Heidi Nousiainen

# Market Research Regarding the Need for Medical Engineering Services in a New Market Area

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The role of medical devices in the healthcare is increasing all the time and the sector is highly regulated. Currently there are both political and legislative changes going on in the healthcare and medical device sector, and this is affecting every operator in the field. Due to these political changes HUS Medical Engineering should be prepared to expand the market area to cover all the public primary healthcare units in the Helsinki-Uusimaa Region.

The purpose of this quantitative market research was to get better understanding of the current state of the new possible market and customers' needs, in order to get support for decision-making on what would be the most effective way to provide medical engineering services to these municipalities. The aim was to determine what kind of need there is for medical engineering services in the public health centres, nursing homes and maternity clinics of the area of Uusimaa outside the capital area. A descriptive cross sectional survey design was used, and the data was gathered with a web survey and analysed with Excel and SPSS 24.0 program. The research participants were healthcare professionals responsible for the medical devices of the health care units surveyed. The response time was between the 12th of April and 5th of May 2018, and the response rate was 68%.

The results showed that, in general, there is a need for medical engineering services, and that the need for registration services is greater than the need for the maintenance services. Quality and short duration of the service was valued and maintenance service was hoped to be organized centrally in the future. Maintenance services of the device suppliers were not particularly needed in the future. Device amounts were mainly estimates and whether the devices were registered or not, did not appear to be relevant to the accuracy of the device amounts given. Besides the registration and maintenance, some of the other responsibilities of a professional user were met better than I expected, even if there is still enough work in that area.

The results of the research help the HUS Medical Engineering department to better understand the potential new market area. The study provided information on the size of the market as well as the need for medical engineering services in the area, to support better decision-making.

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| Keywords | biomedical, clinical, medical engineering services, market research, medical device management, public sector strategy |

**Contents**

**Abbreviations and terminology**

| | |
|---|---|
| B2B | Business-to-Business |
| HUS | The Hospital District of Helsinki and Uusimaa |
| HUS Medical Engineering | Department that provides medical engineering services for the specialized medical care units around the HUS area and also for the primary healthcare units of the cities of Helsinki, Vantaa and Espoo |
| Healthcare Unit | Refers to the public health centres, nursing homes and maternity clinics of this study |
| Karviainen | Municipal federation of Karkkila and Vihti |
| Maintenance Service | Refers in this study both to the preventative maintenance and repair services (in Finnish: huolto) |
| Medical Engineering Services | Cost-effective medical device management in a way that the safety and effectiveness of the devices can be assured for the sake of the patient and user safety |
| PESTLE | A tool for business environmental analysis. The letters represent the words: political, economic, sociocultural, technological, legal and environmental |
| PHHYKY | Päijät-Häme Welfare Incorporation (in Finnish: Päijät-Hämeen hyvinvointiyhtymä) |
| Professional User | Social and healthcare unit as well as a person who in their profession uses or passes on medical devices |

# 1 Introduction

The role of medical devices in healthcare has increased over the past hundred years and the range of the devices is nowadays enormous and comprehensive. The medical devices have become self-evident in the diagnosis and treatment of patients, and as the population is aging rapidly, the role of the devices is likely to grow. For example the role of various monitoring devices and assistive technology in home care has increased in recent years, and this brings new challenges for the medical device management. (Enderle - Bronzino, 2012: 2; Storm, 2017.)

Healthcare sector is highly regulated and well supervised by several actors. In the European Union, new regulations on medical devices (*MDR*) were entered into force on May 25th 2017 replacing the existing directives (*MDD*). Currently there is a transitional period before the new rules will apply, and during this period the member states should react to these changes. (European Commission, 2017). National laws regulate medical devices and supplies in parallel with the European Union medical device regulations for a transitional period. Finland has also reacted to these changes and in December 2017 the Finnish Parliament made alterations to the Medical Devices Act 629/2010 and it was amended under a Medical Devices Act 936/2017. (Medical Devices Act 936/2017; Valvira, 2017.) These legislative requirements obligate the manufacturer to determine the maintenance procedures for the safe use of the device, and a professional user to ensure that they are implemented according to the manufacturer's instructions. This means that the professional user is obligated to arrange the maintenance services of the device. In addition, the law requires the device to be traceable and therefore both the manufacturer and the professional user of the device should have a device register. Any harmful medical device related incidents that have led to, or could have resulted in endangering health of the patient, the user or other person must always be reported to the National Supervisory Authority for Welfare and Health as soon as possible (Valvira 2015.) This obligation applies to the professional user as well as to the supplier, manufacturer and their authorized representatives of the medical devices. And it concerns incidents related to the characteristics, inadequate marking, performance deviation or disturbance, and inadequate or incorrect user manual of the medical device. (Medical Devices Act 629/2010 §15, §17-18, §25; Valvira 2015; Regulation 2017/745 on medical devices: article 10, annex I.)

Among other things, in order to comply with the national and international legislative requirements, many hospitals and healthcare units have an own department responsible for providing medical device management services to ensure the safety and cost effectiveness of the devices. (Enderle - Bronzino, 2012: 2; 17, 21-22; Hinrichs 2009.) For example, HUS Medical Engineering department is part of HUS Logistics which is an unincorporated enterprise that provides support services for the Hospital District of Helsinki and Uusimaa, also known as HUS. At the moment HUS Medical Engineering department is for example responsible for the registration, maintenance and repair services for the medical devices around the HUS area and also for the cities of Helsinki, Vantaa and Espoo. Due to the regional government, health and social services reform in Finland, HUS Medical Engineering should be prepared to expand the market area to cover the public health sector of the entire Helsinki-Uusimaa Region. A market research helps to determine company's future growth prospects. Understanding the current state of the market and customers' needs is important so that right services can be directed to the right target group. (Lotti, 2001: 19, 26; Abu Al Rous, 2015; Xu, 2005: 23, 80, 105.) Therefore it was decided that to get information on the market situation, a market research regarding the registration and maintenance of the medical devices in the public health sector of Uusimaa outside the capital area was conducted.

## 2 The aim, purpose and objectives

The aim of this research is to determine what kind of need there is for medical engineering services in the public health centres, nursing homes and maternity clinics of the area of Uusimaa outside the capital area. The purpose is to better understand the current state of the market and customers' needs, in order to get support for decision-making on what would be the most effective way to provide medical engineering services to these municipalities.

Specific research objectives are:

1. What is the current condition of the registration and maintenance of the medical devices in these municipalities?
2. What is the desired condition of the maintenance of the medical devices in these municipalities?
3. How much medical devices there are in each of the municipalities?

# 3 PESTLE

PESTLE, also known as PEST, PESTE or PESTEL analysis is a tool, or more specifically a checklist for business environmental analysis in which each of the letters represents an item that have an impact on business. There are several different combinations of letters for the same method but in this thesis the PESTLE is used because it is the most comprehensive. PESTLE analysis is a good starting point to environmental analysis as it can be used for analysing the past or forecasting the future. However, listing the items does not have much value if the aspects are not thoroughly analysed or have any relation to the strategic management process. According to Richard Lynch (2015: 74) it is more beneficial to explore and justify a few of the items and their impact on the matter, than to have a longlist of all of the possible factors. (Lynch, Richard, 2015: 73-74; 106; Xu, 2005: 25-32; Seinäjoki University of Applied Sciences, 2018.)

The table 1 shows the meaning of the letters and how they are related to this research. A few of the items that are affecting HUS Medical Engineering department's operational area are explained more thoroughly in the following chapters.

Table 1. PESTLE-analysis

| **Perspective** | **A Need for Medical Engineering Services in a New Market Area** |
|---|---|
| Political | Regional government, social and healthcare reform |
| Economic | Central government debt is increasing rapidly, public sector savings, too much devices on standby, maintenance costs |
| Sociocultural | Demographic change: more devices in the home care as people live home longer, digitalization |
| Technological | Digitalization: more health technology devices, AI, applications |
| Legal | MDR, Medical devices act: registration, maintenance, freedom of choice |
| Environmental | Transportation costs, device waste |

## 3.1 Medical devices and medical engineering services

The role of medical devices is nowadays essential to the healthcare and it is increasing all the time. The range of products in this sector is enormous and diverse, from simple thermometers and body scales to very complex da Vinci Surgical System robotics and MRI imaging systems. (Enderle - Bronzino, 2012: 2, 10; Mequsoft, 2018.) In addition, some other products, such as eye drops and cranberry capsules are classified as medical devices. The pace of development of medical devices has been rapid, and

only in just over a hundred years the number and versatility of medical devices has increased dramatically. For example, the first X-ray device invented in 1895 was introduced to the public in 1904. In 1924 Willem Einthoven received a Nobel Prize for inventing a first electrocardiogram in 1903 that showed how the electrical currents of the heart were functioning. And a few years later, in 1929 also the electrical signals of the brain were able to be measured. Back then the devices were enormous as in nowadays there are portable versions of all of these example devices. (Enderle - Bronzino, 2012: 510-511; The Nobel Foundation, 2018.)

Medical devices sector has an important role in the diagnosis, prevention, monitoring and treatment of diseases, as well as in the improvement of the quality of life of those with disabilities (World Health Organization WHO, 2018.) The medical technology has also a role in extending life expectancy. Approximately in 1870s the life expectancy at birth in Finland was around 40 years and that time it started to rise slightly. After the wars, in 1920s the rise accelerated slightly and between the years 1921-1930 the life expectancy for men was 50 years and for women 55 years, as in 1951-1955 the expected lifespan for men was 63 and for women 70. Currently a boy born in 2016 can expect to live over 78 years and girl 84 years. (Enderle - Bronzino, 2012: 45; Official Statistics of Finland (OSF), 2018.)

### 3.1.1 Definitions of medical device and medical engineering

According to a World Health Organization WHO (2018) a medical device is an “instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article” that is used for diagnosis, monitoring, treatment, prevention, alleviation of disease or injury, as well as for the investigation, replacement, modification, or support of the anatomy or of a physiological process, control of conception or supporting or sustaining life of a human being. Addition to this, a medical device which is used for a specific purpose, and which requires calibration, maintenance, repair, user training and decommissioning performed usually by engineers, is referred as medical equipment. (European Commission, 2018; World Health Organization WHO, 2018.) The industry that performs these actions is referred as biomedical engineering, medical engineering, clinical engineering or healthcare engineering depending on the source. The terminology is not entirely unambiguous but according to Enderle and Bronzino (2012: 17) the term biomedical engineering is considered to be the most comprehensive, and it is widely

used. Previously, in the 1950's and 1960's the term was associated mainly with the development of the medical devices but nowadays the concept is much wider. For example, biomedical engineers can work as a research scientist or as a biomedical design engineer for industry. Besides this a biomedical engineer who is working in a hospital environment is in many cases referred as clinical engineer or a medical engineer. And therefore the hospital department is usually called either clinical engineering department, medical engineering department or biomedical engineering department. (Association for the Advancement of Medical Instrumentation, 2018; Enderle - Bronzino, 2012: 2; 17, 21-22; Hinrichs 2009.) In this Thesis the term medical engineering will be used as it is the term used by the Hospital District of Helsinki and Uusimaa where this study was conducted. HUS Medical Engineering department is introduced more thoroughly in the chapter 4 Research Work Setting.

### 3.1.2 Medical engineering services

Despite the fact that it is difficult to define the term, there are a lot of similarities between the organizations and their services. For example the Biomedical Engineering of the Royal Children's Hospital Melbourne (2018) provides a variety of different kind of services related to the medical device management and maintenance very similar to the Finnish services. These services include acceptance testing and registration for the new medical devices. During the acceptance test the condition and safety issues of the new device is checked and it is ensured that the delivery is in line with the order. The device is given a barcode number with an individual ID number of the device, and the information is registered in the device register. All the maintenance, performance and safety events are recorded to the register based on the barcode number. According to Turkish Ministry of Health (Kuru et. al, 2013) the benefit of identifying and registering the device is, among the safety issues, the monitoring of the lifespan costs of the device. For example, it can be estimated how much electricity is consumed or how much electronic or other waste is generated, and thus need to be disposed of. In addition, the maintenance costs including the spare parts and external repair work can be seen from the register. This helps to identify the poor quality specimens in the early stage, and also to determine whether or not the device should be repaired or disposed of. The benefits are also reflected in the device tendering, when the cost of maintaining the device can be taken into account in addition to the sales price of the device. In addition, the registration helps to identify how much money the hospital or other

healthcare unit is invested in the medical devices and how to put unnecessary equipment into circulation. (Kuru et al., 2013.)

After the device is registered and taken into clinical use, the functionality of the medical device must be guaranteed throughout its lifetime. It is a duty of the medical device manufacturer to define the maintenance procedures and frequency of maintenance for the medical devices and to ensure that these issues are stated in the user instructions of the medical device (Regulation 2017/745 on medical devices: article 10, annex I.) The purpose of the preventative maintenance or routine maintenance is to ensure the safety of the device that is already in use. This might include for example replacement of parts, software updates, calibration or only a performance test depending what the manufacturer has specified for the specific device. The user of the medical device is responsible for ensuring that the manufacturer's instructions are followed, and this includes the arrangement of maintenance services. However, often the user does not have any technical training and therefore many hospitals have their own medical engineering department in order to ensure the technical maintenance of their devices. Preventative maintenance reduces the number of faults in the device, but in spite of this, they cannot be avoided completely. In case the device is defective, medical engineering will investigate and repair the device, or outsource the repair service. The service history and test reports are recorded in the register and in case any harmful medical device related incidents happen they can be found from the register. (The Royal Children's Hospital Melbourne, 2018.)

Besides the registration and maintenance services medical engineering provides expertise and technical assistance in medical device and systems procurement and maintenance contracts as well as in the planning of the customer's operations and investments related to the medical devices. (Kastek, 2018; Tampere University Hospital, 2017.) Different healthcare units have different needs when it comes to medical device management. For example a small maternity clinic might only have a few simple devices such as scales, examination table, fetal Doppler, hemoglobin meter and some thermometers, while in an operating room there might be dozens of devices during one surgery. In summary, it can be stated that the baseline of the medical engineering services is the cost-effective medical device management in a way that the safety and effectiveness of the devices can be assured for the sake of the patient and user safety.

## 3.2 Legislation related to the medical devices

The European Commission proposes and enforces EU legislation by making regulations and directives. In addition to this, EU issues decisions and recommendations. The EU's regulations will come into force immediately in the member states. The implementation of the directives, on the other hand, often requires changes to national legislation. (European Union 2018; The Finnish Parliament 2018.) Medical Device Directive 93/42/EEC was established by European Commission in 1993 to harmonise laws relating medical device manufacturing inside the European Union. Two new European Commission regulations on medical devices were adopted on April 5th 2017 and they entered into force on May 25th 2017 replacing the existing directives. Before the new legislation will apply, there is a transitional period during which national law is in parallel with the new regulations. This will give the member states of European Union time to react to changes and adjust their own legislation to meet the new regulations. (European Commission, 2017)

### 3.2.1 The Finnish Medical Devices Act

The Finnish Medical Devices Act 629/2010 implements the old medical device related EU directives 90/385/EEC, 93/42/EEC and 98/79/EC. The act applies to the design and manufacture of a device, a supplies or an accessory, as well as to the assembly of packages and systems. Also placing products on the market, including the sterilization, commissioning, installation, maintenance, professional use, marketing and distribution are included in the law. (Medical Devices Act 629/2010 §1, §5.) Due to the changes in the European legislation Finland has also made alterations to the Medical Devices Act 629/2010 and it was amended under a Medical Devices Act 936/2017 in December 2017 by the Finnish Parliament. (Medical Devices Act 936/2017; Valvira, 2017.)

According to the Finnish Medical Devices Act the supplier must ensure that when the device is hand over to the end user, the device is in the condition where the manufacturer intended it to be used (Medical Devices Act 629/2010 §15.) The device manufacturer is responsible for the safety of the device they have manufactured. They make the device conformity classification, and the manufacturer or a supplier is required to provide the Declaration of Conformity to the end user as proof of conformity. They also have a duty to determine the aspects of the maintenance of the device. These include, for example, the preventative maintenance interval and the tests

and procedures to ensure the efficiency and safety of the device throughout its lifespan. The manufacturer must also ensure that the information on the device is in Finnish, Swedish or English, unless it is in commonly known reference or warning labels. All the information related to the safe usage of the device must be in Finnish and Swedish. This includes for example the user manuals. (Knuuttila, 2016; Medical Devices Act 629/2010 §12-13.) The manufacturer and their authorized representatives are also obligated to report any harmful medical device related incidents that have led to, or could have resulted in endangering health of the patient, the user or other person. This obligation concerns incidents related to the characteristics, inadequate marking, performance deviation or disturbance, and inadequate or incorrect user manual of the medical device. They have a duty to remove non-compliant products from the market if the deficiencies found cannot be corrected. The manufacturer informs the potential risks with Field Safety notice and Valvira monitors the implementation of the actions taken. (Knuuttila, 2016; Medical Devices Act 629/2010 §15, §17-18; Valvira 2015.)

### 3.2.2 Responsibilities of professional user

According to the definition given in the section 5 of the Finnish Medical Devices Act 629/2010, a professional user can be classified as both a social and healthcare unit and a person who in their profession uses or passes on medical devices for the diagnosis, prevention, monitoring, treatment or alleviation of the disease, disability or shortcoming; or for the purpose of research, replacement or modification of anatomy or physiological function. (Valvira, 2016; Medical Devices Act 629/2010 § §24-26.) The Medical Devices Act 629/2010 defines that professional users must have a nominated person in charge of compliance with the Medical Devices Act and the provisions and regulations issued by it. Professional users have an obligation to ensure the availability of instructions. They have also a duty to follow the given instructions and give training for all users, to ensure the safe usage of the medical device. They are also responsible for the traceability and functionality of the medical devices used by them. This includes the correct installation of the device, systems connection and of the routine maintenance of the device. (Medical Devices Act 629/2010 § 24-26.) However, usually they are not qualified to perform a preventive maintenance on the device or repair it. For that reason Medical Devices Act 629/2010 defines that the manufacturer or their authorized representative are obligated to take action to prevent harmful incidents that may occur if the device in use is defective. (Medical Devices Act 629/2010, §47)

In Finland the Healthcare sector is currently supervised by the National Supervisory Authority of Welfare and Health called Valvira. As stated in their website “proper use of the device must not endanger the safety or health of the patient, of the user or of other persons”. (Valvira 2015.) Any harmful incidents related to medical devices must always be reported to Valvira as soon as possible (Medical Devices Act 629/2010 § 24-26.) The notification must include adequate information for the identification of the medical device. The information needed may include: manufacturer, supplier, trade name, device or article title, model or product number, serial number or batch number and, where applicable, information on the used accessory and software version, manufacturer and importer contact details, year of manufacture and year of purchase of the device as well as the expiry date. This means that the social and healthcare organizations or any other professional users must have a register to ensure the traceability of the device. Usually in these incidents Valvira is also interested to know the service history of the defective device. And as it is a responsibility of a professional user to ensure the functionality of the devices and to arrange the routine maintenance and repairs, these things should also be recorded in the register, as well as the previous incidents related to that device. (Partanen – Knuuttila, 2010.)

### 3.3 Regional government, health and social services reform

The state of Finland's national economy and the public sector are affecting the credit risk associated with government bonds. In other words, the better the financial condition is, the smaller the credit risk and interest payments of the Finnish government debt are. As the central government debt continues to grow, the cost-effectiveness of the public sector has to be further examined and controlled. (State Treasury, 2015.) The purpose of the regional government, health and social services reform is to modernize services and improve the sustainability of public finances. The biggest change is the division into three levels of government: the state, the county and the municipality. (Ministry of social affairs and health – Ministry of finance, 2016.)

In its negotiation on 5th of July 2017, the Finnish Government decided that the reform will enter into force on 1st of January 2020. However, in the beginning of June 2018 the Constitutional Law Committee of Finnish Parliament issued its opinion on the key legislative proposals regarding the reforms, some of which will be modified as required by the Constitutional Law Committee’s statement. Therefore, on 27th of June 2018, the

Finnish Parliament announced that reform's entry into force will be postponed by one year, and thus the reform will enter into force on 1st of January 2021. At that time the responsibility for arranging social and health services will be transferred to the counties. The integration of healthcare and social welfare services means that all services will be under the management of a single structure, the county. At the moment the organising of health and social services are the responsibility of municipalities. As a result of the reform, this responsibility will be transferred from nearly 190 different designated authorities to only 18 counties. The counties will be responsible for coordination and management of the public, private and third sector services within the scope of the clients' freedom of choice. They will also have to ensure that these services meet quality criteria. The counties are also responsible for the establishment of effective care chains, as well as the improvement of the equality and cost-effectiveness of these services. (Finnish government, 2018.)

## 3.4 Strategy

Peter Drucker has stated that "Only three things happen naturally in organizations: friction, confusion, and underperformance. Everything else requires leadership" (Story, 2016.) The leadership is crucial when dealing with change. Successful organizations have leaders who understand the effects of external change. They have the will and the ability to actively manage the organization's strength, as well as the ability to develop effective strategies that take the external change into consideration. This kind of set of actions is known as strategic management. (Ginter, 2013: 5; Länsisalmi, 2013: 15) Strategic thinking is targeted at positioning the organization most effectively within its changing external environment. Strategic decisions define the direction and competitiveness of an organization by taking into account the predictable, unpredictable and even unknown changes in its environment. Strategic decisions determine company's effectiveness by assessing whether the company's resources are properly targeted against its main aspirations, rather than just in order to perform the individual tasks efficiently. The most typical problem in the ability to develop new successful product or service innovations is poorly defined strategy. (Ginter, 2013: 36, 40; Länsisalmi, 2013: 20; Mintzberg – Lampel – Quinn –Ghoshall, 2003: 6, 10.)

Expansion of scope strategy is used when an organization is thinking to expand its business to perform the mission and realize the vision. Market development strategy is part of the expansion of scope strategy. It is a strategy used to enter new markets with

present products or services and its purpose is to achieve greater volume through the extension of the geographical market area. Before a market development strategy can be implemented, it is useful to consider whether extending the market area is profitable and whether it requires changes to products or services. It is also important to think about things like whether there is enough information about the customer and the channels in order to make decisions. (Ginter, 2013: 215, 221; Lynch, 2015: 282; Wikipedia, 2016.)

### 3.4.1 Market research as a strategic planning tool

A market research is needed to provide information about the market when a company is thinking about to expand its business. According to Xu (2005: 105), the choice of the market area determines the organization's success or failure. For example, it is important to understand the market area to be able to determine the right products and services for it. Therefore, if an organization is considering expanding its operations to a new market, a variety of analyses should be carried out to help to determine whether this kind of move would be profitable, or if it might weaken the organization's prospects instead. Market research is an essential tool for strategic business development and decision-making, as it provides information on market structure, trends and customer needs and requirements. Market research enhances understanding of market opportunities and therefore reduces business risks. (Lotti, 2001: 19, 26; Abu Al Rous, 2015; Xu, 2005: 23, 80, 105.)

Planning and achieving market growth requires some fundamental activities which are included in the following steps. The first step is to identify the target market, in other words, to whom to offer the services. Once a customer profile is created and the extent of the target market is identified, a market research should be conducted to answer the question whether customers are using these services and whether they need them. It should be found out, if the customers are aware of having a problem that needs to be fixed, and would they buy a solution for that if there was one. And if they would, whom would they buy it from. It is also important to find out how much they would be willing to pay and are there some other services they would be interested in. After enough information to understand the customer is gathered it is possible to determine if it is profitable to enter new markets or not. Once the decision to enter the market has been made, a plan to do that will have to be created. (Edward Lowe Foundation, 2018; Länsisalmi, 2013: 23.)

### 3.4.2 Public sector strategy

Although the public sector differs in many ways from the private sector, public sector organizations also benefit from having a strategy. Due to differences between these sectors there are also differences in management and strategy processes. Because the services provided by the public sector are defined by society in the form of laws and regulations, the public sector strategy is above all influenced by legislation and thus by political decisions. Therefore, political and legislative changes have a strong impact on the strategy of the public sector organization. (Lindroos – Lohivesi, 2010: 141-143) For example, there has previously been little competition from customers in the public sector, but this has changed. Especially in the healthcare sector, alternative service providers are available to citizens on the private sector. In addition, political changes, such as health and social services reform, will increase competition. (Lindroos – Lohivesi, 2010: 147-149.) The public sector should gradually move away from a production-driven approach, where the cost of services guides the operation, towards a customer-driven approach. In social and healthcare services the significance of the customer is widely acknowledged, but customer orientation is created and defined very easily by the needs and the interests of the service providers. (Virtanen – Suoheimo – Lamminmäki – Ahonen – Suokas, 2011: 11.)

In Finland, the importance of customer orientation to organizations operating in the social and healthcare sector has been emphasized in the 21st century, regardless of whether it is a public, private or a third sector. (Virtanen et. al, 2011: 9-10.) However, there have already been changes in the public healthcare sector since the sector has shifted from optimizing service costs, to optimizing the quality and quantity of services. That is to say that, instead of the treatment costs, they have been focusing on the amount of different treatment procedures and the reduction of waiting times, and thus shifting to a more customer-oriented approach. (Virtanen et al., 2011: 9-10; Lindroos – Lohivesi, 2010: 147, 149-150.)

### 3.4.3 Segmentation

The purpose of segmentation is to help allocate organization's limited resources and customer needs by dividing the broad market that consists of current and potential customers into groups according to certain defined criteria. As Kamensky (2012: 99-103) stated, a business can be approached from many perspectives, but in many occasions there is some driving force behind a successful business. Organizations should think about what this driving force for them is, and thus become aware of their own business approaches. These approaches can, for example, be based on need, customer, market, product or service as well as organization's resources. This thought about the driving force should be utilized when the customers are divided into different segments. (Kamensky, 2012: 99-103; Lynch, 2015: 99.)

According to Lindroos and Lohivesi (2010: 149-150), the means to define the public sector strategy can be divided into two categories: the choice of customers and the choice of services. These choices are intended to determine who the customers using these services are, and what kind of services to offer them. Public sector services aim to meet customer expectations and take into account their individual needs. Customers can be grouped, or segmented, based on their needs, to provide more individualized services to these groups in order to meet their expectations. (Lindroos – Lohivesi, 2010: 149-150.) Segmentation should result in each segment being as uniform as possible and clearly differing from other segments. The main differentiating factors are demand, customer behaviour, competitive behaviour, knowledge and resources and industry success factors. (Kamensky, 2012: 96.) In business-to-business (B2B) marketing, segmentation has previously been commonly performed based on the firmographic factors such as industry, turnover or size and location of the business. However, firmographic or demographic criteria rarely work, and they are often not the best if the goal is to be a customer-oriented organization. (Kamensky, 2012: 92, 99-103; Lynch, 2015: 99; Heliskoski, 2016.)

According to Lynch (2015: 99) the *prescriptive development of market segmentation and positioning* can be divided into three steps shown in the figure 1. The first step is to *identify the segments*. This is the step where the specific groups of customers and customer profiles are created. (Kamensky, 2012: 141; Lynch, 2015: 99-100.) According to Tuulaniemi (2011: 155) the customer profile is a description of a particular group, which can be used to build different solutions and services (Tuulaniemi, 2011: 155.) The identified segments, or customer profiles, can be given personas to make it easier to remember them. The personas are not real people, but they represent the archetypes of these customer profiles. Besides the demographic characteristics, they describe the needs and values of the customer as well (Stickdorn – Hormess – Lawrence – Schneider. 2018:40-41.)


Figure 1. Segmentation process (Lynch, 2015: 99)

Segmentation criteria should always be chosen from the point of view of the organization's vision, mission and values, and successful segmentation is always based on the studied information. This first step requires a deep understanding of the customer, and assumptions should be avoided. Instead, a root cause of customers' behaviour and customer value chain should be carefully studied, in order to understand how to create more value for the customer while saving the customer's costs. According to Tuulaniemi (2011: 154-155) all people have a predominant behavioural profile that guides their activities. When these different behavioural profiles are understood, it is possible to create the conditions for a customer experience that will increase customer loyalty, and change customer behaviour in a meaningful direction from a business point of view. (Kamensky, 2012: 141; Lynch, 2015: 99-100; Heliskoski, 2016.)

Once the segments have been identified, they should be carefully *evaluated* and the importance and profitability of each segment should be recognized. According to Kamensky (2012: 143), a customer profitability analysis consists of several factors that have an impact on profitability. For example, profitability is affected by the fact that

different customers buy different amounts, or different customers pay different prices. The product ranges and service concepts may also vary, as well as the service level and response time requirements. In addition, it should be noted that there might be different distribution channels for different customers, and that the geographical distance might cause different transport and production costs. In addition to this, potential competition should also be taken into account when evaluating the attractiveness of each segment. (Kamensky, 2012: 143-144, 150-151.) Other segments may turn out to be more attractive than others. These identified and evaluated segments should be categorized into different groups according to their importance. In addition to volume and profitability, other criteria such as length and security of customer relationship, learning from the customer and customer interaction should be taken into account. Identifying these strategically important segments is crucial so that the organization can allocate its resources properly. (Kamensky, 2012: 140-143; Lynch, 2015: 99-100.)

After the segments have been identified and their importance for the organization's strategy evaluated carefully, the next step is to position the product or service on the market. It should be taken into consideration what kind of products or services should be offered to the strategically important segments in order to gain competitive edge.
According to Lynch (2015: 99-103) this step is called *position within the segment*. Blomster (2012) states that positioning means placing the image of the company, product or service into desired position in the minds of customers compared to competitors. Positioning is practically a choice of target market, meaning where and in which market to compete. Differentiation means distinguishing from competitors' products or services with some significant difference, for example by creating specialized products that provide competitive advantage in a particular market segment. (Blomster, 2012; Lynch 2015: 99-103.)

## 3.5 Summary of the theoretical background

The medical device industry has developed over the last hundred years and the pace has only accelerated. Medical devices are nowadays essential to the healthcare sector as they are widely used for the diagnosis, prevention, monitoring and treatment of diseases, as well as in the improvement of the quality of life of those with disabilities (World Health Organization WHO, 2018.) The medical device industry is strictly regulated both nationally and internationally, and legislative changes have recently taken place in the European area. In Finland the Medical Devices Act 629/2010 defines that a professional user is responsible for the traceability and functionality of their medical devices. This means that they must have some kind of a register where the device information can be found, and they also have a duty to arrange the maintenances for the devices according to manufacturer's instructions. However, professional users often do not have the technical training required for the device maintenance. (Medical Devices Act 629/2010; Medical Devices Act 936/2017; Valvira, 2017; European Commission, 2017.) In order to ensure the safety and effectiveness of the medical devices, for the sake of the patient and user safety, the devices must be managed in accordance with the requirements set for them. To do this, there is a specific industry, referred to as biomedical engineering, medical engineering, clinical engineering or healthcare engineering, depending on the source. In addition, many hospitals and healthcare units have their own department responsible for their medical device management, and this department is usually called either clinical engineering department, medical engineering department or biomedical engineering department. (Association for the Advancement of Medical Instrumentation, 2018; Enderle - Bronzino, 2012: 2, 10, 17, 21-22; Hinrichs, 2009; Mequsoft, 2018.)

According to Lindroos and Lohivesi (2010: 141-143) the political and legislative changes have a strong impact on the strategy of the public sector organization. In addition to legislative changes, there are also political changes going on in the healthcare sector when the Finnish government is building up a health and social services reform. Since after the reform the counties are responsible for harmonizing the services between their municipalities, HUS Medical Engineering should also be prepared to expand the market area to cover also all the public primary healthcare units in the Helsinki-Uusimaa Region. (Finnish government, 2018.) Due to these political and legislative changes affecting the whole health and social care services, every operator in this sector should develop its strategic thinking and decision-making

processes in order to be prepared for these external changes. It is important to make adjustments to the strategy so that change can be implemented in a controlled manner and ensure that all employees are involved and aware of change. According to Lindroos and Lohivesi (2010: 149-150), the means to define the public sector strategy can be divided into two categories: the choice of customers and the choice of services. These are used to determine, who the customers using these services are, and what kind of services should they be offered to. Customers can be segmented according to their needs and thus provide more individualized services to these groups in order to meet their expectations. Segmentation helps to allocate organization's limited resources to better meet customer needs. (Lindroos – Lohivesi, 2010: 149-150; Lynch, 2015: 99.) Market research is an essential tool for strategic business development and decision-making, as it provides information on market structure, trends and customer needs and requirements. It can be used to study if the customers are aware of having a problem that needs to be fixed, and would they buy a solution for that if there was one. And if they would, whom would they buy it from. Understanding the current state of the market and customers' needs is important so that right services can be directed to the right target group. (Lotti, 2001: 19, 26; Abu Al Rous, 2015; Xu, 2005: 23, 80, 105; Länsisalmi, 2013: 23.)

# 4 Research work setting

The HUS Medical Engineering is part of the Hospital District of Helsinki and Uusimaa, also known as HUS, which is a Joint Authority formed by 24 municipalities. These are Askola, Espoo, Hanko, Helsinki, Hyvinkää, Inkoo, Järvenpää, Karkkila, Kauniainen, Kerava, Kirkkonummi, Lapinjärvi, Lohja, Loviisa, Mäntsälä, Nurmijärvi, Pornainen, Porvoo, Raasepori, Sipoo, Siuntio, Tuusula, Vantaa and Vihti. HUS is responsible for offering specialized medical care to all patients in its member municipalities. As shown in the figure 2, the Joint Authority includes five hospital areas: Helsinki University Hospital Area, Hyvinkää Hospital Area, Lohja Hospital Area, Porvoo Hospital Area and Västra Nyland Hospital Area. (HUS, 2018.)


Figure 2. The HUS area (HUS, 2018.)

The Joint Authority has also unincorporated enterprises that provide support services for HUS. For example HUS Real Estate Ltd. provides construction services and Uudenmaan Sairaalapesula Oy provides textile and laundry services. HUS has also its own occupational healthcare unit that is responsible for providing occupational healthcare services for the employees. Besides of these there are also Assistive Equipment Centre, HUS Pharmacy, HUS Logistics, HUS IT Management, HUS Facilities Centre and the HUS Support Services which started in September 2017 when service providers previously known as HUS Desiko, HUS Servis and Ravioli merged. (HUS, 2018; HUS Support Services, 2018.) HUS Medical Engineering department was

previously part of HUS Imaging Center, but after beginning of the year 2018 it is currently part of HUS Logistics. (HUS Medical Imaging Center, 2016.)

The mission of the HUS Medical Engineering is to provide competitive medical engineering services that support customers' operations. HUS Medical Engineering department is a matrix organization that provides services as medical device lifecycle management, supplier and contract management, strategic development projects and photography and videotaping services. HUS Medical Engineering department has a several years of experience on the medical device management. At the moment HUS Medical Engineering department is, for example, responsible for the registration, maintenance and repair services for the medical devices of specialized medical care units around the area of Hospital District of Helsinki and Uusimaa and also for the primary healthcare units of the cities of Helsinki, Vantaa and Espoo. The lifecycle history of the devices is located in the ERP Mequsoft where over 130 000 devices are registered (Mequsoft, 2018.) HUS Medical Engineering employs almost 100 people and there are 12 service facilities around the HUS area. Six of them are located in Helsinki and others are in Jorvi, Länsi-Uusimaa, Lohja, Hyvinkää, Peijas and Porvoo Hospitals. There are two separate “central service facilities” in Meilahti and for years these two have been responsible for providing services also for the City of Helsinki. Since the beginning of the year 2017 Medical Engineering department of Peijas has been responsible for providing services for the City of Vantaa, that has over 4500 devices of health centres, nursing homes and maternity clinics registered in the Mequsoft. In addition to this, Medical Engineering department of Jorvi is responsible for the devices of the City of Espoo, which has approximately 5700 devices in the same type of units. (Mequsoft, 2018.) Previously the City of Espoo purchased only the registration services from HUS, but currently also the maintenance work is responsibility of the HUS Medical Engineering. Furthermore, in the future the device management might be transferred entirely from the City of Espoo to HUS Medical Engineering’s responsibility, if the new leasing service begins in 2019. However, not all devices are maintained by HUS Medical Engineering as there is a huge variety of different devices. Approximately 35% of the maintenance and repair services are done by external operators (Mequsoft, 2018.) When needed, supplier and contract management makes service contracts with third party, and one huge device group has already been tendered out, and there are also many service contracts for specific devices.

# 5 Materials and methods

The thesis project (Figure 3.) is rather similar to any project, at first the research problem has to be identified. After that, the planning phase starts, and the research plan is conducted. The research plan includes the purpose, aim and objectives of the study together with the theory, scheduling and plan for the data collection and data analysis. Also the data collection instrument is prepared at this point. (Ojasalo - Moilanen – Ritalahti, 2014: 23-47, 54; Lotti, 2001: 121-122; Lahtinen – Isoviita, 1998: 30.)

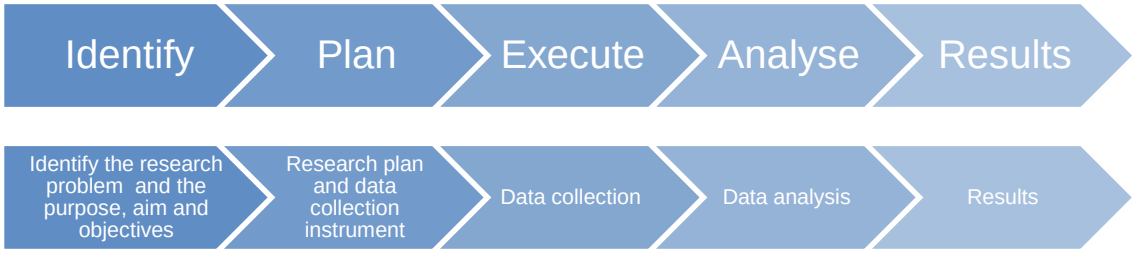


Figure 3. The Project Steps

After the project has been planned carefully and all the permits have been obtained and contracts signed, the data collection begins. After the data collection is completed, processing, analysing and interpreting received data is done to draw conclusions and apply data to practice. Finally the results are presented together with the suggestions on how to proceed. (Ojasalo - Moilanen – Ritalahti, 2014: 23-47, 54; Lahtinen – Isoviita, 1998: 30.)

## 5.1 Research design

In this quantitative research a descriptive cross sectional survey design with total sample of 18 sampling units was used to find answers to the research questions. Data gathered with E-lomake web survey was analysed with SPSS 24.0 program and Excel. Sampling, data collection and data analysis processes are described in the following chapters.

## 5.2 Research method

At first the research problem has to be identified. However, it is important to remember that one research cannot answer to all the questions. Therefore it is important that the focus is on the right matters and that the research problem is specific enough. (Lahtinen – Isoviita, 1998: 31.) As the Finland is going through political changes in a form of regional government, health and social services reform, it is important for any healthcare provider to think about the effects of the change to them. As the purpose of the reform is to harmonize the services between the municipalities, HUS Medical Engineering department should also be prepared to expand the market area to cover the public health sector of the entire county of Uusimaa. The big question behind this thesis is what the most efficient way to do this would be. To answer this question HUS Medical Engineering should at first get an understanding about the new market area.

To determine the need, at first it should be studied how many devices there are and how the registration and maintenance has been performed previously. In addition, it should be studied how satisfied the potential customers are with the current state and what things they value when it comes to the medical device registration and maintenance services. Therefore it was decided that to answer these questions a quantitative market research by using web survey as a data collection method was conducted. However, before the web survey was conducted it was necessary to know who to send it. In the research plan also the sample size and sampling was determined, as well as the research participants of the study.

## 5.3 Sampling

In this study a total sample of 18 sampling units of the area of Uusimaa outside the capital area was used. After doing sampling at the municipality level, public health care facilities inside these sampling units were identified as well as the research participants. These are introduced more thoroughly in the following chapters 5.3.1-5.3.3.

### 5.3.1 Grouping of sampling units at municipality level

To identify the sample size it was at first important to understand the geographic area. There are only 26 municipalities in Uusimaa (Figure 4) and four of them are part of the capital area. As HUS Medical Engineering already has the information from the Helsinki, Vantaa and Espoo, and Kauniainen is a small municipality located inside the Espoo area, they were not included in the research. Therefore, the amount of municipalities included in this study was 22.


Figure 4. Uusimaa area with the hospitals where HUS Medical Engineering has service facilities (modification from source HUS, 2018.)

Some municipalities are organizing the health services together. For example Karkkila and Vihti form a municipal federation Karviainen. Addition to Karviainen, also Mäntsälä and Pornainen as well as Loviisa and Lapinjärvi are organizing health services together. These alliances were treated as one sampling unit in this study. Päijät-Häme Welfare Incorporation, PHHYKY, produces the social and health services of the municipalities of Myrskylä and Pukkila, and they are not currently part of the HUS area. However, the future is unknown due to the regional government, health and social services reform and therefore they were included in the study, and treated as a one sampling unit in this study. Therefore the total amount of sampling units of this research was 18.

### 5.3.2 Selecting public sector healthcare units inside the municipalities

It was decided that the healthcare units participating in this research are health centres, nursing homes and maternity clinics of the municipalities of Uusimaa, outside the capital area. Each of the 18 sampling units had one to ten healthcare facilities. Because the size of population was smaller than 100, it was not worthwhile to perform sampling, and therefore it was more profitable and reliable to use the total sample. (Ojasalo - Moilanen – Ritalahti, 2014: 124; Lahtinen – Isoviita, 1998: 50.) As the aim of this research was to determine what kind of need there is for medical engineering services in the public health centres, nursing homes and maternity clinics of the area of Uusimaa outside the capital area, the desire was to receive device information from all of these municipalities. As the interest was equally emphasized by the entire population of the research, total sample was used (University of Jyväskylä, 2015). Total sample is the most reliable, because no sampling error will occur (Ojasalo - Moilanen – Ritalahti, 2014: 122; Lahtinen – Isoviita, 1998: 50.)

### 5.3.3 Identifying research participants

The first step of the data collection was to identify the research participants. Because we are dealing with the public sector, the information was assumed to be rather easy to find from the internet. Almost every municipality had their own websites that included the health and social service information. After all the municipalities were identified, the health centres, public nursing homes and maternity clinics were looked up from the webpages. In many cases also the contact information for the person responsible of the services was found there. The information was gathered in an Excel file.

After all the facilities were identified and some of the possible contact persons found, it was important for the validity of the research to confirm that they are correct persons to answer the questions and that they represent the entire population. Some of the maternity clinics and nursing homes were found to be included to the health centre. In these cases it was necessary to find out if the same person that was in charge of the health centre, was also in charge of these. Therefore, all the presumptive respondents were contacted beforehand via phone or email for to be sure that the research participants were correct persons to answer the questions. In some municipalities the information was easy to find and presumptive respondents confirmed to be the correct persons to answer the question. In addition, some of them even provided contact

details also for other contact persons of the municipality. However, in some municipalities this was much more difficult and several phone calls had to be made and several emails had to be sent. There were some differences between the municipalities in the number of respondents. In some, there were only one or two contact persons, who confirmed that they can provide the device information of the whole municipality, but in others the web survey had to be sent up to eight people. All presumptive respondents were sent a preliminary notice via email to clarify the purpose and aim of the research, and to test the functionality of the given email address. In total, 67 respondents confirmed beforehand to be the correct persons to answer the questions.

## 5.4 Data collection methods

HUS Medical Engineering has all the device information of the cities of Helsinki, Vantaa and Espoo in the ERP system Mequsoft. However HUS Medical Engineering has only a very little information about the devices of the public health centres, nursing homes and maternity clinics of the county of Uusimaa outside the capital are. Therefore it is also unknown whether this information is comparable to the previous data. At first, it had to be found out what kind of devices the health centres, nursing homes and maternity clinics of the cities of Espoo and Vantaa had, and a list of these device types was gathered in a table. The table (appendix 3.) was sent to the respondents attached to the preliminary notice e-mail and in addition it was inserted to the questionnaire. From the previous experience it is also known that the maintenance and registration practices may vary a lot even inside the municipalities. Therefore the goal was to find out how these services were handled currently in these municipalities and if the respondents are satisfied with the current state. In addition, the goal was to find out the device amounts of these municipalities.

### 5.4.1 Web survey

According to Ojasalo, Moilanen and Ritalahti (2014: 40-41, 122), a web survey is a good tool when the research topic is well known, but the desire is to make sure that the information is accurate. The survey should be based on existing knowledge whose concepts can be transformed into measurable variables. In this thesis the web based questionnaire E-lomake was used for the data collection instrument because it is easy to use and the wanted data could be gathered with it and analysed with the SPSS-

instrument and Excel. Addition to this, it is fast and inexpensive way to gather data widely even from a large group. (Ojasalo - Moilanen – Ritalahti, 2014: 121, 128.) It also enables the respondent to choose the answering time more freely and fill the questionnaire in their own pace. In addition, the researchers do not affect the answers with their appearance because there is no interaction with the respondent. (Lotti, 2001: 124, 142.)

The survey was sent to 76 persons via e-mail on the 12th of April and the response time was at first given two weeks. The e-mail included the cover letter (appendix 2.) and the link to the E-lomake questionnaire. The cover letter explained the purpose and the aim once again, and informed the research participants that the participation in the survey is voluntary and that the answers are addressed in anonymous and confidential terms. Addition to this it explained that the personal data of the research participants will not be exposed in the results. The e-mail was both in Finnish and Swedish, but the questions were only in Finnish. During the two weeks' response time, two reminders were sent: the first one on the 20th of April and the second on 26th of April. However some respondents asked more time and thus the deadline was postponed to the 5th of May. In all 52 persons answered and thus the respond rate was 68%.

### 5.4.2 Measures

The questions (appendix 1) of the web survey were chosen to be SMART, in other words, they were meant to be:

- Specific, short and simple
- Measurable
- Achievable and applicable
- Realistic and relevant
- Timely, time-saving and tied with one another (Järvensivu, 2018, Ojasalo - Moilanen – Ritalahti, 2014: 41.)

The research participants' background factors (e.g. municipality, position in the organization, healthcare unit) were studied with three structured questions. In addition, three structured questions with yes, no and partly answering options were used to study the medical devices related background factors (e.g. nominated persons in charge, availability of the user manuals, familiarity of HUS Medical Engineering department). The current state of the registration and maintenance were studied with

two structured questions with yes, no and partly answering options and 11 structured questions with the possibility to choose multiple answers. The five-point Likert scales was used to measure the satisfaction with the current state and the factors research participants valued when it comes to medical device maintenance services. This was done with six statements with the scale ranging from 1 (strongly disagree) to 5 (strongly agree).

As some of the maternity clinics and nursing homes were found to be included to the health center, some of the respondents answered on behalf of several healthcare units. To increase user-orientation and to improve usability, the questions regarding the number of devices in the specific healthcare unit (e.g. health center, nursing home, maternity clinic) were opened based on the selection. The device amounts were measured with 12 open-ended numerical questions and six structured questions (with “accurate” and “estimation” answering options).

## 5.5 Statistical analysis

The data were gathered with the E-lomake online. The survey was mainly analysed with Excel, as it is easy to use and figures and tables were easy to create with it. Addition to Excel also SPSS 24.0 program was used to calculate the standard deviations of the dependent variables of the Likert scale. Frequencies, percentages and central tendency figures were used to analyze the dependent variables related to the current condition and the desired condition. In addition, Pearson's chi-square was used to study the association between registration and satisfaction, and maintenance and satisfaction. In both cases test the result (p= 0,000) was found to be statistically significant. The device amounts given by the respondents were added together at the municipal and healthcare unit level, and presented in a table. In case there was found to be some overlap in the device amounts received, the incorrect values were ignored, or in situations where incorrect values could not be established with certainty, the average of the obtained values was calculated and used.

# 6 Results

The survey was sent to 76 persons via e-mail on the 12th of April and in addition to this, reminders were sent on the 20th and on 26th of April. Before the first reminder, during the 12th and 19th of April, 27 responses were received (figure 5).

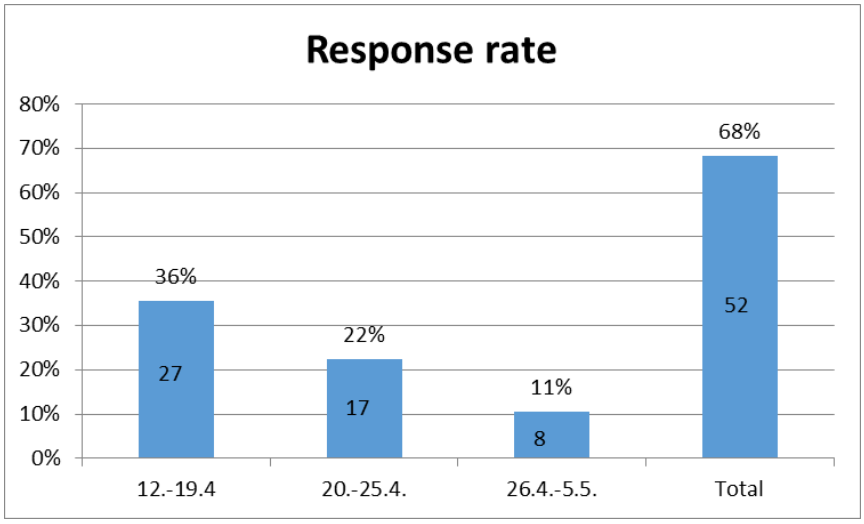


Figure 5. Response rate during the response time

Between the first and second reminder 17 responses were received, but during the last week the amount was only 8. In all 52 persons out of 76 answered and thus the respond rate was 68%.

In the figure 6, the response rates are presented in a municipality level. The lowest response rates came from the municipalities of Askola, Lohja and Tuusula, and municipality alliance of Mäntsälä and Pornainen.

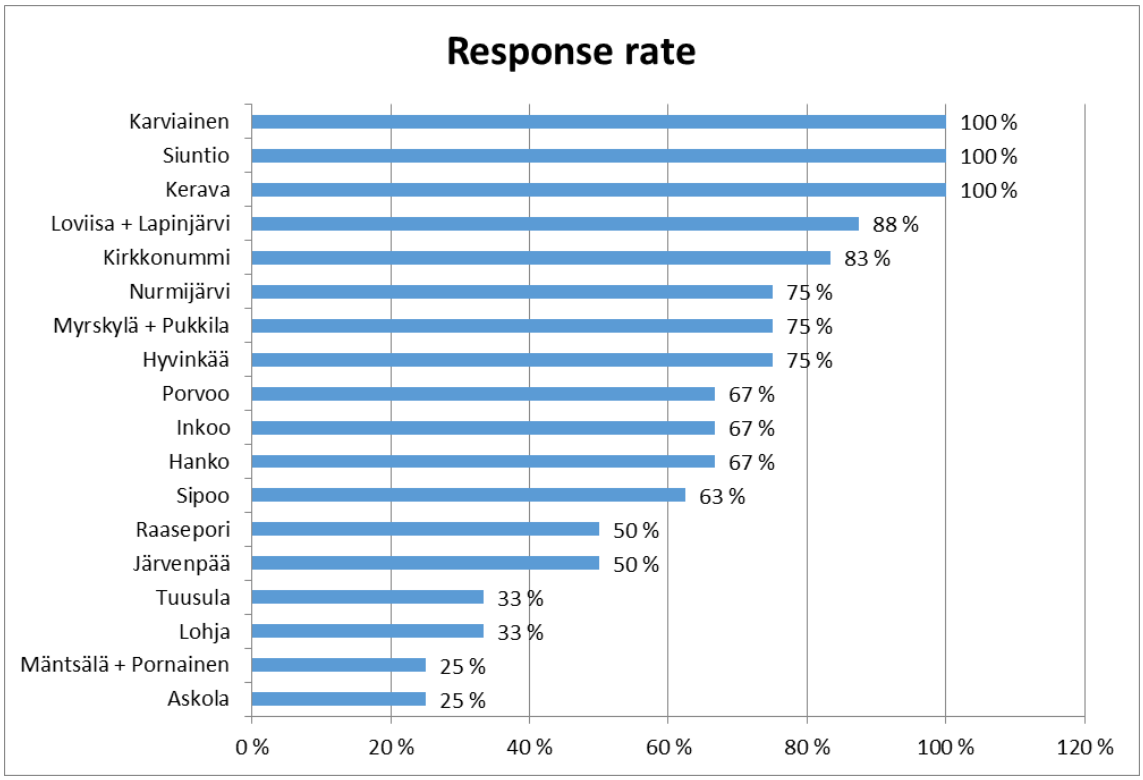


Figure 6. Response rates of the municipalities

From Siuntio, Kerava and Karviainen all of the respondents answered, and thus the response rate was 100%. However, for some reason there was some overlap between the answers from Karviainen. The responses were received from 83% of the maternity clinics, 71% of the nursing homes and from 53% of the health centres.

Most of the respondents of the web survey were Head Nurses (in Finnish osastonhoitaja) or Managers of the Unit (in Finnish yksikön päällikkö tai esimies). In addition, only 6% of the respondents were something other than the given alternatives. In the table 2 the distributions of the different positions are demonstrated.

Table 2. The distribution of the positions of the respondents in the organization

| Position in the Organization | In Finnish | Pcs. | Percentage |
|---|---|---|---|
| Head Nurse | Osastonhoitaja | 23 | 44 % |
| Manager of the Unit | Yksikön päällikkö tai esimies | 10 | 19 % |
| Nurse in charge | Vastaava hoitaja | 5 | 9 % |
| Nurse | Terveydenhoitaja/sairaanhoitaja | 4 | 8 % |
| Person in Charge of Devices | Laitevastaava | 4 | 8 % |
| Other | Muu | 3 | 6 % |
| Director of the Unit | Yksikön johtaja | 2 | 4 % |
| Director of nursing | Ylihoitaja | 1 | 2 % |
| Total | | 52 | 100% |

## 6.1 Current condition

As shown in the table 3, HUS Medical Engineering was not familiar to almost half (48%) of the healthcare units surveyed and in addition to this, 35% of them knew it only partly. The table also shows that the user manuals were in most cases easily available and only 8% of the cases they were not. Also, most of the healthcare units surveyed had a nominated person or persons in charge of the devices either fully (50%) or at least partly (25%).

Table 3. Medical device related background factors

| | Yes | Partly | No |
|---|---|---|---|
| Is HUS Medical Engineering familiar to you | 17 % | 35 % | 48 % |
| Do you have a nominated person(s) in charge of the medical devices | 50 % | 25 % | 25 % |
| Are the medical device user manuals easily available | 52 % | 40 % | 8 % |
| Have your medical devices been registered | 42 % | 29 % | 29 % |
| Have your medical devices been periodically serviced | 58 % | 36 % | 6 % |

### 6.1.1 Registration

The pie chart (figure 7) is showing the percentage distribution of the current state of the registration. The majority (42%) of the healthcare units surveyed had their devices registered. In addition, 29% of the healthcare units surveyed had their devices partly registered and equally many did not have them registered.

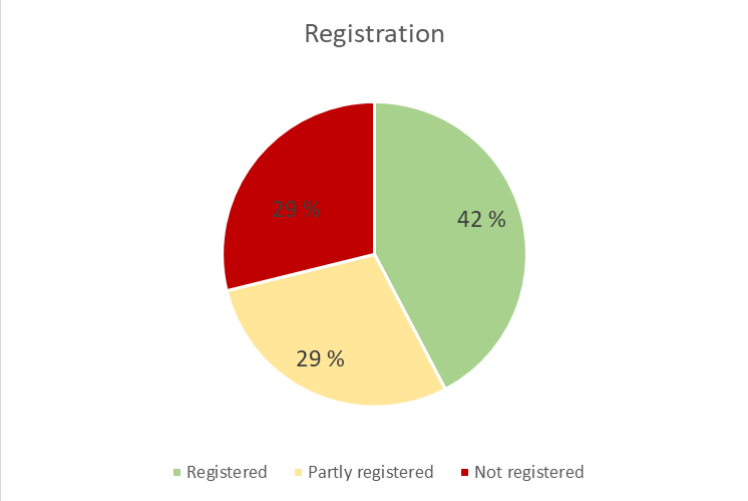


Figure 7. Distribution of the device registration

The figure 8 shows the difference between the healthcare units (e.g. health centres, nursing homes, maternity clinics) in how well the devices were registered.

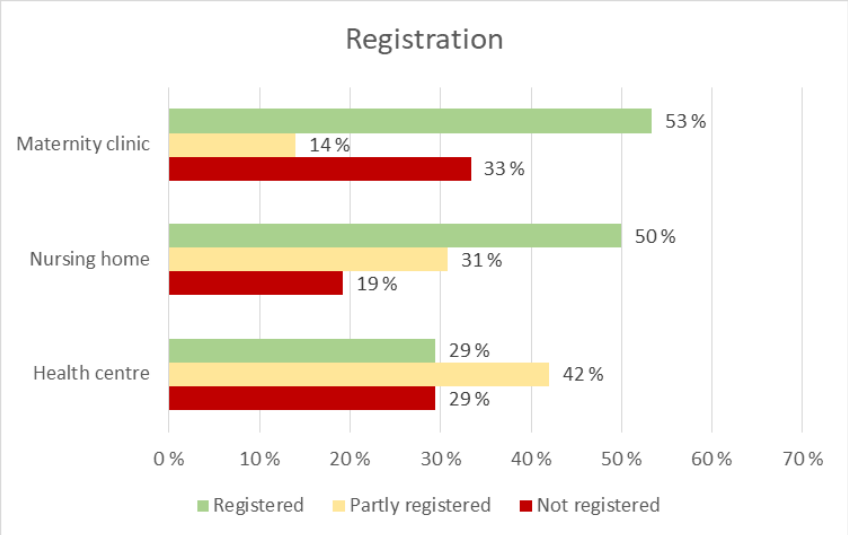


Figure 8. Distribution of the device registration between the healthcare units

Most of the maternity clinics (53%) and nursing homes (50%) had their devices registered. However, similar results were not received from the health centres, as only 29% had their devices registered and the majority (42%) had their devices only partly registered. In general, the nursing homes seemed to have better situation than the others, as in 19% of cases the devices were not registered.

It was also studied that in what way the registration has been performed, and there was a possibility to choose multiple alternatives. The table 4 shows the distribution of the different ways. 52 respondents answered and overall 84 responses were received.

Table 4. The way the registration have been performed

| **How are the medical devices been registered** | **Pcs** | **Percentage (/52 responses)** |
|---|---|---|
| We have our own device database | 11 | 21 % |
| The device information of our medical devices is listed in a table (e.g. Excel) | 29 | 56 % |
| The devices have been registered by an external operator | 4 | 8 % |
| The device registration has been performed by the device suppliers | 5 | 10 % |
| Device related papers are archived in folders | 22 | 42 % |
| The devices have not been registered | 13 | 25% |

Most (56%) had a table, for example an Excel file, where the device information was stored. In addition, 42% had the papers related to the purchased medical devices archived into folders. 10% were in the belief that the device suppliers have performed the registration, and only 8% had the devices were registered by an external operator. In addition, 25% replied that the devices have not been registered.

To determine the need for medical engineering services, it was important to find out how satisfied the respondents were with the current state. Therefore, respondents were asked to evaluate their satisfaction with the current state of registration on a five-point Likert scale where 1 was to strongly disagree and 5 strongly agree. Thus, it can be deduced that the larger the number, the more satisfied the respondent was.

The table 5 shows that most of the healthcare units surveyed whose devices were not registered, were not that satisfied with the current state of the registration (meaning the way the registration has been performed).

Table 5. The association of the satisfaction rate and the device registration

| **I am satisfied with the current state of the registration** | | **Has the devices been registered associating with how satisfied the respondents are with the current state of the registration** | | | |
|---|---|---|---|---|---|
| | | **Has the devices been registered** | | | |
| | | **No** | **Partly** | **Yes** | **Total** |
| **Not satisfied** | **1** | 9 | 1 | 1 | 11 |
| | | 60,0% | 6,7% | 4,5% | 21,2% |
| | **2** | 2 | 4 | 3 | 9 |
| | | 13,3% | 26,7% | 13,6% | 17,3% |
| | **3** | 4 | 10 | 10 | 24 |
| | | 26,7% | 66,7% | 45,5% | 46,2% |
| | **4** | 0 | 0 | 5 | 5 |
| | | 0,0% | 0,0% | 22,7% | 9,6% |
| **Satisfied** | **5** | 0 | 0 | 3 | 3 |
| | | 0,0% | 0,0% | 13,6% | 5,8% |
| | | 15 | 15 | 22 | 52 |
| | | 100,0% | 100,0% | 100,0% | 100,0% |
| Average | | 1,67 | 2,60 | 3,27 | 2,62 |
| Mode | | 1 | 3 | 3 | 3 |
| Median | | 1 | 3 | 3 | 3 |

However, the corresponding similarity could not be established for those whose devices were registered. Overall, however, these respondents were much more satisfied, as can be seen from the table 5 above. Based on the Pearson's chi-square test the result (p= 0,000) was found to be statistically significant.

There was not that much difference between health centres, nursing homes and maternity clinics, as can be seen from the table 6 below. However, the nursing homes seemed to be a somewhat more satisfied than the other types of units surveyed. There was a little less variation in the attitudes of the maternity clinics, than with the other types of units.

Table 6. The differences between the healthcare units regarding the association of the satisfaction rate and the device registration

| | | Health centre | | | Nursing home | | | Maternity clinic | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Have the devices been registered | | | Have the devices been registered | | | Have the devices been registered | | |
| | | No | Partly | Yes | No | Partly | Yes | No | Partly | Yes |
| **Not satisfied** | **1** | 60 % | 14 % | 0 % | 60 % | 0 % | 8 % | 60 % | 0 % | 0 % |
| | **2** | 20 % | 14 % | 20 % | 0 % | 37 % | 8 % | 20 % | 0 % | 25 % |
| | **3** | 20 % | 72 % | 40 % | 40 % | 63 % | 38 % | 20 % | 100 % | 50 % |
| | **4** | 0 % | 0 % | 20 % | 0 % | 0 % | 31 % | 0 % | 0 % | 25 % |
| **Satisfied** | **5** | 0 % | 0 % | 20 % | 0 % | 0 % | 15 % | 0 % | 0 % | 0 % |
| | | 100 % | 100 % | 100 % | 100 % | 100 % | 100 % | 100 % | 100 % | 100 % |
| **Average** | | 1,6 | 2,57 | 3,4 | 1,8 | 2,63 | 3,38 | 1,6 | 3 | 3 |
| **Mode** | | 1 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 3 |
| **Median** | | 1 | 3 | 3 | 1 | 3 | 3 | 1 | 3 | 3 |
| **Total average** | | | | 2,53 | | | 2,85 | | | 2,53 |
| **SD** | | | | 1,12 | | | 1,12 | | | 0,99 |

The figure 9 demonstrates the relationship between the registration and satisfaction. The responses of healthcare units surveyed whose devices were not in the register are shown in red, and the responses of respondents whose devices are in the register, are shown in green. The yellow illustrates those whose devices are partially registered.


Figure 9. The relation of the satisfaction and device registration

From the figure 9 it can be seen that the healthcare units surveyed whose devices were not in the register were less satisfied than those whose devices were registered or partially registered. The results were rather similar between the healthcare units.

### 6.1.2 Maintenance

As shown in the pie chart (figure 10) below, in the majority (58%) of the healthcare units surveyed preventative maintenance service had been performed for the medical devices. However in 36% of the healthcare units surveyed medical devices were partly maintenance serviced. Only in 6% of the units preventative maintenance service had not been performed for the medical devices.

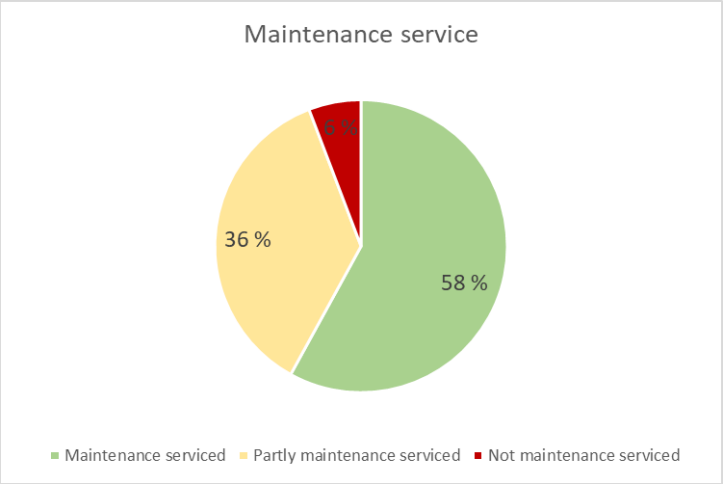


Figure 10. Distribution of the device maintenance services

The figure 11 below shows the difference between the health centres, nursing homes and maternity clinics. According to the results, none of the maternity clinics surveyed had left the maintenance services unperformed.

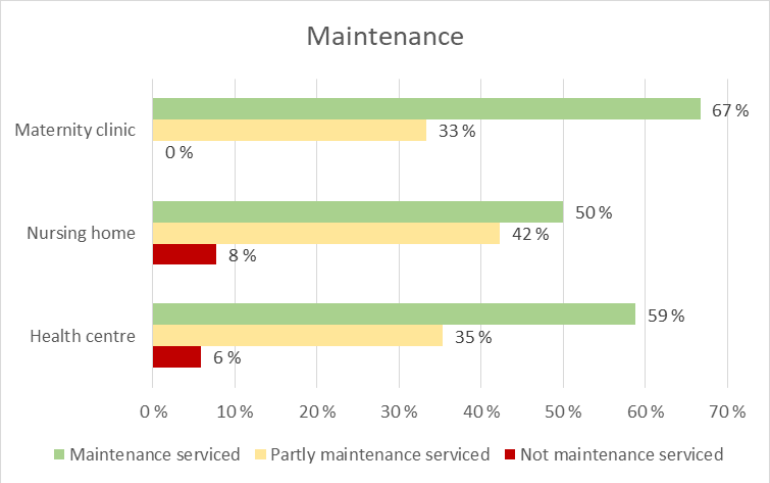


Figure 11. Distribution of the device maintenance services between the healthcare units

In addition, only a few of the nursing homes (8%) and health centres (6%) had left the maintenance services unperformed. The responses between the healthcare units were also much more homogenous when it comes to the maintenance than the registration.

The way of how the maintenance service has been performed was also studied and there was a possibility to choose multiple alternatives. The table 7 shows the distribution of the different ways. 52 respondents answered and overall 83 responses were received.

Table 7. How the maintenance service has been performed

| **How is the maintenance of your medical devices organized** | **Pcs** | **Percentage (/52 resp.)** |
|---|---|---|
| By our own maintenance organization | 8 | 15 % |
| The device maintenance services has been performed centralized by an external operator | 36 | 69 % |
| The device maintenance has been performed by the device suppliers | 23 | 44 % |
| No preventative maintenance services. Devices are repaired only when they are broken | 14 | 27 % |
| No preventative maintenance or repair services. Devices are replaced with new ones | 2 | 4 % |

Most (69%) had an external operator performing the maintenance service centralized on the devices. Addition to this, in 44% of the healthcare units surveyed the device maintenance service had been performed by the device suppliers, and 15% had their own maintenance organization. However, all the devices of the respondents were not periodically maintenance serviced, as in 27% of the healthcare units surveyed the devices were only serviced when they are broken and in 4% the devices were only replaced with new ones.

In addition, the desire was to find out how satisfied the respondents were with the current state of maintenance services. The five-point Likert scale, where 1 was to strongly disagree and 5 strongly agree, was used to study this. In the table 8 the association between satisfaction and maintenance rate is demonstrated. Based on the Pearson's chi-squared test the result (p= 0,000) was found to be statistically significant.

Table 8. The association of the satisfaction rate and the device maintenance

| **I am satisfied with the current state of the maintenance** | **Has the devices been periodically serviced associating with how satisfied the respondents are with the current state of the maintenance** | | | |
|---|---|---|---|---|
| | **Have the devices been periodically maintenance serviced** | | | |
| | **No** | **Partly** | **Yes** | **Total** |
| **Not satisfied 1** | 1 | 0 | 0 | 1 |
| | 33,3% | 0,0% | 0,0% | 1,9% |
| **2** | 1 | 7 | 1 | 9 |
| | 33,3% | 36,8% | 3,3% | 17,3% |
| **3** | 1 | 11 | 10 | 22 |
| | 33,3% | 57,9% | 33,3% | 42,3% |
| **4** | 0 | 1 | 15 | 16 |
| | 0,0% | 5,3% | 50,0% | 30,8% |
| **Satisfied 5** | 0 | 0 | 4 | 4 |
| | 0,0% | 0,0% | 13,3% | 7,7% |
| | 3 | 19 | 30 | 52 |
| | 100,0% | 100,0% | 100,0% | 100,0% |
| Average | 2,00 | 2,68 | 3,73 | 3,25 |
| Mode | N/A | 3 | 4 | 3 |
| Median | 2 | 3 | 4 | 3 |

In general, the healthcare units surveyed, whose devices had been periodically maintenance serviced, were much more satisfied than the units whose devices were not, or were only partially. The averages are shown in the table 8 above.

There was not that much difference between health centers, nursing homes and maternity clinics, as can be seen from the table 9 below. However in general, the health centers were a little less satisfied than the other types of units surveyed. Those nursing homes, whose devices had been maintenance serviced, were a somewhat more satisfied than the health centers and maternity clinics in a similar situation.

Table 9. The differences between the healthcare units regarding the association of the satisfaction rate and the device maintenance

| | | Health centre | | | Nursing home | | | Maternity clinic | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Have the medical devices been maintenance serviced | | | Have the medical devices been maintenance serviced | | | Have the medical devices been maintenance serviced | | |
| | | No | Partly | Yes | No | Partly | Yes | No | Partly | Yes |
| **Not satisfied** | **1** | 100 % | 0 % | 0 % | 0 % | 0 % | 0 % | N/A | 0 % | 0 % |
| | **2** | 0 % | 17 % | 10 % | 50 % | 45 % | 0 % | N/A | 20 % | 0 % |
| | **3** | 0 % | 83 % | 40 % | 50 % | 45 % | 31 % | N/A | 80 % | 50 % |
| | **4** | 0 % | 0 % | 40 % | 0 % | 10 % | 46 % | N/A | 0 % | 50 % |
| **Satisfied** | **5** | 0 % | 0 % | 10 % | 0 % | 0 % | 23 % | N/A | 0 % | 0 % |
| | | 100 % | 100 % | 100 % | 100 % | 100 % | 100 % | N/A | 100 % | 100 % |
| **Average** | | 1 | 2,83 | 3,5 | 2,5 | 2,64 | 3,92 | N/A | 2,8 | 3,5 |
| **Mode** | | N/A | 3 | 3 | N/A | 3 | 4 | N/A | 3 | 3 |
| **Median** | | 1 | 3 | 3,5 | 2,5 | 3 | 4 | N/A | 3 | 3,5 |
| **Total average** | | | | 3,12 | | | 3,27 | | | 3,27 |
| **SD** | | | | 0,93 | | | 0,96 | | | 0,59 |

The figure 12 demonstrates the relationship between the maintenance and satisfaction. The responses of healthcare units surveyed whose devices were not periodically maintenance serviced are shown in red, and the responses of those whose devices were, are shown in green. The yellow illustrates the ones whose devices were partly maintenance serviced.

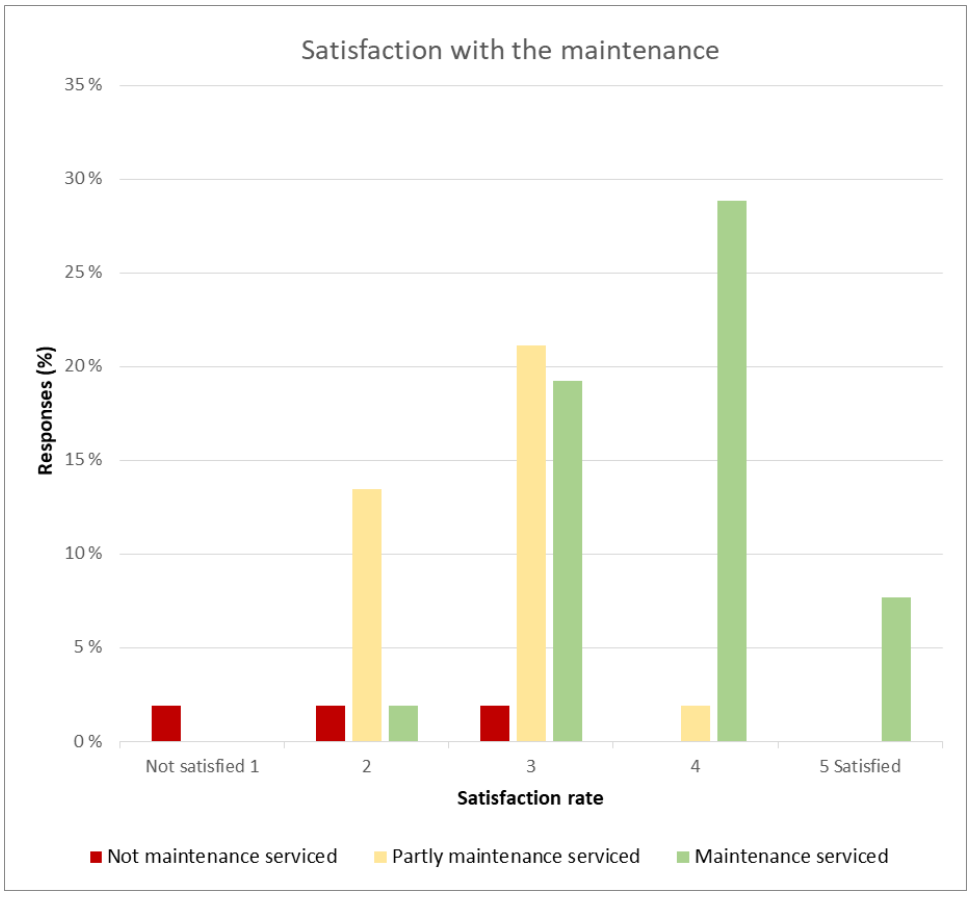


Figure 12. The relation of the satisfaction and device maintenance

In general, the healthcare units surveyed whose devices had been preventative maintenance serviced were much more satisfied than the ones whose devices were not, or were only partly preventative maintenance serviced.

### 6.1.3 Summary

The state of the maintenance seemed to be better than the state of the registration, as only in 6% of the cases the devices had not been maintenance serviced while in 29% of the cases the devices were not registered. Furthermore, there was less variation between the healthcare units surveyed in the fulfilment of the maintenance services than in device registrations. Regarding the registration, the differences between the different healthcare units were easier to detect, as there were more variation in how large portion of the devices were registered.

The current state of registration and maintenance also had an association to satisfaction, as the healthcare units surveyed were more satisfied with the state of the maintenance than with the state of the registration. From the table 10 below, it can be seen that there were hardly any differences between the units, when it came to satisfaction with the registration and maintenance services. The maternity clinics, however, seemed to be more unanimous (SD=0,59) in their responses when it comes to the satisfaction with the maintenance services.

Table 10. Satisfaction averages between the units

| | **Registration** | | **Maintenance** | |
|---|---|---|---|---|
| | **Average** | **SD** | **Average** | **SD** |
| **All** | 2,62 | 1,11 | 3,25 | 0,90 |
| **Health centre** | 2,53 | 1,12 | 3,12 | 0,93 |
| **Nursing home** | 2,85 | 1,12 | 3,27 | 0,96 |
| **Maternity clinic** | 2,53 | 0,99 | 3,27 | 0,59 |

On average, the healthcare units surveyed were more satisfied with the current state if the devices were maintenance serviced and registered, than in those cases where they were only partially or not at all maintenance serviced and registered. In addition, as can be seen from the figure 13 below, the units were consistently more satisfied with the current state of maintenance than the registration, even when the devices were only partially or not at all maintenance serviced and registered.

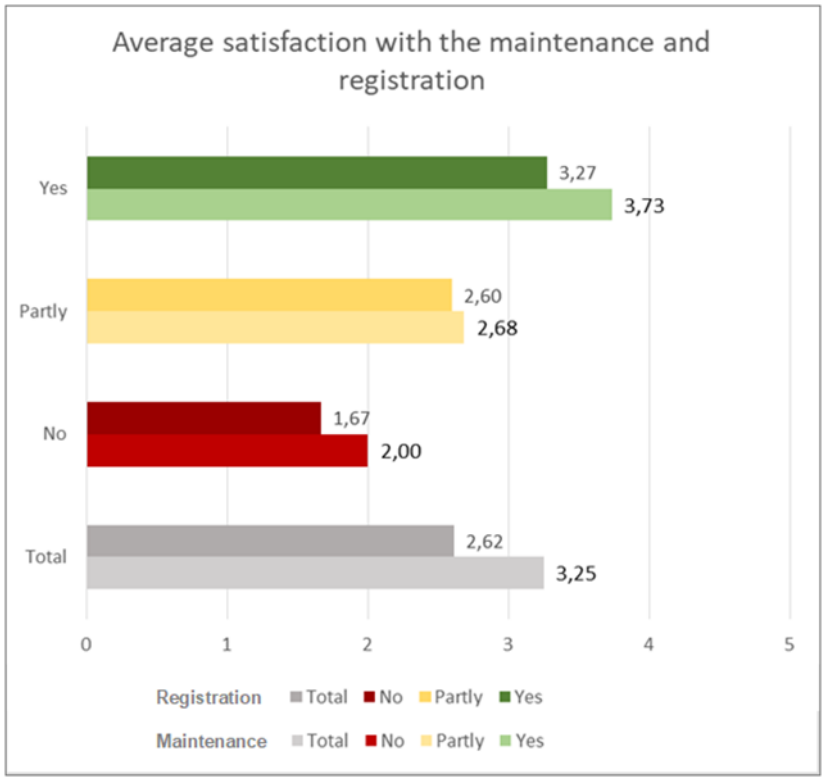


Figure 13. Satisfaction averages of the registration and maintenance

## 6.2 Desired condition

In order to understand what factors the respondents valued when it comes to medical devices and medical engineering services, the respondents were presented with statements and asked how strongly they agree with them on a scale of 1 to 5, where 1 was to disagree and 5 agree.

As shown in the table 11, in general the quality of the service was found to be more important than the costs. The healthcare units surveyed seemed also to value a short service time more than the costs or that they receive exactly same device from the maintenance service.

Table 11. Statements regarding the factors the research participants valued

| | | **Factors the respondents valued** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **The quality of the service is more important than the service costs** | | **I am prepared to pay a little more if that way I get the device in a use quicker** | | **I find it important that exactly the same device is returned from the maintenance service** | | **I do not care if it is the same device if that way I can get similar device in a use quicker** | |
| **disagree** | **1** | 0 | 0 % | 1 | 2 % | 5 | 10 % | 7 | 13 % |
| | **2** | 4 | 8 % | 7 | 13 % | 10 | 19 % | 6 | 12 % |
| | **3** | 12 | 23 % | 19 | 37 % | 16 | 31 % | 13 | 25 % |
| | **4** | 23 | 44 % | 20 | 38 % | 10 | 19 % | 18 | 35 % |
| **agree** | **5** | 13 | 25 % | 5 | 10 % | 11 | 21 % | 8 | 15 % |
| **Average** | | 3,87 | | 3,40 | | 3,23 | | 3,27 | |
| **SD** | | 0,88625 | | 0,91308 | | 1,26205 | | 1,25425 | |
| **Mode** | | 4 | | 4 | | 3 | | 4 | |
| **Median** | | 4 | | 3 | | 3 | | 3,5 | |

In general, there was more variation (SD=1,26; SD=1,25) in the attitudes of the healthcare units surveyed, when it came to the factor whether they want exactly the same device to return from service.

One of the goals of this research was to find out how the healthcare units surveyed would like the maintenance services to be organized. In this question it was possible to choose multiple alternatives. In total, 52 respondents replied. However, only 7 respondents chose more than one option and 59 answers were received.

The table 12 demonstrates the distribution of how the healthcare units surveyed would like the maintenance services to be organized. Percentages illustrate how many of the healthcare units surveyed out of 52 wanted their maintenance services to be organized in that way. Most (63%) of them wanted the services to be organized by an external operator and 37% wanted an own maintenance organization to do this. In addition to this, only 12% wanted the device suppliers to organize the maintenance services.

Table 12. How the respondents would like the maintenance service been performed

| **How would you like the maintenance of your medical devices to be organized** | **Pcs** | **Percentage (/52 resp.)** |
|---|---|---|
| By our own maintenance organization | 19 | 37 % |
| Centralized by an external operator | 33 | 63 % |
| By the device suppliers | 6 | 12 % |
| No preventive maintenance. Devices would be only repaired when they are broken. | 1 | 2 % |
| No preventive maintenance or repair services. Devices would be replaced with new ones | 0 | 0 % |

None of the units surveyed would prefer to only replace the devices by buying new ones, and only one respondent would prefer the devices to be only repaired when they are broken.

From every municipality except Askola, some respondent would have wished their maintenance serves to be organized centralized by an external operator. In addition to this, some respondent from 12 out of 18 municipalities would like the maintenance to be organized by an own maintenance organization. The distribution of how the municipalities would like the maintenance services to be organized is shown in the figure 14.

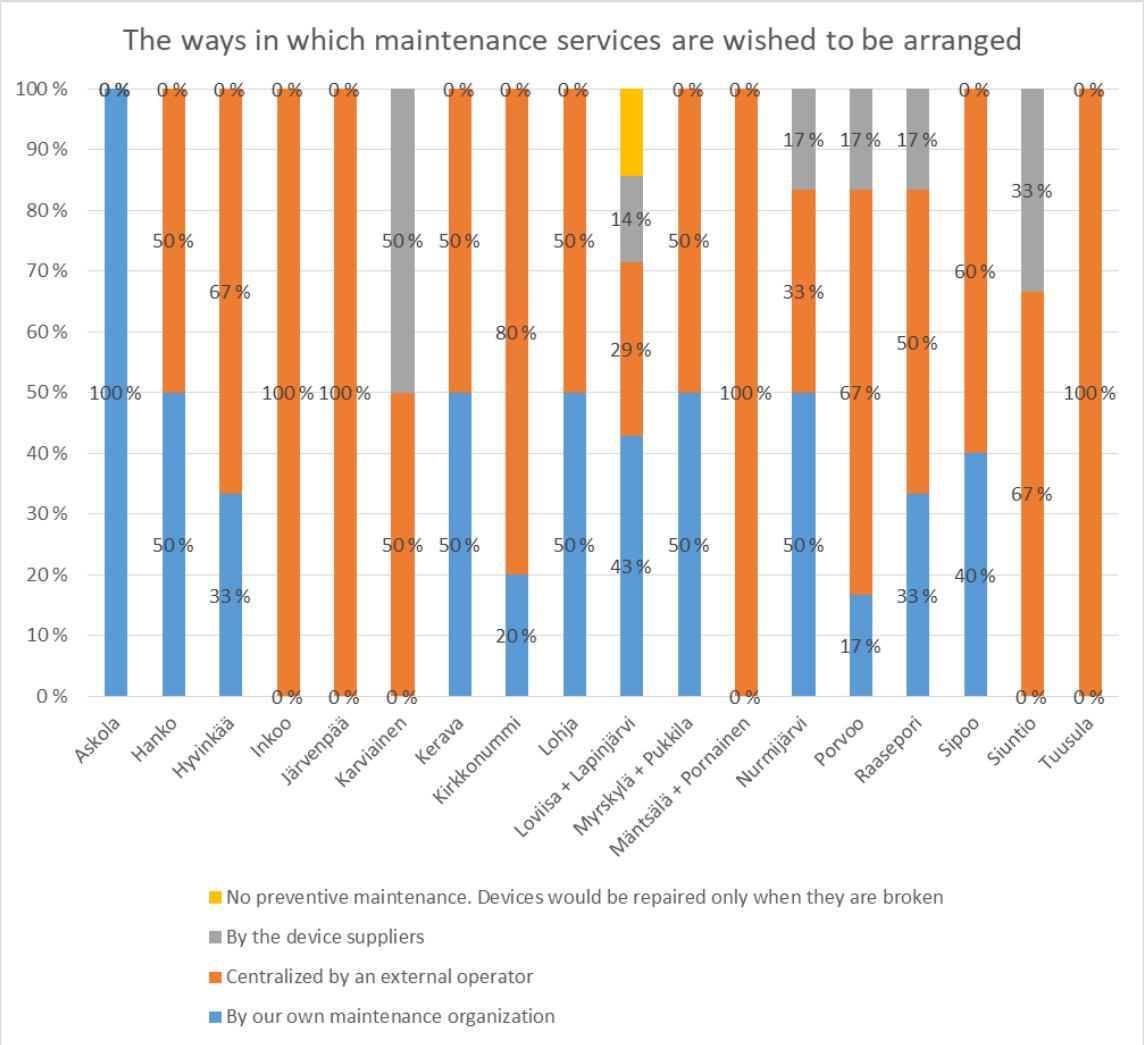


Figure 14. The distribution of different ways between the municipalities, in how the municipalities would like the maintenance services to be organized

Similarities and differences between the desires of health centres, nursing homes and maternity clinics can be seen from the table 13. The answers were received from 17 health centres, 26 nursing homes and 15 maternity clinics. The percentages illustrate how many respondents out of the total amount of responses of the unit would like their maintenance services to be organized that way.

Table 13. The distribution of the ways the healthcare units surveyed would like the maintenance services to be organized

| **How would you like the maintenance of your medical devices to be organized?** | **Health centre** | **Nursing home** | **Maternity clinic** |
|---|---|---|---|
| By our own maintenance organization | 47 % | 19 % | 60 % |
| Centralized by an external operator | 59 % | 65 % | 53 % |
| By the device suppliers | 12 % | 19 % | 7 % |
| No preventive maintenance. Devices would be only repaired when they are broken. | 0 % | 4 % | 0 % |
| No preventive maintenance or repair services. Devices would be replaced with new ones | 0 % | 0 % | 0 % |

In general, the nursing homes would prefer (65%) an external operator to perform the maintenance services centralized, rather than to have an own maintenance organization (19%) or to have the device suppliers (19%) to perform the services. The majority (60%) of the maternity clinics preferred the maintenance services to be organized by their own maintenance organization. Almost as many (53%) would like to have the services organized by an external operator, and only 7% required the services of the supplier. The desires of the health centres were also in line with the general viewpoint, as majority (59%) favoured the centralized maintenance services performed by external operators, and the second most favoured way was to have their own maintenance organization for this purpose. A small portion of the health centres favoured suppliers as maintenance service providers.

## 6.3 Device amount

Data about device amounts were received from respondents of 17 health centres, 26 nursing homes and 15 maternity clinics. The respondents were asked if the device amounts they gave were accurate or estimations. The table 14 shows that most of the respondents gave only estimated amounts and only a few of the amounts were stated to be factual. In the table 14 the distribution of the accurate and estimated device amounts per health centres, nursing homes and maternity clinics is shown.

Table 14. The distribution of the accurate and estimated device amounts between the healthcare units

| | Health centre | | Nursing home | | Maternity clinic | |
|---|---|---|---|---|---|---|
| | **Pcs.** | **%** | **Pcs.** | **%** | **Pcs.** | **%** |
| **Estimates** | 11 | 65 % | 21 | 81 % | 11 | 73 % |
| **Accurate** | 6 | 35 % | 5 | 19 % | 4 | 27 % |
| **Total** | 17 | 100 % | 26 | 100 % | 15 | 100 % |

From the table 14 it can be seen that nursing homes in general gave less accurate information on their number of devices than the maternity clinics or health centres. However, when the device amount accuracy (meaning how many of the given device amounts were accurate and not estimations) is compared with the registration rate (meaning how many of the devices were registered), it can be seen in the table 15 that the results were to some extent inversely proportional.

Table 15. Association of the registration rate and the number of accurate device amounts

| | Device registration | | | Device amounts | |
|---|---|---|---|---|---|
| | **Not registered** | **Partly registered** | **Registered** | **Estimates** | **Accurate** |
| **Health centre** | 29 % | 42 % | 29 % | 65% | 35 % |
| **Nursing home** | 19 % | 31 % | 50 % | 81% | 19 % |
| **Maternity clinic** | 33 % | 14 % | 53 % | 73% | 27 % |

In general, the health centers seemed to be more aware of their device amounts, as 35% of the device amounts received from the health centers were stated to be accurate instead of an estimation, regardless the fact that only 29% of their devices were registered and 42% were partly registered. Only 19% of the given device amounts

of the nursing homes were discovered to be accurate, even if in 50% of the nursing homes surveyed the devices were in fact registered. It was assumed that if the response rate was 100%, the device amount would be equivalent to the total number of devices of the health centers, nursing homes and maternity clinics. However, 100% response rate was received from nursing homes of only 5 out of 18 municipalities. The number was a somewhat better when it comes to health centers, as 100% response rate was received from 8 out of 18 municipalities, while in the case of maternity clinics, the figure was 15. The table 16 shows the indicated device amounts of the healthcare units where the 100% response rate was received.

Table 16. Given device amounts with 100% response rate

| Municipality | Health centre | Nursing home | Maternity clinic | Total |
|---|---|---|---|---|
| Askola | N/A | N/A | N/A | N/A |
| Hanko | **285**[1] | N/A | *45* | 330 |
| Hyvinkää | N/A | *500* | *100* | 600 |
| Inkoo | **66** | N/A | **6** | 72 |
| Järvenpää | N/A | **311** | *164* | 475 |
| Karviainen | *200*[2] | **68** | *100* | 368 |
| Kerava | *100* | *200* | **110** | 410 |
| Kirkkonummi | N/A | N/A | *250* | 250 |
| Lohja | N/A | N/A | **103** | 103 |
| Loviisa + Lapinjärvi | **75** | N/A | *60* | 135 |
| Myrskylä + Pukkila | *100* | *120* | *20* | 240 |
| Mäntsälä + Pornainen | N/A | N/A | *30* | 30 |
| Nurmijärvi | N/A | N/A | *150* | 150 |
| Porvoo | N/A | N/A | **150** | 150 |
| Raasepori | N/A | N/A | N/A | N/A |
| Sipoo | N/A | N/A | *72* | 72 |
| Siuntio | *50* | *50* | *20* | 120 |
| Tuusula | *480* | N/A | N/A | 480 |

[1] **bolded** figures mean that the values of device amounts given by institutions are stated to be accurate

[2] figures marked by *italic* mean estimates of device amounts given by institutions

The table 17 shows the total number of devices in the different healthcare units of the municipalities, received with the survey. In addition to this, the number of respondents and the number of how many respondents the questionnaire was sent to, can be seen from the table 17.

Table 17. Device amounts at the municipal level and unit level

| Municipality | Health centre | | | Nursing home | | | Maternity clinic | | | Sum of amounts |
|---|---|---|---|---|---|---|---|---|---|---|
| | Dev. amount | Resp. rec. | Resp. tot. | Dev. amount | Resp. rec. | Resp. tot. | Dev. amount | Resp. rec. | Resp. tot. | |
| Askola | N/A | 0 | 1 | **150** | 1 | 2 | N/A | 0 | 1 | 150 |
| Hanko | **285**[1] | 1 | 1 | N/A | 0 | 1 | **45** | 1 | 1 | 330 |
| Hyvinkää | 265 | 1 | 2 | **500** | 1 | 1 | **100** | 1 | 1 | 865 |
| Inkoo | 66 | 1 | 1 | N/A | 0 | 1 | **6** | 1 | 1 | 72 |
| Järvenpää | N/A | 0 | 2 | **311** | 1 | 1 | **164** | 1 | 1 | 475 |
| Karviainen | **200** | 1 | 1 | **68** | 1 | 1 | **100** | 1 | 1 | 368 |
| Kerava | **100** | 1 | 1 | **200** | 1 | 1 | **110** | 1 | 1 | **410** |
| Kirkkonummi | 340 | 2 | 4 | 80 | 1 | 1 | **250** | 1 | 1 | 670 |
| Lohja | N/A | 0 | 1 | N/A | 0 | 1 | **103** | 1 | 1 | 103 |
| Loviisa + Lapinjärvi | **75** | 1 | 1 | **267** | 5 | 6 | **60** | 1 | 1 | 402 |
| Myrskylä + Pukkila | **100** | 1 | 1 | **120** | 1 | 2 | **20** | 1 | 1 | 240 |
| Mäntsälä + Pornainen | N/A | 0 | 1 | N/A | 0 | 2 | **30** | 1 | 1 | 30 |
| Nurmijärvi | 1051 | 3 | 6 | 75 | 1 | 1 | **150** | 1 | 1 | 1276 |
| Porvoo | N/A | 0 | 1 | **322** | 3 | 4 | **150** | 1 | 1 | 472 |
| Raasepori | 90 | 1 | 2 | **166** | 3 | 5 | N/A | 0 | 1 | 256 |
| Sipoo | 405 | 2 | 4 | 86 | 2 | 3 | **72** | 1 | 1 | 563 |
| Siuntio | **50** | 1 | 1 | **50** | 1 | 1 | **20** | 1 | 1 | **120** |
| Tuusula | **480** | 1 | 1 | N/A | 0 | 1 | N/A | 0 | 1 | 480 |
| Total | 3507 | 17 | 32 | 2395 | 22 | 34 | 1380 | 15 | 18 | 7282 |

[1] **bolded** figures mean that the values reflect the total number of devices in the municipal area

In addition, a table 18 (appendix 4) was made, from which device amounts can be seen at unit and municipal level and compared to a population-based device estimate.

# 7 Discussion

The development of medical devices over the last 100 years has been rapid and their importance in healthcare has been emphasized recently (Enderle - Bronzino, 2012: 2; Storm, 2017.) In Finland the medical device related guidelines are very clear and rather specific, and they are mainly based on the European guidelines. The responsibilities are clearly divided between various stakeholders such as manufacturers, suppliers and professional users. Also the compliance with the regulations is monitored by the National Supervisory Authority of Welfare and Health called Valvira. (European Commission, 2017; Medical Devices Act 629/2010.) As stated in the chapters 3.1 and 3.5, the Finnish Medical Devices Act 629/2010 requires the professional user to register their medical devices, and to make sure that they are maintenance serviced according to manufacturers' instructions. Unfortunately it is not very often that these requirements of the Medical Devices Act 629/2010 are completely fulfilled, and regional and ethnographic differences can be found. This is perhaps due to the fact that the responsibility to comply with the act is enormous compared to the level of medical device related education nurses and other professional users have received. (Metropolia 2018.) And as the healthcare field has faced a lot of changes especially with the digitalization, I think the education of nurses and other professional users should also focus more on the training of the devices and the regulations related to these.

According to Lindroos and Lohivesi, (2010: 141-143) political and legislative changes have a strong impact on the strategy of the public sector organization, as services provided by the public sector are defined by society in the form of laws and regulations. It is therefore important for the public sector organization to be aware of the political and legislative changes, in order to be prepared to make changes to their strategy, if necessary. As stated in the chapters 3.3-3.5, in Finland, the healthcare sector is undergoing both political and legislative changes, such as the Medical Devices Act amendment as well as the health and social services reform, and therefore it is worthwhile that HUS Medical Engineering also makes changes to their strategy and prepares for these changes. As stated in the chapter 3.2, it is important to understand the current state of the market and customers' needs, if an organization is thinking to expand its business. Since HUS Medical Engineering had only little knowledge of the amount of medical devices in the public health sector of Helsinki-Uusimaa Region, or of the state of maintenance and registration, it was important to examine this. In addition

to this, the opinions and needs of potential customers had to be explored in order to direct right services to the right target group.

As stated in the chapter 3.4.2 previously there has not been that much competition from customers in the public sector. This has, however, changed and with the ongoing potential political changes competition will increase even further. Lindroos and Lohivesi (2010: 149-150) stated that the strategic choices available to the public sector are usually the choice of customers and the choice of services. This means that the public sector needs to define who the customers using these services are, and what kind of services to offer them. (Lindroos – Lohivesi, 2010: 141-150.) However, I think that it should be kept in mind that the public sector cannot choose their customers in the way the private commercial sector can. Therefore, position within the segment, introduced in the chapter 3.4.3, gets a little different meaning, as the public sector cannot exclude any less desirable segments. (Blomster, 2012; Lynch 2015: 99-103.) Even if the basis of segmentation in the public sector is slightly different from the private sector, I think that the importance of segmentation should not be understated. By segmentation the limited resources can be targeted to maximize the benefits. For example by utilizing differentiation, different segments can be offered different services that serve their individual needs, and any excessive and unnecessary can be eliminated.

## 7.1 Current condition

In this research one of the objectives was to study the current condition of the registration and maintenance of the medical devices in the participating municipalities. The devices of the healthcare units surveyed were better maintenance serviced than registered. In addition, the healthcare units surveyed were a bit more satisfied with the current state of the maintenance than with the registration. They seemed to value the importance of registration higher as on average, the healthcare units surveyed were less satisfied with the fact that the devices were not registered (average 1,67) than with the fact that they were not maintenance serviced (average 2,00). However, in only three of the units surveyed the maintenance service had not been performed, and therefore the association is not entirely reliable. However in general, the state of the maintenance was better than the state of the registration, and this was also reflected in the satisfaction. From this it can be concluded that the respondents are at least partly aware of the regulations relating to medical device registration and maintenance, and they seem to appreciate their importance. (Medical Devices Act 629/2010 § 24-26.)

One interesting fact was that 10% of the respondents announced that their medical devices were registered by the device supplier, which is most likely true, as the law also obliges medical device suppliers to keep track of the devices they supply (Regulation 2017/745 on medical devices: article 25, annex III.) This does not, however, remove the obligations of the user of the device. All except one respondent, who stated that their medical device registration was performed by the device supplier, also reported that their device information was registered in a database or a table. From this it can be concluded that these respondents are also aware of the requirements of law that apply to others than professional users. In addition, the maintenance situation seemed to be better than expected, as well as the other responsibilities of the professional user that were studied, for example, how the user manuals were available and if there was a nominated person in charge of the devices (Medical Devices Act 629/2010 § 24-26.) However, some research participants might have given false information if they are aware of the legal requirements and know that they do not completely comply with them.

It was interesting that an external operator already provided centralized maintenance services for many (69%) of these municipalities and therefore it can be assumed that there is competition. In addition, the respondents seemed to be rather satisfied with the current situation of how the maintenance has been organized, and as HUS Medical Engineering was not familiar to most of the research participants the customer insight should be further investigated, in order to understand the customers' needs. In addition to this, it is not known who the service providers are, and in what extent they offer their services to these municipalities. Also this issue should be taken into consideration and further investigation if the HUS Medical Engineering is going to expand the market area.

## 7.2 Desired condition

One of the findings was that not so many (15%) healthcare units surveyed had their own maintenance organization, but despite that, a large number (37%) of them wanted maintenance to be arranged by an own maintenance organization. This might mean that perhaps they have had an own maintenance organization previously, or they find the idea desirable for some other reason. For example they might think that an own maintenance organization might serve them quicker, and take the responsibility of

arranging the maintenance services away from the users. The results were reversed, yet equally interesting, when it came to device suppliers. Currently the second most common way (44%) to perform maintenance on the medical devices was by the device suppliers, and yet only a few (12%) wished this procedure in the future, despite the fact that the device suppliers are sometimes the only authorized service providers for the medical devices in Finland. In addition to this, it could have been thought that they are considered to be the most reliable and the highest quality service providers, as in many occasions they receive the medical device service training straight from the manufacturers, and they are often also authorized to provide medical device service training to others as well. The reasons for this finding can only be guessed, but it might be due to the fact that it may be difficult for a user to order services from multiple service providers, as they might have several different medical devices from several different suppliers. This assumption is supported by the results of the study, according to which the desire is either to have the maintenance service performed by an own maintenance organization (37%) or centralized by an external maintenance organization (63%).

The quality of the maintenance service was found to be more important factor than the service costs. However, the word *quality* might mean different things to different people and therefore it should be further investigated. In addition, since the healthcare units surveyed are operating in the public sector, it is very possible that the amount of costs is to some extent irrelevant to them, since something that is seemingly free is used differently than the kind that one has to pay for oneself (Lindroos – Lohivesi, 2010: 143.) In addition to the quality, short service times were valued more than costs or the fact that exactly same device would return from the maintenance service. However, the importance of the return of the same device did not reach full consensus among the healthcare units surveyed. These findings may indicate that some of the units might be more interested, for example, in the leasing or rental procedure than other units, and this should be further investigated as well.

There were differences between both municipalities and healthcare units in how they would like the maintenance services to be organized. The study did not reveal any clear group whose needs would have been very similar, and therefore, no conclusions can be drawn solely on the basis of a municipality or healthcare unit. In other words, the research did not lead to the conclusion that, for example, the needs of all maternity clinics would be the same. Therefore, segmenting customers based solely on location

(i.e. municipality) or industry (i.e. healthcare unit) is not adequate, and further investigation is needed.

## 7.3 Device amounts

Other objective was to study the device amounts of these participating municipalities, to better understand the possible workload. Whether the devices were registered or not, did not appear to be relevant to the accuracy of the device amounts given. As for some reason, the accuracy of the amount of devices was higher in health centres, although the average status of their device registration was somewhat worse than that of nursing homes and maternity clinics. Furthermore, the accuracy of the number of devices in nursing homes was considerably weaker, even though their devices were better registered than the devices of two other types of healthcare units. The reason for this may be the fact that the respondents were given the opportunity to answer that the given device amounts were estimates, and therefore some of the respondents might have chosen an easy way and give an estimated amount even if they had a register where the real amounts could have been checked. It should also be noticed, that even if the units have a device register, it may not be easy to use, and not everyone necessarily have access to it. And if this is the case, they hardly went to calculate devices only for this study. Another possible reason for this may be that some respondents might consider the device information to be confidential and not public information, and therefore give only roughly estimations. Also some of the units surveyed might have wanted to give a better, or worse, picture of the state of registration.

Because the device amounts received with the survey were very inaccurate, no reliable profitability analysis can be made based on them. However, compared to Espoo's and Vantaa’s device amounts, they were small, as all the healthcare units surveyed had approximately the same amount of devices together, as the Vantaa and Espoo have together. Therefore it has to be taken into consideration, that because the distances between the municipalities and the current service facilities are long, the current service model may not be the most effective way to provide the services. However, not all the device amounts received with the survey were estimates, and some of the amounts received with the survey were stated to be accurate. These can be utilized to calculate device estimates for those municipalities whose data were inadequate.

Rough estimate received with the survey might be more accurate than full guess or even a population-based estimate shown in the table 18 (appendix 4).

## 7.4 Ethical issues

Research permission was applied from HUS and approved in April 2018. The research participants were contacted beforehand via phone or email to assure that the research participants are correct persons to answer the questions, and to explain the purpose and aim of the research. Also a cover letter (appendix 2.) was sent together with the survey. The cover letter explained the purpose and the aim once again, and informed the research participants that the participation in the survey is voluntary and that the answers are addressed in anonymous and confidential terms. Addition to this it explained that the personal data of the research participants will not be exposed in the results. The e-mail was both in Finnish and Swedish, but the cover letter and questions were only in Finnish. The questionnaire also included my contact information, in case something was unclear for the respondents. To ensure the research ethics, the data was handled anonymously and names or any other information of the participants was not revealed. The results were handled municipality level or operation level, for example referring to health centres in general.

## 7.5 Reliability and validity of the research

The survey was sent to 76 persons via e-mail on the 12th of April and the response time was at first given two weeks. During the two weeks' response time, two reminders were sent: the first one on the 20th of April and the second on 26th of April. However some respondents asked more time and thus the deadline was postponed to the 5th of May. In all 52 persons answered and thus the response rate was 68%.

It was assumed that because the research participants were working in the public sector, their contact information would be easy to find. However, it came very clear that in some of the municipalities it was not know who would be such a person who would have the knowledge to answer these medical device related questions. Therefore, in some municipalities it was much more difficult to find the correct persons, and several phone calls had to be made and several emails had to be sent. This was mainly because the responding responsibility was delegated forward to the subordinates.

Therefore, there were also some differences between the municipalities in the number of respondents. In some, there were only one or two contact persons, who confirmed that they can provide the device information of the whole municipality, but in others the web survey had to be sent up to eight people. There are several reasons for this difference. One of them is the amount of public nursing homes in the municipality, as some municipalities organized the nursing home services by themselves while others bought at least part of the services from private companies. One interesting fact was that in each municipality there was only one contact person for the maternity clinics although there were several maternity clinics inside the municipality.

Another assumption was that some of the research participants might question the reason for doing this research. However, what was interesting is that none of the persons I contacted wanted to know more precisely why this research was done. Instead, everyone seemed to be willing to answer, or at least provide contact information of the correct persons. This observation was even more surprising when it became clear that HUS Medical Engineering was familiar to only a fraction of the healthcare units surveyed. This does not, however, mean that they were not familiar with HUS in general. Therefore, it is possible that the reason for the willingness to help is that HUS is a respected operator and in some extent looked up to. In addition, HUS works closely with primary health care units because they have, at least partly, common patients. Perhaps a private-sector operator might have been considered to be more untrustworthy, and the information might not be given to them as easily.

### 7.5.1 Reliability and validity of the data collection instrument

In general terms, for the trustworthiness of the market research it is essential to verify the validity of the questionnaire layout, that is to say, the validity of the data. It is important to be sure that it is measured what is supposed to be measured. In addition, it is important that the researcher knows and understands the industry, activity, products and services that are to be measured. (Lotti, 2003: 119.) In this research these are taken into consideration, as the researcher is working as a specialist in the HUS Medical Engineering.

The reliability and validity of quantitative research can be reduced if the respondent understands the question incorrectly. If this happens, the answers are also distorted. In this study, the goal was to reduce the amount of misunderstandings by testing the

questionnaire with several persons before sending it. Some of the test persons were also healthcare professionals like the research participants, and some were ordinary people who did not have any healthcare education. Some minor alterations and corrections to the questionnaire were made on the basis of the comments received from the test persons. Still for example the term “medical device” might mean different things to different people. Therefore a list of medical device types currently found in the register was attached to the survey. Still this does not, however, completely solve this problem. Also the term “registration” might mean different things to different people. Some of the respondents may think that registration means that there has to be a database or at least a table, where the information can be found, even though the law does not dictate how the devices of the professional users should be registered. Therefore, in certain situations, archiving the device related papers to folders might be sufficient, if the necessary information can easily be found from those. To reduce the amount of misunderstandings the meaning of the term in this study was reported in a web questionnaire alongside of the question related to the registration. However, the info icon in the E-lomake questionnaire was rather small, and perhaps not all respondents noticed it. That is why the questionnaire also included my contact information, in case something was unclear for the respondents.

### 7.5.2 Response rate

It was also taken into consideration that the questions were clear, and as short as possible, because too long questions may reduce the response rate. The coincidence should not affect the result, and thus the basic idea is, the more respondents, the more reliable conclusions can be drawn. (Lotti, 2001: 119; Dawson, 2002: 110; Ojasalo - Moilanen – Ritalahti, 2014: 130-131.) Unfortunately all respondents did not reply. Some respondents might not have been willing to answer and some might have been absent at the time of the survey. The absence may be, for example, due to an illness or a vacation, and thus it could have not been influenced (Lotti, 2001: 171.) Trustworthiness is also influenced by the validity of the sampling and the sample, in other words the generalization of the results. In this research a total sample was used, and thus the reliability of the sampling and the sample are somewhat irrelevant. (Lotti, 2001: 119; Dawson, 2002: 110; Ojasalo - Moilanen – Ritalahti, 2014: 130-131.) However, there was some overlap in the responses which might be due to that some respondents have replied more than once or delegated the responsibility to some others during the response time. Attempts were made to reduce this problem by contacting the research

participants beforehand to be sure that they are correct persons to answer. As a whole, 67 out of 76 respondents confirmed beforehand to be the correct persons to answer the questions.

According to the research of Baruch and Holtom, when gathering data from organizations, the average response rates are smaller than when collecting data from individuals. On the other hand, they found the standard deviation to be lower. The average response rate for organizations was 35,7 percent and the standard deviation 18,8 percent. (Baruch – Holtom 2008.) Despite this, the goal was to have a response rate of at least 50-70 percent. The survey was sent to 76 persons and in all 52 persons answered, and thus the respond rate was 68%, which is a rather good. The aim was to increase the response rate by highlighting the benefits to the respondents, and by contacting them in advance by telephone and e-mail. In addition two reminders were sent during the response time.

### 7.5.3 Device amounts

Device amounts were rather inaccurate as reliability was reduced by the fact that most of them were estimates. Although a large proportion of the amounts given may be very close to reality, it should be kept in mind that there may also be very rough estimates. The reliability of the device amounts was in some occasions further weakened by the inadequate response rates of the different healthcare units of the municipalities surveyed. As a result, no comprehensive overview of the number of devices in a healthcare unit (i.e. nursing home) of a specific municipality was found out because the device amounts were not received from one or more respondents. However, in general, the response rate of maternity clinics was rather high and the responses were received from all of the maternity clinics of a specific municipality. In addition to this there was some overlap in some of the device amounts received. This might be due to that some of the respondents might have answered twice or on behalf of other health care units than they in the beginning informed. In these cases the values found to be incorrect were removed, or in situations where incorrect values could not be established with certainty, the average of the obtained values was calculated and used.

# 8 Conclusion

The purpose of this research was to better understand the current state of the market and customers' needs, in order to get support for decision-making on what would be the most effective way to provide medical engineering services to these municipalities. The aim was to determine what kind of need there is for medical engineering services in the public health centers, nursing homes and maternity clinics of the area of Uusimaa outside the capital area. As expected, the research provided information about the possible new market area, and especially about the current state of the registration and maintenance. The results showed that, in general, there is a need for the medical engineering services in the area. The current state of registration was not particularly good, as only four out of ten units had their devices registered completely. The device amounts were found to be mainly estimates and whether the devices were registered or not, did not appear to be relevant to the accuracy of the device amounts given. The current condition of the maintenance was, however, better than expected and this was also reflected in the satisfaction. In addition to registration and maintenance, other responsibilities of a professional user were met better than expected, even if there is still enough work in that area.

Based on the results it seems that there is more need for the registration services than for the maintenance services, and it should be taken into consideration that there is competition when it comes to the maintenance services. A large part of the maintenance services in the healthcare units surveyed were currently performed centralized by an external operator, and this practice seemed to satisfy the needs of the healthcare units surveyed rather well. Their desire was either to have the maintenance service performed centralized by an external operator or by an own maintenance organization. Contrary to expectations, maintenance services of the device suppliers were not particularly needed, even though a large portion of the maintenance services was currently performed by them. The healthcare units surveyed seem to value the quality and short duration of the services more than the costs. However, to determine if they would be willing to replace the current device with a similar device that has already been maintenance serviced, a further research is needed. In addition to this, there were differences both between municipalities and between healthcare units in the way they wanted the maintenance services to be organized in the future. Therefore the research did not lead to the conclusion that, for example, the needs of all maternity clinics would be the same. Thus, segmenting

customers based solely on location (i.e. municipality) or industry (i.e. healthcare unit) is not adequate.

## 8.1 Development suggestions

I already presented some further research needs in chapter 7. In addition, based on the results of the research and the theoretical framework, customer segmentation should be made on the basis of other criteria than the municipality, or even the healthcare unit. The needs and wishes of customers should be taken into closer examination and different segments should be offered service packages that serve their individual needs. After the segments have been identified, HUS Medical Engineering should consider if the current organization structure is beneficial and divide its operation based on the customer segments. The leasing approach should be further explored, as a clear majority wanted their devices maintenance serviced centralized in the future as well. In addition to quality, a short duration of service was also highly valued and therefore, some customers may be interested in exchanging their devices that require maintenance, to similar devices that has already been serviced. However, the profitability of this procedure should be explored first, and the customer insight should be further explored using qualitative research methods.

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## Questions in Finnish

Metropolia

### Lääkintäteknisten palveluiden tarpeen kartoitus

Arvoisa vastaaja, tämän opinnäytetyön tarkoituksena on määrittää, millainen tarve Uudenmaan maakuntien julkisissa SOTE-keskuksissa on lääkintäteknisille palveluille. Tutkimuksen tulosten perusteella pyritään löytämään tehokkain tapa lääkintäteknisten kokonaispalvelujen tarjoamiseksi Uudenmaan maakuntiin. Teidät on valittu kyselyn vastaajaksi asemanne perusteella, ja vastaamalla kyselyyn annatte arvokasta tietoa oman kuntanne laitekannasta ja autatte Lääkintätekniikkaa kehittämään palveluitaan. Jokainen vastaus on äärimmäisen tärkeä mahdollisimman kattavan kokonaiskuvan saamiseksi.

**Vastaajan tiedot**

* Kunta --Valitse tästä--

* Asemasi organisaatiossa? ? --Valitse tästä--

Terveydenhuollon yksikkö tai yksiköt, joiden puolesta vastaat ?

- Terveysasema
- Ikääntyneiden palvelut
- Neuvola

**Perustiedot**

| | Kyllä | Ei | Osittain |
|---|---|---|---|
| * Onko HUS:n Lääkintätekniikka teille entuudestaan tuttu | | | |
| * Onko teillä nimetty laitevastaava/nimetyt laitevastaavat | | | |
| * Laitteiden käyttöohjeet on helposti saatavilla | | | |
| * Onko omistamanne lääkintälaitteet rekisteröity | | | |
| * Onko omistamanne lääkintälaitteet määräaikaishuollettu | | | |

Miten omistamanne lääkintälaitteet on rekisteröity? (voit valita useamman) ?

- Meillä on oma laitetietokanta
- Omistamiemme lääkintälaitteiden laitetiedot on kirjattu taulukkoon (esim. Excel)
- Laitteiden rekisteröinti on suoritettu ulkopuolisen toimijan toimesta
- Laitteiden rekisteröinti on suoritettu laitetoimittajien toimesta
- Laitteita koskevat paperit on arkistoitu kansioihin
- Lääkintälaitteitamme ei ole rekisteröity

Miten omistamienne lääkintälaitteiden huolto on järjestetty? (voit valita useamman)

- Meillä on oma laitehuolto
- Laitteiden huollot on suoritettu keskitetysti ulkopuolisen toimijan toimesta
- Laitteiden huollot on suoritettu laitetoimittajien toimesta
- Laitteita huolletaan ja korjataan vain niiden rikkoutuessa
- Laitteita ei ole huollettu eikä korjattu, vaan tilalle on ostettu uusia

**Laitekanta terveysasema**

*Paljonko teillä on lääkintälaitteita terveyskeskuksessa (kpl)

Esimerkkejä lääkintälaitteista

| | Todellisia | Arvioituja |
|---|---|---|
| *Laitemäärät ovat | ○ | ○ |

Paljonko teillä on sänkyjä (kpl)

Paljonko teillä on verenpainemittareita (kpl)

Paljonko teillä on potilasvaakoja (kpl)

| | Todellisia | Arvioituja |
|---|---|---|
| Laitemäärät ovat | ○ | ○ |

**Laitekanta ikääntyneiden palvelut**

*Paljonko teillä on lääkintälaitteita ikääntyneiden palveluissa (kpl)

Esimerkkejä lääkintälaitteista

| | Todellisia | Arvioituja |
|---|---|---|
| *Laitemäärät ovat | ○ | ○ |

Paljonko teillä on sänkyjä (kpl)

Paljonko teillä on verenpainemittareita (kpl)

Paljonko teillä on potilasvaakoja (kpl)

| | Todellisia | Arvioituja |
|---|---|---|
| Laitemäärät ovat | ○ | ○ |

## Laitekanta neuvola

*Paljonko teillä on lääkintälaitteita neuvolassa (kpl)

Esimerkkejä lääkintälaitteista

| | Todellisia | Arvioituja |
|---|---|---|
| *Laitemäärät ovat | ○ | ○ |

Paljonko teillä on sänkyjä (kpl)

Paljonko teillä on verenpainemittareita (kpl)

Paljonko teillä on potilasvaakoja (kpl)

| | Todellisia | Arvioituja |
|---|---|---|
| Laitemäärät ovat | ○ | ○ |

## Toivetila

Miten toivoisitte omistamienne lääkintälaitteiden huollot järjestettävän? (voit valita useamman)

- ☐ Oman laitehuollon toimesta
- ☐ Keskitetysti ulkopuolisen toimijan toimesta
- ☐ Laitetoimittajien toimesta
- ☐ Laitteita huollettaisiin ja korjattaisiin vain niiden rikkoutuessa
- ☐ Laitteita ei huollettaisi eikä korjattaisi, vaan niiden tilalle ostettaisiin uusia

Kuinka samaa mieltä olette seuraavista väittämistä (1 = täysin eri mieltä, 5= täysin samaa mieltä)

| | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| *Olen tyytyväinen rekisteröinnin nykytilaan | ○ | ○ | ○ | ○ | ○ |
| *Olen tyytyväinen huoltojen nykytilaan | ○ | ○ | ○ | ○ | ○ |
| *Huollon laatu on tärkeämpää, kuin huollosta aiheutuvat kustannukset | ○ | ○ | ○ | ○ | ○ |
| *Olen valmis maksamaan hieman enemmän, jos siten saan laitteen nopeammin käyttööni | ○ | ○ | ○ | ○ | ○ |
| *Minulle on tärkeää, että juuri sama laite palautuu huollosta | ○ | ○ | ○ | ○ | ○ |
| *En välitä onko kyseessä sama laite, jos saan vastaavan laitteen nopeammin käyttööni | ○ | ○ | ○ | ○ | ○ |

## Lopuksi

Mitä muuta haluaisitte sanoa (kommentteja, terveisiä, jne.)?

## Cover letter

Arvoisa vastaanottaja,

Olen huoltoinsinööri Heidi Nousiainen HUS:n Lääkintätekniikasta, ja opiskelen Metropolia ammattikorkeakoulussa Health Business Management -linjalla ylempää insinöörityötutkintoa. Opinnäytetyöni tavoitteena on määrittää, millainen tarve Uudenmaan maakuntien julkisissa SOTE-keskuksissa on lääkintäteknisille palveluille.

HUS:n lääkintätekniikka vastaa tällä hetkellä HUS:n lisäksi Helsingin, Espoon ja Vantaan kaupunkien lääkintälaitteiden rekisteröinnistä ja huolloista. Maakuntauudistuksen luomasta muutostarpeesta johtuen, Lääkintätekniikka on kiinnostunut selvittämään, millainen lääkintälaitekanta Uudenmaan maakuntien julkisella SOTE-puolella on. Tutkimuksen avulla pyritään löytämään tehokkain tapa lääkintäteknisten kokonaispalvelujen tarjoamiseksi myös muihin Uudenmaan maakuntiin. Teidät on valittu kyselyn vastaajaksi asemanne perusteella, ja vastaamalla kyselyyn annatte arvokasta tietoa oman kuntanne laitekannasta ja autatte meitä kehittämään palveluitamme. Jokainen vastaus on äärimmäisen tärkeä mahdollisimman kattavan kokonaiskuvan saamiseksi.

Opinnäytetyö toteutetaan kvantitatiivisena kyselytutkimuksena, johon pyytäisin Teitä osallistumaan. Osallistuminen merkitsee oheisen lyhyen online kyselylomakkeen täyttämistä, eikä siihen pitäisi kulua 5 minuuttia kauempaa. Suurin osa kysymyksistä on monivalintakysymyksiä, joihin voitte valita sopivimman vastauksen valmiista vastausvaihtoehdoista. Joukossa on kuitenkin myös laitemääriä koskevia numeerisia kysymyksiä, joihin toivoisin mahdollisimman tarkkaa vastausta.

Osallistuminen kyselyyn on vapaaehtoista, ja antamanne vastaukset käsitellään nimettöminä ja ehdottaman luottamuksellisesti. Vastaajien tiedot eivät paljastu tuloksissa. Kyselyyn vastaamiseen on aikaa kaksi viikkoa. Tutkimus valmistuu vuoden 2018 aikana, jonka jälkeen se on luettavissa Theseus-julkaisuarkistossa. Tutkimuksen tekemiseen on saatu asianmukainen lupa.

Mikäli sinulla on jotakin kysyttävää tutkimukseen liittyen, niin minut tavoittaa sähköpostitse osoitteesta heidi.nousiainen@metropolia.fi tai puhelimitse 050 447 6531.

Suuri kiitos osallistumisesta!

Ystävällisin terveisin
Heidi Nousiainen
Huoltoinsinööri, HUS-lääkintätekniikka
heidi.m.nousiainen@hus.fi

## Medical Device examples

# Esimerkkejä yleisimmistä lääkintälaitteista

| | | |
|---|---|---|
| ALASVETOLAITE | LAITE/INVENTAARIOTIETOJEN YLLÄPITO | **POTILASVUODE,SÄHKÖKÄYTTÖINE** |
| ALKOHOLIMITTARI | LASTANKUUMENNUSALLAS | **PULSSIOKSIMETRI** |
| ANTIDEKUBITUSPATJA | **LIHASTEN HARJOITUSLAITE** | **PYÖRÄTUOLIT** |
| APUVÄLINE, ERITTELEMÄTÖN | LIHASVOIMAMITTARI | RASVAPROSENTTIMITTARI |
| DEFIBRILLAATTORI, EKG-SYNKRONOITU | LÄMPÖKAAPPI | **SEISOMATELINE** |
| DERMASKOOPPI | LÄMPÖLEVY | **SEULONTA-AUDIOMETRI** |
| DIAGNOSTIIKKA-AUDIOMETRI | **LÄMPÖMITTARI, KORVAKÄYTÄVÄ** | **SIKIÖN SYDÄNÄÄNTEN KUNNTELULAITE, ULTRAÄÄNI** |
| EKG-PIIRTURI (J) | LÄMPÖMITTARI, SÄTEILYTUNNISTUS | SUMUTIN |
| **GLUKOOSIANALYSAATTORI** | **LÄÄKEJÄÄKAAPPI** | SUODATINFOTOMETRI, NÄKYVÄ VALO (400...750 nm) |
| HAPPIRIKASTIN | OFTALMOSKOOPPI | SÄHKÖIMULAITE |
| HEMOGLOBIINIFOTOMETRI | OTOSKOOPPI | SÄHKÖSTIMULAATTORI, MODULI |
| **HENKILÖKOHTAISET LAITTEET JA APUVÄLINEET** | **OTSALAMPPU** | TEHOIMURI |
| HOITOPÖYTÄ, FYSIATRINEN | PAINEMITTARI, NONINV KÄSIKÄYTTÖ | TESTILIUSKAN LUKULAITE |
| HOITOTUOLI | **PAINEMITTARI, NONINVASIIVINEN, AUTOMAATTINEN** | TONOMETRI |
| HUIPPUVIRTAUSMITTARI | | **TUTKIMUSPÖYTÄ, SÄHKÖKÄYTTÖINEN** |
| HYYTYMISEN MITTAUSLAITE | PAINENAUHURI, PITKÄAIKAIS- | **TUTKIMUSVALAISIN** |
| INFRAPUNASÄTEILIJÄ ( -LAMPPU) | PARAFIINIVALUKESKUS | TYMPANOMETRI |
| INFUUSIOPUMPPU, JATKUVATOIMINEN | PESUSÄNKY | ULTRAÄÄNIHOITOLAITE |
| JALKAHOITOYKSIKKÖ | PISSAILMAISIN | ULTRAÄÄNIKUVAUSLAITTEISTO |
| JÄRJESTELMÄKAMERA | PITUUSMITTARI | ULTRAÄÄNILAITE, REAALIAIKA |
| KARVANLEIKKURI | PLETYSMOGRAFI, RAAJAVERENKIERTO | ULTRAÄÄNIVIRTAUSMITTARI, NONINVASIIVINEN |
| KIPSIN LEIKKURI | POLKULAITE | UNITUTKIMUSLAITTEISTO |
| KIPULÄÄKEPUMPPU | POTILASNOSTURI, KIINTEÄ | **VALOKAAPPI** |
| KIRURGINEN DIATERMIALAITE, TEHO ALLE 50 W | POTILASNOSTURI, LIIKUTELTAVA | VEDEN LÄMMITIN |
| KIRURGINEN DIATERMIALAITE, TEHO YLI 50 W | POTILASTUOLI, SÄHKÖTOIMINEN | VETOKAAPPI |
| KUNTOPYÖRÄ | **POTILASVAAKA** | VIDEOMONITORI |
| KUVANTAMISLAITTEET, ERITTELEMÄTÖN | POTILASVUODE | **VIRTALÄHDE, TUTKIMUS- JA HOITOLAITTEIDEN** |

## Device amounts

The device amount estimations, shown in the table 18, were calculated based on the factor received by calculating the device amounts of the health centers, nursing homes and maternity clinics per inhabitant of the cities of Vantaa and Espoo. The amounts differed only 0,37% from each other and as the amount of Vantaa was considered to be more accurate it was decided that the factor used would be based on that (0,020988787). The municipality population in a year 2016 was used for this. (Mequsoft, 2018; Official Statistics of Finland, 2016.)

Table 18. The association of device amounts received with the survey and the device amount estimation based on the population of the municipality

| Municipality | Health centre | | Nursing home | | Maternity clinic | | All | |
|---|---|---|---|---|---|---|---|---|
| | Amount based on the answers | Estimation based on the population | Amount based on the answers | Estimation based on the population | Amount based on the answers | Estimation based on the population | Amount based on the answers | Estimation based on the population |
| Askola | N/A | 48 | *300* | 37 | N/A | 22 | 300 | 107 |
| Hanko | **285**[1] | 83 | N/A | 63 | 45 | 38 | 330 | 184 |
| Hyvinkää | *530*[2] | 441 | 500 | 335 | 100 | 200 | 1130 | 976 |
| Inkoo | **66** | 53 | N/A | 40 | **6** | 24 | 72 | 117 |
| Järvenpää | N/A | 391 | **311** | 297 | 164 | 177 | 475 | 865 |
| Karviainen | 200 | 359 | **68** | 273 | 100 | 163 | 368 | 795 |
| Kerava | 100 | 336 | 200 | 255 | **110** | 152 | 410 | 743 |
| Kirkkonummi | *680* | 368 | *80* | 280 | 250 | 167 | 1010 | 815 |
| Lohja | N/A | 448 | N/A | 341 | **103** | 203 | 103 | 992 |
| Loviisa + Lapinjärvi | **75** | 171 | *320* | 130 | 60 | 77 | 455 | 378 |
| Myrskylä + Pukkila | 100 | 38 | 120 | 29 | 20 | 17 | 240 | 84 |
| Mäntsälä + Pornainen | N/A | 246 | N/A | 187 | 30 | 111 | 30 | 544 |
| Nurmijärvi | *2102* | 398 | *75* | 302 | 150 | 180 | 2327 | 880 |
| Porvoo | N/A | 475 | *429* | 361 | **150** | 215 | 579 | 1051 |
| Raasepori | *180* | 268 | *277* | 204 | N/A | 121 | 457 | 593 |
| Sipoo | *810* | 186 | *129* | 142 | 72 | 84 | 1011 | 412 |
| Siuntio | 50 | 59 | 50 | 45 | 20 | 27 | 120 | 131 |
| Tuusula | 480 | 365 | N/A | 278 | N/A | 165 | 480 | 808 |
| Total | 5658 | 4733 | 2859 | 3599 | 1380 | 2143 | 9897 | 10475 |

[1] **bolded** figures mean that the values of device amounts given by institutions are accurate
[2] figures marked by *italic* mean that the missing values have been replaced with an estimation based on the results (i.e. the obtained figure was divided by the response rate)

**References**

Mequsoft. 2018. HUS Medical Engineering ERP. Read 8.1.2018.

Official Statistics of Finland (OSF), PX-Web database. Average population 2016, variables Year, Region, Sex and Age (in Finnish Keskiväkiluku 2016 muuttujina Vuosi, Alue, Sukupuoli ja Ikä). 2017. Web document. < http://pxnet2.stat.fi/PXWeb/pxweb/fi/StatFin/StatFin__vrm__vaerak/statfin_vaerak_pxt_021.px/table/tableViewLayout2/?rxid=cd089534-70f7-44cf-ad60-c1ecef8722db> Read 5.1.2018