device must allow rapid repeated measurements when needed, within 15 s.
15	The device must provide clinically reliable SBP and DBP measurements with an accuracy of approximately ± 5 mmHg.
16	There shall be an IFU manual available at the DCP.
17	The device that regulates cuff pressure shall not require the user to visually monitor the device for more than 3 s to detect a single SBP or DBP value.
18	The device needs to include cuffs with different dimensions.
19	The device shall fit within the available space and not obstruct other equipment used during CPET.
20	The device shall be portable within the room where the CPET is performed.
21	A stethoscope needs to be available in the room where CPET is performed.
22	The device needs to be able to start a new measurement within 5 s from the previous completed measurement.
23	The device shall not significantly restrict the patient's movement during CPET.
24	The device must enable a controllable deflation velocity.

4.6 Conceptual design, prototyping and evaluation

The evaluation of the developed prototypes identified differences in pressure control, response time, usability and ergonomics. In addition, feedback from healthcare professionals at the DCP at SS highlighted important clinical considerations for future development.

4.6.1 Feasibility test on prototype no. 1

The specifications of the regulator said that it was able to deliver an output pressure in the range of 0.07–0.7 bar, which includes most of the desired operating range of 0–0.4 bar (0–300 mmHg). Although, result shows that the regulator was able to reduce the pressure to include all of the desired range. The manometer readings were found to be in close agreement with those of the calibrated reference manometer, the difference was $< \pm 5$ mmHg. The cuff functioned well overall, although, in some cases, residual air remained in the cuff after deflation.

The T-port ball valve allowed rapid inflation (< 3 seconds) and controlled deflation. The deflation rate could be adjusted by the operator in a precise way, enabling both rapid and gradual pressure release. This was also available for inflation, even though the inflation does not require the same precision. When the outlet (port C) was not blocked during inflation, this created a direct flow path between the inlet (port A) and the outlet (port C), see Figure 3.1, bypassing the cuff. Furthermore, the adjustments during the deflation process required much attention from the operator. So in summary, the prototype performed well in terms of precise airflow control and time, on the other hand, it did not perform well in terms of usability.

4.6.2 Feasibility test on prototype no. 2

The handle of the L-port ball valve required more force to operate than expected. The inflation of the cuff was achieved successfully, with inflation times below 3 seconds. During deflation, the system did not allow for precise control of the pressure release. When rotating the valve from the inflation position towards the deflation position, a direct flow path was created between the inlet (port A) and the outlet (port C), as can be seen in Figure 4.1. This resulted in a pressure airflow bypassing the cuff, and the pressure in the cuff was held at a steady level of 200 mmHg at this position. When the valve was rotated further so that only port B and port C where open the pressure in the cuff dropped quickly to 0 mmHg. To conclude, the cuff inflated and deflated rapidly, but the deflation could not be controlled in a gradual and precise manner.

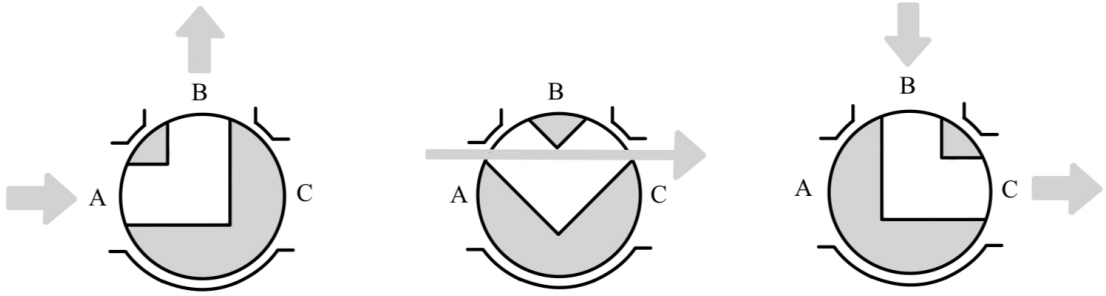


Figure 4.1: To the left in the image the L-port ball valve can be seen in its inlet position, to the right in the image the outlet position can be seen. In the middle of the image is the in-between position when switching between these modes, blue arrows surrounding the ports demonstrate that air flows from port A to port C in this position.

4.6.3 Leakage test and regulator identification on prototype no. 3

No visible bubble formation was observed on the regulator during the application of leak detection spray. However, a slight airflow could be detected manually. Visual inspection revealed two exhaust ports located beneath the adjustment knob. Leak testing of the system connections identified a minor leakage at one connection point. Measurements performed using the expansion volume and calibrated manometer showed a pressure decay of < 1 mmHg/s.

4.6.4 Effect of tubing length on inflation and deflation time on prototype no. 3

No significant differences were observed between the tests conducted with different tubing lengths. The results are summarized in Table 4.6. Although the short tubing configuration resulted in slightly shorter inflation and deflation times than the long tubing configuration, the differences were not statistically significant.

The flow meter used in the test had a maximum flow capacity of 15 L/min. When introduced into the system, it resulted in an increased total time (inflation + deflation time), as shown in Table 4.6. Due to the limitation of the flow meter, it was not possible to directly measure the system flow rate above 15 L/min. However, the observed system behaviour indicated that the actual flow rate exceeded this value.

Table 4.6: Comparison of inflation and deflation performance for different configurations.

Configuration	Inflation Time (s)	Deflation Time (s)	Total Time (s)
Short tubing (57 cm)	2.93	1.78	4.71
Long tubing (436 cm)	3.29	2.51	5.80
With flow meter	–	–	9.89
Without flow meter	–	–	5.00

4.6.5 Feedback from SS on prototype no. 3

The feedback session with DCP at SS addressed usability, ergonomics and safety aspects of the prototype. The feedback session evaluated prototype 3, but the L-port was also brought to demonstate it as an alternative solution. Manual inflation and deflation were reported to provide tactile feedback, allowing the BMA to perceive the pressure going into the cuff. It was noted that a similar form of feedback may be achievable with a rotary knob through user experience.

The use of a rotary knob was associated with the removal of the pedal, used in their current device, which reduces the number of components and eliminates the amount of trip hazards. Questions were raised regarding the resistance of the rotary knob. It was mentioned that the resistance needs to be balanced, so the knob is not to effortless to adjust and not to demanding either. In addition, the response time between adjustment of the rotary knob and pressure changes in the cuff was identified as an important factor. From an ergonomic perspective, a rotary knob was preferred over a smaller handle. It was also stated that the device should be usable from both the left and right side of the patient. The placement of the device in relation to the bicycle was highlighted as a challenge due to limited space, and mounting the device on an adjustable arm was suggested as a possible approach.

Safety-related aspects that was discussed included the requirement that the device can be moved quickly in emergency situations and that it does not obstruct the working environment. Robustness was also mentioned, particularly with respect to potential drops during handling.

4.6.6 Feasibility test on prototype no. 4

The new regulator showed improved inertia compared to the donated regulator. However, more rotations of the control knob were required to increase the pressure to 300 mmHg, typically requiring 4–5 hand repositionings (re-grips) to complete the inflations. Despite this, the cuff could still be inflated rapidly. The response time was improved, as the pressure changed immediately when the knob was turned.

The regulator was able to fully release the pressure in the cuff, and the manometer returned to 0 mmHg after reaching 300 mmHg. The time required to inflate the cuff

to 300 mmHg was 2.89 s, while complete deflation took 1.74 s. These measurements were obtained during maximum-speed operation, and minor variations due to human handling may occur.

After reducing the pressure, continued rotation of the knob resulted in a delay before pressure increased again during reinflation, as multiple rotations were required before the cuff began to inflate.

The pressure relief valve included in prototype no. 4 did not function as intended. When set to its lowest release level (0.3 bar) and expose it to a higher pressure (0.5 bar), no pressure release was observed. The applied pressure remained unchanged regardless of how the connections were configured. Although sealing the third connection manually by one of the authors hand allowed the system to operate, it did not enable pressure release at the specified threshold. The valve did not demonstrate functional pressure relief.

4.6.7 Feedback from SS on prototype no. 4

The feedback indicated that the resistance of the rotary knob attached to the regulator in prototype no. 4 was improved compared to previous prototypes. The increased resistance enabled better control when releasing pressure slowly, which was perceived as a positive aspect.

On the other hand, several usability limitations were identified. The current design required multiple re-gripping actions to adjust the pressure. Approximately 4–5 re-grips were needed to increase the pressure from 0 mmHg to 300 mmHg and similarly to decrease it back to 0 mmHg again. This was considered inefficient, and the concern that it would lead to a loss of patient focus in practice arose. The need for repeated re-gripping also made it more difficult to both increase and release pressure quickly. In addition, the regulator required continued rotation in the same direction to continue releasing more pressure. In contrast, the current device that DCP at SS use for this function today is a needle valve. This allows a small rotary adjustment to create a continuous deflation flow, without further interaction.

The grip of the regulator's rotary knob was also perceived as not optimal. The current surface was described as uneven and a more even or knurled surface was suggested to improve handling. It was further suggested that a larger manometer would be preferable, as this would provide a better understanding of pressure control and accuracy, even for the feedback session. Finally, it was emphasized that rapid inflation to a maximal pressure of 300 mmHg is essential in clinical use. While the increased resistance was appreciated, the re-gripping of the rotary knob was seen as something that would not work in clinical practise.

5
Discussion

This section discusses the results of the project in relation to the identified clinical needs, regulatory requirements and technical feasibility of the developed prototype. Strengths, limitations and future improvements are also addressed.

5.1 Interviews and requirement identification

The reason for using interviews as a data collection method was to gain a deeper understanding of users' experiences, needs, and preferences regarding blood pressure measurement during CPET. Since the study aimed to support the development of a practical solution, it was essential to involve end users and capture insights that may not be evident from literature alone. The interviews made it possible to identify differences in the working methods between the DCPs, as well as knowledge for the development process, such as the importance of tactile feedback and the need for rapid and flexible pressure control. This type of qualitative data is particularly valuable in the early stage design processes, as it helps ensure that the proposed solution is suitable for real clinical environment workflows. This makes it easier to not waste time and resources on a bad solution.

It proved challenging to develop a single solution that would satisfy the needs of all three DCPs. This difficulty can be explained by the differences in clinical workflow and priorities identified in Result from interviews. In particular, the DCP at SS highlighted the importance of a system with a pedal combined with manual inflation, by hand. According to their experience, an adjustable knob mechanism controlling both inflation and deflation would not be sufficient, as it would occupy the hands, which are needed to monitor the patient and assess their condition. This highlights the importance of tactile feedback and hands on interaction, which was perceived as clinically valuable.

Given these differing requirements, it was necessary to make a design decision based on what was considered the most balanced and feasible solution. The concept of a rotary knob was selected as the primary control mechanism. One argument for this choice was that holding and adjusting a rotary knob is functionally similar to using a manual pump, meaning that one hand would still be occupied in both cases. Therefore, the assumed disadvantage of losing one hand was not unique to the solution with the rotary knob, since the user still would lose one hand with a manual hand pump. In addition, eliminating the pedal reduces the risk of tripping

hazards in an environment with already a lot of equipment, which benefits both patient and staff safety, as well as it reduces the risk of falling and damaging other equipment in the event of a fall. This is particularly relevant in CPET settings, where rapid movements between bed and bicycle/treadmill and other adjustments may be required.

The decision to initially present the prototype only to the DCP at SS can also be justified based on the results. Since this group expressed the strongest opposition to the proposed concept, their feedback was considered critical for validating the feasibility of the design before proceeding with further iterations. Gaining acceptance from the most critical ones can be seen as a strategic approach to ensure a better applicability of the solution.

Another important finding from the interviews was the consistent need for access to doppler measurements when Korotkoff sounds cannot be detected using a stethoscope, for example in noisy environments. Although this was initially considered an important aspect of the design, it was less important than the primary BP measurement. Therefore, it was not prioritized. The main reason for this was that the type currently used by the DCPs is no longer commercially available. Existing doppler devices on the market are not suitable for CPET measurements, meaning that a new device would need to be developed. Doing this in parallel with the development of the BP measurement system would have significantly increased the project scope, with a considerable risk of limiting progress in both areas. Instead, the project focused on improving the BP measurement process itself rather than the doppler, since they still can use an updated BP measurement with the current doppler and a stethoscope. This decision was made to keep the project scope focused and to ensure a high quality development of the main BP measurement function, rather than trying to address too many aspects at once.

A precise and controlled pressure regulation, particularly during deflation, was identified as important by all three DCPs. This aligns with the clinical need to perform rapid and repeated measurements during CPET, as described in the results. Based on this, integrating both inflation and deflation control into a single interface could be preferable. Such a design reduces complexity by allowing the user to focus on one control element, which enables greater attention to the patient and the measurement process. This is especially important in high stress situations where quick clinical decisions are required.

Finally, the importance of a large and easily readable manometer was clearly expressed, particularly by the DCP at QSCH, where the currently available manometer was considered too small and badly placed. However, since suitable large manometers are already commercially available, this component was not prioritized in the design process. Instead, it is assumed that the final product would incorporate an existing manometer with an already proved function. This decision allowed the project to focus on developing novel aspects of the system rather than redesigning components that already meet clinical requirements.

5.2 Prototype implementation and design choices

In this section the implementation of the developed prototypes and the design choices made throughout the development process. The selection and use of components, practical limitations during implementation and design parameters such as tubing length and inflation and deflation requirements are evaluated in relation to system performance and usability.

5.2.1 Prototype implementation

The development of a comprehensive component list proved to be a time-consuming step in the design process. However, the results showed that only a limited number of these components were ultimately required, as suitable alternatives were already available within the department. This highlights the uncertainty inherent in early-stage design and suggests that a more iterative approach to component selection could improve efficiency in future work.

In addition, the availability of existing components within the department reduced both costs and delivery time, allowing more focus to be placed on testing and system integration. As a result, future projects could benefit from a more flexible implementation strategy that allows component selection and design decisions to appear in parallel during the development process, to spare time from searching for components.

Another challenge observed during the implementation phase was the long delivery time of certain ordered components, which temporarily slowed down parts of the project. Although other aspects of the project could continue during this period, such as report writing and documentation, the delay still affected the overall workflow and prototype progression. This highlighted the importance of considering delivery times and component availability early in the planning process.

5.2.2 The components

The selected cuff connection type for the developed device was bayonet connectors compliant with ISO 80369-5. This standard was introduced to reduce the risk of accidental wrong connections between medical systems using small-bore connectors [79]. Earlier connector solutions, such as Luer connectors, have been associated with patient safety incidents caused by unintended connections between different medical systems [79]. The use of ISO 80369-5 compliant connectors is a risk control measure for a hazard related to incorrect system connections identified in the risk analysis, as can be seen in R28 in Appendix D. The use of ISO 80369-5 compliant connectors therefore contributes to improved safety for both patient and clinician.

An important reason for selecting bayonet connectors was related to the product requirements established during the project. According to PR 19 in Table 4.5, the device must support the use of multiple cuffs. To ensure compatibility, all cuffs connected to the system therefore need to use the same standardized connection

type. The increasing implementation of ISO 80369 compliant connector systems within healthcare and medical device manufacturing indicates a transition toward standardized connector solutions for medical applications [80]. Because of this, the use of ISO 80369-5 compliant bayonet connectors may therefore enable compatibility with future cuffs. It is important to note that this component has been researched and chosen theoretically but not implemented in any of the prototypes, due to the limitation of time for the project.

5.2.3 Tubing length

An investigation was conducted to assess the effect of tubing length on the prototype's response time and pressure. The purpose of this test was to determine whether tubing length had a significant impact, or if both long and short tubes could be used without affecting performance. Longer tubing could be advantageous if the device needs to be flexible and allow movement within a room. However, longer tubes may also increase the risk of tripping or interfere with the overall usability of the system. Since tubing length was found to have no significant impact on pressure or response time, no restrictions were placed on its length. This allowed flexibility to be maintained in the design, enabling focus on the optimization of other device parameters.

The tests were conducted using prototype no. 3 only and were not repeated for other iterations, as the results were considered sufficiently reliable and similar outcomes were expected across prototypes. Consequently, priority was given to further development and design improvements rather than repeating identical tests.

5.2.4 Inflation and deflation requirement

The decision to limit both cuff inflation and deflation to 4 s, as specified in PR 02 and PR 04 in Table 4.5, was based on UR 01 in Table 4.3, which defines the acceptable total duration of a BP measurement. As described in Result from interviews, the DCPs expressed a need for the device to provide a BP measurement within 15-20 s. To ensure that the system met the most demanding clinical expectations, the lower limit of 15 s was selected as the design target.

A complete measurement within this time frame requires both rapid inflation and controlled pressure release. Here, a large part of the measurement time must be dedicated to the gradual pressure release phase, during which the BMA listens for the Korotkoff sounds in order to determine the BP values. Since this phase requires controlled and relatively slow pressure reduction to ensure measurement accuracy, both inflation and final deflation need to be completed rapidly. By limiting inflation and deflation to 4 s each, approximately 7 s remain available for controlled pressure reduction. This balance was considered necessary to achieve both sufficient measurement accuracy and an acceptable total measurement time from a clinical usability perspective.

5.3 Risk management

Since the risk analysis is based on the relationship between hazards, hazardous situations and harm, it is important to note that a hazard in itself is not necessarily dangerous. It becomes dangerous only when it, in combination with a hazardous situation, can lead to harm. A single hazard may result in multiple hazardous situations, and these situations may in turn lead to different types of harm. Therefore, it was important to include the DCP at SS in order to identify and assess the different types of harm arising from various hazardous situations. It was essential to gather the appropriate expertise from both a physician and a BMA, as they could contribute with different professional perspectives and areas of knowledge.

Risks 3, 4 and 5, shown in Table 4.1 and 4.2, illustrate the concept of the same harm arising from different backgrounds. Risks 3 and 4 represent hazards that lead to the same harm, which can be seen in Table 4.1 but is caused by different hazardous situations. In both cases, the hazard is overpressure in the cuff. However, the underlying causes differ. In Risk 3, the issue is related to the pressure relief valve, while in Risk 4, it is related to the regulator. Despite these different hazardous situations, both lead to the same harm, which is compression injury in the patient. In contrast, Risks 4 and 5 involve different hazards but the same hazardous situation, which results in different harms. This highlights how variations in hazards or situations can influence the final outcome.

Following this, the identified harms were evaluated to determine whether they could be eliminated or reduced through design modifications. It was determined that two independent pressure limiting mechanisms were necessary to ensure that the pressure does not exceed 300 mmHg, even in the event of a component failure. This resulted in the implementation of both a regulator and a pressure relief valve. For example, if the regulator fails, the pressure relief valve acts as a backup mechanism. But under normal operating conditions, the valve remains inactive and does not interfere with the function of the device.

A similar process was applied to all identified risks. For Risk 7, shown in Table 4.1 and 4.2, its implementation was initially considered. However, since the final design is entirely mechanical and does not rely on electricity, this risk was effectively eliminated through design and is no longer relevant. Verification of this decision was based on the product documentation, which demonstrates the mechanical structure of the solution. Furthermore, in the event of a power outage, other equipment used during CPET within the clinical setting would stop functioning, making it impossible to conduct the test. However, it is uncertain whether this limitation will apply to such equipment in the future. Should other systems become capable of operating during a power outage, the developed device would not hinder the ability to conduct the test.

An example of a low risk scenario is Risk 14, shown in Table 4.1 and 4.2. This risk involves the hazardous situation where a stethoscope is unavailable and the probability of this occurring was assessed as low. Furthermore, since the stethoscope

is not included in the device, the only reasonable mitigation measure is to inform users that additional stethoscopes should be available. Responsibility for this issue does not lie with the product itself and user information is therefore considered as a sufficient measure.

Finally, Risk 25, shown in Table 4.1 and 4.2, represents a high risk scenario that must be addressed. With a risk value of 12, it is associated with infection and contamination due to improper cleaning of the cuff between patients. The probability of occurrence was assessed as high if adequate cleaning procedures are not followed. In critical cases, this could lead to serious infection or even death, particularly in sensitive patients. Consequently, this risk must be minimized. An effective mitigation strategy is the use of CE-marked cuffs that can be easily cleaned between patients. This approach also reduces the workload associated with device handling. Verification of this measure is achieved through the device's IFU, which refers to the cuff's IFU specifying the appropriate cleaning procedures.

The designed test cases, presented in Appendix E, focused on the risks that required practical testing for verification. The reason why the other risks did not need testing was that they could instead be verified through documentation or design review. As mentioned earlier, one example is Risk 7, where Table 4.2 shows that the only required verification is the design document. The design document demonstrates that the product does not require electricity and is therefore fully mechanical, meaning that the risk is considered adequately managed. In this case, no additional physical testing is necessary to verify that the product is mechanical.

In contrast, Risk 3, shown in Table 4.2, requires both documentation and a pressure test to verify that the safety relief valve and regulator function as intended. This pressure test is described in the test cases presented in Appendix E. Several risks can be verified within the same test case, meaning that each individual risk does not necessarily require a separate test case. Consequently, the number of test cases is lower than the total number of identified risks. The test cases are not described in detail. Although, when performing the tests, the procedure and approach must be detailed documented to ensure traceability.

5.4 Evaluation of prototypes

This section presents the results obtained from the different prototypes and evaluates their performance.

5.4.1 Feasibility test on prototype no. 1

The regulator provides a pressure range that exceeds the required operating range. While this ensures that the desired pressure can be achieved, it also introduces a risk of exceeding the intended pressure range. Therefore, it would be preferable to select a regulator with a more suitable range or alternatively implement a mechanical restriction to prevent pressures above 0.4 bar (300 mmHg). Another

risk of having a regulator with a higher range than needed is the precise measurement. The risk is that the regulator becomes less reliable with small adjustments.

The T-port ball valve demonstrated good functionality in terms of enabling both rapid inflation and controllable deflation. The observed inflation time fulfils the UR for rapid inflation and the ability to manually control the deflation rate provides flexibility during operation. This could have been a preferred solution with a calibrated regulator so that it always stands at a maximum of 300 mmHg. In this way, the risk of a decreased accuracy with small adjustments is removed if you calibrate the regulator to a fixed value. This means that the regulator does not need to be activated during the test itself, since the user can adjust the pressure using the T-port.

However, the small size of the T-port valve knob negatively affected usability, as precise control required greater user attention. This represents a limitation in a clinical setting, where ease of use is essential and the operator's attention should primarily be focused on the patient. Usability was further reduced by the need to rotate the valve counter clockwise for proper operation, since clockwise rotation created a direct flow path between the inlet (port A) and the outlet (port C). This together with having to hold one opening closed manually, in order to not let air flow between the two parallel ports, increased the cognitive load on the user and further reduces the ease of operation.

The presence of residual air in the cuff suggests that complete deflation was not always achieved, which may have affected the repeatability of the measurements. One possible explanation is the limited quality of the cuff used during testing. Although the use of an expansion volume helped mitigate this issue during the experiments, it is not considered a practical long-term solution. Yet, evaluating the quality and performance of the cuff itself was beyond the scope of this project.

In summary, the prototype demonstrated functional feasibility, but limitations related to usability and pressure control indicate the need for further design improvements in subsequent prototypes.

5.4.2 Feasibility test on prototype no. 2

The results indicate that, although the L-port ball valve improves usability in terms of handle size, it introduces significant limitations in pressure control. The valve was expected to prevent simultaneous flow between more than two ports, but the test showed that this assumption was not fulfilled.

The inability to regulate the deflation rate is a critical issue, as controlled pressure release is required to detect Korotkoff sounds and thereby determine BP. The observed direct flow path between the inlet and outlet prevents the gradual pressure decrease necessary for accurate measurements. This behaviour is attributed to the internal geometry of the L-port, which was wider than anticipated and did not allow

for partial flow restriction when the valve is adjusted. Therefore, the L-port valve failed to meet the PR of controlled deflation.

Furthermore, the higher operating force required for the valve handle negatively affects usability, as it reduces the operator's ability to perform fine adjustments and limits ease of operation. The design of the L-port with a handle instead of a rotary knob made the movement even more difficult, since it is a movement the operator is not comfortable with since before. Therefore, this valve configuration is not suitable for the intended application.

5.4.3 Effect of tubing length on inflation and deflation time on prototype no. 3

The results of this test indicated that increased tubing length leads to slightly longer inflation and deflation times. The increased deflation time observed for the longer tubing can be attributed to a larger internal volume. However, the observed differences are relatively small and the influence of human reaction time must be considered when interpreting the results. Consequently, no strong conclusions can be drawn regarding the performance difference between the two configurations. Despite this, it can be concluded that both configurations, regardless of tubing length, exhibit sufficiently short inflation and deflation times. Consequently, both sets of equipment meet the URs regarding rapid pressure increase and release. Based on these findings, a shorter tubing length is preferable from a response time perspective. However, it is also important to consider the impact on device mobility. Since the device is intended to be used at different positions within the CPET room, the tubing must be sufficiently long to allow flexible use. The results suggest that the relatively small differences in performance are unlikely to significantly limit the mobility of the device.

The increased total time for inflation and deflation observed when using the flow meter indicates that components that restrict flow can significantly impact system performance. The test shows that the flow meter acted as a limiting element in the system. Consequently, components that restrict flow must be carefully selected to ensure sufficiently rapid pressure release. Avoiding unnecessary flow restrictions is therefore an important design consideration. Due to the lack of a flow meter with higher capacity, direct measurement of the maximum system flow rate was not possible. As a result, a safety relief valve was selected based on estimated flow requirements and will be evaluated in a later stage to verify its performance.

5.4.4 Leakage test and regulator identification on prototype no. 3

The presence of airflow and identified exhaust ports indicate that the regulator exhibits a self-relieving function. This functionality enables pressure adjustment and controlled pressure release. The measured leakage rate of < 1 mmHg/s is considered negligible and is therefore not expected to significantly affect system performance in

the intended application.

Feedback from clinical users at both ÖS and SS indicated that a self-relieving regulator is preferred, as it allows for intuitive and precise manual control during CPET. Based on these findings, it was determined that the selected regulator for the proposed system should incorporate a similar relieving functionality. However, improvements in response time are required compared to the donated regulator in order to better meet clinical requirements for rapid pressure adjustment.

5.4.5 Feedback from SS on prototype no. 3

The feedback from SS highlights several important considerations for the design of the device. One key aspect identified was the importance of tactile feedback during inflation and deflation. This suggests that user interaction with the device plays a critical role in perceived control. While manual pumping inherently provides such feedback, the results indicate that a rotary knob may be a suitable alternative, provided that sufficient feedback can be achieved through its design in combination with user experience.

The preference for a rotary knob over a handle, as well as the potential removal of the pedal, indicates a shift towards a simpler and more compact system. Reducing the number of components may improve reliability and decrease the risk of component failure, while also addressing environmental factors such as trip hazards. Altough, the concerns regarding the resistance of the rotary knob highlight the need for careful design considerations. The balance between too low and too high resistance is important to ensure both precision and ease of use. Similarly, the identified requirement for a fast system response emphasizes the importance of minimizing delays between user input and system output.

Ergonomic considerations, such as the ability to operate the device from both sides of the patient, reflect the need for flexibility within the clinical workflow. In addition, the challenge of device placement due to limited space suggests that integration into the existing environment is a key design constraint. The suggestion of mounting the device on an adjustable arm indicates a potential solution, although this would require further evaluation in terms of stability, usability and safety.

Safety aspects were highlighted in the feedback, particularly the requirement that the device must be easily movable in emergency situations and should not obstruct the working environment. This highlights the importance of designing for worst case scenarios, such as cardiac arrest, where rapid access to the patient is critical. The robustness topic that was mentioned, indicates that the device must be able to function safely when it is handled in its indented environment, which can include for example droping it on the floor. This is relevant for ensuring durability of the device. To sum up, the feedback provides valuable guidance for further development, emphasizing the need to balance usability, safety and integration within the clinical

environment.

5.4.6 Feasibility test on prototype no. 4

The results indicate that the new regulator improves system responsiveness and enables rapid pressure changes. This is particularly important in a CPET test, where measurements must be performed quickly and the monitoring of BP requires a fast response to operator input in order to determine BP without delays. The regulator responds immediately when the rotary knob is adjusted, which contributes to improved accuracy and controllability compared to prototype iterations using the donated regulator.

Although multiple re-grips of the rotary knob were required to reach 300 mmHg, the cuff could still be inflated within the required time frame of under 4 seconds, fulfilling the system PR. However, the need for repeated re-grips negatively affects precision control of the pressure, as it reduces the operator's ability to perform smooth adjustments.

Despite the regulator having a pressure range of 0.02–0.5 bar, the system was able to fully release the pressure, with the manometer returning to 0 mmHg after reaching 300 mmHg. This indicates that a regulator with an exact range of 0–0.4 bar (0–300 mmHg) is not necessary, although it would not have been a disadvantage either. However, with this regulator, it is possible to rotate the knob beyond the zero position, which could lead to a delay during reinflation, as several turns are required before pressure begins to increase again. This behaviour reduces usability and control efficiency. A mechanical stop could prevent over rotation and ensure that the regulator returns to a defined zero position, allowing immediate pressure increase at the start of a new measurement when starting to turn the rotating knob.

Furthermore, the pressure relief valve included in prototype no. 4 did not perform as intended. The valve failed to release pressure at its specified threshold and no controlled pressure relief was observed. Since the relief valve serves as a safety mechanism in case of regulator failure, this malfunction represents a critical limitation, as the cuff may otherwise be exposed to high supply pressure.

Temporary sealing of the third port by manually blocking it allowed basic testing of the valve. But this approach is not suitable for long term use. As the valve did not function correctly under these conditions, further efforts to modify this configuration were not prioritized. Consequently, the valve was considered defective. Since controlled pressure release could not be achieved, the current configuration does not meet the system requirements and requires further development.

5.4.7 Feedback from SS on prototype no. 4

The feedback from the DCP at SS on prototype no. 4 provided valuable insights into the usability and controllability of the pressure regulation mechanism. The

increased resistance of the regulator's rotary knob improved fine control during slow pressure release, which is beneficial for accurate BP measurements. On the other hand, this improvement introduces a trade-off, as the need for multiple re-gripping actions reduces usability and efficiency. In a CPET setting, where the BMA must continuously monitor the patient, such an interaction can lead to increased cognitive load and reduce patient monitoring.

An important aspect highlighted during the feedback session was the comparison to the needle valve currently used in clinical practice for cuff deflation. The ability to initiate a continuous airflow with minimal adjustment is a more intuitive interaction for the clinical staff. However, the authors do not consider the need for continued rotation of the knob during deflation to be a limiting factor, provided that the need for repeated re-gripping of the knob is eliminated. Although this interaction differs from the control mechanism currently used in clinical practice, the authors believe that clinicians would be able to adapt to such a system through repeated use, allowing the regulation process to become intuitive without requiring excessive attention. As a result, patient monitoring during CPET measurements would likely not be negatively affected by the proposed control mechanism.

The identified issues related to grip design highlight the importance of ergonomics. A more even or knurled surface could improve both precision and comfort during use, especially when re-gripping is needed. Even though this is a preference that could improve the usability on the prototype, it is difficult to say if it would be as important if the need for re-gripping of the rotary knob could be eliminated. In addition, the difficulty in achieving rapid pressure changes effortlessly indicates that the current design does not fully meet clinical needs. While rapid pressure adjustment is technically possible with the current mechanism, it cannot be performed smoothly due to the repeated need for re-gripping. As a consequence, pressure changes occur in pulses when attempting fast adjustments, which does not align with the clinicians' preference for a continuous and controlled pressure release.

To sum up, prototype no. 4 represents an improvement in terms of controllability, especially for finer pressure adjustments, but further design modifications are required to meet both usability and workflow requirements. Future work should therefore focus on developing a pressure regulation mechanism that combines precise pressure control with ergonomic and efficient operation.

5.5 MDR limitations

As described in the Theory section Limitations of MDR and proposed regulatory revisions, the regulation of medical devices within the EU has been updated into the MDR. While these changes have strengthened requirements related to safety and performance, they have also increased the complexity of manufacturing and marketing medical devices within the EU market. The updated framework introduces both advantages and disadvantages for the industry. One of the main advantages of the new requirements is the increased focus on patient safety. Stricter demands are

placed on clinical evidence and post market surveillance. This also implies stronger requirements for clinical evaluation and the collection of data from the real world. In addition, the regulation applies throughout the whole life cycle of the device, meaning that manufacturers must ensure product quality and safety throughout the entire lifespan of the device. Moreover, clearer classification rules for medical devices have been introduced, contributing to more consistent regulatory assessments. As a result, the overall reliability and quality of medical devices are improved. These improvements also reduce the risk of low quality or unsafe devices entering the market and enhance patient confidence in medical technologies.

The introduction of databases such as EUDAMED has also enhanced transparency and traceability. This makes it easier to track products, monitor their performance and detect potential issues at an earlier stage. Furthermore, MDR harmonizes regulations across the EU, creating a unified framework that simplifies market access across different countries within the EU and also makes it easier to buy from international suppliers. The updated framework also increases responsibility for manufacturers and NBs, ensuring stricter oversight in developing process and post market surveillance.

Although the new regulatory framework has many benefits, it also presents several challenges. One major challenge is the significant increase in documentation and administrative requirements, including the burden associated with recertification of already existing devices. This shifts focus and resources away from product development toward regulatory compliance. Consequently, manufacturers require more specialized expertise, which increases development costs. These higher costs are further driven by certification procedures and ongoing post market surveillance activities. Additionally, the limited availability of NBs can lead to long waiting times for certification, which contributes to longer time-to-market for new devices. These challenges are particularly difficult for small and medium sized companies, which may struggle to meet the financial and administrative demands. As a result, some companies may take back their products from the market or delay the introduction of new technologies. This raises an important concern. While MDR improves safety standards, it may also limit access to certain medical devices. Products that were previously considered sufficiently safe may disappear from the market if manufacturers are unable to meet the new regulatory requirements. If such products are not replaced by equivalent alternatives, this could negatively impact patient care and therefore also patient safety. Furthermore, delays in certification processes may delay the access to new technologies among patients, while increased compliance costs can contribute to higher product prices and consequently increased costs for healthcare systems.

To address some of these challenges, the European Commission has proposed revisions to the regulatory framework, as described in section Limitations of MDR and proposed regulatory revisions. The aim of this proposed revisions is to reduce administrative burden, improving the efficiency of regulatory processes and supporting the availability of medical devices within the EU market. These proposed adjustments

intend to maintain the high safety and performance standards introduced by the MDR, while making the regulatory system more efficient and sustainable for manufacturers and healthcare providers.

5.6 Future work

At the current stage of development, the product is not yet ready to be implemented or used clinically by the DCP at SU. Although the developed prototypes demonstrated functional feasibility, several important aspects still require further development and verification before the device can be considered safe and suitable for clinical use. In particular, improvements related to the pressure relief valve are essential, since the current configuration did not reliably perform its intended safety function. A properly functioning pressure relief mechanism is critical to ensure patient safety in the event of regulator malfunction or excessive pressure. Therefore, further development and validation of this solution must be prioritized before the device can be introduced into a clinical environment.

In addition, the planned test cases described in Appendix E still need to be fully performed and documented in order to verify that the identified risks have been adequately managed. Due to the limited timeframe of the project, completion of all planned verification activities was not possible. As a result, further testing is necessary to confirm compliance with the defined product requirements, evaluate the effectiveness of the implemented risk control measures and ensure that the device performs safely and reliably under its intended operating conditions.

Another important aspect for future development is the usability of the regulator. The repeated need for re-gripping the regulator during pressure adjustment negatively affects ergonomics and ease of use for the BMAs performing the measurements. Since CPET requires continuous patient monitoring and rapid interaction with the device, minimizing unnecessary hand movements and cognitive load is important from a clinical workflow perspective. Future work should therefore focus on improving the regulator design to enable smoother, more intuitive and ergonomically efficient operation while maintaining precise pressure control. Furthermore, the regulator should have a mechanical stop to prevent the pressure from exceeding 300 mmHg and to ensure that the regulator cannot be rotated below the zero pressure position. This would allow pressure to increase immediately when the knob is turned, thereby improving both usability and response time during operation.

Another aspect that should be considered in future development is the physical placement and integration of the device within the clinical environment. Feedback and interviews with the DCP at SS, showed in Feedback from SS on prototype no. 3, highlighted the importance of flexible and ergonomic device positioning during CPET. But within the scope of this project, the primary focus was placed on the functionality and feasibility of the pressure regulation system rather than on the final mounting solution. One potential solution would be to mount the device on an adjustable arm connected to a movable trolley positioned near

the cycle ergometer, treadmill or examination bed. Such a configuration could improve accessibility and allow the device to be repositioned quickly and easily depending on the clinical situation. Further evaluation of mounting solutions is therefore necessary to optimize workflow integration, ergonomics and patient safety.

Additionally, several employees said they preferred to use a Doppler device in situations where Korotkoff sounds are difficult to detect using a stethoscope. Unfortunately, the Doppler device currently preferred in clinical practice is no longer commercially available. Although the development of an alternative Doppler solution could be valuable in future work, it was considered outside the scope of this project.

Another important step before clinical implementation would be to present the developed prototype to all DCPs at SU in order to gather additional feedback regarding the advantages, disadvantages and practical usability of the device. Broader clinical evaluation could provide valuable perspectives from different users and contribute to further optimization of the design before implementation in routine clinical practice.

Lastly, the risk management process must be sufficiently completed before the device can be implemented in clinical practice. Since risk management documentation is a continuous and an ongoing process, it can never be considered completely finalized. Still, all identified risks must be evaluated, minimized and managed as far as reasonably possible. Due to the limited timeframe of the project, it was not possible to perform this. Consequently, further work with the risk management are required before the device can be safely introduced into clinical use.

6
Conclusion

The aim of this project was to investigate the feasibility of developing a BP measurement system for use during CPET. The results showed that a mechanical solution can achieve rapid cuff inflation and controlled pressure release while fulfilling several identified user and product requirements. The project also highlighted the importance of usability, ergonomics, safety and clinical workflow integration, as well as the value of involving end users early in the development process. Although the developed prototypes demonstrated functional feasibility, further development, verification testing and risk management activities are required before the device can be implemented in clinical practice. Nevertheless, the project provides a foundation for continued development of a BP measurement system adapted for CPET.

Bibliography

[1] T. L. Brazile, B. D. Levine, and K. M. Shafer, "Cardiopulmonary exercise testing," *NEJM Evidence*, vol. 4, no. 2, 2025. DOI: 10.1056/EVIDra2400390. [Online]. Available: https://evidence.nejm.org/doi/full/10.1056/EVIDra2400390.

[2] National Guideline Centre (UK), *Preoperative Tests (Update): Routine Preoperative Tests for Elective Surgery* (NICE Guideline 45). London: National Institute for Health and Care Excellence (NICE), 2016, ch. 7, Cardiopulmonary exercise testing (CPET), Accessed: 2026-05-18. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK367902/.

[3] P. Nivedahl, *Ergospirometri (arbetsprov med gasutbytes- och ventilationsanalys)*, https://www.internetmedicin.se/klinisk-fysiologi/ergospirometri-arbetsprov-med-gasutbytes-och-ventilationsanalys, Internetmedicin, accessed 2026-05-18, 2026.

[4] D. Datta, E. Normandin, and R. ZuWallack, "Cardiopulmonary exercise testing in the assessment of exertional dyspnea," *Annals of Thoracic Medicine*, vol. 10, no. 2, pp. 77–86, 2015. DOI: 10.4103/1817-1737.151438. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC4375746/.

[5] N. N. McLaurin, T. Wang, L.-S. Chen, and H. Tanaka, "A new and specific automated blood pressure device for exercise stress testing," *Journal of Human Hypertension*, vol. 37, pp. 150–154, 2023. DOI: 10.1038/s41371-022-00784-9.

[6] P. Pesova et al., "Exercise-induced blood pressure dynamics: Insights from the general population and the athletic cohort," *Journal of Cardiovascular Development and Disease*, vol. 10, no. 12, p. 480, 2023.

[7] D. J. Chambers and N. A. Wisely, "Cardiopulmonary exercise testing: A beginner's guide to the nine-panel plot," *BJA Education*, vol. 19, no. 5, pp. 158–164, 2019. DOI: 10.1016/j.bjae.2019.01.009.

[8] Socialstyrelsen, "Statistik om dödsorsaker år 2024," Socialstyrelsen, 2025-9-9775, 2025. [Online]. Available: https://www.socialstyrelsen.se/contentassets/53d951607fb1421382954e156700a206/2025-9-9775.pdf.

[9] Hjärt-Lungfonden. "Därför ska du hålla koll på ditt blodtryck." Accessed: 2026-01-16. [Online]. Available: https://www.hjart-lung.se/vart-arbete/tidningen-status/artiklar/darfor-ska-du-halla-koll-pa-ditt-blodtryck/.

[10] Institute for Quality and Efficiency in Health Care (IQWiG). "In brief: How is blood pressure measured?" Accessed: 2026-01-16, NCBI Bookshelf, National Library of Medicine, NIH. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK279251/.

[11] Metro Hospital Faridabad. "Impact of high blood pressure on heart health." Accessed: 2026-01-16. [Online]. Available: https://metrohospitalfaridabad.com/blog/impact-of-high-blood-pressure-on-heart-health/.

[12] Vårdhandboken. "Andra mätmetoder." Accessed: 2026-01-16, Inera AB. [Online]. Available: https://www.vardhandboken.se/undersokning-och-provtagning/blodtrycksmatning-manuell/andra-matmetoder/.

[13] M. Börjesson, A. Onerup, S. Lundqvist, and B. Dahlöf, *Fysisk aktivitet vid hypertoni*, Accessed: 2026-01-16, FYSS – Fysisk aktivitet i sjukdomsprevention och sjukdomsbehandling, 2016. [Online]. Available: https://www.fyss.se/wp-content/uploads/2018/01/Hypertoni-1.pdf.

[14] A. S. Meidert and B. Saugel, "Techniques for non-invasive monitoring of arterial blood pressure," *Frontiers in Medicine*, vol. 4, p. 231, 2018. DOI: 10.3389/fmed.2017.00231.

[15] World Federation of Societies of Anaesthesiologists. "Invasive blood pressure monitoring." Accessed: 2026-03-31.

[16] S. Romagnoli et al., "Accuracy of invasive arterial pressure monitoring in cardiovascular patients: An observational study," *Critical Care*, vol. 18, p. 644, 2014. DOI: 10.1186/s13054-014-0644-4.

[17] S. Romagnoli et al., "Accuracy of invasive arterial pressure monitoring in cardiovascular patients: An observational study," *Critical care*, vol. 18, no. 6, p. 644, 2014.

[18] J. Lidman and S. Van der Horst, Personal communication, Biomedical Engineers, Sahlgrenska University Hospital, 2026.

[19] K. Babadağ and A. Zaybak, "Comparing intra-arterial, auscultatory, and oscillometric measurement methods for arterial blood pressure," *Florence Nightingale Journal of Nursing*, vol. 29, no. 2, pp. 194–202, 2021. DOI: 10.5152/FNJN.2021.19103.

[20] M. Brunström et al., "2023 esh guidelines for the management of arterial hypertension the task force for the management of arterial hypertension of the european society of hypertension: Endorsed by the international society of hypertension (ish) and the european renal association (era)," *Journal of hypertension*, vol. 41, no. 12, pp. 1874–2071, 2023.

[21] P. Muntner et al., "Measurement of blood pressure in humans: A scientific statement from the american heart association," *Hypertension*, vol. 73, no. 5, e38–e49, 2019. DOI: 10.1161/HYP.0000000000000087.

[22] R. Pal et al., "From cuffs to code: Machine learning in non-invasive blood pressure monitoring," *Anaesthesia Critical Care & Pain Medicine*, vol. 45, p. 101 655, 2026. DOI: 10.1016/j.accpm.2025.101655.

[23] K. P. Sylvester and P. Agostoni, "Cardiopulmonary exercise testing," in *Respiratory Physiology: New Knowledge, Better Diagnosis (ERS Monograph)*, R. Dellacà and A. Aliverti, Eds., Sheffield: European Respiratory Society, 2025, pp. 172–181, ISBN: 978-1-84984-188-7. DOI: 10.1183/2312508X.10007224.

[24] A. Pritchard et al., "Artp statement on cardiopulmonary exercise testing 2021," *BMJ Open Respiratory Research*, vol. 8, e001121, 2021. DOI: 10.1136/bmjresp-2021-001121.

[25] S. K. Parasuraman, K. Schwarz, N. D. Gollop, and B. L. Loudon, *Healthcare professional's guide to cardiopulmonary exercise testing*, https://bjcardio.co.uk/2015/12/healthcare-professionals-guide-to-cardiopulmonary-exercise-testing/, Accessed: 2026-01-16, Nov. 2015.

[26] K. Albouaini, M. Egred, A. Alahmar, and D. J. Wright, "Cardiopulmonary exercise testing and its application," *Heart*, vol. 93, pp. 1285–1292, 2007. DOI: 10.1136/hrt.2007.121558.

[27] B. Xia, P. Cao, L. Zhang, H. Huang, R. Li, and X. Yin, "Exercise-induced excessive blood pressure elevation is associated with cardiac dysfunction in male patients with essential hypertension," *International Journal of Hypertension*, vol. 2022, p. 8 910 453, 2022. DOI: 10.1155/2022/8910453.

[28] H. Dores et al., "Cardiopulmonary exercise testing in clinical practice: Principles, applications, and basic interpretation," *Revista Portuguesa de Cardiologia*, vol. 43, pp. 525–536, 2024. DOI: 10.1016/j.repc.2024.01.005.

[29] J. E. Sharman and A. LaGerche, "Exercise blood pressure: Clinical relevance and correct measurement," *Journal of Human Hypertension*, vol. 29, pp. 351–358, 2015. DOI: 10.1038/jhh.2014.84.

[30] T. Shinohara et al., "Can blood pressure be measured during exercise with an automated sphygmomanometer based on an oscillometric method?" *Journal of Physical Therapy Science*, vol. 29, no. 6, pp. 1006–1009, 2017. DOI: 10.1589/jpts.29.1006.

[31] T. Wibmer et al., "Blood pressure monitoring during exercise: Comparison of pulse transit time and volume clamp methods," *Blood Pressure*, vol. 24, no. 6, pp. 353–360, 2015. DOI: 10.3109/08037051.2015.1053253.

[32] K. Kabbadj, N. Taiek, W. El Hjouji, O. El Karrouti, and A. J. El Hangouche, "Cardiopulmonary exercise testing: Methodology, interpretation, and role in exercise prescription for cardiac rehabilitation," *US Cardiology Review*, vol. 18, e22, 2024.

[33] Department of Clinical Physiology, Sahlgrenska Hospital, Sahlgrenska University Hospital, Personal communication, 2026.

[34] Department of Clinical Physiology, Östra Hospital, Sahlgrenska University Hospital, Personal communication, 2026.

[35] Department of Clinical Physiology, Queen Silvia Children's Hospital, Sahlgrenska University Hospital, Personal communication, 2026.

[36] Department of Medical Engineering, Sahlgrenska Hospital, Sahlgrenska University Hospital, Personal communication, 2026.

[37] Department of Medical Engineering, Östra Hospital, Sahlgrenska University Hospital, Personal communication, 2026.

[38] MediStore. "Doppler equipment." Accessed: 2026-04-06. [Online]. Available: https://medistore.se/category/medicinsk-utrustning/doppler/.

[39] Etikprövningsmyndigheten, *Medicintekniska produkter (mdr och ivdr)*, Hämtad 2026-03-24, 2021. [Online]. Available: https://etikprovningsmyndigheten.se/medicintekniska-produkter/.

[40] European Commission. "New regulations for the medical devices sector." Accessed: 9 March 2026. [Online]. Available: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en.

[41] E. Commission, "New eu rules to ensure safety of medical devices," *European commission—Fact Sheet*, 2017.

[42] Medical Device Coordination Group, "Guidance on classification of medical devices," European Commission, Directorate-General for Health and Food Safety, Tech. Rep., Oct. 2021, Accessed: 10 March 2026. [Online]. Available: https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf.

[43] Swedish Medical Products Agency. "Risk classification of medical devices." English title based on official terminology, Accessed: Apr. 15, 2026. [Online]. Available: https://www.lakemedelsverket.se/sv/medicinteknik/tillverka/riskklassning.

[44] European Parliament and Council of the European Union, *Regulation (eu) 2017/745 of the european parliament and of the council on medical devices*, Official Journal of the European Union, L 117, 5 May 2017, 2017.

[45] Swedish Medical Products Agency. "The pathway to the ce mark." English title based on official translation, Accessed: Apr. 15, 2026. [Online]. Available: https://www.lakemedelsverket.se/sv/medicinteknik/tillverka/vagen-till-ce-market.

[46] Medical Device Coordination Group. "Guidance on the health institution exemption under article 5(5) of regulation (eu) 2017/745 and regulation (eu) 2017/746," Accessed: Apr. 15, 2026. [Online]. Available: https://health.ec.europa.eu/system/files/2023-01/mdcg_2023-1_en.pdf.

[47] Läkemedelsverket. "Egentillverkning av medicintekniska produkter enligt mdr." Accessed: 2026-02-02. [Online]. Available: https://www.lakemedelsverket.se/sv/medicinteknik/tillverka/egentillverkning/egentillverkning--mdr.

[48] Medical Device Coordination Group, "Guidance on the health institution exemption under article 5(5) of regulation (eu) 2017/745 and regulation (eu) 2017/746," European Commission, Directorate-General for Health and Food Safety, Tech. Rep., Jan. 2023, Accessed: 9 March 2026. [Online]. Available: https://health.ec.europa.eu/document/download/05b15d55-1bcf-4e17-99c4-15c706325847_en?filename=mdcg_2023-1_en.pdf.

[49] HSLF-FS 2021:32, Läkemedelsverkets föreskrifter om kompletterande bestämmelser till EU:s förordningar om medicintekniska produkter, Konsoliderad version med ändringar till och med HSLF-FS 2025:13. [Online]. Available: https://www.lakemedelsverket.se/sv/lagar-och-regler/foreskrifter/2021-32. Accessed: Jun. 6, 2026, Läkemedelsverkets författningssamling, 2021.

[50] Regeringskansliet, "En översyn av det medicintekniska regelverket," Socialdepartementet, 2025/26:FPM70, 2026. [Online]. Available: https://www.regeringen.se/contentassets/e1cd89e9b06e459fb9d26e5e2f2c4f52/fakta-pm-70-medicinteknik.pdf.

[51] Swedish Medical Products Agency. "Regulatory framework for medical devices." English translation of page title from Swedish original, Accessed: Apr. 15, 2026. [Online]. Available: https://www.lakemedelsverket.se/sv/medicinteknik/regelverk.

[52] P. Maresova, L. Rezny, L. Peter, L. Hajek, and F. Lefley, "Do regulatory changes seriously affect the medical devices industry? evidence from the czech republic," *Frontiers in Public Health*, vol. 9, p. 666 453, 2021. DOI: 10.3389/fpubh.2021.666453.

[53] T. Melvin, D. Kenny, M. Gewillig, and A. G. Fraser, "Orphan medical devices and pediatric cardiology – what interventionists in europe need to know, and what needs to be done," *Pediatric Cardiology*, vol. 44, pp. 271–279, 2023. DOI: 10.1007/s00246-022-03029-1.

[54] C. Amaral, M. Paiva, A. R. Rodrigues, F. Veiga, and V. Bell, "Global regulatory challenges for medical devices: Impact on innovation and market access," *Applied Sciences*, vol. 14, no. 20, p. 9304, 2024. DOI: 10.3390/app14209304. [Online]. Available: https://doi.org/10.3390/app14209304.

[55] Swissmedic. "Applicable eu legal acts, harmonised standards and common specifications." Accessed: 2026-04-15. [Online]. Available: https://www.swissmedic.ch/swissmedic/en/home/medical-devices/regulation-of-medical-devices/anwendbare-rechtsakte-gemaess-eu-mdr.html.

[56] Swiss Confederation, *Medical devices ordinance (meddo), sr 812.213*, Accessed: 2026-03-10, 2020. [Online]. Available: https://www.fedlex.admin.ch/eli/cc/2020/552/en#art_1.

[57] A. K. Sarata, "Fda regulation of medical devices," Congressional Research Service, Tech. Rep. R47374, 2023, Accessed: 2026-03-23. [Online]. Available: https://www.congress.gov/crs_external_products/R/PDF/R47374/R47374.2.pdf.

[58] Inter Scientific. “Eu mdr vs us fda: Key differences and how to navigate.” Accessed: 2026-03-23. [Online]. Available: https://inter-scientific.com/eu-mdr-vs-us-fda-key-differences-and-how-to-navigate/.

[59] MDS Finland. “Understanding fda’s 510(k) and de novo pathways for faster market access.” Accessed: 2026-03-24.

[60] SwedenBIO. “Proposals for the simplification of the eu medical device regulations (mdr/ivdr).” Accessed: 2026-03-24.

[61] Kioscert. “Fda 510(k) / de novo / pma: Roadmap and pitfalls.” Accessed: 2026-04-16. [Online]. Available: https://kioscert.com/blog/fda-510-k-de-novopma-roadmap-and-pitfalls.

[62] T. Gupte et al., “Regulatory landscape of accelerated approval pathways for medical devices,” *Journal / PMC Article*, 2025, Accessed: 2026-04-16. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC12119601/.

[63] M. Aboy, C. Crespo, and A. Stern, “Beyond the 510(k): The regulation of novel moderate-risk medical devices, intellectual property considerations, and innovation incentives in the fda’s de novo pathway,” *npj Digital Medicine*, vol. 7, p. 29, 2024, Accessed: 2026-04-16. DOI: 10.1038/s41746-024-01021-y. [Online]. Available: https://www.nature.com/articles/s41746-024-01021-y.

[64] U.S. Food and Drug Administration. “Premarket notification 510(k).” Accessed: 2026-04-16. [Online]. Available: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k.

[65] Council of the European Communities, *Council directive 93/42/eec of 14 june 1993 concerning medical devices*, Official Journal of the European Communities, L 169, Published 12 July 1993, Jul. 1993.

[66] U.S. Food and Drug Administration. “Premarket approval (pma).” Accessed: 2026-04-16. [Online]. Available: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma.

[67] U.S. Food and Drug Administration. “De novo classification request.” Accessed: 2026-04-16. [Online]. Available: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request.

[68] M. Fink and B. Akra, “Comparison of the international regulations for medical devices–usa versus europe,” *Injury*, vol. 54, p. 110 908, 2023. DOI: 10.1016/j.injury.2023.110908.

[69] Svenska institutet för standarder (SIS). “Vad är en standard?” Hämtad 13 april 2026. [Online]. Available: https://www.sis.se/standarder/vad-ar-en-standard/.

[70] Swedish Medical Products Agency, “Regulatory framework for medical devices,” n.d. [Online]. Available: https://www.lakemedelsverket.se/sv/medicinteknik/regelverk (Accessed: Apr. 15, 2026).

[71] Läkemedelsverket. "Regulations for medical devices." Accessed: 2026-04-07. [Online]. Available: https://www.lakemedelsverket.se/sv/medicinteknik/regelverk.

[72] *Medicintekniska produkter – Tillämpning av ett system för riskhantering för medicintekniska produkter*, SS-EN ISO 14971:2020, Svenska institutet för standarder, Stockholm, Sweden, 2020.

[73] A. Sharma, C. Prakash, and A. Vora, "Enhancing safety and compliance in syringe manufacturing: A study of risk management strategies based on iso 14971," *Journal of Advances in Medical and Pharmaceutical Sciences*, vol. 26, no. 7, pp. 57–78, 2024. DOI: 10.9734/jamps/2024/v26i7702.

[74] O. Kheir, A. Jacoby, and S. Verwulgen, "Risk identification and analysis in the development of medical devices among start-ups: Towards a broader risk management framework," *Medical Devices: Evidence and Research*, vol. 15, pp. 349–363, 2022. DOI: 10.2147/MDER.S375977.

[75] A. Sharma and G. Luthra, "A comprehensive review of risk management in the medical device industry," *Journal of Pharmaceutical Research International*, vol. 35, no. 6, pp. 14–23, 2023. DOI: 10.9734/JPRI/2023/v35i67330.

[76] *Medicintekniska produkter – del 1: Tillämpning av metoder för att säkerställa medicintekniska produkters användarvänlighet*, SS-EN 62366-1:2015 (IEC 62366-1:2015), Kista, Sweden: SEK Svensk Elstandard, 2016.

[77] *Medicintekniska produkter – Del 2: Vägledning vid tillämpning av metoder för att säkerställa medicintekniska produkters användarvänlighet*, SEK Teknisk rapport 62366-2 (IEC TR 62366-2:2016), SEK Svensk Elstandard, Kista, Sweden, 2016.

[78] *Medicintekniska produkter – ledningssystem för kvalitet – krav för regulatoriska ändamål*, SS-EN ISO 13485:2016, Svenska institutet för standarder, Stockholm, Sweden, 2016.

[79] J. Zappulla. "Preventing medical mishaps: Understanding the importance of iso 80369-5." Accessed: 2026-05-04, SunTech Medical. [Online]. Available: https://www.suntechmed.com/blog/entry/hypertension/how-iso-80369-5-impacts-medical-device-connectors.

[80] Eastman, *Reducing the risk of medical device tubing misconnections: Incompatibility by design—progress toward iso 80369 standards for small-bore connectors*, Technical white paper, 2023. [Online]. Available: https://www.eastman.com/content/dam/eastman/corporate/en/literature/s/spmbs1784.pdf.

A

Interview Questions

1. What is your title?
2. What is your role during CPET?
3. Which patient groups do you most commonly test using CPET?
4. How is blood pressure currently measured during CPET?
    - Is it always measured in the same way, or is a different method sometimes used? If so, which method and why?
    - Are there any limitations or shortcomings of the current system?
    - Do movement and sweating affect the measurement quality?
    - When are systolic and diastolic blood pressure measured, respectively?
    - Do you prefer Doppler or a stethoscope?
    - Is blood pressure always measured on the same arm of the patient? If not, what determines which arm is used?
5. What is the maximum pressure the cuff must not exceed?
    - What pressure must it be able to reach in order to measure blood pressure?
6. How is blood pressure measurement scheduled over time during CPET?
    - At what points during the test are measurements taken, and how many times? Why?
    - At which times before, during, and after the test is blood pressure measured?
    - How many times before, during, and after?
    - What determines the need for repeated measurements?
    - Are repeated measurements sufficient, or is there a need for continuous monitoring?
7. How quickly does a value need to be presented from the moment the measurement starts?
8. How is the measured blood pressure value documented, and how well do you think this works?

9. What are the most common problems encountered during blood pressure measurement, and how are they handled when they occur?
10. How can you determine whether a measured blood pressure value is reliable or unreliable?
    - Approximately how often do you obtain an unreliable blood pressure value, and how is this handled?
    - When unreliable blood pressure values occur, what are they most often due to?
11. In relation to other parameters measured during the test, such as ECG and spirometry, how important is blood pressure measurement?
12. What would be required of a blood pressure monitor for it to fit into your workflow?
    - Is it sufficient to move a single device between setups, or would it be more convenient to have multiple units available?
    - Are there any physical limitations in the room or around the patient that affect how equipment can be positioned?
13. Is there anything in a new method that you would not want to use?
14. Do you feel that the blood pressure measurement interferes with the test or the patient?
    - How does the blood pressure monitor currently used affect the patient during the test?
15. What would be required for you to have confidence in a new method for blood pressure measurement during CPET?
    - How accurate does the measurement of systolic blood pressure need to be to be clinically useful?
    - Do you have any specific requirements that an updated/new method must meet?

B

Interview Results

Questions	Läkare SS	BMA SS	BMA SS	BMA ÖS	BMA OSCH
Vad är din titel?	Läkare.	BMA + sektionledare.	BMA.	BMA + sektionsledare	BMA + Sektionsledare för Klinfys barn
Vad är din roll under CPET?	Dokumentera värden, observera pat. kliniska status.	Primärt fokus pat., observerar också EKG. Utför BP mätningen. Dubbelkollar rätt dokumenterat BP.	Primärt fokus pat., blodtrycksmätning, få pat. hålla rätt tempo, ställa frågor till pat.	Tar blodtryck, observera & pusha på pat., ställa frågor	Ta emot pat., koppla upp utrustning, genomföra alla mätningar.
Vilka är de vanligaste patientgrupper ni testar med CPET?	Pat. m. hjärt-kärlsjukdom & lungproblem, sjuka pat.	Hjärttransplanterade pat., Lungcancerpat. Pat. inför hjärttransplantation, pat. med hjärtsvikt, CF-pat.	Hjärttransplanterade pat., Pat. med frågeställning kring blodtrycksfall vid ansträngning.	Inliggande pat., 1 akuttid/dag, poliklinisk pat.: kända hjärtfel. Arytmifrågeställningar	Barnpat. 6-17 år. Arytmiutredning, vissa hjärtdiagnoser.
På vilket sätt mäts blodtrycket under CPET idag? - Mäts det alltid på samma sätt eller mäts det ibland på något annat sätt? Vilket & varför? - Finns det några brister med dagens system? - Påverkar rörelse och svett mätkvaliteten? - När mäts det systoliska respektive det diastoliska trycket? - Föredrar du doppler eller stetoskop? - Mäter ni alltid BP på samma arm på patienten? Annars, vad avgör vilken arm som mätningen görs på?	Mäts m. doppler elr stetoskop, automatisk uppumpning, kan fortsätta pumpa manuellt. Manuellt utsläpp Otast cykeltest, ibland test på gångband Brister: dokumentation, nogrannhet, mätfel? Rörelse påverkar mycket, svett påverkar relativt lite. Före: SBP & DBP liggande, under: SBP varannan min, efter: SBP & DBP under 5,5 min Vid gångband är doppler bättre, svårt att följa armens rörelse med stetoskop. Mäts alltid på höger arm (bestämt det) om inte andra faktorer påverkar, såsom operation i kärlen, olicka tryck i armarna.	Manschett, med: Oftast stetoskop, doppler vid svårhörda pat. Automatisk uppumpning via fotpedal, möjlighet till manuell efterpumpning. Brister: Oklar kalibreringsstatus, ingen regelbunden service. Ej automatisk dokumentation. Rörelse påverkar mycket, svett påverkar lite. Under arbete: endast systoliskt Efter test: SBP efter 2 och 4 min. SBP + DBP efter 6 min. Mäts oftast i höger arm, vänster arm om höger ej möjligt.	Manschett med automatisk uppblåsning via fotpedal, kompletering via handpump. Manuell urtömning. Oftast doppler, ibland med stetoskop. Brister: Dopplern som används tillverkas inte längre -> en av dem mer sliten. Mycket sladdar som stör. Svårt att höra vid rörelse. Anpassat för höger arm. Före: SBP + DBP liggande. Stetoskop. Under arbete: endast systoliskt blodtryck. Rörelse påverkar mätkvaliteten. Efter: Liggande på brits, stetoskop. Mäts oftast i höger arm. Vänster mer omständligt.	Manschett med: Doppler, går inte det -> stetoskop På brits: stetoskop Ratt på boxen som vrider upp tills önskat tryck och sedan släpper ut i önskad fart Dagens box: on/off knapp + ratt Brister: Svårt att höra med steotkop, doppler glider runt av svett. Boxen måste flyttas mellan brits & cykel. Kort sladd så är mäckigt.	Manschett pumpas upp för hand. Under arbete: Doppler används som standard, undantagsfall stetoskop. På brits: Stetoskop används. Brister: Manometern är liten och svår att läsa, särskilt när visaren hoppar. Doppler tar upp mycket brus. Muskelspänning och rörelse ger störningar och gör att visaren hoppar. Svett kan påverka position av doppler.
Vilket tryck får manschetten inte överskrida? - Vilket tryck måste den klara av att uppnå för att man ska kunna mäta blodtrycket?	Manschetten pumpas till 240 mmHg, efter det är manuell upppumpning	Pumpar upp till 240 mmHg, kan pumpa upp högre för hand, till max 280 mmHg.	Man pumpar inte över 280 mmHg. Minst 220 mmHg automatiskt. Möjlighet att manuellt nå högre vid behov.	Manometer går upp till 300, finns stoppkriterie men kom ej ihåg detta.	Systemet måste kunna gå upp till ca 300 mmHg.
Hur är blodtrycksmätningen upplagd tidsmässigt under CPET? - När under testet görs mätningarna och hur många gånger? Varför? - Vid vilka tillfällen innan, under och efter testet mäts blodtrycket? Hur många gånger innan, under och efter? - Vad styr behovet av upprepade mätningar? - Är upprepade mätningar tillräckliga eller finns ett behov av kontinuerlig mätning?	SBP mäts varannan minut, vissa fall varje minut pga. pat. Sjukdomsbild, status under test. Före: SBP & DBP liggande, under: SBP varanan min, efter: SBP & DBP under 5,5 min. Sjunker trycket -> mäter direkt igen. Kontinuerlig mätning: Upprepade mätningar räcker.	Innan testet: Mäter man SBP + DBP. Under testet: Standard är mäta varannan minut under ansträngningen, varje min vid behov (hjärtsviktspat.). Efter testet: SBP vid 2 och 4 min, vid 6 min SBP + DBP. Kontinuerlig mätning: Inget behov om det inte kan uppvisa mycket hög prestanda.	Före: En mätning SBP + DBP. Under: SBP varannan eller varje min. Efter: SBP vid ca 2 och 4 min, vid 6 min SBP + DBP. Kontinuerlig mätning: Inget behov men mer läkarfråga.	Mäter SBP och DBP på brits innan, förflyttas till cykel 5-10 min efter. På cykel: bara SBP. En mätning innan cykling börjar, sedan varannanm minut, vid behov, oftare. Om läkare vill ha SBP på cykel efter avslutat tas det, annrs ned på brits. Efter: övervaka under 6 min, sista mätning är SBP + DBP Vid osäker mätning tas ny direkt efter Beroende på frågeställning: mätningar varje minut Kontinuerlig mätning är positivt men måste vara pålitlig, inget måste	Före: Liggande på brits (SBP + DBP). Sittande på cykel innan start. Under: Standard varannan minut med behöver kunna mäta oftare. Om gångband mäts oftast inte BP. Efter: Direkt efter på brits och efter 4 min, SBP är det viktigaste. Om osäkert värde, mät om direkt. Kontinuerlig mätning: Bra om det går att lita på, inget upplevt problem att det inte finns.
Hur snabbt behöver ett värde presenteras från det att mätningen börjar?	Inom 15 sekunder.	Helst inom 15 sek.	Helst inom 15-20 sek.	Ca 20 sek.	Ca 20 sek.
Hur dokumenteras det uppmätta blodtrycksvärdet och hur tycker du att det fungerar?	Läkaren knappar in värdet manuellt i systemet under testetn, när BMA sagt vad det är. Fungerar, men kan innebära avrundningsbias.	BMA säger värdet. Läkare dokumenterar. BMA kontrollerar att rätt värde skrivits in. Kan se fördel med att automatisera dokumentationen men det fungerar överlag bra ändå.	Värdet sägs högt av BMA. Läkaren dokumenterar manuellt i Caddolex Fungerar, men automatisk överföring hade varit att föredra.	BMA sägervärdet till läkare som skrivier in. Ibland kan ej läkare deltaga -> då skriver dem själva in. Fungerar. Bra med automatiskt men ingen prioritet, anträngningsnivå ska ändå dokumenteras.	BMA säger värdet, läkare dokumenterar. Automatisk överföring anses inte avgörande eftersom annan data ändå skrivs manuellt.
Vilka är de vanligaste problemen ni kan stöta på vid blodtrycksmätningen och hur hanteras de när de uppkommer?	Mätfel, rörelseartefakter. Ibland svårt att mäta snabbt nog -> stress hos personal när värde inte fås snabbt. Åtgärd: Ny mätning direkt. Klinisk helhetsbedömning.	Svårt att höra (pga. ljud från cykel, omgivning). Patientrörelser. Osäkerhet kring exakt tidpunkt för Karotkoffljud. Åtgärd: ommätning direkt, tätare intervall.	Rörelseartefakter. Svårt att höra pulsljud. Störande ljud från EKG-sladdar. Sliten doppler med knaster. Åtgärd: Ommätning.	Pat. spänner arm mot slutet så manometern hoppar, svår aviäsning, coachar pat. att slappna av men fortsätta trampa. Dopplern glider runt av svett, då får man mäta med steoskop.	Manometervisaren hoppar -> svårt att läsa värdet. Dopplerljud störs. Svårt att hålla allt samtidigt (arm, doppler, pump). Barn spänner sig eller slutar trampa. Slitna manschetter kan glida. Hantering: justera armposition. Tejpa dopplerproben bättre. Måta om.
Hur kan man avgöra ifall blodtrycksvärdet man mätt upp är pålitligt eller opålitligt? - Ungefär hur ofta får ni ett opålitligt blodtrycksvärde, och hur hanteras det? - Vid de tillfällen ni får opålitliga blodtrycksvärden, vad beror det oftast på?	Stämmer värdet med förväntad fysiologi? Om SBP sjunker oväntat -> mät om direkt. Förekommer regelbundet. Hanteras genom ommätning och klinisk bedömning. Vanliga orsaker: Rörelse. Arytmier. Brister i mätmetod eller utrustning. Patient som spänner sig.	Om osäker kring värdets tillförlitlighet jämför med tidigare värden. Misstanke felvärde -> ommätning. Opålitliga mätvärden förekommer då och då, särskilt i början av belastningen. Vanligaste orsaker till mätfel: Rörelse, Ljudstörningar, Doppler som flyttar sig, Osäker hörbarhet.	BMA bedömer ljudkvalitet. Vid doppler kan också läkaren höra. Vid osäkerhet: omedelbar ommätning. Opålitliga mätvärden förekommer inte jätteofta, med ibalnd. Vanligaste orsaker: Rörelse. Kärlens anatomiska läge. Störande ljud från utrustning.	Om ljud är tydligt är det lättare. Opålitliga mätningar beror på muskelspänningar eller störande ljud.	Pålitligt om ljudet hörs tydligt och kurvan är rimlig. Om osäkert -> ny mätning direkt. Vanlig orsak till opålitliga värden: Muskelspänning, rörelse, brus.
I förhållande till andra parametrar som mäts under testet, som (EKG, spirometri) hur viktigt är blodtrycksmätningen?	EKG är viktigast. Blodtryck är sekundärt, men kritiskt vid fallande tryck. Är ett brytkriterium.	Avgörande i vissa patientgrupper, särskilt vid blodtrycksfall. Mindre viktig så länge trycket stiger normalt. EKG och prestation (watt) är primära.	Viktig vid blodtrycksfall, är ett brytkriterium.	EKG viktigast, sedan är blodtrycket., det är avbrottskriteriet.	Läkarfråga. Beror på frågeställningen, ibland mycket viktigt, i andra fall mindre viktigt. EKG viktigare.
Vad skulle krävas av en blodtrycksmätare för att den skulle passa in i erat arbetsflöde? (ex. behöver man ha flera olika kopplingar till tryckluft, eller flera olika manometrar beroende om patienten ligger eller cyklar) - Räcker det att flytta runt en som finns eller underlättar det om flera finns? - Finns det fysiska begränsningar i rummet eller runt patienten som påverkar hur utrustning kan placeras?	Snabb mätning. Möjlighet till att fungera manuellt, fungera vid strömavbrott.. Återanvändningsbara, lättstädade manschetter. Stor och tydlig manometer/display. Det underlättar om flera finns, men går att flytta runt. Fysiska begränsningar: Begränsat utrymme runt patienten. Utrustning får inte störa cykling eller patientens rörelser.	Krav för att passa in i arbetsflödet: Mycket hög tillförlitlighet. Möjlighet till manuell mätning. Enkel att flytta mellan brits och cykel. Tydlig manometer (stor). Enkel rengöring. Service och kalibrering via MT. En enhet räcker men flera hade underlättat logistiskt. Fysiska begränsningar: Trångt runt patienten. Mycket sladdar och utrustning.	Krav för att passa in i arbetsflödet: Fotpedal är att föredra. Inte fler sladdar. Lättare växling mellan cykel & gångmatta. Helst separata eller automatiskt växlingsbara system. En enhet räcker men knapptryckning istället för manuell omkoppling hade underlättat. Fysiska begränsningar: Trångt runt pat., mycket befintlig utrustning och många sladdar.	Snabbt upp i tryck, släppa ut trycket som man vill. Robust men med finlir. Pålitlig Helst två olika så att man slipper flytta runt den man har. Enda begränsningen är längden på sladden (om det endast finns en som måste flyttas).	Önskemål: Större och stabilare manometer (helst analog). Möjlighet att styra tryck kontrollerat. Flera enheter är inget uttryckt behov, flyttbar lösning verkar acceptabel.
Finns det något i en ny metod som du inte skulle vilja använda?	En helt automatisk lösning utan manuell kontroll. Metoder som tar lång tid eller saknar fingertoppskänsla.	Trådlösa lösningar utan säker backup. Helautomatiska system som inte går att verifiera manuellt. Metoder där användaren inte själv kan höra eller kontrollera mätningen.	En metod som inte går att lita på, så som helautomatiska värden utan möjlighet till egen rimlighetsbedömning.	Opålitlig metod.	System som automatiskt pumpar upp till höga tryck utan att BMA har kontroll. Opålitlig metod.
Upplever ni att mätningen stör testet eller patienten? - Hur påverkar den blodtrycksmätare som används idag patienten under testet?	Ja, varje mätning stör patientens prestation något. Vissa upplever smärta eller obehag. Ju mer utrustning, desto mer oro hos patienten. Därför ska mätningen gå snabbt och störa så lite som möjligt.	Ja, mätningen stör patienten. Vissa upplever smärta vid uppumpning. Patienten måste släppa styret, tappar tempo och fokus. Därför är snabb mätning extremt viktig.	Inte nämnvärt, vissa patienter upplever obehag/smärta vid höga tryck. Svårt för pat. att hålla armen stilla vid mätning.	Nej, pat. kan tappa fart när armen ska slappna av, men är upp till BMA att coacha bra.	Barn pat. kan sluta trampa när mätning görs. Armen behöver tas från styret vilket påverkar prestation negativt. Dopplerljud kan vara högt. Därför undviks ibland mätning under arbete hos mindre barn.
Vad skulle krävas för att du ska känna förtroende för en ny metod för blodtrycksmätning under CPET? - Hur noggrann behöver mätningen av det systoliska blodtrycket vara för kliniskt nytta? - Har du några specifika krav en uppdaterad/ny metod behöver?	Tydlig och robust validering. Tillräcklig noggrannhet för kliniska beslut, SBP-noggrannhet cirka 5 mmHg. Snabb. Möjlighet till manuell mätning. Hygienisk, kostnadseffektiv och driftsäker lösning.	Bevisad hög noggrannhet genom klinisk validering, gärna jämfört med invasivt tryck. Möjlighet till regelbunden kalibrering och service. Kunna fungera enbart manuellt vid behov. Robust, får inte sluta fungera. Noggrannhet: Viktigare med korrekt förändring över tid än absolutvärde. Krav: Tillförlitlig, snabb, enkel, inte mer störande än dagens system. Helst med möjlighet till automatisk överföring av mätvärde.	Krav: Att den stämmer överens med manuella mätningar. Hög noggrannhet (mindre än 10 mmHg fel). Möjlighet att själv höra/bedöma signalen. Färre sladdar. Önskemål: Gärna en handledsburen doppler, ev. trådlös.	Pålitlig, måste mäta med noggrannhet av 5. Går mer precis är det bra, men inget krav. Snabb	Framförallt pålitlighet. Noggrannhet ungefär 5 mmHg.

C

General Safety and Performance Requirements

Information om produkt som egentillverkas | Produktmodell/namn | Version

ID = punkt i bilaga I, MDR	Krav bilaga I, MDR	Tillämpbar/ ej tillämpbar Välj i rullistan	Tillämpbar/ ej tillämpbar Motivering	Referensdokument som visar att produkten uppfyller kravet	Referens till standard	Uppfyllt / riskminimerat Välj i rullistan	Uppfyllt / riskminimerat Motivering
10	**Kemiska, fysikaliska och biologiska egenskaper**						
10.1	Produkter ska konstrueras och tillverkas på ett sådant sätt att det säkerställs att de krav på egenskaper och prestanda som avses i kapitel I uppnås. Särskild uppmärksamhet ska ägnas åt a) valet av material och substanser, särskilt vad gäller toxicitet och i tillämpliga fall eldfarlighet, b) de använda materialens och substansernas kompatibilitet med biologiska vävnader, celler och kroppsvätskor, med beaktande av produktens avsedda ändamål och, i tillämpliga fall, absorption, distribution, metabolism och utsöndring, c) kompabiliteten mellan olika delar hos en produkt som består av fler än en del för implantation, d) processernas inverkan på materialegenskaperna, e) i förekommande fall, resultaten av biofysisk forskning eller modelleringsforskning, vilkas validitet har styrkts på förhand, f) de mekaniska egenskaperna hos de material som används, som i förekommande fall ska grundas på sådant som styrka, duktilitet, brottfasthet, slitstyrka och utmattningshållfasthet, g) ytegenskaper, och h) bekräftelsen på att produkten uppfyller eventuella fastställda kemiska och/eller fysiska specifikationer.	Tillämpbar					
10.2	Produkter ska konstrueras, tillverkas och förpackas på ett sådant sätt att de risker som föroreningar och restämnen utgör för patienterna minimeras, med hänsyn tagen till produktens avsedda ändamål, liksom riskerna för de personer som transporterar, lagrar och använder produkterna. Särskild hänsyn ska tas till de vävnader som utsätts för dessa föroreningar och restämnen och till hur länge och ofta dessa vävnader är utsatta.	Tillämpbar					
10.3	Produkter ska konstrueras och tillverkas på ett sådant sätt att de kan användas på ett säkert sätt tillsammans med de material och substanser, inklusive gaser, som de kommer i kontakt med när de används på avsett sätt; om produkterna är avsedda att administrera läkemedel ska de konstrueras och tillverkas så att de är kompatibla med läkemedlen i fråga i enlighet med de bestämmelser och begränsningar som gäller för dessa läkemedel och så att både läkemedlens och produkternas prestanda bibehålls i enlighet med deras respektive indikationer och avsedda ändamål.	Tillämpbar					
10.4	**Substanser**						
10.4.1	Produkters konstruktion och tillverkning Produkter ska konstrueras och tillverkas på ett sådant sätt att riskerna med substanser eller partiklar, inklusive slitagepartiklar, nedbrytningsprodukter och bearbetningsrester, som kan frigöras från produkten, minimeras så långt det är möjligt. Produkter eller delar av dem, eller de material som används i dem, som — är invasiva och kommer i direkt kontakt med människokroppen, eller — (åter)administrerar läkemedel, kroppsvätskor eller andra substanser, inklusive gaser, till/från människokroppen, eller — transporterar eller lagrar sådana läkemedel, kroppsvätskor eller substanser, inklusive gaser, som ska administreras till människokroppen, får endast innehålla följande substanser i en koncentration högre än 0,1 viktprocent, när detta är berättigat i enlighet med avsnitt 10.4.2: a) ämnen som är cancerframkallande, mutagena eller reproduktionstoxiska enligt kategori 1A eller 1B i enlighet med del 3 i bilaga VI till Europaparlamentets och rådets förordning (EG) nr 1272/2008 (1) (CMR- ämnen), eller b) substanser med hormonstörande egenskaper för vilka det finns vetenskaplig evidens som visar att de sannolikt kan ha allvarliga effekter på människors hälsa och som identifieras antingen i enlighet med förfarandet i artikel 59 i Europaparlamentets och rådets förordning (EG) nr 1907/2006 (2) eller, när kommissionen har antagit en delegerad akt i enlighet med artikel 5.3 första stycket i Europaparlamentets och rådets förordning (EU) nr 528/2012 (3), i enlighet med de av de där angivna kriterierna som gäller människors hälsa.	Tillämpbar					
10.4.2	Motivering till förekomsten av CMR-ämnen och/eller hormonstörande substanser Motiveringen till förekomsten av sådana substanser ska vara grundad på följande: a) En analys och uppskattning av patienters eller användares potentiella exponering för substansen. b) En analys av möjliga alternativa substanser, material eller konstruktioner, inklusive tillgänglig information om oberoende forskning, fackgranskade studier, vetenskapliga yttranden från relevanta vetenskapliga kommittéer och en analys av tillgången till sådana alternativ. c) Motivering till varför möjliga ersättningssubstanser och/eller -material, om sådana finns tillgängliga, eller möjliga konstruktionsändringar, inte lämpar sig för att upprätthålla produktens funktionalitet, prestanda och nytta/riskförhållande; detta inbegriper ett beaktande av om sådana produkters avsedda användning omfattar behandling av barn, behandling av gravida eller ammande kvinnor eller behandling av andra patientgrupper som anses vara särskilt sårbara för sådana substanser och/eller material. d) De senaste relevanta riktlinjerna från vetenskapliga kommittéer i enlighet med avsnitten 10.4.3 och 10.4.4, om sådana är tillämpliga och finns tillgängliga.	Ej tillämpbar					
10.4.3	Riktlinjer för ftalater Vid tillämpningen av avsnitt 10.4 ska kommissionen snarast möjligt och senast den 26 maj 2018 ge den relevanta vetenskapliga kommittén i uppdrag att utarbeta riktlinjer som ska färdigställas före den 26 maj 2020. Kommitténs uppdrag ska åtminstone omfatta en bedömning av nytta/riskförhållandet vad gäller förekomsten av ftalater som hör till endera av de grupper av substanser som avses i avsnitt 10.4.1 a och b. Bedömningen av nytta/riskförhållandet ska ta hänsyn till produktens avsedda ändamål och det sammanhang i vilket produkten används, tillgängliga alternativa substanser, samt alternativa material, konstruktioner eller medicinska behandlingar. Riktlinjerna ska när så anses lämpligt uppdateras på grundval av den senaste vetenskapliga evidensen, dock minst vart femte år.	Ej tillämpbar					
10.4.4	Riktlinjer för andra CMR-ämnen och hormonstörande substanser Kommissionen ska därefter ge den relevanta vetenskapliga kommittén i uppdrag att, i förekommande fall, utarbeta sådana riktlinjer som avses i avsnitt 10.4.3 även för andra substanser som avses i avsnitt 10.4.1 a och b.	Ej tillämpbar					
10.4.5	Märkning Om produkter, delar av dem eller de material som används i dem enligt avsnitt 10.4.1 innehåller substanser som avses i avsnitt 10.4.1 a eller b i en koncentration högre än 0,1 viktprocent, ska förekomsten av dessa substanser anges på själva produkten och/eller på varje enhets förpackning eller, i förekommande fall, på försäljningsförpackningen med förteckningen över dessa substanser. Om den avsedda användningen av sådana produkter omfattar behandling av barn eller behandling av gravida eller ammande kvinnor eller behandling av andra patientgrupper som anses vara särskilt sårbara för sådana substanser och/eller material, ska information om kvarvarande risker för dessa patientgrupper och, i tillämpliga fall, om lämpliga försiktighetsåtgärder tillhandahållas i bruksanvisningen.	Ej tillämpbar					
10.5	Produkterna ska konstrueras och tillverkas på ett sådant sätt att riskerna med substanser som oavsiktligt tränger in i produkterna minskas så långt det är möjligt, med beaktande av produkten och den miljö som den är avsedd att användas i.	Tillämpbar					
10.6	Produkterna ska konstrueras och tillverkas på ett sådant sätt att de risker som är kopplade till storlek och egenskaper hos de partiklar som frisläpps eller kan frisläppas i patientens eller användarens kropp minskas så långt det är möjligt, om produkterna inte enbart kommer i kontakt med intakt hud. Nanomaterial ska ägnas särskild uppmärksamhet.	Ej tillämpbar					
11	**Infektion och mikrobiell kontamination**						
11.1	Produkterna ska vara konstruerade och tillverkningsprocesserna utformade på ett sådant sätt att risken för att patienterna, användarna och i förekommande fall andra personer infekteras elimineras eller minskas så långt det är möjligt. Produktionens konstruktion respektive tillverkningsprocessens utformning ska vara sådan att a) risken för oavsiktliga snitt och stick, såsom nålsticksskador, minskas så långt det är möjligt och lämpligt, b) hanteringen är lätt och säker, c) eventuellt mikrobiellt läckage från produkten och/eller mikrobiell exponering vid användningen så långt det är möjligt minskas, och d) mikrobiell kontaminering av produkten eller dess innehåll, såsom prover eller vätskor, förhindras.	Tillämpbar					
11.2	När det är nödvändigt ska produkterna vara konstruerade så att säker rengöring, desinficering och/eller resterilisering av dem underlättas.	Tillämpbar					
11.3	Produkter som är märkta med uppgift om att de befinner sig i ett specifikt mikrobiellt tillstånd ska vara konstruerade, tillverkade och förpackade på ett sådant sätt att de förblir i detta tillstånd när de släpps ut på marknaden och under de av tillverkaren angivna lagrings- och transportförhållandena.	Ej tillämpbar					
11.4	Produkter som levereras sterila ska vara konstruerade, tillverkade och förpackade i enlighet med lämpliga förfaranden som säkerställer att de är sterila när de släpps ut på marknaden och att de, såvida inte den förpackning som är avsedd att se till att de förblir sterila är skadad, förblir sterila under de av tillverkaren angivna lagrings- och transportförhållandena, tills förpackningen öppnas vid användningstillfället. Det ska säkerställas att det för slutanvändaren klart framgår att den sterila förpackningen är obruten.	Ej tillämpbar					
11.5	Produkter som är märkta som sterila ska behandlas, tillverkas, förpackas och steriliseras med hjälp av lämpliga och validerade metoder.	Ej tillämpbar					
11.6	Produkter som är avsedda att steriliseras ska tillverkas och förpackas under lämpliga och kontrollerade förhållanden och i lämpliga och kontrollerade anläggningar.	Ej tillämpbar					
11.7	Förpackningssystemen för icke-sterila produkter ska hålla produkterna intakta och rena och, om produkterna ska steriliseras före användning, minimera risken för mikrobiell kontamination; förpackningssystemet ska vara lämpligt med beaktande av den steriliseringsmetod som tillverkaren angett.	Ej tillämpbar					
11.8	Produktens märkning ska särskilja mellan identiska eller liknande produkter som släppts ut på marknaden i både sterilt och icke-sterilt skick, och detta i tillägg till den symbol som används för att ange att produkterna är sterila.	Ej tillämpbar					
12	**Produkter som innehåller en substans som anses vara ett läkemedel och produkter som består av substanser eller kombinationer av substanser som absorberas av eller sprids lokalt i människokroppen**						
12.1	När det gäller produkter som avses i artikel 1.8 första stycket ska kvaliteten, säkerheten och användbarheten av en substans som, om den används separat, skulle betraktas som ett läkemedel enligt definitionen i artikel 1.2 i direktiv 2001/83/EG, kontrolleras i analogi med de metoder som anges i bilaga I till direktiv 2001/83/EG, i enlighet med kraven för det tillämpliga förfarandet för bedömning av överensstämmelse inom ramen för denna förordning.	Ej tillämpbar					
12.2	Produkter som består av substanser eller kombinationer av substanser som är avsedda att föras in i människokroppen och som absorberas av eller sprids lokalt i människokroppen ska, i tillämpliga fall och begränsat till de aspekter som inte omfattas av denna förordning, uppfylla de relevanta kraven i bilaga I till direktiv 2001/83/EG för utvärdering av absorption, distribution, metabolism, utsöndring, lokal tolerans, toxicitet, interaktion med andra produkter, läkemedel eller andra substanser och potential för biverkningar, i enlighet med kraven för det tillämpliga förfarandet för bedömning av överensstämmelse inom ramen för denna förordning.	Ej tillämpbar					
13	**Produkter som innehåller material av biologiskt ursprung**						
13.1	För produkter som tillverkas av derivat av humana vävnader eller celler som är icke-viabla eller har gjorts icke- viabla och som omfattas av denna förordning i enlighet med artikel 1.6 g gäller följande: a) Donation, tillvaratagande och kontroll av vävnader och celler ska ske i enlighet med direktiv 2004/23/EG. b) Bearbetning, konservering och annan hantering av sådana vävnader och celler eller derivat därav ska ske på ett sätt som är säkert för patienter, användare och, i förekommande fall, andra personer. I synnerhet ska säkerheten vad gäller virus och andra smittämnen tillgodoses genom lämpliga metoder för val av ursprung och genom tillämpning av godkända metoder för eliminering eller inaktivering under tillverkningsprocessens gång. c) Spårbarhetssystemet för dessa produkter ska komplettera och uppfylla de krav på spårbarhet och uppgiftsskydd som fastställs i direktiv 2004/23/EG och i direktiv 2002/98/EG.	Ej tillämpbar					
13.2	För produkter som tillverkas av sådana vävnader eller celler av animaliskt ursprung eller derivat därav som är icke-viabla eller har gjorts icke-viabla gäller följande: a) Om det är möjligt med hänsyn till djurarten ska vävnader och celler av animaliskt ursprung eller derivat därav komma från sådana djur som har genomgått veterinärkontroller som är anpassade till vävnadernas avsedda användning. Information om djurens geografiska ursprung ska bevaras av tillverkarna. b) Val av ursprung, bearbetning, konservering, provning och hantering av vävnader, celler och substanser av animaliskt ursprung eller derivat därav ska ske på ett sätt som är säkert för patienter, användare och i förekommande fall andra personer. I synnerhet ska säkerheten vad gäller virus och andra smittämnen tillgodoses genom tillämpning av validerade metoder för eliminering eller inaktivering av virus under tillverkningsprocessens gång, utom när användningen av sådana metoder skulle innebära en oacceptabel försämring av produkten som äventyrar dess kliniska nytta. c) I fråga om produkter som tillverkas av vävnader eller celler av animaliskt ursprung eller derivat därav enligt förordning (EU) nr 722/2012 gäller de särskilda krav som anges i den förordningen.	Ej tillämpbar					
13.3	I fråga om produkter som tillverkas av andra icke-viabla biologiska substanser än dem som avses i avsnitten 13.1 och 13.2 ska bearbetning, konservering, provning och hantering av dessa substanser, inklusive inom avfallskedjan, ske på ett säkert sätt för patienter, användare och i förekommande fall andra personer. I synnerhet ska säkerheten vad gäller virus och andra smittämnen tillgodoses genom lämpliga metoder för val av ursprung och genom tillämpning av validerade metoder för eliminering eller inaktivering under tillverkningsprocessens gång.	Ej tillämpbar					
14	**Produkters tillverkning och interaktion med sin omgivning**						
14.1	Om produkten är avsedd att användas tillsammans med andra produkter eller annan utrustning ska hela kombinationen, inklusive sammankopplingssystemet, vara säkert och inte försämra produkternas angivna prestanda. Eventuella användningsbegränsningar för sådana kombinationer ska framgå av märkningen och/eller bruksanvisningen. Anslutningar som användaren ska hantera, t.ex. koppling för vätske- eller gasöverföring eller elektrisk eller mekanisk koppling, ska vara konstruerade och tillverkade på ett sådant sätt att alla möjliga risker, såsom felaktiga sammankopplingar, minimeras.	Tillämpbar					
14.2	Produkterna ska vara konstruerade och tillverkade på ett sådant sätt att följande risker elimineras eller minskas så långt det är möjligt: a) Risken för skada kopplad till deras fysikaliska egenskaper, inklusive volym/tryckförhållandet, mått och i förekommande fall ergonomiska egenskaper. b) Risker kopplade till yttre faktorer eller miljöförhållanden som rimligen kan förutses, som magnetfält, yttre elektrisk och elektromagnetisk påverkan, elektrostatisk urladdning, strålning i samband med diagnostik eller behandling, tryck, fuktighet, temperatur, tryckvariationer, acceleration eller störning orsakad av radiosignaler. c) Riskerna i samband med användningen av produkten när den kommer i kontakt med material, vätskor och substanser, inklusive gaser, som den exponeras för under normala användningsförhållanden. d) Riskerna i samband med eventuell negativ interaktion mellan programvara och den it-miljö där produkten används och interagerar. e) Riskerna för att substanser oavsiktligt tränger in i produkterna. f) Riskerna för ömsesidig störning med andra produkter som normalt används vid undersökningarna eller vid den aktuella behandlingen. g) Risker som kan uppstå då det är omöjligt att underhålla eller kalibrera produkten (som vid implantat), vid åldrande av det använda materialet eller minskad noggrannhet hos någon mät- eller kontrollmekanism.	Tillämpbar					
14.3	Produkterna ska konstrueras och tillverkas på ett sådant sätt att risken för brand eller explosion är så liten som möjligt vid normal användning och vid ett första fel. Särskild uppmärksamhet ska ägnas åt produkter som är avsedda att utsättas för eller användas i anslutning till lättantändliga eller explosiva substanser eller substanser som skulle kunna orsaka brand.	Tillämpbar					
14.4	Produkterna ska vara konstruerade och tillverkade på ett sådant sätt att justering, kalibrering och underhåll kan utföras på ett säkert och effektivt sätt.	Tillämpbar					
14.5	Produkter som är avsedda att användas tillsammans med andra produkter eller artiklar ska konstrueras och tillverkas på ett sådant sätt att interoperabiliteten och kompatibiliteten är tillförlitliga och säkra.	Tillämpbar					
14.6	Skalor för mätning, övervakning och bildskärmar ska vara ergonomiskt konstruerade och tillverkade och ta hänsyn till produktens avsedda ändamål och användare samt de miljöförhållanden under vilka produkten är avsedd att användas.	Tillämpbar					
14.7	Produkterna ska vara konstruerade och tillverkade på ett sådant sätt att säkert bortskaffande av produkten och relaterade avfallsämnen underlättas för användare, patienter och andra personer. För att uppnå detta ska tillverkarna fastställa och testa förfaranden och åtgärder som innebär att deras produkter på ett säkert sätt kan bortskaffas efter användning. Sådana förfaranden ska beskrivas i bruksanvisningen.	Tillämpbar					
15	**Produkter med diagnos- eller mätfunktion**						
15.1	Produkter för diagnostik och produkter som har en mätfunktion ska konstrueras och tillverkas på ett sådant sätt att de är tillräckligt noggranna, precisa och tillförlitliga för sitt avsedda ändamål, baserat på lämpliga vetenskapliga och tekniska metoder. Toleranser avseende noggrannhet ska anges av tillverkaren.	Tillämpbar					
15.2	De mätningar som görs med produkter som har en mätfunktion ska uttryckas i författningsenliga enheter som är förenliga med bestämmelserna i rådets direktiv 80/181/EEG (1).	Tillämpbar					
16	**Strålskydd**						
16.1	Allmänt a) Produkterna ska konstrueras, tillverkas och förpackas på ett sådant sätt att den bestrålning som patienter, användare och andra personer utsätts för minskas så mycket som möjligt och på ett sätt som är förenligt med det avsedda ändamålet, utan att begränsa användningen av adekvata strålningsnivåer för terapeutiska eller diagnostiska ändamål. b) Bruksanvisningarna för produkter som avger farlig eller potentiellt farlig strålning ska innehålla närmare upplysningar om typen av strålning, skyddsåtgärder för patienter och användare, sätt att undvika felanvändning och sätt att minska riskerna förenade med installation så mycket som är möjligt och lämpligt. Information om acceptans- och funktionsprovning, acceptanskriterierna och underhållsförfarandet ska också anges.	Tillämpbar					
16.2	Avsiktlig bestrålning a) Om produkterna är konstruerade för att avge farliga eller potentiellt farliga mängder joniserande och/eller icke-joniserande strålning som krävs för ett visst medicinskt syfte vars nytta anses uppväga de inneboende riskerna med strålningen, ska det vara möjligt för användaren att kontrollera bestrålningen. Sådana produkter ska konstrueras och tillverkas på ett sådant sätt att relevanta variabla parametrar kan reproduceras med tillfredsställande noggrannhet. b) Om produkterna är avsedda att avge farlig eller potentiellt farlig joniserande och/eller icke-joniserande strålning ska de, där så är möjligt, förses med ett varningssystem som ger synliga och/eller hörbara varningar för sådan strålning.	Ej tillämpbar					
16.3	Produkterna ska konstrueras och tillverkas på ett sådant sätt att exponeringen av patienter, användare och andra personer för oavsiktlig strålning, spridd strålning eller spridd strålning blir så liten som möjligt. Där så är möjligt och lämpligt ska metoder väljas som minskar strålningsexponeringen för patienter, användare och andra personer som kan påverkas.	Tillämpbar					
16.4	Joniserande strålning a) Produkter som är avsedda att avge joniserande strålning ska konstrueras och tillverkas med beaktande av kraven i direktiv 2013/59/Euratom om fastställande av grundläggande säkerhetsnormer för skydd mot de faror som uppstår till följd av exponering för joniserande strålning. b) Produkter som är avsedda att avge joniserande strålning ska konstrueras och tillverkas på ett sådant sätt att det, om möjligt och med beaktande av det avsedda ändamålet, är möjligt att under behandlingen variera och kontrollera den avgivna strålningens kvantitet, geometri och kvalitet. c) Produkter som avger joniserande strålning avsedd för diagnostisk radiologi ska konstrueras och tillverkas på ett sådant sätt att en bild- och/eller resultatkvalitet som är lämplig för det avsedda medicinska ändamålet uppnås samtidigt som den strålning som patienten och användaren utsätts för minimeras. d) Produkter som avger joniserande strålning och är avsedda för radioterapi ska konstrueras och tillverkas på ett sådant sätt att stråldosen, strålslaget, energin och, i förekommande fall, strålningens kvalitet kan övervakas och kontrolleras på ett tillförlitligt sätt.	Ej tillämpbar					
17	**Elektroniska programmerbara system – produkter som innefattar elektroniska programmerbara system och programvara som i sig är produkter**						
17.1	Produkter som innefattar elektroniska programmerbara system, inklusive programvara eller programvaror som i sig är produkter, ska konstrueras så att repeterbarhet, tillförlitlighet och prestanda i enlighet med den avsedda användningen säkerställs. I händelse av ett första fel ska produkten vidta lämpliga åtgärder för att eliminera eller så långt det är möjligt minska risker eller försämring av prestandan till följd av felet.						
17.2	I fråga om produkter som innehåller programvara eller i fråga om programvara som i sig är produkter ska programvaran utvecklas och tillverkas i enlighet med det allmänt erkända tekniska utvecklingsstadiet och med beaktande av principerna för utvecklingslivscykel, riskhantering, inbegripet informationssäkerhet, kontroll och validering.						
17.3	Sådan programvara som avses i detta avsnitt och som är avsedd att användas i kombination med mobila datorplattformar ska konstrueras och tillverkas med beaktande av den mobila plattformens specifika egenskaper (t.ex. skärmens storlek och kontrastförhållande) och de yttre faktorerna i samband med användningen (varierande miljö som ljus- eller ljudnivå).						
17.4	Tillverkare ska ange minimikrav för hårdvara, it-nätverks egenskaper och åtgärder för it-säkerhet, inklusive skydd mot obehörigt tillträde, som behövs för att programvaran ska kunna köras som avsett.	Ej tillämpbar					
18	**Aktiva produkter och produkter som är kopplade till dem**						
18.1	I fråga om aktiva produkter som inte är implantat ska lämpliga åtgärder vidtas i händelse av ett första fel, för att eliminera eller så långt det är möjligt minska riskerna till följd av felet.	Tillämpbar					
18.2	Om patientens säkerhet är beroende av att produkterna har en intern energikälla ska produkterna vara utrustade med en möjlighet att kontrollera energikällans tillstånd och med en lämplig varning eller indikation när energikällans kapacitet blir kritisk. Om så är nödvändigt ska en sådan varning eller indikation ges innan energikällans kapacitet blir kritisk.	Ej tillämpbar					
18.3	Produkter där patientens säkerhet är beroende av en extern energikälla ska vara utrustade med ett larmsystem som signalerar strömavbrott.	Tillämpbar					
18.4	Produkter som är avsedda att övervaka en eller flera kliniska parametrar hos en patient ska vara utrustade med lämpliga larmsystem som gör användaren uppmärksam på situationer som skulle kunna leda till patientens död eller en allvarlig försämring av patientens hälsotillstånd.	Ej tillämpbar					
18.5	Produkterna ska konstrueras och tillverkas på ett sådant sätt att riskerna för att de skapar elektromagnetisk störning, som skulle kunna störa funktionen hos produkten i fråga eller andra produkter eller utrustning i den avsedda miljön, minskas så långt det är möjligt.	Tillämpbar					
18.6	Produkterna ska konstrueras och tillverkas på ett sådant sätt att deras inbyggda tålighet mot elektromagnetisk störning är tillräcklig för att de ska kunna fungera som avsett.	Tillämpbar					
18.7	Produkterna ska konstrueras och tillverkas på ett sådant sätt att risken för oavsiktliga elektriska chocker för patienten, användaren eller någon annan person både vid normal användning av produkten och vid ett första fel i produkten i möjligaste mån undviks, under förutsättning att produkterna installeras och underhålls enligt tillverkarens anvisningar.	Tillämpbar					
18.8	Produkterna ska konstrueras och tillverkas på ett sådant sätt att de i möjligaste mån skyddas mot obehörigt intrång som skulle kunna hindra produkten från att fungera som avsett.	Tillämpbar					
19	**Särskilda krav för aktiva implantat**						
19.1	Aktiva implantat ska konstrueras och tillverkas på ett sådant sätt att följande risker elimineras eller blir så små som möjligt: a) Risker i samband med användning av energikällor och, då elektricitet används, i synnerhet när det gäller isoleringen, läckströmmar och överhettning av produkterna. b) Risker i samband med medicinsk behandling, särskilt sådana risker som uppstår vid användning av defibrillatorer eller kirurgisk högfrekvensutrustning. c) Risker som kan uppstå då underhåll och kalibrering är omöjligt, inklusive — alltför stor ökning av läckströmmar, — åldrande av de använda materialen, — överskottsvärme, alstrad av produkten, — minskad noggrannhet hos någon mät- eller kontrollmekanism.	Ej tillämpbar					
19.2	Aktiva implantat ska konstrueras och tillverkas på ett sådant sätt att följande säkerställs: — I förekommande fall produkternas förenlighet med de substanser de är avsedda att administrera. — Energikällans tillförlitlighet.	Ej tillämpbar					
19.3	Aktiva implantat och i förekommande fall deras komponenter ska kunna identifieras för att göra det möjligt att vidta nödvändiga åtgärder om potentiella risker upptäcks avseende produkterna eller deras komponenter.	Ej tillämpbar					
19.4	Aktiva implantat ska ha en kod genom vilken de och deras tillverkare entydigt kan identifieras (särskilt vad gäller typen av produkt och dess tillverkningsår); det ska vara möjligt att, om så är nödvändigt, läsa denna kod utan behov av ett kirurgiskt ingrepp.	Ej tillämpbar					
20	**Skydd mot mekaniska och termiska risker**						
20.1	Produkterna ska konstrueras och tillverkas på ett sådant sätt att patienter och användare skyddas mot mekaniska risker avseende t.ex. rörelsemotstånd, instabilitet och rörliga delar.	Tillämpbar					
20.2	Produkterna ska konstrueras och tillverkas på ett sådant sätt att de risker som uppstår genom vibrationer som alstras av produkterna blir så små som möjligt, varvid hänsyn ska tas till de tekniska framstegen och de medel som finns tillgängliga för att begränsa vibrationer, i första hand vid källan, såvida inte vibrationerna är en del av den angivna prestandan.	Tillämpbar					
20.3	Produkterna ska konstrueras och tillverkas på ett sådant sätt att de risker som uppstår i samband med buller blir så små som möjligt, varvid hänsyn ska tas till de tekniska framstegen och de medel som finns tillgängliga för att minska buller, i första hand vid källan, såvida inte bullret är en del av den angivna prestandan.	Tillämpbar					
20.4	Terminaler och anslutningsdon till elektrisk, gasformig eller hydraulisk och pneumatisk energitillförsel som användaren eller någon annan person ska hantera ska konstrueras och tillverkas på ett sådant sätt att alla potentiella risker minimeras.	Tillämpbar					
20.5	Fel som sannolikt kan begås vid montering eller återmontering av vissa delar som kan ge upphov till risker ska undanröjas genom delarnas konstruktion och tillverkning eller, om detta inte är möjligt, genom att information anbringas på själva delarna och/eller deras höljen. När rörelseriktningen måste vara känd för att en risk ska kunna undvikas ska samma information lämnas på rörliga delar och/eller på deras höljen.	Tillämpbar					
20.6	Åtkomliga delar av produkterna (med undantag för delar eller områden som är avsedda att tillhandahålla värme eller nå vissa temperaturer) och deras omgivningar får inte uppnå potentiellt farliga temperaturer under normala användningsförhållanden.	Tillämpbar					
21	**Skydd mot risker från produkter som avger energi eller substanser för patient eller användare**						
21.1	Produkter som tillför patienten energi eller substanser ska konstrueras och tillverkas på ett sådant sätt att mängden som ska tillföras kan fastställas och bibehållas tillräckligt noggrant för att patientens och användarens säkerhet ska kunna säkerställas.	Tillämpbar					
21.2	Produkterna ska förses med en funktion som förhindrar och/eller påvisar felaktigheter som skulle kunna utgöra en fara i den tillförda mängden energi eller substanser. Produkterna ska ha en lämplig funktion som i största möjliga utsträckning förhindrar att farliga mängder energi eller substanser oavsiktligt avges av energi- och/eller substanskällan.	Tillämpbar					
21.3	Kontrollernas och indikatorernas funktioner ska anges tydligt på produkterna. Om det finns en bruksanvisning på produkten eller om funktions- eller justeringsparametrar markeras genom ett visuellt system på produkten, ska dessa anvisningar vara förståeliga för användaren, och i förekommande fall, för patienten.	Tillämpbar					
22	**Skydd mot de risker som utgörs av produkter som av tillverkaren är avsedda att användas av lekmän**						
22.1	Produkter som ska användas av lekmän ska konstrueras och tillverkas på ett sådant sätt att de fungerar i enlighet med det avsedda ändamålet med hänsyn till lekmännens kompetens och de medel som står dem till buds, samt till de variationer som rimligen kan förutses i lekmännens teknik och omgivning. Det ska vara lätt för en lekman att förstå och tillämpa tillverkarens information och anvisningar.	Ej tillämpbar					
22.2	Produkter som ska användas av lekmän ska konstrueras och tillverkas på ett sådant sätt att — produkten kan användas på ett säkert och korrekt sätt under processens alla steg av den avsedda användaren efter lämplig utbildning och/eller information om så krävs, — risken för oavsiktliga snitt och stick, såsom nålsticksskador, minskas så långt det är möjligt och lämpligt, och — risken för att den avsedda användaren använder produkten felaktigt och, i förekommande fall, tolkar resultatet felaktigt minskas så långt det är möjligt.	Ej tillämpbar					
22.3	Produkter som ska användas av lekmän ska, när så är lämpligt, innefatta ett förfarande genom vilket lekmannen — kan kontrollera att produkten vid tidpunkten för användning kommer att fungera som tillverkaren avsett, och — i tillämpliga fall varnas om produkten inte har gett ett tillförlitligt resultat.	Ej tillämpbar					

D

Risk analysis for NIBP device for CPET at SU

Information om produkt som egentillverkas — Produktmodell/namn — Version

Riskhantering

Steg 1 - Identifiering av risk				Steg 2 - Riskbedömning					Steg 3 - Riskkontroll												
Riskområde Almänna krav på säkerhet och prestanda ID=Punkt i bilaga1 MDR, Riskområde = huvudrubrik (rullista)	**Risk ID**	**Fara (hazard)** Potentiell källa till skada.	**Farofylld situation** Omständighet under vilken person, egendom eller omgivning är utsatta för en eller flera faror. Problem/brister/orsaker som leder till att faran inträffar.	**Skada** Troligt resultat om situationen inträffar. Trauma eller men för personers hälsa eller skada på egendom eller omgivningen.	**Riskbedömning innan åtgärd**			**Fortsatt analys?** Vilka risker som ska vidare till steg 3?	**Åtgärdsförslag** Vad kan göras för att eliminera, begränsa eller bevaka riskerna och dess grundorsaker? Definiera också typ av åtgärd: design, skydd och/eller info. Ta hjälp av fliken åtgärdsprioritering				**Ansvarig för åtgärd** Vem/vilka ansvarar för åtgärderna?	**Ägare risk om annan än produktägare** Vem äger risken och har övergripande ansvar för att åtgärderna genomförs?	**Riskkontrolls-verifiering** Hur verifieras att risken tagits om hand?	**Tidplan** När ska åtgärden vara genomförd?	**Riskbedömning efter åtgärd**			**Ny risk introducerad?** Har åtgärderna infört några nya risker?	**Kvarvarande risk** Eventuella kommentarer kring kvarvarande risker.
					Allvarlighet	Sannolikhet	Riskvärde										Konsekvensnivå	Sannolikhet	Riskvärde		
Riskområde	*ID*	*Fara*	*Situation*	*Skada*					*Design*	*Skydd*	*Info*	*Åtgärd*	*Ansvarig*	*Ägare*	*Verifiering*	*Tidplan*				*Ny risk?*	*Kommentar*
	R01	Manschett kan inte blåsas upp, mätning kan ej genomföras	Läckage i luftslang	Upptäcker inte blodtrycksfall	3	2	6	Ja - Hantera risk	Ja			Val av slang, kopplingar, etc. Design som inte kräver att slangar kläms med ex peang.	Jacob, Selena		Dokumentation för komponenter och material. Trycktest för att se att kopplingr är täta. Ta fram testfall.						
	R02	Manschett kan inte blåsas upp, mätning kan ej genomföras	Läckage i luftslang	Byter till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja			Val av slang, kopplingar, etc. Design som inte kräver att slangar kläms med ex peang.	Jacob, Selena		Dokumentation för komponenter och material. Trycktest för att se att kopplingr är täta. Ta fram testfall.						
	R03	Manschett blåses upp med för högt tryck	Ingen, otillräcklig eller skadad övertrycksspärr/ventil	Klämskada, nervskada. Osannolikt med 4-5 bar. Kardborre släpper.	3	2	6	Ja - Hantera risk	Ja			Flera säkerhetsfunktioner. Ex dubbla ventiler, ventil + regulator. Kontroll eller varningsystem?	Jacob, Selena		Dokument för övertrycksventil och regulator. Trycktest.						
	R04	Manschett blåses upp med för högt tryck	Felinställd tryckregulator	Klämskada	3	2	6	Ja - Hantera risk				Kan man "spärra" så regulatorn inte går att ställa in för högt? Annars någon typ av varning?	Jacob, Selena								
	R05	Manschett blåses upp med för lågt tryck	Felinställd tryckregulator	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk				Varning? Möjlighet att manuellt pumpa upp	Jacob, Selena								
	R06	Felaktigt mätvärde	Trasig/felaktigt kalibrerad manometer, visar fel (lika mycket hela tiden)	Innan arbetsprov: kan ställa in prov om tryck verkar för högt. Under arbetsprov: Tryckförändringar det viktigaste, absoluta tryck inte lika viktigt. Väldigt stora avvikelser bör upptäckas av användare.	2	3	6	Ja - Hantera risk	Ja			Val av CE-märkt manometer, ev regelbunden kalibrering (vad säger dokument för manometern?)	Jacob, Selena		Dokumention, CE-märke, nogrannhet etc.						
	R07	Mätning kan ej genomföras	Strömavbrott	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja			Produkten är helt mekaniskt och drivs inte av el.			Designdokument.		2	1	2		
	R08	Mätning tar lång tid	Trycket i manschett släpps ut för långsamt	Kan inte ta snabba mätningar, risk att prov avbryts istället för att man kan dubbelkolla ett värde	2	3	6	Ja - Hantera risk	Ja			Val av komponenter, ex dimensioner på slangar och ventiler	Jacob, Selena		Testning, ta fram krav						
	R09	Felaktig eller utebliven mätning	Trycker i manschett släpps ut för snabbt	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	3	6	Ja - Hantera risk	Ja			Val av komponenter, ex dimensioner på slangar och ventiler. Styra utsläppshastighet manuellt	Jacob, Selena		Testning, ta fram krav						
	R10	Felaktig eller utebliven mätning	Trycket släpps ut i varierande hastighet	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	3	6	Ja - Hantera risk	Ja			Val av komponenter, ex dimensioner på slangar och ventiler. Styra utsläppshastighet manuellt	Jacob, Selena		Testning, ta fram krav						
	R11	Manschett blåses upp med för högt tryck	Trycket inte anpassat för patienten (patientgruppen)	Klämskada. För högt tryck på barn kan leda till smärta och rädsla för framtida prov.	3	4	12	Ja - Hantera risk	Ja		Ja	Regulator där "in-tryck" kan regleras. Behöver specificera gränser för patientpopulationer eller utesluta vissa.	Jacob, Selena		Designdokument, dokument för regulator. Ev test? Med användare?						
	R12	Manschett blåses upp med för högt tryck	Tryck som krävs är över patients smärttröskel	Övergående smärta, påverkar prestation under arbetsprov. Underpresterar på arbetsprovet, vilket kan leda till fler tester etc.	2	2	4	Ja - Hantera risk			Ja	Informera patient och användare får göra bedömning om patient kan göra undersökning.			Ska informeras om i bruksanvisning						
	R13	Felaktig eller utebliven mätning	Doppler trasig	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja		Ja	Använda CE-märkt doppler. Info om att ha ett stetoskop som back-up. Exkl ev i egentillverkningen, utanför produkten?									
	R14	Felaktig eller utebliven mätning	Stetoskop trasigt	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	1	2	Nej - Acceptera risk			Ja	Stetoskop ska finnas. Själva stetoskopet ingår inte i produkten. Upp till användaren att bedöma om back-up krävs.									
	R15	Felaktig eller utebliven mätning	Patient svettas och mätprob för doppler flyttas	Behöver sätta proben rätt, alternativt använda stetoskop. Stör provet.	2	2	4	Ja - Hantera risk	Ja		Ja	Ev armband som håller proben. Info om att både doppler och stetoskop bör finnas. Exkludera ev i egentillverkningen.									
	R16	Felaktig eller utebliven mätning	Högljud omgivning gör att karotkoff-ljud inte hörs	Felaktig bedömning/utebliven mätning	2	3	6	Ja - Hantera risk	Ja			Hateras endast om dopplern ska ses som en del av systemet. Kontrollera att vald doppler läter tillräckligt högt. Exkludera ev i egentillverkningen.	Jacob, Selena		Testa med användare som får tycka till.						
	R17	Felaktig eller utebliven mätning	Patient har låga karotkoff-ljud	Felaktig bedömning/utebliven mätning. Om det är låga karotkoff-ljud använder man doppler istället för stetoskop.	1	2	2	Nej - Acceptera risk													
	R18	Manschett kan inte blåsas upp, mätning kan ej genomföras	Ingen tryckluft in i systemet	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja		Ja	Info om att kolla tryck innan arbetsprov påbörjas. Manuell mätare ska finnas tillgänglig.									
	R19	Utebliven mätning	Trasig ratt/knapp/pedal för att starta mätning	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja		Ja	Val av komponenter. Funktionskontroll innan arbetsprov påbörjas.			Dokument för komponenter. Testning?						
	R20	Utebliven mätning	Kardborreband på manschett släpper	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja		Ja	Använda CE-märkta manschetter. Kontroll innan påbörjat arbetsprov.			Dokumentation för mnschetter och/eller hänvisa till CE-märkta manschetter ska användas. Specificera kontakt i IFU.						
	R21	Utebliven mätning	Trasig on/off-knapp, systemet kan inte startas	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja			Val av komponenter. Funktionskontroll innan arbetsprov påbörjas.									
	R22	Brand	Brandfarligt material i produkten	Brand	4	2	8	Ja - Hantera risk	Ja			Val av material i komponenter.			Dokumentation för komponenter						
	R23	Felaktig eller utebliven mätning	Komponenter går sönder i systemet	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja		Ja	Val av komponenter. Funktionskontroll innan arbetsprov påbörjas. Manuellt system ska finnas tillgängligt.			Dokument för komponenter. Designdokument? Testning?						
	R24	Farliga material	Farliga, toxiska, (etc) material i systemet		4	2	8	Ja - Hantera risk	Ja			Val av material i komponenter.			Dokumentation för komponenter.						
	R25	Smittorisk	Manschett kan ej rengöras adekvat	Infektion	4	3	12	Ja - Hantera risk	Ja			Använda manschetter som är CE-märkta för flergångsbruk och kan rengöras			IFU - hänvisa till CE-märkta manschetter ska användas						
	R26	Manschett blåses upp med för högt tryck	Felkalibrerad tryckregulator	Klämskada, nervskada. Osannolikt med 4-5 bar. Kardborre släpper.	3	2	6	Ja - Hantera risk	Ja	Ja	Ja	Val av komponent. Ev regelbunden kalibrering. Info om att den måste kontrolleras om den ex tappats.			Dokument för regulator Test.						
	R27	Manschett blåses upp med för lågt tryck	Felkalibrerad tryckregulator	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja	Ja	Ja	Val av komponent. Ev regelbunden kalibrering. Info om att den måste kontrolleras om den ex tappats.			Dokument för regulator Test.						
	R28	100% syrgas kopplas in i systemet	System anslutet till fel gasuttag	Brand/explosion	4	3	12	Ja - Hantera risk	Ja			Använda kopplingar som följer SS XXXX			Dokumentation för komponenter						
	R29	Tryck i manschett släpps inte ut	Ventiler fastnar/ self-relief-funktion i regulator slutar fungera.	Klämskada	2	3	6	Ja - Hantera risk	Ja		Ja	Val av komponent. Manschett skalätt kunnas tas bort om det krävs.									
	R30	Felaktig eller utebliven mätning	System/apparat utsätts för våld	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	3	6	Ja - Hantera risk	Ja		Ja	Möjlighet att placera delar av systemet så de inte är i vägen. Info om att om den utsätts för våld krävs service/kontroll.			Designdokument. Testa att placera produkten på avdelningen.						
	R31	Felaktig eller utebliven mätning	Manschett passar inte på patienten	Felaktig mätvärde, troligtvis kan man följa tryckförändringar.	2	3	6	Ja - Hantera risk	Ja		Ja	Val av CE-märkta manschetter med olika storlekar som tycker täcker den avsedda patientgruppen.			IFU - hänvisa till CE-märkta manschetter ska användas.						
	R32	Felaktig eller utebliven mätning	Användare väljer fel manschettstorlek	Felaktig mätvärde, troligtvis kan man följa tryckförändringar.	2	2	4	Ja - Hantera risk	Ja		Ja	Val av CE-märkta manschetter med olika storlekar som tycker täcker den avsedda patientgruppen. Väljs fel manschett och informationen är tydlig är det inte rimlig förutsägbar felanvändning.			IFU - hänvisa till CE-märkta manschetter ska användas.						
	R33	Felaktig eller utebliven mätning	Manschett sätts på felaktigt på patienten	Felaktig mätning, kan leda till felaktig medicinsk bedömning.	3	2	6	Ja - Hantera risk	Ja		Ja	Val av CE-märkta manschetter med olika storlekar som tycker täcker den avsedda patientgruppen. Avsedda användare är utbildad klinisk personal (på klinfys).			IFU - hänvisa till CE-märkta manschetter ska användas.						
	R34	Manschett blåses upp med för högt tryck	Trycket inte anpassat för patienten (onödigt högt tryck för mätningen)	Övergående smärta, påverkar prestation under arbetsprov. Underpresterar på arbetsprovet, vilket kan leda till fler tester etc.	2	2	4	Ja - Hantera risk	Ja		Ja	Undersöka möjlighet att använda regulator där maxtryck kan ändras för respektiva patient.			Användartest.						
	R35	Felaktig eller utebliven mätning	Användare kan inte läsa av manomentern	Utebliven mätning, leder till byte till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	3	6	Ja - Hantera risk	Ja			Stor manometer med en stabil infästning.			Användartest.						
	R36	Manschett kan inte blåsas upp, mätning kan ej genomföras	stopp i slang	Byter till manuell mätning eller fortsätter utan NPB-mätning. Stress för användare. Ev bryta undersökning.	2	2	4	Ja - Hantera risk	Ja		Ja	Manuell mätning ska finnas tillgänglig. Design som inte kräver att slangar kläms med ex peang.			Designdokument.						
	R37	Felaktigt mätvärde	Trasig/felaktigt kalibrerad manometer, mätaren fastnar på ett mätvärde	Felbedömning, kan leda till felaktig medicinsk behandling av remittent.	3	3	9	Ja - Hantera risk	Ja			Använda CE-märkt manometer. Regelbunden kontroll? Upptäckbarhet?									
	R38	Mätning tar lång tid	Trycket i manschett släpps ut för långsamt	Stas, stoppat blod under en tid. Tar tid att återställa blodflöde. Blodtryck uppmäts högre för att sedan gå ned. Kan tolkas som blodtrycksfall och test kan avbrytas.	2	3	6	Ja - Hantera risk	Ja			Val av komponenter, ex dimensioner på slangar och ventiler. Kunna reglera utsläppshastigheten manuellt.			Testning, ta fram krav						
	R39	Snubbelrisk	Sladd/slang på golv	Fallskada	3	3	9	Ja - Hantera risk	Ja			Slangar och kablar ska vara tillräckligt långa och helst inte gå via golvet.			Designdokument och användartest.						

E

Test cases of verification and validation

Testfall Verifiering	Tillvägagångssätt	Godkändkriteium	Risk ID	UR, PR
T.Ver-01	1. Starta mätning. 2. Öka trycket så snabbt som möjligt, mät tid. 3. Släpp ut trycket så snabbt som möjligt, ta tid för varje mätning. 4. Upprepa 3 gånger.	Genomfört testfall.	R19.	
		Inflationstid < 4 s, deflationstid < 4 s, möjligt att påbörja ny mätning inom 5 s.	R08,R38.	UR01,UR12, PR01, PR02, PR04, PR14, PR22.
T.Ver-02	1. Koppla in extern kalibrerad manometer i systemet. 2. Starta mätning. 3. Öka trycket så högt det går. 4. Läs av så att extern kalibrerad manometer visar samma som systemets manometer. 5. Håll trycket i 60 s. 6. Släpp ut trycket med varierande hastighet.	Tryckfall < 1%, då tryck hålls stabilt.	R01, R02, R09.	PR03
		Maxtryck = 300 mmHg.	R04, R05, R26, R27.	PR05, PR06, PR09,
		Tryck i systemets manometer = tryck i kalibrerad manometer ± 1%.	R06.	
		Trycket släpps ut i den valda varierande hastigheten.	R10.	UR02, PR01, PR24.
T.Ver-03	1. Koppla ur regulator ur system. 2. Tillsätt tryckluft.	Tryck ≤ 300 mmHg.	R03.	PR06, PR09.
T.Ver-04	1. Starta mätning. 2. Öka trycket till valfritt värde mellan 0-300 mmHg.	Tryck = valfritt värde ± 1%.	R11.	UR02.
T.Ver-05	1. Utsätt produkt för våld. 2. Koppla in extern kalibrerad manometer i systemet. 3. Läs av så att extern kalibrerad manometer visar samma som systemets manometer. 4. Utför en blodtrycksmätning.	Tryck i systemets manometer = tryck i kalibrerad manometer ± 1%.	R23, R37.	PR15.
		Tryck går att sänka till 0 mmHg.	R29.	
		Genomfört testfall.	R30.	

Figure E.1: Verification test cases.

Testfall Validering	Tillvägagångsätt	Godkändkriteium	Risk ID	UR, PR
T.Val-01	1. Producera högljudd omgivning. 2. Påbörja blodtrycksmätning. 3. Lyssna efter simulerade karotkoff-ljud.	Karotkoff-ljud kan urskiljas.	R16.	UR11
T.Val-02	1. Starta mätning. 2. Öka trycket till valfritt värde mellan 0-300 mmHg. 3. Läs av manometer. 4. UX-fråga: Vilket betyg får manometerns läsbarhet på en skala 1-4?	Tryck = valfritt värde ± 1%.	R34.	UR02, PR01.
		Manometer kan läsas av, får genomsnittligt betyg ≥ 3/4 av användarna.	R35.	UR09, PR11, PR17.
T.Val-03	1. Installera produkten i avsedd användningsmiljö. 2. UX-frågor: a. Hur hög snubbelrisk på skala 1-4? b. Hur mycket uppmärksamhet kräver apparaten (skala 1-4)? c. Hur mycket litar du på apparaten på en skala 1-4? d. Hur bra fungerar apparaten tillsammans med övrig utrustning och arbetsflödet (skala 1-4)?	Användarsvar: a. Genomsnittligt betyg ≤ 1/4.	R39.	
		b. Genomsnittligt betyg ≤ 1/4.		UR04.
		c. Genomsnittligt betyg ≥ 3/4.		UR05,UR06.
		d. Genomsnittligt betyg ≥ 3/4.		UR08, PR13, PR19.
T.Val-04	1. Utför blodtrycksmätning vid britsen. 2. Förflytta till ergometer/löpband. 3. Utför en ny blodtrycksmätning. 4. Repetera testet och mät på andra armen. 5. UX-frågor: a. Hur lätt är systemet att förflytta på en skala 1-4? b. Hur smidigt var det att mäta på båda armarna på en skala 1-4? c. Hur mycket upplever du att patientens rörelseförmåga under testet begränsats på p.g.a. apparaten?	Användarsvar: a. Genomsnittligt betyg ≥ 3/4. b. Genomsnittligt betyg ≥ 3/4.	R40.	UR10,PR12,PR20.
		c. Genomsnittligt betyg ≤ 1/4.		PR23.

Figure E.2: Validation test cases.

F

Assessment criteria for risk analysis

Information om produkt som egentillverkas	Produktmodell/namn	Version

Allvarlighet				
1	Försumbar	Patient/medarbetare/invånare	Liten påverkan på liv, hälsa, rättigheter.	Obehag eller obetydlig skada
		Process	Liten negativ effekt på verksamhetens förmåga att uppnå sina mål eller fullgöra sina primära uppgifter.	
2	Lindrig	Patient/medarbetare/invånare	Påverkan på liv, hälsa, rättigheter.	Tillfälliga skador eller besvär som kan återställas Mindre komplikationer som inte leder till permanent skada
		Process	Begränsad negativ effekt på verksamhetens förmåga att uppnå sina mål eller fullgöra sina primära uppgifter.	
3	Allvarlig	Patient/medarbetare/invånare	Stor påverkan på liv, hälsa, rättigheter.	Allvarlig försämring av en persons hälsotillstånd och/eller kräver en kirurgisk intervention.
		Process	Stor negativ effekt på verksamhetens förmåga att uppnå sina mål eller fullgöra sina primära uppgifter.	
4	Mycket allvarlig	Patient/medarbetare/invånare	Mycket stor påverkan på liv, hälsa, rättigheter (skadade eller dödsfall).	Dödsfall eller en oåterkallelig försämring av en persons hälsotillstånd.
		Process	Mycket stor negativ effekt på verksamhetens förmåga att uppnå sina mål eller fullgöra sina primära uppgifter.	

Sannolikhet		Förslag 1	Förslag 2	Ange använt förslag eller egen
1	Osannolikt	Inträffar en en gång per år	Det finns mycket få eller inga tecken på att risken är verklighet i dag.	Förslag 2
2	Liten sannolikhet	Inträffar en gång på per månad	Inträffar sannolikt inte under normala omständigheter och i vart fall inte frekvent. Det finns vissa tecken på att risken är verklighet i mindre omfattning i dag.	Förslag 2
3	Stor sannolikhet	Inträffar en gång per vecka	Kan mycket väl inträffa men troligtvis inte särskilt frekvent. Det finns tydliga tecken på att risken är verklighet i vissa delar av verksamheten redan i dag.	Förslag 2
4	Mycket stor sannolikhet	Inträffar en gång dygn	Sannolikheten är stor att det ska inträffa. Det är bekräftat att risken är verklighet i väsentliga delar av verksamheten redan i dag eller att den väntas bli det i närtid.	Förslag 2

Department of Electrical Engineering
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden
www.chalmers.se

CHALMERS