Middleware for Medical Device Interoperability using Ontology-based Description and Mapping

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***Abstract*—Medical devices are pivotal in the modern healthcare services. The advantages increase when the data from devices are acquired seamlessly by Electronic Medical Record (EMR) systems. This paper proposes a middleware to implement plug-n-play medical device communication for ensuring interoperability across the variety of medical devices. The middleware uses HL7 FHIR and ontology-based description of the devices and communication protocol to bridge the gap in heterogeneity in case of different vendors and incompatible data formats. The proposed middleware acts as an intermediary for collecting native data from devices and generating HL7 complaint device observation reports. The representation of device observations in a standard form may become a recognizable product to the healthcare industry.**

***Keywords*—Laboratory Automation (D057205), Laboratory Information Systems (D002984), Knowledge Representation (D001185), Reference Standards (D012015)**

I. Introduction

The healthcare professionals can potentially improve the quality and safety of the care through strengthened 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 diversity 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.

This paper proposes a medical Device Interoperability Middleware, referred as DIM hereafter, for achieving device interoperability. 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 depicts a high level overview of the middleware.

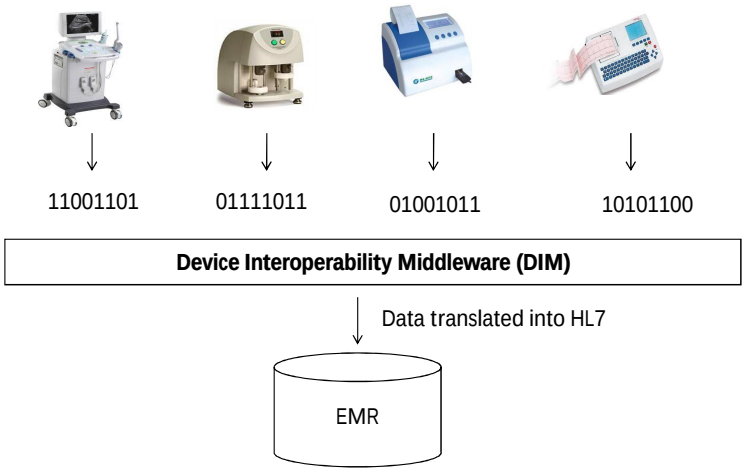

Fig. 1. High Level Architecture of the Middleware

The rest of the paper is organized as follows. Section 2 reviews the previous work and related healthcare standards. Section 3 describes ontology based data model for device description. Section 4 provides the system architecture followed for implementing the interoperability solution. Section 5 explains the results and experiments and finally Section 6 concludes this paper.

II. Background and Related work

A. Medical Devices

Commonly used laboratory devices include blood, urine and chemistry analyzers. A blood or hematology analyzer takes the 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].

B. Healthcare Standards

Many healthcare standards play a role for communicating with a medical device. These standards are categorized into three classes as depicted in the Figure 2. Prominent standards from each category are explained subsequently.

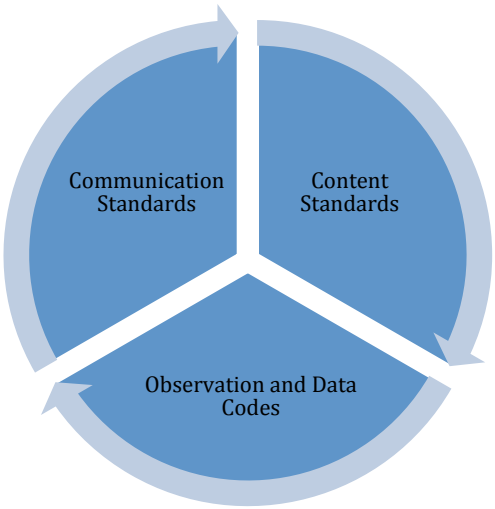

Fig. 2. Healthcare Standards

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

TABLE I. 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

FHIR is the latest content standard developed by HL7 [7]. 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 [8] 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 with other components of a healthcare enterprise or with a broader community of healthcare providers. More specifically, the 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 [9]. Some of the terminologies of LAB-TF used in this paper 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.

C. 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 [8]. The later only covers bedside devices and portable laboratory devices for point of care [10].

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 [11] other effort the data from medical device mCare 300 was transformed into a HL7 message [12]. It followed the HL7 V3 standard that covers many healthcare domains for medical data including reports and observations. Wipro technologies [13] 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 [14] 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.

The work mentioned above is on adopting the Medical Device Interoperability standards. The usual practice is that device manufacturers use their built protocols, having full control on them and at the other hand, third party designs software and hardware for the device manufacturers protocol, enabling devices with differing protocols to interoperate. This gives the flexibility for hospitals 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) [8] 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. hoffamn????

III. Device Description Ontology

The Device Description Ontology 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 Realtime 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.

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

A. 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.

B. DeviceObservationReport

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

C. 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.

D. 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.

E. Token

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

F. 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.

G. 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 4

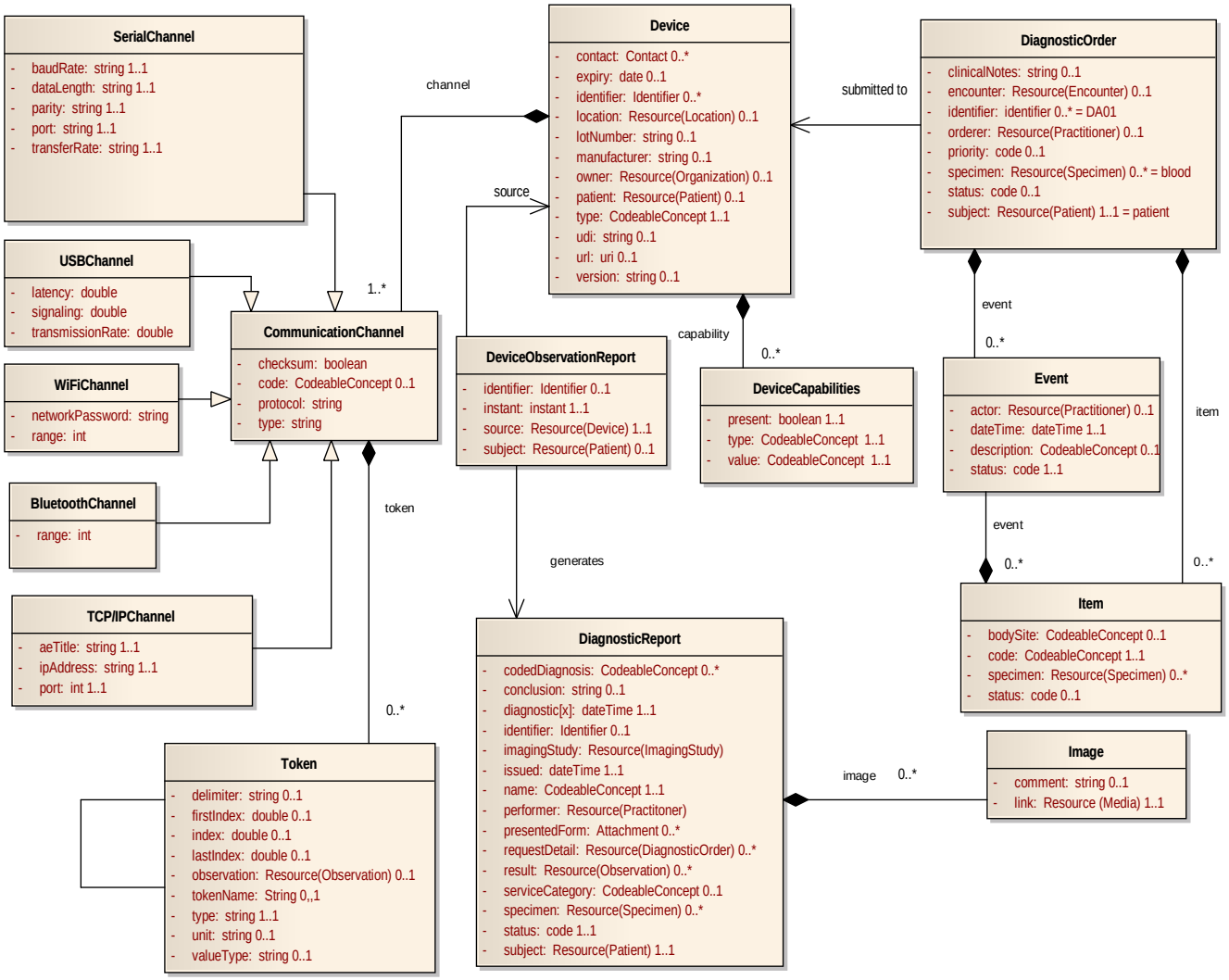

Fig. 3. Data Model

H. Example

IV. Middleware 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 the Figure 5.

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 Manager 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).

V. Results and Experiments

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

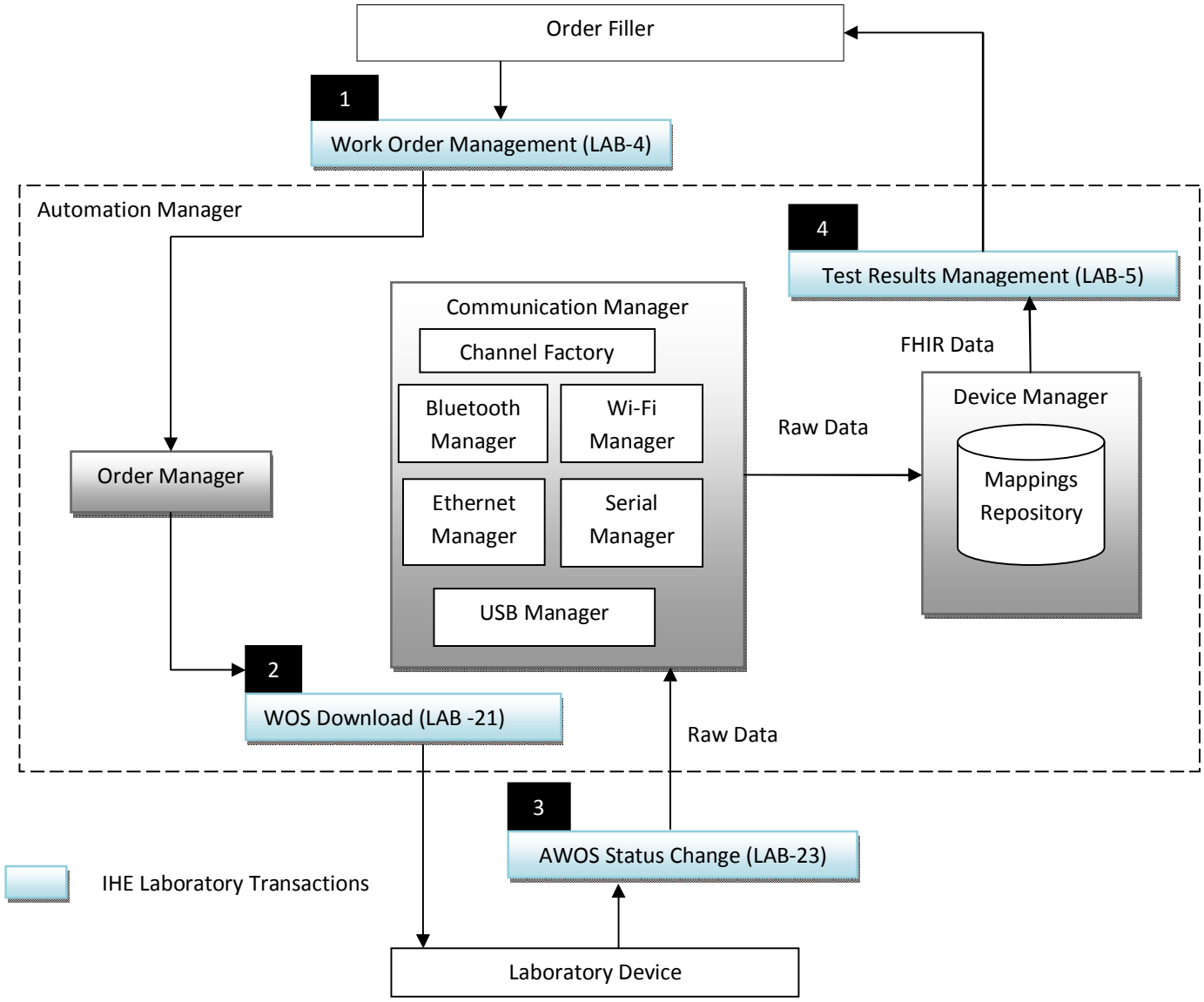

Fig. 5. Architecture of Medical Device Interoperability Middleware

A. *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 send following ASTM communication protocol from the device. Its received by middleware 6 and following the architecture it generates FHIR complaint data. The Figure shows that the data received from device is translated into FHIR

B. *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 data packet is received in ASCII codes by middleware and following the architecture it generates FHIR complaint data.

VI. Conclusion

This paper presented the medical Device Interoperability Middleware (DIM) for achieving medical device interoperability. MDIM has supported the heterogeneity of devices aswell. The medical device when modeled with our data model ensures plug and play manner. The proprietary data formats are effectively converted into HL7 FHIR, which can be transmitted to any information system. More experiments will be conducted for making other medical devices interoperable.

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Fig. 4. Representation of Urine Analyzer in Data Model

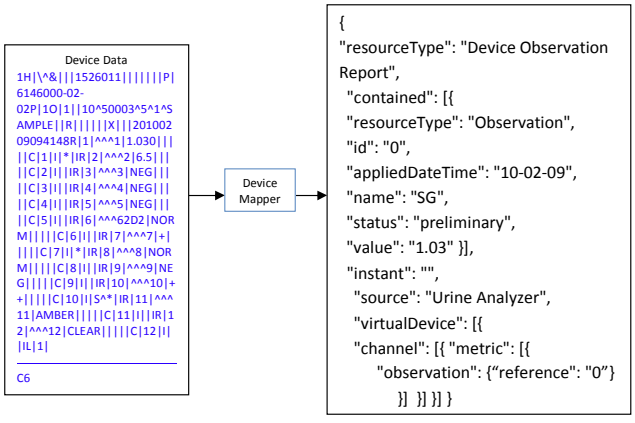

Fig. 6. Result of Urine Analyzer

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