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Medical Device Diagnostics Data in IoT System

Metropolia University of Applied Sciences

Bachelor of Engineering

Information Technology

Bachelor's Thesis

7 November 2023

Abstract

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Title: Medical Device Diagnostics Data in IoT System
Number of Pages: 40 pages + 1 appendix
Date: 7 November 2023

Degree: Bachelor of Engineering
Degree Programme: Information Technology
Professional Major: Smart IoT Systems: Embedded Devices
Supervisors: Martin Granholm, Lead Designer, Software
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As the value of data is increasing, this thesis explores practical solutions for diagnostic data collection in a medical X-ray imaging device with an external communication component. Medical devices by their nature are required to be as accurate as possible at all times when used; however, just like any other product, different parts of the device wear out over time. To remedy this problem, a solution for diagnostic data collection of the hardware components both during and outside of usage can decrease the possibility of malfunctions, as the deviations outside of tolerance values can be readily spotted from a set of data. This data could also be used for device specific maintenance plans and reduce costs relating to onsite device troubleshooting.

A practical solution was developed for Planmeca Oy. Planmeca Oy manufactures dental equipment and devices, including dental instruments, chairs, and imaging devices for dentists all over the world. The practical data collection solution was developed within the company's product ecosystem, using a recently launched full body X-ray device and Planmeca IoT product. Initially development started with studying all the components of the X-ray device ecosystem and creating an initial proof of concept solution for end-to-end acquisition and storage of diagnostics data. This proof of concept was then used as a basis to draft plans for further development of the prototype.

The results suggested that the data collection in an IoT environment is both practical and useful. As the proof of concept was developed with effortless integration into the X-ray device ecosystem, further development, and optimization of the proof of concept should result in a useful diagnostic tool to maintain device hardware, reduce personnel onsite travel cost, and provide insight to device usage, especially in troubleshooting situations.

Keywords: Medical Device, IoT, Data Collection

The originality of this thesis has been checked using Turnitin Originality Check service

Tiivistelmä

Tekijä:	Mikael Wiksten
Otsikko:	Lääketieteellisen laitteen diagnostiikka data IoT-järjestelmässä
Sivumäärä:	40 sivua + 1 liite
Aika:	7.11.2023
Tutkinto:	Insinööri (AMK)
Tutkinto-ohjelma:	Tieto- ja viestintätekniikka insinööri
Ammatillinen pääaine:	Smart IoT Systems: Embedded Devices
Ohjaajat:	Vastaava ohjelmistosuunnittelija Martin Granholm Lehtori Joseph Hotchkiss

Tässä insinööriyössä tutkitaan käytännönläheisiä ratkaisua diagnostiikkatiedon keruuseen röntgenkuvantamislaitteen erillistä ulospäin kommunikoivaa komponenttia hyödyntäen. Lääketieteellisten laitteiden luonteen vuoksi niistä saatavien tulosten täytyy olla jatkuvasti luotettavia ja tasaisia, mutta kuten mikä tahansa muu laite, niiden sisältämät osat kuluvat käytön aikana. Tämän ongelman parantamiseksi voidaan kehittää ratkaisu niin käytönaikaisesta kuin käytön ulkopuolisesta diagnostiikkatiedon keruusta, jolloin poikkeamat kerätyistä arvoista voidaan huomata ja todentaa vaivattomasti. Tätä käyttötietoa voitaisiin hyödyntää tuotekohtaisten huolto-ohjelman laatimiseen sekä vähentää paikan päällä tapahtuvaan ongelmanratkaisuun liittyviä kuluja.

Insinööriyötä varten tehty ratkaisu kehitettiin Planmeca Oy:lle. Planmeca Oy valmistaa laitteita ja tarvikkeita hammaslääkäreille, kuten instrumentteja, työasemia ja kuvantamislaitteita. Yritys lanseerasi hiljattain uuden koko kehon röntgenkuvantamislaitteen ja tähän liitettävän yrityksen IoT-tuotteen avulla saadaan luotua ympäristö, johon yllä mainittu ratkaisu voidaan kehittää. Kehitys aloitettiin tekemällä prototyyppi päästä päähän tapahtuvasta tiedon keruusta ja lähetyksestä, jota testaamalla ja tutkimalla saatiin luotua ideoita ja tarpeita toiminnallisuuden jatkokehitykselle.

Prototyypin tuloksista voidaan päätellä, että tiedonkeruusta on hyötyä tilaajayrityksen ekosysteemissä. Koska prototyypin kehityksen tavoitteissa oli helpottaa integraatiota röntgenkuvauslaitteen järjestelmiin, jatkokehityksen tuloksena olisi hyödyllinen työkalu laitteen komponenttien ylläpitoon, huoltohenkilöstön matkustuskulujen vähentämiseen ja käytön havainnollistamiseen ja tutkimiseen, varsinkin ongelmatilanteissa.

Avainsanat: lääketieteellinen laite, IoT, tiedonkeruu

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List of Abbreviations

- IOT: Internet of Things. Name given for a system where interconnected devices have autonomous functionalities for remote tracking and controlling.
- SOM: System on a Module. A processing circuit that includes all functional components of a computer system in a singular module.
- DCS: Data Collection System. A computer program designed for data collection.
- HTTP: Hypertext Transfer Protocol. An application layer communication protocol that enables hypertext network communications.
- API: Application Programming Interface. Software or a program that allows communication between different computer programs.
- DDS: Data Distribution Service. Network Communication software for devices connected to each other.
- IDL: Interface Definition Language. A programming language used to describe data types and communication structures between different programming languages.
- GDPR: General Data Protection Regulation. European Union regulation for data and information privacy.
- HIPAA: Health Insurance Portability and Accountability Act. Federal level regulation of the United States of America for medical data privacy and usage.
- TCP: Transmission Control Protocol. A transport layer communication protocol to deliver stream of bytes between applications or devices.

- IP: Internet Protocol. A network layer communication protocol, providing data such as network addresses to deliver data packets to the correct receiver.
- DB: Database. Electronic data storage to record information in an organised format that can be accessed through software or manually.
- SIM: Subscriber Identity Module. A small card with integrated circuits and an international mobile subscriber identity number that enables authentication for devices to use cellular connection technologies, such as phone calls, text messages or mobile internet connection.
- MQTT: Message Queuing Telemetry Transport. Message. Publish-Subscribe communication protocol used by devices for data sending and retrieval.

1 Introduction

The trend for collecting and utilising data appears to prevail increasingly within the IT sector. As computational and storage costs have decreased, analysing data for outliers and abnormal values for prevention of undesired behaviour within high performance systems is becoming an important feature [1, p. 3-5]. The same logic can be applied to medical devices, as it is critical and lifesaving for these devices to function as expected and as well as possible. However, like devices of all kinds, medical devices wear out over time and require maintenance throughout their lifecycle, no matter how foolproof these devices are developed and manufactured. With proprietary technology incorporating high expenses for both maintenance and troubleshooting, the collection and the analysis of hardware and diagnostic data for troubleshooting situations can be critical, as it provides logical paths for errors and reveals wear within hard-to-access components. This leads to the topic of this thesis; how to create a practical solution for diagnostic data collection within high performance systems using modern communication solutions, such as internet connectivity and IoT technology?

This is the research question that the company, Planmeca Oy, would like an answer to. Planmeca is an international manufacturer and solution provider within the dental and medical industries originating from Finland. Planmeca Oy is a part of Planmeca Group, which develops dental products and equipment, such as instruments, workstations, clinic management software and imaging devices. The company group also provides software solutions for dental clinics and implants for fractures around the skull and facial area [2]. Planmeca Group recently revealed a new full body X-ray imaging device, Planmed XFI, that has been in development for a while now. The aim of Planmed XFI is to give a relatively low cost, high performing X-ray device capable of imaging any area of the body, creating a cost-effective solution for professional medical organisations of varying sizes. [3.] As the device is planned to be sold internationally eventually, both troubleshooting and maintenance costs are high when travelling to locations all over the world from Finland. This is why the

company is looking for a practical solution for diagnostic data collection, to decrease costs relating to troubleshooting and maintenance by collecting data remotely to better help customers with both the usage and maintenance of their products. The roots for the solution already happen to exist. Planmeca is also developing an IoT product that allows secure and easy connection and communication between cloud storage and the company's products. The goal of the IoT product is to provide insights into the usage of dental equipment among other available data from the connected products. The same product can be used with XFI, providing a foundation for the data collection process solution.

The following sections will go further into the theory and the methods for data collection, covering advantages and disadvantages and glossing over the system architecture for the Planmeca products when in use. Subsequently, a plan for the initial prototype solution and its implementation is presented, with results of the system and recommendations for further development.

2 Theory of Data Collection and Internet of Things

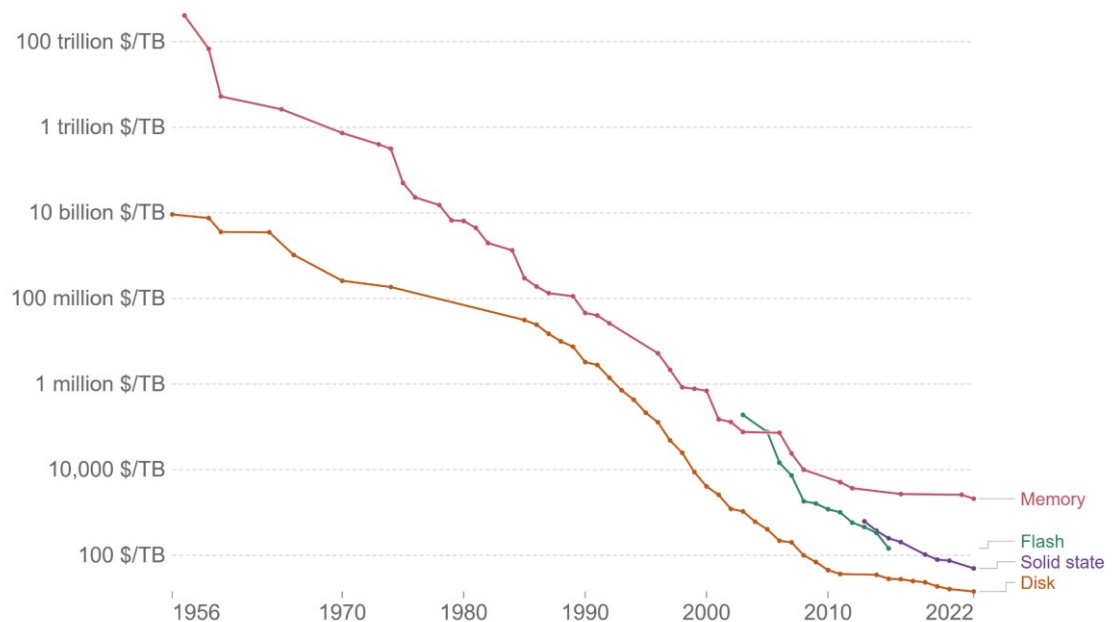
This chapter covers the theoretical background of the thesis, including the data collection and the Internet of Things. This chapter also includes a case study to present relevant theoretical concepts.

From ancient times onwards, humans have collected information to better understand systems and concepts of all kinds, from population growth to finance, logistics and science. Concrete and accurate data provides indisputable insights, which in return allows for more informative decision-making and action. Analysing data, understanding the behaviour pattern behind statistics and evolving processes have been at the core of the development of humankind. However, the human society has evolved considerably since the time of clay tablets of the ancient Near East civilizations [4]. Microprocessors have evolved enormously within the last 50 years, and with ever increasing calculation power, the feasibility of data collection, even in constrained computational environments, exists more readily day by day [5]. When combined with the decreased cost of data storage over the same period and the price of storage in 2022, as presented in the figure 2, the potential for data collection has risen exponentially as cloud and server storage opportunities can provide better services with decreasing prices.

Now just because the technological potential and infrastructure for data collection exists, it does not automatically mean that all the collected data is useful. Without understanding what type of data is collected, why the said data is collected and how the said data can be utilised, the result would be just a quantity of pointless numbers and text with wasted resources. To understand data collection, data collection systems and the internet of things better for the context of the final year project, the following chapters will dive further into these topics.

Historical cost of computer memory and storage

This data is expressed in US dollars per terabyte (TB). It is not adjusted for inflation.



Source: John C. McCallum (2022)

OurWorldInData.org/technological-change • CC BY

Note: For each year, the time series shows the cheapest historical price recorded until that year.

Figure 1: Cost of computer and memory storage between 1956-2022 [6]

2.1 Data Collection Theory

Noteworthy at this point of the thesis is that while there are a multitude of ways of data collection, for example questionnaires, forms and interviews, this thesis focuses mostly on electronic, software-based data processing systems. This is because the project was implemented as a software data collection system.

Data collection can be defined as a method of accumulating information from pre-defined and specific variables in an accustomed environment to research results for a specific issue, question, or situation [7]. Although data collection processes vary based on the line of study or business, the core of the process consists of recording desired data, analysing recorded data, and creating conclusions based on the given data. To understand data collection as a subject a little better, the following sections will go over three founding principles of data collection.

2.1.1 Type of Data

In data collection, the type of data can be split into two general categories: quantitative and qualitative data. Quantitative data, also known as numerical data, covers values that include numbers and other mathematical statistical information. Qualitative data is opposite of quantitative, and represents attributive data that cannot be statistically quantised, such as concept maps or interviews. [8, pp. 8-9.]

2.1.2 Data Quality

Data quality is more of a broad subject, but in essence represents how important, relevant, and accurate data or specific variables in a dataset are. Data quality is an important part of planning, as the quality of data has huge ramifications, both positive and negative, especially if incorrect or irrelevant data is collected. [8, pp. 15.]

2.1.3 Measurement and Sampling

When collecting data, it is important to understand the measurement process and the sampling rate of the value.

Measurement means how the value of a variable is obtained. While the complexity of understanding how a variable is measured and creating a method for the measurement can differ heavily, the significance of knowing how a value is obtained never changes. A part of measuring is to discover as best as possible a balance between accuracy and precision, with accuracy representing if a measured value is correct most of the time and precision conveying similarity between successive values. [8, pp. 26-27.]

Sampling is the process of choosing a portion of the data from the entire dataset for analysis to observe attributes and features of the entire dataset. The size of a sample is determined by the size of the dataset, but generally the size of the sample should have enough contrasting values for analysis. Since the size of a dataset and the quality of data differ a lot, multiple samples should be taken to verify the results of the analysis. [8, pp. 28-29.]

2.2 Data Collection Systems

Data Collection System, referred to as DCS, is a purpose-built system for data collection that gathers, processes, and evaluates data for collection purposes. Although these systems vary based on the specific purpose they are built for, in the case of this project, the systems that are of interest include software-based systems that collect the data from electronic sources, be they sensors or other electronic input devices. One of the aspects of the data collection systems is data storage location. For traditional, survey based electronic data collection systems, most of the software required could be run on one server computer. [9.] However, what to do if data collection itself is happening in a system of limited computational power or more importantly, limited amount of local storage space for data? This is where the concept of Internet of Things, referred to as IoT, comes into play.

2.3 Internet of Things

Internet of things is a term and concept about a network for interconnected devices using wireless communication technologies to interface between each other for remote functionality. This functionality can either be passive, like sensor data collection or active, such as driving a small electric motor. IoT systems usually include devices with limited capabilities, whether due to size or available hardware, known as edge devices, which interact with devices of significant capabilities, for example data centre servers and cloud computers.

Cloud computing usually handles data storage and processing and hosts the required interface infrastructure between edge devices and users. Typical IoT applications include functions such as task automation, sensor data logging and remote access through embedded edge devices. By leveraging IoT technologies, the functional burden of a system can be better distributed across several devices. [10, pp. 7-10.]

2.4 Case Study: Public Transportation Data Collection

To understand the data collection concepts and opportunities provided by data, this section goes over a research article by De Oliveira et al. [11]. The case study is about environmental data collection within public transport, and the potential of the data in a potential system designed around intelligent transportation systems. This case study is meant to be an example introduction to the subject of the thesis through a familiar subject, such as public transport.

In this case study, De Oliveira et al. present how data accumulated from a bus route could be utilised not only for passenger comfort but also applied in the context of Intelligent Transportation System, known as ITS. Intelligent transportation systems utilise sensors, communication technologies and data to enhance road and transportation safety, efficiency, and usage. The study first introduces the concepts of ITS and its sub-component, Advanced Traveller Information System, known as ATIS. ATIS applications collect available system data automatically. For example, bus geo-location data, can then be leveraged in route-design and schedule planning. With publications from major cities around the world, like New York, Chicago and Moscow, the case study presents how data collection and big data can be used to improve public transportation. The case study also identifies potential problems with the big data collection with respect to public transportation services, as shown by figure 2 below from the case study. [11, pp. 1-2] The figure divides data collection into four separate categories to convene issues regarding data collection in big data environment.

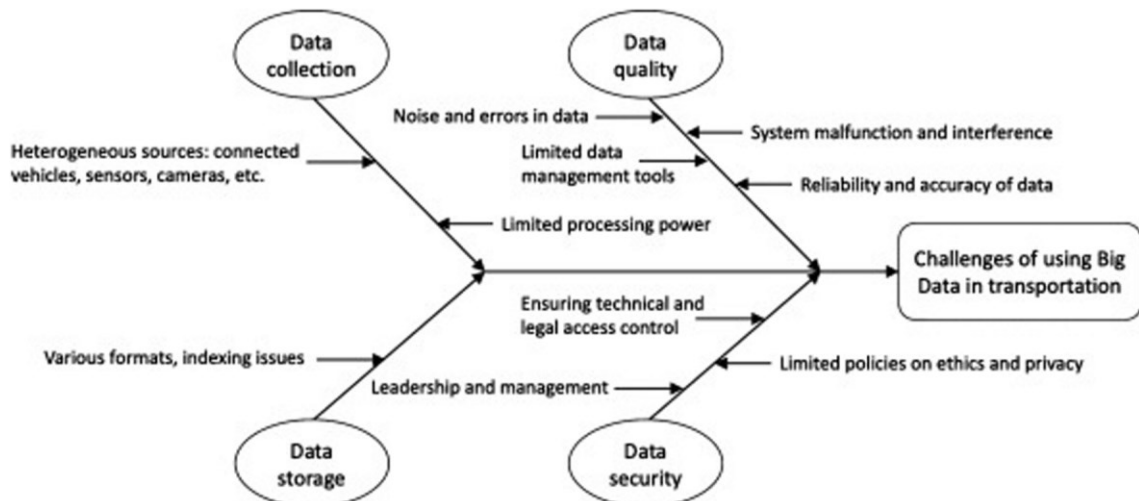


Figure 2: Issues relating to data collection in transportation [11]

The study then goes over the methods and variables for the bus route data collection. The measurements were taken from a sample stretch of a route that includes both downtown and highway roads with a singular bus stop. The following variables were collected: temperature within the bus, minimum and maximum noise level during the trip, speed on the highway and the downtown after the highway, the number of people at the start of the stretch and after stopping at the bus stop and delay of the bus leaving from the starting point comparing to the scheduled start. The data was collected every day for a three-week period, with trips at the same time in the morning, noon, and afternoon. Activity periods of vacation, school and carnival weeks were included in the three-week period. Ultimately, about 1700 data points were recorded during the period. [11, pp. 5-7]

In the results of the case study, the variables were analysed both individually by boxplot, also known as box-and-whisker diagram and together by studying the correlation between variables through Pearson coefficient analysis. For the box plots, displayed in figures 3 to 6 below, the charts visualise the following values: minimum and maximum values through data points, quartiles, where the coloured area shows the second and third quartiles with outlier values on the outside, and the median value through the horizontal line inside the box. [11, pp. 8]

The individual box-plot charts can be used to improve the services of the public transportation, as provided by the examples under the respective charts shown below in figures 3, 4, 5 and 6.

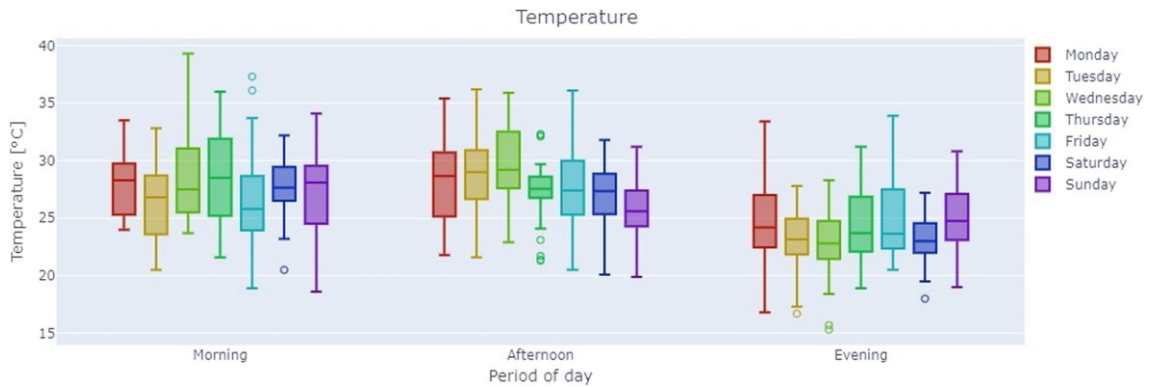


Figure 3: Temperature distribution chart [11]

For temperature, the data shows evidently the effect of weather in the differences of average temperature between the periods of day. Better air conditioning could be used in the buses to mediate this. As the measurements were taken using a digital infrared thermometer on different surface materials, some outliers can seem more excessive than the reality provides, which influences the accuracy of the results. [11, pp. 8]

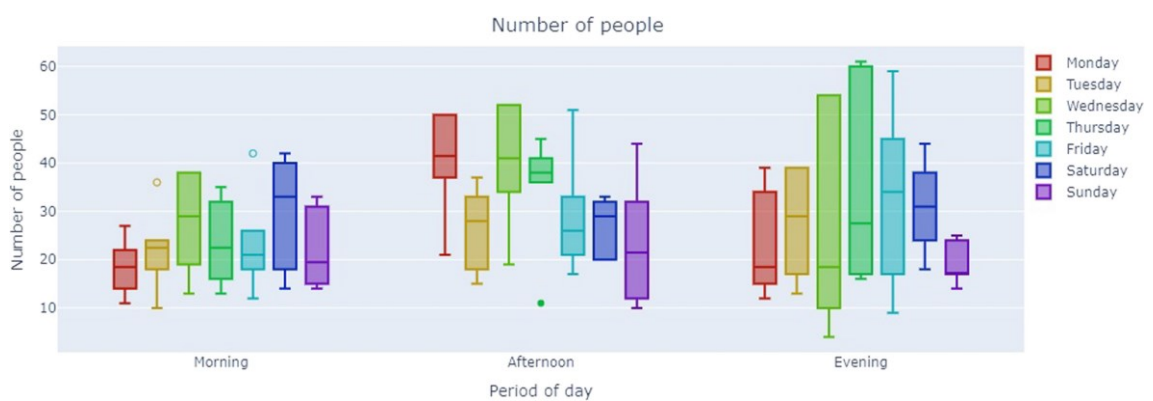


Figure 4: Distribution chart showing the number of people [11]

The number of people chart shows increased traffic during the evening period, to which the case study suggests correlation with the schedule of the university on the route of the bus. While the availability of the bus allows a less time constrained usage according to the article, figure 4 data suggests that shifts of

the bus could be concentrated and increased for weekday evenings to relieve the higher number of customers. [11]

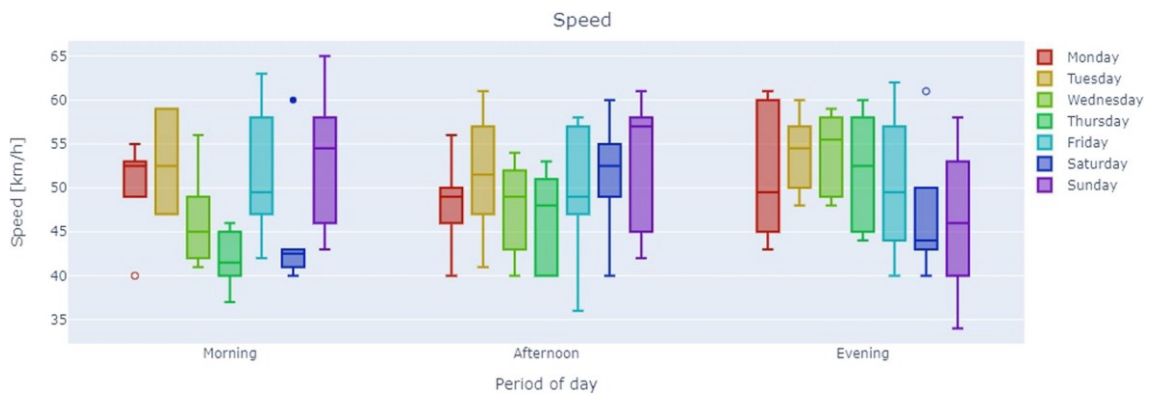


Figure 5: Speed distribution chart [11]

The speed is measured with two values, one taken when travelling through a highway and one taken when travelling through downtown. The road legal speed for these routes is 50 km/h, with a 7 km/h error margin. The median values regardless of the period suggest that most bus drivers stay within this limit. However, for the safety of the passengers, the evening and weekend quartile speeds can be improved by self-control, as there is a lack of supervision by authorities.

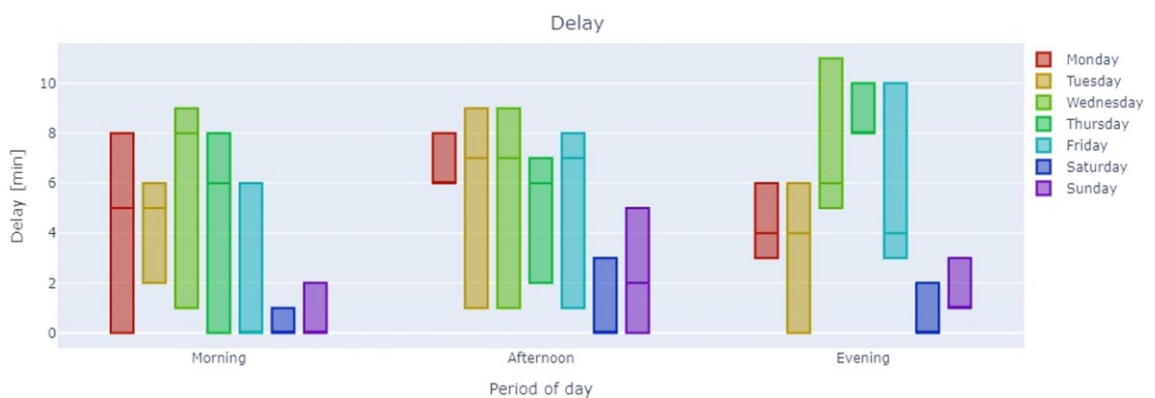


Figure 6: Delay duration distribution chart [11]

Delay data shows that a lesser amount of people, as shown by figure 4, affects the delays positively for the weekend. Delays for weekdays could be improved for more time accurate public transportation by increasing shifts for the days and periods with increased delays.

The case study also includes correlation coefficient charts between the variables both divided per day of the week and for the three activity periods during the measurement period. These coefficients are displayed in figures 7 and 8 below. The Pearson coefficient charts show the correlation between the five variables between the values of -1 and 1, where the sign of the number signals the positivity of correlation between the variables, and the absolute correlation value indicates the strength of the correlation, where 0 is no correlation and 1 is perfect. Absolute values over 0.5 are considered to have strong correlation [11, pp. 10].

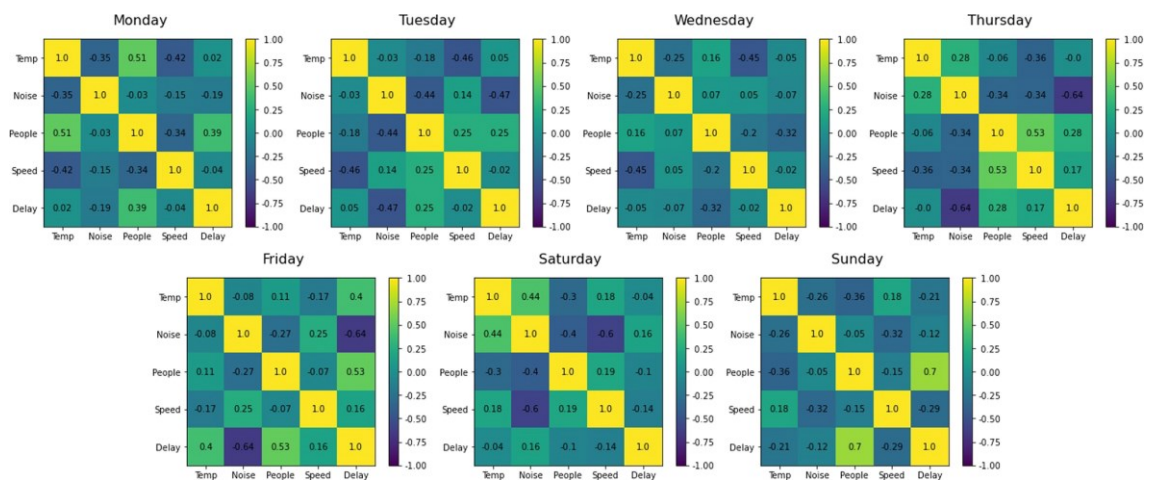


Figure 7: Correlation charts divided per day [11].

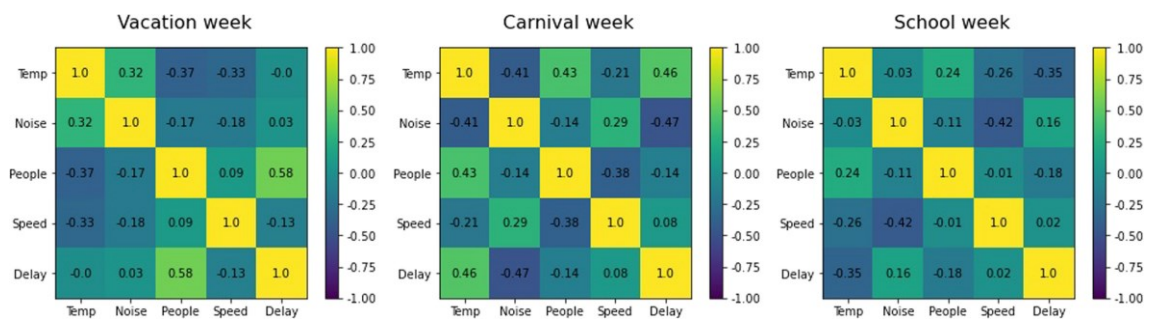


Figure 8: Correlation coefficient charts per week [11].

As shown by figure 7, at first glance, there is a considerable difference in the correlation values, but taking a closer look at the values reveals some repetition suggesting correlation, especially when compared to the individual values shown in figures 3 to 6. For instance, the number of people and delay times

have a positive correlation on Fridays and Sundays or on Mondays with temperature and people. However, other correlations like noise and delay seem not to have correlation with other singular variables, suggesting that the noise is caused by foreign elements, although engine revving higher due to attempts to catch the time difference could affect the numbers. As for the per week charts, as showcased by figure 8, strong correlation can be found from the vacation week, when looking at the people and delay correlation value, suggesting that the smaller number of people during a vacation week meant that delay times were lower. Looking at the same figure on the carnival week there are some less stronger correlation values. However, when comparing them to the individual values, the values seem inconsistent to create a clear relevancy [11, pp. 11-12].

The authors of the case study conclude the paper with reviewing the data collection methods, stating that the collection method could be extended to other forms of public transportation. They also list the three main problems with their data collection suggesting some correlation values cause false positives due to spread of the data points, insufficient amount of collected variables and a data set being too thin to make more accurate observations. The authors conclude the article adding that using a purpose-built system with cloud computing and big data systems could create more thorough analyses and create better statistical suggestions for improving public transportation, especially when connected to ITS and ATIS types of systems. To quote de Oliveira et al:

In this regard, this research can serve as a basis for future works by developing automatic systems for data collection, which could generate a more robust dataset and, as consequence, achieve higher accuracy for the decision-making process. [11, pp. 13]

2.5 Conclusions about Data Collection Systems for Practical Work

To conclude and summarize the theory part, the following aspect should be taken into consideration when developing a DCS with IoT capabilities:

- Measuring is an important part of data collection; inadequate understanding of variables, lack of variables or incorrect variables can undermine the entire data collection process.
- Optimum combination of quantity and quality of data is important, as both too much and too little data can harm end results.
- When sampling the dataset for analysis, the sample should have sufficient contrasting values. Multiple samples should be taken to ensure the quality of the dataset.

3 Planning and Development of Initial Full System Prototype

This section goes over both the planning and development of the practical work done in this project. A noteworthy comment about this section of the thesis is that, due to legal and system security reasons, certain aspects of the system cannot be described completely. For this reason, generic terms will be used to explain certain aspects of the practical work ecosystem and most of the information about relevant devices and products are from publicly available sources.

The concept of the practical work was to develop and integrate a diagnostics data collection program into the Planmeca XFI full body X-ray device ecosystem, where the XFI X-ray device's hardware component data would be collected both during imaging sessions, idle use and when the device encounters errors during operation. While the data will be collected and measured within the XFI ecosystem software, it will not be directly sent by the XFI ecosystem. For this purpose, Planmeca has an upcoming product, referred to as Gateway for the purposes of the project. The purpose of the Gateway in general is to connect products within Planmeca device catalogue for statistical analysis and data collection of general device usage, including for example imaging session times, instrument usage and wash periods, medical device log acquisition, remote status monitoring and other related functionalities. In the case of the project, the Gateway receives the packets of data, that either include hardware data register values or absolute sensor values. This data is meant to be more detailed than what is currently received as the current data includes basic information about the device and its usage. The Gateway software will then do light examination of the data, such as deciphering the hardware data registers to the absolute value representations, before sending the values to the backend API for data storage and further analysis. The goals of the data collection system once implemented are the following:

- Diagnostics data from the hardware components can be sent from the XFI to the Gateway and then recorded to the cloud database.

- The data collected can display XFI's hardware component status and sensor values.
- This data could then be used to predict component lifecycle or used for remote troubleshooting.

3.1 Devices and Components of the Wystem

This section covers and presents the relevant devices and components for the diagnostics data collection system. The system architecture, where the components are combined, will be presented later.

3.1.1 Planmed XFI

Planmed XFI is a full body capable Cone Beam Computed Tomography (CBCT) imaging X-ray system, able to take images of both patients lying on the patient bed and standing up under natural load. Illustration can be found in Figure 9.



Figure 9: Illustration of Planmed XFI device with a patient in a lying down position [12]

In CBCT imaging, an X-ray tube produces a cone-shaped beam that is typically rotated 360° around patients. During the rotation, the beam strikes against a detector panel, which generates signals for image reconstruction. Illustration

can be found in Figure 10. When comparing CBCT to other computational tomography examinations, the radiation doses are usually reduced. However, the overall amount of radiation delivered is commonly higher in CBCT imaging, which can be a concern with patients sensitive to radiation, especially with 3D imaging [13]. However, the accuracy and ability of 3D imaging over a traditional 2D image taken with a regular X-ray device outweighs the risks of radiation when X-ray images are necessary [14]. Planned XFI has also an Ultra Low Dose mode for sensitive patients and utilises lower dosage cone beam technology [12, pp. 4].

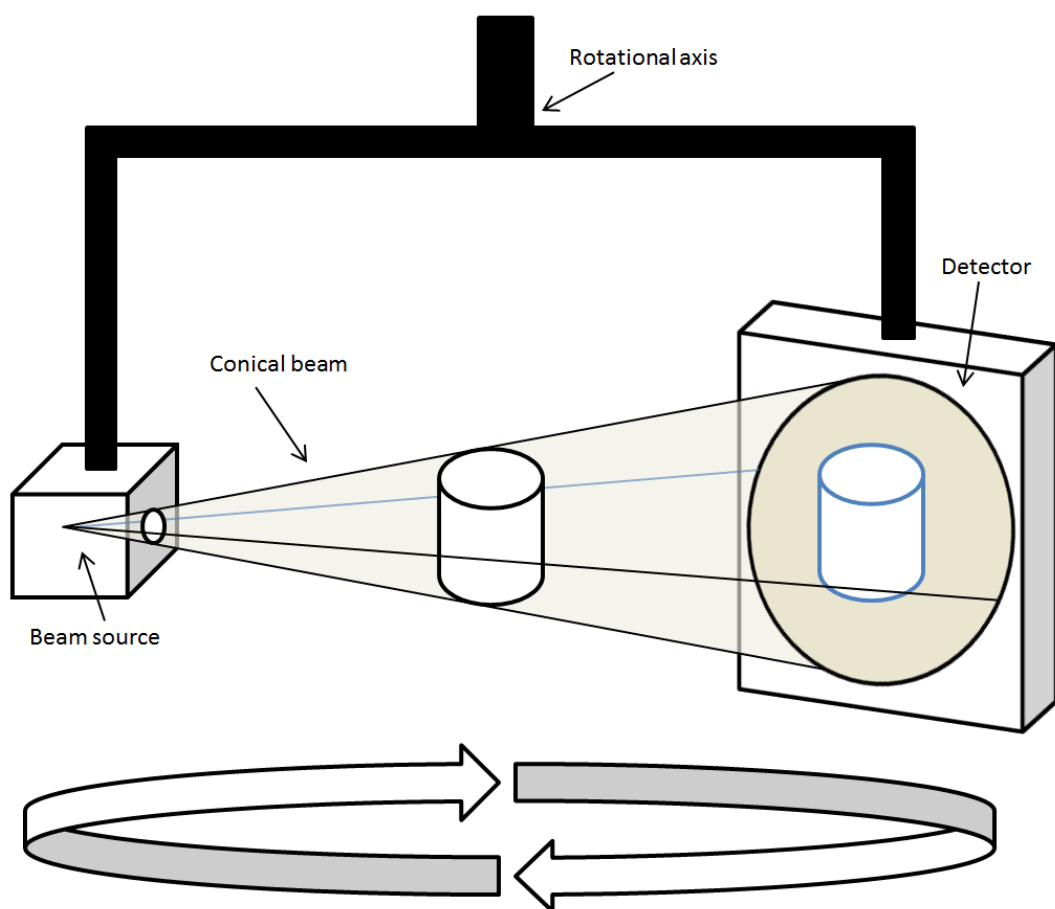


Figure 10: Illustration of CBCT imaging, the cylinder in the middle representing a patient or a point of interest. [15]

XFI can take both 2D and 3D images including musculoskeletal imaging which helps with orthopaedic treatment planning, head and neck area imaging, oral and maxillofacial imaging and full body imaging with the patient standing up. XFI is equipped with a remote controller that allows the use of device

functionalities without requiring the device operator to stay on the workstation [14].

At the time of writing this thesis, the Planned XFI is in the process of being approved and marked by both CE and FDA [12].

3.1.2 Gateway

The Gateway is a router-like device, measuring about 8 centimetres in width, 20 centimetres in length and 5 centimetres in height. The Gateway is equipped with both wired and wireless network connections, including multiple RJ-45 ethernet ports, wireless WiFi radio and a cellular broadband network router with an internet connection enabled SIM-card as backup connection. The Gateway is an embedded device, running an embedded Linux operating system, that then runs all the software developed for the Gateway.

The Gateway principle of design is to be able to connect to Planmeca Group's products via the Ethernet connection and collect data from Planmeca's devices to benefit the customer, for example tracking the washing cycle of dental instruments and enforcing appropriate hygiene through data logging. The data is sent to the cloud database for storage and analysis. In addition to the Gateway system, a user interface website also exists that displays the data collected by the Gateway through user friendly graphical charts. Illustration can be found from Figure 11.

The Gateway's functionalities provide the opportunity for the proposed data collection system, as it acts as the link between the XFI and the cloud storage and filters the data sent by XFI. While the data collection system concept is presented below, it is important to note that the Gateway is one of the main components in realising the central concept in this project.

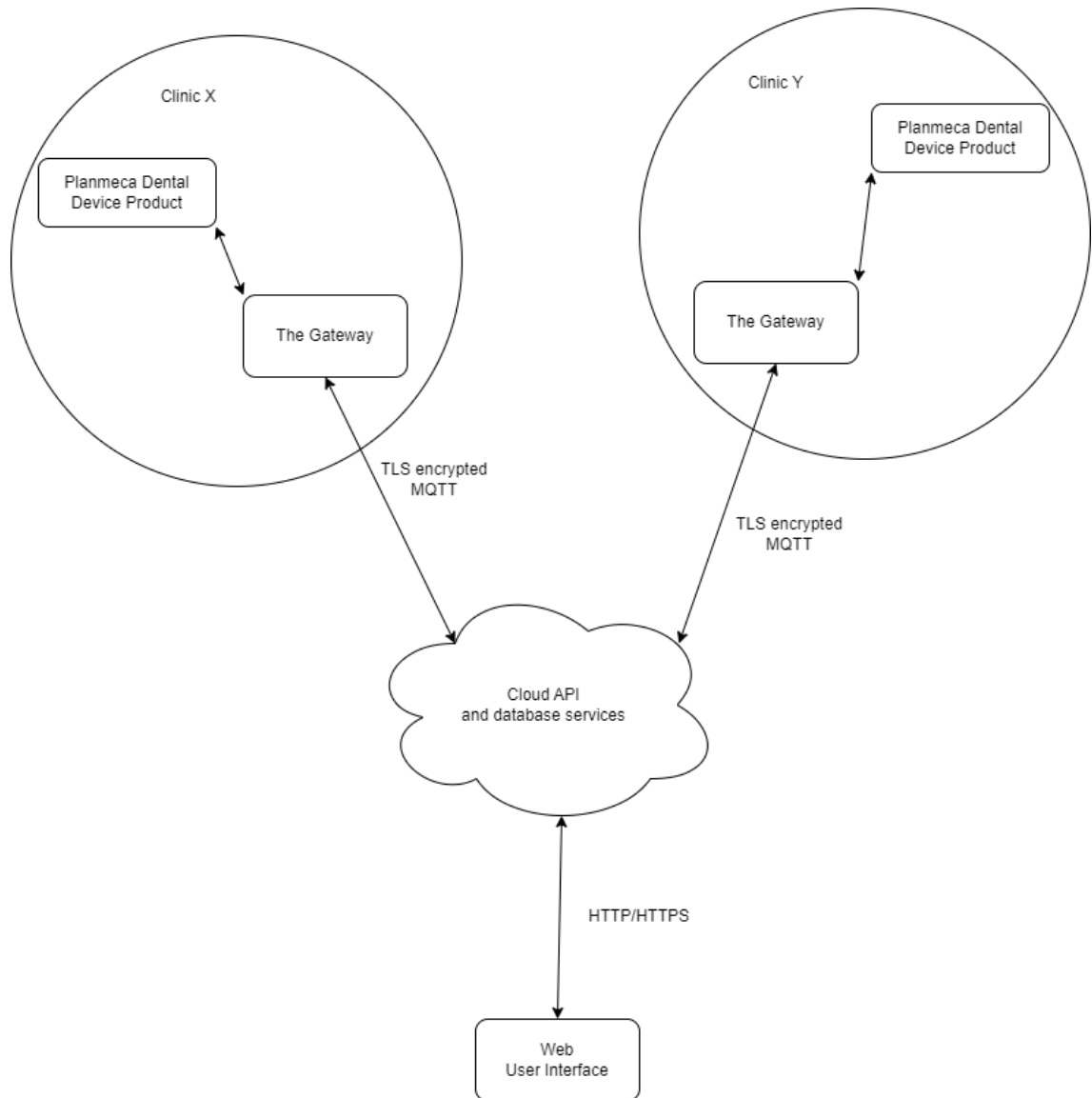


Figure 11: The Gateway ecosystem illustration

3.1.3 Backend and Frontend systems for the Gateway

Backend systems contain all non-user visible system components that run in the background, for example application programming interfaces between the Gateway and the user interface. The backend is running on a cloud server. The backend includes all the services related to data and event collection of the Gateway. Backend also stores all the event and usage data in database service and provides the processed data to the user interface.

The Frontend is a user interface that comes in the form of a web application that is compatible with both desktop and mobile users. The web user interface will be a part of Planmeca Group's extranet called Planmeca One. Planmeca One is a web platform for distributors of Planmeca products among other provided functionalities.

3.2 Inter-device Communication Technologies

This chapter explains the communication technologies used in the diagnostics data collection system between the devices and systems mentioned in the previous chapter.

3.2.1 DDS

DDS, an abbreviation for Data Distribution Service, is a software protocol and application programming interface standard designed around data messaging in systems of scalable size. DDS is managed by The Object Management Group, a Non-Profit technology standardisation consortium. As quoted by the DDS foundation's webpage explaining the protocol: "It integrates the components of a system together, providing low-latency data connectivity, extreme reliability, and a scalable architecture that business and mission-critical Internet of Things (IoT) applications need." [16.] The DDS functions using common networking protocols, TCP (Transmission Data Protocol) and UDP (User Datagram Protocol) to create a communication layer for a predetermined DDS Domain. Devices with the same domain can then communicate under defined topics to publish messages meaning to send messages to other devices under the same topic. These are referred to as data writers. Devices can also subscribe to the topic, meaning listening and receiving messages from the said topics. These are referred to as data readers. Timing and content filters can be added to both data writers and readers. Topics, data writers and readers have the quality-of-service specification, which determines settings and parameters in matters of security, data delivery methods, priorities, received topics and resource limits

among others. In figure 12, shown below, shows an illustration of how DDS functions can be found. [16.]

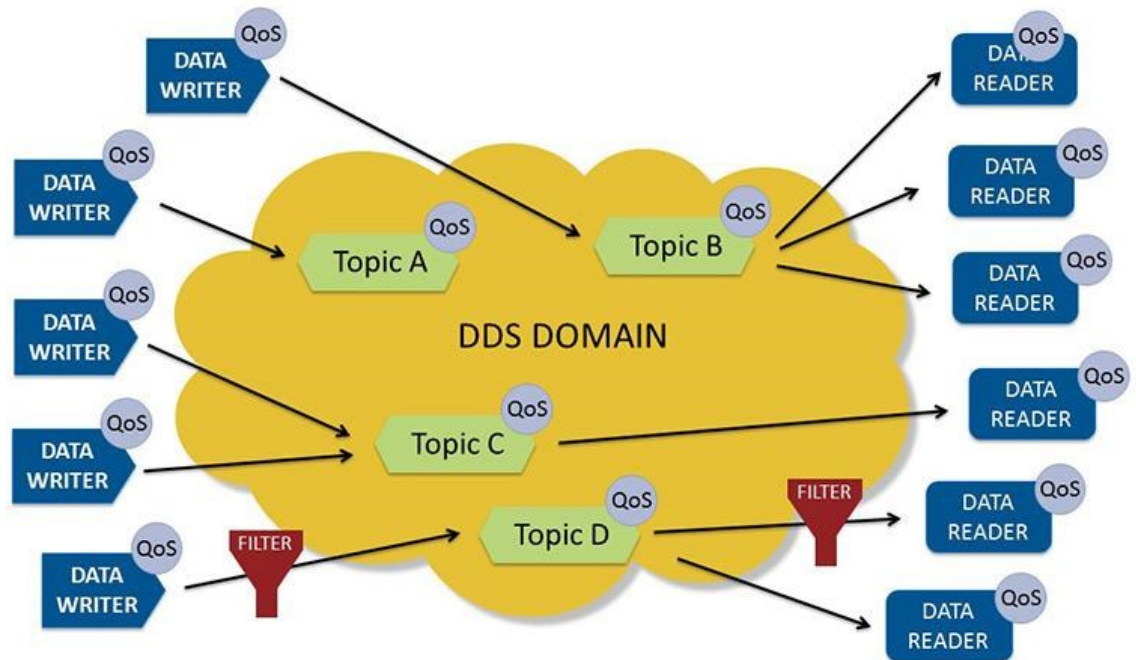


Figure 12: DDS functionality illustration [16]

Data storage within DDS from an application's perspective happens on a device's local storage. Devices store only the amount of data required. Sending messages automatically update relevant nodes within the network; however, when connected, the system is given an illusion of a global data store due to all the nodes creating the complete set. This system is referred conceptually as a global data space. DDS has its core software implementations in multiple different programming languages. [16.]

3.2.2 MQTT

Message Queuing Telemetry Transport (MQTT) is publish-subscribe type messaging protocol designed to be as lightweight as possible for devices of varying computational power. The protocol is used by IoT devices to send and receive data. MQTT communication works on a client-server model. Client devices connect to a MQTT server, referred by the protocol as 'broker', that

enables the communication between MQTT clients. Clients send messages to specific topics, referred by the protocol as 'publishing messages. Other clients connected to the broker can then bind to the said topic, referred to by the protocol as 'subscribing to a topic' to receive and interact with the messages under the topic. The communication in a topic is bi-directional, meaning that a single client can both publish and receive data from a topic. [17.] An example of MQTT communication architecture can be found from Figure 13.

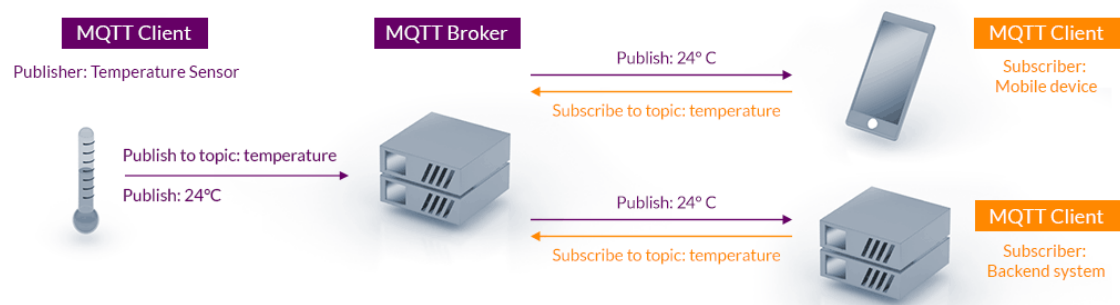


Figure 13: Example of MQTT communication architecture [17]

MQTT was originally designed and developed by Andy Stanford-Clark and Arlen Nipper to connect oil pipeline telemetry system communicating through satellites in 1999. The protocol was released for public use in 2010 and standardised by the non-profit organization OASIS Open in 2014. [18; 19.]

3.2.3 HTTP

Hypertext Transfer Protocol (HTTP) is an application-layer client-server model communication protocol, designed to transfer different types of media, including plain text, HTML documents, videos, and pictures. The HTTP protocol was initially proposed as one of the pillars of the World Wide Web by Tim Berners-Lee in 1989 to transfer hypertext documents over already existing IP and TCP protocols. HTTP has been standardised, with different iterations adding features to the protocol and HTTP has become the de facto transfer protocol on the Internet, and it is used to transfer multitude a of hypermedia, including

webpages and application data. HTTP also includes a secure communication protocol, HTTPS (Hypertext Transfer Protocol Secure) which includes Transport Layer Security, commonly known as TLS, to encrypt the data transmitted by HTTP. Below, figure 13 shows how HTTP provides content for a web document. [20]

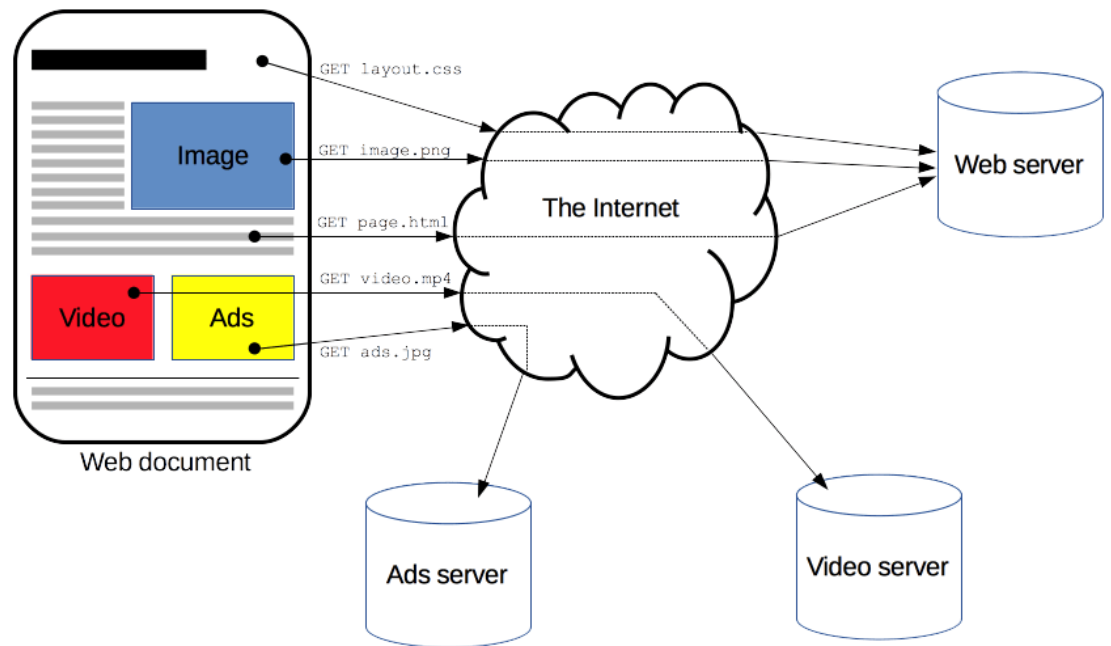


Figure 13: HTTP usage in a web document [21]

HTTP functions by HTTP requests and responses, where the client sends an HTTP request, which includes an HTTP method, protocol version and header-information such as host address, type of content request, timestamp, and other related information. The server then responds with the HTTP response, which includes HTTP protocol version, version code, headers like the request and the content requested in a form specified by the request. Common types of content are text based. The HTTP protocol includes different types of request methods and response codes to determine the type of request or the success of the response. [21.]

3.3 Data Privacy and Health Data Regulation and Security Standpoint

When collecting data, whether it be electronically or physically, it is important to consider the data privacy laws, especially in an international environment. While the goal of the project is neither to collect nor process any personal data and limit accidental exposure to such data as much as possible, it is important to understand how such data is defined in regulation for the purposes. However, going over all the 193 UN listed countries of the world with separate data privacy laws would take up an entire thesis on its own [22]. Due to this reason, example cases of data privacy laws regarding medical data are used from the European Union's General Data Protection Regulation (GDPR) and the United States Health Insurance Portability and Accountability Act (HIPAA).

3.3.1 GDPR Medical and Personal Data Privacy

The European Union introduced the General Data Protection Regulation on 14th May 2016 and started to enforce the legislation on 25th May 2018. This legislation defines rules and requirements around personal data of natural persons, referred to as data subjects, on how personal data is to be managed and access to personal data by their respective data subjects. Under the article 4(1) of the aforementioned regulation, personal data is defined as follows: “‘personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;”. [23.] The same article also defines the terms genetic data, biometric data and data concerning health in paragraphs 13, 14, and 15 as follows in their respective order:

‘genetic data’ means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question. [23]

'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopy data;”, “data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status. [23]

Under articles 5 and 6, the regulation defines how data shall be processed and the lawfulness of personal data, which states that processing of personal data shall be lawful, transparent, adequate, defined transparently and explicitly, purposefully, securely and limited to only what is necessary. The lawfulness of the collection and processing of personal data can be acquired through the data subjects' permission, under legal obligation, be necessitated through protection of essential interests, public interest or under performance of contract. The regulation also defines how to process special purpose personal data, such as the ones defined before. In article 9 of the regulation, special data category processing is prohibited unless allowed by mostly the same reasons as the general lawfulness in article 6, although these also include data processing for medical reasons, public interest, and health or archival of data for scientific and historical purposes. [23.]

3.3.2 HIPAA Medical Data Privacy

In the United States of America, the key legislation relating to matters of healthcare information is the Health Insurance Portability and Accountability Act of 1996 also known as HIPAA. While there exists separate regulation for medical device standards, data protection for healthcare industries, which includes medical device manufacturers, fall under HIPAA. Medical devices that are used to create data points, are protected by HIPAA [24]. Figure 14 presents the basic information about HIPAA. HIPAA includes a section added in August of 2002 referred to as Privacy Rule. Privacy rule introduces regulations regarding medical and healthcare data such as which data constitutes as protected data which is referred in the standards as protected health

information, how the said data can be disclosed and what legal entities are considered protected under Privacy Rule standard. [25.]





HIPAA	<p>The Health Insurance Portability and Accountability Act (HIPAA) is a national standard that protects sensitive patient health information from being disclosed without the patient's consent or knowledge. Via the Privacy Rule, the main goal is to</p> <ul style="list-style-type: none"> • Ensure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well-being. 		<ul style="list-style-type: none"> • Every healthcare provider who electronically transmits health information in connection with certain transactions • Health plans • Healthcare clearinghouses • Business associates that act on behalf of a covered entity, including claims processing, data analysis, utilization review, and billing 		<p>Protected Health Information²: Individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates, excluding certain educational and employment records</p>		<ul style="list-style-type: none"> • To the individual • Treatment, payment, and healthcare operations • Uses and disclosures with opportunity to agree or object by asking the individual or giving opportunity to agree or object • Incident to an otherwise permitted use and disclosure • Public interest and benefit activities (e.g., public health activities, victims of abuse or neglect, decedents, research, law enforcement purposes, serious threat to health and safety) • Limited dataset for the purposes of research, public health, or healthcare operations
<p><small>1. Permitted disclosures mean the information can be, but is not required to be, shared without individual authorization.</small></p> <p><small>2. Protected health information or individually identifiable health information includes demographic information collected from an individual and 1) is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse and 2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual; and</small></p> <p><small>(i) That identifies the individual, or</small></p> <p><small>(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.</small></p>							

Figure 14: HIPAA information card [26]

HIPAA Privacy Rules cover most aspects of the healthcare industry, including health plans, health care providers, health care clearinghouses and related business associates relating to the aforementioned. While there exist some outlier cases, the regulation covers entities either directly or indirectly involved in healthcare. Information, that is labelled as Protected Health Information includes all of individuals' physical or mental health information and conditions, treatments to individuals or payments for treatments done by the individual, regardless of the time of occurrence, so future cases are also protected, past or present. This type of protected data requires careful and secure handling, use and disclosure and for example notifying related individual(s) if data is shared. However, information, such as de-identified health information, is not restricted in use or disclosure, and under certain limits, protected health information can be used for research purposes and limited data sets are allowed but require removal of information directly associated with an individual. Incidental use and disclosure are also permitted but the said shared information should be reduced to minimum necessary and safeguards for data sharing per standard must be implemented. [25.]

3.3.3 Conclusions Relating to Data Privacy

To satisfy at least the regulatory requirements, set forth in the previous chapters, it should be noted in the data privacy agreements of the XFI system, or the Gateway explicitly which type of diagnostics data is collected and why to avoid regulatory challenges. While the intention of the diagnostics data collection is not to collect personal data or personally identifiable data, confirmation is required by the XFI program managers that absolute values of the diagnostics systems are not considered personally identifiable settings. For example, is the size of the patient identifiable from the diagnostics data that is collected. Furthermore, while X-ray images themselves are considered by both regulations to be sensitive medical data; the diagnostics data does not reflect the final image, nor can it be re-created from the said data. What also seems to be important based on the set forth regulations is to disclose the diagnostics data collected under data privacy related contracts for effortless diagnostic data collection and handling. Datasets created by the diagnostic data collection can also be obfuscated by removing or generalising the collected device identification information to help comply with regulatory requirements.

3.4 Concept of the Prototype Data Collection Solution

The planning of the prototype started in February 2023 with going over both internal documentation and publicly available sources regarding relevant technologies and systems affecting the data collection process. As there exists multiple components that affect the data collection process, ranging from real-time embedded frameworks to networking middleware software and the related hardware components of both X-ray machine and the Gateway, some time was required to grasp at least a basic understanding of full system architecture to make informed decisions about the direction of the development for the prototype solution.

This study revealed well both the existing tools and the data created by them and the scope of the prototype project itself. Going over internal documentation,

the study showed that the system already sends some data through the DDS interface, that the Gateway can access. It also showed that there already are some diagnostic tools for the XFI system, but these tools can be only accessed manually and locally from the device itself. These data sources and diagnostic tools provided insight for how the data sending can be done and what type of data sources can be used for the diagnostics data collection. The study also demonstrated that to create the prototype solution and the initial structure for the data collection, software changes were required for multiple devices, both to the devices presented in this thesis and to internally presented devices, and to multiple, separate internal software source code repositories. The development of the software and communication interfaces would require using multiple different programming languages, for example Go, C and C++. While the proportion of changes would vary individually, the amount of work would be tremendous.

After going through the relevant material and mapping out the amount of work required for the initial prototype, it was decided that the data collection system development would be done one step of a system layer at a time, starting from the X-ray machine software, continuing to the related software API and components within the XFI ecosystem, then to the DDS interface communication definitions and finally to both the Gateway software and relevant database data tables. Figure 15, found below illustrates the prototype solution for the data collection on the system device and component level and how the devices in the system communicate with each other.

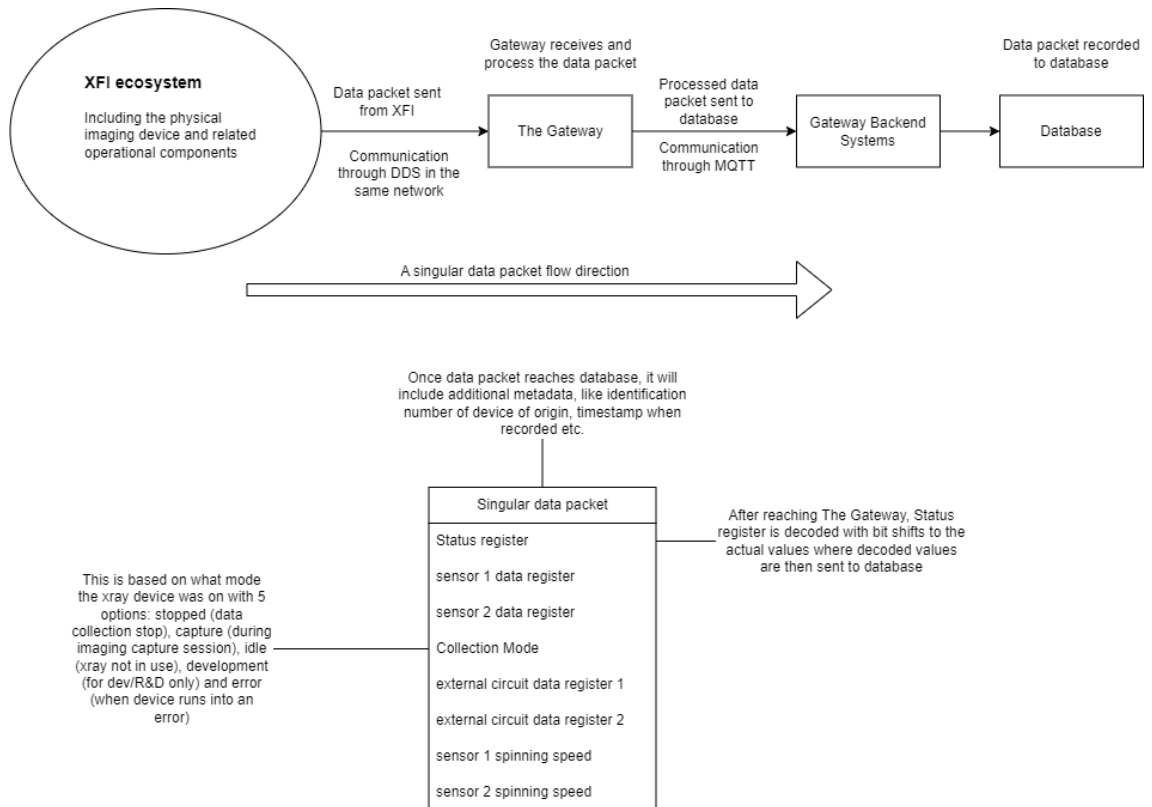


Figure 15: Illustration of the data collection ecosystem plan

As shown in figure 15, the diagnostics data collection is based on data packets sent from the XFI X-ray device to the Gateway, which then processes them and forwards them to the database for record retention. Starting and stopping of the data collection is designed to require manual activation in the prototype solution, but the design considers future development of automating the data collection process, for example through the collection mode of the data packet. Manual activation is situated in the XFI ecosystem's workstation user interface under a protected setting menu. The menu has four settings for data collection, as shown in figure 16 found below. The data collection is started by pressing on one of the "Start ... Data Collection" buttons and stopped by pressing the "Stop Data Collection" button. The data collection modes are related to an enumeration variable of collection modes, details of which are explained in further detail later in this chapter.

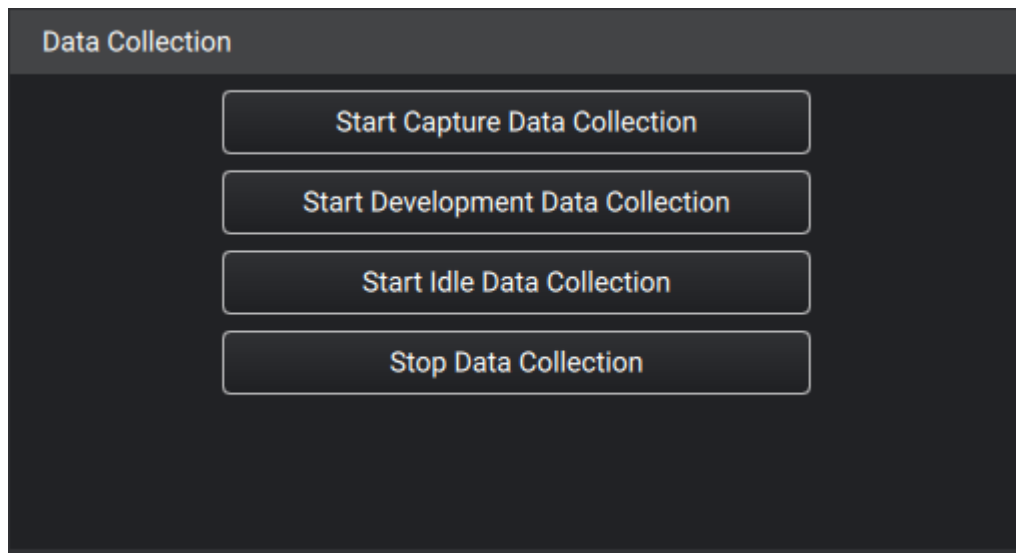


Figure 16: Data collection activation menu

A singular data packet consists of 7 unsigned integer values taken from different hardware data register addresses of the XFI X-ray machine. The size of the integers varies between 16- and 32-bit variables based on the size of the register address value. Going through the available data sources for the register addresses and comparing them to other diagnostics tools already on the XFI device, it was revealed that not all data sources are available for the central processing unit of the XFI. The decision was then made that the prototype solution would send certain existing values to prove the system works and further data sources could be added after the initial prototype development. A singular data packet also contains a collection mode value. This value is an enumeration value of different collection modes, which are: stopped, capture, idle, development and error. The explanation for these values goes as follows:

- The 'stopped' value is used during the manual activation of the collection, and not usually visible on a data packet.
- The 'capture' value is used to indicate that the data packet was sent during image capture session.
- The 'idle' value is used to send data packets when the device is not in use during an image capture session.
- The 'development' value is reserved for research and development purposes for the developers of the XFI.

- The 'error' value is sent when the XFI device encounters an error in the device and sends a diagnostic data packet of hardware values during the error state.

These enumeration values are also used for both the manual activation of the data collection and programming the interval setting of the data packets. In Table 1, the interval times are listed in relation to collection mode. The table does not include stopped and error collection mode, as both are situational collection modes instead of interval-based collection modes.

Table 1: Collection mode packet send intervals.

Collection mode	Interval in relevant time unit(s)
Capture	3000 milliseconds, 3 seconds
Development	900 milliseconds, 0.9 seconds
Idle	5 minutes

Once a data packet is handled by the XFI ecosystem, it is sent out to the Gateway through the DDS communication interface. The DDS message and its data fields are built to be like the data packet, but include certain metadata required by the communication interface, for example node identification field referring to the identifier in the network that sent the DDS message. The Gateway connected within the same network and under the same domain identification should receive the DDS message. The gateway will then first decode the DDS message and then encode it in a different format. The values of the data packet are then obtained from this encoded message. While the data packet field values are captured as sent, the status register, as shown in Figure 15 singular data packet table, includes multiple data variables based on bit manipulation, meaning that this register is decoded to receive all the variables included. Once the status register is decoded and all the data packet values are captured, data is sent through a secure and encrypted MQTT

message to the Gateway's backend systems, which will then provide the data packet to the cloud database for recording. The recorded fields are presented in Table 2. Once data is recorded in the database, it can then be accessed for further purposes. The database API allows to fetch data in different formats and styles, such as from a certain period or only to fetch certain data fields.

Table 2: Singular database record key names

Data field-key	Explanation for the field
messageType	String, metadata for the database API
deviceId	String, identification of the device of origin
messageId	String, metadata for the database API
timestamp	Date, the time when the data was recorded to the database
gatewayId	String, identification for the gateway of origin
collectionMode	String, the mode of collection from the data packet
safetySwitchStatus1...3	Boolean, activity state of three switches, included in status register
testMeasurement1...3	Number, test measurement from three different sources
testBusyBit	Boolean, shows whether test run is active

readyForExposureBit	Boolean, shows whether XFI is ready for radiation exposure
synchronizationLedBit	Boolean, show whether data synchronisation LED is on or off
circuit1DataValue	Number, Circuit 1 data register value
circuit2DataValue	Number, Circuit 2 data register value
sensor1DataValue	Number, sensor 1 data register value
sensor2DataValue	Number, sensor 2 data register value
sensor1SpinningSpeed	Number, speed of the spinning of sensor 1
sensor2SpinningSpeed	Number, speed of the movement of sensor 2

The data will be initially presented through Microsoft Excel charts by manually importing the requested data to Excel and then creating charts and other presentations from the data. There exists a graphical user interface for the Gateway system, as discussed in the previous chapter. However, due to company internal reasons, the plans to present the collected data will be developed later.

While the plans for this data collection system, such as to use data for preventive maintenance or to predict lifetime of the hardware components, have been discussed with the company, these concepts are out of the scope of the solution and unobtainable in the presented timeframe for the project. The products mentioned in this thesis are still in development and as such the data

required for the concepts is unavailable. Moreover, the skills to understand these concepts require understanding unavailable for now.

3.5 Development of the Prototype

After the overarching plan, as described in the previous chapter, for the development of the prototype was conducted, the practical work for the prototype development started. As described in the plan for the prototype, the software would be developed one system component at a time, starting from the XFI ecosystem.

The software development for the XFI ecosystem proved to be the most difficult part of the entire process. While producing the necessary code for the data collection system was not the most difficult task, attempting to run the code hardware of the XFI device proved difficult initially. This was solved after better hardware tools were provided and loaned by the team in charge of the XFI software development. What also corroborated the difficulties encountered were differences in the operating system used to develop the software and run the software, as some of the operating components of the XFI ecosystem used a different operating system than the provided computer for the development. This issue was mitigated to an extent by utilising virtualisation of certain systems through a virtual machine. However, this limited certain functionalities of the XFI ecosystem. Although these limitations did not affect the data collection system directly, they affected the timeline of the development, delaying the progress for about a month's time. In the end, the software developed for the XFI ecosystem mostly resembled the plan described in the previous chapter, with some notable exceptions:

- The idle collection time had to be changed from 5 minutes to 1 minute due to the limitations with the maximum number representable by the XFI device delay-function.
- The available data sources for the data packets had some overlapping with other diagnostic data sent out by the system and the relevance of some of the available data were questioned. Some of the responsibility of which can be blamed on lack of understanding and research of the data sources, although for the prototype solution

the current data sources were deemed good enough by the XFI team management.

- Due to the lack of different data sources available, there also exists a lack of error specific data sources when the device encounters an error, and an error data packet is sent.

The next step of the development process was to develop the interface definition for DDS to establish a common communication logic between the XFI and the Gateway. This interface definition was developed with the help of the company employee responsible for DDS communication and was a relatively simple task in the entire data collection system implementation. The DDS interface matched the plan and did not offer any major issues.

The final step of the development process was the Gateway implementation and related database definition implementation. Software changes for the Gateway were developed to a couple of different software components mainly due to internal communication of the Gateway and how DDS messages are processed. The data packet status register value decoding was developed to happen through bit manipulation to obtain the separate parameters. The planned implementation translated well to the practical software implementation and did not cause major issues or deviations from the plan.

Overall, the development of the prototype solution complemented the plan effectively, with some deviations in the XFI part as listed above but the effect of these did not greatly affect the overall goal of the implementation.

4 Results and Objectives for Further Development

This chapter goes over the results of the prototype system, including the performance, data produced by the system, the limitations of the prototype and plans for the further development of the prototype.

4.1 Results of the Development of the Prototype

Once all the parts of the diagnostics data collection system were developed, the resulting prototype began testing in the company laboratory. A test setup was installed in the laboratory to match the intended operating environment for the entire system. An illustration of the test setup can be seen in Figure 17.

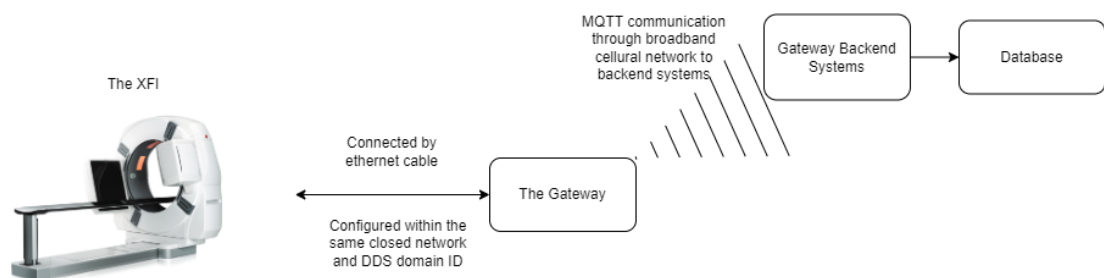


Figure 17: Illustration of the laboratory test setup

As shown in Figure 17, the Gateway and the XFI are connected to each other through an Ethernet cable to establish the connection in the same network, which is important for the DDS communication. The Gateway requires some internal configuration done manually to its network settings to facilitate the communication in the same DDS domain, but most of the setup on its end is automatic. In the test setup, the broadband cellular network is used to facilitate the communication and while the Gateway can use either wired or wireless internet connection to send MQTT requests, both the laboratory setup and some client installations usually create closed networks for security purposes, meaning that the broadband cellular network provides an independent connection for the Gateway to function as intended.

The expected functionality of the test setup was confirmed during the development of the data collection system, while simultaneously the basic functionalities were tested. Both the test setup and the system functionalities met the requirements of functionality, and testing proceeded to the next step, testing the diagnostic data collection system during imaging sessions.

The test was conducted using two different 3D imaging protocols. These two protocols were chosen, because these modes had confirmed support in the XFI's development version and were from different areas of the body, meaning the values of the sensor data would theoretically be different and data include visible variation of quantitative data.

While running the imaging protocols with diagnostics data collection active, the test also observed how running the diagnostics data collection affected the performance of the XFI device and the Gateway during an imaging session. Observing the overall performance, there seemed to be no visible effects. Moreover, neither of the devices have major deficits in the software during an imaging session. The reliability for the retrieval of data packets was determined to be on a high level, as no data packets loss was perceived when observing the data packets separately from each of the data collection system's components log messages.

The test data results referred in the following paragraphs can be observed in Tables 1, 2, 3 and 4 in Appendix 1.

When observing the data records from the imaging sessions, the captured data did not match the expectations. The data observed included less variance than initially expected. When observing the data with Capture mode interval, the interval proved to be too long to see enough variety in the status register's decoded variables. The development mode interval seemed to be better for overall data collection, as it proved to show more variety even on the status register decoded values. Although the data variance was low, consistency and repetition in some of the values were found to match expectations: For

example, the safety switch statuses did not change during imaging sessions and the exposure ready status was consistent with exposure states during a single imaging session. Motor movements were visible from the spinning speed data, as driving the motor would cause the spinning speed of sensor 2 to its maximum data value. Another expected data behaviour was the test bit, as every time it would be active, meaning the status would be TRUE, the values of the test measurement values were zero, and the values would be visible once the test bit was FALSE. The data point with most variance regardless of collection mode or imaging protocol was the sensor 1 data register as it had multiple unique values, the amount of which varied per collection mode.

The data did provide status information, which was one of the intents of the data collection system. However, due to only obtaining results from normal operating conditions, the data did not produce any significant outliers. When comparing the data to the information provided by other diagnostics tools, the results of the data collection did not match as expected as the data shown by other diagnostics tools seemed to provide results of interest set by the XFI team managers. The collection of non-essential data and its understanding was somewhat caused by the lack of understanding and lack of documentation on certain data points. When comparing the results to Figure 2 of the case study chapter about the issues of big data collections, this issue realised in the system can be recognised in the 'Data Quality' branch of the figure, through the reliability and accuracy of the data when considering the mistakes made in choosing which data sources were chosen for collection. Also considering changes required due to these errors, the data formatting can arise as an issue due to different type of sensor data collected, as noted in the 'Data Storage' branch of the figure.

Sometime after these datasets were taken, it was noticed that there was a missing field, the sensor 2 spinning speed. After investigating the issue, it was noticed that in the database definitions, the field had been forgotten from the record. This issue was fixed. However, due to equipment issues in the laboratory, replaceable data was unobtainable at the time and for this thesis.

4.2 Reception and Plans for Future Development.

After running the tests and observing the results of the test data and overall development and performance of the system, conclusions about the data collection system were made.

The development managers of the XFI overall were excited about the functionality the system provided, how it performed while running imaging protocols and the fact that the recording of the data was successful from end-to-end in the test setup. However, the validity of the collected data was raised as an issue, as the data registers collected in the prototype version seemed not to be the priority data wanted by either the hardware or the software team, meaning that one of the prior goals for further development of the prototype should be to acquire and develop beneficial data sources. This led to a meeting with the hardware engineers discussing data sources for future development, where suggestions for what type of data the hardware engineers find interesting and important were told. After further discussions with the XFI team management, a following development plan was agreed to for the data collection:

- Change the collected data registers to better match the requisites set by both the hardware and software teams, including temperatures of components, different status registers, voltage, and current values of components.
- Reflect changes on collected register to both the DDS communication interface and to the Gateway software.
- Move the diagnostics data collection software to a separate processing unit within the XFI device to give better access to hardware resources for the diagnostics data collection.
- Automate the starting and stopping of the data collection by placing the start data collection commands to the collection modes they represent, for example to put capture collection at the start of an imaging session. This also requires adding a master switch to the diagnostics data collection to ensure it can be manually activated and deactivated if needed.
- Add a level of filtering within the XFI ecosystem for the data packets to for example better process repetitive data.

- Change the intervals of data collection to better match both current diagnostics tool intervals and overall times of the imaging sessions for improved data quality.
- Change idle collection interval to be multiple minutes, to ensure the idle diagnostics data collection functions as initially outlined by the development plan.

As these changes will be done later, the actual effectiveness of the changes will not be noted in this thesis. However, on paper, the changes should have a positive effect on the diagnostics data collection system as a whole and influence the major issue with the prototype, being the validity of the data collected, and bring the planned vision of the diagnostics data collection system closer to reality.

4.3 Potential Issues on Future Software Changes

As previously mentioned in the planning of the prototype chapter, the software of the system exists over multiple different repositories, as for example the code for the two main devices of the data collection system, the XFI and the Gateway, have their code on different repositories. As the software within the repositories is under constant development, problems may arise with the integration of the data collection system collection, if there is a lack of communication when making changes that affect other components of the system. Due to this reason, research into adding a new part to the data packet, denoting the system version should be added, as this could be used to indicate major changes for example in situations where collected register value addresses are changed. This type of version control information already exists in some public APIs in the web development world. However, due to the multiple components of the data collection system, this cannot be exactly copied without proper understanding.

5 Conclusion and Discussion

The overall result of the diagnostics data collection system prototype is positive. The reliability of the system regarding the recording of data packets from the XFI to the Gateway database and performance of the system provide an important foundation for the aspirations and objectives of the diagnostics data collection system, despite the flaws on the data validity. The prototype demonstrates the capability of detailed data collection within medical devices, which achieves one of the main intentions behind the project. As the plans for further development of the system are provided, and if these plans are followed and implemented, the final product should result in an adequate diagnostics data collection system for the XFI device for Planmeca Group. While only field tests and actual use within customer or testing environment can prove the capabilities and usability of the implementation, having the ability to obtain insights on device status remotely has potential to both the manufacturer and the customer. The manufacturer can, for example, better understand the lifecycle of a device and thus provide service to the customer to increase the usability of the device. Especially in an international market, a diagnostics tool as such can provide better service in reduced time due to access to the device status without the need for onsite personnel.

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Test Measurement 1	Test Measurement 2	Test Measurement 3	Test Busy Status
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Test Measurement 1	Test Measurement 2	Test Measurement 3	Test Busy Status
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Ready For Exposure Status	Synchronization Led Status	Circuit 1 Data Value	Circuit 2 Data Value
FALSE	TRUE	35761	35845
FALSE	TRUE	35761	35845
FALSE	TRUE	35761	35845
FALSE	TRUE	35761	35845
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FALSE	TRUE	35761	35845

Sensor 1 Data Value	Sensor 2 Spinning Speed	Sensor 2 Data
4294879514	0	17033
4294879514	0	17033
4294879514	0	17033
4294879514	0	17033
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4294879514	65535	11987
4294879514	65535	4294923355
4294879514	65535	4294856283
4294879514	65535	4294789149
4294879514	65535	4294722036
4294879514	65535	4294654899
4294879514	65535	4294588396
4294879514	65535	4294555288

4294879514	0	4294554745
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4294879514	0	4294818836
4294879514	0	4294885481
4294879514	0	4294952163
4294879514	0	51534
4294879514	0	118174

4294879514	0	1102990
4294879514	0	1102990
4294879514	65535	1102033
4294879514	65535	1058488
4294879514	65535	1013271
4294879514	65535	968151
4294879514	65535	877668
4294879514	65535	922874
4294879514	65535	832500
4294879514	65535	787266
4294879514	65535	742106
4294879514	65535	696908
4294879514	65535	651714
4294879514	65535	606458
4294879514	65535	561274
4294879514	65535	516101
4294879514	65535	425651
4294879514	65535	470828
4294879514	65535	380468
4294879514	65535	335217
4294879514	65535	290023
4294879514	65535	244861
4294879514	65535	199625
4294879514	65535	154415
4294879514	65535	109248
4294879514	65535	64029
4294879514	65535	19436
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Ready For Exposure Status	Synchronization Led Status	Circuit 1 Data Value	Circuit 2 Data Value
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FALSE	TRUE	35761	35845
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FALSE	TRUE	35761	35845
FALSE	TRUE	35761	35845
FALSE	TRUE	35761	35845

Sensor 1 Data Value	Sensor 2 Spinning Speed	Sensor 2 Data
4294879514	0	17031
4294879514	0	17031
4294879514	0	17031
4294879514	65535	4294886802
4294879514	65535	4294663036
4294879514	0	4294557013
4294879514	0	4294557009
4294879514	0	4294557008
4294879514	0	4294557007

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4294879514	0	4294557007
4294879514	0	4294557006
4294879514	0	4294557006
4294879514	0	4294557006
4294879514	0	4294636760
4294879514	0	4294859867
4294879514	0	115569
4294879514	0	186129
4294879514	0	186130
4294879514	0	186131
4294879514	0	186131
4294879514	0	186131
4294879514	0	264248
4294879514	0	488065
4294879514	0	711759
4294879514	0	935535
4294879514	0	1159302
4294879514	0	1247574
4294879514	0	1247572
4294879514	0	1247572
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4294879514	0	1247572
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4294879514	65535	400624
4294879514	65535	4294841455
4294879514	65535	4294315249
4294879514	65535	4293948542
4294879514	0	4293948500
4294879514	0	4293948499

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Table 4: Imaging protocol 2, development collection mode

Collection Mode	Safety Switch Status 1	Safety Switch Status 2	Safety Switch Status 3	Test Measurement 1
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	0
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
DEVELOPMENT	FALSE	FALSE	FALSE	0
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
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DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
DEVELOPMENT	FALSE	FALSE	FALSE	0

DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
DEVELOPMENT	FALSE	FALSE	FALSE	0
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
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DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	0
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5

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DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5

DEVELOPMENT	FALSE	FALSE	FALSE	0
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DEVELOPMENT	FALSE	FALSE	FALSE	6
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
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DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	5
DEVELOPMENT	FALSE	FALSE	FALSE	6
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