TALLINN UNIVERSITY OF TECHNOLOGY
SCHOOL OF ENGINEERING
Department of Mechanical and Industrial Engineering

DESIGNING A PRODUCTION SYSTEM IN A CLEANROOM ENVIRONMENT

TOOMISSÜSTEEMI KAVANDAMINE PUHASRUUMI TINGIMUSTES

MASTER THESIS

Student: Krismar Epner

Student code: 221957MARM

Supervisor: Kristo Karjust, professor

Tallinn 2024

(*On the reverse side of title page*)

AUTHOR'S DECLARATION

Hereby I declare that I have written this thesis independently.
No academic degree has been applied for based on this material. All works, major viewpoints and data of the other authors used in this thesis have been referenced.

"20" May 2024.

Author: ....
/signature /

Thesis is in accordance with terms and requirements

"......." .... 20….

Supervisor: ….........................
/signature/

Accepted for defense

".......".....................20… .

Chairman of theses defense commission: ....
/name and signature/

Non-exclusive license for reproduction and publication of a graduation thesis[1]

I Krismar Epner (author's name)

1. grant Tallinn University of Technology free license (non-exclusive license) for my thesis

DESIGNING A PRODUCTION SYSTEM IN A CLEANROOM ENVIRONMENT,
(*title of the graduation thesis*)

supervised by Kristo Karjust,
(*supervisor's name*)

1.1 to be reproduced for the purposes of preservation and electronic publication of the graduation thesis, incl. to be entered in the digital collection of the library of Tallinn University of Technology until expiry of the term of copyright.

1.2 to be published via the web of Tallinn University of Technology, incl. to be entered in the digital collection of the library of Tallinn University of Technology until expiry of the term of copyright.

2. I am aware that the author also retains the rights specified in clause 1 of the non-exclusive license.

3. I confirm that granting the non-exclusive license does not infringe other persons' intellectual property rights, the rights arising from the Personal Data Protection Act or rights arising from other legislation.

______________ (date)

[1] *The non-exclusive license is not valid during the validity of access restriction indicated in the student's application for restriction on access to the graduation thesis that has been signed by the school's dean, except in case of the university's right to reproduce the thesis for preservation purposes only. If a graduation thesis is based on the joint creative activity of two or more persons and the co-author(s) has/have not granted, by the set deadline, the student defending his/her graduation thesis consent to reproduce and publish the graduation thesis in compliance with clauses 1.1 and 1.2 of the non-exclusive license, the non-exclusive license shall not be valid for the period.*

Department of Mechanical and Industrial Engineering

THESIS TASK

Student: Krismar Epner, 221957MARM

Study programme: Industrial Engineering and Management (MARM06/22)

Supervisor: Professor, Kristo Karjust, +372 6203260(position, name, phone)

Consultants: ……………………………………………………………(name, position)

…………………………………………………………………………………… (company, phone, e-mail)

Thesis topic:

(in English) *Designing a Production System in a Cleanroom Environment*

(in Estonian) Toomissüsteemi kavandamine puhasruumi tingimustes

Thesis main objectives:

1. Develop production layout design matching requirements
2. Evaluate the effectiveness of the layout design
3. Identify improvement opportunities

Thesis tasks and time schedule:

No	Task description	Deadline
1.	Production and product data collection	08.03.2024
2.	Theory about production layout design	21.03.2024
3.	Developing the layout	12.04.2024
4.	Analyzing the results	21.04.2024
5.	Solution and summary	17.05.2024

Language: English **Deadline for submission of thesis:** "20" May 2024a

Student: Krismar Epner (signed digitally) "……." May 2024a

/signature/

Supervisor: Kristo Karjust (signed digitally) "……." May 2024a

/signature/

Consultant: ………………… ………………………. "……." May 2024a

/signature/

Head of study programme: Kristo Karjust (signed digitally) "……." May 2024a

/signature/

CONTENTS

PREFACE

The thesis was initiated by a commercial need in Karl Storz Video Endoscopy Estonia OÜ (hereinafter also referred to as KSVEE) to design a production system into cleanroom conditions and limitations. Most of the thesis work was done in co-operation with KSVEE and its Continuous Improvement department, who were helpful enough to help the author collect data of the existing cleanroom and the production processes. The thesis is written under the supervision of professor Kristo Karjust.

The author would like to express gratitude to KSVEE and its Continuous Improvement Department who were supportive of the author on his path of master's studies at TalTech, professor Kristo Karjust for supervision of the thesis and girlfriend Kaia Saar who has been supporting the author for the past six years in all his studies.

The thesis focuses on designing a production system to assemble sterile single use endoscopes inside a cleanroom. The system is designed by the demand of product, cleanroom limitations and overall best practice to create a work environment fulfilling the company's needs and ease of production.

Keywords: cleanroom, production system, layout design, cycle time, master thesis

List of abbreviations and symbols

KSVEE – Karl Storz Video Endoscopy Estonia OÜ

DTA – distal tip assembly

LED – light-emitting diode

WS – workstation

QA – quality assurance

3D – three dimensional (model)

EPA – electrostatic protected area

ESD – electrostatic discharge

HEPA – high-efficiency particulate air

VC – Visual Components, simulation software

KPI – key performance indicator

IRR – internal rate of return

List of figures

List of tables

1. INTRODUCTION

Single use medical products have been defined an exact lifespan of lasting for one medical procedure. A company that produces single use medical devices must keep up with the lifespan of the product to ensure medical personnel to be ready to perform procedures that sometimes may be critically time-sensitive to save the patient's life or maintain their quality of life. Requiring the production system for these single use products to be highly efficient and reliable to deliver the required quantities of product pacing the cycle time of consumption.

This thesis focuses on designing a production system in a cleanroom environment for single use medical devices meeting the customer demand of product. The devices are medical flexible endoscopes that are used to look inside of the patient's body using non-invasive techniques and entering from natural body cavities.

A production system is a collection of resources, people, equipment and procedures or processes organized in a predefined sequence to perform manufacturing operations [1]. The production system must ensure the throughput demanded and the required quality for the product being processed in the system. Designing it requires careful thought and sequencing processes to use the least of resources needed to make the system efficient and cost-effective.

The author of the thesis is employed at Karl Storz Video Endoscopy Estonia OÜ. The company aims to start the production of single use medical flexible endoscopes. The thesis topic is due to necessity of a production system in a cleanroom environment on the grounds of KSVEE. The system is to be designed inside an existing cleanroom and the aim is to design a production system that meets the customer demand of 170 000 products in a year.

Factories use combinations of layouts that are mainly defined by the type of production whether being a project production with a high variety of product and low production volume to a continuous production where the product is produced in large volumes with low or no product variety such as electricity or steel. Based on product quantity, the companies need and precept, results from the relationship rating method and the existing constraints a suitable layout must be created that fits into the existing cleanroom. The theoretical foundations of the thesis are brought out in chapter two, where production systems and production layout types are discussed more thoroughly with relevant examples to vividly depict why different solutions are used based on product quantity and variation. The chapter also describes the method of relationship rating and why it is used and how it should be compiled for the effectiveness of the layout based in its purpose.

Chapter three gives an overview of the product families. Involving the production process with the description of the assembly sequence including the production times. The cleanroom environment sets a requirement of maximum number of operating personnel to the count of 40. Operating in a cleanroom sets some restrictions and special conditions to workers and tools inside the cleanroom that are all found in the chapter. The existing cleanroom is presented and described to the reader with different areas and operation description to ensure the environment meets the requirements of ISO 14644-1: 2015 Cleanrooms and associated controlled environments.

KSVEE has been a manufacturer of flexible endoscopes since the beginning of the company in 1994. The company has knowledge in manufacturing and operating for three decades which has given the legacy of internal requirements and documentation combined with existing best practices. Designing a layout in KSVEE must be done in consideration with the company’s existing workstations and internal documentation.

The customer demand is based on two different product families that sum up to a yearly demand of 170 000 products. Production processes are predefined, and the processing times are known. To clarify the demand, cycle time of the product is to be calculated and cycle time is to be used to calculate the minimum number of workstations needed to supply the market with the product. For placing the number of workstations in a functioning layout the relationship rating method ought to be used. The layout design and its basis parameters are calculated in chapter four. The initial concept of the layout is designed and the creation of it is described based on different data, decisions, and methods.

Simulation methods are a low-cost opportunity to test and analyze created production systems. Simulations enable to validate and test production systems and factory layouts before making investments into real-world. They help to predict what will happen when the system is brought to life and where are the shortcomings and bottlenecks of the processes resulting in an opportunity to improve the systems and reduce waste. Visual Components (hereinafter also referred to as VC) is a simulation software that enables to create a manufacturing process in a 3D environment and simulate it with given parameters. The designed layout ought to be tested with VC for analyzing purposes to understand if the system can perform as needed. The designed layout is simulated using VC in chapter five with analysis results to find improvement points and to determine what could be improved.

The essence of continuous improvement and lean manufacturing shadows today's companies as main tools for cutting costs. Therefore, every improvement in a process is welcomed. The designed production system must be analyzed keeping continuous improvement in mind and improvements should be pointed out.

Understanding the labor cost of the entire production system is essential. The cost of labor and investments returns into the decrease of production workers are calculated in chapter six. Production companies sometimes find themselves producing without knowing the exact cost of labor and the thesis points out the importance of labor costs.

Final thoughts and key improvements are written in chapter seven, where the final designed layout of the production system is presented. The objective of the thesis is fulfilled with the design of a production system that can produce 5% less than the initial demand of 170 000 products. The system contains bottlenecks that can be improved to reach the target output of products.

2. LITERATURE REVIEW

2.1 Types of production systems and characteristics

Production in general terms means a process in which goods and services are created through a combination of materials, work, and capital. A production system is a collection of people, equipment, and procedures organized to perform manufacturing operations [2]. Inside a company's production system materials flow through workstations and value is added to them through processes. A product starts as a bill of material and exits the system as a fully functional product or a sub-assembly. The product's purpose is to meet the customers' demands. Depending on the product the customer can be the next production step, following process, an assembling process in another production location or the end customer.

Producing products meeting customers' demand requires carefully designed production systems to ensure competitive products on the market that the customers desire. The production system guarantees that the product is produced with the demanded quality, sufficient cost and with the least amount of resources used.

A well-designed production system enables the company to produce and sell the outcome of the system. If the outcome is of quality, meets the customers' demands, and is of sufficient cost then the product in whole is a competitive product and the company is enduring on the market.

Production systems can vary in complexity and can be influenced by various factors such as the type of industry, available resources, and specific constraints within the environment [1]. These constraints can include space limitations and a maximum limit on the number of workers that can be accommodated in the production area. Based on the need of the study, the production system needs to be designed in a manner that maximizes efficiency and effectiveness within these constraints [2]. Based on production type a production system must be selected. Based on production volume and production variety production systems Figure 2.1 Production type selection are classified into different types such as project production, job production, batch production, mass production and continuous production.

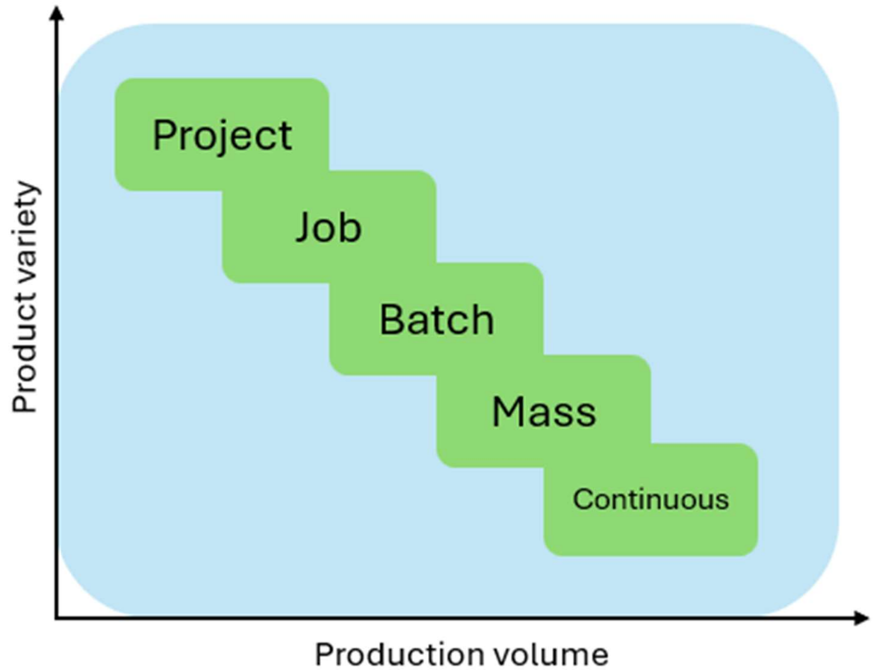


Figure 2.1 Production type selection [3]

Project production usually deals with discrete and highly customized products. Production is often long scale and involves numerous phases and different manufacturing processes to ensure the completion of the product. Good examples of project productions are software design, ship building, movie production, most construction work and fabricating large operations such as windmills. Project production deals with very high product variety and very low production volume, mostly one product at a time.

Job production like project production deals with high product variety and low production volumes. It involves creating products or providing services based on specific customer orders [4]. In this type of production system, each product is unique and requires special attention and customization. However resources in jobbing processes are shared with other processes, which can lead to longer lead times and decreased efficiency [2].

Batch processes may seem similar as job production as they also involve producing a variety of products in smaller quantities [4]. However, batch production differs in that multiple units of the same product are produced together in a batch and variety of product is lower. This allows for greater efficiency in terms of setup and changeover times, as well as better utilization of resources. Batch production can be repetitive and can result in reduced production waste by optimizing the use of materials and resources.

Therefore, batch production can be found in many manufacturing industries such as pharmaceuticals, food processing, and automotive.

Mass production, on the other hand, involves producing large quantities of standardized products using automated and continuous flow processes. This type of production system is highly efficient and allows for economies of scale, but it does not offer much flexibility or customization. Product change on a mass production line needs to be carefully planned and executed to minimize downtime and maximize productivity. Examples of mass production include manufacturing industries such as electronics, automotive, and consumer goods where there is a high demand for standardized products [2].

Simply no product variety and a very high volume of products is produced with a continuous production system. The term continuous means that the product is produced almost without any interruptions or product stops. Examples of continuous processes are continuous chemical refining, oil refining, and steel production. Usually, designing a continuous process needs careful consideration of the flow of materials, automation, and quality control measures to ensure consistently high output and minimize disruptions in production, therefore much capital.

2.2 Production layout types and characteristics

Production system defines the way the production process is organized but the layout of the production facility plays a crucial role in optimizing efficiency. The layout should be designed in such a way that it minimizes the movement of materials and workers, reduces bottlenecks, and maximizes utilization. The layout type must be selected based on the specific needs and constraints of the production system.

Most practical layouts are usually a derivation of the four most basic layout types [3]:
1) line layout,
2) functional layout,
3) cellular layout,
4) fixed position layout.

A manual assembly line is a production line that consists of a sequence of workstations where assembly tasks are performed by human workers [5].

Line layout is set up in a way that each product follows a prearranged route according to the products need from location to location. This is why sometimes line layout is referred to as flow or product layout. The manufacturing flow is clear and predictable therefore, easy to control. Examples of a line layout are an automobile assembly line and a self-service cafeteria. Line layout is used where large quantities of same-type products are produced.

Functional layout is a type of layout where similar transforming resources are located together. Products flowing through take a route from activity to activity. When similar resources are located together then different types of products have different routes according to their needs when flowing through the line. Typical examples are hospitals and supermarkets or libraries, where products with similar features are located on the same aisle.

Cellular layout or cell layout is where a manufacturing cell contains an organized setup of transforming resources. After being processed in a cell the product might enter another manufacturing cell. The cell itself might be arranged in a line or functional layout. An example of a cell layout is the lunch products area in a supermarket, where the customer themselves can “assemble” their lunch.

Fixed-position layout is a type where the transforming resources are brought to the product. The processing resources move as necessary to transform the product. Classical examples of a fixed-position layout are construction and shipbuilding.

Table 2.1 Potential layout based on process type [3]

Manufacturing process type	Potential layout types	
Project	Fixed position layout Functional layout	Fixed position layout, Functional layout, Cell layout
Jobbing	Functional layout Cell layout	
Batch	Functional layout Cell layout	Functional layout, Cell layout
Mass	Cell layout Product layout	
Continuous	Product layout	Cell layout, Product layout

2.2.1 Line Layout

Line layout Figure 2.2, often called a product layout is a straight-line layout design in which the resources i.e. workstations, tools and equipment needed to manufacture are organized sequentially in a straight line of production [6]. It has a product-oriented layout, and the primary importance is given to the product. Hence, they are created specific to one type of product and all the resources i.e. tools and materials are located at the point of demand. All the workstations in this kind of layout are the input for the next workstation in line. Trying to implement predesigned assembly processes on a product layout can cause line balancing issues if processes have time variability.

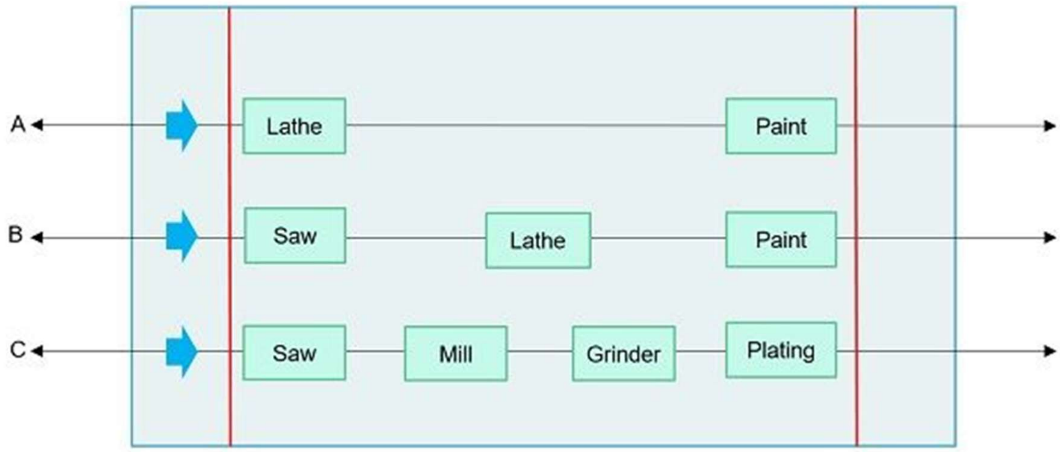


Figure 2.2 Material flow in a line layout [7]

2.2.2 Functional Layout

Functional layout Figure 2.3 is a type of layout where identical processes or functions are categorized together [6]. It is mainly used when products and services to be delivered are diversified in nature and it is not feasible to allot specific resources to product. In this type of layout raw materials are supplied to a workstation located anywhere in the factory. After processing the materials are transported to further processing somewhere else. This layout causes the need for transportation of half-finished goods and creates buffers in front of processes.

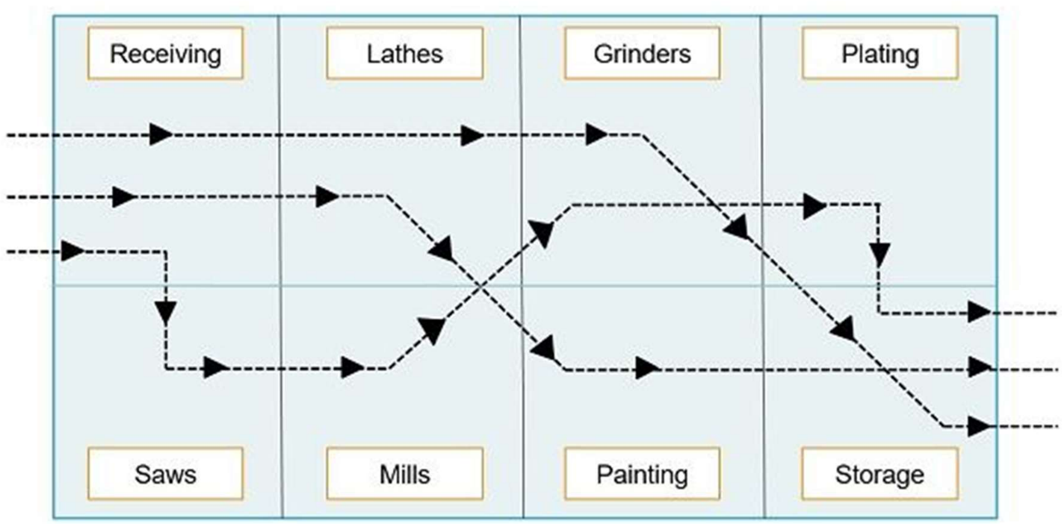


Figure 2.3 Material flow in a functional layout [7]

2.2.3 Cellular layout

Cellular layout involves grouping machines and workstations together based on the flow of the production process seen on Figure 2.4 Cellular layout. This layout promotes a more streamlined and efficient flow of materials and workers, as it allows for greater coordination and communication between team members within each cell. After being processed in a cell the material may flow to another cell for further processing. This modular approach to production is especially suitable for constrained environments. It allows for flexibility and adaptability within the limited space and allows a worker to change working positions to reduce cell workers quantity if the cycle time allows it. By utilizing a cellular layout in the production system design, the limited space can be efficiently utilized, and the flow of materials and workers can be optimized to achieve maximum productivity.

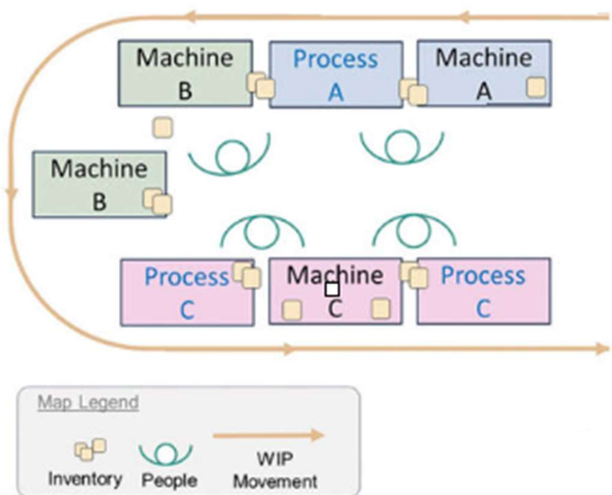


Figure 2.4 Cellular layout [8]

2.2.4 Fixed position layout

When the product being produced is too large or heavy to be moved easily the fixed-position layout is used. In a fixed-position layout, the production process revolves around the product, and the necessary equipment and resources flow through the production area seen on Figure 2.5 Fixed position layout. All the resources needed are being moved to the product being produced. This layout is commonly used in industries such as shipbuilding, construction, and large-scale manufacturing where the product cannot be easily moved [9]. For example, open-heart surgery, where the patient is too delicate to move and remains stationary and the medical team and equipment move around them or motorway construction where the road is built in a fixed location and the construction equipment, and materials are brought to the site.

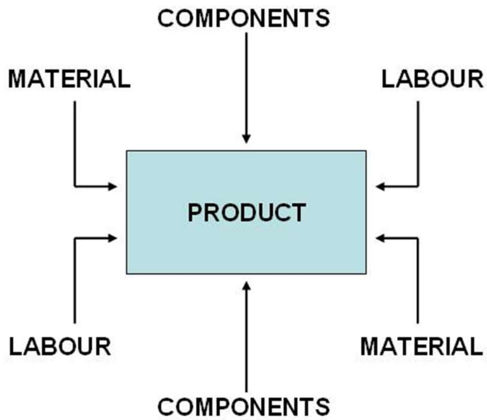


Figure 2.5 Fixed position layout [10]

By carefully selecting and implementing the appropriate layout type, taking into consideration the constraints of the production system, such as limited space and maximum worker capacity, an efficient and effective production system can be designed.

Designing a production system is closely related to production types and layouts. When implementing a new production process, both factors must be carefully considered to achieve optimal efficiency and productivity. The production process requires many resources, and if the design phase is poorly executed, excessive resources are needed. To avoid unnecessary resource usage and high costs, it is necessary to consider every aspect of the production as well as the constraints of the process design.

2.3 Relationship rating method

Relationships between different processes sometimes cannot be rated by quantitative data. In that case managers or designers rate the best locations for departments relative to one another based on their best-known practice and understanding. The technique called relationship rating was developed by Richard Muther and is used to design new layouts or redesign existing ones based on qualitative criteria [11]. After collecting the qualitative data, a visual representation of the data is formed as a grid where symbols or letters represent the relationships between departments. The representation itself is named after the creator Richard Muther and called the Muther’s grid seen on Figure 2.6 Muther's grid. The figure shows an example of the grid created for a grocery store based on store managers experience.

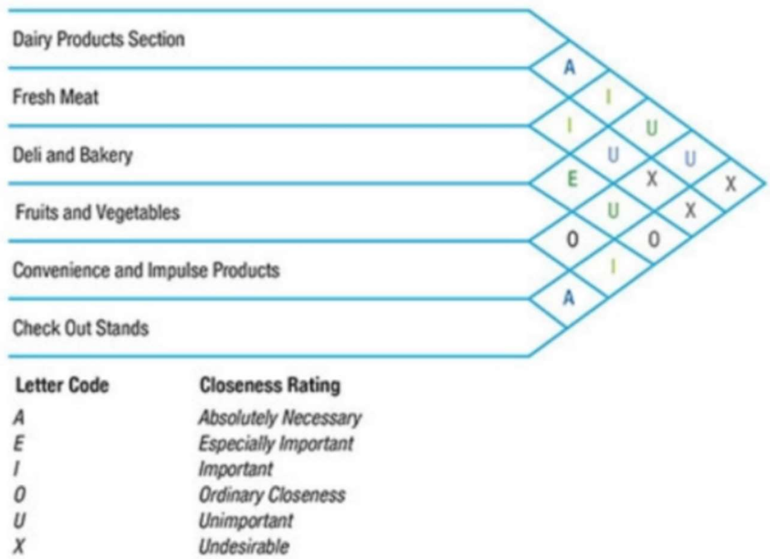


Figure 2.6 Muther's grid [11]

The letters on the grid on Figure 2.6 Muther's grid represent the desirability of the location of pairs of departments. The letter "A" indicates that the closeness between two departments is absolutely necessary. The letter "X" indicates closeness undesirable.

Based on the grid "Convenience and impulse products" are to be located near the "Check out stands" is absolutely necessary and "Fresh meat" is not desired to be located near the "Convenience and impulse products".

Quantitative data decisions can be important when no or low qualitative data exists. A good example of this is designing a new production system where real operation data of the production system does not existent. In these situations, designers of the system can decide based on their best knowledge how to locate different processes, machines, departments and more. When the possibility of qualitative data arises, improvements can always be implemented to reach a better result from the operating layout.

In some cases, quantitative data exists in the first step. In such cases the relationship rating method can be used as well, and scores can be used to fill the grid instead of letters representing qualitative data.

2.4 Layout evaluation criteria

When designing a layout, it ought to be judged against a common set of criteria [3]. The first of them is the flow of transformed resources. Usually, the objective of a layout is to achieve high flow efficiency that minimizes travelling distance. This might not always be the outcome that is desired. In some cases, the layout must direct the transformed resources to flow naturally in a desired way. Additional objectives can be clarity of the flow and/or effective use of the manufacturing space.

The interaction between parts of the processes. Interaction between processes can be beneficial or not for the processes as they may be positioned close to each other. Noisy processes should not be positioned near to processes that require concentration; dirty processes should be near to processes that clean the product exiting the dirty one. Some processes might benefit from being positioned near as they can encourage communication between staff.

Staff experience is obvious that the layout designed does not constitute physical or emotional danger to staff. For example, pathways should be clear and marked for ease of use and not stumble upon resources to avoid unnecessary movement and loss of productive time. Experience when working on the production line is also important as is when the person working behind the workstation is experiencing the way to work. The layout should encourage morale and ease of use for the worker to feel comfortable.

Customer experience is important when the designed layout is used for a service, for example a retail shop or a servicing station. The layout design should feel natural in a way that the customer knows how to act when using the service. Which routes to follow, how to and where to get the service, how to find what they need and how to exit. Not being familiar with the production layout could be counted as customer experience. For example, line input and output should be defined clearly for the transportation workers to notice where the finished goods ready for transportation are. A production layout should be as easy to understand as possible, as it reduces the time newcomers and other workers finding resources and understanding the system.

3. OVERVIEW OF THE SITUATION

Karl Storz Video Endoscopy OÜ is on the verge of implementing single use endoscopy production. An endoscope is a medical device with a light attached. It is used to look inside a body cavity or organ [12]. Single use medical devices are packaged at the end of the manufacturing process and next time opened when a medical procedure needs to be executed. Therefore, the products need to be manufactured in a cleanroom area. A cleanroom is a closed space which dust and germ-free air is admitted via filter system [13].

Designing a production system for a closed area sets many limitations and they must be considered in creating a layout that can produce the throughput demanded by the customer.

The cleanroom size is given (~260 m^2). The room has a sluice, exit for the produced and packaged endoscope, already located. Therefore, the last process ought to be near the sluice for a shorter exit from the cleanroom. There is an air lock for incoming materials located on a general supply route of the company, a safety exit in case of emergency and a gowning area where production workers enter. Gowning area has a maximum capacity of 10 people at once. Meaning the room has limited throughput of production workers who can be in the process of preparing for the entry to the cleanroom area. The production workers passing through the area must perform a special hygienic procedure to ensure cleanroom area environment and product safety.

The production of a single use endoscope is already divided into nine different production steps. The steps' length in time has been measured and no improvement work in production processes is carried out through the thesis. According to the steps a production system and layout must be created and simulated to ensure the demanded throughput. Limiting parameters of the thesis are cleanroom parameters and measures, maximum number of workers in the area. Two pillars in the middle of the cleanroom that cannot be moved due to constructional reasons of the building.

Currently no production system in KSVEE exists to manufacture single use endoscopes in the cleanroom. The thesis task is to find a solution that fulfills the demand of the product considering the existing cleanroom measures and limitations of production in the cleanroom area.

3.1 Description of the product families

The production system under design has to be capable of assembling two product families which are seen on Figure 3.1 FIVE S 3.5x65, sterile, for single use and Figure 3.2 FIVE S 5.3x65, sterile, for single use. Production processes of these two product families differ in assembling time and in production process steps.

An endoscope is a handheld device. It is important that the handle has a good grip and is ergonomic to handle since the medical procedures the endoscopes are used for may be long lasting and require rugged use. Most of the endoscope does not get in contact with the patient. The handle is the main part of the endoscope that has all other parts connected to it. Handle may be twisted or used with force to perform the medical procedures; due to the use the endoscope needs to be robust enough to stay in one piece to avoid harming the patient but be carefully designed since the lifespan is limited.

The insertion part of the endoscope is called a working shaft. This part of the endoscope is inserted and gets into direct contact with the patient and is flexible in all of its length. The working shaft has a proximal and a distal tip where a camera and light emitting lenses are located. Proximal tip is connected to the handle. Some endoscopes have a working channel. A working channel is a tube that starts from the endoscope's handle (proximal tip) and leads to the distal tip assembly. The working channel is used for inserting additional tools into the patient or for suction if some kind of fluid or materia needs to be extracted from the area where the distal tip is located.

The working shaft has an articulating end on the distal tip which is about 30 millimeters long. It can be manipulated using the articulation lever which is located on the handle. The end of the working shaft articulating seen on Figure 3.3 Distal tip articulating. The articulating end makes it possible to move inside a patient and to operate the camera to various angles depending on the needs of the procedure being performed.

The end of the working shaft is called a distal tip assembly (hereinafter DTA) here the output of the working channel is located. Additionally in the distal tip is a camera and a light emitting diode (hereinafter LED). A camera is needed for the purpose of transmitting a picture. LED is needed for light as there is no light inside a human body and for the camera to operate a light is needed. In the case of an additional tool being inserted through the working channel, with the help of a camera and an LED it is possible to perform various medical procedures inside a patient. The procedures vary from being diagnostic to therapeutical.

As the products function electronically then they need to be connected to a monitor to transmit the picture of the camera. The monitor provides electrical power to the device and displays the image received from the camera. The product has a connection cable for that use.

The products are called sterile single use because they are designed for single use and must be operatable right from the package for a single procedure. This creates the need for being manufactured in a cleanroom environment to be particulate free and have no contamination risk of transmission of particles or microbiology to the patient. Both can be hazardous to the patient causing damage to the body or carrying infections.

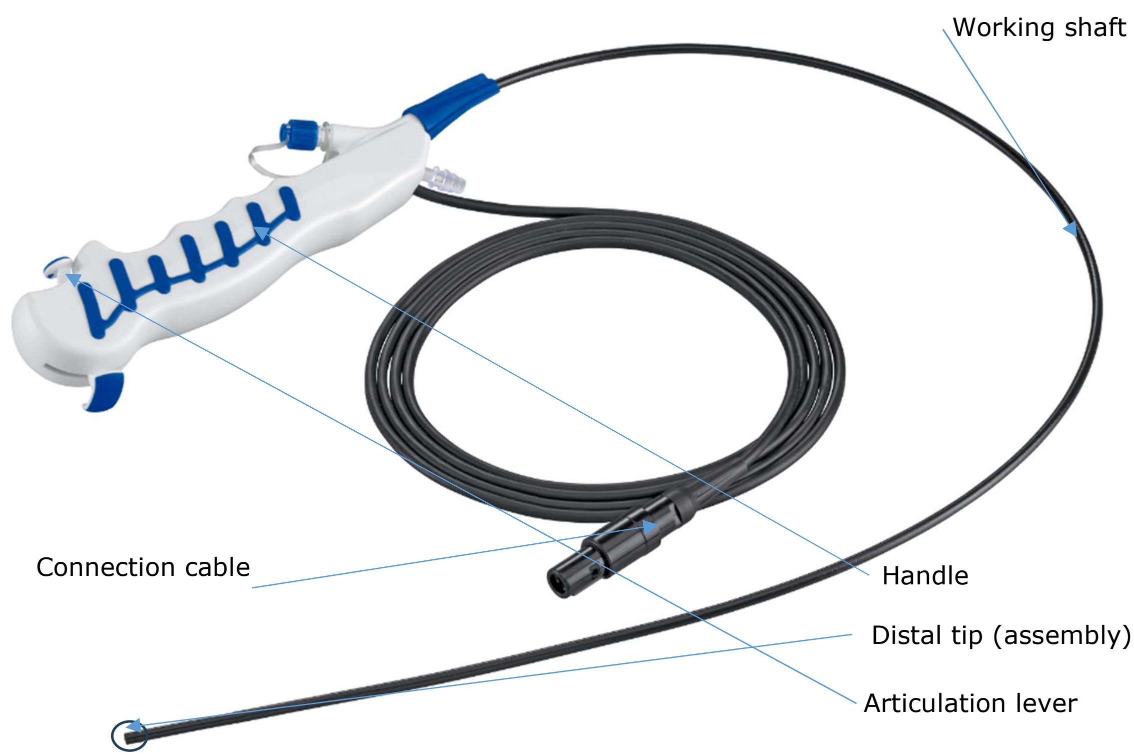


Figure 3.1 FIVE S 3.5x65, sterile, for single use [14]

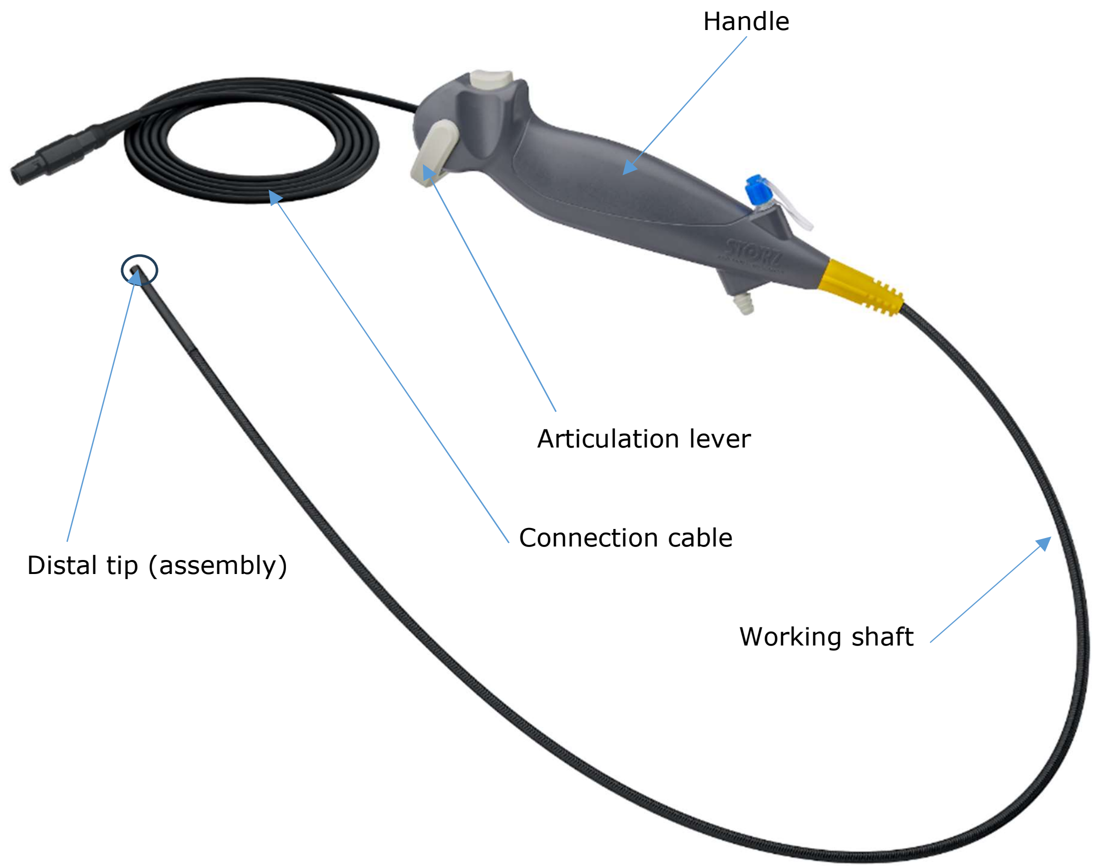


Figure 3.2 FIVE S 5.3x65, sterile, for single use [15]

The distal tip is articulating on one plane and the degree of articulation is about one hundred and fifty degrees on both sides. If additional movement is needed, then the handgrip of the instrument is twisted. It is possible due to rigid contact between the endoscopes working shaft and the handgrip of the instrument. Rigid contact is assured in the assembly process of the endoscope.

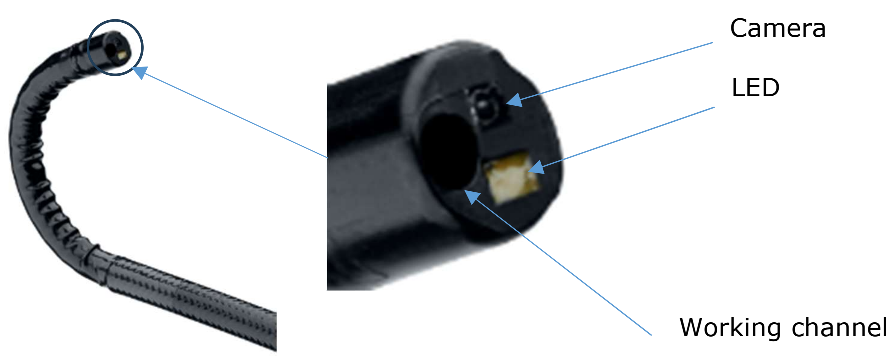


Figure 3.3 Distal tip articulating [14]

3.2 Existing production area description

The production system must be designed into an existing cleanroom which has the production area of about 260 square meters. The area width is 19,3 meters and length is 14,1 meters. The clean room has two structural pillars in the area that limit positioning workstations and resource flow. The existing production area with all its extra spaces is seen on Figure 3.4 Cleanroom area. Cleanroom itself is an ISO class 8 cleanroom which ensures a minimum of 20 air exchanges per hour and air cleanliness of less than 29 300 particles per square meter with the maximum particle size of 5 microns. The cleanroom uses HEPA filters to ensure room air cleanliness [16].

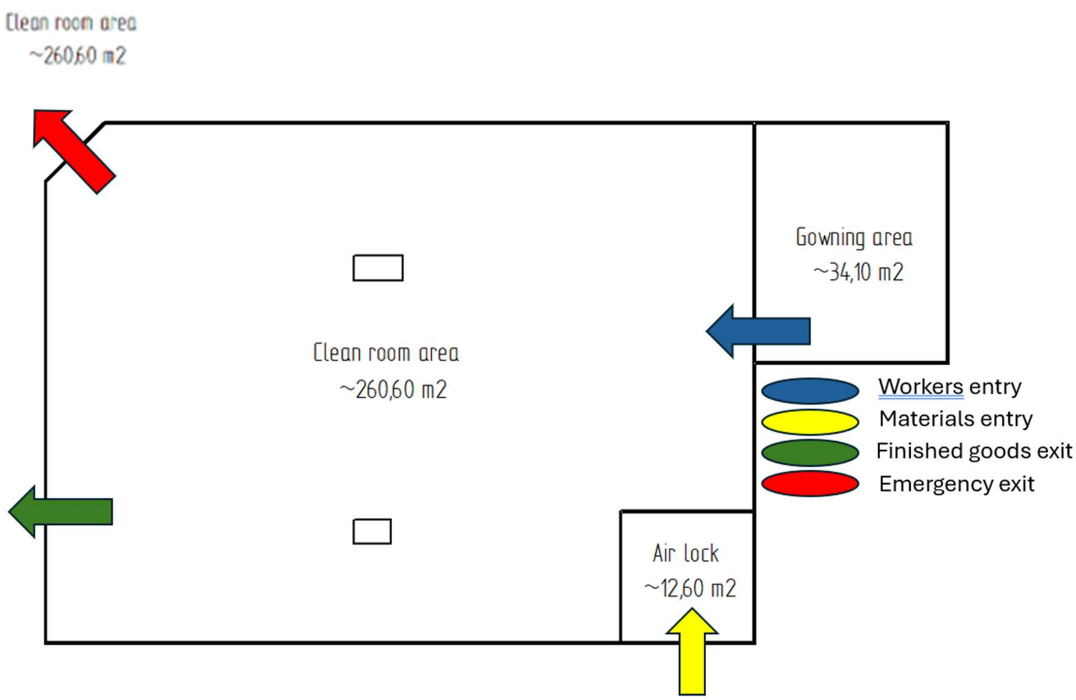


Figure 3.4 Cleanroom area

Resource flow is seen on Figure 3.4 Cleanroom area Workers who enter the cleanroom production area must go through the gowning area, where they must perform a standardized process before entry. The process combines hand washing and applying certain protective workwear in a specific order to avoid contamination of the cleanroom and its environment.

Materials to be assembled move into the cleanroom area through an air lock. There is a requirement of double packaging for the materials meaning that the materials are packaged into two separate plastic bags and in the air lock the outer package is removed from the material. Materials are double packaged by the supplier and supplied inhouse ready for cleanroom entry. Some materials are processed for cleaning purposes after production and prior double packaging. Others may be produced in an environment that complies with ISO class 8 requirements or higher. Materials entry is a specific process in certain order to avoid contamination. Air lock has a restriction of maximum two persons being in the area. The air lock is divided into two separate areas, one being "clean" and the other "non-clean". Moving from one area to another is physically restricted to avoid contamination risks. When materials enter the air lock then they are left to certain "non-clean" area where the packaging gets removed and the intents of the package are moved to the "clean" area.

Finished goods are packed inside the cleanroom and exited through a small sluice. The packaging of the product altogether ensures that the product will not be contaminated with particulate matter and the packaging protects the product from mechanical damage during product transportation to the end customer. After exiting through the sluice an additional package is added outside the cleanroom. This process is out of the thesis scope.

In case of emergency there is an emergency exit for the workers to exit the cleanroom area. After an emergency the cleanroom must be restarted by a certain procedure that demands extra careful cleaning and time.

3.3 Production processes of the products

The assembly processes of the two product families are predefined. Within this thesis no improvement to the assembly process is carried out.

Production processes are divided into different stages and the stages, descriptions and cycle times of the Five S 3.5 product family is seen in Table 3.1 Five S 3.5x65 assembly processes. Product Five S 5.3 assembly process by the same criteria is shown on Table 3.2 Five S 5.3x65 assembly process. The total processing time of both product families is about the same being on the first product family 2219 seconds and slightly shorter on the Five S 5.3 product family of 2053 seconds.

Table 3.1 Five S 3.5x65 assembly processes

Stage	Description	Cycle time [sec]
a	Control wire	147
b, c	Articulation assembly	161
d, e	Shaft assembly	180
1	DTA	204
2	Angle cover	212
3	Shaft loading	269
4	Glueing	188
5	Tensioning wires	246
6	Final assembly	231
7	QA test	239
8	Packaging	142
	Total processing time	**2219 [sec]**

Production processes of the two product families are mainly assembled using manual production technology. Most of the work is done with the help of magnifying glasses or microscopes and with the help of hand operated tools. Some processes that require force are done with the help of machines. Due to the smallness of the components fixtures are needed to ensure quality and the assembling accuracy of the products.

Due to the complexity of the assembling processes an assumption of each workstation requiring a production worker is made. Reasoning that the number of workstations equals the number of production workers needed to operate the production system.

Table 3.2 Five S 5.3x65 assembly process

Stage	Description	Cycle time [sec]
a	Control wire	79
b	Articulation assembly	90
c	Shaft assembly	57
d	Valve assembly	45
e	PCB assembly	30
1	DTA assembly	141
2	Articulation connection	149
3	Glueing	155
4	DTA connecting	130
5	Installation of wires	110
6	Angle cover	127
7	Tensioning wires	160
8	Shaft assembly installation	153
9	Valve installation	144
10	Final assembly	136
11	QA test	205
12	Packaging	142
	Total processing time	**2053 [sec]**

Assembly steps of product families are seen on

Figure 3.6 Five S 5.3x65 assembly steps and Figure 3.5 Five S 3.5x65 assembly steps. The flow charts show the production steps which are converted into workstations. Main assembly steps are marked with green. Yellow is for final quality assurance testing and packaging of the products. Blue is for preassembly steps. The following processes relate to arrows. Therefore, workstation a "Control wire assembly" is a preassembly process for workstation 1 "DTA assembly".

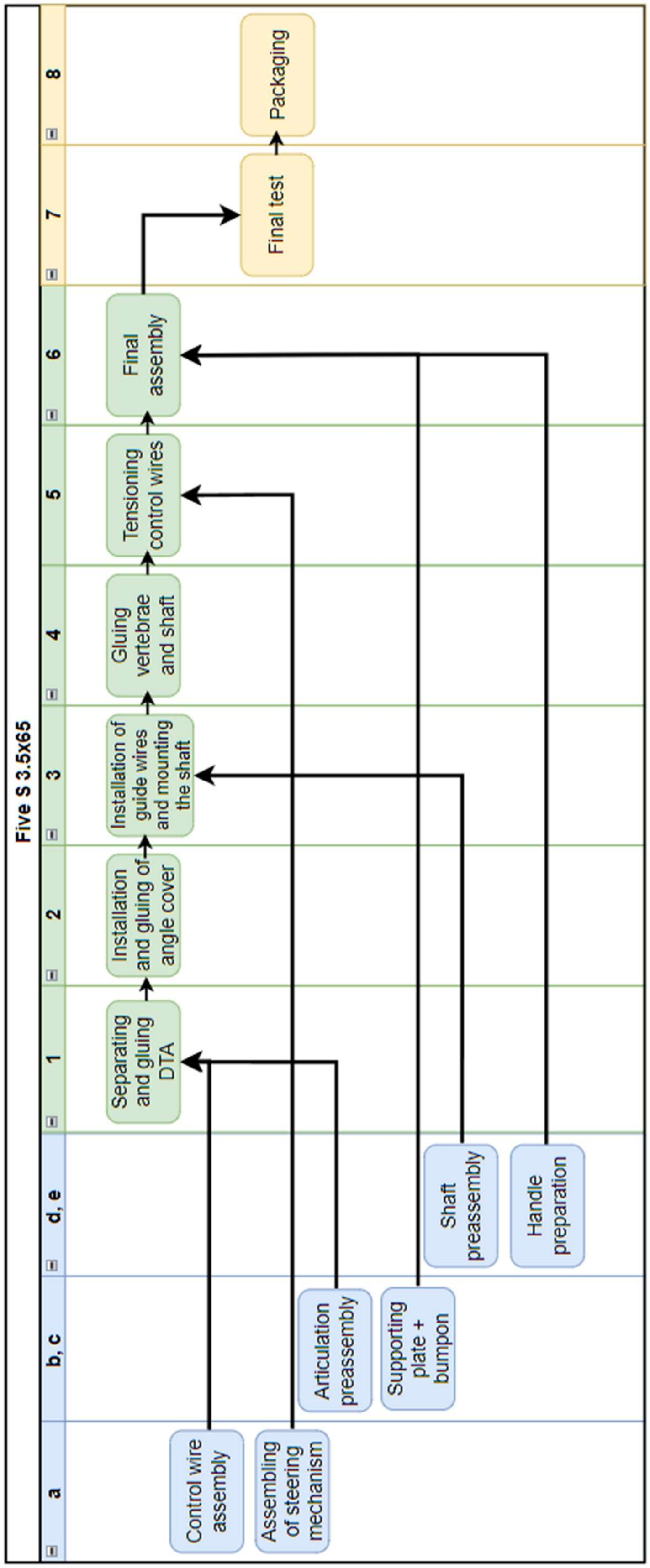


Figure 3.5 Five S 3.5x65 assembly steps

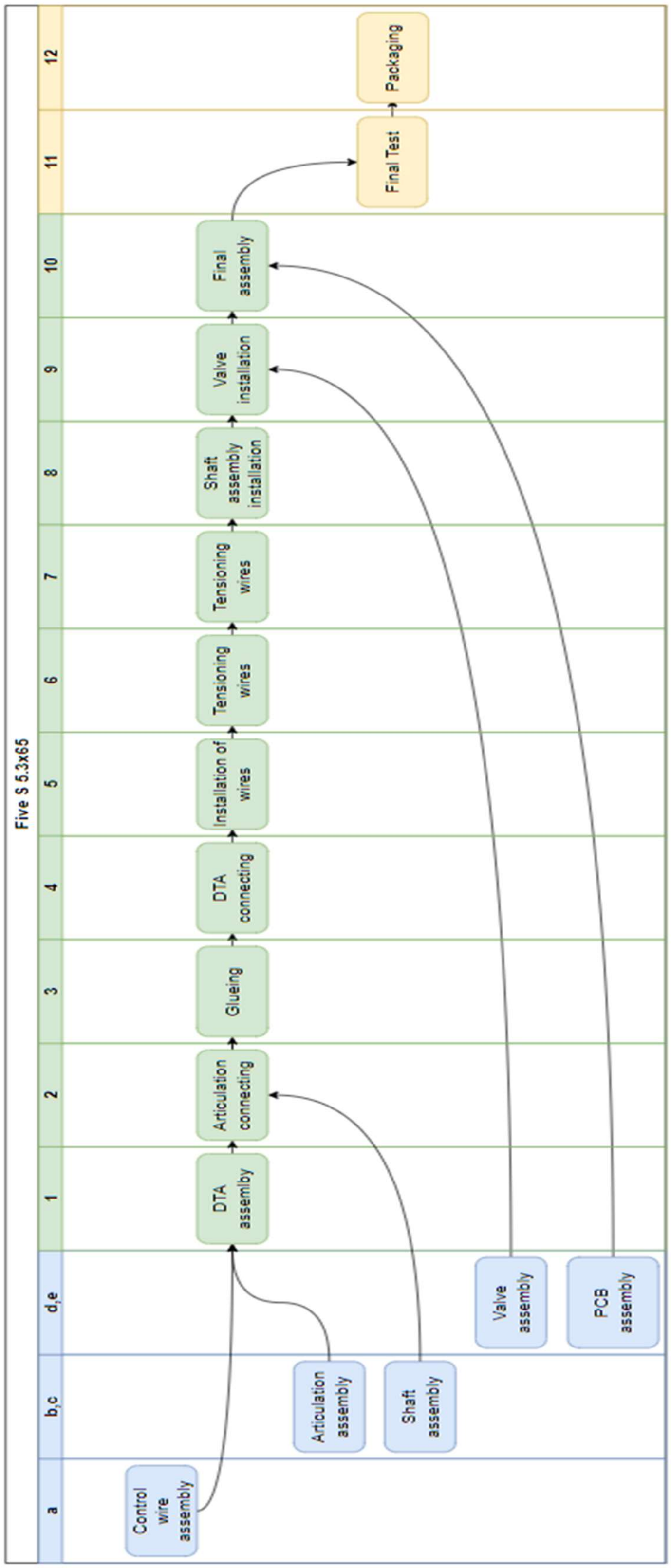


Figure 3.6 Five S 5.3x65 assembly steps

3.4 Workstations in the production

KSVEE uses standardized worktables as workstations. It is known that the cleanroom will be fitted with workstations with table measures of 645 millimeters to 1500 millimeters seen on Figure 3.7 Workstation. As the endoscope has a working shaft with a length of about 650 millimeters then the total width of a worktable of 1500 millimeters is needed. The standardized worktable is used throughout the factory to be agile if workstations need to be moved or disassembled. Workstations are made of Minitec [17] aluminum profile and with a few steps can be disassembled to store in warehouse. In case of extra workstations needed they can be assembled, and workstations added.

One workstations footprint in the cleanroom will be dimensioned as 1500 by 645 millimeters, which is exactly 0,9675 m^2 or about $1m^2$.

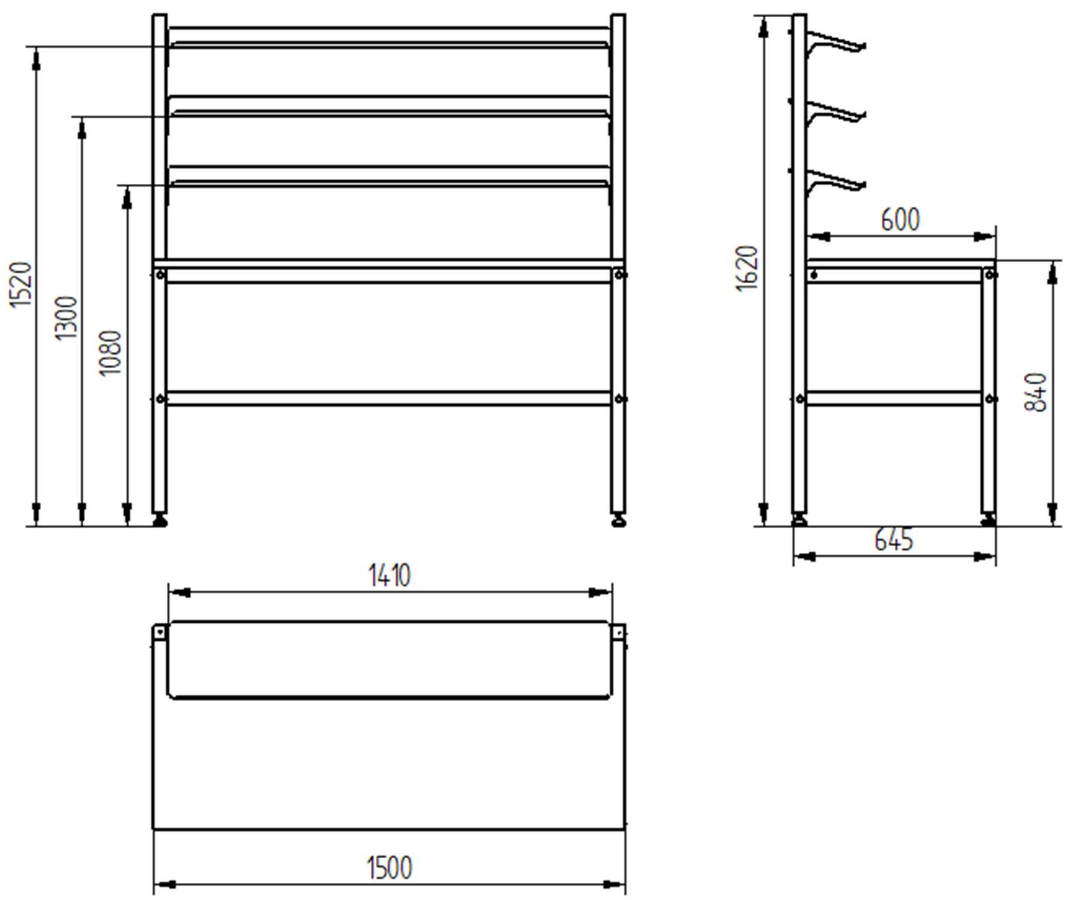


Figure 3.7 Workstation

The endoscope contains a small camera at the distal tip. The sensor captures the image seen by the camera, and additional components in the endoscope process these signals to generate a high-quality image for the operator's observation. To maintain optimal performance and precision of the endoscope's camera, it is essential to minimize electrostatic discharge risks during production. The tabletops at workstations are protected with electrostatic protected area (hereinafter EPA) measures and grounded to prevent any potential electrostatic discharge that could impact the endoscope's camera or other electronic components. Production workers must wear electrostatic discharge (hereinafter ESD) protective wrist straps as a preventive measure against electrostatic discharge. The strap is electronically connected with the entire system and ensures that the worker is grounded, making sure all the components in the area have the same electrical potential.

The dimensions of the working table are designed according to best known practice. On Figure 3.8 Working area on a workbench can be seen that most of the work behind a workbench is done in 25 cm from the body of the worker. Area total width symmetrically divides to a 100 cm wide area where the worker’s body represents the center point. Occasional work is done in the area range of 50 cm and width of 160 cm. KSVEE uses workstations which have a tabletop on previously mentioned workstations with the width of 150 cm and depth of 60 cm. Construction of the workbench has measures described before.

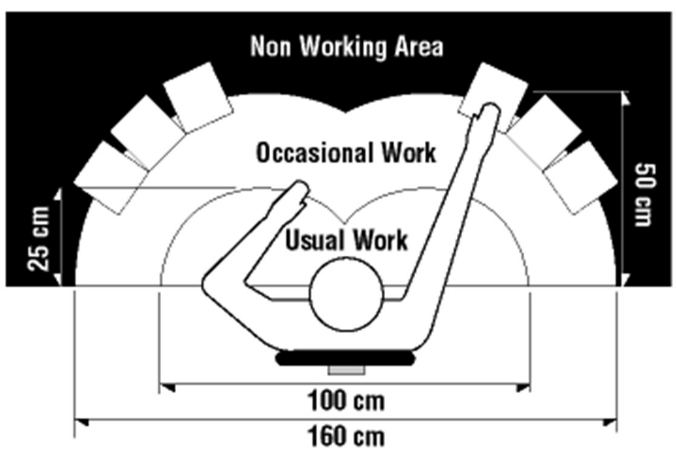


Figure 3.8 Working area on a workbench [18]

For material storage at the workstation every station has three shelves which are predetermined for different usage. The highest shelf is for finished product ready for moving to the next process, the middle one is for components that are needed for assembly and the third shelf is used for material income. Storing the finished product on the top shelf creates a visual notification for the transportation worker meaning that the product is ready to move to the next process.

3.5 Expected output

The company is expecting production to begin in the designed area. The anticipated yearly demand for product Five S 3.5x65 is 100 000 units, while the demand for product Five S 5.3x65 is 70 000 units. Achieving this output may require one or more shifts per day. However, it's crucial to consider that the maximum capacity of workers in the cleanroom is restricted to a total of 40 individuals including logistics staff if they are required onsite.

One work shift length is 8 hours. Due to cleanroom entering procedures the effective working shift length for calculations will be 7 hours. The extra hour will be used when entering and exiting the cleanroom area as it requires some special procedures and gowning to maintain the environment.

3.6 Cleanroom requirements

The production system under design in the thesis will be set up in a cleanroom that conforms with ISO 14644 class 8 requirements. ISO 14644-1: 2015 Cleanrooms and associated controlled environments standard specifies the classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and other clean zones [19]. ISO 14644-1 classifies cleanrooms and clean zones into nine classes which are based on the concentration of airborne particles. Classes range from ISO class 1 to ISO class 9. Where class 1 has the least concentration of airborne particles and class 9 the most. The cleanroom must maintain a controlled environment with regards to airborne particles, temperature, humidity, and pressure. Typical requirements for the ISO class 8 are:

- Airborne particle count, no more than 29 300 particles per cubic meter of air with the size of 5 µm and larger, 832 000 particles per cubic meter of air with the size from 1 µm to 5 µm and 3 520 000 particles per cubic meter of air with the size of 0,5 µm to 1 µm,
- filtration, the air pumped into the cleanroom environment passes through HEPA filters,
- airflow to the cleanroom ensures at least 20 air changes in the cleanroom in an hour,
- surfaces in the cleanroom must be smooth and easy to clean to minimize particulate generation and accumulation,
- personnel control, strict protocols of gowning including the use of appropriate garments like footwear and headgear,

- equipment used in the cleanroom must be designed and constructed to minimize particulate generation and be regularly cleaned and maintained.

In KSVEE to enter the cleanroom a person must be trained according to internal documentation. The person must start entering from the personnel sluice, where they must wash and disinfect their hands. Apply a hairnet and facial hair net if applicable. Wear special shoes and put on a gown that covers all other clothing. Run a test for personal grounding equipment and apply rubber gloves before entering the working area [20].

Requirements for entry into the cleanroom area are specified in KSVEE internal documentation S5.5.2550.WI004 named "Cleanliness and hygiene instruction for SSU production area" [20].

KSVEE has currently validated the cleanroom to have a maximum capacity of 40 persons. Validation being a process for conforming that the cleanroom environment conforms to the ISO 14644-1: 2015 standard whilst 40 people in presence. In case of need the process of revalidating the existing cleanroom with more people in presence could be considered if a need might emerge.

A maximum of 40 workers inside the cleanroom will be taken as one of key constraints.

A visualization of correct protective working clothes in the cleanroom area are seen in Appendix 3 S5.5.255.WI004 section on protective clothin.

4. LAYOUT DESIGN

4.1 Cycle time calculation

Starting the design of a production system in a cleanroom environment, it is important to calculate the cycle time. The cycle time can be calculated using cycle time calculation formula (4.1) and it refers to available time divided by the number of products needed. This calculation helps determine the rate at which products can be produced within the given constraints [21]. To calculate the cycle time, it is known that a total output of 100 000 pieces of product Five S 3.5 is demanded, and a throughput of Five S 5.3 demands 70 000 pc of product. Total quantity of 170 000 pc. According to Estonian legislation in the year of 2025 the total working days in a year are 251 [22]. The total quantity of units required by day is 678 pc. For current calculations production will run in two shifts and total productive time per shift will be 7 hours per day as stated before. So total production time available per day will be 14 hours or 840 minutes per day.

$$Cycle\ time = \frac{Production\ time\ available\ per\ day}{Units\ required\ per\ day}\ [7] \tag{4.1}$$

where production time available per day is the amount of production time is available in a day, summing shifts, in minutes;

units required per day is the number of products needed to produce in a day.

Cycle time for the production system is calculated using formula (4.1) and the calculations can be seen in formula (4.2).

$$Cycle\ time = \frac{840}{678} = 1{,}2389 \ldots \approx 1{,}24\ (minutes) \tag{4.2}$$

The minimum number of workstations can be calculated based on cycle time. By dividing the cycle time by the minimum time required to complete each workstation task, the minimum number of workstations can be determined. This calculation is essential in finding the minimum number of workstations needed to reach the desired output of product. Using the calculations mentioned it is possible to find out if the existing process can be set up in the cleanroom as we have a constraint of 40 workers. For minimum number of workstations each individual task time for both product families are taken from chapter Production process from Table 3.1 Five S 3.5x65 assembly processes and Table 3.2 Five S 5.3x65 assembly process. Calculation results and the minimum numbers of workstations can be seen in Table 4.1 Five S 3.5 minimum number of workstations and Table 4.2 Five S 5.3 minimum number of workstations. Calculations in the tables are made by using formula (4.3). Calculations are made using Microsoft Excel for the ease of use and to reproduce the results if needed.

$$Minimum\ number\ of\ workstations = \frac{Time\ for\ task}{Cycle\ time}\ [7] \tag{4.3}$$

where time for task is the time required to complete a production step in minutes;

cycle time is the general cycle time of the production system.

The number of workstations in Table 4.1 Five S 3.5 minimum number of workstations and in Table 4.2 Five S 5.3 minimum number of workstations are rounded up to the first digit resulting in whole numbers.

Table 4.1 Five S 3.5 minimum number of workstations

Five S 3.5 Stage	Description	Cycle time [min]	Number of stations
a	Control wire	2,45	2
b	Articulation assembly	2,68	3
d	Shaft assembly	3,00	3
1	DTA	3,40	3
2	Angle cover	3,53	3
3	Shaft loading	4,48	4
4	Glueing	3,13	3
5	Tensioning wires	4,10	4
6	Final assembly	3,85	4
7	QA test	3,98	4
8	Packaging	2,37	2
		Total number of workstations	35

Table 4.2 Five S 5.3 minimum number of workstations

Five S 5.3 Stage	Description	Cycle time [min]	Number of stations
a	Control wire	1,32	2
b	Articulation assembly	1,50	2
c	Shaft assembly	0,95	1
d	Valve assembly	0,75	1
e	PCB assembly	0,50	1
1	DTA assembly	2,35	2
2	Articulation connection	2,48	3
3	Glueing	2,58	3
4	DTA connecting	2,17	2
5	Installation of wires	1,83	2
6	Angle cover	2,12	2
7	Tensioning wires	2,67	3
8	Shaft assembly installation	2,55	3
9	Valve installation	2,40	2
10	Final assembly	2,27	2
11	QA test	3,42	3
12	Packaging	2,37	2
		Total number of workstations	36

Cycle time calculations demonstrate that the total number of workstations is less than 40, which in this case is the maximum number of workers that can be accommodated in the cleanroom. This number expresses that the throughput of 170 000 products is achievable within the given worker constraints in the case of if every workstation must be manned with a production worker. By utilizing a simulation-based approach, the production system can be assessed, and decision-making can be made more precise.

4.2 Layout selection

Based on the given information the current production throughput is 170 000 pieces per year and the product variety is relatively low with high product quantity, it is important to consider the most suitable production layout based on the selected production type.

When dealing with high product quantity and low variety, a production layout that allows for efficient and continuous flow of the production process is essential. Considering the throughput and constraints, a product layout or a process layout may be the most suitable options for the production system.

The selection of the production type is crucial in optimizing efficiency and ensuring the smooth flow of materials and workers. With the given constraints and production requirements, the chosen production layout should maximize the utilization of resources while minimizing bottlenecks. By carefully analyzing the specific needs of the production system, the most appropriate production type can be determined to achieve optimal productivity and efficiency. Based graph the production type in this case should be a product layout, as it allows for a more efficient flow of materials and workers in a high-volume, low-variety production.

Most practical layouts are a combination of the main four [3] and considering the given constraints and production requirements, a hybrid layout that combines elements of both product layout and process layout may be the most suitable option [23]. The layout in this case should be a combined product layout in combination with a cell layout, as it enables a streamlined flow of materials and workers while minimizing space constraints.

4.3 Positioning workstations

When locating workstations inside a production unit the relationships between different cells and workstations must be carefully considered. For developing the workstation locations Muther grid was used. The base criteria of developing the grid were the materials flow between workstations. By analyzing the materials flow between workstations, the Muther Grid can assist in determining the optimal locations for each workstation within the production unit. Using the Muther grid can help to minimize material handling time and streamline the production process by strategically placing workstations near each other.

A Muther grid Figure 4.1 Muther grid of workstations was developed based on product family of Five S 3.5 workstations and material flow. Five S 3.5 were picked for the basis because of having a longer total processing time and fewer total workstations needed to reach the desired production output. From the perspective of KSVEE the product family will sooner emerge into production and has a larger quantity of need. Therefore, it is more sensible to use the product with larger demand and longer production time for the basis of the production system design. The Muther grid was used to identify the optimal locations for workstations in the production unit based on the flow of materials.

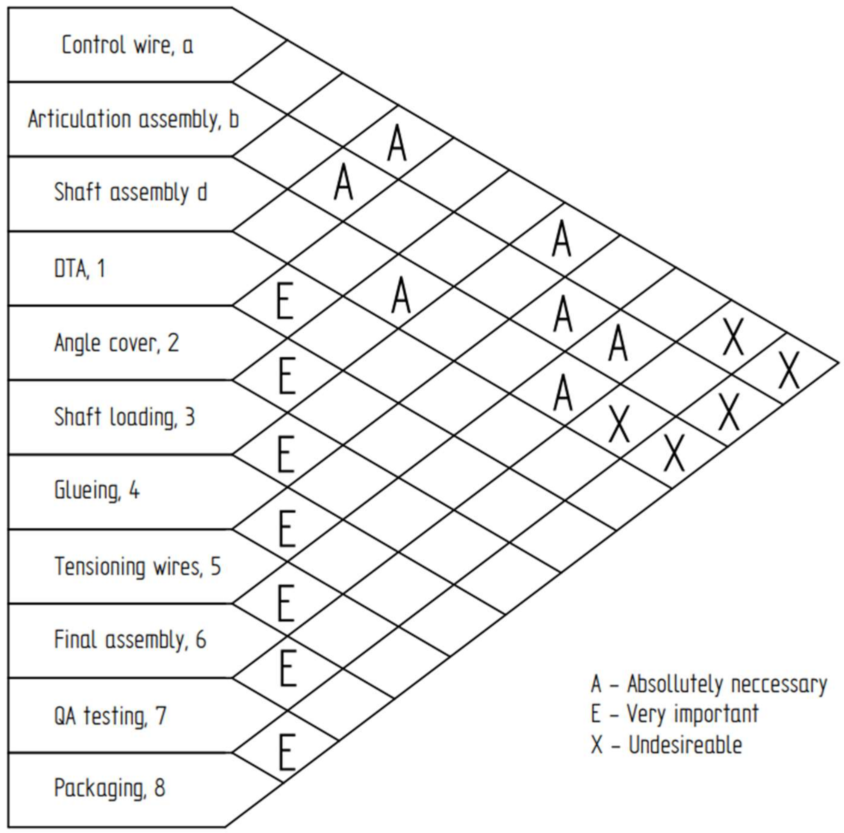


Figure 4.1 Muther grid of workstations

To visualize Muther grid results Table 4.3 Muther grid relationship table was developed using qualitative data and best-known practices known to the author. The table shows the desired relationships between the workstations in terms of material flow. Relationships marked with an A are necessary, relationships with an E are very important and undesirable relationships are marked with an X. Based on the relationship table a layout for the workstations inside the cleanroom can be developed. This layout will ensure that the workstations are strategically placed to facilitate smooth material flow and minimize material handling time, resulting in an efficient and productive production system.

Table 4.3 Muther grid relationship table

A	E	X
a - 1	1 - 2	a - 7
b - 1	2 - 3	a - 8
d - 3	3 - 4	b - 7
a - 4	4 - 5	b - 8
b - 5	5 - 6	d - 7
b - 6	6 - 7	d - 8
d - 6	7 - 8	

The layout of the cleanroom is divided into twelve sections on Figure 4.2 Workstations location according to Muther grid. One section which has the air lock inside will serve as the entrance point for materials and no workstation will be fitted there. The remaining eleven sections of the cleanroom will be divided into cells with individual workstations based on the Muther Grid analysis, ensuring that each workstation is strategically located. Characters and numbers in the sections represent the workstations needed to assemble the products. Based on the drawing the workstations can be located and it can be used as the basis of locating workstations in the cleanroom.

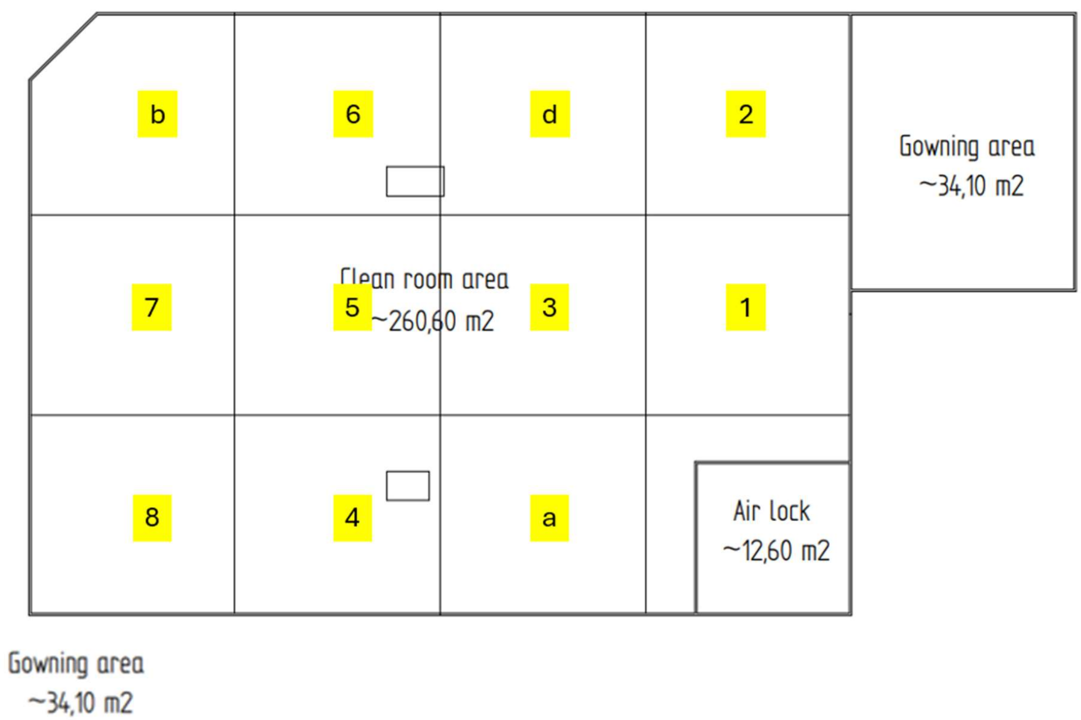


Figure 4.2 Workstations location according to Muther grid

One must consider the developed workstation locations as a point of consideration rather than fixed. The real layout development has to consider room constraints and workstation measurements to fit it into the cleanroom for optimal material flow and production area efficiency.

4.4 Layout designed

The layout designed for the production system considers the Muther Grid analysis and aims to strategically place workstations in the cleanroom to maximize material flow and keep the overall footprint of the production line as low as possible. The workstations have some room around them to allow the workers to move from their positions to access other workstations and to locate additional equipment or tools. This enables workers to move away from their workstation whatever the case may be, without interfering with other workers and the overall workflow. This layout design not only improves efficiency in material flow, but also ensures a safe and comfortable working environment for the personnel. Layout created after considering the production system and positioning of the workstations can be seen on Figure 4.3 Developed layout.

The unfilled area of the cleanroom can be used to store materials and enable the production workers to move and internal logistics to move. Materials and half assemblies are going to be moved by an internal logistic that uses a cart designed to carry products. In the simulation it should be checked if one logistics worker is enough to move the sub-assemblies between workstations. Therefore, on the layout is left a special cargo way where 1,2 meters of width is left between workstations.

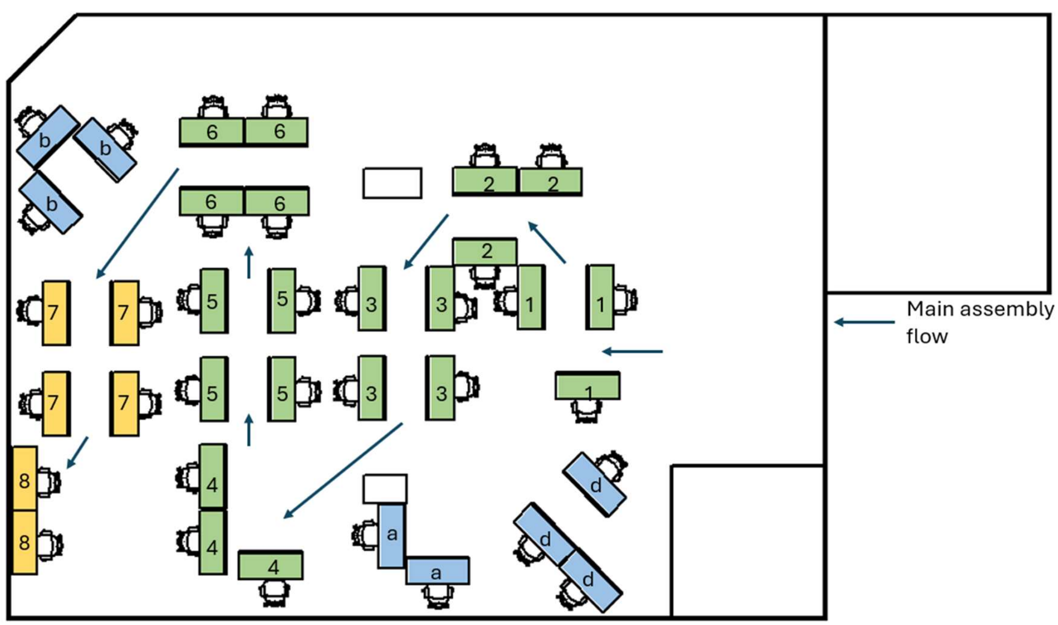


Figure 4.3 Developed layout

The layout follows one single product flow leading the products from the start of the line to the packaging process and exiting from the product exit sluice.

Rating the layout based on the flow of the transformed product, interaction between processes and staff experience. Product flow on the line is singular and follows a natural route from start to exit, which creates an easily understandable flow for the production staff. Processes on the line combine as work cells and each product goes to the following cell. Workstations are located rather near to enhance communication between workers. Production tables are designed to follow the best practice of reaching objects on the worktable and create a satisfactory experience for the staff. They are convenient enough to work without being packed all together and are available to leave the workstation in any case.

KSVEE internal documentation requires 1,2 meters of width for in-house transportation routes. The least possible room between to non-facing workstations is 1,2 meters. The least distance left between workstations is 1,2 meters for worker comfort and ease of transportation. The distance between a wall and a workstation ought to be 1 meter. More room was left between stations where possible. After placing workstations, keeping in mind the described requirements the created layout requires 176,10 m^2 of cleanroom space leaving 84,60 m^2 of cleanroom space unused. The final solution of the layout can be seen in Appendix 2 Layout designed. The unused space could be used for storage purposes or populated with workstations if needed.

The best layouts are known to be a combination of the basic layout types [3]. This designed layout of the production system is a combination of a line layout and a cell layout. The production steps consist of one or more workstations, and they are concentrated as production cells where assemblers assemble a certain part of the product and the sub-assembly is moved to another process step (cell) where more value is added to the subassembly and the flow carries the product to the end of the line where it gets finished, quality assured and packed ready for shipping. The sum of production steps or cells forms a full line layout where the product follows a single flow from the start of the line to the exiting sluice where the product is ready and packaged.

5. LAYOUT SIMULATION

Layout simulation is an essential step in the design process as it allows for the evaluation and validation of the proposed layout before implementing it in the actual production environment [24]. Using computer simulation, the proposed layout for the production system can be tested and analyzed in a virtual setting. Simulating the created layout gives a low-cost opportunity to test out the designed system and identify any potential issues or bottlenecks in the production process without making any investments in hardware and real resources.

5.1 Simulation model

The layout needed to be built in a virtual environment using Visual Components, a 3D manufacturing simulation software. VC offers a possibility to create a 3D model of the production that needs to be simulated and this helps to understand if the designed layout fits into the environment it is supposed to be in real-world situations. The model of the layout is on Figure 5.1 Layout model in Visual Components.

Visual Components was selected for the simulation software because it provides a comprehensive set of tools to design and simulate manufacturing processes. Setting up a manufacturing layout in VC is fast and very graphical which helps to understand what is happening on the production floor when the simulation is running. Graphic visualization helps to find bottlenecks and errors if there were any during creation. KSVEE has a license of VC and the simulation created in the thesis can be used as a basis for future research in manufacturing design or implementing new products on the production line created.

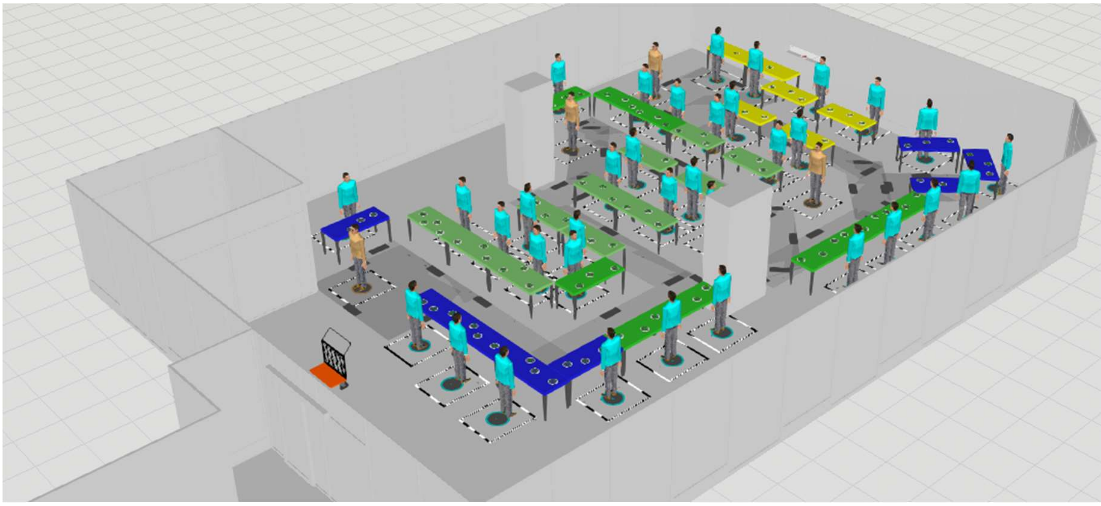


Figure 5.1 Layout model in Visual Components

In the model the positioning of the workstations is improved to improve product flow and ease the movement of transportation. Comparing the layout designed on

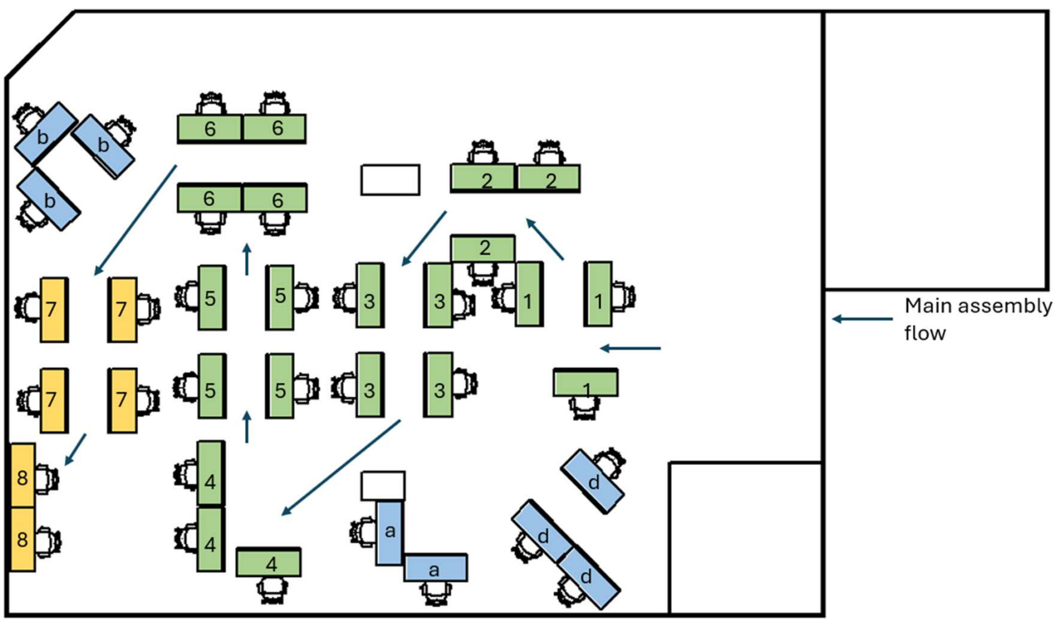


Figure 4.3 Developed layout and the simulation layout on Figure 5.2 Simulation model top view it can be seen that sub-assembly stations "A" and "D" are merged into the line flow in order to eliminate the need of extra transportation routes. The simulation layout uses only one single product flow route starting from process "A" and flowing to process "8" of packaging and exiting the cleanroom as a fully assembled product ready for use. The color coding from

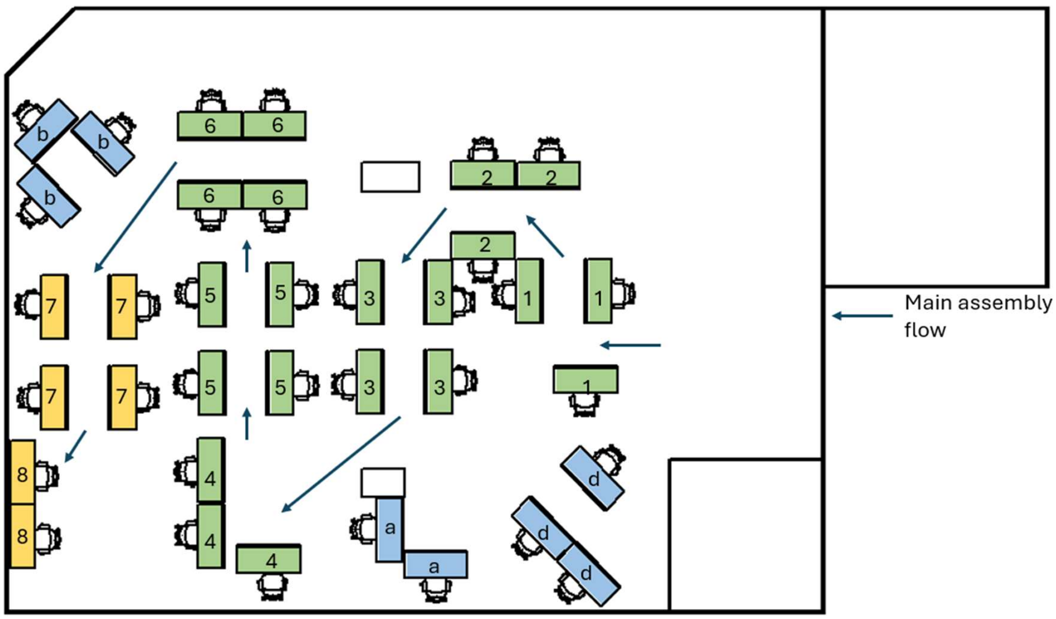


Figure 4.3 Developed layout has been implemented on the Visual Components model to ease understanding of the model. Process times to the simulation are taken from Table 3.1 Five S 3.5x65 assembly processes. On Figure 5.2 Simulation model top view can be seen that the designed layout follows product flow from the start of the layout until the exiting sluice where the produced and packaged endoscopes exit the cleanroom area. The sluice is marking the end point of the production system flow for the simulation where the throughput of product is counted.

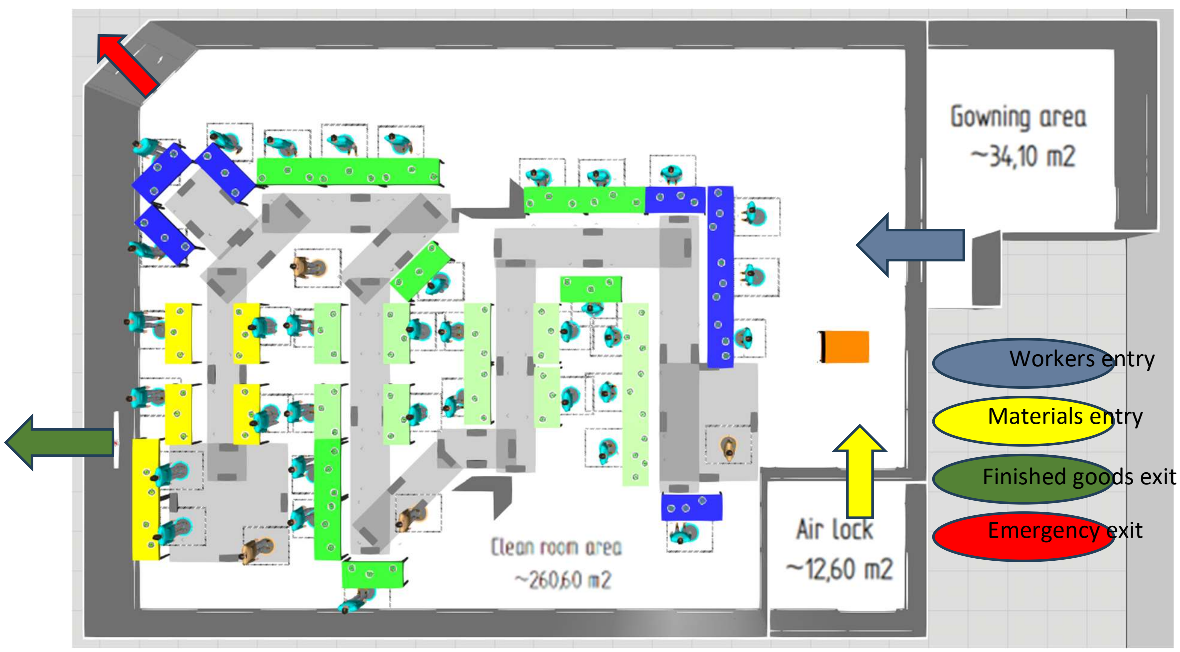


Figure 5.2 Simulation model top view

The total number of workstations is 35 as on the designed layout. Every workstation needs a production worker, so 35 workers are needed. 29 of them assemblers, 4 quality assurance inspectors and 2 who manage packaging of the assembled and quality checked products. To transport the sub-assemblies from one workstation to another a total of 4 transportation workers are required. Otherwise, the total output will decrease. Transportation workers can pick up one sub-assembly at a time and transport it to the next process.

5.2 Simulation cycle time

A discreet simulation model was created using the designed inputs of workstations. The system consists of many production steps which are divided into workstations that are calculated based on the cycle time. To verify the layout a cycle time of 1,24 minutes must be reached. To calculate simulation cycle time an author created formula is used (5.1):

$$Simulation\ cycle\ time = \frac{Simulation\ run\ time - startup\ time}{Parts\ produced} \quad (5.1)$$

where simulation run time is the time that the total simulation was run for, in minutes;

startup time is the time needed to fulfill the production system with product;
parts produced is the amount of products assembled during the simulation.

The layout has a startup time of 45 minutes which means that filling the line within work products takes time since production on the line starts with sub-assembly workstations “A”, “B”, “D” and then subassemblies push products to following workstations. When starting the production, it takes 45 minutes for the first product to be assembled in the system.

The simulation produces 645 products in 14 hours and 44 minutes. The initial input is that a shift in the designed area has 7 hours of productive working time. For calculation purposes simulation time must be converted from hours to minutes. Using formula (5.1) and taking the results from the simulation the cycle time of the designed production system is calculated in formula (5.2).

$$Simulation\ cycle\ time = \frac{884 - 45}{645} = 1{,}3007 \ldots \approx 1{,}30(minutes) \quad (5.2)$$

Simulation cycle time indicates that the designed layout is capable of producing the product in demand with about 5% larger cycle time as does comparing product units required 678 pc by day with simulation results of 645 pc in a day shown on Figure 5.3 Simulation parts produced.

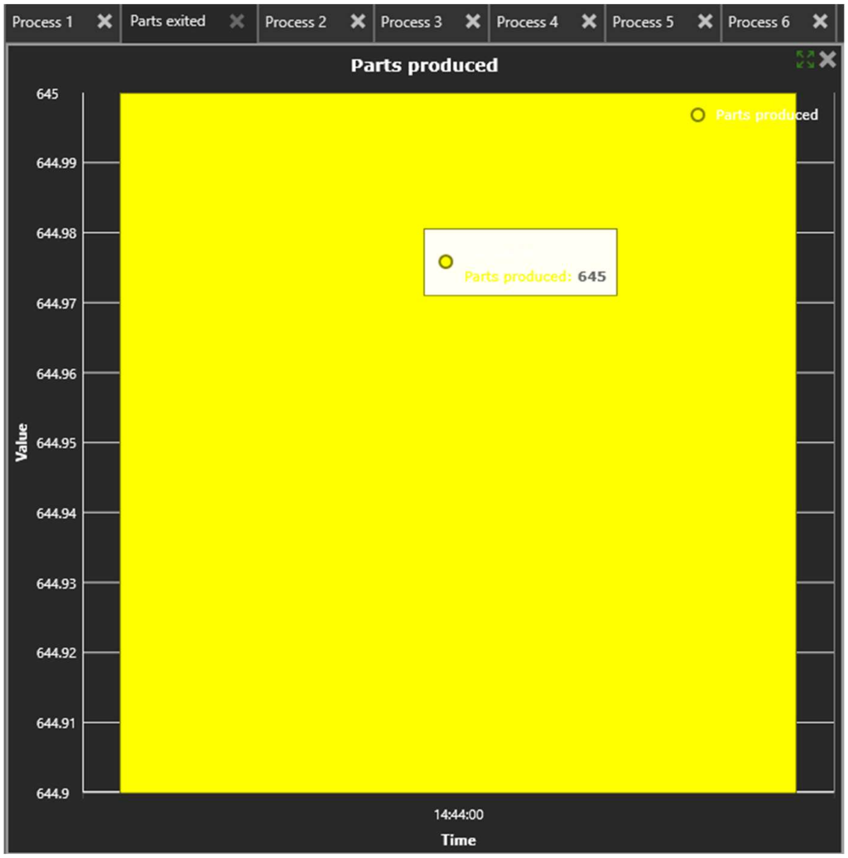


Figure 5.3 Simulation parts produced

5.3 Layout simulation observations

Simulating the created production system revealed key observations:

- The layout can produce goods with the cycle time of 1,30 minutes,
- to produce with the cycle time 4 transportation workers are required,
- the production systems cycle time is 5% less than the need.

The notifications indicate that to produce the demand improvements are needed. One restriction of the cleanroom is that a maximum number of 40 people can be in the working area. Currently the system needs a total of 39 workers. Which leaves one extra workstation available. If the number of transportation workers could be reduced extra workstations can be added to the line.

To understand the usage of workstations extra statistics were collected from the simulation. Four main types of workstation usage are determined:

- working – when the workstation is assembling,
- waiting – when the workstation is doing no operations, waiting parts from previous process,
- blocked – when the workstation is waiting for the product to be transported to next process,
- sub-assy – when the sub-assembly workstation has not completed a sub-assembly yet (used only in processes "1", "3" and "6").

Figure 5.4 Workstation usage

From Figure 5.4 Workstation usage can be seen that processes "A", "2" and "8" are working at least 91% of the time. Therefore, they could be described as bottlenecks in the production system. Following along the line from process "3" to process "7" the working percentage drops indicating that the processes have extra time available which currently is waiting time that could be transformed to working time and create more value of assembling more products along the production line.

Production processes that do not work most of the time leave the assemblers determined to workstations without work and currently that time is spent as waiting without adding no value to the performance of the production system nor to the products being assembled. The time could be converted into value adding time when the assemblers could change their workstations inside processes. For example, process 6 workstations all work for 75% of the time. The process consists of four independent workstations and if there were three production workers operating in the workstations then it would be able to reduce the need of production workers. A similar change could be implied on process “B”, process “D” and processes “4”, “5”, and “7”. If cross functional training of the production workers could be done then this could be applied to the whole system, resulting in some assemblers could divide their time between two or more workstations and processes. Using this kind of workstation manning is usually used in cell manufacturing. Workers moving from workstation to workstation is sometimes referred to as jumping.

Analyzing outcomes and new information gained from the simulation process improvement ideas to reach the target cycle time. The system designed has three processes as bottlenecks. To each of the bottlenecks an extra workstation could be added.

Currently the system has 39 workers and an area limit of 40 workers. Transport personnel can pick up and transport one product at a time. Before adding workstations to bottleneck processes the transporting process must be improved. To reduce the need for transportation the process should be redesigned keeping in mind that the object count that the workers can transport should be scaled higher to increase the availability of transported goods and to reduce the number of transportation workers needed for the production system to operate at demanded output. This could affect the startup time of the production line but would reduce the need for transportation workers significantly.

Combining transportation process improvements and workstation jumping can lead to the improvement of the production cycle time reaching the required target of 1,24 minutes or lower. All the improvements would need to be made into the simulation to understand how the improvements impact on the production system and its output of product and resource consumption.

6. CALCULATIONS

6.1 Cleanroom output KPI

To compare cleanroom production output with other competitors and production locations a KPI of cleanroom total area and output is usually compared. To calculate the cleanroom output KPI an author created formula is used (6.1).

$$Cleanroom\ output\ KPI = \frac{Product\ output\ per\ shift}{Production\ line\ area} \tag{6.1}$$

where product output per shift is the quantity of product the production system outputs in a single shift;

production line area is the footprint of the production system.

Using formula (6.1) the cleanroom output per shift per cleanroom area is calculated.

$$Cleanroom\ output\ KPI = \frac{323}{176{,}1} = 1{,}8341\ \approx 1{,}83\ (\frac{pc}{m^2}) \tag{6.2}$$

The designed clean room production system produces 1,83 endoscopes per shift per production line square meter as calculated with formula (6.2).

If KSVEE could overcome the restriction of 40 workers inside the cleanroom production area and the total cleanroom area of 260,6 m^2 could be populated with workstations the potential of the cleanroom total output of endoscopes in a shift is 476 pieces. Which is a 48% increase in output. Using formula from cycle time calculations (4.1) leads to a cycle time of 0,88 minutes or ~53 seconds.

6.2 Workforce cost

The production system designed uses a total number of 39 workers. For better monetary comparison and quick analysis of workforce cost influence on production costs salary data and other costs calculated are seen in Table 6.1 Workforce cost. The calculation basis is the gross salary of a production worker which in current case is the gross hourly salary of 7 euros and 90 cents. This is calculated to total cost to the employer. Productive time in a shift is seven hours and one extra hour is used for special gowning procedures and work-breaks, so the employer is entitled to pay for 8 hours of work in one shift. The current number of needed employees in the clean room is 39 people.

From Table 6.1 Workforce cost it is seen that a shift in clean room with the designed production system costs 3297,89 euros to KSVEE which is calculated to labor cost per product of 10,21 euros. If improvements would be done and the output of product would not increase reducing one worker from the cleanroom production area would decrease the labor cost per product of 0,26 euros.

Table 6.1 Workforce cost

Gross salary	7,90 €	per hour
Employer cost	10,57 €	per hour
Hours in shift	8	h
Number of workers	39	pc
Shift output	323	pc
Single worker cost	84,56 €	per shift
Shift cost	3.297,89 €	per shift
Labor cost	10,21 €	per product
Worker cost	0,26 €	per product

The labor cost of running a third shift would result in a yearly cost of 827757,84 euros if such possibilities ought to come into consideration and it would increase the total output of the production system by 50% from 161 500 pieces to 242 250 pieces.

6.3 Return on improvement

Using the worker cost per product on an improvement perspective from Table 6.1 Workforce cost it can be calculated what is the rate of return for the company if it invests in process improvement 100 000 euros for the next five years and in return they will reduce one production worker from the system starting from year 2026. For this calculation the formula of internal rate of return (hereinafter IRR) is used (6.3).

$$0 = CF_0 + \frac{CF_1}{(1+IRR)} + \frac{CF_2}{(1+IRR)^2} + \cdots + \frac{CF_n}{(1+IRR)^n} \text{ [25]} \quad (6.3)$$

where CF_0 is the initial investment;

CF_1, CF_2, CF_n are cashflows of the period;

IRR is the internal rate of return.

For the ease of calculations, the results are presented in Table 6.2 Internal rate of return on improvement. It can be seen from the table that if KSVEE uses the designed production system to produce single-use endoscopes and invests into process improvements starting from 2025 one hundred thousand euros with a result of reducing one production worker starting from the year 2026 then the investment of one hundred thousand euros will compound with an annual rate of return of 25% in earnings. If the return on investments is higher than the required rate of return determined by the company board then it is reasonable to invest in improvements to the production system.

Table 6.2 Internal rate of return on improvement

Year	2025	2026	2027	2028	2029
Worker cost per product	0,26 €	0,26 €	0,26 €	0,26 €	0,26 €
Reduction of workers	0	1	1	1	1
Production quantity	161500	161500	161500	161500	161500
Cost reduction	- €	42.280,68 €	42.280,68 €	42.280,68 €	42.280,68 €
Investment	100.000,00 €	- €	- €	- €	- €
Cash flow	- 100.000,00 €	42.280,68 €	42.280,68 €	42.280,68 €	42.280,68 €
IRR	25%				

Current production quantity is calculated based on the designed production system. If the system were improved to match the demand for products which in this case was 170 000 products, then the investment of one hundred thousand euros to reduce one production worker would have the IRR of 28%.

When the initial investment is doubled with the aim of reducing two production workers the IRR would stay the same with a rate of 25% of return on investment. Therefore, it may be profitable to focus on improvements to reduce the total quantity of production workers to reduce production costs.

7. KEY INSIGHTS

The final layout designed in the thesis is seen in Appendix 2 Layout d. The final layout differs from the Figure 5.2 Simulation model top view with the process "B" positioning. Process step "B" production tables are merged into the line better to eliminate the cell of three tables on a 45-degree angle and improve product transportation flow. Solution is seen on Figure 7.1 Process B layout positioning improvement.

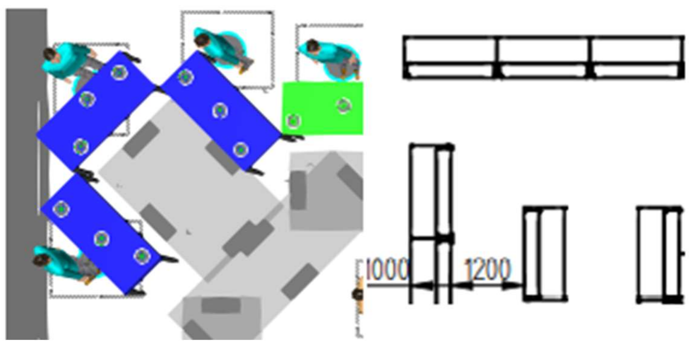


Figure 7.1 Process B layout positioning improvement

The developed layout was simulated in the thesis with Visual Components simulation software. The simulation result was 5% lower than the demand in the initial task resulting in the output of 161 500 pieces instead of 170 000 pieces. The result of the designed production system was expectable since minimum number of workstations was calculated based on product cycle time and the cycle times of each process differ from each other. This created a system where process steps do not share a common denominator and create imbalance in the production system leading to some of the workstations being more loaded with work than others as did the simulation analysis result on Figure 5.4 Workstation usage.

The imbalance of the system creates possibilities for improvements. As some workstations could be operated with less than one production worker per workstation then the possibility of reducing production workers from cells could be implemented and as calculated in chapter 6.2 Workforce cost shown in Table 6.1 Workforce cost each reduced production worker from the production system reduces the manufacturing cost of 0,26 euros per product. Multiplying the cost with production quantity is 42 280,68 euros per year.

The imbalance of the production system could be used to increase the output. As stated in chapter 5.3 Layout simulation observations processes "A", "2" and "8" are currently bottlenecks. If the throughput of these processes could be increased, the total throughput of the production system would increase.

There is a possibility of combining both previously stated improvements and therefore increasing the output of the production system and reducing the cost of the workforce on the system. This way the initial demand for the product can be reached and cost reductions made. The reduced count on the workforce could be achieved either from reducing the assemblers on the production line or the transportation workers who move the sub-assemblies from workstation to workstation or both.

As calculated in chapter 6.3 Return on improvement it may be viable to invest into reduction of workforce. As calculations show an investment of 100 000 euros in reducing one production worker will return at a 25% internal rate of return.

The internal rate of return result and the overall cost of labor per shift, per year and worker cost per product refers to the importance of the number of production workers needed in the system as they convert into the company’s fixed costs.

The free space of 84,60 m^2 of the cleanroom could be used for material storage or could be populated with workstations if the condition of revalidation the cleanroom is possible. This would be necessary if the customer demand for the product increased. Revalidation could be achieved when the validation process ensures the cleanroom environment to withstand the ISO 14644-1: 2015 Cleanrooms and associated controlled environments standard requirements with more than the current of 40 people inside the cleanroom.

SUMMARY

The production system is the basis of a production company. It secures the existence of a company on the market or loss out. The aim of the thesis was to design a production system to a medical flexible endoscope producing company Karl Storz Video Endoscopy Estonia OÜ. The system will produce flexible single use endoscopes in a cleanroom environment. Making the design process more complicated due to existing physical limitations and requirements proceeded from the cleanroom environment and its management.

The cleanroom environment must comply with ISO 14644-1:2015 requirements. Currently the existing cleanroom where the production system was designed for has the maximum requirement of 40 people present in the cleanroom. The needed output of the system is 170 000 pieces of products in a year. The production process for the system is predefined and consists of eleven different work operations that are predetermined, and the duration of the processes are measured. The available space in the cleanroom is ~260 m^2 and can be used for production. One of the targets of the thesis is to spare cleanroom space to use it for storing materials or expand the production system for the increase of output.

In the first part of the thesis theoretical bases of production systems and production layouts was described on how to use the relationship rating method and on how to position the workstations to enhance the material flow and overall experience of working in the system and operating it. Examples were included to bring forward on how to use and combine the four main layout types.

Using theoretical knowledge and the yearly demand of product the production type swings on the edge between batch and mass production. The production layout based on the system type was selected as a combination of product and cell layouts where, the identical workstations are grouped into a production cell and the production line consist of consecutive production cells that form a straight flow of product from start to the exit from the cleanroom sluice.

Through the design of the production system, it was discovered that a system fits into the existing cleanroom. Requiring 35 workstations, 29 of them being the assembly stations, 4 stations are needed for quality assurance and 2 for the packaging process. The footprint of the designed system is 176,10 m^2.

To analyze and confirm the viability of the production system a simulation model of the system was created in VC software. Simulating the designed system represented three

bottlenecks on the layout and the need of 4 transportation workers to maximize the output. This results in a total output of about 5% less than the required 170 000 pieces of product. The initial requirement of output in a workday containing two shifts was 678 pieces and the system resulted 645 pc or a yearly number of 161 500 pieces.

To increase the output to the required number improvement suggestions were proposed in the thesis. Simulation analysis showed three bottleneck production processes in the system. Processes "A", "2" and "8" are working 91% of the time and others are working for less. The suggestion of increasing the number of workstations in these processes was made. Since currently KSVEE has validated the existing cleanroom environment to correspond to ISO 14644-1 requirements with the total number of 40 people inside, it would be necessary to reduce the count of workers beforehand. This could be made with a decrease in the need for transportation workers from 4 to 2.

Understanding the cost of labor is sometimes not considered in the initial phases of designing production systems. To understand the effect of labor cost on the production system calculations were made. Resulting with a single shift labor cost to the company being 3297,89 euros. The total yearly cost of a shift for the company is 827 770,39 euros. The cost of labor effects as 0,26 euros to a single product and if a single worker could be removed from the designed production system would bring a yearly reduction of 42 280,68 euros. Investment of 100 000 euros with the time frame of five years to the production system with the target of reducing one production worker would result in an internal rate of return of 25%.

To conclude the production system designed in the thesis fits into the existing cleanroom as required. The designed system has a cycle time of 1,30 minutes, which is about 5% less than the needed cycle time of 1,24 minutes. The system leaves 84,6 m^2 of free cleanroom space. Improvement opportunities were offered in the thesis to reach the target cycle time that meets the customer demand of product.

KOKKUVÕTE

Tootmissüsteem on tootmisettevõtte alus. See kindlustab ettevõtte olemasolu turul või turuosa kaotuse. Lõputöö eesmärk oli projekteerida tootmissüsteem meditsiiniliste painduvate endoskoopide tootmise ettevõttele Karl Storz Video Endoscopy Estonia OÜ. Süsteem hakkab tootma ühekordseid painduvaid endoskoope puhasruumi keskkonnas. Projekteerimisprotsessi teevad keerukamaks olemasolevad füüsilised piirangud ja puhasruumi keskkonnast ning selle haldamisest tulenevad nõuded.

Puhasruumi keskkond peab vastama ISO 14644-1:2015 nõuetele. Hetkel kehtivate nõuete järgi võib puhasruumis, kuhu tootmissüsteem projekteeriti, olla maksimaalselt 40 inimest. Süsteemi vajalik aastane toodang on 170 000 toodet. Süsteemi tootmisprotsess on ette määratud ja koosneb üheteistkümnest erinevast tööoperatsioonist, mille kestus on mõõdetud. Puhasruumis kasutatav pindala on umbes 260 m² ja see on mõeldud tootmiseks. Üks lõputöö eesmärkidest on säästa puhasruumi ruumi, et kasutada seda materjalide ladustamiseks või tootmissüsteemi laiendamiseks toodangu suurendamise eesmärgil.

Lõputöö esimeses osas käsitletakse tootmissüsteemide ja tootmispaigutuste teoreetilisi aluseid, sealhulgas kuidas kasutada töökohtade suhete hindamise meetodit ja kuidas paigutada tööjaamu, et parandada materjalivoogu ja süsteemi üldist töökogemust. Näited on toodud, et illustreerida nelja peamise asendiplaani kasutamist ja kombineerimist.

Teoreetilisi teadmisi ja aastast tootenõudlust kasutades on tootmissüsteem tüüp partii- ja masstootmise piiril. Süsteemi tüübile tuginev tootmispaigutus valiti kombinatsioonina toote- ja rakupaigutusest, kus identsed tööjaamad on grupeeritud tootmisrakuks ja tootmisliin koosneb järjestikustest tootmisrakudest, mis moodustavad sirge tootmisvoo algusest kuni puhasruumi lõpus asuva toodete väljapääsulüüsini.

Tootmissüsteemi projekteerimise käigus avastati, et süsteem sobib olemasolevasse puhasruumi. Nõutud on 35 tööjaama, millest 29 on koostamisjaamad, 4 töökohta on vajalikud kvaliteedi kontrollimiseks ning 2 pakkimisprotsessiks. Kavandatud süsteemi pindala on 176,10 m².

Tootmissüsteemi elujõulisuse analüüsimiseks ja kinnitamiseks loodi süsteemi simulatsioonimudel Visual Components tarkvaras. Kavandatud süsteemi simulatsioon näitas kolm pudelikaela paigutuses ja vajadust 4 transporditöötaja järele tootmissüsteemi maksimaalse tootmisvõimekuse tagamiseks. Tulemuseks on umbes 5% väiksem toodangumaht kui nõutud 170 000 toodet. Esialgne nõutav toodang kahe vahetusega tööpäevas oli 678 toodet ja süsteemi tulemuseks oli 645 toodet ehk aastane toodang 161 500 toodet.

Selleks, et suurendada toodangut nõutud arvule, tehti lõputöös parandusettepanekuid. Simulatsioonianalüüs näitas tootmisprotsessides kolm kitsaskohta. Protsessid „A‟, „2‟ ja „8‟ töötavad 91% ajast ja teised vähem. Tehti ettepanek suurendada nende protsesside tööjaamade arvu. Kuna praegu on KSVEE valideerinud olemasoleva puhasruumi vastavaks ISO 14644-1 nõuetele juhul kui tootmisalas on kokku 40 inimest, oleks vaja töötajate arvu eelnevalt vähendada. Seda saaks teha, vähendades transporditöötajate arvu 4-lt 2-le.

Tööjõukulude mõistmine on tootmissüsteemide projekteerimise algfaasides vahel alahinnatud. Tööjõukulude mõju mõistmiseks tootmissüsteemile tehti hulk arvutusi. Ühe vahetuse tööjõukulu ettevõttele on 3297,89 eurot. Aastane vahetuse kulu ettevõttele on 827 770,39 eurot. Tööjõukulu mõju ühe toote kohta on 0,26 eurot ja ühe töötaja eemaldamine kavandatud tootmissüsteemist tooks aastaseks kokkuhoiuks 42 280,68 eurot. Investeering 100 000 eurot tootmissüsteemi ühe tootmistöötaja vähendamise eesmärgil viieaastase ajaraamiga annaks sisemise tulumäära 25%.

Lõputöös kavandatud tootmissüsteem sobib olemasolevasse puhasruumi vastavalt töös esitatud nõuetele. Kavandatud süsteemi tsükliaeg on 1,30 minutit, mis on umbes 5% pikem kui arvutuslikult vajalik tsükliaeg 1,24 minutit. Süsteem jätab 84,6 m^2 vaba puhasruumi pinda. Lõputöös pakuti välja parendusvõimalusi, et saavutada eesmärgiks seatud tsükliaeg, mis vastab kliendinõudlusele.

LIST OF REFERENCES

[1] S. T. T. a. F. F. Faddoul, "Lean Management—The Journey from," *Rambam Maimonides Medical Journal,* pp. 1-4, April 2013.

[2] V. F. L. a. M. B. W. R. Sidik, "IOP Science," [Online]. Available: https://iopscience.iop.org/article/10.1088/1757-899X/662/2/022002. [Accessed 22 March 22].

[3] A. B.-J. Nigel Slack, Operations Management 9th edition, Harlow: Pearson Education Limited, 2019.

[4] C. P. P. Nikos I. Karacapilidis, "ScienceDirect," 30 September 1996. [Online]. Available: https://www.sciencedirect.com/science/article/abs/pii/0166361596000383?via%3Dihub. [Accessed 2024 03 23].

[5] M. P. Groover, "Automation, Production Systems, and Computer-Integrated Manufacturing," in *Third Edition*, Harlow, Pearson Education Limited, 2014, p. 413.

[6] "Key Differences," [Online]. Available: https://keydifferences.com/difference-between-product-and-process-layout.html. [Accessed 18 March 2024].

[7] B. R. &. C. M. Jay Heizer, Principles of Operations Management Sustainability and Supply Chain Management 10th Edition, Harlow: Pearson Education Limited, 2017.

[8] Kaufman Global, "Kaufman global," [Online]. Available: https://www.kaufmanglobal.com/glossary/cellular-manufacturing-definition/. [Accessed 5 May 2024].

[9] A. G.-A. M. G.-S.-R. I. M.-M. J. L.-L. Mildrend Montoya-Reyes, "Method for Evaluating the Effect of the Design and the," *Hindawi,* vol. 2020, pp. 1-3, 14 October 2020.

[10] A. K. Sharma, "E-Courses Online," [Online]. Available: http://ecoursesonline.iasri.res.in/mod/page/view.php?id=1133. [Accessed 05 May 2024].

[11] J. K. P. Ray R. Venkataraman, Operations Management: Managing Global Supply Chains, Erie, Penn State: SAGE Publications, 2018.

[12] "MedlinePlus," [Online]. Available: https://medlineplus.gov/ency/article/002360.htm. [Accessed 18 March 2024].

[13] Schilling Engineering GmbH, [Online]. Available: https://schillingengineering.de/en/products/cleanrooms. [Accessed 18 March 2024].

[14] KARL STORZ, KARL STORZ ENDOSKOPE, [Online]. Available: https://www.karlstorz.com/us/en/product-detail-page.htm?productID=1000065193&cat=1000105430. [Accessed 18 March 2024].

[15] KARL STORZ, KARL STORZ ENDOSKOPE, [Online]. Available: https://www.karlstorz.com/us/en/product-detail-page.htm?productID=1000134420&cat=1000104640. [Accessed 18 March 2024].

[16] "American Clean Room Systems," [Online]. Available: https://www.americancleanrooms.com/what-is-iso-8-cleanroom-classification/. [Accessed 19 March 2024].

[17] MiniTec GmbH & Co. KG, "MiniTec Aluminum profiles of profile series 45," MiniTec, [Online]. Available: https://www.minitec.de/en/products/profile-system/profile-series-45. [Accessed 19 May 2024].

[18] "Canadian Centre for Occupational Health and Safety," [Online]. Available: https://www.ccohs.ca/oshanswers/ergonomics/standing/standing_basic.html. [Accessed 2 May 2024].

[19] "ISO.org," [Online]. Available: https://www.iso.org/standard/53394.html. [Accessed 02 May 2024].

[20] E. Vahtmäe, *Cleanliness ang hygiene instruction for SSU production area,* Laagri: Karl Storz Video Endoscopy Estonia OÜ, 2023.

[21] E. C. B. &. P. C. Kaminski, "Taylor and Francis Online," 13 July 2018. [Online]. Available: https://www.tandfonline.com/doi/full/10.1080/23311916.2018.1482984. [Accessed 25 March 2024].

[22] "Kasulikku.ee," 2024 March 14. [Online]. Available: https://kasulikku.ee/2025-aasta-kalendaarne-tooajafond/. [Accessed 25 March 2025].

[23] H. I. B. D. A. T. Marti Widya Sari, "Design of Product Monitoring System Using Internet of Things Technology for Smart Manufacturing," *IOP Conference Series: Materials Science and Engineering,* pp. 1-2, September 2020.

[24] P. B. Visuwan D., "Plant Layout Analysis by Computer Simulation for Electronic Manufacturing Service Plant," *Zendo,* pp. 1-3, 2014.

[25] T. Vipond, "Corporate Finance Institute," [Online]. Available: https://corporatefinanceinstitute.com/resources/valuation/internal-rate-return-irr/. [Accessed 12 May 2025].

[26] S.-A. M. Patrik Jonsson, "Manufacturing Planning and Control," Maidenhead, McGraw-Hill Higher Education, 2009, p. 21.

[27] T. S. Rodriguez, "Medium," 2018 June 2018. [Online]. Available: https://medium.com/drill/lean-production-the-method-that-made-toyota-the-most-valuable-car-brand-in-the-world-13279db0b224. [Accessed 22 March 2024].

[28] "Eesti Standardimis- ja Akrediteerimiskeskus," [Online]. Available: https://www.evs.ee/et/evs-en-iso-14644-1-2015. [Accessed 7 May 2024].

APPENDICES

Appendix 1 Production layout planning instruction KSVEE

STORZ KARL STORZ—ENDOSKOPE	Production layout planning Tootmisala planeerimine	Document-No.: **S5.5.2550.WI002** Version: BC

tööluadade jätkukarbikud ühendatakse eelmistega. Elektriühenduste tegemine karbikute sees on keelatud!

Ühendused vee ja kanalisatsiooniga on võimalikud enamasti postide ümbruses, esimesel korrusel on kanalisatsiooniluugid põrandas.

through the power pole. Subsequent supply boxes shall be connected to the previous ones. It is forbidden to make electrical connections inside the boxes!

Connections to water and sewerage are possible mostly around the posts, on the ground floor there are drainage holes in the floor.

4.4 Tootmisala paigutus / Production area layout

Liini paigutust planeerides tuleb arvesse võtta

- Töö, materjalide ja info voogu
- Materjalide paigutamist liinil
- Materjalivarustamise korraldamist
- Tööohutust
- Evakuatsiooni- ja logistikateid
- Tulekustutite asukohtasid
- Seadmete (nt flowboxid) paigaldustingimusi

The following must be taken into account when planning the layout of the line

- The flow of work, materials and information
- The placement of materials on the line
- Arrangements for material supply
- Safety at work
- Evacuation and logistics routes
- Fire extinguisher locations
- Installation requirements of devices (Flowboxes, etc.)

Soovituslik liini kuju L või U ühe töökoha väljund arvestab järgmise töökoha sisendit.

Liin paigutada ruumis seinast eemale, logistikatee äärde. Akendele jätta 0,4m ligipääs. Suurema materjalivajadusega liinide kaubavahetus alad peavad asuma logistikatee ääres. Suurematele aladele on soovitav planeerida läbikäigutee (liinide vaheline logistikatee).

The recommended line shape is L or U the output of one workstation takes into account the input of the next workstation.

The line should be positioned away from the wall of the room, along the logistics route. Allow 0,4m access to windows. For lines with higher material requirements, the goods handling areas must be located along the logistics route. For larger areas, it is desirable to plan a thoroughfare (logistics route between the lines).

Ligipääs akendele	Access to windows	0,4m
Liinide vaheline käigutee	Corridor between lines	0,8m
Liinide vaheline logistikatee	Logistics route between lines	1,2m
Logistikatee	Logistics route	1,8m

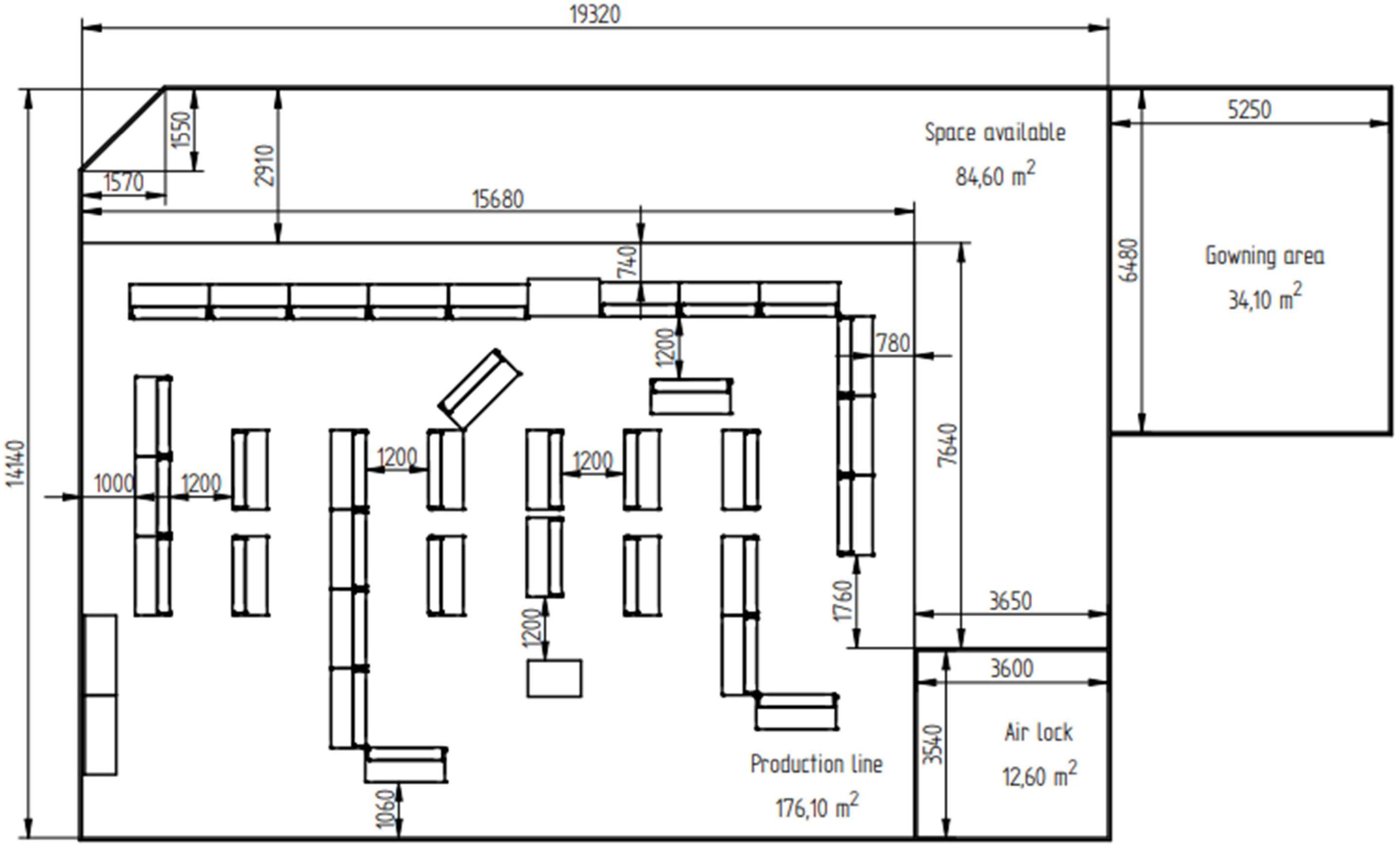
Liini nurkade planeerimisel tuleb arvesse tööalade võimalikku kattuvust, soovitav on kasutada nurgaalasid seadmete hoidmiseks või jätta tühjaks.

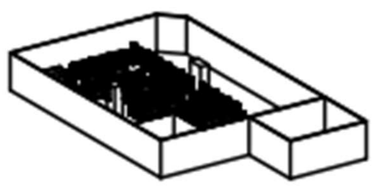
When planning the corners of the line, account should be taken of the possible overlap of work areas, and it is desirable to use corner areas to hold equipment or leave them empty.

Osakonna laudade ümberpaigutamisel tuleb aktualiseerida korruseplaanid.

Floor plans should be updated when relocating department desks.

Appendix 2 Layout designed





Sheet size A3
Measures in millimeters

Material: -		Unmarked tolerance: -	Mass: -	Scale: 1:100
Drawn	Krismar Epner	Title: Cleanroom layout		
Checked	-			
Approved	-			
TAL TECH		Sheet: 1 / 1	Document no.: 20240504	Rev.: 1

Appendix 3 S5.5.255.WI004 section on protective clothing

Tööriietus puhasruumis ja tsoonis 3 / Working clothes in cleanroom and in zone 3

Korduvkasutatav tööriietus puhasruumis Re-usable workwear in cleanroom.

Ühekordsed tööriided mõlemal alal Single use workwear in both areas.