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Process mapping and improvements: A case study in the medtech industry

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Lund, June 2019

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Abstract

Title: Process mapping and improvements: A case study in the medtech industry
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Background: Atos Medical is a global company producing sound valves and other medical equipment. Their current production process of sound valves is complex, with many manual steps and high work in progress levels. The lead time is perceived to be too long, making production planning challenging. The company wants to improve the current process in order to make it more efficient.

Purpose: The purpose of this master thesis is to derive suggestions for Atos Medical in order to improve their production process of SV manufacturing, focusing on reducing lead time.

Research questions:

- RQ1: What is the current state of Atos Medical's sound valves production process?
- RQ2: What problems exist in the current sound valves production process and how can they be categorised?
- RQ3: What improvements can be derived from the identified problems in Atos Medical's sound valves production process in order to reduce lead times and work in progress?

Method: A single case study was used with data gathered from observations, interviews and archival records. A current state of the investigated process was concluded. The data was analysed through a categorisation of the problems identified, Lean tools and two process maps with different levels of detail. Lastly, short term and long term recommendations are presented.

Findings: Utilising process mapping and tools from Lean manufacturing, waste in the sound valves production process could be identified and improvements analysed. The current state of the production experience long lead times where waiting time is a majority, high levels of work in progress and manual planning and documentation. Identified problems were categorised into planning, information, work activities, resources and defects. The highest prioritised problems were linked to suggestions of change, which was analysed based on the current state of the process and the theoretical framework. A future state map was developed to visualise the potential future state of Atos Medical's sound valve production with improvements incorporated. Recommendations for short term are to decrease the batch sizes, implement 5S, update parameters in the ERP system and introduce CONWIP as a production control policy. For the long term, it is recommended that Atos Medical replaces their old machines and equipment, digitalise the documentation and further investigate if it is necessary to sterilise all sound valves. By focusing more on finishing one batch at a time, reducing batch sizes and production steps, the average lead time could be reduced with over 50 %.

Sammanfattning

Titel: Processkartläggning och förbättringar: En fallstudie i medicinteknikbranschen
Författare: Jens Sundgren och Rebecka Lönnbratt
Handledare: Dag Näslund, Lunds tekniska högskola

Bakgrund: Atos Medical är ett globalt företag som producerar ljudrör och annan medicinsk utrustning. Deras nuvarande produktionsprocess av ljudrör är komplex med många manuella steg och höga nivåer av produkter i arbete. Ledtiden upplevs som för lång, vilket gör produktionsplaneringen utmanande. Företaget vill att den nuvarande processen ska förbättras för att göra den mer effektiv.

Syfte: Syftet med examensarbetet är att föreslå förbättringar till Atos Medical för deras produktion av ljudrör med fokus på att minska ledtider.

Frågeställningar:

- Hur ser den nuvarande produktionsprocessen av ljudrör ut?
- Vilka problem existerar i den nuvarande produktionsprocessen av ljudrör och hur kan de kategoriseras?
- Vilka förbättringar kan göras utifrån de identifierade problemen i Atos Medicals produktionsprocess av ljudrör för att förkorta ledtiderna och minska produkter i arbete?

Metod: En fallstudie genomfördes med data från observationer, intervjuer och arkiv. En beskrivning av nuläget gjordes. Data analyserades genom kategorisering av identifierade problem, Lean-verktyg och genom två processkartor med olika detaljnivå. Slutligen presenteras rekommendationer på kort och lång sikt.

Slutsats: I den nuvarande produktionsprocessen återfinns ledtider som är mycket längre än processtiden där väntetid är en majoritet av tiden, nivåer av produkter i arbete vilka betraktas som höga och en i stor utsträckning manuell planering och dokumentering. Problem som identifierats i processen härrör från planering, information, arbetsmoment, resurser och defekta produkter. De högst prioriterade problemen kopplades till förbättringsförslag och analyserades med hjälp av nulägesbeskrivningen och det teoretiska ramverket. Processkartor utvecklades också där rekommenderade förändringar är inkluderade för att visa ett potentiellt framtida läge. Rekommendationer på kort sikt ges att minska batchstorlekar, implementera 5S, uppdatera parametrar för ERP-systemet och introducera CONWIP som styrningsmetod i produktionen. På längre sikt rekommenderas att maskiner och utrustning uppdateras, att dokumentation digitaliseras samt att vidare undersökningar görs kring huruvida sterilisering av alla produkter är nödvändig. Genom att färdigställa varje batch direkt, minska batchstorlekar och produktionssteg kan den genomsnittliga ledtiden minskas med över 50 %.

List of Abbreviations

VSM - Value Stream Map
ERP - Enterprise Resource Planning
WIP - Work In Progress
FSM - Future State Map
SV - Sound valve
R&D - Research and Development
MRP - Material Resource Planning
FIFO - First In first Out

Terminology

WIP - All material and components which are released from raw material inventory but have not yet finished all processing steps.

Lead time - Following Martin & Osterling (2014), lead time is defined in this report as time elapsing from when material enters a process until it exits the process.

Process time - Setup time plus runtime if a batch size is determined, otherwise only runtime is implied.

Waiting time - For all WIP, the time in a process or between processes where no processing is conducted.

Table of content

1 Introduction

In this chapter, an introduction to the company where this study has been conducted is presented together with the problem at hand and the specific product that is focused on. The research purpose, questions and delimitations are stated as well.

1.1 Note to the reader

Due to confidentiality reasons, some of the terms regarding the manufacturing process and regarding products are altered on behalf of Atos Medical. Metrics and numbers presented in the report are multiplied by a factor of X.

1.2 Background

Performance improvements are essential for most companies today, the ability to keep improving in order to beat the competition is needed to not lag behind in ever changing competitive business climates (Mcdonald, Van Aken, and Rentes, 2002). Holweg (2006) also emphasises the increasing importance of the ability to adapt to a changing market and that flexibility and responsiveness are important factors to consider.

Long lead times, according to Ahmad and Soberi (2017), typically results in higher forecast uncertainty, making it more difficult to match production and customer demand. Thus, for manufacturing firms reducing lead times is an essential part of staying competitive. Typically, lead times are reduced by improving production processes through identification and removal of non-value adding activities (Azizi and Manoharan, 2015).

For a company to start improving processes, the first step is to understand the current situation, otherwise it is not possible to come up with an improved state (Hines and Rich, 1997; Martin and Osterling, 2014).

Process mapping is an important approach to process improvements (Bowles and Gardiner, 2018) that facilitates understanding of processes (Siha and Saad, 2008; Martin and Osterling, 2014).

Numerous other methodologies exist which can be applied for improving processes and performance. One method commonly used in different organisations and industries is Lean. Rohani and Zahraee (2015), Mahendran and Kumar (2018), Womack and Jones (1996) describe Lean as a concept derived from Toyota's production system with the objective to produce just-in-time, meaning not to produce more products than what is demanded and not building up high inventory levels. Connected to this is the notion of pull production which is also fundamental to Lean, meaning that the production starts when demand arises in downstream processes, generally resulting in shorter lead times and reduced inventory (Hopp and Spearman, 2008).

The philosophy of Lean entails striving for perfection and to focus on the customers and what creates value for them. It is a rather widely spread methodology applied in many different types of organisations and industries.

1.3 Company description

Atos Medical is a Swedish medtech company making products for medical use. In 1986, the two brothers Gert and Jan-Ove Persson started Atos Medical, in Hörby, Skåne. Soon they initiated a collaboration with the Dutch Cancer institute and could start producing SVs. In 1990 the first SV model was launched and sold successively around Europe. During the next years several generations and different products launched and Atos Medical expanded internationally to countries like the UK, United States, Germany and the Netherlands. In 2014, a new version was released that gave patients the possibility of hands-free use. (Atos Medical a))

Today, the headquarter is situated in Malmö but manufacturing as well as R&D facilities are still located in Hörby. There are 750 employees in the world whereof 130 of these work at the Hörby site. Atos Medical is an international company with more than 25 years of experience and customers in over 70 countries and affiliates in 19 countries. The company works closely with end-users and health care professionals to innovate improvements and new products. They mainly sell their products to end-users directly and are for example active within Tracheostomy care and Jaw mobility. (Atos Medical a))

1.4 Product description

Laryngectomy is a surgical procedure performed on patients with advanced stages of cancer in or around the voice box. The voice box, also called larynx, is removed in the procedure and it is not possible to breathe as before, instead, patients have to breathe through an opening in the neck. The nasal functions are lost and the vocal folds that makes the voice sound are removed. The nose does more than just smell, it moisturises and heats the inflowing air, and when that function is removed, the lungs produce more mucus. (Atos Medical b))

Using Atos Medical SV, the functions of the nose are imitated and the patient can also, with practice, speak again. Figure 1 displays three stages, before, after a laryngectomy and how the SV is placed. The SV connects the food pipe and the windpipe with one flange on each side. When speaking, the valve between the two pipes open and then close while breathing to prevent foreign particles entering the windpipe. By pressing on the stoma, the exhaled air will be redirected to the food pipe and make the tissue vibrate, causing a sound. Atos Medical also produces complementing products such as tubes and patches, and different kinds of SV for different kinds of activities.

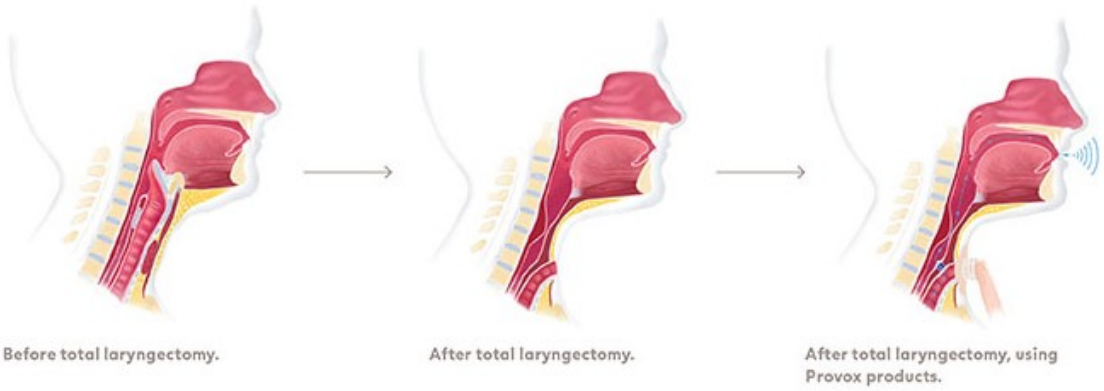

Figure 1 The stage before and after a total laryngectomy, and the placement of the sound valve. Source: Atos Medical b)

1.5 Problem description

The production of SV is a complex process due to the fact that the products require a clean environment and many time consuming manufacturing steps. There are especially heavy regulations in the medtech industry that differ from country to country, and the traceability of the products and validated manufacturing processes is essential if any defects are found later on, which means that documentation is important. Atos Medical utilise a make-to-stock policy but they are experiencing difficulties in keeping set safety stock levels. The production planning is currently conducted weekly in an ERP system where suggestions for production are automatically generated through MRP. Production orders need to be manually reviewed and compared to inventory levels, WIP and previously released production orders.

The complex line of production steps contain a lot of manual work, manual documentation and long processing times. Once assembled, the SV products are sent outside Sweden for sterilisation since this service does not exist in Sweden. These factors contributes to long lead times and high levels of WIP which increases the difficulty of planning for future demand. A dependency on sales forecasts leads to reprioritisations, or expediting, in the daily production planning and thereby increased waiting times for products.

1.6 Research purpose

The purpose of this master thesis is to derive suggestions for Atos Medical in order to improve their production process of SV manufacturing, focusing on reducing lead time.

1.7 Research questions

- RQ1: What is the current state of Atos Medical's SV production process?
- RQ2: What problems exist in the current SV production process and how can they be categorised?
- RQ3: What improvements can be derived from the identified problems in Atos Medical's SV production process in order to reduce lead times and WIP?

1.8 Focus and delimitations

The SV production process that will be investigated starts when raw material is retrieved for injection moulding and ends when the product is finished and available in the finished goods warehouse. Due to time constraints, the focus of the study was narrowed down to only two product variants of SV models even though Atos Medical has several different models. A Pareto-analysis was conducted in order to find a suitable model to represent the highest demanded volumes. To provide an opposite perspective, another variant of the products selected was added into the study. This variant was selected by the company supervisor and production planner and is one of the low volume SV models.

Only the main components of the SV, as presented later in this report, are investigated. It is assumed that other input materials and components always are available at the site. Quality problems in terms of scrapping or defective products are not explicitly considered in this study, meaning data about it is not gathered. Scrapping could be a significant factor in some of the process steps considered and should be considered but scrapping is not part of the developed process maps. The study will focus on the overall SV production process, it will not investigate technology of individual process steps. Further on, a limited number of problems are further investigated in this study even though there were several more problems identified.

Costs are not included in the calculations in this study but is still a relevant factor to the problems, analysis and recommendations. External suppliers and customers are not included within the defined process under study.

1.9 Report structure

The first chapter is an introduction to the research problem, the company where the master thesis was conducted and the research questions and limitations. Following is the methodology chapter, where different types of methodologies for conducting scientific research is discussed and the methodology for this master thesis project is presented. The third chapter presents theory relevant to the study. Different process mapping techniques and methods are discussed and compared. An introduction to Lean and the theoretical framework follows. The gathered

data from interviews, observations and archival records are presented in chapter four and summarised in a description of the current state. The fifth chapter is an analysis of the current state, problems identified and suggested changes. The result of the analysis is summarised in the FSM section and through the recommendations to Atos Medical also presented in chapter five, both on a short term basis and a long term basis. Chapter six presents a conclusion of the study and suggestions for future research.

2 Methodology

This chapter introduces methodologies for research and the purpose, approaches and strategies that can be used. Further on, case study research is focused on as it is applied in this study. Concluding the chapter, the method used in this study is extensively described.

2.1 Introduction

Research revolves around producing knowledge (Patel and Davidson, 2003), employing appropriate scientific methodologies in research which enables independent reviews and relates to other relevant research (Höst, Regnell, and Runeson, 2006). Researcher's own contributions and sources should be clearly declared as well as limits, assumptions and potential sources of error (Höst et al., 2006).

In general, research approaches can be distinguished by their use of quantitative, qualitative or mixed methods which entails ways of generating and analysing data (Patel and Davidson, 2003). Creswell (2014) suggests that a research approach should be based on what philosophical worldview a study is built upon, what type of research design relates to philosophical assumptions and what specific methods to employ in practice. Another distinction can be made between: deductive and inductive research. Deductive research aims to derive conclusions from theory and test them empirically while inductive research derives theories from observations (Holme and Krohn Solvang, 1997; Patel and Davidson, 2003).

2.2 Research purpose

Any research purpose should be of an explanatory, exploratory, experimental or problem solving nature (Höst et al., 2006). Explanatory studies refers to finding out and explaining how phenomena works. An exploratory purpose implies a more in-depth research of unknown phenomena, investigating it from different perspectives (Patel and Davidson, 2003). Experimental purposes imply an attempt at finding causal relationships to how a phenomenon works or is conducted while the objective of a problem solving purpose is simply to find a solution to an identified problem (Höst et al., 2006).

2.3 Research approaches and design

2.3.1 Quantitative research

Research that is testing theories and examining relationships among variables are addressed through quantitative studies where quantitative data analysis based on statistical methods is performed on numbered data (Creswell, 2014; Bell and Waters, 2016; Patel and Davidson, 2003). Structured and standardised data collection tools are utilised in quantitative research giving researchers strong control of information (Holme and Krohn Solvang, 1997). Employing quantitative research implies conducting deductive research (Creswell, 2014). Testing theories

in this manner enables generalisability from samples to populations (Holme and Krohn Solvang, 1997; Bell and Waters, 2016).

Main quantitative research designs are according to Fowler (2009), survey research and experimental research. Survey research renders quantitative descriptions of a studied issue, by collecting data through questionnaires and structured interviews the intention is to generalise theory from sample to population. Experimental research works to determine whether specific variables influence an outcome.

2.3.2 Qualitative research

The qualitative approach to research is used for achieving a deeper understanding and exploration of problems or phenomena in order to gain new insights (Creswell, 2014; Bell and Waters, 2016). This is achieved by collecting data about fewer objects through unstructured observations according to Holme and Krohn Solvang (1997) who further on argue that qualitative data is collected primarily in participant's settings and analysed inductively on particulars to generalisability. Adding that qualitative researchers make their own interpretations of collected data and include complex perspectives of a situation.

2.3.3 Mixed methods research

By utilising mixed methods, a researcher is assuming that quantitative and qualitative data approaches in combination renders a more complete understanding of an issue than either method does on its own (Creswell, 2014). Patel and Davidson (2003) suggest that the categorisation between quantitative and qualitative should be seen as a spectrum where emphasis can be on either side. The mixed methods design originate from the idea that all research methods are inherently biased and entail weaknesses, thereby assuming that collecting both quantitative and qualitative data works towards neutralising the weaknesses of each method respectively (Creswell, 2014; Holme and Krohn Solvang, 1997).

2.3.4 Philosophical worldview

Creswell (2014) argues that research implies an underlying philosophical worldview and main assumptions which are summarised and presented in table 1.

Table 1 Philosophical worldview and their main assumptions and ideas, adapted from Creswell (2014).

Philosophical worldview	**Main assumptions**
Postpositivism	● Quantitative research approach ● Knowledge regarding human behaviour and actions is not absolute ● Causes determine outcomes ● Research starts with a theory that is supported or refuted by empirical evidence.
Constructivism	● Qualitative research approach ● Research should reflect complexity stemming from individuals (including researcher) subjective interpretations
Transformative	● Applicable for mixed methods approach ● Focus on studying marginalised groups ● Political and social action should connect to research
Pragmatism	● Applicable for mixed methods approach. ● Focus on successfully addressing problems

2.4 Research strategy

Another component of a research framework is the specific research strategy, or method, to follow which include forms of data collection, analysis and interpretation (Creswell, 2014).

Yin (2009) suggest three different questions for selecting an appropriate research method as presented in table 2. Research that try to predict an outcome would likely benefit from working with survey or archival analysis. Case studies, experiments and histories on the other hand are

more appropriate for explanatory and exploratory research questions. Case studies differ from histories in that it may study contemporary phenomena. If the investigator has control over a phenomenon under study, an experimental method is used but in case studies, the investigators have no or little control. The conditions suggested are not definite, meaning that there is overlap between different methods utilised.

Table 2 Research methods and relation to three conditions, adapted from Yin (2009).

Method	**Form of research question**	**Control of behavioural events required?**	**A focus on contemporary events?**
Experiment	How, why?	yes	yes
Survey	Who, what, where, how many, how much?	no	yes/no
Archival analysis	Who, what, where, how many, how much?	no	yes
History	How, why?	no	no
Case study	How, why?	no	yes

Höst et al. (2006) on the other hand, describe four major methods within applied research; mapping, case study, experiment and action research. Mapping and explaining the current state is a suitable method to get a holistic view of the situation and potential problems. It is commonly used to describe a broad question. A case study is a deeper research into one or several cases where the studied object should not be affected. Höst et al. (2006) suggest that an experiment strategy is used to compare two or several alternatives where a few factors are isolated in order to find connections and relationships to manipulate. This is a fixed method which means that it is difficult to change once the experiment has started. Action research is thoroughly documented studies of activities which aims at solving a problem. To understand the current situation, mapping or conducting a case study can provide a basis for implementing suggestions and validating them.

2.5 Case study

2.5.1 Conducting a case study

According to Meredith (1998), case studies provide relevance and understanding of a problem or phenomenon and can contribute with in depth exploration. The same conditions for different cases are difficult to obtain although, multiple cases could be used to test replicability.

Yin (2009) states that case study research investigates a contemporary phenomenon within its real-life context, arguing that this form of study can use different sources of data in a

triangulating manner. Designing a case calls for defining the unit of analysis, developing theory and propositions, determining the number of cases to be studied and defining procedures to maintain the quality of the case study. Adding that the quality of a case study in turn depend on the degree of construct validity, internal validity, external validity and reliability achieved.

Voss, Tsikriktis and Frohlich (2002) also highlight the importance of skilled interviewers and carefulness when drawing generalisable conclusions from limited data sets, as in qualitative data. Case studies are time consuming and a thorough planning and execution is important. Case studies can be divided into four categories, as presented in table 3.

Table 3 The different categories that case studies can be divided into, adapted from Voss et al. (2002)

Purpose	**Research question**	**Research strategy**
Exploration Uncover areas for research and theory building	Is there something interesting enough to justify research?	In-depth case studies Unfocused, longitudinal field study
Theory building Identify/describe key variables Identify linkages between variables Identifying "why" these relationships exist	What are the key variables? What are the patterns or linkages between variables? Why should these relationships exist?	Few focused case studies In-depth fields studies Multi-site case studies Best-in-class case studies
Theory testing Test the theories developed in the previous stages Predict future outcomes	Are the theories we have generated able to survive the test of empirical data? Did we get the behaviour that was predicted by the theory or did we observe another unanticipated behaviour?	Experiment Quasi-experiment Multiple case studies Large-scale sample of population
Theory extension/refinement To better structure the theories in light of the observed results	How generalizable is the theory? Where does the theory apply?	Experiment Quasi-experiment Case studies Large-scale sample of population

The starting point is according to Voss et al. (2002) to define the research framework and questions, even though these could evolve over time. The cases selected should predict similar results or contrary results to the hypothesis and could either be longitudinal or retrospective,

meaning either observed over a long period of time or through historical data. Longitudinal cases require resources over a longer time and could therefore be difficult to conduct while determining cause and effect in retrospective cases may prove difficult if participants do not recall exactly what happened.

Voss et al. (2002) state that after the research framework and questions are defined, a research protocol should be developed, including research instruments, procedures, and general rules that will be applied when using the instruments and a suggestion of how data and information will be collected. The most informed persons should be consulted when collecting data. Both Voss et al. (2002) and Stuart, McCutcheon, Handfield, McLachlin, and Samson (2002) state that the use of many data sources will provide more valid results. Case study data is typically collected from many different sources, interviews and observations are the most common sources (Bell and Waters, 2016).

According to Stuart, et al. (2002) there are five stages of conducting case research, presented in figure 2.

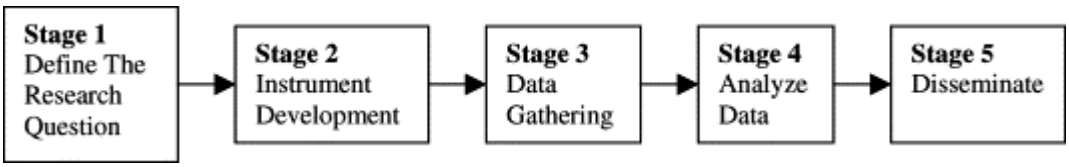

Figure 2 Stuart et al. (2002)'s five stages research process model

The first stage is to define the research question and building a body of knowledge to develop theory. The aim is to understand and explain the current situation but also to investigate existing research of the same phenomena. Mapping activities and events to find relationships between cause and effect is a crucial step as well as validating the proposed models and limitations of the study. During the second stage, a study protocol should be developed, including research instruments and how the data will be linked to the propositions. Data gathering is the third stage, both Yin (2009) and Stuart et al. (2002) emphasise the importance of reflecting back to the protocol and the purpose of the study in this stage. The fourth stage according to Stuart et al., (2002) is analysing the data where existing models applicability should be tested and unless perfectly matched, new models could be developed. To structure the data in a variety of patterns could simplify the analysis. The fifth stage, disseminate, refers to arguing about the study's validity and reliability.

According to Yin (2009), in generalising theory through case studies, analytic generalisation is used. This method utilises previously developed theory for comparing the empirically obtained results. Analytic generalisation is possible to achieve through both single and multiple case studies. Statistical generalisation on the other hand, derives conclusions about a population based on empirically collected data about a sample from that population.

Bell and Waters (2016) argue that the main critique of case study research revolves around questionable conclusions drawn from studying single events or phenomena that are not generalisable.

2.5.2 Literature review

Thomé, Scavarda and Scavarda (2016) propose that conducting a systematic literature review does not only entail reviewing previous research, it should also reflect on the research questions and report evidence in order to conclude what is known. Before the search, the scope of the study needs to be clearly stated. Defining the objective and limitations of the study will help directing the research and to structure the results found. When searching the literature, appropriate databases needs to be selected and should correspond to the research scope. At least two different databases should be used to increase the credibility. A first criteria to assure quality is to filter the search to peer reviewed journals and articles since it lowers the risk of bias. In the search, reputed conferences, publications from trade and industry magazines, thesis and dissertations could also be included.

Both Thomé et al. (2016) and Höst et al. (2006) argue that selecting search keywords is difficult and they should be broad enough not to restrict the study results but also specific enough to narrow down the search to relevant results for the study. To select sources for further investigation, the abstract should be reviewed in order to confirm that it fulfils the search criteria, if it does not, the credibility of the research could be questioned. The search will be finished when additional searches returns to the same articles or results in fewer results.

According to Höst et al. (2006), after the broad search, a more thorough search of the references in the lists of the articles should be done to not miss anything. Documentation about the search methodology should be done accordingly. Rowley and Slack (2004) state similar to Höst et al. (2006) that searching within already retrieved set of documents in order to reduce a large number of documents. Another approach is brief search where a quick scan of documents leads to which will be further studied. Building blocks approach extends the search term to synonyms and other related terms which results in a more thorough search.

2.5.3 Data collection

Objective

The objective of data collection as part of a case study should be to collect confirmatory evidence about the main topics of the study while at the same time attempting to investigate rival explanations (Yin, 2009). Yin (2009) suggests that researchers collecting data for case studies should continuously think about why evidence appear as they do and be ready to investigate new leads. Further on suggesting that bias in collected data can be addressed by constantly being open to alternative explanations to findings in the study. Another important issue in case study research recognised by Yin (2009) is protecting human subjects participating in research, which can be achieved by gaining informed consent of participation, protecting participants from harm, avoiding any type of deception towards participants and protecting the

participants privacy and confidentiality. Ethically conducting research necessitates following the ethical guidelines of the research institution.

The quantitative approach is suitable if the researched phenomenon is not too complex, structured observations are available, the goal is to find what is in common, representative or average. Sampling must be statistically correct and interview templates should be standardised. The primary purpose of qualitative research is to understand a problem and get a holistic view. There should be plenty of information about a few units to be investigated. Characteristic is unstructured interviews and observations aiming to find what is unique and deviates. An advantage is if the unit or phenomenon to be studied is close to get an as true translation as possible.

Yin (2009) suggest that there are six sources of evidence available in doing case study research, documents, archival records, interviews, direct observation, participant-observation and physical artefacts. Three principles lay the foundation for data collection in case studies: using multiple data sources, establishing a database for evidence and establish a chain of evidence that connects questions asked to inferences made.

Observations

Complementary information is often drawn from observations, the method can be divided into two types: direct observations and participant-observations. The difference in the observational methods depend on the investigators own involvement in the phenomenon under study (Yin, 2009). Meredith (1998) states that the importance of direct observation instead of receiving having secondary sources explain the phenomena. The disadvantage of direct observations are mainly high cost and that it is time consuming.

An obstacle for observations is observer-bias which could lead to invalid data collection (Voss et al, 2002). Stuart et al. (2002) also raise the question of bias and that the observation will be affected of the observers' prior knowledge of the phenomena and experiences. Biased samples will impact the interpretation of the phenomena. Taking precaution for this early in the study will increase the study's validity.

Interviews

This type of data collection can according to Yin (2009) provide good insights but is also limited in that it is a verbal report, subject to bias and may be influenced by poor recollection and articulation. Evidence of this kind should be used to corroborate with other evidence and having data from only one or a few interviews typically does not constitute a solid base for drawing conclusions.

Interviews can be conducted in three general ways:

- Unstructured interviews
- Semi-structured interviews
- Structured interviews

Höst et al. (2006) state that unstructured interviews is controlled by subjects and questions can be asked in different ways to different interviewees. The interview should be recorded and will be directed by what the interviewee wants to talk about. Structured interviews are more similar to an oral survey. Semi-structured interviews is a mix of open and fixed questions with pre decided alternative answers.

One interview approach that Voss et al. (2002) proposes is using the funnel model where the interview starts with broad and open-ended questions and as the interview progress, the questions become more specific and detailed. It could also be an advantage to be a team that interviews since it will result in two perspective and one could focus on taking notes.

Yin (2009) states that longer in-depth interviews provide important evidence but generalizing conclusions should not be based on only one or a few sources. Focused interviews on the other hand should be shorter and the questions derived from the case study protocol. The objective is to confirm already known facts but the questions need to be genuinely naive and commentary be free of preconceptions. To mitigate bias, individuals that on beforehand has different views should be consulted. Interviews resembling a survey questionnaire could be used to get quantitative evidence.

Recording the interviews will increase the correctness but could make the interviewee uncomfortable (Yin 2009; Höst et al. 2006). Stuart et al. (2002) also state that this as a dilemma for the interviewer since building trust between the researcher and the interviewee is crucial.

Stuart et al. (2002) emphasise the importance for the interviewer to be flexible and able to change tactics during the interview to uncover all wanted data. Structured interviews can be a barrier for best getting the information. Letting the interviewee steer the interview and the interviewer just guiding to cover all areas.

Physical artefacts

Artifactual evidence are things such as tools or instruments, they can give insight into technical operations or cultural features. However it is not frequently used in contemporary case study research (Yin, 2009).

Documents

The most important use of documents, such as letters or memoranda, is in corroborating evidence. Typically the evidence of this sort are subject to personal bias based on the producer (Yin, 2009).

Archival records

The usefulness of this type of data is varying, examples would be service records or organisational records. When finding relevant evidence of this kind, the conditions under which the evidence was produced and the accuracy of the information must be carefully considered (Yin, 2009).

2.5.4 Validity

The validity of research could be divided into four categories, construct validity, internal validity, external validity and reliability (Yin, 2009). Construct validity focus on the correct operational measures being used for the phenomenon studies. The variables used should be specific enough such that they rule out any subjective conclusions, operational measures should also match concepts from earlier research (Yin, 2009). Internal validity is about establishing a causal relationship between cause and effect, while external validity is measured by how well the conclusions from the research can be applied to other studies. The degree to which research procedures can be replicated and still obtain the same results is referred to as reliability (Voss et al, 2002; Yin, 2009).

How samples are picked is of great importance from a validity perspective according to Holme and Krohn Solvang (1997). In order to receive a statistically correct conclusion there are different sets of methods for sampling. Probability sampling is done by controlled tables for the right sample size. Cluster sampling is another sampling method where the units are grouped together in clusters and random clusters are selected for sampling. The sample could consist of either all units within the cluster or a new random sampling within the cluster.

Table 4 presents quality tests for case studies, tactics for addressing these tests and which phase of research is concerned with each test respectively.

Yin (2009) suggest that the goal of addressing the validity of the research in this manner is to minimise errors as well as bias occurring in the study. For a high-quality study, same findings and conclusions are reached if the same procedures are followed by another investigator. Procedures must therefore be documented thoroughly, a case study protocol can be used to address documentation and a database be developed to handle all evidence. The typical way to approach this is to make as many steps as possible operational.

Table 4 Tactics in case study for design tests, adapted from Yin (2009).

Tests	**Case study tactic**	**Phase of research in which tactic occurs**
Construct validity	Use multiple sources of evidence, establish chain of evidence, have key informants review draft case study report	Data collection composition
Internal validity	Do pattern matching, do explanation building, address rival explanations, use logic models	Data analysis
External validity	Use theory in single-case studies, use replication logic in multiple-case studies	Research design
Reliability	Use case study protocol, develop case study database	Data collection

2.6 Research method in this study

A summary of the research methods used in this report is presented in table 5. Following are more explicit descriptions of the execution of the study.

Table 5 Summary of the research parts in this study.

Part of research	**Study context**
Approach	Mixed methods research
Strategy	Case study - single case
Data collection	Interviews, observations, archival records
Analysis	Value stream analysis, thematic qualitative analysis
Validity	Triangulation

2.6.1 Selected approach

For this thesis a mixed methods approach was selected, drawing on both quantitative and qualitative data to develop an in-depth knowledge of the process studied. Qualitative data was collected in order to describe current operations, identify problems in the investigated process as well as suggestions for improvements. In order to facilitate process mapping and compare the current state with potential improvements, quantitative data was collected.

2.6.2 Selected strategy

The purpose of this study is exploratory, which is suitable for a case study. The unit of analysis is a production process within a manufacturing company. This study sets out to conduct an in-depth investigation of a phenomenon which according to Yin (2009) case studies enable. Utilising the case study method does not limit the data collection to quantitative or qualitative data and Höst et al. (2006) suggest that more data sources improve a study. As part of the research questions formed as questions of "how" suggests that a case study is appropriate following Yin (2009). Following this, a case study is applied to this thesis.

2.6.3 Research execution

Defining the study

The case study was performed according to the case study methodology presented in section 2.5 but some alterations were made to fit the purpose and situation. As a first step, an introduction to Atos Medical and their production was presented. The purpose and limitations were stated, even though it was an iterative process and some limitations were made throughout the study. Regarding the product family and specific product models upon which the scope of the study was narrowed down to, this was defined in collaboration with the company supervisor. The study was conducted as presented in figure 3.

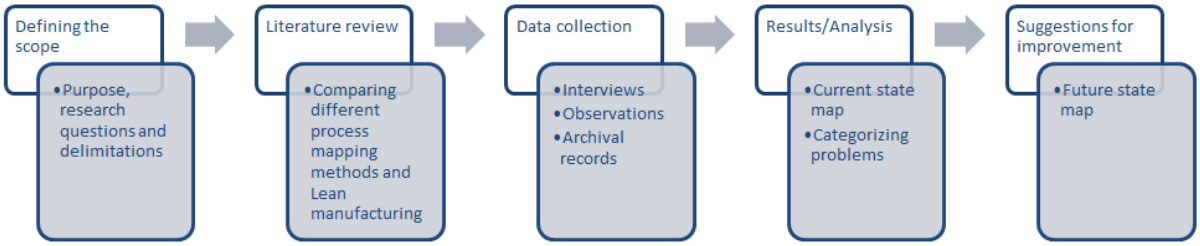

Figure 3 The stages in the research execution.

Literature review

The second stage was to conduct a literature review, where methodologies on how to perform scientific research was summarised. A literature review for theory about process improvement with a focus on decreasing lead times was conducted with an extended search on LUBSearch (Lund University Libraries) database for relevant articles. The first search was broad with the term "process mapping" which resulted in over 150 000 search results. Limits were set to a publication year between 2010 and 2019 to narrow the results down to more recently published works. The search term was also narrowed down to "process mapping AND lead time" to receive articles with a focus on lead times since the purpose of the study is to suggest improvements for Atos Medical to reduce the current lead times. More limitations were selected in order to reduce the number of articles. A building blocks approach were used to extend the search terms to synonyms in order to not exclude relevant sources. By reading abstracts, the most relevant articles were selected. Only peer reviewed articles are used in this report and articles not selected in the scanning procedure were those that had no clear connection to business processes. By checking the reference list in articles relevant to the study, more articles

were found and keywords from these articles were used for further searches. The most recurring process mapping methods in the literature according to 20 articles, presented in table 9, was summarised. These articles were reviewed from the first rounds of search with process mapping and improvement in the keywords. Another round of literature search, with the different process mapping methods in the keywords and title, was conducted to create a comparison between them. Table 6 shows the searched terms, limitations and number of search results.

Table 6 The result from the literature review.

Search term	**Language**	**Peer reviewed**	**Year of publication**	**Subjects**	**Number of results**
process mapping flowchart (Keyword)	English	Yes	2010-2019	All	75
process mapping AND lead time AND improvement (Keyword)	English	Yes	2010-2019	All	246
SIPOC model (Keyword)	English	Yes	All	All	29
IDEF0 manufacturing (Keyword)	English	Yes	2010-2019	All	72
Role activity diagram (Title)	English	Yes	2010-2019	All	4
flow chart (Title) AND process (All text)	English	Yes	2010-2019	All	108
swim lane* (All text) AND business (Subject terms)	English	Yes	2010-2019	All	101
"Process map*"(Abstract) AND business (Subject terms)	English	Yes	2010-2019	All	13
"value stream mapping" (Title) AND "process map*" OR "process improvement" (Abstract)	English	Yes	2010-2019	All	12
"lean manufacturing" OR "lean implementation" (Title) AND "lead times" (Abstract) AND implement* (All text)	English	Yes	2010-2019	All	11

The trend in research articles found in LUBSearch database is that process improvement is becoming more and more important during the last years. A search for the term “Process improvement” and “Process mapping” as a keyword resulted in figure 4. There are a lot of articles about process improvement but few about process mapping although it is commonly suggested to start process improvement projects with process mapping in order to facilitate

understanding of the current situation (e.g. Fadahunsi and Sathiyanarayanan, 2016; Hines and Rich, 1997).

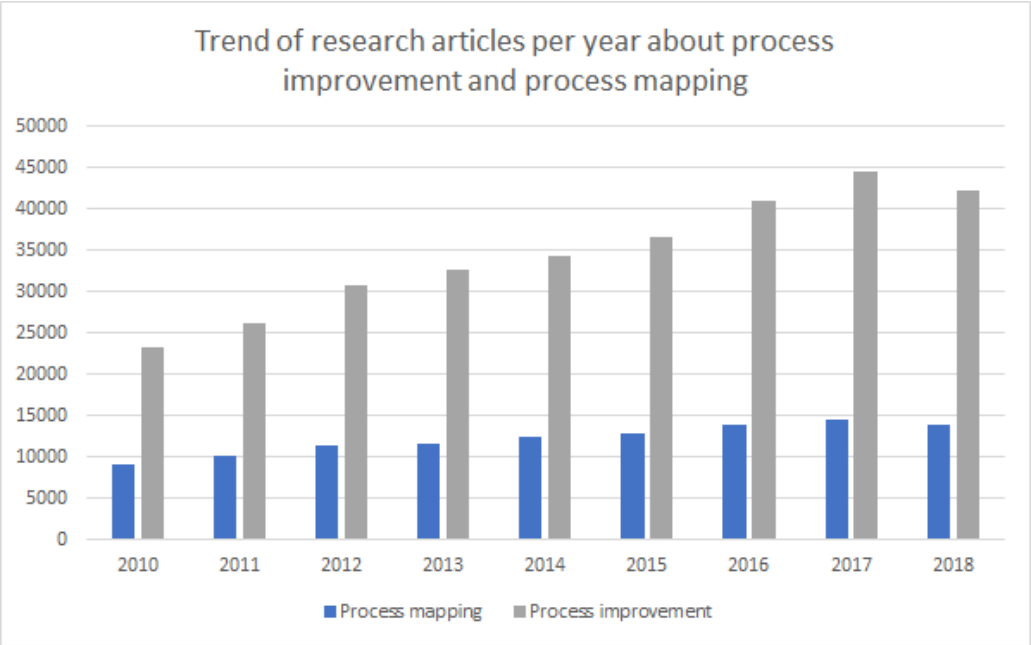

Figure 4 The trend for articles about Process mapping and Process improvement from 2010 to 2018.

Further on, a literature search was conducted for Lean, which is a common process improvement methodology, and a summary of the methodology was presented.

Observations

In several sessions, observations of the process steps also referred to as Gemba walks (Martin and Osterling, 2014; Rother and Shook, 2001) were conducted by following the products under investigation, a protocol, presented in Appendix B, was used as a basis for observations. The first Gemba walk had the focus of understanding the process, inputs and outputs. During the second walk, metrics, characteristics, barriers to flow and current performance was identified. The time required to do each process step was measured either quantitatively, by measuring a sample of 100 products, or qualitatively with an operator estimating the process times. The operator currently assigned to the work activity investigated was aware of the purpose of the study and performed the tasks as usual while describing the different activities. In some cases, one operator followed products through many process steps and in others, different operators conducted sequential work activities.

Interviews

An interview guide, see Appendix A, was developed to conduct the semi-structured interviews with 14 employees having different roles at Atos Medical. The interviews were recorded and lasted about 30 minutes. Notes were also taken by one of the interviewers. Conference rooms and production offices served as interview rooms. The focus for the interviews was to identify

problems from different perspectives in the company. In meetings with the company supervisor, the production planner and one of the process leaders, suggestions for which employees that would be suitable to include as interviewees was discussed. Employees with different roles, representing all parts of the production process were selected to include different perspectives. Table 7 shows the different roles and number of interviewees.

Table 7 The titles and the number of interviewees.

Title	**Number of interviewees**
Production and Process Leader	1
Process Manager	1
Production Team Leader	2
Production Operator	4
Logistics Operator	1
Manager Operations Controlling	1
Production Leader and Production Planner	1
Process Leader	1
Senior Vice President Operations & Quality	1
Director Production, Operations	1

Archival records

Based on archived documents and the company's ERP system, process lead times was derived for the current state. ERP system registrations served as a basis for selecting the most recent batches of products that was injection moulded to follow through the process from processed raw material until finished products. The five and two most recent batches respectively was chosen to investigate for the two models followed. Archival records in the form of production orders was then retrieved of selected batches to provide detailed start and finish dates of different process steps.

Process mapping

In this study, VSM and flow chart was the two process mapping methods selected based on the theoretical framework in order to visualise the process from two different levels of detail. The focus of the study is on one process within a company and it was therefore considered suitable to get a more detailed visualisation with a flow chart. Since lead time is a central subject in this study, VSM was selected as another mapping method, in part because it includes lead time as a metric. A segmented value stream map, as presented by Martin & Osterling (2014), was considered to provide a sound basis for a higher level map of current operations. The method

visualises both material and information flow as well as metrics. The metrics in the process maps are based on observations, data gathered from internal documents and the ERP system. The two process mapping methods complement each other and provide an analytical basis for improvement suggestions both on strategic and operational level.

Analysis

An adaption of the causal tree model and "5Why" was used to find categories for the identified problems. The purpose was not to find the root cause, instead it was to develop a limited number of suitable categories. Identified problems were then categorised according to closes connected category. The problems were placed in a matrix according to ease of improving and impact on lead time. This was conducted by the authors assessments based on their knowledge about the process from theory, observations and interviews. This concluded in 11 problems with the priority 1 which were then focused on and further investigated. Complementing quantitative data from company archives, observations and information systems were used to validate issues in a triangulating manner. The qualitative problems were compared with the VSMs and quantitative data gathered from archival records. The identified change suggestions were then linked to the prioritised problems and compared with best practice of relevant Lean tools in order to develop recommendations for the process. A FSM was developed with implemented recommendations to illustrate improvements achievable.

2.6.4 Validity

This study used multiple data sources, increasing the construct validity. Problems in the process were identified both by observational and interview data. In collecting data through observations, both authors were always present, contributing to investigator triangulation. Throughout observations, most process times were measured at a sample of 100 times which should be enough to give the measures reasonable utility. However, setup times typically was measured one time only and thus are more likely to show high variation relative to average time measures. Process times including manual work may also vary between different operators, a significant part of the data was based on operator's conduct during observations, results could therefore be skewed depending on who performed the tasks. It is also possible that the observation in itself affected the processing times, causing distraction or behaviour not prevalent in the observed process. In addition, qualitative estimates made regarding process times cannot be totally accurate and would also likely vary depending on situation and respondent. The process maps were validated by employees at Atos Medical and cross checked with internal documents to increase the construct validity.

Regarding interview data, interviewees from all different process steps participated, also including employees with different roles in the company contribute to mitigating biased responses from this data source. Two interviewers were also present during all interviews which should mitigate any interviewer bias. The interviews were recorded in order to review them if needed.

One risk regarding the validity is that in the analysis of this study where the authors own assessment was applied in deciding the prioritisation of identified problems. This could result in not attending to important problems. This way of conducting the analysis was done because Atos Medical wanted a new perspective on the situation at hand.

The single case study does not provide external validity as it stands in a unique context. Any problems and solutions as investigated in this study would naturally not be exactly the same as in another case. However, there may be many similarities which could be explored through replicating studies.

Concerning the internal validity, a theoretical framework was developed, literature used is based on the authors' search strategy and which information was considered useful for this study. Further on, the reliability of this study was upheld mainly by keeping a case study database.

3 Theory

In this chapter, process mapping is introduced and definitions of some of the existing process mapping techniques are presented. A comparison between the different methodologies reviewed are summarised in table 9. An introduction to Lean principles and some of the Lean tools commonly mentioned in the literature follows. The chapter is concluded by the theoretical framework.

3.1 Process mapping

3.1.1 Introduction to process mapping

Process mapping is a method for visualising, analysing and improving processes and several different techniques exist with various applications (Windisch et al., 2013; Fadahunsi and Sathiyanarayanan, 2016; Siha and Saad, 2008). Biazzo (2002) defines process mapping as a graphical tool for showing relationships between activities, materials, information and personnel. Rother and Shook (2001) state that process mapping highlights material and information flows, while Aguilar-Saven (2014) states that it could also focus on roles and responsibilities.

In some research, process mapping is equivalent to a method called flowcharting (Ungan, 2006). The notion of process mapping as a main process improvement approach is well supported (e.g. Siha and Saad, 2008; Ungan, 2006) as well as its ability to align process understanding in organisations.

White and Cicmil (2016) suggest that process maps should not be too complicated if they are to be adopted by the organisation where they are developed, connecting the complexity of the process maps to the method of mapping. Selecting a process mapping technique thereby should be based on the appropriate level of complexity as well as business situation.

Typically, process mapping starts with gaining an understanding of the process investigated (Hines and Rich, 1997). Process mapping is most commonly developed through observations and interviews regarding the concerned process (Greasley, 2006; Martin and Osterling, 2014).

Process mapping requires engagement of everyone working in the concerned process in order to ensure the owners future commitment to the maps and improvement efforts (Siha and Saad, 2008; White and Cicmil, 2016). The mapping activity is most appropriately facilitated by people independent of the processes being mapped, furthering objectivity. This will likely allow facilitators to avoid potential corporate political issues.

3.1.2 Benefits of process mapping

The benefits of process mapping can be concluded as follows:

- Increasing understanding of the process
- Improving visibility
- Increasing communication, responsibility and team atmosphere
- Identifying areas of improvement
- Reduced lead times
- Cost reduction
- Quality improvements
- Increasing process performance

As Fadahunsi and Sathiyanarayanan (2016) suggests, improving processes requires understanding them and how they are perceived. The common denominator of different process mapping methods is the attempt to facilitate an understanding of the current state of the processes (Hines and Rich, 1997). Process mapping has also been shown to enable the acquisition and transfer of knowledge throughout organisations and improving process visibility (White and Cicmil, 2016; Klotz, Horman, Bi and Bechtel, 2008). Along the same lines, improvements in team atmosphere, communication and sense of responsibilities were found in several studies where process mapping was applied (e.g. Klotz et al., 2008; Bowles and Gardiner, 2018). Aikenhead, Farahbakhsh, Halbe and Adamowski (2015) also found that process mapping facilitated the identification of problem areas. Eliminating problem areas with non-value adding activities could enable reduced lead times and cost reductions (Klotz et al., 2008). Further on, Van Assen (2018) show in a survey study that companies working with process mapping have a better operational performance and quality improvements.

3.1.3 Common problems

Common problems in applying process mapping can be concluded in the following bullet points:

- Not defining the scope
- Selecting a suitable method matching the scope
- Not determining the level of detail
- Hesitancy towards investing resources
- Not adopting a process-based view
- Gathering adequate data
- Capture the real state of the process, not a wanted state

Some common problems in process mapping implementation are to not properly define the process limits or the purpose of improvement (Siha and Saad, 2008). Ungan (2006) states that an appropriate level of detail should be determined, guided by the objective of the mapping effort while White and James (2014) highlight the difficulties of deciding the level of detail

when mapping processes. Soliman (1998) categorise process maps as being on a macro or micro level, depending on the level of detail incorporated. Companies tend to seek the most cost-effective way of mapping and detailed maps could reveal waste to a higher degree making the more resource demanding mapping project worth investing in (Soliman, 1998).

In a survey study by van Assen (2018), findings indicate that process orientation or thinking is a prerequisite for process mapping, suggesting that a company which have not yet adopted a process-based view of their business may find difficulties in succeeding with process mapping efforts.

The number of methodologies for mapping processes is increasing and selecting the suitable methodology has become more complex than ever. The guidance of the differences between methods and when to use which methodology is lacking according to Aguilar-Saven (2003). Although, later on Lasa, Laburu and de Castro Vila (2008) introduce a few methods and their applications. Their findings suggest that difficulties in matching the correct method to the scope of process mapping and a hesitancy towards investing a lot of resources seems to be barriers to process mapping implementation within companies.

Martin and Osterling (2014) state that gathering adequate data might be difficult and to mitigate the risk of collecting non-useful data, a well thought-out plan and definition of the scope should be developed. To capture how the process actually performs, the process should be observed. Otherwise, there will be several different versions of how the process is performing.

3.2 Process mapping methods

Some of the methods for developing a process map are described below. The authors recognise the fact that there are other methodologies and techniques for process mapping which are not presented in this study. The methodologies and techniques described are the most recurring and relevant techniques found in the literature review for this study. Figure 5 shows the number of hits for each method in 20 different articles about process mapping. These articles were found during the first search round with process mapping and improvements in the keywords and selected based on relevance to this study. Table 36, Appendix C, presents the articles reviewed and which methods which are mentioned. The methods with two or more hits were selected for this study. Value stream mapping was by far the most mentioned methods, referred to in half of the articles reviewed.

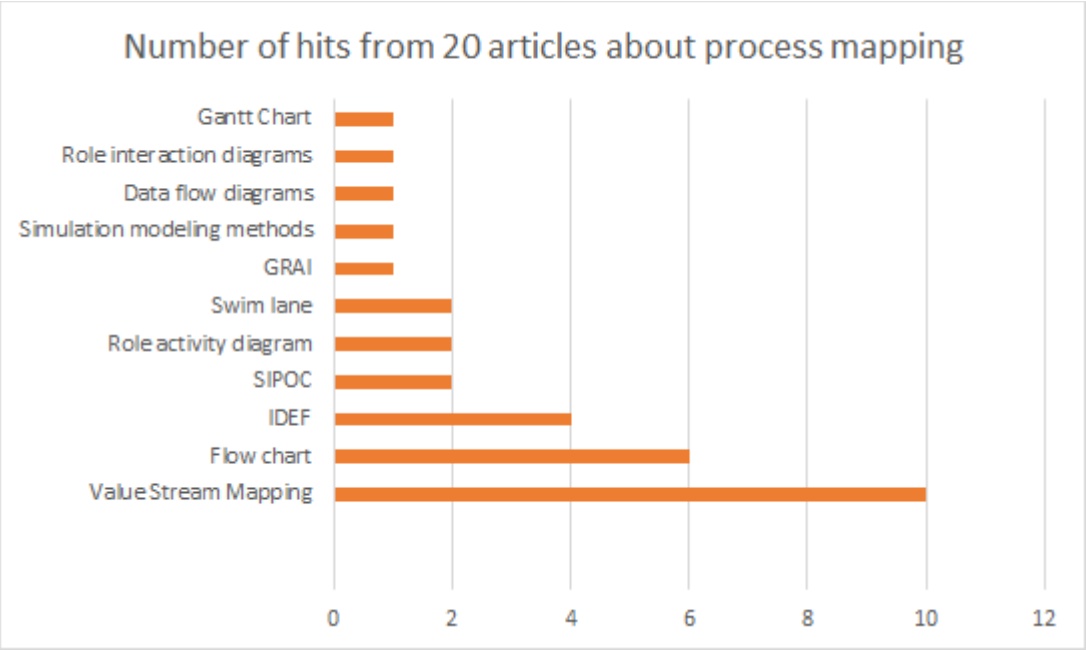

Figure 5 The most recurring process mapping methods mentioned in 20 articles found.

After introducing each method, applicability, level of detail, advantages, disadvantages, expected outcome and barriers are presented which from the literature review are found to be important factors when implementing process maps, the factors were chosen in order to get an understanding of the respective strength and weaknesses of each method. The methods are presented in the order of the level of detail, from the highest to the lowest.

3.2.1 SIPOC

What is SIPOC?

SIPOC is the acronym for suppliers, inputs, process, output and customer (Mishra and Sharma, 2014). As a part of improving processes, SIPOC is a methodology commonly used to analyse suppliers, inputs, processes, output and customers. It is a tool that is beneficial to use to understand the inputs, improve individual processes, develop missions and identify key suppliers, customers and non-value adding processes (Parkash and Kaushik, 2011).

Application

SIPOC diagrams can be used to identify inputs, outputs, bottlenecks, internal and external customers and procurement of resources (Mishra and Sharma, 2014). SIPOC is commonly used for improving and understanding a process within an organisation. SIPOC is a tool to incorporate in Total Quality Management. The method should preferably be used on existing processes that needs improvements rather than for creating new ones, and these processes should involve multiple groups or functions (Parkash and Kaushik, 2011).

Foster (2013) states that SIPOC diagrams are commonly used for Six Sigma projects and could be used when specifications for inputs exist and customer requirements needs clarification.

SIPOC has in several cases been combined with six sigma tools such as Define-Measure-Analyze-Improve-Control and Lean techniques to improve processes. Krishnaiyer, Chen, Burgess and Bouzary (2018) propose a combined model of SIPOC and VSM to sustain process excellence.

Level of detail

SIPOC is a methodology for process understanding on a high level to receive a broad perspective of the design, planning and communication. The diagram is commonly used early in projects to get a holistic view of the process (Krishnaiyer et al., 2018).

Advantages

Parkash and Kaushik (2011) state that SIPOC is a tool for understanding required inputs in order to receive desired result as well as to develop objectives and purposes for teams and to identify non-value added outputs and eliminate them. It is also a method for identifying important customers and supplier relationships that needs improvement. An advantage with SIPOC is that it gives a holistic and lucid view of a process that all departments in the organisation can exploit.

Disadvantages

Since the SIPOC diagram is on a high level it does not display much details leading to difficulties making decisions on an operational level (Krishnaiyer et al., 2018).

Expected outcome

The expected outcome when conducting a SIPOC model is a greater understanding of the process on a high level, and to identify problems as well as key customers and suppliers (Parkash and Kaushik, 2011). The model works as a base for strategic decisions improvement projects (Krishnaiyer et al., 2018).

Barriers

According to Krishnaiyer et al. (2018), the objectives must be clearly stated, otherwise the gathered data might not be what is really needed and a second round of data gathering becomes necessary. An unclear objective could also result in too little information of the inputs and outputs.

3.2.2 VSM

What is VSM?

Originating from mapping techniques used at Toyota motor company, VSM is considered a tool of Lean manufacturing which graphically represent material and information flows (Rother and Shook, 2001). The method also incorporates many Lean techniques and thereby facilitates the holistic Lean philosophy (Martin and Osterling, 2014; Azizi and Manoharan, 2015). Many studies recognise VSM as a good approach towards process improvements within

manufacturing (e.g. Dadashnejad and Valmohammadi, 2018; Yuvamitra, Lee and Dong 2017). Martin and Osterling (2014) offer a definition for value streams as a series of processes that connect and transform customer requests into a good or service, similarly Klimecka-Tatar (2017) refers to value streams as "process flow". Further on, Martin and Osterling (2014) present three different types of value streams: full customer-facing value stream, value stream segment (a portion of a larger value stream) and value-enabling value stream that is made up of supporting processes. Figure 6 depicts a VSM presenting processes in a value stream including metrics. Common metrics used are process times, lead times and WIP.

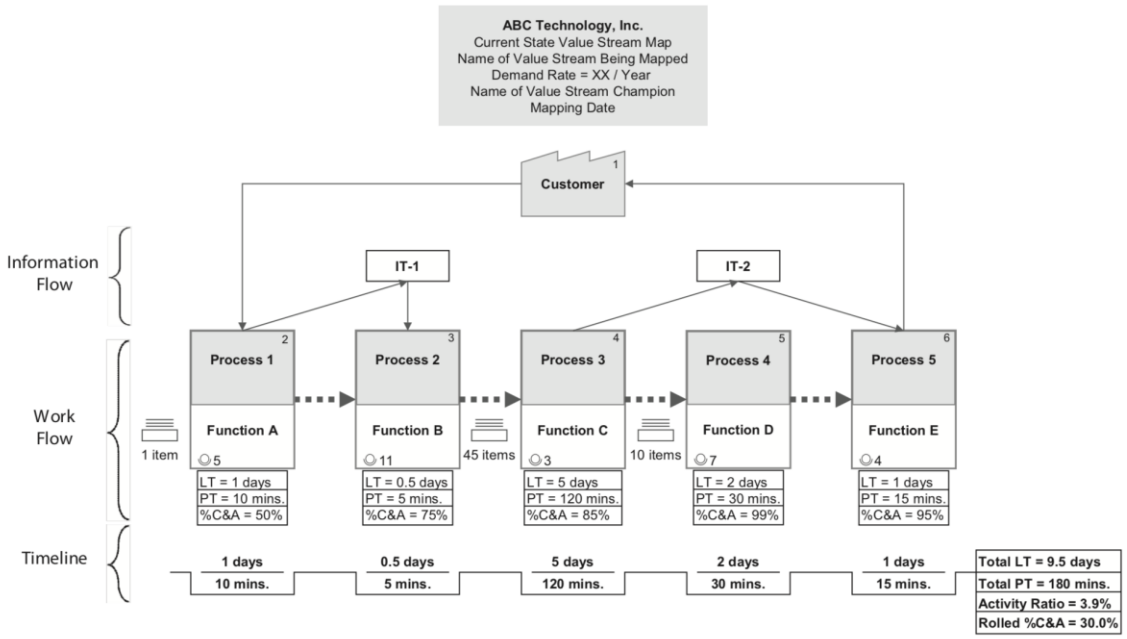

Figure 6 Example of a VSM. Source: Martin and Osterling (2014)

The objective of VSM is to identify and eliminate all types of waste in a value stream while improving flow of materials and information (Rother and Shook, 2001; Dadashnejad and Valmohammadi, 2018).

Hines and Rich (1997) state that waste can be identified by categorising activities as types of operations performed in the process; non-value adding which is unnecessary actions that should be removed, necessary but non-value adding actions that needs to be done but does not add customer value, and value-adding activities that adds value to the products. Waiting time is one example of non-value adding activities while unpacking of deliveries constitutes a necessary but non-value adding activity. Processing time of material as another example is categorised as a value-adding activity.

Rother and Shook (2001) summarise the VSM procedure as simply following the value stream, preferably backwards from customer to supplier and drawing representative figures for every process being part of the material or information flow. Martin and Osterling (2014) argue that

identification of problems and opportunities within a company should clarify which value streams to focus on. Adding that different VSM approaches should be applied depending on whether a company is experienced with Lean methods. Inexperienced companies should work with a value stream that is not too complex, has opportunity for improvement, is visible and has a motivated executive sponsor. Experienced companies are recommended to integrate VSM into their strategy deployment. Martin and Osterling (2014) also suggest that a VSM charter is developed before mapping the current state of the value stream which will aid planning, communication and aligning understanding of the direction forward.

Data gathering regarding VSM is mainly conducted in value stream walks, also referred to as Gemba walks (Martin and Osterling, 2014). Essentially this means going to where the work of the value stream is conducted, making observations, talking to employees within their environment and learning about phenomena that impedes flow. Martin and Osterling (2014) suggest doing a first Gemba walk in order to depict the value streams in process blocks, learning about inputs, outputs and when flow stops in the value stream processes. The second walk will then be conducted to get an understanding of current value stream performance, identify barriers to flow that are significant and unique characteristics of the value stream. Barriers to flow can be defined as any action or condition impeding the work progression. Some examples of this is: batching, system downtime, shared resources, task-switching and prioritisation rules (Martin and Osterling, 2014). Arbulu, Tommelein, Walsh and Hershauer (2003) state that batching also leads to increased lead times in supply chains.

Rother and Shook (2001) recommend that one VSM is applied per product family, meaning products going through similar processes in the value stream. Further on, several authors recognise the need for someone to be responsible over the value stream across company functions (e.g. Rother and Shook, 2001; Martin and Osterling, 2014).

After the current state map is developed a desired future state of the value stream should be mapped, according to Rother and Shook (2001) there are seven Lean principles guiding this, as presented in table 8.

Table 8 Guiding principles for future state development in VSM, adapted from Rother and Shook (2001).

1. Produce according to Takt time
2. Develop continuous flow to the highest degree possible
3. Control production using Kanban system where continuous flow is not possible
4. Send customer orders to one process only, the pacemaker process that sets the pace for the surrounding system
5. Level the production mix in the pacemaker process such that product variations are produced over fixed time intervals.
6. Level production volumes
7. Develop an ability to manufacture every article every day

Martin and Osterling (2014) recommend utilising a prioritisation grid for improvement ideas to narrow the focus of starting out implementation towards a future state. The prioritisation grid would rank solutions according to ease of implementation and impact of solution, the ideas with the highest combined score would then be prioritised. Martin and Osterling, (2014) add that future state mapping efforts should focus primarily on what changes are needed to reach a future state rather than how the changes can be implemented.

Application

VSM has proven its applicability in manufacturing contexts in different parts of the world and has been utilised outside of the manufacturing realm as well (e.g. Dadashnejad and Valmohammadi, 2018; Azizi and Manoharan, 2015; Martin and Osterling, 2014). Aziz, Qasim and Wajdi (2017) suggest that VSM is well suited to apply on simple processes experiencing stable patterns of demand, adding that the static nature of VSM cannot be made to analyse processes where dynamic demand, complex mixes of products or shared resources are present. Lasa et al. (2008) present recommendations for a successful VSM application; have a team ready with roles according to the standardised method (following Rother and Shook, 2001), involve management to a high degree, set aside resources for the monitoring of value stream activities which may take up considerable time, corroborate and simplify data gathering by utilising information systems and training of the mapping team should be done on beforehand with respect to Lean methodology.

Level of detail

This type of mapping provides a holistic, visual way for understanding how work is conducted on a macro level and provides strategic direction for improvements but does not focus on optimising isolated processes (Martin and Osterling, 2014; Rother and Shook, 2001).

Advantages

According to Martin and Osterling (2014) one of the strengths of VSM is the metrics used, working to drive improvement based on time metrics has shown to be an effective approach through Lean methodology. One of the advantages with VSM is that it considers material flow as well as information flow, facilitating the identification of bottlenecks. Martin and Osterling (2014) also argue that VSM reveal clarifying connections between company and customer as well as disconnects, redundancies and unnecessary complications in the value stream.

Disadvantages

There are also challenges recognised with VSM. Given a macro level perspective of VSM, a drawback would be the loss of process details (Martin and Osterling, 2014). Seth and Gupta (2007) point out that the pictorial view derived from the mapping process may not be a correct one and that this could lead to misled conclusions, further on stating that the method only gives a direction for improvement efforts and not addressing how to achieve them. Batra, Nanda, Singhal and Singari (2016) argue that the limitations of VSM is that it does not take into account different routings and flows, making it less suitable to some work environments where work does not move in a linear fashion.

Expected outcome

Martin and Osterling (2014) argue that the expected outcome from a VSM is a visualisation of processes that highlights value-adding processes and bottlenecks. It will provide a greater understanding for employees and provide strategic direction for improvements.

Potential barriers

One common failure according to Martin and Osterling (2014) is companies that use VSM to only define tactical improvements. The decisions should not be on a too detailed level, rather on a strategic level in order to reap the benefits of VSM. Using VSM metrics is important to measure improvements and to understand how processes perform but it can be quite time consuming to conduct measurements.

3.2.3 Swim lanes

What is Swim lanes?

Ezeonwumelu, Kalu, and Johnson, (2016) state that swim lanes is a methodology for modelling business processes by mapping the different process steps and order them by function or department. The inputs and outputs from each activity is not visualised, the focus is on the activity itself and the responsible person or department. Figure 7 shows an example of a swim lane chart.

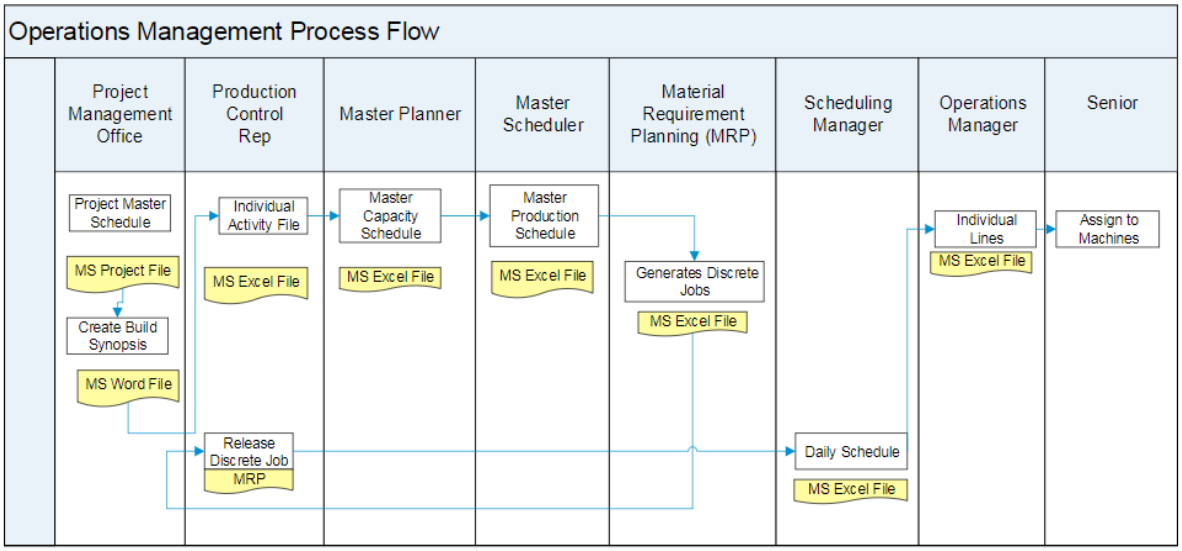

Figure 7 Example of swim lane chart. Source: Krishnaiyer, Chen, Burgess, Bouzary (2018)

Application

Swim lanes are especially useful for understanding and improving information flows but could also visualise material flows. For each step, employees involved in the activity are visualised and the connections between each step enables discovering bottlenecks and establishing who is responsible for the activity (Ezeonwumelu et al., 2016).

Level of detail

The level of detail in a swim lane depends on the creator of the chart, respective knowledge about the process and how it is performed (Aarnio, 2015).

Advantages

Swim lanes are clearly visualising the persons or departments involved in each step of the process (Bowles and Gardiner, 2018). By conducting a swim lane chart, a greater understanding of employee's responsibilities in the process, where and which duties are overlapping and who is in charge of which activity can be visualised (Chen and Cheng, 2018).

Disadvantages

If a process has many steps or people involved, the swim lane map tends to be big and not lucid (Bowles and Gardiner, 2018). The result of the swim lane diagram can be different if several people are contributing to the drawing, which can make it difficult to get an overview of the process since there are no standards for this modelling technique (Aarnio, 2015).

Expected outcome

By creating a swim lane, it will be clear who is responsible for which activities and to identify where potentially overlapping work occurs (Chen and Cheng, 2018).

Potential barriers

There is a risk of missing activities due to the fact that they have not been identified or because of low compliance if the understanding of the process is not high enough and (Aarnio, 2015).

3.2.4 Role activity diagram

What is role activity diagram?

The focus for role activity diagrams is like swim lanes the roles and responsibilities within a process and they are visualised through a graphic view (Aguilar-Saven, 2004). Both Aburub (2016), citing Ould (2005), and Nagesh, Keast and Ceglarek (2014) state that in order to understand the relationship between decisions by different roles and activities in the process, role activity diagrams are a useful technique. Different symbols in the diagram represent the different tasks and roles. Roles are marked as shaded areas while activities are symbolised with black boxes and between these are lines representing how they interact (Aburub, 2016). Figure 8 is an example of a role activity diagram.

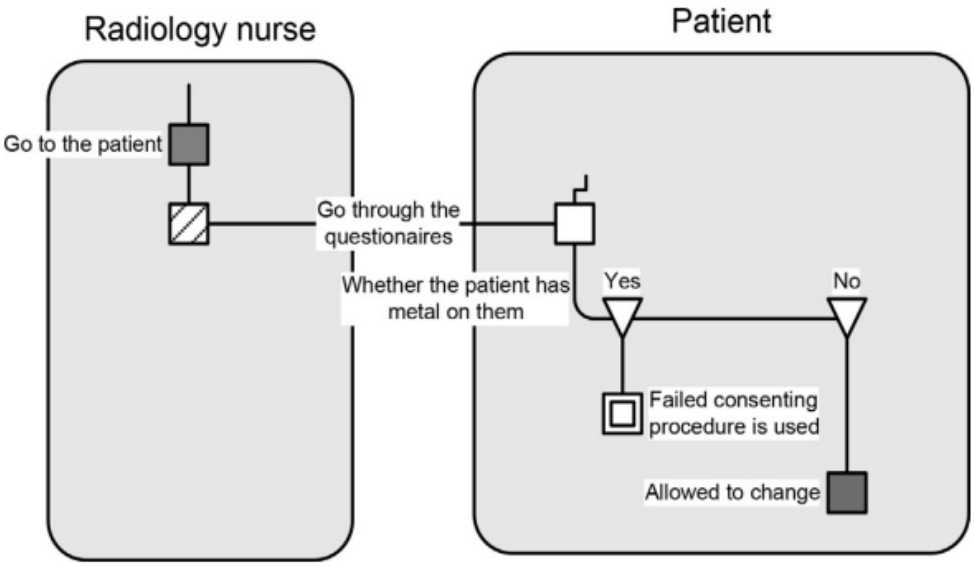

Figure 8 Example of a role activity diagram. Source: (Nagesh et al., 2014)

Application

Role activity diagrams are commonly used in supporting communication and includes software systems, customers and suppliers (Aguilar-Saven, 2004). According to Aburub (2016) citing Ould (2005), role activity diagrams are suitable for analysing organisations functions since it divides the activities in the process to different roles.

Level of detail

The complexity of the diagrams is low while still presenting details. How the roles change state following actions and interactions throughout the process are displayed in the diagram.

Machines and products are not visualised and obtaining an overview could therefore be difficult (Aguilar-Saven, 2004).

Advantages

The benefits of using role activity diagrams is the simplicity of the method and the fact that it makes it easy to understand roles, activities and connections between them. Parallel and collaborative processes are visible as well as multiple interactions between activities or roles (Aburub, 2016; Nagesh et al., 2014). Nagesh et al. (2014) suggests that role activity diagrams could help identify unknown problems and thereby improve the process.

Disadvantages

The role activity diagram could according to Aguilar-Saven (2004) in some cases include too much information. Further on, the model focus on roles and responsibilities but does not typically show how activities behave or interact with each other.

Expected outcome

The expected outcome from a role activity diagram is a detailed description of the process with a focus on the roles and responsibilities. The connections between activities and roles will become clearer and could be a basis for analysing functions in the organisation (Aburub, 2016).

Potential barriers

Aguilar-Saven (2004) suggests that the role activity diagram should not be too complex and detailed, otherwise it will be too difficult to understand and not easily used for process improvements.

3.2.5 Flow charts

What is flow charts?

A flow chart is a representation of an organisational chart, manufacturing process, program logic sequence or a similar process. Each step in the process and the execution order is visualised. Symbols represent different steps, data, direction of the flow and equipment, see example in figure 9. (Aguilar-Saven, 2004; Nagesh et al. 2014). Flow chart diagrams was introduced in 1921 and circles, rectangles or ovals are usually the symbols representing the start and finish of the process.

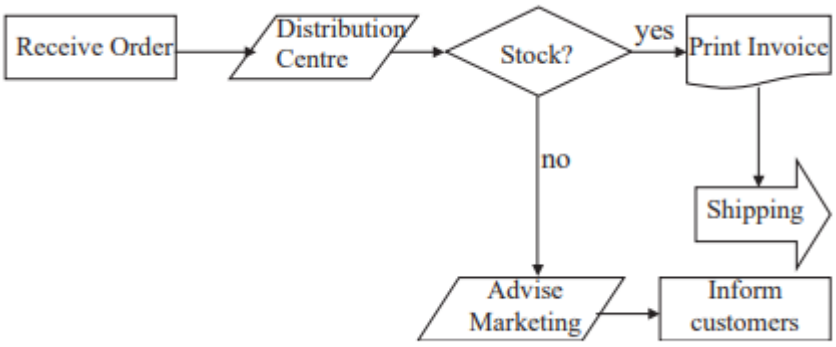

Figure 9 Example of a flow chart. Source: Aguilar-Saven (2004)

Application

The flow chart is a basis for analysis or problem solving but does not provide the opportunity to break down the activities. Identifying bottlenecks and potential improvements are possible when visualizing the process with a flow chart. Connecting the responsibilities with the right role can be a challenge but flow charts are best suitable for processes with many details (Aguilar-Saven, 2004).

Level of detail

Flow charts are usually developed on a detailed level and frequently used for designing programming logic but could be used for other areas as well. The step-by-step logic of the process provides much details and the methodology is mostly suitable for micro level understanding (Aguilar-Saven, 2004).

Advantages

One of the main advantages of a flow chart is that it offers creativity to the designer of the chart and offers a lot of flexibility. It is an easy to use and a fast method for getting a holistic view of a specific process (Aguilar-Saven, 2004). Yilmaz and Yazgan (2018) state that flow charts are easily understandable since all steps in the process are visible and in order of occurrence.

Disadvantages

Some of the disadvantages with flow charts is that they could be too flexible since there are unstructured boundaries and that the navigation can be difficult. This is due to the fact that main activities and sub-activities are presented with the same symbol which can lead to confusion when reading the map (Aguilar-Saven, 2004). Another drawback with flow charts is, according to Nagesh et al. (2014) that parallel activities and collaborative processes cannot be represented. If the process is complex, the model tends to be big.

Expected outcome

The flowchart will provide a detailed map over the steps in the process and ease decision making for improvements on an operational level (Aguilar-Saven, 2004).

Potential barriers

The activities presented in flow charts cannot be broken down which could result in mixed levels of detail. The mapping method could also be too complex and difficult to understand (Aguilar-Saven, 2004).

3.2.6 Integrated Definition for Function Modelling

What is Integrated Definition for Function Modelling?

Aguilar-Saven (2004) states that this is actually a family of methods, most commonly used for business process modelling is IDEF0 and IDEF3. IDEF0 is a graphical representation of a process including major activities, inputs, outputs and mechanisms for each activity on a high level. Arrows show the connections between process steps which are represented with boxes and is structured hierarchically. An IDEF3 diagram is derived to describe processes and presents how things work while IDEF0 diagrams show what is done. An example of an IDEF0 diagram is presented in figure 10.

IDEF1 is used to gather the information a process requires and IDEF2 is used for documenting how the process behaves. The methodology origin from the United States Air Force and IDEF0 is a highly structured method and the one in the IDEF family of methods which is further discussed in this chapter (Fülscher and Powell, 1999).

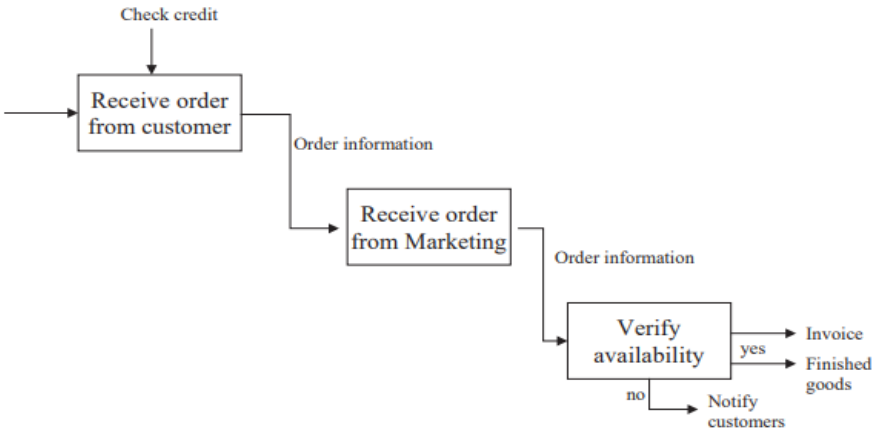

Figure 10 Example of an IDEF0 diagram. Source: Aguilar-Saven (2004)

Application

Since the models are considered to be three dimensional with different layers, they are suitable for complex systems and commonly used by system engineers (Waissi, Demir, Humble, and Lev, 2015).

Level of detail

The hierarchical up-down approach that IDEF0 uses makes it, according to Fülscher and Powell (1999), possible to get an overview rather than getting stuck on a micro level discussing details.

The method could be mixed up with flowcharts at a first glance but is a relatively easy method to learn and use. The method is adjustable considering level of detail to fit the purpose (Waissi et al., 2015).

Advantages

Due to the fact that IDEF0 models are standardised, they are easy to understand and well-structured. According to Waissi et al. (2015) IDEF0 is flexible in the sense that it can easily be modified to suit different conditions and level of details.

Disadvantages

Winch and Carr (2001) state that IDEF0 could be too detailed and complex for non-specialists to understand and that the model does not consider organisational context.

Expected outcome

The expected outcome from an IDEF0 is a structured hierarchical model of the process with many details (Fülscher and Powell, 1999).

Potential barriers

A barrier with the model could be that it does not differentiate value adding and non-value adding activities resulting in no ability to analyse which activities are the most important in order to create as much value as possible (Winch and Carr, 2001).

3.2.7 Comparison between the different process mapping methods

The decision of selecting a mapping method is both important and quite complex, guidance can be sought in the following summary. In the literature there are few other comparisons between mapping methods and none with the same focus on when which method is suitable and why.

There are plenty of parameters to consider when conducting process mapping. The purpose of process mapping is important to consider to match the application of a method, level of detail and the expected outcome of the mapping. The methods have advantages and disadvantages which also needs to be taken into consideration for every situation. With process mapping, there are potential barriers that if known before can be mitigated or avoided.

A comparison of the reviewed process mapping methods presented in section 3.2 and important factors to consider were developed and presented below in table 9. The comparison incorporates the factors and methods highlighted in the literature making it a useful tool for selecting a suitable method for process mapping. The different categories can be seen as tools for identifying weaknesses and strengths with each method.

Table 9 A comparison between different process mapping methods.

Process mapping type	Application	Perspective	Advantages	Disadvantages	Expected outcome	Potential Barriers
SIPOC	Identify customers, suppliers, inputs and outputs	High level	Holistic view Possible to combine with other methods and requires little/no training	Lack of process details	High level understanding Basis for improvements on a strategic level	No clearly stated objectives
Value Stream Mapping	Strategic improvements for cross-functional processes	Flexible	Both material and information flows Time based metrics	Does not incorporate dynamic states or details of processes	Basis for aligning strategic direction Highlighting value-added time and bottlenecks	Applying on a too detailed level Not including process metrics
Swim lanes	Understanding roles and responsibilities Information flows	Flexible	Facilitates understanding of who is responsible for any activity	Customers and suppliers are undefined Can become too big if many components are involved	Increased knowledge about responsibilities and identified overlapping activities	Capturing all process activities

Process mapping type	**Application**	**Perspective**	**Advantages**	**Disadvantages**	**Expected outcome**	**Potential Barriers**
Role activity diagram	Identifying the coordinated behaviour between roles and tasks	Low level	Easy to understand connections between roles and activities	Becomes complex if containing too much information Does not represent interaction or behaviour of activities	Understanding of roles and responsibilities	Mapping on a suitable level of detail
Flow charts	Processes with many steps and details Identifying potential improvements or solving problems	Low level	Offers creativity and flexibility to the designer Fast mapping and easy to understand	Could be too flexible with unstructured boundaries Only one level of process representation	Detailed overview of each step in the process Facilitate operational level decision making	Mixing the level of detail
IDEF0	Software development and implementation	Low level	Standardised method	Too complex and detailed	Structured hierarchical model of the process	Does not distinguish between value-adding and other activities

3.3 Lean

In this section, Lean is introduced through the main philosophy followed by pull production strategies and specific tools. Followed by factors to consider when implementing Lean.

3.3.1 Lean philosophy

The main focus of Lean, derived from the Toyota production system, is to eliminate unnecessary waste (Womack and Jones, 1996; Rohani and Zahraee, 2015; Dhiravidamani, Ramkumar, Ponnambalam and Subramanian, 2017). Lean is widely recognised as an improvement methodology (e.g. Büyüközkan, Kayakutlu and Karakadilar, 2015; Oliver, Schab and Holweg, 2007). Womack and Jones (1996) who popularised the term Lean in their first book, summarise the five principles underlying Lean as:

- Value is defined by the end customer
- Working with value streams
- Making value-adding steps flow
- Employing pull production
- Improving continuously

According to Hopp and Spearman (2008) Toyota developed a philosophy of producing just-in-time with the objective to not produce more than is demanded from the market. Similarly Parry, Mills and Turner (2010) define Lean manufacturing as being characterised by pull production focused on avoiding unnecessary inventory and a constant strive for perfection.

The concept of Lean manufacturing was derived from Toyota's production, but the philosophy is not limited to a certain type of industry, rather it is widely spread and used in many different types of organisations (e.g. Rohani and Zahraee, 2015; Mahendran and Kumar, 2018; Womack and Jones, 1996). To conclude, the commonly applied Lean concept entails a focus on customers and what creates value for them, improvement of the value stream, implementing a pull strategy and a strive for perfection.

Typically, the following seven types of wastes, presented also in table 10, are considered within the Toyota production system perspective: Overproduction, waiting, transport, inappropriate processing, unnecessary inventory, unnecessary motion, defects.

Table 10 The seven types of waste adapted from Hines and Rich (1997).

Type of waste	Description
1. Overproduction	Impeding a smooth flow while inhibiting both quality and productivity. Resulting in lower detection of defects, deteriorating products and too high pressure on workers. Typically leads to unnecessarily long lead times, WIP levels and storage times. Kanban is a method for countering this.
2. Waiting	Waste of waiting occurs both for products and workers when goods are not moving or being processed. Workers that are waiting can conduct maintenance, training or improvement activities.
3. Transport	Essentially all movement within factories could be seen as waste, the objective is usually to minimise movements. Double handling and excessive movements are typical wastes of transport which in turn tends to delay information transfers and increase damages to products.
4. Inappropriate processing	Over-complicating procedures through investments in inflexible machinery is one example, tending to result in poor layouts. Objective should be to use the smallest machine possible to produce according to quality requirements and locate it close to connecting processes. Also pointing to producing bad quality because no attempt towards fail-proofing have been made.
5. Unnecessary inventory	Increasing lead times, inhibits fast problem identification and necessitates more space, and increase storage costs.
6. Unnecessary motion	Regarding ergonomics, movements that are tiring or damaging to workers should be avoided, often leading to poor productivity and quality.
7. Defects	Should be seen as potential improvement areas, rapidly be addressed through improvement activities.

3.3.2 Pull production

To control the release of work according to continuously match supply and demand a pull production system is often employed, as opposed to a push system. There are several methods for achieving this way of working, Kanban system is the most common method connected to Lean manufacturing (Bicheno, 2009). No matter the method employed, the main difference between the systems is that pull systems have a built-in WIP limit which does not exist in push systems. In a pull system the production of a product typically starts when demand arises in a downstream activity while in a push system, workstations produce according to schedule, and

material is “pushed” to the next station, in general a production line controlled through pull instead of push will reduce its WIP levels (Hopp and Spearman, 2008).

Kanban system

Kanban is the Japanese name for card and in the Toyota production system, the name stems from the guiding of material flow by cards, but another type of signal could be used. There is for example the single product Kanban that could be in the form of just empty slots on the production floor. Another type is using production Kanban in combination with transportation Kanban, the former controlling production and the latter controlling the transportation of material between workstations (Bicheno, 2009). Rother and Shook (2001) use the term supermarkets for the stock points existing between workstations that cannot achieve a continuous flow.

The way Kanban typically works is that WIP of all manufactured products are stocked between workstations with no continuous flow, the number of components stocked is governed by a set number of Kanban cards. Whenever a Kanban card is freed up, meaning the quantity of the Kanban card is consumed by a workstation, this triggers an upstream workstation to start producing the same amount, or similarly it triggers a movement for transportation Kanban cards. When all stations have the same procedure, there is (supposedly) always WIP available between workstations, the number of Kanban cards should cover the downstream demand during the lead time of processing material to the next process (Hopp and Spearman, 2008). The fixed number of Kanban cards in a pull production line sets the level of WIP that will not be exceeded (Hopp and Spearman, 2008).

Bicheno (2009) argues that setup time reduction, standardised work, machine downtimes and product defects need to be addressed before implementing a Kanban system. This can be explained by the lower WIP levels implied in a pull system, leading to less buffers in the production line which then does not allow for as much variation in processing times or in market demand. The applicability of Kanban is consequently limited to settings with quite steady production rates and product mix, otherwise production flow will be disrupted, and given that changing card counts can be time consuming it is not desired to do this frequently (Hopp and Spearman, 2008).

CONWIP

Another specific policy under the pull production category is CONWIP, which aims to keep a constant level of WIP in a production line. Spearman, Woodruff and Hopp (1990) explain the method as utilising cards or signals that can be used to achieve this policy similarly to the Kanban system. The difference is that CONWIP cards are not item specific and all WIP variants, in other words components, are not continuously kept in stock throughout a production line. Instead, material is released into a production line based on when it needs to be finished. The CONWIP system rely on WIP in a production line will pile up in front of a bottleneck

which is where it is needed in order to maximise throughput, such that the bottleneck process is not at risk of starvation.

Planning for a CONWIP system means setting the total level of WIP in a production line and keeping an updated release list, possibly automatically generated from the ERP system. Hopp and Spearman (2008) suggest that CONWIP can be combined with MRP and that it can work well if the MRP consider realistic lead times including effects from queueing and batch sizes adapted to capacity. When a product exits the production line, the production planner releases the next item from the prioritised release list. While a FIFO policy should be used to sequence products at workstations, it is possible to expedite jobs between workstations (where WIP is allowed to pile up) by separating them into two different priority categories (Hopp and Spearman, 2008).

Comparison between Kanban system and CONWIP

A comparison between the two pull systems introduced above is presented in table 11. Applicability to different situations, flexibility, WIP cap, how they affect planning and expediting are factors considered.

Table 11 Summary of differences between Kanban system and CONWIP

	Kanban system	**CONWIP**
Applicable	Low variation, repetitive manufacturing. Not efficient for infrequent products. Components should practically always be available.	Repetitive manufacturing with limited number of different product flows.
Flexibility	Not flexible to changes in product mix and demand which entails setting new Kanban levels.	Flexible to changes in product mix and demand, only one setting of card level needed.
WIP cap	All products available constantly leading to higher than necessary WIP levels for high product mix settings.	Low WIP cap achievable by not keeping all products available constantly, trade-off is existing lead time from when demand arises.
Planning	Automatic sequencing of production by planning for one process only, setting the pace for the rest of the line. Setting and maintaining many card levels necessary.	Demands manual prioritisations of orders into a release list but WIP levels only needed to be specified per each production line. Compatible with MRP.
Expediting	Not convenient.	Separate two different product priority groups.

3.3.3 Kaizen

Bicheno (2009) states that Kaizen is the Japanese word for improvement and describe the concept within Lean as continuously improving systems. The focus with Kaizen is the customer satisfaction and that the customers' requirements and expectations are always changing, in order to adapt to that, continuously improving the company is a necessity. Everyone working within a process can be a part of finding improvements, from top-management to operators. Questioning non-value adding activities, finding creative solutions and root-causes to problems are some of the principles of Kaizen.

3.3.4 5 Whys

Identifying the root causes to a problem can be done with a Lean technique known as "5 Whys" which is an iterative process of asking the question "why?" five times (Bicheno, 2009). Sometimes referred to as Ishikawa diagrams, a quality tool, Foster (2013) similarly suggest that these diagrams can aid in lowering the abstraction level of problems adding that too often only symptoms of problems are addressed instead of their underlying causes. Along the same lines, Bicheno (2009) argue that this rather simple technique calls on practitioners to not accept the first answer about a problem's cause, instead seek the origin of the problem and its cause.

3.3.5 5S

The basis for Lean quality and safety can be described with 5S according to Bicheno (2009) which can also be used in other industries and contexts than production (Lopes, Freitas and Sousa, 2015). Rohani and Zahraee (2015) state that the 5S tool aims to provide effectively organised workstations and standardised operations. Bicheno (2009) explain the meaning of each "S" as follows. The first of the 5S stands for Seiri, meaning sort, and refers to classification according to frequency of use and throwing away all things around workstations that are not used. Straighten or Seiton means to place tools and resources on the best spot and all should have their own place. No one should spend time searching for things instead of spending time on value creation. Shine, or Seiso, refers to cleaning as well as moving misplaced tools to their right place. The fourth S stands for Standardise, or Seiketsu, meaning that the company should implement standardised work and procedures to follow the first three S. The last S stands for Sustain, or Shitsuke, and refers to creating self-discipline in order to keep all the 5S by taking own initiatives.

3.3.6 Poka-yoke

The concept of Poka-yoke means to prevent mistakes from happening, or mistake-proofing (Bicheno, 2009; Womack and Jones, 1996). To prevent human errors Poka-yoke automatically controls the process and sends a warning or stops a process if a failure or deviation is noticed. Shigeo Shingo, the developer of Poka-yoke, differ mistakes from defects, since mistakes are unavoidable, but defects will be the results from mistakes once delivered to customer.

3.3.7 Takt time

Hopp and Spearman (2008) describe Takt time as the average time between outputs and state that it is equivalent to a production quota. The basic formula for computing Takt time is: production time available divided by demand over a certain time period. In other words, the Takt time or production quota shows the amount of work that will most of the times be complete for a stated time period. If not enough is produced during regular working hours, overtime is an option to make up for shortages.

3.3.8 Production smoothing

Production smoothing (also known as Heijunka) means levelling production mix and quantity over fixed intervals as to match Takt times (Hopp and Spearman, 2008). Sequencing should be mixed as much as possible to produce smaller batches (Bicheno, 2009). Achieving a mixed model production necessitates flexible production lines with short setups (Hopp and Spearman, 2008).

3.3.9 Pareto charts

One of the tools for prioritising problem solving is according to Foster (2013) Pareto charts, often mentioned as one of the seven quality tools. In fact, the Pareto chart utilises the 80/20 rule saying that 80 percent of problems result from 20 percent of the causes. Singling out the few important causes then would lead to great improvements. Development of Pareto charts start with gathering categorical data, then drawing a frequency chart and finally the tallest bars in the chart should be the focus of improvement efforts.

3.3.10 Implementing Lean

There has been mixed results for companies implementing Lean manufacturing methods (Singh, Garg, Sharma and Grewal, 2010), Womack and Jones (1996) emphasise the importance of adopting a Lean philosophy throughout a company or a supply chain to achieve success. Many examples can be found of reported improvements in lead times, process times and WIP from working with Lean (e.g. Singh et al., 2010; Rohani and Zahraee, 2015; Mahendran and Kumar, 2018).

Ivarsson, Molin, Lishajko, Wiestål and Johnson (2013) conducted a study on Lean implementations at 50 Swedish companies. Only a few companies were regarded successful in that they had achieved a high degree of lean application in combination with a high level of impact. Most of the successful companies had in common that their Lean efforts had been ongoing for a few years, and they focused more on communication, leadership and co-workers as compared to less successful companies. Following a root cause analysis of why Lean efforts of many companies devolve over time, Ivarsson et al. (2013) identify the underlying reason in that companies do not make the main goal of the Lean implementation to improve operational excellence. In addition, the problem arises because the complex change involved in implementing Lean is only addressed on a lower level in the organisation. This means that the

goal of Lean implementation is not strategic and long term which is an issue when working with Lean. Ivarsson et al. (2013) further suggest that part of this issue lies in the measurement systems, if companies do not integrate their target measurements with the Lean effort, leaders will likely lose focus or interest in the effort when other change projects are started. As presented in table 12, Ivarsson et al. (2013) present main factors that determine success and factors that do not affect the outcome of Lean implementation efforts.

Table 12 Different factors and their effect on Lean implementations, adapted from Ivarsson et al. (2013).

Factor	**Significance in Lean implementation**
Consultants and experts involved	No significant effect
Setbacks	No significant effect
Customer focus	No significant effect
Application of typical Lean tools and methods	No significant effect
Continuous improvements and organisational learning	Significant effect
Persistent Lean effort	Significant effect
Employee involvement and target measurements	Significant effect
Integration of Lean into company culture, company structure and	Significant effect

Companies that are successful with Lean tend to follow these principles according to Ivarsson et al. (2013):

- Systematically working with preventive measures with regard to customers.
- Persistence, successful companies typically have worked more than three years with Lean.
- Lasting management commitment, the commitment of top management is based on a clearly communicated view of results desired in a midterm perspective.
- The current situation of operations is aligned and continuously updated in relation to the desired results throughout the organisation, including the way that contributions from all departments are working together.
- Involve personnel in developing performance measurements, have a clear view of the goal and communicate it well throughout the organisation.
- Balancing the management of continuity and change and integrate target management on all levels of the company.
- Continuous result oriented coaching of management.

Management commitment and engagement is also recognised as a critical success factor by Netland (2015), as is training of workers and management in general. Further on, Nordin, Deros, Wahab and Rahman (2010) suggest that the most important factors in Lean implementation are: having a capable change agent, strong management and leadership, effective communication, empowering workers and continuous Lean reviews.

Lodgaard, Ingvaldsen, Gamme and Aschehoug (2016) found that perceived barriers to Lean implementation differ significantly depending on hierarchical levels in the organisation they studied. Where top management considered the tools and practices of Lean as the main barrier, shop floor workers emphasised issues relating to management while middle management identified problems connected to undefined roles and responsibilities, and that no best practices were selected. The results from Lodgaard et al. (2016) indicate that lacking communication of what the Lean implementation means and who is responsible for what, may impede the process. Rafique, Rahman, Saibani, Arsad, and Saadat (2016) found the following barriers important to Lean implementation: management attitudes, Lean company culture, bad employee administration, unbalanced inventory control, worker attitudes, unstable customer scheduling and a lack of finances.

Engagement and communication stand out as especially recognised factors within companies attempting to implement Lean, concerning employees and management alike. In addition, to achieve continuous improvements and benefits from Lean, a strategic and long term effort is likely necessary.

3.4 Theoretical framework

An extensive review of process mapping and different methods as well as the Lean methodology has been presented in this chapter. A conclusion regarding process mapping methods and their applicability in different situations and with different purposes serves to guide the selection of mapping methods in this study. Further on, the Lean methodology and tools reviewed provide a basis for application in different contexts and what benefits and drawbacks are typically encountered.

Applying process mapping in this study, would provide a basis for understanding the current state of the process investigated. As concluded in the summary of mapping methods, the level of detail is important for the selection of method and combining different levels should provide a thorough understanding of the process.

VSM has the advantage of utilising time based metrics, the method is also originally developed for manufacturing industry which should be beneficial in this case, investigating a production process. The focus on reducing lead time in this study further favours the application of VSM which naturally includes this metric. While providing some flexibility of scope, VSM is typically applied on a higher level with no process details but instead allows an overview.

VSM does not capture variability or dynamic states which is a drawback, with the risk of representing overly simplified processes. To include process details, a mapping method with a lower level of detail should be applied. Flow charts are commonly used for processes with many steps and details which arguably would capture the complexity of the process investigated. Flow charts also enable dynamics to be modelled in decision points for example.

While focusing heavily on details with a flow chart map, the overview of a process will be lost. If there are different levels of activities, flow charts have no natural way of differing between them.

The combination of VSM and flow chart was selected in this study incorporating different levels of detail and thereby attempting to work as a basis for operational as well as strategic improvements. The two methods are also suggested to mitigate disadvantages of the other method.

Lean methodology has proven to be an effective methodology for process improvements in many applications in dealing with removing waste to reduce lead times while focusing on the WIP level. There are several tools developed in the methodology facilitating improvement.

To further provide improvements of the process, the two process mapping methods was applied and facilitated the analysis together with some of the Lean tools presented.

4 Empirical data

In this chapter, the empirical data, collected from observations, archival records and semi-structured interviews are presented. The process map in figure 13 shows an overview of the different steps in the process. The flow chart illustrated in figure 22, Appendix D, is based on observations of the production process and presents details of the process steps. Value stream metrics have been obtained from production documents and the ERP system and the VSM with best case and worst case are presented in figure 24-27, Appendix D. Described process steps are also based on observations. Following is problems identified from interviews and observations. From conducted interviews and observations, suggested changes are also presented.

4.1 Current state

The current state of the process was captured through observations, interviews, data from the ERP system and archival records. The observations were conducted by both authors during several occasions and the majority part of process steps was observed where they took place. 14 employees were interviewed and each interview took no more than 30 minutes. Both authors participated as interviewers for all interviews, where information about which problems and suggestions for improvements exist for the production process was focused on.

Due to time limits and a high number of models produced, two types of SV were selected for investigation in this study. In order to investigate differing situations one high volume model and one low volume model was selected. Only the high volume product was observed in the production, but the process steps are the same for the low volume product and process time measured could be used for both types. ERP system registrations served as a basis for selecting the five and two most recent batches for the high volume and low volume model respectively. The batches investigated went from injection moulding of products until finished products. Archival records in the form of production orders was then retrieved of selected batches to provide detailed start and finish dates of different process steps.

4.1.1 Selecting the product models

To select a suitable model for investigation, a Pareto chart of SV models was developed according to section 3.3.9. Figure 11 shows the chart where the percentage of sales per SV model during 2018 is visualised. The data was gathered from the ERP system. The models in the Pareto chart are the highest 17 selling models, each model consisting of different variants. Together the presented products make up 80 % of the product family sales. The top selling model Product A, with variants HV1 and HV2 as per the material number for the final product was then selected to represent the high volume model because it constitutes for the largest part of the sales 2018 for the SV products.

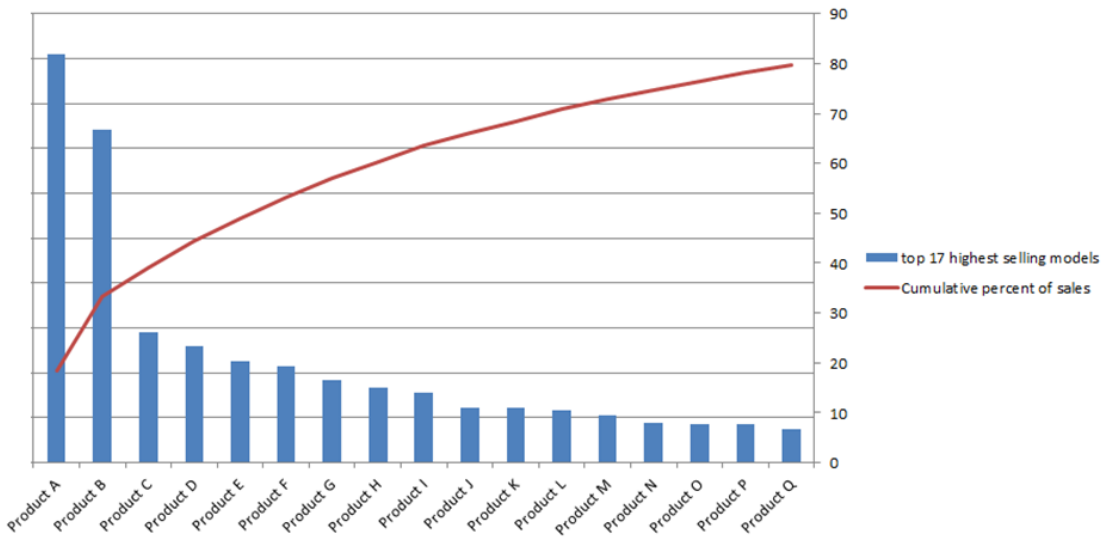

Figure 11 Pareto chart for SV models and part of total sales

The selected SV model's progression through the manufacturing process is presented in figure 12. The figure is based on information from the ERP system and validated by operators. The model produced in the assembly stage afterwards becomes four different types of sterile products and six different final products. In order to limit the process mapping, all types and final products were not mapped. The limit was set after the products are assembled, meaning only one sterile product and two final products. The sterile puncture set has a similar process to the sterile insertion system and was also observed. Although, the puncture set model was included in the detailed flow chart, figure 22, but not included in calculations of the lead time. The components going from Housing to final products, HV1 and HV2, represents the high volume products focused on in this study because the Sterile HV12 products are the most frequently produced products within the Product A family. The low volume model was selected by the company supervisor and production planner. The same chain of products exists for the selected low volume model only with other material numbers, correspondingly product LV1 and LV2 with its subcomponents similar to the high volume model are investigated in this study.

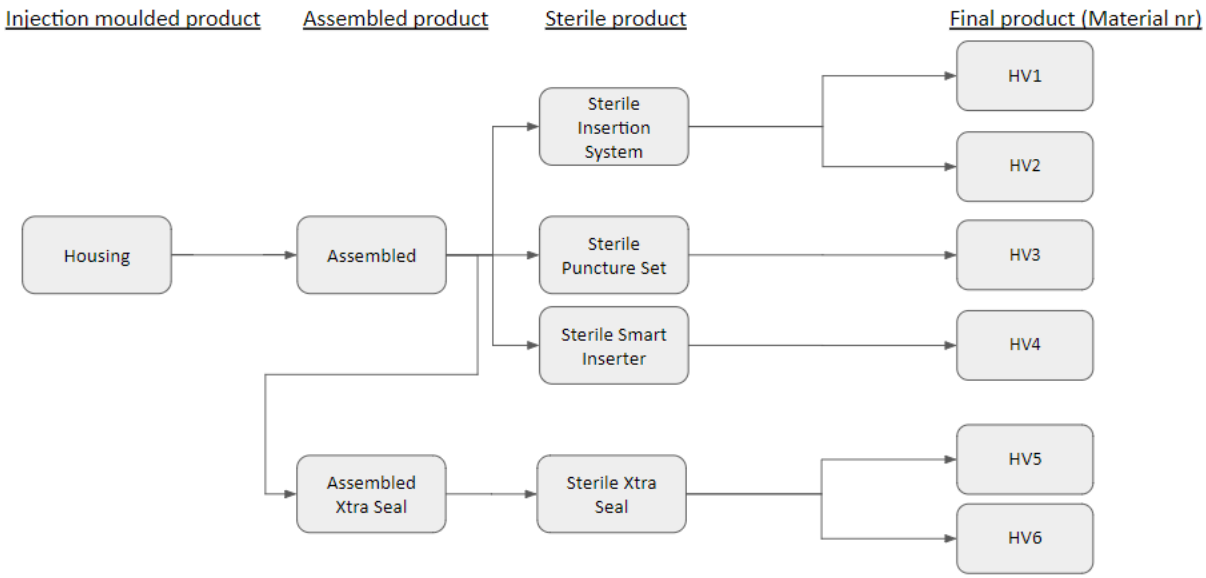

Figure 12 Chain of SV products followed

4.1.2 Sales data

Table 13 shows the sales data for the selected high volume model (product HV1 and HV2), for the low volume model selected (LV1 and LV2) and for all SV products based on 2018 sales, gathered from the ERP system.

The selected models' sales data was used to determine the percentage of the final products represented by the high volume products and the low volume products, since the assembled product can become different finished products. The sales data was also used to determine the annual demand and to further analyse batch sizes and capacity for machines.

Table 13 Sales data for the selected models and total sales of SV products 2018. The data is approximated.

High volume product	**Total sales**	18 000 pcs
	Sales of products HV1 and HV2	4 000 + 5 000 pcs
	Product HV1 and HV2, percentage of the total sales	50 %
Low volume product	**Total sales**	180 pcs
	Sales of LV1 and LV2	40 + 80 pcs
	Product LV1 and LV2, percentage of the total sales	67 %
All SV final products	**Total sales**	71 000 pcs

Product HV1 and HV2 constitutes 50 % of the total sales for the high volume products, with and annual demand of 9 000 pcs. Product LV1 and LV2 constitutes for 67 % of the total sales for the low volume products, with and annual demand of only 120 pcs.

4.1.3 Process overview

In order to provide a visualisation of the process investigated, an overview of the current state of the process is presented in figure 13, as a VSM without metrics. This is on a high level, illustrating the different departments as process blocks and in what order the production steps are performed. The figure is based on observations and showing the higher level process blocks identified. The blocks are selected because WIP levels are situated between these process steps.

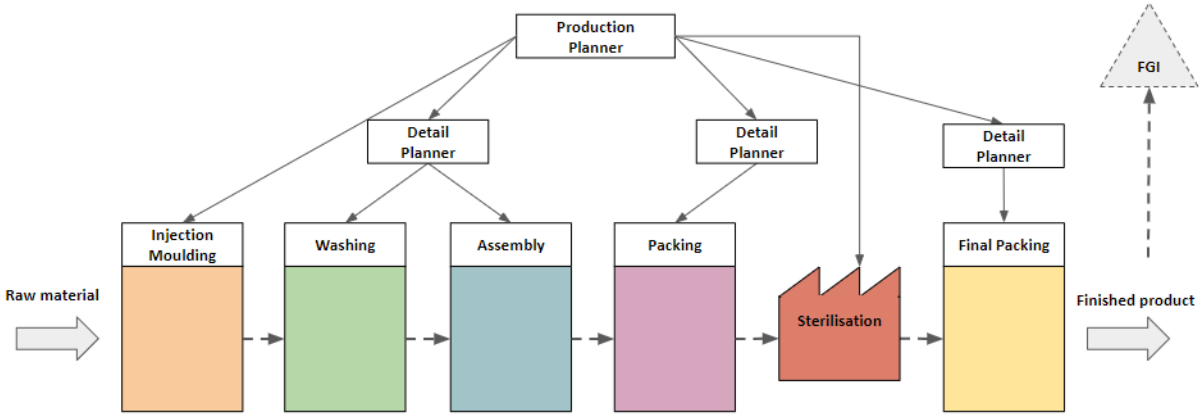

Figure 13 The current state of the production process visualised in a VSM without metrics.

Raw material is firstly injection moulded, then washed and assembled. The packing is then conducted before the products are sent to sterilisation. The sterilisation is conducted by an external company and thereby has another shape in the process map than the production steps performed internally. After the sterilisation, the products are packed and placed in the finished goods inventory, marked as FGI in the process map. The customer for the studied process is the finished goods inventory, meaning it is an internal customer. Planning is an overreaching activity conducted for all process steps.

4.1.4 Description of current operations

In this section, a description of the process steps and the overreaching planning in figure 13 is presented to illustrate the scope of the process. The descriptions are based on the process observations conducted.

Injection moulding

The first process step, transforming raw material into desired shapes, is conducted by a few larger machines, each dedicated to specific kinds of material and products. The SV housing products are produced in one machine, taking up an estimated 66% of used machine hours. The machine is currently not fully utilized, if no breakdowns happen, the machine can run 24 hours per workday. Batches that run over more than a workday can produce regardless of operator supervision. There are two teams of operators conducting these process steps, where the first team prepare the injection moulding machines and start up the machine, ensuring that output is according to specifications. Afterwards, machine operators hand over the responsibility of the batch under production to another operator. The new operator continuously inspects samples of the production following a set interval for the product type concerned. Should any defects be detected in the process, tools are adjusted and repaired in order to fix the issue. After the whole batch is finished in the injection moulding machine, all products are inspected according to specification drawings. The inspections might take place during the production if there is a shortage of products downstream in the process. After inspections, products are moved to the assembly department where they are prepared for the next process step.

Washing

After the injection moulding, SV housing products are washed. Typically washing is conducted within a few hours of arrival from the injection moulding department. One operator performs this process where specific equipment is used for washing that has a set process time, afterwards products are rinsed and moved to a drying area.

Assembly

The housing of the SV is assembled together with other components. The SVs are then processed and inspected before tests are conducted. Two product tests are conducted in the same department as the rest of the assembly, while a third test is conducted in the R&D department. After the SV products have passed testing, they are counted, rinsed, dried and passed on to the packing station. All steps are manually performed and documented with some machines and equipment as aid. In the assembly process step, operators work mainly one shift per day of eight hours, but individual employees may work during the afternoon and night instead.

Packing

Firstly, the packing operators add several components to the assembled SV. SV products are then packed and sealed by a welding machine. The puncture set SV models that are inserted during surgery is punched after the welding machine, with a cooling delay of half an hour. Then products are tested and get packed onto a pallet.

Sterilisation

The SVs are currently sterilised and approximately one shipment per month is sent to a sterilisation facility in Germany. The transportation and the sterilisation process in total take about four weeks. The facility is an external organisation supplying the service for Atos Medical. Sterile SV products make up the majority of the SV product family. Upon return, sterilised products are moved to the quality control department for inspection before moving on to final packing.

Final packing

The final packing of the SV is mainly conducted on a manual assembly line where two employees collaborate. Manuals and components are put together with the SV in a box, weighed to confirm that the right components are in the box and labelled with the material number, batch number and expiration date.

Planning

The production planning requires a lot of manual decisions. The overall planning is conducted by one employee who plans the production on a weekly basis. When the weekly planning is done, the production planner walks to the different departments in the production that plan out the detailed schedules, and hands them the schedule for the next two weeks.

Due to long lead times, the forecasts are uncertain which in turn affects the planning. This makes it difficult to match the supply of products to the market demand. Prioritisation of orders are continuously altered when demand differ from forecasts. The changes in prioritisations means that the production planner delivers updated production priorities daily to the detail planners and in turn make their own changes and prioritisations.

Standard batch sizes vary between process steps in production, the injection moulding produces the largest batches. However, several different product variants are derived from these batches, in assembly, packing and final packing the batch sizes are significantly smaller.

4.1.5 Flow chart

To more in detail show the different manufacturing steps, a flow chart was developed, depicted in figure 22, Appendix D. The basic outlines for flow chart based on Chapin (1970) and presented in table 37, Appendix D as well. The flow chart is based on observations but a few process steps, like the sterilisation, was instead explained to the authors by operators. To increase the credibility, operators from different departments validated the flow chart.

The input for the process is raw material and the output is finished products. The boundaries are set from processing of raw material in the injection moulding stage, until finished products are placed in the finished goods inventory. External suppliers are thereby not a part of the process, similarly the customer is internal and the process does not include the warehouse operations or deliveries to external customers. As visualised in the flow chart, there are many different production steps and many different departments involved in the production process.

4.1.6 Value stream map

Introduction

VSMs with a higher level of the production process than the flow chart was developed based on observations and archival records. The VSMs was conducted in line with the theory in section 3.2.2. Process times presented in the maps are based on observations and represent the time to process standard batch sizes. The majority being based on direct measurements while a few are based on estimations by employees working in the process. Lead time metrics included in the VSMs are based on a few selected batches of each product. The batches with shortest and longest time from start until end in the process was selected as per registrations in the ERP system. Archival records were then investigated regarding selected batches to represent the lead times. Estimated WIP levels are based on the waiting time and the assumption of a steady production (and demand) rate. Thus, they reflect the waiting time multiplied by demand rate. The total lead time exceeding total process time can be categorised as either waiting time between process steps or waiting time in process steps. The complete VSM with metrics are shown in figures 24-27, Appendix D.

Metrics

Table 14 illustrates the key metrics from the best and worst case for both the high and low volume products, meaning the shortest and the longest lead times observed respectively. The process times are collected from the VSMs in figures 24-27, Appendix D, and based on observations. The lead times are gathered from the ERP system and internal documentation. The table shows the actual process time and how much longer the current lead time is, even for the best case found. The times presented in table 14 are used in the analysis for comparing the lead time for the alternative changes.

Table 14 Summary of the VSMs metrics.

Model	**Process time**	**Lead time: Worst case**	**Lead time: Best case**
High volume	38,3 days	223 days	92 days
Low volume	26 days	716 days	112 days

Using the process times per batch shows that for the best case, 42 % of lead time is represented by process time for the high volume model and 23 % for the low volume model. Similarly for the worst cases, process time make up 17 % of the high volume lead time and 4 % of the low volume model.

In table 15 below, average lead times have been calculated for product “HV1”, “HV2”, “LV1” and “LV2”. Average lead times are based on the selection of batches as stated in table 38 and table 39, Appendix E, which are based on ERP system data and internal documents.

The presented average lead times show when compared to the worst and best case measures in to what extent the latter measures are skewed from the average, when including all batches investigated.

Table 15 Average lead times for the products under study based on the same starting batches as the VSM, see table 38 and table 39, Appendix E for details of registered dates used.

Product	**Average lead time**
HV1 and HV2	142,5 days
LV1 and LV2	461,5 days

Subtracting the process time for each model, as presented in table 15, show that on average the high volume model is spending 104,2 days waiting in the production process before moving to the finished goods inventory. For the low volume model the same measure is 435,5 days. The time spent waiting is for these products substantial when comparing to the process times and thus indicating there is a lot of room for improvement.

High volume model

For the high volume model worst case, the injection moulding batch had a size slightly larger than the standard and the lead time was significantly longer than the process time. The best case had a batch size smaller than half of the standard size and the lead time was only one day longer than the process time.

Washing is the fastest process step with a machine that has a capacity of 2000 housing products at a time. Between the washing and the assembly substantial amounts of WIP is gathered, with waiting time reflecting that.

Packing has a shorter process time than the assembly and the waiting time between these process steps are zero days for the worst case and eight days for the best case. This shows that the individual lead times for each process step might not be the best or worst even though the total lead time is. The lead time for packing is almost the same as the process time both for the worst case and best case.

The waiting time between packing and sterilisation might not be represented as an average since the products are sent to sterilisation once a month and the waiting time for a single batch could be anything between one day and one month. How often the products are sent to sterilisation depends on the cost versus benefits. Atos Medical's products are small and the volumes sent to sterilisation are low, making it expensive to send even lower volumes more often. Both the best and worst case has a significantly longer lead time than process time in the final packing.

Low volume model

For the low volume model, in figure 26, Appendix D, showing the worst case for the low volume products, this is visualised with 603 days of waiting time before the batch was assembled. The best case has few waiting days between process steps but a long lead time in the assembly and the final packing. The batch sizes in both the best case and the worst case were larger than the standard batch size in assembly but more accurate compared to the standard batch size in the rest of the process steps.

4.1.7 Process capacity

In order to find out if machines constitute bottlenecks in the process, the capacity of machines in the process were calculated with different average weighted batch sizes. Larger batch sizes are likely to impede the flow of products. If machines constitute a capacity constraint, batch sizes will directly affect throughput of products. Table 16 below is used to analyse this issue in chapter 5.

Observed time measurements are used in table 16 in order to estimate the annual capacity of specific production machinery. The table compares how different average weighted batch sizes would impact capacity of these machines given that there are always employees ready to work on the machines during work hours.

The basic formula used for calculating annual capacity:

$$\frac{\text{Workdays per year} * \text{Batch size} * \text{Available machine hours per day}}{\textit{Run time } (h) + \textit{Setup time } (h)}$$

Eight hour workdays, 250 days per year are assumed for machine availability. Run times and setup times for the different machines are based on observations. Utilisation rate of 75 % for the step 14 is used as an example to show the potential capacity rate. The steps and test in table 16 are from the flow chart, figure 22, Appendix D.

Table 16 Total annual machine capacity assuming only Housing, Assembled and sterile products are made, subject to weighted average batch sizes. Considering only the machines indicated to be bottlenecks from observations, based on 250 workdays in a year.

Batch size:	**100**	**500**	**1000**	**4000**	**8500**	**10000**
Injection moulding (step 2)	Annual Capacity: 74 250	Annual Capacity: 176 435	Annual Capacity: 213 412	Annual Capacity: 469 943	Annual Capacity: 634 744	Annual Capacity: 637 637
Washing machine (step 6)	Annual Capacity: 81 817	Annual Capacity: 409 090	Annual Capacity: 818 180	Annual Capacity: 2 288 741	Annual Capacity: 2 571 428	Annual Capacity: 3 025 209
Assembly (test 1)	Annual Capacity: 411 428	Annual Capacity: 483 220	Annual Capacity: 496 551	Annual Capacity: 505 262	Annual Capacity: 506 692	Annual Capacity: 507 042
Assembly (step 14)	Annual Capacity: 216000	Annual Capacity: 216000	Annual Capacity: 216000	Annual Capacity: 216000	Annual Capacity: 216000	Annual Capacity: 216000
Packing (step 19)	Annual Capacity: 201 116	Annual Capacity: 204 778	Annual Capacity: 205 244	Annual Capacity: 205 596	Annual Capacity: 205 656	Annual Capacity: 205 714
Final packing (step 28)	Annual Capacity: 106 666	Annual Capacity: 117 391	Annual Capacity: 119 008	Annual Capacity: 120 250	Annual Capacity: 120 471	Annual Capacity: 120 502

From table 16 it can be concluded that the capacity is depended on the batch sizes in specific machines and in some not that sensitive. The annual capacity would in all cases cover the annual demand, which is 71 000 pcs, as seen in table 13.

4.2 Observed problems

In order to identify where improvements can be made, problems were noted during observations. Several problems were identified and they are described below, reflecting the authors' perception of the current situation of the production process. The mentioned steps and test are from the flow chart in figure 22, Appendix D. The problems from interviews together with the observed problems are categorised and prioritised in chapter 5.

Planning

The production planning is manual and time consuming. Only one production planner is employed whom the organisation is dependent on since a lot of knowledge regarding the planning process is not documented, it is information that the production planner just knows by experience. This makes the organisation susceptible to risk, if the individual is sick, on holiday or similar, planning of production will not work efficiently. The planning in each process department is also dependent on detail planners who are the only ones having knowledge of how the planning for each process step is conducted.

Throughout the process, as depicted also in figure 24-27, Appendix D, there are substantial levels of WIP waiting between process steps. The production operators do not necessarily work on the same batch all day, some process steps require processing which does not necessitate constant attention from operators and sometimes the operators assist each other.

Reprioritisation, or expediting, is perceived to be a result of the current inventory levels being lower than set safety stock levels. Production planners need to expedite orders whenever the sterilisation shipment date is approaching and specific products need to be on it to cover demand. There are also occasions when detail planners need to prioritise a certain type of SV but lack components from upstream process steps, creating a delay in the production of needed products.

Equipment

Some of the problems observed are linked to the equipment in the production process. There is, in several production stages only one machine that Atos Medical is dependent on. If those particular machines break down, the whole production would stop. External technicians handling some machines are based in Switzerland meaning that time to repair will be long. If machines or other devices experience problems, the prioritisation is not always on the production of SV and the time before internal technicians has time to fix problems is often long.

Many machines are old and slow, which may impede the production flow and since much of the equipment require manual work, the risk of mistakes due to human errors are larger and output results vary substantially.

The manual work also cause discomfort for the operators since many of the work activities are perceived to be unergonomic. Allergies or repetitious work activities can be reasons for the operators to not being able to perform certain activities, leading to limited number of operators who can conduct the activity.

Another identified problem is that some shared tools are difficult to locate and unnecessary time is spent looking for these. Due to the fact that materials are stored in different parts of the production, unnecessary transportation occur when the operators have to walk around the production to gather materials and tools or search for equipment.

There are some steps in the process where machines are potential bottlenecks, e.g. the machines used for packing, test 1 and test 2. Another example of this is that both the assembly and the injection moulding process steps utilise the washing room which can only handle one batch at a time.

Documentation

Documentation and traceability are important in the medtech industry but all steps in the production are manually reported, which is time consuming. Complete inspections are performed throughout the production process taking up a lot of time from resources.

Another problem with the documentation is that results from tests in the process are written down, but the results are just archived and the data is not utilised. The data is intended to be used for statistical analysis but as of now it is not.

Work activities

The test 2 is conducted in the R&D laboratory which means that the operators have to walk from the production to another department in the facility. Not all operators are trained to conduct the test 2 and each result is written down manually. Then they are transferred back to the production where the production leader manually writes the result into a computer, performs a statistical analysis and makes a decision based on this, approving the batch or not. The documentation is then put in a box back to the operators but it is not certain that they check the box exactly when the decision has been made and the waiting time for the batch increases. That process is complicated and demands that at least two people that can time their actions in order for the products not to be delayed.

Setup times are significant in some process steps such as injection moulding, washing and step 22. Typically this will lead to higher batch sizes and impede the flow of products.

Defects

In assembly and injection moulding there is noticeable amounts of defects which vary a lot between each batch. The uncertainty of defects makes the outcome of each production step difficult to foresee. In some process steps using a different material would reduce defects but it

cannot currently be obtained from suppliers. Many defects can occur with the products and specifically defects that have not occurred before are difficult for inspection operators to notice.

4.3 Problems identified from interviews

In order to further capture the range of problems existing in the production process, interviews were conducted. Interviews were held with employees from different departments. Both observing the process and interviewing employees about problems served as methodological triangulation.

The interviewees were categorised into either management or operators showcasing the balance between hierarchical perspectives represented. Interviewees and categories are visualised in table 17. From the table it can be concluded that half of the interviews fall into the management category and half of them in the operator category.

Table 17 The different roles of the interviewees.

Title	**Number of interviewees**	**Source name**
Production and Process Leader	1	Management
Process Manager	1	Management
Production Team Leader	2	Operator
Production Operator	4	Operator
Logistics Operator	1	Operator
Manager Operations Controlling	1	Management
Production Leader and Production Planner	1	Management
Process Leader	1	Management
Senior Vice President Operations & Quality	1	Management
Director Production, Operations	1	Management

The identified problems from interviews are stated below in table 18. Some problems were identified from several interviewees, some by both management and operators. Some problems identified are more general for the whole process and some are more specific or technical. All problems identified during interviews are presented in table 18 to visualise the broad spectre of the problems. The problems from interviews together with the observed problems are categorised and prioritised in chapter 5.

Table 18 Problems identified from interviews.

Problem	**Source**
High WIP levels	Management
Dependent on detail planners and production planner	Management
Detailed and manual planning	Management
Capacity: recipes are not correct in the ERP system. Suggestions automatically derived in ERP system are not always correct. Possible to make unlimited work releases in ERP system even though capacity may not match	Management
Safety stock levels lagging - leading to a list of prioritised products being necessary for expediting.	Management and Operator
Batch sizes does not match the different steps and becomes unsynchronised	Management and Operator
No clear communication between departments or hierarchical levels	Management and Operator
Personnel does not know what is allowed, who is authorised to do what and where, and no direct information	Operator
No changes are made, perceived as difficult and not prioritised as daily work takes up all time	Management and Operator
Too few personnel and increasing product volumes	Operator
Lack of resources from technicians and maintenance	Management and Operator
Dependent on old, manual and time consuming machinery that may break down.	Management and Operator
Picking errors in final packing	Management
100 % inspections in many steps	Management
Not enough structured operation method	Management
Production processes are not ergonomic. Personnel cannot perform all production steps.	Management and Operator
Specialised roles leading to vulnerability	Management and Operator
Unnecessary distance/transportation	Management
Small batches lead to a lot of scrapping for product testing	Management
Product defects	Management and Operator

4.4 Suggested changes from interviews

The suggested changes from the interviews are presented in table 19. The change suggestions were gathered with the purpose of mitigating identified problems in the process. The suggested changes are presented with respective category of interviewee making the suggestion. The mentioned steps and test are from the flow chart in figure 22, Appendix D. All suggestions are presented in table 19 and serves as basis for selecting the changes that are relevant to the highest prioritised problems in chapter 5.

Table 19 Change suggestions from interviews.

Change suggestion	**Source**
Replace air jet cleaning	Operator
Implement a VSM in order to get an overview of production measurements such as lead time and value-added time	Management
Becoming less dependent on forecasts	Management
Optimise the planning of production through more efficient batch sizes or Kanban system	Management
Improve visibility of the production capacity and utilisation rate in the information system.	Management
Restoring safety stock levels of production as set in the ERP system	Management
Update the process times in the ERP system and show production capacity there	Management
Implement a higher degree of digitalisation in the production planning	Management
Implement a higher degree of digitalisation in the production	Management
Simplify production steps and remove unnecessary process steps to simplify planning	Management
Remove inspections, step 3, conducted after injection moulding	Management
Investigate if sterile products need to be sterilised	Management
Problems are dealt with and projects finished regarding equipment	Operator
Materials are available at all times	Operator
Improve the test 1 and test 3 to be more ergonomic and effective	Management
Replace old machines	Management
Move the test 2	Management
Move machine used for step 5 closer to production	Management
Replace family tools in injection moulding	Management
More focus on work training	Management
Sign-offs on all documentation	Management
Work in a more structured way, employ easy to understand work descriptions for all things.	Management
Be more thorough regarding and prioritise maintenance work	Management

Simple solutions in the assembly and packing, prioritise these processes more	Operator
Label everything in final packing such that no error are made there and enable automation	Management
Continuously check parameters in the ERP system and update batch size policy	Management
More communication and collaboration between operators and other departments to utilise all knowledge and competence, make sure other departments go into the production and help create a team spirit between departments as well	Operator
Merge to one group in the assembly and packing teams to facilitate flexibility of employees to work where mostly needed.	Operator

4.5 Suggested changes derived from observations

Observations also resulted in a number of ideas which possibly could improve the current operations, identified by the authors. They are based on the observations and all problems identified. These suggested changes are listed below. The mentioned steps and test are from the flow chart in figure 22, Appendix D. The changes relevant to the highest prioritised problems are listed are further discussed in section 5.4.

- Outsource all punching work to suppliers
- Stop counting products before step 17
- Run test 2 and analysis of the test 2 in parallel with test 1
- Install a computer where the test 2 is conducted
- Conducting the test 2 and analysis should be done by the same person
- Install a rack to use for test 3
- Increase capacity in order to restore safety stock levels
- Plan to utilise bottleneck operations to maximum
- Perform a 5S initiative
- Limit number of released work orders in the production
- Is it enough to just see if all the SV are approved? It is not possible to track a single SV anyway, regarding manual documentation of the results from test 1
- Organise work stations more in an assembly line like structure
- Skip rinsing the SV in ionised water before ethanol, eliminate an unnecessary step

A combination of the employees and the authors' perspective of the process and current problems provides as a basis for analysing and identify all of the most important problems. Using more sources should improve the validity of the data. Many of the suggestions are operational and some tools from theory are applicable. The derived suggestions are affected by the authors conduct and previous experiences.

5 Analysis

In this chapter, the problems identified during observation and interviews are categorised and placed in matrices in order to obtain the most important problems according to ease of improving and impact on lead time. The suggested changes derived from interviews and observations are discussed and linked to the relevant problems. Both types of process maps are analysed and a future state of them is presented in figure 20 and figures 28-31, Appendix F. The chapter is summarised with results and recommendations for Atos Medical.

5.1 Categorisation of the problems identified

In order to categorise the range of problems identified from interviews and observations, a variant of the "5 why" method was applied to find suitable categories. The answers to the "Why?" questions concluded from a brainstorm session with the two authors. "Why are there long lead times in the process?" was the first question which was broken down into waiting time and process time under factors stage 1. The same question was then posed about process time and waiting time. The concluded factors stage 2, driving process time and waiting time, was based on the previous observations as well as identified problems. The factors presented in column 3 of figure 14 thus reflect the authors' perception of key factors for the process time and waiting time. The factors stage 2, were then differentiated into the five overreaching categories shown in the fourth column in figure 14. Similarities on a higher level among the factors were the basis for choosing the categories. The five categories were selected in order to sort the many identified problems under a few categories, thereby clarifying where they exist on a higher level and thereafter to prioritise them. Figure 14 illustrates the process of how the different categories were decided.

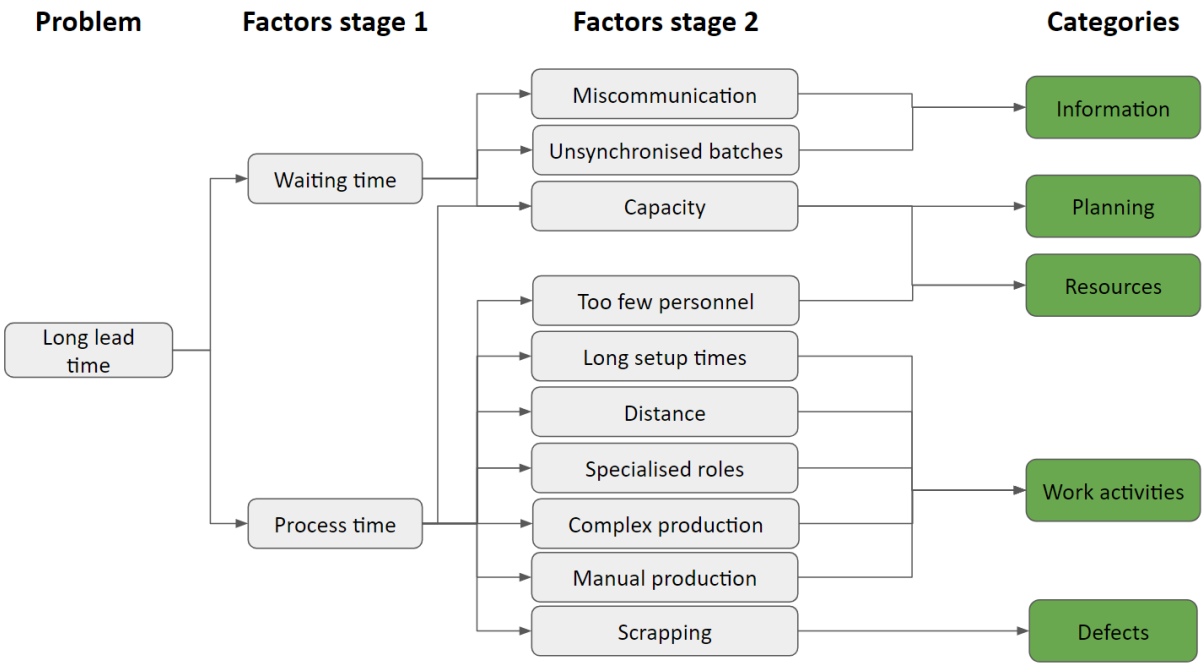

Figure 14 The causal tree leading to categories for the identified problems.

According to the authors' assessment of the process observed, waiting time depends on miscommunication, unsynchronised batches and capacity. Process times are estimated to be driven by too few personnel, long setup times, distance, specialised roles, complex production, manual production and scrapping. These factors are then categorised into information, planning, resources, work activities and defects.

5.2 Prioritising problems

In order to limit the number of problems to address in this study, identified problems were prioritised. In sections 5.2.1-5.2.5 below, all identified problems from section 4.2-4.3 are categorised into the five categories from figure 14. The related problems in each category are listed in table 20-24. They were categorised based on what the problem mostly affects.

An adaption of a prioritisation grid stated by Martin and Osterling (2014) was applied in section 5.2.1-5.2.5 by placing the problems of each category in matrices with lead time impact on the x-axis and ease of improving on the y-axis, presented in figures 15-19. Ease of improving is the effort needed to mitigate the problem. The purpose of the matrices is to prioritise the problems within each category identified as to decide which ones are most suitable to focus on. The prioritisation in the matrices was conducted by the authors' own assessments.

The two lines in the matrices divides the matrices into three categories, priority 1, 2 and 3. The problems which are either easily improved or has a big impact on the lead time are prioritised as the most important for this study. These prioritisations are based on the authors' prior knowledge, observations and the VSMs. The problems in priority 3 are problems with low impact on the lead time that are difficult to improve, while the problems in priority 2 are easier to mitigate and/or has higher impact on the lead time. The problems which are most suited to address according to the authors are problems with priority 1 and those are listed in section 5.3. The impact on lead time is important but it still has to be somewhat easy to improve. Further on, these problems were matched with improvement suggestions that the authors consider to be relevant and analysed based on current state of operations and the theoretical framework.

5.2.1 Planning

Table 20 shows the problems identified from observations and interviews that are categorised as planning which is one of the five categories presented in figure 14. Next to the problem, the sources are presented. The problem number corresponds to the circles in figure 15, where the problems are prioritised.

Table 20 The identified problems regarding planning.

Problem number	**Problem**	**Source**
1	High WIP levels	Management and Observed
2	Dependent on detail planners and production planner	Management and Observed
3	Detailed and manual planning	Management
4	Capacity: recipes are not correct in the ERP system. Suggestions automatically derived in ERP systems are not always correct. Possible to make unlimited work releases in ERP system even though capacity may not match	Management
5	Safety stock levels lagging - leading to a list of prioritised products being necessary for expediting	Management, Operator and Observed
6	Batch sizes does not match the different steps and becomes unsynchronised	Management and Operator
7	Shortage of products for packaging	Observed

Figure 15 shows the problems regarding planning placed in the matrix to prioritise which problems are to be further investigated. The numbers in figure 15 are retrieved from the problems in table 20. The problems estimated to be priority 1 are: high WIP levels, dependent on detail planners and production planner, detailed and manual planning, expediting of orders in production and batch sizes does not match the different steps and becomes unsynchronised. These are further analysed in section 5.4.

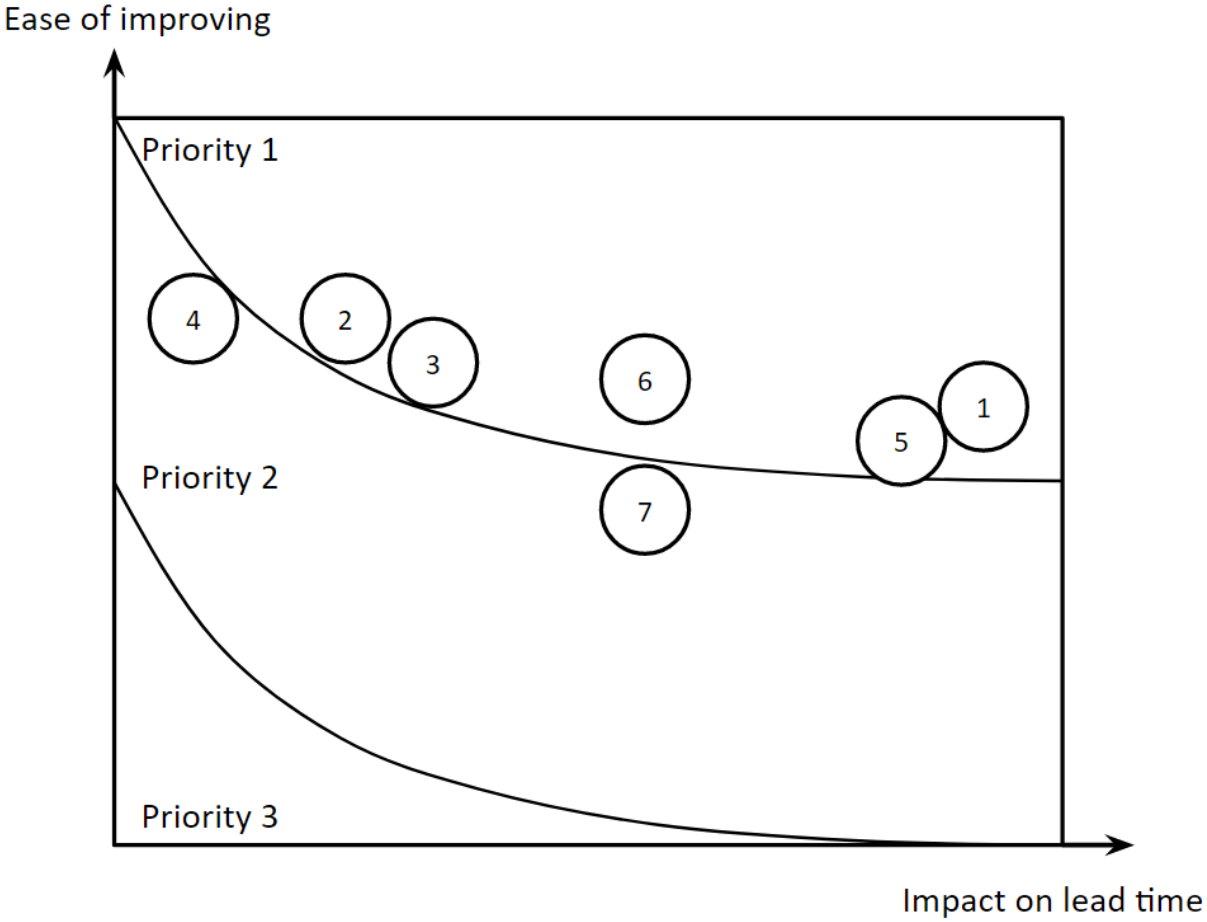

Figure 15 The categorised problems for planning.

5.2.2 Information

Table 21 shows the problems identified from observations and interviews that can be categorised as information, which is one of the five categories presented in figure 14. Next to the problem, the sources are presented. The problem number corresponds to the circles in figure 16, where the problems are prioritised.

Table 21 The identified problems regarding information.

Problem number	**Problem**	**Source**
8	No clear communication between departments or hierarchical levels	Management and Operator
9	Personnel does not know what is allowed, who is authorised to do what and where, and no direct information	Operator
10	Information is not communicated clearly and instantly	Observed
11	Results from test are written down but not used, just archived.	Observed

Figure 16 shows the problems regarding information placed in the matrix to prioritise which problems are to be further investigated. The numbers in figure 16 are retrieved from the problems in table 21. The problems estimated to be priority 1 are: no clear communication between departments or hierarchical levels. This is further analysed in section 5.4.

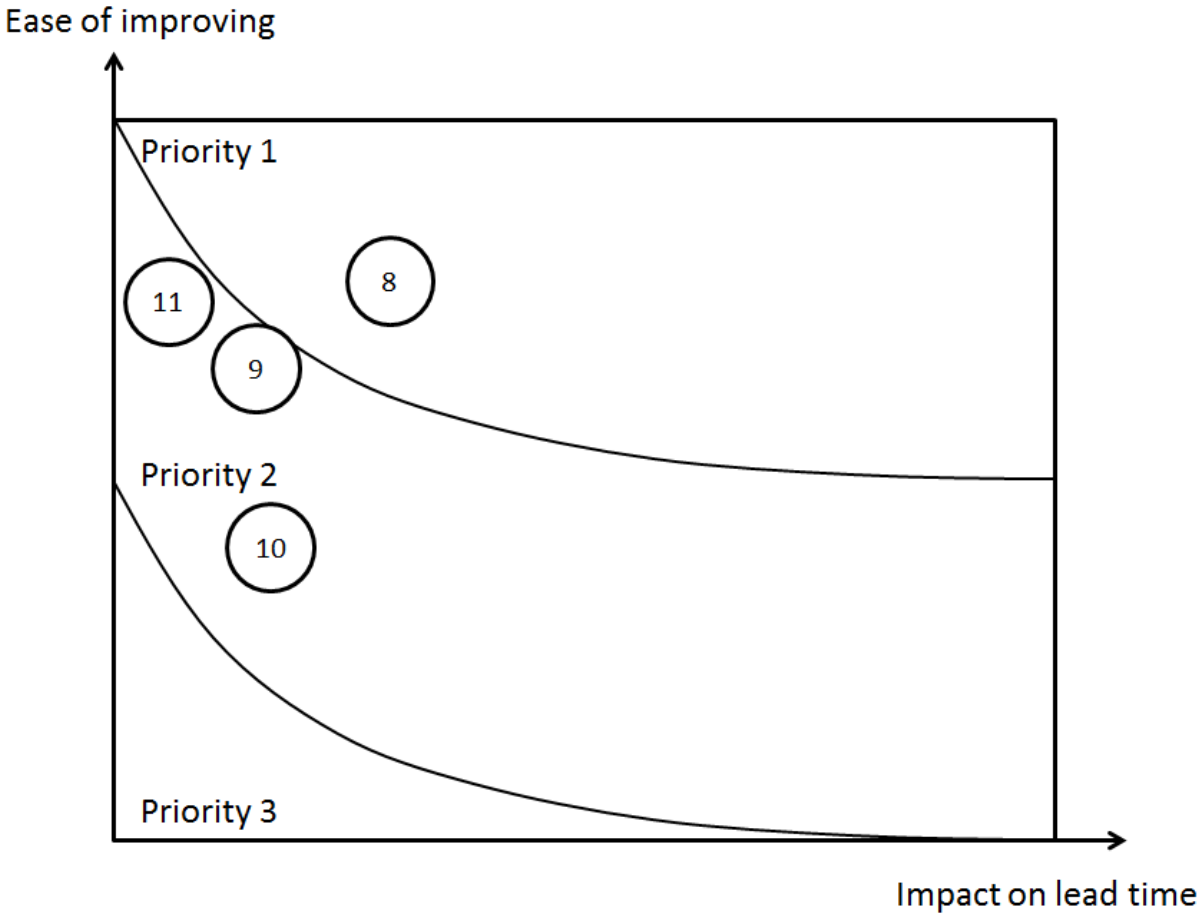

Figure 16 The categorised problems for information.

5.2.3 Resources

Table 22 shows the problems identified from observations and interviews that can be categorised as resources, which is one of the five categories presented in figure 14. Next to the problem, the sources are presented. The problem number corresponds to the circles in figure 17, where the problems are prioritised.

Table 22 The identified problems regarding resources.

Problem number	**Problem**	**Source**
12	No changes are made, perceived as difficult and not prioritised as daily work takes up all time	Management and Operator
13	Too few personnel and increasing product volumes	Operator
14	Lack of resources from technicians and maintenance	Management and Operator
15	Limited number of employees that can make a decision regarding reprocessing after test 2	Observed

Figure 17 shows the problems regarding resources placed in the matrix to prioritise which problems are to be further investigated. The numbers in figure 17 are retrieved from the problems in table 22. The problems estimated to be priority 1 are: too few personnel and increasing product volumes. This is further analysed in section 5.4.

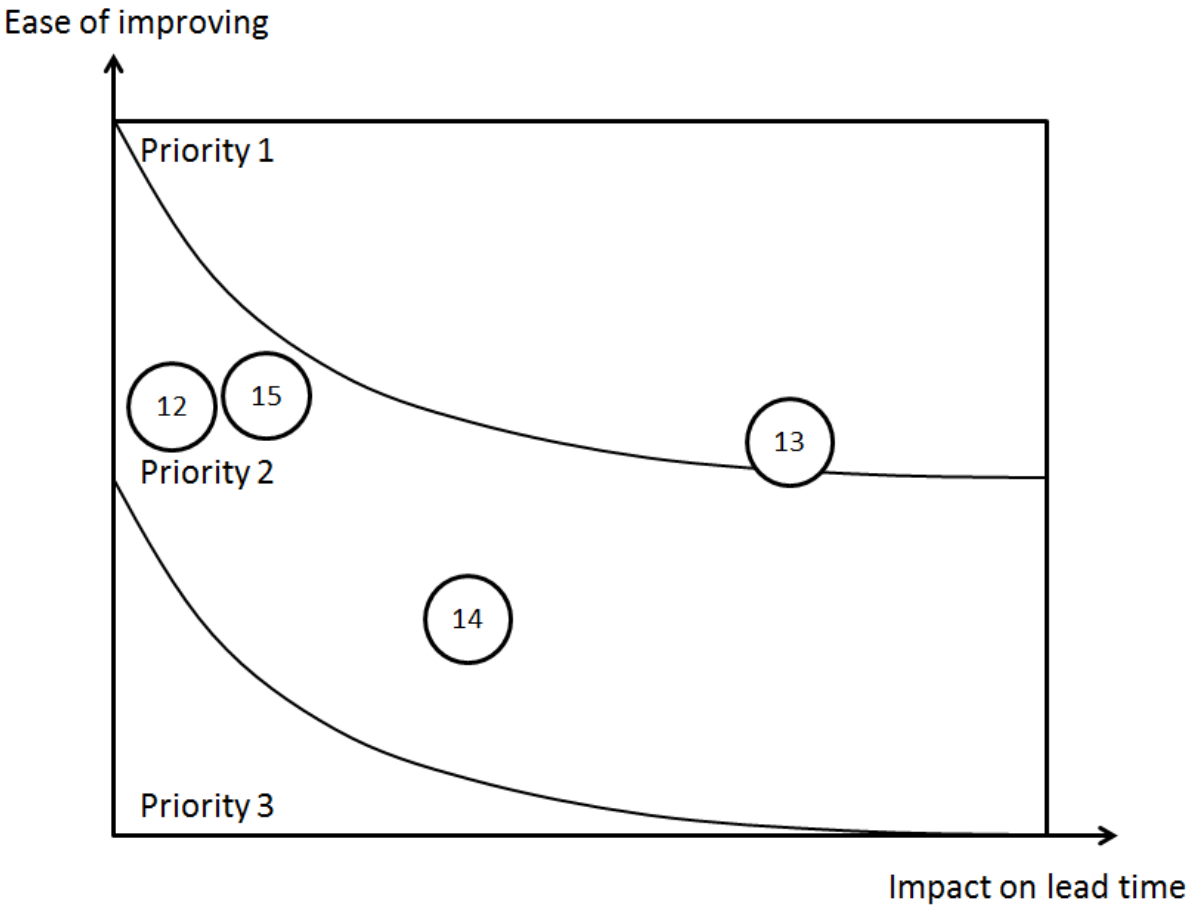

Figure 17 The categorised problems for resources.

5.2.4 Work activities

Table 23 shows the problems identified from observations and interviews that can be categorised as work activities, which is one of the five categories presented in figure 14. Next to the problem, the sources are presented. The problem number corresponds to the circles in figure 17, where the problems are prioritised.

Table 23 The identified problems regarding work activities.

Problem number	**Problem**	**Source**
16	Dependent on old, manual and time consuming machinery that may break down.	Management, Operator and Observed
17	Picking errors in final packing	Management
18	100 % inspections in many steps	Management and Observation
19	Not enough structured operation method	Management
20	Production processes are not ergonomic. Personnel cannot perform all production steps.	Management, Operator and Observed
21	Specialised roles leading to vulnerability	Management and Operator
22	Unnecessary distance/transportation	Management and Observed
23	The company cannot obtain needed material from suppliers.	Management and Operator
24	Long setups between process steps	Observed
25	Tools are missing in the production when needed	Observed
26	Capacity constraints	Observed
27	Unnecessary documentation	Observed

Figure 18 shows the problems regarding work activities placed in the matrix to prioritise which problems are to be further investigated. The numbers in figure 18 are retrieved from the problems in table 23. The problems estimated to be priority 1 are: dependent on old, manual and time consuming machinery that may break down, tools are missing in the production when needed, capacity constraints and unnecessary documentation. These are further analysed in section 5.4.

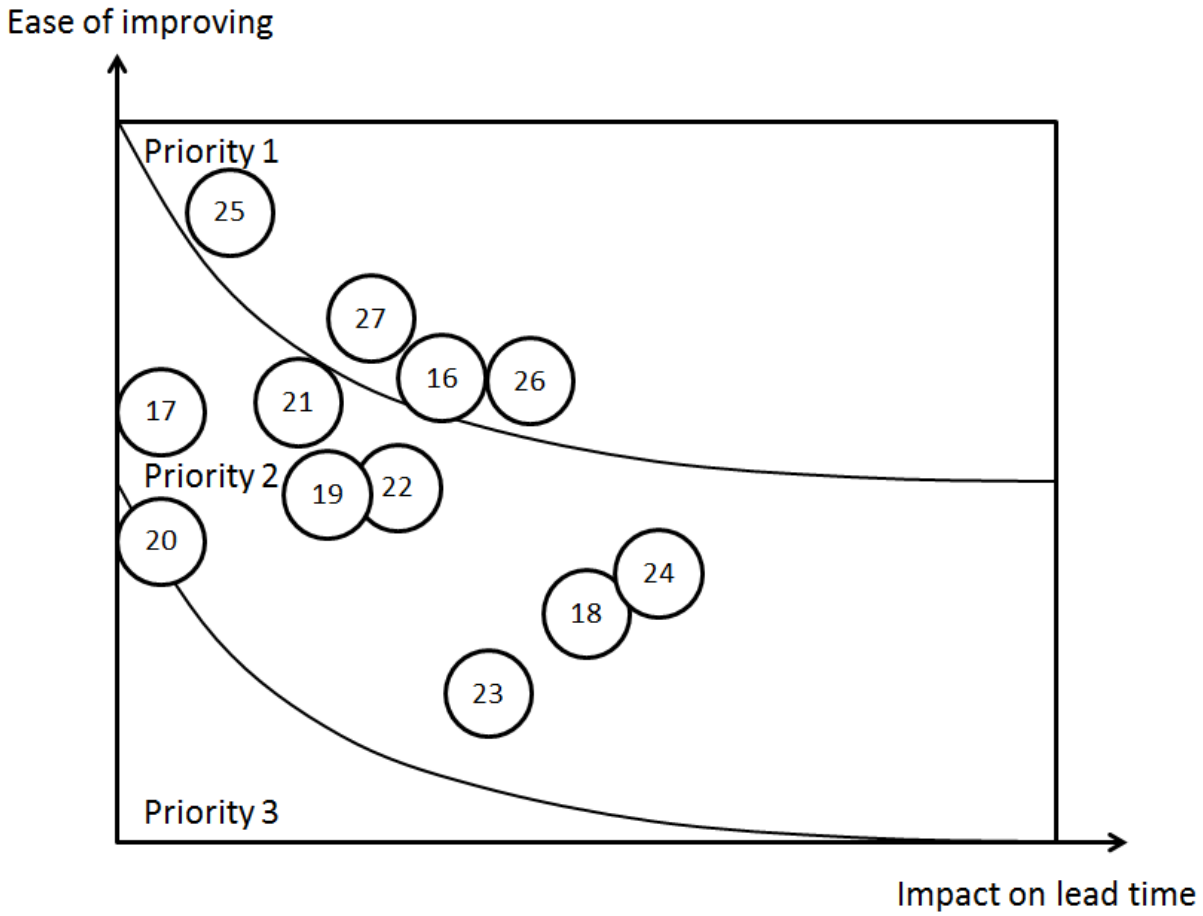

Figure 18 The categorised problems for work activities.

5.2.5 Defects

Table 24 shows the problems identified from observations and interviews that can be categorised as defects, which is one of the five categories presented in figure 14. Next to the problem, the sources are presented. The problem number corresponds to the circles in figure 17, where the problems are prioritised.

Table 24 The identified problems regarding defects.

Problem number	**Problem**	**Source**
28	Small batches lead to a lot of scrapping for testing	Management
29	Product defects	Management and Operator and Observed
30	Difficult to detect defects never seen before	Observed

Figure 19 shows the problems regarding defects placed in the matrix to prioritise which problems are to be further investigated. The numbers in figure 19 are retrieved from the problems in table 24. No problems were identified as priority 1 regarding defects.

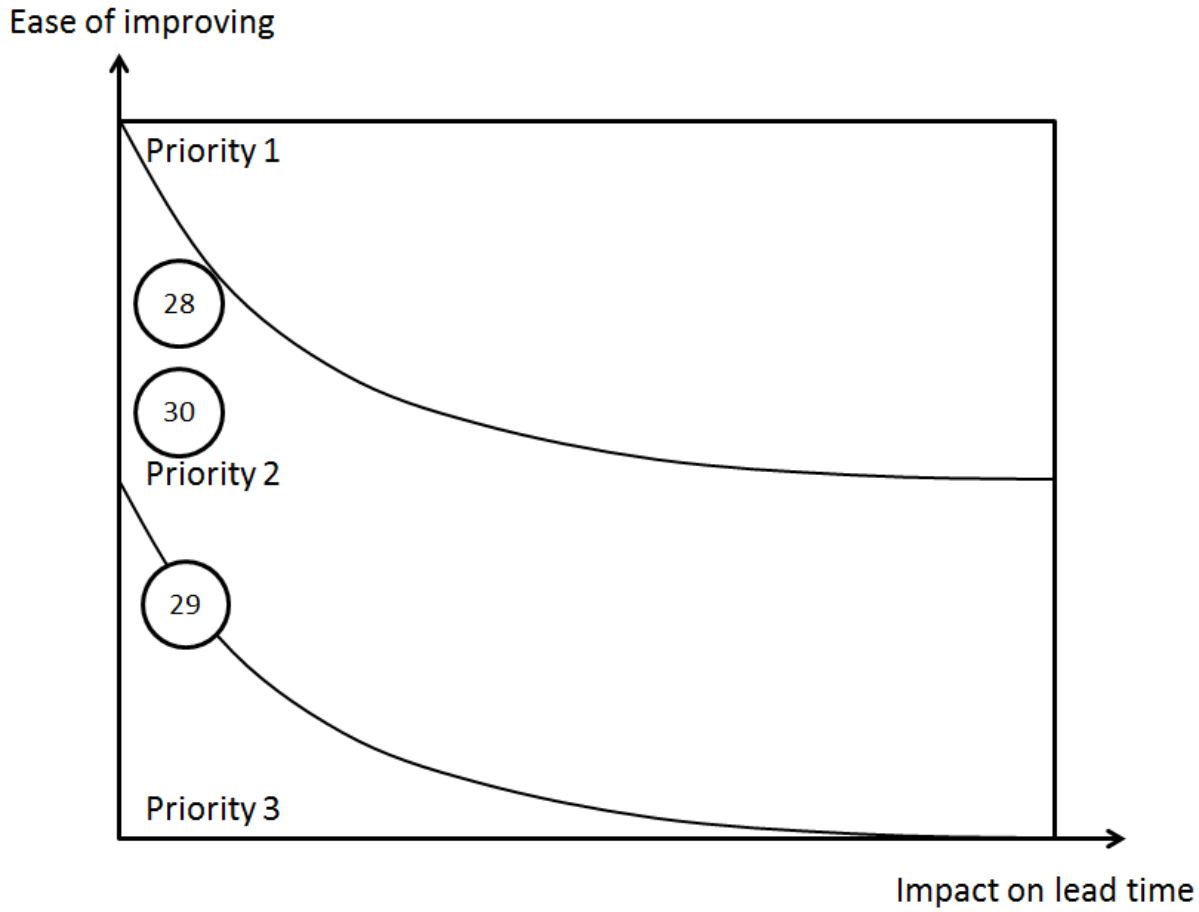

Figure 19 The categorised problems for defects.

5.3 The identified problems with the highest priority

From the figures 15-19, the problems suggested to be the easiest to improve or have a large impact on lead times, or both, were selected to investigate further in this study. The selection was made of the problems placed in the priority 1 section in figures 15-19. The problems under priority 1 are listed below:

- High WIP levels
- Dependent on detail planners and production planner
- Detailed and manual planning
- Expediting orders in production
- Unsynchronised batches
- No clear communication between departments and hierarchy levels
- Too few personnel while increasing product volumes
- Dependent on old, manual and time consuming machinery that may break down
- Tools are missing in production when needed
- Capacity constraints
- Unnecessary documentation

The problems presented above range from operational to strategic levels and by focusing on these, the greatest improvements of lead time should be achieved with the lowest effort.

5.4 Suggested changes to the highest prioritised problems

Based on the problems in section 5.3 and improvement suggestions from interviews and observations, a categorisation of improvements was conducted to show connections between the selected problems and improvements. The suggestion could mitigate or eliminate the problems in the process according to the authors' assessment. Table 25 below presents the conclusion from this. The suggestions and their respective linked problem or problems are further analysed in section 5.4.1-5.4.11.

Table 25 Suggested changes that are linked to selected problems.

Problem	**Linked change**
High WIP levels	Implement a VSM in order to get an overview of production measurements such as lead time and value-added time
High WIP levels Unsynchronised batches	Optimise batch sizes and implement a Kanban system
Detailed and manual planning High WIP levels	Visualise capacity utilisation of production processes and update ERP information and recipes
Expediting orders in production	Restore safety stock levels
Detailed and manual planning Unnecessary documentation	Digitalise documentation
Too few personnel while increasing product volumes	Simplify and remove production steps
Dependent on old, manual and time consuming machinery that may break down Capacity constraints	Replace old machines
Dependent on detail planners and production planner Capacity constraints	More cross-training of employees
Dependent on old, manual and time consuming machinery that may break down	Thorough and consistent maintenance
No clear communication between departments and hierarchy levels Too few personnel while increasing product volumes	Utilise competence and collaborate more
Tools are missing in production when needed	5S initiative

5.4.1 Value stream map

VSMs are developed in this project concerning two of the models in Atos Medical's product portfolio. The usefulness of this tool should be evaluated and then applied to other product families where it is deemed worthwhile to manage value streams to a higher degree in the future. The literature has shown that VSM implementations increases the understanding of processes for employees involved. Further on, it facilitates WIP levels and lead time reduction since non-value adding activities are discovered and can be eliminated.

In continued work with VSM a value stream champion should be appointed who can lead development and maintain the VSMs already developed while also assuming responsibility over the improvement work.

5.4.2 Optimise batch sizes and implement a Kanban system

Introduction

Optimisation of batch sizes in the production process for this study is not feasible due to lacking information regarding costs and shared resources. However, from a flow perspective the Lean philosophy aims to reduce batch sizes as much as possible targeting a "one piece flow". Connected to this is also the Lean concept of production smoothing, which is further described in section 3.3.8, making smaller batches and varying between models should improve flexibility in meeting market demand while also lowering WIP levels. In a Lean context the current batch sizes would be considered overproduction, which is further described in section 3.3.1, because the forecasted demand to be covered by some batch sizes does not arise until long after batches are finished.

Table 26 exemplifies how long the produced standard batch sizes will cover demand from the market, assuming an even demand with a constant ratio of product variants. Demand is based on the sales data for each product respectively during 2018. This highlights that large batch sizes will not be demanded for a long time and increase the WIP levels throughout the process. The days of demand covered were calculated by dividing the injection moulding and assembly batch sizes with the average demand per day.

Table 26 Days of demand covered based on standard batch sizes for injection moulding and assembly, the low volume model and high volume model.

High volume model Average demand per day 37,9	Std. batch size Injection moulding: 5600 (50 % are sold as material number HV1 and HV2)	Days of demand covered: 74
	Std. batch size assembly: 700 (50 % are sold as material number HV1 and HV2)	Days of demand covered: 9
Low volume model Average demand per day 0,5	Std. batch size Injection moulding: 700 (67 % are sold as material number LV1 and LV2)	Days of demand covered: 938
	Std. batch size assembly: 50 (67 % are sold as material number LV1 and LV2)	Days of demand covered: 67

The low volume model batches will be able to meet demand for a much longer time period than the high volume model batches. Injection moulding batches for the low volume model will not be demanded for over 3 years. The discrepancy between demand and batch size seems hard to justify in that case. In the other cases demand will be covered for a more reasonable time frame.

Machine capacity

Without knowing the bottleneck resource, a lower limit for average batch sizes that does not affect total output negatively cannot be determined with any reasonable certainty.

Table 16 depicting machine capacity, indicate that even with quite small average weighted batch sizes machines can meet annual sales of 71000. When the average weighted batch size is 100 which is estimated as quite conservative for most process steps the machine capacity does not go below the annual sales for SVs. The capacity of machines as presented in table 16 do not seem to constitute bottlenecks for the SV production process.

The bottleneck may instead be in the number of operators currently employed in the process. Operators in the production share their work time among other product families, making it complicated to estimate how many work hours are available for SV products. If the number of employees is in fact the bottleneck resource it is likely that output will decrease proportionally to increased setup times where the limited staffing currently exists.

Batch sizes

A number of assumptions are made in order to derive new batch sizes that will facilitate lower lead times and be feasible for the process state under study:

- Steady demand of approximated 9000 pcs per year for high volume products
- Constant scrapping rate of 700 pcs per setup for injection moulding
- Maximum setup scrap rate of 25 % in the injection moulding
- One operator working with each batch at a time
- Additional components are always available
- Improvements of process times from the improved flow chart, figure 20, dotted marking 1, 2 and 3 are included
- The improvement suggestion to remove sterilisation is not incorporated
- Shipment to sterilisation occurs once a month with the full monthly demand

In order to derive improved batch sizes for the high volume products, a rough estimation was made that there is a steady demand of 9 000 pcs per year, based on 2018 sales, and that production occur in fixed intervals based on steady demand. It is also assumed that one operator has the time to work with each batch whenever the steady demand requires production. It was also assumed that there is a constant scrapping rate of 700 pcs in the beginning of every new batch in the injection moulding, based on observations. With a maximum scrap rate of 25 %, the minimum batch size for the injection moulding is 2 800.

The times in table 27 and table 28 are based on the process times in the VSMs, figure 24-27, but altered according to batch size. The batch sizes presented in the injection moulding does not consider all the material needed, instead it is the outcome from the injection moulding, where 50 % (calculated in table 13) of the batch progress to become the two end product variants studied. The outcome of the injection moulding is presented within the brackets in table 27 and table 28, and the amount of SV that is used for the two end products investigated is presented after.

The batches are rounded to an even number of hundreds to make the cases easier to follow. The improvements of the process times, dotted marking 1, 2 and 4, based on the improved flow chart, figure 20 in section 5.4.6, are implemented in table 27 and table 28 below such that process times are shorter than in the current state VSMs.

For the first example, using current standard batch sizes, see table 27, it is assumed that the monthly sterilisation shipment occurs without waiting time after packing. For the second example, with smaller batch sizes, see table 28, it is assumed that the sterilisation occurs directly after two batches are produced, since the monthly demand (around 700 pcs) is approximately two batches. Which means that some waiting will occur after the packing process step. A best case and a worst case is presented for both examples in table 27 and table 28. The best case is the first batch from the injection moulding batch to be finished and the worst case is the last

batch from the same injection moulding batch to be finished. The last batch from the injection moulding is what determines how long the waiting time is for the worst case because it will not be processed until downstream demand arises.

Table 27 Example 1: Current standard batch sizes high volume model. The estimated days in the best case and the worst case for one injection moulding batch to be finished for the different process steps.

Process step	**Batch size**	**Best case finished**	**Worst case finished**
Injection moulding	(5600) ~ 2800 pcs	3,4 days	3,4 days
Washing	1400 pcs	4,1 days	4,1 days
Assembly	700 pcs	10,3 days	70,3 days
Packing	700 pcs	12,5 days	72,5 days
Sterilisation	700 pcs	32,5 days	92,5 days
Final packing	356 pcs	34,3 days	104,3 days

Table 28 Example 2: Reduced batch sizes high volume model. The estimated days in the best case and the worst case for one injection moulding batch to be finished for the different process steps.

Process step	**Batch size**	**Best case**	**Worst case**
Injection moulding	(2800) ~1400 pcs	1,9 days	1,9 days
Washing	1400 pcs	2,6 days	2,6 days
Assembly	350 pcs	7,0 days	37,0 days
Packing	350 pcs	8,2 days	38,2 days
Sterilisation	350 pcs	38,2 days	58,2 days
Final packing	350 pcs	40,0 days	70,0 days

Synchronised batch sizes will by the authors' estimation eliminate most waiting times between process steps by working similarly to a continuous flow. Waiting times because of variation and differences in process time would still be present. However, it is the case in any production line. Producing the same batch size throughout the manufacturing steps then, would probably result in the shortest average lead time but unless those batches are relatively small, the production will still have low flexibility in meeting short term market demand. Lower batch sizes should increase the flexibility and thereby lower dependency on forecasts.

The monthly demand is just over 700 pcs for the high volume model and producing in batches according to monthly demands would make sense with respect to the monthly sterilisation shipments. It will also increase the risk of missing the shipping date to sterilisation or at least having to expedite orders. If the batch sizes instead is half the monthly demand, there will almost always be at least 350 pcs of a product sent to sterilisation and 1 050 pcs the next month. With a safety stock level in the finished goods inventory able to cope with these variations there is no emergency to send the whole months demand in every shipping. Further on, smaller batch sizes will improve the flow of products through production steps with less risk of starving or blocking work stations.

For the high volume products, in the first example, the lead time for the fastest batch finished is shorter than for the second example but the flow will be smoother for the second example. For the first example, it is assumed that the first batch is sent directly to sterilisation while in the second example, the first batch awaits the second batch before being sent to sterilisation to send the whole monthly demand, which increases the waiting time.

The lead time for the last batch will be longer for the first example. The average lead time for a batch of 350 to be finished was calculated for the two examples. The times were based on steady demand and the time for an injection moulded batch to be completely finished. The first example demands eight batches to final packing while the second example demands four batches to finish, resulting in 64 days for example 1 and 51 days for example 2.

For the low volume model, the same general reasoning can be applied but the injection moulding batches should not be too small since there is a fixed number of pieces that are scrapped in the beginning of each new batch. The 25 % maximum scrapping rate in setups may not be viable in this case because demand is so much lower than for the high volume model. In the assembly, there is also a fixed number of SV products that are scrapped after test 2. It is probably not cost-effective to scrap large parts of a batch even if it means that the total lead time for the low volume batches would be significantly shorter and better matched to market demand. Since the annual demand only is about 180 SVs, larger batches than that in the injection moulding would result in covering demand for more than one year.

Proposed reduced batch sizes for the low volume products and the day the best case and the worst case of one injection moulding batch is finished for the different process steps are presented in table 29.

Table 29 Proposed reduced batch sizes for the low volume products and the estimated day the best case and the worst case for a batch of one injection moulding batch is finished for the different process steps.

Process step	**Batch size**	**Best case**	**Worst case**
Injection moulding	(90) ~ 60 pcs	0,8 days	0,8 days
Washing	60 pcs	1,5 days	1,5 days
Assembly	30 pcs	4,4 days	64,4 days
Packing	30 pcs	4,6 days	64,6 days
Sterilisation	30 pcs	24,6 days	103,6 days
Final packing	30 pcs	25 days	104 days

These smaller batch sizes leads to more batches being produced in particular injection moulding batches and thereby more time for setups are required. The reduced batches will not cover several years of demand as the current batches does and thereby lead to significantly shorter lead times. Further investigations are required comparing the cost-effectiveness of increased material scrapping and setups to lower WIP levels and shorter lead times.

Table 30 presents the potential days of lead time for both the high volume and low volume products that could be saved if the batch sizes were reduced and the production was able to finish one batch at a time.

Table 30 The lead time for the best and the worst case identified in the current process and the best and the worst case for reduced batch sizes, assuming steady demand.

	Best case current lead time	Best case reduced batch sizes	**Saved lead time**	Worst case current lead time	Worst case reduced batch sizes	**Saved lead time**
High volume models	92 days	40 days	**52 days**	223 days	70 days	**153 days**
Low volume models	112 days	25 days	**87 days**	716 days	104 days	**612 days**

A comparison between the best case for the current process and the best case for proposed reduced batch sizes showed that for the high volume products, the lead time could be reduced by 52 days for the best case. The same comparison between the two worst cases showed that 153 days could be removed with the reduced batch sizes. The lead time for the low volume products could be reduced by 87 days for the best case and 612 days for the worst case. How

the lead times for the reduced batch sizes were calculated is further explained in the section "Batch sizes" below.

Kanban system

As noted in section 3.3.2, manufacturing environments with a high mix of products typically does not benefit from utilising a Kanban system because it entails having all products in buffers, even though some products may not be in demand for long periods of time, leading to long lead times for those items. This might increase the total WIP levels even though there will still be a cap on WIP levels, which is the primary benefit of pull systems. High variability in the different process steps also lead to higher WIP levels in the form of safety stock in order to have components available when needed, thus the pull system likely needs to be preceded by improvements regarding variability.

With a Kanban policy, the planning of production would be less time consuming because the process will manufacture by its own command to maintain the set levels of WIP, equal to the number of and amount specified on the Kanban cards.

A partial implementation of a Kanban system could be utilised for the more frequently requested products which could relieve the condition of having all components stocked throughout production. This would still require a prioritisation between Kanban products and others as well as manually releasing work orders for low volume products. If prioritisation still is needed, the production planner will still have to work a lot with scheduling but the products under Kanban control will only need to be scheduled in terms of updating the number of Kanban cards, according to shifts in demand. Developing and maintaining a Kanban system requires setting card levels according to current demand which entails continuous work, especially when demand is frequently changing.

To conclude, Kanban implementation would limit WIP levels in the production process and ease the manual decisions for planning production. It would also necessitate all components to be stocked throughout the process steps and that Kanban card counts are updated continuously according to shifts in demand.

CONWIP

Another example of a pull system is CONWIP, which is further described in section 3.3.2, and may be used in this manufacturing context, alleviating the need to have all products in storage, instead the number of products independent of material number is limited. A fixed level of WIP can be kept by the production planner keeping a list of which work orders are released and by measuring the number of orders, and products that are released into production but not finished. More than one CONWIP loop can be applied in the production process.

The production planner then only needs to release orders in the beginning of the process when products are completed. Released work orders will then go through the whole production

process and by limiting the number of WIP, time spent waiting is reduced if there are fewer things to work on. A release list will work to schedule production and expediting products would be possible if necessary. The amount of work carried by the production planner will not be alleviated by this solution alone because the list of needed products still needs to be maintained and work orders released accordingly, further on keeping a list of what work orders exist already in the system could result in more work for the production planner. Given less expediting and more reliable lead times are used in the ERP system, the production planner should be able to not manually go through all MRP suggestions and the planning would become less time consuming and easier. Adding to that, if it is clearer to operators what they should work on, as a result from limited WIP, there is no reason they could not determine how to split orders among material numbers if necessary and could print out work orders themselves.

A CONWIP implementation would necessitate an even flow through production and safety stock to account for variations. It would limit the WIP levels and enforce started batches to be finished, thereby reducing the lead times.

5.4.3 Visualise capacity utilisation of production processes and update ERP information and recipes

The ERP system is in need of updated process times, current incorrect process times make planning more difficult. Further on, there is no limitation on production capacity in the ERP system and the planning suggestions derived by the ERP system has to be double checked for each product and manually changed if they are not suitable. Although, the production planner has an idea of the production capacity, the ERP system does not visualise utilisation levels and offer no guidance as to how many process orders should be released.

In order to understand the manufacturing processes and their capacity utilisation a visual aid would likely be of help. This might be in the form of a module in the ERP system, without knowing the utilised capacity it is more difficult to manage the release of raw materials into production. A prerequisite for this improvement would also be updated information regarding the time needed for work activities, otherwise the capacity utilisation will not be correct either way. The WIP level is a function of the ingoing raw material released through process orders and throughput. Visualising this should facilitate the control of WIP, the frequent contact between production planners and detail planners as of current operations likely provide a similar form of control given that employees are focusing on reducing WIP.

Visualisation is proven a useful tool for understanding processes connected to mapping as noted in section 3.1.2, and similar benefits should be possible to achieve for the capacity utilisation as well. The planning will become easier and less time consuming if the information and recipes are true to the production process.

5.4.4 Restore safety stock levels

Given that expediting is experienced as a large problem with frequent expediting of work orders, one suggested reason for this is safety stock levels throughout the production process that are currently lagging behind. Restoring these to their set levels would require an increase in capacity or that more products are made according to actual short term demand. Reducing the total lead time would likely contribute to this, given that forecasts are more certain with a shorter time frame and thereby products can be better matched with demand.

The shortage in safety stock levels contradicts the notion that WIP levels are too high, indicating that products not needed consistently are in the production process, relative to what is demanded. This would mean that products not demanded from the market for a long time period are being produced instead of products demanded in the short term. The table 26 in section 5.4.2 indicates that this is the case at least for the low volume product where in the start of the production process batch sizes are large enough that they will cover current demand rates for all low volume finished products for 3,9 years.

The improvement suggestion analysed in section 5.4.2 concerning reduced batch sizes should be able to significantly mitigate the need for expediting orders. This would be achieved by producing a larger number of product variants per time interval and thereby continuously utilising more available processing time to meet demand in the short term, the disadvantage being more setups. There will not be the same need for safety stock levels of semi-finished products throughout the process when the lead time is shorter and the WIP levels can further be reduced.

5.4.5 Digitalise documentation

The production has a lot of manual documentation that at the moment is not always utilised. Digitising the documentation would make it less time consuming and more viable to make use of the data and results from testing to statistically test and improve the quality of the products and processes.

One example is that the production planner spends considerable time physically moving production orders. If this can be done automatically, the production planner could use that time for value-adding activities.

5.4.6 Simplify and remove production steps

The produced volumes at Atos Medical are increasing, which puts a pressure on the employees that have a lot to do. The production is complex and strictly follows quality regulation. To save time, production steps should be removed wherever possible. These suggestions are visualised in the improved flow chart in figure 20.

Suggestions of change from interviews and observations linked to the flow chart

- Implement a higher degree of digitalisation in the production
- Remove inspections, step 3, conducted after injection moulding (dotted circle 1 in figure 20)
- Run test and analysis of the test 2 in parallel with the test 1 (dotted circle 2 in figure 20)
- Move the test 2
- Install a computer where the test 2 is conducted
- Conducting the test 2 and analysis should be done by the same person
- Is it enough to just see if all the SV are approved? It is not possible to track a single SV anyway, regarding manual documentation of the results from the test 1
- Stop counting products before step 17 (dotted circle 3 in figure 20)
- Organise work stations more to resemble an assembly line
- Skip rinsing the SV in ionised water before ethanol, eliminate an unnecessary step
- Outsource all punching work to suppliers (dotted circle 4 in figure 20)
- Investigate if sterile products need to be sterilised (dotted circle 5 in figure 20)

Improved flow chart

With a higher degree of digitalisation, several steps in the production process could be simplified and less information handling would be conducted manually. As of now, information regarding the production processes such as test results, defect products and time stamps are manually handled with pen and paper, documents are later archived manually as well. For several activities every single test of a product is noted, taking up considerable work hours for the operators. Double handling of information is also noted in test 2 and analysis of it which could be remedied by digitally registering information the first time.

Inspections, step 3, after injection moulding is another time consuming activity, removing it would free up time for injection moulding operators that could be used to prepare setup for the next batch or more frequently adjust the injection moulding which could reduce the number of defects from injection moulding. This is visualised in figure 20, dotted marking 1. The argument for frequent inspection has been to keep a tight control of what is happening in each process step. The same arguments for removing the inspections, step 3, after the injection moulding applies to counting of products before step 17, where the counting itself does not provide any value other than the frequent control of all products. Traceability is important for the company and removing counting activities may not be feasible from a quality assurance perspective.

If test 2 and test analysis is conducted in parallel with test 1, as visualised in figure 20, dotted marking 2, this would decrease the processing time while the same amount of man hours would be required. For larger batch sizes, the test 2 and test analysis should easily be conducted within the timeframe of the test 1 process.

Moving the test 2 machine into the production area would further reduce the process of several minutes for each batch and thus reducing the number of man hours needed. Another step towards digitalisation would be to have a computer adjacent to the test 2 where the test results could be recorded and sent for analysis immediately. Doing so would further reduce the processing time and potentially reduce the time that test results spend waiting for the test to be analysed. Training employees such that everyone performing the test 2 also can conduct the analysis would certainly remove waiting time between those two process steps.

The test 1 is an example where manual documentation is conducted that could be improved by implementing a computer and making the documentation digital which could lead to automatically derived statistical analyses. Traceability is important in the medtech industry but when the results for each SV is manually written down, it is not possible to track that specific SV since they are mixed in the same container afterwards.

Another improvement that could be made, especially in the assembly where many detailed process steps take place, is to order the workstation layout according to processing sequence. At the moment, the different activities are performed in different places and non-value adding time is thereby consumed by transportation. This could also increase the visibility of the WIP levels and where products are waiting.

Before step 17, they are counted, which seems unnecessary because they are counted in test 2 before and again in step 19, in the packing. Skipping this step, as depicted in figure 20, dotted marking 3, would shorten the process lead time.

During observations, it was identified that the SV are rinsed in ionised water before being rinsed in ethanol. The operator observed did not know why this is done since the ethanol should eliminate all bacteria. If the rinsing in ionised water could be skipped, unnecessary time would be saved in that process step. Operators should either way be informed why procedures are made.

After the SV are packed before sterilisation, puncture set SV has to be cooled down and then punched since the packaging material is received in pairs from the supplier. The other type of SV has packaging material that is received already separated and if the supplier could send all packaging material in the same way, a lot of time could be saved in the packing process. This is visualised in the improved flow chart, figure 20 dotted marking 4, where all types of the same size of SV moves along the same routing and two process blocks for puncture set products (the type inserted during a laryngectomy) could be eliminated.

A suggestion from the interviews was that the Sterile HV12 does not have to be sterile which could save time in the process. The SV inserted during the laryngectomy still has to be sterile since it is inserted in connection to the surgery. This suggestion, visualised in figure 20, dotted marking 5, would shorten the lead time for Sterile HV12 products with at least four weeks. The products do not risk transportation delays and does not need to time the monthly shipment to

sterilisation. Instead, the production can run more smoothly at all times. The decision of keeping the SV sterile could be based on what the market wants and not only on economic feasibility, still it might be interesting to investigate since the sterilisation process is one of the most time consuming parts of the process.

The following changes should be implemented:

- Removing inspections, step 3, conducted after injection moulding
- Run test 2 and analysis of test 2 in parallel with test 1
- Stop counting products before step 17

For the high volume products, the process time can be reduced from 38,3 days to 34,3 days. The change in dotted marking 4 in figure 20, does not apply to the Sterile HV12. If removing the sterilisation step, illustrated in dotted marking 5 in figure 20, the process time can be reduced by an additional 20 days.

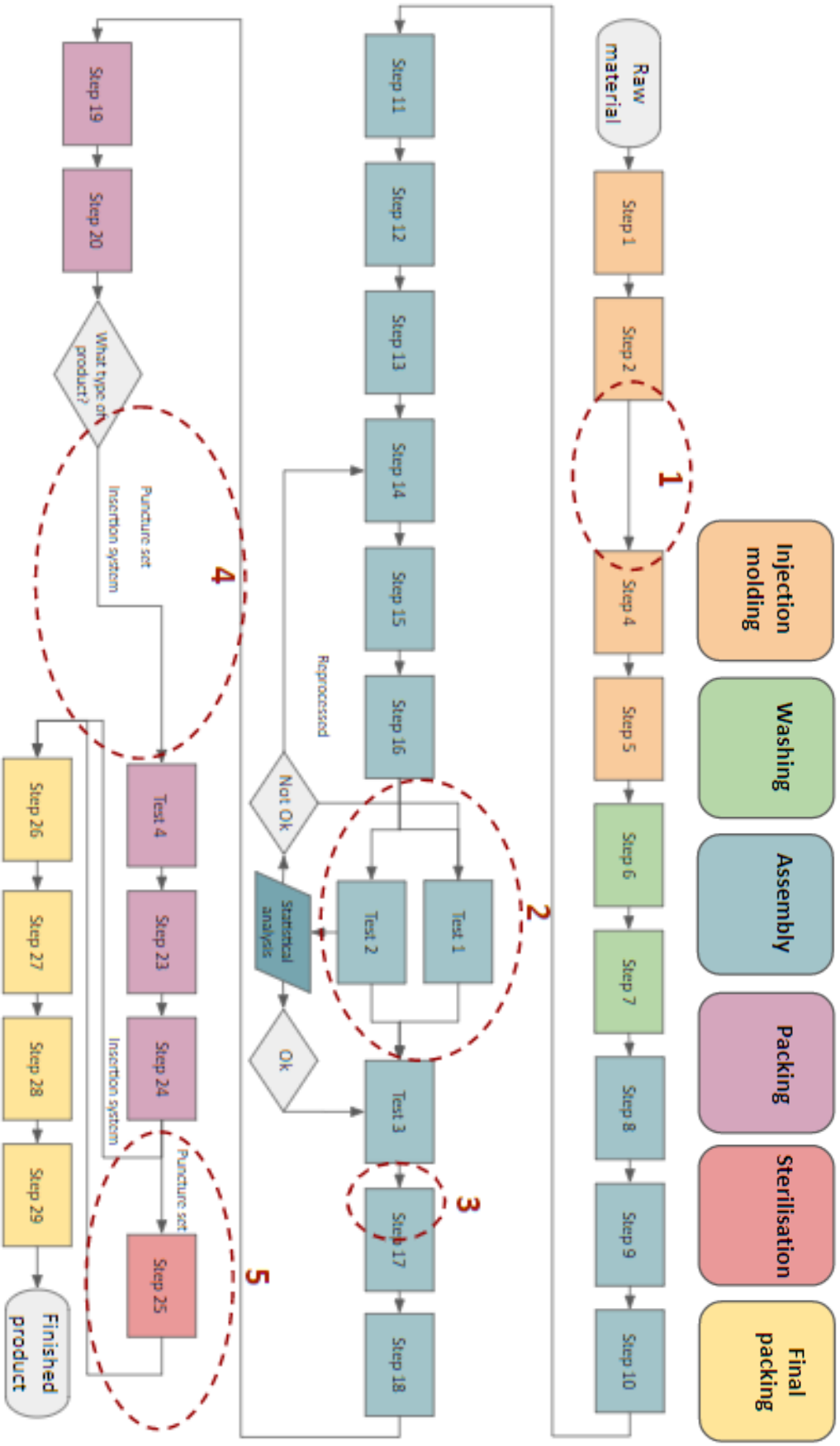

Figure 20 Improved flow chart

5.4.7 Replace old machines

This was a recurring suggestion during the interviews and observations since there are many machines that Atos Medical is dependent on. Some of the machines are not ergonomic and there is a desire to improve them from both operators and management side. Investing in new machines can be expensive and time consuming but there are currently some projects ongoing to improve the machines. This suggestion of change is linked to the limited resources, in the sense that employees working with these types of projects do not have enough time to complete them.

Investing in automatic machines would not only free up time for the operators to do something else, the quality would increase when there are fewer human errors. This study has not found indication that currently machines constitute bottlenecks and thus replacing machinery to increase capacity would only be viable if they also reduce manual labour hours needed for processing.

5.4.8 More cross-training of employees

Some process steps in the production has a limited number of employees with sufficient training or possibility of performing certain tasks. In the assembly, ergonomic reasons or allergy can be an issue resulting in only a few employees being can perform the tasks. The assembly and packing used to be one group that had general knowledge of all processes within these functions but some years ago they decided to split the group into smaller groups and made operator roles more focused on a limited number of work activities. This meant that sharing employees between process steps on a daily basis is not as easy as before. This is connected to the constant change of prioritisations that lead to changed schedules. If the production was running smoothly, being experts in a few work activities would be beneficial but in the current situation it is a disadvantage. By increasing the knowledge and training, more employees know different process steps and are able to make decisions independent of detail planners which would benefit the production flexibility.

5.4.9 Thorough and consistent maintenance

A commonly raised problem is that maintenance of machines takes time and the technicians at the Hörby site do not have time to prioritise the SV production, leading to frustration for the operators. Suggestions for improvements are considered but the management and technicians do not have time for these, and operators do not see the point of suggesting improvements that are not taken action on. A more thorough and consistent maintenance routine would improve machines and processes earlier, while increasing employee's involvement in improvement work and problem solving. Consistency of maintenance activities likely also prevents machine downtimes which typically leads to high variability and extra costs when they occur. Reducing variability in the production process will also enable production to run with less WIP without reducing output. Putting more resources into the maintenance would be beneficial in this sense even though the extra costs incurred by this should be compared with the potential savings.

5.4.10 Utilise competence and collaborate more

The information flow at Atos Medical can sometimes lack between departments and process steps. It has been identified that some operators do not always know what they are allowed to do and what they should do, leading to non-value adding time when they wait for instructions. The communication could be improved and the different department managers should share the same information at the same time with all employees. Communication between the departments would eliminate unnecessary time used on for example debating what the current plan or prioritisation is or if a machine should be used or not. An increased understanding of the production process as a whole and what happens after each employee's own work could increase employees' ability to reduce non-value adding processes.

The production should further on utilise existing competence more by allocating operators to the process step with the highest workload at each time. If a department has less operators, other departments should assist them in order to run the production more smoothly. Given that the number of employees is likely a constraint on total production capacity, some flexibility will enable to increase the production capacity.

5.4.11 5S initiative

A 5S initiative, which is further described in section 3.3.5, would decrease the non-value adding time for the operators to search for tools and components in the production. In line with Lean principles, organising the tools, cleaning every day and returning the tools to the right place would be beneficial for Atos Medical. As noted from observations, employees' time is spent looking for tools, this may not be so common that it is happening to all operators every day. If only five of the employed operators spend five minutes per day looking for a tool or material needed, then over 100 man hours is spent looking for tools every year. The hours spent on this could be used much more productively and the resources spent for organising these things according to a 5S initiative will likely have a short payback time.

5.5 Results

From the analysed improvements it is suggested that reducing and evening out batch sizes in combination with an implementation of a pull production control policy will have the biggest impact on production lead times. The VSM conducted visualises where unnecessary time that can be reduced. Waiting times stand for the majority of the lead time in the process and the focus should therefore be on reducing these. Comparing Kanban to CONWIP, it was concluded that CONWIP is preferable since it would give more flexibility while not requiring to have all products in stock throughout the process steps. Removing production steps, digitalising the documentation and implementing a 5S initiative to reduce process times would also reduce the lead time. Cross-training of employees and utilising competence will make the production more flexible and reduce risk while not directly affecting lead times. Restoring safety stock levels will be possible with reduced batch sizes and then the ERP system can be updated with correct data. Investing in new equipment and keeping the maintenance consistent would not only improve the lead time, it would also increase the quality of the products.

The result of the analysis is summarised in FSMs and as recommendations for Atos Medical. The recommendations are the authors opinions based on the analysis and divided into short term and long term suggestions. The short term recommendations are deemed easier to implement or has a great impact on reducing the lead time while the long term recommendations demands more investment both regarding time and costs. Atos Medical should investigate if these recommendations are feasible and develop an implementation plan as well as a cost-estimate.

5.5.1 Future state map

The FSMs in figures 28-31, Appendix F are based on the suggested improvements in section 5.4, and shows an increased improvement for the lead time and WIP levels, both for the best and worst cases. The process times are updated with the improvements from the improved flow chart, except for dotted marking 4 in figure 20, which does not apply to the Sterile HV12 and dotted marking 5 in figure 20, which is not to sterilise the products. The new suggested batch sizes and lead times are based on one operator performing each activity for steady demand.

For the high volume products, the best and the worst case reduced the current lead time. Although, decreasing the batch sizes means that batches have to be produced more frequently. Keeping the batch sizes the same throughout the process decreases the lead time but the injection moulding in particular has other parameters to consider. A lot of scrapping in the beginning of each new injection moulding limits the smallest possible batch size. If possible, the batch sizes in the injection moulding should be even smaller. If no reprioritisations are made, the production should run more smoothly and the lead time for each process step should be closer to the process time.

To cover the annual demand, injection moulding batches of 2 800 pcs (whereof 50 %, 1400 pcs are used for the two high volume material numbers) are produced six times a year. The monthly demand is around 700 pcs but if that exact amount is the standard batch size, missing the shipping to sterilisation will affect the safety stock more than if the batch sizes are half the monthly demand. There will probably always be at least 350 pcs in each shipment and the next month there would be 1050 pcs. This means that the production gets more flexible and more resilient to sudden changes in demand, and will likely need less expediting. Smaller batches for the high volume products would mean increased set up times. For the best case, there is still waiting time before the sterilisation because it is assumed that the first shipping is after one month, for the monthly demand, meaning that the first batch awaits the second one.

The WIP levels between and especially in the process steps are lower and less products are waiting to be processed, as seen in the FSMs in figure 28-31, Appendix F. The waiting time after the injection moulding and before the sterilisation is difficult to totally eliminate since the batches in the injection moulding are larger and the products are only sent to sterilisation once a month.

The low volume products have a smaller amount of demand per year and the injection moulding batch sizes should also be smaller in order to not increase the WIP levels in the process. Although, having batches smaller than 700 pcs would mean a high percentage of scrapping in the injection moulding. Further investigation of how much it would cost should be considered. In the FSM for the low volume products in figures 30-31, Appendix F, it is assumed that the steady demand leads to two injection moulding batches of 90 pcs per batch (whereof 67%, approximately 60 pcs are the low volume material numbers) will cover the demand.

5.5.2 Short term recommendations

Atos Medical should start by involving all their employees in improvement projects and communicate what new projects will mean for them, who will be responsible for what and why the projects are conducted. This is as stated in chapter 3, crucial for lean implementations to be successful, and management needs to continuously stay involved as well. The short term recommendations are either easily implemented or has a big impact on the lead time, but could also be both. The recommendations are concluded in the following list and then further described below.

- 5S
- Allocate resources for better communication between departments
- Cross-training of operators
- Reduce batch sizes
- Update information in ERP system
- Implement a CONWIP production policy
- Reduce and simplify process steps

5S

The authors recommend that Atos Medical introduce the lean concept of 5S, which is further described in section 3.3.5, to organise and keep all tools and products in order, inside production departments. This is a rather easily implemented solution that does not require an excessive amount of resources and would reduce the non-value adding time when searching for needed items or transporting WIP. For example could over 100 man hours could be saved per year if these non-value adding activities could be eliminated, assuming that five operators search for tools during 5 minutes per day.

Allocate resources for better communication between departments

Another suggestion that does not require an excessive amount of resources either is making an effort to communicate more between departments and to utilise competence better. Making sure that everyone receives the same information at the same time reduces the risk of misunderstandings and wasting unnecessary time on non-value adding activities. Although, communication between departments are essential, this recommendation will not have a huge impact on the lead time but more indirectly improving it through a better information flow.

Cross-training of operators

By more cross-training, additional employees can make decisions regarding the production or the planning, thus reducing the dependency on individual employees while also increasing staffing flexibility between production departments. Having specialist roles could be an advantage but the authors' recommendation is for Atos Medical to become more flexible by cross-training operators. The flexibility could make it possible to allocate operators to the process step with the lowest capacity, mitigating the risk of slowing down the process and increasing the lead time.

Reduce batch sizes

Reducing batch sizes would have a large impact on the process lead time. In particular, the injection moulding is currently producing comparatively large batches. WIP levels are relatively high between the washing and assembly process step, both regarding the high and the low volume product, which also indicate a flow barrier stemming from injection moulding batching. The explicit cost for reducing the batch sizes which would imply more setups and potentially more material waste because of it, should be weighed against the benefits of shorter lead times.

By reducing the setup times in the injection moulding, smaller batches are more feasible. The new proposed batch sizes are compared with the current batch sizes in table 31 for the high volume products and table 32 for the low volume products. The batch sizes for the low volume products in the washing, assembly, packing, sterilisation and final packing could possibly be the same amount as the injection moulding. Meaning practically no waiting time and a short lead time. Although, a higher number of products are fixed and cannot become other types in the packing, leading to tied up capital in the finished goods warehouse. Within parenthesis of

proposed batch sizes in table 31, the injection moulding batch size is presented, and the following number represents how much of that batch would be used for HV1 and HV2 models. Correspondingly in table 32 the injection moulding batch size is presented within parenthesis and the following number represents how much of that batch would be used for LV1 and LV2 models.

Table 31 The proposed batch sizes compared to the current standard batch sizes for the high volume products.

Process step	**Current batch sizes**	**Proposed batch sizes**
Injection moulding	5600 pcs	(2800) ~1400 pcs
Washing	1400 pcs	1400 pcs
Assembly	700 pcs	350 pcs
Packing	700 pcs	350 pcs
Sterilisation	700 pcs	2 x 350 pcs
Final packing	356 pcs	350 pcs

Table 32 The proposed batch sizes compared to the current standard batch sizes for the low volume products.

Process step	**Current batch sizes**	**Proposed batch sizes**
Injection moulding	700 pcs	(90) ~ 60 pcs
Washing	700 pcs	60 pcs
Assembly	50 pcs	30 pcs
Packing	50 pcs	30 pcs
Sterilisation	7 pcs	30 pcs
Final packing	7pcs	30 pcs

The average lead time for a batch in the current process is estimated to 142,5 days for the high volume products but with reduced batch sizes as table 31 shows, the average lead time can be reduced with an estimated 64 % to only 51 days.

Table 33 presents the reduction of waiting time and lead time for the high volume products that can be made for the best and the worst case, comparing the current batch sizes and the recommended sizes. The table is based on the VSMs and FSMs presented in figure 24-27, Appendix D and figure 28-31, Appendix F.

Table 33 Reduction of waiting time and lead time for the high volume products.

	Best case today	**Best case future**	**Worst case today**	**Worst case future**
Waiting time	24 days	10 days	47 days	40 days
Waiting time reduction	**58 %**		**15 %**	
Lead time	92 days	40 days	223 days	102 days
Lead time reduction	**57 %**		**54 %**	

The waiting time can be reduced by 58 % for the best case and 15 % for the worst case. The lead time can be reduced by 57 % for the best case and 54 % for the worst case. The estimated reduction in lead time does require production of more frequent injection moulding batches.

Table 34 presents the reduction of waiting time and lead time for the low volume products that can be made for the best and the worst case, comparing the current batch sizes and the recommended sizes. The table is based on the VSMs and FSMs presented in figure 24-27, Appendix D and figure 28-31, Appendix F.

Table 34 Reduction of waiting time and lead time for the low volume products.

	Best case today	**Best case future**	**Worst case today**	**Worst case future**
Waiting time	8 days	0 days	653 days	79 days
Waiting time reduction	**100 %**		**88 %**	
Lead time	112 days	25 days	716 days	104 days
Lead time reduction	**78 %**		**85 %**	

The waiting time can be reduced by 100 % for the best case and 88 % for the worst case. The lead time can be reduced by 78 % for the best case and 85 % for the worst case. The estimated reduction in lead time does require production of more frequent batches.

Shipping products monthly to sterilisation leads to significant waiting times before shipment and after, the VSMs also point to this seeing as WIP is quite high especially in the final packing process step, just before sterilisation. Reducing intervals between shipments would therefore likely lead to significantly more reduction in total lead time. In table 16, calculations show that capacity of machines should not be an issue for lower batch sizes. However, more employees are probably needed to achieve this, in order to not result in reduced outputs. As the Lean methodology suggests, the lowest batch sizes will likely result in the shortest lead times. However, there will always be trade-offs to consider and the new suggested standard batch sizes should be seen as a goal on a short term and should be evaluated and updated as changes occur.

Update information in ERP system

Assuming that batch sizes are reduced, the authors conclude that more products are produced which are demanded from the market in the short term. Utilising available processing time to meet short term demand instead of meeting demand forecasted to occur further in the future, at least to a higher extent, should improve the current safety stock deficit and perhaps remove it altogether. Updating information in the ERP system connected to planning would likely make it easier to develop feasible schedules.

Implement a CONWIP production policy

In order to further reduce lead times by limiting WIP levels, a pull production policy should be put in place. The authors suggest that a CONWIP policy would be the easiest to implement, putting a cap on the WIP levels by enabling the production planner to hold the release of new process orders until the next batch enter the finished goods inventory. By doing this and gradually decreasing the CONWIP level, lead times in manufacturing should decrease proportionally. As depicted in figure 21, an example of how a CONWIP system could be implemented at Atos Medical.

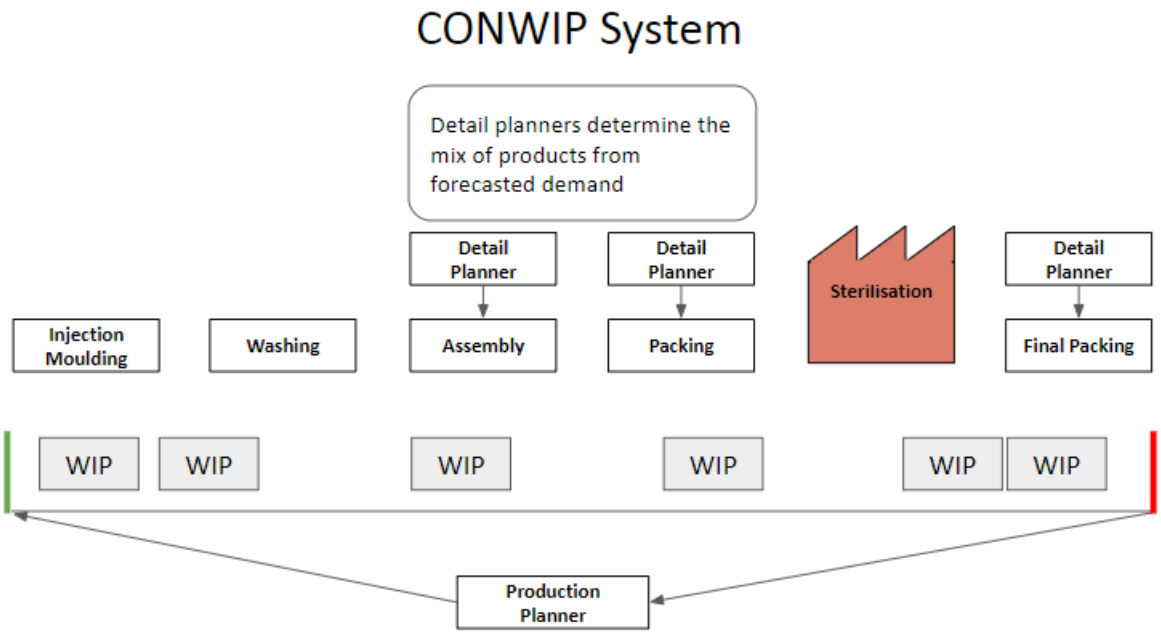

Figure 21 Illustration of a potential CONWIP system.

Reduce and simplify process steps

Although, waiting time for the products investigated in this report is considered to make up a majority part of total lead times, reducing process times should be attempted to be done continuously. The improvements from the improved flow chart to skip the inspection in the injection moulding, conduct test 1 and test 2 at the same time and skipping counting the SV before step 17 could reduce the process time from 38,3 days to 34,3 days. The implementation will not only save time and costs, the operators will have more time to produce other products as well.

5.5.3 Long term recommendations

The long term recommendations demand more investments and should be further looked into before being implemented. Cost estimates should be done to compare with achieved benefits. The authors believe that these suggestions would reduce the lead time and WIP levels, and thereby reduce cost as well in the future. The recommendations are concluded in the following list and then further described below.

- Digitalise documentation
- Invest in equipment
- Investigate if the currently sterile SV products needs sterilisation

Digitalise documentation

The production today requires many manual steps with unnecessary documentation that is not used. Digitalising the documentation would not only save time, it would reduce human errors and make it possible to instant statistical analyses that the R&D could benefit from. Digitalising the production would increase traceability but changing the current production procedure requires time and validation to be approved.

Invest in equipment

As a long term investment, Atos Medical should direct resources to new machines and equipment in the production. Existing machines and equipment are slow, not ergonomic and Atos Medical is dependent on only one machine in several production steps. Preferably investing in automatic equipment where human errors can be eliminated. This is a long term investment that requires resources and time before decisions can be made and implemented but the potential advantages are high.

Investigate if the currently sterile SV products needs sterilisation

Atos Medical should consider if it is necessary to sterilise all their products. The products that are inserted directly after the laryngectomy has to be sterile, but the rest might not have to be. Skipping the sterilisation would mean a reduced lead time of at least 20 days, could be even more since the waiting time before the shipment to sterilisation is removed as well. The market could demand sterile products and possible patent and licences may have to be altered but the time added because of the sterilising is a significant part of the total lead time and removing it could outweigh those challenges.

If the products still have to be sterile, another solution to shorten the lead time is to send the SV to sterilisation twice a month instead of only once a month. This would increase the costs but at the same time, as demand increases in the future, it may be more feasible. The lead time would become shorter on average and missing one shipment is not devastating.

6 Conclusion

In this chapter, answers to the research questions are presented, followed by suggestions for further research that could be conducted. Lastly, the study's contribution to theory follows.

6.1 Answering the research questions

- **RQ1: What is the current state of Atos Medical's SV production process?**

Capturing the current state of the SV production process was done through observations, interviews and archival records. Described in text as well as visualised in process maps, the current state has been presented in this report. The process maps in figure 22 and figures 24-27, see Appendix D, provide two levels of process maps. As the higher level VSMs show, there are significant WIP levels throughout the production process, mainly focused in or before the assembly and final packing process steps. There are long waiting times both in and between the process steps. The lead times for the worst case regarding high volume products are in the current process 223 days and regarding low volume products 716 days while the process times are 38,3 days and 26 days respectively.

The different batch sizes used in the process steps mean that WIP is stocked between processes, at the same time component shortages regularly occur. Expediting of orders to meet demand is occurring regularly. The process steps depicted in the VSM can further be broken down into smaller steps and this is shown in the flowchart, figure 22. Further on, dependency on the production planner and detail planners for the production process is quite high. Manual work make up the majority of processing and several of the work activities are perceived as unergonomic.

- **RQ2: What problems exist in the current SV production process and how can they be categorised?**

By conducting interviews with employees working with the process and observations of the process, problems were identified as presented in section 4.2 and in table 18. A categorisation of the problems was based on an adapted "5 Why" method resulting in the following categories: information, planning, defects, work activities and resources. All problems are not covered in this report, however many of them were identified. From the identified problems in the production process, an assessment was made for what problems should be prioritised based on lead time impact and the ease of improving the problems, shown in section 5.3. The highest prioritised problems were concluded into:

- High WIP levels
- Detailed and manual planning
- Dependent on detail planners and production planner
- Expediting orders in production
- Unsynchronised batches
- No clear communication between departments and hierarchy levels
- Too few personnel while increasing product volumes
- Dependent on old, manual and time consuming machinery that may break down
- Tools are missing in production when needed
- Capacity constraints
- Unnecessary documentation

- **RQ3: What improvements can be derived from the identified problems in Atos Medical's SV production process in order to reduce lead times and WIP?**

The list of prioritised problems, was in turn connected to suggested improvements, which are shown in table 19 and section 4.5. Based on the current state description and identified problems, suggested improvements were analysed and a list of recommendations were developed, summarised in table 35 below. The recommendations were categorised into short term, which should be implemented directly, and long term, that requires more resources and investigation. With these improvements, the average lead time will be reduced with over 50 % for both the high volume and the low volume products. As a result of shorter lead times, the WIP levels will be reduced accordingly. The focus for Atos Medical should be to reduce or eliminate waiting time since it constitutes the majority part of lead times in the production process.

Table 35 Recommended improvement efforts and respective time perspective.

5S	Short term
Allocate resources for better communication between departments	Short term
Cross-training of operators	Short term
Reduce batch sizes	Short term
Update information in ERP system	Short term
Implement a CONWIP production policy	Short term
Reduce and simplify process steps	Short term
Digitalise documentation	Long term
Invest in equipment	Long term
Investigate if the currently sterile SV products needs sterilisation	Long term

6.2 Future research

For future research, it would be interesting to make a cost-estimate of the possible investments in new machines and equipment, and how much of the lead time that could be reduced by this. A review of the ergonomic situation for the operators could also be looked into further and possibly influence the decision of investing in new machines and equipment.

Introducing cost as a factor would probably affect the recommendations made. The cost of scrapping could be compared to the possible winnings of having a more flexible production and not to store as much inventory and WIP throughout the process. The product's value increases throughout the process and it would possibly be more profitable to scrap the products already in the injection moulding instead of over-producing and then scrap products from the finished goods inventory. To further compare cost versus time savings, a quality perspective could be included to find the optimal solutions for the production.

It would also be interesting to further follow all the SV in the production and make process maps of the different types in order to further optimize and allocate time and batch sizes for the production and planning. Including all components used to produce SV would also be an extension to better understand the production of SV. The study could be used to get a hint of how different types and sizes of the SV should be planned but to optimize the whole production, process times for each individual type is needed. To increase the validity, more observations

could be made, possibly with several different operators performing the same activities to receive an average and more accurate process times.

In the study, it is assumed that components and materials from suppliers are always available but, in the future, this could be investigated further and included in the process maps. Optimizing supply and components is also important and the production is dependent on that raw material is available, to be able to start a new batch.

The possibility of not sterilising some of the SV should be looked into, since it would eliminate a large part of the lead time. Even if the sterilisation could be done twice a month instead of once could be investigated, since the lead time would be shortened but the costs would increase.

As an additional analysis, the identified problems could be analysed from different perspective in the company by comparing the management and operators most important problems and suggested changes. All problems identified were not addressed in the analysis of this study but for future research, those could be further investigated.

In this study, the improvement methodologies used were from Lean and process mapping. It would be interesting to look into different types of improvements methodologies, production strategies, process maps and tools in order to improve the lead time and WIP levels.

For future research it would also be interesting to replicate the study on similar products or in another production process in the medtech industry. Applying a combination of two or more process maps could be conducted in other studies to further support the value of using different mapping perspectives.

6.3 Contribution to theory

The theoretical framework developed included a comparison between different process maps. This topic is quite limited and few explicit comparisons was found during the literature review. One example is Aguilar-Saven, R.S. (2004) but the comparison in this study is more focused on guidance for selecting and applying suitable mapping methods. This study includes methods with a higher level perspective such as VSM and SIPOC that Aguilar-Saven, R.S. (2004) does not. As a contribution to theory, the comparison between some of the commonly used process mapping methods is presented in table 9. Applicability, level of detail, advantages, disadvantages, expected outcome and potential barriers were the categories discussed.

The use of two different process maps on different level of detail can be considered to be useful and complement each other. The flow chart most suitable for investigating operational improvements that could be integrated in the VSM, where more strategic direction and analysis could be made. Further on, comparisons of the best and the worst case in VSMs was not found in the literature review about VSM (e.g. Martin and Osterling, 2014; Rother and Shook, 2001).

This could through application in more studies prove to be a feasible way for highlighting variation and making the VSM method more dynamic.

The study showed that lean tools could be useful for improving production lead time and reduce WIP also in a medtech industry context which was not found previously in the literature search about Lean methodology. An evaluation of implemented changes, and the proposed future state would need to be conducted in order to strengthen this conclusion.

7 References

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Appendix A

Interview guide

- What is your role at Atos Medical?
- Could you name three problems in the current process? Where in the process are they?
- What kind of changes would you like to happen?

Appendix B

Observation & measurements protocol

- Process step:
- Setup time:
- Process time (per piece):
- Waiting time:
- Does this process differ with regards to product variations?
- How many people can work in this process simultaneously? How many typically does?
- How does the operator report/register the batch when the process is done?
- Scrapping:
- How does the employees know what work activities to do?
- What interruptions takes place in this process during a work shift? Are there resources that this process shares with other processes?
- Where does WIP tend to build up? Where is WIP stored after this process step?
- Barriers of flow?

Appendix C

Table 36 The articles about process mapping and if the different methods are mentioned.

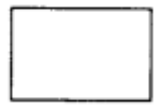
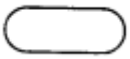
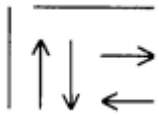
	Value Stream Mapping	Flow chart	IDEF	SIPOC	Role activity diagram	Swim lane	GRAI	Simulation modeling methods	Data flow diagrams	Role interaction diagrams	Gantt Chart
Windisch et al. (2013)	Yes	Yes	-	-	-	-	-	-	-	-	-
Fadahunsi and Sathiyanarayanan (2016)	-	-	-	-	-	-	-	-	-	-	-
Siha and Saad (2008)	-	-	-	-	-	-	-	-	-	-	-
Biazzo, (2002)	-	Yes	Yes	-	Yes	-	-	-	-	-	-
Rother and Shook (2001)	Yes	-	-	-	-	-	-	-	-	-	-
Aguilar-Saven (2014)	-	Yes	Yes	-	Yes	-	-	-	Yes	Yes	Yes
Ungan (2006)	-	Yes	-	-	-	-	-	-	-	-	-

	Value Stream Mapping	Flow chart	IDEF	SIPOC	Role activity diagram	Swim lane	GRAI	Simulation modeling methods	Data flow diagrams	Role interaction diagrams	Gantt Chart
White and Cicmil (2016)	-	-	-	-	-	-	-	-	-	-	-
Hines and Rich (1997)	Yes	-	-	-	-	-	-	-	-	-	-
Martin and Osterling (2014)	Yes	-	-	-	-	-	-	-	-	-	-
Greasley (2006)	-	-	-	-	-	-	-	-	-	-	-
Klotz, Horman, Bi and Bechtel (2008)	Yes	-	-	-	-	-	-	-	-	-	-
Bowles and Gardiner (2018)	-	-	-	-	-	Yes	-	Yes	-	-	-
Aikenhead, Farahbakhsh, Halbe and Adamowski (2015)	-	-	-	-	-	-	-	-	-	-	-

	Value Stream Mapping	Flow chart	IDEF	SIPOC	Role activity diagram	Swim lane	GRAI	Simulation modeling methods	Data flow diagrams	Role interaction diagrams	Gantt Chart
Van Assen (2018)	Yes	-	-	-	-	-	-	-	-	-	-
White and James (2014)	Yes	Yes	Yes	-	-	-	-	-	-	-	-
Soliman (1998)	-	-	-	-	-	-	-	-	-	-	-
Lasa, Laburu and de Castro Vila (2008)	Yes	Yes	Yes	-	-	-	Yes	-	-	-	-
Krishnaiyer, Chen, Burgess and Bouzary (2018)	Yes	-	-	Yes	-	Yes	-	-	-	-	-
Haefner, Kraemer, Stauss and Lanza (2014)	Yes	-	-	Yes	-	-	-	-	-	-	-
Number of hits	10	6	4	2	2	2	1	1	1	1	1

Appendix D

Table 37 Basic outlines for flow chart based on Chapin (1970).

Symbol	**Description**
	Process
	Terminal
	Input/output
	Flow lines
	Decision

The flow chart, showing details of the current state is presented in figure 22. The different colours represent the different overreaching process blocks.

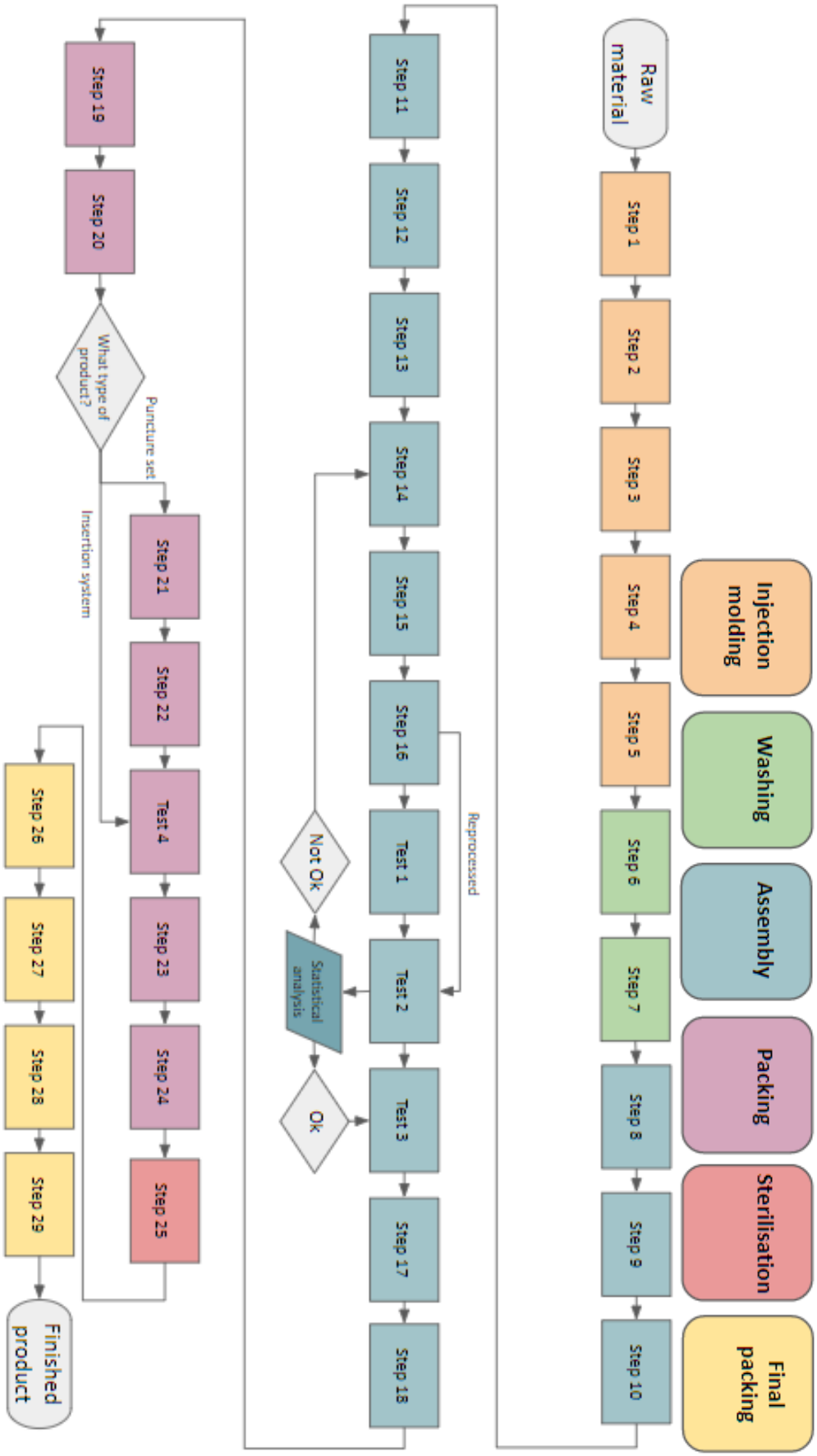


Figure 22 Flow chart of the SV production.

Figure 23 below depicts typical illustrations in a VSM and their respective meaning. The same icons are used in the VSMs presented in the following pages.

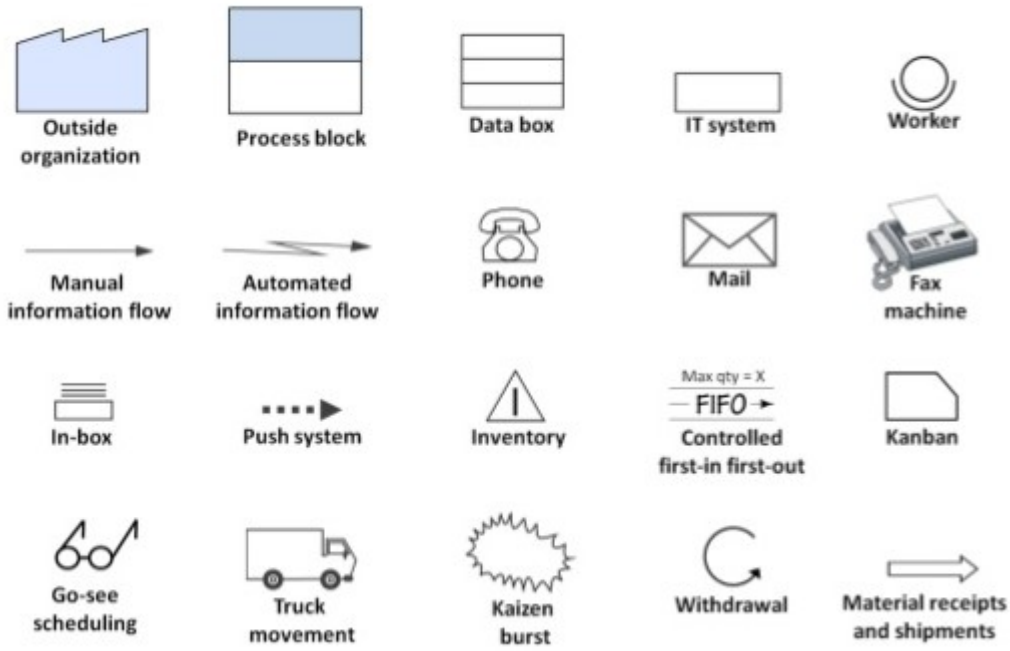


Figure 23 Some of the most common VSM icons. Source: Martin and Osterling (2014).

In the figures 24-27 below, the standard batch sizes for each process step is presented inside each step. In the brackets is the real batch size for the specific case.

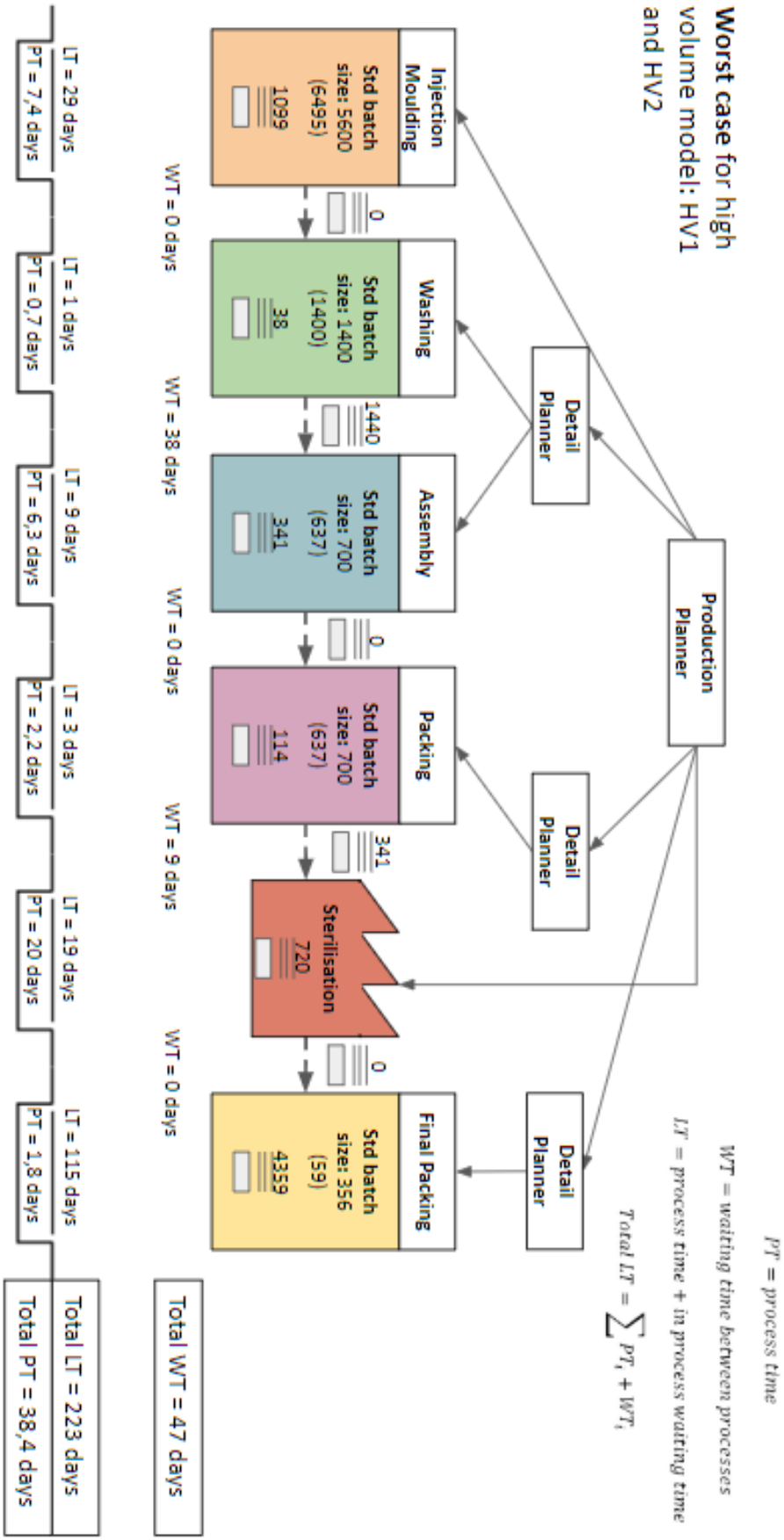


Figure 24 VSM - Worst case for high volume model: HV1 and HV2

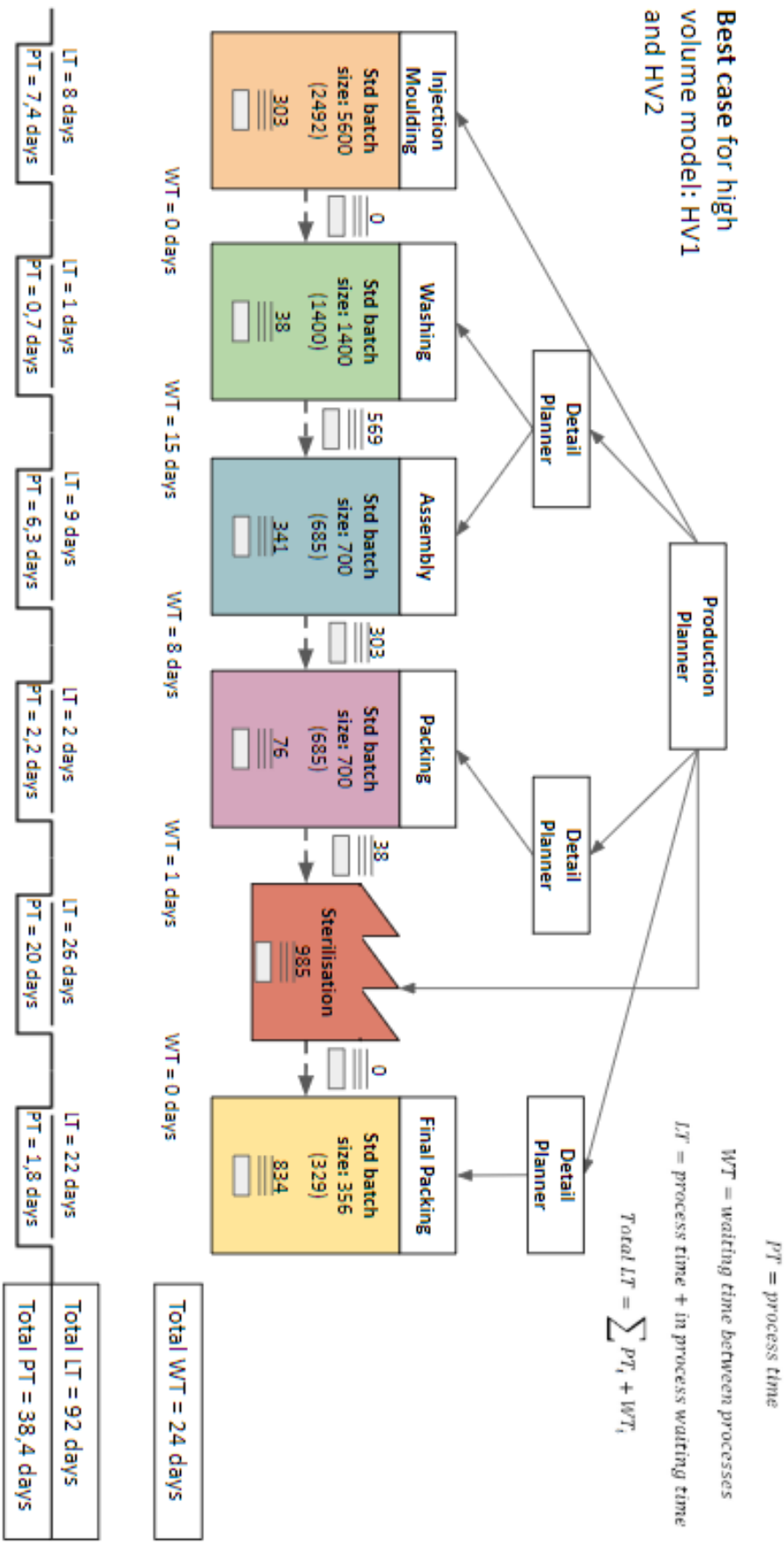


Figure 25 VSM - Best case for high volume model: HV1 and HV2

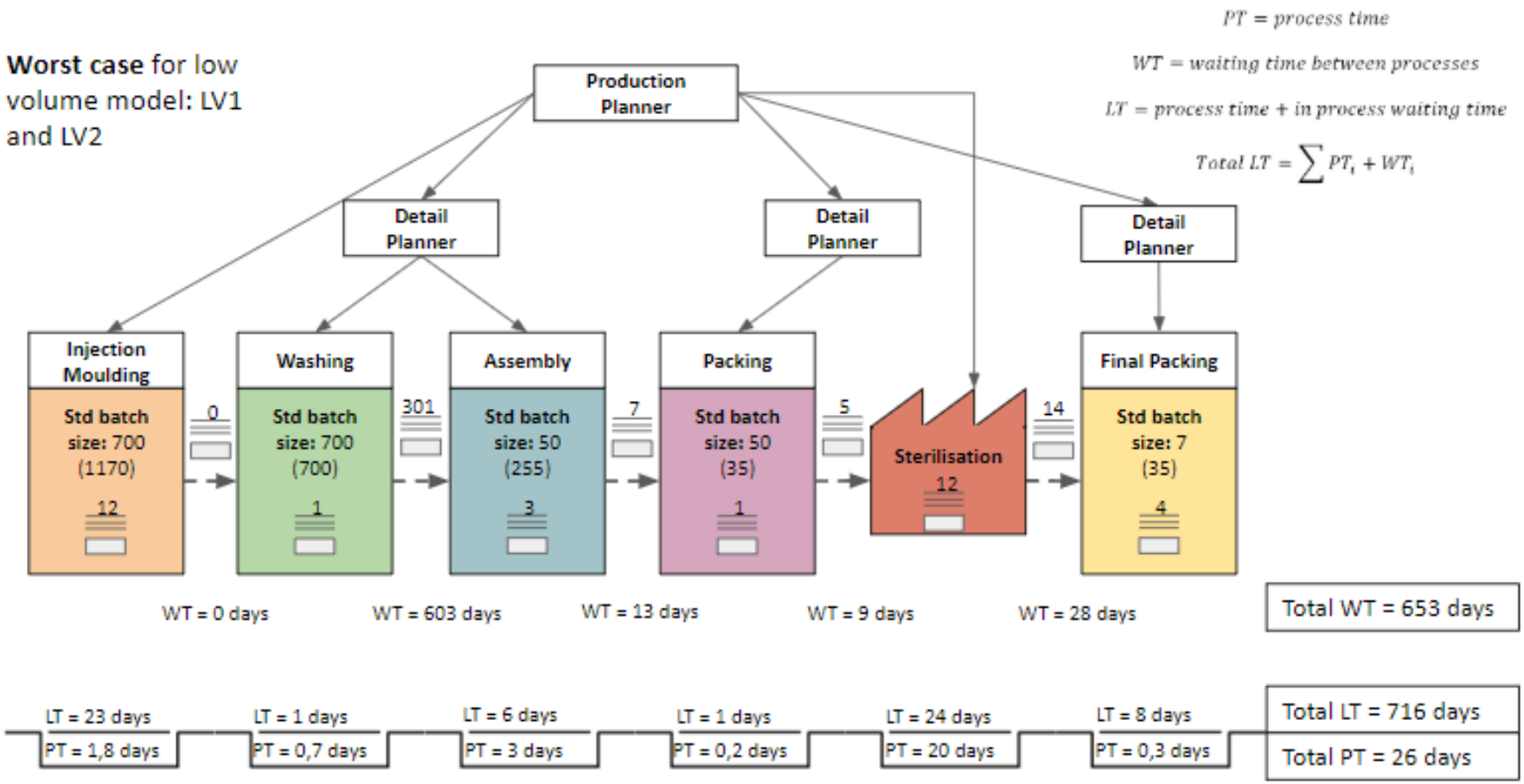


Figure 26 VSM - Worst case for low volume model: LV1 and LV2

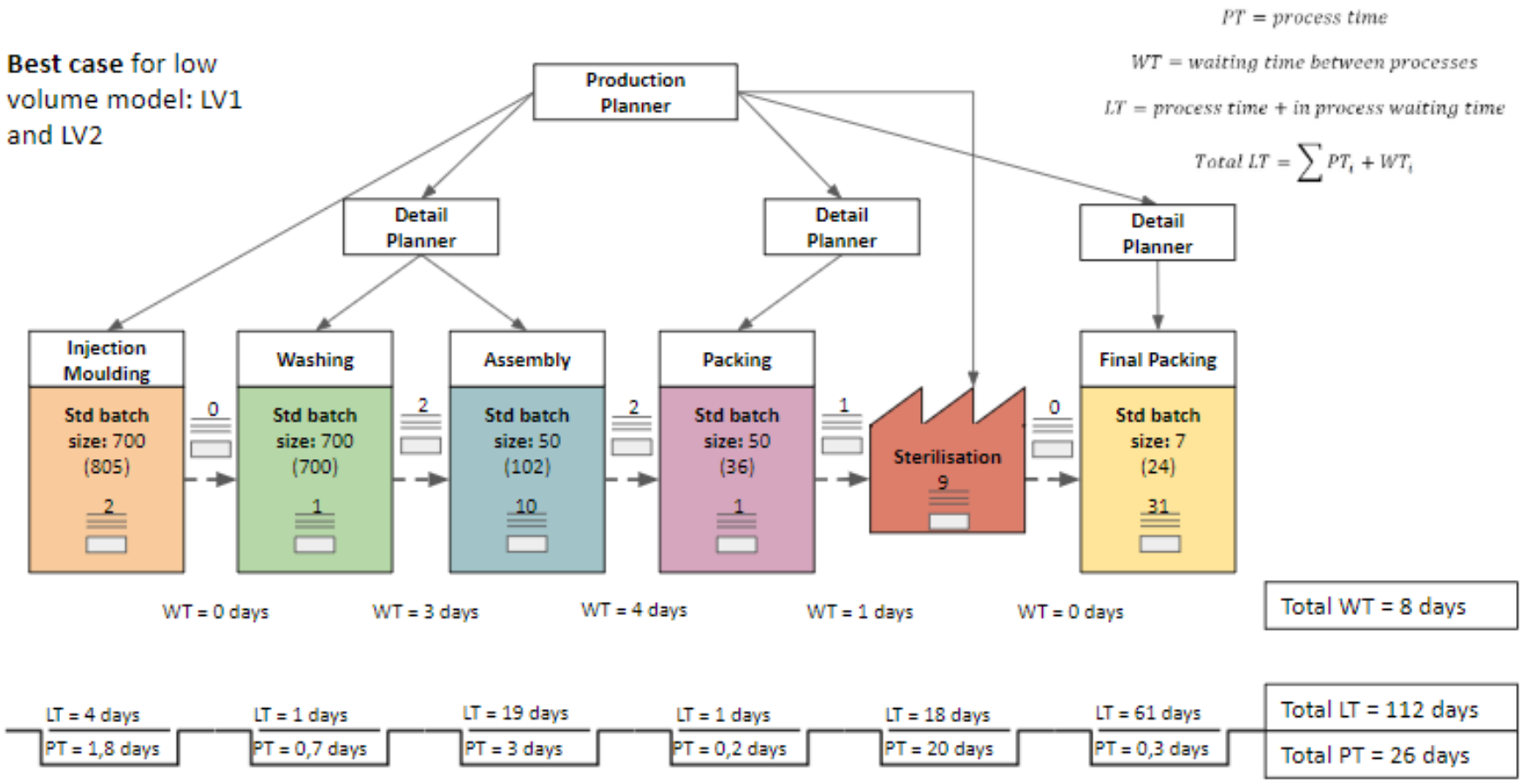


Figure 27 VSM - Best case for low volume model: LV1 and LV2

Appendix E

Table 38 Batches analysed for high volume products: HV1 and HV2.

Batch nr injection moulding	Batch nr finished		Total lead time
A	A1		120,7
	A2		175,7
	A3		161,4
	A4		154,3
	A5		134,3
	A6		120
		Average	144,4
B	B1		107,9
	B2		92,1
	B3		97,1
		Average	99,0
C	C1		223
	C2		135,7
	C3		147,9
	C4		167,9
	C5		149,3
		Average	170,1
D	D1		125,7
	D2		149,3
		Average	137,5
E	E1		160
	E2		125,7
		Average	142,9

Table 39 Batches analysed for low volume products: LV1 and LV2.

Batch nr injection moulding	**Batch nr finished**	**Finish date**	**Total lead time**
F	F1		689,3
	F2		648,6
	F3		583,6
	F4		716,4
	F5		700
	F6		655,7
	F7		626,4
	F8		551,4
	F9		508,6
	F10		470,7
		Average	615,7
G	G1		142,2
	G2		115,0
	G3		228,6
	G4		174,3
	G5		112,0
		Average	154,4

Appendix F

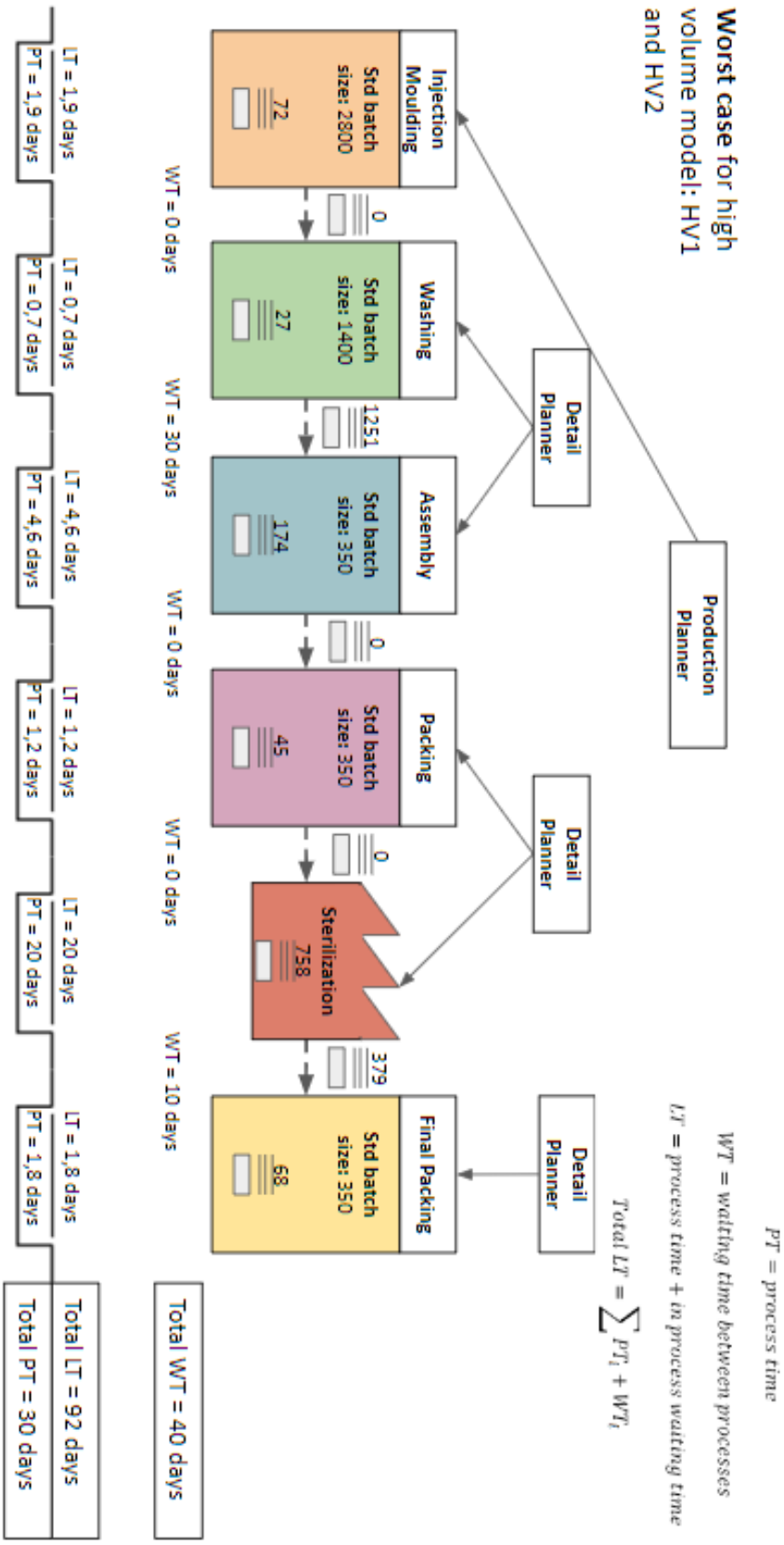


Figure 28 FSM - Worst case for high volume model: HV1 and HV2

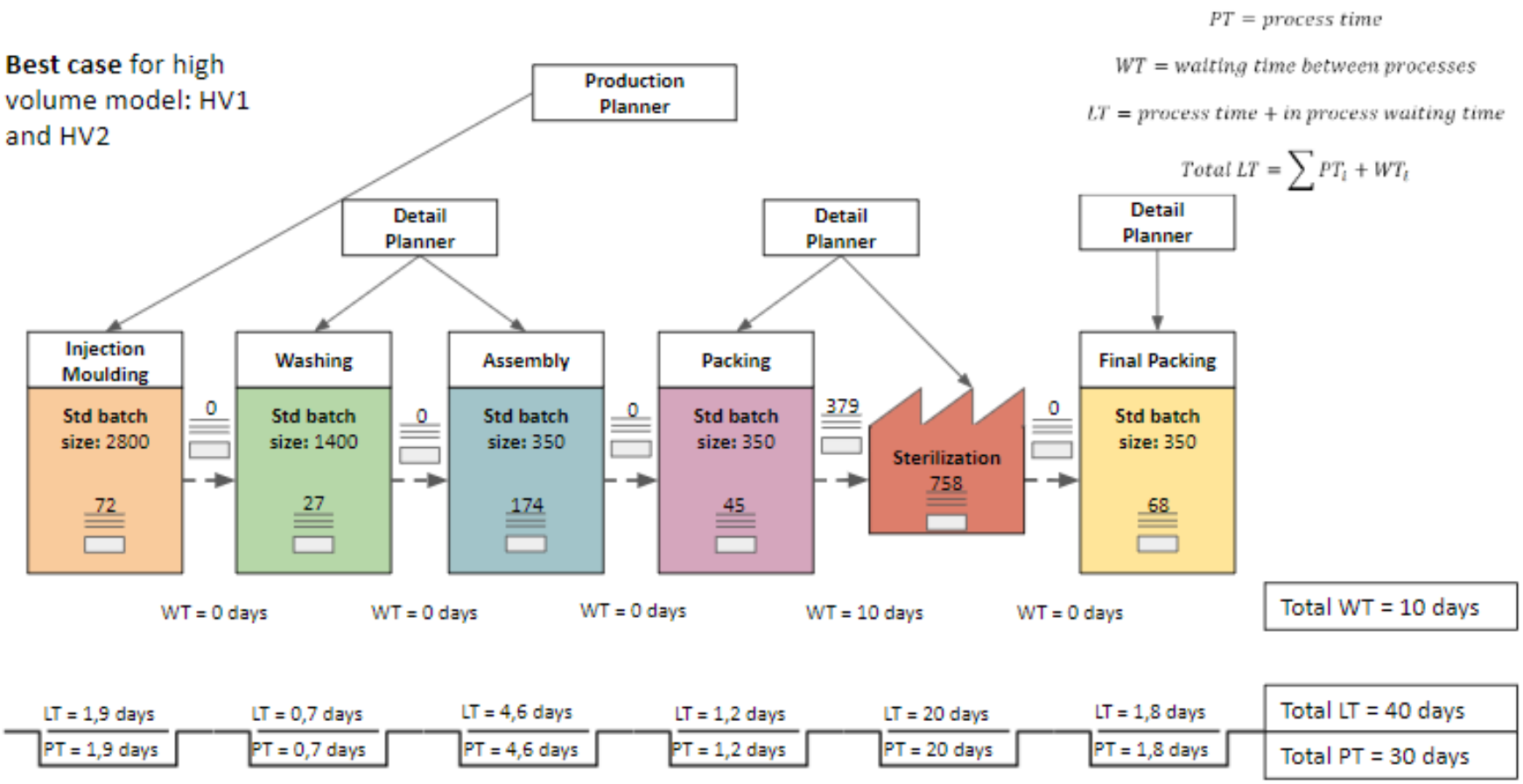


Figure 29 FSM - Best case for high volume model: HV1 and HV2

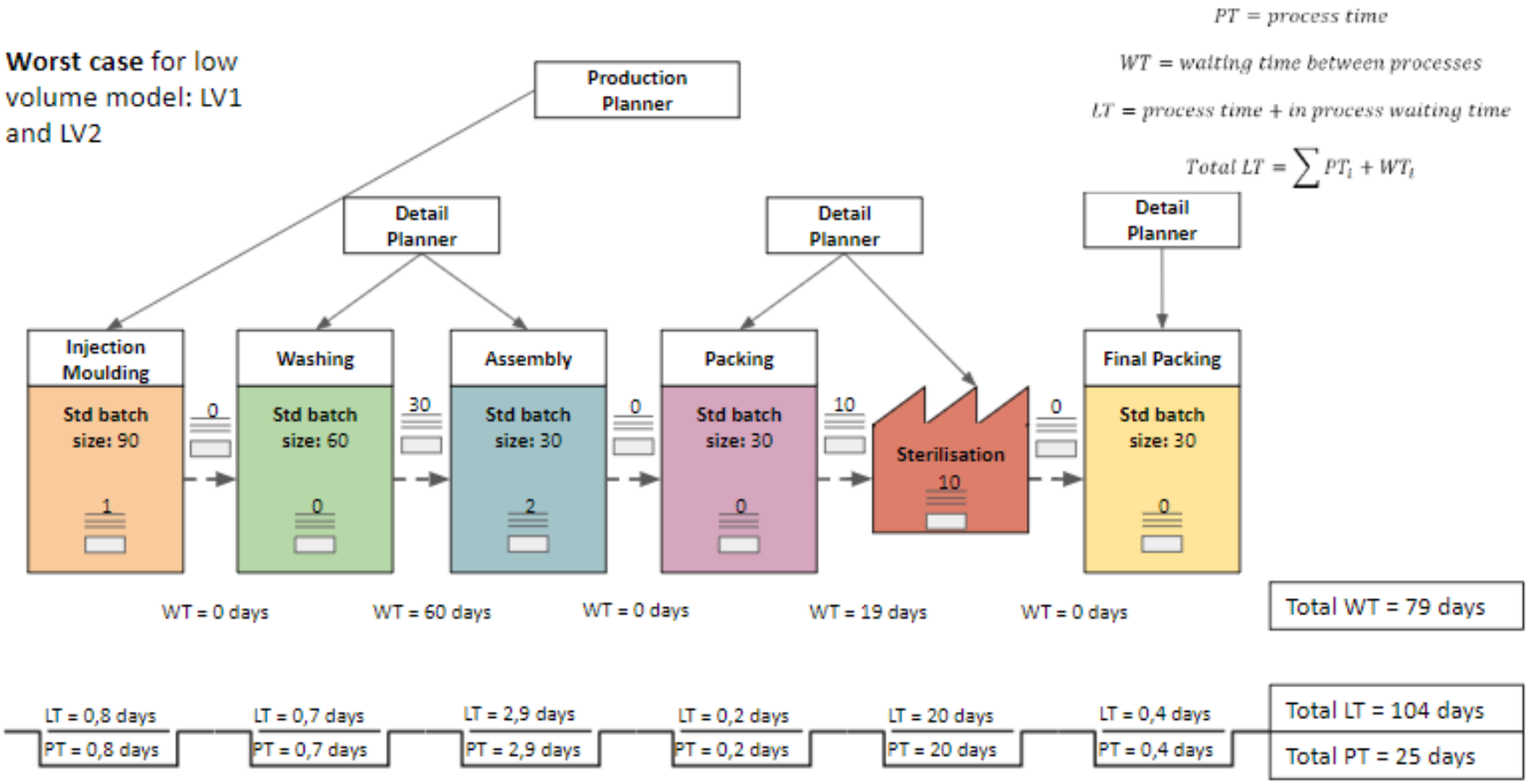


Figure 30 FSM - Worst case for low volume model: LV1 and LV2

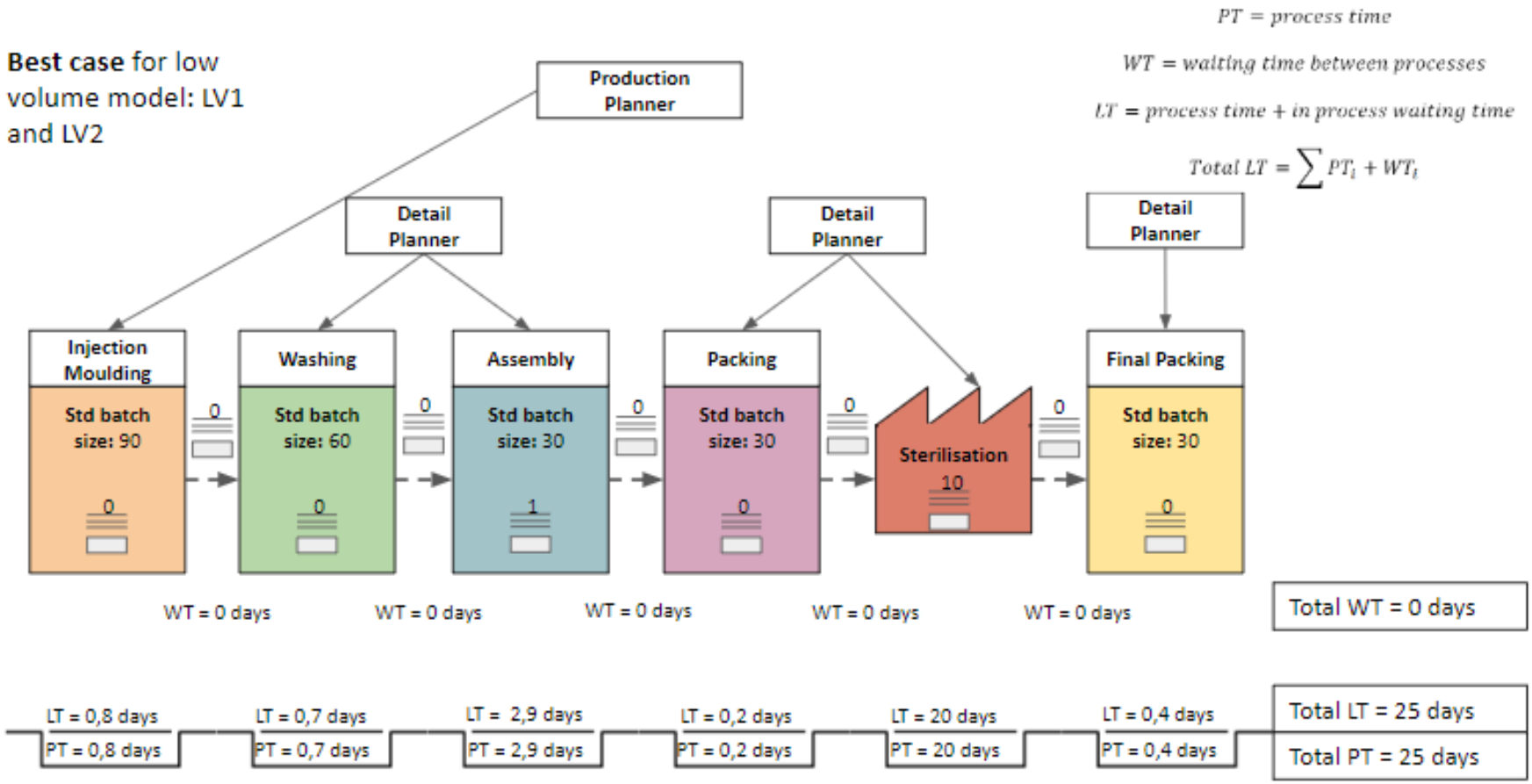


Figure 31 FSM - Best case for low volume model: LV1 and LV2