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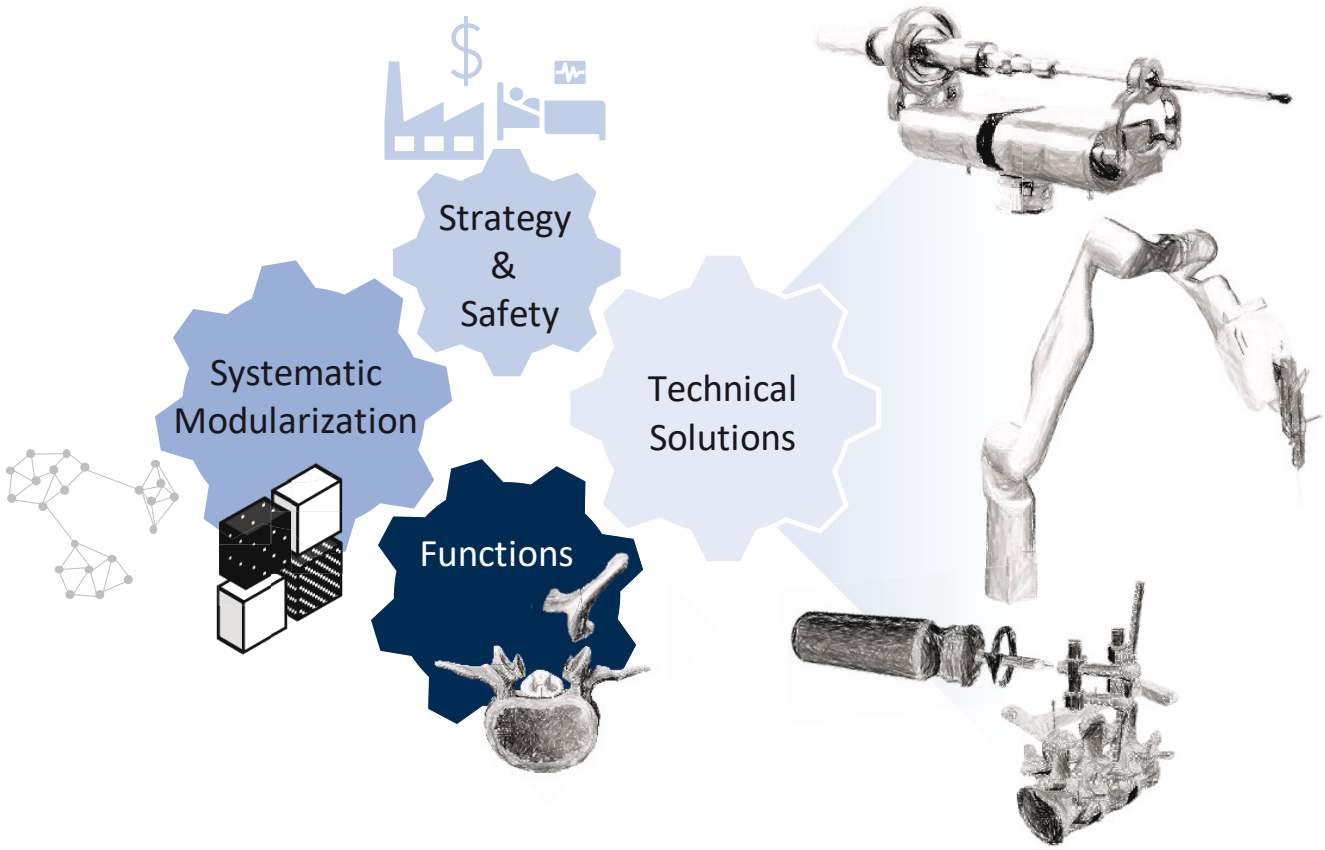
Lukas Theisgen

Process Model for the Systematic Design of Modular Surgical Robots



Aachener Beiträge zur Medizintechnik

Herausgeber:

Univ.-Prof. Dr.-Ing. Dr. med. Dr. h. c. Steffen Leonhardt
Univ.-Prof. Dr.-Ing. Klaus Radermacher
Univ.-Prof. Dr. med. Dipl.-Ing. Thomas Schmitz-Rode

Process Model for the Systematic Design of Modular Surgical Robots

Prozessmodell zur systematischen Entwicklung modularer Chirurgieroboter

Von der Fakultät für Maschinenwesen der Rheinisch-Westfälischen Technischen Hochschule Aachen zur Erlangung des akademischen Grades eines Doktors der Ingenieurwissenschaften genehmigte Dissertation

vorgelegt von

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Process Model for the Systematic Design of Modular Surgical Robots

Ein Beitrag aus dem Lehrstuhl für Medizintechnik der RWTH Aachen
(Direktor: Univ.-Prof. Dr.-Ing. Klaus Radermacher).

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Gewidmet meinem Großvater

Heinrich Bauer

Schreinermeister aus Zehnstelle

Abstract

The potential of robot-assisted surgery is huge in terms of surgical outcome, safety, ergonomics, and cost efficiency. Most commercial robots and research projects focus on optimizing a few aspects while unwittingly worsening the others. Appropriate design methods are missing. The manufacturing industry faces similar problems and uses systematic modularization to harmonize conflicting goals during product development. A prerequisite for the adaptation to surgical robotics is the adequate consideration of intraoperative hazards, deficits of current robots, and the safety and usability of emerging intraoperative interfaces.

Here, a process model was developed for the systematic modularization of surgical robots with integrated risk estimation (MORE) and recommendations for the subsequent design of intraoperative interfaces. Main requirements were being traceable, use case independent, value-based, risk-preventive, usability-enhancing, and suitable for digitalization and integration into Product Lifecycle Management (PLM) systems. First, the state of the art of surgical robots, modularization methods, and development practices for medical devices were examined. A modularization method for surgical robots was created as the first part of the process model. For the second part, hazard and risk analysis were added. A reference architecture model (RAM) approach was developed to allow computer assistance. Lastly, appropriate Design-for-X (DfX) guidelines and a representative functional mock-up were analyzed to develop a Design-for-Intraoperative-Assembly (DfIA) checklist. The MORE process model, the approach for computer assistance, and the checklist were formatively evaluated, separately.

The resulting modularization method uses 11 reference functions to suit various use case scenarios and 59 module drivers as quality criteria based on the analysis of 15 surgical robots and the feedback from 51 experts. The Point-of-View (PoV) framework expands the search area for hazards suggesting seven predefined perspectives while the Catalogue of Hazards (CoH) provides a database to store them and complement future risk analyses. PoV and CoH were initially tested on the example of robotically assisted laminectomy, which led to the identification of 133 hazards and 108 hazardous situations. The RAM approach provides structural and procedural rules between functional and physical system elements based on SysML. The DfIA checklist contains 44 control questions of which 18 refer to hygiene and 26 to the assembly process.

The formative evaluations confirmed the usefulness of the approaches and revealed opportunities for improvement. Most promising seems the integration of surgical workflow modeling, the formation of system scores, and the improvement of the user experience. Overall, the methodological approach proved to be crucial for the effective modularization of surgical robots.

Zusammenfassung

Chirurgierobotik bietet im Hinblick auf Operationsergebnis, Sicherheit, Ergonomie und Kosteneffizienz großes Potential. Dennoch konzentrieren sich nur wenige Roboterentwicklungen auf die Optimierung aller Aspekte, sodass die nicht betrachteten oft unwissentlich verschlechtert werden. Die Fertigungsindustrie nutzt für ähnliche Problemstellungen kriterienbasierte Modularisierungsmethoden. Voraussetzung für die Übertragbarkeit auf die Chirurgierobotik ist die Adressierung allgemeiner intraoperativer Gefährdungen, bekannter Defizite aktueller Roboter sowie intraoperativer Schnittstellen bezüglich Sicherheit und Gebrauchstauglichkeit.

Diese Arbeit zeigt ein rückverfolgbares, allgemeingültiges und zieleorientiertes Vorgehensmodell zur systematischen Modularisierung von Chirurgierobotern, mit integrierter Risiko-Einschätzung (MORE), konstruktiven Gestaltungsempfehlungen für intraoperative Schnittstellen und der Möglichkeit zur Digitalisierung und Integration in Produkt Lifecycle Management (PLM)-Systeme. Zunächst wurden aktuelle Chirurgieroboter sowie Modularisierungs- und Konstruktionsmethoden analysiert. Die vielversprechendste Modularisierungsmethode wurde weiterentwickelt und um Möglichkeiten zur integrierten Risikoanalyse ergänzt. Außerdem wurde der Ansatz eines Referenzarchitekturmodells (RAM) als Grundlage zur Computerunterstützung entwickelt sowie eine Design-for-Intraoperative-Assembly (DfIA)-Checkliste. Das Prozessmodell, der Ansatz zur Computerunterstützung und die Checkliste wurden formativ evaluiert.

Die Modularisierungsmethode verwendet 11 Referenzfunktionen zur Anpassung an diverse Anwendungsszenarien und 59 Modultreiber als Qualitätskriterien, basierend auf der Analyse von 15 Chirurgierobotern und dem Feedback von 51 Experten. Zur allgemeinen Risikooptimierung vor und nach der Modularisierung wurde das Point-of-View (PoV) Schema entwickelt, welches den Suchbereich für Gefährdungen erweitert, indem es sieben vordefinierte Perspektiven anbietet. Am Beispiel der robotergestützten Laminektomie wurden in einer ersten Gefährdungsanalyse 133 Gefährdungen und 108 Gefährdungssituationen identifiziert. Außerdem dient ein Gefährdungskatalog der Strukturierung und Archivierung von Gefährdungen. Der RAM-Ansatz bietet strukturelle und prozedurale Regeln zur SysML-basierten Modellierung funktionaler und physischer Systemelemente. Für die DfIA-Checkliste wurden 44 Kontrollfragen formuliert, 18 betreffen die Hygiene und 26 den Montageprozess.

Die formative Evaluation der Ansätze bestätigte deren Nutzen und zeigte Optimierungsmöglichkeiten. Zukünftig sollten chirurgische Arbeitsabläufe modelliert, System-Scores definiert und die Nutzerzufriedenheit verbessert werden. Insgesamt erwies sich der methodische Ansatz als hilfreich für die effektive Entwicklung von Chirurgierobotern.

Abbreviations

CoH	Catalogue of Hazards
CPL	Clinical Product Lifecycle
CSSD	Central Sterile Services Department
DfA	Design for Assembly
DfH	Design for Hygiene
DfIA	Design for Intraoperative Assembly
DMM	Domain Mapping Matrix
DoA	Degree of Autonomy
DoF	Degree of Freedom
DSM	Design Structure Matrix
FAC	Functionality Acceptance Criterion
FAS	Functional Architecture for Systems
FC	Function Carrier
FDA	Federal Drug Administration
HAW	FDA code: Orthopedic and Neurological Stereotaxic Instruments
LAM	Laminectomy
MADM	Multi-Attribute Decision Making
MBSE	Model-Based Systems Engineering
MC	Module Candidate
MCDM	Multi-Criteria Decision Making
MD	Module Driver
MDD	Directive 93/42/EEC, also “Medical Device Directive”
MDR	Regulation (EU) 2017/745, also “Medical Device Regulation”
MDSM	Multiple Design Structure Matrix
MFD	Modular Function Deployment
MIM	Module Indication Matrix
MIS	Minimally Invasive Surgery
MM	Modularization Measure
MO	Module Operator
MODM	Multi-Objective Decision Making
NAY	FDA code: Endoscopes and Accessories
OLO	FDA code: Stereotaxic Instrument (Orthopedic)
OR	Operating Room

ORT	Operating Room Time
OT	Operating Table
PKA, PKR	Partial Knee Arthroplasty/ Partial Knee Replacement
PLM	Product Lifecycle Management
PoV	Point of View
PSP	Pedicle Screw Placement
RAM	Reference (System) Architecture Model
RAS	Robot-Assisted Surgery
RBMD	Review-Based Module Driver
RTHA	Revision Total Hip Arthroplasty
SAC	Strategy Acceptance Criterion
SDC	Service-Oriented Device Connectivity
SD	Scenario Decision (Sheet)
SoS	System of Systems
SSD	Smart Screwdriver
SUS	Systems Usability Score
SysML	Systems Modeling Language
TCP	Tool Center Point
THA/ THR	Total Hip Arthroplasty/ Total Hip Replacement
TKA/ TKR	Total Knee Arthroplasty/ Total Knee Replacement
TLX	Task Load Index
TOT	Turnover Time
TPL	Technical Product Lifecycle
UCP	Use Case Parameter
UKA, UKR	Unicompartmental (or Unicondylar) Knee Arthroplasty/ Unicompartmental Knee Replacement
VMD	Virtual Medical Device

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1. Introduction

Surgical robots are not intended to replace surgeons, but to improve their skills and relieve them. Therefore, surgical robots perform tasks that are either outside the natural scale of humans, physically or cognitively demanding, or too dangerous for the operator.

Improving skills means pushing dexterity beyond the surgeon's natural ability, filtering undesired motion (e.g., tremor), seeing through tissue, moving precisely, and parallelizing actions (multi-tasking). Relief addresses repetitive tasks, process forces, weight, and unergonomic working postures. Safety regions can be implemented purely mechanically or based on virtual fixtures to increase the safety of patients and bystanders. Surgeons can further be protected using the fact that machines are immune to radiation and infection. [Taylor et al. 2008; Schleer et al. 2019a]

However, today's surgical robotics faces four major challenges: costs, clinical integration, intraoperative safety, and surgical outcome.

Costs - Although the potential of surgical robots is huge, the acceptance of the associated costs is often low. The market for robotic surgery has been growing for over three decades but covered only 10% of surgeries in the US, and only 2% globally in 2019 [Medtronic Inc. 2019]. One reason may be that robotic surgery is generally more expensive than manual procedures [Cairns 2019]. Jayne et al. [2017] named acquisition costs and maintenance costs as main concerns about robotic surgery in laparoscopy, followed by operative costs. This is evident in the case of the daVinci robots (Intuitive Surgical Inc., Sunnyvale, US), which cost about 1.5–2.6 million dollars for acquisition, 1,500-2,500 dollars per use, and about 175,000 dollars for annual maintenance [Rao 2018; Menger et al. 2018; Cairns 2019; Ho et al. 2011]. Additionally, operating room (OR) time is about 50 min longer in robotically-assisted laparoscopy compared to conventional surgery [Jayne et al. 2017]. However, even orthopedic robots with the sole task of statically holding a guide sleeve for pedicle screw placement, range in acquisition cost from 700,000-1.5 million dollars [Vo et al. 2020; Malham and Wells-Quinn 2019].

Clinical Integration - Besides high expenses, poor clinical workflow integration is a key barrier to the acceptance of surgical robots. Most robots are associated with bulkiness, setup overhead and immobility [Medtronic Inc. 2019; Troccaz et al. 2019; Taylor and Stoianovici 2003]. Illustrative examples are CASPAR (Orto MAQUET GmbH & Co. KG, Rastatt, DE) and TCAT (THINK Surgical Inc., Fremont, US), the successor to ROBODOC [Zimmer Biomet 2020; Jakopec et al. 2003]. Both robots carry heavy and powerful anthropomorphic robot arms, which were originally designed for the manufacturing industry [Vogt 2020; Troccaz 2012]. Due to their size, these

robots occupy much space during surgery, require extensive draping procedures, and are usually confined to a specific operating room. The same drawbacks are associated with newer robots like ExcelsiusGPS (Globus Medical Inc., Audubon, US) and ROSA ONE (Zimmer Biomet Holdings Inc., Warsaw, US). In 10 spinal fusion surgeries, the use of ExcelsiusGPS required 2.3 times more preparation time than freehand surgery [Vaccaro et al. 2020]. Lonjon et al. [2016] reported a prolongation of two hours with the ROSA ONE, including one hour for the surgery itself, compared to freehand surgery and averaged over 20 cases of spinal fusion.

Safety - The aforementioned bulkiness of kinematics is accompanied by safety hazards. Warnings were already issued in 1996, because large, anthropomorphic arms were oversized in power and workspace and could uncontrollably move in any direction, injuring patients, surgeons and other bystanders [Davies 1995; Brandt et al. 1997]. For illustration, the CASPAR robot, used between 1998 and 2005, was based on a Stäubli RX 90 and therefore must set approximately 100 kg in motion to perform small-scale osteotomies [Brandt 2003]. In fact, only one hundredth of the provided workspace is required for the surgical task. Therefore, it is remarkable that the huge discrepancy between required and provided kinematics has persisted until today. TCAT, for example, weighs 500 kg and still looks like ROBODOC did 30 years ago [THINK Surgical, Inc. 2017]. Further examples of oversized kinematics are ROSA ONE and ROSA Robotics (Zimmer Biomet Holdings Inc., Warsaw, US). Both got FDA clearance in 2019 for brain, spine and knee surgeries using a Stäubli TX 60 arm [FDA 2019b].

However, from the 1980s until now, orthopedic robots have used oversized arms with oversized power, working volumes, and masses [Kwoh et al. 1988; Vogt 2020] although many solutions of inherently safe kinematics have been presented, for instance, by Brandt et al. [2000], Pott and Schwarz [2007], Niggemeyer et al. [2012], de la Fuente et al. [2013], and Vossel et al. [2021]. O'Toole et al. [2010] might have provided an explanation for this. According to the authors, solutions for the improvement of surgical techniques (surgeon-led research) or for finding new applications (engineering-led research) often use existing technology (such as industrial robots or available prototypes) as a starting point. This trend must be viewed critically because surgical robots work in high-risk environments, where the patient is the workpiece.

Adverse Events - The persistent lack of safety is underlined by the 2.2 % increase in malfunctions and adverse events in robotic surgery between 2004 and 2013 in the US [Alemzadeh et al. 2016]. Moreover, Ferrarese et al. [2016] collected data from 18 articles on malfunctions of surgical robots between 2005 and 2014 of which 20.9% were caused by robotic instruments and arms. Ramirez et al. [2018] reported that survival rates in mastectomy procedures were even lower in robot-assisted minimally invasive surgery (MIS) than in open surgery. As a result, the

Federal Drug Administration (FDA) published a safety warning against robot-assisted devices in 2019.

Surgical Outcome - The safety issues with robots adopted from industry must be addressed, especially since appropriate solutions already exist. The shortcomings regarding costs and clinical integration, by contrast, might be justifiable if the surgical outcome were massively increased by surgical robots. Surgical outcome addresses the accuracy of executing the surgical plan, the invasiveness, the patient's length of hospital stay and the time for recovery. In fact, the surgical outcome of surgical robots often remains questionable. For instance, Joseph et al. [2017], Kim et al. [2017], Solomiichuk et al. [2017] and Perdomo-Pantoja et al. [2019] reported that the accuracy and length of hospital stay of the small-sized bone-mounted Renaissance robot (Medtronic PLC, Dublin, IE) were not improved compared to the freehand instrumentation of pedicle screws.

Modularization as a Solution - Taylor and Stoianovici [2003] name modularity as a precondition for low-cost robots because they could be configured to suit a broad spectrum of applications. During the last few years, also medical companies, such as Medtronic and CMR Surgical, have recognized modularity as an opportunity to make robots more mobile and versatile in use [Cairns 2019]. In other industries, such as the consumer goods industry or for tool and mold making [Boos 2008], manufacturers already benefit significantly from modularization. The approach enables concurrent engineering [Yassine and Braha 2003; Sanchez and Mahoney 1996] resulting in shorter product development cycles and the reduction of production costs (through *Economies of Scale* [Ulrich and Eppinger 2016], *Economies of Scope* [McGee 2014], and outsourcing [Ethiraj and Levinthal 2003]). Furthermore, modularity is used to decrease risks of product launch, increase product survivability, enable continuous product change and to react quicker to market demands and altered business conditions [Sanchez and Mahoney 1996; Marshall 1998; Robertson and Ulrich 1998; Ethiraj and Levinthal 2003; Feldhusen and Gebhardt 2008; van der Beek 2017].

Current Shortcomings - Referring to the technical product lifecycle (TPL) stages of VDI 2221:2019, most modularization methods address the manufacturing stage. Consequently, they are driven by economic reasons and mostly beneficial for the manufacturers. Surgical robots, on the other hand, have deficits in the use stage, as shown before. Accordingly, the perspectives of patients, operators, hospitals, and regulatory authorities are underrepresented in current methods.

Additionally, it is important to note that large manufacturers in particular work with product lifecycle management (PLM) systems. A characteristic of PLM systems is their use of reference system architectures to derive specific products and associated processes from a template. An integration of a modularization method into such a computer-based infrastructure of a company would enable a rule-based evaluation of modularization decisions and could draw on databases of, for instance, known technical solutions. Furthermore, integration into PLM systems may even be beneficial to automatically generate technical documents, like those required for certification and approval.

Aim - The research question of this work is how methodology can help increase the effectiveness of modular surgical robots placing special emphasis on the prevention of hazards, the consideration of different stakeholders, the usability and safety of intraoperative interfaces, and the possibility to support PLM systems. A process model needs to be developed that defines the sequential and structural relations between modularization, risk analysis, and interface design and embeds them into the established development processes for medical devices.

Outline - To respond the research question and develop the process model, this work is structured as shown in Figure 1.1. First, the technical and methodical state of the art is presented in Chapter 2. Representative surgical robots are analyzed and classified (Chapter 2.1). In Chapter 2.2, existing approaches and methods of modularization are investigated.

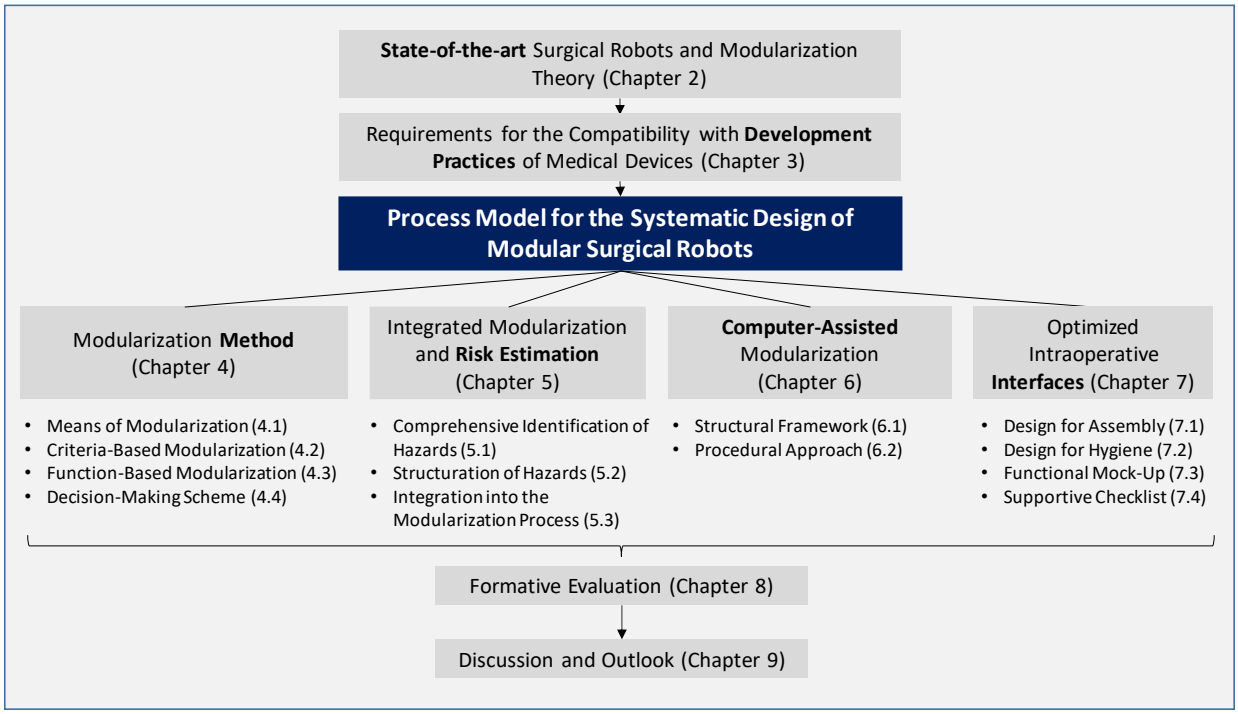


Figure 1.1: Outline of the following chapters

It is crucial to ensure similarity and compatibility with existing and established development practices or guidelines of medical devices to lower the barriers to the application of the process model and to ensure general acceptance. Current development practices and stakeholders are analyzed and compared in Chapter 3. In Chapter 4, a modularization method is developed. Since intraoperative safety is of outmost importance, Chapter 5 focusses on the integration of hazards into the process model. This includes the elaboration of a comprehensive hazard identification method and an open and growing database of hazards that supports modularization decisions. Chapter 6 refers to the integration of the method into a reference architecture model required for computer assistance. Besides providing a template for deriving surgical robot concepts, a strategy to categorize technical solutions and link them to hazards and stakeholder needs is presented. Since modularization creates interfaces, and interfaces occurring during surgery affect usability and safety, Chapter 7 presents a Design-for-Intraoperative-Assembly (DfIA) guide for optimizing such intraoperative interfaces as a follow-up step after modularization. Finally, the complete modularization method and the DfIA guide are applied to use case scenarios, and formatively evaluated in Chapter 8. The discussion and outlook are presented in Chapter 9.

2. State of the Art

The systematic development of modular surgical robots requires both technical and methodological background knowledge. The technical background is formed by today's surgical robots. The methodological background refers to established methods of modularization. Chapter 2.1 presents the state of the art of relevant surgical robots whereas Chapter 2.2 introduces approaches and methods of modularization.

2.1 Surgical Robots

The manufacturing industry defines a robot as a system that performs an intended task while being programmable in two or more degrees of freedom (DoF) and providing a degree of autonomy (DoA) within its environment (ISO 13482:2014, ISO 8373:2021). In medical standards, such as IEC 80601-2-77:2019 and IEC TR 60601-4-1:2017, neither the number of DoF nor the metrics for classifying the DoA are specified. The term *medical robot* in particular requires a robot to be intended for use as a *medical electrical system* or *equipment*. A system following the definition of a medical robot but lacking the degree of autonomy is called a *robotically assisted surgical system* or *equipment* (IEC 80601-2-77:2019). Based on the definitions of IEC 80601-2-77:2019 and IEC TR 60601-4-1:2017, a surgical robot is

- a programmed actuated mechanism with
- a degree of autonomy (DoA) that
- moves within its environment to
- perform intended tasks
- in a surgical context.

The common goal of surgical robots is to support humans (physicians) in their shortcomings through automation. However, surgical robots that comply with the definition are manifold and further classification is useful. The simplest distinction is between robots for soft-tissue and hard-tissue manipulation. Troccaz et al. [1998] further divided surgical systems into passive, semi-active, synergistic and active systems, which is an appropriate manner to specify the DoA. *Active* robots execute tasks autonomously whereas the surgeon has supervisory control. Semi-active systems automate positioning tasks before the physician actively performs the surgical intervention. Pure semi-active systems are usually rigidly mounted to the patient’s bone. In cases where

semi-active systems are not rigidly fixed to the bone, motion compensation is needed to prevent unplanned relative motion between robot and patient.

Since the surgical intervention in semi-active systems is fully controlled by the surgeon, the procedures are inherently susceptible to human errors. This is why *synergistic* approaches came up. In synergistic systems, the human-robot collaboration is a parallel process. The robot not only provides static instrument guidance but also simultaneously supports the surgeon in executing a surgical plan. Of course, the elimination of human induced risks does not eliminate the general risk of injury. But shifting the responsibility to the system for tasks that can be done more safely by a robot, reduces unjustified risks.

Variations regarding the DoA and the degree of control (on pose, speed and forces) [Radermacher 1999] provide various possibilities of user interaction (hands-on, hand-held, telemanipulated) and virtual assistances for planning-based (patient-specific) and planning-independent tasks (e.g., scaling or damping) [Schleer et al. 2019b].

Since this work concentrates on spatial modularization, the structural integrity of a robot is another important differentiator. In the following, bone-shaping robots and soft-tissue robots are examined and distinguished according to their spatial structure.

2.1.1 Bone-Shaping Robots

The group of hard-tissue or bone-shaping robots comprises those surgical robots that are used to remove bony tissue and create a desired bone shape. This shape is usually required to provide an implant bed and must match the geometries of the implant. Implants are, for instance, screws, plates, cages, or artificial joints. Also in tumor resection, the volume to be removed can be aligned to the shape of the tumor. This work focuses on bone-shaping robots for the creation of implant beds since it is crucial for the surgical outcome to match the effective target shape of the bone with the effective implant shape. Thereby, geometries must be planned by the surgeon, processed by a computer, and translated to execution commands for the robots. The computer responsible for the latter is often referred to as robot control unit (RCU). Concluding, bone-shaping robots have in common to assist the surgeon by executing a surgical plan and associated plan-based tasks.

In Figure 2.1, representative bone-shaping robots are sorted by size and grouped into their type of fixation, which is cart-mounted, rail-mounted, bone-mounted or handheld. CRIGOS/ CRANIO, MINARO, MINARO HD, and the Smart Screwdriver system were research projects developed

as miniaturized modular robots at the Chair of Medical Engineering of RWTH Aachen University (Aachen, DE). The others are commercial robots.

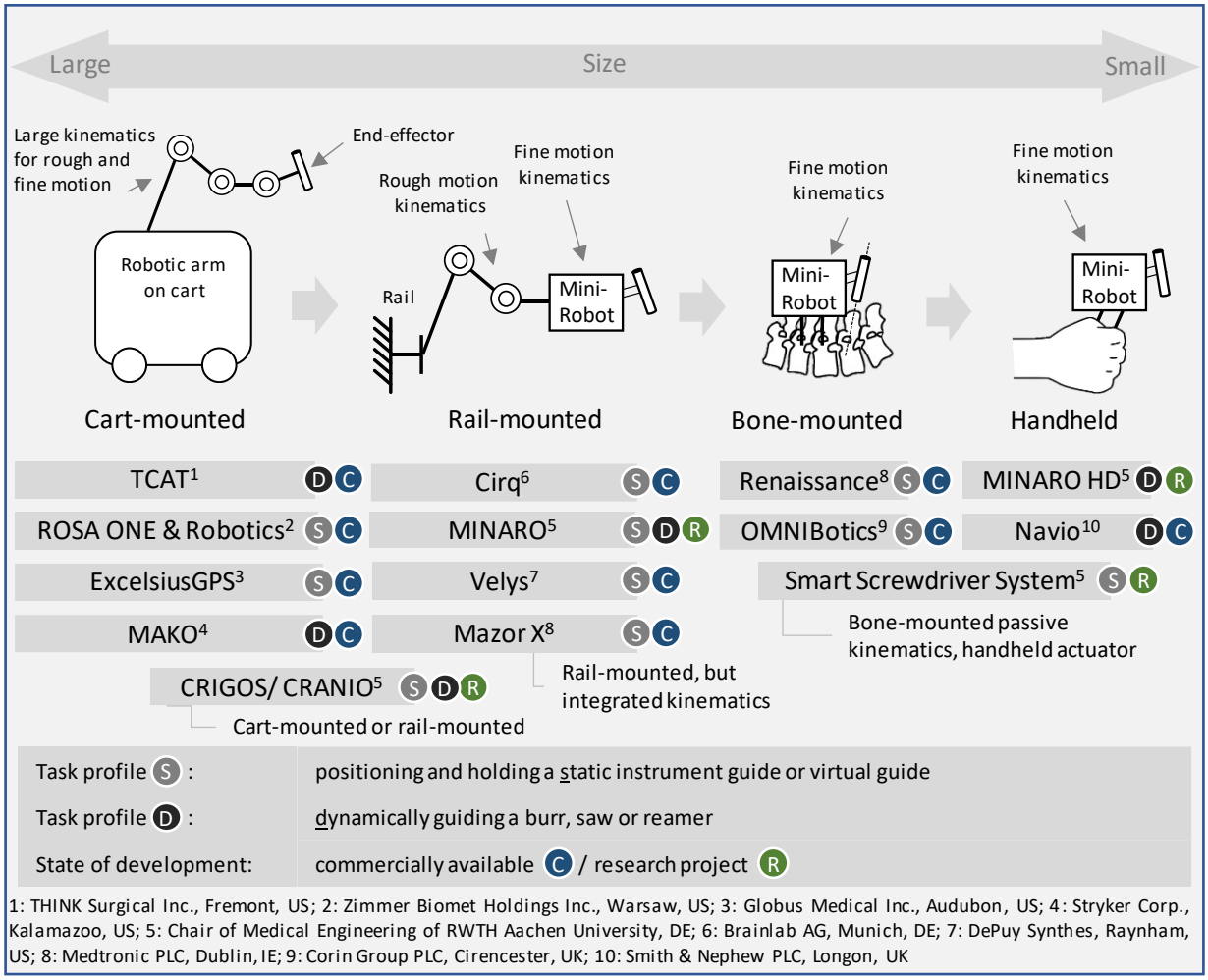


Figure 2.1: Classification of bone-shaping robots according to size and type of fixation

The surgical tasks of bone-shaping robots range from a) positioning and holding a static instrument guide or virtual guide to b) dynamically guide a burr, saw or reamer. Systems of group a) are ROSA ONE and Robotics, ExcelsiusGPS, CRIGOS/CRANIO, Cirq, MINARO, Velys, Mazor X and Renaissance, OMNIBotics, and the Smart Screwdriver system. Group b) comprises TCAT, MAKO, CRIGOS/ CRANIO, MINARO, MINARO HD, and Navio. Affiliations to companies and universities are shown in Figure 2.1.

Cart-Mounted Robots

Commonalities of most cart mounted robots are large-size kinematics usually adopted from industrial applications and permanently fixed to a cart. Motion functions of rough pre-positioning and for the precise execution of the surgical plan are not distributed to different mechanisms.

Representatives are TCAT, ROSA ONE, ROSA Robotics, ExcelsiusGPS, MAKO, and the cart-mounted configuration of the CRIGOS/ CRANIO.

The TCAT robot (THINK Surgical Inc., Fremont, US) is part of the TSolution ONE platform, which has been approved for the US market since 2014 and comprises TPLAN, a surgical planning software, and TCAT, the executive robot. The active robot can be used for total knee (TKA) and total hip arthroplasty (THA) and is based on the industrial 5-DoF SCARA robot arm SR8437 from Sankyo Seiki Co., Ltd, Kyoto, JP [Jakopec et al. 2003; THINK Surgical, Inc. 2017; Sankyo Robotics 2001]. The system was already introduced to the European market for THA in 1997 under the name ROBODOC (now TCAT) and ORTHODOC (now TPLAN) as the first commercially available surgical robot for orthopedics [Troccaz et al. 2019]. Although the approval process of the Federal Drug Administration (FDA) of the USA had started in 1993, the system received clearance only in 2008 [Sobh and Xiong 2012]. However, due to several complications, ROBODOC lost its reputation, to the detriment of surgical robotics in general [Da Caetano Rosa 2007].

ROSA ONE, ROSA Robotics (Zimmer Biomet Holdings Inc., Warsaw, US), and ExcelsiusGPS (Globus Medical Inc., Audubon, US) are semi-active robots. ROSA ONE and ExcelsiusGPS are used for spinal decompression and cranial stereotaxic procedures. ROSA ONE can be reconfigured preoperatively from ROSA ONE Spine to ROSA ONE Brain and assist biopsies. ROSA Robotics addresses orthopedics and can be configured into ROSA Knee for TKA, ROSA Partial Knee for partial or unicompartmental knee arthroplasty (UKA) and ROSA Hip for THA. All ROSA robots look alike and use the anthropomorphic TX2-60 6-DoF industrial arm of serial kinematics from Stäubli AG, Pfaeffikon, CH, according to a company representative. While the neurosurgery version of the ROSA robots can be recognized by the pink color, pink was replaced by blue in the version of orthopedic surgery. The robotic SCARA arm of ExcelsiusGPS also provides serial kinematics in six DoF. In all systems, the robotic arm is used to preposition an instrument guide, which is static to the patient, and therefore compensates patient-induced motion. [Vo et al. 2020]

The surgical treatments of ROSA Robotics are also addressed by the MAKO robots (Stryker Corp., Kalamazoo, US). The robot with 6-DoF serial kinematics is available in three configurations: MAKO Hip for THA, MAKO Total Knee for TKA and MAKO Partial Knee for UKA [Rosen et al. 2011]. Mechanically, the configurations only differ by their end-effectors. In contrast to ROSA, MAKO is synergistic. The hands-on robot virtually constrains the surgeon’s working volume [Roche 2015] using haptic guidance through virtual fixtures, as systematized by Schleer et al. [2019a].

The CRIGOS robot (Chair of Medical Engineering of RWTH Aachen, DE) was developed as part of a research project in 1996 that aimed to show the benefits of using a manipulator of parallel kinematics to conduct versatile osteotomies and shape implant beds [Brandt et al. 1996]. CRIGOS stands for compact robot for image guided orthopedic surgery. The robot was based on a Stewart platform with six parallel DoFs and a response to the oversized anthropomorphic arms adopted from the manufacturing industry. Mechanisms of parallel kinematics are usually beneficial in terms of payload-to-weight ratio, size, workspace utilization, positioning error, and the technical complexity compared to those of serial kinematics [Brandt et al. 1996]. The CRIGOS robot provided a position accuracy of ± 0.1 mm, a payload-to-weight ratio of 1 and could be cart-mounted or rail-mounted [Brandt et al. 1999; Brandt 2003]. Four operation modes were implemented: active, semi-active, hands-on, and telemanipulation [Brandt et al. 2000]. The workspace of the robot could be modified to different requirements by adding application-specific attachments at the distal or proximal end of the hexapod. For instance, CRANIO is the cart-mounted adaptation of the CRIGOS architecture to skull surgery [Bast et al. 2002]. The open and modular system architecture of CRIGOS enabled modification to other disciplines and future applications [Brandt et al. 1999].

Rail-Mounted Robots

Unlike cart-mounted robots, rail-mounted robots are limited in weight to minimize the physical workload during installation and the loads carried by the table rail. The latter is usually the weakest link in the load path in terms of elasticity. As shown in the following, some robots prioritize lightweight design whereas others use supporting measures to carry the weight. Rail-mounted robots are, for instance, Cirq, Velys, MazorX, CRIGOS, and MINARO.

Cirq (Brainlab AG, Munich, DE) is a surgical device platform comprising a support arm and four alternative end-effector modules. The support arm provides seven DoFs, is passive in motion and equipped with permanent magnet brakes that significantly contribute to its arm's weight of 11 kg [Khalsa and Park 2020]. According to the definition of IEC 80601-2-77:2019, the system only counts as a robot if configured with the Cirq Robotic Alignment Module. This end-effector module provides four actuated DoFs, which move a drill guide axis into a planned pedicle screw axis [Pojskic et al. 2021]. Motion compensation is not provided. The rigidity of the system is increased by fixing the holding arm to the ipsilateral and contralateral rail from below the table.

Velys (DePuy Synthes, Raynham, US) and MazorX (Medtronic PLC, Dublin, IE) are both rail-mounted robots that are brought to the table on a cart. Velys assists TKA whereas MazorX is used for PSP. Both systems are semi-active systems. While MazorX is additionally bone-mounted to close the loop of load transmission, Velys actively compensates patient movements

in three DoFs. Three DoFs are mathematically sufficient to correct the deviation of a cutting plane. The saw tool of the Velys is attached to the distal end of the robot by means of a planar serial linkage and thereby constrained to the target plane. MazorX provides a static drill guide sleeve, instead, that represents the distal end of the 6-DoF serial kinematics. The drill tool is a separated handheld device. Different than MazorX, Velys and Cirq have their active kinematics mounted on a passive mechanism for pre-positioning, which are smaller than those of their permanently cart-mounted competitors.

The lightweight MINARO system (Chair of Medical Engineering of RWTH Aachen University, DE) is entirely steam-sterilizable and based on two sets of five-bar linkages plus different linear drives that can be assembled in different ways to provide two to five DoFs and create specific workspaces for each addressed application. Each kinematic module is plugged onto a universal motor module with two drivetrains. As a result, a burr can be controlled for bone or cement removal in (revision) total hip arthroplasty ((R)THA) and TKA, an ultrasound probe for 3D bone cement scanning in RTHA, or just a drill guide can be positioned for pedicle screw placement (PSP) [Heger et al. 2010; Niggemeyer et al. 2012; Theisgen et al. 2018]. The system is connected to the table rail using, for example, a passive holding arm. To increase rigidity, the system can be additionally mounted to the bone, as shown in Figure 2.2, or hold by a second holding device. Since kinematics for manipulation and pre-positioning are split, weight is reduced during assembly.

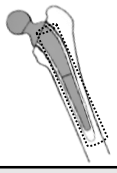
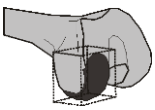
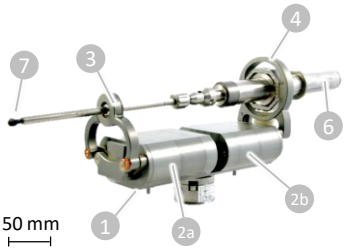
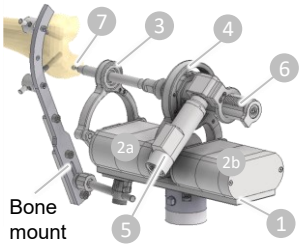
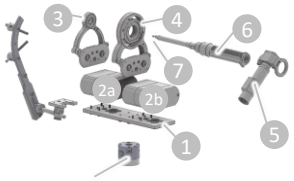
	Use Cases		Configurations	Functional Modules
Application	RTHR 	UKA 	Configuration for total hip arthroplasty (THA), incl.revision total hip replacement (RTHR)  50 mm Configuration for unicondylar knee arthroplasty (UKA) 	  Connection to holding arm
Degree of automation	Active	Active		
Key requirements				
Motion task	Dynamic guidance on 3D curve	Dynamic guidance on 3D curve		
Workspace	Cylindrical ∅ 30 x 200 mm³	Cubic 50 x 50 x 50 mm³		
Degrees of freedom	5	5		
Accuracy	0.5 mm	0.5 mm		
1: Base plate; 2a: Motor unit front; 2b: Motor unit back; 3: Front kinematics; 4: Rear kinematics; 5: Motor unit feed; 6: Round gear rack; 7: Tool				

Figure 2.2: Configurations of the MINARO robot for (Revision) Total Hip Arthroplasty (RTHA/ THA) and Total Knee Arthroplasty (TKA), based on Niggemeyer et al. [2012]

Bone-Mounted Robots

When robots are directly mounted on the bone that is to be processed, relative motion between the end-effector and the target is avoided by structure. Those systems don't need tracking devices for motion compensation. Pre-positioning is done by the surgeon who places the robot. Drawbacks are the increased invasiveness and difficulty of installation. Examples of bone-mounted robots are OMNIBot, Renaissance and partially the Smart Screwdriver system.

OMNIBotics (Corin Group PLC, Cirencester, UK) is a surgical platform comprising the OMNIBot, which is a robotic bone-mounted cutting guide, the BalanceBot, which is a robotic device to measure the tension of ligaments, and the workstation, for planning and control [Corin Group PLC 2022]. The OMNIBot provides two active DoFs with parallel axes to approach the different planes of TKA and is the successor of Praxiteles. The two missing degrees of freedom required to define a plane are passive. The correct passive alignment of the device is navigated by optical tracking. [Plaskos et al. 2005]

The main components of the Renaissance (Medtronic PLC, Dublin, IE), formerly SpineAssist [Togawa et al. 2007] and MARS [Shoham et al. 2003], are robot, workstation, frame, and instruments. The robot is based on hexapod kinematics, which adjusts the pose of a cantilever in six DoFs to position a guide sleeve for PSP. The robot weighs about 200-250 g and is as big as a soda can with about 5 x 5 x 7 cm^3. A bone-mounted frame is used to mechanically combine the spine with the manipulator. Once the guide sleeve is positioned, K-wires can be implemented through the sleeve and pedicle screws can be inserted. [Shoham et al. 2003; Barzilay et al. 2006]

The Smart Screwdriver system (Chair of Medical Engineering of RWTH Aachen University, DE) consists of a bone-mounted application-specific and adjustable passive tool guide mechanism and a universal handheld Smart Screwdriver (SSD). The SSD encloses the entire drivetrain and associated electronics. Passive tool guide mechanisms have been developed for PSP with four DoFs and TKA with three DoFs. The guide mechanism for PSP is called SpinePilot and illustrated in Figure 2.3. The SpinePilot is equipped with four motion screws (each for one DoF) that are actuated and rotated automatically after inserting the SSD in an arbitrary sequence. [de la Fuente et al. 2013; Theisgen et al. 2017]

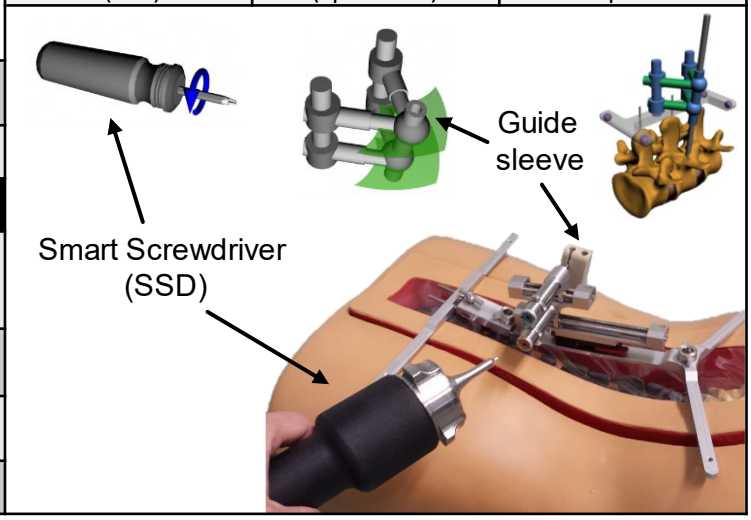
Use Case		Functional Modules		
Application	PSP 	Handheld device (SSD)	Kinematic module (SpinePilot)	Configuration on spine
Degree of automation	Semi-active			
Forces	User-specific			
Key Requirements				
Motion task	Positioning a guide sleeve onto a pre-planned axis			
Workspace	Tapered / cylindrical			
Degrees of freedom	4			
Accuracy	1.5 mm			

Figure 2.3: Configuration of the Smart Screwdriver (SSD) system for Pedicle Screw Placement (PSP) [Theisgen et al. 2018]

Handheld Robots

Handheld robots are comparable in size with bone-mounted robots but less invasive. The additional disturbing hand motion induced by the operator must be compensated. Weight is limited to not increase the physical workload of the operator. However, the surgeon is usually freer in finding the most ergonomic working pose and virtual fixtures become more important to constrain the field of action. In this chapter, MINARO HD and Navio are presented as examples.

MINARO HD (Chair of Medical Engineering of RWTH Aachen University, DE) is a handheld manipulator that highly dynamically (HD) moves a burr in 3 DoFs for unicondylar knee arthroplasty (UKA). The 3-DoF burring robot is based on a five-bar linkage and controlled by optical tracking. The robot weighs 2.5 kg and can be hold with two hands and optionally laid on the patient's lower leg using a support attachment. Although the robot as a system is handheld and thus synergistic, the burr trajectory is traversed automatically to be most efficient. Therefore, the operator is optically guided into appropriate pre-positions, which can always be changed. [Vossel et al. 2021]

Different than MINARO HD, Navio (Smith & Nephew PLC, London, UK) does not provide a burring trajectory to create an implant bed. UKA and TKA can be performed by steering the optically tracked handheld robot like a navigated instrument. A single DoF characterizes the system as a robot. This DoF actively withdraws the burr into a safety sleeve as soon as the operator moves the burr out of the pre-planned volume of bone removal. In 2020, Navio was integrated into the

CORI Surgical System, which uses the same concept of retracting the burr into a sleeve. [Lonner et al. 2015; Smith & Nephew, Inc. 2021]

2.1.2 Soft-Tissue Robots

Minimally invasive soft-tissue manipulators and robots can be grouped into biopsy devices and endoscopic devices. The latter either uses a single port or multiple ports to enable the insertion of the endoscope and instruments. Devices that let out the endoscope and instruments through a common duct can be referred to as single-channel manipulators [Navaratnam et al. 2018]. In contrast to bone-shaping robots, high dexterity is more important for soft-tissue manipulators than high rigidity. For instance, liver tumor resection does not require high cutting forces, instead accessibility is challenging. Furthermore, soft-tissue is compliant and cannot be used as a reference structure to register the target anatomy of the patient with the tissue-shaping tool. Except for single-channel manipulators, large angular mobility is required to pivot around the ports due to the limited percutaneous access to the situs. Kinematics with a remote center of motion (ROM) become more important than for bone surgery [Taylor and Stoianovici 2003].

In the following, single-channel robots are neglected and endoscopic robots with external kinematics are focused on, to address large-size robots. Representative robots are the daVinci systems (Intuitive Surgical Inc., Sunnyvale, US), Versius (CMR Surgical Ltd., Cambridge, UK), and Hugo RAS (Medtronic PLC, Dublin, IE). All systems are used for general single- or multi-port surgeries, such as laparoscopies. All presented endoscopic robots are also cart-mounted. While the daVinci robot has all four arms mounted on one cart, Versius and HugoRAS have one cart per arm (Figure 2.4). Other robots, such as Revo-I (Meerecompany Inc., Gyeonggi-do, KR), Avatera (avateramedical GmbH, Jena, DE), Hinotori (Medicaroid Inc., Kobe, JP) and Senhance (Asensus Surgical Inc., Durham, US) can also be categorized as either robots with single-cart or multiple-cart kinematics.

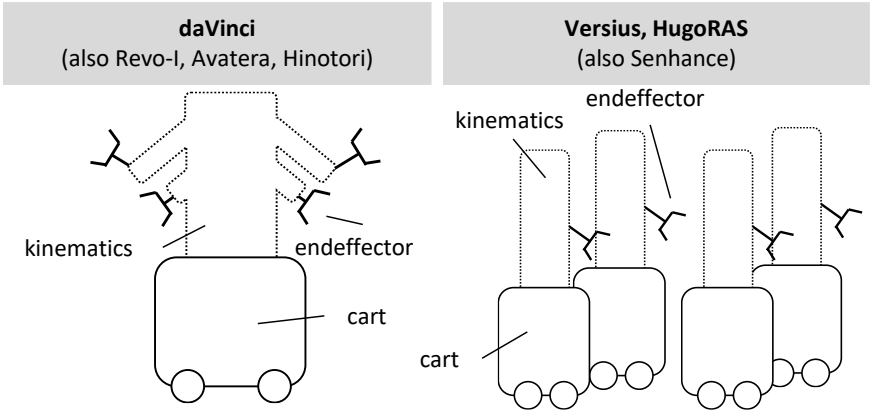


Figure 2.4: Classification of ductless endoscopic soft-tissue manipulators with external kinematics

2.2 Modularization Theory

When Aristoteles said that the whole is greater than the sum of its parts, he described the effect of emergence, often referred to as synergy effects. Emergence occurs when the interaction of parts creates properties that go beyond the properties of the individual parts [Kopetz et al. 2016]. Simon [1962] used the same words to explain a complex system already in 1962. A means to control and optimize the emergence of a system is modularization. By modularization, a system is structured according to certain aspects [Feldhusen and Gebhardt 2008]. This structuring can be seen as clustering (Figure 2.5). A clustering process decomposes a (usually complicated) system into (usually simpler) subsystems [Tseng and Wang 2018] or vice versa. The goal is always to increase cohesion (integrity) and decrease couplings (inter-modular dependencies), as commonly known in software engineering [Lucia and Ferrucci 2013]. An alternative term for cohesion is near-decomposability, which was introduced by Simon [1962] and used by several other authors like Sanchez and Mahoney [1996] and Göpfert [1998]. Since cohesion describes the degree of independency of subsystems, it also describes a system's degree of modularity [Göpfert 1998]. This deductive definition of modularity complies with the five characteristics of modules that Salvador [2007] elaborated in a meta-analysis about different perspectives on modularity: separability (strong cohesion), commonality (reuse), functional binding, combinability (with other modules) and interface standardization. Göpfert [1998], on the other hand, named three principles of modularization, which partially comply with Salvador [2007]: independence, integrability (into a common system) and decomposability. Decomposability means that the principles of independence and integrability also apply on lower system levels. Thus, modularization is not limited to a certain level of detail.

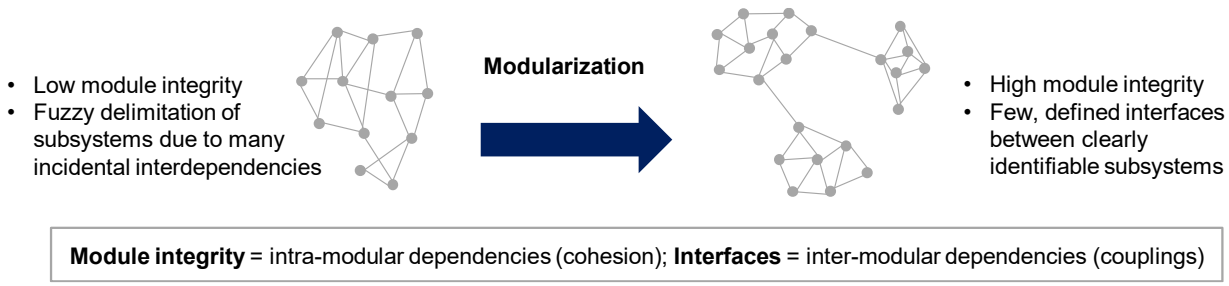


Figure 2.5: Clustering effect of modularization

Modularity defines a system's architecture. The architecture is the totality of the system's physical and functional structure and the relations between the structural elements [Ulrich 1995; Krause and Gebhardt 2018]. According to Göpfert [1998], functionally modular product architectures are characterized by high functional independency between components. Physically modular architectures, on the other hand, provide spatially independent components.

Some authors, such as Ulrich [1994], claimed that ideal modularity represents a one-to-one mapping between physical components and functions. However, reasons for modularization are diverse and justify a deviation from the one-to-one mapping rule. For instance, a system that can be disassembled could be beneficial, in terms of facilitating cleanability, or detrimental as mounting errors can occur. Such a modularization would not affect the functionality of the system.

The following chapters discuss the two types of modularization. A system can either be modularized based on a) similar properties of system elements or b) the interdependencies between them [Gershenson et al. 2004].

2.2.1 Dependency-Based Methods

In 1981, Steward introduced a method to manage the design of complicated systems. Until today, his Design Structure Matrix (DSM), sometimes referred to as Task Structure Matrix (TSM) [Baldwin and Clark 2000], is widespread and has been used as a generic tool for mapping and clustering interdependencies in various contexts, including product modularization [Börjesson and Sellgren 2010]. The modularization goal can be quantitative (to reduce the number of interdependencies) or qualitative (based on the type of interdependencies). Figure 2.6 explains how to use a DSM for quantitative modularization. In the example, physical entities (components) are partitioned and clustered to reduce the number of spatial interfaces between subsystems. A chain structure represents the lowest number of interfaces which is not necessarily ideally modular. According to Ulrich [1994], it is only the number of *incidental* interdependencies that needs to be minimized. Therefore, other sparsity patterns are justified that result in different spatial structures and types of modularity [Koller 1998; Ulrich 1995; Hölttä-Otto and Weck 2007].

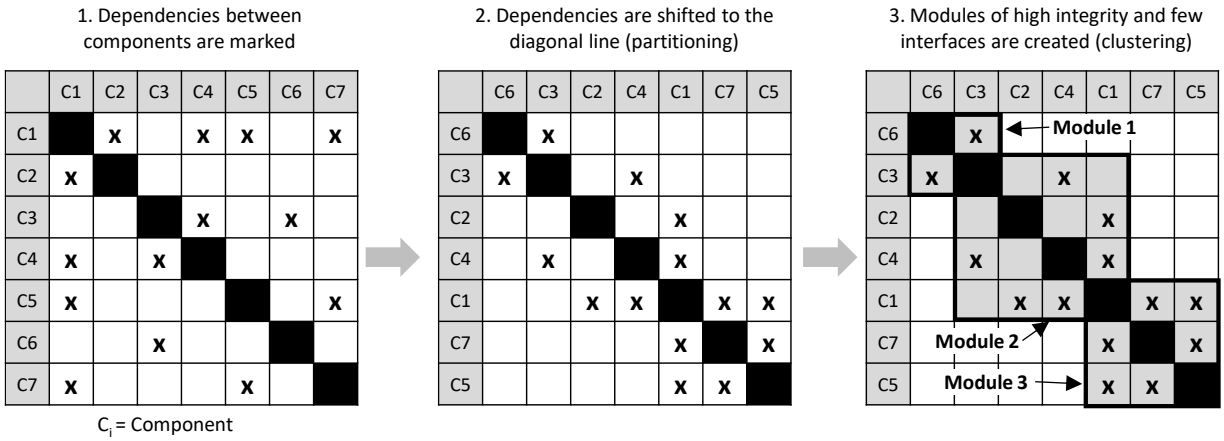


Figure 2.6: Modularization with the Design Structure Matrix (DSM) according to Steward [1981]

In the manufacturing industry, product and process development cannot be separated as they happen simultaneously and agile [Olesen 1992]. Baldwin and Clark [2000] provide examples of manufacturers, mainly coming from the computer industry, that have used DSM for the optimization of product structures based on tasks for design and production. When used for task optimization, DSM representation shows temporal relations such as parallel, sequential or pooled tasks [Danilovic and Sandkull 2005; Ulrich and Eppinger 2016].

Pimmler and Eppinger [1994] refined the conventional DSM, replacing the crosses that represent interfaces by squared fields containing four numbers, one in each corner. The value of the numbers represents the strength of the interface whereas the location in the square determines the type. Göpfert [1998] only defined two types of interfaces relevant for modularization: *Spatial* and *Functional*. Pimmler and Eppinger broke down the functional flows in accordance with Pahl et al. [2007] and distinguished between *Spatial*, *Energy, Information* and *Materials*. Theisgen et al. [2018] proposed *Temporal* as an additional type of dependency to be able to cluster according to a predefined use process. Schuh [2012] and Brecher [2012] further increased the benefit of DSMs by adding information about the impact of interface direction and strength also to non-adjacent modules.

Technically, the term DSM indicates intra-domain mapping, for instance, between components only. Danilovic and Sandkull [2005] uses the expression *Domain Mapping Matrix* (DMM) to describe mapping across design domains. Four design domains exist according to the Axiomatic Design Theory by Suh [1998], which are customer, functional, physical and process domain. In this theory, a matrix that maps functional requirements (functional domain) to design parameters (physical domain) should be diagonal (uncoupled design) or triangular (decoupled design) in order to make a design robust against requirements changes. Schuh et al. [2016] used this approach to establish an electric car platform with independent *Mechatronic Function Modules*.

A matrix that shows the combination of DSM and DMM is called *Multiple Design Structure Matrix* (MDSM) [Eichinger et al. 2006]. Gershenson et al. [1999] used MDSM representation to map between components but also between processes and between components and processes for the spatial modularization along the technical product lifecycle. An overview of different DSM-based use cases for process and product modularization (Table 2.1) shows the applicability of the tool across all design domains.

Table 2.1: Use of Design Structure Matrices (DSMs), Domain Mapping Matrices (DMMs) and Multiple Design Structure Matrices (MDSMs) for mapping relations between and inside the customer (C), functional (F), physical (Ph) and process (Pr) domains

References	Domains				Type of matrix	Entries of the matrices	
	C	F	Ph	Pr		Entries represent:	Value of entry
[Steward 1981]	-	-	-	x	DSM	related tasks	predecessors
[Pimmler and Eppinger 1994]	-	-	x	-	DSM	spatial-, energy-, information-, and material-type interactions	strength and relevance
[Suh 1998]	-	x	x	x	DMM	relations between (1) functional requirements (FR) and design parameters (DP), (2) DPs and processes	yes/ no
[Gershenson et al. 1999]	-	-	x	x	MDSM	(1) similarity or (2) dependency of Ph-Ph, Ph-Pr, Pr-Pr relations	extend of dependency or similarity
[Baldwin and Clark 2000]	-	-	x	x	DSM, DMM	related DPs, related tasks	yes/ no
[Danilovic and Sandkull 2005]	-	-	-	x	DSM, DMM	related intra- and inter-project tasks	strength relations
[Eichinger et al. 2006]	x	x	x	x	DSM, DMM, MDSM	tasks, physical interfaces, requirement representations	amount of direct or indirect relations
[Albers et al. 2008]	-	-	x	-	DSM	interfaces between physical entities (liquid, gas, solid)	numbering of interfaces
[Boos 2008]	x	x	x	-	MDSM	relations between C-F, F-Ph and Ph-Ph domain	yes/no, degree of geometric dependency
[Börjesson and Sellgren 2010]	-	-	x	-	DSM	related components	yes/ no
[Schuh 2012; Brecher 2012]	-	-	x	-	DSM	related components	impact (direction and strength) of modification
[Ulrich and Eppinger 2016]	x	-	x	x	DSM, DMM	relations between (1) design tasks, (2) requirements and DPs	yes/ no
[Schuh et al. 2016]	-	x	x	-	DMM	relations between (1) FRs and mechatronic function modules (MFM), (2) MFMs and DPs	yes/ no

Dependencies can be illustrated in matrices but also in block diagrams, for instance, in a functional structure. Functions represent the tasks of a system and are either structured hierarchically (functional decomposition), sequentially connected via functional flows (energy, material, information) or presented in a hybrid form [Pahl et al. 2007]. In 1998, Stone et al. presented a method to identify modules using a functional description of a product [Stone et al. 1998]. Stone's method is subdivided into three heuristics based on the behavior of functional flows, illustrated in Figure 2.7. A dominant flow modularization aims to identify chained functions as candidates for being combined into a larger, integrated module, whereas branching flow modularization is used to find platform modules. Conversion-transmission modules can reduce assembly steps and ease testing. The heuristics could also be applied by using a functional DSM representation if functional dependencies were specified. For instance, Hölttä-Otto et al. [2008] used a quantitative algorithm for clustering similar functions. Furthermore, diagram-based modularization was adopted to product family creation by Zamirowski and Otto [1999].

However, modularization that is based on different heuristics can be ambiguous. As a solution, the rules to be followed can be weighted according to customer needs (or strategic goals) [Stone et al. 1998], similar to the approach discussed in the following chapter.

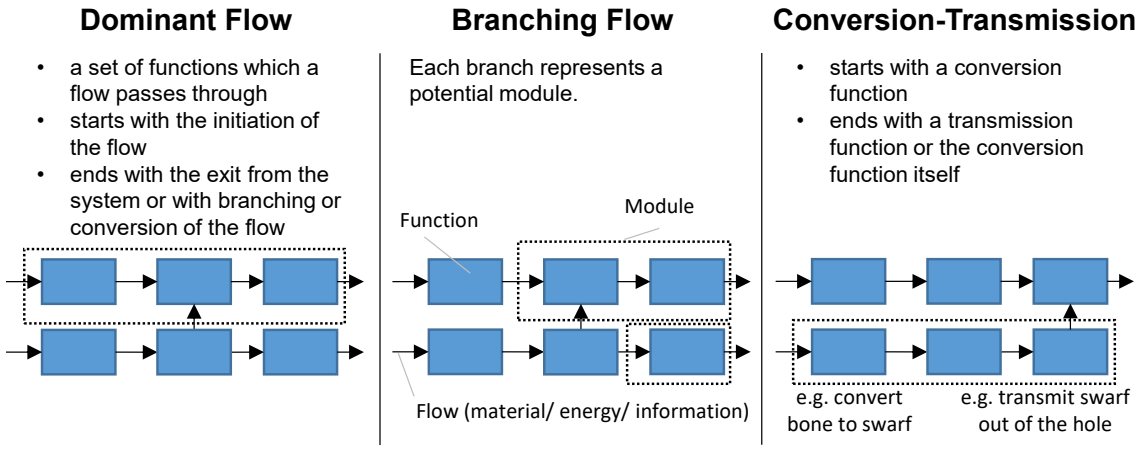


Figure 2.7: Functional modularization according to Stone et al. [1998]

2.2.2 Similarity-Based Methods

When Erixon [1998] established the *Modular Function Deployment* (MFD) method for optimizing the manufacturing process of products, he provided a tool for module indication based on the similarity of components. His *Module Indication Matrix* (MIM) helps to identify potential modules by mapping strategic modularization goals, so-called module drivers, to technical solutions. The solutions can already exist or must be assumed. The two types of module indication are illustrated in Figure 2.8. In the case that module indication is based on the similarity to a dominant module driver (module 2), Erixon suggests applying corresponding *Design for X* (DfX) approaches to further optimize the module.

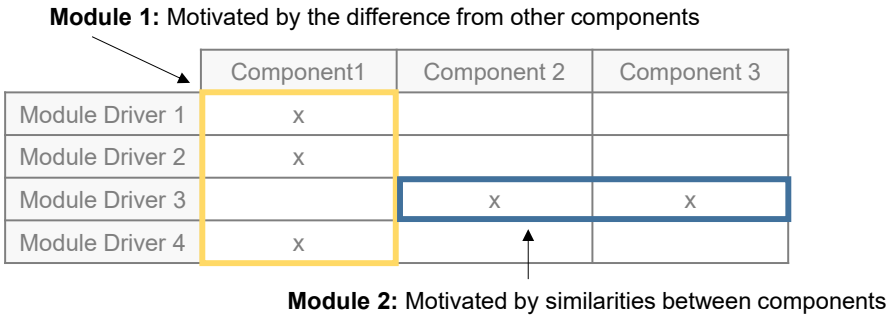


Figure 2.8: Module definition possibilities of the Module Indication Matrix (MIM) by Erixon [1998]

Erixon defined 12 module drivers that were found by case studies and identified as generic but can be complemented by company-specific drivers. Table 2.2 lists modularization goals defined by Erixon and other authors that chose a different naming, like *motives for product change* ([Ulrich and Eppinger 2016]) or *horizontal and vertical leveraging* ([Park and Simpson 2008]). The goals are sorted by the technical product lifecycle (TPL) stages they occur in. Modularization

goals of one author correspond to those of others in the same row. As the level of detail differs between authors, the more general goals are repeated.

Table 2.2: Comparison of modularization goals

TPL stages derived from [Erixon 1998]	Modularization goals (= module drivers)				
	[Erixon 1998]	[Politze et al. 2012]	[Park and Simpson 2008]	[Ulrich and Eppinger 2016]	[Ulrich 1994]
Product Development and Design	Carry-over (between product generations and families; long life of certain components)	Carry-over (of functions): portfolio re-use, product re-use, component usage	Horizontal leveraging (to efficiently suit different market segments with regionally different requirements)	Reuse	Product change
	Technology evolution/ technology push (during a component's lifecycle)	Technical evolution (subject to technology, technology switch, redundant technology)	-	Upgrade	Product change
	Product planning/ planned design changes (e.g., to plan a change at a specific time)	-	-	Reuse	Product change
Customization [Piran et al. 2016] (Erixon: Variance)	Technical specification (e.g., due to regional differences of power grids)	Technical solution (e.g., functions that result in the same effect but are realized in a different way)	Horizontal & vertical leveraging (to address different market tiers, e.g. price segments)	Adaptation	Product variety
	Styling (when influenced by trends and fashion)	-	Horizontal & vertical leveraging	-	Product variety
Production	Common unit (increased volume of certain components)	Common unit (common functions with common interfaces)	Horizontal leveraging	Reuse	Components economies of scale
	Process and/or organization reuse (e.g., to increase integrity and efficiency of teams)	Process (bottleneck, special resources), company strategy (responsibility, outsourcing, management effort, special attention, required precision)	-	-	Decoupling of tasks, design & production focus, economies of specialization, order lead-time
Quality Management	Separate testing of functions	Process (special resources)	-	-	Component verification & testing
Purchasing	Black box engineering (purchase of components)	-	-	-	-
After-Sales	Service and maintenance	-	-	Wear	Ease of product diagnosis, maintenance, repair
	Upgrading	-	-	Add-ons	Product change
	-	-	-	Flexibility in use	Flexibility in use
	-	User perception (operator)	-	-	-
	-	User intention (operator)	-	-	-
	Recycling (e.g., number of different materials)	-	-	Consumption	Differential consumption
Module Drivers	12	8	2	7	11

Politze et al. [2012] transferred Erixon's approach from the physical to the functional domain. They developed the holistic function-oriented product description (FOPD) to be able to modularize solution-neutral functions based on function module drivers. This is different to Erixon's MIM

as technical implementations of functions must not be known. To quantify the similarity of functions, Minkowski distance metrics were applied to weighted indicator functions. Indicator functions quantify the degree of similarity between two functions regarding a specific criterion. A criterion is, for instance, whether functions are complementary or alternative.

2.2.3 Product Structuring Strategies

A set of different products that share common components and functions and target similar application areas or manufacturing processes is called a product family [Krause and Gebhardt 2018]. The similarity criteria that lead to the creation of a product family are company-specific [Hofer 2001]. Products of the same family are called product variants [Blees 2011]. The totality of common components and non-physical modules that does not vary between product variants, is called a platform [Hölttä-Otto 2005; Krause and Gebhardt 2018]. Accordingly, modules that serve as a common basis for several products are usually referred to as *platform modules*. The others can be seen as *hat modules* [Feldhusen and Gebhardt 2008].

Since every product relies on a system architecture [Weilkiens et al. 2015], a product family is usually based on a reference system architecture (or reference structure [Feldhusen and Gebhardt 2008]). This reference architecture serves as a template to derive variants. According to Borky and Bradley [2019] and ISO/IEC/IEEE 42010:2011, a reference system architecture should abstract the structure, behavior and rules of one or more successful system architectures. If a reference architecture is rational and robust, it can withstand several product generations.

The reference architecture of a product family is determined by commonality and variety. Product variety is broadly known as *external variety* because it is externally demanded by the market. Customer requirements on a product are therefore suitable to describe external variety. Economic efficiency is achieved when a company manages to map the highest possible external variety with the lowest possible variety of variant modules, which is called *internal variety*. [Krause et al. 2021; Robertson and Ulrich 1998]

From an economic point of view, internal variety is decreased by standardization. Standardization helps to reduce the average costs of a single product by increasing the volume of production. This strategy is called *Economies of Scale*. In *Economies of Scale*, the production volume of a component is higher due to its multiple use across products. *Economies of Scale* is beneficial for the manufacturer either due to the ability to manufacture more efficiently or to buy standard components from suppliers at lower costs. [Ulrich 1994]

A similar strategy, *Economies of Scope*, uses leverage effects to reduce costs and is not primary motivated by the increase of production volume. The leverage can be a core capability (e.g. specific knowledge), the common use of resources (e.g., for manufacturing), or spreading fixed costs over a wider range of products [McGee 2014]. The two latter aspects of *Economies of Scope* are based on standardization measures, as well. A side-effect can be an increased diversity of products [Gershenson and Prasad 1997].

Several authors differently described the effects of standardization from a manufacturer's point of view: decreased variance-induced complexity and number of different parts, more flexible changeability of products [Krause et al. 2021], reduced throughput times, shorter lead times (implying less working capital, increased quality and faster delivery), less work in progress [Erixon 1998], reduced time of design and development [Ethiraj and Levinthal 2003; Ulrich and Eppinger 2016], mass customization [Piran et al. 2016], configurability in use (e.g., exchangeable seats in a van) [Ulrich 1994], increased frequency of product introduction [Vickery et al. 2016], and quick response to changing markets [Sanchez and Mahoney 1996]. As economic standardization also offers financial advantages for manufacturers of surgical robots, they cannot be neglected in the present work.

While commonality is desired to significantly decrease manufacturing costs, differentiation of product properties is meaningful for the customer [Hölttä-Otto et al. 2008]. Robertson and Ulrich [1998] developed an iterative approach of three steps to design a reference architecture that decouples the increase of commonality from the decrease of diversity. They suggest conducting the following steps:

1) Elaborate a commonality plan (which components are common across variants?) and a differentiation plan (which differentiating attributes are required by the customer?) to identify the costs and importance of variation.
2) Identify dependencies and conflicts by mapping the plans.
3) Brainstorm on architectural changes to solve the conflicts.

Iterations between the three steps could possibly be reduced if additional metrics were used. Thevenot et al. [2007] presented two commonality indices that can be applied to various development stages and indicate the occurrence of unplanned commonality and variety.

Consequently, the balance between communality and variety depends on the underlying reference architecture and the associated product structure strategy. Eilmus et al. [2011] and Eilmus [2016] defined three types of product structure strategies:

a) Family-intern platform strategy: All standard modules and individual hat modules are family-specific. Thus, the products are optimized to family-specific requirements, but variants are constrained to a common platform.
b) Portfolio-wide module kit strategy: All modules are used throughout the portfolio. Characteristics are the high carry-over potential on one hand and many interfaces on the other.
c) Variant-driven family strategy: Mixture of family-intern standard and individual modules as well as portfolio-wide standard and individual modules.

Since a) and b) are idealized types, most companies pursue a variant-driven family strategy to varying degrees, as a result of differently weighted modularization criteria. Strategies with strong focus on using standardized platforms are often referred to as platform design strategies [Piran et al. 2016; Park and Simpson 2008].

2.3 Conclusion

Manufacturers aim to reduce manufacturing costs. Therefore, the manufacturing industry widely uses modularization as an approach. Systematic modularization promises to decrease the (internal) variety of components and production-related tasks while sufficiently maintaining the (external) diversity of products required by the market.

Modularization methods restructure products, concepts or functions and help define a product reference architecture. Such an architecture serves as a template for deriving product variants that represent a company's product structuring strategy. Characteristics of reference architectures and product structuring strategies, such as platform modules and product families, can already be seen in recent surgical robots.

In the case of the MAKO robots, the cart-mounted arm is a platform module, which can be configured into three different product variants for UKA, TKA and THA by using different end-effector modules as hat modules. A similar approach seems to be followed by Zimmer Biomet regarding the ROSA robots. Brainlab uses the Cirq arm as a platform module in different variants.

In contrast to the other presented robots, the ROSA product line divides into two families: ROSA ONE for neurosurgical applications and ROSA Robotics for orthopedics [Zimmer Biomet 2023]. Since the base cart with the robotic arm and the satellite cart with the camera are used across both families but end-effectors are specific to the variants, the product structuring strategy could

be a portfolio-wide module kit strategy or a variant-driven family strategy according to Eilmus [2016]. Different housings, which are white-pink for the neurosurgical family and white-blue for the orthopedic family, indicate the latter.

If modularization methods were used by clinical operators instead of manufacturers, the reduction of internal variety would rather address the number of devices in the hospital or the OR, instead of manufacturing resources. The external variety would include the diversity of applications that are addressed by a device. The vision behind MINARO and the SSD system, for instance, is to provide maximum application diversity to the operator by providing the drivetrains of the MINARO and SSD systems as platform modules that can be combined with application-specific hat-modules.

This work aims to close the gap between manufacturer-driven modularization methods and the unused potentials of surgical robots. A corresponding reference architecture must be robust and beneficial for the manufacturer, the users, and other stakeholders.

3. Requirements for the Compatibility with Development Practices of Medical Devices

The process model to be developed must be compatible with existing development practices and easy to use to be acceptable. First, the most relevant stakeholders, the target group of the model, are identified in Chapter 3.1. In Chapter 3.2, an overview is given on various theoretical process models by which medical products can be developed. Main requirements for a computer-assisted model are identified in Chapter 3.3. Chapter 3.4 concludes how a process model for the systematic design of modular surgical robots should be structured.

3.1 Target Group

The stakeholders to surgical robotics are manifold. Important stakeholders must be addressed by the process model to strengthen the effectiveness of the method.

Stakeholders are persons either impacted by the system or that impact the system at some point during its lifetime. They can be classified according to their affiliation to an organization as internal or external stakeholders [Abbott et al. 2020]. From a manufacturers point of view, internal stakeholders are involved in product development, like design or product engineers, salespersons, and others. In the consumer goods industry, an external stakeholder is usually equated with a customer. The word *customer* is misleading in the context of surgical robots because a customer is defined as a person or company that purchases goods or services independently of benefiting from them [Santos 2013]. Since the benefit is crucial here, the *customer* is seen as a *user*, instead.

For medical devices, Santos [2013] classified users into primary and secondary users. *Secondary users* of medical devices are trainees, students, researchers, technicians, and engineers since they do not directly benefit from the system neither they create explicit requirements to the use of the device. Accordingly, there are two types of *primary users* [Bevan et al. 2018]: the *end-user* [Shah and Robinson 2008], who directly benefits from the output of the system, and the *direct user*, who creates requirements on the use of the interactive system. End users of surgical robots, for instance, are patients. Direct users of surgical robots are operators like surgeons, surgical technicians, sterile service technicians, and hospital administration. Direct users of the process model, on the other hand, are design and project engineers (who use it as a tool) and

software engineers, in case they develop a tool for computer assistance. The users of the process model and modular surgical robots are categorized in Figure 3.1. Since regulatory authorities define requirements but cannot be seen as direct user, they are listed separately.

The target group that must be addressed with the process model for the systematic design of surgical robots are the direct users, the design or project engineers (model target group). The end-users of the process model are those that also benefit from optimized surgical robots and constitute the target group of the resulting robot (robot target group).

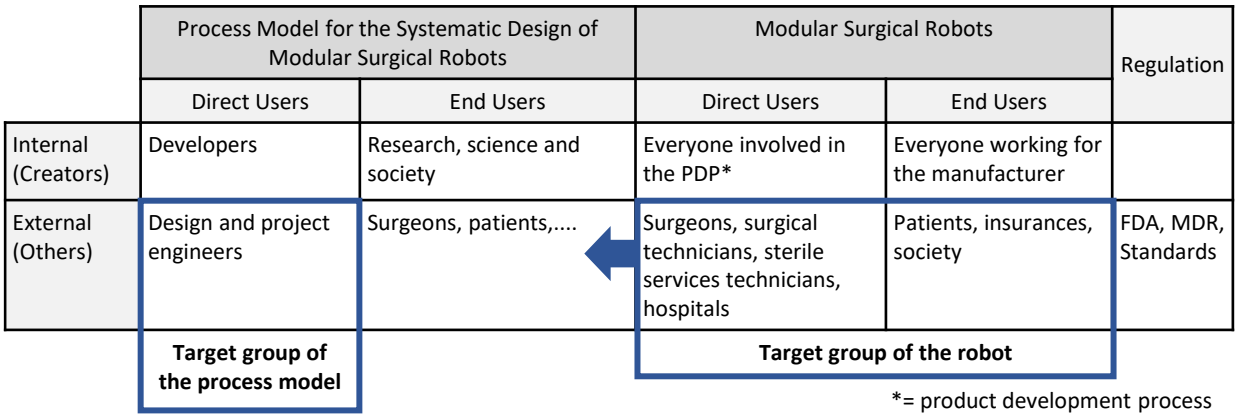


Figure 3.1: Target group of the process model and modular surgical robots

3.2 Process Models for the Development of Medical Devices

The environment in which product development happens is made up of four domains: the customer domain, the functional domain, the physical domain and the process domain [Suh 1998]. Regardless of the underlying development method or model, requirements must be defined, functions derived, and physical solution principles must be searched, selected, and implemented to realize the functions and satisfy the requirements.

This chapter reviews seven different internationally recognized models usable for the development of medical devices. First, two general product development process models are reviewed: (1) the product creation process of VDI 2221:2019, and (2) the V-model for cyber-physical systems of VDI/ VDE 2206:2021. Then, process models are analyzed that emphasize the development of medical products in the regulatory context: (3) the FDA stage-gate process for medical devices, (4) the Stanford model, and (5) the usability engineering process of IEC 62366-1:2015. Subsequently, two agile process models are presented that find increasing application in the context of product development projects: (6) Scrum and (7) Design Thinking. Since the relationship between the presented models is not apparent, they are briefly introduced and then an

explanation is given on how to ensure conformity of those models with the model to be developed in this work.

VDI 2221 - An idealized process of the creation of technical products is described in the German guideline VDI 2221:2019. Therein, product creation is defined as the combination of product planning, product design and product introduction. The provided model is generic as a template but can be adapted to specific use cases through so-called contextual factors and context-specific process knowledge. Contextual factors are such as society, environment, market, costumers, corporate structure, strategy, sector, competences, and others. Consequently, the VDI model can be specified for the development of medical devices, such as surgical robots. The *intended use* and *risk classification* would be defined in phase 1: clarification [Kuhl et al. 2020].

V-Model – Since a surgical robot is a mechatronic system, it is a product of mechanical, electrical and software engineering. The reliable integration of all intra- and interdisciplinary activities is crucial for the outcome of product development. The V-model, which originally comes from software engineering, emphasizes the importance of integration and iteration in system development. For this reason, the German guideline VDI 2206:2004 adopted the V-model to be suitable for the design of mechatronic systems. Later on, VDI/ VDE 2206:2021 refined the model to cyber-physical mechatronic systems meaning mechatronic systems that interact via a digital network.

FDA Stage-Gate Process - The FDA provides a particular stage-gate process model for the development of medical products. The model consists of five steps: device discovery and concept, preclinical research, pathway to approval, FDA review and FDA post-market device safety monitoring [FDA 2018].

Stanford Model - Since the FDA model still offers a lot of freedom regarding the implementation and design of individual steps, Pietzsch et al. [2009] developed a five phases model that formulates the processes (activities) necessary from the FDA's point of view, but also from a company's point of view. For this purpose, 86 experts from industry and authorities were interviewed and contributed their experiences. The activities were allocated to temporal phases (from bench to bedside), which are connected by control points, the gates. Appropriate activities represent cross-phase validation and risk management processes. In addition, the activities were assigned to functional groups so that responsibilities become visible. Functional groups are, for instance, *research and development*, *regulatory* and *clinical*. For convenience, this model will be referred to as the *Stanford model* hereafter.

Usability Engineering Process - It is crucial that a medical device provides good usability in terms of effectiveness, efficiency, learnability and user satisfaction, according to IEC 62366-1:2015 and EN 60601-1-6:2016. Part 2 of IEC 62366-1:2015 provides a process model of usability engineering, which complements the risk management process defined by ISO 14971:2019. Four phases are given: user research, analysis, design and formative evaluation, summative evaluation.

Scrum – This agile project management approach origins from software development and focusses on time intervals, called sprints. Sprints are the periods between the beginning and the end of the development of functioning versions of a product. The Scrum process model comprises six activities. The *first sprint planning* meeting defines the requirements to the sprint. *User stories* or other requirements identification methods are used [Dalpiaz and Brinkkemper 2018]. In the *second sprint planning* meeting, the team members elaborate a strategy to achieve the required goals. *Daily scrum* meetings are used to coordinate tasks. *Estimation meetings* allow the strategy to be corrected during the sprint. At the end of the sprint, *sprint review* and *sprint retrospective* meetings serve to present the results and lessons learned. [Gloger 2016]

Design Thinking – Design Thinking is an approach to finding innovative solutions that are desirable, feasible, and viable. The approach is used in product development, but also change management and other business areas that strive for innovation. Design Thinking divides the product creation process into six sections: *emphasize, define, ideate, prototype, test,* and *implement.* The sections represent perspectives and not necessarily successive stages. [Brown 2008; Plattner 2013]

Compatibility of the Process Models - Concluding, seven internationally recognized models, which are applicable for the design of surgical robots, have been presented. Even though all models seem to have little in common at first glance, they are compatible with each other. The *stages* of the FDA model as well as the *activities* of the VDI model are mostly represented in the Stanford model. Additionally, the Stanford model could be refined through other activities or *functional groups*. Also, the integration and iteration steps highlighted in the V-model and procedures of usability engineering could be represented by activities in a stage-gate process. In Figure 3.2, a scheme is derived that represents the common structure of all presented process models for the development of medical devices on an abstracted level.

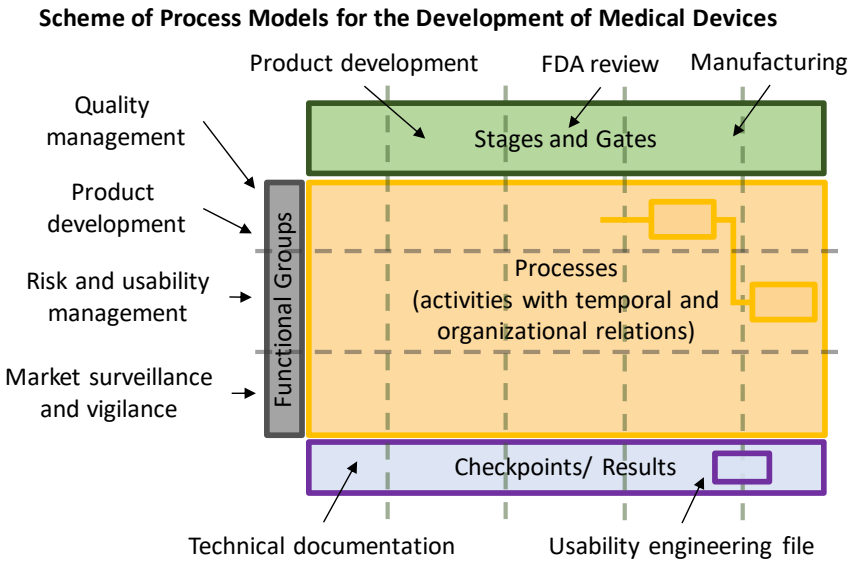


Figure 3.2: Common scheme of product development practices for the development of medical devices with exemplary elements

The common scheme addresses (primarily) linear product development models and agile approaches. For instance, Scrum sprints or sub-processes of those can be assigned to the stages they are executed in. Agile methods that suit for various project management approaches instead of defining product development activities, like Design Thinking, can be assigned to different functional groups at different product development stages.

However, a document-based common process model would not be able to provide all sub-processes and relationships between activities, functional groups, and engineering disciplines in a concise and user-specific form. Instead, the elaborated scheme suits as a basis for the implementation of a computer-based development model in which different established process models and the model to be developed in this work can be combined. Such a computer-based development model could be used for Model-Based Systems Engineering in PLM environments.

3.3 Product Development in Model-Based Systems Engineering

Nowadays, product development practices are computer-assisted, part of systems engineering, and embedded in PLM infrastructures. Systems engineering is an interdisciplinary theory that aims to handle the complexity of systems over design domains, engineering disciplines, and product lifecycle stages. The original idea of systems engineering is still document-based and uses models and simulations only for individual activities. Model-Based Systems Engineering (MBSE), on the other hand, complements the classical systems engineering approach. In integrated MBSE [Blumör et al. 2017], documents are replaced by a single integrated, consistent,

and coherent system model that is the central artifact of all activities. [Walden et al. 2015; Fernández and Hernández 2019]

A *model* is a representation of entities that can be realized in the physical world [Fernández and Hernández 2019]. In the context of MBSE, the term model refers to an abstraction or representation of a system, entity, phenomenon, or process of interest [Walden et al. 2015]. System models of entire technical systems are usually so extensive and interdisciplinary that no single engineer can keep track of every aspect. In addition, certain aspects of the system are more or less relevant for different stakeholders. Thus, a software model of the system enables to take specific views onto the system, tailored to different users. MBSE offers the opportunity to develop across lifecycle stages with specified views for several users or stakeholders. To create a model and different viewpoints, semantics is needed, whereby a *common modelling language* is fundamental. [Weilkiens et al. 2015]

The OMG Systems Modelling Language (*SysML*) was developed by a consortium of large companies, such as EADS, Motorola, Artisan and Boing, as an extension of the Unified Modelling Language (UML). The language distinguishes between the model and the representation (view) of the model while defining notation, syntax and semantics of model elements. Views are defined by diagrams. Accordingly, SysML enables to model any kind of systems, such as mechatronic systems, software systems or organizational systems. In SysML, existing diagram types of UML have been adapted and new diagram types have been defined. The language provides structure diagrams, including block definition diagrams, requirements diagrams and behavior diagrams. However, SysML is a language and a collection of diagram types and does not provide a procedure of how to model a system. [Gehrke 2005; OMG 2017; Weilkiens et al. 2015]

Summarizing, the design domains defined by Suh [1998] can be illustrated through different views and diagrams in MBSE using SysML as a standardized modelling language. [Ulrich 1995; Bender and Gericke 2021]

3.4 Process Model for the Systematic Design of Surgical Robots

A process model for the systematic design of modular surgical robots must directly address the target group of the method but also indirectly the target group of the resulting robots. The direct target group comprises design or project engineers of the robot manufacturer. Thus, the usability of the process model refers to them. To create robots that are acceptable for the target group of the robots, the process model must consider their needs as much as possible. Patients, clinical

users, and healthcare systems have been identified as the target group of the robots and should be considered when defining modularization criteria.

The four domains, which Suh [1998] declared as necessary for product development, can also be used to describe modularization. Modularization criteria can be seen as relative requirements (wishes, customer domain), which are used for the evaluation of design solutions (physical domain). They can be targeted by modularization measures (process domain). For instance, the wish to decrease the weight of components to be carried can be addressed by separating heavy components into smaller and lighter ones. To do so, the property *mass* of the corresponding components must be known (physical domain). Furthermore, components carry one or more functions to be purposeful (functional domain). Use case specific requirements lead to these functions (customer domain).

Concluding, a use-case specific functional description, modularization criteria, and physical solutions must be input parameters for a modularization method. Since components only describe a solution because they carry a required function, they can be referred to as function carriers (see Chapter 6.1 for derivation). Apparently, modularization of function carriers is feasible for existing robots where components are known. Original robots, which are developed from scratch, do not provide function carriers in the beginning. However, each of the analyzed design methods provides for a conceptual design phase in which potential technical solutions are defined. Thus, a modularization method could be applied to the function carriers of these concepts and support the decision of which concept should be pursued. The criteria-based process of modularization through modularization measures (MMs) would be an activity according to the common scheme of product development practices (Figure 3.2). The activity of modularization could be a parallel branch of the concept evaluation process. A concept evaluation process is still required to evaluate concepts against relevant requirements that do not particularly address modularity [Wartzack 2021].

In the case of document-based development, a parallel branch would cause iteration, which could be avoided in a computer-based approach of MBSE. Interdependent sub-processes could be merged using background calculations, which make iterations obsolete or at least reduces them. For instance, the composition of function carriers to concepts could be facilitated by already showing compatibility and suitability of solution principles to evaluation criteria, including modularization criteria, for each solution principle and the combination of those. On the other hand, this approach requires that the elements considered, at least the function carriers and evaluation criteria, are based on a common structural template to make information processable

by a computational algorithm. As shown in Chapter 3.3, SysML is a standardized and well-established modelling language that can be used to create a reference architecture model (RAM) as a template. The required steps identified in this chapter are summarized and illustrated in a preliminary process model in Figure 3.3. Step five, interface design, can be done after modularization. In this work, the elements of the process model are developed in such a way that they add value with and without MBSE.

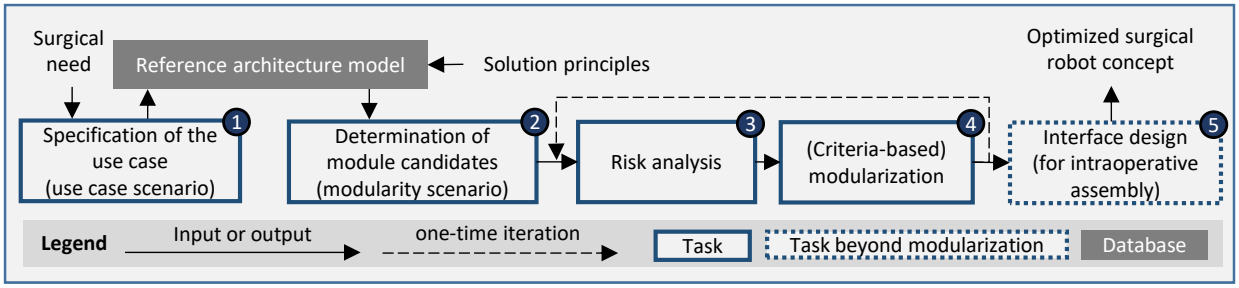


Figure 3.3: Preliminary process model approach compatible with current development practices and Model-Based Systems Engineering (MBSE); 1-5: order of execution

4. Modularization Method

A major goal of this thesis is to improve surgical robots by guiding the design engineer through a systematic modularization process. Systematic modularization requires a method that allows to address versatile prospective use cases.

With respect to the previously identified four challenges of surgical robots (cost, clinical integration, intraoperative safety, surgical outcome), formulating criteria regarding similarities of functional carriers (e.g., same MR compatibility) is likely to be more intuitive than those regarding their interdependencies. Similarity-based modularization methods, different than dependency-based methods, can be applied in early stages of development without knowing future interfaces. Whether and at what point interfaces emerge depends more on how function carriers meet certain criteria than the other way around. It would be even possible to formulate the smallest reasonable number of intraoperative interfaces as a modularization criterion. A criteria-based approach is taken in the following since modularization criteria can be formulated for both, similarities of function carriers and dependencies between them.

Module drivers can be used as criteria to compare entire systems. Consequently, the MFD method by Erixon [1998], which uses the Module Indication Matrix (MIM), seems suitable to be extended to surgical robotics. Among the similarity-based approaches compared in Chapter 2.2.1, the MFD method provides the most specific definition of generic module drivers. To investigate the suitability of the MFD method and suggest modifications, this chapter is structured around three aspects that a modularization method must consider to be functional:

a) **Purpose**: The method must result in a robot concept that is functional and driven by strategic goals.
b) **Means**: There must be basic operators that create modularity.
c) **Structure**: There must be a scheme that facilitates decision making in terms of which solution principles are modularized and to what extent.

First, possible means of modularization, module operators, are identified in Chapter 4.1. These module operators allow the user to impact the degree of modularity. In Chapter 4.2, the existing economic module drivers by Erixon [1998] are reviewed, modified, and supplemented by novel module drivers that are specific to the field of robot-assisted surgery (RAS). The RAS-specific module divers are assessed by means of an online survey. Functionality of a resulting modular robot is supported by using reference functions introduced in Chapter 4.3. Finally, a suitable decision-making structure is elaborated in Chapter 4.4.

4.1 Means of Modularization

Modularization is the process of transforming module candidates (MCs) into modules (Figure 4.1). This transformation process requires special means or tools. Like the tools of a toolbox that one needs to repair his or her bike, it is fundamental to know the available means of modularization. Additionally, these means, from now on referred to as *module operators*, may facilitate the search for new module drivers.

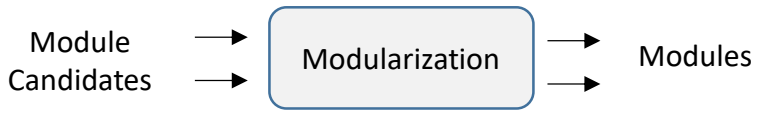


Figure 4.1: Input and output of modularization (simplified)

All analyzed methods in Chapter 2.2 have in common that the formulation of module drivers is influenced by subjective factors. Although Erixon [1998] attempts an objectification by orienting himself to the technical product lifecycle stages (see Table 2.2), it is apparent in the same table that similar or equal module drivers are named differently by different authors. Furthermore, modularization goals are sometimes formulated in very general or diffuse terms (compare e.g., Ulrich [1994] with Piran et al. [2016]). Determining module operators could help better distinguish module drivers from one another and support the identification of new module drivers.

For identifying possible module operators, Erixon's MFD method serves as a starting point. The method aimed to suggest whether physical module candidates should be combined into common supra-modules or left separate under the aspect of cost-efficient standardization (Chapter 2.2.2). Since combining components is provided as an option, *splitting* could be another possibility. For instance, splitting could help to optimize a robot for transport, storage, or sterile reprocessing. However, the possibility of splitting a module candidate into smaller submodules is not considered in Erixon's MIM. [Erixon 1998]

According to Baldwin and Clark [2000], *splitting* is one of six so-called *modular operators*, besides *substituting, augmenting, excluding, inverting* and *porting*. *Inverting* refers to the inversion of outer and inner structure. For instance, if a platform module A carries a hat module B, inversion would transform module A into a hat module and module B into a platform module. *Splitting* impacts the integrity of a single product. The *substitution* of modules drives differentiation by enabling different configurations of a product or variant creation in a product family. *Porting* modules from one product to another creates standardization (commonality) in a product family. From a strategic point of view, commonality and differentiation are often seen as the only opposing forces of modularization (Chapter 2.2.3). *Augmenting* and *exclusion*, as

defined by Baldwin and Clark [2000], can be understood as the extension or reduction of a system's functionality by adding or removing a module. For instance, spatially decoupled input devices that allow a master-slave configuration could add the functionality of scaling motion.

While functional modules add or remove functionality to or from the system, components could also be added to the system without changing the functionality. For instance, the endurance and the operational readiness of a battery-powered surgical drill relies on the ability to exchange broken or empty batteries by identical spare batteries. Thus, a fourth aspect of modularity exists that can be named *redundancy*.

The contradiction matrix of the TRIZ theory provides another source of module operators [Rantanen and Domb 2008]. These are *segmentation/division (=splitting), taking out (=excluding), merging* and *nesting/ embedded structures.*

As a conclusion, all presented module operators can be assigned to one of four dimensions, which span the modularization space and impact the number of spatial or functional modules, as shown in Figure 4.2. The dimensions are integrity (splitting versus integrating MCs), variety (varying versus standardizing MCs), redundancy (multiplying versus reducing MCs), and functionality (including versus excluding functions). For the sake of clarity, *functionality* and *redundancy* are summarized to the term *extent* and arranged on the same axis. *Integration* is used as a collective term for *nesting, combining,* and *merging*.

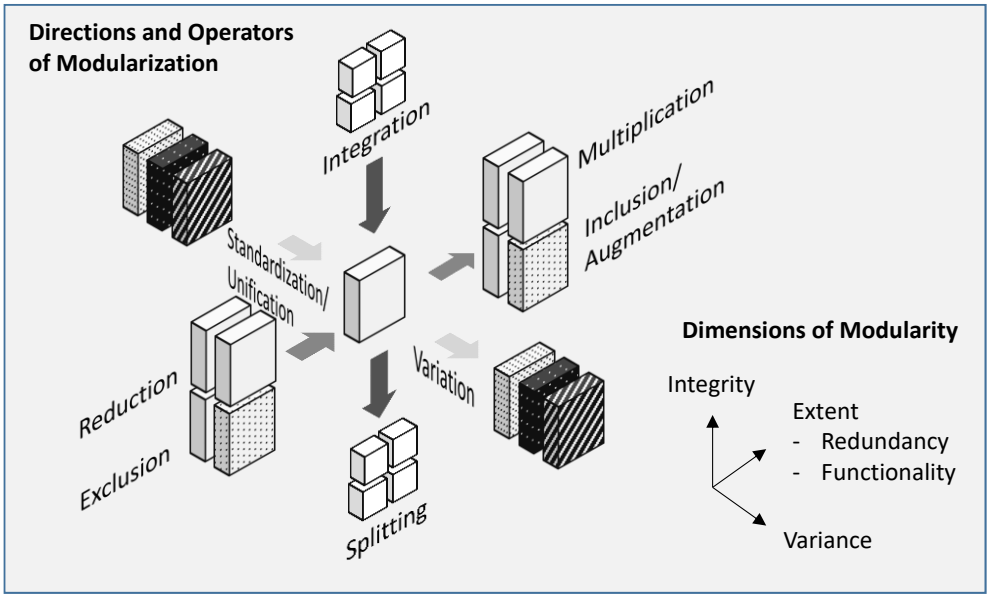


Figure 4.2: Dimensions, directions, and operators of modularization

Spatial modularization is directly determined by the module operators of the dimension *integrity*. However, even the other dimensions indirectly need spatial modularization. For instance, if the

robot cart shall be a hat module that can be exchanged by a rail mount, the corresponding dimension is *variance.* Yet, *integrity* is indirectly addressed because a spatial interface is required to allow the decoupling and the exchange of the hat modules. Consequently, only three module operators are needed to spatially modularize a device: *split* an MC into smaller modules, *integrate* two or more MCs into a common module or *keep* an MC as it is. Furthermore, Chapter 4.4.1 discovers the need for operators that functionally modularize a robot and enable the redistribution of functions between function carriers.

4.2 Criteria-Based Modularization

All 12 economic module drivers (MDs) by Erixon [1998] are potentially relevant for surgical robots due to their generality. In Chapter 4.2.1, literature about the 15 representative surgical robots discussed in Chapter 2.1 is used to identify the generic economic MDs and adapt them to the context of RAS if useful. Chapter 4.2.2 defines new RAS-specific MDs based on literature. In Chapter 4.2.3, the identified MDs are grouped in a way that makes them suitable for an online survey, where they are rated by experts. Further classifications lead to a final list of 59 MDs in a concise form that can be used for modularization (Appendix II). To distinguish the preliminary MDs identified in this chapter from the final MDs listed in the appendix, the preliminary MDs are marked with RBMD-, which stands for *review-based module driver,* followed by a number (e.g., RBMD-1). The 59 final MDs are abbreviated with MD-, such as MD-1 for module driver 1.

4.2.1 Generic Module Drivers

Table 4.1 shows the assignment of surgical robots to one or more of the generic MDs. In the table, the robots are linked to the MDs by the corresponding references that directly or indirectly substantiate the argument. A generic MD is marked by *G*, a new RAS-specific MD that could be derived from a generic MD is marked by *GR*. Systems in the column *positive* provide a modularity that has a positive impact on the regarded MD. The column *negative* indicates deterioration. Some systems provide modularity that can be positive or negative depending on the context. Those are listed under *ambiguous*. Systems that are not substantiated by references are assumptions based on similarities to another system or profound considerations.

Most module drivers by Erixon aim at cost optimization in the manufacturing process, such as RBMD-1 (carry over), RBMD-2 (technology push) and RBMD-9 (black box engineering). RBMD-9 also applies to surgical robots but this is rarely substantiated by literature. Such strategic decisions are usually not publicly available, except for marketing purposes. Yet, Vogt [2020]

and Jakopec et al. [2003] allow to assume that TCAT and the ROSA robots suit the criteria of black box engineering, because the robotic arms had been adopted from the manufacturing industry.

Table 4.1: Generic module drivers by Erixon [1998] found in surgical robots and adaptations of those

Cat.	RBMD-	Explanation of module drivers	positive	negative	ambiguous
G	3	No. 3: planned design changes; modularity based on attributes that will be changed according to a product plan		**MX**: [O'Connor et al. 2021]	
GR	3.1	→ planned certification/ approval: modularity to accelerate certification	**CRQ**: [FDA 2019c, 2020]		
GR	8.1	No. 8: separate testing of functions → modularity based on functions that can be tested isolated in sterile reprocessing	**MIN**, **SSD**: [Theisgen et al. 2018]		
G	9	No. 9: black box engineering; modularity for being manufactured from a specialized supplier at lower costs, because of specialized know-how, or for other reasons	**ROS**: [Vogt 2020] **TCAT**: [Jakopec et al. 2003]		
G	10	No. 10: service and maintenance; modularity based on similar maintenance intervals	**MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018]		
GR	10.1	→ modularity eases replacement of mechatronic units (sensing, processing, actuation)	**MAK**: [Hagag et al. 2011]		
GR	10.2	→ modularity reduces sensitivity to malfunction	**MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018]		
GR	10.3	→ modularity eases replacement of components after surgery	**HUG, VER**: [Longmore et al. 2020] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018]		
GR	10.4	→ modularity eases replacement of components during surgery	**HUG, VER**: [Longmore et al. 2020] **OMN:** [Plaskos et al. 2005]		
GR	10.5	→ independence from suppliers for consumables/ spare parts due to modularity		**EXC**: [Khalsa et al. 2021]	
GR	11.1	No. 11: upgrading → modularity for enabling alternative solutions for a function	**CR, CRQ:** could be steered through a remote input device **MIN:** [Niggemeyer et al. 2012]		
GR	11.2	→ modularity for enabling functional augmentation	**CR, CRQ:** remote control could allow scaling of motion **MIN:** [Niggemeyer et al. 2012]		**EXC**: [Khalsa et al. 2021]
GR	11.3	→ modularity eases upgrade for other surgical procedures	**CR**: [Brandt et al. 1999; Brandt 2003] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018] **REN**: [Shoham et al. 2003] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2018]		

GR	11.4	→ redundant modules allow scalability	**HUG, VER:** [Longmore et al. 2020] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018]		
GR	12.1	No. 12: recycling → modularity to reduce waste per procedure	**MIN**, **SSD**: [Theisgen et al. 2018] **NAV** **OMN**: [Plaskos et al. 2005] **VEL**: [Newmarker 2019]		

Abbreviations: Cat.= category, G= generic module driver, GR= RAS module driver derived from generic, (RB)MD= (review-based) module driver, No. = number, CR= CRIGOS/ CRANIO, CRQ= Cirq, EXC= ExcelsiusGPS, HUG= HugoRAS, MAK= MAKO, MIN= MINARO, MX= MazorX, NAV= Navio, OMN= OMNIBotics, REN= Renaissance, ROS= ROSA ONE & Robotics, SSD= SSD & SpinePilot, VEL= Velys, VER= Versius

Among the generic module drivers, important characteristics of surgical robots are missing, such as the need for approval as a medical device. Cost and duration of regulatory processes prolong product launch. However, market entry can be accelerated if critical modules are isolated from the rest. Then, practical experience can be made with uncritical variants already while critical variants of the same system remain under development. In the case of the Cirq robot, modularity allowed to first get FDA clearance for the arm and the passive hand module in 2019 [FDA 2019c] and a year later for the robotic hand module [FDA 2020]. Thus, RBMD-3.1 (planned certification/ approval) can be derived from the generic MD *planned design changes*. MazorX is listed in the negative column regarding this MD because the system was integrated into the Stealth navigation system from Medtronic and the integrated infrared camera became obsolete but not removed [O'Connor et al. 2021].

Service and maintenance (RBMD-10) are eased in the SSD system [Theisgen et al. 2018]. Components that are more likely to fail than others, sensitive to steam-sterilization or costly to replace were separated into an individual module: the handpiece of the SSD system (Chapter 2.1.1). In the cases of Versius and Hugo RAS, a faulty arm could be replaced by a spare arm if available (RBMD-10.3, RBMD-10.4) [Longmore et al. 2020]. OMNIBotics provides the possibility to use actuators until their end of life and dispose and replace them during surgery without having to dismount the system (RBMD-10.4) [Plaskos et al. 2005]. In the MAKO system, all drive elements that are required to operate a single joint are clustered in an adjacent segment to ease maintenance, testing and assembly (RBMD-10.1) [Hagag et al. 2011]. This is similar to the approach by Schuh et al. [2016] that uses mechatronic function modules to create a modular platform for mechatronic systems.

Upgrading includes functional augmentation (RBMD-11.2). New functionality occurs by either using existing components in a different way or by adding additional function modules. For instance, an added function of the robotic arm of the ExcelsiusGPS is to provide a mounting location for another passive arm (7 DoFs), which holds a retractor for interbody fusion [Khalsa et al. 2021]. Although the passive arm looks like an ordinary FISSO articulated arm (Baitella AG,

Zurich, CH), such an arm would not be compatible without a special interface (RBMD-10.5). To illustrate functional augmentation through new function modules, a potential use scenario with the MAKO platform can be conceived: If MAKO were augmented by a remote input device, physical bounds would be uncoupled (master-slave) and functionality could be increased, for instance, through scaling of motion, different haptic modes [Schleer et al. 2019a], freedom to choose an ergonomic posture, or increased space at the operating table. A robot could further be upgradable through component scalability (RBMD-11.4). For instance, multiple redundant actuators could be used to parallelize actuation. In terms of recycling (RBMD-12), DePuy Synthes reduces waste per procedure (RBMD-12.1) by providing the possibility to use the Velys system without disposable instruments. According to the company, operative costs are reduced as well by 1,500-2,000 dollars per procedure [Newmarker 2019].

4.2.2 Context-Specific Module Drivers

Since it has been hypothesized in the beginning that effective modularization can improve surgical robotics, the challenges of today's surgical robots presented in Chapter 1 serve as implicit categories for MDs. In this chapter, the module operators are used as guides to reveal RAS-specific MDs that are hidden in literature (see Figure 4.3). In cases where it is useful, the four main challenges of surgical robotics are also used as indicators.

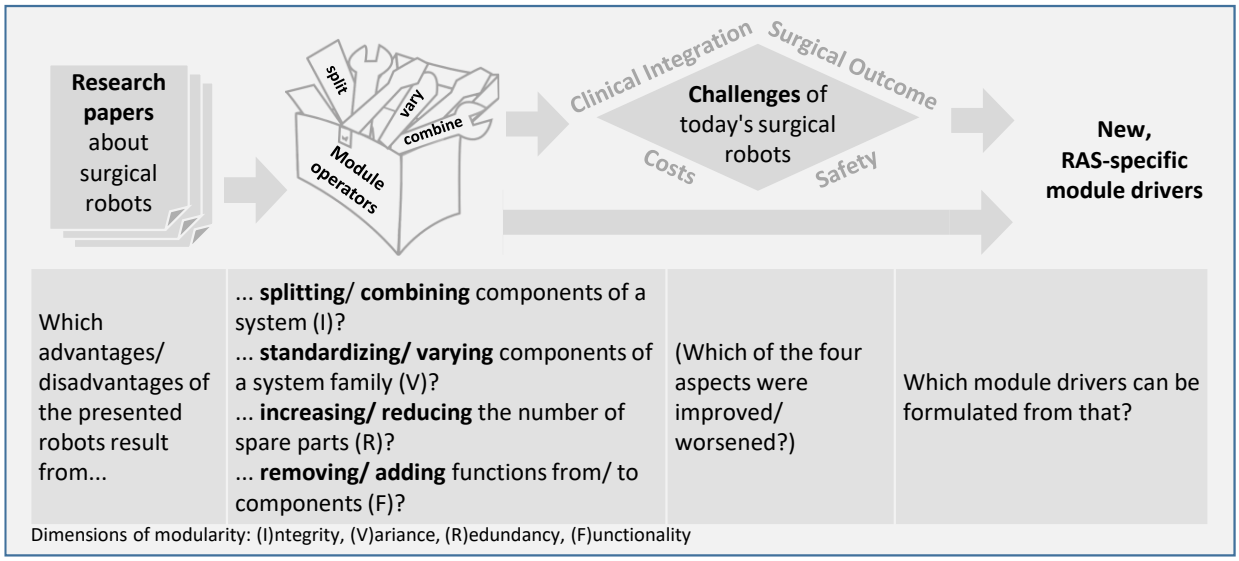


Figure 4.3: Scheme to identify module drivers specific to Robot-Assisted Surgery (RAS)

New MDs specific to RAS were identified by comparing the literature on the 15 surgical robots mentioned above. The results are shown in Table 4.2, Table 4.3, and Table 4.4.

Table 4.2: Identified RAS-specific module drivers (part 1)

RBMD-	Explanation of module drivers	positive	negative	ambiguous
13	modularity favors learnability	**CR**: [Brandt et al. 1999] **VER**: [Morton et al. 2021]	**REN**: [Barzilay et al. 2006]	
14	modularity to improve user satisfaction and/or acceptance	**CRQ**: [Brainlab AG 2023a]		**HUG** **VER**: [Haig et al. 2020]
15	modularity reduces the physical workload	**VER**: [Hares et al. 2019]		**CRQ**: [Brainlab AG 2023a]
16	modularity reduces the cognitive workload		**REN**: [Barzilay et al. 2006]	**HUG** **VER**: [Hares et al. 2019; Morton et al. 2021; Haig et al. 2020]
17	modularity improves use case balance		**VER**: [Hares et al. 2019; Morton et al. 2021; Haig et al. 2020] **HUG**	
18	modularity improves accessibility to the situs	**VER**: [Mills et al. 2013] **HUG**		**DAV**: [Mills et al. 2013]
19	modularity increases free OR (operating room) space	**CRQ**: [Brainlab AG 2023a; Malham and Wells-Quinn 2019; Pojskic et al. 2021] **MHD**: [Vossel et al. 2021] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018] **NAV**: [Lonner et al. 2015] **OMN**: [Plaskos et al. 2005] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018] **VEL**: [DePuy Synthes 2021]	**DAV**: [Haig et al. 2020] **EXC**: [Malham and Wells-Quinn 2019] **MAK**: [Stryker 2015, 2016] **MX**: [Malham and Wells-Quinn 2019] **ROS**: [Zimmer Biomet 2020] **TCAT**: [THINK Surgical, Inc. 2017; Pott and Schwarz 2007]	**HUG** **REN**: [Malham and Wells-Quinn 2019] **VER**: [Haig et al. 2020; Morton et al. 2021]
20	modularity increases free OT (operating table) space	**CRQ**:[Brainlab AG 2023a; Malham and Wells-Quinn 2019; Pojskic et al. 2021] **MHD**: [Vossel et al. 2021] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018] **NAV**: [Lonner et al. 2015] **OMN**: [Plaskos et al. 2005] **REN**: [Malham and Wells-Quinn 2019] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018] **VEL**: [DePuy Synthes 2021]	**DAV**: [Haig et al. 2020] **EXC**: [Malham and Wells-Quinn 2019] **MAK**: [Stryker 2015, 2016] **ROS**: [Zimmer Biomet 2020] **TCAT**: [THINK Surgical, Inc. 2017; Pott and Schwarz 2007]	**HUG** **MX**: [O'Connor et al. 2021] **VER**: [Haig et al. 2020; Morton et al. 2021]
21	modularity reduces setup and take-down time		**CRQ**: [Pojskic et al. 2021] **EXC**: [Vaccaro et al. 2020] **REN**: [Kim et al. 2017] **ROS**: [Lonjon et al. 2016]	**DAV**: [Ruurda et al. 2003; van der Schans et al. 2020] **MIN** **SSD**
22	modularity simplifies registration	**DAV:** [Longmore et al. 2020]	**HUG, VER**: [Longmore et al. 2020]	

Abbreviations: (RB)MD= (review-based) module driver, CR= CRIGOS/ CRANIO, CRQ= Cirq, DAV= daVinci, EXC= ExcelsiusGPS, HUG= HugoRAS, MAK= MAKO, MIN= MINARO, MX= MazorX, NAV= Navio, OMN= OMNIBotics, RAS= Robot-Assisted Surgery, REN= Renaissance, ROS= ROSA ONE & Robotics, SSD= SSD & SpinePilot, VEL= Velys, VER= Versius

Politze et al. [2012] used MDs to assess the similarity between product functions. Besides other MDs, they defined *user perception* as new. Taking EN 60601-1-6:2016 for orientation, user perception can be seen as an umbrella term for *learnability* (RBMD-13) and *user satisfaction* (RBMD-14). Also the physical (RBMD-15) and cognitive workload (RBMD-16), footprint and size (RBMD-19,20), turnover time (RBMD-21) and the assembly process address user perception. An example for learnability and cognitive workload was provided by Barziley et al. [2006], who identified these aspects as weak points of the SpineAssist, the predecessor of Renaissance, caused by excessive miniaturization and assembly effort (Table 4.2). However, if the reduced integrity of a robot leads to more configuration options and thus increased application diversity, it can also lead to the user recognizing familiar functionalities from known configurations and thereby improve learnability.

It is evident that highly integrated, cart-mounted robots negatively impact space availability. A distinction must be made between the footprint in the OR and the space occupied at the operating table (OT) (RBMD-19, RBMD-20). Oversize regarding both MDs can be attributed to TCAT, ROSA ONE and Robotics, ExcelsiusGPS, MAKO and daVinci, as shown in Table 4.2. The Renaissance system is bone-mounted and does not claim any space around the OT. Yet, the manipulator is wired to a remote workstation cart that is slightly bigger than those of the cart-mounted arms and cannot be reused for other systems [Malham and Wells-Quinn 2019]. OMNIBotics is also bone-mounted and compact at the surgical site [Plaskos et al. 2005], as well as the handheld Navio [Lonner et al. 2015]. More OT space is occupied by MazorX, which is rail-mounted but brought to the rail using a cart [O'Connor et al. 2021]. The passive Cirq, which weighs 11 kg [Khalsa and Park 2020], can be attached to the rail by hand [Brainlab AG 2023b; Pojskic et al. 2021], at cost of physical workload (RBMD-15). Velys also saves OT space by being rail-mounted [DePuy Synthes 2021]. When comparing daVinci with Versius and Hugo RAS, if just one arm is deployed, the latter are more compact and provide a smaller footprint than daVinci. In the case of needing four arms, the four independent robot arms of the Versius system would occupy even both sides of the OT. Since in this example the benefit of modularity depends on the use case, RBMD-17 (use case balance) was defined as a module driver. However, the increased flexibility to arrange the arms may allow better accessibility and reduce positioning injuries, which can occur with the daVinci system (RBMD-18) [Mills et al. 2013].

The turnover time (TOT) is the time required to clean and prepare an OR between two surgical cases [Cohen et al. 2020]. The intraoperative time or operating room time (ORT) is the time the patient spends in the operating room [Zaubitzer et al. 2022]. Besides the time needed for registration (RBMD-22) and planning, ORT includes time for assembly and draping (RBMD-21). Both,

TOT and ORT are shortcomings of many robots on the market, including ROSA ONE [Lonjon et al. 2016]), ExcelsiusGPS [Vaccaro et al. 2020], Renaissance [Kim et al. 2017]) and Cirq [Pojskic et al. 2021].

Increasing application variety while decreasing device variety can either be achieved by oversizing or separating components with application-specific properties from those of universal utility (Table 4.3). Application versatility is increased if functions can be reused for different tasks, procedures, treatments or in other surgical disciplines (Figure 4.4).

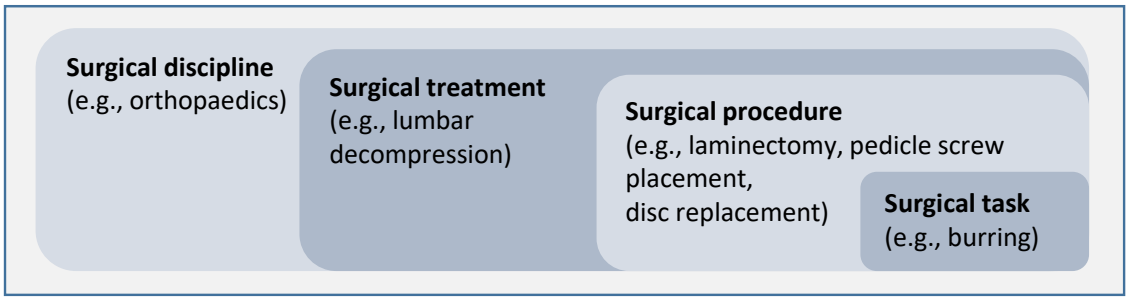


Figure 4.4: Different target levels for increased application variety

An example for increased versatility across treatments and disciplines is the universal handheld actuation module of the SSD system. The module can be used to adjust any kind of tool guide module as long as the guide pose is static to the target, which means that all DoF can be actuated sequentially (RBMD-31). This type of modularity provides the ability to use one actuator across multiple procedures (RBMD-24) and clinical or surgical disciplines (RBMD-23) [de la Fuente et al. 2013; Theisgen et al. 2018]. The Renaissance system could be versatilely applicable according to Shoham et al. [2003] if the robotic part were certified for applications of similar mechanical requirements. On the other hand, Barzilay et al. [2006] described the kinematics as already too small for pedicle screw placement. Cirq uses a universal arm that can be equipped with different end-effector modules [Brainlab AG 2019]. Robots that serve multiple applications using oversized kinematics are TCAT for TKA and THA [Troccaz et al. 2019] as well as ROSA for PSP, TKA and stereotaxic applications [Kelly 2019a].

The aforementioned interbody fusion application of the ExcelsiusGPS also increases application variety since spinal fixation with pedicle screws is required during the same treatment. Re-using the already installed robotic arm as an extended table rail seems to be justified (RBMD-24). However, the proprietary passive arm is customized to the ExcelsiusGPS and must be bought from the manufacturer. If a standardized rail would be integrated into the cart, any kind of available holding arm could be mounted without occupying the table rail and while increasing independence from the supplier (RBMD-28). [Globus Medical Inc. 2020a; Khalsa et al. 2021]

Table 4.3: Identified RAS-specific module drivers (part 2)

RBMD-	Explanation of module drivers	positive	negative	ambiguous
23	functions can be used for other surgical disciplines	**CR**: [Brandt et al. 1999] **CRQ**: [Brainlab AG 2023a] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017] **VER**: [Morton et al. 2021]		**REN**: [Shoham et al. 2003]
24	functions can be used for other surgical procedures	**CR**: [Brandt et al. 1999] **CRQ**: [Brainlab AG 2023a] **MAK**: [Stryker 2015, 2016] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018] **ROS**: [Kelly 2019a] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017] **TCAT**: [Troccaz et al. 2019] **VER**: [Morton et al. 2021]		**EXC**: [Khalsa et al. 2021] **REN**: [Shoham et al. 2003]
25	system can be used directly for consecutive surgeries (depends on the sterility concept)		**MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018] **NAV**: [Lonner et al. 2015] **OMN**: [Plaskos et al. 2005]	
26	modularity allows to exchange components before surgery (configuration)	**CR**: [Brandt 2003] **CRQ**: [Pojskic et al. 2021; Brainlab AG 2019] **DAV** **HUG**: [Medtronic Inc. 2022] **MAK**: [Stryker 2015, 2016] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018; Heger et al. 2010] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017] **VER**: [CMR Surgical Ltd.]		
27	modularity allows to exchange components during surgery (reconfiguration)	**CR**: [Brandt 2003] **DAV** **HUG**: [Medtronic Inc. 2022] **MIN**: [Heger et al. 2010] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017] **VER**: [CMR Surgical Ltd.]	**CRQ**: [Brainlab AG 2019]	
28	modularity increases mounting or positioning options	**CR**: [Brandt et al. 1999; Bast et al. 2003] **MHD**: [Vossel et al. 2021] **MIN**: [Heger et al. 2010] **VER**: [Morton et al. 2021]	**EXC:** [Khalsa et al. 2021]	
29	modularity allows to use intuitive kinematics tailored to the task	**MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018; Heger et al. 2010] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017]		
30	unification of components enables distribution between ORs	**HUG** **VER**: [Morton et al. 2021; CMR Surgical Ltd.]		

31	modularity based on the possibility to sequentially actuate static DoF	**SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018]		
32	modularity provides the possibility for cross-compatibility with other vendors		**EXC**: [Khalsa et al. 2021]	**CR**: [Brandt et al. 1999] **CRQ**: [Khalsa et al. 2021; Brainlab AG 2019] **ROS**: [Khalsa et al. 2021]
Abbreviations: (RB)MD= (review-based) module driver, CR= CRIGOS/ CRANIO, CRQ= Cirq, DAV= daVinci, EXC= ExcelsiusGPS, HUG= HugoRAS, MAK= MAKO, MIN= MINARO, MX= MazorX, NAV= Navio, OMN= OMNIBotics, RAS= Robot-Assisted Surgery, REN= Renaissance, ROS= ROSA ONE & Robotics, SSD= SSD & SpinePilot, VEL= Velys, VER= Versius				

In the case of parallel actuation of motion axes, application variety can be increased by configuring modules before or during surgery (RBMD-26, RBMD-27) [Niggemeyer et al. 2012; Heger et al. 2010; Brainlab AG 2019; Medtronic Inc. 2022]. Furthermore, the Versius carts can be distributed to different ORs if needed (RBMD-30) [CMR Surgical Ltd.]. The kinematic modules of the MINARO can be substituted and reconfigured to create application-specific workspaces that facilitate the imagination of the motion of the end-effector and therefore improve learnability (RBMD-29). Similar systems could follow this approach and use kinematic modules with a remote center of motion to suit needle insertion applications, for instance [Taylor and Stoianovici 2003]. MINARO also provides the flexibility of mounting as it can be mounted on a simple passive support or a robotic holding arm (RBMD-28). CRIGOS/CRANIO can be mounted directly on a cart [Bast et al. 2003] or at the rail [Brandt et al. 1999].

Since RBMD-9 (black box engineering), which originally supports manufacturing and Economies of Scope, is also helpful for the clinical operator, RBMD-32 was defined. Under the condition that open and standardized interfaces exist, as explained in IEEE 11073-20702:2018 and Janß et al. [2018], RBMD-32 also addresses the better integration of small and medium-sized enterprises (SME) into existing ORs.

Based on the prevalence of industrial arms in surgical robotics, intraoperative safety must be addressed by RAS-specific MDs. Kinematic safety can be achieved by limiting kinetic energy with lightweight and compliant structures, limited speed, and limited application-specific workspaces (Table 4.4). Two indicators for kinematic safety have been defined: the ratios (provided vs. needed) of surgical (invasive) workspaces and the kinetic energy (RBMD-33, RBMD-34). For instance, the only task of ROSA ONE when processing a pedicle is to hold a tool guide and compensate for respiration-induced vertebral motion. This motion is always far below 5 mm [Liu et al. 2016] at about 4 mm/s [Guha et al. 2019]. The resulting ratio of provided and needed workspaces is about 100 and the speed ratio is more than 1000, referring to the robot's capability

to move at 8.4 m/s [Stäubli International AG 2020a]. The speed may be limited by software, as it is required for critical situations in industrial applications (250 mm/s, ISO 10218-1:2011), but software can be faulty. Adverse events, related to the software of ROSA [Kelly 2019b] and comparable robots [Theisgen et al. 2020], have been reported. Similar arguments apply to TCAT [THINK Surgical, Inc. 2017; Pott and Schwarz 2007] for the same reasons. Better kinematic safety is shown by those systems whose kinematics have been separated task-specifically into those for rough pre-positioning and precise fine motion.

Increased risk of collisions with the environment or internal parts was observed with the Versius system due to the multiple-cart concept (RBMD-35) [Morton et al. 2021]. If arms are fixed to the same cart, as in the case of daVinci, they potentially know the poses of the other arms. Furthermore, it can be assumed that the likelihood of collisions is smaller for miniaturized parallel kinematics than for large serial arms. Haig et al. [2020] also named maintaining sterility, locking the brakes of the carts and not trapping cables as most challenging with the Versius system (RBMD-36). Since these hazards increase with the number of carts, they must be considered, too, in the case of other multiple-carts kinematics, such as Hugo RAS.

Table 4.4: Identified RAS-specific module drivers (part 3)

RBMD-	Explanation of module drivers	positive	negative	ambiguous
33	modularity to decrease the ratio of workspaces (provided/ required)	**CR**: [Brandt et al. 1999] **CRQ**: [Pojskic et al. 2021] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018; Heger et al. 2010] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018] **REN**: [Shoham et al. 2003] **OMN**: [Plaskos et al. 2005] **MHD**: [Vossel et al. 2021]	**TCAT**: [Pott and Schwarz 2007] **ROS**: [Stäubli International AG 2020b]	**MX**: [O'Connor et al. 2021]
34	modularity to decrease the ratio of kinetic energy (provided/ required)	**CR**: [Brandt et al. 1999] **CRQ**: [Pojskic et al. 2021] **MHD**: [Vossel et al. 2021] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018; Heger et al. 2010] **OMN**: [Plaskos et al. 2005] **REN**: [Shoham et al. 2003] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018]	**TCAT**: [Pott and Schwarz 2007] **ROS**: [Stäubli International AG 2020b]	**MX**: [O'Connor et al. 2021] **NAV**: [Lonner et al. 2015]
35	modularity to decrease the likelihood of collisions (with internal and external parts)	**CR**: [Brandt et al. 1999] **CRQ**: [Pojskic et al. 2021] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018; Heger et al. 2010] **OMN**: [Plaskos et al. 2005] **SSD**: [de la Fuente et al. 2013; Theisgen et al. 2017; Theisgen et al. 2018]	**ROS**: [Stäubli International AG 2020b] **VER**: [Morton et al. 2021]	**DAV**: [Longmore et al. 2020]
36	modularity based on hazards inherent to the assembly process		**VER**: [Haig et al. 2020]	**HUG** **MIN:** [Niggemeyer et al. 2012]

37	modularity required for sterility or cleanliness	**CR**: [Brandt 2003] **MHD**: [Vossel et al. 2021] **MIN**: [Niggemeyer et al. 2012; Theisgen et al. 2018; Heger et al. 2010]		
Abbreviations: (RB)MD= (review-based) module driver, CR= CRIGOS/ CRANIO, CRQ= Cirq, DAV= daVinci, EXC= ExcelsiusGPS, HUG= HugoRAS, MAK= MAKO, MIN= MINARO, MX= MazorX, NAV= Navio, OMN= OMNIBotics, RAS= Robot-Assisted Surgery, REN= Renaissance, ROS= ROSA ONE & Robotics, SSD= SSD & SpinePilot, VEL= Velys, VER= Versius				

The modularity of a system and the location of interfaces can further be motivated by sterility reasons. Modularity enables the separation of sterile and non-sterile parts (RBMD-37). The unsterile linkage of the MINARO HD is draped whereby the sterile burr handpiece must be attached after draping [Vossel et al. 2021]. Despite increased waste (RBMD-12.1) and potential difficulties for setup, a drapable system could be favored as it would be available for consecutive surgeries (RBMD-25) and must not enter the cycle of sterile reprocessing.

Concluding, reviewing the literature about 15 surgical robots led to the identification of 37 MDs. Through categorization, these MDs were further refined and transformed into a catalogue of 59 MDs. For the sake of conciseness, the full catalogue of MDs is provided in Appendix II.

4.2.3 Expert Feedback

Chapter 1 highlighted the benefits of systematic modularization that meets the objectives of various stakeholders. Thus, the value of the identified MDs should also be assessed by these stakeholders. A simple way to get as many different opinions as possible is to conduct an online survey. Recipients of the survey link can participate and pass on the link to relevant colleagues. However, an online survey, which is rather beneficial to the researcher than the recipient, must be very simple and quick to conduct. Therefore, the SoSci Survey tool from SoSci Survey GmbH, Munich, DE was used to create a user interface that is optimized for smartphone use and allows the survey to be completed in less than five minutes. The recipient could participate to the survey using unused time in public transportation or during breaks at work.

The survey is bilingual. On the first page, the user can select between German or English. On the second page, personal data is asked for that is required to categorize the knowledge of the user. The name, which can be real or fictional, as well as the profession (surgeon, engineer, surgical technician or other) and the practical experience with surgical robots is asked for. If the user selects *other* as the profession, a text field can be used for specification. The second page asks about experience with surgical robots. The user can select up to 13 commercial surgical robots, of which 10 are bone-shaping and three are large-size endoscopic robots. The suggested robots are the same that were used to identify the MDs, except for those that were research projects. A free text field provides the possibility to name additional systems. Pages three to nine

present three criteria each that should or should not be improved in today's surgical robots. In total, 21 criteria were shown to the user. Each page, which means three criteria, represents another category of MDs. Thereby, the survey could be short but comprehensive. Since sliders were used to locate a criterion between *improvement not needed* and *improvement needed*, the user should not need to slide through a page. Otherwise, they might unintentionally manipulate a slider when using a touchscreen as an input device, like with a smartphone or a tablet. That was another reason for subdividing the criteria to separate pages of three. The categories and criteria as well as an exemplary page of the survey is illustrated in Figure 4.5.

Categories	Criteria
Size	Footprint in the OR
	Space at the surgical site
	Impairment of assisting staff
Interaction	Total operating time
	Ease of assembly
	Ease of operation
Utilization	Utilization for standard procedures
	Utilization for complex procedures
	Direct availability for consecutive surgeries
Cooperation and Ergonomics	Ergonomic working posture
	Virtual assistances (fixtures and guides)
	Augmentation of sensorimotor skills
Independence	Independence from technical support (company representatives)
	Independence from proprietary implants
	Upgradability to other surgeries (same clinical discipline)
Costs	Acquisition costs
	Maintenance costs
	Operational costs
Others	Upgradability to surgeries from other clinical disciplines
	Possibility to move the system to other rooms
	Waste per case

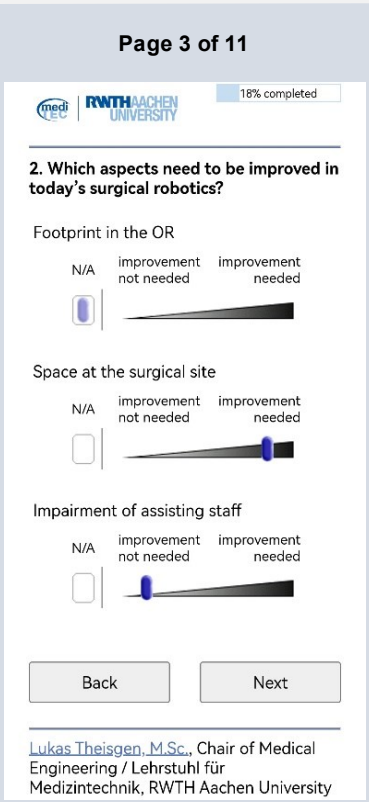


Figure 4.5: Categories and criteria for the assessment of module drivers and smartphone view; OR= operating room

On page ten, additional criteria can be formulated as well as comments in case the users come up with an additional idea. On the last page (eleven), the users can provide their e-mail address if they want to be kept informed about the result of the survey.

The survey link was sent to selected individuals and broadcasted via the robotics focus group distribution list to all members of the International Society for Computer Assisted Orthopedic Surgery (CAOS). The selected individuals were colleagues, surgeons, persons in charge for the OR management and engineers from surgical robot companies.

The survey was done by 92 persons. 51 data sets were considered as valid for evaluation of which 23 were surgeons, 22 engineers, 3 from OR management, and 3 others (1 from marketing and 2 without specification). Two criteria were defined for being valid. First, the pre-last page of the survey must have been reached and second, the user must have spent more than one minute in total to do the survey. The valid results are shown in Figure 4.6. The results are represented by box plots with whiskers indicating maximum and minimum values. Points indicate the average responses from different stakeholder groups.

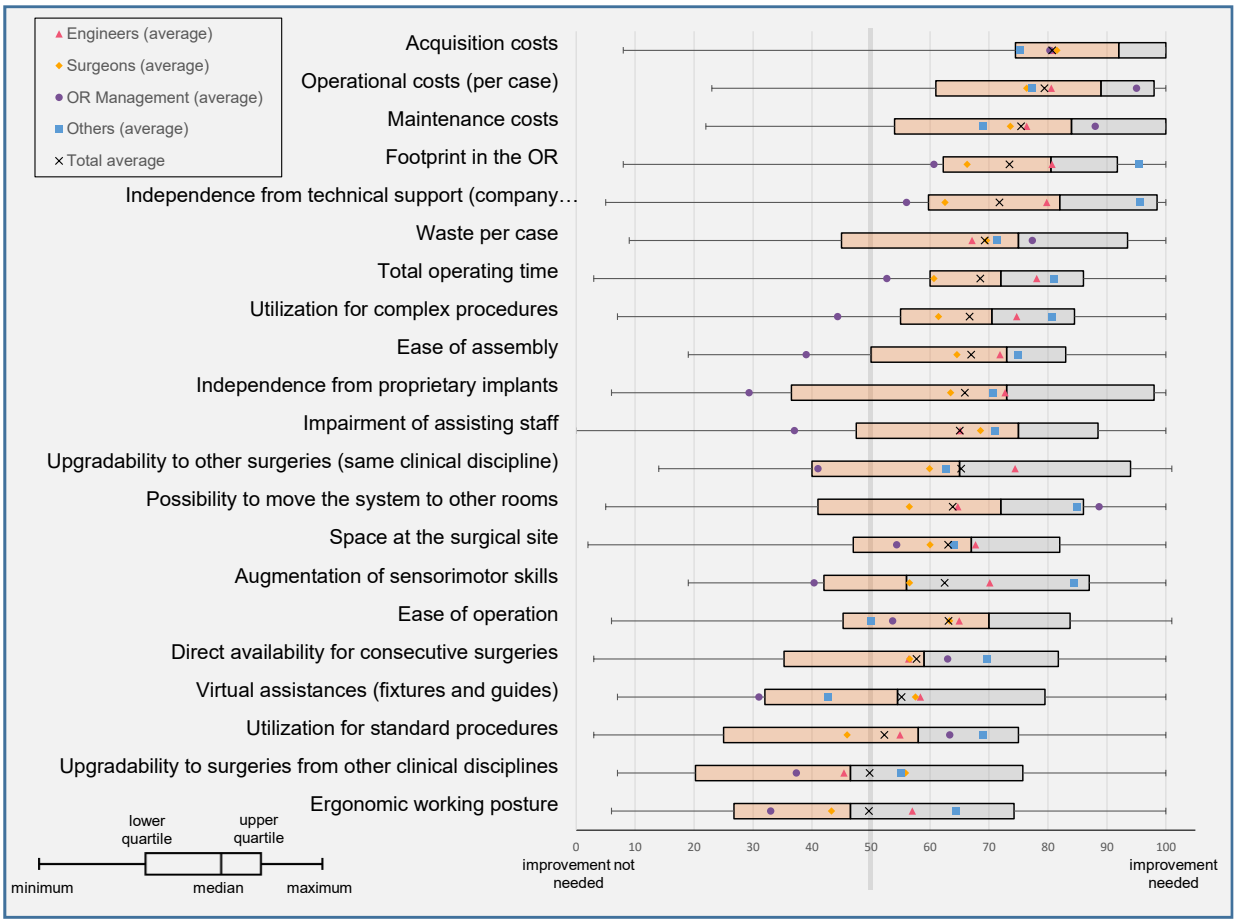


Figure 4.6: Survey results sorted by the average values over all professions from highest to lowest; OR= operating room

Most of the total average values are above 50%. Only for *upgradability to surgeries from other clinical disciplines* and *ergonomic working posture* the total average is 47%. Nevertheless, all criteria show some need to be improved. It is also shown that the three participants from the OR management underrate 14 of the 21 criteria compared to the total average – nine of which are below the lower quartile. On the other hand, it is remarkable that the *possibility to move the system to other rooms* is seen as an urgent need from the OR management (89%) but not as urgent from engineers (65%) and surgeons (57%).

The highest need of improvement addresses acquisition (1st, 81%), operational (2nd, 80%) and maintenance costs (3rd, 75%) followed by footprint (74%), independence from company representatives (72%) and waste (69%). Interestingly, the total operating time was only at rank seven (68%), followed by the utilization for complex procedures (8th, 67%), whereas that for standard procedures was at rank 19 (50%). Although, robots still provide unused potential to assist the surgeon especially in complex surgeries since they could take over or simplify more complex handling tasks, for instance.

All criteria were ranked higher by engineers than by surgeons except for the *upgradability to other surgeries from the same and other disciplines* and *waste per case*. However, the difference between the average ratings of the two professions was always smaller than 11%. Figure 4.7 illustrates the need for improvement in the category *size* (others are shown in Appendix I). Surprisingly, all three criteria were ranked higher by engineers than by surgeons. From these 21 surgeons, 16 had experience with the MAKO robots, nine with ROSA Knee, four with daVinci, two with MazorX, two with Navio, one with ROSA ONE, one with Renaissance and one with OMNIBot. Those surgeons that had experience with the small-size robots OMNIBot and Navio also knew the large MAKO robots.

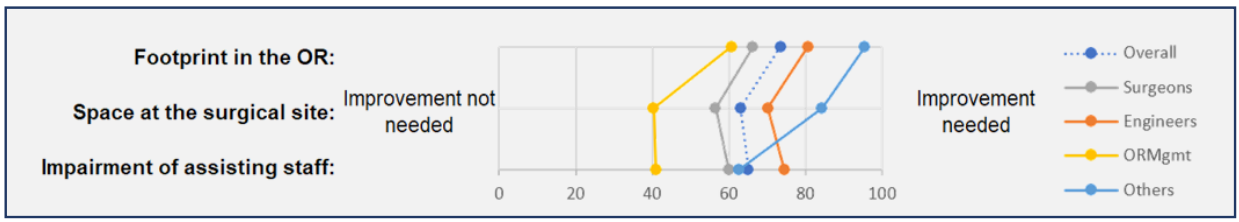


Figure 4.7: Comparison among professions in the category *size*; ORMgmt = operating room management

The results must be interpreted with caution, as the sample of 51 participants is still relatively small and even only three individuals represent *OR management* and *others*. Furthermore, the degree of experience with surgical robots is mixed, as illustrated by Figure 4.8. The answers are subjective and represent how confident a user feels with surgical robotics. Note that the statement *through surgeries* only indicates practical clinical experience for surgeons. The other professions are more likely to have their experience from anatomy labs or hospitations. However, most of the average values in Figure 4.6 are between 60 and 90% and strengthen the hypothesis that the identified module drivers are underrepresented in today's surgical robots.

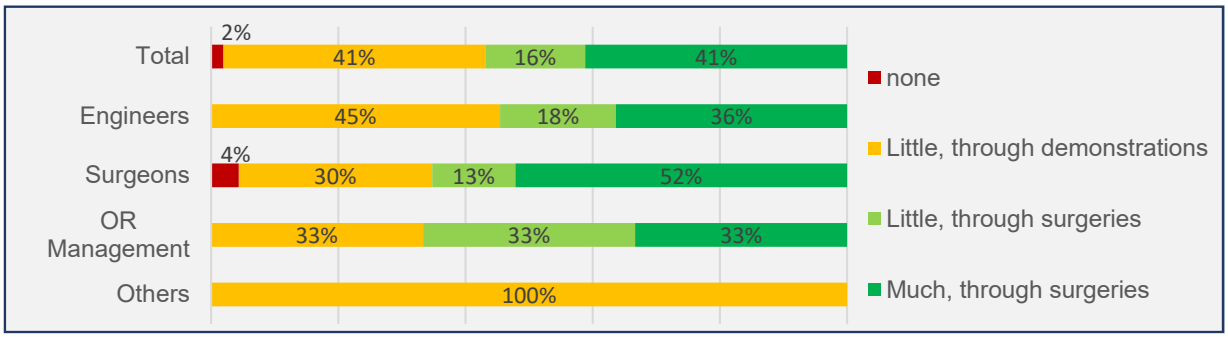


Figure 4.8: Experience with surgical robots; OR= operating room

4.3 Function-Based Modularization

The modularization of an existing robot or robot concept based on predefined criteria promotes optimization but does not necessarily guarantee the required functionality of the robot. For a robot to serve its purpose optimally, functionality must be seen as a necessity and the criteria-based optimization as sufficiency. This chapter explores what a function is, which types exist, which syntax should be used, and how functions can be generalized to reference functions that apply to generic surgical robots as part of a modularization method. Then, reference functions are identified on one hand by functional analysis of existing robots (top-down approach), and on the other hand by analyzing the surgical needs (bottom-up).

4.3.1 Fundamentals

A technical function is the abstract, solution-neutral, and intentional relationship between the input and output of a system with the goal of accomplishing a task [Feldhusen and Grote 2013; Politze et al. 2012]. In order to be intentional and remain purposeful, a function should be as specific as possible but abstract enough to not limit the solution space (VDI 2803:2019). For instance, the formulation *bring robot to bed* would be too specific, unless the task is supposed to be done by a robot. Instead, the scope should be at the human-machine system to include solutions of human-machine cooperation and interaction. On the other hand, the function *modify bony structures* would be too abstract as it would address solutions that could miss the target. Although bone-shaping robots are used to modify bones, it is not their purpose. A more appropriate function that addresses the purpose of creating an implant bed would be *create an implant-matching geometry in bone*. This geometry can then be a simple hole, a surface, or a volume, depending on the use-case. According to VDI 2803:2019, a design engineer must find the borderline between iconic and symbolic language as a trade-off between abstraction and concreteness. It helps to understand that functions are only intended to identify solution principles but

should never be as concrete as it would impact the solution [Gehrke 2005]. For the determination of reference functions, as part of an RAM or a general template for modularization, especially those functions of the human-machine system must be considered that impact modularity.

VDI 2803:2019 distinguishes between function classes, which are basic functions or secondary functions. Basic functions are those functions that directly serve the purpose of the system and are solution independent. Thus, reference functions must be basic functions to be generic. Secondary functions only contribute indirectly to the purpose as auxiliary functions. Due to their supportive or supplementary character, they can be solution-neutral, too, or determined by a type of solution that implements a basic function. [Bender and Gericke 2021]

All basic functions of a system are equally important by definition because they are necessary to fulfil the purpose of the system [Pahl et al. 2007]. Functions that are not necessary or superfluous should be eliminated. A function should further be described by a verb in its infinitive form and a quantifiable noun or even following the syntax of noun-verb-noun [Gehrke 2005] in order to be goal-oriented.

Any technical function can be broken down into a combination of elementary functions [Koller 1998], also referred to as generic functions [Roth 2000]. Accordingly, functions can be logically combined. Functions that are difficult to logically combine are general functions (e.g., safety functions) or rare functions (infrequent or non-recurring), according to VDI 2803:2019. For the pure assignment of module candidates to reference functions or specifications of those, division into rare and frequent functions is not needed. Thus, logical and general functions are focused on in the following.

The functionality of a system is fully described if the formulation of all functions allows to assign exactly one function carrier to each function. General functions like *ensure safety* are not suitable for being a reference function because they cannot be linked to a single function carrier. If these general functions express a requirement that can be influenced by modularity, they can be used as module drivers, as shown in Table 4.5.

Table 4.5: Suitability of functions as part of a modularization method

Type of function	Sub-type	Example	Relevance for modularization
General functions…	…that cannot be assigned to single function carriers and apply to the entire concept	*Achieve maximum safety*	Module driver (requirement to modularity)
	… that apply to various function carriers and can be realized by different solution principles	*Guarantee sterility, interact with user*	Scenario (assumption)
Logical functions…	…that can be realized by function carriers of the surgical robot	*Interact with tissue or implant, follow a planned trajectory*	Reference function
	…that cannot be realized by function carriers of the surgical robot	*Prepare patient for surgery*	Neglected

The other group of general functions could be used to assume a scenario for the entire concept. For instance, a sterility concept would be the combination of all sterility measures that are applied to each relevant function carrier. How such a scenario can be implemented in a modularization tool is subject of Chapter 4.4.

4.3.2 Reference Functions

According to the previous chapter, reference functions must meet certain conditions to be suitable for modularization:

1) Reference functions must be logical functions, which can be linked to function carriers of the robotic system or the operator, and
2) reference functions must be complete and necessary to fulfil the purpose.

Logical functions can either be derived from a procedural view of a robot's tasks, or via hierarchical decomposition of the overall purpose [Pahl et al. 2007]. A procedural view horizontally links functions via functional flows (energy, material, information) and provides a sequential structure [Koller 1998; Roth 2000; Gehrke 2005]. While this does not specify a temporal order, it does specify interdependences of functions and may narrow the solution space. In a purely hierarchical structure, only vertical connections exist. The vertical connections decompose the overall function (purpose of the invention) into sub-functions. Weilkiens et al. [2015] suggested in their Functional Architecture for Systems (FAS) method to use hierarchical function structures for modelling functions, and sequential structures for use case activities. Since reference functions must address various robots with different use scenarios while not narrowing the solution space, neither a procedural structure nor a hierarchical decomposition down to elementary functions seems reasonable (Figure 4.9). In this work, the hierarchical decomposition approach with only as many breakdowns as needed is pursued to identify reference functions.

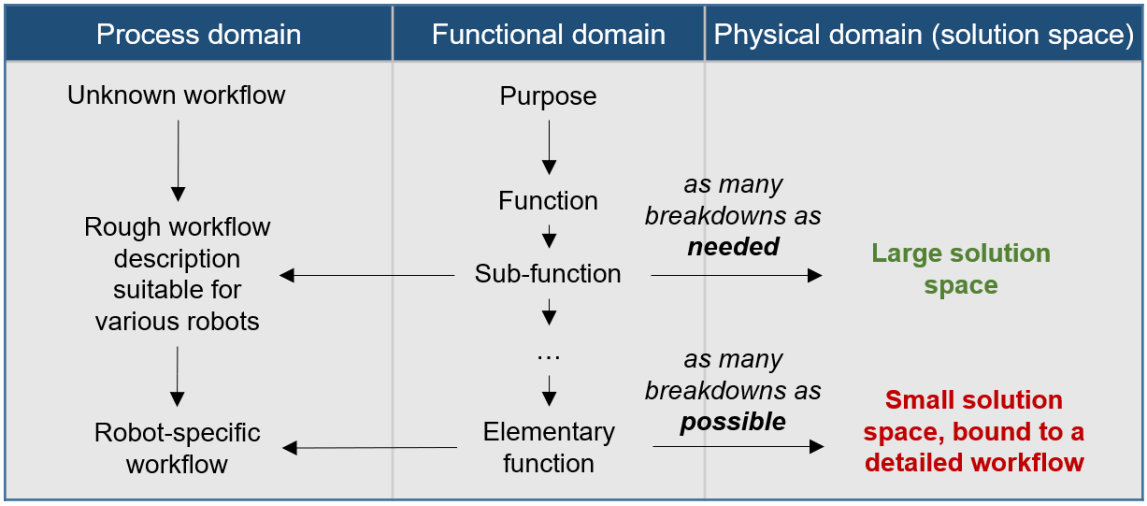


Figure 4.9: Solution space based on the degree of functional decomposition

It was shown beforehand that only those logical functions can be reference functions that can be derived from the overall purpose of surgical robots, without limiting the solution space more than needed. Only then, the purpose of a surgical robot can be fully described by specifying the reference functions to a use case, and module operators can be applied.

Reference functions as a type of technical functions can be determined by deductive or inductive analysis of technical systems. The deductive analysis identifies functions by analyzing existing products and implemented solution principles. In other words, the deductive search for functions is a top-down approach, which is also referred to as *functional analysis* in VDI 2803:2019 and often part of reverse engineering. When performing a functional analysis, it is important to distinguish between basic functions (purpose-bound) and secondary functions (solution-bound), as explained in the previous chapter.

The aim of the inductive approach is to derive fundamental functions from generic surgical tasks and functional needs. The inductive creation of functions is a bottom-up approach. In engineering design theory, the process of transforming requirements into task-based functions is referred to as *function synthesis* [Koller 1998]. If done correctly, function synthesis only determines basic (purpose-bound) functions.

Reference functions must be based on surgical tasks, which are required to conduct a surgical treatment. Thus, the bottom-up approach is crucial. On the other hand, the modularization method aims to allow comparing surgical robots. If implemented in MBSE, linking existing commercial robots to reference functions must be possible. Thus, the top-down approach is beneficial to determine appropriate reference functions, as well. Table 4.6 shows the reference functions for surgical robots that were identified using functional analysis and function synthesis.

Without ordering the functions chronologically, it is nevertheless useful to assign them to the rough and generic stages associated with surgery to which they belong. Since temporal classification of surgery-associated procedures is ambiguous in literature, the following definitions are used in this work. Any surgery subdivides into (1) preoperative processes, (2) intraoperative processes, and (3) postoperative processes. Accordingly, only intraoperative processes happen inside the OR. Preoperative imaging, for instance, could be done hours or days before the intervention. Rehabilitation belongs to postoperative patient care. The intraoperative stage is further subdivided into (2a) presurgical, (2b) surgical, and (2c) postsurgical stages. Everything that happens before the first cut, would be presurgical and everything after suturing but inside the OR would be postsurgical. Some tasks can be done preoperatively or intraoperatively, such as acquiring anatomy through pre- or intraoperative imaging and planning, as indicated in Table 4.6.

All functions assigned to tasks that can be done presurgically are named F1.X. F2.X refer to functions of rough pre-positioning and F3.X to functions of fine motion. The first requires good reachability to the situs and therefore higher kinematic flexibility whereas the latter prioritizes accuracy inside a usually small situs. Accordingly, invasive tasks belong to F3. Post-surgical tasks, starting with suturing and associated sub-tasks, are represented by F4.X. Post-operative tasks are neglected.

Table 4.6: Derivation of reference functions for surgical robots from functional analysis and function synthesis

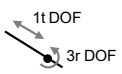
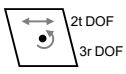
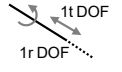
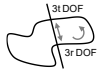
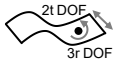
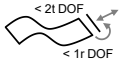
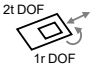
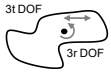
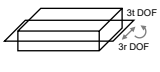
Reference functions		Procedural classification	Direct impact on modularity	Function synthesis (purpose-based)	Functional analysis (product-based)																	
					ExcelsiusGPS	ROSA ONE	ROSA Robotics	MAKO	TCAT	MazorX	Velys	Navio	OMNIBotics	Renaissance	Cirq	CRIGOS/ CRANIO	MINARO	MINARO HD	SSD	daVinci	HugoRAS	Versius
F1.1	Acquire anatomy	1, 2a	(x)	[Mezger et al. 2013; Brandt 2003]	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F1.2	Plan and adjust parameters	1,2a, 2b	x	[Mezger et al. 2013; Brandt 2003]	d	c	d	c	c	d	c	c	c	c	c	c	c	c	c	c	c	c
F1.3	Prepare patient for surgery	2a		[Brandt 2003]	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F1.4	Bring the systems(s) to its working position	2a	x	[Brandt 2003]	d	c	d	c	c	d	c	c	c	c	d	c	c	c	c	c	c	c
F1.5	Set up/ take down the system	2a	x	[Brandt 2003]	c	c	c	c	c	d	c	c	c	c	d	c	c	c	c	c	c	c
F1.6	Register patient and robot	2a	(x)	[Mezger et al. 2013]	d	c	d	c	c	d	c	c	c	c	c	c	c	c	c	(n)	(n)	(n)
F2	Bring/ remove the end-effector to/ from the situs (pre-/reposition)	2b	x	[Brandt 2003]	d	c	d	c	c	d	c	c	c	c	d	c	c	c	c	c	c	c
F3	Remove tissue according to a surgical plan	2b	x	[Mezger et al. 2013]	c	c	c	c	c	d	c	c	c	c	d	c	c	c	c	c	c	c

F3.1	Mechanically constrain the DoFs to a surgical plan	2b	x	[Radermacher 1999; Troccaz et al. 1998]	c	c	c	c	c	c	c	c	c	c	d	c	c	c	c	(n)	(n)	(n)
F3.2	Mechanically limit progression within the DoFs	2b	x		c	c	c	c	c	c	c	c	c	c	d	c	c	c	c	(n)	(n)	(n)
F3.3	Feed/ forward tissue shaping tool	2b	x		c	c	c	c	c	c	c	c	c	c	d	c	c	c	c	c	c	c
F3.4	Maintain registration between anatomy and end-effector	2b	x	[Brandt 2003]	d	c	d	c	c	d	c	c	c	c	d	c	c	c	c	(n)	(n)	(n)
F3.5	Remove tissue	2b	x	[Radermacher 1999; Mack 2001]	c	c	c	c	c	c	c	c	c	c	c	c	c	c	c	c	c	c
F4.1	Prepare patient for postoperative treatment	2c		conclusion	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	(n)	(n)	(n)
F4.2	Clean up equipment and room	2c		conclusion	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
d=used to derive a reference function, c= used to confirm a reference function, -= outside the system boundaries, (n)=not needed but conceivable, 1: preoperative; 2a: intraoperative and presurgical; 2b: intraoperative and surgical; 2c: intraoperative and postsurgical																						

Function Synthesis (Bottom-Up Approach)

The bone-shaping robots addressed by this work create implant beds, or in the words of design theory: working surfaces with the implant. For instance, simple cylindrical working surfaces can be bore holes for screws whereas combined planar working surfaces with peg holes define the pose of the femoral and tibial components in TKA and UKA. For all bone-shaping surgeries applies that the working geometry of a bone-shaping tool geometry must be constrained to a pre-planned target geometry. Feasible combinations of tool geometry and constrains are shown in Table 4.7. For instance, the cutting edge of a saw (linear working geometry) must be constrained to a planar surface in TKA operations. Since the orientation of the cutting edge is important to create the cut, C3 applies. The saw blade can be maintained inside a pre-planned plane allowing two translational DoFs (2t) and one rotational (1r) inside the plane.

Table 4.7: Possibilities to constrain the working geometry of a bone-shaping tool

Constraint (mechanically or virtually)			**Working geometry of bone-shaping tool (to be moved by surgeon and/or robot)**			
			point	**line**	**plane**	**polyhedron**
			A	**B**	**C**	**D**
No extension in any dimension:	**on a point**	**1**				
Extension in one dimension:	**on a trajectory**	**2**				
Extensions in two dimensions:	**on a surface**	**3**				
Extensions in three dimensions:	**in a volume**	**4**				

However, not all combinations of Table 4.7 are useful in orthopedic surgery. Radermacher [1999] used a more practical approach to identify planning-based functions. The author defined six groups of similar planning-oriented motion tasks that can be guided by an individual template: a) finding an entry point and aligning a drill axis, b) reproducing an entry point and a target point on an axis, c) aligning to a cutting plane, d) limiting the cutting depth, e) burring along a volumetric contour and f) guiding along a volumetric contour. These motion constraints are still valid for any type of tool guidance. For instance, the burr of the handheld manipulator (MINARO HD) developed by Vossel et al. [2021] automatically moves along a milling trajectory and fits into category e.

Schleer [2021] defined motion tasks for robotic collaboration in a similar way, addressing bone-shaping and soft-tissue robots. First, he distinguished between planning-based patient-specific (PBPS) and planning independent (PI) tasks. Since planning independent tasks are neither purpose-based in terms of being mandatory to achieve a solution-independent surgical result, it is sufficient to formulate them as module drivers. The PBPS tasks divide into finding a pose (position and orientation), following a trajectory, and being volumetrically constrained.

Based on the aforementioned categories, the following reference functions were formulated:

1) The DoFs virtually constrained by a surgical plan must be mechanically constrained by a robotic system (F3.1).
2) Progression inside these DoFs must be limited (F3.2).
3) Feeding or forwarding the tissue-shaping tool must be possible (F3.3).
4) If registration is needed: The coordinate systems of the targeted anatomy and the end-effector must remain registered to each other during surgery (F3.4).
5) Tissue must be removed (F3.5).

The DoFs required to perform for a surgical plan must be provided by a mechanical structure. Depending on the task, the number of DoFs is constrained partially or fully (F3.1). For instance, in the case of PSP, at least four DoFs must be enabled to move an end-effector axis from a random pose into the planned axis (DoFs are partially constrained). Then, motion must be constrained to exactly one DoF to enable feed along the axis (DoFs are fully constrained). In the case of LAM, at least three DoFs are required to move the burr and remove a planned volume (DoFs are partially constrained). Besides constraining the number of DoFs, the progression inside these DoFs may need limitation (F3.2). In terms of drilling, penetration of the distal cortical bone must be prevented and for burring, progression can be limited to a planned boundary surface (safety area).

As explained by Mezger et al. [2013], the acquired image data must be matched to the current pose of the target anatomy via a registration process already in navigated bone-shaping procedures. In the case of robotically assisted bone-shaping, the robot must be registered, as well (F1.6). It may seem trivial to mention that registration must be maintained during surgery. Yet this is of great importance, because it makes a great difference from a risk perspective whether an oversized robotic arm is only used for initial registration and then fixed, or whether it actively compensates for patient movement throughout the surgery. To account for that, F3.4 was set as a reference function. All four reference functions are transferrable to other bone-shaping activities due to their generality.

Function Analysis (Top-Down Approach)

For the commercial systems that served as a basis to derive reference functions (marked by *d* in Table 4.6), hierarchical physical product structures were established and broken down to principle solutions. The procedure was as follows: First, the respective system was divided into modules, which were defined based on manufacturer descriptions. Descriptions were found in data sheets, operating manuals, and other technical documentation. Then, the identified modules were abstracted into principle solutions and functions. In addition to technical documentation, application videos and reports helped to abstract solution principles and derive functions. Only those functions were transferred into reference functions that complied with the definitions of Table 4.5.

In the case of ExcelsiusGPS, for instance, Crawford et al. [2020], Globus Medical Inc. [2020b], Jiang et al. [2018], and product videos were analyzed. As a result, eight solution-based and three purpose-based functions were identified. The purposed-based functions could be assigned to F1.2 (*Plan and adjust parameters*), F1.4 (*Bring the systems to its working position*), F1.6 (*Register patient and robot*), F2 (*Bring/ remove the end-effector to/ from the situs*), and F3.4 (*Maintain registration between anatomy and end-effector*).

The robots marked by *c* in Table 4.6 were used to confirm the reference functions, which means that sub-systems could be assigned to these functions. In the case of the CRIGOS system, the established reference functions were compared with 24 functions for boring and 23 functions for milling type interventions that had been defined by Brandt [2003] to develop CRIGOS.

4.4 Decision-Making Scheme

Module operators, module drivers and reference functions that address surgical robots have been elaborated. In this chapter, they are embedded in an appropriate structure that can be used as a decision tool to modularize a regarded system.

A modularization decision may be simple if only one or a few module drivers are regarded. In the case of many module drivers, the decision becomes more complicated. Just like requirements, module drivers can be independent (indifferent), supportive (complementary) or conflicting to each other (competing) [Bauer 2009]. Especially in case of surgical robots, several stakeholders (such as surgeons, technicians, manufacturers) define goals from different perspectives. Conflicts between module drivers need to be solved to be able to make a modularization decision. Two possibilities exist: a) trade-offs are made or b) contradictions are solved through innovation.

Innovative Conflict-Solving - In the TRIZ theory, over 50,000 patents were examined and principles were derived to solve physical and technical contradictions through innovation [Rantanen and Domb 2008]. In technical contradictions, one parameter gets worse when another gets better. For instance, stronger motors are usually heavier. Instead, a physical contradiction means to desire opposite solutions: A screen must be wide for good visibility but small to save space in the room. Technical contradictions are allocated to 40 inventive principles in a *Contradiction Matrix*. For physical contradictions, TRIZ provides four *Separation Principles*: Separation in time, in space, on condition, or in scale [Gadd 2016]. The relevance of separation in time for modularization in surgery was demonstrated by Theisgen et al. [2018]: the instrument guide of the SSD for pedicle screw placement (PSP) with four degrees of freedom (DoF) could be successfully actuated by using only one drivetrain through the separation of tasks in time. As shown in Chapter 4.1, those of the separation principles of the TRIZ theory that address spatial modularity are already implemented as module operators. Technical and physical contradictions are represented by appropriate module drivers (Appendix II). For instance, *maximum kinematic versatility* (MD-38) physically contradicts to *as few degrees of freedom as possible* (MD-59). *Waste per procedure is low* (MD-13) can be achieved by replacing drapable with reprocessable components, which technically contradicts MD-14 *energy consumption associated with sterile reprocessing is low*. Consequently, the contradiction matrix of TRIZ could be a valuable tool to support the decision-making process of modularization.

Trade-Off Conflict-Solving - Finding a trade-off between competing goals is subject of *Multi-Criteria Decision Making* (MCDM). MCDM distinguishes between *Multi-Objective* (MODM) and

Multi-Attribute Decision Making (MADM) [Ossadnik 1998]. In MODM, specific solutions are not known beforehand and need to be calculated based on target criteria. The solution space is continuous and an optimum can be found, for instance, through Pareto optimization [Nitzsch 1992; Schmitt and Verstege 2001]. MODM is widely used in simulation, for instance, to optimize the shape or topology of a component. Qiao et al. [2017] and Sinha and Suh [2018] have also applied MODM to partition DSMs. In MADM, potential solutions are first defined and then weighed against each other. Accordingly, the solution space is discontinuous. Besides in quality management tools like ABC analysis and others, MADM is used in Erixon's MFD and for cost-utility analyses in product development, as it is easy to apply.

Referring to the dilemma of conflicting module drivers, several opportunities exist from deciding purely subjective to purely analytical. An analytical decision can solve a complicated problem and therefore be automated. In a complex problem, on the other hand, a large number of parts interacts in a non-simple way so that the whole is more than the sum of the parts [Simon 1962]. This effect of emergence is also a characteristic of modularity, as shown in Chapter 2.2. Emergent effects are, by definition, difficult to predict. Thus, a decision on modularity may be computer-assisted but should never be automated completely.

Although the final modularity decision cannot be automated, recommendations could be suggested to the user derived from a Pareto front created through Pareto optimization (MODM). If the optimization regarding one module driver is not allowed to worsen the suitability to another, the solution would be the Pareto optimum, as illustrated in Figure 4.10. The curve that connects all Pareto optima is called Pareto front. A visual representation of the Pareto front would be capable to relate two or three module drivers. Alternatively, potential conflicts could be shown to the user.

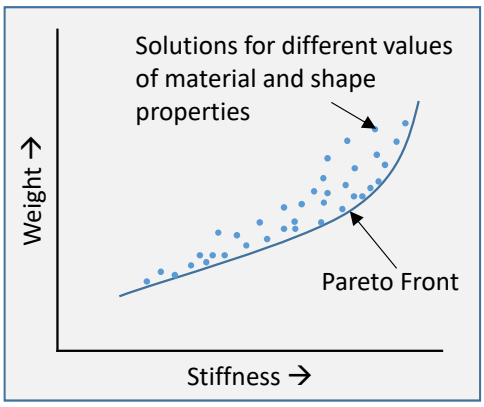


Figure 4.10: Pareto optimization based on Schmitt and Verstege [2001]

In a purely MADM approach or as a precondition to the Pareto optimization, the module drivers could be weighted by the user. Still, it is not recommended to only make a decision based on weighting because emergent effects are not apparent when comparing one to one. A matrix representation would widen the view, similar to Erixon's MIM or the House of Quality [Zairi and Youssef 1995].

Concluding, it is possible to make decisions either by algorithm or by the operator. On one hand, a modularization method must allow an objective decision, but on the other hand, a subjective assessment must lead to the final decision on modularity to account for emergent effects. The modularization tool could support the decision-making process by providing recommendations. Systematic errors, which may occur in automated decision making, could be prevented, or corrected by the operator. Weak points in the logic of the framework as well as emergent effects would become visible. Furthermore, the application would be more user-friendly if the method provided an easy-to-use decision support and not restricted the user in his or her usual way of working. Eventually, an MADM structure is sought that can be computer-assisted to also provide the benefits of MODM but that leaves the final decision to the informed user. Therefore, Chapter 4.4.1 assess the feasibility of the matrix-based modularization approach used in the MIM. In Chapter 4.4.2, an optimized approach is presented.

4.4.1 Module Indication Matrix

This chapter aims at assessing the feasibility of the matrix-based modularization approach used in the MIM for surgical robots. The MINARO robot was chosen as a subject for the assessment because it represents a highly split robot (high granularity). A highly integrated robot, like the ROSA ONE, would either require a *splitting* option, which is not provided by the MIM approach, or a previous decomposition of the robot into smaller modules. However, the latter requires detail information about the robot, which is not is not available for the ROSA ONE or any other highly integrated robot. Finally, it is important to know that not the robot but the matrix-based approach will be assessed, since the aim is to develop a method for modularization and not a modularized robot.

The MIM by Erixon [1998] is a matrix with module drivers (MDs) in its rows and the components to be modularized in the columns. In other words: MDs are mapped to module candidates (MCs). The strengths of the MDs regarding the MCs are shown by points in the intersection cells: 9 stands for a *strong* driver, 3 for *medium* and 1 for *some* strength. As shown in Chapter 2.2.2, a large row sum regarding an MD recommends combining the corresponding MCs, whereas a

large column sum regarding an MC separates it from the others and stands for isolation. Thus, the module operators that can be applied are combining or keeping components as they are.

Since some RAS-specific MDs favor integration and some isolation or even splitting, an MIM for RAS (from now on named MIMRAS) was created where the cells are marked with operators instead of the strengths of the MDs. Instead, the MDs are weighted line by line. To create module candidates (MC) of the MINARO, the robot was divided into those eight MCs that must be taken from a sterile container and assembled before surgery. Figure 4.11 presents the modified MIM for the MCs of MINARO and representative module drivers that are relevant for the system.

Module Drivers (MD)		Points	Base plate	Motor unit front	Motor unit back	Front kinematics	Rear kinematics	Motor unit feed	Round gear rack	Tool
			Module Candidates (MC)							
Production-related										
2	Master technological evolution/ technology push	1	-	o!	o!	-	-	o!	-	-
4	Efficient technical specification (e.g. to allow varying loads)	1	o!	o!	o!	o!	o!	o!	-	-
6	Advantages through scaling	1	-	o!	o!	-	-	o!	o!	-
8	Seperate testing or evaluation of functions (in manufacturing)	2	-	o!	o!	o!	o!	∞	∞	∞
10	Efficient service and maintenance	2	-	o o	o o	-	-	o!	-	-
11	Efficient upgrading	3	o!	-	-	-	-	-	o!	o!
12	Efficient recycling	2	o!	o o	o o	o!	o!	o!	o!	o!
OR management										
Availability of componeents in the OR										
15	Lead times of sterile reprocessing are short or prevented	3	∞	∞	∞	∞	∞	∞	-	-
Sterile reprocessing										
17	Components fit into a standardized sterile container	1	o!	o!	o!	o!	o!	-	-	-
18	Functions can be tested isolated in the CSSD	3	-	o!	o!	o!	o!	∞	∞	∞
Versatility of use cases										
23	Components can be reused for: *motion tasks of different workspaces*	1	o!	o!	o!	o!	o!	-	-	-
24	Components must be exchanged before surgery to suit: *different workspaces*	3	o!	o!	o!	o!	o!	-	-	-
25	Components must be exchangead during surgery to suit: *tissue detection*	3	-	-	-	-	-	-	o!	o!
Surgical work environment										
Minimal workload for pre- and post-surgical processes										
28	Only lightweight components are carried by the staff for setup and take-down	3	-	o!	o!	o!	o!	-	-	-
29	As few assembly tasks as possible	3	∞	∞	∞	∞	∞	∞	∞	-
33	Quick assembly	2	∞	∞	∞	∞	∞	∞	∞	-
Safe assembly										
48	Components cannot fall down during assembly	2	∞	∞	∞	∞	∞	∞	∞	-
Efficient and effective workflow										
51	Components sensitive to wear can be exchanged during surgery	3	-	-	-	-	-	-	-	o!
			Evaluation of MCs							
			# MDs: 18	neglected MDIs: 41		Comprehensiveness: 31%				
	non-relevant MDs for MC		8	3	3	6	6	7	9	12
			weighted							
consider **combination** with other MCs (weighted)		∞	48%	33%	33%	38%	38%	68%	57%	31%
do not combine with other MCs (weighted)		o!	52%	67%	67%	62%	62%	32%	43%	69%
consider **splitting** MCs (weighted)		o o	0%	13%	13%	0%	0%	0%	0%	0%

o! = yes, if remains isolated
∞ = yes, if combined
o o = yes, if separated
- = driver cannot be assessed

Figure 4.11: Similarity-based modularization of the MINARO system with the MIMRAS

Module drivers that cannot be assessed with the MINARO system were excluded from the matrix. If an individual MC is not addressed by a module driver or cannot be assessed, it is marked by “-”. MCs that meet the module driver if they remain isolated are marked by “o!”. Combination with other MCs is indicated by “∞“ and splitting by “o o”.

In the example, the matrix was applied to uncover first limitations. Only 18 of 59 module drivers (comprehensiveness of 31%) were used because the others refer to production or reliable data was missing. It is not surprising that the matrix confirms the modularity of the subjected system because most of the regarded module drivers had been previously identified by analyzing this and similar robots. However, only the matrix structure should be tested, and the result can be read as an example.

Although the matrix-based approach seems to work with the MINARO system, some limitations appeared. First, the operator “∞“ indicates that combination is useful, but it does not specify the MC with which it should be combined and under which condition. Second, the benefits that different MCs contribute to a module driver may vary. A quantification for each MC regarding each module driver could provide more information for the user. Third, the three operators do not allow to redistribute the functions the different MCs provide. For instance, the motor module provides the function to drive the kinematics but also to fix and position the kinematics on the base plate. A potentially beneficial alternative may be to fix the linkages directly to the base plate. Göpfert [1998] differentiated between physical (spatial) and functional independence as characteristics of modularity. High functional independence implies that a component only satisfies one function. Still, a functionally independent component could further be decomposable for other reasons, like for spatial requirements. Moreover, if sub-functions were formulated differently but resulted in the same overall function, the distribution to components could be different although the spatial modularity has not changed. Concluding, the previously formulated module operators that refer to the spatial independence of parts must be complemented by operators that allow a redistribution of functions. A modularization tool should provide the operators: keep components isolated, combine components, split component, remove function from component and insert function into component.

The fourth limitation is that the generic module drivers are production-related and determine interfaces that only appear during production whereas RAS-specific module drivers often create interfaces the user must interact with. Interfaces based on MD-1 (carry-over) and MD-9 (black box engineering) are hidden to the user since off-the-shelf components can be combined before sold to the customer. In contrast, intraoperative interfaces may impact safety and usability. The

last and important limitation was noticed when a similar, also matrix-based approach was tested on a representative mechanical engineer who works in research with surgical robots. Since he was not very familiar with the system, neither with the module drivers or modularization at all, he went through the matrix very structured from row to row and in each row from column to column. Since he did not bring some experience that would have made him identify most beneficial modularization opportunities, the matrix-based approach was not time-efficient for him and therefore not practical. Presumably awkwardly formulated module drivers may have amplified this effect. An approach that encourages to question the robot concept as a whole and not column by column could ease the entry into the method also for unexperienced users.

4.4.2 List-Based Modularization Scheme

A matrix-based modularization tool encourages the user to go row-wise and column-wise through the matrix (Figure 4.12). For a user who is not familiar with the method, this could result in significant overhead. An alternative approach might be to not use a matrix representation but to only guide the user through the list of module drivers. The user would then have to think about how to optimize the robot as a whole for each module driver.

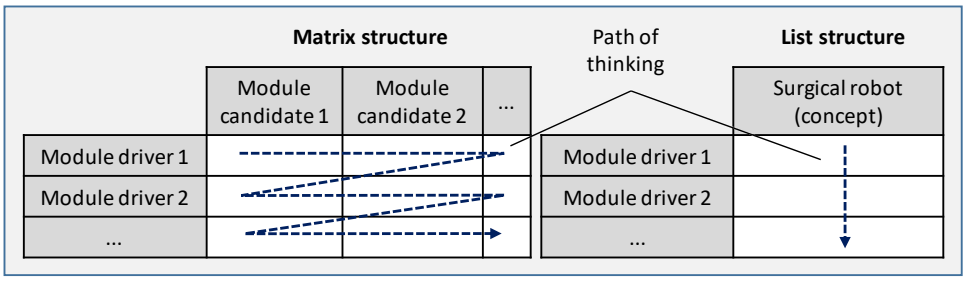


Figure 4.12: Path of thinking in a matrix structure and in a list structure

Syntax - In a list structure, the specification of module operators is not sufficient to formulate a modularization measure. A syntax must be specified that supports the user in choosing a module operator and ensures that each measure is rated in terms of the benefit it brings to the module driver. Third, the semantics for the formulation of measures must be predefined. For instance, if one MC is to be combined with another, at least two MCs must be selected. Accordingly, the user would have to specify the MCs to which he or she wants to apply an operator. Another shortcoming of the MIM was the missing possibility to redistribute functions between MCs. However, the syntax should be open enough to allow any number of modularization measures per module driver. A certain module driver could be satisfied by combining, for instance, MC-A with MC-B but also by splitting MC-C and keeping MC-D isolated. Without limiting the number of measures, combination of MC-A with MC-B and combination of MC-A with MC-D and MC-E could be realized by applying the module operator *combine* two times, which was a limitation of

the MIM approach. Then, each time a module operator is applied, it would have to be specified by the components it addresses. A suitable syntax for the formulation of a modularization measure is shown by Equation (4.1). For instance, if combining MC-A with MC-B had a high capability to improve MD-1 (value of the modularization measure), while removing RF-1 from MC-B had only a small effect, the orders “combine+A+B+high” and “remove function+B+RF1+small” in the row of MD-1 would deliver all the required information.

$$< MO > + < MC > + \begin{cases} if\ MO\ combines\ MCs\text{:} \sum_{1}^{n} < MC_i > \\ if\ MO\ involves\ RFs\text{:} \sum_{1}^{m} < RF_j > \end{cases} + < v > \qquad (4.1)$$

$$with\ MO = module\ operator, MC = module\ candidate, RF = reference\ function,$$
$$v = value\ (or\ capability)\ of\ the\ modularization\ measure\ to\ improve\ the\ module\ driver$$

Scenario View - Furthermore, although a column-wise representation of MCs would favor the meandering way of thinking of the matrix-based approach, the MCs must be shown somehow to provide the user with the original modularity scenario and the information of which function carrier carries which function. Only then, functions can be redistributed among the function carrying module candidates. These function carriers and functions could be shown on the same page, sheet or view as the module drivers and operators (as shown by Figure 4.13), or in a separated view. By adding scenarios for general functions that can be differently implemented by several function carriers (see Table 4.5), additional information can be provided to the user. For instance, draping, housing, one time sterilization or sterile reprocessing are *sterility measures* that can be applied coexistingly to different function carriers. Another example is *user interaction*. Scenarios can be accounted for in the decision-making scheme by adding scenario rows, as illustrated in Figure 4.13.

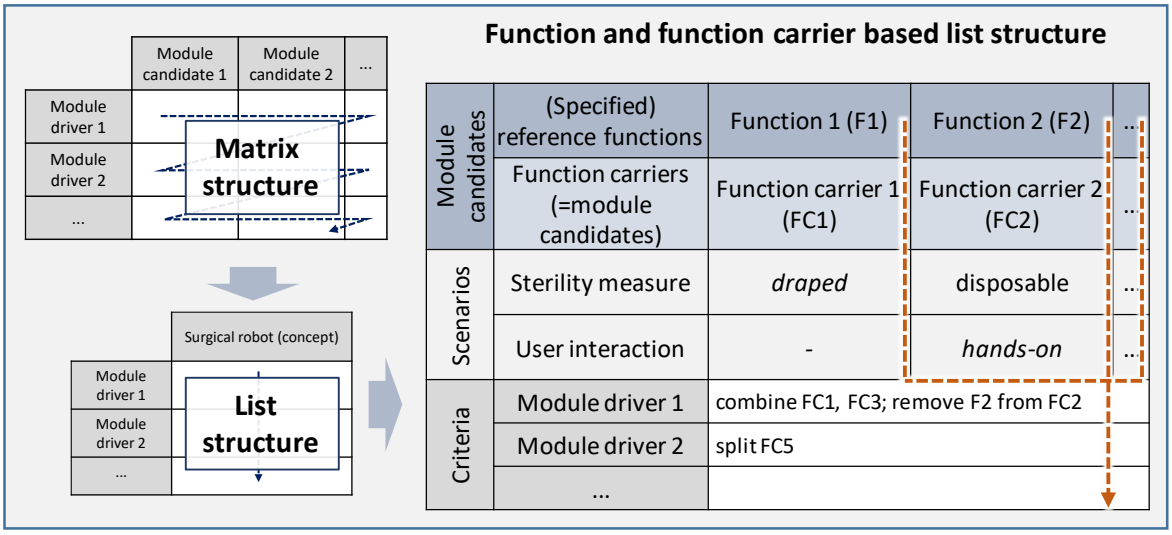


Figure 4.13: Integration of functions and function carriers into a list-based modularization scheme

Weighting of Module Drivers – Since module drivers are a kind of evaluation criteria, which are derived from objectives, they should be weighted and formulated positively [Pahl et al. 2007]. Depending on the number of module drivers, different approaches exist. For a higher number of module drivers, an objective tree facilitates the weighting process [Zangemeister 2014]. Due to the tree structure, weighting starts on an abstract level between a few categories and then continues inside those categories. Multiplication of all weights along a branch results in the absolute weight of a criterion. For a small number of criteria, established methods are the balance sheet of arguments, pairwise comparison, or the preference matrix (very similar to the ranking method) [Wartzack 2021].

Most module drivers are directly or indirectly related to safety. The weighting of safety-related module drivers could be linked to a risk priority number or similar key indicators that result from a risk analysis for the considered use case. Chapter 5 investigates the possibilities to combine modularization with comprehensive hazard analysis.

5. Integrated Modularization and Risk Estimation

Work in this chapter has been presented in parts in:

- Theisgen, Strauch, de la Fuente, Radermacher (2022): Safe design of surgical robots - a systematic approach to comprehensive hazard identification. In: Biomedizinische Technik/Biomedical Engineering. DOI: 10.1515/bmt-2022-0202.
- Theisgen, Strauch, de la Fuente, Radermacher (2020): Catalogue of hazards: a fundamental part for the safe design of surgical robots. In: Current Directions in Biomedical Engineering 6 (1). DOI: 10.1515/cdbme-2020-0009.

Numerous reports of adverse events relate to surgical robots. According to the IEEE Robotics & Automation Society, the maturity of medical robots is comparable to that of manufacturing robots in 1980 [IEEE Robotics & Automation Society 2022]. While in manufacturing, robots can be separated from humans, a surgical robot shares its workspace with patient, staff, and bystanders. In the event of failure, a surgical robot can be a serious hazard since it modifies the patient in a similar manner to how an industrial robot modifies a workpiece. Both arguments, the low maturity of the technology and the potentially high risk due to direct patient contact, require robust safety measures for surgical robots.

Ferrarese et al. [2016] analyzed robotic system malfunctions in surgery between 2005 and 2014. 20.9% of which were allocated to the robot arms and instruments. Other categories were console (cart), software, and optical tracking. In the US, the number of malfunctions and adverse events due to robotic systems increased between 2004 and 2013 by 2.2% [Alemzadeh et al. 2016]. Ramirez et al. [2018] reported that mortality rates in radical hysterectomy were higher in robot-assisted minimally invasive surgery (MIS) than in open abdominal surgery. Regarding the use of robotic-assisted devices for women's health, the Federal Drug Administration (FDA) published a safety warning [FDA 2019a].

Several standards, directives and regulations, for instance, for machinery (Directive 2006/42/EG, ISO 12100:2010, ISO 13849-1:2015), and collaborative robots (DIN ISO/TS 15066:2017) as well as for medical devices require intrinsic safety by design as a principle to be preferred over other safety measures. Medical devices are particularly addressed by Directive 93/42/EEC (medical device directive, MDD) and Regulation (EU) 2017/745 (medical device regulation, MDR). Yet, from the 1980s until now, orthopedic robots have used oversized arms with oversized power, working volumes, and mass inertia [Kwoh et al. 1988; Vogt 2020]. As a logical response, many solutions of smaller and safer kinematics have been developed, for instance, by Davies et

al. [1991], Brandt et al. [2000], Shoham et al. [2003], Plaskos et al. [2005], Pott and Schwarz [2007], Niggemeyer et al. [2012], de la Fuente et al. [2013], and Vossel et al. [2021]. However, miniaturized robots are rarely represented on the market. Reviewing these miniaturized robots by applying the module drivers presented in Chapter 4.2 may uncover some reasons.

Further reasons are given by the FDA approval process. In the US, the Premarket Notification (PMN or 510(k)) process is applicable when a medical device is substantially equivalent (SE) to a predicate device. This pathway is attractive for manufacturers as it is significantly less costly, time saving, and also less stringent then the premarket approval (PMA) process [Yang et al. 2017; Hines et al. 2010]. Lefkovich [2018] highlighted that since the existence of surgical robots, they have never been completed to the PMA process. Also the clearance process of the ROBODOC system (Integrated Surgical Systems Inc., Sacramento, US), started as a PMA process in 1993 but was converted into a 510(k) process after nine years [Haidegger 2012]. ROBODOC was rated as substantially equivalent to three systems of the product codes OLO, HAW (orthopedic and neurological stereotaxic instruments), and NAY (endoscopes and accessories), according to the 510(k) database of the FDA. The so-called endoscope with accessories was the Da Vinci Surgical System from 2004 (K043153). The approval of the Da Vinci Si Surgical System (Intuitive Surgical Inc., Sunnyvale (US)) was based on 2618 predicates of which the original one had been approved before 1976 [Lefkovich 2018].

Although causality was not evident, the FDA observed a correlation between the number of predicates and the Medical Device Reporting rate of adverse events [FDA 2017]. Hines et al. [2010] emphasized the effect of *predicate creep*: Over multiple cycles, a new device can be similar to the predecessor but dissimilar to the original predicate device. Griffin [2017] concluded that, if not controlled, the latest device may be as unsafe and ineffective as the weakest link in the predicate chain.

Further examples from neurosurgery and orthopedics are shown in Table 5.1. Although risk analyzes are always mandatory for FDA Clearance and CE-certification according to MDR and MDD, Table 5.1 emphasizes that associated risk classes are not a good indicator for the hazard potential of surgical robots. Very different robots in terms of degree of automation, complexity, invasiveness, and other criteria, representing a variety of potential hazards, belong to similar or equal classes.

However, it must at least be ensured that hazard and risk analysis methods are as comprehensive (effective) as possible while being easy and efficient to conduct. The methods should not only be based on differences to the latest predicate but should address the actual

context of use and state-of-the-art technology to prevent predicate creep. In the context of modularization, it is further important to consider hazards that come with modularity already in early phases of product design.

Table 5.1: List of robots that received FDA clearance through 510(k) Premarket Notifications based on Theisgen et al. [2022], extended with the corresponding risk classes of Directive 93/42/EEC (MDD); OLO: Stereotaxic Instrument (Orthopedic), NAY: Endoscope and Accessories, HAW: Stereotaxic Instrument (Neurological)

Company	Robot	US market (FDA)				European market (MDD)
		510(k) Number	Decision Date	Regulatory Class	Product Code	Risk class
Brainlab AG, Munich (DE)	Cirq	K202320	2020-12	II	OLO	2b
Globus Medical Inc., Audubon (US)	ExcelsiusGPS	K190653	2019-04	II	OLO	2b
Intuitive Surgical Inc., Sunnyvale (US)	Da Vinci X and Xi Surgical System	K192803	2020-04	II	NAY	2b
Medtronic, Dublin (IE)	Mazor X	K203005	2020-10	II	OLO	2a
Smith & Nephew PLC, London (UK)	Navio	K191223	2019-06	II	OLO	2a
Stryker Corp., Kalamzoo (US)	Mako Partial Knee Application	K172301	2017-11	II	OLO	2b
	Mako Total Hip Application	K193128	2020-02	II	OLO	2b
	Mako Total Knee Application	K193515	2020-07	II	OLO	2b
THINK Surgical Inc., Freemont (US)	TSolution One Total Knee Application (formerly ROBODOC Surgical System)	K203040	2020-11	II	OLO	2b
Zimmer Biomet Holdings Inc., Warsaw (US)	ROSA ONE Brain Application	K200511	2020-05	II	HAW	2b
	ROSA ONE Spine Application	K192173	2019-10	II	OLO	2b

In Chapter 5.1, a framework for the comprehensive identification of hazards related to surgical robots is presented. Chapter 5.2 investigates how the identified hazards can be integrated into the modularization method and how risk control measured can be derived. Thereby, four main requirements must be complied with: 1) to be applicable at all stages of development, 2) to increase comprehensiveness and systematics, 3) to be compatible with robot design methods and 4) to be simple to use.

5.1 Comprehensive Identification of Hazards

The risk management process for medical devices defined by ISO 14971:2019 starts with the identification of hazards. According to the standard, a hazard is a potential source of harm. The circumstances leading to harm are hazardous situations. The probability of the occurrence of harm would be a risk. Figure 5.1 provides an overview of how the medical standard complies with the Failure Mode and Effect Analysis (FMEA), which is well established in many companies and institutions, including those in healthcare [Liu et al. 2020]. According to McDermott et al. [2009], an FMEA can either be applied to processes (process FMEA) or the different stages of a product's design (product/ design FMEA). Both have in common to identify failure modes, corresponding causes, potential harm, and safety measures, while quantifying risks with and

without these measures. The probabilities leading to the formulation of a risk refer to the occurrence of a cause, the detection and prevention of an error (failure), and the severity of the effect. In ISO 14971:2019, probabilities are more broadly defined. While regarding the cause of a risk, the FMEA only considers the probability of occurrence, the standard emphasizes that the combined probability of the occurrence of causes and the occurrence of hazardous circumstances leads to a hazardous situation. Since a hazardous situation is a clearly undesired event, it can be seen as an analogy to the failure mode in FMEA. The probability P_2 in the standard refers to the transformation of the hazardous situation into harm. This probability is analogous to that of detecting and preventing a failure. The comparison between ISO 14971:2019 and FMEA aims to show that the terms used in the following address both approaches, although they are taken from the standard.

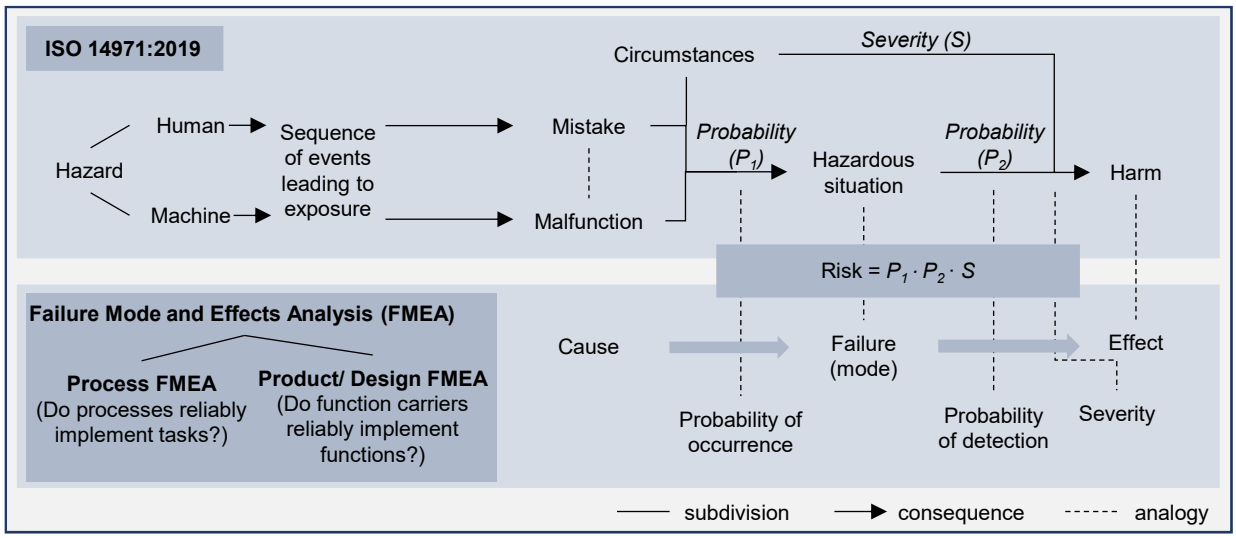


Figure 5.1: Analogies between ISO 14971:2019 and the Failure Mode and Effect Analysis (FMEA)

The basis of all hazard analyses is a process model of how a system works and how it is used. Thereupon, methods are applied to identify malfunctions and failure. A Preliminary Hazard Analysis (PHA) is to be done early in product development. Prominent tools are the FMEA, the Fault Tree Analysis (FTA), and the Hazard and Operability Study (HAZOP). The FTA is deductive in terms of braking down potential failures hierarchically to identify their causes. The FMEA, on the other hand, analyzes faulty behavior inductively so that possible consequential faults can be identified. HAZOP is a procedural approach assuming deviations from an ideal operation that may cause an accident [Grespan et al. 2019]. Guide words are used to describe the directions and extents of these deviations. Variations of methods exist, such as Bow-Tie Analysis (based on FTA) and Hazard Identification Analysis (HAZID, based on HAZOP). Eppinger and Browning [2012] presented the Technical Risk Design Structure Matrix (TR-DSM) as an approach to identify risks and hazards from interactions. For the identification of hazards

in human-machine interactions in medical engineering, Janß [2016] developed the HiFEM method.

No matter which method is used, they all recommend taking different viewpoints to discover as many hazards as possible. Members from different teams are supposed to contribute with viewpoints from different professions, departments, and lifecycle phases. Nevertheless, individual viewpoints are subjective and should be guided by predefined viewpoints integrated in a multi-perspective approach for hazard identification.

Such an approach was presented by Chan et al. [2017] for complex system-of-systems, but would need modifications to be applicable to the high risk context of use of surgical devices. Furthermore, besides looking on local hazards, the viewpoints would have to discover hazards emerging from the combination of tasks [Grespan et al. 2019]. Finally, a comprehensive approach should combine multiple established methods, because methods simplify a complex problem differently [Janß et al. 2016] and leave a gap, as Potts et al. [2014] have shown on two exemplary methods.

5.1.1 Point-of-View Framework

As indicated in the previous chapter, a framework is needed that supports using established methods of hazard analysis. Such a framework should provide the user with different overlapping viewpoints to increase comprehensiveness and guide the hazard identification process. Different possibilities exist from where viewpoints can be derived, as shown in Figure 5.2.

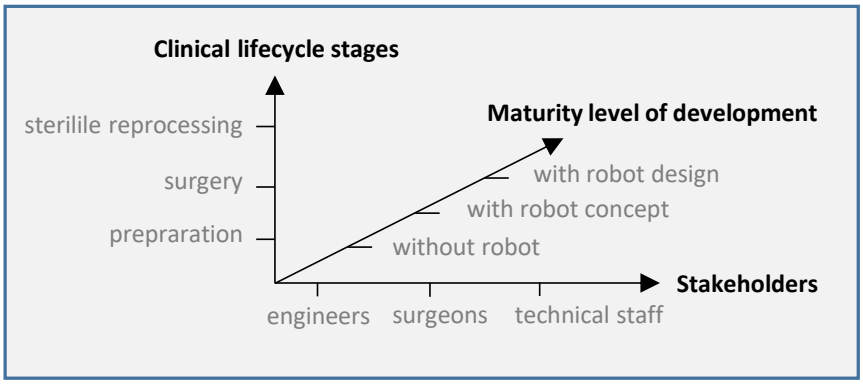


Figure 5.2: Three dimensions that provide different perspectives on a surgical robot in clinical use

Stakeholders can be represented by members of the risk analysis team. Assumingly, clinical lifecycle phases are more familiar to team members than perspectives derived from a robot's stage of development. Perspectives were therefore derived from the latter. Within these perspectives, it is useful to sensitize the user to certain problem areas by asking guiding questions. These can be supplemented by questions on different life cycle phases, so that in the end, all

three dimensions from Figure 5.2 are represented. An overview of the seven Points of Views (PoVs) that will be discussed in the following is shown in Figure 5.3.

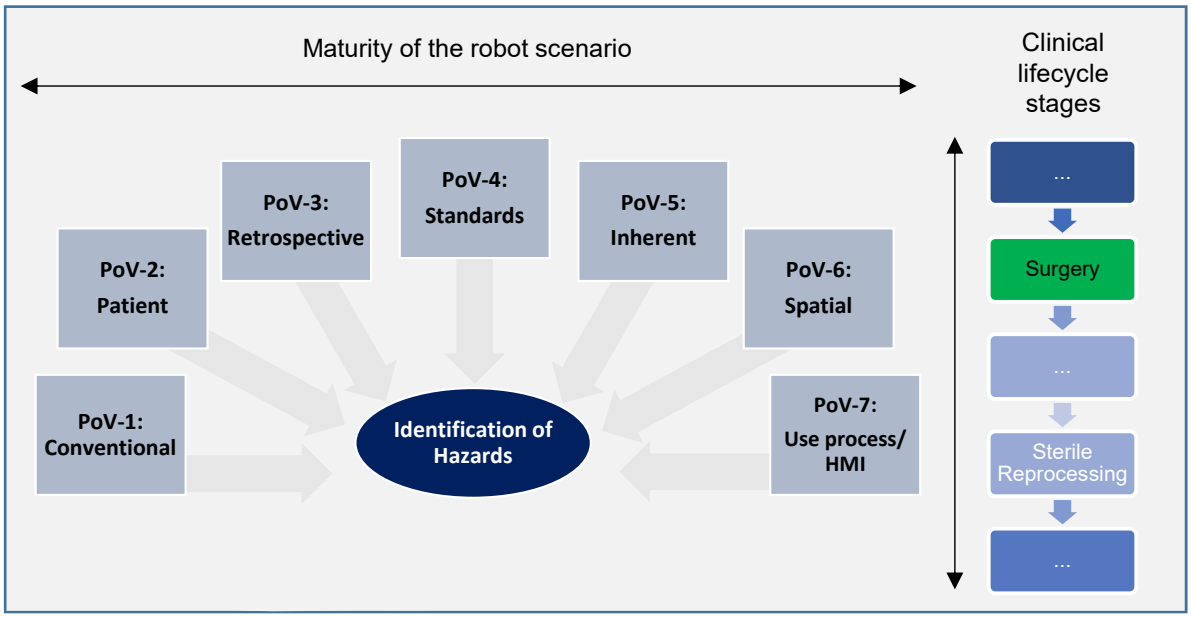


Figure 5.3: The seven Points of View (PoVs) of the scenario-based PoV framework for the comprehensive identification of hazards related to Robot-Assisted Surgery (RAS)

PoV-1: Conventional

The earliest maturity level of surgical robots is before development starts. Thus, PoV-1 is named *conventional* aiming at hazards that occur in conventional techniques for the addressed surgery. Hazards that have been controlled in conventional surgeries should also be controlled in robotically assisted surgeries. In case a Standard Operating Procedure (SOP) or the underlying workflow is based on the prevention of hazards of conventional surgeries, the procedure may need to be critically assessed when using a robotic solution. The following guide questions were derived from literature, open-source videos of surgical procedures, and own field observations:

- How was the surgery done before? Was it done manually, navigated, or already robotically assisted? What reasons led to these approaches? What speaks against it?
- What is dangerous in conventional approaches?
- What can be more dangerous than before if using a robot?
- Should the robot comply with SOPs/ established workflows?
- What would be different to the conventional approaches in other clinical lifecycle stages, e.g., in sterile reprocessing?

PoV-2: Patient

Some hazards can be inherent to the patient and should be considered during the development process of surgical robots. For instance, the bone quality could impact the stability of bone-

mounted robots, be sensitive to the thrust force of a tool, or distort registration [Tsai et al. 2017]. But not only the material, also the morphology of bones can be important. Depending on the region of the surgery, the age of the patient, or the ethnicity, the geometry of the effective surfaces where the tool engages with the bone may vary significantly. For instance, a drill can slip off in case of an irregular bony surface or a large angle between the tool axis and the surface normal [Tsai et al. 2017]. In risk analyses, discussion must be made on:

- Which hazards relate to the age or sex of the patient?
- Are there critical sizes, bone morphology, or surface structures?
- Can the bone quality directly or indirectly impact the result of the surgery?
- Can obesity impact the view to the situs (directly or through images)?
- Can obesity increase the soft-tissue pressure onto the tool and favor deviations?
- What must be considered to ensure biocompatibility and -functionality?
- What are indications for the surgery? Traumas, deformity (e.g., scoliosis), degeneration? If trauma was the indication, surrounding tissue could be damaged, too.
- What hazards can come from the patient that lead to hazardous situations in case of malfunction or failure? For instance, a robot end-effector may have to be quickly removable to treat a sudden bleeding.
- Which patient-related hazards occur during pre- and postoperative treatment or rehabilitation?

PoV-3: Retrospective

In PoV-1 and PoV-2, hazards were derived without thinking of the robot to be developed. In PoV-3, the focus is on surgical robots, but on those with which experience has already been gained. The PoV addresses lessons learned from previous projects and publicly available empirical knowledge from literature and public databases. Exemplary databases are the User Facility Device Experience Database (MAUDE) and the Medical Device Recalls database from the FDA. Guide questions are:

- What are known or documented hazards or malfunctions of systems that address the same use case?
- Are similar systems listed in public or proprietary databases?
- What are own experiences from previous projects?
- Which negative aspects of similar systems are discussed in literature?
- What are the worst risks that occurred with similar systems?
- What are the most frequent risks that occurred with similar systems?

PoV-4: Standards

The more advanced a development is, the more standards the developer must adhere to. Standards that always apply for surgical robots are those for risk management (such as ISO 14971:2019), robotics and surgical devices (such as ISO 10218-1:2012, IEC/ISO 80601-2-77:2019, ISO/TR 15066:2017, IEC 60601-1:2012, IEC/TR 60601-4-1:2017, IEC 62304:2016), and usability engineering (IEC 60601-1-6:2016, IEC 62366:2007). Depending on the sterility measures the robot requires, sterility management standards may become relevant, too (DIN EN 556-1:2006, EN 27740:1992). As mentioned before, relevant standards and regulations, for instance, for machinery (ISO 12100:2010, ISO 13849-1:2015) and collaborative robots (DIN ISO/TS 15066:2017) as well as for medical devices (MDD, MDR), require intrinsic safety by design as a principle to be preferred over other safety measures. Other standards provide further indicators for hazard analysis. ISO 14971:2019, for instance, offers a list of exemplary hazards like kinetic energy of falling objects or moving parts, potential energy for bending procedures or compression, biological hazards through bacteria, fungi, parasites and prions, and many others.

PoV-5: Inherent

PoV-5 refers to the technology that is used for the robot. The PoV addresses hazards that are inherent to mechatronic or robot devices. For instance, a mechatronic device always consists of sensors, processors, and actuators, carried by a (mostly mechanic) frame system. A robot may carry hazards due to its degree of autonomy or the interaction mode. Thus, guide questions, which were mainly identified in a brainstorming workshop, are:

- Which types of energy are needed? Where and how are they converted and which hazards exist?
- Are there hazards based on the possibility of data loss?
- Are there hazards related to control circuits? What are disturbances (e.g., objects obstructing a line-of-site)?
- Do hazards come from dynamics being too fast or too slow?
- Is the system back-drivable and is this an advantage or a disadvantage?
- Could hazards be prevented or risks mitigated if there were redundancies?
- Where are safety-relevant limits and could they be exceeded?
- Do hazards exist because the system is semi-active?
- Do hazards exist because the system is hands-on synergistic?
- Do hazards exist because the system is handheld synergistic?
- Do hazards exist because the system is telemanipulated?

- Can hazards be prevented by changing the degree of autonomy or interaction?

PoV-6: Spatial

With the increased knowledge about the physical appearance of the robot raises the ability to assess spatial hazards. An environmental analysis was conducted for a hypothetical usual operating room with common surrounding devices and persons. Relevant module drivers have been included. These guide questions came up:

- Are there sources of confusion? Are there several similar input devices (e.g., footswitches), which are difficult to reach or likely to be confused?
- Is there the possibility that moving parts of the robot collide with each other (internal collisions)?
- Is there the possibility that the robot collides with surrounding systems or bystanders (external collisions)?
- Are there restrictions coming from the system, for instance, regarding line-of-sights, accesses to the situs, reachability, and range of motion of kinematics?
- Are energy emissions a hazard? Are threshold values exceeded, for instance, regarding radiation, heat, or electromagnetic energy?
- Are spaces shared? Do different systems or persons need the same space at the same time (simultaneously shared spaces)? Must systems be removed because other systems or persons need the space afterwards (sequentially shared spaces)?
- Are there spatial conflicts in other clinical lifecycle stages? Is the system supposed to be moved between ORs? What are hazards related to the required mobility of the systems?

PoV-7: Human-machine interaction

In 2016, Janß [2016] developed the HiFEM method as a tool to identify hazards corresponding to the interaction between human and machine. The method groups all hazards into the categories: perception, cognition, action, and system response. In order to identify hazards of human-machine interaction, the HiFEM method should be applied to all relevant clinical lifecycle stages, like pre-surgical assembly, post-surgical disassembly, surgery and sterile reprocessing. For instance, components with sharp edges that must be manually cleaned in the central sterile services department (CSSD) of a hospital provide the hazard of harming and infect the technical staff. Generic guide questions referring to assembly tasks (in surgery or sterile reprocessing) are:

- Is there the possibility that wrong parts can be combined?
- Is there the possibility that mating parts can be mounted incorrectly?

- Is there feedback for correct fixation?
- Is there any ambiguity regarding mating parts and the positions these parts can be combined?

5.1.2 Use Case Example

ROSA ONE, ExcelsiusGPS, Mazor X, Renaissance, Cirq, and the Smart Screwdriver system are used for pedicle screw placement. Pedicle screw placement is required for spinal fusion. Spinal fusion means the fixation of vertebrae to each other. Physiologically, vertebrae are separated by elastic intervertebral discs, which enable relative motion between them. Some indications require to remove a disc, for instance, if the disc is herniated and painfully presses against the spinal cord or branching nerve roots. Spinal fusion involves inserting pedicle screws into the pedicles of adjacent vertebrae and connecting them with rods.

A neurosurgeon was interviewed to identify surgical procedures that are often performed in conjunction with spinal fusion. Accordingly, spinal fusion is often combined with spinal decompression. In spinal decompression, the lamina is opened to perform a discectomy, insert a cage, or perform a microdecrompression. Laminotomy refers to the removal of a portion of the lamina whereas a laminectomy is the complete separation of the lamina in cranial-caudal direction on both sides of the spinous process. A hemilaminectomy describes a unilateral separation of the lamina. A hemilaminotomy, on the other hand, refers to the removal of the unilateral portions of two adjacent hemilaminae. Associated ligaments have been neglected here. When decompressing the cervical spine, (hemi-) laminectomy or laminotomy can be part of a laminoplasty. In a laminoplasty, the spinal canal is widened by cutting the lamina, which is hinged open and then rejoined by implants. Three techniques of laminoplasty are distinguished: open-door (or single door) laminoplasty, French-door (or midline) laminoplasty and the z-plasty. [Ars Neurochirurgica 2022; Güler et al. 2020; Patel et al. 2002; Drumm et al. 2010]

Since the stabilization of the spine requires spinal fusion, which is usually not needed in laminotomy, spinal fusion tends to be combined with laminectomy. For this reason, and due to the fact that surgical robots can already assist spinal fusion but not laminectomy, laminectomy was chosen as a use case example.

133 different hazards were identified with the PoV framework, associated to 108 different hazardous situations. The distribution of hazards among the PoVs is shown in Figure 5.4. 34 hazards were found with PoV-1, 10 with PoV-2, 36 with PoV-3, four with PoV-4, 34 with PoV-5,

12 with PoV-6, and 40 with PoV-7. 26 Hazards of PoV-3 were found in literature, 10 in the recalls database, and none in the MAUDE database.

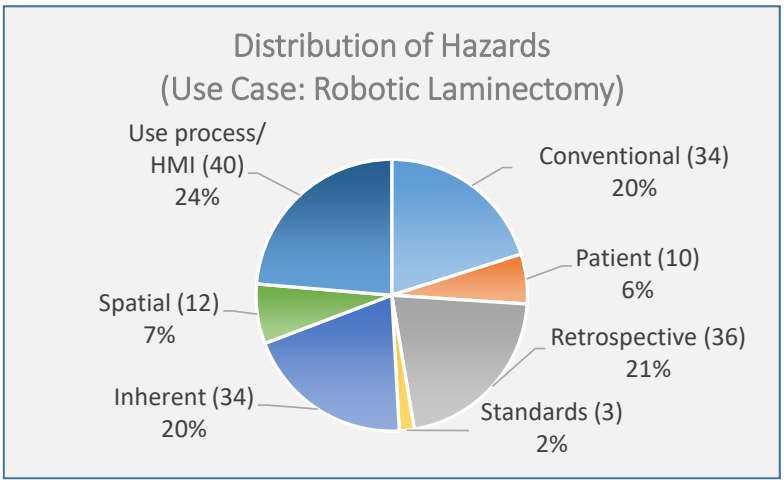
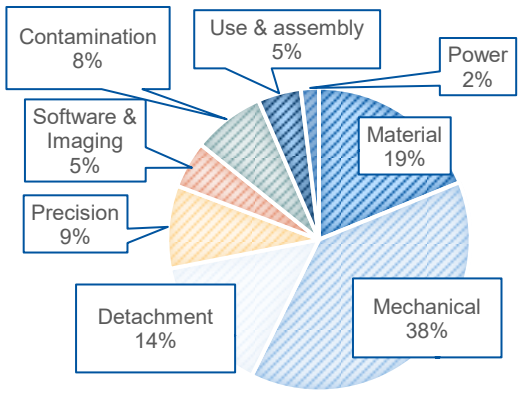


Figure 5.4: Distribution of identified hazards among the points of view (PoVs)

Although the MAUDE database did not deliver hazards specific to laminectomy, generic hazards could be identified. After analyzing the database for OLO over the last 500 entries (until 01/01/2020), 330 (66%) could be assigned to robotic systems. The entries range from 08/2017 to 12/2019. Named robots were Mazor X, ROSA Spine, ROSA Brain, Navio and MAKO (sometimes referred to as RIO, the former version). Figure 5.5 shows the results for the robotic systems. The failure descriptions were too generic to derive concrete hazards. Nevertheless, eight categories of failures have been defined based on keywords that appeared in the descriptions. *Mechanical* includes the failures that contain at least one of the keywords *fracture*, *break*, *crack*, or *mechanical*. *Precision* comprises *inaccuracy* and *positioning error*.

MAUDE Database
(last 500 entries with OLO until 01/2020, only robots (66%))



MAUDE Database
(last 500 entries of robot until 01/2020)

Robot	Mazor X	ROSA Spine	ROSA Brain	NAVIO	MAKO
Manufacturer	Medtronic	Zimmer Biomet		Smith & Nephew	Stryker
Event Type					
Malfunction	28 (60%)	52 (70%)	> 500	60 (61%)	78 (41%)
Injury	19 (40%)	22 (30%)	110	38 (39%)	114 (59%)
Death	0	0	1	0	0
Total	47	74	> 611	98	192

Figure 5.5: Failure categories and consequences of robots of the category OLO according to the MAUDE database; OLO= Stereotaxic Instrument (Orthopedic)

The analysis of the Medical Device Recalls database for systems of the product code OLO yielded 62 hits, of which 24 (39%) were attributable to the MAKO systems. Other robots represented were Navio, Mazor X, ROSA Spine, TCAT, Cirq, and OMNIBotics. Each of the aforementioned systems accounted for less than 5%. Except for one Class 3 entry (lowest risk), all recalls were Class 2.

5.2 Structuration of Hazards

The PoV framework aimed at identifying hazards. Classical risk analysis methods, such as FMEA, for which the PoV framework is intended to provide a framework, include risk analysis, and enable the derivation of risk control measures. There are various software solutions on the market that facilitate the processes of hazard analysis, and risk assessment while also capturing control measures. However, to be able to use hazards, risks, and countermeasures most effectively for the modularization of surgical robots, it would be useful to store the results of risk analysis tools in a database linked to the modularization method. Such a database should have a structure that encourages the user to consider safety measures for all three safety levels with respect to a particular risk or hazard, so that these can be checked for feasibility in a defined order. The aim must always be to implement the highest safety level, level 1. Only if this is not possible, level 2 and then level 3 should be aimed for. The three safety levels according to Directive 2006/42/EC (machinery directive), MDD, MDR, and ISO 14971:2019 are:

- Level 1: direct safety (also referred to as inherent or intrinsic safety): choosing a solution that precludes danger from the outset by design
- Level 2: indirect safety: choosing solutions that provide protective measures
- Level 3: warnings (also referred to as descriptive safety): point out dangers and indicate danger areas, can be used to support direct and indirect safety measures

When searching for safety measures, the structure of the database should help to distinguish between measures relating to modularity and others. If safety can be increased through modularity measures, the database should provide the possibility to formulate associated module drivers.

Hazards, unlike risks, can be independent from the use case. For instance, a sharp cutting edge is a sharp edge in any use case and therefore a hazard. Only the use context defines the risk. Accordingly, a database for archiving hazards could serve as a hazard reminder for later developments. Accessing hazards listed in a database corresponds to PoV-3 of the PoV framework.

The reuse of recurring hazards could be simplified by using suitable classifications. Furthermore, hazards can be principle-dependent. Then they would be assignable to a certain solution principle and could be considered in a computer-based approach already during concept development. For instance, sharp edges are hazards associated to the principle of cutting. If the function is to separate something, cutting would be a principle solution but also tearing. Tearing may come with other specific hazards but not with hazards of sharp edges.

In the following, a database is developed complying with the conclusions of the previous sections. This database is named Catalogue of Hazards (CoH). The structure of the CoH is designed to serve the PoV framework. To be generic and reusable for other developments, the CoH aims to only capture hazards, which must be transferred to risks by means of a case-specific risk analysis. In contrast to FMEA, where cause, failure and countermeasure focus on a certain level of consideration (e.g., assembly), the CoH should trace back any hazardous situation to original hazards, which are inherently linked to functions or technical solution principles.

As a first step, categories were defined to ease application. For classification, the definition of *hazard* (potential source of harm) by ISO 14971:2019 resulted to be too fuzzy as hazards can be ambiguous. For instance, two persons could describe the same hazard with different words and not see the commonality. The same hazard would then appear twice in the CoH. Furthermore, a consequence of a hazard could be misinterpreted as a hazard while overlooking the actual underlying hazard. Accordingly, a derived safety measure would address the consequence of a hazard and not the cause.

As a solution, three auxiliary definitions are used: the hazard object (who or what is directly affected by the hazard, HO), the hazard carrier (who or what carries the hazard, HC) and the hazardous property (HP) of the carrier. For instance, a *worn burr* can be seen as a hazard according to ISO 14971:2019, but also *blunt blades.* The latter contains more information and emphasizes that every tool with blunt blades carries the regarded hazard. By encouraging the user to first define an HC (blade) and then the HP (blunt), specificity is increased. Consequently, the HP is extendable to other HCs as it becomes more independent from the device it is used in. *Blunt blades* is a hazard of burrs, drills, saws, and other principles of mechanical cutting. The simple distribution of a hazard into object, subject (carrier), and property also facilitates the projection of archived hazards onto new developments and linking them with technical design principles. Another benefit is the possibility to systematically analyze the CoH by filtering, sorting, categorizing, and refining causes, consequences, and affected persons or objects. Figure 5.6 highlights the role of the CoH and the PoV framework in the context of ISO 14971:2019.

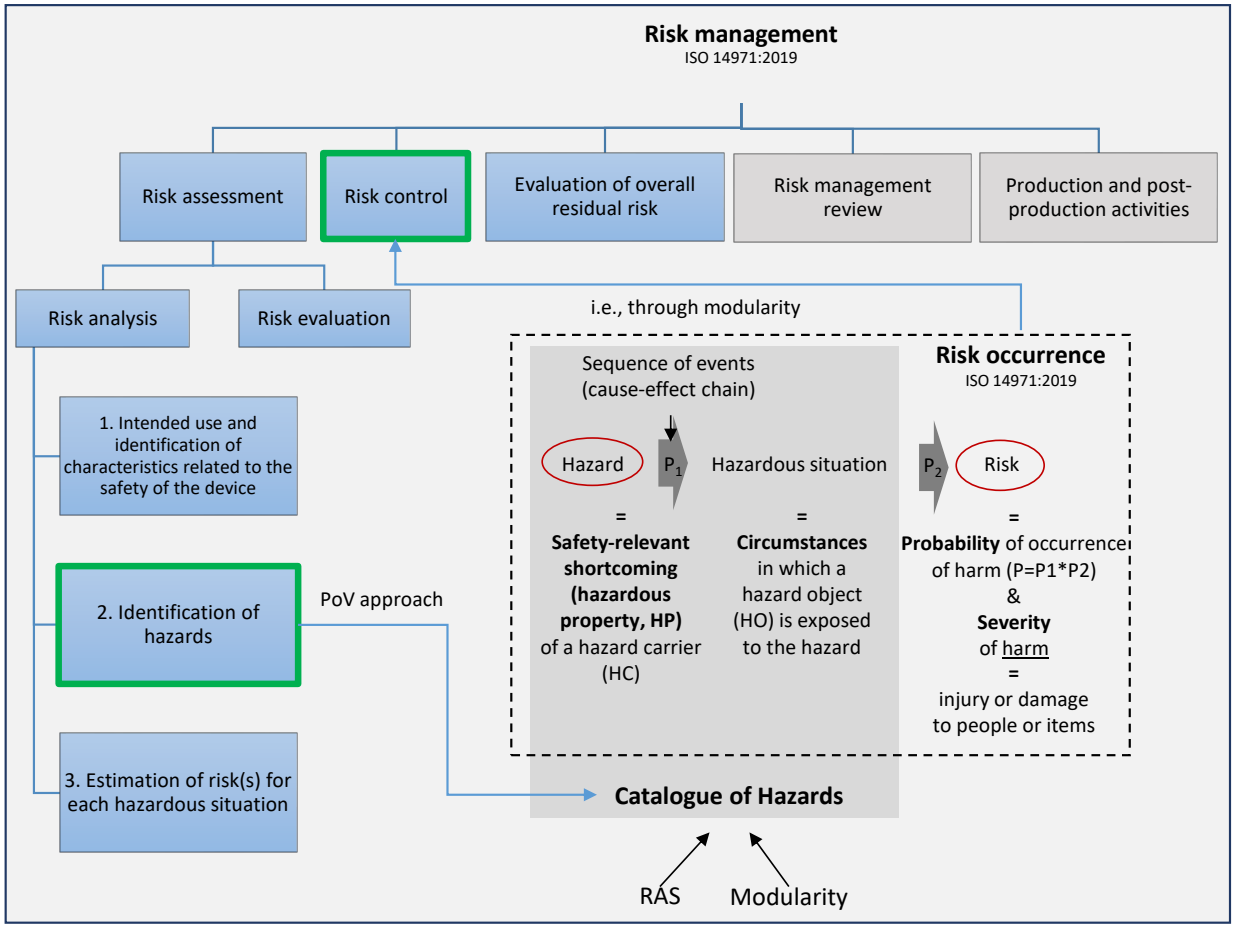


Figure 5.6: Role of the Point-of-View (PoV) framework and the Catalogue of Hazards (CoH) in the context of ISO 14971:2019; RAS= Robot-Assisted Surgery

In many cases of hazard analyses, not hazards but harm and hazardous situations are identified. As a response, the CoH connects hazards with hazardous situations by going backwards a chain of actions or states that happen sequentially from hazard to hazardous situation. As the aim was to identify hazards and not resulting situations, it is not important in the first place if the hazardous situations are specific or ambiguous. On the contrary, the possibility to start with different and subjective inputs to result into a specific but widely suitable hazard, eases the use of the CoH.

However, through the concretization and systematization of hazards, other associated aspects can be integrated into the CoH and increase analyzability. Thus, hazards can be linked directly to the underlying detection method (e.g., brainstorming, HiFEM), because thereby the method can be evaluated and improved at any time. In accordance with the HiFEM method, the CoH provides the possibility to link each hazard with one of the four categories *system*, *perception, cognition,* or *action*. Furthermore, the type of socio-technical safety measures and lessons-learned can be linked to a hazard. Also, the user-interaction scenario and the degree of autonomy could be linked to associated hazards. Nevertheless, the overhead should be as little as

possible when cataloguing hazards. Therefore, these presented associated aspects are supposed to be optional input parameters, which can be filled-in any time after hazard identification. Figure 5.7 shows the layout of the CoH with an exemplary hazard. Since the number and selection of optional categories depends on many factors, only the mandatory fields are shown.

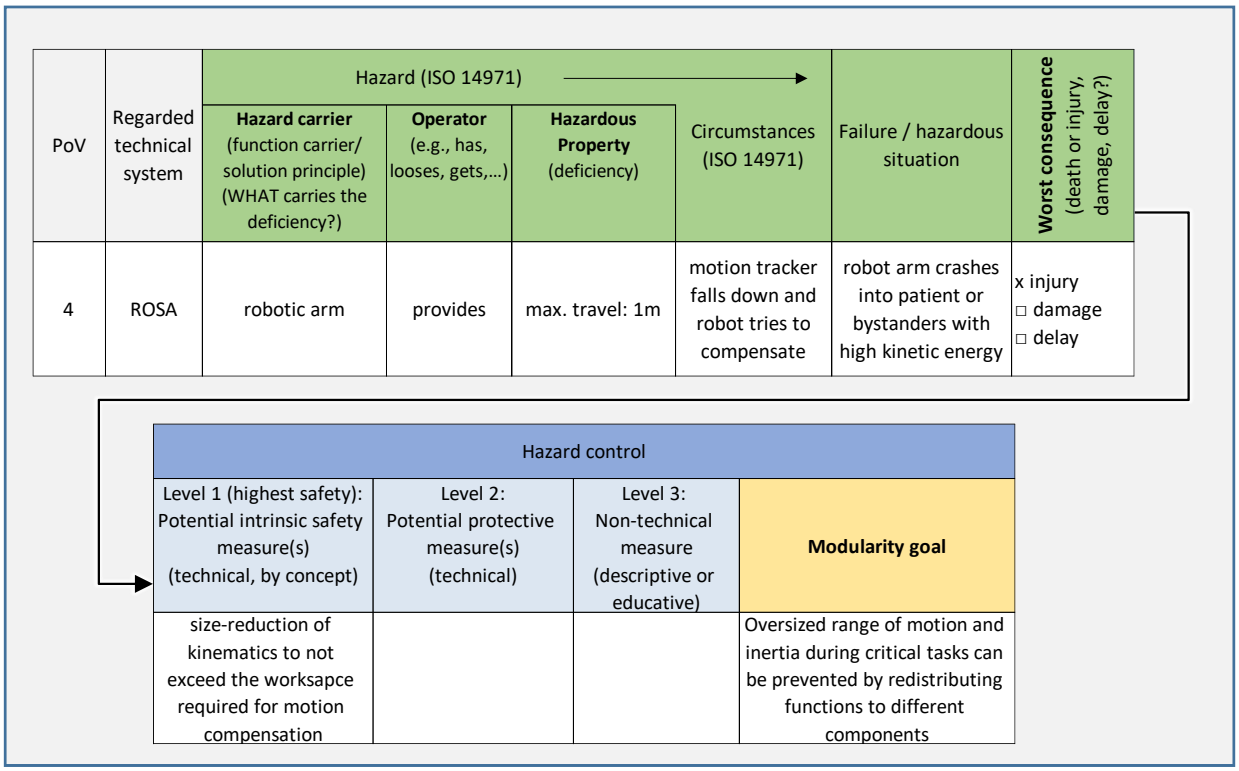


Figure 5.7: Structure of the Catalogue of Hazards (without optional categories)

Here, PoV-4: *Standards* is listed as the PoV that led to the detection of the failure, although PoV-3: *Retrospective* or PoV-5: *Inherent* may have led to the same. When using the PoV framework for the ROSA robots and reading *kinetic energy* as source of failure in the ISO 14971:2019, the first thought might address the hazardous situation: the robot arm could crash into the patient or bystanders with high kinetic energy in case of malfunction. Hazard carriers are oversized motors but also oversized structural elements that leverage forces, speed, and distance. Thus, one hazard is the oversize of segments of the robotic arm. In this case, the robotic arm is the hazard carrier. It would be a solution to further divide the robotic arm. However, in the case of ROSA, the arm was bought as a whole from Stäubli International AG, Pfäffikon, CH. Furthermore, the criticality of the oversized arm as a hazard carrier depends on the criticality of tasks it is used for. Under this aspect, another solution might be to distribute critical tasks to different, maybe additional, components. On the whole, the hazardous property is a specification of the robotic arm, which only leads to a hazardous situation if, for instance, the motion tracker falls down and the robot tries to compensate this. There can be more than these circumstances,

which would lead to different risks. Thus, computer-assistance would be highly beneficial to capture several hazardous situations while keeping the application simple for the user.

In the beginning of Chapter 5, four main requirements for the CoH and PoV framework have been defined. The first requirement, applicability at all stages of development, is guaranteed because of the pre-defined PoVs. While for PoV-1 and PoV-2 the robotic concept can be unknown, it becomes more relevant in PoV-3 to PoV-6. Eventually in PoV-7, a concrete user-interaction scenario with the specific concept or even prototype must be assumed. With goal-oriented scenarios that are independent from predecessors, predicate creep is prevented systematically.

Comprehensiveness is increased (requirement 2) since PoVs overlap and hazards of the use case laminectomy appeared redundantly. For instance, in PoV-1 the loose fixation of an instrument or tracking array was detected as a hazard already occurring in conventional surgery. In PoV-3, the same hazard appeared as it was reported for robotic applications. Although hazards could not be derived from the MAUDE database, mechanical issues have been identified as important. Finally, the PoV framework supports the consideration of inner (inherent to the system), outer (environment and stakeholders), and historical (state-of-development, experiences) factors.

The third aspect, simple to use, was considered acceptable by the author but must be evaluated with groups of representative users in the future. User satisfaction is highly depending on the design of the user interface, which has not been implemented, yet.

The fourth requirement, compatibility with design methods, is given, since the division of hazards into HS, HO and HP enables the objective assignment of hazards to technical functions and solution principles or concepts. Furthermore, technical solutions in terms of countermeasures could be integrated into the catalogue as well as classifications of hazardous situations into technical and human-induced situations.

5.3 Integration into the Modularization Process

Based on the proposed modularization method for RAS (Chapter 4) and the developed structure for preparing hazards for the integration into the modularization method (Chapter 5.2), Figure 5.8 presents a process model of how modularization and risk analysis should be applied while developing a surgical robot.

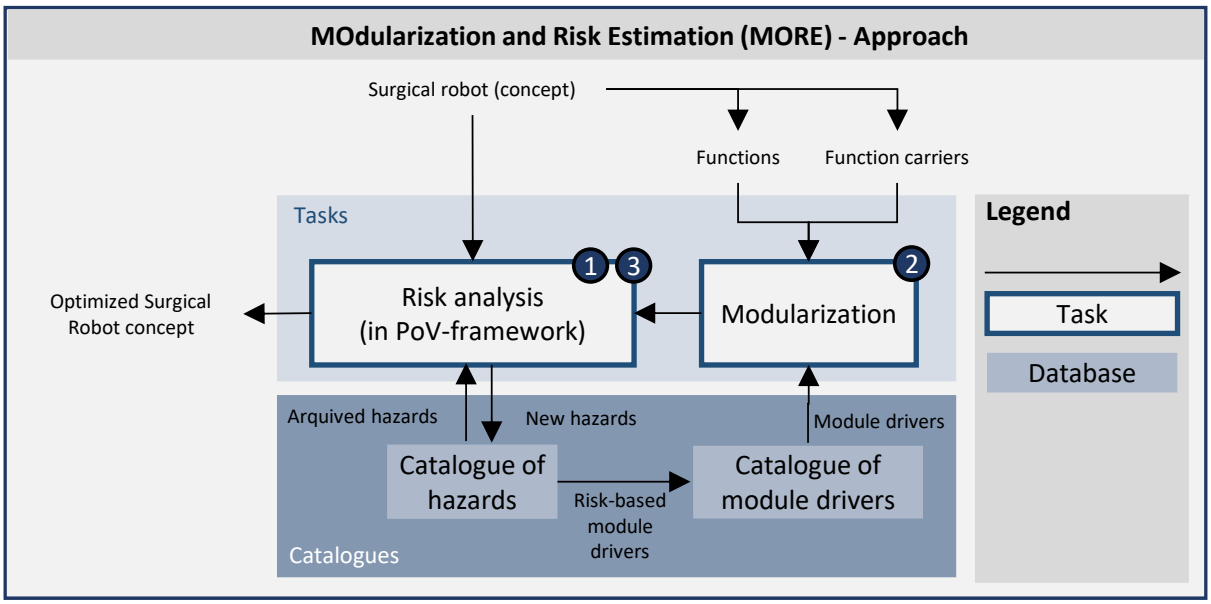


Figure 5.8: Integration of risk analysis into the modularization method; PoV= Point of View; 1,2,3: order of execution

As a basis, a surgical robot concept must be determined. This can be developed, for instance, according to the product creation process (VDI 2221:2019), the V-model (VDI 2206:2004, VDI/ VDE 2206:2021) or abstracted from an existing product applying functional analysis (VDI 2803:2019-01). Functional analysis, sometimes referred to as *reverse engineering*, basically means that the functions of a system are identified and associated to parts of the system. These parts are then the function carriers (see Chapter 6.1).

The first step of the Modularization and Risk Estimation (MORE) approach is an initial risk analysis. For this risk analysis, the most advanced development stage must be used because the more details are known about the robot, the more hazards can be identified. Identified hazards can be archived in the CoH and already archived hazards can be used for the current risk analysis, as part of PoV-3: *Retrospective*. When all hazards are identified, a risk analysis is conducted. Safety measures are derived, and new module drivers are formulated, if possible. Then, in step 2, the concept of the robot can be revised applying the modularization method. Since module operators address physical components as well as functions (Chapter 4.1), functions and associated function carriers are important inputs, besides the module drivers as evaluation criteria. After applying module operators to modify the modular layout of the robot concept, additional modularity-based risks may occur. Thus, another risk estimation must be done (step 3). To increase user acceptance, a streamlined approach could be to first do the modularization and then the risk analysis, if the implementation of the modularization method allows for defining new module drivers during modularization and guides the user towards the consideration of hazard-based module drivers.

The MORE approach would be most beneficial if it were computer-assisted, as indicated in Chapter 3.4. Properties of function carriers could be used for automated comparison with quantified use case requirements. Thereby, rule-based evaluations could run in the background showing the user the suitability of module candidates regarding module drivers. At the same time, he or she could autonomously assess the suitability of module drivers (Chapter 4.4) regarding emergent effects (Chapter 2.2), which cannot be calculated automatically. Additionally, complicated interrelations between function carriers, requirements, module drivers, and hazards could be provided to the user by means of user-specific views (according to MBSE, Chapter 3.3), which could also ease the weighting process of module drivers. In Chapter 6, the foundation is made for computer assistance.

6. Computer-Assisted Modularization

In software engineering and systems engineering, the term *system architecture* covers all structural relationships within a system and to its environment (ISO/IEC/IEEE 42010:2011). In design theory, the functional architecture of a system represents functional relations, sometimes called functional structure. The term product architecture is used when functional and physical relationships (product structure) are mapped to each other [Krause et al. 2021].

For a variety of different surgical robots, which share the common purpose of performing a surgical procedure, a solution-neutral functional description can be found on an abstract level, as shown in Chapter 1. Accordingly, functions can be seen as the least common denominator of systems by describing different solutions for the same purpose. On the other hand, functions combine functional requirements with technical solutions. Assuming that reference functions can be used and specified to various surgical use cases, these reference functions can serve as a template to compare use case requirements to technical solution candidates archived in a database. An RAM could be created based on reference functions enabling traceable and rule-based computer assistance during system development (Chapter 3.4). The basic idea of specifying use case functions from reference functions is illustrated in Figure 6.1.

Reference	Specification	Example
Function (What must be done?)		
Reference Function (RefFun)		*Create implant bed*
	Specified Function (SpFun) = RefFun + ∑ Use case parameters (UCPar)	*Create a hole with a length of 10mm and a diameter of 3mm beginning at...*

Figure 6.1: Specification of a reference functions according to use case parameters

The aim of this chapter is to elaborate the foundation for a generic RAM from which modular surgical robots can be derived. First, a SysML-compliant structural framework is elaborated comprising basic elements and structural relations. Therein, reference functions are included as the least common denominator of surgical robots. In Chapter 6.2 an approach is presented of how the established reference architecture can be specified to use cases and conclusions are drawn.

6.1 Structural Framework

In Chapter 3.3, MBSE and SysML were introduced as a generic and widely used modelling approach and language for mechatronic systems. Since a method or model is only as good as it can be applied, the reference system architecture should be embeddable in existing computer-based modelling environments. The description of the RAM with SysML allows the implementation of the model by any kind of software.

SysML provides *Block Definition Diagrams* (BDD), which are useful for describing the structural relationships of a system, for instance, by representing a **system architecture** in a particular view. Relevant elements of a block definition diagram are presented in Table 6.1.

Table 6.1: Relevant elements of a Block Definition Diagram based on Weilkiens et al. [2015]

Model Element	Explanation
Block	defines the structure of things that share the same characteristics and semantics
Activity	defines the behavior of things that share the same characteristics and semantics
Value Type	defines a SysML quantity, expressed as a measurable dimension with specific units
Property	defines a structural feature of a block or value type
Value Property	property of the type *value*
Instance Specification	specifies a concrete object based on the blueprint specified by the block or value type
Composition (= part association)	structural decomposition in which the end cannot exist without the start
Aggregation (= shared association)	structural decomposition in which the end can exist without the start
Generalization	the specialized element inherits all features of the general element
Containment	the source element contains the target element
Allocation <<allocate>>	mechanism for associating elements of different types, or in different hierarchies, at an abstract level

Weilkiens et al. [2015] suggested to model functions in SysML notation as *block* and not as *activity,* which would either describe a system's behavior. According to Weilkiens [2020], a block defines the structure of things that share the same characteristics and semantics. A compliant SysML block notation for reference functions is shown by Figure 6.2.

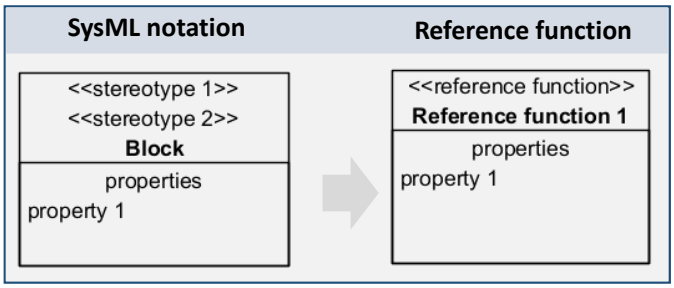


Figure 6.2: SysML block notation used to present a reference function; SysML= Systems Modeling Language

Stereotypes can be used to mark the block element as a function. Weilkiens et al. [2015], for instance, declared functional blocks with the stereotype <<functionalBlock>> in his SysML-based FAS method. In the case of the RAM, the stereotype <<reference function>> seems to

be appropriate to mark this. Stereotypes, and also associations between blocks, can further be used to represent a technical solution, as done by Gehrke [2005].

Figure 6.2 also illustrates the possibility to characterize block elements through *properties*. Some researchers differentiate between *parameters* and *properties* of design solutions to distinguish between attributes that are directly determined by the engineer (e.g., color, material, dimensions) and those that indirectly result from the engineering process, such as weight, ease-of-use and costs [Baldwin and Clark 2000; Bauer and Meerkamm 2007; Weber and Werner 2001]. However, in the SysML standard, this differentiation is not made and not needed for modularization. In the following, the terms *use case parameter* and *solution property* are used to specify requirements and describe potential solutions, respectively.

A technical solution describes a function through its technical specification, the properties. However, different levels of abstraction exist. For instance, a motion function can be solved by using serial kinematics or parallel kinematics. Both solutions have different properties and can be compared and evaluated. Although, these solutions are very abstract since they provide no concrete physical representation. Even a more detailed description through categories, which compares, for instance, anthropomorphic arms and SCARA arms as representatives of serial kinematics, does not provide a physical product. Consequently, the most detailed description of a technical solution would be a physical product, such as the Stäubli TX2-60 from Stäubli International AG, Pfäffikon, CH. Thus, in the solution space, the different levels of abstractions can range from physical effects to off-the-shelf products, as shown in Figure 6.3. This hierarchical decomposition of the solution space supports innovation. The solution space can be augmented by varying characteristic or non-characteristic properties of a solution, which is based on the method of systematic variation with classification schemes [Pahl et al. 2007; Dreibholz 1975]. If properties are varied that are characteristic for the solution, a new class or stereotype may be defined. For instance, electric power supply is characteristic for a DC motor. When hydraulic motors are added to the solution space, the categories *electric energy* and *hydraulic energy* can be formulated to enable comparison on a more abstract level. A non-characteristic property, for instance, is the remote center of motion, which can exist in serial and parallel kinematics.

In Pahl et al. [2007], Feldhusen and Grote [2013], and Bender and Gericke [2021], physical components and assemblies that implement a function are named *function carriers*. The authors use the similar expression *effect carrier* to describe only the material that carries a physical effect. Although not using the term *function carrier,* also Koller [1998] describes an *effect carrier* as either a material, which can be solid or fluid, or space in terms of vacuum, as a carrier for magnetic or electric fields. Being compliant with literature, the term *function carrier* is used to

describe a physical representation of technical solutions in this work. A *working principle* [Pahl et al. 2007] is determined by a physical effect, an effect carrier and the geometric description of the working location. The combination of working principles is called working structure or solution principle in Bender and Gericke [2021]. Koller [1998], on the other hand, used the term *solution principle* to describe a *working principle.* He further specified that a *physical* effect can be physical, chemical, or biological. It can be assumed that *working effect* would be a better expression but since *physical effect* is an established expression, it is not changed in this work.

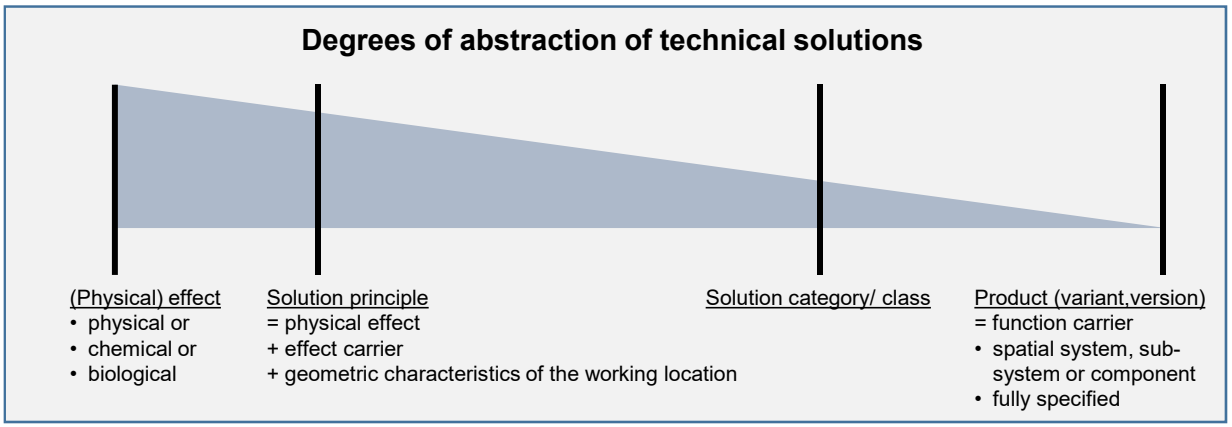


Figure 6.3: Degrees of abstraction of technical solutions

In a RAM that models different levels of abstraction, the conceptual pre-development and evaluation between different technologies could be done as well as the development of concrete products. In a SysML-based model, categories of function carriers can be seen as classes while properties of classes could be inherited to more detailed function carriers. For instance, the Stäubli TX2-60 could be a function carrier of the class *serial kinematics* but also of the class *off-the-shelf product* or *mechatronic device*.

Inheritance would be useful to give specialized solutions the same properties as their abstracted parents. For instance, kinematic mechanisms always possess the properties *number of DoF* and *size of workspace* and could inherit those to their specifications. Through multiple inheritances, a solution could be assigned to several stereotypes and inherit properties from different parents. An anthropomorphic arm that uses snap-in brakes could inherit the property *DoF* from the stereotype *kinematics* and the property *angular resolution* from the stereotype *form-closure.* Also, it may be beneficial to add human-based solutions, which exploit the capabilities of human beings or new solutions in general. In the following, the term *socio-technical solutions* is used as an umbrella term for technical and human-based solutions.

In the context of model-based system architectures, Weilkiens et al. [2015] discovered a phenomenon called *zigzag pattern*. The effect describes the mapping of functions to solutions that

require auxiliary functions, which must be solved by other solutions themselves. Concluding, there cannot be a purely functional structure that is mapped to a purely physical product structure on the highest level of detail. Since most of technical solutions require auxiliary functions, there will be a zigzag pattern between both structures. For instance, if an automated holding arm with electromagnetic brakes is used to carry a surgical device instead of being carried by the surgeon or a passive arm, electric energy is needed as an input for the function *provide energy for actuation* or the like. This function is an auxiliary function since the function would not be needed if the solution principle was different. As a conclusion, the RAM should not be built up from two separate models of reference function structure and technical solution structure but rather as a single structural model that starts with reference functions and a database of technical solutions assigned to the reference functions through corresponding stereotypes. For use case specification, a specific system architecture can be modelled having zigzag patterns between technical solutions and auxiliary functions.

A block can carry properties, including value properties. According to Weilkiens [2006], a value property consists of a unit (e.g., kilogram) and a quantity kind (e.g., mass) and can be classified by the stereotype <<valueType>>, as shown in Figure 6.4. Since stereotypes cannot inherit properties in SysML, the relationship *generalization* is used to inherit between two blocks (Table 6.1). This is useful to inherit properties of solution categories to subordinate solutions. For example, the value *DoF* and the property *kinetic energy* are inherited from *kinematics* to *serial kinematics* through a generalization relationship. This example illustrates, that also hazardous properties (see Chapter 5.2) could be shared among solutions. Other types of relations, such as *aggregation* or *composition* may be used alternatively (compare Table 6.1). For the structural decomposition of functions, the relation *containment* was used to illustrate that, for example, function F3 contains function F3.1 and others.

The blocks of reference functions and solutions shown in Figure 6.4 are templates from which concrete instance specifications can be derived. Only instances allow to give values to the deposited properties. By linking several classes with the instance, the instance receives the properties belonging to the classes.

In the function space, the instance of a reference function would be the function specified to the use case. In the solution space, the most concrete form of an instance would be a physical product. Properties that always need to be associated with a physical product, such as *acquisition costs* and *manufacturer*, have been grouped together in the block *product*. Similarly, this can be done for deriving specific functions (instances) from reference functions. Another alternative is to assign properties to individual reference functions and then inherit them. Since

no accompanying software is developed in this thesis, the various modelling options will not be discussed further. In this chapter, only the ability to model with SysML is described to illustrate the prospective added value of software support.

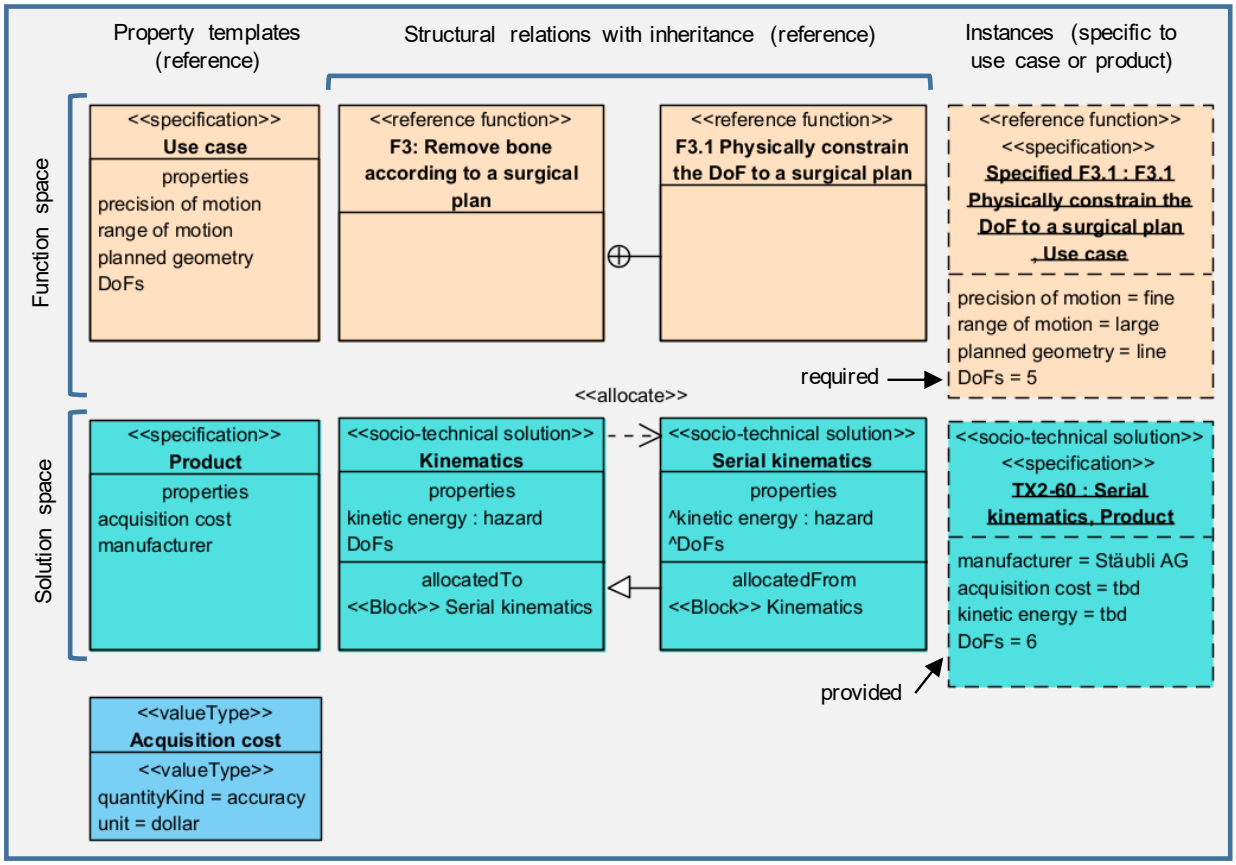


Figure 6.4: Potential structural elements and relations of a reference architecture model for surgical robots; DoF= Degree of Freedom, tbd= to be defined

6.2 Procedural Approach

After the modularization method has been developed in Chapter 4, which has been supplemented by safety-enhancing module drivers in Chapter 5, and structural principles for computer assistance in Chapter 6.1, this chapter focuses on describing the logic of using the model for a specific use case. Figure 6.5 shows the basic process model.

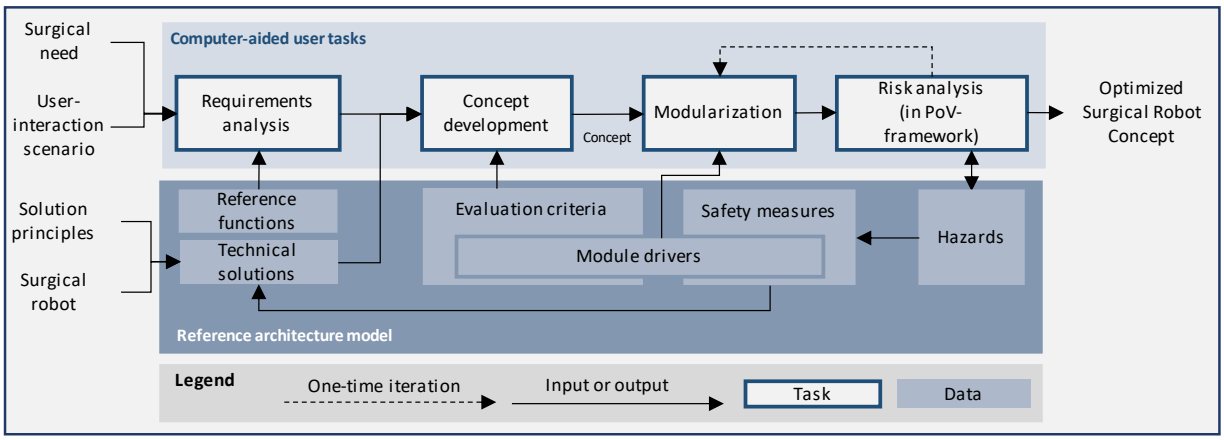


Figure 6.5: Process model for the derivation of use case specific solutions using computer assistance; PoV= Point of View

Use case specification basically means that a user-friendly graphical user interface must query the values for all properties of the functions that must be specified to the use case. Furthermore, a workflow or user interaction scenario must be defined. This shall be illustrated on the example of pedicle screw placement. In the case of current, mostly semi-active surgical robots, a drill sleeve is first placed automatically, through which the surgeon drills the holes and places the screws. The insertion of K-wires (e.g., ROSA ONE) already represents a different workflow than the direct insertion of screws (e.g., ExcelsiusGPS). Hands-on (synergistic) robotic drilling would be another and novel workflow. The solution space of the robot-assistant system to be developed is therefore not only composed of technical principles, but also of principles of user interaction. Thus, it is not sufficient to only find a technical solution for pre-defined functions or to only consider technical functions. An optimal interaction scenario must also be found. In a computer-assisted model, compatibility matrices could enable the parallel finding of an interaction scenario and a suitable technical concept. Without computer assistance, an iterative approach would have to be taken and an optimal workflow would have to be found first. Both topics are beyond the scope of this thesis. Reference is made to the surgical process modelling approach by Neumuth [2017].

Assuming that a semi-active approach is to be pursued by means of a guide sleeve for setting pedicle screws, an exemplary query to the user could include the following questions:

1. Which planning-specific tasks must be performed?
2. How many DoFs are required for this?
3. Which DoFs must be controlled simultaneously, and which can be controlled consecutively?
4. Which DoFs require the prior locking of which other DoFs?

5. What is the criticality of harming sensitive tissue (e.g., cardiovascular/ central nervous system)?

Targeted questions like these increase safety and drive innovation because, as in the SSD system, sequential actuation of DoFs is considered, which otherwise might have been disregarded. On the other hand, solutions that cannot provide simultaneous actuation of a demanded number of DoFs are not considered for tasks requiring this, such as burring tasks.

Besides knockout criteria, which exclude or include solutions to the use case solution space, evaluation criteria can be formulated. Knockout criteria can be seen as functionality acceptance criteria (FAC) because they guarantee that functional requirements are met. Evaluation criteria, on the other hand, can be seen as strategy acceptance criteria (SAC), comprising those that refer to the modularity of a system (module drivers), and others (as indicated in Figure 6.5). Also safety measures can be SAC. In Chapter 4.2.2, MD-33 and MD-34 favor a modularity that increases kinematic safety by decreasing the ratios of workspaces and possible kinetic energy. The possible kinetic energy could be reduced, for instance, by using lightweight structures with lower mass inertia. A threshold mass could be defined based on studies or evaluation workshops. The acceptance criteria shown in Equation (6.1) and Equation (6.2) could be defined from the pre-defined properties of the function and solution space of the RAM. The criteria assume that an oversize of 100 and 50 were acceptable for the required workspace and threshold mass.

$$risk_{oversize} = \frac{workspace_{provided}}{workspace_{required}} \leq 100 \tag{6.1}$$

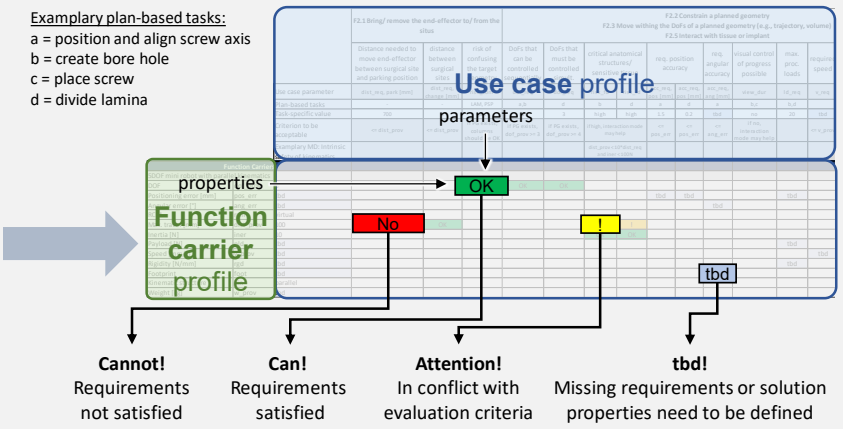
$$risk_{oversize} = \frac{m_{provided}}{m_{threshold}} \leq 50 \tag{6.2}$$

Figure 6.6 illustrates the above-mentioned relationships between the specification of reference functions on a use case and the mapping to possible function carriers. After the reference functions have been specified through the user by means of queries in a graphical user interface, use case parameters are filled with values that are automatically compared to the FAC and SAC. In Chapter 6.1, function carriers have been presented as entities in the solution space that inherit properties from the classes they belong to. Thus, each function carrier that is archived in a database can be read as a function carrier profile showing its properties. The key function of computer assistance would then be to map the parameters of the use case profile to the properties of available function carrier profiles and then calculate their suitability. If function carrier properties fail the FAC, the function carrier is excluded (marked red in Figure 6.6). If they pass (green), they can still be in conflict with SAC (yellow). In accordance with Chapter 4.4, which elaborated

the possibilities of multi-criteria decision making, the final decision would be left to the user, who is now being aware of potential conflicts of interest.

Reference function	**F2 Bring/ remove the end-effector to/ from the situs**	**F3.1 Mechanically constrain the DoFs to a surgical plan, F3.2 Mechanically limit progression within the DoFs, F3.3 Feed/ forward tissue shaping tool, F3.5 Remove tissue**								**F3.4 Maintain registration between anatomy and end-effector**	
Query (in a graphical user interface)	Distance needed to move end-effector between surgical site and parking position	DoFs that can be controlled se-quentially	DoFs that must be controlled simul-taneously	Critical anatomical structures/ sensitive tissue		Req. position accuracy		Max. proc. loads	Req. travel (max.)	Anatomic motion induced by res-piration	Movability of anatomy makes it sensitive to external loads
Plan-based task, PBT	-	a	d	b	d	a	d	b,d	d	a,b,c,d	a,b,c,d
Use case parameter, UCP	trv_req, park [mm]	dof_req	dof_req	risk_fd	risk_fd	acc_req, pos [mm]	acc_req, pos [mm]	ld_req [N]	trv_req [mm]	mot_rsp	mot_ext
Task-specific value	700	5	3	high	high	1.5	0.2	20	10	yes	yes
Functionality acceptance criterion, FAC	700 <= trv_prov	dof_prov >= 5	dof_prov >= 3			pos_err <= 1.5	pos_err <= 0.2	ld_req/ pos_err >= rgd	10 <= trv_prov	dof_prov>=3; v_prov>4; trv_prov>5	
Strategy acceptance criterion, SAC (e.g., MD: Intrinsic safety of kinematics)				trv_prov < 10*trv_req and iner < 100N						iner<100N; v_prov<2*4mm/s; trv_prov<=20*5mm	

Function Carrier		
MAKO arm		
DOF	dof_prov	6
Positioning error [mm]	pos_err	tbd
Angular error [°]	ang_err	tbd
RCM	rcm	virtual
Travel [mm]	trv_prov	1000
Inertial force [N]	iner	tbd
Payload [N]	pld	tbd
Speed [mm/s]	v_prov	tbd
Rigidity [N/mm]	rgd	tbd
Footprint	foot	tbd
Kinematic structure	kin	serial
Mass [kg]	m_prov	tbd



acc= accuracy, ang= angular, err= error, ext= external, dof= degree of freedom, fd= feed, foot= footprint, iner= inertial force, kin= kinematics, ld= load, m= mass, MD= module driver, mot= motion, park= parking position, pld= payload, pos= position, prov= provided, rcm= remote center of motion, req= required, rgd= rigidity, rsp= respiration, tbd= to be defined, trv= travel, v= velocity, ☐ = filled in by the user during the query

Figure 6.6: Scheme of mapping a use case to function carriers

It may happen that for future use cases, new use case parameters (UCPs) must be defined. Then, new FAC or SAC must be formulated and function carrier profiles may need to be extended by additional properties. Techniques for requirements identification, such as user stories, the persona method, the scenario technique, or others could be used to identify new UCPs [Bender and Gericke 2021]. A user story, for instance, takes a perspective of a stakeholder (who?), describes his or her desire (what?), and highlights the motivation behind it (why?) [Dalpiaz and Brinkkemper 2018]. An appropriate software could automatically create new properties of function carriers and mark their values by default as *to be defined* (tbd).

7. Optimized Intraoperative Interfaces

Erixon suggested applying suitable *Design for X* (DfX) approaches to design module candidates in detail [Erixon 1998]. DfX is a well-known design practice to guide development towards the most relevant requirements for a specified X. Usually, the letter X represents (a) a key property of the product (e.g. costs, quality, environmental aspects), (b) a TPL stage (e.g. manufacturing, assembly) [Tichem 1997; Schäppi 2005] or (c) a combination of both, like costs in manufacturing [Olesen 1992]. Accordingly, if X stood for a module driver, it could be called *Design for Module Driver* (DfMD). However, the number of RAS-specific module drivers identified in Chapter 4.2.2 is quite large and there is the possibility that several module drivers impact an individual module. Consequently, various DfMD guidelines would have to be applied. As an alternative, instead of focusing on the module drivers, one could also concentrate on the TPL stage the interfaces occur in.

Erixon's 12 generic module drivers aimed at low internal variety (from a manufacturer's perspective), while keeping as much external variety as possible (from the customer's perspective). The other RAS-specific module drivers relate to the clinical use of surgical robots. The aim is to decrease device variety and increase application variety. Corresponding interfaces relate to the (clinical) use stage of the TPL. It would therefore make sense to establish a guideline that rather deals with the optimization of these interfaces than with individual module drivers.

A modular system consists of modules and interfaces connecting them. Thus, a comprehensive process model for the development of modular surgical robots would benefit from a strategy for the effective design of interfaces. As a first step into that direction, a DfX approach is developed to optimize the design and modularity of surgical robots for intraoperative assembly.

According to Krause and Gebhardt [2018], an interface is an area of interaction between two (sub-) systems or, for example, between modules of a product. This interaction can be the exchange of signals, material, or energy, including the prevention thereof. The authors emphasize that if an interface is used more frequently or for interchangeability, it makes sense to design the interface correspondingly simple and standardize it. An intraoperative interface implies the combination of modules intraoperatively by surgical staff. Accordingly, an intraoperative interface is also a human-machine interface.

Intraoperative interfaces imply intraoperative assembly. Intraoperative assembly pursues two different objectives at the same time. On one hand, modules are to be combined and, on the other, the special boundary conditions in the operating room, particularly pre-surgical conditions,

are to be taken into account. Special conditions are, for instance, the high demands on hygiene. Both aspects, assembly and hygiene, address all surgical robots presented in the state of the art. The presented robots are therefore suitable as material for the development of the DfIA guideline.

At the same time, both objectives can be treated separately. The manual assembly of mechanical or mechatronic modules is subject of industrial interfaces in manufacturing. For this reason, established methods for error-free assembly in manufacturing already exist, which can be found, for instance, under the keywords DfA (Design for Assembly [Miles 1989]) and DfMA (Design for Manufacturing and Assembly [Boothroyd 1994]). Recommendations for compliance with important hygiene requirements in the OR can be taken from corresponding standards and other similar areas of application, such as the food industry.

In the following, recommendations for the design of intraoperative interfaces are taken from established DfX approaches, standards, and known modular surgical robots. Known surgical robots include suitable commercial robots from the market and non-commercial examples from research.

7.1 Design for Assembly

The assembly process can be subdivided into storing, handling, positioning, joining, adjusting, securing, and inspecting [Pahl et al. 2007]. Handling includes identifying parts, picking them up, and moving them. Positioning means placing and aligning before joining. Adjusting is, for instance, to equalize tolerances or restore the required play. The parts are secured against unwanted movements under operational loads and finally inspected. Pahl et al. [2007] describe that assembly operations must be structured, reduced, standardized and simplified in order to achieve an easy-to-assemble layout of a product. For this reason, the authors provide a catalogue of recommendations on how interfaces should be embodied to meet these requirements. For instance, function integration shall be used, and self-adjustment and positioning shall be aimed for to reduce the number of parts and assembly operations. Another example is the aim for uniform joining directions to standardize assembly operations. Similar DfA recommendations have already been formulated by Sackett and Holbrook [1988], Miles [1989], and Boothroyd [1994]. Schuh [2012] provides recommendations for DfA and DfD (Design for Disassembly).

Poka Yoke is not a collection of design recommendations but an approach from the manufacturing industry to develop own preventive safety measures. The term Poka Yoke combines the

Japanese words *poka* (inadvertent mistake) and *yoke* (prevent) [Shingo 1986]. Accordingly, malfunctions of a system are not addressed in the first place, but rather mistakes of the user. This prevention of mistakes can be fail-safe (e.g., faulty assembly would not be possible) or fault-tolerant. The latter means that mistakes are detected and counteract before they have consequences. Poka Yoke provides a matrix of safety measures to prevent inadvertent mistakes (Table 7.1). The combination of one principle of each category with the others provides a prevention measure category. *Source inspection* means that the error cause is detected before interaction. During an *informative self-inspection,* the staff identifies his or her mistake and corrects it. In *informative successive inspection,* the staff of the successive working step identifies the mistake, which can then be traced back to the previous step. Successive inspection is useful when errors only become visible in later process steps where the causes cannot be clearly identified anymore. The *contact method* describes mistakes based on the contact of two components. Accordingly, the constant value and motion-step methods refer to failure based on deviations from the process. The regulative functions do not differentiate between intrinsic safety measures (level 1) and protective measures (level 2), which were presented in Chapter 5.2. Both are referred to as *control method*, while level 3 is equal to the warning method. [Shingo 1986; Bayer and Bläsing 2009]

Table 7.1: Matrix for the prevention of inadvertent mistakes in manufacturing according to Shingo [1986]

Inspection method	Setting function	Regulative function
Source inspection	Contact method	Control method
Informative inspection (self)	Constant value method	Warning method
Informative inspection (successive)	Motion-Step method	

7.2 Design for Hygiene

Asepsis is the state of being free from disease-causing microorganisms. Three aseptic measures can be applied to ensure the sterility of components like medical devices in the OR. A) the non-sterile component is isolated from the sterile area by using a drape, b) the sterile device is used as a disposable (single use) or c) the sterile device is reprocessed (multi-use) before re-use. Legally binding standards, such as the MDR in Europe, obligate the manufacturer of sterile components to comply with validated sterilization procedures. Nonetheless, medizin&technik [2016] reported that every year up to 600,000 people suffer from hospital-acquired infections as a result of their stay in hospitals or care facilities. Of these, 40,000 are fatal. Most of the infections are caused by bacteria. Fortunately, the Robert Koch Institute (RKI) and

the Working Group Instrument Preparation (AKI) permanently elaborate new recommendations to improve the process of sterile reprocessing. In 2012, the Robert Koch Institute (RKI) classified reprocessable medical products according to their risk into non-critical, semi-critical A, semi-critical B, critical A, critical B, and critical C products. For instance, only products that do not have specific requirements to reprocessing (semi-critical A, critical A) should be sterilized with hot-air and only if steam sterilization is not possible. Because of its minimal dependence on influencing factors, steam sterilization at 134°C should always be preferred in hospitals. In terms of hot-air sterilization, the mass of the goods, their specific heat and specific thermal conductivity, the packaging, and especially different loading patterns are critical. [RKI 2012]

However, Oppermann [2018] remarked that there is no dedicated regulation or guideline that declares approved methods for sterile processing of freshly manufactured products. Nor is there any documented knowledge about which sterile processing technique is best suited for a specific geometry or material. According to the author, regulatory requirements can be fulfilled without being able to verify inner cleanliness of medical products. Additionally, guidelines for sterilization processes provide test criteria for the operators (e.g., hospitals) but do not help engineers design for sterility. However, some test-based recommendations exist: Metzing [2009a] gives recommendations for the dimensions of hollow bodies and Metzing [2009b] provides remarks on narrow gaps, threads, hollow spaces, seals, lubricants, and care agents.

In some aspects, the food industry faces similar challenges. There, *hygienic design* is a well-established umbrella term for design recommendations to food processing machines. The respective DfX term would be Design for Hygiene (DfH). In order to advance DfH, the European Hygienic Engineering and Design Group (EHEDG) has made it its mission to regularly publish guidelines for food-safe hygienic design [Hargarten 2018]. The following examples illustrate that some recommendations could be adopted. For instance, Denk and Brandes [2018] discuss different types of surface finishing and resulting roughnesses that allow bacteria (0.5-5 µm) to colonize. The EHEDG recommends that larger surfaces, which are in contact with the product, shall have roughnesses of Ra=0.8 µm or better [Hargarten 2018]. Some notes from DIN EN 1672-2:2021 (hygiene and cleanability requirements for food processing machines) can also be adopted. The standard prescribes that surfaces coming into contact with food should be smooth, easy to clean and disinfect, as well as accessible for cleaning, if necessary through the disassembly of parts. Furthermore, corresponding parts should be free of undercuts, gaps, cracks, depressions, protruding edges, internal protrusions, or dead spaces. Liquids, such as cleaning agents or disinfectants must be able to flow out.

A design method based on the Contact and Channel approach by Albers and Sadowski [2014] has been presented by Beetz et al. [2018] to reduce the risk of contaminating sterile surfaces in dosing pumps for the production of chocolate pralines.

7.3 Functional Mock-Up

The practical implementation of DfA and DfH guidelines is shown in this chapter using a functional mock-up as an example. The mock-up demonstrates a universal mechatronic and sterile hand-arm interface for the intraoperative (re)configuration of bone-shaping robots. A corresponding patent application was published as US2023045591A1 in 2023. The interface provides a modular coupling mechanism between a carrier structure (arm) and different end-effectors (hands), as shown in Figure 7.1. One of the end-effectors was designed as a rigid, passive, and single-use guide sleeve for drilling tasks (module S1). The required DoFs to position the sleeve are provided by a lightweight collaborative off-the-shelf arm with seven DOFs. The second end-effector is a mini robot with parallel kinematics that controls a burr for three-dimensional bone shaping tasks. The system is a representative intraoperative interface for surgical robots because it implements requirements (R) that address a variety of surgical use scenarios. The system aims to be fail-safe (R1), easy to use (R2), quickly reconfigurable (R3), suit disposable, reprocessible and draped end-effectors and carrier structures (R4), enable unambiguous and reproducible positioning (R5), absorb weight, process and user forces (R6), transmit electric (prospectively also kinetic) energy and signals (R7) and allow wipe disinfection (R8).

Fail-safety is addressed by safety-lock rings. Three different safety-lock principles were used to show three possibilities. In the final product, only one principle could be used to not confuse the user or different principles to prevent losing adjacent rings unintentionally. The latter is also the reason why the three rings have different diameters. The first safety-lock principle (interface A1-A2) is based on snap-in pins that provide acoustic and haptic feedback. To switch between open and close, the user must rotate the ring by 90°. The second safety-lock principle (A2-S1/N1) uses radial form closure. When the user squeezes the ring with two fingers from opposite sides, the circumferential teeth engage, and rotation opens or fixes the interface. The third principle (N1-N2) uses axial form closure. The user must press the ring against a spring to axially engage the teeth and be able to rotate the inner ring and open or close the interface.

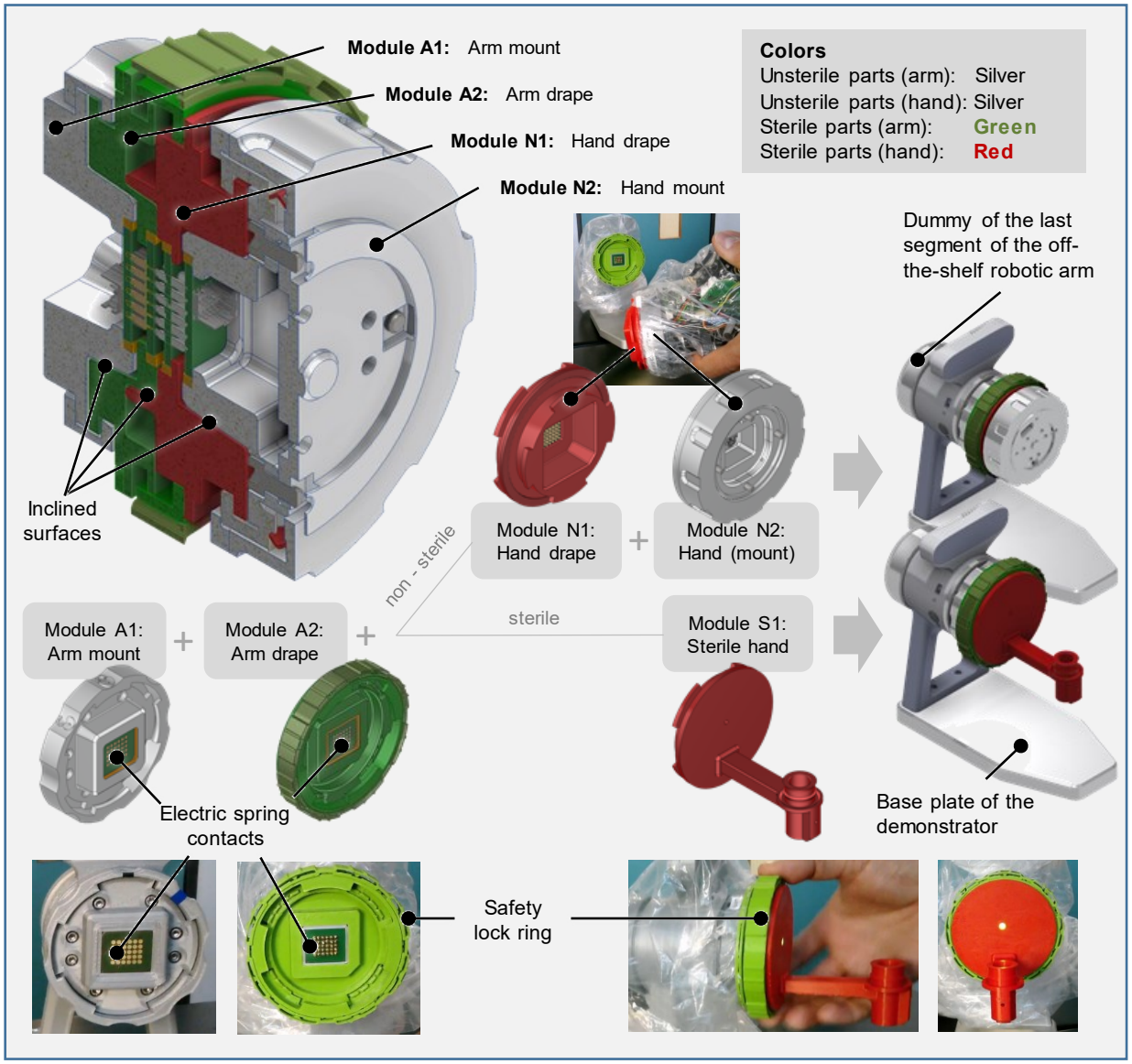


Figure 7.1: Concept overview of the universal mechatronic and sterile interface for the intraoperative (re)configuration of bone-shaping robots

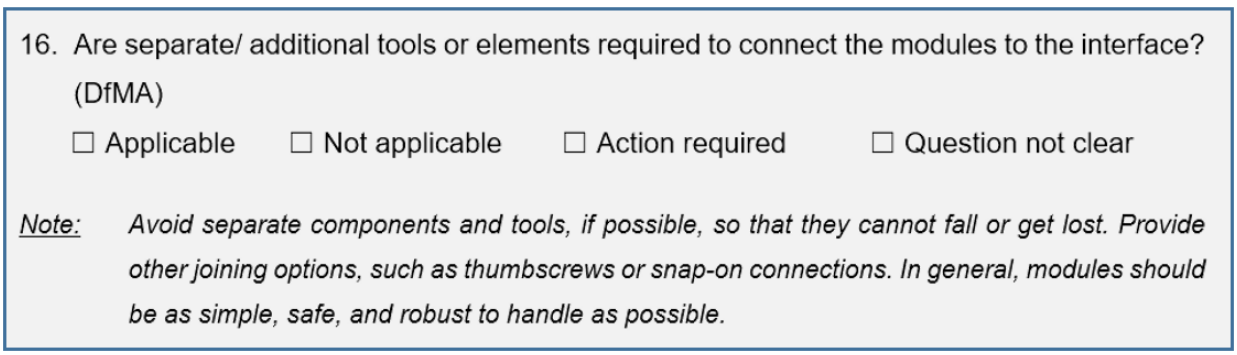
Unambiguous and reproducible positioning (R5) is implemented through inclined surfaces. In the demonstrator, a four-sided truncated pyramid was used at each of the three interfaces. Due to the inclination of the interacting surfaces, any radial and axial play is overcome when rotating the respective fixation ring. However, a three-sided truncated pyramid would even be the best option since the system would be statically determined. In any case, the large surfaces favor the homogenous transmission of weight, process, and user forces (R6). A single chamfer at one of the four edges of each truncated pyramid guarantees that the modules can only be mounted in one orientation. An alternative solution would be to arrange the pins repetitively and use certain pins for the identification of the orientation. Thereby, the user could assemble the modules in any orientation.

In order to enable transmission of electric energy and signals (R7) while allowing wipe disinfection (R8), flat contact pads were used on A1, N1 (directing to A2) and S1. At S1, the electrical contacts were only used to verify electric contact through an identifier LED. The respective counterparts were equipped with spring-loaded pins, which prevent double fitting. The prevention of double fitting is important to guarantee that forces are transmitted through the inclined surfaces and not through electric contacts, which would break otherwise.

7.4 Supportive Checklist

Based on suitable design recommendations of DfA and DfH guidelines and analyzed interfaces of state-of-the-art robots as well as the universal sterile interface of Chapter 7.3, a checklist of design recommendations was elaborated. The overall goal of a prospective comprehensive checklist is to support the engineer in new developments. Here, the primary objective is to find out the general added value of a checklist using a user-centered evaluation. For this purpose, the checklist does not claim to be complete.

The checklist starts with a short introduction about the objectives and then divides into the categories *hygiene* and *assembly*. Hygiene comprises 18 recommendations, assembly 26. Each recommendation consists of a question, four checkboxes with answer options and a note that gives additional information, sometimes by means of sketches. Figure 7.2 provides an example.


16. Are separate/ additional tools or elements required to connect the modules to the interface? (DfMA)

☐ Applicable ☐ Not applicable ☐ Action required ☐ Question not clear

Note: *Avoid separate components and tools, if possible, so that they cannot fall or get lost. Provide other joining options, such as thumbscrews or snap-on connections. In general, modules should be as simple, safe, and robust to handle as possible.*

Figure 7.2: Example question from the checklist; DfMA= Design for Manufacturing and Assembly

Multiple answers are possible. For example, it may be the case that a question applies, but action is still required. If the question cannot be answered because the question is not clear, this must be clarified first. The fourth answer option can be used as an indicator. The evaluation of the checklist is subject of Chapter 8.2.

8. Formative Evaluation

Put simply, usability is the *ability* to *use*. According to ISO 9241-11:2018, usability is the extent to which a product can be used by a *particular user* to achieve specific goals effectively, efficiently, and satisfactorily in a particular context. The criteria *effectiveness*, *efficiency* and *user satisfaction* are applied to general medical devices by IEC 62366-1:2015, and IEC 62366-2:2016. DIN EN 60601-1-6:2021, which defines usability for electrical medical devices, adds *learnability* as a criterion.

IEC 62366-1:2015 distinguishes between two types of usability evaluations for user interface designs. *Summative evaluation* aims to obtain objective evidence that a user interface can be used safely by complying with the four usability criteria. Thus, summative evaluation should be conducted with representative users at the end of development. This type of evaluation is called interaction-centered, as illustrated in Figure 8.1. *Formative evaluation* aims to explore the strengths, weaknesses, and unanticipated user errors during development, according to the standard. Formative evaluation is therefore iterative. IEC 62366-2:2016 gives an example with three iterative steps using cognitive walkthroughs, expert reviews, and usability tests. Since a user-friendly software for the modularization method can only be developed in later stages of development, the modularization method is formatively evaluated in this work. This also applies to the interface design checklist. For both, the modularization method and the interface design checklist, separate user-centered evaluations are conducted and discussed in the following.

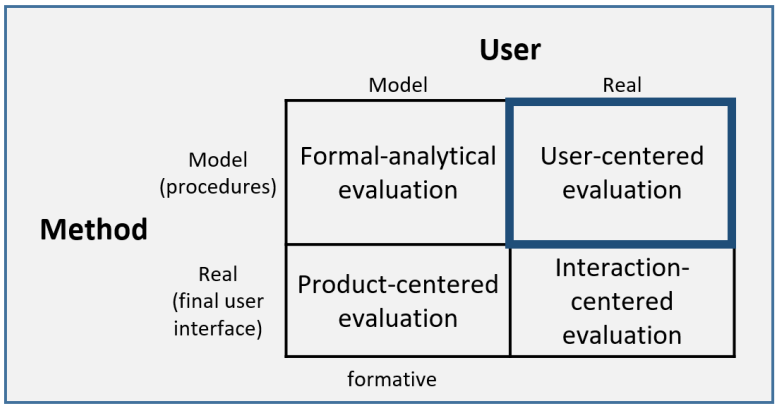


Figure 8.1: Different approaches to the evaluation of usability based on Rauterberg [1992]

8.1 Modularization

The user-centered evaluation of the modularization method is designed as an expert review workshop. For organizational reasons, the evaluation was carried out on different dates with

different sized groups. A total of 16 subjects in eight teams participated in the evaluation study. In the case of an even number of subjects, teams of two were formed, and in the case of an odd number, one team of three. Two subjects had to participate in the evaluation alone for organizational reasons. With one of them, the evaluation was done online because he was located in another country. The creation of teams aimed at encouraging a neutral conversation, preferable between a more and a less experienced person, based on the *constructive interaction* approach by Miyake [1986]. The overall time cap was adapted to the knowledge of the subjects.

Material

In the beginning of the workshop, a presentation was given providing background information that is needed to conduct the tasks. The presentation included information about bone-shaping robots, the potentials of modularity with and without computer assistance, the integrated MORE approach (explaining operators, drivers, reference functions, function carriers, CoH and PoV framework), the use case of spinal decompression (with PSP and LAM), the robots to be optimized (ROSA ONE and MINARO), the tasks, and the given material. The teams were provided with a printed *scenario and decision sheet* (SD sheet) for each robot, a Microsoft Excel *modularization tool* for each robot, a printed *module drivers sheet* (MD sheet) of 59 module drivers (Appendix II) for each person, and a printed questionnaire for each person (Figure 8.2).

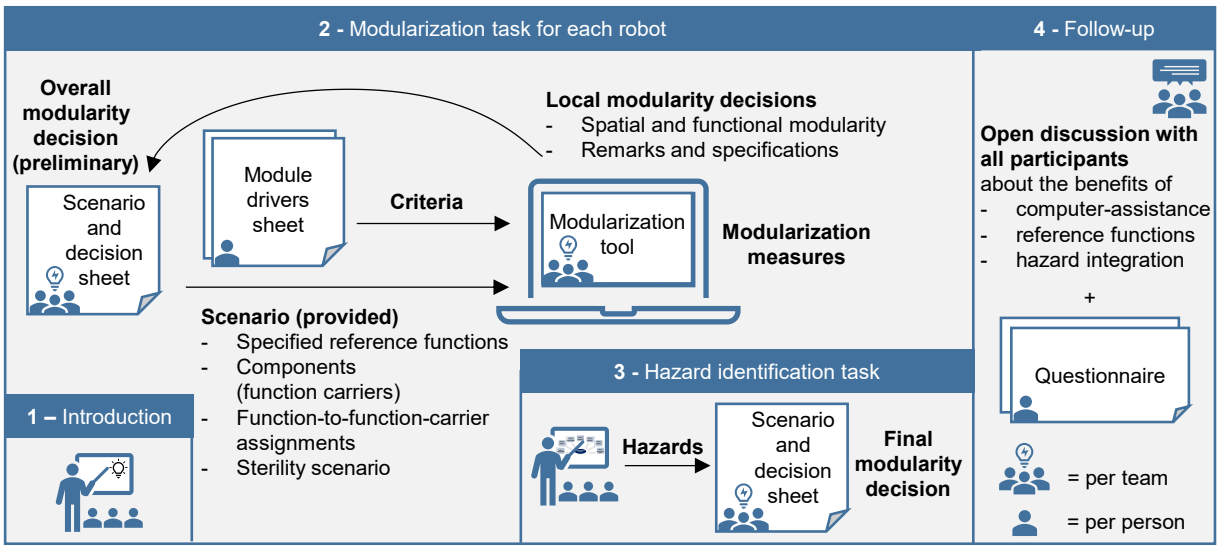


Figure 8.2: Material used during the evaluation workshop

Within the MD sheet, three module drivers had to be specified by the user. For MD-23, MD-24, and MD-25, a surgical discipline, treatment, procedure, or task had to be specified that would benefit if function carriers were reused or replaced before or during operation. The possibility to define own module drivers was given as an option.

The *modularization tool* consists of two parts: an input area and a lookup area (Figure 8.3). The *input area* is a table with four sections representing areas where modularization measures (MMs) can be made for one of four MDs. According to Chapter 4.4.2, an MM consists of an operator, the addressed function carriers and functions, the capability or value of the measure, and the weighted MD it refers to. The user can choose to keep the preselected MDs or to change them by overwriting the respective number in the first column. After choosing four suitable MDs, they must be weighted from 1 (low importance) to 3 (high importance), or as a must criterion (!). To prevent incorrect inputs, only white fields were enabled to be filled out by the user. Correspondingly, the impact of the measure to the MD is the multiplication of the weight of the MD with the value of the measure. If *must* (!) was chosen as a weighting, the value of the measure is set to 1000. The operators and reference functions can be chosen from a dropdown menu, as shown in Figure 8.3.

After all modularization measures are defined, the users go through all function carriers using the *lookup area* (a - g for ROSA and a - m for MINARO) and make a modularity decision for the respective function carrier on the SD sheet. In the example, the lookup area shows for the FC c (base station cart) an indicator value of 29 to separate (split) the robotic arm from the cart and a value of 1000 to remove function F3.1 for LAM due to the oversized kinematics. Since the measures are compatible to each other, both can be realized. In case of incompatibility of measures, the table shall help to make an informed decision (Chapter 4.4). For the operators *keep* and *split*, 3 rows are reserved to show the three measures that have the highest impact to the operator, starting with the highest. In the example, MD-43 contributed with 72,4% to the recommendation *split* and MD-9 with 27,6%. For the sake of clarity, only one row is reserved for the other operators, respectively, which shows the MD with the highest impact.

The SD sheet follows two purposes: On one hand, it serves as an auxiliary sheet where the components (function carriers) are shown, assigned to a sterility measure, and mapped to the reference functions they implement (scenario). On the other hand, the final modularity decision can be made based on the recommendations from the lookup table and identified hazards. The SD sheet is attached in Appendix III.

Function carriers, which are shown on the SD sheet (Appendix III), are represented here to ease understanding

Function carriers	Satellite station	Arrays	Base station cart	Guide sleeve	Drill	Burr	User
	a	b	c	d	e	f	g

Input area

Robot:	ROSA-Scenario	Weight of MD	Operator	Function Carriers	Functions	Value of measure	Benefits (optional)	Hazards and disadvantages (optional)
No.	Module Driver (MD)	1=small, 2=medium, 3=high, !=must		(a, b, c, ...)	(2.1, ...)	1=smallest improvement, 10= highest improvement	Here you can speficy the benefits, if useful	Only those that are not module drivers themselves
9	Advantages through black box engineering	1	o|o split	c		8	off-the-shelf arm can be bought	supply bottleneck
			o keep	f		10	specialized know-how from the supplier	
23	Components can be reused for: other tracking tasks, drilling or burring tasks	2	o keep	a,b,e,f		4		
43	Minimal occupied space around the operating table (OT space)	3	o|o split	c		7	use the cart only to bring the arm to the table and then fix the arm at the table	current arm may be too heavy to provide required rigidity at the rail
53	Kinematics are not significantly oversized when used for critical tasks	!	o>● remove function	c	F3.1LAM	10	critical motion tasks should be done by application-specific small-sized kinematics	additional robot must be developed

1. Selection and weighting of module drivers

2. Completion of modularization measures

- O keep
- O|O split
- O-O combine
- O>● remove function
- ●>O insert function

Lookup area

FC	Function Carier	Image	Operator		Value	Most important module drivers	Specification of benefits	Hazards and disadvantages
c	Base station cart		o keep		0	none		
						none		
						none		
			o|o split		29	72,4%: Minimal occupied space around the operating table (OT space) (MD43)	use the cart only to bring the arm to the table and then fix the arm at the	current arm may be too heavy to provide required rigidity at the rail
						27,6%: Advantages through black box engineering (MD9)	off-the-shelf arm can be bought	supply bottleneck
						none		
			o-o combine	with a:	0	none		
				with b:	0	none		
				with d:	0	none		
				with e:	0	none		
				with f:	0	none		
			o>● remove function	F3.1PSP	0	none		
				F3.1LAM	1000	100%: Kinematics are not significantly oversized when used for critical tasks (MD53)	critical motion tasks should be done by application-specific small-sized kinematics	additional robot must be developed
			●>o insert function	F3.3LAM	0	none		
				F3.5PSP	0	none		
				F3.5LAM	0	none		

3. Going through function carriers

4. Making a modularity decision for each function carrier

Empty rows are cut out for illustration

Figure 8.3: Views of the modularization tool applied to the ROSA-Scenario; LAM= laminectomy, PSP= pedicle screw placement, SD sheet= scenario and decision sheet

Besides the task sheets, a questionnaire was given to each user. The questionnaire consists of 41 questions of which 36 are five-level Likert questions. *1* stands for *strongly disagree* and *5* for *strongly agree.* The five remaining fields are left for comments. An odd Likert scale was chosen to not force the choice of the respondent into any direction. According to Franzen [2019], a question is mostly answered positively in case of doubt with an even number of choices. The answer options would further not be equidistant anymore. Offering a neutral response option, on the other hand, carries the uncertainty that the respondent's motivation for the respective answer is unclear. Someone may choose the neutral answer because they don't understand the question, underestimate their expertise, or don't think carefully about the question. Although doubts were clarified at any time during the evaluation, the effect was analyzed after the evaluation by additionally interpreting the responses without considering the neutral position. The mean values were always slightly better when the neutral option was not considered. Thus, even after the evaluation, using an odd Likert scale seems justified.

The questionnaire is divided into the categories *context, systems and use cases, module drivers, modularization tool (excel),* and *PoV framework.* The contextual questions aim to get an impression of the respondent's attitude towards modularization in general. It is also important to find out how confident the subjects feel in working with the assumed systems and use cases. The module drivers and the PoV framework sections review whether the intended added values of the respective approaches have been achieved by querying them. Although the modularization tool is a first version and not expected to be mature, it is evaluated like a mature product in order to identify shortcomings systematically. Therefore, the well-established and standardized System Usability Score (SUS) by Brooke [1996] is applied, which consists of 10 questions. The word *system* is consistently replaced by *modularization tool*. Additional comments are also asked for.

Use Case Scenario ROSA

ROSA ONE and MINARO were chosen as examples because ROSA ONE is a commercial and highly integrated robot with limited applications whereas the MINARO is highly granular and versatile. Both allow to create scenarios for PSP and LAM. The ROSA ONE is already certified and used for PSP. Regarding the LAM application, a hypothetical variant of the ROSA robot had to be assumed. Zimmer Biomet's existing robot families were analyzed to create a variant scenario that could suit the portfolio of the manufacturer. According to the definition of a product family explained in Chapter 1, two hypothetical families were identified: ROSA ONE (recognizable by the white-pink housing) and ROSA Robotics (white-blue) [Zimmer Biomet 2023]. ROSA ONE addresses the surgical discipline *neurosurgery* and can be configured intraoperatively into ROSA ONE Brain and ROSA ONE Spine. The blue line, ROSA Robotics, comprises product

variants for *orthopedic surgery*: ROSA (Total) Knee, ROSA Partial Knee, and ROSA Hip. The company's product structuring strategy can be assigned to the *variant-driven family strategy*, according to Eilmus [2016] (see Chapter 1). This strategy aims to reuse as many assemblies as possible across product variants and families. Some standardized and individual modules only occur inside a family, while others are used portfolio-wide. The base cart, with the Stäubli arm and screen mounted on it, as well as the satellite cart, seem to be shared across the families. Accordingly, they are assumed to be identical in the ROSA ONE and in the ROSA robotics variants. Spatially seen, only the housing seems to vary between the families. Between individual variants, also the end-effectors change. Virtually seen, a different software may be sold with each variant. As a conclusion and based on the current product structuring strategy, it is assumed that a robot variant for LAM would belong to the ROSA ONE family because it addresses neurosurgery. Furthermore, the standardized carts, arm, camera, and screens would be reused. Therefore, a scenario can be assumed for this evaluation, in which PSP and LAM is addressed and in which the drill guide is exchanged by a burr to switch between these surgical procedures.

Part of the use case scenario is the user interaction scenario. Here, it is assumed that the burr is guided hands-on by the surgeon and the Stäubli arm cooperatively. Motion is assumed as being constrained in three DoFs by means of virtual fixtures, as defined by Schleer et al. [2019a]. Even if the ROSA robot may never be used for LAM, it is a justified example to test the modularization method with a highly integrated robot structure serving more than one use case.

Use Case Scenario MINARO

The assumed scenario of the MINARO robot for spinal surgery, which means LAM and PSP, is illustrated in Figure 8.4. The required burring workspace for LAM is in the range of that for UKA. As shown in Figure 2.2, a cubic workspace of 50 mm x 50 mm x 50 mm was determined to be sufficient for UKA. Xu et al. [1999] measured the laminae of 37 adult specimen from C2 to L5 and determined a maximum height of the lamina with 25.1 ± 2.5 mm at T11, and the greatest laminar width with 15.7 ± 2.0 mm at L5. Even after adding a maximum respiration-induced motion of 4.30 ± 0.35 mm [Guha et al. 2019], the UKA workspace would be sufficient for LAM. However, to create a higher variety of modules and possibilities for standardization, a scenario for LAM and PSP is assumed in which the motor units (7) are generic for UKA, TKA, LAM, PSP and other applications but spine-specific front and back kinematics (8, 9) are used for LAM and PSP. As end-effector, a burr (12) is mounted between the kinematic modules for LAM and equipped with a feed motor, resulting in five DoFs. Although only three DoFs are sufficient to guide the tool center point (TCP), the additional two DoF may be beneficial to decrease the required incision. For PSP, a drill guide sleeve is mounted perpendicular to a non-driven carrier (10) to exploit the

four DoFs provided by the two motor modules. According to the definitions derived in Chapter 1, modules that are used in an application-specific variant are referred to as hat modules and those that are specific to a surgical treatment meet the definition of a family-specific module.

The user interaction scenario for LAM is as follows: The user steers the burr with the robot in all DoFs cooperatively. The forces the user applies are measured and with an admittance control scheme the motors move the burr into the desired directions. When boundaries are reached, the motors do not assist and the non-back-drivable gears prevent undesired motion. In the PSP configuration, prepositioning is navigated and manually done by the user. Then, the four DoFs required to position the axis move in active mode (autonomously). The position of the sleeve end-stop is adjusted manually under navigation.

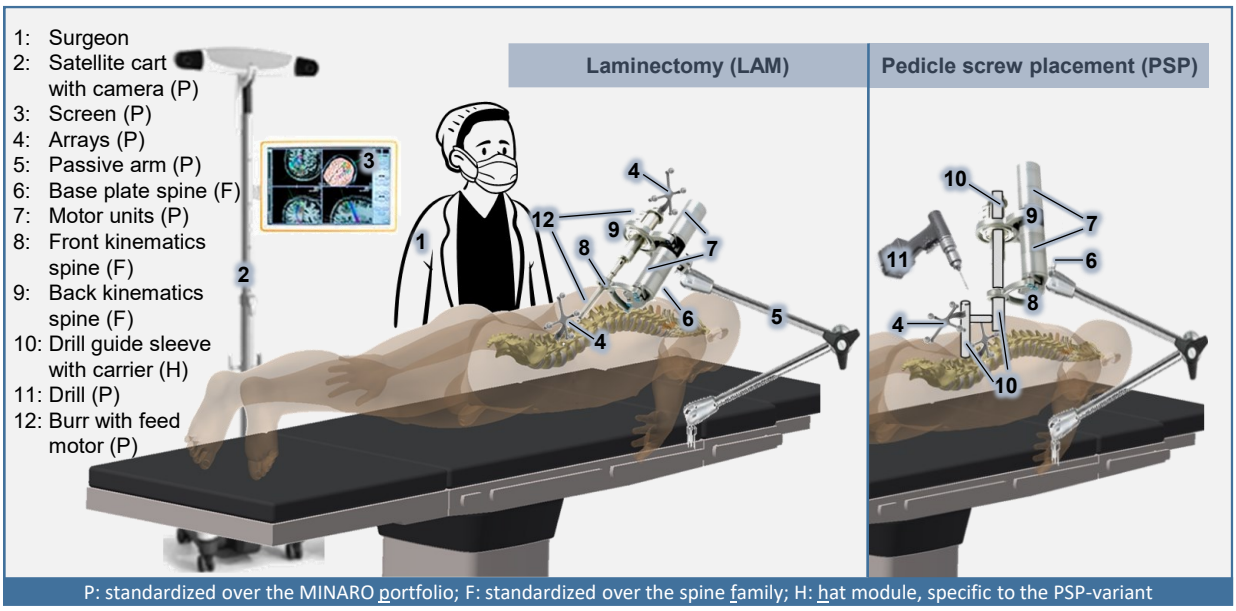


Figure 8.4: Assumed configurations of the MINARO robot for Laminectomy (LAM) and Pedicle Screw Placement (PSP)

Procedure

After hearing the presentation, teams of 1 to 3 persons were formed and provided with the material. Then the procedure was as follows. The time caps are reference values that were given to the teams. The task was not aborted when the time limit was exceeded.

1. Each subject filled in personal information in the questionnaire to allow estimation about their expertise.
2. 20 minutes were scheduled to review the list of MDs.
3. 30 minutes were scheduled to select four suitable MDs and modularize the ROSA robot.
4. 30 minutes were scheduled to select four suitable MDs and modularize the MINARO robot.

5. 15 minutes were scheduled to guide the whole group through PoV-1 to PoV-7 by means of a presentation aiming at giving the subjects an impression about the benefits of the PoV framework applied on their just modularized robot.
6. 15 minutes were scheduled for an open discussion about the benefits of computer assistance, reference functions, and hazard integration.
7. 10 minutes were scheduled to answer the questionnaire.

8.1.1 Results

An overview of the affiliation and expertise of the 16 subjects is shown in Figure 8.5. All values are self-assessed and were asked for in the questionnaire. Most of the subjects were mechanical engineers (56%) who worked in medical engineering projects at the time of evaluation. All subjects had a background in medical engineering. Two of the three subjects from industry worked with usability studies and risk management methods of medical devices. Nine out of 16 subjects (56%), including the three from industry, rated their expertise with surgical robots as *rather high* or *high*. In terms of *medical engineering,* it was 13 of 16 (81%), and five (31%) for surgical treatments in general. 12 (75%) believe they have *rather high* or *high* expertise with the product development process and six (38%) with hazard and risk analysis. There was only one person without experience on hazard or risk analysis. Although a small majority of subjects works with surgical robots, the majority is unexperienced with modularization and very unexperienced with PLM systems. This is not a limitation, as it represents the small-volume surgical robotics industry.

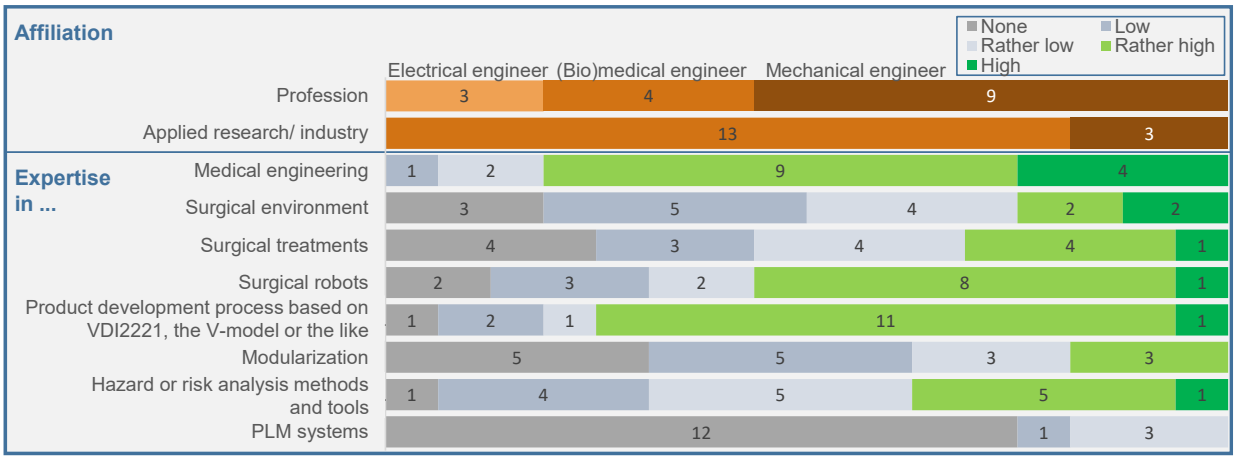


Figure 8.5: Subject profiles: overview of the affiliation and expertise

Due to the relatively small and heterogeneous group of subjects, a purely statistical analysis of the questionnaire is not appropriate. The main added value of the evaluation workshops with experts results from personal conversations and individual answers. Still, the mean values of the

36 Likert questions (shown in the following figures) give an impression about the quality of the developed method. For most questions, five points would be the best result. Only questions 23, 27, and 29 (Figure 8.8) were inverted. To still be able to quickly see whether a question was positively or negatively answered, the corresponding bars have been color-coded. Dark green means that an answer is less than one point away from the best result. Light green is above one and up to two points away. Yellow is above two and up to three points away. Red would be above three and up to four, which did not occur with any question. The greatest distance from the best result was 2.75 points. Except for those regarding the modularization tool (Figure 8.8), all questions (Q) were positively answered (green). Figure 8.6 summarizes the results regarding the categories *context* and *systems and use cases*. Besides the total mean values, also those of the respondents with *high* and *rather high* expertise are illustrated.

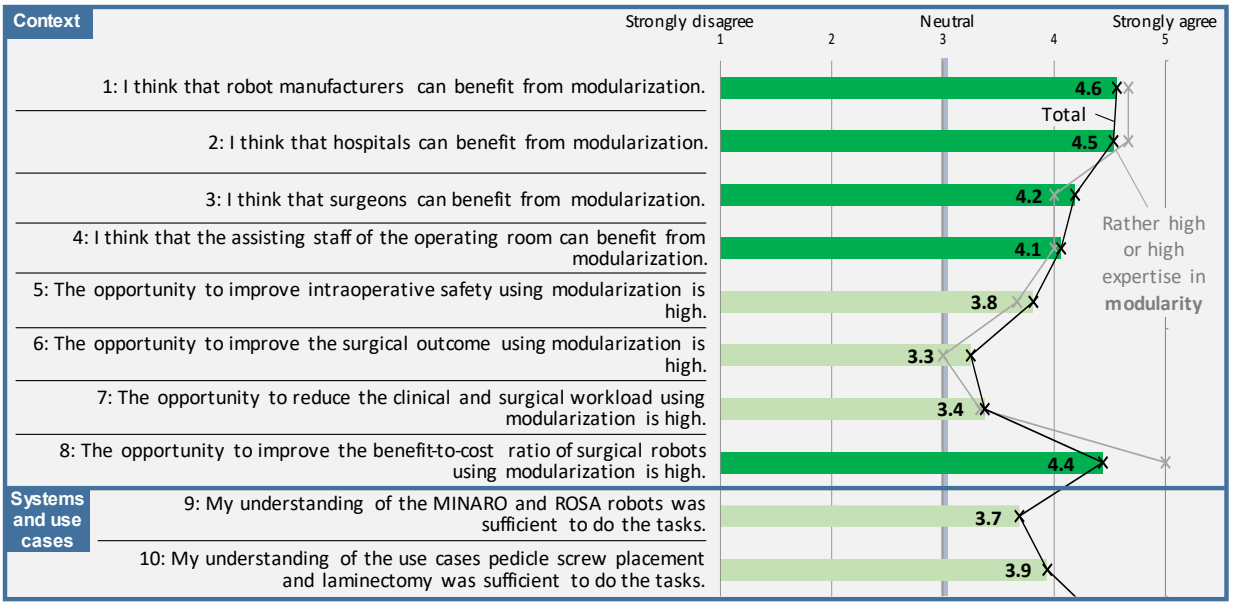


Figure 8.6: Evaluation of the checkbox questions in the categories *context* and *systems and use cases*

Module Drivers

Independent from the expertise with surgical robots, the surgical environment or surgical treatments, the approach of using module drivers was perceived as helpful to be comprehensive (Q11, 4.4), to prevent conflicting goals (Q12, 3.8), to account for different stakeholders (Q13, 4.2) and to be break habits (Q14, 4.1), as shown by Figure 8.7. The benefit of using module drivers for the systematic modularization of surgical robots was considered high (Q15, 4.3), while RAS-specific module drivers were slightly ranked better (Q16, 4.5). Nevertheless, comprehensiveness of all module drivers and comprehensibility of generic module drivers have been ranked lower (Q17 with 4.1, Q18 with 3.6).

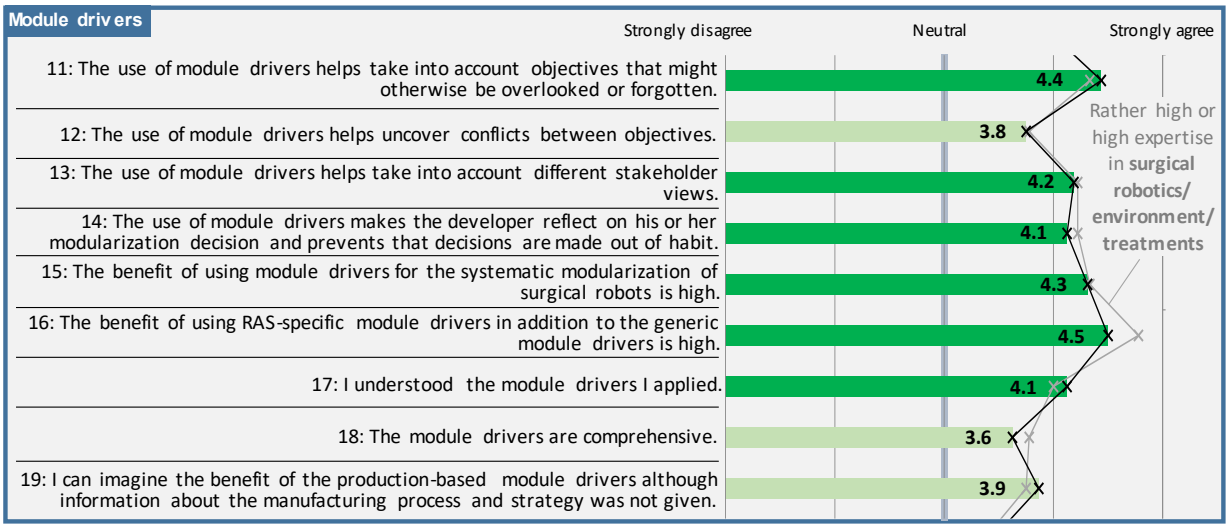


Figure 8.7: Evaluation of the checkbox questions in the category *module drivers*

The positive averaged answers regarding the MDs match with the individual comments and discussions. However, potential for improvement was also identified. Two respondents remarked that the generic MDs were less comprehensible than the RAS-specific ones and that explanations and examples could be complemented with pictures. Another person understood some explanations and examples as biased and influencing the user. Reference was made to MD-23. An overview of all MDs that were commented is given in Table 8.1. Three persons noticed that MD-24 and MD-25 had been formulated preventively and not formulated as a goal, like all other questions. MD-2 was once considered hard to estimate due to the uncertainty of technological progress. Another subject criticized MD-20 because gas sterilization with ethylene oxide was only one example of many sterilization techniques and could be used for clinical reprocessing, according to his or her opinion. The example of MD-4 was found difficult to understand by two persons. One of them did also not understand MD-33 since he or she saw a contradiction between avoiding interfaces and quick assembly. The same person mentioned that the example for MD-6 was not appropriate. One person was confused because MD-14 only relates energy consumption to sterile reprocessing and does not account for production-related energy consumption. While working on the modularization task, one team was confused about MD-18. They would have preferred a combined testing instead of testing isolated, which would capture also interface related errors like wear. Another respondent, on the other hand, emphasized the importance of isolated testing during sterile reprocessing. Furthermore, MD-29 was considered as too similar to MD-34 and MD-41 too similar to MD-46. Also MD-51 was misleading for one person because *wear* would either occur after multiple uses and not during a single surgery. One person remarked that *simplification* as used in MD-39 was too generic. According to one person, MD-53 and MD-54 referred to size and not to criticality. The other subjects recognized that MD-53

and MD-54 express the danger of oversized kinematics during critical tasks. Finally, proposals were made for additional module drivers: 1) “patient well-being or rehabilitation and invasiveness”, 2) “ability/ ease of assembly and disassembly” or “tool-free (dis)assembly”, 3) “increased precision of pre-positioning”, 4) “as less handling steps for the user as possible”, and 5) “reuse components”.

Table 8.1: Module drivers that were commented during the evaluation

Module Drivers		**Explanation and Examples**
Production-related		generic, based on Erixon [1998]
2	Master technological evolution/ technology push	The aim is to master technological evolution during a component’s lifecycle with as little effort as possible. Indicators: a) Components are affected by expected, radically changing customer demands or technical progress. Examples: from micro-USB to USB-C, from screen to VR, better camera solution
4	Efficient technical specification (horizontal leverage)	The aim is to reduce complexity caused by the creation of variants through specification as late as possible in the product creation process. Variants for different market regions leverage products across markets. Indicators: Components vary with regionally different power grids or standards. Examples: AC power plugs and sockets; The delivery of an ink-jet printer is simplified if power units for different market regions are separated modules.
6	Advantages through scaling	From a manufacturer’s perspective, the module driver addresses the strategy economies of scale: Standardization results in an increased volume of certain components. From the user’s perspective, configurability increases versatility of use. Indicator: Components can be used in multiple product variants or configurations. Example: tracking arrays.
RAS-specific		
14	Energy consumption associated with sterile reprocessing is low	e.g. by using more drapes, cases or disposables
18	Functions can be tested isolated in the CSSD	CSSD= Central Sterile Services Department
20	Gas sterilisation with ethylene oxide is prevented	to enable sterile reprocessing inside a hospital, because sterilization with ethylene oxide is not possible there
23	Components can be reused for: [ ]	Refers to a specific surgical discipline/ treatment/ procedure/ task. This module driver can be used multiple times. Attention: Function carriers that suit more use cases should not disadvantage a single use case (pareto principle). For instance, the Versius system occupies little space compared to the daVinci robot if only two arms are needed, but more space if four arms are needed.
24	Components must be exchanged before (!) surgery to suit: [ ]	Refers to a specific discipline or treatment. This module driver can be used multiple times. Addresses use case specific module, e.g., the end-effector modules of MAKO and Cirq.
25	Components must be exchanged during (!) surgery to suit: [ ]	Refers to a specific surgical procedure or task. This module driver can be used multiple times. Addresses use case specific modules. E.g., the robot can be re-configured during surgery to switch from pedicle screw placement to laminectomy.
33	Quick assembly	Interfaces should be avoided. If they cannot be avoided, they must be as intuitive and safe as possible.
34	As few persons as possible required for assembly	E.g., a sterile power tool that uses unsterile batteries needs a sterile person and an unsterile person to insert the battery.
39	Simple interaction with input devices and user interfaces	should be evaluated beforehand. Haptic guidance can help.
41	As few draping during surgery as possible	
46	Image can be made without the need to re-drape the system	
51	Components sensitive to wear can be exchanged during surgery	e.g., burr or drill bits as well as saw blades should be easily exchanged.
53	Kinematics are not significantly oversized when used for critical tasks	The aim is to decrease the provided-to-required ratio of the surgical workspace and prevent risks of oversize. E.g., splitting functions to different components.
54	Inertial forces cannot become significantly higher than required during critical tasks	The aim is to decrease the mass and acceleration of moving parts and prevent risks of oversize. E.g., splitting functions to different components

Modularization Tool

The SUS usability score was used to evaluate the modularization tool, including the SD sheet, for the ROSA and MINARO systems. Since the evaluation of the modularization tool implies the evaluation of the user interface, which has not been developed yet, shortcomings of the excel-based user interface have been expected and appreciated as a valuable input for improvements. Potentials for improvement are indicated by the fact that the modularization tool was considered not very easy to apply (Q24, 2.9), an expert would be needed to apply the tool (Q25, 3.7), and further education would be required (Q31, 3.3), according to Figure 8.8. Q30 summarizes with 2.8 points that the users did rather not feel confident using the tool. In the individual comments and discussions, the users remarked that the user experience could be improved if an appropriate software tool was provided that guides the user through the process.

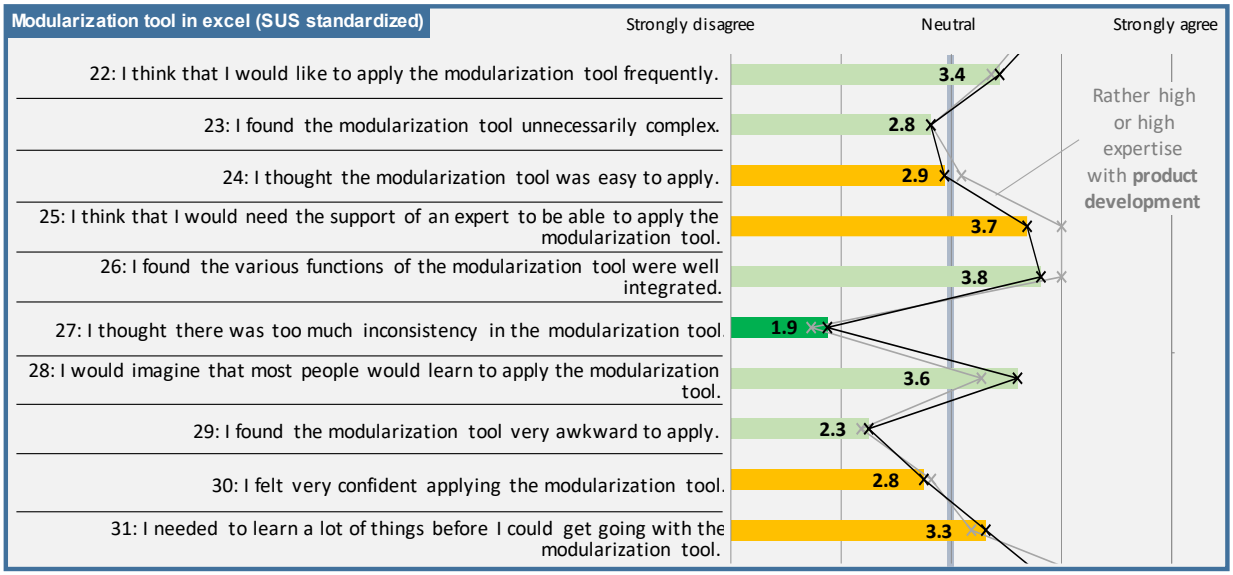


Figure 8.8: Evaluation of the checkbox questions in the category *modularization tool*; SUS= Systems Usability Score

Most operators have been used correctly across all groups. Although, questions regarding the use of operators came up and revealed requirements for the future user interface:

1) The dropdown menu for the selection of functions could be more convenient if more than one function per row could be selected.
2) An *exchange* operator could be used to exchange several functions with one action, as remarked by one team.
3) A *transfer* operator was preferred by two teams since using the two operators *remove function* and *insert function* in combination was not convenient in the current implementation of the tool.

4) A blank column on the decision sheet would be beneficial to account for added function carriers.
5) One person remarked that the operator *keep* can be misleading if modularity shall be kept although the function carrier is to be exchanged. In a particular case, the drill guide was to be exchanged by a saw guide to serve sawing applications and the operator *keep* would have been formally correct because the guide must be kept as a separate module to be exchangeable.
6) Another person wanted to exclude the function of joining kinematics with the baseplate from the MINARO motor modules. Since only reference functions could be excluded by means of the dropdown menu, this function could not be addressed by that. The user was instructed to do the corresponding spatial modularization and use the *benefits* column of the modularization tool or the *remarks* field on the SD sheet to specify the functional operations that do not address reference functions.
7) One subject missed having an initial and resulting *system score* that allows to compare the suitability to module drivers before and after modularization.
8) Another person had a similar idea and further suggested to weigh stepwise, first the module driver categories and then the individual drivers. Alternatively, only module driver categories could be weighted and selected. Thereby, upcoming modularization ideas would be less restricted to chosen module drivers.
9) During the modularization task, one team came up with the idea of joining drill and sleeve but did not finish thinking about it because the idea could not be allocated to one of the selected module drivers.

The results of the modularization process are shown in Table 8.2 for the ROSA ONE scenario and in Table 8.3 for the MINARO scenario. All teams achieved functional and reasonable results for the ROSA ONE scenario. Three teams independently suggested to mount the camera directly onto the base station cart (A, G, H) motivated by OT and OR space and other reasons that can be seen in the column *selected module drivers and weight*. Team C recommended to mount the camera at the ceiling as it is used for many applications that rely on navigation. The strategy of team B was to replace the industrial arm by a lightweight arm and to bring the arm to the table by means of a cart but then mount the arm at the table rail and remove the cart. This is similar to the MazorX. However, the subject did not know the MazorX and came up with the idea by following the selected module drivers. Splitting the arm into kinematic modules of rough and fine motion tasks was suggested by team A, B, D, E and H. Team G suggests controlling the end-effector with telemanipulation using a console in the non-sterile area, which would result in another user interaction scenario.

Table 8.2: Modularization results for the ROSA ONE scenario; CSSD= Central Sterile Services Department, DoF= Degree of Freedom, LAM= Laminectomy, MD= Module Driver, OR= operating room, OT= operating table, Pers.= persons

		ROSA ONE Modularity	
Team	Pers.	Description	Selected module drivers and weight
A: bone-shaping robots experts	2	- The camera is mounted on the base station cart --> removal of satellite station cart - The LAM-specific motion functions (DoFs, limitation, feed) are removed from the arm and shall be done by a smaller LAM-specific end-effector robot.	- MD-9 (medium): Advantages through black box engineering - MD-23 (medium): Components can be reused for *other navigation tasks* - MD-43 (medium): Minimal occupied space around the operating table (OT space) --> line-of-sight, versatility - MD-53: Kinematics are not significantly oversized when used for critical tasks --> intrinsic safety prioritized by international standards
B: mechanical engineer working with stents	1	- The arm is replaced by a lightweight arm and the cart is only used to bring the arm to the table. Then, the arm is mounted onto the table and the cart is retracted. - The loose interface between arm and cart is also important for production: the arm should be an off-the-shelf arm. - The arm is only used for rough positioning and not for fine motion or motion compensation.	- MD-23 (high): Components can be reused for *other tracking tasks, bone shaping tasks* - MD-43 (high): Minimal occupied space around the operating table (OT space) - MD-53: (high) Kinematics are not significantly oversized when used for critical tasks - MD-~~13~~→**9** (medium): Advantages through black box engineering
C: medical engineers working with soft-tissue surgery	2	- Ceiling-mounted camera instead of stand or cart. - Base station cart is split into control unit, robot arm and monitor to enable ergonomic locations. - The guide sleeve is split in order to exchange the inner part for different diameters and drill length. Also the drill and burr must be split from the bits to enable exchange. - Camera and arrays should be bought as a black box since they rely on each other and functionality can be guaranteed by the vendor.	- MD-43 (high): Minimal occupied space around the operating table (OT space) - MD-~~13~~→**9** (medium): Advantages through black box engineering - MD-23 (medium): Components can be reused for: *other tracking tasks, drilling or burring tasks* - MD-53 (medium): Kinematics are not significantly oversized when used for critical tasks
D: medical engineer, no experience with topic	1	- The arm is split into modules of rough and fine kinematics - The drill is not inserted into a guide but attached at and moved by the fine kinematics	- MD-~~13~~→**9** (high): Advantages through black box engineering - MD-~~23~~ →**6** (high): Advantages through scaling - MD-~~43~~→**1** (high): Advantages through carry over - MD-53 (medium): Kinematics are not significantly oversized when used for critical tasks
E: bone-shaping robots experts	2	- Arrays shall be attached to the drill and burr to enable navigation as a backup solution in case of technical problems. - The small robot carries a burr or a guide sleeve and is separated from the arm. - The small robot does the motion compensation. - The arm is optional for prepositioning and can be replaced by a bone mount, the surgeon or assistant	- MD-~~9~~→**18** (high): Functions can be tested isolated in the CSSD - MD-43 (high): Minimal occupied space around the operating table (OT table) - MD-23 (medium): Components can be reused for: *other tracking tasks, drilling or burring tasks* - MD-53 (medium): Kinematics are not significantly oversized when used for critical tasks
F: mixed team of surgical robots and risk analysis experts	3	- Satellite station and arrays shall be bought from the same manufacturer - Arm shall be a separate module mounted at the base station cart and can be exchanged by other kinematics.	- MD ~~23~~→**61** (high): *Reuse components* - MD-43 (high): Minimal occupied space around the operating table (OT space) - MD-60 (medium): *As less handling steps for the user as possible* - MD-9 (low): Advantages through black box engineering
G: mixed team of surgical robots and risk analysis experts	2	- The camera is mounted on the base station cart, to increase OR and OT space. - Screens are removed from the base station cart to increase space and facilitate draping. - The arm is replaced by a lightweight arm. - The surgeon sits on a surgery console that is universal for various surgeries, where he or she plans the procedure and does the propositioning and plan based surgery telemanipulated.	- MD-53 (must): Kinematics are not significantly oversized when user for critical tasks - MD-~~23~~→**32** (high): As little draping time as possible - MD-~~9~~→**17** (medium): Components fit into a standardized sterile container - MD-~~43~~→**42** (medium): Minimal footprint in the operating room (OR space)
H: mixed team with surgical robotics expert	3	- Camera is mounted at the base station arm, if useful positioning of camera is possible and collisions can be avoided with the arm. - The arm is exchanged by a smaller one and a small robot with parallel kinematics is mounted on top for fine positioning. - The robot array is shifted from the distal end of the arm to the end-effector.	- MD-~~53~~→**54** (must): Inertial forces cannot become significantly higher than required during critical tasks - MD-~~23~~→**60** (high): *Higher accuracy* - MD-43 (high): Minimal occupied space around the operating table (OT space) - MD-9 (low): Advantages through black box engineering

With the MINARO scenario (Table 8.3), all teams again achieved functional results. Three teams (A, C, E) confirmed the original modularity and considered it important to meet the selected module drivers. While team A and E were familiar with the system, team C only had expertise with soft-tissue robots.

Table 8.3: Modularization results for the MINARO scenario; CSSD= Central Sterile Services Department, MD= Module Driver, OT= operating table, PSP= Pedicle Screw Placement, Pers.= persons, SDC= Service-Oriented Device Connectivity, TKA= Total Knee Arthroplasty, UKA= Unicondylar Knee Arthroplasty

		MINARO Modularity	
Team	Pers.	Description	Selected module drivers and weight
A: bone-shaping robots experts	2	original modularity is kept	- MD-18 (medium): Functions can be tested isolated in the CSSD - MD-29 (medium): As few assembly tasks as possible - MD-24 (medium): Components must be exchanged before surgery to suit: *UKA, TKA* - MD-10 (low): Efficient service and maintenance (functioning)
B: mechanical engineer working with stents	1	The base plate, front kinematics and back kinematics are specific for the "spine" family and should therefore be combined to reduce assembly tasks. The rest is kept as it was.	- MD-10 (high) : Efficient service and maintenance (functioning) - MD-~~18~~→**13** (medium): Waste per procedure is low - MD-29 (medium): As few assembly tasks as possible - MD-24 (medium): Components must be exchanged before surgery to suit: *UKA*
C: medical engineers working with soft-tissue surgery	2	original modularity is kept	- MD-29 (must): As few assembly tasks as possible - MD-10 (high): Efficient service and maintenance (functioning) - MD-18 (medium): Functions can be tested isolated in the CSSD - MD-~~24~~→**30** (low): Components can be assembled before they are made sterile
D: medical engineer, no experience with topic	1	- The motor modules and kinematics are combined for usage. - The robot array is attached to the arm.	- MD-29 (must): As few assembly tasks as possible - MD-10 (high): Efficient service and maintenance (functioning) - MD-18 (medium): Functions can be tested isolated in the CSSD - (MD-24 (not used): Components must be exchanged before surgery to suit *UKA (knee)*)
E: bone-shaping robots experts	2	original modularity is kept	- MD-18 (high): Functions can be tested isolated in the CSSD - MD-10 (high): Efficient service and maintenance (functioning) - MD-~~24~~→**9** (high): Advantages through black box engineering - MD-29 (medium): As few assembly tasks as possible
F: mixed team with expert in surgical robotics and risk analysis	3	- Mostly kept as it is. Only the screen on the camera cart is split to be optional (also for other SDC-compliant systems). - For PSP, the feed (velocity) is automated and only initiated by the user. Therefore a motor is needed to drive the relative motion between guide sleeve and robot.	- MD-~~10~~→**61** (high): *Reuse components* - MD-~~29~~→**43** (high): Minimal occupied space around the operating table (OT space) - MD-~~24~~→**60** (medium): *As less handling steps for the user as possible* - MD-9 (low): Advantages through black box engineering
G: mixed team with expert in surgical robotics and risk analysis	2	- One motor unit, the rear motors, is fixed to the base plate to facilitate assembly and still enable different configurations. - The rest is kept as it was.	- MD-18 (high): Functions can be tested isolated in the CSSD - MD-~~10~~→**49** (high): Mating components cannot be assembled incorrectly - MD-29 (medium): As few assembly tasks as possible - MD-23 (low): Components can be reused for: UKA (knee)
H: mixed team with surgical robotics expert	3	- The base plate and the kinematics modules are spine-specific, the motors are generic. Therefore, the base plate is fixed to the kinematics modules. - The motor units are split to reuse individual motors for other arrangements. - The arm, base plate, motor unites and kinematic units are draped.	- MD-~~10~~→**15** (medium): Lead times of sterile reprocessing are short or prevented - MD-29 (medium): As few assembly tasks as possible - MD-~~24~~→**9** (medium): Advantages through black box engineering - MD-18 (low): Functions can be tested isolated in the CSSD

Team B, which was inexperienced with surgical robots (none), modularization (none), the use cases (both 2 on the Likert scale), and did not know the systems before, exploited the fact that the base plate and the kinematic modules are specific for spine, knee, and hip applications. Team B suggested to pre-assemble the base plate and the kinematic modules during the manufacturing process and thereby meet the selected module drivers. Since always two motor units are used for the spine, knee, and hip applications, team G suggests to pre-mount the rear motor unit onto a universal base plate having different interfaces at application-specific locations for the frontal motor unit. In the original MINARO system, the connection of the kinematics to the base plate is made by using the motor units as connectors. Since the motor units are not application-specific, team H wanted to only mount the motor modules to the kinematic modules and directly mount the kinematic modules at the base plate during manufacturing. Only team H suggested to drape the system.

PoV Framework

The PoV framework was assessed positively in all aspects. As illustrated in Figure 8.9, the mean values were always higher than 4 points on the Likert scale. The value given by those that had *rather high* or *high* expertise with hazard or risk analysis methods was even higher. One user mentioned that he or she missed an economical PoV. The subjects were guided through the PoVs as a group while corresponding examples were shown. Before, the subjects had been instructed to note on the SD sheet whether they identify a hazard relevant for their modularity scenarios. They were told to focus on the ROSA ONE scenario but also identified hazards for the MINARO scenario. The results are shown in Table 8.4.

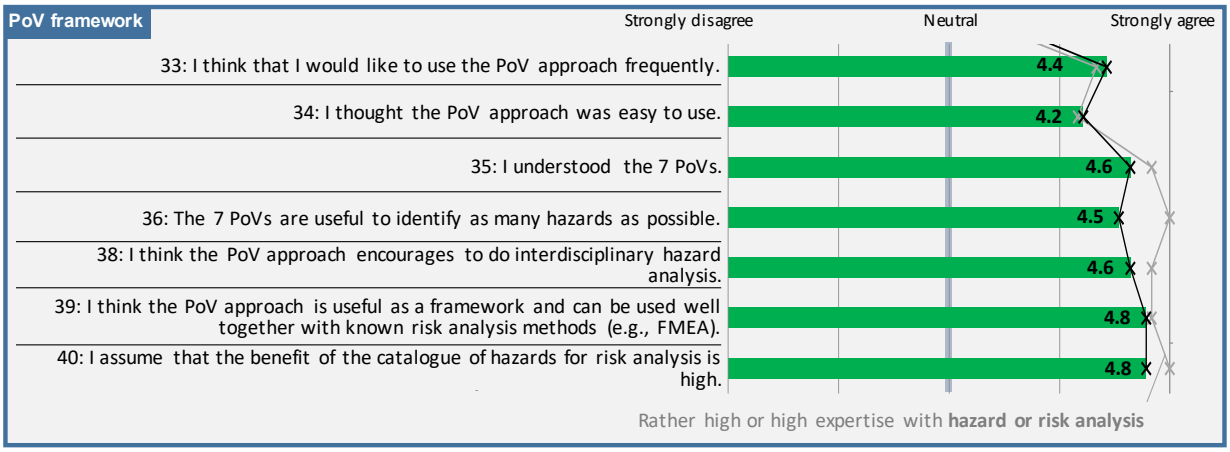


Figure 8.9: Evaluation of the checkbox questions in the category *PoV framework*; PoV= Point of View

Table 8.4: Hazards identified for the modularity scenarios after going through the seven points of view (PoVs); CSSD= Central Sterile Services Department

	Hazards based on the PoV-approach
Team B	ROSA ONE scenario: - PoV-4: falling of the arm during the transfer from the cart to the rail must be avoided - PoV-5: how does the arm react in case there is no signal from the camera and no information about the current position? - PoV-6: arrays must never be able to move relative to their fixation MINARO scenario: - PoV-7: incorrect assembly is possible. The interfaces should always be unambiguous
Team C	MINARO scenario: - open interfaces of the drivetrain that are required for isolated testing may be hazards when tested in the CSSD
Team D	MINARO scenario: - PoV-7: cleaning of combined modules may be a challenge
Team E	ROSA ONE scenario: - robot does not fit on the table for obese patients. - removal of the robot in case of sudden bleeding is difficult. - crushing of the patient when attaching the robot. - dropping of the robot - robot on table restricts accessibility (partially).
Team G	ROSA ONE scenario: - possible false feedback through remote control - robot could collide with camera - line-of-sight problems
Team H	ROSA ONE scenario: - PoV-2: sudden bleeding - PoV-4: falling/ moving parts, too fast, too much - PoV-5: camera vibrates - PoV-6: collision with camera and lights, line-of-sight problems MINARO scenario: - if the passive arm is released, it may collapse since the user carirers all the weight and the robot could fall down.

Computer Assistance with Hazard Integration

The idea of computer assistance was presented as an opportunity to facilitate the specification of a use case, to check compatibility of function carriers for a use case, to suggest suitable function carriers to the design engineer, and to link function carriers to solution-inherent hazards. After the presentation, the feedback was consistently positive. The comments of the audience were as follows:

1) The possibility to instantly notice when all known solutions are not properly fulfilling their function would push for innovation.
2) Target functions could be defined, and automated parameter comparisons could result in a calculated weighting of module drivers.
3) It could be difficult to automate the rating regarding evaluation criteria that do not refer to isolated function carriers but to the overall product.
4) Computer assistance would be important to enable the development of rather abstract concepts and their later specification.
5) It seems to be beneficial that also hazards could be assigned to function carriers and considered in a very early stage of development.

6) Quantifiable risks that grow, for instance, with the size of a component, could be calculated.
7) How can different configurations (e.g., MINARO configurations) be distinguished from new products? Must the design engineer be an expert of the systems to be able to differentiate between them?
8) The idea is very good.
9) Computer-based mapping seems to be useful, also the idea of using colors within the graphical user interface to indicate compatibilities. Integrating hazards helps to keep them visible.
10) Integrating hazards as properties of function carriers would be great. Thereby, experiences with former products can be reused for the approval of new products. Such an approach could also have a huge benefit for regulatory authorities.

Reference Functions

Finally, the subjects were asked about the usefulness of reference functions as a link between surgical requirements and technical solutions. One person was familiar with function-based development from his or her company and thinks the approach is beneficial in promoting solution-neutral development. The other subjects saw reference functions as positive to foster innovation, to avoid redundancies, to integrate off-the-shelf modules (black boxes), and to enable modular risk management. One subject suggested to use elementary functions instead of reference functions to cover a greater solution space. Two other subjects underlined the benefit of using predefined functions as a recipe that encourages engineers to design for functionality. They have experienced that industrial partners have not considered it necessary to use function structures for product development.

8.1.2 Conclusion

The questions 1-8 of the questionnaire aimed at getting the participants' general attitude towards modularity. Most of the participants attributed modularization a high to very high benefit for manufacturers, hospitals, surgeons, and particularly the benefit-to-cost ratio of surgical robots. The opportunity to improve the surgical outcome and the clinical and surgical workload using modularization has been ranked higher than three points on the Likert scale. The limited confidence regarding safety, surgical outcome and workload could be explained by the fact that modularization is often understood as the decomposition of larger modules into smaller ones, which would always lead to more interfaces. In other words, modularity is confused with granularity. In the context of this work and in the questionnaire, modularization was meant bidirectionally,

standing for the possibilities of a systematized restructuring of module candidates, potentially also into more integral modules.

The module drivers have been rated positively overall. However, a neutral formulation should be strictly adhered to in the future and additional examples seem to be necessary. More open formulations like *as reasonable* instead of *as possible* (see MD-29: *As few assembly tasks as possible*) should be aimed for. During the workshops, the need for an additional module driver *functions can be tested combined in the CSSD* (or similar), became clear. Remarks on the formulation of MDs could be addressed by allowing reformulation prior to application and thereby steepening the learning curve. Since the benefit of the production-based module drivers was hard to assess by the participants of the study (Q19), the next formative evaluation should further be done with industrial experts that manufacture surgical robots while using one or more of their robots as use case examples.

The functionality of the modularization tool has been seen as highly consistent (Q27). Shortcomings only address the user interface, which was preliminary implemented within the possibilities of Microsoft Excel and must be refined in any case. For future applications, two scenarios can be differentiated: The modularization tool could either be implemented as a consistent software package, or as part of an open (paper-based and software-supported) toolbox. While a consistent software package could be better integrated into PLM systems and permanently applied by an experienced design engineer during development, a toolbox could facilitate the conduction of dedicated modularization workshops. An expert of the method would still be required, but he or she could guide also unexperienced participants through the process.

The possibility to add new function carriers was missed by some users and could be easily implemented in a software. In the workshop approach, the SD sheet could be extended by some blank columns. To avoid neglecting any strategic goals, evaluation criteria for concept assessment that are not related to modularity should always be considered together with the modularization criteria, the module drivers. As suggested by one respondent, system scores could be formed before and after modularization, which use all evaluation criteria. The first would measure the quality of the original concept and the second the quality of the improvement. Since these scores would address two scenarios of the same system and maybe even the same concept, the term *scenario score* seems most appropriate. In any case, the module drivers would have to be absolute, meaning not be formulated as an improvement.

Since the users had some ideas for MMs that could not be assigned to the selected MDs, either an additional area should be provided in which driver-independent improvements can be entered, or instead of MDs, only the MD categories should be provided for deriving MMs. The users could then still have a list of MDs to help them but could also allocate their own ideas to one of the more general categories.

The module operators (keep, split, combine, remove function, insert function) have been understood but some users missed an *exchange* operator to exchange an entire function carrier and a *transfer* operator to remove several functions from a function carrier and add them to another by using just one operation. The need for a *transfer* operator could be mitigated if the modularization tool did not use a dropdown menu but allowed to select more than one function per operation. Exchanging the function carrier could change the underlying concept, which seems to be appropriate if scenario scores encompassing all evaluation criteria were used. The operator *keep* should be renamed to avoid misunderstanding. It could be named *module* to clarify that the corresponding function carrier shall remain a standalone module.

It is remarkable that the modularity of the ROSA robot was changed in all teams (Table 8.2), while three teams kept the modularity of the MINARO (Table 8.3). Also, in six of the eight teams, fewer MMs were applied to the MINARO than to the ROSA. This may be coincidence, may represent a learning effect, may be related to the pre-selected module drivers, but may also mean that the ROSA has a higher optimization potential than the MINARO. However, the fact that for three teams the modularity of the MINARO remained the same despite applying different MMs confirms the modularity of the system and indicates the possibility of using the tool to confirm a well-modularized system.

The recommendation of one of the experts to include an economic perspective in the PoV framework is plausible since every risk analysis aims to weigh up risks against benefits. However, the benefits of the examined concepts are already represented by corresponding module drivers during modularization, which is why the PoV framework was developed exclusively to identify hazards. In a sense, module drivers can themselves already be considered as PoVs concerning the use value of a product. Still, should the PoV framework be used in another context for risk analysis without modularization, additional PoVs regarding the overall benefit would certainly be useful.

The function-based modularization was perceived as good by all subjects. Chapter 4.3.2 already explained why the use of elementary functions, as suggested by one participant, would not be

appropriate. However, one team was confused about how the reference functions were formulated. It was criticized that F3.1: *mechanically constrain the DoFs to a surgical plan* only allows purely mechanical and no mechatronic solution principles. In the sense of the method, the word *mechanically* aimed at clarifying that unwanted motion must be prevented by means of rigid bodies. It is irrelevant whether the actuation is electromechanical or, for example, hydraulic. Nevertheless, a more understandable formulation could be found. The aim is to express that a solution principle is searched that physically (not virtually) limits the DoFs or, in other words, the mobility of an end-effector to the surgical plan. An alternative function name could be F3.1: *physically enable only plan-required DoFs* or F3.1: *physically constrain the end-effector to a plan-required mobility* or F3.1: *physically implement the planned geometry*. An alternative name for F3.2: *mechanically limit progression within the DoFs* could be F3.2: *enforce plan-based limits within the allowed mobility*. *DoFs* could be replaced by *mobility* or *movability* in all cases. Either way, it makes sense to formulate names that are as self-explanatory as possible and to evaluate them against each other. Since a formulation that everyone understands without an associated explanation is not possible, the SD sheet should further be supplemented by a short description of the reference functions in addition to the explanation in the presentation.

8.2 Interface Design Checklist

A formative evaluation was conducted with 12 subjects one after the other to evaluate the DfIA checklist. Nine subjects (75%) were mechanical engineers, three (25%) electrical engineers. Seven subjects were research assistants and five students. All subjects worked in projects with companies from the medical device industry at the time of evaluation. Each subject was given three tasks. The first task was a practical assembly task of selected modules of the MINARO system. MINARO was selected because a working prototype of the final product could be used with interfaces that must be sterilely reprocessed. The second part was applying the checklist. Subjects who had not yet designed an intraoperative interface could refer to the interfaces of the MINARO system they had become familiar with. The other subjects were free to refer to any interface they had designed personally. In the third part of the study, the test persons were given a questionnaire with 16 questions. In addition, the workload of applying the checklist was evaluated using the five NASA-TLX scales for mental demand, physical demand, performance, effort, and frustration level. The temporal demand was neglected since the evaluation time was not limited. The average duration of the evaluation was one hour. Furthermore, the scales were not weighted against each other, as this would require a strong awareness of the benefit of the checklist in the context of use, which could not be presumed. The application of the NASA TLX

without weighting is known as Raw TLX (RTLX) and is the most common modification of the index [Hart 2006].

8.2.1 Results

Five of 12 subjects have already designed or are currently designing an interface for use in surgery or the operating room (Figure 8.10). Another three have designed a mechanical interface for other applications. Of these eight persons, four indicated that they have proceeded systematically, and six made use of risk analysis.

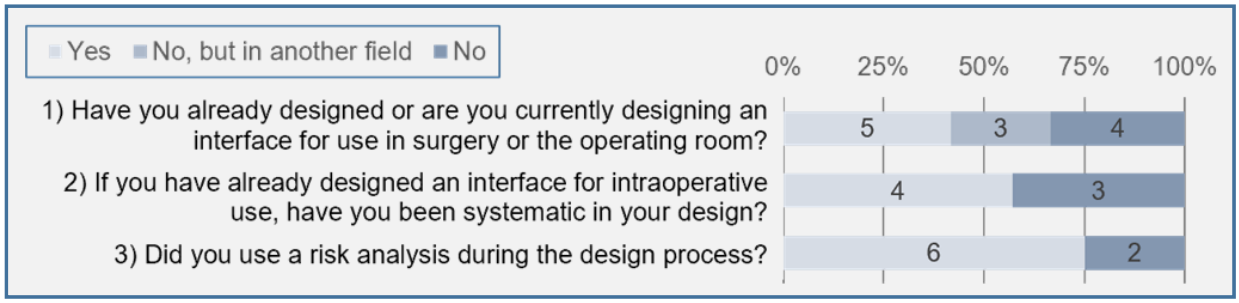


Figure 8.10: User profiles - experience with interfaces, design methodology, and risk analysis

Checklist Design

The results of the NASA-TLX section are presented in Figure 8.11. Boddy and Smith [2009] suggested to only use a box plot representation for sample sizes higher than 15 values. Since, on one hand, only 12 individuals completed and evaluated the checklist, but, on the other hand, the quartiles and the median are demonstrative parameters, box plots were created and supplemented with the 12 individual values for each workload category.

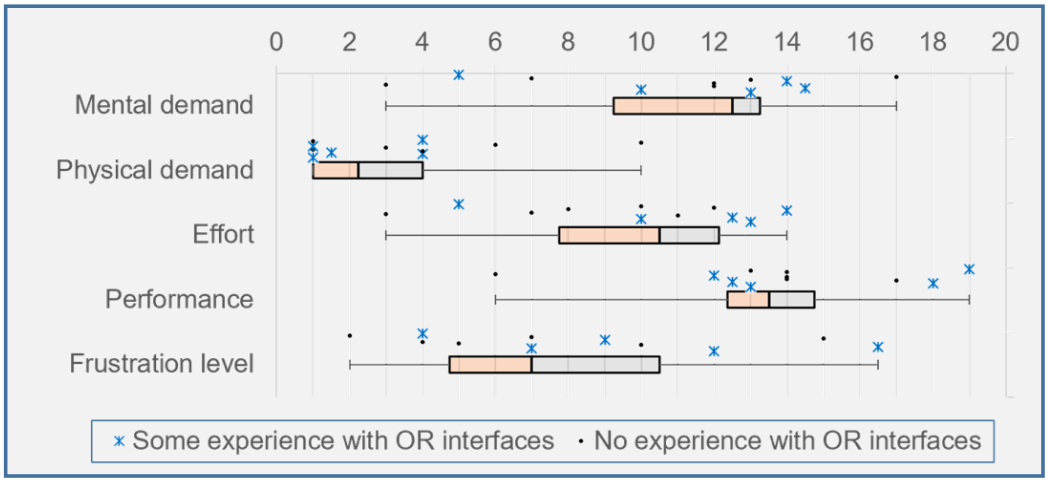


Figure 8.11: Subjective workload assessment using the categories of the NASA Task Load Index (TLX), except for *temporal demand* [Hart and Staveland 1988].

No notable differences are apparent between users with and without experience. However, perceived mental demand and effort were rather high. Also the performance and the frustration level leave room for improvement. The answers to the questions regarding the presentation format of the checklist in Figure 8.12 provide some explanation.

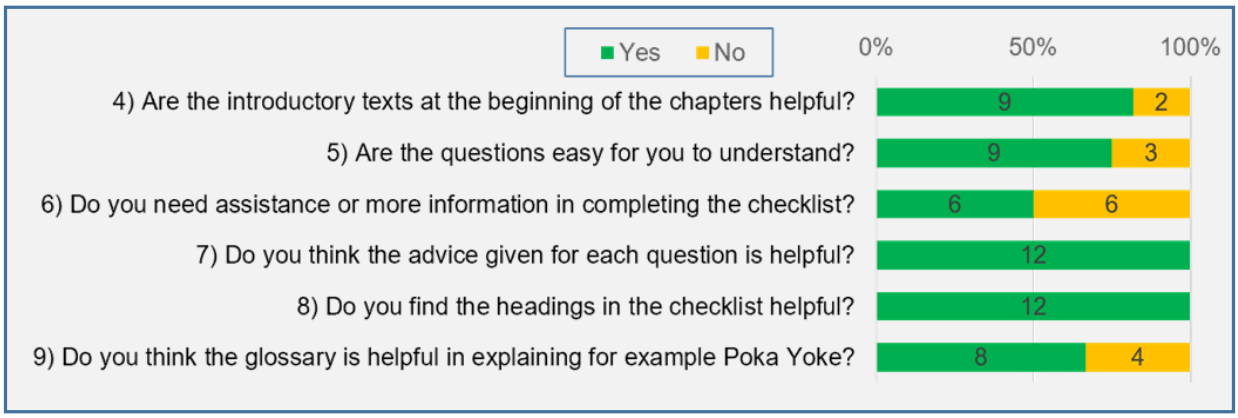


Figure 8.12: Questions related to the design of the checklist

Relating to the first questions, one user stated that he or she is experienced but cannot imagine that an unexperienced user understands the recommending questions of the checklist. Accordingly, another user without experience mentioned that he or she didn't read the introductory text of the checklist because it was not comfortable to read. Users who found the recommendations difficult to understand referred to inverted questions that changed the meaning of the standardized response options. More information was desired regarding 1) the behavior of the component materials, such as the sensitivity to corrosion, 2) the use scenario, and 3) references. Most users who questioned the value of the glossary would have preferred footnotes.

Overall Benefit

The answers to the questions regarding the general usefulness of the checklist are shown in Figure 8.13. All users responded that a checklist would be useful for designing a robust and hygienic interface, that the presented checklist would support them and that they would recommend the checklist. Five users felt that detail questions from other domains were missing, such as electronics, but were aware of the fact that a universally applicable checklist cannot be complete, in any case.

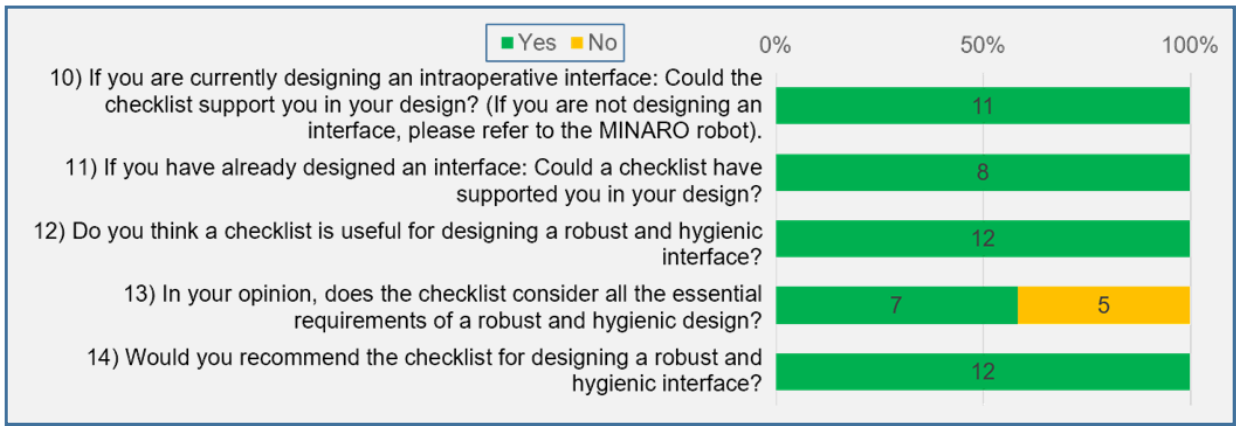


Figure 8.13: Overall benefit of the checklist

In question 15, the users were asked to mark in a flow chart (Figure 8.14) at which stage of development they think the checklist should be applied. Multiple answers were allowed.

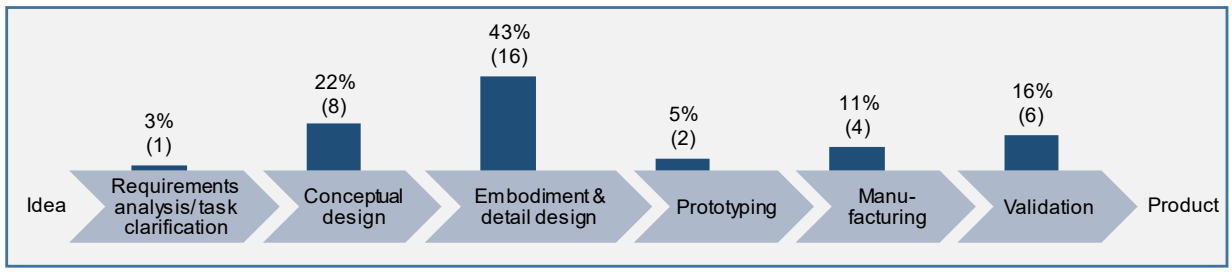


Figure 8.14: Benefit of a DfIA checklist by stage of development, based on VDI 2221:2019; DfIA= Design for Intraoperative Assembly

The last question asked for additional comments about the checklist. Four comments referred to the formulation of questions and the answer options. Two users noted that their own knowledge was not profound enough to answer all questions.

8.2.2 Conclusion

The usability of a modular surgical robot depends to a large extent on the usability of its intraoperative interfaces. Although human-machine interaction, which addresses intraoperative interfaces, must be evaluated for the final product, design errors must be discovered as early as possible already during the design process to save time and money, and to enable most effective solutions. As a first step into that direction, a first version of a checklist for the design of intraoperative interfaces was elaborated and evaluated.

Questions 4-9 and 15 confirmed that the design of the checklist still needs improvement. This was expected since the evaluation was initial, formative, and iterations are desired. For instance, questions regarding electric safety or electromagnetic compatibility have not been considered, yet, but would be useful.

The need for a checklist in general and the value of the information of said checklist was assessed high according to the questions 10-14. Regarding the assignment to development stages, the highest benefit was seen for the conceptual, embodiment, and detail design stage. These are the stages in which the design engineer has the most influence.

Although the checklist was considered valuable for validation, this result must be critically questioned. A checklist for verification, in other words for checking requirements, is useful in any case. However, the goal of such a checklist is different. A development-accompanying checklist with general design recommendations must be less strict to only give ideas which may also be disregarded. A quality control checklist, on the other hand, aims at fulfilling previously defined requirements. Within MBSE it would be possible to create a kind of checklist database, from which individual documents for design recommendations and quality assurance could be created using different questions and answer options. In this context, also domain-specific checklists could be drawn from the database. A mechanical engineer could get a different checklist than an electrical engineer, for instance.

On one hand, the checklist could be constantly updated. On the other hand, too specific recommendations and references to standards mean that the status of the checklist would have to be checked on a regular basis. Furthermore, there would be a risk that, if the level of detail were too high, the user would rely on the perceived completeness of the checklist. As already suggested for the modularization tool, questions should rather be formulated as categories, with exemplary explanations in the information texts. Although this has already been attempted, the effect can only be evaluated conclusively if a newer version of the checklist is used during development and a control group carries out the same development in parallel without the checklist. Only then it can be checked whether the group with or without the checklist has considered standards that were not mentioned or has forgotten relevant aspects.

9. Discussion and Outlook

According to Stoianovici [2000], the development of surgical robots is more demanding than for industrial applications due to the criticality of working on human beings, the need for sterility and compactness, compatibility with medical imaging equipment, special requirements to ergonomics, and other specific operating room requirements. Based on this and on various references presented in Chapter 1, four major challenges of today's surgical robotics have been defined: (benefit-to-) costs, clinical (workflow) integration, intraoperative safety, and surgical outcome.

Motivated by the four presented major challenges of surgical robotics, this work aimed at providing a solution approach based on systematic modularization. While in industry the benefit-to-cost ratio is increased by reducing internal variety and maintaining or increasing external variety [Krause et al. 2021; Robertson and Ulrich 1998], it was hypothesized that for clinical operators, modularization can reduce device variety and increase application variety, as already indicated by Taylor and Stoianovici [2003]. In addition, it was assumed that modularization in the form of spatial decomposition could achieve positive downsizing effects. For instance, safety risks could be spatially constrained and mitigated. Examples have been provided by Brandt et al. [2000], Pott and Schwarz [2007], Niggemeyer et al. [2012], de la Fuente et al. [2013], and Vossel et al. [2021]. Since additional spatial interfaces and intraoperative assembly processes may arise and could increase workload as well as create new hazards, in this work, modularization was seen as a bidirectional process that can lead to both, increased and decreased granularity. For this purpose, a systematic approach is important that reconciles all goals of multidimensional and therein bidirectional modularization (such as splitting and combining with regard to integrity) in a traceable, functional, and value-based manner.

A modularization method was developed which is criteria-based on the one hand and functional, or function-based, on the other. The inclusion of weighted criteria enables pursuing strategic goals, whereas the inclusion of functions supports functionality of the modularized robot. Furthermore, the modularization method was embedded into an integrative process model of modularization and risk estimation (MORE model), and first steps were made into the direction of Model-Based Systems Engineering (MBSE) to be able to benefit from leverage effects that computer assistance could provide. Subsequently, a design aid for intraoperative interfaces was developed as a useful supplement to modularization, since modularization not only forms modules but also interfaces, including critical intraoperative interfaces. A first formative evaluation revealed important improvement potential for further development.

First, state-of-the-art modularization methods were examined and assigned to two categories: similarity-based modularization methods and dependency-based modularization methods [Gershenson et al. 2004]. Within the latter, interfaces are the starting point of modularization. Interfaces can be optimized quantitatively, in terms of reducing the number of interdependencies [Steward 1981; Hölttä-Otto and Weck 2007], and qualitatively, based on the type of interdependencies [Pimmler and Eppinger 1994]. Similarity-based modularization, on the other hand, focusses on similarities of modules according to certain criteria. Different methods have been presented by Ulrich [1994], Erixon [1998], Park and Simpson [2008], Politze et al. [2012], and Ulrich and Eppinger [2016].

Criteria-based modularization after concept development turned out to be the most beneficial approach and complies with common procedural models for medical device development, such as the FDA stage-gate process [FDA 2018], the Stanford model [Pietzsch et al. 2009], the V-model by VDI/ VDE 2206:2021, the product development process by VDI 2221:2019 and the usability process according to IEC 62366-1:2015 and EN 60601-1-6:2016.

Among the compared and frequently cited similarity-based approaches, the Modular Function Deployment method by Erixon [1998] is the most comprehensive. The method uses the Module Indication Matrix (MIM) as a tool to apply 12 economic and generic pre-defined module drivers onto module candidates (MCs). Based on this, the compatibility of the method with the needs of robot-assisted surgery (RAS) was investigated. Three aspects have been examined: module operators (the means of modularization), purpose fulfillment (functional and strategic), and the modularization scheme (the structural framework for decision making). Although different dimensions of modularization exist (integrity, variety, functionality, redundancy), the following module operators have been identified to be sufficient for spatial modularization: *combine* two or more MCs, *split* the MC into two or more modules and *keep* the MC as an independent module.

The strategical purpose is driven by criteria, the module drivers. For all 12 generic module drivers, positive or negative examples have been found among 15 representative surgical robots. Five could be specified to additional RAS-specific module drivers. During a comprehensive literature review and under consideration of the four challenges of surgical robotics, further context-specific RAS-specific module drivers have been formulated. The total of 59 module drivers (12 generic, 47 RAS-specific) were generalized and reformulated into 21 *aspects that need improvement in today's surgical robotics* to increase comprehensibility for a user-friendly online survey targeting surgical experts. Of the 51 experts that were surveyed (23 surgeons, 22 engineers, three OR managers, and three others), all aspects were rated as needing improvement. The

greatest need was seen in acquisition costs (need of 81%), operational costs (80%), maintenance costs (75%), and footprint in the OR (74%). In total, most of the averaged values were between 60% and 90%, which strengthens the hypothesis that the identified module drivers are underrepresented in today's surgical robots. Besides, the large differences observed in how some module drivers are evaluated by different professions highlight the importance of involving multiple stakeholders. For instance, the possibility to move a system to other operating rooms was ranked 32% higher by the OR management than by surgeons. The total operating time and independence from technical support were 17% more important for the engineers than for the directly affected surgeons. The reasons for this could be misjudgments made by the engineers, but since all engineers have already had experience with surgical robots, 36% of them intensively, it can rather be assumed that the engineers are better able to assess technical optimization potentials due to their technical expertise.

Besides the strategic (criteria-driven) modularization, functionality of the modularized robot was aimed for. Reference functions were defined as generic templates to be able to derive specific functions for any surgical use case and to assign solution principles or function carriers to these functions. To ensure suitability of the reference functions to diverse robots, a purpose-based (bottom-up, inductive) and a market-oriented (top-down, deductive) approach were combined. The inductive approach followed the principles of function synthesis according to VDI 2221:2019 [Feldhusen and Grote 2013; Koller 1998]. The deductive approach, also known as reverse engineering, used functional analysis by VDI 2803:2019. 15 reference functions have been formulated of which 11 have been classified as having a direct impact on spatial modularity.

Regarding the suitability of the matrix-based modularization scheme, an adaptation of the MIM by Erixon [1998] was applied to the MINARO robot. Of the 12 generic and the 47 RAS-specific module drivers, only those were applied that could be assessed at the MINARO's current stage of development. Since the modularization scheme and not the MINARO itself was to be evaluated, module drivers derived from MINARO could also be used. Furthermore, each module driver was weighted and for each matrix entry the MC-specific strength of the regarded module driver was replaced by the operators *combine*, *split*, *keep,* and *cannot be assessed*. For each MC, the column sum of each operator was formed, so that tendencies became visible. The matrix scheme works, but limitations became clear: 1) it is not easily possible to specify which MCs should be combined with each other and under which conditions, 2) to specify the improvement potential of an operation with respect to the considered module driver, each cell would have to be filled twice: with the improvement potential and the operator, 3) operators referring to the functional domain would be useful and could be added to the matrix scheme, 4) an assignment

of module drivers to technical product lifecycle stages would make sense to locate interfaces, 5) the matrix structure tempts to proceed line- and column-wise (meandering), especially with inexperienced users, which can significantly increase the complexity of use, 6) only one operation per MC and MD is possible, which is not always useful. As a solution, the matrix structure was replaced by a list structure that allows for multiple operations, rating of operations and specifications. A syntax was elaborated that allows each modularization measure (MM) to be logically interpreted. The product of a weighted module driver and a rated operator applied to at least one MC gives the strength of an MM. Additionally, the module operators *remove function* from MC, and *insert function* into MC were defined to include the functional domain.

Drawing an interim conclusion, the modularization approach according to Erixon could be adapted to RAS. The method can be used for product development and to identify drawbacks of commercial robots. Three follow-up questions came up: First, can the approach be merged with the risk management process of ISO 14971:2019 in a way that both support each other? Second, which preconditions must be made to enable integration into company-specific product lifecycle management (PLM) systems? And third, how to ensure high usability and safety of intraoperative interfaces?

A process model was elaborated of how modularization and risk analysis should be applied while developing a surgical robot. The first step of this modularization and risk estimation (MORE) model is an initial risk analysis. By means of the invented point-of-view (PoV) framework, hazards can be identified and archived in the catalogue of hazards (CoH). The PoV framework is a structural guide for established risk analysis tools providing seven overlapping viewpoints that lead the user through the hazard identification process and increase comprehensiveness. The PoV framework was tested on the example of robotic laminectomy. 133 different hazards were identified, associated to 108 different hazardous situations. 34 hazards were found with PoV-1 (conventional), 10 with PoV-2 (patient), 36 with PoV-3 (retrospective), four with PoV-4 (standards), 34 with PoV-5 (inherent), 12 with PoV-6 (spatial), and 40 with PoV-7 (human-machine interaction). 26 hazards of PoV-3 were found in literature, 10 in the recalls database of the Federal Drug Administration (FDA). The CoH serves as a tool to systematize the identified hazards and provide hazards from previous developments for new projects. This was motivated on one hand by the effect of predicate creep [Hines et al. 2010; Griffin 2017; Lefkovich 2018] and on the other hand by the potential leverage effect that computer assistance could create. When hazards are identified, risks can be estimated, safety measures derived, and module drivers formulated, if possible. Then, in step 2, the robot concept is revised using the modularization method. Reference functions, function carriers (the module candidates), and the module drivers

are inputs to the method. After applying module operators to modify the modular layout of the robot concept, additional modularity-based risks may occur. Thus, another risk estimation must be done (step 3).

Especially the CoH provides potential for computer assistance. The greatest benefit from computer assistance can be achieved using Model-Based Systems Engineering (MBSE), since many other product-relevant processes can be included [Blumör et al. 2017; Walden et al. 2015; Fernández and Hernández 2019]. The basis for MBSE is the ability to model system architectures. Fundamentals for modelling a generally valid reference system architecture, from which specific system architectures can be derived, have been elaborated. As a modelling language, SysML was chosen to ensure general validity. SysML is an adaptation of the UML language to physical systems [Weilkiens 2006]. A conceptual structural framework has been developed that can deal with zig-zag relationships between the functional and physical domains [Weilkiens et al. 2015] and uses block notation to model functions and solutions, which can be specified and simplified using classification and inheritance. A procedure for working with the approach was also proposed. First, a user is asked general questions about reference functions. By answering the questions, a use case is specified. Then, strategic evaluation criteria are selected and weighted, which are linked to acceptance criteria that relate the specified use case parameters to solution properties stored in a database. Subsequently, a desired degree of abstraction of the solution can be selected, so that either rough concepts consisting of principle solutions or physical effects can be created, or detailed concepts in which, for example, off-the-shelf modules can already be considered.

The effective and efficient handling of module interfaces during production is subject to company-internal quality controls and not decisive for clinical application. For the user, usability and safety of interfaces that occur in everyday clinical practice, especially intraoperatively, are much more important. Based on the industry-established design for X guidelines for product optimization regarding a specific X, a design for intraoperative assembly (DfIA) checklist was developed. Design for assembly (DfA) guidelines, hygienic aspects and lessons learned from a universal functional mock-up for robotic applications contributed to the formulation of 44 control questions of which 18 refer to hygiene and 26 to assembly.

Finally, the process model for the systematic design of modular surgical robots, with special emphasis on the modularization method, as well as the DfIA checklist, have been evaluated. The evaluations were formative in the sense of IEC 62366-1:2015 and aimed to uncover shortcomings in the current development stages and to provide direction for further developments. The user-centered evaluation of the process model was designed as separate expert review

workshops with 16 experts in total. Two robot scenarios were created to test the modularization method. The MINARO robot served as an example of high modular granularity and the ROSA ONE was used to represent highly integrated robots. The main task was to modularize both robots for being usable for pedicle screw placement and laminectomy using four of 59 module drivers and a prototypical modularization tool implemented with Microsoft Excel. The users were also introduced to the PoV framework and the catalogue of hazards as parts of the process model, and to the potentials of computer assistance. After modularizing both robots, all participants of a workshop were guided together through the seven PoVs, so that they could gain first experiences regarding the applicability of the framework to the robots they just had modularized. After an open discussion about computer assistance, reference functions, and the integration of hazards, a questionnaire was completed with questions about the user experience with the module drivers, the modularization tool, and the PoV framework. Therein, the questions of the modularization tool were based on the standardized System Usability Score (SUS) by Brooke [1996] in order to already cover standardized criteria, which would be important for future summative evaluation.

Except for those concerning the user interface of the modularization tool, the arithmetic mean of all questions was positive. The module drivers, especially the RAS-specific drivers, were rated as helpful with high potential for improving surgical robots. Within the modularization tool, scenario scores should be implemented in the future to provide a quantitative way to compare the quality of a robot (concept) before and after modularization. Required improvements of the user interface relate to the implementation of module operators, the weighting of module drivers, and the use of module driver categories instead of module drivers in the input area. Module driver categories could be *production-related*, *OR management*, *surgical work environment*, and *others*. A list of module drivers from which strategic measures can be derived should still be provided to the user. The method could further gain added value by assigning interfaces and modularization measures to technical product lifecycle stages and provide innovative solutions based on TRIZ to answer contradicting module drivers. Overall, the modularization tool was effective in that all teams produced functional and appropriate results for the ROSA ONE and MINARO scenarios.

Feedback was also positive with regard to the reference functions. The only point of criticism was the lack of possibility to define additional functions during modularization to be able to redistribute sub-functions between function carriers. The value of the PoV framework was also consistently rated as high, since the mean scores of the rating questions were always above

four out of five points on the Likert scale, even higher when rated by experts. A total of 17 hazards were identified out of five PoVs regarding the modularized MINARO or ROSA ONE scenarios. The approach for computer assistance was seen as positive, but aroused the concern that an available database of solutions could hinder innovative new developments and creativity in general.

The evaluation of the DfIA checklist was conducted independently of the first evaluation and was carried out with 12 other subjects. Standardized questions on usability were not asked since the aim was first to investigate whether a checklist is regarded as the right tool for improving intraoperative interfaces at all. Instead, selected questions from the NASA-TLX by Hart and Staveland [1988] were integrated as an indicator for the workload associated with a checklist in general. All users consider a checklist useful for designing a robust and hygienic interface and indicated that the presented checklist would support them and that they would recommend the checklist to others. However, room for improvement was seen in the integration of domain-specific recommendations, for instance, regarding electronics.

In the future, great potential could be achieved by using checklists in combination with MBSE. A common database could be used to generate domain-specific or process-specific checklists from the same set of requirements. Domain-specific checklists could differ for electrical engineers and mechanical engineers, for instance. Process-specific checklists could be lists of non-binding recommendations for systems in development and lists with acceptance criteria for quality assurance.

The MBSE approach seems promising, but as indicated above, it is imperative to implement it in a way that fosters creativity and innovation. Furthermore, refinements of the process model for MBSE should not diverge too much from other approaches emerging at the same time. Wyrwich et al. [2021] and Jacobs et al. [2022] presented an MBSE approach that uses elementary functions to link functional requirements with principle solutions. The authors also propose to provide solution preferences to the user by means of a software tool, in their case a product configurator. However, the concern remains that elementary functions and their relations to each other already limit the solution space. Advantages and disadvantages of using elementary and reference functions as well as possibilities to merge them should be investigated. Another possibility to encourage innovation is to formulate the degree of innovation as a module driver, which could then be weighted and displayed next to the previously mentioned scenario scores. This would raise awareness of whether a search for new principle solutions would make sense. Innovation criteria could be formulated by automated comparison of use case parameters and solution properties, similar to acceptance criteria.

Consideration could further be given to streamlining the overall MORE process model to a 2-step model and thereby increasing user acceptance. The first step could be modularization and the second risk analysis. This requires that the implementation of the modularization method allows for defining new module drivers during modularization and guides the user towards the consideration of hazard-based module drivers.

Another door in the direction of medical device optimization is opened by the presented possibilities to functionally describe a system and assign function carriers to reference functions. The SDC standard family for safe and interoperable medical device communication ISO/ IEEE 11073 regulates the interoperability of medical devices in the operating room, which is seen as a system-of-systems according to ISO/ IEC/ IEEE 21839:2019. Such medical device systems are characterized through standardized Virtual Medical Devices (VMD) that represent different functionalities, similar to the function carriers of the MORE process model. VMDs are described by so-called metrics, analogous to the description of function carriers by properties in the presented MBSE approach. If VMDs were described by the same functions as used in the MORE model, SDC-compliant VMDs could potentially be created through modularization. Wickel et al. [2023] already provided an approach to transform planning-based patient-specific (PBPS) and planning independent (PI) tasks of collaborative surgical robots ([Schleer 2021], Chapter 4.3.2) into metrics of appropriate VMDs.

Finally, user interaction modeling must be integrated into the MORE process model, since the concept of use and the technical concept are interdependent and iterations are necessary. Surgical workflow models, like introduced by Neumuth [2017], could be integrated and adapted to the MBSE environment to define most suitable interaction scenarios. Furthermore, since the MORE process model has only been applied to bone-shaping robots in this work, it should be applied to soft-tissue robots in future evaluations.

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II Related Student Theses

The presented results are partly based on bachelor's and master's theses submitted to the Chair of Medical Engineering at RWTH Aachen University and on knowledge available at the Chair. The theses, which were supervised by Univ.-Prof. Dr.-Ing. Klaus Radermacher and the author of this work, are:

- Görtz, Philipp (2018): Entwicklung einer Leitlinie zur Zuordnung von Modulen robotischer Chirurgiesysteme zu geeigneten aseptischen Maßnahmen. Bachelor's Thesis.
- Reinartz, Simon (2019): Entwicklung eines modular optimierten robotischen Chirurgiesystems. Bachelor's Thesis.
- Strauch, Florian (2020): Risikoanalyse und Konformitätsbewertung für mechatronische Assistenzsysteme in der Chirurgie. Master's Thesis.
- Beerwerth, Robert (2021): Entwicklung einer Referenzfunktionsstruktur für allgemeine Chirurgieroboter. Master's Thesis.
- Mund, Maja (2022): Entwicklung von Sicherheitsprinzipien zur Konstruktion modularer Chirurgieroboter auf Basis einer Gefährdungsanalyse. Bachelor's Thesis.

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Terminology

Modularity

Complex system A large number of parts that interact in a non-simple way so that the whole is more than the sum of the parts (emergence effect) and it is not trivial to infer the properties of the whole [Simon 1962]. *Parts* can be physical but also organizational or from other domains.

Component In this work, a collective term for a part or assembly in the physical design domain. The sum of all components is the product.

Concurrent/ simultaneous engineering Activities of various departments associated to product development run in parallel or at least significantly overlap [Pahl et al. 2007]. Downstream concerns are incorporated into the upstream phases of a development process to accelerate product development, improve product quality, and lower development-production costs. [Yassine and Braha 2003]

Configuration ISO 22166-1:2021: Arrangement of modules in terms of the number and type of modules used, the connections between those modules, and the settings for those modules, to achieve the desired functionality of the modular robot as a whole.

Design domain Engineering design is made up of four domains: the customer domain, the functional domain, the physical domain, and the process domain [Suh 1998].

Emergence Emergence occurs in modularity and Systems-of-Systems and is the effect of creating properties by combining parts that go beyond the properties of the individual parts [Kopetz et al. 2016].

Function A technical function is the abstract (solution-neutral) and intentional relationship between the input and output of a (sub-)system with the goal of accomplishing a task [Feldhusen and Grote 2013; Politze et al. 2012].

Function carrier Physical component or assembly that implements a function [Feldhusen and Grote 2013; Bender and Gericke 2021; Pahl et al. 2007]. In contrast, the term *effect carrier* only describes the material that carries a physical effect.

Granularity	ISO 22166-1:2021: The degree to which a robot module can be broken down into separate modules.
Interchangeability	ISO 22166-1:2021: Module property allowing it to be capable of being used to replace another module.
Model-Based Systems Engineering	A formal application of a single integrated, consistent, and coherent system model that is the central artifact of a wide range of systems engineering activities, such as requirements definition, conceptual and detail design, analysis, verification, and validation [Walden et al. 2015; Fernández and Hernández 2019; Borky and Bradley 2019].
Modularization	Modularization is a structuring method of products under different aspects. On one hand, modularization creates independence between the elements through less strong relationships between each other and on the other hand by few standardized interfaces. [Feldhusen and Gebhardt 2008]
Modularization Measure	In this work, a rated operation using a module operator on functions and/ or function carriers to change or confirm modularity regarding a weighted module driver.
Module	A module results from a modularization process and provides the following characteristics: separability, commonality (reuse), functional binding, combinability (with other modules) and interface standardization [Salvador 2007].
Module candidate	In this work, a function, component (function carrier) or process which is subject of modularization. Modularization transfers module candidates into modules.
Module driver	A criterion or reason for modularization, based on Erixon [1996].
Module kit/ module set	Collection of different modules that can be used to configure products with different functions or only with different properties by combining these modules using standardized interfaces [Krause and Gebhardt 2018].
Module Operator	Means or mechanisms that change modularity, based on Baldwin and Clark [2000].
Product family	A set of different products that share common components and functions and target similar application areas [Blees 2011]. A product family is the sum of its product variants.

Product platform	The common set of standardizable (physical or non-physical) modules of a product family from which product variants can be derived. [Meyer and Lehnerd 1997; Hofer 2001; Hölttä-Otto and Weck 2007]
Product range, product portfolio	All products that a company offers to the market. [Blees 2011]
(Product) variant	Product variants are products that belong to the same product family. [Blees 2011]
System-of-Systems (SoS)	ISO/ IEC/ IEEE 21839:2019: Set of systems or system elements that interact to provide a unique capability that none of the constituent systems can accomplish on its own. Characteristics: a) each system can interact independently and has its own purpose, b) the individual systems of the quantity are independently organized to fulfil their purposes, c) the combination of systems delivers results that cannot be achieved by individual systems.
Technical product lifecycle	VDI 2221:2019: Technical product lifecycle consisting of the stages: product creation, product usage, and end of life. Product creation is further subdivided into product planning, product design and implementation/ production.
Technical solution	In this work, it is the collective term for any kind of the technical specification of a function. A technical solution can be a physical effect, a principled solution, a physical product, or anything in between.
Variety (internal, external)	*External variety* is externally demanded by the market and should be maximized from a manufacturer's perspective. *Internal variety* is described by the number of variant modules. Economic efficiency is achieved when a company manages to map the highest possible external variety with the lowest possible internal variety. [Krause et al. 2021; Robertson and Ulrich 1998]
Risk Management	
Error	ISO 22166-1:2021: The discrepancy between a computed, observed, or measured value or condition, and the true, specified, or theoretically correct value or condition.
Failure	ISO 22166-1:2021: The loss of ability to perform as required.
Fault	ISO 22166-1:2021: The inability to perform as required, due to an internal state.

Harm	ISO 14971:2019: An injury or damage to the health of people, or damage to property or the environment.
Hazard	ISO 14971:2019: A potential source of harm
Hazardous situation	ISO 14971:2019: The circumstance in which people, property, or the environment is/are exposed to one or more hazards.
Malfunction	Technical failure to work or operate correctly, based on Cambridge University Press & Assessment [2023]
Mistake	A human action, decision, or judgment that produces an unwanted or unintentional result, based on Cambridge University Press & Assessment [2023]
Risk	ISO 14971:2019: The combination of the probability of occurrence of harm and the severity of that harm.

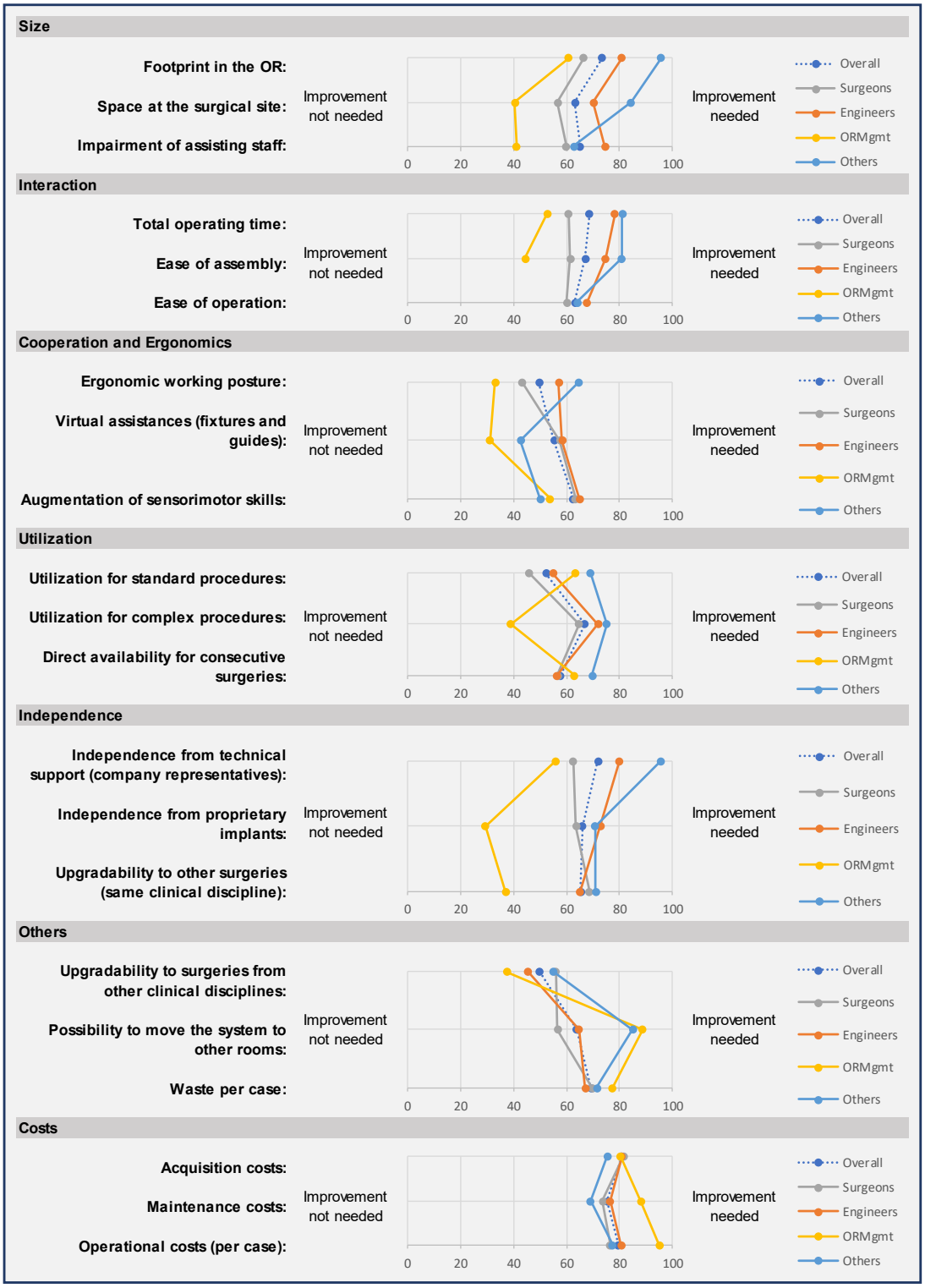
Robot-Assisted Surgery

Clinical product lifecycle	The technical product lifecycle (TPL) stage *product usage* (VDI2221:2019) specified to products used in hospitals and clinics. Clinical lifecycle stages are sterile reprocessing, surgery, and others.
Degree of Autonomy	In this work, the degree of autonomy by IEC TR 60601-4-1:2017 is specified through the degree of passivity by Troccaz et al. [1998] and divides into: passive, semi-active, synergistic, and active. Synergistic itself divides into handheld, hands-on, and telemanipulated according to Schleer et al. [2019b].
Degree of Freedom	ISO 8373:2021: A degree of freedom is one of the variables (maximum number of six) required to define the motion of a body in space.
End-Effector	In this work: The last segment of a kinematic chain.
Hip arthroplasty/ replacement	Surgical treatment for hip osteoarthritis where the acetabular and femoral parts of the hip joint are replaced (THA). [Siopack and Jergesen 1995]
Knee arthroplasty/ replacement	Surgical treatment for knee osteoarthritis where the tibial and femoral parts of the knee joint are replaced totally (TKA) or only the medial or lateral compartments (UKA). [Beard et al. 2019]
Laminectomy	The complete separation of the lamina in cranial-caudal direction on both sides of the spinous process.
Manipulator	Based on ISO/ TR 11065:1992: An actuated mechanism for grasping and/or moving objects (pieces or tools), usually in several degrees of freedom.

Minimally invasive surgery	Minimally invasive surgery is the performance of surgery through incisions that are considerably smaller than incisions used in traditional surgical approaches. Procedures are generally less invasive than traditional surgical approaches, which minimizes trauma to soft tissue, reduced post-operative pain, earlier mobilization, shorter hospital stays, and faster rehabilitation. [Hagag et al. 2011]
Pedicle Screw Placement	Pedicle screw placement refers to the instrumentation of pedicle screws as parts of a Fixateur interne [Dick 1987] used for spinal fusion. The screws are rigidly connected via longitudinal rods.
Registration	Intraoperative process of locating systems whose exact relative locations are mechanically decoupled but important to the execution of the surgical plan, such as the patient anatomy, handheld instruments, end-effectors of surgical robots, and pre-operative or intraoperative images.
Medical discipline	In this work, a branch of medical practice that describes a speciality like orthopedic surgery, neurosurgery, cardiology, dermatology, oncology.
Spinal decompression	Surgical treatment of a spinal stenosis, e.g., through laminectomy. [Austevoll et al. 2021]
Spinal fusion	Two or more vertebrae are joined together. Instrumented fusion is the use of pedicle screws, rods, plates, or other implants to assist in achieving fusion between vertebral bodies by bone grafts. [Austevoll et al. 2021; Wiesel and Delahay 2011]
Surgical procedure	In this work, a procedure that is needed to conduct a surgical treatment – in combination with other procedures, as part of other procedures, and also for other treatments.
Surgical task	In this work, a purpose-oriented task required to complete a surgical procedure – in combination with other tasks, and also in other procedures.
Surgical treatment	In this work, a surgery that is indicated by a clinical diagnosis.
Turnover time	The turnover time (TOT) is the time required to clean and prepare an operating room (OR) between two surgical cases. [Cohen et al. 2020]

Appendix

Appendix I Distribution of Expert Feedback by Profession



Appendix II Module Drivers

Module Drivers		Explanation and Examples
Production-related (generic, based on Erixon [1998])		
1	Advantages through carry over	Components can be reused over product generations or families. Indicators are: a) components can persist over multiple product generations, b) components can persist over multiple products c) components have a high impact on the company's image; Example: The "super-flat" motor from the Sony Walkman that survived at least two consecutive product platforms from 1984-1990.
2	Master technological evolution/ technology push	The aim is to master technological evolution during a component's lifecycle with as little effort as possible. Indicators: a) Components are affected by expected, radically changing customer demands or technical progress. Examples: from micro-USB to USB-C, from screen to VR, better camera solution
3	Ability to plan design changes or approval	…according to a company's strategy. Indicator: Attributes of function carriers will be changed according to a product plan. Example: a car manufacturer could plan the transition to e-mobility. Approval: Components that require sophisticated studies and effort to get approval can be separated. Example: If parts of the product are critical in terms of usability or reliability. E.g., the approval process for the Cirq robotic module ran in parallel with gathering field experience with the approved Cirq arm and passive end-effector.
4	Efficient technical specification (horizontal leverage)	The aim is to reduce complexity caused by the creation of variants through specification as late as possible in the product creation process. Variants for different market regions leverage products across markets. Indicators: Components vary with regionally different power grids or standards. Examples: AC power plugs and sockets; The delivery of an ink-jet printer is simplified if power units for different market regions are separated modules.
5	Efficient styling	The aim is to influence the appearance of products in a simple way. Indicator: Form and colour of components are affected by trends and fashion or brand or trademark or have a signal character. Example: The case of a MAC book.
6	Advantages through scaling	From a manufacturer's perspective, the module driver addresses the strategy economies of scale: Standardization results in an increased volume of certain components. From the user's perspective, configurability increases versatility of use. Indicator: Components can be used in multiple product variants or configurations. Example: tracking arrays.
7	Advantages through process and/ or organization reuse	The aim is to increase the integrity and efficiency of teams and the efficiency of machines. It provides an opportunity for automation. Indicators: Components share machine or personnel ressources.
8	Separate testing or evaluation of functions	The aim is to increase the efficiency and effectiveness of quality management in production. Indicator: Functions can be tested isolated in manufacturing.
9	Advantages through black box engineering	The aim is to improve administration and to reduce costs of purchasing, production, development and side costs by buying modules from one major supplier instead of many minor or none. Indicators: A specialist supplier can manufacture components at lower costs or provides better know-how to produce or develop the components; ressources can be used more efficiently by outsourcing the production; components are not crucial for the product's performance or market differentiation.
10	Efficient service and maintenance (functioning)	The aim is to release functional couplings between modules that are sensitive for service and maintenance. Indicators: components belong to a mechatronic function module (sensing, processing, actuation), have similar maintenance intervals or similar sensitivity to malfunction. Modules that provide functions of sensing, processing and actuation can be exchanged, produced and tested as a whole. Example: the arm segments of the MAKO robot.
11	Efficient upgrading (vertical leverage)	The aim is to leverage products across market tiers (e.g. to provide standard versions, premium or user-specific variants with better user acceptance). Indicators: components carry surprise or delight attributes (Kano model); users require alternative solution principles for the same function; components provide a functional augmentation. Example: the possibility to move a burr in a hands-on mode or telemanipulated according to user preferences; an additional display at the end-effector to improve hand-eye coordination.
12	Efficient recycling	The aim is sustainability and refers to recycling after the product's lifetime. Indicator: component contains highly polluting material.
OR management		
	Sustainability	
13	Waste per procedure is low	e.g., the number of drapes or disposables can be reduced if components are reprocessible.
14	Energy consumption associated with sterile reprocessing is low	e.g. by using more drapes, cases or disposables
	Availability of components in the OR (refers to pre- and post-surgical procedures)	
15	Lead times of sterile reprocessing are short or prevented	Using disposables or drapes can increase independence from the sterile reprocessing time.

16	Operational readiness is independent from suppliers	Sterile reprocessing increases independence from manufacturers - e.g., during the corona crisis it was temporary difficult to get disposables from Asian countries. Sterile reprocessing instead was still possible.
	Sterile reprocessing	
17	Components fit into a standardized sterile container	
18	Functions can be tested isolated in the CSSD	CSSD= central sterile services department
19	Components are compatible with the same sterility procedure	e.g., batteries must be removed from a steam-sterilizable power tool or batteries must be avoided
20	Gas sterilisation with ethylene oxide is prevented	to enable sterile reprocessing inside a hospital, because sterilization with ethylene oxide is not possible there
	Versatility of use cases	
21	Drive components can be reused for various DoFs in the same use case	Examples for drive components are acutators, PCBs or batteries. The number of actuators may be reduced if the DoF can be acutated sequentially. E.g., positioning a guide sleeve for PSP requires 4 DoF which can be actuated sequentually. The Smart Screwdriver is an example where 4 drivetrains were unified to 1.
22	Drive components can be reused for various configurations and use cases	E.g., batteries could be reused for other use cases/ configurations/ tools
23	Components can be reused for: _____	Refers to a specific surgical discipline/ treatment/ procedure/ task. This module driver can be used multiple times. Attention: Function carriers that suit more use cases should not disadvantage a single use case (pareto principle). For instance, the Versius system occupies little space compared to the daVinci robot if only two arms are needed, but more space if four arms are needed.
24	Components must be exchanged before (!) surgery to suit: _____	Refers to a specific discipline or treatment. This module driver can be used multiple times. Addresses use case specific module, e.g., the end-effector modules of MAKO and Cirq.
25	Components must be exchanged during (!) surgery to suit: _____	Referes to a specific surgical procedure or task. This module driver can be used multiple times. Addresses use case specific modules. E.g., the robot can be re-configured during surgery to switch from pedicle screw placement to laminectomy.
	OR network integration	
26	Stand-alone systems can be combined with other devices in the OR network	E.g., "systems of systems" according to ISO/ IEC/ IEEE 21839:2019 that comply with the SDC standard IEEE 11073. E.g., displays and footswitches can be shared and virtually modified to the context.
Surgical work environment - The aim is to ease the pre-/ intra- and post-surgical tasks that must be done in the OR to conduct a surgery		
	Minimal workload for pre- and post-surgical processes (including robot setup and take-down)	
27	Simple and effective cleaning and disinfection of components	E.g., by splitting parts that are difficult to access with cleaning agents
28	Only lightweight components are carried by the staff for setup and take-down	Refers to the physical workload during assembly and setup.
29	As few assembly tasks as possible	The aim is to keep the number of assembly tasks as low as possible but only if not inhibiting the purpose of the product.
30	Components can be assembled before they are made sterile	E.g., components could be first assembled and then covered with a drape. The aim is to reduce the risk of contamination.
31	Sterile barriers are as few as possible	The aim is to reduce the physical and cognitive workload in terms of complexity of interfaces, the draping process and the need of two persons for sterile assembly.
32	As little draping time as possible	
33	Quick assembly	Interfaces should be avoided. If they cannot be avoided, they must be as intuitive and safe as possible.
34	As few persons as possible required for assembly	E.g., a sterile power tool that uses unsterile batteries needs a sterile person and an unsterile person to insert the battery.
	Quick registration	
35	Relative motion of registered systems is avoided by design	e.g., by fixation and avoiding relative motion of sub-systems
	Minimal workload during surgery (refers to the physical and cognitive workload of staff during operation)	
36	Only lightweight components are carried by the staff during operation	refers to the physical workload during operation
37	Many possibilities of ergonomic postures during operation exist	E.g., a master input device that enables tele-operation could increase the possibilities of ergonomic postures.

38	Maximum kinematic versatility	E.g., through kinematic redundancy: 6 DoF are required to define a pose in space. In serial kinematics, additional DoF enable repositioning parts of the structure while keeping the end-effector pose.
39	Simple interaction with input devices and user interfaces	should be evaluated beforehand. Haptic guidance can help.
40	Line-of-sight problems do not occur or are limited to a small area	e.g., sequential tracking tasks could reuse a common tracking array and the associated line-of-sight
41	As few draping during surgery as possible	
	Minimal footprint and size	
42	Minimal footprint in the operating room (OR space)	e.g., robot-specific workstations could be reused for other robots
43	Minimal occupied space around the operating table (OT space)	e.g., cart-mounted robots could be transferred into rail-mounted, bone-mounted or handheld robots
44	Good visibility and access to the situs	e.g., by using small size end-effectors
	Minimal effort for imaging The aim is to locate sensitive components into modules that are outside the imaging area)	
45	Image can be made without the need to remove the system	Image degrading components can be permanently removed from the imaging region by design.
46	Image can be made without the need to re-drape the system	
47	Robot can be used for MRI operations	Hazardous MRI-sensitive components can be removed from the critical zone
	Safe assembly	
48	Components cannot fall down during assembly	Addresses function carriers that can be damaged or contaminated in case of down falling during assembly.
49	Mating components cannot be assembled incorrectly	
50	Non-mating components cannot be plugged together	
	Efficient and effective workflow	
51	Components sensitive to wear can be exchanged during surgery	e.g., burr or drill bits as well as saw blades should be easily exchanged.
52	As few repositionings as possible	E.g., the Cirq arm allows to make an intraoperative CT while keeping the arm at the table
	Kinematic safety The aim is to provide the highest level of safety, which is intrinsic safety by design. Therefore, kinetic energy must be reduced. E.g., an oversized industrial anthropomorphic arm that massively exceeds the workspace, speed and inertia needed for a surgical (invasive) task, is a safety hazard because of unnecessarily high kinetic energy.)	
53	Kinematics are not significantly oversized when used for critical tasks	The aim is to decrease the provided-to-required ratio of the surgical workspace and prevent risks of oversize. E.g., splitting functions to different components.
54	Inertial forces cannot become significantly higher than required during critical tasks	The aim is to decrease the mass and acceleration of moving parts and prevent risks of oversize. E.g., splitting functions to different components
55	RCM kinematics decrease invasiveness	The aim is to search for kinematics that decrease the invasiveness, e.g., by providing a remote centre of motion (RCM)
56	Collision of components with each other is prevented by design	e.g., the Versius and HugoRAS systems can be freely positioned. Thus, arms can clash with each other (internal). However, clashes of the integrated arms of daVinci have also been reported (internal).
57	Collision of components with other systems is prevented by design	External collisions refers to collisions with other systems and persons.
58	Proximity to singularities is avoided by design	
59	As few degrees of freedom as possible	If the number of DoF exceeds the number required to perform the motion task, the additional DoFs are sources of malfunction.

Appendix III Scenario and Decision Sheets

Reference functions			ROSA-Scenario						
F1.4 Bring the system to its working location			x		x				x
F1.2 Plan and adjust parameters			x		x				x
F2 Bring/ remove the end-effector to/ from the situs (roughly)					x				x
F3 Remove bone acc. to a surgical plan (precisely)	F3.1 Mechanically constrain the DoF to a surgical plan	PSP: axis			x	x			
		LAM: 3D surface			x				
	F3.2 Mechanically limit progression within the DoF	PSP: end-stop				x	x		
		LAM: boundary contour			x				
	F3.3 Feed/ forward bone shaping tool	PSP: feed on axis							x
		LAM: feed on 3D surface			x				x
	F3.4 Maintain registration between anatomy and end-effector		x	x	x				
	F3.5 Remove bone	PSP: along axis					x		
		LAM: in 3D surface						x	
Function carriers			Satellite station 	Arrays 	Base station cart 	Guide sleeve 	Drill 	Burr 	User 
Sterility measures			None	Disposable	Draped	Reprocessed	Reprocessed	Reprocessed	Prepared
Abbreviation			a	b	c	d	e	f	g
Keep									
Split									
Combine									
Remove function									
Insert function									
Remarks/ Specifications									

Hazards	Hazard control

Reference functions			MINARO-Scenario												
F1.4 Bring the system to its working location			x												x
F1.2 Plan and adjust parameters				x											x
F2 Bring/ remove the end-effector to/ from the situs (roughly)						x									x
F3 Remove bone acc. to a surgical plan (precisely)	F3.1 Mechanically constrain the DoF to a surgical plan	PSP: axis					x	x	x	x	x	x			
		LAM: 3D surface					x	x	x	x	x				
	F3.2 Mechanically limit progression within the DoF	PSP: end-stop										x			
		LAM: boundary contour					x	x	x	x	x				
	F3.3 Feed/ forward bone shaping tool	PSP: feed on axis													x
		LAM: feed on 3D surface					x	x	x	x	x				x
	F3.4 Maintain registration between anatomy and end-effector			x	x		x	x	x	x	x				
	F3.5 Remove bone	PSP: along axis											x		x
		LAM: in 3D surface												x	
Function carriers			Sterile container 	Camera-monitor cart 	Arrays 	Mechanical arm 	Base plate spine 	Motor unit front 	Motor unit back 	Front kinematics spine 	Back kinematics spine 	Guide sleeve 	Drill 	Burr 	User 
Sterility measures			Reprocessed	Draped	Reprocessed	Reprocessed	Reprocessed	Reprocessed	Reprocessed	Reprocessed	Reprocessed	Reprocessed	Reprocessed	Reprocessed	Prepared
Abbreviation			a	b	c	d	e	f	g	h	i	j	k	l	m
Keep															
Split															
Combine															
Remove function															
Insert function															

Remarks/ Specifications

Hazards	Hazard control

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