Assistive Systems for Quality Assurance by Context-Aware User Interfaces in Health Care and Production

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Dissertation

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Bielefeld, October 2014

Printed on permanent paper according to ∞ ISO 9706.

Abstract

The reprocessing of medical devices is an essential procedure to keep hospitals operational. Workers at the Central Sterilization Supply Department (CSSD) clean, disinfect and sterilize medical devices and have to obligate to the manifold of legal and hygiene prescriptions. Failures during reprocessing can endanger patients' safety and increase costs. The process of decontamination has rich sources of failures because of the complexity of hygiene, medical devices and regulatory specifications.

The benefits of an assistance system helping workers in preventing failures are therefore obvious and crucial. New interaction technologies such as augmented reality can potentially help workers in the CSSD to avoid failures during the reprocessing of medical devices. Challenging requirements for the application of new interaction technology within the CSSD arise through process complexity, legislation, integration and hygiene restrictions.

This thesis proposes an assistance system that supports the worker in the unclean area of a CSSD with respect to these requirements. The system provides a user interface for context-aware worker guidance and collection of process relevant data from the worker. The proposed interaction mechanism of 'virtual touches' fulfills the hygiene requirements and is realized by an adapted workspace which is equipped with a depth camera and a projected user interface. The 'business process modeling notation 2.0 (BPMN 2.0)' standard is utilized to define process models that control the workflow, coordinate the system's components and maintain a database for quality assurance and worker guidance.

In addition to an in depth description of the system, an evaluation with two user studies and interviews with CSSD domain experts are conducted throughout this thesis. The results reveal a high capability for failure avoidance during the reprocessing of medical devices without delaying the process compared to today's CSSDs. Additionally, CSSD experts appraise a high practical relevance and underline the feasibility of the underlying concepts for the CSSD domain.

The concepts of the process integration, the standardized modeling of the workflow and workers' tasks as well as the context-aware interface are also helpful, relevant and applicable in the domain of manual assembly processes. Thus, this thesis describes, how the system can be transfered to the domain of manual production. The presentation of a prototype at a renowned international industrial fair and the accompanying feedback from manufacturing experts underline the scalability and the portability of the proposed assistance system to the production domain, which is a result of a component based system architecture utilizing process models for the coordination of computational devices and human workers.

Contents

Chapter 1

Introduction

People are treated at health care facilities to be cured from diseases and injuries. Microorganisms cause many diseases and they are contagious if hygiene is neglected. The microbiological processes and the resulting hygiene restrictions require special attention, especially for the medical devices that come into contact with pathogens. The patients are often weak and therefore vulnerable to disease-causing microorganisms. The absence of germs and pathogens on medical devices is mandatory for patients' treatment. Especially nowadays, where multidrug-resistant organisms are a serious threat for health care units.

Although the fundamentals of hygiene and microbiology are well understood, the observance of hygiene rules is not self-evident as recent hygiene scandals in Munich [1] or Fulda [2] showed. This thesis addresses the topic of medical device decontamination by the development of an assistance system that helps workers in health care facilities to adhere to hygiene restrictions during the reprocessing of medical devices. The proposed assistance system supports the worker in the Central Sterilization Supply Department (CSSD) with the decontamination of medical devices by providing context- and process-aware working instructions and supportive functions.

Hygiene can be considered as a quality property of a productive environment that must be continuously optimized. For this purpose, existing quality management methods such as the ISO 9001 [3] and others offer methods to continuously increase the quality of products and goods. In productive environments, the quality management is a general concern as well. The process of creating sterile instruments can be compared to the process of creating goods. A common goal of these processes is the ongoing process optimization comprising of: product or service quality, efficiency, costs and process documentation. Although this thesis focuses on interaction technology for the CSSD domain, the assistance system can also be used for guiding workers in manual production because of similar requirements.

1.1 Background and Motivation

Medical care is continuously evolving and new medical devices increase the quality of patients' treatments. Moreover, medical instruments get smaller and more complex. By use of a micro-invasive processes (MIP), a patient may require only a band-aid on the incision, rather than multiple stitches or staples to close a large incision, which usually results in quicker recovery time. The decrease in size and increase in complexity of medical device provides benefits concerning the treatment but bears challenges for the decontamination. Due to the high cost of instruments, reusage of medical devices is important for hospitals. Therefore devices must be cleaned, disinfected and sterilized for this purpose after usage, e.g. surgeries.

Hospitals usually have a dedicated facility, the Central Sterilization Supply Department (CSSD), where instruments are reprocessed. A CSSD is divided into three areas with different hygiene levels. Used instruments are first delivered to the unclean (contaminated) area where instruments are cleaned and disinfected manually or by machine. In this process step the worker has to assure the correct preparation, disassembly and loading of the disinfector machines. After disinfection, instruments are maintained, assembled, checked and compiled to sets in the clean area of a CSSD. The compiled sets of instruments are sterilized and stored in the sterile area.

Commonly, there are several thousand different medical instruments in a hospital with a range from very simple to highly complex instruments with very special requirements for sterilization. This inventory is additionally changing over time. Workers in a CSSD are often under high time pressure and must comply with many legal and hygienic restrictions as well as internal working instructions. There are a lot of failure sources in this domain because the workers in a CSSD cannot always be aware of the correct instructions for every single instrument and every single process step. Currently, one can find electronic data processing (EDP) mostly in the clean area of a today's CSSD to help workers to compile sets of instruments. The unclean area has no such guidance by an EDP-system, because safety clothes as well as the wet and contaminated environment constrain the usability of classical EDP-systems. Failures during the reprocessing process, however, can lead to dangerous residues on and especially within instruments, e.g. minimal invasive surgery instruments, and can cause nosocomial infections. Broken or incomplete sets of instruments affect proper and correct treatment in the operating room. When failures occur, the overall costs of the reprocessing increases, since process steps must be repeated and the instruments wear off faster or break due to improper handling. The CSSD as central service for hospitals has to assure the quality and efficiency of its service in order to keep its customers (e.g. hospital wards, surgery rooms) functional.

The process of decontamination and sterilization is critical, since unsterilized instruments can cause dangerous patient infections and imply higher costs. Thus avoiding even only a single such incident is worth much effort and directly contributes to the quality of health care.

So, how can failures be avoided during the reprocessing of medical devices? A sensor-based quality assurance automatically detecting all or at least most failures that could occur during the reprocessing is not conceivable, because the variety of manual procedures and the variety of medical devices leads to a complexity for object detection and recognition which exceeds today's sensor technology capabilities by far. Instead, it is more promising to extend the workers cognitive abilities by drawing his or her attention to critical procedures and to provide concise working instructions when they are needed.

Worker guidance is a general concern in research and industry and often relies on information technology. Research topics in human computer interaction such as augmented reality and motion recognition could be a method of choice to overcome the usability issues of common interfaces in wet and hazardous environments. Augmented reality enriches real objects with virtual information. Concerning the work in a CSSD, an instrument could be augmented with its handling instructions by utilizing augmented reality. Hypothetically, the worker avoids failures because of the direct relation between instrument and corresponding instructions.

This work contributes in four ways: First, a domain analysis of CSSDs reveals potential improvements of the workflow by introducing new interaction technologies. Requirements are derived from the domain analysis. Second, an approach for a new assistive system is proposed, which combines state of the art interaction technology and process models for process automation. Third, qualitative and quantitative evaluations of the proposed system show encouraging results. Fourth, the concepts of the proposed systems can be applied in other domains, such as manual assembly process in industry with low effort.

1.2 Outline

This thesis focuses on the development of an assistance system for the CSSD that helps worker preventing failures during reprocessing of medical devices. Worker guidance in the CSSD requires the availability of working instructions. The worker needs information that depends on the state of the workflow and the context of use. The necessary instructions and workflow models that the system utilizes must be up-to-date and consistent with more general prescription, such as legislation. Furthermore the quality management and process documentation could benefit from process data added by the workers.

The development of such a system requires a deep understanding of the domain and the potential uses case of assistive technologies. What are requirements that assistive systems within the CSSD must fulfill? Obviously, a system will fail in application if its usability is unacceptable. Thereby, usability is of major concern in order to provide an applicable assistance system. But usability is not the only issue that an assistance system must deal with. Acceptance and practical applicability of trending interaction technologies within the CSSD domain must be considered as well. Further requirements must be defined for concrete use case derivation and technical implementation. Chapter 2 identifies requirements for worker assistance in the CSSD. A domain analysis is presented to derive the implementation path with most potential for avoiding failure by deploying assistive technology.

But how should the assistive system look like? Which interaction paradigms and technologies are applicable in the CSSD? The assistance system needs an implementation in hard and software that addresses the challenging requirements of a CSSD. The related work in the field of assistance technology in productive environments is discussed in Chapter 3 to provide an overview of the state of the art for worker guidance. The topics of Chapter 4 are different concepts for the combination of technologies for the desired assistance system. Different ideas show, how existing technologies could be combined to provide assistance.

The implementation of a first prototype is explained in Chapter 5. The system description includes the process-aware software architecture and a context-aware user interface. The prototype system supports workers by providing valid and context-specific instructions for a dynamically changing inventory of medical instruments. This helps workers to keep up-to-date with the dynamic inventory and processes. The overall quality of the reprocessing could increase in terms of error rates and less repetitions of single process steps. Business Process Models combine the definition and execution of workflows and are the foundation for the information management.

This first prototype was evaluated for usability and its influence on process parameters such as failure avoidance and process time. The user study and the results are described in Chapter 6. The evaluation revealed potential improvements in the user interface design. The iteration and evaluation of the user interface with a second quantitative user study is the topic of Chapter 7.

Chapter 8 discusses the practical relevance for the CSSD domain by presenting results of a qualitative study with domain experts. The modularity and process modeling capabilities of the assistance system allow to transfer the system to other use cases and domains. Chapter 9 describes how this flexibility was exploited to use the assistance system for worker guidance in manual assembly. The system was presented at the Hannover Fair 2014 [4, 5]. Summarized feedback from the exhibition visitors shows that the assistance system developed in this thesis is not only practically relevant for medical device reprocessing but can also be deployed into the manufacturing domain. The thesis concludes in Chapter 10 with a summary and outlook on further research questions.

Chapter 2

Domain Analysis

As stated in the introduction, the goal of this thesis is to develop and evaluate an assistance system for the CSSD domain that supports the workers and therefore increases the overall process quality of the reprocessing of medical instruments. Developing an innovative prototype for an assistance system requires a sustainable concept which meets the CSSD needs and offers potential for improvements of the process of medical device decontamination. The needs (requirements) and restrictions can be separated into three major categories. First, technological requirements arise from CSSDs' infrastructures and already existing tool support. The technological requirements also include general guidelines for human-machine interaction that concern interaction and information presentation principles as well as the process of development interactive systems. Second, process requirements determine how different activities are organized and also consider legal prescriptions. Third, the user perspective and human factors of the practical application are crucial for the development and evaluation of concepts for worker guidance by interaction technology. Summarized, requirements from the business process perspective, the practical workflow and the underlying technology and infrastructure arise and must be concerned during the development of an assistance system to provide a meaningful and sustainable application of new interaction technology in the CSSD. If one of these requirements categories is not regarded, the assistance system will probably fail in application. For instance, assuming an assistance system performs pretty well in supporting the workers with crucial information. This system will not be used in real world CSSDs, if these data can not be edited or changed easily. Fig. 2.1 depicts the relation of the three requirement categories.

A domain analysis was performed to identify the potential of new interaction technology for the CSSD and to define the requirements arising from the CSSD domain. This chapter describes the results of the domain analysis that were identified by analyzing different sources of information. The analysis takes into account domain specific literature, practical insights from an internship and participation of the technical sterilization assistance course grade I, interviews with domain experts (CSSD worker and heads of departments, software vendors).

Sec. 2.1 focuses on the processes within and around the CSSD. It provides a description of the instrument cycle, the legislation and process administration requirements from a theoretical point of view. Sec. 2.3 focuses on human factors and typical failures within the CSSD from a practical point of view. Sec. 2.4 introduces the structural and technical environment of today's CSSD. Additionally, standards for the design and development of user interfaces are discussed before the technological requirements are defined. Sec. 2.5 provides a summary of the derived requirements and a scenario description for assistive technology in a CSSD, which will be the basis for conceptualization described in Chapter 4.

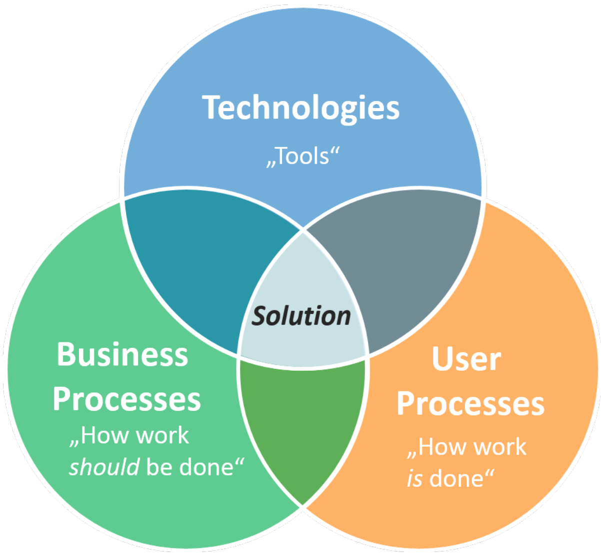

Fig. 2.1: Requirements arise from the business processes, the user processes and the technology

2.1 Central Sterilization Supply Department: Processes and Restrictions

The microbiological complexity of pathogens and germs are invisibility to the human eye and due to their growing resistances to known treatment pathogens challenge health care units every day. After each use of a medical device, the device is potentially contaminated with dangerous pathogens. Before the next usage of an instrument, this potential contamination must be removed. The process of decontamination takes places in the CSSD and is a well defined and a well understood process that will be introduced in the following. Although the theory of hygiene is well understood, the practical application can be improved, as many hygiene scandals showed [1, 2, 6]. This section introduces the CSSD, its processes and complexity.

2.1.1 The Instrument Decontamination Cycle

The CSSD is responsible for the processing and sterilization of surgical instruments and other medical devices required for operations and sterile procedures in hospitals. Medical devices are subject to a thorough washing and disinfection treatment followed by inspection, packing and sterilization by qualified technicians. The CSSD is therefore a part of the instrument life cycle as depicted in Fig. 2.2. Each step of this cycle will be explained in the following to describe the today's state of the art in the CSSD domain.

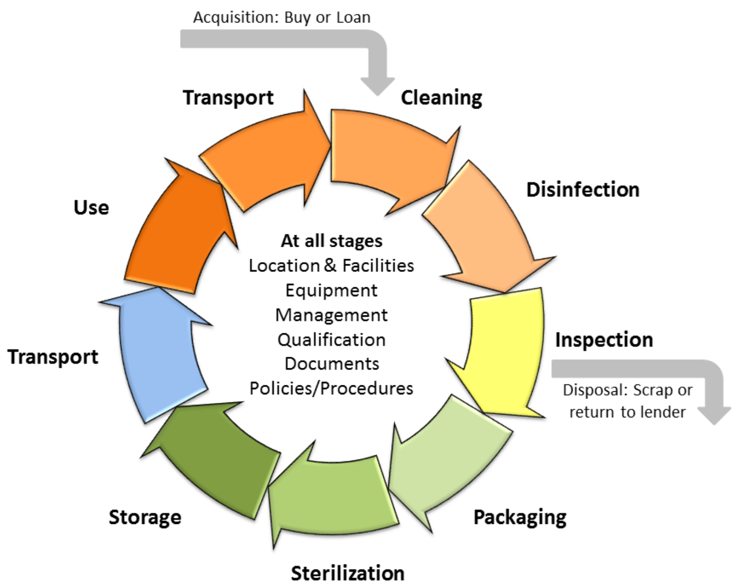

Fig. 2.2: The instrument decontamination cycle as per Potomac Labs [7]

Use

Customers of the CSSD are mainly hospital stations and surgery rooms. The customers use sterile instruments for the patients' treatment, for example during surgeries.

Sterile instruments are foiled or packed into sterilization containers to protect the instrument's sterility during transportation. For the preparation of the patient's treatment, the operating room technicians or nurses catch sterile instruments from the sterile storage and unpack them from the protective container or foil. This implies the breaking of sterility seals, which are attached to the packaging of sterile goods. When a sterility-seal is broken, the instruments loose their sterility by definition, no matter if they were used during the treatment. The physician uses the instruments to cure the patient. Thereby instruments get contaminated and dirty. An operating room technician or a nurse collects the contaminated instruments after their usage and puts them into the instrument container (usually the same one, from which the instruments were taken out). Eventual issues regarding the instrument functionality are documented and assigned to the container[1]. The instruments are now ready for transportation to the CSSD.

Not all treatments require sterile instruments. Often, especially at hospital stations, disinfected instruments are sufficient for proper patient care. In short, while on disinfected instruments *most* harmful microorganisms from instruments were removed, (nearly) *all* microorganisms were killed or inactivated on sterile instruments[2]. Hence, sterility has higher requirements for decontamination than disinfection. Medical devices are categorized into groups according to the risk of medical devices. The risk of medical devices is defined by the ISO 14971 as "combination of the probability of occurrence of harm and the severity of that harm." [8]. The categorization rules are given in [9] and a concise form of the medical device classification rules can be found in e.g. [10].

Briefly summarized, the instrument's field of application can be uncritical (e.g. medical devices that have contact only with intact skin), semi-critical (medical devices, that have contact with diseased skin or mucosa) or critical (medical devices, that have contact with blood, sterile drugs or internal organs including wounds or that penetrate skin or mucosa). The requirements for decontamination and sterilization depend not only on the instrument criticality but also on the properties of the medical devices that influence the process of decontamination. This second classification defines three levels of requirements: First, group A refers to instrument with no special requirements for the decontamination. These devices are usually only cleaned and disinfected. Group B describes instruments with higher requirements, for example medical device with hollow bodies, limited number of reprocessing cycles, or with effects on decontamination, that could influence safety and function of the medical device. Medical devices of group C have the highest requirements for decontamination and effect critical medical devices which require special care during decontamination. [9, 11]

Transport

Contaminated instruments from surgery are delivered to the unclean area of a CSSD within special and sealed containers. Often paper bound information such as delivery notes or reclamations come with the instruments. Reclamations at this stage refer to issues within the set of instrument, such as defects, missing instruments or problems with the last decontamination cycle. The operating room technician is responsible for loading and sealing the instruments into the container correctly. This includes the correct labeling of the container, removing disposables and other trash, preparation of the cleaning and disinfection as far as possible and meeting the requirements for work safety and proper loading. For example, the improper loading of sharp or spiky instruments can endanger the worker safety at the decontamination. If these dangerous items are hidden within the other instruments the worker could easily hurt himself by grasping into the container and not noticing dangerous instruments.

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[1] The practical dealings with such reclamation can vary much. Depending on the hospital structures and organization, the issue reports can be communicated by phone, email, reclamation paper, or even not at all.

[2] After sterilization, the probability for residual content of colony forming units within a sterilization unit must be below 10^{-6} (and 10^{-5} after disinfection).

After the container is packaged correctly, it is delivered to the unclean area of the CSSD, where the CSSD worker acknowledges the receipt of the sealed medical devices. Practically, it depends on the hospital infrastructure and the CSSD customers, how or if the delivery has to be acknowledged. Often hospitals have a system for process documentation based on barcodes. In this case, the CSSD worker scans barcodes of the sealed instrument sets and a documentation software automatically acknowledges the receipt.

Cleaning

The worker starts the cleaning process by opening the container and taking the sieves onto the workplace. Since, most instruments can be cleaned and disinfected by machine, the worker prepares the instruments for cleaning by machine and loads the instruments on special machine racks as shown in Fig. 2.3. Although the washer and disinfection machines are quite powerful, they require proper loading to ensure proper cleaned and disinfected instruments. Fig. 2.4 depicts an example for washer and disinfector machines in a common CSSD. The image also illustrates how typically missing working instructions at the unclean area are retrieved by communication with other workers. The worker at the unclean area in Fig. 2.4 asks a colleague at the clean area via the returning hatch, whether a special drilling unit has to be cleaned manually or by machine and how it has to be disassembled.

Fig. 2.3: Racks for washer and disinfector machines. The racks are loaded with dirty medical devices before they are loaded into the washer and disinfector machine. The worker use carts to move the racks.

The work safety guideline suggests to keep the contact between the worker and the contaminated medical devices at a minimum. Ideally, most instruments can be unloaded from the container and directly loaded into the cleaning and disinfection machine without manual operations. But due to the complexity of medical devices and tubular parts, common issues are known regarding the container loading or high degree of contamination. It is commonly necessary to prepare the devices for the cleaning and disinfection machine. This includes manual working steps such as precleaning, disassembly, sorting, rack loading, putting tubular parts on fitting rack pipes, labeling defects among others. Often an ultra-sonic bath is used to remove stubborn dirt. There are also medical devices, that can not be processed by machine, for instance thermo-labile optics. These devices have to be cleaned and disinfected manually.

At the end of the cleaning step, coarse dirt and disposables are removed from the medical devices and the instruments are either loaded on a rack for automatic disinfection or are prepared for manual disinfection.

Fig. 2.4: Two washer and disinfector machines and a CSSD worker. In this CSSD five disinfector machines are installed. The machines also separate the clean area from the unclean area by a two way door system. In this image, the worker uses the return hatch to ask a colleague for help with a specific instrument. He has to prepare a motor unit for machine disinfection and misses instructions how to disassemble the device.

Disinfection

The worker loads the instruments on disinfector racks, if they can be cleaned and disinfected by machine. Otherwise he or she manually disinfects the instruments. The disinfector machines usually have a two door system for building a hygiene barrier: contaminated instruments are loaded into the machine on the contaminated or 'unclean' area of a CSSD and are removed on second door at the 'clean area' after the disinfection process is complete.

The washer and disinfector machine proceeds a combination of mechanical, temperature and chemical treatment in order to clean the instruments and to reduce the amount of pathogens and germs. The standard EN ISO 15883 defines the requirements for washer and disinfection machines [12].

For a successful cleaning and disinfection by a machine, the washer and disinfector must be loaded correctly. Typical failures that occur while loading the machine are for instance: blocking the rotary spray header, choosing wrong dimensions of water adapters (so called 'Luer-Locks') for hollowed instruments, spray shadows by cluttered loading, accidentally loading of thermo-labile instruments or loose, unsecured instruments that throw up during washing resulting in damage to the machine or other instruments. Additional frequent tests such as the bowie-dick test or disinfection with a data logger devices ensure the correct function of the disinfector machine. The test results are part of the process documentation, that is mandatory in the CSSD. Especially the disinfection and sterilization process parameters must be retrievable for each single instrument as obligation to produce proof.

Inspection

After the disinfection, the worker at the clean area takes over the instruments and moves to the packaging work place that is depicted in Fig. 2.5. When the instruments reach the packaging area, the worker visually checks the instruments for proper cleaning and absence of residues. Instruments that fail the visual check return to the unclean area and run through the cleaning and disinfection again. If the worker detects no obvious issues, than he or she reassembles, maintains and briefly tests the disinfected instruments. At this stage, the workers handles reclamations from the CSSD customers, e.g. the exchange of broken instruments. The inspection process step ensures the cleanliness and proper function of single instruments before the instruments can be compiled to sets.

Fig. 2.5: Packing workplace at the clean area. The computer is used for retrieving working instructions, such as sieve compilations and for documentation issues. The workplace also contains tools for instrument maintenance and a barcode printer.

Packaging

The packaging of the clean and inspected instruments either prepares the sterilization or, in case of devices that must not be sterilized, for the distribution to the CSSD customers. The packaging workplace provides a computer for documentation and instruction purposes. The software allows to print identification labels with a name of the instrument or container, an expiration date when the sterility expires and a barcodes. The worker prints and attaches these labels to the containers or single foiled instruments.

Instruments and other items that are prepared for sterilization must be packaged such that their sterility can be maintained to the point of use. The materials and techniques used for packaging must allow the worker to contact the device during the sterilization process as well as to protect the device from contamination during storage and handling before it is used. The time between sterilization and use may range from a few minutes to several weeks to several month. The selected packaging material must also permit the device to be removed aseptically. [13]

For each surgical kit, there is a list or recipe, which guides the worker on how to compile the set. This information is usually deposited in the CSSD software tools and created by the CSSD technicians and/or the operating room technicians. The instruments' positions in the set list refers to the position within the compiled sieve: At the top of the packaging list a position for the first instrument is given. The worker compiles the set by going through the ordered list and placing the instruments one after another. The set list also contains direction changes, in case instruments must be placed at another location or direction within the sieve. Pictures of interim and final results complete the instructions. Therefore, the ordered set list regulates the alignment of instruments within the sieves.

After the compilation, the worker puts the sieves into sterilization container. Single instruments are welded in sterilization foil. The worker labels the packed instruments and seals the container and loads them into the sterilizer.

Sterilization

The worker scans the barcode of the medical devices or container, before the sterilization. The CSSD software groups the scanned instruments into a charge for documentation purposes. Afterwards he or she loads the packed instruments into the sterilizer machine, which usually is an autoclave. Autoclaves achieve sterilization by exposing products to saturated steam by holding a time of at least 15 minutes at 121 $°C$ at a pressure of 100 kPa, or 3 minutes at 134 $°C$ at 100 kPa. The ISO standard 17665 defines requirements for the development, validation and routine control of a moist heat sterilization process for medical devices. [14]

Except the correct packaging, scanning the instruments' barcodes and choosing the right sterilization program, the worker has no influence on the sterilization procedure. The sterilizer machines document the process parameter during the sterilization and with the previously scanned barcodes of the load, the obligation for process documentation is regarded. This documentation must be kept as a proof for sterility, which is very important for insurance reasons in case of nosocomial infections.

Analogous to the washer and disinfection machines, the sterilizers usually provide a two door system that serves as a second hygiene barrier within the CSSD by separating the packing area from the sterile storage.

Storage and Transport

At the sterile area of the CSSD the worker takes the instruments out of the autoclave. If the sterilization protocol is within the normal limits, the worker releases the instruments. After the release, the sterile instruments are either stored or directly delivered to the stations or operating rooms. The sterile instruments are now ready for treatment and the instrument cycle is closed. Sterile instruments have a expiration date, which is half a year after the last sterilization.

2.1.2 Legislation and Quality Management

In Germany, several legal restrictions regulate the use and the reprocessing of medical instruments as described in [15], [16] or [17]. A brief overview of these regulations is presented in this section to derive requirements for assistive technology within the CSSD.

Terms and restrictions for medical devices are regulated by the German Medical Devices Act (Medizinproduktegesetz, MPG). This act defines the term ‘reprocessing of medical devices’ in §3 No. 14 MPG as: “The reprocessing of medical devices intended to be applied semi-sterile or sterile, is the cleaning, disinfection and sterilization, including the processes connected therewith, as well as the testing and restoration of technical-functional safety, following their use for the purpose of renewed use” [15, 18].

The MPG imposes regulations concerning medical devices in a general manner. It was complemented by the Medical Devices Operator Ordinance ’MPBetrV’[3] [19]. MPBetrV demands validated processes for the cleaning disinfection and sterilization (§4 Abs. 2 MPBetreibV). Appropriate procedures and products according to scientific and technological standards must be used by the operator of medical devices. It also states that proper operation of medical devices is suspected, if the common recommendation from the German Robert Koch Institute (RKI) and the German Federal institute for medication and medical products (BfArM) “requirements to the hygiene for the preparation of medical products”, is regarded. [19] Several standards and guidelines consider the validation of reprocessing medical devices and define the technological and scientific standard. Additional documents, such as the ’red booklet’ specify details for practical application of these standards [10]. The MPG also obliges manufacturer to provide device manuals, that include information about cleaning, disinfection and sterilization for the specific device. The standard ISO 17664 specifies ’the information to be provided by the manufacturer for the processing of resterilizable medical devices’ [20].

The legislator also intends for quality assurance. The German Social Code [21] (§137 Sozialgesetzbuch V) obliges hospital operators to apply measures for quality assurance. Concluding, all hospital departments (CSSD included) should have measures for quality assurance. Since quality assurance is enshrined in legislation, every CSSD has to document the following four major pieces of information in a quality manual (see WFHSS - World Forum for Hospital Sterile Supply website [22]). (1) *Working instructions*: Regulations and provisions, procedural steps, explicit working instructions and job descriptions must be present. (2) *Documentation*: Expert opinions, technical

[3] German: Medizinproduktebetreiber-Verordnung

leaflets, warranties and processing instructions must be filed separately and updated. (3) *Validation, periodic tests, routine tests and technical maintenance*: The validation part of the quality manual serves as proof that the specified procedural steps and processes are compiled within a reproducible manner and checked at regular intervals. (4) *Staff training and briefing*: Written records must be kept and filed of staff training courses and briefing [22]. An assistance system should help to gather and maintain this data.

Two quality management certificates exist in Germany with relevance for CSSDs. The ISO standard 9001:2008 defines requirements for quality management systems. This standard targets at organizations that "have to show their continual provision of goods, that meet customer and legal prescription" [3] and pursue continuous improvement of customers' satisfaction and processes by effective application of the systems. The ISO 9001 describes, how to apply and maintain the six documented procedures: Control of documents and records, internal audits, control of nonconforming product and service, as well as corrective and preventive actions. Similar to the ISO 9001, the EN ISO 13485:2010 "Medical devices - Quality management systems - Requirements for regulatory purposes" specifies requirements for a quality management system. Although this standard is quite similar to the ISO 9001 the requirements are adjusted for medical device regulations and related services and therefore this standard has more relevance for CSSDs.

This review of the legal restrictions and corresponding guidelines showed that the processes and quality assurance is very well regulated and documented. The legislation prescribes the general procedure within a CSSD. As a consequence, these manifold documents must be regarded during the practical and daily work within the CSSD to ensure that medical devices are reprocessed under validated procedures.

For application of assistive technology following requirements arise from the highly regulated process.

First, the procedure and documents forced by law must be regarded. Each hospital and CSSD is responsible for the application of the legal prescriptions and restrictions. Assistive technology should support both, the administration and the worker at this point. The installed quality management system should be supported by the assistance system to continuously improve the process.

Second, the quality management and external prescriptions, such as legislation have a dynamic effect on work flows within the CSSD. An assistance system should be flexible enough to adapt to changing processes and work-flows.

Third, the assistance systems needs a data basis to support workers. Although the data exists as described above, this data can not directly used for assistance during daily work. For example, when the worker reprocesses a critical endoscope, there is usually not enough time for carefully reading all related documents that come from the manufacturer or from hygiene institutes. Missing working instruction must be retrievable, readable and understandable during the operational work flow. Additionally, they have to be consistent with the dynamic prescription.

Fourth, the above mentioned definition of reprocessing medical devices by the MPG [18] clearly shows, that reprocessing of medical devices is not only cleaning, disinfection, sterilization. Instead, customer needs, related processes and technical tests must be regarded, to ensure the *renewed usage* of medical devices. This results in the requirement for sensing and communication of process parameters, such as failure reports for instance. The duty of process documentation and communication of process relevant data is therefore a requirement that regards the development of assistive technology for the CSSD.

2.2 CSSD as a Value Chain

The CSSD is a department within a hospital that produces goods: sterile medical devices. As generally stated in the introduction, the goal is to improve the CSSD's quality and efficiency by exploiting state of the art human-machine interaction. First, we have to identify stages in the CSSD process where human machine interaction (HMI) methods could be deployed that have a high potential for increasing quality and efficiency. Improving quality and efficiency is a common goal in business to get and stay competitive. This section briefly looks at methods of economics for analyzing and improving business units. Requirements are derived by looking at the CSSD from an economics point of view.

There are models for competitive business environments that focus on the question, how competitive advantages can be gained and maintained. Porter proposed the value chain in the 1980's: "Every firm is a collection of activities that are performed to design, produce, market, deliver, and support its product. All these activities can be represented using a value chain [...]. A firm's value chain and the way it performs individual activities are a reflection of its history, its strategy, its approach to implementing its strategy, and the underlying economics of the activities themselves." [23]

The core concepts for building competitive advantage described by Porter are still relevant even though the book was published in 1985. In Fig. 2.6 depicts Porter's value chain. The value chain consists of activities, that are common to almost all businesses. More in detail, it consists of five primary activities which add value to the product. Four supporting activities influence the primary activities. Margin is the difference between the created value minus the costs for adding this value.

For the CSSD domain, the value of a product refers to the quality (e.g. failure rate) of its sterilization process as well as the costs of the sterilization. Increased quality and efficiency regard the margin in Porter's value chain. This margin depends on the way, how the primary and supporting activities are performed and how well their linkage is managed. These linkages regulate the flow of information, products and services and are crucial for corporate success. For instance, if the human resource management fails to employ enough workers in a CSSD, the CSSD can not satisfy all of its customers and 'value' will be lost. The main point here is that each primary activity has supporting activities and their linkage must be regarded and supported in order to increase the overall quality of the reprocessing.

Since 1985 the value chain evolved and models such as value shop [24], value network [25], reverse value chain, Concept of Core Competencies or Balanced Scoreboard were introduced as methods for analyzing business strategies [26].

The common goal of these methods is to identify business and organizational strategies for improving the value generated within an organization. The methods emphasize, that facilitated communication and a service oriented organization structure can improve the value chain.

Transferring these high level strategies to the CSSD leads to a sterilization service that involves its customers by facilitating communications. The communication between customers, the CSSD and the hospital management could be supported by web services. For example the CSSD could provide a web interface, where the customers can log in and asses the sterilization service or request prioritized reprocessing of specific instruments. An assistance system communicates the relevant information from the customer to the CSSD worker at the place within the instrument cycle, where it must be handled. The communication can also work vice versa, for example if a set is delivered improperly, the CSSD worker enters a reclamation via the assistance system that the responsible person in the operating room receives. This offers transparency and documentation of reclamation and orders. Subsequently, an assistance system should either provide or integrate services for communication with customers. Additionally, it should at least provide interfaces for the efficient coordination with primary and supporting activities.

Nowadays business departments rely on IT infrastructure and tools, that support the generation of value within the business unit. The deployment of new technology into the CSSD targets the increase of the margin (e.g. decreased failure rate). As Porter's value chain illustrates, the new technology must deliver three major points:

First, it must enhance the specific tasks that it was build for. This is a sort of functional requirement of improving a primary or supporting activity by utilizing new assistive technology. This directly improves the value generated by a primary activity.

Second, the new technology must integrate with the other (primary and supporting) activities in order to improve communication and organization effort between the primary activities (the tasks the system directly improves) and supporting activities. The linkage or in other words the integration of the new assistance technology into the CSSD processes is crucial for the quality and efficiency of the overall process.

Third, the CSSD administration is responsible for the proper functionality of the CSSD. Concluding, new assistive technology should support the administration and process transparency. The system's behavior and communication with other departments or activities as well as its processes must stay controllable and maintainable by the domain experts. "Too smart" black boxes of assistive technology could potentially endanger proper reprocessing of medical devices, if they are not maintainable by the domain experts. In other words, new assistive technology can be smart, but must remain controllable and transparent for the CSSD domains. But here a problem arises:

Both management and IT functions are crucial for continuously enhancing the different process parameters. But managers and software engineers do not speak the same language. Software engineers usually do not have the knowledge to model CSSD processes, because they do not know the workflows and the CSSD in deep detail. In turn, CSSD administration usually does not have the skills to program their software. Ideally the assistive systems comes with a system behavior and configuration description that domain experts can understand and manage. As an example domain specific language or graphical representation of processes that uses common symbols and naming used in the CSSD domain controls the system behavior.

In summary, the value chain model shows that the integration of new IT technology into the department is crucial. New assistive technology must regard the supporting processes and should provide sophisticated interfaces between supporting and primary activities to generate a margin in value. The responsibility for processes and procedures must remain by the domain experts.

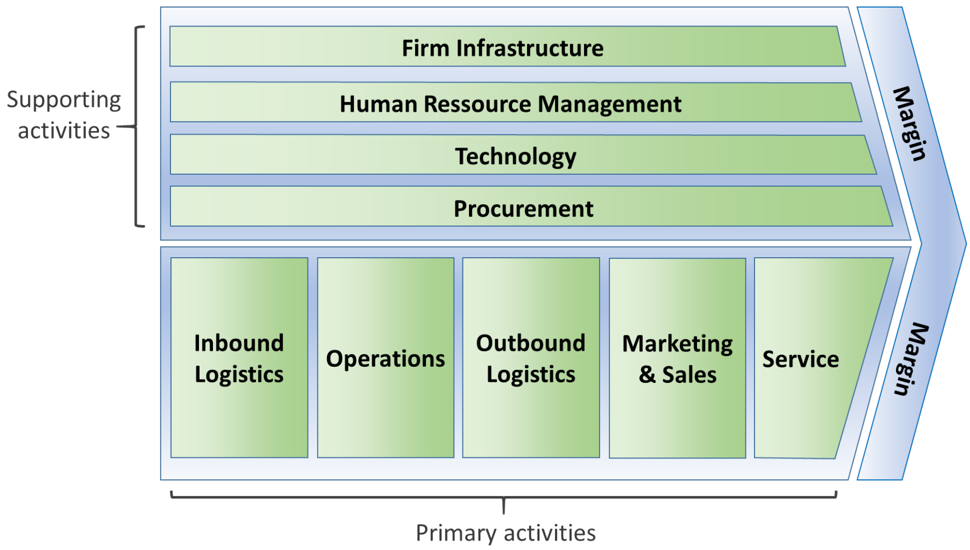


Fig. 2.6: The value chain according to Porter [23]. A value chain consists of five primary and four supporting activities.

2.3 Working in a CSSD - Human Factors

This section describes the tasks of the workers within the CSSD, their qualification and human factors that apply in the CSSD. A practical insights complement the domain analysis before requirements for assistive technology are discussed from the user perspective.

2.3.1 Worker Qualifications

The workers in the CSSD are the users, who should be supported in their work by new assistive technology. It is important to know their skills and qualification to provide a meaningful assistance. The World Forum for Hospital Sterile Supply and German Society for Sterile Supply (Deutsche Gesellschaft für Sterilgutversorgung - DGSV) suggest three training programs called "Technical Sterilization Assistant" (TSA). The three grades of the courses TSA impart the knowledge as listed in the following [22,27]:

TSA I - Basic grade technician

The course TSA I consists of 120 lessons (45 minutes each) and covers the basic knowledge about the sterilization process. Each worker in a CSSD *should* have completed the course before working in a CSSD. The listing below shows the course's content. Each participant has to pass an oral, written and practical test to complete the course successfully. The author successfully completed a course during the domain analysis.

Content of the DGSV-accredited TSA I course of the 'FHT/DSM - Fachschule für Hygienetechnik/ Desinfektorenschule'[4]:

1. Introduction and practical-relevant legislation prescriptions
2. Fundamentals of microbiology
3. Occupational safety and health
4. Hygiene for departments reprocessing medical products
5. Fundamentals of cleaning and disinfection of medical products
6. Fundamentals of instrumentation
7. Fundamentals of sterilization
8. Packaging and labeling
9. Quality management, validation and documentation
10. Cooperation with other departments
11. Medical product cycle

It should be mentioned, that practical experience within a CSSD is a precondition for the TSA I course. This contrasts the requirement that only TSA I qualified worker should work in the CSSD, since the necessary experience can only be gained while working in the CSSD without the TSA I qualification. Meanwhile there is a preparation course for the TSA for people with no experience to solve this problem.

TSA II - Supervision

The TSA II course imparts more detailed knowledge about the CSSD and qualifies for the occupational designation of 'Supervisor, CSSD' with extended responsibilities, e.g. shift supervisor. Precondition for this course is a TSA I qualification and at least 150 hours of practical experience. The course lasts 80 lessons (45 minutes each) and contains the following modules [22, 28]:

1. Building design and technical equipment
2. Statutory legal requirements/directives, recommended standards
3. Hygiene and infection prevention
4. Introduction to financial and accounting systems for health care facilities
5. Human Resource and Staff Management
6. Communication and team coaching
7. Specific instrumentation knowledge and decontamination methods
8. Specific questions on Cleaning, Disinfection, Validation
9. Quality Management II

At least one person with TSA II qualification must be present at any time in the CSSD.

[4] `http://www.fht-dsm.com`

TSA III - Management

The TSA II and practical experiences in an executive position are the prerequisite for the participation of the TSA III course. The course TSA III offers the highest CSSD specific qualification with its 200 lessons (45 minutes each) and prepares for the management of a CSSD. Therefore the content focuses on economical, personal and quality management topics [28]:

1. Economics for health care facilities
2. Human resource management
3. Quality management
4. Validation
5. Final examination paper

2.3.2 Practical Insights

The author did a one week internship a CSSD and accomplished the course TSA I to get practical insights from the CSSD domain and to identify typical failure sources within the process that could be potentially suppressed by assistive technology. The internship took place in 2011. The impressions and findings are summarized in the following.

Internship

During the internship in a German hospital's CSSD in Bielefeld, the author experienced typical working tasks within the CSSD, mostly at the clean area of a CSSD. The work at the packaging area included inspection, maintenance, packaging, sieve compilation and instrument assembly.

Because of work safety restriction (missing immunization), the author was not allowed to work in the unclean area. Fortunately, the observation of workers operating in the decontamination area was granted and further material such as videos and pictures could be recorded. The following main findings of the internship and corresponding data analysis reveal potential for worker guidance by interaction technology, especially at the decontamination area.

Packaging area. The author was wearing a head mounted camera while working at the packaging area to record video data for later analysis and to see how the worker react on wearable computing and the resulting implicit observation. The reaction were two-fold. Generally, the workers were open-minded to new interaction technology such as the wearing head mounted camera, displays and augmented reality (see Sec. 3.1). Although quite sceptically, they could imagine to use such devices, if they do not annoy and work properly. However, the workers had severe consideration regarding the privacy and observation issues with such devices. Although almost every worker's tasks have to be documented with the CSSD, the recording of videos and speech is a new dimension that the worker would refuse as a supplement for process documentation. Thankfully, they agreed to the use of the head mounted camera for short duration of the internship and the work at the packaging area could be recorded from the workers viewpoint.

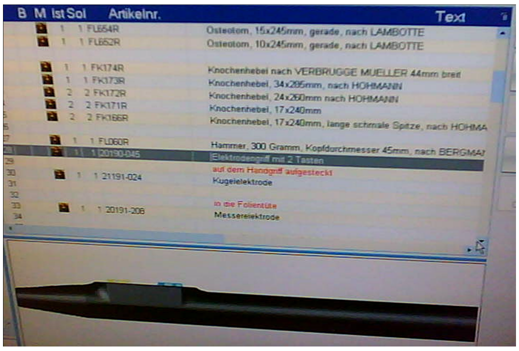
The inspection of medical devices takes place at the packaging workplace before the compilation to verify the cleaning and disinfection. Packing instructions for the instruments are presented by the system, but specific working instructions for controlling and verification are usually not filed and therefore the quality check of the cleaning and disinfection depends directly on the worker's qualification. Additionally, there is no explicit form for the documentation of the quality of the cleaning and disinfection for a single instrument. As a result, returning instruments[5] are not documented properly. Hypothetically, the implementation of a software supported checkpoint for instrument coming from disinfector could provide instrument specific disinfection to improve the documentation of returns.

During the internship an intentional neglect could be observed. An experienced worker had to process an obviously broken instrument, because it's sterilization date was expired. Instead of creating a repair order or at least a damage report, the broken instrument was sterilized and put into storage. Upon request the worker reasoned this obviously wrong handling with the assumption, that this 'instrument was and never will be used again'. Maybe, the worker was right, because the instrument was for very rare and special applications. But the intentional storage of broken instruments, whether they will be used or not endangers patients' safety. The physician have to rely on proper functionality of sterile goods. Instead of reprocessing broken instruments again and again each half year, there must be an intuitive way to remove broken or unused instruments from the instrument cycle. The worker obviously spared the effort to remove the instrument from the inventory. Instead it was easier for her to reprocess the device each half year when its sterility expires. This observed example shows the relevance of efficiently usable data management. Considering the development of assistive systems, it should be more comfortable to follow the correct process restrictions than intentionally circumvent them.

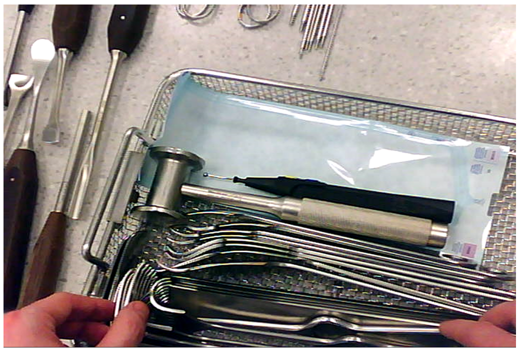
IT tools support the worker at the clean area and provide information on how to assemble instruments and provide functionality for documentation and labeling instruments before sterilization. The information on instruments and sieves are linked to barcodes to simplify process documentation. At the packaging workplace, the software tool provide an ordered list on how to compile sieves and how to assemble specific instruments, if the barcode of an instrument set is scanned. These ordered lists define a starting position, which determines where the worker has to put the first instrument. Further instruments are placed directly next to the previous instrument. A list item refers either to a specific instrument or a change in placing direction. The iteration of the ordered list leads to a orderly compiled set of instruments. Fig. 2.7.1 and Fig. 2.7.2 depict the packing process of an electrode handgrip. The image was extracted from the videos recorded with the head worn camera. The software for sieve packaging supports the work sufficiently. Minor issues such as the frequent head movements or the list iteration could potentially be improved by other interaction modalities, such as auditory displays or projection.

The practical insight revealed that the inspection and packaging process are well

[5]Instruments that must be cleaned and disinfected again, e.g. due to improper disassembly.



2.7.1: The software tells the worker what to pick next. The placement in the sieve is implicitly given by the position within the list and starting position as well as position change instructions.



2.7.2: The worker places the instrument into the sieve. The placement and arrangation of device requires some skill: the instruments must stay in position and enough space must be spared for the last instruments.

Fig. 2.7: Examples for the video material recorded during the domain analysis at the packaging area. For proper packaging, the worker has to go through the ordered list and pick each instrument before he places it into the sieve at a position.

supported by IT software. Despite the software support, beginners have a distinct feeling of insecurity during packaging which leads to double and triple checks. Especially, in cases where the software-provided instructions were insufficient or imprecise. The main difficulties were to correctly identify the different instruments and the proper assembly. The CSSD administrative stated that this requires at least half a year of experience. Thus, trainees are often spared from time pressure during the inspection, assembly and packaging. Additionally, only the simpler sets of instruments were given and an experienced worker supervises the operations. Assuming the time pressure, more complex instruments or lack of supervision the task gets more difficult for inexperienced workers and mistakes are likely to happen. Even with supervision, mistakes during instrument maintenance, such as forgotten oil on clamp hinges are very common.

However, the IT support is established within the packaging area, even if some features like the navigation and maintenance of instructions can be improved. Further typical mistakes that could easily occur at the packaging area are accidentally skipped list items during packaging or confounded instruments. Often the software provides only a single image that depicts how the final sieve compilation should like. The CSSD personnel commented that one reason for the lack of images provided by the software lies in a quite high effort to add figures and working instructions.

Another observation during the internship regards the speech that is used by the workers to communicate with each other in cases of insecurities while processing instruments. The CSSD language was not scientifically analyzed, but the experience during the internship showed that the workers' language differs much from the instruments' manuals, due to the naturalness of colloquially spoken words. The workers use a more ordinary language supported by gestures, which seems to be easier to understand because the often artificial and technical terms of manuals are substituted. For example, a worker explained the proper handling of a special air mask by using the term "the greater tube" instead of the term "recoil-operated inner-tube valve" like this special part was described in the manual. An instruction presenting assistive system must be aware of such possible differences between instrument manufacturers' manuals and the worker's language needs, because it has to present proper working instructions in an understandable manner.

Decontamination area. The clean area has to ensure the proper cleaning and disinfection, which takes place at the unclean area. Failures at the unclean area often occur due to missing instructions. During *three* hours of watching an experienced worker within the CSSD's unclean area, the following failures were observed This list also includes reports of the workers that were gained by short interviews.

- *Broken instruments.* Because of its similarity to another more robust instrument a thermo-labile optical instrument broke several times by improper loading into the cleaning and disinfection machine.
- *Overloading.* Often, too many instruments are loaded on a single sieve. This leads to higher returns, since the water within the machine could not cover all instruments correctly.
- Wrong sieve and basket loading. Especially for hollow instruments, needles for instance, the lumina of the washing tip must fit the instrument lumina.
- *Loose instruments.* The flowing water within the cleaning and disinfection machine could whirl loose instruments. The instruments could stop the rotary arm or damage other instruments or the machine.
- *Confusion.* The worker could not remember how to proceed with a drilling unit. He asked a college at the clean area via the hatch. The asked worker took the contaminated instrument in his hand before he answered the questions. The worker bypassed the hygiene barrier.
- *Documentation.* Returning instruments from the clean side are not documented. Instead they were reprocessed again without documentation. Therefore the documents of the returning instruments refers to it's previous charge.
- *Working safety.* The worker had to search a sieve with very small parts. Sometimes, sharp or spiky instruments are hidden unintentionally within the sieve by the operating room. The instruments can sting the worker and cause dangerous infections. A worker reported his experience with such accident.

This list shows a small cut of typical failures within the unclean area of a CSSD. Not included in this list are failures concerning the organization and documentation issues, such as maintenance intervals of the machines, because they require a much greater time interval of observation. Unfortunately, a detailed view into the hospital internal failure statistics and quality reports was not permitted.

The lack of easy accessible working instructions is one issue that most failures at the unclean area have in common. This is intensified by a lack of IT tools, due to the wet and contaminated area. The safety clothes and aggressive cleansing material hinders the application of usable IT systems. For instance, the worker would not prefer to search for information within a personnel computer, if the mouse and keyboard is covered with hygiene foil while he additionally wears thick safety gloves.

In addition to the internship, a CSSD in Herford, Germany was visited for half a day to see whether the above findings are hospital specific or not. The main findings from the internship could also be observed in the CSSD in a hospital in Herford and were confirmed by the administration: Lack of IT support at the unclean area, wall mounted instructions at the unclean area, issues with documentation of failures and high effort to keep processes and working instruction consistent.

Concluding, the unclean area could be improved by assistive technology, that provides context-sensitive information holding short but meaningful working instructions. The interaction technology must provide a usable interface despite the hygiene restrictions. Since classical computer interfaces lack in usability within the unclean area, new technologies and modalities must be considered.

Human Factors

The practical insights from the internship showed, that there is a lot of variety in the CSSD domain and many potentials for failures. The complexity of microbiological mechanism and huge variety of medical devices as well as the regulatory affairs claim for continuously qualification of the workers. The author participated the course TSA I. Among the theoretical lessons, knowledge and opinions of CSSD experts' and the contact with the CSSD workers were valuable to derive the following human factors that apply in the CSSD.

- The effort and necessity for proper decontamination is often not appreciated by CSSD customers or even the hospital management
- Missing appreciation of the work by CSSD customers leads to demotivation
- More generally, the majority of workers are motivated and want to do a good job, but organizational issues inhibit their commitment
- Improper disposal by the operating room are annoying and dangerous. Often these issues are not documented or communicated.
- The quality management requires a cooperative communication between all participants of the sterilization cycle in order to support the fast and flexible adaption of processes.
- Errors can easily sneak in, if the work instructions and their abidance are not verified on a regular basis.
- The workers do not use EDP-system at the unclean area, because it is either not available or they shun the effort.
- Workers are sometimes confused due to changing procedures and legal prescription
- The time pressure of peak times leads to the disregard of working instructions

An established and open-minded communication with other departments and the support by the hospital management is mandatory for the CSSD administration for applying processes, that are in line with the manifold prescriptions. For example, the CSSD administration should be involved in process of purchasing new instruments. Otherwise instruments are purchased, that can not be reprocessed properly in the specific CSSD. The quality of communication with other departments as well within the CSSD is major issue for worker motivation.

2.4 Technological Preconditions

Technological requirements for new interaction technology supporting workers in a CSSD can be derived by the given infrastructure and the existing standards for human machine interaction.

This section describes the state of the art CSSD infrastructure, that could (at least should) be found in every hospital. The complexity of microbiological mechanisms and hygiene requirements is reflected among others in the machines and IT tool support, that support and encapsulate critical process steps during the decontamination.

The focus of Sec. 2.4.1 is to describe the commonly available hardware and existing structural aspects to describe the technological state of the art within today's CSSDs. Common terms of the CSSD domain are introduced and arising technological requirements for new assistive technology within this domain are discussed. Together with a review on relevant standards for human machine interaction in Sec. 2.4.2, requirements can be defined, that a new assistive technology should meet to be applicable in a CSSD.

2.4.1 Central Sterile Supply Departments' Infrastructure

Fig. 2.8 by Tuttnauer Europe B.V. [29] shows a typical floorplan of a (small) CSSD with its three hygiene areas: contaminated (unclean), clean and sterile area. These areas are separated by two-doors disinfector- and sterilization-machines, which form hygiene barriers between the different hygiene levels. A CSSD usually has a cart washer machine, where larger vehicles and containers must be clean routinely to remove dust and spillage. The unclean and clean area have a hatch for moving returning instruments into the unclean area, in case they were not cleaned and disinfected properly. Each hospital comes with specific structural conditions and therefore the floor plans of CSSD differ, but the separation into the three hygiene areas is mandatory. Often limited space requires careful planning of the working areas before the CSSD starts operation.

Medical devices can be hot, when they are unloaded from machine. This can require the instruments to cool down before further processing. The worker have to be aware of potentially hot instruments. Safety restriction are especially relevant for the unclean area of a CSSD. The mandatory safety clothes influence the potential interaction between the worker and a assistance system. The safety clothes for the unclean area consists of a protection vizor, face mask, bandana hood, protective gown and apron, protective gloves and autoclavable clogs. At the unclean area the safety restrictions must be kept, to prevent workers from harmful infections. Concepts for assistive technology, especially attaching wearable computing devices on the worker clothes must incorporate with the safety clothes, which either are disposables or washed (autoclaved) with high temperatures.

Among the observance of worker safety restriction process documentation is mandatory. Existing software tools ease this task. Medical devices, and instruments sets have barcodes, which are scanned at specific process steps, such as disinfection, packaging and sterilization. By scanning the barcodes of instruments at specific working stations, the documentation software can easily assign process parameter to the specific instruments. For instance, by scanning a container label directly before the container moves into the sterilizer, the software link the sterilization process parameter to the instrument.

Computers are an essential tool in the CSSD. Mostly used at in the clean area a CSSD specific software help workers compiling sets of instruments. However, the application of similar tool support for the unclean area is limited because of the hygiene restrictions. For the potential deployment of new software tools such as an assistive system, interfacing the existing CSSD software and especially its data regarding the instrument inventory must be considered. Ideally the effort of entering instructions and other data can be minimized by accessing to the existing data pool. Typical CSSD software is described in Sec. 3.3.1 of the related work.

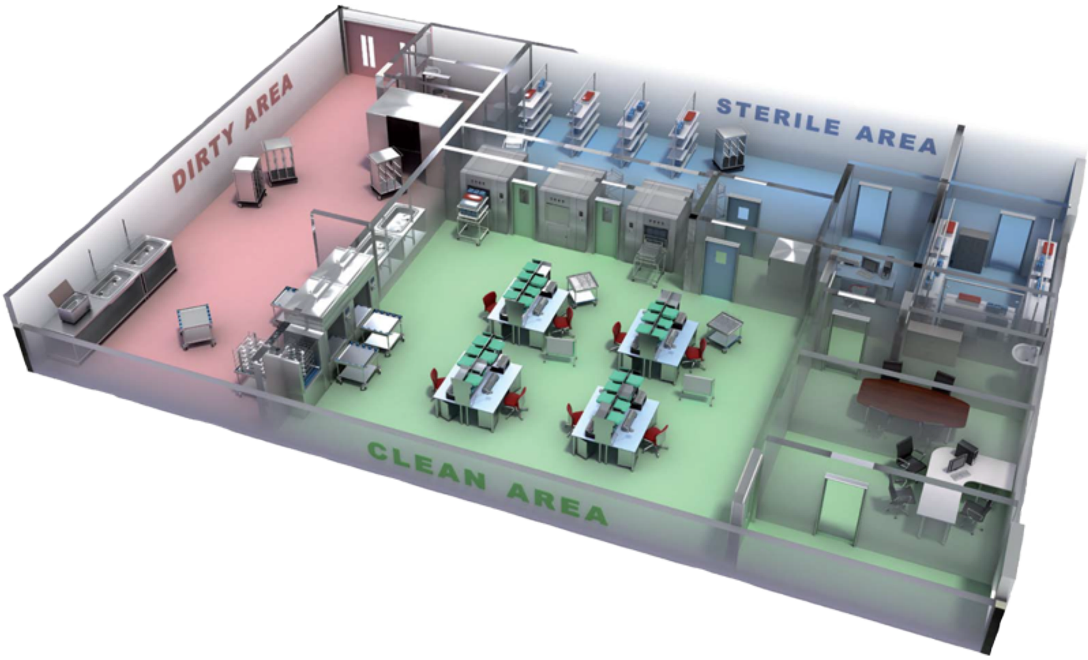


Fig. 2.8: Typical floor plan of a CSSD. Image courtesy of Tuttnauer [29].

2.4.2 Principles of Human Machine Interaction

Assistance in the CSSD includes the presentation of working instruction in a consistent, concise and interactive form. The design principles of a interactive systems and the

Fig. 2.9: Example for a workspace in the contaminated area of a CSSD.

disciple of human machine interaction are thus very relevant. An assistance system must provide a proper usability to support the CSSD worker in a meaningful manner. The term usability is defined by the ISO standard 9241 *Ergonomics of Human System Interaction* [30] as follows:

> The effectiveness, efficiency and satisfaction with which specified users achieve specified goals in particular environments.

This definition states, that there are users that want to fulfill a task or goals in an environment. Usability is not only about how good a system works. Moreover, it includes a context of use, a user and the system that provides functions to achieve a specified goal. In other words, the usability of a system can vary depending on the context of use and the user who operates it. The ISO standard 9241 part 110 [31] specifies design requirements for the fundamental dialogue principles of interactive systems. This general ergonomic principles which apply to the design of dialogues between humans and information systems should be regarded during the development of an assistance system for the CSSD:

- Suitability for the task
- Suitability for learning
- Suitability for individualization
- Conformity with user expectations
- Self descriptiveness
- Controllability
- Error tolerance

Among these standardized requirements for human machine interaction, Nielsen formulated ten heuristics of usability, which offer 'best-practice guidelines' of interactive systems [32]:

- Visibility of system status
- Match between system and the real world
- User control and freedom
- Consistency and standards
- Error prevention
- Recognition rather than recall
- Flexibility and efficiency of use
- Aesthetic and minimalist design
- Help users recognize, diagnose, and recover from errors
- Help and documentation

These proposed guidelines from ISO 9241 and Nielsen are mostly self-evident. The development of the assistance system should regard these principles of usability as 'technical requirements' in order to achieve a sufficient usability. Furthermore a user-centered design process according to ISO 9241 part 210 [33] is recommendable to get early feedback from the system's during the development and to meet the user needs.

2.5 Requirements for Assistive Technology - Summary

There are several thousand medical instruments in a hospital with a range from very simple to highly complex instruments. This inventory is additionally changing over time. Workers are often under high time pressure and must comply with many legal and hygienic restrictions as well as internal working instructions. There are a lot of error sources in this domain, because the workers in a CSSD can not always be aware of the correct instructions for every single instrument and every single process step. Failures during the reprocessing process however, can lead to dangerous residues on and especially within instruments, e.g. minimal invasive surgery instruments and can cause nosocomial infections. Broken or incomplete sets of instruments affect proper and correct treatment in the operating room. When failures occur, the overall costs of the reprocessing also increases, since process steps must be repeated and the instruments wear off faster or break due to improper handling. The CSSD as central service for hospitals has to assure the quality and efficiency of its service in order to keep its customers (e.g. stations, surgery rooms) functional.

The following seven requirements[6] for assistive technology in the CSSD result from the domain analysis:

R1. Since quality assurance is enshrined in legislation every CSSD has to document the following four major pieces of information in a quality manual (see WFHSS - World Forum for Hospital Sterile Supply website [22]). (1) *Working instructions*: Regulations

[6] The requirements have previously been published by Rüther *et al.* [34]

and provisions, procedural steps, explicit working instructions and job descriptions must be present. (2) *Documentation*: Expert opinions, technical leaflets, warranties and processing instructions must be filed separately and updated. (3) *Validation, periodic tests, routine tests and technical maintenance*: The validation part of the quality manual serves as proof that the specified procedural steps and processes are compiled within a reproducible manner and checked at regular intervals. (4) *Staff training and briefing*: Written records must be kept and filed of staff training courses and briefing [22]. An assistance system should help to gather and maintain this data.

R2. The information on how to correctly reprocess medical instruments exists and a quality management is present in today's CSSDs to assure quality. But in practice, it is often not possible for the worker to get the necessary information in an appropriate amount of time, especially in the unclean area. The system must provide a fast and robust user interface (UI) with useful information for the current instrument, as soon as the worker needs it. Usefulness of data implies a precise and concise form, which the worker understands quickly.

R3, R4. The UI must enable the worker to input information about the instrument or the process, which can be utilized by the quality management. Since the CSSD is a service for a whole hospital, the system integrates in larger scale hospital processes and communicates with its customers (e.g. other hospital departments, surgery rooms). For instance, running short consumable material, like cleansing material could be ordered automatically. Issues with the delivery of instruments by the operating room could be reported by the CSSD worker while reprocessing the instruments and the system automatically communicates the report to the responsible operating room technician. Workers are also a good source for getting condensed and precise instructions about critical handling instructions, because they know best what points of an instruction are important for them. For example, an experienced worker adds an instruction for correct handling of a specific instrument, which helps him remembering or helps an inexperienced worker to do the work efficiently. The assistance system should gather this data and check its correctness or ask a CSSD administrative for validation. Afterwards the data can be used as short and easily understandable instruction with high relevance for workers' task.

R5. In today's CSSDs typically barcode scanners for automatic process documentation can be found. A set of instruments is collected in a container with unique identification tag (barcode). For every process step the barcode is scanned and the process step is automatically documented. Since instrument tracking already exists, it should be utilized or improved by the desired assistance system.

R6. The workers at the unclean area can benefit from an assistance system. This is a challenging environment for interaction technology, because of soiled and contaminated surfaces. Interaction technology must meet hygienic requirements and the workers wear safety clothes. Desktop PCs with keyboard and a mouse as well as touch screens are not applicable in this area without special effort, because of hygiene regulations. Biohazard residues and aggressive cleansing material on the worker's hand gloves would stick on the interaction surface. The hardware of an assistance system must be applicable within this environment.

R7. Interaction design of a guidance system for reprocessing medical instruments must fulfill many requirements. Acceptance of the system is crucial, because if the workers do not accept the system they will not use it and the process/data mining mechanics of the system are compromised. Acceptance implies usability and unobtrusive interaction design. The system should neither delay nor disturb the regular workflow. The workers do not need instructions for handling ordinary instruments such as clamps or forceps, but should have the opportunity to easily get this information if desired. In practice, the workers could handle many single instruments even blindfolded. For these instruments, the system ideally 'disappears' and thus remains in a silent reactive mode in order to not annoy the worker. On the other hand, if there is a complex instrument which has to be treated carefully, the system must attract the worker's attention to the crucial issues.

Summarized, the requirements for an applicable assistance system at the unclean area of a CSSD are:

- *R1.* Data for the quality manual must be gathered and maintained.
- *R2.* Worker guidance: a UI provides condensed and precise information on demand.
- *R3.* Worker input: getting process-relevant information from the worker within the workflow.
- *R4.* Hospital integration: communication with CSSD customers and hospital departments.
- *R5.* Automatic documentation of process steps.
- *R6.* Applicability of hardware in the unclean area.
- *R7.* Acceptance: implies usability and an unobtrusive amount of interaction.

Chapter 3

Related Work

The field of assistive technology for worker guidance is very interdisciplinary, as the requirements from Chapter 2 indicate. Fields of interests include engineering, computer science, psychology, ethics, legislation and economics. This chapter focuses on the technical aspects that are related. Commercially available software is described and related work from computer science and engineering is discussed in order to explore the state of the art of assistance system in the CSSD and production.

The preparation of medical instruments is a manual task and does not differ much from manual assembly tasks which are more frequent subject of publications. Although the main focus of this work is an assistive system for the workers of a CSSD, many concepts and requirements are directly relevant for the more general domain of manual assembly processes as can be found for example in industrial production lines.

Supporting workers by electronic assistance within a CSSD or productive environment can potentially increase the worker's performance and the process, as described in Chapter 2. Helpful information and useful functions can be provided in several ways and with a high variety and combination of already existing user interface and interaction technology. In this section, a review on interaction concepts, modalities and devices is given to describe the state of the art of worker assistance as well as technical basics.

3.1 Mixed Reality

Worker guidance within production environments or CSSDs implicitly rely on the augmentation of the workspace by working instructions and other work-related data. This can either be in physical representation of data in form of papers or in digital representation in form of digital data that is accessible via a user interface. Because the paper bound representation is more or less static after the print out, the augmentation of the working place by digital content offers benefits for fast and flexible data communication and context awareness of the presented data. In computer science different terms refer to the amount of virtual information that a real environment is augmented with. In Fig. 3.1 the so called reality-virtuality continuum is depicted that was proposed by Milgram *et al.* [35]. On the one site there is only the reality with no virtual content. In contrast, the virtuality refers to a environment which is not represented physically. Mixed reality is the interval in between, which can further be distinguished into augmented reality where the virtual content augments the reality and the augmented virtuality where the reality augments the virtuality.

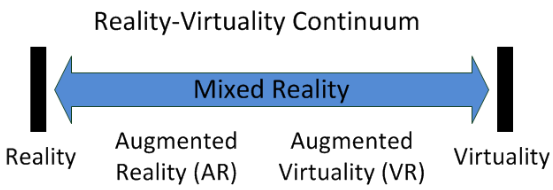


Fig. 3.1: The reality-virtuality continuum according to Milgram *et al.* [35]

For assistive systems in productive environments and CSSD the virtual content like working instructions augment the reality that is given by the working place and therefore augmented reality is more relevant in this domain. In contrast the virtual reality is more considered for product development and virtually simulating products or product lines before they are manufactured.

According to Azuma *et al.* augmented reality systems have the following three characteristics [36, 37]. First, they combine real objects with virtual content. Second, the systems are interactive in real-time. Third, the reality and virtual augmentation are registered in three dimensions for accurate alignment of virtual objects in the reality. Development of an complete augmented reality system requires six major factors that directly influence the quality of an augmented reality system. According to Azuma *et al.* [36, 37] and Zhou *et al.* [38] these factors are:

1. **Rendering hardware and software** prepare the virtual content for the overlay into the view of reality.
2. **Tracking techniques** recognize position changes of the viewer to properly effect the rendering of virtual content.
3. **Tracker calibration and registration tools** are necessary for proper alignment of virtual and real environment.
4. **Display hardware** merges virtual data into the view of the real environment.
5. **Computer processing hardware** supports input and output modalities and provide a device-platform for the interaction between the user and the virtual content.
6. **Interaction techniques** define how the interaction dialog affects the system functions.

Augmented reality systems can further be categorized by their application or by the position of the augmented display in relation to the user. According to [39] typical applications for augmented reality are personal information systems (personal assistance and advertisement, navigation and orientation, tourism and exhibits), industrial and military applications (design, assembly, maintenance, combat and simulation), medical applications, entertainment (sports broadcasting, collaboration) and education and training. Although augmented reality is by definition not restricted to visual displays, the optical presentation of information is the most common way to augment the reality. The augmented reality display can be located at the users head (head-worn AR) in the users hand (hand-held) or spatially located in the environment (spatial augmented reality) as depicted in Fig. 3.2 and discussed in the following. [37, 38, 39]

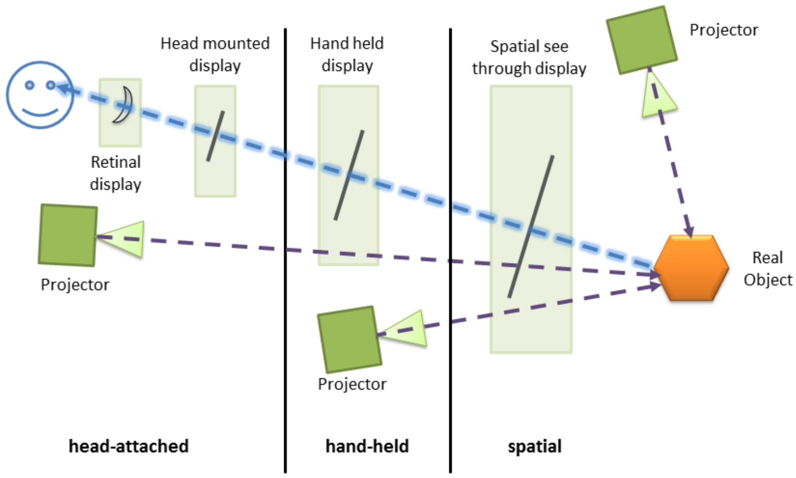


Fig. 3.2: Classification of augmented reality systems by the position of the display in relation to the user and object. Figure adapted from [40]

Displays for Augmented Reality. For mixed reality applications, the environment can be augmented by Head Mounted Displays (HMDs), Projection, mobile and smart Devices. HMDs are displays, that are worn on the head and which the user looks through. In case of HMDs the augmentation of reality can be achieved by two technological principles: Video-See-Through devices that interrupt the optical flow of an real word object to the users eye by deploying a display. The real world is captured with camera that is usually mounted on the HMD as well. The video stream is augmented with data and the augmented video is shown in the HMDs display. The other principle "Optical-see-through" does not interrupt the optical flow from the environment to the user's eye. Instead a transparent display allows the user to perceive the environment and information as well.

Another technical method for augmentation real world objects is to project information on the objects. The coordinates of the tracked objects are transformed the coordinate system of the projector. Since no wearable computing is required in projection based AR this approach recommends for multi-user scenarios. This kind of augmentation is well known as spatial augmented reality. Another projective approach of AR can be found in head-up displays. As an first application these device could be found in fighting jets, where information was projected on the cockpits glass. A application domain for head-up displays are assistive systems in cars. These systems project helpful information such as orientation lines on the car's windshield.

3.2 Natural Interaction

A natural user interface (NUI) is a user interface designed to use natural human behaviors for interacting directly with content. This emerging paradigm in shift human-computer interaction refers to user interfaces that are effectively invisible to its user or become invisible with successive learned interactions. NUI are inspired by the natural interaction between humans and the real world. For instance humans use gestures, expressions, gaze, movements and speech to communicate naturally and can manipulate objects by touches. In analogy to interaction between human and real world, NUIs offers a way of interaction with computers by observing and interpreting natural human behavior. NUI therefore focus on traditional human abilities such as touch, vision, speech, handwriting, motion and more importantly higher level processes such as cognition, creativity and exploration. [41, 42]

For an assistive system within the CSSD or productive environments NUIs are of special interests, because they are considered to be intuitive and invisible. Potentially, computer-functions could be controlled by the user with low to zero effort because the NUI observes and interprets the natural behavior of the human. For example, the user could start a washer and disinfector machine by saying a verbal command, furthermore an assistance system could identify when a user is confused and provide help by observing user face expressions eye movements. By interpreting natural human body language, stress could be identified and included in the context-awareness of the assistance system. However, stress is very person-specific and therefore the robust classification of stress levels is technical challenging [43, 44]. Nevertheless, NUIs should be considered for the user interface concept of the assistive system, which is the topic of Chapter 4. They have the potential to provide a natural, intuitive, immersive and invisible way to augment the working place with virtual content.

Multimodal Interfaces. Multimodal interfaces enable the user to interact with automated systems by using multiple different channels or modes. The hypothesis of such systems is that the usability of a system increases, because the user can choose the most suitable modality for interaction depending on the context of use or situational comfort. Typical modalities found on the input side include speech, handwriting, classic computer interfaces (e.g. mouse and keyboard), hand and gaze gestures. Multimodal output can consist of speech synthesis, sonification, force-feedback, graphics, etc.. Technical challenges for multimodal systems include the fusion of different input streams, the generation of context-aware output and the fission of the output to different output modalities, which usually has to performed in real-time as depicted in figure Fig. 3.3. [45, 46]

The computational complexity for fusion and fission is a drawback for field application. According to Atrey *et al.* [47], the appropriate synchronization of the different modalities for fusion is still a research question, which is supplemented by issues regarding the fusion process such as the weighting of modalities, integration of context, correlation, optimal selection and evaluation metrics [47].

Among the fusion and fission, each unimodal technology is an active research area itself. Multimodal integration methods and architectures and improvements in perception, performance, machine learning, personalization and adaptability are necessary for sophisticated multimodal interaction to become a commonplace, indispensable part of computing. [48]

The domain-analysis in Chapter 2 showed that standard computer interface within the unclean area of a CSSD lack in usability, because this modality does not match the context of use within a hygiene critical environment. To overcome this issue, interaction modalities such as speech recognition or motion recognition should be considered. Multimodal interfaces can enhance usability, but come at the costs of fusion, fission and system complexity. This kind of trade-off must be considered during the conceptualization of assistive systems as discussed in Chapter 4.

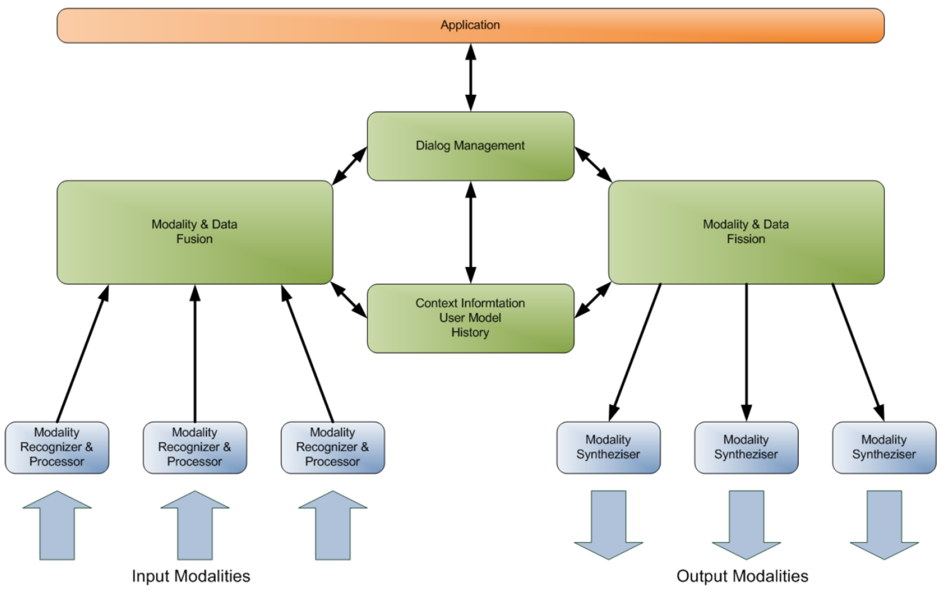


Fig. 3.3: General architecture of multimodal systems. The technical challenges include the fusion, context-aware output generation and fission in real-time. Figure adapted from Dumas *et al.* [45].

Automatic Speech Recognition. Speech recognition translates spoken words and phrases into a machine-readable format, which enables spoken language as an input for user interfaces. One advantage of spoken language is that it comes naturally and it does not require the user to move his hands or arms. The benefit is of special interest for the CSSD or manual production, where the worker usually needs his hands to work on instruments or work pieces. However, speech recognition is quite complex, because differences in pronunciation, accents, speaking cadence and noise must be processed by the recognition algorithms [49]. This complexity of recognition manifests in high error rates even after 60 years of speech recognition [50]. However, existing commercial products like Siri [51] or Google Now [52] show that speech recognition works under certain circumstances and therefore speech recognition could be an option for the assistance system user interface.

Gesture Recognition. Traditional and most popular user interfaces rely on simple mechanic devices: mouse and keyboard. These devices require the user to interact in an artificial way. Human body recognition is an interaction paradigm to overcome this cumbersome interaction with traditional devices. The motion of the human body is recognized and interpreted to control computer functions. Especially gestures are considered as a natural way of communication. By understanding gestures, a natural user interface is closer to the communication pattern of human being than the artificial classical computer interfaces [43, 53].

Gesture recognition requires sensory input in the first place, which is capable of tracking the motion of human body parts and which enables software algorithms to recognize and classify motion, such as hand gestures for instance. The choice of sensing technology refers to the kind of gestures that needs to be recognized. For example gaze gestures need other sensory than hand gestures.

The emerge of low cost depth image cameras had a huge impact on gesture recognition. Especially the commercial release of the Microsoft Kinect [54,55] made it possible to use the human body as a controller for video games. The Kinect was released in November 2010 and integrates a color (RGB) video camera, a microphone, 3-axis accelerometer, tilt motor and a RGB-D sensor, which further consists of an infrared emitter and a monochrome CMOS[1] sensor. The emitter emits a grid of infrared light. The structure deforms when the lights hits objects. The CMOS-sensor is adjusted to the infrared light and senses the reflected and deformed light structure. The distance to objects can be derived from the deformation. The Kinect made capturing a depth image possible at much lower costs than the traditional 3-D cameras (such as stereo cameras and time-of-flight cameras) and facilitated applications for object tracking and recognition, human activity analysis, hand gesture analysis as well as indoor 3D mapping. [56] Meanwhile released new RGB-D sensor applications like the ASUS Xtion [57] and the recently released Microsoft Kinect for Windows V2 [58] improve the resolution and accuracy of low-cost depth sensing devices. The first Kinect has a quite low resolution of 320x240 pixels for the depth image and 640 x 480 pixels for the RGB image resulting in relatively high sensory noise. The Kinect Version 2 comes up with 1920x1080 pixels for RGB-D and 512-424 pixels for the depth image.

However, depth images must be processed in order to interpret the perceived motion and to enable interaction. The framework "dSensingNI" by Klompmaker *et al.* describes a middleware for multitouch and tangible interaction with arbitrary objects by processing depth images from a depth-sensing camera [59]. Depth cameras can be used as a touch-screen like interaction modality, as the following related work demonstrates. Harrison *et al.* proposed the "OmniTouch" system, which combines a depth camera with a projector to setup a wearable device that augments "everyday surfaces, includ-

[1] complimentary metal-oxide semiconductor

ing the human body for graphical multitouch interaction" [60]. The "WorldKit" by Xiao *et al.* shows how common surfaces can become an interactive surface by pairing depth cameras and projectors [61]. Wilson *et al.* described how a depth camera can be utilized as a touch sensor [62] and how multiple touch sensors can be combined for interactions on, above and between surfaces [63]. The "Ubi Display Toolkit" by Hardy and Alexander pursues to facilitate the development of pervasive displays that are realized by depth tracking and projection [64]. The related work on combination of depth cameras and projection focuses on domestic and office scenarios. The combination of projection and motion recognition is a promising option for worker guidance in the CSSD as discussed in Chapter 4.

3.3 Assistive Systems for Worker Guidance

Assistive systems for the CSSD domain is a rarely discussed topic in the scientific literature. The state of the art in this domain was partly described in the domain analysis in Chapter 2. This section provides a brief review on commercially available software products to describe the state of the art of assistive technology of the CSSD. The reprocessing of medical devices can be compared to the manual production of goods. Thus, related work for worker guidance in productive environments and manual assembly is reviewed to explore existing technologies for worker guidance, that could potentially applied in the CSSD.

3.3.1 Commercial CSSD Software

Today's software for the CSSD provides tools for the logistics, process documentation, quality management. The software EuroSDS by IBH Datentechnik GmbH provides tools for the management and documentation of the CSSD logistics. According to the vendors description, it covers all relevant functional areas of the instrument cycle. The software comes in a basic package, which supports the tasks packaging, preparation of batches, registration and release of sterilization processes, manual batch assignment, as well as the long-term archiving and analysis. Additional modules extend the basic packages and offer tool support for the unclean area, such as receipt and cleaning and disinfection. Further modules support the sterile storage, instrument management and transportation. [65]

Another example for CSSD software is the software 'instacount' by INVITEC. Similar to EuroSDS it is distributed with a basic package 'Core Modul'. Additional modules extend the core functions such as instrument management, quality management, documentation, etc. by ware-housing, process and cost control as well as communications tools. The 'instacount.DECON' module allows the registration of contaminated devices at the point of receipt at the unclean area of the CSSD. It also yields advisories for the processing of sets and special guidelines for the treatment of individual instruments as depicted in Fig. 3.4. [66]

Although EuroSDS and instacount provide assistance at the decontamination area of a CSSD by automatically displaying working instructions, they are bound to standard interaction technology: touchscreen, mouse, keyboard, barcodes and RFID are

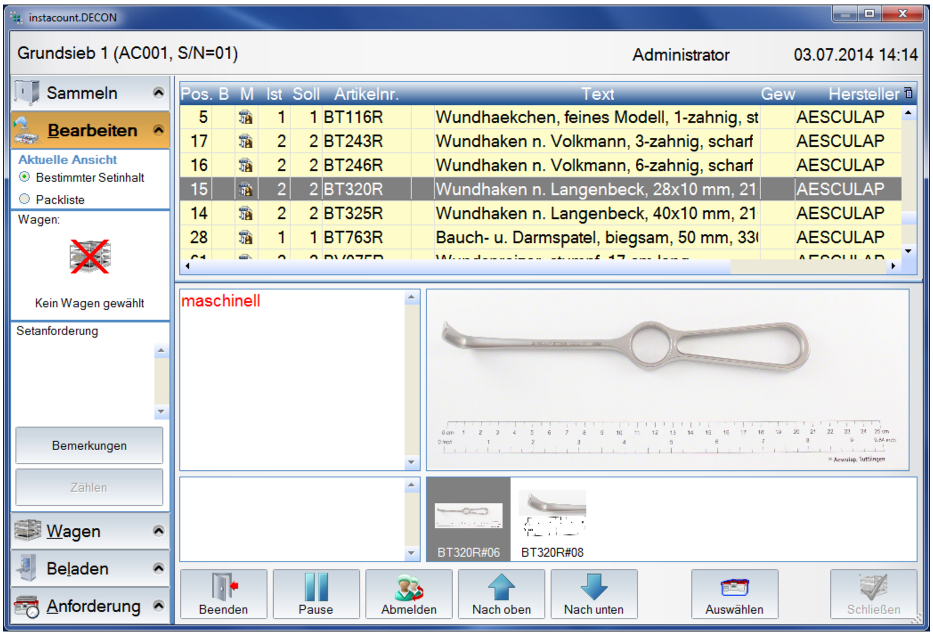


Fig. 3.4: instacount.DECON as an example for commercially available CSSD software. The picture shows the interface for the decontamination area that contains working instructions. Image courtesy of INVITEC [66].

the interaction technology that must be used for operating with commercially available software solutions. The usability issues of such devices within the wet and contaminated area of the CSSD were already discussed in Chapter 2.

Aside from the commercial products, Mislimi proposed the “WiFlow Prozessnetz” which enables the worker to access information and working instructions from a electronic quality manual [67]. Data is attached to tasks of process models. A web interface at the CSSD workplaces allows the workers to navigate through the process models and to retrieve the working instructions. The approach of structuring data according to its relevance within the CSSD workflow seems to be reasonable: the worker can locate his current task assignment in the structured workflow and thereby get detailed working instructions if necessary. However, the system does not provide working instructions in an automated manner. The worker has to know the general workflow to find information with low searching effort. The system utilizes the standard computer technology with its usability issue at the unclean area of the CSSD.

3.3.2 Commercial Systems for Worker Guidance in Manual Production

Assistive system within production environment commonly support workers with commissioning tasks, working instructions or quality assurance. These use cases are not complementary and are sometimes combined. The tasks reflect the primary activities of inbound logistics, procedure and outbound logistics of a value chain. The following examples show how these applications are supported by state-of-the art assistive technology.

Assembly guidance. Commercially available systems often use touchscreen or a keyboard and mouse, to enable interaction with the assistive functions. Additional hardware is often required for either documentation, assembly or testing quality. The company *erfi* is a vendor of working place systems, measuring and testing devices as well as test equipment for electric safety and function. Fig. 3.5 shows an erfi workplace and the software erfi AWM (Assembly Workflow Manager) which supports the assembly of workpieces by showing ordered images and short texts. The working instructions are entered before the assembly process. [68]

Fig. 3.5: The image from erfi Ernst Fischer GmbH & Co. KG shows a modular working cell and the erfi software AWM which provides working instructions. The software screen shots show the assistance user interface and the software tool for the definition of workflows. Image courtesy of erfi GmbH & Co. KG [68]

Another example for worker guidance is the system "ELAM" by Armbruster Engineering [69]. Its module ELAM-worker yields working instructions for the assembly process as shown in Fig. 3.6. In both systems, the instructions for the assembly procedure are previously entered into the system with a dedicated tool for data maintenance. The presentation and the workflow for the assembly is linear: the product is built step by step in a defined order.

The research project motionEAP targets to increase the efficiency and assistance of production processes within companies on the basis of motion detection and projection [70]. Korn *et al.* discuss among others the requirements for context-aware assistive systems, the transition into a generic model and the impact of a projector based context aware system on the work speed and quality. A prototypical implementation of a context-aware assistance system is shown in Fig. 3.7. The system utilizes projection, motion recognition and gamification[2] was positive evaluated in terms of acceptance,

[2]Gamification is the use of game thinking and game mechanics in non-game contexts to engage

Fig. 3.6: The ELAM system by Armbruster Engineering GmbH & Co. KG supports the worker during manual assembly. Image courtesy of Armbruster Engineering GmbH & Co. KG [69].

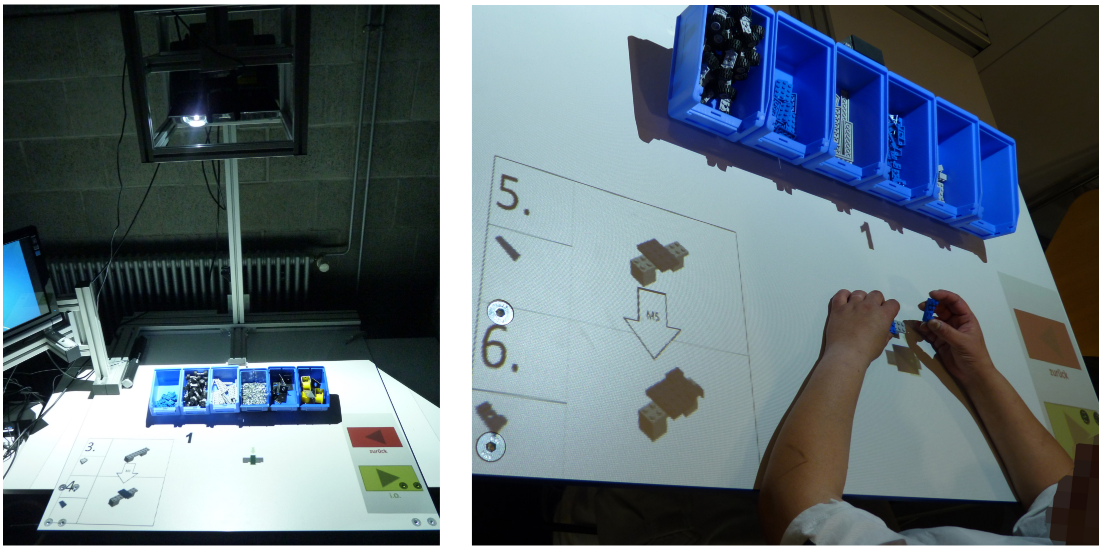
usability and handling. The evaluation was performed by a user study with impaired persons. [74, 75, 76].

In their earlier work Korn *et al.* describe the growing need for assistance systems in production and propose three paradigms for the design of such systems: scalability to competence and process level, small chunks of information at the right time and increasing motivation and fun while working. They propose a design study that combines motion recognition and gamification to assist disabled or impaired workers. [77]

The project ACIPE focuses on intuitive and naturalistic interaction between a worker and an assistance system for human manual workplaces. It proposes mental, cognitive and process models for adaptively presenting instructions, according to working situation [78]. The “Attentive Workbench” assists the worker in manual assembly with automatic parts delivery and projection of assembly instructions [79, 80]. Ziola *et al.* propose an augmented reality system for guidance with the assembly of Lego bricks [81]. Additionally, the system detects constructed objects via computer vision and augments the environment with multimedia content. Zhang *et al.* combine RFID, inertial sensors and a head mounted display to support the assembly of a 3D-puzzle and a computer mouse [82].

Commissioning and quality assurance. Pick-by-light is a way to support workers at commissioning, which is commonly a task of locating the correct parts within a storage or set of boxes. The concept of pick-by-light is that lights mounted on the boxes show the worker where he or she has to pick. These systems often use motion

users in solving problems [71, 72, 73]



3.7.1: Technical Setup of the assistive system. A projector augments the workplace with working instructions.

3.7.2: The assistive system is used during manual assembly of objects from Lego bricks

Fig. 3.7: An implementation of a context-aware assistive system for manual assembly in sheltered workshops. Figures courtesy of Oliver Korn [74].

recognition to track the picking sequence. They target to improve the workers performance in speed and failure avoidance by displaying the information where to pick next directly to the item that should be picked. More suitable for order picking tasks within warehouses is the concept of pick-by-vision, which uses augmented reality to guide the worker to the goods he or she has to pick up. First evaluations of the system showed potential for decreasing errors within the order picking. But the evaluation also showed that the application of such systems in practice is at least questionable, because of costs as well insufficient robustness and ergonomics of the hardware. [83,84]

An example for such a system within the productive environment is the Sarissa QualityAssist System which uses a triangulation of ultrasonic tones to locate a marker on the workers wrist. The system compares the current picking of products with a predefined sequence. In case of unexpected picking, the system sets off an alarm. The acoustic markers can also be attached and combined with tools. For example a driller can be located in 3D with an attached marker. The tool will only activate, if it is located at the correct position. [85]

3.4 Business Process Modeling and Information Management

For CSSD the overall procedures are defined by the several guidelines and standards as described in Chapter 2. Hence, process models are available that define the series of actions and procedures to achieve sterile goods. A process or process instance

Fig. 3.8: A worker is commissioning an order with the Sarissa quality assist system. Image courtesy of Sarissa GmbH [85].

is the concrete processing of an instrument or workpiece under the series of action defined by the process model. Additionally so called process-meta-models explain the key concepts for process model development, which concerns methods, guidance and tools for creating and maintaining process models. From a theoretical point of view, meta-models define what can be described with a process model, while process models describe how a workflow should be executed and the process instance is the execution of a process model.

The widely adopted definition by Davenport and Short in 1990 describe business processes as:

> *"... a set of logically related tasks performed to achieve a defined business outcome."* [86]

By this definition, three basic characteristics of business processes are described: 1) logical relation 2) of tasks or activities for 3) business outcome, which can be a product or service. This definition was extended by Davenport in 1993:

> *"A business process model is a structured, measured set of activities designed to produce a specific output for a particular customer or market. It implies a strong emphasis on how work is done within an organization, in contrast to a product focus's emphasis on what. A process is thus a specific ordering of work activities across time and space, with a beginning and an end, and clearly defined inputs and outputs: a structure for action. [...] Taking a process approach implies adopting the customer's point of view. Processes are the structure by which an organization does what is necessary to produce value for its customers."* [87]

Following this definition, the process are customer-oriented. The input becomes a valuable output for a customer by applying a structured set of activities. The process is therefore customer-oriented and part of an organization. A similar definition by Rummler and Brache from 1995 additionally shows the relation to Porter's value chain by distinguishing between primary processes and supporting processes:

> *"A business process is a series of steps designed to produce a product or service. Most processes [...] are cross-functional, spanning the 'white space' between the boxes on the organization chart. Some processes result in a product or service that is received by an organization's external customer. We call these primary processes. Other processes produce products that are invisible to the external customer but essential to the effective management of the business. We call these support processes."* [88]

A new point in this definition is the statement, that supporting processes are essential for business management. From these definition the following characteristics of business processes can be derived [89]:

- Boundaries: Business process have clearly defined input and outputs.
- Flow: Sequence of logical ordered activities or operations.
- Value-adding: the activities or operations create business value.
- Owner: Business processes are embedded in an organization which thereby owns the processes.
- Customer-orientation: The outcome is of value for a customer.

It should be pointed out that business process have at least one owner, who is responsible for the definition and application of such business process. The administration and maintenance of business process is described by the term business process management. Further details of this domain can be found for example in the survey by van der Aalst [89].

Business process management is relevant for the development of an assistance system for the CSSD because of three reasons: First, concerning the software architecture of the assistance system, a representation for processes must be found that allows to align the software functions to the prescriptions of the CSSD domain. Second, the assistance system should support not only the worker but also the process which defines the workflow. A process-sensitive or process-aware software takes into account that processes may change based on the captured process data. Third, the hierarchy and management of processes must be considered when an assistance system is developed. Workflows and working instructions must be continuously adapted and there is always a person who is responsible for changing the processes. The management process should be supported by meaningful measures of the process instances and a process management that allows to easily change and deploy workflows.

3.5 Industry 4.0 and the Internet of Things

In the history of industrial manufacturing three major leaps increased productivity of industrial processes significantly. The steam engine and machinery tools induced the first industrial revolution. In the early 20th century, assembly lines and electricity increased productivity drastically and triggered the second industrial revolution. Microelectronics, computers and robotics are the core technology of the third industrial revolution that begun in the mid 1970s. [90]

Nowadays, computers and electronics are developing towards autonomous, embedded, wireless connected systems that communicate either directly or via cloud computing. The high-tech strategy “Industry 4.0” of the Federal Ministry of of Education and Research pushes the concept of “smart factories” forward that facilitates new business models by a higher level of networking. Smart Factories offer adaptability, flexibility, resource efficiency and directly integrate customer and partners into its business and value processes. A key-role within the development of the industry 4.0 are cyber-physical systems [90,91]. According to Mikusz [92] “Cyber-Physical Systems (CPS) are systems of collaborating computational entities which are in intensive connection with the surrounding physical world and its ongoing processes, providing and using, at the same time, data-accessing and data-processing services available on the internet” [92]. Fig. 3.9 depicts the structure of a cyber-physical system.

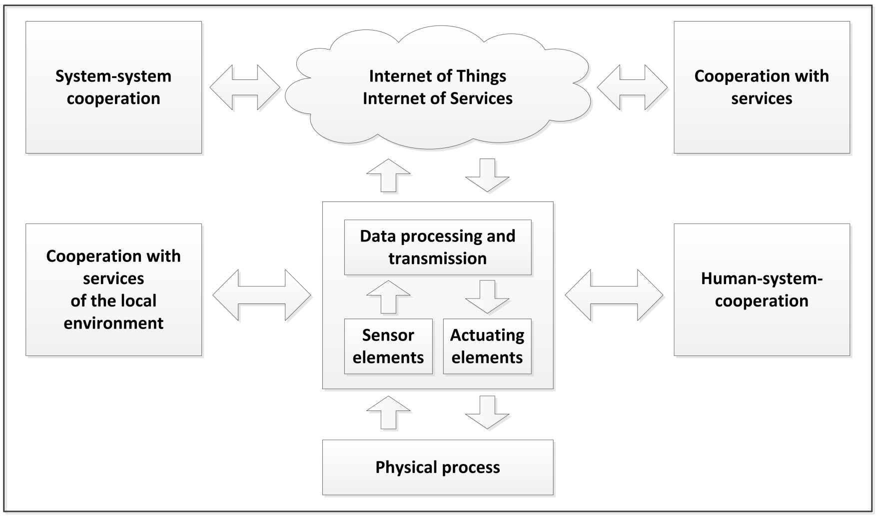


Fig. 3.9: The structure of a cyber-physical system. Figure adapted from [93].

The VDI/VDE [93] argues, that the classical automation hierarchy[3] as shown in Fig. 3.10 could be replaced by connected, decentral and partly self-organizing services. Cyber-Physical Production Systems (CPPS) allow to locate, retrieve and execute data, services and functions, where they offer the highest advantage regarding a flexible, efficient development and production, which must not necessarily be on one of the classic automation levels. CPPS allow to cluster abstract function into an “automation cloud”, which utilizes and combines functions of all classic automation hierarchy layers into services. It is therefore conceivable that the classic automation pyramid gets successively superseded by decentral, linked-up services [93, 94].

Technical prerequisites for the next generation of industry are 1) standardization

[3]Also known as automation pyramid.

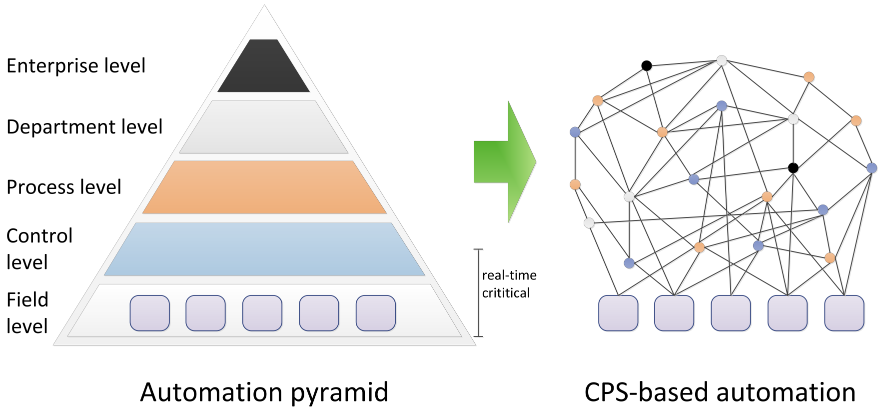


Fig. 3.10: The classical automation pyramid (left) changes to the automation cloud (right). Picture adapted from [93].

and a reference architecture to achieve interoperability of devices and services 2) Mastery of complex systems and products 3) Resource efficiency. Furthermore the new business models, changing tasks and competence profiles for worker require progress in the fields of work organization, ergonomics, education and legislation [95].

These high-level key concepts of industry 4.0 are related to the development of an assistance systems that guides workers in CSSD and manual production. As already argued in the Chapter 2 the value generated in a productive environment can be increased by profound connection of devices and services. The question is, how a technical solution for a worker guidance system can be achieved. The technical challenge is to integrate heterogeneous hardware devices and software services into a connected assistance system, that increase the value generated in a productive environment. The underlying software architecture must be capable of flexible configuration and orchestration of the different hardware devices.

Within the project "Internet of things - architecture" an architectural reference model developed, that offers "interoperability of internet-of-things systems, outlining principles and guidelines for the technical design of its protocols, interfaces, and algorithms" [96]. Corresponding mechanisms allow the integration into the service layer of the future internet. [96] The project was funded by the EU within the 'Information and communication technologies' (ICT) Theme of the EU's Seventh Framework Programme (FP7). Meyer *et al.* [97] describe detailed requirements, design principles and concept components proposition for a IoT-aware process modeling methodology. They emphasize the standard "business process modeling notation 2.0 (BPMN 2.0) for the creation of a graphical and executable process model that uses IoT-technology for executing some or all process tasks in form of services. Although the Architectural Reference Model (ARM) is very abstract it provides views and perspectives on different architectural aspects that are of concern to stakeholders of the compliance to the IoT Reference Architecture and could be helpful during the development of a concrete architecture for the targeted assistance systems [98]. However, this thesis focuses on an assistive system for worker guidance, where the software architecture is one of many concerns. Applying the methodologies, guidelines and the ARM for the concrete use case of an assistance system in CSSD and manual production would require too high effort, because the very high abstraction of the ARM must brought down to a concrete architecture, which is time intense process. Nevertheless, some concepts like the business process models are of interest for this thesis as discussed in Chapter 5.

3.6 Summary

This chapter has discussed approaches, technologies and assistances systems with relevance for worker guidance in the CSSD and productive environments. To the best of the author's knowledge, there are no published studies about assistance systems for workers in the unclean area of a CSSD. The preparation of medical instruments is a manual task and does not differ much from manual assembly tasks which are a more frequent subject of publications. There are approaches for worker guidance within a smart workbench, often using augmented reality for highlighting work pieces and guiding workers through assembly processes.

Although this literature review has described assistance systems that are to some extent applicable in the CSSD domain, these systems provide a constant-at-run-time set of data for worker guidance and constant workflows, which are given by the system designer beforehand. The dynamical extension of the data-base is critical for an efficient guidance of the worker, especially in hospitals with several thousand instruments. Guidance in a CSSD must allow the worker to add or edit instructions, short reports or notes, which can be used for either supporting quality assurance or for guiding other (inexperienced) workers. Within the approaches mentioned above, changes to this data and the workflows require special user interfaces and knowledge and are not possible while working with the assistance system. The worker can not add, remove or edit instructions or failure reports at run-time. More generally, the related work review shows, that recent assistive technology has at least one of the following issues:

- Working instructions are static during use.
- Missing input capability for quality reports at the work place.
- Missing context-awareness of working instructions.
- Missing workflow flexibility because of systems that are build for special processes or process steps.
- Usability issues of devices and interface.
- Missing applicability for the unclean area of a CSSD (robustness, ergonomics).

Summarized and to the best of the author's knowledge, there is no system, that meets all of the requirements from the domain analysis for worker guidance at the unclean area of a CSSD.

Chapter 4

Applicable HMI Technologies for the CSSD

The domain analysis showed that the presentation of working instructions and data maintenance at the unclean area of a CSSD offers a high potential for improving the decontamination process. The presentation of concise, precise, consistent and context-aware working instruction at the right time, at the right place in the right form is desirable to draw the worker's attention on failure sources and critical handling instructions. A realization of such assistance implies to concern three major technical aspects.

First, hardware and computational devices such as sensory or displays build the foundation for worker assistance. The hardware setup of the system shapes the type of user interface that supports the worker. The sensory equipment of the assisted workplace determines, how the system captures the workplace, the context of use and the user input.

Second, the UI and the interaction dialogue must be designed to provide meaningful assistance in a usable manner. This requires to adjust the provided assistance functions to the task-specific requirements and the user needs. The UI design options depend on the display and the sensory input.

Third, data and information management must be enshrined in a software architecture. Software services and hardware devices must be coordinated according to the requirements of the workflow. Software services are responsible to maintain and provide a valid set of process data and instructions.

This chapter addresses the first point by concerning different concepts for the hardware setup of the assistance interfaces and the corresponding use cases. The potential of the concepts is analyzed by discussing the technical restrictions and potential fulfillment of the requirements from Chapter 2.

4.1 Augmented Reality for the CSSD

Worker guidance by augmented reality and HMDs is a frequent topic in research publications. A general assumption and motivation for augmented reality in productive environments is that the worker benefits from the proximity and spatial relations of virtual and real objects. Especially working instructions could be displayed in the worker's field of view and in direct relation to the work piece or medical device. Thereby the worker safes time and the overall performance can be increased [99, 100].

An augmented reality application concept within the CSSD is depicted in Fig. 4.1. In this design study the worker wears a HMD which visualizes working instruction for loading a washer and disinfector. The augmented working instruction is referenced with the optically captured position of the disinfector basket. The displayed working instruction are recognized by the worker, because it gets part of the currently operated object. Thus, confusion and failures are expected to be avoided during the processing of the medical device.

Fig. 4.1: Design study for augmented reality for machine loading. The worker wears a HMD (left image) which presents working instructions on how to correctly load a washer and disinfector (right image). Images courtesy of Maik Mracek.

Fig. 4.2 illustrates the idea of maintaining machines and devices with an HMD and augmented reality. Again, the augmentation of machine parts facilitate the identification of machine parts that are relevance for the current operation. This idea could also be used for remote maintenance. If the HMD is connected with the service department of the washer and disinfector manufacturer, working instructions can be provided remotely from an expert that is not physically present in the CSSD. A machine expert remotely perceives the same scene as the CSSD worker and guides him through the maintenance of the washer and disinfector machine. A third idea for augmented reality concerns the packaging area CSSD and is depicted in Fig. 4.3. The figure hints that the inspection, assembly and the packaging of sieves could be supported by augmenting the worker's view with working instructions, e.g. on where to put specific instruments.

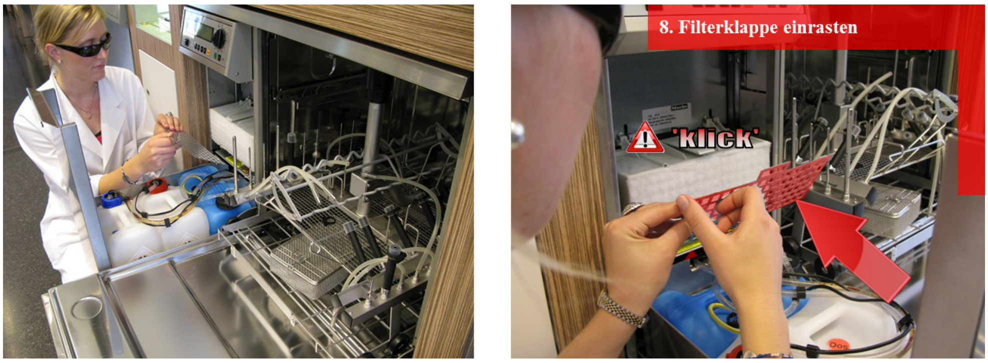


Fig. 4.2: Design study for an augmented reality based assistance during machine maintenance. The HMD provides handling instruction for exchanging a filter. Images courtesy of Maik Mracek.

Among the usage of head mounted displays, projectors, wearable devices or see-through monitors are also conceivable to provide an augmented reality based user interface. Regarding the augmented reality classification from Fig. 3.2 stationary mounted see-through displays or wearable devices could also be used to augment the working scene. Fig. 4.4.1 shows a conceptional draft how such a workplace could be set up with a see-through monitor. In this “see-through screen” concept, the worker operates the medical device underneath a transparent monitor. The sensory input detects the work-pieces position and orientation. A second camera tracks the workers head movement. With the known and fixed position of the display, working instruction can be rendered into the workplace and over the instruments. Working instructions are aligned to the instrument that is currently processed. Thus, the working instruction is directly located on or near the instrument or workpiece. The technical realization requires high effort for tracking and rendering as well as maintaining working instructions that comply to the augmented reality approach (e.g. 3D-virtual objects of medical devices). The tracking and rendering requires a preparation of the environment, to robustly identify and track medical device in position and orientation. Furthermore, recent HMD come with ergonomic issues, e.g. virtual sickness [101, 102].

Tracking and rendering effort. A system for the augmentation of real world objects has to determine the position and orientation of the real object, the position of the display and the human eye. The rendering algorithm can render the virtual object in alignment to the real object, if these three position are known and continuously updated. The knowledge about how a virtual information should be rendered into a real scene is a supplemental prerequisite. More in detail, objects must be recognized and identified by the system in order to determine the correct information that is related with the specific object. The tracking and rendering must be very precise and computed in real-time to adapted to the movement of the human body and objects. For an application within the CSSD, the classification rate of current computer vision algorithm is not sufficient to robustly track and identify medical devices. Due to the manifold different types of medical devices and the adherence from the operating room

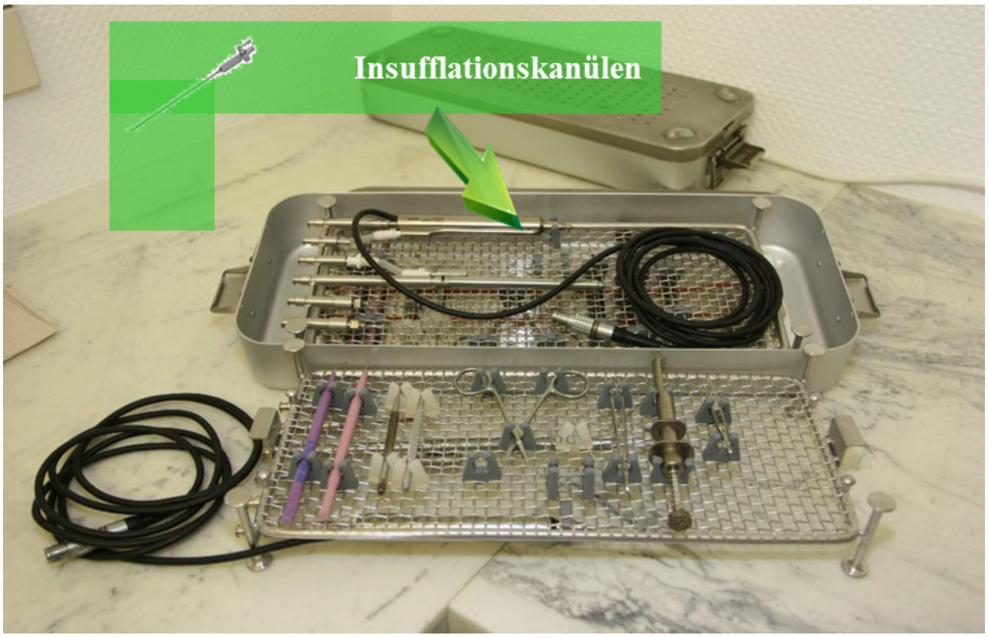
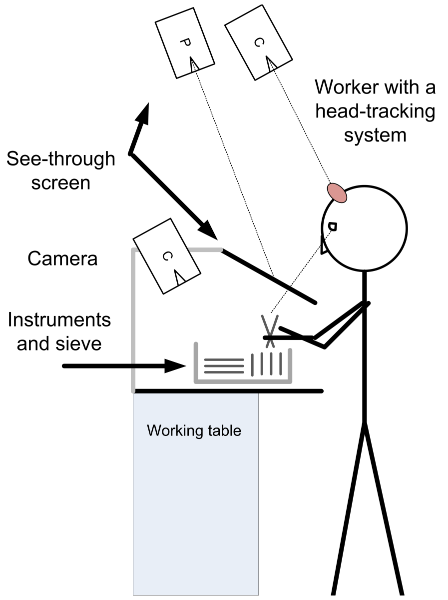


Fig. 4.3: Design study for augmented reality supported packaging. The presented instructions shows the worker how to place instruments into the sieve for proper loading.

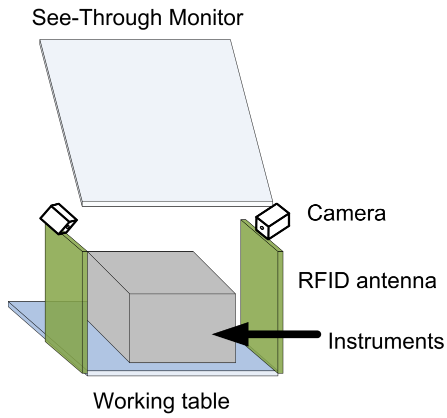
that change the color and shape of instrument, a optical recognition by computer vision is practically not feasible. *Maybe* this issue could be addressed by preparing the environment with fiducial markers[1] or exploiting the workflow and the process requirements (e.g. barcode process documentation for instrument identification). However, the preparation of the hygiene critical environment and the accompanying continuous maintenance comprise a high effort for keeping the augmented reality system functional.

An additional issue regards the availability of instruction data. If a real object's position is determined by the tracking algorithm, the rendering requires the information on where to place or how to map the virtual data onto the real objects position. Instruction data must provide a mapping information or a model that defines how the virtual data is aligned to the real object. For example, a screws must be tightened on an instrument. The tracking detects the real world object and determines its position and rotation and the rendering should highlight the screw by showing an instruction near to the screw. The spatial relation of the screws and the virtual information is required in order to overlay the instruction accordingly to the captured scene. Compared to common working instructions, such as picture series and text explanations, the working instructions of an augmented reality system get more complex, because spatial relations must be regarded additionally. The effort for aligning working instructions with a (3D-)model of an instrument is practically not feasible, due to the manifold types and vendors of medical devices.

[1] Fiducial markers provide a geometric figure which eases the tracking of objects. The ARToolKit [103] with its squared markers is a well known example for the preparation of the environment.



4.4.1: The user head movements is tracked with spatially mounted sensors. Additional sensors such as cameras and RFID antennas track the working scene under the display. The defined environment eases the tracking of objects.



4.4.2: Front view of the example with RFID antennas at the sites. The antennas could also be mounted into the table plate. The working space under the display is quite limited though.

Fig. 4.4: Concept study of augmented reality with spatial optical-see-through displays. The medical device is operated under a transparent projection surface by the worker. Instructions and status are projected onto the transparent screen in alignment to the working piece and the user head position.

Ergonomics and workplace preparation. The ergonomics of recent HMD displays inhibit their application within the CSSD. Concerning an eight hour working day, wearing comfort and display ergonomics get important. Tracking and rendering requires computation time and the rendered image lags behind the user movements. This results in a gap between the user's visual perception and the user's sense of balance and can lead to so-called virtual sickness, where the user feels sick during the visual perception of a virtual or augmented scene [104, 105]. HMD are wearable computing device and thus requires the worker to carry additional weight. Furthermore they constrain the field of view and interrupt the natural optical flow, which amplifies discomfort. The concept in Fig. 4.4 illustrates an augmented reality system with a stationary see through monitor. The concept shows, how the workspace is extended with a see-through display. Augmented reality intends to arrange the display on a direct line between the worker's eye and the workpiece. As a consequence, the display can easily get an obstacle for the natural hand or head movements. This constraint of movement freedom area leads to discomfort for the human worker. A long term use in a productive environment is thus put at the risk of rejection by the workers.

User interface guidelines. According to van Krevelen [39], an augmented reality system requires guidelines for the design of interaction and information presentation. The user should not be overloaded with information and should also be prevented to overly rely on the augmented reality system. Otherwise important queues from the environment can be missed [106]. For example, the virtual content must not overlay on physical obstacles in the users environment. Otherwise, the user could hit the obstacle while moving around. Especially in the CSSD with manifold small, sharp and spiky instruments, the workers perception should not be constraint by virtual objects. The UI-design is thus limited. The virtual objects that are rendered into the real scene must not endanger the workers safety, due to occlusion of obstacles.

Social acceptance. Among the technical and design limitations of augmented reality, the social acceptance demand for many other factors ranging from unobtrusive fashionable appearance to privacy concerns [39]. These factors must be addressed before augmented reality is acceptable [107]. Especially privacy is an issue in a working environment and enshrined in legislation. An augmented reality system must respect the privacy of the workers and people in the near environment, which can conflict the required sensory devices.

Augmented reality in the CSSD: effort vs. benefit The application of augmented reality in the CSSD requires to overcome the limitation and issues of augmented reality. The effort is quite high, as the following summary of "issues with augmented reality" illustrates:

1. Technical complexity and robustness of tracking, object identification and (auto-)calibration.
2. Preparation of environment (e.g. fiducial markers on medical devices).
3. High effort for instruction data and environment maintenance.
4. Working safety (virtual objects can overlay dangerous obstacles).
5. Lag of guidelines for the interaction with virtual content in augmented reality working scenarios.
6. Ergonomic issues of HMDs and see-through devices, e.g. constrained field of view, latencies, distortion, ...
7. Virtual sickness.
8. Social acceptance and privacy.

The benefit of an augmented reality system compared to common information presentation is quite small regarding the effort needed for addressing the issues above. Additionally, the manifolds issues of augmented reality indicate that this technology will not be accepted in a productive environment such as the CSSD. The main advantage of augmented reality is the enrichment of a real object with virtual content. Working instruction can be aligned to the work piece's position and orientation. Potentially, this helps the worker to find work pieces quickly and without confusion. However, the domain analysis in Chapter 2 showed, that the *association* between working instructions and instruments' parts is not an issue in the CSSD. Instead, the *availability* of working instructions in general should be improved. Thus, the high effort of augmented reality approaches is to be avoided and other "more common" user interfaces are discussed in the following.

4.2 Touchscreens and Tablets

Touchscreens, smartphone and tablets are widely spread and highly integrated computing devices. They provide a display and an touch-based interaction. The standardized interfaces and interaction paradigms shape a powerful tool for information access that could help workers in the CSSD. However, the CSSD demands very robust hardware that is not damaged by accidental contact with medical devices or corrosive liquids. Additionally, if the worker directly touches the display of such device at the unclean area of a CSSD, dirt, residues and liquids are attached on the device. Recent devices are not robust enough to meet the mechanical robustness requirement for the wet and contaminated area. Thus touchscreens and tablets are not further concerned for the application in the CSSD in the remainder of this work. However, for other domains and application, that do not have such a mechanical robustness requirement, touch screens and tablets can be an option for the hardware basis of an assistance system.

4.3 Projection-based Approaches

In order to provide a meaningful and usable assistance in the CSSD, other displays than touchscreens, tablets and optical-see-through devices must be considered. Projectors come with the advantage of separating the display screen from the electronic device. Projector displays consists of two parts: the projector device and the projection surface. The projection surface requires no electronic components. The surface material can be of any material as long as it reflects the projected light properly. This makes projection attractive for the unclean area of a CSSD. Within the unclean area of a CSSD, the projector can augment the working table's surface, which must be robust enough to deal with the daily work on sharp and heavy instruments as well as aggressive cleaning material. Another advantage of projection is, that no physical device is present in the working area. Compared to e.g. tablets no additional physical obstacle is deployed in the workplace.

The projection of a user interface (UI) onto the workplace allows to present working instruction near to the working piece. Head-movements are thereby reduced and the worker can compare the work piece with the presented instructions. Further, projection allows to augment objects within their projection field and a augmented reality system can be realized by adding tracking technology if needed. However, the lightning conditions of a workplace must be adjusted to make a projected UI readable and a dedicated space on the workplace should be reserved for the projection display.

The projection of working instructions is a very conceivable concept, because it meets the requirements for a physically robust display. The screen size can easily be scaled and the projection can be extended with additionally sensory input, e.g. motion recognition.

4.4 Interaction Modalities and Context-Sensing

The user of the assistance system must be able to retrieve and manipulate the provided instructions and annotations as discussed in Chapter 2. This section discusses the applicability of different interaction modalities.

Auditory displays and speech recognition. The CSSD is a very noisy environment because of cleaning and disinfection machines are running in background nearly all the time and workers handle metallic instruments on metallic surfaces. This inhibts the application of auditory displays and speech recognition. The noise of the CSSD environment would result in high classification error rates of the speech recognition algorithm. At least, additional effort is needed to filter the spoken audio signal from the environment. Additionally the number of non-native speakers is commonly quite high in CSSD. Therefore many workers speak with accent which further tightens the recognition issues of speech recognition. During the domain analysis, workers also stated that privacy is important for them. Concerning speech recognition as an input modality, the spoken words of a worker can be heard by his or her colleagues.

Due to the noise in the CSSD audio signals can only transport sparse information, e.g. beeping alarms or auditory icons.Auditory displays may be of interests in further iterations of the assistance system, but at this stage the information density of this modality is too low compared to visual options that are more conceivable for the CSSD. Because of the high effort for applying auditory interaction methods in the CSSD and the low potential for increasing process quality, this modality is not considered for the implementation of the assistance system.

Gesture recognition. Gesture recognition allows to interact with an assistance system without touching any surfaces. Avoiding direct contact with contaminated surfaces meets the requirement for hygiene safe interaction. However, gestures are not self-explanatory by default. Users have to explore a system's gesture set to figure out which gesture controls which function. The tracking of complex hand movements and user specific variations of gestures are technical challenging and lead to classification errors. Thus the interaction with complex hand gestures becomes time intense. However, simple gestures such as touches for example, can be detected very robustly, e.g. by dSensingNI [59]. The touch-interaction is a paradigm that is very common due to the widely use of smartphones and tablets. If combined with a projected surface, a touch-screen like interaction can be realized [59]. Simple gestures can provide a feasible interaction modality if a direct contact with the contaminated surfaces can avoided and the principle of touch screen like interaction is kept.

Instrument tracking. Instrument tracking is already established in the CSSD. Barcodes and datamatrix codes attached on medical devices or sets of instruments ease the process documentation and the device-specific data access. Radio-frequency identification (RFID) provides a wireless use of electromagnetic fields to identify responder chips (tags). RFID is discussed to be used in the CSSD for instrument tracking to ease the tracking and utilization of medical devices [108, 109, 110]. RFID scanning can be done by sophisticated antenna mounting. For example RFID antennas could be encapsulated in a working space. Every time a work piece is placed on the table the system automatically detects, which ID-tag is of interest currently. This facilitates the presentation of context-aware information and it spares an interaction step: Scanning of a medical device is not necessary if the arranged antennas robustly detect the instrument currently reprocessed. The RFID-antenna could also be integrated in the worker hand glove. Every time a worker picks an instrument, the wearable RFID-antenna communicates the captured ID-tag to the assistance system. The antenna can be placed on the back of the hand to minimize ergonomic discomfort. The transmitting device can be mounted on the arm.

However, instruments must be easy to identify during the work. For this purpose both technologies, the trending RFID and the established barcodes must be considered for the implementation of an assistance system. RFID has several advantages over barcodes, but it has not arrived in CSSDs yet.

4.5 Input and Output Technology Decision

The arguments for or against specific technologies for their application within the unclean area of a CSSD were discussed in the previous sections. The decision for input and output devices of the assistance system is mandatory and has a huge impact on the applicability usability of the system.

The total set of relevant technologies, their possible combination, implications and technical details results in complex decision problem for the realization of a prototype. For the structuring and investigation of the problem space ("which input and output technologies, devices or modalities to combine?") a General Morphological Analysis (GMA) [111, 112] was performed in co-work with Marcel Pahl (bachelor thesis) [110].

For the GMA, technical features were collected and prioritized according to the requirements from Chapter 2. The analysis considered devices and technologies available in May 2011. HMDs and optical identification of medical devices were not regarded, because these technologies are not applicable due to the ergonomical and robustness issues. Fig. 4.5 shows the morphological box of considered technologies for the purpose of instrument tracking, input and output of the assistance system as well as the augmentation of disinfection racks. Each input and output device/ technology were discussed and rated for their potential fulfillment of the requirements. The rating were estimated according to discussion results with technology experts, users and engineers.The scale for estimated parameter fulfillment ranges from 'very poor (0)' up to 'very good' (6). With the priority of the parameters ranging from 'unimportant (0)' to 'very important(4)' a weighted sum can be calculated for each device or technology.

The results of the GMA for possible input devices are listed in Tab. 4.1 and possible output devicesTab. 4.2 [110].

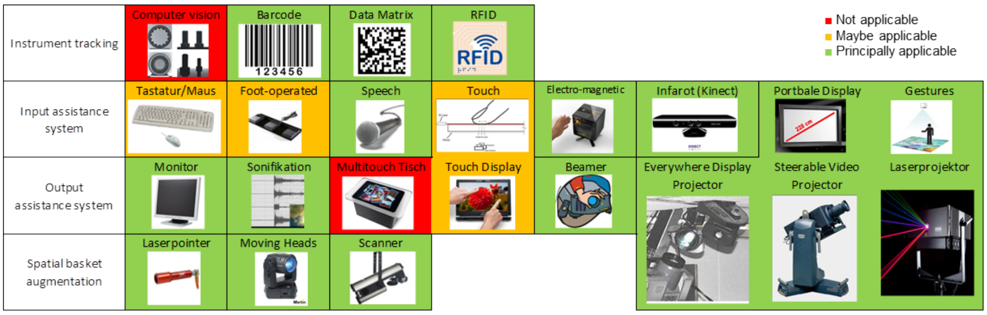


Fig. 4.5: Morphologic box for the assistance system's hardware [110].

Input system	Technical Require-ments	Ergonomics Require-ments	Other Require-ments	Summary
Depth-image motion recog-nition	132	73	60	265
Mouse & keyboard	128	64	44	236
Mobile devices	120	62	51	233
Touch displays	120	54	48	222
Foot-operated switch	104	56	44	204
Electromagnetic motion recognition	104	57	36	197

Tab. 4.1: Summarized results of the GMA for input devices and technologies. The values represent the estimated potential of the technologies to fulfill the use case specific requirements. Table adapted from [110].

Although this method is an estimation and thus vague, it supports a systematic decision process for or against input and output devices. The results indicate, that projection and a depth sensor for motion recognition offer the most potential for fulfilling the assistance systems requirements. These findings reflect and undergird the discussion of the different technologies in the previous sections.

4.6 Hardware Setup

In this chapter, different concepts for worker guidance within the CSSD were introduced and discussed. Summarized, the most potential for effective and applicable worker guidance offers a projector based approach as depicted in Fig. 4.6.

The prototype of the assistance system augments the workplace in a CSSD with a table-top projector to display information in the workers field of view, a depth camera

Output system	Technical Requirements	Ergonomics Requirements	Other Requirements	Summary
Laser-projector	202	42	50	294
DLP-projector	186	42	58	286
LCoS-projector	178	42	58	278
LED-projector	170	42	58	270
Auditory displays	172	36	48	254
Touch display	170	18	52	240
Standard monitor	174	18	42	234

Tab. 4.2: Summarized results of the GMA for output devices and technologies. Table adapted from [110].

to track hand-movements, a RFID-reader and barcode scanner. The RFID-reader is mounted in the front of the working place station. The prototypical setup assumes that a RFID-tag is attached on each instrument and that the worker scans an instrument before the decontamination. Alternatively, a barcode scanner is integrated and can be used for documentation and information retrieval as well. The depth sensor is mounted at the top of the table such that motion recognition is available for the working area. In particular, user hand movements over the tabletop are tracked. A touch-screen provides capabilities for testing and debugging and is used for assistive functions as well. This setup serves as the development and evaluation platform of the assistive system. A set of medical instruments is used to simulate the reprocessing workflow. RFID-tags were attached to these instruments, to uniquely identify each instrument. Two web-cams in the setup can be utilized to record videos and pictures during the reprocessing. The touchscreen is intended for development purposes only (e.g. debugging). Details on a first software implementation has been published by Rüther *et al.* [113].

The chosen hardware for the assistance system prototype regards the hygiene and physical robustness requirement by providing motion tracking for touchless interaction and a robust projection surface. No hardware devices (except the barcode-scanner) are placed on the table. The RFID-antenna could be mounted into or under the tabletop, if necessary. With this integrated and invisible antenna, the assistive system can identify instruments, as soon as they are moved onto the working place. Therefore, the worker must not explicitly scan the instrument to get information. But then the system must be able to deal with more complex or unintended workflow situations, such as accidentally scanned ID-tags.

The hardware setup is a platform for research and development. Although augmented reality is not applicable at the CSSD work place, the proposed hardware setup allows to integrate and explore augmented reality based approaches. Fig. 4.7 depicts the idea of such an (projected) augmented reality based quality assurance system. The worker has scanned an instrument's ID-tag and now moves the instrument towards the cleaning rack. In this example the system generates the context of the scene from the instrument's unique RFID-tag, the corresponding data stored in a database and

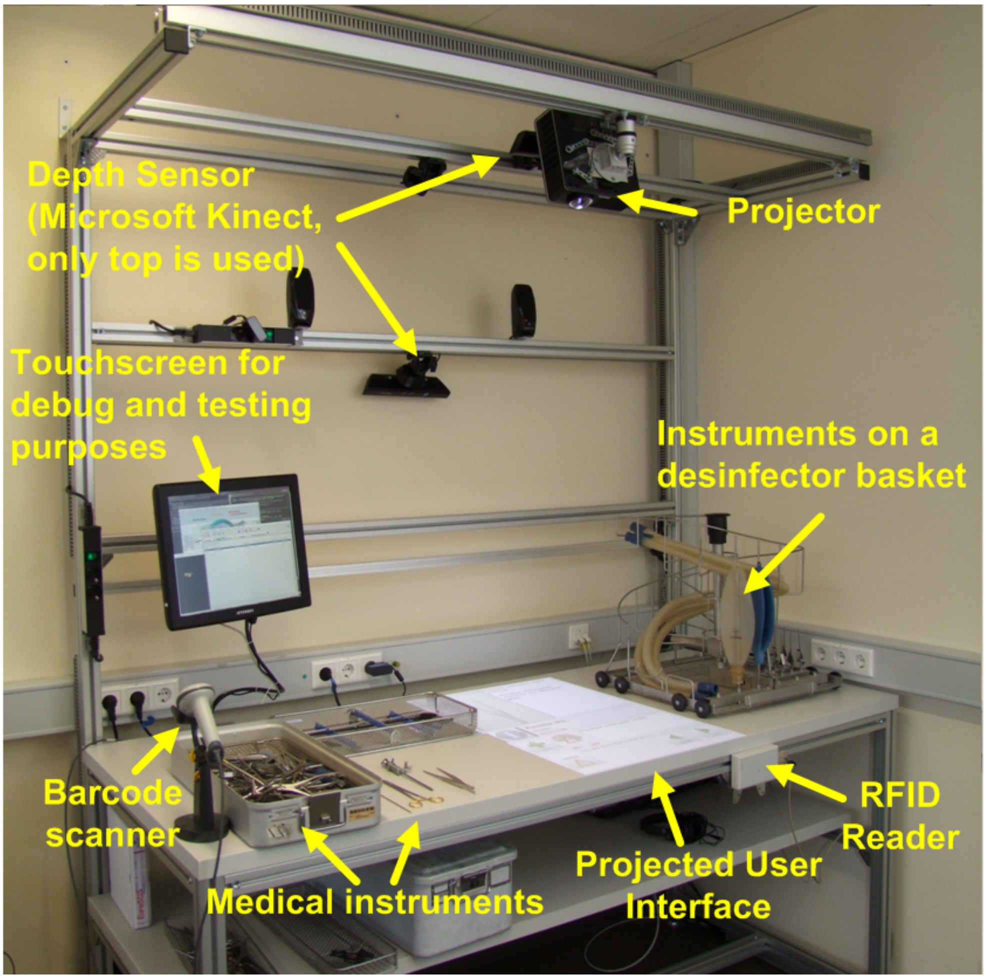


Fig. 4.6: Hardware setup of the prototype. A depth camera and a projector provide a tabletop UI that can be controlled via touch interaction. A barcode scanner and a RFID-reader are used to track medical devices.

the worker hand position in relation to the cleaning rack. With this context, the system decides, that the instrument can not be reprocessed by machine. The worker is informed by a red dot, that is directly projected on his hand.

As shown in this chapter, the projection of instructions is the method of choice to deploy a user interface in the wet and contaminated area of a CSSD. To summarize, the assistance system augments the workplace with a table-top projector to display information in the workers field of view, a depth camera to track hand-movements, a RFID-Scanner and barcode scanner, which is used for instrument tracking and documentation (*R5*). A depth sensor allows interaction in 3D space. In particular, interactions near a surface can be tracked without the need of touching the surface.

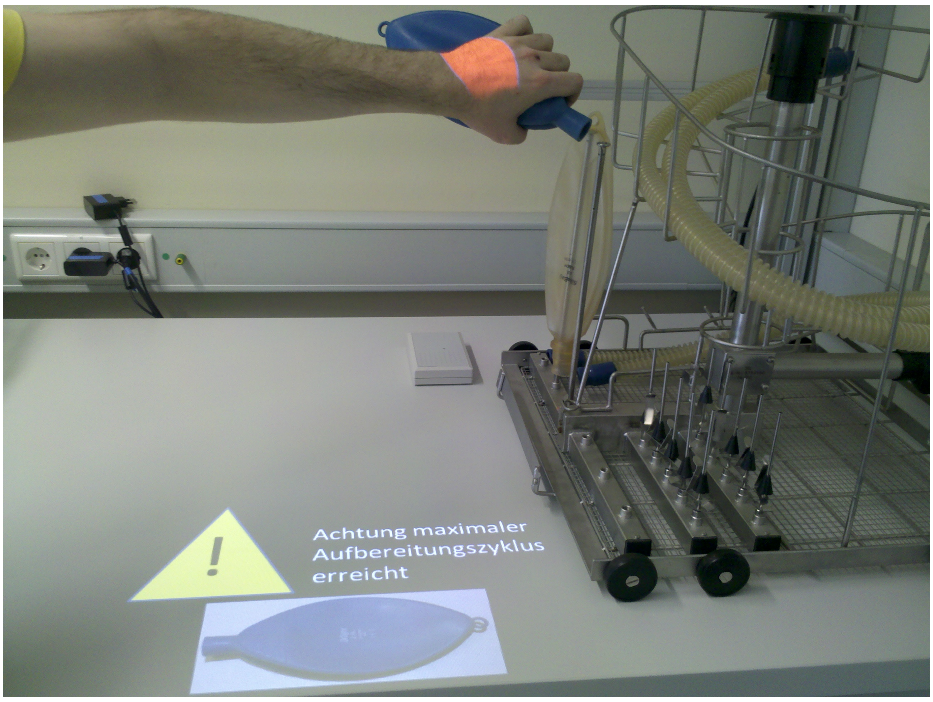


Fig. 4.7: Design study for augmented reality at the unclean area of a CSSD: hand projection could be realized to display warning directly onto the worker hands, for example if the worker intents to perform a handling that requires special attention. In this case a red dot symbolizes, that the breathing bag must be disposed instead of loaded onto the cleaning rack. This concept was not pursued because of the limitations of augmented reality (discussed in Sec. 4.1).

Chapter 5

Assistance System Architecture and Implementation

This chapter proposes a system architecture and an exemplary technical implementation of a modular assistance system that supports workers in the CSSD with context-aware information and functions for quality assurance. The system uses projection and a touch-screen like interaction based on a depth image sensor. The data maintenance and process-awareness is regarded by utilizing BPMN 2.0 process models.

The basic idea for utilizing process automation is depicted in Fig. 5.1. It is a method to close the gap between the "theory" of medical device reprocessing and its "practice" in daily work: on the one hand process obligation must be kept. Here, process automation coordinates devices and UIs according to obligations as represented in the process model. The devices and UIs functions help the worker to regard the obligations. On the other hand, the worker has knowledge about the quality of work, because he is doing it. This practical 'real world' knowledge about the process is needed to assess the process quality and enable the CSSD administration to improve the process obligation. In this case process automation helps to analyze and react on worker input systematically and comprehensibly.

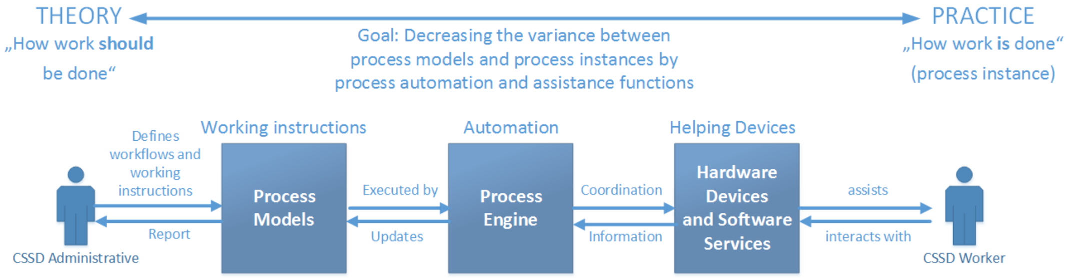


Fig. 5.1: Utilizing process models, process automation and worker assisting devices to close the gap between theory and practice of work.

In order to provide meaningful assistance the implementation must provide a software architecture, that allows the orchestration of system functions by a process engine. The architecture has to be flexible to support changing and evolving use cases. Additionally the user interface and its interaction dialogue must meet the requirements of the worker during practical work. The presented implementation is the technical representation of the use case identified in Chapter 4. The goal of this implementation is to setup a system that allows evaluation of the projection based, process- and context-aware assistance system. In the following, the scenario of the assistance system is sharpened towards a first system description by going through the assisted workflow. This overview introduces the different components and functions that the implementation must cover.

Assisted workflow. The use case from a high level point of view was introduced in Chapter 4. The description of the use case results in a domain specific model for worker guidance: The manner of interaction requires data-types and process description that are specific for the task. Scalability, reusability and portability increase, if the domain specific data can be separated from the generic pieces of code. The domain specific aspects and their implementation details are introduced in the following by going through the assisted workflow use case.

In the proposed system, the worker starts reprocessing of an instrument by scanning the instrument's RFID-tag or barcode which is a unique identifier of the instrument. Default instructions for reprocessing are previously assigned to the instrument (respectively to its RFID-tag) by a CSSD administrative with a desktop PC running a dedicated application ("AdminstrationGUI"). Workers can annotate these initial instructions during assisted reprocessing in order to report process-relevant data, e.g. reclamations on defect instruments. The system guides the worker through the disassembly and rack loading. The image from the depth camera extracts the worker's hand and gestures to allow interaction with the projected user interface. The system supports trigger actions analogue to a mouse click, i.e. a 'touch-less finger event' (defined by hand sufficiently close to table) allows initiating a software function connected to a button or widget element at that location. Thus, direct touches with the contaminated surfaces in a CSSD can be avoided by specifying a desired distance between the hand and the surface. The requirement for hygiene safe interaction (*R6*) is thereby respected.

The CSSD workflows and its quality management are represented as executable BPMN 2.0 process models. Among others the process models are utilized to classify an instrument's criticality[1]: The operating room or a CSSD worker annotates an instrument if any problem such as a defect or wrong assembly occurs. The system uses this reclamation history of a given instrument to influence the interaction behavior. A business process model continuously classifies the criticality of the reclamation history: If a specific instrument has a long or severe reclamation history, the workflow model ensures that precise reprocessing instructions are displayed in the worker's field of view. Additionally, a confirmation dialog must be acknowledged, to assure that the worker is aware of the typical issues with the instrument. In contrast, no information

[1] The criticality or severity level refers to the risk for improper operation on a specific instrument and is derived from the failure history.

is shown for instruments that are classified as non-critical, because it can be assumed that the workers are already familiar with the correct reprocessing, and therefore they are not disturbed by unnecessary information and dialogs. If there is no or not enough information available for a specific instrument, the system automatically asks a CSSD administrative to submit reprocessing instructions. The technical challenge is to integrate the assistance system into the overall quality management of the hospital. The CSSD processes can be modeled very well, since legislation and reprocessing guidelines exist. By utilizing business process models and the powerful "Activiti"-framework [114] for the definition of the UI and system behavior, the application potentially integrates smoothly with other processes in the CSSD and the hospital, e.g. purchase logistics.

This example use case illustrates the need of the basic components:

1. Domain specific data and process models. The instrument specific data must be stored in a data structure, that carries all information about an instrument, especially working instructions for instance. Process model define, how the workflow *should* look like. The process model covers the orchestration of system functions and the worker. The process instance or the practically executed workflow may differ from the process definition, because there is no self-evidence for workers to regard the process definitions. By the guidance of the system, the proper consideration of the instruction and workflow specific systems function help the worker to adhere to the process definitions. The implementation of data and process models is proposed in Sec. 5.1

2. Component based software-architecture. The software architecture that allows the integration all of different subsystems into a runnable system is described in Sec. 5.2. The software architecture combines domain specific elements, such as data types and components by utilizing generic concepts such as abstract component descriptions.

3. The design and implementation of the user interface is the topic of Sec. 5.2.5. The UI is the part of the system implementation that the worker uses for instrument reprocessing. Thus, the UI has a major impact on the usability of the system and careful design is necessary.

4. The basic assistance system requires the following components: Instrument tracking (RFID and barcodes), database for instructions, process models and process execution engine, projected user interface and motion tracking for the realization of the virtual touch concept.

The following section describes the details of the software architecture and emphasizes how scalability, context- and process-awareness were realized to achieve flexibility during the development process and how different use cases can be approached.

5.1 Data and Process Models

For the described use case of the system, the assistance data are stored for each instrument in a data model class with the name "InfoStruct". The process models define how instances of this data model are updated and how context is generated from the RFID-chip and the corresponding InfoStruct.

Data structure 'InfoStruct'. The assistance function for showing context-aware working instructions needs a representation in a data structure. According to the domain analysis, working instructions for medical devices should be presented in concise from, to support the worker. Reclamation should also be assigned to instruments or sets of instruments. The instruments can be tracked with an attached barcode or RFID-chip. During the domain analysis, several working instructions were reviewed and especially within medical device manuals, a set of ordered media items such as figures and text seems to be sufficient for helping workers. Thus, the assistance system should provide at least this standard working instructions. This helping information can be extended by annotated figures, videos, hyperlinks and PDF-files.

Additionally, to support a quality management of a CSSD or more generally a productive environment, data for measurement of process quality must continuously gathered. If a new assistance system is deployed within a productive environment, the feature of gathering quality metrics must be considered (*R1*). In the implementation presented here, one main indicator for process quality are the reclamations, which describe issues and frequency of instrument or work piece procedures. Confirmations and acknowledgement of critical process steps can also be seen as quality measurement elements.

These helping instructions and quality data are aggregated in the data structure 'InfoStruct' as depicted in Fig. 5.2. The data granularity of storing data is therefore on the instrument level, which offers high flexibility during the development process. However, sets of instruments can easily be stored by aggregation of multiple InfoStruct in a class, that maintains this list of instruments. The InfoStruct holds all assistance relevant information for a single instrument and consists of the following data types:

- Coredata. This class holds the core elements for describing a medical device, such as Name, Type, Vendor, ID-tag(s), . . .

- MediaList. Working instructions are listed in this data object. This class maintains a list of classes with the type 'MediaFile'.

- MediaFile contains instruction data for a single process step of the working instructions. The main fields of this class are a String file, which specifies which medial file illustrate the working step. A type and option field to set details for presentation of the Media. The type defines which common formats can be used. For the prototype, Images, Videos and text-only were integrated while PDF and hyperlinks were prepared for later integration. A further field holds the text describing the worker's task.

- ReclamationHistory. Here all issues that were observed with the specific instrument (more precisely InfoStruct) are stored. This data structure holds a list of reclamation, which are described below.

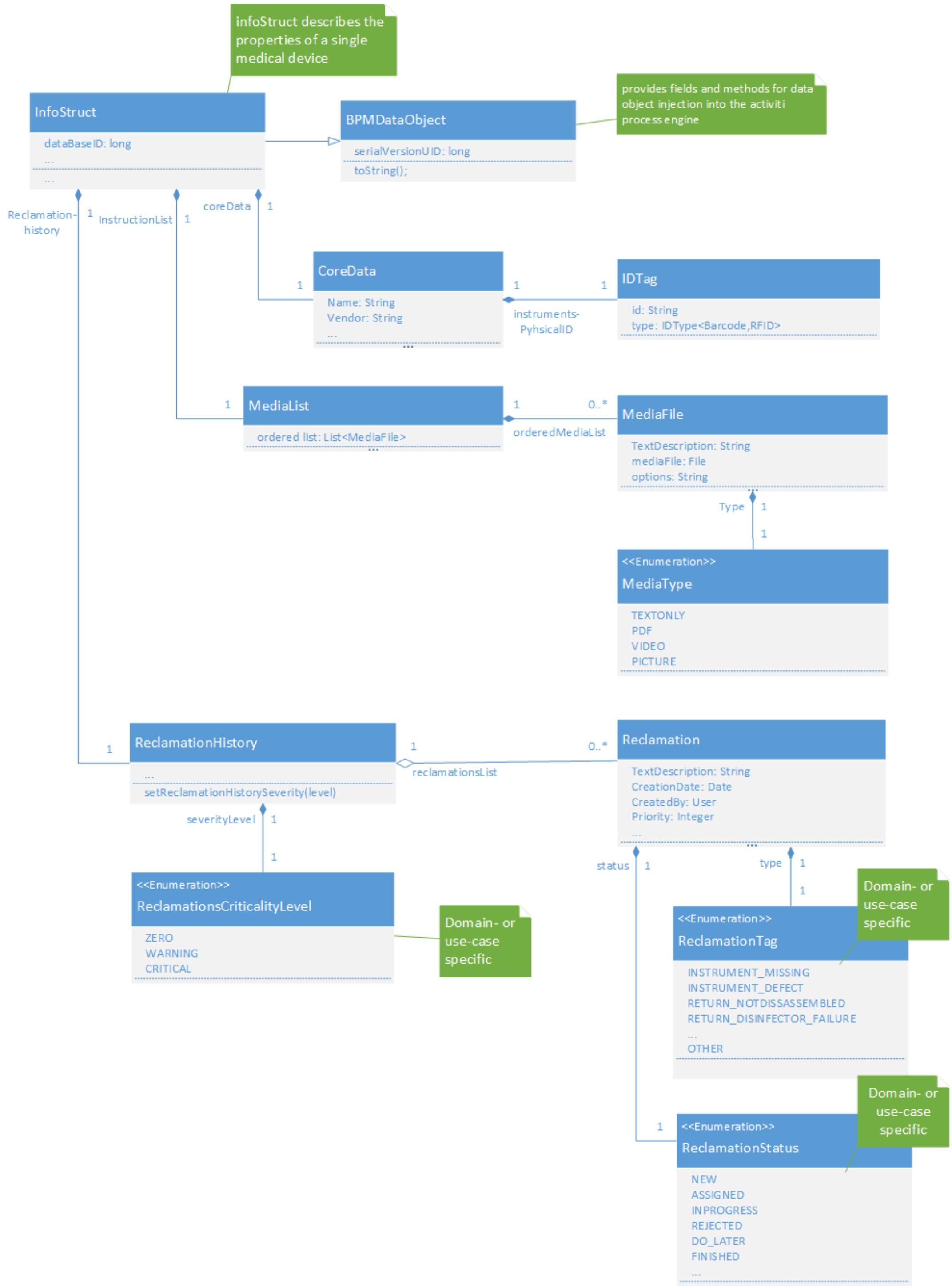


Fig. 5.2: The assistance system's central data structure 'InfoStruct' aggregates medical instrument specific information such as core data, working instructions and reclamations. The data structure can be injected into business process model executed by the Activiti process engine.

The InfoStruct is therefore a container for instrument labeling, working instructions, and it includes quality information. Concerning the life-time of data the fields of the InfoStruct can be categorized: CoreData represent data that probably never change, while Media instructions change rarely, and reclamation can change multiple times within an reprocessing cycle. The different dynamics of the data fields must be regarded during the implementation of a user interface. Especially, often changing data fields, should be concerned for easy change or emphasized readability by carefully choosing UI elements.

Although the data object InfoStruct was encouraged by the CSSD domain, it provides general data fields, that are also needed in other productive environments e.g. manual assembly. For example instead of describing a specific instrument, a work piece also comes with core data (name, type, etc.), working instructions, and quality parameters. Additionally, the working instructions must not only be bound to specific instruments or work pieces and workplace specific instructions can be stored in the InfoStruct as well, e.g. using an ultra-sonic bath. This data struct can therefore be seen as a general concept of the assistance system architecture, that can be reused or adapted to some extend to meet requirements of other use cases. Examples for such reuse in other domains are presented in Chapter 9.

Process models. The BPMN 2.0 is a global standard for process modeling. It is a method for aligning business and IT. The standard is very well supported by many software products. The expression of the standard is powerful for describing precise and imprecise business models. The standard is also extendable by definition. The BPMN 2.0 defines graphical elements of process modeling, the representation in XML notation and how process engines has to execute the different tasks, events and transitions. Notably, BPMN 2.0 is a powerful notation that allows to describe high-level down to low-level processes. The BPMN 2.0 standard can be used to describe management, procedural and work place specific workflows in a consistent way. The CSSD or more generally, productive environments can benefit from a process notation, that allows to transparently and consistently define workflows in almost all levels of hierarchy. Additionally, these processes can be automated.

The assistance system pursues a modular architecture, that comes with a flexible configuration for different use cases and rapid prototyping as well. Depending on the use case, the configuration and coordination of the modules form the functions that the assistance system supports. The representation of workflows by the BPMN 2.0 standard allows to separate the domain specific process models from the execution layer. The assistance system utilizes this mechanism to coordinate the different components by the execution of BPMN 2.0 process models within a process engine. The implementation uses the “Activiti”-framework which provides an execution engine that allows to model the CSSD processes in detail and that allows to bind software functionality to the different states of workflow. The domain specific configurations of components and the process models can reuse the coordination engine of the system. For adapting use cases or approaching new use cases, only the process models and configuration must be changed. If necessary, use case specific components can be integrated.

A simple example illustrates the coordination of system components by BPMN

2.0 process models. Concerning a simple use case of showing instructions as soon as an RFID-tag is scanned requires the following coordination of system components: a RFID-reader, a database with instructions, a user interface for presenting the instructions and the human worker. The software components RFID-reader, database and UI must be coordinated according to the handling of the user, which has two options in this simple example: scanning an ID-tag and reading instructions. Coordination in this case is very simple: after the worker scans an instrument, a database lookup retrieves the instructions, that are than presented by the user interface. The process for this simple example of presenting instructions is depicted in Fig. 5.3. Notably, this process does not only coordinate the systems actions from RFID to instruction presentation, moreover it also covers the coordination between the human and the system: The process definition intends the human to start the process by picking an instrument. As soon as the instrument is scanned the system presents the related instructions.

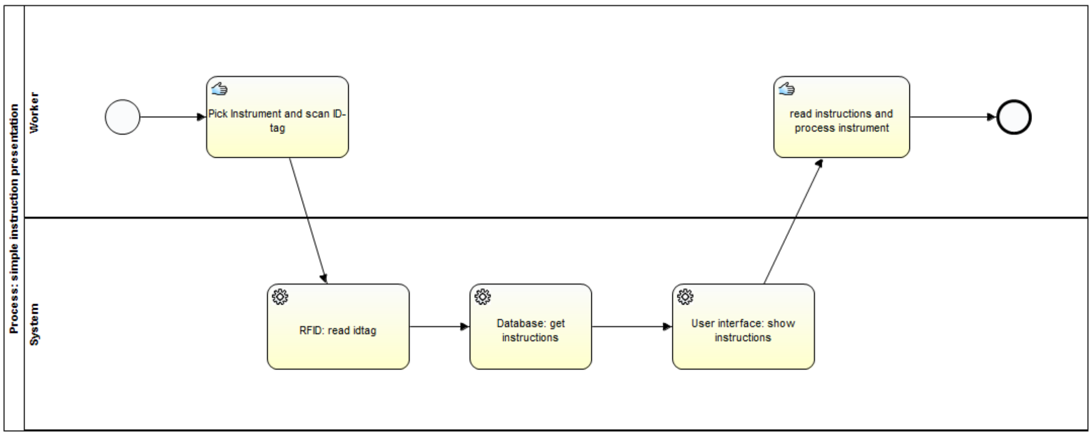


Fig. 5.3: Example process model for simple coordination of workflow participants: The worker picks and scans an instruments ID-tag and the system presents the related instructions.

The example from Fig. 5.3 illustrates, how process models can be used to describe what is expected to happen during the work. The execution of the process model helps the worker to comply with the workflow definition (process model).

Generally, a difference between the workflow definition and its disregard during the work can be an issue for the quality of medical device decontamination and production as well. Process models that define how work should be done can be as good as will, if they are not considered or even neglected during the work than they do not increase the process quality. The process instances or in other words the practical performance of workflows produces the value – not the model. Workers should keep to the workflow definitions and instructions. By combining automated process models with system functions, such as user interfaces, assistance functions and quality assurance methods, the worker's tools and environment complies to the workflow definition. By providing a process-aware working environment, the worker's obligation of working instructions and workflow prescription is facilitated. Summarized, automated process models can model and coordinate both: expected human behavior and components behavior. It can help the worker to respect the process specification by providing process-aware tools.

The example from above (Fig. 5.3) can be extended with a simple method for achieving a valid set of instruction data. The process depicted in Fig. 5.4 pursues, that a CSSD administrative submits missing instructions: In case the database has no or insufficient data, an email is automatically sent to the CSSD administrative that instructions for a specific instrument are missing. This simple example shows, how the process model supports the CSSD administrative in maintaining a valid set of working instructions. A valid set of working instructions is an important element of the quality manual. More sophisticated process models can consider additional information before the system automatically asks for new instructions, for example depending on the reclamation history density or date of latest change.

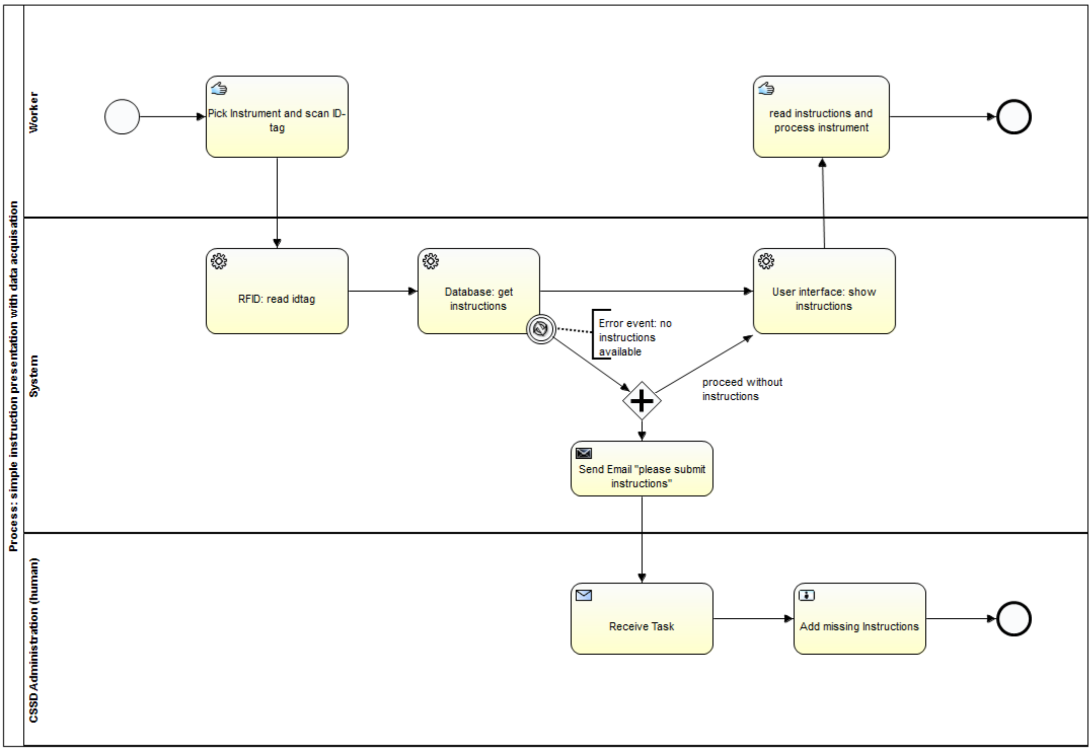


Fig. 5.4: Extended process model of the example from Fig. 5.3 for coordination of workflow participants: The worker picks and scans an instruments ID-tag and the system presents the related instructions. In case of missing instructions (e.g. new instruments), the systems informs the CSSD administration via email to add new instructions. Applying this process pursues a complete set of instructions by identifying missing data and assigning the task for completion to the responsible persons.

However, process modeling for optimization and defining processes for real world scenarios is a research area itself. Ideally, process models are designed and optimized by the domain experts themselves, because, they know best how the procedures and resources must and can be coordinated. Thus, the optimization of process *models* for the CSSD is not the topic of this thesis, instead the focus lies on optimizing process *instances* (practical work) by providing a new tool, the assistance system, for the worker. The tool helps, reminds or requires the worker to respect the process model.

The workflow definitions and process models are very well described in the domain specific related work (see Chapter 2). Especially for the CSSD the manifold processes restrictions, standards, procedures and responsibilities has been presented in the domain analysis in Chapter 2. BPMN 2.0 process models can easily be derived from the almost existing workflow descriptions for the CSSD domain. Within the productive environment, process models can be derived either from existing sources within the production line or from the theory of managing quality controlled value chains and production lines. Concluding, usually process definition already exist in productive environments and thus BPMN 2.0 process models can be derived from these to some extend.

A tenor from the domain analysis is, that "quality management must be lived by the people" otherwise it will not work. Automation of process models for controlling UIs with methods of quality managing further supports the people in "living the quality management". For example a user interface asks the worker to add missing instructions or quality reports. Additionally, the acquired data is digital and can further be analyzed for possible process improvements. The domain analysis in Chapter 2 showed that this is often not the case in the CSSD practice, where issues are reported on paper – if at all.

One motivation for using process models for coordination of humans and system functions within productive environments is to decrease the variety of process instances by a higher degree of automation. Further advantages are the standardized and transparent description of processes, which allows administrative to define coordination between different departments as well. The coordination can range from management to workplace level: for example escalation levels can be defined: The worker inputs an issue for a specific instrument. The process model checks the criticality of this reclamation, and depending on the criticality the different managing instances can be informed directly.

The range for assuring proper practical realization of process models can cover all levels of work: from the managing level down to the decontamination workplace, because of the powerful descriptiveness of the BPMN 2.0 standard. For assisting the worker at the low lever of production, custom software tools, such as working place specific user interfaces must be implemented that are coordinate-able by process models. How this could be achieved is discussed in the next chapters. For the higher level, IT tools for administration of instruction data, quality reports, statistics of production, collaboration are of interest among others.

5.2 Component Based Software-Architecture

The development and application of an assistance system for worker guidance requires a flexible and scalable software architecture, that allows to adapt to changing process and methods for quality assurance. Component based software engineering [115, 116] approaches the requirement analysis, system design and implementation of reusable and maintainable software-building blocks by composition of reusable off-the-shelf and custom build components. The tutorials by Brugali *et al.* [117, 118] provide useful information and guidelines, how a flexible component based software architecture can be achieved. These tutorials focuses on robotic applications with typical requirements such as embedded, concurrent, real-time, distributed, data-intensive as well as safety, reliability, and fault tolerance. Although the assistance system is not a robotic application, many requirements are tied to complex systems and therefore Brugali's tutorials for component based architectures apply. The principles of component based software engineering significantly reduce the effort to develop new software applications by promoting the systematic and routine use of existing solutions. [117, 118]

In this section, an approach is proposed, how software components can be coordinated and orchestrated via BPMN 2.0 process models. For the development of the assistance system, different components are required, such as RFID, Barcode, User interface, Database, control component, and others. If these components can be flexibly combined and configured, changing a process can easily be addressed. Additionally modalities can also be integrated into the workflow, if interoperability is defined by sophisticated interfaces. Furthermore, providing a process designer can enable the domain experts to set-up processes graphically and by themselves. The resulting processes models define the workflow as a coordination of workers and system component functionalities.

In order to achieve such a component based architecture, a brief introduction is described in the following, before the implementation of the assistance system is proposed. According to Szyperski [116] a software component is defined as follows:

> "A software component is a unit of composition with contractually specified interfaces and explicit context dependencies only. A software component can be deployed independently and is subject to composition by third parties." [116]

Following this definition, a component must have a contract, how it functions can be accessed. For the implementation of the assistance system, component functions should be building blocks of BPMN 2.0 process definitions. The context dependencies of a component is thus given by the composition of a process model. The composition of components is ideally done by the domain or process experts themselves, which can be seen as "third party" of the development process to meet the above definition from [116].

The component definition by Szyperski [116] motivates the component's key ingredients as depicted in Fig. 5.5. The component specification is an abstract view on the details of components. It consists of the declaration of provided interfaces, required interfaces and contracts. Provided interfaces are offered to the component's client and define which functions are available from the component. Required interfaces define the dependencies of a component. Obligation and constraints on how to access functions of a component are encapsulated in the contract. The implementation of an component defines, how the component works, and how the interfaces are supported. It has realizing objects of classes and class instances that realize the functionality defined in the component specification. [117]

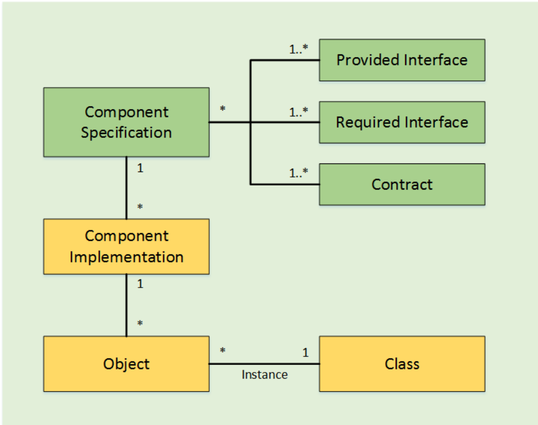


Fig. 5.5: Component key ingredients, according to Szyperski [117].

Brugali *et al.* [118] emphasize the need for separation of concerns for component development. A component-based system with frequently changing requirements needs components, that can easily be adapted. Four software design concern are defined in [119]: communication, computation, configuration and coordination. The *communication* part of a component defines, how the component communicates with other components. *Computation* refers to the code for data manipulation. The *configuration* holds parameters for the component such as algorithm thresholds for instance. The *coordination* defines the pattern of interaction, for example when to communicate data or call system functions. This separation of concerns is expected to increase reusability and maintainability. [118, 119]

This structure of components was regarded during the design of the assistance systems architecture. The assistance system uses the abstract factory pattern [120] to instantiate the different components. The factory requires components to have a specific interface with is defined in the abstract class “SubSystem”. The subsystem class serves as the main part of the abstract component specification. It is supplemented with the interface specifications for provided functions, dependencies and contract for its use.

A class derived from a subsystem must provide the following methods and fields for the automatic instantiation of the subsystem factory:

- String Name: a unique identifier, that is used during runtime for subsystem identification and type-casting purposes
- Init(): component-specific initialization, such as setting up network communication
- Property provider: Java 'PropertyProvider' containing component specific properties
- Run(): dedicated thread of the subsystems, which provides the operation of the component
- AddTriggerCallbacks: methods called when specific BPMEvents occur. BPMEvents notify the process engine about process relevant events.

The abstract class “SubSystem” is one part of the interface, that a component must fulfill to be integrate-able within the assistance system. Furthermore a component has to define delegates, that are called from the process models during execution. The delegates are directly associated with process models elements. During the modeling process, a graphical representation of the workflow is drawn with the process designer. For process elements, that require a operation from a subsystem, the delegate of such subsystem is specified within the properties of the BPMN 2.0 element. The execution automatically calls the delegate, if the execution of the process reaches the process element. Delegates serve therefore as an interface from the process engine towards specific subsystem functionality.

For the direction from component towards process instance an event-based approach is utilized: The class BPMEvents defines component events, that are of relevance for the execution of process models. A component can extend this abstract class to component specific data such as EventType for example. These component-specific BPMEvents communicate events and data, that affect the execution of a business process. For example the component RFID-reader fires an BPMEvent with the type NewIDTag and the data “string ID” if the reader detects a new ID-tag. The process engine listens to these events and injects this data into the corresponding process instance(s). The further behavior of the system is subject of the process models.

The definition of abstractions levels for communication objects is often a difficult task during the development of components. For the development of the assistance systems, the following guideline worked as a kind of best practice: “Every event of a component, that potentially affects the execution of process models must be communicated as BPMEvents”. This can be understood as the contract on how components within the assistance system architecture have to communicate in order to achieve a coordination within BPMN process models. Other events are thus considered as component specific and are subject of the component-specific implementation.

Summarized, a subsystem defines a component within the assistance system by:

- providing a interface for the coordination by the process engine (component’s delegates)
- requiring an interface and configuration file (subsystem inheritance, specific component’s dependencies and settings)
- a contract on communication (BPMEvent guideline)
- an implementation of the computation part which is separated from the coordination (located in the process engine) and communication (BPMEvents)

The “SubSystemFactory” instantiates components from loading a property file, that holds the configuration of subsystems. According to the system configuration, each subsystems is instantiated with a default or use-case specific property file. Thus, depending on the subsystems configuration and process models different use cases can be addressed with this architecture. Fig. 5.6 provides an overview of the assistance system for the unclean area of the CSSD. The implementation of the different components is discussed in the following subsections. The careful separation of business logic, component functionalities and configuration increase the reusability of components and code. As a consequence, the architecture presented in this section can easily be transferred to other use cases like industrial and domestic applications. Chapter 9 discusses the transfer in more detail.

5.2.1 BPMService

The process engine Activiti [114] is encapsulated in a subsystem called BPMService. The BPMService is responsible for the execution of the process models and is therefore the subsystem which coordinates the other subsystems according to the process model specification. Process models can but must not be located within the process engine subsystem. The BPMService uses a configuration file which specifies, which process models are relevant for the desired use case. Activiti was chosen because it is an open source Java Framework with an active community and many useful tools, like the Activiti process designer, process history management, user management among others.

The computational logic of the process engine is separated from the business logic specified in the process models. The process models are stored in BPMN 2.0 XML files, which are the input for the BPMService. The configuration file for BPMService, defines which processes are required and which BPMEvents start or change the execution of process instances. This separation of concerns allows to build up a library of process models and components for different use cases. The system can be configured for different use cases by specifying the relevant process instances, the BPMEvent to Process mapping and the components configuration.

In the case of the CSSD, the following main processes are used to provide assistance: “presenting instructions”, “instrument’s criticality computation”, “context-awareness with respect to instrument’s criticality”. Further processes concern the automatic asking workers for instruction and missing data input, the refinement of instructions added during work or the escalation cascade in case of very critical or very often incidents. The BPMEvent “new RFIDTag received” is mapped to the process model “new instruments scanned” which further invoke the process instances as described above. The process models control subsystem functions in turn. Concluding, the use case of assistance within the CSSD is specified by a configuration of components, event to process mapping and process models. The ’core’ of the assistance system therefore generalizes to other use cases, while only use specific configurations and process models must be adapted.

5.2.2 Database

The assistance system uses two databases. One database is implicitly given by the usage of Activiti and is therefore encapsulated within the BPMService subsystem. This database is managed and maintained by the Activiti framework and persists data on the execution of processes. Since the Activiti framework uses this database implicitly or internally, it is no explicit component of the assistance systems.

The second database is managed within the subsystem “CSSDDataBase”. It persists the CSSD-specific data such as InfoStructs with instruments’ core data, working instructions and reclamation history. The subsystem CSSDDataBase provides Activiti-

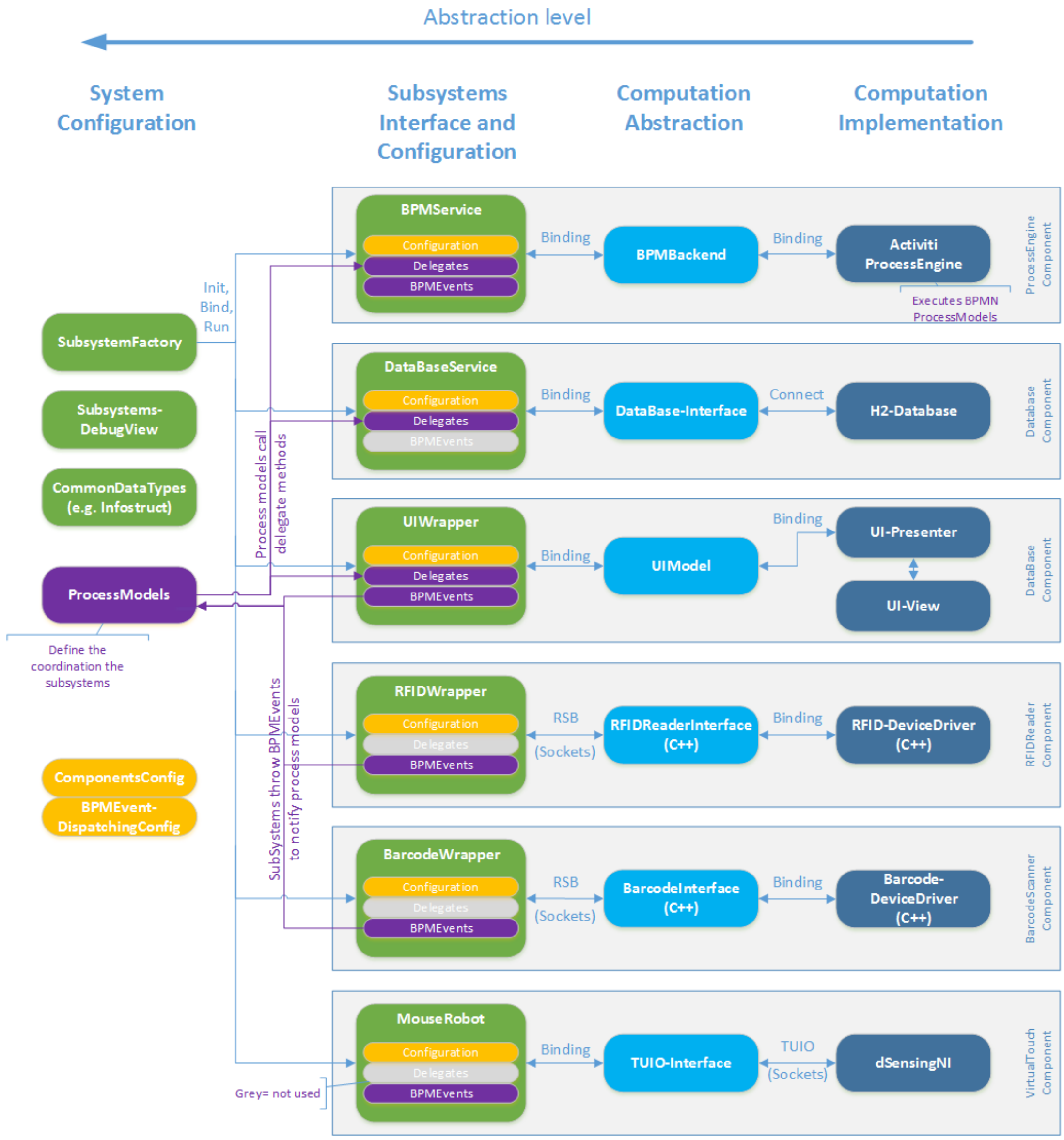


Fig. 5.6: Architectural system overview for the assistance at the unclean area of the CSSD. The system coordination (purple elements) is defined within the BPMN 2.0 process model, which relies on component delegates and BPMEvents.

conform delegates to allow database access from process models, such as searching for an InfoStruct by ID-tag or saving changes.

5.2.3 MouseRobot

The framework "dSensingNI" [59] processes the image from the depth camera and extracts the worker's hand positions and gestures which it communicates via the TUIO protocol [121]. The system supports trigger actions analogue to a mouse click, i.e. a 'touch-less finger event' (defined by hand sufficiently close to table) allows initiating a software function connected to a button or widget element at that location. Direct touches with the contaminated surfaces in a CSSD can be avoided by specifying a desired distance between the hand and the surface.

dSensingNI was chosen over other tracking frameworks such as Community Core Vision [122] and other proprietary tracking solutions (like vision-algorithm based on the OpenCV computer vision library) because it detects tangible objects, finger and hand positions with a sufficient robustness, the source code is available and the calibration and parametrization is doable with low effort. The software was developed in the programming language C# but provides the platform independent TUIO interface.

Virtual touches are implemented as described in the following: The depth-image from the Kinect sensor is processed by "dSensingNI". dSensingNI extracts hand, finger and tangible objects positions which it communicates via TUIO-events [121]. With the TUIO-protocol was used to bind the Java-based subsystem 'MouseRobot'[2]. The MouseRobot matches the TUIO-events containing hand and finger positions to standard mouse events of the operating system. Thereby it transforms the TUIO coordinates from the sensory input coordinate system into projected screen resolution.

More in detail, dSensingNI fires TUIO events in case a hand or finger is moved. The TUIO events contain the 3D-position of the hand and fingers. The MouseRobot classifies the depth-coordinate by comparison to a threshold. In case that the depth-coordinate of a received TUIO hand or finger event is above this threshold, no MouseEvent is fired. In case the depth-coordinate of the received TUIO event is below the threshold a mouse event is fired.

For the registration of the sensory coordinate system and the screen resolution (two dimensional display coordinate system) a calibration is necessary to determine the transformation matrix. The calibration is done offline, before the MouseRobot runs. A pattern of red dots is sequentially projected onto the surface and the user has to virtually touch each of the dots. If a virtual touch is detected by the dSensingNI framework, the coordinates of the center of the back of the hand is stored with the known screen position of the shown dot. In the proposed implementation, 16 combinations of screen coordinates and corresponding hand positions are recorded before the transformation matrix is calculated. Fig. 5.7 shows the calibration process, which can usually be done in less than five minutes. The adjustment of the Kinect and the dSensingNI properties requires approximately ten minutes.

[2]Notably, the TUIO-protocol provides a UDP-based network communication, which allows to run the image processing (dSensingNI) on a dedicated PC, which is helpful in case of constrained computational power.

Fig. 5.7: Calibration of the hand tracking and the projection display: The system projects dots sequentially. After the user touches a point, the next dot is presented until a grid of dots is completed. The system captures the given dot positions and corresponding hand positions. The transformation matrix for sensory-to-display coordination system conversion is calculated from the recorded data pairs.

Additionally, the MouseRobot regards the history of events within a simple state machine, to avoid undesired site effects, such as multiple clicks triggered by a single hand gestures. The state machine is also needed for the detection of ongoing mouse events, such as drag and drop. Due to sensory noise, the hand and finger positions are noisy too which can lead to flickering mouse movements. This issue was addressed with the implementation of a Kalman-filter that smooths the hand and finger positions and therefore leads to smooth mouse movements.

The sensory noise of the Microsoft Kinect plus uncertainties within the hand and finger classifications influence the design of the user interface. Control elements such as Buttons for instance must be big enough to reduce sensory noise to a level, that allows robust interaction. The parameter for button size were determined by qualitatively testing the interaction robustness of different sized control elements. As a result, for the setup described in Sec. 4.6 with the depth Sensor approx. 115 cm above the projection surface center, the control-elements of the projected UI should not be smaller than 50 mm x 50 mm. For often used elements, a size of at least 75 mm x 75 mm is advisable (the used hardware setup projects 100 pixel on 87 mm of the workspace). This technical restriction is a constraint for the development of the user interface proposed in Sec. 5.3.

Among the calibration of the sensory and display for coordinate system transformations as well as large and thus sensory noise-robust UI widgets, the user needs feedback of his interaction with the system, especially to avoid or adapt his movements to tracking errors. This feedback is provided by utilizing the operating system's mouse cursor.

This is analogous to the very common computer mouse. The user gets feedback as a cursor, that moves on a screen corresponding to the movements of the mouse device, which is located somewhere around. By using the mouse device the user builds up a relation between his hand movements and the virtual object on the screen. The proposed interaction uses the same mechanism, instead of moving a mouse, the user moves his finger or hand. In case the tracking works correctly, the cursor is projected in the user's finger tip. In case of systematic tracking errors, for example because of imprecise calibration, the projected cursor is shifted from the finger tip position. The effects of systematic tracking noise can be interpolated by the user, as long as the correlation between his movements and the system's feedback is sufficiently constant and constrained. Summarized, if the user has feedback about where the system locates his finger or hand position, than he is able to match between his hand position and the system's registered hand position. Thus, the user gets continuously feedback on the system beliefs about his hand position in case of hand movements.

As a result, the MouseRobot allows to control the standard computer mouse by hand gestures and realizes a 'virtual touch screen', without the need to physically touch the projection surface. Summarizing this allows to deploy an UI in the wet and contaminated area of a CSSD (*R6*), because direct touches on surfaces are not necessary and due to the projection, the visualization area can be more robust than a standard touchscreen or monitor. Notably, the combination of a depth sensor with a projector can be used similar to a touchscreen. Buttons and user-controllable widgets must be large enough, to be controllable in a robust manner.

5.2.4 RFID and Barcode Component

The use case of the assistance system involves a barcode scanner or an RFID-reader for the identification of medical devices. The system uses a Motorola DS4208 barcode scanner and a Feig ISC-PR101 RFID-reader. Both devices come with native C++ libraries provided by the vendor. An abstraction from the specific hardware interface is desirable to follow the concepts of reusable subsystems and component-based architecture.

For the prototype, RFID-tags are attached to the medical devices. These unique identifiers allow the instrument identification by moving the ID-tag into the range of the RFID-reader antenna. The RFID-reader detects the ID-tag and reads its unique identifier. This identifier must be communicated to the process execution, where the business logic uses this information to assist and control the workflow. The physical association between instrument and RFID-tag must also be present in the data base. The data object InfoStruct has an association to the class IDTag for this purpose. The IDTag class covers information on the ID-tag, such a the mandatory identifier string and optional information such as ID-tag vendor, or type of ID-tag. The type of an ID-tag can be of 'Barcode' or 'RFID'.

The subsystem RFIDWrapper integrates the RFID-reader device into the assistance system. The abstraction from the RFID device's native C++ driver library towards BPMEvents is done in two steps as depicted in Fig. 5.8. First, a proprietary C++ program “RFIDNativeInterface” abstracts the hardware specific code by providing a network accessible interface and utilizing the driver library provided by the device vendor. The RFIDNativeInterface utilizes the RSB middleware [123] and Google protocol buffers [124] for the network interface. With the RSB middleware a TCP-based communication is established that provides a communication bus. The communication objects are generated by the Google protocol buffer library. The protocol buffer library provides useful tools such as versioning and consistent classes for different programming languages (C++ and Java in this case). The RFIDNativeInterface publishes events as soon as the RFID device detects new ID-tags. Interested communication bus participants are automatically notified, if they are registered to these events. Within the RFIDNativeInterface the communication part NetworkService is separated from computation part, that yields the hardware specific code. Second, the subsystem "RFIDWrapper" registers to RFID-reader events on the RSB-provided bus. In case a new ID-tag is received, the RFIDWrapper wraps the IDTag-event from the protocol buffer class into a BPMEvent and thereby abstracts process-relevant events from the component specific communications objects.

The barcode scanner is implemented by exchanging the RFID-specific code with the barcode specific-code. The communication service and the communicated data object IDTag remains the same. Thus, the implementation of a different instrument tracking technology needs minimal effort, by partly reusing RFID-reader component's classes, such as the communication service, the communication data object and subsystem wrapper.

The integration of the RFID-Reader and the barcode scanner hardware demonstrates the generic way of integrating components into the assistance system. Hardware or computational specific code is separated from the communication logic. Parameters of computation or communication are separated from the implementation by the use of configuration files. The implementation as a subsystem interfaces the component specific communication and abstracts its process-relevant data and events towards BPMEvents, that are injected into the process engine, which executes the coordinating process models.

5.2.5 User Interface Integration

The UI of the assistance system presents helpful instructions and provides input capabilities for instructions and quality parameters. The assistance system realizes a projection with virtual-touches for user input. The user gestures on the projection surface are mapped to the operating system's mouse cursor. Following, the development of a UI is similar to the development of desktop applications. Besides, the UI is a subsystem of the assistance system, and the UI behavior is coordinated via the process models that are executed by the process engine. This manipulation of the UI's behavior by process models claims for separation of concerns: While the UI sub-system encapsulates the data visualization by low-level coordination of UI elements, the process models are responsible for processing the data. Display and data processing are separated, to catch the common benefits of the separation-of-concerns paradigm: "reduced complexity, better understandability, increased flexibility and reusability [125]". The separation between the UI visualization and the business logic is realized with two

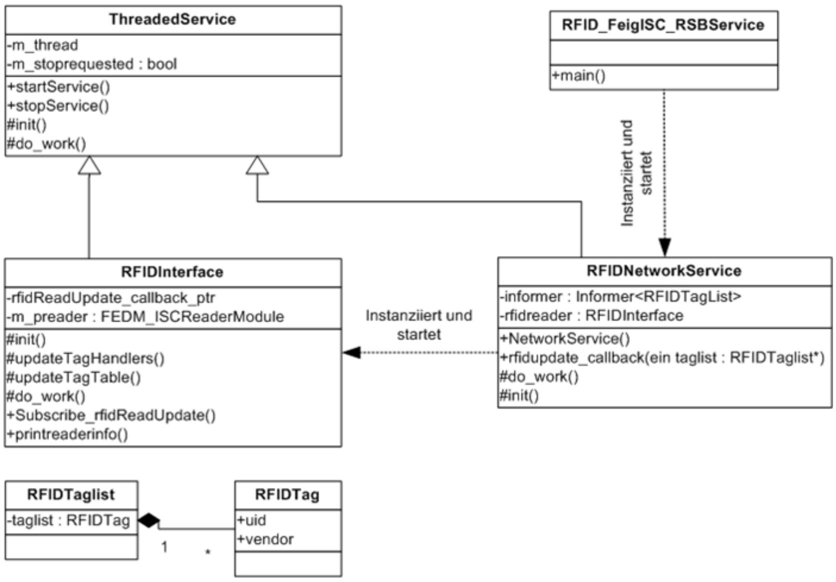


Fig. 5.8: Model for the RFID-reader integration as an example for integrating specific hardware devices into the system's infrastructure. The depicted classes encapsulate the computation (RFIDInterface) and the communication (RFIDNetworkservice) of the RFID device. The subsystem 'RFIDWrapper' from Fig. 5.6 utilizes the RFIDNetworkservice to abstract the implementation details of the RFID-reader device and to integrate the RFID device into the assistance system.

concepts: First, the *UIModel* defines the functions that are accessible by the process engine. The UIModel provides a representation of the UI, which abstracts UI details that are unimportant for the process execution. Second, the *UIWrapper* inherits from the subsystem class and implements a Model-View-Presenter (MVP) pattern to further split the UI into sub-components. Both concepts are explained in the following.

UIModel. The use case description or the domain model determines the functional requirements which the user interface must provide. The BPMN process models describe when and how these function are used in order to provide a meaningful assistance according to the domain specific workflows. Technically, the BPMN process models need an interface to access and coordinate the UI functions. This is the purpose of the UIModel. The UIModel provides the methods and fields on a high abstraction level in order to enable the BPMN 2.0 process designer to easily set up combinations of UI functions. The UIModel can be derived from the UI feature description. The domain analysis and the chosen hardware setup define the use case, which requires the UI to fulfill the following requirements. The related UIModel method is listed in brackets.

1. Showing the system's state, for example the person who is currently logged in [UIModel.setUser(user)]

2. Presentation or retrieving of instrument's data (core data, instructions, reclamations) [UIModel.setInfoStruct(infostruct)]

3. Confirmation dialogues for ensuring the worker's attention on critical operations [UIModel.getConfirmation()]

4. Input of new reclamation for a specific instrument [UImodel throws BPMEvent 'ReclamationAdded']

5. Input of new instructions [UImodel throws BPMEvent 'InstructionAdded']

6. Context awareness: depending on the reclamation severance level, a less or more obtrusiveness visualization mode should be used

These functions require context data from the process execution. For example, the RFIDWrapper informs the process engine that a new instrument was scanned. The running process model gets the instrument's description from the database, checks the reclamation severance and calls the UIModel to visualize the data. The Fig. 5.9 shows a simple process for setting the UI visualization mode according to severance of the instruments reclamation history. The process counts the amount of reclamation. If no reclamation is attached to the instrument, the UI is set to a "silentMode" which refers to low obtrusive way for information presentation. In case of two or more attached reclamations, the process designer intended the visualization to be obtrusive by setting the UI mode to "critical". Notably, the UIModel methods called from process do not define how the UI should visualize the functions. Instead, they only describe which UI features the process designer can access within the process models. Thus, the UIModel decouples the visualization details from the process execution.

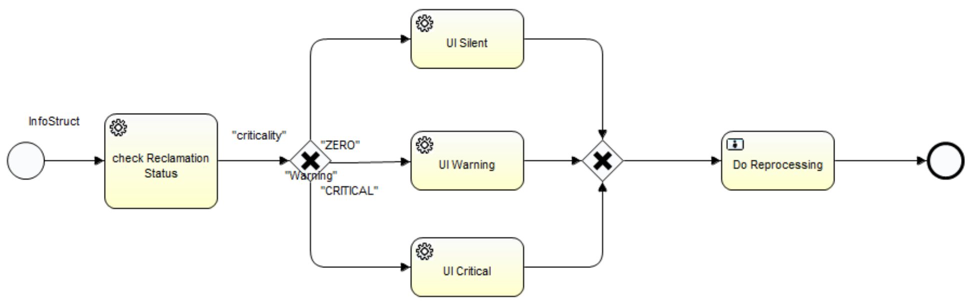


Fig. 5.9: BPMN 2.0 Process model 'Context-aware UI obtrusiveness': the service task 'check reclamation status' checks the severance of an instrument's reclamation history by threshold the amount of reclamations. Depending on the reclamation history's criticality, the process engine either calls the service task 'UI silent', 'UI warning' or 'UI critical'. These service tasks call the delegates on the UI subsystem which set the obtrusiveness of the assistance view accordingly.

More sophisticated process models are conceivable that provide more sophisticated context awareness, that comprise more information on the reclamations such as reclamation date, priorities or information from other subsystems. The point is, that the domain experts are enabled to define their own context-awareness without being overwhelmed by technical details. This is achieved by providing a set of UI functions and their coordination by BPMN 2.0 process models. A domain specific process designer tool can provide the UIModel functions as graphical building blocks. These blocks can be arranged graphically to define a system behavior. Such a domain specific process designer can enable domain or process experts to define the system behavior depending on the process or workflow needs.

Model-View-Presenter. Decoupling the view implementation from the business logic is necessary to allow the coordination of the UI states via process models. The UI visualization was implemented with a variation of the Model-View-Presenter (MVP) pattern [126]. The MVP pattern distinguishes three components:

The **Model**-component holds all domain-specific information such as instruments' data, workflows, sub-processes, guidelines, among others. Workflows are represented as BPM and utilize the BPMN 2.0 standard. Process documentation data and instructions for correct reprocessing persist in a database. A functional UI model defines the software interface and the functionality of the UI, in other words with features has the UI to come with in order to be controllable from the business processes. The UI interface model covers abstracts the function description of the UI from the its look and feel. The functions are given that the user interface must provide can be derived from the use case or in other terms, from the domain specific model of the use case.

The **View** is responsible for the visualization of the model. The view consists of widgets and control elements for this purpose. These elements also have basic control logic, such as button changes its borders if clicked. The UI's widgets and control elements hand off user input to the presenter.

The **Presenter** does the abstraction and interfacing between low level UI logic and business logic (model). If the user presses a button within the view, the button code notifies the presenter. The presenter communicates the change event to the business logic in case that the button click is relevant for the business logic. In case of events that are not relevant for the business logic layer, the presenter can update only view-elements. The following example illustrates this abstraction by the presenter: if the user clicks on another item in a list widget within the view, than updating other widgets such as labels may be mandatory for a consistent view. If the data that the list item visualizes is not manipulated by the view, than the list changing event is not relevant for the business logic and the presenter will not modify the business model.

Process model to view communication. For the assistance system implementation a model of the view 'UIModel' was defined, which describes, which functions are callable from the process models. The process engine calls the methods of this UIModel during the execution of process models. The UIModel is bound to the presenter during initialization of the UIWrapper subsystem with an Observer patter. Changes on the process models are observed by the presenter, which further changes the view elements.

View to process model communication. In case the user performs an action on the UI widgets, which requires to update the business process model (e.g. input of a new reclamation) the widget informs the presenter. The presenter creates and raises a BPMEvent according to the user interaction. The BPMService subsystem is an observer of BPMEvents by default. The BPMService has a configuration which determines the dispatching of BPMEvents. This is necessary, because different BPMEvents from different subsystem can be relevant for different process models and instances. The BPMEvent dispatching ensure that the process models are informed about BPMEvents they are interested in. Returning to the example, the BPMEvent generated from the user input is either injected to the related and running process model instance or a new process instance is started, according to the dispatching configuration. The process model instance that is executed by the BPMService can now react on the user input and it can coordinate other subsystem, depending on the process model. Simplified, the dispatching configuration realizes an observer pattern for process models and BPMEvents.

5.3 User Interface Design

The measures for quality assurance can only be effective if the worker accepts and uses the system. The UI is the surface of the assistance system that the worker operates with and thus plays a key role for the usability of the system. This section focuses on the development of the assistance system's UI, that the worker uses during the work at the unclean area.

Preconditions The implementation of the view is separated from the business logic layer as described in Sec. 5.2.5. The view must fulfill the functional interface (UIModel) that defines the features of the view. The UIModel was derived from the results of the domain analysis and describes the assistance functions which support the worker at the unclean area. Summarized the View must fulfill the following UIModels functions:

- Visualization of the instrument data (InfoStruct)
- Visualization of BPMN-triggered confirmation dialogs
- Visualization in three criticality modes with different obtrusiveness levels (UIMode: 'silent', 'warning' and 'critical')
- Input of instructions and annotations (update an InfoStruct)
- Input and Visualization of Reclamations (update an InfoStruct)

These workflow-related, functional requirements are supplemented by the general UI design principles as described in Sec. 2.4.2. Especially the UI should not interrupt the natural workflow and it should not annoy the worker with unnecessary information or dialogs ($R7$). For example the input of reclamation must be doable in a few seconds. Otherwise, if the reclamation input lasts too long, the worker would avoid the effort of data input. The input of reclamation has no short-term benefit for the worker. Instead, it demands the worker to do an additional task, which can be annoying if the worker currently has to process instruments under time pressure. However, the submission of reclamations while working provides valuable information to assess process quality and to identify potentials of improvement.

The question arises: "how to motivate workers to do the extra effort of data input while working?". This issues can be addressed in several ways. First, the effort of making annotations or reporting reclamation should be as low as possible. Second, the process of reclamations and data input should not only be a one way communication from the worker to the system. Instead, the worker should see, how the submitted data influences and improves the workflows (e.g. worker notifies that his submitted instructions really help an unexperienced worker). Third, the worker must be convinced that the input of reclamation provides a benefit and facilitates his or her work. The positive feedback or the transparent presentation of results from the reclamation submission can motivate the worker. Fourth, general working prescriptions from the CSSD administration can obligate the worker to document reclamations. Fifth, the input of reclamation could also provide a way to let the worker express his emotions. For example, a worker can get upset if medical devices were disposed improperly by the operating room. The worker could easily get hurt due to the improper disposal. The assistance system allows the worker to vent his displeasure by blaming the instruments delivery. In turn, positive reclamations, such as "commendable delivery" are also conceivable. The first and second point of these ideas for motivating data input are subject to the interaction and UI design of the assistance system.

UI-Guidelines Among the general UI principles from Sec. 2.4.2 UI guidelines can be defined to facilitate the design process. Supplementing these design principles with the requirements resulting from the CSSD domain and the hardware setup leads to design guidelines listed below.

This brief summary of UI-guidelines support the design of the view component of the assistance system.

- Keep the UI simple and functional.
- Carefully consider if a widget is really necessary for the use case. Avoid UI widgets if possible.
- Group functional related widgets.
- Place instrument related informations near to the working area.
- Place use-controlled widgets in the comfortable reaching zone.
- Respect the minimal widgets sizes (see Sec. 5.2.3) for robustness of interaction.
- Use common interaction concepts of touch screens.
- Provide feedback for each user intended interaction.
- Reduce information density to a minimum. Present only information which is necessary for the worker to fulfill the task.
- Respect the material flow on the workplace, when placing UI widgets.

With the guidelines in mind, concepts and pen&paper prototypes for the UI design were developed and discussed. The implementation of the resulting concept is proposed below.

Design of the UI's view component The implemented UI design assists the worker by visualization and manipulation of the instrument related information (aggregated in the InfoStruct data object) during the workflow. The worker starts the reprocessing by scanning an instrument's RFID-tag. The system immediately displays the available information relevant to the instrument. Depending on how many issues are reported for the instrument more or less information is shown. The requirement for unobtrusive interaction (*R7*) is regarded by adapting the information density that depends on the issue report history of an instrument. In the following, the basic workflow is explained, which utilizes different information densities for worker guidance.

There are four panels in the UI, see Figure 5.10 with all panels visible. The first panel **'CoreData'** is relatively small and shows only core data, like the instrument name and ID. It is present whenever there is an instrument processed. The second panel **'Instruction'** displays handling instructions for the instrument. The third panel **'Reclamation'** displays reported issues or reclamations for the instrument, e.g. "wrong assembly last time". The fourth panel **'Menu buttons'** is located on the right side of the UI and offers context-sensitive menu elements. It is present at all times.

To meet the requirement (*R3*) for data input, the user can easily add issue reports or reclamations to a single instrument by hitting three buttons (buttons are: "add reclamation", select a "predefined type of reclamation", "confirm"). This allows for a fast acquisition of process relevant data (e.g. condition of an instrument) as depicted in Fig. 5.11. This data is used by a BPM-process that decides, how much information the worker must consider (see Sec. 5.2.5). For example, an instrument with two or more critical issues in the past is classified as "high risk" and all panels are therefore automatically shown when the worker scans the instrument (UI-mode critical).

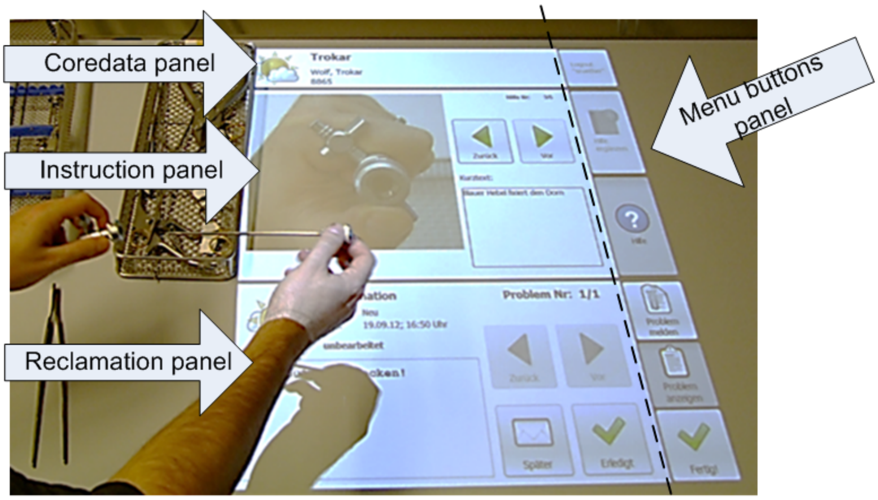


Fig. 5.10: The worker follows instruction from UI. Four panels are visible.

An additional confirmation dialog assures that the worker attends to the critical instructions. The system informs about major issues that happened with a "high risk"-instrument in the past and provides instructions, which the worker must acknowledge. If the worker does not acknowledge, a highlighted dialog is shown, as soon as he wants to work on the next instrument. The system interrupts the regular workflow (and also the disinfection machines could be blocked), until the correct treatment of the “high-risk”-instrument is confirmed.

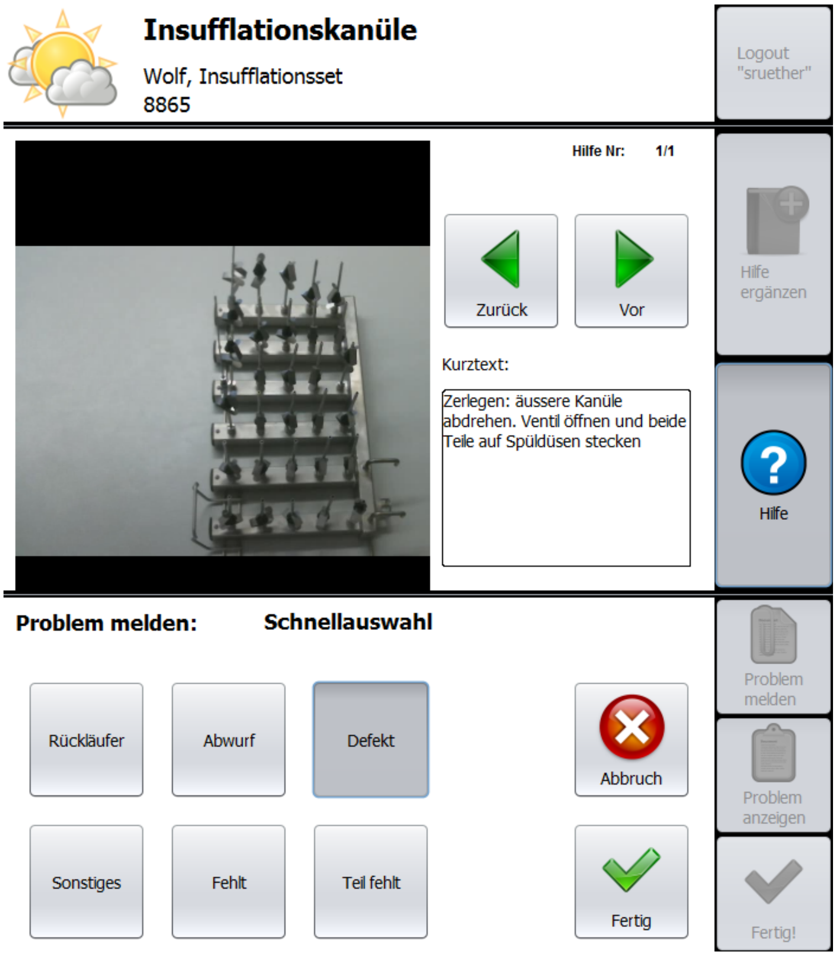


Fig. 5.11: The UI allows to submit predefined reclamations. Three buttons clicks are necessary: 1) add reclamation, 2) select predefined type of reclamation, 3) confirm. The predefined reclamations describe regular issues with medical devices.

Instruments with no reclamation history are classified as “low risk”. Since no issues are known, it can be assumed that the worker knows how to handle the instrument correctly. In this case, the system shows no instructions and remains unobtrusive when the worker scans the instrument’s RFID-tag (UI-mode ’silent’). Especially for trivial instruments such as clamps, scissors, etc. superficial information is not shown. This targets an assistance system that does not disturb or annoy the worker (*R7*). However, instructions are retrievable with one button hit (*R2*). Instruments are classified as “medium-risk” when minor issues appeared in the past. In this case, the UI shows the latest issue report (UI-Mode: ’warning’). A context-aware weather icon symbolizes the severity of the reclamation history: in case of no reclamations a shining sun is shown, while the cloudy and stormy weather icons symbolize a medium or high severity.

Fig. 5.12 shows the UI in mode silent (top), critical (middle) and the confirmation dialog (bottom).

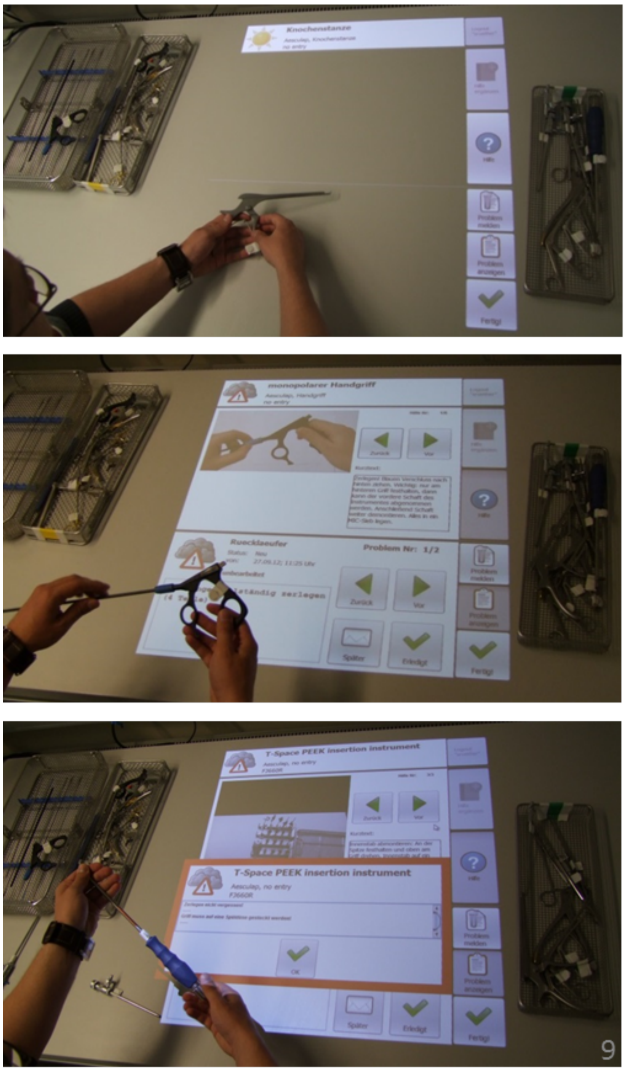


Fig. 5.12: Worker follows instruction from UI. The UI at the top shows the 'silent mode'. The critical mode is illustrated in the middle. The confirmation dialog at the bottom image asks the worker to confirm a critical operation.

Chapter 6

User Study: Applicability and Usability

The first evaluation of the prototype focuses on the principle applicability, interaction and usability of the system. The following sections explain the method, present the results and discuss the implications of the user study.

6.1 Method

The assistance system is evaluated by means of a comparative study with 16 participants. The performance of the participants using the system was compared to paper-bound instructions as they can be found in current hospital CSSDs. Two real-world examples for such paper-bound help are depicted in Figure 6.1[1].

Every participant did four experiments. For each experiment the task was to prepare the automatic cleaning and disinfection of a sieve with medical instruments. To do this correctly, instructions were provided either with a folder of paper-bound instructions ('condition P') or with the assistance system ('condition S'). Provided instructions were the same, but the assistance system additionally showed some short videos for instrument handling as a consequence of taking advantage from EDP-guidance. The assistance system presented the instructions with the UI design described in Sec. 5.3. Instruments must be disassembled and loaded correctly on sieves for the cleaning and disinfection machine. Additionally and with regard to common practical workflow, two issues with instruments were reported by the operating room via a paper placed in the sieves, which had to be noted by the participants.

The assistance system and the paper-bound help were introduced very briefly before experiments. The experimenter briefly showed the principle of virtual touch interaction. The participants were asked to prepare the set of medical devices for the cleaning

[1]The instructions on the right picture were mounted on the wall after this instrument broke several times and even with the instruction in front of the workers the instrument broke again. The instrument costs around 7000 Euro and broke seven times in total due to wrong handling.

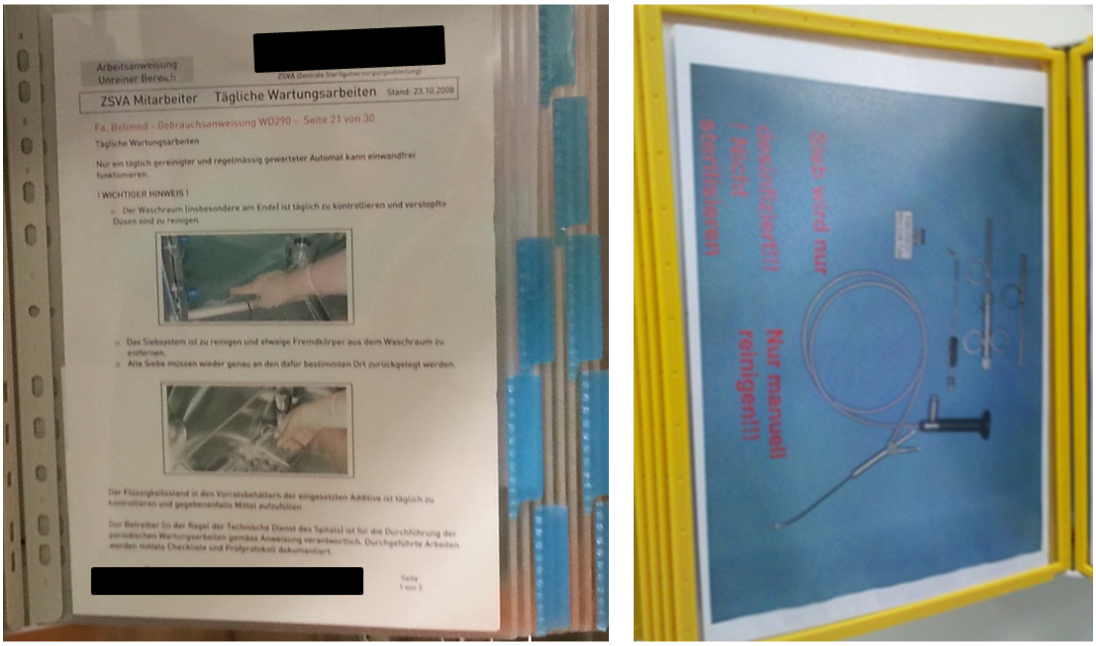


Fig. 6.1: Two examples for paper-bound instructions as found in two different German hospitals.

and disinfection machine and were told that all required information can be found at the workplace. The participants were requested to think out loud.

The ordering of the experiment conditions were equally balanced according to Tab. 6.1 to minimize average carryover effects between the two conditions. Also for this reason, two different sieves of instruments ('A' and 'B') were used to let the participants work on conditions S and P with different instruments. The instruments on sieve A and B had nearly the same reprocessing difficulty[2].

Participant	Condtion Experiment 1	Condtion Experiment 2	Condtion Experiment 3	Condtion Experiment 4
1, 5, 9, 13	AP	AP	BS	BS
2, 6, 10, 14	AS	AS	BP	BP
3, 7, 11, 15	BP	BP	AS	AS
4, 8, 12, 16	BS	BS	AP	AP

Tab. 6.1: First user study: experiment conditions for participants. 'A' and 'B' refer to the sieve (set of medical devices) A or B. 'S' and 'P' refer to assistance system or paper guidance.

The completion time was measured and as well as the number of handling errors for each experiment. After each experiment, the participants had to fill in a questionnaire.

[2]Sieve A comprised 13 and sieve B 12 instruments. To assure same difficulty of the sieves, the instruments were carefully selected before the study. A comparison after the study between the overall error rate for sieves A and B showed no significant difference.

The participants' errors were partitioned into 'major' and 'minor'. Major errors represent improper handling with an instrument in the way that the instrument could not be cleaned and disinfected by machine correctly, according to expert knowledge of the task[3]. For example, a not or wrongly disassembled trocar is such a major error. Minor errors are noncritical mistakes by the participant, meaning that violated instructions decrease process efficiency but do not endanger the success of disinfection. For example, two or more parts of an instrument are loaded on different sieves, which only leads to increased search times after disinfection or if reclamations were noted wrongly. For each participant the total number of errors for each assistance condition was calculated by adding the number of minor and major mistakes from two experiments with the same condition. The total duration for each condition was determined analogously. The usability was tested for condition S with a questionnaire of nine questions inspired by Ong [127] and Huang [128].

For statistical tests of significance[4], the following null hypotheses were formulated:

- $H1_0$: There is no difference in total error rate between conditions S and P.
- $H2_0$: There is no difference in completion time between conditions S and P.
- $H3_0$: Participants feel equally confident with the task under condition S and P.
- $H4_0$: Participants equally like the work under condition S and P.
- $H5_0$: Participants do not prefer any condition (S or P) over the other for solving the task.
- $H6_0$: Participants equally rely on the provided instructions under condition S and P.

Participants. The experiments were performed by 16 participants (11 men, 5 women) with minor or no knowledge of reprocessing medical instruments. The participants were 32.4 years old in mean. Eight participant had a technical background due to their job. All but one participants were right-handed.

6.2 Results

Error rate and completion time. On average, the participants made 4.37 errors less in total under condition S (assistance) as compared to the paper-bound baseline P. The error rate is shown in Figure 6.2. Tab. 6.2 holds the statistical test results. The null hypothesis $H1_0$ for error rates must be rejected, in conclusion the difference for error rate is statistically significant.

Concerning the paper-bound help as ground truth, the total error rate is reduced by 56.95% with the assistance system, while the rate of major errors is decreased by 62.79%.

[3]The experimenter participated the course 'Technical Sterilization Assistant I (TSA)' and did an additional internship in a German CSSD during the domain analysis to acquire detailed knowledge about the correct reprocessing of medical instruments.

[4]The term 'statistically significant' is used for a p-value (two-tailed significance of a t-test) of $p \leq 0.05$. The toolkit SPSS 20 was used for all statistic tests

The average total duration for two experiments under the same condition shows no significant difference between S and P as depicted in Figure 6.3. t-test results listed in Tab. 6.2 show that the null hypothesis $H2_0$ for duration of the task cannot be rejected.

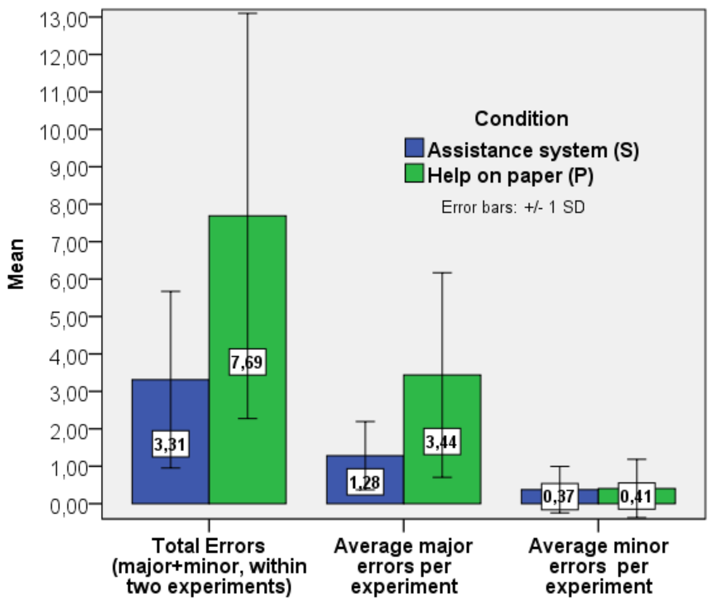


Fig. 6.2: Observed errors during reprocessing depending on the guidance condition.

Variable	Mean Cond. S	Mean Cond. P	p
Total number of errors	3.31	7.69	0.006
Average number of major errors	1.28	3.44	0.009
Average number of minor errors	0.38	0.41	0.901
Total time [secs]	1286	1220	0.453
Average time for one experiment [secs]	643	610	0.453

Tab. 6.2: Paired t-test results for error rate and experiment duration.

Usability. The results for the usability related questions are illustrated in Figure 6.4. The compatibility of the data was tested with the null hypothesis: “The participants answer the neutral element ‘3’ in the five point Lickert scale for usability related questions”[5]. One can see that the participants appraised the system a clear, comprehensible and easy to use UI.

[5]In other words, participants experienced the system neither usable nor non-usable.

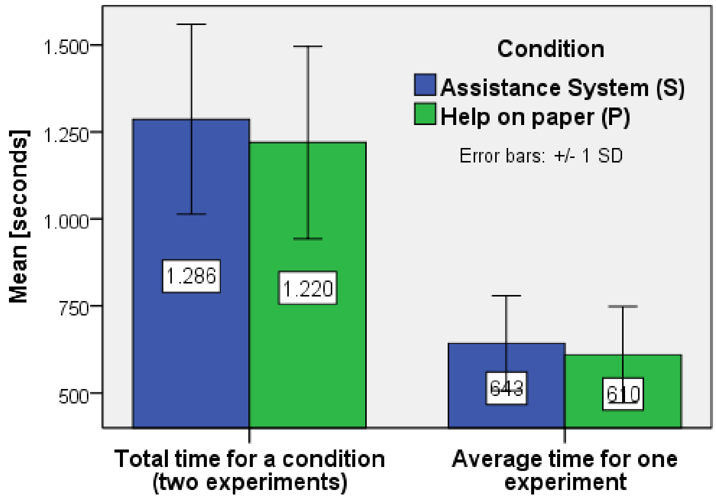


Fig. 6.3: Total and average durations for task completion depending on the guidance condition.

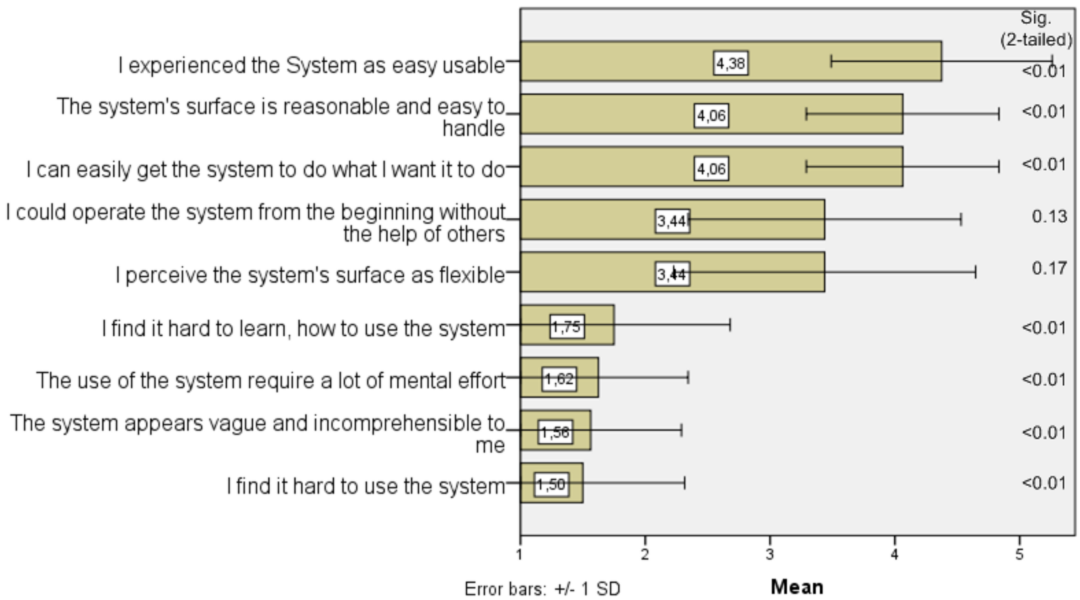


Fig. 6.4: Usability results. Participants answered questions with a 5-point Lickert-scale ranging from 1= 'no, not at all' up to 5= 'yes, very much'.

The participants' confidence was measured with questions Q1, Q2, Q3, Q7 and Q8 shown in Table 6.3 to test $H3_0$. The t-test revealed that participants feel more confident during reprocessing medical instruments with the system while making fewer mistakes. With the results of question Q4 the null hypothesis $H4_0$ is falsified. Participants found the assistance system significantly more appealing than the paper-bound help. Questions Q5, Q6 and Q9 measured how much the participants oriented to the given assistance ($H6_0$). The results show that $H6_0$ is incompatible with the observed data. So, participants significantly pay more attention to the instruction when using the assistance system.

The hypothesis $H5_0$ was tested with "Q10: Which kind of aid would you prefer for the processing of instruments?". The participants answered this question after they had completed task four. They clearly preferred the system over the paper bound version, as the mean value of 4.88 on the 5-Lickert-scale with '1= Paper and Folder', ... , '5= Assistance system' shows. The t-test against the neutral element of the Lickert-scale[6] confirms the strong statistical significance of < 0.001. Thus, $H5_0$ must be rejected. The assistance system is significantly preferred by the participants for accomplishing the task of medical device reprocessing.

No.	Question	Mean Cond. S	Mean Cond. P	p
Q1	How confident did you feel during the task?	3.81	2.41	<0.001
Q2	Could you imagine to reprocess instruments in a real hospital with the given help	3.75	2.25	<0.001
Q3	Did you have problems with issue reporting?	2.31	4.13	0.001
Q4	How much did you like the task?	3.84	2.72	<0.001
Q5	Did you follow the given instructions exactly?	4.09	3.38	0.004
Q6	Did you feel sufficiently supported with the processing of instruments?	3.88	2.56	<0.001
Q7	Do you think, that the help and instructions prevented you from mistakes with the treatment of instruments?	4.41	3.09	<0.001
Q8	Do you think, that you did mistakes during the task?	2.44	3.72	0.003
Q9	What did you orient yourself more to? (Scale: 1='instruction and help', ... , 5='gut instinct')	2.19	3.28	<0.001

Tab. 6.3: Average questionnaire results for condition S and P. Participants answered question Q1 to Q8 with a 5-point Lickert-scale ranging from 1= 'no, not at all' up to 5= 'yes, very much'.

[6] Null-hypothesis: "neither the paper aid nor the assistance system is preferred for the task"

6.3 Discussion

This chapter introduces a user study to evaluate the effectiveness of the proposed assistive system an compares it to the state-of-the-art. The presented first evaluation focused on interaction with lay users, which is quite typical in real-world CSSDs because of high fluctuation and low training of workers. Also interaction with lay users can be compared to a training phase of new workers.

The results in Sec. 6.2 show that the system helps to prevent failures during instrument reprocessing without any significant increase of the required time. The participants liked system much more than the paper-bound help and paid more attention to the given instructions. Additionally, the system shows satisfactory results in terms of usability, although the UI could further be improved, especially in terms of flexible and self-explanatory interaction. These encouraging results show, that the combination of projection and virtual-touches is sufficient interaction concepts and worked robustly enough, despite its prototype status. The UI is capable of to support workers with the relevant working instructions. Although the user only had a very rough explanation about the assistance system before the experiments started, they were able to operate it and achieve better results in comparison to the paper-bound help.

The user study also revealed that several improvements of the assistive system are possible and senseful. The reclamation panel often confused the participants. The reclamation panel shows only one item of the reclamation history. It provides no overview of issues except a number indicating how many reclamation exist. Additionally the participants experienced trouble while identifying whether a reclamation already has been handled or not. The unclear status of the reclamation history plus the effort of browsing through all the history confused the participants. Further issues arose from the placement and labeling of buttons. Especially the 'confirm-reclamation button' was often mistaken for the "instrument-done button" because of its similar appearance and spatial proximity. By concerning the input of information, the evaluated system's prototype only allows the workers to input issue reports – adding instructions with a setup-integrated camera and annotations by simple gestures and finger movements is a promising option. The identified improvement potentials and issues motivate the design iteration described in Chapter 7.

Among the presented results, Beuchel [129] carefully analyzed the video material of the user study by utilizing the conversation analysis method to investigate the human-machine dialog. Beuchel derived detailed requirements for the design of the UI and provided suggestions for design improvements. Unfortunately, these findings could not be considered during the design iteration discussed in Chapter 7, because they were available after the design iteration.

Chapter 7

User Interface: Iteration and Evaluation

The evaluation of the UI design in Chapter 6 showed satisfying results regarding the failure avoidance capabilities and usability of the assistance system. The first user study revealed that the user interface and interaction patterns work in principle. However, the results of the quantitative study and interviews with domain experts indicated missing features and further improvements that are important for a real world applicable CSSD assistance system. These opportunities for improvement mainly regard the user interface of the system, since this was the focus during the user study as described in Chapter 6. This chapter describes the development of a new user interface design for the assistance system based on the user study results and domain experts' feedback. Sec. 7.1 briefly discusses the goals and constraints of the system iteration. Sec. 7.2 derives the UI concept and concerns aspects of implementation. The method and results of an quantitative evaluation[1] of the new user interface are described and discussed in Sec. 7.3.

7.1 Improving the User Interface: Goals and Constraints

Design iteration goals. This section addresses possible improvements for the UI of the assistance system that arise from the evaluation of the systems' prototype as described in Chapter 6. The main goals for the UI iteration are to further improve usability, integrate new functions, improve the reclamation panel, remove the sidebar panel, explore new look and feel concepts and to explore ergonomic improvements for widgets' placement. The first study has shown that the basic interaction with virtual-touches and the structure of the UI are sufficient for worker guidance. Thus, the working concepts of the UI are considered as 'design constraints', which the new UI should keep while the design changes address the following issues with the previous design.

[1]The implementation and the data recording of the user study were supported by Benjamin Errouane during his bachelor thesis [130].

Potential UI improvements. First, the previous design showed the reclamations and instructions at the same time. This could potentially result in a **high mental workload** of the worker, because the presented reclamation must not be regarded to the shown instructions. For instance, a failure showing the wrong delivery or labeling of a sieve has no direct association with the instructions for disassembling the instrument.

Second, participants experienced some trouble while using the **reclamation panel**, because of a confusing presentation of the reclamations. In the evaluated prototype the UI only showed one reclamation at a time. The user must actively browse through the reclamation history in order to see all reclamations. Therefore reclamations could easily "get lost" during the workflow. Redesigning the reclamation panel should provide an overview of all the relevant reclamations, ideally without the need of user interaction. However, a trade-off between showing too much and showing to less information must be addressed by the presentation of the reclamation history.

Third, the context sensitive states for **sidebar menu does not scale** with desired new function such as taking pictures, annotating, retrieving workplace depending data, undo and others. The development of a new UI-design should consider the migration of the context-sensitive sidebar menu buttons into the different panels. Despite the higher space requirements within the panels for control widgets, the issue of to many context-sensitive states within the sidebar menu is stemmed. Additionally, the restructure of data-presentation and data-manipulating functions potentially improves the UI's clarity.

Fourth, as the evaluation of the previous iteration showed, **new functions** should be integrated into the system and therefore into the UI. A feature of taking and annotating pictures during the regular work is expected to help the data management of a CSSD. Although the fast input of reclamations worked, this feature should be enhanced to deal with more different types. More in detail, instruments with reclamations come either from the operating room (*delivery*) or from the clean area as a control instance for the unclean area (*returns*). The fast reclamation input should provide a corresponding distinction to enable the system for more precise failure statistics.

Design iteration constraints. Among the discussed ideas for improving the UI design the following UI details retrieved sufficient feedback from the user study and should be kept or only slightly adapted during development of a new design. Notably, the general design principles described in Sec. 2.4.2 and Sec. 5.3 can be considered as design rules as well.

The first of such design constraint is the **visual data separation** into instrument core data, instructions and reclamations because the separation into instructions, reclamations and workplace-depended data showed feasible results in the first user study. From the feedback of domain experts, these data should be complemented by workplace related information or in other words: context-independent data, e.g. steeping disinfection lotions. Therefore this visual separation was kept in nearly all sketches.

The second constraint is the **context-sensitiveness** of the UI. The criticality of instruments was categorized in the previous evaluation into high risk (UI mode 'critical'), medium risk (UI mode 'warning'), and low risk (UI mode 'silent'). Each category correlates with an obtrusiveness level of the UI. Meaning that, high risk instruments result in a obtrusive UI to attract the workers attention while the UI is very unobtrusive for low risk instruments, to avoid interrupting the worker. This context-aware obtrusiveness has been well-recognized in the first user study. The dynamic obtrusiveness pursues to keep the mental workload during the interaction with the system at an appropriate level for the current task. To further explore this kind of context-awareness the dynamic obtrusiveness should be reused in the UI design iteration.

The third constraint concerns the integration and development of the UI and demands that the new **UI integrates with the existing system's software architecture** in order to keep the implementation effort low. In particular, the existing data structure for the BPMN integration, the component-based-architecture as well as the model-view-presenter pattern for the UI integration should be reused.

The fourth constraint results from the hand tracking infrastructure. The prototypical implementation of 'virtual touches' worked satisfactorily. For the UI iteration this interaction mechanism should stay the same, in order to avoid integration of new sensors or programming of new classification and user input controls. More in detail, gesture-control or multi-touch finger tracking are appealing but demand higher integration effort. Low robustness and low intuitiveness (e.g. gestures) of usage are additional drawbacks. The expected impact of integrating complex multitouch- or gesture-tracking technologies for the interaction is thus too small compared to the necessary effort. For this reason, the usage of the existing hand-tracking infrastructure[2] is a constraint in the design iteration. This implies that, the buttons and control-elements have to be large enough to deal with the sensory noise. The button and UI size was appropriate in the previous iteration, so this should also be kept during the UI improvement as a subsequent constraint.

7.2 Improving the User Interface: Concepts and Implementation

With the design goals and constraints in mind, low fidelity design sketches and wireframes were explored with pen and paper. Pen&paper prototypes allow to develop and assess different UI designs with relatively small effort. The fidelity for the most promising "pen&paper-sketches" were slightly increased by using UI prototyping software, such as 'Microsoft Visio' and 'Pencil'. Fig. 7.1 shows a selection of these design sketches.

These sketches were discussed with two professional industrial designers. The experts' feedback was captured by introducing the different sketch ideas and doing cognitive walk through for the task of reprocessing with each sketch. Additionally, common usability heuristics (see Sec. 2.4.2) resulting from ISO 9241 [30] and Nielsen [32] were discussed for each walk through. The industrial designer's feedback was valuable and as a result the UI-Design sketch "vertical sliding panels" was selected and has been elaborated as shown in Fig. 7.2. The UI-design "vertical sliding panels" keeps the data structure from the previous design by providing a separate panel for instrument's

[2]dSensingNI's output is mapped to a mouse controller, see Sec. 5.2.3

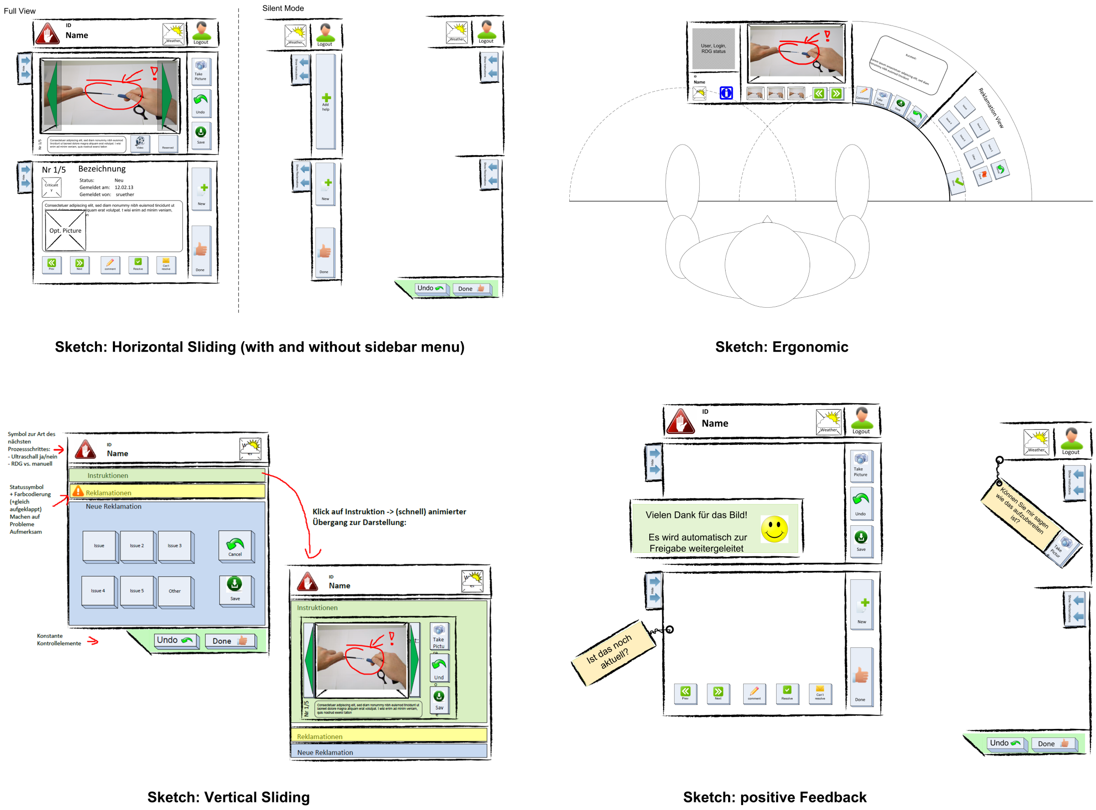


Fig. 7.1: Examples for 'pen&paper-sketches' created during the UI design iteration. The picture illustrates a selection of different design sketches, that were conceived for the improvement of the UI. The sketches has been discussed with industrial designers and as a result the "vertical sliding panels"-design was selected for implementation.

core data, instructions and reclamations. The sidebar menu was completely removed. Instead, the panels now have two states: opened and closed. While the opened view shows all elements of the panel, the closed view shows only the panel's header and provides the important status information. Therefore, closed panels look like a status-bar, providing the important information in short and additional information on demand (by opening the panel). Only one panel can be open at any times. A closed panel can be opened by touching (clicking) its closed view. The state changes for closing and opening panels can be slightly animated for an "aesthetic" look and feel. This mechanism ensures, that the worker sees important status information in a concise form but he or she must only consider more than one panel with detailed information. The reduction of information details to either reclamation or instruction specific details targets at reducing the amount of required mental resources of the worker.

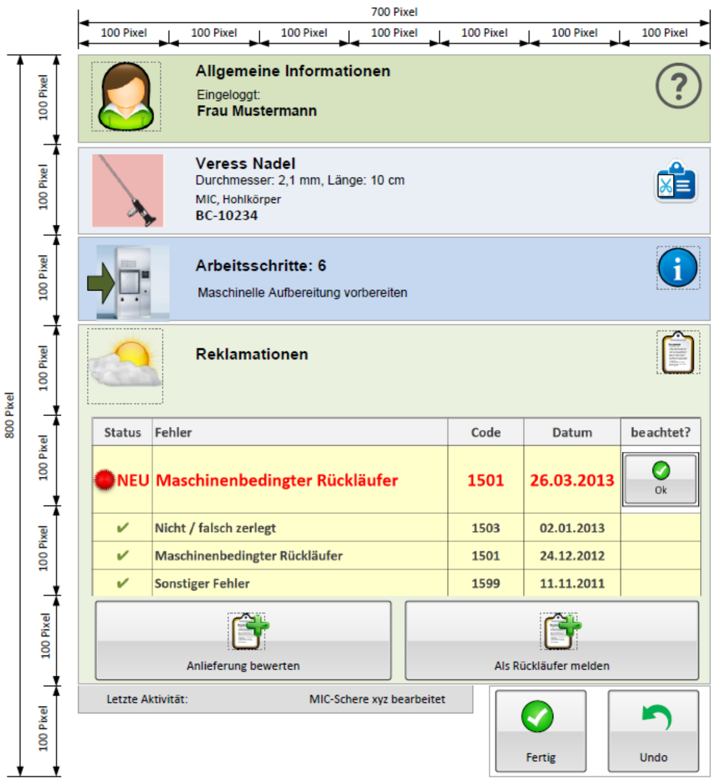


Fig. 7.2: The selected design sketch provides four panels each containing data either related to the workplace, to the instrument or to quality related issues. The panels' headers are always visible. A panel is opened by clicking its header. Only one panel can be opened at any time.

The implementation of the UI iteration is depicted in Fig. 7.3 and slightly differs from the design sketches. Each panel provides a status header for the closed view and content for the opened view due to the new design. In the case of the Instruction-panel, the panel state is determined from the core-data of the instrument that is currently processed, because the instructions (content of the panel) refer to this specific instrument. Therefore the CoreData panel from the design sketch has been merged into the instruction panel. The resulting free space has been used to integrate workspace-related data, such as login information. Although, this “workplace data panel” is only intended as a 'header containing the most important workplace status data' it can easily be extended to a full sliding panel with detailed working instructions regard the current workplace, such as how to mix a disinfection solution or how to use the ultra-sonic bath. Thus, the UI provides three different groups of widgets for the three different information types: 1) workplace specific data and instructions ('workplace data panel'), 2) instrument specific data ('instruction panel'), and 3) quality management related data ('reclamation panel'). Fig. 7.3 also illustrates, that the colors of the reclamation panels changes according to the severity of reclamation history. The colors were chosen according to the general standards [131]: blue for handling instruction, yellow for warnings and abnormal conditions, red for dangerous or critical conditions and green for normal operation.

Concerning the input of reclamations, the sliding-panel UI enables the worker to submit two types of reclamations: 1) “returns” (Button “Rückläufer” in Fig. 7.3) allows to document instruments returning from the uncleaning area and the reason why the instrument is returning. 2) “delivery” (Button “Anlieferung” in Fig. 7.3) allows to assess the disposal by the operating room, which is responsible for the condition of arriving instruments.

Other implementation aspects concern the working instruction input and the interaction modalities of the virtual touch component. The instruction input and annotation feature is depicted in Fig. 7.4. The worker uses the installed camera of the assistance to take a picture for the new working instruction. In the second step, the finger is annotated by 'finger-painting' within the projected image. Notably, a BPMN 2.0 process running in the background processes the submitted instructions and induces the approval by the CSSD responsible in order to assure the compliance of the new working instruction with the general CSSD restrictions. The approval process is automated by utilizing the business process models to directly communicate new instructions to the person that is responsible for approval. To enable the user for painting within pictures, the finger from the dSensingNI motion tracking system must be processed within the mouse-controller (SubSystem 'MouseRobot') in the way that the mouse of the computer moves correspondingly to the hand movements within the workspace. This adds more complexity to the MouseRobots since it must deal with two different type of events: hand movements and finger movements, that both must be matched to the mouse functions of the operating system.

The implementation of the “sliding-panel UI” provides an overview about the instructions order. For this purpose the instruction panel provides a listing at the left site, that shows the order of all process steps for the instrument exists and highlights which process step is currently shown in detail (depicted in image 4 of Fig. 7.3).

The UI offers a single starting point for worker by presenting only up to one panel with detailed information. For instance, if a critical instrument's ID-tag is scanned the UI shows the opened reclamation panel because of the instrument reclamation state. The size of the opened reclamation panel tempt the worker to start the task

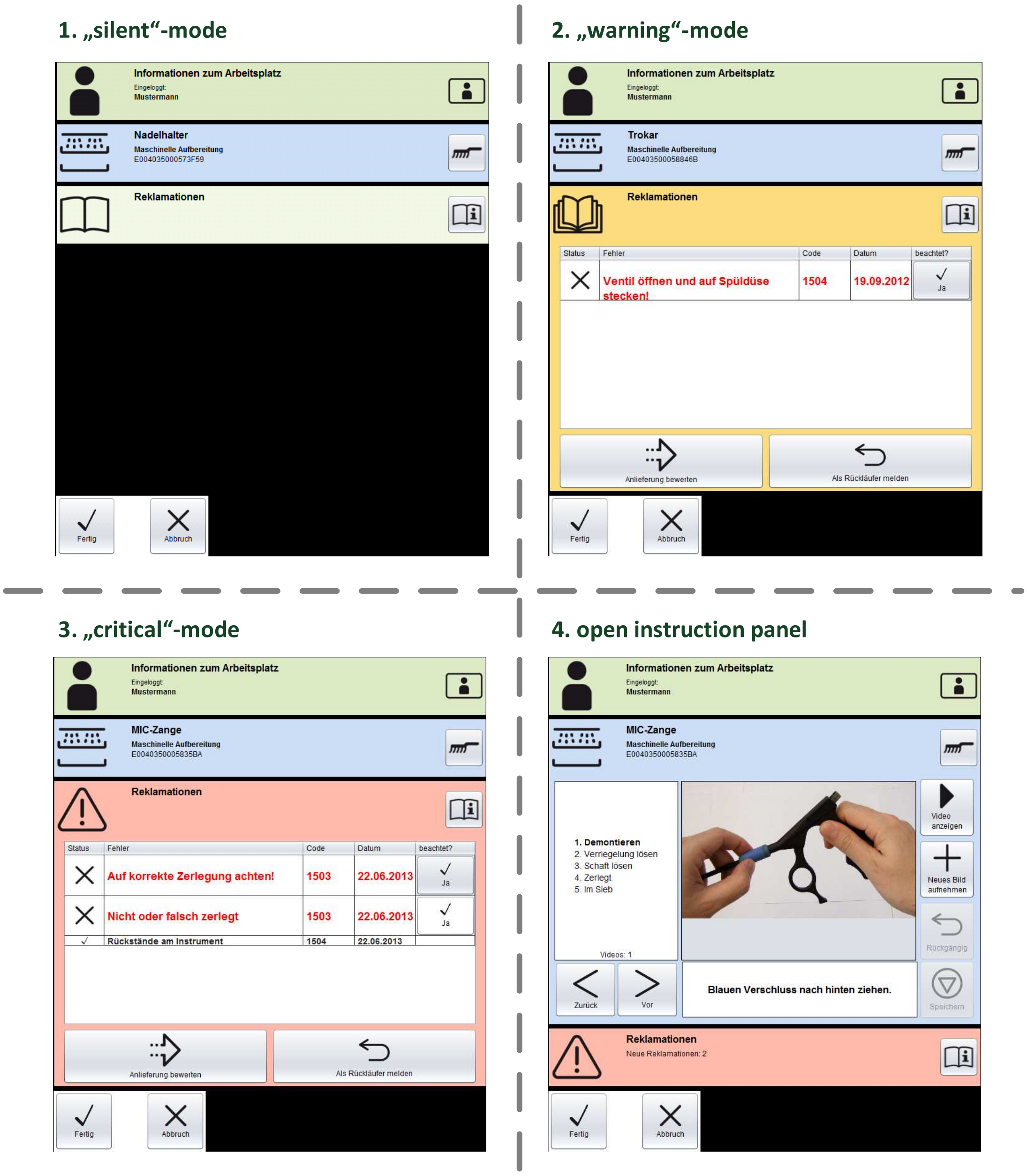


Fig. 7.3: The implemented 'Sliding Panel' UI in four different modes. Image 1 shows the silent mode, which is shown if the severity of the medical device is classified as 'low-risk'. Image 2 shows the warning mode of the UI, which is shown in case of medium risk instruments. Image 3 depicts the 'critical mode' of the UI, in case of a severe reclamation history. Image 4 illustrates the instruction panel. The buttons for browsing instructions and the buttons for acknowledging the instrument's processing (bottom) are placed near to the working area (left side of the UI), while less often used widgets are placed at the border of the comfortable reaching zone.

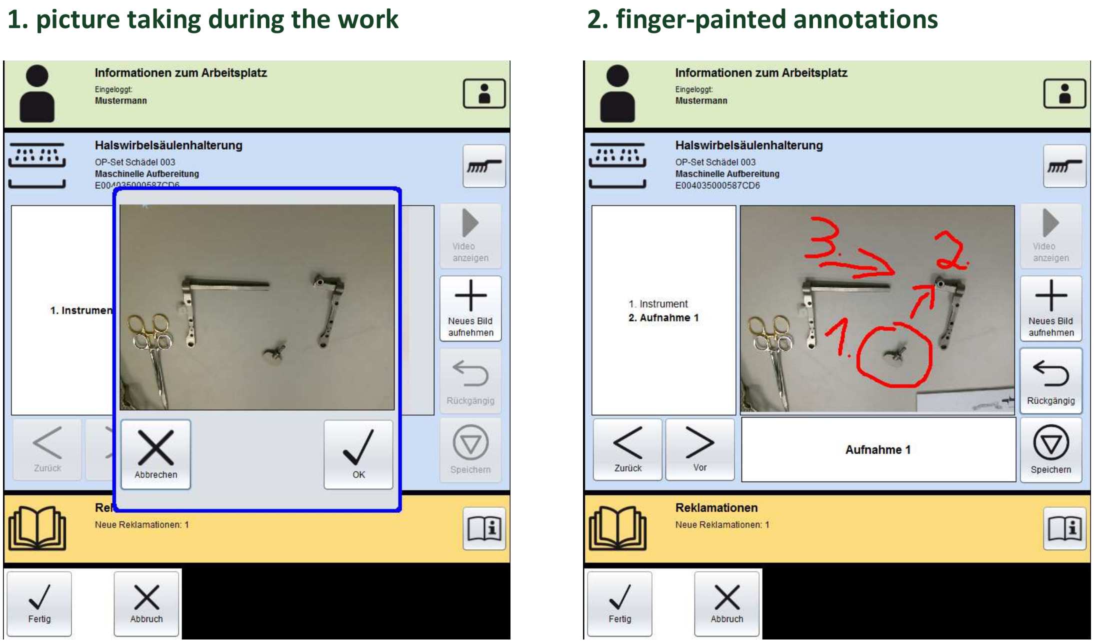


Fig. 7.4: The 'Sliding Panel' UI allows submission of new working instructions. The worker first takes a picture with the workplace-integrated camera (left image) before he annotates the picture by finger-painting (right image). The system communicates the instruction proposal to the responsible CSSD administrative for approval, according to workflow definition of the corresponding BPMN 2.0 process model (not depicted).

by reading the reclamations first. After the worker has perceived the reclamations, mainly two options are available: In case the worker knows the instrument well, he or she handles the instrument and acknowledges the reclamations. In case that the worker is uncertain about the instrument's handling he opens the instruction panel, recognizes the instruction and processes the instrument before he finally acknowledges the correct handling by touching the 'Done'-button or scanning the next instrument. In case of critical instruments, the UI additionally asks the worker for acknowledgment of unconfirmed reclamations by showing a confirmation dialog. Compared to the previous design this interaction dialog is more straight-forward and less confusing. In the previous design, the worker had to choose the starting point of the interaction himself: either he starts with reading the reclamations or with reading the instructions before he or she decides what actually to do. As experienced during the user study this "two-way starting option" sometimes confused the users. Additionally, the "one-starting point dialog" (hypothetically) improves the recognition of reclamation, which are the most recent (or important) information during the interaction dialog. Still, the user stays in control, since he can simply open the other panels to receive the information or system's functions to fulfill the task. The user's mental workload is probably decreased by removing the decision, which detailed information must be read first.

Considering the ergonomic placement of user-operated widgets, the often used buttons has been placed in the comfortable reaching zone of the worker. For instance, the main menu for acknowledging or aborting reprocessing of instruments moved to the bottom. Since the place within this ergonomic zone is limited, not all functions could be integrated here. Notably, open panels provide more space for placing widgets compared to the previous design.

The previous design had a context-sensitive symbol ('weather icon') for indicating the severity of the reclamation history. The new UI-design also utilizes context-sensitive icons, but in a more consistent manner: The status symbol in the upper left corner refers to the most important context-sensitive information for each panel. More precisely, a picture of the user within the working place panel indicates who is logged in. A cleaning and disinfection machine or a warning symbol in the instructions header indicates of a medical device is reprocessed by hand or by machine. The reclamation header utilizes a weather or book icons to symbolize the severity of the reclamation history.

For the status symbols of the instruction panel the instrument classification symbols from the standard literature "Red Brochure" [10] could be concerned over the integrated 'manual' or 'by machine' symbols. Workers know the red brochure from their qualification for TSA I. It provides reprocessing guidelines for different classes of instruments. For quick navigation within the guidelines, the red brochure uses a small set of icons, that symbolically classify the instrument types. Utilizing this icon set for the interaction dialog provides standardized symbolic communication, that the workers already know. However, the symbols for communicating the reprocessing procedure (manually or by-machine) was preferred, because the domain analysis showed, that the disregard of the correct reprocessing procedure is a common and cost-intense failure source. Because misunderstanding the meaning of icons is a general issue, short texts to complement the status symbol. For this reason the status of each panel is communicated in two ways: a context-aware icon and an accompanying short text. Besides the context-sensitive status-symbols, a constant 'function-icon' is located at the upper right corner of each panel and symbolizes the main content of the panel. This should help the user to identify the panel quickly, that he or she needs to fulfill the current task.

The effort of designing an icon set for the assistance system UI has been avoided. Instead, icons from some free-ware icon sets were reused as shown in Fig. 7.5. Colored icon sets might look more friendly but lack in consistency. Thus a more consistent icon set (kindly provided by a manufacturer of cleaning and disinfection machines) was reused as already depicted in Fig. 7.3. The professional icon set offers more consistency, but is less self-explanatory as the figures illustrate. The industrial icon-set often had a low fitting for icons to represent the system's functions and status messages. Although the industrial icon-set was originally designed for other purposes such as showing status and control function of cleaning and disinfection machines it was reused for the assistance system prototype, because it looks more 'professional' due to its consistency and minimalistic design. Additionally, the icon-set is in line with existing icons already used in real world CSSDs. With the same icon design for the assistive system and its surrounding devices, the interaction with technical devices in the CSSD uses the same symbolic language, which probably avoids misunderstanding and failure rates during interaction. This professional icon set design is closer to the CSSD than the colored icon set. For future development, the extension of the icon-set for assistive system related symbols is recommendable. However, the system allows to easily add or change the icon set by simply editing a configuration file.

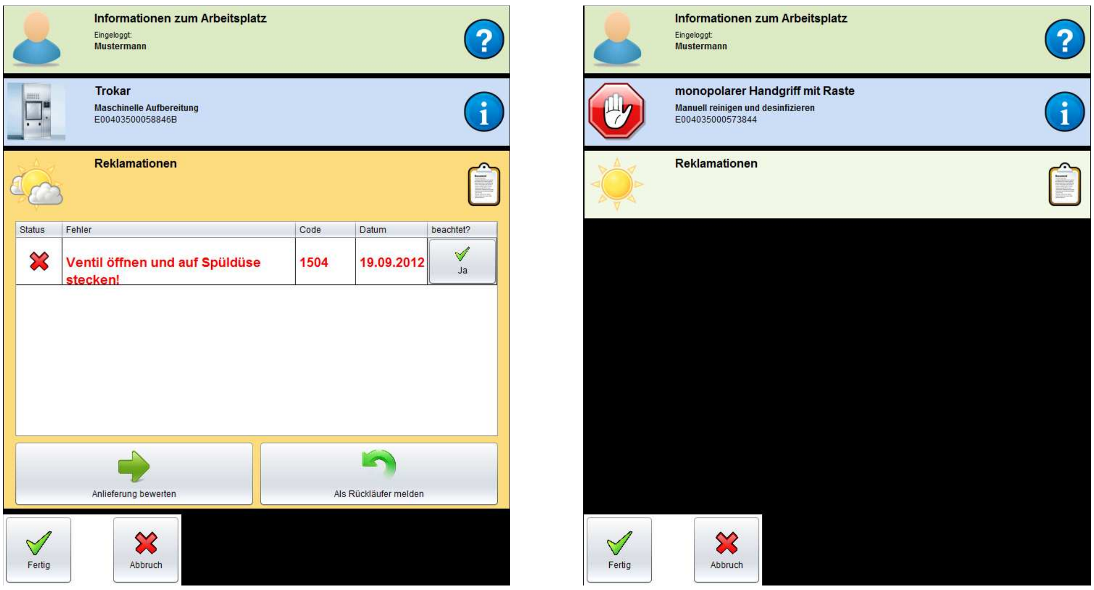


Fig. 7.5: The 'Sliding Panel' UI with a colored icon set. The left image shows that the instrument has to be processed by machine. The UI in right image uses a warning icon to drag the workers attention, that the instrument has to be processed manually.

7.3 Sliding-Panel User Interface: User Study

The assistance system with the sliding-panel UI proposed in Sec. 7.2 was evaluated in a user study concerning the usability, failure avoidance and task completion times. This section covers the evaluation method, results and a discussion.

7.3.1 Method

The study method of Sec. 6.1 was largely reused and slightly adapted for the second user study: The participants worked with medical devices in four experiments. The participants reprocessed the sieves with instruments either with the assistive system (condition 'S') or with instructions provided by paper (condition 'P'). The sieves A and B contained the same instruments of the previous study Sec. 6.1 and the conditions were equally distributed in four task to avoid carry over effects according to Tab. 7.1. Generally, the scenario and tasks were introduced very briefly. The participants were told, that instruments come from the operating room and now have to be prepared for the cleaning and disinfection machine. As in the previous study, the experimenter gave the information about how to use the virtual touches and also showed, how to open the sliding panels. All other information and system functions had to be explored by the participants themselves during the experiments.

The experiment variables measurement was also reused from the first user study. Among others, the failure rate, the completion time as well as the usability related questions were captured. The observed errors were classified into major errors and minor errors as in the first study. The details described in Sec. 6.1 apply here.

However, the previous study method was extended by means of a fifth experiment to examine the new input and annotation capabilities of the system. In this fifth task, each participant had to add instructions for three different instruments and they had to annotate "something that is important" in their own opinion. The participants had to use the setup-integrated camera and the finger-painting feature of the system for this purpose.

Participant	Condtion Exp. 1	Condtion Exp. 2	Condtion Exp. 3	Condtion Exp. 4	Condition Exp. 5
1,5,9,13,17	AP	AP	BS	BS	Add instructions
2,6,10,14,18	AS	AS	BP	BP	Add instructions
3,7,11,15	BP	BP	AS	AS	Add instructions
4,8,12,16	BS	BS	AP	AP	Add instructions

Tab. 7.1: Second user study: experiment conditions for participants. 'A' and 'B' refer to the sieve (set of medical devices) A or B. 'S' and 'P' refer to assistance system or paper guidance. 'Add instructions' refers to the task of instruction input and annotation with the assistance system.

The null-hypotheses $H1_0$ to $H6_0$ from the first user study (Sec. 6.1) were also tested in this second study by reusing the from the first user study. The questionnaire comprises nine usability related questions and ten questions concerning the user's experiences and confidence (Q1 - Q10).

- $H1_0$: There is no difference in total error rate between conditions S and P.
- $H2_0$: There is no difference in completion time between conditions S and P.
- $H3_0$: Participants feel equally confident with the task under condition S and P.
- $H4_0$: Participants equally like the work under condition S and P.
- $H5_0$: Participants do not prefer any condition (S or P) over the other for solving the task.
- $H6_0$: Participants equally rely on the provided instructions under condition S and P.

Although the methods for the evaluation and the instruction data sets were largely reused from the first user study, further adaptations were necessary due to the new UI design and minor issues with experimental setup. The annotation of instructions by finger painting is an additional feature of the sliding-panel UI, that was not available in the first study. To allow the painting by finger, the MouseRobot-component had to be elaborated, to enable the tracking of fingers. The earlier prototype only used hand tracking to realize the virtual-touch interaction.

The working instruction data had to be slightly expanded for the new user interfaces. The sliding panel UI provides new fields such as an listing of all workflow steps for the currently processed instruments. This kind of workflow overview requires short headers for each presented instructions, that had to be added to the original data set of the first user study. Accompanied minor improvements were also slightly changed the instruction data set of the first study, such as typos or removed redundant information. The paper-bound version of the instructions were adapted accordingly.

Participants. The participants group consisted of six men and twelve women. The majority (14) of the participants were students (mostly in social or teaching courses). The minority were university secretaries (3) and a dental assistant (1). Five participants did not specify their study course. The average age of 30 years reflects the high amount of students. All participants are right-handed and their first language is German. The participants answered to have low experience and low emotions about medical instruments as the questionnaire results from Fig. 7.6 show. In average the participants had 'some experience' with computers and used the internet regularly. The participant's average self-assessment on mechanical skills is moderate.

7.3.2 Results

Completion time and error rate. Fig. 7.7 shows the results for the mean error rates for the condition "assistance system (S)" and "paper-bound instructions (P)".

In total, the participants did 3.17 errors less while reprocessing the sieves with guidance from the assistance system in comparison to paper-bound guidance. The average errors for two tasks under condition P is 8.11 and for condition S it is 4.94

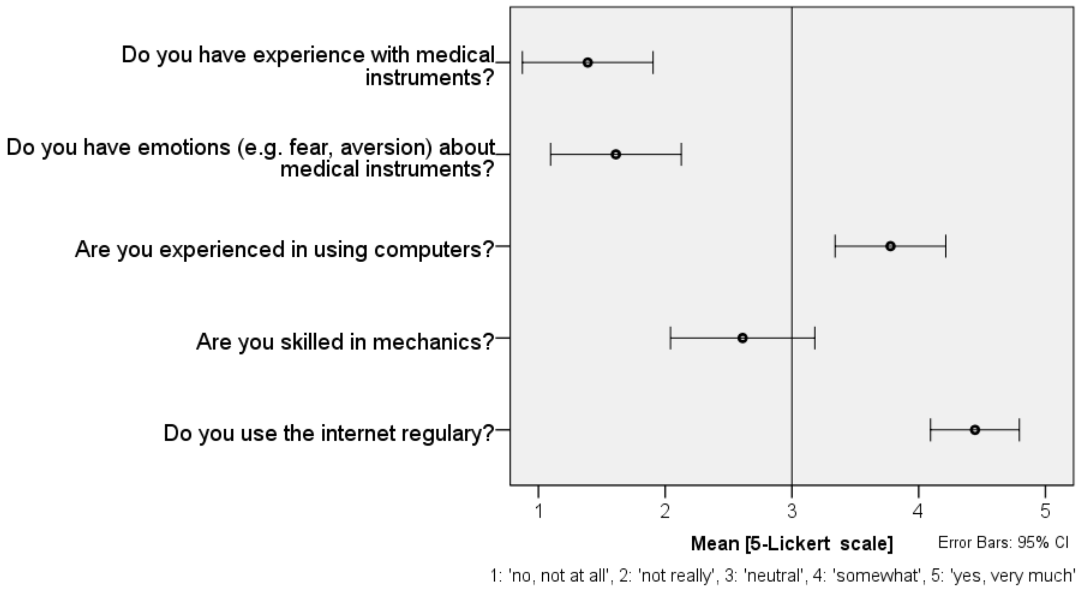


Fig. 7.6: Average participants self-assessment of experiences and skills with relevance for the study tasks.

and the error rate is reduced by 39.08% by the assistance systems while concerning the paper-bound help as ground truth. The participants did 50.74% less major errors while performing the task with the assistance system. The participants did 0.33 more minor errors with the assistance system compared to the paper-bound help.

The observed mean error rates are statistically significant, which was tested with a paired t-test. The 2-tailed significance of the paired t-test amounts to $p < 0.01$ for the overall errors per condition, $p < 0.01$ for the mean of major errors per condition and $p = 0.05$ for the mean of soft errors per condition. With these results, hypothesis $H1_0$ can be rejected. Concerning the paper-bound help as a ground truth, the total error rate is significantly reduced by approx. 39% when the assistance system is used for supporting the task.

The completion time for each condition was measured from the started of reprocessing until the task participants said they are finished. The average completion times for all participants is depicted in Fig. 7.8 and is in average 152.6s higher for the assistance system than the control condition. Concerning the completion time for condition P as ground truth, the participants were 14.42% slower under condition S. But the hypothesis $H2_0$ was statistically tested with a paired t-test which results in a 2-tailed significance of 0.125. Consequently, hypothesis $H2_0$ can not be declined, because the difference for the completion times is statistically not significant.

Usability. Fig. 7.9 shows the questionnaire results for the questions Q1-Q10, which were used to test the hypotheses $H3_0$ to $H6_0$. Except for question Q5, all observed differences are statistically significant[3]. The participants felt significantly more confi-

[3] Q1-Q9 were tested with paired t-test, CI=95%, N=18.

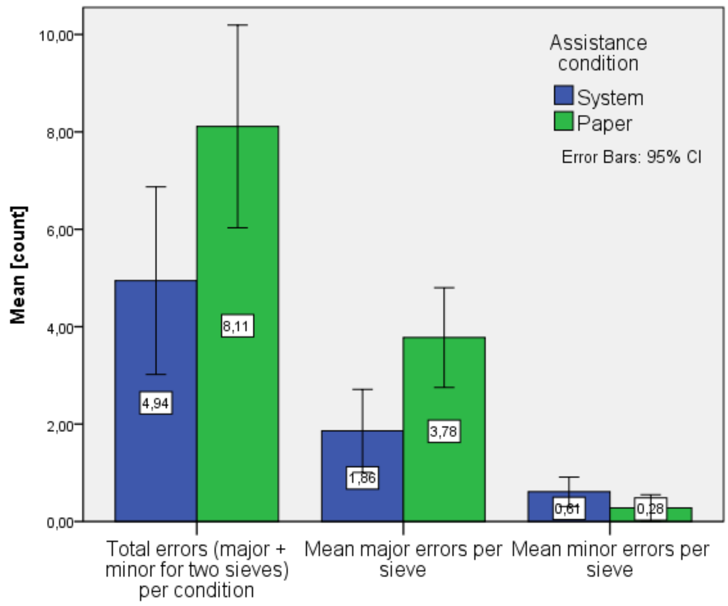


Fig. 7.7: Mean errors after task completion per condition.

dent and better supported by using the system (Q1, Q6) and they could imagine to work in a real hospital rather with the system than with the paper bound help (Q2). They subjectively thought to avoid errors with the system (Q7, Q8) and they experienced less issues during the reporting of reclamations (Q3). The null-hypotheses $H3_0$ is false, as the results of the confidence-related question (Q1, Q2, Q3, Q7, Q8) show. Consequently, the participants feel more confident while working with the assistance system compared to the paper-bound help.

The participants found the task with guidance by the system significantly more pleasant (Q4). Thus hypothesis $H4_0$ is rejected. Working with the system is more pleasant than working with the paper-bound help.

The participants significantly orientated themselves rather to the assistance system than to the paper help (Q9). In combination with the increased assistance sufficiency for the system (Q6), the null-hypothesis $H6_0$ must be rejected. People rely rather on the system's instructions than on the paper-bound version. Information presented by the system is rather regarded than the paper version (Q9). Although the participants referred more to the system provided help than to the paper-bound help, the results for comparing the exact abidance of the instruction (Q5) has no statistical significant difference. The participants' compliance of instructions does not differ between the information provided by the paper aid or the system assistance.

The hypothesis $H5_0$ was tested with "Q10: Which kind of aid would you prefer for the processing of instruments?". The participants answered this question after they had completed task four. They clearly preferred the system over the paper bound version (mean value of 4.56 on the 5-Lickert-scale with '1= Paper and Folder', . . . , '5= Assistance system'). The t-test for Q10 against the neutral element of the Lickert-scale

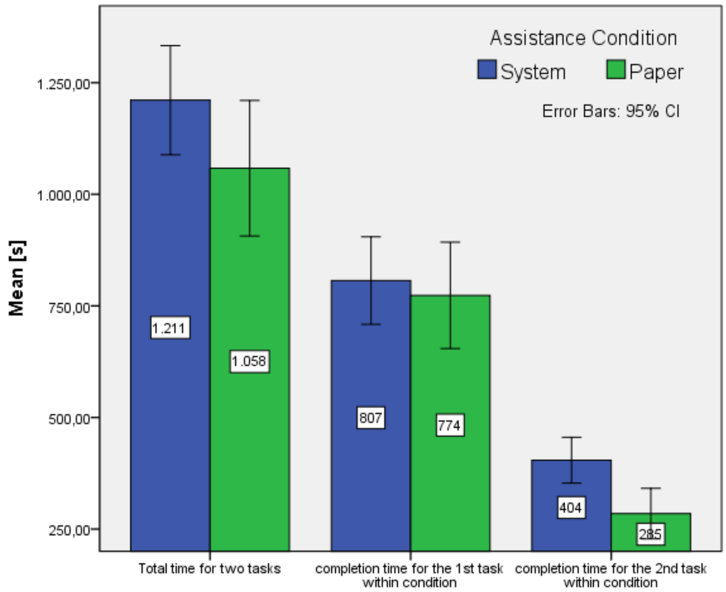


Fig. 7.8: Average participants' completion times.

(null-hypothesis: "neither the paper aid nor the assistance system is preferred for the task") expose a strong statistical significance of $p < .001$.

The usability was measured with the same questions from the first user study. The results are depicted in Fig. 7.10. Summarized, the participants appraised the system a sufficient usability. The UI is reasonable and can be operated without much learning effort. Although, still in the positive scale, the results for flexibility and the operability indicate for potential improvement. Statistical significance was determined with a t-test against the neutral element of the Lickert-scale. As a result from the significance test, the null-hypothesis "The participants answer the neutral element '3' " is rejected for the observed answers of questions U1-U9.

System robustness. The extended finger tracking of the MouseRobot-component resulted in a slightly worse robustness of the UI's buttons. The finger tracking is requires a more complex technical implementation than the hand tracking. This increase of motion tracking complexity decreased the robustness of the virtual-touch interaction. Especially if the user spreads the thumb of his hand but touches control elements with one of the other fingers, the UI-widget is not activated. Thus, participants were sometimes confused, why the system does not react on their intended input. The issue has been fixed after the experiments by elaborating the MouseRobot.

Another issues affect the system latency to user input, due to a minor software bug: if the user performed an action that is associated with function of the workflow engine (such as confirmation of an instrument), than the system reacted reacted with small but recognizable delay. The investigation after the experiments revealed, that all business processes were started twice and therefore all related system internal actions

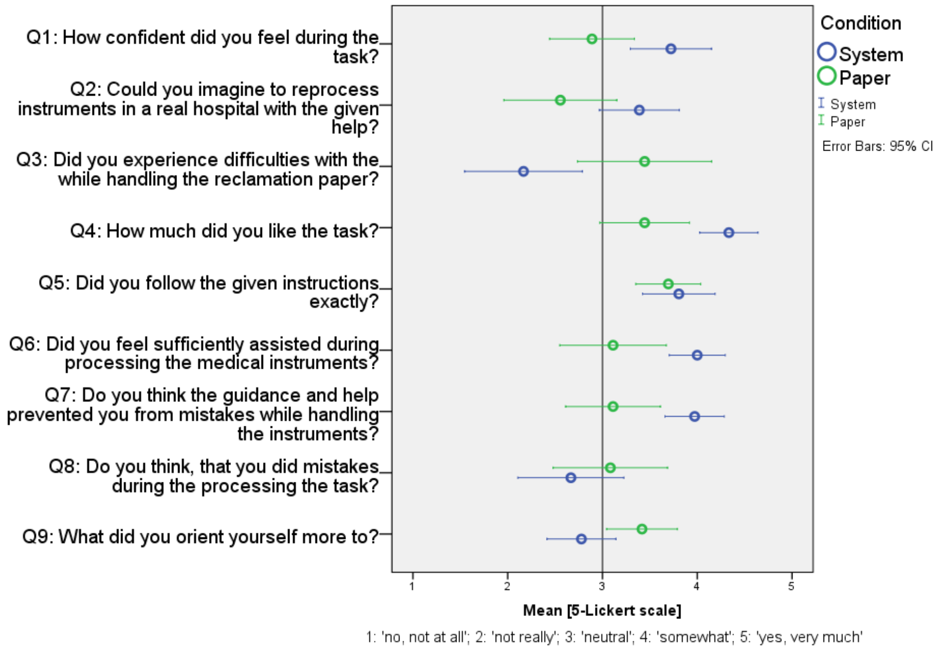


Fig. 7.9: Average questionnaire results for questions regarding confidence.

were performed twice. The issue was fixed after the study and the system's delay distinctly decreased.

Working instruction input. The questionnaire results regarding the fifth experiment are depicted in Fig. 7.11. Question 1 to 5 consider the participants' experience of taking pictures with help of the assistance system. Generally, the participants find the instruction submission at the workplace with the integrated camera useful (question 1). The function is also easy to use (questions 2, 3 and 5). However, participants are not satisfied with the taken pictures (question 4). Question 5 to 10 investigate the participants experiences with the working instruction annotation feature. The annotation feature is rated as usable, easy to use (question 6 and 10) and to easy learn (question 7). But the usage (question 8) and the the results of the annotation procedure (question 9) did not convince the participants.

Fig. 7.12 illustrate typical annotation results. Notably, 17 of the 18 participants tried to paint arrows or circles to highlight important areas on the instruments. Only one participant painted numbers (right image in Fig. 7.12). The annotations are blurred, due to the lag of motion tracking precision. The participants also directly touched the surface with their fingers instead of painting slightly over the surface.

7.3.3 Discussion

The assistance system helped the participants to avoid 38% of the failures, while the completion time slightly increased compared to the paper-bound help. Additionally, the participants appraised a sufficient usability. These findings confirm the system

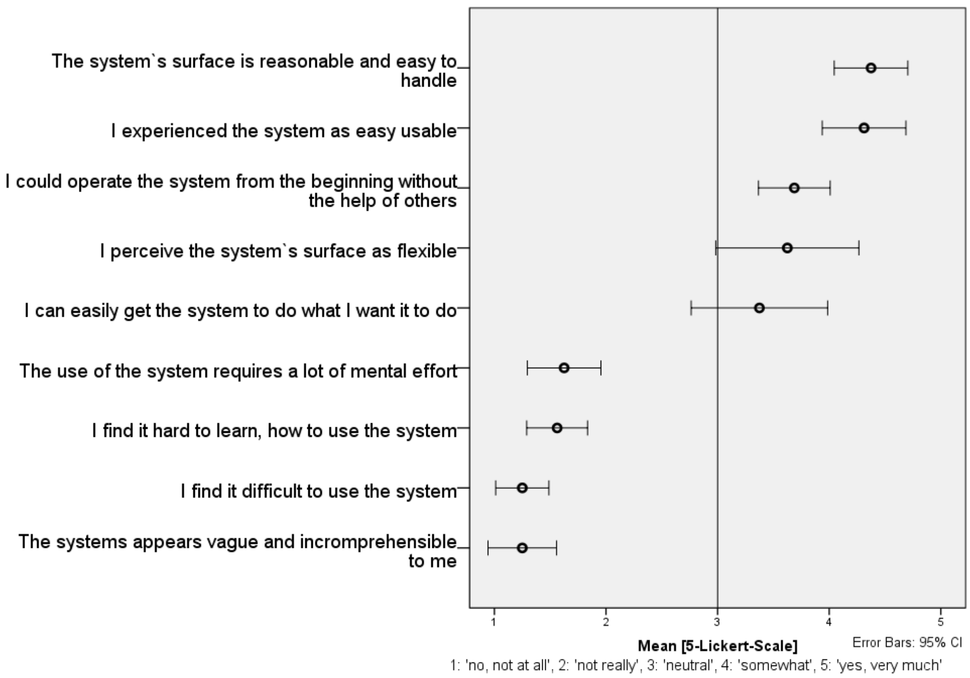


Fig. 7.10: Results of the usability related questionnaire.

concepts in general, but the results are slightly worse compared to the first study. A precondition for the investigation of this issue is to assess the comparability of the two user studies. By looking at the experiments' execution three issues prohibit the direct comparison between the two user studies. First, the participants group of the first study had 8 from 16 people with a professional technical background. In the second study only 2 from 18 participants had a technical profession. Thus, the first study measured the effects of the assistance systems with a technically more competent group. Second, the prototype of the second user study had more functionality. The "adding and annotating instructions" feature as well as the distinction between reclamation of either returns or delivery required more widgets within the Sliding-panel UI. Especially, the doubled options of predefined reclamation tags doubles the possibility of failures for reclamation reporting (regarding the experiment task). Third, the robustness issues delayed and narrowed a smooth interaction with the assistance system. Participants occasionally had to touch widgets twice or even multiple times to activate the widget's function. Thus, the participants of the second user study experienced more issues with the motion tracking as the participants of the first study one. These different presets of the user studies inhibit the direct comparison of the study results.

The participants proposal for improvements mainly regard three topics. First, the quality of the presented working instructions should be optimized. Although this feedback regards the data that the assistance system visualizes, a zooming function provided would be helpful. With a robust motion tracking system, multi-touch gesture could be used for this purpose, as they provide a meanwhile common interaction concept and spare the need of additional control elements within the UI. Second, due to the

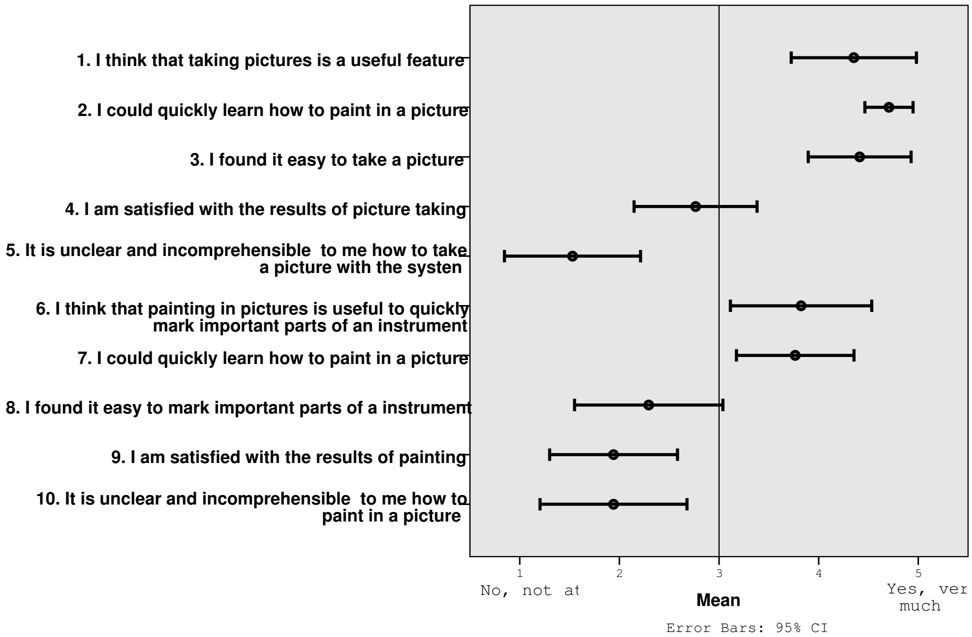


Fig. 7.11: Questionnaire results of the fifth experiment: 'Taking and annotating Pictures'.

issues with the hand-tracking, the participants encouraged a more obvious feedback by the system about the recognized hand and finger positions. Third, often participants did not find the button for playing videos. As a suggestion the button should move from the upper right corner of the instruction panel near to the browsing buttons. Furthermore participants missed the control elements for pausing and fast forwarding a video, which should be added in a next system iteration.

Notably, the reclamation panel were nearly not considered in the improvement suggestions of the participants. Only one participant encouraged a more distinct feedback in case of submitted reclamations. The very small number of improvement suggestions regarding the reclamation panel imply that the reclamation panels worked sufficiently, which was not the case in the first user study.

Generally, the second user study affirms the results of the first user study. The assistance system helps its users to avoid failures while reprocessing medical devices. The participants of two user studies clearly prefer the assistance system for retrieving working instructions over the paper-bound help. The assistance systems allows workers to add instruction and reclamations, which is a new feature which for the unclean area of CSSDs.

Fig. 7.12: Two examples for submitted instructions. The study participants were asked to add instruction or information on the given instrument and mark “something that might be important” in their own opinion. The pictures were taken with a webcam provided by the assistance system. The annotations (red) were added by finger-painting within the table-projected image. The participants often circled parts of the instruments (left image). One participant used numbers to mark the parts of the instruments (right image).

Chapter 8

Qualitative Evaluation: Domain Expert Reviews

The user studies in Chapter 6 and Sec. 7.3 were performed by non-domain experts, because the domain experts could not be acquired to perform a quantitative study with significant results in terms of statistics. For the overall evaluation of the prototype, domain-experts[1] reviews are important to estimate the potential practical impact of the proposed assistance system. Four domain-experts participated in this study. Four CSSD experts assessed the assistive system prototype by answering questions of a semi-structured interview during a presentation of the prototype. This chapter discusses each of the participants feedback.

8.1 Method

The interview started with a short preliminary talk to enlighten the participants about the institute, the project, the goal and procedure of this study and to get information about their qualification. After this general briefing, the interviewer presented the assistance system and started the semi-structured interview. The interview covered questions about the project assumptions, practical relevance of the use case, chosen concepts for human-machine interaction, potential process impacts and other topics.

The demonstration of the system started with the explanation of the system hardware, the interaction concept ('virtual touches') and basic workflow. The system's functionality were introduced step by step, going from the basic use case for retrieving information, over adding reclamations and adding new data, up to the proposal of the business process models. After the demonstration, the participants were asked to try the system themselves, while answering questions about applicability and practical relevance of the system.

[1] Domain-expert: executive function in the CSSD or in CSSD related research and development

8.2 Results: Participants 1 and 2

The feedback of two CSSD practitioners on the demonstration of the assistance is presented in the following. Both experts participated as the demonstration and the interview as group of two.

8.2.1 Participants' qualification

The CSSD department head and the deputy department head of a hospital in Bielefeld, Germany reviewed the system. The department head has 13 years experience in reprocessing medical instruments and has completed the TSA courses I, II and III. The deputy head has 3.5 years practical experience in reprocessing medical devices and had worked as an technical surgery assistant for several years before he changed to the CSSD. He has completed the TSA courses I and II. In the following, the deputy Head will be referred as 'P2' and the CSSD head will be referenced as 'P1'.

Their CSSD is not certified and a certification is not planned so far, because there is no reprocessing for external customers and medical devices of category 'critical C' are not reprocessed.

8.2.2 Results

During the preliminary talk, the basic assumptions of the project were presented, such as the non-applicability of HMDs, RFID and assistance for the unclean area. During the introduction the experts confirmed, that there is a trend of tagging instruments via RFID for process documentation, but they also stated that RFID is very cost-intense at the moment and therefore not used in CSSD "broadband application".

The results of the interview during the demonstration of the system are thematically given in the following.

Project assumptions. As described in Chapter 2 the main use case for this system is the unclean area of a CSSD, because there EDP-systems are not used here, due to hygiene restrictions. The experts confirmed this assumption and said, the have a computer at the unclean area, but it is not used, because it's mouse and keyboard is covered by foil and therefore poorly to use.

The interviewer questioned, what are the typical and frequent failures at the unclean area. P1 answered, that most failures occur in the operating room and that small, spiky and sharp instruments are most dangerous for the CSSD worker, if they are loaded wrongly on the sieve. Also, defect instruments from the operating room occur often and must be documented.

Interaction modalities. The prototypical interaction of virtual touches were introduced in the first place. During the interview the participants tested the interaction themselves and concluded, that the type of interaction needs to get used to, but that it is overall usable. The experts discussed that the ergonomics of the system could be improved. For P2 the UI was too big, while P1 liked the size of the UI. Both could imagine, that the UI could be projected on a flexible “wall-mounted board” or projection on the wall. Both suggested, that the location of the projection could be a feature in user-depended UI personalization.

Both missed sound as an output modality. In their opinion sound could help to draw workers attention, especially in case of critical messages, even despite the loud and noisy environment. Additionally soft blinking UI-elements should occur during critical messages.

Granularity of the data presentation. A first question by P2 was how the systems deals with several instruments at the same time. As a short discussion result, the system should be able to deal with set of instruments, such as sieves. Expert P1 agreed and said that especially in case of basic sieves (“which most workers can process blindfolded”) the presented data and reclamations should refer to the whole sieve and not only to each single instrument. The time effort for scanning each simple instruments would be too high. Both experts did not contradict the three parts of data representation: workspace specific data (“workspace panel”), instruction data and reclamation data.

Data injection and annotations. The interviewer asked the experts, how they do find the feature for adding and annotating data after its demonstration. P1 excited “grandiose” and supplemented that the “[...] fastness is important for this task and here it is really good”. He further explained, how this is actually done in the daily work: After a call from the worker, he catches a camera, goes to the working place (through the hygiene lock), take the pictures, go back to the office, opens the software, navigates to the right instrument, connects the camera to the PC, uploads the images and maybe adds a description. This procedure takes about ten minutes for a single failure report or instruction taking and with the assistance system this is in done in thirty seconds. P1 concluded: “The data input and data maintenance are currently very time expensive and the proposed systems deals with this key point in a very good manner.”

P2 would prefer small symbols that could be dragged and dropped for the annotation of images instead of using the finger to paint. Both, P1 and P2 said, that the feature of recording and annotating pictures, should also be available for reclamations.

Business process models and communications with customers. The business process models were introduced after the input of instructions were shown. P1 could imagine, that the proposed feature of using business process models to achieve a valid data pool, to organize and automate communication and documentation could be used in practice as shown with the prototype. The interviewer asked, if they could imagine to use a domain specific tool for modeling their own CSSD processes. P1 clearly stated, that a domain-specific modeler would be a great help, for example to automatically send emails in case of specific mistakes.

Another discussion was about the user management and permission levels. Permission levels reference to the ability for changing process relevant data. With the lowest permission level, a worker can only view instructions, with the highest he or she can change process definitions. In P1's and P2's opinion, the permissions should not restrict the work at the unclean area of a CSSD: any worker should be able to do the work, even if he or she has no permission or qualification to do specific tasks. Permission levels should only restrict the access to reclamation and instruction input features.

Additionally, the interviewer asked the CSSD administrative, if the system should suggest worker permissions on its own. For instance, if a worker reprocessed a sieve several times successfully, than the system promotes the worker to a higher permission level. The experts reacted restrainedly. The statistics on how well worker perform should only be accessible for the CSSD administrative, to avoid a "reprocessing competition". The system's suggestions for users' permission levels must be acknowledged or declined by the CSSD heads.

An interesting point arose during this discussion. Currently, the process documentation covers only mistakes and failures for each worker. It reveals how badly a worker performs his or her tasks and neglects good performance by the workers. With the assistance system, the reclamation history can not only be used to warn in case of issues with a specific instrument, it can also generate positive statistics. For example, if a worker performs very well, than the systems informs the head. The head now has an objective tool, which he or she can use to laud the worker. This would probably lead to high motivation and improved working morale. As an outlook, the CSSD administrative can configure and define "lauding suggestions in case of good work" as a feature within the business models. P1 and P2 appraised this as a desired feature.

Context sensitive interface. The context-sensitiveness of the UI was appreciated by the experts. The reclamation history of the currently processed instruments determines the UI appearance. The experts stated that they want to be in control of the classification of reclamation history. A configuration for the rating of reclamation history is a desired feature (which the system already provides by customizing the business process models).

The experts would like to have the possibility to define the relation between reclamations and UI's obstructiveness themselves. They could imagine to use a software tool with a graphical notation of the process and the system's behavior for this purpose.

Applicability and additional features. The experts clearly stated, that they and the CSSD worker would use such a system. They lauded the fastness of interaction and the features of adding reclamations to specific instruments. The UI with the three panels for data separation (workplace information, instruction, reclamations) was honored by the experts. They also liked the concept of defining graphical process models to orchestrate tasks between workers, systems and management and could imagine to use a dedicated tool for that purpose.

The experts motivated some features in the system. First, photos and annotation should be possible for reclamations to document issues more clearly. Second, a weight control should be integrated as a sieve testing utility for detecting missing instruments or too heavy loading. Third, sound output should be integrated for better attracting workers' attention.

Additional features. Asked for missing features, P1 and P2 missed instruction for instrument containers. The system should be extended to provide working instructions on a set of instruments and single instruments as well. Further adding photos and annotations should also be available for reclamations. P1 suggested warning sounds to drag the workers attention, but P2 disagreed on this point, because “to much sound can make the loud environment even more annoying”.

8.3 Results: Participant 3

The third participant of the CSSD domain expert study is referenced as P3 in the following.

8.3.1 Participants’ qualification.

P3 works as a head of a CSSD since 2008 has the TSA I, II and III qualification. P3 also teaches operating room technicians for qualification and train people for the TSA I qualification. Together with her background of a qualified operating room technician and qualified nurse, P3 is an expert for the CSSD domain. Thus, P3’s feedback is valuable for evaluation of the practical relevance of the assistance system’s prototype and is presented in the following.

8.3.2 Results

After a preliminary talk, P3 saw a demonstration of the protoype and discussed the presented concepts with the interviewer. In total the interview lasted two hours and 15 minutes.

Project assumptions. P3 was asked for typical problem cases at the unclean area of a CSSD. She mentioned incidents, where three workers cut themselves by processing sieves, that were not properly disposed by the operating room. Often instruments were not or not properly disassembled before cleaning and disinfection by machine. Reminders or instructions would help at this place. P3 continued, sometimes instruments are missing in the containers delivered by the operating room. Although, the CSSD software provides a powerful tool for the CSSD it does not show sieves packing lists at the unclean area. The worker can thus not control if the operating room delivered all instruments of a set.

The interviewer asked P3 for the documentation and reclamation handling at the unclean area. P3 said, currently there is no documentation of manual work at the unclean area. In case of defect instruments, the operating room marks the instrument and attaches a ’PostIt’-paper onto the instrument’s container with information about the issue. This instrument accompanying note goes through the unclean area and is handled at the clean area. According to P3 failures, incidents or issues at the unclean area are currently not documented and a failure statistic does not exist.

Instructions presentation and input. The interviewer asked P3 what instruction could be useful at the unclean area. P3 answered, “often, it would even help to get the instrument’s item number, the exact name and an picture showing how to disassemble the instrument”. P3 liked the instruction presentation for instruments and motivated, that the instruction presentation should be referenced not only to single instruments but also for sets of instruments. Especially in case of ’system-sieves’ it would be useful to get information about the sieve at a whole and to have the option for retrieving detailed information on a specific instruments within the system-sieve.

P3 liked the system function of adding new instructions by pictures and the option to annotate the instruction via finger-painting. P3 supplemented: “This would decrease the time effort for data maintenance. [. . .] The annotations could be useful for sieves with many instruments. One can not always know every thing in advance. P3 said the annotating feature could be improved, by using pre-designed graphical elements, such as arrows or circles, which could be applied per drag on drop to the photo. P3 also missed the function for text input. But P3 also mentioned, that text input could inhibit workers with less language skills to submit instructions or reclamations.

The interviewer touched upon auditory displays and speech recognition. In P3’s opinion, this is no option for real world application. For using speech recognition, every worker must be able to speak German fluently, which is often not the case. A sound output of the assistance system would also be a problem for the worker, because it would be another source of noise emission. P3 further said, workers in the department had work-related health problems, such as sleep disturbances due to the noise at the unclean area. Thus, hearing protectors were introduced and further noise sources should be avoided.

Reclamation presentation and input. Regarding the reclamation panel, P3 appraised the input of reclamations: “the possibility to assess of the instruments’ delivery with predefined tags is practically relevant and would surely be used by the workers”. The “relative simple and almost self-explanatory” way of reclamation input makes the assessment of the delivery very easy. P3 continued this function should linked with the exposer at the operating room to provide direct feedback of the disposal.

P3 emphasized reclamations should summarized for a container of instruments and should be printable. She continued, that the person who made a mistake should not be visible by the system. Only the CSSD administration should have access to a statistics that allow to derive information on how well a single worker performs. P3 pointed out generally, that a human-human communication in case of repeating human errors is preferable over an automated human-machine communications, such as the automated sent emails with the system. P3 liked the idea, that only the CSSD responsible gets an email from the assistance system in case a human worker performs bad over a given time period. But P3 emphasized that the system’s ability of processing a human-related failure statistic requires sensitive consideration because of ethically and labour law issues.

UI design and context awareness. The interviewer asked P3 about the interface design and structure. P3 said “The surface is really user-friendly, you can not tell otherwise" and P3 continued: "The structure is pretty convenient, it is also big enough, it should remain in the size."

But P3 also criticized the UI for the icon set and the chosen colors. The icon-set is not self-explanatory in P3's opinion and the changing background color of the reclamation depending on the instruments criticality could lead to a stimulus satiation. P3 advised to keep the interface color-less and to use "as many as necessary, as less as possible" UI-elements. Information with photos and text is sufficient.

P3 suggested further improvements regarding the ergonomics of the display. The projection should be lifted at the top to provide a more convenient view angle. The UI size should adapt to the user's height, e.g. the UI 'shrinks' for small users, which makes UI widgets easily reachable.

The interviewer questioned if the system would be used by the workers. P3 answered: "Our workers would definitely test and use the system. How well it proves itself in practice, is the second thing. We are quite demanding."

Additional features. P3 mentioned additional features, which the system should provide. The system should not only deal with single instruments, but with sets of instruments as well. P3 would prefer an interface without colors and with a more consistent icon set.

Existing medical device vendor catalogs should be directly integrated to provide a information foundation. The presentation surface should be slightly lifted and adapt to the worker's height. The integration of a automated weight scale would be helpful to detect material leakage.

Participant's conclusion. At the end of the demonstration and interview, P4 was asked for a short summary. The gist of what P3 answered is: "I find it exciting as development continues and what ideas and possibilities exist, to make the work easier for the employee, which is ever desirable. The basis exists. The system is a prototype but this allows refinement. The refinement should be done with CSSD practitioners. The features of the system are very appealing. I would wish, that we could test it. And I would welcome, if the system can be combined with our existing software."

8.4 Results: Participant 4

8.4.1 Participants' qualification.

The third participant works as a regularity affairs manager in a larger company that produces cleaning and disinfection among others. He accompanied the development of CSSD related products for several years and has more than twenty years experience in the CSSD. The participant is referenced as P4 in the following.

8.4.2 Results

The results of one and a half and an hour lasting system presentation and interview are presented in the following.

Project assumptions. P4 confirmed the project assumptions: in his opinion, the unclean area of today's CSSD is insufficiently supported by interaction technology. He estimated that less than 50% of hospitals document the instruments at the unclean area. Even less hospitals document reclamations in systematically or maintain a failure statistics.

Usability and virtual touches. P4 tested and explored the UI and the virtual touch. He praised the system a good operability ("The system is easy to use and that interface is well structured"). At the end of the interview P4 further explained: "The touch-less interaction is the right approach. It is very conceivable for the unclean area."

Instruction and reclamation input. The interviewer asked P4 about the relevance of the instruction and reclamation input function for the practical work within a CSSD. P4 explained, although these functions are very useful, their correctness must be ensured, especially in case of instruction submission. The instructions must regard the hygiene and the medical devices' vendor manuals. The interviewer explained the definition and coordination of responsibilities by business process models. P4 captured the idea and told that the feature is necessary and a good option to set up valid reprocessing instructions. He had the idea of constraining the input features depending on the user's level qualifications: For example, the CSSD head can add and change instructions directly at the table, while an inexperienced worker can only make suggestions for instruction changes. Furthermore, the assistance system should be available at the clean area as well, to provide a consistent way of reclamation management.

Workflow transparency. Questioned for the transparency of workflow descriptions in today's CSSDs, P4 answered that transparency of workflows and working instruction must increase. Procedure and working instructions must be as transparent as possible to ensure the proper reprocessing of medical devices. The process models of the assistance system could clearly help here to see and documented responsibilities and procedures. P4 continued, the assistance system would thus probably facilitate the certification process of hospitals.

Granularity of the data presentation. In P4 opinion the granularity of the presented instructions should vary depending on the complexity of instruments. Often a short description for a whole sieve is sufficient, especially in case of standard sieves. In case of more complex instrument sets, the instructions for difficult single instruments should be available. Thus, instructions should be available on the single instrument level and on the container of instruments level as well.

Applicability and additional features. P4 attested the assistance system the applicability in the real world CSSD. The virtual touches are a valid input method for the wet area. The reclamation and instruction input capabilities provide a feasible way to support the quality standards. The implementation of flexible checkpoints and interaction dialogs is reasonable. Although they would slightly delay the process, such confirmation dialogs will lead to a more valid decontamination cycle.

In P4's opinion, the system will help the worker to prevent from failures. Further he concerned the future development of such a system and its certification. Based on the current legislation, the medical system is not a medical device product and thus it is not government by the medical device obligation. He further explained, that the MPG will probably change in near future and that the documentation software within the CSSD will be concerned as a medical device. As a result the development process and the assistance system must fulfill strict requirements and he mentioned the IEC 62304 "Medical device software - software life cycle processes" [132] where these requirements for medical device software are defined.

P4 mentioned: "It would be nice to interface existing CSSD such as EuroSDS or Instacount, but a complete new system based on the assistance system is also conceivable and probably reasonable. However, it is a question of development effort."

Participant's conclusion. P4 answered the question for a short summary of what he has seen during the demonstration as follows: "That is a good approach with practical relevance for the CSSD. The system's approach should be pursued because it helps to prevent failure and it helps to practice quality assurance."

8.5 Summary and Discussion

The feedback from the CSSD domain experts is quite encouraging. All participants confirmed the results of the domain analysis and its resulting use case of supporting workers at the unclean area with instructions and reclamation documentation. All participants attests the system to help workers avoiding failures. Furthermore, all participants recommend the further development of the prototype towards a fully functional assistance system. The refinement of the prototype and a field test within a real CSSD should be the next step.

According to the experts feedback, future version should provide information on the container and on single instruments. The UI were generally perceived as well-structured and usable. The context-aware UI offers a practically relevant reminder function for critical handling steps and is thus very desirable. The renunciation of auditory display and speech recognition was acknowledged by three of four participants.

The results show further, that the system could unfold its full potential if it is installed not only at the unclean area, but also at the operating room and the clean area. The consistent way of dealing with reclamation and instructions provided by the system enables the work.

The handling of potential person-related failure statistics is a very delicate topic and requires careful consideration. An ethic question arises here: which has higher priority? The employee's rights for privacy or the quality of medical device reprocessing and its implications on patients' health. The question can not be answered in this thesis, but maybe there are ways to avoid this weighing by restricting the access to failure statistics.

Chapter 9

Approaching Productive Environments: Industrial Use Cases

The evaluation of the assistance showed encouraging results for the CSSD domain. The component-based software architecture allows to transfer the assistance system to other use cases by changing the process models and configuration files. This chapter discusses how well the assistance system can be transferred to other domains such as industrial assembly or domestic appliances. Four projects are proposed in the following section which utilize the assistance system architecture.

9.1 ProMiMo: Process-aware worker assistance for manual assembly

The assistance system was adapted for the assembly of gear motors and was presented at the Hannover Fair 2014 under the name ProMiMo[1]: process-aware worker assistance for manual assembly. The ProMiMo-system comes with two use cases for the illustration of process aware assistance and quality assurance.

Assembly assistance. The assembly of the gear motor requires the worker to assemble different machine parts such as axis and cog wheels to the motor frame. The parts of the gear motor are carried in a box to the working place. The gear motors can be assembled in many variations regarding different transmissions or axis mounting. The structure of working instructions for the assembly of these gear motor are similar to the processing of medical devices: for each motor assembly the worker must proceed a series of operation on the workpiece. The use case for the industrial scenario is similar to the CSSD domain as well: The worker starts the assembly by scanning

[1] ProMiMo is the abbreviation for German term "Prozessintegrierte Mitarbeiterunterstützung in der Montage".

an RFID-tag, that is attached to the motor frame or its carrying box. The assistance system provides working instruction and allows the worker to add quality relevant data such as instructions or reclamations. The similarity of the use cases allows to reuse much of the CSSD assistance system, like the InfoStruct data type, process models and the UI. For the reuse of the UI the text of UI-elements such as labels must be slightly adapted (e.g. instrument - work piece). The component based approach and its separation of coordination, communication, configuration and computation comes handy here: the UI component allows to adjust the UI label texts by changing a configuration file. Thus, the assistance UI was easily adapted for the new domain. Furthermore, a localization was implemented to make the UI available in different languages (german and english were implemented). The localization of the interface supports migrant workers, who do not speak the native language. The adapted interface is depicted in Fig. 9.1. The process model setting the UI's obtrusiveness depending on the reclamation history was also reused from the CSSD assistance system. Notably, the features for adding and annotating instructions and submitting reclamations are also accessible for the industrial use case. To summarize, the CSSD assistance system was transfered to a industrial assembly use case with low effort: only the instruction sets and the UI-labeling had to be changed, which is the result of the careful separation of concerns within the modular system architecture and the capability of the data type InfoStruct to describe working instructions in a generic way.

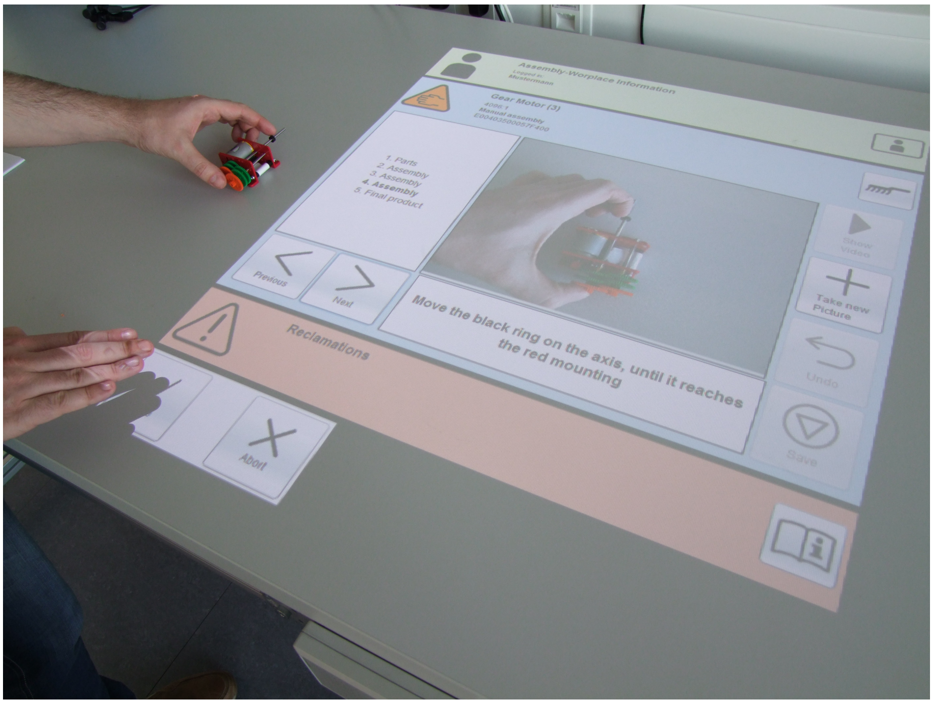


Fig. 9.1: The ProMiMo system supports the assembly of gear motors. The user interface was reused from the CSSD assistance system.

Quality assurance. The transferability from hospital's CSSD to industry's manual assembly workplace was also tested by the implementation of a quality control workplace with the assistance system. Fig. 9.2 shows the workflow for quality assurance of the assembled gear motor in order to document the quality of the processed work piece. The process model defines that the worker has to perform two tests in coordination with the assistance system: First, he has to document a safety critical feature of the product (Fig. 9.3.1): For example the black stopper ring must be mounted on the axis. If it is not assembled, than the gear motor can break in the customers end product during use. To avoid liability issues, the correct mounting of the black ring must be documented during the assembly of the gear box. Thus, the process model asks the worker to make a picture of assembled product. The second quality measurement depicted in Fig. 9.3.2 asks the worker to measure the motor's characteristic curve. This is a functional test and a indicator for the friction of the gear box: the less power the motor consumes, the less friction the gear runs with. After the motor current measurement the process models generates a quality report for the work pieces. The quality report is automatically communicated to interested people, which is the customer in this case. The quality report is send via email. Of course, instead the customer, a quality management officer can be informed – The process designer decides.

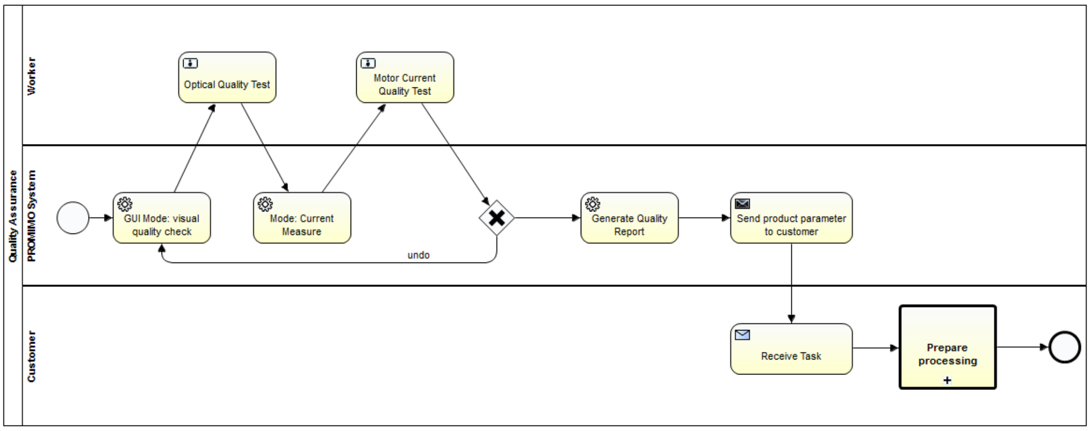
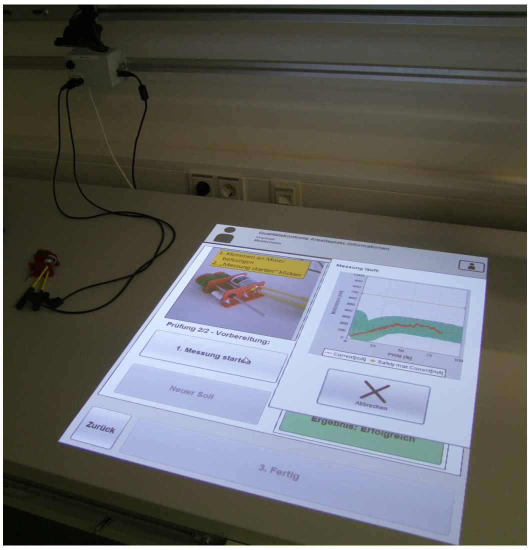


Fig. 9.2: ProMiMo: Quality assurance process model. The worker has to make a picture of the work piece and to perform a motor current test with the help of the assistance system. The process model coordinates two new subsystems: the QualityAssuranceUI and the MotorTester. After the worker tested the device, the process model induces the generation of a quality report and the propagation by email.

This use case was chosen to test the expandability and scalability of the assistance system architecture because four new components or features must be integrated. First, a new UI is desirable to guide the worker through the quality tests. Second, a hardware device is required to measure the motor current. Third, the test results are documented in a file using the PDF-document standard. Thus, a service component is necessary, that builds the PDF document depicted in Fig. 9.4. Fourth, a email client must be integrated to communicate the quality report in a common way. These four components were implemented analogue to the other subsystems as described in Chapter 5.

The system structure and especially its separation of concerns regarding coordination, computation, configuration and communication facilitated the development of these components, because the component developer uses the existing architectural patterns, instead of developing new ones.

9.3.1: First test: The quality assurance UI prompts the worker to take a picture of the workpiece for the quality documentation.



9.3.2: Second test: After the worker attached the wires of the motor tester to the workpiece, the system measures the motor current.

Fig. 9.3: The quality assurance UI of the ProMiMo system provides features to assist the worker in testing the product: First, the correct assembly of a safety critical workpiece is documented by taking a picture. Second, the motor current curve is measured.

Hannover Fair 2014. The ProMiMo system with the two example use cases was presented live to industrial professionals at the Hannover Fair 2014 as part of the 'it's OWL'-booth. The Hannover Fair is the world's leading trade fair for industrial technology. During the five day exhibition of the ProMiMo system many booth visitor saw a demonstration of the two use cases discussed above. Typical backgrounds of the booth visitors were for example supply chain managers, assembly line managers or teachers. The visitors liked the persuasion of the assembly process by the assistance system and the process engine. Especially the demonstration of the quality assurance use case was well received, as it shows the flexibility and the automated process documentation of the ProMiMo system. The feedback confirmed that the involvement of supporting activities and the feedback from the working places are very important for the practical application. Both points are addressed by the assistance system: Supporting activities can be regarded within the process models and the open interfaces of the ProMiMo system and the Activiti process engine as well. The feedback from the worker is achieved with the fast and simple input method for reclamations and instruc-

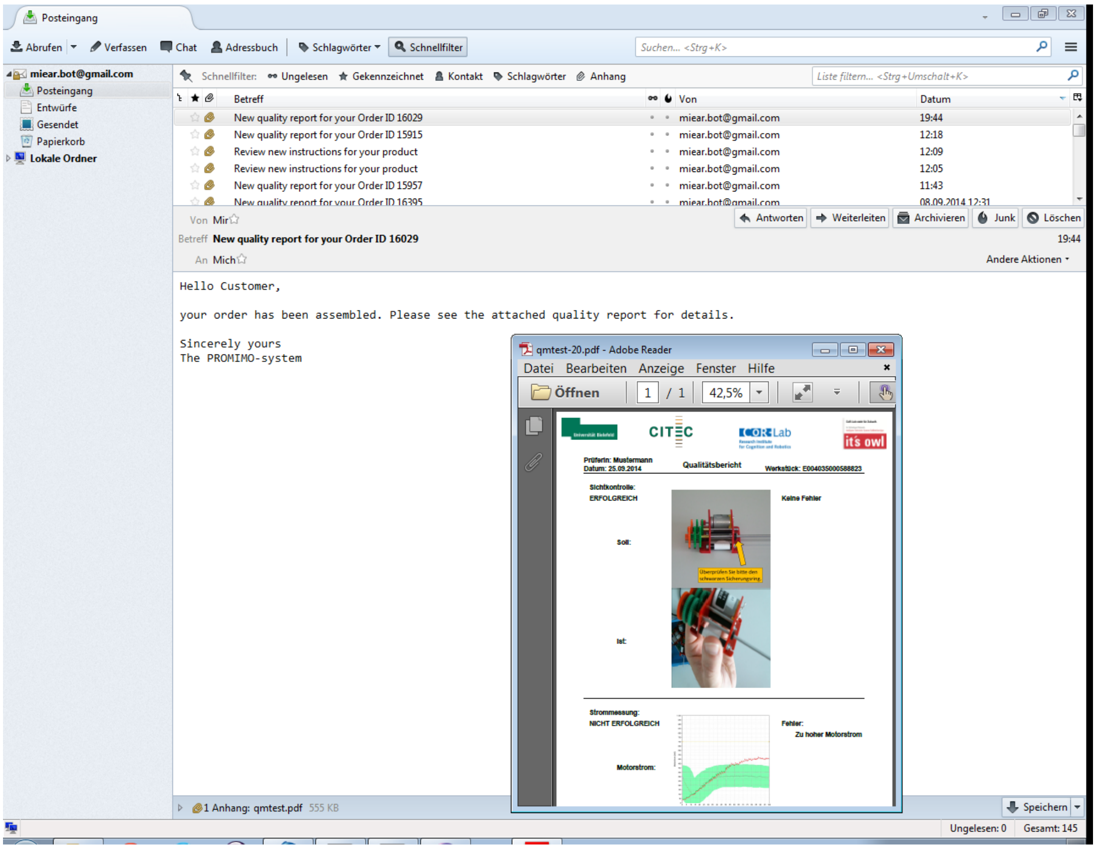


Fig. 9.4: ProMiMo: a quality report documents the two tests, that the worker applied to the work piece.

tions. The combination of getting input and coordinating system functions via process models plus the flexibility of the system were the major points that were praised by the booth visitors with professional background in manufacturing. Additionally, the system worked very stable during the five days demonstration marathon and no system crash or major issue occurred.

The feedback also brought criticism which can be summarized by three points. First, the virtual touches worked sufficiently to demonstrate the system, but the visitors argued, that the virtual touch mechanism will not be robust enough for real world application. Instead, existing interaction devices such as touch screens are preferable for industrial use cases. Notably, the hygiene requirement from the unclean area of the CSSD does not exist at standard assembly work places. However, per design the system has a very loose coupling to the virtual touch software component due to the MouseRobot-component such that using other (standard) input devices is easy and can also be done in parallel.

Second, costs of the assistance system and the required hardware is a major concern. Some visitors argued that it is often more expensive to install and maintain such a system, than outsourcing the manual production towards a low-pay country. However, not all processes can be outsourced. Especially procedures and workflows can contain procedure expertise, which is a pillar of a firms competitiveness. If this knowledge is outsourced, the firm puts one pillar of competitiveness to the risk of pirate copy. Furthermore, processes with a local or constrained supply chain (e.g. CSSD) can not be outsourced. The booth visitor agreed that the ProMiMo system still provides a good option for supporting these processes, as it provides quality assurance at the process and the working level.

Third, for real world application the assistance system must be able to communicate with existing software in a firms infrastructure. For example, the firms logistics or storage management software could be connected with the assistance system to ensure a consistently flow of parts and assemblies at the assembly workplace. The IT landscape in production ranges widely. Due the individual sets of IT software within industry, often custom build interfaces must be developed in order to integrate another IT tool such the assistance system. However, the ProMiMo architecture provides open Java interfaces, notably to the use of the framework Activiti, which comes with many standard interfaces for data bindings. The integration of the ProMiMo system within an existing IT landscape is thus possible in principle. Notably, instead of integrating the assistance system into the IT landscape of a firm, it is also conceivable to use the assistance systems process model coordination engine to coordinate and integrate the different existing IT tools into the system. However, this discussion goes beyond the scope of this thesis.

Generally, the Hannover Fair showed, that the concepts and ideas of the ProMiMo system are very interesting for the industry. Especially the holistic approach of the assistance system found the industrial professionals' approval. The resulting relevance of the ProMiMo system is also emphasized by the it's OWL transfer project discussed in the following section.

9.2 Outlook: it's OWL transfer-project ProMiMo

The transfer and application of the ProMiMo system for a real world manufacturing scenario is planned in the it's OWL tansfer project "it's OWL ProMiMo"[2].

In cooperation between the CoR-Lab at Bielefeld University and Steute Schaltgeräte GmbH & Co. KG the project pursues to adapt, apply and evaluate the ProMiMo-system within a real world industrial scenario. Fig. 9.5 shows the today's workplace where foot-operated control device for medical applications are manufactured, which is to be extended with the ProMiMo system. The foot-operated control devices are used for operating medical devices, e.g. lasers during eye surgeries. The quality standard for the foot-operated control is thus very high and especially safety critical parts such as stopper and safety mechanics must be guaranteed. On the other hand the foot-operated control device consists of 184 parts and the assembly of one device lasts approximately

[2]"it's OWL" stands for Intelligent Technical Systems OstWestfalenLippe and is an network of 174 businesses, universities and other partners, and can be briefly described as per [133]: "Named as a Leading-Edge Cluster by the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF), it [the technology network] is involved in 46 research projects to develop intelligent technical systems and make Industry 4.0 a reality."

three hours. The expected major advantage of utilizing the ProMiMo system are fault prevention, quality assurance and documentation. Failures are expected to be avoided by dragging the workers attention to critical operations during assembly. Quality assurance and documentation is subject of guiding the worker through assisted testing procedures. The project is currently work in progress and thus no results are available yet. However, Fig. 9.6 illustrates the use and how the ProMiMo could support the assembly of the foot-operated control device.

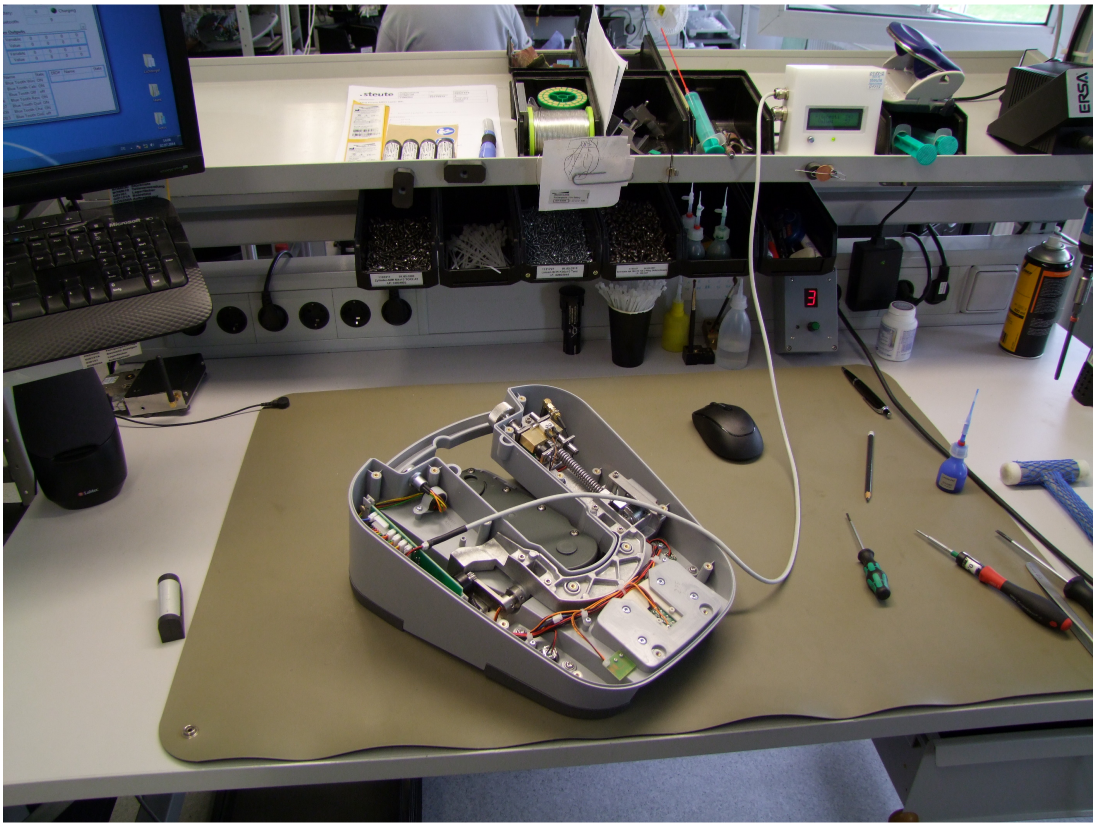


Fig. 9.5: Assembly workplace for a foot-operated control device. The workplace provides hand tools, a computer and hardware devices for programming and testing the electronics of the work piece. The assemblies storage is located behind the worker (not depicted).

9.3 Student Projects

The assistance system approach was also successfully applied in two student projects described in this section. The student projects took part within the computer science course “intelligent systems lab” which is a one year course module within the M. Sc. program ’Intelligent Systems’ at the Faculty of Technology at Bielefeld university. The first project “Handicapped Worker Guidance (HWGUIDE)” examined the portability of the assistance system towards a commissioning task during one semester. The second

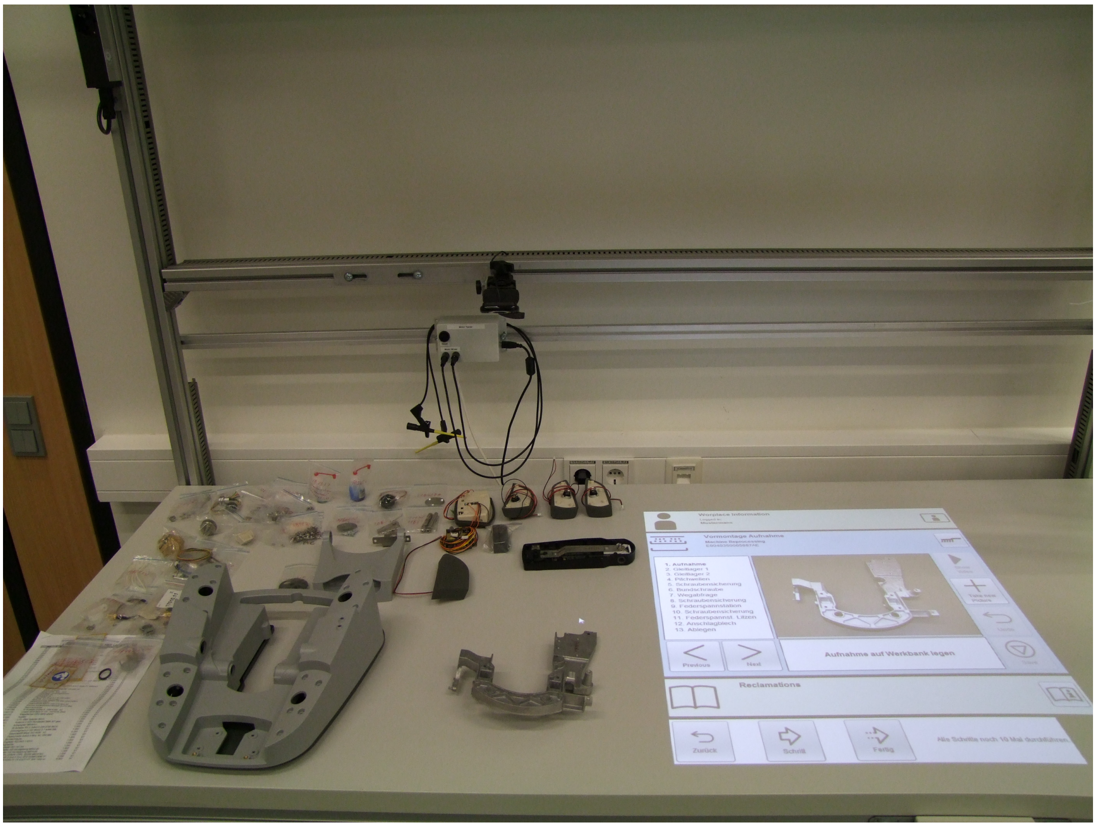


Fig. 9.6: The depicted prototypical setup, illustrates the application of the ProMiMo system for the assembly of a foot-operated control device (work in progress, hand tools are missing).

project “Cooking with a Robot (CWAR) – The cognitive kitchen net” prototyped a cooking assistance and lasted two semesters. In each project three master candidate students worked practically to gain project experience and to improve related skills.

HWGUIDE. The idea behind HWGUIDE is to guide handicapped workers in sheltered workshops during commissioning of orders. The exemplary use case foresees to support a handicapped worker with the workplace organization and to control the correctness of the compiled order. The compilation of an order requires the worker to place boxes with the different products or parts onto the workplace as well as to pick the correct number of products or parts from these boxes and to place these items into the packet for delivery. For the realization of supporting functions, the CSSD assistance system had to be extended at two major points: First, a user interface had to be implemented, which provides help during workplace organization and assistance during the packet compilation. Second, for the detection of the parts containing boxes and the picking of parts from the boxes, the motion recognition had to be extended for object detection. As a result two new SubSystems were integrated into the system’s architecture: The “BoxClassificator” detects the parts boxes on the table and classifies whether the user's hand has picked up an item from a specific box by utilizing the computer vision library 'dSensingNI' [59]. The SubSystem "HWGGUI" provides the user interface for the task. It uses the Java processing library [134][3] for rendering the UI.

The process model for the order picking ('Commissioning') task is depicted in Fig. 9.7. It coordinates the activities of the worker and the system. Fig. 9.8 shows the interaction of the worker with the assistance system. According to the process model, the user first has to login into the system. After the login, he starts to organize the workspace by scanning an RFID-tag attached to the box and placing the parts box onto a highlighted area. Each parts box contains a different kind of product. The order picking requires the worker to pick a certain number of the parts from the boxes and to put them into the packet. The workplace preparation is finished, when all boxes and the packet are placed. The boxes have a small cardboard stripe which is used as a projection display for showing how many items have to be picked out of the box and how many items are currently available in the box. The UI now indicates how many parts have to be picked from each box. The motion tracking detects when a hand goes into the box. The system decreases the item counter in assumption that one item is picked out of the box[4]. The picking process is finished when all parts were picked and placed into the packet. Failure avoidance is also regarded: in case the worker picks an item from the wrong box, the system shows a warning dialog and a red 'ambient light' of the interface to inform the worker about his mistake.

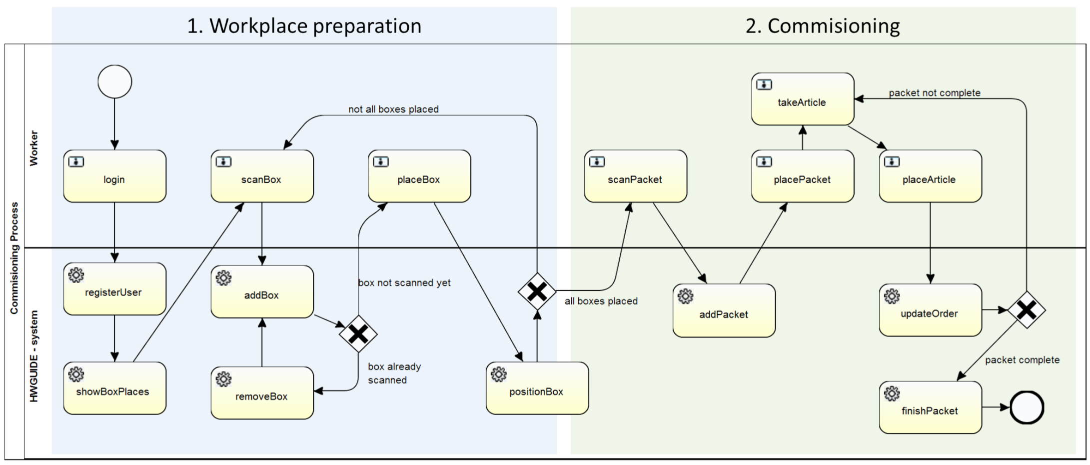


Fig. 9.7: HWGUIDE: 'Commissioning' process model for the workplace organization and order picking task.

The HWGUIE project demonstrates the scalability and flexibility of the assistance system. The HWGUIDE system used motion and object tracking to check if the order was picked correctly. With the extended object tracking, the small projection surfaces

[3] 'Processing' is a programming language and development environment for the electronics arts, new media art, and visual design communities. It pursues to allow fast sketching of new user interfaces.

[4] The assumption, that the worker only picks one product per grip into a box is a prototype's shortcut to avoid tracking complexity.

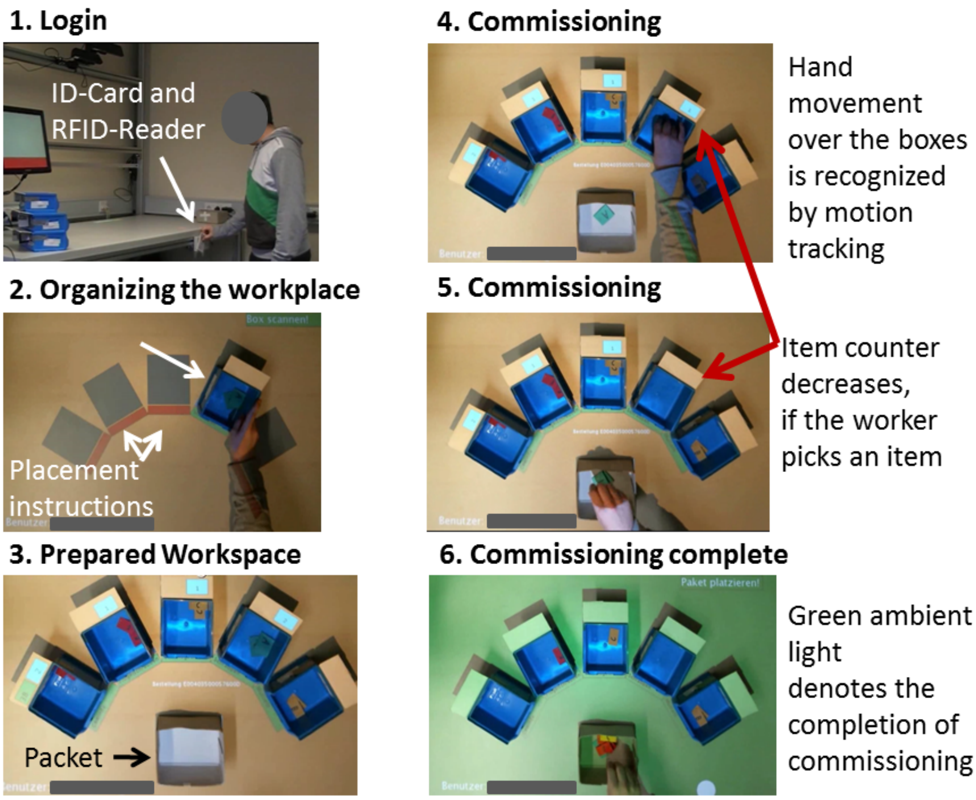


Fig. 9.8: HWGUIDE: The worker uses the system to organize the workplace and to pick an order. The system detects the boxes and the hand movements of the worker, which allows to count the products the worker picks.

attached to the boxes can be detected and used as an augmented reality projection display. The projector displays the number of items to be picked onto the boxes' projection surface, while the boxes can be moved within the workspace. Augmented reality applications and failure avoidance by motion tracking are thus feasible with the assistance system proposed in this thesis. Additionally, the integration of the Java processing library paves the way to utilize a rapid prototyping tool for UI development. Details on the project can be found on the project technical report website [135].

Cooking with a Robot. The project "Cooking with a robot (CWAR)" prototyped a cooking assistance system. The CWAR-system utilized BPMN process models, a simulated robot head and speech and gesture recognition to assist the cooking process within an ambient assisted kitchen kitchen scenario. The project was divided into three sub-projects with three students each. The first group "CWAR: The Cognitive kitchen" adapted the ProMiMo software architecture for modeling and coordination of the assisted cooking procedure. The group "CWAR: A virtual FloBi cookbook" provided an interactive cooking book with gesture control and the simulation of the robot head 'FloBi'. The third group "CWAR: The Dialogue System" focused on the speech recognition and the dialog system. The students realized a prototype of a multimodal cooking assistance. The ProMiMo software architecture was successfully applied for the coordination the subsystems such as the dialog system and the cooking book. Implementation and evaluation details can be found in the seminar proceedings [136]. The CWAR project hints at the applicability of the proposed assistance system in domestic scenarios.

Chapter 10

Conclusion

10.1 Summary

Failures and incidents during the reprocessing of medical devices occur and threaten the patients' health, the operators' safety and the hospital's wealth. The aim of this dissertation has been to explore options of assistive technology to help workers at the CSSD to avoid failures and incidents.

This thesis has proposed and evaluated a new assistance system, which enables the worker to retrieve and submit working instructions as well as quality reports while processing medical devices. Among the design for usability of a context-aware user interface and the hygiene-safe interaction method of virtual touches, the assistance system utilizes process automation based on the standard BPMN 2.0 to coordinate various devices and the user interface. The results of two user studies showed that the assistance system helps its users to avoid failures without delaying the workflow significantly. Additionally, the feedback from domain experts attests this concept of worker assistance a high practical relevance.

The main quality assurance concepts of presenting context-aware working instruction and capturing process quality data from the working place are of special interest for the CSSD domain and other domains like the industrial manual assembly. The combination of the automated process models for flexibility and the component-based system architecture for reusability allows to transfer the system to other use cases and domains.

The practical relevance of the proposed assistance system has been achieved by careful consideration of requirements and holistic concepts as the thesis structure reflects. The detailed domain analysis in Chapter 2 has revealed the demand and requirements for worker assistance at the unclean area of the CSSD. The requirements have been derived from a practical point of view as well as a management perspective. Summarized, the user needs usable access to working instructions during the regular workflow. The quality management benefits from shared information including the data submitted from the worker during the work.

The environment of the unclean area of the CSSD challenges existing computing devices and interaction techniques. Chapter 3 and Chapter 4 have discussed assistive devices and concepts for their potential application within the CSSD. The resulting hardware setup especially addresses the hygiene requirements arising from the CSSD's wet and contaminated area by providing a 'virtual touch'-controlled projection display.

For the adaption of the assistance functions to changing process prescriptions or requirements, the component-based software architecture was proposed in Chapter 5. Components such as software services and hardware devices are coordinated by graphically defined BPMN 2.0 process models. The elements of the process models abstract the implementation details of software or device functions, which perspectively allows domain or workflow experts to define and adapt the system's behaviors themselves.

Another core element of the assistance system is the context-aware user interface proposed in Sec. 5.3. The interface visualizes working instructions and typical issues of the currently processed instrument with a context-aware information density. The interface further enables the worker to input or annotate instructions and reclamations with minimal effort. This enables detailed and consistent documentation of the process quality.

The results of the user study in Chapter 6 have shown that the assistance system helps its users to avoid over 62% of critical failures, while the time for processing medical devices is not significantly delayed compared to the current situation in the CSSD. The encouraging results of the user study has been used in Chapter 7 to optimize the user interface and to increase its functionality. A second user study confirmed the system's ability to prevent users from failures while not delaying the work. The feedback from CSSD domain experts in Chapter 8 has underlined the practical relevance of the assistance system.

Quality assurance is important in other value creating departments as well. The domain of manual assembly is very similar to the CSSD domain. Chapter 9 has demonstrated how the concepts of the context- and process-aware assistance system can be transfered to the industrial domain of manual manufacturing. Thus, not only the decontamination of medical devices but also manual assembly process benefit from the worker and workflow supporting capabilities of the new context- and process-aware assistance system.

10.2 Discussion

Workers have to be aware of how to create and assess quality in order to produce high quality products such as sterility for medical devices or such as handcrafted products. To produce such quality, workers must be enabled to retrieve working instructions and they must be enabled to report incidents and issues that inhibit the creating of high quality products. Here, the proposed assistance system comes into play. It supports the worker with context-aware working instructions to attract the worker's attention to the quality-critical operations on the currently processed work piece or medical device. The workers feedback is directly used to highlight incidents within the working instructions. Furthermore the assistance enables the worker to submit quality reports and working instructions can be added or annotated during the regular workflow.

Although the system pursues to continuously identify and avoid quality issues, its quality assurance capabilities are limited. The system drags the worker's attention to the quality-critical features and operations, but it is the human worker who is finally responsible to comply with the presented working instructions and to control specific quality criteria. Thus, the intentional disregard of working instructions by the worker can not be avoided.

Quality management systems pursue to continuously improve value creating processes such as the CSSD or manual assembly of products. An effective quality management system requires continuously measurement of the process quality, the identification of improvement potentials and the possibility to adapt processes. The quality reports submitted by the worker directly contribute to the process quality measurement. The process and incidents documentation helps the workflow responsible person to identify measures to avoid the observed problems. The flexible and scalable component-based software architecture allows to adapt the system functionally to changing workflows and use cases, which has been demonstrated in Chapter 9.

This thesis has focused on the CSSD as productive environments with very high requirements for process quality and working environment. The evaluation of the assistance system in Chapter 6, 7 and 8 has shown that the projected user interface and the virtual-touch interaction provides a meaningful assistance. In both user studies the failure rate during the reprocessing of medical devices has been decreased by supporting the user with context-aware instructions. Psychological aspects like the implications of the assistance system on the worker's motivation and fatigue have not been covered in the system evaluation. However, a field study of the assistance system is necessary to assess the full potential of the various concepts. The latter probably requires a long-term evaluation within a CSSD to get significant results because it needs some time until quality reports are relevant enough to affect the workflow prescriptions. A field study would also require to increase the functionality and robustness of the assistance system prototype to a higher level. The prototype provides developer tools for designing and editing process models and working instructions. These tools should be developed towards user tools that allow domain experts to edit the process models and working instructions according to their needs. For the field application within the CSSD the robustness of the virtual touch interaction is of concern. The second user study showed that a finger-precise tracking is not robust enough with the proposed system. However, this field has rapidly developed and commercial products (e.g. Epson BrightLink 595Wi [137]) are available today that directly combine a projector and finger-precise motion tracking.

Sec. 9.2 introduced the it's owl transfer project ProMiMo, which pursues to apply and evaluate the assistance system in a real world manufacturing process. The transfer of the assistance system's prototype from the CSSD to the industrial productive environment implies changing requirements. First, for the manual assembly the requirement for a hygiene-safe interaction does not exist. Thus, the virtual interaction is not of interest in this use case and other devices such as touch screens maybe more suitable for the manufacturing domain. The implemented UI of the assistance system is independent from the virtual-touch interaction and thus the adaption to other touch interaction devices is feasible with very low effort. Second, the production of single products differs from the decontamination of medical device in the terms of work piece variations. In the CSSD manifold variations and different types of medical devices are processed. The reprocessing of a single medical device is straight forward by following the sequence of the presented instruction. Compared to the CSSD the variation in types of workpieces in the industrial domain and thus the amount of different working instructions is probably smaller. But the content of working instructions and the duration of the assembly process increases. Additionally, workflows with parallel operations come into play. Sec. 9.2 for example has presented the assembly of a foot-operated control. The assembly of the foot-operated control requires usually about three hours for one product. The worker can assemble multiple products in parallel by doing single assembly steps for all products at once instead of assembling the complete product one after another. In order to assist the worker properly and keeping the system manageable, the working instructions and the workflow must be chunked into atomic tasks and furthermore parallel workflows must be supported by the assistance system. More generally, the granularity of process model definitions must be discussed: What is the sufficient granularity level of working instructions for a given use case? Should there be a dedicated process model task for each single instructional image or is it sufficient to provide ordered lists of instructions as the atomic building blocks of workflow descriptions? Fine-grained building blocks of process models requires slightly more effort of modeling, but allow to address parallel workflows on a very fine grained level.

Third, among the consideration of process model granularity, the practical implication of the assistance system requires to extend the reclamation processing. In the domain experts' opinion the capturing of reclamations during the work is one of the most important features that the system provides. However, in its prototypical development state the system only provides the processing of workpiece-related reclamations. The input of workflow- or environment-related reclamations must be added to enable the worker to give more detailed feedback about the running workflows. For this purpose the UI must be extended but at the same time functionality must be limited to avoid confusing interaction dialogs. Notably, the UI already has a reserved area for workplace information and features. Although the "workplace panel" is not implemented in the proposed system, it can be used to deploy workplace related information and functions without breaking the UI design consistency.

Concluding, this thesis has presented a new approach for supporting workers at the unclean area of a CSSD. Workers benefit from context-aware working instructions, which they can extend and annotate on demand. The quality management benefits from the continuously gathered quality reports at the workplace. The system is flexible and scalable by its component-based software-architecture and workflow coordination engine. Thus, the proposed system can be adapted to continuously changing requirements and workflows. The encouraging evaluation results and the portability to industrial use case attests the relevance for the CSSD and manual assembly.

10.3 Outlook

The proposed assistance system is a prototype. The results of the early evaluation strongly motivate a further development. Although this thesis has proposed a very broad approach to improve the quality of work in productive environment, it could not discuss all important fields of interests and thus several topics can be addressed in future work.

The study results of the assistance system showed that the concepts for quality assurance and the flexibility of the system are of interest for productive environments. Thus, it is worth to question, what must a “ready for series-production system” provide to deploy the proposed concepts in a real world productive environment. The following components should be improved to overcome the prototypical development state of the assistance systems.

The assistance system must provide a meaningful number of devices and software services that form a library of workflow supporting building blocks. This component library is used by a dedicated tool to design the BPMN 2.0 process models. The process designer should come with a domain specific skin to abstract the implementation details from the workflow relevant function. With the process designer and a set of predefined standard process models, the domain expert is enabled to define the systems behavior according to the workflow needs. Furthermore, the process designer needs a tool to access the process documentation, quality statics and reclamation history in order to derive potential workflow improvements. The UI that assists the worker during the assembly procedure should be available as web-interface in order to allow deployment and flexible access to the assistive functions where it is needed, by utilizing a web-browser. The development and improvement of these tools require a user-centered design process to meet the manifold requirements of real world productive environments.

More research-related topics of future work should consider ’real-world’ evaluation, psychological, ergonomic and ethical implications of the assistance systems. The presented prototype has shown encouraging results in laboratory evaluation. However, in order to asses the full potential of the combined concepts of human-machine interaction and process automation, an evaluation in real-world productive environment is mandatory. The ’it’s owl’-transfer-project ProMiMo already addresses such a real world evaluation, but is currently work in progress. Such a field evaluation should consider the influence of the assistance system on the different process parameters, such as efficiency, ejection rate, process documentation, and other.

The process models defined by the standard BPMN 2.0 are the backbone of the assistance system, because they coordinate the system components and data flow. Although the BPMN standard is very powerful, it does not provide a sufficient graphical notation for modeling material or process-data flow. Defining and regulating the material and product flow is a major concern for productive environments. The BPMN is extendable per definition. Future work should investigate BPMN-extension for describing material flow to further increase the transparency of workflow definitions.

Among the business related effects, the effects on the human worker should be investigated from a psychological point of view. The presented assistance systems assumes that an annotated picture and a small description text are sufficient working instruction in most cases. This assumption should be evaluated systematically for different use cases. Further questions concern the influence of the assistance system on the worker’s motivation and fatigue during an eight hours lasting day of work. The ergonomic design and the workplace organization can also be improved (or inhibited) by the assistance system. Although ergonomic aspects have implicitly been discussed during the system development, findings from a systematic research on the ergonomic effects of projection based display within the workplace can be useful to further increase the system's ergonomics. This thesis has a technical focus and thus it has not addressed the ethical implications of worker monitoring, which is theoretically possible with the assistance system. Further development requires ethic and legislation-conform guidelines, which user-specific data can be recorded and how they can be processed in order to protect the users' privacy. For the CSSD a trade-off arises: Are the quality of sterility and its implications on patients' health or the workers' privacy right more important from a legal point of view? However, it would also be interesting to investigate how an assistance system continuously gathering process-relevant data from the worker and integrating in larger scale hospital processes influences the overall process quality and efficiency of a CSSD.

List of Figures

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