Development of a Risk Management Approach for Data Gloves Used in Assembly

by

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Développement d'une approche de gestion des risques pour les gants intelligents utilisés dans la fabrication (assemblage)

Alimeh MOFIDI NAEINI

RESUME

Le développement rapide d'industrie 4.0 augmente les interactions entre les humains, les technologies et les organisations. Ce qui augmente la complexité des systèmes de fabrication et amène de nouveaux défis. De nouveaux sujets de recherche voient ainsi le jour, pour répondre à ces défis et élargir les connaissances nécessaires à l'industrie pour y faire face.

La sécurité en tant que priorité dans la conception de tout système est un sujet qui nécessite plus d'attention dans la fabrication dans l'industrie 4.0. L'utilisation de technologies émergentes dans le contexte de la fabrication 4.0 peut introduire de nouveaux dangers. Par conséquent, les méthodes qui peuvent aider à identifier ces dangers sont essentielles. De nombreuses approches, du classique au systémique, ont été étudiées dans le contexte de la fabrication 4.0. Cependant, les approches classiques peuvent ne pas identifier tous les facteurs qui affectent la sécurité du système. Par conséquent, des approches innovantes et différentes sont nécessaires pour faire face à la complexité de ces systèmes et supporter les analystes dans l'analyse des risques. Ces approches innovantes devraient considérer une perspective systémique au lieu d'une perspective linéaire telle qu'utilisée dans les approches classiques.

Les méthodes Functional Resonance Analysis Method (FRAM) et Systems-Theoretic Accident Model and Processes (STAMP) sont deux nouvelles approches systémiques qui ont fait l'objet de nombreuses recherches dans divers domaines d'études au cours de la dernière décennie. Dans cette étude, elles seront utilisées dans un contexte d'assemblage 4.0 pour fournir une compréhension du système du point de vue de la santé et de la sécurité au travail (SST) et de l'analyse des risques opérationnels.

Dans un premier temps, la SST et les préoccupations opérationnelles de l'utilisation des vêtements intelligents dans la fabrication sont discutées pour montrer l'importance et l'originalité du projet. Ensuite, une description des études de cas, de leurs composants et de leurs interactions entre elles sera élaborée. Concernant la complexité des systèmes étudiés, FRAM et STAMP seront utilisées pour tirer des conclusions. Les résultats obtenus de chaque application ont révélé de nouveaux facteurs qui pourraient être pris en compte dans la conception d'un système d'assemblage 4.0 lorsqu'une nouvelle technologie (dans cette étude, un gant de données) est introduite.

Malgré les avantages considérables de ces outils en SST et en analyse des risques opérationnels, des recherches supplémentaires sont encore nécessaires pour les développer, en particulier pour notre contexte d'étude spécifique. Alors que FRAM capte un aperçu des composants du système et de leurs interactions, STAMP permet une analyse détaillée des différents composants du système. Par conséquent, une intégration de FRAM/STAMP est proposée pour tirer profit des avantages offerts par FRAM et STAMP sans sacrifier leurs caractéristiques et en couvrant leurs points faibles dans l'analyse. L'approche intégrée proposée aidera à analyser la SST et les risques opérationnels des systèmes d'assemblage 4.0, en particulier dans la phase de conception, afin de garantir des conditions de travail plus sûres pour les interactions entre les humains et les machines. De plus, les résultats peuvent améliorer la conception des gants de données qui seront utilisés dans la fabrication et fournir une perspective aux concepteurs pour développer cette technologie émergente.

Enfin, cette étude espère apporter des réponses aux chercheurs et des perspectives pour des questions plus émergentes, le développement de la méthode proposée et son application dans d'autres domaines dans les études futures.

Mots clés: Industrie 4.0, FRAM, STAMP, Assemblage 4.0, Analyse des risques SST, Analyse des risques opérationnels.

Development of a risk management approach for data gloves used in manufacturing (assembly)

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ABSTRACT

Integrating manufacturing into industry 4.0 has attracted researchers' attention to deal with the emerging challenges and broaden knowledge in manufacturing in the context of industry 4.0. The rapid development of industry 4.0 increases the interaction of humans, technologies, and organizations. Thus, the possibility of increasing complexity and new challenges. Hence, new topics in the research area will arise to address these complexities and challenges.

Safety as a priority in designing any systems is one subject that requires more attention in manufacturing in industry 4.0. Applying emerging technologies in the manufacturing 4.0 contexts may introduce new hazards to the system. Therefore, methods that can help identify these hazards are of interest. Many approaches, from classical to systemic, have been studied in the manufacturing 4.0 contexts. However, classical approaches might not identify all factors that affect system safety. Hence, innovative and different approaches are required to address the complexity of these systems and assist analysts in risk analysis. These innovative approaches should consider a systemic perspective.

Functional Resonance Analysis Method (FRAM) and Systems-Theoretic Accident Model and Processes (STAMP) are two new systemic approaches that have attracted many types of research in various fields of study in recent decades. In this study, they will be applied in an assembly 4.0 context to provide an understanding of the system from the perspective of occupational health and safety (OHS) and operational risk analysis.

Firstly, smart wearables use in manufacturing and their OHS and operational concerns are discussed to show the project's relevance and priority and originality. Then, a description of case studies, their components, and their interactions with each other will be elaborated. Regarding the complexity of the studied systems, FRAM and STAMP will be applied to draw conclusions. The obtained results of each application revealed new findings of the systems' components and their interactions that could be considered in designing an assembly 4.0 system when a new technology (in this study, a data glove) is introduced.

Despite the considerable advantages of these tools in OHS and operational risk analysis, there is still the need for more research to develop them, particularly for our specific study context. While FRAM captures an overview of the system components and their interactions, STAMP allows for a detailed analysis of different system components. Therefore, the integration of FRAM/STAMP is proposed to benefit the analysts from advantages offered by FRAM and STAMP without sacrificing their characteristics and covering their weak points in the analysis. The proposed unique integrated approach will assist in analyzing OHS and operational risks

of assembly 4.0 systems, especially in the designing phase, to ensure safe working conditions for humans and machines interactions. Moreover, the results can improve the design of data gloves that will be applied in manufacturing and provide a perspective for designers to develop this emerging technology.

Finally, this study hopes to provide answers for researchers and an outlook for more arising questions, the proposed method's development, and application in other fields in future studies.

Keywords: Industry 4.0, FRAM, STAMP, Assembly 4.0, OHS risk analysis, Operational risk analysis.

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LIST OF ABREVIATIONS

AHP	Analytic Hierarchy Process
AI	Artificial Intelligence
AR	Augmented Reality
AV	Automated Vehicle
BDD	Behavior Driven Development
BOM	Bill of Materials
CAST	Causal Analysis based on STAMP
CREAM	Cognitive Reliability and Error Analysis Method
CRP	Capacity Requirement Planning
CRS	Comfort Rate Scale
CV	Cumulative Variability
DoF	Degree of Freedom
EAST	Event Analysis of Systemic Teamwork
EEG	Electroencephalography
ERP	Enterprise Resource Planning
ESD	Electro Static Discharge
FMEA	Failure Mode and Effect Analysis
FMECA	Failure Mode Effect and Criticality Analysis
FMV	Functional Model Visualizer
FRAM	Functional Resonance Analysis Method
FTA	Fault Tree Analysis

GPS	Global Positioning System
GSN	Goal Structuring Notation
HAZID	Hazard Identification study
HAZOP	HAZard and OPerability study
HF/E	Human Factors/Ergonomics
HFACS	Human Factors Analysis and Classification System
HMD	Head-Mounted Display
ICT	Information and Communication Technologies
IoT	Internet of Things
IT	Information Technology
MCS	Monte Carlo Simulation
MTO	huMan, Technological, and Organizational
NER	New and Emerging Risk
OHS	Occupational Health and Safety
PO	Purchase Order
PSA	Probabilistic Safety Assessment
RAG	Resilience Assessment Grid
RID	Retinal Image Display
RRP	Resource Requirements Planning
SC	Safety Constraint
SCM	Swiss Cheese Model
SPC	Specific Performance Condition

STAMP	System-Theoretic Accident Model and Processes
STECA	System Theoretic Early Concept Analysis
STPA	System Theoretic Process Analysis
STPA-sec	System Theoretic Process Analysis-Security
TRL	Technology Readiness Level
UCA	Unsafe Control Action
VML	Virtual Motion Lab
VR	Virtual reality
WMSD	Work-related MusculoSkeletal Disorders

INTRODUCTION

Safety is an essential need for humans and driven by this need, many approaches have been introduced to ensure their safety. From classical to systemic, these approaches have been developed within the history of the industry. They have been developed to analyze risks and prevent hazards. While classical approaches focus on identifying hazards at the root by decomposition and eliminating them, systemic approaches try to find how the variability of the system interactions can affect the system during the system activities. Systems are dynamic and the humans' interactions with new systems and dealing with their complexity will introduce new challenges to safety and risk analysis methods. Therefore, both classical and systemic approaches are required to deal with these challenges (Melanson et Nadeau, 2019).

Industries are evolving rapidly and we are experiencing a new generation of industry called industry 4.0. There are many concepts in industry 4.0 and one of them is the internet of things (IoT) (Hermann, Pentek et Otto, 2015; Hirsch-Kreinsen, 2015; Stoltz et al., 2017; Toro, Barandiaran et Posada, 2015). The IoT's capability allows manufacturing to have a greater insight into operations by using data efficiently (Thibaud et al., 2018). IoT provides a network of different objects that have the following characteristics:

1. Having unique identification;
2. Enabling the collection of data from the environment mainly via sensors;
3. Operating and interacting with the real physical world through the processing of collected data;
4. Using internet standards for communication and analyzing data in order to offer more services (Miorandi et al., 2012; Thibaud et al., 2018).

Considering IoT characteristics, it has been applied in various fields like smart wearables, smart homes, smart cities, and smart enterprises (Perera, Liu et Jayawardena, 2015). Smart wearables, particularly data gloves are one kind of smart wearables and are the main concern of this study.

Safety should be considered as the priority in systems advancement. The fast technology advancements have introduced new types of hazards, especially when applied in modern and complex systems in the industry 4.0 context. This study investigates occupational health and safety (OHS) and operational concerns of introducing a data glove as an IoT-based technology to an assembly 4.0 context (the reader is invited to consult Chapter 3 as for the assembly 4.0 concept). The application of these new technologies in manufacturing is growing; thus, the possibility of OHS and operational risks increases. Moreover, few researchers have studied human interactions with these emerging technologies from the perspective of human factors engineering (Mofidi Naeni et Nadeau, 2020). Hence, a comprehensive understanding of the system components interactions would ensure the provision of desired safety level in a complex manufacturing system. It would also provide valuable results for designing such systems as they are in the early stage of development.

This study provides an introduction to wearables, data gloves and their different applications, particularly in manufacturing (chapter 1). A critical review of the literature related to the use of data gloves in manufacturing and associated OHS and operational risks will be discussed in chapter 2 to provide a better understanding on the background of the research topic. An illustration of case studies in assembly 4.0 context and the application of data gloves will be presented. Accordingly, the research questions regarding the OHS and operational concerns, the main objective and three underlying objectives of conducting this study will be provided. Followingly, a review of Functional Resonance Analysis Method (FRAM) and Systems-Theoretic Accident Model and Processes (STAMP) as the methodology for finding appropriate answers and reflections on them for our specific study will be discussed comprehensively in chapter 2.

Chapter 3 and 4 consist of two journal papers (one is published, one is submitted) that discuss the result of applying FRAM and STAMP that addresses the first and the second research objectives. Chapter 5 describes the proposed integrated approach as the novel method for materializing the third research objective. Finally, we conclude, based on the findings of chapters 3,4, and 5, and provide some recommendations for future studies.

A list of scientific contributions to journals and conferences and contributions to vulgarization in the format of three minutes thesis (3MT) competitions is presented in Annex I. Annex II, III, IV, V, and VI include the comprehensive results of the second journal paper in chapter 4, accepted papers for AQHSST 2020, GfA 2021, ICOH 2022, AHFE 2022 conferences, respectively.

CHAPTER 1

CRITICAL REVIEW OF LITERATURE

1.1 Wearables

1.1.1 Introduction to wearables

"Internet of Things" (IoT) is one of the most important concepts in industry 4.0 (Hermann, Pentek et Otto, 2015; Hirsch-Kreinsen, 2015; Stoltz et al., 2017; Toro, Barandiaran et Posada, 2015). IoT refers to a collection of physically interconnected and recognizable objects that can communicate and interact with other objects, and collect data from the environment (Miorandi et al., 2012; Thibaud et al., 2018). Regarding these characteristics of IoT, they are applied in various fields and products (Perera, Liu et Jayawardena, 2015). Wearables are one type of IoT (Perera, Liu et Jayawardena, 2015).

Size reduction of Information and Communication Technologies (ICT) has increased the interest of wearables (Marwedel, 2011). An electronic device that besides its primitive functions is worn by a person is called a wearable (Tao, 2005). Providing different sensors that can collect information from selected areas of interest, provides collaboration of embedded systems and wearables (Corff, 2016). Different terms such as wearable electronics (Tao, 2005), wearable devices (Kucukoglu et al., 2018), wearable sensors (Chen et al., 2016) have been used for a common purpose in different studies. In this study, we call them wearables (Marras et Karwowski, 2006).

Introduction of Industry 4.0 to manufacturing transformed manufacturing. Industry 4.0 has changed existing manufacturing system through digitization and capturing data from different sensors and information systems (Mannhardt, Petersen et Oliveira, 2019). The development in wearable technologies and their IoT-based charachteristics has increased the possibility of designing a smart and automatic system that can evaluate people's activity in various working conditions (Cook et Krishnan, 2015). Smart technologies and sensors such as wearables will support the collaboration among the workers as well as between the human and technology.

This collabortion provides sophisticated analytics and insight for workers in smart manufacturing (Mannhardt, Petersen et Oliveira, 2019). Wearables are applied to connect workers to digital assistance systems in companies and enhance the quality of production (Krzywdzinski et al., 2022). Beside the main functions of wearables, they can improve health and safety at workplace. For example, they can give us valuable information about the users' body. For instance, the data about heartbeats (or variability of heart rate) can assess the function of physiological systems (Pomeranz et al., 1985) or evaluate humans' stress level and health level (Thayer et al., 2012). There are also other biometric indicators such as respiration rates and the temperature of the human body that can provide information about the human system (Widmaier, Raff et Strang, 2006). When a worker is doing his tasks where he/she is exposed to heat or high temperatures (working in a foundry or smelters) or is doing a job that has to carry heavy loads (extereme conditions) (Arslan et al., 2014; Corrales et al., 2012; Mayton et al., 2012; Mrugala et al., 2012; Yang et al., 2011) his/her data gloves can analyze his/her biometric indicators like the heartbeat. Then when those indicators are in a border range, some preventive action can be recommended or a warning can be sent. For example, they can warn the worker to leave the area or take some rest. However, this study, focuses on OHS and operational concerns of using data gloves; and their application for measuring biometric indicators provided an example of use of this emerging technology.
However different kinds of wearables have been introduced, this technology still is in an early development phase. Meaning that their usage and design is being tested and examined in different situations by developers, customer companies and researchers (Krzywdzinski et al., 2022).

1.1.2 Introduction to data gloves

Different kinds of human-machine interactions have been proposed due to the fast development in computer technology (Fang et al., 2018). Among different human-machine interactions, interaction with hand gestures can be considered as the most important human-machine interaction (Fang et al., 2018).

This study will investigate data gloves as one of the different glove-based human-machine interactions (Regazzoni, de Vecchi et Rizzi, 2014) and OHS and operational risks related to their usage in manufacturing.

A data glove is a specific glove that has some sensors inside the glove (including magnetic, optic, ultrasonic, and inertial (Burdea et Coiffet, 2003)) and can track the movements of fingers and hand (Arkenbout, de Winter et Breedveld, 2015; Fahn et Sun, 2010; Gentner et Classen, 2009; Wang et Popović, 2009) or can provide feedback such as haptic feedback, the feeling of touch and resistance (Chen, Wang et Li, 2002).

Feedback is very useful for manufacturing purposes. For instance, assembly workers can be independent of external stimuli like changing lighting conditions. When workers wear warning gloves for doing maintenance (replacing a spindle), it provides feedback for the worker. There are different feedback regarding the task done. For example, LEDs on the gloves will turn on, or the LED's color will be changed, or vibration sensors will send a vibration to the hand when they put the part in its place correctly (Schmuntzsch et Feldhaus, 2013).

Moreover, it can reduce errors in performance to enhance the quality of the task (Kucukoglu et al., 2018). For example, a data glove that has force sensors helps workers in assembling connectors to avoid faults. When two different parts of a connector are assembled (male and female parts), the click noise and vibration of the connector means that they are assembled properly. The click noise might not be heard due to environmental noise of a real manufacturing condition. Moreover, vibration might not be detected by the hand that holds the connector as the routine operation might decrease the sensitivity of the hand to vibration. Therefore, data gloves can detect when appropriate force is used, and the vibration of the connector to alert workers (Kucukoglu et al., 2018).

1.1.3 Application of data gloves

Data gloves are applied in many sectors. They can be used in various industries such as

1. **Design and manufacturing**: Data gloves are used to interact with computer-generated environments. The user can control the actions while he/she is on-site or remotely via the internet. (Li, Lau et Ng, 2003). Some articles demonstrate the usage of data gloves

for simulation in a virtual reality (VR) system. Daimler-Benz used virtual reality for designing. Daimler-Benz used data gloves to select furnishings of the interior of Mercedes. Moreover, Boeing designers and maintainers used data gloves to simulate maintenance tasks in aircraft. (Steffan, Schull et Kuhlen, 1998) In addition, data gloves can be used in 3D modeling, especially in the last stages of designing, for creating 3D shapes using hands. (Keefe et al., 2001). Moreover, they are used for interactions with virtual components of a sample that should be assembled, while the augmented reality system is used for assembly simulation. (Valentini, 2009; Wang, Ong et Nee, 2013). In a study by Kucukoglu et al (2018) data gloves were used for assembling a connector and provided vibration feedback to ensure the quality of assembly (Kucukoglu et al., 2018).

2. **Information visualization**: To better understand data, computer graphics will be used to produce a visual representation. This is very helpful for complex numerical demonstrations of scientific concepts or results. (Dipietro, Sabatini et Dario, 2008) For instance, in a project in NASA, Bryson and Levit presented the feasibility of this concept for a virtual wind tunnel. (Bryson et Levit, 1991)
3. **Robotics**: Glove-based systems can facilitate robot programming. (Dipietro, Sabatini et Dario, 2008) For example, in order to teach a robot for assembly purposes, a data glove is used for the identification of objects to manipulate and steps to be done. The object's dimensions and its situations can be sent to a robot via data gloves. Also, the assembly processes can be learned by the robot. (Lee et Suh, 2013)
4. **Art and entertainment**: Many video games and animations of computer-generated characters are equipped with glove-based systems. Since playing some kinds of games needs a considerable Degree of Freedom (DoF), gloves can address this requirement very well. (Adamo-Villani et Wilbur, 2007; Burdea et Coiffet, 2003; Damasio et Musse, 2002; Rezzoug et al., 2006; Sturman et Zeltzer, 1994). In a study by Gromala and Sharir (1994), in a dance performance, dancers wore data gloves to interact with a virtual environment in real-time. (Gromala et Sharir, 1994)
5. **Understanding of sign language:** Data gloves can be used for deaf persons for the understanding of gestural language. (Sturman et Zeltzer, 1994) In addition, data gloves

are used for recognition of the alphabet in different languages; for instance, Japanese (Murakami et Taguchi, 1991; Takahashi et Kishino, 1991) and Korean (Kim, Jang et Bien, 1996) language. Moreover, other forms of glove-based systems have been used for recognition of other languages like Australian (Kadous, 1995; Vamplew et Adams, 1996), Chinese (Gao et al., 2000; Wang, Gao et Shan, 2002), Taiwanese (Liang et Ouhyoung, 1996; 1998; Liang et Ouhyoung, 1995). It is also used for recognition of language to help deaf and mute people (Ahmed et al., 2018; Cheok, Omar et Jaward, 2019).

6. **Medicine and healthcare**: Glove-based systems have been used for different surgery operations and medical purposes (Greenleaf, 1995) like using for evaluating tremors of hands caused by Parkinson's diseases or fatigue (Shi et Chiao, 2018). Chen et al (2010) suggested the use of data gloves for distinguishing the area of disability or dysfunctionality of patients' hands to have physiotherapy for the identified area (Chen, Wang et Cao, 2010).
7. **Wearable and portable computers**: Recently, the application of glove-based systems such as text entry (Babic, 2002; Cho et al., 2002), pointing devices for portable and wearable devices has developed considerably.

1.1.4 Factors that should be considered for data gloves

Some factors that need to be considered in the design of data gloves to provide the possible ergonomic condition for the body have been discussed in different studies. If these factors are not met completely, they might cause some OHS and operational risks. Some of them are as follows:

1. Choosing an appropriate type of sensor, it is necessary to know the requirements of collecting data. So, regarding the required data for evaluation, an appropriate sensor set should be selected and integrated (Tsao, Li et Ma, 2019).
2. Positions of sensors (Kucukoglu et al., 2018); since the position of sensors can increase the thickness of gloves. Normally, manual dexterity will decrease when workers use gloves in comparison to when we do the task with bare hands (Yao et al., 2018).

Accordingly, when the thickness (Hu et al., 2008; Yao et al., 2018) and flexibility (Harrabi et al., 2008; Larivière et al., 2010; Vu-Khanh et al., 2007) of gloves increases, hand dexterity and precision at work will decrease (Hu et al., 2008; Yao et al., 2018). Moreover, the location of sensors can affect the accuracy as well as the magnitude of the feedback (Wang et al., 2018)

3. The number of sensors; The number of sensors to be embedded in the data gloves should be kept small to consider ergonomics and robustness of the gloves (Stelzer, Kraus et Pott, 2016).
4. The connection of data gloves to the receiver (choosing a wire or wireless system for connection) (Simone et al., 2007)
5. Suitability for the task and controllability (ISO 9241-110:2006)(FDIS, 2006); the flexibility of sensors to increase their precision in measuring bending angles of the fingers (Fahn et Sun, 2000), and the amount of force that fingers apply to an object (Zheng et al., 2016). In addition, the required time to control switches and levers when the workers wear gloves will increase (Banks, 1979; Plummer et al., 1985). Therefore, if the sensors are not flexible enough, they might increase the cycle time.
6. Wearability, some factors such as weight (no oppressive feeling when attached to user's body (Ngô, Nadeau et Hallé, 2017; Wang et al., 2018), no feeling of the glove weight that causes fatigue (Wang et al., 2018), shape (Pacchierotti et al., 2017), the anthropometric of the fingers (Bhattacharya et al., 2017), the way of mounting the glove to the worker's hand (Wang et al., 2018) e.g. wearing and removing data gloves should be easy to have less hand and fingers motion (Simone et al., 2004), and other ergonomic considerations (Borisov, Weyers et Kluge, 2018) can define the level of wearability (Pacchierotti et al., 2017).
7. Suitability for individualization (ISO 9241-110:2006) (FDIS, 2006); the adaptability of the glove to different workers' hands (Wang et al., 2018).

For risk analysis, not only we need to do risk analysis according to predefined standards and design factors, but also we need to consider new emerging (NER) risks (Brocal et al., 2019b; Fernández et Pérez, 2015) that are related to the intelligent function of the data glove. moreover, if data gloves besides their intelligent functions, are used for the protective purpose, it is necessary to be sure that the combination of smart function and protective function does not cause a new risk (Marchal et Baldwin, 2019).

1.2 Critical review of literature

Industry 4.0 in operating context carries sources of complexity. This context introduces various risks including traditional and emerging risks that need to be managed (Brocal et al., 2019a). Wearables, as one of the emerging technologies in industry 4.0, can introduce risks to industries. These industrial risks contain different types of risks. This study focuses on occupational health and safety (OHS) and operational risks of the use of wearables, specifically data gloves, as these two risks are linked to each other (Brocal et al., 2018).
OHS risk refers to the likelihood that a person may be harmed or suffer injuries, illnesses, or adverse health effects resulting from exposure to workplace hazards (Safeopedia, 2020). Operational risks concerns the risk of losses that are caused by inadequate, flawed or failed processes, procedures, systems or events, human errors, external events and might lead to disruption of business operations is called operational risk (Morgan, 2021).

1.2.1 The methodology of the literature review

In this study, we consider the use of data gloves in manufacturing and their challenges from the perspective of the OHS and the operational risks. To obtain related studies, ETS library resources (IEEE, Compendex & INSPEC, Scopus, ETS library search engine, science direct, and Espace ETS) from 2000-2021 mostly in English have been consulted. Table 1.1 shows the diversity of words that have been used to find more related papers.

Table 1.1 Keywords for research

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
OHS	risk	data glove	industry	operational	wearable
ergonomics	risk management	electronic glove	manufacturing	cycle time	wearable electronics
human factors	risk analysis	sensor glove	assembly	throughput	wearable device
occupational health and safety	risk assessment	smart glove	production	tact time	wearable sensor
		intelligent glove		operation shut down	

First, different combinations of keywords that are related to OHS risks of data gloves (columns 1, 2, 3, and 4) were searched. Since up to this step, the number of papers that have been found is very limited (6 papers); keywords related to wearables (column 6) were added to the combination of keywords to have more findings (e.g. columns 2, 3, 4, and 6). Although wearables have been used for many different purposes, the number of papers that consider occupational health and safety concerns are limited (Tsao, Li et Ma, 2019).

When we limit the results of research to manufacturing (column 4), we could see fewer results. Therefore, we looked for the OHS risk related of different wearables (the combination of keywords in columns 1, 2, and 6) without considering the industry that wearables have been studied in. To find papers related to the operational risks of data gloves, at the first step, we considered the operational risks of wearables without considering the industry that they have been applied to (columns 2, 5, and 6). To narrow down the results, the area that wearables have been used for was added to our search (column 4). Then, in order to have more results about operational risks, we applied the same strategy, but instead of column 6, we used keywords in column 3 and then narrowed the results by adding column 4 to the search results. The found papers were reviewed by their titles to find more relevant studies. In the next step, the abstracts of the remaining papers were studied to narrow down the results and select the most related papers. Then, the remaining papers were studied to extract the whole idea, including the main objective of the study, the types of wearables that have been studied, the area where wearables have been applied, the identified risk(s), and the result of the study.

1.2.2 Literature Review of the OHS risks

We present the overview of studied papers (33 papers) in two tables. The first table (table 1.2) shows the studies (15 papers) that have investigated the OHS risk related to the use of wearables. The second table (table 1.3) shows some different kinds of wearable that have been applied to study OHS risk related to a specific task (18 papers). A comprehensive review on this subject is provided by Stefana 2021 (Stefana et al., 2021).

Table 1.2 Summary of the literature review about the documented OHS risks of the use of wearables

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result	OHS risk
(Lin et Kreifeldt, 2001)	Proposing a wearable design considering the ergonomic approach	Different kinds of wearables were studied generally	Designing	Incorporating ergonomic processes to industrial processes will ensure ease of use and safety of products.	Ergonomic consideration
(Baber, 2001)	Investigate the human factors aspect of three kinds of wearables	A paramedic wearable computer Information appliance that can be worn Computer as clothing (a glove interface)	General (lab experiment)	Wearables can help to perform a task more efficiently due to the presented information while working, but they can have some ergonomic effect on the users' bodies.	Ergonomics and physical effects on the users' body
(Bodine et Gemperle, 2003)	Evaluate the effect of perceived comfort on the functionality of wearable	An armband A backpack	General (lab experiment)	If wearers feel more comfortable, they will accept using it better. For some functions, some bodies' locations may be preferred.	Human perception towards the use of data gloves
(Knight et Baber, 2005)	Assessing the comfort of wearables by a qualitative tool (comfort rate scale (CRS)) through comparison of four types of wearables	A hot helmet An armband A glove A Web-Enhanced Context-Aware Personal Computer is worn over one shoulder	General (lab experiment)	CRS can measure the comfort of wearables, moreover, it can compare comfort before and after changes in design	Feeling of comfort

Table 1.2 Summary of the literature review about the documented OHS risks of the use of wearables (Continued)

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result	OHS risk
(Knight et Baber, 2007b)	Assessing the effects of wearable based on a head-mounted display (HMD) on head position and stress on the musculoskeletal system	The head-mounted display (HMD)	Healthcare (experienced paramedics)	While paramedics wear HMDs, they have to have more neck flexion and deviation to perform their work. So, it can put the musculoskeletal system under more stress	musculoskeletal stress
(Knight et Baber, 2007a)	The risk of a physical load of a wearable (armband) has been assessed and the impact on postures with different weights (seven) has been demonstrated.	An armband	Manufacturing (workers that are predisposed to different mechanical stresses)	Using wearables may lead to some physiological effects on users' bodies like the fatigue, level of stress. In the short term, stress can result in pain and discomfort and in the long term, stress can lead to musculoskeletal disorders.	The physiological effects of the wearable load on the wearer's body (fatigue and stress level)
(Kuru et Erbuğ, 2013)	Users' perception toward the quality of wearables (from the perspective of pleasing aesthetics, novelty, wearability, interactivity, usefulness) has been investigated through interviews.	Five conceptual on body mobile phone	Entertaining 30 interviewers (users)	The perceived quality, especially from the point of view of comfort and usefulness is acceptable.	Human perception towards the use of data gloves
(Schmuntzsch, Sturm et Roetting, 2014)	Evaluation of user's perceived toward warning gloves and its effect on the speed of response	Gloves with sensors	Manufacturing (maintenance)	Users' attitude toward warning gloves is "fairly appropriate" and these gloves can reduce the time of response	Human perception towards the use of data gloves
(Schertzer et Riemer, 2014)	Investigating the effect of a load of mass on users' body and the location of mass on metabolic rates as well as the users' walking speed for designing wearables through a new method	Knee wearable Ankle wearable Backpack	Sport and entertainment	The method shows fewer errors in comparison to previous methods that have been presented	The physiological effects of the wearable load on the wearer's body and metabolic rate
(Claudio et al., 2015)	Assessing perceived ease and usefulness of wearable sensors in nurses and patients in emergency departments	Sensors on patients' wrist	Healthcare	For both studied groups (patients and nurses) perceived usefulness is higher than perceived ease of use	Human perception towards the use of wrist sensors

Table 1.2 Summary of the literature review about the documented OHS risks of the use of wearables (Continued)

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result	OHS risk
(Nakanishi et Sato, 2015)	Investigating the behavioral, psychological and physiological effects of wearable digitals on workers	Retinal Image display (RID) glasses	Manufacturing (assembly)	It can reduce the time of processing data while it would be effortless for performing a task. In addition, it will increase motivation and satisfaction, accuracy and task efficiency.	Behavioral, psychological and physiological effects of wearables on workers
(Amick et al., 2016)	Using sensor gloves to develop a method for assessing injury risk factors for the use of spacesuit gloves	A sensor glove	Astronavigation (lab experiment)	Sensor gloves were useful for measuring different physical and environmental variables related to fingers and hand injuries	Fingers and the hand injuries
(Zheng et al., 2018)	Designing a force-feedback glove that provides immersive sensation for using in virtual reality systems	Data glove	General (lab experiment)	The designed glove can be used as an interface in virtual reality but there are some improvements. The designed glove is not usable for each kind of hand size.	Limitation in the hand size
(Ahn et al., 2019)	An overview of the application of wearables to measure kinematics, cardiac activity, skin response, muscle engagement, eye movement, and brain activity is provided.	Wearable sensors for eye tracking, chest and arm sensors.	construction	Wearables are useful for preventing musculoskeletal disorders and falls, measuring physical workload and fatigue and monitoring workers mental. However challenges and risks such as users' resistance should be considered.	User's resistance
(Sochor et al., 2019)	Proposing an approach to increase the workers' acceptance toward the use of different human-machine interactions as cognitive assistance systems that help worker to reduce strain on workers	AR glasses, data gloves, loudspeakers, a headset, a data wristband.	Manufacturing (assembly)	Since trust on the information accuracy and the performance of the system are essential for acceptance of a technology when there is a demonstration worker can accept the systems more easily.	Workers' acceptance (trust)

Table 1.2 Summary of the literature review about the documented OHS risks of the use of wearables (Continued)

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result	OHS risk
(König et al., 2019)	The application of augmented reality in assembly using data gloves and AR glasses	A data glove AR glasses	Manufacturing (assembly)- Lab experiment	The AR and new technologies in the context of industry 4.0 can assist assembly and learning of the process of assembly. In addition, workers can communicate with this technology through gesture and voice.	The ease of use of data gloves and AR glasses in assembly. The comparison of the gesture and voice for communicating with new technologies
(Torrecilla -García, Pardo-Ferreira et Rubio-Romero, 2020)	Applying blockchain for wearable-based ergonomic management	General wearable	Manufacturing	The proposed approach of blockchain is an appropriate method for OHS risk analysis in the manufacturing in industry 4.0 context.	General OHS risks
(Meyer et al., 2022)	Investigating the effect of robotic hand orthoses on reduction of degree of freedom and movement of upperlimb by using sensors	Wearable sensor on hand, arm, shoulder	Lab experiment	Soft textiles or silicon based orthoses may provide more natural grasp and be less heavier for the hand.	Movement of workers and degree of freedom

These 18 papers have investigated the OHS risk associated with the use of wearables in various areas such as manufacturing, healthcare, sport, lab experiment, etc. Figure 1.1 indicates the percentage of documented OHS risks of wearables according to areas of application. Some physical effects like injuries of hand, physical and ergonomic effects on wearers' bodies, musculoskeletal disorder, and psychological effects such as human's perceptions toward the use of wearables, feeling of comfort have been identified as OHS risks. Not only data glove is an emerging use of technology, but also different risks can emerge during the use of the technology (Dorsey et Siewiorek, 2002; Marchal et Baldwin, 2019). Considering the limited number of studies, it seems risks have not been fully identified and investigated yet.

It should be mentioned that while only 7 of the papers (38%) have studied gloves as one kind of wearables (underlined), only 3 studies in the manufacturing area have studied data gloves.

To the best of our knowledge, the number of studies about the OHS risk of using wearables, especially data gloves is very limited and needs to be investigated more.

Although most studies focus on adapting new technology to Industry 4.0, humans should keep a central role and therefore, how he/she will be able to work with new technologies such as wearables, sensors, etc. efficiently and ergonomically should be tackled (Fallaha et al., 2020; Kong et al., 2019).

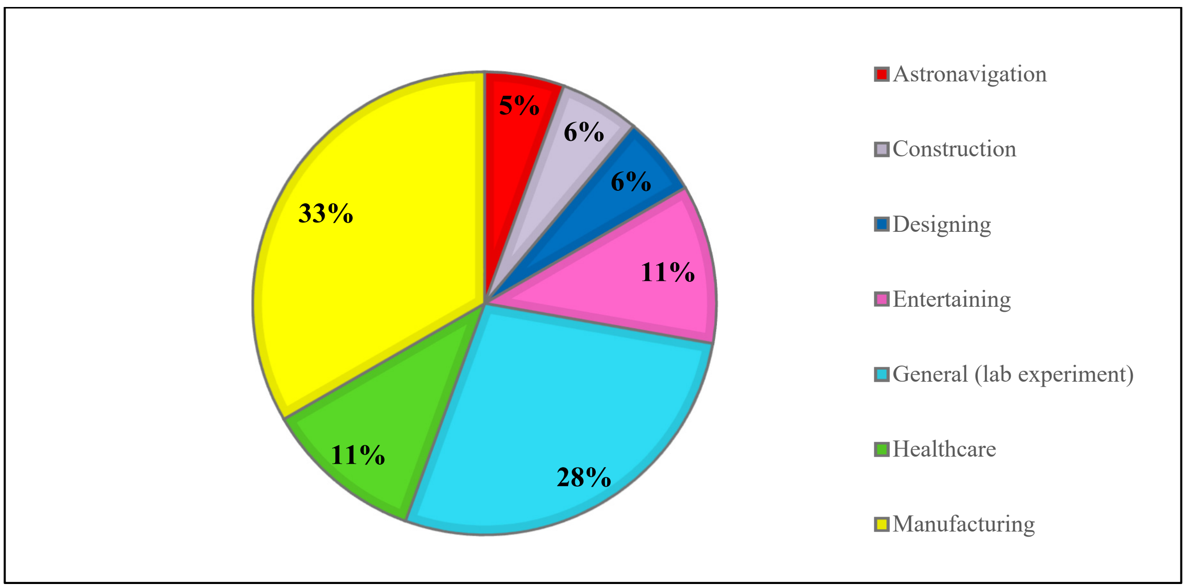

Figure 1.1 The percentage of documented Occupational Health and Safety (OHS) risks of wearables according to areas of application

Table 1.3 Summary of the literature review for the use of wearables for investigating OHS risks

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result
(Draicchio et al., 2012)	Using surface electromyography and a data glove to analyze surgeons' ergonomic during laparoendoscopic surgery	A data glove	Health care	The method of surgery has some challenges like the reduction of movement, triangulation loss, and also applying more workload while surgical performance reduces.
(Vignais et al., 2013)	Using wearable sensors to introduce an innovative system that provides real-time ergonomics feedback	Armbands Wrist bands A sensor on the head	Manufacturing	The real-time feedback can help to decrease the risk of musculoskeletal disorders and also optimize worker's performance
(Rashedi et al., 2014)	Using wearable sensors for ergonomic evaluation of overhead work	An exoskeletal vest A mechanical arm	General (lab experiment)	The vest can be used for reducing the physical demand for overhead work although more studies need to propose better alternative designs
(Reinvee et Jansen, 2014)	Developing and using a sensor glove to assess the pressure on the handle-hand interface (working with a screwdriver)	A sensor glove	Manufacturing	Although the experiment shows the amount of force through fingers and palm on the tool, it needs more study to assess accuracy in the curved space of the hand.
(Caputo et al., 2016)	Tracking the upper body of a worker in real-time	4 wearable sensors in the wrist, elbow, shoulder, and glasses of workers	Manufacturing	Results help to improve the feeling of comfort, safety, as well as productivity of workers while doing their duties.
(Peppoloni et al., 2016)	Using wearables for conducting a real-time assessment of muscular effort of the upper limb	Wearable sensors on arm, elbow, wrist, and palm	Manufacturing	Work-related Musculoskeletal Disorders (WMSD) can be assessed online via sensors
(Lee et al., 2017b)	Investigating the location of sensors on the trunk posture analysis in construction tasks	2 sensors that have been placed in 8 spots of a worker's body including armpit, chest, head, shoulder, chest near to neck, center waist, side waist, back waist, back	Construction	According to findings, the selected area in the study (introduced in wearable type column) are the most acceptable places from the point of view of workers that need to be protected.

Table 1.3 Summary of the literature review for the use of wearables for investigating OHS risks (Continued)

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result
(Nath, Akhavian et Behzadan, 2017)	Using wearables to assess the risk of some construction postures	2 sensors on the arm and waist of a worker	Construction	The methodology can help to assess the ergonomic risk of some manual tasks on workers and the methodology can be used for other industries in which some awkward postures are needed to perform some of their tasks.
(Parker et al., 2017)	Assessing the firefighters' tasks in extreme condition	A wearable camera on a helmet GPS on shoulder Heart rate monitor under firefighter's shirt	Firefighting	Measuring firefighters physiological workload can be collected easily
(Zhao et al., 2017)	Using wearables for monitoring patients' health and propose a model for risk assessment	Different kinds of wearables for different patients	Health care	Using a model, data can be monitored well to assess patients' risk factors
(Mijović et al., 2017)	Wearable electroencephalography (EEG) has been used to assess the workers' attention	Head wearable	Manufacturing	Real-time response to workers' attention can lead to fewer accidents, workers' injuries and material waste
(Maman et al., 2017)	Using wearable sensors to detect the physical fatigue during working and estimate physical fatigue level by heart rate, acceleration and inclination angles, the variability of movement, duration, and repetition of movements.	Right ankle right wrist hip torso	Manufacturing	Modeling of fatigue considering the nature of work and wrist, torso sensors have had the most contribution in detecting fatigue
(Lee et al., 2017a)	3 wearable sensors on the chest were used to control heart rate of workers in construction activity. In addition, a wearable sensor (ActiGraph GT9X Unit which is able to process accelerometer data) on their non-dominant wrist were used to estimate energy expenditure, on-duty and off-duty physical activity levels, metabolic equivalence, and sleep quality of workers	Wearable sensor on chest Wearable sensor on wrist	Construction	The workers articulated that the sensors in their wrist are much preferred than sensors on their chest. They usually had some unfavorable response to comfort, weight, and usage of those sensors on the chest. Using these sensors provides explanation of how physiological reactions of a worker can influence on his/her safety, performance, also job demands.

Table 1.3 Summary of the literature review for the use of wearables for investigating OHS risks (Continued)

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result
(Ranavolo et al., 2018)	Review the implementation of wearables to prevent biomechanical risk (musculoskeletal disorders)	Different kinds of wearables	Different industries	There are a few studies that consider the use of wearables for biomechanical risk assessment.
(Selvaraj et al., 2018)	Using wearable sensors to predict the risk of stairs fall in older people	A sensor shoe	Health care	Using these kinds of sensors helps in the prediction of fall risks.
(Tsao, Ma et Papp, 2018)	Using wearable sensors to propose a method for estimating fatigue level by analyzing bioindicators (electrodermal activity, photo-plethysmography, and respiration)	A belt around the breast for measuring respiration A sensor attached on the ear for measuring blood volume pulse and heart rate Electrodes on the neck and left shoulder to track the activation level of a worker	Manufacturing	Using the regression model (individualized and universal models) can estimate the fatigue level although in this experiment individual model shows better results
(Raso et al., 2018)	Using wearable sensors and software based on machine learning to track operations at work to identify inconvenient behavior and processes from the OHS aspect	A shirt with some sensors	Manufacturing (automobile)	Data from sensors provide information about the process (to optimize it)and OHS related risks (to mitigate it).
(Szymczyk et Skulimowski, 2019)	Humans' behavior (by measuring heartbeat, involuntary hand and body movement, walking, body temperature, skin moisture) toward using new technology (Virtual Reality (VR)) were examined.	Different sensors to collect data data gloves cameras	General (lab experiment)	Using different kinds of sensors and tools helps to have a lot of related data. Also during the test participant did not comment about discontinuities and no disturbance was detected among recorded signals from sensors.

Table 1.3 Summary of the literature review for the use of wearables for investigating OHS risks (Continued)

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result
(Ahn et al., 2019)	An overview of the application of wearables to measure kinematics, cardiac activity, skin response, muscle engagement, eye movement, and brain activity is provided.	Wearable sensors for eye tracking, chest, arm.	Construction	Wearables are useful for preventing musculoskeletal disorders and falls, measuring physical workload and fatigue and monitoring workers mental. However challenges and risks such as users' resistance should be considered.
(Hajifar et al., 2021)	The application of time series for forecasting rates of perceived exertion	Sensor around shank	Lab experiment	Data from wearables can be a good source of data collection for providing data for a proper prediction.

Among 38 papers that have been investigated, 20 of them use wearables to assess OHS risk parameters both physically and psychologically like fatigue (modeling and estimating fatigue levels), the posture of the body while performing a task, musculoskeletal disorders, and human behavior. Data gloves have been used only in 3 papers to measure the OHS risk.

1.2.3 Literature review of the operational risks

In addition to the OHS risk, operational risks of wearable (especially data gloves) according to the research methodology discussed earlier (Section 1.2.1) have been extracted and studied. The results according to our research methodology are as follows:

Table 1.4 Summary of the literature review (the documented operational risks of the use of wearables)

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result	Operational risk
(Dorsey et Siewiorek, 2002)	Presenting 245 wearable design defects including electronics, manufacturing, software, mechanics, and general during the six years in four-phase design, bring up, integration and operation.	Spot wearable computer	General	About half of the mechanical defects can be found in the operation phase and near half of the defects occur in the operation phase.	Different risks that emerge during the use of wearables
(Stiefmeier et al., 2008)	Using wearable sensors for training in car assembly line workers	Sensor glove Sensor jacket	Manufacturing	Embedded sensors in standard workers' clothes will not obstruct their activity sensing	Obstructing the workers' sensing
(Kukliński et al., 2014)	Comparing two modes of teleoperation of a robot by using data gloves and a control object (peg)	A data glove A control object (peg)	Manufacturing (assembly)	Using control object (peg) leads to fewer errors in comparison to using data glove also performing different assembly tasks take less time while using a control object (peg) in comparison to using data gloves.	- Increasing the number of errors while doing tasks - Increasing cycle time
(Seref et Bostanci, 2016)	Opportunities and challenges of medical wearables especially with processing big data	Medical wearables	Healthcare and Medical	Development in big data can affect development in wearables and solve the challenges.	Processing of data from wearables
(Nakai, Maekawa et Namioka, 2016)	Measuring cycle time by using wearable sensors	Different sensors attached to the worker's body	Manufacturing (assembly)	By measuring each process through wearable sensors and machine learning, the cycle time of assembly can be measured automatically by using predefined standards, so, the reduction of the installation cost of the work management would be possible.	Cycle time
(Carlson, Vance et Berg, 2016)	Presenting the effectiveness of two kinds of bimanual interaction for assembly in a virtual environment by measuring the time for assembling	A haptic/non-haptic Omni A 5DT data glove	Manufacturing assembly	There is no considerable difference in the time of completion of work in 5 states of using a data glove and haptic/non-haptic Phantom Omni Near half of the participants, prefer the combination of using both haptic and data gloves for assembly in the virtual system.	Increasing cycle time

Table 1.4 Summary of the literature review (the documented operational risks of the use of wearables) (Continued)

Author(s) & Year	Main Objective	Wearable Type	Area of Application	Result	Operational risk
(Kohani et al., 2017)	Evaluating electrostatic discharge (ESD) events in medical wearables at 5 different voltages from 2-10 KV	Medical wearable	Healthcare and Medical	ESD during usage can jeopardize patients' health so using only IEC 6100-4-2 standard for checking the qualifying is not enough.	Electrostatic discharge of wearable
(Zheng et al., 2018)	Designing a force-feedback glove that provides immersive sensation for using in virtual reality systems	Data glove	General (lab experiment)	The designed glove can be used as an interface in virtual reality but there are some improvements. Controlling the accuracy of magnitude of the force perpendicular on the user's finger that may cause an error in real feedback is difficult and need to add more sensors. The designed glove is not usable for each kind of hand size.	Errors in feedback
(Vedant, Krugh et Mears, 2019)	To detect the defect that may cause during the assembly processes, the performance of hands in assembly will be assessed.	Data glove	Manufacturing (Assembly)	Since in the real situation of assembly, the noise in the environment causes mishearing or wrong hearing of feedback like click noise, some smart wearables can be used to reduce the defect during operations. If the placement of sensors is not appropriate, or the workers use their fingers in a way that had not been predicted, the receiving feedback may not be real and cause defects.	Making defect due to wrong feedback
(König et al., 2019)	The application of augmented reality in assembly using a data glove and AR glasses	A data glove AR glasses	Manufacturing (assembly)-Lab experiment	The AR and new technologies in the context of industry 4.0, can assist assembly and learning of the process of assembly as well as documenting different assembly steps. In addition, workers can communicate with this technology through gesture and voice.	The number of assembly errors

Applying the search methodology discussed earlier, we could find 10 papers that investigated operational risks of the use of wearables. Figure 1.2 shows the percentage of documented operational risks of wearables according to areas of application. Some operational risks like increasing cycle time and errors, electrostatic discharge of wearables, processing of data from wearable are studied. Among 10 studies, the number of papers that have considered the operational risk of data gloves is 6 (underlined).

Considering the limited number of papers related to the operational risk of the use of data gloves, it is necessary to consider the operational risk of using data gloves in manufacturing.

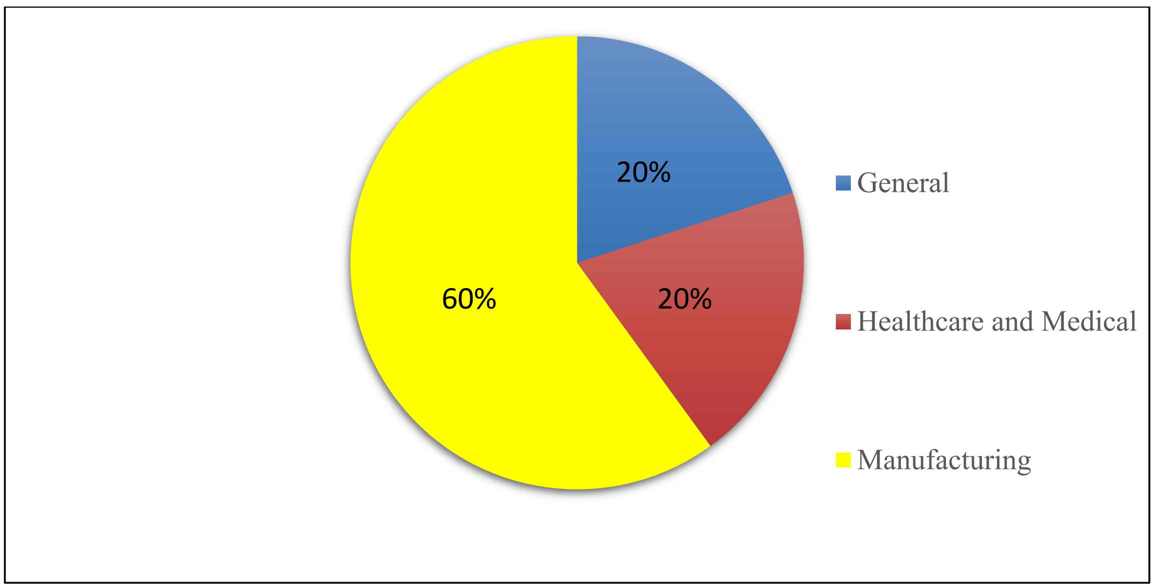

Figure 1.2 The percentage of documented operational risks of wearables according to areas of application

A comparison of documented OHS and Operational risks of the use of wearables according to the area of application is presented in figure 1.3.

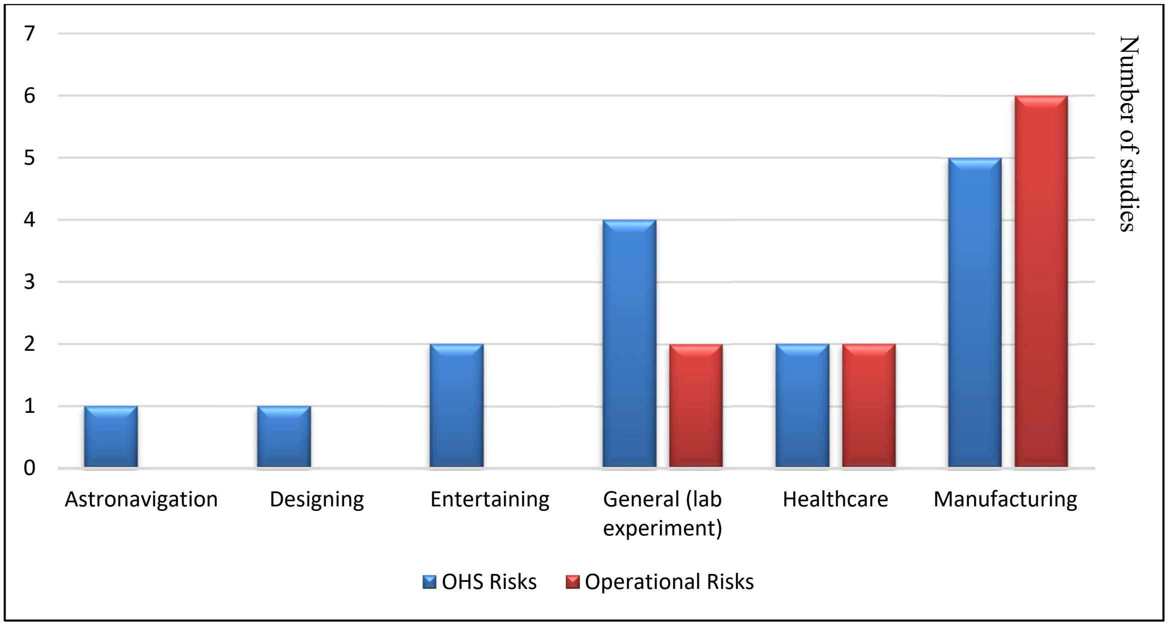

Figure 1.3 A comparison of documented OHS and Operational risks of the use of wearables according to the area of application

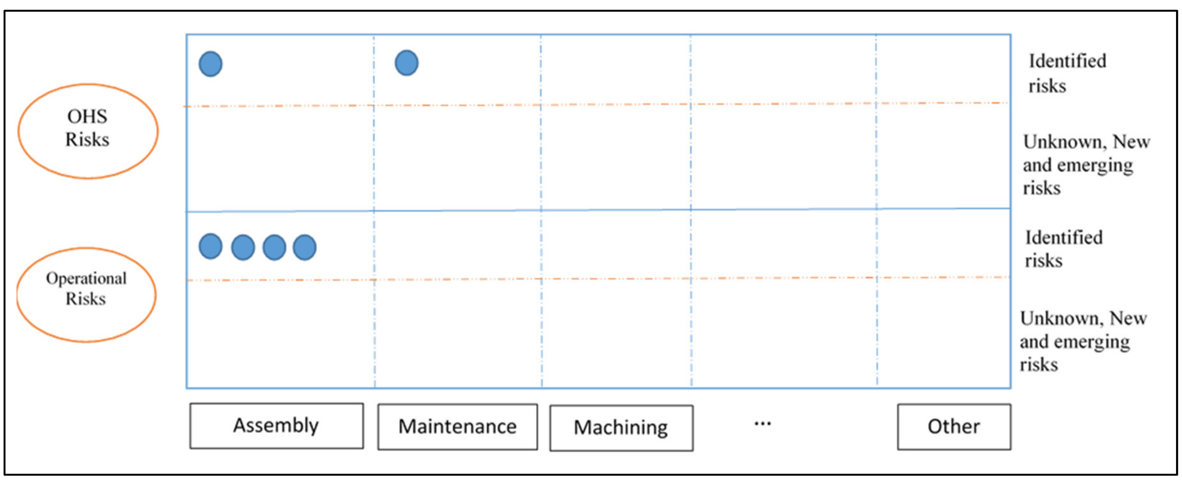

Figure 1.4 The overview of the study (family picture) in the manufacturing field

Each blue circle shows one risk that has been identified in studies that use wearables in the manufacturing sector. As we can see in the picture, there are many OHS and operational risks that need to be identified. Then, we need to find a way to mitigate or prevent them.

Most researches investigated the micro ergonomic risks of the use of wearables while there is limited number of studies that investigated OHS and operational risks of the application of wearables as an emerging technology from the perspective of macro analysis of the system. An approach that is able to assist analysts in identifying or predicting remaining risks and systems behavior have not been discussed in the literature.

CHAPTER 2

OBJECTIVES AND RESEARCH METHODOLOGY

2.1 Research questions

As discussed in the first chapter, few studies have considered OHS and operational risks of the use of data gloves in manufacturing. Considering the increasing use of data gloves (Dipietro, Sabatini et Dario, 2008), it is necessary to pay more attention to occupational health and safety as well as operational concerns while using data gloves in manufacturing. In order to develop an approach to risk management for the use of data gloves in manufacturing (especially in assembly), in this study, we are looking for appropriate answers to the following questions:

1. What are the OHS and operational risks when a data glove is used in manufacturing (assembly)?
2. How can we possibly identify, analyze and categorize those risks that have not been documented yet in the literature?
3. What is the appropriate systemic method to manage risks of the introduction of data gloves to assembly 4.0 context?

Answering these questions, eventually will help developing a risk management approach for the use of data gloves in assembly.

However, manufacturing is vast and different kind of data gloves available (Caeiro-Rodríguez et al., 2021). Our research is limited to a specific kind of data glove (Virtual Motion VGM30) that has been used in assembly (specific assembly case studies) to find more precise answers. It should be noted that, we are studying OHS and operational risks from the perspective of risk management. In other words, the main focus of this project is not ergonomics/human factors per se.

2.2 Objectives

Since the use of data gloves in manufacturing is growing (Dipietro, Sabatini et Dario, 2008), a lot of knowledge areas of this application are unknown and need more research. Considering the importance of workers' safety, the use of data gloves cannot be successful unless there is enough consideration as well as examined methods for dealing with hazards and risks related to workers integrated to operational risks in the context of industry 4.0.

To address the above-mentioned questions, the main objective of conducting this project is to propose an approach to managing the OHS and operational risks of the use of data gloves in assembly. To realize our objective, the specific listed objectives as follows have been considered:

1. To identify OHS and operational risks for using data gloves in assembly, categorize and analyze them through the application of Functional Resonance Analysis Method (FRAM) to the specific case study. The application of this method will eventually help present a network of risks and address the issues, limitations and safety concerns for the application of such technology.
2. To identify, analyze, and categorize OHS and operational risks of the use of data gloves in assembly through the application of System-Theoretic Accident Model and Processes (STAMP) to the specific case study. This application will eventually present an analysis of the system in the form of tables of safety constraints, unsafe control actions, and loss scenarios that can provide recommendations for managing risk and designing the system.
3. Finally, to compare the result of the application of FRAM and STAMP on specific case studies to see which one of them is more capable and efficient in risk analysis. This shall help propose a novel risk management method to analyze the risks of using data gloves in the assembly according to the findings of objectives 1 and 2 and their comparison. As discussed before, besides known risks, there are possibly some new and emerging risks when data gloves are used in assembly tasks. (Brocal et al., 2019b; Fernández et Pérez, 2015). Dealing with these risks needs a novel method that can appropriately analyze OHS and operational risks in the assembly 4.0 context. This novel method can be an improvement of one of the two applied methods, their integration or a new method that is completely different from the two mentioned methods.

However, the results of the application of FRAM and STAMP in chapters 3, 4 concluded that an integrated FRAM/STPA would be suitable for the specific case studies in this research. The general structure of the research is presented below.

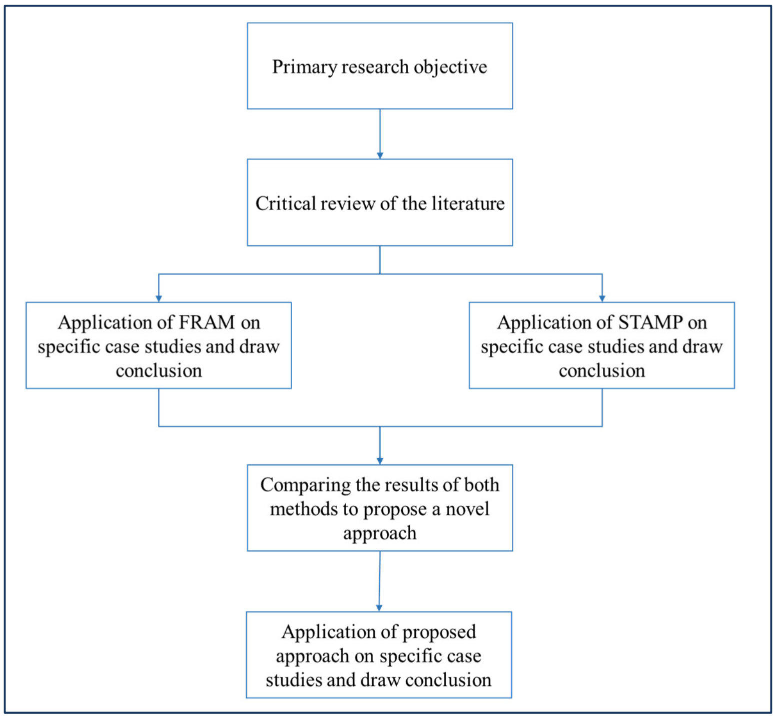

Figure 2.1 Structure of the research methodology

2.3 Introduction to complexity

In order to realize the research's objectives, it is necessary to have a good understanding of the studied system. Therefore, a review of simple and complex systems and brief specifications of two system types will be provided first. Then, a description of case studies' scenarios will be provided. Regarding the systems' specifications, the reflection on choosing FRAM and STAMP as appropriate methods for the research will be discussed.

2.3.1 Simple and complex systems

Simple system

A simple system consists of a small number of components. It has the following characteristics:

1. There are a single cause and a single effect.
2. Effects are directly related to causes. A small change in the cause can bring about a small effect.
3. Predictability (Érdi, 2007).

A problem is “simple” when we can identify a single cause and a single effect (Érdi, 2007).

Complex system

A large number of components that interact to perform a function cohesively is called a complex system (Bodenschatz, 2009). A complex system has the following characteristics:

1. Logical Paradoxes: Paradoxes are the deviation between the expected and the actual behaviours of the system. It usually happens due to a false assumption. It means an observer's opinion may oscillate between a "true" and a "false" value (Érdi, 2007).
2. Feedback: Despite simple systems (there is one cause and one effect), at least one effect feeds back into its cause. Most systems around us are complex. For instance, biological cells, business relationships, ecological networks, organizational relationships, etc. (Érdi, 2007; Ladyman, Lambert et Wiesner, 2013).
3. Nonlinearity: When self-amplification is greater than the threshold due to unbalanced positive feedback, finite-time singularities will increase exponentially. In other words, variables tend to have value during a finite time in such systems. For example, in a chemical system, this tendency leads to an explosion, and in a business system (stock price), it cannot go up unlimitedly forever. Not only the nature of the process is unstable, but a compensatory process will also follow it. It means that in a complex system, a small change in the system's initial condition can cause a very considerable effect on the system (the so-called butterfly effect). (Érdi, 2007; Ladyman, Lambert et Wiesner, 2013).

4. Emergence: Complex systems may react in a collective phenomenon that sometimes is not easy to predict based on the behaviour of single constituents. Therefore, chaos might emerge due to the interaction of different system constituents in a specific condition (Érdi, 2007; Ladyman, Lambert et Wiesner, 2013).
5. Distributed systems: Complex systems are distributed. Their structure can be widespread. Moreover, the resources that are required for the function of the system can be distributed within a large area (Pavard et Dugdale, 2006).
6. Lack of central control: In a complex system, the components of the system will be controlled by more than one component of the system. It means that a malfunction cannot significantly affect the performance of a complex system compared to a system with central control. In a system with central control, a failure in the central control can make the system vulnerable (Ladyman, Lambert et Wiesner, 2013).
7. Hierarchical organization: In a complex system, there are different levels of the organization. They create a system, and we call them subsystems. These subsystems interact with each other for the system's performance.

It should be noted that each of these characteristics solely is not sufficient to consider a system as a complex system. A combination of different discussed characteristics can cause to consider a system as a complex system (Ladyman, Lambert et Wiesner, 2013).

2.3.2 Sociotechnical systems

The sociotechnical systems are systems with both social and technical components (Hettinger et al., 2015). The social aspect concerns the human factors from both individuals (workers' characteristics) and organizational perspectives (work environment, the organization's structure, policies, etc). On the other hand, the technical aspect includes different technical subjects that are required for the systemic function execution such as tools, resources, devices, and any other (Hettinger et al., 2015). A sociotechnical system includes hardware and software technologies, humans and organization of humans and these components interact with each other (Günebak et al., 2016). Regarding the above-mentioned characteristics of sociotechnical systems, it can be inferred that the concept of the sociotechnical system can extend to different complex systems in the world. For example, systems such as economy, manufacturing, healthcare, education, etc. could be considered as sociotechnical systems (Carayon, 2006; Hettinger et al., 2015).

The interactions among different components of a system also between the system as a whole and its environment can show its failure or the success (Carayon et al., 2015). Therefore, it is necessary to pay attention to both the human and technical factors together for any design or assessment approach (Baxter et Sommerville, 2011; Hughes et al., 2017). Meaning that, from sociotechnical resilience orientation's view point, humans should be treated as a system's component that interact with technical components, not considering them in isolation. Therefore, information is collected and integrated at a system level to study events under working conditions (either a normal or an accident condition) (Patriarca et al., 2018).

2.4 Designing case studies

This study aims to analyze OHS and operational risks of the introduction of a data glove as a smart wearable to the assembly system. Therefore, realistic case studies are designed for this purpose. The data glove that will be used in realistic case studies is a data glove model VMG30 produced by Virtual Motion Lab (VML). This data glove has 30 sensors, including bending sensors and pressure sensors (https://www.virtualmotionlabs.com/vr-gloves/vmg-30/).

The sensors include:

- Thin bend sensors (less than 0.35mm thickness).
- 12 bit ADC sampling for accurate bend detection.
- 2 Sensors per finger.
- 4 Abduction (spread) sensors.
- 1 Palm arch sensor.
- 1 Thumb crossover sensor.
- 5 Pressure sensors, very thin: less than 0.35 thickness.
- Complete 9-DOF orientation sensors (roll, pitch and yaw) for hand orientation and wrist orientation; the sensors mount a 3 axis gyroscope, a 3 axis accelerometer and a 3 axis magnetometer.

The data glove is in first stags of Technology Readiness Level (TRL) (the concept design) (Straub, 2015), therefore realistic case studies are simulated to help in generating data for modeling, and there is no lab experiment with human participants.

Figure 2.2 The data glove used in the study

2.4.1 Case study 1: Using a data glove for assembling connectors

This scenario is related to the assembly of connectors, which was studied by Kucukoglu et al. 2018 (Kucukoglu et al., 2018). Connectors are electrical parts that are used in car manufacturing. The connectors with wire are usually used during the assembly processes (Kucukoglu et al., 2018). A disassembled connector with its parts of the connector is presented in figure 2.2.

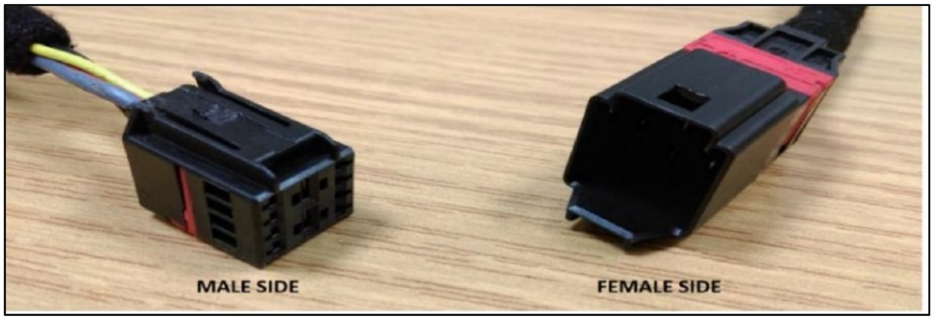

Figure 2.3 Parts of a connector[1]

In the operations of the assembling connector, the worker should place the male side (which has the clip) into the female side (with slots). When the cable is correctly placed, a clicking noise and a slight vibration occur. Figure 2.3 presents two different status that shows if the connector is inserted correctly or not.

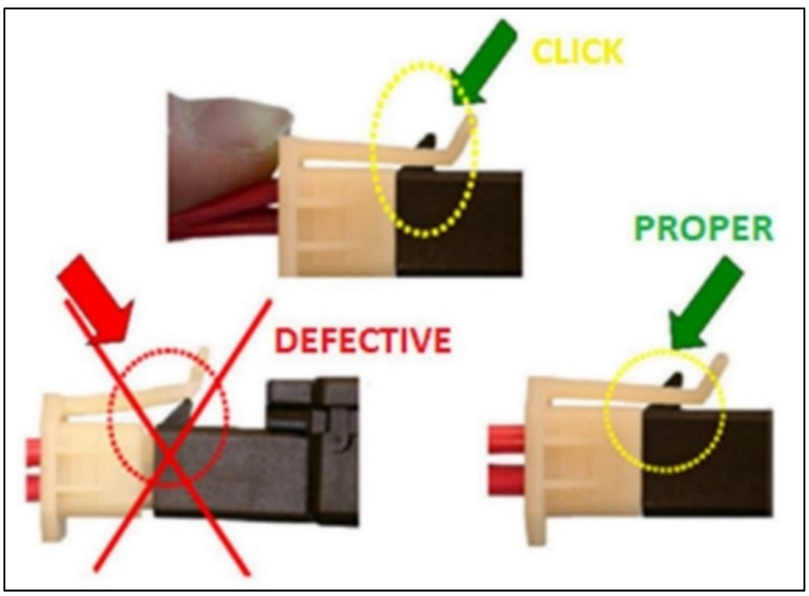

Figure 2.4 A connector in two states of correct and incorrect assembly[2]

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[1] Source of the figure: Kucukoglu et al. (2018)
[2] Source of the figure: Kucukoglu et al. (2018)

Due to environmental noise during production, the speed of the conveyor, notable assembly load, and insensitivity of fingers that hold the connector because of performing routine operations (Kucukoglu et al., 2018), the noise and vibration might not be detected during the assembly process. Therefore, workers mostly cannot be sure if the connector is correctly inserted into the plug or not (Kucukoglu et al., 2018).

In our realistic case study, a connector and a conveyor (Figure 2.4) will be used to simulate the condition of the assembly in a company.

The following items will be used in the first case study:

1. A connector (male and female parts)
2. A conveyor that connector will be carried through it
3. A data glove

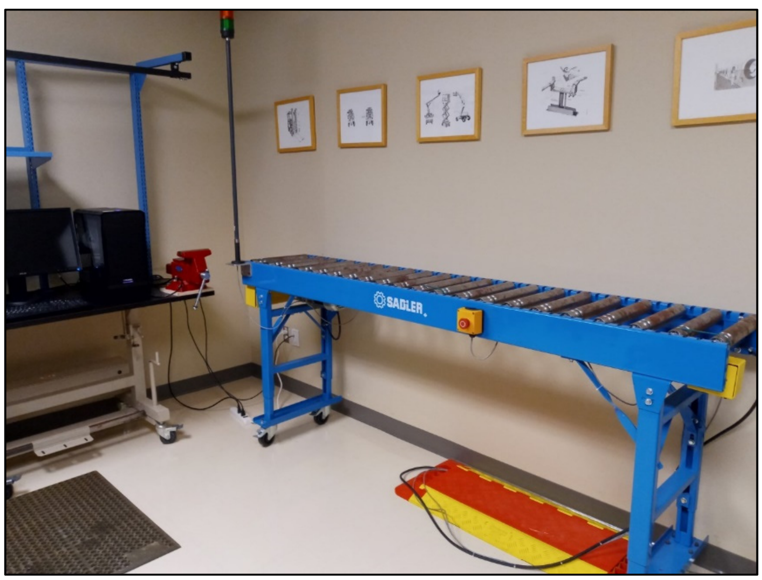

Figure 2.5 Conveyor for carrying connectors (before machine safety improvements)

The worker with the data glove on his/her dominant hand and another hand uncovered will do the assembly task. A conveyor will be used to move the connectors between stations. The conveyor is equipped with an emergency stop button that controls the on/off of the conveyor and a receiver that controls the speed of the conveyor according to the speed of the worker's hand when he/she takes/puts the connector. The sensors in the data glove can detect the position of the hand in taking and putting the connector and send data to a receiver. Analyzing data provides real-time feedback for the receiver of the conveyor to control the speed of the conveyor. Therefore, the technology can be adapted to every specific worker's speed to provide a more ergonomic situation for humans. It should be noted that the standard speed of assembly and conveyor are defined (through known methods like time study, MTM, MOST, and work study) and it can be deviated (higher or lower to the standard time) as much as has been allowed in the programming. Moreover, a supervisor who is responsible for managing some workers in the assembly process can communicate with them through a screen (Hao et Helo, 2017). The data from the data glove can also be used for the next assembly station (Guo et al., 2020a). The data sent from the data glove also can affect the resource provision since the number of assembled items and the rate of assembly is calculated based on received data. Considering the analyzed data from the data glove, the supply department will decide to place orders for supplying raw materials at the right time (Guo et al., 2020a). The worker will take the male part with the dominant hand and the female part with the bare hand and assemble together. The upper side of the male part will be pushed by the thumb of the dominant hand until hearing the click noise. When the worker puts the connector on the conveyor, the assembly process will be finished. The worker has been trained on using the data glove and communicating with the screens in the assembly station (Xu et al., 2014).

In this case, the use of data gloves for pushing the upper side of the male part and sensing vibration will be analyzed. The effect of data gloves on the speed of assembly, the received feedback from the data glove, the effect of the data glove's feedback on the speed of the conveyor and the received feedback of a supervisor, and the effect on the worker's hand, especially on the thumb, will be simulated.

2.4.2 Case study 2: Using a data glove for detecting the right component

In this case, a data glove will be used for assembling complex devices, or devices that have lots of similar components for assembly (Saarland University, 2019), or for bulky or fragile products that need to be assembled in a fixed position (Guo et al., 2020a). During the process of assembly, a worker might find that has assembled wrong components or in a wrong place.

So, the worker has to take apart assembled components. Reworks will lead to an increase in cycle time and in consequence, delays in production. In a study by Stefan Seelecke's team at Saarland University (Saarland University, 2019), the use of a data glove was proposed to solve the problem. By using the data glove, sensors of the glove will send data of the bending angles of fingers to recognize the component. Or, if a wrong component is taken from the storage bin, vibration feedback in the glove will alert the worker (Figure 2.6). Therefore, personalized assistance will be provided by the data glove (Saarland University, 2019). If the worker wears smart glasses, data about the object will be sent to the smart glasses through the data glove. Therefore, the worker will be able to detect the right place for assembling the object in the screen of the smart glasses (Hao et Helo, 2017; Kong et al., 2019; Pierdicca et al., 2017; Robertson et al., 2018). Smart glasses and a microphone is provided for the worker to communicate with a support department and ask for guidance when one faces a problem during assembly (Hao et Helo, 2017; Kong et al., 2019). The data glove and the smart glasses send information about the component and tools for assembly to the support team (Kong et al., 2019). In this case study, the worker works in a fixed-position assembly place that we call Assembly Island. The island can be in a different city or even in a different country or in a different time zone (wide countries like Canada, the US, China, Russia) (Guo et al., 2020a). The data glove and smart glasses provide data about accomplished tasks, worker's productivity, the rate of the use of raw materials, and etc. Therefore, logistic planning, instructions for monitoring workers in islands, managerial decisions for allocating resources for providing raw materials and collecting accomplished tasks from islands, a supervisor who is responsible for supervising some islands is one of the system components.

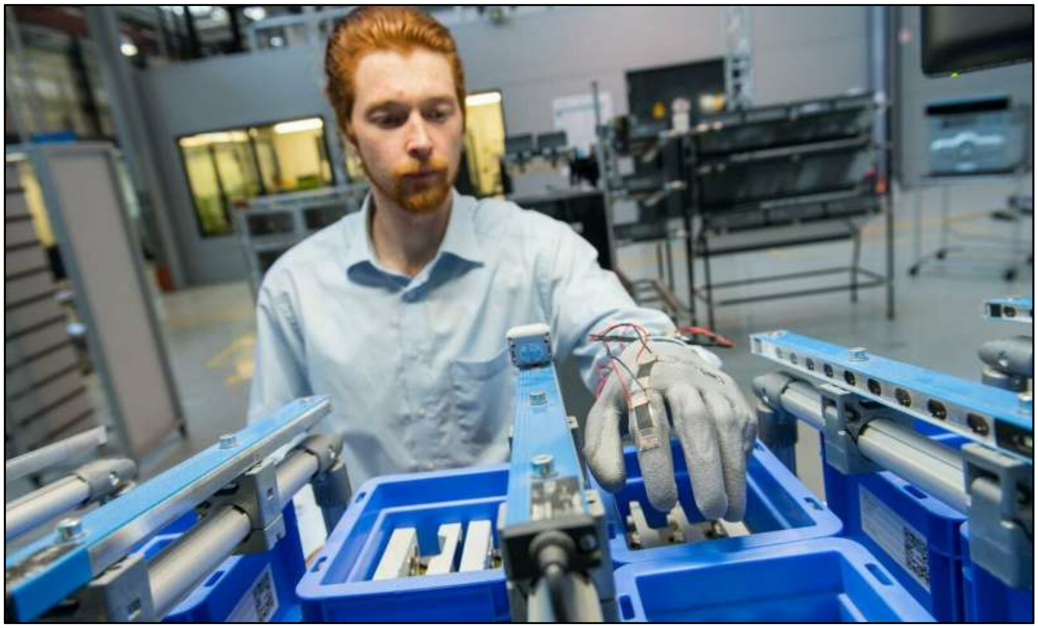

Figure 2.6 Using data glove for taking the right component[3]

As discussed earlier, the angle of fingers in grasping components is the key data to detect the assembly components. Therefore, in our case study, we are going to simulate taking components from the storage bin.

In this study, the following items will be used:

1. A data glove
2. Some storage bins that contain objects
3. A smart glass

[3] Source of the figure: Smart glove for Industry 4.0: Connecting the physical hand to the virtual world (2019)

Figure 2.7 The smart glasses used in this study

The worker will take an object from the storage bin. If the right object is taken, the worker will put it on the assembly desk at its predetermined place. Otherwise, the object will be returned to the storage bin. The effect of data gloves on gripping objects, such as required force to grip them, the effect on the operation, and possible defects, will be analyzed. Moreover, the effect of data gloves on the other components of the studied system (discussed earlier) will be considered.

2.5 Methodology

The studied system is a complex system. The following elaborates why the system is considered as a complex system. In the system that we are analyzing, there are humans, a device (a data glove) equipped with sensors and provides data and feedback, and it is used for assembly tasks. For a proper system working, the data glove, the worker, the other tools, different organizational departments should work well together (*hierarchical organization*). It means the sensors should be in the right place, and the connection between the receiver and sensor should be well enough to transfer data and provide real-time feedback for the worker (*feedback*). In addition, the worker needs to work in the right situation (ergonomic considerations, including psychological and physical) according to the type of work. The relationship between the components of this system is nonlinear because it can affect the system in a nonlinearity manner. For instance, in the studied system, the worker may push the button on the connector but in the wrong place, the amount of force is enough so the sensor may send the feedback and insure the worker that the performed task is OK. Therefore, the number of nonconformities will increase while the data received from the gloves cannot show it and the incompatible output will go up nonlinearily. Or a delay in providing of materials will increase the production time considerably (*nonlinearity*). Moreover, there is not a central control for the orders in the system. Some orders are given by workers, some by feedback from the receiver, and some by sensors of the glove, and some orders and feedback come from other organizational departments such as resource provision, training, etc. These are examples of *robustness and lack of central control* in the studied system. As discussed before, data gloves are an emerging technology; their use can cause new and emerging risks (*emergence*). In the studied system, many components are not the same types. For example, a new technology (data glove) connected to a receiver via sensors, a human as a worker, assembly tools such as a screwdriver, fixture, and assembly components (connector, nuts, bolts, etc.) meaning that they are *heterogeneous* (Günebak et al., 2016). The connection between data glove and receiver via sensors plays a significant role in the assembly process since the received feedback from the glove affects the next behaviour and actions of the worker as well as the quality of the assembly process (*coupling*) (Günebak et al., 2016).

Different studies articulated some properties that are associated with the complex system idea, including nonlinearity, feedback, lack of central control, emergence, hierarchical organization (Ladyman, Lambert et Wiesner, 2013), heterogenous, coupling (Günebak et al., 2016). Besides, industries have become dramatically complex during the last decades. Their complexity involves components' interactions, automation levels, the structure of processes, and the number of components (Gattola et al., 2018; Melanson et Nadeau, 2016; 2019). Therefore, regarding the complex socio-technical system characteristics (Hollnagel, 2017; Ladyman, Lambert et Wiesner, 2013), and the characteristics of assembly scenarios discussed before, we can consider the studied system as a complex (socio-technical) system. The more increasing complexity of systems, the more emerging hazards will be introduced (Leveson, 2011).

Different studies have shown that incidents usually happen under normal conditions. It means that the state of the system does not show any components failure (Hollnagel, 2018; Rosa, Haddad et de Carvalho, 2015). During work activities, transient connections that are hardly detectable can be created due to the complex dynamic nature of work. This can happen especially in systems with a large number of components including technical, human and organizational components (Soliman et Saurin, 2017). As discussed before, when the components of a sociotechnical (complex) system interact tightly, they might behave in a nonlinear manner (Soliman et Saurin, 2017). In contrast, classical risk management approaches usually analyze risks in a linear cause effect. It means classical approaches look at accidents and risks in terms of single root causes, errors or component's failure (Hollnagel, 2012).

Before we begin to model technological or human failures, we need to understand the dynamic nature of the system and performance variability. In addition, human actions should not be treated in isolation, but they need to be considered in interaction with other components of the system (Hollnagel, Hounsgaard et Colligan, 2014). The understanding of how a task goes right is a key step to understand how some tasks go wrong. Meaning that work should represent the required adjustments for a successful performance instead of showing the difference between work as done or work as imagined within the occurrence of errors and non-compliance (Hollnagel, Hounsgaard et Colligan, 2014).

The OHS management can be done in a proactive or reactive way. Reactive methods investigate previous events (accidents) and try to identify and predict risks in the future. Most of the approaches (usually classical methods) to risk management are working based on the reactive way (Melanson et Nadeau, 2019).

Following a brief overview of classical OHS operational risk analysis methods and their shortcomings in analyzing complex systems will be provided. Then, an introduction to systemic approaches will be presented. The reason for choosing systemic approaches (FRAM and STAMP) is discussed briefly. Chapter 3 (Mofidi Naeini et Nadeau, 2022a) and ANNEX IV (Mofidi Naeini et Nadeau, 2021a) provide a comprehensive explanation for this.

The classical methods such as Fault Tree Analysis (FTA) and Failure Mode and Effects Analysis (FMEA) are suitable for simple systems as their physical component's failures lead to losses. They can decompose systems to small parts and analyse each part separately not in interaction with other components (Mutlu et Altuntas, 2019). Some classical accident analyses consider the worker as the cause of the failure. This approach without considering other reasons that might attribute to accidents (failures), judges workers and represents the accidents (failures) as tasks that should have been accomplished well (Zheng et Tian, 2017). Hence, some classical methods cannot illustrate how the system components interactions, including management, organizational and humans might cause an accident (Underwood et Waterson, 2013a). Moreover, the application of classical methods such as FTA, FMEA, HAzard and OPerability study (HAZOP) has shown to be error-prone, time-consuming, and tedious (Mahajan, Bradley et Pasricha, 2017; Papadopoulos et al., 2001).

Finding an appropriate approach for measuring and assessing new and emerging hazards is imperative to prevent their occurrence or diminish their effects on both the technical and human sides (Hulme et al., 2021b). Considering the weakness of classical risk analysis methods discussed earlier, they cannot analyze the system well. In the context of industry 4.0, when interactions of humans and machines are increased, the possibility of prediction and managing risks will decrease (Adriaensen, Decré et Pintelon, 2019; Badri, Boudreau-Trudel et Souissi, 2018). Adriaensen et al demonstrated that FRAM, STAMP, and Event Analysis of Systemic Teamwork (EAST) are appropriate for risk analysis (Adriaensen, Decré et Pintelon, 2019) regarding their ability in providing a systemic view. Hence, we will use FRAM and STAMP to model our assembly scenarios.

Introducing industry 4.0 to industries, couplings and complexity will increase. The introduction of new technologies to industry 4.0 can enhance more tightening of couplings (Hollnagel et Speziali, 2008), and more nonlinear and unpredictable system's behavior that is not easy to manage (Rodríguez et Díaz, 2016). Introducing data gloves as an emerging technology to the assembly system might make a tighter coupling between components and also it might cause lower manageability of the system. Therefore, the use of FRAM and STAMP could be acceptable. The details for choosing these two approaches have been demonstrated in (Mofidi Naeini et Nadeau, 2021a; 2022a).

2.6 Functional Resonance Analysis Method (FRAM)

2.6.1 Introduction to Functional Resonance Analysis Method (FRAM)

Although the intellectual background for dynamic, nonlinear models goes back to the 1960s, the need for the use of such models was not fully recognized until several decades later. Since it was believed that when technological risks could be identified and accounted through probability methods such as Probabilistic Safety Assessment (PSA), everything would be fine. Therefore, the classical safety methods, such as Fault Tree Analysis (FTA), Failure Mode and Effects Analysis (FMEA) and hazard and operability study (HAZOP), were developed.

During those decades, the way of thinking and analyzing risks has remained on the same track until the twentieth century. At the end of the 20th century, the necessity for a new approach to socio-technical systems risk analyzing was accepted. Resilience Engineering is one of the new approaches which was proposed back then (Slim et Nadeau, 2019).

Resilience engineering has been considered in terms of safety management in different domains during the last decades. The ability of a system that enables to adjust its functioning (before, within, or following changes or disturbances) to keep the sustainability of required operations under expected or unexpected conditions is defined as resilience (Hollnagel, 2011). Resilience engineering is based on a complexity-oriented analysis of processes. It means that processes should be studied as work as done rather than work as imagined.

FRAM was introduced in 2004 by Erik Hollnagel (Hollnagel, 2004).

"*The Functional Resonance Analysis Method describes system failures (adverse events) as the outcome of functional resonance arising from the variability of normal performance*" (Hollnagel, 2012).

FRAM is a systemic model that describes interactions of a system components. It studies system activities in a normal condition, considers functional variabilities and deviations from expected performance (Hollnagel, 2004). Variabilities are a normal part of any operation. A sociotechnical system never performs as designed. Its performance varies each time depending on the working conditions, individuals and equipment (Hollnagel, 2004).

Each time that operation is performed, the performance is different. FRAM will consider the variability in performance and study how these functional variabilities might resonate together to create unwanted events (Hollnagel, 2004). In a study by Gattola and al 2018, FRAM has been used to analyze a manufacturing system in a normal condition. FRAM has shown the potential emerging events that can be positive outcomes. Manufacturing conditions are complex. The analysis can be done more precisely when the complexity is understood well, which means that the effects and consequences of changes on a system can be predicted better (Gattola et al., 2018).

This method works on four principles:

1- The equivalence of successes and failures.

Correct and fault happen fundamentally in the same way. There are not any particular reasons that only make failures. The system's ability for adapting to changes and predicting undesired events before they happen is called a success, while failure is the absence of that ability (Hollnagel, 2012).

2- Approximate adjustments

The performance of socio-technical systems is adjusted regarding the condition. The performance of humans varies in different situations due to different internal and external factors (Hollnagel, Hounsgaard et Colligan, 2014). It is necessary, ubiquitous, and unavoidable for people to have variable performance and adjust what they do to adapt to each situation. The performance of socio-technical systems is related to two factors: a) it is not possible to imagine a real condition of operation accurately in advance, b) the condition of operation is dynamic and variable. Variability is a permanent and inherent condition of the operation system. Therefore, it is necessary to make performance adjustments to face functional variability. Since the available resources (time and other resources) are limited and infinite, the adjustment will be approximate (Hollnagel, 2012).

3- Emergence

The performance variability of a single function usually cannot cause accidents or malfunctions on its own. Multiple functions may interact in an unanticipated way that finally leads to the emergence of severe and disproportionate consequences. Both success and failure as an outcome neither can be attributed nor illustrated by the system's function results. They are emergent nonlinear outcomes of the interactions of multiple functions in a system (Hollnagel, 2012).

4- The principle of functional resonance

FRAM is a systemic approach that concentrates on the relationship among different functions in a system. Functional resonance happens when the variability of the different functions in a sociotechnical system might intensify and finally lead to considerable outcomes. These outcomes usually exceed the normal limits, either positively or negatively. Outcomes that are related to safety are naturally considered as negative outcomes that might cause accidents or malfunctions (Hollnagel, 2012).

From the perspective of FRAM, accidents are investigated as what should have gone right but did not instead of looking for reasons or causes of what went wrong (Hollnagel, Hounsgaard et Colligan, 2014).

Application of FRAM method includes four steps:

1) Identifying and characterizing the functions,

2) Recognizing the variability,

3) Specifying how variability can be included,

4) Finding ways that the consequences of FRAM analysis could be applied in improving practices (Hollnagel, 2012).

Step 1: In the first step, functions that are required for performing studied work will be identified. This step aims to provide an in-detailed explanation of performing activities rather than describing it as a general task. A function in FRAM model is specified by the six different aspects that are described below:

1. Time (T): Temporal aspects can have effects on the way of accomplishing a function.
2. Input (I): an item (it can be activities, materials, documents) is used or transformed by a function to make output is called input. Input also establishes some links to upstream functions.
3. Output (O): The result of performing a function that makes the connection to downstream functions is an output.
4. Precondition (P): A function cannot be performed unless some system conditions are fulfilled before.

5. Control (C): A control arranges or supervises a function to obtain the desired output. It could be a plan, a method, procedures, instructions, rules or algorithms, or so on.
6. Resources (execution conditions) (R): What functions need to consume during functioning, such as energy, workforce, material, tools, information, and so on, is a resource. It should be mentioned that "time" can be counted as a resource. Since time has a special status in the FRAM method is treated as a separate aspect (Hollnagel, 2012).

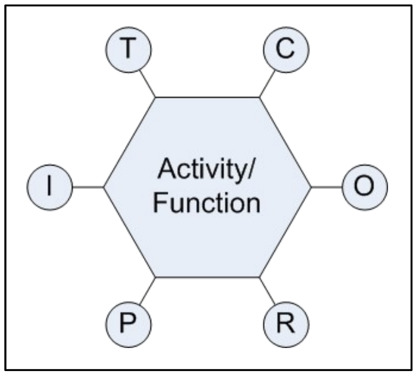

Figure 2.8 Six aspects of a function in FRAM[4]

Step 2: In this step, variabilities of different functions that form the FRAM model is specified. Variabilities include both the potential and the anticipated actual variabilities. Moreover, variability identification should be considered in both "normal" and ‘out of range" conditions (Hollnagel, 2012).

Step 3: The FRAM model represents a collection of functions and their connection with each other. An instantiation describes the existing available or probable coupling or maybe existing based on different scenarios and circumstances. The FRAM model can illustrate only the potential performance variability since it does not stand for a special situation. To predict the range of the potential performance variability, the scientific knowledge and practical experiences are used (Hollnagel, 2012).

[4] Source of the figure: Hollnagel (2012, p41)

Step 4: This step aims to provide suggestions for managing events that might happen because of uncontrolled performance variability or a possible situation of functional resonance of previous steps. If performance variability brings about negative or undesired outcomes, the goal would be preventing of occurrence of it. When the variability makes positive or desirable results, try to enhance and facilitate the possibility of results with no loss of control.

Variability in FRAM

The variability of the function itself regarding the nature of the heterogeneous functions are MTO (huMan, Technology, Organization). In addition, two different resources of variability have been introduced for each kind of function as follows (Macchi, 2010; Macchi, Hollnagel et Leonhard, 2009).

1- Technology:

Internal: the default assumption of a FRAM analysis is that technological functions are stable. However, new technologies might be variable (Hollnagel, 2018)

External: technological functions can vary because of improper maintenance. Other external factors are ambient operating conditions, particularly if they exceed the design specifications; sensor failures due to external conditions (for example, ice in Pitot tubes); overload, overspeed, excessive stress; improper use (meaning that the technology is used for a purpose different from the intended one) and so on (Hollnagel, 2012).

2- Human function:

Internal: Functions can vary because of physiological and psychological factors. Among the physiological factors, fatigue and stress (workload) are the ones that have been most thoroughly studied. Others are circadian rhythm, well-being (or illness), various physiological needs (relating to ‘input’ or ‘output’), disabilities, traits and biases, judgment heuristics, decision heuristics, problem-solving style, cognitive style, and so on. To provide a complete, or even representative list, is out of scope for the current purpose, since there are far too many details.

External: Social factors are external factors. Social factors describe what the person perceives that others expect of him/her. Others can be other humans or the organization, depending on how one looks at it. The social factors include group pressures, implicit norms, and so on, many of which overlap somewhat with organizational culture (Hollnagel, 2012).

3- Organizational:

Internal: performance from the organizational perspective can vary due to different reasons. For instance, effectiveness of communication, authority in an organization, trust, organizational memory, flexibility or inflexibility of organizational culture, and so on can affect organizational performance.

External: The operating environment is the main external source that can affect the organizational performance. The operating environment includes physical, legislative, and the business environment (Hollnagel, 2012).

In addition to the above-mentioned variabilities, variability from the perspective of time and precision is also considered when FRAM is applied (Macchi, 2010; Macchi, Hollnagel et Leonhard, 2009).

2.7 Introduction to System- Theoretic Accident Model and Processes (STAMP)

System-Theoretic Accident Model and Processes (STAMP) is a model based on systemic theory that its focus is on system safety rather than preventing failures. STAMP looks at safety as a control problem rather than a reliability issue. This method aims to find causes of an accident by identifying why they are controlled ineffectively. STAMP emphasizes control and feedback between components of the studied system (Lower, Magott et Skorupski, 2018). The STAMP accident model is constructed on three bases: 1) safety constraints, 2) hierarchical safety control structures, 3) process models (Leveson, 2011).

1- Safety constraints

After system hazards are identified, it is necessary to specify the safety level of the system. Additionally, the constraints that are required to prevent the occurrence of hazards should be designed.

2- Hierarchical safety control structures

In system theory, systems are considered hierarchical structures and each level imposes some restriction on under levels' activities. Constraints or lack of them in upper levels can permit or control the behavior of the lower levels. Control processes manage levels to reinforce lower levels in the hierarchy. If these processes cannot provide sufficient control, safety constraints are responsible for lower-levels' behavior. Generally, inadequate control can emerge from missing constraints, insufficient safety controls, inaccurate or weak execution in the lower levels, and inadequate feedback about constraints' performance.

3- Process models

Process models are a main part of the control system. To control a process, four conditions are required (Leveson, 2011). These conditions include:

1. Goal: in the STAMP model, the goal is the safety constraints that are required to be accomplished by any controller in the hierarchical safety control structure.
2. Action condition: For downward control, channels are fulfilled.
3. Observability control: It compromises upward feedback or evaluating channels.
4. Model condition: For any control, a model that represents processes of effective control is required (Leveson, 2011).

Besides system controls, human operators need an appropriate process or model to be able to control the safety of actions. The process model needs to encompass information like the essential relationship among system variables (the control laws) and the current situation. This model demonstrates the required action and improves or updates them through received feedback.

For using STAMP model, the system should include one or more of the following conditions:

1- The controller cannot execute the safety constraints model.
2- The control actions should induce related safety constraints at any level of the socio-technical control structure for the system.
3- The required control actions are done in an inappropriate time (too early or too late or stop too soon)
4- Using unsafe control actions makes an infringement of the safety constraints.
5- Although suitable control actions have been considered, they have not been followed correctly (Leveson, 2011).

Generally, the casual factors in the occurrence of an event are categorized in three classes: 1) the controller operation, 2) actuators and controlled processes' behavior, 3) controllers and decision-makers' communication.

To sum up, STAMP not only can be used in analyzing accidents but also it can help in preventing accidents and hazards by developing new or improved effective system engineering methodologies and recommendations (Goncalves Filho, Jun et Waterson, 2019). It is also applicable in improving the performance of system analyses and assists the system in behaving more efficiently and correctly in different complex situations. Finally, this method represents a different approach to risk assessment (Leveson, 2011).

Using STAMP, safety is considered as a dynamic control problem rather than preventing a failure problem. It is useful for very complex systems since it is a top-down analysis rather than a bottom-up. It includes all components of a system like software, humans, organizations, safety culture, etc. It also introduces powerful tools like STPA, CAST, STPA-sec, STECA (Leveson et Thomas, 2018).

Different approaches to using STAMP are as follows (Leveson et Thomas, 2018):

Table 2.1 Different approaches to STAMP[5]

Analysis abbreviation	Complete Name	Type of analysis
STPA	System Theoretic Process Analysis	Hazard analysis
CAST	Causal Analysis based on STamp	Accident/event analysis
STPA-sec	System Theoretic Process Analysis-Security	Hazard analysis-security focus
STECA	System Theoretic Early Concept Analysis	Safety-guided design/Hazard Identification

When STAMP is applied for hazard analysis, it is called STPA, and for accidents and incidents analysis, it is called CAST (Pricop et al., 2020).

[5] Source of the table: Leveson et Thomas (2018)

2.7.1 System-Theoretic Process Analysis (STPA)

STPA is one of the most used STAMP-based tools that is a proactive analysis. This tool analyzes the system to find the potential cause of accidents in the system. Finding potential causes can help to eliminate or control hazards (Leveson et Thomas, 2018).

The hazard analysis should include different design hazards such as software flaws, interactions of components, cognitive complex decision-making, human errors, organizational and managerial stakeholders that might have an impact on accidents (Leveson, 2011).

STPA is a model of the system and includes some "guide words" to help analysts. Since in STAMP technic, accidents are considered as a result of inadequate control, the STPA has the following characteristics (Leveson et Thomas, 2018):

1- The model used is considered as a functional control diagram.
2- The guide words are usually based on the lack of control to provide complete assurance of the analysis.
3- It can be used before the creation of design and provides the required information to guide the design proofs.
4- It can be used in any system's life cycle steps.

STPA is applied through these steps (Leveson et Thomas, 2018):

1- Identifying the possible inadequate control of a system that might bring about hazards. Inadequate control or the strict enforcement of the safety constraint results in a hazardous state.
2- Determining how potential hazardous control that has been identified in the first step can happen.

Regarding what we discussed the methodology of this research would be the following steps:

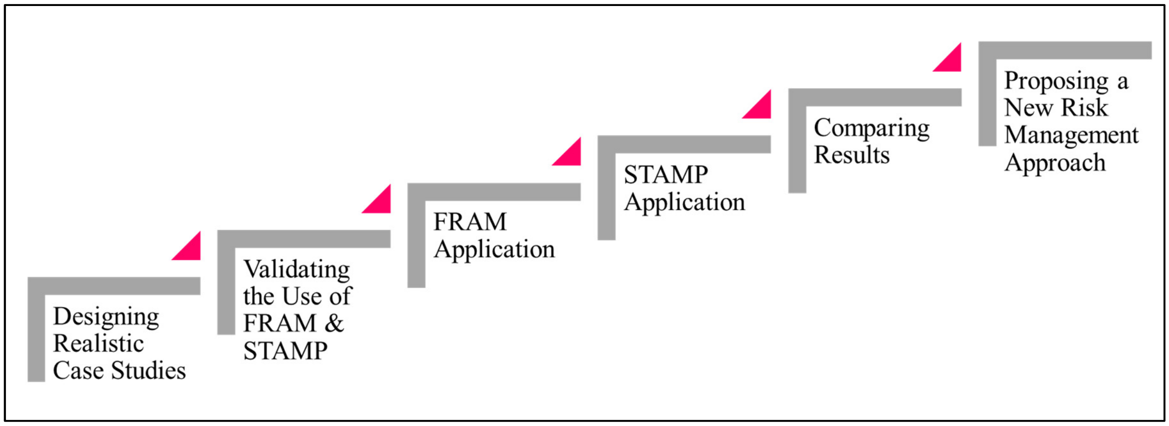

Figure 2.9 An overview of the research methodology

2.8 Assumptions

Applying two discussed methods on case studies we consider some assumptions. Firstly, we assume that workers will stay the whole working shift in the assembly islands. Meaning that transportation of workers and delays of their presence in assembly islands will not be considered as variability. In addition, smart glasess, as an emerging technology, is considered without variability to simplify the analysis of data gloves' variability on the systems behavior. Secondly, case studies happen under normal working conditions to minimize the effect of them on humans' behavior in the studied system.

CHAPTER 3

APPLICATION OF FRAM TO PERFORM RISK ANALYSIS OF THE INTRODUCTION OF A DATA GLOVE TO ASSEMBLY TASKS FRAM

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This chapter presents the paper that has been published in Robotics and Computer-Integrated Manufacturing Journal. This paper addresses the research questions and, followingly, the first objective of the study. This paper analyzed the assembly system (specific case studies) from the FRAM perspective to answer what OHS and operational risks are when a data glove is introduced to an assembly system and how to analyze and categorize them. This paper has materialized the paper's first objective for identifying and analyzing the specific case studies through the application of FRAM. The results showed that FRAM is a useful tool for understanding the system's behavior. It provides an overview of the whole system and shows how different levels could be affected by variability in system components. Regarding the review of the literature and FRAM results, the paper provided a classification of risks based on humans' interactions with technical systems, organizational systems, and information systems and the interactions of those systems with each other.

Introduction of industry 4.0 to assembly introduces a new generation of assembly called assembly 4.0. This transformation leads to some changes in the design of assembly systems. An assembly system contains three organizational levels including the strategic level, tactical level, and operational level (Dolgui, Sgarbossa et Simonetto, 2022). These levels are developed in assembly 4.0 to service layer, cognition layer, interaction layer, perception layer and assembly layer. The following figure shows the development of assembly layers in assembly 4.0.

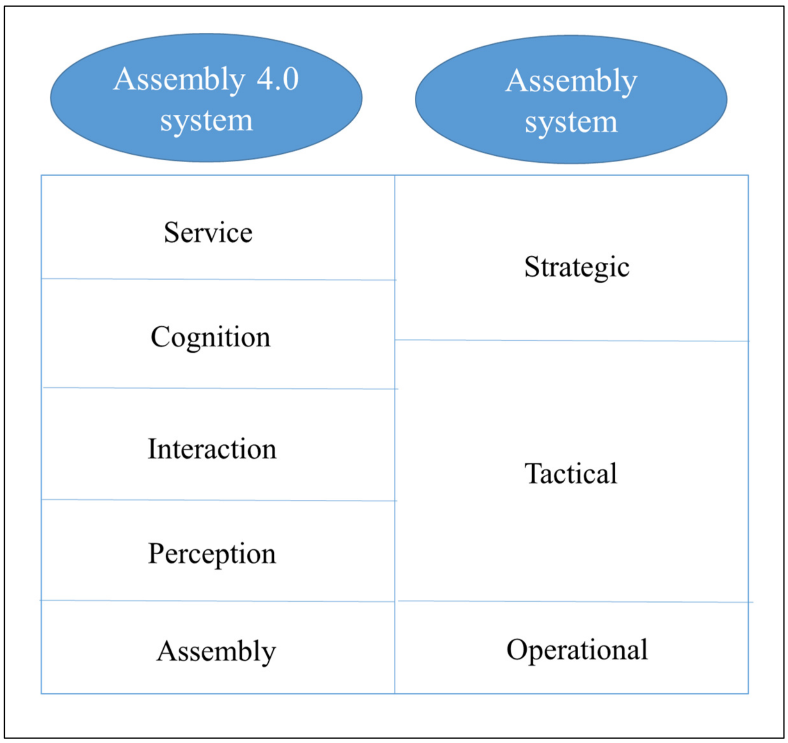

Figure 3.0 Assembly structure in industry 4.0

Abstract

The manufacturing sector is an increasingly complex operational structure. This complexity is compounded when a new technology is introduced. In the context of industry 4.0, the development of new technologies and their introduction into assembly lines will lead to emerging and new occupational health and safety (OHS) and operational risks. In this study, these risks will be assessed using the Functional Resonance Analysis Method (FRAM) on realistic case studies to provide insight into OHS and the operational risks posed by the introduction of a data glove to an assembly system. FRAM presents components of the system as human, organizational and technological functions whose interactions might lead to a risk for the system. Findings show that FRAM is an appropriate method for risk analysis of such complex systems and provides a prospective approach to design an assembly 4.0 system that interacts with a data glove. However, FRAM provides less precise and detailed results in a proactive analysis than in a reactive analysis.
Keywords: FRAM, Assembly, Data glove, OHS and Operational risk, industry 4.0

3.1 Introduction

Advancements in emerging technologies have led to a transition towards digitization, automation, and intelligence (Askarpour et al., 2019; Guo et al., 2020a). One of these emerging technologies are data gloves, which are gloves that are specially equipped with sensors (magnetic, optic, ultrasonic, and inertial) (Burdea et Coiffet, 2003). They can track the movements of fingers and the hand (Arkenbout, de Winter et Breedveld, 2015; Fahn et Sun, 2010; Gentner et Classen, 2009) or provide feedback such as haptic feedback and proprioception (Chen, Wang et Li, 2002). Regarding the growing application of data gloves in manufacturing (Dipietro, Sabatini et Dario, 2008), the associated risks of the use of a data glove while it is introduced to a system and its interactions with the other components of a system (Dorsey et Siewiorek, 2002); (Marchal et Baldwin, 2019) need to be considered. In this paper, the application of data gloves in manufacturing (assembly) and their associated occupational health and safety (OHS) and operational risks will be investigated. To the best of our knowledge, the number of studies that have considered OHS and the operational risks of wearables, especially data gloves, is very limited (Mofidi Naeni et Nadeau, 2020). The following OHS risks have been investigated from a HF/E micro ergonomics perspective (Reiman et al., 2021) in some studies: finger and hand injuries (Amick et al., 2016), the users' perception toward the use of wearables (Kuru et Erbuğ, 2013); (Sochor et al., 2019), ergonomic and physiological considerations (Knight et Baber, 2007a);(Nakanishi et Sato, 2015), the comfort of wearables (Knight et Baber, 2005); (Bodine et Gemperle, 2003), limitations regarding hand size (Zheng et al., 2018), ease of use (König et al., 2019), and potential strain (Ragu-Nathan et al., 2008). The scope of our study is focused on the macro-level. Moreover, operational risks such as discharge of wearables (Kohani et al., 2017), obstruction of the workers' senses (Stiefmeier et al., 2008), increase of cycle time and number of errors (Kukliński et al., 2014);(Carlson, Vance et Berg, 2016), and cause of defects due to incorrect feedback (Vedant, Krugh et Mears, 2019) have also been studied. To the best of our knowledge, a joint OHS and operational risks analysis on the use of a data glove in a system have not been studied and sectors introducing this type of technology could benefit from an in-depth analysis.

This paper aims to show how using FRAM to analyze the possible risks surrounding the use of a data glove in an assembly system can provide a systemic and holistic view. We will begin by discussing the reason for choosing FRAM to conduct the risk analysis by reviewing sociotechnical systems and appropriate risk analysis methods in light of the studied system. Then, FRAM will be applied to realistic case studies and the results will be presented. The suitability of FRAM for OHS and operational risk analysis as to the introduction of a data glove to the assembly system in the context of industry 4.0, and FRAM's strengths and limitations will be outlined. Finally, the usefulness of FRAM in providing a prospective approach for risk analysis of assembly systems in the context of industry 4.0 and the need for further studies will be examined. The following diagram shows the research process.

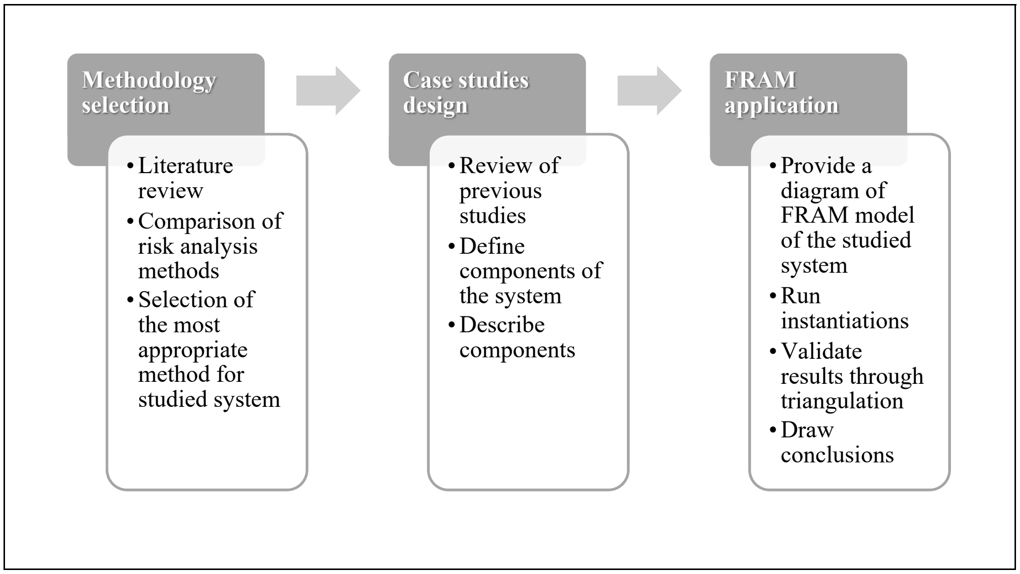

Figure 3.1 The research process for application of FRAM

3.2 Methodology

3.2.1 Choosing the proper method

This section explains the reason for choosing FRAM for this study by defining the sociotechnical perspective of the assembly system, and by comparing the classical methods to the systemic methods for risk analysis. The section will also provide an introduction to FRAM. A complex system that includes social and technical components is called a sociotechnical system (Hettinger et al., 2015). The social aspect involves human factors that are both individual (characteristics of workers) and organizational (work environment, organizational structure, policies, etc.). The technical aspects are more various, such as tools, resources, devices, and any requirements that meet the systemic function execution (Hettinger et al., 2015). Therefore, it can be stated that the concept of sociotechnical system can be applied to a wide variety of complex systems in the world, such as manufacturing (assembly), education, healthcare, economy, etc. (Carayon, 2006; Hettinger et al., 2015).

Over the last few decades, industrial plants have become increasingly complex. This complexity can be seen in interactions, levels of automation of work, process structure, and the number of components (Gattola et al., 2018; Melanson et Nadeau, 2019).

Moreover, the introduction of smart technologies to assembly systems can increase work complexity (Nikolakis, Maratos et Makris, 2019), for instance, by introducing the need to manage the data input generated by the smart device. Excessive data can cause overloading or conversely, a limited provision of information. Moreover, if the provided information needs time and cognitive activity to make it understandable for the user, it will increase the complexity of the system (Ragu-Nathan et al., 2008); (Funk, Hartwig et Wischniewski, 2019). For many decades, the methods used to think about and analyze risks were limited to a certain line of reasoning. However, at the end of the 20th century, the need for a new approach to analyze risks in sociotechnical systems became prevalent (Slim et Nadeau, 2019) since some of the classical methods were incapable of illustrating how a system components' interactions including management, organizational and human parameters could cause an accident (Underwood et Waterson, 2013a).

Classical approaches for managing risks usually consider risks in a linear cause-effect analysis. From the perspective of classical approaches, this means that accidents and risks are described in terms of single root causes, errors, or component failures (Hollnagel, 2012).

Classical methods such as fault tree analysis (FTA) and failure mode and effects analysis (FMEA) work well for relatively simple systems when losses are mostly due to physical component failures. In some traditional accident analyses, the cause of the failure is attributed to a worker. This approach judges the worker and represents the accidents (failures) as tasks that should have been accomplished well, without considering other reasons that might have affected the performance of the worker and led to the accidents (failure) (Zheng et Tian, 2017). Moreover, it is argued that the use of classical methods such as FTA and FMEA are error-prone, time-consuming, and tedious (Mahajan, Bradley et Pasricha, 2017; Papadopoulos et al., 2001).

In describing a system, the term coupling means being connected and dependent upon each other in functional terms (Hollnagel et Speziali, 2008) and tractable means how easy it is to describe the system (Hollnagel et Speziali, 2008). In a classification of systems based on these terms, an assembly line is considered as a tractable system with an average coupling (Figure 3.2 – 3rd quadrant) (Underwood et Waterson, 2013a). Figure 3.3 proposes a category of different risk analysis methods according to the coupling and description of the system components (Hollnagel et Speziali, 2008). It can be inferred that when, in the components of a system, the tractability is lower and the interaction (coupling) is higher, methods including FRAM, System-Theoretic Accident Model and Processes (STAMP), and to some extent CREAM are better suited for risk analysis (Adriaensen, Decré et Pintelon, 2019). To limit the length of this paper and scope of this study, the comparison of each of these methods is not discussed here (for more details see (Hollnagel et Speziali, 2008), (Hollnagel, 2008)). However, studying their application for the same case studies might be of interest for future studies.

FRAM has been applied to conduct analyses in the manufacturing sector in the industry 4.0 context and has proven its worth (Mofidi Naeini et Nadeau, 2021a). The introduction of industry 4.0 to industries will increase the complexity of couplings among system components (Slim et Nadeau, 2020b) (Adriaensen, Decré et Pintelon, 2019). The complexity of human-machine interfaces and of new technologies that transform the work processes will also increase. Therefore, some changes in the quadrant positioning of different industries are expected (Adriaensen, Decré et Pintelon, 2019). The introduction of new technologies in the context of industry 4.0 can accelerate an increased tightening of couplings (Hollnagel et Speziali, 2008) as well as more nonlinear and less predictable system's behavior that could be difficult to manage (Badri, Boudreau-Trudel et Souissi, 2018; Rodríguez et Díaz, 2016). If we take for example the introduction of a data glove to an assembly system, the data glove as an emerging technology in the context of IoT, may render the coupling between components tighter and the tractability of the system lower. Therefore, the positioning of such an assembly system could be closer to the 2nd quadrant, for which FRAM is one of the recommended methods for risk analysis. Thus, FRAM could be a promising method for analyzing risks involving the IoT (Mock et al., 2017).

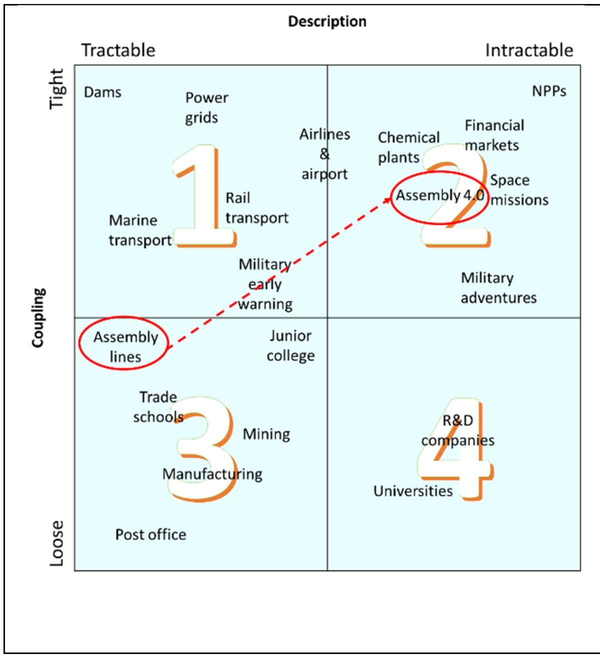

Figure 3.2 Classification of systems based on description and coupling[6]

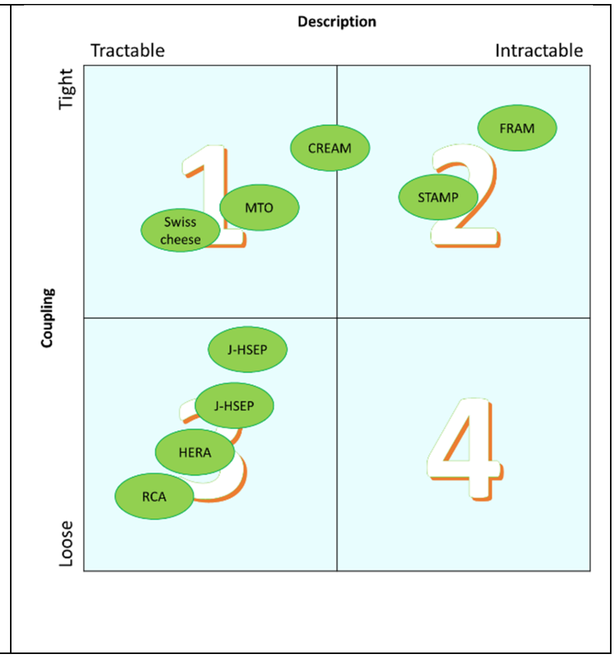

Figure 3.3 Characterization of different methods for risk analysis[7]

In this paper, considering the flexibility of FRAM and its descriptive nature, the analysis of the OHS and operational risks associated to the introduction of data gloves to an assembly line in the context of industry 4.0 will be studied by applying FRAM to realistic case studies. Case studies can provide a better understanding of a subject when there is a limited body of knowledge related to the research topic. When an analysis of the effect of variables on the behavior of a system cannot be performed in a real situation, case studies are useful to perform a qualitative investigation of an event (Rashid et al., 2019). They are helpful tools for establishing a basis, especially for the preliminary and exploratory steps of a research study, making it possible to further develop the topic in the future (Harrison et al., 2017). Designing multiple case studies to achieve replication logic is preferred. In other words, multiple case studies are regarded as different experiments that can provide more robust research outcomes

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[6] Source of the figure: Hollnagel et Speziali (2008)

[7] Source of the figure: Hollnagel et Speziali (2008)

(Harrison et al., 2017) and the possibility of triangulating the results (McNair, 2006), by using the results of applying FRAM to the first case study, the second case study, and the results found in the literature review. Therefore, triangulation will allow us to overcome the issue regarding the limited number of studies associated to our subject and in verifying the obtained results (Heale et Forbes, 2013), (McNair, 2006). Based on the characteristics of data gloves for manufacturing, previous knowledge, and reflection, realistic case studies were designed for this study. The case studies are original and innovative, as, to the best of our knowledge, the application of data gloves in a whole system has not been designed. The function description of different components has been simplified to facilitate the analysis. Then, a description of the whole system is provided.

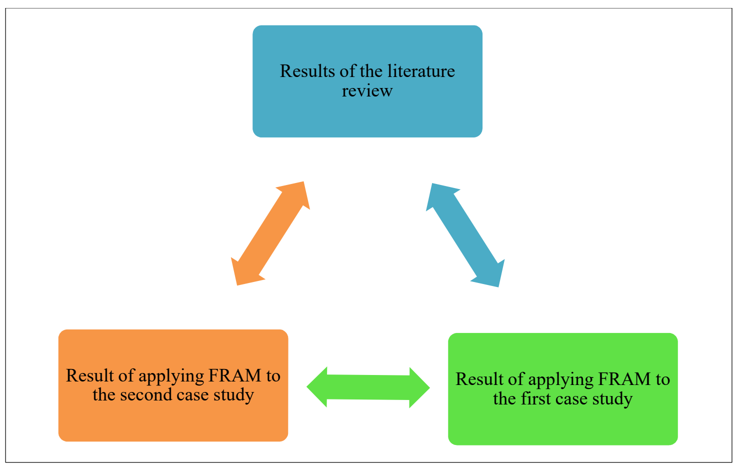

Figure 3.4 Triangulation of data

3.2.2 Introduction to FRAM

FRAM is a systemic model that describes nonlinear relationships and interactions between different functions in a studied system. It analyzes normal system activities, considers functional variabilities and deviations from expected performance (Hollnagel, 2004). Manufacturing conditions can be complex. Therefore, when the complexity is well understood, an analysis can be properly conducted. In other words, regarding the results of the analysis, the effects and consequences of changes on a system can be better predicted (Gattola et al., 2018). In order to apply the FRAM method, the following steps should be taken:

Step 0: Determine the purpose of the analysis.

Prior to the analysis, the purpose of the analysis should be clear, as an analysis can assist FRAM practitioners in several ways, such as understanding how an event (accident) happened (retrospective analysis), evaluating how an accident may occur (prospective analysis), or assessing the effects of measures to improve system design (new systems or redesigned systems) (Hollnagel, 2012).

Step 1: Functions that are required to perform the activities related to the studied system need to be identified. Thus, step 1 aims to detail the way the activities are performed rather than describing them as a general task. In the FRAM method, a function is specified based on six aspects:

1. Time (T): temporal aspects can affect the way a function is accomplished or completed.
2. Input (I): input is an activity that a function uses or transforms to make an output; it also establishes some links to upstream functions.
3. Output (O): output is the consequence or result of a performed function and it connects to downstream functions.
4. Precondition (P): is a system condition that must be fulfilled before a function can be performed.
5. Control (C): is a procedure or supervision of a function that provides the desired output. Controls can be a plan, a method, guidelines, an instruction, an algorithm, etc.

Resources (execution conditions) (R): are what an active function requires or consumes to perform a task, such as energy, workforce, material, tools, information, etc. (Hollnagel, 2012). These FRAM function specifications can be represented graphically using a Functional Model Visualizer (FMV) (Hill, 2018; Hill et Hollnagel, 2016).

Step 2: This step specifies the variability of the functions that are part of the FRAM model. This includes both the potential variability and anticipated actual variability. Determining variability should be done in both "normal" or "every day work-as-done" and "out of range" conditions that might involve harm or profit (Hollnagel, 2012).

Step 3: The FRAM model demonstrates a collection of functions that together are responsible for analyzing activities and their potential connection among functions. An instantiation shows the available or probable couplings that exists or might exist based on different intended scenarios and circumstances. In this step, scientific knowledge and practical experience are applied to anticipate the range of the potential performance variability in a domain (Hollnagel, 2012).

Step 4: This step suggests ways to manage possible events that are due to uncontrolled performance variability or a possible situation of functional resonance from the previous steps. If performance variability leads to negative or unwanted consequences, the goal is to prevent this variability.

3.3 Application of FRAM

In this section, we will analyze the application of FRAM on designed case studies. The case studies are described comprehensively to depict details of the system that are necessary to identify functions, understand their interactions in the system, and eventually conduct an analysis. Before introducing the case studies, we will briefly explain the assembly structure in the context of industry 4.0, which was used to present the FRAM model. Then, aspects of the functions' variabilities that are investigated in the case studies will be discussed.

3.3.1 Description of the FRAM model

The integration of new technologies to assembly systems is giving rise to the next generation of assembly in the context of industry 4.0, called assembly 4.0 (Guo et al., 2020b). The designing of assembly 4.0 comprises five layers:

1- The service layer is composed of various customized services, for instance, production planning and scheduling, quality control, navigation, remote diagnosis, resource management, and forecast (Guo et al., 2019).

2- The cognition layer integrates artificial intelligence (AI) technologies, such as, data mining, optimization technologies, machine learning (Wuest, Irgens et Thoben, 2014) (Shahrabi, Adibi et Mahootchi, 2017).

3- The interaction layer provides the interaction of workers and of the smart wearables used to communicate with objects and perform operations (Kong et al., 2019).

4- The perception layer involves the technologies used to ensure the connectivity of certain objects through IoT, such as sensors and communication technology (Xu, Huang et Fang, 2015; Zhao et al., 2018).

5- The assembly layer, in which assembly operations are managed (Bortolini et al., 2017).

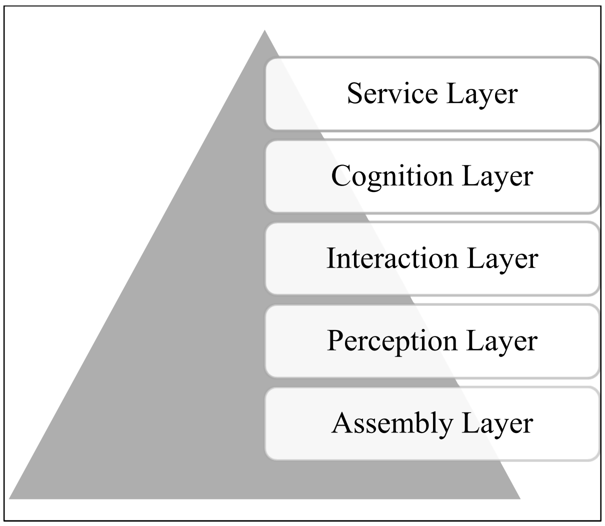

Figure 3.5 Assembly layers in industry 4.0

The use of the IoT will connect the operational level (assembly layer) directly to the tactical level (Service layer) (Hao et Helo, 2017). However, investigating the system from the perspective of information technology (IT) and its associated concerns is not the scope of this study and requires in-depth analysis. The FRAM model is an invariant scale method, meaning that a) the processes that lead to the phenomena are considered the same regardless of whether they are large or small scale and b) there are no levels in the FRAM model (Hollnagel, 2012). This being said, the organization levels of the functions will be taken into consideration (Galar et al., 2011) to depict how the coupling of functions can affect the different levels of the organization. For example, a malfunction (from OHS or operational aspects) in a lower level of the organization can affect the higher organization levels and vice-versa. Moreover, as discussed earlier, the introduction of a data glove into manufacturing is in the early stages of development, therefore, the description of different functions in different levels of an organization can provide a better understanding of the designed system and its functions.

3.3.2 FRAM model variabilities

The proper integration of a data glove to an assembly system and its interactions with various system components as well as between the system as a unit and its environment can determine the failure or the success of a system (Carayon et al., 2015). In other words, from the perspective of sociotechnical resilience orientation, humans should be considered as a component of a system in relation to technical components and not in isolation. Therefore, from a sociotechnical analysis perspective, information is gathered and integrated at the system level, and then events will be studied under working conditions (this can be a normal or an accident condition) (Patriarca et al., 2018). Therefore, FRAM will be applied to investigate the unknown and emerging effects associated to the introduction of a data glove to an assembly system in case study scenarios (Tsao, Li et Ma, 2019). As they are realistic case studies, instantiations of the FRAM model will describe a situation in the future rather than describing an event that has happened. There are two approaches for assuming variabilities (Hollnagel, 2012):

1- Take an analytical stance and investigate how the potential variability of the function will change to an actual variability. For cases with 30-40 functions, this approach is almost unfeasible.
2- Consider the lessons learned from a previous risk analysis related to our case, and see which functions were the most variable. Then, apply the variabilities in the instantiation.

As there are only a few studies in the literature associated with the risk of wearables, and data gloves in particular (Mofidi Naeni et Nadeau, 2020), we chose the first approach to present the instantiations. There are some internal and external sources of variability that might lead to variability in output. Although technological functions are considered more reliable and it is difficult to produce variable outputs since from Hollnagel's perspective the number of reasons for their variability is very slight (Hollnagel, 2012), less mature technologies are considered as possible sources of variability (Hollnagel, 2014). Moreover, the introduction of new technologies to a system, or the use of known technologies in a new context (Tsao, Li et Ma, 2019), (Hollnagel, 2014) and technology readiness level (TRL) in industry 4.0 context (Saad, Bahadori et Jafarnejad, 2021) can cause variability in a technological function. Therefore, we assume some source of variability for all three types of functions, that is, huMan, Technological, and Organizational (MTO)(Macchi, 2010).

Regarding the different variabilities of functions (Hollnagel, 2012), there are many instantiations of the model that show the effect of one or more function variabilities on other components of the system. This means that in every instantiation we will assume one or more functions are variable, and the others are non-variable unless they are affected by the assumed variable functions. In this study, to simplify the analysis, we consider variability from the perspective of "time" and "precision" (Slim et Nadeau, 2019).

3.4 Case studies description

3.4.1 Case study 1: using data glove in the assembly of connectors

1) Description of the first case study

In the assembly operations of a wired connector, the operator should insert the male end (with the clip) into the female end (with knob). The worker will take the male part with the dominant hand and female part with the other hand and join them. When the dominant hand's thumb pushes the upper side of the male part, a clicking noise can be heard and a small impact vibration can be felt. Due to environmental noise, the click might not be heard by the worker. In addition, when the worker’s hand becomes fatigued or insensitive to the vibration, the vibration might not be felt properly by the worker (Kucukoglu et al., 2018). When this occurs, the quality of the assembly task might be affected. To lower or mitigate the risk of reduced assembly quality, a data glove will be introduced in the assembly process to assist workers (Funk et al., 2016a);(Funk, Hartwig et Wischniewski, 2019). The data glove, as a user-centered assistance, can mitigate variabilities in assembly task performance, and guide the worker in his/her assembly tasks (Hinrichsen et Bornewasser, 2019). Moreover, the data glove can be used to assist in integrating the IT infrastructure with the tactical and operational levels of manufacturing (Hao et Helo, 2017). Data captured through sensors (of data glove and the conveyor) will be sent to a receiver and will be processed to provide feedback for different components of the system (Guo et al., 2020a). The workers wearing the glove can be given feedback in different ways (haptic, auditory, and visual feedback) (Hao et Helo, 2017). Haptic feedback could be appropriate to ensure the worker's safety, whereas auditory feedback could be distracting. However, haptic feedback is slower than visual feedback (Funk et al., 2016a). A light (visual feedback) can quickly indicate the quality of the performed task, leading to faster assembly time and less error in assembly (Funk, Mayer et Schmidt, 2015). Thus, visual feedback using a light would be the preferred choice for the assembly system. Therefore, in this case study, feedback will be presented through several channels: an on/off light signals appearing on the data glove, reports and notifications in the enterprise resource planning (ERP) systems, and reports and analyses that can be used by other departments. To provide such feedback, designing an appropriate IT infrastructure is imperative, but this is beyond the scope of this study (Friedemann et al., 2016) (Hao et Helo, 2017).

2) Work as Imagined

The operator will wear the data glove on his/her dominant hand (Hao et Helo, 2017) and the other hand is not covered. Sensors in the data glove send data to the receiver. Data includes the amount of applied force used to push the clip with the worker's thumb, the vibration feedback of the connector, and the spatial position of the worker's hand (upward and downward movements of the hand when reaching for connector parts, assembly parts, and placing the connector on the conveyor). Therefore, the sensors will detect the vibrational impact or absence thereof as the parts connect and the amount of force applied by the worker's thumb. Then, the sensors will send these data to the receiver, which in turn will analyze them and provide feedback to the worker. If the assembly is completed, the glove's light will turn on. Seeing the light on the glove, the worker can then place the connector on the conveyor and start a new assembly task. The conveyor delivers the assembled connectors to the next assembly station.

When the data glove is introduced to the assembly system, the following must be considered:

1. The worker must receive proper training on how to use the data glove for the assembly task (Xu et al., 2014) in such a way that promotes trust and acceptance towards the wearable (Funk, Hartwig et Wischniewski, 2019).
2. The specifications of the data gloves for training, programming, and calibration purposes should be provided by the manufacturer.
3. The various programs used to analyze the received data in the receiver, considering the specification of the receiver and senders, are provided by the manufacturer and integrated to the assembly system by a programmer. As different studies in the literature argue, the precision and accuracy of programming and computerization of wearables, and studying of variabilities in this function requires expertise in software, IT and electrical engineering to measure different concerns related to their programming (Gentner et Classen, 2009); (Hammond, Mengüç et Wood, 2014; Li et al., 2018; Wan et al., 2016). Therefore, we assume this function as a background function.
4. The data glove should be calibrated prior to being used by workers. The manufacturer provides the maintenance and calibration instructions.
5. A conveyor will move the connectors from one assembly station to the next. In addition to the emergency stop button that controls the activation and halting of the conveyor, a receiver controls its speed to match the speed of the operator's work. Data will be analyzed and real-time feedback will be sent to the receiver that controls the conveyor’s speed. The fact that the speed of the technology is programmed to match the worker's speed provides more ergonomic work conditions for workers (Hinrichsen, Riediger et Unrau, 2016).
6. A supervisor will be responsible for managing and communicating with a set of assembly workers, receiving orders or commands from the production planning department and transferring these orders to specific assembly stations and workers (Hao et Helo, 2017).
7. Regarding the sales orders, the production planning department provides production plans for each production station with regards to the supervisors’ reports, the result of

data analysis, including the rate of material usage, and the speed of assembly. Results of the analysis of the data received from the data glove can show the number of assembled items (amount of material used) and the speed of assembly, which is useful for the resource management department in placing orders for the timely supply of materials (Guo et al., 2020a).

8. The resource provision department will be responsible for providing the necessary material to the different parts of the production line, including the assembly stations, according to the provision plan received by the resource management department.

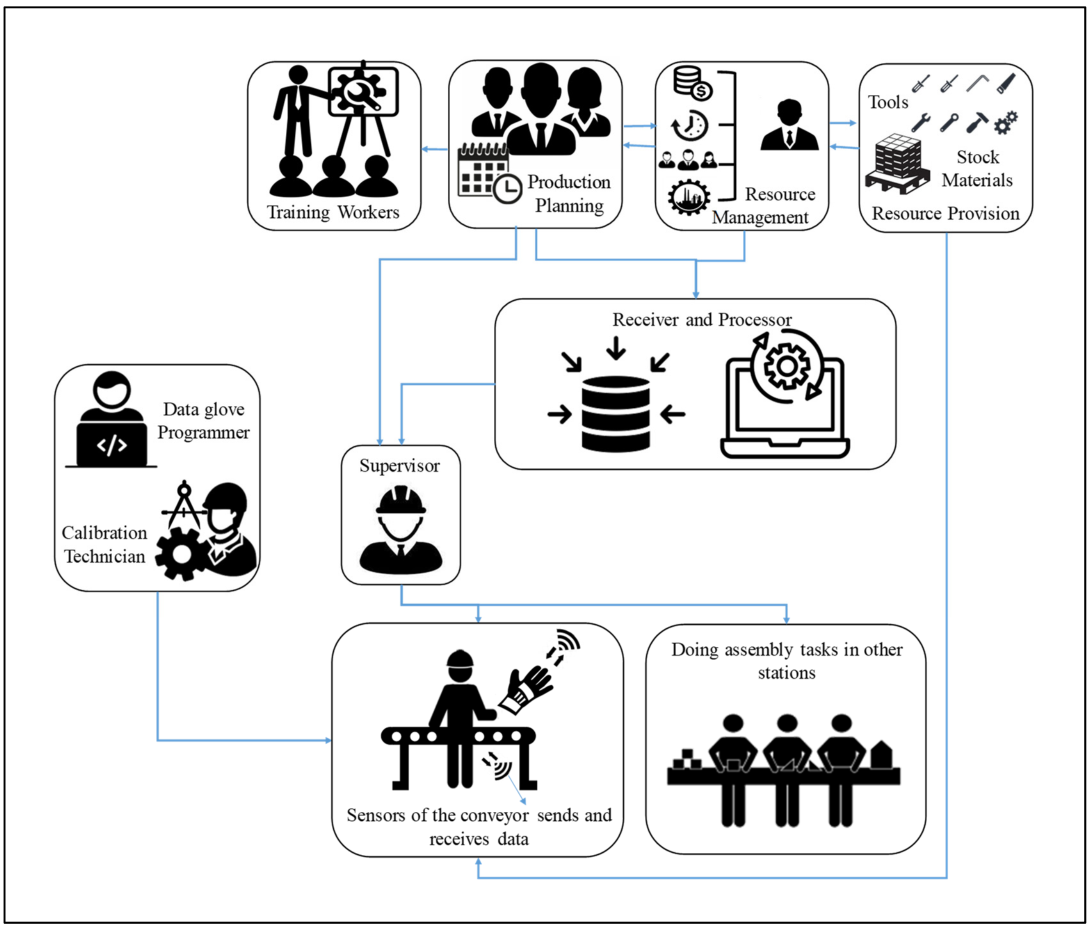

Figure 3.6 Case study 1- the use of data gloves in assembling connectors

3) FRAM model of case study 1

Fifteen functions including 4 background functions, 4 organizational functions, 3 human functions, 3 technological functions and 1 sink function were identified. In the FRAM model in Figure 3.7, the various functions are color-coded: organizational functions in green, technological functions in yellow, human functions in blue, background functions in gray, and sink function in red.

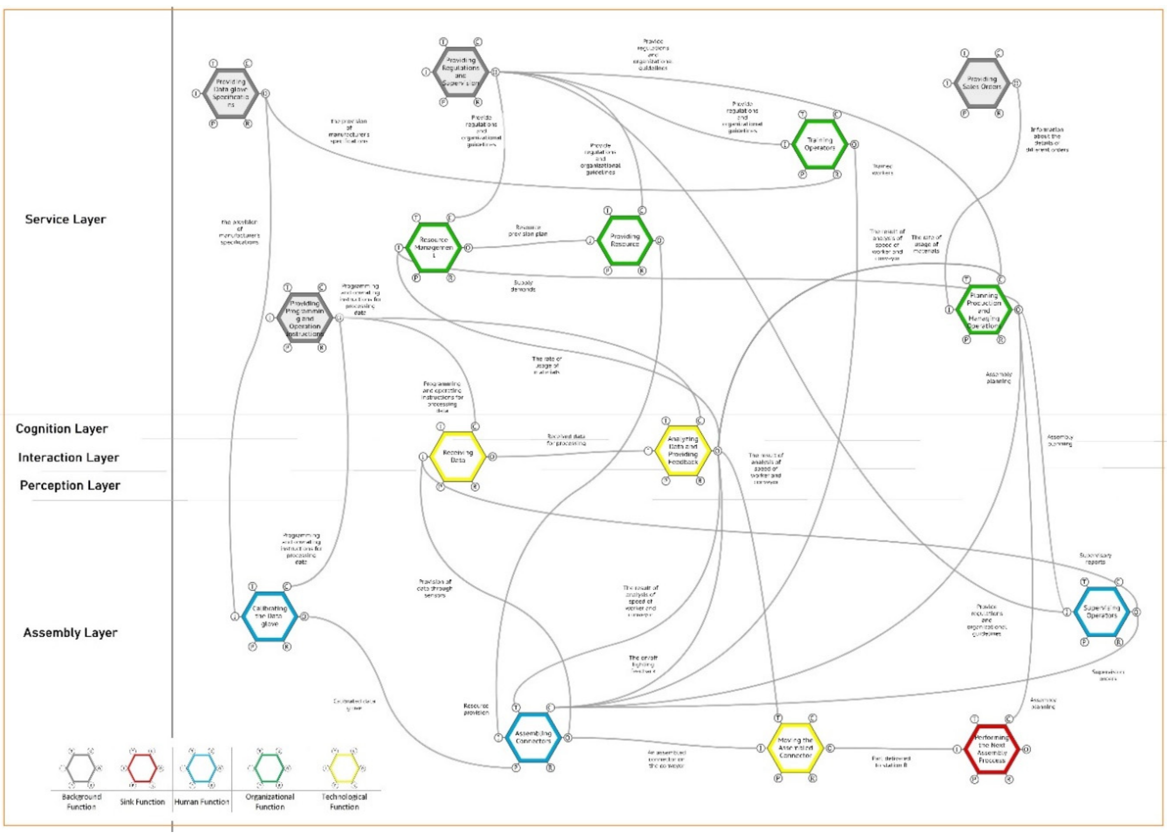

Figure 3.7 FRAM model of the first case study

4) Output variability

The following table (Table 3.1) presents the functions and their possible variabilities.

Table 3.1 Possible output variabilities of the first case study with respect to "Time" and "Precision"

Function	**Type of function**	**Output**	**Variability**
Receiving data	Technological	Received data for processing	Imprecise and late- The received data is sent late or imprecisely.
Analyzing data and providing feedback	Technological	On/off light signal feedback	Imprecise and late/too early- the feedback is provided late/too early or is imprecise.
		Rate of usage of materials	Imprecise and late- the provided result is late or imprecise.
		Feedback related to productivity, workers' performance, overall quality of assembly line	Imprecise and late- the feedback is provided late or is imprecise.
		Result of the analysis of the speed of workers (time study methods) and programmed speed of the conveyor	Imprecise and late- the provided result is late or imprecise.
Moving the assembled connector	Technological	Part delivered to station B	Late/too early – speed of the conveyor is slower/faster than expected.
Training operators	Organizational	Trained workers	Imprecise – if the training process is not performed properly, or due to internal variabilities, such as ineffective communication.
Resource Management	Organizational	Resource provision plan	Imprecise or late – the plan of resource provision might have been prepared imprecisely or late.
		Other organizational department feedback	Imprecise or late – the provided feedback might be imprecise or late.
Providing Resources	Organizational	Resource provision	Imprecise or late/too early – the resource might be provided imprecisely or late/too early.
Planning Production	Organizational	Assembly planning	Imprecise – the provided plan might be incomplete, or may contain incorrect information.
		Supply demands	Imprecise or late – supply demands might be provided late or be imprecise.
Calibrating the data glove	Human	Calibrated data glove	Imprecise or late – the data glove might be calibrated late or imprecisely for use in the assembly line.

Table 3.1 Possible output variabilities of the first case study with respect to "Time" and "Precision" (Continued)

Function	Type of function	Output	Variability
Assembling connectors	Human	An assembled connector on the conveyor	Imprecise or late – the connector could be assembled late or imprecisely by the worker.
		Provision of data through sensors	Imprecise or late/too early – sensors might not be able to send all data, or might miss some parts of data or might not send data on time.
Supervising operators	Human	Supervision orders	Imprecise or late – due to internal or external factors influencing the supervisor, supervision orders could be provided late or imprecisely.
		Supervisor feedback for training programs	Imprecise – feedback might be imprecise and not provide appropriate information for the training department.
		Supply demands	Imprecise or late – the supervisor might provide the supply demands imprecisely or late with regard to internal or external variabilities.
		Supervisory reports	Imprecise or late – the reports might be provided imprecisely or late with regard to internal or external variabilities.

The effect of receiving realtime dat on the workers' behavior is analyzed from the perspective of time and precision. The possible micro ergonomic effects such as stress is considered as internal vaiability that might affect time or precision or both.

3.4.2 Case study using a data glove to detect the right component for the assembly

1) Description of the second case study

In this case, a data glove is used to assemble complex products, or products that have a medium (Guo et al., 2020a) to a large number of components to assemble (Saarland University, 2019), or for the assembly of bulky or fragile products that need fixed-position assembly workstations (Guo et al., 2020a). In this case study, we suppose that the worker works in a fixed-position assembly station that we will call an assembly island and that all the processes of assembly are done by a worker. Moreover, assembly islands can be located in a different city or even country or time zone of a same country (for example, wide countries such as Canada, the U.S., China and Russia) (Guo et al., 2020a). In an assembly island layout, the product remains in one assembly island during the entire assembly process and it is the worker's equipment and materials that move according to the assembly plan and processes.

Fixed-position assembly operations are complex and sophisticated. Given that their processes require skilled workers, assembly islands are error-prone (Guo et al., 2019). Also, providing assistance in real-time feedback and coordinating the use of new technologies will introduce more complexity to the system (Guo et al., 2019).

During the assembly process, a worker sometimes discovers that the wrong components have been assembled. The worker must then disassemble the components that were previously assembled. Rework such as this leads to an increase in the cycle time and consequently, to delays in production processes. Therefore, a data glove is proposed to the assembly system to tackle this problem (Guo et al., 2020a); (Saarland University, 2019). Sensors in the glove will assist the worker in component recognition using the bending angles of the fingers (Saarland University, 2019) or the location of bins (tiny assembly objects) (Funk et al., 2016a; Funk et al., 2016b).

2) Work as Imagined

When the worker takes the object from a bin, the data glove will send data (the bending angles of the fingers) about the object to a receiver to be processed. The results of the data analysis will be displayed on the small screen in front of the worker to show him/her the order and the correct place of the object in the assembly operation (Hao et Helo, 2015). Therefore, personalized assistance will be provided by the data glove (Saarland University, 2019). In addition, the task schedule for the work shift, assembly instructions, and communications from the supervisor are displayed on the screen (Huang, Zhang et Jiang, 2007). If the worker takes a wrong component (based on the assembly order of components) from the storage bin, it will alert him/her by turning on a red light (Funk, Mayer et Schmidt, 2015);(Zhao et al., 2017). Moreover, the worker is given a pair of smart glasses, which are equipped with a speaker, camera, and microphone. If at some point, the worker faces a problem during assembly, he/she can communicate with the support department (technicians) and ask for guidance through a microphone to discuss the problem (Hao et Helo, 2017; Kong et al., 2019). The information about the component and tools for assembly will be sent to the support team via the data glove and a camera in the smart glasses (Kong et al., 2019) and because they can see the worker's operation desk and his/her actions, they will be able to guide the worker to resolve the issue. In addition, a supervisor can communicate with the workers he/she is overseeing through the microphone, speaker and screen. Data about accomplished tasks, the rate of the use of raw materials, etc. are provided through the data glove and reports made by the worker through the system are provided in each island. Moreover, logistic planning (resource management), resource provision, transportation management for loading assembled objects to the factory center or the customer, the delivery of raw materials to the islands, and production planning instructions need to be integrated through an industry 4.0 infrastructure. 4.0 equipment could use received data and feedback from the data glove and other reports provided by workers in islands. Feedback to the workers can be represented in different forms for users (Hao et Helo, 2017). In this case, several types of feedback are possible, such as the light of the data glove turning on/off, assembly instructions provided on the screen, received guidance from technical support team, reports and notifications in the enterprise resource planning (ERP) systems, reports and analysis (which are used by some departments), and the communication of supervisors and workers in islands. Providing such integrated and reliable feedback will require an appropriately designed IT infrastructure, which is beyond the scope of this study (Friedemann et al., 2016) (Hao et Helo, 2017).

Although experienced workers are preferred for these kinds of jobs (Guo et al., 2020a), they still need to learn how to use the provided technologies, including the data glove and smart glasses provided by the manufacturer (Xu et al., 2014).

The data glove needs to be programmed so that it performs properly in the assembly station as well as to integrate it with other IT infrastructures. Investigating programming (Qin et Huang, 2010) and designing a suitable and efficient IT platform (Bestjak et Lindqvist, 2020; Guo et al., 2020b) requires expertise and knowledge in the fields of software engineering, thus, we consider this as a background function and assume that it is not variable. However, it still needs to be studied to examine its accuracy, trustworthiness and the potential variability of the programing (Hammond, Mengüç et Wood, 2014; Li et al., 2018; Wan et al., 2016). In addition, periodic calibration of the data glove and maintenance of the other technologies used in the assembly islands are needed.

A supervisor is responsible for managing a number of workers in the assembly islands, communicating with them or receiving orders or commands from the production planning department, and transferring these to the specific assembly islands (Hao et Helo, 2017).

Results of the analysis of the data received from the data glove can show the number of assembled items (amount of used material) and the speed of assembly. Regarding these results, the resource management department oversees the placing of orders to supply materials at the right time (Guo et al., 2020a).

Due to space limitations in the assembly islands, the buffer space for raw materials is very small (Huang, Zhang et Jiang, 2007). Therefore, the resource management department is responsible for planning the provision of required raw materials, tools, and equipment for each assembly island according to data obtained through the data glove, worker's reports, reports of the supervisor as well as production planning. The resource provision department is responsible for providing required materials, tools, and equipment to the different islands at the right time according to the provision plan received by the resource management department. As products are not moved during assembly, all of the required materials, tools and equipment need to be transported from a supplier (main center) to every island by the transportation management department (Huang, Zhang et Jiang, 2007).

The technical support team is a group of experienced technicians that helps guide island workers based on their requests regarding assembling procedures, troubleshooting, etc.

A quality control worker will check the assembled product. If products meet the requirements of quality control, they will be transported to the main center for further process. If the quality control inspector finds any defects, the product will remain on the island to be disassembled and reassembled.

Even though workers sometimes transfer from one assembly island to another according to their skills in assembly (Guo et al., 2020b), in this study, we assume that every worker remains in the same assembly island until the end of the assembly process and the final product is sent to the main center.

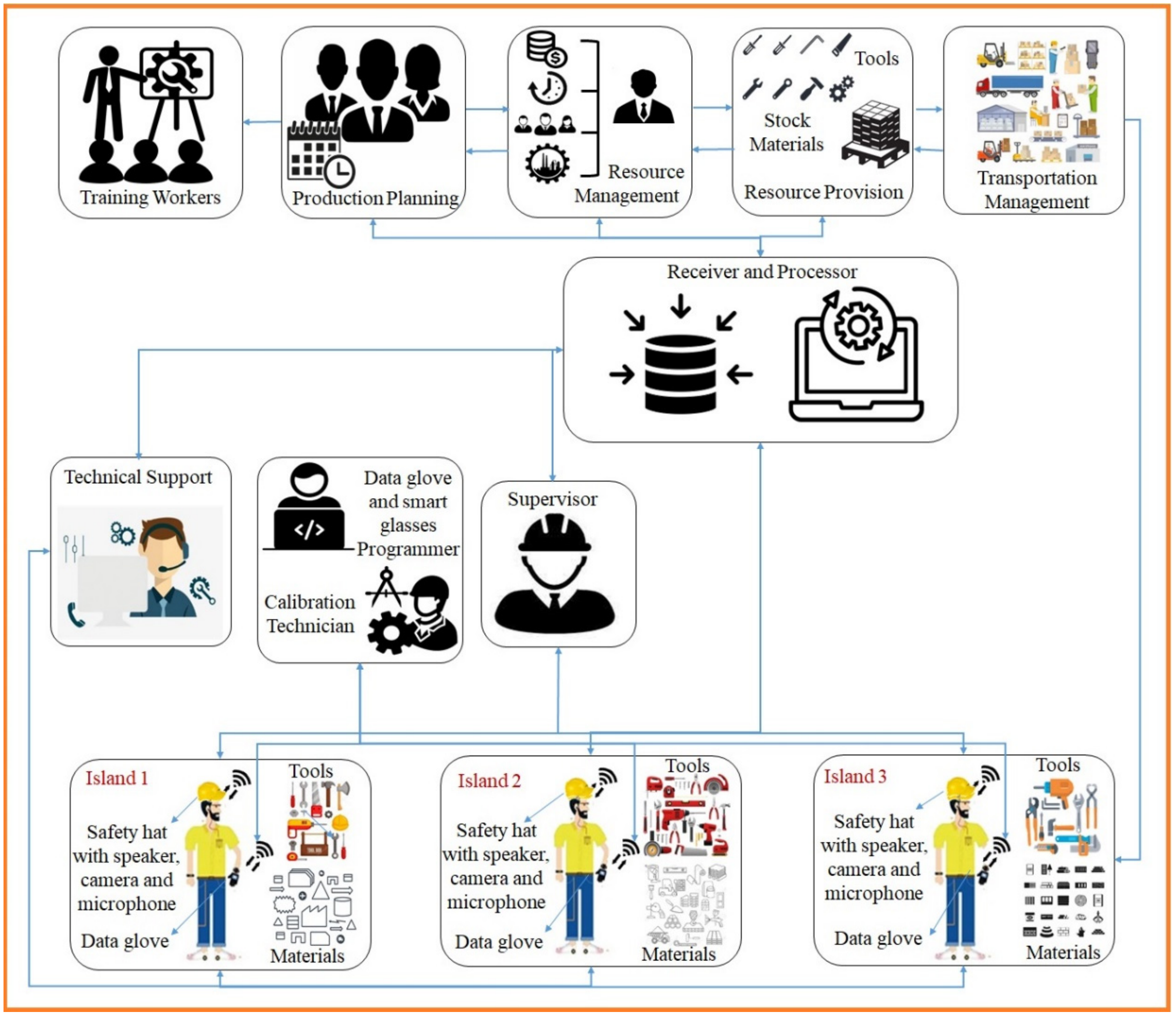

Figure 3.8 Case study 2 - the use of data gloves to detect the right component of assembly

3) FRAM model of case study 2

In this case study, there are 18 functions comprising 5 background functions, 6 organizational functions (one of which is a sink function with no output), 2 technological functions, and 5 human functions (Figure 3.9).

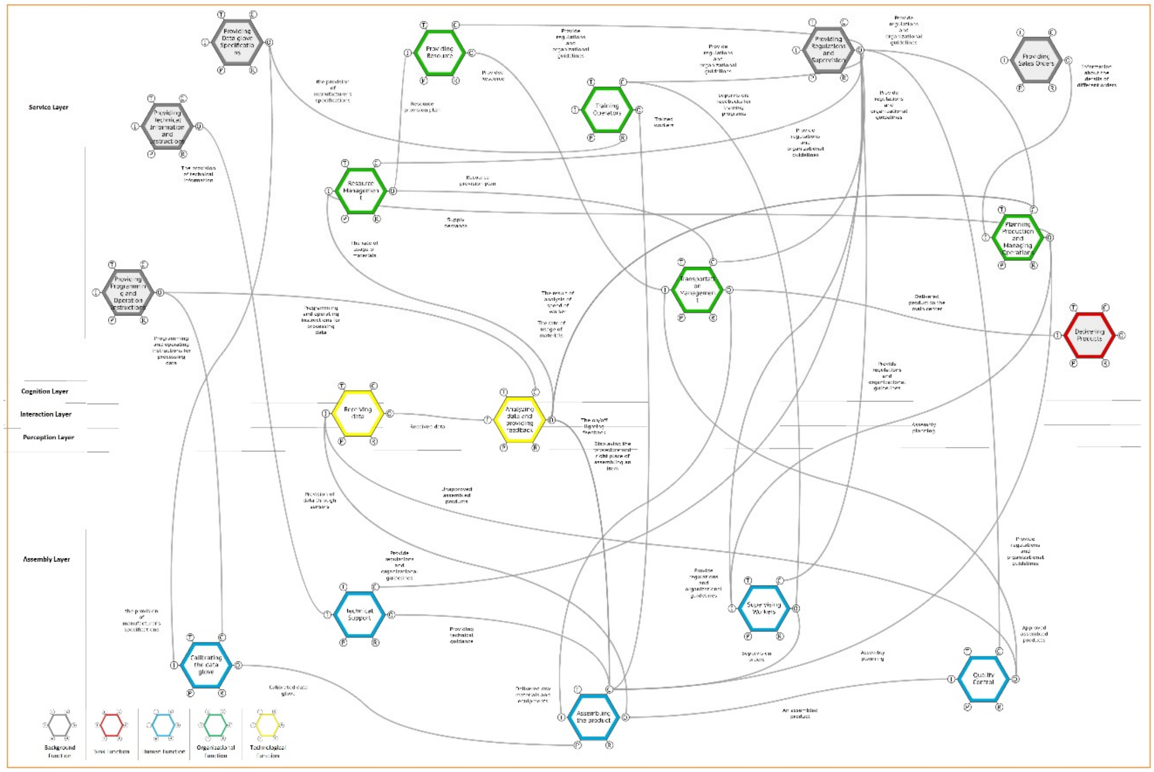

Figure 3.9 FRAM model of the second case study – data glove for assembly-component recognition

4) Variability of functions

In the following table (Table 3.2), the functions and their possible variabilities are presented.

Table 3.2 Possible output variabilities of the second case study relating to “Time” and “Precision”

Function	Type of function	Output	Variability
Receiving data	Technological	Received data for processing	Imprecise and late – the received data is sent late or imprecisely.
Analyzing data and providing feedback	Technological	On/off light feedback	Imprecise and late/too early – the feedback is provided late/too early or is imprecise.
		Rate of usage of materials	Imprecise and late- the provided result is late or imprecise.
		Displays the position of assembly object on screen	Imprecise and late – the feedback is provided late or is imprecise.

Table 3.2 Possible output variabilities of the second case study relating to "Time" and "Precision" (Continued)

Function	Type of function	Output	Variability
Transportation management	Organizational	Unloaded raw material	Late and imprecise – raw materials might reach the island late or wrong items are delivered, insufficient quantity of raw materials are unloaded at the assembly island.
		Load assembled product	Late and imprecise – the assembled product might be collected late from islands, or rejected items (wrong items) might be loaded.
Training operators	Organizational	Trained workers	Imprecise – if the training process is not performed properly or there arises some internal variabilities such as ineffectiveness of communication.
Resource management	Organizational	Resource provision plan	Imprecise or late – prepared plan of resource provision might be imprecise or late.
		Other organizational department feedback	Imprecise or late – the provided feedback might be imprecise or late.
Providing resources	Organizational	Resource provision	Late/too early and imprecise – the resource might be provided late/too early or wrong items might be provided.
Planning production and managing operations	Organizational	Assembly planning	Imprecise – provided plan might be incomplete, or contain incorrect information.
		Supply demands	Imprecise or late – supply demands might be provided late or be imprecise.
Calibrating the data glove	Human	Calibrated data glove	Imprecise or late – the data glove might be calibrated late or imprecisely for use in the assembly.
Assembling the product	Human	An assembled product	Imprecise or late – product could be assembled late or imprecisely by the worker.
		Provision of data through sensors	Imprecise or late/too early – due to imprecise data capture or incomplete data capture due to a system malfunction, a wrong location for assembling could be displayed and imprecise information will be sent to the receiver or data will be sent too early or late to the receiver to be processed.
Quality control	Human	Approved assembled products	Imprecise or late – the result of quality control might be prepared late or imprecisely considering the worker's present performance conditions.
		Unapproved assembled products	Imprecise or late – the result of quality control might be prepared late or imprecisely considering the worker's present performance conditions.
Technical support	Human	Providing technical guidance	Imprecise or late – the technical guidance might be prepared late or imprecisely considering the technician's present performance conditions.

Table 3.2 Possible output variabilities of the second case study relating to "Time" and "Precision" (Continued)

Function	Type of function	Output	Variability
Supervising workers	Human	Supervision orders	Imprecise or late – due to internal or external conditions related to the supervisor (present performance conditions), the supervision orders could be provided late or imprecisely to workers.
		Supervisor feedback for training programs	Imprecise – feedback could be imprecise and thus not provide appropriate information for the training department.
		Supply demands	Imprecise or late – the supervisor might provide the supply demands (e.g., providing tools or other required items that are requested by workers) imprecisely or late with regard to the supervisor's present performance conditions.
		Supervisory reports	Imprecise or late – the reports might be provided imprecisely or late with regard to the supervisor's present performance conditions.

3.5 Results

In this section, three instantiations for every case study will be presented. In each one, we he that at least one function will be directly affected by the introduction of a data glove and contribute to system variabilities. The functions will be analyzed regarding the descriptive analysis provided in the instantiations. Then, we will triangulate with the literature findings (See Introduction) and two case studies (Figure 3.4) to categorize the source of the variabilities.

3.5.1 Variability analysis through the instantiations

Instantiations of models can demonstrate how the variabilities of each functions' output (internal and external) can affect other functions and lead to their variabilities. More instantiations can be studied. However, we considered instantiations for which the variabilities are directly or indirectly related to the use of data gloves and the effect of the introduction of data glove to the system as this is the purpose of the study.

3.5.2 Instantiations of the first case study

1) The 1st instantiation of the model:

In this case, we suppose that the worker who is responsible for assembling connectors has accumulated fatigue (internal variability). Because s/he is fatigued, the worker is doing the task late or too late (i.e. the worker does not accomplish the work within a normal time). Moreover, his/her fatigue might lead to an imprecise connection of the assembly components. While the worker is pushing the knob on the connector by his/her covered hand with the data glove, he/she might not pay adequate attention to the received feedback. It may be that the assembled connector will be put on the conveyor even though the light on the glove has not turned on. As we can see in the FRAM model, the outputs of this function are used in “Moving the assembled connector” and “Receiving data”. Therefore, regarding the upstream-downstream couplings of the function named “Analyzing data and providing feedback”, outputs will be imprecise and late. The imprecise output (the result of the operation speed analysis is estimated less than normal speed) will be analyzed by “Planning production and managing operations” and “Resource management”. In “Resource management” the result of the analysis leads to late order planning. Therefore, the output of the function “Providing resource” might be late (the provided resource would not be ready for the assembly line, specifically “Assembling connectors”, on time). Since defects in the connector assembly will be detected later, the required material might not be available on-time to compensate for the inexact number of correctly assembled items. Therefore, the upstream-downstream coupling of “Resource management” and “Providing resource” can also cause a delay in the assembly. It can be inferred from the model that internal variability in a function can cause variabilities in the output of some functions. In this instantiation, we investigate the effect of one variability on the system.

In addition, for each instantiation we can investigate which functions can go right. For instance, in “Resource management” and “Providing resource”, the imprecise data related to the rate of usage of materials could be moderated by implementing a safety stock (Nadeau et al., 2016), which could prevent late provision (delayed) in resources.

2) The 2nd instantiation of the model:

In this iteration, the effect of imprecise calibration as a variable output of the “Calibrating the data glove” function will be studied. This instantiation investigates the effect of the data glove on the connector assembly as well as other components of the system. As this function is performed by a human, it is likely that it presents a degree of variability. We studied the effect of an imprecise output as variability in assuming that the data glove is not properly calibrated. In other words, one or more calibration steps are missed by the worker. For instance, the sensors' location is not properly checked, and the required force to turn on the light on the glove is not accurately calibrated in the programming step. As a calibrated data glove is a precondition for the function “Assembling connectors” (as guidance for workers) (Wiesbeck, 2014), it can affect the “Assembling connectors” function and its down-stream function. The worker with the data glove relies on the feedback provided by the data glove to ensure proper assembly. This means that the worker might apply more force than actually needed to connect the knob in order to see the data glove light turn on (which can be considered as an OHS risk in the long term), or the late feedback might make the worker anxious (OHS risk) (Ragu-Nathan et al., 2008). Moreover, imprecise data glove calibration might lead to the light turning on even if the connector is not assembled properly. Incorrect feedback might cause unreliability (Funk, Hartwig et Wischniewski, 2019), reluctance toward the use of the data glove, and finally, a rejection of the technology by workers (Hinrichsen et Bornewasser, 2019). The wrong information will be distributed to other components of the studied system as discussed in the first instantiation and cause variability in functions named “Supervising operators”, “Planning production and managing operations”, “Resource management”, “Providing resource”, “Receiving data” and “Analyzing data and providing feedback”.

3) The 3rd instantiations of the model:

In this iteration, the effect of variability of output in the “training operators” will be studied. We assume here that workers are not well trained on the topics associated with the assembling of different models of connectors or working with tools, especially a data glove, which is new to them. For instance, the worker will wear a data glove on his/her non-dominant hand or use the pointer finger to push the knob on the connector. Since this finger of the data glove is not equipped with force sensors, it cannot send feedback to the worker. Therefore, even if the job is well done, the feedback and analysis of data show deficiencies in the performed task. This variability in output can affect different functions, including “Supervising operators”, “Planning production and managing operations”, “Resource management”, “Providing resource”, “Receiving data”, “Analyzing data and providing feedback”, and “Moving the assembled connector”.

3.5.3 Instantiations of the second case study

The source of variabilities in functions can be internal or external (Hollnagel, 2012). Here are some assumptions that we considered for the instantiations of the models.
The worker will stay in the assembly island until the end of the assembly process.
Although the introduction of smart glasses (as a smart wearable) to the system might cause some variability in output (Tsao, Li et Ma, 2019) (Hollnagel, 2014), we assume that it will not.
First instantiation of the model
In this instantiation, we suppose that the data glove has not been properly calibrated due to variability in the calibration due to the technician’s state (internal variability). Therefore, this variability affects the assembly directly. When the worker takes the components using the hand covered with the data glove to detect the right place for assembly, the glove will detect a wrong component or cannot identify it, and the light on the data glove does not turn red to alert the worker.

We suppose that even though the worker takes a wrong component, the red light does not turn on to show the worker’s error and consequently, the place for assembly displayed on the screen will be wrong. The worker assembles components based on the received feedback (assembly instruction) to finish the assembly. The assembled components are ready to be loaded and sent to the main center. Before loading products, they need to be verified by quality control. Therefore, they will be rejected by quality control and will need to be disassembled for rework. Thus, the product will remain in the island to be reassembled and finally, will cause a delay in output. As no problems were reported during the assembly, no repairs will be made to the data glove and consequently, it might be considered as a human error and the faulty assembly process will be repeated. The wrong information about the rate of the usage of materials that was sent to the receiver to be used by production planning, resource management, and resource provision, will lead to an imprecise output of these functions requiring that the worker (or his/her supervisor) report it in order for it to be modified.

This being said, the rejection of the entire assembled product will lead to an investigation aimed at finding the source of the problem. First, the worker will ask the "Technical support" for guidance. As the worker takes hold of each component using the hand wearing the data glove, data related to the size, dimension and shape of the component will be sent to technical support through the smart glasses. At this point, technical support might realize that the feedback provided by the smart glasses and data glove are not the same. Upon discovering this discrepancy, technical support will help the worker to find the cause of poor assembly and fix it. As variability in smart glasses is considered very low (see assumptions of the second case study, Section 4-1-2), the probable cause will be an error with the data glove. After properly calibrating the data glove, the product will then be reassembled, and the product will be sent to the main center with a delay. As such, given the delay in delivering the product, the resource management, production plan, and resource provision departments will need to be adjusted and reviewed for the specific assembly island. As discussed earlier, there is limited buffer space, but raw material should be provided. Therefore, assembled products need to be collected promptly to optimize the use of buffer space.

In some cases, the assembly error might be identified by the worker during the assembly. When the worker figures out that parts have been wrongly assembled (for instance, by discovering that the assembly step is after or before the step that is displayed on the screen), he/she will begin to take apart assembled items to identify the incorrect step (this rework might cause stress for the worker). Since the data glove is not calibrated, the worker has to ask for help from technical support to be able to do the task correctly. The technical support team can assist the worker based on the information that is provided by the data glove and smart glasses. As data given by the glove is unreliable, the support team must provide guidance to the worker based on the information provided by the smart glasses. Therefore, more time is required to identify each component to find the right place for assembly. This can lead to delays in assembling the product as well as delays in the guidance provided.

Considering the second assumption in this instantiation, if the data glove cannot detect the components, the worker might attempt to resolve the issue by taking hold of the component with more force than necessary to receive feedback and this forced gesture might affect the worker's hand (OHS risk). Therefore, the worker should use the smart glasses to communicate with technical support to ask for guidance. The technical support technician will assist the worker in the assembly task. The problem will be reported to the supervisor who will ask to have the data glove's calibration verified. As assembly with the technical support takes more time in comparison to when the worker is assembling alone, the final product will be ready later. Also, functions including production planning, resource management, and resource provision will need to be adjusted due to the delay in the assembling function and there might be delays in those functions.

4) The 2nd instantiation of the model

In this instantiation, we assume that the worker is not well trained on how to use the data glove and smart glasses. Because of this, he/she might not be able to use the feedback that appears on the screen. Hence, the assembly will take more time, as the worker needs time to find the right place and the right tool to assemble items. Moreover, if the worker cannot find the right place for assembly, the worker will need to contact technical support for guidance. However, due to ineffective training, the worker will encounter problems when trying to contact technical support. For example, being unable to contact technical support via the smart glasses or to use the received feedback to assemble components. Consequently, technical support will need to spend more time providing instructions. This might lead to a delay in the assembling function as well as a backlog (late) in guidance for other islands (if technical support is in high demand). The delay in assembling can affect production planning, resource management, resource provision, and transportation management and cause lateness in these functions.

3.5.4 Functions analysis

Regarding the description of the Cognition, Interaction, and Perception layers in the assembly 4.0 structure, functions “Receiving data” and “Analyzing data and providing feedback” can be associated to all three layers. As the function's description implies, different tasks associated with these three layers (for example, data mining and machine learning (Cognitive layer) are applied to analyze received data, the interactions of workers with smart wearables for communicating with different objects and perform operations (Interaction layer), and the connectivity of manufacturing objects through IoT, such as sensors, a microphone and camera in the assembly island (Perception layer)) occur in this function. This means that this function, in comparison to other functions, covers a larger proportion of the assembly 4.0 system and thus, it can significantly affect the performance of the system both as a whole and at each of its individual functions. Not to mention that the output variability of the assembling function, for which the data glove plays a significant role, can considerably affect the system. Regarding the instantiations and the presented model, “Receiving data”, “Analyzing data and providing feedback” and “assembly” are functions with the most variability.

3.5.5 Categorized source of variabilities

To design an ergonomic manual assembly process in the context of industry 4.0, the system must be viewed through four main aspects, namely, informational system design, organizational system design, technical system design (Hinrichsen et Bornewasser, 2019), and the behavior of humans in interaction with information, technologies and organizations of the studied system (Khanzode, Maiti et Ray, 2012).

As the instantiations showed, the couplings of different functions in the system can lead to risks (Hollnagel, 2012). This means that risks can be categorized based on the resources they are derived from. Resources comprise a) single variability (variability in only one activity leads to risk), b) multiple variabilities (couplings of the variability of different activities lead to risk) (Zheng, Tian et Zhao, 2016) (Salmon et al., 2017). Instantiations of the model showed that introducing a single variability or interaction of single variabilities would eventually lead to the coupling of different functions that enhance the amount of variability (risks) in the assembly system.

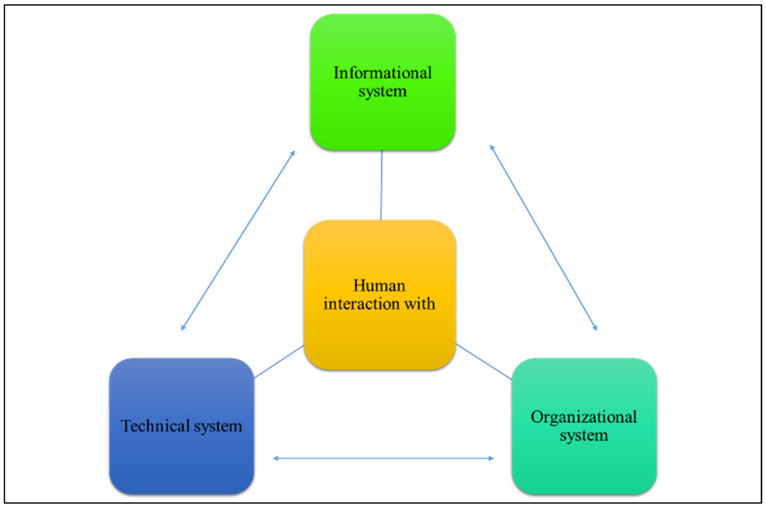

Figure 3.10 Classification of risk factors

Considering the findings of instantiations as well as what can be found in the literature related to OHS and operational risks of wearables (Mofidi Naeni et Nadeau, 2020), there are some concerns related to the four main aspects of an assembly system in the context of industry 4.0.

1- Informational concerns:

1-1- Ensure that the information available to users is of quality and correct quantity (Hollnagel, 1987).

1-2- Information provided for different components of the system is incomplete, vague or imprecisely defined, or wrong (Hollnagel, 1987).

1-3- Ensure that sufficient information is provided at the right time (Hollnagel, 1987) (Hinrichsen et Bornewasser, 2019).

1-4- Information overload that exceeds the amount necessary for users' decision-making (Hollnagel, 1987).

1-5- Necessary information is missing for the assembly system (Hinrichsen et Bornewasser, 2019).

1-6- Display of unnecessary information (Hinrichsen et Bornewasser, 2019).

1-7- Information provided is not easy for workers to comprehend (Hinrichsen et Bornewasser, 2019) (Büttner et al., 2017).

2- Technological concerns:

2-1- Hardware and software used for the data glove is compatible and appropriate (Masood et Egger, 2019) (Hinrichsen et Bornewasser, 2019) (Büttner et al., 2017).

2-2- Appropriate infrastructures are used (Masood et Egger, 2019) (Hinrichsen et Bornewasser, 2019).

2-3- Reliable components are used for the data glove (in this case, sensors, receivers) (Tsao, Li et Ma, 2019).

2-4- Ensure the accuracy of the sensors relevant to the wearers' movements (Tsao, Li et Ma, 2019).

3- Organizational concerns:

3-1- Behavioral classification and decision-making varies from fully automated to fully manual (Hollnagel, 1987).

3-2- The performance of different levels of decision makers (Hollnagel, 1987)

3-3- The strategy of decision-making and operational control (Hollnagel, 1987)

3-4- The scheduling of decisions from the perspective of planning and controlling. This means decisions should be taken at the right time and using the right resources (Hollnagel, 1987).

3-5- Conflicts, interpretations that affect decision-making (Hollnagel, 1987)

4- Human interaction with information, technology, and organization concerns:

4-1- Acceptability, and trustworthiness of the data glove (Sochor et al., 2019) (Lee et See, 2004).

4-2- Ease of use of the data glove (König et al., 2019) (Büttner et al., 2017).

4-3- Perceived level of complexity in relation to organization and applied technology (data glove) (Hinrichsen et Bornewasser, 2019).

4-4- Ergonomic, physiological, and psychological effects of the technology on the individual and his/her behavior (ethics (Büttner et al., 2017)), strain (Ragu-Nathan et al., 2008), (Schertzer et Riemer, 2014)).

3.6 Discussion

It is vital to understand the nature of system dynamics and performance variability before one begins modeling individual technological or human failures (Hollnagel, Hounsgaard et Colligan, 2014). Understanding how a task goes smoothly can be considered as a prerequisite to understanding how some tasks go wrong. In other words, work should represent the adjustments required for successful performance (Hollnagel, Hounsgaard et Colligan, 2014). However, the application of FRAM in industry 4.0 is rare. It can be inferred from the limited number of relevant scientific papers that not only does industry 4.0 need to embrace complexity methods, but also, that complexity methods need to be introduced to industry 4.0 (Adriaensen, Decré et Pintelon, 2019; Askarpour et al., 2019). The strong point of FRAM is its flexibility regarding the fact that it is a method-sine-model, which makes it suitable for various contexts (Grabbe et al., 2020). The graphic form used to represent the model provides a “map” of the functions and their input and output and how inputs and outputs are linked to each other(Hollnagel, 2012). The application of FRAM on case studies provides a better perspective of OHS management because it is not only based on the knowledge of past events, but also it is a proactive approach (Grabbe et al., 2020; Melanson et Nadeau, 2016). It helps in understanding outcomes that are both non-causal (emergent) and nonlinear and makes predictability and control possible (Hollnagel, Hounsgaard et Colligan, 2014). The application of FRAM on assembly 4.0 represents a systemic perspective to analyzing a system. This does not mean that FRAM is a substitute to classical methods of risk analysis in industry 4.0, but rather that FRAM is an appropriate complementary tool to the established methods for risk analysis in a complex system (Grabbe et al., 2020; Melanson et Nadeau, 2019; Slim et Nadeau, 2019). Considering the variability of work performance will ensure the safe design and operation of the studied sociotechnical system (Grabbe et al., 2020). However, due to its elaborate nature, the application of FRAM requires a fair amount of time (Hollnagel et Speziali, 2008) as well as a thorough knowledge of the studied system as a whole and of its different components (Melanson et Nadeau, 2019). Moreover, FRAM as a prospective approach (proactive or predictive) is less precise in comparison to retrospective approaches whose events and consequences are previously described (Slim et Nadeau, 2020a). The basic application of FRAM provides qualitative results rather than probabilities (Hollnagel, Hounsgaard et Colligan, 2014). Nonetheless, results can provide guidelines for better compliance of the technology in practical areas of manufacturing (assembly) and minimize its associated OHS and operational risks (Zheng, Tian et Zhao, 2016). This study showed that although the use of IoT (in this study, the data glove) will promote the easy and direct connection of an organization's upper to lower level, a single variability can affect different levels of the organization. FRAM's prospective insight into risk analysis will help improve the system design as well as technology design since risk control in the early stages of the product/system lifecycle will be more effective and less expensive to tackle (Schlichting, 2018) (Leveson, 2018). As the use of wearables in manufacturing, especially in assembly, is new and emerging, access to real data of real case studies is limited. Therefore, analyzing a system can be performed through the analysis of various realistic scenarios, which can assist in identifying elements that might contribute to OHS and operational risks (Belmonte et al., 2011; Melanson et Nadeau, 2019). Realistic case studies are designed based on previous knowledge and reflections about manufacturing systems and are meant to offer a simplified representation of the system to facilitate the analysis. As there are a limited number of studies in the literature on the use of a data glove in a real manufacturing context (Mofidi Naeni et Nadeau, 2020), collecting real data associated with the use of a data glove (a wearable) in manufacturing (assembly) is needed. This limits the analysis, which uses an approach based on previous studies about variabilities of functions. Additionally, analyzing such assembly systems in a real laboratory case study requires knowledge with respect to the design of software, hardware and information processing (Hammond, Mengüç et Wood, 2014; Li et al., 2018) as well as controlling the variability of these in laboratory experiments, which was not the objective of this study. However, in analyzing scenarios, we had to make assumptions (non-variability of smart glasses as a new technology and assuming the function "Providing programming and operation instructions" as a background function without variabilities) to control the variability of other functions in the system.

3.7 Conclusion

The main contribution of this study is that it confirms that FRAM can be applied to analyze OHS and operational risks of the use of smart wearables (in this study, a data glove) in manufacturing (assembly) in the context of industry 4.0 and to provide a proactive perspective for the analyst. To the best of our knowledge, although FRAM has been applied in manufacturing (Mofidi Naeini et Nadeau, 2021a) it has not been applied in the assembly 4.0 context and risk analysis of introducing wearables (data glove) to an assembly system. Assembly in the context of industry 4.0 with regard to the complexity of the system needs to be viewed from a systemic perspective, which can be achieved through FRAM. FRAM makes it possible to consider the system as a combination of different functions (huMan, Organizational, Technological) whose variability can introduce risks to the studied system. Although data associated with the use of data gloves in manufacturing is very limited, the provided preliminary results represent the potential variabilities of the assembly system and FRAM is a promising approach for analyzing such assembly systems. It can help assembly systems align with the rapid growth of new technologies and the complexity of sociotechnical systems. As industries are in the early stages of adapting to the fourth generation of industry, FRAM should be applied as an assistive method in delivering recommendations and guidance for the safe design of systems involving human interaction with wearables and other components of an assembly system in the context of industry 4.0. Nevertheless, when analyzing the introduction of a data glove to an assembly system, there is room for other risk analysis methods and this would only increase the reliability and validity of the results (Melanson et Nadeau, 2019; Thatcher, Nayak et Waterson, 2020). Another avenue for further research is quantifying the results (Patriarca, Di Gravio et Costantino, 2017; Slim et Nadeau, 2020a) to make it possible to compare the effect of variabilities on functions from a numerical perspective. Moreover, preparing a computerized simulation of case studies and repetition (instantiations) of different states might provide results that improve the preliminary results and also validate them.

CHAPTER 4

SYSTEMIC APPROACH FOR OHS AND OPERATIONAL RISK ANALYSIS OF DATA GLOVE USE IN 4.0 ASSEMBLY

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This chapter presents the paper submitted to the Journal of Manufacturing Science and Technology. This paper addresses the research questions and, followingly, the second research objective. This paper analyzed the assembly system (specific case studies) from the STAMP (STPA) perspective to answer what OHS and operational risks are when a data glove is introduced to an assembly system and how to analyze them. This paper has materialized the research's second objective for identifying and analyzing the specific case studies through the application of STPA. The results showed that STPA is an appropriate method for understanding and analyzing systems components interactions. It provides an overview of the system components and their interactions in the form of control actions and feedback. STPA helped in identifying safety constraints and unsafe control actions that might lead to risks in some scenarios. These scenarios are described to take appropriate measures for avoiding or mitigating risks.

Abstract

The complexity of manufacturing is rising considerably and it enhances through the introduction of new technologies to the system. Advancements in new technologies (in this study data gloves) and their application in the 4.0 assembly context will bring about new and emerging occupational health and safety (OHS) and operational risks. This study aims to apply STAMP (Systems-Theoretic Accident Model and Processes)-based approach to analyze these risks when a data glove is introduced to an assembly system. The application of STPA (Systems-Theoretic Process Analysis) on realistic case studies provides a systemic view of systems' control structure from OHS and operational concerns. Findings indicate that STPA is a promising method for OHS and operational risk analysis when a wearable is introduced to a complex assembly system, especially in designing step. However, technology readiness level limits access to numerical and detailed data in providing insight into intensity of the different control structure's effect and system components and their interactions on the studied system.

4.1 Introduction

Industry 4.0 and its associated technologies have transformed industrial workplaces, for instance, by enabling a seamless integration of humans and technologies (machines, robots, etc.) (Kong et al., 2019).

One of the newer technologies in industry 4.0 are wearables. Wearable technologies have made it possible to design smart and automatic systems able to detect and support humans in various working conditions (Cook et Krishnan, 2015). When used in assembly systems, the interconnectedness of controllers, sensors, and actuators control assembly processes and operational information exchanges (Bortolini et al., 2021).

While industry 4.0 undoubtedly offers remarkable advantages, it also increases the complexity of assembly systems. Therefore, traditional and emerging risks can potentially arise along with operational and occupational risks, as they are closely related (Brocal et al., 2019b; Julien et al., 2005). To understand how the interactions of different components in complex systems can introduce these risks, systemic approaches must be developed that are able to manage operational and occupational risks in complex systems (Brocal et al., 2019b).

All too often, health and safety is not sufficiently involved in the early concept development stages of system engineering processes (Leveson, 2018; Neumann, Kolus et Wells, 2016). Aside from being obliged to consider Occupational Health and Safety (OHS) in legislative requirements, it is cost-wise to consider and analyze safety in the early stages, along with other aspects of concept analysis (Leveson, 2018). Although safety of the system is not the ultimate goal of the system design requirements, considering safety in a systemic approach will assist in creating an optimized design (Leveson, 2018).

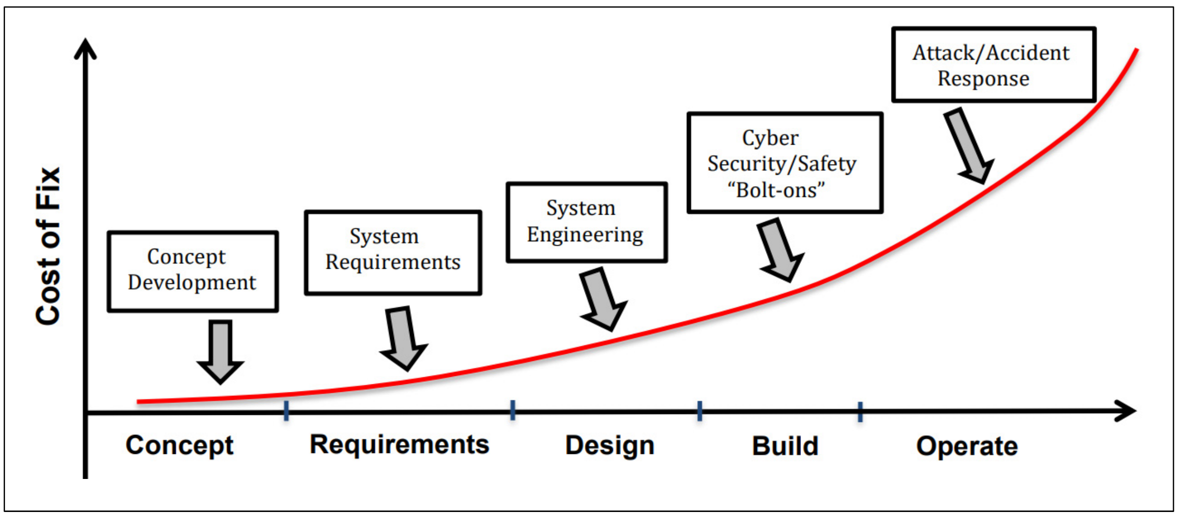

Figure 4.1 Expense associated with fixing issues at the different lifecycle stages of designing a system[8]

The V-Model shows the development phases involved in the implementation of wearable technologies in 4.0 manufacturing. The system properties that need to be tested will decrease during the concept phase and increase during the implementation (execution) phase. Meanwhile, the objective of research and tests of the system design will shift to the validation of the application of the intended design (Grabbe et al., 2020). It should be noted that OHS risks related to the application of wearable technologies in manufacturing have not been widely

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[8] Source of the figure: Young (2016)

studied (Mofidi Naeini & Nadeau, 2020). Also, the introduction of IoT-based technologies to manufacturing systems is mainly in the designing phase (Hao et Helo, 2017; Hao, Helo et Gunasekaran, 2020; Helo et al., 2021; Helo, Phuong et Hao, 2019; Rymaszewska, Helo et Gunasekaran, 2017; Shamsuzzoha et al., 2019). Thus, the development of OHS and operational risk management approaches could aid in concept development and design as well as its application in the real world (Grabbe et al., 2020).

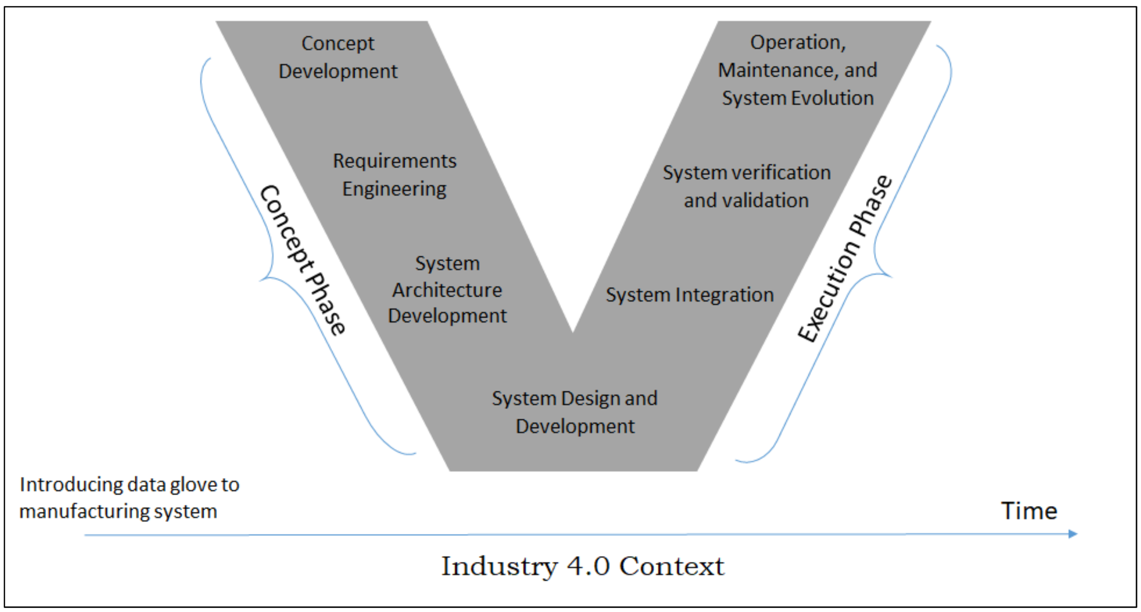

Figure 4.2 V-Model phases for data glove introduction to manufacturing in the context of industry 4.0 [9]

In this study, OHS and operational concerns associated to the introduction of a data glove to an assembly system in the context of industry 4.0 will be investigated using STPA. This approach will be applied to realistic case studies, the results will be presented and discussed, and finally, conclusions will be drawn.

[9] Source of the figure: Leveson (2018), and Winkle (2016)

4.2 Methodology

A system that includes both technical and social components is considered as a complex system (Hettinger et al., 2015; Slim et Nadeau, 2020b). In particular, an assembly system that includes social (humans such as workers, supervisors, technicians) and organizational and technical parts (hardware and software technologies) is considered a socio-technical system (Günebak et al., 2016). The operation scenario of manufacturing in the context of industry 4.0 is complex and requires several controls comprising human (workers, supervisors, technicians, etc.), machines (wearable technologies, transportation vehicles, conveyors, etc.) and organizations (Li et al., 2021). When components of a socio-technical system in a manufacturing context interact, they might potentially behave in nonlinear ways (Soliman et Saurin, 2017). Therefore, understanding the nature of system dynamics and the behaviour of components in relation to each other in a system to foresee how a system could fail is essential (Hollnagel, Hounsgaard et Colligan, 2014). Studies have shown that classical risk analysis approaches are unable to properly analyze complex systems (Mahajan, Bradley et Pasricha, 2017; Papadopoulos et al., 2001; Zheng et Tian, 2017). Hence, new systemic approaches such as Functional Resonance Analysis Method (FRAM) and System-Theoretic Accident Model and Processes (STAMP) have been developed and proven suitable (Adriaensen, Decré et Pintelon, 2019; Mofidi Naeini et Nadeau, 2021a). In a complex system, unsafe controls can occur even when there is no component failure. (Mahajan, Bradley et Pasricha, 2017). The Systems Theoretic Process Analysis (STPA) helps identify unsafe scenarios that are not identified by classical methods (Abdellatif, 2021), so that new factors, including software flaws, human errors, and organizational factors, can be considered (Mahajan, Bradley et Pasricha, 2017). STPA shows the organization of components (hierarchy), which is the basis for understanding or anticipating unpredicted interactions among the components of the studied system (Hollnagel, 2012).

STPA will be applied to analyze the OHS and operational risks of the introduction of a data glove to an assembly system in two realistic case studies.

4.3 STAMP

4.3.1 Introduction to STPA

System-Theoretic Accident Model and Processes (STAMP) is based on a system theory focused on system safety rather than preventing failures. Therefore, safety is considered as a control problem rather than a reliability issue. STAMP tries to find the causes of the occurrence of an accident by specifying the reasons for it being controlled ineffectively. STAMP emphasizes control and feedback between components of the studied system (Lower, Magott et Skorupski, 2018). The STAMP accident model is based on three aspects: 1) safety constraints, 2) hierarchical safety control structures, 3) process models (Leveson, 2011).

When STAMP is used to analyze hazards, it is called STPA (Pricop et al., 2020). In this study, STPA will be applied to case studies as follows (Leveson et Thomas, 2018):

Step 1: Identify the purpose of the analysis:

1- Identify system boundaries and losses
2- Identify hazards in the studied system
3- Identify system-level constraints required to mitigate or prevent hazards' losses

Step 2: Model the control structure:

1- Illustrate the configuration of the studied system's control structure
2- Identify variables of the studied system

Step 3: Identify unsafe control actions:

1- Identify control actions of the studied system
2- Elaborate different control action scenarios
3- Determine unsafe behavior of each control action according to the scenarios

Step 4: Identify possible losses:

1- Identify possible causes that could lead to unsafe control actions or control actions that, if not executed properly, might cause hazards

2- Mitigate or eliminate identified hazards by applying scenario recommendations

4.3.2 Application of STPA in case studies

STPA will be applied to an assembly system using a data glove wearable technology.

4.3.2.1 Case study 1: using a data glove to assemble connectors

A data glove is introduced to a connector assembly line (Kucukoglu et al., 2018). First, the production planning department sends a resource request (Bill of Materials (BOM)) to the resource management department to know the estimated time of delivery to prepare resources (lead-time) based on the resource requirements planning (RRP). Resource management uses the information and reports it receives from the receiver and processor, production planning, and resource provision. The resource provision department provides the stock material for every station according to the received purchase order prepared by resource management. Based on its feedback (capacity requirement planning (CRP), lead-time, resource requirements planning (RRP), etc.) and reports generated by the receiver and processor, the production schedule (assembly schedule) and all relevant information is sent to the assembly supervisor. The supervisor then sends the assembly schedule to the specific assembly stations and communicates with the workers. Workers must be trained for the tasks of their assembly station and on how to use the data glove. The data glove assists in assembling connectors. It is calibrated for each station and sends information (degree of force applied by worker's finger, the position of the worker's hand, etc.) to the receiver and processor, which monitors the correct assembling of the two parts of the connector. A light indicator on the data glove tells the worker whether the connectors are properly assembled or not. The assembled connectors are moved to the next station by a conveyor whose speed is controlled by the receiver and processor to ensure an ergonomic speed matching each worker’s assembly time and allocations (time study). The conveyor speed varies based on a standard time, anticipated time and learning curve (Franceschini et Galetto, 2004; Linton et Walsh, 2004) and the capacity of other assembly stations (Hopp et Spearman, 2011). The receiver and processor should be programmed to provide required reports, commands, and feedback for every component of the system (Mofidi Naeini et Nadeau, 2022a).

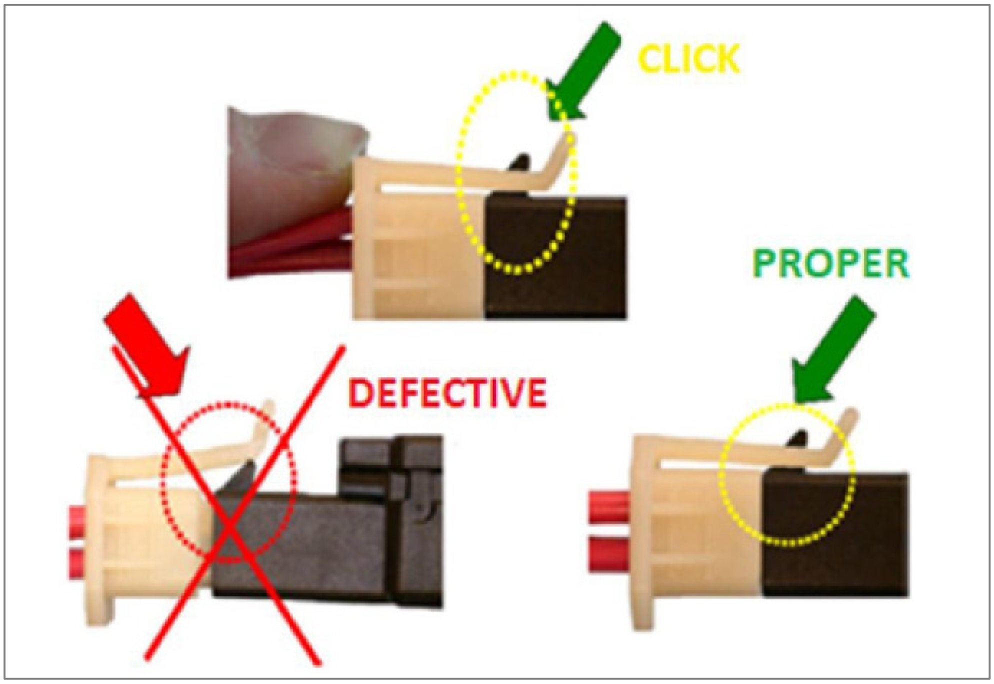

Figure 4.3 Assembled connectors in two situations defective and proper [10]

4.3.2.2 Case study 2: using a data glove in assembly to detect the right component

A data glove and smart glasses are introduced to a fixed-position assembly system, also called assembly islands (Guo, Zhong, Lin, et al., 2020). Assembly islands imply that the product stays in one place and workers, required materials, and equipment are sent to it. The worker's activities are monitored by IT technologies and infrastructures. The data glove and smart glasses assist workers in assembling products with medium variable components (Hao et Helo, 2017; Lawrence, 2016; Saarland University, 2019). When the worker takes the component

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[10] Source of the figure: Kucukoglu et al. (2018)

using the calibrated data glove, its sensors send the angle of the bent fingers to the receiver and processor to identify the component. The feedback is displayed on a screen that shows the worker the correct assembly location of the component (Hao & Helo, 2017). If the assembly is incorrect or a wrong item is taken, the light on the data glove will alert the worker (Funk, Mayer et Schmidt, 2015);(Zhao et al., 2017). The receiver and processor are programmed to provide required supervision, feedback, or information for the various system components. If the worker requires assistance, the smart glasses can show the worker's desktop to the help technician and the worker can speak to him using a microphone mounted on the smart glasses. In the central factory, the production planning department is responsible for providing assembly schedules considering information and reports from the resource management department, supervisor, and the receiver and processor (data/information/reports about the rate of usage of materials, and production reports). Provision reports are provided by the receiver and processor and accessible to different departments. The assembly schedule is sent to the supervisor and specific schedules are sent to each worker's assembly island. A supervisor oversees workers in different assembly islands and communicates with them indirectly through each island's IT technologies. Resource management provides the required resource plan (purchase order (PO)) with reports from the receiver and processor, production planning, and resource provision departments. Required resources (stock materials) are provided by resource provision and will be transferred to the assembly islands by transportation management. Transportation management also collects final products from the islands and delivers them to a specific destination. Before the final product is collected from the assembly island, it must go through quality control. If the product fails to meet the quality criteria, it will remain on the island to be reassembled. Workers must be trained to use the provided technologies (e.g., smart glasses and data glove) (Mofidi Naeini et Nadeau, 2022a).

Before we go on to applying STPA to analyze the discussed system, it should be noted that in this study, the control structure is based on OHS and operational control. As the system is studied in the context of industry 4.0, it is important that the relationship between the system's components and their integration as a whole be understood (Kong et al., 2019). However, this is not the focus of this study. An in-depth investigation would be needed regarding information technology (e.g. wireless technology, sensors, 5G technology) and their associated risks in the context of industry 4.0 (e.g. transmission, reliability, delays, security) (Alam, Selim et Kaddoum, 2019; Essaadali et al., 2016; Gingras, Pourranjbar et Kaddoum, 2020; Hamza et Kaddoum, 2019; Kaur et al., 2020). However, expertise in software and computer programming would be required to study the programming risks associated to (Can et al., 2019; Dewangan et al., 2020; Dogo et al., 2019; Kong et al., 2019; Kucukoglu et al., 2018; O'Donovan et al., 2019) the receiver and processor and smart wearables (e.g. data glove and smart glasses), as well as concerns related to data interaction on the device, operational stability, external software and hardware integration of smart wearables (Kong et al., 2019), which is not the aim of this research.

4.4 Results

The comprehensive details of the Unsafe Control Action (UCA) analysis and loss scenarios are provided in the appendix B.

Step1: identifying the purpose of the analysis

We aim to identify the OHS and operational hazards regarding the introduction of a data glove to an assembly system. Thus, we need to identify losses, hazards and system-level constraints.

Losses: In the case studies above, losses are occupational health and safety injuries (OHS risks), operational errors and issues with quality that might occur during use of the data glove. Losses for the purpose of this study are as follows:

L1: Injury to workers involved in the job

L2: Loss of or damage to assembled product

L3: Loss of or damage to sensitive information

Hazards in case studies are identified with regards to identified losses.

Table 4.1 Identified hazards

Hazard #	Identified Hazard	Case1	Case2
H1	**Wrong/no data or material is sent or received. (L1, L2, L3)**		
H1-1	Wrong/no data sent/received from the data glove to the “receiver and processor”.	*	*
H1-2	Wrong/no data received/sent between “receiver and processor” and “production planning”.	*	*
H1-3	Wrong/no data received/sent between “receiver and processor” and “resource management”.	*	*
H1-4	Wrong/no data sent/delivered between “supervisor” and “production planning”.	*	*
H1-5	Wrong/no data sent/delivered between “resource management” and “production planning”.	*	*
H1-6	Wrong/no data provided by the worker's hand for the data glove's sensors.	*	*
H1-7	Wrong/no data sent/delivered between “resource management” and “resource provision”.	*	*
H1-8	Wrong/no data received/sent between “worker” and “supervisor”.	*	*
H1-9	Wrong/no program, rules, instructions used for the “receiver and processor”.	*	*
H1-10	No/wrong calibration of data glove provided for the worker.	*	*
H1-11	Wrong/no required resources (stock materials) are provided.	*	
H1-12	Wrong/no required resources (stock materials) are purchased.		*
H1-13	Wrong purchased resources (materials) are carried to the assembly island.		*
H1-14	Wrong/no data sent/received from “smart glasses” to the “receiver and processor”.		*
H1-15	Wrong/no data sent/received from the “receiver and processor” to the “technicians”.		*
H1-16	Wrong/no data sent/delivered between “transportation management” and “resource provision”.		*
H1-17	Wrong/no data sent from the “receiver and processor” to the “worker’s screen”.		*
H1-18	Wrong/no data sent/received from the “smart glasses” (the worker) to the “technicians”.		*
H1-19	Unqualified products/ (qualified products) are (not) permitted to be loaded for transportation.		*
H2	**Commands (feedback) or materials are not provided on time (L1, L2, L3)**		
H2-1	The supervisor's commands and messages are delivered on time to the worker.	*	*
H2-2	Stock materials (resources) are provided late to assembly stations (islands).	*	*
H2-3	Feedback from “receiver and processor” will arrive late/soon (or not at all) to data glove.	*	*
H2-4	Feedback/reports for the “resource management department” are provided late.	*	*
H2-5	Feedback/reports for the “production planning department” are provided late.	*	*
H2-6	Feedback/reports or commands are not provided on time for the “receiver and processor”.	*	*
H2-7	Speed commands for the conveyor are not provided on time.	*	
H2-8	Feedback and commands from “smart glasses” (worker) to “technicians” sent/received late.		*
H3	**Potentially harmful workers’ activities that could lead to injury (L1, L2, L3)**		
H3-1	Potentially harmful activities of workers' hands that could lead to injury.	*	*
H3-2	Potential stress to workers during routine activities.	*	*
H4	**Inefficient worker training (L1, L2)**		
H4-1	Training needs are not appropriately described.	*	*
H4-2	Training of workers is not accomplished properly.	*	*

Consideration of hazards and system-level constraints required to prevent hazards is as follows:

Table 4.2 System-level constraint

SC No	System-level Constraint	Hazards	Case1	Case2
SC-1	Programming and calibration of data glove to ensure correct data is sent.	H1-1,	*	*
SC-2	Consider sensor positioning and glove fit to worker's hand during design phase.	H1-1, H1-6, H3-1	*	*
SC-3	Check proper functioning regularly of connection between the "receiver and processor" and the "data glove".	H1-1, H2-3, H3-2	*	*
SC-4	Program the "receiver and processor" properly to ensure correct information is sent/received and detect wrong information.	H1-2, H1-3	*	*
SC-5	Check regularly communication channels between "production planning" and other components.	H1-2, H2-5	*	*
SC-6	Define organizational processes appropriately to reduce the chances of making errors when sending information.	H1-2, H1-3, H1-4, H1-5, H1-7, H1-14, H1-16	*	*
SC-7	Ensure effective communication channels between the "supervisor" and "production planning" to avoid misunderstanding, loss of data or wrong data.	H1-4	*	*
SC-8	Ensure effective communication channels between "resource management" and "production planning" to avoid misunderstanding, data loss or wrong data.	H1-5	*	*
SC-9	Ensure effective communication channels between "resource management" and "resource provision" to avoid misunderstanding, data loss or wrong data.	H1-7	*	*
SC-10	Ensure effective communication channels between "worker" and "supervisor" to avoid misunderstanding, loss of data or sending wrong data.	H1-8	*	*
SC-11	"Programing department" must apply the proper program, instructions and rules to ensure "receiver and processor" sends correct commands (feedback).	H1-9, H1-17, H2-3	*	*
SC-12	Instructions for calibration processes should be accurate.	H1-10	*	*
SC-13	Buffer stock needs to be considered.	H1-11, H2-2	*	
SC-14	Buffer stock needs to be considered for the storage space in assembly islands.	H1-12, H1-13		*
SC-15	Define organizational processes for stock being delivered to assembly islands.	H1-13		*
SC-16	"Smart glasses" need to be programmed properly to send the correct data.	H1-14		*

Table 4.2 System-level constraint (Continued)

SC No	System-level Constraint	Hazards	Case1	Case2
SC-17	Check connection between "receiver and processor" and "smart glasses".	H1-14		*
SC-18	Check the connection between the "receiver and processor" and the "technicians" regularly.	H1-15		*
SC-19	Effective communication is needed between "transportation management" and "resource provision" to avoid confusion, loss of data or wrong data.	H1-16		*
SC-20	Define quality control criteria clearly to avoid mistakes.	H1-19		*
SC-21	Check communication channels between “workers” and “supervisors” to ensure the supervisor's messages and commands are received on time.	H2-1	*	*
SC-22	Define properly organizational processes providing resources to reduce delays.	H2-2	*	*
SC-23	Check communication channels between "resource management" and other components regularly.	H2-4	*	*
SC-24	Check the connection between the "receiver and processor" and the components regularly.	H2-6	*	*
SC-25	Check the timing programming of technologies for sending feedback, commands and reports regularly.	H2-6	*	*
SC-26	Check the connection between the "receiver and processor" and the "conveyor" and the timing programming of "receiver and processor" in sending commands to "conveyor" regularly.	H2-7	*	
SC-27	Check the connection between "smart glasses" and "technicians" regularly.	H1-18		*
SC-28	Train the worker adequately on how to use the smart glasses.	H2-8		*
SC-29	Train the worker so he/she can avoid unnecessary pressure on his/her fingers.	H3-1		*
SC-30	Training department must ensure workers that their personal data will not be used for controlling purposes.	H3-2	*	*
SC-31	Workers should know to report any errors or late feedback from data glove.	H3-2	*	*
SC-32	Adapt conveyor speed to each worker to ensure ergonomic work conditions.	H3-2	*	
SC-33	Technical support must be provided promptly at the request of the worker.	H3-2		*
SC-34	Provide instructions describing training needs.	H4-1	*	*
SC-35	Appropriate tools/measures should be applied to assess the training process.	H4-2	*	*
SC-36	Organizational instructions and training should be properly prepared.	H4-2	*	*
SC-37	The performance of the connection between the "receiver and processor" and the "worker’s screen" should be checked regularly.	H1-17		*

Step 2: Model the control structure

A hierarchical control structure is a system model that contains elements such as feedback, control actions, controllers, and input and output from components and controlled processes.

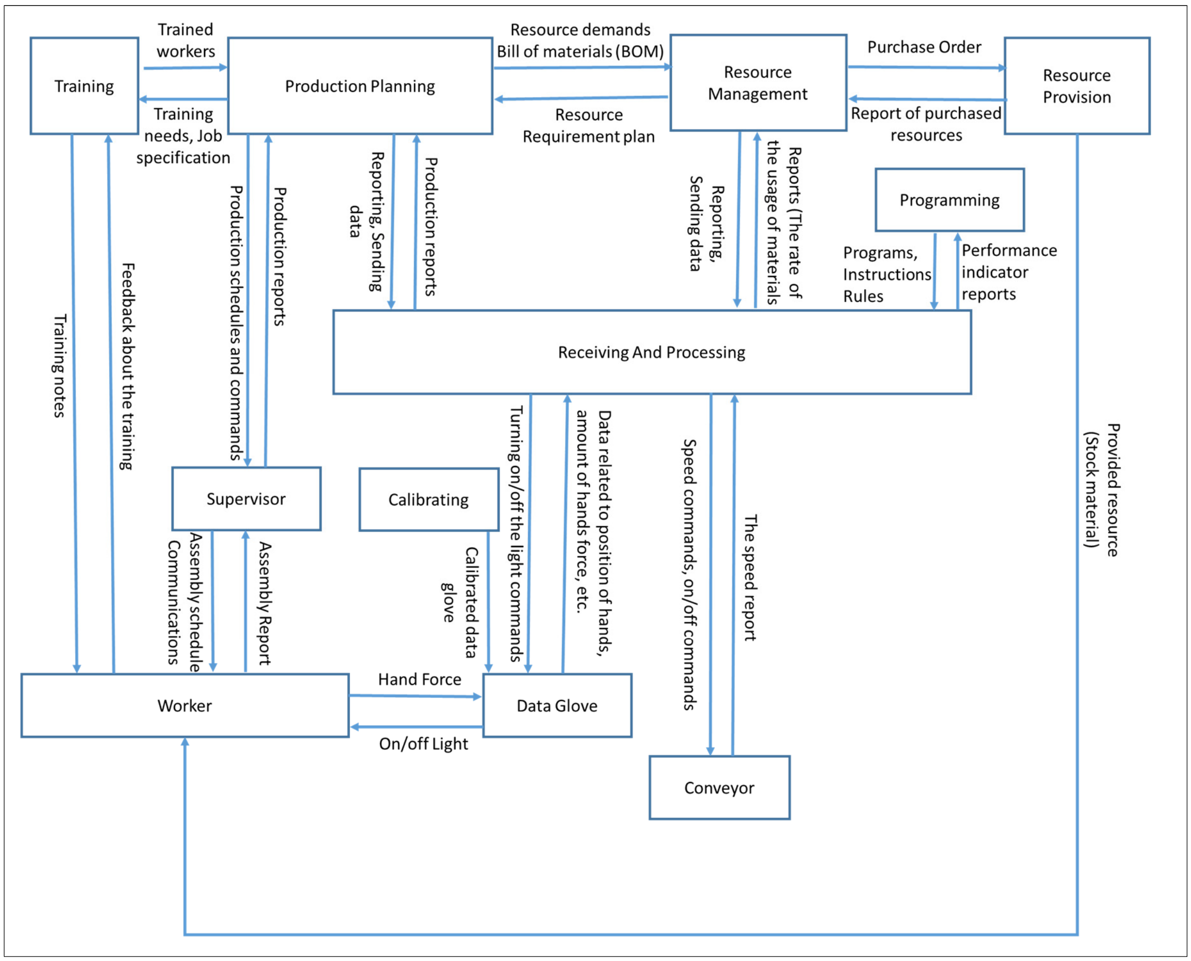

Figure 4.4 Control structure of case study 1

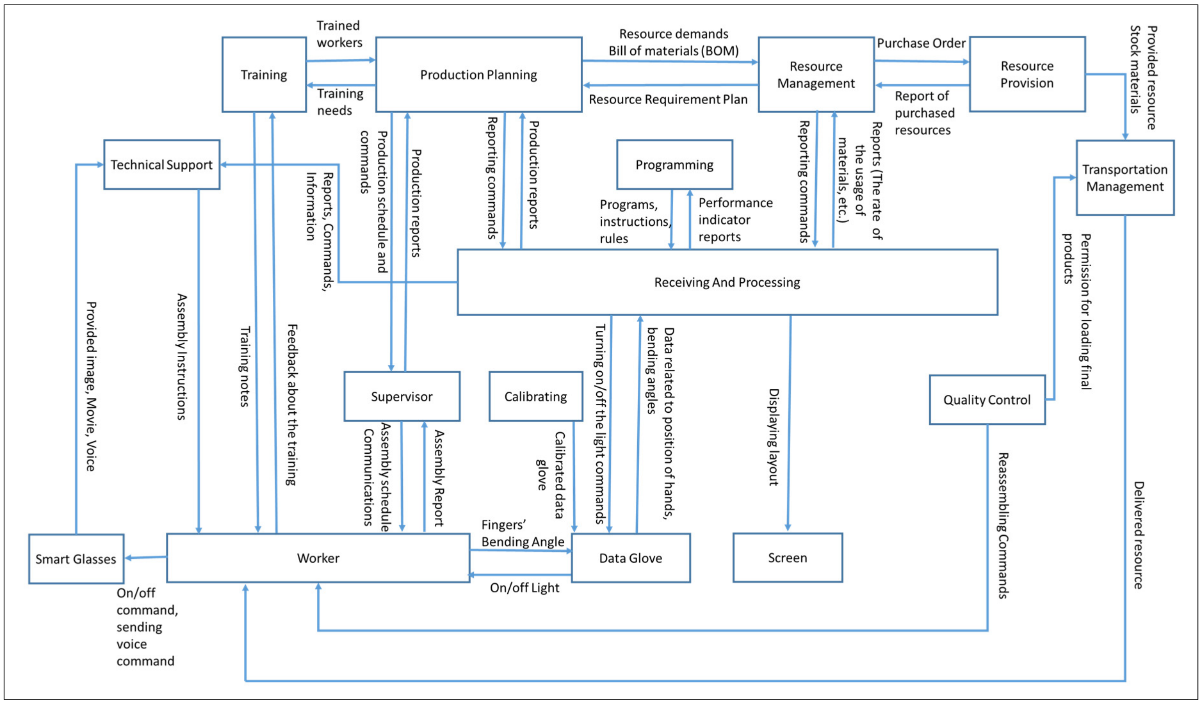

Figure 4.5 Control structure of case 2

3- Identify Unsafe Control Action

The purpose of STPA is to show how safety constraints (used to mitigate, eliminate, and control hazards that might emerge or develop into an accident) might be violated or insufficiently enforced. STPA investigates dysfunctional controller interactions that could cause process execution malfunctions (Yang et al., 2020).

To find unsafe control actions in the system, an analysis of the system can be done using the Swiss Cheese Model (SCM), which identifies the system's different layers (Larouzée et Guarnieri, 2015; Larouzee et Le Coze, 2020). However, SCM cannot properly analyze accidents in highly automated and complex systems (Larouzée et Guarnieri, 2015). Therefore, SCM provides us with an understanding of what might go wrong and illustrates risks in the form of unsafe control actions, whereas STAMP is better suited as a risk analysis tool for complex and automated systems (Larouzée et Guarnieri, 2015; Underwood et Waterson, 2014). The holes in the slices represent weaknesses in each of the system's parts, including the organizational layer (management decisions, sector management, organizational process, corporate culture), preconditions (workplace, preconditions (precursor conditions for errors or infringements), fatigue), human (errors, infractions and unsafe gestures at the production level and inadequate means of defense), technology (failure or malfunction of technology), all of which are continually varying in size and position across the slices.

Regarding the SCM model, to identify an unsafe control action (UCA), it is useful to consider the layers discussed earlier and identify which layer for every control action might cause a hazard.

Table 4.3 Unsafe Control Action

Control action	Not providing causes hazard	Providing causes hazard	Providing too early, too late, or out of sequence	Stopped too soon, applied too long	Case 1	Case 2
Training notes (provided by training department for workers)	UCA-6: The training department does not provide training for workers (H4-2).	UCA-7: Training department provides inefficient training for workers (H4-2).	UCA-8: Training department is late in providing training for workers (H4-2).		*	*
Turn light on the data glove on/off	UCA-15: The "receiver and processor" does not provide on/off light commands for the worker during assembly when pressing the lock pin on the male connector (case 1) or taking a component (case 2) (H1-1, H3-1, H3-2, H2-3).	UCA-16: The "receiver and processor" provides wrong on/off light commands for the worker during assembly when pressing the lock pin on the male connector (case 1) or taking a component (case 2) (H1-1).	UCA-17: The receiver and processor provides on/off light commands to worker during assembly when pressing the lock pin on the connector too early before pin is pressed or too late after pin is pressed (case 1) or component taken (case 2) (H1-1, H3-1, H3-2, H2-3).		*	*
Providing calibrated data glove	UCA-66: Data glove not calibrated prior to assembly use (H1-10).	UCA-67: Data glove incorrectly calibrated prior to assembly use (H1-10).			*	*

Table 4.3 Unsafe Control Action (Contiued)

Control action	Not providing causes hazard	Providing causes hazard	Providing too early, too late, or out of sequence	Stopped too soon, applied too long	Case 1	Case 2
Finger force	UCA-36: When the worker takes a component in hand, fingers that push sensors of the data glove do not send information to the “receiver and processor” during assembly (H1-6).	UCA-37: When the worker takes a component in hand, fingers that push sensors of the data glove send wrong information to the “receiver and processor” or push the wrong position of sensors during assembly (H1-6).			*	*

4- Identify Loss Scenarios

Scenarios involve improper or failed execution of control actions, such as a) unexecuted control action, b) improper control action execution, c) improper time execution of control action (Leveson et Thomas, 2018).

Table 4.4 Loss scenarios considering unsafe control action

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: The training department provides training for workers. UCA-6 Scenario 1. Organizational errors: omission of information for data glove training guidelines for workers. UCA-7 Scenario 2. Training department does not have specific guidelines (instructions) for training: it cannot provide efficient training for workers. Scenario 3. Data glove manufacturer fails to provide proper information for training: workers are not trained properly. UCA-8 Scenario 4. Delays in organizational planning: the training of workers will be held late.	*	*

Table 4.4 Loss scenarios considering unsafe control action (Continued)

Loss scenarios regarding to Control Action	**Case 1**	**Case 2**
Control action: Data glove light turns on when the assembly is done correctly / correct component is taken. UCA-15 Scenario 5. Programming error: on/off light commands are not sent from the "receiver and processor" to the data glove when the worker has completed the assembly (e.g when the assembly is completed correctly the glove does not turn on). Scenario 6. Malfunctioning connection between the "data glove" and "receiver and processor": On/Off commands are not sent to the data glove. UCA-16 Scenario 7. Programming error: incorrect on/off light commands are sent from the "receiver and processor" to data glove e.g., the light stays off even though the worker has completed assembly correctly or the light on data glove turns on even though assembly is incorrect. UCA-17 Scenario 8. Malfunctioning connection between the "data glove" and "receiver and processor": On/Off commands are received late to the data glove and the worker needs to wait a time for the feedback. Scenario 9. Programming timing error: on/off light commands are provided late in the "receiver and processor" to be sent to the data glove when the worker has completed the assembly correctly.	*	*
Control action: Worker's hand (fingers) activates sensors of the data glove. UCA-36 Scenario 10. Incorrect positioning of sensors in the data glove: the worker's hand (fingers) cannot activate sensors to receive feedback. Scenario 11. Poor calibration of data glove: fails to detect the worker's hand (fingers) pressure (bending). UCA-37 Scenario 12. Incorrect positioning of sensors in the data glove (design error): the sensors detect the worker's hand position wrongly, thus incorrect feedback data will be sent to the receiver and processor. Scenario 13. The size of data glove is incorrect (improper hand fit): the worker pushes the wrong position of sensors to receive feedback.	*	*

Table 4.4 Loss scenarios considering unsafe control action (Continued)

Loss scenarios regarding to Control Action	**Case 1**	**Case 2**
Control action: A technician will calibrate the data glove periodically prior to its use in assembly tasks. UCA-66 Scenario 14. Organizational errors (human error): the technician does not calibrate (forgets or data glove is not listed in calibration plan) the data glove before use in the assembly. UCA-67 Scenario 15. Human error in calibration (the technician is fatigued or the technician does not follow the calibration instruction appropriately): the data glove is not calibrated properly. Scenario 16. Planning error (absence of clear, uniform instructions for calibrating data gloves): each technician calibrates the data glove in a different way and the data glove might be calibrated incorrectly.	*	*

4.5 Discussion

To deal with management challenges of complex socio-technical systems, systemic approaches can be used. The results obtained from these methods are coherent but vary with regards to details and scope (de Linhares, Maia et Ferreira Frutuoso e Melo, 2021).

STPA can be applied at any stage of the system lifecycle to identify potentially inadequate or unsafe control actions that might lead to a hazard (Hulme et al., 2021a). Applying STPA provides the opportunity to analyze complex systems and identify risks that usually emerge during operations. It assists the system designer in identifying safety requirements and constraints and more detailed design properties. STPA includes all system components (human, technology (software, hardware), organization) to consider all aspects in hazards identification. STPA can be applied in many system engineering processes (Leveson, 2018).

The use of STPA in the early phases of concept design helps designers consider safety in designing manufacturing systems, especially for software used to design parts. It can provide functional safety requirements for the system as a whole as well as for the components that make up the system, namely, human, software, hardware, organization, machines, etc. (Leveson, 2018).

Manufacturing operations scenarios in the context of industry 4.0 are complex and require several control actions comprising human (workers, supervisors, technicians, etc.), machines (wearable technologies, transportation vehicles, conveyors, etc.) and organizations (Li et al., 2021). An unsafe control action not only creates casual scenarios, but can also provide useful information that can be considered as safety requirements and constraints that need to be considered in designing a system (Leveson, 2018).

STAMP divides a system into several control loops and analyzes it (Thapaliya et Kwon, 2018). From the STPA perspective, the interaction of unsafe actions of system components' can cause risks even if they are not failing, which is similar to FRAM, in which functions variabilities can cause risks even though they may not have failed (Toda, Matsubara et Takada, 2018). Defining control structure in hierarchical levels, STPA provides control recommendations (Yousefi, Rodriguez Hernandez et Lopez Peña, 2019), as well as guidance for the compliance of wearable technology in the assembly system (Zheng, Tian et Zhao, 2016).

STPA provides a holistic view of the system and an explicit description of system components' relationships in terms of safety control action. It guides the analyst substantially on the system theory. It is a qualitative method, and the findings of the analysis are presented in several documents. However, its graphical presentation of a system to illustrate risks is limited and not suited for non-experts (Underwood et Waterson, 2014). Moreover, a qualitative presentation of hazards does not distinguish the severity of identified hazards for the analyst. STPA emphasizes the complexity of systems and considers risks as a result of an inadequate control of safety constraints. It provides a description of the control structure system and identifies failures in the control structure to assist in identifying risks. STPA provides an insight for the designer (analyst) on how the studied system should be controlled (Salmon, Cornelissen et Trotter, 2012).

STPA is a valuable approach for identifying hazards in autonomous and remote industries (Wróbel, Montewka et Kujala, 2018a; 2018b; Yang et al., 2020). When the characterization of system components and their function is the issue of analysis, STPA presents many advantages for designing activities (de Linhares, Maia et Ferreira Frutuoso e Melo, 2021), whereas the allocation and consideration of proper functions that impose appropriate constraints and feedback might be better achieved by applying STPA (de Linhares, Maia et e Melo, 2020). STPA is a better solution for the identification and classification of technical control failures than for assisting in complex human decision-making (behavior) and anticipating organizational failures (Kontogiannis, 2010; Salmon, Cornelissen et Trotter, 2012). Although the qualitative analysis does not show the severity of risks, the frequent repetition of control structures related to the "receiver and processor" in loss scenarios and the connection of other components to it, especially the data glove, indicates that this component can affect the system considerably. Moreover, efficient workers' training, particularly on the use of wearable technology (e.g. data glove and smart glasses), will mitigate the OHS and operational hazards of its introduction to an assembly system. Furthermore, STPA cannot show which processes are considered preconditions for the system's performance (in this study, provision of a calibrated data glove is a prerequisite for the assembly). Moreover, the control structures is a simple model of interconnection of the system components. We analyzed the operational risks of the provision of resources simply in terms of being/not being provided and the risks of supply chain at the micro level has not been considered (Bensaci et al., 2020). The application of data gloves is studied here in realistic case studies. Therefore, details in design are only moderate touched upon. STPA mostly deals with accidents or safety scenarios rather than a generalized understanding of system behavior in normal operations (Thatcher, Nayak et Waterson, 2020). As STPA can be considered a method for analyzing a system in the design phase, access to numerical data can help the analyst better analyze crucial components and zoom in to find more control loops in the micro-level structure. Since STPA can feasibly assess in-depth different levels of a system, the first analysis can be a non-detailed analysis to gain an overview of the studied system. Then the analysis can go into detail for each constraint or selected constraints. Therefore, the analyst has more freedom in studying a system and can focus more on the constraints that seem more important (Hoel, 2012).

4.6 Conclusion

This study addresses the OHS and operational challenges of the introduction of a data glove to an assembly system in the context of industry 4.0. The interaction of different assembly system components (human, machines, organizations, software, etc.) might give rise to risks that need to be identified before the data gloves are used throughout the assembly. Various components of the different levels will enhance the complexity of the system. Therefore, studying such a complex system requires systemic methods. STPA is a systemic approach that uses a control structure, which has been applied here to analyze two case studies. Results of these case studies indicate risks from the control structure as well as system-level constraints that can prevent (or mitigate) hazards. They show STPA as a promising method for OHS and operational risk analysis for the introduction of a data glove to a 4.0 assembly system. STPA also provides guidance and recommendations for designing the system. Nonetheless, the application of STPA with another systemic approaches that are able to provide more details about the type of interactions between each component (e.g. preconditions, time, control) and a holistic view of the system can be the topic for further research. Meanwhile, the access to numerical results that highlight more clearly the comparison of risks as well as a comparison of the application of other systemic methods in risk analysis for the introduction of a wearable technology (in this study a data glove) to a manufacturing system would be an avenue for future studies.

CHAPTER 5

PROPOSED INTEGRATED FRAM/STPA RISK ANALYSIS OF DATA GLOVES IN ASSEMBLY 4.0 SYSTEM

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This chapter presents the paper submitted to the Robotics and Computer-Integrated Manufacturing Journal. This paper addresses the research questions and, followingly, the third research objective. This paper provides a brief comparison of the results of the application of FRAM and STPA on specific case studies. This paper answers how OHS and operational risks when a data glove is introduced to an assembly system are analyzed and managed. This paper has materialized the research's third objective for proposing an innovative approach to risk management of the use of a data glove in assembly 4.0 context. The proposed approach was applied to case studies, and results showed that the integrated approach benefits of the advantages of both FRAM and STPA and covers their weak points. While it provides an overview of the system components and their interactions, an in-detailed STPA analysis could show functions' inside precisely. It is also helpful in identifying risks that had not been identified when FRAM or STPA were applied solely.

Abstract

The increased levels of complexity in manufacturing lead to increased potential occupational health and safety (OHS) and operational risks. Dealing with this requires new approaches that are able to not only analyze complex systems in detail but also provide analysts an overall understanding of the studied system. This study aims to introduce a novel approach integrating FRAM and STPA for OHS and operational risk analysis of assembly in industry 4.0. This integrated approach combines the specific strengths of both methods to provide a detailed analysis of the studied system. The proposed approach will be applied to two assembly 4.0 case studies, and it will be validated using data from previous studies. The results showed that the integrated approach could provide a better understanding of the system compared to the sole application of either FRAM or STPA. Moreover, it could identify risks that were not identified when solely using FRAM or STPA. The new approach provides an in-detail analysis of organizational functions. However, more studies are required to confirm this capability firmly. Although the proposed approach is helpful to conduct a risk analysis in the context of assembly 4.0, its efficiency needs to be examined in other contexts in future studies.

5.1 Introduction

Industry 4.0 is currently being introduced to various systems, such as in manufacturing, further increasing the complexity of these systems (Mourtzis et al., 2019). Systemic approaches have been developed to respond to the safety management challenges of these complex systems (Underwood et Waterson, 2013b). System-Theoretic Accident Model and Process (STAMP) and the Functional Resonance Analysis Method (FRAM) are two systemic methods that have been applied successfully for risk analysis (Patriarca et al., 2020) in different systems, including manufacturing (Mofidi Naeini et Nadeau, 2021a). These methods have been applied either alone or combined with other methods (de Linhares, Maia et Ferreira Frutuoso e Melo, 2021) as graphed in Figure 5.1.

STAMP was used as the main or complementary method to proactively analyze risk in complex systems (Patriarca et al., 2022). There are four types of analysis based on the STAMP approach, of which STPA is used for hazard analysis (Pricop et al., 2020). STPA was combined with Goal Structuring Notation (GSN) to provide a graphical notation to document dependability and analyze safety in a safety case for the construction of train door controllers (Hirata et Nadjm-Tehrani, 2019a). STPA has also been applied in combination with the Hazard Identification study (HAZID) to improve dynamic positioning and mooring systems in Arctic regions. HAZID was applied to the system structure and STPA was used for the control system (Joung et al., 2018). Behavior Driven Development (BDD) and STPA has been used simultaneously for safety verification and analysis. For example, it was applied to the destoning of an automated vehicle (Wang et Wagner, 2018b). STPA has been combined with model checking analysis to present a clear and formal presentation of the system under analysis and, consequently, improve the analysts' understanding of the design phase (Dakwat et Villani, 2018). The bow tie method has been applied to achieve a better comparison of control actions analyses in different loss scenarios obtained by STPA analysis. This approach helped to improve the STPA outcomes and facilitate the choice of an appropriate approach for analysts (Bensaci et al., 2020).

Over the years, FRAM has evolved due to its having been combined with other methods (Patriarca et al., 2020). By applying the Monte Carlo Simulation, a considerable change was introduced by (Patriarca, Di Gravio et Costantino, 2017). This change provided a qualitative analysis using a quantitative scale of functions variability description. Different approaches have been applied in various contexts to improve FRAM risk analysis (Patriarca et al., 2020). For example, FRAM has been integrated with Bayesian Networks (Toroody, Toroody et De Carlo, 2017), Fuzzy logic and rough sets (Slim et Nadeau, 2019; 2020a), Fault Tree Analysis (FTA) (Toroody, Abaei et Gholamnia, 2016), and Analytic Hierarchy Process (AHP) (Bellini et al., 2016) to provide quantitative results. The combination of FRAM with Failure Mode and Effects Analysis (FMEA) and MEHARI (MEHARI, 2010) approaches in an IoT case study has also been studied (Mock et al., 2017).

Although various studies have explored the combination of FRAM with other methods to improve its functionality for their specific context (Patriarca et al., 2020), to the best of our knowledge, its combination with STAMP as a systemic approach has been explored in only two studies. Toda (2018) proposed a FRAM/STPA approach that uses the four STPA keywords: considering providing/not providing, too early/too late, and stopping too soon/applying too long of actions that cause hazards, for every aspect of a function in the FRAM model (Toda, Matsubara et Takada, 2018). In other words, the four STPA keywords help the analyst to analyze the variability of functions in a more organized way and from an STPA perspective. Thapaliya (2018) developed an approach that applied both STPA and FRAM. In this approach, STPA was first used to identify safety controls and then FRAM was used to model the system regarding the control structure resulting from the STPA analysis. A symbolic model checking was used to verify whether the FRAM model met the STPA constraints identified in the previous step of the analysis (Thapaliya et Kwon, 2018). These two approaches were developed for a railroad crossing context.

The findings of previous studies show that FRAM and STAMP (STPA) are appropriate methods for occupational health and safety (OHS) and operational risk analysis in manufacturing 4.0 (Mofidi Naeini et Nadeau, 2021a). To the best of our knowledge, a combined approach of FRAM and STAMP (STPA) has not yet been developed for OHS in manufacturing and operational risk analysis in the context of industry 4.0. Recent studies have shown the effectiveness of FRAM and STAMP (STPA) to identify risks and hazardous interactions in realistic assembly 4.0 case studies (Mofidi Naeini et Nadeau, 2021b; 2022a). However, the results can be improved by applying innovative combined approaches to reinforce their capabilities and enhance the weak points of these methods in assembly 4.0 (Mofidi Naeini et Nadeau, 2022b) (Thapaliya et Kwon, 2018). This study aims to develop an innovative approach that applies both STPA and FRAM to provide a risk analysis of an assembly system in industry 4.0. This approach aims to consider humans' interaction with new technology (a data glove in this study) introduced to the assembly 4.0 system to enhance the safety and resilience of the designed system.

This paper is structured as follows: Section 1 reviews the literature on hybrid approaches that have been combined with FRAM or STAMP (STPA). In section 2, the methodology of the proposed approach is explained. Then, case studies and the results of applying the proposed approach are discussed in Section 3. The obtained results will be validated using results from previous studies in Section 4. Section 5 discusses the proposed approach's results and draws the final conclusions.

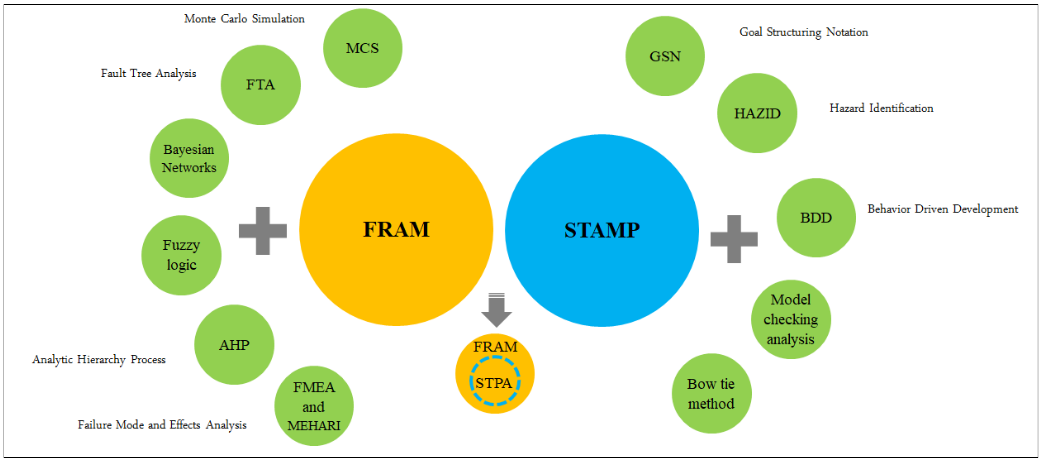

Figure 5.1 Overview of the methods combined with FRAM and STAMP

5.2 Methodology

In this paper, the proposed integration of STAMP-STPA and FRAM for OHS and operational risk analysis in assembly 4.0 is based on recent findings on the application of FRAM (Mofidi Naeini et Nadeau, 2022a) and STPA (Mofidi Naeini et Nadeau, 2021b) on case studies and the comparison of results (Mofidi Naeini et Nadeau, 2022b). Therefore, the proposed approach applies both FRAM and STPA in a model to analyze a function's internal dynamics.

When we apply FRAM, the description for each function allows us to reveal variabilities in the six aspects of the FRAM model. To further analyze and zoom in on a function, the STPA approach can provide a better description of the internal functioning of the function, especially when the system is in the designing phase, as the identified controls will assist in designing a safe system (Thapaliya et Kwon, 2018). Moreover, when different components from an MTO perspective cooperate in a function, a STPA approach can provide better insight into the controllers and controlled object in a function. Thus, more efficient safety controls regarding the type of internal components of a function could be designed and reviewed. By applying this approach, we can identify each control action or feedback in the system and attribute it to an aspect from FRAM. This method is innovative in two ways. First, it integrates two different models for a specific case study, and second, it provides an insight for every control action and feedback according to what type of FRAM aspects they are. Hence, the analyst can design more precise safety control actions to reduce or prevent the variability of the functions.

The FRAM model represents a sociotechnical system's dynamic interaction, including all aspects (human, organizational, technological). This model demonstrates how and why conditions of operation, variabilities and resonance will result in risks (Herrera et Woltjer, 2010). Compared to classic methods, STAMP is probably closer to FRAM from the perspective of terminology and philosophy (Kaya, Ozturk et Sariguzel, 2021; Toda, Matsubara et Takada, 2018).

FRAM analysis develops a model of functions that shows their variability and their effects on other functions while it would not be clear how to provide safety (prevent variability) (Toda, Matsubara et Takada, 2018). STAMP-STPA models the interaction of different components in the form of safety controllers and feedback especially in a digitalized context that their interaction is more complicated (Shin et al., 2021). From an STPA perspective, a system components' non-safe interactions (control actions) might lead to hazards even if they are not failing. Likewise, in FRAM modeling, hazards might occur due to the variability of functions and their interactions.

At first sight, there are considerable differences in the application of FRAM and STAMP. However, there are similarities, such as their systemic view and common keywords, such as ‘Not providing’, ‘Providing causes hazard’, ‘Too early/Too late’, ‘Stop too soon/Applying too late’, which can be applied in analyzing time variability in FRAM.

In the integrated approach, internal components of a function are analyzed from the perspective of STPA. The innovation here is that controlled actions are labeled using the six aspects of FRAM analysis. The proposed approach thus benefits from both the FRAM and STAMP approaches combining both into one model, meaning that control actions and feedback are shown in the six aspects of FRAM. This makes it possible to analyze the most variable functions in detail. The STPA analysis results provide considerable safe control actions that improve systems performance and safety, specifically in the first stage of designing systems. Moreover, it may reveal aspects and new safety recommendations for analysts that might not have been noticed if only one method had been applied. When only FRAM is applied, the behaviour of internal components and their interactions cannot be seen clearly.

Moreover, the application of STPA cannot show the behaviour of system components as precisely as FRAM can. At the same time, the proposed method provides their interaction as both control action and feedback from six aspects of FRAM. Hence, identifying the type of required safety control action that can affect a function will assist in identifying more hazards and consequently, ensure that the system is designed to be safer and more efficient.

The integrated approach is preferred regarding the benefits and drawbacks of applying only FRAM or STPA to case studies (Mofidi Naeini et Nadeau, 2022b). When FRAM is applied, zooming on the most variable functions requires that an increasing number of functions be defined. This consumes a considerable amount of time as it would require not only identifying functions but analyzing them as well (Toda, Matsubara et Takada, 2018). Providing a detailed description for each component in the function cannot reveal more findings than would be found by applying STPA. Moreover, safety control actions and recommendations provided by STPA are other important points that need to be considered. If STPA is solely applied, it cannot show the interactions between components, such as preconditions, input, resources, controls.

In other words, STPA is better suited for analyzing system components at the micro-level, and FRAM is better for analyzing a system at the macro-level. Hence, when the object-oriented approach is better at studying systems, STPA can be combined with FRAM to analyze the systems, especially at the design phase (Toda, Matsubara et Takada, 2018). This analysis model provides a system overview and detailed control actions and feedback of components of the most variable functions. Therefore, after the system structure has been designed, a more detailed analysis can be conducted by applying this approach. Figure 5.2 shows the steps of the proposed approach.

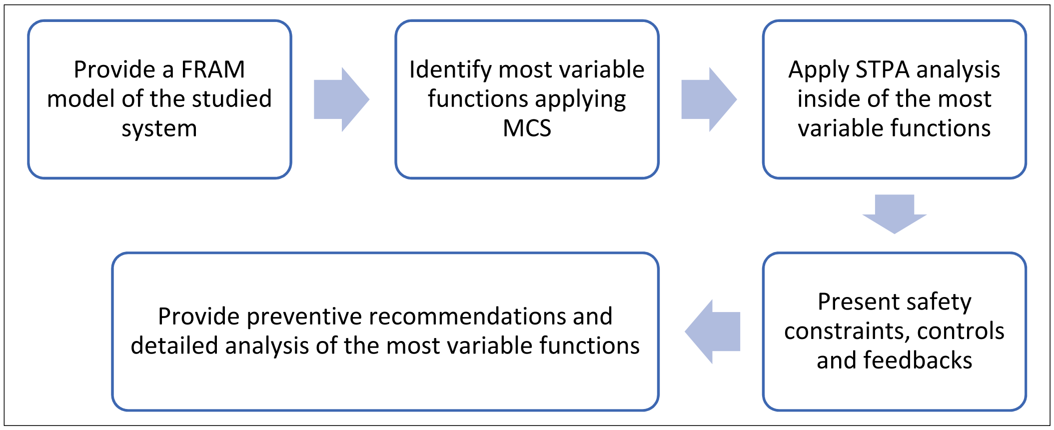

Figure 5.2 Concept of the proposed approach

5.3 Results: Application of the proposed approach

5.3.1 Case studies

5.3.1.1 Case study 1: using a data glove to assemble connectors

A data glove is used in an assembly line to assist in assembling connectors (Kucukoglu et al., 2018). When the worker assembles a connector correctly, the green light on the data glove turns on and the assembled connector is sent to another work station on a conveyor. Workers who use the data glove are trained and work under the supervisor's commands. The assembly line was designed in industry 4.0, and other components of the system such as the production planning department and resource management department use the processed data from the data glove (Golan, Cohen et Singer, 2020). Therefore, providing Bill of Materials (BOM), resource requirements planning (RRP), capacity requirement planning (CRP), and lead-time all depends on the processed data of the data glove. Data are received and processed in a receiver and processor to provide appropriate feedback for other components of the system. A detailed description of the system is provided in (Mofidi Naeini et Nadeau, 2022a).

5.3.1.2 Case study 2: Using a data glove to detect the right component

A data glove and smart glasses (Nadeau, Bruder et Hof, 2021) are used in assembly islands (Guo et al., 2020a) to assist workers by for instance, showing them the correct place of an item for assembly (Hao et Helo, 2017; Lawrence, 2016; Saarland University, 2019). Workers in assembly islands need to be trained on how to use assistive equipment for assembly. A supervisor is responsible for certain islands to communicate with and supervise workers. In case of technical issues, a technical support team will remotely help the worker. Data from the data glove and other system components are analyzed in a receiver and processor to provide feedback for scheduling, resource management, transportation among islands, etc. The quality of the assembled products is controlled, and if they meet the criteria, they will be transported to the main factory. A detailed description of the system components is presented in (Mofidi Naeini et Nadeau, 2022b).

5.3.2 FRAM Model

The FRAM model for the case studies are presented below (Figure 5.3, 5.4). The models provide a holistic view of the functions' interactions and their effect on each other. Each type of function is presented in a specific colour. Human functions are shown in blue, technological functions in yellow, organizational functions in green, background functions in gray and a sink function in red. Therefore, the model presents an overview of the studied system and its different functions.

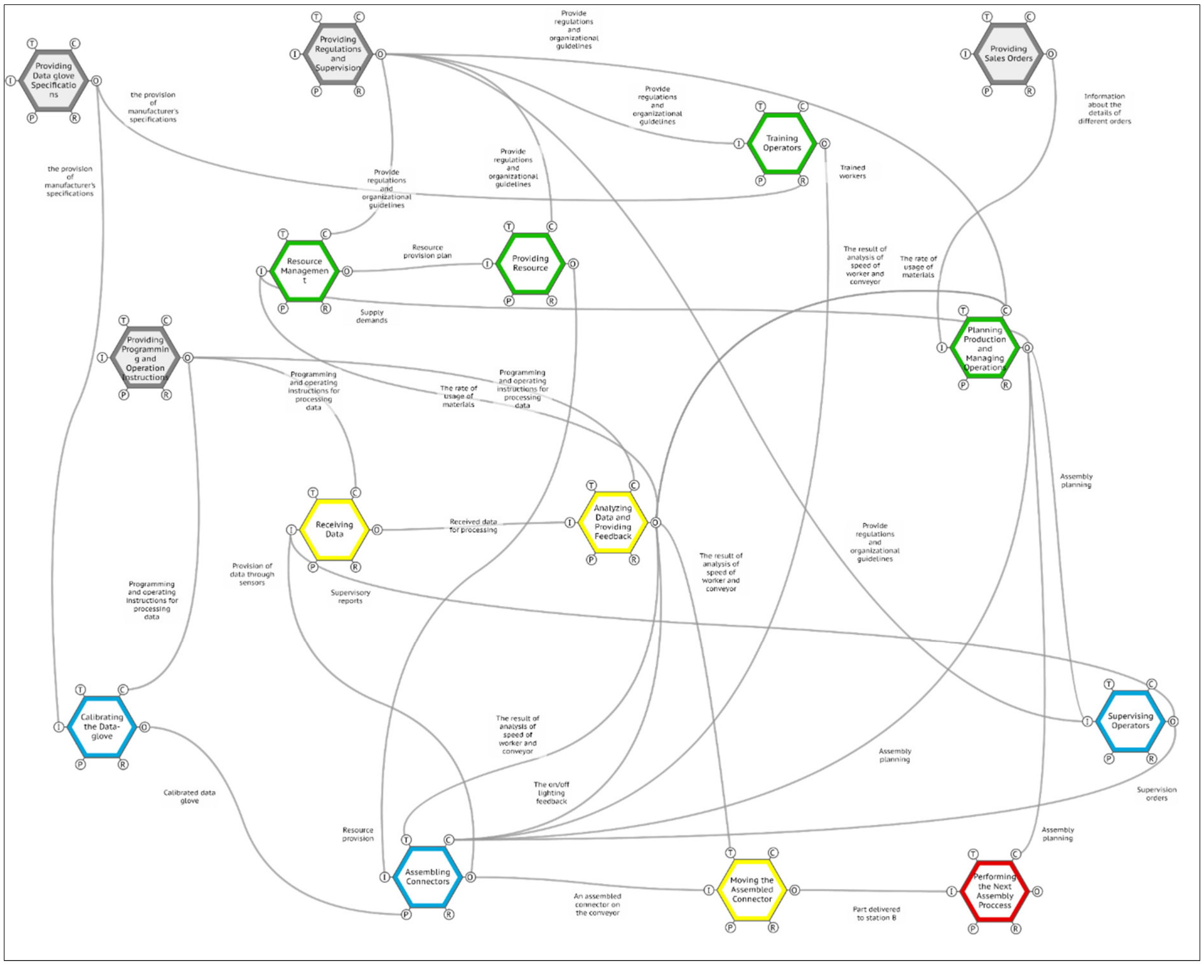

Figure 5.3 FRAM model of the first case study

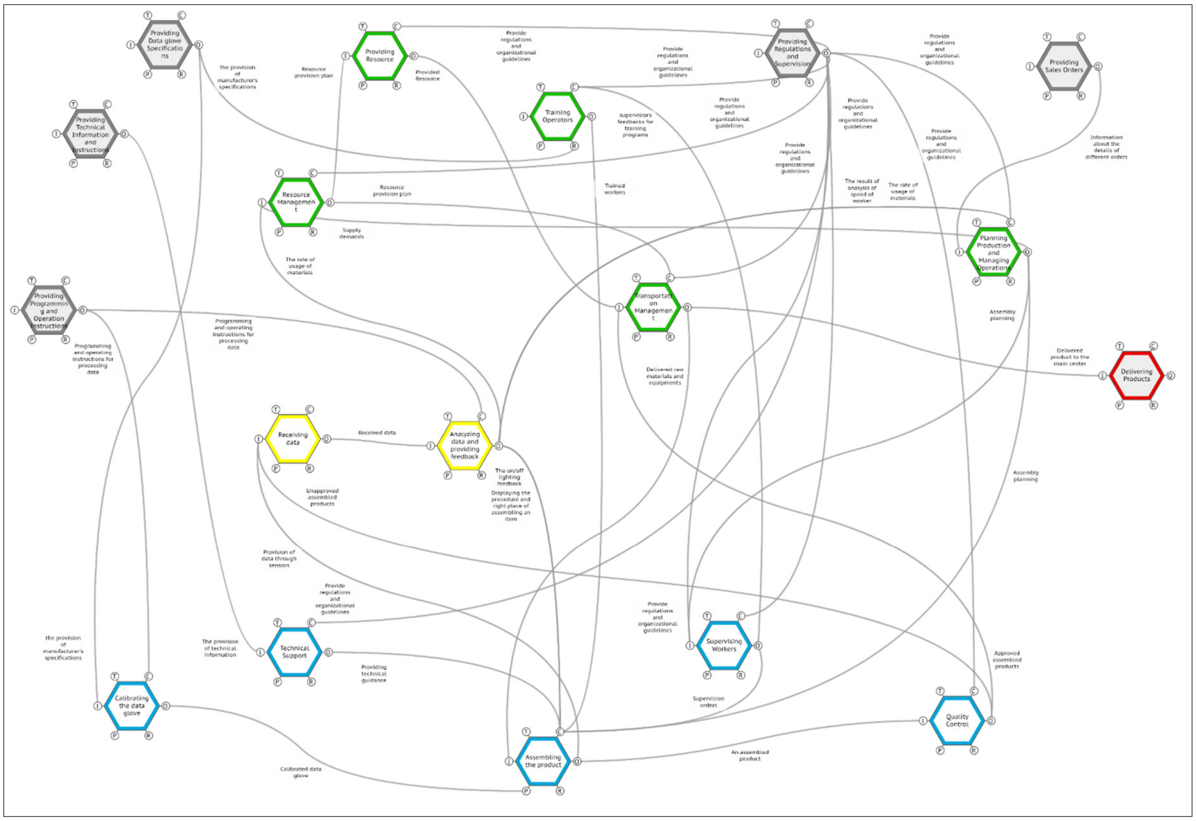

Figure 5.4 FRAM model of the second case study

5.3.3 Coupling variability calculations

Since we face a qualitative problem in this study, we needed a quantitative approach to enable us to present the variability of functions in numerical format to avoid misunderstandings in verbally articulating the functions' variabilities and, consequently, the most variable functions. Hence, the Monte Carlo Simulation for FRAM proposed by Patriarca (Patriarca, Di Gravio et Costantino, 2017) was of interest to calculate the variability of couplings (Cumulative Variability (CV))(Equation 1). This approach assists in translating linguistic evaluation of functions variability to a semi-quantitative term, which makes the understanding of the system and the effects of different variabilities more comparable (Patriarca et al., 2017). MCS provides close outcomes to reality by using random sampling (Li et al., 2017). It is mainly an applied simulation of complex problems, one of which is the risk analysis of engineering systems (Marseguerra et al., 2003). It helps the analyst to predict and understand the impact of variabilities on systems, especially systems with uncertainties and the emergences of a combination of different variables (Stroeve, Blom et Bakker, 2009).

Because the couplings with critical variabilities are those most likely to cause accidents, the MCS aims to find these couplings. Identifying functions for which the output variabilities are critical will make it possible to manage them to mitigate or prevent their risks (Kaya, Ozturk et Sariguzel, 2021; Patriarca, Di Gravio et Costantino, 2017).

$$CV = V_{jn}^{T} * V_{jn}^{P} * a_{ijn}^{T} * a_{ijn}^{P} * e_j \tag{5.1}$$

V_{jn}^{T}, V_{jn}^{P}: Variability of the output n from function j in terms of Time and Precision, respectively

a_{ijn}^{T}, a_{ijn}^{P}: Variability effect of the output n from upstream function j to downstream function i in terms of respectively Time and Precision.

e_j: The impact of downstream functions variability on the upstream function j. It is determined by the analyst of the system (as the expert).

The numerical value attributed to the variabilities is based on their effectiveness as follows:

Table 5.1 Variability in terms of Time and Precision

	1	2	3	4
V_{jn}^{T}	Too early	On time	Too late	Not at all
V_{jn}^{P}	Precise	Acceptable		Imprecise

Table 5.2 Effect of variability on upstream function in terms of Time and Precision

	0.5	1	2
a_{ijn}^{T}*	Dampening effect	No effect	Amplifying effect
a_{ijn}^{P}	Dampening	No effect	Amplifying effect

* Providing functions output too early will usually have a dampening effect on the system. The only exception is for ‘Assembling connectors’ as the upstream function of ‘Moving connectors’ and ‘Analyzing data and providing feedback’ as an upstream function of ‘Assembling connectors’ and ‘Assembling the product’ functions for which the ‘too early’ variability will amplify their effect.

To the best of our knowledge, applying the Monte Carlo Simulation to quantify the FRAM model of an assembly system in the context of industry 4.0 has not yet been studied. To apply the simulation, we needed probability data for the functions. In practice, to run the simulation, the step of defining every function’s variability score is one of the main challenges in quantifying FRAM outcomes. For example, technological functions are generally precise and rarely have errors. Therefore, finding a correct and realistic probability of errors is difficult. This challenge is harder for human and organizational functions (Nayernia, Bahemia et Papagiannidis, 2021; Patriarca et al., 2017). Given that realistic case studies are at the designing stage, practical data is unavailable. Thus, this study used data from the literature, more precisely statistical data from other studies that are somewhat similar to the system being analyzed. Most data were drawn from a study by Patriarca (Patriarca et al., 2017) providing an MCS for a steel-slab manufacturer, which was conducted in a manufacturing context that is considered to be a complex system. However, there are differences between the studied system and the system that was analyzed by Patriarca. Data related to probability distribution of human, technological and organizational functions are obtained by auditing processes in the factory (Patriarca et al., 2017). Moreover, the statistical data for the precision of the data glove was taken from Kucukoglu (Kucukoglu et al., 2018). In the assembling function, the variability of the function was dependent on both Human (the worker) and Technology (the data glove). In a study by Kucukoglu (Kucukoglu et al., 2018), the performance possibility of a data glove was investigated. Therefore, the simulated data for this function is a product of both data glove and human. For other functions in both case studies, we applied the statistical distribution shown in Table 5.3.

Table 5.3 Probability of Human, Technology, and Organization in terms of Time and Precision[11]

Aspect / Type	Timing				Precision		
	On time	Too early	Too late	Not at all	Precise	Acceptable	Imprecise
Technological	0.80	0.05	0.10	0.05	0.80	0.10	0.10
Human	0.50	0.15	0.30	0.05	0.20	0.50	0.30
Organizational	0.60	0.10	0.15	0.15	0.10	0.20	0.70

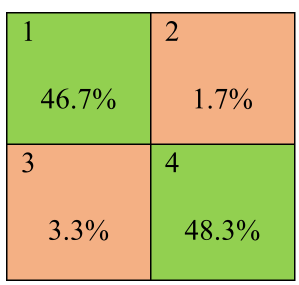

Figure 5.5 Probability of the precision of performance of the data glove[12]

[11] Sourse of the table: Patriarca et al. (2017)

[12] Source of the figure: Kucukoglu et al. (2018)

In Figure 5.5, the numerical values represent:

The percentage of proper samples classified as proper (Precise)

The percentage of proper samples classified as defective (Imprecise)

The percentage of defective samples classified as proper (Imprecise)

The percentage of defective samples classified as defective (Precise)

Regarding the explanation of probabilities, the distribution of probabilities in terms of Precision for the data glove is considered as:

Table 5.4 Probability of the data glove Precision[13]

Precise	Acceptable	Imprecise
95%		5%

Regarding the probabilities for functions in different types (Human, Technological, and Organizational), random numbers were simulated. As in the assembly function as a human function, a new technology has been added. The probabilities of the precision of the data glove were calculated as follows:

Table 5.5 Probability of Precision in assembly function[14]

Precise	Acceptable	Imprecise
0.19	0.475	0.335

Random numbers were generated in Excel and 1000 iterations were applied. Random numbers were generated based on the set of the discrete statistical distribution of variability of functions (Patriarca et al., 2017) discussed earlier. a_{ijn}^{T}, a_{ijn}^{P} are based on random numbers attributed to V_{jn}^{T}, V_{jn}^{P}. Thus, the increasing of variability of time and precision will have an amplifying effect

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[13] Soure of the table: Kucukoglu et al. (2018)

[14] Soure of the table: Kucukoglu et al. (2018)

except for the 'Assembling connectors' and 'Analyzing data and providing feedback' functions that provide 'too early', which will cause an amplifying effect on the downstream functions, respectively 'Moving connectors' and 'Assembling connectors'.

$$a_{ijn}^{T}, a_{ijn}^{P} \begin{cases} 2 \text{ if } V_{jn}^{T}, V_{jn}^{P} \text{ is 3 or 4} \\ 1 \text{ if } V_{jn}^{T}, V_{jn}^{P} \text{ is 2} \\ 0.5 \text{ if } V_{jn}^{T}, V_{jn}^{P} \text{ is 1} \end{cases} \quad (5.2)$$

And e_j is considered for function j as follows:

$$e_j \begin{cases} 4 \text{ if the variability of downstream functions has a high impact on an upstream function.} \\ 2 \text{ if the variability of downstream functions has a moderate impact on an upstream function.} \\ 1 \text{ if the variability of downstream functions has a low or no impact on an upstream function.} \end{cases} \quad (5.3)$$

The MCS approach proposed by Patriarca 2017 (Patriarca, Di Gravio et Costantino, 2017) was applied to semi-quantify the FRAM model as to the use of a data glove in the assembly system. However, some adjustments have been applied to fit our case studies:

1) The functions' outputs are not a single output, contrary to the initial study that considered every function with an output. Each function can have more than one output, which represents more accurately real work conditions, and the maximum amount of outputs will be considered as the final output score.

The variability of output of every upstream function might be different on downstream functions. For example, providing 'too early' for an upstream function's output might have a dampening effect on one downstream function and no effect or amplifying effect on other downstream functions (Hollnagel, 2012). Therefore, the effect of an upstream output on a downstream function was determined individually.

2) This study investigated the coupling variability in a normal Specific Performance Condition (SPC) and assumed that the SPC had no effect on all the downstream functions.

CVs were calculated for 1000 random numbers, and the mean of calculation was considered for each output of the upstream function. MCS were applied for 1000 iterations and critical functions in case studies 1 and 2 were highlighted in red.

Table 5.6 CV of the first case study functions

Downstream Function	**Aspect**	**Upstream Function**	**Function type**	**CV**			
Function		**Function**		**CV_{Mean}**	**CV_{max}**	**e_j**	**VPN**
Analyzing data and providing feedback	Input	Receiving Data	T	1.109	1.109	4	4.435
Assembling connectors	Control	Training operators	O	10.175	11.152	4	44.608
Assembling connectors	Precondition	Calibrating the data glove	M	6.160			
Assembling connectors	Control	Supervising operators	M	6.788			
Assembling connectors	Control	Planning Production and Managing Operations	O	11.152			
Assembling connectors	Input	Providing Resource	O	10.066			
Assembling connectors	Control	Analyzing data and providing feedback	T	1.155			
Assembling connectors	Time	Analyzing data and providing feedback	T	1.069			
Moving the assembled connector	Time	Analyzing data and providing feedback	T	0.949	7.515	2	15.031
Moving the assembled connector	Input	Assembling connectors	M	7.515			
Planning Production and Managing Operations	Control	Analyzing data and providing feedback	T	1.193	1.193	2	2.386
Providing Resources	Input	Resource Management	O	9.984	9.984	2	19.968
Receiving data	Input	Supervising operators	M	6.750	7.144	4	28.576
Receiving Data	Input	Assembling connectors	M	7.144			
Resource Management	Input	Planning Production and Managing Operations	O	11.097	11.097	2	22.194
Resource Management	Input	Analyzing data and providing feedback	T	1.188			
Supervising operators	Input	Planning Production and Managing Operations	O	10.057	10.057	1	10.057

Table 5.7 CV of the second case study functions

Downstream Function	**Aspect**	**Upstream Function**	**Function type**	**CV**			
Function		**Function**		**CV_{Mean}**	**CV_{max}**	**e_j**	**VPN**
Analyzing data and providing feedback	Input	Receiving Data	T	1.145	1.145	4	4.58
Assembling the product	Control	Training operators	O	10.220	10.997	4	43.988
Assembling the product	Precondition	Calibrating the data glove	M	6.209			
Assembling the product	Control	Supervising Workers	M	6.780			
Assembling the product	Control	Production Planning and Managing Operations	O	10.997			
Assembling the product	Input	Transportation Management	O	9.993			
Assembling the product	Control	Analyzing data and providing feedback	T	1.267			
Assembling the product	Control	Technical Support	M	6.358			
Quality Control	Input	Assembling the product	M	6.704	6.704	2	13.408
Production Planning and Managing Operations	Control	Analyzing data and providing feedback	T	1.176	1.176	2	2.352
Providing Resource	Input	Resource Management	O	9.937	9.937	2	19.874
Receiving data	Input	Quality Control	M	6.799	7.174	4	28.698
Receiving Data	Input	Assembling the product	M	7.174			
Resource Management	Input	Production Planning and Managing Operations	O	11.095	11.095	2	22.191
Resource Management	Input	Analyzing data and providing feedback	T	1.094			
Supervising workers	Input	Production Planning and Managing Operations	O	10.015	10.015	1	10.015
Training Operators	Control	Supervising Workers	M	6.811	6.811	4	27.244
Transportation Management	Input	Providing Resource	O	9.98625	9.986	4	39.944
Transportation Management	Control	Resource Management	O	9.9755			
Transportation Management	Input	Quality Control	M	6.786			

MCS makes it possible to analyze systems with a different number of functions and in less time, as compared to a qualified analysis. MCS generates a different variability of functions that might happen in real life over a short period of time and provides an in-depth view of critical functions (couplings) in a quantified perspective (Kaya et Hocaoglu, 2020). MCS facilitates the analysis of FRAM models, particularly complex FRAM models, that have several functions, the interaction scenarios analysis of which is challenging (Belmonte et al., 2011; Hulme et al., 2019). MCS can also help safety management understand systems behavior and uncertainties propagation (Patriarca, Di Gravio et Costantino, 2017; Sujan, Embrey et Huang, 2020). The provision of semi-quantified results helps the analyst focus on high variable couplings (critical functions) to better manage and reduce or prevent risks (Kaya et Hocaoglu, 2020).

On the other hand, from Hollnagel's perspective, FRAM's focus is on variability rather than the probability of variabilities (Hollnagel, 2012). Quantifying might mislead the analyst into focusing on failure probabilities, whereas variabilities that are low might still lead to system malfunction (Kaya et Hocaoglu, 2020). Nevertheless, integration of a semi-quantitative approach with the FRAM method might enhance performance variability management (Kaya et Hocaoglu, 2020).

The analysis was limited to a variability analysis in terms of 'Time' and 'Precision' to decrease the required time of analysis and complexity of the model. Still, other aspects can be considered.

Regarding the results of the MCS for the case studies, the functions 'Assembling connectors' and 'Receiving data' in the first case study and 'Assembling the product' and 'Transportation Management' for the second case study were the most variable functions. Thus, an internal analysis using STPA was done for these functions (Figure 5.6). The STPA model of the function's inside shows the interaction of components that are functioning inside a function as well as the type of control actions and feedbacks which affect a function from outside. The external interactions have been provided in the FRAM model discussed earlier (figure 5.3, 5.4) and figure 5.6 zooms in the most variable functions to show in-detailed functions' inside from STPA's perspective.

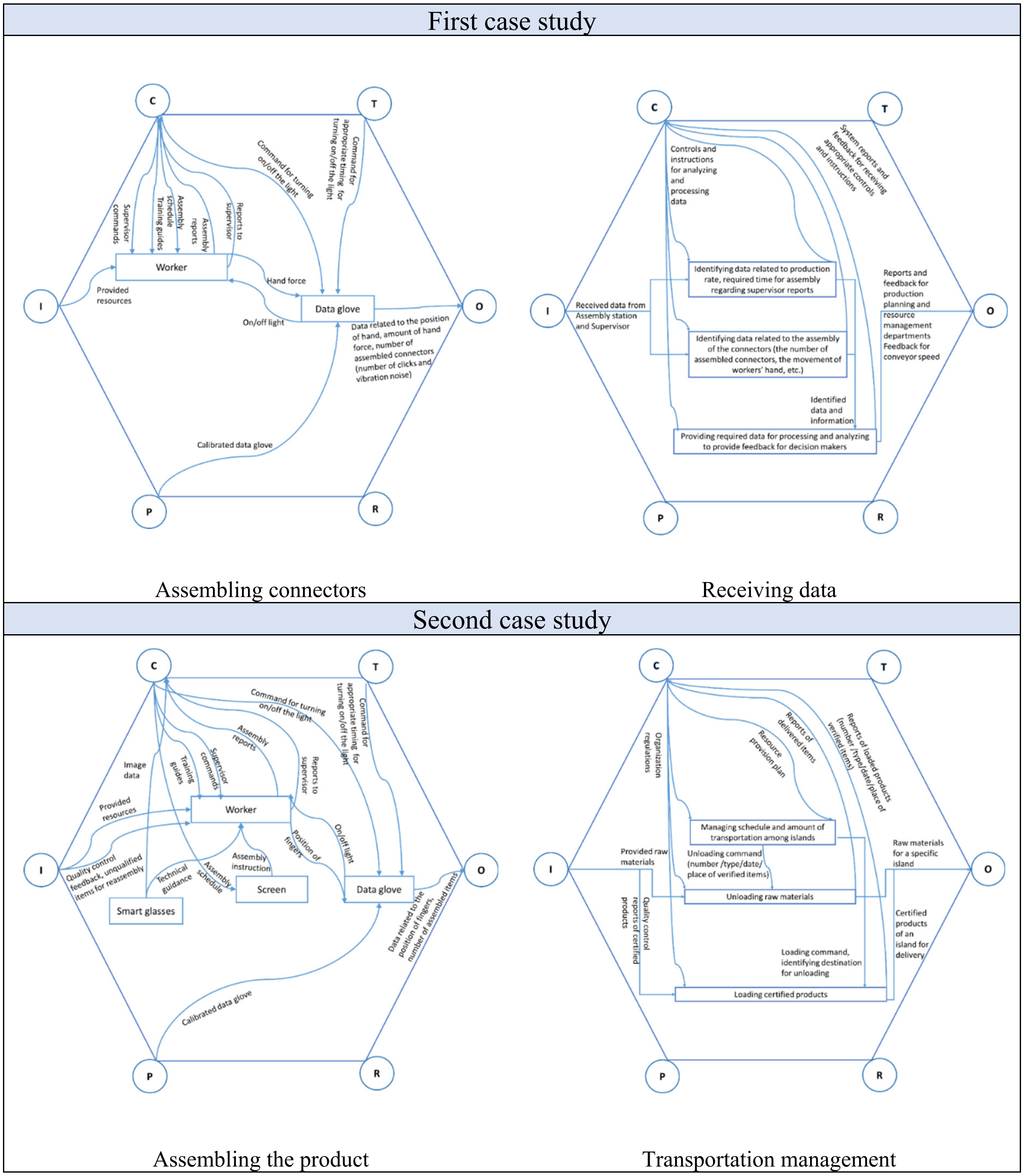

Figure 5.6 STPA internal analysis of the most variable functions

In addition to the safety constraints that ensure that the most variable functions connect with functions that send control actions or receive feedback from the most variable functions (Mofidi Naeini et Nadeau, 2021b), there were safety constraints that were not identified when only STPA was used for the analysis. For example, in the ‘Transportation management’ function, the loading and unloading commands to the transportation system in islands might be provided late, early, or not provided (communication problem). This could lead to variability in the function. Unsafe control actions were not identified in the previous study, but could be identified thanks to the in-detail analysis of the internal STPA (Mofidi Naeini et Nadeau, 2021b). Moreover, this could enable the analyst to identify which function is affected by each control action/feedback and how this can lead to variability, providing a more precise analysis.

By applying this approach, we could analyze the function in more detail and know how the control action or feedback affected a function. For example, in the function ‘Assembling connectors’ control actions from the ‘training’ function and ‘supervising workers’ affected the function from the ‘control’ perspective. At the same time, the ‘provide resources’ was an ‘input’ type of control action for the function. The other advantage of this approach is that it can factor in time. Since STPA can provide more detailed results compared to FRAM (micro analysis vs macro analysis) (Toda, Matsubara et Takada, 2018) (Thapaliya et Kwon, 2018), it offers more insight for the analyst, who can then focus on more variable functions for in-detailed STPA analysis and identify unsafe control actions. Consequently, less time is required for analysis.

The results showed that FRAM and STAMP can be considered as complementary (de Linhares, Maia et Ferreira Frutuoso e Melo, 2021). A function in FRAM could include a different component of a system in STAMP according to how the function is defined (de Linhares, Maia et Ferreira Frutuoso e Melo, 2021). Therefore, in FRAM, component interaction is not bound to a single component, and this provides a holistic view of the system and the interactions of the components. The six aspects of FRAM can be explained in more detail in STPA to consider appropriate constraints in the system (Alvarenga, Frutuoso E Melo et Fonseca, 2014). Meanwhile, using FRAM is helpful for the development of requirements dedicated to safety and resilience analysis (Alvarenga, Frutuoso E Melo et Fonseca, 2014).

5.3.4 Validation

To validate this study's results, a triangulation using results from previous studies was performed. Both case studies were analyzed by applying FRAM (Mofidi Naeini et Nadeau, 2022a) and STPA (Mofidi Naeini et Nadeau, 2021b). Applying FRAM and its instantiations showed that 'Assembling connectors' and 'Receiving data' in case 1 and 'Assembling the product' and 'Receiving data' in case 2 were the most variable functions. The application of STPA resulted in the identification of various unsafe control actions (UCA) and loss scenarios, a considerable number of which related to assembly and data processing. The quantitative results showed that 'Assembling connectors' and 'Receiving data' in case 1 and 'Assembling the product' and 'Transportation management' in case 2 were the most variable functions. However, the function 'Receiving data' was the third most variable function in case 2.
Triangulation of the obtained results from previous studies (Mofidi Naeini et Nadeau, 2021b; 2022a) with the integrated approach results ensured that the proposed approach can analyze the system efficiently and with even more detail for functions with the most variability.

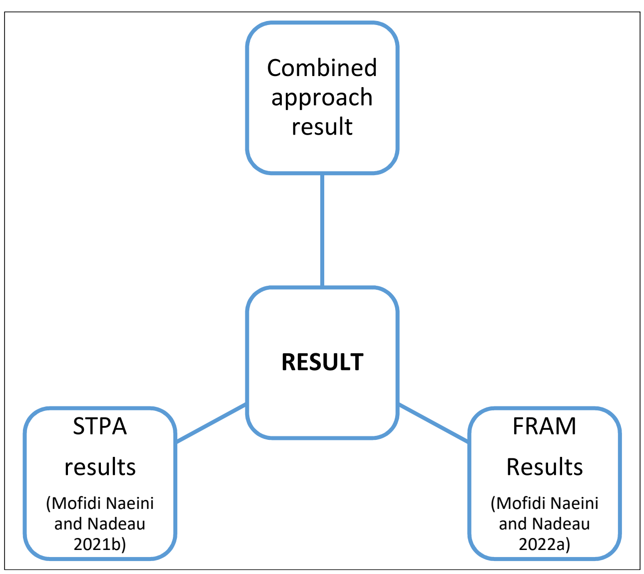

Figure 5.7 Triangulation of the results

5.4 Discussion

The proposed approach applied both the Monte Carlo Simulation and FRAM to identify the most variable functions. Applying the Monte Carlo Simulation provided quantified results based on qualitative analyzes by an analyst. Therefore, it should be noted that different analysts might find different results (Kaya et Hocaoglu, 2020). This study applied statistical distribution from other studies. Given that the case studies were in their designing stage, empirical data related to their precision and timing for each system component was not available. Therefore, identifying the most variable functions might change when the system is in actual operation. However, the validation of the results did verify the obtained results.

The German automotive project (PEGASUS) (Sun, Li et Zio, 2021) recommended applying STPA to identify hazards caused by systems interactions that were not from local causes, such as the interaction between the AV system and humans. Hence, applying STPA for risk analysis of human and data glove interaction would be helpful (Sun, Li et Zio, 2021). FRAM provided an all-encompassing picture of the system and upstream-downstream relations and their complexity (Sun, Li et Zio, 2021). STPA could make it possible for the analyst to consider possible hazards comprehensively within the control structure (Sun, Li et Zio, 2021).

FRAM and STPA can be applied at the various stages from concept designing to system modification and verification. While FRAM is based on the resonance concept, STPA is based on system theory (Sun, Li et Zio, 2021; Toda, Matsubara et Takada, 2018). FRAM and STPA are helpful in finding hazards in loop designs within the system structure (Toda, Matsubara et Takada, 2018). STPA analysis highlights safety control actions that must be considered during the designing of the system to reduce the variability of functions. Then, running a FRAM variability analysis might show which safety control actions might be considered within the function. Consequently, loops could be identified to be redesigned to prevent hazards.

For systems with sensors and software systems in which loss scenarios are complex with dynamic uncertainty, FRAM and STPA are suitable (Sun, Li et Zio, 2021). More consideration should be given to hazards caused by technologies especially the ones with less maturity (Hollnagel, 2018), as the application of different software and programming has increased in the systems designed for industry 4.0 (Sun, Li et Zio, 2021).

The proposed approach takes advantage of the benefits of both FRAM and STAMP (STPA). This approach uses FRAM to see into the whole system, especially in the concept designing phase (de Linhares, Maia et Ferreira Frutuoso e Melo, 2021). FRAM is a decentralized analysis method, meaning that the analyst can start from any function within the system boundaries and continue to other functions. The task of documenting analysis results and variability analysis is not as constructed as documenting analysis results in STPA (Sun, Li et Zio, 2021). FRAM helps the analyst to analyze the system without the need to break down system components (Sun, Li et Zio, 2021; Yousefi, Rodriguez Hernandez et Lopez Peña, 2019). At the same time, STAMP (STPA) can provide control structures and recommendations to prevent hazards (Yousefi, Rodriguez Hernandez et Lopez Peña, 2019). STAMP (STPA) can recommend a proper allocation of system constraints and controls, sensors and feedback and in more detail (de Linhares, Maia et Ferreira Frutuoso e Melo, 2021). Thus, applying the proposed approach made it possible to zoom-in on ‘transportation management’ as an organizational function, providing a detailed analysis, which is a result that had not been obtained in previous studies (Mofidi Naeini et Nadeau, 2021b; 2022a). However, the proposed approach was applied to two case studies and more applications would be required to firmly confirm its capability to provide detailed analyses of organizational functions.

The limitation of this study is access to practical statistical data related to the probability distribution of identified ‘human’, ‘technological’, and ‘organizational’ functions. This might affect the capacity to identify the most variable functions. However, the proposed approach proved its validity when a triangulation of the results was performed. Moreover, functions variability was investigated in terms of ‘time’ and ‘precision’, while considering the time, simplicity and understandability of the analysis.

5.5 Conclusion

The proposed approach combined two systemic methods, FRAM and STAMP/STPA, to analyze the OHS and operational risks implied in the introduction of a data glove technology to assembly 4.0, more particularly in the designing phase. While FRAM provided a holistic analysis of the designed system, a detailed analysis of the most variable system’s components structure was provided by STPA. This approach allowed the analyst to have an overview of functions from the STPA perspective and describe control structure and feedback in terms of the six aspects of the FRAM. Therefore, the proposed approach helped to provide recommendations and safety controls to ensure the design of a robust system with fewer hazards. This approach also provided more recommendations for designing system control structures in comparison to applying solely STPA. The approach was applied to two case studies for OHS and operational risks analysis under normal conditions. Its application in other contexts and to analyze other kinds of risks would be of great interest for future studies.

CONCLUSION

Manufacturing has become more complex in the industry 4.0 context. Assembly 4.0 context is a complex sociotechnical system that requires novel risk management approaches to deal with new and emerging OHS and operational risks. The systemic methods provide a better understanding of the studied systems for the analyst and a better representation of the outcomes of such systems' behavior.

In assembly 4.0 context, a data glove as new technology was introduced to the assembly system, and systemic methods were applied to elaborate the systems' components behavior. The majority of tasks in the assembly system are done by humans or by an organization of humans. Introducing novel technology to this system and the interactions of human-technology might cause some OHS and operational risks despite its assistive purpose. Therefore, it is vital to have a clear and precise view of the system that enables us to analyze the system more precisely and in detail. The systemic approaches can provide an outlook of the system from different views to ensure the safe deployment of such emerging technology.

Considering the complex nature of the studied system discussed previously (Chapter 2), classical approaches are not sufficient for risk analysis in such systems. Hence, the application of new systemic methods, including FRAM and STAMP, was proposed. These systems are powerful tools in providing valuable frameworks for complementing classical approaches and presenting interactions of the system components from systemic lenz.

Case studies were described, and their FRAM model was used to provide a prospective OHS and operational risk analysis of the system. FRAM could provide a good understanding of the system, a big picture of functions and their interactions, and the effect of variability on other functions. It allowed analyzing the dynamic interactions and dependencies among different functions (contribution 1, objective 1). In the next step, case studies were modelled using STAMP (STPA). A control/feedback structure of the system components for each case study could show in-detailed interactions of system components (contribution 2, objective 2). The results were presented in different tables showing the effect of safety controls and loss scenarios (Annex II).

The application of these methods showed that they are capable of predicting systems' behavior from different perspectives. FRAM considered the system from a resilience perspective in variability in six aspects of a function. STAMP (STPA) looked at the system from the control structure and provided safety control actions and recommendations regarding different loss scenarios. FRAM could provide a comprehensive view of the system's components and their interactions, while STAMP (STPA) provided better zooming on the system's components (contribution 1, 2, objective 1, 2).

However, both approaches provided valuable results; a comparison of the results of their application revealed a novel approach is needed. As the results could not show the preference and superiority of one method over another, there is a need for a novel approach that benefits of the advantages of both approaches. It means that the new approach should be capable of presenting a whole perspective of the studied system while when we zoom in on one function, it can analyze them precisely and in detail.

On the ground of the findings of the application of FRAM and STAMP (STPA), an integrated FRAM/STPA approach was proposed. This approach starts with a FRAM model of the system, and then to provide a detailed analysis of the most variable functions, a Monte Carlo Simulation was applied. The results of the simulation depend on the probability distribution of the functions from the perspective of time and precision and the analyst's opinion on the impact of function's variability on other functions. Considering the fact that the studied system is in the first steps of designing (TRL) and empirical data related to the use of data gloves in actual assembly situation is not available to the best of our knowledge, the probabilities data were taken from a study in the manufacturing domain. Regarding the obtained value for the functions, the most variable functions are identified. Then, the internal interactions of the functions will be modelled by applying STPA. Hence, the analyst could label the type of control and feedback in a function from six aspects of FRAM. On the other hand, the analyst can identify the source of variability of a function in terms of feedback and control (contribution 3, objective 3).

The main objective of this study was to propose an approach to risk management of the use of data gloves in assembly and illustrate it through applications in case studies. The need for the application of an integrated approach to maximize the benefits obtained by both approaches are explained comprehensively (Chapter 5, Annex IV). Admittedly, the proposed approach requires application in many other contexts and real experiments and still needs more optimization. However, functions' variability has been quantified using the Monte Carlo Simulation, finding methods that are less dependent on the probability distribution would be of interest.

The findings of this study could be applied as preliminary results for the application of artificial intelligence and machine learning in risk analysis (McGraw et al., 2020). We hope the proposed integrated FRAM/STPA approach reveals results and provides insights to the design of assembly 4.0 systems as well as data gloves designers. We hope the provided results related to the OHS and operational concerns of the use of data gloves open new doors to future studies. Finally, we hope the proposed approach contributes to the safety of humans and systems, especially in assembly and risk management, and an outlook for further research.

RECOMMENDATIONS

The findings of this study could offer many benefits to both the industrial and academia. The proposed approach might address risks in future studies. However, the study faced some limitations that could be addressed to provide better results. Following, a list of limitations and areas for further studies will be presented.

1- The proposed approach was applied to realistic case studies. Therefore, the application of the new approach to real case studies, either field studies or laboratory experiments, would be of interest. This application will verify the usefulness and efficiency of the proposed approach.
2- The proposed approach was applied in the manufacturing context (specifically assembly context). Therefore, an application of this approach on other contexts could help generalize and validate its usefulness for other contexts.
3- Data for quantifying the FRAM results were taken from other studies. Hence, the application of this approach in real scenarios will provide accessibility to actual data of probabilities of functions, and consequently, the simulation would be closer to the real world.
4- Case studies were constructed on the basis of the literature of other studies and were somehow challenging. We simplified systems and their functions. Hence, the boundaries of the system function characteristics, controls could be better identified with more detailed in a real case study.
5- To the best of our knowledge, the OHS and operational risk of the use of data gloves in the industry 4.0 context has not been studied so far, and the proposed integrated FRAM/STPA approach has not been utilized in any study. This innovative approach could be applied to more wearables in future researches to explore possible advantages and findings for the industry and research communities.

ANNEX I ACADEMIC ACCOMPLISHMENTS

Journal Articles

1- **Published**

Alimeh Mofidi Naeini, Sylvie Nadeau, Application of FRAM to perform Risk Analysis of the Introduction of a Data Glove to Assembly Tasks, Robotics and Computer-Integrated Manufacturing, Volume 74, 2022, 102285, ISSN 0736-5845, https://doi.org/10.1016/j.rcim.2021.102285.

2- **Submitted**

Alimeh Mofidi Naeini, Sylvie Nadeau, Proposed integrated FRAM/STPA risk analysis of data glove in assembly 4.0 system, Robotics and Computer-Integrated Manufacturing Journal, January 2022.

Alimeh Mofidi Naeini, Sylvie Nadeau, STPA systemic approach for OHS and operational risk analysis of data glove use in 4.0 assembly, CIRP Journal of Manufacturing Science and Technology, April 2021.

Conference Articles and abstracts

1- **Published**

Alimeh Mofidi Naeini, Sylvie Nadeau, Comparing FRAM and STAMP for occupational health and safety (OHS) and operational risks analysis: the case of data gloves in assembly 4.0 production, 33rd International Congress on Occupational Health (ICOH 2022), Italya-Australia, 6-10 February 2022 (Virtual format), Accepted November 2021 .

Alimeh Mofidi Naeini, Sylvie Nadeau, FRAM and STAMP new avenue for risk analysis of manufacturing in the context of industry 4.0, In Frühjahrskongress der Gesellschaft für Arbeitswissenschaft (Bochum, Germany, Mar. 03-05, 2021) Coll. « Kongress der Gesellschaft für Arbeitswissenschaft », vol. 67. Dortmund : GfA-Press.

Alimeh Mofidi Naeini, Sylvie Nadeau, Data Gloves in Manufacturing, a Review of OHS and Operational Concerns. Accepted (Feb) Congrès AQHSST, 20-22 mai 2020, Boucherville, Reported COVID19, 5 May 2021 on line, Canada.

2- **Accepted**

Alimeh Mofidi Naeini, Sylvie Nadeau, Application of Functional Resonance Analysis Method and SystemTheoretic Accident Model and Processes approaches combined with other methods, the International Conference on Applied Human Factors and Ergonomics and the Affiliated Conferences to be held at New York, United States of America, 24-28, July, 2022, Accepted December 2021.

Alimeh Mofidi Naeini, Sylvie Nadeau, An integrated FRAM/STPA approach for risk analysis of assembly 4.0, Student Forum 5.0 to be held at Québec City, Canada, June 8, 2022.

Vulgarization activities

Alimeh Mofidi Naeini, Sylvie Nadeau, The Need for Systemic Approaches for Risk Analysis in Digital Manufacturing, Substance, May 2022.

The winner of the first stage of the « Three Minute Thesis (3MT) - Ma thèse en 180 secondes » competition at ETS, March 2022: Alimeh Mofidi-Naeini - YouTube https://www.youtube.com/watch?v=2d0Zf6wINTk.

The winner of the first stage of the « Ma thèse en 180 secondes » Acfas competition at École dété - Réseau Innovation 4, Transformation numérique : innovation et gestion, May 06, 2021.

The winner of the first stage of the « Three Minute Thesis (3MT) - Ma thèse en 180 secondes » competition at ETS, February 2020: Alimeh Mofidi-Naeini - YouTube https://www.youtube.com/watch?v=sjvvMqVX5v8.

ANNEX II STPA RESULTS

Table II.1 Identified UCAs (case 1 and 2)

Control action	Not providing causes hazard	Providing causes hazard	Providing too early, too late, or out of sequence	Stopped too soon, applied too long	Case 1	Case 2
Assembly plans and commands (provided by supervisor)	UCA-1: Assembly plans or related commands for the worker are not provided during assembly (H1-8, H3-2).	UCA-2: Wrong assembly plans or commands for the worker are provided during assembly (H1-8, H3-2).	UCA-3: Assembly plans or related commands for worker provided late/soon during assembly (H2-1, H3-2).		*	*
Programs, instructions, and rules (provided by programming)	UCA-4: Programs, instructions, and rules not provided by programming department to receiver and processor to perform the specific assembly task (H1-9).	UCA-5: Wrong programs, instructions, and rules from the programming department to receiver and processor to perform specific assembly tasks (H1-9).			*	*
Training notes (provided by training department for workers)	UCA-6: The training department does not provide training for workers (H4-2).	UCA-7: Training department provides inefficient training for workers (H4-2).	UCA-8: Training department is late in providing training for workers (H4-2).		*	*

Table II.1 Identified UCAs (case 1 and 2) (Continued)

Control action	Not providing causes hazard	Providing causes hazard	Providing too early, too late, or out of sequence	Stopped too soon, applied too long	Case 1	Case 2
Speed/on-off commands for the conveyor	UCA-9: The "receiver and processor" does not provide ergonomic personalized speed commands while the worker is doing assembly tasks (H3-2). UCA-10: The receiver and processor" does not provide Off commands in an emergency while the worker is doing assembly tasks (H3-2).	UCA-11: The "receiver and processor" provides speed commands that have not been ergonomically personalized according to the worker's performance during the assembly task (H3-2).	UCA-12: The "receiver and processor" provides speed commands late/soon while the worker is doing assembly tasks (H3-2, H2-7). UCA-13: The "receiver and processor" provides Off commands while the worker is doing assembly tasks (H3-2, H2-7).	UCA-14: The "receiver and processor" stops providing speed commands too soon while the worker is still doing assembly tasks (H3-2, H2-7).	*	
Turn light on the data glove on/off	UCA-15: The "receiver and processor" does not provide on/off light commands for the worker during assembly when pressing the lock pin on the male connector (case 1) or taking a component (case 2) (H1-1, H3-1, H3-2, H2-3).	UCA-16: The "receiver and processor" provides wrong on/off light commands for the worker during assembly when pressing the lock pin on the male connector (case 1) or taking a component (case 2) (H1-1).	UCA-17: The receiver and processor provides on/off light commands to worker during assembly when pressing the lock pin on the connector too early before pin is pressed or too late after pin is pressed (case 1) or component taken (case 2) (H1-1, H3-1, H3-2, H2-3).		*	*

Table II.1 Identified UCAs (case 1 and 2) (Continued)

Control action	Not providing causes hazard	Providing causes hazard	Providing too early, too late, or out of sequence	Stopped too soon, applied too long	Case 1	Case 2
Production plans and commands (for the supervisor)	UCA-18: Production planning does not provide production plans to the supervisor (H1-4).	UCA-19: Production planning provides wrong production plan to the supervisor (H1-4).			*	*
Reporting commands and information about the resource provision plan	UCA-20: resource management commands and reports are not sent to receiver and processor during tasks (H1-3).	UCA-21: Wrong resource management commands and reports are sent to receiver and processor during tasks (H1-3).	UCA-22: resource management commands and reports are provided late to receiver and processor during tasks (H2-4).		*	*
Reporting commands and data on production management	UCA-23: production planning reporting-commands and data are not sent to the receiver and processor during tasks (H1-2, H2-6).	UCA-24: Wrong production planning commands or data is sent to the receiver and processor during tasks (H1-2, H2-6).	UCA-25: Commands or data about production planning is provided late to the "receiver and processor". during tasks (H2-5).		*	*
Provided resources	UCA-26: resource provision fails to provide materials for assembly (H1-12, H1-16).	UCA-27: resource provision send wrong materials for assembly (H1-12, H1-16).	UCA-28: resource provision sends materials for assembly too late (H2-2).		*	*
Training needs	UCA-29: Training of workers is inadequately defined by production planning (H4-1).				*	*

Table II.1 Identified UCAs (case 1 and 2) (Continued)

Control action	**Not providing causes hazard**	**Providing causes hazard**	**Providing too early, too late, or out of sequence**	**Stopped too soon, applied too long**	**Case 1**	**Case 2**
Resource provision plan (for resource provision)	UCA-30: Resource management fails to provide resource provision with plan of required assembly materials (H1-7, H2-2).	UCA-31: Wrong resource provision plan is sent to provide materials for assembly (H1-7, H2-2).	UCA-32: Resource management sends the resource provision plan to provide required assembly materials late (H2-2).		*	
Resource provision plan (for production planning)	UCA-33: Resource provision plan is not considered by the production planning department in preparing assembly plan (H1-5).	UCA-34: wrong resource provision plan for the production planning department is considered in preparing the assembly plan (H1-5, H2-5).	UCA-35: resource management provides the resource provision plan too late for production planning to be considered in preparing the assembly plan (H2-5).		*	*
Finger force	UCA-36: When the worker takes a component in hand, fingers that push sensors of the data glove do not send information to the “receiver and processor” during assembly (H1-6).	UCA-37: When the worker takes a component in hand, fingers that push sensors of the data glove send wrong information to the “receiver and processor” or push the wrong position of sensors during assembly (H1-6).			*	*

Table II.1 Identified UCAs (case 1 and 2) (Continued)

Control action	Not providing causes hazard	Providing causes hazard	Providing too early, too late, or out of sequence	Stopped too soon, applied too long	Case 1	Case 2
Production reports	UCA-38: The "receiver and processor" does not send the assembly status input required for production planning (H1-2).	UCA-39: Wrong assembly status data required for production planning is applied by production planning (H1-2).	UCA-40: The "receiver and processor" sends required assembly status to production planning too late (H2-5).		*	*
Report of the rate of the usage of materials (for resource management)	UCA-41: The "receiver and processor" does not send data about the rate of material usage required for resource management (H1-3).	UCA-42: Wrong data about the rate of material usage required for resource management is applied (H1-3).	UCA-43: The "receiver and processor" sends the data about the rate of material usage required for resource management too late (H2-4).		*	*
Resource requests	UCA-44: Production planning fails to send resources requests to resource management for assembly of specific items (H1-5).	UCA-45: Production planning provides wrong resource request to resource management for assembly of specific items (H1-5).	UCA-46: Production planning sends resource demands to resource management for assembly of specific items too late (H2-4).		*	*
On/off command, sending a voice command	UCA-47: The worker's actions e.g. on/off smart glasses, and sending worker's voice is not applied (H1-18).					*
Delivered resource	UCA-48: Resource is not transported to the assembly island (H1-13, H1-16).	UCA-49: Wrong/insufficient resource is transported to assembly island (H1-13, H1-16).	UCA-50: Resource is transported late to the assembly island (H2-2).	UCA-51: Resource is transported too soon to the assembly island (H2-2).		*

Table II.1 Identified UCAs (case 1 and 2) (Continued)

Control action	Not providing causes hazard	Providing causes hazard	Providing too early, too late, or out of sequence	Stopped too soon, applied too long	Case 1	Case 2
Reassembling commands		UCA-52: Quality control issues the reassembling command wrongly (H1-19).				*
Reports, commands, information (sent to technical support)	UCA-53: Receiver and processor does not send reports and information to the technical support (H1-15).	UCA-54: Receiver and processor sends wrong/insufficient reports and data to technical support (H1-15).	UCA-55: Receiver and processor sends reports and information late to the technical support (H2-6, H2-8).			*
Permission for loading assembled product	UCA-56: Quality control does not accept qualified products (H-19).	UCA-57: Quality control permits loading of unqualified products (H-19).				*
Assembly instruction (provided by technical support)	UCA-58: Assembly instructions are not delivered to assembly island worker (H1-17).	UCA-59: Wrong instructions are sent to assembly island worker (H1-17).	UCA-60: Assembly instructions are sent late to assembly island (H2-8).			*
Provided image, video of the worker's desktop (for technical support)	UCA-61: Smart glasses fail to transmit, video, images of desktop and worker's voice to the technician (H1-14, H1-15).	UCA-62: Smart glasses provide imprecise/wrong video, image of worker's desktop and voice to the technician (H1-14, H1-15).	UCA-63: Smart glasses provide a video and images of the worker's desktop and worker's voice to the technician late (H2-8).			*
Displaying layout	UCA-64: The receiver and processor does not send the data (command) to display the right assembly layout (H1-17).	UCA-65: The receiver and processor send the wrong data (command) to display the assembly layout (H1-17).				*

Table II.1 Identified UCAs (case 1 and 2) (Continued)

Control action	Not providing causes hazard	Providing causes hazard	Providing too early, too late, or out of sequence	Stopped too soon, applied too long	Case 1	Case 2
Providing calibrated data glove	UCA-66: Data glove not calibrated prior to assembly use (H1-10).	UCA-67: Data glove incorrectly calibrated prior to assembly use (H1-10).			*	*

Table II.2 Identified loss scenarios (case 1 and 2)

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: Supervisor sends assembly plans and command UCA-1 Scenario 1. The supervisor forgets to send the assembly plan to the worker in the assembly station (island): the worker must work without a schedule, which might lead to stress and delays. Scenario 2. The communication channel between the supervisor and worker is dysfunctional: supervisor's command and assembly schedule are not received by the worker. UCA-2 Scenario 3. The supervisor is in a hurry or mentally is not in a good place (due to fatigue, mental workload, etc.): he/she sends wrong commands or assembly schedules to the worker. Scenario 4. The worker is not focused (due to fatigue, mental workload, stress, etc.): he/she misunderstands commands and plans. UCA-3 Scenario 5. The supervisor receives the assembly plan late: he/she sends it to the worker late. Scenario 6. Error/problem in the communication channel between the supervisor and the worker: information such as commands and assembly plans are sent late to the worker. Scenario 7. The supervisor sends schedule early: the worker might apply it at the wrong time (human error).	*	*
Control action: Programming department provides programs, instructions, and rules for the “receiver and processor”. UCA-4 Scenario 8. Organizational errors in the programming department, programs, instructions, or rules are not provided for the receiver and processor. Scenario 9. Malfunctioning connection between "programming" and the "receiver and processor": programs, instructions or rules cannot be provided for the “receiver and processor”. UCA-5 Scenario 10. Programming errors: the wrong programs, instructions or rules are sent to the “receiver and processor”.	*	*

Table II.2 Identified loss scenarios (case 1 and 2) (Continued)

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: The training department provides training for workers. UCA-6 Scenario 11. Organizational errors: omission of information for data glove training guidelines for workers. UCA-7 Scenario 12. Training department does not have specific guidelines (instructions) for training: it cannot provide efficient training for workers. Scenario 13. Data glove manufacturer fails to provide proper information for training: workers are not trained properly. UCA-8 Scenario 14. Delays in organizational planning: the training of workers will be held late.	*	*
Control action: The "receiver and processor" controls the conveyor speed (according to the data received from data glove about the worker's speed in assembling connectors) and the conveyor's on/off status. UCA-9 Scenario 15. Programming error: the "receiver and processor" fails to adapt the conveyor speed to the worker's assembling rate. Scenario 16. Dysfunctional connection between "conveyor" and "receiver and processor": speed commands are not sent to the conveyor. UCA-10 Scenario 17. Programming error: the "receiver and processor" fails to detect the emergency situation and does not send Off command to the conveyor when the worker is assembling connectors. Scenario 18. Malfunctioning connection between "conveyor" and "receiver and processor": off commands cannot be sent in an emergency. UCA-11 Scenario 19. Due to an error in programming, the receiver and processor sends speed commands to the conveyor that are not adapted to the worker who is assembling connectors. UCA-12 Scenario 20. Malfunctioning connection between "conveyor" and "receiver and processor" does not work properly, so speed commands are not provided on time. If command is applied late, the worker has to wait for the assembled connector's move, and if it is applied too early, the worker has to hurry to assemble them before moving to the next station. Scenario 21. Programming timing error: ergonomic personalized speed commands are provided late in the "receiver and processor" to be sent to the conveyor when the worker is assembling connectors. UCA-13 Scenario 22. Malfunctioning connection between "conveyor" and "receiver and processor": Off commands are provided late for the conveyor. Scenario 23. Programming timing error: the Off command is provided late in "receiver and processor" to be sent to the conveyor when the worker is assembling connectors. UCA-14 Scenario 24. Programming error: ergonomic-speed command was stopped too soon in "receiver and processor" to be sent to the conveyor when the worker is assembling connectors.	*	

Table II.2 Identified loss scenarios (case 1 and 2) (Continued)

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: Data glove light turns on when the assembly is done correctly / correct component is taken. UCA-15 Scenario 25. Programming error: on/off light commands are not sent from the “receiver and processor” to the data glove when the worker has completed the assembly (e.g when the assembly is completed correctly the glove does not turn on). Scenario 26. Malfunctioning connection between the “data glove” and “receiver and processor”: On/Off commands are not sent to the data glove. UCA-16 Scenario 27. Programming error: incorrect on/off light commands are sent from the “receiver and processor” to data glove e.g., the light stays off even though the worker has completed assembly correctly or the light on data glove turns on even though assembly is incorrect. UCA-17 Scenario 28. Malfunctioning connection between the “data glove” and “receiver and processor”: On/Off commands are received late to the data glove and the worker needs to wait a time for the feedback. Scenario 29. Programming timing error: on/off light commands are provided late in the “receiver and processor” to be sent to the data glove when the worker has completed the assembly correctly.	*	*
Control Action: Production planning sends the production schedule and commands to the supervisor. UCA-18 Scenario 30. Organizational error in production planning: production schedule is not prepared for the supervisor. Scenario 31. Organizational error in production planning (forgotten production schedule): the production schedule is not sent to the supervisor. Scenario 32. Malfunctioning connection between the "supervisor” and “production planning": the production schedule is not received by the supervisor. UCA-19 Scenario 33. Organizational error in production planning: incorrect production schedule is prepared for the supervisor.	*	*
Control action: Resource management sends reports, commands, and information about the resource provision plan (such as purchase order) to the receiver. UCA-20 Scenario 34. Programming error: the “receiver and processor” fails to process and receive reporting commands and information during operations. Scenario 35. Organizational error in resource management: reporting commands and information about the resource provision plan were forgotten and thus not sent to the “receiver and processor”. Scenario 36. Malfunctioning connection between "resource management” and the “receiver and processor": the “receiver and processor” cannot receive the reporting commands and information about the resource requirement plan during operations. UCA-21 Scenario 37. Organizational error in resource management: wrong reports, commands and information about the resource provision plan are sent to the “receiver and processor”. UCA-22 Scenario 38. Organizational error in resource management: reporting commands and information about the resource requirement plan is sent late to the “receiver and processor” during operations.	*	*

Table II.2 Identified loss scenarios (case 1 and 2) (Continued)

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: Production planning sends reports, commands, and information about production management to the "receiver and processor". UCA-23 Scenario 39. Programming error: the "receiver and processor" cannot process reporting commands and information about production management during operations. Scenario 40. Organizational error in production planning: reporting commands and information about the production management have been forgotten, thus are not sent to the receiver and processor. Scenario 41. Malfunctioning between "production planning" and "receiver and processor": the receiver and processor cannot receive the reporting commands and information about production management. UCA-24 Scenario 42. Organizational error in production planning: reporting commands and information about production management is sent incorrectly to the "receiver and processor". UCA-25 Scenario 43. Organizational error in production planning: reporting commands and information about production management are sent late to the "receiver and processor" during operations.	*	*
Control action: Resource provision provides resources (stock material) to assembly stations (islands) UCA-26 Scenario 44. Organizational error in resource provision: purchasing forgets to list needed resources (stock material) in the resource requirement plan. Scenario 45. Organizational error in resource management: omission of required resources in the purchase order needed to replenish resources of the assembly station (islands). UCA-27 Scenario 46. Organizational error in resource management: incorrect resources are listed in the purchase order delivered to resource provision. Scenario 47. Organizational error in resource provision: the wrong required resources (stock materials) are provided to the assembly station (islands). UCA-28 Scenario 48. Organizational error in resource provision: the stock material is provided late to the assembly station (islands). Scenario 49. Organizational error in resource management: the purchase order (PO) is provided late to resource provision.	*	*
Control action: Production planning helps to establish the training needs for different work stations (islands). UCA-29 Scenario 50. Tasks and processes in a station (an island) are not defined properly: the required training for each station (island) is not described accurately. Scenario 51. Organizational error in training (e.g., unspecified organization instructions and human error in the preparation of guidelines): preparation required for training guidelines cannot be done properly.	*	*

Table II.2 Identified loss scenarios (case 1 and 2) (Continued)

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: The resource management department sends the purchase order (PO) to the resource provision planning department to provide resources (stock materials) based on the received plan. UCA-30 Scenario 52. Organizational error in resource management: purchase order (PO) is not sent to the resource provision department. Scenario 53. Malfunctioning connection between "resource management" and "resource provision": the purchase order (PO) is not sent to the resource provision department. UCA-31 Scenario 54. Organizational error in resource management: incorrect purchase order (PO) is sent to the resource provision department. Scenario 55. Incorrect data is sent from the "receiver and processor" to resource management: incorrect purchase order (PO) will be prepared for the resource provision department. UCA-32 Scenario 56. Organizational error in resource management: purchase order (PO) is sent late to the resource provision department. Scenario 57. Data is sent too late from the "receiver and processor" to resource management to prepare a purchase order (PO): it will be sent late to the resource provision department.	*	*
Control action: Resource management sends the purchase order (PO) form to the production planning department to be considered when preparing a production (assembly) schedule. UCA-33 Scenario 58. Organizational error in resource management: a purchase order (PO) is not sent to the production planning department to be considered in preparing the assembly schedule. Scenario 59. Malfunctioning connection between "production planning" and "resource management": purchase order (PO) is not sent to production planning to be considered in preparing the assembly schedule. Scenario 60. Organizational error in production planning: a purchase order (PO) is not considered in preparing the assembly schedule. UCA-34 Scenario 61. Organizational error in resource management: the wrong purchase order (PO) is sent to production planning to be considered in preparing the assembly schedule. Scenario 62. Organizational error in production planning: the wrong purchase order (PO) is considered in preparing the assembly schedule. UCA-35 Scenario 63. Malfunctioning connection between "production planning" and "resource management": the purchase order (PO) is sent late to production planning for consideration in the assembly schedule. Scenario 64. Organizational error in order (resource management: purchase PO) is sent late to the production planning department to be considered in preparing the assembly schedule.	*	*

Table II.2 Identified loss scenarios (case 1 and 2) (Continued)

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: Worker's hand (fingers) activates sensors of the data glove. UCA-36 Scenario 65. Incorrect positioning of sensors in the data glove: the worker's hand (fingers) cannot activate sensors to receive feedback. Scenario 66. Poor calibration of data glove: fails to detect the worker's hand (fingers) pressure (bending). UCA-37 Scenario 67. Incorrect positioning of sensors in the data glove (design error): the sensors detect the worker's hand position wrongly, thus incorrect feedback data will be sent to the receiver and processor. Scenario 68. The size of data glove is incorrect (loose for the worker's hand): the worker pushes the wrong position of sensors to receive feedback.	*	*
Control action: The "receiver and processor" sends production reports and information needed by the production-planning department. UCA-38 Scenario 69. Malfunctioning connection between "production planning" and "receiver and processor": production reports cannot be sent to production planning for consideration in the assembly schedule. Scenario 70. Programming error: the "receiver and processor" fails to send production reports to production planning for consideration in preparing the assembly schedule. UCA-39 Scenario 71. Programming error: the "receiver and processor" sends incorrect information in production reports to the production planning to be considered in the assembly schedule. Scenario 72. Organizational error in production planning: received information from production reports is applied wrongly in the assembly schedule. UCA-40 Scenario 73. Programming timing error: the "receiver and processor" sends information and reports to the production planning late.	*	*
Control action: The "receiver and processor" sends rate of usage of materials reports to resource management who use them to prepare purchase order (PO) and resource requirement plan (RRP). UCA-41 Scenario 74. Malfunctioning connection between "resource management" and the "receiver and processor": reports on rate of materials consumption cannot be sent to resource management department. Scenario 75. Programming error: the "receiver and processor" fails to send consumption of materials reports to the resource management department. UCA-42 Scenario 76. Programming error: the "receiver and processor" sends incorrect reports of the rate of materials consumption to the resource management department. Scenario 77. Organizational error in the resource management department: incorrect reports of the rate of materials consumption are applied in preparing purchase order (PO). UCA-43 Scenario 78. Programming timing error: the "receiver and processor" sends materials consumption rate reports to resource management late.	*	*

Table II.2 Identified loss scenarios (case 1 and 2) (Continued)

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: The production planning department sends resource request (BOM) to resource management. UCA-44 Scenario 79. Malfunctioning connection between "resource management" and "production planning": resource requests (material requirement plan (MRP)) cannot be sent to resource management department. Scenario 80. Organizational error: production planning does not send (or forgets to send) resource requests (BOM) to resource management. UCA-45 Scenario 81. Organizational error: incorrect resource requests (material requirement plan (MRP)) are sent to resource management. UCA-46 Scenario 82. Organizational errors: production planning sends resource requests (BOM) to resource management late. Scenario 83. Malfunctioning connection between "resource management" and "production planning": the resource material requirement plan (MRP)) is sent late to resource management.	*	*
Control action: The worker turns off/on the smart glasses when its use is required. UCA-47 Scenario 84. Maintenance (design) error: smart glasses malfunction (e.g. low battery, unresponsive) when the on/off command is used.		
Control action: Transportation management delivers required resources to assembly islands. UCA-48 Scenario 85. Organizational error: one or more assembly islands is missed during delivery of resources. UCA-49 Scenario 86. Organizational errors: incorrect/insufficient resources are delivered to assembly island. Scenario 87. Resource provision planning error: assembly island receives insufficient resources. UCA-50: Scenario 88. Organizational error in timing: resources are transported to the assembly island late. Scenario 89. Resource provision provides resources late: resources are delivered late to assembly island. UCA-51 Scenario 90. Organizational error in timing: resources will be transported to the assembly island too soon, and they cannot be unloaded in the assembly island due to storage space limitations.		*
Control action: Quality control asks the worker to reassemble the products if they cannot meet quality criteria. UCA-52 Scenario 91. Quality control human error: quality control rejects product and asks that it be reassembled.		*

Table II.2 Identified loss scenarios (case 1 and 2) (Continued)

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: The “receiver and processor” provide reports and information for technical support. UCA-53 Scenario 92. Malfunctioning connection between the "receiver and processor” and “technical support": reports and information are not sent to technical support. UCA-54 Scenario 93. “Receiver and processor” programming error: wrong/insufficient reports and information are sent to technical support. UCA-55 Scenario 94. Error in the “receiver and processor” timing programming: reports and information are sent to the technical support late.		*
Control action: Quality control issues the permit for loading assembled products on the assembly island. UCA-56 Scenario 95. Human error in quality control: qualified products are rejected and not permitted for loading. UCA-57 Scenario 96. Human error in quality control: unqualified products are permitted for loading.		*
Control action: “Technical support” provides assembly instructions to the assembly island worker. UCA-58 Scenario 97. Malfunctioning connection between "worker" and "technical support": assembly instructions cannot be provided to the worker. UCA-59 Scenario 98. Error in data sent from smart glasses to technical support: the technician receives the wrong data and consequently guides the worker incorrectly. Scenario 99. Technician misunderstands the problem (technician’s mistake): technician provides incorrect guidance to the worker. UCA-60 Scenario 100. Malfunctioning connection between "worker" and "technical support": the technician's guidance to worker is delayed or late. Scenario 101. Delay in sending data from smart glasses to technical support: the technician's guidance to worker is delayed or late.		*
Control action: The smart glasses provide images and video of the worker's desktop. UCA-61 Scenario 102. Malfunctioning connection between "smart glasses" and "technical support": images and videos of the worker’s desktop and the worker’s voice are not provided. UCA-62 Scenario 103. Malfunctioning connection between "smart glasses" and "technical support": the provided voice, image or video for the technical support is imprecise/wrong (blurry). Scenario 104. Programming error: image/video provided to technical support is imprecise (blurry). UCA-63 Scenario 105. Malfunctioning connection between "smart glasses" and "technical support": the voice, images and videos of the worker’s desktop are provided late to the technical support.		*

Table II.2 Identified loss scenarios (case 1 and 2) (Continued)

Loss scenarios regarding to Control Action	Case 1	Case 2
Control action: “Receiver and processor” provides assembly layout to be displayed on assembly island screen. UCA-64 Scenario 106. Programming error: the “receiver and processor” fails to display the correct assembly layout. Scenario 107. Malfunctioning connection between "screen" and "receiver and processor": the voice, images and videos of the worker’s desktop are provided late to the technical support.		*
Control action: A technician will calibrate the data glove periodically prior to its use in assembly tasks. UCA-66 Scenario 108. Organizational errors (human error): the technician does not calibrate (forgets or data glove is not listed in calibration plan) the data glove before use in the assembly. UCA-67 Scenario 109. Human error in calibration (the technician is fatigued or the technician does not follow the calibration instruction appropriately): the data glove is not calibrated properly. Scenario 110. Planning error (absence of clear, uniform instructions for calibrating data gloves): each technician calibrates the data glove in a different way and the data glove might be calibrated incorrectly.	*	*

ANNEX III CONFERENCE PRESENTATION (AQHSST)

DATA GLOVES IN MANUFATURING, A REVIEW OF OHS AND OPERATIONAL CONCERNS

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Abstract

Data gloves are a type of wearables with embedded sensors that can track hand movements to provide haptic or vibration feedback. Since their invention, data gloves have been applied in several fields such as product design, manufacturing, healthcare, robotics and entertainment etc.

Given that the use of data gloves in manufacturing is an emerging application, potential OHS and operational risks need to be considered. In this study, a critical review of literature was conducted to identify documented OHS and operational risks associated with the use of data gloves. For this purpose, scientific databases such as IEEE, Compendex & INSPEC, science direct, and Espace ÉTS were searched for relevant studies from 2000 to 2019. The applied search keywords included OHS risk, operational risk, data glove, sensor glove, wearable and wearable device.

The results were classified into two categories: OHS risks and operational risks. OHS risks consider factors as weight and position of wearables, hand injuries, feeling of comfort and the user's perception of ease of use. On the other hand, operational risks can include the obstruction of workers' tactile sense affecting task feedback, risks of errors and increasing cycle time. Aspects as field of application, types of wearables, and associated risks were discussed for both categories.

The number of studies addressing data gloves was found limited. As an emerging technology, the application of data gloves requires more evaluation to identify and eliminate any associated OHS and operational risks and ensure a safe deployment of this technology under complex real-world conditions.

ANNEX IV CONFERENCE PRESENTATION (GfA)

FRAM AND STAMP: NEW AVENUE FOR RISK ANALYSIS IN MANUFACTURING IN THE ERA OF INDUSTRY 4.0

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Abstract
Manufacturing in the context of industry 4.0 has become increasingly complex. As the complexity of these systems increases, so to will the potential for emerging hazards. Consequently, finding an appropriate approach to identify, measure and assess new and emerging hazards is imperative to prevent their occurrence or lessen their effects on the human, organizational, and technical scales. FRAM and STAMP applications are two known methods for analyzing risks in complex systems. This study conducts a critical review of the literature on FRAM and STAMP specifically with regards to their application in the manufacturing sector. For this purpose, scientific databases such as IEEE, Compendex and INSPEC, Science Direct, Google Scholar, and Espace ÉTS were consulted for relevant studies from 2004 to 2020, mostly in English. The search keywords included FRAM, STAMP, STPA, manufacturing, risk, industry, and industry 4.0. The results are presented in two tables including the year of publication, the study's aim and results, the type of analyzed risks, and applied methods. Despite the limited number of studies that have applied FRAM or STAMP in manufacturing, the results show that they are suitable for understanding, explaining, and analyzing complex manufacturing systems. They can offer a different perspective on the analysis of the system. However, to the best of our knowledge, their application in manufacturing in the context of industry 4.0, particularly with regards to the use of wearable technologies in manufacturing, has not yet been studied. The results of this review conclude that the use of FRAM and STAMP in manufacturing could be promising for the analysis of digital manufacturing risks, especially wearable technologies used in manufacturing, a point which needs further consideration in future studies.

Keywords: Risk analysis, manufacturing, FRAM, STAMP

1. Introduction

Over the last decades, the management of industrial plants has become increasingly complex regarding various aspects such as interactions, work automation, process structure, and number of components (Gattola et al. 2018; Melanson & Nadeau 2019). Regarding occupational safety, the increasing complexity of industrial systems could lead to an increase in emerging hazards (Leveson 2011). For decades, the way of thinking and analyzing risks were confined to a certain line of reasoning. However, at the end of the 20th century, things began to change as the need for a new approach able to analyze risks in socio-technical systems became prevalent (Slim & Nadeau 2019). Some of the classical methods were not able to illustrate how the interaction of elements of a system including management, organizational and human parameters could cause an accident (Underwood & Waterson 2013). In addition, the use of classical methods such as Fault Tree Analysis (FTA), Failure Mode Effect and Analysis (FMEA), HAzard and OPerability study (HAZOP) have been said to be error-prone, time-consuming, and tedious (Mahajan et al. 2017). To help countermeasure the shortcomings of classical risk analysis methods (Adriaensen et al. 2019; Badri et al. 2018), the application of new approaches such as Functional Resonance Analysis (FRAM) and System-Theoretic Accident Model and Processes (STAMP) are proposed in this paper for the risk analysis of complex manufacturing systems.

2. Methodology

This paper studies the application of FRAM and STAMP in manufacturing. To obtain studies related to our subject, scientific resources at ÉTS library (IEEE, Compendex & INSPEC, Science Direct, Google Scholar, and Espace ÉTS) from 2004 to 2020, mostly in English, were consulted. The applied keywords were: FRAM, STAMP, STPA, manufacturing, risk, industry, and industry 4.0. The search results were narrowed down first by reviewing the titles and then by studying the abstracts. The selected papers were consulted to extract a comprehensive context, including the year of publication, the study's aim and results, the type of analyzed risks, and applied methods. The findings are presented in two tables that show the application of FRAM and STAMP in manufacturing and explain why FRAM and STAMP are more suited for risk analysis in complex manufacturing.

3. Results

3.1 FRAM

FRAM is a systemic model that describes nonlinear relationships and interactions between different functions in the studied system. Introduced in 2004 by Erik Hollnagel, FRAM analyzes normal system activities, considers functional variabilities, and deviations from expected performance. It also considers the variability in performance and studies how these functional variabilities might resonate with one another to create unwanted events (Hollnagel 2004). The application of FRAM for risk analysis in manufacturing is presented in Table 1.

Table IV.1 The application of FRAM for risk analysis in manufacturing

Author(s) & Year	Main Objective	Result	Type of Manufacturing process	Type of risk	Method
(Sekeľová & Lališ 2020)	Using Resilience Assessment Grid (RAG) and FRAM to evaluate changes in the process of producing aircraft's components	FRAM will help the analyst to better clarify the relationships among different functions.	Producing aircraft components	OHS and operational risk	FRAM + Resilience Assessment Grid (RAG)
(Melanson & Nadeau 2019)	Compared application of Failure Mode Effect and Criticality Analysis (FMECA) and FRAM	Manufacturing can use FRAM to have a good insight into their operations as socio-technical systems.	Manufacturing of motor vehicles (chassis assembly)	OHS and emerging risk	FRAM and FMECA
(Gattola, et al. 2018)	Using FRAM for analysis of safety-related issues in metal manufacturing (Forging process)	Using FRAM helped to identify different activities that can potentially resonate within the system and introduce emerging events. Hence, the prediction of the changes' effects on the system is easier.	Forging process	OHS risk	FRAM
(Gholamniaet al. 2018)	Evaluating the OHS risk using FRAM and two classic methods including Failure Modes (FM) and Effects Analysis (EA)	Since FM and EA mostly deal with technical issues and FRAM provides an overall view of the system, using both classical methods (FM and EA) and FRAM can significantly improves the system's safety.	Pressing process in car manufacturing	OHS risk	FRAM
(Patriarca, et al. 2017)	Application of a developed FRAM with Monte Carlo simulation in a sinter plant	The application of developed FRAM with Monte Carlo simulation will provide a more accurate assessment with iterative simulation.	Sinter plant	Environmental risk	FRAM + Monte Carlo
(Z. Zheng & Tian 2017)	Assessing risks of the manufacturing process in an assembly case study (assembly of the rotor)	Applying the new approach provides a new perspective on risk analysis, a deeper understanding and insights on the interaction and dynamics among different components in a manufacturing system.	Manufacturing (the assembly of a rotor on an elevator)	Operational risk (quality of products)	FRAM+ Finite State Machine + model checker SPIN

Table IV.1 The application of FRAM for risk analysis in manufacturing (Continued)

Author(s) & Year	Main Objective	Result	Type of Manufacturing process	Type of risk	Method
(Z. Zheng & Tian 2017)	Assessing risks of the manufacturing process in an assembly case study (assembly of the rotor)	Applying the new approach provides a new perspective on risk analysis, a deeper understanding and insights on the interaction and dynamics among different components in a manufacturing system.	Manufacturing (the assembly of a rotor on an elevator)	Operational risk (quality of products)	FRAM+ Finite State Machine + model checker SPIN
(Zixia al. 2016)	FRAM was used to refine the operation guidelines and improve production processes by reducing the number of unqualified products	FRAM helped to identify the gap between work as imagined and work as done, and finding defects in guidelines to improve manufacturing processes to reduce manufacturing risks.	The forging of aero-engine titanium alloy blades	Operational risk (quality)	FRAM
(Albery et al. 2016)	Evaluation of the use of question sets (in four methods including work as done, work as imagined, risk matrix, FRAM approach) that are based on FRAM (Safety II)	Questions inspired by Safety II can encourage stakeholders to look for different sources of variability in the working system. It also provides a more in-depth learning of the system's performance to manage variability.	Manufacturing site that includes different processes such as assembly, welding, cutting, etc.	OHS and operational risks	FRAM + safety II

3.2 STAMP

STAMP is a model based on system theory that focuses more on system safety than the prevention of failures. In this method, safety is considered as a control problem rather than a reliability issue. This method tries to find the causes of an accident by specifying the reason for its being controlled ineffectively. The following table (Table 2) shows the application of STAMP in manufacturing.

Table IV.2 The application of STAMP for risk analysis in manufacturing

Author (s) & Year	Main Objective	Result	Type of Manufacturing process	Type of risk	Method
(Pope 2019)	Applying STPA for risk analysis of the reproduction of a widget (an item for which production is too expensive, its components are hazardous and it is made by the government)	Using STPA provides a useful perspective on risk analysis and facilitates risk review.	Manufacturing a widget	Governmental, Operational, Environmental, and OHS risks	STPA
(Sousa, Torres et al, 2017)	Application of STAMP and Lean philosophy to eliminate or decrease waste in manufacturing	The combination of STAMP and the Lean approach can help make better decisions, reduction of waste and acquire more in-depth information about the system than Lean philosophy.	Car assembly	Operational risk (risk of making waste)	STAMP + Lean philosophy
(Schmittner et al. 2016)	Application of STAMP-based method for assessing safety and security risks (battery management system)	Although STPA-sec is an appropriate approach for managing risks, using with other methods (ISO 26262) provides a comprehensive assessment.	Automotive vehicle	Security risk	STPA-sec + ISO 26262
(Montes 2016)	Applying STPA to test product development after the design completion to ensure quality and safety.	The developed STPA can provide essential human considerations in controllers and analyze social and organizational factors influence on controllers	Governmental manufacturing	Safety risk, Operational risk	STPA + Refined Controller (RC)
(Martínez 2015)	Comparison of the application of FMEA and STPA on electric power steering in the product development phase	STPA can be applied in product development in the early stages. STPA is insightful in that it is able to discover hazards in the system in comparison to FMEA.	Manufacturing (vehicle manufacturing)	Operational risk	STPA
(Li 2012)	Applying STAMP (STPA) and PFMEA to manage the quality risks in the production of printed circuit sheets.	The comparison of the application of STPA and PFMEA shows that STPA provides a structured analysis of the system controls and identifies more potential hazards.	Manufacturing (medical device sensor assembly)	Quality (operational) risk, Safety risk	STAMP (STPA)

Regarding the results of these studies (Tables 1 and 2), FRAM is proposed to help understand outcomes that are non-causal (emergent) and nonlinear to enable predictability and control (Hollnagel et al. 2014). FRAM can introduce a different perspective (systemic view) in the system analysis process, and help identify variabilities that might be critical for the proper functioning of the system (Slim & Nadeau 2020). Moreover, STAMP provides a better and more in-depth understanding of the system and its hierarchy, an overview of the required controls, also the relationships between system components (Salmon et al. 2012).
In a proposed classification of systems based on manageability and coupling, manufacturing and assembly lines are considered as a system with average coupling and good manageability (Figure IV.1- quarter number 3) (Hollnagel 2008; Underwood & Waterson 2013). Given the classifications of appropriate methods for analyzing risks (Hollnagel & Speziali 2008), when the tractability (manageability) is lower and the interaction (coupling) is higher, methods including FRAM, STAMP, and to some extent Cognitive Reliability and Error Analysis Method (CREAM) are better suited for risk analysis (Adriaensen et al. 2019) (Figure IV. 2).

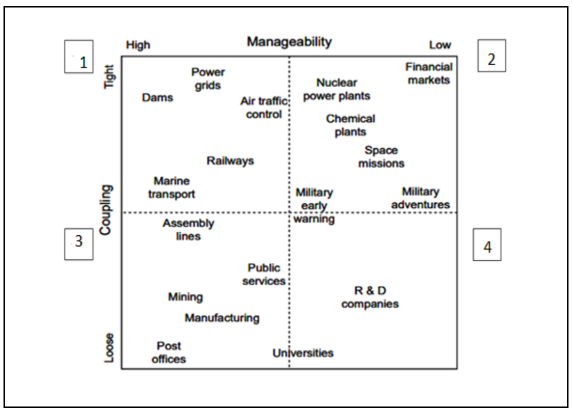

Figure IV.1 Classification of systems based on manageability and coupling[15]

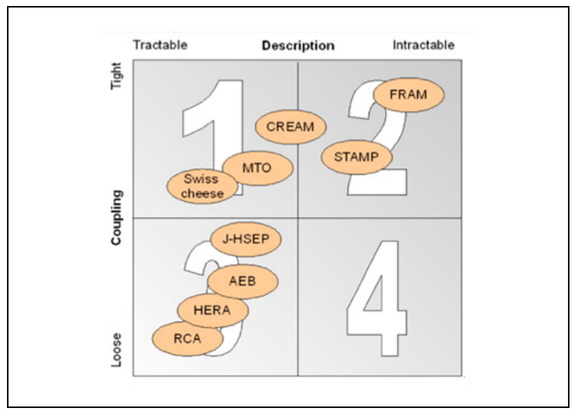

Figure IV.2 Characterization of different methods for risk analysis[16]

Considering results of the application of FRAM and STAMP as well as the complexity of the studied manufacturing systems, FRAM and STAMP are considered the most appropriate approach for analyzing risks (Adriaensen et al. 2019; Hollnagel & Speziali 2008). In addition, with the introduction of industry 4.0 to manufacturing, couplings and complexity will consequently increase. Therefore, some changes in the positioning of the manufacturing sectors within the quadrants are to be expected (Adriaensen et al. 2019). The introduction of new technologies can accelerate an increased tightening of couplings (Hollnagel & Speziali 2008) and generate more nonlinear and unpredictable system behaviors that are not easy to manage (Pope 2019; Rodríguez & Díaz 2016). Introducing wearables to the manufacturing

[15] Source of the figure: Underwood & Waterson (2013), and Hollnagel (2008)

[16] Source of the fidgure: Adriaensen et al. (2019), and Hollnagel & Speziali (2008)

system as an emerging technology could make the coupling between components tighter and lower the system's manageability. Thus closer to quarter 2, the preferred methods of risk analysis are FRAM and STAMP.

4. Conclusion

Different studies have shown that FRAM and STAMP can provide a systemic view of system analysis. The deployment of new technologies such as wearable technologies in manufacturing systems increases the couplings among components and manageability will decrease. Regarding the characteristics of FRAM and STAMP, they could be considered as promising methods for manufacturing risk analysis in the context of industry 4.0. However, more studies are required to investigate the effect of the deployment of wearable technologies in manufacturing.

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ANNEX V CONFERENCE PRESENTATION (ICOH)

COMPARING FRAM AND STAMP FOR OCCUPATIONAL HEALTH AND SAFETY (OHS) AND OPERATIONAL RISKS ANALYSIS: THE CASE OF DATA GLVOES IN ASSEMBLY 4.0 PRODUCTION

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Introduction: Manufacturing in the context of industry 4.0 faces increasing complexity. Thus, emerging occupational and operational hazards might become a concern if not considered early in the design process. Systemic and innovative approaches can be used to address hazards in complex socio-technical systems. FRAM and STAMP (STPA) are appropriate and promising methods to analyze OHS and operational risks “at the source” in such systems.

Material and Methods: This study briefly compares the application of FRAM and STAMP in case studies regarding the use of data gloves in manual assembly. An overview of the applied methods regarding the literature from 2004 to 2021 will be provided. Following, the FRAM and STAMP (STPA) models will be presented and their use for the analysis of three case studies will be discussed.

Results: Our results show that these systemic methods can provide a good understanding, explaining, and analysis of manufacturing systems in the context of industry 4.0. While FRAM can provide a holistic and positive view from six aspects of defined functions, STPA considers system components in more detail regarding controls and feedback.

Conclusions: To provide more comprehensive and valid results, applying a combined approach of these methods is promising. It has the potential to enhance the analyst’s understanding and capability to analyze an assembly system and its components when a smart wearable is introduced, especially in the first stages of system design. Further research and developments are needed.

ANNEX VI CONFERENCE PRESENTATION (AHFE)

A REVIEW OF THE APPLICATION OF FRAM AND STAMP APPROACHES OMBINED WITH OTHER METHODS

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Abstract

When dealing with risks associated with complex sociotechnical systems, one needs to employ approaches that will make it possible to better understand the systems' complexity and analyze them more efficiently. Several approaches have been proposed and in the recent literature, the System-Theoretic Accident Model and Processes (STAMP) and Functional Resonance Analysis Method (FRAM) stand out. These have been applied both separately and integrated with other methods for risk analysis.This study aims to provide an overview of the literature related to the application of FRAM and STAMP integrated with other methods. Papers from various scientific resources, including Scopus, IEEE, Compendex and INSPEC, Google Scholar, and Espace ÉTS from 2004 to 2021, in English, were consulted. The keywords used to narrow our search were FRAM, STAMP, STPA, and risk analysis.
The results show that FRAM and STAMP have been used in combination with other methods such as fuzzy logic, Monte Carlo Simulation, bow tie, and model checking. Their combination with other methods has enhanced their efficiency and capability in risk analysis and provides better and more precise outcomes for some specific contexts of study. These combined proposed approaches have been applied and validated for specific contexts in specific studies. Therefore, the generalization and validation of the combined methods in different contexts could be an outlook for future studies.

Keywords: combined approach, FRAM, STAMP, STPA, risk analysis

Introduction

Systems safety has always been an essential part of manufacturing. Over the years, the proposed methods for systems' risk analysis have evolved both in response to the evolution of the systems and to address the new challenges and risks these systems face (Grabbe et al., 2020). Different methods, from classical to systemic, have been introduced over the past decades, and their usefulness and efficiency have been examined and evaluated within several contexts of study (Grabbe et al., 2020). As systems evolved, experts developed the concept of sociotechnical system, and findings have showed that classical methods are unable to provide adequate risk analysis for such systems (Adriaensen et al., 2019).

Therefore, finding appropriate approaches that provide a comprehensive analysis of the studied system has been an interesting subject for many researchers in recent decades. Among different approaches introduced by researchers, a considerable number of studies have been devoted to the application of Functional Resonance Analysis Method (FRAM) (Hollnagel, 2012) and System-Theoretic Accident Model and Process (STAMP) (Leveson, 2011) in different contexts. These methods look at the system from a systemic and non-linear perspective to identify component interactions that might lead to a hazard. By providing a good understanding of the system and its components, they enable the analyst to explore variabilities and hazardous interactions within the complex system.

However, even if many studies proved the worthiness of these methods in risk analysis, some researchers introduced novel approaches by combining FRAM (Pardo-Ferreira et al., 2019) or STAMP (Patriarca et al., 2022) with other methods. They found that when FRAM or STAMP were applied alone, there was a gap between the expected and the obtained result. Moreover, some analyses needed quantified results to achieve more precise results for a specific context. These innovations improve the obtained results and enhance these methods' capabilities. This study aims to provide a review of the methods that have been combined with FRAM and STAMP. The results show that their combination with other methods improved the analysis within the study's specific context. Many combinations have been proposed of other methods with FRAM and STAMP, but only one study considers a combination of these two methods with each other. Applying FRAM and STAMP is a novel combination, which needs further study both to develop it and examine it in various specific contexts, and to validate its efficiency.

The remainder of this study is structured as follows. Section 2 discusses the methodology applied to retrieve the related studies. This is followed by the results in Section 3. Section 4 discusses the results and draws conclusions.

Methodology

To retrieve the related studies, various scientific databases, including Scopus, IEEE, Compendex and INSPEC, Google Scholar, and Espace ÉTS from 2004 to 2022, in English, were consulted. The keywords used to narrow the number of results were risk analysis, FRAM, STAMP, STPA, and combined approach. The papers were chosen by their title, and then for screening, abstracts were studied to verify their relevance to the study's objective. Finally, a brief review of the obtained papers through discussed methodology was presented in two tables, one for FRAM and one for STAMP, noting the objective of the study, applied methods, results of the application of the proposed method, and the domain of study. The results are shown in the next section.

Results

By applying the methodology discussed in Section 2, we retrieved 59 papers. Thirty-three of them studied the application of FRAM combined with other methods. The other 26 investigated the application of STAMP (mostly STPA) with other methods. The proposed methods go by different names, such as integrated, combined, hybrid, development, and extended. For this study, these are considered as the same. Also, these approaches have been applied in different domains such as software development, cyber-physical systems, rail transportation, process industry, manufacturing, construction, and aviation. Aviation is where the most references were found.

Table VI.1 FRAM application combined with other methods

Author & Year	Main Objective	Applied Methods	Results	Domain
(Zheng et Tian, 2015)	Application of finite state machine and model checker to formally present FRAM.	FRAM + finite state machine (FSM) and model checker NuSMV	Application of proposed methods with FRAM gave a new perspective about accidents and complemented the understanding of the system.	Herald of Free Enterprise car ferry accident
(Yang et Tian, 2015)	Application of FRAM and the Model-Based Safety Assessment (MBSA) checking model to identify potential hazards.	FRAM + MBSA -model checking	The combined approach was useful in verifying the FRAM analysis model by model checking and ensuring whether the safety requirements were upheld or needed further analysis.	Landing process of an airplane
(Rosa, Haddad et de Carvalho, 2015)	Analyze risks through the application of FRAM and the AHP.	FRAM + analytic hierarchy process (AHP)	The combined application provided a new perspective of the system and a better understanding of critical functions.	Construction
(Duan, Tian et Wu, 2015)	Develop FRAM by bridging theory and practice through model checking.	FRAM + model checking	The proposed approach refined the results by redefining and categorizing couplings. It helped to identify more couplings and provide a better understanding of the system's behavior.	Aviation (air accident)
(Hirose, Sawaragi et Horiguchi, 2016)	Analyze the feasibility of procedures for highly automated systems.	FRAM + Fuzzy CREAM	The proposed method was not only useful for the analysis of accidents but also for the pre-analysis of the safety of documented procedures.	Flight-deck procedures (Cali airport air crash accident)
(Zheng, Tian et Zhao, 2016)	Propose an approach to refine operation guidelines and to reduce the risk of producing unqualified products.	FRAM + Finite State Machine (FSM)+ model checker SPIN	The application of the proposed approach showed its feasibility and effectiveness in refining process guidelines.	Aero engine blade forging (manufacturing)
(Patriarca, Di Gravio et Costantino, 2017)	Propose a semi-quantitative FRAM model based on the Monte Carlo Simulation.	FRAM + Monte Carlo Simulation (MCS)	The proposed approach helped highlight the most critical functions and facilitated the understanding of analysis through the provision of numerical results.	Air Traffic Management (ATM)

Table VI.1 FRAM application combined with other methods (Continued)

Author & Year	Main Objective	Applied Methods	Results	Domain
(Patriarca, Bergström et Di Gravio, 2017)	Use Abstraction Hierarchy (AH) to provide a detailed representation of functions at a different level.	FRAM + Abstraction Hierarchy (AH)	The proposed approach provided an Abstraction/Agency framework presenting the studied system in a structured and systemic manner. The multilayer presentation of the system enhanced the knowledge of the system.	Railway domain
(Bellini, Ceravolo et Nesi, 2017)	Investigate and quantify resilience enhancement of Urban Transport System equipped with Internet of Everything (IoE).	FRAM + Network analysis techniques	The study concluded that the variability rate would be enhanced with the deployment of IoE.	Urban Transport System (UTS)
(Yang, Tian et Zhao, 2017)	Analyze and model (Minimum Safe Altitude Warning) MSAW-in-ATM system, formalizing variabilities and interactions.	FRAM + formal verification tool SPIN	The results showed that achieving a successful design is possible through a comprehensive analysis of the system safety within system development.	Air Traffic Management
(De Felice, Zomparelli et Petrillo, 2017)	Develop a novel approach to Human Reliability Analysis (HRA) that evaluates the variability of the human error probability.	FRAM + HRA	The method could evaluate quantitively the probability of human functions and their effect on downstream functions.	Petrochemical company
(Jensen et Aven, 2017)	Propose a new hazard identification method by applying Anticipatory Failure Determination and FRAM.	FRAM + Anticipatory Failure Determination (AFD)	The combined approach provided creative methods for inventing potential hazards in complex systems.	Lifting operation
(Toda, Matsubara et Takada, 2018)	The application of four keywords of STPA analysis in the FRAM method.	FRAM + STPA	The proposed approach was suitable for risk analysis in the concept and design phase. It could find more hazards compared to solely applying STPA.	Railroad crossing, Car lane changing
(Lee et Chung, 2018)	Propose a new FRAM-based approach to improve the resolution of crew interactions.	FRAM + human-system interaction (HSI)	The proposed approach assisted in analyzing the interaction of human and systems better and suggested critical parts at the HIS level to be considered in the strategy for variability management.	Maritime domain
(Riccardo et al., 2018)	Enhance the strength of FRAM-based analyses through the application of the Resilience Analysis Matrix (RAM).	FRAM + RAM	While FRAM is a powerful method in the variability analysis of operational scenarios, RAM provided a two-dimensional representation of couplings.	SkyWest Flight 5569 and USAir Flight 1493 accident
(Sekeľová et Lališ, 2019)	Apply a Resilience Assessment Grid (RAG) in aircraft components production to propose an approach specific to aviation.	Resilience Assessment Grid (RAG) + FRAM	The approach provided a model of a managed change process. It also helped develop better safety awareness and increase the organization's resilience performance.	Aircraft components production
(Slim et Nadeau, 2019)	Improve the descriptive FRAM results in the quantitative outcomes by integrating fuzzy logic.	FRAM + Fuzzy logic	The proposed approach provided a representation of the outcomes in numeric format and a comprehensive representation of potential performance variabilities.	Aircraft on-ground de-icing operations

Table VI.1 FRAM application combined with other methods (Continued)

Author & Year	Main Objective	Applied Methods	Results	Domain
(Li et al., 2019)	Integrate Accident Causation Analysis and Taxonomy (ACAT) with FRAM model to propose a closed-loop analysis method.	FRAM + Accident Causation Analysis and Taxonomy (ACAT)	When applying the hybrid method, more functional constraints and factors that contribute to accidents could be found. It also provided more details that helped to understand systems even though its application was more complicated than when solely applying ACAT or FRAM.	Opening a valve on a gas pipeline - Coal shearer process
(Yu et al., 2020)	Propose a FRAM-based framework to help to overcome the dependency on expert elicitation for systemic hazard identification.	FRAM + Human performance model (CREAM) + equipment performance model	The proposed approach provides a framework to aggregate the upstream variabilities quantitatively and proactively simulates the functions' interaction.	Process industries (Methyl methacrylate (MMA) batch polymerization process)
(Eljaoued, Yahia et Ben Saoud, 2020)	Propose a qualitative-quantitative approach to risk analysis.	FRAM + Graph theory	The use of graph theory provided a quantitative assessment of the functions' interactions and evaluates their effect on functions' variability.	A simulation of crisis organization
(Hirose et Sawaragi, 2020)	Develop a tool to validate and verify safety based on the FRAM model.	FRAM + cellular automaton	The extended FRAM approach is helpful in providing insights into experienced workers' operations characteristics and identification of critical points for safety management.	Steel production line
(Falegnami et al., 2020)	Represent the FRAM model in a multi-layer network.	FRAM + Network theory	The combined method made it possible to interpret the FRAM model in multilayer networks that could enable analysts to prioritize critical functions.	Industrial plant (A power-tool accessory production plant)
(França et al., 2020)	Develop an approach to identify complexity level and critical human factors.	FRAM + AHP	The proposed approach made it possible to model the “work as done” properly to identify critical functions and worker’s behavior that might be ignored in procedures.	Offshore drilling systems
(Bellini, Coconea et Nesi, 2020)	Propose a method to quantify FRAM results.	Q-FRAM	The results were obtained with a robust and fast-forward method in a practical way and provided a good insight into the system's status for decision-makers.	H2020-RESOLUTE pilot definition
(Slim et Nadeau, 2020a)	Improve the size of rules and classify outcomes for the use of fuzzy logic combined with FRAM.	FRAM + rough sets/fuzzy logic	The number of rules was decreased considerably, and it was suitable especially for decision making regarding uncertain and incomplete data.	Aviation (Aircraft on-ground de-icing operations)
(Yu et al., 2021)	Propose a data-driven approach to provide quantitative results of functions’ couplings.	FRAM + Association rule mining	The application of association rule mining provided quantitative metrics for functions couplings. It was also helpful in identifying the path that leads to hazard.	Polymerization process (process industry)
(Alboghobeish et Shirali, 2021)	Identify and prioritize emerging risks through an integrated application of FRAM	FRAM + analytical hierarchy process	The integrated approach was useful for risk analysis and identifying emerging risks based on "work as done", not "work as imagined".	Water reservoirs management in agriculture

Table VI.1 FRAM application combined with other methods (Continued)

Author & Year	Main Objective	Applied Methods	Results	Domain
(Salehi et al., 2021)	Propose a dynamic FRAM-based tool for variability analysis.	DynaFRAM (programming FRAM via Python programming language)	DynaFRAM could capture the different variabilities' characteristics and facilitate understanding and analyzing complex operations' variability.	Healthcare case study
(de Souza et al., 2021)	Apply a layered FRAM to analyze work as done in HVAC system maintenance.	Layered FRAM	The proposed approach provided a better perspective of functions, decreased the analysis complexity by dividing the analysis into layers, and facilitated model analysis.	Maintenance of heating, ventilation, and air-conditioning (HVAC)
(Zinetullina et al., 2021)	Quantify the FRAM's analyzing resilience for a chemical process.	FRAM + Dynamic Bayesian Network (DBN)	The proposed approach provided a rigorous quantitative analysis of the system and assessed resilience in both probabilistic and temporal aspects.	Chemical process systems (a separator of an acid gas
(Kim et Yoon, 2021)	Develop an approach to quantify FRAM results and variability propagation.	Rule-based FRAM	The proposed method was useful for assessing potential risks in a crisis and supporting decision-makers in their response to a crisis.	Emergency response system for infectious disease
(Huang et al., 2022)	Formulate the variability mechanism of FRAM through the risk pulse theory.	FRAM + N-K model	The proposed approach provided quantitative results for variabilities; however, the historical statistical frequency of every risk factor was required.	An accident in railway hazardous goods transportation
(Liu et al., 2022)	Evaluate the safety of operating procedures of medical equipment.	FRAM–Moran's I and CREAM	The proposed approach provided a systematic perspective regarding the ergonomic reliability of medical equipment.	Operation procedure of a medical equipment

Table VI.2 The application of STAMP combined with other methods

Author & Year	Objective	Applied Methods	Results	Domain
(Colley et Butler, 2013)	Propose an approach to hazard analysis for system requirements that are captured as monitored, controlled, mode, and commanded phenomena.	STPA + Event-B	Event-B applied with STPA helped provide a formal representation of safety constraints as "invariants" or "guards" in the formal model.	Washing machine system
(Mason-Blakley, Weber et Habibi, 2014)	Propose a combined approach of FMEA and STPA for hazard analysis of an information system.	STPA + Failure Modes and Effects Analysis (FMEA) = Information Systems Hazard analysis (ISHA)	The combined approach addressed the weakness of the FMEA method in the qualitative aspect that compromises reproducibility and improves the obtained results.	Clinical Information Technology (CIT)

Table VI.2 The application of STAMP combined with other methods (Continued)

Author & Year	Objective	Applied Methods	Results	Domain
(Abdulkhaleq, Wagner et Leveson, 2015)	Develop an STPA-based approach for comprehensive safety engineering of software.	STPA + software testing and model checking approach	The proposed approach could be integrated into software development processes. It was helpful in identifying unsafe control action and performing analysis in system levels. It improved workflow and communications between	A software
(Montes, 2016)	Product testing through the application of STPA to refine the human controllers' analysis.	STPA + Refined Controller (RC)	The approach improved the results and identified additional unsafe behaviors that might affect inherent system safety.	The U.S. Air Force product
(Johnson, 2016)	Introduce an STPA extension called STPA-Coordination.	STPA + unsafe coordination analyses	The extended approach helped to identify more hazardous coordination scenarios and	Unmanned aircraft systems
(France, 2017)	Propose a new approach to analyze the role of humans in complex automated systems.	STPA + Engineering for Humans (STPA-Engineering)	The approach guided analysts in identifying casual scenarios related to human interactions with automation and understanding why an unsafe behavior appears appropriate in an operational context. It also provided a special dialogue framework for communicating between human factors experts and engineers from other fields. It was useful in comparing the effect of human behaviors on different system	Automated driving system (Automated Parking Assist)
(Thapaliya et Kwon, 2017)	Propose an integrated approach for safety analysis from the perspective of reliability and control theory.	STPA as revolutionary safety method + results of the application of hazard and operability study (HAZOP), failure mode and effect analysis (FMEA), and fault tree analysis (FTA) as evolutionary safety methods	The integrated approach was shown to be more comprehensive than the separate application of risk analysis methods.	Green Line Metro System (train control system)
(Howard et al., 2017)	Propose an approach for safety and security risk analysis of cyber-physical systems.	STPA + Event-B	The inclusion of Event-B to STPA analysis provided integrated critical requirements that are represented formally (not simple text) as variants, guards, etc. These requirements could then be mitigated.	Cyber-physical systems

Table VI.2 The application of STAMP combined with other methods (Continued)

Author & Year	Objective	Applied Methods	Results	Domain
(Sousa, Torres et Jorge, 2017)	Apply STAMP and Lean philosophy to eliminate waste in a production system.	STAMP + Lean philosophy	The combined application of Lean and STAMP provided more information through a better representation of the organizational structure of the production system compared to applying Lean alone for waste elimination.	Production system
(Friedberg et al., 2017)	Propose a novel approach to safety and security analysis of cyber-physical systems.	STPA-SafeSec	The proposed approach provided a description of a generic component layer diagram and a generic casual factors diagram in the security domain. It could provide an in-depth security analysis of the critical system components.	Power grid (synchronous -islanding)
(Dakwat et Villani, 2018)	Provide a formal and unambiguous representation of the studied system analysis and identified hazards using STPA.	STPA + model checking	Combining STPA and model checking improved the results and knowledge of the system being designed. It was also consistent with the design changes suggested to deal with identified safety constraints in the STPA analysis results.	Robotic flight simulator
(Wang et Wagner, 2018a)	Propose an approach to agile development that addresses the lack of appropriate safety analysis and verification methods.	STPA + Behavior Driven Development (BDD)	The preliminary results showed that the combined STPA-BDD is capable of providing effective communications between developers and business analysts.	Agile software development
(Joung et al., 2018)	Develop an approach to risk and hazard identification of a Dynamic Positioning (DP) and mooring system in design and operation.	STPA + Hazard identification study (HAZID)	A comprehensive hazard analysis through the application of multiple hazard identification methods was recommended to benefit from each method's capability and compensate for their weaknesses.	mooring system in Arctic condition
(Torkildson, Li et Johnsen, 2019)	Improve co-analysis of safety and security by applying threat modeling approaches as a complementary strategy.	STPA-sec + Threat modeling approaches (Misuse of cases, data flow diagram, attack tree, Business Process Modelling Notation	Among different approaches, the data flow diagram showed better results in combination with STPA-sec for the specific case study; however, other threat approaches could complement STPA-sec from different aspects. It also helped identify more unsafe control actions than if STPA-sec had been solely applied.	Autonomous boat
(Hirata et Nadjm-Tehrani, 2019b)	Investigate the combination of STPA and GSN for a safety risk analysis approach.	STPA + Goal Structuring Notation (GSN)	The use of GSN in combination with STPA was feasible for supporting certification decisions. This approach improved the safety engineers' communication and was useful in importing the argumentation structure from the STPA method. It was a useful generic approach for documenting quality insurance cases in any system that applies STPA and GSN for risk analysis.	The train door controller

Table VI.2 The application of STAMP combined with other methods (Continued)

Author & Year	Objective	Applied Methods	Results	Domain
(Silva Castilho, 2019)	Propose an integrated hazard analysis for Safety Management Systems (SMS).	STPA + SMS = Active STPA	The integrated approach enabled the proactive identification of leading indicators that showed risk increments. It also provided good qualitative information and helped to manage hazards in an SMS.	Aviation
(Bensaci et al., 2020)	Apply a combination of STPA and Bowtie for safety assessments of robot collaborations for a better comparison of different controls.	STPA + Bowtie	The combined approach provided detailed hazard identification and risk classification that improved STPA outcomes and facilitated decision-making on finding the most suitable approaches.	Multi-robot systems
(Souza et al., 2020)	Propose a method for simulation and formal verification of system models through the combination of STPA and SysML modeling activities.	STPA + Systems Modeling Language (SysML) modeling activities	The combined approach was helpful to structure STPA analysis with clarification and clear specifications of assumptions, requirements, system boundaries, and their interactions through the application of SysML diagrams.	An automatic door system
(Dunsford et Chatzimichailidou, 2020)	Embed the STPA application into CSM-RA as a supplement to ensure the understanding of safety requirements.	STPA + Common Safety Method for Risk Evaluation and Assessment (CSM-RA)	The use of STPA with CSM-RA produced a powerful safety assessment process and saved money and time. However, there are still challenges regarding the limitation of CSM-RA framework bounds.	The rail sector
(de Souza et al., 2020)	Apply STPA extension with threat model ((STRIDE= Spoofing, Tampering, Repudiation, Information Disclosure, Denial of Service, and Elevation of Privilege) for a simultaneous safety and security risk analysis of system developments in the concept stage.	STPA + threat model	The proposed approach provided a more complete analysis and identified loss scenarios.	Electronic voting system by smartphone
(Carreras Guzman et al., 2021)	Compare a novel extension of STPA and Uncontrolled Flows of Information and Energy (UFoI-E) in terms of differences and potential for combination by applying it to the same case study.	STPA-Extension (both safety and security analysis) + Uncontrolled Flows of Information and Energy (UFoI-E)	Both methods were useful for safety and security risk assessment. However, a combination of results obtained by both methods provided higher and more reliable levels of result completeness.	Cyber-physical systems- Case study: ReVolt, a conceptual autonomous ship
(Liew et al., 2021)	Propose a safety and security (S&S) approach to use STPA for cyber-physical systems.	STPA (for safety and security) + 8 Matrix Diagram presentation	The methods enabled analysts to oversee the correlation between safety and security.	Cloud-based monitoring and control system for residential energy storage systems

Table VI.2 The application of STAMP combined with other methods (Continued)

Author & Year	Objective	Applied Methods	Results	Domain
(Xing et al., 2021)	Introduce FSM to complement risk analysis results of STPA application.	STPA + Finite State Machine (FSM)	The combination of STPA and FSM compensated for the weaknesses of the STPA method in the risk analysis of high-level autonomous vehicles, with several automated modes and functions. It also provided more details and found more hazardous events to generate testing scenarios.	Autonomous Vehicles
(Dghaym et al., 2021)	Develop an approach to identify and analyze the mission requirements for autonomous missions in autonomous systems.	STPA + formal modeling	The proposed approach continuously reviewed factors that might affect formal modeling. On the other hand, formal modeling could improve system requirements by identifying new requirements, removing ambiguity and ensuring the consistency of the requirements.	Unmanned Surface Vehicle
(Ge et al., 2022)	Proposing a new approach for risk analysis based on Systems-Theoretic Accident Model and Processes (STAMP) and Risk Management Framework (RMF) fundamentals called Interaction Theory of Hazard-Target System (ITHTS), and proposing a new systemic accident analysis method of work systems (SAAMWS) since ITHTS cannot be applied	STAMP + Risk Management Framework (RMF)	The proposed approach was powerful in providing a good explanation of the accident. It is a feasible approach for accident analysis.	Tianjin Port fire and explosion accident
(Duan, 2022)	Formalize the results of STPA application by integrating it with model-based systems engineering (MBSE)	STPA + model-based systems engineering (MBSE)	The quantification of the outcome obtained by the proposed method showed that it is effective and feasible for the safety and risk analysis of the system designs. It linked system development and safety analysis.	Autonomous Vehicle (autonomous emergency braking system)

Discussion and Conclusion

FRAM and STAMP were introduced to academia and industry about20 years ago. Since then, a considerable number of studies have been devoted to the application of a combination of one of these methods with other methods, which demonstrates the significant contribution these methods have to offer in risk analysis regarding a comprehensive understanding of the studied system (Riccardo et al., 2018, Patriarca et al., 2022). The FRAM and STAMP methods have been applied in various contexts proving they can be applied in different sociotechnical systems. They have also been applied with other methods in various contexts. The results of this review show that the proposed approaches are more effective combined with other methods than when used alone. They benefit analysts through the provision of a comprehensive and detailed perspective of the studied system. In addition, some proposed approaches provided quantified results for better result comparisons and provided a good insight into the studied system for decision-makers. This combined approach was often used for a specific context, and its application to other contexts would require further research. Among the different methods studied, the combined application of FRAM and STAMP was studied in only one paper (Toda et al., 2018). Regarding the dynamic characteristics of complex sociotechnical systems, combining the application of both FRAM and STAMP with other methods, there is still room for improvement. Nevertheless, it is a promising development for risk analysis (de Linhares et al., 2021).

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