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ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

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Medical Device Interoperability 4.0: Disruptive Innovation for the ICU

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Original Title (Master Thesis):

Analysis of Current Innovation Barriers for Functional Medical Device Interoperability in Hospital Intensive Care and Development of a Conceptual Approach to Overcome Them.

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List of Abbreviations and Acronyms

6LoWPAN	IPv6 Low Energy WPAN, see IPv6 and WPAN
AAMI	Association for the Advancement of Medical Instrumentation
ACA	Affordable Care Act
ACCE	American College of Clinical Engineering
ACO	Accountable Care Organization
AHD	Application Hosting Device
AHIC	American Health Information Community
AIS	Anesthesia Information System
ALG	Device-to-Application Layer Gateway
ANSI	American National Standards Institute
ARRA	American Recovery and Reinvestment Act
ASA	American Society for Anesthesiology
ASTM	American Society for Testing and Material
ASTM-ICE	ASTM - Integrated Clinical Environment (see also ASTM)
ATM	Asynchronous Transfer Mode
BiPaP	Bi-Level Positive Air Pressure (ventilation mode)
BIS	Biospectral Index Monitor (used to measure the depth of anesthesia)
BLE	Bluetooth LE (Low Energy)
BMBF	(German) Federal Ministry of Education and Research
CAGR	Compound Annual Growth Rate

CBS	Cyber-Physical System
CCIS	Critical Care Information System
CDDS	Clinical Decision Support System
CDS	Clinical Decision Support
CEN	Comité Européen de Normalisation
CEN/TC	CEN - Technical Committee (see also CEN)
CIM	Computer Integrated Manufacturing
CIS	Clinical Information System
CoAP	Constraint Application Protocol
CPOE	Computerized Physician Order Entry
CT	Computed Tomography
CVP	Central Venous Pressure
DEC	Device Enterprise Communication (belongs to IHE-PCD)
DICOM	Digital Imaging and Communications in Medicine
DNS	Domain Name Service
DoD	Department of Defense
DOS	Disk Operating System (Microsoft's first operating system)
DPWS	Device Profile for Web Services (software architecture)
DSL	Digital Subscriber Line
EDIS	Emergency Department Information System
EHR	Electronic Health Record
eMAR	electronic Medication Administration Record
EMR	Electronic Medical Record
ERP	Enterprise Resource Planning
FDA	Food and Drug Administration (regulatory agency, USA)

GDP	Gross Domestic Product
GE	General Electric
GUDID	Global Unique Device Identification Database (FDA term, see UDI)
H2H	Hospital-to-Home
HIMSS	Healthcare Information and Management Systems Society
HIS	Hospital Information System
HITSP	Health Information Technology Standards Panel
HL7	Health Level 7: Standards Developing Organization (SDO) accredited by the American National Standards Institute (ANSI); synonymously used to refer to a communication protocol that is widely accepted and used in healthcare data exchange
HPRIM	Harmonie et PRomotion de l'Informatique Médicale: synonymously used to refer to a protocol of communication used for transmittal of laboratory results
HR	Health Record
HRRP	Hospital Readmission Reduction Program
HTTP	Hypertext Transfer Protocol: is the foundation for application-level communication on the internet
IAB	Internet Architecture Board
IABP	Intra-Aortic Balloon Pump (medical device)
ICMP	Internet Control Message Protocol
ICU	Intensive Care Unit
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise
IHE-PCD	IHE - Patient Care Devices (see also IHE)

IIC	Industrial Internet Consortium
IIoT	Industrial Internet of Things
IoT	Internet of Things
IP	Internet Protocol
IPv4	See IPv6
IPv6	IPv6 is the successor version of IPv4, which is the internet protocol address for any computer or device that is connected to the internet. IPv4 does allow only for 12 digits, e.g. 2.280.197.209, whereas IPv6 allows for 32 digits (hex), e.g. 8701:7ac8:85a3:09s3:1319:8a2e:0370:7344. This way the address range was extended to meet the needs of the ever growing number of internet devices, especially in the light of the upcoming Internet of Things.
IR	Infrared
ISO	International Organization for Standardization
ISO/TC	ISO - Technical Committee (see also ISO)
ISP	Internet Service Provider
LAN	Local Area Network
LF	Low frequency
LIS	Laboratory Information System
LOINC	Logical Observation Identifies Names and Codes
M2M	Machine-to-Machine communication
MAN	Metropolitan Area Network
MAP	Manufacturing Automation Protocol
MD PnP	Medical Device Plug and Play (standards development organization)
MDAP	Medical Device Application Profile (belongs to the MIB)

MDDL	Medical Device Data Language (belongs to the MIB)
MDDS	Medical Device Data Systems
MDIB	Medical Data Information Base (belongs to the MIB)
mHealth	mobile Health: a term used for the practice of medicine and public health supported by mobile devices
MIB	Medical Interface Bus (standardized as ISO/IEEE 11073)
MQTT	Message Query Telemetry transport (protocol)
MRI	Magnetic Resonance Imaging
MRP	Manufacturing Resource Planning
NeHC	National e-Health Collaborative
NICU	Neonatal Intensive Care Unit
NIH	Not-Invented-Here Syndrome
NIST	National Institute of Standards and Technology
NIV	Non-Invasive (medical)
OR	Operating Room
OR.NET	Project name for OSP, see OSP
OSCP	Open Surgical Communication Platform
OSI	Open Systems Interconnection
OSP	Open Surgical Platform
PACS	Picture Archiving System
PAN	Personal Area Network
PCA	Patient Controlled Analgesia (e.g. pain relief with morphine)
PCWP	Pulmonary-Capillary Wedge Pressure (medical)
PDA	Personal Digital Assistant
PHM	Population Health Management

PHR	Personal Health Record
POIS	Perioperative Information System
QoS	Quality of Service (in computer networks)
R&D	Research and Development
RFID	Radio Frequency Identification
RIS	Radiology Information System
RPM	Remote Patient Monitoring
RS232	Recommended Standard 232 (computer serial interface)
RSSI	Received Signal Strength Indicator
RTLS	Real-Time Locating System
RTM	Rosetta Terminology Management (part of IHE-PCD)
RTOS	Real-Time Operating System
RTP	Real-Time Protocol
SDO	Standards Development Organization
SIS	Surgical Information System
SMTP	Simple Mail Transfer Protocol
SNMP	Simple Network Management Protocol
SNOMED	Systematized Nomenclature of Medicine
SOA	Service Oriented Architecture
SONET	Synchronous Optical NETwork
SRTB	Surgical Real-Time Bus
TCP	Transmission Control Protocol
TIVA	Total IntraVenous Anesthesia: is using a combination of agents given solely by the intravenous route and in the absence of all inhalational agents including nitrous oxide

UDI	Unique Device Identification (FDA requirement for medical devices)
UDP	User Datagram Protocol
UWB	Ultra-Wide Band
VLAN	Virtual LAN (see also LAN)
VPN	Virtual Private Network
WAN	Wide Area Network
WHI	West Health Institute (San Diego, USA)
WiFi	see Wireless LAN
WLAN	Wireless LAN (see also LAN)
WPAN	Wireless PAN (see also PAN)
X.25	Standard protocol suite for packet switched wide area network (see WAN) communication
XML	Extensible Markup Language
XMPP	Extensible Messaging and Presence Protocol
Z-Wave	Wireless communications protocol designed for home automation

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1 Motivation

Back in the year 1990 I was doing my internship at Hewlett-Packard Medical Systems - R&D Labs in Böblingen (Germany) which was part of my studies in electronics engineering. One of my tasks was to get heart-rate data out of a patient monitor through its serial data interface for product validation purposes. The patient monitor was one out of the 78352 series used at that time in Intensive Care Units (ICU) and Operating Rooms (OR) with critically ill patients.

Fig. 1: Hewlett-Packard 78352C Patient Monitor (Source: www.ebay.de)

The serial data interface (RS232) was connected through a cable to a serial interface of a personal computer (PC) running a DOS operating system on which I wrote a program in (ANSI) C language to access data from the patient monitor. For a student this was a quite interesting and funny task.

Meanwhile we have reached the year 2016. Since 1990 a lot of technology innovations did happen like the commercial breakthrough of the internet, the use of GPS navigational systems, the mobile phone and later the smart phone were developed, laptops where invented, the LCD TV had its breakthrough, social media came up, the electro mobility is a fast growing sector, alternative energy is vastly used, first trucks and cars are driving autonomously in public, and certainly many more great things where invented that I have not listed here.

But looking at medical devices that are used in ICUs and ORs, still the serial interface is the most used interface for data integration of devices from different vendors. This has led to the development of very complex and expensive Medical Device Data Systems (MDDS) to achieve that data integration.

Knowing that the serial interface (RS232) was originally specified in 1962 with its last major update in 1969 (RS232C) and finally ceased in 1997 by Microsoft [Web01] from the original IBM PC design, it appears odd that this interface is still the state-of-the-art technology in cross-vendor medical device data integration.

Fig. 2 Modern Philips MX800 Patient Monitor (Source www.philips.com)

Now that we have reached the age of the 4th industrial revolution, with the Internet-of-Things (IoT) playing a big role in it, and being predicted to be used basically with all coming electronic devices and sensors, it is my motivation to research in this master thesis why the medical device interoperability in critical care settings got stuck a quarter of a century ago, on the technology side as well as on the functionality side, and conclude how this could be overcome.

The customer need for what is called “functional” medical device interoperability is there, which will be further outlined and researched in the following chapters of this thesis.

2 Introduction

2.1 Goal of this Master Thesis

The theme of this master thesis “Analysis of Current Innovation Barriers for Functional Medical Device Interoperability in Hospital Intensive Care and Development of a Conceptual Approach to Overcome Them.” speaks about *Functional Medical Device Interoperability* and *Innovation Barriers* which prevent medical device interoperability from being “functional”.

The setting for this theme will be centered in the acute care departments of hospitals. On the other hand medical device interoperability does have impact outside the acute care environment as well and that is why the thesis will not limit itself to the inside world of acute care departments in hospitals.

The *Conceptual Approach*, which shall be the result of this master thesis, is expected to have global validity meaning it will not be limited to e.g., Germany or the United States of America.

2.2 Research Methodology

This master thesis will be purely based on secondary research. There is much literature, may be too much, available for interoperability in healthcare, hundreds of books on innovation theory, market studies on the topic, different marketing approaches in general, and vast material on technology and technology trends. Thus no need exists for doing primary research e.g., by conducting surveys or interviews. Even though the topic is complex, as technology solutions, business requirements, customer requirements, and patient safety concerns are closely interwoven and often are contradictious, even the more this topic is suited for taking a structured academic approach for resolution, which leads to the following research methodology being applied in this master’s thesis:

1. Current situation:
    a. Definition and delineation of medical device interoperability
    b. Assess current state of medical device interoperability and the current market forces
    c. Give an overview of standardization efforts in medical device interoperability
    d. Assessment of economic impact of outdated connectivity technology in healthcare

2. Literature review:
    a. Diffusion of innovation
    b. Theory of computer networks (interoperability)
    c. Aspects of real-time systems
    d. Technology trends outside of healthcare
    e. Technology trends inside healthcare
    f. Investigate value of medical device interoperability
    g. Critical review of literature research

3. Conclusion:
    a. Identify barriers and synthesize an approach for resolution from steps 1.) and 2.)

4. Summary and discussion

5. Outlook to future research

2.3 Introduction to Regulated Industries

Medical device development, manufacturing, and distribution is part of what is called regulated industries. That means that certain notified bodies exist around the world that need to be consulted for certifications, approvals, audits, etc. before and after a medical device was brought to market. The widest known notified body is the FDA (Food and Drug Administration) of the United States of America.

Related to the field of responsibility for medical devices this is what the FDA states on their webpage under what-we-do: “FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.”

This is of course a description on a very high level. In the development of medical products the FDA approval (and the same is true for other notified bodies) is the cause for a lot of work on processes, quality, testing, documentation, etc. with the goal of ensuring, mainly, patient safety which can be positively and negatively influenced by many factors.

When looking at medical device interoperability it is interesting to note that when someone (vendor, manufacturer, customer, etc.) creates a system by connecting certain devices together it is not sufficient that each part of the system has undergone FDA certification, but that the one who creates the system becomes ultimately responsible for the certification of the whole system, regardless if the individual parts of the system are from one or from several vendors.

That means, when medical device vendor A wants to offer a data connection to a medical device of vendor B, vendor A needs to test the resulting system with both devices that of vendor A and that of vendor B. Many times vendor A and vendor B are competitors.

Another important aspect of regulations is that the FDA classifies medical devices from class I to class III. The risk, and consequently the effort to achieve FDA approval, rises with the higher classification. Most medical devices in ICU and OR are class II devices.

Many of the computer systems that make use of medical device data are either no medical devices, class I devices, or fall under the MDDS (Medical Device Data Systems) directive which reclassifies an MDDS from class III to class I.

No further literature will be referenced here as this topic would result in another master's thesis by itself. However, more information can be found in the internet on the FDA's homepage [Web02].

Summarized this means that regulatory requirements are an important matter in medical devices development, but so far it did not hinder any (patient safe) innovation to come to market. The question is more about time and investment that is needed. Therefore any further regulatory aspects will not be considered in this thesis.

2.4 Number of ICU and OR Beds in the World

To get a better understanding on how big the economic impact of workflow or other improvements in ICUs and ORs could be, an estimate of total number of ICU beds in the world was assembled. The number of OR beds was assumed as a fraction of the total number of ICU beds (one OR bed on 10 ICU beds).

Tab. 1 Number of ICU and OR beds in the world [Web03]

Geography	**Number of ICU *(OR)* Beds**
USA	77.809
Canada	3.170
Europe	73.585
China	53.053
India	70.000
Australia & New Zealand	2.256
Asia Pacific[1] *(estimated)*	7.600
Add 10% for OR	*28.747*
Total	**316.220**

The result is more than 300.000 ICU beds in the world. Making the assumption that only 30% of the Chinese and Indian ICU beds can afford high-end medical devices, this results in 220.000 ICU beds (including the estimated OR beds) comprising the total market size.

[1] Includes only Singapore, Thailand, South Korea, and Malaysia

Main cost driver per ICU bed is the patient monitor with a yearly market volume of 2.6B€ [Web04]. Let's assume that the patient monitor reflects approximately 60% of the ICU bed devices cost, then we can calculate 4.3B€ as the yearly market volume for medical devices in the ICU.

Further assuming that the value of interoperability for a customer is not more than 5% of the overall value that the device offers, then the yearly market volume for interoperability would be at 215 M€. This appears to be a very small market size and is probably one of the innovation barriers already. If on the other side, one considers the evolution of the mobile phone to the smart phone, the enhanced interoperability functions of a smart phone were not a value of a certain percentage of the price for the buyers, but the cause for a buy or no-buy decision.

2.5 Typical Devices that are Used in an ICU and OR

Table "Tab. 2" lists commonly used devices in an ICU and an OR. It is not a complete list, but it lists many of the medical devices that typically have an RS232 (or in rare cases a LAN) interface for 3rd-party device interfacing. 3rd-party device interfacing means that the device has an "open" interface and an interface is considered "open" when a specification of the physical interface and the "protocol of communication" is provided with the device.

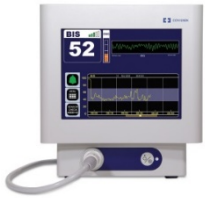
For communication between devices of a single vendor usually a second interface is available which is not "open". Especially infusion/syringe pumps and patient monitors utilize their own "closed" network. This will be further detailed in chapter "3.3 Components and Topology".

Fig. 3 ICU at Boston Children's Hospital (Source www.childrenshospital.org)

Picture "Fig. 3" shows an example of how many devices can be around an ICU bed. This picture makes it easy to understand that there are generally issues in an ICU with cable management, noise by all types of alarms and irritation by their flashing lights or blinking indicators, different user interfaces and use-philosophies with each device, and all types of data integration issues, apparent for the hospital's staff.

Looking from the patient's and his/her relatives' side above set-up is certainly not considered a very human-friendly environment. It is even hard to find the newborn in the picture.

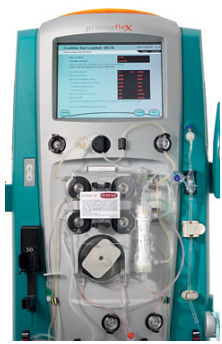
Tab. 2 List of typical devices in an ICU and OR

Anesthesia Machine[2] 	An *Anesthesia Machine* (continuous-flow) provides an accurate and continuous supply of medical gases (such as oxygen and nitrous oxide), mixed with an accurate concentration of anesthetic vapor (such as isoflurane), and deliver this to the patient at a safe pressure and flow. In most cases an anesthesia machine is integrated with a ventilator, suction unit, and patient monitoring devices.
Biospectral Index Monitor (BIS)[3] 	*BIS™ technology* noninvasively measures and interprets brain wave activity directly related to the effects of anesthetic agents.
BiPAP Ventilator[4] 	A *Bi-Level Positive Air Pressure (non-invasive) ventilator* is a device that assists with a patient's breathing. It is connected by flexible tubing to a face mask worn by the patient. The BiPAP machine helps push air and oxygen into the lungs and then helps to hold the lungs inflated, thereby allowing more oxygen to enter the lungs.

[2] Example: GE Aestiva 7900 (www.gehealthcare.com)

[3] Example: BIS™ Complete 2-Channel Monitor (www.medtronic.com)

[4] Example: Philips Respironics V60 Non-invasive Ventilator (www.philips.com)

Clinical Information System (CIS)[5] 	*Clinical information systems (CIS)* are used to collect, process, and present data for use in patient care. Common applications in the intensive care unit are charting, computerized physician order entry (CPOE), clinician decision support (CDS), and health information exchange. Benefits of CIS include increased efficiency, increased quality of care, and improved data availability, structure, and security. [Mas16] A clinical information system is not a hardware medical device like the other devices in this list, but a software medical device that is available at many ICU beds today. One of its many functions is to chart the data coming from all other devices in this list, if present at the bed side and make it available in its database for further processing, e.g. for clinical decision support.
Dialysis Machine[6] 	*Renal Dialysis Machines* are commonly known as kidney machines because they assist the kidneys to work. There are many reasons why someone may need to be dialysed: If the kidneys are not working satisfactorily because of disease or injury, to remove harmful wastes, and to remove extra fluid.

[5] Example: iMDsoft MetaVision (www.imdsoft.com)

[6] Example: Gambro PrismafleX eXeed™ (www.gambro.com)

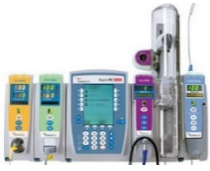
Feeding Pump[7] 	Enteral feeding refers to the delivery of a nutritionally complete feed, containing protein, carbohydrate, fat, water, minerals and vitamins, directly into the stomach, duodenum or jejunum, which often is supported by a *Feeding Pump*.
Heart Lung Machine[8] 	A *Heart-Lung Machine* is a device used in open heart surgery to support the body during the surgical procedure while the heart is stopped. The heart-lung machine is often referred to as the "pump", and does the work of the heart and lungs during the operation. Except “pumping” that means that it also does the oxygenation of the blood and removes the CO2 of it.
Infusion Pump (Syringe)[9] 	In a *Syringe Pump*, fluid is held in the reservoir of a syringe, and a moveable piston controls fluid delivery. Like the volumetric infusion pump it is used to control both the rate and amount of fluid or medication that is given to a patient. But a syringe infusion pump can do this with a higher precision and can be used for highly effective medication.
Infusion Pump (Volumetric)[10] 	Intravenous *Infusion Pumps* are used in hospitals to control both the rate and amount of fluid or medication that is given to a patient.

[7] Example: Kangaroo™ ePump Enteral Feeding Pump (www.medtronic.com)

[8] Example: Sorin S5 Heart Lung Machine (www.livanova.sorin com)

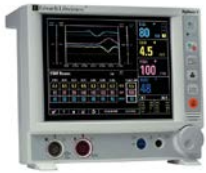
[9] Example: BBraun Perfusor® Space (www.bbraun.com)

[10] Example: Fresenius Kabi Volumat Agilia (www.fresenius-kabi com)

Intra-Aortic Balloon Pump (IABP)[11] 	An I*ntra-Aortic Balloon Pump (IABP)* is used to assist the heart to pump more blood around the body. It also improves the delivery of oxygen to the heart. The IABP is connected to a catheter that is inserted via the groin. The catheter is guided up a large blood vessel until it is near the heart. The IABP machine is synchronized to the patient's heart rhythm and pumps gas into a balloon at the end of this catheter. This balloon rhythmically inflates and deflates pushing blood forward around the body and also pushes blood back into the coronary arteries of the heart. In this way both the body and the heart get improved blood circulation and oxygen delivery.
Patient Controlled Analgesia (PCA)[12] 	A *Patient Controlled Analgesia (PCA) Pump* delivers pain relief medication to a patient through an intravenous cannula when they push a button. A PCA pump is usually used for patients after they have had an operation. The pump is programmed by the nurse using specific orders from a doctor before it is attached to the patient so that the safety features and alarms are enabled. This programming allows the patient to safely deliver small doses of pain medication to themselves without the danger of over medication. Usually the medication (e.g. morphine) is locked in the device, so that it cannot be stolen.

[11] Example: Arrow AutoCAT 2 WAVE® IABP System (www.arrowintl.com)

[12] Example: Alaris® PCA module administration set (www.carefusion.com)

Patient Monitor[13] 	There are basically two types of patient monitors, whereas many times both types are integrated into one monitor: *Vitals Signs Monitor* measures vital signs such as heart rate, blood pressure, respiratory rate, temperature, and urine output, to the more technologically demanding noninvasive techniques such pulse oximetry, end-tidal CO2, and techniques for the assessment of cardiac output, and to invasive intravascular measurements of pressures such as the central venous pressure (CVP), arterial pressure, pulmonary artery pressure, measurements of cardiac output, airway pressures and flows, and cerebrospinal pressure. *Hemodynamic Monitoring* is the continuous monitoring of the movement of blood and the pressures being exerted in the veins, arteries, and chambers of the heart. Current invasive techniques permit the monitoring of intra-arterial blood pressure, pulmonary artery pressure, left atrial pressure, and central venous pressure. Invasive pressure monitoring requires the insertion of a catheter into an artery (usually the radial, brachial, or femoral artery), vein (the antecubital, jugular, or subclavian vein), or a heart chamber.
Swan-ganz Catheter Monitor[14] 	*Swan-ganz Catheter Monitor* uses a pulmonary catheter that can permit measurement of pulmonary artery diastolic and systolic pressure, pulmonary-capillary wedge pressure (PCWP), left atrial filling pressure, central venous pressure, and cardiac output.

[13] Example: Spacelabs XPREZZON™ Patient Monitor (www.spacelabs.com)

[14] Example: Edwards Vigilance II Monitor (www.edwards.com)

Urine Meter[15] 	*Urine meters* are primarily used with post-operative patients or those critically ill, where precise monitoring of urine output is necessary. Accurate measurement of urinary output, is extremely important in fluid management and in assessing kidney function.
Ventilator[16] 	A *Ventilator* is assisting the patient's own breaths to full support by taking over a patient's breathing completely. A patient is connected to a ventilator via a breathing tube (endotracheal tube) that is inserted into the windpipe (trachea).

For all of the devices in an ICU or an OR there are of course many manufacturers per device type and often each device type in a specific ICU/OR is from a different manufacturer. This is because most companies that offer more than one device type are often not the market leader for all device types they offer. For that reason hospitals might buy the patient monitor and the ventilator from two different companies even that one of the manufacturers has both device types in its product offering.

[15] Example: BARD® CRITICORE® Monitor (www.bardmedical.com)

[16] Example: Dräger Evita® Infinity® V500 Ventilator (www.draeger.com)

Usually those devices have product life cycles in the hospital of 10 years or even longer. Therefore it does also happen (often) that in different wards there are, e.g. patient monitors from different manufacturers, depending on which company made the best offer or was considered the leading manufacturer for that device type at that time.

Many times there are devices still in use even that they went out of support by the manufacturer years ago. Due to the long life cycles and usually high quality of the devices they might run for years without the need for spare parts or specific maintenance.

Summarized this means that the devices around an ICU or OR bed are very heterogeneous in terms of manufacturer, model, device type, and age. Also across the different wards (departments) in a hospital the same heterogeneous picture is seen. If going on the next higher level, and looking from a country to country perspective more heterogeneity is found, as there are a lot of niche companies that are active in only one or in a few countries. Thus, looking from a global perspective, each ward in a hospital has its own specific mix of medical devices with only a few coming from global acting companies.

2.6 Data: Importance and Evolution

At the end interoperability, connectivity, device data interfacing or however it is named is about the exchange of data.

A critically ill patient in an ICU/OR is monitored by certain medical devices. The different types of monitors measure vital signs and hemodynamic parameters of the patient, which results in the creation of data. This data is further analyzed and processed, e.g. to create alarms when the patient comes into a life-critical situation. Or the data can be used to realize the need to, e.g. adapt the settings of therapy device like a ventilator to a certain patient situation. In technical terms we speak here of an open loop system. This means that the data is interpreted by a user (here the physician) and the user takes then action to control the loop.

In a closed loop system the medical devices would interoperate in a way that they keep the patient stable without user intervention. This closed loop control does not exist as of today. If we had “functional” medical device interoperability in place the controlled loop scenario could be brought to reality.

This will be further researched and outlined in the coming chapters.

All of these measurement data, the alarms that went off, the settings that were changed at devices, etc. are gone after they were displayed for a short period of time, if they are not recorded and stored. Together with other data, e.g. the patient’s demographics, laboratory results, diagnosis, treatment plans, medication administration, images from ultrasound/MRI/CT, documentation of surgery, adverse events, and more they form what is called the Electronic Medical Record (EMR) of the patient. This will also be further evaluated in the coming chapters.

Today this EMR data is still in most hospitals stored on local data servers, but more and more this data is stored in the cloud which does lead to new scenarios on how data from many hospitals can be further processed. But first let’s look on how data has evolved in its importance in the creation of industrial goods over the past decades. The following is derived from a White Paper on the topic of digital sovereignty about data ([Fra16], p. 10) published by the Fraunhofer Institute:

1) Data as result of processes: With the first information systems introduced in industry in the 60s and 70s data had a supporting role in manufacturing process. E.g. if an employee wanted to know if a certain part is on stock, the employee had no longer to walk to the shelf to find that out, but could get that information from the warehouse program. Though this data was helpful, the company's value creation was still seen in the physical product only.

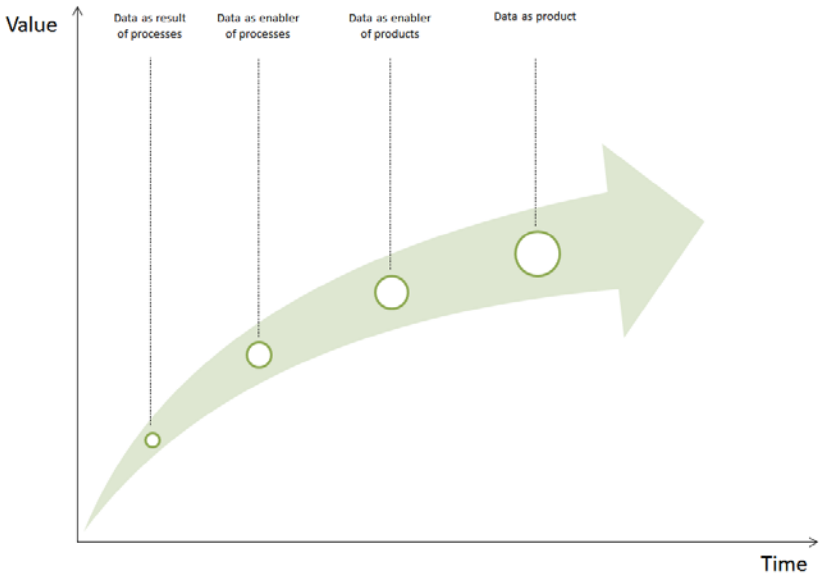


Fig. 4 Role of data in the creation of goods and services ([Fra16], p. 10)

2) Data as enabler of processes: In the 80s when Manufacturing Resource Planning (MRP) and Enterprise Resource Planning (ERP) systems were introduced the data became essential for company-wide business processes management. It did allow for standardized processes on a global, or at least regional, level like Order-to-Cash, Procure-to-Pay etc. Data became a strategic resource for operational excellences in manufacturing, logistics, and service.

3) Data as enabler of products: Since around the year 2000 products are offered by companies that would not be possible without have data of quality available. E.g. the miCoach of Adidas, the leasing- and fleet-management model of Hilti, and other smart services for our personal life.
4) Data as product: In recent year market places have developed for data. Consuming that data is charged by volume or time. The data is no longer the enabler of the product, but the product itself.

This means, that when EMR and other data is stored in the cloud and can there be further processed to derive, e.g. diagnosis, treatment plans, medication recommendations, medical device setting changes, etc., the end product which is sold to the customer is purely digital.

In healthcare this is covered by the term *population health management*, which covers the storage of all of this data in the cloud and its further processing, with the goal of *personalized healthcare* in mind. Population Health Management will also be further researched in the coming chapters.

2.7 Summary

Next to outlining the goal of this thesis and the research methodology to achieve it, this introduction's intent was to give an overview of which devices are used in an ICU and an OR, what their purpose is, and demonstrating the heterogeneity of those from even ward to ward. Further the issues that are present today in an ICU/OR were described.

The market size for medical devices was calculated and estimation was given on how much, in the current situation, could be allotted to medical device interoperability.

As the medical device industry is a regulated industry also a short overview was given on that topic.

And finally, the two main aspects, that will create value from "functional medical device interoperability", were introduced:

- Closed-loop control to keep patient stable
- Population Health Management for personalized healthcare

These are the two main topics to be researched further in this master thesis.

3 Current State of Medical Device Interoperability

3.1 Definition of Medical Device Interoperability

Probably the most comprehensive definition is coming from the *Healthcare Information and Management Systems Society (HIMSS)*[17], which is a global acting not-for-profit-organization headquartered in Chicago, IL (USA). The HIMSS activities are centered around their vision: "Better health through information technology". HIMSS' definition is:

"In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged." Further HIMSS makes the distinction between three levels of interoperability: "1) Foundational; 2) Structural; and 3) Semantic". [Him13]

1) "Foundational" interoperability is just the data exchange between two information technology system without the need to interpret or understand the data that was exchanged.
2) For "Structural" interoperability the exchanged data is organized in structured messages, which means that fields can be interpreted in the exchanged data. This is also called syntactical data exchange.
3) Next is the "Semantic" interoperability level on which not only the syntax is used to exchange data, but now also the content of data fields can be understood. This can be seen as a certain vocabulary being used, and coded within the fields of the syntactical interoperability, to give them a meaning.

Throughout this thesis the term "medical device interoperability" is used in most cases, but also other terms can be found in literature, e.g. medical device connectivity, medical device interfacing, medical device communication, or medical device integration. Usually they all mean the same, if not it can be recognized from the context which subtle difference the respective author has in

[17] http://www.himss.org/

mind. E.g. “medical device integration” is often used in the context of sending medical device data to an Electronic Medical Record (EMR).

3.2 Delineation of Medical Device Interoperability

Often when people are speaking about interoperability in the context of healthcare, the speaker has something totally different in mind than the listener. This is due to the many interoperability needs within hospitals (intra-hospital), between hospitals (inter-hospital), and meanwhile also with the home of patients (hospital-to-home), and more and more on a national and even international level.

The following list gives an overview of where else interoperability in healthcare is happening, than just medical device interoperability which is mainly used within ICUs and ORs. This list does not claim to be complete, but will cover most of the important interoperability scenarios to understand the heterogeneity of interoperability in the healthcare environment:

Clinical Information System (CIS): This type of information systems was already introduced in “Tab 2: List of typical devices in an ICU and OR”. It is typically in use in the high-acuity care environment of hospitals. CIS systems can be further sub-divided into ([MRG12], pp. 19):

- *Critical Care Information System (CCIS)* used in ICUs and NICUs (Neonatal Intensive Care Units) and are the “typical” representatives of CIS systems,
- *Perioperative Information Systems (POIS)* that cover the scheduling, workflow-planning, resource planning, etc. for the induction rooms and operating rooms in a hospital,
- *Anesthesia Information Systems*[18] *(AIS)* that are used to document a surgery and provide decision support,
- *Perinatal Information Systems* (no abbreviation available) that are used to monitor and to document fetal and maternal parameters during pregnancy, and the

[18] POIS and AIS systems are also covered by the overlaying term *Surgery Information Systems (SIS)*

- *Emergency Department Information System (EDIS)* that is used to manage the workflow in the emergency department of a hospital, which has its own pretty unique requirements. It covers managing the triage, tracking, registration, and treatment of patients there.

Laboratory Information Systems (LIS): The management of specimen and the storage of the results of pathology investigations are handled by a laboratory information system. The results are transmitted to the requestor either manually (printed document) or by fax, or through electronic data exchange with the help of communication protocols like HL7, ASTM, or HPRIM.

Picture Archiving and Communication System (PACS): Those systems are used to produce, display, store, process, send, retrieve, query, or print medical images and related documents. Images are produced by different modalities like ultrasound, magnetic resonance imaging (MRI), computed tomography (CT), or X-ray. To ensure interoperability basically all PACS systems and image producing machines conform to (or to parts of) the DICOM standard. [Web05]

Radiology Information Systems (RIS): Are used in an imaging center or radiology department to manage patient's schedule, results reporting, history tracking, and billing. Also image tracking and management can be part of a RIS system, but is usually achieved by the use of a dedicated PACS system with interoperability being ensured by the DICOM standard.

Hospital Information Systems (HIS): Traditionally the HIS systems are coming from the hospital's administrative side taking care of controlling, billing, inventory, procurement, etc. and managing patient demographics. Especially for managing the patient in terms of ADT data (**A**dmission-**T**ransfer-**D**ischarge) the HIS system is important in interoperability scenarios. It is usually the master system which knows where the patient is in the hospital and can share that information, and the patient's demographics, with other systems.

Electronic Medical Record (EMR): "An electronic record of health related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one health care organization" ([Hor08], p. 6).

Under the American Recovery and Reinvestment Act (ARRA), signed by US President Obama in 2009, there were incentives offered to hospitals that implement EMR systems. To get the incentives they needed to follow the rules of 3 stages which are called "meaningful use". This caused an investment boost in the EMR market in the US during the years after 2009. With the income from this boost EMR vendors invested in extending their EMR systems to cover also other areas in the hospital like the high-acuity care systems market. From Fig. 5: Inpatient EMR market in US, 2015 [Web06], it can be seen that Epic and Cerner are the leading EMR vendors in the US market. In Tab. 3: High-acuity information systems market leaders, US 2012 [MRG12], it can be seen that Epic and Cerner, which were first active in the EMR business only, have meanwhile occupied all fields in the high-acuity information systems markets as well, were before other vendors were the pre-dominant players.

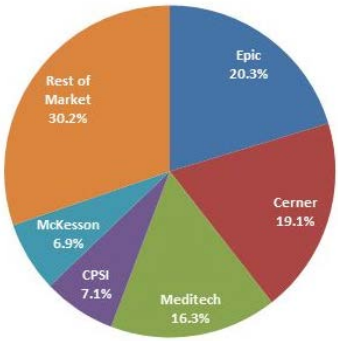


Fig. 5 Inpatient EMR market in US, 2015 [Web06]

Tab. 3 High-acuity information systems market leaders, US 2012 [MRG12]

Position	SIS	CCIS	Perinatal Information Systems	EDIS	Total Market
1st	Surgical Information Systems	Philips Healthcare	GE Healthcare	Cerner	Cerner
2nd	Picis	Epic Systems	Philips Healthcare	Epic Systems	Epic Systems
3rd	Cerner	Cerner	Other	Allscripts	Picis

Electronic Health Record (EHR): "An electronic record of health related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization" ([Hor08], p. 6). The distinction to the EMR is that the EHR for a patient is accessible nationwide for data entry and retrieval, and not only hospital wide. The mentioned nationally (US) recognized interoperability standards are not yet

in place. Like with the EMR several stages are planned by the US government to achieve the needed interoperability for EHR realization.

Personal Health Record (PHR): "An electronic record of health related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared, and controlled by the individual" ([Hor08], p. 6). The idea is to have the PHR online accessible for the individual through the internet by, e.g. a smartphone. This is also not reality at the time this thesis is being written. Finally EHRs and PHRs shall be the enablers for "population health", which will be further outlined in chapter "4.4.3 Value-Based Care and Population Health".

Home Monitoring which is also called *Remote Patient Monitoring (RPC)* or *Hospital-to-Home (H2H)* is driven by two causes. One is the *Affordable Care Act (ACA)* in the US and the other one is the customer segment of elderly patients with chronic conditions ([F&S15a], p. 63).

The Affordable Care Act (ACA), or simply "federal health reform", was signed on March 23, 2010 by US President Obama. One of its many programs is the *Readmissions Reduction Program (HRRP),* which asks for a reduction of patient readmissions within a month after their hospital discharge, and penalizes hospitals, that don't achieve the required numbers, by lower reimbursement through their payers (Medicare and Medicaid in the US) [Web07]. In the year 2013, nearly 18 percent of Medicare patients who had been hospitalized were readmitted within a month. While that is lower than past years, roughly 2 million patients return a year, costing Medicare $26 billion. Officials estimate $17 billion of that comes from potentially avoidable readmissions [Web08].

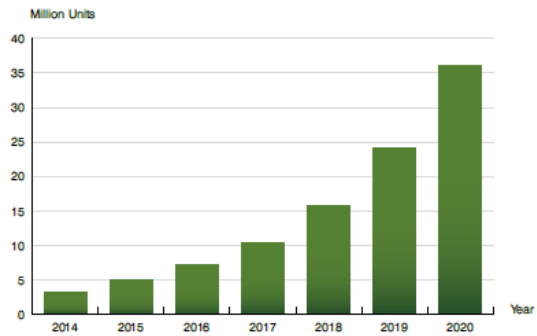


Fig. 6 Connected home medical monitoring devices (World 2014–2020) [Ber15]

“Berg Insight estimates that revenues for remote patient monitoring (RPM) solutions reached € 6.2 billion in 2015, including revenues from medical monitoring devices, mHealth connectivity solutions, care delivery platforms and mHealth care programs. RPM revenues are expected to grow at a CAGR of 32.1 percent between 2015 and 2020 to reach € 25.0 billion at the end of the forecast period. Connected medical devices accounted for 71.0 percent of total RPM revenues in 2015 [Ber15].” This is why home monitoring is experiencing a hype at the moment.

Summarizing market trends from above described systems the EMR/EHR and Home Monitoring initiatives are addressing markets that promise huge revenues and an interesting annual growth rate for solution providers. As well, but a little bit further out, Population Health is expected to become a big revenue generator for companies. In contrast, PHR initiatives lost attraction especially when Google stopped its Google Health project (online personal health record) in 2011, which they had launched back in 2008. Investing in EHRs, Home Monitoring, and Population Health means also investing in interoperability and interoperability standards as without interoperability these systems will not function.

All of the above described systems are (or will be) provided by different vendors. Each of them keeps a fragment of the patient’s health condition and history. To get an integrated view of that data, e.g. in an EMR, all of those different systems need to be interoperable. As barely any standards exist for bringing together all of this fragmented patient data, or exchange that data in between the systems, a lot of pressure and discussion is around the topic of how to solve these interoperability issues.

Medical devices (for the ICU and OR) were not listed with above systems even though they need to be able to exchange data with those as well. This is because medical devices are different; their software usually runs on embedded hardware and has real-time requirements. This means that despite the other systems, that run on powerful personal computers and servers, or on even more powerful mainframes in the cloud, medical devices are pretty limited in their software processing power and, as a consequence, in their interoperability capabilities. Therefore addressing interoperability issues for medical devices needs other

technical approaches than addressing the interoperability issues for above described computer systems.

Summarized this means that when for healthcare topics the talk comes to “interoperability” the talk does (normally) not apply to “medical device interoperability”, but to interoperability of the systems listed and explained above. The same is true for investments made in interoperability; these did not affect medical device interoperability at all, which is the cause that it is still as limited as it was two decades ago.

3.3 Components and Topology

3.3.1 Typical Components

Medical Device Interface: Usually the physical device interface is an RS232 interface. This can be a 9-pin, 25-pin, male, or female connector, and any combination thereof.

In most cases only 3 pins of the connector are used, which are Ground, RxD (receive data), and TxD (transmit data). Sometimes RxD and TxD are not used in line with the standard, but are swapped. Also sometimes other pins are used for special purpose which is also not in line with the standard.

Different types of mechanics are used to fix the cable to the device’s connector, e.g. screws of different length, diameter, thread (metric vs. inch); or special clamps.

Fig. 7 Rear side of Dräger Evita XL (Photo Rainer Binder)

In rare cases medical device manufacturers design proprietary connectors for their RS232 interface, so the connection cable can only be bought from them.

Given above, easily a set of hundred different RS232 cables is needed to physically connect to the medical device interfaces of the most common medical devices in the hospital.

On the electrical level data is transmitted as a serial stream of bits. Here also some configurations can be made, e.g. for the speed of transmission (baud rate), number of data bits, number of stop bits, parity checking (error detection), and flow control (which can be done by hardware or software). That two devices can communicate through RS232 those settings need to be the same for both sides, whereas many of the devices do not support all possible settings.

Theoretically the standard allows a length of 20m for the RS232 cable. Practically, as devices use low power integrated circuits, the cable length is limited to 2-5 meters.

Protocol of Communication: The protocol of communication defines the semantics so that devices can exchange understandable data. Also the syntax is defined in the protocol of communication, which enables the receiving device to interpret the data from the sending device. There is no standard protocol of communication. Vendors, and many times even devices of the same vendor, have different protocols of communication. From version to version of the device the protocol is updated as, e.g. new parameters or other new functionality was added. These updates can happen as often as every six months.

Device Driver: If a medical device data integration system, wants to receive data from a medical device, the above mentioned protocol of communication needs to be implemented as a software module. This software module is called a device driver. The more device drivers are available for such an integration system, the more medical devices it can connect to. As outlined above, basically for each device its own dedicated device driver is needed and, in worst case, needs to be updated every six months.

ID-Module: The concept of the ID-module is to provide plug and play functionality. In an ICU many of the devices at a bed are mobile and are moved to the patient who is in need of them, e.g. not all patients in

Fig. 8 ID-Module with RS232 cable (Source www.philips.com)

ICU need ventilation. To enable interoperability, after a device was moved to a new patient, the RS232 cable needs to be connected to the medical device and the receiving device. Then the receiving device needs to run the appropriate device driver to start communication. The ID-Module is connected in between the medical device and the RS232 cable, and it stays always with the device. When a device is connected to a receiving device it inserts a message in the RS232 communication, which identifies the medical device, so that the receiving system can start the correct device driver. Otherwise the receiving device would not know which medical device is connected and how to communicate with it.

Intelligent Medical Device Hub: This hub is installed at the patient's bed and medical devices can be connected with their RS232 cable to it. This setup is mainly used when the device data is needed in a CIS or EMR system. The hub routes the data, that is received through RS232, to the Hospital LAN network. The device driver can either run inside the hub or it runs on a remote PC which is connected through the hub to the medical devices. The Intelligent Medical Device Hub needs to be able to receive the device ID from the ID module and either interpret it or send it on to the remote PC to start the correct device driver. Because the hub is in patient vicinity it is a regulated medical device.

Fig. 9 Intelligent Medical Device Hubs from different vendors [Web09]

Device Interfacing Engine: This is the software that runs on above mentioned remote PC. If the Intelligent Medical Device Hub is not executing the device drivers they will be executed by the Device Interfacing Engine. The Device Interfacing Engine is also funneling the many data streams it receives from the connected medical devices into one data stream and converts the resulting data stream to a standard protocol, e.g. HL7. This data stream feeds then the CIS or EMR system, which wants to integrate the medical device data.

3.3.2 Topology for Integration with Patient Monitors

A common use case for device data integration is the integration with a patient monitor. As each of the devices has its own way of displaying measured parameters, wave forms, and device settings, and as well its own way of alarm indication, it can become pretty difficult for clinicians to keep an overview of what is going on with the patient. As keeping the overview is very important with critically ill patients, or during a surgery, the customer need is present to integrate all of this information and alarm indications with one device, which is the patient monitor. Fig. 10 shows the integration of an anesthesia machine with a patient monitor.

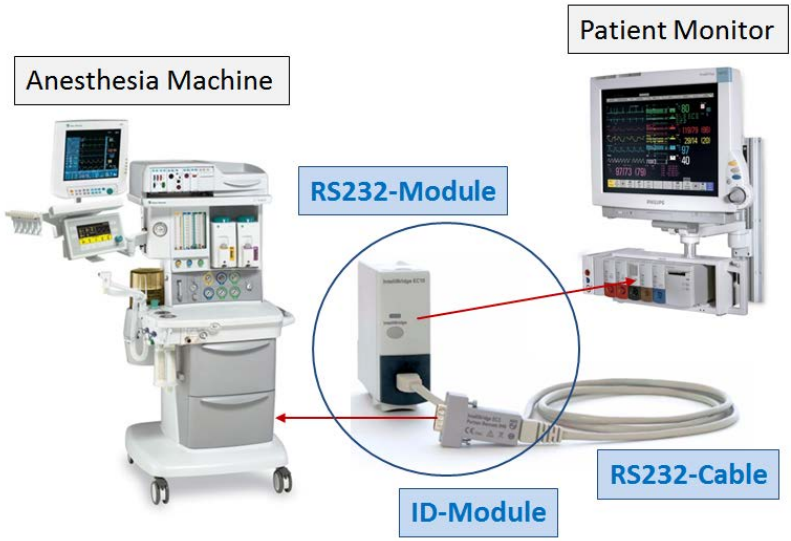


Fig. 10 Device data integration with patient monitor [Web11]

The patient monitor vendor provides the means for integration, which are:

- *Device Driver* which implements the *Protocol of Communication* for the specific device
- *RS232-Module* which hosts and runs the device driver
- *ID-Module* for automatic detection of the interfaced device
- *RS232-Cable* to connect the devices

This is common approach across patient monitor vendors, just the design of the RS232-Modules and the ID-Modules (if present) are different.

All of the hardware and software used for device integration are regulated medical devices as they are used for patient monitoring. Therefore development cost is high and the solution is expensive. Also not all devices at a patient's bed can be connected as one RS232-Module per device is required, and also a Device Driver, which is not available for all existing devices (due to the high development cost).

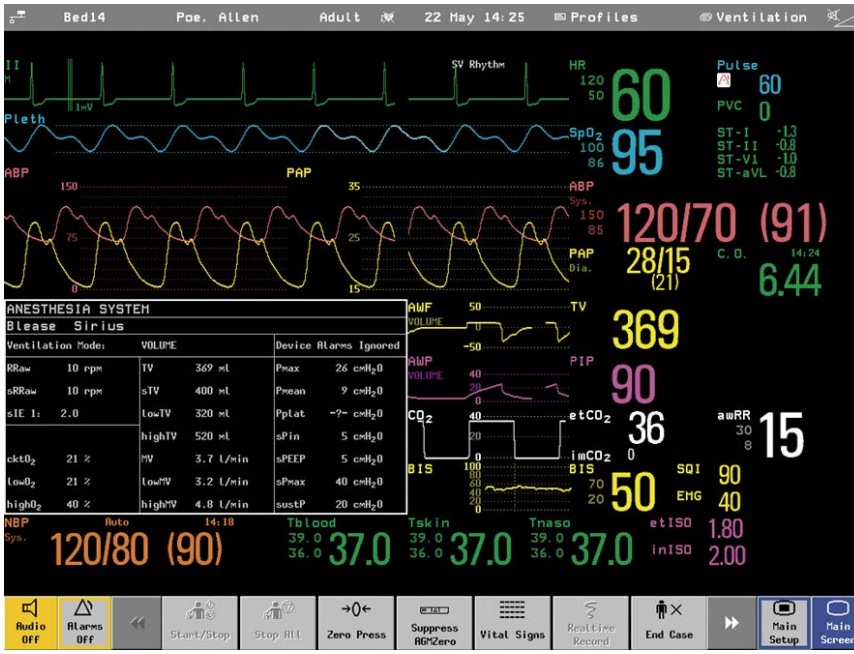


Fig. 11 Patient monitor screen with data from anesthesia machine (Source www.philips.com)

Another aspect of this type of integration is the central alarming. In an ICU the monitors are connected through a LAN network. That LAN is often called the *Clinical LAN* as it needs to be separated from the other network, which is called then the *Hospital LAN*. This separation is needed to guarantee that data, especially alarms from a monitor are displayed at the central station, or other patient monitors, within the required time set by country regulations. For each device that is connected through the RS232-Module to a patient monitor its data and its alarms will also be transmitted to the central station, which is always

provided by the vendor of the respective patient monitors. The whole set up of patient monitors, central stations, and clinical network is a closed system; main argument here is patient safety. A central station, is like the name says, in a central location, which allows one person to have an overview of all connected patient monitors, and devices that are connected to them, within the dedicated clinical network. This is especially important during night shifts, when staffing is low.

As those are all closed systems (across all vendors), but their data needs often to be integrated with CIS and EMR systems, *gateways* are offered by the vendor for that purpose. The *gateways* can be standalone or integrated, e.g. with the central station, and export the data in a structured format, e.g. HL7.

The connection of the medical device to a patient monitor and the connection of the patient monitors to the central station require real-time data transmission, as the patient's life might be dependent on the timely indication of alarms. The export of the data through the *gateway* is not in real-time anymore, it could be even minutes (or longer) delayed after the data was generated and sent by the patient monitor and its connected devices.

Because Medical Device Data Solutions (MDDS) treat the *gateway* as just another Medical Device Interface, it was not listed as an own component in chapter "3.3.1 Typical Components".

3.3.3 Topology for Integration with CIS or EMR Systems

The other common use case is integration of device data with CIS or EMR systems to document patient history, provide clinical decision support, and perform other clinically relevant things. Real-time data transmission is not a requirement here, but low-latency is desired, as the receiving systems are used to derive clinical decisions that might impact medication and generally the treatment of the patient.

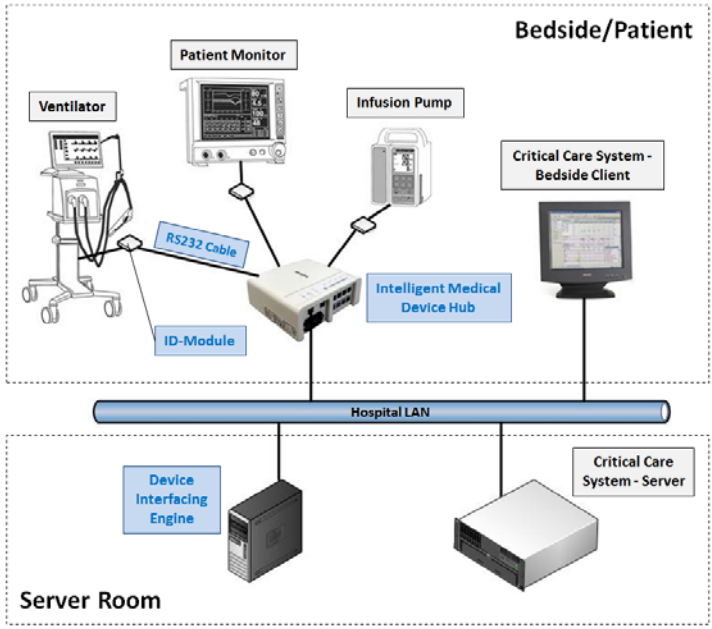


Fig. 12 Device Interfacing with Intelligent Medical Device Hub

Ideally all devices at the patient's bed should be connected to the CIS or EMR system. Therefore, a different topology was chosen, than the integration with the patient monitor, to achieve that.

The Intelligent Medical Device Hub is the device that integrates the medical devices for one bed. Patient monitors are in most cases not connecting to the Intelligent Medical Device Hub as they deliver their data through a *gateway* to the CIS and EMR system directly, or to the Device Integration Engine. Same is true for syringe and infusion pumps, if they are used within a rack that has a LAN interface which connects them to the Hospital LAN. All other devices, provided they have a device interface at all, are connected through RS233 cables

to the Intelligent Medical Device Hub. The Intelligent Medical Device Hub forwards the data to the Device Interfacing Engine, which sends then the combined data of all devices to the CIS or EMR system. The Device Drivers are either hosted by the Intelligent Medical Device Hub or the Device Interfacing Engine. Also, ID-Modules are used for device identification, which allows plug and play functionality. Plug and play functionality is important to not lose any data, especially in emergency cases, where there is no time to first configure devices.

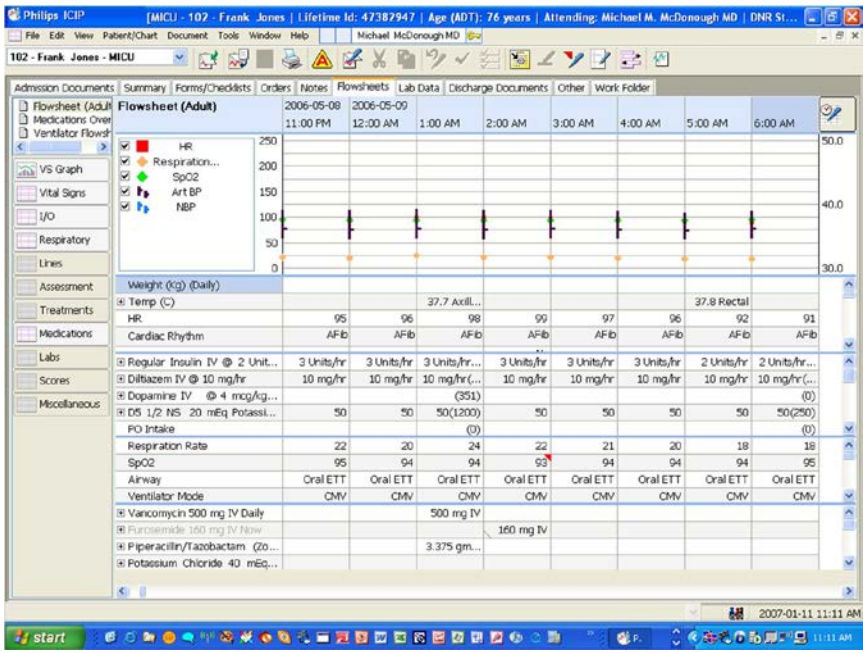


Fig. 13 Flowsheet of a CIS system with integrated device data (Source www.philips.com)

3.3.4 Considerations for Choosing a Topology

1) *The two described topologies are exclusive*, which means that, either or can be chosen, but not both. This is because the devices have one physical interface only, which can either be connected to the patient monitor or to the Intelligent Medical Device Hub. Theoretically the *gateway* that exports patient monitor data to other systems could help here, but often only the data of the native patient monitors is exported, and if device data was really added to the data export, it is often not the complete data, but only a few selected (frequently used) parameters.

2) *Device Driver* availability is the biggest topic to consider as those are not easily developed. A study of HIMSS Analytics [Him10] with the title “Medical Devices Landscape” did, amongst other, research how many different medical device types are available in a hospital (in USA). They found 11 different device types ([Him10], p. 7), whereas they did include the Intelligent Medical Device Hub in this count, which is neither a monitoring nor a diagnostic device. Not all hospitals had all device types the median did range from 6 to 9. Only device types that would need to be interfaced with an EMR were considered. List of device types ([Him10], p. 7):

- Cardiac output monitors
- Defibrillators
- Fetal monitors
- Electrocardiographs
- Infant incubators
- Infusion pumps
- Intelligent medical device hubs
- Interactive infusion pumps
- Physiologic monitors
- Ventilators
- Vital signs monitors

No research was done by this study [Him10] about how many different vendors supply these devices, so above list unfortunately implies that device interfacing to an EMR is a pretty straightforward undertaking with just 10 different device types to be supported.

Reality is that a dedicated *Device Driver* is needed for each of the combinations of: vendor, product, model, and revision. In addition, some devices offer RS232 and LAN interfaces, some only WLAN, and some use dedicated *gateways* with either LAN or RS232 interfaces. Because of that the number of possible variations is huge and hundreds of different *Device Drivers* are needed ([Bik11], p. 1) to just cover the interfacing of the devices from the leading manufacturers.

For that reason only three of the approximately ten different device types are at the end interfaced with the CIS or EMR system in a hospital ([WHI13], p. 6).

Depending on the vendor of the device interfacing solution, and the chosen topology, different sets of *Device Drivers* are available, which might influence the decision for a certain vendor and a certain topology. Concerning the topology, it is important to note that the integration with the patient monitor is only offered by the respective monitoring vendor and thus a vendor cannot be freely chosen amongst the MDDS vendors.

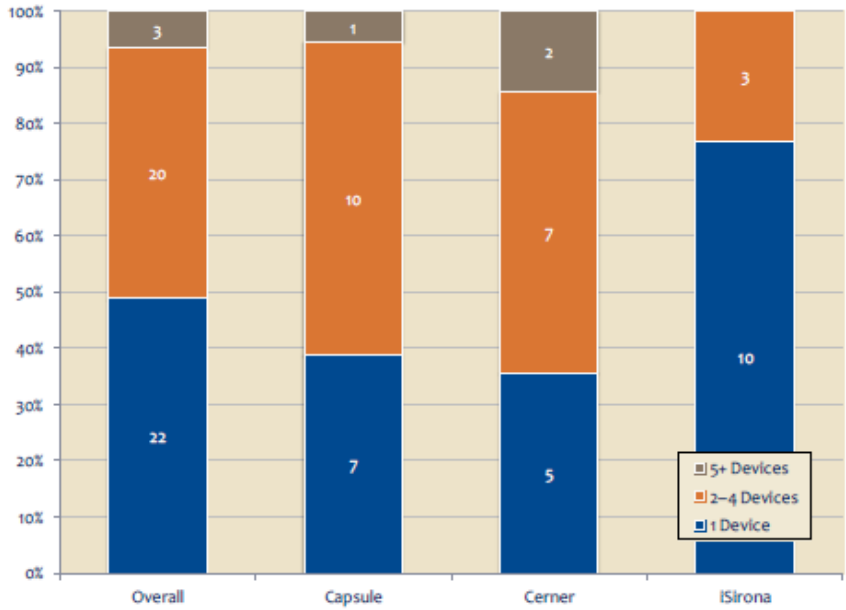


Fig. 14 Average number of devices connected per bed ([Kla12], p. 33)

3) *Patient association* is an important topic when looking at medical device interfacing. Patient association means that the data that is sent by a device is unambiguously assigned to a patient ([McA09], p. 1-2) as this directly affects patient safety.

As patient monitors and Intelligent Medical Device Hubs are permanently assigned to a certain bed, each device that will be interfaced through either this patient monitor or this Intelligent Medical Device Hub is automatically assigned to that bed as well. In the CIS or EMR system the bed is assigned then to a patient which creates the final association.

However for certain devices and gateways this doesn't work. E.g., there are smart infusion pumps that connect only through WLAN to the Hospital LAN and others, like infusion pump racks (multiple infusion pumps can be plugged into a rack), connect through wired LAN to the Hospital LAN. In case the rack is also permanently assigned to a bed the same patient association mechanism applies as described above, but often the racks are small, carrying only up to three pumps, so that they can be used mobile.

Of course one could type the patient ID into each, e.g. infusion pump that has a LAN or WLAN connection. Knowing that infusion pumps don't have a keyboard and that there can be many of them at a single patient bed this is not a workable solution.

McAlpine did discuss several work arounds to this patient association problem in his article "Biomedical Device Integration: The Impact on Clinicians at the Point of Care" [McA09]:

Barcode & PDA Based Association: Use a PDA with respective software on it to make the association at the bedside. The software would guide the nurse through the steps needed, the PDA could also be equipped with a barcode reader.

Medical Device Based Association: The vendor of the medical device, e.g. infusion pump vendor provides a bar code scanner with the pumps to scan patient ID from a wrist band or some other patient documentation.

Application Based Association: The user (physician, nurse) assigns the medical devices in the CIS or EMR application to a patient.

ADT Based Association: The medical device will access the patient list in the hospitals HIS system, which includes the ADT sub-system, and the user can select a patient from there at the medical device's user interface.

RTLS Based Association: Use of Real-time Location Systems (RTLS) to perform an auto-identification of the device, e.g. by using active RFID, passive RFID, ultrasound, infrared, and others.

All of above associations were discussed in the article, all of them had severe cons, especially as they all require manual intervention, which makes the clinical workflow more complex and adds additional risk to patient safety.

Though the issue of patient association only indirectly affects which topology to choose, it is an important topic to consider when planning medical device data integration with CIS and EMR systems, especially as no common solution exists for this issue today.

3.4 MDDS Vendors

As mentioned in the previous chapters the integration of medical device data with the patient monitor can only be done by the manufacturer of the respective patient monitor.

Tab. 4 Vital Signs System Revenue Market Shares, US, 2013 ([MRG14], p. 44)

Company	Market Share
Philips Healthcare	48.2%
GE Healthcare	27.0%
Mindray Medical International	6.8%
Spacelabs Healthcare	5.2%
Dräger Medical	3.8%
Nihon Kohden	3.5%
Other	5.5%
Total	100.0%
Other includes Criticare Systems, Ivy Biomedical Systems, Mennen Medical, Nonin Medical, and Welch Allyn.	
Notes: Numbers reflect rounding.	
Source: Millennium Research Group	

The top five patient monitoring vendors as shown in Tab. 4 provide solutions for medical device integration with the monitor. Some of them, e.g. Philips and GE Healthcare, also provide device integration with CIS and EMR systems, independent of the patient monitor, and also including other vendor's medical devices.

As customers are skeptical on how intensive the effort of one patient monitor vendor will be to integrate the data of the other vendor(s) patient monitor and medical devices, some prefer to work with vendor-agnostic Medical Device Data Systems (MDDS) companies ([F&S15b], p. 27). The four prominent players in this niche market are: Capsule, iSirona, Nuvon, and Cerner ([Kla12], p. 4). Whereas Cerner is an EMR company which does also provide an MDDS system, but (so far) only in combination with their EMR solution.

When the first CIS systems came to market it caused development of a niche market for medical device data systems (MDDS). The device interfacing niche market got another push when EMR systems became widely adopted, partially superseding CIS systems, and for the last years being heavily pushed by the US government with financial incentives under the American Recovery and Reinvestment Act (ARRA); signed by US President Obama in 2009. Fig. 15 shows the market growth of the US EMR market from 2005, with $7 billion, to an estimated $18 billion in 2012. Newer studies show that the US EMR market has reached $24.9 billion in 2014 and is predicted to grow to $35.2 billion until 2019 [Web10]; with the MDDS niche market growth following these numbers.

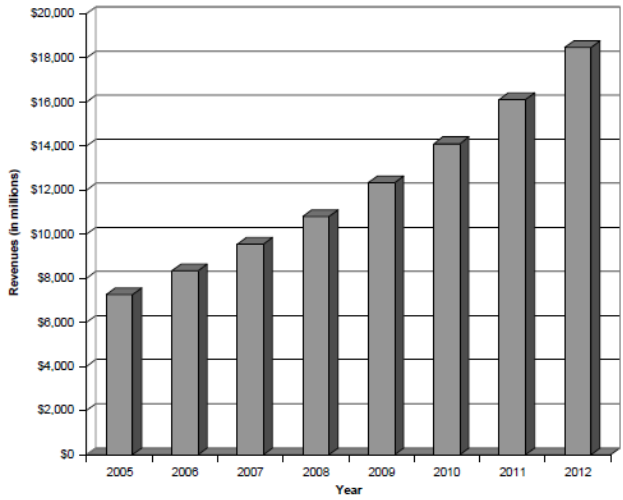


Fig. 15 US EMR Market Analysis 2015 - 2012 ([Kal09], p. 6)

MDDS niche market players (taken from [Kla12]):

Capsule: Capsule, calling itself the market leader in the medical device interfacing market, is in the business since more than 15 years. It is a globally acting company with the biggest device driver library in the world. Many medical device vendors work directly with Capsule to ensure that their device works with the Capsule solution: “Considering the sheer volume and varying ages of physiological monitors, researching and developing drivers can be costly, making the possession of an extensive library a valuable asset.” ([Kla12], p. 5). Capsule’s products, services, and support are perceived by customers as very professional, which justifies a bit for the large price tag on their solution. “Capsule Tech is the preferred vendor for hospitals and device manufacturers

alike, and its solution is currently implemented in 1,835 hospitals across the US, the Middle East, Asia-Pacific, and Africa." ([F&S15b], p. 29).

Cerner: Cerner is an EMR vendor and the only one that has its own device interfacing solution the Cerner CareAware iBus. Owning the medical device interfacing solution allows Cerner for tighter integration of medical devices which leads to solutions like "…addressing multiple workflows, such as alarm integration, IV programming, waveform integration, and staff assignment. The integrated platform also allows users to leverage other technologies, such as smart pumps, into their monitoring network, and the solution allows for redundant alerts in high-acuity environments." ([Kla12], p. 7). From the pricing point of view Cerner's iBus is also on the up-side.

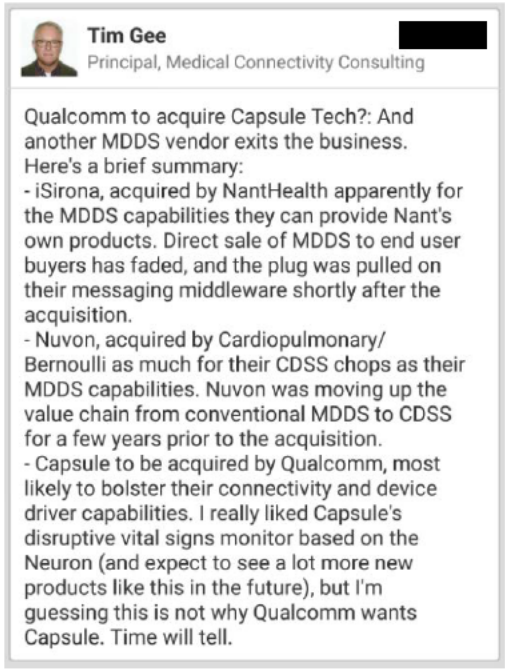


Fig. 16 Tim Gee about MDDS vendor acquisitions (Source [redacted])

iSirona: iSirona is considered a pretty new company in the MDDS field, their first install was done only a couple of years ago. iSirona positions itself as a software-only company and uses existing hardware in the hospital to run their software on it. However, for the interfacing of the medical device they also need a proprietary hardware, called DeviceConX, which connects to the device interface on one side and to the hospital's WLAN on the other side. iSirona, next to Capsule, supports the widest variety of EMR vendors. Pricewise iSirona is way lower than Capsule and Cerner. As iSirona just started to grow its customer base, first customers complain now about lower support responsiveness.

Nuvon: In 2012 (when this study was conducted) Nuvon had only six installs of their VEGA solution. Nuvon is coming from a background in network surveillance and communication. Pricewise they are in the lower range and offer

a large device driver library. Customers seem to be happy with their architectural approach: "…with specific mentions around slick management tools and elegant programming architecture." ([Kla12], p. 3).

Back in 2015, a few interesting acquisitions happened in the MDDS world, see also Fig. 16.

Capsule was acquired by Qualcomm Life. Qualcomm Life is a subsidiary of Qualcomm, a mobile chipmaker, and has a focus on connected health solutions. E.g., Remote Patient Monitoring and Population Health are markets for which they offer products or want to offer products.

Nuvon was acquired by Cardiopulmonary/Bernoulli a company extending its reach from MDDS into Clinical Decision Support Systems (CDSS), in which Nuvon was also active in the recent years before the acquisition took place.

iSirona was acquired by NantHealth a company that claims to transform healthcare by building an integrated, evidence-based, omically-informed, personalized approach to the delivery of care and the development of next generation healthcare solutions.

That means that now all three formerly independent main players in MDDS were acquired by companies that want to become active in personalized clinical decision support provided by population health management eco systems. It appears that this will be the third large market growth opportunity for (former) MDDS vendors after first, the data integration with CIS systems, and second, with EMR systems.

3.5 Standardization Efforts

3.5.1 Overview

Since the mid-1980s ([Schr01], p. 11) there are standardization efforts underway for medical device interoperability. Moorman [Moo10] describes in her article "Medical device interoperability: Standards overview" four of them: The Continua Alliance, Integrating the Health Environment - Patient Care Devices Domain (IHE-PCD), American Society for Testing and Materials - Integrating the Clinical Environment (ASTM-ICE), and the Health Information Technology Standards Panel (HITSP). Bikram ([Bik11], p. 3) adds in his article "Standards

for Medical Device Interoperability and Integration" some more to the list: HL7, Medical Interface Bus (MIB) – IEEE 11073, Medical Device "Plug and Play" (MD PnP) Interoperability Program which meanwhile became the Integrated Clinical Environment (ICE) (ASTM F2761:2009) program, and IEC 80001 which is a framework to manage risk associated with networked medical devices. Further Bikram is introducing the separation between "Fundamental or Base Standards" and "Composite or Meta Standards". E.g., IHE-PCD builds on existing standards like MIB. Thus IHE-PCD is considered a *Meta Standard* and MIB a *Base Standard*. Another effort in terms of standardization is the OR.NET project for "Secure and dynamic networking in operating room and hospital" which is sponsored by the German Federal Ministry of Education and Research and which is partnering with other standardization platforms [OR16]. Currently the OR.NET project drafted three amendments to the IEEE 11073 standards family, replacing their syntactical data interoperability part by a Service Oriented Architecture (SOA) based on the Device Profile for Web Services (DPWS) [Poe09].

3.5.2 Base Standards

Health Level 7 (HL7): The HL7 protocol is a definition on the syntax level (which is called "structural" interoperability in HIMSS terms, see also chapter "3.1 Definition of Medical Device Interoperability"). It can be used upon any lower level "foundational" (physical) protocol level. It defines the fields for data exchange, and in version 2.x, barely any semantics. In version 3.x data semantics were added. It is interesting to note, that version 2.x is widely used for medical device interoperability, whereas 3.x, which is way more capable, but also more complex, isn't used at all. Though HL7 is pretty widespread, when taking a closer look we see that HL7 is too "verbose" for simple medical devices, like a pulse oximeter, and thus is mostly seen with gateways that export medical device data, e.g. from otherwise closed patient monitoring networks ([Bik11], p. 3).

To confirm above stated success story of HL7, here a quote from a recent study "In the US, 90% of healthcare IT vendors use HL7, making it the most commonly used and accepted interoperability standard for connected health. HL7 enables sharing and re-use of patient information among several healthcare systems, and reducing costs of integration and need for incremental investments

in new technology." ([F&S15b], p. 14). This does also confirm that HL7 is more used in data exchange between healthcare systems, to which data gateways belong, than in direct interfacing of individual medical devices.

ISO/IEEE 11073: This standardization started originally as the Medical Interface Bus (MIB) which became the IEEE 1073 standard and further developed into a set of standards, the ISO/IEEE 11073 family in 2004 ([Bik11], p. 3).

The core specifications of the standard go back to the MIB as defined in IEEE 1073 [Schr01]:

The core of the standard is the *Medical Data Information Base (MDIB)* which is an abstract object-oriented data model representing the information and services provided by the medical device.

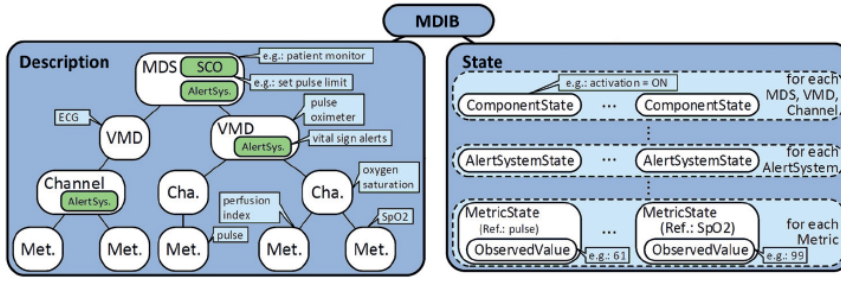


Fig. 17 Domain information and service model for semantic interoperability- based on the IEEE 11073 standard ([OR16], p. 13)

The *Medical Device Data Language (MDDL)*, which is standardized in IEEE 1073.1, covers the nomenclature to name elements in the data model, the generic object patterns used for different applications (e.g., an alarm pattern), and the device-specific standards, which are standardized in the respective subchapters:

- MDDL - Nomenclature (1073.1.1)
- MDDL - Generalized Device (1073.1.2)
- MDDL - Specialized Device (1073.1.3).

The *Medical Device Application Profile (MDAP),* which is standardized in IEEE 1073.2, defines the services that are used to exchange the MDDL information between the medical devices or systems. The MDAP includes the following subchapters:

- 1073.2.0: MDAP-Base Standard
- 1073.2.1: MDAP-Baseline Profile
- 1073.2.2: MDAP-Polling Mode Profile
- 1073.3 and 1073.4: Transport Profiles
- 1073.3.1: Transport Profile-Connection Mode
- 1073.3.2: Transport Profile-IrDA Based-Cable Connected
- 1073.3.3: Transport Profile-IrDA Based-Infrared Wireless
- 1073.4.1: Physical Layer Interface-Cable Connected

Due to the sheer complexity of the IEEE 1073 standards, and its successors the ISO/IEEE 11073 standards, Bikram states: “Commercial implementations of this standard in medical devices are very scarce, with at the most two device vendors supporting this, in an insignificant fraction of their medical device offerings.” ([Bik11], p. 3). However, he also states that the important work put into these standards is not lost as parts of them are reused in other (meta) standards.

3.5.3 Meta Standards

IHE-PCD: The following is taken from the article “Medical device interoperability and the Integrating the Healthcare Enterprise (IHE) initiative” by Rhoads et al. [Rho10]:

Integrating the Healthcare Enterprise (IHE) is an organization that was founded in 1997 to improve the integration of imaging data into the hospital’s infrastructure. Since that its scope expanded in many other domains, one being Patient Care Device (PCD) which cares about medical device interoperability. Domain participants are drawn from manufacturers of medical devices, healthcare providers, government agencies, e.g. NIST or FDA, and technical and clinical experts. Sponsors of IHE PCD are the Healthcare Information and Management Systems Society (HIMSS) and the American College of Clinical Engineering (ACCE).

IHE does not create new standards, but “integration profiles” that show how to apply existing standards from internationally recognized standards development organizations (SDOs). Those are standards and organizations like AAMI, HL7, DICOM, ISO/IEEE 11073, HITSP, ASTM-ICE, Continua Alliance, and Cen/TC 251 and ISO/TC 215.

The first profile developed by IHE-PCD was the Device Enterprise Communication Profile (DEC) which allows sending device data to an enterprise system using HL7 v.2.6, specifying a subset of device data to subscribe to. Another profile is the Rosetta Terminology Management (RTM) which is specifying uniform terms and codes for clinical and technical observations from devices, to reduce risk of mistaken or lost measurement identity, and also permissible valid units of measure for observations. To achieve that, first many hundreds of terms currently used by vendors were collected, and then correlated with the terms of ISO/IEEE 11073 (ISO/IEEE 11073-10101), with SNOMED (Systematized Nomenclature of Medicine), and with LOINC (Logical Observation Identifies Names and Codes). The best fit was found with ISO/IEEE 11073, however as many terms, e.g. for ventilators and anesthesia machines, did not exist the ISO/IEEE 11073 was, and is being, extended in close cooperation with the respective ISO/IEEE 11073 committees.

Also strong cooperation exists with other organizations, e.g. NIST for conformance testing, or ASTM-ICE (former MD PnP) in analyzing clinical scenarios in order to identify technical requirements from these.

When profiles are implemented by manufacturers the certification is done in so called “Connectathons” where manufacturers come together and do physical connectivity testing of their newly implemented profiles. The certification also allows participating in the yearly IHE Interoperability Showcases held in North America, Europe, and the Asia/Pacific region.

IHE-PCD was adopted meanwhile by many medical device manufacturers, but similar to HL7, in most cases on PC-based gateways, like for patient monitoring or for infusion pumps management.

Continua Health Alliance: Like described by Moorman [Moo10] the Continua Health Alliance takes care of personal telehealth applications, which includes disease management, health and wellness, and aging-independently. The Alliance

was founded in 2006 as a non-profit industry coalition with meanwhile more than 180 members.

Their products are small, portable, and battery powered. For that purpose Continua has defined PAN and LAN interfaces that communicate with an application hosting device (AHD), which then delivers any data through the WAN to a remote health record (HR). Though this approach seems not to be of interest for in-hospital medical device interoperability it is interesting to note, that the standard for the PAN devices bases upon the Medical Interface Bus ISO/IEEE 11073, which is quite successfully used in PAN device communication but not in medical device interoperability. To achieve that success an Optimized Data Exchange (IEEE 11073-20601) standard was written and for each device type, e.g. pulse oximeter, blood pressure monitor, thermometer, etc. one IEEE 11073-104ZZ standard was created. This way only two simple standards apply per device. Before, IEEE 11073 had a reputation of being descriptive and not standalone, which is still the case for in-hospital medical device interoperability.

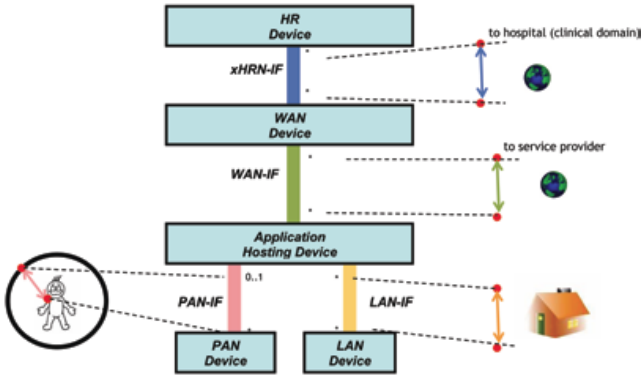


Fig. 18 Continua's interoperability paradigm [Moo10]

MD PnP / ASTM-ICE: ASTM stands for American Society for Testing and Materials and ICE for Integrating the Clinical Environment. The ICE project is co-sponsored by the American Society for Anesthesiology (ASA) ([Moo10], p. 4). The project was pioneered by Julian Goldman, MD, and colleagues of the Medical Device "Plug and Play" Interoperability Program (MD PnP) hosted at the Center for the Integration of Medicine & Innovative Technology, Cambridge, MA, USA ([Rho10], p. 6). The project is focusing on medical device interoperability in the OR (operating room) and has the goal to increase patient safety, treatment efficacy, and workflow efficiency. Interesting is, that the contention in this project is, that these goals can only be achieved by bi-

directional device communication without the need of human interaction. Technically spoken this is a closed-loop system [Moo10]. ASTM-ICE does also work with other standards organizations like IHE-PCD, ISO/IEEE 11073, and HITSP [Moo10].

OR.NET: OR.NET is a lighthouse project of the German Federal Ministry of Education and Research (BMBF). The following is taken from the project's OR.NET brochure [OR16].

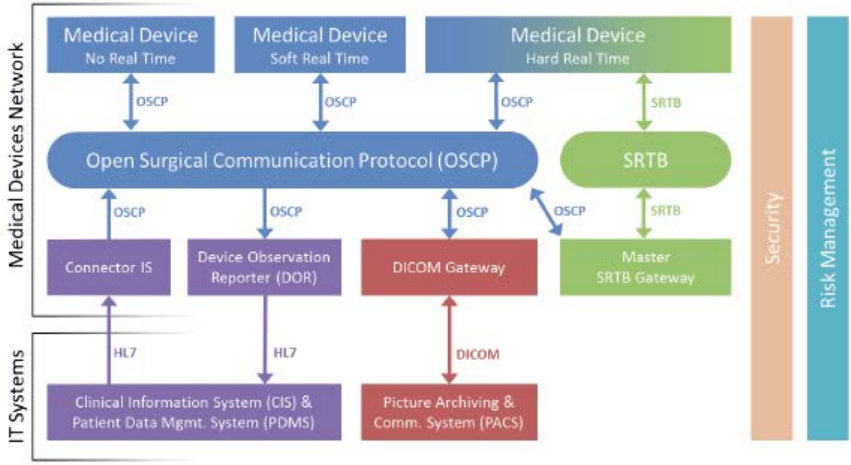


Fig. 19 OR.NET architecture [OR16]

The goals of the project are many-fold, a main topic is the development and standardization of open source libraries for open network communication of medical devices in the OR. In order to achieve that an Open Surgical Platform (OSP) was developed containing all functions and the data models for networking and integration. Communication is done by the Open Surgical Protocol (OSCP). Protocol and data model were submitted for standardization as:

- IEEE 11073-10207 Domain Information & Service Model for Service-Oriented Point-of-Care Medical Device Communication
- IEEE 11073-20702 Medical Devices Communication Profile for Web Services
- IEEE 11073-20701 Service-Oriented Medical Device Exchange Architecture & Protocol Binding.

Interesting to note is that considerations were made on hard-real time requirements of medical devices (which are all that can generate patient alarms).

Those communicate over the Surgical Real Time Bus (SRTB). Integration of those in OSCP happens through a SRTB-OSCP-Gateway, see Fig. 19.

The main intent of the standardization effort is to replace the syntactical interoperability level of ISO/IEEE 11073 by a modern architecture. This modern architecture utilizes the Service Oriented Architecture (SOA) based on the Device Profile for Web Services (DPWS). For the semantical interoperability still IEEE 11073 or HL7 will be used. DPWS includes the Web Service Dynamic Discovery (WS-Discovery) which will be used for automatic device detection, and the WS-Eventing which will be used for point-to-point event (e.g. alarm) communication. In the case that real-time bulk information needs to be transmitted to many listeners this will be achieved by using the networks multicast functionality and SOAP-over-UDP (e.g. alarm of one bed to be annunciated at all other beds) [Poe09].

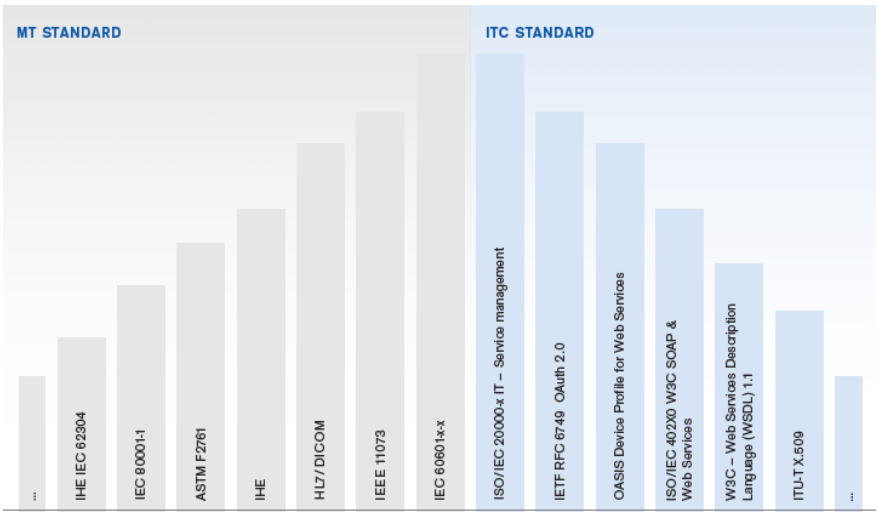


Fig. 20 Medical device standards and related IT (de facto) standards [Dra15]

Basically the concept is to replace as many medical device technology standards with IT (de facto) standards to enable medical devices for bi-directional communication and participation in the internet-of-things (IoT) [Dra15].

Consequently the propagated DPWS approach will be fundamental for a Dräger supported open source solution (openSDC) that will also allow for an ASTM F2761-09 (see ASTM-ICE above) conform implementation [Dra15].

Healthcare Information Technology Standards Panel (HITSP): "HITSP was chartered by the U.S. Department of Health and Human Services to provide standards harmonization in the health information technology arena to meet the federal mandate for a universal electronic medical record. HITSP bases each of it interoperability specifications (IS) on use cases as promulgated by the National e-Health Collaborative (NeHC), formerly known as American Health Information Community (AHIC). The interoperability specifications are meant to be compulsory on any players in the healthcare realm who are contributing to an electronic medical record for a US citizen." [Moo10].

HITSP is also working closely with IHE-PCD to avoid replication efforts [Bik11].

IEC 80001: This is not a standard for medical device interoperability itself, but for managing the risk introduced by creating complex infrastructures in medical device interoperability. Its purpose is to identify and manage risks and hazards that may not have been foreseen when the product was developed [Bik11].

3.5.4 Summary

These are the most important standardization efforts for medical device interoperability. Beneath these, also partnerships exist between individual vendors to move, e.g., certain workflow optimizations forward through enhanced medical device interoperability [Web11].

From the entire standards activities one can see that customers are asking basically for three fundamental things:

- Device Integration (at the bed side)
- Closed-loop control (at the bed side)
- Medical device data populated to other IT-Systems (at the bed side or remote)

To make these customer requests easy to realize and implement (plug and play is here the keyword) the underlying assumption is, that standards would help here. As we can see plenty of standards were developed, and are being further enhanced, but unfortunately not with a lot of success: Closed-loop control is not a standard as of today, device integration is limited, expensive and not standards based, and medical device data can be populated only partially to CIS, EMR, and

other systems, but in most cases without the use of standards. After decades (more than 30 years) of standardization efforts going on, this is not a promising outcome.

Reasons for that, which are mentioned in the used references, are:

- Complexity of standards
- Standards not made for embedded low-performance hard real-time systems

Due to its sheer complexity the ISO/IEEE 11073 was barely implemented anywhere. However its semantic interoperability is reused in many other standards (which are also barely used) as nothing comparable does exist.

HL7 had a lot of success, but in most cases on PC-based gateways only, as it is considered too “verbose” for embedded systems. Meanwhile HL7 is more and more replaced by IHE-PCD, but again on PC-based gateways only which export data of otherwise closed patient monitoring and infusion pumps networks.

On the medical device itself we still see in 98% of the cases an RS232 interface with a proprietary protocol of communication even after more than 30 years of standardization. This raises the question, if standardization is really the solution for functional medical device interoperability?

3.6 Considerations for Medical Device Interoperability

On the good side, the medical device interoperability standards document a huge amount of expert knowledge in that field, especially on topics that one would not consider otherwise when thinking of a new medical device interface.

List of important considerations for functional medical device interoperability:

(1) Wireless communication ([F&S15b], p. 21-24)
(2) Patient safety [Schr01]
(3) Unambiguous patient association [Schr01]
(4) Unambiguous device identification (worldwide) [Schr01]
(5) Wide range of topologies [Schr01]
(6) Fault tolerant (modified from [Schr01])
(7) Cost effective [Schr01]
(8) Off-the-shelf-technologies [Schr01]
(9) Run on low-performance embedded systems (modified from [Schr01])
(10) Low-power device [Sch01]
(11) Time synchronization (for time the measurement was taken, or synchronizing wave forms) [Schr01]
(12) Data security [Schr01]
(13) Remote control (bi-directional communication) [Schr01]
(14) Alarm management (real-time aspects) [Schr01]
(15) Hard real-time communication [OR16]
(16) Closed-loop communication (MD PnP/ASTM-ICE in [Moo10])
(17) Semantical interoperability [Rho10]

This is an impressive list of considerations which makes one understand why a single large standard cannot fully cover of all these topics (see also [Bik11] chapter “Drawbacks to Standardization”), also as the list kept growing over the years.

3.7 Cost of Medical Device Interoperability

Looking at the cost of medical device interoperability, one can look from three different angles: customer perspective, MDDS vendor perspective, and medical device manufacturer perspective.

The cost for the *customer* to integrate medical devices with an EMR is estimated to be ***10k$ per bed*** (in the US) plus a yearly ***maintenance fee of 15%*** of the one-time cost [WHI13]. That means, if a customer wants to integrate 30 beds with an EMR the one-time cost for device interfacing is 300k$ and the yearly maintenance fee is 45k$.

From the *MDDS vendor* point of view the cost of one EMR interface for one device is between 350k$ and 1.2M$ [WHI13]. This first appears to be a too high number, but let's assume a company like Capsule that has may be a yearly operational cost of 20M$ and producing per year 25 new device drivers, lets one argue that the ***cost per driver is 800k$***. Of course this cost does also include all supporting activities, like hardware development, cables development, support etc. and not just the pure cost of coding the device driver. This is why companies like Capsule finances themselves from mainly three sources: (1) customers that purchase the solution with 10k$ per bed and (2) a 15% maintenance fee, and (3) from medical device vendors who want a device driver for their product to be available, which costs them approx. 30-50k$ per device driver and 10-15k$ upon device driver updates.

The *medical device manufacturer* has its cost mainly with providing the medical device interface and the protocol of communication. In chapter "2.4 Number of ICU and OR Beds in the World" a rough estimate came up with a total addressable market of 215M€ for medical device interfaces, which is 5% of the total addressable medical device market for ICU and OR. Assuming a company that is in a sub market segment of 25% of the ICU/OR devices market (e.g. ventilation) and owns there a 10% market share, it would have revenues of 107.5 M€ per year. With an R&D spending of 10% this company could invest 10.7M€ a year in innovations. Spending one engineer (with assumed cost of 120k€ per year) on device interfacing would equate to more than 1% of the total R&D budget. This will certainly not happen as the medical device interface is still seen as a small contributor in the overall value proposition of a product that shall

provide a clinical benefit. So, more likely will be that 20% of a hardware engineer, 20% of software engineer, and 10% of support engineer will be assigned to the medical device interface development and maintenance and this "team" being staffed up with summer students. That means that the maximum investment is at ***approx. 50 k€ per year for device interfacing for a company with approx. 100 M€ revenue***. To develop an RS232 interface and a protocol of communication this is just a big enough investment. For the same investment one could of course also develop a LAN interface and provide some modern protocol of communication, e.g. based on web services, but the device could not be integrated easily anymore by MDDS vendors because the unambiguous patient identification (Intelligent Medical Device Hub) and the unambiguous device identification (ID Module) would be gone as those work only with RS232 interfaces.

3.8 Known Issues

To summarize the issues of current medical device interfacing we look at the previous chapters and also on real use cases [Schl12] which leads to the following list:

- Not all parameters of a device are made available by the MDDS. A device can provide more parameters than the MDDS hardware is capable to transmit. As the parameters, which are to be transferred, are normally hard coded, the developer of the device driver decides which ones are to be transmitted and which ones are not.
- Beds need unique names for patient association in the EMR system (field name length and characters to use might be limited). See use case [Schl12] were the patient monitor did allow 6 digits only for the bed name.
- Workflow changes when introducing MDDS (more steps needed): cables need to connected/disconnected when moving the device, patients need to be assigned to beds, patient IDs might need to be scanned, or even a handheld (PDA) needs to be used for positive patient identification [McA09].

- Conflicting topologies: Integration with patient monitor vs. MDDS. Only one topology can be selected per device, with each one having advantages and disadvantages, see chapter "3.3.4 Considerations for Choosing a Topology"
- Parameter selection and mapping for EMR use is very time consuming (only a subset is to be charted, agreement across medical staff needed). This is one of the biggest issues. Also unit of measure can be different for different devices. Some might send a pressure in mmHg and others kPa, some might send a coma instead of decimal point which could lead to wrong reporting of measured patient parameters, etc. ([Rho10], pp. 25).
- Device drivers are not available for all devices, in average only 3 device types can be interfaced (out of 10) ([WHI13], p. 7)
- When medical devices are upgraded by service engineers updated device drivers might not be available. This could mean no data recording for this device type for several months. Medical device upgrades can usually not be postponed as many times they affect patient safety. Also "downgrades" are not possible for the same reason.
- MDDS systems are complex and therefore are sources for new potential errors in the workflow.
- Training requirements for an MDDS are high for clinical staff and biomedical engineers.
- Cost per bed is high for MDDS systems [WHI13].
- Mix of different connection types at one bed: devices that are not connected, devices that are connected through a gateway, devices that are connected through an MDDS solution, and in the worst case devices that are integrated with the patient monitor whilst others are connected through an MDDS. Patient association is different for the different connection types, see chapter "3.3.4 Considerations for Choosing a Topology" and there the topic *patient association*. This mix of connection types and different patient association methods might even negatively impact patient safety.

3.9 Summary and Discussion

The term “medical device interoperability” implies a picture that is much different than what we found in this chapter about the current state of medical device interoperability. With interoperability being defined as data exchange, on different protocol levels, it implies that medical devices could talk to each other, e.g. sending data to another device that has requested them, or perform a calculation on received data and send the result back, or change settings on the other device due to measured data by own sensors, etc. In fact this is not the case. We have found only data integration, meaning that several devices send their data to one receiving system. E.g., several devices being integrated with a patient monitor, or all devices at the bed side, which includes the patient monitor, are sending their data to a CIS or an EMR system.

Both described topologies for medical device data integration require expensive proprietary hardware and specialized device drivers per to be connected device type and also per revision of that device type. Associating the collected data with the right patient is a project in itself and the solution will differ from customer to customer.

If one thinks standards are the way to solve this dilemma, 30 years of standardization efforts prove the opposite. Even if a medical device manufacturer wants to invest into a better device interface the options are pretty limited. First of all, there is not a single accepted standard for the medical device interface. Second, if the manufacturer goes away from the RS232 interface, the device will be excluded from the integration possibilities of today’s MDDS systems. E.g., utilizing WLAN or LAN will require an own method for patient association. Whatever method is chosen will work only for this device and the others will have other methods, which complicates the workflow at the bed side and usually adds hardware cost in the form of barcode scanners, RFID scanners, etc. Third, the medical device manufacturer will not achieve a higher price for the interface as it will not be transparent to the customer what the additional value shall be, if it appears that it complicates the workflow at the bed side.

The MDDS vendors have no intent to change the game as they are niche market players, and their niche would disappear if really functional medical device interoperability would exist; that wouldn’t require all of the proprietary hardware

and specialized device drivers for data integration. In the cost calculations we have seen that an MDDS vendor can spend 800k$ (in average) for a new EMR interface, whereas a medical device vendor (with 100M€ revenue per year) can spend reasonably only 50k€ for device interfacing in a year. This is because the MDDS vendors support the much bigger EMR/EHR market which is in the US alone 25 B$ per year whereas we calculated the global ICU/OR medical device market to be approx. 4 B€ per year. Assuming that customers would also be willing to spend 5% of the total cost of the EMR purchase to medical device data integration then the MDDS market would be at 1.25 B$ per year in the US. Probably this number is too big, but as we used the same logic to calculate the medical device interface market for the medical device manufacturers (with 200 M€), we see an approximately five times bigger market for MDDS vendors than for medical device manufacturers in the medical device interoperability market segment.

Now looking at the upcoming Population Health Management market, with way higher market expectations than for the EMR/EHR business, and having the same data integration requirements, it becomes clear why all (few) MDDS vendors were acquired end of 2015 by companies targeting products in the Population Health Management market segment.

Finally, comparing the content of chapter “3.6 Considerations for Medical Device Interoperability” with the content of chapter “3.8 Known Issues” it becomes pretty obvious that the 800k$ that are spend on a single EMR device interface, is not well spent money. Looking at the total investment for all EMR interfaces (in the US) it sums up to 521M$ ([WHI13], p. 40). This is a remarkable amount of money, which would be certainly enough to resolve the data interoperability dilemma, if it would not be spend in the wrong place and for the wrong technologies.

4 Literature Research

4.1 Introduction

In this chapter the focus of research shall be on innovation barriers. Though medical device interoperability seems to be in existence today, at least from a very high level view, the question remains why it is so awkward, especially in the light of the exorbitant high price customers have to pay.

Starting with the fundamentals of how an innovation is created, one simple theory is that innovation is triggered by either of two ingredients: “demand pull” or “technology push”. This means that there is either a customer group who wants a solution for a problem, and has money to spend, or there is a new technology that can enable new solutions for a problem or can replace current solutions with a more efficient way to solve a problem. There is a famous quote from Henry Ford which reflects on these two, sometimes disparate, ingredients quite good: “If I had asked people what they wanted, they would have said faster horses.”

The demand pull for functional medical device interoperability is certainly there, but for closed-loop control and bi-directional device communication the pull is weak. For integration of the device data with CIS and EMR systems the pull was strong, especially as for EMR systems (in the US) there was a governmental demand to implement EMR systems.

Hypothesis 1 is that when functional medical device interoperability would be available, it would be the applications that make use of this interoperability that would create the customer pull (see quote from Henry Ford). E.g., if a total intravenous anesthesia (TIVA) could be controlled by the patient monitor, the ventilator, and the infusion/syringe pumps in a closed-loop system, at a reasonable price, customers would want it as it would increase patient safety and relief the anesthetist. Further it would create a strong demand pull for more applications of this type.

Hypothesis 2 is that the needed technology to provide functional medical device interoperability is available, but not yet identified. Going for relevant technology monitoring, will certainly provide insights in possible and affordable solutions and thus provide the needed technology push.

In the following chapters literature research will be performed that is related to these two hypotheses.

4.2 Theory of Innovation

4.2.1 Diffusion of Innovation

Rogers was, amongst other, a researcher of innovation diffusion and wrote the famous book "Diffusion of Innovation" [Rog83] from which the following excerpts are taken. He introduced the today well-known categories for innovation adopters: *innovators, early adopters, early majority, late majority, and laggards*, which define an S-shape curve showing the cumulated adoption rate of an innovation over time. His results are based on studying communication and social system impacts on the success of innovations. The important part of the S-shape curve is between 10 – 25% of adoption rate. If this part of the adoption succeeds, the remaining innovation adoption cannot be stopped anymore. Rogers describes the five *ideal types* of adopters as follows:

Innovators: Venturesome

Innovators are almost obsessed by their venturesomeness. They are willing to take risk, and by their financial status can afford to lose money in case the innovation does not give them what they had expected. Innovators are spread around the globe. They use similar communication patterns and often are friends. They can cope with highly complex technical systems and can handle any uncertainty that exists normally with a new innovation. Even though innovators might not be respected by their social system, they play an important role in it by being the gatekeeper for new ideas flowing into the social system.

Early Adopters: Respectable

The early adopters are more integrated into the social system than the innovators. They build local groups despite the innovators who are cosmopolitans. The early adopters are the people that other people refer to before they are trying something

new. Only if the early adopter has tested it and found it to be usable they will accept it as well. Thus most *opinion leaders* of a social system are found in this group. Basically the early adopters are the ones that take the uncertainty out of a new idea and then are communicating their subjective evaluation results through interpersonal networks.

Early Majority: Deliberate

The early majority is deliberate for some time before accepting new ideas. They communicate regularly and often amongst themselves. They don't want to be the first to try something new, but also not the last, that is why they are in between the group of innovators and of late majority. Opinion leaders are found seldom in this group.

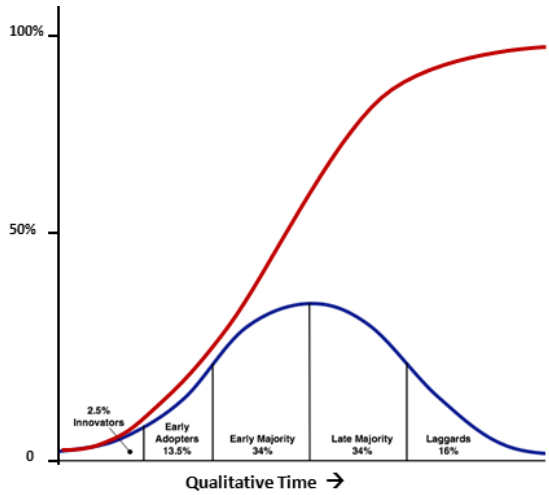


Fig. 21 Adopter categorization and cumulative curve for adaptor distribution ([Rog83], p. 243, 247)

Late Majority: Skeptical

The late majority will adapt only if the pressure is up, e.g. by peers, economic necessity, etc. They are skeptical and cautious and want to be absolutely convinced that they are safe when they adopt the new idea. This is also because they have limited resources and cannot afford failure. It is helpful if the system norms support the adoption of the new idea to convince the late majority.

Laggards: Traditional

Laggards are the last group to adopt innovation. Their decisions are often driven by what was done in past generations. They communicate only within their group and are near isolates in social networks. Often when they adopt an innovation it was already superseded by a new one. As their resources are extremely limited they need to be absolutely sure that the "new idea" will not fail. Instead of looking at the road ahead, the view of laggards is fixed to the rear-view mirror.

Rogers used what he calls the *four main elements* of innovation diffusion for describing the differences of the ideal adopter types above: “Diffusion is the process by which (1) an innovation (2) is communicated through certain channels (3) over time (4) among the members of a social system.” ([Rog83], p. 11).

For a company the biggest question for successful innovation is how the adoption rate can be ramped up quickly. The answer is given by Rogers in Fig. 22.

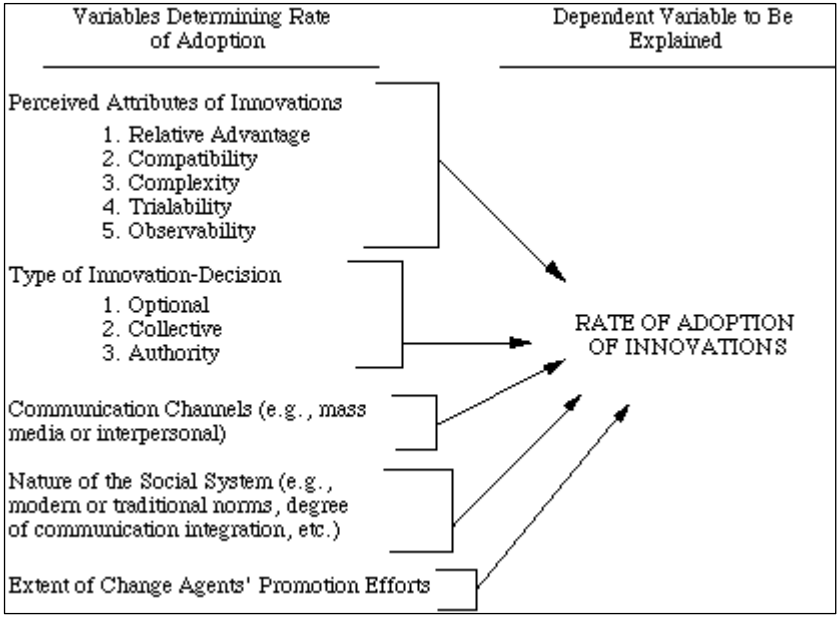


Fig. 22 Variables determining the rate of innovation adoption ([Rog83], p. 233)

Perceived Attributes of Innovations

The perceived attributes of an innovation determine, amongst other, how quickly an innovation will be adopted. Rogers [Rog83] describes five attributes:

1. *Relative Advantage:* Though this is the most influential attribute to the adoption rate it is mainly about perception. If the advantage of the new idea is perceived as better than the idea it supersedes the adoption rate will be high. Advantages could be lower prices, higher social status, convenience, satisfaction, and the like.

2. *Compatibility:* Compatibility of the new idea with current values, past experiences, and needs will increase the adoption rate. An innovation can be compatible or incompatible (1) with sociocultural values and beliefs, (2) with previously introduced ideas, or (3) with client needs for innovations. Though compatibility is important its influence on the adoption rate is not as big as for the *Relative Advantage*. What is also important about compatibility is the name of the innovation and how it is positioned in the market. Market research can be used to find the optimal name and positioning.
3. *Complexity:* If an innovation is difficult to understand and to use, it is perceived as complex. Again it is about perception and only judgements can be made on a complexity-simplicity continuum. In general it can be said that the complexity of an innovation, as perceived by members of a social system, does negatively impact its adoption rate.
4. *Trialability:* The adoption rate of an innovation will be higher if the innovation is available for experiments before purchasing it. This is because the trial will take out uncertainty for the adopter.
5. *Observability:* The degree to which the results of the innovation can be easily observed by others. Especially technology advancements in hardware and software are not easily observable and need a lot of explanation to make them understandable. The more observable the result of the innovation is the higher the adoption rate will be.

These five attributes determine between 49 to 87 percent of the variation in adoption rate. The other variables listed in Fig. 22 do not have such a high impact except the *change agent's* promotion effort. The greatest response to *change agent's* effort occurs when *opinion leaders* are adopting the innovation, which is happening in most systems between 3 and 16 percent adoption rate.

Opinion Leadership

Opinion leaders are individuals who lead in influencing others' opinions about innovations. Opinion leaders cause the typical S-shape of the adoption rate curve, as it is them who activate at the very beginning of the curve the diffusion network in a social system. Characteristics of opinion leaders are:

External Communication: Opinion leaders have access and are accessed by mass media channels. This way they can bring new ideas into their social system.

Further they are more cosmopolite than their followers and have greater change agent contact, which might be reasons for their linkage to the mass media channels.

Accessibility: Opinion leaders must have interpersonal networks with their followers to spread news on innovation, e.g. through meetings of formal organizations or through informal discussions.

Socioeconomic Status: Followers seek opinion leaders that have a higher social status than themselves: "Invention can start from the lowest ranks of the people, but its extension depends upon the existence of some lofty social elevation."[19]

Innovativeness: As opinion leaders are recognized as experts in innovation by their peers it is likely that they are innovators themselves, but they don't need to be. Their expert status will probably induce that they adopt innovations earlier than their followers. This suggests that opinion leaders are more innovative than their followers.

Innovativeness, Opinion Leadership, and System Norms: Here the question is how opinion leaders can be system norm conform and at the same time lead the adoption of new ideas? The answer is that this is dependent on the system norms, if they favor change then opinion leaders are more innovative, if the norms do not favor change then the opinion leaders will be less innovative. In social systems with very traditional norms the opinion leaders and the innovators will be two distinct groups with different social status, where often innovators are faced with disrespect.

Change Agent

A change agent's role is to influence a client's decision on innovation adoption. The direction the change agents have to take is determined by their change agency. The direction could also be to not adopt a certain innovation. Change agents can be teachers, consultants, public health workers, agricultural extension agents, development workers, salespeople, and many others. Change agents have to bridge the social and/or technical chasm between the change agency and the clients. They achieve this by following the sequence of seven steps:

[19] Quoted from [Rog83] p. 282 with reference to Tarde (1903, p. 221)

1. *Develops need for change:* The first step is often to make the client aware of needed changes and then propose alternatives to solve their existing problems. Consultative (sales) skills are helpful here.
2. *Establishes an information-exchange relationship:* This step is about how the change agent is perceived by the customer. Through information exchange trust in the skills of the change agent is built.
3. *Diagnoses their problems:* Analyzes the client's problem in detail and demonstrates why existing alternatives (not the innovation) do not work for solving their problem. The analysis has to be done from looking from the client's side and not just the change agent's side.
4. *Creates intent to change in the client:* Create interest in client for the innovation to solve their problem(s). The focus shall not be centered on the innovation, but being client-centered with a focus on their problems.

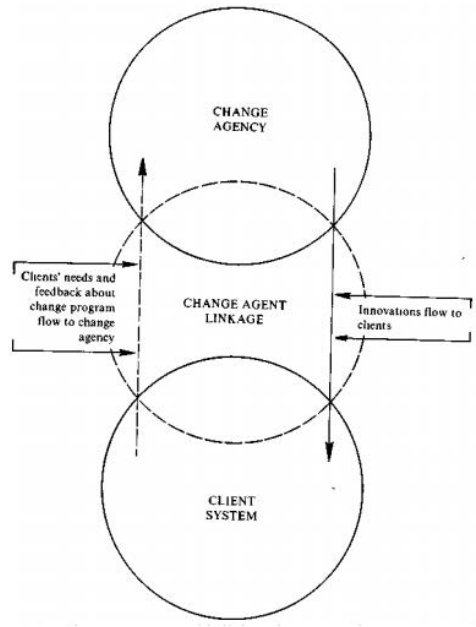


Fig. 23 Change agent linkage ([Rog83], p. 314)

5. *Translates intent into action:* Trying to influence the client based on the client's need. As persuasion is best done indirectly this is the phase to activate peer networks to take influence, e.g. through an opinion leader.
6. *Stabilizes adoption and prevents discontinuances:* Stabilizing the new behavior by reinforcing messages, thus "freezing" the new behavior.
7. *Achieves a terminal relationship:* The goal of this step is to develop a self-renewing behavior with the client, so that they can be their own change agent from now on and don't need to rely any further on the current change agent.

In step 5. we have seen the *opinion leader* to be activated to help to bring the customer to really take action on implementing the innovation. If that step doesn't succeed the client will not adopt the innovation. This is why the *opinion leadership* resides high on the impact scale of variables for innovation adoption, right after the *perceived attributes of innovations*.

Another interesting observation which Rogers made is the Innovativeness-Needs Paradox ([Rog83], p. 263):

Innovativeness-Needs Paradox

The individuals which would most need a new technological innovation, e.g. as it brings economic benefits, are the last ones to adopt. In contrary, the ones who would need it least are the first ones to adopt. Those are the innovators and early adopters who are usually wealthy people. For certain innovations this paradox can even widen the socioeconomic gap in social systems.

In closing the researches on Rogers book "Diffusion of Innovation" here some truth from Machiavelli which is often overseen in creating technology innovations:

"The innovator makes enemies of all those who prospered under the old order, and only luke-warm support is forthcoming from those who would prosper under the new." Niccolo Machiavelli (1513, p. 51), The Prince. ([Rog83], p. 241).

Takeaways: The innovation adoption rate is determined at the very beginning of the S-shape curve. The innovators and the early adopters, and especially the *opinion leaders* amongst them, are driving, or are not driving, the adoption rate depending on their subjective experience with the new idea. If change agents want to be successful in convincing clients of a new idea, they will be more successful if they can engage opinion leaders and their interpersonal network.

But even more important, than the change agent and the opinion leader, are the *perceived attributes of an innovation*. Looking at a technical innovation it needs to have a *relative advantage* compared to the predecessor product which means that it needs to satisfy customer needs that were not addressed before. It needs to be *compatible* with values, experience, and needs of the consumer. E.g.,

introducing an innovation that puts the life of patients in the responsibility of computers is an incompatibility with current experience and values, even though it might satisfy customer needs for increased patient safety and workflow improvements. Perceived *complexity* needs to be reduced with the new idea to achieve a higher adoption rate, which correlates for a technical innovation with the *observability*. The relative advantage and the reduction in complexity need to be easily observable otherwise it will not adopt well. The more explanations are needed to demonstrate the improvements of the new idea, the less it will be adopted. In other words, the relative advantage and reduced complexity should be easily demonstrable, which brings us to *trialability*. Even better than a demonstration is, when customers can try the innovation themselves. This will take out uncertainty, if they experience that it satisfies their need(s), and thus lead to a higher adoption rate.

One *weak point* in this argumentation is the role of opinion leaders. Looking at Machiavelli's quote above, and the characteristics of opinion leaders, it becomes obvious that they might be against certain technical innovation that would question their authority in that field. E.g., we have seen that medical device interoperability, or better medical device data integration, is a highly complex and expensive field to be in, with questionable outcomes. Those who can master this complexity might have higher incomes and a higher social status due to that. Taking now out the complexity of this technical system and sell it at a reasonable price (as it would be easy to install, configure, and use) would question the expert status of the opinion leaders. This might cause that they fire against the innovation, especially if they have a high position in the hospital, or are leading standards organizations, or are working for an MDDS vendor deriving their income from the current complexity, or being a self-employed consultant helping hospitals with the complexity and gaining a certain reputation (and income) based on that. This of course would slow down the adoption rate dramatically or even prevent adoption from happening at all.

4.2.2 Open Innovation

Open Innovation is a topic that when looking at disruptive innovation cannot be ignored anymore. All following explanations are taken from Nedon's dissertation with the title "Open Innovation in R&D Departments" [Ned14]:

Though Chesbrough was not the inventor of open-innovation, he was it who created the term open-innovation in his famous book "Open Innovation: The New Imperative for Creating and Profiting from Technology" published in 2003. He defined open innovation as "… a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as the firms look to advance their technology.".

In the "closed innovation" model R&D is the center point for new innovations.

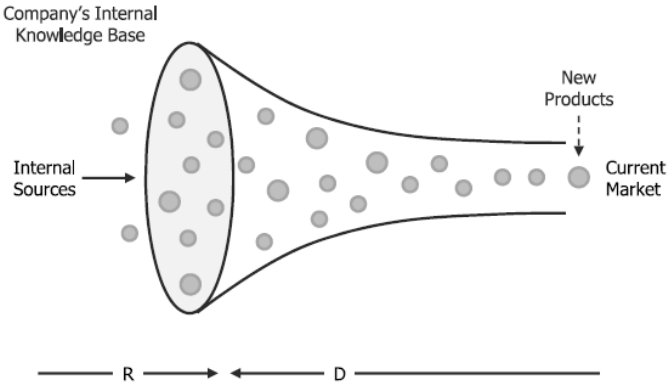


Fig. 24 Closed Innovation Model ([Ned15], p. 8)

R&D does the research, starts the invention, realizes promising ideas, and finally develops products and starts their commercialization. In a vertical integrated R&D process R&D is centralized and all R&D efforts take place solely in-house. This is the conventional way of how R&D worked quite successful for decades and did deliver disruptive innovations, which proved the process to be right. This process created higher revenues and more profit for the company, which in return did allow for bigger R&D budgets and more innovations. Over time this did grow R&D's knowledge base, and R&D was able to protect and control their intellectual property. Finally this led to the conviction that good quality products could come only from internal R&D, which ended in the so called NIH-syndrome. NIH stands for *not invented here*, which means that not only

collaboration with externals is avoided, but even external ideas and innovations are neglected.

Despite the Closed Innovation Model, like illustrated in Fig. 24, the company border in the Open Innovation Model, see Fig. 25, is permeable and allows communication and interaction with its environment throughout the whole innovation process. Not only in-flow of external ideas and knowledge can happen at any point, but also out-flow of ideas and knowledge in the form of spin-offs or licensing out. This way ideas that do not fit the company's business model can also create revenue, or bring in return ideas and knowledge from others, that

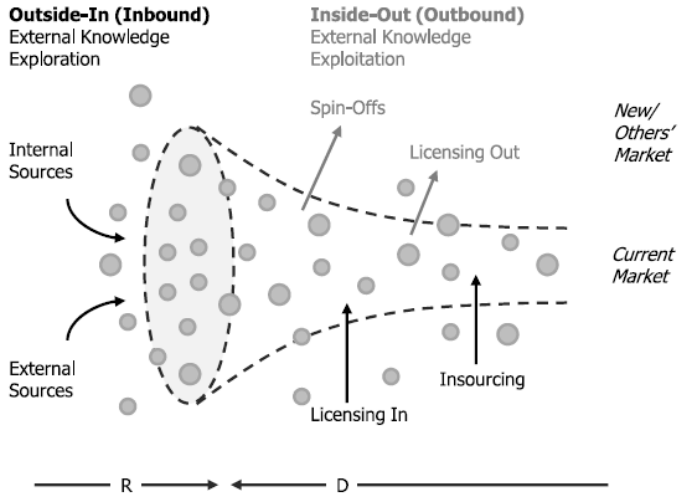


Fig. 25 Open Innovation Model ([Ned15], p. 10)

support the company's business model. The open innovation model assumes that it is impossible for a company to have all required knowledge and expertise in-house. It is rather expected that knowledge and expertise is widely spread and of high quality. Therefore it is mandatory that a company does knowledge exchange with external sources. The difficulty is to figure out the right balance of internal and external activities in the innovation process.

Often internal and external sources are treated as substitutes of each other, which led to "make-or-buy" discussions in the innovation process. However, the open innovation approach treats internal and external sources as equally important and sees them as complementary.

Based on Chesbrough's research, Gassmann and Enkel (2004) introduced three archetypes of innovation processes:

Outside-in (inbound): The knowledge flows from outside in to the company and enters its innovation process. The assumption is that the locus of knowledge can differ from the locus of innovation. External partners can be integrated in the form of co-creation with customers, open-innovation alliances with competitors, collaborations with universities, collaboration with suppliers, and investment in external intellectual property, e.g. in the form of acquisitions or in-licensing.

Inside-out (outbound): In this case knowledge is flowing out of the company's innovation process to the external environment. The assumption is that the locus of invention can be different from the locus of knowledge exploitation. Companies that are doing this want to bring products faster to market by leveraging their ideas and technologies. Additionally profit can be made by licensing or selling IP, and by transferring ideas and technologies to other applications or industries (cross industry innovation). Outbound open innovation is often seen with large companies or research driven companies that want to establish a technological standard, or just want to bring their R&D cost down.

Coupled processes: This is the combination of inbound and outbound processes. It is realized with complimentary partners with which a long term relationship is established. In this relationship it is a give and take between the partners. The aim of such alliances is the establishment of technological standards or a dominant design. However, the partners need to be aware that the development time will not be reduced by these partnerships as the close collaboration needs additional co-ordination efforts.

Nedon's research did prove that the majority of R&D managers see that the advantages of open innovation are bigger than its disadvantages. They did also state that it is important, but also very difficult, to find the right partners. At the end it needs to be considered for each individual project if the advantages outweigh the disadvantages of open innovation, see illustration by Nedon in Fig. 26.

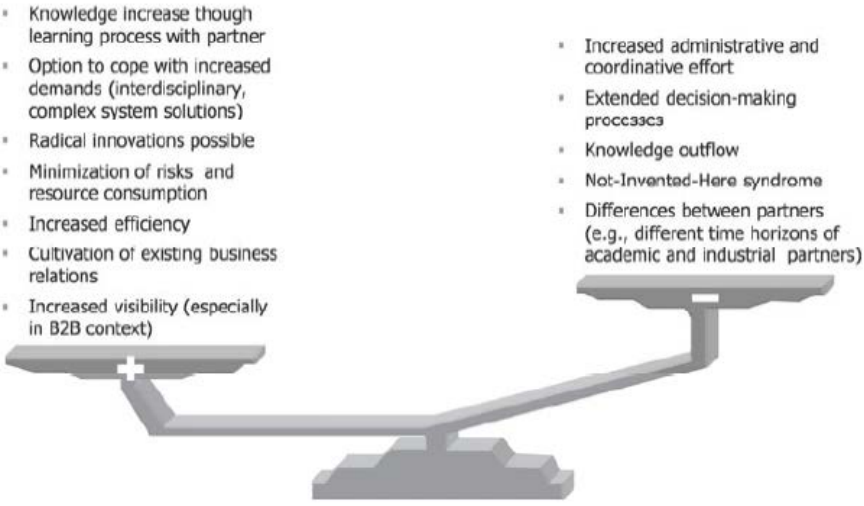


Fig. 26 Advantages and disadvantages of open innovation ([Ned15], p. 100)

In summary open innovation is an important topic to consider for every company regardless of the business it is in. Especially when looking at the workflows in hospitals the goals for optimization and improvement are not so much different than those in other industries. Healthcare in the past was a market segment with high revenue and good profits, and the outlook is still promising, which is why more companies, that had so far nothing to do with healthcare, are turning into this market. On the other side the established companies in healthcare seem to be still suffering a lot from the NIH-syndrome. With open innovation and partnerships with companies from IT and networks, automotive, automation engineering, and other industries certainly new technological standards could be developed and established in clinical healthcare much faster and at lower cost.

4.2.3 Business Model Innovation

New technologies and new ideas are commercialized by companies through their business model. Entering the market with the same technology or idea through two different business models, will yield two different economic outcomes. This is what Chesbrough states in his paper "Business Model Innovation: Opportunities and Barriers" [Che10]. All following is taken from that paper.

It might happen that for a new technology a company has an already established business model for commercialization, or it might have to license a certain technology, because that is the company's business model, or the company might not have an appropriate business model then management needs to expand their perspectives to find an appropriate business model.

Functions of a business model:

- Describes value proposition: value created for the users by the offering.
- Defines market segment and revenue generation mechanism (to whom is the technology useful and for what purpose).
- Describes structure of the value chain to create and distribute the offering.
- Details revenue mechanisms: how will the firm be paid for the offering.
- Estimates cost structure and profit potential.
- Describes position of the company in the value chain compared to suppliers and customers, and identifying potential complementors and competitors.
- Formulates competitive strategy to stay ahead of competition.

Chesbrough postulates: "… companies need to develop the *capability to innovate their business models*, as well as their ideas and technologies".

If companies don't innovate their business models they might miss big chances of additional revenue and profit. E.g., Xerox gave away a lot of new technologies resulting from their fundamental research, as they did not fit Xerox' business model. The may be best known technology, which they gave away, is the Ethernet networking protocol developed by fundamental researchers at Xerox PARC. Xerox gave the technology to a former employee for a one-time payment of 1,000 $. The employee did raise venture capital and founded 3Com in 1979, which was acquired in 2009 by Hewlett-Packard for the sum of 2.7 B$.

Changing or enhancing business models is often not easy as there are *barriers* to it:

One barrier is that in the established business model the cost to manufacture and distribute is optimized for the existing technology and thus its gross margin is often way higher compared to a new disruptive technology. As companies are looking for the most profitable ideas to be commercialized the new disruptive technology will not make it on the list, meaning that it will not be moved forward as no resources will be allocated to it at all.

Another cognitive barrier to business model innovation is that the established business model strongly influences which information is routed to or is filtered out of the corporate decision process. In literature this is also called *"dominant logic"* of how a company creates value and then capitalizes on that value. That means that any information fitting that dominant logic will be seen as important and other information will be ignored, which leads to missed potentially valuable uses of technology.

Chesbrough sees basically three ways out of the dilemma: experimentation, effectuation, and organizational leadership:

Experimentation: In short, the approach is to try out an alternative business model with real customers paying real money in real economic transactions. Though this sounds easy the test set up is quite complex and also on the results (if negative) there is a distinction between "failures" and "mistakes". A failure is a valid test result whereas a mistake indicates a poorly done test set up. It is important to note, that the experiment is based on cumulative learning from (perhaps) a series of failures before finally discovering a new working business model for the new idea or technology.

Effectuation: Effectuation is the opposite of causation, which means that actors, e.g. a company, do not analyze the environment but take action which will create new information to understand possibilities in that environment. So the market is not studied, because there might anyhow not be sufficient data available, but the market is enacted. Based on the effects from the actions taken the dominant logic of the current business model can be reframed.

Organizational leadership: In this process the management is key to experiment and establish the new business model. Question here is who in management could lead the change? Functional managers have not enough responsibility to change business models. In smaller companies the CEOs might be the right

person, but they came to their position by knowing the current business model well and feel comfortable with it. In bigger companies it could be the general managers, but as they usually rotate every 2-3 years the timeframe is too short for making the change. The best possible solution seems to be to build up a second organization that experiments and forms the new business model. The issue here is that two business models will co-exist for a certain time and it is a delicate balancing act knowing when to shift resources towards the new business model.

Takeaways: First, companies need to learn how to innovate business models for their own sake. Second, if the commercialization of a new idea or technology requires a change in business model, and the company is not used to that, it gets difficult. Either the innovation is sold or licensed to the outside, or the idea will not even make it to the decision process (see *"dominant logic"*), or the innovation project is canceled due to its gross margin appearing to be too small (in the current business model), or the company positively acts on it by applying either one of the *experimentation*, *effectuation*, or *organizational leadership* approaches to innovate its business model.

Assuming that most medical device manufacturers are highly specialized companies in their field of expertise, it might be hard for them if not even impossible, to change their business model from developing and distributing "high-tech boxes" to, e.g. the commercialization of data integration solutions that are based on open-innovation and collaboration, and being sold through consulting.

4.3 Technology Trends in Industry

4.3.1 Theory of Computer Networks (Interoperability)

4.3.1.1 Introduction

In chapter 3 "Current State of Medical Device Interoperability" a lot of different needs for interoperability between medical systems and devices were described. For most of the systems the interoperability challenge exists on the semantical level. There are communication protocols available on the syntactical level, but putting all the bits and pieces of, e.g. an EHR document, together in one place, in

a way that the data can be further interpreted by computer software (semantical level), is not a simple task and yet unresolved in a wide area.

However, medical device interoperability has issues already at the physical connectivity level, which is not an issue for a medical systems, like EHR systems, because they are computer based. Thus they can easily use LAN or WLAN to communicate on the physical level. But as we have seen already, LAN or WLAN (alone) would not resolve the issues of medical device interoperability, because it would still lack of certain functions, e.g. the correct patient association.

4.3.1.2 Computer Networks

The book of Tanenbaum and Wetherall with the title “Computer Networks” [Tan11] gives deeper insights into computer interoperability over networks, with a focus on the Open Systems Interconnection model (OSI model), which was standardized under the identification ISO/IEC 7498-1. The OSI model is the reference whenever it comes to interoperability between computer systems. All following is taken from the book of Tanenbaum and Wetherall:

Computer networks are distinguished by their different scales (see Fig. 27):

Personal Area Network (PAN): These are networks that communicate over the range of a person. This could be the peripherals connected to a PC either through cables (wired connection) or without cables (wireless connection) through, e.g. Bluetooth. A PAN can also be an implanted pacemaker that communicates with a user’s remote control.

Local Area Network (LAN): A local area network spans across a single building, e.g. home, office, or factory. The network is private, which means that it cannot be accessed from outside the building. The most common type of a wired LAN is the so called Ethernet which conforms to the IEEE 802.3 standard. If wires are an issue WLAN (Wireless LAN) can be used, which conforms to the IEEE 802.11 standard and is often referred to as WiFi. A special type of LAN is the Virtual LAN (VLAN), which provides logically separated (isolated) networks on the same physical network. If the LAN is owned by a company (or hospital) it is also called *enterprise network.*

Metropolitan Area Network (MAN): MANs are networks that span a city. The best-know MAN network might be the cable television network in a city. Another one, which is less known, is the WiMAX which is the result of developments in high-speed wireless internet access, and which is standardized in IEEE 802.16.

Interprocessor distance	Processors located in same	Example
1 m	Square meter	Personal area network
10 m	Room	Local area network
100 m	Building	
1 km	Campus	
10 km	City	Metropolitan area network
100 km	Country	Wide area network
1000 km	Continent	
10,000 km	Planet	The Internet

Fig. 27 Classification of interconnected processors by scale ([Tan11], p. 18)

Wide Area Network (WAN): A wide area network spans a country or a whole continent. If a company has several offices in a country and in each office a LAN network, the individual LANs can be interconnected through the WAN. One option is to use leased lines from a telephone company, which has the advantage that the data bandwidth is defined and guaranteed. Another option is to use the internet and create a virtual private network (VPN) between the offices. This is a quite flexible solution, as other offices could be connected easily, but the speed of the network is dependent on the network service.

The Internet: If VPNs over the internet are used, the service to connect to the internet needs to be provided by an internet service provider (ISP). This connection does also allow then to connect to other resources in the internet, and not just to the VPN. The networks of all ISPs are connected together which comprises the internetwork or the internet.

4.3.1.3 Open Systems Interconnection (OSI) Model

In the OSI (Open Systems Interconnection) model there are *layers*, *services* and *protocols* defined for connecting open systems (all following is from [Tan11]):

Services: Each layer does provide services for the next layer above it. A service is a set of operations. The lower layer is the service provider and the higher layer is the service user. The services are defined in the standard, but only the operations they provide, and not how those are implemented.

Protocols: The protocol takes care of the governing and meaning of packets that are transmitted between the layers of two peer entities. Protocols are used to implement the service definitions. The protocols can be changed as long as the services, visible to the user, stay the same. This way services and protocols are completely decoupled. Fig. 29 shows an example of how a message, that is to be send from the source entity to the destination entity with the layer 5 protocol, gets fields added on each layer down and then removed again moving on the destination entity the layers up again.

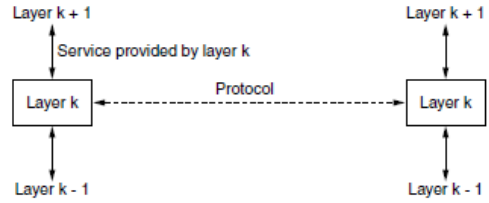


Fig. 28 The relationship between a service and a protocol ([Tan11], p. 41)

Why these additional fields are added in the communication, we see when we look at the ***7 layers*** of the OSI model (see Fig. 30):

The Physical Layer: This layer transmits the raw bits over a communication channel. By design it needs to be ensured that if a 1 is sent that also a 1 is received by the other side. This has mainly to do with electrical signals and timing of them. Also by design it needs to be determined, if the communication can go only in one direction at a time (unidirectional) or in both directions at a time (bidirectional). Further the physical transmission medium needs to be considered which exists below the physical layer.

The Data Link Layer: This layer has to ensure that the raw data is submitted without error. It does this by breaking up the raw data stream into data frames. If the service is reliable the receiver confirms correct receipt of the data frames by replying with an acknowledgement frame. The data link layer needs also to control the speed of transmission in case sender and receiver work at different speeds. The *medium access control* is a sub layer in the data link layer which deals with access to the shared channel in broadcast networks.

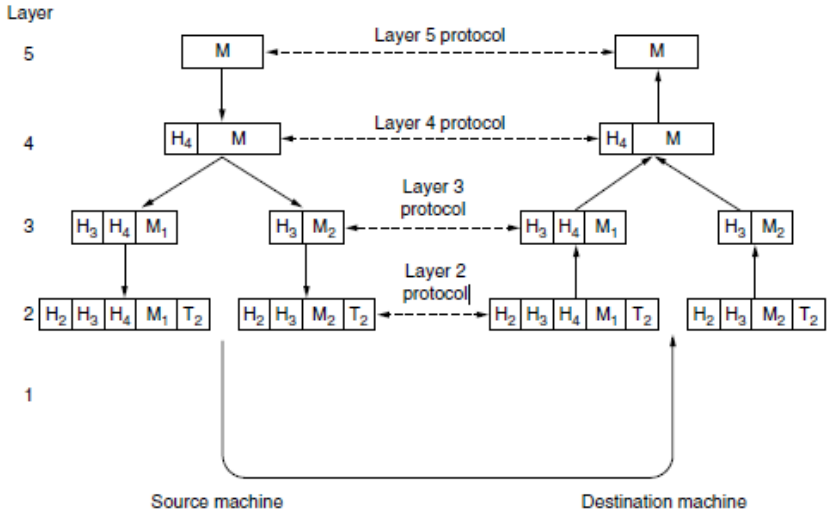


Fig. 29 Example of virtual communication in layer 5 ([Tan11], p. 33)

The Network Layer: This layer controls the subnet. Layer 1 and 2 can send data only within the subnet. On layer 3 (Network Layer) data can also be routed to other subnets. The Network Layer is also responsible for avoiding congestion (bottleneck) and diagnosing the quality of service provided.

The Transport Layer: This layer provides the end-to-end communication between the source and the destination. In the layers below the Transport Layer this is not the case, they just know about their immediate neighbors, whereas the data frames finally might travel through several subnets (across routers). The Transport Layer is also the hardware abstraction layer which ensures that the higher layers do not need to care about the underlying network hardware. And, this layer also determines which type of transport connection is provided to the higher levels, the most common are:

- Error-free point-to-point channel that delivers bytes in the order they were sent
- Connectionless channel that delivers bytes in any order, even duplicates could happen
- Broadcasting messages to multiple destinations

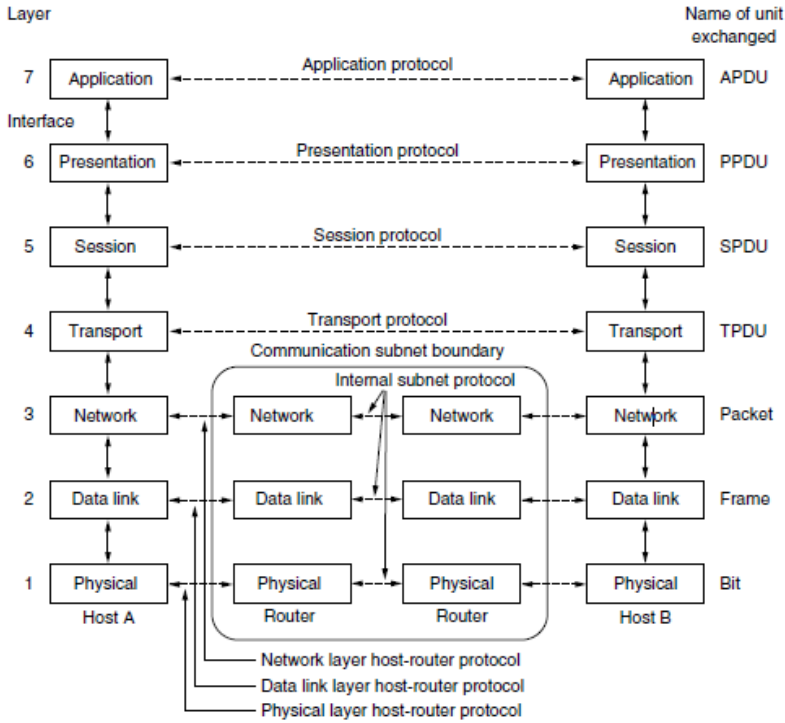


Fig. 30 OSI reference model ([Tan11], p. 42)

The Session Layer: By the help of this layer users on different machines can open sessions between them. The offered session services are: dialog control (who is allowed to send), token management (exclusive access to critical operations), and synchronization (e.g. a long transmission was interrupted, picking it up again where the transmission had stopped).

The Presentation Layer: On this level syntax and semantics of the transmitted information is considered. Here the higher-level data structures (e.g. banking records) are defined and exchanged.

The Application Layer: A variety of protocols exist on the Application Layer that are commonly needed by users. The HTTP (Hyper Text Transfer Protocol) is one

of them and used to access web pages in the World Wide Web. Other protocols are used for email, file transfer, network news, etc.

4.3.1.4 Comparison of OSI and TCP/IP Models

If not noted otherwise, all following is taken from the paper "A Comparative Evaluation of OSI and TCP/IP Models" published by P. Ravali in 2015 [Rav15].

TCP/IP stands for Transmission Control Protocol / Internet Protocol. It is the most widely used protocol in the world, which allows electronic devices (e.g. computers) to communicate across networks, including the internet, with each other. Its origin goes back to the ARPANET which was a research network sponsored by the U.S. Department of Defense (DoD). It did connect hundreds of universities and government institutions through leased telephone lines. The intent was, that when parts of the network should get destroyed, that the current data transmission just takes another route to the recipient, without any interruption. The two main protocols TCP and IP are the ones to ensure that behavior. The TCP protocol builds up a connection between sender and receiver and breaks down the to be send data in smaller data packets. The IP protocol has to send these packets to the right address, where each gateway in the network decides were the packet is sent next. Thus packets take different routes through the network and arrive at different order at the recipient. The TCP protocol puts them back into the right order before passing them on to the next higher layer. Despite the OSI model the TCP/IP model has not 7 but only 4 layers. It might be interesting to know that the TCP/IP model was developed before the OSI model.

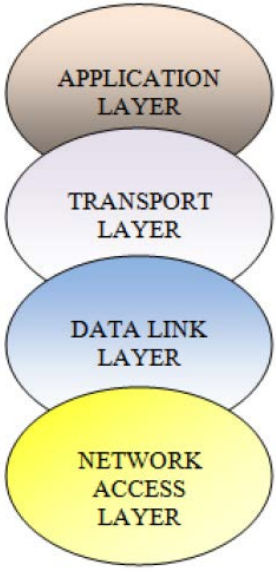


Fig. 31 TCP/IP Layers [Rav15]

Network Access Layer (or Link Layer): This is the lowest layer of the TCP/IP model. It is concerned with how the data is sent physically through the network. It is designed in a way that it is independent of the network access method, frame format, and medium. Thus TCP/IP can work with Ethernet, Token Ring, X.25, Frame Relay, and others. And it can be adapted to new technologies like

Asynchronous Transfer Mode (ATM). The network layer in the TCP/IP model represents the Physical and the Data Link Layer of the OSI model. The network access layer assumes an unreliable service and just puts the TCP/IP packets on the network (or receives them), packet sequencing and acknowledgement is the responsibility of the transport layer.

Internet Layer: This layer ensures that the data packets are routed to their destination, if needed, across multiple networks. Each packet has a source and a destination address. The packets can arrive in any order at the destination. The two main protocols on this layer are the IP (Internet Protocol) and the ICMP (Internet Control Message Protocol) protocols. Also other protocols are available to be used by this layer.

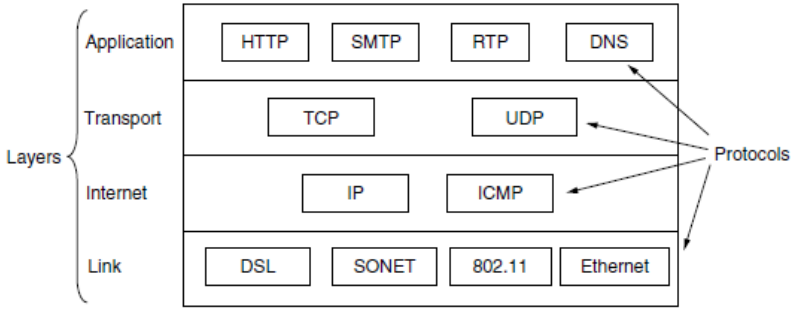


Fig. 32 TCP/IP model with some protocols ([Tan11], p. 48)

Transport Layer: Here the session management between host computers is maintained, by establishing end-to-end (host-to-host) communication. The Transmission Control Protocol (TCP) builds a reliable, connection-oriented transport between two endpoints (sockets) of two computers that want to communicate. Whereas the User Datagram Protocol (UDP) establishes an unreliable, connectionless transport of data, which means that the data packets are just send without any flow control or getting acknowledgements of receipt.

Application Layer: This layer provides the communication to the user through the web-browser, e-mail client, file transfer client, etc. The used protocols on this level are HTTP (Hypertext Transfer Protocol), DNS (Domain Naming System), Telnet, and others. Each communication that uses TCP or UDP requires a pair of IP addresses and a socket port with each IP address, which are handed over to the Transport Layer to maintain the connection.

Comparing the TCP/IP model with the OSI model one can see that the TCP/IP model has 3 layers less than the OSI model (see Fig. 33). Above the TCP/IP Transport Layer, the TCP/IP model assumes that everything else, which is not handled in the lower layers, is taken on by the Application Layer, whereas the OSI model defines a Session Layer and a Presentation Layer between the Transport and the Application Layer. Also the Physical Layer of the OSI model is incorporated in the TCP/IP model into the Link Layer. A reason for the differences is certainly that the TCP/IP model was developed before the OSI model, and was not intended to be a reference model for other network communication.

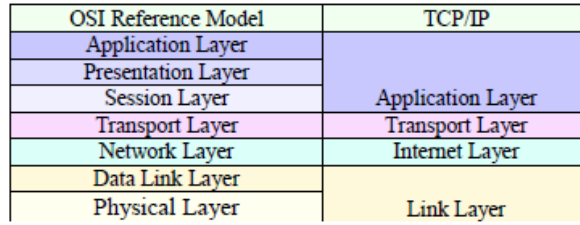


Fig. 33 OSI and TCP/IP model [Rav15]

Interesting to note is that the OSI model, when printed and stacked up, gives close to a meter of paper. The standard is extraordinarily complex, which led to unsuccessful implementations, and OSI became associated with “poor quality”. Even though OSI does not really have implementations, it did stay the “one” reference model for all network communications development ([Tan11], pp. 52).

4.3.1.5 Comparison of OSI Model and IEEE 11073 Standard

Coming back to the paper of Schrenker and Cooper on Medical Device Plug-and-Play Interoperability [Schr01], it does include a comparison of the IEEE 11073 (at that time being the IEEE 1073) with the OSI reference model, see Fig. 34.

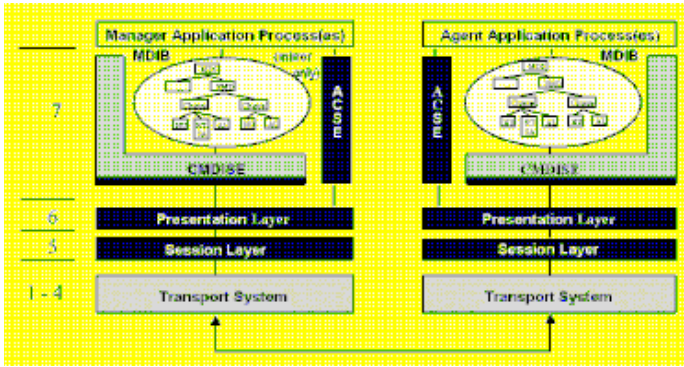


Fig. 34 Medical Interface Bus and OSI layers (modified from [Schr01], p. 7)

OSI layers 1-4 are represented in the Medical Interface Bus (MIB) standard as the “Transport System”. The layers 5 and 6 of the OSI model (Session and Presentation) are very thin: “The choice of seven layers was more political than technical, and two of the layers (session and presentation) are nearly empty, whereas two other ones (data link and network) are overfull.” ([Tan11], p. 52). From the description of those two layers given in the paper of Schrenker and Cooper [Schr01] it appears that the layers 5 and 6 in the MIB standard are even thinner than in the OSI model, which might raise the question if they exist it all. The majority of the MIB standard is represented in the Application Layer of the OSI model, where one can put everything which isn’t covered by the lower layers.

When looking next at the master thesis of Hofman with the subject “Modeling Medical Devices for Plug-and-Play Interoperability” [Hof07], one can see a similar picture when the IEEE 11073 standard is compared with the OSI model, see Fig. 35.

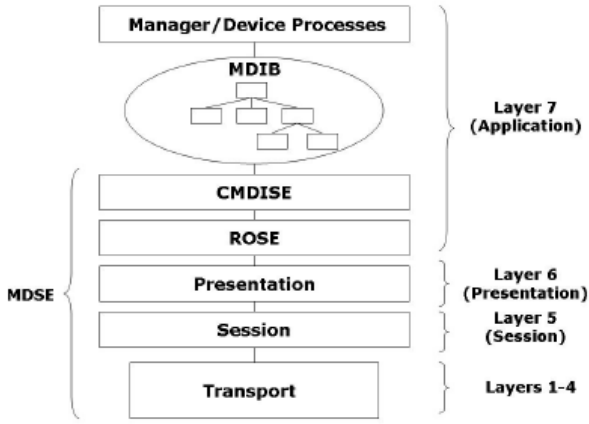


Fig. 35 IEEE 11073 standard and OSI layers ([Hof07], p. 76)

The Transport Layer of IEEE 11073 corresponds as well with the OSI model layers 1-4 and also the description of the Session Layer and the Presentation Layer in the IEEE 11073 standard is represented as very thin. When it comes to the Application Layer, again a very lengthy description is given, which is outlining the major parts of the IEEE 11073 standard.

As in both papers the Transport Layer of the IEEE 11073 standard spans the lower four layers of the OSI model, and is only separated by a very thin Session and Presentation Layer from the Application Layer, it is very questionable if the OSI model was taken as a reference for the design of the IEEE 11073 standard. Its design looks more like two monolithic blocks, one for transport of data and one for the application. May be this monolithic design is also contributing to the regularly mentioned complexity of the IEEE 11073 standard, which seems not really well structured or in line with any existing design reference model.

4.3.1.6 Internet of Things (IoT) Technologies by OSI and TCP/IP Layers

The Internet of Things (IoT) will be covered in more detail in chapter "4.3.3.3 Internet of Things (IoT)". In this chapter it is about technologies that exist in the area of IoT, and in which layer of a reference model they can be found.

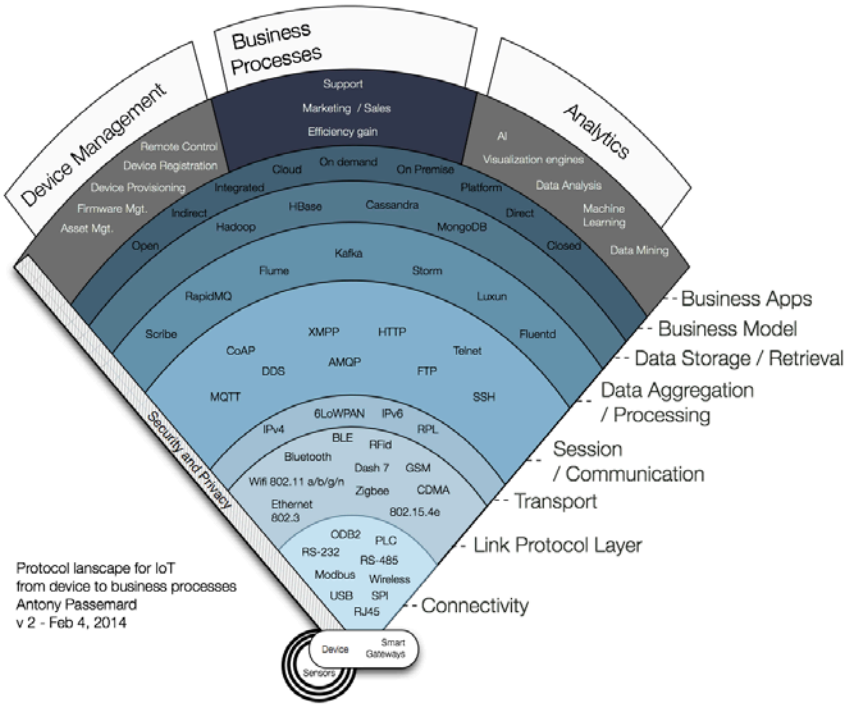


Fig. 36 IoT technologies and OSI layers (and other layers) [Web12]

In Fig. 36 [Web12] the four lower layers of the model compare well to the OSI and TCP/IP reference models, with the lowest layer being the Physical Layer, above it the Link Protocol Layer, then the Transport Layer, and one higher the

Session (Communication) Layer. Here the differences to the respective reference models are not that important, as anyhow the technologies shown in these layers might span more than just one layer. It is to get an idea of how many technologies exist in the field of IoT, because when talking or reading about IoT it might sound like the IoT would be as well defined as, e.g. the OSI reference model, which is not the case. As there are trillions of dollars of market size predicted for the IoT, at which we will have a look in a later chapter, everyone wants to be the first with new IoT products. As no standard exists, either already available technologies are taken, or new ones are invented, which keeps the number of technologies growing.

The upper four layers shown in Fig. 36 [Web12] are correlating with the Application Layer in the OSI and TCP/IP models. Interesting in that figure is also the split in Device Management, Business Processes, and Analytics for the whole field of IoT.

The protocols listed in the lower four layers of Fig. 36 [Web12] are not intended to be an exhaustive list, but it shows the most commonly used protocols and technologies in the area of the Internet of Things, which are quite a lot.

4.3.1.7 Summary

In this chapter we looked at the theory of computer communication (interoperability) and its main standard the OSI reference model. The OSI model was then compared to the most widely used communication protocol TCP/IP and to the IEEE 11073 (Medical Interface Bus) standard.

It can be seen that in the OSI model the strength is on *services* whereas in the TCP/IP model it is on *protocols*, with the TCP/IP model being the truly successful model.

For the IEEE 11073 standard we observed that it does not really compare well with any of the two reference models, which might be one of the reasons for its complexity and thus avoidance by the medical device industry.

It can be concluded that for any design of interoperability mechanisms, it is very important for its later success, that *layers, services,* and *protocols* are well defined. In the TCP/IP model even on the Application Layer many different protocols for maintaining sessions between computers exist. Further we have seen that in the field of IoT on the lower four layers, which are the most

important for interoperability, an awful lot of technologies exist (each one with its advantages and its disadvantages) which makes the choice for the “right one” not a simple task.

4.3.2 Aspects of Real-Time Systems

4.3.2.1 Introduction

The slide seen in Fig. 37 is from a slide deck created by GE (General Electric) Healthcare and RTI (Real-Time Innovations) company. The topic of the slide deck is about real-time requirements in the Industrial Internet of Things (IIoT), to which we will come in a later chapter. The picture shows a medical device

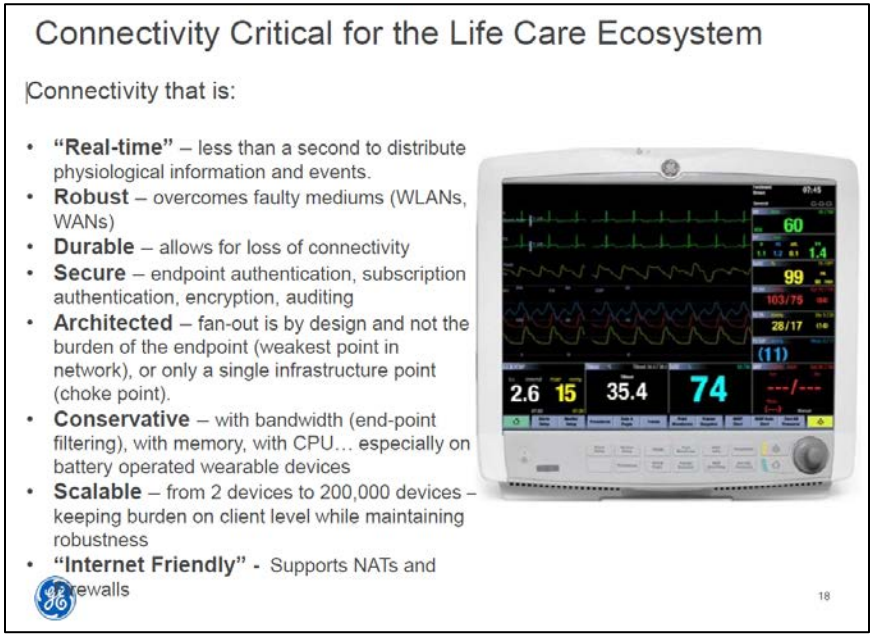


Fig. 37 Real-time requirements in medical device connectivity ([GE15], p. 18)

(patient monitor) that is used in ICU and OR. The first bullet on the list says “’Real-time’ – less than a second to distribute physiological information and events.”. This is especially relevant for alarms that are also annunciated at a central station or at other patient monitors, see chapter “3.3.2 Topology for Integration with Patient Monitors”.

As ‘real-time’ is an important requirement for medical devices in the ICU and OR, and is somewhat contradictory to the requirement “(1) Wireless

communication ([F&S15b], p. 21-24)" like outlined in chapter "3.6 Considerations for Medical Device Interoperability", we will have a closer look at the aspects of 'real-time' in this chapter.

4.3.2.2 Definition of Real-Time Systems

"Real-time systems have wide-spread use in industrial, commercial, and military applications. These system are often complex because they have to deal with multiple independent streams of input events. These events have arrival rates that are often unpredictable, although they must be responded to within predefined timing constraints.", this is how Gomaa ([Gom89], p. 1) summarizes what real-time systems are.

Definition of 'real-time' system as stated by Witzak: "A real-time system is said to be time-deterministic, if for each possible state at the input the reaction time of the system can be predicted within fixed time limits." (translated from [Wit00], p. 28).

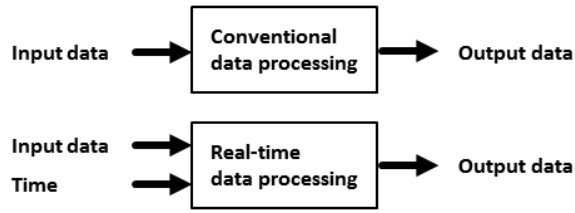


Fig. 38 Time as additional input for real-time systems ([Wit00], p. 27)

The other important attribute of real-systems, despite time, is the multiple independent input streams of input events. This can be seen quite good in the "subsumption architecture" defined by Brooks [Bro89] in 1989. The subsumption architecture is the predecessor of real-time operating systems, and changed the way how autonomous robots were programmed until that time. Without going deeper into the subsumption architecture, it can be seen in Fig. 39 that the independ-

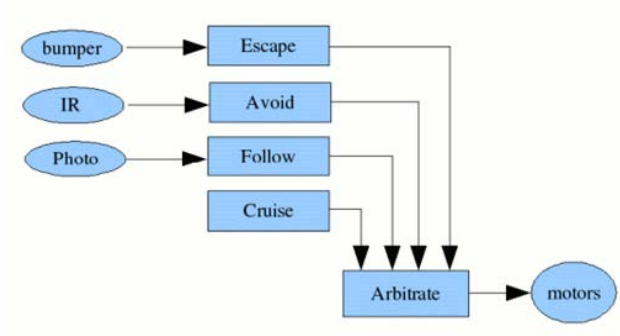


Fig. 39 Subsumption Architecture as defined by Brooks [Bro89]

ent levels of behavior (of a robot) called Escape, Avoid, Follow, and Cruise are all triggered by different sensors, except Cruise, which are Bumper, IR, and Photo. Bumper stands for a mechanical detection of a collision, IR can detect any obstruction, which is in the way of the robot, by infrared signals, and Photo are photosensitive sensors that can detect light shining from a certain side to the robot. These three sensors provide multiple input events that are streamed, in the worst case all at the same time, to the real-time system. Now the arbitration logic needs to master the incoming data streams, and their respective behaviors, and activate the effectors respectively (which are the motors of the robot in this example).

In the subsumption architecture we can identify the third important point of real-time systems (despite dealing with time and multiple event inputs), which is that real-time systems use sensors to follow movements in the physical world by activating their effectors accordingly [Ill91].

Finally, the fourth important difference to other data processing systems is: “Real-time systems are frequently classified as ‘hard real-time systems’ or ‘soft real-time systems’” [Gom89]. This means that for hard real-time systems the

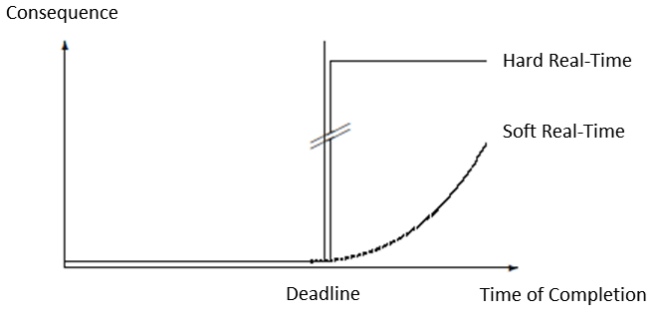


Fig. 40 Hard real-time vs. soft real-time ([Ben09], p. 4)

consequences will be fatal, e.g. death, if the deadline is missed, whereas for soft real-time systems the consequences are moderate, when a deadline is missed. But, despite non-real-time-systems, the consequences for the soft real-time systems also escalate the longer the deadline is missed, see Fig. 40.

4.3.2.3 Characteristics of Real-Time Systems

According to Gomaa real-time systems have the following characteristics ([Gom89], p. 5):

Embedded Systems: Often real-time systems are embedded systems, which means that they are part of a larger hard- or software system. E.g. a computerized automobile cruise system is embedded in the automobile.

Interaction with External Environment: Typically a real-time system interacts with its external environment, e.g. manufacturing processes, monitoring chemical processes, etc. With sensors the external environment is observed and with actuators (effectors) the external environment can be controlled. Actuators can also be displays that report observations to a user.

Real-time Constraints: Events must be processed within a certain time, which can be milliseconds, seconds, or even minutes depending on the application. However, in any case, if the deadline is missed the result might be catastrophic, e.g. for an air traffic control system, missing the deadline, it could mean that two aircrafts collide.

Real-time Control: That means that the real-time systems make control decisions, based on its sensors inputs, without human intervention, e.g. an automobile cruise control system that adjusts the throttle.

Reactive System: The real-time system reacts on external stimulus observed by its sensors. However the reaction often is state driven, which means that previous stimuli or reactions are taken into consideration for the final reaction.

Concurrent Processing: As external events can and will happen in parallel, with random (asynchronous) patterns, the real-time system needs to able to process these events in parallel and being able to handle different input loads.

4.3.2.4 Real-Time Operating Systems

When a real-time system has to deal with many asynchronous events and needs to fulfill hard real-time requirements, it’s usually best to make use of a real-time operating system. Here are three examples of real-time operating systems (RTOS):

FreeRTOS: FreeRTOS is a popular RTOS that is used by hobbyists and students as well as professionals. It is used in embedded systems and has ports available

for many microprocessors. It is very simple, has low memory requirements, low overhead, and executes fast. Only the functions that are used by the application will be added to the binary file at compilation time. More information can be found at: freertos.org

VxWorks: VxWorks from Wind River (owned by Intel) has with 30 years probably the longest history in RTOS systems. Wind River claims that VxWorks is the industry's leading operating system for embedded devices with more than 2 billion installs. For example, NASA trusted VxWorks to control the $2.5B Mars Curiosity rover and land it perfectly on a planet 352 million miles away. VxWorks supports 32-bit, 64-bit, and multi-core silicon architectures, including ARM®, PowerPC®, and Intel®, and offers in addition to the "standard" RTOS features options for safety, security, and virtualization. More information can be found at: windriver.com

Xenomai: Xenomai is complementing a Linux kernel to make it a hard real-time operating system. The focus of Xenomai is on embedded systems. One intention of Xenomai is that real-time applications running on proprietary real-time operating systems can be migrated to Linux. More information can be found at: xenomai.org

4.3.2.5 Real-Time Communication

According to Benra and Halang ([Ben11], pp. 101) communication protocols that have real-time requirements also take the 7-layer OSI model as their reference, see chapter "4.3.1.3 Open Systems Interconnection (OSI) Model". As the OSI model das not foresee any services for keeping deadlines, like required by real-time systems, not a single layer is responsible for the real-time behavior, but all layers working together.

That is the reason why layers were removed from the design, when it comes to "small" and fast communication protocols. The Manufacturing Automation Protocol (MAP)

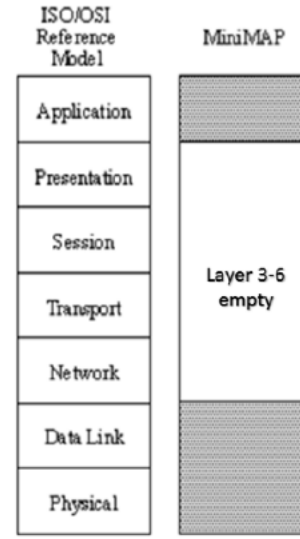


Fig. 41 OSI and Mini-MAP layers ([Ben11], p. 102)

that was released in 1982 by GE (General Electric) has a modified version that was trimmed for real-time communication, called Mini-MAP. End of the 1980s there was the question how many layers a real-time communication protocol would need. The result is seen in Fig. 41. Only the Physical and the Data Link Layer did remain from the lower layers of the OSI model, and on top of the OSI Model the Application Layer.

4.3.2.6 Summary

Often embedded systems are confused with real-time systems. Though most real-time systems are embedded systems, only 10-15% of the embedded systems have any real-time requirements, and approximately half of those have hard real-time requirements [Wei01], see Fig. 42. All others have either soft real-time requirements or no real-time requirements at all. The existence of this confusion demonstrates that even amongst engineers real-time systems are not well known.

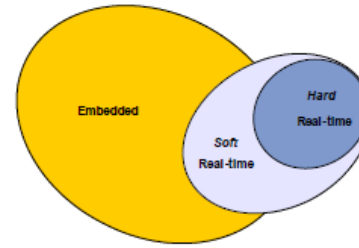


Fig. 42 Embedded vs. real-time systems [Wei01]

Due to not knowing the definition and characteristics of real-time systems it is hard to identify during a products design phase, if it has hard real-time requirements. Knowing that, would change the design of the system dramatically and might often lead to the use of a real-time operating system. Not acknowledging this, might still lead to a fast system, but not to a deterministic system that does meet the deadlines all the time and thus avoiding catastrophic consequences. Medical devices in the ICU and OR, that are used to monitor the patient's condition or are even therapeutic devices, all have hard real-time requirements in their application as well as in their communication interface. Basically none of the existing external medical device interfaces, of the past 30 years, does acknowledge this.

4.3.3 Industry 4.0 and Internet of Things (IoT)

4.3.3.1 Introduction

Industry 4.0 is pushed by the German government as part of a bigger governmental innovation program (high-tech strategy). Its intent is to start the 4th industrial revolution, after the 1st one started with the industrial use of the steam-engine, the 2nd one with the introduction of assembly lines in manufacturing, and the 3rd one being the digital revolution that brought the PLC (programmable logic controller) to manufacturing machines.

Here a nice overview taken from the article "Industry 4.0 – no hype, no revolution, but a strong force" [Jam14]: At latest in 2013 at the Hannover trade fair the term Industry 4.0 became well known when the German Chancellor Merkel stated in her opening speech, that the current fusion of different technologies from IT, data processing, and industrial manufacturing will lead to an innovation leap comparable to the invention of the steam-engine.

There are a lot of other terms around which more or less belong to Industry 4.0, like Ubiquitous Computing, M2M communication, Internet of Things, and Cyber-Physical Systems. Cyber-Physical Systems (CBS) are systems that enrich the interactions between physical and virtual worlds in the areas of sensor-based autonomous systems like robots, vehicles, airplanes, and medical monitors, to name a view. Industry 4.0 can be seen as one instance of the gross of cyber-physical systems, being the logical evolution of the Computer Integrated Manufacturing (CIM).

In the book "Business Models in Industry 4.0 and the Internet of Things" [Kau15] the author gives an example of an Industry 4.0 Cyber-Physical System. In that example the buyer of a new car wants a seat that is 20cm lower than the standard seat of the ordered car. This is a change for which no construction design exists. The systems of the car manufacturer would now talk to the systems of the seat manufacturer and the systems of the airbag manufacturer to see if that constructional change is possible at all. If yes, it would also calculate the price for that change and, if reasonable, would make the changes to this one car. This is what a cyber-physical system could do, at the extreme.

4.3.3.2 Industry 4.0 and Industrial Internet Consortium (IIC)

According to the German "Manager Magazin" [Web13] the German government wanted to wake up the German industry to not miss the 4th industrial revolution. That's why the "Plattform Industrie 4.0" was founded as a pure German organization by the German government. However, after two years of talking and not moving forward in the "Plattform Industrie 4.0" CEOs of German companies became nervous and joined the global acting Industrial Internet Consortium (IIC) in the US. Officially the IIC and the German Industry 4.0 organizations work together, but the real progress is clearly coming from the IIC.

"The Industrial Internet Consortium was founded in March 2014 to bring together the organizations and technologies necessary to accelerate the growth of the Industrial Internet by identifying, assembling and promoting best practices. Membership includes small and large technology innovators, vertical market leaders, researchers, universities and government organizations."[20]

Though there are a lot of terms for the same things around for the 4th industrial revolution, there seems to be agreement on the following components of the industrial internet ([Kau15], pp. 5):

Intelligent Machine: Objects, devices, machines, or systems are made smart/intelligent by adding sensors, actuators, software and a unique identity to them. All data they produce is handed on by M2M communication.

Machine-to-Machine (M2M): This is the general name for the communication between machines and also for the communication between machine and IT-system.

Internet of Things: Broadly spoken all the intelligent machines are connected to the Internet of Things which monitors and controls them. The Internet of Things is based on a global network infrastructure.

Big Data and Smart Data: Understanding that there can be millions or even billions of intelligent devices connected to the Internet of Things, and each one sending data at second or minute interval, this will be large amounts of data, which led to the term Big Data. Before any application makes decisions or proposals on this data, it is preprocessed by filters or algorithms to find or

[20] http://www.iiconsortium.org/about-us.htm

assemble data that is meaningful for the application. This will be only a fraction of the Big Data, and is called *Smart Data*.

Machine Learning: With 'machine' not the intelligent machines from above are meant, but software applications in the Internet of Things, which can learn new algorithms from analyzing data.

Augmented Reality: Reality is overlaid with data in the context of the observed situation. Google glass is probably the best known tool to achieve that. E.g. a repair technician wearing Google glass and looking at the to be repaired machine, would immediately get the technical documentation and frequent errors to show up in Google glass.

Fig. 43 End-to-End Industrial Internet of Things (Source www.rti.com)

Fig. 43 shows the different levels (called data bus) at which applications can reside, which make use of *Smart Data* to, e.g. control intelligent devices. The applications can be down at the machine/device level or on the highest level in the cloud.

Looking at the technologies used in the Industrial Internet nothing is really new, but the concept of how they work together in the Industrial Internet is new ([Kau15], p. 7).

This raises the question where the challenges reside that the IIC and Industry 4.0 organizations are trying to resolve. Fig. 44[21] shows the answers when professionals were asked to identify the biggest challenge when facing the Industrial Internet. 77% said: Interoperability, whereas only 3% said: Connectivity. This sounds quite familiar, as we have seen in chapter "3.3.2 Topology for Integration with Patient Monitors " how medical devices at a bedside in the ICU or in the OR can be 'integrated' with the patient monitor, which is meant here with 'connectivity', but the integration does not provide interoperability, like defined by HIMSS and outlined in chapter "3.1 Definition of Medical Device Interoperability".

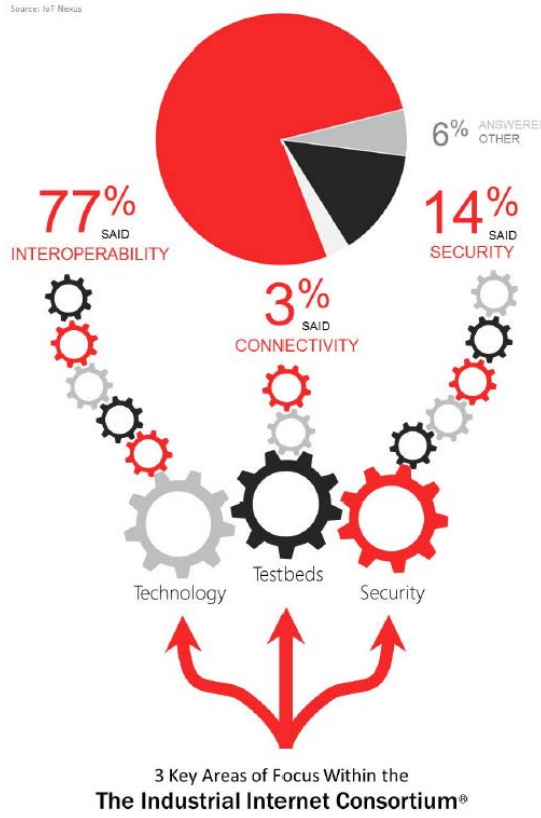


Fig. 44 Biggest challenge in facing the Industrial Internet

4.3.3.3 Internet of Things (IoT)

In chapter "4.3.3.2 Industry 4.0 and Industrial Internet Consortium (IIC)" the focus was on the Industrial Internet. In this chapter the focus will be on the 'things' in the Internet of Things, or in the context of the Industrial Internet, also called the Industrial Internet of Things (IIoT).

[21] http://www.iiconsortium.org/about-us.htm

This is how ‘things’ can be defined: “For purposes of this paper, the terms “Internet of Things” and “IOT” refer broadly to the extension of network connectivity and computing capability to objects, devices, sensors, and items not ordinarily considered to be computers.” ([Ros15], p. 17).

In Fig. 43 the ‘things’ are on the ‘intelligent machine’ machine level, e.g. a medical device. On the machine level different communication models for device interoperability can be present. Four of these are outlined in the paper “The Internet of Things: An Overview” [Ros15] from the Internet Society. These communication models are from a guiding architectural document for networking of smart objects (RFC 7452) released by the Internet Architecture Board (IAB) in March 2015 ([Ros15], pp. 18). In Fig. 45 graphical representations of the four communication models are shown.

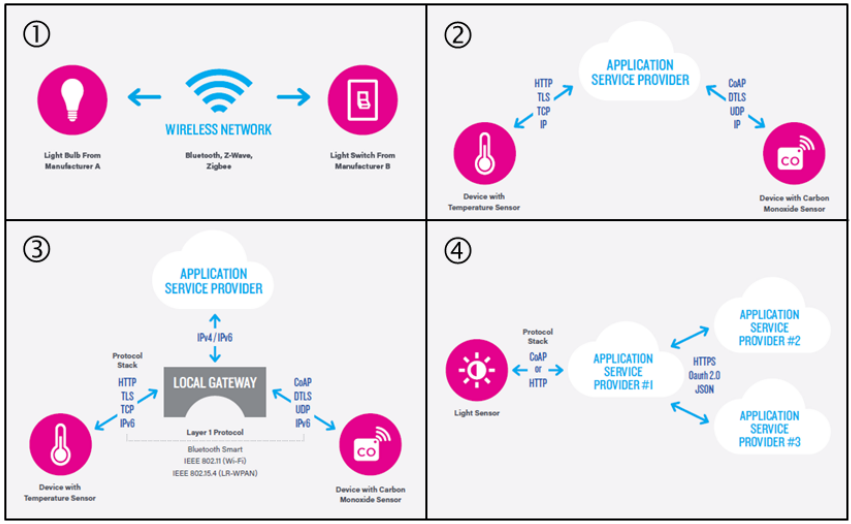


Fig. 45 Internet of Things Communication Models ([Ros15], pp. 18)

1) Device-to-Device Communication: In this model two or more devices connect and communicate directly with each other. They can use many types of networks, like IP networks or the internet. Often they use protocols like Bluetooth, Z-Wave, or ZigBee for their direct communication model. This model is found in home automation and connects light bulbs, light switches, thermostats, and door locks. As the protocols used are often not compatible from manufacturer to manufacturer only certain product families, i.e. from one manufacturer, will work together in home automation.

2) Device-to-Cloud Communication: In this case the device interacts directly with an application service provider through the internet. To connect to the internet, usually already existing wired Ethernet or WiFi-connections are used that have access to the internet through an Internet Service Provider (ISP). An example is the Samsung Smart TV, which sends information to its internet application analyzing what the user has viewed and also provides the voice recognition to control the TV for voice commands. The issue here, not looking at data privacy issues, is that the provided features work only for TVs and applications of the same vendor, which is commonly referred to as "vendor-lock-in".

3) Device-to-Gateway Model: The device-to-gateway model, or often called device-to-application-layer gateway (ALG) model, allows the device to reach a cloud service. This model is used when protocol translations are needed to access the cloud service and also to bridge any interoperability gaps between the devices themselves. An example for the protocol translation need is Bluetooth devices that use smart phones as gateways to the cloud service in the internet, as they themselves cannot access the internet. Acting not only as a protocol translator but also as a hub for interoperability amongst the connected devices is, e.g. the SmartThings hub, which is interoperable with ZigBee and Z-Wave devices and connects them to the internet. The SmartThings cloud service allows then to control these devices through a smart phone or another internet connection. The evolution of this type of gateways and their larger role in addressing interoperability issues amongst IoT devices is still unfolding.

4) Back-End Data-Sharing Model: This approach is an extension to the single device-to-cloud communication model. Here a cloud service can analyze data that was acquired by other cloud services, thus having a bigger data sample to control the devices or derive decisions from the data. E.g. if on a premise IoT sensors from different vendors collect data on energy consumption, temperature, etc. this would cause the above described vendor-lock-in, unless another cloud service would take that data and combine it for further cross-vendor analysis and decision making.

Comparing above described communication models with the medical device interoperability issue, it can be seen that the device-to-application-layer gateway (ALG) is not only the translator to communicate with the services in the cloud, but also the "hub" that deals with interoperability issues of the devices themselves. Further we have seen in chapter "4.3.3.2 Industry 4.0 and Industrial Internet Consortium (IIC)" that filter or algorithms have to create *Smart Data* out of *Big Data*. Rather than doing this in the cloud this could of course happen, to a certain degree, already on such an ALG gateway.

4.3.3.4 IoT Communication Technologies and Protocols

In chapter "3.6 Considerations for Medical Device Interoperability" we have seen the need for wireless medical device interoperability. Although new technologies were not yet developed for the Internet of Things, we will have a look at available wireless technologies that can be used for device interoperability in the IoT. The most prominent are:

- *Wireless LAN (WLAN)* consists of Access Points (AP) to which devices can connect and then use the broadband connection to surf the Internet. The architecture of the IEEE 802.11a/b/g/n (WLAN) standard allows the stations mobility within the BSS (basic service set) cell, provided by an Access Point, which is transparent for the upper layers of the protocol. The nominal range of a WLAN is 100m, its max. signal rate at 300 Mb/s, and the frequency bands are either 2.4 GHz or 5 GHz [Lee15]. Issues with WLAN interfaces for a device or sensor in the Internet of Things are its high power consumption of up to 500mA and the long time it needs to connect and authenticate with an Access Point which can be between 200ms and 1s. The advantage of WLAN is that it is basically available everywhere ([And15], p. 21).
- *Bluetooth*, also known as the IEEE 802.15.1 standard, was initially designed to replace the cable of computer peripherals, e.g. mice, keyboards, printer, etc. It is a short-range radio, thus good for use in wireless personal area networks (WPAN). For a description of a PAN network, see chapter "4.3.1.2 Computer Networks". There are two connectivity topologies defined in in Bluetooth: the piconet and the scatternet. The piconet is formed by one master and several slave devices. Slave devices can only communicate in a

point-to-point fashion with their master device. A scatternet is a collection of piconets that overlap in time and space. The nominal range of Bluetooth is 10m, the max. signal rate at 1 Mb/s, and the used frequency band is at 2.4 GHz [Lee07]. The disadvantages of Bluetooth are that it was originally designed for the use with computers and phones with no special design considerations for being used with sensors and devices in an industrial environment, and no routing, e.g. to the internet, is foreseen ([And15], p. 21).

- *ZigBee* as defined in the IEEE 802.15.4 standard offers a low-rate wireless personal area network (LR-WPAN). ZigBee provides self-organized, multi-hop, and reliable mesh networking with long battery lifetime. The nominal range of ZigBee is 10m, the max. signal rate at 250 Kb/s, and the used frequency band is at 0.3/0.6 MHz and 2 MHz [Lee07]. Advantage of ZigBee is its mesh net functionality that allows data to hop from node to node in the network and does not require any central access points or routers. Its low power consumption is another advantage. The low data rate of ZigBee can be seen as a disadvantage, depending on the application ([And15], pp. 21).
- *Ultra-Wide Band (UWB)* offers indoor short-range high-speed communication. It is standardized in IEEE 802.15.3. Data rates are higher than 110 Mbps (up to 480 Mbps). This satisfies multimedia needs, which

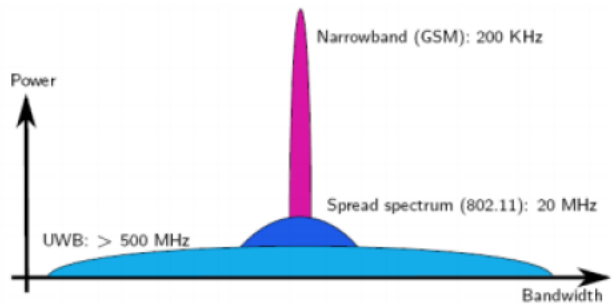


Fig. 46 UWB Bandwidth and Power (Source uwb.epfl.ch)

means that video and audio delivery can be handled. The nominal range of UWB is 10m, the max. signal rate at 110 Mb/s, and the used frequency band is 3.1-10.6 GHz [Lee07]. Advantages of UWB are its low cost, low complexity (no mixers, filters, amplifiers, and local oscillators required),

ultrawide frequency bandwidth allows for very high data rate, works through lossy opaque media, immune from multipaths, extremely low power transmission thus no interference with other systems, and low probability of detection and interception due to its noise-like signal ([Ra08], pp. 5).

- *6LoWPAN* is like ZigBee implemented on the lower layers (physical and data link layer of the OSI model, see chapter "4.3.1.3 Open Systems Interconnection (OSI) Model") provided by the IEEE 802.15.4 standard. The name 6LoWPAN stands for IPv6 Low Power Wireless Personal Area Network. IPv6 is the new version of IP addressing in the internet, which allows for a unique IP address for each device globally, which is not the case with the predecessor version IPv4, which is still mostly in use today, see chapter "4.3.1.3 Open Systems Interconnection (OSI) Model" for IP addressing. 6LoWPAN is basically the embedded internet for use with small devices and sensors in the Internet of Things. The concept of 6LoWPAN is to take the advantages that are given by IP networks, e.g. that they are well known since decades, all documentation is public, tools for managing IP-based networks are available, but does simplify the more complex protocols for security, web services, SNMP management, and others, which made the traditional internet protocols too demanding for small embedded devices ([She09], pp. 3).

Having looked at the five most prominent wireless technologies that can be used with the Internet of Things, we got an overview of what could be used for medical device interoperability on the foundational level (see chapter "3.1 Definition of Medical Device Interoperability"). The next question is, which protocols could be used on the structural level that provides the syntax. At the moment three protocols are most prominent for the use with the Internet of Things:

- *MQTT (Message Queuing Telemetry Transport)* is described as machine-to-machine (M2M) IoT communication protocol. The protocol is so lightweight that it can be used with the smallest devices and can transmit data even over intermittent networks. Its five characteristics that describe and distinguish MQTT from other protocols: 1) Publish and subscribe architecture which keeps communication overhead small, 2) Ideal for constrained networks (low bandwidth, high latency, data limits, and fragile connections), 3)

Quality of Service (QoS) can be chosen out of 3 levels: QoS 0 (At most once), QoS 1 (At least once), and QoS 2 (Exactly once), 4) MQTT client abnormal disconnect notification, and 5) MQTT clients are very simple to implement. Summarized the protocol is lightweight, fast, has low latency, and can deal with fragile communication channels, like all type of wireless connections are. This makes it the ideal protocol for the 'things' in the Internet of Things [Web14].

- *CoAP (Constrained Application Protocol)* is another lightweight protocol for the use in the IoT environment. From the principle it is similar to HTTP, but optimized for machine-to-machine (M2M) communication [Web15].

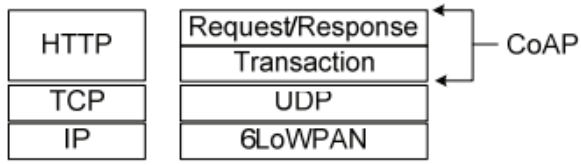


Fig. 47 HTTP and CoAP protocol stacks [Col11]

Differences to HTTP can not only be found in the protocol simplifications but also in a different protocol stack. On the Physical and Data Link Layer CoAP is suited well for using 6LoWPAN and on the Transport Layer it is using only UDP, whereas HTTP is using TCP. On the Application Layer CoAP has two sublayers, the Transaction Layer and the Request/Response Layer. All in all, CoAP allows easy integration of small devices and sensors with HTTP based networks [Col11].

- *XMPP (Extensible Messaging and Presence Protocol)* is a more heavyweight protocol with a lot of features, which is often used in chat protocols [Web15]. XMPP is a TCP protocol based on XML. It allows the exchange of structured data between two or more connected devices. As it started as a chat protocol it supports presence and contact list maintenance out of the box (it allows to address any recipient in the world by an email-like address) At the downside XMPP lacks end-to-end encryption and does also not provide a quality-of-service functionality [Web16].

4.3.3.5 IoT Predicted Market Size

As the Internet of Things was positioned to be the 4th Industrial Revolution also market growth predictions are huge. Gartner [Web17] says "In 2009, there were 2.5 billion connected devices; most of these were mobile phones, PCs and tablets. In 2020, there will be over 30 billion devices connected, of far greater variety"; see Fig. 48 for more details. This of course will impact market sizes.

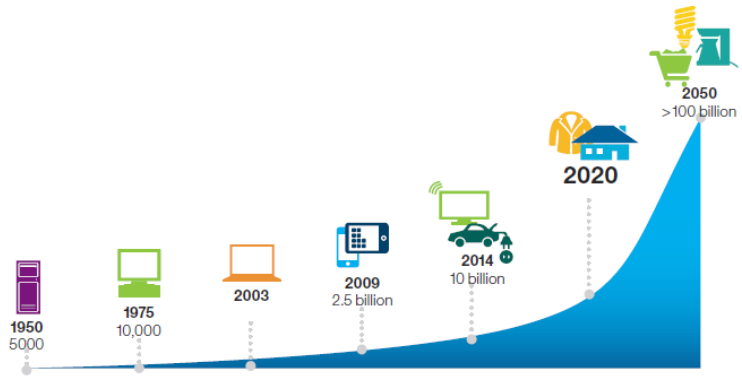


Fig. 48 Number of connected devices until 2050 [Web17]

Gartner [Web17] predicts that the incremental revenue generated by the Internet of Things suppliers will be $309 billion per year by 2020. Half of this will come from new start-ups and 80% will be in services rather than in products. Further Gartner states: "… that the total economic value add for the Internet of Things will be $1.9 trillion dollars in 2020, seen across a number of industries. The verticals that are leading its adoption are manufacturing (15 percent), healthcare (15 percent) and insurance (11 percent).".

One can see that those numbers are not only vague predictions, but taken seriously by industry, by the example of Bosch (and there are certainly many other examples). Bosch and Siemens had a joint venture for white goods, called BSH. In 2014 Bosch took over the 50% share of Siemens for 3 billion Euros. Bosch is a privately held company. In the German Manager Magazin [Web18] Bosch claimed that they see a huge market in the Internet of Things and foresee that white goods soon will participate in that. In addition Bosch wants to become more independent from automotive. Bosch is also a member in the Industrial Internet Consortium, see chapter "4.3.3.2 Industry 4.0 and Industrial Internet Consortium (IIC)".

4.3.3.6 Summary

In this chapter a condensed view on the Internet of Things was given, with a focus on ingredients for device interoperability, and how this device interoperability does fit into the bigger picture. Interesting to note is, that not only in medical device interoperability there is a huge gap, but also in the industrial internet of things for the general device interoperability the same issue can be seen. Connectivity, in the sense of integration, of data seems not to be an issue. As the Internet of Things is predicted to cause a huge market growth, a lot of focus is given by industry on making device interoperability happening by lightweight technologies and protocols of communication. Of course, medical device interoperability can take its advantage of these efforts.

Still looking from a high-level on the communication models, wireless technologies, and IoT capable communication protocols the following look pretty interesting: the Device-to-Application-Layer Gateway (ALG), the ultra-wide band communication, and the MQTT protocol as these technologies resonate best with the requirements for medical device interoperability that we have seen in earlier chapters of this thesis. However, it is too early here to draw final conclusions, this will be done in a later chapter.

4.3.4 Real-Time Locating Systems (RTLS)

In chapter “3.3.4 Considerations for Choosing a Topology” we have seen that patient association is an important topic, which directly affects patient safety. The shown possibilities were all not practical. As of today no good solution exists for this problem, and if the data connection becomes wireless also the association with the “intelligent hub”, by plugging in the data cable, goes away. A reasonable way to automatically assign a device to a patient (or bed) would be by determining its physical location. E.g. if it is within a certain distance to the patient it will be assigned to that patient. The solution needs to be robust, in terms of electrical interferences as well as physical interferences, and in addition it needs to be cost effective. A system with 98% accuracy in terms of correct patient association would be a not working system! The most promising technologies for a real-time device locating solution (RTLS) are: Bluetooth LE (Low Energy), RFID, and Ultra-wide Band, as they were designed with location identification and object tracking in mind.

- *Bluetooth LE (BLE):* Bluetooth was discussed already in chapter "4.3.3.4 IoT Communication Technologies and Protocols". With its latest version, Bluetooth LE (Low Energy) not only reduced battery consumption, and other features were introduced, but also Apple developed so called iBeacons that can communicate with, e.g. the BLE in a smartphone. Those iBeacons can be placed in shopping malls and whenever a smart phone with BLE comes close, it could send offers, or coupons, or other advertising to the smart phone [Web19].

Fig. 49 iBeacon ([Weh15b], p. 3)

More interesting is that the iBeacon does also send, together with its ID, the received signal strength indicator information (RSSI). With the help of a minimum of three senders (iBeacons) the position of a smartphone can be calculated by triangulation. This feature of BLE was used at the airport of San Francisco (USA) to create an indoor navigation system for visually impaired people. With the help of iBeacons and and a smartphone app, the app could tell the way through the airport to its user ([Weh15a], p. 25).

In a student research project [Weh15b] the triangulation approach was evalutated in a field test to find out the accuracy of the locating system . Unfortunately the results did not meet the requirements for an automated medical device localitiy determination. The biggest interference was observed when a person was in the line of sight of sender and receiver. Also LTE and WLAN signals caused significant interference. The conclusion was that the technology is good enough to detect if an object is in a certain room and in which direction the object is moving, but the accuracy of only 1-2 m is too big for an exact locality determination. With more beacons and better mathematical algorithms the accuracy could certainly be improved. A master thesis conducted in 2012 at the University of Geneva [Bek12] came to similar results with an accuracy of around 1.5 m. Obviously newer hardware generations of Bluetooth LE did not improve the locality determination.

- *RFID:* Components of an RFID system are the tag (that is attached to an object), anntenna (tag detector, creates magnetic field), and a reader (receives tag information). The antenna creates a magentic field which "wakes" up the tag that sends then its stored information to the antenna. The information is captured by the reader and given to an application for further processing. All tags that are in the range of the anntenna will send their information simultaneously, which could lead to a reader overflow. Typically a reader can handle 50 to 200 tags at once [Ahs10]. RFID tags are used in different applications for object tracking and identification. In supermarkets and other stores the RFID tags replace the barcodes for easier scanning. The issue here is the price of the tag, which ideally should be below 1 cent per tag, as hundred thousands of them are needed by big stores. The same is true for the use of RFID tags in logistics. A standard RFID system is not available. Tags differ in their frequencies, which also determines the range for detection, and there are active and passive tags available. Active tags are battery powered and don't need to be activated by an antenna. An active tag could be used to measure a temperature and frequently send it to the reader. A challenge is reading tags that move, e.g. scanning the load of a whole truck while driving through a scanner. Summarized RFID systems are used to track and identify objects that are in the thousands or hundred thousands, or follow people, when they enter a room/building or leave it, but the intent of RFID is not to locate the exact coordinates of an object within a room or building ([Bul07], pp. 243).

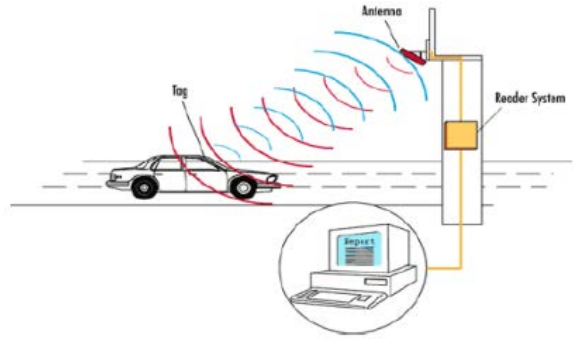


Fig. 50 A typical RFID system [Ahs10]

- *Ultra-wide Band (UWB)* we had looked at already as a communication protocol standardized by IEEE 802.15.3, but originally UWB was designed for radar systems which functions are standardized in IEEE 802.15.4. UWB sends very short narrow impulses, so the time of flight of RF signals through air can be measured with extreme precision, down to the tens of centimenters (particularly indoors), see Fig. 51. All other advantages of UWB, like outlined earlier, stay valid with 802.15.4. E.g. UWB's power consumption in energy per bit is 5-7 times lower than that of ZigBee, it has a high immunity to interference, and it is expected to be cost-wise soon close to the cost of a Bluetooth interface [Web20].

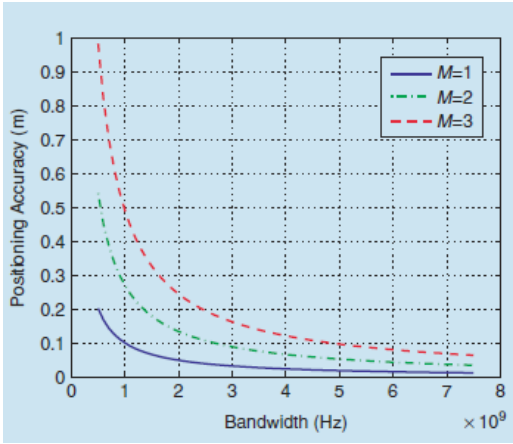


Fig. 52 UWB Positioning Accuracy [Sin05]

Ubisense company, which is probably the current market leader in UWB real-time locating systems, has compared the accuracy of different locating system technologies, which shows that the UWB system is closest to the "ideal" system, see Fig. 52 [Bat11].

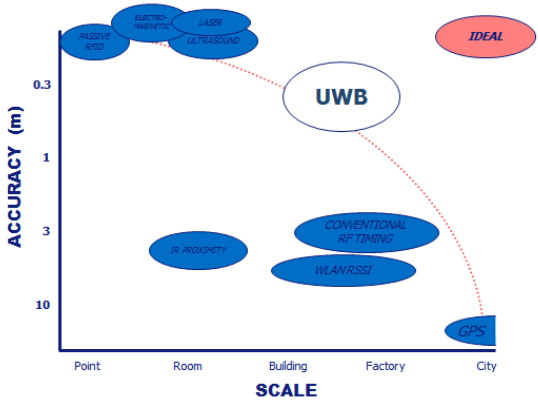


Fig. 51 Positioning Accuracy of different technologies [Bat11]

UWB is used, e.g. in the Daimler shop floor in Rastatt, Germany with power tools (this is explained during the factory tour). This way it can be ensured that no screw is forgotten to be tightened, and that the right torque is loaded

in the power tool for each screw depending on its location. Fig. 54 shows such a power tool with an integrated UWB module.

Fig. 54 Power tool with Ubisense UWB module [Bat11]

As part of the Industrial Internet Consortium, see chapter "4.3.3.2 Industry 4.0 and Industrial Internet Consortium (IIC)", Bosch is driving the first European testbed, together with Cisco and Tech Mahindra, called the "Track and Trace" project for connected tools in manufacturing: "The first outcome … is the ability to determine the position of a cordless nutrunner on the shop floor with extreme precision ... This positioning information is used to automatically select the correct torque for the respective task, making it possible to tighten safety-relevant bolts with exactly the required torque, …". The goal of the project is an open standard that allows the system to be used universally with industrial power tools used to drill, tighten, measure, and rivet. [Web21]. Though it is not mentioned explicitly in the article which locating system technology is used, the likelihood is pretty high that it will be UWB.

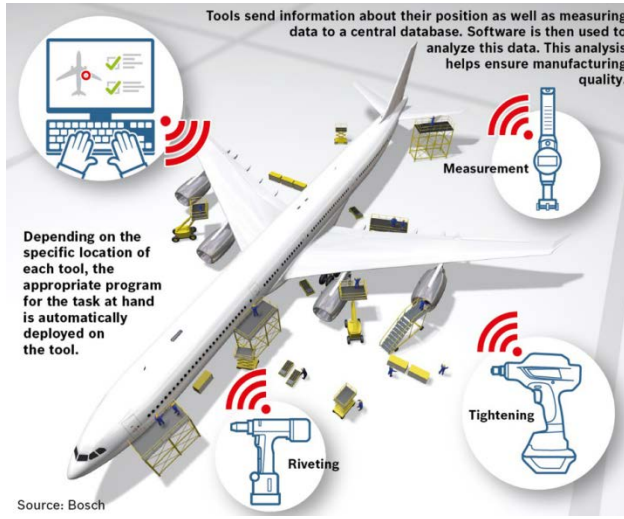


Fig. 53 IIC "Track and Trace" testbed overview [Web21]

Another interesting technology trend is seen in the RTLS (real-time locating systems) hospital market. RTLS systems at the moment are used in hospitals for identification and tracking only. The US market for that was in 2013: 292 M$. It did split up in Asset Tracking (76%), Patient and Staff Management (19.9%), and Hygiene Management (4.1%). The used technologies were Barcode and passive RFID for the first generation of technologies, and active RFID and IR for the 2nd generation. Since end of 2014 the technology trend for RTLS systems in hospital for the 3rd generation is towards Wi-Fi, Mixed IR/Wi-Fi/LF, and UWB, with the latter two being predicted for 2017 [F&S15c].

Reviewing the three locating technologies above, in terms of usage for patient association in medical device interoperability, Bluetooth does not have the needed accuracy, RFID is not intended for locating coordinates of an object, whereas UWB provides the needed accuracy and is also suitable for an industrial environment with a lot of potential interferences. With Bosch, Cisco, and Tech Mahindra working on an open standard, it is expected that prices for the solution will become reasonable, and as in addition the RFID technology, used mainly for logistic management in hospitals, might migrate to UWB as well, expected introduction barriers of UWB in hospitals might become manageable.

4.4 Technology Trends in Clinical Healthcare

4.4.1 Unique Device Identification (UDI)

The FDA states: “FDA is establishing a unique device identification system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form. Device labelers must also submit certain information about each device to FDA’s Global Unique Device Identification Database (GUDID). The public can search and download information from the GUDID.”

The GUDID will contain information like Device Identifier (DI), Company Name, Device Brand Name, Device Common Name, Device Version or Model.

The unique device identification system will be phased in over several years, the phase-in period has started in September 2014 [Web22].

With the help of the UDI, assuming it is also available through the device's data interface, a device could not only be uniquely defined, but all data coming from it could also be associated with this one device. By the help of cloud services even malfunction devices could then be identified by doing statistics across all devices of this type, even at other customer sites.

4.4.2 Alarm Fatigue

Research has demonstrated that 72% to 99% of clinical alarms are false. This has led to alarm fatigue, which means that clinicians don't react on alarms anymore as they are desensitized. What was intended to be a safety feature (alarms) now has become itself a safety issue. Already in 2003 the Joint Commission (USA) took on the challenge to improve effectiveness of clinical alarms. Also other institutes became involved over time, like the ECRI Institute, the Healthcare Technology Foundation, and the American Association of Critical-Care Nurses. The Joint Commission released a "National Patient Safety Goal on Alarm Management" in June 2013, with two implementation steps: one set for July 1, 2014 and the other for January 1, 2016. Basically the most important alarms need to be identified and managed, which has to result in policies and procedures, followed by education of the clinical staff [Sen13].

This means additional rules and work for the clinical staff, which could be largely taken on by the medical devices themselves, if they would be truly interoperable and an alarm escalation policy being technically implemented that would span all of the connected devices.

4.4.3 Value-Based Care and Population Health Management

It is expected that in the US by 2021 the national health care spending will reach nearly $5 trillion, or 20% of the gross domestic product (GDP). In an effort to reduce cost and enhance outcomes the healthcare delivery system is being shifted from volume to *value based care*. Key is to achieve the Triple Aim, which is to improve patient outcomes, enhance patient experience, and reduce per capita costs. This has led to numerous Value-Based Programs, e.g. Accountable Care Organizations (ACOs), whereby providers, payers, and plans are all incentivized

to provide high value care. The emerging payment models with a focus on value, quality and reduced costs, have led to new themes of which the following three are the most prominent ones ([Str15], p. 4-8):

- Investment in Data Management Capabilities
- Transformation of Systems of Care
- Increase in Provider Accountability

In the following we will look only at "Investment in Data Management Capabilities" namely Population Health Management (PHM). A population can be defined in various ways, e.g. as members of a health plan, as recipients of a surgical procedure, as admissions to a hospital etc. One, often used approach, is to select individuals diagnosed with a condition of interest, e.g. coronary artery disease, diabetes, asthma, chronic obstructive pulmonary disease, end-stage renal disease, hypertension, HIV/AIDS, osteoporosis, tumors/cancer, or abdominal aortic aneurysm; those eligible for breast cancer or cervical cancer screening; or those with central venous catheter insertions, total joint replacement or solid organ transplants ([Gre14], p. 366).

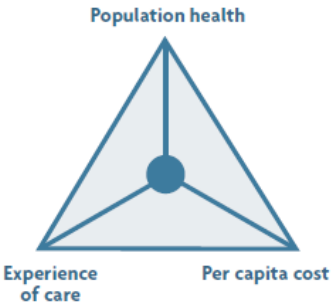


Fig. 56 The Triple Aim ([Str15], p. 4)

Fig. 56 shows how patient data is used on the different levels of practice, population, and public. Basically the data flows from the patient to the PHR, EHR, PHM, and on a National and International level for research. At the

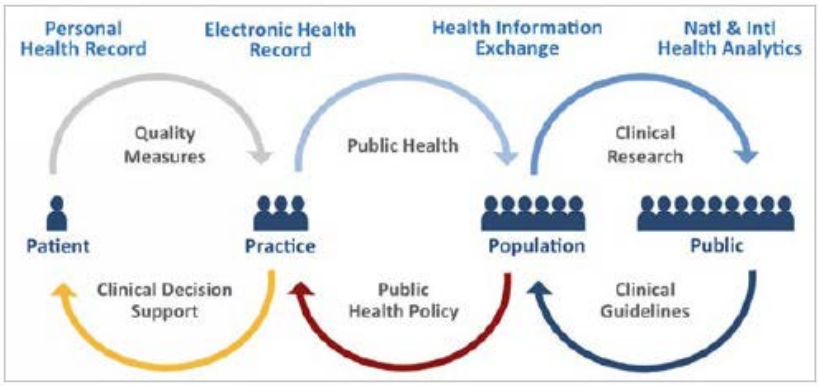


Fig. 55 The Health IT Ecosystem as a Learning Health System ([HIT15], p. 19)

different instances Clinical Guidelines, Public Health Policies, or Clinical Decisions are generated, by the involved software tools or by research. In case of a patient in the ICU, a good portion of the data will come from the medical devices around the patient and will flow to the EHR and PHM, which would return clinical decision support for that individual patient, and could also want to change the settings of the devices, e.g. ventilator, to adapt the therapy to the findings (which is not possible today due to the lack of functional medical device interoperability) [HIT15].

The Population Health Management market is expected to grow from 11 B$ to 32 B$ until 2020 (with a CAGR of 23%), see Fig. 57. North America accounts for the biggest share in 2015 with 84%. Approximately 80% of the market is towards software and 20% towards services. The software is delivered either Web-based (60%), On-Premise (31%), or Cloud-based (9%) ([Mar16], p. 34-37). IBM is the market leader in the PHM segment with a market share of 22%. IBM PHM deployments have helped customers in improving quality of care, reducing needless costs, ensuring the delivery of the appropriate care, and ensuring follow-up for every patient, which enhances care coordination and reduces unnecessary readmissions ([Mar16], p. 47-48).

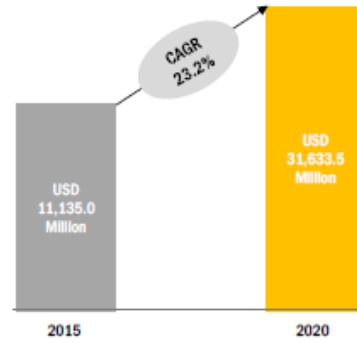


Fig. 57 PHM Market Size ([Mar16], p. 34)

In a report from Frost and Sullivan about the HIMSS 2016 trade show, they claim: “The move to value-based reimbursement is already a key driver for health IT; the momentum to build out solutions for care coordination and PHM is accelerating significantly and literally thousands of companies are chasing this space.” ([F&S16], p. 24), thus it is likely that market shares will change over the coming years.

As mentioned above already, population health management systems will not only need data from the medical devices in an ICU and OR, but also can provide the needed decision support for the individual patient to automatically change the settings of those devices, provided that functional medical device interoperability would exist.

4.5 The Value of Medical Device Interoperability

In a study performed by the West Health Institute (WHI), located in San Diego, CA, USA, in 2013 the amount of "waste" expressed in US Dollar was researched, caused by the lack of functional medical device interoperability. All following is from this study [WHI13]:

With "waste" any activity that does not add value to the health care system is meant. Waste is an expression from lean management, which is about increasing efficiency across supply chains by identifying "waste" and remove it. Without going deeper into "lean" this is the approach taken.

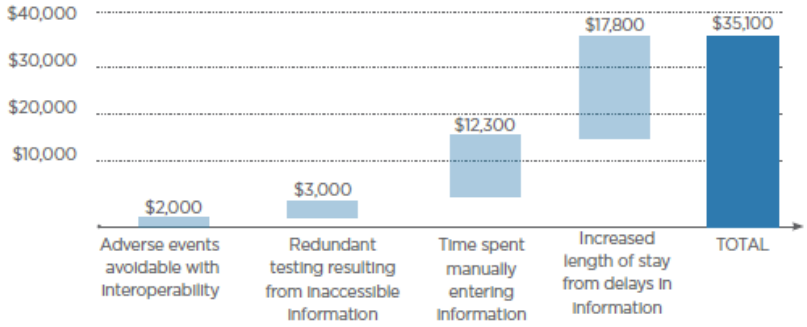


Fig. 58 Estimated Waste from Lack of Medical Device Interoperability ($M) ([WHI13], p. 10)

In the sum the identified waste (for the USA only) is $35 billion. This splits up into:

1) quality improvement through reduction of adverse events due to safety interlocks ($2 billion)
2) reduced cost of care secondary to avoidance of redundant testing ($3 billion)
3) increased clinician productivity secondary to decreased time spent manually entering information ($12 billion)
4) increased capacity for treatment secondary to shortening length of stay ($18 billion)

This brings us to hypothesis 3 of this thesis:

> *Hypothesis 3* is that if *functional medical device interoperability* for the ICU and OR would be in place, to address the topic *"Adverse events avoidable with interoperability"*, not only the $2 billion of "waste" associated with that topic would go away, but as a side-effect also the other $33 billion of waste would diminish.

"Medical errors result in as many as three million *preventable adverse events* each year, driving as much as $17 billion in excess annual medical costs and as many as 98,000 deaths per year." ([WHI13], p. 13). Examples of how preventable adverse events can be avoided by functional medical device interoperability are ([WHI13], p. 13-21):

- *Drug Errors:* Ordering errors account for 39% of all drug errors. Relevant to this is the impact of closed-loop e-prescribing, automated dispensing, bar-code and eMAR systems that integrate the flow of information among the subsystems that comprise the closed-loop. A study in 'Quality & Safety in Healthcare' found that such a closed-loop system reduced prescribing errors by 47%. E.g. for Patient Controlled Analgesia (PCA) a closed-loop system would avoid adverse event. In PCA a patient gets medication against pain (morphine) by a syringe pump. The patient himself or herself can by the push of a button give themselves shortly a higher dose (bolus), if this is used too often the patient might die. If the Computerized Physician Order Entry (CPOE) system, the syringe pump, and the patient monitor would be truly interoperable, the patient could be held at a pain-free state, without killing him or her.
- *Failure to Prevent Injury:* "A patient is intubated and on a ventilator in the ICU for brain injury. The physician orders a ventilator setting with specific physiological parameters per evidence-based guidelines. Repeat blood gas testing is ordered to maintain these specific parameters. The nurse notifies a respiratory therapist, who draws blood and sends it to the lab. The nurse receives results and calls the physician with findings, which requires a change in the ventilator settings. This cycle occurs four to six times a day based on the patient's dynamic clinical status." Assuming the involved devices and systems could communicate directly with each other this could

eliminate unnecessary steps and potential delays, minimizing time on a ventilator and thus reducing the duration of hypoxia, the impact of acid-base disturbances and the risk of ventilator-associated pneumonia.

There are more examples outlined in the study, and also in this thesis in chapter "4.1 Introduction" the closed-loop example of a Total Intravenous Anesthesia (TIVA) is given. The WHI study demonstrates how big the financial impact due to the lack of medical device interoperability is and how the value of care in terms of patient outcome and quality of care can be significantly elevated by functional medical interoperability. Since we have the shift from volume to value based care, see chapter "4.4.3 Value-Based Care and Population Health Management", this might weigh even more now than in 2013 when the study was performed.

4.6 Critical Review and Discussion

In chapter "4 Literature Research" we looked at the theory of innovation, technology advancements in industry, technology advancements in clinical healthcare, and analyzed the value of medical device interoperability.

This gave us deeper insights on innovation barriers that are multifaceted: First the new product needs to have a *relative advantage*, but on the other side not being "too new", which is stated by the attribute *compatibility*. Further it should be perceived as *not complex* and the benefit of the new product should be *easily observable*, meaning with not a lot of explanations.

In terms of medical device interoperability, there is anyhow nothing that could be observed by the end user, other than that data shows up in the EMR, or not. The current high price of device integration will be seen by a few people in the customer's organization, but usually not by the end users (clinical staff). This is another reason why standardization efforts in medical device interfacing did fail; the first one was its sheer complexity, see chapter "3.5.4 Summary". Regardless of how easy and elegant the data would flow into the EMR, for the end user it would not be observable.

Developing interoperability for medical devices would require that R&D organizations of different companies would team up in the form of open

innovation. As we have seen in chapter “4.2.2 Open Innovation” open innovation causes by many traditional companies, and no company can be more traditional than a medical devices company, big resistance. Those companies were so far pretty successful in developing their products without any contact to the outside. This developed a strong not-invented-here (NIH) syndrome in their R&D organizations.

However, if a company would make it, and find a way to make medical device interoperability happen, it could still be that the product is canceled before introduction as it might not fit the company’s current business model, see chapter “4.2.3 Business Model Innovation”.

And even, if that hurdle could be taken, suddenly and unexpectedly the opinion leaders of the previous model could fire against the new approach, thus severely hindering the adoption of the innovation in the market (see chapter “4.2.1 Diffusion of Innovation”).

Fortunately on the technology side things are looking brighter. Due to the hype of the Internet of Things, respectively the Industrial Internet, a lot of technologies for small devices communication are coming to live that before had rare and highly specialized usage. We have seen that we better don’t overload the medical device interface with the full OSI model, nor with the smaller TCP/IP model. The most successful communication technologies are those that kept their number of communication layers to the minimum, see chapter “4.3.2.5 Real-Time Communication”. This leaves us with PAN devices, and as wireless is required, with WPAN (Wireless Personal Area Network) devices, for which several technologies are available and standardized.

For communication protocols we have seen that in the medical field HL7 version 2.x is pretty successful, whereas HL7 version 3.x, which adds semantics, isn’t used at all, see chapter “3.5.2 Base Standards”. Therefore we leave the semantics part of the protocol unattended, for the moment. Looking in the field of IoT there is a protocol called MQTT that perfectly fits the needs of a wireless PAN communication that has safety aspects and real-time requirements.

Keeping the interfaces for the medical devices small and lightweight requires that we will have a gateway (ALG), see chapter “4.3.3.3 Internet of Things (IoT)”, connecting the medical devices with each other, being the router to the rest of the

LAN or Internet, and hosting applications, like for TIVA (Total Intravenous Anesthesia).

Further we have seen in chapter “4.3.2 Aspects of Real-Time Systems” that the medical interface and the gateway (ALG) have hard real-time requirements, which can be best handled by the use of a real-time operating system (RTOS). Though this might sound “heavy”, we had learnt that real-time systems are embedded systems, therefore these RTOS systems are optimized for small devices.

Resolving one of the current and future big impediments is the use of ultra-wide band for locating the medical device’s position in real-time. This will allow to assign the device’s data to the patient (bed) based on its distance, e.g. closeness, to the patient (bed). Seeing, that exactly this issue (real-time location detection with very high accuracy) is the first European testbed in the Industrial Internet Consortium, gives trust that this will soon be a widely accepted solution, see also chapter “4.3.4 Real-Time Locating Systems (RTLS)”.

Finally looking at advancements in clinical technologies, one finds that alarm fatigue is a huge issue, that Population Health Management will be the next big wave after EMR/EHR, and that medical device interoperability could help to avoid many adverse events in the hospital. Alarm fatigue could be resolved, if the devices escalate their alarms through the gateway (ALG) rather than directly “ringing the bell”. Population Health Management (PHM), see chapter “4.4.3 Value-Based Care and Population Health Management”, will be the enabler for individualized clinical decision support, which will directly impact the treatment of the patient and thus device settings, medications, alarm levels, etc. Avoiding adverse events by medical device interoperability sounds like a *relative advantage* that is *easily observable*, which brings us closer to removing a few of the so far listed innovation barriers.

Summa summarum, one can say that all needed technology is available for resolving the issue of lack of medical device interoperability, although these technologies need be arranged in a new way (at least new for medical devices) and also that the customer need is there, but latent only, which is a problem that needs resolution.

5 Conclusion

5.1 Summary of Innovation Barriers

"Analysis of Current Innovation Barriers for Functional Medical Device Interoperability in Hospital Intensive Care and Development of a Conceptual Approach to Overcome Them." is the theme of this master thesis. Before developing the conceptual approach based on the analysis and research done in this thesis, the *innovation barriers* will be summarized in table Tab. 5., and their cause of blockage being assigned (TP = Lack of Technology Push, CP = Lack of Customer Pull).

Tab. 5 Summary of identified innovation barriers and cause of blockage

Page	Innovation Barrier	Description	Block
8	Small market size	Very small market size of approx. 200 M€ worldwide for the device interface itself	TP
27	Other (more prominent) interoperability issues	Usually when the talk comes to interoperability in healthcare it refers to PACS, HIS, EMR, EHR, and the like systems and not to medical device interoperability. Basically the issue of medical device interoperability is widely unknown.	CP TP
41	MDDS vendors	Since MDDS vendors can integrate medical devices with EMR/EHR systems, and the tremendous cost of it disappears in the light of the even more expensive EMR system, no strong customer pull exists for a different interoperability solution.	CP TP
50	Standards	Too many, too complex, not designed for embedded low-performance hard real-time systems	TP
51	Requirements for medical device interoperability	Huge list of partially conflicting requirements for medical device interoperability	TP

55	Locked-in	If medical device manufacturers go away from RS232 interfaces they lock themselves out from existing device interfacing solutions from MDDS vendors.	CP TP
56	Return on investment	Offering different interfaces with medical devices will not bring higher revenue, in the worst case the device might not sell, if it has no RS232 interface (see Locked-in)	TP
56	Niche players	MDDS vendors have established themselves in a niche market, they will undermine every effort that might change that. After making good revenue in the EMR/EHR business, the next wave is coming with Population Health Management (PHM)	CP TP
57	Missing applications for functional medical device interoperability	Hypothesis 1 is that when functional medical device interoperability would be available, it would be the applications that make use of this interoperability that would create the customer pull.	CP
58	Perception that no better technology is available	Since all MDDS vendors have common solutions, with ID modules, device driver, intelligent hubs, etc. the perception is there that no other technology would solve the problem. Hypothesis 2 is that the needed technology to provide functional medical device interoperability is available, but not yet identified.	CP TP
64	Perceived attributes of innovation	The most important attribute is relative advantage compared to the predecessor product, which needs to compatible with values and beliefs, not being complex, and easy observable. This is challenging for a product that works "behind the scenes".	CP

65	Opinion leaders	The current MDDS solution is favored by opinion leaders as they have advantages because of understanding and mastering the current complex MDDS vendors' solutions. They will fire against any new product that takes these advantages away from them.	CP
69	Not-invented-here syndrome	R&D organizations of medical device vendors are not in favor of open innovation. But an interoperability product cannot be developed in isolation.	TP
72	Business model	Most medical device manufacturers would need to undergo a business model innovation to participate in a market opportunity that will deliver interoperability systems rather than boxes.	TP
89	Knowledge of real-time systems	Most manufacturers do not know how to design real-time systems	TP
101	Knowledge of networks and IoT	Most manufacturers do not have knowledge on networks and IoT in house	TP
106	Knowledge of RTLS systems	Most manufacturers do not know about the latest technologies in real-time locating systems which could be used to achieve the important need for patient association	TP
112	Economic impact of lack of medical device interoperability	Customers don't know how big the economic impact of lacking medical device interoperability is, and how much the quality of care could be elevated by functional medical device interoperability. E.g. the rate of preventable deaths, which are 98,000 per year in the US, could be brought down significantly.	CP

5.2 Conceptual Approach

5.2.1 Technical Concept

The technical concept will address (in the course of this thesis) the medical device interface and the device-to-application-layer gateway (ALG), see chapter "4.3.3.3 Internet of Things (IoT)", only.

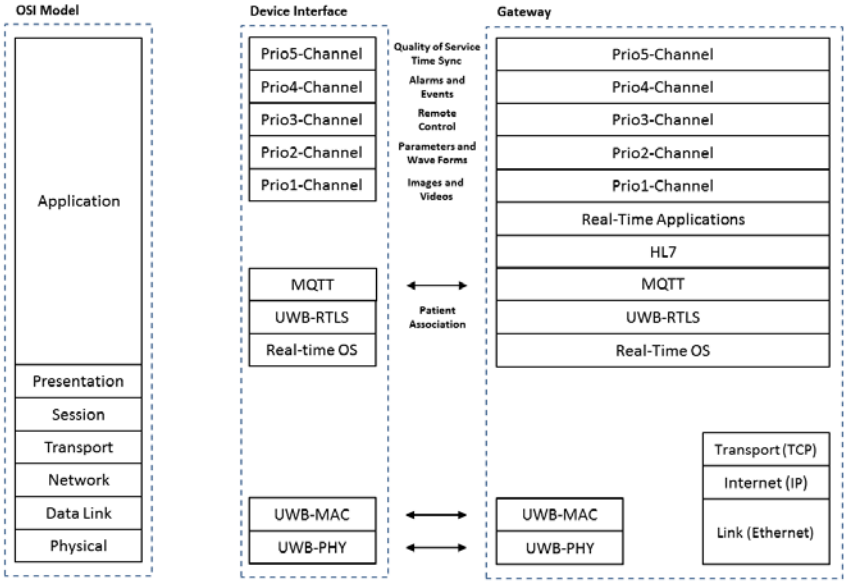


Fig. 59 Medical Device Interface and Gateway OSI layers (Source own figure)

Medical Device Interface: The medical device interface needs to be simple and cost effective to be adopted by manufacturers, and wireless to be accepted by customers. This has led to the conclusion that for the lower layers of the OSI reference model Ultra-wide Band (UWB) shall be selected, which will also be the choice for the Real-time Locating System (RTLS). The technical reasons to select UWB are outlined in the chapters "4.3.3.6 Summary" and "4.3.4 Real-Time Locating Systems (RTLS)" respectively. The ideal protocol of communication to run over UWB is the MQTT protocol, like outlined in chapter 4.3.3.6 too. In addition a real-time operating system will be implemented on the application layer. This will allow that messages can be send at different priorities.

Basically there are five message types in decreasing priority:

1) A quality-of-service message is needed, which could be a ping to check if the wireless communication has the required speed and latency time
2) Alarms and events need to be send with high priority
3) Device remote control messages, which need a high priority as well
4) Parameters, e.g. vital signs or hemodynamic parameters, and wave data with lower priority
5) For devices that can create pictures or videos, e.g. ultrasound, these would be sent with lowest priority.

Message type 1) would also be used to keep time synchronization between device and gateway, which is quite important for the synchronization of the measured data, e.g. wave forms, when they will be displayed, or analyzed for research purposes.

Device-to-Application-Layer Gateway (ALG): The gateway has the same layers and functionalities as described for the medical device interface and in addition it is running real-time applications, like the mentioned TIVA protocol, or alarm management (alarm fatigue). Further it will have a LAN interface through which it can send data to other systems, e.g. in HL7 format, and receive data from, e.g. a Population Health Management (PHM) system (see chapter “4.4.3 Value-Based Care and Population Health Management”).

As we are in a safety relevant area here, the gateway will also have the function to act as a safeguard. E.g., it could host an application that implements safeguards, in the sense that whenever remote control data shall be sent to a device, the safeguards application will conduct a plausibility test on the data, to ensure that the patient will not get harmed by the new settings.

All data that the gateway sends to other systems through its LAN port will have the Unique Device Identification (UDI), see chapter “4.4.1 Unique Device Identification (UDI)”, of the originating device associated and the data will be assigned to the respective bed ID. This allows to retrospectively assign data in, e.g., an EMR system, to a patient. Often a patient ID will be available after treatment has started, due to emergency cases or delayed patient ID assignments.

In chapter "3.6 Considerations for Medical Device Interoperability" the requirements, found in the researched literature, for medical device interoperability was summarized:

Tab. 6 Medical device interface requirements

#	Requirement	Implementation	?
(1)	Wireless communication ([F&S15b], p. 21-24)	Ultra-wide band wireless personal area network	✓
(2)	Patient safety [Schr01]	Real-time safeguard app	✓
(3)	Unambiguous patient association [Schr01]	Ultra-wide band location detection to automatically assign devices to bed	✓
(4)	Unambiguous device identification (worldwide) [Schr01]	Unique Device Identification (UDI)	✓
(5)	Wide range of topologies [Schr01]	Gateway can connect to LAN and Internet	✓
(6)	Fault tolerant (modified from [Schr01])	Quality-of-service is constantly checked	✓
(7)	Cost effective [Schr01]	Medical device interface kept small and simple	✓
(8)	Off-the-shelf-technologies [Schr01]	Yes, all of them	✓
(9)	Run on low-performance embedded systems (modified from [Schr01])	MQTT and RTOS very well suited for small embedded systems	✓
(10)	Low-power device [Sch01]	Only low-power components to be used	✓

(11)	Time synchronization (for time the measurement was taken, or synchronizing wave forms) [Schr01]	Time sync service available	✓
(12)	Data security [Schr01]	Needs further evaluation	-
(13)	Remote control (bi-directional communication) [Schr01]	Yes	✓
(14)	Alarm management (real-time aspects) [Schr01]	Yes	✓
(15)	Hard real-time communication [OR16]	Yes	✓
(16)	Closed-loop communication (MD PnP/ASTM-ICE in [Moo10])	Yes	✓
(17)	Semantical interoperability [Rho10]	No, by intent not	-

As can be seen from Tab. 6 all requirements are fulfilled by above outlined technical concept, except "(12) Data security", which needs further evaluation, and "(17) Semantical interoperability", which is not fulfilled by intent:

Semantical Interoperability: Adding semantic interoperability to a protocol of communication makes it very complex and it would need frequent updates as the definition of semantics extends over time. Therefore each device will send a unique identifier, comprised of the Unique Device Identifier (UDI) and a company chosen ID, with each parameter, or other data, which is then used as key to add semantical data. The plan is to maintain a *cross collaboration server* in the internet, on which all semantic data, e.g. data labels and associated information like used measurement method, the translations of the labels in the respective languages, the unit of measure, etc. is stored. From there any application can download at installation and configuration time the semantical information needed. Also the gateway can download from there, e.g. the needed labels, in the correct language, when sending parameters from one device to

another, e.g. for displaying it. The *cross collaboration server* will be the only way to keep semantic information about all interoperable devices accurate and complete, including versioning, because maintenance will be done by the respective manufacturers themselves and not by some standardization body.

5.2.2 Technology Push and Customer Pull Concept

Looking at Tab. 5: Summary of identified innovation barriers, it becomes obvious that neither from them medical device manufacturers side there is a strong *technology push*, nor from the customers side there is a strong *customer pull*, for improved medical device interoperability. As those two behaviors build the foundation for innovation, one could conclude that there is also no need for an innovation in that area.

The manufacturers don't see a need to introduce a new technology, as they would not get additional revenue from it, the MDDS vendors could not interface with their new interface, standardization is out of scope as too complex and not a single one being widely accepted, the list of requirements for medical device interoperability is huge and hard to fulfill, and manufacturers would need to go for open innovation which is against their current culture. And again, they would not sell a single unit more, and also not less, of their medical device than when implementing a simple and cost effective RS232 interface with a proprietary protocol of communication, which they own and can change at their own convenience without first agreeing with any partners in an open innovation project. Even the most enthusiastic R&D engineer or product marketing manager could not build a reasonable business case here for the innovation of the medical device interface.

From the customers' side, we can see (Tab. 5) that they are usually not aware that a problem exists at all, because when the talk comes to interoperability issues it's about EMRs and other systems that cannot exchange their data with each other, they are told by manufacturers, MDDS vendors, and EMR vendors that medical device interoperability is not a problem and is part of the offer. There are opinion leaders who recommend the current solution and tell them that even standardization is underway, which will protect their investment. Until they recognize what they bought it's too late, and it is hard to say that they were fooled, as no better solutions exist and opinion leaders tell them that they bought

the most modern solution (which is not a lie). Chapter "3.8 Known Issues" outlines the issues that customers will face and chapter "3.7 Cost of Medical Device Interoperability" outlines the immense cost of the (pretty limited) solution they bought. So even if a customer gets the "feeling" that this could be done better, and they are normally clinical experts, they are told by the technical experts and the opinion leaders that they are wrong as they don't understand the technical complexity behind it. And the worst, if a very detailed and plausible study like from the West Health Institute [WHI13] shows the negative impact of current medical device interoperability and express it even in dollars, but does then recommend standardization as the solution, we begin to understand why we are caught in the treadmill since three decades.

How to break the loop: As the underlying problem is purely technical the loop needs to be broken through a massive *technology push* from the manufacturers' side, but then followed by a strong *customer pull* for more.

Chapter "4.3.4 Real-Time Locating Systems (RTLS)" shows how in the Industrial Internet Consortium (IIC) technology push is created. For the locating system three companies (out of the consortium with dozens of companies) work together (on a so called testbed) to drive the project and standardization forward. Its three specialists Bosch, Cisco, and Tech Mahindra, so no start-ups or companies from unrelated industries, which are involved and which everyone trusts that they can make it.

The same needs to happen for medical device interoperability. The dominant medical devices around the patient's bed in the ICU are the patient monitor, the ventilator, and the infusion/syringe pumps. In the OR the ventilator's place would be taken by the anesthesia machine, except when a Total Intravenous Anesthesia (TIVA) is performed then the ventilator keeps its place.

If a patient monitor manufacturer could win a ventilator manufacturer and an infusion/syringe pump manufacturer on the basis of an open innovation project (see chapter "4.2.2 Open Innovation") the work on a testbed for *functional medical device interoperability* could start. Market leaders in patient monitoring are Philips, GE, and Mindray, in ventilation Dräger and Hamilton, and in infusion/syringe pumps Carefusion (Alaris), BBraun, and Fresenius. The consortium would now need to apply the technical concept, like outlined in

chapter 5.2.1, to the medical device interface and to a to be developed gateway (ALG), which will be the core of the project. Especially the company that takes ownership of the gateway (ALG), which most likely will be the patient monitor vendor that traditionally integrates the other devices, will face issues with its current business model, which doesn't foresee products with such a high level of integration and such a depth of application (TIVA); see chapter "4.2.3 Business Model Innovation". A solution to that could be the start of an incubator business which runs isolated from the current business model. If none of the companies would want to take on the ALG gateway, a player like Bosch, which just started to make huge investments in IoT (see chapter "4.3.3.5 IoT Predicted Market Size"), and is used to open innovation, and wants to establish its footprint in healthcare technology, could be added to the consortium and take on the ALG gateway responsibility. Why this might not be a good idea from the perspective of the patient monitor manufacturer will be explained at the end of chapter "7 Implications for Future Research".

Ideally this project is kept secret at the beginning, and it is a *must* that it delivers a demonstrator, like the TIVA (Total Intravenous Anesthesia) closed-loop application. The application is a *must* to fulfill the customer *perceived attributes of innovations* like outlined in chapter "4.2.1 Diffusion of Innovation". When going live with the first demonstration of this application this will be a strong *technology push* towards customers, and also other medical device companies would be keen to implement the new medical device interface as the enabler for more closed-loop applications.

An important aspect during the project will be to build up new opinion leaders (see chapter "4.2.1 Diffusion of Innovation"), who come from the clinical side, and not anymore from the technical side.

Now that the new functionality of the innovation is easy to observe, and doesn't appear complex, as it automates the current workflow of a TIVA, a *customer pull* will start to develop, and customers, driven by their clinical expertise, will start to ask for more applications. As more applications come to market an effect will be that the rate of preventable deaths ([WHI13], p. 12) will significantly drop, which can be used to create more momentum by directly advertising this to the potential patients, meaning to everyone.

The next step for the manufacturers is to keep the momentum with customers, and broaden the open innovation project(s) so that a true standardization of the innovated medical device interoperability can happen. This way all innovation barriers that were summarized in Tab. 5 caused by either lack of *technology push* or lack of *customer pull*, can be overcome.

6 Summary and Discussion

Throughout the flow of this document three hypotheses were formulated:

Hypothesis 1 is that when functional medical device interoperability would be available, it would be the applications that make use of this interoperability that would create the customer pull (see quote from Henry Ford).

Hypothesis 1 will stay a hypothesis until really the technical concept from chapter 5.2.1 was implemented together with a first demonstrable clinical application. This is not an easy undertaking neither from the technical nor from the clinical side. Remote control of clinical devices is not really new, but a closed-loop control, or the device settings being changed by a population health management system that is hosted in the cloud (see chapter "4.4.3 Value-Based Care and Population Health Management"), is really new and will require significant investment to obtain FDA (and other regulatory agencies) approval.

Hypothesis 2 is that the needed technology to provide functional medical device interoperability is available, but not yet identified. Going for relevant technology monitoring, will certainly provide insights in possible and affordable solutions and thus provide the needed technology push.

For hypothesis 2 the required technology monitoring was done in this thesis. The outcome looks pretty promising, especially in the light of the "Internet of Things" 4th industrial revolution just taking up. The summary of the technology monitoring can be found in chapter "4.3.3.6 Summary".

Hypothesis 3 is that if *functional medical device interoperability* for the ICU and OR would be in place, to address the topic *"Adverse events avoidable with interoperability"*, not only the $2 billion of "waste" associated with that topic would go away, but as a side-effect also the other $33 billion of waste would diminish [WHI13]

Assuming that the technical concept from chapter 5.2.1 would be in place, then all devices could talk through the MQTT protocol with each other on the syntactical level. If the gateway (ALG) would export data in HL7, which would be a simple mapping exercise from MQTT to HL7, it could enrich the outgoing HL7 data stream with semantical information, by just downloading the localized labels, unit-of-measures, etc. from the *cross collaboration server* based on the

unique device identifications (UDI) of the devices. This way everything that is needed for device integration is a given, and the complex, expensive, and function-limited device integration solutions as described in chapter “3.3 Components and Topology”, would be history. Of course the gateway device would need to be offered in different “sizes” starting from a pure data export device with lowest price point, to a closed-loop control system, to a clinical decision support system getting its settings from a population health management (PHM) system in the cloud at the highest price point. Thus functional medical device interface would be a given and the $33 billion of waste would diminish in total.

7 Implications for Future Research

Future research certainly needs to focus on the following five topics:

1. The identified *technologies and protocols*, though they are not new, were never used together in the constellation specified in chapter "5.2.1 Technical Concept". Here certainly more in-depth research is required.
2. A lot of *clinical research* needs to go into future closed-loop applications, whereas it is important to note that the first application needs to make the break-through, otherwise the innovation will become a flop.
3. The *"open innovation"* projects need to carefully planned as most of the attendees will not be used to it. Thus more research needs to be done here to ensure a proper transition from NIH to Open Innovation.
4. The *cross collaboration server*, though a very important and also a new topic, needs more research. A broker needs to be established to ensure the proper use of the data. The server needs to be set-up and processes for data validation, test procedures, etc. need to be defined.
5. *Non-medical input devices:* For control of the medical devices that communicate with a gateway (ALG) also speech input (like iPhone Siri), or gesture control (like with Microsoft's Industrial Kinect) could be considered, which will be another important topic for future research.

Another aspect, that becomes obvious if thinking into the future, and which will need more research ahead of the above five topics, is how, what started as functional medical device interoperability, will evolve in its next phases. Assuming the gateway (ALG) is reality, the closed-loop control and the remote clinical decision support work well, what would be the next step?

The answer can be found in Fig. 39: Subsumption Architecture as defined by Brooks [Bro89]. Though the subsumption architecture is not the concept that we want to look at, it is the real-time systems concept of having sensors on one side and actuators on the other side with an arbitration logic in the middle. Taking the gateway (ALG) and put in the middle it could send data through ultra-wide band technology also to a standard screen, e.g. a 60" TV flat screen. In addition a tablet-type device can be used to change the settings (remote control) of all connected medical devices for a certain bed. Thus none of the devices would need their own input devices or displays anymore, they would reduce to pure

sensors for monitoring, e.g. for vital signs and for hemodynamic parameters, and to pure actuators for therapy devices, e.g. ventilators or syringe pumps.

This might be considered as an advantage by companies that want to concentrate on their core competency in therapy devices. For them it would be certainly a relief to not bother about the displays or input devices anymore, e.g. by virtualizing them through the device interface and give control to the tablet-like device that also controls the other medical devices for a bed.

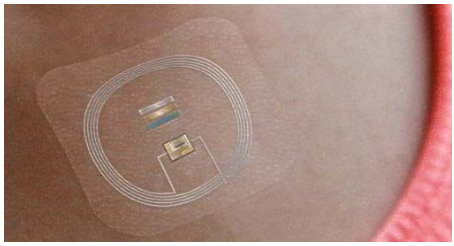


Fig. 60 Wireless, disposable wearable patch sensor [Web23]

However, companies that manufacture patient monitors will then face severe problems, because all of their current functionalities will be taken over by: 1) WPAN sensors that measure the patient parameters, see Fig. 60 2) the new gateway (ALG) that controls and integrates the other devices 3) the Clinical Decision Support and Population Health Management software that runs in the cloud and 4) the user display, which can be any standard LCD screen that has a wired or a wireless connection to the gateway (ALG). Thus the patient monitor companies need either to innovate their business model and take the steps like outlined in chapter "5.2.2 Technology Push and Customer Pull Concept", or they will lose their high-end patient monitoring market segment, which represents the majority of the currently 2 B€ patient monitoring market.

In conclusion, the biggest interest for *functional medical device interoperability*, like researched and outlined in this master thesis, should come from the top three vendors in patient monitoring which are Philips, GE, and Mindray. On the other hand, this will be an opportunity for companies like Bosch, coming from the IIoT side, or IBM, which could give "Dr. Watson"[22] the needed eyes (sensors) and hands (actuators) to not just provide clinical decision support, but directly treat patients.

[22] http://www.ibm.com/smarterplanet/us/en/ibmwatson/health/

Appendix A

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