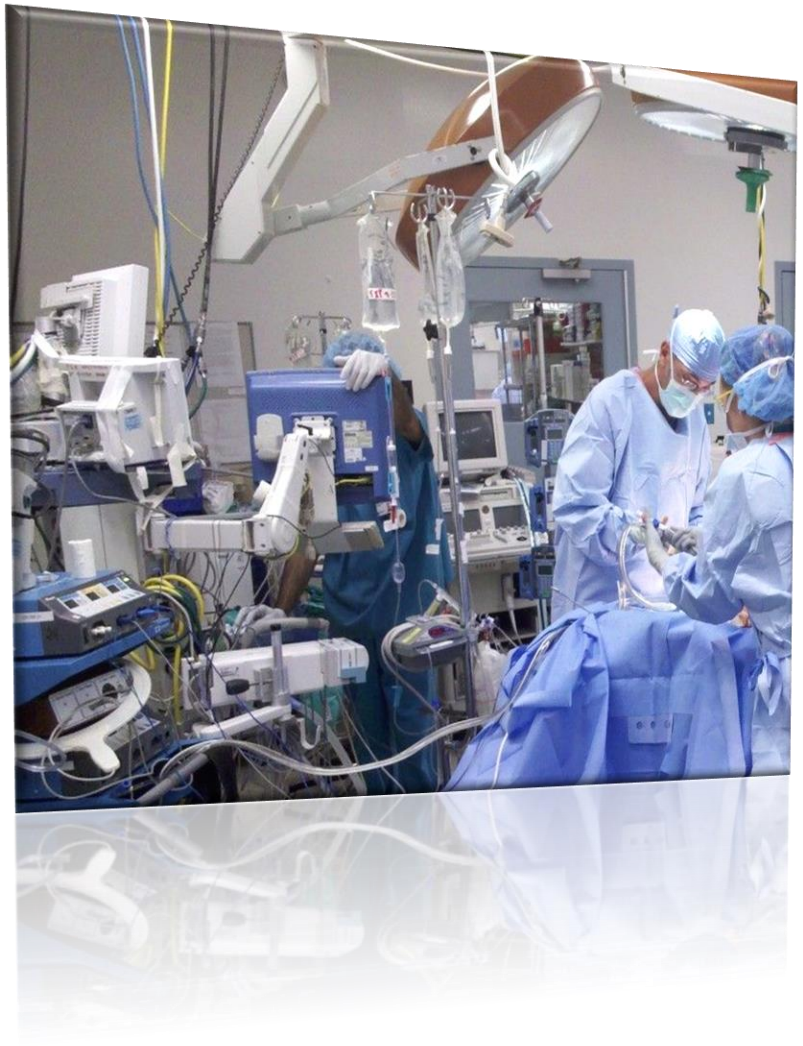
Regulatory implications for medical devices, used in an interoperable open network ecosystem

March 2022

Interoperability



interoperability noun

Save Word

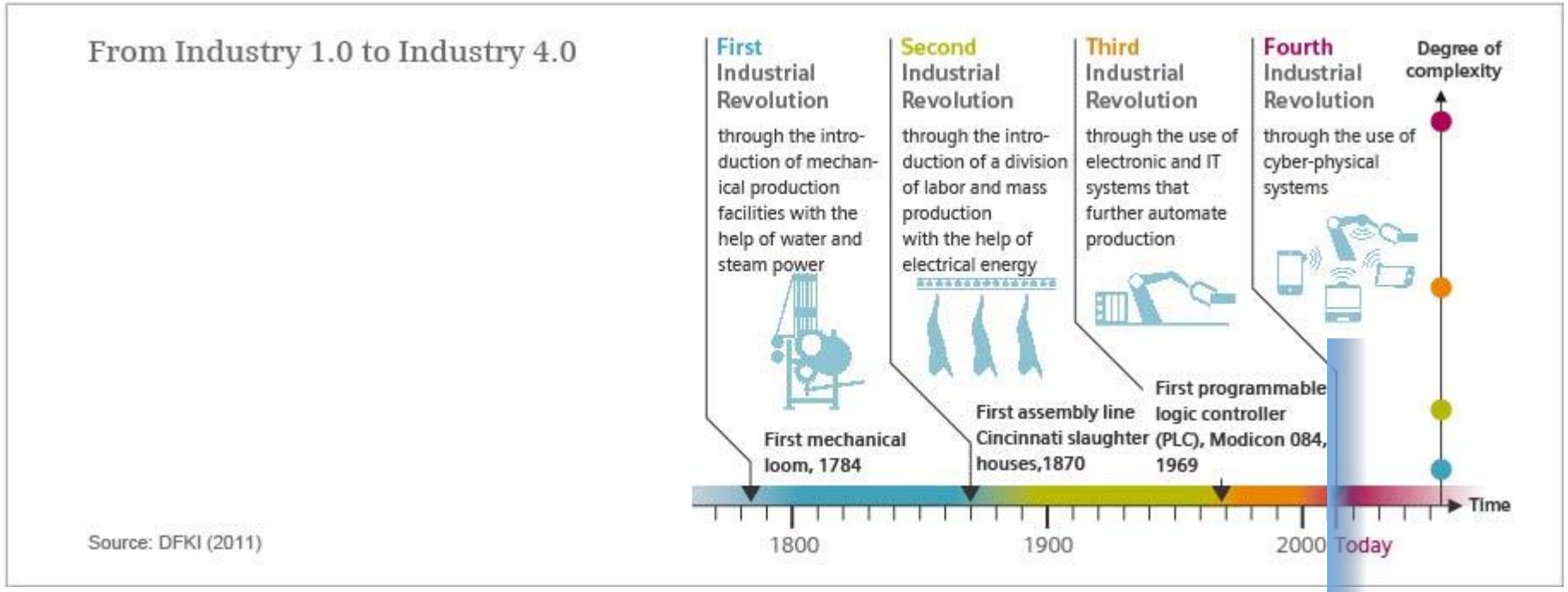
in·ter·op·er·a·bil·i·ty | \ ˌin-tər-ˌä-p(ə-)rə-ˈbi-lə-tē \

Definition of *interoperability*

: ability of a system (such as a weapons system) to work with or use the parts or equipment of another system

https://www.merriam-webster.com/dictionary/interoperability

Why?



object ive

connect ive

autonomy

synergy

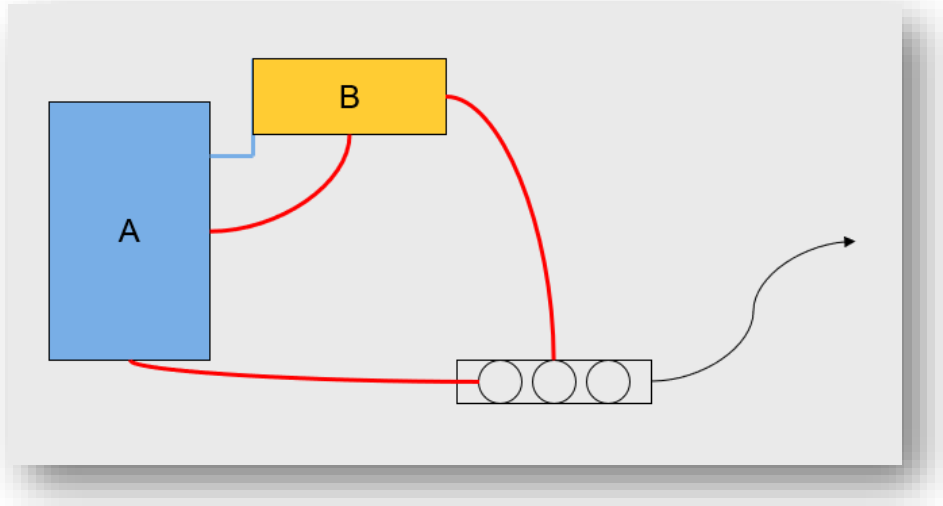
Scope IEC 60601 series

This International Standard applies to the
BASIC SAFETY and ESSENTIAL PERFORMANCE of
MEDICAL ELECTRICAL EQUIPMENT
and MEDICAL ELECTRICAL SYSTEMS,
hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so.
If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

Definitions

3.64
* MEDICAL ELECTRICAL SYSTEM
ME SYSTEM
combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET
NOTE Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.



3.33
* FUNCTIONAL CONNECTION
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances
NOTE Connection to a FIXED SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

ME Systems Aproach

RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

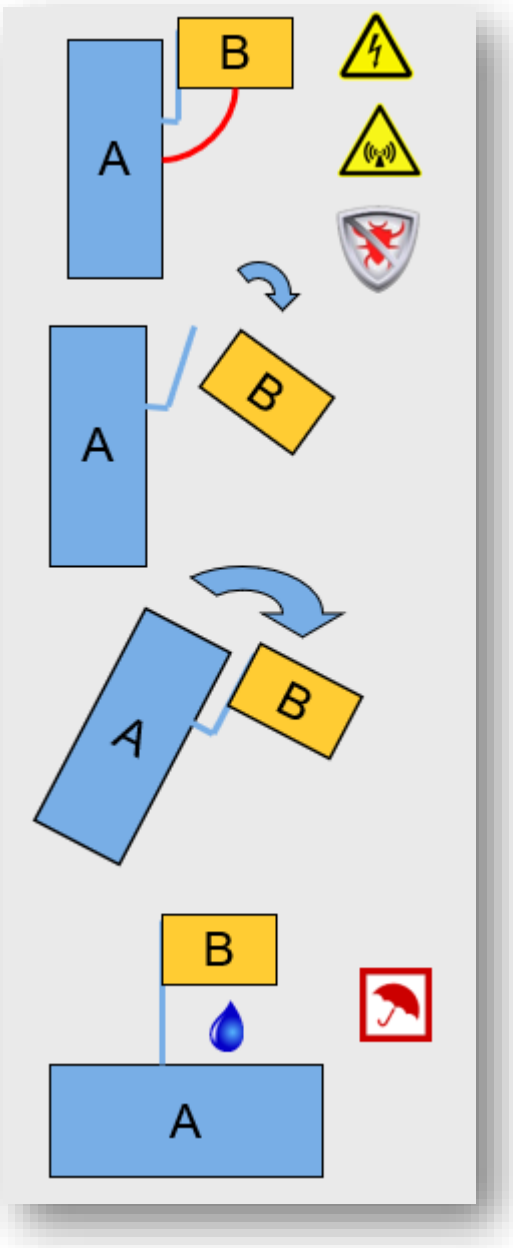
Protection against electric shock

Protection against harmful ingress of water or particulate matter

Protection against MECHANICAL HAZARDS

Protection against unwanted and excessive radiation HAZARDS

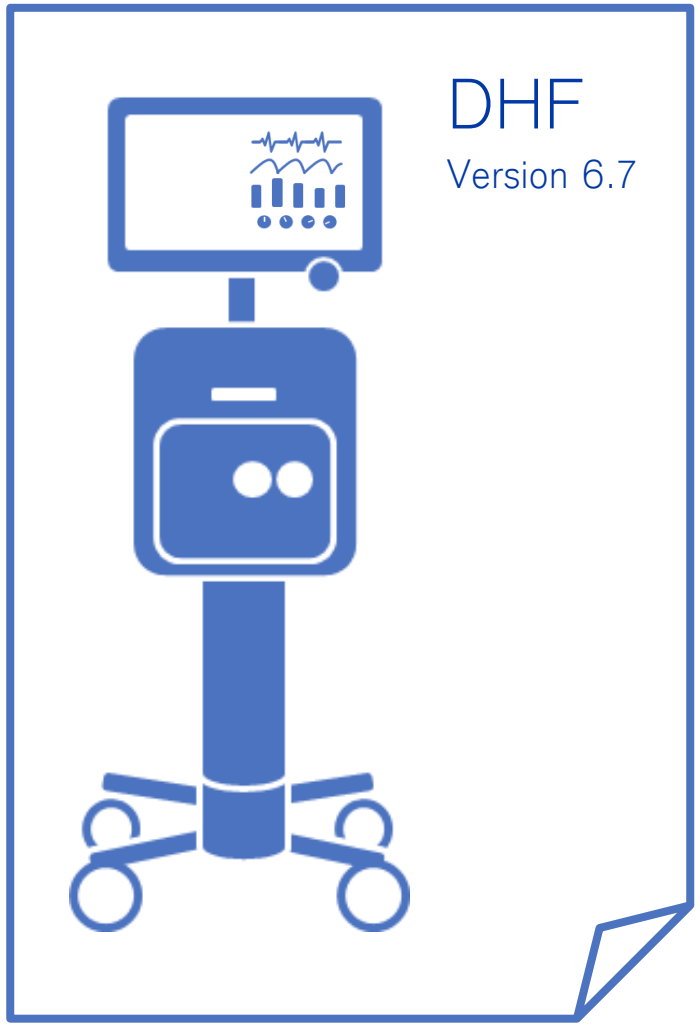
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

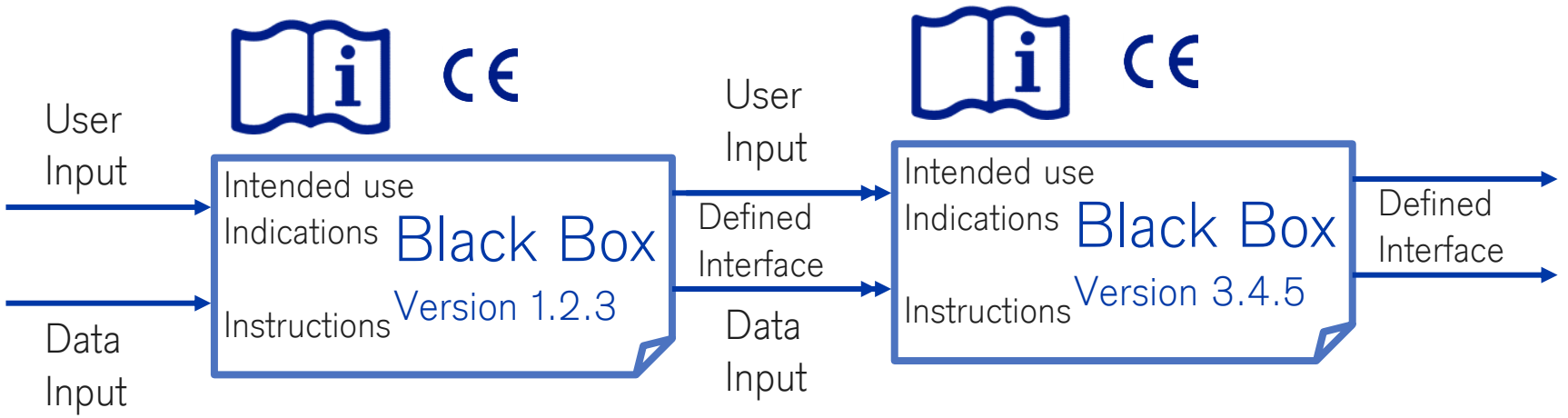


MDR

Article 22
Systems and procedure packs
1. **Natural or legal persons** shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, **in order to place them on the market** as a system or procedure pack:
(a) other devices bearing the CE marking;
(b) in vitro diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746;
(c) other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.

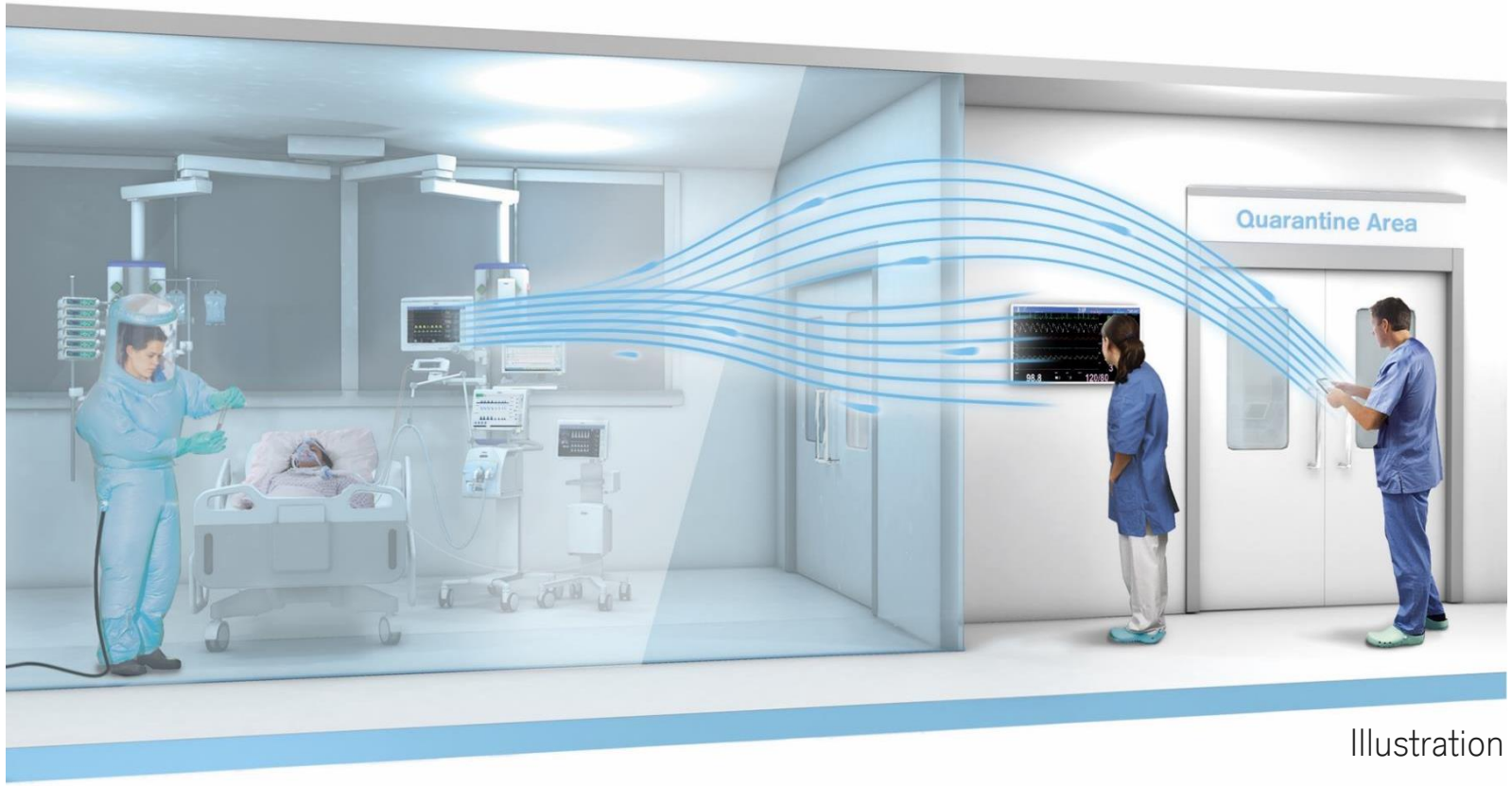
Regulatory cookbook (yesterday!)





3rd Party combination testing on Black Box level
(Art. 22 MDR)

Products

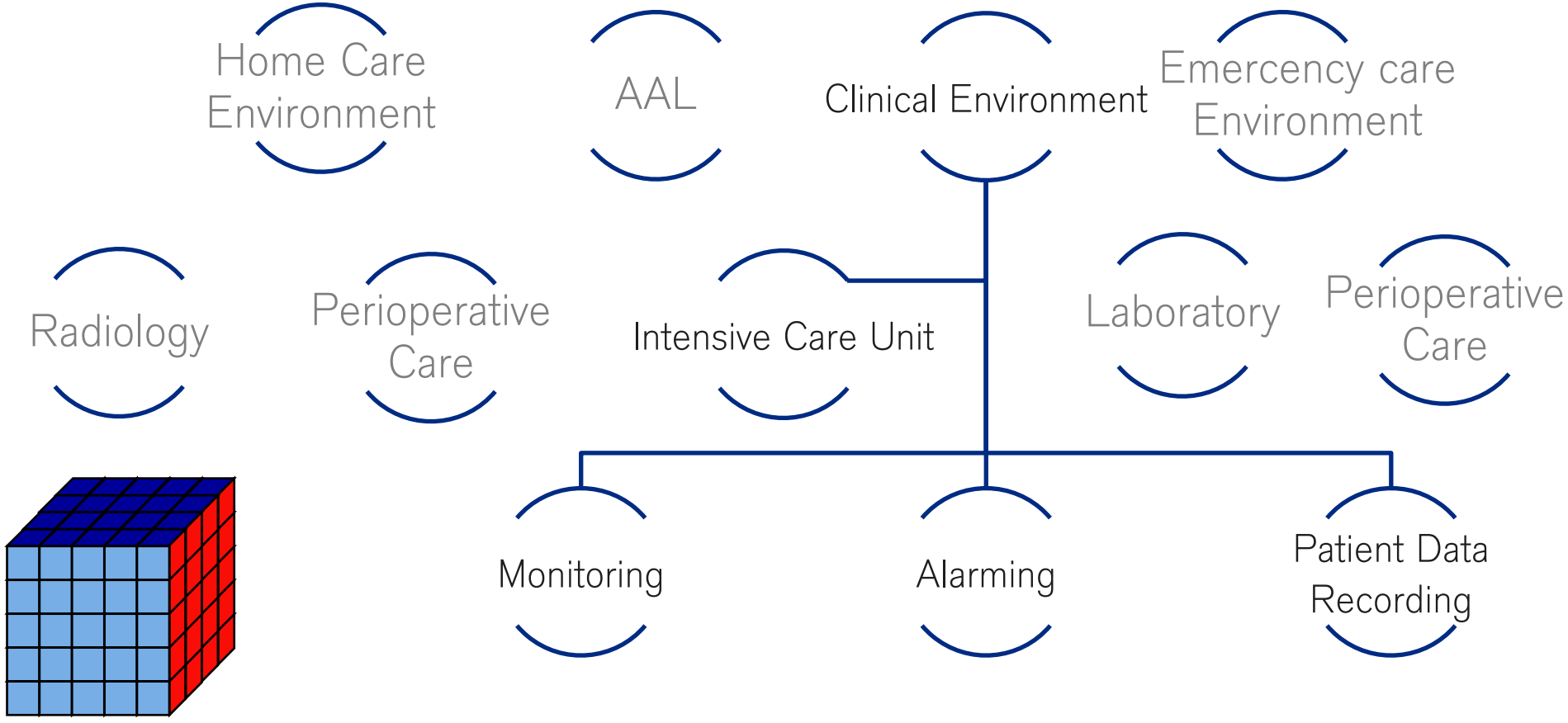


Illustration

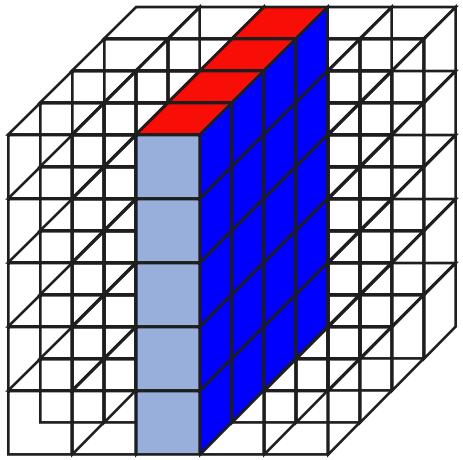
used in the digital age

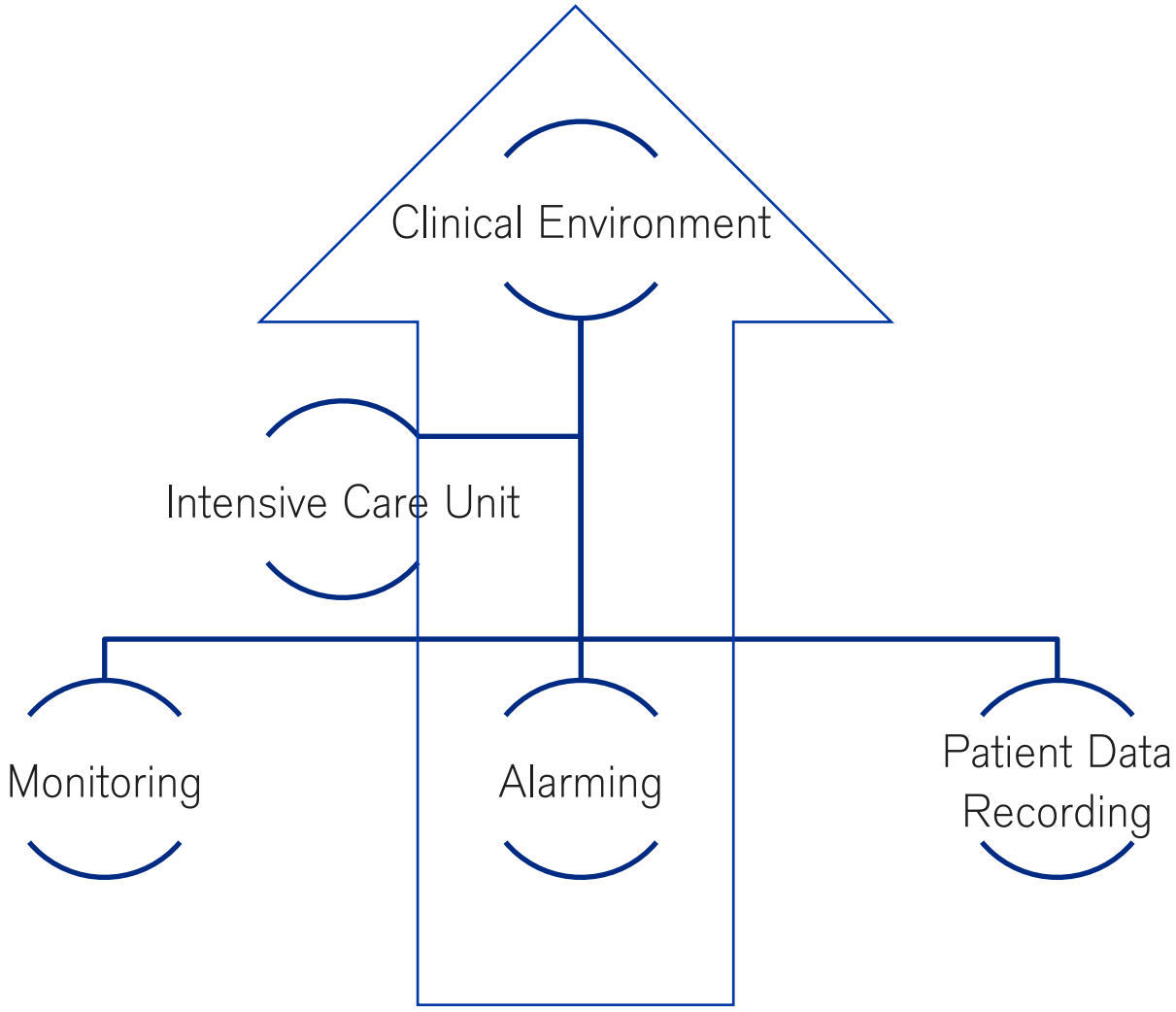
follow new rules

Products in a “System”

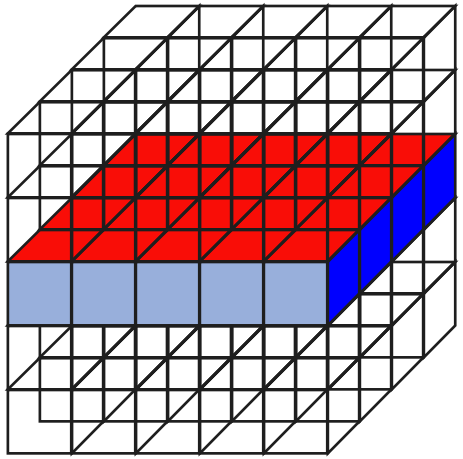


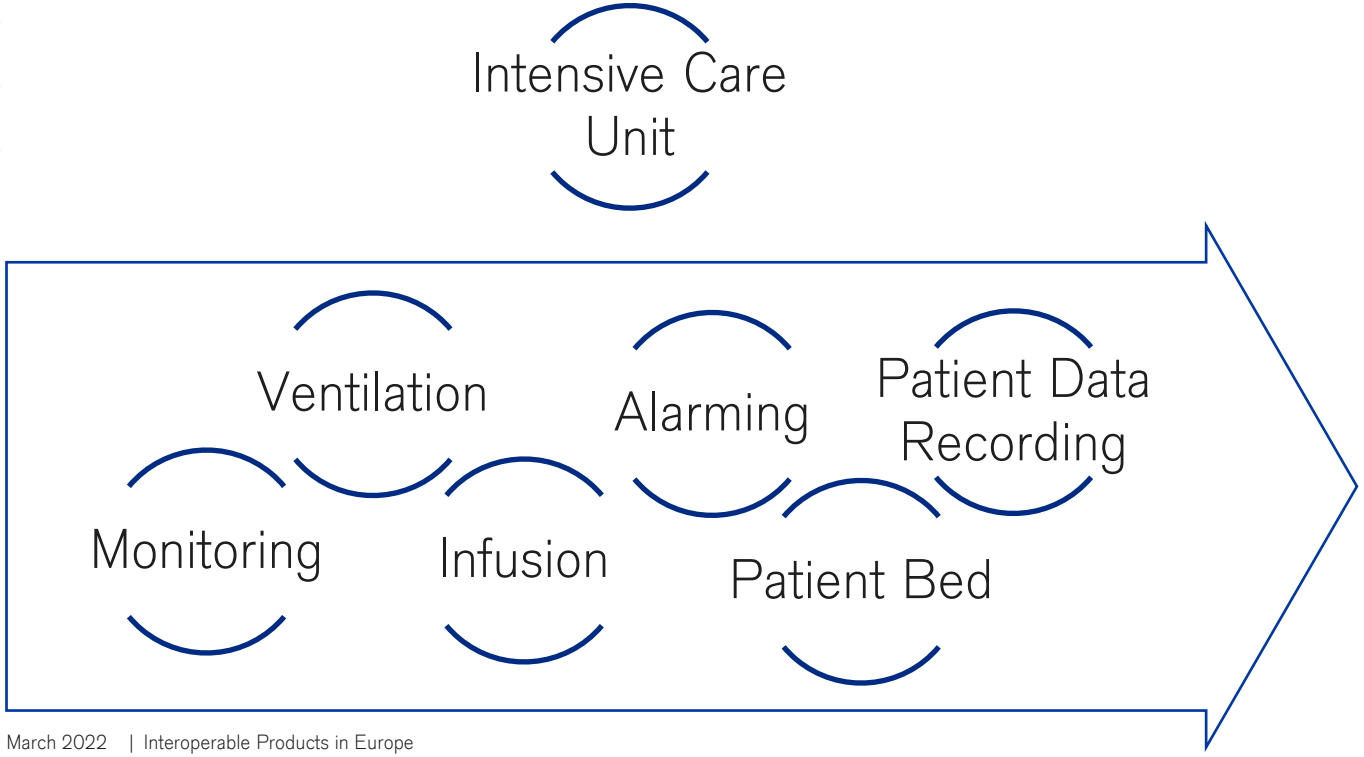
The box view – ME Equipment



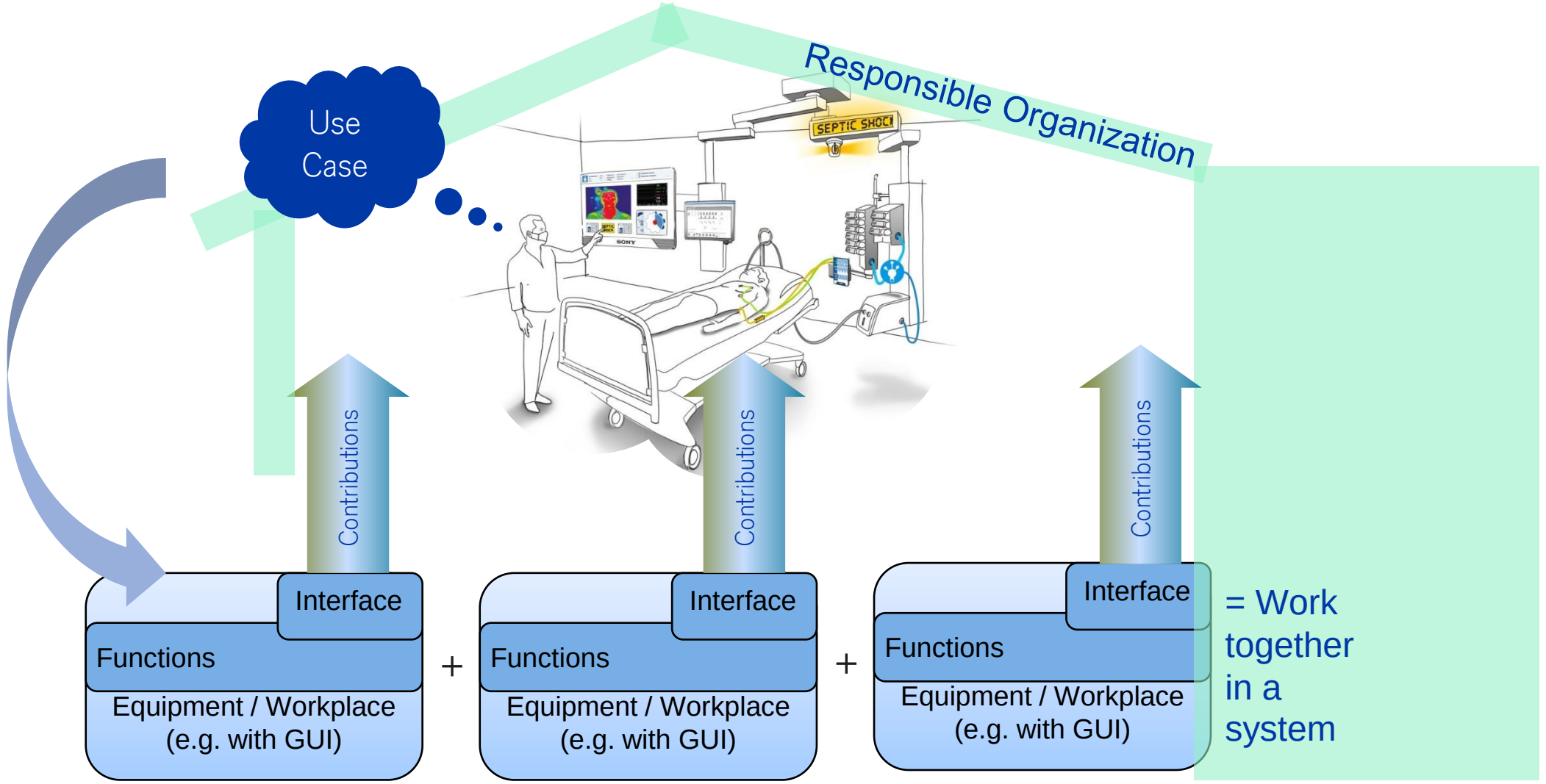


The clinical process view for clinical outcome

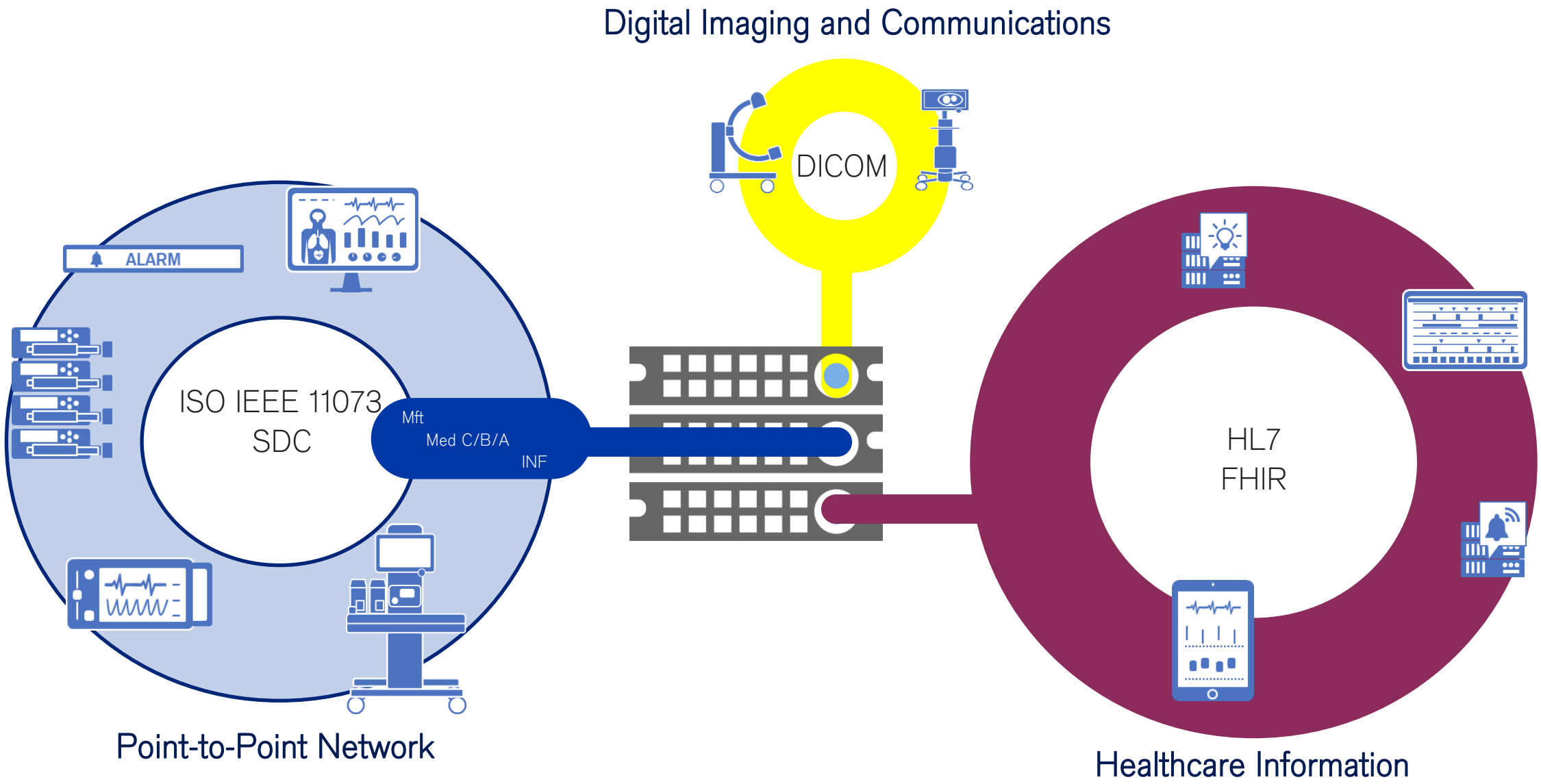




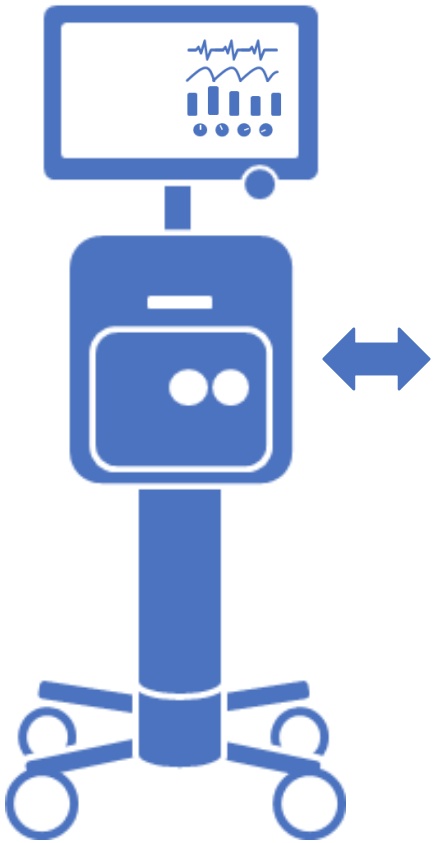
The mental model



Examples of Interoperability



Regulatory strategy



Safety and performance requirements for the medical device

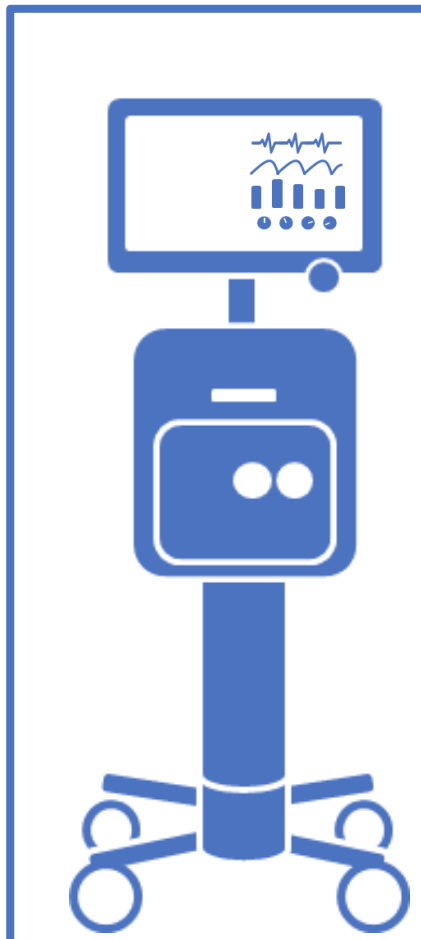
+

System Functionality

+

Interoperability contributions

Regulatory cookbook (tomorow!)

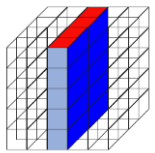


DHF

Coherent validation against clinical functionality

Baseline 1.2.3.4

Interface test and description:
- Structural level
- Syntactic level and
- Semantical level



Use Case

Use Case

Publicaltion and baseline of:

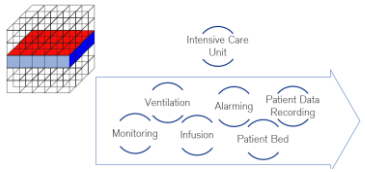
Safety and performance requirements for the medical device

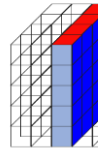
+

System Functionality

+

Interoperability contributions





Regulatory cookbook
Manufacturer Approach

Specify product clinical use and clinical functionality

Specify interface conditions with its safety and security for the component as well as eco-system used

Specify consistent risk management and human factors engineering for all SDC participants

→

STANDARDIZED

Define and publish methods and steps necessary to verify and validate correct functionality of an SDC participant without knowing the other participants in an SDC system

Specify and publish test baselines

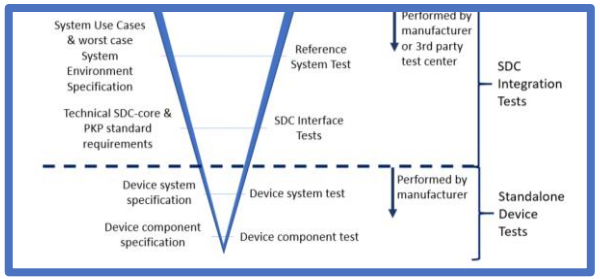
STANDARDIZED

→

Develop product incl. IFU and technical description of the product with all relevant interface aspects (e.g. ISO20417 cl. 6.6.4 c))

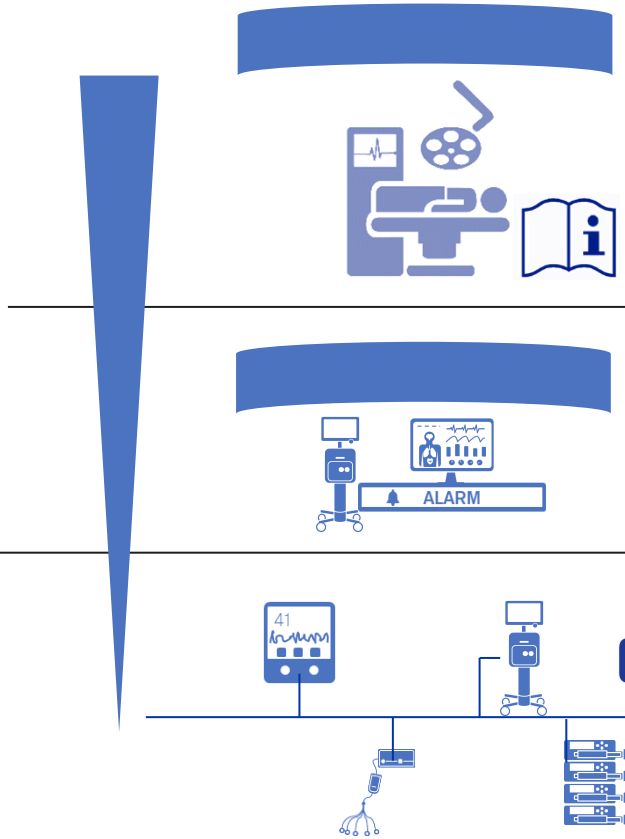
→

Product testing, VV and approval against GSPRS or approval against substantial equivalent product



→ CE

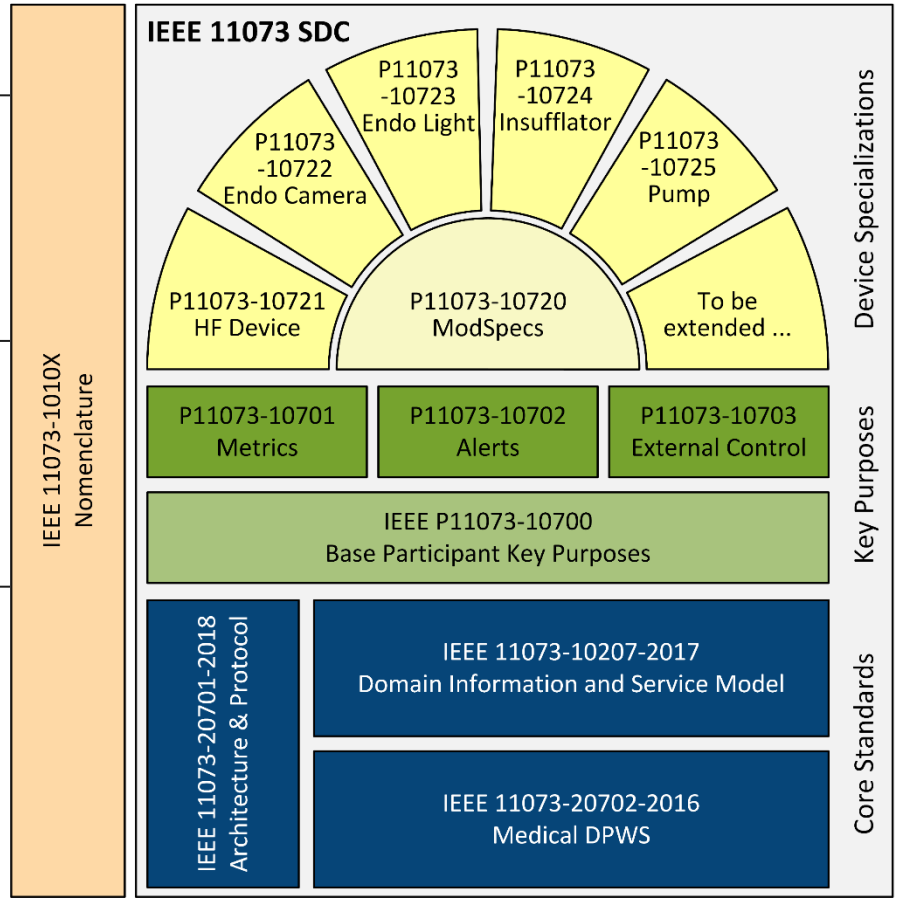
Level of Interoperability



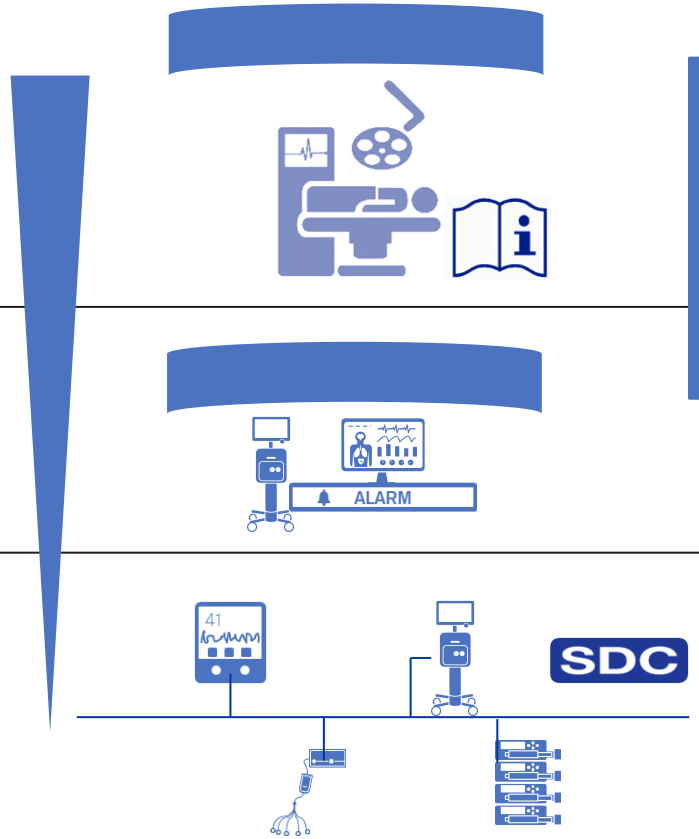
Integration of function

Domain Specific standardized Information models (PKP)

Standardized Safe and Secure meshed network



Impacting GSPRs



Integration of function

For devices intended for use together with other devices and/or general purpose equipment: information to identify such devices or equipment, in order to obtain a safe combination, and/or information on any known restrictions to combinations of devices and equipment;

Domain Specific standardized Information models (PKP)

Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

Integration Roles, Responsibilities and Activities for Health Care Facilities		IEC 80001-1 IEC 81000 series
Integration: • Typical functionality in reference System		*Annex I – 14.5*
Validation: • PKB • RM • HF • TDoc	IEEE P11073-xxx ISO 14971 IEC 60601-1-6 ISO 20417	*Annex I – 14.1* *Annex I – 3* *Annex I - 6.1* *Annex I - 5* *Annex I – 14.1* ***Annex I - 23***
Verification: • Interfacetest • Cybersecurity • Authentication • Encryption	IEEE P11073-10700 IEC 60601-4-5 IEC 60601-xxx	***Annex I – 14.5*** *Annex I – 17* *Annex I – 18*

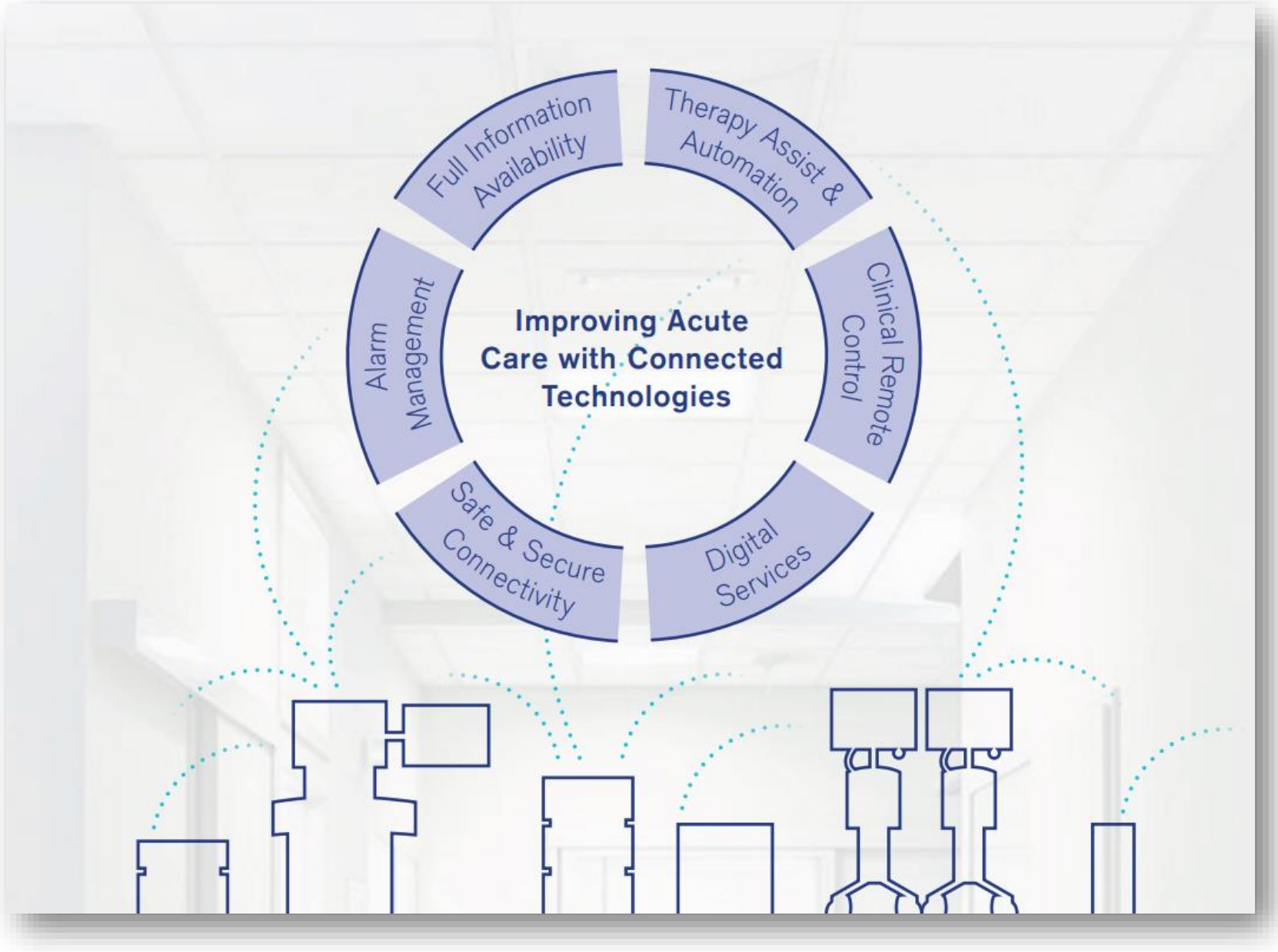
ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

6.2. Additional information required in specific cases

(g) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including **proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer**.



Looking forward to connecting with you

Matthias Marzinko
Director International
Standards Management (ISM)
RA Lead Open Network Ecosystems (ONE)

23558 Lübeck, Germany
matthias.marzinko@draeger.com

Dräger. Technology for Life®