CZECH TECHNICAL UNIVERSITY IN PRAGUE

Faculty of Biomedical Engineering

Department of Biomedical Informatics

Mobile application Mobile CIMED for collecting medical data from sensors

Bachelor Thesis

Study program: Biomedical and Clinical Technology

Branch of study: Biomedical Informatics

Thesis advisor: Ing. Michel Kana, Ph.D.

Alina Ospanova

Prague (Kladno) 2016

Acknowledgement

I would like to extend my gratitude to my thesis advisor Ing. Michel Kana, Ph.D. for dedicating the time, for helpful advices in resolving of the task and for the right direction during the work. In addition, I want to thank Ing. Petr Kudrna, Ph.D. for provision of medical device documentation.

Declaration

I declare that I worked out the presented thesis independently and I quoted all used sources of information in accord with Methodical instructions about ethical principles for writing academic thesis.

I do not have a compelling reason against the using of schoolwork within the meaning of §60 Zákon č. 121/2000 Sb., o právu autorském, o právech souvisejících s právem autorským a o změně některých zákonů (autorský zákon).

Place: Kladno

Název bakalářské práce:

Mobilní aplikace Mobile CIMED pro sbírání medicínských dat ze sensorů

Abstrakt:

Cílem dané práce je navrhnout řešení problémy komunikace mezí zdravotnickou technikou a nemocničním informačním systémem. Teoretická část obsahuje přehled různých vyskytujících ve Světě zdravotnických zařízení a jejich použití v medicíně, taky obsahuje přehled komunikačních protokolů použitelných v komunikacích mezi zařízením a nemocničním informačním systémem. Praktická část se skládá z navržené metody řešení problémy komunikace mezí zdravotnickou technikou a nemocničním informačním systémem a implementační částí, ve kterou byla použita daná metoda v programování mobilní aplikaci CIMED. Mobilní aplikace CIMED sbírá data ze sensoru a posílá je do nemocničního informačního systému.

Klíčová slova:

Telemedicína, mobilní aplikace, sensor, medicínské zařízení, nemocniční informační systém

Bachelor's Thesis title:

Mobile application Mobile CIMED for collecting medical data from sensors

Abstract:

The aim of this thesis is to propose solution for problem of connectivity between medical devices and hospital information system. The theoretical part provides an overview of the various existing medical devices in the World and their using in medicine, also contains an overview of communication protocols using in communications between medical devices and hospital information system. The practical part consists of the proposed method for solving problems of connectivity between medical devices and hospital information system, and the implementation part, in which was used the proposed method in developing of mobile app CIMED. Mobile application CIMED collects data from the sensor and sends it to the hospital information system.

Key words:

Telemedicine, mobile application, sensor, medical device, hospital information system

Contents

1 Motivation

“Telemedicine (also referred to as "telehealth" or "e-health") allows health care professionals to evaluate, diagnose and treat patients in remote locations using telecommunications technology” (1)

AMD Global Telemedicine

This definition by AMD Global Telemedicine exactly expresses the meaning of telemedicine. It is a very widespread concept for today. A vast number of companies, manufacturers, research groups and so on make efforts to develop and to improve technologies in the area of telemedicine. Telemedicine is developing very rapidly due to new technologies. Day by day, the need of application of telecommunication technologies in medicine increases and it is really necessary. One of the first usage of telecommunications for the purposes of medicine was in 1905. Dutch physiologist, the Nobel laureate in physiology and Professor of Medicine Einthoven experimented with ECG transmission over a distance of 1.5 km from the hospital to his laboratory by telephone cable. (2) Unfortunately, it was just an experiment because of analog telephony technology limited this type of data transferring by telephone cables. Nevertheless, establishment of telecommunication between two medical points is already an evidence of existence telemedicine many years ago. Gradually with the development of the global technology, developing telemedicine is also observed. Features in telemedicine allow communication between:

- a patient and a physician;
- medical facilities;
- medical devices and patient, physician or medical information system;
- and so on.

There are a number of common standards for telemedicine communication. In some countries like in the USA or in Germany practical use cases of these standards are spread and it helps to exchange medical data between information systems of medical facilities. Some scenario are supported for example by HL7 protocol.

The other side of the coin is communication between medical information systems and medical devices. It is a sore point for telemedicine. Every day a huge amount of patient medical data is collected from medical devices. Certainly, today it is not longer relevant to record all patient medical data at the paper, technologies give the opportunity to make use of computers for this purpose. Therefore, the data from medical devices should be also transferred to medical information systems. It allows easy manipulation with data and fast data processing. What ways and standards exist for medical device connectivity with hospital information systems? It is a real question and problem for medical device connectivity in telemedicine.

The aim of this thesis is to propose solutions for connectivity issue between medical devices and hospital information systems. We should look at the existing solutions for this problem and only then propose a novel method. A second aim is to develop a mobile application that collects sensor data and send it to the a hospital information system.

2 The world of medicine devices

Medical devices are widely used in all fields of medicine. Today it is difficult to imagine a visit to the doctor without intervention of diagnostic devices, for example ultrasound in gynecology or therapeutic devices for removing plaque in the dental office. According to Global Medical Device Nomenclature (GMDN), medical devices can be classified as follows (3):

1. by *security degree*
   - Class 1 - medical instruments with low risk
   - Class 2 - medical devices with an average degree of risk
   - Class 2b - medical devices with a more than average degree of risk
   - Class 3 - medical devices with a high degree of risk
2. by *functionality*
   - time of usage
   - invasive/noninvasive way
   - way to interact with the human body
   - energy source
   - vital functions

Thus, medicine devices can be divided into two large categories: diagnostic and therapeutic devices. Exploring the world of medical equipment; it is possible to describe every detail of two groups, what it contains and what functions are performed. (Figure 1)

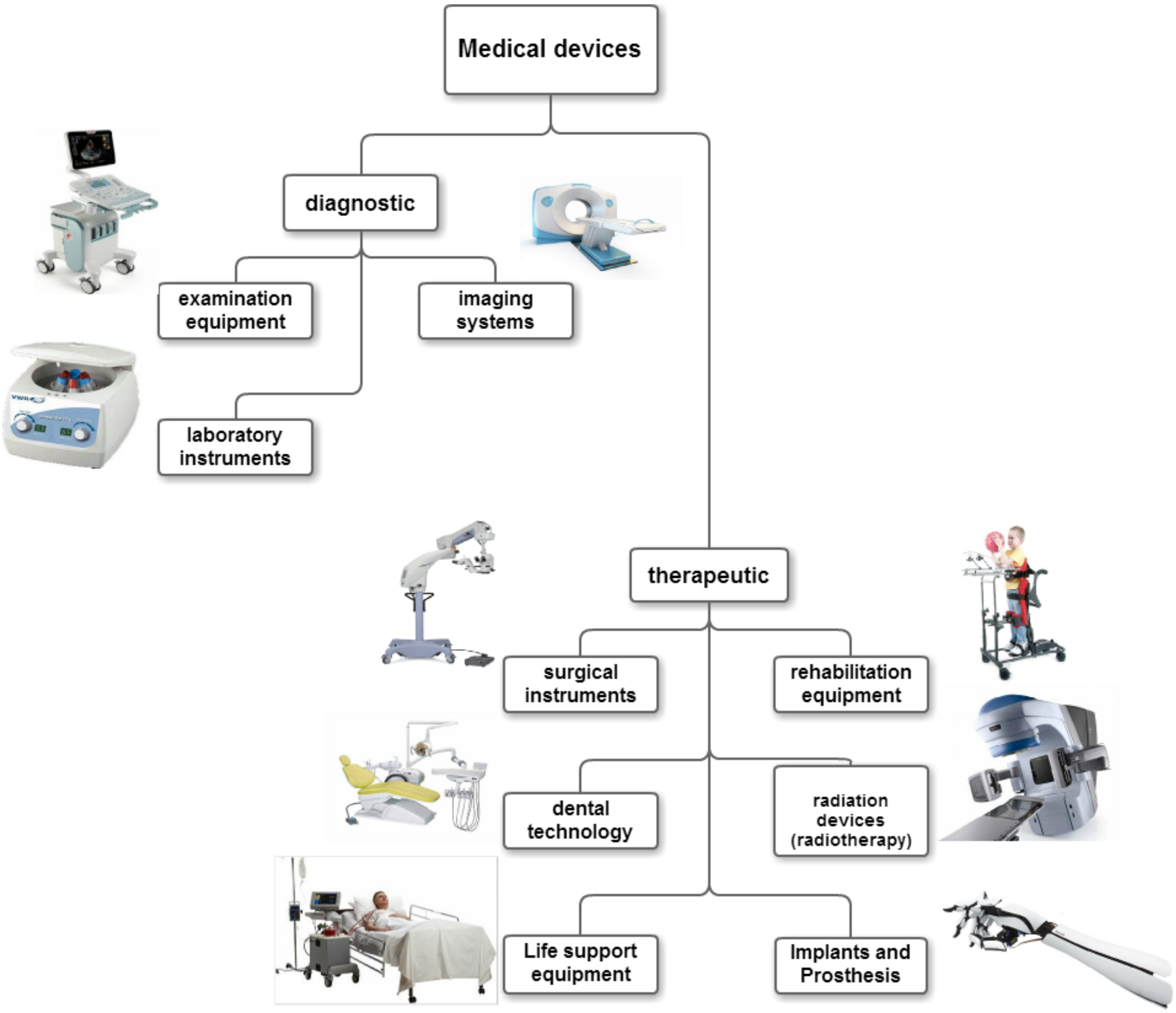


Figure 1. Types of medical devices (figure by author of this thesis)

2.1 Diagnostic equipment

Diagnostic equipments make a large group of different medical devices. Diagnostics instrument is a very important part of the medical examination to confirm the diagnosis or to prescribe a treatment. Examination equipment are among this group. It includes "small" applications such as thermometers, blood pressure meters, etc., and the "large" medical applications that request professional assistance in specially equipped rooms in medical points, such as ECG[1], X-ray, ultrasound examination etc. However, the later ones are also included in the imaging systems, what we will be described later. We will look at the devices from the technical point of view. The most common medical device is a blood pressure meter. We can find it in every office of the practitioner. Today the market of medical devices offers us a huge amount of blood pressure meters. Most of them are digital and blood pressure can be measured quickly and without problems. This measurement method is called oscillometry. There are many devices with Bluetooth technology. It allows us to send data to a smartphone immediately. Certainly, it is an advantage of oscillometric method. Auscultation method is based on the principle of operation of the blood pressure meter with a stethoscope. This method of blood pressure is still very popular among doctors. Also, there exists invasive pressure measurement, which are used worldwide in complex operational processes (4). Group of “small” diagnostic applications includes pulse oximeters, audiometers for evaluating hearing acuity, spirometers for exam pulmonary function, etc.

Group of "large" diagnostic appliances, which can be found as equipment of ambulatory room, is large. Today, many vendors are offering modern instruments with a huge amount of functions that allow easy and efficient diagnosis of patients. Group of "big" medical appliances includes diagnostic instruments such as electrocardiography (ECG), electroencephalogram (EEG), electromyography (EMG), monitors vital signs, etc.

The main aim of all diagnostic devices is to collect data for further usage. Principe of working diagnostic devices is always identical. (*Figure 2*) We have a data input as some signal that is processed in a next step and then we have some output data in readable form for our understanding.

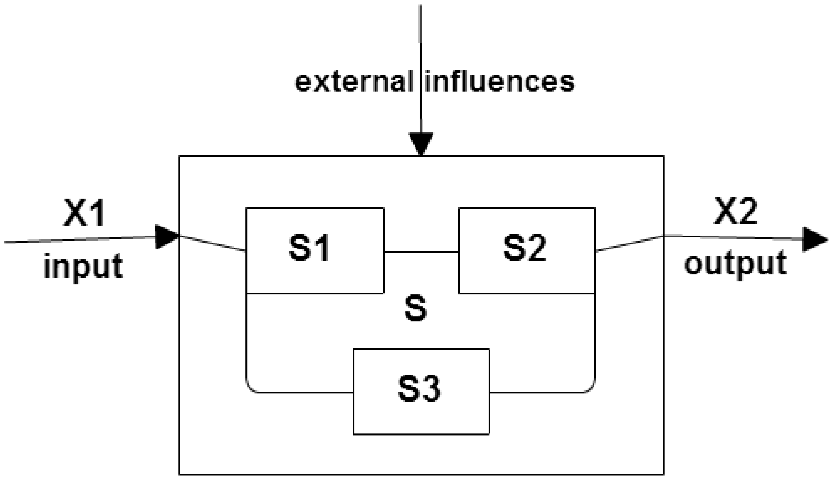


Figure 2. Principe of diagnostic devices (5)

Before we describe the most popular examples of these devices in medical pratices, we should talk about market situation of Medical Device Companies in the World. Using the online and print resource from Medical Device and Diagnostic Industry (MD+DI) (6) we can analyze statistics data about Top 100 Medical Device Companies during 2015. (7) (*Figure 3*)

[1] Electrocardiograph

No.	Company Name (Exchange: Ticker)	Total Revenue, Last 12 Months ($USDmm, Historical rate)	Market Capitalization ($USDmm, Historical rate)	52-Week Low Price ($USD, Historical rate)	52-Week High Price ($USD, Historical rate)
	Johnson & Johnson (NYSE:JNJ)	$25 836,0	$258 689,9	$81,8	$109,5
1	Medtronic plc (NYSE:MDT)	$23 127,0	$98 839,9	$55,5	$79,5
2	General Electric Co. (NYSE:GE)	$18 030,0	$280 909,2	$19,4	$29,6
3	Fresenius Medical Care AG & Co. KGAA (DB:FME)	$16 982,3	$24 506,3	$57,3	$92,7
4	Baxter International Inc. (NYSE:BAX)	$16 326,0	$17 604,5	$32,2	$75,3
5	Siemens AG (DB:SIE)	$14 600,4	$79 439,8	$88,2	$120,4

Figure 3. TOP 5 Medical Device Companies of 2015 (7)

In hospitals in the Czech Republic, it is also possible to find devices of Czech manufacturers. On territory of the Czech Republic we find the Association of Manufacturers and Suppliers of Medical Devices. Their goal is to support the expansion of all of their members on the Czech and global markets. On-line Catalogue of members of the Association of Manufacturers and Suppliers of Medical Devices is available on the website. (8) List of product ranges of these companies could be obtained on their company's websites, which can be found in that online catalogue for further research.

2.1.1 Examination equipment

One of the most world successful companies that manufacture electrocardiographs is General Electric Co. We can observe that this company is third rated by total revenue for last 12 months (2015). (*Figure 3*) Looking at the technical specifications of newest electrocardiograph MAC 5500 HD that we were offered on their website, we read that "Electrocardiograph - an instrument used in the detection and diagnosis of heart abnormalities that measures electrical potentials on the body surface and generates a record of the electrical currents associated with heart muscle activity. Also called cardiograph." (9) Electrocardiographic signal is very often "measured and monitored vital signs". (10)

"To understand the origin (electrogenesis) of biopotential signals like ECG, we should consider the following:

1. Electrical activity (bioelectric phenomena) at the cardiac cellular level and the extracellular potentials generated as the result of the electrical activity of single cardiac cells placed in a large homogeneous bathing (conducting) medium with the same composition as body fluids (volume conductor fields of simple bioelectric sources).

2. Extracellular potentials generated as the result of the electrical activity of a large number of myocardial cells (tissues) placed in a large conducting medium with the ionic composition of body fluids (volume conductor fields of complex bioelectric sources).

3. The relationship between these extracellular potentials and the gross electrical activity recorded on the body surface as ECG signals." (10)

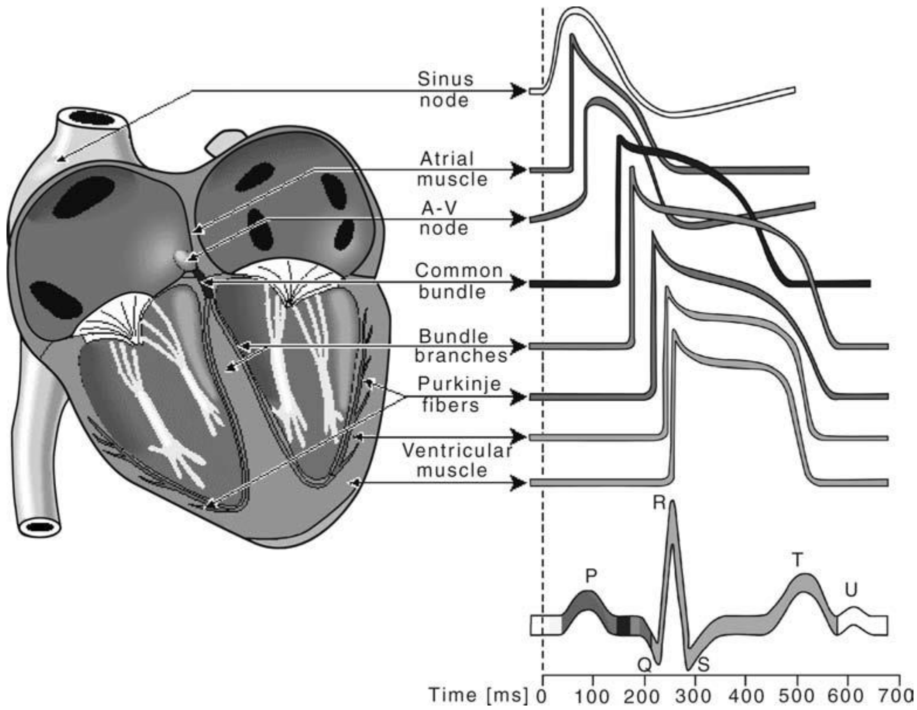


Figure 4. Waveforms of action potentials in different specialized cells and their contribution with color coding to the surface ECG (10).

MAC 5500 HD (*Figure 5*) is very modern electrocardiograph that allows collect, display, analyze and record data from 3, 6, 12, or 15 lead ECG's, interpretive analysis, vector loops. GE Healthcare Diagnostic Cardiology products and systems have an open system architecture. This architecture supports communication standards including Microsoft® SQL server and Health Level Seven. Detail information about this device is available in brochure with technical characteristics. (11) Today it's very important thing for medical devices' systems is interoperability, when all around the world try to find universal speed and easy way of communication between hospital information system and medical devices.

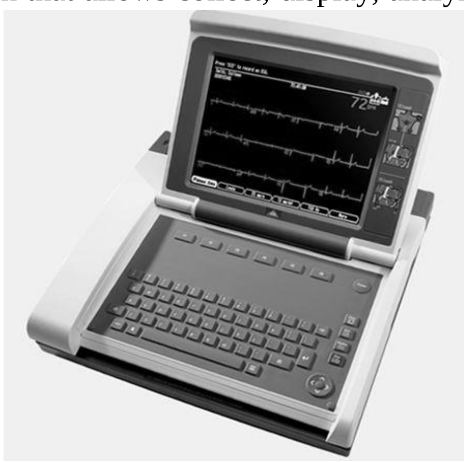


Figure 5. Electrocardiograph MAC 5500 HD (11)

2.1.2 Imaging systems

The next category of diagnostic equipment is imaging system. Imaging systems are intended for the distinction of structure in human body organs and fluid. X-ray, ultrasound diagnostic, magnetic resonance tomography, positron emission tomography, single-photon emission computed tomography and endoscopy are diagnostic imaging methods. Group of diagnostic x-ray devices it is possible to divide by functional aspects: fluoroscopy-radiographic devices in ambulatory diagnostic; specific diagnostics: tomography, in urological surgery – pyelography, angiography, in orthopedic surgery, etc.; computer tomography; dental x-ray devices – in stomatology. (5) X-ray devices consist of many components. The main part of X-ray machine is X-ray tube that contains a cathode and an anode. Electrons are emitted from $^{-}$Cathode and flight in vacuum targeting $^{+}$Anode. The functional organization of an X-ray imaging system is shown in *Figure 6*. (10)

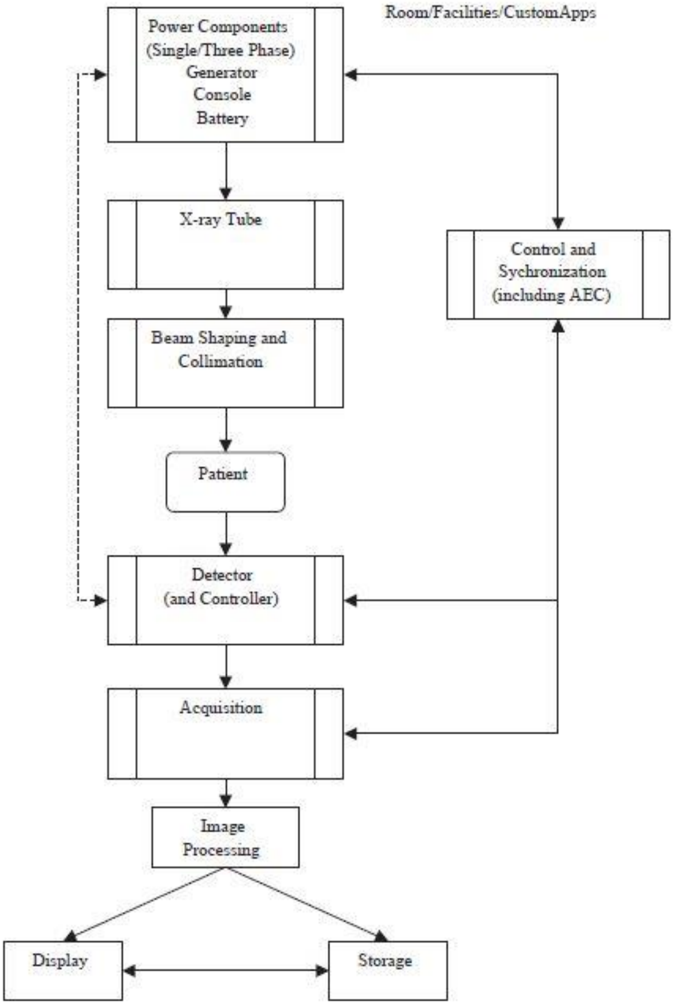


Figure 6. Functional diagram of an X-ray imaging (10 p. 3702)

Like a high-end manufacturer of medicine devices in the market, General Electric Co. produces X-ray machines. The company has in their assortment fixed RAD systems and mobile RAD systems. For example, let us look at representative from fixed system, because in medical points we can meet it more often than mobile RAD systems.

Discovery XR656 Plus (*Figure 8*) (12) is an advanced digital radiographic system powered by FlashPad (*Figure 7*), a wireless detector that was designed—from the beginning—for advanced digital imaging. FlashPad is a modern concept of detector that can be used across compatible GE radiography systems. “FlashPad is the first wireless detector to operate with Ultra-Wideband (UWB) connectivity. Rather than compete with other information on WI-FI networks, it

communicates independently on a dedicated, high-priority channel—so data is transferred with speed and reliability.” (13)

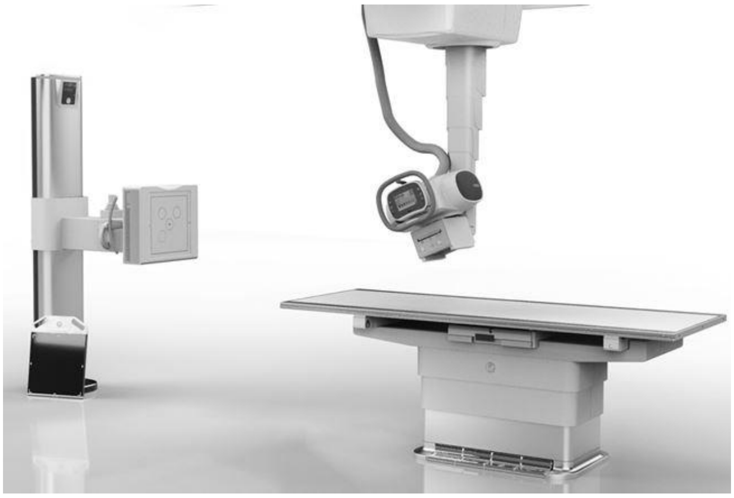


Figure 8. Discovery XR656 Plus (12)

2.1.3 Laboratory instruments

The last one from diagnostic category is laboratory instruments. It is very important equipment for diagnostic procedure. Count of analysis in every laboratories has reached very high, so that today almost all laboratories are semi-automatic or fully automatic. (5) Facility of every laboratory is depending on kind of laboratory. Of course, there exists some classical equipments, which we can find in almost every laboratory: microscopes, calorimeters, centrifuges, analytical balance, etc. Medical laboratories are divided into two groups: (14)

1. Anatomic pathology (histopathology, cytopathology)
2. Clinical pathology
    - Clinical Microbiology (bacteriology, virology, parasitology, immunology, and mycology).
    - Clinical Chemistry (enzymology, toxicology and endocrinology).
    - Hematology (coagulation and blood bank).
    - Genetics (cytogenetics).
    - Reproductive biology (Semen analysis, Sperm bank and assisted reproductive technology).

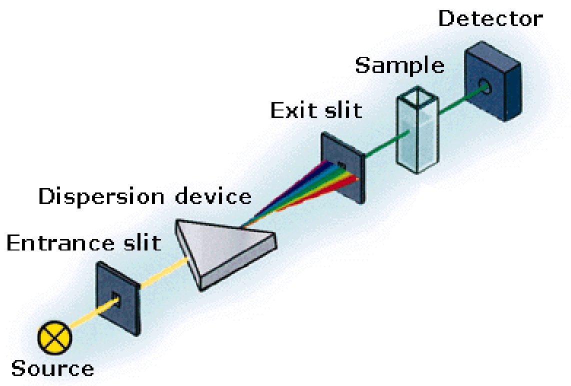
Basic methods like optical, electrochemical, electrophoresis, immunochemistry, genetic, chromatography, mass spectrometry and others methods can be used in in clinical diagnostics.

What about technical side of laboratory equipment? Measuring in a laboratory equipment starts with some sample or samples. Then after processing, we get output in the form of numerical values. Most of laboratories have a laboratory information system (LIS). Ideally, measurements should be sent directly to this LIS. In the worst case, laboratory assistant must rewrite all manually. It can lead to the existence errors in measurement.

Let us acquaint with one of optical methods in laboratory. “Spectrophotometry is the quantitative measurement of the reflection or transmission properties of a material as a function of wavelength.” (15) Usually, spectrophotometers (*Figure 9, Figure 10*) are used in the UV[2] (from 400 nm to 10 nm) and visible regions (from 390 nm to 700 nm) of the spectrum.

[2] Ultraviolet

Figure 10. UV - VIS spectrophotometr SPECORD® PLUS by Analytikjena (16)



2.2 Therapy equipment

“Therapy (often abbreviated tx, Tx, or Tx) is the attempted remediation of a health problem, usually following a diagnosis.” (17) Today for therapy purposes lasers, electromagnetic field, ultrasound, ionizing radiation, temperature treatment and water treatment are used.

2.2.1 Surgical instruments

One large subcategory of therapy equipment is surgical instruments. Technologies is very rapidly developing in surgical instruments contributing to faster and more professional process during operation. What methods and technologies we can meet in the present surgery?

- Cryosurgery – “the selective exposure of tissues to extreme cold, often by applying a probe containing liquid nitrogen, to bring about the destruction or elimination of abnormal cells.” (18) Destruction pathology tissues by cryosurgery is not bleeding way. Lowering the temperature of tissues to -13 °C (260 K) occurs necrotic of it. In cryosurgery is working with temperature ranging between -20 and -40 °C. (19)
- Ultrasound surgery – eye surgery (for example cataracts), removal of tartar, osteosynthesis, etc. In surgery applications is mainly using cavitation and thermal effects of ultrasound. Intensity of ultrasound should be more than 100 kW/m^2 and time of using varies between 1 and 20 s. (19)
- Lasers in surgery – “a device that emits a very narrow and intense beam of light or other radiation” (18). Advantages of application lasers in surgery instead of scalpel are contactless and bloodless.
- Lung ventilation and anesthesia systems – is very important parts of surgery equipment. Lung ventilation serves to keep blood gases in appropriate amounts. Ventilation systems intended for dosing inhalation anesthesia.
- Thermocoagulation - during heating of tissues to 45 °C occurs changes in cell structure, then necrotic. By heating from 45 to 60 °C proteins in cell become solid - coagulation, from 60 to 100 °C evaporation water from cells – drying, over 100 °C solid sell content reduces carbon – carbonization. (19)
- etc.

In the future robotic surgery systems will be more popular like the da Vinci® Surgical System (*Figure 11*) that “enables surgeons to perform operations through a few small incisions and features several key features, including:

- Magnified vision system that gives surgeons a 3D HD view inside the patient’s body
- Ergonomically designed console where the surgeon sits while operating
- Patient-side cart where the patient is positioned during surgery
- Wristed instruments that bend and rotate far greater than the human hand” (20)

Figure 11. The da Vinci® Surgical System (20)

2.2.2 Dental technology

The next group of therapeutic equipment is dental. This group is a little different from all the rest, because dentist work is directly proportional to the quality of the equipment. Basic equipment of dental office are dental chairs, delivery systems, dental lights, monitor mounts and other small equipment. For example, we will take domestic manufacturer CHIRANA Medical. (21) Dental unit Chirana CHEES contains all basic instruments including syringe, turbine, micro-motor, handpieces, LED ultrasonic scaler. (*Figure 12*)

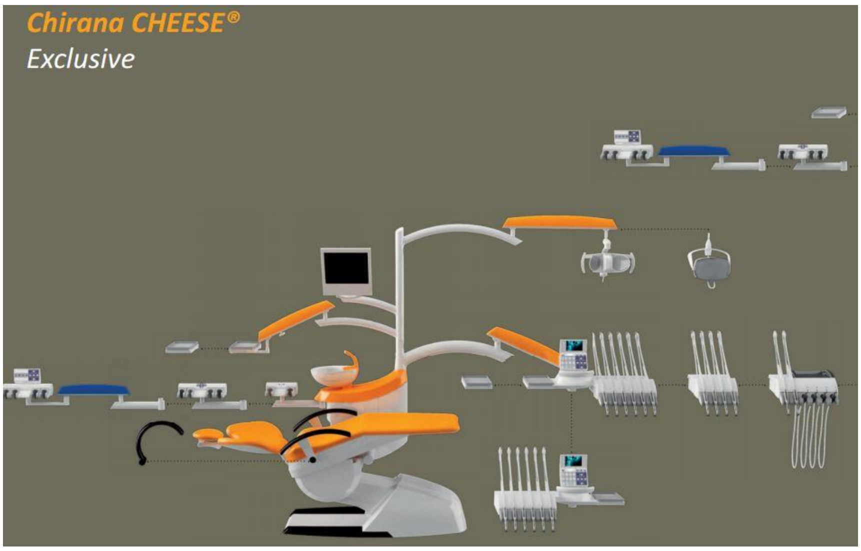


Figure 12. Chirana CHEESE dental unit (21)

2.2.3 Rehabilitation equipment

“Rehabilitation describes specialized healthcare dedicated to improving, maintaining or restoring physical strength, cognition and mobility with maximized results. “ (22) The main specializations in rehabilitation:

- Kinesiotherapy – it is treatment by passive and active muscular movements. There are medical devices that make vibration waves for activing and stimulating muscles (Figure 13). (23)

Figure 13. Electro – stimulator (24)

- Therapeutic massage (mechanotherapy) - it is common medical treatment that helps us to restore muscle tone and just feel better
- Orthotics – is medical field dealing with the manufacture and application of orthoses. An orthosis is "an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system". (25)

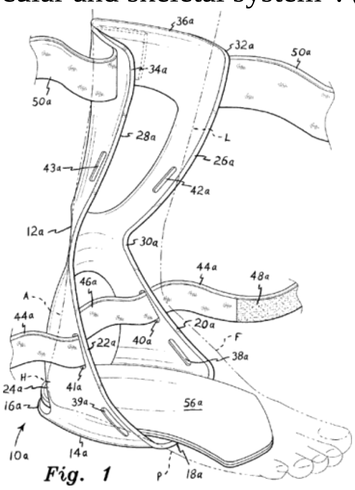


Figure 14. Schematic ankle-foot orthosis (25)

- Physiotherapy – “is a healthcare profession that assesses, diagnoses, treats, and works to prevent disease and disability through physical means.” (26) Physiotherapists apply a lot of methods physical therapy like electrical stimulation tissues and organs, magnotherapy, ultrasound therapy, diathermy (using of high-frequency electromagnetic currents), thermotherapy, hydrotherapy and others.

- reflexology – application of pressure to the points of feet and hands with specific hand techniques.
- Psychotherapy and etc.

2.2.4 Radiotherapy

Radiation therapy - "treatment of disease with radiation, especially by selective irradiation with x-rays or other ionizing radiation and by ingestion of radioisotopes." (18) Purpose of radiotherapy is the application of an accurate dose of radiation to the human body avoiding damage of healthy tissue. The common types of radiation in medicine are X-ray and Gamma ray. Source of radiation may be radionuclides (radium-226, cobalt-60, caesium-137 and iridium-192) or particle accelerator (beams of electrons, protons, bremsstrahlung – Cu, Pb, W, Ta, U, Au). We can differentiate radiotherapy by source of radiation and patient position.

- Teleterapie – source of ionizing radiation is outside from human body.
- Brachytherapy – source of radiation is inside of patient body. (19)

Radiotherapy treatment planning has been based initially on CT[3] images. Advantages of CT images are high spatial resolution and excellent bony structure depiction. The ability to provide relative electron density information by CT analyze used for radiation dose calculation. In conjunction with CT images magnetic resonance imaging (MRI) and positron emission tomography (PET) are used. This analyze is input for next step in planning dose. Method Monte Carlo program MCNP is used for the simulation of nuclear processes. Output of this step is radiation transport in an object. The last phase brings us the graphical result and overall dose. (10) (19)

Figure 15. TrueBeam™ Radiotherapy System (27)

One of most successful manufacturers of radiotherapy equipment is Varian Medical Systems. Varian Medical Systems, Inc. products and services for treatment process from diagnosis to post treatment care. Their product TrueBeam Radiotherapy System platform is integrated system for image-guided radiotherapy and radiosurgery (*Figure 15*). "TrueBeam treats cancer anywhere in the body where radiation treatment is indicated, including lung, breast, prostate and head and neck." (27)

[3] Computed tomography

2.2.5 Life support equipment

After the failure of some vital organs of human body, it is necessary to provide substitution of organ functionality by life support equipment. Often using this special equipment is encountered in surgery, intensive treatment unit and emergency departments. There are many techniques may be used in hospitals for sustaining life:

- mechanical ventilation
- cardiopulmonary bypass
- defibrillation
- total parenteral nutrition
- dialysis
- pacemakers
- neonatal incubators (*Figure 16*)
- and others.

Figure 16. Neonatal incubator with resuscitation unit - GE Healthcare (28)

2.2.6 Implants and prosthesis

Special group of medical technical instruments consists of implants and prosthesis. Present medicine is able to substitute or reinforce the damage part of skeleton or organs. For surgery purposes different types of implants are manufactured from polymers, which are used for reconstruction of tubular organs like ureter, esophagus, trachea, etc. In addition, surface of implants might be made of a biomedical material such as titanium, silicone, or apatite and others. Cardiovascular implants are used to treat conditions such as heart failure, cardiac arrhythmia, ventricular tachycardia, valvular heart disease, angina pectoris, and atherosclerosis. Orthopedic implants help to resolve problem with the bones and joints of the body. The most popular specialization of surgery is plastic surgery, which are using silicone implants in mammoplasty. In cases of non-implantable organs it is possible to provide at least support of functionality. So for example, hearing aid helps to make sounds more accessible. (5) (29)

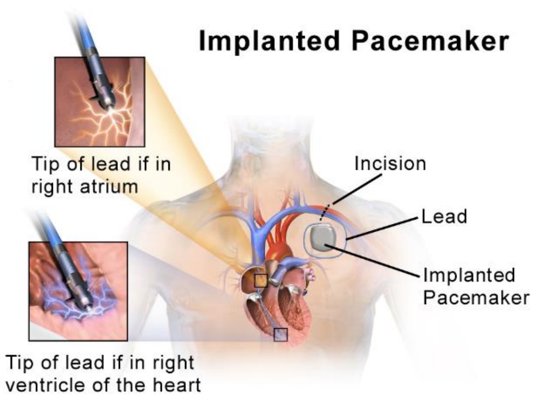


Figure 17. Illustration of Implanted Pacemaker (30)

3 Medical device connectivity

Medical device connectivity is a very wide conception in the world of medical devices. Diverse sources name it differently. According to medical research organization The West Health Institute, Medical Device Interoperability is "the ability for clinical medical devices to communicate in a consistent, predictable and reliable way, allowing for the exchange of, and interaction with, data from other medical devices and with patient data sources and repositories, such as electronic health records (EHR), in order to enhance device and system functionality." (31) Interaction between medical devices or between medical device and some information systems is key to the health care system. According to Transparency Market Research, the annual growth rate in the market for medical device connectivity is expected to increase from $3.4 billion worldwide in 2012 to 38% through 2019. (32)

What kind of improvements can that be? Today almost all hospitals use medical/hospital/clinical information systems. These information systems contain vast amount of information such as patient demographics, heart rate records, electrocardiogram, results of analyzes; drug administration, data including dose; ventilator therapy data and so on. How data being received from medical devices are being fed into information systems? Generally, it is manually entered by nurses. In accordance to The West Health Institute's research calculations in United States of America, $12.4 billion annually is wasting in the health care system, because of manually entered information. (31) Of course, local health care system is not an exception. This problem can be found in every health care system without medical device interoperability. Unfortunately, it is the only side effect derived from the lack of Medical Device Interoperability. Medical device connectivity allows for the collection of vital signs data to be automatically sent from medical devices directly to the hospital information system. The chart below by The West Health Institute's research represents large amount of waste in the health care system in U. S. (*Figure 18*). It is useful example for understanding, how great can be a loss due to lack of Medical Device Interoperability in every information system.

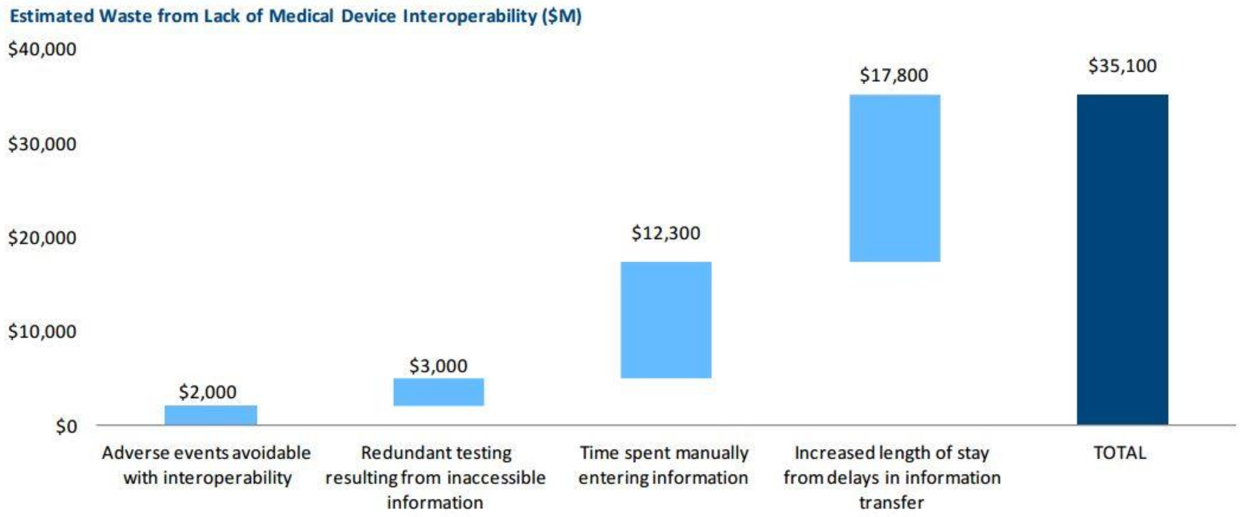


Figure 18. Estimated Waste from Lack of Medical Device Interoperability ($M) (31)

Other issues such as adverse events avoidable, redundant testing and increased length of stay are not the only problems due to lack of Medical Device Interoperability. The other side of the coin is under the control of manufacturers of medical devices. Today most manufacturers use proprietary and closed communication methods among devices. It means every medical hardware have own "black box" software that contains proprietary communication protocols. Consequently, every manufacturer has own designed devices, which are not able to interact with another manufacturer's device or with customer's medical information system in the hospital.

By HIMSS Analytics (33) today the average hospital is using about 800 common medical devices (*Figure 19*). For example, in the health care system in U. S. A. and in European Union, like in Germany such concept like electronic health record (EHR) or electronic medical record (EMR) is widespread. "It is an evolving concept defined as a longitudinal collection of electronic health information about individual patients and populations." Additionally, these records are shared through network, information systems or other exchanges. (34) The table below (*Figure 19*) shows the percent of hospitals that interact between at least one of those devices and EMR.

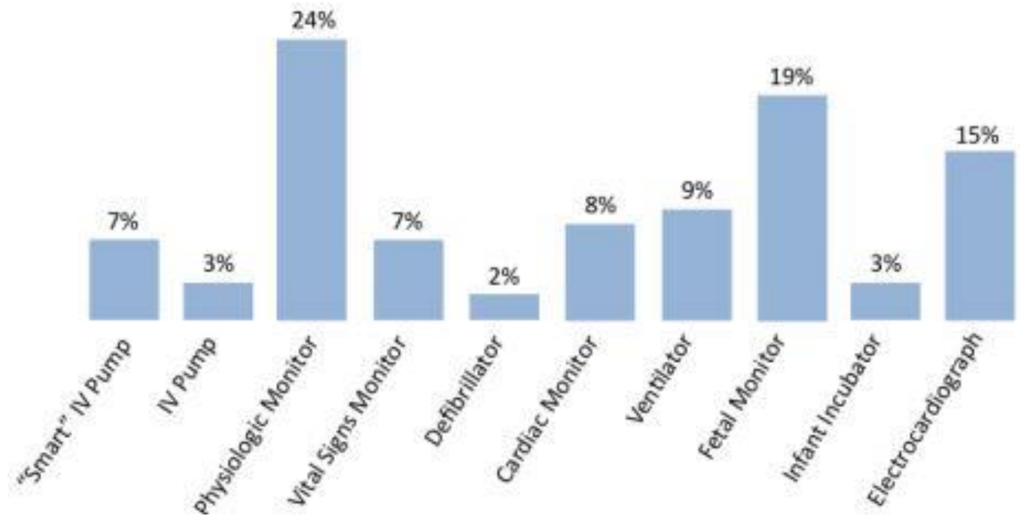


Figure 19. The percentage of hospital devices connected to an EMR (35)

It is a vivid example and evidence of symbiosis between the two concepts of medical device and information systems that bring efficiency to the health care systems.

Is it really so difficult to establish standards for medical device communication? Different vendors and manufacturers supply vast number medical devices to the hospitals. Only some part of these devices able to connect with hospital information system in the same format that can be effectively received.

3.1.1 Medical device communication standards

Vast number of organizations made efforts to develop some standards for medical data exchange between devices. In order to reach an efficiency from medical device interoperability, mainly need to focus on connection between many disparate devices over a network. Let us look at the state of art of medical device communication standards.

IEEE 11073 is an extremely significant and common standard, as it is "the only existing standard explicitly designed for medical device plug-and-play interoperability. Specifically, IEEE 11073 proposes an open systems communications model providing an interface between bedside medical instrumentation and healthcare information systems, focusing on the acute care environment" (36). In spite of complexity of this standard, it is still very popular among organizations. The main goal of this standard is real-time plug-and-play interoperability for medical devices. For example, The Continua Health Alliance that is building "system of interoperable personal health solutions" (37). It has more than 180 member companies involved. Every product that has Continua logo is able to interact with any other Continua-branded product. This company is using the expansion of IEEE 11073 to the personal health devices. A diagram of how the standards are used in a hierarchical fashion for the PAN[4] interface is shown is *Figure 20* (38).

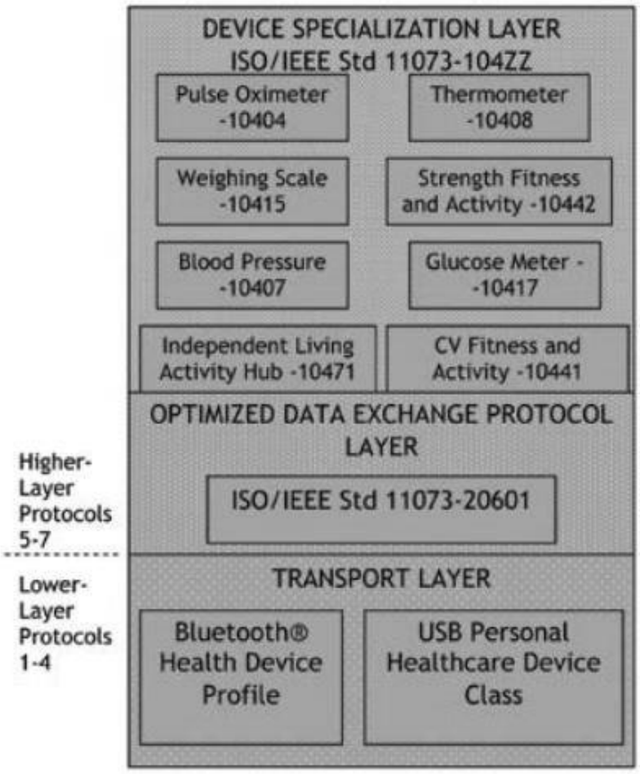


Figure 20. Continua OSI 7 layer model construct with applicable standards. (38)

Of course, Continua has other lower-layer protocols like serial, IrDA, ZigBee and LAN too.

IEEE 11073 standard works with medical data exchange between point-of-care devices and medical/hospital information systems, but there are other medical information systems that also need to receive data from an external medical information system or medical device. There are two common standards for exchange medical data - DICOM and HL7.

DICOM (Digital Imaging and Communications in Medicine standard) is a standard for formatting and transferring digital images in radiology, cardiology, radiotherapy (X-ray, CT, MRI, ultrasound, etc.), ophthalmology and dentistry. "DICOM specifies a set of network protocols, message syntax and semantics, media storage services and a medical directory structure for imaging systems. By complying with these specifications, devices within a hospital picture archiving and communication system (or PACS[5]) can easily and efficiently interoperate." (39). This standard defines two information levels: DICOM File for representing image or images and DICOM Network Protocols for transferring DICOM files and control commands by networks with TCP / IP support. DICOM file is object-oriented file (patient -> study -> series -> image) with tags. DICOM Network Protocols use TCP/IP protocols for connection between PACS and between PACS and medical device. There are three levels: DICOM Upper Layer, DICOM Message protocol, Association Control protocol. *Figure 21* presents the general communication model of the Standard, which spans both network (on-line) and media storage interchange (off-line) communication. (40)

[4] Personal Area Network
[5] Picture Archiving and Communication System

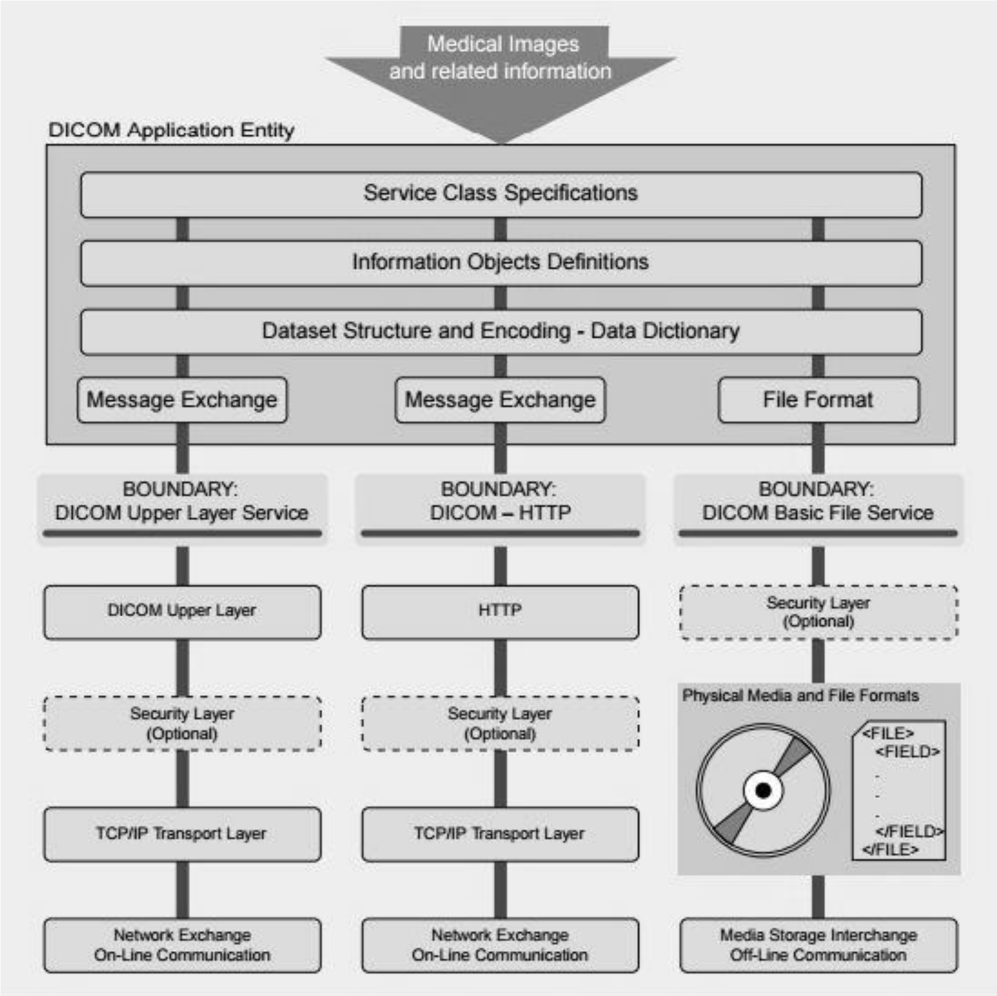


Figure 21. General Communication Model (40)

Another worldwide protocol is HL7. Health Level Seven International (HL7) is "a not-for-profit, ANSI[6]-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services" (41). The latest version of the standard, HL7 v3.0 is based on the Reference Information Model (RIM), which provides an object model for all of the messages used to communicate medical data within a health care system. HL7 v3.0 uses XML[7] to structure its different messages. RIM objects are grouped into templates for use in specific 36 messaging contexts, such as patient administration, order entry, financial management, laboratory reporting, medical records, and hospital room scheduling. (39) A typical HL7 V3 message consists of structural and dynamic components. The structures include Domain Message Information Models (DMIMs) such as Clinical Genomics and Pharmacy. The dynamic part describes interactions between humans and between systems. *Figure 22* shows core XML content of the Care Record message from the perinatology, representing the highest blood pressure during pregnancy as an example. (42)

[6] American National Standards Institute
[7] eXtensible Markup Language

```
<CareProvisionEvent classCode="PCPR" moodCode="EVN">
   <templateId root="2.16.840.1.113883.2.4.6.10.90.50"/>
       <id root="2.16.840.1.113883.2.4.99.23444.6" extension="cp16645"/>
        <statusCode code="active"/>
              <effectiveTime>
                     <low value="20130603"/>
              </effectiveTime>
    <subject typeCode="SBJ">
      <patient classCode="PAT">
      <!-- Item: 10 - SocialSecurityNumber -->
       <id root="2.16.840.1.113883.2.4.6.3" extension="100202020"/>
                <addr>
                   <postalCode>12008</postalCode>
                </addr>
                <statusCode code="active"/>
                <patientPerson classCode="PSN" determinerCode="INSTANCE">
                   <name use="L">
                      <given>Francesca</given>
                      <family qualifier="SP">Johnson</family>
                   </name>
                   <birthTime value="20110801"/>
                </patientPerson>
             </patient>
          </subject>
          <!—Item example - Highest diastolic blood pressure -->
          <pertinentInformation3 typeCode="PERT" contextConductionInd="true">
             <observation classCode="OBS" moodCode="EVN">
                <code code="X_IVDIASTPREG" codeSystem="2.16.840.1.113883.6.1"/>
                <value xsi:type="IVL_PQ">
                   <high value="95" unit="mm[Hg]"/>
                </value>
             </observation>
          </pertinentInformation3>
      <!-- rest of the message content starts here-->
      <!-- rest of the message content ends here-->
</CareProvisionEvent>
```


Figure 22. XML fragment of the Care Record message (42)

Despite comprehensiveness standard HL7 is very popular in implementation between medical information systems in U. S. A. and in over 50 countries.

In the Czech Republic there is one common standard DASTA supporting by the Ministry of Health of the Czech Republic. DASTA is open DAta STAndard for transferring medical data between medical/hospital information systems. In practice usage there are two verses of DASTA: DS3 a DS4. DASTA able to transfer information from medical domain:

- identifiable patient data
- basic information about the patient (personal data,birth number, address, height, weight, etc.)
- urgent information (allergies, diagnosis)
- payments, insurance information
- anamnesis
- drugs and vaccination
- orders, results, reports (laboratory, X-ray, different documentation, special investigations according to the nomenclature of clinical events, etc.)
- end others

Innovation in DS4 is the description of clinical events such as laboratory tests, X-ray examination, ECG, operating report, daily report forms, ambulatory report, etc. DASTA similarly to HL7 v3 uses XML to structure different messages. (43)

```xml
<ds:dasta dat_vb="2015-03-05T10:23:07" typ_odesm="NN" ur="U" bin_priloha="T" verze_nclp="02.51.01" verze_ds="04.12.01"
   id_soubor="UNN1450_123456780011" xsi:schemaLocation="urn:cz-mzcr:ns:dasta:ds4:ds_dasta ds_dasta-4.03.06.xsd" xmlns:
   xmlns:ds="urn:cz-mzcr:ns:dasta:ds4:ds_dasta">
        <ds:zdroj_is kod_prog="JMENOAPP" kod_firmy="STAPRO__"/>
        <ds:pm ico="00023833">
                <ds:as typ="I">
                        <ds:vnitrni>NZIS</ds:vnitrni>
                </ds:as>
                <ds:a typ="P">
                        <ds:jmeno>ÚSTAV ZDRAVOTNICKÝCH INFORMACÍ A STATISTIKY</ds:jmeno>
                        <ds:adr>Palackého náměstí 4</ds:adr>
                        <ds:dop1>P.O.BOX 60</ds:dop1>
                        <ds:psc>12801</ds:psc>
                        <ds:mesto>Praha 2</ds:mesto>
                </ds:a>
        </ds:pm>
        <ds:is ico="12345678" pcz="001">
                <ds:as typ="I"></ds:as>
                <ds:a typ="O">
                        <ds:jmeno>Nemocnice XX</ds:jmeno>
                        <ds:adr>Oddělení informatiky</ds:adr>
                        <ds:dop1>Ulice 5/45</ds:dop1>
                        <ds:mesto>Obec</ds:mesto>
                </ds:a>
```

Figure 23. Example of DASTA standard (43)

3.1.2 Existing Solutions of medical device connectivity

Despite the existence of several common standards, medical device community and organizations continue making efforts to develop alternative technologies for medical device connectivity. We will talk about some successful company developing such technologies.

Capsule is global clinical data Management Company with over 2,000 hospital clients in 39 countries. Their product SmartLinx "is an enterprise-wide medical device Information System™ that can be deployed in virtually any care environment where a medical device is used for patient care. From high acuity environments (e.g. the ICU[8] and the OR[9]) to lower acuity environments (e.g. medical-surgical units and clinics), SmartLinx adapts to clinical workflows and technical requirements of your healthcare enterprise" (44). The system consists of four core components such as connectivity, monitoring, integration, analytics. Connectivity module is able to connect with vast number of medical device type and manufacturers suitable for customer's information system. Next monitoring module responsible for patient monitoring system like a vital signs monitoring. With help of integration module hospitals are capable to adapt and collect data to the needs of the receiving system(s) for clinical documentation, alarm management, clinical research, and more. Analytics module "highlights areas for improvement and suggests steps that can be taken to better manage your medical devices, reduce clinical disruption due to technical issues, and improve clinician satisfaction and efficiency" (44). Capsule applications are able to communicate with different medical device: physiologic monitors, cardiac monitors, pulse oximeters, beds, glucometers, ventilators and so on (*Figure 24*). On Capsule web site a Demo version of this application is available.

[8] Intensive care unit

[9] operating room

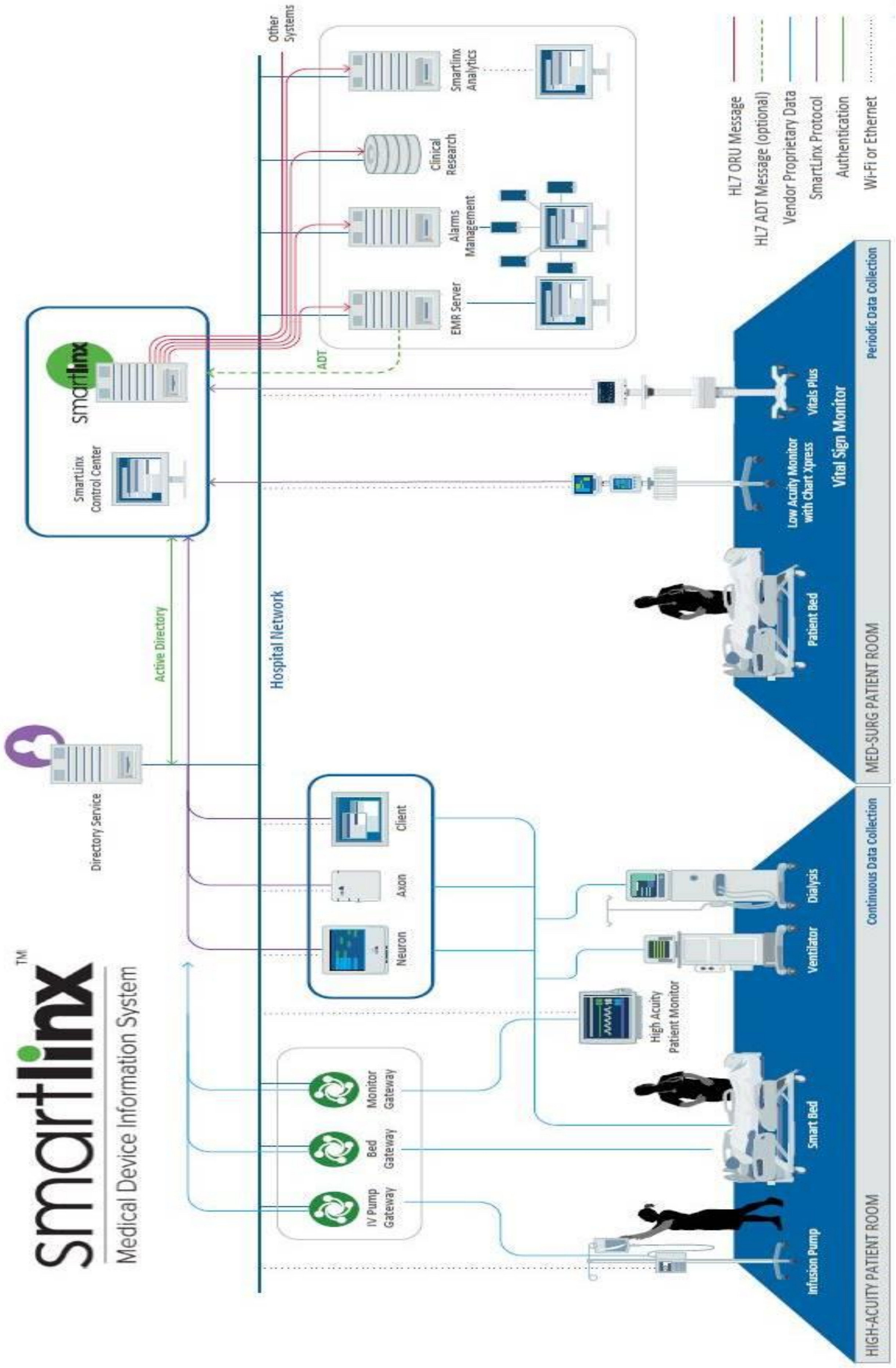


Figure 24. SmarLinx System Diagram (44)

Infosys Company provides another medical device connectivity solution. Infosys's Medical Device Connectivity solution (*Figure 25*) acquires, convert and uploads device data into standard formats providing continuous stream of medical data between devices and information systems. This solution consists of SDK[10] that "allow access to patient demographic and device data using application-programming interfaces (APIs) for EMR[11] integration" (45). The solution supports communication over Wi-Fi, Bluetooth, USB, ZigBee, Ethernet and serial cable. For medical device integration, it uses IEEE 11073, HL7 and DICOM standards that were mentioned earlier (page 14).

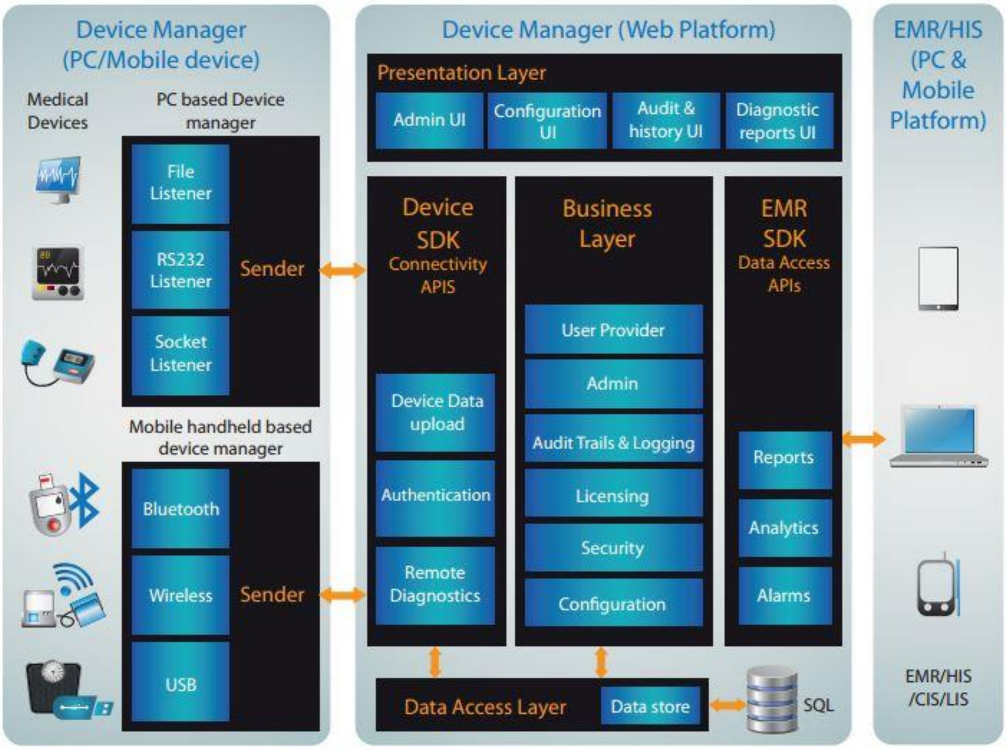


Figure 25. Infosys Medical Device Connectivity solution diagram (45).

By analyzing Capsule and Infosys commercial solutions, we can conclude that installing such systems for medical device connectivity will be very expensive for hospitals or medical care points. Besides that the health care systems spend a lot of money into buying medical devices expecting that interoperability will be already included.

[10] Software development kit
[11] Electronic medical record

4 Current problem solution

In this chapter, we will describe the problem of medical device connectivity with medical information systems by reviewing several real life solutions. First, we look at examples of medical devices, which support communication standards, for better understanding the problem of connectivity. The aim is to define parameters, which are collected by selected medical device. Second, we aim to offer a novel problem-solving method of medical device connectivity with current medical systems while taking into account the disadvantages of existing solutions.

4.1 Communication standards in the reality

On the market of the manufacturers it is easy to find the required medical device. The only differences are the price and quantity of the functions. The most successful manufacturers, in addition to having designed device, have technological ideas and development in order to improve performance. Others manufacturers prefer the usage of commonly accepted technology enabling to establish communication between medical devices and information systems. Let us to make review of state of communication technology on the market of manufacturers.

4.1.1 Cardiograph SE-12 by EDAN Instruments

In chapter 3 page 13, we talked about the common medical devices in hospitals according to HIMSS Analytics research. This research shows that one of the most popular diagnostic medical device is electrocardiograph. After visiting a laboratory of medical technics in CTU at faculty FBMI under the supervision of a professional assistant Ing. Petr Kudrna, Ph.D., we checked the existence of medical devices. One of them is 12-channel cardiograph model SE-12 by EDAN Instruments.

Figure 26. Electrocardiograph SE-12 (46)

This electrocardiograph collects information from 12 leads, represents it by LCD display 320x240 pixels and concurrently records the signal on a registration paper. First, we are interested in hardware communication standards and second, in application layer communication standards. Hardware structure of this device comprises seven input/output places.

№	Name	Describe
1.	Patient cable	Connection for patient cable
2.	Serial port 1	Connection for PC
3.	USB connector 1	Standard USB connector for PC
4.	USB connector 2	Standard USB connector for USB devices (for example USB printer)
5.	External output	Connection for external devices
6.	Serial port 2	Reserved
7.	Net port	Standard network PC connection

Figure 27. Table of cardiograph input/output (46)

The manufacturer offers his own data management software Smart ECG Viewer. This accessorial software is able to collect, to display and to analyze ECG data. This is an evidence of tendency to patent everything by almost all manufactures of medical devices. Nevertheless, hardware communication standards remain unchangeable and we know that for example through serial port information transfers in or out one bit at a time. Receiving ECG data for this medical device is possible from serial port (RS 232) and net port. Type of parameters and its size depend on work modes, which is setting up on the start of measurement. Input data such as name of patient, ID, age, gender, weight, height, blood pressure (mmHg), race, medications, ward No (number of bed), medical (name of doctor), technician (name of technician specialist) are filled manually. There are four types of work modes: manual, auto, rhythm and R-R. In the manual mode, it is possible to choose which lead group will be recorded. Second auto manual mode lead groups are changed automatically as soon as last one was recorded. In rhythm mode, rhythm wave is selected as 60 s or 20 s for recording rhythm leads. The last R-R mode allows to select a lead to record its R-R Histogram, R-R Trend Chart, 180 s ECG wave and different R-R values. After recording in the selected mode, we will have some output data. First part of output data is patient data, which we had like input data. It is logical, because it is needed for collecting output data. The second part of output data is information about measurement such as:

- HR (Heart Rate)
- P Dur----P wave duration: the average P-wave duration from several selected dominant beats;
- PR int----P-R interval: the average P-R interval from several selected dominant beats;
- QRS Dur----QRS complex duration: the average QRS complex duration from several selected dominant beats;
- QT/QTC int----Q-T interval: the average Q-T interval from several selected dominant beats / Normalized QT interval;
- P/QRS/T axis----Dominant direction of the average integrated ECG vectors;
- RV5/SV1 amp----The maximum of the amplitude of R or R' wave of one selected dominant beat from lead V5 / The maximum absolute value of the amplitude of S or S' wave of one selected dominant beat from lead V1;
- RV5+SV1 amp---- Sum of RV5 and SV1;
- RV6/SV2 amp---- The maximum of the amplitude of R or R' wave of one selected dominant beat from lead V6 / The maximum absolute value of the amplitude of S or S' wave of one selected dominant beat from lead V2; (46)

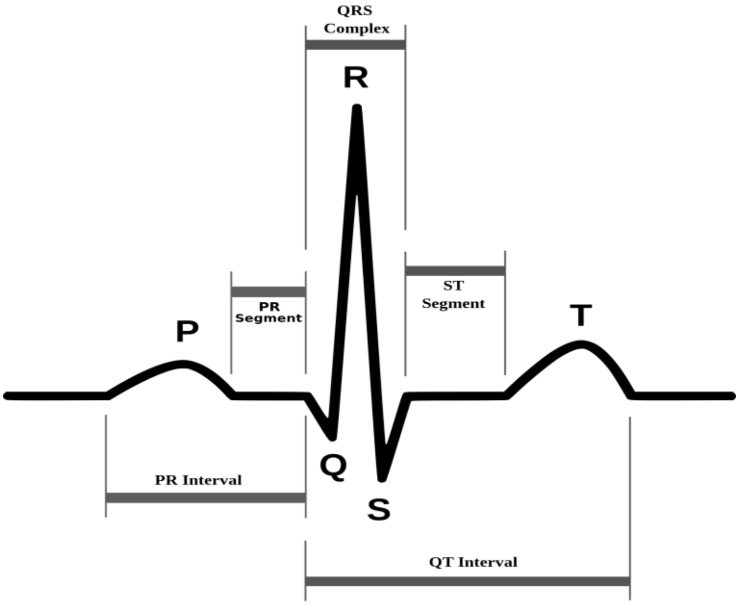


Figure 28. Normal sinus rhythm for a human heart as seen on ECG (public domain)

The third part is diagnosis information. Only in R-R work mode information about measurement is significantly different from previous one.

- HR (Heart Rate)
- RR Avg Interval (Average RR interval)
- RR Max Interval (Maximum RR interval)
- RR Min Interval (Minimum RR interval)
- Max/Min (Ratio of Maximum RR interval to Minimum RR interval)
- SDNN (Standard Deviation of Normal to Normal Intervals)
- RMSSD (Root Mean Square Successive Difference)
- RR Histogram
- RR Trend. (46)

Of course, besides numerical values the basic part of output data is ECG waves. Smart ECG Viewer software is able to create PDF file from ECG report.

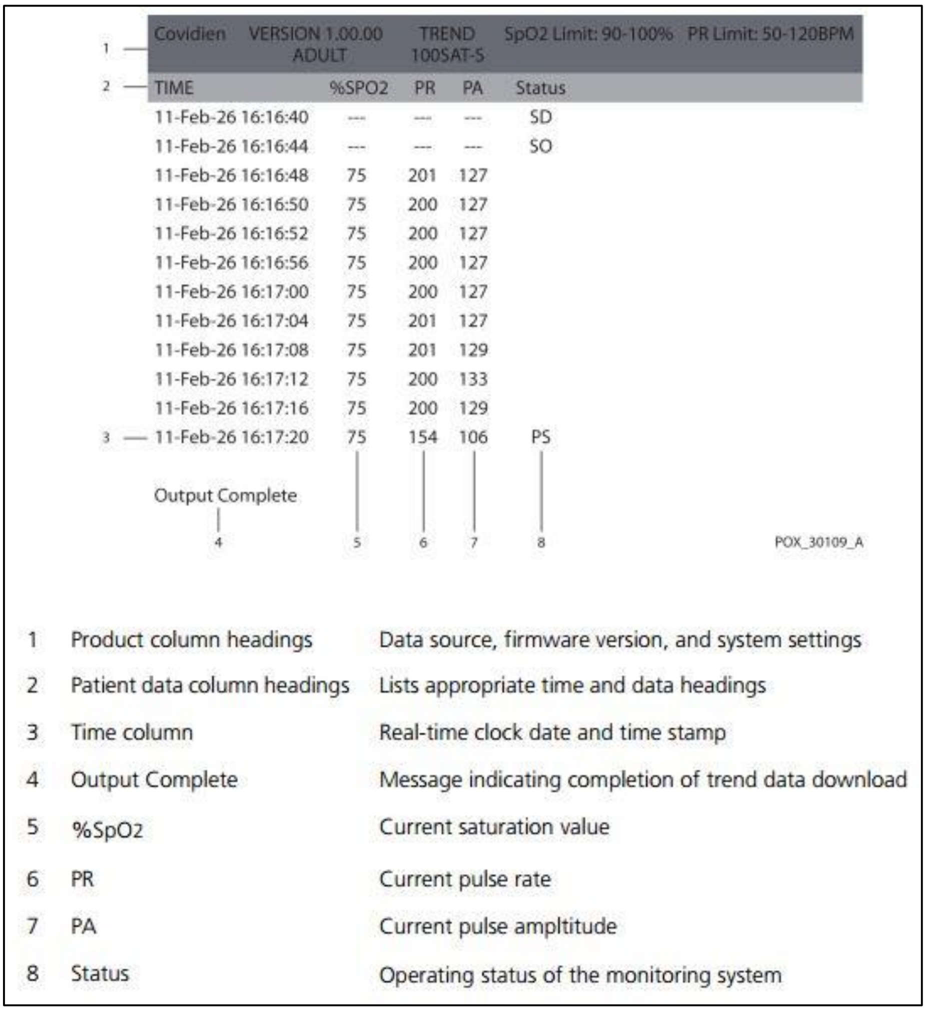
4.1.2 Pulse oximeter Nellcor™ Bedside SpO_2 Patient Monitoring System by Covidien

The second selected segment of example of medical device in laboratory at faculty is pulse oximeter. It is a very common and popular diagnostic device in hospitals. The name of the chosen pulse oximeter is Nellcor™ Bedside SpO_2 Patient Monitoring System by Covidien manufacture. This device allows monitoring of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. On a photo of this device (*Figure 29*) connector for SpO_2 sensor is clearly visible. Additionally to pulse oximeter, Covidien manufacture offers different types of SpO_2 sensors: adhesive, reusable; adult, pediatric or neonatal; forehead, nasal and so on.

Figure 29. Nellcor[tm] Bedside Patient Monitoring System (front and side panel)

As usually we are mostly interested in hardware and software communication standard. Let us look at side panel components. The panel has two USB ports: USB A type and mini USB B type. In operator’s manual documentation external data communication is described. USB interface enables firmware updating unlike mini USB interface. Mini USB interface is intended for connection to a personal computer and downloading collected trend data from device. “Any PC connected to the data port must be certified according to IEC Standard 60950.” (47) This standard control the safety of information technology equipment. For transferring the data ASCII format is used, that is compatible with several spreadsheet programs (ASCII 2). It means that users can import trend data to a spreadsheet program such as Microsoft Office Excel. Example of output trend data is shown on *Figure 30*. De facto, output parameters are the following:

- Time column
- Saturation value (in percentage)
- Pulse rate
- Pulse amplitude
- Status of device



Covidien	VERSION 1.00.00 ADULT	TREND 100SAT-S	SpO2 Limit: 90-100%	PR Limit: 50-120BPM

TIME	%SPO2	PR	PA	Status
11-Feb-26 16:16:40	---	---	---	SD
11-Feb-26 16:16:44	---	---	---	SO
11-Feb-26 16:16:48	75	201	127	
11-Feb-26 16:16:50	75	200	127	
11-Feb-26 16:16:52	75	200	127	
11-Feb-26 16:16:56	75	200	127	
11-Feb-26 16:17:00	75	200	127	
11-Feb-26 16:17:04	75	201	127	
11-Feb-26 16:17:08	75	201	129	
11-Feb-26 16:17:12	75	200	133	
11-Feb-26 16:17:16	75	200	129	
11-Feb-26 16:17:20	75	154	106	PS

Output Complete

POX_30109_A

1	Product column headings	Data source, firmware version, and system settings
2	Patient data column headings	Lists appropriate time and data headings
3	Time column	Real-time clock date and time stamp
4	Output Complete	Message indicating completion of trend data download
5	%SpO2	Current saturation value
6	PR	Current pulse rate
7	PA	Current pulse ampltitude
8	Status	Operating status of the monitoring system

Figure 30. Sample Trend Data from Nellcor™ Bedside Patient Monitoring System. (47)

Obviously, this type of output data is prepared for further usage such as sending collected trend data to a hospital information systems or EHR.

4.1.3 Patient monitoring platform Root™ by Masimo Company

One of the most successful medical device manufacturers in America is Masimo Company. Masimo Company is specialized in developing and manufacture noninvasive patient monitoring devices and many types of sensors. One of their product is present in faculty laboratory. It's patient monitoring platform Root™. Root™ collects huge amount parameters from their own different sensors and devices. On *Figure 31*, we depicted the backside of this device with its connectors. Four ports named Iris™ are designed for communication with ventilators, IV pumps, "smart" beds and other patient monitors. Through Wi-Fi technology this information from other medical devices, connected by Iris ports, transfer via Iris Gateway to patient's EHR or hospital information system. In this way are connected other medical device and sensors by Masimo. One of this noninvasive pulse oximeter Radical-7. Radical-7 is using standard wireless connectivity from integrated 802.11 and Bluetooth® technology for the transferring measured data to patient monitoring platform Root™. In addition, this device has serial port for communication with PC, monitoring platform or printers. Serial port transfers data consist of date, time, SpO_2, pulse rate, perfusion index and alarm values on ASCII format.

Figure 31. Backside of Masimo's Root Monitor. Iris™ ports.

Root is also designed to collect and represent measurements from their own measurement devices through Masimo Open Connect—or MOC-9™. (*Figure 32*)

- SedLine® brain function monitoring
- Phasein™ capnography[12] monitoring
- Designed for third-party measurement expansion. (48)

Figure 32. Side view of Masimo's Root Monitor. MOC-9™ ports. (48)

Almost of all Masimo's technologies are proprietary. It indicates difficulties in communication with another medical system without their proprietary software. Despite this, export data from some medical devices in ASCII format is possible for this manufacturer also.

[12] Capnography - is the monitoring of the concentration of carbon dioxide in the respiratory gases

4.1.4 Personal diagnostic medical devices

Next group of medical devices is personal medical devices. In our modern life, these technologies are called Smart Health. It offers very useful equipment for personal measurement similar to those used in hospitals. Such devices as blood pressure meter, hear rate meter, weight scales, pulse oximeters, glucose meter, thermometer and so on are very commonly used at home. With the help mobile technologies, it is possible to collect and to record measured data to mobile devices. Visiting e-shop websites on the Czech market, we noticed that the bestseller of smart weight scales is Beurer BF 700. Beurer BF 700 measures body weight, body fat, body water, muscle ratio, bone mass, AMR[13]/BMR[14] and BMI[15]. These smart scales have Bluetooth® SMART technology whereby transfer data to your smart device. As well as many other manufacturers of medical devices this manufacturer also has own proprietary software for mobile devices. It is called Beurer Healthmanager.

For the prototype of our work, we will take fitness bracelet Mi Band by Xiaomi. For communication with smartphone Bluetooth® technology is used. There are several advantages in purchasing exactly this fitness bracelet: the price is affordable and a reverse-engineering protocol is available for the developing mobile applications. Fitness bracelet collects information about the overcome distance, the number of steps traveled and calories burned. Xiaomi Company also offers mobile application for collecting and analyzing data.

Figure 33. Fitness bracelet Mi Band by Xiaomi with optical sensor.

Additionally, Mi Band is equipped with optical sensor for collecting heart rate data. What is the principle of optical sensor processing? (*Figure 34*) Mi Band optical sensor consist of green LED which lights on blood vessels through the skin and the photodetector that captures the non-absorbed by blood light from vessels and process this signal for the measuring heart rate. Photo Plethyamo Graphy (PPG) method is used for measuring heart rate. PPG is “a simple and low-cost optical technique” (49) that is widely popular among commercially measuring medical devices. Waveform of PPG consist of pulsatile ('AC')[16] physiological waveform that depend on cardiac changes. Second component is varying ('DC')[17] baseline with lower frequency that is depending on sympathetic nervous system activity. (49)

[13] Activity Metabolic Rate
[14] Body Mass Reduction
[15] Body Bass Indexes
[16] Alternating current
[17] Direct current

Equipment required for using this fitness bracelet are mobile platforms from Android 4.4 and from IOS 7.0. The owners of this bracelet can use the proprietary mobile application Mi Fit for fully using Mi Band functions.

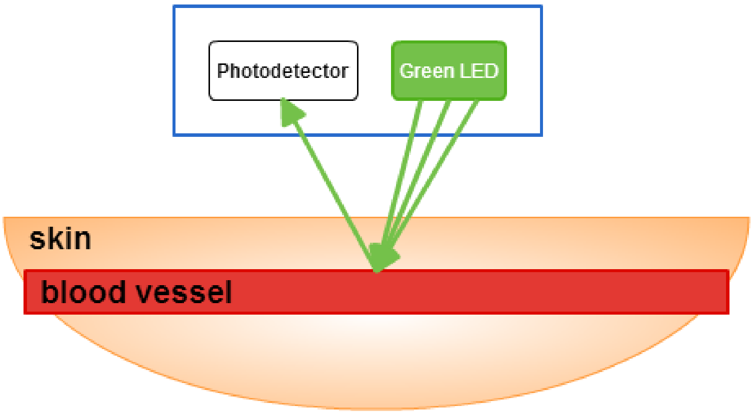


Figure 34. The principle of optical sensor detecting. (Figure by author of this thesis)

4.1.5 Communication protocols on application layer

The amount of efforts to reach interoperability among some part of manufacturers increase but slowly. The main advantages of establishing interoperability between medical device and hospital information systems is that groups of medical devices have almost the same output parameters. However, communications standards on application layer[18] such as HL7, DASTA, DICOM and so on are already defined and well known to everybody. While these protocols act on application layer, communication protocols on physical layer build the other side of the coin.

In chapter 3.1.1 these data transfer protocols were described for acquaintance. Now we will explore where exactly it is used. Primarily, the aim of these protocols is to transfer structured medical data between different medical information systems. The most demanded data transfer protocol is HL7. The HL7 mainly describes the following cases:

- Patient management – admit, discharge, transfer patient (ADT);
- Medical documents, records, treatments;
- Queries, resources (rooms, beds, devices, transport etc.);
- Medical procedures, results, clinical trials;
- Financial management; (50)

The information unit of this standard is a message that is sent from a medical application to another. Typical scenario for sending data is a request for laboratory observation from hospital information system to laboratory information system. The data generated from medical devices can be also encoded as HL7 message. On *Figure 35* the result message of medical observation containing trend data of the individual measured vital parameters is depicted. The advantage of HL7 coding is readability. We are able to read what parameters the message contains.

[18] Open Systems Interconnection model (OSI model)

```
MSH|^~\&|NIHON KOHDEN|NIHON KOHDEN|CLIENT APP|CLIENT FACILITY|20130910095014||ORU^R01^ORU_R01|20130910011092|P|2.4|||NE|AL|Japan|ASCII||ASCII
PID|||2013046||^^^^^^L^A|||O
PV1||I|^^OR-1^10.2.56.5:1
ORC|RE
OBR|1|||VITAL|||20130910095013||||||||||||||||A
OBX|1|NM|001000^VITAL HR|1|94|bpm|||||F|||20130910095013|||
OBX|2|NM|002000^VITAL VPC|1|0|/min|||||F|||20130910095013|||
OBX|3|NM|003000^VITAL ST1|1|0.00|mV|||||F|||20130910095013|||
OBX|4|NM|003001^VITAL ST2|1|0.02|mV|||||F|||20130910095013|||
OBX|5|NM|003002^VITAL ST3|1|0.02|mV|||||F|||20130910095013|||
OBX|6|NM|003003^VITAL STVR|1|0.00|mV|||||F|||20130910095013|||
OBX|7|NM|003004^VITAL STVL|1|-0.01|mV|||||F|||20130910095013|||
OBX|8|NM|003005^VITAL STVF|1|0.02|mV|||||F|||20130910095013|||
OBX|9|NM|004001^VITAL APSEC(RESP)|1|2|sec|||||F|||20130910095013|||
OBX|10|NM|004073^VITAL rRESP(co2)|1|21|/min|||||F|||20130910095013|||
OBX|11|NM|005000^VITAL RESP|1|21|/min|||||F|||20130910095013|||
OBX|12|NM|005001^VITAL APSEC(RESP)|1|2|sec|||||F|||20130910095013|||
OBX|13|NM|007000^VITAL SpO2|1|100|%|||||F|||20130910095013|||
OBX|14|NM|007001^VITAL PR(spo2)|1|94|/min|||||F|||20130910095013|||
OBX|15|NM|058000^VITAL ICP(S)|1|140|mmHg|||||F|||20130910095013|||
OBX|16|NM|058001^VITAL ICP(D)|1|140|mmHg|||||F|||20130910095013|||
OBX|17|NM|058002^VITAL ICP(M)|1|140|mmHg|||||F|||20130910095013|||
OBX|18|NM|072007^VITAL rPR(spo2)|1|94|/min|||||F|||20130910095013|||
OBX|19|NM|073000^VITAL RESP(co2)|1|21|/min|||||F|||20130910095013|||
OBX|20|NM|073001^VITAL EtCO2|1|43.0|mmHg|||||F|||20130910095013|||
OBX|21|NM|073003^VITAL APSEC(CO2)|1|2|sec|||||F|||20130910095013|||
OBX|22|NM|103005^VITAL SQI(bis)|1|0.0|%|||||F|||20130910095013|||
```

Figure 35. Sample of HL7 message from Patient Monitor (study materials).

The second DICOM standards is universal. DICOM Network Protocol is one of DICOM levels that using TCP/IP protocols for transferring medical images from devices to PACS[19]. DICOM standard allows data transferring from different device manufacturers. A medical device using this standard is named as a DICOM-“compliant” device that is able to connect to the DICOM network exchange data. (51) One of such examples of using DICOM standards is ETIAM DICOM Izer TS that is installed on a medical station equipped and connected to the hospital information system. This system works properly in the Notre Dame du Perpétuel Secours Hospital (HPS) in Levallois-Perret. ETIAM DICOM Izer TS is integrated with an endoscopic tube. (Figure 36) (52)

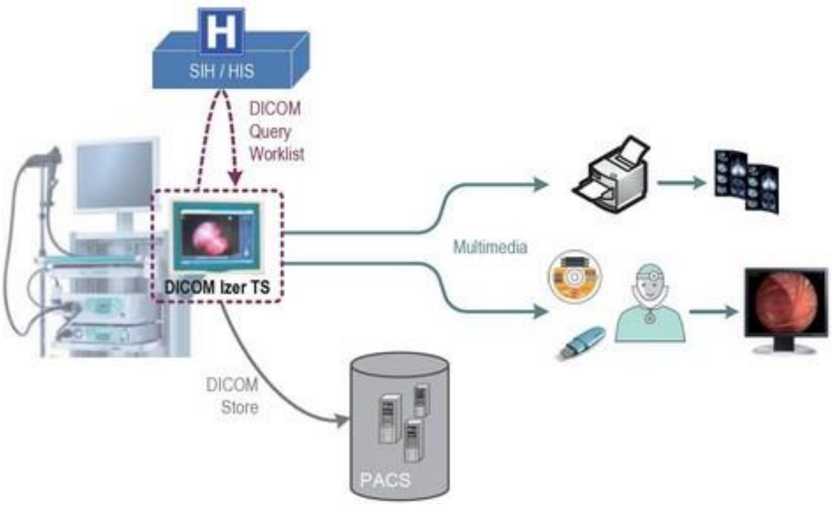


Figure 36. System architecture of ETIAM DICOM Izer TS. (52)

The data transfer standards are real and functioning standards that is working locally in the world of medical device connectivity. What is the problem of global distribution? We talk about the problems and potential solutions for better connectivity between medical information systems and medical devices in the next chapters.

[19] Picture Archiving and Communication System

4.2 Problem of exporting data from medical devices and its solution

No matter what technology is used for transferring data between medical devices and mobile device or PC, the main problem is processing and understanding these data. Physical layer deals with bit-level transferring by using various physical layer protocols/technologies: Bluetooth, Ethernet, USB, 802.11 Wi-Fi, GSM, RS-232 etc. For example, we can have a PC and a medical device with serial output. After connecting serial cable from medical device to PC port, we will get nothing besides raw bits. It is not enough for processing these encoded data. In case of medical devices, manufacturers have proprietary protocol, which is intended for decryption received data. In other words, these protocols describe meaning and sequence of bytes. For example, we received an array of bytes and we have protocol for decryption. Consequently, meaning of every byte we will know, for example, first four bytes contain data about patient, second five bytes contain data about results of medical measurements and so on. Therefore, manufacturers with open source documentation about their products resolve the problem in establishing the connection between medical devices and information systems. However, manufacturers with proprietary communication protocols do not allow easy communication between their products and any external medical information system. The first option to solve the problem is to request manufacturers about providing their proprietary protocol. However, this way is not always possible. If the protocol is provided from manufacturer, then it is possible to develop a driver for the given device or a client program, which will be able to process data according to proprietary protocol rules and to send it to a server.

Nevertheless, in some cases we can work around this problem. Some medical devices are able to export files in different formats. This offers a second option for solving the connectivity problem. Mostly, diagnostic devices can provide a huge number of different output parameters, which are exported to PC as files. Having examined documentations of different representatives from diagnostic medical devices, we can identify formats of output files for each group of medical devices.

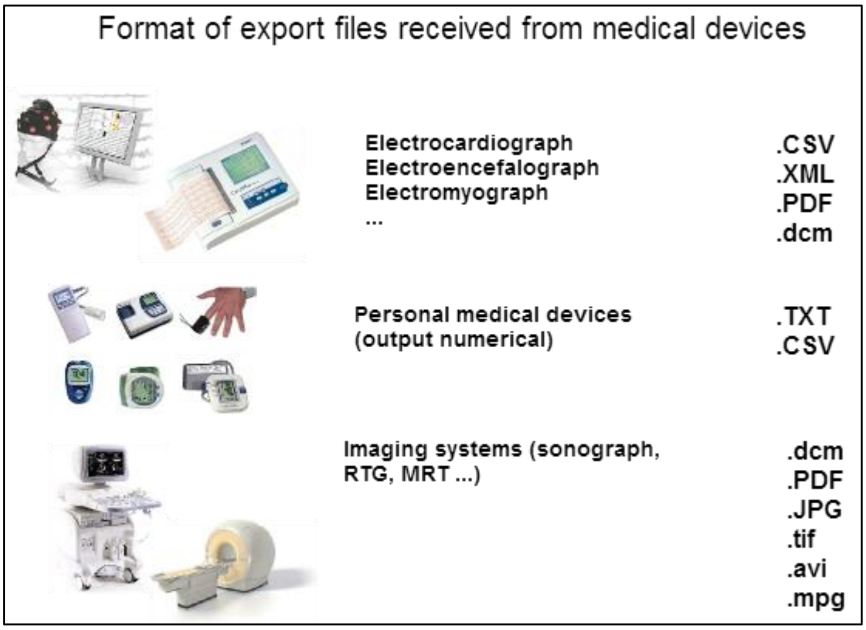


Figure 37. Format of export files received from medical devices. (Figure by author of this thesis)

After receiving measured data by this way, next step will be to upload it to the medical information system or server application, which will read data from received files. Thus, having avoided reading data from cable stream in real-time, it is now possible to extract necessary information from data files offline.

Within our aim to offer a flexible all-purpose method for connectivity between medical device and information system, we can define the following basic steps:

1. Every medical device has hardware outputs (ports). It is necessary to study the manufacturer's documentation about these ports and determine which port is designed for communication with outside (e.g. PC).
2. It is very important to define what protocol is used by the medical device for transferring data though the given port. If this information is unknown, the manufacturer should be contacted. In some cases, the manufacturer can provide proprietary protocol. Sometimes like in the example of the cardiograph presented in chapter 4.1, it is possible to have several ports such as USB, net port and so on. Usually the USB port allows to export data in some file format.
3. Next step is processing received data using client software on a PC, smartphone or any other processing unit. The client can be an application written in third-generation programming language (C++/C#, Java, Python and so on) or fourth-generation programming language (Matlab and others). These data can be parsed in some communication standard, in the application layer such as HL7 or DASTA, or it can be XML or JSON formats. It depends on the targeted information system.
4. Before sending data to server backend medical information system, it is necessary to define parameters that give meaning to the data received from medical device. In other words, a uniform data model should be defined in the target system for storing recorded data in a meaningful way.
5. Processed data are sent remotely to the target system by HTTP requests or to local medical information system.
6. The target system accepts measured data has according to all parameters, which can be received from that given medical device.

4.3 Implementation of solution in real information system

We will use an existing "Telecardiology Data Collection System in Low-Resource Environments" as backend. This Telemedicine system was implemented as a research information system within the master's thesis by Rosion Versace DZIAN (53) under the guidance of Ing. Michel Kana, Ph.D. The system makes use of a generic metadata model authored by Mr. Kana (54). The principle of this metadata model is "mutability". The idea is to allow each organization that will use the generic model to build its own specific model for a particular use case with minimal software development effort. For example, in the office of private therapist only patient visits and their diagnosis are managed, but a hospital with 1000 beds needs a bigger management system with salaries, transport information, canteen management and so on. The telemedicine system implemented by Mr. Dzian using the generic data model was a good illustration about how the generic data model could support low resources environment for collecting arterial pulse data remotely. We believe that the generic data model authored by Mr. Kana can also help solving the mobile device data connectivity problem. In the following chapters, we demonstrate how.

4.3.1 System Architecture

For better understanding of transferring measured data from devices to backend server, we describe a system architecture based on REST[20] technology. This type of architecture allows us to design and describe the networking principle of our solution. Additionally, we divide medical devices into two groups: the ones used privately and the ones used in a medical facility. *Figure 38* also depicts communication standards and client software platforms.

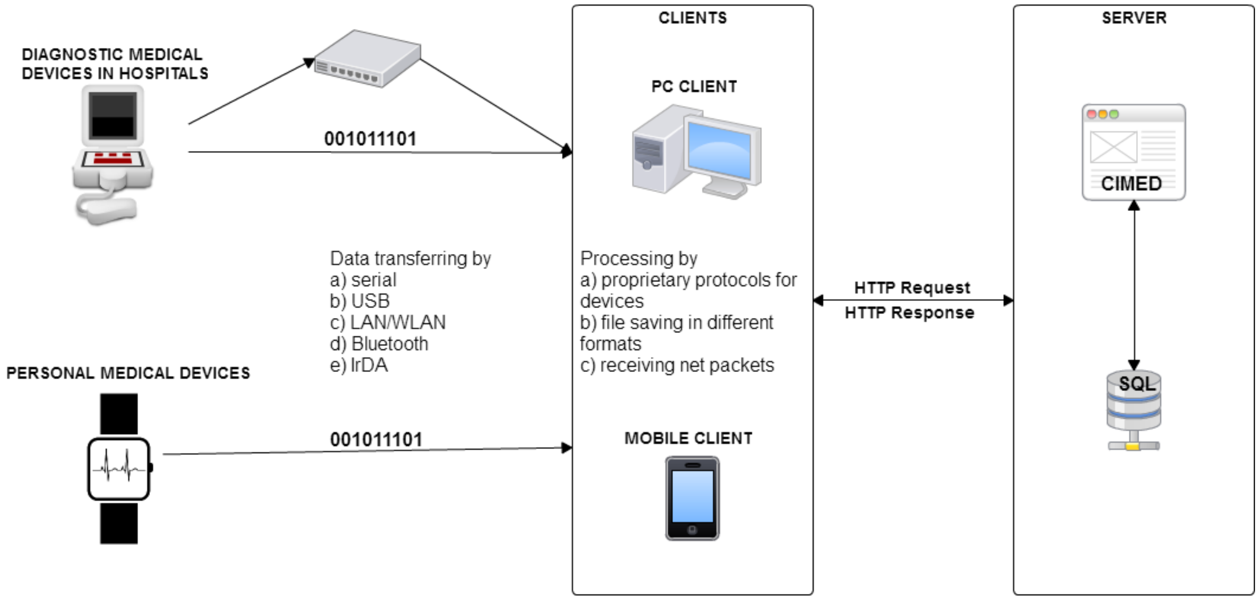


Figure 38. System architecture

4.3.2 Data structure

Our aim is to design and to develop a new module for the Telemedicine system developed by Mr. Dzian in order to establish connectivity with various medical devices. For this purpose, we will adapt Mr. Kana's metadata model for receiving data from different diagnostic devices. We shortly describe this data model and show how we can modify it for new connectivity module. The objects from the data model that will be used for supporting medical device connectivity are presented below:

- *Resource Type*
  It is Meta class used to define specific classes such as Patient, Physician, Diagnosis, Device and so on.
- *Resource Meta Type*
  All resource type should be grouped in categories, such as Patient, Physician and Nurse can be categorized as Human; Hospital, Device and Room are Material and so on.
- *Resource Type Attribute*
  A resource type has attributes, for example Name, ID, Age, Address, etc.
- *Resource Type Attribute Type*
  Attributes can be mandatory or not, it can be binary, printable, etc.
- *Resource Type Binding*

[20] Representational State Transfer

Resource Types can have bindings with other resource types. In our case, some device can belong to the Patient.

- *Organization*
  Define an institution, for example Hospital, Clinic, Medical point and so on.
- *Users, User Groups…*
  Typical and basic data classes for every information system. (53)

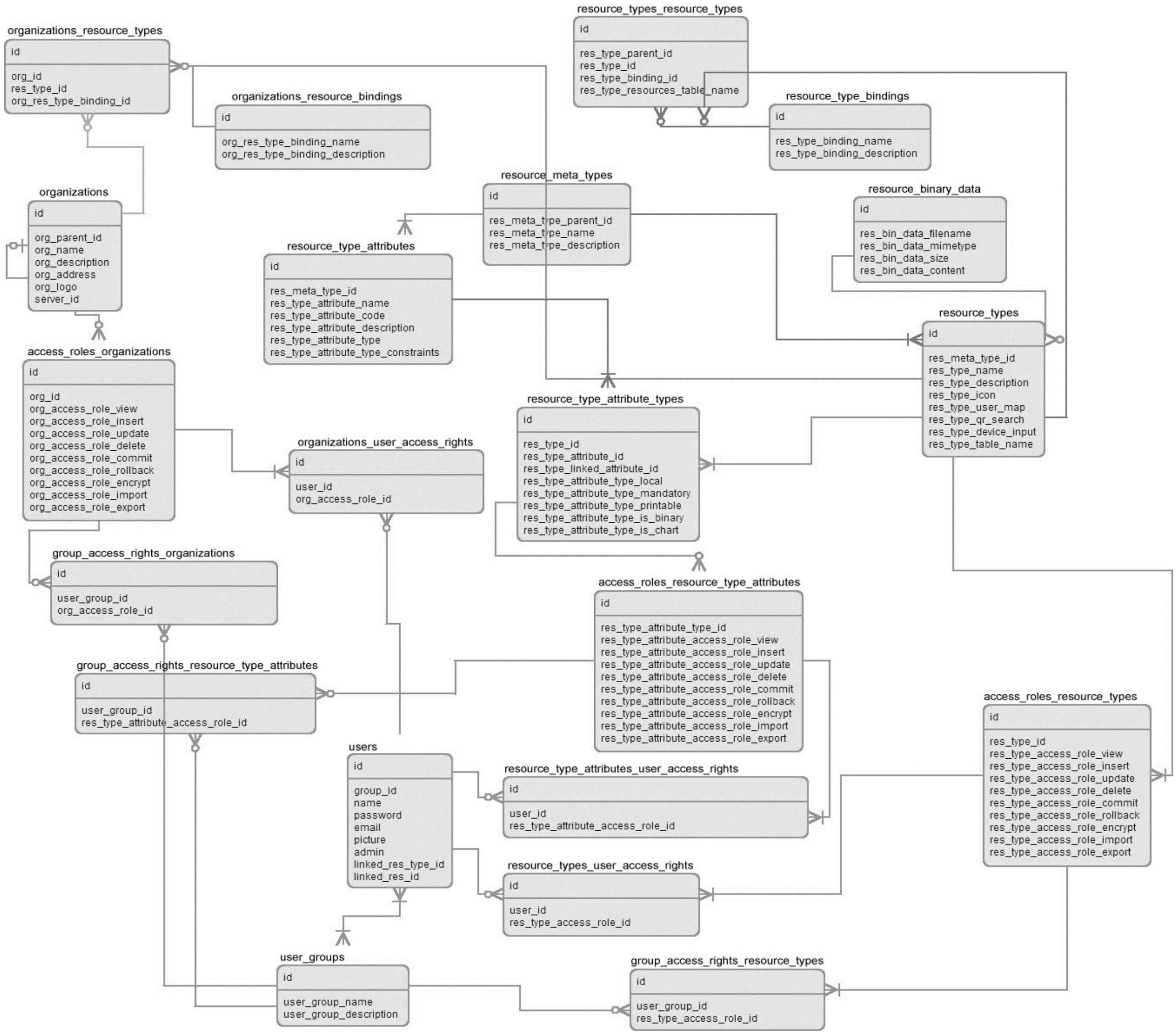


Figure 39. Data model of Telemedicine system. (53 p. 32)

Now, we can derive a data model for our case. Let us assume that our challenge is to connect a certain amount of medical devices with the Telemedicine information system. There are pulse oximeter, glucometer, electrocardiograph, weight scales, fitness bracelets etc. following methods described in chapter 4.2. It helps for us define the list of supported devices. In order to define new supported medical devices in our information system it is required to do following steps:

1. First step is to describe all types of medical devices and their parameters (attributes).
2. Next, it is necessary to model the types of communication between device and PC, smartphone or any other processing unit, i.e. to describe every type of supported communication protocol.
3. The important part of medical device communication is measurement data. Describing all kinds of measurement is necessary for receiving data from different medical devices.

Now we will apply the Data Model of Telemedicine system for creating Resource Types needed for describing every medical device with its parameters. *Resource Meta Types* should include such concepts as *Device, Connection, Measurement* and *Protocol Service* for full description of device medical connections.

Devices can be divided into different groups such as: Client Device, Diagnostic Device, Therapeutic Device, Pulse Oximetry Device, Fitness Bracelet, Weight Scales, Electrocardiograph and so on. *Connection* are described as Physical layer, Serial connection, USB connection, LAN connection, Wi-Fi connection, Bluetooth connection and so on. *Measurement* are Cardiac measurements, Physical measurements, Chemical measurements and so on. *Protocol Service* defines the all services which protocol maintains.

At the end of this process, we will have implemented Resource Meta Types in the database of the system. Column *res_meta_type_parent_id* in the table allows attribute inheritance, meaning that all attributes which belong to parent resource meta type can also belong to child resource meta type. The following table shows the defined data:

res_meta_type_id	res_meta_type_parent_id	res_meta_type_name	res_meta_type_descriprion
grsy5y		Human	Represents all Resources that are human
erghe4		Material	Represents all Resources that are physical materials
Gf565ty		Abstract	Represents all abstract resources
Dfhy6u	erghe4	Device	Represents all materials resources that are devices
bfnga4	Dfhy6u	Diagnostic Device	Represents all devices resources that are diagnostic
6njgf	Dfhy6u	Therapeutic Device	Represents all devices resources that are therapeutic
7htjekis	bfnga4	Pulse Oximeter	Represents all diagnostic devices resources that are Pulse Oximeters
jtsy785	bfnga4	Fitness Bracelet	Represents all diagnostic devices resources that are Fitness Bracelets
jhgc57	bfnga4	Electrocardiograph	Represents all diagnostic devices resources that are Electrocardiographs
kjflu564	Dfhy6u	Client Device	Represents all devices resources that are Client Devices
46gdh	kjflu564	Mobile Device	Represents all client devices resources that are Mobile Devices
7865hfdh	kjflu564	PC Device	Represents all client devices resources that are PC devices
fvg5hs	erghe4	Connection	Represents all material resources that are Connections
7fdnhr56	fvg5hs	Physical layer	Represents all connection resources that are on Physical layer
8fhe4d	7fdnhr56	Serial Connection	Represents all physical layer resources that are Serial Connections
fsfw356g	7fdnhr56	Bluetooth Connection	Represents all physical layer resources that are Bluetooth Connections

6thrwr6	7fdnhr56	USB Connection	Represents all physical layer resources that are USB Connections
8gdjsg4	Gf565ty	Measurement	Represents all abstract resources that are Measurements
6fdhjk	8gdjsg4	Cardiac Measurement	Represents all measurement resources that are Cardiac Measurements
trd546BZf	8gdjsg4	Physical Measurement	Represents all measurement resources that are Physical Measurements
6hdeej5	8gdjsg4	Chemical Measurement	Represents all measurement resources that are Chemical Measurements
5rhdhaeu	Gf565ty	Protocol Service	Represents all abstract resources that are Protocol services

Figure 40. Resource Meta Type table.

Next, our aim is to define all attributes for every Meta Type: *Device, Connection, Measurement* and *Protocol Services*.

Every *Device* has common parameters, such as Model Name, Manufacturer, Serial Number, Country of Production, Year of Manufacture, Service Life and so on. Every *Diagnostic Device* has specific parameters such as Type of Use (home or hospital) and others. *Pulse Oximeter Devices* are typically characterized by Type of Monitor, Size of Monitor, Portability and so on. *Serial Connection* is commonly described by Modulation Speed, Parity, Number of bits per character etc. *Bluetooth Connection* has parameters like Class of Permitted Power and Version. *Measurement* will consist of all measurement parameters, which we can collect during medical measurements. *Physical Measurement* are everything what is possible to measure physically. For example, weight scales measure Body Mass, special medical device measures Height or thermometer Temperature. Parameters for *Cardiac Measurement* can be Heart Rate, Diastolic Volume and Systolic Volume may be in group of the *Physical Measurement*.

We recall that, from documentation we found out that, pulse oximeter has following output parameters:

Identifier (OBX-3)	Vital Sign	Units (OBX-6)	Unit of Measure
SpO2	Oxygen Saturation (SpO2)	%^Percent^UCUM	%
BPM	Pulse Rate (PR)	{beats}/min^beats per minute^UCUM	BPM (1/min)
PI	Perfusion Index (PI)	%^Percent^UCUM	%
SpCO	Carbon Monoxide (SpCO)	%^Percent^UCUM	%
SpMet	Methaemoglobin (SpMet)	%^Percent^UCUM	%
SpHb	Noninvasive Haemoglobin (SpHb)	g/dL^g/dL^UCUM	g/dL
CAO2	Oxygen Content (SpOC)	mL/dL^mL/dL^UCUM	ml O2/dL blood
PVI	Pleth Variability Index (PVI)	%^Percent^UCUM	%
RR	Acoustic Respiration Rate (RRa)	{breaths}/min^breaths per minute^UCUM	Breaths/min
PORR	Pleth Respiration Rate (RRp)	{breaths}/min^breaths per minute^UCUM	Breaths/min
PSIF	Patient State Index (PSI)	{PSI}^PSI^UCUM	{dimensionless index}

Figure 41. Output parameters from pulse oximeter by MASIMO manufacturer. (48)

Parameters from *Figure 41* can be modelled as attributes of *Cardiac Parameters and Chemical Measurement*. In case of adding another pulse oximeter from a new manufacturer, probably, parameters will remain the same, because the purpose for every pulse oximeter is to measure oxygen saturation, pulse rate and some additional parameters. By this way, we can adopt any new device of type pulse oximeter.

Therefore, we can fill the table *Resource Type Attributes* for example for some medical devices, which were introduced in chapter 4.1. Due to the big size of table *Resource Type Attribute*, we will depict only a part of it in the table *Figure 42*.

res_type_attribute_id	res_meta_type_id	res_type_attribute_name
6dfheu	Dfhy6u	Model Name
s57dfth	7htjekis	Size of Monitor
6kjbvk4	6thrwr6	Type
6fhgdk8	8fhe4d	Modulation Speed
7jdtrg	8gdjsg4	Heart Rate
5htgkfr	8gdjsg4	Oxygen Saturation

Figure 42. Resource Type Attribute table.

Now, when we have all we need defined in *Resource Meta Type* and *Resource Type Attribute* tables, we should fill *Resource Type* table. The information stored in *Resource Type* table will be used to dynamically generate tables where information such as the list of supported device will be defined.

res_type_id	res_meta_type_id	res_type_name
5fge4y	7htjekis	Pulse Oximeter
7hgd44	jtsy785	Fitness Device
gf5ueh	46gdh	Mobile Device
6u6rstj	8fhe4d	Serial Connection
9jfbsk4	6thrwr6	USB Connection
u65ejht	fsfw356g	Bluetooth Connection
67bfdgee	8gdjsg4	Measurement of Pulse Oximeter
reu54jw	5rhdhaeu	Bluetooth service

Figure 43. Resource Type table.

An advantage of *Resource Type* tables is binding. Bindings can be used to link the medical devices to support connectivity/signal parameters. For example, Pulse Oximeter will be linked to Serial Connectivity. This allows saying that serial port is enabled for that pulse oximeter. Another example is binding between medical device and measurement. So that we will understand that Pulse Oximeter measures Heart Rate, Oxygen Saturation and other parameters.

With help of the data mapping algorithm described above, admin or users are able add the new device to the list of supported devices. Finally, the generated tables will look like these:

id	Type
6kjbds3	USB A type

Figure 44. USB Connection data table.

id	Model Name	Manufacturer	Size of monitor
vghf6dy	Nellcor™ Bedside SpO_2	Covidien	480 × 272

Figure 45. Pulse Oximeter data table.

pulseoximeter_id	usbconnection_id
vghf6dy	6kjbds3

Figure 46. Pulseoximeter_connection resource binding table.

id	user_id	Oxygen Saturation	Heart Rate	Date
76jehnyt	gfhtrbfst564wy	95	88	0000/00/00

Figure 47. Pulse Oximeter Measurement

After receiving some measured data from the medical device, the binding table with *src_id* (Pulse oximeter measurements) and *dest_id* (Pulse Oximeter) will be alike the follow:

measurement_pulse_oximeter

id	src_id	dest_id
lgmjb3	76jehnyt	vghf6dy

Figure 48. Measurement_pulse_oximeter resource binding table

This table means that this measurement from table Pulse oximeter measurements was done with pulse oximeter from table Pulse Oximeter.

Summarizing this chapter, we can say that our novel method described in chapter 4.2 helps for establishing medical device connectivity with real hospital information systems. Certainly, all aspects of this field is impossible to capture, because of the medical device diversity. Prior to defining the novel method we had to research a big amount of technical device documentations and gain a deep understanding how devices operate: technical functions, input and output parameters, output ports, software accompaniment, device compatibility with other devices and medical information systems, the lists of supporting standards integrated in devices structure and others. It is important to understand and to catch the similar characteristics needed to define medical device groups. By this way, we can identify the similar output parameters for the groups of medical devices, the connectivity ways and the ways of transferring medical data from devices to information systems, etc. Every additional documentation gives more information about these concepts. All this information may be useful for adapting any medical information system for any medical device connection. This novel method commonly describes and clarifies the concepts of medical device connectivity. In case, if is required to connect and start the transferring data from the defined medical device to some hospital information system, after reading this method it should be possible to have the understanding how it works and what steps should be done for establishment connectivity. Following this method, we think that it is possible to configure and to adapt almost every medical information system for connectivity with any medical device. We will demonstrate our approach in the next chapter.

5 Implementation of mobile application for collecting heart rate data from fitness bracelet

The backend for our mobile application was configured following the novel problem-solving method of medical device connectivity described in chapter 4.2. The next aim is to design and to develop our mobile application for collecting and storing to the server data from fitness bracelet. It might be not only a fitness bracelet, but also any other medical device from which user wants to collect medical data. The expected result will show the ability of implementing our novel method for medical device connectivity with hospital information system by the mobile client. Fitness bracelet that we will use is Mi Band by Xiaomi as described in chapter 4.1.4.

5.1 Used technologies

From the beginning of our research, we have planned to code the mobile application with HTML5[21], CSS[22] and JavaScript languages. It means it would be an hybrid mobile application that is supported by popular mobile platforms such as Android, IOS and Windows. HTML is well known standard markup language used to develop web pages. HTML5 is the latest version of HTML that is available to use for development of cross-platform applications. The other possibilities of using HTML5 for mobile app develop is not different from other mobile app development languages. HTML5 implements the features such as local storage, local SQL databases and caching. As framework for development we selected Monaca. Monaca is a framework that allows development of mobile applications on the cloud without the installing different tools on user's PC. The development experience has shown that we cannot use this framework, because of unavailability to use the plugin for Bluetooth Low Energy protocols for our fitness bracelet. This was due to limitation on the free plan of our account profile in this framework. For the paid plan we would have got Bluetooth BLE support. The situation is similar for other HTML5 frameworks.

Ultimately, the mobile application is programmed on the Android platform with helping Android Studio integrated development environment. Android Studio is based on JetBrains IntelliJ IDEA software that is a Java integrated development environment. Android Studio framework is free for using, and a huge amount of plugins for various purposes are available for the mobile app development.

5.2 Backend API for mobile app

All communication between our server and clients is going on HTTP requests and responses. Our mobile application, i.e. client will send data to the server by HTTP POST methods. Response is represented by JSON[23] format that is human-readable and quickly generated and parsed. Our client will make HTTP requests consist of request URL and request parameters.

[21] HyperText Markup Language
[22] Cascading Style Sheets
[23] JavaScript Object Notation

Requests allow mobile application to authenticate and to receive resource data, for our application it is the list of supported medical devices accessible to the user and the list of existing measuring data. Requests can also be used to send the new measuring data from client to the server.

5.3 Dynamical data model

According to the data model that we described in 4.3.2 the tables for interaction with our mobile application were dynamically generated. The model of data tables on *Figure 49* describes bindings between the tables. Such tables as USERS and ORGANIZATIONS were placed and are shown schematically. We refer to section 4.3.2 and see that dynamical tables MOBILE_DEVICE, FITNESS_DEVICE, HEART_RATE, BLUETOOTH_CONNECTION and BLUETOOTH_SERVICE were generated from records in *Resource Type* table. These tables are only for fitness bracelets, if we want to add new supported device to the list, we will dynamically generate the new tables for the new medical device.

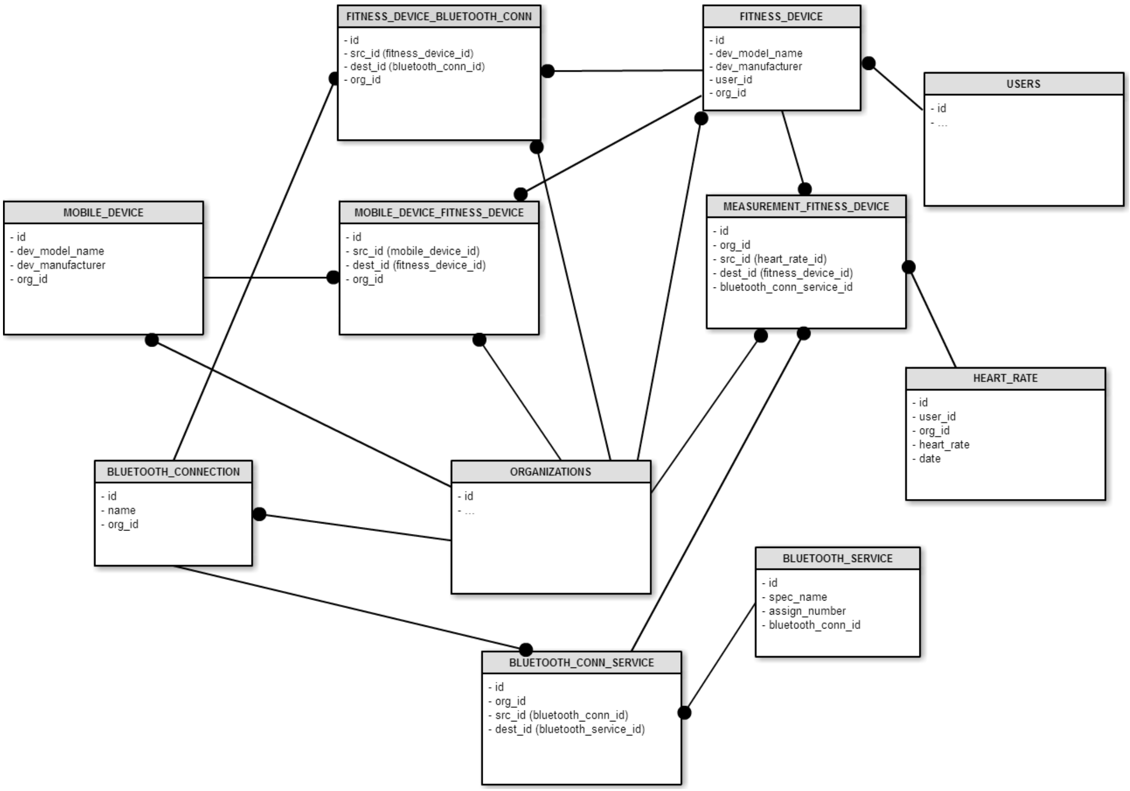


Figure 49. Data model for mobile application.

5.4 Design of the mobile app

A demonstrative design of our mobile application is depicted on *Figure 50*. User will authenticate by QR code. The advantage of the using QR code for authentication is security. Nobody cannot see your input parameters such as e-mail and password. QR code is generated by an admin and sent personally to users. After successful authentication, user can see the list of all supported devices accessible for him. If admin registers some device for the given user, then this user will see that new device in this list. In our case, after selecting Xiaomi Mi Band record, user will see the list of measurements. In this activity, it is possible to start new measurement by “plus” button.

This action calls Find device by scanning available devices using Bluetooth technology. After that, the Measure activity performs a connection to this device and starts measurement.

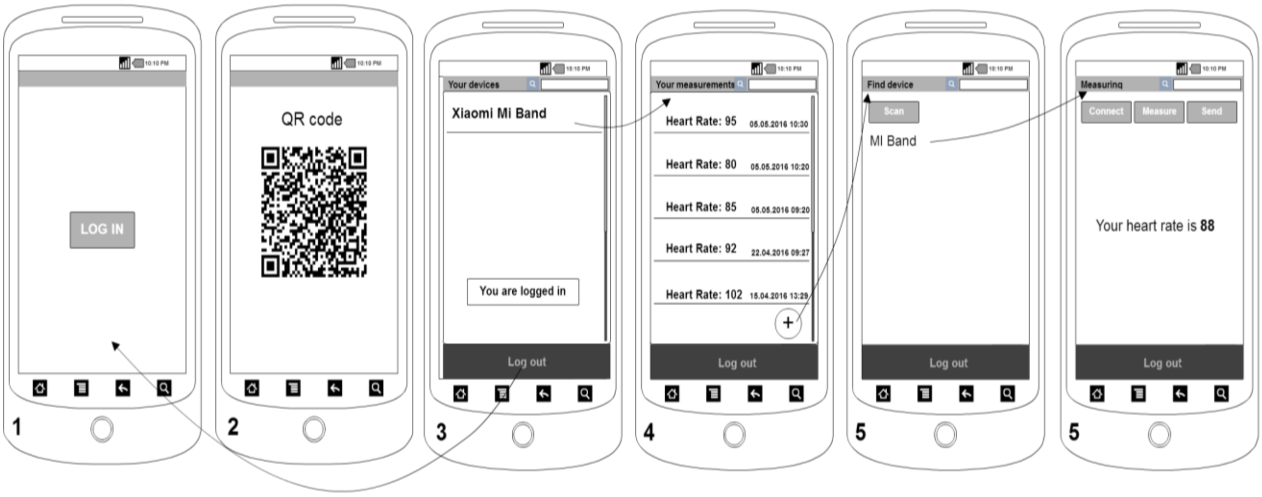


Figure 50. Design of mobile application.

5.5 The application Use Case Diagram

The use case in *Figure 51* provides an elementary overview of user's action during the usage of the mobile application. Standardly, user is able to log in with QR code or just log out. From the list of available diagnostic devices, a user should choose the one, which he wants to use for a measurement. In our case, fitness bracelet connects by Bluetooth that means a user should find it and establish a connection with it. The main use case for our mobile application is the measuring. A user can provide a measurement of heart rate by fitness bracelet and send data to the server.

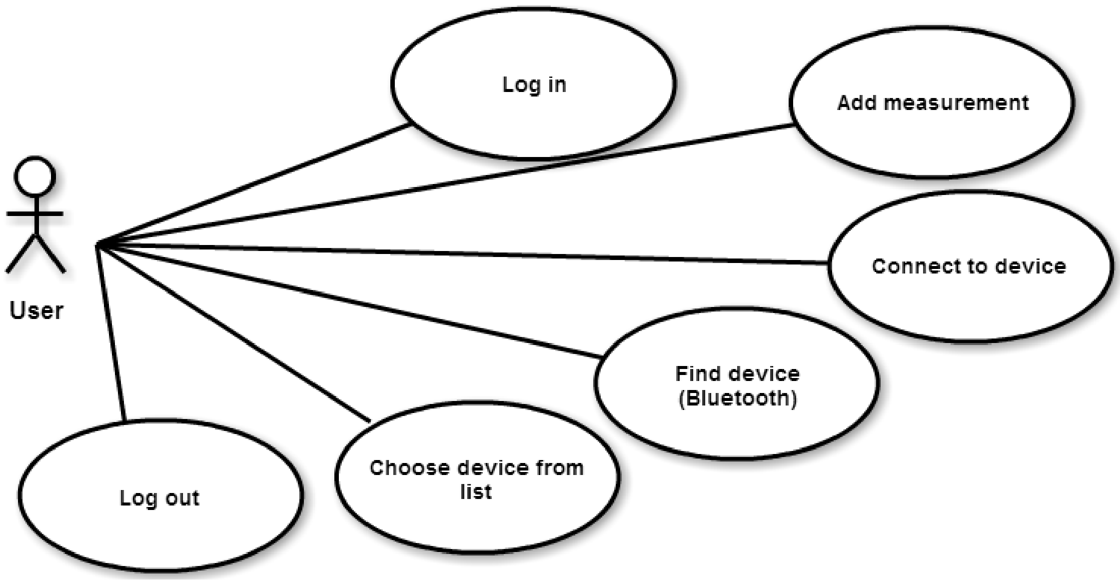


Figure 51. Use case diagram.

5.6 Bluetooth Low Energy protocol and its reverse-engineering

Xiaomi Mi Band is using Bluetooth Low Energy protocol for transferring data to smartphone and vice versa. The Bluetooth Special Interest Group designed this protocol for modern application in healthcare, fitness, security and others. On application layer of this protocol there is a Generic Attribute Profile (GATT). GATT consists of services, each of which contain characteristics and descriptor. BLE Protocol's service, characteristics and descriptor are located by a UUID. UUID has length 16bits or 128bits.

uuid: 00001800-0000-1000-8000-00805f9b34fb
uuid: 00001801-0000-1000-8000-00805f9b34fb
uuid: 0000fee0-0000-1000-8000-00805f9b34fb
uuid: 0000fee1-0000-1000-8000-00805f9b34fb
uuid: 0000fee7-0000-1000-8000-00805f9b34fb
uuid: 00001802-0000-1000-8000-00805f9b34fb

Figure 52. Example of UUID in communication between Mi Band and server. (55)

UUID contain information about service. In communication between app and Mi Band there are different services. According to BLE protocol there are various number of standard services such as Generic Access (0x1800), Generic Attribute (0x1801), Immediate Alert (0x1802) and others. Furthermore, UUID contains the three customized vendor's services (0xfee0, 0xfee1, 0xfee7). Characteristics for this vendor's service are known, but only one service (0xfee0) is using for transferring data. (55)

UUID	Meaning	Property
0xff01	DEVICE_INFO	Read
0xff02	DEVICE_NAME	Read and Write
0xff03	Notification	Read and Notify
0xff04	USER_INFO	Read and Write
0xff05	CONTROL_POINT	Write
0xff06	REALTIME_STEPS	Read and Notify
0xff07	ACTIVITY_DATA	Read
0xff08	FIRMWARE_DATA	Write without response
0xff09	LE_PARAMS	Read and Write
0xff0a	DATE_TIME	Read and Write
0xff0b	STATISTICS	Read and Write
0xff0c	BATTERY	Read and Notify
0xff0d	TEST	Read and Write
0xff0e	SENSOR_DATA	Read and Notify

Figure 53. The meaning of every characteristic in 0xfee0 service. (55)

According to this, in implementation of our mobile app, we will use this protocol and its reverse engineering for receive data. (55) (56)

BLE protocol has service Heart Rate with Assigned Number 0x180D. By this service is transferred heart rate from a Heart Rate Sensor intended for fitness devices. (57)

For implementing the heart rate measuring feature in our mobile application, we have to use the open source plugin from user *pangliang* that is situated in GitHub repository. (58) In order to use this plugin in our Android project we add dependencies to build.gradle file:

```
dependencies {
    compile 'com.zhaoxiaodan.miband:miband-sdk:1.1.2'
}
```

On *Figure 54* the method of Mi Band class from library is shown, which is scanning all available devices around. Beside, we use the following methods:

- miBand.stopScan(scanCallback);
  After the scanning devices, it should stop scanning session
- miband.connect();
  If find the needed device, for next actions with it, it should to connect with this device
- miband.setDisconnectedListener();
  For the noting connected devices
- miband.setUserInfo();
  For measuring actions we should set user info (gender, ages, height, weight and name)
- miband.setHeartRateScanListener();
  Before sensor start to measure heart rate, it should call this method for measuring data
- miband.startHeartRateScan();
  Start the heart rate sensor scanning

```
MiBand miband = new MiBand(context); // MiBand class

final ScanCallback scanCallback = new ScanCallback() // abstract class ScanCallback
{
    @Override
    public void onScanResult(int callbackType, ScanResult result)
    {
        BluetoothDevice device = result.getDevice(); // Bluetooth device class
        Log.d(TAG,
                "Name:" + device.getName() + ",uuid:"
                        + device.getUuids() + ",add:"
                        + device.getAddress() + ",type:"
                        + device.getType() + ",bondState:"
                        + device.getBondState() + ",rssi:" + result.getRssi());

    } // writing all characters of detected devices
};
miBand.startScan(scanCallback); // application ScanCallBack method for MiBand class
```

Figure 54. Scan device method for searching fitness bracelet by Bluetooth. (58)

In the next chapter we will test our mobile application.

6 Prototype testing

Finally, we got the results of our thesis implementation part, it is a mobile application, that collects heart rate data and send it to the server of hospital information system. The first feature of our mobile app is interaction with real hospital information system. Collected user medical data from the mobile clients is sent to the server backend, where for example nursing staff have access to these data any time. Users of mobile application have the ability to send their data without attending any medical facilities. The second advantage of our mobile app is variability. Fitness bracelet is not the only device that can be compatible with our app due to data model on the backend. Admins of information system only need to configure a new device to the list of supported device on the backend. The next release of our mobile application will then support the new personal device for measuring and collecting medical data.

The actual REST architecture of our prototype system looks like on *Figure 55*. Fitness bracelet Mi Band represents the group of personal medical devices. Communication between the client and the personal medical devices is provided by Bluetooth technology. On application layer we used Bluetooth Low Energy protocol that decrypts the data from fitness bracelet. Client, i.e. our mobile application collects this data local in SQLite database and then communicate with API of telemedicine information system in order to send collected data.

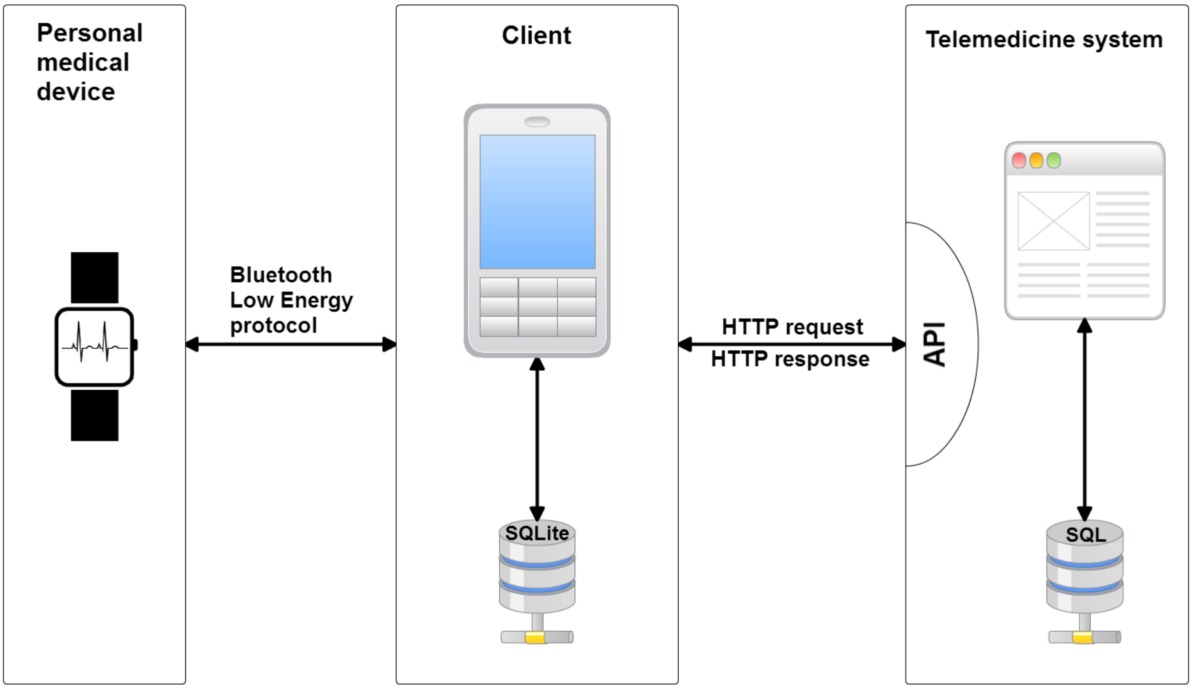


Figure 55. REST architecture of prototype

The implementation part depends heavily on novel problem-solving method of medical device connectivity that we described in detail in chapter 4.2. The main implementation part was to analyze data model of the telemedicine system and adapt the knowledge we gain by studying a lot of technical documentation of different medical devices. In consequence of this, we got the results of this work and implemented the prototype as the mobile application that collects data from the fitness bracelet. Adhering to the planned design for our mobile application, the mobile application has follow activities: *LoginActivity.java, ResourceActivity.java, MeasurementListActivity.java, ScanDeviceActivity.java and MeasurementActivity.java*. The main part of our application is measurement activity, where user can measure heart rate and send it to the backend. On *Figure 56* we depict layout screenshots of *ScanDeviceActivity.java and MeasurementActivity.java* activities.

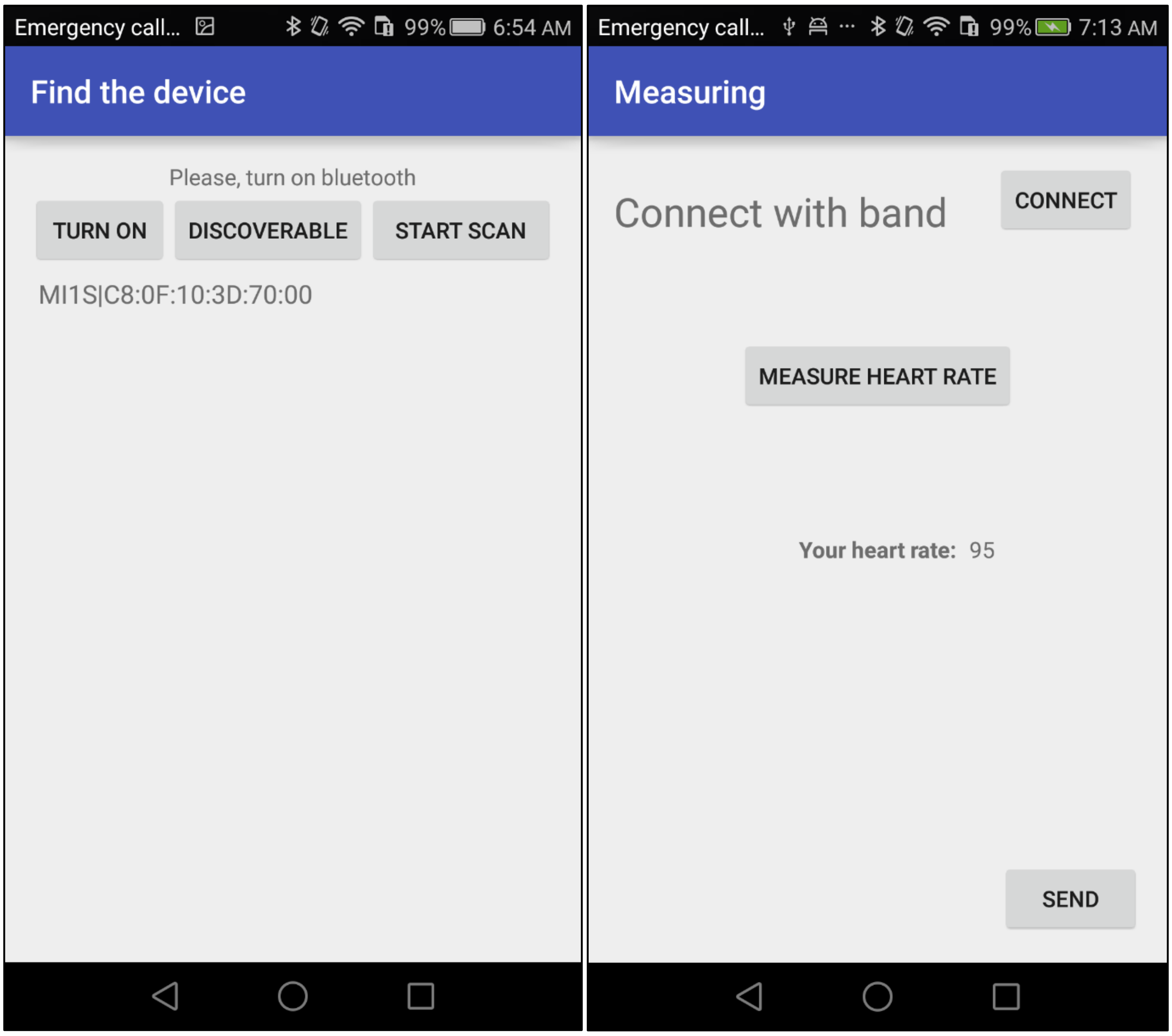


Figure 56. Screenshots of the mobile application.

The aim of this implementation was to show the possibility to apply our novel method for medical device connectivity and develop the mobile application as an example of this.

7 Discussion

In the beginning of bachelor thesis, we defined the aim of thesis: to work out a novel method for of the issue of medical device connectivity in the field of telemedicine. The first step was to explore the different types of medical devices and to find out what standards are used for communication between hospital information systems and medical devices. We found that almost all manufacturers have proprietary communication protocols and proprietary software for these devices. It is not difficult to notice that this problem of medical device connectivity is not actively solved by manufacturers. Nevertheless, exploring the documentations of different types of medical devices we suggested that solution of connectivity for some amount medical devices in the global market is possible. Of course, this thesis could have been more extended and be in details, but we were overwhelmed by the amount of explored medical device documentation. It would take a year or more. Unfortunately, this question is still open and nobody knows who could solve this issue. Only cooperation of hospital information systems developers and manufacturers of medical devices would be very productive in solving this problem. However, the problem of medical device connectivity can be solved for individual cases, i.e. for defined hospital information system with defined medical device. Our implementation part consists of configuring a backend hospital system and development of mobile application that collects data from fitness bracelet and send the data to this information system.

The results of our thesis are:

- novel problem-solving method of medical device connectivity with the hospitals information systems
- backend data model for defining the list of supported medical devices for this information system
- prototype of mobile application implementing this method for communication with the hospital information system

8 Conclusion

Further work on this issue could bring even more benefits to solve this problem of medical device connectivity. It is possible to explore the more technical documentations of medical devices for a deeper study of medical device connectivity problems. It will help to describe our novel method in more details to entail a more precise configuration of any information system for the best connectivity with the medical devices.

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