Medical Device Interoperability Framework

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Approval

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Dedication

With affection and gratitude, I would like to dedicate this thesis to my family and teachers who have been a continuous source of inspiration and motivation for me and supported me all the way throughout my education.

Certificate of Originality

I hereby declare that this submission is my own work and to the best of my knowledge it contains no materials previously published or written by another person, nor material which to a substantial extent has been accepted for the award of any degree or diploma at NUST SEECS or at any other educational institute, except where due acknowledgement has been made in the thesis. Any contribution made to the research by others, with whom I have worked at NUST SEECS or elsewhere, is explicitly acknowledged in the thesis.

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Acknowledgment

In the name of Allah the beneficent and merciful, on whom we all are dependent for eventual support and guidance.

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Table of Contents

List of Tables

List of Figures

Abstract

Medical devices are pivotal in the modern healthcare services. The quality of service increases when the data from the devices are acquired seamlessly by Electronic Medical Record (EMR) systems. Ensuring Interoperability, seamless communication between medical devices and EMR systems, is a particularly challenging task because of heterogeneity in case of different device vendors and incompatible data formats. This thesis proposes a middleware to implement plug-n-play medical device communication for ensuring interoperability across a variety of medical devices. The middleware uses HL7 FHIR and ontology-based description of the devices and communication protocols to bridge the gap in heterogeneity. The proposed middleware acts as an intermediary for collecting native data from devices and generating HL7 compliant device observation reports. The representation of device observations in a standard form may become a recognizable product to the healthcare industry. The reliability of DIM is assessed using probabilistic model checking, i.e., a formal probabilistic analysis and evaluation approach. In particular, the PRISM model checker is used to analyze the Markov Decision Process (MDP) model to assess the failure and success probabilities of the overall system.

Chapter 1

Introduction

This chapter gives the basic idea of the concepts involved in this research. It also presents the background and motivation for this study. Moreover, it provides an idea of expected results, and methodology to get and evaluate the results. Finally, it presents the structure of this thesis document.

1.1 Introduction

The healthcare professionals can potentially improve the quality and safety of the care through seamless coordination across the various points of care delivery. A study from West Institute of Health [1] estimated that the healthcare industry is suffering from the loss of 700 billion dollars out of which 30 billion dollars may be saved annually by practicing interoperability. For ensuring coordination and integration, the diagnostic information gathered from medical devices should be shared seamlessly with the health information systems. The main problem in achieving device interoperability is attributed to the heterogeneity of medical devices. Many devices work on different communication protocols and produce data in different formats that do not conform to content standards [2]. Then, the method of collecting data from devices is mostly manual that results in human intervention and increases the chances of errors in patient records. Few device vendors have even developed their proprietary solutions for the device integration. This process requires rewriting device integration layer in case the laboratory replaces an existing device with a latest device from a different vendor.

1.2 Motivation

The existing healthcare standards are not adopted widely either because they require the medical devices to be its compliant or the device manufacturers produce their own proprietary protocols. The main challenge faced is to achieve medical device interoperability in healthcare. So there is a dire need of ensuring device interoperability, so DIM provides the solution.

1.3 Objective

The main objective of the research is to achieve the medical device interoperability. The devices communicate with the DIM with the assistance of device mappers. The DIM is responsible for ensuring interoperability with the medical information systems. It maps the device data and then translates into HL7 compliant form.

1.4 Problem Statement

Devices among health care systems generate device specific diagnostic data that is mostly not compatible with standard data models. Due to this reason interoperability cannot be achieved among diverse systems. There are many associated research issues:

1. What device information should be modeled for enabling communication with the device?
2. Which diagnostic data from device should be mapped with standard such as HL7 FHIR and LOINC and how?
3. How to enable interoperability among EMR and different versions or models of similar devices?

1.5 Contribution

Major Contribution of the work include:

- Device Interoperability Middleware (DIM) is developed to automate the medical devices.

- Developed a middleware with built in device Plug and Play interoperability framework.
- Device simulators depicting default device behavior are developed for testing DIM in absence of devices.
- DIM is deployed in Bewal International Hospital for the medical devices Chemistry Analyzer Roche Cobas c111, Blood Analyzer Sysmex KX21-N and Urine analyzer Roch Urisys 1100.

1.6 Evaluation

The evaluation is based on following perspectives.

- DIM correctness is checked using formal methods.
- Unit testing is conducted to test the parts of middleware to check their fitness.

1.7 Methodology

This methodology follows a device description ontology forms the backbone of the middleware. Any medical device may be plugged on to the DIM and communication readily starts taking place provided a device description is available in the DIM repository. The device description provides metadata for the observations and the communication channel used by the device. The DIM produces output in HL7 compliant format. Fig 1.1 depicts a high level overview of the middleware.

Furthermore, DIM maps its device observations to the medical terminology LOINC that ensures that when reports are exchanged, the data can be interpreted easily.

1.8 Expected Results

As per proposed methodology, the DIM will generate HL7 compliant data. The Device Observation Reports will be FHIR Compliant. This data will show the same results as received from the devices.

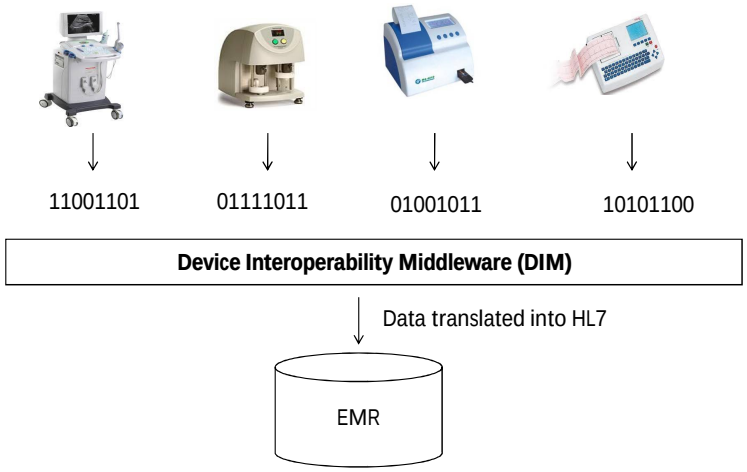

Figure 1.1: High Level Architecture of the Preferred Middleware

1.9 Structure

Rest of the thesis is structured as follows:

- Chapter 2: This chapter reviews the previous work and related healthcare standards that include FHIR, IHE profiles and IEEE 11073 standards.
- Chapter 3: This chapter describes the Ontology based data model for device description which follows the HL7 FHIR standard.
- Chapter 4: This chapter shows the contribution of the DIM System Architecture and Implementation. The implementation has focused on mapping the device data on the available mapper of the particular device.
- Chapter 5: This chapter covers the evaluation part. The system is evaluated using Formal Evaluation, Load testing and Unit testing.
- Chapter 6: This chapter provides the conclusion and future work.

Chapter 2

Background and Related Work

2.1 Medical Devices

Commonly used laboratory devices include blood, urine and chemistry analyzers. A blood or hematology analyzer takes blood sample as input and counts the number of different types of red and white blood cells, hemoglobin, blood platelets and hematocrit [3]. Automated urine analyzers run tests on the urine specimen and extract pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, and bilirubin values [4]. Chemistry analyzers determine concentration of certain metabolites, electrolytes in samples of serum, plasma, urine, cerebrospinal fluid, or other body fluids [5]. Communication channels, particularly serial and TCP/IP are used for connecting with a medical device and transferring data to a host computer. The medical devices use different data formats that are analyzed for extracting meaningful clinical information out of control signals and binary data [6].

2.2 Healthcare Standards

Many healthcare standards play a role for communicating with a medical device. These standards are categorized into three classes as depicted in Figure 2.1. Prominent standards from each category are explained subsequently.

SNOMED-CT is a systematically organized collection of medical terms, codes, synonyms and definitions used in general for clinical documentation and reporting [7]. The Logical Observation Identifier Names and Codes (LOINC) [8], more specifically, provides a code system for reporting lab-

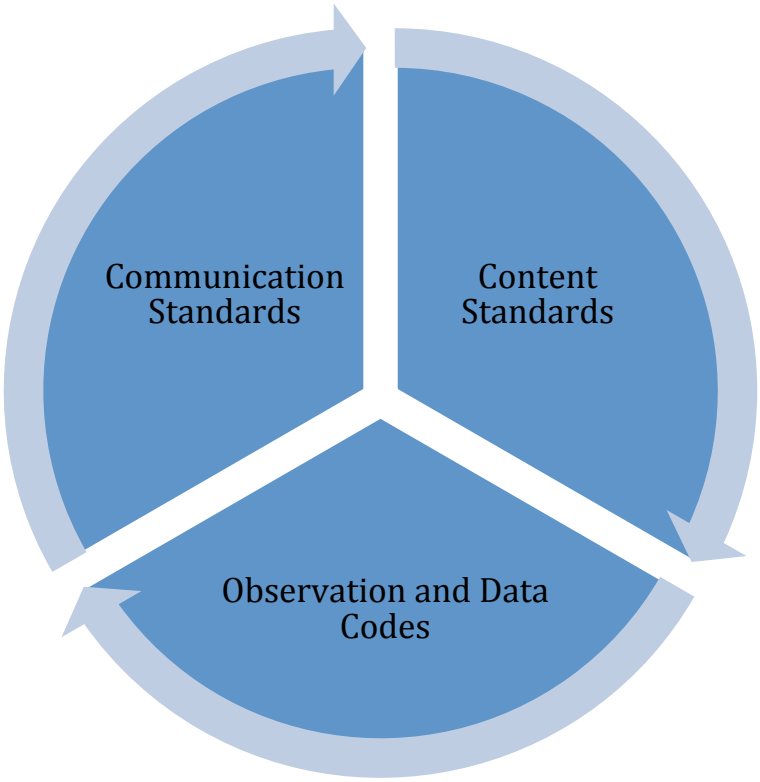

Figure 2.1: Healthcare Standards

oratory and other clinical observations. However, the health information encoded using LOINC is identified by a multiplicity of code values that may vary according to the entity producing such results. The LOINC codes for some of the laboratory tests are given in the Table 2.1.

FHIR is the latest content standard developed by HL7 [9]. FHIR combines the features of HL7 V2, V3, and CDA while leveraging the latest web standards. It is worth noting that FHIR specifications provide a set of modular components called resources covering a wide variety of clinical concepts including diagnostic reports and device observations. The proposed DIM adapts the specification of the standard resources and provides extensions where necessary such as for covering device communication.

ISO/IEEE 11073 (X73) is a family of standards [10] designed to facilitate the communication between mobile medical devices belonging to Body Area Networks (BAN). In contrast, the IHE Laboratory Technical Framework (LAB-TF) defines standards to integrate clinical laboratory workflows

Table 2.1: LOINC Laboratory Codes

LOINC Code	Description
26453-1	Erythrocytes [#/volume] in Blood
33028-2	Leukocytes [#/volume] in Blood from Blood product unit
51632-8	Platelets reticulated [#/volume] in Blood
48705-8	Leukocytes+Platelets [Morphology] in Blood

with other components of a healthcare enterprise or with a broader community of healthcare providers. More specifically, LAB-TF covers integration profiles for Laboratory Testing Workflow, Laboratory Device Automation, Laboratory Specimen Bar Code Labeling, Laboratory Point Of Care Testing and Laboratory Code Set Distribution [11]. Some of the terminologies of LAB-TF used are as follows:

- Order Filler: The role played by the laboratory information system, which manages orders on the laboratory side.
- Automation Manager: The system or component that manages the automation in the laboratory or a part of it.
- Laboratory Device: The actor that is either a pre/post processor or analyzer.
- LAB-4: Work Order Management is the transaction in which Order Filler issues, cancel or modify the order to Automation Manager.
- LAB-5: Test Results Management is the transaction in which Automation Manager transmits test results to Order Filler.
- LAB-21: Work Order Step WOS Download to Laboratory Device is the transaction in which Automation Manager issues a new WOS to the Laboratory Device.

- LAB-23: AWOS (Analytic Work Order Step) is the transaction used by the Laboratory Device (Analyzer) to send test results to the Automation Manager.

2.3 Related Work

The previous attempts to achieve device interoperability emphasized on using content standards for medical devices data. Standardization efforts in medical device data communication are very limited. The only major exception include DICOM for radiology devices and IEEE-11073 standards [10]. The later only covers bedside devices and portable laboratory devices for point of care [12].

The HL7 organization is playing a key role in developing healthcare interoperability standards. For instance, IEEE 11073 DIMs model has been mapped to HL7 v3 refined Message Information Model(RMIM) which can be easily traced back to HL7 RIM that is a building block for all HL7 interfaces [13]. Another effort for achieving interoperability was to collect data from medical device mCare 300 was transformed into a HL7 message [14]. It followed the HL7 V3 standard that covers many healthcare domains for medical data including reports and observations. Wipro technologies [15] has also provided an interoperability solution for medical devices. This solution supports interfacing with devices that use proprietary or IEEE 11073 standard by using HL7 V2 format. This HL7 V2 is supported by a range of software vendors, but its adaption by device manufacturer is rather bleak.

Integrated Clinical Environment Manager (ICEMAN) is another solution [16] for plug-and-play interoperability of devices. The ICEMAN was a model-based control system to enable communication with medical devices. The manager was concerned with communicating and controlling the medical devices as per the defined rules and workflows. It facilitated different low level protocols such as RS232 and USB supported different medical nomenclatures. The ICEMAN SODA (Service Oriented Device Architecture) acted as middleware to help in communication with ICEMAN without relying on platform and technology dependent device drivers. The SODA was comprised of application and device interfaces. When the device was plugged in, the SODA must be told that device was connected and provided with its device model. The soda was concerned with comparing application data requirements with device model contents and matched requirements with

compatible device capabilities in order to assure that applications are compatible with the medical devices.

Few patents have been published on device interoperability for device communication and plug and play of devices to the clinical systems. The patent Systems, methods and apparatus for medical device interface connectivity [17] provides a method for exchanging information from device to clinical system in figure 2.2. As the connection is made the systems serial agent finds the appropriate device driver and data is also collected by this agent.

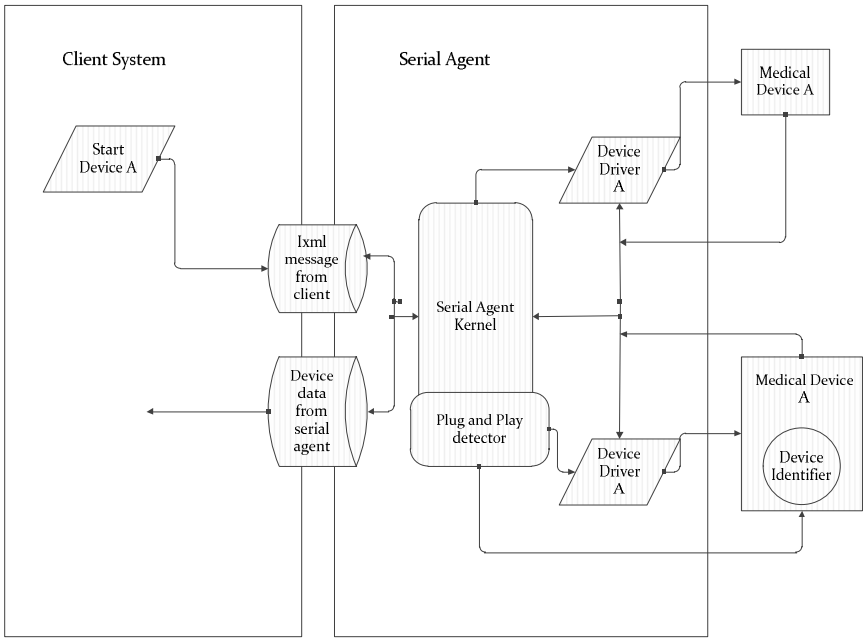

Figure 2.2: Systems, Methods, and Apparatus for Medical Device Interface Connectivity

Another patent [18] Systems and methods for providing interoperability among healthcare devices, it covers patient care devices as they transmit data in an interoperable format and at server side its stored in the same format. Hence, interoperability is ensured by the use of standard format at both ends (server and devices). The figure 2.3 shows a system block diagram of the network-based patient monitoring system in a hospital or nursing home setting. The system has a patient component, a server component, and a client component. The patient component has one or more mesh network patient

transmitters for transmitting data to the central station. The central server comprises one or more Web servers, one or more waveform servers and one or more mesh network receivers. The output of each mesh network receiver is connected to at least one of the waveform servers. The waveform servers and the servers are connected to the network. The Web servers are also connected to a hospital database. The hospital database contains patient records. The plurality of nurse stations provides a plurality of nurse computer user interface. The user interface receives data from an applet that communicates with the waveform server and updates the display of the nurse computers for treating patients. The network client component comprises a series of workstations connected to the network. Each workstation runs a World Wide Web (WWW or Web) browser application. Each Web browser can open a page that includes one or more media player applets. The waveform servers use the network to send a series of messages to the Web servers. The Web servers use the network to communicate messages, shown as a path, to the workstations. The media player applets running on the workstations use the network to send messages over a path directly to the waveform servers. The patent System and method for interfacing medical device information [19] has focused on designing a system in which the medical information from the devices are combined to the electronic medical record of the patient through interfacing the data.

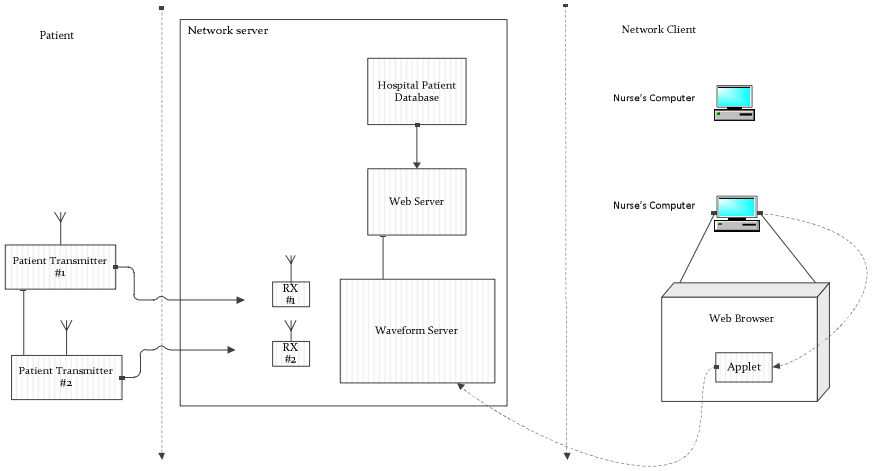

Figure 2.3: Systems and methods for providing interoperability among healthcare devices

The patent Medical device communication system with communication

controller using interface device [20] has provided a system that constitutes of medical device, an interface device and a communication controller. They have made communication modules for each component in the system. The communication controller module configures medical device communication module and the device interface communication module, which is coupled with the information server as well. The user communicates with the medical device through user interface of the interface device via interface of the communication module server.

The existing work mentioned emphasizes on adopting the Medical Device Interoperability standards. The usual practice is that device manufacturers use their built protocols, having full control on them. It is observed that third party designer writes interfacing program for device manufacturers, so that their devices interoperate easily. The hospitals get the flexibility to buy devices of their own choices and by writing custom device drivers interoperability is achieved. The standard IEEE 11073 is not widely been accepted by the industry because of its complexity and the market strategy is to lock-in the customers by providing their own proprietary protocols. IEEE 11073 core standard Part 10201: Domain information model (DIM) [10] does not follow a specific implementation language. It provides Abstract Syntax Notation codes to explain each attribute. Its abstract description and complex coding system makes it difficult to be implemented. The IEEE 11073 assumes that the devices are compliant to it for starting the communication. So its harder for hospitals to replace their existing system. Hofmann thesis provided the standard ICEMAN but still it only provides weak support for the legacy devices. These are the main reasons that creates hurdle for vendors in adopting the existing standards.

Chapter 3

Device Description Ontology

The Device Description Ontology [21] defined for the medical Device Interoperability Middleware (DIM) is based on the HL7 FHIR standard. FHIR very comprehensively fulfills content modeling requirements with only a limited need to extend the core model with device communication information. The extension has been carried out to include device metadata, capabilities, token information and communication channels in the FHIR data model. Observations, devices and mapping of devices data with observations are modeled as Device Description Ontology (DDO). Ontological data of devices and their communication acts as a catalyst to enable plug-n-play communication. Some considerations are helpful in achieving the plug and play behavior of the devices with our system. Considerations are as follows:

- Both systems (medical device and DIM) understanding the communication messages.
- Medical devices on Real-time mode should be able to begin the communication with DIM as soon as the results are produced.
- Receiver(DIM) can interpret the messages received.
- DIM having the capability of parsing the message and extracting useful information.

This is depicted in Figure 3.1.

The Ontology is comprised of the concepts DiagnosticOrder, DeviceObservationReport, Device, Token, Observation and DiagnosticReport, briefly described next.

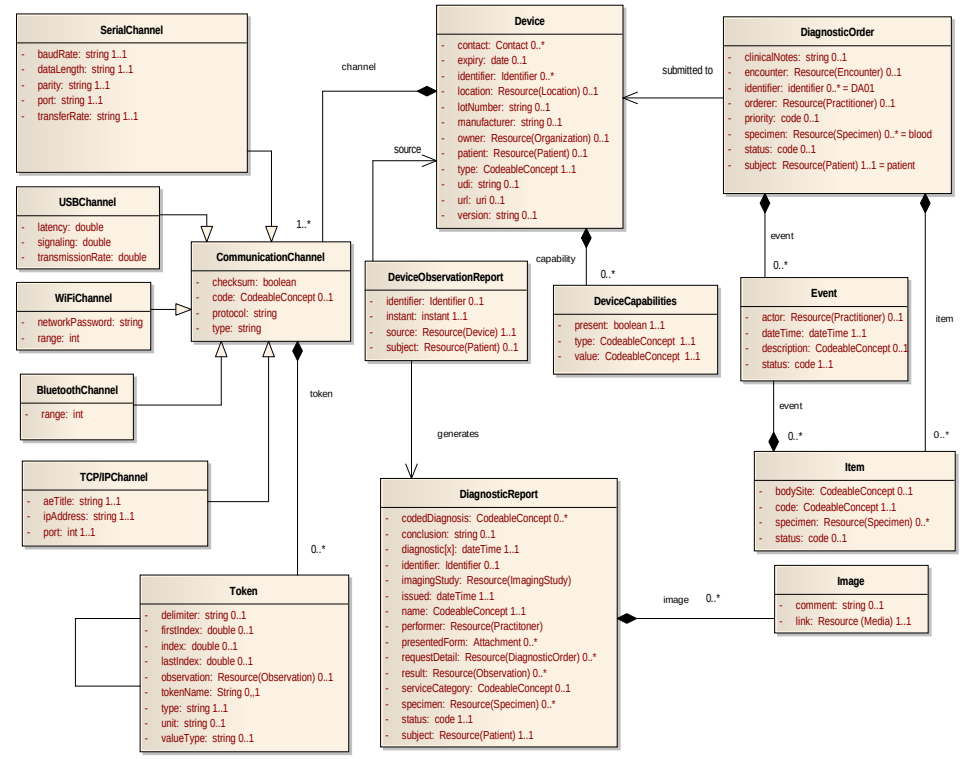

Figure 3.1: Data Model for Device Interoperability Middleware (DIM)

3.1 DiagnosticOrder

The DiagnosticOrder is FHIR resource, this records the patient orders and acts as a request for performing the test. The DiagnosticOrder has containments, event and item. The event is responsible for summarizing the events that occurred while the order was processed. The item is the part of the diagnostic investigation where there can be one item and can be more than one investigation as well.

3.2 DeviceObservationReport

The DeviceObservationReport DOR concept is helpful in modeling the overall concept of the Device Interoperability Middleware DIM. The DeviceObservationReport records set of observations produced by a device. DOR source is the medical device and its subject is definitely a patient.

3.3 Communication Channel

The device sends data on the communication channel. This concept provides details of that particular channel. For example as in DIM the medical device (Urine Analyzer) works on serial protocol for communication. The SerialChannel concept provides properties such as channel name, baud rate, data length, port, parity bits, stop bits etc.

3.4 Device

The Device class from FHIR resource tracks the details of the device features and its location as well. The device in our case will be a laboratory machine or radiology machine.

3.5 Token

Token is the concept in which parsing information is stored for retrieving the observations from raw data of device.

3.6 Observation

Observation class from FHIR class caters the most important elements of the diagnosis of a patient examination. Each and every parameter is defined in this resource.

3.7 DiagnosticReport

This concept of ontology is fulfilled when the investigations are complete and verified by the diagnostic service. It supports following kinds of reports: LAB, PATHO, IMAGING, CARDIO.

The medical device Urine Analyzer is modeled on our data model. The representation is shown in Figure 3.2

```
{
   "resourceType": "Device",
   "type": {  "text": "Urisys2400"  },
   "manufacturer": "Roche Diagnostics",
     "channel": [{
         "code": {
            "text": "Serial Communication" },
         "port": "COM1",
         "baudRate": "9600",
         "dataLength": "8",
         "stopBit": "1",
         "parity": "none",
         "communicationFormat": "ASTM ",
         "token": [  {
               "tokenName": "Leucocytes",
               "startIndex": "161",
               "lastIndex": "164",
               "observation": {
                  "resourceType": "Observation",
                  "name": {  "coding": [ {
                        "system": "http://loinc.org",
                         "code": "46702-7",
                       "display": "Leukocytes
                      [#/area]      in Urine sediment
                      by Automated count"
                        } ] }
 } } ] } ] }
```


Figure 3.2: Representation of Urine Analyzer in Data Model

Chapter 4

Middleware Architecture and Implementation

4.1 Architecture

The medical Device Interoperability Middleware (DIM) assures that medical devices work in an automated manner to achieve device interoperability. It conforms to the HL7 FHIR standard for contents and IHE standard for processes and transactions. The Automation Manger from IHE Laboratory Framework is implemented for automation and device interoperability. The DIM further divides the Automation Manager role into Order Manager, Device Communication Manager and Mapping Manager to fulfill middleware requirements. The architecture is shown in Figure 4.1.

Firstly, the IHE transaction (LAB-4) is used in which Order Filler issues an order to Order Manager. The Order Manager divides Order into Work Order Steps (WOS) and assigns to the Laboratory Device. The transaction (LAB-21) downloads the WOS for the particular specimen from Order Manager to Laboratory Device (IHE actor). The laboratory device analyzes the sample and generates results.

The Communication Manager has channel managers for connecting to the medical devices. It initiates the communication based on the mode of connectivity such as serial, USB, Bluetooth or Wi-Fi. As the connection is established the Channel Manger receives the data from the device using transaction (LAB-23).

The device's data is then forwarded to the Mapping Manager. This Man-

ager keeps a repository for the mappers of devices. The mapper contains information of the device meta data, channel configuration and observations. This helps the mapper to extract the test observations from device's data and assigns the test values to its correspondent test IDs. The observations are then translated into FHIR resources (Observation, Device Observation report). These results are then delivered to Order Filler using transaction (LAB-5).

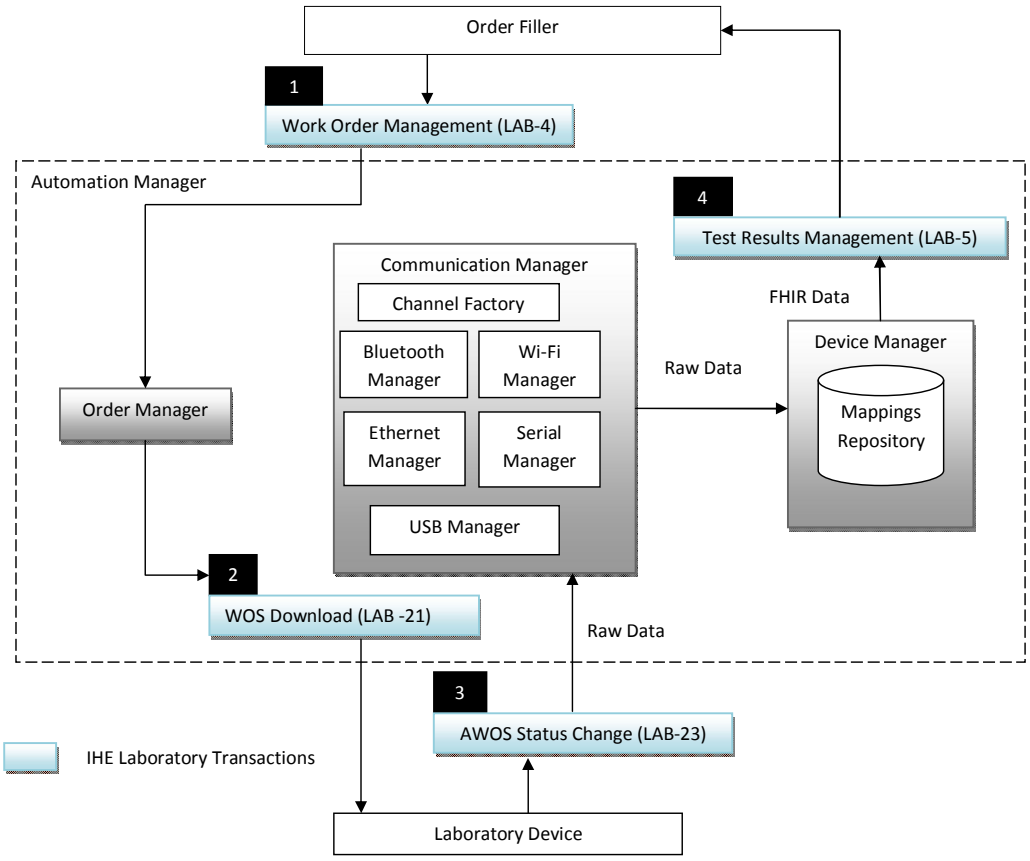

Figure 4.1: Architecture of Medical Device Interoperability Middleware

4.2 Implementation

Based on the DIM architecture, we have developed the middleware that ensures the interoperability of the device with the health information system. The algorithm 4.1 is as follows:

Algorithm 4.1 Device Interoperability Middleware (DIM) Mapping Algorithm

```
Function Parser
Require: Data d, Mapper m
Ensure: Generated DeviceObservationReport
Read d
Get Device Mapper m
INIT results, date, sampleID to NULL
for index=0 to mapper.Tokens do
    mapperToken mt=mapper.Tokens[index]
    tokenValue=substring(d,mt.firstIndex,mt.lastIndex)
    if mt.type=Observation then
        result.push(Map2FHIR(tokenValue,mt))
    else {mt.type=date}
        date=tokenValue
    else {mt.type=sampleID}
        sampleID=tokenValue
    end if
end for
createDOR(results,date,sampleID)
```

The DIM currently supports the following medical devices. Communication and data format of these devices may vary depending on the manufacturer.

4.2.1 Urine Analyzer

An automated urine analyzer Urisys 2400 uses urine specimen and under goes to produce these parameters pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood (erythrocytes/hemoglobin), color (Clarity, specific gravity). It communicates with host device on serial communication. The data is sent following ASTM communication protocol from the device. It is received by middleware and following the architecture it generates FHIR complaint data. The Figure 4.2 shows that the data received from device is translated into FHIR.

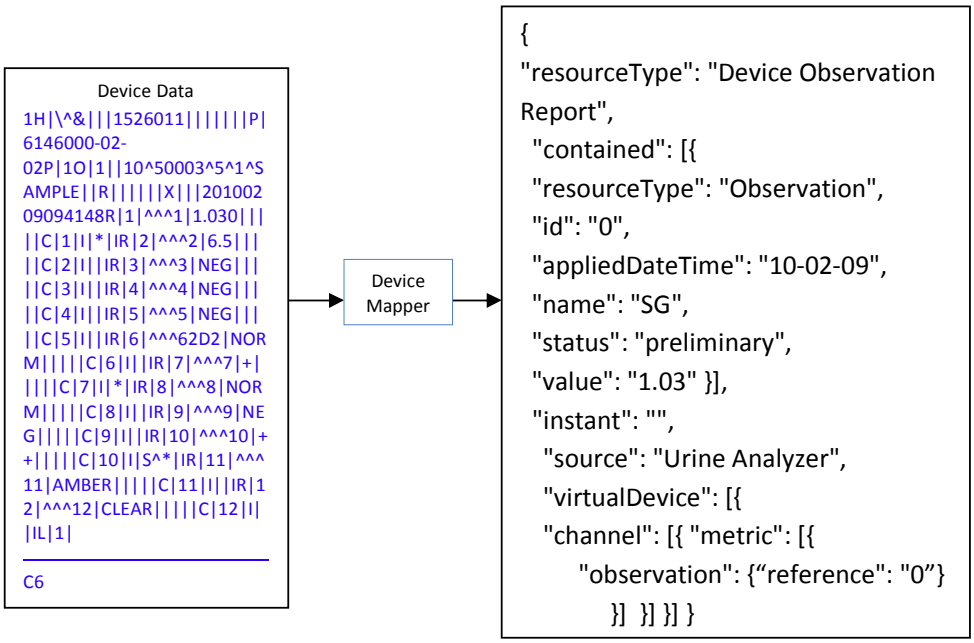

Figure 4.2: Result of Urine Analyzer

4.2.2 Blood Analyzer

The medical device KX21N is an automated hematology analyzer by Sysmex Corporation. It runs two types of specimens i.e. whole blood mode and pre-dilute mode. It communicates with host device on serial communication. The device has implemented the index based protocol. The data packet is received in ASCII codes by middleware and following the architecture it generates FHIR complaint data. This is shown in Figure 4.3.

4.2.3 Chemistry Analyzer

The medical device cobas c111 is an automated chemistry analyzer by Roche. It runs various tests like Alt, LFT, Glucose, creatinine etc. It communicates with host device on serial communication. The device follows the ASTM protocol to generate its data in ASTM. DIM receives it and generates FHIR complaint data. This is shown in Figure 4.4.

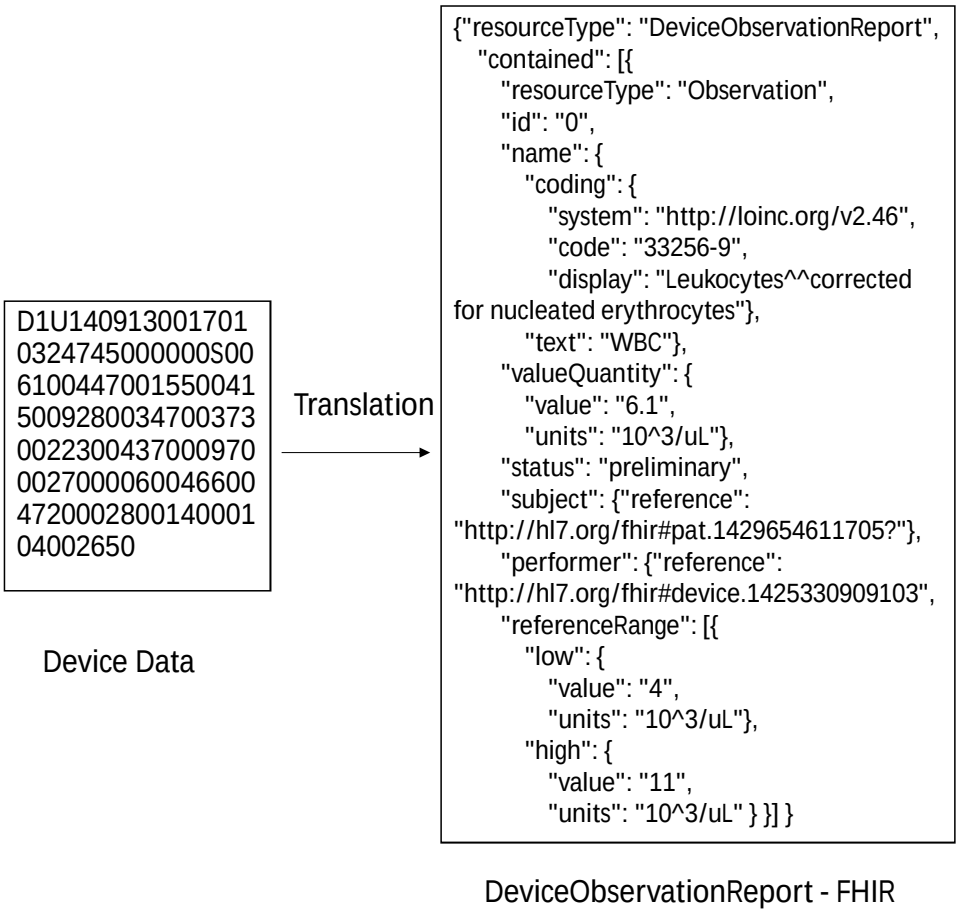

Figure 4.3: Result of Blood Analyzer

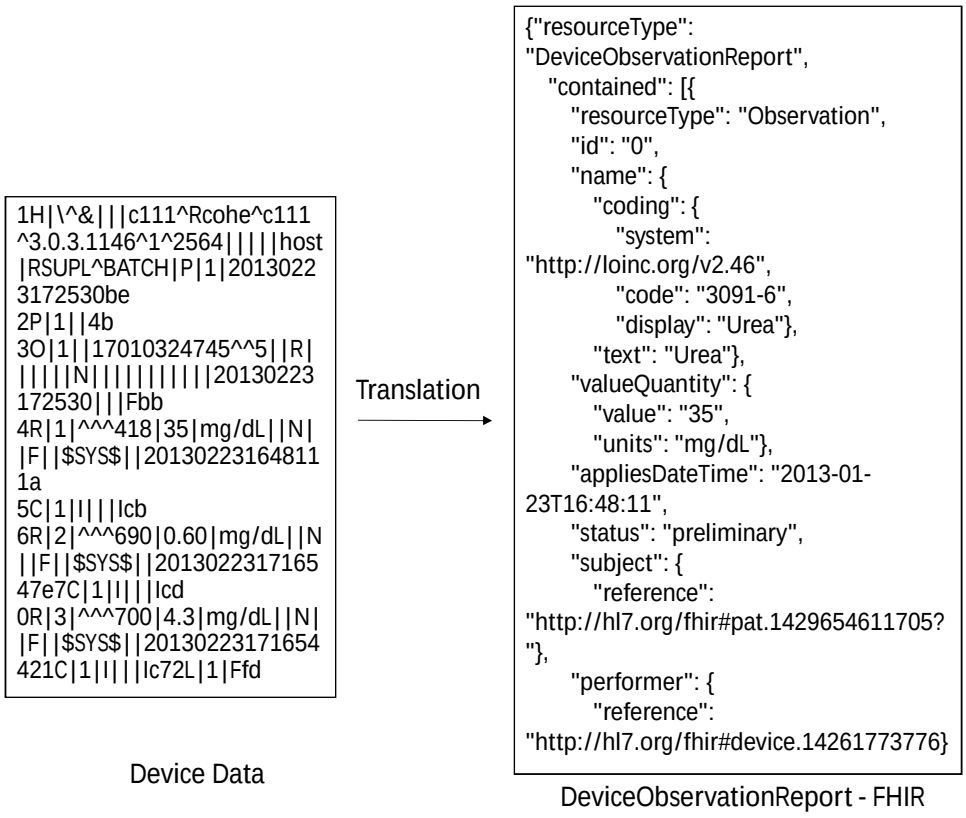

Figure 4.4: Result of Chemistry Analyzer

Chapter 5

Evaluation and Results

5.1 Evaluation Criteria

The middleware is evaluated for the failure and success cases. The system is also tested when load is enforced on it so the efficiency in terms of response time and throughput is measured. Its performance is tested by checking the functionality of middleware units.

5.2 Formal Evaluation

The formal reliability analysis is presented of the medical Device Interoperability middleware. This is the most widely used approach also known as Formal Methods. These methods provide the verification of software and hardware into two categories that includes Theorem proving and Model checking. We selected the model checking approach which is then tested on probabilistic model of the system. The model checking criteria exhausts the system by checking its all possible states which it undergoes during the execution. The probabilistic model checking is mostly performed by using the Markov Chain. The Markovian model of the DIM is developed to and is analyzed using the probabilistic model checker PRISM. The Markov Decision Process MDP is used in PRISM to find the probability of the occurrence of failure and success results of the middleware. In the execution of state machine the properties of DIM are verified. We verified the properties against the system and calculated the probabilities of failures/successes.

We have considered three scenarios to formally validate the DIM. The

comparative analysis is conducted to figure out the best system.

5.2.1 Manual Laboratory Workflow

The patient visits the laboratory for the tests which are either prescribed by doctor or self-diagnosis. The patient specimens are collected which may be rejected by laboratory. When specimen is accepted it undergoes the test in the laboratory device. The laboratory technician manually generates the report. The report may have errors in it so it has to be corrected. The pathologist verifies the report and may ask from change if required. Hence, the manual flow involves the human intervention and increases the chance of errors in patient laboratory results. The Figure 5.1 depicts the state machine of this scenario. The Table 5.1 shows the probabilities of the state transitions in manual laboratory system.

Table 5.1: Probabilities of the State Transactions of Manual System

State Transition	Probability	State Transition	Probability
λ_0	1.0	λ_7	1-λ_4-λ_5=0.93
λ_1	2%	λ_8	0.4
λ_2	0.174%	λ_9	1-λ_8=0.6
λ_3	1-λ_1-λ_2=0.97	λ_{10}	0.25
λ_4	1.0	λ_{11}	0.75
λ_5	0.035	λ_{12}	1.0
λ_6	0.035		

5.2.2 DIM

The second scenario involves the DIM in laboratory workflow, its state machine is shown in Figure 5.2. This scenario does not include Triple Modular Redundancy TMR. The Table 5.2 shows the probabilities of the state transitions in DIM without TMR.

5.2.3 DIM-TMR

DIM incorporates TMR in the automated laboratory system. TMR is a fault tolerant strategy in which three systems perform a process and that

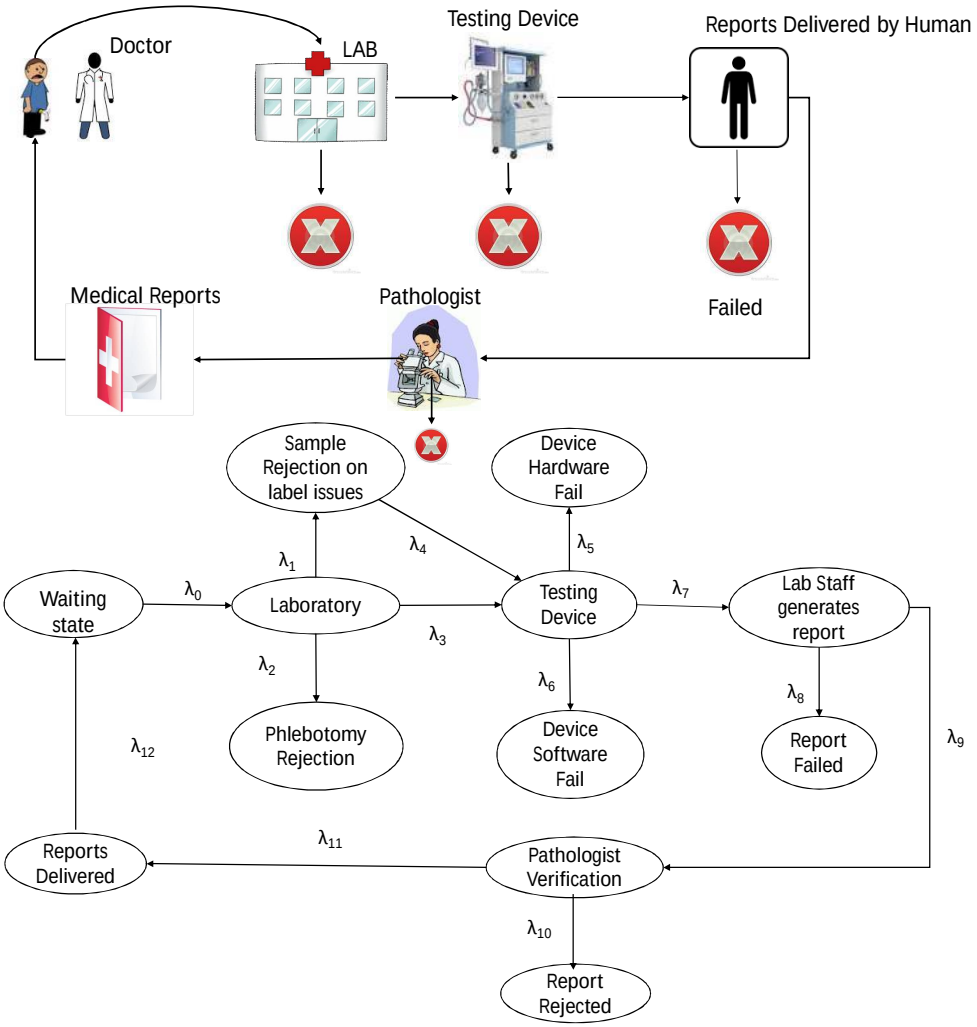

Figure 5.1: State Machine of the Manual Laboratory System

result is processed by a majority-voting system to produce a single output. If any one of the three systems fails, the other two systems can correct and mask the fault. The Figure 5.3 shows DIM with TMR. The Table 5.3 shows the probabilities of the state transitions in DIM without TMR.

The Tables 5.1, 5.2 and 5.3 provides input probabilities of each state transition involved in the systems. The state machines are fed into the PRISM software and properties are generated in the software against which the accumulative probabilities are calculated. The graphs show the results of the formal evaluation for the manual laboratory, DIM and DIM-TMR. The Graph

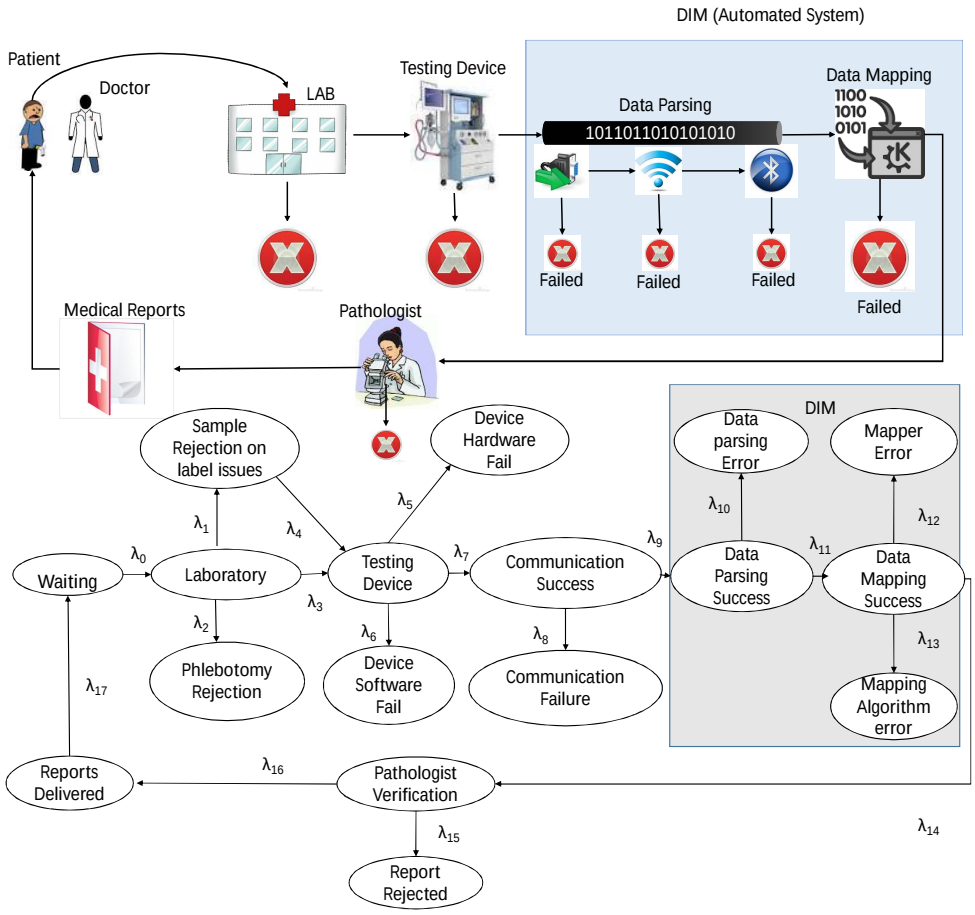

Figure 5.2: State Machine of DIM without TMR

5.4 depicts the probabilities against the success properties. The Graph 5.5 demonstrates the probabilities against the failure properties.

We concluded from the Markov decision Process that the failure rates of manual laboratory system is more than DIM, where DIM-TMR chances of failure is the least among these three systems. Similarly, DIM-TMR success chances are higher than DIM and manual laboratory system.

5.3 Load testing

DIM efficiency was measured using J-meter by calculating its response time and throughput. Both the factors were measured against the heterogenous device messages. Three types were considered ASTM based messages,

Table 5.2: Probabilities of the State Transactions of DIM

State Transition	Probability	State Transition	Probability
λ_0	1.0	λ_9	1-λ_8=0.9
λ_1	0.02826	λ_{10}	0.2
λ_2	0.00174	λ_{11}	0.8
λ_3	1-λ_1-λ_2=0.97	λ_{12}	0.065
λ_4	1.0	λ_{13}	0.065
λ_5	0.035	λ_{14}	1-λ_{11} -λ_{12} =0.87
λ_6	0.035	λ_{15}	0.25
λ_7	1-λ_4-λ_5=0.93	λ_{16}	0.75
λ_8	0.1	λ_{17}	1.0

Index based messages and combination of these messages. The response time increases as the number of users were increasing. Initially system was used by 10 users and the number of users were kept on increasing till 1200. The Figure 5.6 shows the response time in ms against the users.

Similarly, the throughput was calculated for 1200 concurrent users to check how efficiently the system behaves for its functionality. The graph 5.7 shows the throughput for DIM.

5.4 Unit testing

The Unit testing was conducted to check the functionality of the DIM. The Table 5.4 provides the test cases and their results.

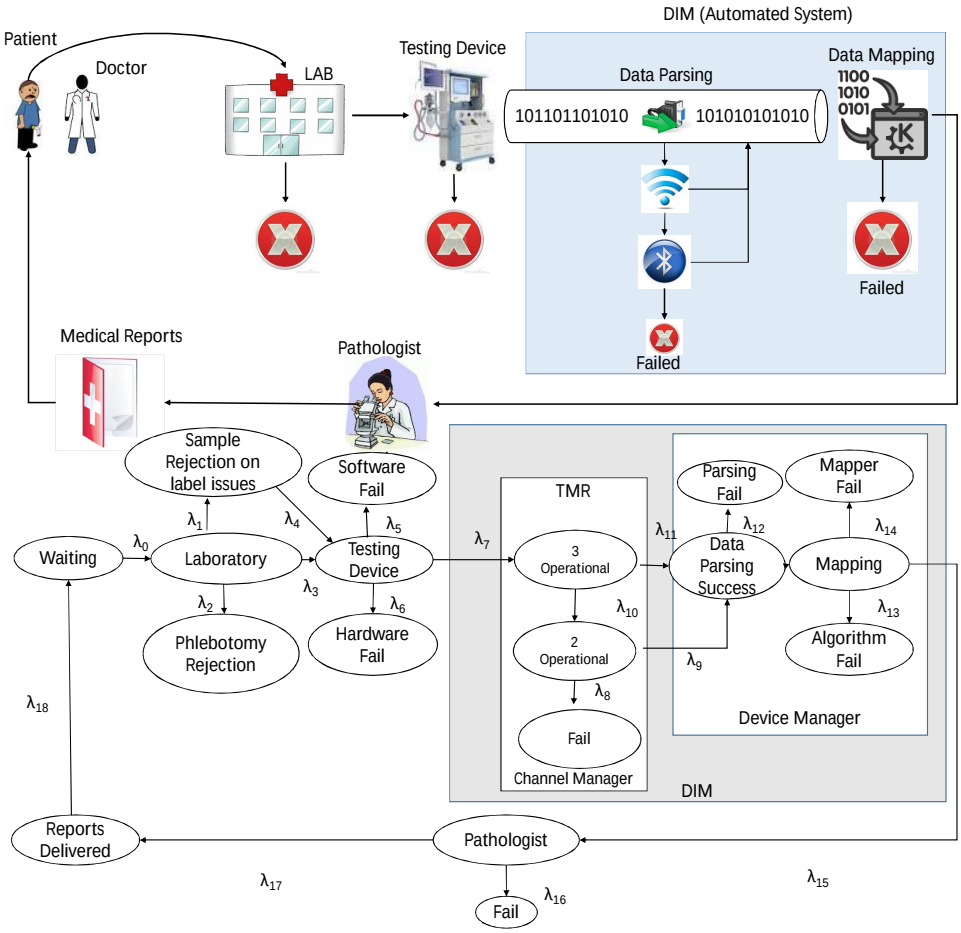

Figure 5.3: State Machine of DIM with TMR

Table 5.3: Probabilities of the State Transactions of DIM-TMR

State Transition	Probability	State Transition	Probability
λ_0	1.0	λ_{11}	1-2λ
λ_1	0.02826	λ_{12}	1.0
λ_2	0.00174	λ_{13}	0.2
λ_3	1-λ_1-λ_2=0.97	λ_{14}	0.01-λ_{11}=0.8
λ_4	1.0	λ_{15}	0.065
λ_5	0.035	λ_{16}	0.065
λ_6	0.035	λ_{17}	1-λ_{13}-λ_{14}
λ_7	1-λ_4-λ_5=0.93	λ_{18}	0.25
λ_8	0.3	λ_{19}	1-λ_{14}=0.75
λ_9	1-λ_4-λ_5-λ_6=0.7	λ_{20}	1.0
λ_{10}	0.2		

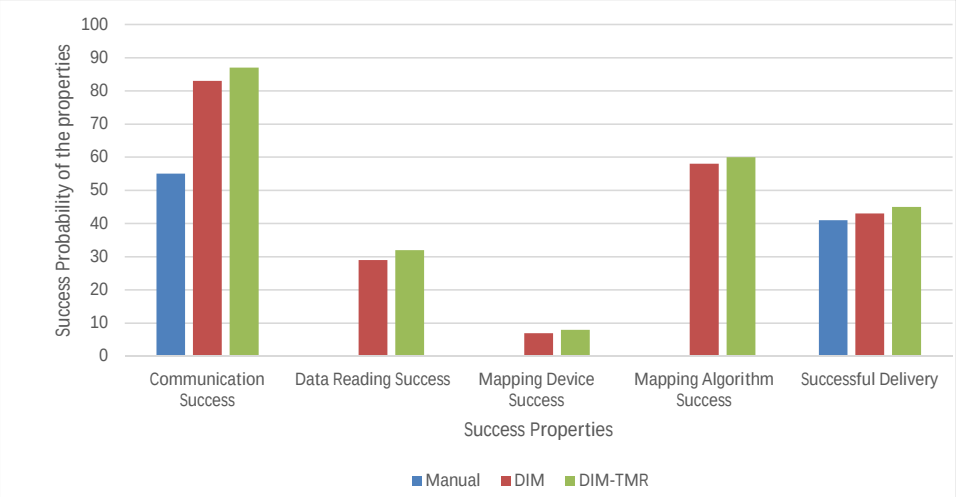

Figure 5.4: Probabilities for the Success Properties

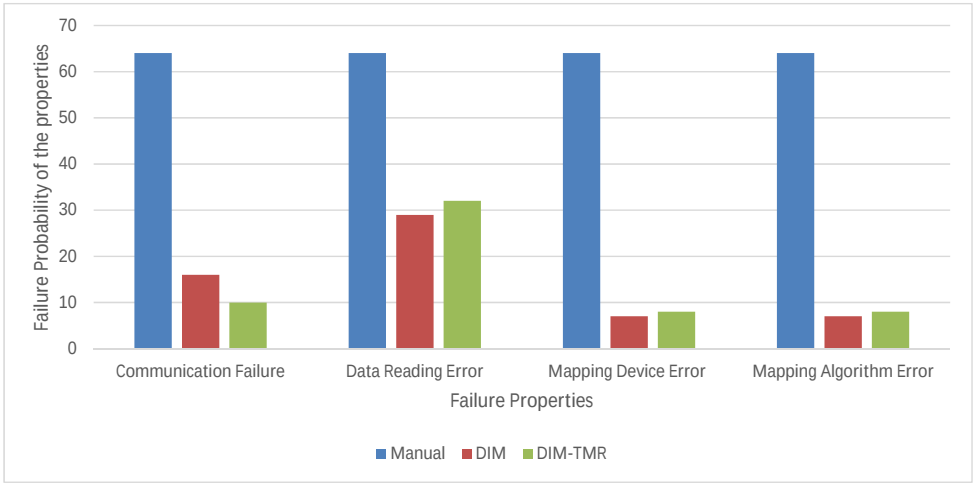

Figure 5.5: Probabilities for the Failure Properties

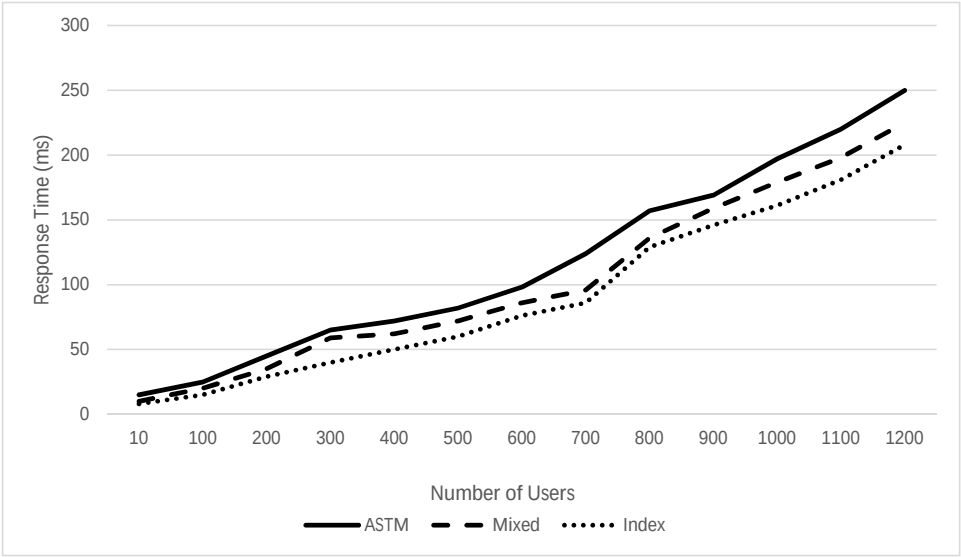

Figure 5.6: Response Time

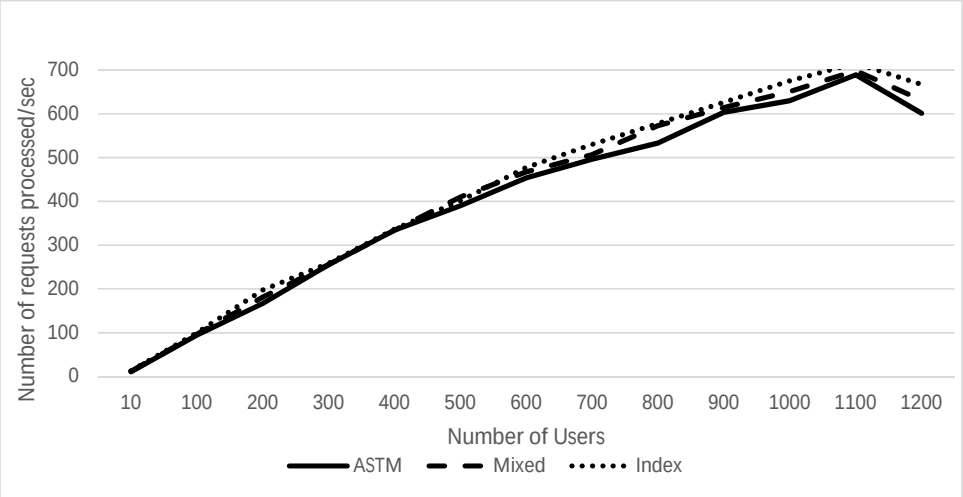

Figure 5.7: Throughput

Table 5.4: Test Cases

Sr No.	Test Case	Input	Expected System Response	Actual System Response	Pass/Fail
1	Validate ASTM Frame for Correct frame	Correct Frame	True (Frame validated)	True (Frame validated)	Pass
2	Validate ASTM Frame for Incorrect frame	Incorrect Frame	DIM exception	DIM exception	Pass
3	Validate ASTM Frame for Null Frame	Null Frame	DIM exception	DIM exception	Pass
4	Parse Correct Device Data	Correct data	Not Null	Not Null	Pass
5	Parse Incorrect Device Data	Incorrect data	DIM exception	DIM exception	Pass
6	Mapped Data for Blood Analyzer Test 1	Blood Analyzer Test 1	Device values equal returned values	Device values equal returned values	Pass
7	Mapped Data for Blood Analyzer Test 2	Blood Analyzer Test 2	Device values equal returned values	Device values equal returned values	Pass
8	Mapped Data for Urine Analyzer Test 1	Urine Analyzer Test 1	Device values equal returned values	Device values equal returned values	Pass
9	Mapped Data for Urine Analyzer Test 2	Urine Analyzer Test 2	Device values equal returned values	Device values equal returned values	Pass
10	Mapped Data for Chemistry Analyzer, Urine Test	Urea test string	Device values equal returned values	Device values equal returned values	Pass
11	Mapped Data for Chemistry Analyzer, Uric Acid Test	Uric Acid test string	Device values equal returned values	Device values equal returned values	Pass
12	Mapped Data for Chemistry Analyzer, Creatinine Test	Creatinine test string	Device values equal returned values	Device values equal returned values	Pass

Chapter 6

Conclusion and Future Work

6.1 Conclusion

The solution is provided for achieving the interoperability in health domain, the diagnosis area that is concerned with the medical devices. DIM is the technique through which we resolved the problems faced when the heterogeneous data formats and medical devices are being encountered in the laboratory field. The mapping approach is being the key component in sorting the heterogeneity and device interoperability problem. The data model is designed which is followed by the device in order to write its mapper. The mapper incorporates the communication and device protocol information that enables the device to operate seamlessly with the EMR systems. This way it ensures the interoperability. Hence, an effort is made to map device data and then translating the test results received from medical device into compliant HL7 FHIR format. The DIM is formally evaluated following probabilistic model in which DIM reliability is verified for the failure and success chances. Its also tested when concurrent users access it, response time is increased and the throughput also increases. Unit testing is performed for ensuring the individual functionality of its modules.

6.2 Future Work

We will include more medical devices into the DIM such as devices that send periodical data. More communication channels can be implemented for facilitating various type of devices such as USB, Bluetooth and HTTP. Later

DIM can provide a ubiquitous computing infrastructure for devices. Other future applications include two way communication with the devices where using the middleware healthcare applications will be able to automate the lab orders as well.

Appendix A

Device data strings

Some data strings received from devices.

- Correct ASTM Frame: Ascii.STX+1H|\& |||c111 R̂oche ĉ111 2̂.0.0.0710 Î 3̂33444|||||host|RSUPLB̂ATCH |P|1|20071210091358 +Ascii.CR+Ascii.ETB+ 22 +Ascii.CR+Ascii.LF;
- Incorrect ASTM Frame: Ascii.STX+1H|\& |||c111 R̂oche ĉ111 2̂.0.0.0710 Î 3̂33444|||||host|RSUPLB̂ATCH |P|1|20071210091358 +Ascii.CR+ 22 +Ascii.CR+Ascii.LF;

Appendix B

Implementation Test Cases

B.1 Test Case 01: Load Device Mappers

Table B.1: Test Case 01: Load Device Mappers

Sr No.	Input	Expected System Response	Actual System Response	Pass/Fail
1	Configurations were loaded	Mappers loaded	Mappers loaded	Pass
2	Configurations set Null	DIM exception	DIM exception	Pass

B.2 Test Case 02: Open Communication Channel

B.3 Test Case 03: Calculate ASTM Checksum

- Correct data: D1U1409130000000000000000000S006100447
  00155004150092800347003730022300437
  00097000270000600466004720002800140001040026 50

Table B.2: Test Case 02: Open Communication Channel

Sr No.	Input	Expected System Response	Actual System Response	Pass/Fail
1	Correct Device Object	Connection Opened	Connection Opened	Pass
2	Device set as Null	DIM exception	DIM exception	Pass

- Incorrect data: D1U14091300000000000000000000006100447
  00155004150092800347003730022300437
  00097000270000600466004720002800140001040026 50

- Correct Data: Ascii.STX+"1H|\\& |||c111 R̂cohe ĉ111 3̂.0.3.1146 1̂
  2̂564 |||||host |RSUPL B̂ATCH |P |1 |20130223172530"+Ascii.CR+ Ascii.ETB+"be"+Ascii.
  Ascii.STX+"2P |1 ||"+Ascii.CR+Ascii.ETB+"4b"+Ascii.CR+ Ascii.STX+"3O
  |1 ||3093

Table B.3: Test Case 04: Calculate ASTM Checksum

Sr No.	Input	Expected System Response	Actual System Response	Pass/Fail
1	Correct data	True (expected value equals returned value)	True (expected value equals returned value)	Pass
2	Incorrect data	False (expected value not equals returned value)	False (expected value not equals returned value)	Pass

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