Cleaning of hollow instruments
Graduate Study

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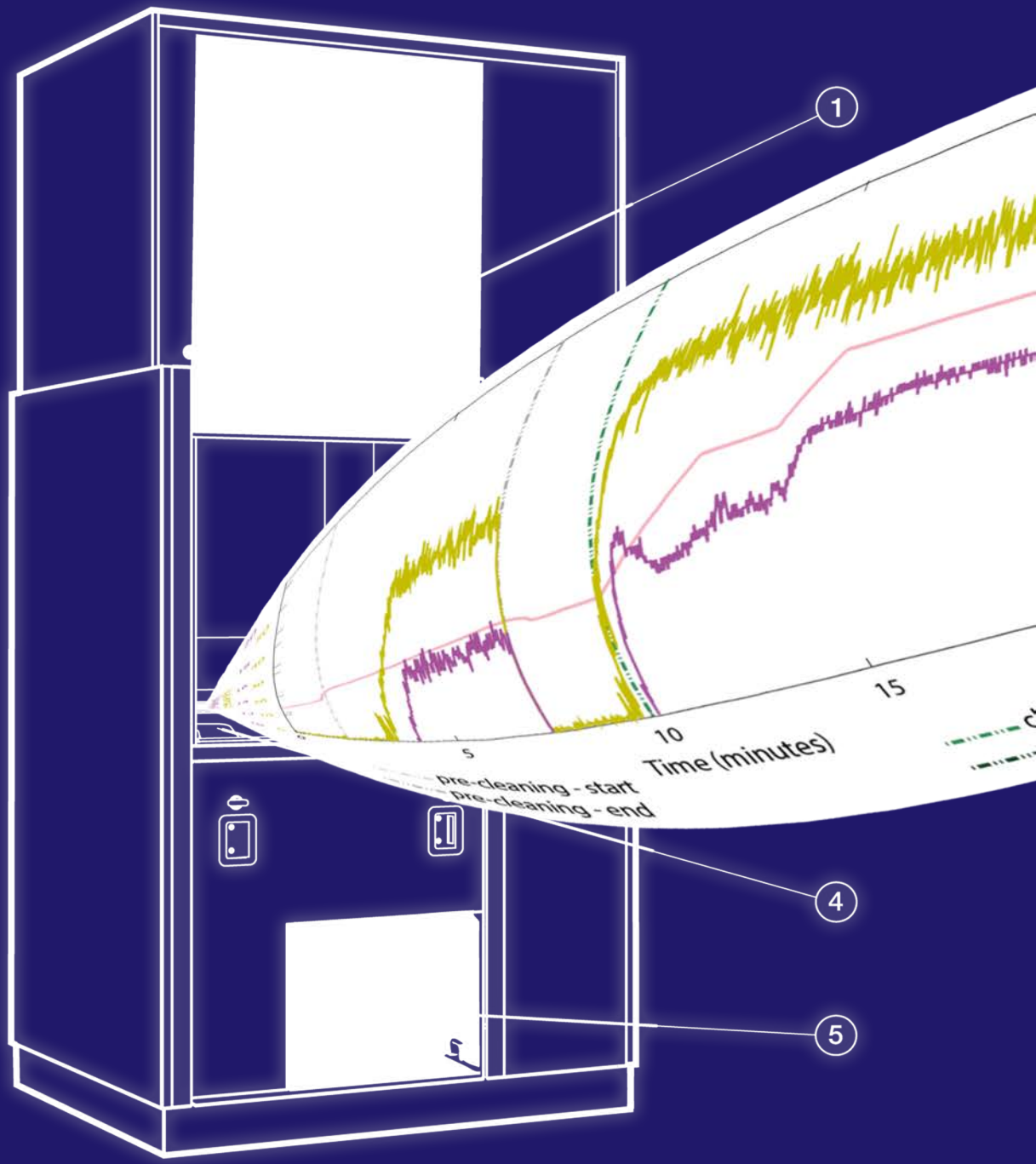

TU Delft Delft University of Technology

Erasmus MC University Medical Center Rotterdam

Challenge the future

CLEANING OF HOLLOW INSTRUMENTS

GRADUATE STUDY

by

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Main conclusion of this study:

To clean hollow instruments, the following aspects must be maintained:

1. **The rinsing of hollow instrument with sufficient flow, pressure and turbulence.**
2. **Connecting of the hollow instruments by the staff at the CSSD**
3. **Maintenance of cleaning applications, so that cracks, blockages and leakages can be prevented**

These issues are rarely encountered in practice and also not noticed. To improve the current situation it is important that: The employees at the CSSD have to recognize the importance of correctly connecting hollow instruments. Sufficient connections are needed to connect all hollow instruments. And furthermore, the flow and pressure of the cleaning flow through instruments need to be monitored.

SUMMARY

Since a few decades, the use of Minimally Invasive Surgical (MIS) instruments has increased very fast. Minimally Invasive Surgery uses much smaller incisions compared to the traditional open surgery. The procedure is less invasive than open surgery and there is minimal damage to biological tissues at the point of entrance of the instrument. This results in a quicker healing for the patients and a shorter hospital stay. The downside of these reusable MIS instruments is that they are more difficult to clean than conventional surgical instruments. MIS instruments consist of mostly narrow channels and therefore they are also called hollow, or cannulated instruments. Narrow channels are ideal places for human tissues, residuals and bacteria to nestle. This offers a challenge to the Central Sterile Supply Department (CSSD) in cleaning these instruments on the outside as well as on the inside. During the automated cleaning process, hollow instruments are rinsed on the inside in a washer-disinfector. In order to make this possible, these instruments have to be connected to the washer-disinfector.

The aim of this study is to get more insight into the cleaning performance of several cleaning applications for hollow instruments based on their mechanical performances, expressed as flow and pressure through an instrument. A cleaning application is a device that connects a hollow instrument to the washer-disinfector. At present there are several applications and cleaning methods available without the knowledge for which instruments they are most suitable, and what their effect is on the cleanness of the instrument. In this study a comparative analysis is made of cleaning applications of hollow instruments at the CSSD. The study is limited to the first phase of the decontamination process; the cleaning process. This study focuses on the mechanical performance (flow and pressure) of a cleaning application. The mechanical performance was recorded by a measurement system that was able to measure flow, pressure and temperature in eight separate channels at the same time. The study consists of four sub studies; each study is worked out as a separate study.

In the first study a comparison is made of several commercially available cleaning applications. A cleaning application or insert differs in design, number of connecting possibilities and way of connecting to a mobile unit. The flow and pressure performances are determined for each output channel of an insert. Furthermore, the effect of connecting instruments to an insert is determined. Different dummy instruments are used to investigate if a connected instrument has an effect on the mechanical performances in an adjacent connecting possibility. All the tested inserts showed a more or less uniform flow distribution among the adapters. That means that all the adapters have an equal flow and pressure and that the position of an adapter has no effect. However, it is important that the insert is connected correctly, allowing for a sufficient input flow. Connected instruments have hardly any effect on the flow in the adjacent adapters. That means it does not make much of a difference if an instrument with a large diameter and little resistance is situated adjacent to a narrow lumen with high resistance.

Roughly, there are two ways to connect the instrument to an insert, a contact or contactless connection. A contact connection means that the instrument has to be pushed into a silicone holder in the insert. This contact adapter has the disadvantage that the outside of the instrument tip is enclosed by the holder, therefore the tip cannot be cleaned properly. A contactless connection is like an injector nozzle, the instrument has to be placed close to the nozzle. This means no contact between the instrument and the nozzle, and results in better cleaning. This study makes a comparison between the contact and contactless adapters based on the mechanical performance. This study has shown there is a significant difference in flow and pressure of an contact vs. a contactless connection. There is a pressure and flow loss in an contactless connection between adapter and instrument. Therefore there was no measurable flow or pressure in the contactless setup. This result is a cause for concern, because it could be that there is hardly any fluid flow in instruments which are connected in this way.

The da Vinci robotic system has tiny wristed instruments that bend and rotate far more than the human wrist. The instruments are difficult to clean, because the shaft is substantially closed at both ends. At one side the shaft is attached to the housing of the instrument and at the other side there is an ingenious tip. Through the holes of the guide wires to the tip, contamination can enter the shaft. The da Vinci mobile unit is developed specially for the cleaning of da Vinci instruments. In the third study, this new cleaning

application is compared with the current application. The flows as well the pressure are lower for the current configuration. From this perspective it is recommendable to use the da Vinci mobile unit.

The Tosi LumCheck (Perag, Germany) simulates cannulated instruments and is used for monitoring the cleaning efficiency in the reprocessing of hollow instruments in the washer-disinfectors. The dummy device has a stainless steel plate with composed blood components attached to the surface. After the cleaning cycle the test soil has to be visually checked for residues. In the last study the effect of the flow through an instrument is investigated and its result on the cleanness of the test soil. The main finding of this study is that the rinsing of hollow instruments is very important to remove internal residues.

In conclusion, sometimes hollow instruments are insufficiently cleaned, due to: non-functioning of adapters and/or inserts, insufficient flow and pressure of the fluid flow rinsed through hollow instruments, blockages and leakages of connecting tubes, too less connecting possibilities for hollow instruments and wrong use or incorrect connection by the staff at the CSSD. These factors deteriorate the mechanical performance of the cleaning process, defined as the flow, pressure and level of turbulence of the rinsing fluid through the lumen. The lack of performance is not noticed because the flow and pressure are not monitored. Improvements in all these areas are needed to reach a sufficient cleaning of these hardly accessible instruments.

SAMENVATTING

Minimaal Invasieve Chirurgie (MIC) is de laatste twee decennia enorm toegenomen. Minimaal Invasieve Chirurgie geeft veel kleinere snede dan bij traditionele open chirurgie. The methode is veel minder invasief waardoor er minder schade is aan het weefsel op de plek waar instrumenten het lichaam in zijn gegaan. Dit geeft een sneller herstel voor de patient en een kort ziekenhuisverblijf. Het nadeel aan herbruikbare MIC-instrumenten is dat zij veel moeilijker te reinigen zijn dan de conventionele instrumenten. MIC-instrumenten hebben vaak een smalle kanalen, ze worden dan ook wel holle instrumenten genoemd. Smalle kanalen zijn ideale plaatsen voor menselijk weefsel, residuen en bacterien om zich te nestelen. Dit betekent een extra uitdaging voor de Centrale Sterilisatie Afdeling (CSA) om deze instrumenten niet alleen aan de buitenzijde maar juist ook binnenin schoon te krijgen. Holle instrumenten worden tijdens het automatische reinigingsproces aangesloten op de washer-disinfector zodat ze aan de binnenzijde doorgespoeld kunnen worden.

Het doel van deze studie is om meer inzicht te verkrijgen in de reinigingsprestaties van verschillende reinigingstoepassingen voor holle instrumenten. De reinigingsprestatie is gebaseerd op de mechanische prestatie en die wordt bepaald door de flow en druk van de reigingsvloeistof door het instrument. A reinigingstoepassing is een hulpmiddel om een instrument te kunnen aansluiten op een washer-disinfector. Er zijn verschillende toepassingen beschikbaar zonder dat er kennis is voor welke instrumenten ze geschikt zijn en wat hun invloed is op de reinheid van het instrument. In deze studie is een vergelijkingsanalysie gemaakt van verschillende toepassingen voor holle instrumenten. Hierbij is gefocust op de mechanische prestatie als flow en druk die de toepassing levert. Het onderzoek is beperkt tot de eerste fase van het decontamineringsproces, namelijk het reinigingsproces. De mechanische prestatie is gemeten met een meetsysteem dat geschikt was om tegelijkertijd de flow en druk te meten in acht afzonderlijke kanalen. Het onderzoek is opgedeeld in vier afzonderelijke studies.

In de eerste studie zijn verschillende commercieel beschikbare reinigingstoepassingen met elkaar vergeleken. De toepassingen, ook wel inzetten genoemd, verschillen in ontwerp, aantal aansluitmogelijkheden, en de manier van aansluiten. De flow en druk is bepaald voor elke uitgangsadapter van de verschillende inzetten. Bovendien is het effect van het aansluiten van een instrument op een inzet onderzocht en is er gekeken naar het effect van een aangesloten instrument op de naastgelegen uitgangskanalen. Voor alle getest inzetten geldt dat de flow en druk van een inzet nagenoeg gelijk is in de verschillende kanalen. Het is wel belangrijk dat een inzet goed is aangesloten, zodat het voldoende ingangs flow heeft. Instrumenten die zijn aangesloten op een adapter hebben nagenoeg geen effect op de flow in de naastgelegen adapters. Dat betekent dat het niet zoveel uit maakt als een instrument met een grote diameter is aangesloten naast een instrument met een nauw lumen en een hoge weerstand.

Grofweg zijn er twee manieren om een instrument aan te sluiten op een inzet, respectievelijk een contact en een contactloze verbinding. Bij een contactverbinding moet de instrumenttip in een silicone houder geduwd worden. Het nadeel hiervan is dat de buitenkant van de tip helemaal is omsloten, waardoor de reinigingsvloeistof er niet bij kan komen. Een contactloze verbinding is er geen contact tussen het instrument en de inzet. Het instrument moet kort voor het spuitmondje geplaatst worden, zodat de vloeistof in het instrument gespoten wordt maar er geen contact is. In dit onderzoek zijn beide ontwerpen met elkaar vergeleken op basis van hun mechanische prestaties. Hieruit is gebleken dat er een significant verschil is in de flow en druk van een contact vs. een contactloze verbinding. Er treedt een flow en druk verlies op in aan contactloze verbinding tussen de adapter en het instrument. Zelfs zo dat er geen flow en druk meetbaar was in de contactloze situatie. Dit is een reden tot zorg, omdat het kan zijn dat er dus nagenoeg geen reinigingsvloeistof stroomt door instrumenten die op deze manier zijn aangesloten.

De daVinci robotsysteem heeft instrumenten die lastig te reinigen zijn. De schacht van het instrument is nagenoeg aan beide zijde afgesloten. Aan het ene uiteinde zit het besturingsmechanisme en aan de andere zijde een ingenieus bestuurbare tip. Via de gaten van de aanstuurdraden naar de tip kan contaminatie in de schacht komen. De da Vinci mobile unit is speciaal ontwikkeld voor de da Vinci instrumenten. In het derde onderzoek is deze nieuwe methode vergeleken met de huidige methode. De flow en druk zijn lager voor de huidige configuratie. Op basis hiervan kan gesteld worden dat de da Vinci mobile unit de voorkeur verdient voor het reinigen van da Vinci instrumenten.

De Tosi Lumcheck is een dummy instrument voor holle instrumenten en kan worden gebruikt om de reinigbaarheid van holle instrumenten te onderzoeken. Het instrument heeft in de schacht een los stalen plaatje waarop bloedcomponenten zitten. Om de reinheid te bepalen moet het plaatje na reiniging visueel worden beoordeeld. In het laatste onderzoek is het verband onderzocht tussen de flow door een instrument en de reinheid van het testplaatje. Uit het onderzoek blijkt dat het doorspoelen van holle instrumenten erg belangrijk is voor het verwijderen van interne verontreinigingen.

Tot slot, holle instrumenten worden soms onvolledig gereinigd, dat is te wijten aan meerdere oorzaken: niet goed functioneren van adapters en/of inzetten, onvoldoende flow en druk van de reinigingsvloeistof door de holle instrumenten, verstoppingen en lekkages van aansluitslangen, te weinig aansluitmogelijkheden voor holle instrumenten en verkeerd gebruik of verkeerde aansluiting door medewerkers op de CSA. Deze factoren hebben een negatieve invloed op de mechanical performance van het reinigingsproces; uitgedrukt in de flow, druk en mate van turbulentie van de spoelvloeistof door het lumen. Het gebrek aan voldoende doorspoeling wordt niet opgemerkt, aangezien de flow en druk niet wordt gemonitord. Verbeteringen op deze gebieden zijn nodig om goede reiniging van deze moeilijk toegankelijke instrumenten te realiseren.

CONTENTS

1

INTRODUCTION

Louis Pasteur was the founder of the principle of sterilization. In the 19th century he discovered that harmful microorganisms cause diseases. He managed a remarkable breakthrough in reducing diseases by sterilization. His discoveries have saved countless lives ever since. The process of sterilization is much more developed now, but the principle is still comparable to the ideas of Pasteur. The development of medical instruments constitutes an ongoing challenge to optimize the decontamination procedures in order to minimize the infections through non-sterile instruments. A trend in the design of medical instruments shows that the instruments are becoming smaller and more complex. Since a few decades, the use of Minimally Invasive Surgical (MIS) instruments has increased very fast. Minimally Invasive Surgery uses much smaller incisions compared to traditional open surgery. These procedures involve the use of arthroscopic, laparoscopic and remote-control manipulation of instruments with indirect observation of the area of surgical operation through an endoscope. The procedure is less invasive than open surgery and there is minimal damage to biological tissue at the point of entrance of the instrument, which enables quicker healing for the patients and a shorter hospital stay. Figure 1.1 shows a large incision for a conventional open kidney surgery and some small incisions for a minimally invasive surgery. The downside of these MIS-instruments is that they are more difficult to clean than conventional surgical instruments. MIS-instruments consist of mostly narrow channels. Narrow channels are ideal places for human tissues, residuals and bacteria to nestle. The challenge is twofold, first the designer has to develop instruments in such a way that current cleaning equipment is able to clean the device sufficiently. And secondly the maximal cleaning efficacy has to be reached for the cleaning process, allowing MIS-instruments to be cleaned both inside and out.[1]

The aim of this study is to get more insight into the cleaning performance of several cleaning applications for hollow instruments based on their mechanical performances, expressed as flow and pressure through the lumen of an instrument. Cleaning application is a term for a device what can be used for the rinsing of hollow instruments. In this study two types of applications are used: mobile units and inserts. A mobile unit is a load carrier and instrument trays can be put on. During the cleaning process the mobile unit is rolled into the cleaning chamber of a WD. An insert is an extra device which can be connected to a mobile unit. Inserts are used for the connecting of hollow instruments to the pump circuit of the WD therefore a hollow instruments are rinsed at the inside. Inserts mostly have multiple outputs for the connecting of multiple hollow instruments. The flow and pressure through the outputs of mobile units and inserts were analyzed in this study.

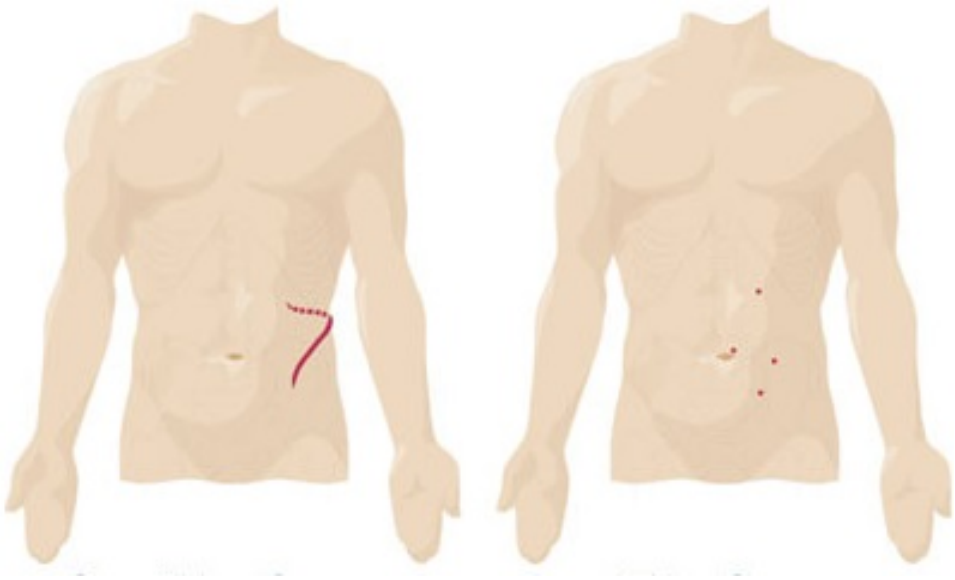


Figure 1.1: a large incision for open kidney surgery vs. several small incisions for minimally invasive surgery. The advantage of several small incisions is a minimal damage to biological tissue at the point of entrance of the instrument, which means quicker healing for the patients and a shorter hospital stay.[2]

1.1. OUTLINE OF THIS THESIS

The analysis of the several cleaning applications is worked out in four sub studies. The first two studies are focused on inserts, the third study on a special mobile unit and in the last study the link is determined between the cleaning performance and the mechanical performance by using a dummy instrument with a test contamination.

In the first study a comparison is made of several commercially available inserts. An insert is used for the connecting of hollow instruments to the pump circuit of the WD therefore connected hollow instruments are rinsed at the inside. Several types of inserts are available in sterilization departments. The inserts differ in design, number of connecting possibilities and way of connecting. Inserts have the working principle of manifolds, they consist of one or two input channels and multiple output channels. That means that the input flow and pressure is distributed among the multiple output channels The flow and pressure performances are determined for each channel of an insert. Furthermore, the effect of connecting instruments to an insert is determined. Different dummy instruments are used to investigate if a connected instrument has an effect on the mechanical performances in an adjacent connecting possibility.

The second study is focused on the effect of the design of an adapter, a contact or contactless adapter respectively. A contact adapter means that the tip of an instrument has to be pushed into a silicone holder in the insert. A contact adapter has the disadvantage that the outside of the instrument tip is enclosed by the holder, which prevents it from being cleaned. A contactless adapter is like an injector nozzle, the instrument has to be placed close to the nozzle, and there is no contact between the instrument and the nozzle. In this study a comparison is made between the contact and contactless adapters based on the mechanical performance.

The da Vinci robotic system has tiny wristed instruments that bend and rotate at far greater angles than the human wrist. The instruments are difficult to clean, because the shaft is substantially closed at both ends. On one side the shaft is attached to the housing of the instrument and on the other side there is an ingenious tip. Contamination can enter the shaft, via the holes of the guide wires to the tip. The da Vinci mobile unit is developed specially for the cleaning of da Vinci instruments, but this unit is still not used at the Erasmus MC. In the third study the new cleaning method with the da Vinci mobile unit is compared with the current method for the cleanin of da Vinci instruments.

The Tosi LumCheck simulates cannulated instruments and is used for monitoring the cleaning efficiency for reprocessing hollow instruments in washer-disinfectors. The dummy device has a stainless steel plate with composed blood components. After the cleaning cycle the test soil has to be visually checked for residues. In the last study, the effect is determined of the flow and pressure through an instrument on the cleanness of the test soil.

The four studies are described in chapter 4 to chapter 7 of this report. In chapter 2 the methods and materials of the study are worked out. A theoretical approach of the phenomenon flow is given in the third chapter. In the Discussion (chapter 5) the main conclusions of the sub studies are drawn and the limitations of this study are described. It is important that the findings of this study are translated into practical guidelines. The last section of the discussion gives attention to the practical lessons learned in this study for the practice at the CSSD and gives recommendations for further study and the development for better and safer reprocessing of hollow surgical instruments.

1.2. MOTIVATION FOR THIS STUDY

The demand for more research on the cleaning processes of hollow instruments was made by the Erasmus Medical Center in Rotterdam, the Netherlands, and addressed to the Biomechanical department of Delft University of Technology (The Netherlands). For the researcher, it was an interesting topic for this graduation study. Interviews with experts on Medical Sterile Devices and Endoscope Cleaning and Disinfection and with employees of the Central Sterile Supply Department (CSSD) have been conducted to get more insight into this research field and to find perspectives for the research.

1.3. BACKGROUND: DECONTAMINATION PROCESS

The reprocessing of medical devices takes place at the Central Sterile Supply Department. A regular CSSD has three separated areas: a dirty area, a clean and a sterile area (Figure 1.2). Instruments come from the operating theatres to the CSSD. In the first room the dirty and contaminated instruments are manually pre-cleaned. After a manual pre-cleaning, there are three automatic processes. The first two processes, cleaning and disinfection, take place in a washer-disinfector and thereafter the cleaned instruments have to be free of surgery residues and should be visibly clean. The last phase is sterilization, to make the devices sterile and ready for reuse.

Before the decontamination process is explained in more detail, it is good to have a complete overview at the entire life-cycle of reusable instruments (Figure 1.3). Depending on guidelines and types of instruments the sequence of the life-cycle can be different. For example, French instruments have to be decontaminated after use and before transport to the Central Sterile Supply Department (CSSD), whereas the Dutch instruments do not have to be cleaned before transport. Furthermore, not all instruments should be sterilized. This depends on the function of the instrument and the area in which it is used. Instruments that come in contact with sterile tissue, organics and body fluids have to be sterilized. Instruments which bore into the skin or mucous membranes, or are in contact with an open wound, also have to be sterile. Endoscopes are inserted in the body via natural openings and do not come in contact with sterile tissue, therefore cleaning and disinfection after use is sufficient.

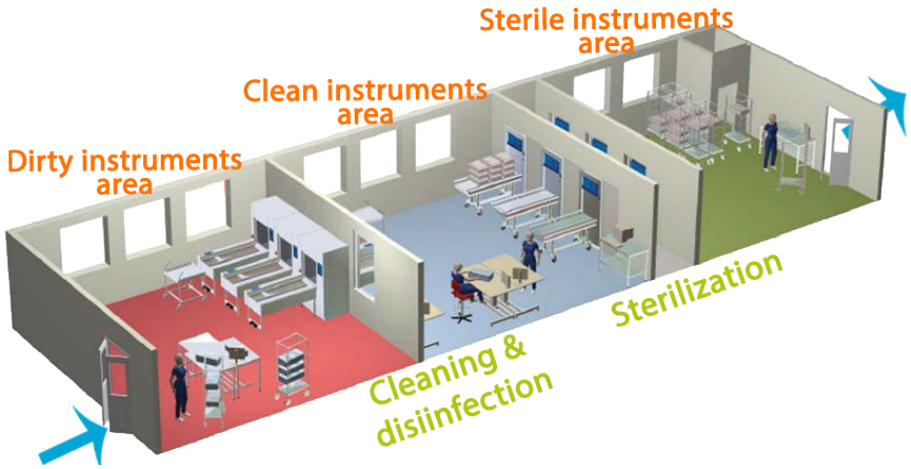


Figure 1.2: reusable instruments were reprocessed at a Central Sterile Supply Department. This department consists mostly of three separate parts. In the first room the instruments were dirty and contaminated. After the cleaning and disinfection process the instruments were clean. In the last phase the instruments were sterilized, at the end the instruments were clean and sterile.

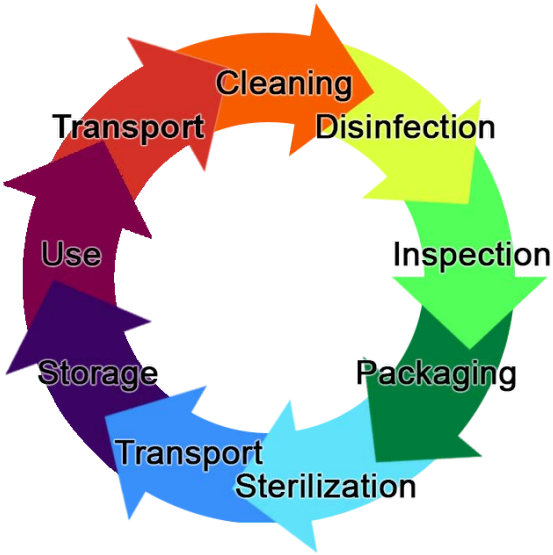


Figure 1.3: life-cycle of reusable instruments. This study focuses on the cleaning process. The aim of cleaning is to remove tissues, blood and all visible residuals.

The cycle starts with the acquisition of instruments. All different steps are described sequentially.
Use: It is important that instruments are used in accordance with the Intended Use specified by the manufacturer of the instruments. Correct use of instruments prevents incidents and damage to the instrument and is required by law. In some cases instruments are pre-rinsed after use in the operating theatre.
Transport to the CSSD: Instruments are transported to the Central Sterile Supply Department after use in order to be cleaned. The instruments are dirty, contaminated and patient residuals can cling to the instruments.
Cleaning: The aim of cleaning is to remove tissues, blood and all visible residuals. The cleaning process is described in more detail in the section Cleaning.
Disinfection: The disinfection is mostly performed in the same machine as cleaning. The disinfection process is described in more detail in the section Disinfection.
Inspection and assembling sets: The processed instruments should be inspected visually to check if they are free of visual dirt, like blood and tissue. Instrument sets are checked for cleanness, intactness and completeness and then the sets are fixated in special instruments trays (Figure 1.4). The decontamination process is finished for non-sterile instruments and they are ready for reuse.
Packaging: Instruments which must be sterile are packaged in special packaging. The packaging is designed in such a way that the sterilizing media are able to penetrate the package, but micro-organisms cannot penetrate it, with the result that the instruments remain sterile after sterilization.
Sterilization: The aim of the sterilization process is to kill living micro-organisms. This process is described in more detail in the section Sterilization.
Storage: The sterilized sets have to be stored under special environmental circumstances in order to guarantee their sterility.
Transport to the user: If sterile devices are needed, they are transported from the sterile storage to the user. The instruments are used and the cycle starts again.

1.3.1. CLEANING PROCESS

The first step of the decontamination process is cleaning. The aim of cleaning is the removal of all visible dirt, dust and patient residuals like blood, tissue and organic material[4] Cleaning is the first step in reducing the bioburden, and cleaning protects instruments against corrosion.

Cleaning techniques
Cleaning can be done in different ways, depending on materials to be cleaned and available resources. Some materials can be washed in automatic washer-disinfectors; others can only be cleaned manually. In many cases a combination of manual and automated washing will be used. Another possibility is cleaning by an

Figure 1.4: surgical instrument tray.[3]

ultrasonic cleaner. Automated cleaning is preferable above manual, because it is better validatable and more reproducible. For the scope of this study we will focus on automated cleaning using a washer-disinfector.

Washer-disinfector
A washer-disinfector (WD) is used for the cleaning and disinfection process (Figure 1.6a). A WD is available as a batch machine and continue to wash. In a batch machine the cleaning takes place in batches: a load is processed completely in a single chamber and then taken out of the machine. Figure 1.5 shows a simplified diagram of a washer-disinfector. Spray arms are placed at the bottom, the top and sometimes also in the middle of the cleaning chamber. A spray arm runs laps during the process. Nozzles on the spray arms spray cleaning fluid into the chamber. After cleaning and disinfection hot air is injected to the chamber to dry the load. Depending on its size, a number of standardized instrument trays can be put on a mobile unit and rolled into the cleaning chamber (Figure 1.6b). A mobile unit is connected to the central fluid pumping system of a WD. Instruments can be connected to a mobile unit for rinsing the inside of an instrument. Because a growing number of MIS-instruments are used in hospitals, also more and more hollow instruments have to be cleaned in the CSSD, with the consequence that there is a need for more connectors to rinse the inside of hollow instruments. Therefore special inserts have been developed that features many connecting possibilities for MIS instruments (Figure 1.6c). An insert can be considered as a manifold, it has one or two inputs and multiple outputs. On each output adapter an instrument can be connected and powerful jets of cleaning fluid rinse the channel inside. The process parameters of the cleaning program are determined by the manufacturer of the washer-disinfector. Most of the WDs have multiple cleaning programs, for different types of loads. A typical cleaning process is shown in Figure 1.7. Before the actual cleaning process there is often a pre-rinse. This is an initial rinse of the load with cold water. Thereafter hot water is added to the chamber and the load is heated up. The cleaning fluid consists of water mixed with a detergent. There are many available cleaning detergents are available; the supplier advises which products are most suitable for the specific situation. The chosen detergent has to conform to the instrument and the WD. Studies have shown the effects of cleaning detergents on the cleaning efficacy.[7, 8] After the cleaning process has taken place, chemical residues may be left on the instruments and materials. These chemical residuals can cause serious damage to the instruments or to the patient during drying, and especially when it is followed-up by steam sterilization, where the moist environment can easily cause corrosion. Therefore water is chemically neutralized in order to prevent corrosion. By an intermediate rinse all remaining soils are carefully washed away with cold fresh water.

1.3.2. DISINFECTION PROCESS

The neutralization and intermediate rinse process is followed-up automatically by the disinfection process. The disinfection process takes place in the same machine. The instruments are flushed with approximately 90-95°C hot water for 1-10 minutes (Figure 1.7). The aim of disinfection is to kill all vegetative micro-organisms.[5] The bioburden is decreased, therefore further actions with the instruments are safer.

1.3.3. STERILIZATION PROCESS

The definition of sterile is “the chance of a viable microorganisms is 1E-6”[9]. However, in practice, the absolute statement regarding the absence of microorganisms cannot be proven. In a sterilization process, the nature of microbial inactivation is exponential and thus, the survival of a microorganism on an individual item can be expressed in terms of probability. A product can considered as sterile if the theoretical probability of there being a viable micro-organism present on or in an object shall be equal to or less than one in a million (1E-6). Steam sterilization takes place in a sterilizer or autoclave. Steam sterilization is the common method for medical instruments; other sterilization methods are chemical or radiation. The principle of steam sterilization is based on inactivation of cells through heat transfer by steam under pressure and through high temperatures, whereby coagulation of proteins occurs.

1.4. PROBLEM ANALYSIS

This study is a sequel to a literature study about the cleaning of medical instruments with narrow channels. The aim of the literature study was to get more insight into the factors determining the efficacy of the cleaning process of medical devices in a Washer-Disinfector. An effective cleaning process depends on many factors (Table 1.1). The determining factors are divided into two categories. First, the factors that are determined by the washer-disinfector. These are physical parameters of the cleaning process, like: contact time, pressure, temperature and velocity of the rinse fluid in the lumen. The chemical properties of the fluid are also important factors. The chemical properties are determined by the cleaning agent, cleaners and disinfectants. Several studies have shown the significant effect of chemical composition of the fluid on the cleaning efficacy.[7, 8] The chemical depends on the cleaner, and the quality of water (e.g. hardness). Furthermore the quantity of loading matters the cleaning efficacy. Also, the way of loading cannot be underestimated, e.g. a tray should be placed with the open side downwards and hollow instruments be connected to special connectors for rinsing on the inside.

The second category consists of factors determined by the devices that have to be cleaned. There is a large difference in how easy it is to clean a device, mostly determined by the design of an instrument. Long, narrow channels or ridges and edges are difficult to clean most of the time.[10, 11] The level of contamination and the attachment of contamination to the instrument affect the cleaning efficacy. Another issue is the level of pre-rinsing after use or if the contamination has dried.

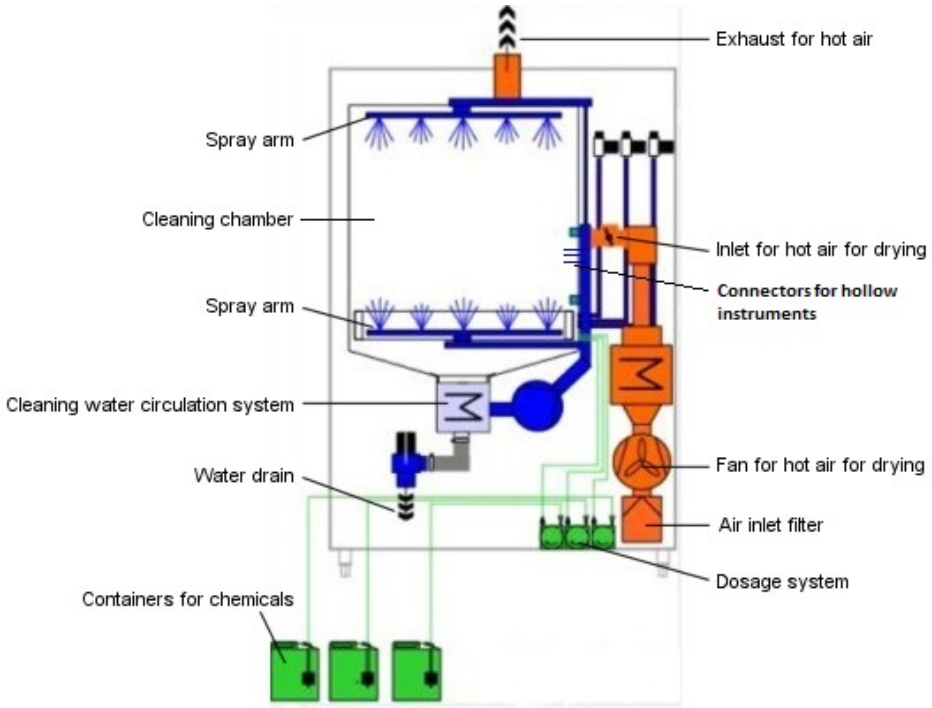


Figure 1.5: simplified diagram of a washer-disinfector. Spray arms are placed at the bottom and the top of the cleaning chamber. Adapters for hollow instruments are at the side. [5]

(a) (b) (c)

Figure 1.6: a) Miele washer-disinfector PG8528, b) instruments trays on a mobile unit, c) insert with twenty two connecting possibilities. The insert can be connected to a mobile unit and the mobile unit can be rolled into the chamber of the WD.[6]

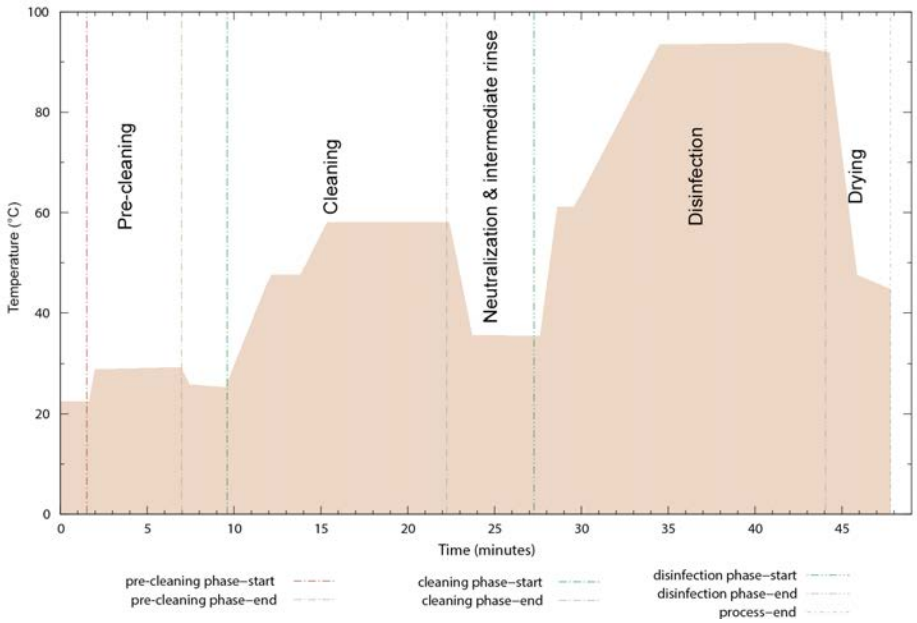


Figure 1.7: typical cleaning process for an automatic washer-disinfector. The cleaning and disinfection process takes place in the washer-disinfector. The cleaning process starts with a pre-cleaning at room temperature. Thereafter the temperature increases to 55°C and detergents are added to the cleaning fluid for 14 minutes. After the cleaning process has taken place, chemical residues may be left on the instruments and materials. Therefore cleaning fluid is chemically neutralized in order to prevent corrosion. By an intermediate rinse all remaining soils are carefully washed away with cold fresh water. During the disinfection process the instruments are flushed with hot water of approximately 90-95°C for 1-10 minutes.

The way how an instrument has to be evaluated after the cleaning process is not uniform. The International Guidelines do not prescribe a uniform test method to evaluate the cleanness of processed devices.[12] There are differences in the guidelines between European countries. For example, each country has its own prescribed test soils to test the cleaning efficacy.[13, 14] Studies have proven that not all the test soils match realistic soils. Also the methods to detect contamination after cleaning differ. There are multiple usable methods, but there is a significant deviation in the sensitivity of the methods. The differences in test soils, test objects and detection methods between countries results in cleaning efficacy being assessed differently and that the acceptable quality of the cleaning process can differ.

Hollow instruments are mostly too narrow for visual inspection on their cleanness after the cleaning process.[11] Therefore it is important that the cleaning process of hollow instruments is reliable and effective. Flow through hollow instruments is required in order to ensure that the inside of an instrument comes into contact with detergents and cleaning fluid of the desired temperature.[15] Several applications have been developed to connect instruments to the pumping system with cleaning fluid of the washer-disinfector. How-

Table 1.1: essential factors for the cleaning efficacy of MIS-instruments

Washer-Disinfector	Medical Device
• Cleaning program – Pressure – Temperature – Flow – Contact time • Chemical – Cleaning agent, cleaners, disinfectants – Quality of water (water hardness) • Loading – Quantity – Position in WD – Inserts – Way of connection – Tray	• Design of instrument – Length – Diameter lumen – Edges / ridges – Surface roughness and material • Contamination – Level of contamination – Size of partitions – Level of attaching to the instrument – Level of dryness – Pre-rinsing efficacy

ever, the mechanical performances of these applications are unknown. There are no validation reports of the applications; the flow and pressure through connected instruments is unknown. The consequence is that there are many obscurities.

Finally, there is little known about the extent to which factors affect the cleaning process. The number of studies on the efficacy of the cleaning process has increased in recent years. However, there is a lack of translation to practical guidelines for the staff at the CSSD. Therefore it is unknown whether many of the manual operations in the CSSD justified. For example, multiple validation methods are available to assess the cleaning process, but no method has general support and scientifically justified benchmarks are lacking to interpret the results of the validation methods.[16, 17] The general idea is to rinse hollow instruments on the inside during the cleaning process, however, there is a proliferation of cleaning applications for hollow instruments. Validation reports and IFUs are missing, which means that it is not known how to use them in a responsible manner. Can different types of instruments be connected randomly or has a connected instrument an effect on the flow and pressure to the adjacent instrument?

2

METHODS AND MATERIALS

2.1. METHODS

The international guidelines for cleaning and disinfection of medical instruments prescribe that an instrument has to be visually clean after the cleaning cycle. For the traditional instruments is it relatively easy to check whether they are free of visible dirt and blood residuals. This is totally different for the minimally invasive surgical instruments which, with their complexity in their design they are often inaccessible for visual inspection. Many times the MIS instruments have a hollow shaft. Patient residuals can enter during an intervention, which leads to contamination of the internal housing of the shaft and damage to or dysfunction of the instrument. In order to clean the internal housing of an instrument, the instrument has to be rinsed on the inside. In the traditional cleaning cycle, instruments are placed on a mobile unit and the mobile unit is placed in the cleaning chamber of a washer-disinfector (Figure 2.1). The basic principle of a mobile unit is intended as a rack to place instruments or instrument sets on. Since the increased use of Minimally Invasive Surgery instruments there is a lack of adapters to connect hollow instruments in order to facilitate their inside rinsing. Inserts are the solution to this problem. An insert is like a manifold. It has one or two input channels and multiple output channels to connect to instruments. In this study the current cleaning process at

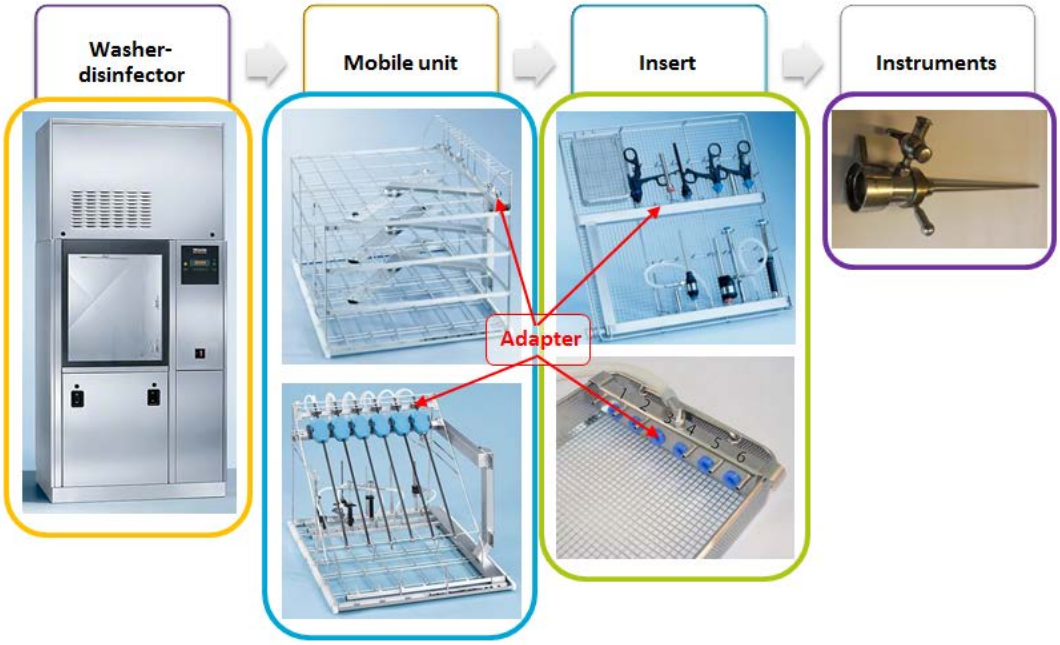


Figure 2.1: an overview of the chain of elements. A mobile unit can be rolled into a washer-disinfector. Instrumentsets are placed on a mobile unit and a mobile unit has adapters for hollow instruments to connect them to the pumping system of the WD. Sometimes an insert is connected to the mobile unit and the insert has more adapters or adapters specifically for special hollow instruments.

the CSSD of the Erasmus MC (Rotterdam, the Netherlands) is analyzed. Several systems are analyzed on the basis of their mechanical performance. The mechanical performance is determined as flow (ml/s) and pressure (kPa) in the adapters of an insert. A measurement system was used to measure the flow and pressure of the flow through hollow instruments. This system was developed by causa bv (Eindhoven, the Netherlands) and is able to measure the flow and pressure of eight separated channels. The focus of this study is limited to the cleaning process.Therefore the cleaning cycle was canceled after the cleaning process and before the disinfection process. The tests were performed at the Central Sterile Supply Department of Erasmus Medical Center in the Netherlands. The used washer-disinfector was a Miele Professional type PG 8528 (Miele & Cie. KG, Germany). The wash cycle used was the pre-programmed 'instrument' cycle that was stopped after the cleaning process. The cycle consisted of: a pre-wash of 5 min using cold water (i.e. room temperature) and a cleaning phase for 14 min using hot water (55°C) and a detergent (Neodisher MediClean Forte) (Figure: 2.2). Reverse Osmosis (RO) water was used for all stages of the program.

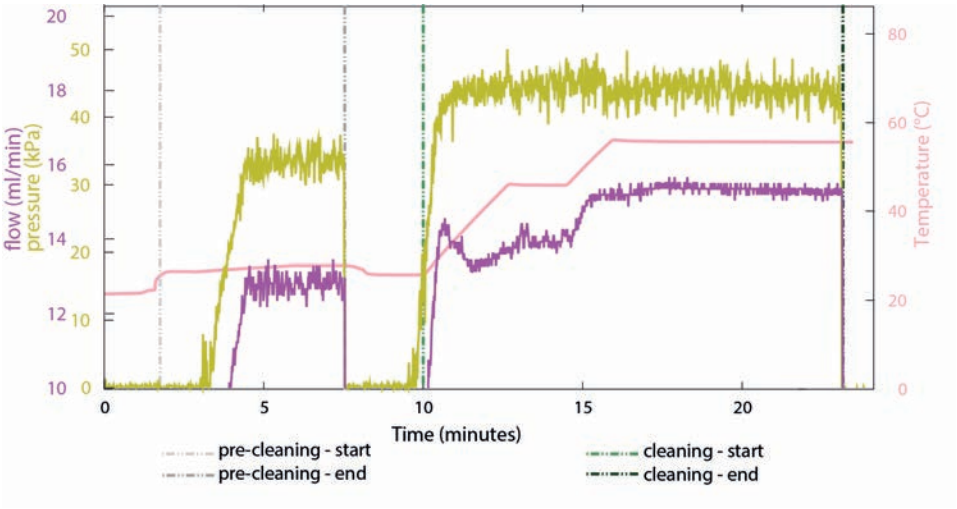


Figure 2.2: a measured flow, pressure and temperature profile during pre-cleaning and cleaning process. The flow and pressure is measured in an adapter of a mobile unit. The temperature was measured at the wall of the washer-disinfector chamber. The pre-wash is with cold water (i.e. room temperature for 5 minutes. Thereafter there is a short break, so the cleaning fluid is running out of the machine. With fresh hot water the cleaning process is started after 10 minutes for 14 minutes. The temperature is about 55°C and a detergent is added to the cleaning fluid. After the cleaning cycle the process was canceled for this study.

2.2. MATERIALS

An overview of all the used materials are given in Appendix A. Each part will be described in the sections below. The washer-disinfector consists of a bottom and a top spray arm and at the right side there is a large adapter for a mobile unit. A mobile unit can be placed in the chamber of the WD. The cleaning program called *Instruments* is used for all the tests.The tests are performed in a washer-disinfector situated at the department of the Central Sterile Supply Department (CSSD) at the Erasmus MC (Rotterdam, the Netherlands). The washer-disinfector is a Miele Professional PG 8528 (Miele & Cie. KG, Germany) (Figure: 2.4).

2.2.1. MOBILE UNIT

A mobile unit is like a rack with multiple levels to lay instruments or instrument trays on (Figure: 2.6a). A standard mobile unit is used for the tests. This mobile unit is equipped with multiple spray arms and an adapter block to connect instruments or inserts for hollow inserts. The adapter block consists of nine small adapters and four large adapters (Figure 2.5).

The four small adapters on the top are normally open and connected to a silicone tube. The tube can be connected to connectors of instruments or trays. The other five small adapters are mostly closed with a blind stopper. The large adapters are only open if they are connected to an insert. There are also special mobile units for minimally invasive surgically instruments. The advantage of this kind of insert is that it has many more adapters to connect different types of hollow instruments, but the disadvantage is that it is not suitable for standard instrument trays.

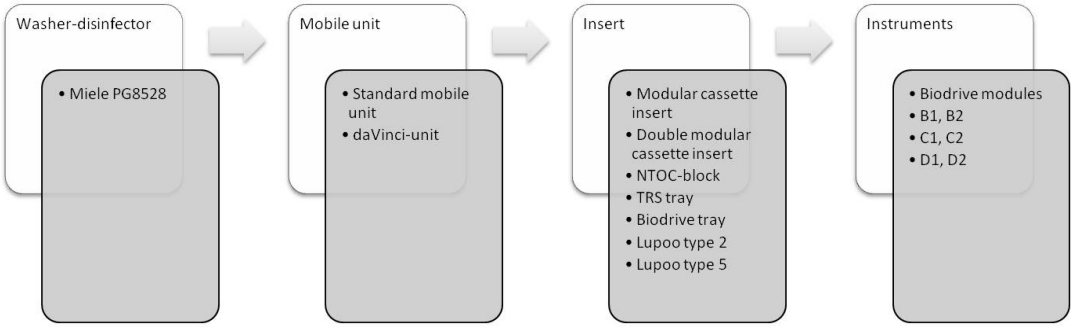


Figure 2.3: an overview of the chain of elements. A mobile unit can be rolled into a washer-disinfector. Instrument sets are placed on a mobile unit and a mobile unit has adapters for hollow instruments to connect them to the pumping system of the WD. Sometimes an insert is connected to the mobile unit and the insert has more adapters or adapters specifically for special hollow instruments.

Algemeen	
merknaam	Miele Professional
type	PG 8528
bouwjaar	2012
fabrikant	Miele & Cie. KG
leverancier	Miele Nederland B.V.
serienummer	SN 51/74360891
datum ingebruikname	13-02-2013

Figure 2.4: The used washer-disinfector is of the type PG8528 (Miele Professional).

Figure 2.5: close-up of the top level of a mobile unit with an adapter block. The adapter block has nine small adapters and four large adapters. Some inserts have to be connected to the large and others to the small adapters. Hollow instruments or injector nozzles can also be directly connected to a small adapter. The adapters of the mobile unit are fed by the central pumping system of the washer-disinfector.

da Vinci mobile unit

The da Vinci-unit is a very specific mobile unit. It is developed for instruments of the da Vinci Surgical System. The da Vinci is a robotic surgical system, designed to facilitate complex surgery using a minimally invasive approach and is controlled by a surgeon from a console. These Endowrist instruments have two connectors for rinsing the inside of the housing. The da Vinci mobile unit used in this test is developed by Miele (Miele & Cie. KG, Germany) and is able to clean six instruments at the same time (Figure 2.6b).

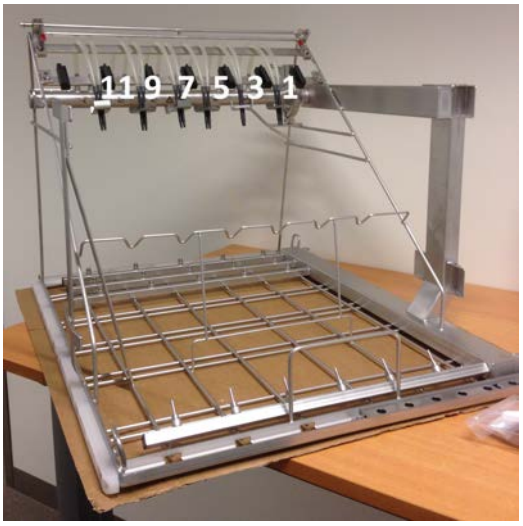
2.2.2. INSERTS FOR HOLLOW INSTRUMENTS

The standard mobile unit does not have many adapters for hollow instruments and often, their number is insufficient. Several types of inserts are used to create more possibilities for rinsing the hollow instruments. An insert can be considered as a distribution block; it requires one (or two) input adapters and it has multiple output adapters. Several inserts are tested in this study. Inserts from different manufacturers are chosen and it is taken into account whether or not they were available at the CSSD at the Erasmus MC.

Modular cassette insert

The modular cassette insert can be used for long MIS instruments (Figure: 2.10a). This insert has to be connected to one of the large adapters of the mobile unit. The insert has 13 adapters and the adapters consist of a silicone holder into which the instrument should be pressed. A random modular cassette of the CSSD is used

(a) Mobile unit Miele E909 with 9 small adapters and 4 large adapters



(b) daVinci insert with 12 adapters for 6 Endowrist instruments

Table 2.1: Overview of tested inserts and distribution blocks

Description	# adapters	Connected to
Modular cassette insert	13	Mobile unit, large adapter
Double modular cassette insert	22	Mobile unit, large adapter
NTOC-block	8	Mobile unit, small adapter
TRS tray	8	Mobile unit, small adapter (double connector)
Biodrive tray	1	Mobile unit, small adapter
Lupoo type 2	12	Mobile unit, small adapter
Lupoo type 5	3	Mobile unit, small adapter

in this study. The insert showed some signs of use, but all the silicone holders were intact. If the adapters are not connected to an instrument or measurement system, the silicon holders are open.

Double modular cassette insert

The double modular cassette insert is comparable with the insert above (Figure: 2.10b). The difference is that this insert has two levels with eleven adapters each; only short MIS instrument can be connected in this insert.

NTOC-block

The NTOC-block (NTOC, Oss, the Netherlands) is a small mobile insert which can be placed in trays or on the mobile unit (Figure: 2.10c). The distribution block used consists of 8 adapters and has to be connected to one of the small adapters of the mobile unit. This insert has a contactless connection between the adapter and the instrument. The instrument is not placed in a silicone holder, but it is placed just before the adapter so that there is no contact between the end of the adapter and the entrance of the instrument. This is called a contactless adapter (Figure: 2.7).

TRS tray

The TRS-insert is a part of a TRS-tray (Figure: 2.10d). TRS is Trauma Recon System a battery-driven power system designed for traumatology and arthroplasty. The set consists of a TRS battery handpiece and some attachments with e.g. drilling and sawing functionalities. The used set is a drilling set and consists of six drilling attachments; these attachments have a hollow shaft and therefore they have to be rinsed on the inside. The tray is equipped with a distribution block for rinsing the drilling attachments. They also have a contactless connection between the adapters of the distribution block and the attachments.

Figure 2.7: an insert fixed in an instrument tray with 8 adapters, allowing eight instruments to be connected to this insert. The insert is able to fix and rinse eight hollow drilling attachments. The attachments are placed close to the adapter, but there is no contact between instrument and adapter, this connection is called a contactless connection.

Table 2.2: Specifications of the dummy instruments

Instrument	Diameter (mm)	Length (mm)	Volume (mL)
B1, B2	2	255	3.2
C1, C2	3	375	2.7
D1	6	260	7.4
D2	7	230	8.9

Biodrive tray

Trays for hollow instruments are sometimes equipped with single adapters for one instrument and each adapter is separately connected to a small adapter of the mobile unit. The Biodrive tray consists of multiple hollow instruments. Each hollow instrument has its own injector nozzle and each nozzle is individually connected to one small adapter of the mobile unit. This adapter is a contactless type and the input is directly connected to the mobile unit (Figure: 2.10e).

Lupoo type 2 and type 5

The Lupoo blocks (PMT Partners Medische Techniek BV, Alblasserdam, the Netherlands) are loose blocks, which can be attached in a tray (Figure 2.10f). Two blocks are tested, one with 12 adapters and the other one with 3 adapters. To connect instruments to the Lupoo block, they have to be placed in the silicone holders.

Filter-adapter

The Miele filter-adapter E478/1 (Miele & Cie. KG, Germany), is an easy application to rinse the daVinci instruments (Figure 2.10g). The filter-adapter can be screwed onto a small adapter of a mobile unit. It has four Luer-Lock output connectors. There are special tubes that can be connected to the adapter which are suitable for the da Vinci connecting ports.

2.2.3. INSTRUMENTS

A few medical instruments are used to research the effect of connecting instruments to an insert on the mechanical performance of an insert. The instruments were selected on the base of their internal diameter (Table 4.2). Two pieces were available of each type of instruments (Figure 2.8).

2.2.4. MEASUREMENT SYSTEM

In the analysis of the cleaning techniques it is important to get more insight in the flow distribution among the different rinse adapters. A measurement system is required with multiple pressure gauges and flow sensors to measure the flow properties in multiple channels at the same time. The temperature of the cleaning process is in the range of 0-60°C, so the sensors must be suitable for these temperatures. The sensors must also be resistant to chemically aggressive liquids with a ph of 11. The flow range of the flowmeter has to be in the range of $0-1 l/min$. The required range of the pressure gauges is $0-4 bar$.

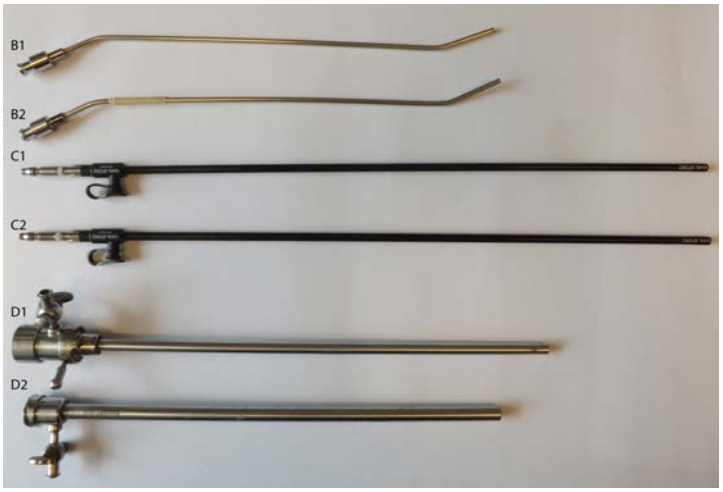


Figure 2.8: six dummy instruments. These instruments were used in the test with hollow instruments. The dummy instruments can be categorized in three types based on their design: short plus curved, long plus straight and short plus straight.

The used measured system is developed by the company Causa BV (Eindhoven, The Netherlands) and they have made available a prototype for the tests of this study. Causa BV is an internationally oriented company for measurements and inspections in the field of decontamination. The measurement system is developed for validation of washer-disinfectors of endoscopes. The measurement system can measure the flow and pressure of eight separate channels (Figure: 2.9). The flowmeters of the system are of the branch Biotech, type FCH-m-PP-LC, the product details are attached in Appendix B. The flowmeters satisfy the criteria of the required temperature and medium, only the maximal acceptable flow is less than required (0-0.8l/min). The pressure gauges are silicone sensors and they are temperature compensated. The datasheet of the pressure gauges is attached in Appendix C.

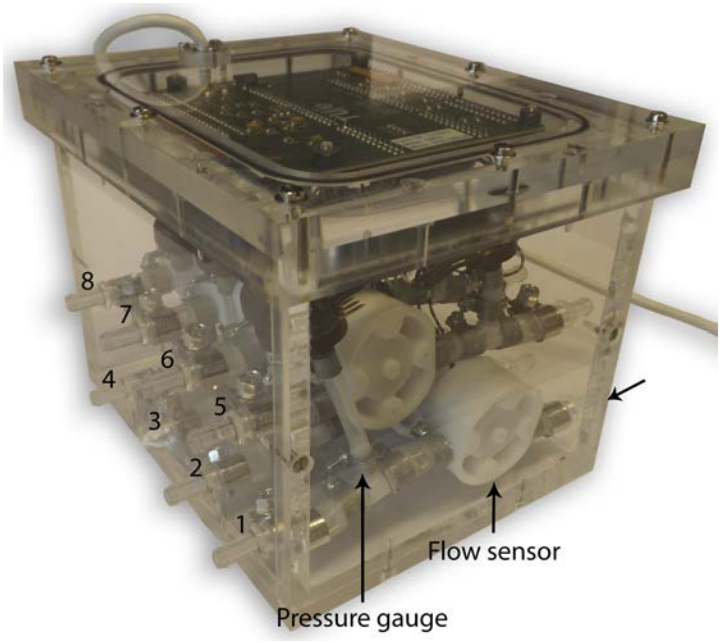
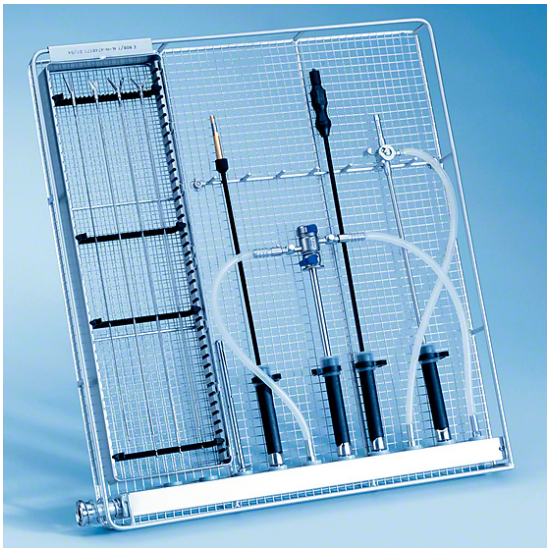
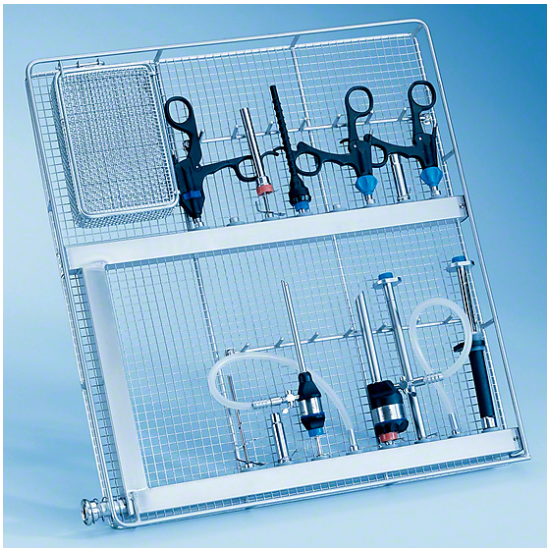


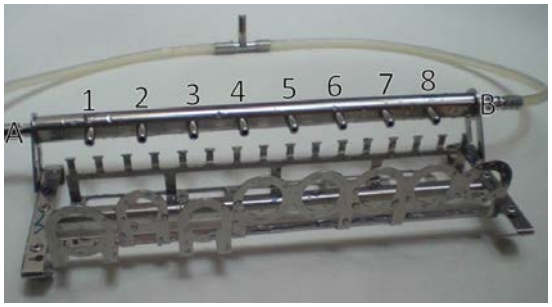
Figure 2.9: Measurement system, developed by *Causa BV*, Eindhoven, The Netherlands. The system is able to measure the flow and pressure in eight separated channels.



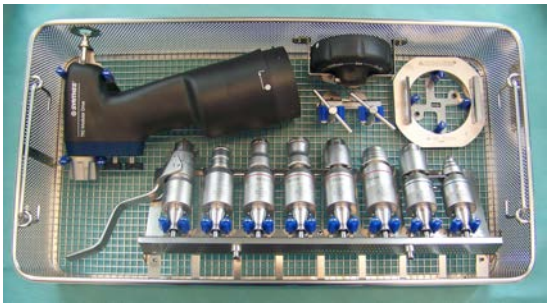
(a) Modular cassette insert, 13 adapters.



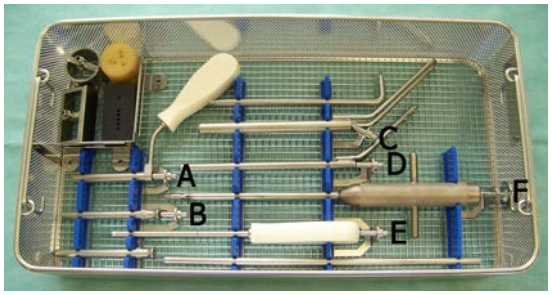
(b) Double modular cassette insert, 22 adapters.



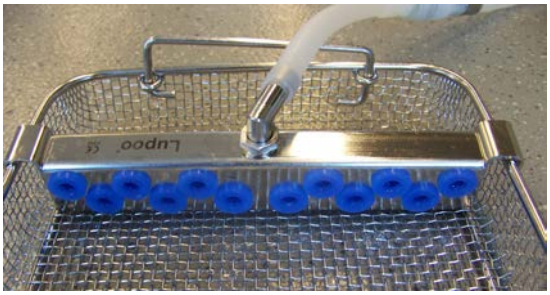
(c) NTOC-block, 8 adapters.



(d) TRS tray, 8 adapters.



(e) Biodrive tray, 1 to 1 connectors .



(f) Lupoo type 2, 12 adapters.

(g) Filter-adapter, 4 adapters.

Figure 2.10: Overview of all the tested inserts

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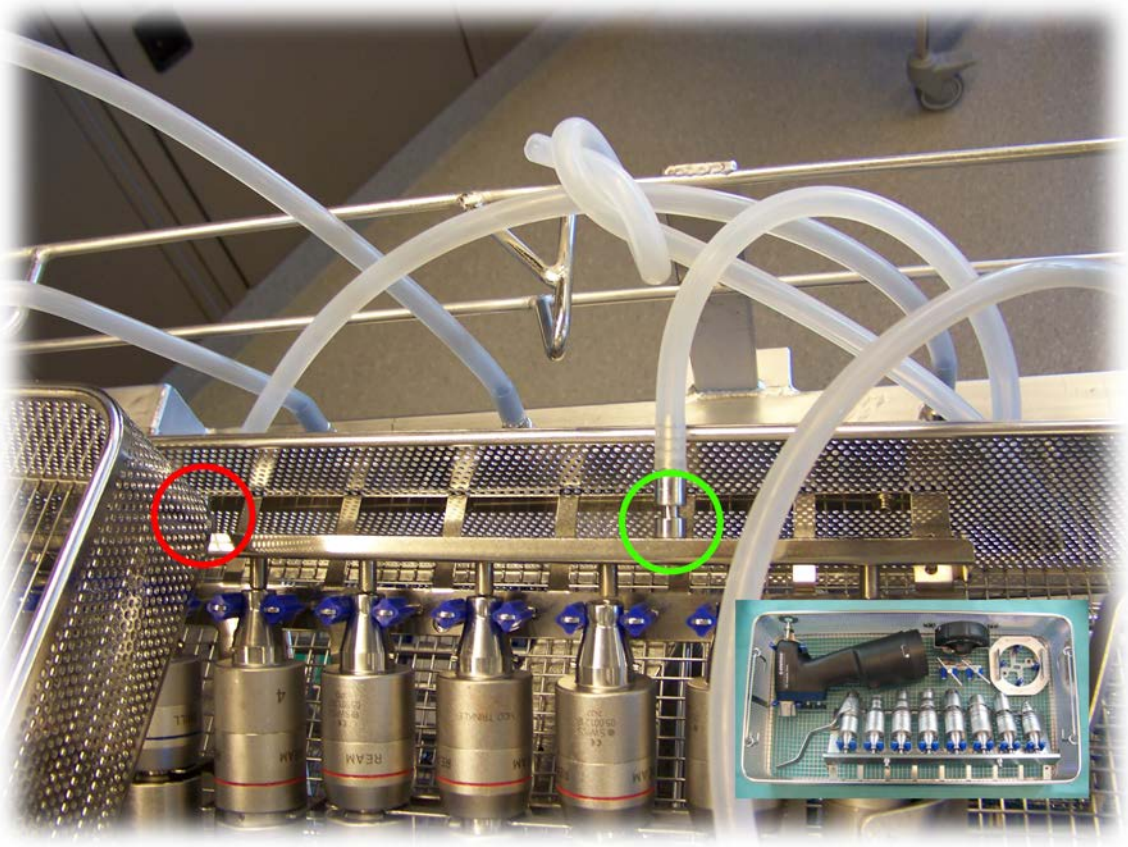


a tray with hollow biodrive attachments. The distribution block is developed specially to ensure that each attachment can be rinsed on the inside. The distribution block has two inlet ports to build up pressure and get enough flow for the eight attachments. The attachments are placed correctly before the adapter and the inlet adapters are connected to the mobile unit. It seems to be a correct situation. However, they thought it is sufficient to connect one inlet adapter...

3

INTRODUCTION TO THE FLUID MECHANICS IN NARROW CHANNELS

The cleaning capacity of a fluid flow through a tube depends on multiple factors. Sinner (1960) suggests that cleaning efficiency is a combination of four cleaning parameters: temperature, chemicals, time and mechanical action. The temperature and chemicals weaken the bond between soil and surface as a function of temperature, strength of chemicals and contact time between detergent and soil. The contact time is the time a specified temperature and strength of detergent are present at the interface between soil and detergent. Any cleaning procedure can be considered as a process of applying the energy required to remove soil from a surface. The energy may according to Sinner be divided into four sources. Additionally, detergent and heat have to be transported to the soil on the surface to be effective and the soil must be removed from the surface and out of the equipment to avoid reattachment. The rinsing of a hollow instrument can be considered as a fluid flow through a pipe (Figure 3.1). To create a flow in the shaft of an instrument, hollow instruments are connected in a washer-disinfector allowing the inside of the shaft to be rinsed. In this section the basics of the working principle of a cleaning effect of fluid flow will be explained, as well as the factors determining the force of a flow to the wall.

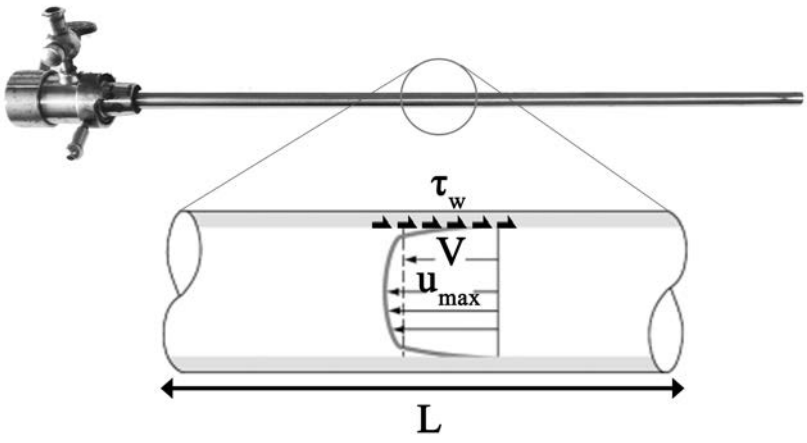
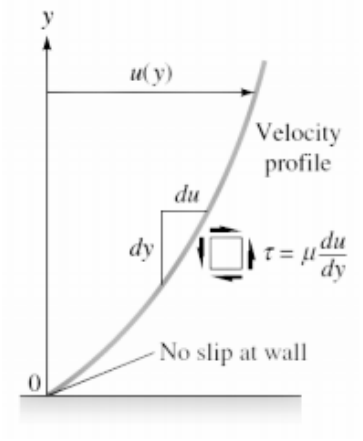


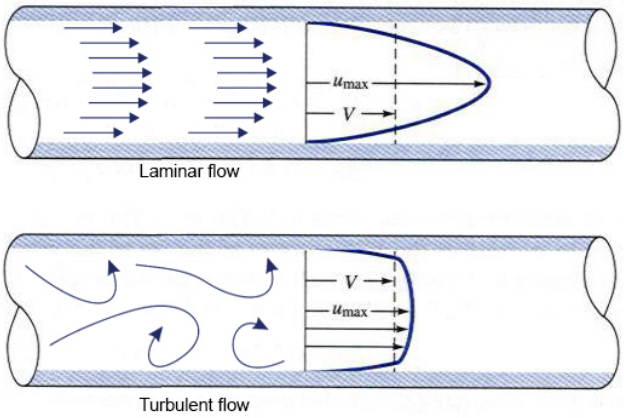
Figure 3.1: a schematic view of the flow in a hollow instrument. The flow streams from right to left. The flow applies a force to the wall, this force is called 'wall shear stress '. It is desired that the wall shear stress is as high as possible to realize an optimal cleaning capacity.

3.1. TYPE OF FLUID FLOW - REYNOLDS NUMBER

In fluid mechanics, the Reynolds number is an important dimensionless number and gives an indication of flow patterns of the fluid flow. And of course the type of flow patterns has an effect on the cleaning capacity of a fluid flow. In more technical terms the Reynolds number describes the ratio of the inertia with respect to



(a) velocity profile of a fluid near a layer. At the wall the fluid velocity is relative to the wall (no-slip condition), if the wall has no velocity than the velocity at the wall is also zero.



(b) a laminar flow (Re < 2300) is a tidy layered flow and has a parabolic velocity profile, a turbulent flow (Re > 4000) is characterized by a chaotic flow and the velocity profile is smoother.

Figure 3.2: Velocity profiles of a fluid

the viscous forces. This ratio indicates the type of fluid. The formula of the Reynolds number is defined as:

$$Re = \frac{inertial forces}{viscous forces} = \frac{\rho V d}{\mu} \tag{3.1}$$

where ρ is the density of the fluid [kg/m^3], V is the mean velocity of the fluid [m/s], d is the diameter of the tube [m] and μ is the dynamic viscosity of the fluid [kg/m/s]. The Reynolds number is also used to characterize different flow regimes within a similar fluid, such as laminar or turbulent flow: a laminar flow (Re < 2300) spells a tidy layered flow, where viscous forces are dominant and is characterized by smooth constant fluid motion. A turbulent flow (Re > 4000) is dominated by inertial forces which tend to produce a chaotic flow (Figure 3.2b). A laminar flow in a pipe has a parabolic velocity curve. A turbulent flow has a lot more friction perpendicular to the pipe, therefore the velocity curve is much smoother. For an optimal cleaning capacity a turbulent flow is required, characterized by chaotic property changes.

3.2. FORCE OF FLOW TO THE WALL - WALL SHEAR STRESS

A moving fluid can be mathematically considered as layers sliding over each other (Figure 3.2b). The layers apply a shear stress to each other, therefore the fluid is deforming continually. The needed force to deform a fluid is called the shear stress. The shear stress (τ) is determined by the force per surface (μ) and a deviation of the velocity to the height ($\frac{du}{dy}$):

$$\tau = \mu \frac{du}{dy} \tag{3.2}$$

It is interesting for the scope of this study to look on the force of a fluid acting on the wall of an instrument, because contaminants are attached to the wall and by the fluid flow is tried to reattach the contaminants of the wall. Therefore there is focused on the shear force at the wall, also called wall shear stress. The cleaning capacity of a fluid flow is actually the shear force acting on soil at the surface. The shear force removes the soil from the surface. The dimensions of the shear stress are the same as pressure [N/m^2]. The difference between pressure and shear stress is the direction of the gradient. The gradient of the pressure is perpendicular to the flow direction and the shear stress is parallel. The shear stress is independent with time, and the formula applies only to a fully developed, stationary and steady flow. The wall shear stress can be calculated for a fluid flow through an instrument based on the measurements of the flow and pressure. The calculated wall shear stress has to be larger than the attachment forces of the contaminants to the wall, in that case the contaminant will be soak off and removed from the wall. For an optimal cleaning capacity it is desired that the wall shear stress is as high as possible.

To calculate the wall shear stress of a constant flow in a pipe, has to be start with the energy equation, which is given by:

$$\underbrace{p_1}_{\text{Input pressure}} + \underbrace{\frac{1}{2}\rho g V_1^2}_{\text{Kinetic energy}} + \underbrace{\rho g z_1}_{\text{Potential energy}} = \underbrace{p_2}_{\text{Output pressure}} + \underbrace{\frac{1}{2}\rho g V_2^2}_{\text{Kin. energy}} + \underbrace{\rho g z_2}_{\text{Pot. energy}} + \underbrace{\rho g h_f}_{\text{Pressure drop}} \tag{3.3}$$

In a pipe, showed as above (Figure 3.2b), a differential pressure occurs by the kinetic energy, potential energy and the friction caused by the wall. The rinsing of a hollow instrument can be considered as a pipe with a fluid flow (Figure 3.1). Assuming that the instrument is placed horizontally ($z_1 = z_2$), and where the input velocity is the same as the output velocity ($V_1 = V_2$), there is only a differential pressure caused by the friction:

$$p_1 - p_2 = \Delta p = \rho g h_f \tag{3.4}$$

The term h_f is called the pipe head loss $[m]$ or pressure loss and is the energy dissipation due to friction along a given length of pipe, created by the roughness of the pipe material. This resistance is usually known as pipe friction and is measured is meters head of the fluid, thus the term head loss is also used to express the resistance to flow. Many factors affect the head loss in pipes, the size of the pipes, the viscosity of the fluid being handled, the roughness of the internal surface of the pipes, the changes in elevations within the system and the length of travel of the fluid.[18] The head loss of a fluid flow in a pipe can be determined by the Darcy-Weisbach equation:

$$h_f = f\frac{L}{d}\frac{V^2}{2g} \tag{3.5}$$

$$\text{Where f = fcn(Re, } \varepsilon/\text{d, duct shape)} \tag{3.6}$$

This equation shows that h_f is proportional to (L/d) and approximately proportional to V^2. The dimensionless parameter f is called the *Darcy friction factor*, and is a function of the Reynolds number, the relative roughness of the material and the "duct shape" effect. The quantity ε is the wall roughness height, which is important in turbulent pipe flow. The relative roughness is expressed as the roughness (ε) in relation to the diameter of the pipe: $Relativeroughness = \frac{\varepsilon}{d}$.

The friction factor can be approached by interpolation with the formula of Colebrook:

$$\frac{1}{f^{1/2}} = -2.0log\left(\frac{\varepsilon/d}{3.7} + \frac{2.51}{Re_d f^{1/2}}\right) \tag{3.7}$$

This is the accepted design formula for turbulent friction. It was plotted by Moody into what is now called the *Moody chart* for pipe friction. This approach is only valid for smooth pipes with a fully developed flow. There are many alternative approximations in the literature from which f can be computed explicitly from Re:

$$f = 0.316Re^{-1/4}\ 4000 < Re < 10^5\ H.\ Blasius\ (1911) \tag{3.8}$$

$$f = (1.8log\frac{Re}{6.9})^2\ [19] \tag{3.9}$$

The linear momentum relation for a deformable control volume is another approach to analyze the fluid flow through a pipe. The moment equation for the applied forces in the x-direction becomes:

$$\sum F_x = \Delta p\pi R^2 + \rho g(\pi R^2)\Delta L sin\phi - \tau_w(2\pi R)\Delta L = \dot{m}(V_2 - V_1) \tag{3.10}$$

This formula accounts the applied x-directed forces due to pressure, gravity and shear. Assuming that the instrument is placed horizontally ($\phi = 0$), and where the input velocity is the same as the output velocity ($V_1 = V_2$), that means that the x-directed forces due to gravity are zero and the sum of all the x-directed forces are also zero:

$$\sum F_x = \Delta p\pi R^2 - \tau_w(2\pi R)\Delta L = \dot{m}(V_2 - V_1) = 0 \tag{3.11}$$

$$\frac{\Delta p}{\rho g} = \frac{\tau_w 2L}{R\rho g} \tag{3.12}$$

$$\rightarrow h_f = \frac{4\tau_w L}{\rho g d} \tag{3.13}$$

A combination of the equations above results in the next equation for the wall shear stress:

$$\tau_w = \frac{f\rho V^2}{8} = 0.316\left(\frac{\rho V d}{\mu}\right)^{-1/4} \cdot \frac{\rho V^2}{8} = \frac{0.316}{8} \cdot \rho^{3/4} V^{7/4} d^{-1/4} \mu^{1/4} \; for 10^4 < Re < 10^5 \tag{3.14}$$

The wall shear stress depends on the fluid properties, as density and dynamic viscosity, velocity of the flow and the diameter. The fluid properties are determined by the type of detergents which is used. The diameter is a fixed parameter of the instrument and depends on the instrument design. An increase of the diameter results in a decrease of the wall shear stress. To ensure the same wall shear stress for different type of instrument designs, the velocity of the fluid flow has to be depending on the diameter of the instrument. The increase of the diameter and hence the decrease of the wall shear stress can be compensated by a higher flow.

These formulas are only valid for a fully developed flow. An undeveloped flow does not have a constant velocity profile and wall shear stress. The region of developing of the flow is called the entrance region. In this entrance region a nearly inviscid upstream flow converges and enters the tube. For a constant mechanical cleaning performance over the length of the tube, it is important that the flow is fully developed. In a turbulent flow the boundary layers grow faster, and the entrance length is relatively shorter. For a turbulent flow the entrance length can be calculated by:

$$\frac{L_e}{d} \approx 4.4 Re_d^{1/6} \tag{3.15}$$

3.3. PRACTICAL CASES

Two practical cases are worked out to get an indication of the flow in the instrument during the cleaning process. Hollow instruments, a suction tube and a trocar, are connected to a cleaning application for rinsing the inside of these instruments (Figure 3.3). The properties of both instruments are shown in Table 3.1. The mechanical performance, expressed as flow and pressure, was measured during the cleaning process (Figure 3.4). The fluid properties, as density and dynamic viscosity, are based on water of 55°C. Assuming that the cleaning fluid has the properties of water, the Reynolds number can be calculated by:

$$Re_{B1} = \frac{\rho V d}{\mu} = \frac{988 kg/m^3 \frac{8ml/s}{\pi(1mm)^2} 0.002m}{0.548E-3 Ns/m^2} = 9E3 \tag{3.16}$$

$$Re_{D1} = \frac{\rho V d}{\mu} = \frac{988 kg/m^3 \frac{11ml/s}{\pi(3mm)^2} 0.006m}{0.548E-3 Ns/m^2} = 4E3 \tag{3.17}$$

For flow in a pipe laminar flow occurs when Re < 2300 and turbulent flow occurs when Re > 4000. In the interval between these marks, laminar and turbulent flow are possible and are called “transition flows”. In both cases there is a turbulent flow. Based on the equations above the friction factor and wall shear stress can be calculated:

$$f_{B1} = (1.8 log \frac{Re}{6.9})^2 = (1.8 log \frac{9E3}{6.9})^{-2} = 0.006 \tag{3.18}$$

$$\tau_{w,B1} = \frac{f\rho V^2}{8} = \frac{0.006988 kg/m^3 (\frac{8ml/s}{\pi(1mm)^2})^2}{8} = 4.8 N/m^2 \tag{3.19}$$

$$f_{D1} = 0.316 Re^{-1/4} = 0.316(4E3)^{-1/4} = 0.04 \tag{3.20}$$

$$\tau_{w,D1} = \frac{f\rho V^2}{8} = \frac{0.04988 kg/m^3 (\frac{11ml/s}{\pi(3mm)^2})^2}{8} = 0.75 N/m^2 \tag{3.21}$$

The flow through instrument D1 is higher than the flow through instrument B1. There was assumed that the higher the flow the higher the wall shear stress. This assumption is only valid for situation with the same diameter. In this case, two instruments with a different diameter are compared. Then the flow [ml/s] is less important, but the velocity [m/s] of the fluid flow is important, because from the equations can be derived that the higher the velocity the higher the wall shear stress. The velocities for instrument B1 and D1 are:

$$V_{B1} = Q/A = \frac{8ml/s}{\pi(1mm)^2} = 2.5 m/s \tag{3.22}$$

Table 3.1: Instrument properties. The roughness value is taken from a new commercial stainless steel duct [20]. The flow and pressure was measured during a cleaning process at a temperature of 55°C.

Instrument	Diameter (mm)	Length (mm)	Volume (mL)	Roughness (mm)	Measured flow (ml/s)	Measured pressure (kPa)
B1	2	255	3.2	0.002	8	10
D1	6	260	7.4	0.002	11	16

$$V_{D1} = Q/A = \frac{11ml/s}{\pi(3mm)^2} = 0.39m/s \tag{3.23}$$

It turns out that the velocity in the suction tube (B1) with a lower flow is higher than the velocity in the trocar with the higher flow. In conclusion, a higher wall shear stress is required and that is achieved by increasing the velocity of the flow.

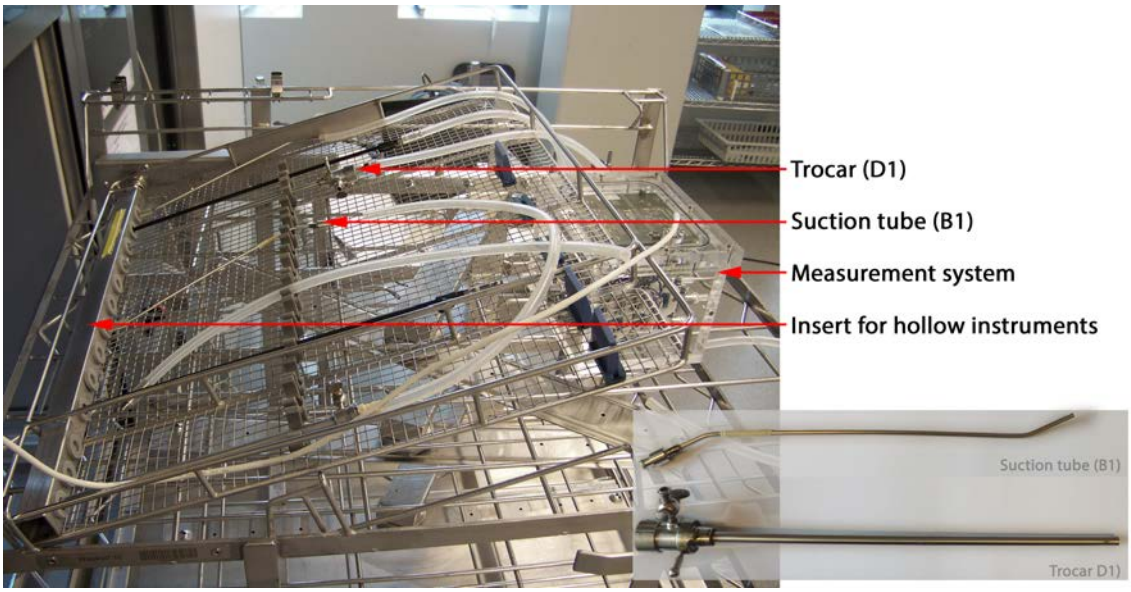


Figure 3.3: test setup consisting of instruments that are connected to a cleaning application on a mobile unit for rinsing of the inside of the instruments.

3.4. DISCUSSION

Studies have proven that beside the wall shear stress a pulsating jet also improves the cleaning efficacy. The current cleaning systems use more or less a constant pulse. To determine the cleaning capacity of a constant fluid flow, the wall shear stress is an important parameter. Multiple studies have shown that removal kinetics are a function of wall shear stress ([21–23]). The higher the velocity the higher the wall shear stress.

An important note is that a high wall shear stress alone is insufficient. In the calculation for the wall shear stress it is assumed that the flow is fully developed. The formulas are not valid for an undeveloped flow, because the velocity profile is not constant, therefore the wall shear stress to be much lower. An instrument design with curves, narrowing's and obstacles is more difficult to clean, because each restriction gives rise to a subsequent area where the flow is undeveloped and has a lower velocity and therefore a lower wall shear stress.

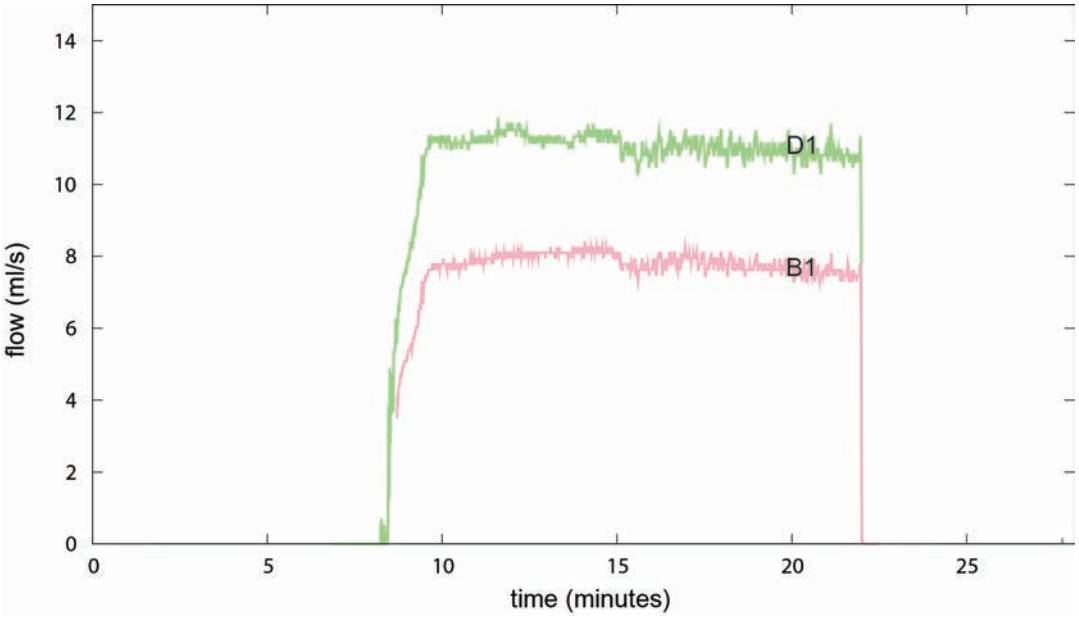
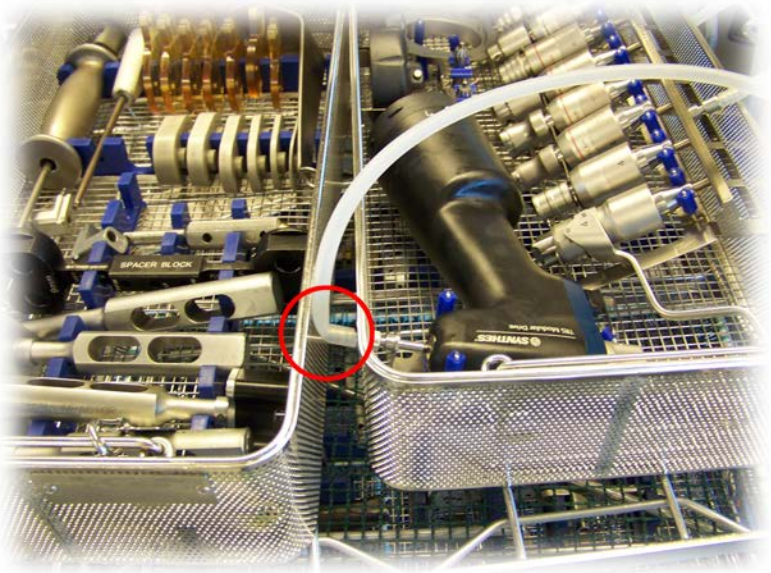


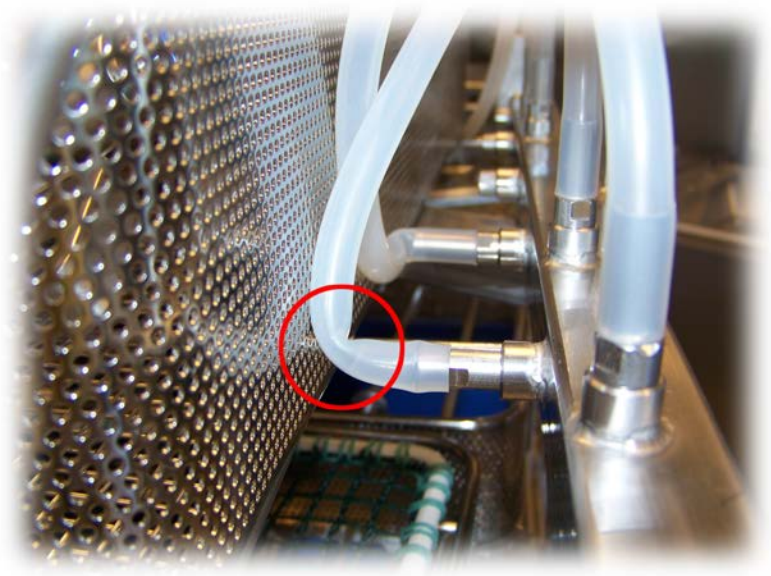
Figure 3.4: the flow through the dummy instruments during a cleaning process.

Main findings of this chapter:

- **The rinsing of hollow instruments can be characterized by the mechanical performance, defined as the flow, pressure and level of turbulence of a fluid through an instrument.**
- **To better release the attached contaminants from the wall of an instrument, the force applied to the wall (called wall shear stress) needs to be increased, which is achieved by increasing the velocity of the flow.**

BLOOPER 2...





the mobile unit has multiple adapters to connect hollow instrument for rinsing inside. The connection between the adapter and the instrument consists of a flexible silicone tube. A flexible tube is not always convenient, a kinked tube leaves little fluid...

4

MECHANICAL PERFORMANCE OF COMMERCIALLY AVAILABLE INSERTS; A COMPARATIVE STUDY

The technical devices for surgical operations have changed drastically in the last decades.[24] Conventional open surgery has given way to shared-control surgery. Shared-control robotic systems aid surgeons during surgery, whereby the human does most of the work. The robotic system monitors the surgeons' performance and provides stability and support by force feedback. Besides the positive effects in that surgeons have more accuracy and that more complex interventions are possible, there is the large benefit that the incisions are smaller. A traditional kidney intervention needed a large incision in the belly. Now several small incisions give enough possibilities to perform kidney surgery using minimally invasive surgical instruments. The downside of these MIS instruments is that they are more difficult to clean than conventional surgical instruments. MIS instruments consist of mostly narrow channels. Narrow channels are ideal places for human tissues, residuals and bacteria to nestle.

As a result of the development of these new surgical instruments, the world of cleaning and disinfection of surgical instruments has changed as well in the last decade. There is more attention on the cleaning aspects of medical instruments, international guidelines have become stricter and the cleaning facilities are catching up. From a technical point of view there are big developments; the available applications for the cleaning of minimally invasive surgical instruments have been increased. There is a growing realization that it is unthinkable not to rinse the inside of hollow instruments during the cleaning process in a washer-disinfector. The development of washer-disinfectors also follows this trend by extending the connecting possibilities for hollow instruments. But in many cases there are still more hollow instruments than connecting possibilities, also not all the instruments are suitable to connect to these connectors. Therefore inserts are used. Inserts are used for the connecting of hollow instruments to the pump circuit of the WD therefore a hollow instruments are rinsed at the inside. Inserts mostly have multiple outputs for the connecting of multiple hollow instruments. An insert can be placed on a regular mobile unit. The working principle is like a flow distributor or manifold, it consists of one or two input adapters and it has multiple output adapters, to which such multiple instruments can be connected (Figure 4.1).

In contact with suppliers of these inserts, it seems as if validation reports are hardly available. It is unknown what the flow and pressure is through the adapters of an insert during a regular cleaning process and the flow distribution among the different output channels is also unknown. There are no instructions about the type of instruments that can be rinsed through the insert. There is also a lack of recommendations for the staff at the Central Sterile Supply Department in order to connect instruments to the insert properly. This lack of knowledge can be a risk, because an insert can perform differently, or less well than expected. For example, assume an insert gets too little input flow, the consequence is that there is too little pressure in the insert with the consequence of a non-uniform flow distribution is created (Figure 4.2). A non-uniform flow distribution among the different channels constitutes a risk for the connected instruments. For example, the instrument that is connected to the first or last adapter of the insert shown (Figure 4.2) will not be rinsed, because there is hardly any flow through these adapters. Another risk may occur by the effect from a connected instrument

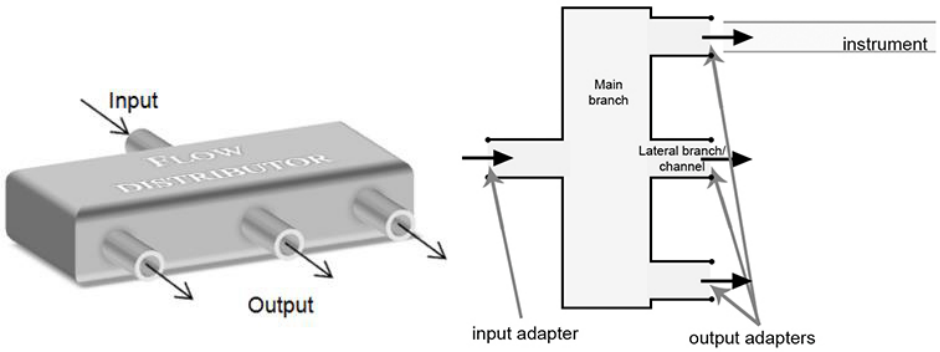


Figure 4.1: schematic view of an insert. The working principle is like a manifold: the input flow is distributed among multiple outputs. The input adapter of the insert is connected to a mobile unit and instruments can be connected to the output adapters.

on the flow through adjacent channels. Therefore it is important that these cleaning devices are tested in practice.

This study consists of a comparison of the mechanical performances of several commercially available inserts. An analysis is made of the flow and pressure distribution among the different output adapters. Important questions for this study are: what is the flow and pressure through the output adapters of an insert? Is there a flow distribution among the different channels of an insert and what is the effect of connecting different types of instruments?

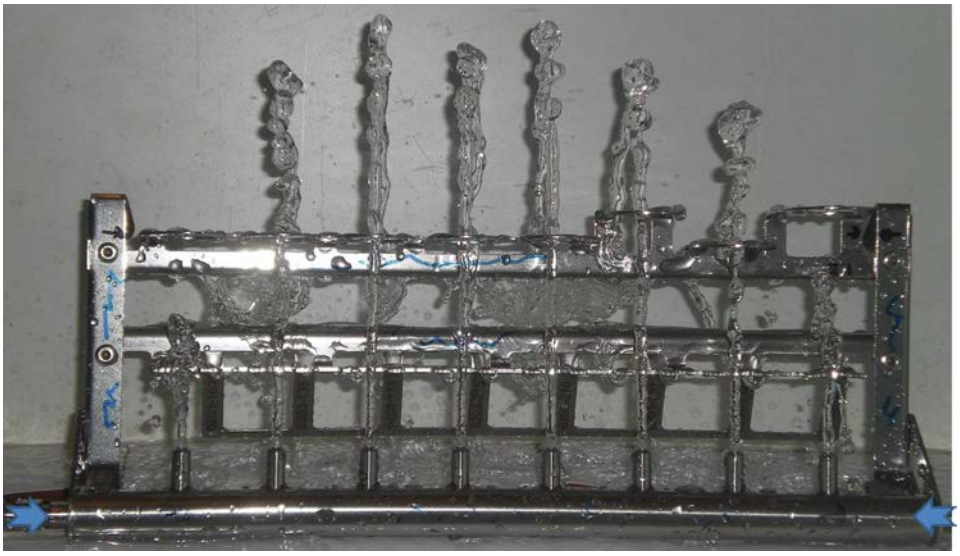


Figure 4.2: a simulation of what happens if there is too little input flow in a manifold. The picture shows an insert placed upright. The input flow comes into the insert from the left and the right side and there are eight output adapters. The height of the water jets are an indication of the pressure at the adapter. The higher the jet, the higher the pressure. The jets at the middle are the highest, so there the flow is also the highest. That means that the pressure is not the same for all of the eight adapters. The reason is that the input flow is too little, therefore there is too little pressure in the tube of the insert. The consequence is a non-uniform flow distribution among the different channels. The channels on the sides have much lower pressure and flow than the channel in the middle.

4.1. METHODS AND MATERIALS

For pictures of the materials, see Appendix A!

The tests were performed at the Central Sterile Supply Department of Erasmus Medical Center in the Netherlands. The used washer-disinfector was a Miele Professional type PG 8528 (Miele & Cie. KG, Germany). The wash cycle used was the pre-programmed 'instrument' cycle that was stopped after the cleaning process. The cycle consisted of: a pre-wash 5 min using cold water (i.e. room temperature) and a cleaning phase for

14 min using hot water (55°C) and a detergent (Neodisher MediClean Forte). Reverse Osmosis (RO) water was used for all stages of the program. A measurement system was used to measure the flow and pressure of the flow through hollow instruments. This system was developed by Causa BV (Eindhoven, the Netherlands) and is able to measure the flow and pressure of eight separate channels.

The instrument was connected to a mobile unit, designed to be placed into the washing chamber. A standard mobile unit of the CSSD was used for the tests. This mobile unit consists of two multiple spray arms and 9 connecting possibilities (small adapters) for inserts and hollow instruments (Figure 4.3). Pictures and specifications of the test materials are given in Appendix A.

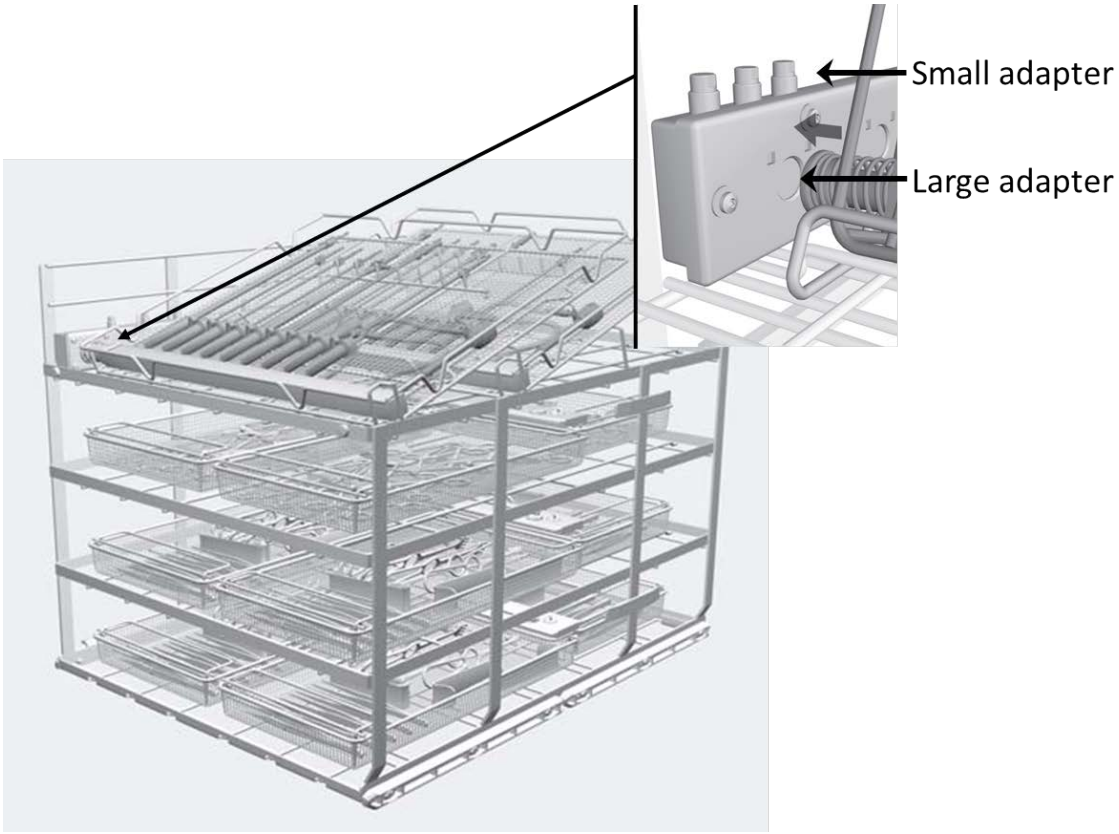


Figure 4.3: a standard mobile unit. The mobile unit can be placed in the chamber of a washer-disinfector. Instrument trays can be placed on the levels of the mobile unit. An adapter block is placed on the top level of the mobile unit. The adapter block can be used to connect inserts and hollow instruments. There are large and small adapters. The small adapters are suitable to connecting inserts or hollow instruments. The large adapters are suitable for special inserts.

4.1.1. INSERTS

The small adapters of a mobile unit are not always suitable for connecting to hollow instruments. Therefore inserts can be used, which can be connected to an adapter of a mobile unit and instruments can be connected to the output of the insert. An insert is actually a flow distributor, it has one or two input channels and multiple output channels for the hollow instruments. Several inserts are analyzed in this study (Table 4.1). The Lupoo inserts were connected to two small adapters of the mobile unit. This is not fully consistent with the supplier's instructions, actually a special hole has to be drilled in a mobile unit for the special connectors of the Lupoo-inserts. The NTOC, TRS and biodrive inserts are connected to a small adapter. The design of the output adapters of the inserts is also different, there are contact and contactless adapters (Figure 4.4). The principle of a contact adapter is that an instrument has to be pushed into a silicon holder, thus the tip of the instrument to be fully enclosed and so there is no loss of flow. With contactless adapters an instrument should be placed just before the adapter. There is no contact between the instrument and the adapter. In the first instance the contactless adapters were considered as contact adapter, the tube from the insert to the measurement system to be pushed over the adapter and therefore the nozzle was fully enclosed (Figure 4.5).

(a) (b)

Figure 4.4: a contactless adapter vs. a contact adapter. A) contactless adapter: the instrument has to be placed near to the injector nozzle. B) contact adapter: the instruments are pushed into the silicone holder, allowing the instrument tip to be fully enclosed.

The effect of a contactless connection is researched in another study[1].

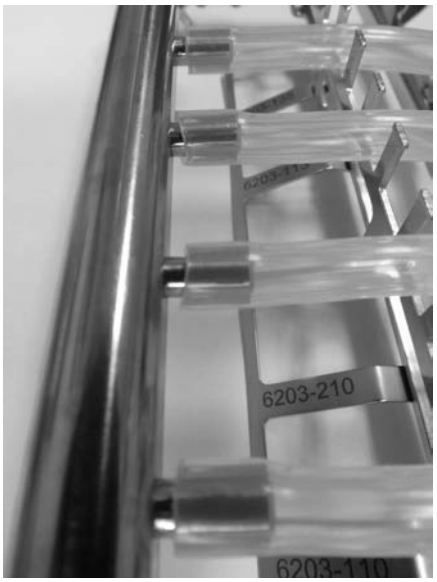


Figure 4.5: the test setup of an insert with contactless adapters. For the measurement the inserts were considered as contact adapters: a tube of the measurement system was pushed over the injector nozzles, allowing the nozzle to be fully enclosed.

4.1.2. INSTRUMENTS

This study also investigated the extent to which there is an effect of connecting instruments to an insert. Thereby six instruments (three types of instruments) were used as dummy instruments (Table: 4.2).[2] All instruments were hollow instruments which differed in internal diameter and design. The instruments were connected to the Lupoo insert and the Modular Cassette insert (Table 4.3).

4.1.3. METHODS

In each test one insert was tested per batch. The output adapters of the insert were connected to the measurement system (Figure 4.6). The measurement system can measure the flow and pressure of seven channels,

[1] See: Effect of the adapter design on the mechanical performance. Section 5.
[2] For an explanation of the instruments, see Section 2.2.5.

Table 4.1: overview of cleaning configurations. The insert is specified for each configuration. The inserts differ in number of adapters and the way how to connect.

Cleaning configuration	Used insert	Number of adapters	Connected to
A	*Without an insert, the mobile unit was connected directly to the measurement system*		
B	Modular cassette insert	13	Mobile unit, large adapter
C	Double modular cassette insert	22	Mobile unit, large adapter
D	NTOC-block	8	Mobile unit, small adapter
E	TRS tray	8	Mobile unit, small adapter (double connector)
F	Biodrive tray	1	Mobile unit, small adapter
G	Lupoo type 2	12	Mobile unit, small adapter
H	Lupoo type 5	3	Mobile unit, small adapter (double connector)

Table 4.2: specifications of the dummy instruments.

Instrument	Internal diameter (mm)	Length (mm)
B1, B2	2	255
C1, C2	3	375
D1	6	260
D2	7	230

therefore a maximum of seven output adapters were connected to the measurement system. The adapters which were not connected to measurement system were open, this is comparable with the use in practice. Then adapters which are not connected to an instrument are also open. In the second phase, the dummy instruments were connected to an insert and the outputs of the instruments were connected to the measurement system (Figure 4.7).

Figure 4.6: an overview of the order of elements. The measurement system is the last part of the chain and is connected to the instruments. The instruments were connected to an insert, the insert was connected to a mobile unit and the mobile unit was placed in the washer-disinfector.

4.2. RESULTS

The flow and pressure values for the different inserts are shown in Figure 5.4. The flow and pressure is the highest in a small adapter of the mobile unit, it is comparable with application F. In application F a small adapter is connected to an injector nozzle and the output of the nozzle is connected to the measurement system. These two applications use no insert, therefore there is also no flow distribution among multiple channels. The modular cassette insert with 13 output adapters (application B) has the highest flow and pressure. The double modular cassette insert with 22 output adapters also has a higher flow than the other inserts. The flow and pressure in the instruments connected to the Lupoo and the modular cassette insert respectively are shown in Figure 4.9. The flow and pressure is significantly higher for all three instruments connected to the modular cassette insert compared to the connection to the Lupoo insert.

(a) (b)

Figure 4.7: a) test setup of cleaning application A, without an insert. The measurement system was connected directly to the mobile unit. b) Test setup of cleaning configuration L, M and N with the modular cassette insert. Instruments were connected to the insert and the output of the instrument was connected to the measurement system, so flow and pressure through the instruments were measured.

Table 4.3: overview of tests with instruments connected to an insert.

Cleaning configuration	Insert	Instrument
I	Lupoo-5	B
J	Lupoo-5	C
K	Lupoo-5	D
L	Modular cassette insert	B
M	Modular cassette insert	C
N	Modular cassette insert	D

4.3. DISCUSSION

The highest flow in a configuration with an insert was obtained in configuration B with the modular cassette insert. An important reason why the other inserts (D, G, E, H) have a lower flow is that these inserts are connected to one or more of the small adapters. The modular cassettes (B and C) are connected to a large adapter of the mobile unit. The diameter of a large connector is larger, so it is logical that the flow is larger as well. The inserts of application G and H were connected to small adapters. Actually, the instructions of the manufacturer prescribe a special hole in the mobile unit for a connector of these inserts. The flow is maybe higher with this special connector. This configuration is manipulated in order to try getting more input flow (Configuration H*). This insert has 12 output adapters and in the manipulated configuration two output adapters were also used as input adapters, therefore the insert to be connected to two standard small adapters and two extra small adapters. In these special configuration the flow and pressure was higher, but still smaller than for application B and C.

The cleaning applications C, D and E consist of contactless adapters, but for the test measurements they are connected as contact adapters. Therefore the tube of the measurement systems was pushed over the adapter allowing the tip to be fully enclosed. The effect of a contactless adapter is described in another study.[3] Therefore the measured performances are not in accordance with real performances if they are used as contactless adapters. It was attempted to do measurements with the tubes placed very close to the injector nozzles. But the flow and pressure could not be measured in this test setup, because there was no flow. The cause of the low flow is probably because there is not enough pressure. The connection between the nozzle and instrument is open with the contactless adapter; therefore there is a pressure drop, and then the flow has to less pressure to flow through the measurement system. In conclusion, there are two options: the first means that there is flow through the instruments, but too little to measure, and in the second case, there is no flow, and that is the reason that there is no flow measurable. That is why this remains a very interesting

[3] See section 6: Effect on adapter design on mechanical performances.

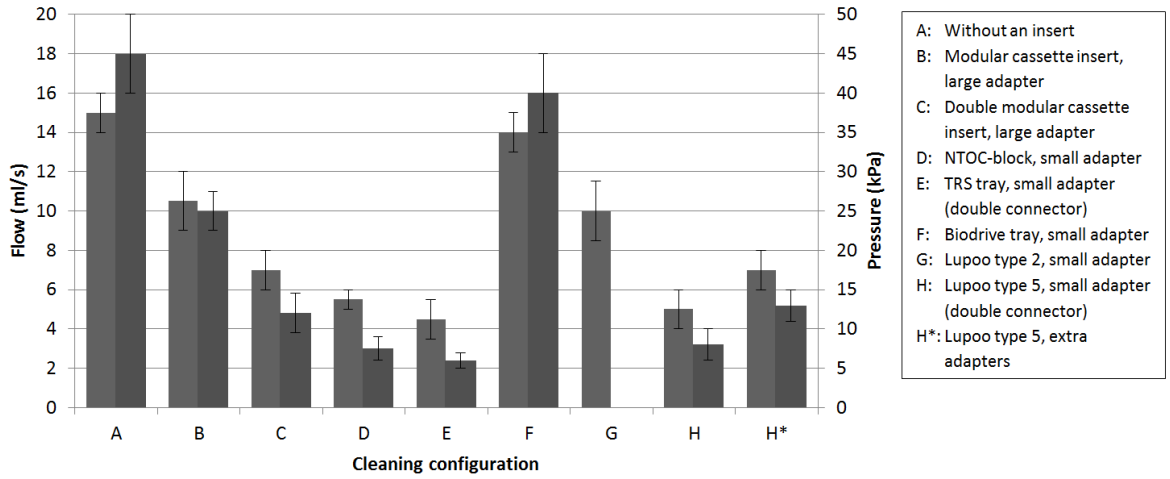


Figure 4.8: flow and pressure in the adapters for several cleaning configurations.

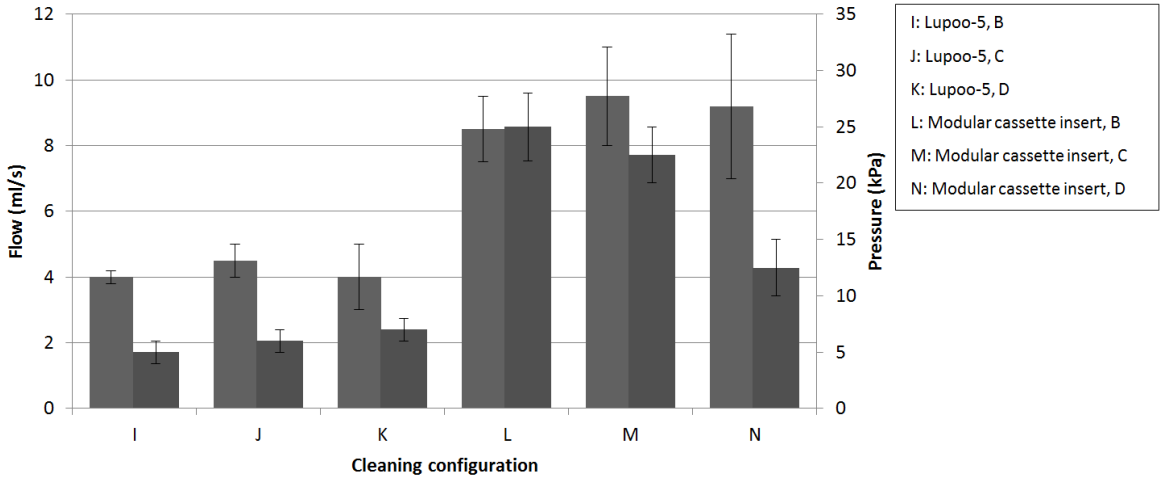


Figure 4.9: flow and pressure in instruments connected to respectively the Lupoo insert (configuration I, J, K) and the modular cassette insert (configuration L, M, N).

topic for further studies.

THE EFFECT OF THE NUMBER OF OPEN SMALL ADAPTERS ON THE FLOW AND PRESSURE

The standard mobile unit used at the Erasmus MC has nine small adapters. In the standard case four adapters are open and the other five adapters are closed with a blind stopper. What is the effect if multiple adapters are open? Or is it better to close an unused adapter? Cleaning application A (only with a mobile unit) is repeated with more open adapters. The regular cleaning cycle with four open adapters performed a flow of $14-16 ml/s$ and a pressure of $40-50 kPa$, these performances are equal for the configuration with seven and nine open adapters. Based on these measurements it can be concluded that the number of open small channels has no effect on the flow in these adapters.

THE EFFECT OF AN OPEN LARGE ADAPTER ON THE FLOW IN THE SMALL ADAPTERS

A mobile unit consists of nine small and four large adapters. The large adapters can be used for inserts, like the modular cassette insert. It is concluded that the number of open small adapters has no effect on the flow, but is this also the case for the large adapters? For cleaning application B the modular cassette insert was connected to a large adapter of the mobile unit. In this setup the flow and pressure of the small adapter were also measured. With a connected modular cassette insert to a large adapter the flow in the small adapters was reduced to $13-14 ml/s$ and with the double modular cassette (22 adapters) connected to a large adapter, the flow was reduced to $11 ml/s$ in the small adapters. That means that the opening of a large adapter has an effect on the flow in the small adapters.

Table 4.4: Flow results per instrument, the instruments were connected to a modular cassette insert.

Instrument	Position	Flow (ml/s)	Position	Flow (ml/s)
B1	13	9	9	6
B2	1	8	13	-
C1	2	10	1	9
C2	10	9	8	-
D1	3	11	3	11
D2	7	7	7	8

Table 4.5: Pressure drop over the measurement system for two flow levels and the pressure drop over the dummy instruments.

	Flow (ml/s)	Pressure drop (kPa)
Measurement system	7	14
Measurement system	10	25
B1, B2	8	18
C1, C2	9	8
D1	10	5
D2	10	5

THE EFFECT OF SIDE BY SIDE CONNECTED INSTRUMENTS WITH DIFFERENT DESIGNS ON THE FLOW

The connecting of instruments takes place randomly; the design of an instrument is not taken into account. Therefore it can happen that an instrument with a large internal diameter is connected next to an instrument with a small diameter. It is possible that the flow goes through the large instrument and that the small instrument has hardly any flow. This phenomenon is investigated by using the dummy instruments. The dummy instruments have different designs with different internal diameters.

In the tests a difference was made between free positioning and clustered positioning. Free positioning means that the adjacent channels of a connected instrument are open and nothing is connected to that. In the case of clustered positioning a few instruments are connected side by side. The hypothesis was that free instruments have a lower flow than clustered instruments, because the flow can easily find its way through the free open adjacent adapters than through the instrument. This expectation cannot be justified by the results (Table 4.4). On the base of the results is it hard to come to clear conclusions. In this test too many parameters may vary, because several instruments with different designs were used and the connecting positions varied. To do research on the effect of the connecting position, it is better to use the same instruments.

The difference in instrument design of the dummies has no justified effect on the flow through these instruments. However, the issue is whether the measurement system used is able to detect these differences. The pressure drop caused by the measurement system is significantly higher than the pressure drop caused by the instruments (Table 4.5). The pressure drop of the instruments B, C and D is 18,8 and $5kPa$ respectively versus $425kPa$ of the measurement system.

4.3.1. CONCLUSIONS

In short, the most important conclusions of this chapter are as follows: For proper functioning of an insert it is important that there is enough input flow. If there is too little input flow the main branch is not filled completely with fluid and therefore the lateral branches have a non-uniform flow distribution. In the tested inserts, there were non-uniform flow distributions measured, and hence there were no significant differences in flow among the lateral branches of the same insert.

In this comparative study multiple inserts were tested. It is proven that the mechanical performance between the tested inserts differs significantly. The insert with the best mechanical performance has a flow about $10ml/s$ and a pressure of about $25kPa$ and the baddest insert had a flow of $4-5ml/s$ and a pressure of $7kPa$. However, it is unknown what the minimal required flow and pressure have to be in an instrument. Also the cleaning instructions of instruments do not prescribe a minimal required flow. That means that it is impossible to conclude that a specific insert has “failed” and is therefore “unacceptable” to use. More study is needed in order to determine the required flow and pressure. The conclusion that can be drawn is that

there is a difference in mechanical cleaning performance of several commercially available inserts based on the flow and pressure in the output adapters.

In the current situation, the unconnected adapters are not closed. In this study is proven that it does not matter whether or not the unconnected adapters are open or closed. The pressure of the pump of the washer-disinfector is sufficiently powerful to provide enough pressure to the complete system, and therefore the number of open small adapters has no effect on the flow and pressure in the adapters. Only the opening of a large adapter of the mobile unit has a significant effect and results in a flow decrease.

The differences in instrument design and internal flow resistance of the tested dummy instruments do not show a clear effect on the magnitude of the flow through the instrument. A possible explanation is that the resistance of the measurement system is too high, however the resistance differences of the dummy instruments are too small in relation to the resistance of the measurement system.

4.3.2. FURTHER RESEARCH

This study was a first step in getting more knowledge about the use of inserts for rinsing hollow instruments. A few topics are made clearer, but there is still work to do. An interesting and important topic is to do further research in the minimal required flow and pressure. This study has shown that the mechanical performances of some inserts differ. To make a more complete decision about an insert and whether or not it is able to clean hollow instruments, the minimal required flow to effectively clean a hollow instrument must be known.

Three different dummy instruments were used to investigate whether the instrument design has an effect on the flow and pressure. It is recommended to repeat this study in a more systematic way. The internal flow resistance of an instrument can be simulated by a clip or valve on a tube, then the flow and pressure can be measured for a number of resistances.

Main findings of this chapter:

- **The mechanical performance differs for the currently available inserts caused by the manner of the input of the insert is connected to the mobile unit and the number of output adapter.**
- **Inserts with multiple output adapters are recommended to use them only as they are connected to a large adapter of a mobile unit as these provide a higher flow.**
- **Connected instruments to inserts have no effect on the flow in the adjacent channels, which implies that instruments can be connected randomly and open channels do not have to be closed.**

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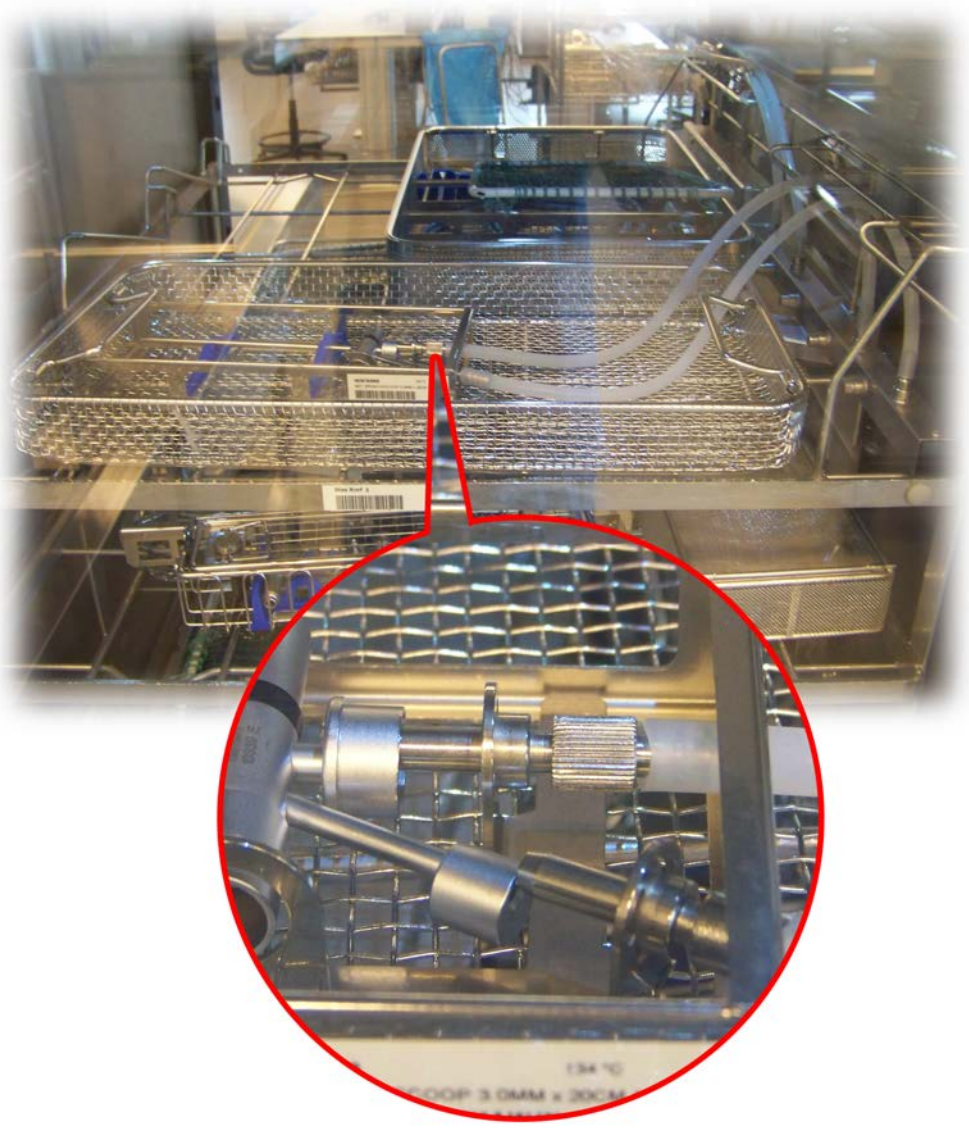


a tray with two hollow instruments, the adapters are connected correctly to the mobile unit. But if we look more in detail then we see that the instrument is not placed in front of the nozzle…

5

EFFECT OF THE ADAPTER DESIGN ON THE MECHANICAL PERFORMANCE

The reprocessing of medical instruments takes place at the Central Sterile Supply Department (CSSD). This reprocessing consists of three automatic processes and preceded by a manual pre-wash. The first process is the cleaning process. The aim of cleaning is the removal of all visible dirt, blood, tissue and other patient residuals from the instrument. The cleaning and disinfection takes place in a washer-disinfector (WD). Disinfection is the second phase of the reprocessing; the last one is sterilization. The cleaning is done with water and detergents that are sprayed into the chamber of a washer-disinfector by spray arms. A disadvantage of this system is that sometimes spray shadow occurs, that means that an areas are not reached by the cleaning fluid. Some parts of the instrument are therefore not cleaned effectively. Another disadvantage is that minimally invasive surgical instruments cannot be cleaned very well with only spray arms. These instruments must not only be cleaned on the outside but also on the inside. They consist of a shaft, a hollow part, where contaminants can enter. These instruments are called “hollow” instruments or “cannulated” instruments. To clean the hollow instruments on the inside during the cleaning process, the instruments are connected to the water pumping system of the WD. The instrument can be connected to an adapter of an insert and the insert is connected to the WD.

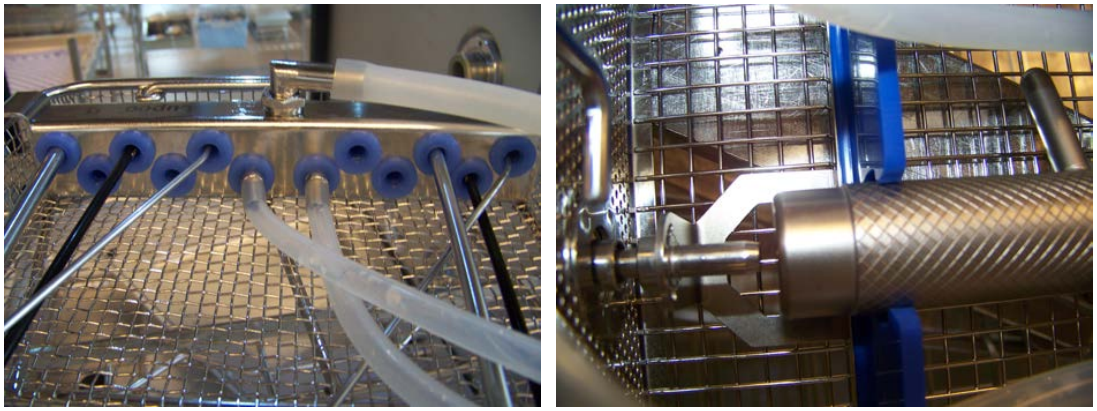
In general there are two kinds of adapter designs for connecting hollow instruments: contactless and contact adapters (Figure 5.2b). For the contactless adapters, there is no contact between the adapter or injector nozzle and the instrument. The hole of the shaft of the hollow instrument has to be placed immediately in front of the injector nozzle allowing there to be no contact between them. A contact adapter often consists of a silicone holder and then the tip of the instrument is pushed into this holder. With a contact adapter the tip of the instrument is fully enclosed by the silicone holder. An important advantage of contactless adapters is that the tip can be cleaned also, in contrast to the contact adapter where the tip is enclosed (Figure 5.2a). A possible disadvantage is that there is flow and pressure loss between the adapter and the instrument. In this study the effect of the adapter design on the mechanical performance is investigated. The mechanical performance is expressed as the flow and pressure through an instrument.

5.1. METHODS AND MATERIALS

For pictures of the materials, see Appendix A!

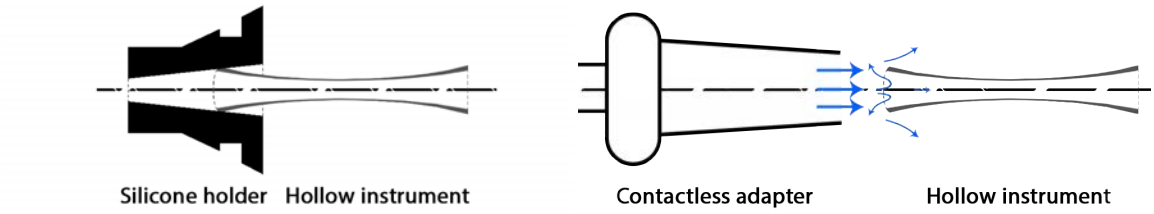
The tests were performed at the Central Sterile Supply Department of Erasmus Medical Center in the Netherlands. The used washer-disinfector was a Miele Professional type PG 8528 (Miele & Cie. KG, Germany). The wash cycle used was the pre-programmed ‘instrument’ cycle that was stopped after the cleaning process. The cycle consisted of: a pre-wash 5 min using cold water (i.e. room temperature) and a cleaning phase for 14 min using hot water (55°C) and a detergent (Neodisher MediClean Forte). Reverse Osmosis (RO) water was used for all stages of the program. A measurement system was used to measure the flow and pressure of the flow through hollow instruments. This system was developed by Causa BV (Eindhoven, the Netherlands) and is able to measure the flow and pressure of eight separate channels.

Inserts are used to connect hollow instruments to the liquid system of the washer-disinfector. In this study



(a) (b)

Figure 5.1: a contactless adapter vs. a contact adapter. A) contactless adapter: the instrument has to be placed near to the injector nozzle. B) contact adapter: the instruments are pushed into the silicone holder.



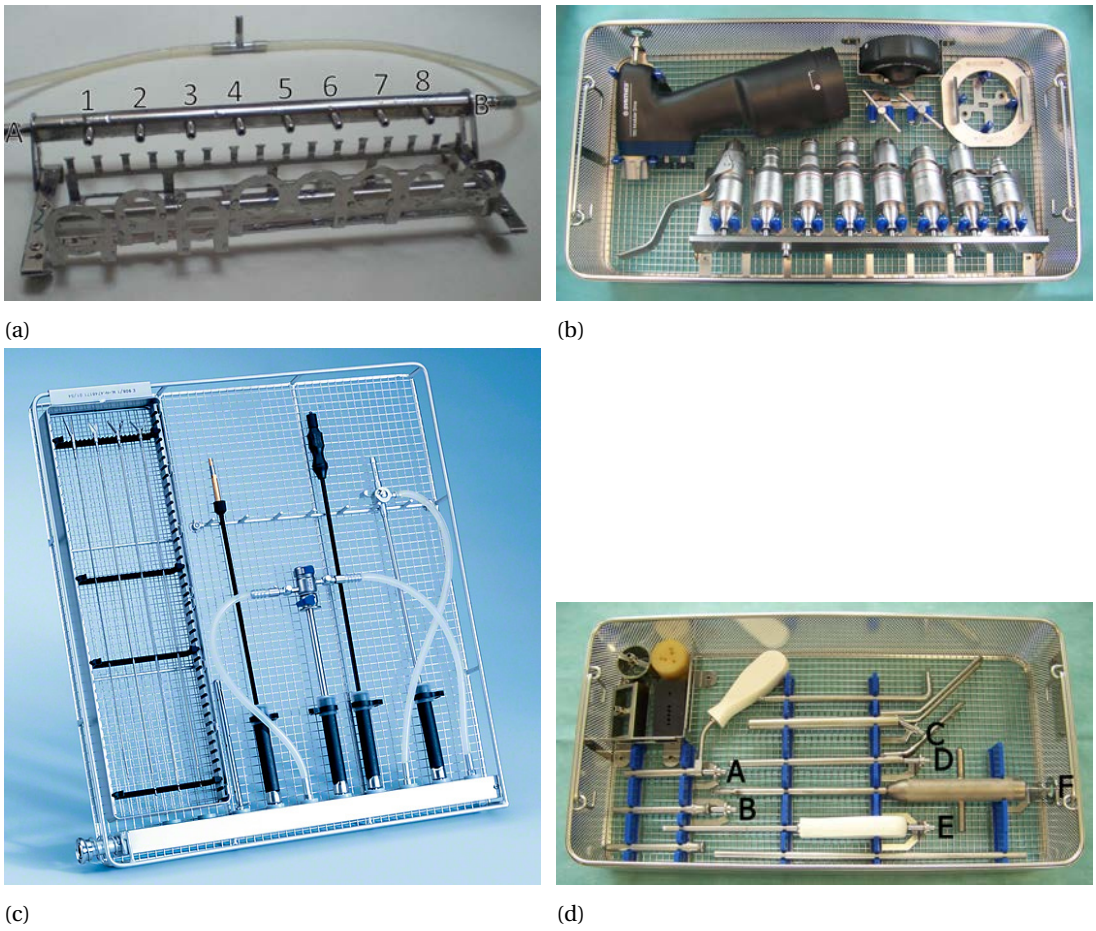
(a) (b)

Figure 5.2: a) a schematic view of a contact adapter. An instrument is pushed into a silicone holder, therefore the tip of the instrument is enclosed by the holder and cannot be cleaned very well. b) a schematic view of flow loss in the open contactless connection between an adapter and the instrument.

three inserts are used: NTOC-tube, TRS-insert and a modular cassette insert and an instrument tray with an injector nozzle for hollow instruments. The first two inserts are manifolds with two adapters for the input of the cleaning fluid and multiple contactless output adapters (Figure 5.3a). Instruments have to be placed close to these output adapters, allowing for no contact between the adapter and the instrument. The TRS-insert is a part of a TRS-tray (Figure 5.3b). Trauma Recon System (TRS) is a battery-driven power system designed for traumatology and arthroplasty. The set consists of a TRS battery hand piece and some attachments with e.g. drilling and sawing functionalities. The used set is a drilling set and consists of six drilling attachments, these attachments have a hollow shaft and so they have to be rinsed on the inside. The tray is equipped with a distribution block for rinsing the drilling attachments. They also have a contactless connection between the adapters of the distribution block and the attachments. The modular cassette insert is suitable to connect to a large adapter of a mobile unit (Figure 5.3c). The used cassette has the capacity to connect thirteen hollow instruments. The instruments have to be pushed into a silicone holder. In this test, the modular cassette insert is used to rinse the TRS drilling attachments. The Biodrive tray consists of multiple hollow instruments (Figure 5.3d). Each hollow instrument has its own injector nozzle and each nozzle is individually connected to one small adapter of the mobile unit. This adapter is a contactless type and the input is directly connected to the mobile unit. An overview of the different cleaning configurations for this study is shown in (Table 5.1).

5.2. RESULTS

The mechanical performance is expressed as the flow and pressure in an adapter. The results for all the cleaning configurations are shown in Figure 5.4. There was no flow and pressure measured for the configuration with the NTOC and TRS insert in the contactless setup. The NTOC, TRS and modular cassette are inserts with a distribution effect. That means that there is one or two input adapters and multiple output adapters, therefore the flow and pressure are distributed among the multiple output adapters. The Biodrive injector nozzle is not a distributor, it has one input and one output.



(a) (b)

(c) (d)

Figure 5.3: a) NTOC insert with eight contactless adapters. b) TRS set with the TRS insert and the eight drilling attachments. c) Modular cassette inserts with thirteen connecting possibilities. d) the Biodrive tray with multiple hollow instruments.

Table 5.1: overview of the cleaning configurations for this study

Cleaning configuration	Description	Adapter type
A	NTOC-tube without instruments	Contact
B	NTOC-tube without instruments	Contactless
C	TRS-insert without instruments	Contact
D	TRS-insert without instruments	Contactless
E	TRS-insert with trs-attachments	Contactless
F	Modular cassette insert with trs-attachments	Contact
G	Biodrive injector nozzle without instrument	Contact
H	Biodrive injector nozzle with instrument	Contactless

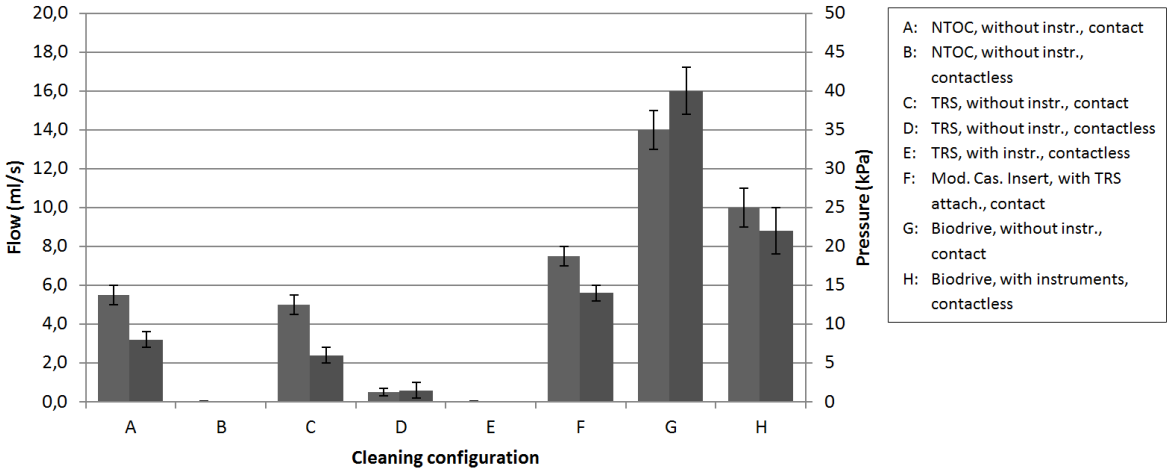


Figure 5.4: the mechanical performances - expressed as flow and pressure - for the different cleaning configurations.

5.3. DISCUSSION

The mechanical performance of contactless adapters (configuration B, D, E and H) showed a significant difference compared to the contact adapters (configuration A, C, F and G). In the case of configuration B and E there was no measurable flow and pressure. An obvious conclusion should be that contactless adapters are not able to rinse hollow instruments. But this is too premature and insufficiently justified. The test setup is not the same as the real setup (Figure 5.5). For the tests a measurement system was connected to the adapters, this is an extra component compared to the practical setup. For a good interpretation of the measured results is it important to know the resistance of the measurement system relative to an instrument. It is possible that there was no flow and pressure measured, because the resistance in the measurement system was too high. And it is possible that in the real configuration there is still flow and pressure, because the resistance of instruments could be smaller. As described in another section, the resistance of the measuring sensors is sizable and larger than the resistance of some instruments.[1] The conclusion that can be drawn is that for all the tested configurations the mechanical performances of the contact adapters are better than for the contactless adapters. There is significant pressure and flow loss in a contactless adapter. The cause of this loss is the open connection between the adapter and the instrument. Therefore the fluid is sprayed onto the tip of an instrument, but because there is too much resistance the fluid streams back out of the instrument (Figure 5.2b). Configuration F is a special case. The insert of this configuration, a modular cassette insert, has contact adapters. The insert is used for the TRS-instruments. The TRS-insert is specially developed to rinse the inside of TRS-attachments. But based on the results of this study (configuration E) there is no or hardly any flow. Therefore an extra test is performed with these TRS-attachments connected to a regular insert. It is remarkable that the flow and pressure in this configuration are much higher ($7.5 ml/s$ and $14 kPa$). This is even higher than the TRS-insert without instruments and directly connected to the measurement system (configuration D). An advantage of the specially developed TRS-tray is that this tray is suitable for the com-

[1] As described in Section 5.4.3.

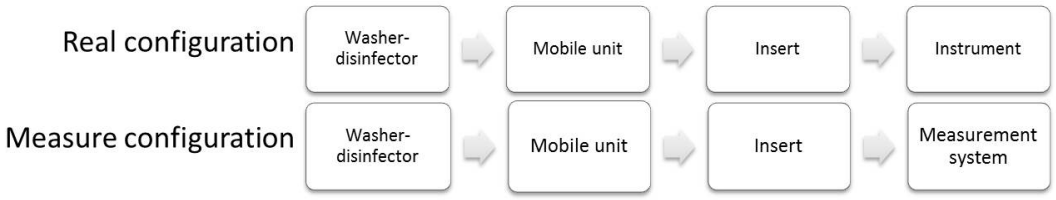


Figure 5.5: schematic view of the real configuration compared to the measure configuration. For a good interpretation of the measure results is it important to know the pressure drop of the measurement system relative to an instrument.

plete TRS-set, included the hand piece and some other small attributes. The complete set can be cleaned in the same handling. If the drilling attachments were cleaned in a separated insert then the attachments would have to be disengaged from the tray, which implies more manual work and more chances of loss of the tiny parts. The consideration to be made is what is more important; either less manual work and less mechanical performance or more manual work and more flow and pressure through the drilling attachments.

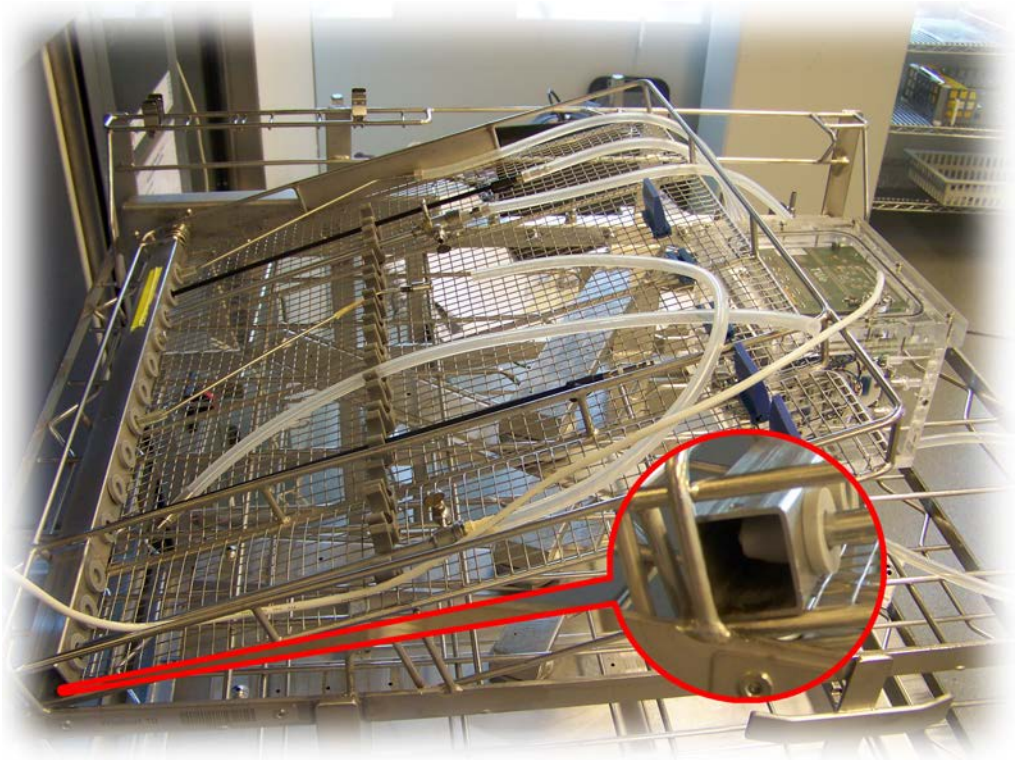
5.3.1. CONCLUSION

There are contact and contactless adapters to connect a hollow instrument to the mobile unit for rinsing the inside of an instrument. A contact adapter means that an instrument has to be pushed in a silicone holder, allowing the tip of the instrument to be fully enclosed by the holder. A contactless adapter means that there is no contact between the instrument and the adapter. The instrument has to be placed close to the injector. In this study, the contact adapters were compared with the contactless adapters with respect to the mechanical performance. The mechanical performance is expressed as the flow and pressure in the instruments. The conclusion is that the contact adapters have a significantly higher flow and pressure than the contactless adapters. There is flow and pressure loss in a contactless connection between adapter and instrument.

Main findings of this chapter:

- **The current contactless inserts generate any flow and give the incorrect idea that instruments are rinsed on the inside.**
- **Contactless nozzles which are connected directly to a mobile unit and without a distribution block generate a measurable flow and pressure inside the instruments.**

BLOOPER 4...



the number of hollow instruments are increasing very fast. The standard equipment of a washer-disinfector has too few connecting possibilities. Therefore inserts are used with much more possibilities for connecting hollow instruments. These inserts can apply sufficient flow and pressure to rinse thirteen instruments, although the end stopper should not be missing...

6

AUTOMATED CLEANING TECHNIQUES FOR DA VINCI INSTRUMENTS: A COMPARATIVE STUDY

Technical developments have changed surgical possibilities. Surgical interventions that decades ago were still science fiction are now reality. A trend in the design of medical instruments is that the instruments are becoming smaller and more complex. Since a few decades the use of Minimally Invasive Surgery (MIS) instruments has increased very fast. Minimally Invasive Surgery can be described as the use of scopes and smaller incisions that use long instruments to maneuver through small areas, thus eliminating the need for large incisions.[25] MIS uses much smaller incisions compared to the traditional open surgery. These procedures involve the use of arthroscopic, laparoscopic and remote-control manipulation of instruments with indirect observation of the area of surgical operation through an endoscope. The procedure is less invasive than open surgery and there is minimal damage to biological tissue at the point of entrance of the instrument, which results in quicker healing for the patients and a shorter hospital stay. MIS is one of the precursors to robotics. With the growth of MIS came the advancement of Computer-Assisted Surgery (CAS), also known as image guided surgery, surgical navigations, 3-D imaging. Then robotic surgery evolved, which requires the use of a robot and may or may not involve the direct role of the surgeon during the procedure. Robotic surgery is defined as a computerized system that interacts with the surgical field by a mechanical arm or arms. Tele surgical robotic surgery is manipulated by the surgeon from a remote area and uses sensor data from the robot; technically, the robot is performing the surgery. With shared-control systems, the surgeon controls and performs the procedure, and the robot offers different manipulations. The da Vinci Surgical System (Intuitive Surgical, Inc, Sunnyvale, CA, USA) is an example of a shared-control surgical system, it is designed to facilitate complex surgery using a minimally invasive approach, and is controlled by a surgeon from a console. The robot system consists essentially of a console to operate the instrument and the operation robot itself, with four arms, through which three surgical instruments (EndoWrist®instruments) as well as the 3D camera system are controlled.

The downside of these MIS instruments or robotic instruments is that they are more difficult to clean than conventional surgical instruments. MIS instruments consist of mainly instruments with narrow channels. Narrow channels are ideal places for human tissues, residuals and bacteria to nestle. Additionally the spiral wrapping of the Bowden cables is another factor impeding the cleaning. The Central Sterile Supply Department (CSSD) has the challenge to clean these complex instruments. In the past years there are several systems developed for cleaning the da Vinci instruments, also called Endowrist instruments. These applications can be used in the regular instrument washer-disinfectors and makes it easier to clean the inside of the Endowrist instruments after intensive manual pre-cleaning.

The aim of this study was to compare the mechanical performance of a new cleaning system versus the current system. The da Vinci mobile unit (mobile unit E928, Miele & Cie. KG, Germany) is developed specially for the Endowrist instruments. The current system makes use of a filter-adapter (Filter-adapter E478/1, Miele & Cie. KG, Germany). The E478/1 has been developed by Miele only for reprocessing opthalmic narrow lumen instruments. It is important that Miele never declared the intended use for robotic instruments for E478/1.

Table 6.1: flow and pressure results for both configurations

Configuration	Flow (ml/s)	Pressure (kPa)
I	7-12	30-35
III	11-15	80

Miele's declaration for intended use with robotic instruments is only valid for E928. For both systems the mechanical performance is measured. The mechanical performance is expressed as the flow and pressure through an instrument.

6.1. METHODS AND MATERIALS

For pictures of the materials, see Appendix A!

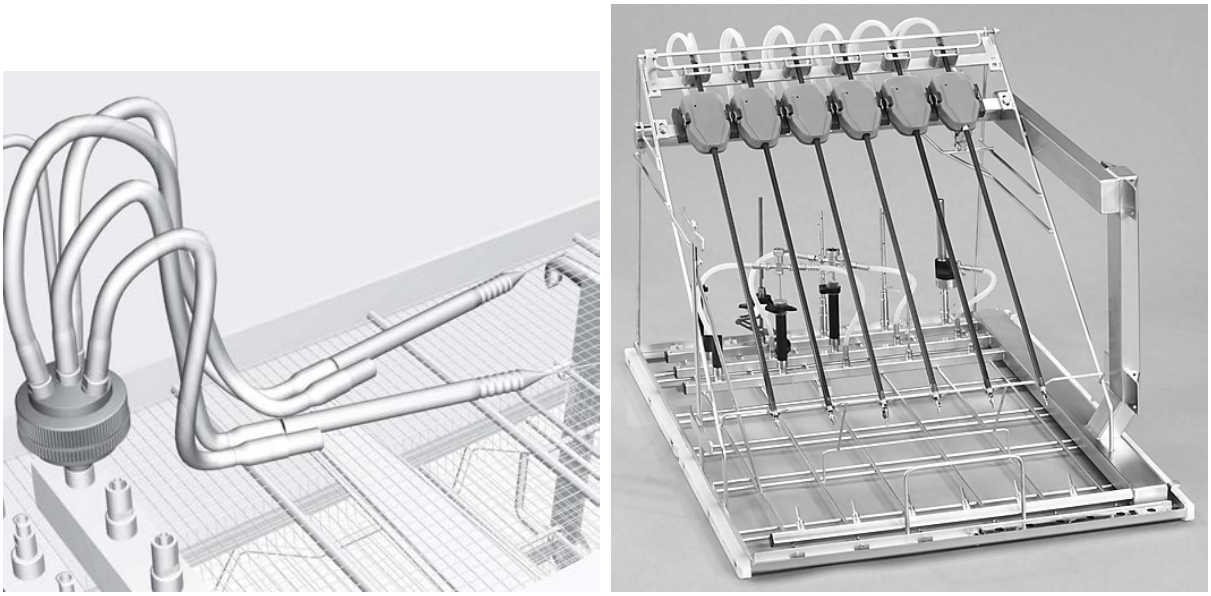
The tests are performed at the Central Sterile Supply Department of Erasmus Medical Center in the Netherlands. The used washer-disinfector was a Miele Professional type PG 8528 (Miele & Cie. KG, Germany). The wash cycle used was the pre-programmed 'instrument' cycle that was stopped after the cleaning process. The cycle consisted of: a pre-wash 5 min using cold water (i.e. room temperature) and a cleaning phase for 14 min using hot water (55°C) and a detergent (Neodisher MediClean Forte). Reverse Osmosis (RO) water was used for all stages of the program. A measurement system was used to measure the flow and pressure of the flow through hollow instruments. This system was developed by causa bv (Eindhoven, the Netherlands) and is able to measure the flow and pressure of eight separate channels.

6.1.1. MATERIALS

After a labor-intensive pre-cleaning process the instruments are cleaned in a washer-disinfector with a pre-programmed program for MIS instruments. In the current cleaning method of Endowrist instruments at the CSSD of the Erasmus MC, a filter-adapter is used (Figure 6.1). The instruments are connected to a special adapter (filter-adapter E478/1, Miele & Cie. KG, Germany), allowing them to be rinsed on the inside as well. This MIS-adapter has four connectors to connect MIS instruments. An Endowrist instrument has two inlet ports: one for rinsing the inside of the housing and the other port for rinsing the shaft of the instrument. That means that a MIS-adapter can be used for two Endowrist instruments. The working principle of the filter-adapter is like a manifold: the input flow is distributed among the four output adapters. Recently, a special unit for da Vinci instruments was released (Figure 6.1a). This mobile unit (type E928, Miele & Cie. KG, Germany) has twelve connectors to rinse in total six Endowrist instruments in the same batch (Figure 6.1b). This unit can be placed directly in the chamber of a washer-disinfector and the instruments can be connected to the connectors of the unit. The principle of the test setup was the same for both systems. A standard mobile unit was used for the first test and the da Vinci mobile unit for the second configuration. During the pre-wash and the cleaning process the flow and pressure was measured. The tests were repeated at least twice. The chain of elements and the sequence how they are connected is shown in Figure 6.2.

6.2. RESULTS

This study is limited to the cleaning process, so the cleaning cycle was stopped before the disinfection process. The tests were performed multiple times. During the cleaning cycle the flow and pressure were measured, an example of configuration II is shown in Figure 6.3. The first peak is the pre-cleaning process and the longer peak is the cleaning process, after the cleaning process and before the start of the disinfection process the cleaning cycle was stopped. Six instruments were connected to the da Vinci mobile unit, of which three instruments were connected to the measurement system. The flow in the channels was about 11 to $15 ml/s$ and the pressure is about $80 kPa$. It is remarkable that the flow in the channels connected to port 1 of the Endowrist was lower than the flow in channels connected to the second port. The differences between the results of the tested configurations are mainly in the pressure values (Table 6.1). Configuration I performed a pressure of $\approx 30 kPa$. The pressure from the da Vinci insert was much higher, namely $\approx 80 kPa$.



(a) (b)

Figure 6.1: a) Filter-adapter E478/1 with four connectors for rinsing MIS instruments. The inlet of the adapter can be connected to a standard mobile unit. b) da Vinci mobile unit E928 with twelve adapters for rinsing of six Endowrist instruments. The da Vinci mobile unit can be placed directly in the chamber of a washer-disinfector.

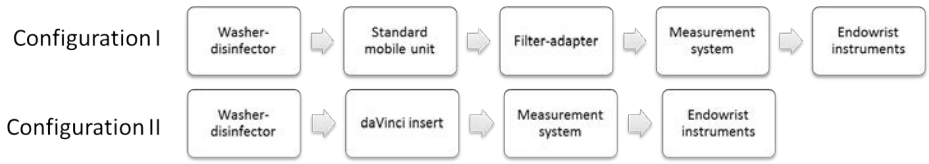


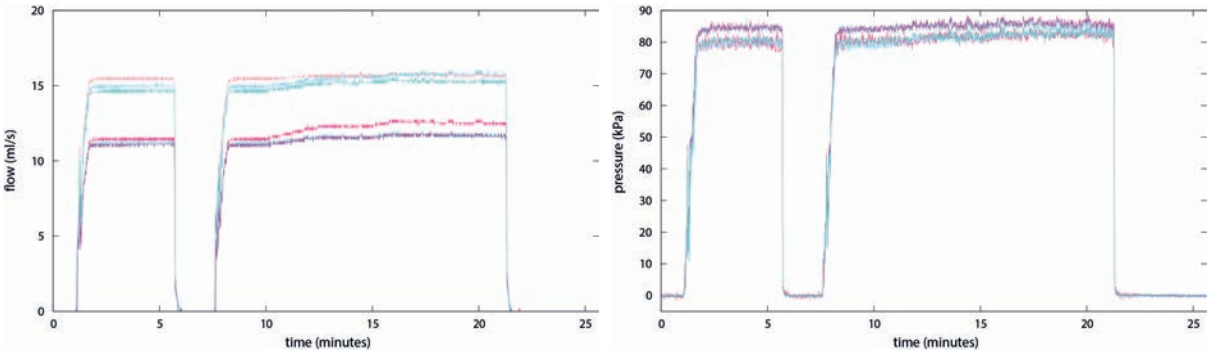
Figure 6.2: Overview of both test configurations. In the first configuration the filter-adapter was tested. The filter-adapter was connected to a standard mobile unit. The measurement system was placed between filter-adapter or the da Vinci mobile unit and the Endowrist instruments.

6.3. DISCUSSION

The cleaning performance depends on different factors. The Sinner circle makes clear that important parameters are: temperature, (contact) time, detergents and mechanical force. An optimal interaction between these factors makes the process more efficient and economical. Optimal washing results can only be achieved when all parameters are harmonized.

This study made a comparison of the mechanical force of three different configurations for cleaning of Endowrist instruments. The mechanical force is defined as the flow and pressure of the fluid through the instrument. A higher flow and pressure results in a higher wall shear stress of the fluid flow to the wall.

The mechanical cleaning performance of configuration I is the lowest. The flows as well the pressure are lower for this configuration. The flow profile of the da Vinci mobile unit (Figure 6.3) shows a remarkable phenomenon; three channels have a flow of about $11 ml/s$ and the three other channels have a higher flow. Expanded research on these differences in flow values have shown that it is caused by the design of the Endowrist instrument (Figure 6.4). The instrument consists of two irrigating ports, the main port irrigates via a flush tube the inner distal end and the second port is for rinsing the housing of the instrument. The second port irrigates only the inside of the housing therefore no tube is connected and therefore there is much less resistance, which leads to a higher flow. The inner distal end is rinsed with less flow and pressure than the housing, while the importance of cleaning is greater in this area. To improve the mechanical performance of the rinsing fluid the flow and pressure has to be as high as possible. From this perspective it is recommendable to use the da Vinci mobile unit. Besides the mechanical performances, other arguments can also play a role. Each Central Sterile Supply Department already has the standard mobile unit, therefore it is easy and cheaper to use this unit for rinsing the robotic instruments. The da Vinci mobile unit is developed specially



(a) (b)

Figure 6.3: flow and pressure results of configuration II with three Endowrist instruments.

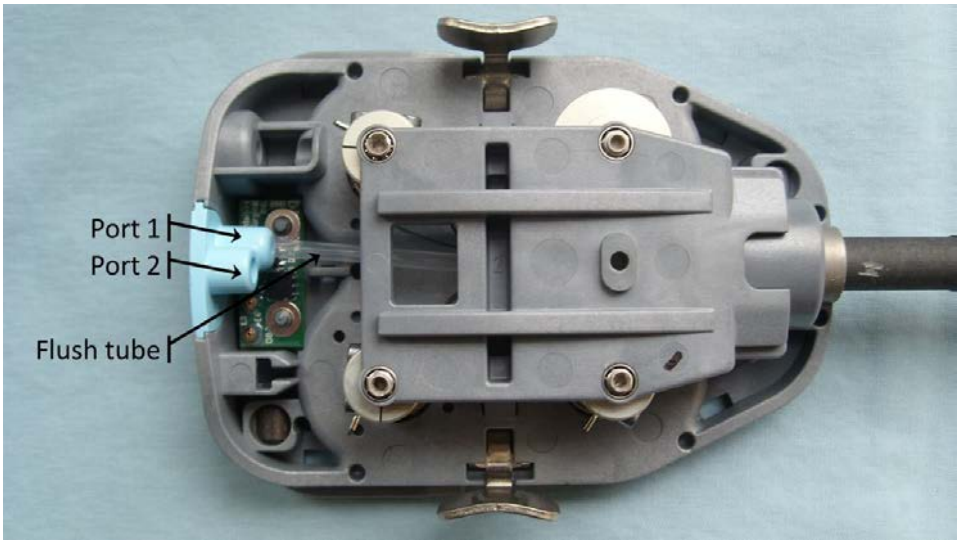


Figure 6.4: inside housing of an Endowrist instrument. The instrument consists of two irrigating ports, the main port irrigates the inner distal end via a flush tube and the second port is for rinsing the housing of the instrument. The second port irrigates only the inside of the housing therefore no tube is connected. Thus there is much less resistance, which leads to a higher flow.

for the Endowrist instruments, and as such, it is only usable for these kinds of instruments. That means that a batch with the da Vinci mobile unit consists of only robotic instruments, because there is hardly any place for other instrument trays. This study focused on the fluid mechanical performances of different cleaning systems. To get a more complete view of the cleaning performances of the different cleaning techniques, a microbiological study has to be done.

Main findings of this chapter:

- **The da Vinci mobile unit applies more flow and pressure than the current used cleaning method with the filter-adapter. Therefore the da Vinci mobile unit is preferred for the cleaning of the da Vinci instruments.**
- **The inner distal end of an Endowrist poses a higher risk to be contaminated than the housing of the instrument and should be best cleaned. The reverse is the case in practice: the end of the inner distal is rinsed with less flow and pressure than the housing.**

6.4. APPENDIX: PICTURES OF TEST SETUPS

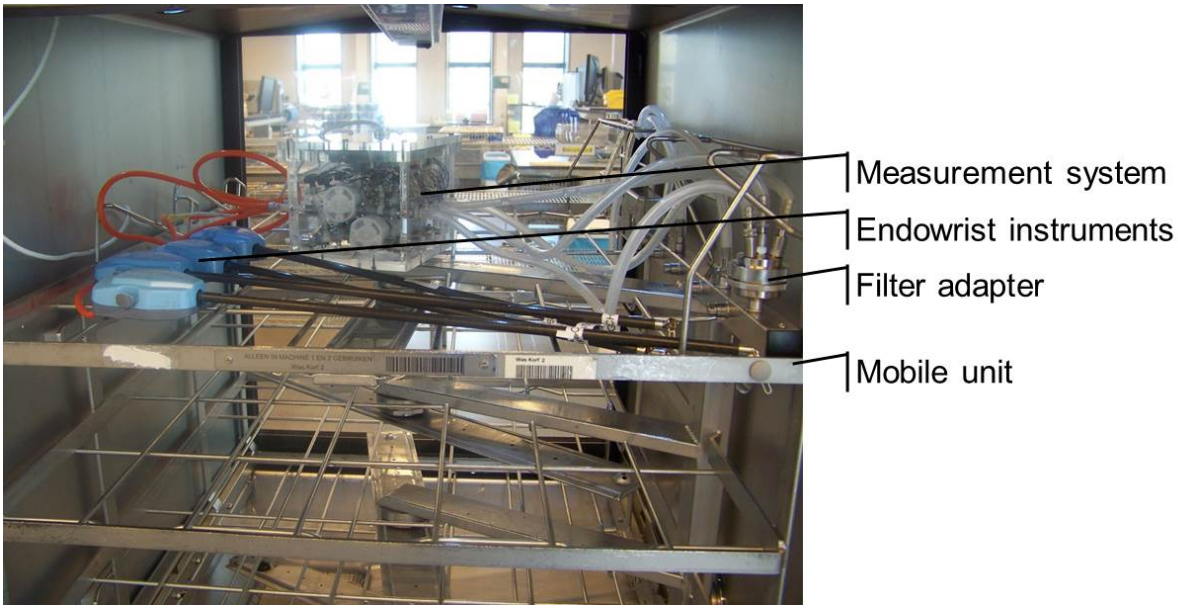
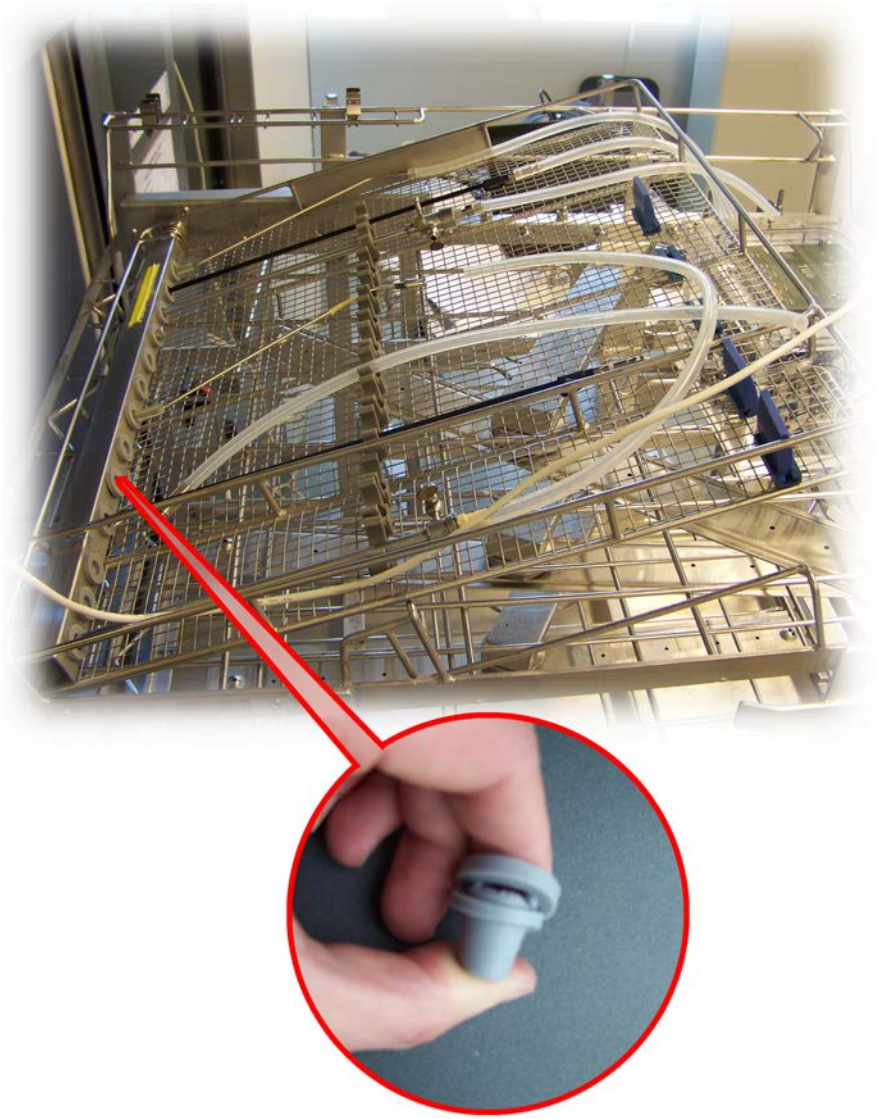


Figure 6.5: test setup of configuration I. The filter adapter was connected directly to a mobile unit and the outlet tubes of the adapter were connected to the measurement system. The four original tube-connectors of the filter-adapter were connected to the output channels of measurement system and the main port of an Endowrist instrument.

Figure 6.6: test setup configuration II. The da Vinci mobile unit placed in a washer-disinfector. Three Endowrist instruments were connected as in real situation and three instruments are connected to the measurement system. The measurement system was placed between the instruments and the mobile unit.

BLOOPER 5…



cracks may arise from the insertion and removal of instruments in the silicone holders. Cracks in the silicone holder cause leaks and result in flow and pressure loss. Maintenance is of great importance!

7

EFFECT OF THE FLOW THROUGH THE TOSI LUMCHECK ON THE CLEANNESS OF TEST SOIL

Blood is doubtlessly the most frequent contaminant of surgical instruments. In order to exclude any cross-contamination risks for patients and/or personnel, maximum cleaning efficacy must be achieved when re-processing medical devices. Sinner has stated that the efficacy of cleaning depends on four main factors: temperature, time, mechanical action and chemical action. The *temperature* stimulates the solving capacity of the fluid and detergent.[26] The *chemical action* includes the used detergents and the type of the cleaning fluid. A detergent is added to water to soak off the residuals from the surface. The *mechanical action* is wiping, brushing, spraying, and scrubbing with water under pressure or ultrasonic vibrations in water. The mechanical and chemical action needs a specific *contact time* to clean efficiently. These four factors influence each other: the lower the activity of a factor the more activity of another factor will be needed for cleaning and the other way around. This principle is known as the Sinner circle. He states the interaction between these factors makes the process efficient and economical; an optimum washing result can be achieved when all four factors are harmonized.

Many minimally invasive surgical instruments consist of narrow lumen. Blood, tissue and other patient residues can enter the lumen during surgeries and the narrow channels are ideal places for them to nestle. Of course it is important that reusable instruments are cleaned very well before they are reused. Many of today's advanced medical instrument cleaners, so-called washer-disinfectors, have the ability to irrigate hollow instruments. Hollow instruments are connected to the pump circuit of the washer-disinfector during the cleaning process, allowing them to be rinsed on the inside. Instruments are rinsed on the inside with water and chemicals during which the contamination is soaked off the wall of the instrument and can be washed away.

A study has proven that the flow through lumina varies depending on the used rinsing application.[1] The guidelines and standards for cleaning do not predict how large the flow should be for a clean and safe instrument after the cleaning process. A possibility is to conduct microbiological tests on a large number of contaminated instruments after the cleaning process and to compare the results. But the results are specific for that kind of instrument and we want to get more generic knowledge. Therefore a dummy hollow instrument is used in this test. The goal of this study is to investigate the effect of the flow through a TOSI LumCheck on the cleanness of the test soil during a cleaning process.

7.1. METHODS AND MATERIALS

For pictures of the materials, see Appendix A!

The TOSI LumCheck device is designed to evaluate narrow lumen instrument washer (Figure 7.1). The TOSI LumCheck was provided by Interster International (Wormerveer, the Netherlands). The LumCheck is

[1] See section 5

Table 7.1: several ways to connect the test instrument to the WD with varying flow values. The temperature was measured in the chamber and not in the lumen of the test instrument. The cleaning process was stopped after the cleaning process and before the disinfection process.
* there was no flow through the test instrument, but the lumen was filled with cleaning fluid.

Cycle name	Insert	Max. Temp (°C)	Max. flow (ml/s)	Wash time (min)
A	Not connected	55	0	23
B	Mobile unit	55	14	23
C	NTOC	55	0*	23
D	Lupoo type 2	55	5	23
E	Modular cassette	55	9	23

made up of three key components: the test soil, a stainless steel plate and the LumCheck Holder. The soil is composed of blood components mixed and applied in a precise manufacturing process.[27] The carrier consists of a stainless steel plate which is "scratched," replicating the uneven interior of lumen instruments.

The tests were performed at the Central Sterile Supply Department of Erasmus Medical Center in the Netherlands. The used washer-disinfector was a Miele Professional type PG 8528 (Miele & Cie. KG, Germany). The wash cycle used was the pre-programmed 'instrument' cycle that was stopped after the cleaning process. The cycle consisted of: a pre-wash 5 min using cold water (i.e. room temperature) and a cleaning phase for 14 min using hot water (55°C) and a detergent (Neodisher MediClean Forte). Reverse Osmosis (RO) water was used for all stages of the program. A measurement system was used to measure the flow and pressure of the flow through hollow instruments. This system was developed by Causa BV (Eindhoven, the Netherlands) and is able to measure the flow and pressure of eight separate channels.

The instrument was connected to a mobile unit; designed to be placed into the washing chamber (Figure 3.3). A standard mobile unit used by the CSSD was used for the tests. This mobile unit consists of two multiple spray arms and nine adapters which can be used for rinsing hollow instruments. Two adapters were used for the two test instruments and two other adapters were open and the other five adapters were closed with a blind stopper.

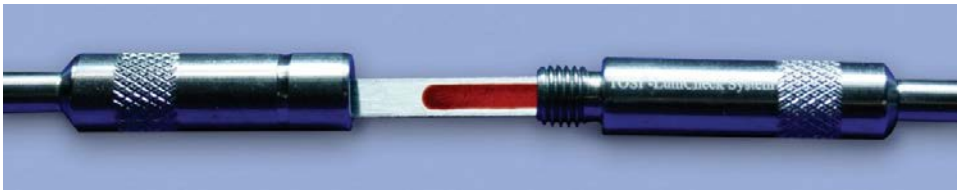


Figure 7.1: TOSI LumCheck. The LumCheck is a dummy instrument to imitate hollow instruments. A plate with a test soil is placed in the channel of the LumCheck. The test soil is composed of blood components. After the cleaning cycle the test soil has to be assessed visually. An optimal result indicates that the test soil is completely dissolved, no test soil residuals are left.

7.1.1. METHODS

The instrument with test soil was connected to the tubes of a mobile unit in the same way as hollow instruments are connected in a standard cleaning batch. The test instruments were connected to the small adapters of the mobile unit. The measurement system was connected to the end of the test instrument. Only two test instruments were connected during the tests and further the chamber of the washer-disinfector was empty. This study was developed to determine whether the effect of suboptimal temperature and mechanical action is detectable in a washer-disinfector. The cleaning process was adjusted to evaluate the 12 different conditions indicated in 7.1 and Table 7.2. Three parameters were varied for the different tests: temperature, time and flow. This study examines the pre-cleaning and cleaning process, and hence the process was stopped before the disinfection process took place.

The tests were performed with different flow values through the instrument. This was accomplished by connecting the test instrument to different inserts (cycle A-E). The type of insert used has an effect of the flow through the instrument. A second type of tests was done whereby the cleaning result was evaluated after a shorter cleaning cycle (cycle F-L).

The test soils of the test instruments were assessed visually afterwards. The TOSI Troubleshooting Guide

Table 7.2: in these tests contact time is the varying parameter. The test instrument was connected to mobile unit and the temperature was measured in the chamber and not in the lumen of the test instrument.

Cycle name	Max. Temp (°C)	Max. flow (ml/s)	Wash time (min)
F	23	11	3
G	24	15	5
H	24	15	7 (end precleaning)
I	24	15	10
J	43	15	13
K	56	15	17
L	56	15	23 (end cleaning phase)

was used to determine the cleaning efficacy (see Appendix D.[28] This guideline scores the result from 0 (optimum result) to 5 (negative result). Figure 7.2 shows pictures of test soils corresponding with their score. The difference between score 0 – 2 is in practice difficult to determine. If a water droplet has dried on the test soil it looks like a remaining fibrin layer (score 1 and 2).

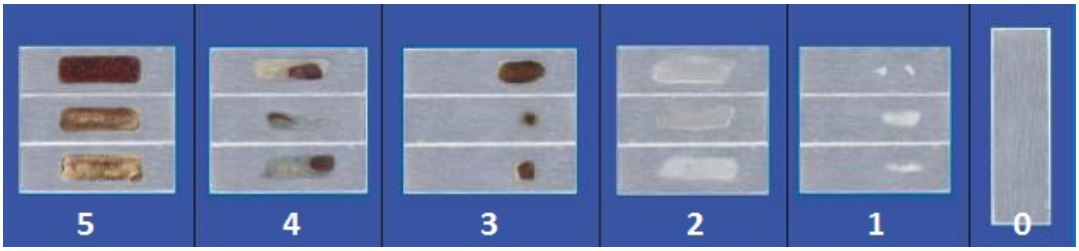


Figure 7.2: the test soils have to be assessed visually after the cleaning process. This figure shows pictures of test soils as a guide to assess the TOSI test soils. A cleaning score of 5 means a negative score, there is a major lack of cleaning and the test soil is largely or completely unaffected. With a cleaning score of 3 small residuals of water soluble (red) proteins are visible. None or only a small amount of the fibrin layer remains visible. Score 1 indicates that there are no water soluble proteins visible, but small amount of fibrin residuals remain. And the optimum result indicates that the test soil is completely dissolved, no test soil residuals are left.

7.2. RESULTS

A hollow instrument can be connected to a washer-disinfector in different ways (cycle A-E). The cycles A-E were regular cleaning cycles. The effect of not connecting is clear. In cycle A the test instrument was placed free in the chamber of the WD, hardly any fluid entered the lumen of the instrument. The results were that the test soil was still completely intact, the red protein layer only showed some small cracks. There was no flow measured through the test instrument in cleaning cycle C. However, the lumen was filled with cleaning fluid during the cleaning cycle, allowing the test soil to come into contact with the cleaning fluid. In the case of the test instrument being directly connected to a mobile unit (B) or to a modular cassette insert (E) the test soil was completely dissolved and no test soil residuals were left (Figure 7.3).

The cycles F to L are a step-by-step evaluation during the cleaning process (Figure 4). For cycle F, the process was stopped at the beginning of the pre-cleaning; a large amount of the red protein remained. The cycles G, H and I were all stopped during the pre-cleaning. There was no visible difference between these cycles. All the test soils showed a large amount of fibrin residuals. A difference in the cleanness of the test soil occurred when the temperature was increased (cycle K). Cycle J was at the beginning of a temperature increase and detergents were added, but the effect was still not visible. After some minutes the test soil was completely cleaned.

7.3. DISCUSSION

In this study three parameters were varied to determine their effect on the cleaning efficacy, therefore the Tosi LumCheck was used as a test instrument. The Tosi troubleshooting guide shows an overview of test results linked to a rating to assess the test soil. Only in practice, it is not as clear and easy as this guide suggests. It is difficult to distinguish between a water droplet and residuals of the transparent fibrin layer. Therefore a

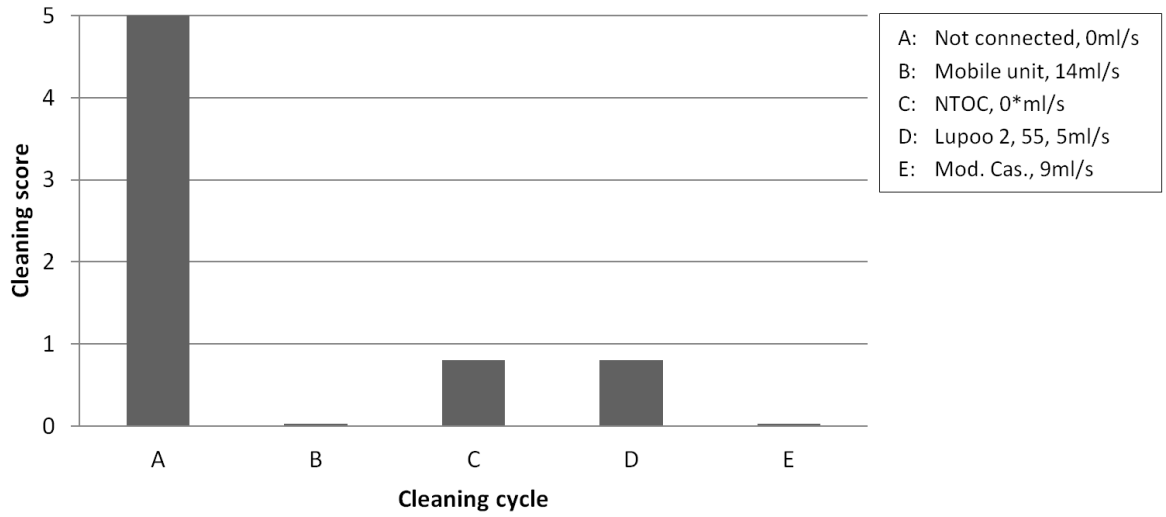


Figure 7.3: the five cycle conditions (Table 7.1) were evaluated after a complete cleaning process.

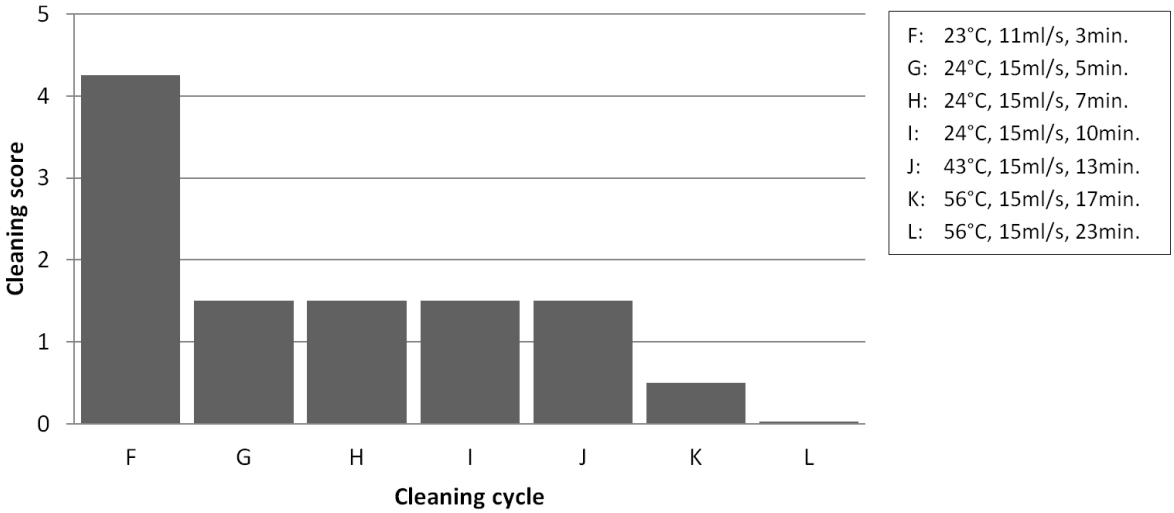


Figure 7.4: the test soil was evaluated during the cleaning process (Table 7.2).

relationship between the flow through the test instrument and the cleaning efficacy could not be justified in this study.

A conclusion which can be drawn is that if there is no fluid in the lumen, the test soil is largely or completely unaffected. It seems that the temperature has more effect on removing the test soil. A longer pre-cleaning process with a low temperature of 24řC shows no better cleaning result. The cleanness improves if the temperature increases and if detergents were added, which corresponds to the findings of other studies[29–31]. The low temperature removes the red protein layer, but to remove the fibrin layer the temperature has to be increased.

7.3.1. DESIGN OF LUMCHECK

The LumCheck is presented as a representative for a hollow instrument. However, the extent to which it is compatible with hollow instruments is debatable. The test soil is placed free in the hollow tube. This means that the test soil is not positioned at the wall of the LumCheck but more in the center (Figure 7.5a). Contamination in a hollow instrument is mostly attached to the wall of the instrument (Figure 7.5b). From a fluid mechanics point of view it is known that an obstacle in the center of the flow causes a more turbulent flow. A more turbulent flow gives a higher shear stress, so the force of the flow to remove the contamination is higher. It gives a better simulation of practice if the test soil is fixed and positioned at the wall of the hollow tube (Figure 7.5c). The design of the LumCheck is easier to clean as compared to many minimally invasive surgical

instruments. The design is a straight instrument with a relative large diameter for a hollow instrument.

In conclusion, this study has demonstrated that the effect of the temperature is more detectable with the Tosi LumCheck compared to the flow or contact time. However, with only with high temperature and no flow, the soil will still be unaffected. And so returning to the Sinner circle, a good interaction between the different factors achieves an optimal washing result.

Further research has to be done to develop a less subjective indicator to determine the cleaning efficacy of a WD cycle. Finally, there is a need to correlate the cleaning indicator to the levels of organic residuals.

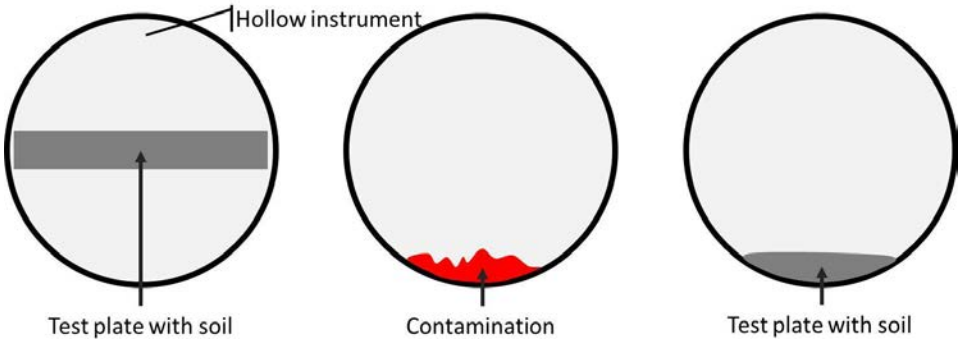


Figure 7.5: a cross-section of the test instrument with the test plate in the center, a contamination fixed at the wall of a hollow instrument and a test plate to the wall of an instrument.

Main findings of this chapter:

- **The test soil is unaffected for a not-connected dummy instrument, which is therefore not rinsed. Connecting the hollow instruments is essential to get them clean.**

8

DISCUSSION

For an understanding of the used terminology, see Glossary!

A discussion is a look backwards and forwards. In the look backwards, the main conclusions of the sub studies are drawn and an assessment is made of the extent to which the goal is reached. As it should be in a critical reflection on a study, the limitations of the study and the methods used are described in the second section. Finally, the look forward provides a study on the cleaning of hollow instruments. The gained insights are translated into guidelines for the CSSD and suggestions for further research are made.

8.1. MAIN FINDINGS

The aim of this study was to make an analysis of cleaning methods of hollow instruments at the CSSD and to get more insight into the cleaning performance of several cleaning applications for hollow instruments based on their mechanical performances.

Hollow instruments are insufficiently cleaned, due to:

- Non-functioning of adapters and/or inserts
- Insufficient flow and pressure of the fluid flow rinsed through these instruments
- Blockages and leakages of connecting tubes
- Too less connecting possibilities for hollow instruments
- Wrong use or incorrect connection by the staff at the CSSD

These factors deteriorate the mechanical performance of the cleaning process, defined as the flow, pressure and flow and level of turbulence of the rinsing fluid through the lumen. The lack of performance is not noticed because the flow and pressure are not monitored. Furthermore the cleanness of the inside of hollow instruments is hardly visually inspected. Improvements in all these areas are needed to reach a sufficient cleaning of these hardly accessible instruments.

8.1.1. MAIN FINDINGS PER CHAPTER

Chapter 3:

- The rinsing of hollow instruments can be characterized by the mechanical performance, defined as the flow, pressure and level of turbulence of a fluid through an instrument.
- To better release the attached contaminants from the wall of an instrument, the force applied to the wall (called wall shear stress) needs to be increased, which is achieved by increasing the velocity of the flow.

Chapter 4:

- The mechanical performance differs for the currently available inserts caused by the manner of the input of the insert is connected to the mobile unit and the number of output adapter.
- Inserts with multiple output adapters are recommended to use them only as they are connected to a large adapter of a mobile unit as these provide a higher flow.
- Connected instruments to inserts have no effect on the flow in the adjacent channels, which implies that instruments can be connected randomly and open channels do not have to be closed.

Chapter 5:

- The current contactless inserts generate any flow and give the incorrect idea that instruments are rinsed on the inside.
- Contactless nozzles which are connected directly to a mobile unit and without a distribution block generate a measurable flow and pressure inside the instruments.

Chapter 6:

- The da Vinci mobile unit applies more flow and pressure than the current used cleaning method with the filter-adapter. Therefore the da Vinci mobile unit is preferred for the cleaning of the da Vinci instruments.
- The inner distal end of an Endowrist poses a higher risk to be contaminated than the housing of the instrument and should be best cleaned. The reverse is the case in practice: the end of the inner distal is rinsed with less flow and pressure than the housing.

Chapter 7:

- The test soil is unaffected for a not-connected dummy instrument, which is therefore not rinsed. So, connecting the hollow instruments is essential to get them clean.

Bloopers:

- However, in most cases the cleaning equipment is effective; insufficient cleaning is achieved by equipment breakdown, wrong use or incorrect connection.

8.2. DISCUSSION

In this discussion some limitations of the tests and this study are highlighted.

8.2.1. STUDY WAS LIMITED TO ONE WASHER-DISINFECTOR AND CLEANING PROGRAM

A limitation of the study is that this study is limited to one type of washer-disinfector, one type of mobile unit and one cleaning program. Therefore the results are only valid for the situation of the Central Sterile Supply Department at the Erasmus MC (Rotterdam, the Netherlands). However, it remains a fact that trends in the results also apply to other washer-disinfectors with other cleaning programs. For example, a contactless adapter could be performing more flow and pressure with other cleaning machines but the results will remain less efficient than a contact adapter.

8.2.2. HIGH INTERNAL RESISTANCE OF THE MEASUREMENT SYSTEM

If you want to measure, you have to apply an outside influence. The flow and pressure were measured by connecting a measurement system. That means that an extra resistance was added to the chain, which is not normal (Figure 8.1). A normal chain of a connected instrument consists of an insert and an instrument that is connected to the insert. For the tests a measurement system was connected to the instrument. That means that the flow and pressure in the chain were affected by this extra element.

It would be relevant to know the effect of adding the measurement system to the chain of WD, mobile unit, inserts and instruments. The extra resistance caused by the pressure gauges is negligible compared with the resistance of the flow sensors. The resistance of the flow sensors depends on the magnitude of the flow. During a cleaning cycle the pressure drop caused by a flow sensor is determined (Table 8.1). The pressure drop caused by the measurement system is significantly higher that the pressure drop caused by the dummy instruments. The pressure drop of the measurement system is about $25 kPa$ (at a flow of $10 ml/s$) and the drop

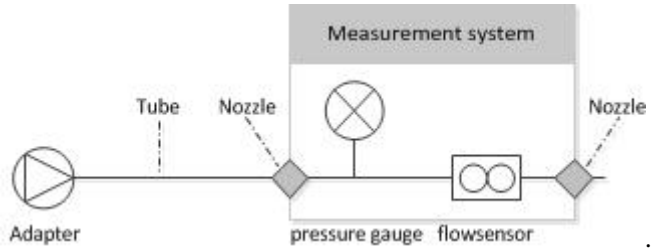


Figure 8.1: schematic view of the chain of connected elements. The adapter is the output of an insert. A tube or instrument is connected to the adapter. In a normal case the instrument is the last element of the chain. For the tests a measurement system was connected to the instrument/tube. That means that the flow and pressure in the chain is affected by this extra element. It is important to know the extent to which the measurement system has affected the results for a good interpretation of the measured values.

Table 8.1: the pressure drop of a flow sensor for two flow levels.

Flow (ml/s)	Pressure drop (kPa)
7	14
10	25

of the used dummy instruments 5,8 and 18kPa respectively. The pressure drop of the first two instruments is relatively small compared to the pressure drop of the flow sensor. Therefore it is up for discussion to which extent the effect on instruments could be determined in combination with this flow sensor. For example, in the tests with the contactless adapters[1] there was no measurable flow or pressure. The resistance in the measurement system was too high, allowing no flow. But maybe in real practice, without the high resistance of the measurement system, there is some flow and pressure. To determine the effect of connected instruments on the flow and pressure in the adjacent adapter or instrument, it is recommended to do the test without a flow sensor or with a flow sensor with low resistance.

8.2.3. INCONSISTENT WAY OF MEASURING PRESSURE CAUSED BY THE CONFIGURATION OF THE MEASUREMENT SYSTEM

The measurement system is built up from two layers with four measuring channels each (Figure 8.2). Each channel consists of a pressure gauge and a flow sensor. But the configuration of the upper layer differs from that of the lower layer (Figure 8.3). The sequence of the upper layer is first a pressure gauge and then a flow sensor, and the order is reversed for the lower level (first flow sensor, then pressure gauge). This has no effect on the measured flow value, but it has an effect on the measured pressure. In the upper level the pressure at the input of the measurement system is measured, but in the lower level the pressure at the output is measured. The output pressure is lower than the input pressure, caused by the pressure drop of the flow sensor. To compare the measured pressure results, the pressure results of the lower levels are corrected with the pressure drop caused by the flow sensor. The difficulty is that the pressure correction factor is not constant, because the pressure drop of the flow sensor depends on the amount of flow. A recommendation is given to the developer of this measurement system (Causa BV, Eindhoven, the Netherlands) that it is better to keep the same configuration in all the channels of the measurement systems. The configuration of the upper level is the desired configuration, because the pressure value is affected by the flow sensor in the reversed configuration.

8.2.4. THE VARIETY IN DESIGN AND NUMBER OF DUMMY INSTRUMENTS WAS TOO LIMITED

In the study of the mechanical performances the effect of connected instruments was also investigated. Therefore three different instruments were used and there were two instruments of each type. The instruments differed in shape, internal diameter and length, so the resistance of the instruments was different. The goal was to select three instruments with different resistance, but during the test it seemed that the pressure drop of instrument C and D was almost the same, 8 and 5kPa respectively. For a more complete study about the effect of instruments, a more extended assortment of instruments should be taken into account.

[1] See Chapter 5: effect of the adapter design on the mechanical performances

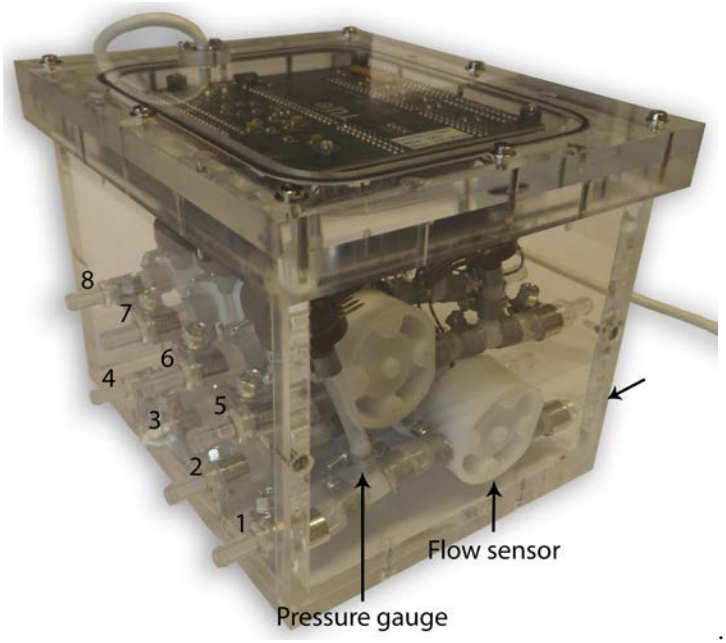


Figure 8.2: measurement system consists of two levels with four measurement channels each. A measuring channel consists of a flow sensor and a pressure gauge. The configuration of the upper level is reversed by the configuration of the lower level. The lower level first has a flow sensor and then a pressure gauge, and for the upper level is it reversed.

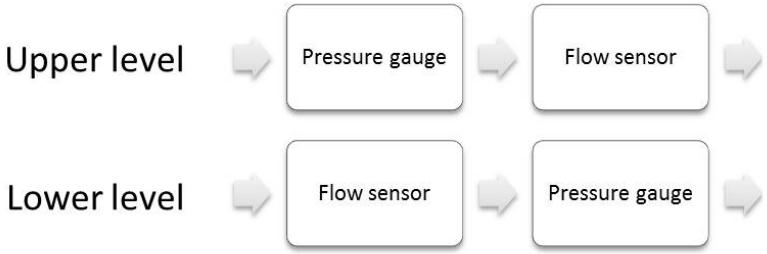


Figure 8.3: schematic view of the configuration of the measurement system. The upper level of the channels first consist of a pressure gauge and then a flow sensor and for the lower level the configuration is reversed.

8.3. FURTHER RESEARCH

The scientific field about cleaning efficacy in washer-disinfectors is trending and the last couple of years more and more papers about cleaning efficacy of hollow instruments have been published. Recently, there was a publication of a paper about the impact of temperature and cleaning cycle parameters on the cleaning efficacy.[29] But there is less research on the impact of the flow through cannulated instruments. This study attempts to take a first step by analyzing the current situation. In this section some topics for further research shall be described.

8.3.1. MORE MONITORED CONNECTING POSSIBILITIES IN WDS

The cleaning of endoscopes takes place in special endoscope washer-disinfectors (EWD). The new generation of EWDs has a high degree of channel monitoring and instrument recognition.[32, 33] An endoscope has to be scanned before it can be placed in the EWD. The number of channels and pressure values are registered in the system of the EWD and the machine checks if all the channels are connected correctly. During the cleaning cycle there is a blockage and leakage check. In this regard, the cleaning of endoscopes is far ahead the cleaning of other medical cannulated instruments. The number of minimally invasive surgical instruments will be increasing in the coming decade. The instruments will be more complex and smaller and therefore

also more difficult to clean. To check the cleanness of the internal part of an instrument will be almost impossible. To make sure that the increasingly complex instruments can be cleaned in automated processes in a WD, the developing of WDs must continue. The next WDs should be designed with more connecting possibilities for hollow instruments and with built in monitoring of the flow and pressure in the adapters.

8.3.2. MINIMAL DESIRED FLOW FOR RINSING OF HOLLOW INSTRUMENTS

Steps must also be taken from the side of instrument manufacturers. It is the responsibility of the designers to think about their design and to prescribe instructions for cleaning. In this study an analysis was made of the flow and pressure profiles of several cleaning techniques. For a good interpretation of these results a study is required on the minimal desired flow for the rinsing of hollow instruments. Is it enough to rinse a hollow instrument with a flow of $5ml/s$ during a cleaning cycle or should the flow be at least $20ml/s$? In this study different types of instruments should be taken into account. Probably the minimal required flow depends on the design of the instrument and also on the level and type of contamination.

8.3.3. A STUDY ON THE PROPERTIES OF AN EFFECTIVE FLOW

In chapter 4 of this report it was indicated that the velocity of the flow has to be as high as possible, because the higher the flow the higher the wall shear stress. The wall shear stress is the force of the flow to the wall and to possible contaminants on the inside of an instrument. It sounds logical that a higher force is preferable, because then attached contaminants will come off faster from the wall, but a higher velocity results in a larger entrance region, that means that after an obstacle (narrowing, curve, etc.) in the shaft the region is larger before the flow is fully developed again. The cleaning capacity is lower in the entrance region, therefore it is preferable to narrow down the entrance region. An interesting flow for further investigation is a pulsating jet.

8.3.4. A CONTACTLESS ADAPTER WITH RETENTION OF FLOW AND PRESSURE

A disadvantage of a contactless adapter is the loss in flow and pressure. It is a challenge to design a contactless adapter with a minimal loss in flow and pressure and with the advantage of no contact between instrument and adapter.

8.3.5. A REPRESENTATIVE DUMMY HOLLOW INSTRUMENT

The Tosi LumCheck is a dummy hollow instrument. This instrument is a straight design and the contamination is not on the wall of the inside but more in the center. An interesting topic is to do a comparative study on the level of cleanness of the LumCheck compared to a random contamination in hollow instruments after a cleaning cycle. Another possibility for further study is the design of a dummy hollow instrument for the worst-case scenario.

8.3.6. A CLEANING PROCESS WITHOUT MANUAL PRE-CLEANING

Is it possible to clean effectively without manual pre-cleaning? Pre-cleaning is a labor-intensive manual process. A study can be done on the possibility of cleaning without pre-cleaning, maybe with a longer and optimized cleaning cycle.

8.3.7. INSERT FOR COMPLETE INSTRUMENT SETS WITH CONNECTING POSSIBILITIES

The disadvantage of some effective inserts is that the instruments cannot stay in the tray. To keep instrument sets complete it is better that a tray has connecting possibilities for the hollow instruments on the tray itself. The challenge is to design this kind of tray without much extra handling to connect the instruments properly prior to washing.

Main conclusion of this study:

To clean hollow instruments, the following aspects must be maintained:

1. **The rinsing of hollow instrument with sufficient flow, pressure and turbulence.**
2. **Connecting of the hollow instruments by the staff at the CSSD**
3. **Maintenance of cleaning applications, so that cracks, blockages and leakages can be prevented**

These issues are rarely encountered in practice and also not noticed. To improve the current situation it is important that: The employees at the CSSD have to recognize the importance of correctly connecting hollow instruments. Sufficient connections are needed to connect all hollow instruments. And furthermore, the flow and pressure of the cleaning flow through instruments need to be monitored.

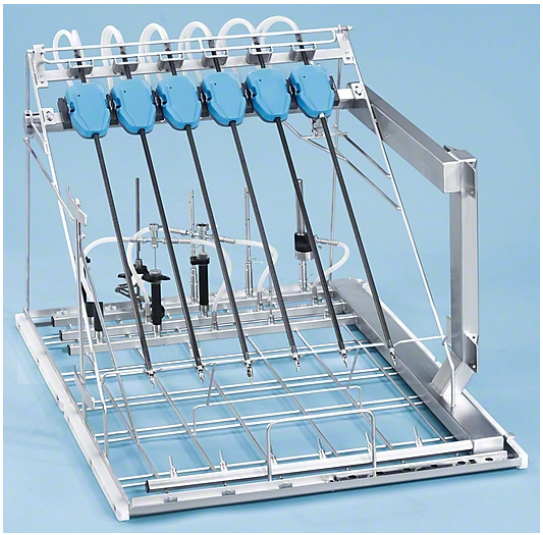
Appendices

Appendix A: Overview of test applications

Mobile unit

Standard mobile unit

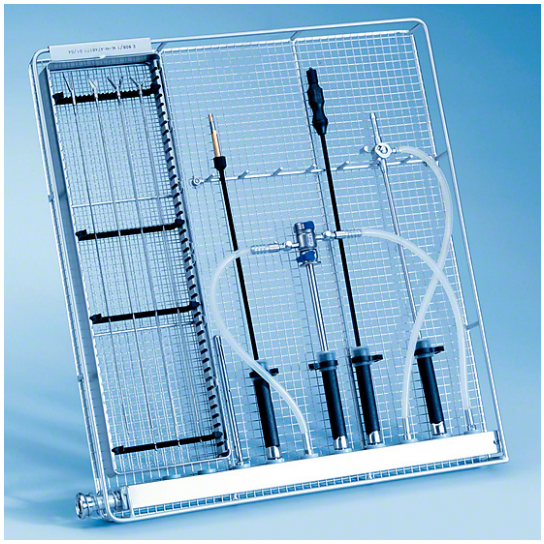
- Rolled in chamber of WD
- Input: connected to the pump circuit of WD
- Output: 4 large adapters & 9 small adapters
- Manufacturer: Miele & Cie. KG, Germany



da Vinci mobile unit

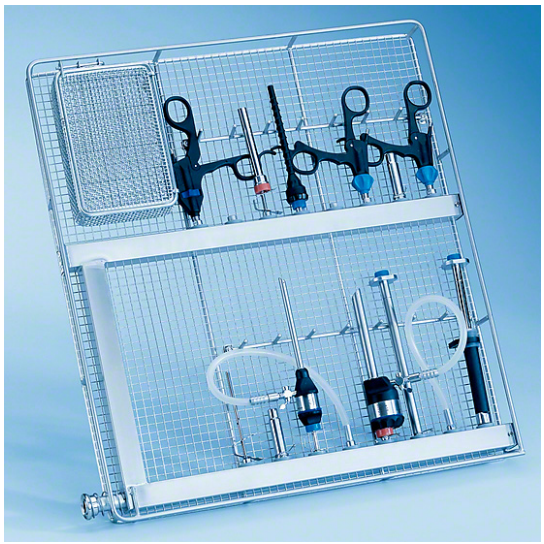
- Rolled in chamber of WD
- Input: connected to the pump circuit of WD
- Output: 12 adapters (able for 6 instruments)
- Manufacturer: Miele & Cie. KG, Germany

Inserts



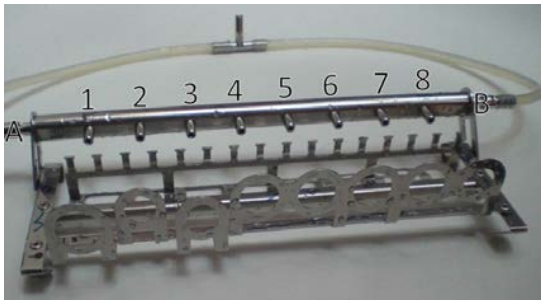
Modular cassette insert

- Input: Large adapter, mobile unit
- Output: 13 contact adapters
- Manufacturer: Miele & Cie. KG, Germany



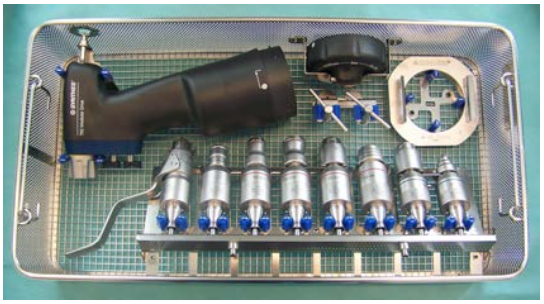
Double modular cassette insert

- Input: Large adapter, mobile unit
- Output: 22 contact adapters
- Manufacturer: Miele & Cie. KG, Germany



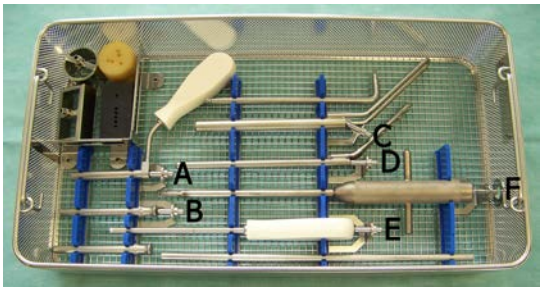
NTOC

- Input: 1 small adapter, mobile unit
- Output: 8 contactless adapters
- Manufacturer: NTOC



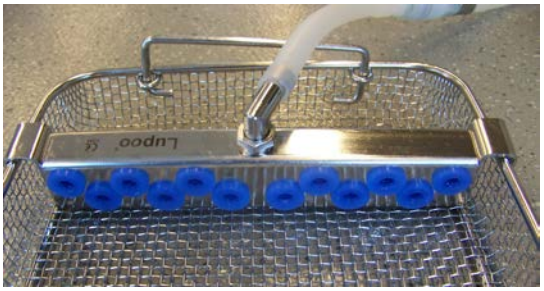
TRS tray

- Input: 2 small adapters, mobile unit
- Output: 8 contactless adapters
- Manufacturer: NTOC



Biodrive tray

- Input: 6 small adapters, mobile unit
- Output: 6 contactless injector nozzles
- Manufacturer: NTOC



Lupoo

- Input: 2 small adapters, mobile unit. This is not in accordance with the IFU.
- Output: 12 contact adapters
- Manufacturer: PMT

Filter-adapter

- Input: 1 small adapters, mobile unit.
- Output: 4 contact adapters
- Manufacturer: PMT

Instruments

B1, B2

- Suction tube
- Diameter: 2mm
- Length: 255mm
- Pressure drop: 18kPa (@10 ml/s)

C1, C2

- Trocar
- Diameter: 3mm
- Length: 375mm
- Pressure drop: 8kPa (@10 ml/s)

D1, D 2

- Trocar
- Diameter: 6mm & 260mm
- Length: 260mm & 230mm
- Pressure drop: 5kPa (@10 ml/s)

Dummy instrument with test soil

- Tosi LumCheck
- Interster, Wormerveer

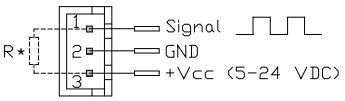
APPENDIX B: DATASHEET FLOW SENSORS

Mini Durchflussmesser
Low Flow Flowmeter

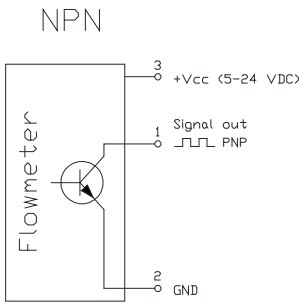
Technische Daten **Messprinzip**	Technical specification	**Anwendung**: chemisch aggressive Medien Metall frei **Application:** chemically aggressive liquids. Metal free.
Messprinzip	Measurement principle	Turbine
Abtastsystem	Sensing principle	Hall Sensor / Hall effect, non-contacting
Ausgangssignal	Output: square wave	NPN open collector sinking
Durchflussrichtung	Flow direction	in Pfeilrichtung / at arrow-direction
Durchflussbereich L/min.	Flow range LPM	0,015 – 0,8 L/ min (H_2O bei / at 20°C)
Düse	Nozzle	D= 1,0 mm integriert/ integrated
Impulszahl/ Liter	Pulses output/ Litre	ca. 10.500 I/L (bei / at H_2O 20°C) 2 x I/U
Viskosität der Medien v	Viscosity v	0,5 - 10 mPas
Messgenauigkeit (v =1 mPas)	Accuracy (v = 1 mPas)	+/- 2% (bei gleichen Betriebsbedingungen)
Wiederholgenauigkeit	Repeatability of frequency response	+- 0,5 % (bei gleichen Betriebsbedingungen +- 0,5 % (at the same operating conditions)
Betriebs/ Berstdruck max.	Continuous-/ Burst in pressure	-0,7- 4 bar / 10 bar (bei / at 20°C)
Betriebstemperatur	Running temperature	-10°C... + 90°C
Einbaulage	Installation position	beliebig / any
Anschluss	Port Connection	2x D 6 mm Schlauchanschluss / Hose-C
Material / Rotor / O-Ring	Materials/ Rotor/ Gasket	PP-natur / PVDF/ FKM
Achse / Lagerung	Axle/ Bearing	Achse/Axle = PVDF, Lager/ Bearing PP
Spannungsversorgung	Electrical Connection	5- 24 max. VDC
Strombelastung I max.	Output current $I_{max.}$	25 mA max.
Gebergewicht	Weight	25 Gramm
Abmessung in mm	Dimensions in mm	s. Zeichnung / see drawing

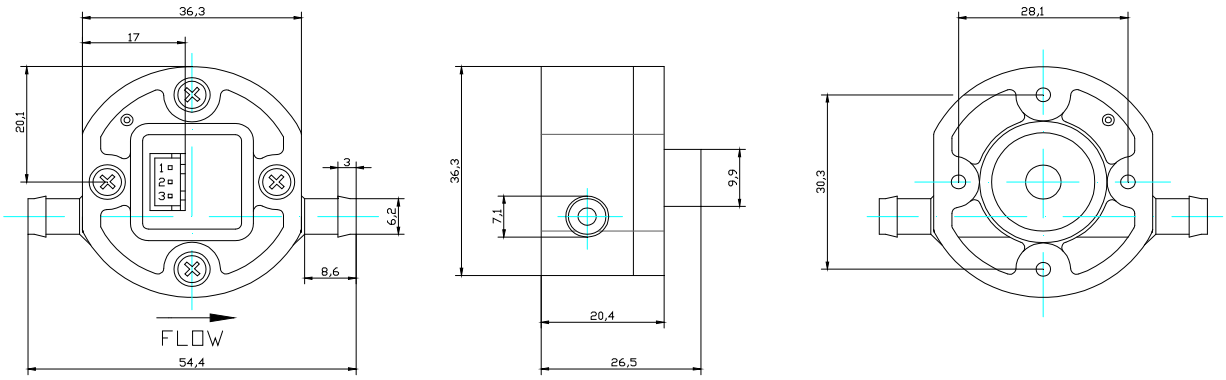
Serie: FCH-m-PP-LC
Art.-Nr: 155374

Gegenstecker mit Kontakten im Lieferumfang enthalten.
Connector with crimp contacts included



R* pull up for PNP R=1,6 - 2,2 kOhm





B.I.O-TECH e.K. | Zeitlarner Str. 32 | D- 94474 Vilshofen | Germany
Tel: +49 (0) 8541-91 00 47 | **Fax:** +49 (0) 8541-96 89 98 0
E-Mail: info@btflowmeter.com | **Internet:** www.btflowmeter.com

APPENDIX C: DATASHEET PRESSURE GAUGES

Pressure

Freescale Semiconductor
Data Sheet: Technical Data

MPX5700
Rev 10, 10/2012

Integrated Silicon Pressure Sensor On-Chip Signal Conditioned, Temperature Compensated and Calibrated

MPX5700 Series

0 to 700 kPa (0 to 101.5 psi)
15 to 700 kPa (2.18 to 101.5 psi)
0.2 to 4.7 V Output

The MPX5700 series piezoresistive transducer is a state-of-the-art monolithic silicon pressure sensor designed for a wide range of applications, but particularly those employing a microcontroller or microprocessor with A/D inputs. This patented, single element transducer combines advanced micromachining techniques, thin-film metallization, and bipolar processing to provide an accurate, high level analog output signal that is proportional to the applied pressure.

Features

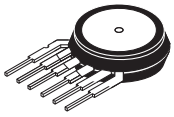
- 2.5% Maximum Error over 0° to 85°C
- Ideally Suited for Microprocessor or Microcontroller-Based Systems
- Available in Absolute, Differential and Gauge Configurations
- Patented Silicon Shear Stress Strain Gauge
- Durable Epoxy Unibody Element

ORDERING INFORMATION

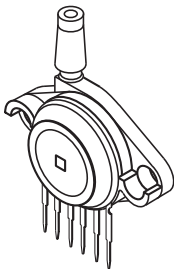
Device Name	Case No.	# of Ports			Pressure Type			Device Name
		None	Single	Dual	Gauge	Differential	Absolute	
Unibody Package (MPX5700 Series)								
MPX5700A	867	•					•	MPX5700A
MPX5700AP	867B		•				•	MPX5700AP
MPX5700AS	867E		•				•	MPX5700A
MPX5700ASX	867F		•				•	MPX5700A
MPX5700D	867	•				•		MPX5700D
MPX5700DP	867C			•		•		MPX5700DP
MPX5700GP	867B		•		•			MPX5700GP
MPX5700GP1[1]	867B		•		•			MPX5700GP
MPX5700GS	867E		•		•			MPX5700D

1. MPX5700GP1 has 90 degree lead form.

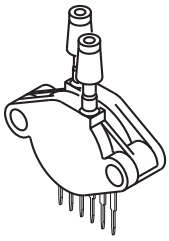
UNIBODY PACKAGES



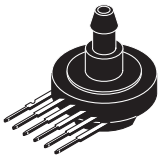
MPX5700A/D
CASE 867-08



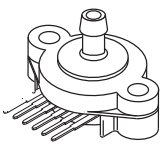
MPX5700AP/GP/GP1
CASE 867B-04



MPX5700DP
CASE 867C-05



MPX5700AS/GS
CASE 867E-03



MPX5700ASX
CASE 867F-03

Pressure

Operating Characteristics

Table 1. Operating Characteristics (V_S = 5.0 Vdc, T_A = 25°C unless otherwise noted, P1 > P2. Decoupling circuit shown in required to meet electrical specifications.)

Characteristic		Symbol	Min	Typ	Max	Unit
Pressure Range[1]	Gauge, Differential: MPX5700D Absolute: MPX5700A	P_{OP}	0 15	— —	700 700	kPa
Supply Voltage[2]		V_S	4.75	5.0	5.25	Vdc
Supply Current		I_O	—	7.0	10	mAdc
Zero Pressure Offset[3]	Gauge, Differential (0 to 85°C) Absolute (0 to 85°C)	V_{off}	0.088 0.184	0.2 —	0.313 0.409	Vdc
Full Scale Output[4]	(0 to 85°C)	V_{FSO}	4.587	4.7	4.813	Vdc
Full Scale Span[5]	(0 to 85°C)	V_{FSS}	—	4.5	—	Vdc
Accuracy[6]	(0 to 85°C)	—	—	—	±2.5	$\%V_{FSS}$
Sensitivity		V/P	—	6.4	—	mV/kPa
Response Time[7]		t_R	—	1.0	—	ms
Output Source Current at Full Scale Output		I_{O+}	—	0.1	—	mAdc
Warm-Up Time[8]		—	—	20	—	ms

1. 1.0 kPa (kiloPascal) equals 0.145 psi.
2. Device is ratiometric within this specified excitation range.
3. Offset (V_{off}) is defined as the output voltage at the minimum rated pressure.
4. Full Scale Output (V_{FSO}) is defined as the output voltage at the maximum or full rated pressure.
5. Full Scale Span (V_{FSS}) is defined as the algebraic difference between the output voltage at full rated pressure and the output voltage at the minimum rated pressure.
6. Accuracy (error budget) consists of the following:
   Linearity: Output deviation from a straight line relationship with pressure over the specified pressure range.
   Temperature Hysteresis: Output deviation at any temperature within the operating temperature range, after the temperature is cycled to and from the minimum or maximum operating temperature points, with zero differential pressure applied.
   Pressure Hysteresis: Output deviation at any pressure within the specified range, when this pressure is cycled to and from the minimum or maximum rated pressure, at 25°C.
   TcSpan: Output deviation over the temperature range of 0° to 85°C, relative to 25°C.
   TcOffset: Output deviation with minimum rated pressure applied, over the temperature range of 0° to 85°C, relative to 25°C.
   Variation from Nominal: The variation from nominal values, for Offset or Full Scale Span, as a percent of V_{FSS}, at 25°C.
7. Response Time is defined as the time for the incremental change in the output to go from 10% to 90% of its final value when subjected to a specified step change in pressure.
8. Warm-up Time is defined as the time required for the device to meet the specified output voltage after the pressure has been stabilized.

Pressure

Maximum Ratings

Table 2. Maximum Ratings(1)

Parametrics	Symbol	Value	Unit
Maximum Pressure(2) (P2 ≤ 1 Atmosphere)	$P1_{max}$	2800	kPa
Storage Temperature	T_{stg}	-40 to +125	°C
Operating Temperature	T_A	-40 to +125	°C

1. Maximum Ratings apply to Case 867 only. Extended exposure at the specified limits may cause permanent damage or degradation to the device.
2. This sensor is designed for applications where P1 is always greater than, or equal to P2. P2 maximum is 500 kPa.

Figure 1 shows a block diagram of the internal circuitry integrated on a pressure sensor chip.

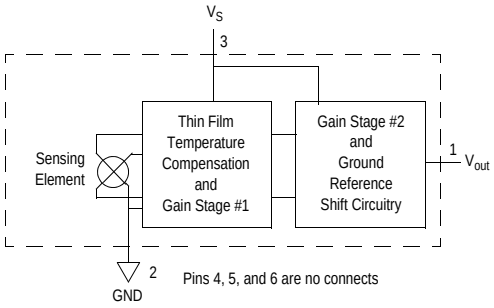


Figure 1. Fully Integrated Pressure Sensor Schematic

Pressure

On-chip Temperature Compensation and Calibration

Figure 3. illustrates both the Differential/Gauge and the Absolute Sensing Chip in the basic chip carrier (Case 867). A fluorosilicone gel isolates the die surface and wire bonds from the environment, while allowing the pressure signal to be transmitted to the sensor diaphragm. (For use of the MPX5700D in a high-pressure cyclic application, consult the factory.)

The MPX5700 series pressure sensor operating characteristics, and internal reliability and qualification tests are based on use of dry air as the pressure media. Media, other than dry air, may have adverse effects on sensor performance and long-term reliability. Contact the factory for information regarding media compatibility in your application.

Figure 2. shows the sensor output signal relative to pressure input. Typical, minimum, and maximum output curves are shown for operation over a temperature range of 0° to 85°C using the decoupling circuit shown in . The output will saturate outside of the specified pressure range.

shows the recommended decoupling circuit for interfacing the output of the integrated sensor to the A/D input of a microprocessor or microcontroller. Proper decoupling of the power supply is recommended.

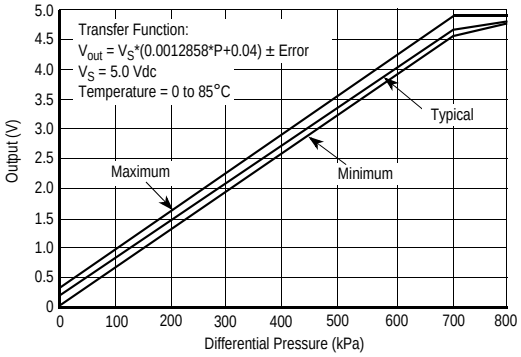


Figure 2. Output vs. Pressure Differential

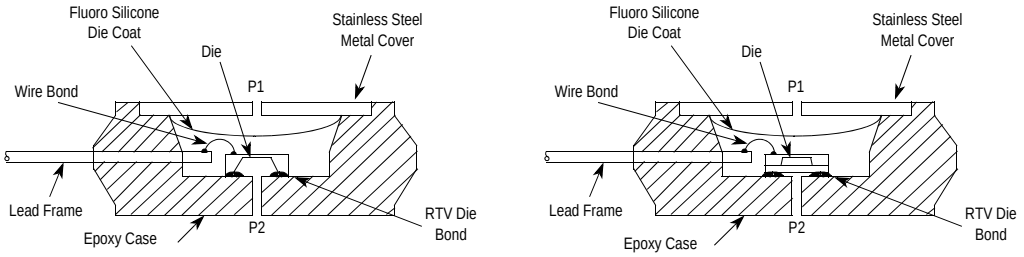


Figure 3. Cross-Sectional Diagrams (not to scale)

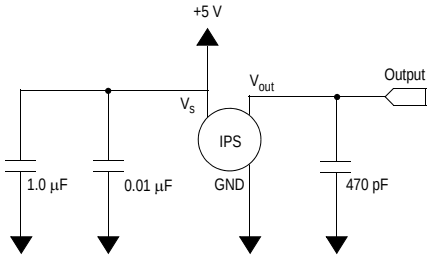


Figure 4. Recommended Power Supply Decoupling and Output Filtering (For additional output filtering, please refer to Application Note AN1646)

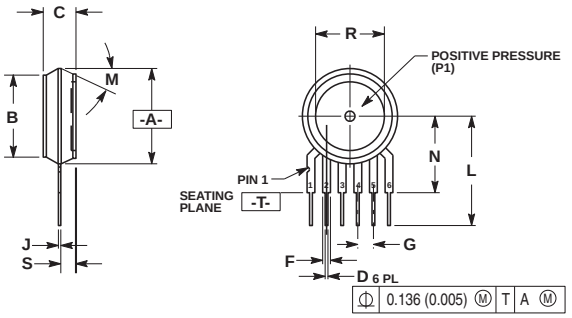
PRESSURE (P1)/VACUUM (P2) SIDE IDENTIFICATION TABLE

Freescale designates the two sides of the pressure sensor as the Pressure (P1) side and the Vacuum (P2) side. The Pressure (P1) side is the side containing fluorosilicone gel which protects the die from harsh media. The Freescale MPX pressure sensor is designed to operate with positive differential pressure applied, P1 > P2.

The Pressure (P1) side may be identified by using the following table.

Part Number	Case Type	Pressure (P1) Side Identifier
MPX5700A/D	867	Stainless Steel Cap
MPX5700DP	867C	Side with Part Marking
MPX5700GP/AP	867B	Side with Port Attached
MPX5700GS/AS	867E	Side with Port Attached
MPX5700ASX	867F	Side with Port Attached

PACKAGE DIMENSIONS



NOTES:
1. DIMENSIONING AND TOLERANCING PER ANSI Y14.5M, 1982.
2. CONTROLLING DIMENSION: INCH.
3. DIMENSION -A- IS INCLUSIVE OF THE MOLD STOP RING. MOLD STOP RING NOT TO EXCEED 16.00 (0.630).

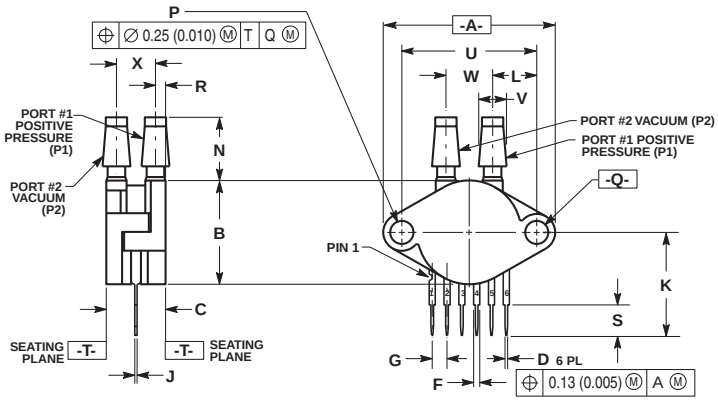
	INCHES		MILLIMETERS	
DIM	MIN	MAX	MIN	MAX
A	0.595	0.630	15.11	16.00
B	0.514	0.534	13.06	13.56
C	0.200	0.220	5.08	5.59
D	0.027	0.033	0.68	0.84
F	0.048	0.064	1.22	1.63
G	0.100 BSC		2.54 BSC	
J	0.014	0.016	0.36	0.40
L	0.695	0.725	17.65	18.42
M	30° NOM		30° NOM	
N	0.475	0.495	12.07	12.57
R	0.430	0.450	10.92	11.43
S	0.090	0.105	2.29	2.66

STYLE 1:
PIN 1. VOUT
2. GROUND
3. VCC
4. V1
5. V2
6. VEX

STYLE 2:
PIN 1. OPEN
2. GROUND
3. -VOUT
4. VSUPPLY
5. +VOUT
6. OPEN

STYLE 3:
PIN 1. OPEN
2. GROUND
3. +VOUT
4. +VSUPPLY
5. -VOUT
6. OPEN

CASE 867-08
ISSUE N
BASIC ELEMENT



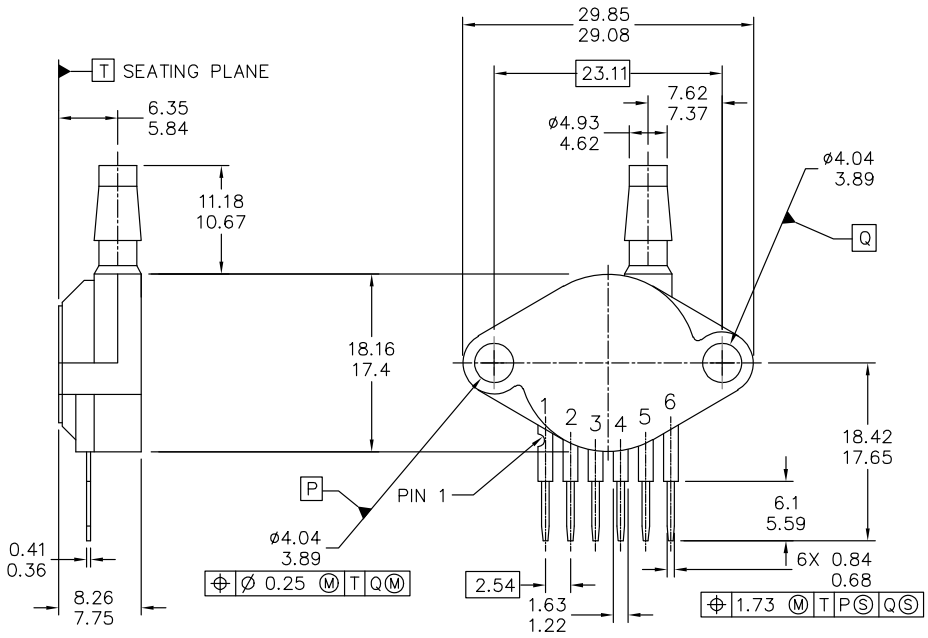
NOTES:
1. DIMENSIONING AND TOLERANCING PER ASME Y14.5M, 1994.
2. CONTROLLING DIMENSION: INCH.

	INCHES		MILLIMETERS	
DIM	MIN	MAX	MIN	MAX
A	1.145	1.175	29.08	29.85
B	0.685	0.715	17.40	18.16
C	0.405	0.435	10.29	11.05
D	0.027	0.033	0.68	0.84
F	0.048	0.064	1.22	1.63
G	0.100 BSC		2.54 BSC	
J	0.014	0.016	0.36	0.41
K	0.695	0.725	17.65	18.42
L	0.290	0.300	7.37	7.62
N	0.420	0.440	10.67	11.18
P	0.153	0.159	3.89	4.04
Q	0.153	0.159	3.89	4.04
R	0.063	0.083	1.60	2.11
S	0.220	0.240	5.59	6.10
U	0.910 BSC		23.11 BSC	
V	0.182	0.194	4.62	4.93
W	0.310	0.330	7.87	8.38
X	0.248	0.278	6.30	7.06

STYLE 1:
PIN 1. V_{OUT}
2. GROUND
3. V_{CC}
4. V1
5. V2
6. V_{EX}

CASE 867C-05
ISSUE F
PRESSURE AND VACUUM SIDES PORTED (DP)

PACKAGE DIMENSIONS



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TITLE: SENSOR, 6 LEAD UNIBODY CELL, AP & GP 01ASB09087B	DOCUMENT NO: 98ASB42796B	REV: G
	CASE NUMBER: 867B-04	28 JUL 2005
	STANDARD: NON-JEDEC	

PAGE 1 OF 2

CASE 867B-04
ISSUE G
PRESSURE SIDE PORTED (AP, GP)

PACKAGE DIMENSIONS

NOTES:

1. DIMENSIONS ARE IN MILLIMETERS.
2. DIMENSIONS AND TOLERANCES PER ASME Y14.5M–1994.
3. 867B–01 THRU –3 OBSOLETE, NEW STANDARD 867B–04.

STYLE 1:

PIN 1: V OUT
2: GROUND
3: VCC
4: V1
5: V2
6: V EX

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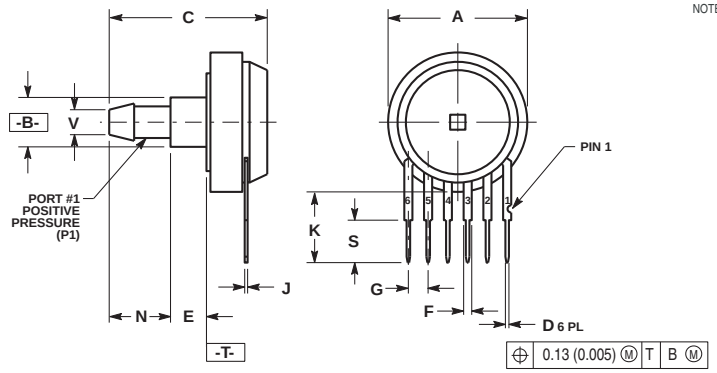
TITLE: SENSOR, 6 LEAD UNIBODY CELL, AP & GP 01ASB09087B	DOCUMENT NO: 98ASB42796B	REV: G
	CASE NUMBER: 867B–04	28 JUL 2005
	STANDARD: NON–JEDEC	

PAGE 2 OF 2

CASE 867B-04
ISSUE G
PRESSURE SIDE PORTED (AP, GP)

PACKAGE DIMENSIONS

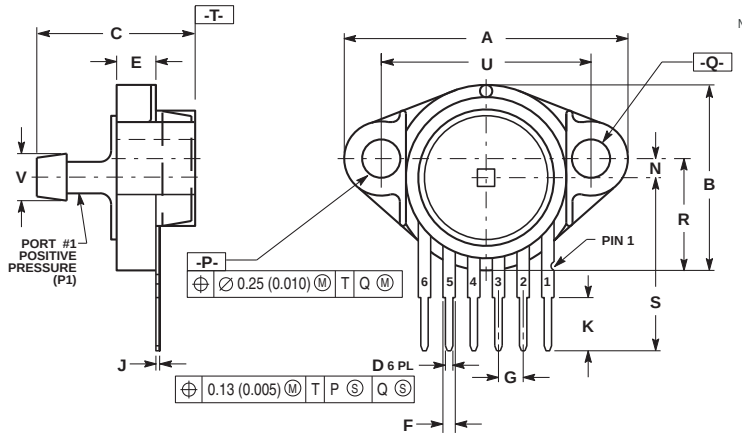


NOTES:
1. DIMENSIONING AND TOLERANCING PER ANSI Y14.5M, 1982.
2. CONTROLLING DIMENSION: INCH.

DIM	INCHES		MILLIMETERS	
	MIN	MAX	MIN	MAX
A	0.690	0.720	17.53	18.28
B	0.245	0.255	6.22	6.48
C	0.780	0.820	19.81	20.82
D	0.027	0.033	0.69	0.84
E	0.178	0.186	4.52	4.72
F	0.048	0.064	1.22	1.63
G	0.100 BSC		2.54 BSC	
J	0.014	0.016	0.36	0.41
K	0.345	0.375	8.76	9.53
N	0.300	0.310	7.62	7.87
S	0.220	0.240	5.59	6.10
V	0.182	0.194	4.62	4.93

STYLE 1:
PIN 1. V_{OUT}
2. GROUND
3. V_{CC}
4. V1
5. V2
6. V_{EX}

CASE 867E-03
ISSUE D
PRESSURE SIDE PORTED (AS, GS)



NOTES:
1. DIMENSIONING AND TOLERANCING PER ANSI Y14.5M, 1982.
2. CONTROLLING DIMENSION: INCH.

DIM	INCHES		MILLIMETERS	
	MIN	MAX	MIN	MAX
A	1.080	1.120	27.43	28.45
B	0.740	0.760	18.80	19.30
C	0.630	0.650	16.00	16.51
D	0.027	0.033	0.68	0.84
E	0.160	0.180	4.06	4.57
F	0.048	0.064	1.22	1.63
G	0.100 BSC		2.54 BSC	
J	0.014	0.016	0.36	0.41
K	0.220	0.240	5.59	6.10
N	0.070	0.080	1.78	2.03
P	0.150	0.160	3.81	4.06
Q	0.150	0.160	3.81	4.06
R	0.440	0.460	11.18	11.68
S	0.695	0.725	17.65	18.42
U	0.840	0.860	21.34	21.84
V	0.182	0.194	4.62	4.93

STYLE 1:
PIN 1. V_{OUT}
2. GROUND
3. V_{CC}
4. V1
5. V2
6. V_{EX}

CASE 867F-03
ISSUE D
PRESSURE SIDE AXIAL PORT (ASX)

Pressure

Table 3. Revision History

Revision number	Revision date	Description of changes
10	10/2012	• On page 1, added a table note to the Ordering Information table indicating that the device MPX5700GP1 has 90 degree lead form.

How to Reach Us:

Home Page:
freescale.com

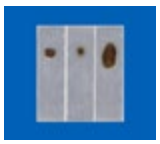
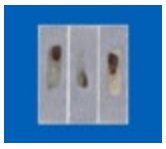
Web Support:
freescale.com/support

MPX5700
Rev. 10
10/2012

Appendix D: TOSI Troubleshooting Guide

GETINGE
GETINGE GROUP

TOSI®:Troubleshooting Guide

TOSI® Test Results	Rating	Description	Possible Reasons for TOSI® Test Results	Immediate corrective action (to be conducted by CSSD personnel)	Proposal for optimisation of relevant process parameters (typically requires Service Representative)
	0	**Optimum Result** Test soil is completely dissolved, no test soil residuals are left	Optimum result	Not necessary	Not necessary
	1	**Negative Result 1** TOSI® is completely rinsed = no water soluble proteins visible, but small amount of fibrin residuals remain	a) Incorrrectly positioned or blocked TOSI® b) Cleaning time too short c) Temperature not optimal d) Dosage of detergent too low	a) Repeat test protocol with small load b) Investigate cleaning time c) Investiagte cleaning temperature d) Check dosage/concentration of detergent	a) Consider other possible reasons b) Adjust cleaning time to type of detergent or extend time c) Adjust cleaning temperature to type of detergent d) Increase dosage
	2	**Negative Result 2** TOSI® is completely rinsed = no water soluble proteins visible but most or all of the fibrin layer remains	a) Incorrectly positioned or blocked TOSI® b) Overloading/incorrect loading c) Cleaning time too short d) Temperature not optimal e) Dosage of detergent too low d) Insufficient detergent efficiency	a) Repeat test protocol with small load b) Repeat test protocol with correct load c) Investigate cleaning time d) Investigate cleaning temperature e) Check dosage/reservoir of detergent f) Check storage conditions/expiry date of the detergent	a) Consider other possible reasons b) Consider other possible reasons c) Adjust cleaning time to type of detergent or extend time d) Adjust cleaning temperature to type of detergent e) Increase dosage or refill/replace reservoir f) Replace incorrectly stored or expired detergent
	3	**Negative Result 3** TOSI® is completely rinsed = small residuals of water soluble (red) proteins are visible. None or only a small amount of the fibrin layer remains visible	a) Incorrectly positioned or blocked TOSI® b) Overloading/incorrect loading c) Non-uniform water distribution d) Blocked spray system e) Blocked filter f) Insufficient water pressure g) Foaming residuals left over from pre cleaning or ultrasonic bath	a) Repeat test protocol with small load b) Repeat test protocol with correct load c) Check load + installation of spray system d) Check movement of spray arms & clean e) Check filter f) Refer to Service Representative g) Rinse instruments more carefully after pre-cleaning and ultrasonic bath	a) Consider other possible reasons b) Consdier other possible reasons c) Install spray system correctly or replace by suitable one d) Replace defective spray arms if necessary e) Replace filter if necessary f) Check/increase water pressure, check function of pump g) Not applicable
	4	**Negative Result 4** TOSI® is completely rinsed = significant residuals of water soluble (red) proteins are visible. In addition, most or all of the fibrin layer remains	a)-g) Same as rating 3 but more distinct h) Defective pump i) Loss of pressure or other defect j) Incorrect temperature for detergent k) Failure of chemistry in use	a)-g) Same as rating 3 h) Refer to Service Representative i) Check spray arm and rack connection j) Investigate cleaning temperature k) Check tube connections/reservoir/storage conditions/expiration date of detergent	a)-g) Same as rating 3 h) Replace pump i) Repair leaks and/or replace defective spray parts j) Select and set appropriate parameters for detergent in use k) Reconnect tubing/refill or replace reservoir/replace incorrectly stored or expired detergent.
	5	**Negative Result 5** TOSI® - test soil is largely or completely unaffected	a)-k) Same as rating 4 l) No cold pre-rinsing step in place or pre-rinsing too hot m) Complete breakdown of the washer and or chemistry	a)-k) Same as rating 4 l) Investigate pre-rinsing temperature and/or availability of pre-rinsing step m) It is strongly recommended not to use the washer/disinfector until problems are resolved	a)-k) Same as rating 4 l) Reduce pre-rinsing temperature below 40ºC or install cold pre-rinsing cycle m) Investigate carefully all relevant cleaning parameters and make necessary corrections

Important note:
In case of unsatisfactory test results these results should be confirmed by rerunning the test program with a smaller load. In the case of a confirmation of the inital test results it is recommended to investigate potential reasons for the failure. In case the cause of a failure cannot be resolved by the CSSD staff the technical service of the machine or detergent manufacturer should be contacted.

Getinge USA, Inc. 1777 East Henrietta Road Rochester, New York 14623-3133 Phone: 800.475.9040 Fax: 585.272.5033 www.getingeusa.com

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GLOSSARY

IMPORTANT FIGURES

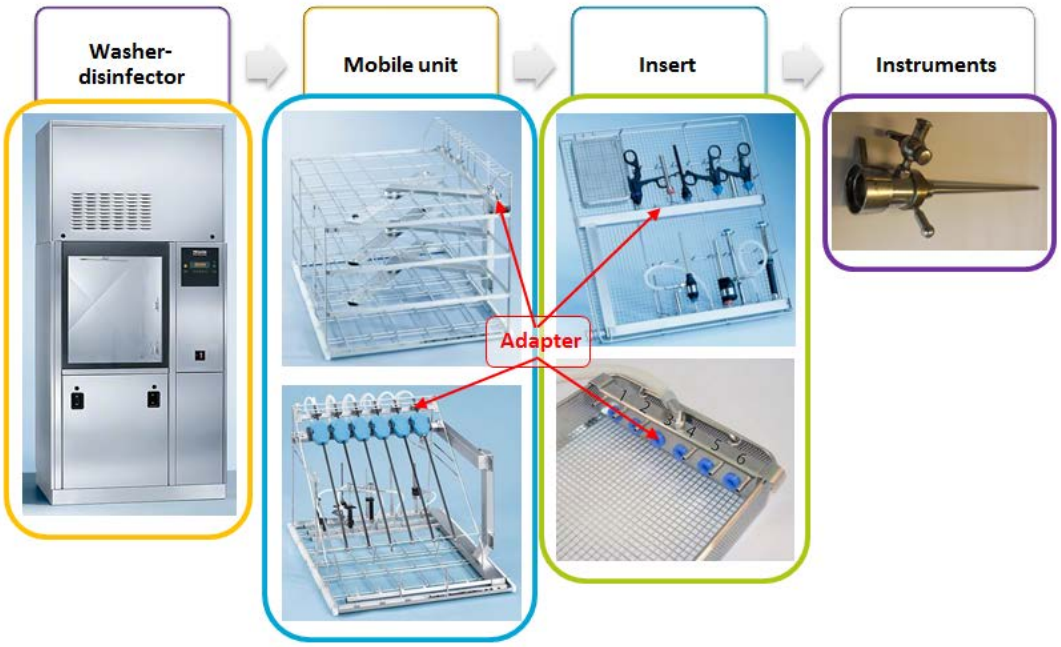

Figure 8.4: an overview of the chain of elements. A mobile unit can be rolled into a washer-disinfector. Instrumentsets are placed on a mobile unit and a mobile unit has adapters for hollow instruments to connect them to the pumping system of the WD. Sometimes an insert is connected to the mobile unit and the insert has more adapters or adapters specifically for special hollow instruments.

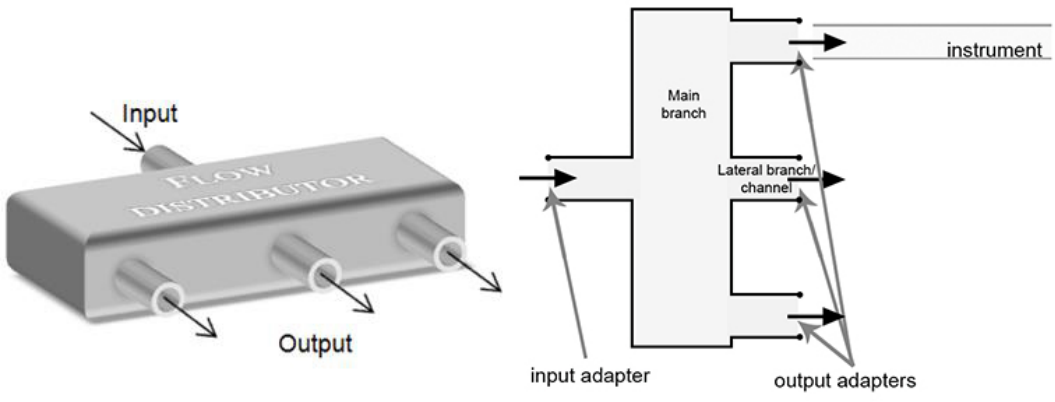

Figure 8.5: schematic view of an insert. The working principle is like a manifold: the input flow is distributed among multiple outputs. The input adapter of the insert is connected to a mobile unit and instruments can be connected to the output adapters.

TERMS AND DEFINITIONS

Adapter	Inserts for hollow instruments able to rinse the inside of hollow instruments. Normally an insert is like a manifold; it consists of one or two input channels and multiple output channels. At each output channel a device or instrument can be connected. The connector between the insert and instrument is called adapter.
Cannulated instrument	See hollow instrument
Central Sterile Supply Department (CSSD)	A service unit in a hospital that processes, issues, and controls the sterile stores supply to all departments of the hospital. The purpose of such a CSSD is to provide all the departments of a hospital with guaranteed sterile equipment ready and available for immediate use in patient care.
Cleaning process	Removal of contamination from an item to the extent necessary for its further processing and intended subsequent use. First process of the decontamination process of medical instruments.
Cleaning application	A term for a device what can be used for the rinsing of hollow instruments
Disinfection process	Reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use. Second process of the decontamination process of medical instruments.
Endoscope Washer-Disinfector (EWD)	Washer-disinfector intended to clean and disinfect loads containing flexible endoscopes
Hollow instrument	A medical device consisting of a shaft, channel or hollow part. The narrow, hollow parts are ideal places for human tissues, residuals and bacteria to nestle.
Insert	Application for the rinsing of the inside of hollow instruments. Inserts have to be connected to a mobile unit. Multiple instruments or devices can be connected to the outputs of an insert. The working principle of an insert is like a manifold or flow distributor; it consists of one or two input channels and multiple output channels.
Mechanical performance	In this study expressed as flow and pressure through a channel
Mobile unit	The dirty instruments are placed in trays, the trays can be put on a load carrier (also called mobile unit) and rolled into the cleaning chamber. An insert can be connected to a regular mobile unit. A mobile unit is connected to the central fluid pumping system of the WD. There are also specific mobile units, like the da Vinci mobile unit. This mobile unit is only suitable for the da Vinci instruments.
Minimally Invasive Surgery	Surgery performed with only a small incision or no incision at all, such as through a cannula with a laparoscope or endoscope.

Sterilization process	Killing all forms of life. Sterilization is mostly achieved by applying heat. Final process of the decontamination process. A sterile device is free of living micro-organisms.
Washer-disinfector (WD)	Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

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De onderstaande personen en instanties hebben medewerking verleend aan dit onderzoek maar zijn op geen enkele manier verantwoordelijk voor deze studie.

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