



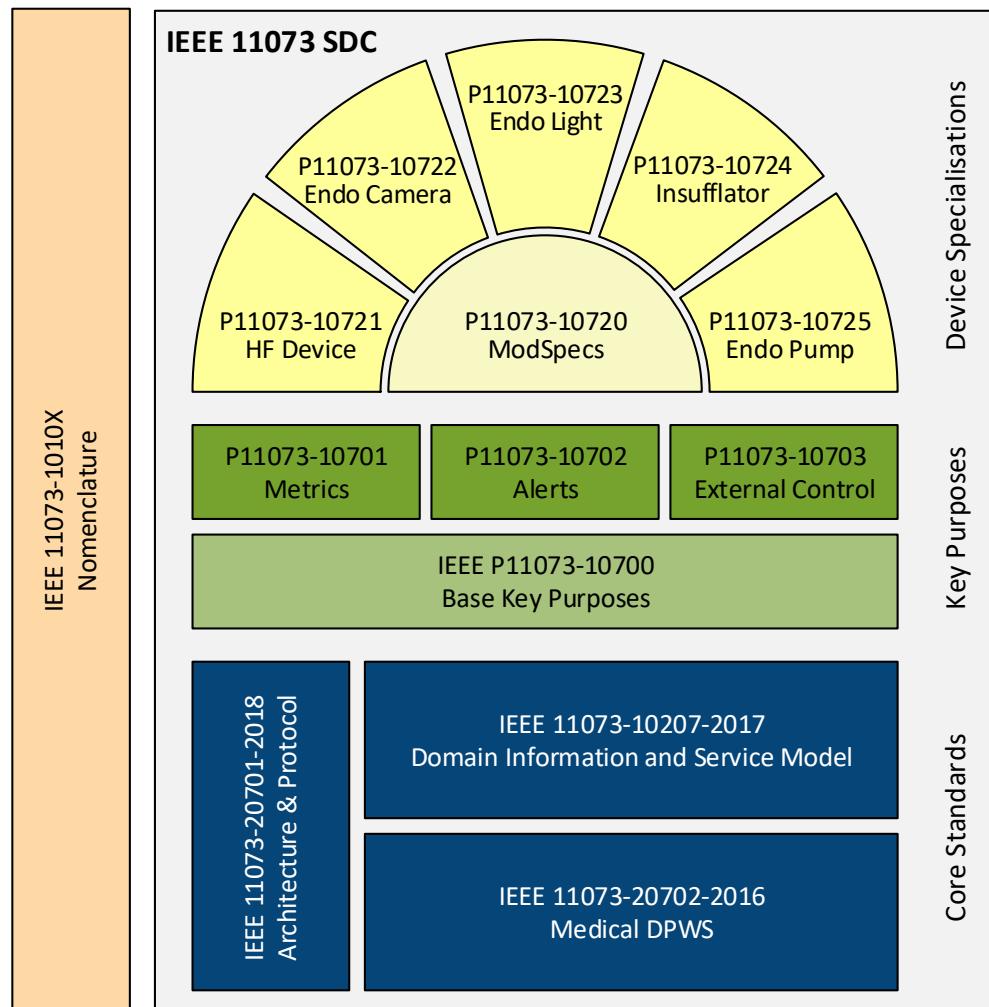
## Update: IEEE 11073 SDC Standardization Activities

Anton Keller (Aesculap AG), Martin Kasparick (University of Rostock),  
Stefan Schlichting (Drägerwerk AG & Co. KGaA)

# IEEE 11073 SDC at DMEA Trade Fair 2019 in Berlin, Germany



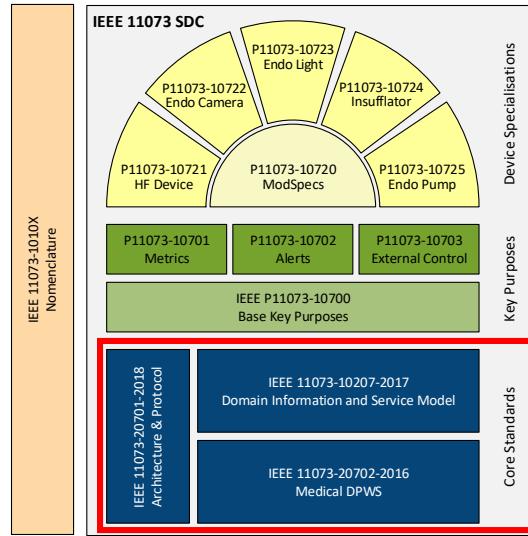
# IEEE 11073 SDC Family of Standards





# IEEE 11073 SDC Core Standards

- Adopted and published:
  - ISO/IEEE 11073-20702: Medical DPWS
  - ISO/IEEE 11073-10207: Domain Information and Service Model
  - IEEE 11073-20701: Architecture and Binding  
→ ISO adoption in progress
- Current work: Errata, corrigenda and amendments (discussion can be tracked publically)
  - <https://sourceforge.net/p/opensdc/ieee11073-10207>
  - <https://sourceforge.net/p/opensdc/ieee11073-20701>
  - <https://sourceforge.net/p/opensdc/ieee11073-20702>





# IEEE 11073 SDC Core Standards

SOURCEFORGE

Open Source Software Business Software Services Resources Help Create Join Login

Home / Browse / openSDC / 11073-10207 Amendments, Corrigenda & Errata

 **openSDC**  
OpenSDC facilitates development of dist. systems of medical devices.  
Status: Beta Brought to you by: d-gregorczyk, klotzt, schlich09, steph96

Summary Files Reviews Support Tickets ▾ Git ▾

Search 11073-10207 Amendmen

Create Ticket View Stats Milestone Errata (32) Amendments (19) Corrigenda (15) Searches Changes (66) Closed Tickets (0)

11073-10207 Amendments, Corrigenda & Errata

Showing 25 results of 66

#	Summary ▾	Milestone ▾	Status ▾	Owner ▾	Created ▾	Updated ▾	<input type="button" value="⚙"/>
66	B.66, B.382, B.383 'Used by' missing	Errata	open		2019-04-09	2019-04-09	
65	B.9 AbstractContextState - clarify relations between binding versions and context association	Errata	open		2019-04-05	2019-04-05	
64	Instance Identifier comparison fix	Corrigenda	open		2019-03-21	2019-03-21	
63	Change documentation of RealTimeSampleArrayMetricDescriptor	Corrigenda	open	Stefan Schlichting	2019-03-19	2019-03-19	
62	Add information about the effect of Standby	Corrigenda	open	Stefan Schlichting	2019-03-19	2019-03-19	
61	Non-linear technical ranges	Amendments	open		2019-02-27	2019-02-27	
60	Clarify the behavior of pm:VersionCounter in case of multiple changes	Amendments	open		2019-02-27	2019-02-27	

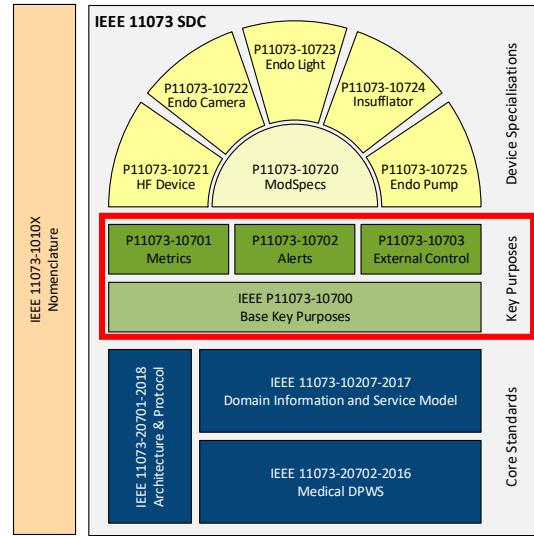
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# IEEE 11073 SDC Key Purposes

- Active IEEE projects
  - IEEE P11073-10700: Base Key Purpose
  - IEEE P11073-10701: Metrics
  - IEEE P11073-10702: Alerts
  - IEEE P11073-10703: External Control
- Approved as ISO/PWI by ISO/TC 215





# SDC Conformance Principles

This document describes the concepts

- how Safety and Effectiveness of these Medical Devices and their System Functions Contributions is achieved
- and defines rules for the development of an SDC Participant and for post-production activities of the manufacturer.

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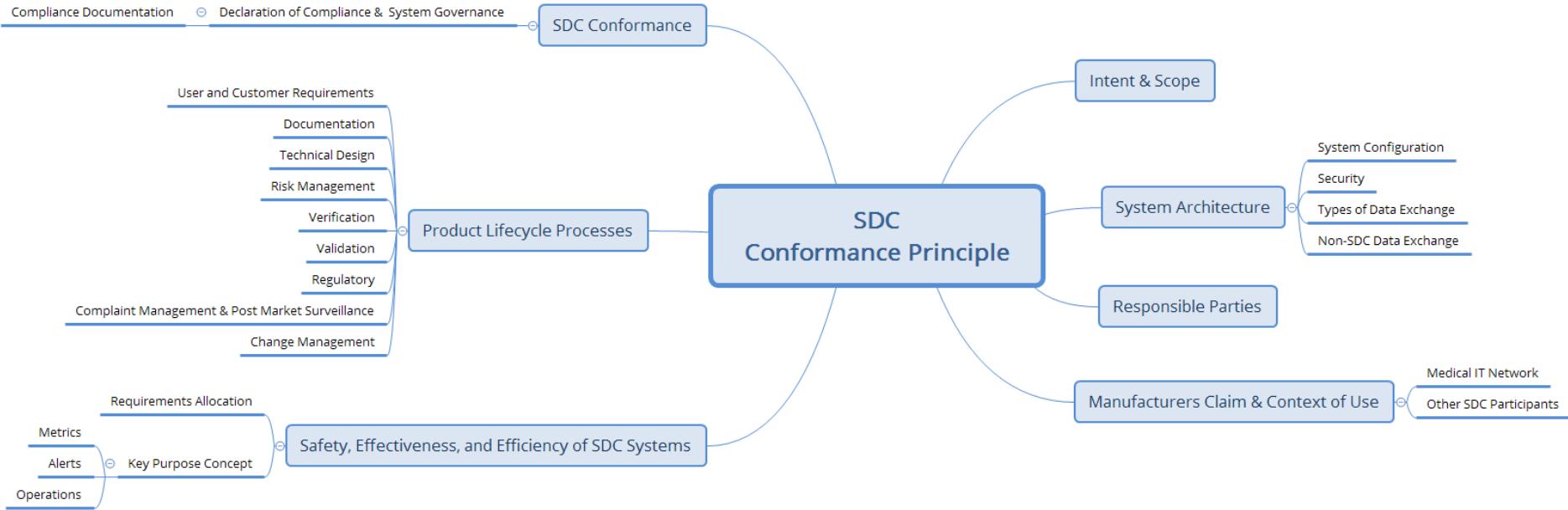
SDC Conformance Principles

WORK IN PROGRESS

REV: 01 | SDC Conformance Principles | Page / of 1 / 25

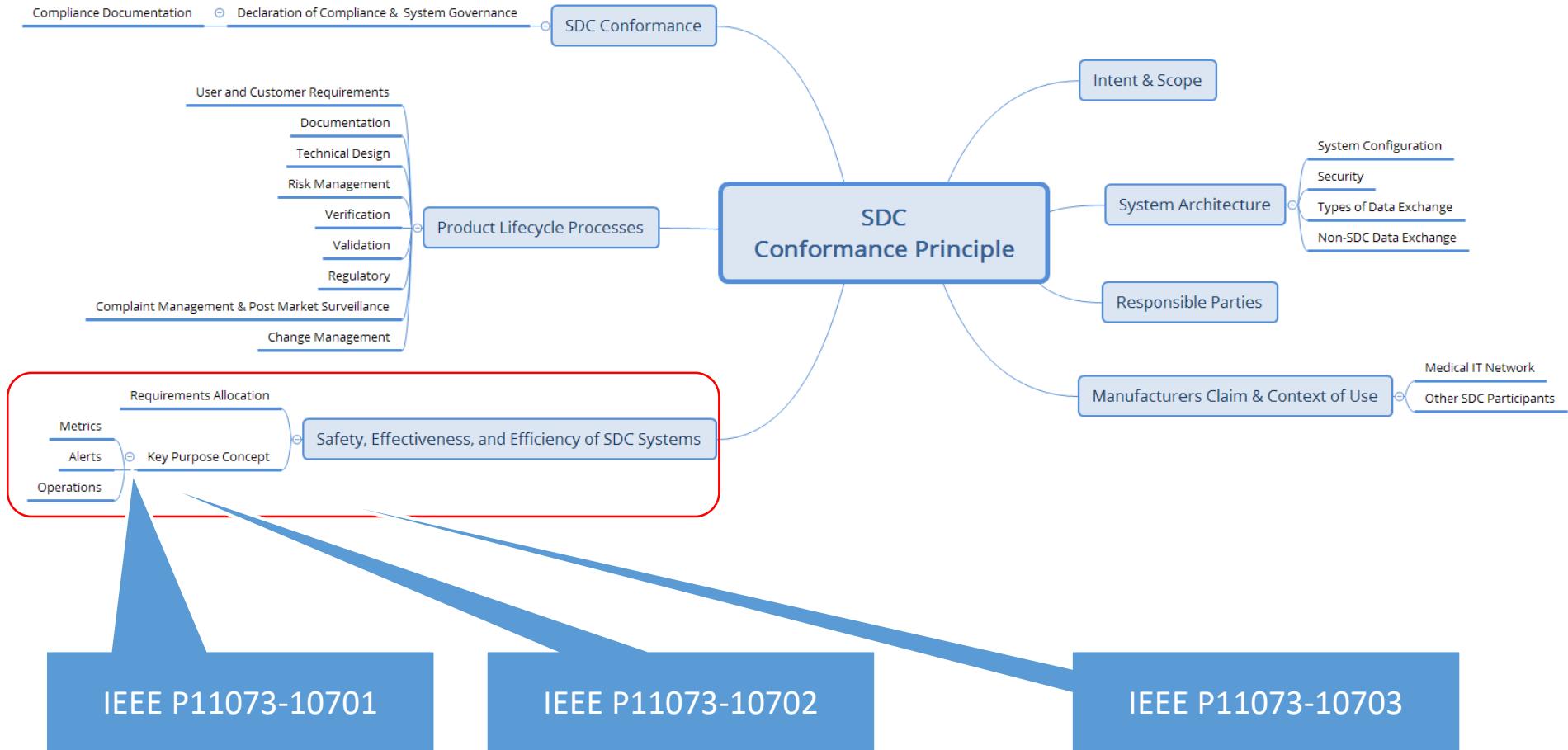


# SDC Conformance Principles System Function Contributions





# SDC Conformance Principles System Function Contributions



# IEEE P11073-10700 D0 „Process Requirements“



## 6 Responsibilities for Participants

### 6.1 Labelling

In order for determining which System Functions can be expected from a combination of SDC Participants, the Responsible Organization has to use the information given in the IfUs or accompanying technical documentation.

This section contains general requirements regarding Labelling. Labelling requirements for specific topics can be found in the corresponding sections.

#### 6.1.1 Conformance

The Manufacturer of a Participant shall make available a list of all non-conformities affecting its system function contributions.

The Manufacturer of a Participant shall state its intended system function contributions in its IfU.

#### 6.1.2 Medical IT Network

The accompanying documentation of the Participant should declare



# IEEE P11073-10700 D0 Conformance check statements

~~SDC. Log into system to analyze system actions.~~

An SDC Participant shall protect log information required by an SDC Participant Key Purpose against undetectable manipulation.

An SDC Participant shall use timestamps in the log book that have the same resolution as the clock object

## 7.3 Load Conditions

### 7.3.1 Maximum Load Conditions

An SDC Participant shall provide its declared system function contributions under maximum load conditions of normal use.

#### 7.3.1.1 Conformance Evidence

Conformance is checked by functional testing using the following constraints.

Maximum load conditions of normal use for cable-bound SDC Participants comprise:

- bandwidth restricted according to minimum required bandwidth



# IEEE P11073-10700 D0 Considered Risks

## 9 Considered Risks (Informative)

System participation is a necessary precondition to contribute to system functions, but it does not constitute a user function on its own.

This chapter therefore does not focus on hazards related to a system function, but rather on contributing factors that are common to all Participants .

Considered hazards related to all Participants are:

- Participants impairs IT network communication of other devices
- Participants becomes a stepping stone for cybersecurity attacks

Considered contributing factors for a Participant are:

1. a Participant consumes available network bandwidth
2. a malicious attacker extracts a Participants certificate and uses it to impair other Participants
3. a malicious attacker comprises the software of a device and uses it to impair other Participants

# IEEE P11073-10107 External Control Nomenclature



- Currently we expect approx. 100 Terms for Operations
- If you have a more Operations, please provide them!

Ref Id	Common Name	Description
MDC_ACT_SET_TIME_ZONE	Set Time Zone	An Operation to set the TimeZone of a Clock.
MDC_ACT_SELECT_MODE	Select Mode	An Operation to set the Value of a mode Metric from AllowedValues.
MDC_ACT_SET_LOWER_LIMIT	Set Lower Limit	An Operation to set the lower limit value of a limit alert condition.
MDC_ACT_SET_UPPER_LIMIT	Set Upper Limit	An Operation to set the upper limit value of a limit alert condition.
MDC_ACT_CLEAR_PATIENT_VALUES	Clear patient Values	An Operation to clear the patient specific values of a Containment Tree Entry.
MDC_ACT_SET_TIME_SYNC_REF_SRC	Set Time Sync Ref Src	An Operation to set the active reference source of a clock for time synchronization.
MDC_ACT_UNLOCK_OPERATOR_PANEL	Unlock Operator Panel	An Operation to activate the operator panel of a device for operator interaction.
MDC_ACT_LOCK_OPERATOR_PANEL	Lock Operator Panel	An Operation to deactivate the operator panel of a device for operator interaction.
MDC_ACT_SET_ALL_AUDIO_PAUSE	Set All Audio Pause	An Operation to set the audible systems signal activations of a alert system to paused .



# Status of PARs

- IEEE P11073-10107 (External Control Nomenclature)
  - Content collection
- IEEE P11073-10700 (Base Purpose)
  - Draft 0
- IEEE P11073-10701 (Device Status, Metrics)
  - Draft 0
- IEEE P11073-10702 (Alerting)
  - Content collection
- IEEE P11073-10703 (External Control)
  - Content collection

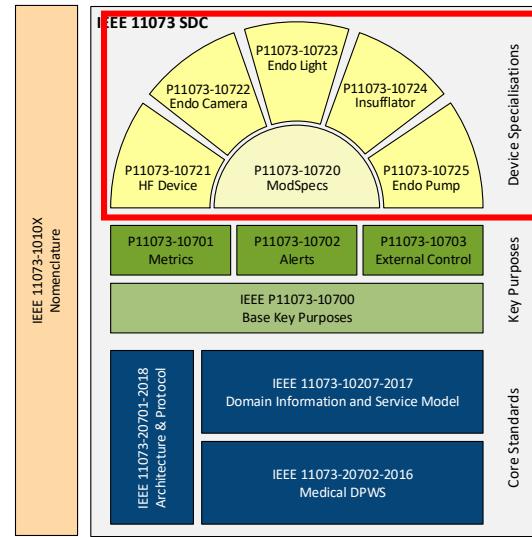
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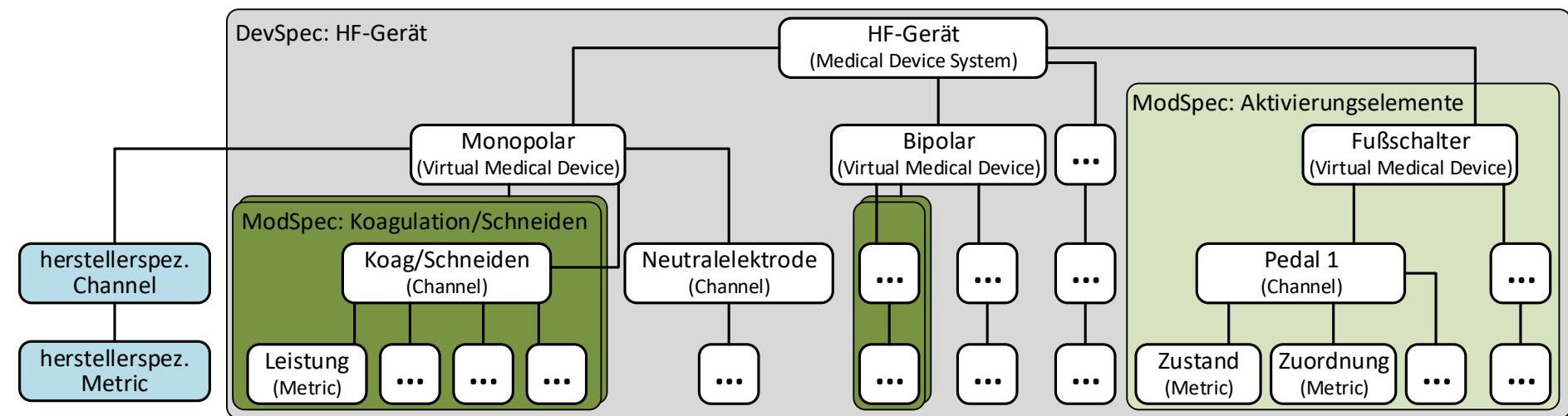
# IEEE 11073 SDC Key Purposes

- Device Specializations:
  - High Frequency (200 kHz to < 5 MHz) Surgical Equipment
  - Endoscopic camera
  - Endoscopic light source
  - Endoscopic insufflator
  - Endoscopic pump
- Module specifications





# DevSpecs and ModSpecs





# PoCSpec Project – Developing DevSpecs

- Strong manufacturer involvement:
  - Funded partners: Aesculap, BOWA, embeX, Erbe Elektromedizin, Karl Storz, Olympus Winter & Ibe, Open Connections
  - Associated partners: Dräger, Schöelly Fiberoptic, steute Technologies, surgiTAIX
- Academic partners: University of Lübeck, University of Rostock, OFFIS Institute for Information Technology Oldenburg (coordinator)

# PoCSpec

Modular Specialisations for  
Point-of-Care Medical Devices

# PoCSpec Project – Current Work



- Deep discussion between partners
  - Evaluation of common and different devices features
  - Classification into mandatory, recommended, optional, etc. features
  - First steps towards IEEE 11073 SDC DIM modelling

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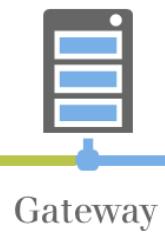
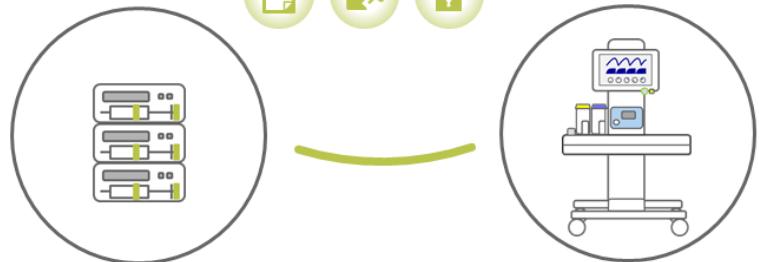
# IEEE 11073 SDC and HL7 Complementing Standards



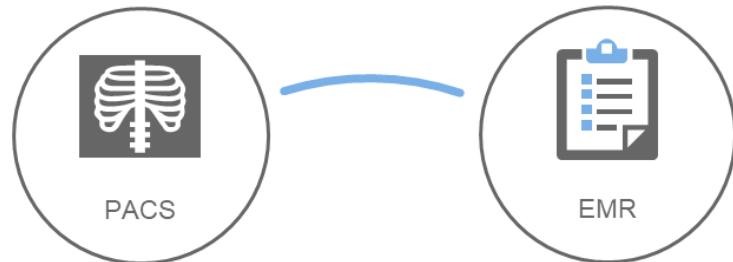
POINT OF CARE NETWORK



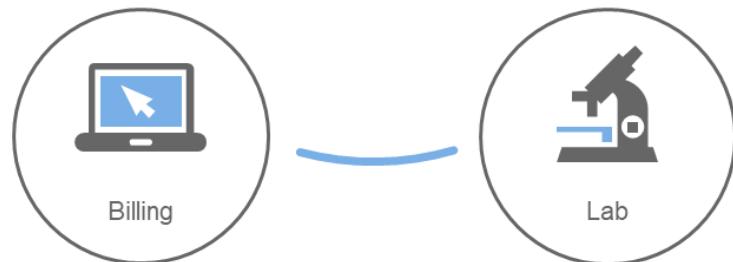
IEEE 11073 SDC  
bidirectional device-to-device  
communication



HOSPITAL IT NETWORK



e.g. HL7 or  
DICOM  
exchange and storage of healthcare  
information





Thank you!

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