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Specialization:	Transport Engineering and Logistics
Report number:	2015.TEL.7955
Title:	**Improving the efficiency of the delivery of surgical instruments at the Leiden University Medical Center**
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Title	Efficiëntie verbetering van de levering van chirurgische instrumenten in het Leids Universitair Medisch Centrum

Assignment:	Master thesis
Confidential:	Yes (until November 11, 2020)
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Date:	November 11, 2015

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Subject: **Improving the efficiency of the delivery process of surgical instruments at the Leiden University Medical Center (LUMC)**

In the health care system patient safety is the primary focus. Hospitals and staff travel great lengths in order to ensure the highest possible patient. New rules and regulations to improve patient safety come into effect on a regular basis. An area of current development is the global Unique Device Identification (UDI); it will become mandatory to apply an UDI to every reusable medical device. The CSSD (Central Sterile Supply Department) will be affected by the introduction of UDI; it will require a large investment and will increase operational cost. Furthermore, the cost of healthcare is increasing on a yearly basis for the last decades.

These two drive CSSD to cost reduction as well. However, the current operation is not well suited for process optimization. The demand of the customer is unknown, which should be the focal point of production, and process parameters are not known or used. The UDI system offers an opportunity to address the latter issue, using the infrastructure required for the traceability of instruments as a means of acquiring process parameters and Key Performance Indicators (KPIs), the manufacturing and delivery of sterile instruments can be operated at a higher efficiency. Production environments such as the CSSD can be redesigned in order to take customer demand into account. This is called Demand Driven Supply (DDS), the supply (and production) of the exact customer demand.

This assignment will propose a Demand Driven Supply method combined with visibility that is applicable on the LUMC. The research of this assignment will cover:

- Survey on Demand Driven Supply methods and visibility methods/technologies;
- Selection of feasible methods/technologies;
- Design of Demand Driven Supply & visibility system;
- Verification of the system;
- Economical analysis of the system.

The final report should be arranged in such a way that all data is structurally presented in graphs, tables and lists with belonging descriptions and explanations in text.

The report should comply with the guidelines of the research section of TEL. Details can be found on the website.

The professor,

Prof.dr.ir. G. Lodewijks

Summary

The Central Sterile Supply Department (CSSD) of the Leiden University Medical Center (LUMC) is part of the sterilization cycle and provides sterile surgical instruments to the Operation Room (OR). In the production process of the CSSD used instruments are transformed into sterile instruments, fit for use in the OR. The coming years several changes are imposed on this department such as the requirement of Unique Device Identification (UDI) of all instruments and an increased focus on budgeting and cost reduction. Currently, the CSSD is not well suited to reduce cost, demand of the customer and relevant process parameters are unknown. This thesis provides a solution for the use of UDI, incorporation of customer demand and acquisition of process parameters in the CSSD and its effect on the delivery efficiency.

In the search for an optimal solution the current sterilization cycle is described and analysed. Production of the CSSD is not based on a production planning and there is little knowledge about process performance. In production environments the customer demand is placed central by use of Demand Driven Supply (DDS) methods. And process performance can be improved by an Automatic Identification (AutoID) solution, which is used to provide UDI as well.

A literature survey is performed on DDS methods and AutoID solutions. A total of five DDS methods are suitable for use in the sterilization cycle, the Manufacturing Resource Planning (MRPII) is selected as the optimal method. This is based on compliance to handling of: demand variability, demand volatility, product mix, capacity constraints and planning. Similar, six different AutoID concepts are made from four suitable AutoID technologies. A selection procedure yields the concept that uses Radio Frequency Identification (RFID) as optimal.

The MRPII method and AutoID solution are integrated into one system, Manufacturing Resource Planning & Automatic Identification (MR-PAID), and is implemented into the sterilization cycle. The implementation shows that there are three essential factors of success of MR-PAID:

1. Good communication between CSSD and OR;
2. A Service Level Agreement (SLA) has to be defined;
3. Data quality has to be good.

Furthermore, MR-PAID requires a redesign of the sterilization cycle, the main inventory location has to be changed and a safety stock should be added.

The redesigned sterilization cycle with MR-PAID is evaluated on performance and cost. The performance evaluation provides that the delivery efficiency can be improved in two ways, reduction of stock and postponement. The economical evaluation presents a return on investment period of 3.7 years for MR-PAID. This is based on a capital expenditure of €328,400, an increase in operational expenditure of €52,300, a decrease in inventory value of €356,700 and a reduction of 5% on staff cost due to increase in production efficiency. Furthermore, an additional cost of 6% was introduced to cover the cost of not receiving interest.

At the end of this thesis the conclusions are presented and recommendations are given. Subsequently a discussion is shown in which decisions and assumptions are elaborated on and possibilities for future research are presented.

Samenvatting

De Centrale Sterilisatie Afdeling (CSA) van het Leids Universitair Medisch Centrum (LUMC) is onderdeel van de sterilisatiecyclus en levert steriele chirurgische instrumenten aan de Operatie Kamer (OK). Het productieproces van de CSA zet gebruikte instrumenten om in steriele instrumenten, geschikt voor een volgend gebruik in de OK. Een aantal veranderingen worden de komende jaren aan deze afdeling opgelegd, zoals de eis van Unieke Instrument Identificatie (UII) van alle instrumenten en een vernieuwde focus op budgettering en kostenreductie. Op dit moment in de CSA niet gereed voor kostenverlaging, de vraag van de klant en relevante procesparameters zijn niet bekend. Deze scriptie biedt een oplossing voor het gebruik van UII, het in acht nemen van de vraag en het verkrijgen van de procesparameters in de CSA en het effect op de leveringsefficiëntie.

De eerste stap in het verkrijgen van een oplossing is een beschrijving en analyse van de huidige sterilisatiecyclus. De productie van de CSA is niet gebaseerd op een productie planning en de procesprestaties zijn nagenoeg onbekend. In productie-omgevingen wordt de vraag van de klant centraal geplaatst door het gebruik van Demand Driven Supply (DDS) methoden. Daarnaast kunnen de procesprestaties worden verbeterd door een Automatic Identification (AutoID) oplossing, die tevens geschikt is om UII te verlenen.

Een literatuuronderzoek is uitgevoerd naar DDS methoden en AutoID oplossingen. In totaal zijn vijf DDS werkwijzen geschikt voor toepassing in de sterilisatiecyclus, de Manufacturing Resource Planning (MRPII) is gekozen als de beste werkwijze. Dit is gebaseerd op de nakoming van de behandeling van de variabiliteit van de vraag, volatiliteit van de vraag, de productmix, capaciteitsbeperkingen en planning. Op eenzelfde manier zijn zes verschillende AutoID concepten tot stand gekomen van vier geschikte AutoID technologieën. Een selectieprocedure resulteert in een Radio Frequency Identification (RFID) concept als best geschikt voor gebruik.

De MRPII methode en AutoID oplossing zijn geïntegreerd in één systeem, Manufacturing Resource Planning & Automatic Identification (MR-PAID), en is geïmplementeerd in de sterilisatie cyclus. De implementatie laat zien dat drie factoren van invloed zijn op het succes van MR-PAID:

1. Goede communicatie tussen de CSA en de OK;
2. Een Service Level Agreement (SLA) moet worden gedefinieerd;
3. De kwaliteit van de data moet goed zijn.

Bovendien is een herontwerp van de sterilisatie cyclus vereist, de voornaamste voorraad locatie moet verplaatst worden en een veiligheidsvoorraad moet worden toegevoegd.

De vernieuwde sterilisatiecyclus, met MR-PAID, is beoordeeld op prestaties en kosten. De prestatie-evaluatie laat zien dat de levering efficiëntie verbeterd kan worden op twee manieren, vermindering van de voorraad en vertraging van productie. De economische evaluatie geeft een terugverdientijd van 3,7 jaar voor MR-PAID. Dit is gebaseerd op kapitaaluitgaven van €328.400, een stijging van de operationele uitgaven van €52.300, een daling van de inventaris waarde van €356.700 en een vermindering van 5% op de personeelskosten als gevolg van verhoging van de productie-efficiëntie. Hiernaast is een rentevoet van 6% in acht genomen om de kosten van gemiste rente te dekken.

Aan het einde van deze sciptie worden de conclusies gepresenteerd en de aanbevelingen gedaan. Vervolgens is een discussie gegeven waarin beslissingen en aannames worden behandeld en mogelijkheden voor toekomstig onderzoek worden aangedragen.

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List of Abbreviations

$\frac{P}{D}$ **ratio** production to delivery lead time ratio.

AHP Analytic Hierarchy Process.
ATM Automated Teller Machine.
ATO Assemble-To-Order.
Auto-ID Automatic Identification.

BAP Battery Assisted Passive.
BOM Bill of Materials.

CAPEX capital expenditure.
CDF Cumulative Distribution Function.
CFF model Cross Functional Flow model.
CODP Customer Order Decoupling Point.
CONWIP Constant Work-In-Process.
CRP Capacity Requirement Planning.
CSSD Central Sterile Supply Department.
CV Coefficient of Variation.

DDS Demand Driven Supply.
DES Discrete Event Simulation.

EAN International Article Number.
ETO Engineer-To-Order.

FDA Food and Drug Administration.
FIFO First-In, First-Out.
FLC Fuzzy Logic Controller.

GPS Global Positioning System.

HF High Frequency.

ID identification.
IMDRF International Medical Device Regulators Forum.
IQR Inter Quartile Range.
ISO International Organization for Standardization.

KPI Key Performance Indicator.

LUMC Leiden University Medical Center.

MF Membership Function.
MPS Master Production Schedule.
MR-PAID Manufacturing Resource Planning & Automatic Identification.
MRP Material Requirement Planning.
MRPII Manufacturing Resource Planning.
MTO Make-To-Order.
MTS Make-To-Stock.

OCR Optical Character Recognition.

OCT Order Completion Time.
OPEX operational expenditure.
OPP Order Penetration Point.
OR Operation Room.

QR code Quick Response code.

RCCP Rough-Cut Capacity Planning.
RDV Relative Demand Volatility.
RFID Radio Frequency Identification.
RNG Random Number Generator.
ROI return on investment.
RTLS Real-time Location System.

SIM Subscriber Identity Modules.
SLA Service Level Agreement.
STD standard deviation.

T&T Track and Trace.

UDI Unique Device Identification.
UHF Ultra High Frequency.

WIP Work-In-Progress.

Chapter 1

Introduction

The Leiden University Medical Center (LUMC) is a modern university medical center with a high quality profile and a strong scientific orientation. The main subjects the hospital focusses on are research to new techniques, education of aspiring doctors and patient care. These three main functions are supported by many sub-functions, such as the supply of sterile reusable instruments, performed by the Central Sterile Supply Department (CSSD).

1.1 Central Sterile Supply Department

The CSSD provides the Operation Room (OR) with sets of sterile medical instruments, which are used for patient care. These instrument sets, called baskets, are cleaned, maintained and sterilized in the CSSD. The relation between the CSSD and OR can be seen in Figure 1.1. Considering the sterilization cycle to be a production process, the supplier is the CSSD and the customer is the OR. The production aims at the transformation of used (dirty) baskets, returned from the OR, into sterile baskets that are fit for use during surgery. Approximately 7000 baskets of instruments are produced per month.

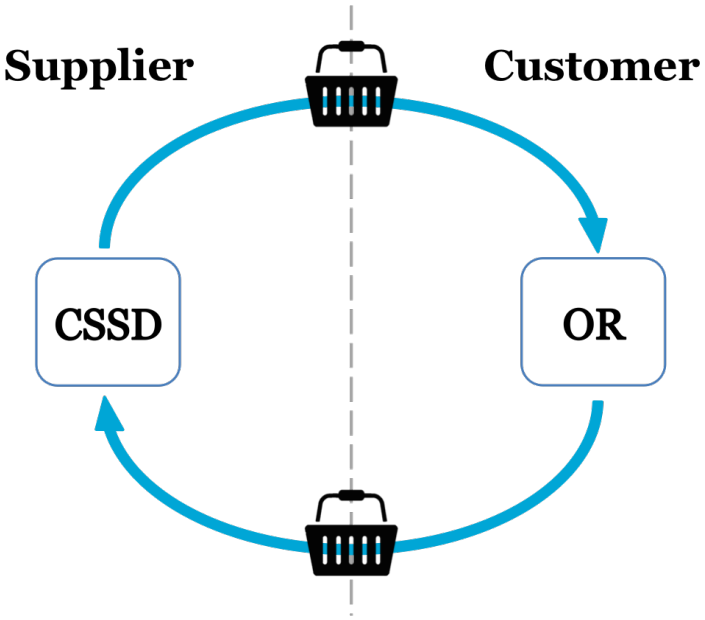


Figure 1.1: Relation between the CSSD and the OR in basket delivery

1.2 Problem definition

In the health care system patient safety is the primary focus. Hospitals and staff travel great lengths in order to ensure the highest possible patient safety. The leading driver imposing changes on the healthcare system is the government. New rules and regulations to improve patient safety come into effect on a regular basis. An area of current development is the global Unique Device Identification (UDI); it will become mandatory to apply an UDI to every reusable medical device [IMDRF, 2013]. According to the International Medical Device Regulators Forum (IMDRF), an advisory body of the European Commission, there are five main reasons for this obligation [IMDRF, 2013]:

"A globally harmonized and consistent approach to UDI is expected to increase patient safety and help optimize patient care by facilitating the:

1. *Traceability of medical devices, especially for field safety corrective actions;*
2. *Adequate identification of medical devices through distribution and use;*
3. *Identification of medical devices in adverse events;*
4. *Reduction of medical errors;*
5. *Documenting and longitudinal capture of data on medical devices."*

The European Commission is working on the adoption of the new regulations and preparing delegated acts concerning UDI, which should be finished in 2016. After completion of the regulatory framework, it will be phased in over several years. This is alike the Food and Drug Administration (FDA) variant of UDI, which started in 2013 and comes into full effect in 2020 [FDA, 2015]. Since the CSSD processes reusable medical devices, its current operation will be affected by the introduction of UDI. The UDI system will require a large investment and will increase the operational cost, compared to the current process. The initial investment can be broken down into application of UDI on the instruments and the required hardware and infrastructure. The operational cost will increase due to maintenance and depreciation of the UDI system and the addition of an extra processing step, the scanning of the UDI of the instruments.

Besides the increase in operational cost, there is the trend of increasing healthcare cost on a yearly basis for the last decades. In 1999 the expense per capita was €2744, which has doubled to €5630 in 2014 [CBS, 2015]. The main causes for this increase in cost are the ageing of the population on one hand and the commoditization of advanced technologies on the other. The LUMC has a renewed focus on budgeting and cost reduction to counter act the increasing healthcare expenses.

These two factors drive the CSSD to cost reduction as well. However, the current operation is not well suited for process optimization. The demand of the customer is unknown, which should be the focal point of production, and process parameters are not known or used. The UDI system offers an opportunity to address the latter issue, using the infrastructure required for the traceability of instruments as a means of acquiring process parameters and Key Performance Indicators (KPIs), the manufacturing and delivery of sterile instruments can be operated at a higher efficiency. Production environments such

as the CSSD can be redesigned in order to take customer demand into account. This is called Demand Driven Supply (DDS), the supply and production of the exact customer demand. To study the effect of incorporating customer demand into the production process and the addition of process visibility onto the efficiency of the delivery of sterile instruments, the following central research question is formulated:

How can the efficiency of the delivery of sterile surgical instruments be increased, whilst taking DDS, process visibility and UDI into account?

The delivery efficiency of sterile surgical instruments is amongst others dependent on the demand planning. The level of demand planning can be obtained from the sterilization cycle through the time baskets spend in sterile storage. When instrument production is based on planning, the time instruments are in sterile storage will be low; every instrument is used at surgery shortly after production. However, currently the CSSD processes everything that comes through the doors as soon as possible, regardless of the next use date of the instruments. This leads to a production push to the main inventory, the sterile storage, located close to the customer. The majority of instruments available in the LUMC are situated in this sterile storage. This has the advantage that the instruments are finished and can be used during surgery in mere minutes. However there are disadvantages as well, the inventory holding costs are higher compared to a storage situation in semi-finished state [Waller et al., 2000]. At the LUMC the higher inventory holding cost is caused by three mechanisms, 1) more labour and material are put into the instruments, 2) the sterility of instruments can easily be compromised due to damage of the packaging material and 3) the square meter prices of sterile storage is higher than non-sterile storage, due to the requirements to air quality. All in all, the reduction of the time in sterile storage will increase the delivery efficiency. Equation 1.1 takes both the time in sterile storage and in the CSSD process into account to quantify the delivery efficiency. Therefore the delivery efficiency is to be seen as a efficiency ratio. A higher value of $\eta_{Delivery}$ equals a production process that takes demand planning into account.

$$\eta_{Delivery} = 1 - \frac{T_{SS}}{T_{SS} + T_{CSSD}} \tag{1.1}$$

In order to provide an answer to the central research question the next four supporting questions are answered in the various parts of the report:

1. What is the most viable system for DDS of surgical instruments at the LUMC?
2. Which process KPIs have to be known for the successful operation of DDS?
3. Which methods are feasible for providing the visibility of the KPIs of the DDS system and provision of UDI on instruments?
4. To what extend can the DDS system combined with KPI visibility decrease the time in sterile storage of surgical instruments?

In search for an answer to the central and research questions first an analysis of the current situation of the CSSD is made. In this analysis it became clear that the sterilization cycle involves three different departments, the CSSD, OR and the Transport department. The first step in the sterilization cycle is cleaning, the used instruments are manually cleaned and prepared for disinfection, in one of six washing machines. After disinfection the instruments are inspected for any damage and are send to the packaging phase. During packaging, with ten work stations, multiple instruments are combined into a basket, which is put through one of four autoclaves during sterilization. The result is a sterile basket containing sterile instruments. The basket is transported to the OR complex where it is stored until it is used. After use the basket and instruments are returned to the CSSD. The production of the CSSD is based on the entering baskets, no orders or planning are used.

The principal flow in the sterilization cycle is composed of baskets of reusable surgical instruments. Over 9,000 different instrument types are present in the LUMC, which can be part of almost 950 different basket types. Out of the 9,000 instruments, 7,500 are only present on a single basket type; there is a very large diversity in basket contents and there are very little similarities. In order to limit the data size a selection of three out of 14 specialisms is made. The selection is based on a good overview of the different characteristics of specialism. Plastic surgery, a specialism focussed on the alteration of the form of the human body (also known as cosmetic surgery), is evaluated since most surgeries are known well in advance. General surgery, a specialism focussed on the abdominal contents of the human body, is analysed because it is the largest specialism, which performs the most surgeries. And lastly Transplantation surgery, a specialism focussed on transplantation of organs from one patient to another., is included because the surgeries for this specialism is seldom planned. For the baskets of these specialisms the CSSD process time and time in sterile storage have been analysed, this showed that 90% of the baskets are processed within one day and that the average time in sterile storage is almost 200 hours. The analysis of process and storage time second the inability of the CSSD to take the demand planning of the OR into account. A method widespread in production environments that make customer demand the focal point of production is DDS.

A DDS method is used throughout industry as a method to integrate customer demand in the production process. Five different DDS methods are evaluated, which are: Kanban, Constant Work-In-Process (CONWIP), Material Requirement Planning (MRP), Manufacturing Resource Planning (MRPII) and the Packing Centre. Following, the requirements cast upon the DDS methods by the sterilization cycle are determined, which are: demand variability, volatility, product mix, capacity constraints and the incorporation of planning. The Analytic Hierarchy Process (AHP) method is used to determine the most feasible DDS which is MRPII. The MRPII method can be used for the generation of production orders of baskets for planned surgeries, acute surgeries have to be supplied from a safety stock. Various inputs are used for the generation of feasible production schedules and for the generation of work orders: qualitative and quantitative input data. The qualitative data consists of amongst others the OR planning, capacity

constraints and the instruments on different baskets. The quantitative input data is inventory and production performance based, these two data inputs have to be provided from measurements of the sterilization cycle.

Process visibility methods are used in many different industries for the acquisition of process parameters and KPIs. Furthermore are process visibility methods capable of the provision of the UDI to instruments. There are four groups of technologies that comply to both, the barcode system, Optical Character Recognition (OCR), smart cards and the Radio Frequency Identification (RFID) system. The technology will be applied on instrument level to comply to the UDI guidance and will be used in a gate point Real-time Location System (RTLS) system. Following the literature survey and selection of RTLS the requirements to the visibility technology are determined. The technology has to be able to handle the use conditions in the sterilization cycle, the invasiveness of the technology has to be low, it has to comply to the UDI guidance and the technology can not change the classification of the instruments. On instrument level only the 2D-barcode system and passive RFID tags comply to the UDI guidance and classification constraints, and are evaluated further. On basket level smart cards can not be applied because it is unable to handle the use conditions. The analysis yielded the passive RFID tag and 2D-barcode system as possible technologies on basket level as well. Using the two visibility technologies on instrument and basket level a total of six concepts are proposed to provide the UDI to instruments, two only have an instrument solution, four an basket solution as well. The six concepts are evaluated using the AHP method on compliance to two functional requirements, identification of unique instruments and baskets, and to four non-functional requirements, readability, reliability, cost effectiveness and impact on process. The result of the AHP method is that a solution with passive RFID tags on baskets and instruments is best applicable for use in the sterilization cycle.

The MRPII method and visibility solution is integrated into one system and implemented into the sterilization cycle. The connection of between the two has to be made using a database. The database stores the data supplied by the visibility solution and makes it available for use by the MRPII system. A second data source of the MRPII system comes from the OR, which is the planning data. This shows the necessity of good communication between the OR and CSSD, if the planning is incorrect, the production schedule will be incorrect as well. Furthermore, the process has to be redesigned to incorporate the integrated system, the main inventory is placed after inspection of the instruments in clean storage, combined with a safety stock of sterile baskets.

The performance and cost of the integrated system is evaluated to come to a final conclusion. The time in sterile storage can be reduced in two ways, reduction of dead stock and postponement. Reduction of dead stock can decrease the time in sterile storage by 9.12%, which is based on data analysis. Simulation result analysis shows a decrease in time in sterile storage of almost 79% due to postponement. However, the actual reduction is less caused by amongst others complexity and demand fluctuations. A reduction in the range of 12 to 36% is realistic, when the characteristics of the sterilization cycle are taken into account. This will relate to an increase in delivery efficiency of 12 to

28%. The initial investment of implementation of the integrated system is €328,359; the operational cost will increase with €52,303. However, a reduction in instrument value can be achieved of €356,675. When this is combined with a decrease in staff cost (5%) due to higher production efficiency a return on investment (ROI) of 3.68 years is achieved.

1.3 Thesis outline

With introduction of the motivation for this thesis, the problem definition, research question and the boundaries of the research known, the outline of this thesis is given to provide a brief overview of the study.

Chapter 2 gives the analysis of the sterilization cycle in order to give insight into the current processes and material flow. Furthermore, the particulars of operation of the CSSD are described. The necessity for DDS is shown as well. In Chapter 3 a literature survey is presented on methods that are applicable for DDS. A selection of the most feasible method is presented, which requires various process parameters as input. The applicable visibility technologies to acquire the process parameters are described in Chapter 4, of which the most viable for use is selected. The integration of both the DDS method and visibility technology into one system is discussed in Chapter 5. In Chapter 6 the integrated system is evaluated on performance and cost. This thesis is concluded with the conclusions and recommendations for future research in Chapter 7.

Chapter 2

Analysis of the Central Sterile Supply Department

In order to provide a solid base for the research the current situation has to be analysed. Three subjects will be discussed in this chapter, sterilization cycle description, quantitative analysis and cost analysis of the CSSD. The sterilization cycle description concerns the description of the different process steps in the continuous cycle of use (Figure 1.1) and the surgical instruments that are being precessed in the system. The quantitative analysis of the current situation will go further into detail on the numerical performance of the CSSD processes and the composition of the instruments. The cost analysis presents the invested capital and operational cost breakdown of the current operation. This chapter is concluded with the concluding remarks.

2.1 Sterilization cycle description

This section will give the particulars of the CSSD based on qualitative description. Two subjects are addressed, a model of the sterilization cycle is given and the characteristics of the reusable surgical instruments that are processed by the CSSD are discussed.

2.1.1 Model of the sterilization cycle

The sterilization cycle presented in Figure 1.1 is expanded to show the various steps in production. The result of this expansion is given in Figure 2.1.

The continuous loop of use, cleaning and sterilization shown in Figure 2.1 shows the different steps taken in the continuous sterilization cycle. However the different departments that perform the actions are not included in this representation. Therefore a Cross Functional Flow model (CFF model) [Rummler and Brache, 1995] is made from the sterilization cycle, shown in Figure 2.2. A CFF model uses multiple rows to show the various functional departments or units within a business (process). The tasks of the different units are placed in the corresponding row to give a clear picture of the dependencies and relations between the units. The three rows of this diagram are the different departments which are part of the sterilization cycle: the CSSD, Transport and the OR. The black arrows give the flow direction of the surgical instruments, the dashed arrows are a request for additional instruments. Additional instruments might be required because of incomplete baskets or complications during surgery.

The first step in the process is cleaning, the used instruments are manually cleaned and prepared for disinfection, in one of six washing machines. After disinfection the

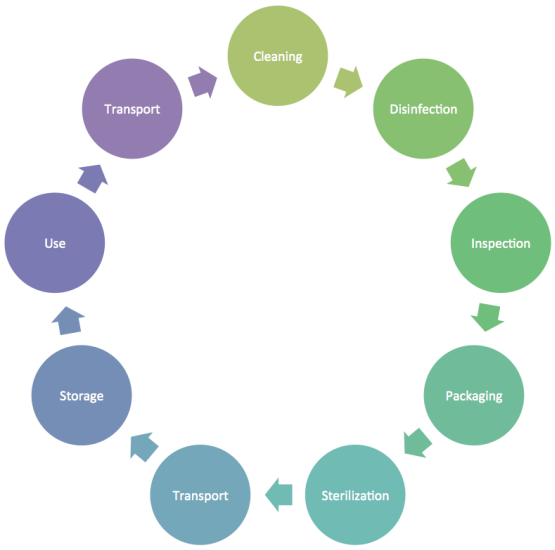


Figure 2.1: Different processes in the sterilization cycle

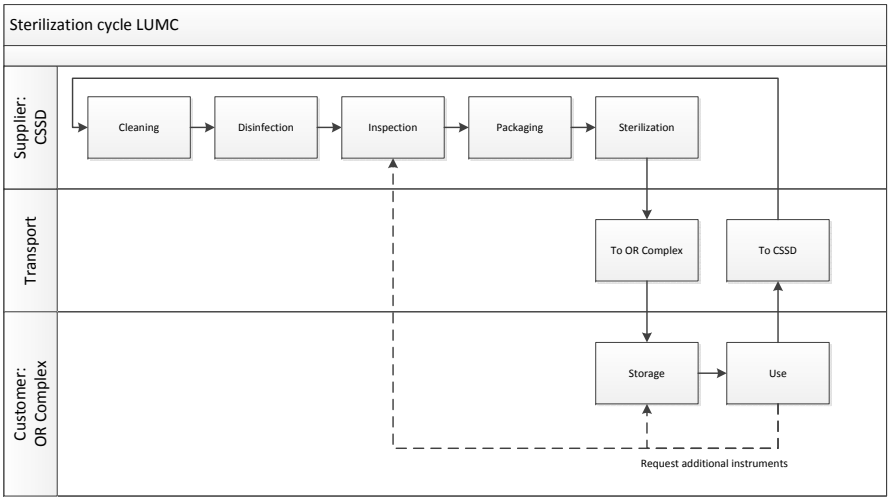


Figure 2.2: CFF model of the sterilization cycle

instruments are inspected for any damage and are send to the packaging phase. During packaging, with ten work stations, multiple instruments are combined into a basket, which is put through one of four autoclaves during sterilization. The result is a sterile basket containing sterile instruments. The basket is transported to the OR complex where it is stored until it is used. After use the basket and instruments are returned to the CSSD. A detailed description of the different sub-processes within the nine blocks can be found in Appendix B.

2.1.2 Reusable surgical instruments

The principal flow of products (and focus of this research) in the CSSD is composed of reusable surgical instruments. The total number of instruments used throughout the LUMC is tens of thousands (a *very* rough estimate is 40,000), but this number is not exactly known. They are available as part of a basket or as individual instrument. This section shows the different classes of instruments and the two before mentioned categories of instrument flow will be elaborated; individual instruments and instrument baskets and sets.

Classification of instruments

Without classification the instruments can not be used during surgery. When changes are made to the instruments the classification may become void. All surgical instruments have to be approved by a Notified Body. The Notified Body has been accredited to validate instruments to the compliance to European Directive 93/42/EEC [EEC, 1993]. This directive distinguishes four different classes of instruments, shown in Table 2.1[1].

Table 2.1: Classification of surgical instruments following 93/42/EEC

	Description of instrument
Class I	Reusable surgical instruments, not connected to an active device
Class IIa	Active devices intended for diagnosis or control
Class IIb	More hazardous Class IIa instruments
Class III	Implantable and long-term invasive devices

The following criteria are taken into account when the classification of an instrument is accredited: invasiveness, duration of continuous contact, nature of the tissue contact and distinction between non-active and active devices.

Individual instruments

All instruments used in the LUMC are available as individual instrument. An individual instrument is packaged in a double laminate to keep it sterile (Figure 2.3) and stored as a single unit. Over 9,000 different types of individual instruments are in the database of the CSSD. Next three different types of individual instruments are shown to give an impression of the diversity, the telescope, needle holder and Jacobs chuck.

Telescope
Figure 2.4 shows the Endocameleon telescope that is used during cardiovascular keyhole surgery. This type of specialist procedure requires specialist tools. This telescope is used together with other tools that are specially made for keyhole surgeries.

[1]This table shows the general idea of the different classes, not all exceptions are taken into account.

Figure 2.3: Laminate package [TI, 2015]

Figure 2.4: Telescope [Karl Storz, 2015]

Needle holder

Figure 2.5 shows a needle holder that is used during (almost) every surgery. This type of instrument is very common and is available to the doctor in multiple sizes. Sometimes an extra needle holder is needed, therefore it is made available as individual instrument (same applies for other run of the mill instruments such as pliers, tweezers, clamps and scissors).

Jacobs Chuck

The Jacobs chuck with key shown in Figure 2.6 is used during most orthopaedic surgeries to hold different drills or screw bits. This type of specialized instrument is not used as often as the needle holder and comes in some different sizes.

Figure 2.5: Needle holder [Aesculap, 2015]

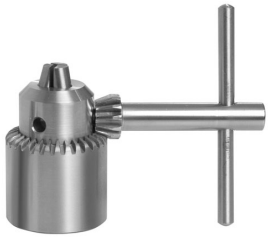


Figure 2.6: Jacobs Chuck [Albrecht, 2015]

Instrument baskets and sets

An instrument basket or set is a collection of two or more instruments (such as the needle holder), which are used together during surgery. These standard collections are formed in order to reduce the time that is needed for the collection of instruments before surgery. A basket can have a open or closed top, a set can be either put in a blue plastic tray or a double laminate. Baskets are packed in two layers of sterile paper, the inner layer is blue and the outer green (Figure 2.7). During most of the surgeries multiple different baskets and sets are used which have different contents. In all the different departments of the LUMC nearly 900 different types of baskets are used, with a total

of approximately 1,600. Next a description of some common and specialist baskets is given.

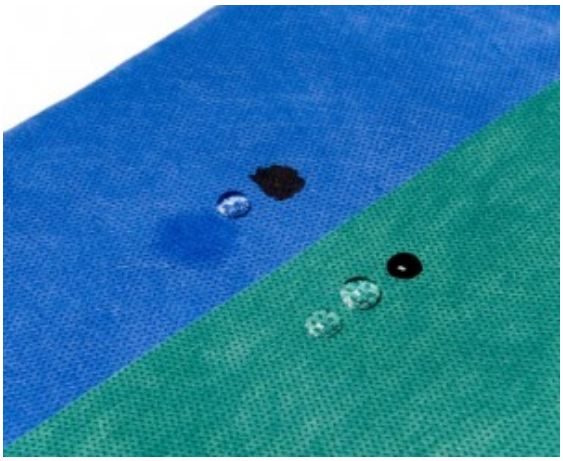


Figure 2.7: Two layers of sterilization paper [Interster, 2015]

Universal basic surgery set
The basic surgery set is composed of 12 instruments such as tweezers, claps, scissors and surgical knife holders. It is used for most minor surgeries. It can be found in Figure 2.8.

Figure 2.8: Universal basic surgery set

Acute surgery basket
The acute basket is a complete set that can be used emergency surgeries. It is held standby in many other cases such as during laparoscopic (keyhole) operations. When something goes wrong during a keyhole surgery the necessary instruments for an open surgery are not available on the regular baskets that are used. The acute basket is needed to ensure all the possible required instruments are at hand. Therefore it consist over 90 instruments in different sizes, it can be found in Figure 2.9.

Figure 2.9: Acute surgery basket

2.1.3 Customers of the CSSD

The CSSD supplies different specialisms, which are the customers shown in Figure 2.2, with sterile surgical instruments. An overview of the different specialisms together with the internal department number is given in Table 2.2. All the different baskets and instruments 'belong' to a certain department, but can be used by other departments. In this report the different departments will be referenced to by their internal number.

Table 2.2: List of department number and specialism

No	Specialism
2074	Neurosurgery
2075	Ear, Nose & Throat surgery
2076	Eye surgery
2077	Plastic surgery
2078	Oral & maxillofacial surgery
2080	General surgery
2081	Surgical oncology
2083	Thoracic surgery
2084	Vascular surgery
2085	Orthopaedics
2086	Trauma surgery
2087	Urology
2088	Transplantation surgery
2089	Gynaecological surgery

2.2 Quantitative analysis

This section will give the particulars of the CSSD based on quantitative analysis. Three different subjects are discussed, the basket composition for all different surgery groups, followed by the process time analysis and concluding the storage time analysis for a selection of the baskets. For the quantitative analysis raw data is collected from the process documentation program of the CSSD named T-DOC [Getinge AB, 2015]. T-DOC is used to document all the different characteristics of instruments, baskets and production. The instrument and baskets have to be described manually, whilst the production characteristics are automatically obtained from the process. The raw data is processed to the required format and used as input for data analysis using Matlab [The MathWorks, Inc., 2014]. Matlab is a numerical cumputing environment in which users can preform amongst others vector calculations, data manipulation, generate data plots and the definition of custom algorithms. It is widely used in academic and research environments.

2.2.1 Basket composition

As stated in the previous section each basket is a collection of multiple instruments. Since 950 different baskets are available for use in the LUMC and on average a baskets consists of 17.8 instruments. Similarities between baskets are inevitable when considering the 9,000 different instruments. The question that arises is how unique the different baskets are: Are there certain instruments that are part of most baskets?

The answer to this question lies within the Bill of Materials (BOM) of all the baskets of the different departments, which is defined within T-DOC. The BOM gives an overview of which instruments are part of a basket and in what quantity. From these BOM a list of unique instruments has been obtained. This list is cross checked against all the different baskets to find the occurrence of the unique instruments. Figure 2.10 shows the distribution of the number of baskets a single instrument is part of. On the left-hand side y-axis the occurrence is given, the right-hand side y-axis the percentage is shown and the x-axis shows the different bars.

Each bar number (1 to 61) represents how many basket types an instrument is part of. The different bars are given in blue and has to be read against the left-hand side y-axis, the red line represents the cumulative percentage which corresponds to the right-hand side y-axis and finally the actual number of occurrences is given above each bar in red. For example the 9^{th} bar has a occurrence of 17. Which means that out of the 9,000 instruments, 17 instruments are part of 9 different baskets.

As can be seen in Figure 2.10 the majority (82%) of instruments is unique, they only are part of one basket. Furthermore 18% of the instruments exists on two or more baskets, however it has to be noted that 10% of the instruments out of the 18% is actually on just two different baskets.

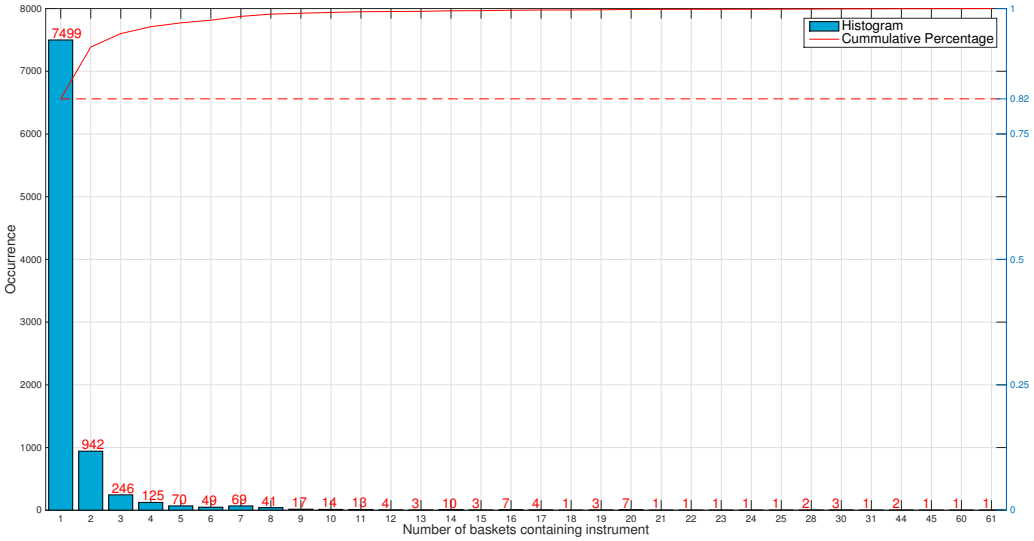


Figure 2.10: Distribution of the number of baskets a single instrument is part of

It can be concluded that there are very few similarities between baskets when looking at single instruments. Therefore further analysis into similarities for groups of instruments is not necessary, this will show the same correlation, only magnified. There are two possible reasons for the large variety in basket content, firstly the LUMC is a research hospital. In a research hospital more difficult and specialized surgeries are performed at the OR. These complicated surgeries require different sets of specialized instruments, which are unique for the surgery. Hereby the similarities between baskets is reduced. The second reason is closely related to the previous reason. Besides the specialized sets of instruments generic baskets are used. These generic baskets can be used for multiple surgeries and thus reducing the number of different baskets.

2.2.2 Process time analysis

This paragraph discusses the analysis of the process time at the CSSD for a selection of baskets (Appendix C). First the detailed cycle time is shown for a single Acute basket, after that the general process time for all Acute baskets is given. Finally the results for various baskets is shown.

Detailed process time of Acute basket

From T-DOC the time of the individual steps in the process can be obtained. Since this data has to be obtained manually a vast analysis is not feasible, therefore only ten cycles of one Acute basket are evaluated. The resulting data can be found in Table 2.3. The process time for the CSSD processes is obtained from this data by adding the Packaging

and Sterilization time from the current cycle, to the Pre-clean, Down time, Disinfection and Down time from the previous cycle. This causes the missing process time for *Cycle 1*, there is no data from *Cycle 0* in Table 2.3. For *Cycle 2* the calculation is:

$$T_{process} = 00:00:05:51+00:00:07:53+00:01:49:46+02:16:16:57+00:03:24:37+00:01:45:46 = 02:23:30:50$$

Most of the times of the process steps described in Appendix B are known within T-DOC, but there are two exemptions. Firstly the time needed for inspection is included in the packaging time, since these two processes are intertwined. And secondly the time in sterile storage, use, transport and manual pre-clean is only available as the sum of all parts, under the Use phase. T-DOC relies on the scanning of the baskets to determine the time stamp at a certain location. During these steps the basket is not scanned using T-DOC: the time stamp is unknown and thereby the process time as well.

Table 2.3: Detailed cycle time for ten cycles of one Acute basket (format is dd:hh:mm:ss)

	Cycle 1	*Cycle 2*	*Cycle 3*	*Cycle 4*	*Cycle 5*
Packaging	00:00:32:26	00:03:24:37	00:01:45:47	00:10:10:46	00:01:44:20
Sterilization	00:02:15:49	00:01:45:46	00:01:42:00	00:01:31:15	00:02:19:47
Transport	00:00:35:30	00:00:19:30	00:00:10:47	00:01:26:26	00:00:19:51
Use	01:21:29:53	00:23:28:43	00:21:13:45	01:02:50:41	04:13:50:56
Pre-clean	00:00:05:51	00:00:08:10	00:00:06:06	00:00:06:02	00:00:06:06
Down time	00:00:07:53	00:00:01:14	00:00:01:14	00:00:01:17	00:00:01:14
Disinfection	00:01:49:46	00:01:17:23	00:01:05:27	00:01:12:47	00:01:07:45
Down time	02:16:16:57	00:00:22:06	00:03:40:29	00:00:16:26	00:03:05:20
Process time		02:23:30:50	00:05:16:40	00:16:35:17	00:05:40:39
	Cycle 6	*Cycle 7*	*Cycle 8*	*Cycle 9*	*Cycle 10*
Packaging	00:00:54:32	00:23:25:54	00:05:13:04	00:01:46:51	00:00:00:29
Sterilization	00:01:52:05	00:01:29:57	00:01:28:17	00:01:48:49	00:01:26:50
Transport	00:00:24:47	00:00:02:38	00:00:21:37	00:00:16:38	00:00:07:03
Use	02:20:30:45	01:18:17:07	01:14:10:42	01:19:17:22	01:17:50:27
Pre-clean	00:00:05:56	00:00:06:44	00:00:06:37	00:00:06:00	00:00:05:58
Down time	00:00:02:04	00:00:01:16	00:00:01:12	00:00:01:14	00:00:01:15
Disinfection	00:01:00:02	00:01:01:36	00:01:44:31	00:01:07:19	00:01:29:10
Down time	00:02:03:09	00:01:26:59	00:01:01:39	00:00:36:13	
Process time	00:07:07:02	01:04:07:02	00:09:17:56	00:06:29:39	00:03:18:05

The order of cycle time components in Table 2.3 does not follow the processes in the CSSD, which start after the Use step. This is caused by the way T-DOC defines cycle time: it is based upon the different steps of a unique batch number. The new batch number is assigned to the basket at the moment the basket is clean, at the packaging step. Therefore the Packaging step is the top of Table 2.3.

Table 2.4 shows the minimum, mean and maximum process time of the CSSD for the ten cycles from Table 2.3. It has to be noted that some data is excluded from this

Table. *Cycle 10* has got a Packaging time of only 29 seconds, this is impossible since numerous instruments have to be inspected and placed inside the basket. Most likely the employee that produced this basket waited until the very last moment with assigning a new batch number. And 29 seconds after the new batch number was created the basket was finished and released for the next process step. The maximum time of the Down time after Disinfection stands out as well, it is more than 2.5 days. This is caused by the operation of the CSSD in the weekend. At Friday afternoon this baskets was used and send to the CSSD, where it was disinfected. On Saturday and Sunday there are employees at the CSSD to process the priority baskets and instruments. The Acute basket is not a priority and therefore the packaging is postponed until next the Monday.

Table 2.4: Summary of detailed cycle time for ten cycles of one Acute basket (format is dd:hh:mm:ss)

	Min	*Mean*	*Max*	*Median*
Packaging	00:00:32:26	00:04:53:53	00:23:25:54	00:01:46:19
Sterilization	00:01:26:50	00:01:46:03	00:02:19:47	00:01:43:53
Pre-clean	00:00:05:51	00:00:06:21	00:00:08:10	00:00:06:04
Down time	00:00:01:12	00:00:01:59	00:00:07:53	00:00:01:15
Disinfection	00:01:00:02	00:01:17:35	00:01:49:46	00:01:10:16
Down time	00:00:16:26	00:07:59:28	02:16:16:57	00:01:26:59
Process time	00:03:22:47	00:16:05:19	03:20:08:27	00:06:14:46

The minimal process time from the analysis is 03:22:47, of which one and a half hour is consumed by the Sterilization step, one hour by the Disinfection and 30 minutes by Packaging. The remainder of the process time is caused by the Pre-clean and the two Down times. The maximum process time is 03:20:08:27, of which the Down time consumes the largest part.

Besides the process time the time in use is obtained as well from this analysis. On average a basket is 01:22:06:02 in Use, for these 10 cycles.

General process time of Acute basket

As described previously T-DOC is unable to automatically provide the detailed cycle time, however it the general cycle times are available as output. Therefore this sub-paragraph will give a general overview of the process time for all the different Acute baskets. The Acute basket has been selected for this because it is used often and therefore there are more data points (2,031) in the same range. The time range of this analysis is from January 1, 2014 up to January 1, 2015.

The general overview supplied by T-DOC consists of the time stamp a basket enters the CSSD and the time stamp a basket exits the CSSD. The process time is the time in between these two time stamps. A small fault is introduced in this process time

since the first observation of the basket is just before the pre-clean step (see previous chapter). The resulting process times have to be cleaned to remove any infeasible data points. The process time is deemed infeasible when it is shorter than 3 hours, which resulted from the analysis in the previous paragraph (time for sterilization, disinfection and packaging). The maximum process time is set on 5 days, this includes processing delays of (long) weekends, but excludes other problems that could cause longer delays.

Figure 2.11 gives the results from this analysis. The data is represented in two different ways, on the left-hand side y-axis a histogram is plot, showing the distribution of the process time. The red line is the Cumulative Distribution Function (CDF) of this distribution and is plotted against the right-hand side y-axis. The CDF can be used to determine the process time for a uniformly distributed random value between zero and one. The range of process times that are included in the analysis can be obtained from this Figure, the first bar is empty (process time $<$ 3 hours) and there are no process times in excess of 120 hours. The minimal value of the process time is 3 hours, the mean 11.7 hours, the max 114.2 and the standard deviation (STD) 12.1 hours. Furthermore is the median value 6.1 hours, the first quartile 4.0 and the third quartile 16.8 hours. The first and third quartile give an Inter Quartile Range (IQR) of 12.8 hours.

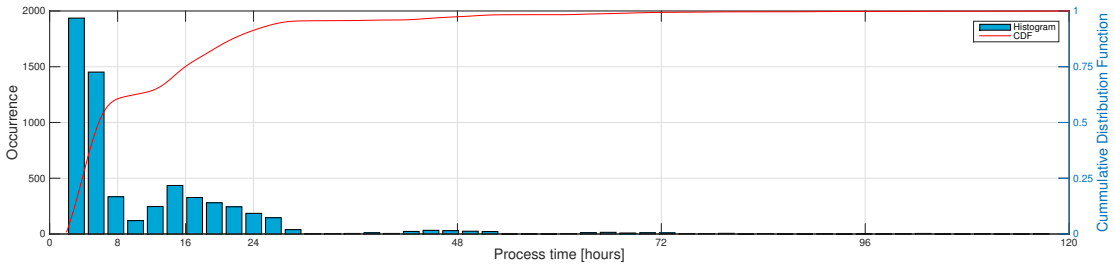


Figure 2.11: Process time distribution and CDF for all Acute baskets

Figure 2.11 shows that the CSSD handles most the Acute baskets that enter the system within 8 hours and that the other peaks in production are between 16 and 24 hours, around 40 to 48 hours and near 64 to 72 hours. These peaks in production correspond to the different shifts that are worked in the CSSD. The largest peak comes from the baskets that are processed during the shift in which they arrive. The second peak is processed during the next shift on the same or next day. The last two peaks are caused by (long) weekends, the baskets are disinfected on Friday, but sterilized the next week.

The general results from this sub-paragraph are in-line with the detailed results from the previous sub-paragraph. The mean process time differs 4 hours, which is caused by the small data set on which the detailed analysis is based. The maximum value of both types of analysis are in the same ball park, the difference is once more caused by the small dataset of the detailed analysis. The minimum value from the detailed analysis was used as input for the analysis of this paragraph and cannot be evaluated. In general it can be said that the CSSD processes the Acute baskets that enter the system as fast as possible. The underlying reasons for this remains unclear from Figure 2.11.

General process time of selected baskets

The analysis of the Acute basket shown in the previous sub-paragraph can be expanded to incorporate multiple baskets over various departments in the LUMC. A selection of three departments has been made, Plastic surgery (2077), General surgery (2080) and Transplantation surgery (2088). These departments have been selected since the number of baskets is relatively low (combined 58) and they should give a good overview of different types of surgery, when the time frame is taken into account. At one end of the spectrum there is the transplantation surgery, it is unknown when a surgery has to take place and therefore these baskets should be available at all time. The other end of the spectrum is occupied by Plastic surgery, where procedures are planned weeks ahead.

Figure 2.12 shows the histogram of the data from all baskets, together with the CDF of all data (black continuous line), department 2077 (red dotted line, 24 baskets), department 2080 (yellow dotted line, 29 baskets) and department 2088 (purple dotted line, 5 baskets). The three departments and 59 basket provide a dataset of 5,724 process times. For all baskets the following statistical data is valid: The minimal value of the process time is 3 hours, the mean 11.2 hours, the max 118.4 and the STD 12.3 hours. Furthermore is the median value 5.8 hours, the first quartile 3.8 and the third quartile 16.0 hours. The first and third quartile give an IQR of 12.2 hours.

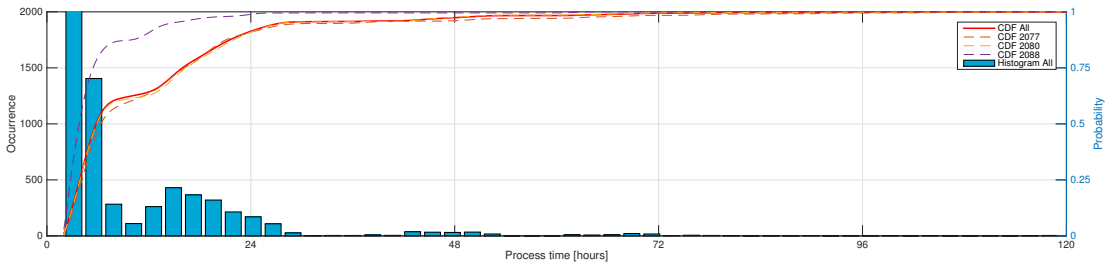


Figure 2.12: Process time distribution and CDF for all selected baskets and the CDF for all baskets per department

From the extended analysis shown in Figure 2.12 it can be found that the most baskets are processed within 8 hours. The second peak is between 16 and 24 hours, a third around 40 to 48 hours and the last near 64 to 72 hours. Which corresponds to the different shifts of the CSSD. When evaluating the CDF functions of the different departments and the total it is obvious that departments 2077 and 2080 are close to each other concerning the process time distribution. However department 2088 differs substantially from the other two. The chance that a basket is processed within one day is for department 2088 98.88%, for 2077 and 2080 only 90.88% and 90.93%. The difference is explained by the unpredictability of the transplantation procedures that are performed by 2088. It is unknown when the next candidate for transplant is available, therefore the equipment has to be ready to go as soon as possible. The baskets from department 2088 are given priority over the other baskets that are waiting to be processed. The overall CDF is

not much affected by the large difference between department 2088 and the remaining departments, caused by the small amount of baskets in used by departments 2088 and the resulting small dataset. Therefore the general trend is similar to those of department 2077 and 2080.

The results shown in Figure 2.12 are alike to those given in Figure 2.11. Concerning the statistical data: for all parameters the general analysis is slightly lower than the analysis of the Acute basket. This difference is caused by the addition of the data from department 2088, which baskets are processed with priority. However the conclusion that was drawn from Figure 2.11 is still valid, the baskets that enter the system are processed as fast as possible by the CSSD. But there are differences between the different departments, some baskets or departments are give priority processing. The latter observation suggests that the underlying reason for processing baskets as fast as possible is that the next use of all baskets is unknown and they are processed immediately when possible. This suggestion will be further evaluated in the next paragraph, by combining the process time analysis with the storage time analysis.

2.2.3 Storage time analysis

This paragraph discusses the analysis of the time a selection of baskets (Appendix C) is in the sterile storage at the OR. First the detailed cycle time is shown for a single Acute basket, after that the general storage time for all Acute baskets is given. Finally the results for various baskets is shown.

Detailed storage time of Acute basket

This sub-paragraph uses the cycle time data used in Table 2.3. This Table has been used previously to determine the detailed process time of the CSSD. The data supports an analysis of the storage time as well. The storage time can be obtained using the time an Acute basket spends in Use. The Use phase is defined as the time between scanning at location after Transport (basket is in sterile storage) and when the basket is scanned in the CSSD for the first time (before pre-clean). In order to retrieve the storage time from the Use time multiple time fractions have to be subtracted from the total. These are the time to prepare for surgery, in surgery, after surgery, transport and manual clean in the CSSD.

Since no data is available the assumption has been made that this time is constant for all the different cycles, even though this is most likely not the case. Since it does not matter how big the time decrease is when it is not supported by any data, it is assumed to be zero; the time in sterile storage equals the time in Use.

The cycle time analysis shown in Table 2.4 gives a minimum storage time of 00:21:13:45, the average storage time is 01:22:06:02, the maximum storage time equals 03:20:08:27 and the median time in sterile storage is 01:18:03:47 for the the cycles evaluated (format is dd:hh:mm:ss).

General storage time of Acute basket

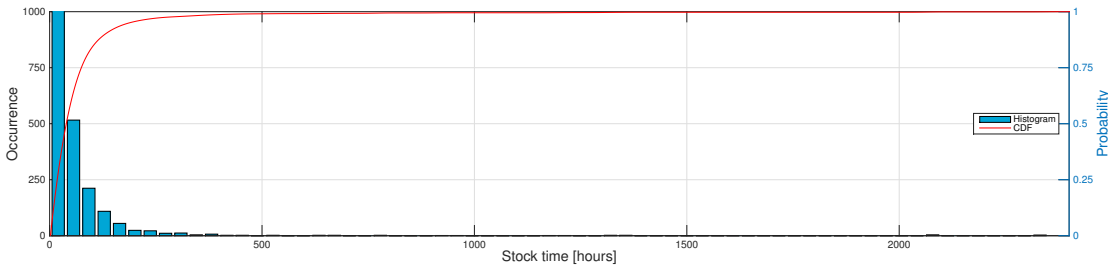
This sub-paragraph will give a general overview of the storage time for all the different Acute baskets, similar to the process time discussed previously. The time range of this analysis is from January 1, 2014 up to January 1, 2015.

The process time resulting from T-DOC was defined as the time between a basket enters the CSSD and exits the CSSD. As explained in the previous sub-paragraph the storage time is given by the time a basket is not being processed; the time between a basket exits the CSSD and enters the CSSD. The resulting storage times have to be cleaned to remove any infeasible data points. The storage time is deemed infeasible when it is shorter than 3 hours, which resulted from the analysis in the previous paragraph (time for sterilization, disinfection and packaging). The maximum process time is set on 365 days, since the time range of the analysis is January 1, 2014 up to January 1, 2015.

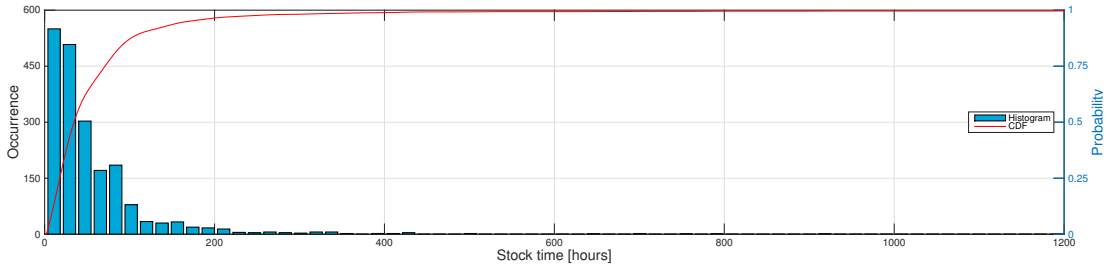
Figure 2.13a shows the results from this analysis. The data is represented in two different ways, on the left-hand side y-axis a histogram is plot, showing the distribution of the storage time. The red line is the CDF of this distribution and is plotted against the right-hand side y-axis. The CDF can be used to determine the storage time for a uniformly distributed random value between zero and one. The range of the x-axis is set on 0 to 2,400 hours, which is nearly 365 days. It can be seen in this Figure that many details about the storage time distribution are lost due to the large bin size, most of the data points are within the first bar. For a better view of the distribution in the first bar the range of the x-axis has been changed. Figure 2.13b shows the distribution on for 0 to 1,000 hours, Figure 2.13c for 0 to 500 hours and finally Figure 2.13d gives the distribution for 0 to 200 hours. The combination of these four Figures gives the complete overview of the distribution, both the global trend over the year, as well as the detailed distribution over a short time span. The minimal value of the storage time is 3 hours, the mean 75.6 hours, the max 2,367.4 and the STD 181.4 hours. Furthermore is the median value 39.2 hours, the first quartile 17.9 and the third quartile 74.6 hours. The first and third quartile give an IQR of 56.7 hours.

Figure 2.13a to Figure 2.13d inclusive show that 95% of the Acute baskets are returned within 200 hours to the CSSD. From the last Figure it can be observed that there are several usage peaks on the interval 0 to 200 hours. These peaks are evenly spaced at 24 hours in between. This is the result from the OR schedule, surgeries start in the morning and afternoon and are finished on the same day. The used baskets are then processed by the CSSD.

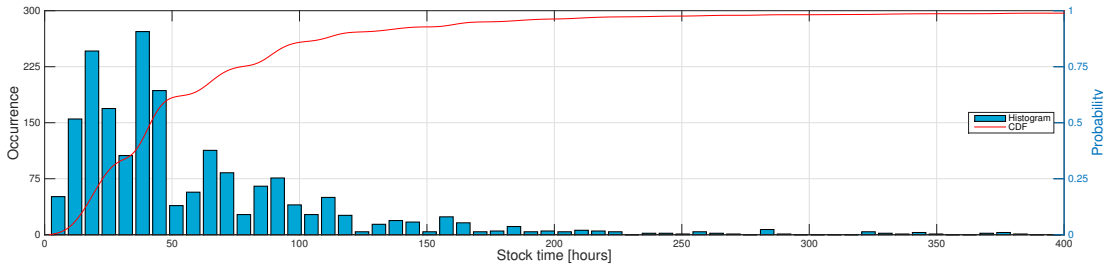
The general results from this sub-paragraph differ from those from the previous sub-paragraph. The difference is caused by the large variation in storage times combined with the small data set of detailed cycle times. The conclusion drawn from Figure 2.13a to Figure 2.13d inclusive is that nearly all Acute baskets are used within 10 days after sterilization. The Acute basket is used often and thus resulting in an higher turn-around-time. Next sub-paragraph will give an analysis of all the selected baskets, to show the storage time distribution for a representative partition of the baskets used at the LUMC.



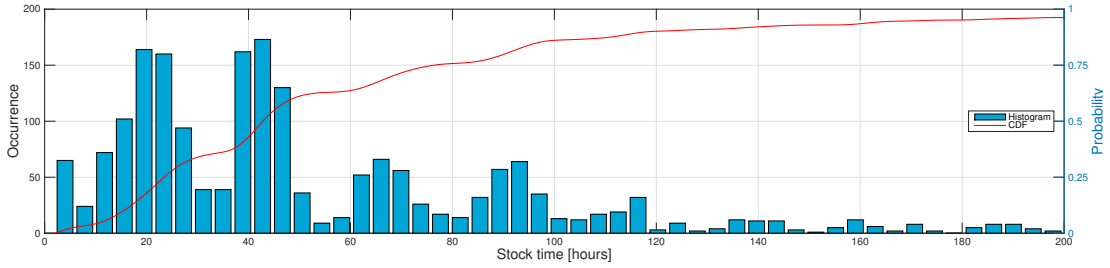
(a) Storage time range of 2400 hours



(b) Storage time range of 1200 hours



(c) Storage time 400 range of hours



(d) Storage time 200 range of hours

Figure 2.13: Storage time distribution for Acute surgery basket

General storage time of selected baskets

The analysis of the Acute basket shown in the previous sub-paragraph can be expanded to incorporate multiple baskets over various departments in the LUMC. The

same three departments are evaluated as for the process time, Plastic surgery (2077), General surgery (2080) and Transplantation surgery (2088).

The results of this analysis is shown in Figure 2.14 for all departments. The top graph shows department 2077, the middle 2080 and the bottom graph department 2088.

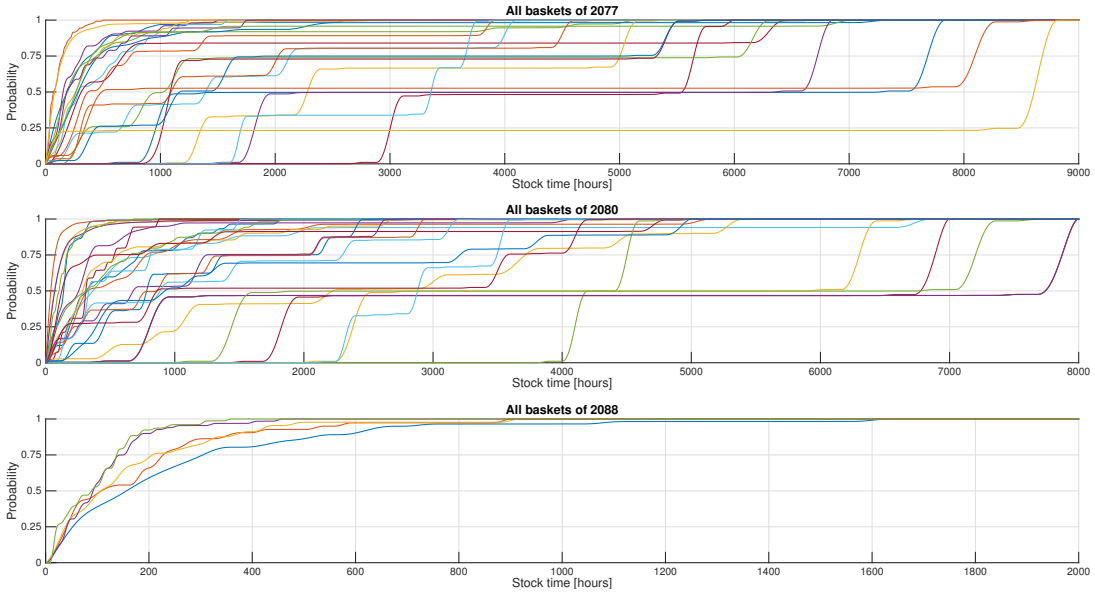


Figure 2.14: Storage time CDFs for all the baskets, broken down by department

The distribution of storage times shows great variety within the departments 2077 and 2080. This is caused by generic baskets that are used for various procedures and specialistic baskets, used for a single surgery. The Acute baskets discussed before is such a standard basket and is used very often. There are however baskets that pass the CSSD only once a year. This could mean that it is used once a year, or not at all (baskets have a use before date, to guarantee sterility). All these different use profiles lead to the range in storage time from 0 to almost 10,000 hours. Department 2088 does not follow this trend, its five baskets have a relative stable storage time distribution. This indicated that these baskets are used for multiple transplantation surgeries year round, and are generic.

The measurements on which Figure 2.14 is based on are given in Figure 2.15 as CDF of the cumulative time in storage. The x-axis shows the cumulative percentage of measurements (a total of 6,067) and the y-axis the cumulative percentage of storage time. The cumulative storage time of the 6,067 measurements is nearly 1.19 million hours, which boils down to an average of 195.75 hours per measurement. The measurement data is sorted descending, in order to determine the effect of the baskets that remain in storage for long periods of time. The resulting black graph is the CDF. Three dashed lines are added to this figure, the first representing 1% of the measurements, the second 5% and the last 25%.

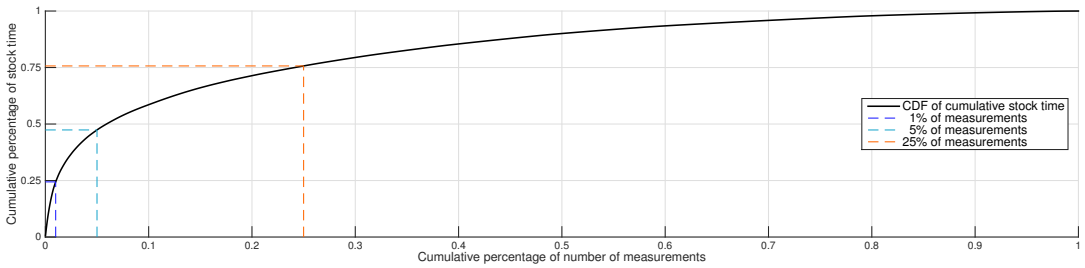


Figure 2.15: Cumulative storage time CDF of all baskets, data sorted descending

Figure 2.15 shows that the 1% slowest measurements in the dataset relate to 24.41% of the cumulative storage time, the highest 5% to 47.39% and the first 25% of measurements cause 75.71% of the total storage time.

Concluding the paragraph on the storage time analysis it can be stated that the differences between baskets are large. A (small) selection of baskets is used very often, with corresponding low storage times. Most of the baskets are moving slower and stay in sterile storage for longer periods of time. After the process time analysis it was suggested that all baskets are processed as fast as possible. This suggestion is supported by the storage time analysis shown in this paragraph. Excessive storage time of various baskets show that the next use date of the basket is not considered when processing the basket. This could be down to either lack of planning or lack of confidence in the timely delivery of the CSSD.

2.3 Chapter summary

This chapter has given the analysis of the current situation of the CSSD and OR based on descriptive and quantitative based methods.

First a model of the sterilization cycle was proposed in which the flows of resources, products, orders and information was presented. It has become clear from the CFF model (Section 2.1.1) of the CSSD that there are two flows in the system, the first are the products and the second a priority request for additional products. There is no feedback from the OR concerning the demand nor are there orders for the products that are manufactured. These products are reusable sterile instruments and baskets containing multiple instruments. Figure 2.16 shows the different types of products that are processed by the CSSD, individual instruments, baskets and sets. Every instrument in the LUMC has to comply with a medical classification, which is based upon invasiveness and activeness during and after surgery (Section 2.1.2). These different instruments belong to certain surgery specialisms, a total of 14 different specialisms can de distinguished in the LUMC (Section 2.1.3).

Most of the instruments on the baskets are unique to that basket, of the 9,000 instruments 7,500 only exist on a single basket. The diversity in baskets is large and commonalities

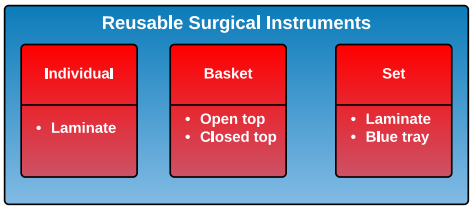


Figure 2.16: Composition of the different instruments

between baskets is rare (Section 2.2.1). The process time analysis (Section 2.2.2), based on nearly 6,000 measurements has shown that the focus of the CSSD is on processing the instruments that enter the system as fast as possible. This is further supported by the analysis of the storage time of multiple baskets, which has presented a large variation in time in sterile storage. Some baskets remain a short time in storage, whilst others sit idle for months. The distribution of these storage times has shown that a small part of the measurements cause the majority of the cumulative time in storage, 1% of the measurements relate to nearly 25% of storage time. Te total storage time of these measurements is 1.19 million hours, which is 195.75 hours on average per measurement (Section 2.2.3).

The sterilization cycle description and quantitative analysis have presented the characteristics of the operation of the CSSD and OR. The qualitative description indicated that the production of the CSSD is not based on planning, there is no production control mechanism. This is further supported by the quantitative analysis, time in sterile storage is long compared to time in process, which indicated that customer demand is not taken into account. As discussed in Section 1.2 DDS can introduce customer demand into the production process and the time in sterile storage is an indication of the delivery efficiency. The requirement of process visibility will be shown in Chapter 3 in which DDS is discussed. These factors substantiate the central question of this research:

How can the efficiency of the delivery of sterile surgical instruments be increased, whilst taking DDS, process visibility and UDI into account?

Chapter 3

Demand Driven Supply methods

From the analysis of the current situation given in the previous chapter it became clear that the average time in sterile storage is too long. Since the lack of knowledge about customer demand was identified as the root cause of this issue, demand planning should be the focal point of the production planning. In production processes demand planning is introduced by means of DDS methods. First a short introduction to DDS methods is given. Next different methods of DDS are presented which are applicable to the LUMC. From these systems the most viable solution is chosen which is given in detail subsequently. The concluding remarks are given at the end of this chapter. Two research questions will be answered during this chapter:

Research question 1: *What is the most viable method for DDS of surgical instruments at the LUMC?*

Research question 2: *Which process KPIs have to be known for the successful operation of DDS?*

3.1 Introduction to Demand Driven Supply

In a production environment a constant workload is the key to efficient operation. The supply should be as level and predictable as possible to achieve the highest throughput at the lowest cost [Lee and Kang, 2007]. This is the starting point of regular supply systems; efficient operation at a constant capacity. The downside to this production philosophy is that customer demand is not taken into account. Due to various reasons customer demand is not constant, it is ever changing and volatile. Due to the demand volatility large buffers and inventories need to be maintained in order to satisfy customer orders at all time [Chakravarty, 2014]. A different point of view is DDS, the volatile demand from the customer is the focal point of this supply type. DDS does not cope with volatile demand using large inventories, but utilizes strategically placed buffers and short production lead times to provide a fast response to changes in demand. Two aspects of DDS methods, the Customer Order Decoupling Point (CODP) and the principle of postponement, will be discussed next.

3.1.1 Customer Order Decoupling Point

The first aspect in DDS methods is the CODP, also known as Order Penetration Point (OPP). The CODP is defined as the point in the manufacturing process at which the product and customer order are coupled. The processes in front of the CODP are forecast driven, since the actual customer demand is not known. Downstream of the CODP the demand is known and the processes are demand-driven.

Four different general locations of the CODP can be distinguished in manufacturing environments: Make-To-Stock (MTS), Assemble-To-Order (ATO), Make-To-Order (MTO) and Engineer-To-Order (ETO) ([Kilger and Meyr, 2008], [Hallgren and Olhager, 2006], [Olhager, 2003], [Olhager, 2012] and [Chakravarty, 2014]). These four strategy types are shown in Figure 3.1.

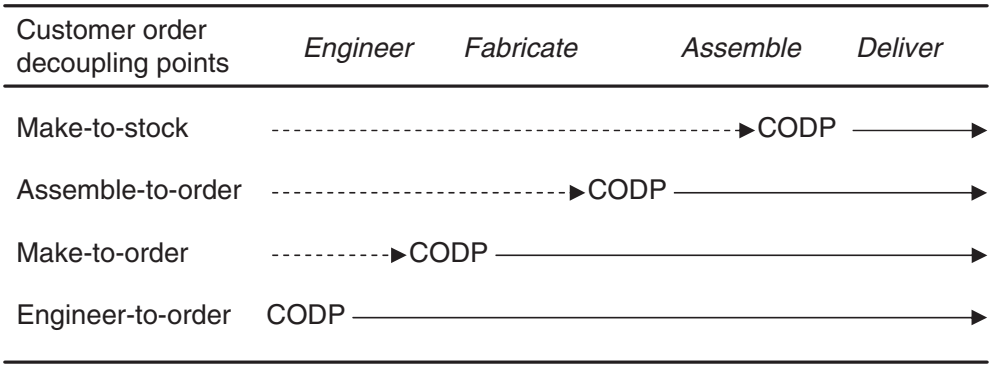


Figure 3.1: Four different locations of the CODP [Hallgren and Olhager, 2006]

Figure 3.1 shows the four strategies for a four stage production process, Engineer, Fabricate, Assemble and Deliver. There are two types of arrows in the Figure, one with a dashed line in front of the CODP and a continuous line down stream of the CODP. The dashed line represents the forecast driven part of the operation, the continuous line the demand driven part. The location of the CODP is MTS the closest to the customer (just before Deliver) and for ETO the furthest away (at the start of the operation, at Engineer). ATO and MTO are in between the two extremes. When considering the same product for all the CODP strategies the effective difference between them is the time it would take to fulfil the customer order. The MTS product is in stock and can be delivered straight away: the production lead time is very short. The ETO product has to be designed and engineered, and will take much longer to be produced: the production lead time is long. ETO is a viable production method for products for which longer production lead times are not a problem. Since the customer enters the fabrication process at an early stage changes to the product can be made, which is impossible with a MTS process.

The choice for CODP and production strategy is partly dependent on the amount of customization, as described above. However the two major factors that affect the CODP positioning are the production to delivery lead time ratio ($\frac{P}{D}$ ratio) and the Relative Demand Volatility (RDV) [Olhager, 2003]. The production lead time is the time required for the production facility to produce a product, the delivery lead time is the amount of time the customer is prepared to wait for the product to be delivered. The RDV is factor that indicates the number of last minute changes in demand, that are within the delivery lead time. The relation between $\frac{P}{D}$ ratio, RDV and the production strategy is shown in Figure 3.2 (the CODP is called OPP).

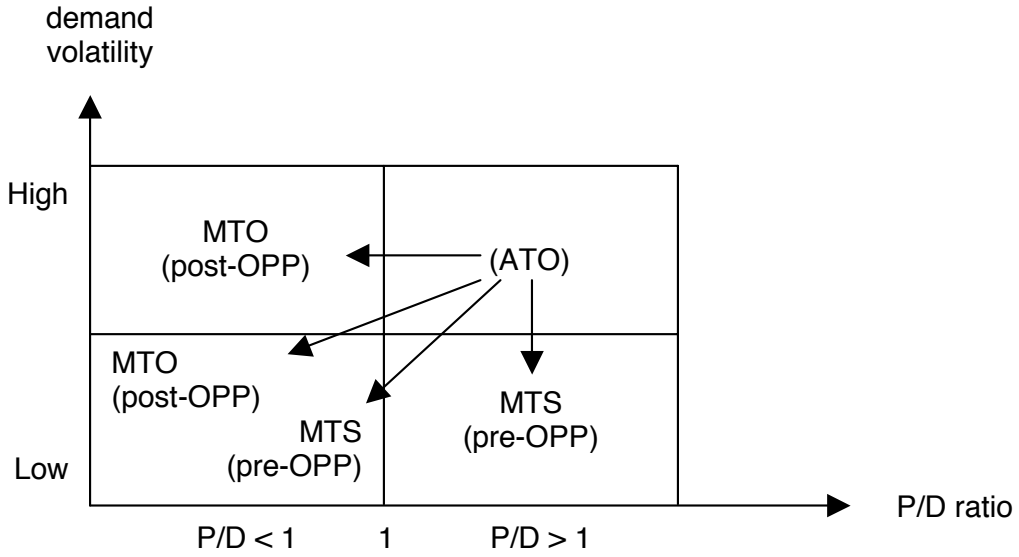


Figure 3.2: Effect of RDV and P/D ratio on CODP placement [Olhager, 2003]

The $\frac{P}{D}$ ratio and RDV can range from low to high, resulting in the four quadrants shown in Figure 3.2. Each of these quadrants have its own production strategy with corresponding CODP placement. Figure 3.2 does not mention the ETO strategy, since it is used for highly specialized products that require large amounts of customization.

MTO strategies can only be used when the $\frac{P}{D}$ ratio is less than one. For products with a stable demand the MTS strategy is viable, production can be forecast driven. These two strategies define three out of four quadrants. The last quadrant, with high RDV and a high $\frac{P}{D}$ ratio the ATO strategy fits best. An MTS strategy is not feasible because the demand uncertainty is to big to hold a large stock of finished products and the production lead time is too long for an MTO strategy. This ATO strategy can however be transformed into a hybrid MTS and MTO strategy. Pre-CODP the MTS strategy should be followed and post-CODP MTO. The resulting strategy ensures that the production lead time is shorter than the delivery lead time and does not require large stocks of finished products.

The revised ATO strategy, together with the MTS and MTO strategy can be seen in Figure 3.2.

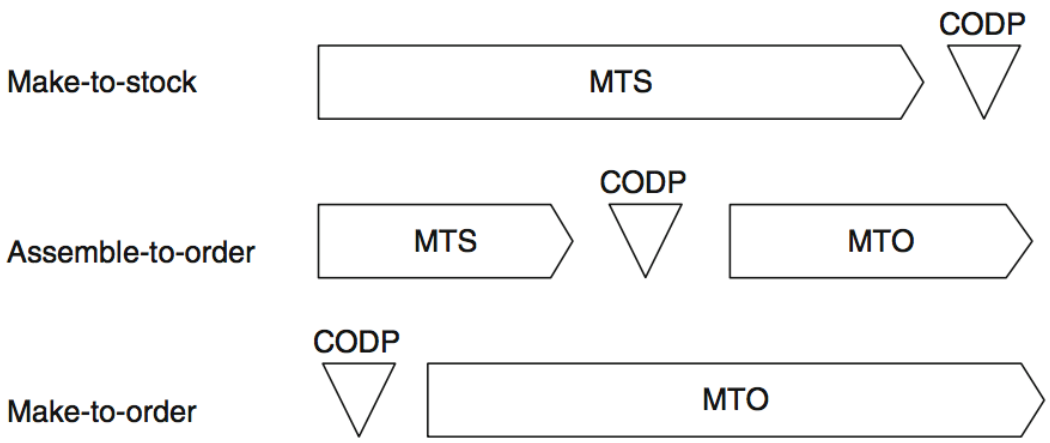


Figure 3.3: The CODP partitions the process into MTS upstream and MTO downstream [Hallgren and Olhager, 2006]

[Hallgren and Olhager, 2006] states that the focus of the upstream MTS is on maximizing productivity, whilst minimizing cost. This is achieved by providing low cost manufacturing and high stock availability at the CODP. On the other hand the focus of the downstream MTO strategy is flexibility and reducing lead-time. The process has to be optimized in order to produce as fast as possible and provide manufacturing to customer specification.

3.1.2 Postponement

The second aspect in DDS is postponement. It involves the delaying of the finalization and customization of a product to the latest possible point in the production process and is hereby closely linked to the CODP and production strategies discussed in the previous section. Two types of postponement are given, form postponement and time postponement [Zinn and Bowersox, 1988]. The advantages of postponement are the reduction of inventory, better order fulfilment and lower cost of manufacturing, purchasing and transport. There are downsides to postponement as well: the cost for developing products and processes that could be postponed.

Form postponement

Form postponement is based around reducing the variety in products until the latest moment. At the moment a customer order is obtained the finalization and customization

of the product can take place. Four types of form postponement are discussed in this paragraph: Manufacturing, Assembly, Packaging and Labelling postponement.

Manufacturing postponement realizes postponement by starting manufacturing activities at the moment the customer order is received. This is nearly identical to the MTO production strategy.

Assembly postponement can be applied when various end product are made from generic modules (sub-assemblies). By stocking the generic modules various products can be assembled quickly. The similarities between assembly postponement and ATO are obvious.

Packaging postponement is similar to assembly postponement, only focusses on the packaging phase. Large bulk inventories of unpackaged products are held, which are packaged until the last moment. Hereby realizing different custom packaging options without holding large inventories of finished products.

In *labelling postponement* product differentiation takes place by addition of different labels. The same product can serve different markets by changing the label lay-out or language.

Time postponement

Time postponement does not focus on the production process itself, but on the delivery of the finished products. It can be used in combination with production postponement or on its own. Inventory is held at one or few centralized, strategic locations. These centralized inventories deliver customer orders directly to the customers, eliminating the need for further inventory locations. Time postponement can be used with all the different production strategies discussed in the previous paragraph.

Critical factors

The success of postponement is depended on many factors, a few [Arlbjørn et al., 2010] will be discussed in the paragraph.

Product design standardization is one of the most important factors in postponement. The manufacturing and assembly postponement strategies are based on proper product design and large similarities between different products, in order to reduce the number of raw materials or sub-assemblies. When there is too much diversity in products these strategy will not work because of large inventories and the accompanying holding cost.

Business process re-engineering must take place. The new way of processing orders using postponement can only take place under the right circumstances. The production process should be engineered in such a way that it can cope with the large fluctuations in demand and product type.

Collaboration between the various parts of the company has to be excellent. The sales department of the company has to communicate the exact requirements of the customer

to the production department, this to minimize delays due to re-processing. The collaboration with customers and suppliers is important as well. On the supply side the agreements on delivery conditions have to be clear and profitable for all parties. The customer has to be collaborative in accepting different deadlines in ordering and changes to the product.

3.2 Methods for Demand Driven Supply

The placement of the CODP can be changed and the principle of postponement can be incorporated in the manufacturing process in numerous ways. This section will discourse five well known methods that are widely used in various production industries. First the Kanban and CONWIP methods are discussed, this is followed by the MRP and MRPII methods. Finally the Packing Centre is presented.

3.2.1 Kanban

Kanban is a method developed by Taiichi Ohno at the Toyota Motor Company in Japan to provide inventory control [Ohno, 1988]. It evolves around not overloading the different stages in manufacturing of the product. This is achieved by creating a pull of products initiated from downstream the production process. When the last process in the production line can handle more work it will signal the preceding process (or buffer) for additional work. All these requests will cascade through the production line such that the used products are replenished on time. The signalling process take place using an actual card or electronically. The number of products that can be processed the same time (Work-In-Progress (WIP)) is depended on the number of actual or electronic cards available to the process. The number of Kanban cards in known as the Kanban number. A model of a Kanban system is given in Figure 3.4.

As can be seen in Figure 3.4 the customer demand is located at the end of the production process, where it signals the delivery of a product. This product is retrieved from the Stage 2 Output store. The Kanban card attached to this product is free from now on and returns to the beginning of the process to the scheduling board. The card is used to pull a new product from the Output store at Stage 1 and the same process takes place there. The manufacturing facilities shown in this model can consists of one or multiple steps. The Kanban pull system applies for the whole stage, including all the sub-processes during manufacturing. Therefore each process inside manufacturing must accept all products with a Kanban card, even if there is no production capacity.

Figure 3.4 shows a two-stage, single-product Kanban system, for multiple-stage, multiple-product Kanban systems the same idea applies. There are more stages in the production process, each having its own Kanban loop. For each product a separate set of Kanban cards has to be used.

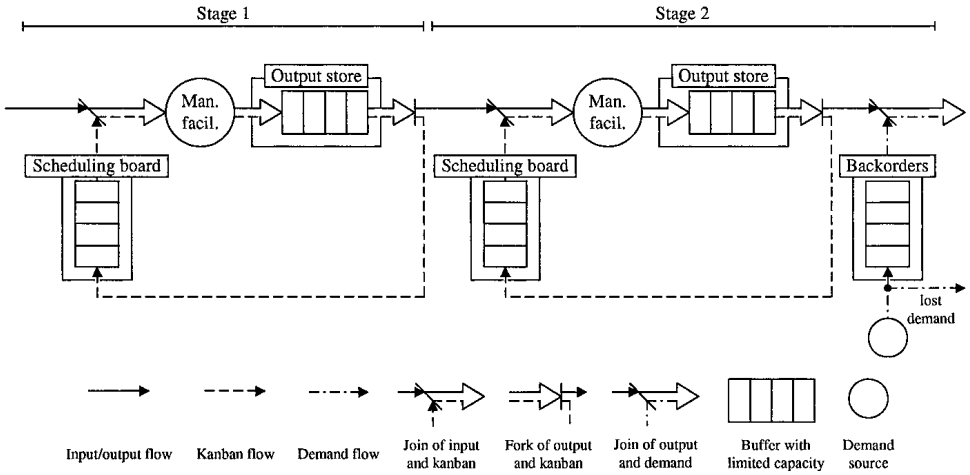


Figure 3.4: Two-stage, single-product Kanban system [Krieg, 2005]

Kanban systems are best equipped to handle repetitive, stable production environments. Kanban provides process improvement by limiting the inventories in between manufacturing stage with the Kanban number, a higher Kanban number equals more Kanban cards equals more inventory. In a stable environment the Kanban number can be low, limiting the inventory level whilst maintaining enough inventory to handle small changes in demand. The low inventory level gives a low inventory holding cost. However, in production environment with demand or supply variability (change outside production lead time) the Kanban system will not work properly. The Kanban number must be high to cope with the fluctuations in demand or supply. This is in contrary to the the low Kanban number the methodology strives for. These two condition cannot be achieved at the same time; Kanban does not function properly in volatile production, supply or demand environments [Li, 2013].

Besides supply and demand variability the number of different products (product mix) is affecting the stability of the production environment as well. When the number of different products is relatively low and production runs are long the Kanban system becomes predictable and can be optimized using the Kanban number. On the other hand for environments with many different products and small production runs the optimization of the Kanban system is quite difficult. A high number of different products relates to a high number of different Kanban card sets (one set of each product). Each card set has its own inventory of products in various stages of completion. The same applies for small production runs, the changeover from one product to the other requires a changeover in Kanban cards and inventory levels. A solution to the high variability in product mix is the use of sub-assemblies and late stage product differentiation. This would result in many different end products with a limited number of WIP products.

3.2.2 Constant Work-In-Progress

The CONWIP method [Spearman et al., 1990] is a modification of the Kanban system. It tackles the limitation occurring in a Kanban system when demand volatility takes place. The Kanban system cannot react to the change in demand adequately and will function not optimal. The difference between Kanban and CONWIP systems is the span of the signalling cards. Kanban uses a card set for each manufacturing stage and the manufacturing process can consist of multiple stages. A CONWIP card set is used for the entire manufacturing process, the cards are not specificly linked to a product. The WIP is kept constant for the whole system by controlling the number of CONWIP cards. This ensures that the changes in demand downstream the process is forwarded straight away to the upstream parts of the process. A model of the CONWIP system is given in Figure 3.5.

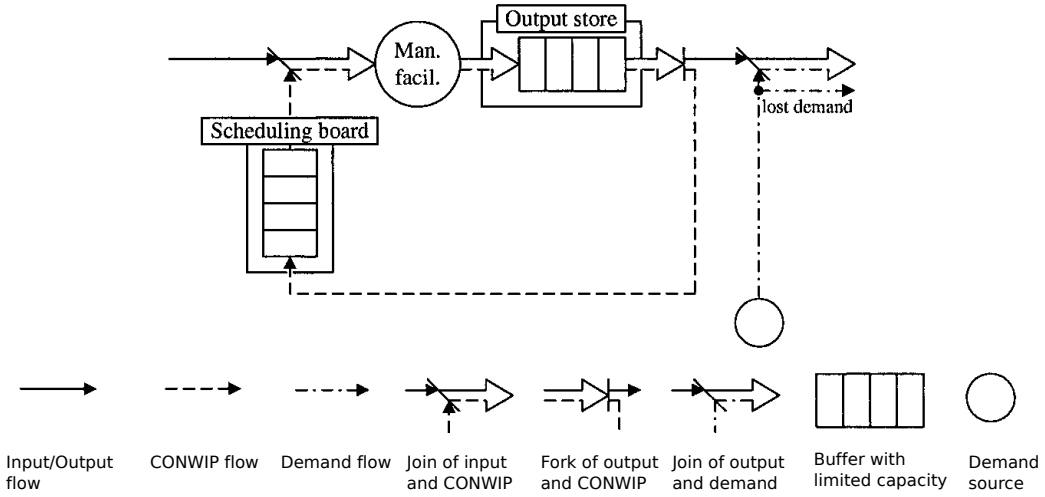


Figure 3.5: General overview of the CONWIP model, adapted from [Krieg, 2005]

As can be seen in Figure 3.5 the customer demand is located at the end of the production process, where it signals the delivery of a product. This product is retrieved from the Output store. The CONWIP card attached to this product is free from now on and returns to the beginning of the process to the scheduling board as a blank card. Here a new product is assigned to the blank card and production commences. Each process inside manufacturing must accept all products with a CONWIP card, even if there is no production capacity.

CONWIP is an improvement over Kanban since it uses the signalling cards over the whole manufacturing process instead of individual stages. Therefore demand changes are put into the process at the earliest stage via adaptation of the scheduling board. This gives CONWIP more flexibility in producing different products. This leads to one of the disadvantages of the CONWIP method. The scheduling of tasks has to be done

manually or with manual input. This human influence on the system has a side effect. An overreaction on the supposed or observed customer demand (based on human decisions) could cause sever quantity swings in the production line, known as the bull-whip effect.

To prevent overloading the CONWIP system uses the quantity of products that can be in the manufacturing process (linked to the number of CONWIP cards). The assumption that is made is that all products manufactured have similar production times and contribute evenly the workload on the process. If this assumption is false the workload on the manufacturing process can change in time, depended on the type of product that is in demand. When lots of fast products are required to fulfil demand the resulting workload will be lower than when slow products have to be produced.

3.2.3 Material Requirements Planning

MRP is a planning system that provides optimal production schedules and invertory levels. Nowadays computers are used to aid the process, but manual calculating MRP schedules is possible. The main purpose is to facilitate the calculation of the required materials and timing for replenishment en production runs for a given time period. The origins of MRP are in 1964, when Joseph Orlicky proposed MRP as a viable alternative for the Toyota Prodcution System (from which Kanban is part). According to [Islam et al., 2013] MRP systems serve three main objectives:

1. Ensure materials and products the availability production and customer orders;
2. Minimize inventory level;
3. Plan manufacturing, delivery and purchasing activities and schedules.

To achieve these three objectives MRP system transforms the Master Production Schedule (MPS), BOM and inventory data into production and purchase schedule. These inputs and outputs of the MRP system are given in Figure 3.6.

An explanation of the different inputs and outputs of a MRP system is given next.

Input: Master Production Schedule

The MPS is an overview of the required production for a certain time period. It is based on two different types of orders, actual customer orders and a forecast of demand. The MPS usually takes the form of a table, an example of a MPS is given in Table 3.1.

Table 3.1: Example of a fictional Master Production Schedule

Time Unit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Product A	0	9	6	0	2	7	13	4
Product B	10	4	0	8	19	3	14	23
Product C	0	25	29	46	17	0	0	0

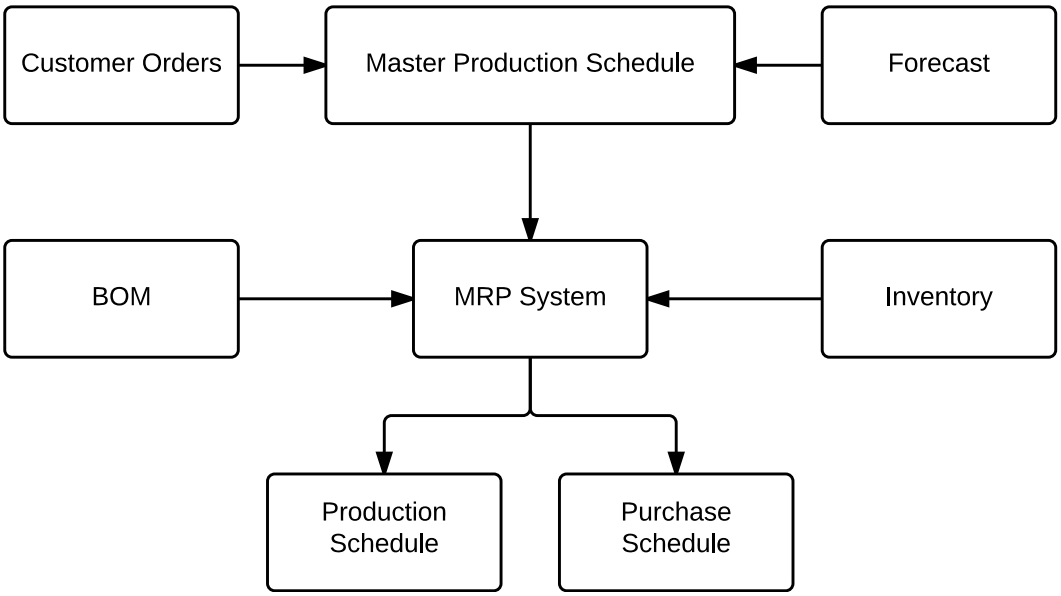


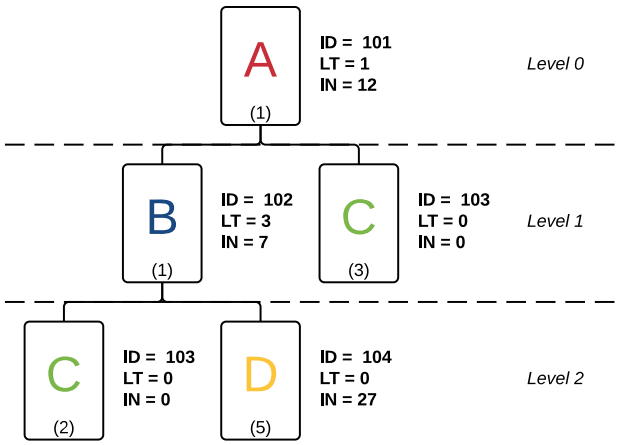
Figure 3.6: Flowchart model of Material Requirements Planning, with inputs and outputs

In Table 3.1 two groups of variables are given, the time unit and the different products. The time unit of a MPS (top row) can be hours, days, weeks or even months and gives the time span of the MPS. All other rows belong to a certain product, and indicated how much of that product has to be produced for the time unit. An increase in time unit (planned production further in the future) corresponds to an increase in uncertainty. The data on which the MPS is calculated is based primarily on forecasts, instead of actual customer orders.

Input: Bill of Materials (BOM)

The BOM is made for each end product a company can deliver. It is either represented in tabular form or as a product tree. Figure 3.7 shows for fictional product A the BOM both as product tree and in tabular form.

The product tree of product A consists of different levels, Level 0 is the end product (product A), Level 1 corresponds to the different sub-assemblies and Level 2 are the parts from which the sub-assemblies are made. As much levels as required can be added to the product tree which shows exactly what the product decomposition looks like. Besides product decomposition the product tree gives additional information about the sub-assemblies and parts. The unique identification (ID) is given besides each product, as well as the production lead time (LT) and the current inventory (IN) of the part. Finally the number of sub-assemblies and parts is stated in between the brackets. The tabular form given next to the product tree can be seen as a summary of the product



Product	ID	QT	LT	IN
B	102	1	3	7
C	103	5	0	0
D	104	5	0	27

ID Identification code of part;
QT Quantity of part needed;
LT Lead time of part;
IN Current inventory of part.

Figure 3.7: Bill of Materials for fictional product A

tree. The different products are listed in the first column, ID in the second, cumulative quantity in the third, LT in the fourth and inventory level in the last column.

Input: Inventory

Inventory data is the third input of a MRP system. The data consists of three main parts, the quantities of inventory, the shelf life of the stored inventory and the production or delivery lead times. On a lower level the quantity data can include the following categories [Kurbel, 2013]:

- *Physical inventory*, quantity that is in stock;
- *Shop-floor stock*, quantity waiting to be processed;
- *Reserved stock*, quantity that is reserved for future production;
- *Open order quantity*, order from supplier or planned for production;
- *Reorder level*, quantity at which a new order is placed;
- *Safety stock*, minimum quantity for safety reasons.

Output: Production & Purchase Schedule

The inputs inputs given previously are transformed in outputs by the MRP system. The two outputs are production and the purchase schedule. The production schedule gives a detailed planning of the required production begin and end dates of the various products to fulfil customer demand, obtained from the MPS. The purchase schedule gives the dates of arrival of products and generation of purchase order such that the inventory level of the different parts and sub-assemblies is sufficient at all times.

Shortcomings of MRP

MRP is a powerful system for calculation of the required materials for production and can aid the reduction of inventory. However, it is not perfect. It does have some limitations [Vrat, 2014], [Lyons et al., 2012]. A MRP system can only function correct if the input data is not corrupt. Incomplete BOM, MPS or faulty inventory data will lead to an output that is not correct. When the incorrect production and purchase schedule will be executed there will occur problems down the line. Furthermore the manufacturing lead time is assumed constant and taken deterministic. The variations in lead time are not taken into account which has to be absorbed by enlarging the safety stock. Lastly, MRP systems do not incorporate the manufacturing capacity when calculating the production schedule. This could lead to infeasible production schedules.

3.2.4 Manufacturing Resource Planning

An evolution of MRP is the MRPII system [Lyons et al., 2012]. It incorporates the MRP resource planning with various capacity checks and feedback loops. A flowchart model of the MRPII system in given in Figure 3.8. Next the three different planning scopes are described.

Long-Range: Strategic Planning

The long-range planning consists of two different types of planning, the demand and business planning. The demand planning is based on, alike MRP, the actual customer orders and the forecast of demand. Since the planning scope is long-range it relies heavier on forecasts that customer orders. The business planning consists of strategic information on emerging markets, innovations in products and equipment and the projected replacement date of the equipment. The demand and business are combined in the Production Plan, which is used to define the general scope of production for the coming weeks or months. To verify the feasibility of the production plan a Rough-Cut Capacity Planning (RCCP) is executed. This will indicate whether the proposed production plan can be performed. If the production plan is feasible it can be detailed in the medium-range planning, when there is a capacity problem the production plan has to be adjusted.

Medium-Range: Operational Planning

The production plan that was deemed feasible by means of RCCP is detailed into the MPS, which is the first step of medium-range planning. The scope of the medium-range planning is days or weeks. A MRP system is used to calculate the required materials for production as described in the previous paragraph. The production schedule (Figure 3.6) is checked for capacity problems using a Capacity Requirement Planning (CRP) system. Although the general production plan is feasible, the more detailed MPS and production

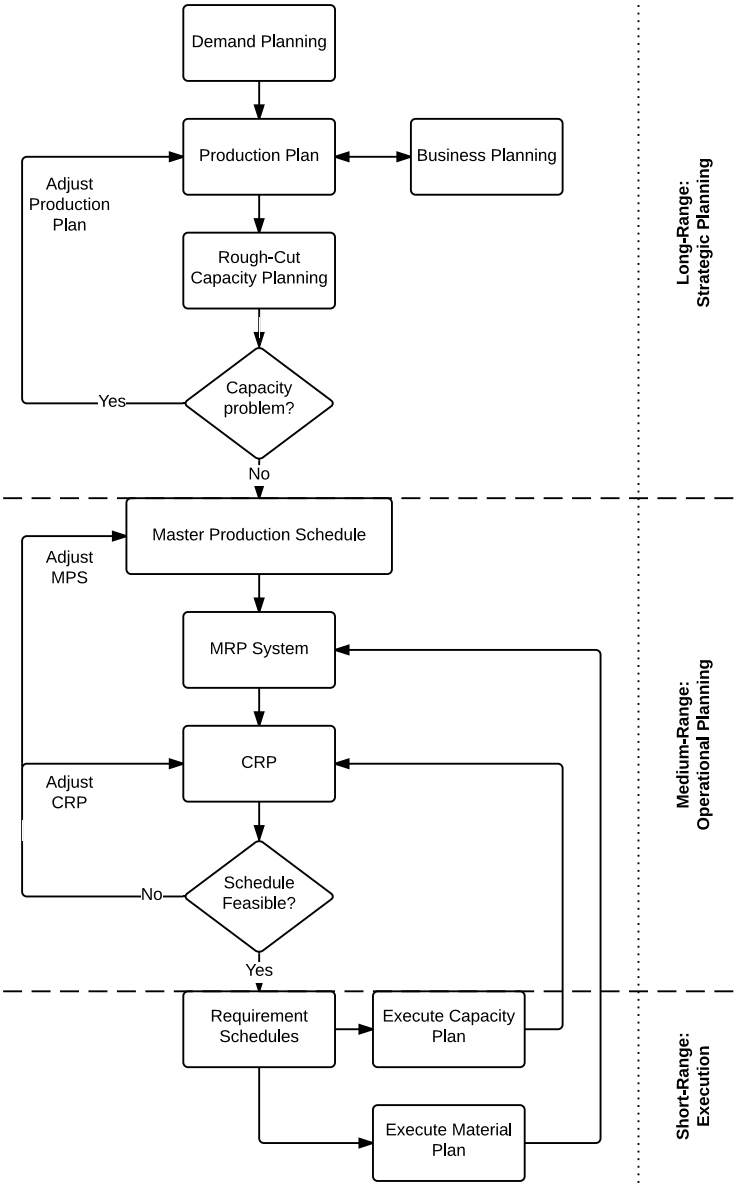


Figure 3.8: Flowchart model of a Manufacturing Resource Planning system

schedule could be infeasible, caused by the higher level of detail. When the production plan satisfies the capacity limits of the manufacturing facility it is detailed into the short-range plan. For production plans that do not comply with the capacity constraints there are two options: the MPS can be changed or the CRP can be altered. The first method is used when there are significant problems in capacity, CRP is adjusted when the problems are small.

Short-Range: Execution

The short-range planning is the most detailed planning of all, given on an hourly or daily basis. The checked production plans are executed in this range and feedback is provided to the MRP and CRP systems. This feedback consist of work progress updates and different production KPIs to provide a smooth operating system. Even when there are disturbances.

(Dis)Advantages of MRPII

MRPII has got two main advantages over MRP: it provides feedback and executes capacity checks. However, the possible problems with data integrity of MRP nor lead time variations are dealt with. The two advantages are elaborated next.

Feedback
From the execution of the production plan proposed by the MRP and CRP systems information is returned to these two systems. This will ensure that the next iteration of the production plan is up-to-date with the current manufacturing characteristics. The MRPII system closes the MRP loop, and is therefore also known as Closed-Loop MRP.

Capacity checks
During the long-range and medium-range planning phases the proposed production plans are checked for feasibility to the manufacturing capacity. Both the RCCP and CRP system should eliminate overloading of the manufacturing facility and the accompanying problems. These capacity checks have got an additional benefit, the production can be levelled over time. The peaks in demand can be dealt with during the lows in demand, which reduces the required production capacity.

3.2.5 Packing centre

The last method for DDS included in the evaluation is the packing centre. The operation of the packing centre is closely linked to the principle of postponement and the placement of the CODP. Products remain in storage in a semi finished state and are finished when a customer order is present. This will reduce the risk and cost of holding inventory. A simplified model of the packing centre is shown in Figure 3.9.

The order from the customer is used as input for the Final assembly step in the packing centre method, from here the correct sub-assemblies are retrieved from storage. The stock level is consequently maintained via a signal to the manufacturing facility, where the used sub-assemblies are produced.

The model shown in Figure 3.9 is a simplification of the actual process, but gives a clear picture of the different steps and characteristics. When taking a closer look at the replenishment procedure of the sub-assembly inventory different options are available such as Kanban, CONWIP or MRP, which have been discussed previously.

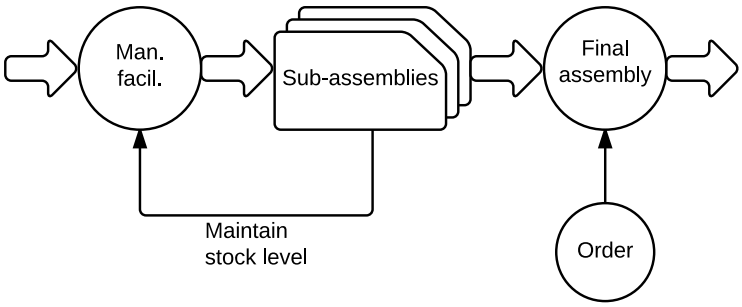


Figure 3.9: General overview of the packing centre

Besides the disadvantages of the inventory replenishment system that is used packing centres have got one major drawback. Since the finalization of the product is postponed by making use of semi-finished sub-assemblies, an inventory of these sub-assemblies has to be maintained to cope with demand fluctuations. If each end product that is offered to the customer has got its own set of sub-assemblies the effect of the packing centre is negligible, looking at inventory reduction. The method is only effective when the number of sub-assemblies is significantly lower than the number of products. All the products produced in a packing centre have to be similar and only differ on the details.

3.2.6 Summary of Demand Driven Supply methods

This paragraph will give a short summary of the different DDS methods. A simplified model of the MRP, Kanban and packing centre is given in Figure 3.10. MRPII and CONWIP are excluded since they are very similar to the MRP or Kanban model shown.

Kanban tries to reduce inventory levels as much as possible. It uses Kanban cards which limit the amount of WIP, which provides a control of overloading at each stage. The Kanban cards are product specific, each products has got an own set of cards, with its own process lead time. The customer demand is used as direct input at the end of the manufacturing line and the demand orders cascade from end to begin of production, albeit with a delay. This type of demand interaction works well for repetitive stable demand settings, but lacks effective measures in demand variability. The product mix produced in a Kanban method cannot be too big, since optimization will become more difficult.

Alike Kanban *CONWIP* uses cards to control inventory levels. However, the cards in CONWIP are not product specific. The benefit of Kanban apply for CONWIP as well, it will prevent overloading. Customer demand enters the manufacturing process at the beginning, which leads to better abilities to cope with demand variability. The use of generic cards makes handling a large product mix less difficult. The generic cards have got one downside, overloading is prevented using these cards as stated above. The

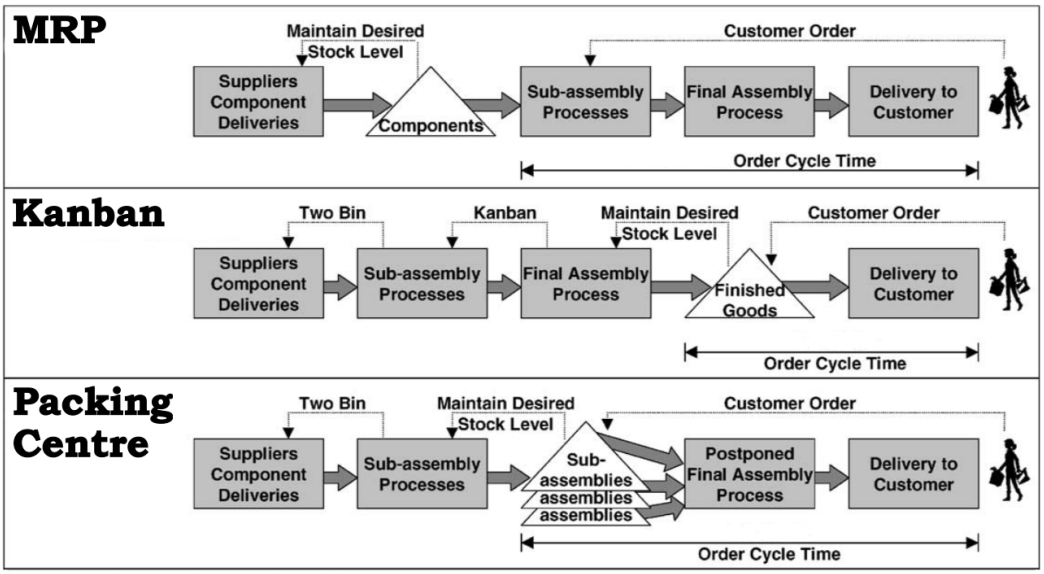


Figure 3.10: Demand Drive Supply systems, adapted from [Childerhouse et al., 2002]

production lead time is assumed to be constant for all products, which is rarely the case. Furthermore is the demand scheduling at the begin of manufacturing based on human interpretation, which could be wrong.

The *MRP* method uses the BOM, inventory data, customer orders and demand forecast to generate the required production schedule and time line. Via this schedule the inventory requirements are known and excess inventory can be minimized. There are multiple shortcomings of MRP methods, the data on which the schedule is based must be correct. Furthermore is the production lead time taken constant and based on deterministic observations and capacity constraints are not taken into account.

MRPII solves the capacity issues of MRP, but the possible problems with data integrity of MRP nor lead time variations are dealt with. MRPII does provide additional feedback to provide up-to-date production schedules that incorporate the current manufacturing metrics.

The *packing centre* uses postponement in producing the different products. A stock of sub-assemblies is maintained from which the products can be assembled on demand. The replenishment of the sub-assembly inventory can be executed in any desired way. There is one main drawback to the packing centre, it relies on sub-assemblies for inventory reduction. If the end products can not be build from sub-assemblies it will not function.

Besides the five DDS methods given in this paragraph a multitude of different methods can be added to the list. These DDS methods are excluded since they are very alike the five methods shown in this chapter. They will differ on details alone, or are hybrids of the five methods. These hybrids use for example Kanban combined with MRP and have the benefits (or drawbacks) of both.

3.3 Selection of Demand Driven Supply method

This section gives the selection of the most feasible method for DDS at the CSSD. First the characteristics of the CSSD and OR for the supply of sterile surgical instruments is discussed. Included in this discussion are mainly quantitative characteristics, based on time, the planning of the OR and the product mix. From these requirements a DDS method is chosen.

3.3.1 Characteristics of CSSD and OR

The DDS method to be selected has to be able to cope with the dynamic characteristics of the OR and CSSD. Three different characteristics will be discussed. First the demand of the OR for sterile baskets is presented. Followed by the production and customer lead time of the CSSD and OR will be presented. This paragraph is concluded with the product characteristics in, and capacity constraints of the CSSD.

Demand of sterile baskets

The demand of sterile baskets has to be known for the DDS method to function properly. These characteristics of the demand can be split into three different parts, the planning horizon, demand variability and demand volatility. The planning horizon is a time period in the future during which the OR plans various surgeries. The demand variability are the changes in demand that can be taken into account in the production schedule. And the demand volatility are the changes in demand that can not be taken into account in the production schedule, due to time constraints.

Planning horizon
On a continuous basis surgeries are added to the planning in the LUMC. A summary of the process from admission to definitive planning is presented in Figure 3.11, which gives the actions required by the different departments in the planning process, as a CFF model. This overview of the planning process is used internally in the LUMC. The starting point of the planning is at the medical specialist that decides upon surgery for a patient during consultation. An order for a surgery and intake request is generated and send to the medical planner.

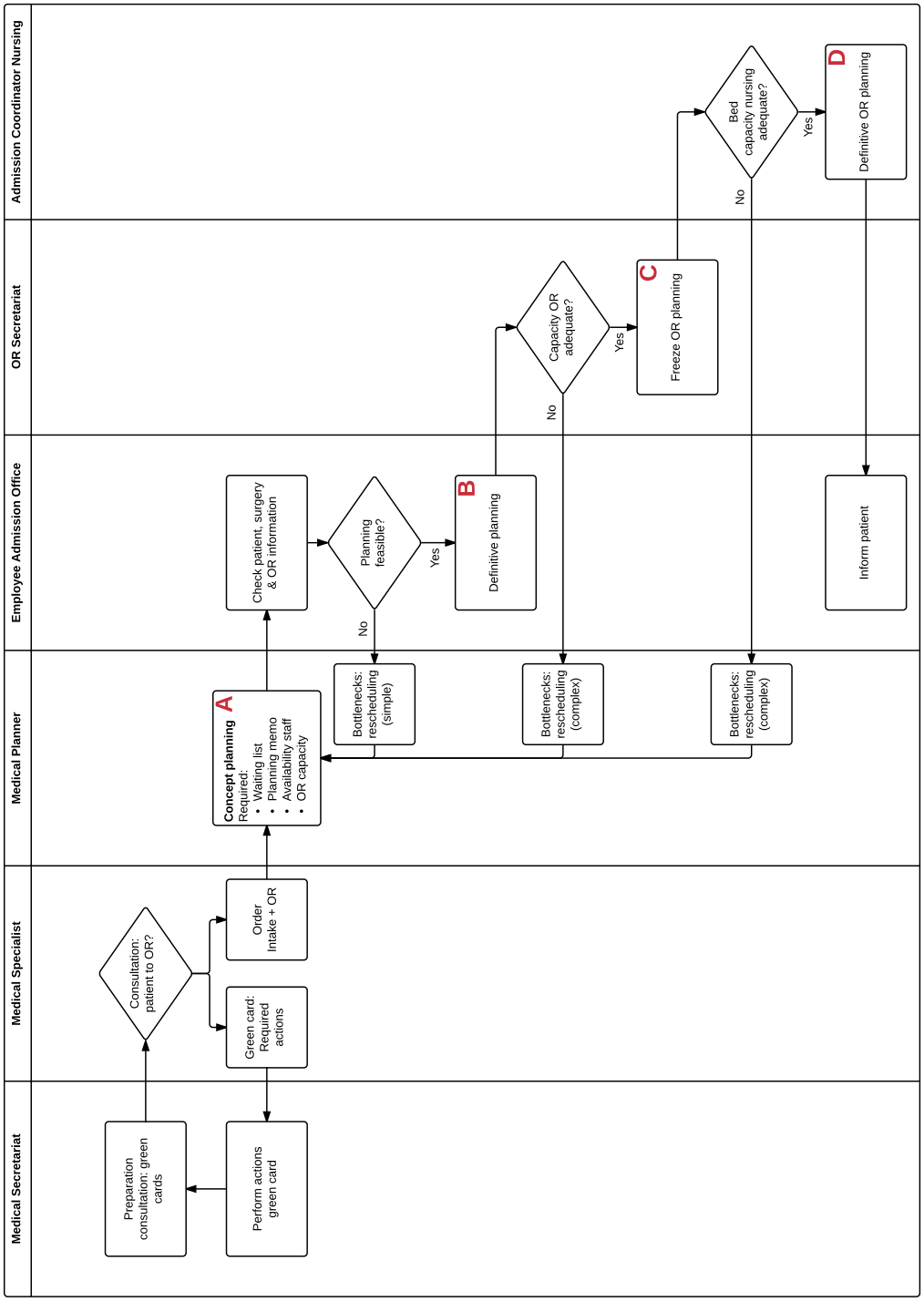


Figure 3.11: CFF model of surgery planning process

The medical planner adds the request to the concept planning (A), taking amongst others waiting lists, availability of staff and OR capacity into account. One-and-a-half week before the surgery is scheduled the concept planning is made definitive by an employee of the admission office. The information regarding patient, type of surgery and the OR is checked for feasibility. The definitive concept planning (B) is passed down to the OR secretariat which double checks the OR capacity. If OR capacity is adequate the concept planning is fixed into the OR planning (C). The preceding week of the surgery a final check is performed on Wednesday, in consultation with the nursing department the availability of beds is checked. From this point the OR planning is assumed to be definitive (D). However, due to various reason the preceding days before the surgery changes can be made. This can occur until 10 'o clock one day before performance of the surgery.

The planning process is valid for the planned surgeries at the LUMC. However there are surgeries that can not be planned, these acute surgeries are decided upon within 24 hours before the surgery commences. Multiple ORs are kept standby for the performance of these acute surgeries.

The quantitative data of the changes in the OR planning is given in Table 3.2. For one week of operation the changes in the weekly (W) and daily (D) planning and realised surgeries (R) are presented, together with the acute surgeries. The first column shows the date of the data. The second column the number of surgeries on the weekly planning, column three gives the cancelled surgeries from weekly to daily planning, the fourth column the number of surgeries that are changed and column five the surgeries that are added before 10 'o clock the preceding day. The resulting daily planning is presented in column six, the cancelled surgeries the last day in column seven. The number realized surgeries is given in column eight and the last column shows the number of acute surgeries of that day. Furthermore, the last two rows of Table 3.2 present the mean and STD of the different columns.

Table 3.2: Changes in planning from weekly (W) to daily (D) planning and to realisation (R)

Date	*Planning week*	*Cancelled W-D*	*Changed W-D*	*Added W-D*	*Planning day*	*Cancelled D-R*	*Realisation*	*Acute*
27 July	30	1	1	6	35	0	38	3
28 July	24	4	1	4	24	2	27	5
29 July	16	2	2	2	16	0	20	4
30 July	24	6	0	1	19	1	28	10
31 July	17	1	5	7	23	2	33	12
MEAN	**22.2**	**2.8**	**1.8**	**4.0**	**23.4**	**1.0**	**29.2**	**6.8**
STD	**5.76**	**2.17**	**1.92**	**2.55**	**7.23**	**1.00**	**6.76**	**3.96**

The change in percentage of the planning data presented in Table 3.2 is shown in Table 3.3. For each of the five types of changes the percentage is calculated, with the number of realized surgeries as a basis.

Table 3.3: Changes in planning shown as percentage, with the realised surgeries as basis

Date	*Cancelled W-D*	*Changed W-D*	*Added W-D*	*Cancelled D-R*	*Acute*
27 July	2.63%	2.63%	15.79%	0.00%	7.89%
28 July	14.81%	3.70%	14.81%	7.41%	18.52%
29 July	10.00%	10.00%	10.00%	0.00%	20.00%
30 July	21.43%	0.00%	3.57%	3.57%	35.71%
31 July	3.03%	15.15%	21.21%	6.06%	36.36%
MEAN	**10.38%**	**6.30%**	**13.08%**	**3.41%**	**23.70%**
STD	**8.00%**	**6.16%**	**6.64%**	**3.40%**	**12.20%**

The LUMC has a summer recess in months July and August, OR staff and surgeons are on holiday and therefore the number of surgeries is lower. Compared to a normal working week the number of planned surgeries is 25 to 50% lower, whilst the acute surgeries remain at their normal height. To incorporate this fact into the analysis all but the realized and acute surgeries have to be multiplied by a factor two to four. The resulting mean and STD values are presented in Table 3.4. It is based on the average of the percentile range, 37.5%.

Table 3.4: Value of mean and STD changes in percentage for normal operation weeks

	Cancelled W-D	*Changed W-D*	*Added W-D*	*Cancelled D-R*	*Acute*
MEAN	12.59%	7.51%	15.52%	4.07%	10.87%
STD	10.08%	7.55%	8.50%	3.84%	6.35%

Table 3.4 shows indicates that around 12.6% of the surgeries on the weekly planning are cancelled, with a standard deviation of over 10.1%. Furthermore, the surgeries on the weekly planning are changed in 7.5% of the occurrences, with a STD of 7.6%, 15.5% of the surgeries are added to the weekly planning (STD is 8.5%). Considering the daily planning, from planning to realisation 4.1% of the surgeries are cancelled at the last moment, with a deviation of 3.8%. And finally there are 10.9% acute surgeries, the STD is 6.4%. These different changes are used in the next parts of this sub-paragraph for the description of the demand variability and volatility.

Demand variability
The demand variability is determined by the volume of baskets required at a certain time. The data supporting this factor is given in Appendix D. The properties of the planning discussed previously is used as well.

Each time a baskets passes through the CSSD it has been used during surgery in the OR. Since the time and date of the observation is known within T-DOC, the number of uses per day can be determined. This analysis has returned that only two baskets are used on a daily basis (each business day), 13 baskets are used more than one business day a week, but not daily and 43 baskets are used less than one day a week (of which 21 less than five days per year), on average over 2014. This indicates that the majority of baskets is not used regularly and the variability in baskets types the CSSD has to process is rather large. The CDFs presented in Figure 2.14 (page 22) second this, various baskets remain idle in storage for thousands of hours before the next use.

Table 3.5 shows the demand volume variability for one week of the OR, based on the input baskets of the CSSD. The first column of this Table gives the mean demand of the OR, the second column the standard deviation of the mean, the third column the Coefficient of Variation (CV) and the last column the total baskets used by the OR on the corresponding day. The CV is based on the mean and deviation of the number of baskets per hour on one day. Equation 3.1 presents the formula of the CV.

$$CV = \frac{\sigma}{\mu} \tag{3.1}$$

The CV is a coefficient that shows the relative variability in demand. As can be seen in Table 3.5 the CV is between a half and one for most days of the week. When concerning data measurements, a CV exceeding 0.3 is indicative of problems in measurement or experiment data [Brown, 1998]. The CV is not used to determine the quality of data in this case, but since the CV is a dimensionless factor the indicative value of 0.3 can be used as a transition point between low and high variability. The latter results in a high demand variability from the OR. This is supported by variability in the planning, which is given in Table 3.4, nearly 17% of surgeries on the weekly schedule are cancelled, 7.5% is changed and 15.5% are added.

Table 3.5: Demand variability for one week

	$\mu\ [\frac{Baskets}{hour}]$	$\sigma\ [\frac{Baskets}{hour}]$	$CV\ [-]$	$\sum Baskets$
Monday	17.40	11.39	0.65	261
Tuesday	21.77	13.24	0.61	283
Wednesday	23.92	13.02	0.54	287
Thursday	19.29	16.02	0.83	270
Friday	16.64	14.79	0.89	233
Saturday	5.67	4.51	0.80	17
Sunday	7.00	0.00	0.00	7

Demand volatility
The demand volatility can be expressed using the data on the usage of the different baskets in a year quantitatively and based on the OR planning qualitatively. Both these methods are discussed next.

The first methods bases the demand volatility on two inputs, the stock time and the usage factor. Both these factors are obtained from the historical data over 2014 shown in Paragraph 2.2.2. For each basket these inputs are different, therefore a general statement about the demand volatility can not be given. Each basket in the analysis has got its own volatility, which is calculated using a Fuzzy Logic Controller (FLC). In Appendix E (page 174) this FLC is presented together with some background information. The output of the FLC is the RDV, which can be either low or high. Baskets with a low RDV are used frequently and demand is predictable, opposed to the baskets with high volatility, which are used irregular and unpredictable.

The result of this analysis is that 17 of the 58 baskets have got a low RDV, ranging from 0.50 to 0.87. The other baskets are of high volatility, ranging from 1.05 to 1.50. This two RDVs will require a different manufacturing approach.

The second method to come to the demand volatility is to evaluate the OR planning. The volatility in the planning are the surgeries that can not be planned, which are the acute surgeries. As indicated in Table 3.4 for an average week of operation 10.9% of the surgeries performed on a day are of the acute nature, with a STD of 6.4%. The volatility in the planning is therefore quite low, since in excess of 80% of the surgeries are planned in most of the cases. Furthermore are the acute surgeries defined as surgeries that are not part of the daily planning, which is made 24 hours in advance (before 10 'o clock the preceding day).

Lead time

The $\frac{P}{D}$ ratio is the determining factor in the placement of the CODP (Figure 3.1). Since the placement of the CODP aids in the selection of DDS method it is incorporated as characteristic of the process.

Production lead time
The production lead time of the CSSD is known from the process time analysis presented in Paragraph 2.2.2. From this analysis can be obtained that the minimal process time of the CSSD is about 3 hours. The process time is distributed in the following manner over the different steps: disinfection of the baskets and instruments takes one hour, packaging 30 minutes[1] and time for sterilization is one and a half hour. Between the different processing steps are downtimes where the baskets and instruments are idle. A great variance in total downtime exists, varying from a quarter of an hour to more than two and a half days (Table 2.4). The different process- and down times are presented

[1]Dependent on basket type. 30 minutes is valid for Acute basket, which consists of 90 instruments. Baskets with less instruments can be packaged faster.

on a time line in Figure 3.12. The down times are shown as variables T_{D1} and T_{D2} to indicate their variance.

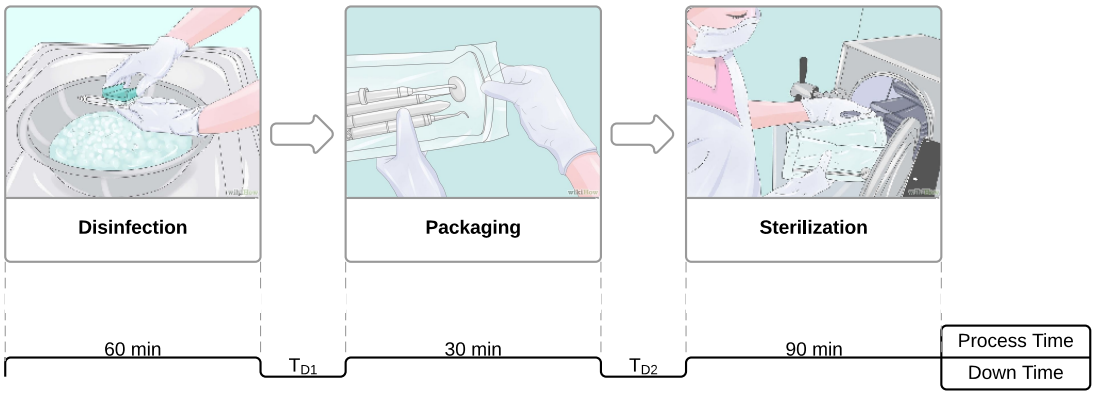


Figure 3.12: Process time of the different steps and down time between steps, down times are shown as variables (renderings from [wikiHow, 2015])

Delivery lead time
In contrast to the production lead time there is no data supporting the delivery lead time. It is impossible to measure and has to be based on a qualitative judgement given by the customer, combined with knowledge about the planning of different surgeries discussed previously.

Two different categories of baskets can be determined when considering lead time. The baskets needed for acute surgeries and those needed for planned ones. The acute surgeries are not included in the planning since a snap decision of a doctor is at the basis of this type of surgery. The time between decision and incision is therefore in the range of 5 minutes to 24 hours (more than 24 hours can be added to the planning). The lead time of the baskets needed for these surgeries is in the same range. The baskets for the surgeries that are planned have got lead times of at least 24 hours, the latest any changes can be made to the planning is roughly 24 hours in advance (preceding day until 10 'o clock).

$\frac{P}{D}$ *ratio*
The production lead time and delivery lead time can be combined into the $\frac{P}{D}$ ratio, a measure of the capabilities of a process to make custom products to order. The $\frac{P}{D}$ ratio is depended on the type of surgery a baskets is required for, planned or acute, and the location of the main inventory in the process. The different locations of the main inventory are before packaging, before sterilization or after sterilization (current situation). Table 3.6 gives the different situations for the $\frac{P}{D}$ ratio, the delivery lead time is worst case scenario, 5 minutes for an acute surgery and 24 hours for a planned surgery.

Table 3.6: Range of $\frac{P}{D}$ ratios for the different situations

Acute surgery			**Planned surgery**		
Packaging	*Sterilization*	*Current*	*Packaging*	*Sterilization*	*Current*
$\frac{[120\ 150]}{5} >> 1$	$\frac{[90\ 120]}{5} >> 1$	$\frac{0}{5} = 0$	$\frac{[120\ 150]}{1440} << 1$	$\frac{[90\ 120]}{1440} << 1$	$\frac{0}{1440} = 0$

The current situation operates under a $\frac{P}{D}$ ratio that approaches zero, everything can be delivered from stock, resulting in no production lead time. For the sterilization case the production lead time ranges from 90 to 120 minutes, based on the time needed for the sterilization process and some down time. When the inventory is placed in front of the packaging step the lead time is 120 to 150 minutes. This lead time range is based on the time it takes to package and sterilize the baskets (120 minutes) and the possible downtime between the different steps (150 minutes). These production lead time values give for both the packaging and sterilization cases a $\frac{P}{D}$ ratio in excess of one for the acute surgery. This means that such a process can not deliver the baskets on time for the surgery. Planned surgeries are no problem for both cases.

Product characteristics

The products that the CSSD processes are baskets of sterile instruments. In total there are over 9000 different types of instruments and 1300 different types of baskets (Paragraph 2.1.2). This indicates that a large variability in both end products (the baskets) and raw materials (the instruments) is present. Furthermore, the contents of the different basket types is rather unique, 7500 instruments can only be found on one basket type (Figure 2.10, page 14). The DDS method has to be able to cope with such a large variation in both raw materials and end products. The data supporting the product mix is available by means of the BOM which is part of T-DOC.

Capacity constraints

The CSSD uses various pieces of equipment to perform the disinfection and sterilization of surgical instruments. The two most important machines in the process are the washing machine and autoclave. As described above (Figure 3.12) these machines have a process time of 60 to 90 minutes. During operation the machine cannot be loaded and has to finish first. Besides this the usage factor of the machines should be as high as possible; no processing runs when the machine is half full. Therefore the batch sizes of the washing machine and autoclave have to be taken into account as well. A third factor that limits the production capacity of the CSSD is the number of employees at work. Without the personnel to operate the equipment, provide the input and handle the output the CSSD will not be able to produce. These three factors affect the operation of the CSSD and have to be taken into account by the DDS method.

3.3.2 Applicability of Demand Driven Supply methods

This paragraph will show the compliance of the different DDS methods to the characteristics of the CSSD and OR. First a short recap of the characteristics is given in which they are translated into requirements. The influencing factor that determine the score of these requirements is given as well. The different DDS methods are evaluated upon compliance to the requirements by means of the AHP method [Saaty, 2008], which results in the most feasible DDS method for use in the CSSD.

Requirements to Demand Driven Supply methods

The characteristics of the CSSD and OR can be translated into five different requirements to which the DDS methods should comply. These are demand variability and volatility, product mix, capacity constraints and planning. The scoring principle of the DDS methods is based on an pairwise comparison. Each system is compared to the others and the best is given a higher score. This will be elaborated in the part about the AHP method.

Demand variability
The demand of the OR is not constant regarding the number of baskets, required delivery time and basket types. The DDS method has to be flexible and able to cope with this high variability.

Demand volatility
Even though the volatility in the demand is in general low, there is some volatility. The DDS method has to be able to cope with this limited volatility. This volatility is best seen in the $\frac{P}{D}$ ratio, which ranges from zero to in excess of ten.

Product mix
Al large variability in product mix is present at the LUMC, both in end products and raw materials. The DDS method should be able to handle both of them.

Capacity constraints
The CSSD does not have unlimited process capacity. The batch sizes of certain production steps is limited, there are fixed process times and the availability of employees (partially) determines the maximal throughput. These different constraints have to be taken into account for the generation of a feasible production schedule.

Planning
The central idea behind DDS of instruments is taking the planning into account. The DDS method that is able to incorporate the planning best is rewarded with the most points, if the system has more difficulty it decreases.

Analytic Hierarchy Process method

The AHP method is a mathematical technique to analyse complex decisions problems.[2] The importance of one of the requirements compared to the other is based on a table in which the different weights are stated. For the final decision these weights are included in the analysis and therefore the relative importance of the requirement as well. The scale of importance is given in Table 3.7, 1 means equal importance, 9 extreme.

Table 3.7: Scale of importance used for AHP, adapted from [Saaty, 2008]

Intensity of Importance	*Definition*	*Explanation*
1	Equal importance	Activities contribute equally to the objective
2	Weak or slight	
3	Moderate importance	Slight favour of one activity over other
4	Moderate plus	
5	Strong importance	Strong favour of one activity over other
6	Strong plus	
7	Very strong importance	Very strong favour of one activity over other
8	Very, very strong	
9	Extreme importance	One activity favoured in the highest order

This scale of importance is used in the actual AHP matrix. This is a square matrix containing the requirements on the rows and columns. The different elements of the matrix are the importance of one requirement compared to another. For example, when requirement 1 (R1) is twice as important as requirement 2 (R2), the following pairwise comparison can be made:$(R1, R2) = 2$ and $(R2, R1) = \frac{1}{2}$. To calculate the weights of the requirements this matrix is evaluated using Equation 3.2.

$$w_i = \frac{\sum_{j=1}^{n} A_{i,j}}{\sum_{i=1}^{n}\sum_{j=1}^{n} A_{i,j}}, \; for\ i \; = \; 1\ to\ n \tag{3.2}$$

In this equation w_i is the weight of requirement on row i, n the number of rows and columns and $A_{i,j}$ is the AHP matrix.

The AHP matrix $(A_{i,j})$ for the requirements of the DDS method is given in Table 3.8. As can be seen the following relation between different elements exists: $A_{i,j} = A_{j,i}^{-1}$. The resulting weights of the requirements are calculated using Equation 3.2 and are shown in the last column.

[2] A detailed description with examples of the AHP method presented in this paragraph can be found in [Teknomo, 2006] and [Mocenni, 2011].

Table 3.8: Weights of the DDS requirements resulting from pairwise comparison AHP

	Variability	*Volatility*	*Product Mix*	*Capacity*	*Planning*	**Weight**
Variability	1	2	0.33	0.5	0.33	**0.106**
Volatility	0.5	1	0.17	0.3	0.17	**0.055**
Product Mix	3	6	1	1.5	1	**0.318**
Capacity	2	3.33	0.67	1	0.67	**0.204**
Planning	3	6	1	1.5	1	**0.317**

The most important aspect of the DDS method is the ability to handle the large product mix at the LUMC. This can be seen as the bottleneck for the DDS method, when it can not handle the large product mix it will not function at all. The central idea of DDS is the use of the demand planning, without proper planning input the system will not work. Therefore the input of planning data has nearly the same weight ads the product mix. The capacity constraints in the CSSD processes are of such a nature that they can not be neglected, however they are not of the importance as the product mix and planning. The handling of variability and volatility in demand are the least important of the five requirements. The demand shows variability and some volatility, but it is not one of the determining factors is the process.

In a similar manner shown in Table 3.8 the DDS methods can be rewarded a score for compliance to a single requirement, compared to the other DDS methods. The resulting five tables are combined into the final result of the AHP. Next the pairwise comparison tables of the compliance of the DDS methods to the requirements are discussed.

Pairwise comparison of Variability (Table 3.9)
Kanban and packing centre systems obtain an equal score on this requirement, they are both best suited for use in a stable environment with low variability, therefore they receive the lowest scores compared to the other systems. CONWIP does score a little better, since it is alike Kanban with the use of cards. The difference is that CONWIP uses one set of cards for all products and the entire production process (single-stage Kanban system). The MRP and MRPII methods are best suited for use under demand variability, however MRPII has the slight overhand. This is mainly caused by fact that more more checks are used for the generation of a feasible schedule.

Pairwise comparison of Volatility (Table 3.10)
It has to be noted that none of the systems can function under demand volatility without safety stock and buffer locations. For the evaluation of this requirement the assumption has been made that the location of the buffers are such that the method is able to deliver. The Kanban and MRP method both receive the lowest score on the volatility requirement. The replenishment of the buffers can become problematic since short notice changes could become effective after some time. The CONWIP and MRPII methods

are better suited to handle this volatility. This is down to the more detail method of planning (MRPII) and the use of the production scheduling at the begin of the process (CONWIP). The packing centre out preforms all other systems when considering demand volatility, the sub-assemblies are made and assembled on time and when required. Only the sub-assemblies need to be replenished.

Table 3.9: Pairwise comparison of the DDS methods on Variability

	Kanban	*CONWIP*	*Packing*	*MRP*	*MRPII*
Kanban	1	0.5	1	0.25	0.20
CONWIP	2	1	2	0.5	0.5
Packing	1	0.5	1	0.25	0.25
MRP	4	2	4	1	1.2
MRPII	5	2	4	0.83	1

Table 3.10: Pairwise comparison of the DDS methods on Volatility

	Kanban	*CONWIP*	*Packing*	*MRP*	*MRPII*
Kanban	1	0.5	0.33	1	0.5
CONWIP	2	1	0.5	2	1
Packing	3	2	1	3	2
MRP	1	0.5	0.33	1	0.5
MRPII	2	1	0.5	2	1

Pairwise comparison of Product Mix (Table 3.11)
The packing centre is very well suited to handle a large product mix of end products (baskets), but can not handle a large variety of raw materials (instruments). This might be solved by completely changing the method and routeing of production, but this is undesirable. Thus the packing centre receives the lowest score. The Kanban method uses a set of cards for each resource of the end product, in the CSSD a many sets of cards are needed. Therefore it does not comply very well on the product mix requirement. A CONWIP method can handle a large product mix better than Kanban, but suffers from the fact that the sequencing at the beginning of the production process has to be changed every time a new basket has to be produced. The MRP is better suited for the large product mix, it uses input data from the BOM and inventory to come to the planning. MRPII receives the same score on product mix, since it is based around the simple MRP method.

Pairwise comparison of Capacity Constraints (Table 3.12)
In the packing centre no limit is cast over the amount of WIP. The same applies for a MRP method, however a very crude capacity check can be implemented with ease. Kanban and CONWIP methods limit the WIP by the number of cards in the process. This type of capacity control is only based on the number of products, not on actual production time. It assumes that the production time for each product is the similar (or the same). The MRPII method uses multiple capacity checks both on number of product and production time, therefore it is best suited to handle the capacity constraints in the CSSD.

Table 3.11: Pairwise comparison of the DDS methods on Product Mix

	Kanban	*CONWIP*	*Packing*	*MRP*	*MRPII*
Kanban	1	0.5	2	0.33	0.33
CONWIP	2	1	1.5	0.67	0.67
Packing	0.5	0.67	1	0.33	0.33
MRP	3	1.5	3	1	1
MRPII	3	1.5	3	1	1

Table 3.12: Pairwise comparison of the DDS methods on Capacity Constraints

	Kanban	*CONWIP*	*Packing*	*MRP*	*MRPII*
Kanban	1	1	2	1.5	0.67
CONWIP	1	1	2	1.5	0.67
Packing	0.5	0.5	1	0.8	0.33
MRP	0.5	0.5	1.25	1	0.5
MRPII	1.5	1.5	3	2	1

Pairwise comparison of Planning (Table 3.13)
The packing centre and Kanban method do not provide an input for the planning. Everything that is used by the customer has to be replenished by means of a cascading demand for a product to the beginning of the production line. Therefore they receive the lowest score. CONWIP uses the cards of the Kanban system as input at the first production step, the planning can be implemented at this step. The MRP and MRPII methods bases the production on the actual customer orders and demand forecast. A MRP method is better suited to handle the planning because it is less complicated. Therefore a new production schedule can be generated faster (it might be infeasible, but that is evaluated under capacity constraints).

Table 3.13: Pairwise comparison of the DDS methods on Planning

	Kanban	*CONWIP*	*Packing*	*MRP*	*MRPII*
Kanban	1	0.5	1	0.25	0.33
CONWIP	2	1	2	0.67	0.67
Packing	1	0.5	1	0.33	0.33
MRP	4	1.5	3	1	0.9
MRPII	3	1.5	3	1.11	1

AHP results

The result of the AHP method is calculated using the different comparisons of compliance to a single requirement, multiplied with the weight of the requirement presented in Table 3.8. The formula for the calculation of the score of a concept on a requirement is given in Equation 3.3. The formula used the calculate the result of the analysis is shown in Equation 3.4. A spider diagram showing the results of Equation 3.3 for the five DDS methods is presented in Figure 3.13.

$$s_j = \frac{\sum_{j=1}^{n} A_{i,j}}{\sum_{i=1}^{n}\sum_{j=1}^{n} A_{i,j}}, \; for \; i \; = \; 1 \; to \; n \tag{3.3}$$

$$r_i = \sum_{j=1}^{n} s_i w_i, \; for \; i \; = \; 1 \; to \; n \tag{3.4}$$

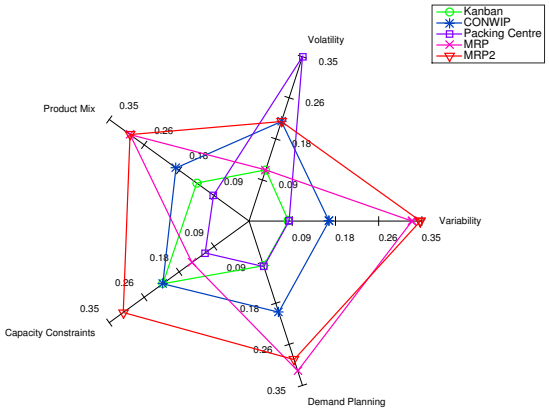


Figure 3.13: Requirement score of the five DDS methods

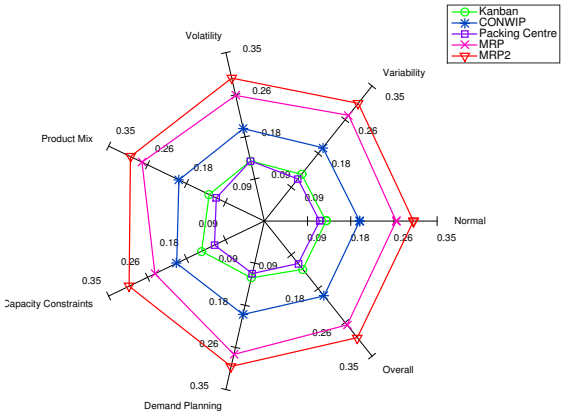


Figure 3.14: AHP method results for the five DDS methods

Sensitivity analysis

The resulting scores are combined into the result of the AHP method, which is presented in Table 3.14 in tabular form and in Figure 3.14 graphically. In total seven columns of results are shown in Table 3.14, the first column (named Normal) is the result for the straightforward analysis using the weights from Table 3.8. The next five columns show the same analysis, but one of the criteria has been given a higher weight. This is done to show the sensitivity of the analysis to changes in the importance of the requirements, the sensitivity is increased by 100% in the analysis. The final column shows the overall score of the DDS methods. The overall score is based on the sensitivity analysis results and the weight of the criteria, according to Equation 3.5.

$$o_i = \sum_{j=1}^{n} sr_i w_i, \ for \ i \ = \ 1 \ to \ n \tag{3.5}$$

Table 3.14: Results of the AHP analysis, with and without sensitivity analysis and overall best DDS method

	Normal	Variability	Volatility	Product Mix	Capacity	Planning	Overall
Kanban	0.125	0.121	0.125	0.124	0.141	0.118	0.125
CONWIP	0.193	0.190	0.192	0.192	0.197	0.194	0.194
Packing	0.112	0.109	0.125	0.108	0.112	0.109	0.110
MRP	0.267	0.274	0.261	0.275	0.246	0.277	0.269
MRPII	0.302	0.305	0.297	0.301	0.304	0.302	0.302

Consistency check

The results of the AHP matrix given in the previous part of this paragraph is based on human judgement. In order to check the consistency of the entered values in the comparison matrix a consistency check is performed, Equation 3.6 [Mocenni, 2011]. λ_{max} is the maximum Eigenvalue of the matrix, n is the number of rows and the Random Index [Donegan and Dodd, 1991], which is a factor linking the size of the matrix to the increase in instability. When the Consistency Index is lower than 0.1 the input comparison matrix is assumed to be stable [Mocenni, 2011].

$$\begin{aligned} Consistency \ Ratio &= \frac{Consistency \ Index}{Random \ Index} \\ &in \ which, \\ Consistency \ Index &= \frac{\lambda_{max} - n}{n - 1} \end{aligned} \tag{3.6}$$

The results of Equation 3.6 for the normal and the different sensitivity cases is presented in Table 3.15. The Consistency Ratio of all the different cases is lower than the indicated 10%, therefore the analysis is considered to be consistent.

Most feasible Demand Driven Supply method

As presented in Table 3.14 the MRPII method is the most feasible DDS method for use in the CSSD when taking demand variability and volatility, the variety in instruments and baskets, the capacity constraints of the CSSD processes and the required input of the planning into account. However, a change to the CSSD process has to be made to handle the demand volatility. A more detailed overview of the MRPII DDS method is given in the next section, together with the required location of the safety stock.

Table 3.15: Results for the Consistency Ratio of the AHP analysis, with and without sensitivity analysis

	Normal	Variability	Volatility	Product Mix	Capacity	Planning
Consistency Index	0.007	0.003	0.056	0.021	0.004	0.003
Random Index	1.120	1.120	1.120	1.120	1.120	1.120
Consistency Ratio	0.006	0.003	0.050	0.019	0.003	0.003

3.4 Detailed Demand Driven Supply method

This paragraph will give a detailed overview of the DDS method. First the location of the required safety stock is discussed. Next a detailed model of the MRPII method is presented. From this model the input data requirements are obtained. Finally the input data requirements are translated into KPIs and process parameters that have to be known.

3.4.1 Location of safety stock

In order to deliver the necessary baskets for acute surgeries the production lead time should be approaching zero minutes (Table 3.6, page 48). The current production sequence of disinfection, packaging and sterilization can not handle such short lead times since the sterilization step takes around 90 minutes to finish. It is impractical to change the order of the production steps since this would lead to a different lay-out of the CSSD. There are difficulties with guaranteeing the sterile nature of the products as well. Therefore the solution has to be found in the application of a safety stock.

The characteristics that primarily determines the location of the safety stock is the CODP (Paragraph 3.1.1). To give a complete overview of the safety stock and inventory locations the multiple use cases from Table 3.6 are evaluated. The CODP of the process is depended on the $\frac{P}{D}$ ratio and the RDV (Figure 3.2, page 27). Both factors are not constant for the different use cases and baskets, therefore a FLC is constructed to evaluate the different cases of CODP. The FLC can be found in Appendix E (page 175).

The evaluation of the FLC shows that the acute surgeries required a MTS or ATO production strategy, the planned surgeries can be supplied via the MTO strategy. Since ATO is deemed infeasible due to the sterilization step at the end of the CSSD process the acute surgeries have to be supplied using the MTS strategy; a safety stock.

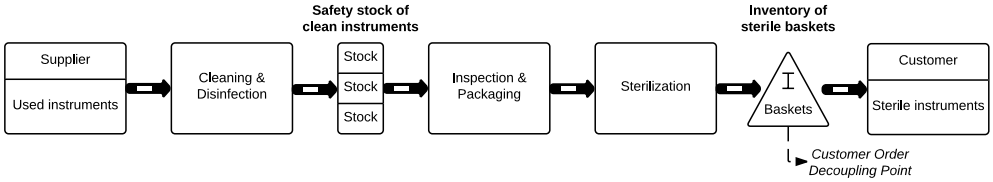
Figure 3.15 presents the location of the CODP for the current situation and two alternatives, which can handle the short lead times for acute surgeries. No adaptations have been evaluated that place the CODP before the disinfection step. It is not desirable or legal to maintain an inventory of dirty instruments. Before disinfection the instruments are possibly hazardous to the personnel handling them. The dirty instruments have to be cleaned and disinfected as soon as possible. The description of the three sub-figures is discussed next. In Figure 3.15 two different production lead times are presented, the inventory lead time (T_{inv}), which is the (range of) time it takes to deliver a basket from the main inventory of the CSSD and the safety stock lead time (T_{stk}), the time (range) required to deliver a basket from the safety stock location(s).

Current situation, Figure 3.15a
The CODP of the current situation is located at the end of the CSSD process. An inventory of sterilized baskets is maintained. The production lead time is therefore 0 minutes, since the baskets are available to the customer when they are needed, no further processing is needed. There is a safety stock or buffer of clean instruments after the disinfection step. This is a buffer of spare instruments, they can be used as a replacement and are not part of the moving stock yet. From this buffer of spare instruments the lead time to the customer is 120 to 150 minutes, depended on the downtime before sterilization. As can be seen the current operation does not reduce the time baskets spend in sterile storage, therefore it is not evaluated any further.

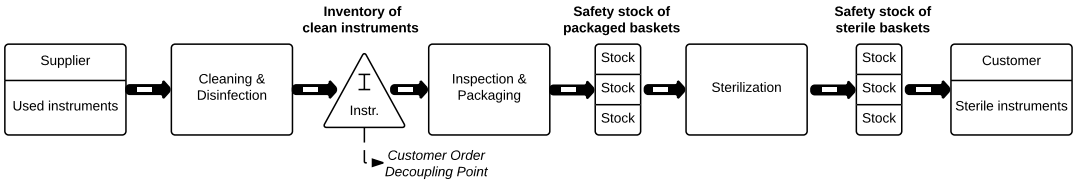
First adaptation, Figure 3.15b
The first possible adaptation places the main inventory after the disinfection step. Furthermore, there are two safety stock locations. The first is before sterilization and the second in front of the customer. From inventory the production lead time is 120 to 150 minutes, from safety stock the lead time is in the range of 0 to 120 minutes. The benefit of this concept is a shorter lead time, whilst decreasing the number of baskets in sterile safety stock.

Second adaptation, Figure 3.15c
The second possible adaptation places the main inventory after the inspection step. There are two safety stock locations in the adaptation as well, at the same locations as the previous adaptation. From inventory the production lead time remains 120 to 150 minutes, from safety stock the lead time is in the range of 0 to 120 minutes. This concept will require a higher processing time, when compared to the previous concept. All instruments have to be handled twice after the disinfection step, with the inventory in between the two. The benefit is that no damaged instruments can be placed in the inventory. This will reduce the error sensitivity of the process since all instruments in storage are in the proper condition to be used during surgery after further processing.

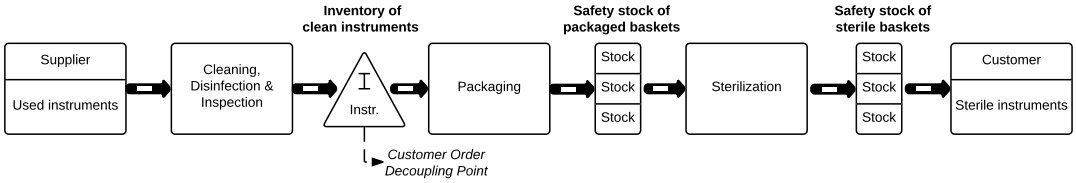
The two proposed adaptations are very similar when concerning production lead time and location of safety stocks. The difference between the two is the location of the main inventory. Both concepts store clean instruments in the main inventory. However, the first adaptation performs inspection of the instruments after the inventory, opposed to the second concept which performs inspection before the instruments are placed in



(a) CODP of the current situation, $T_{inv} = 0\ minutes$, $T_{stk} = 120 - 150\ minutes$



(b) First possible adaptation of CODP, $T_{inv} = 120 - 150\ minutes$, $T_{stk} = 0 - 120\ minutes$



(c) Second possible adaptation of CODP, $T_{inv} = 120 - 150\ minutes$, $T_{stk} = 0 - 120\ minutes$

Figure 3.15: The current and two possible adaptations of the CODP in the CSSD process; the range of production lead time is shown, both from inventory (T_{inv}) and safety stock (T_{stk})

the inventory. As a result the instruments in inventory of the first concept could be damaged or otherwise not fit for future use. This prevented by the second concept due to the inspection step prior to storage of the instruments. All instruments in inventory in the second adaptation are fit for use during surgery after completion of the sterilization process.

3.4.2 Detailed MRPII method

Paragraph 3.2.4 discussed a general introduction to the MRPII method with its characteristics. Besides the characteristics a model of MRPII was given (Figure 3.8). This model gives a good overview of the general functions and inputs of the MRPII system, but does not show the detail required for execution and implementation into a production process. Therefore a detailed MRPII model is presented in Figure 3.16. This model shows all the different inputs, decisions and outputs in the MRPII model. These different aspects of the model are discussed next.

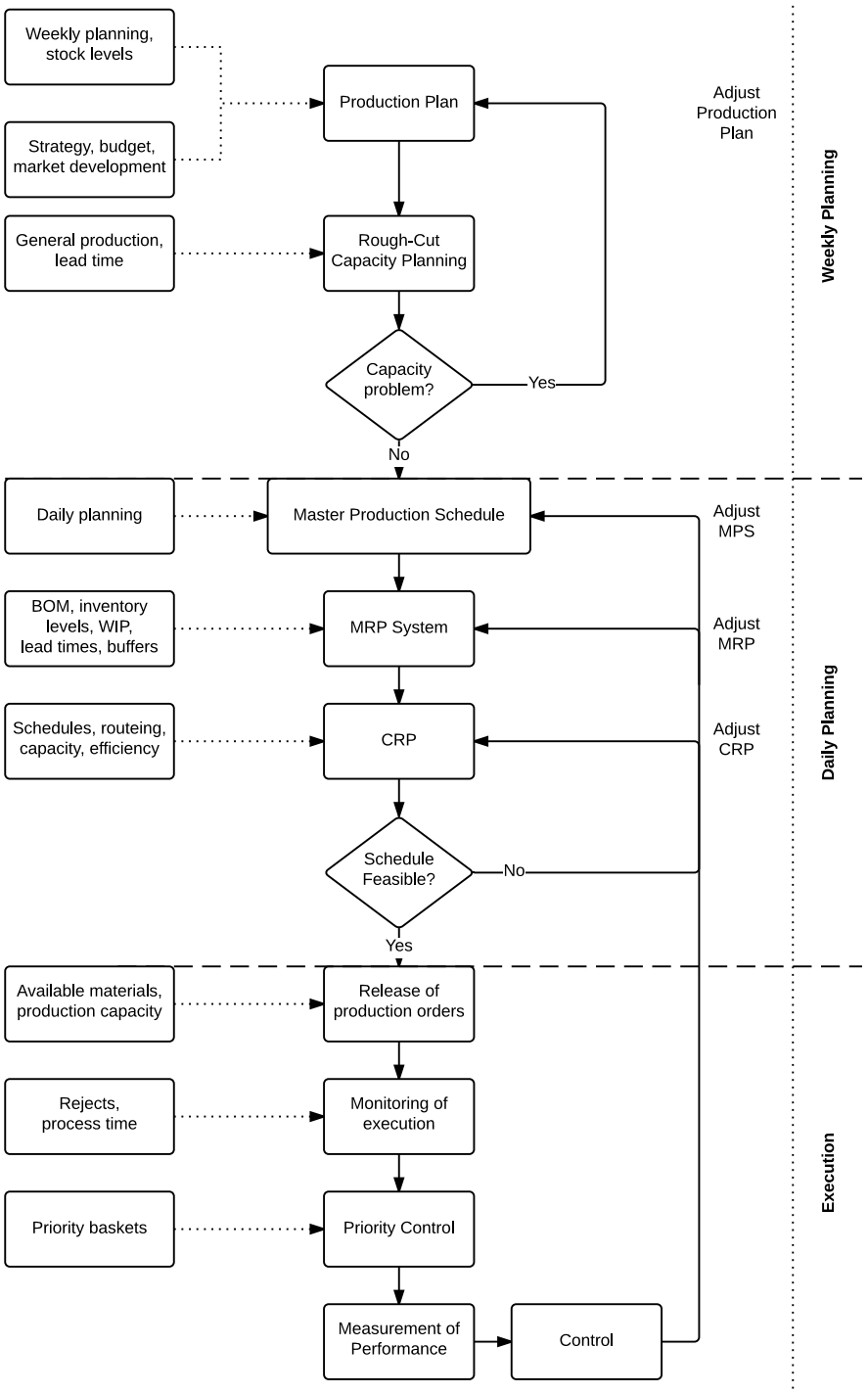


Figure 3.16: Detailed model of MRPII method, showing inputs, decisions and outputs

Inputs of the MRPII method

The inputs of the MRPII method are given in Figure 3.16 on the left-hand side of the figure. They are the function blocks connected by means of the dotted line arrows. A few different categories of inputs can be distinguished: planning data, inventory data, strategic data, production data and basket data.

Planning data
To this category the weekly and daily OR planning belong. These two different plans are used as input for the generation of the production plan and respectively the MPS. Besides these two types of planning the routeing of baskets through the CSSD and schedules of the employees and machines used as input for the CRP are regarded as planning data as well. The last type of data belonging to this category is the required priority baskets, which is used during execution in the Priority Control. The planning data is of great importance to the MRPII method, without the proper inputs is will not generate the required production orders.

Inventory data
The inventory data consists of the current inventory levels, required buffers and the available materials. These are required as input for the general Production Plan, the MRP method and during the release of production orders. Since the inventory data is used in the generation of production orders it is of importance to the MRPII method.

Strategic data
The strategic data can be regarded as the general direction in which the CSSD will moved the coming months or years. The production strategy. available budget and market development are part of the strategic data. The strategic data can alter the way of operation significantly when it changes, however these changes will not occur on a regular basis. Therefore the strategic data has little influence on the weekly and daily course of actions.

Production data
The production data is used to review the performance of the process and to adjust the two capacity checks that are part of MRPII. A large variety of input data can be seen as production data: the production capacity (historical and available), production lead time, batch sizes, WIP, production efficiency and rejects and accurate process times. This category of data is essential for the monitoring and fine tuning of the production processes at the CSSD.

Basket data
Two types of BOM belong to the basket data. The first is the BOM for the planned surgery. Each surgery requires a number of pre-defined baskets and instruments, which has to be known to the CSSD in order to provide timely delivery. Any special items can be added to this BOM as well, to ensure the complete set is delivered to the surgeon. On a lower level the BOM of the baskets itself have to be available. This list shows what instruments belong on a certain basket. The MRPII method needs this data for the generation of a feasible production schedule that is fulfilling customer demand.

Decisions in the MRPII method

The decisions in the MRPII method are presented in Figure 3.16 as two diamond shaped function blocks. The first decision that is made takes place after RCCP and decides upon the feasibility of the proposed MPS. The general production capacity and lead times are taken into account. If the rough-cut capacity is not a problem the MPS is generated. The second decision is made after the CRP. This is another capacity check, the detailed production schedule is evaluated upon feasibility, taking detailed schedules of employee and machine availability, routeing, machine capacity and efficiency into account. If the check is positive the proposed schedule can be executed.

Outputs of the MRPII method

The actual outputs of the MRPII method are the production orders released during the day. There are however some intermediate schedules and plans that can be regarded as sub-outputs, the production plan and MPS.

Production plan
The production plan is generated on a weekly basis. It is primarily based on the weekly planning provided by the OR. The production plan consists of a rough estimate of the required production of the days preceding the operation date. During the capacity check the feasibility is checked, however the OR planning can not be altered. When a planning is infeasible production can not be postponed, the CSSD has to supply the requested baskets on time and thus commence production earlier. The production plan has to take two factors into account, the first factor is that the CSSD not only supplies to the OR, but to amongst others the polyclinics as well. The second factor is the replenishment of the used baskets for acute surgeries. Both these factors require capacity of the CSSD.

Master Production Schedule (MPS)
The MPS is generated from the production plan on a daily basis. The last minute changes in the daily planning are taken into account and the production schedule is adapted to the new situation. Immediately after the MPS is generated the MRP and CRP are called upon to provide a feasible production schedule. The generation of the production orders are release as soon as possible, since the required production of the MPS is needed the next day. The aim of the MPS should be the generation of a schedule that fulfils customer orders whilst achieving the highest efficiency. Capacity for acute surgeries and polyclinics should be reserved in the MPS as well.

Production orders
The production orders are generated during the day when production capacity is available. They are obtained from the MPS and the priority baskets. The progress of the production orders is constantly reviewed in order to check the feasibility of the proposed schedule and if necessary change the production sequence to ensure delivery of the essential baskets. Via the production orders the WIP is kept constant and overloading is prevented.

3.4.3 Required Key Performance Indicators & process parameters

The MRPII model given in the previous paragraph uses various data on the planning of the OR, the inventory, production, baskets and strategic decisions into account to provide the optimal production schedule. These different inputs of the system can be split into qualitative and quantitative data sources. The qualitative data sources are to be obtained from mainly human sources, such as the planning of the OR, the BOM, the strategic decisions and business plan. The quantitative data sources on the other hand can be obtained by monitoring the processes which make up the sterilization cycle. This paragraph will go into detail on the both types of input data, to gain better understanding of the required KPIs for successful operation of the MRPII method.

Qualitative input data

The qualitative input data of the MRPII method is based upon human judgements concerning the next categories:

- OR planning;
- Strategic plan of the CSSD, OR and LUMC;
- Safety stock location(s) and size(s);
- The BOM of surgeries and baskets;
- Production capacity constraints.

The different parties involved in the sterilization cycle should reach agreement upon most of these categories. In order to handle changes in the market periodic reviews of these agreements have to take place. This does not apply for one of the categories, the production capacity constraints. The qualitative input of the production capacity constraints is based on the quantitative production capacity and batch sizes. This production data has to be translated into the capacity using (partly) human judgements.

Quantitative input data

Opposed to the qualitative data, the quantitative inputs can be obtained via process monitoring. The quantitative input data can be split into two parts, the first part is the inventory data, the second concerns the production performance. For both these parts the translation from input data to KPIs is presented as well.

Inventory
The MRPII method uses inventory data throughout the different steps shown in Figure 3.16. The weekly production plan, MPS and production orders are all based on the availability and levels of inventory. The different types of inventory data that have to be known are:

1. Inventory quantity (baskets and instruments);
2. Inventory location (time until ready);

3. Usage factor of baskets (and instruments);
4. Safety stock level(s).

Production performance
Alike the inventory data the production performance is used throughout the MRPII method. During the different production capacity checks the historical or actual performance data is used to ensure the feasibility of the proposed schedule. The different types of production performance that have to be known are:

1. Production capacity;
2. Production lead time;
3. Current level of WIP;
4. Production efficiency;
5. Number of rejects;
6. Process times.

The various forms of production performance and inventory parameters can be obtained from the KPIs and process parameters given in Table 3.16.

Table 3.16: Summary of required process KPIs and parameters

Inventory	*Production performance*
1. Quantity of unique instruments and baskets in the system; 2. Time instruments and baskets spend at certain location; 3. Turn-around time of instruments and baskets; 4. Prognosis of next use time; 5. Number of uses of instrument and basket per time period.	1. Total production per time period; 2. Throughput time; 3. Process time breakdown; 4. Number of rejects; 5. Production efficiency (from total production and rejects); 6. Quantity of baskets and instruments in process; 7. Availability of production resources.

3.5 Chapter summary

An overview of the applicability of DDS in the CSSD has been presented in this chapter. First a general introduction to DDS was shown. This was followed by different methods for DDS, from which the most feasible method for use in the CSSD has been selected. The selected DDS method has be detailed for the CSSD in the last paragraph.

In a production environment a constant workload is key to efficient operation. Regular supply systems achieve this by neglecting the influence of changes in customer demand, which is volatile and ever changing in real life. A method that can achieve high efficiency whilst taking customer demand into account is DDS. All DDS methods have two things in common, they rely on finishing the products as late as possible, when customer demand is known, and thus effectively postponing the production (Section 3.1).

Five different DDS methods that could be applicable for use are: Kanban, CONWIP, MRP, MRPII and the packing centre. The methods of taking customer demand into account differ greatly, Kanban and CONWIP methods use a set of cards to control the production, MRP and MRPII generated an entire production schedule with release of production orders and the packing centre can be seen as a hybrid of both types (Section 3.2).

The selection of the most feasible DDS method has taken the following requirements into account: demand variability and volatility, product mix, capacity constraints and planning. The five methods have been evaluated using the AHP method, to reduce the likelihood of inconsistencies. The result of this analysis was that the MRPII method is most viable to be used in the CSSD (Section 3.3).

The DDS method has been detailed for the CSSD. First the require location of the safety stock was given, to ensure timely delivery to acute surgeries. The MRPII method was shown in detail, containing the different inputs, decisions and outputs. From the inputs the required KPIs and process parameters were obtained (Section 3.4).

In addition, two research questions have been answered in this chapter:

Research question 1: *What is the most viable method for DDS of surgical instruments at the LUMC?*

The MRPII method is most viable for use in the CSSD. It outperforms all other systems when concerning variability, product mix, the capacity constraints and planning. And it is tied with the CONWIP method on the volatility requirement. Changing the sensitivity of the different requirement does not affect the result of the analysis and the consistency check has proven that the data is consistent.

Research question 2: *Which process KPIs have to be known for the successful operation of DDS?*

Various process KPIs and parameters have to be supplied as input for the MRPII method. This quantitative data can be divided into two categories, inventory and process performance KPIs. A summary of these KPIs is presented in Table 3.17.

Table 3.17: Summary of required process KPIs and parameters

Inventory	*Production performance*
1. Quantity of unique instruments and baskets in the system; 2. Time instruments and baskets spend at certain location; 3. Turn-around time of instruments and baskets; 4. Prognosis of next use time; 5. Number of uses of instrument and basket per time period.	1. Total production per time period; 2. Throughput time; 3. Process time breakdown; 4. Number of rejects; 5. Production efficiency (from total production and rejects); 6. Quantity of baskets and instruments in process; 7. Availability of production resources.

Chapter 4

Visibility methods

The DDS system given in the previous chapter requires the right inputs to deliver usable outputs. This chapter presents a method that is suited to achieve the visibility needed for the DDS system and that fulfils the requirement of UDI. First an introduction to process visibility is given. Followed by different methods used for process visibility. Subsequently the required level of detail of the process visibility method is presented. Next the requirements to used technology and method is discussed. These requirements are used in the selection of the most feasible method, described subsequently. After the selection of the most feasible method it is given in detail. At the end of this chapter the concluding remarks are given. Furthermore, this chapter will provide an answer to the following research question:

Research question 3: *Which methods are feasible for providing the visibility of the KPIs of the DDS system and provision of UDI on instruments?*

4.1 Introduction to process visibility

Process visibility can be obtained in various ways amongst others by human observations, measurements or automatic registration of objects. The first two categories are labour intensive and therefore only used for small scale operations. Automatic registration of objects is much more widespread as method to provide process visibility. Automatic registration is known under various names, such as Track and Trace (T&T) and Automatic Identification (Auto-ID). The latter name will be used in the remainder of this report.

Auto-ID solutions provide the possibility to give an unique ID to the different baskets and instruments, that can be followed throughout the system. The fundamentals of Auto-ID solutions are presented in this section. First the different components that are used in Auto-ID systems are given. These components are used in tracking systems which are elaborated next.

4.1.1 Components of visibility systems

An Auto-ID system is composed of multiple different components that are added to the object and the location. These two components are connected to the software by means of middleware. There are many technologies suitable for Auto-ID systems but the components the systems used are similar in function. This section will give an overview of the main functions of the middleware and the different components on location and object level.

Middleware

The middleware acts as the connection between the components that provide the Auto-ID and the client (database or monitoring application). It is essentially a software program that translates the Auto-ID information in such a way that the client can understand it. Middleware fulfils several key functions:

- Hardware component configuration and management;
- Filtering and processing of incoming data;
- Clustering and routering of incoming data.

A schematic depiction of the middleware between the client and multiple servers can be found in Figure 4.1.

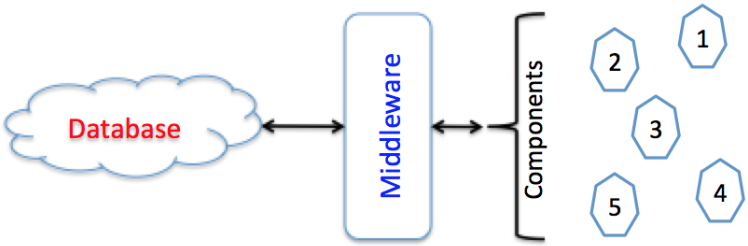


Figure 4.1: The middleware: between the client (database) and servers (components)

Location level components

The components of a Auto-ID system that are used on location level have to provide references points in the location. The reference points are used to determine the location of the objects in the space. There are differences between the different technologies, but all make use of reader or scanners. The main difference between the multiple readers is in the distance between reader and object. Some readers are only able to identify objects that are close-by, other readers are able to read objects from several meters to even hundreds of kilometres.

Object level components

The components that are used on the objects primarily provide the unique identification to the objects. Secondarily the components are there to ensure the visibility of the objects in the system. There are two main types of components that can be used on object level, active and passive components. The active components are suitable to be read from a distance, passive components have to be close to the reader or even make contact.

4.1.2 Tracking system

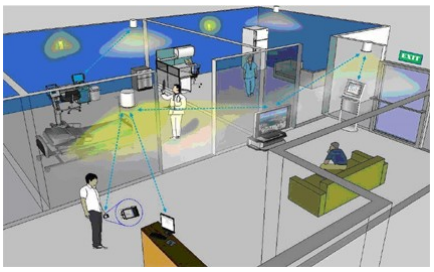
A tracking system is used in various applications for determining the location of unique objects or persons. There are two major groups of tracking systems, the Global Positioning System (GPS) and RTLS. GPSs main application area is the determination of the location of an object on a global scale, such as satellite navigation systems. Indoor applications are challenging since obstacles hinder the connection with the tracking device. RTLS is better suited for indoor use because of the deployment on a system level. A RTLS is used for one building or yard in stead of the whole world. There are two main types of RTLS, the first uses relative coordinates and the second gate points.

Relative coordinate Real-time Location System

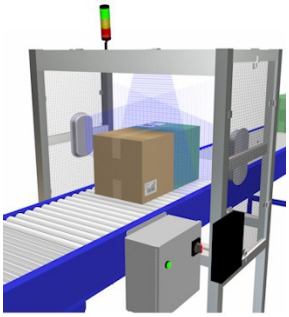
A RTLS system that uses the relative coordinates of the objects has to be able to automatically read the location from a distance at three different points. Because of the remote nature of the scanning process only Auto-ID solutions with a longer range are usable. Using triangulation the exact location of the object is determined. Therefore another name for relative coordinate RTLS is indoor positioning system and is similar to GPS. An example of a relative coordinate RTLS can be found in Figure 4.2a. The advantage of relative coordinate RTLS is that few readers are needed to provide full space coverage.

Gate point Real-time Location System

A RTLS system that uses gate points (or choke points) in the system is able to tell when an object has reached certain key points in the process. An example of a gate point RTLS can be found in Figure 4.2b. At the gate points the objects are scanned and the location and time are coupled to each other.



(a) Relative coordinate RTLS [Engadget, 2009]



(b) Gate point RTLS [RFIDSupplyChain.com, 2015]

Figure 4.2: The two types of Real-time Location Systems

4.2 Technologies for process visibility

There are numerous methods and technologies available for the performance of Auto-ID. They can provide an automatic identification of the object they are attached to. An overview of the most important Auto-ID technologies is given in Figure 4.3. This is a general overview of different Auto-ID technologies, therefore two of the shown systems are infeasible concerning application in the CSSD. These two belong to the biometric group, fingerprint and voice identification. These Auto-ID technologies can be used on people, not on instruments. A first general comparison of the four remaining Auto-ID methods is presented in Table 4.1. These four technologies will be discussed in detail in this section, first the barcode system is evaluated, next OCR, RFID subsequently and finally smart cards.

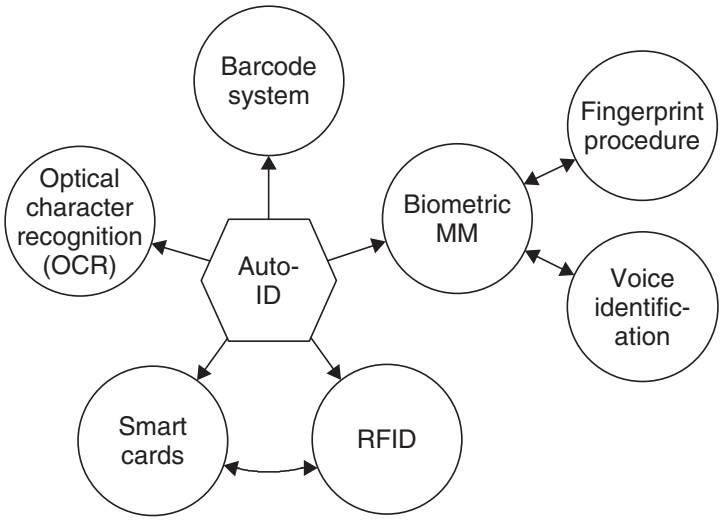


Figure 4.3: Overview of the most important Auto-ID methods [Finkenzeller, 2010]

Table 4.1: Comparison of different Auto-ID technologies, showing their advantages and disadvantages, adapted from [Finkenzeller, 2010]

System parameters	Barcode	OCR	Smart card	RFID systems
Typical data quantity (bytes)	1–100	1–100	16–64 k	16–64 k
Data density	Low	Low	Very high	Very high
Machine readability	Good	Good	Good	Good
Readability by people	Limited	Simple	Impossible	Impossible
Influence of dirt/damp	Very high	Very high	Possible (contacts)	No influence
Influence of (optical) covering	Total failure	Total failure	–	No influence
Influence of direction and position	Low	Low	Unidirectional	No influence
Degradation/wear	Limited	Limited	Contacts	No influence
Purchase cost/reading electronics	Very low	Medium	Low	Medium
Operating costs (e.g. printer)	Low	Low	Medium (contacts)	None
Unauthorised copying/modification	Slight	Slight	Impossible	Impossible
Reading speed (including handling of data carrier)	Low ~4 s	Low ~3 s	Low ~4 s	Very fast ~0.5 s
Maximum distance between data carrier and reader	0–50 cm	<1 cm Scanner	Direct contact	0–5 m, microwave

4.2.1 Barcode system

Barcode systems are part of the vision based solutions, they require line-of-sight between the camera or scanner (Figure 4.4) and the targeted object. The necessity for line-of-sight is the main downside to all vision based solutions, including the barcode system. All different barcodes are subject to industry standards. A set of standards that is commonly used in healthcare (and many other areas) is developed and maintained by GS1 [GS1, 2015], a non-profit, international organisation. The barcodes shown in this section are generated using an online barcode generation tool [Egoditor UG, 2015]. The barcode family can be devided into two parts, the 1D- and 2D-barcodes, which are discussed in this section.

(a) Gryphon Healthcare [Datalogic, 2015b]

(b) Elf Healthcare [Datalogic, 2015a]

Figure 4.4: Two types of hand-held scanners from Datalogic

1D-barcode

Linear barcodes are well known throughout the world. Many different types are available for uses such as the International Article Number (EAN) code or the DataBar, both supported by GS1. The name 1D-barcode comes from the scanner that reads the code along one direction. The black bars and white spaces store the information that the code houses. All linear barcodes use this two-color system, but can be different on concerning other characteristics, these sets of characteristics are called symbologies. The following properties can be distinguished [Barcode Island, 2006]:

1. Supported characters
The type of characters that can be decoded, three types are available: Numeric, Alphanumeric and Full ASCII.

2. Discrete or continuous
Discrete symbologies code the different characters with an start bar and end bar and a space between two characters. Continuous symbologies start with a bar and end with a space. In general the continuous symbologies require less space.

3. Two-width or multiple-width
In two-width symbologies the bars and spaces can be either wide or narrow. For multiple-width symbologies there are three or more widths. Two-width symbologies respond better to low quality prints than multiple ones.

4. Fixed or variable length
A fixed length has got a certain number of characters, a variable length can depict a message of any length.

5. Self-checking
A self-checking symbology can determine if one of the characters is faultily printed or scanned. If this is the case it will most likely produce an error.

Figure 4.5 shows an example of a Omnidirectional DataBar, representing the name of the author.

Figure 4.5: Omnidirectional DataBar of author's name

1D-barcodes in the CSSD

The CSSD makes use of 1D-barcodes for multiple verification steps (Appendix B for details about process steps). The barcodes are attached to: instrument baskets, sterilization carts, sterilization programs and to the labels that are put onto the baskets and individual instruments.

2D-barcode

Alike linear barcodes, the 2D variants are becoming widely used throughout the world since the last decade. There are two main types of 2D-codes, the data matrix and the stacked barcodes. Both have the advantage over linear barcodes that the storage capacity is higher for the same width. Compared to the data matrix the stacked barcode has not that many advantages and is therefore not evaluated. GS1 supports multiple different 2D-barcodes, the DataMatrix is one of them that is used in the healthcare system. Another well known 2D-barcode is the Quick Response code (QR code), it has many applications in various field of logistics. The DataMatrix and QR code have got the following properties: They can encode all the ASCII characters, on a continuous basis. They are single width and single height, furthermore are these 2D-barcodes self-checking and correcting. Both the DataMatrix and QR code are available in different sizes, the DataMatrix ranges from 10 to 144 squares, the QR code from 21 to 177.

Figure 4.6a shows the DataMatrix of the name of the author, in Figure 4.6b a DataMatrix on an instrument is given. This DataMatrix is etched into the instrument by the manufacturer.

(a) DataMatrix of author's name

(b) DataMatrix on instrument [Lawton, 2015]

Figure 4.6: Examples of different DataMatrix codes

Table 4.2 gives a comparison between the Omnidirectional DataBar, DataMatrix and the QR code [HIBCC, 2012].

Similar to the 1D-barcode the 2D variant is used in the LUMC. The OR uses 2D-barcodes for scanning the unique identification number of the baskets before surgery. Some of the instruments have got a DataMatrix etched into them as shown in Figure 4.6b. This functionality is not used since most of the instruments are not equipped with an unique ID and the proper reading hardware is not available.

Table 4.2: Comparison between DataBar, DataMatrix and QR code

	DataBar	**DataMatrix**	**QR code**
Numeric capacity	14	3116	7089
Alphanumeric capacity	-	2355	4296
Binary capacity	-	1556	2953
Minimum size	20 mm	2 mm	20 mm
Minimum contrast	40%	20%	55%
Error-Checking	yes	yes	yes
Error-Correction	0%	30%	30%

4.2.2 Optical Character Recognition

Alike the barcode system is OCR a vision based Auto-ID solution. The difference between barcode and OCR is that the text or numbers represented by the barcode are translated into a code that can be easily read by a machine. OCR reads the actual text and numbers, which improves both the versatility and complexity of the system. Two types of OCR systems can be distinguished, the first is used off-line and the second on-line. The difference between the two is that on-line OCR systems can process the written text during writing, the off-line systems evaluated the finished text. Since the off-line OCR system is applicable to the CSSD it will be evaluated, the on-line type has no benefits for Auto-ID. First an introduction to OCR is given, followed by the different processing steps taken by OCR systems. This paragraph is concluded with the performance affecting factors of OCR system.

Introduction to OCR

This paragraph will give an introduction to OCR. First a short history is given. This is followed by the general types of OCR. The different components of OCR systems are presented last.

History of OCR
The first generation of commercial OCR systems date back to the 1960s [Eikvil, 1993]. This generation of machines was able to read a selection of specially designed fonts, which was limited by the calculation power of the used computers. The increase of calculation power over the decades has proven to be beneficial to the number of fonts OCR machines could read. From the second generation of OCR systems (early 1970s) handwritten text recognition became available. The next generations of machine had a focus on lowering the cost of the OCR systems, whilst increasing performance and accuracy. During the 1990s more functionalities were added to OCR machines such as object comparison, a check to compare the outlines of a scanned object to the desired outlines. During the last decade the OCR machine have become increasingly sophisticated and effective in scanning and processing the image results.

Types of OCR
There are four different types of OCR systems. They differ on two characteristics, the method they read the text and the type of text they can read. The four type are given next.

OCR Optical Character Recognition, reads machine printed text, one character at a time;
OWR Optical Word Recognition, reads machine printed text, one word at a time;
ICR Intelligent Character Recognition, reads machine printed and handwritten text, one character at a time;
IWR Intelligent Word Recognition, reads machine printed and handwritten text, one word at a time.

Most OCR machine work best and fastest when the font type specifies precise character shapes, sizes and constant spacing. These fonts are part of the Unicode Standard [Unicode, Inc, 2015], which standardizes the machine readable fonts.

Components of OCR systems
OCR systems consist of three types of components. Two of the components are stationary, which are the camera and the computer. The last component is the information tag attached to the object that needs to be identified. The camera is used to provide the image of the object with the tag. This image is send to the computer that performs the actual OCR process.

Processing steps in OCR

OCR machines transform the input of an analogue image into a digital file which shows the required data from the scanned object. There are six different steps that can be distinguished in this process. The first step is scanning the image, followed by segmentation of the image. Subsequently the image is preprocessed and the determining features are extracted. These feature are finally recognized and post processed by the OCR system [Eikvil, 1993], [Mithe et al., 2013].

1. Image scanning
A camera is used to capture an image of the object that needs to be recognized. This image can be in gray-scale or in full-colour since (most) OCR systems use thresholding to transform the image into black and white. There are two options concerning thresholding, the fixed and adaptive method. An adaptive method might be desirable since fixed thresholds could have problems with low contrast images. This is shown in Figure 4.7. The original image (top) is low in contrast and the background colour is a gradient from grey to white. The middle image gives the result after thresholding with a fixed threshold. The bottom image gives the result after thresholding with an adaptive threshold. Is is clear that the result of the fixed threshold is sub-par compared to the adaptive threshold.

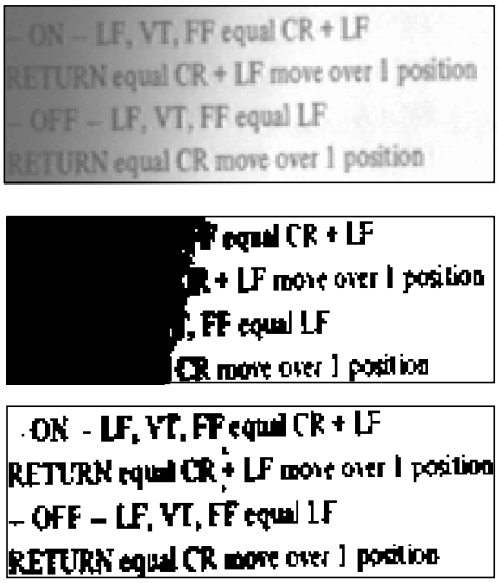


Figure 4.7: Problems in thresholding: *Top:* Original grey-scale image, *Middle:* Image thresholded with global method. *Bottom:* Image thresholded with an adaptive method [Eikvil, 1993]

2. Segmentation

The aim of the segmentation step is to locate the regions of the image where the text is. The text needs to be evaluated, therefore only those regions containing text are passed down to the next steps. There are multiple problems which can occur during the segmentation process, these are [Eikvil, 1993]:

1. Extraction of touching and fragmented characters

The different words are in general evaluated one character at a time. When the characters are touching or frgmented the OCR does not know when one characters ends and the other begins.

2. Distinguishing noise from text

Imperfections in the image (for example dust or dirt on the camera lens) may lead to wrongly segmenting text locations.

3. Mistaking graphics or geometry for text

Text locations without any text are sent to the subsequent steps.

4. Mistaking text for graphics or geometry

Text locations with any text are not sent to the subsequent steps.

3. Preprocessing

Preprocessing targets the noise that is inevitably on the image. Two different methods are used during preprocessing, smoothing and normalization. The smoothing process fills any gaps in the characters or thins the characters. Normalization aims at providing an uniform size, slant and rotation of the individual characters for the following steps.

4. Feature extraction
During feature extraction the OCR system captures the determining characteristics of the characters and symbols. The unimportant characteristics are left out to speed up the recognition step. There are three groups of feature extraction methods:

- Distribution of points;
- Transformations and series expansion;
- Structural analysis.

A complete overview of these three groups can be found in [Eikvil, 1993].

5. Recognition
In the recognition step the actual characters are identified and processed into text. This recognition is based upon the set of characteristics provided by the feature extraction step.

6. Post processing
The recognized text is post processed where the different characters are grouped together to form words. The OCR system looks at the spacing between the different characters, when they are close enough to each other it is assumed that they are part of the same word. An optional step in post processing is error detection and correction. This checks the text for any faults against predefined standards, for example a dictionary.

Performance of Optical Character Recognition

The performance of OCR systems is the number of successful images and correct identifications that follow for the image. Whether an image is successful is depended on the ability of the camera to see the object. Whether an identification is correct depends on the accuracy of the OCR system. Both these factors are elaborated.

Successful image
The camera of the OCR needs to see the object in order to determine its identity. In order for this to take place the path between camera and object has to be unobstructed and the identification code must be visible as a whole.

Correct identification
When the camera obtains an useful image of the object the OCR system translates the image into text. This translation can be affected by any of the problems given in the processing steps. As a result of these problems the accuracy of the OCR is lower than desired. A large study on the analysis of OCR accuracy in large scale historic newspapers has provided an accuracy of OCR systems varying from 71% to 98% [Holley, 2009]. This application is quite different from using OCR as Auto-ID technology, but both use comparable methods for generating the output files.

4.2.3 Radio Frequency IDentification

RFID systems are referred to as proximity based solutions, they are able to scan objects that are near (in the proximity of) the reader. It is not necessary to have a clear line of sight between the object and reader as with vision based solutions.

The main principle of operation of RFID systems is communication via an alternating magnetic field. Information can be send from the RFID tag attached to the item to the reader, but not vice versa. Three types of RFID tags available, passive, battery assisted passive and active tags. Next the characteristics of these types are shown.

Passive RFID tag

Passive tags do not have an onboard power source, the required power for operation is supplied by the reader. The tag is activated when it is within the field of the reader and only when the signal is strong enough to power it. This lack of power causes a short range for passive RFID systems, maximal 3 metres under prefect circumstances. Due to the fact that the tag is not battery operated the size remains small and the lifespan is very long.

Battery assisted passive RFID tag

Battery Assisted Passive (BAP) tags have got an onboard power source, which is used to provide power to the transmitter. The tag is activated when it is within the field of the reader and when an interrogation signal (wake-up call) is send to the tag. The BAP tag has got a larger range than passive tags (upto 50 m), but a shorter lifespan.

Active RFID tag

Active tags are battery powered and are available for communication as long as the battery lasts. The required signal strength is low since it is not needed for powering the tag, only data has to be sent. The range of active RFID systems is much longer (100 m) when compared to passive RFID systems. The downside to this is that the tags are larger and have got a short lifespan. Due to these downsides active tags are not considered for use as visibility system.

Besides the division in passive and active RFID tags there are different operating frequencies too choose from. Table 4.3 gives an overview of the different frequency bands that are available for RFID systems.

RFID in hospitals

Multiple RFID systems have been implemented in hospitals over the past decades. Table 4.4 gives an overview of a couple of RFID applications.

Table 4.3: Different RFID frequencies and their properties

Frequency	**Low**	**High**	**Ultra High**	**Microwave**
	134-135 kHz	13.56 MHz	865-868 MHz	2.4 GHz
Operating principle	Induction		Radio	
Energy supply	Passive		Active and passive	
Passive range (max)	20 cm (1.2 m)	20 cm (1.5 m)	3-6 m	2 m (10 m)
Active range			100 m	
Data transfer rate	$< 1 \frac{kbit}{s}$	$\approx 25 \frac{kbit}{s}$	$\approx 30 \frac{kbit}{s}$	$< 100 \frac{kbit}{s}$
Effect of metal	Negative	Negative	Negative	Negative

Table 4.4: RFID systems in hospitals, enabling technologies, and specific applications [Al Nahas and Deogun, 2007]

System name	**Enabling technologies**	**RFID applications**
Harvard hybrid system.	Passive and active RFID, and bar codes.	Identification of patients, NICU babies, and mother's milk containers; tracking equipment and staff.
Aarhus context-aware application.	RFID, finger-print recognition, and bedside displays.	Patient and clinicians identification, drug administrations (pills), and access to medical records.
Galway RFID/handheld application.	RFID, handheld devices, and IEEE 802.11b network.	Patient identification and access to medical records.
Intel transfusion system.	RFID, mobile RFID readers and programmers, and Cisco wireless network.	Transfusion; donors, recipients, and staff identification.
Auckland drug adminstration system.	Passive RFID.	Drug adminstration (syringes).

The application areas mentioned in this table, from 2007, mainly focus on patient, staff and equipment identification. Since then there have been some notable developments in the application field of RFID in hospitals, which are elaborated next.

Ultra high Frequency

There are two suppliers that offer Auto-ID for surgical instrument using Ultra High Frequency (UHF) tags. These are the Caretag system [Xerafy, 2015] and the KPN MediTracker [KPN, 2015]. The Caretag system has been tested over a period of 18 months in the Rigshospitalet in Denmark. The test has been concluded in April 2015 and the conclusions were positive. The KPN MediTracker solution is relatively new and is still in the testing phase. Both these systems use passive tags and claim an operational range of 0.5 to 1 metre, which is considerably lower than shown in Table 4.3.

High Frequency

Auto-ID solutions of surgical instruments with High Frequency (HF) RFID tags are more mature than the UHF type. Haldor AT ltd. provides the ORLocate [Haldor, 2015] and at the Shimane University Hospital the SIMSAFE [Sawa and Komatsu, 2013] has been implemented. Both these systems offer Auto-ID of instruments combined with software systems to manage the instruments.

4.2.4 Smart cards

Smart cards are used in many applications for identification, authentication and data storage. In the Netherlands an increasing number of smart cards are available to the public, the public transport card (OV Chipkaart), bank cards and access cards. There are two types of smart cards, the first requires contact between the card and the reader, the second is read contact-less.

Contact smart card

The contact smart card (or chip card) has to make physical contact with the reader. The only reason for using a chip card is in situations where a magnetic field is unwanted. They are predominantly used in the financial world for Automated Teller Machine (ATM) cards and credit cards and in mobile phones as Subscriber Identity Modules (SIM) card. Because of the physical contact required for data transfer chip cards are not very abrasion resistant, which is the main downside to them.

Contact-less smart card

The contact-less smart card solves the main downside of contact based cards, it is not necessary for the card and reader to make contact for data transfer to take place. The use has become widespread as entrance cards for restricted areas and recently for wireless payments at the cash register. The contact-less smart card is essentially a passive RFID chip put inside a credit-card. Because of this the contact-less smart card is not evaluated on itself, but as a passive RFID technology.

4.3 Level of detail of process visibility

This section presents the level of detail of the visibility method required in the LUMC. First the various identification steps in the current process are presented. This is followed by the discussion of the requirements that UDI imposes on the system. Subsequently the effect of the KPIs is given. This leads to the selection of the level of detail: the type of tracking system and the object level to be used in the tracking system.

4.3.1 Identification steps in the sterilization cycle

The detailed description of the process presented in Appendix B shows the various identification phases in the process. This identification can be on cart, basket or instrument level. There are three different methods of performing the identification, via barcode attached directly to the container, via a barcode on a label which is attached to the packaging material of the container or based on operator knowledge (human judgement). The sterilization cycle is discussed in two parts, first the CSSD and second the OR part.

Identification steps in the CSSD

During the five sub-processes of the CSSD various identification phases are part of operation. These identification moments are primarily aimed at providing information about the throughput of baskets, in numbers and in time. This is performed by means of a direct scan of the baskets themselves, or the cart containing the baskets. In total there are ten different identification moments of a basket in the CSSD.

The second type of identification that takes place in the CSSD is on instrument level. During inspection and packaging the instruments have to be identified to be assigned to the correct baskets.

Identification steps at the OR

At the OR there are four different identification steps, one in storage, two in the OR itself and one after the surgery. In sterile storage the baskets are placed in the correct spot for storage, which is documented. Before surgery commences the baskets and instruments are evaluated on their state. After surgery the reusable instruments and materials have to be separated from the disposable ones.

4.3.2 Unique Device Identification

The regulations concerning the application of UDI only focus on the identification itself. The following two excerpts are from the Guidance on UDI of Medical Devices [IMDRF, 2013].

1. *"Medical devices that are reusable should have a UDI Carrier on the device itself. The UDI Carrier of reusable medical devices that require reprocessing between patient uses should be permanent and readable after reprocessing cycles for the intended life of the device. Manufacturers may determine that this may not be possible or warranted on some devices due to size, design, materials, processing, or performance issues."*
2. *"No particular AIDC methods should be required by a regulatory authority. Globally accepted AIDC methods based on ISO standards that have been adopted by the global organization (e.g., GS1, HIBCC or ICCBBA) shall be used."*

These excerpts give the most important requirements from the UDI Guidance, applicable on reusable surgical instruments. It essentially indicates that each and every reusable instrument has to be uniquely identifiable and that the method of providing the identification should last a lifetime. Furthermore, there are no limitations on the Auto-ID technology used for the provision of the UDI, besides that it has to he based on International Organization for Standardization (ISO) standards.

4.3.3 Key Performance Indicators

The different KPIs required for successful operation of the MRPII system were presented in Paragraph 3.4.3. Two types of input KPIs are required, inventory and production performance based, both these categories are discussed in this paragraph.

Inventory

The inventory data can be split into two parts, the quantity of baskets and instruments and the time based data. The type of RTLS does not affect the manner of obtaining the quantity of baskets and instruments in the system. It can only be obtained by registering every single item in database. The time based data contains data on the time baskets are in a certain location, the turn-around-time, prognosis of next use and the number of uses in a certain time period. These are all affected by the type of RTLS, these KPIs have to be obtained by means of starting a timer when the item starts a process and stopping the timer when the process is finished.

Production performance

Alike the inventory data the production performance can be split into two parts, the historical KPIs and the real-time KPIs. The historical KPIs are used for process analysis, identifying the bottlenecks and as input for the capacity constraints. The real-time KPIs are used as input for the MRPII system for the calculation of feasible schedules. The timer function described at the part discussing the inventory KPIs is used for the production performance KPIs as well. A second functionality has to be added, a counter that can count the number of items entering and exiting the system or process step.

4.3.4 Type of tracking system

In Section 4.1.2 two types of RTLS (tracking system) were discussed, the relative coordinate and gate point system. A relative coordinates RTLS is actually a indoor positioning system, opposed to the gate point RTLS which can only determine whether an object passes the gate. The latter is therefore less complicated since it does not need full room coverage, it has to be able to scan the objects that are near the gate only. First the selection of RTLS is presented and the corresponding object level second.

Selection of RTLS

The decision which type of RTLS is best suited in the LUMC is based on the different identification steps in the sterilization cycle and the required KPIs. The description of the identification steps in the current sterilization cycle given above shows that actually the only requirement is identification. There is no need for the determination of the exact location of the instruments and baskets within the CSSD and OR. For the identification steps in the sterilization cycle a relative coordinate RTLS will not provide any benefits over a gate point system.

The KPIs that are used in the MRPII system are split into two categories, time based and location based. The time based KPIs indicate how long a process lasts and at what time the object will be available for the next use. The location based KPIs indicate where the objects are at a certain time. The latter could lead to a relative coordinate RTLS since it can provide the exact location of the object at any time. However this level of detail is not needed for the MRPII system. The location of the objects is merely used in combination with the time data to come to a feasible schedule.

For both the identification steps in the sterilization cycle and the acquisition of the KPIs required for the MRPII system the gate point RTLS suffices. The relative coordinate RTLS gives a level of detail that is not needed and will make the system more complicated.

Selection of object level

The object level of the tracking system at the LUMC can basket or instrument level. The selection of the applicable object level is depended on the identification steps, the UDI guidance and the KPIs. Most of the identification steps in the CSSD and OR are on basket level, there are however four different identification phases that the instruments are targeted. This is the case during inspection and packaging in the CSSD and just before and after use in the OR. The UDI guidelines are very clear about the required object level. The instruments have to be identifiable by means of the UDI.

The acquisition of KPIs can take place at basket level in all cases. This is because the contents of the baskets (through the BOM) is known and thus by following baskets the (not unique) instruments on the baskets are followed as well. It can be beneficial to be able to have a database in which the instruments are known on a individual basis, the exact usage of unique instruments can be monitored and used for process improvement.

The required object level is primarily determined by the UDI guidelines. Both the identification steps in the sterilization cycle and the acquisition of KPIs do not require an instrument level tracking system. However, an instrument level tracking system could make the identification process of the instruments in the sterilization cycle easier and the exact usage profile of instruments can be obtained. A basket level tracking system can be used, in addition to the instrument level required by the UDI guidance.

4.4 Requirements to process visibility method

This section gives the different requirements to which the Auto-ID technology has to comply. First the requirements to the object technology are presented. Next the functional requirements are given and thereafter the non-functional requirements.

4.4.1 Requirements to the object technology

The different Auto-ID technologies discussed in Section 4.1 have to comply to the requirements given in this paragraph. First the use conditions of the sterilization cycle are presented, followed by the invasiveness of the technology. Next the UDI guidance is given and finally the classification requirement. The latter two are only valid for instrument level Auto-ID, not for basket level. The UDI has to be applied to instruments and the instruments are subjected to classification, not the baskets.

Use conditions

The Auto-ID technology has to be able to stay in operation during the lifetime of the instrument in the conditions of the sterilization cycle. These include temperatures of 140 °C, an alkaline environment with $pH = 11$, pressures up to 350 kPa and mechanical vibrations.

Invasiveness

The addition of an Auto-ID technology to the instruments and baskets change the appearance and the handling of them. The invasiveness requirement takes this into account. The size and appearance of the technology affects this requirement.

UDI guidance

The UDI guidance states that only technologies based on ISO standards adopted by the global organization should be considered. This requirements is valid for the instrument level Auto-IDtechnology, not for basket level.

Classification

All instruments used in the LUMC are subject to a certain classification (European Directive 93/42/EEC [EEC, 1993]). The Auto-ID technology can not make any changes to the instrument such that the classification becomes invalid. Among the changes that are prohibited are the use of batteries, additions that make the cleaning more difficult and alterations that could affect safe operation of the instrument. This requirements is valid for the instrument level Auto-IDtechnology, not for basket level.

4.4.2 Functional requirements

The functional requirements that the visibility method should meet are closely related to the identification steps, UDI guidance and the acquisition of KPIs given in Section 4.3. These requirements can be split into two categories, identification of instruments and identification of baskets.

Identification of unique instruments

The identification of unique instruments is required for compliance to the UDI guidance. The visibility method to be used has to be able to provide the unique ID to the instruments. Since the baskets consist of multiple different instruments, it is not necessary to perform identification on basket level. However, it might be beneficial to the speed of operation to identify the basket instead of the instrument. Therefore the requirement concerning the identification of baskets is added to the functional requirements.

Identification of baskets

During the sterilization cycle the baskets in the system are identified on various occasions. The visibility method that could be applied to basket level has to provide the identification to the baskets.

4.4.3 Non-functional requirements

The functional requirements have given the tasks of the visibility method, the non-function requirements indicate how it should be operating. These follow from the process steps of the sterilization cycle, combined with peripheral matters such available budgets and legislation.

Readability

The readability of the visibility method is dependent on two factors, the distance between the reader and the object and whether line-of-sight is necessary.

Reliability

The visibility method has to be reliable in operation at the LUMC. This includes that the identification process can be executed at any time (effect of line-of-sight is not included in this requirement). Besides this, the lifespan of the ID carrier has to last as long as the lifespan of the instrument.

Cost effectiveness

The cost effectiveness of the visibility method is not the most important requirement, but it has to be included. The cost of the different technologies is estimated and compared to each other.

Impact on process

The visibility method will change the current way of operation both at the CSSD and the OR. The impact of the addition of process visibility into the sterilization cycle has to be taken into account. A lower impact is desirable since this would mean that the current operation can be maintained with only minor changes.

4.5 Selection of process visibility method

This section presents the selection of the visibility method to be used in the LUMC. First the selection of the different Auto-ID technologies applicable for instrument level identification is presented, which is followed by the same discussion of Auto-ID on basket level. From the set of different technologies multiple different concepts are derived which are evaluated to come to the most feasible concept for process visibility, according to the requirements given in Section 4.4.

4.5.1 Instrument level

The Auto-ID technology to be used on instrument level has to comply with the requirements given in Paragraph 4.4.1. The UDI guidance states that only ISO approved technologies can be used that has been adopted by a global company such as GS1 [GS1, 2015]. GS1 supports standards for barcode and RFID technologies, OCR and smart cards are not supported and can therefore be skipped in analysis. An analysis of the different barcode and RFID technologies is presented next.

Barcode

Two types of barcode are discussed in Section 4.2.1, the linear and 2D-barcode. The main differences between two common variants of linear (DataBar) and 2D-barcode (DataMatrix) is presented in Table 4.2.

From this comparison it is clear that the DataBar is larger than the DataMatrix and the storage capacity is lower. Furthermore, when a DataMatrix is partially visible, or damaged (30%) it still can be read. Due to these distinct advantages over the linear barcode, the 2D-barcode is the best option of the two for use on instrument level in the LUMC.

RFID

Three types of RFID technologies are discussed in Section 4.2.3, passive, BAP and active RFID systems. The main difference between them is the power source used for operation of the tag. Passive tags do not have an onboard power source, it is supplied by the reader. Opposed to the BAP and active RFID tags, which have an onboard power source to power the tag circuits.

All reusable surgical instruments in the LUMC are subjected to classification (Table 2.1). Class I is applicable to most of the instruments, which is valid for instruments that are not connected to an active device. Whether a device is active or not is depended on many factors, including the addition of an onboard power source. When a BAP or active RFID tag is attached to a Class I instrument, the classification will become invalid. Therefore the BAP or active RFID technologies can not be applied to the instruments.

4.5.2 Basket level

Similar to the selection of the technologies on instrument level the Auto-ID technology to be used on the baskets is performed. On basket level the UDI guidance and classification constraints do not apply. However, the contact smart will not be viable for use in the CSSD because of the corrosive alkaline environment of the disinfection process. The contacts of the card will not be able to handle the excessive wear from this process. The two categories of evaluated technologies are vision (linear and 2D-barcode and OCR) and proximity based (RFID).

Vision technologies

The linear and 2D-barcode and OCR technologies are vision based since they make use of a camera or scanner to provide the identification process. The three different methods are very similar in application and operation. There has to be line-of-sight between the object identification and the camera and the size constraints are not as stringent as is the case with instrument level application. The analysis between the different technologies has to be based on other characteristics, such as the error-correcting capabilities, the processing speed and which technologies are used in the current system.

The DataMatrix 2D-barcode is the only technology that has error-correcting capabilities, linear barcodes nor OCR text can be read when partially missing or damaged. The processing speed of the barcode systems is higher than for OCR. The latter has to be optimized for use on the baskets and requires more processing power to perform the six processing steps (Paragraph 4.2.2). Barcodes are standardized and are always similar, white or black and blocks or bars. This extra time required for processing the code is most likely of small influence regarding the current processor speeds. Finally, the CSSD and OR use in their current processes the two barcode systems. These technologies are well known and proven to work, which makes them the better options compared to OCR.

Concluding the best vision based Auto-ID technology is the 2D-barcode. This is because it has error-correcting capabilities built into the barcode and is well known in the LUMC.

Proximity technologies

Three types of RFID technologies considered for instrument level are applicable on basket level as well. The onboard power source of the latter two is not a deal breaker since the baskets are not subjected to a stringent classification. However other characteristics of the three different methods of operation are to be used for analysis. The size of passive tags is generally smaller than powered tags. This is caused by the addition of a space consuming power source in the other two. The downside of this is that the operating range of passive tags is much lower. Finally the powered tags will only last as long as the battery has power. This limits the lifespan of the tags significantly. These three difference will be used in the evaluation.

The main advantages of powered tags will not be used in the CSSD and OR processes. The extended range of operation of tens of meters will not be used in the CSSD because a gate point RTLS will be used. This leaves the disadvantages of powered tags compared to passive tags, larger size and shorter lifespan. On the baskets there is some space to apply a larger tag, however the powered tags are much larger. This is seconded by the lifespan of the batteries, tags with enough battery capacity are too large to be fitted. All in all is the passive RFID tags the only viable RFID technology for use on baskets in the CSSD.

4.5.3 Visibility concepts

The different concepts make use of the different possible Auto-ID technologies following from the previous paragraph. The basis of the different concepts is that they provide the UDI to the instruments. This leads to six concepts, two consisting of only an Auto-ID technology on instrument level and four that combines instrument level Auto-ID with basket level.

Concept 1: IB
The first concept uses Instrument level Barcode (IB). The instruments are individually marked with an unique DataMatrix that can be scanned during the different steps in sterilization cycle. An example of a DataMatrix on an instrument is given in Figure 4.8.

Concept 2: IR
The second concept uses Instrument level RFID (IR). A passive RFID tag is attached to each instrument that is read during the different steps in sterilization cycle. An example of a passive RFID tag attached to an instrument is given in Figure 4.9.

Figure 4.8: DataMatrix on instrument [Lawton, 2015]

Figure 4.9: Passive RFID tag on instrument

Concept 3: BBIB
The third concept uses Basket level Barcode and Instrument level Barcode (BBIB). An example of a DataMatrix that can be attached to a basket is given in Figure 4.10, the instrument level DataMatrix is presented in Figure 4.8. The DataMatrix can be fixed to the basket, or attached via a keyring. The latter option has the preference since the DataMatrix has to be seen by the camera for identification. When the code is fixed to the basket the whole basket has to be moved to align camera and code. When a keyring is used the DataMatrix can move independently from the basket, which would make the scanning less time consuming.

Concept 4: BBIR
The fourth concept uses Basket level Barcode and Instrument level RFID (BBIR). An example of a DataMatrix that can be attached to a basket is given in Figure 4.10, the instrument level passive RFID tag is presented in Figure 4.9.

Figure 4.10: DataMatrix on metal tag [CIM, 2015]

Figure 4.11: Passive RFID tag on basket [Xerafy, 2014]

Concept 5: BRIB
The fifth concept uses Basket level RFID and Instrument level Barcode (BRIB). An example of a passive RFID tag that can be attached to a basket is given in Figure 4.11, the instrument level DataMatrix is presented in Figure 4.8. The same two methods for attaching the RFID tag are available as with the DataMatrix. Using rivets it can be fixed in place (shown in Figure 4.11 or it can be connected to the basket via a keyring. Opposed to the DataMatrix, the RFID tag is best to be fixed in place. The reader does

not need a direct line-of-sight, the orientation of the tag does not affect the identification process.

Concept 6: BRIR
The sixth concept uses Basket level RFID and Instrument level RFID (BRIR). An example of a passive RFID tag that can be attached to a basket is given in Figure 4.11, the instrument level passive RFID tag is presented in Figure 4.9.

4.5.4 Concept evaluation

The six process visibility concepts given in Paragraph 4.5.3 are evaluated upon compliance to the requirements shown in Paragraphs 4.4.2 and 4.4.3. The evaluation of the different concepts is performed using the AHP method, which is used in Paragraph 3.3.2 as well. Further details about the AHP method can be found on page 50.

The AHP matrix ($A_{i,j}$) for the requirements of the process visibility method is given in Table 4.5. As can be seen the following relation between different elements exists: $A_{i,j} = A_{j,i}^{-1}$. The resulting weights of the requirements are calculated using Equation 3.2 and are shown in the last column.

Table 4.5: Weights of the visibility requirements resulting from pairwise comparison AHP

	ID of Instruments	*ID of Baskets*	*Readability*	*Reliability*	*Cost effective*	*Impact on process*	**Weight**
ID of Instruments	1	0.5	1.5	2	2	2.5	**0.214**
ID of Baskets	2	1	2	2.5	2	3	**0.281**
Readability	0.67	0.5	1	1.5	1.5	2	**0.161**
Reliability	0.5	0.4	0.67	1	1	3	**0.148**
Cost effective	0.5	0.5	0.67	1	1	2	**0.127**
Impact on process	0.4	0.33	0.5	0.33	0.5	1	**0.069**

The functions the process visibility methods should perform are the most important requirements cast over the six concepts. Since there are more processing steps in the sterilization cycle that gather information on basket level, it is deemed more important than instrument level. The Readability requirement has the highest weight of the non-functional requirements. This is explained by the fact that the reader has to be able to read the tag connected to the basket or instrument. The reliability of the visibility method is second in line because the operation of the CSSD and OR can not be hindered by non-functioning tags or readers. These disturbances should be kept to a minimum.

An important factor in the decision for the visibility method is the overall cost of implementation, it is not as important as the readability or reliability, since the cost does not effect the actual performance directly. Alike the cost effectiveness the impact on the process does not affect the functions of the process visibility method directly. It does give information about the difficulties in implementing and operating the method and is therefore taken into account.

In a similar manner shown in Table 4.5 the visibility concepts can be rewarded a score for compliance to a single requirement, compared to the other concepts. The resulting six tables are combined into the final result of the AHP. Next the pairwise comparison tables of the compliance of the concepts to the requirements are discussed.

Pairwise comparison of ID of Instruments (Table 4.6)
The six concepts are divided into two groups for the pairwise comparison of the ID of Instruments. The first group uses barcode on the instruments and the second RFID. The RFID concepts perform twice as good as the barcode concepts since the identification process can be faster than with barcode. Each instrument has to be scanned individually when a barcode is applied, whilst the use of RFID would lead to the scanning of multiple instrument in a single sweep of the reader. The difference is only a factor two because of the fact that in the inspection and packaging step of Table B.1 require the individual handling of all the instruments.

Pairwise comparison of ID of Baskets (Table 4.7)
The concepts using the same Auto-ID technology on basket level are rewarded the same score. The two concepts using RFID on baskets are the best equipped for the identification of baskets throughout the sterilization cycle. Since line-of-sight is not required for the RFID tags to be read, they can be identified at the source (tag) in the whole cycle, even when the baskets are in packaging material. The two concepts with barcode ID tags attached can be used throughout the cycle, but the ID tags themselves can not be scanned in the case of packaged baskets. This is solved by scanning the barcode that is on the label on the outside of the packaging material. The two concepts without a basket Auto-ID technology receive the lowest score. The RFID instrument concept is better equipped than barcode variant since the RFID tag can be scanned through the packaging material.

Table 4.6: Pairwise comparison of the visibility concepts on ID of Instruments

	IB	IR	BBIB	BBIR	BRIB	BRIR
IB	1	0.5	1	0.5	1	0.5
IR	2	1	2	1	2	1
BBIB	1	0.5	1	0.5	1	0.5
BBIR	2	1	2	1	2	1
BRIB	1	0.5	1	0.5	1	0.5
BRIR	2	1	2	1	2	1

Table 4.7: Pairwise comparison of the visibility concepts on ID of Baskets

	IB	IR	BBIB	BBIR	BRIB	BRIR
IB	1	0.7	0.4	0.4	0.2	0.2
IR	1.43	1	0.7	0.7	0.5	0.5
BBIB	2.5	1.43	1	1	0.6	0.6
BBIR	2.5	1.43	1	1	0.6	0.6
BRIB	5	2	1.67	1.67	1	1
BRIR	5	2	1.67	1.67	1	1

Pairwise comparison of Readability (Table 4.8)
The score on the Readability requirement of the different concepts is mainly based upon the required distance between the reader and object and whether line-of-sight is required for operation of the concept. Since the readability of RFID tags is better than barcodes, the distance is generally larger and line-of-sight is not required. Most of the scanning steps in the sterilization cycle are on basket level, the two concepts using basket level RFID tags are the top contenders. Followed by the second concept, only RFID on instrument level. It is rewarded a higher score than BBIR since the basket level barcode is scanned during most of the steps, instead of the RFID tag. The two concepts using only barcodes on instrument and / or basket level receive the least points. During most of the sterilization cycle the unique ID can not be scanned directly.

Pairwise comparison of Reliability (Table 4.9)
Again the basket level Auto-ID technology is the determining factor for this requirement. RFID tags can be read at all time, even when the tag is dirty or partially obstructed. This is not the case for the basket level barcode concepts, when the barcode is dirty or partially obstructed it can not be scanned. The same line of reasoning applies for instrument level, RFID tags on instruments can always be read, which does not apply on barcodes.

Table 4.8: Pairwise comparison of the visibility concepts on Readability

	IB	IR	BBIB	BBIR	BRIB	BRIR
IB	1	0.33	0.8	0.7	0.25	0.2
IR	3	1	2	2	0.8	0.7
BBIB	1.25	0.5	1	0.8	0.5	0.3
BBIR	1.43	0.5	1.25	1	0.6	0.5
BRIB	4	1.25	2	1.67	1	0.9
BRIR	5	1.43	3.33	2	1.11	1

Table 4.9: Pairwise comparison of the visibility concepts on Reliability

	IB	IR	BBIB	BBIR	BRIB	BRIR
IB	1	0.7	0.6	0.6	0.4	0.33
IR	1.43	1	0.8	0.8	0.6	0.5
BBIB	1.67	1.25	1	1	0.7	0.5
BBIR	1.67	1.25	1	1	0.7	0.5
BRIB	2.5	1.67	1.43	1.43	1	0.9
BRIR	3	2	2	2	1.11	1

Pairwise comparison of Cost Effectiveness (Table 4.10)
The pairwise comparison of the implementation cost is based on the number of instruments and baskets in the system and a rough estimation of the cost of the different Auto-ID technologies. There are roughly 30,000 instruments to be tagged in the LUMC and about 2,000 different baskets. However, from the 30,000 instruments about 20% has got a barcode already. Besides the instruments the hardware and software has to be taken into account as well, ten scanners are required on instrument level and six on basket level. Concerning instrument level, the application of a barcode is €2.75, RFID is €4.50. The scanners are €5,000 for barcode and €1,000 for RFID. On basket level the following prices are valid: a barcode costs €3.75 and a RFID tag is €7.50. The scanners are €2,500 for barcode and €1,000 for RFID. Furthermore, the required software will cost around €50.000, no matter the technology.

These prices result in an investment for the first concept of €166,000, concept 2 requires €195.000, concept 3 €173,500, concept 4 costs €202,500, concept 5 requires €187,500 and the last concept needs €216,000. These values are compared to each other to come to the cost effectiveness of the different concepts. The differences in cost are very small, since the lower implementation cost of the barcode is offset by the higher price of the readers.

Pairwise comparison of Impact on Process (Table 4.11)
Similar to the comparison on the previous requirement is the basket level solution the focal point. Most of the steps in the process are on basket level, a few on instrument level. Since the current operation already uses barcodes for the identification of baskets in the cycle, the concepts with barcodes on basket level have the least impact on the system. Within this group there is a slight preference for RFID on instrument level because of the less time consuming identification process. However this difference is small, they require both additional processing steps and added work. The impact of the concepts using RFID on basket level is higher, but the same steps in the process can be maintained, only the way of scanning will change. The two concepts based around instrument level identification have the highest impact on the process, the steps where baskets are scanned have to be completely revised.

Table 4.10: Pairwise comparison of the visibility concepts on Cost Effectiveness

	IB	IR	BBIB	BBIR	BRIB	BRIR
IB	1	1.2	1.05	1.25	1.13	1.33
IR	0.83	1	0.87	1.04	0.94	1.11
BBIB	0.96	1.15	1	1.2	1.08	1.28
BBIR	0.8	0.96	0.84	1	0.9	1.07
BRIB	0.89	1.07	0.93	1.11	1	1.2
BRIR	0.75	0.9	0.78	0.94	0.85	1

Table 4.11: Pairwise comparison of the visibility concepts on Impact on Process

	IB	IR	BBIB	BBIR	BRIB	BRIR
IB	1	0.9	0.33	0.33	0.5	0.5
IR	1.11	1	0.33	0.33	0.5	0.5
BBIB	3	3	1	1.1	1.4	1.25
BBIR	3	3	0.91	1	1.4	1.25
BRIB	2	2	0.71	0.71	1	1
BRIR	2	2	0.8	0.8	1	1

AHP results

The result of the AHP method is calculated using the different comparisons of compliance to a single requirement, multiplied with the weight of the requirement presented in Table 3.8. The formula for the calculation of the score of a concept on a requirement is given in Equation 3.3. The formula used the calculate the result of the analysis is shown in Equation 3.4. A spider diagram showing the results of Equation 3.3 for the six Auto-ID concepts is presented in Figure 4.12.

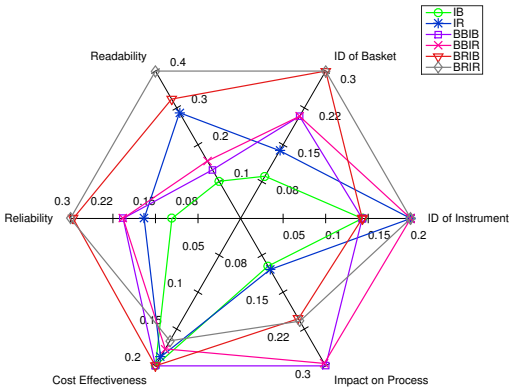


Figure 4.12: Requirement score of the six Auto-ID concepts

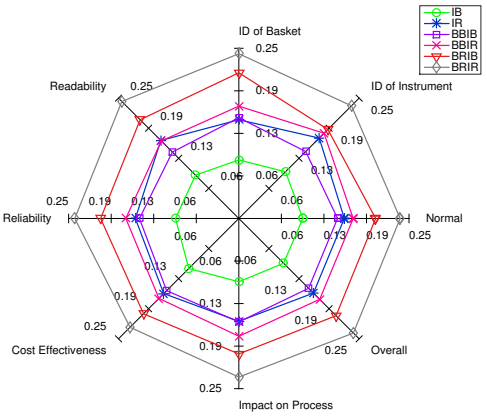


Figure 4.13: AHP method results for the six Auto-ID concepts

Sensitivity analysis

The six pairwise comparisons of compliance to a single requirement is analysed using Equation 3.2 and multiplied with the weight of the requirement presented in Table 4.5. The resulting scores are combined into the result of the AHP method, which is presented in Table 3.14 in tabular form and in Figure 4.13 graphically. The eight columns show the normal, sensitivity analysis and the overall results. For the sensitivity analysis the weight of one of the requirements is doubled with respect to the others. The overall score is based on the sensitivity analysis results and the weight of the criteria, according to Equation 3.5.

Consistency check

The results of the AHP matrix given in the previous part of this paragraph is based on human judgement. In order to check the consistency of the entered values in the comparison matrix a consistency check is performed, based on Equation 3.6. When the Consistency Index is lower than 0.1 the input comparison matrix is assumed to be stable.

The results of Equation 3.6 for the normal and the different sensitivity cases is presented in Table 4.13. The Consistency Ratio of all the different cases is lower than the indicated 10%, therefore the analysis is considered to be consistent.

Most feasible concept

As shown in Table 4.12 the overall most feasible concept is fitted with passive RFID tags on the baskets and instruments (Concept 6: BRIR). The second best visibility concept

Table 4.12: Results of the AHP analysis, with and without sensitivity analysis and overall best visibility concept

	Normal	ID of Instrument	ID of Basket	Readability	Reliability	Cost Effectiveness	Impact on Process	Overall
IB	0.094	0.097	0.086	0.090	0.093	0.104	0.093	**0.093**
IR	0.155	0.167	0.145	0.162	0.152	0.156	0.151	**0.155**
BBIB	0.145	0.139	0.148	0.138	0.146	0.150	0.152	**0.145**
BBIR	0.168	0.177	0.165	0.161	0.166	0.166	0.173	**0.168**
BRIB	0.201	0.185	0.214	0.205	0.203	0.198	0.199	**0.202**
BRIR	0.237	0.234	0.242	0.243	0.241	0.226	0.233	**0.238**

Table 4.13: Results for the Consistency Ratio of the AHP analysis, with and without sensitivity analysis

	Normal	ID of Instrument	ID of Basket	Readability	Reliability	Cost Effectiveness	Impact on Process
Consistency Index	0.025	0.003	0.006	0.009	0.001	0.001	0.001
Random Index	1.180	1.180	1.180	1.180	1.180	1.180	1.180
Consistency Ratio	0.021	0.002	0.005	0.008	0.001	0.001	0.001

uses RFID tags on baskets, but barcode on instrument level (Concept 5: BRIB). When regarding the sensitivity analysis given in Table 4.12 as well, BRIR is best adapted for the change in requirement weight, for all requirements. Thus BRIR is the most feasible concept of the six.

4.6 Detailed process visibility method

This section presents the detailed description of the most feasible concept: basket and instrument level passive RFID tags. For each of the identification steps in the sterilization cycle the scanning process set-up is shown. This includes a description of the required actions and hardware. The different process steps are given in Figure 4.14, Appendix B gives a detailed description of these steps.. Not all 17 different identification steps are elaborated on, since some steps are similar. There are five groups of identification pro-

cesses distinguished, the entry or exit of baskets, batch generation, batch identification, individual basket identification and individual instrument identification.

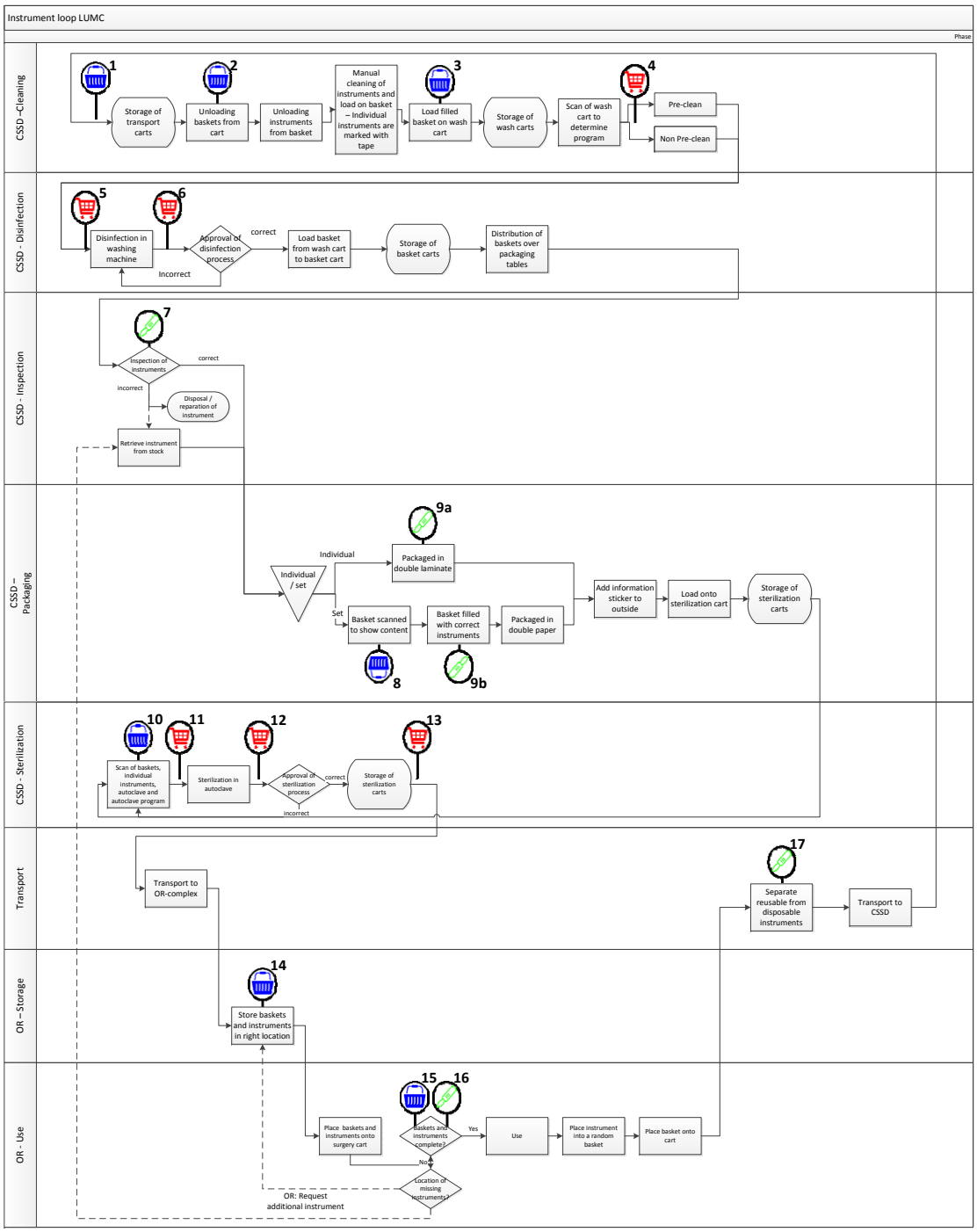


Figure 4.14: Overview of sterilization cycle

4.6.1 Entry or exit of baskets

At two stages in the sterilization cycle the entry or exit of the baskets is recorded. This applies for identification steps 1 and 13 of Figure B.1. At step 1 the different baskets entering the CSSD are scanned and the baskets exiting are identified at step 13. These are the only two entry or exit identification phases in the current process.

The baskets are transported to and from the OR complex in a transport cart, such a cart is shown in Figure 4.15. A transport cart contains between one and twenty baskets. The RFID tag of the baskets has to be read whilst the baskets are in the transport cart, since the individual handling of the baskets would require additional processing steps. To minimize the time consumption of the entry and exit scanning process a fixed RFID reader is placed at the identification points. An example of such wall mounted portal reader is given in Figure 4.16. It is placed besides the door, where it reads all the different RFID tags passing by. The range of this type of reader can be adjusted in the range of 1 to 3 metres, which is sufficient for the identification of the baskets on the transport carts passing the doors of the CSSD.

Figure 4.15: A transport cart containing multiple baskets and items

Figure 4.16: Jamison Strip reader [Jamison, 2015]

Since all RFID reader read every single tag in their read range, measures have to be taken to prevent multiple of the same tag and false reads (called cross-reads). A combination of two methods has to be applied to minimize the number of cross-reads. The first is the reduction of the read range of the RFID reader, the second relies on the implementation of logic in the middleware. By down tuning the read strength of the RFID reader the read range decreases. Tags that are not passing the reader directly are not in the range of the reader and will not be scanned. The cross-read preventing logic in the middleware can have numerous forms and is depended on the actual occurring problems with cross-reads. An example of two types of logic are given next. Since the baskets are equipped with passive RFID tags the strength of the returning signal from the tag is depended on

the strength of the incoming signal. A the tag far away from the reader has a weaker signal than a tag close by. The middleware can check the strength of the signal and only recording a positive read when it surpasses a certain threshold. In essence this type of logic is similar to reducing the read range of the reader. The second method evolves the documentation of the tags that have passed the reader. The sterilization cycle is closed-loop concerning the instruments in the cycle. When the entry and exit data of the different baskets is documented, the middleware logic can check the state of the basket, *inside* or *outside* the CSSD. A basket that is *inside* the CSSD can not be picked up by the entry reader, since it has already entered.

4.6.2 Batch generation

Multiple baskets are processed at the same time in the washing machine and autoclave. The different baskets are loaded onto a cart and a process batch is generated by scanning all the baskets. The identification steps 3 and 10 of Figure B.1 perform this process.

During batch generation the multiple baskets on a wash cart are scanned and assigned in T-DOC to that cart. The batch generation before the sterilization process is similar, the difference is that the batch is not assigned to a cart, but to the autoclave it will be processed in. The baskets are identified via their unique RFID tag and the barcode of the cart of autoclave is scanned to identify it. The reason for maintaining the barcode identification of the wash carts and autoclaves is bi-fold. Primarily the use of different technologies ensures that all baskets are assigned to the batch before it is closed by scanning the washing cart or autoclave. When RFID is used for scanning the cart or autoclave as well, the operator has to switch between selecting baskets and assigning to a batch. This is a procedure that can easily go wrong in a multitude of ways. Secondarily, a barcode scanner only reads the barcode it is pointing at, RFID readers are multi-directional. This is especially of impact on the sterilization process, after batch creation and assigning to an autoclave the autoclave program has to be scanned. This is done by reading one of various barcodes that are placed next to each other. When such a system is implemented with RFID tags it would become challenging to read just one program instead of all of them.

Since the generation of baskets relies on both RFID tags and barcodes both types of reader is required. An example of a reader that incorporates both functionalities into one device is presented in Figure 4.17. This type of handheld reader can be used to run different scanning programs to ensure the proper sequence of actions.

4.6.3 Batch identification

The batches created for disinfection and sterilization are identified before and after the respective process. In identification steps 4, 5, 6, 11 and 12 of Figure B.1 batch identification is performed. The reason for the batch identification is documenting the characteristics of the performed process of disinfection or sterilization in T-DOC. Thus

Figure 4.17: Zebra WAP4 reader [ZIH Corp., 2015b]

Figure 4.18: RadioForce 200USB reader [Agilox, 2015]

the process visibility system is not directly involved in these steps. When the batch generation is performed successful, the electronic identification will be as well.

4.6.4 Individual basket identification

During processing of the baskets they have to be identified. Four different identification steps of Figure B.1 have this type of identification, steps 2, 8, 14 and 15. In these steps an individual basket is processed or handled.

For the identification of individual baskets the handheld reader shown in Figure 4.17 can be used as well. However, the barcode capabilities of the reader are not used for basket identification. Therefore a RFID reader without barcode scanning features would be sufficient for these identification steps. Such a reader is shown in Figure 4.18. This RFID reader can only be operated near a workstation because it uses an USB connection for power and communication. The use of a wired connection between the reader and computer is an advantage for most of the basket identification steps involved if the sterilization cycle. These steps are situated at the beginning of further processing of the scanned basket. In the packaging process (identification step 8) baskets can be assembled and packaged in ten different workstations, which all required a RFID reader. The wired USB readers are connected to the workstation via the USB cable, it is impossible to use the reader of station 1 at station 10, since the cable does not allow such distance. On the other hand, a wireless reader is not limited by a physical connection to a workstation. This increases the risk of exchanging two readers or misplacing a reader and the resulting problems in assembling baskets.

4.6.5 Individual instrument identification

Alike baskets, the instruments on the baskets have to be known as well. The identification steps 7, 9, 16 and 17 of Figure B.1 use individual instrument identification. Identification step 17 will be discussed separate, it does not matter to know any particulars about the instrument for this step, only whether it is reusable or disposable.

Identification steps 7, 9 and 16

During these process steps the details about instrument type, unique ID and history of the instruments have to be known, on an individual basis. This requires for an identification approach that targets instruments one at a time. The instruments are inspected (step 7), packaged (step 9) and checked (step 16) at the same workstations where the identification of baskets takes place. Therefore the same type of RFID reader is used for the identification of instruments. The reader presented in Figure 4.18 can perform all the tasks required at the workstations. However, the scanning process of instruments requires for a fixed reader. It is undesirable from a Health & Safety point of view to use a handheld reader when assembling baskets consisting of dozens of instruments, an entire day. A solution is the use of a handheld & handsfree reader, shown in Figure 4.19. This reader can be used in a mount fixed to the workstation and can be removed from the mount to function as a handheld unit. Nonetheless, the reader has to be connected via a wire, because of the reduced risk of misplacing a reader and exchanging two readers.

Figure 4.19: Zebra Dual Purpose reader [ZIH Corp., 2015a]

Figure 4.20: Haldor Technologies RFID tray [Haldor AT Ltd., 2015]

Identification step 17

During this step the reusable instruments have to be separated from the disposable instruments after completion of the surgery. Any other information about instrument

type or usage does not have to be known or documented, as with the identification steps discussed above. The identification of reusable amongst disposable instruments is fairly simple, only reusable instruments are fitted with a RFID tag. The used materials after surgery have to be split into two, the first part are the reusable instruments, the second part the disposable materials. The disposable materials are subsequently scanned with a RFID reader, when no tags are read there are no instruments between the disposable materials. Various types of scanners can be used, amongst others the wired reader shown in Figure 4.18, dual purpose reader given in Figure 4.19 or a RFID tray reader that identifies everything placed on top, presented in Figure 4.20.

4.7 Chapter summary

For the successful operation of the MRPII system presented in Chapter 3 and to fulfil the requirements set by the UDI guidance a visibility method is proposed in this chapter. First a general introduction to process visibility was presented. Subsequently different methods for process visibility were discussed. The was followed by the required level of detail of visibility for the sterilization cycle. Next the requirements to the visibility method were given. Which led to the selection of the most feasible concept. Finally this concept was given in detail.

Automatic process visibility systems are better known as Auto-ID systems. These systems provide an unique ID to the objects and the possibility tracing them throughout the system. The different components in a Auto-ID system are the middleware, location level components and object level components. The task of the middleware is to communicate with the client of the Auto-ID system. Both components supply the data about the location of the objects. There are two main types of indoor Auto-ID systems, the relative coordinate and gate point RTLS. The first can pinpoint the exact location of the object, the second only knows whether an object has passed by its gate (Section 4.1).

There are numerous technologies available for performance of Auto-ID. The barcode system, OCR, RFID and smart card technologies can be adapted for use in the LUMC. Other technologies involving biometrics can only be applied in Auto-ID of humans and were therefore not taken into account (Section 4.2).

In the LUMC the visibility system has to perform different identification steps, on instrument and basket level. This combined with the requirements of the UDI and the acquisition of process KPIs, showed the need for instrument level visibility. The type of RTLS was based on the requirements of the process steps and KPIs, the gate point RTLS came out on top since pinpointing the location was not necessary (Section 4.3).

Six different concepts using (a combination of) barcode and passive RFID were proposed for evaluation upon compliance to the requirements. The requirements were identification of instruments and baskets, readability, reliability, cost effectiveness and impact on the process. The evaluation resulted that the a system using passive RFID tags on both

instruments and baskets performed best. The higher costs of this concept were offset by the easier acquisition of the identification of the objects (Sections 4.4, 4.5).

The identification steps in the sterilization cycle perform different actions and use different types of scanners. In some cases a wall-mounted scanner scans the passing baskets and for other steps a handheld reader is deemed best suited for the identification process (Section 4.6).

Furthermore, an answer to the following research question was formulated in the chapter:

Research question 3: *Which methods are feasible for providing the visibility of the KPIs of the DDS system and provision of UDI on instruments?*

The two technologies feasible for performing Auto-ID on instrument level are the DataMatrix and passive RFID. The DataMatrix has been selected since it is more compact, can store more data and is error correcting. From the different types of RFID technology, the passive tags are the only one that do not change the classification of the instrument and are small enough to fit on the instrument. On basket level the barcode system and passive RFID tags came out on top as well. Due to the high degree of standardization the OCR method is to complex, all the required information can be put into a linear or 2D-barcode. The error correcting capabilities of the DataMatrix are the determining factor on basket level as well. Even when partially obstructed or damaged the code can be read.

The two technologies can be used in six different ways to perform the Auto-ID of instruments and baskets. The first two concepts use only an instrument level Auto-ID technology, the basket level data is obtained from the instruments and BOM. Concepts 3 and 4 have 2D-barcodes on basket level and a 2D-barcode or RFID on the instruments. Concepts 5 and 6 have RFID tags on basket level and a 2D-barcode or RFID on the instruments.

The last concept is most feasible for use in the LUMC. It is best adapted for the identification of instruments and baskets (together with other RFID concepts). The readability is higher than the other concepts, since the RFID tags can be scanned through the packaging material. The reliability of concept 6 is highest as well, even when the tag is dirty or in any other way obstructed it can be read. The main downside of concept 6 is the cost effectiveness, it is the most expensive of all concepts. The impact is fairly small since the difference between the cheapest (Concept 3 €190,000) and Concept 6 (€216,000) is not even 15%. The impact on the process of the sterilization cycle is lowest for the two concepts using basket level barcodes (3 and 4). In the current operation this system is already used. Concept 6 is third in line, the RFID tags on the baskets are only a change of the scanning process.

Chapter 5

Integration of DDS system and visibility method

In Chapter 3 a DDS system has been proposed and Chapter 4 presented a visibility method that can provide the required input variables for this system. This chapter will discuss the integration of the DDS system and visibility method into one functioning whole. First the combination of the MRPII and Auto-ID system is given. Next the implementation of the integrated system is discussed. At the end of this chapter the concluding remarks are given.

5.1 Combination of MRP2 and Auto-ID system

This section presents an overview of the combination of the MRPII and Auto-ID system. Since both methods are combined into one it will be referred to as Manufacturing Resource Planning & Automatic Identification (MR-PAID). First the different components of MR-PAID are discussed, hardware and software. Subsequently the information flow within MR-PAID is presented.

5.1.1 Components of MR-PAID

Both the Auto-ID and the MRPII system are composed of multiple components. This section will present an overview of the different hardware and software components that are used by MR-PAID.

Hardware

The various hardware components are part of the Auto-ID side of MR-PAID, the MRPII does not use any specific hardware besides the ICT infrastructure. Two types of hardware components can be distinguished, the object level and location level components.

The object level components are attached to the instruments and baskets. The object level components are passive RFID tags, which are shown in Figure 4.9 (instrument level) and Figure 4.11 (basket level). The location level components are different readers and scanners, depended on the identification step. The reader used for entry or exit identification is a portal style reader, given in Figure 4.16. For batch generation a RFID reader and barcode scanner is used which is handheld, shown in Figure 4.17. Figure 4.18 and Figure 4.19 show two types of readers that can be applied for the identification of individual instruments and baskets. A tray style reader is given in Figure 4.20, it can be used for identifying reusable instruments that are placed on top of it.

Software

The MRPII system is in essence nothing else than a software program. And for the successful registration and documentation of the passing baskets and instruments the Auto-ID system makes use of various software routines. In general MR-PAID consists of two software programs, the MRPII system and the middleware of the Auto-ID system.

The MRPII system receives various inputs concerning the demand and process parameters. The demand data originates from the client and the process parameters are supplied by the Auto-ID system. The data inputs are transformed into various aggregation levels of planning, ranging from course to detailed. The most detailed planning is the release of work orders, which is the actual output of the MRPII system. To generate a feasible planning three main sub-programs are called upon, the RCCP, MRP and CRP software.

The middleware acts as the connection between the hardware components that provide the Auto-ID and the client (database or monitoring application). There are multiple levels of middleware in MR-PAID, every individual reader or scanner has got its own middleware (called firmware) that runs the device. The various devices are coupled to the Auto-ID system via the actual middleware that can process all data from these reader and scanners and provide control over these devices. The following functions are fulfilled by the middleware: 1) hardware component configuration and management, 2) filtering and processing of incoming data and 3) clustering and routering of incoming data.

The first function of the middleware is depended on the scanners and readers that are used in the Auto-ID system, therefore it is not discussed in detail. The filtering and processing of incoming data is the process of applying logic to the data supplied by the readers, some reader can perform this process on the device itself as well. The aim of this process is the elimination of cross-reads and invalid data from being send to subsequent steps. The last function of the middleware is the provision of neat and tidy packages of data that can be easily send to and understood by the client or database.

The main components of the Auto-ID system are given in Figure 5.1. Figure 5.2 presents the same for the MRPII system, with the output of work orders.

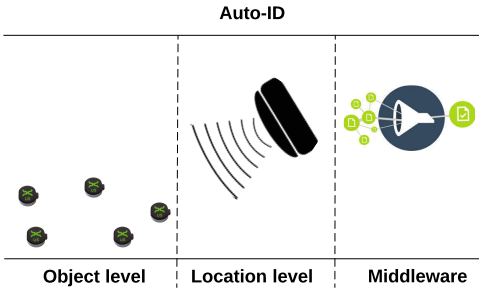


Figure 5.1: Schematic overview of components in Auto-ID system

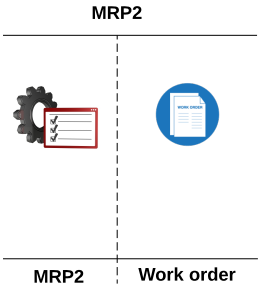


Figure 5.2: Schematic overview of MRPII system

5.1.2 Information flow within MR-PAID

Figure 5.1 and Figure 5.2 show the schematic overview of two parts of MR-PAID. These two systems have to be coupled to each other to function properly. The outputs of the Auto-ID system have to be used as input for the MRPII system. This connection of the two parts is performed by a database.

The database stores the information obtained by the Auto-ID system for future reference by the the middleware and MRPII system. An integrated overview of the MR-PAID is shown in Figure 5.3. On the left side the object level tags are shown, next the location level RFID readers and following the middleware. To the right of the middleware the database is given, on the other side of the database is the MRPII system and the resulting work orders.

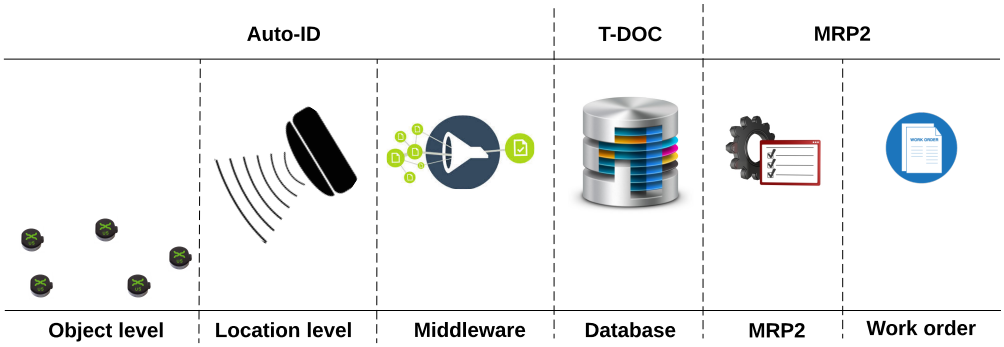


Figure 5.3: Integrated overview of MR-PAID

An overview of the information flows within MR-PAID are given in Figure 5.4. The database of presented in the middle, on the left the Auto-ID system is shown and on the right the MRPII system. Since the CSSD makes use of a database software package (T-DOC) this is used for the MR-PAID as well. Various information flows between the parts are shown by means of arrows. Next the different information flows will be discussed.

The Auto-ID system sends the location and time stamp of the objects that are scanned by the various readers to T-DOC. From T-DOC similar information is send back to the Auto-ID system to perform logical checks, to minimize the risk of wrongfully scanned objects. Furthermore, T-DOC uses the information about the location and time stamp to perform various checks on the generation of batches and the assembly of baskets. The outputs to the MRPII system provided by T-DOC are production capacity data, inventory data, data concerning the process performance, the current WIP and the BOM of the different baskets. Besides input from the database, the MRPII system receives an information flow about the planning data and priorities in production.

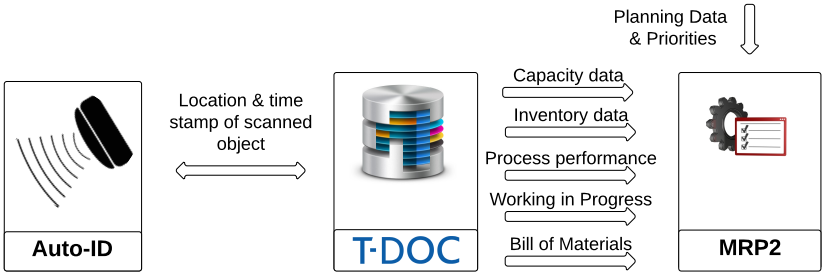


Figure 5.4: Overview of different information flows within MR-PAID

5.2 Implementation of MR-PAID

The MR-PAID system presented in the previous paragraph has to be implemented in the sterilization cycle of the LUMC. Three different levels of implementation or shown, which become gradually more detailed. First the implementation on organisational level is discussed, followed by the system level. Concluding the implementation on process level is presented.

5.2.1 Organisation level

Two departments are part of the sterilization cycle at the LUMC, the CSSD and the OR. The MR-PAID system will affect both these departments. The required changes to these two (internal) organisations for the MR-PAID to be successful is discussed in this paragraph. An overview of the MR-PAID system in the sterilization cycle is presented in Figure 5.5.

In Figure 5.5 the CSSD and OR are connected via the two blue arrows, which represent the flow of sterile and used baskets to and from the OR. In red the MR-PAID system is shown, with the Auto-ID part directed at the two departments. Two information flows are part of Figure 5.5 as well. These are shown by the dashed grey arrows. The first originates from the OR and goes to the MR-PAID system, the planning and priority data. The second information flow connects MR-PAID and the CSSD, which represents the work orders.

The organisational level of the implementation of MR-PAID shows two actors, the CSSD and the OR. Without the cooperation of either of these two departments the implementation of MR-PAID will not succeed. There are three main factors that need to be addressed, communication between the actors, the definition of the Service Level Agreement (SLA) and ensuring quality of data. These factors are discussed next.

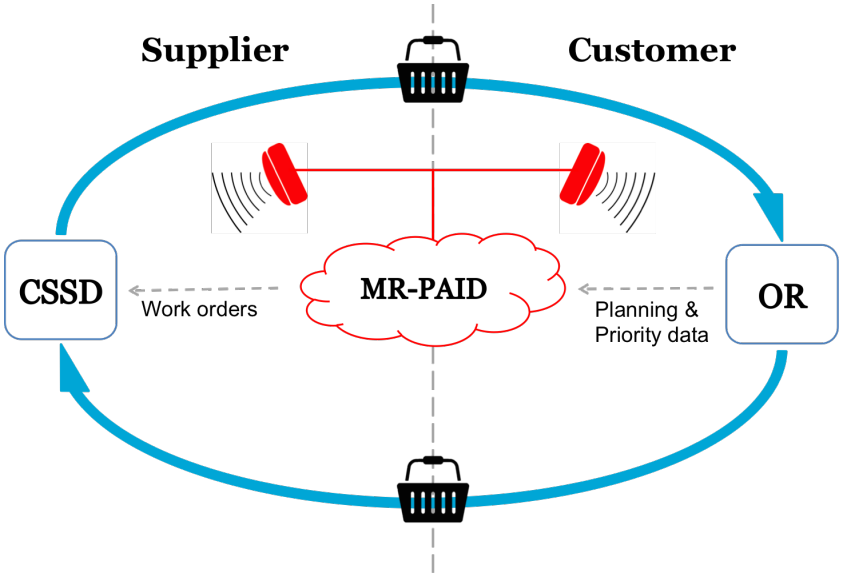


Figure 5.5: Implementation of MR-PAID on organisational level

Communication between actors

The CSSD and OR are both part of the same organisation (the LUMC). There are no considerations of the competitive position of either of the departments to be taken into account. In the communication between the two actors the there is no need for secrecy about any part of operation, delivery or demand planning. This kind of operation is essential for the proper operation of MR-PAID. On of the main inputs of MR-PAID is data concerning planning and priority baskets, which has to be communicated by the OR.

Besides the planning and priority data there are many other factors that affect the success of MR-PAID, that could be solved by (some sort of) communication. For MR-PAID the input of which surgery has to be performed when is not enough for the generation of work orders. The required baskets and instruments have to be known exactly by means of a surgery BOM. Furthermore the responsibilities of the two departments in delivery of the baskets and instruments has to be clearly defined. This can be achieved by means of a SLA, which is explained next.

Definition of Service Level Agreement

Even in a system with two internal departments having the role of supplier (CSSD) and customer (OR) the responsibilities, demands and wishes should be clearly defined. An industry practice is the definition of a SLA. In the SLA various aspects concerning the delivery, quality and fault handling are agreed upon by both departments. Furthermore, the SLA may include parts concerning the definition of the services, performance

measurement and problem management.

By agreeing upon the SLA it is clear for both departments what the minimal responsibilities are concerning delivery of sterile surgical instruments. The SLA acts as a baseline, only when the delivery performance is below the agreed level, actions have to be taken. Between the CSSD and OR (bi-)annual meetings have to be held to provide feedback upon the achieved performance. During these meetings both parties can discuss the concerns they have and the problems they occur, this is closely related to the previous part of the paragraph.

Quality of data

All the data discussed previously (in this section and previous chapters) have to be correct. The MR-PAID system can not generated a feasible production schedule from wrong input data, bad data will lead to bad results. The definition of 'good quality' of data is vague, ambiguous and subjective. However, when the data is incomplete or is out-of-date it is not of good quality. This must be prevented at all time. The data used by the MR-PAID has to be up-to-date and complete, the planning part, the internal Auto-ID system and the various other sources.

5.2.2 System level

A more detailed level of implementation is system level. This paragraph elaborates on the new way of operation of the sterilization cycle in order to perform DDS. On system level the use of MR-PAID changes the way of operation of both the CSSD and OR. Two types of changes can be distinguished on system level, the reordering or addition of processes and addition of various components used by MR-PAID.

Reordering or addition of processes

The use of MR-PAID and the implementation of DDS in the sterilization cycle will evoke some changes to the order of the current processes. A general overview of the changes can be found in Figure 3.15c, Paragraph 3.4.1. The location of the main inventory moves from the OR to inside of the CSSD process, between the inspection and packaging of instruments. Furthermore, two safety stock locations are added to provide the short lead times required for the delivery to acute surgeries.

The model of the sterilization cycle, shown in Figure 2.2, is adapted to include the changes in inventory locations. The redesigned cycle is presented in Figure 5.6. The three changes are indicated by the orange color of the blocks. In the next paragraph a detailed description of the storage process will be given.

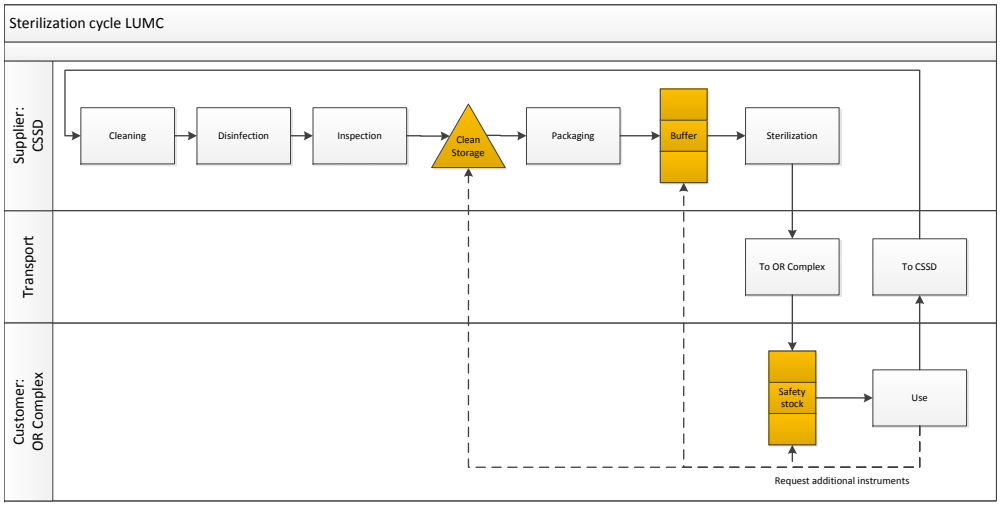


Figure 5.6: Redesigned sterilization cycle, incorporating MR-PAID

Addition of MR-PAID components

Some of the components of the MR-PAID system discussed in Paragraph 5.1.1 have to be implemented on system level. The components have been divided into two categories, hardware and software.

The required hardware for MR-PAID on system level is only the ICT infrastructure needed for the communication between the MRPII and Auto-ID systems. The various components used for the Auto-ID of baskets and instruments do not affect the operation on system level. These hardware components have been discussed in the previous chapter.

On system level two software programs have to be implemented, the MRPII system and the middleware of the Auto-ID system. This is only the top level of these programs, the inputs of both the systems is process level based.

5.2.3 Process level

The redesigned sterilization cycle given in Figure 5.6 imposes significant changes to some processing steps. This paragraph presents the implementation of MR-PAID into the various processes. First of all the functioning of the three inventory locations is discussed, this is followed by a detailed discussion of the identification process given in Section 4.6.

Inventory locations

In the redesign of the sterilization cycle three different inventory location have been added or changed. They will be discussed next in the following order: the clean storage, the buffer and the safety stock.

Clean storage

The clean storage is situated in between the inspection and packaging processes. Here the different instruments and baskets are stored until their next use date. This has been the starting point of the redesign of the clean storage process, all instruments and baskets have to be stored. But, taking the demand planning and different instrument quantities into account. An overview of the different inventory types and decisions that are part of the clean storage process is shown in Figure 5.7. During all the different processing steps the basket or instrument has to be identified, this to provide the input for the decisions and the documentation of the location of the object.

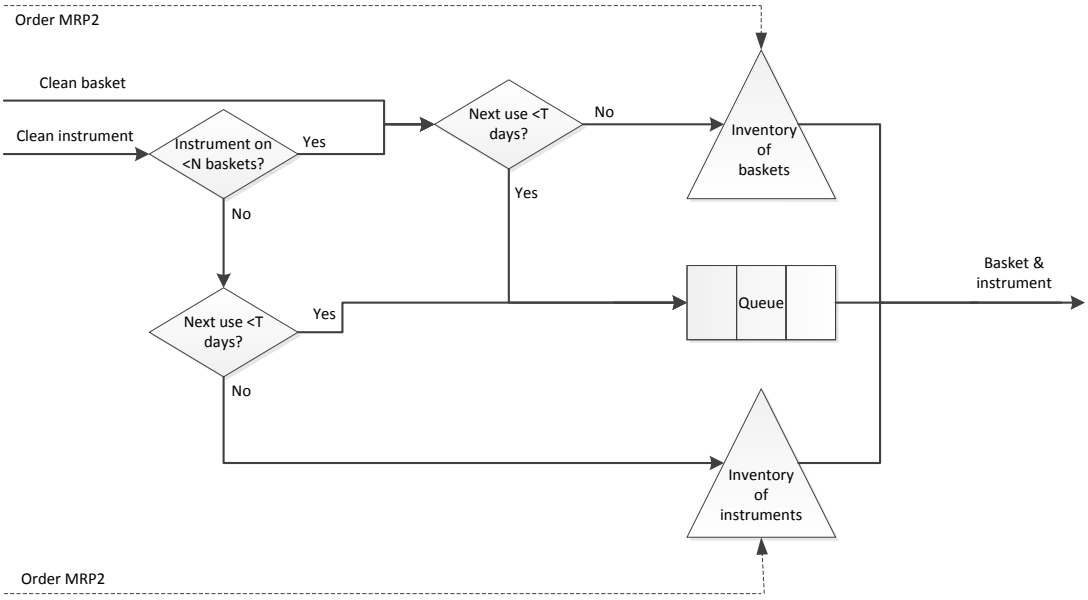


Figure 5.7: Overview of clean storage, with different decision criteria

There are two inputs from the inspection process into clean storage, cleans basket and instruments (the instruments are transported on a basket from inspection). After a decision process the baskets and instruments are divided into three flows which end in three types of storage: an inventory of baskets, a queue or an inventory of instruments, shown on the right side of Figure 5.7.

The decision process is shown on the left side of Figure 5.7. The inventory location of a basket is depended on one decision variable, an instrument on two. The first decision

variable applies on both basket and instrument and takes the next use date into account (T). The second decision variable for instruments evaluates the number of basket types an instrument is part of (N). This indicates whether an instrument is unique on a single (or small amount of) basket(s), or if it is a general instrument used extensively on many baskets. The questions that are answered by the documentation system are:

1. *Is the instrument on less than N baskets?*
2. *Is the next use day less than T days from now?*

The questions will be answered after the basket or instrument is scanned. The different outcomes for an instrument of these questions is given in Table 5.1. When baskets are concerned the first question is always answered with Yes, thus resulting in two storage types possible for baskets, the inventory of baskets and the queue.

Table 5.1: Resulting storage type for various the decision logic cases

Instr. on <N baskets?	*Next use <T days?*	*Storage type*
Yes	No	Inventory of baskets
	Yes	Queue
No	Yes	
	No	Inventory of instruments

The variables N and T in these two questions are user defined and will determine the size of the different types of storage. The queue length and the size of the inventory of baskets is dependent on the variable T, the relationship between them is presented in Figure 5.8. When T is low, for example 1 day, all baskets are placed in the inventory of baskets. As T increases, the number of baskets that bypass the inventory of baskets increases as well. This functionality of the queue ensures that baskets that have to be used in a short while (short while is defined by T) will not be placed in the inventory, but are processed straight away.

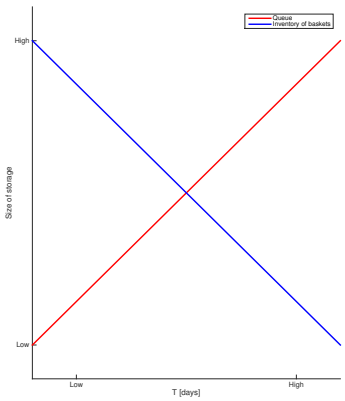


Figure 5.8: Schematic overview of the effect of variable T on the queue length and basket inventory size

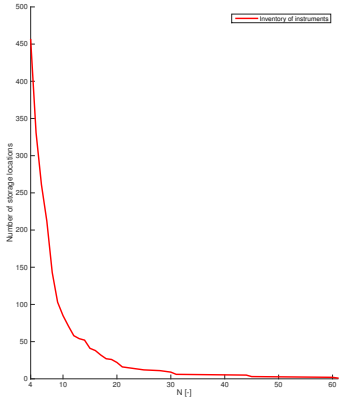


Figure 5.9: Overview of the effect of variable N on the instrument inventory size

The inventory of instruments is determined by variable N, given in Figure 5.9. The data presented in Figure 5.9 is obtained from the analysis of the basket composition (Paragraph 2.2.1). The x-axis gives the value of $N \in [4\ 61]$, the y-axis the number of storage locations. For $N = 4$ the number of storage locations is 456, which decreases to 1 for $N = 61$. The main reason for the use of a separate instrument inventory is based upon the square root law proposed by D.H. Maister [Maister, 1976]. The square root law states that the inventory formerly maintained at a number (m) of locations is centralized to 1 location the reduction in the required inventory level is equal to the square root of the number of locations (m), this formula is presented in Equation 5.1.

$$\frac{decentralised\ inventory}{centralized\ inventory} = \sqrt{m} \tag{5.1}$$

For example, when a basket type is stored at 4 different locations, the centralisation of these baskets to a single location will lead to a reduction of $\sqrt{4} = 2$ in the number of baskets required to fulfil demand.

The logic behind Equation 5.1 can be applied to the storage of baskets in the following way. Each basket can be seen as a decentralized inventory of instruments when it is placed in the inventory of baskets of the clean storage facility. When these instruments are taken from the baskets and are placed the instrument inventory, they are taken from the decentralised basket inventory and are centralised. Due to this centralisation the number of instruments required in clean storage decreases.

When an instrument is on less than N basket types, it will stay on the basket and will be placed in the inventory of baskets. This reduces the number of individual instrument locations.

Buffer
A buffer of packaged baskets is situated after the packaging process. This buffer ensures that the supply to the autoclaves is constant. The benefit of a constant supply of baskets is that the autoclaves will be loaded to the maximum, which increases its efficiency. An additional advantage of the buffer is that some (semi-) critical baskets can be stored in this location. The production lead time will be lower compared to the production from inventory.

Safety stock
The last inventory location given in Figure 5.7 is the safety stock. The safety stock has replaced the sterile storage of the current sterilization cycle. The safety stock has one purpose, supply acute surgeries with sterile baskets and instruments. The production lead time from the safety stock is mere minutes, which satisfies the requirement of immediate delivery needed for acute surgeries. The size and composition of the safety stock can not be determined by means of a single quantitative analysis or a qualitative judgement. The situation the safety stock is designed to control is too complex for a short term decision. The only way of determining the proper stock levels of the safety stock is by starting at a high stock level and reducing it over the months or years. At

steady-state operation of the safety stock eventually no stock-outs will occur whilst stock levels are at a minimum.

The baskets in safety stock are not reserved for acute surgeries alone. To keep the baskets in safety stock moving they are part of the regular operation of basket delivery. This will occur via the First-In, First-Out (FIFO) principle. When a basket is ordered for a planned surgery and the same type is in safety stock, the copy from safety stock is used during surgery when the ordered basket has been sterilized.

Identification process

The implementation on process level of MR-PAID concerning the different identification processes is presented next. Five different groups of identification have been discussed in Section 4.6, namely:

1. Entry or exit of baskets;
2. Batch generation;
3. Batch identification;
4. Individual basket identification;
5. Individual instrument identification.

The first and third group will not be discussed. The entry and exit process is described in detail in Paragraph 4.6.1 and is performed completely automatic. Thus the implementation will be on system and organisational level, not on process level. The batch identification process given in Paragraph 4.6.3 has not changed at all from the current operation, therefore it is not discussed. The remaining three identification groups that will be discussed are: batch generation, individual basket identification and individual instrument identification. All schematic overviews of the identification steps are shown as CFF model. Furthermore, there are two functions included, the operator and the device, since they have a distinct role in the identification processes.

Batch generation
During batch generation the multiple baskets on a cart are scanned and assigned to that cart. This process is performed with the aid of the Auto-ID system but remains a manual operation. An overview of the different processing steps is given in Figure 5.10. There are two function groups, the operator and the device. First the operator uses the handheld device to scan the RFID tag of the basket and repeats this process until all baskets are scanned. On the device the RFID scanning procedure has to be closed and the next step in batch generation commences. This step includes the manual count of the baskets that should be in the batch and the entry of this number on the device. The device checks subsequently whether the number of scanned RFID tags matches the number provided as input by the operator. When they do not match the manual count or the scanning process has to be performed again. If the numbers match the operator can continue with the scanning of the cart of autoclave and program. After this step the operator has to confirm the generation of the batch, which terminates the process.

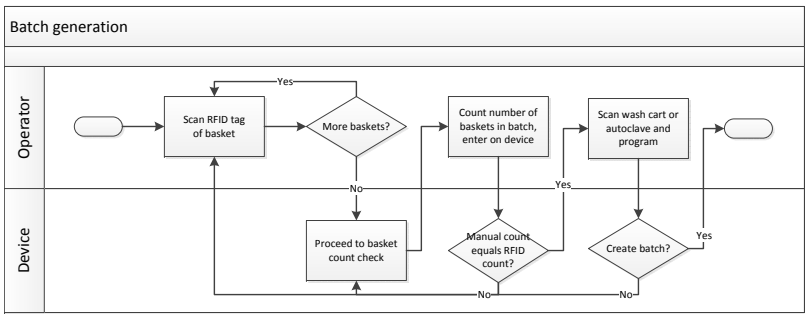


Figure 5.10: Identification process at batch generation

Individual basket identification

The individual basket identification is performed in the redesigned process in three different types, as a general process, at the storage of baskets and at the packaging of baskets.

The general identification process is shown in Figure 5.11. The operator scans the RFID tag of the baskets which is documented by the device (and higher levels of Auto-ID). This type of identification is performed at various steps where only the ID of the basket has to be known.

The identification process at the storage of the baskets differs from the general identification given above because of the decision process presented in Figure 5.7. The storage identification is shown in Figure 5.12. The basket is scanned by the operator, after which the device retrieves the next use date (when known) of the basket. It applies the decision logic from Figure 5.7 and gives as output the location of the basket The operator transports the basket to the correct location, which terminates the process.

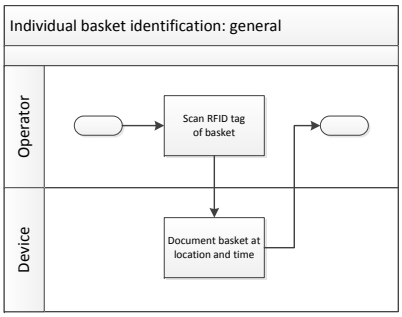


Figure 5.11: General individual basket identification

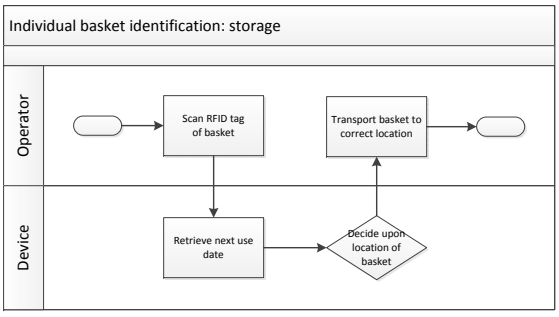


Figure 5.12: Individual basket identification at the Storage facility

Alike the two identification processes discussed above the packaging identification starts with the operator scanning the RFID tag of the basket, it is presented in Figure 5.13. The device retrieves the BOM of the basket from the database. Subsequently the operator

assembles the basket according to the BOM, during the assembly different instruments are added to the basket. When the assembly of the basket is finished all instruments are assigned to the basket, which terminates the packaging identification process.

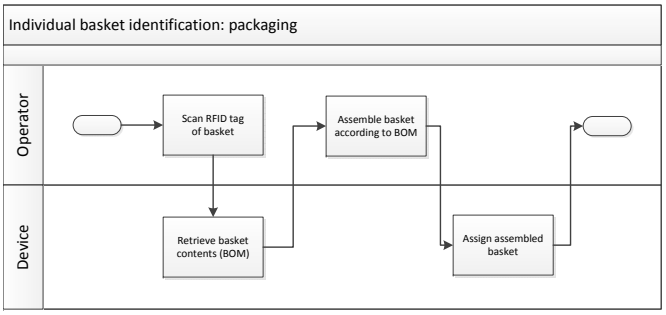


Figure 5.13: Individual basket identification at the Packaging step

Individual instrument identification

The individual instrument identification is performed in the redesigned process in four different types, at the storage of instruments, at the packaging process, at the use step of instruments in the OR and at the inspection phase. All identification types start with the scanning of the RFID tag of the instrument.

The identification process at the storage of the instruments is similar to that of baskets and in shown in Figure 5.14. However, besides the next use date the uniqueness of the instrument is retrieved from the database as well. Both these variables are used in the decision process for instruments presented in Figure 5.7. The location of the instrument is decided upon, after which it is transported to the correct location.

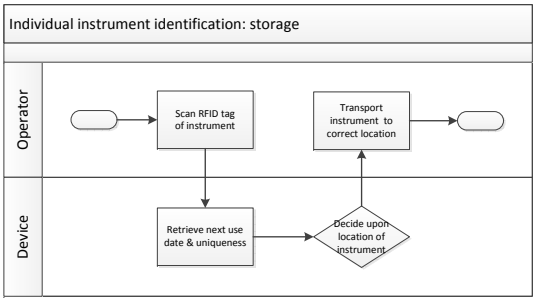


Figure 5.14: Individual instrument identification at the Storage facility

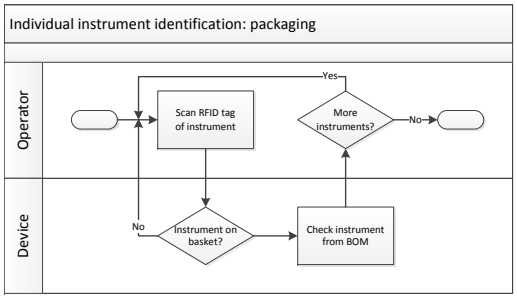


Figure 5.15: Individual instrument identification at the Packaging step

The packaging identification process of instruments is part of the packaging of baskets. Figure 5.15 presents the loop of the assigning of instruments to a basket. The process consists of an iteration of scanning the instrument by the operator and a check by the device whether the instrument belongs on the basket. When all instruments according to the BOM are assigned to the baskets the process is terminated.

Before use in the OR all instruments have to be scanned and counted. This identification process is given in Figure 5.16. First all the instruments are scanned by the operator, subsequently the operator continues to the next part of the process, the instrument count check. The instruments have to be counted by the operator and entered on the device. The device checks whether the manual count equals the RFID count. If the numbers match the identification step is terminated, otherwise the instruments have to be scanned or counted once more.

Figure 5.17 shows the identification of instruments during inspection. After scanning the instruments the device consults the database whether the instrument is fit for next use. When the instrument can be used again the process stops, otherwise the operator has to the necessary actions (i.e. repair or replace the instrument).

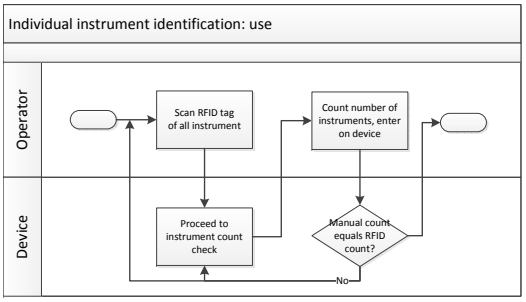


Figure 5.16: Individual instrument identification at the Use phase

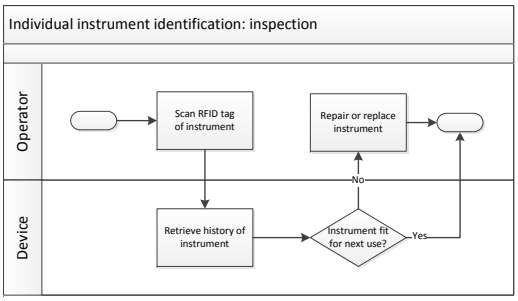


Figure 5.17: Individual instrument identification at the Inspection step

5.3 Chapter summary

This chapter has presented the integration of the DDS method and the Auto-ID system into one: MR-PAID. First the combination of the MRPII method and Auto-ID system was given (Section 5.1). Followed by the implementation into sterilization cycle (Section 5.2).

The combination of MRPII and Auto-ID into MR-PAID showed that both parts of the system need to be connected by means of a database, which is T-DOC. T-DOC performs the function of storing the data supplied by the Auto-ID part and making it available for use by MR-PAID (Paragraph 5.1.1). Furthermore it became clear that one of the inputs of the MRPII system does not come from T-DOC. The planning and priority data has to be provided by the OR (Paragraph 5.1.2).

The implementation of MR-PAID into the sterilization cycle focussed on three levels: organisation, system and process. The organisation level implementation indicated the necessity of good communication between the OR and the CSSD. The use of a SLA was presented as a method to guarantee the delivery of baskets and instruments. It acts as a baseline of performance of the CSSD and OR. A final point concerning organisation level was given, the data used throughout MR-PAID has to be of good quality (Paragraph 5.2.1).

On system level the implementation of MR-PAID provided a redesign of the sterilization cycle. The sterile storage has been replaced with a safety stock, a clean storage facility, after inspection, is added as well as a buffer of baskets after packaging. Furthermore, the required components for MR-PAID on system level were: the hardware of the ICT infrastructure, and the software of the MRPII system and middleware of the Auto-ID system (Paragraph 5.2.2).

The implementation of MR-PAID on process level showed the details of the redesigned storage process. The main inventory location is moved to the clean storage, in which the baskets and instruments divided into three types of storage. A queue stores baskets and instruments that will be used shortly and two inventories store baskets and instruments that will not be used soon. The instruments that are present on many baskets are stored separately since this will reduce the number of required instruments. Besides the clean storage a buffer and a safety stock are part of the sterilization cycle. The buffer acts to level the input of the autoclaves and to reduce the production lead time of baskets. The sole purpose of the safety stock is to provide the acute surgeries with baskets, with a lead time that approaches zero. Various identification processes are part of the implementation on process level. During the identification of baskets and instrument are identified by the operator, making use of the RFID devices and various software programs (Paragraph 5.2.3).

Chapter 6

Evaluation of integrated method

Chapter 5 presented the combination of the MRPII and Auto-ID systems into MR-PAID. During the course of this chapter the evaluation of MR-PAID will be elaborated on. The evaluation is divided into three parts. First the performance evaluation is presented, in which various numerical analyses are used to quantify the benefits of MR-PAID. Secondly the cost analysis of the current operation of the CSSD is given, focussing on invested capital and operational cost. And thirdly the economical evaluation is discussed, in which the capital expenditure (CAPEX), operational expenditure (OPEX) and the ROI are given. Concluding this chapter the concluding remarks are presented. Furthermore, an answer to the following research question will be provided.

Research question 4: *To what extend can the DDS system combined with KPI visibility decrease the time in sterile storage of surgical instruments?*

6.1 Performance evaluation

The performance evaluation of the designed system is presented in this section. Two different subjects are addressed, performance improvement by reduction of dead stock and by postponement. These two are combined in the resulting system performance, which concludes this section.

6.1.1 Reduction of dead stock

Dead stock in the sterile storage facility of the LUMC is the excess stock of baskets that is not needed when regarding the historical demand. Removing these baskets from operation will result in a higher usage factor of the remaining baskets and thus a decrease in stock time. Reduction of dead stock is only feasible when two boundary conditions are met:

1. There have to be multiple copies of basket type;
2. There has to be excess capacity.

The first boundary condition can be obtained from Appendix C, the different baskets included in the analysis are shown with the number of copies is the last column. The second condition follows from the analysis of the cycle time given in Section 2.2. The date stamp of the measurements is used to determine the number of times a basket is used on a day, for each basket type. The result of this analysis for two baskets is given in Figure 6.1, which is based on measurements of 2014.

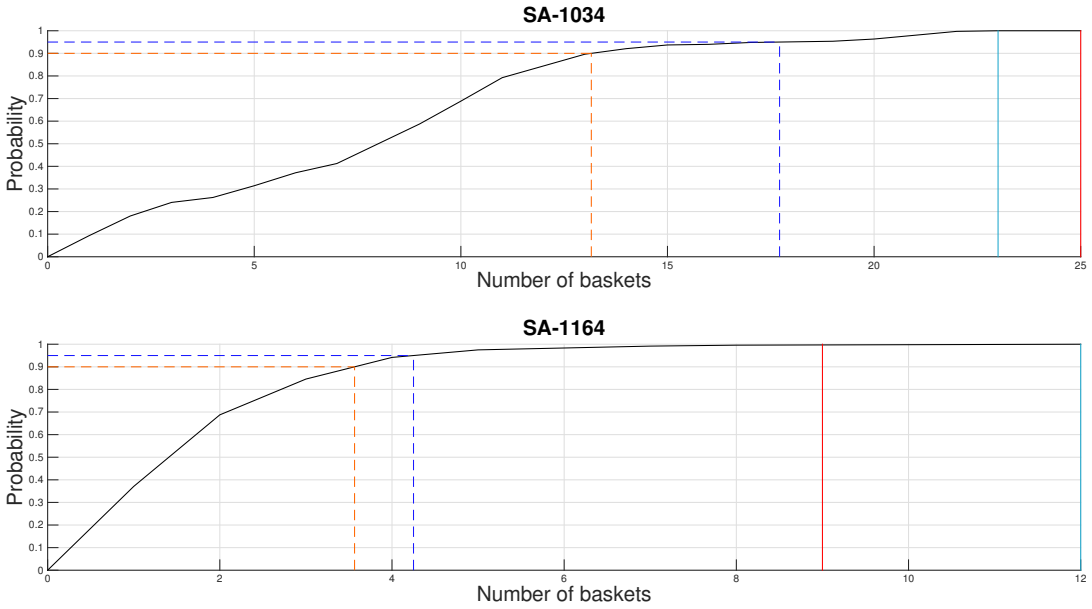


Figure 6.1: Usage profile of baskets with multiple copies

Figure 6.1 presents the usage profile of two baskets with multiple copies. The other 22 baskets can be found in Appendix F. The black line represents the CDF of the number of uses on a day (days the basket is not used are excluded). The solid red vertical line gives the number of copies in circulation of the basket type and the solid blue vertical line maximum of uses on one day. When the maximum number of uses equals the number of baskets the blue line is not shown. There are furthermore two dashed lines included, an orange and a blue one. The orange line gives the number of baskets adequate for supplying the daily need of baskets in 90% of the days; on the remaining 10% baskets will be used twice on a day. The blue line shows this for 95% of the daily need on stock and 5% of double uses.

For top graph, which is the Acute basket (SA-1034), the graph has the following meaning. There are 25 copies of the Acute basket in circulation at the LUMC (red line). However the maximum of daily uses in 2014 was 23 times (blue line). When considering multiple uses of the same basket on the same day the required number of baskets can be further decreased. When on 95% of the days the basket in stock are adequate to provide to the days need and on 5% of the days baskets have to be used twice, the required stock decreases to 17.71 (18) baskets. When these percentages decrease to 90% and 10% of double uses on a day, only 13.16 (14) baskets are required.

The bottom graph, which is a basic basket for laparoscopic (minimal invasive) surgery (SA-1164) differs from SA-1034. The maximum uses of this basket on a single day is 12, whilst only 9 baskets are in circulation. Since there have been three more surgeries on a day than there are baskets, three copies of SA-1164 have been used twice on a

day. In between uses the baskets have undergone the four hour process of disinfecting, packaging and sterilization.

Table 6.1 presents the reduction in baskets for the 24 basket types evaluated from Figure 6.1 in tabular form. The first column shows the basket code, next the number of instruments on the basket and the number of baskets currently in stock are given. Subsequently different percentages of the daily required baskets that can be delivered from stock (and the percentage of multiple uses) are presented namely, 100%, 99%, 97%, 95% and 90%. For each basket type the reduction of the required number of baskets in stock is presented, based on the current stock level. The last row shows the summation of the baskets in stock or that can be reduced for the given categories.

Table 6.1: Results of reduction of dead stock

Basket Code	**# I**	**# B**	**100%**	**99%**	**97%**	**95%**	**90%**
SA-1034	53	25	2	3	4	7	11
SA-1086	29	19	9	10	11	11	12
SA-0838	45	9	2	3	4	4	5
SA-1164	15	9	0	2	4	4	5
SA-1265	20	6	3	3	4	4	4
SA-1004	10	4	0	0	1	1	1
SA-1181	43	4	0	0	0	0	0
SA-0849	9	4	1	1	2	2	2
SA-0428	2	3	0	0	0	1	1
SA-0835	16	3	0	1	1	1	1
SA-1047	4	3	1	1	1	1	1
SA-1165	43	3	1	1	2	1	2
SA-1415	2	3	1	1	1	1	1
SA-2192	23	3	1	1	1	1	1
SA-1136	4	3	0	0	0	1	1
SA-0842	45	2	0	0	0	0	0
SA-1003	10	2	0	0	0	0	0
SA-1011	5	2	0	0	0	0	0
SA-1158	25	2	0	0	0	0	1
SA-1175	109	2	0	0	0	0	0
SA-1234	17	2	0	0	0	0	0
SA-1842	4	2	0	0	0	0	0
SA-1939	2	2	0	0	0	0	1
SA-2142	3	2	0	0	0	0	1
Sum	**-**	**119**	**21**	**27**	**36**	**40**	**51**

From Table 6.1 it can be obtained that there are various baskets in stock that are inactive. When considering the historical usage of baskets, 21 of the 119 baskets (17.7% of total) in the evaluation have not been used considering the maximum daily usage.

These baskets are in stock for no reason and can be removed from operation without any problems. When taking multiple uses of baskets on the same day into account, the reduction can be even larger. When on 1% of the days baskets are used twice, 27 baskets (22.7%) are not necessary to held in stock. For 3% this increases to 36 (30.3%), for 5% to 40 (33.6%) and when the baskets in stock are adequate to supply to the surgeries on 90% of the days and in 10% of the days baskets are used multiple times, 51 baskets out of 119 can be removed from stock (42.9%).

The analysis on the reduction of dead stock is performed on the a selection of the total inventory of the LUMC. In total there are 257 basket types in use that have multiple copies, only 24 have been evaluated (9.3%). The multiple copies of these 24 evaluated basket types bring the total number of baskets to 119, whilst 912 baskets are available in the complete system (13.0%). The evaluation gives a indication of the potential reduction in dead stock, but can not be applied directly to the entire stock of baskets. In order to provide an quantitative result of the reduction of dead stock for all baskets, a reduction factor of 1.5 is applied on the percentile saving. This gives a conservative calculation of the lower bound of the possible reduction in inventory size. The resulting reduction in stock can be found in Table 6.2, for the various daily use percentages.

Table 6.2: Reduction of dead stock, for all baskets

	100%	**99%**	**97%**	**95%**	**90%**
Reduction	107	138	184	204	261
Percentage	11.8%	15.1%	20.2%	22.4%	28.6%

The results of the evaluation given in Table 6.1 and Table 6.2 do not take any recent changes into account. The data used is obtained over the whole of 2014. Therefore the actual reduction of baskets has to be based on the given analysis as well as expert judgement about the usage of the different baskets. A general statement about the percentage of days that baskets have to be used twice can not be given, since is will be different for different basket types. This is taken into account by the reduction factor as well and therefore it can be stated that the 100% case presented in Table 6.2 is viable.

6.1.2 Postponement

Postponement focusses on delaying the production of baskets until the very last moment. Postponement can be applied to all baskets in the system, no boundary conditions have to be met, as with reduction of dead stock. Postponement is used to target the baskets that are needed for operation by minimizing the time they are in sterile storage. The redesigned sterilization cycle enables the use of postponement, the main inventory location has shifted from the sterile storage to a clean storage after the inspection of instruments, which is shown in Figure 5.6. Recalling the stock time distribution given in Figure 2.15, the 1% slowest measurements are responsible for nearly 25% of the cumulative stock time. By producing these baskets on demand the stock time can be

reduced to merely hours. Two subjects will be addressed to in this paragraph. First a simulation model will be presented to provide a quantitative basis of the sterile stock time reduction that can be achieved by postponement. Second a reduction of the number of instruments is discussed, which follows the use of postponement.

Simulation model

A simplified Discrete Event Simulation (DES) model of the current operation and future situation of the sterilization cycle is built to quantify the performance increase of the DDS method. A schematic overview of the five main components of the model of the current operation is given in Figure 6.2. The sterilization cycle is shown by means of four processes: Cleaning & Disinfection, Packaging & Sterilization, Sterile Storage and the OR. Furthermore, an information source is modelled, the Order for a surgery. A similar overview of the future situation is presented in Figure 6.3. It shows the redesigned process: the Sterile Storage is replaced with the Clean Storage. Another difference is the addition of the MRP control function. In the current operation the order flows directly into the system. In the future situation the order is processed by the MRP system, which collects the orders and releases them at the right time. A detailed description of the DES models of Figure 6.2 and Figure 6.3 is presented in Appendix G.

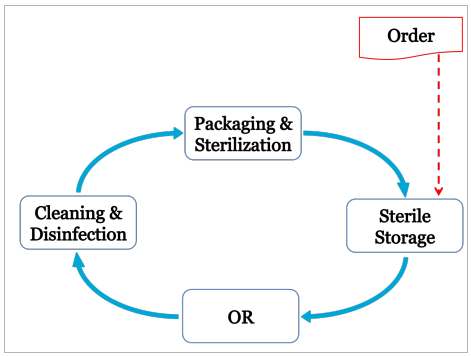


Figure 6.2: Schematic overview of the current operation model

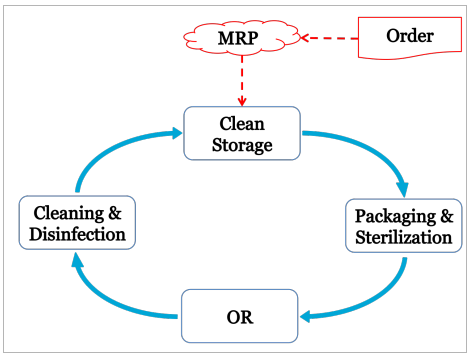


Figure 6.3: Schematic overview of the future situation model

The model of the current operation and the future situation are analysed for 10,000 hours of operation, which relates to in excess of one year. Furthermore, the analysis is performed for a hundred different random seeds. This is to incorporate the performance of the model under different conditions. The random seeds are used during the assignment of process variables to the baskets or surgeries. For both models the random seeds are the same and act upon the same variables. This is essential for the comparison of the current operation and future situation. Both models have to handle exactly the same surgeries, with the same processing times. First a detailed description is given for three seeds, followed by the general results for all hundred.

Acute surgery Order Completion Time (OCT)

The first aspect on which the two models are compared is the handling of acute surgeries. This is vital to the operation of a hospital, the acute surgeries have to be performed immediately, the future situation has to be able to match the current operations performance. The performance metric that indicates the ability to perform acute surgeries is the OCT. The OCT is the time it takes for an acute surgery to be performed. The timer in the model is started right after the acute surgery is generated and stops just before the order is deleted after surgery. Figure 6.4 presents the OCT for both current operation (top graph) and the future situation (bottom graph). The limits of the x-axis are set on 7000 and 8000, to provide a readable overview of the data and to show a steady-state operation.

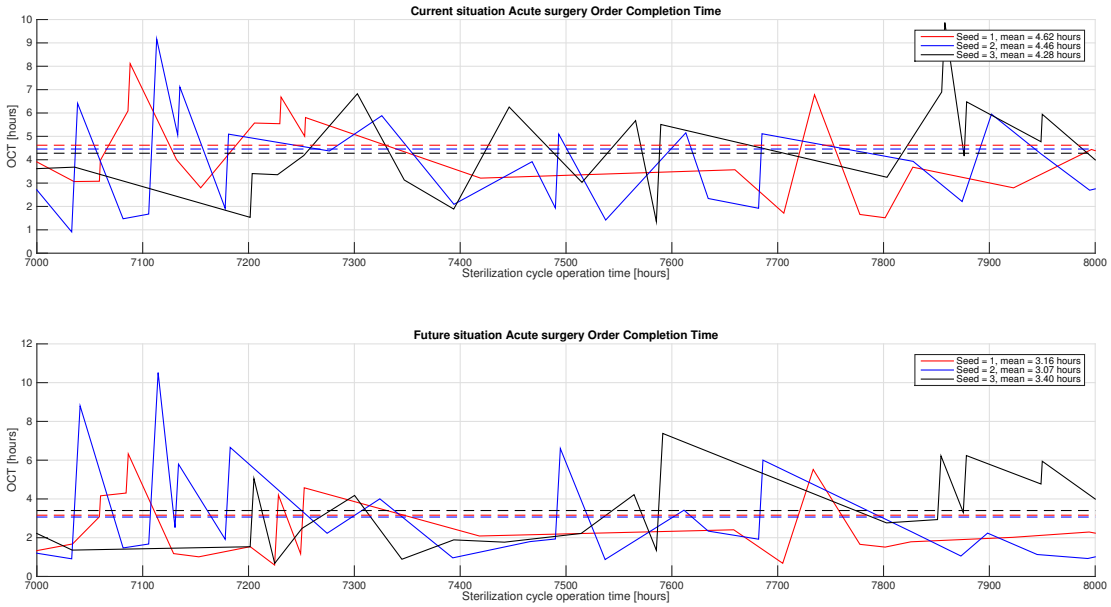


Figure 6.4: Acute surgery Order Completion Time for the current operation (top graph) and the future situation (bottom graph)

As given in Figure 6.4 the average OCT of the current operation is 4.62, 4.46 or 4.28 hours (for the different seeds). The future situation has an acute surgery OCT of 3.16, 3.07 or 3.40 hours. When considering the average OCT the future situation out performs the current operation, a shorter completion time is better. However, there is another aspect of the acute surgery OCT that requires attention, the maximum values. For seeds 1 and 3 the future model does not show a higher maximum value than the current model. However, the future situation does not perform as good as the current operation when seed 2 is considered. There are multiple peaks that are higher than those to be found in the current operation graph.

Both characteristics, lower average and higher peak OCT, are explained by the changed storage operation. The current operation stores all baskets in sterile storage. The acute

surgery is supplied from this inventory location. When there are no baskets available, the surgery is delayed until a basket is available. The future operation is set-up a using a clean storage and an order based production. Furthermore, a safety stock of one sterile basket is maintained, which is reserved for acute surgeries. At the moment an acute surgery has to be performed, the required basket is available. This reduces the acute surgery OCT of the future situation. However, it causes problems when a second acute surgery has to be preformed immediately after the first. The basket reserved for the acute surgery is not replenished yet, and the surgery has to wait until production is finished.

Baskets in main inventory

The second aspect of evaluation is the number of baskets in the main inventory location, presented in Figure 6.5. In the current operation the main inventory location is the sterile storage, in the future situation the clean storage. In both models five baskets are modelled. For this graph the limits of the x-axis are set on 7000 and 8000 as well.

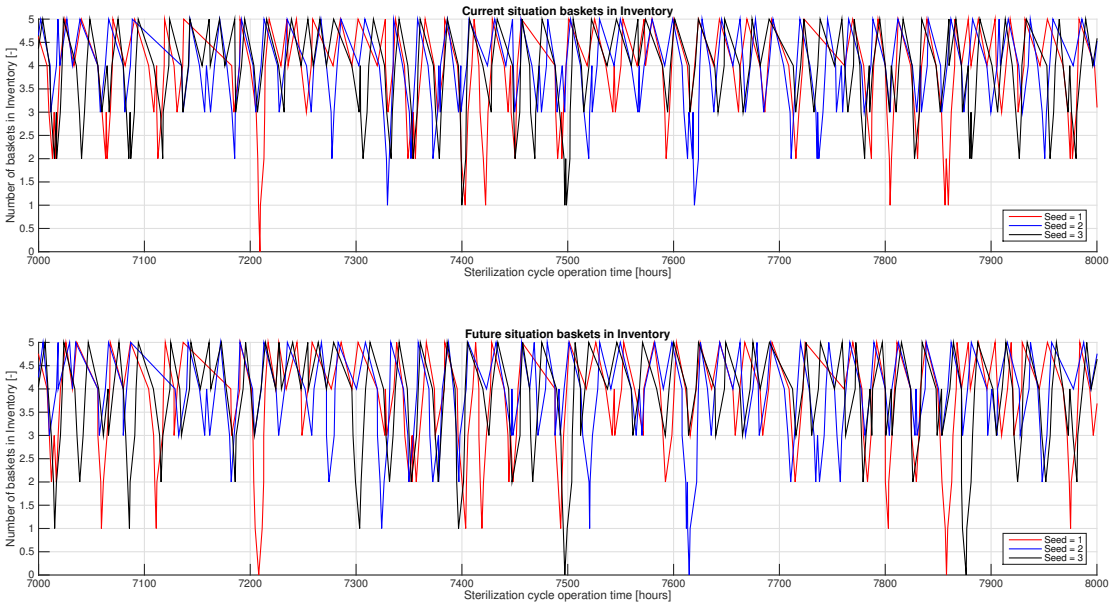


Figure 6.5: Number of baskets in the main inventory for the current operation (top graph) and the future situation (bottom graph)

The current operation uses in general less baskets than the future situation. However, the main inventory location of both models has been empty. The fact that the future situation uses more baskets is explained by the safety stock as well, at all time a basket is placed in this stock location. Nonetheless, it can be concluded that the future situation performs similar to the current operation.

Time in sterile inventory

The third aspect of evaluation is the time in sterile inventory, presented in Figure 6.5. The graphs of both models are nothing alike. The current operation shows an average value around which the graph fluctuates, the future situation shows very large peaks in storage time. Again, the limits of the x-axis are set on 7000 and 8000.

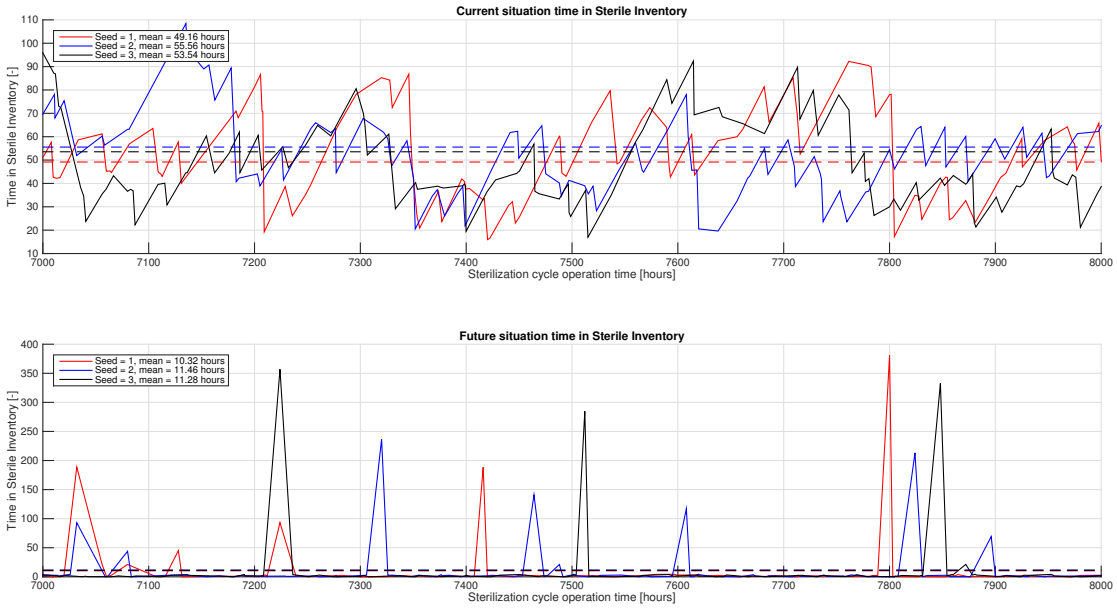


Figure 6.6: Time in sterile inventory for the current operation (top graph) and the future situation (bottom graph)

As given in Figure 6.6 the average time in sterile inventory of the current operation is 49.16, 55.56 or 53.54 hours (for the different seeds). The future situation has a time in sterile inventory of 10.32, 11.46 or 11.28 hours. On average the time in sterile inventory is over five times as low for the future situation, as for the current operation. This decrease is caused by the production on demand, controlled by the MRP system. The large peaks in the future model graph are caused by the baskets in safety stock. They enter the inventory and stay idle until an acute surgery has to be performed. The large peaks can be avoided when the basket in safety stock is used in normal operation as well. When a basket is ordered for a planned surgery and the same type is in safety stock, the copy from safety stock is used during surgery when the ordered basket has been sterilized. However, this will not change the average time in sterile storage, only remove the large peaks.

Time in CSSD process

The last aspect of evaluation is the time in the CSSD process, presented in Figure 6.7. Again, the limits of the x-axis are set on 7000 and 8000.

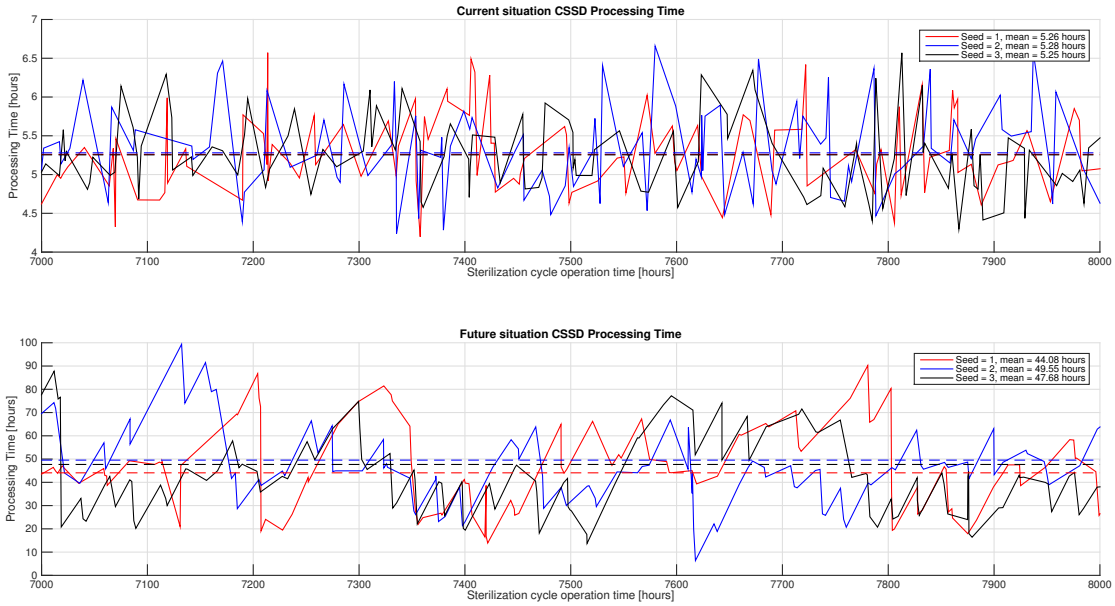


Figure 6.7: Time in sterile inventory for the current operation (top graph) and the future situation (bottom graph)

As given in Figure 6.7 the average time in the CSSD process of the current operation is 5.26, 5.28 or 5.25 hours (for the different seeds). The future situation has a time in the CSSD process of the current operation of 44.08, 48.55 or 47.68 hours. In the future model the baskets remain in the CSSD process nearly nine times as long. This is explained by the use of the MRP system. The main inventory location is the clean storage, which is situated in the CSSD process, and are retrieved from storage when they are required for a surgery.

Evaluation 100 seed sets

The evaluation of the hundred seed sets is presented in Figure 6.8 as a box plot. The mean value of the acute surgery OCT, time in sterile storage and time in CSSD process of the 100 different seeds are used to generate the box plot. The red line indicates the mean value of the population (100 data points), the blue box the indicates the range of values from the first (q_1) to the third quartile (q_3). Furthermore, the whiskers given an indication of the range of values, and there minimum is calculated using $q_1 - 1.5(q_3 - q_1)$ and the maximum is $q_3 + 1.5(q_3 - q_1)$. Values that are outside the whiskers are outliers and are shown as the red crosses. The final aspect of the shown box plots is the notch in the blue box. This notch indicates whether the two medians of the current and future model are significantly different at the 5% significance level. If the notches overlap the medians are not significantly different.

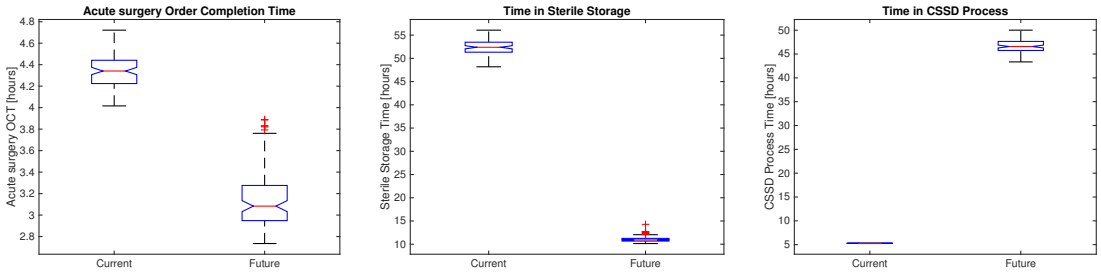


Figure 6.8: Box plots of the 100 different seed sets for the current and future model. Left shows the acute OCT; centre gives T_{SS}; right presents T_{CSSD}

The relation and differences between the current and future model obtained from the detailed figures is seconded by the overview of Figure 6.8. The acute surgery OCT of the future model is lower, however it does show a larger variance and has outliers. The time in sterile storage is lower for the future model, and the time in the CSSD process higher. Furthermore, the notches indicate that the difference is significant.

The box plots give a general overview of the mean of the presented output variables. However, it does not give any information about whether the data is valid and under which circumstances. To come to a better insight in the to be expected values of the output variables a confidence interval is required. A confidence interval gives the upper and lower limit of the mean value of a variable for a given probability. The 95% confidence interval $[l_n, u_n]$ is calculated using Equation 6.1 [Dekking et al., 2005].

$$l_n = \mu - t_{99,0.025}\frac{\sigma}{\sqrt{n}}, \;\; u_n = \mu + t_{99,0.025}\frac{\sigma}{\sqrt{n}} \tag{6.1}$$

Equation 6.1 is based around the t-distribution [Dekking et al., 2005], which gives a confidence interval factor based on the required level of confidence and the degrees of freedom. The degrees of freedom are the number of simulation runs (n) minus one (99). For the 95% confidence case the $t_{99,0.025} = 1.984$. A summary of the mean, STD and confidence interval is given in Table 6.3.

Table 6.3: Mean, standard deviation and 95% confidence interval

	Mean	**STD**	**95% c.i.**	
	μ	σ	l_{100}	u_{100}
Current OCT	4.343	0.154	4.312	4.374
Future OCT	3.165	0.290	3.107	3.222
Current T_{SS}	52.458	1.608	52.139	52.777
Future T_{SS}	11.077	0.619	10.954	11.200
Current T_{CSSD}	5.276	0.018	5.272	5.280
Future T_{CSSD}	46.699	1.389	46.424	46.975

The confidence interval of the variables in Table 6.3 are all within 5% around the mean value. This makes the analysis of the 100 different seed values adequate to draw conclusions from.

Reduction of number of instruments

Another advantage of production postponement, besides reduction of the time in sterile storage, is shown in Paragraph 5.2.3 (page 110). Similar to the reduction of dead stock on basket level, the number of instruments in inventory can be reduced as well. This reduction is due to the centralization of certain instruments to a single location, in stead of multiple decentralized locations. This effect is known as the square root law. Recalling Equation 5.1, the square root law is (Equation 6.2):

$$\frac{decentralised\ inventory}{centralized\ inventory} = \sqrt{m} \tag{6.2}$$

In Equation 6.2, m is the number of locations at which the decentralized inventory is maintained. When the reduction of the number of instrument is considered, m is the number of basket in clean storage and the decentralized inventory is the number of instrument on the baskets in clean storage. This information is provided from the BOM of the different baskets, as well as the analysis of the basket composition (Paragraph 2.2.1), which resulted a list of baskets where an instrument is part of. The data for the five most prevalent instruments in the LUMC is given in Table 6.4. The analysis is executed with the aid of Matlab. Table 6.4 gives the instrument code first, followed by a short description of the instrument. Next the number of basket types the instrument is part of is presented. The last two columns give the total number of baskets (including multiple copies) of the basket types and the total number of instruments on all baskets.

Table 6.4: Summary of characteristics of most prevalent instruments

Code	*Description*	*Basket Types*	*# Baskets*	*# Instruments*
BH111R	Clamp Mosquito 12.5 cm	61	212	1157
BC581R	Scissors Stille 15 cm	60	205	326
BD660R	Tweezers Chir 15 cm	45	148	288
BB073R	Blade handle No 3	44	113	143
BH424R	Clamp Pean 14 cm	44	112	596

The data shown in Table 6.4 can not be used as input of Equation 6.2 straight away. The total number of baskets (*# Baskets*) includes all baskets in the LUMC, not only the baskets in clean storage. Besides baskets in clean storage, there are those in the buffer, safety stock and in other parts of the sterilization cycle (in process). A general indication of the baskets in safety stock is one of every basket type. The resulting number of baskets is lowered by 20% to cover the baskets that are in process or buffer.

The 20% reduction originates from the data concerning the used baskets per hour, given in Appendix D (Figure D.1). On a single day 139 baskets were returned to the CSSD by the OR. The total number of baskets in the LUMC is 1,600. This relates to an usage of 8.7% of the total baskets in the LUMC. However, the data of this usage is from a day during summer recess and production is about half, compared to regular operation. Any additional uncertainty is reduced by rounding the resulting 17.4% to an even 20%.

The resulting data is given in Table 6.5. The first column states the instrument code. The next two columns give the number of baskets and instruments from Table 6.4. Subsequently the number of location m is given. It is calculated using Equation 6.3. The decentralised inventory of instruments is given besides m. It is calculated from the instruments in the LUMC, the instruments on the BOM of the different baskets and reduction factor, shown in Equation 6.4. Using these two inputs, the centralized inventory and reduction are calculated using Equation 6.2.

$$m = 0.8 * (\#\ Baskets - Basket\ Types) \tag{6.3}$$

$$Decentr.Inv. = 0.8 * (\#\ Instruments - BOM_{Basket\ Types}) \tag{6.4}$$

Table 6.5: Reduction of stock due to centralization of instruments in clean storage

Code	*# Baskets*	*# Instruments*	*m*	*Decentr.Inv.*	*Centr.Inv.*	*Reduction*
BH111R	212	1157	121	700	64	90.9%
BC581R	205	326	116	198	19	90.4%
BD660R	148	288	82	162	18	88.9%
BB073R	113	143	55	67	10	85.1%
BH424R	112	596	54	369	50	86.5%

Table 6.5 presents a reduction of 85% to 91% on the number of instruments when the inventory is centralised. For other instrument, which are present on a lower number of baskets this reduction will not be as large. This is caused since the reduction equals the square root of the number of locations m. Instrument that are on a few baskets will have a low m, and therefore a low reduction factor as well. It has to be noted, that when $m = 4$, the percentile reduction is 50%.

6.1.3 Results

The performance evaluation discussed in Paragraphs 6.1.1 and 6.1.2, reduction of dead stock and postponement, both decrease the time baskets are in sterile storage. The first method focusses on using less baskets, the second works by delaying the production until the last moment. This paragraph will present the results of the two methods when they are applied on the three selected departments.

Dead stock reduction

The reduction of dead stock presented in Paragraph 6.1.1 looked into basket reduction of baskets that are not necessary for operation. When these baskets are taken from the sterilization cycle and the number of uses remains the same, the number of uses per basket will increase. This increase in number of uses will lead to an increase in the time a basket is used as well. When a basket is used it can not be in storage. Thus, when the number of baskets is reduced, the time the remaining baskets are in sterile storage will reduce as well.

A conservative percentage of reduction is 11.8%, shown in Table 6.2. It is based on an inventory of baskets that is sufficient for provision to all surgeries on a single day, no baskets have to be used twice a day, on any day. Furthermore, a reduction factor of 1.5 is used as well, in order to incorporate any discrepancies between the baskets in the analysis and those not taken into account. Reduction of dead stock is viable for the baskets with multiple copies, the resulting savings in time in sterile storage as well. Thus the baskets in the analysis that have a single copy in the LUMC have to be excluded. In total there are 59 basket types in the analysis, of which 35 are single copy. The 24 basket types with multiple copies relate to 119 different baskets: in total there are 154 baskets in the analysis. This relates to a percentage of multiple copies to total baskets of 77.27%.

The average time in sterile storage is calculated to be 195.75 hours for all baskets in the analysis (page 23). The potential reduction of this time is based on the percentile reduction in the number of baskets (11.8%) and the ratio multiple to all baskets (77.27%). The product of these two percentages gives the potential reduction, which is 9.12%. The time based reduction of time in sterile storage due to reduction of dead stock is 17.85 hours, which brings the new time in sterile storage to an average of 177.90 hours, for all baskets in the analysis.

Postponement

The reduction of time in sterile storage caused by postponement is presented in Figure 6.6, for a simplified simulation model of the MR-PAID controlled sterilization cycle. However, the results of the simulation analysis can not be used for a qualitative judgement on reduction of time in sterile storage for the real cycle. Due to the simplifications the simulation models are merely a proof of concept for the use of MRP, in a very basic sterilization cycle. The simplifications used in the simulation models compared to the real situation are presented in Table 6.6.

The number of surgeries in the model is five, which use one basket each, the number of baskets in the model is therefore five as well. In reality there are around 950 different basket types, which are used in any combination during surgery. The actual number of different surgery types is in excess of 100. The 9000 different instrument types present in the LUMC are not taken into account at all by the model. Just one OR is present

Table 6.6: Simplifications of the simulation model compared to reality

	Model	**Reality**
1: Surgery types	5	>100
2: Basket types	5	∼950
3: Number of ORs	1	20
4: Surgeries per day	6	∼80
5: Production batch size	1	∼20
6: Disturbances	No	Yes

in the simulation model in stead of the 20 that are part of OR complex of the LUMC. Related to the lower number of ORs is the number of surgeries, only six are preformed on a daily basis in the model, whilst more than 80 are executed in reality. All these factors affect the modelled CSSD as well, the different machines in the CSSD handle around 20 baskets at the same time. Maintaining this batch size would cause a very large delay in production, since the baskets of over three days of surgeries are required to meet the batch size. The capacity of the CSSD can not be the bottleneck of operation and therefore the batch size is a single basket. The last simplification is the lack of disturbances in the simulation model. In reality there are many disturbances that affect daily operation. For example: equipment malfunctions, staff (un)availability, damage instruments or baskets and last minute changes in planning. Acute surgeries are part of the last category and are taken into account by the simulation model. All in all the simulation model does not come close to the complexity of the reality, which includes the various disturbances and variability and volatility in demand and supply. The impact of disturbances and variability and volatility are discussed next.

Disturbances
The effect of disturbances in production environments is discussed in [Barroso et al., 2010]. The disturbances in the supply and demand of products can be counteracted by two strategies, reactive buffer strategies or proactive improvement strategies. The current sterilization cycle uses an reactive buffer strategy, the use of a very large safety stock, to mitigate the various disturbances. By incorporating MR-PAID into the cycle proactive improvement strategies are added to overcome the disturbances. There will be more collaboration between the departments, better information sharing and the supply process is re-engineered. These three methods will reduce the required safety stock size, but will not make it superfluous.

Variability & volatility
The effect of demand and supply variability and volatility in production environments is discussed in [Talluri et al., 2004] and [Xu et al., 2001]. The variability in the demand forecast in a production environment causes an increase in required safety stock size, in order to handle the changes in demand additional products have to be stocked. Alike the demand variability the supply variability has a negative effect on the required safety stock size as well. When the production lead time is considered, a significant reduction

(roughly 25%) in required safety stock size can be achieved when lead time variability is completely eliminated [Talluri et al., 2004].

The current set-up of the sterilization cycle does not use demand forecasts. The demand of the customer (OR) is unknown to the supplier (CSSD), which causes a large safety stock of baskets that are required to counteract the fluctuations in demand. By implementing MR-PAID into the sterilization cycle the collaboration between the CSSD and the OR improves. The actual demand of the OR is known, there is no need for forecasts. This will reduce the required safety stock size. A further reduction of safety stock can be achieved by MR-PAID by providing a constant production lead time.

The above discussion only focusses on the variability part, volatility is not discussed. The reason is that both systems perform exactly the same in handling volatility. There is only one method to counteract demand or supply volatility: using a safety stock. Since both current and future (MR-PAID) operation control the same cycle the required safety stock is the same.

Reduction of time in sterile storage
The analysis of the simulation models showed a decrease of time in sterile storage for the 100 different random seeds, presented in Table 6.3. On average the future model achieved a reduction of 78.88% ($1 - \frac{11.077}{52.458}$) compared to the current model.

As discussed previously in this paragraph the results of the simulation model are not directly applicable on reality due to the simplifications used in the modelling of the sterilization cycle. However, the comparison of the current and future model can be used on the actual sterilization cycle as well. The future model only used postponement of production to reduce time in sterile storage, whilst maintaining a safety stock of baskets for acute surgeries. This function will be no different for a more complex system with additional disturbances, variability and volatility. In literature it has been presented that the addition of these three factors will lead to better performance when MR-PAID is applied, next to the necessary safety stock. However, the better performance can not be quantified. Therefore the reduction of time in sterile storage has to be pertially based on a qualitative judgement. The qualitative judgement is based upon the various basket types in the used in the LUMC. Of most basket types there are only one or two copies in inventory (60% of the baskets). Of which one has to be placed in the safety stock according to the simulation model. Since the effect of the demand variability and volatility is unknown, these baskets are not taken into account when the reduction in time in sterile storage is calculated. The remaining 40% of the baskets is taken into account, but the entire reduction of 78.88% will not be used for these baskets.

The baskets of which the time in sterile storage can be divided into two groups, the first have less than five copies (18%) and the second five or more (22%). This division is necessary since the model uses five different baskets. The unknown effect of variability and volatility is incorporated by increasing the number baskets in safety stock by two, which decreases the possible reduction by a factor two as well. This reduction is only valid for the basket types that have five or more copies. The other baskets are not covered

by the model and therefore a second reduction of 50% is applied on the reduction to cover any differences in between model and reality for unknown behaviour of the baskets with 3 or 4 copies. The factors are used to indicate the lower limit of the to be expected reduction in sterile storage time. A summary of the reduction of the various basket groups is given in Table 6.7.

Table 6.7: Reduction of time in sterile storage for the different basket groups

Number of baskets	Population	Reduction
<3	60%	0%
3,4	18%	19.7%
>4	22%	39.4%

The reduction of time in sterile storage caused by the implementation of MR-PAID is given in Table 6.8. The reduction is based on the given percentages in Table 6.7. Table 6.8 presents two reduction types of reduction, the first is based on the performance of the current sterilization cycle, the second takes the reduction of dead stock into account as well (12.23%).

Table 6.8: Reduction of time in sterile storage [hours] by implementing MR-PAID

	Current	MR-PAID	Reduction
Normal	195.75	171.82	23.93
Dead stock reduction	177.90	153.97	21.75

It has to be noted that the reduction in time in sterile storage will have the most effect for baskets with a single copy. The distribution of time in sterile storage showed that 1% of the measurements cause 25% of the cumulative time in sterile storage, and 25% of the measurements relate to 75% of the cumulative time (Figure 2.15). These very long stock times are not included in the model, which can be found in Figure 6.6. The simulation model of the current operation does not include the basket types that are used only once a year (or not even once), which belong to the slowest 1% of measurements. When these baskets are taken from sterile storage the reduction in time in sterile storage can be expected to be larger. If the 1% slowest baskets are targeted the time in sterile storage will be 137.08 hours or 124.58 hours with reduction of dead stock (35.95%).

Increase in delivery efficiency

The reduction of time in sterile storage will lead to an increase in delivery efficiency, which has been presented in Equation 1.1 (and Equation 6.5).

$$\eta_{Delivery} = 1 - \frac{T_{SS}}{T_{SS} + T_{CSSD}} \tag{6.5}$$

An overview of the variables used in Equation 6.5 and the resulting delivery efficiency is shown in Table 6.9. Three situations are given, the current operation (the base line)

and two situations using MR-PAID and the principle of postponement. The first uses the reduction of 12.23% (quan) and the second a reduction of 35.95% (qual) of time in sterile storage. In total four different time variables are given, the time in sterile storage (T_{SS}), time in CSSD production (T_{Prod}), time in clean inventory (T_{CI}) and the time in the CSSD ($T_{CSSD} = T_{Prod} + T_{CI}$). T_{CI} is the difference between the time in sterile storage of the current and the MR-PAID situation.

Table 6.9: Comparison of the delivery efficiency of the current and MR-PAID operation

	$T_{SS}[h]$	$T_{Prod}[h]$	$T_{CI}[h]$	$T_{CSSD}[h]$	$\eta_{Delivery}[-]$
$Current$	195.75	11.2	0	11.2	0.054
$MR-PAID_{quan}$	171.82	11.2	23.93	35.13	0.170
$MR-PAID_{qual}$	137.08	11.2	58.67	69.87	0.338

Table 6.9 shows that the use of MR-PAID can increase the delivery efficiency with 11.6 to 28.4%. The time in CSSD production is the same for the three situations, which might be incorrect. However, this does not affect the delivery efficiency. A change in T_{Prod} will be offset by an equal but opposite change in T_{CI}. T_{CSSD} and T_{SS} will not change and the delivery efficiency still holds.

6.2 Cost analysis

This section will give an insight into the cost of the sterilization cycle and CSSD at the LUMC. Two different subjects are addressed, first the analysis of the invested capital in instrument. Thereafter the operational cost of the CSSD is presented. The operational cost is for the whole CSSD, not only for the processing of baskets of instruments.

6.2.1 Invested capital

The different instruments and baskets at the LUMC have got different owners. Each specialization is responsible for their own specific instruments and the CSSD for the general instruments. However, for the analysis of the invested capital it does not matter who owns which instrument, therefore the entire storage of instruments on the baskets is analysed as a whole. In order to calculate capital tied up in instruments on the baskets the number of instruments has to be known and the average instrument price.

The number of instruments on all the baskets is obtained from the analysis of the basket composition, presented in Paragraph 2.2.1. There are on average 17.8 instruments on a basket and 1608 unique baskets, which brings the total instruments on the baskets to 28,622. The average instrument price is based upon a recent purchasing order of instruments placed by the CSSD. This purchasing order consists of almost 300 orders for repair work, disposable instruments and reusable instruments, from all specialisms. Since the repair work and disposable items are not part of the analysis these have been

removed from the list, 149 different instrument prices resulted from this reduction. The average instrument price for the selected instruments is €149.42.

Combining the number of instruments and instrument price the total value of the instruments on baskets in the sterilization cycle is calculated. This results in an invested capital of €4.28 million in instruments on the baskets.

6.2.2 Operational cost

The operational cost of the CSSD is split into two parts, the first is staff cost, the second material cost. The budget of the CSSD to cover the operational cost in 2015 and 2016 is presented in Table 6.10. An increase in projected operational cost is shown, which is caused by the higher materials budget. From 2015 to 2016 there is an increase of 7% in budget. The higher operational cost is not an indication of a decrease in efficiency, when the production of the CSSD increases faster than the budget, the efficiency becomes higher. Besides, in the budget an amount of €85,000 is reserved for automation of the process in 2016. This investment will not return on an annual basis and the effects of the automation process is not visible in 2016.

Table 6.10: Budget of operational cost for 2015 and 2016

	2015	**2016**
Staff	€1,726,547	€1,657,983
Materials	€630,500	€865,000
Total	**€2,357,047**	**€2,522,983**

Table 6.11: Detailed realisation of material cost for the first half of 2015

	Realisation S1
Instrument	€120,473
Equipment	€47,161
Consumables	€46,456
Chemicals	€16,074
Miscellaneous	€10,807
Total	**€240,971**

The realisation of the budget for materials of the first half of 2015 is presented in Table 6.11. The material cost is divided into five categories, instrument, equipment, consumables, chemicals and miscellaneous. The instrument category is the cost of instrument repair, maintenance and replenishment. Equipment cost concerns the maintenance and purchase of different pieces of equipment used for the disinfection, packaging and sterilization process. Consumables are all materials that are single use and are part of the sterile product, such as sterilization pouches, paper, labels and tape. The chemicals used during the disinfection process are a separate part of the consumables. And finally the miscellaneous cost are the collection of all other costs not related to the categories described above, such as ICT, office supplies and household articles. As presented in Table 6.11, half of the expenses made during the first half of 2015 were on instruments. Furthermore, nearly 95% of the expenses are related to the processes involved with disinfecting, packaging and sterilizing the baskets and instruments.

6.3 Economical evaluation

The economical evaluation of the MR-PAID system is presented in this section. First the effect on the inventory value is given, followed by the CAPEX required for implementation. Subsequently the OPEX is elaborated on. Concluding the ROI is discussed.

6.3.1 Inventory value

Paragraph **??** has given the invested capital in instruments on the baskets, which is €4.28 million. This is valid for the calculated instrument price of €149.42. The inventory value can be decreased by means of the reduction of dead stock presented in Paragraph 6.1.1 and the reduction of the number of instrument due to centralization.

Reduction of dead stock

Using the data in Table 6.1 and the price of an instrument the reduction in inventory value can be calculated for the baskets shown. The baskets in this analysis represent a value of €523,867. By using the number of instruments on the baskets and the reduction in baskets given in Table 6.1 and combining this with the instrument price, the reduction in inventory value is calculated. The result of this calculation is shown in Table 6.12, for the various percentages. The row below the monetary reduction in inventory value, the percentile decrease is given compared to the current value of €523,867.

Table 6.12: Reduction of inventory value due to reduction of dead stock

	100%	**99%**	**97%**	**95%**	**90%**
Analysis	€89,400	€115,200	€150,900	€169,100	€225,000
Reduction	17.1%	22.0%	28.8.1%	32.3%	43.0%
All baskets	€323,500	€417,100	€546,400	€612,300	€814,700
Reduction	7.6%	9.8%	12.8%	14.3%	19.0%

The results of the reduction of inventory value of the baskets in the analysis is used to calculate the reduction for the complete inventory of baskets in the LUMC. The results of this analysis are shown in the last two rows of Table 6.12. The reduction in investment is calculated using the percentile reduction of the analysis, combined with the increase in the number of instruments on all the baskets in the LUMC, which have more than one copy. On the baskets in the analysis there are 3,506 instruments, on all baskets this number is 19,039. Furthermore, a reduction factor of 1.5 is applied, which has been discussed in Paragraph 6.1.1 as well. The last row of Table 6.12 shows the percentile reduction of inventory value of all baskets, compared to the invested capital tied up in instruments on the baskets of €4.28 million. This is the inventory value of baskets with a single copy and multiple copies.

Reduction due to centralization

The reduction of instruments due to centralization is presented in Table 6.5 for the five most prevalent instruments on all baskets. This reduction of the number of instruments causes a reduction of investment in inventory as well. The instrument price used during the previous evaluation will not yield the desired results. The instrument price of €149.42 is based on all instruments in the system, not the most prevalent. These run of the mill instruments are less complicated and are mass produced and therefore the price is considerably lower. The purchase order discussed in Paragraph **??** has been reviewed and only clamps, scissors, tweezers and blade handles are taken into account to calculate the instrument price for the centralized instruments. A total of five instrument prices are obtained, €20.46, €49.75, €15.63, €18.29 and €20.13. This brings the average instrument price to a mere €24.85. The decrease in investment is given in Table 6.13 and based on price and instrument reduction (Table 6.5).

Table 6.13: Reduction of investment due to centralization of instruments in clean storage

Code	*Instrument reduction*	*Investment reduction*
BH111R	636	€15,804.60
BC581R	179	€4,448.15
BD660R	144	€3,578.40
BB073R	57	€1,416.45
BH424R	319	€7,927.15
Total	**1335**	**€33,174.75**

The analysis shown in Table 6.13 only included the five most prevalent instrument types. When the principle is applied on the other instrument types that are present on more baskets, the inventory value will decrease even further. However, since those instruments are on less baskets than the five evaluated, the reduction per instrument will be lower.

6.3.2 Capital expenditure

The CAPEX required for the implementation of MR-PAID into the sterilization cycle is presented in this paragraph. The CAPEX breakdown is given in Table 6.14.

First the various parts concerning the Auto-ID solution are given: the RFID tags and readers. The required tags is based on the number of instruments and baskets in the LUMC. The number of portal readers comes from the use of two entry or exit scans (Paragraph 4.6.1). Paragraph 4.6.2 shows that two handheld dual function readers are needed, such as the Zebra WAP4. However, for use in storage two additional handheld readers are required, bringing the total to four. Furthermore, the number of wired readers is based on the need for a reader at all workstations (10), per two ORs one reader (10) and two readers are required for the unloading step after basket entry and the separation of reusable instruments after surgery. The total of wired readers is therefore 22.

The second group of cost concerns the implementation of MR-PAID into the system, the required software, adaptations to the infrastructure and construction work. The last group concerns general expenses, the lease-lend of instruments, support and miscellaneous expenses. Because all instruments have to be fitted with a RFID tag, they will be unavailable for use a short while. This has to be solved by lease-lend the instruments that are not available for use during the application process. This is added as an expense of €20,000.

Table 6.14: Detailed capital expenditure breakdown of MR-PAID

Description	Price	Number	Cost
RFID tag instrument	€ 4.50	28,622	€ 128,799
RFID tag basket	€ 7.50	1,608	€ 12,060
RFID reader portal	€ 2,500	2	€ 5,000
RFID reader WAP4	€ 1,500	4	€ 6,000
RFID reader wired	€ 750	22	€ 16,500
Software	€ 100,000	1	€ 100,000
Infrastructure	€ 10,000	1	€ 10,000
Construction	€ 5,000	1	€ 5,000
Lease-lend instruments	€ 20,000	1	€ 20,000
Support	€ 5,000	1	€ 5,000
Miscellaneous	€ 20,000	1	€ 20,000
Total			**€ 328,359**

The overall required initial investment is almost €330,000. However, this is without any additional readers that might be desired as back-up, for redundancy reasons or for additional identification steps.

6.3.3 Reduction of operational cost

The implementation of MR-PAID will require a large initial investment and will increase the operational cost as well. However, the advantage of the use of an information and planning system is a reduction in operational cost. MR-PAID will reduce the search, inventory and communication costs [Poston and Grabski, 2001], [Lee and Whang, 2001] and will increase efficiency through optimized capacity utilization [Lee and Whang, 2001] of the sterilization cycle. The search cost will be lower since the location of all instruments and baskets is known throughout the system. The inventory cost is reduced because of postponement given in Paragraph 6.3.1, less missing instruments and lower inventory holding costs [Waller et al., 2000]. The inventory holding costs will be further reduced by the relocation of the main inventory from a sterile space, to a clean space. The communication cost will decrease since all communication regarding priority baskets and such will be processed by MR-PAID. It will not be necessary to make time consuming phone calls between the CSSD and OR concerning the delivery of certain

baskets, MR-PAID can shown everything. Besides these three factors the production efficiency of the CSSD may be increased as well, due to the improved planning and use of word orders. The production planning is set-up in such a way that little variations in production occur during the day. Such a levelled production environment the number of employees required is the same all over the day and therefore the personnel cost could decrease as well.

However, the various reductions in cost described above can not be quantified before MR-PAID is implemented and has been in use for some time. This combined with the fact that the current performance on search, inventory (holding) and communication costs and the production efficiency is quite unknown.

As for the cost of sterile storage compared to clean storage, the evaluation will be based on qualitative factors. In general the activities executed in a sterile environment are of higher value than those in a clean area. In the sterile area of the OR complex the actual revenue of the LUMC is produced, the hospital gets paid for surgeries. On the other hand, the clean area, such as the CSSD, is not directly profitable. It supports the process of the OR, but does not generated any revenues. Thus the sterile environment is of higher value than the clean area when the performed actions are considered. Besides this, the cost of maintaining a sterile area is higher as well. Requirements to a clean area are aimed at minimizing the risk of contamination with outside air and other particles. For a sterile area the requirements are much more stringent, mainly focussing on the level of air cleaning and air flows in the area.

6.3.4 Operational expenditure

The OPEX required for the implementation of MR-PAID into the sterilization cycle is presented in this paragraph. Two different OPEX expenses will be discussed. First the maintenance and depreciation and second the replacement of instruments.

The maintenance cost of a system such as MR-PAID is unknown in advance. However, a rule of thumb is that the maintenance cost can be calculated as 2-3% of the replacement asset value [Smith and Mobley, 2011]. The asset value of the various parts of the MR-PAID system can be found in Table 6.14. The relevant expenses are: RFID equipment, software and the infrastructure. The sum of these expenses is €228,359. The annual depreciation is the reduction in asset value over the depreciation period. The standard depreciation period used in the LUMC is ten years for such infrastructural systems, which brings the depreciation rate to 10%.

On a continuous basis instruments are replaced in the LUMC. A hefty budget of €225,000 is available in 2016 for this replenishment of damaged or lost instruments. These instruments have to be fitted with a RFID tag as well. When using the average instrument price of €149.42, the number of instruments that can be bought according to the budget 1,505. However, the CSSD does not purchase specialized instruments from its budgets, only the standard instrument types. When these general instruments are considered,

such as in Table 6.13 the number of instruments is considerably higher. An instrument price of €24.85 is calculated for these instrument types, which makes the number of instruments that can be bought according to the budget 9,054.

The three parts of OPEX are given in Table 6.15. Which gives the full range of operational cost that can be expected from MR-PAID.

Table 6.15: Three parts that determine the operational expenditure

Description	Amount		Cost	
Maintenance	2-3	%	€	4,567-6,851
Depreciation	10	%	€	22,836
Tag replacement	1,505-9,054	tags	€	6,773-40,743
Total			**€**	**34,176-70,430**

As shown in Table 6.15 is the tag replacement operational cost the reason for the large variation in OPEX. As a ballpark figure the average of the upper and lower limit is considered as the OPEX for MR-PAID, which is €52,303.

6.3.5 Return on investment

This paragraph will give the ROI of the MR-PAID system. The reduction in inventory value and operational costs combined with the CAPEX and OPEX, which have been given in Paragraphs 6.3.1 up to and inclusive 6.3.4, are used to calculate the ROI.

The ROI calculation starts with the required CAPEX for the system. From this CAPEX the cost savings per year are subtracted until the initial investment is covered by the reduction in costs. Another factor that is taken into account is the interest cost. When the initial investment was not made, the funds could have been used for other investments, which would yield 6% interest per year (6% is used LUMC wide as as the rate of interest on capital). Furthermore, the reduction in inventory value will no occur overnight. The phasing out of unused instruments is taken to be five years and each year the same value is reduced. The current budget of the CSSD does not yield much useful information about the various operational cost, which is presented in Table 6.11 and Table 6.10. Since the material cost will show little change, the production of the CSSD will remain the same, only a reduction on staff may be expected. However, this reduction cannot be quantified, various reduction percentages on staff cost are evaluated: 0%, 1%, 2%, 3%, 4% and 5%. For these cases the ROI will over a period of 10 years is evaluated, which is the depreciation period. An overview of the various groups of the ROI calculation are given in Table 6.16. The results of the analysis of the six reduction percentages in staff cost are presented in Figure 6.9.

For the 0-3% staff cost reduction cases the MR-PAID system will not achieved ROI, as shown in Figure 6.9. When the reduction percentage is 4%, the initial investment will be recovered after 4.49 years. For the 5% reduction case this period decreases to 3.68

Table 6.16: Overview of the various groups of ROI calculation

Group	Amount	Notes
CAPEX	€-328,359	initial
OPEX	€-52,303	per year
Dead stock	€323,500	over 5 years
Centralization	€33,175	over 5 years
Staff cost	€1,657,983	0-5%
Interest rare	6%	per year

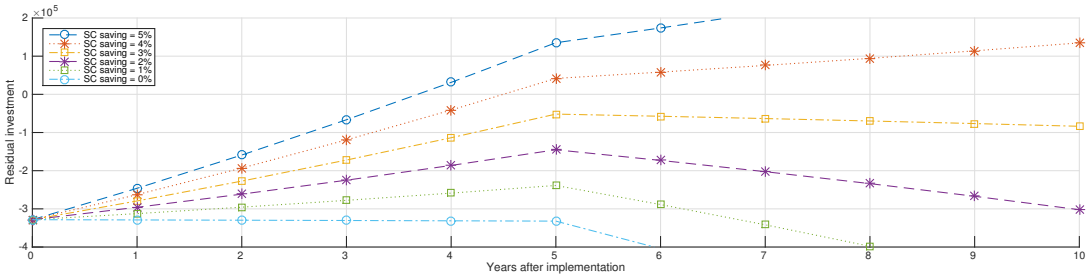


Figure 6.9: ROI

years. It is evident that with even higher staff cost reductions, the payback period will be even shorter.

As discussed in Paragraph 6.3.3 is the operational cost reduction due to MR-PAID not quantifiable. The current baseline data is incomplete or not available all together. However, various literature sources all indicate that there is an effect. The suggested reduction percentages in staff cost are not to be mistaken with the actual reduction, they serve merely as a proof concept. An indication of the required cost saving is presented in this way for a economically viable implementation of MR-PAID.

6.4 Chapter summary

This chapter has presented the evaluation of the integrated MR-PAID system. First the performance evaluation of the system was given (Section 6.1). This was followed by an economical evaluation (Section 6.2 and 6.3).

The performance evaluation showed that the time in sterile storage can be reduced in two ways, reduction of dead stock and postponement. The reduction of dead stock looked into the reduction of baskets that are not necessary when the usage profile is considered; the superfluous baskets. By reducing the number of baskets the remaining baskets will be used more frequently and will spend less time in storage. The resulting reduction has been calculated as 9.12% on the total time in sterile storage for the analysed baskets (Paragraph 6.1.1). Postponement was given to act upon all baskets in the system, not only the types with multiple copies. In order to quantify the reduction in time in sterile

storage a simulation model analysis was presented which yielded a reduction of 78.88% in time in sterile storage in the simulation (Paragraph 6.1.2). It was presented that these simulation results are not directly applicable to reality, due to addition disturbances and variability and volatility. The time in sterile storage will decrease by 12 to 36%, which relates to an increase in efficiency of 12 to 28% (Paragraph 6.1.3).

The economical evaluation presented the calculation of the ROI, which is based on reduction in capital and operational cost and the CAPEX and OPEX of MR-PAID. For the implementation of MR-PAID an initial investment of €328,359 was given. Furthermore, an increase in operational cost of €52,303 was calculated due to maintenance, depreciation and re-tagging of new instruments. The reduction in dead stock and centralization of inventories will cause a reduction in invested capital of €356,675. The ROI was calculated using these numbers and a varying reduction in staff cost of 0 to 5 %. A varying reduction was used because the actual reduction in staff costs is unknown and could not be calculated. This yielded a negative ROI for 0 to 3% reduction in staff cost, a payback period of 4.49 years for 4% and 3.68 years for 5%.

In this chapter an answer to the following research question was formulated.

Research question 4: *To what extend can the DDS system combined with KPI visibility decrease the time in sterile storage of surgical instruments?*

The time in sterile storage of instruments can be decreased in two ways, reduction of dead stock and postponement. Reduction of dead stock looks into the reduction of baskets that are not necessary when considering the usage profile of those baskets. When these baskets are taken from stock the remaining baskets will be used with a higher frequency. Baskets that are in use can not be in storage, and therefore the time in sterile storage will decrease. A reduction of 9.12% on time in sterile storage has been calculated due to reduction of dead stock. However, for reduction of dead stock DDS and KPIs visibility is not required, and the 9.12% reduction will not be taken into account.

Postponement is delaying the production until the last moment and acts on all baskets, regardless of the number of copies. A simulation model of the current and future DDS model has shown that a reduction in time in sterile storage of 78.88% can be achieved. These simulation results are not directly applicable to reality, due to the simplification used in the modelling process. The real system is much more complex and has to deal with more variability and volatility in demand. Therefore, a reduction of 12 to 36% is more realistic.

Chapter 7

Conclusion

In this chapter the conclusions of this thesis are presented and recommendations for a integrated DDS and Auto-ID system in the LUMC is stated. Concluding this chapter a discussion concerning this thesis and possibilities for future research are given.

7.1 Conclusions and recommendations

This thesis is about the improvement of the delivery efficiency of sterile surgical instruments. The motivation for this thesis was found to be bi-fold. First, a new guidance adopted by the European Commission will come into affect that requires every instrument to be individually identifiable. Second, the cost for the healthcare system are increasing, over the last 15 years the expense per capita has doubled. These two factors drive the CSSD to cost reduction, which can be achieved by means of a higher delivery efficiency. The most effective way of increasing the delivery efficiency is to produce and deliver only the required baskets. A group of methods capable of providing this are DDS methods. They require various process parameters as input, which are acquired by a Auto-ID solution. This led to the following central question of this thesis:

How can the efficiency of the delivery of sterile surgical instruments be increased, whilst taking DDS, process visibility and UDI into account?

This central question was divided into four research questions:

1. What is the most viable system for DDS of surgical instruments at the LUMC?
2. Which process KPIs have to be known for the successful operation of DDS?
3. Which methods are feasible for providing the visibility of the KPIs of the DDS system and provision of UDI on instruments?
4. To what extend can the DDS system combined with KPI visibility decrease the time in sterile storage of surgical instruments?

In search for answering these questions the current sterilization cycle, in which the DDS and Auto-ID has to be implemented, was described and analysed. This showed that no production planning is made and there is little knowledge about process performance. The system is complex as well, a great variety of instruments and baskets are being produced and most instruments are present on a small number of baskets. Furthermore, from time series analysis it became clear that a basket is in production for 11.20 hours and in sterile storage for 195.75 hours, on average. An analysis of the investment and cost indicated that €4.28 million is tied up in instruments on the various baskets (instrument price is €149.42). The DDS method was indicated as required for generation of a production schedule and the Auto-ID solution should solve the process performance issues.

For the DDS method and Auto-ID solution multiple candidates have been collected and analysed. A total of five DDS candidates were found suitable for use in the sterilization cycle: Kanban, CONWIP, MRP, MRPII and the Packing Centre. For selection of the optimal candidate, an AHP selection procedure was executed. This showed the compliance of the candidates to handling of: demand variability, demand volatility, product mix, capacity constraints and planning. The various Auto-ID technologies included in the analysis, barcode system, OCR, smart card and RFID, have been analysed upon compliance to the requirements of the cycle. The requirements were: the use conditions in the cycle, the invasiveness of the technology, the UDI guidance and the classification of instruments. Using the best adapted technologies six concepts were presented that could perform the Auto-ID tasks of identification of instruments and baskets. The concepts were evaluated using the AHP method as well, taking the readability, reliability, cost effectiveness and the impact of the process into account. The two selection procedures yielded the MRPII to be best adapted for use as a DDS method and a Auto-ID solution using passive RFID tags on both instruments and baskets as most feasible.

The MRPII and Auto-ID solution were integrated into one system, MR-PAID, for which the implementation into the sterilization cycle was described. The integration of MRPII and Auto-ID showed the necessity of the use of a database connecting the two. T-DOC was selected as the connecting database, since it is in use in the CSSD. Furthermore, the implementation showed that there are three factors that need to be taken into account on an organisational level:

1. Good communication between CSSD and OR is essential;
2. A SLA has to be defined to achieve consensus on the responsibilities of both the CSSD and OR;
3. And, the data used as input for MR-PAID has to be of good quality, since poor quality data will lead to poor production planning schedules.

Furthermore, the sterilization cycle was redesigned for the implementation of MR-PAID. The main focus of the redesign was the relocation of the main inventory location from sterile storage, to clean storage and the addition of a safety stock location.

The new sterilization cycle with implemented MR-PAID system was evaluated on performance and cost. The performance evaluation showed that the time in sterile storage can be reduced in two ways, reduction of dead stock and postponement. The reduction of dead stock was based on a quantitative analysis of the usage profile of various baskets. By removal of the superfluous baskets in stock an decrease in time in sterile storage of 9.12% was presented (195.75 to 177.90 hours). The increase of the delivery efficiency caused by MR-PAID and postponement was calculated as 12 to 28%. This was based on quantitative analysis of the results of a simplified simulation model of the current situation and future operation and a qualitative analysis of the sterilization cycle. The economical evaluation presented a ROI period of 3.68 years for MR-PAID. This was based on a CAPEX of €328,359, an increase in OPEX of €52,303, a decrease in inventory value of €356,675 (spread over five years) and a reduction of 5% on staff cost due to increase in production efficiency. Furthermore, an additional cost of 6% was

introduced to cover the cost of not receiving interest.

7.2 Discussion and future research

This thesis has evaluated the performance the MR-PAID system in the sterilization cycle of the LUMC. Since various decisions in the selection process and performance determination are based on theory and assumptions efforts should be taken to further check the theories and assumptions of this thesis.

Most of the quantitative analyses presented in this thesis are performed on a selection of baskets of 3 specialisms out of 14. The three specialism were selected because they should be representative of all specialism, one has mostly planned surgeries (Plastic surgery), one mostly acute (Transplantation surgery) and the last is the biggest specialism (General surgery). However, it is unknown whether the evaluated baskets are representative for all specializations. Research could be performed in order to check the validity of the selected baskets or a full scale analysis of all baskets could be executed.

The MR-PAID system can improve the production efficiency by means of generating stable production schedules that offer a stable throughput of baskets. The higher production efficiency will lead to lower expenses on staff; less production hours are required for the same number of baskets. In order to provide a solid basis of calculated decrease in cost, the current performance has to be known. The CSSD has no clear definition of production efficiency, which causes an unknown performance on this KPI. A study into the definition of production performance should tackle this challenge combined with benchmarking to gather comparative knowledge about performance of the production efficiency.

The determination of some of the aspects on which the selection procedures are based, e.g. the lifespan of an instrument, are part of a chicken-and-egg problem. The lifespan of an instrument is of interest on the selection of an Auto-ID technology, the technology should last as long as the instrument. To determine the lifespan (in years or use cycles) the unique ID of the instrument has to be known and documented over time. A system that can provide the instrument with an unique ID and that can document the the usage, is an Auto-ID system. The solution to this problem is to perform a scaled down test with various Auto-ID technologies. The instruments are in use and are there performance over time and use cycles is being monitored. This gives a quantitative basis for the selection of the best technology.

Rapid developments in the field of passive RFID tags, suitable for use in the sterilization cycle, occur. The trend of the past years shows that the tags are decreasing in size. It is expected that in the coming years this trend will continue. Besides this, allegedly various manufacturers are designing tags that use the instrument itself as antenna. This would result is a substantial decrease in tag size as well.

The DES models of the current situation and future operation are simplified versions of the actual sterilization cycle. On a qualitative basis it has been shown that the actual

system will reduce time in sterile storage at least as much as the model analysis suggest, but this can not be checked. A better indication of the to be expected reduction in time in sterile storage can be expected from a simulation model that mimics the particulars of the sterilization cycle in more detail. When this (validated) model has been made various process performance KPIs can be obtained from the model. Furthermore, any changes to the operation of the sterilization cycle (in the CSSD or OR) can be included in the model first to show its effects.

The economical analysis of MR-PAID proposed a ROI period of 3.68 years, which was based on the various costs of MR-PAID and savings in inventory value and operational cost due to an increase in production efficiency. A more in depth economical analysis of the implementation would be achievable when the cost breakdown for the sterilization cycle is known. In the LUMC various cost categories concerning amongst others floor space, electricity and water are not assigned to a specific department (such as the CSSD) or function (such as the sterilization cycle). This provides a research opportunity, calculating the cost of the CSSD or sterilization cycle and thus the cost of producing a single basket.

Finally, the possibility of a stepwise implementation of MR-PAID is introduced. The first year (2016) the reduction of dead stock of baskets is performed, which will result in an annual cost saving in the first few years. The second year (2017) the Auto-ID technology is applied to the baskets and the required infrastructure and hardware is for providing the process parameters are installed. The third year (2018) the MRPII system will be implemented and integrated with the infrastructure of the Auto-ID technology. Which leads to the last two years (2019-2020), in which the passive RFID tags are applied to all the instruments and all the hardware required for individual instrument identification is installed. From this moment the MR-PAID system is completely implemented. This stepwise implementation has the advantage that the required investment for MR-PAID is paid from the reduction in inventory value, which makes the entire implementation budget neutral, shown in Table 7.1. Furthermore, the application of RFID tags is delayed until 2019 when the new generation of smaller tags is probably available. It has to be noted that the shown stepwise implementation is valid for the UDI guidance coming into full effect in late 2020. When the UDI has to be applied at an earlier date, the process should be sped up and will not be budget neutral.

Table 7.1: Stepwise implementation of MR-PAID

Year	Savings	Expenses	Result
2016	€71,335	-	€71,335
2017	€71,335	€109,560	€33,110
2018	€71,335	€60,000	€44,445
2019	€71,335	€79,400	€28,316
2020	€71,335	€79,399	€28,316
Total	**€356,675**	**€328,359**	**€28,316**

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Appendix A

Scientific research paper

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Improving the efficiency of the delivery of sterile surgical instruments at the LUMC

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Abstract

The CSSD strives for cost reduction through improving the delivery efficiency. To achieve this goal first the demand of the customer has to be taken into account and process parameters have to be known. Both conditions are met by implementing MR-PAID, a combination of the MRPII method and a RFID Auto-ID solution. A simplified simulation model of MR-PAID shows a steep reduction in time in sterile storage and the accompanying improvement in efficiency.

I. Introduction

In the health care system patient safety is the primary focus. Hospitals and staff travel great lengths in order to ensure the highest possible patient safety. This does come at a price, the last decades the healthcare cost has been increasing steadily. In 1999 the expense per capita was €2744, which has doubled to €5630 in 2014 [1]. To counteract the Leiden University Medical Center (LUMC) has a renewed focus on cost reduction and budget.

On of the areas of interest is the delivery of sterile surgical instruments. During surgery various sets of sterile instruments (called baskets) are used in the Operation Room (OR). These baskets are supplied by the Central Sterile Supply Department (CSSD). After surgery the baskets are returned to the CSSD, which reprocesses them for the next use. Considering the sterilization cycle to be a production process, the supplier is the CSSD and the customer is the OR, shown in Figure 1.

The CSSD strives for cost reduction through improving the delivery efficiency. However, the current operating principle of the CSSD is not fit for process optimization. The demand of the customer is unknown, which should be the focal point of production [2], and relevant process parameters are not known or used [3].

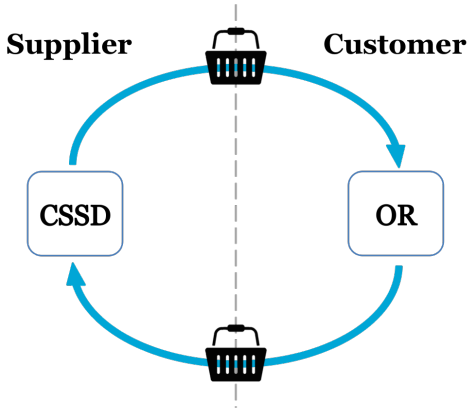

Figure 1: *Relation between the CSSD and the OR in basket delivery*

In industry the demand of customers is incorporated into the production process through Demand Driven Supply (DDS) methods [2], a well known DDS method is the Manufacturing Resource Planning (MRPII)[4]. The acquisition of process parameters is performed using an Automatic Identification (Auto-ID) technology, such as Radio Frequency Identification (RFID) [5]. This paper presents the improvement of the delivery efficiency through the implementation of Manufacturing Resource Planning & Automatic Identification (MR-PAID), a combination of the MRPII method and a RFID Auto-ID solution.

A. Delivery Efficiency

The delivery efficiency of baskets is amongst others dependent on the demand planning. The level of demand planning can be obtained from the sterilization cycle through the time baskets spend in sterile storage. When instrument production is based on planning, the time instruments are in sterile storage will be low; every instrument is used at surgery shortly after production. The improvement of the delivery efficiency is closely related to the time in sterile storage and is calculated using Equation 1.

$$\eta_{Delivery} = 1 - \frac{T_{SS}}{T_{SS} + T_{CSSD}} \tag{1}$$

T_{SS} is the time a basket is in sterile storage, T_{CSSD} the time a basket is in the CSSD.

B. Sterilization cycle

The first step in the sterilization cycle is cleaning, the used instruments are manually cleaned and prepared for disinfection, in one of six washing machines. After disinfection the instruments are inspected for any damage and are send to the packaging phase. During packaging, with ten work stations, multiple instruments are combined into a basket, which is put through one of four autoclaves during sterilization. The result is a sterile basket containing sterile instruments. The basket is transported to the OR complex where it is stored until it is used. After use the basket and instruments are returned to the CSSD. In general there are two types of surgeries, planned and acute surgeries. Planned surgery are known 24 hours before they commence, acute surgeries less than 24 hours and can be split second decisions.

C. Structure of the Paper

This paper presents a way of improving efficiency through MRPII and Auto-ID. Section **??** describes the integrated MRPII and Auto-ID system. Section III gives the various methods used. The results of the analysis are presented in Section IV. Section V concludes this paper and proposes areas of further research.

II. Implementation of MR-PAID

Two departments are part of the sterilization cycle at the LUMC, the CSSD and the OR. The MR-PAID system will affect both these departments. An overview of the MR-PAID system in the sterilization cycle is presented in Figure 2. The planning and priority data flows from the OR to MR-PAID, which generates work orders for the CSSD.

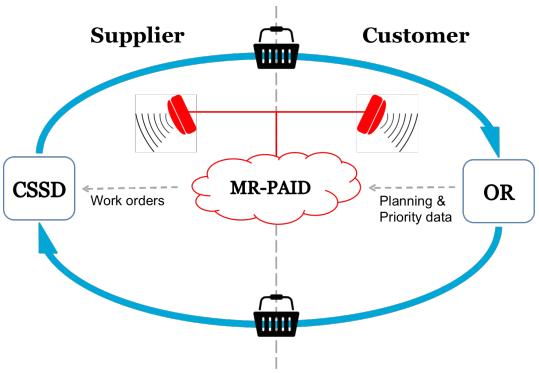

Figure 2: *Implementation of MR-PAID in sterilization cycle*

A. Success factors

The implementation of MR-PAID takes two actors into account, the CSSD and the OR. Without the cooperation of either of these two departments the implementation of MR-PAID will not succeed. There are three essential factors for the success of MR-PAID:

1. Good communication between actors;
2. A SLA has to be defined;
3. Data quality has to be good.

B. Process redesign

MR-PAID requires a change in the location of the main inventory from sterile storage to clean storage and the addition of a safety stock in the sterile storage. The main inventory is situated in between the inspection and packaging processes. The safety stock has the purpose of supplying the baskets to acute surgeries. When a regular supply process takes to long.

III. Simulation model

A simplified Discrete Event Simulation (DES) model of the current operation and future situation of the sterilization cycle is built to quantify the improvement in efficiency of MR-PAID. Both models are made using DES tool SimEvents of graphical programming environment Simulink 8.4 [6].

A. Current operation

A schematic overview of the five main components of the model of the current operation is given in Figure 3. The sterilization cycle is shown by means of four processes: Cleaning & Disinfection, Packaging & Sterilization, Sterile Storage and the OR. Furthermore, an information source is modelled, the Order for a surgery.

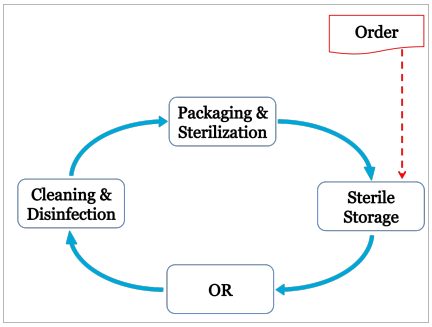

Figure 3: *Schematic overview of the current model*

B. Simplifications

In the process of modelling the current situation various simplifications to reality are applied, which are summarized in Table 1. In reality there are many disturbances that affect daily operation. For example: equipment malfunctions, staff (un)availability, damage instruments or baskets and demand variability and volatility. Acute surgeries are part of the last category and are taken into account by the simulation model.

There are two strategies to counteract disturbances: reactive buffer strategies or proactive improvement strategies [7].

Table 1: *Simplifications of the simulation model compared to reality*

	Model	**Reality**
1: Surgery types	5	>100
2: Basket types	5	∼950
3: Number of ORs	1	20
4: Surgeries per day	6	∼80
5: Production batch size	1	∼20
6: Disturbances	No	Yes

The current sterilization cycle uses a reactive buffer strategy to mitigate the various disturbances. By incorporating MR-PAID into the cycle proactive improvement strategies are added to overcome the disturbances. This strategy will reduce the required safety stock size, but will not make it superfluous. Safety stock size is affected by demand variability and volatility as well. The variability in the demand forecast in a production environment causes an increase in required safety stock size, in order to handle the changes in demand additional products have to be stocked [8] and [9].

C. Future situation

A similar overview of the future situation is presented in Figure 4. It shows the redesigned process: the Sterile Storage is replaced with the Clean Storage. Another difference is the addition of the MRP control function. In the current operation the order flows directly into the system. In the future situation the order is processed by the MRP system, which releases them at the right time.

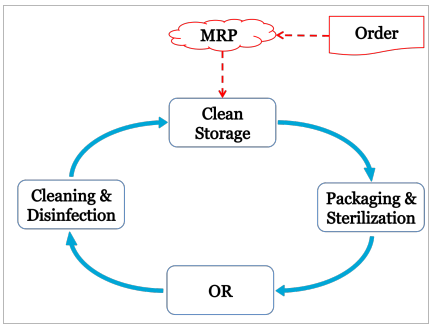

Figure 4: *Schematic overview of the future model*

IV. Results

The model of the current operation and the future situation are analysed for 10,000 hours of operation, which relates to in excess of one year. Furthermore, the analysis is performed for 100 different random seeds. This is to incorporate the performance of the model under different conditions. For both models the random seeds are the same and act upon the same variables. This is essential for the comparison of the current operation and future situation. Both models have to handle exactly the same surgeries, with the same processing times. Matlab [6] is used for data analysis. Table 2 shows the comparison of the current operation and future (MR-PAID) situation on three variables, acute surgery Order Completion Time (OCT), time in sterile storage (T_{SS}) and time in the CSSD process (T_{CSSD}) of the baskets, for the 100 different seeds. The columns show the mean, standard deviation (STD) and 95% confidence interval (c.i.). The 95% c.i. $[l_n, u_n]$ is calculated using Equation 2 [10]. The value of $t_{99,0.025}$ is 1.984 and is based on the t-distribution.

$$l_n = \mu - t_{99,0.025}\frac{\sigma}{\sqrt{n}}, u_n = \mu + t_{99,0.025}\frac{\sigma}{\sqrt{n}} \quad (2)$$

Table 2: *Mean, standard deviation and 95% c.i.*

	Mean	**STD**	**95% c.i.**	
	μ	σ	l_{100}	u_{100}
Current OCT	4.34	0.15	4.31	4.37
Future OCT	3.17	0.29	3.11	3.22
Current T_{SS}	52.46	1.61	52.14	52.78
Future T_{SS}	11.08	0.62	10.95	11.20
Current T_{CSSD}	5.28	0.02	5.27	5.28
Future T_{CSSD}	46.70	1.39	46.42	46.98

A. Acute surgery OCT

The acute surgeries performed in the LUMC have the highest priority and have to be executed immediately. By implementing MR-PAID the performance of the handling of acute surgeries can not be compromised. An indication of the performance is the OCT, the time it takes a surgery to be performed.

When considering the average OCT the future situation out performs the current operation with an reduction in between 25.3% and 28.8% for the 95% c.i.. The reduction is explained by the release of orders by the MRP system. At the moment an acute surgery has to be performed, the required basket is available because it is in safety stock. In the current operation there are no baskets reserved for acute surgeries. When there are no baskets available, the surgery is delayed until a basket is available.

B. Delivery Efficiency

The delivery efficiency is depended on T_{SS} and T_{CSSS}, Equation 1. The current model achieves a delivery efficiency of 0.09, whilst the future model operates at 0.81. The this difference is caused by the postponement of production in the future model, incited by the production on demand by the MRP system. The baskets that are required are produced and spend little time in sterile storage. The future model is better suited for production on demand, which leads to the higher delivery efficiency. The baskets in the safety stock are included in these numbers.

C. Discussion

As discussed previously the results of the simulation model are not directly applicable on reality due to the simplifications. The added complexity in surgeries, baskets and capacity constraints will lead to a lower delivery efficiency. Furthermore, in reality only a few dozen basket types have five or more copies, as used in the model. However, the method of postponement remains the same independent of the number of copies.

In literature it has been presented that the added complexity can be covered by additional safety stocks, or by improving the process. MR-PAID will improve (the control of) the process and thus increase delivery efficiency. Even though the to be expected increase will not be as large as the model suggests. Realistically, the delivery efficiency of the sterilization cy-

cle after implementation of MR-PAID is 2 to 4 times lower than the model achieves.

D. Economical Evaluation

The initial investment of MR-PAID is €328,000, which takes the amongst others various RFID equipment, required software, infrastructure and construction costs into account. Furthermore, the operational cost will increase due to maintenance, depreciation and replacement parts of MR-PAID, which adds up to €52,000 per year. However, due to the increased insight in process parameters various savings can be achieved as well. The capital investment in instruments can be reduced by €357,000 (over five years) and the staffing cost can be reduced by 5%, due to a higher production efficiency. This relates to a return on investment (ROI) of 3.7 years.

V. Conclusions

The following general conclusions are drawn for the improvement of delivery efficiency, based on the results of this study:

- The delivery efficiency of sterile surgical instruments is depended on the time instruments spend in sterile storage;
- A combined system (MR-PAID) of MRPII and Auto-ID can achieve a significant reduction of time in sterile storage;
- The implementation of MR-PAID can be executed in a profitable way, with a ROI 3.7 years.

However, there are some limitations as well. Due to the simplifications the model does not represent reality accurately. The results of the model analysis are merely a proof of concept and give an indication of what may be achieved when implemented. Hence, the model should be expanded to act more alike reality and should be validated and verified to the sterilization cycle.

Furthermore, the cost reduction of the operational cost only focusses on the reduction of staff cost due to a higher production efficiency. However, there are more cost groups that can be reduced. By implementing MR-PAID the search, inventory and communication cost can be reduced [11], [12], [13].

Lastly, the Auto-ID technology used to identify the individual instruments can be used for compliance to the Unique Device Identification (UDI) guidance. In the future it will become mandatory to apply an UDI to every reusable medical device [14]. The simultaneous implementation of MRPII and the UDI results in a cost effective system.

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Appendix B

Detailed process steps

The overall process flow diagram shown in Figure 2.2 is given in detail in this Appendix. First the complete cycle of disinfection, sterilization and use is given in Figure B.1. The different sub-processes to be found in this cycle are discussed independently to give the particulars about the process step. Also, observations about the conditions to which the instruments are subjected are presented here.

The different models are built-up using mostly general blocks of processes, decisions and inventories. There are however three non-generic block types specifically for this research. These blocks describe the different instances in the process where an identification takes place. Table B.1 shows the three different types, with a description of their meaning.

Table B.1: Specific block types used in process flow diagram of the sterilization cycle

	Identification of unique basket ID (or sticker when the basket has been packaged). This is done using the linear and 2D-barcodes that are attached to the baskets.
	Identification of cart containing baskets, using barcodes or magnets attached to the carts. The baskets on the cart are assigned to the cart via a previous scan.
	Identification of instrument, in the current operation this is achieved based on operator knowledge of instruments.

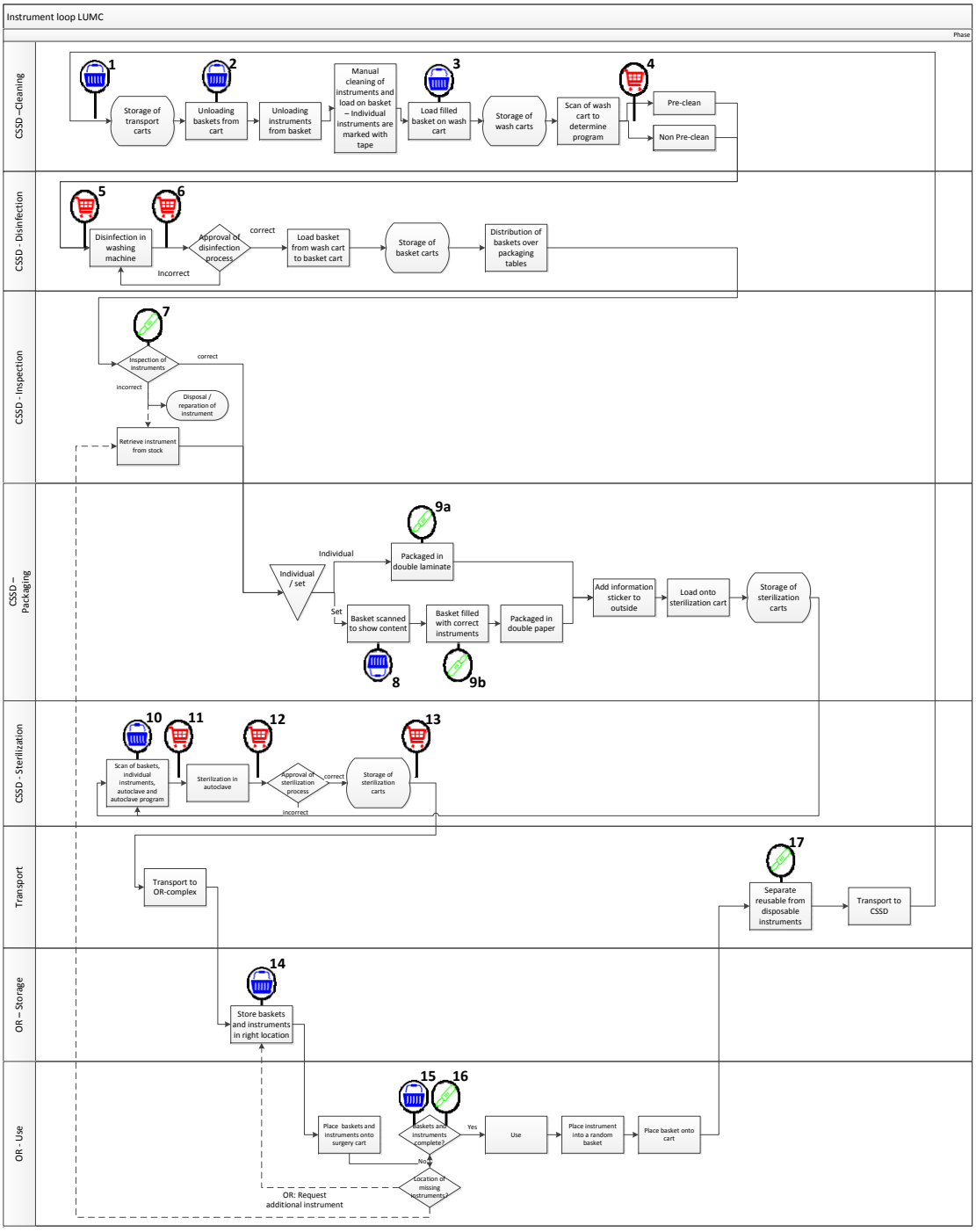


Figure B.1: Overview of sterilization cycle

Cleaning (Figure B.2)

The Cleaning step is the first step that takes place in the CSSD. It receives used instruments and baskets stacked on carts from the OR from the logistics department. First the cart is put in a temporary storage before the baskets are unloaded. This is followed by the unloading of the different instruments from the baskets. The instruments are pre-cleaned by hand and re-loaded onto a basket. The individual instruments are marked with tape if this is necessary. The filled baskets are loaded onto another type of cart that is suitable of enter the washing machine, which is place in a temporary storage. The wash cart is scanned and enters if applicable a second (mechanical) pre-clean stage. This pre-clean uses vibrations combined with water to rinse the instruments.

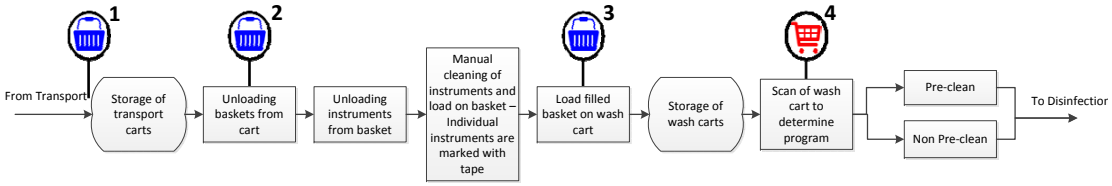


Figure B.2: Detail of cleaning process

The incoming baskets are scanned at entry (1) and before the unloading of the instruments commences (2). After manual cleaning the basket is scanned again and assigned to a wash cart (3). This wash cart is scanned before it enters the (non) pre-clean step (4).

Disinfection (Figure B.3)

After Cleaning the baskets of instruments are disinfected in the washing machine. The disinfection process happens by forcing alkaline water at nearly 100 $^{\circ}C$ onto the instruments. The disinfection process is checked and when it is accepted the baskets are loaded from the wash cart onto a trolley. These trolleys are placed in a temporary storage before they are distributed over the packaging tables.

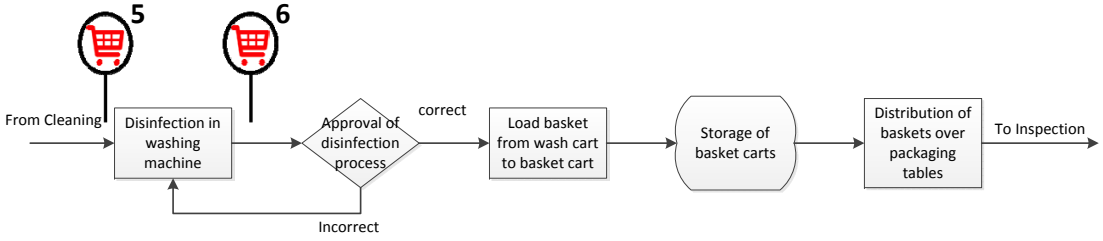


Figure B.3: Detail of disinfection process

The wash carts are scanned in front (5) of and after (6) the disinfection process. The baskets are assigned to the wash carts and are therefore known as well.

Inspection (Figure B.4)
The disinfected instruments are inspected to ensure that they are in good condition and complete. If this is the case they proceed to the packaging step. When not the instrument is replaced by one from the stock (if available) and the faulty instrument is send out to be repaired or replaced. In the Inspection step the incoming requests from the OR for additional instruments are handled as well. When the instrument is available in stock it enters the process in the packaging step.

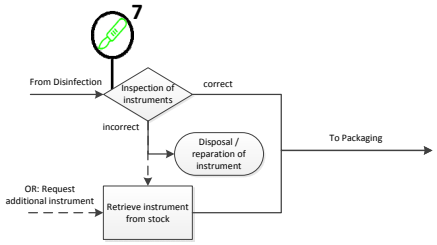


Figure B.4: Detail of inspection process

The instruments are identified by the employees of the CSSD (7). The identification process is based on operator knowledge, combined with the markings on the instruments (manufacturer and type number).

Packaging (Figure B.5)
The inspected instruments are split into two flows, the individual instruments and set instruments. The individual instruments are packed in double laminate. The instruments that form a set are loaded in the correct basket (the basket is scanned first to show its contents). And are packed in two sheets of sterilization paper. Subsequently the information sticker is put on the individual instruments and baskets. Following they are loaded onto a cart fit for the sterilization process, which is put in a temporary storage.

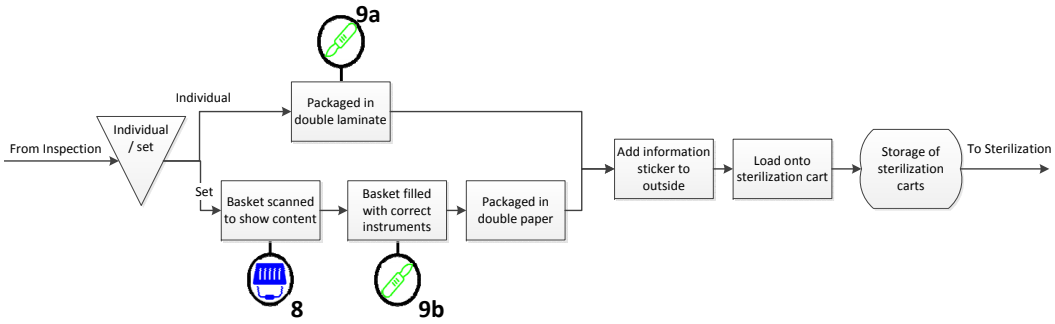


Figure B.5: Detail of packaging process

During the packaging step the instruments are identified by the employees on a similar manner described above. The barcode of the baskets is scanned as well (8). The different instruments that belong to the basket are loaded into the basket, which is documented in T-DOC (9a/b).

Sterilization (Figure B.6)
All the stickers on the individual instruments and baskets on the cart are scanned. The autoclave that will process the batch of instruments is scanned too, just as the autoclave program. When program and instrument batch characteristics match the cart enters the sterilization process. During sterilization the autoclave pressurizes (maximum of 350 kPa) the instruments in a temperature of circa 134 $°C$ in steam. After sterilization the process is checked and approved. When approved the carts enter a temporary storage. When disapproved the sterilization process is repeated.

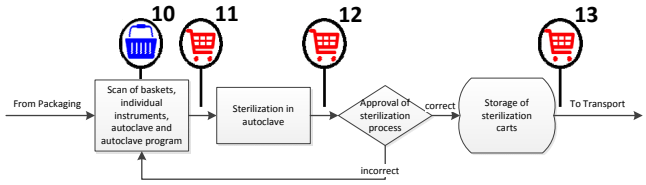


Figure B.6: Detail of sterilization process

The different baskets and instruments are scanned and assigned to the autoclave they will be processed in (10). The batch is identified before (11) and after (12) the process in the autoclave and before the batch is being transported to the sterile storage at the OR (13).

Transport CSSD-OR (Figure B.7)
The carts with sterile instruments and baskets is moved from the CSSD to the OR complex.

Figure B.7: Detail of transport from CSSD to OR

Storage (Figure B.8)
At the OR complex the cart is unloaded and the different instruments are placed in the correct location. Incoming requests from the OR for additional instruments are handled too. When the instrument is available in the OR storage it is moved to the OR.

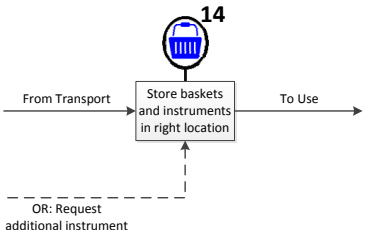


Figure B.8: Detail of storage process

At the sterile storage the baskets are scanned to indicate that they have arrived at the storage facility (14).

Use (Figure B.9)
An OR assistant retrieves the different instruments from storage an puts them on a cart. These are unpacked in a clean room, after which the instruments are checked for completeness, condition and sterility. If one of the instruments is not accepted a request for a replacement is send out. After the check the instruments are used by the surgery team. When the surgery is over the used instruments are placed in a random basket, when the basket is full it is placed onto a cart.

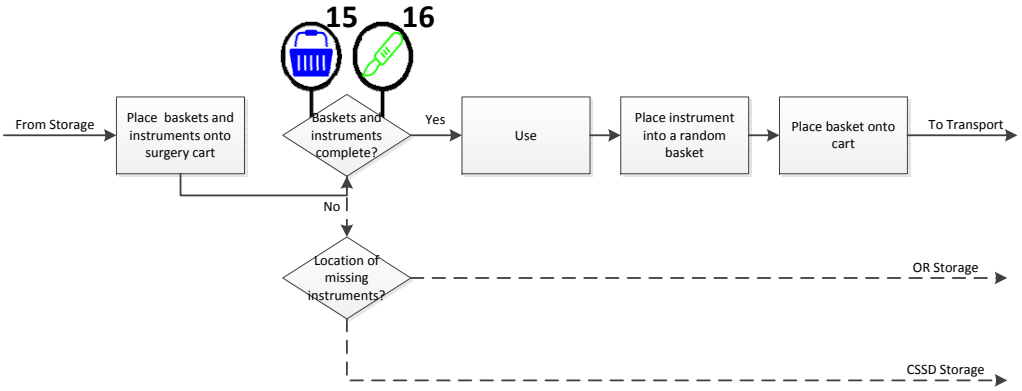


Figure B.9: Detail of use process

Before baskets and instruments are used they are identified by the OR staff (15, 16). This check includes the number and type of instruments that should be there, compared to those present. The baskets are identified using the labels on the packaging, instruments on operator knowledge.

Transport OR-CSSD (Figure B.10)
After surgery the used instruments have to be transported from the OR to the CSSD. The first task in this process is the separation of disposable from reusable instruments. After this the used reusable instruments are transported to the CSSD.

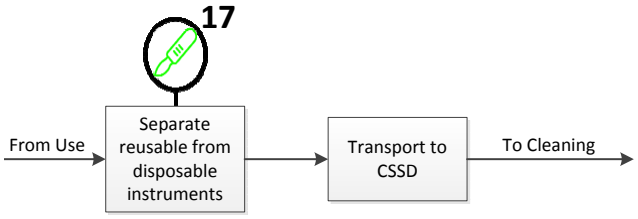


Figure B.10: Detail of transport from OR to CSSD

The identification of the reusable instruments takes place when they are separated from the disposable ones (17). Again, this is based on operator knowledge.

Appendix C

Description of evaluated baskets

A short description of the different baskets used in the various analysis is presented in this Appendix. The list of baskets from Plastic surgery (2077) is given in Table C.1. Table C.2 shows the included baskets for General surgery (2080) and Table C.3 discusses the analysed baskets of Transplantation surgery (2088). All Tables have the same format, the first column shows the basket code, the second column the name of the basket in Dutch and the third and last column states the number of baskets present in the LUMC.

Table C.1: Evaluated baskets of Plastic surgery (2077)

Code	**Description**	#
BT503	BASIS NET PLASTISCH	1
SA-0237	BOT INSTRUMENTEN NET	1
SA-0353	HANDZENUW INSPECTIE NET	1
SA-0428	NEUS CORRECTIE NET	3
SA-0773	AUGMENTATIE NET	1
SA-0835	ZAAG / BOOR NET MINI MET PERSLUCHTSLANG	2
SA-0838	ZAAG / BOOR NET MINI MET PERSLUCHTSLANG	9
SA-0842	DRIVER SET MINI MET ELECTRISCH SNOER	2
SA-0843	DERMATOOM SET ZIMMER	1
SA-0845	FIXATEUR MICRO VINGER NET HOFFMAN	1
SA-0847	AIR PEN DRIVE SYNTHES	1
SA-0848	LIPOSUCTIE NET	1
SA-0849	PALATUM SET	4
SA-0850	VELOFARYNGOPLASTIEK SET	1
SA-0851	GELAAT SET 2	1
SA-0853	GELAAT SET 1	1
SA-1415	LIPOFILLING SET	3
SA-1811	HANDFIXATIE SET	1
SA-1939	TANGEN SET HEMOCLIP MEDIUM 15 CM	2
SA-2141	COUPLER DEVICE SYSTEEM	1
SA-2142	SPERDER SET VLG KILLNER-DOUGHTY	2
SA-2192	ZENUW SET POLIKLINISCH	3
SA-2259	TANGEN SET HEMOCLIP MICRO	1
SA-2343	RETRACTOR KOUDLICHT MET KABEL	1

Table C.2: Evaluated baskets of General surgery (2080)

Code	Description	#
SA-1003	THORACOTOMIE SET	2
SA-1004	STRUMA SET	3
SA-1005	RIBRESECTIE SET	1
SA-1011	HAKEN NET RECTUM	2
SA-1020	HAKEN NET VLG DEAVER 7 STUKS	1
SA-1022	HAKEN SET DR DE LA MARRE	1
SA-1034	ACUUT NET	25
SA-1047	BASIS NET LAPAROSCOPIE AANVULLING	3
SA-1048	BASIS NET LAPAROSCOPIE EXTRA LARGE	1
SA-1086	BUIK NET	19
SA-1136	DERMATOOM II MESHCRAFT	2
SA-1164	BASIS NET LAPAROSCOPIE	9
SA-1165	BEENAMPUTATIE NET	3
SA-1173	DRIVER SET MAXI	1
SA-1174	GALBLAAS NET	1
SA-1175	KINDER NET	2
SA-1176	LEVERPERFUSIE NET	1
SA-1181	MAMMA NET	4
SA-1197	TEM CASSETTE NR 1 OPTIEKEN	1
SA-1198	TEM NET NR 2 RECTOSCOPIE	1
SA-1199	TEM NET NR 3 TANGEN	1
SA-1200	TEM NET NR 4 ARM	1
SA-1201	TEM NET NR 5	1
SA-1234	DILATATOR SET VLG HEGAR 11 T/M 26 MM	1
SA-1265	SETON SET	6
SA-1409	ENDOBOY NET	1
SA-1419	ZAAG NET STERNUM (OUD MODEL)	1
SA-1842	SCHAREN SET BIPOLAIR MET SNOER	2
SA-2196	SCHAAR BIPO MET KABEL TBV ENDO	1

Table C.3: Evaluated baskets of Transplantation surgery (2088)

Code	Description	#
SA-1158	TRANSPLANTATIE NET	2
SA-1040	TRANSPLANTATIE NET MICRO	1
SA-1162	TRANSPLANTATIE NET MICRO	1
SA-1150	INSTRUMENTEN SET MICRO TRANSPLANTATIE	1
SA-1896	INSTRUMENTEN SET MICRO TRANSPLANTATIE	1

Appendix D

Baskets in CSSD per hour

This Appendix will show the variability in the production and input of the CSSD. Raw data is obtained from T-DOC [Getinge AB, 2015] which is processed to the required format and analysed using Matlab [The MathWorks, Inc., 2014]. The data presented in this Appendix is from Monday the 2^{nd} of February 2015 up to and including Sunday the 8^{th} of February 2015 and from the 21^{st} of July. First the data from July is discussed to show the difference in the T-DOC data and more specified manual scanning data. Next an overview of the whole week in February is given, followed by a detailed presentation of a single day. Finally some parts of that day are highlighted to give a clear view of the process particulars.

Since July 2015 the OR returns the used baskets with a feedback form containing the different baskets used for each surgery. These forms are scanned at CSSD when the used instruments are delivered. In this way the exact input time of the baskets which leads to more accurate throughput time and production statistics. This procedure is still in the start-up phase, therefore the quality and completeness of the data is uncertain. In the documentation system of the CSSD the first scanning moment is when the employee commences the manual pre-clean of the instruments. From both the scanning moments measurements are available containing the number of baskets per hour, which are presented in Figure D.1. The x-axis gives the hour of the day and the y-axis the number of baskets processed in one hour. The blue bars show the arrival distribution of the first scanning moment that T-DOC can supply, the yellow bars the scanning results of the manual entry scan. Furthermore, the red dashed line gives the average input based on 24 hours for the T-DOC dataset, the dashed blue line the same for the manual scan.

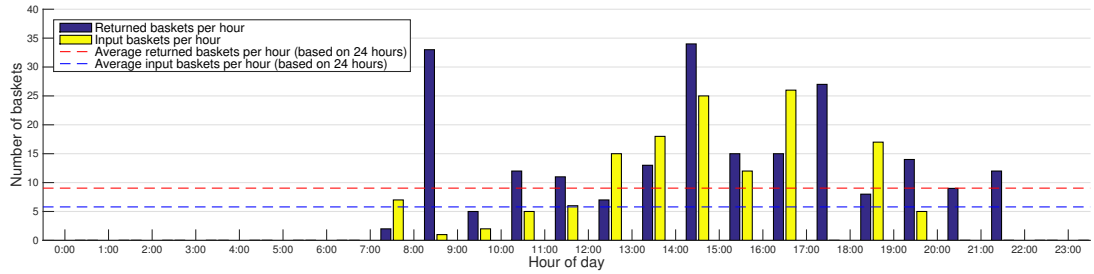


Figure D.1: Number of baskets per hour in the CSSD system for one week

There are differences in arrival distributions of the two measurement types given in Figure D.1. First the average number of baskets processed by the CSSD is according to the manual entry scan 5.8 $\frac{Baskets}{hour}$, whilst T-DOC returns 9.0 $\frac{Baskets}{hour}$. This difference is caused by the fact that T-DOC incorporates all the different baskets and sets entering the CSSD, including those from the polyclinics. The manual entry scan is only performed

for the baskets supplied from the OR, which is only a part of the input of the CSSD. This is the reason for the first blue peak at 08:00, the baskets and sets from the polyclinics are processed in the morning. The second blue peak is situated at 14:00, at this point the morning and evening crew are both working. The number of employees is twice as high, as well as the throughput. The third blue peak at 17:00 is not as high as the first two, and is accompanied by the lack of input baskets (yellow bar). No baskets are entering the system and therefore the employees at work can keep working on cleaning instruments. This causes an increase in production since they are not held up by moving and handling the arriving carts and baskets. Since the measurement data from T-DOC is more complete (polyclinics are taken into account as well), it is the basis for the further analysis of the production of the CSSD per hour.

Figure D.2 shows the total number of baskets in all the CSSD processes. This graph should not be mistaken with the output of the CSSD (end products), it gives a cumulative representation of all the baskets in the system at a certain hour. In this Figure the number of baskets in the systems is given by the blue bars. Two other graph entries can be seen, the red and blue dotted lines. These lines present the average number of baskets in production per hour and have been made for each day to show the differences in production on a daily basis. The red graph shows the average number based on the working hours of the same day, if there are 16 bars on a given day, the number of working hours is 16. The blue dotted line is the idealized number of baskets per hour, the average number of baskets assuming 24 hour per day operation.

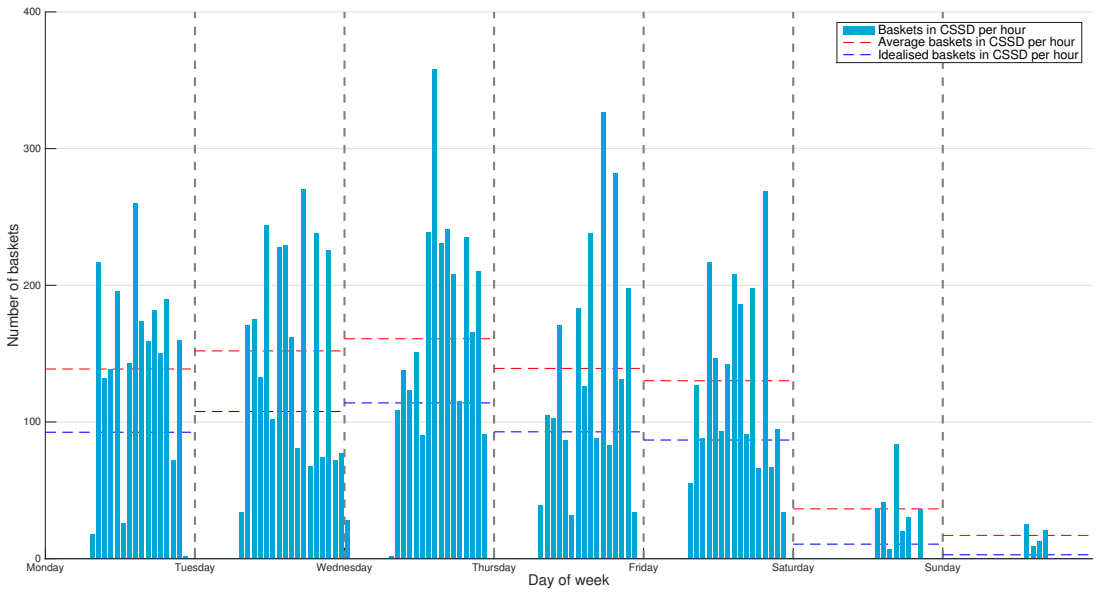


Figure D.2: Number of baskets per hour in the CSSD system for one week

Figure D.2 shows that the production of the CSSD is changing on a daily as well as hourly basis. It must be stated that the weekends should be excluded from this analysis, since the CSSD only processes the vital baskets and instruments during weekends. The number of employees is lower than on weekdays, and they work less hours. On Monday the average production is 138.75 $\frac{Baskets}{hour}$, on Tuesday 152 $\frac{Baskets}{hour}$, on Wednesday 160.88 $\frac{Baskets}{hour}$, on Thursday 139.19 $\frac{Baskets}{hour}$ and on Friday 130.19 $\frac{Baskets}{hour}$. Which leads to an average number of baskets production of 144.20 $\frac{Baskets}{hour}$. This average value is only valid for the given date range, the dataset is not large enough to be applicable for a longer time period. When considering a single day the erratic behaviour of the number of baskets in production is enlarged. On some days the peaks are in the morning and evening, other days show a afternoon increase in production.

The data given in Figure D.2 shows that the variability in number of baskets in production is rather large on a daily basis. This applies for the weekly trend as well, there can be significant differences between the different days of the week, even when the weekends are excluded. A detailed overview of Wednesday from Figure D.2 is presented in Figure D.3 (page 171). Each of the bars are representing the number of baskets in production at that hour. A differentiation is made in the group the baskets belongs to. The following groups can be found in Figure D.3:

Packaging	Baskets that are being packaged
Sterilization	Baskets that are being sterilized
Distributed	Baskets that have been distributed to the OR
Returned	Baskets that have been returned from the OR
Pre-clean	Baskets that have undergone pre-cleaning
Pre-disinfection	Baskets that are being disinfected
Post-disinfection	Baskets that have been disinfected
Cancelled	Baskets that have been cancelled
New	Baskets that have been created

Some of these groups give a better view into the actual production of the CSSD. These are: *1.Pre-disinfection*, these baskets are entering the disinfection stage and relate to the number of baskets delivered to the CSSD. *2.Post-disinfection*, after disinfection two things can happen to the baskets, they are processed straight away or the are put in a buffer. Using the number of baskets in pre-disinfection the number of baskets that are placed in storage van de estimated. *3.Packaging*, all baskets that are send to the OR have to be packaged, after packaging these baskets can be processed immediately or put in a buffer. *4.Distributed*, baskets that are distributed are available for use by the customer. It is the actual production of end products by the CSSD per hour. These four groups are presented in Figure D.4 (page 171), for Wednesday.

In Figure D.4 the number of baskets in the systems is given by the blue bars. Two other graph entries can be seen, the red and blue dotted lines. These lines present the average number of baskets in production per hour. The red graph shows the average number based on the working hours of the same day, if there are 16 bars on a given day, the number of working hours is 16. The blue dotted line is the idealized number of baskets per hour, the average number of baskets assuming 24 hour per day operation.

Top graph: Pre-disinfection
Baskets that are in the pre-disinfection phase are to be disinfected in a short while. This means that these baskets have been used before that by the OR. There are various peaks to be seen in the number of baskets in this category, the first (between 9 and 10) is caused by the delivery of baskets from the polyclinics, later peaks come from batch deliveries of baskets from the OR. The average number of baskets in the system is 33.35 (based on working hours) and 19.46 for a 24 hour per day operation.

Second graph: Post-disinfection
After the baskets are disinfected they are released for further handling in the CSSD. The post-disinfection phase lags pre-disinfection by roughly one hour. This is explained by the process time of the washing machines, which is one hour as well. There are however some side notes to be placed by this comment when taking a closer look. Primarily the post-disinfection processes baskets before pre-disinfection is started, which can be explained by left-over baskets from the day before. Secondly some of the peaks in pre-disinfection do not show the next hour on post-disinfection. This is caused by the exact process time of the washing machine which is slightly over one hour, and can be longer for certain programs. Another reason could be the reprocessing of disinfection batches when something goes wrong during the disinfection process. This is supported by the average number of baskets in the system, which is 28.763 and 19.08 for a 24 hour per day operation. The post-disinfection phase has got more working hours, therefore the average number of baskets is not very useful. The idealized number of baskets shows that there are more baskets in pre- than in post-disinfection. As stated above this can be caused by reprocessing or leaving the last batch for the following day.

Third graph: Packaged baskets
The number of packaged baskets per hour shows a very large variation over the day. At 14:00 nearly 100 baskets are processed, while average number of baskets in the system is 27.93 (based on working hours) and 17.46 for a 24 hour per day operation. Between 14:00 and 16:00 both the morning and evening crew are at work, which means more baskets that are processed.

Bottom graph: Distributed baskets
The distributed baskets leave the CSSD and are send to the OR. On average 30.58 baskets per hour are distributed (based on working hours) and 15.29 for a 24 hour per day operation. The sterilization process takes one and a half hours to complete, which can be is shown by the lag between packaging and distribution. The large peak of packaging at 14:00 is processed at 16:00. There are fewer baskets distributed than packaged, there could be two reasons for this. The baskets that are packaged in the evening are placed in a buffer to be finished the next day. The second cause is could be data inconsistencies. The number of distributed baskets is determined by the input provided before sterilization. The different baskets are scanned and placed in a batch in T-DOC. When something goes wrong in this process the basket is not assigned to the batch and is not distributed after sterilization.

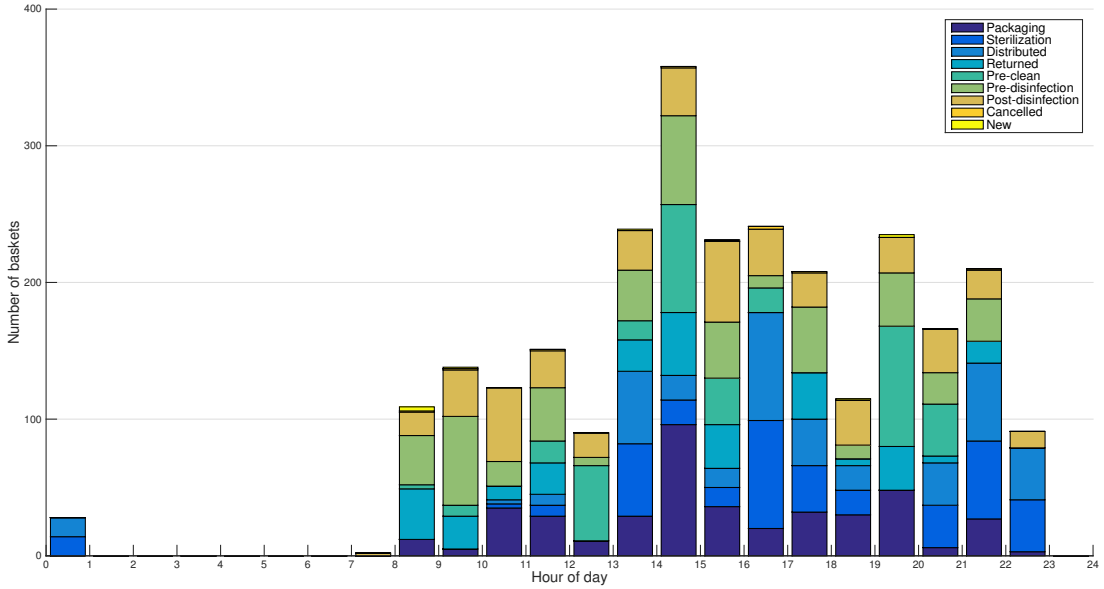


Figure D.3: Number of baskets per hour in the CSSD system for Wednesday

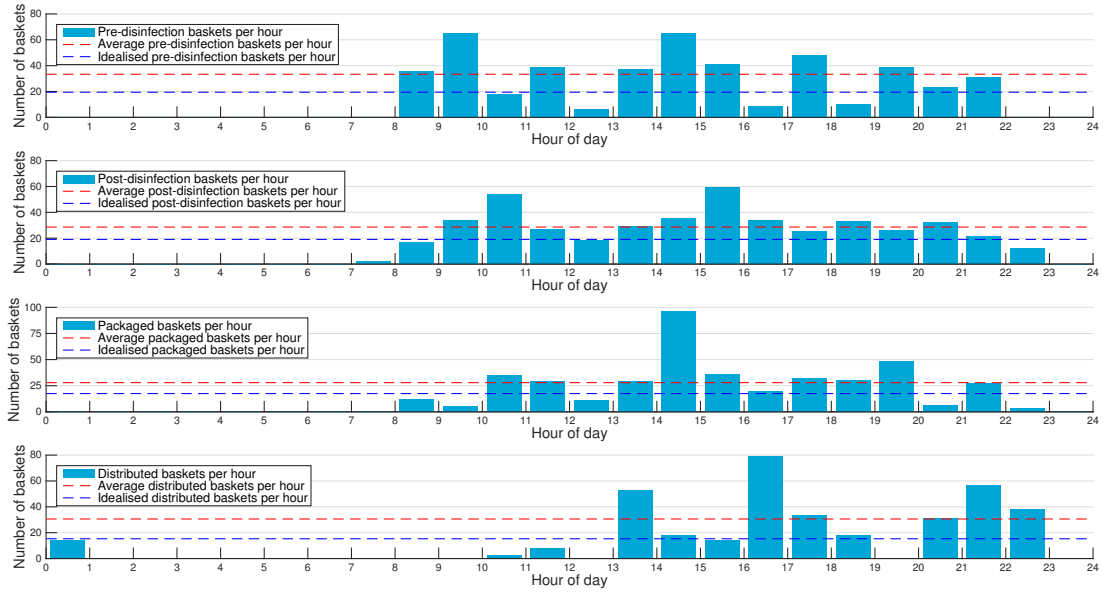
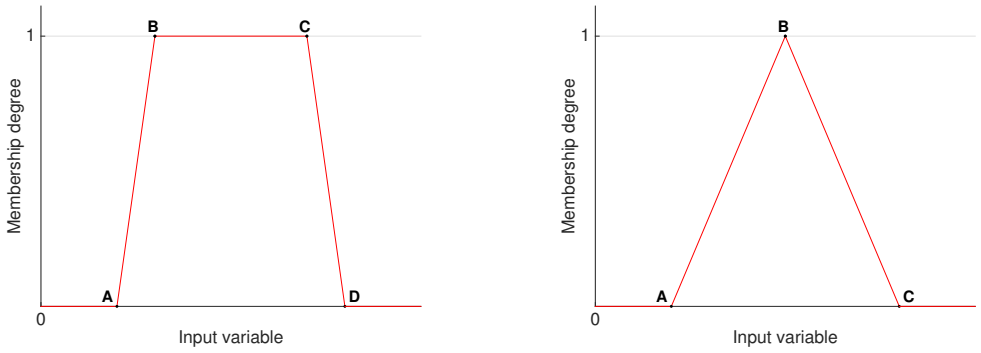


Figure D.4: *Top:* number of baskets at pre-disinfection point per hour, *second:* number of baskets at post-disinfection point per hour, *third:* number of baskets at packaging point per hour, *bottom:* number of distributed baskets per hour

Appendix E

Fuzzy Logic Controller

A FLC is a logic based control system, analogous input variables are transformed into output variables via analysis of logical statements. The value of the logical statements can range form 0 to 1, on a discrete basis, not only true or false as is the case with standard logic systems. The input and output variables of a FLC is described by multiple values. These are in general linguistic values such as *fast*, *slow*, *high* or *low*. The different values are represented with Membership Functions (MFs). The MF represents the degree of truth as a value, ranging from 0 to 1 and can be all possible values on the domain of the input variable [Zadeh, 1965]. Two different MF shapes are presented in Figure E.1: the trapezoidal and triangular shape[1]. This Figure gives the generic representation of the MF shape, with the parameters A, B, C and D (the triangular shape does not use parameter D). The shape of the different MFs values of the input and output variables are shown according to these four parameters. Each input or output variable is therefore represented as multiple MFs, each spanning part of the domain of the input variable. It is not necessary for complete coverage of the entire domain, which makes fuzzy logic discontinuous when needed. The different MFs do allow for overlap in values. In linguistic terms overlap in values would mean that something is not large or small, but somewhere in between: large and small are true to some degree: the membership degree.



(a) Trapezoidal shape (trapmf) **(b)** Triangular shape (trimf)

Figure E.1: Membership functions

The FLC computes the output variable from the input variables via a set of rules. These rules are logic statements, which link one or more input values of variables (i.e. speed is *fast*) to an output value (i.e. time is *short*). The resulting outputs from all the rules is used to compute the final result. The different FLCs used in this research are described next.

[1]Various other shapes are possible, but are not used for description of the values in this research.

Relative Demand Volatility

The RDV is determined for each basket in the analysis using a FLC. The inputs of this controller are the 1^{st} quartile stock time (hours), 2^{nd} quartile stock time (hours) and the usage factor (use days in one year). The MFs shape description of the inputs and outputs is given in Table E.1. The parameters describing the different values are calculated using the distribution of the stock time of all baskets in the analysis. This distribution gives the mean and STD of the stock time which is used to describe the turn around speed of the basket. When the time in stock of the basket is lower than $\mu - \sigma$ it is fast moving, when it is higher than $\mu + \sigma$ it is slow. From these values the MF is monotonically decreasing to the mean value of stock time. Between these two values are the medium speed baskets, which are overlapped by the fast and slow baskets. The peak of medium speed baskets is at the mean, and is monotonically decreasing to the $\mu \pm \sigma$. The usage factor is based upon the number of days a basket is used, and can be low, medium or high. If a basket is used less than 5 days a year the usage factor is low, between 50 and 200 days medium and above 260 high. These numbers are obtained from the number of business days in a year, which is 260. Between the values there is a transition area, where the usage factor can be medium and low or fast. The RDV can either be low (0-1) or high (1-2) and is based on the seven rules given in Table E.2.

Table E.1: Input variable membership functions of RDV FLC

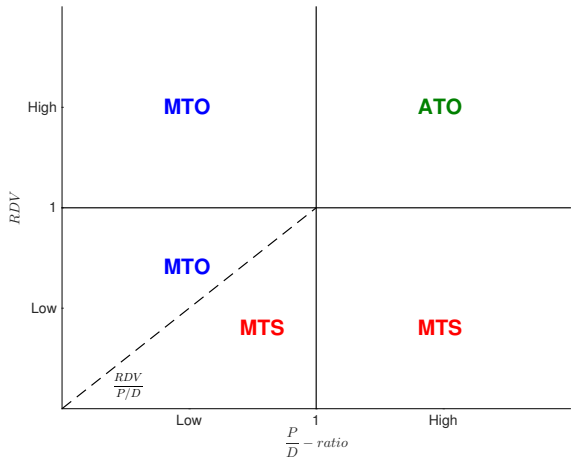
Name	Shape	A	B	C	D
Input: Stock time 1^{st} quartile					
Fast	trapmf	0	0	50	200
Medium	trimf	50	200	1372	-
Slow	trapmf	200	1375	9000	9000
Input: Stock time 2^{nd} quartile					
Fast	trapmf	0	0	120	357
Medium	trimf	120	357	5537	-
Slow	trapmf	357	5537	9000	9000
Input: Usage factor					
Low	trapmf	0	0	5	50
Medium	trapmf	5	50	200	260
High	trapmf	200	260	365	365
Output: RDV					
Low	trapmf	0	0	1	1
High	trapmf	1	1	2	2

Table E.2: Rules of RDV FLC

1. (Q2==fast) & (usage==high) => (RDV=Low)
2. (Q2==fast) & (usage==medium) => (RDV=Low)
3. (Q2==average) & (usage==high) => (RDV=Low)
4. (Q2==slow) | (usage==low) => (RDV=High)
5. (Q1==fast) & (Q2==average) & (usage==medium) => (RDV=Low)
6. (Q1==average) & (Q2==average) & (usage==medium) => (RDV=High)
7. (Q1==slow) & (Q2==average) & (usage==medium) => (RDV=High)

Customer Order Decoupling Point

The CODP and corresponding production strategy is based upon a FLC as well. Each basket is analysed on two aspects, the RDV discussed previously and the $\frac{P}{D}$ ratio. The relationship between the RDV, $\frac{P}{D}$ ratio and production strategy is graphically represented on the left side of Figure E.2. The The MFs shape description of the inputs and outputs is based on this Figure and given in Figure E.2 on the right side. A third input variable is added to the FLC in order to describe the production strategy when both RDV and $\frac{P}{D}$ ratio are low: the $\frac{RDV}{P/D}$. When this ratio is larger than 1, the strategy is MTO, lower than 1 results in a MTS strategy. The five different rules the CODP FLC is subject to are presented in Table E.3 and is based on Figure E.2 as well.



Name	Shape	A	B	C	D
Input: P/D					
Low	trapmf	0	0	1	1
High	trapmf	1	1	10	10
Input: RDV					
Low	trapmf	0	0	1	1
High	trapmf	1	1	10	10
Input: RDV/(P/D)					
Low	trapmf	0	0	1	1
High	trapmf	1	1	100	100
Output: CODP					
MTS	trapmf	0	0	1	1
ATO	trapmf	1	1	2	2
MTO	trapmf	2	2	3	3

Figure E.2: *Left:* Effect of RDV and $\frac{P}{D}$ ratio on production strategy; *Right:* Input variable membership functions for CODP FLC

Table E.3: Rules of CODP RDV

1. (P/D==low) & (RDV==low) & ($\frac{RDV}{P/D}$==low) => (CODP=MTS)
2. (P/D==low) & (RDV==low) & ($\frac{RDV}{P/D}$==high) => (CODP=MTO)
3. (P/D==low) & (RDV==high) => (CODP=MTO)
4. (P/D==high) & (RDV==low) => (CODP=MTS)
5. (P/D==high) & (RDV==high) => (CODP=ATO)

Appendix F

Reduction of dead stock

Dead stock in the sterile storage facility of the LUMC is the excess stock of baskets that is not needed when regarding the historical demand. Removing these baskets from operation will result in a higher usage factor of the remaining baskets and thus a decrease in stock time. Reduction of dead stock is only feasible when two boundary conditions are met:

1. There have to be multiple copies of basket type;
2. There has to be excess capacity.

The first boundary condition can be obtained from Appendix C, the different baskets included in the analysis are shown with the number of copies is the last column. The second condition follows from the analysis of the cycle time given in Section 2.2. The date stamp of the measurements is used to determine the number of times a basket is used on a day, for each basket type. The result of this analysis for two baskets is given in Figure 6.1, which is based on measurements of 2014. Figure 6.1 presents the usage profile of all 24 baskets with multiple copies.

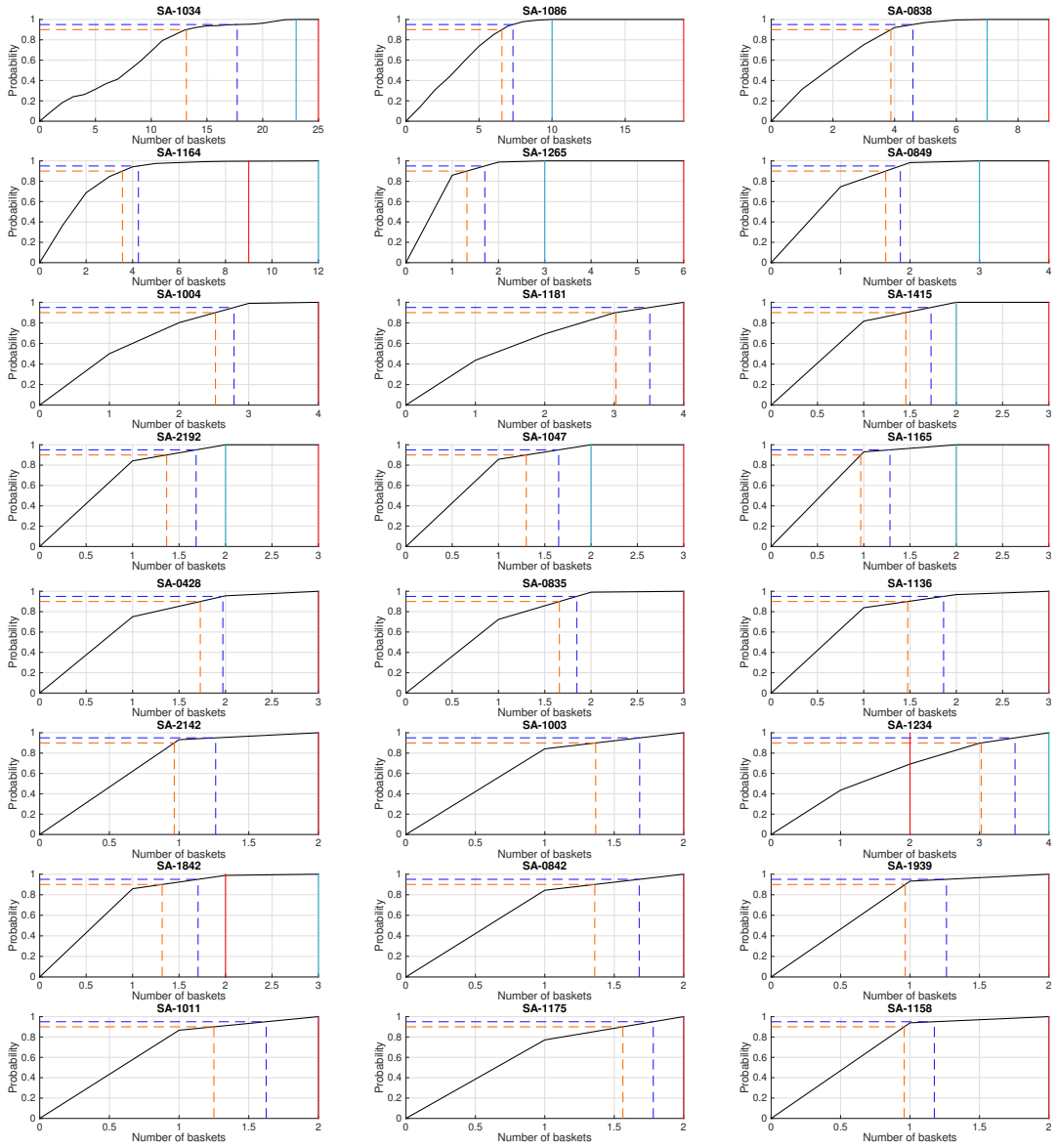


Figure F.1: Usage profile of baskets with multiple copies

Appendix G

Discrete Event Simulation model

The models of the current operation and future situation are made using DES tool SimEvents of graphical programming environment Simulink 8.4 [The MathWorks, Inc., 2014]. Figure G.3 presents the model of the current operation, Figure G.4 of the future situation with the simplified MRPII system. The general description and simplifications that apply for both systems are discussed first.

General description
Both models have an internal clock which ticks at a speed of one hour. To ensure a high level of detail the step size is 0.01 hour. At start of simulation the different baskets are generated that can be used during the simulation, this does not change during the simulation. Five different basket types are generated, which belong to the same number of surgeries. The surgeries are provided by a second generator. Six surgery request, which are called orders in the models, are generated every day (24 hours). During generation three different characteristics are assigned to the orders, the surgery type, whether it is an acute surgery and the time the surgery will take. The probability of occurrence of the five surgery types is given in Table G.1. 10% of the surgeries generated is acute, regardless of surgery type and time.

Table G.1: Probability of occurrence per surgery type

Type 1	40%
Type 2	30%
Type 3	15%
Type 4	10%
Type 5	5%

The surgery time is obtained from the Beta distribution presented in Figure G.1 by the red line, the mean value is given by the dashed red line. Besides the distribution data, the actual recorded surgery times for one week is given by the blue lines, which is based upon 145 measurements. As can be seen in Figure G.1 there is a slight difference in mean values of the actual recording and the used distribution and the overall beta distribution does not follow the actual recording precisely. However, the differences are small and the error introduced will not affect the outcome of the comparison, since both the current and future DES model use the same distribution as input.

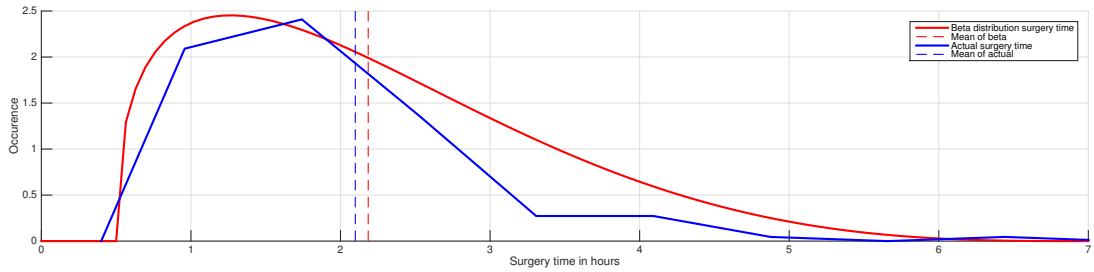


Figure G.1: Beta distribution of the surgery time (min=0.5, max=7, a=1.4, b=4)

The time required for cleaning and packaging is obtained from the Beta distribution presented in Figure G.2. The same distribution is used for cleaning and packaging, since the operators perform similar actions during these steps. At cleaning the instruments are taken out of the baskets on a individual basis and are manually cleaned, after which they are placed in another basket. Afterwards the baskets enter the pre-clean stage. During packaging the clean instruments are taken from the disinfection baskets and placed in the correct basket for sterilization. The completed basket is packaged afterwards. Besides the processing time there are two downtimes connected to the cleaning and packaging process, before and after handling. Table 2.3 presented an detailed overview of the cycle time for an Acute basket. The minimum time required for packaging obtained from Table 2.3 is roughly half an hour, which is the minimum of the distribution. The other characteristics of the distribution is not based on this data.

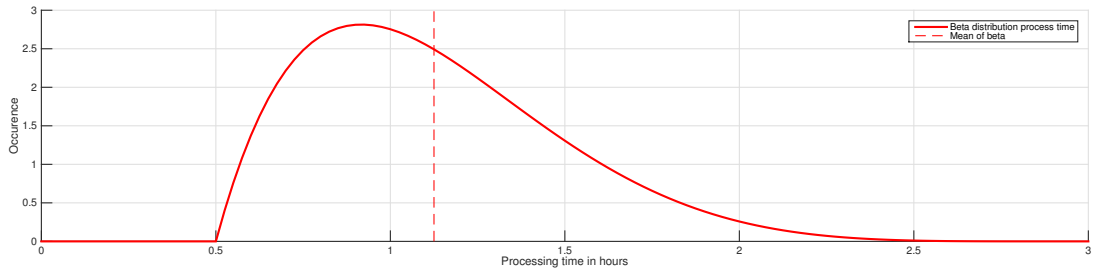


Figure G.2: Beta distribution of the cleaning and packaging time (min=0.5, max=3, a=4, b=10)

The values of the characteristics of the surgeries generated during simulation are based on a Random Number Generator (RNG). The seeds of these RNGs are predefined and the same for both models. Both the current situation and future operation will process exactly the same orders with the same characteristics. Thus the results of the two models can be compared to each other, since the input is the same.

Simplifications
The sterilization cycle of the LUMC is very complex. There are nearly ten thousand different instrument types, a thousand different baskets and these can be used in any combination during surgery. A model consisting of all these variables will become too difficult and the results can not be processed properly. Therefore only five different surgeries are taken into account, which use one basket each.

The OR complex of the LUMC consists of 20 different rooms. Taking multiple ORs into account adds complexity to the model, but does not impose any large changes to the results. Only the number of surgeries generated and therefore the number of baskets will increase.

The single OR can not handle the number of surgeries performed on a daily basis in the LUMC, less surgeries are planned on a day. Just six surgeries are generated on a daily basis.

Corresponding with the the single OR and the six surgeries on a daily basis, the batch sizes used for the different processing steps (disinfection and sterilization) can not be maintained. The simplification is that there are six washing machines and six autoclaves, which handle one basket each. Even in the worst case scenario the capacity is sufficient to process everything. The processing time of the equipment is the same as the actual operation.

The last simplification is that there are no disturbances other than the acute surgeries. The actual operation of a complex process is prone to disturbances such as amongst others breakdowns of equipment and defected products. These are not taken into account in the simplified model. The model represents the ideal, steady-state operation of the CSSD and OR.

Current situation model
The model of the current situation shown in Figure G.3 consists of eight different processes. The purpose of the different processes is discussed in next.

Basket Generator:
At initiation of the simulation the baskets used during the course of events are generated. Each different basket type has got a fixed number of copies, which does not change during simulation.

Order Generator:
The surgery requests (order) are generated, six order for every 24 hours. The different characteristics are assigned to the orders.

Schedule:
The orders that are generated are placed in a priority queue in the scheduling process. The priority of the schedule is based on whether a surgery is acute or not. Acute surgeries are placed in front of the queue, whilst planned surgeries are processed based on their entry position (FIFO).

Sterile Storage:
The generated baskets are stored in the sterile storage. The baskets are stored in a FIFO queue for each type.

Combine, OR, Delete Order:
These processes are nothing more than their name indicates. In the OR there is a single server that processes the surgeries. The processing time is obtained from the surgery time characteristic, which is part of the order (Figure G.1).

Cleaning & Disinfection:
The used baskets from the OR are cleaned and disinfected in this process block. There are two servers that perform the processing, the first is server cleans the baskets. The service time of this server is based on the distribution shown in Figure G.2. The second server represents the washing machine, and has a service time of one hour.

Packaging & Sterilization:
The packaging & sterilization process is nearly identical to the cleaning & disinfection process. The only difference is the time required for sterilization, which is 2 hours.

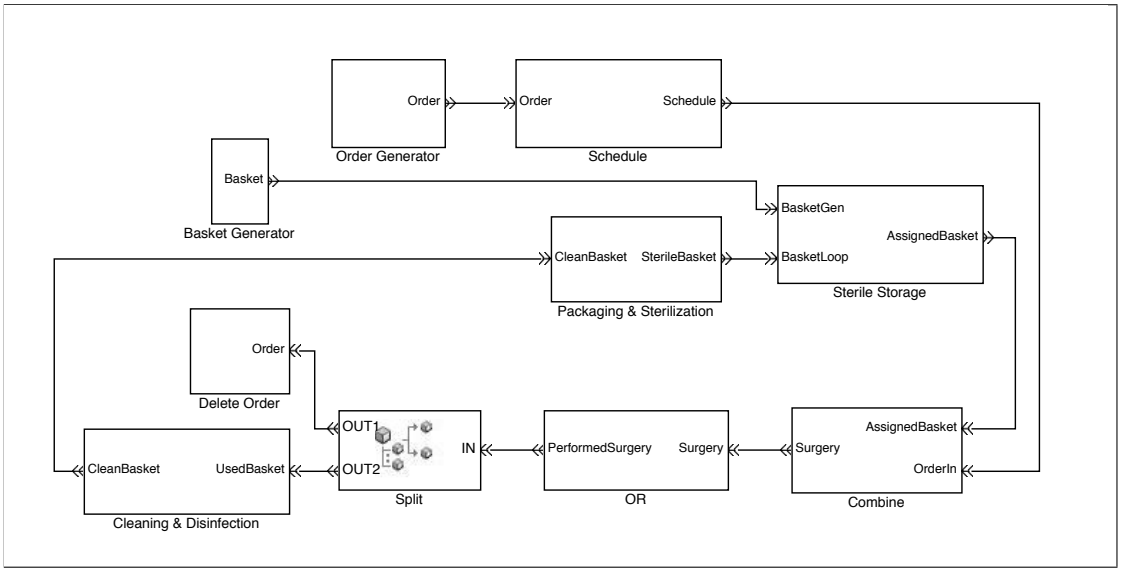


Figure G.3: Simulation model overview of the current situation

Future operation model
The future operation model uses most of the same processes as the current situation and is shown in Figure G.4. The main difference is the addition of the Clean Storage in between the Cleaning & Disinfection and Packaging & Sterilization processes and the addition of various data flows. From the Schedule process a flag for a Planned or Acute surgery is forwarded into the Storage processes of the main loop. Besides the addition of the Clean Storage, the Schedule and Sterile Storage processes have changed. These three processes will be discussed next. The processes that have not changed compared to the current model are not mentioned.

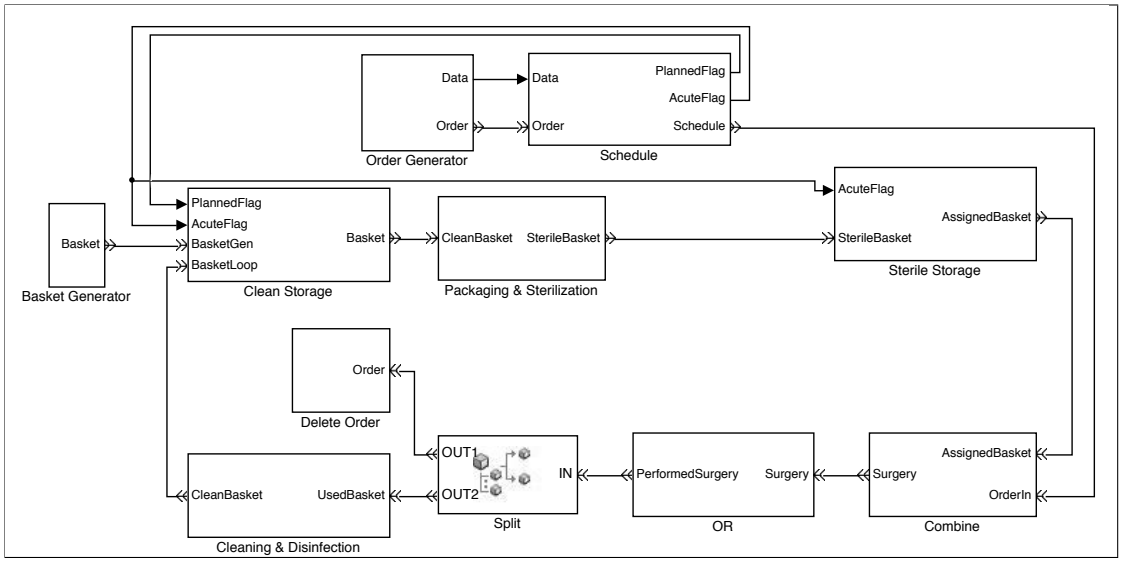


Figure G.4: Simulation model overview of the future operation

Schedule:
The Schedule process of the future operation is shown in Figure G.5. The orders that are generated are fed into the process at the left of the model. They are split into two flows, the acute and planned surgeries. The acute surgeries travel through OUT2, where after the sub process RequestAcute generates an Acute surgery flag. The planned surgeries travel through OUT1, are processed by an server, where after they enter the RequestPlanned process, which generates an Planned surgery flag. After that there is a second server. Both acute and planned surgeries are combined and put into a priority queue which is the same as in the current situation model. After the priority queue an enabled gate is used to control the flow of surgeries into the model. Subsequently the service time of the order is obtained from the order that advances into the system.

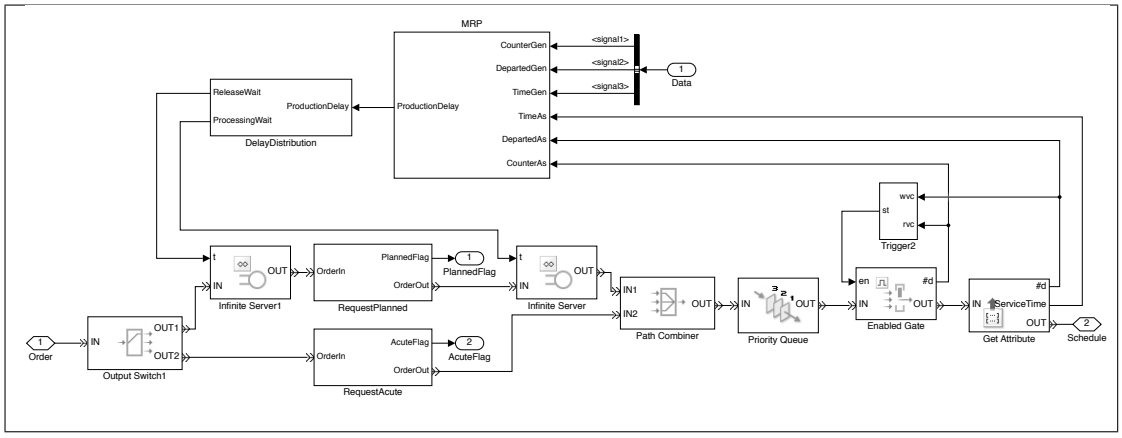


Figure G.5: Future operation Schedule process

A MRP system is used for the control over the scheduling process. It uses various data on the service time of the orders and the number of orders in the queue to come to a feasible schedule. The output of the MRP is the production delay. The planned surgeries are delayed by a number of hours before they are release and the Planned surgery flag is generated. The delay time is fed into the first server of the planned surgery flow path.

The expanded version of the MRP process is presented in Figure G.6. There are six inputs, three from the order generation (two counters and the service time) and three from within the Scheduling process, the departure data (two counters and the service time as well). The MRP system calculates the cumulative sum of the service time of all generated orders and stores in a memory. The same is executed for the service time of the departed orders. The production delay is the output of the MRP system, which is calculated from these two cumulative service times, by subtracting the departed sum from the generated sum. This gives the sum of the service time of all the surgeries present in the priority queue at all time. As described above this production delay is used to postpone the release of the planned surgeries and thereby the generation of the Planned surgery flag.

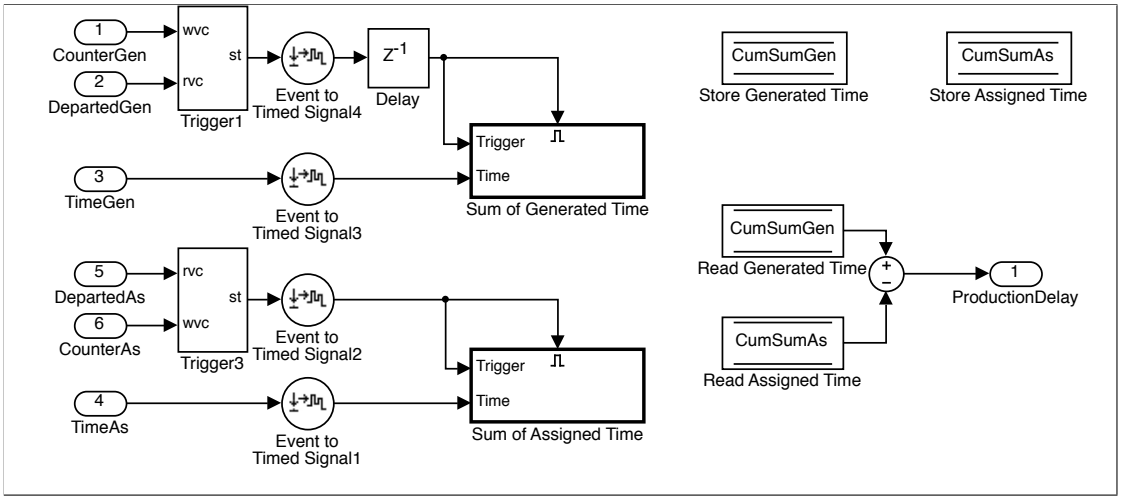


Figure G.6: MRP sub process

Clean Storage:
The Clean Storage is the main inventory of baskets in the future model, it is presented in Figure G.7. The baskets from the Basket Generator and from within the loop are combined at entry of the storage. They are subsequently distributed over different queues based on basket type. These queues have a second input, a production flag, which is based on the Planned and Acute surgery flag from the Schedule process. The production flag is generated when a Planned or an Acute surgery order is released in the Schedule process. The queue sub-process for a Type 1 basket is given in Figure G.8. The baskets are stored in a FIFO queue with infinite capacity. When a production flag is generated for a Type 1 basket the Release Gate is opened and one basket is released.

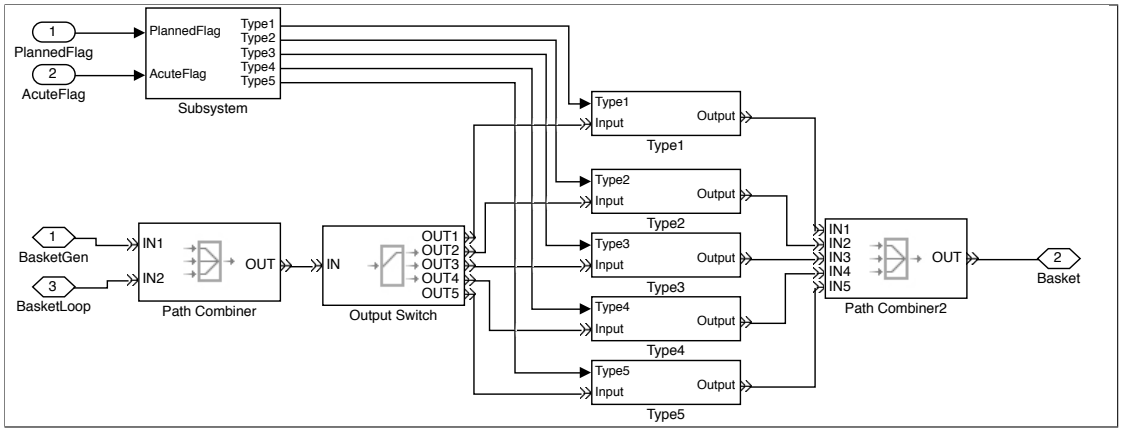


Figure G.7: Future operation Clean Storage

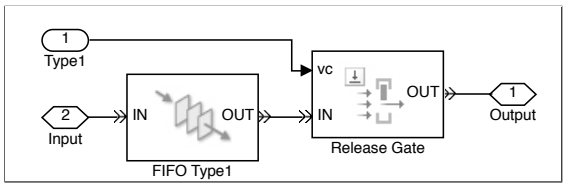


Figure G.8: Detail of Type 1 basket Clean Storage

Sterile Storage:
In the future operation the Sterile Storage has been reduced from the main inventory to a temporary storage and safety stock location. An overview of the different process blocks in the Sterile Storage process is shown in Figure G.9. The main functions are similar to those of the Clean Storage, the baskets entering the Sterile Storage are distributed over different queues based on basket type. These queues have a second input, the Acute surgery flag. This is not a production flag as was the case with the Clean Storage, but merely a release flag. How this release flag is used is shown in the queue sub-process for a Type 1 basket, which is presented in Figure G.10. The input baskets are placed in one of two queues, the Acute Type 1 queue has a capacity of a single basket, the Planned Type 1 queue can hold an infinite number of baskets. Whether the baskets enters the Acute or Planned queue is depended on the number of baskets in the Acute queue. If the Acute queue is empty it will always be replenished first, when full the Planned queue is filled.

After the Acute queue a Release Gate controls the release from this queue. Only when the Acute surgery flag for a Type 1 surgery is given the gate is opened. This is a safety stock location that ensures that a Type 1 basket is always available for use when an Acute surgery has to be performed. The baskets for the planned surgeries are stored in the Planned queue until they are ready to be processed in the OR.

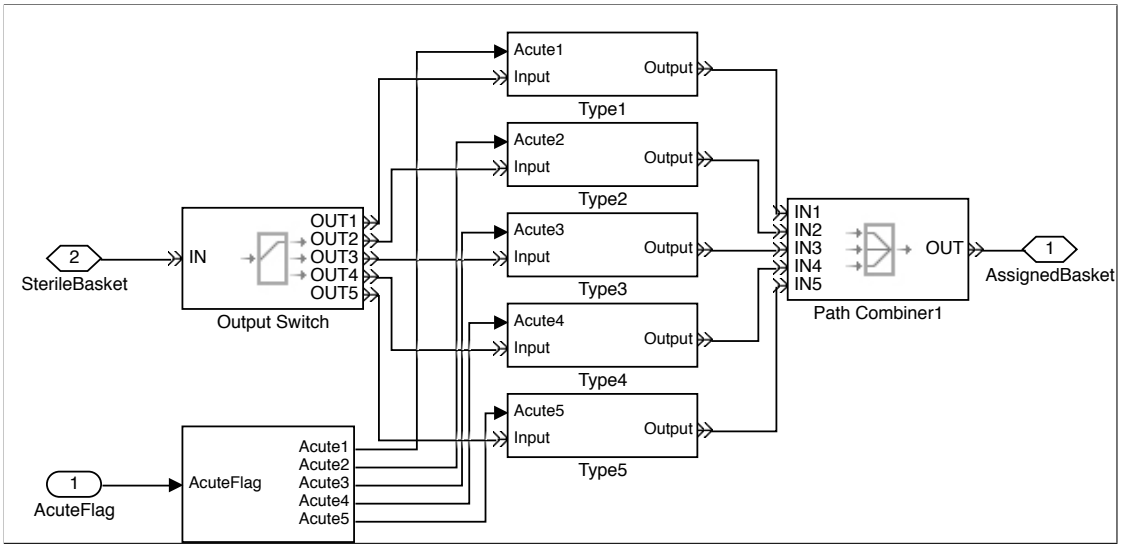


Figure G.9: Future situation Sterile Storage

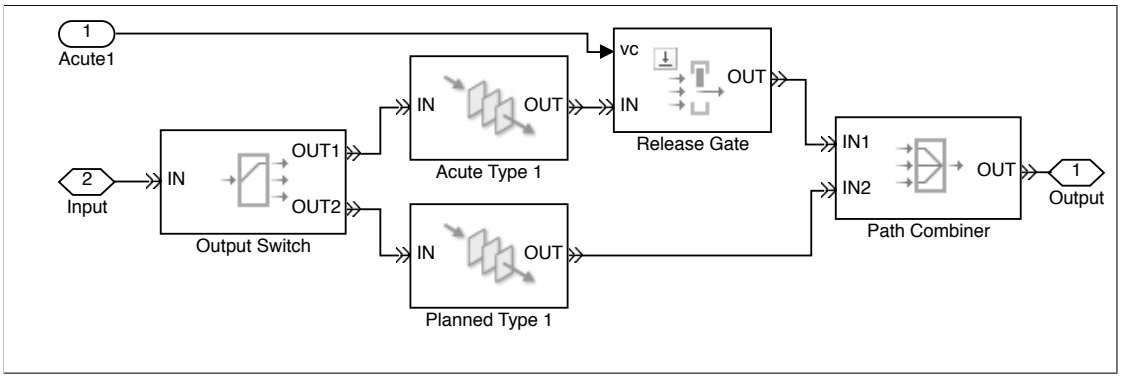


Figure G.10: Detail of Type 1 basket Sterile Storage