Service-Oriented Medical Device Connectivity: Particular Standards for Endoscopic Surgery*

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***Abstract*— To translate recent advances in medical device interoperability research into clinical practice, standards are being developed that specify precise requirements towards the network representation of particular medical devices connecting through ISO/IEEE 11073 SDC. The present contribution supplements this protocol standard with specific models for endoscopic camera systems, light sources, insufflators, and pumps. Through industry consensus, these new standards provide modular means to describe the devices' capabilities and modes of interaction in a service-oriented medical device communication architecture. This enables seamless data exchange and the potential for new assistive systems to support the caregiver.**

***Clinical relevance*— Interoperable medical devices in endoscopic surgery are going to improve the clinical workflow by facilitating smart communication and interaction between the components in the operating room. This allows for new functionality and improved usability; ultimately reducing the stress experienced by the staff and increasing patient safety. In addition, easy access to medical device data will yield high-quality data sets for clinical research.**

I. INTRODUCTION

More than a decade of research and prototyping preceded the successful standardisation of a service-oriented medical device communication architecture that is now known as *IEEE 11073 Service-oriented Device Communication (SDC)* [1]. This series provides a domain information and service model as well as a communication profile for web services, both of which are bound into a data exchange protocol for point-of-care medical device communication. SDC thus enables manufacturer-independent interoperability for integrated systems in the operating room (OR), intensive care unit (ICU), or emergency department (ER).

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To further increase this interoperability, another set of standards is currently being developed. These *Participant Key Purposes* will specify additional requirements towards SDC participants in general, in their roles as providers and consumers of metric data, of alerts, and of external control. These standards are more specific than the core series, yet independent of actual devices and clinical use cases. [2]

Whereas the exchange architecture and protocol are specified in much detail, there remains freedom in applying the standard to modelling the network representation of real-world medical devices [3]. This is intended but only partly desired: If two functionally similar devices from different manufacturers differ greatly in their model structure, their data may still safely be interpreted by a communication partner. Yet there are application cases such as external control in which a service consumer may require a certain standardised structure of the provider in order to keep the implementation complexity manageable [4].

To address this issue, device manufacturers and connectivity experts conceived the research project *Modular Specialisations for Point-of-Care Medical Devices (PoCSpec)*. It aims to translate the research on device modelling, early SDC demonstrator prototypes, and the manufacturers' expertise in specific medical device functionality into a set of particular standards for two prominent surgical domains: endoscopic devices and high-frequency (HF) surgical equipment.

This paper presents the current progress on the draft standards of these so-called *Device Specialisations* for the following types of endoscopic equipment.

- IEEE P11073-10722: Endoscopic camera
- IEEE P11073-10723: Endoscopic light source
- IEEE P11073-10724: Endoscopic insufflator
- IEEE P11073-10725: Endoscopic pump

To cover the common features and operating modes of current and future devices, these specify the structure of the devices' capability descriptions, the semantics of their functionality, requirements towards communication partners, and the patterns of interacting with other components.

The actual images and video streams are out of scope as they are already addressed by other standards such as Digital Imaging and Communications in Medicine (DICOM).

II. MEDICAL DEVICE MODELLING

The models presented in this work are themselves specialisations of the ISO/IEEE 11073-10207 domain information and service model for point-of-care medical devices. Consequently, all instances of these models are organised on four

levels of a tree-like containment hierarchy. The device as a whole is represented by a *MedicalDeviceSystem (MDS)*, whereas specific functionality, logical or physical component, is modelled as a *VirtualMedicalDevice (VMD)*. On the third level, *Channels* are logical groupings of the leaf-node *Metrics* that constitute the actual measurements, calculations, and settings. For the sake of clarity, the individual Metrics are not presented in detail in the following sections.

Functionally similar subsystems that are present in very different types of medical devices are being collected and documented for the IEEE P11073-10720 Modular Specifications standard, which will serve as a library of functionality sub-models. An example can be found in Sec. V-B.

Device Specialisations provide descriptive capabilities for some non-essential functions that are not mandatory in the standards. The rationale behind that is to guide and support manufacturers in modelling their actual devices and to encourage including sophisticated features into the devices' network representation. Custom extensions can be defined in case a specific functionality is not covered by the standards.

All models described in this paper include large amounts of terminology codes in order to semantically describe all their elements. These terms are also being standardised as part of the ISO/IEEE 11073 Nomenclature series. For the sake of brevity, they are not discussed in this publication, neither are alerts and contextual information. The complete formalised model drafts can be viewed and discussed online through the project's development management system [5] that is open to the general public to welcome collaboration.

III. ENDOSCOPIC CAMERA

An endoscopic setup allows for looking inside a patient's body. Arguably its most complex device is the camera system. It is attached to (or includes) the endoscope and consists of a camera head and a camera control unit (CCU).

A. Containment Tree

As these sub-components would typically not have individual network interfaces, they are represented by Virtual Medical Devices of differentiated functionality belonging to one Medical Device System, shown in Fig. 1.

From left to right, the *endoscope* is typically not an electrical instrument, but the camera head may nevertheless be able to identify the scope model and exhibit its (physical) properties on the network. These may be relevant for the *image acquisition* that is the core task of the camera head. Together with the CCU, it measures and controls the illumination, offers a white balance operation for the user to calibrate the image colours, and controls shutter and gain. Depending on the type of camera head and CCU, there may be features available such as 3D imaging and observation modes or filters (see Sec. III-B).

The image acquired by the camera head is usually *processed* before output or display. The model supports an arbitrary number of image Channels that are created from the original image through processing steps that may include, but are not limited to:

- digital zoom, rotation, and (mirror-)inversion,
- contrast or transparency adjustment,
- colour tone or saturation/chroma adjustments, and
- other image enhancement or software filters (see Sec. III-B), e.g., to set anatomic structures apart.

These changes to the image need to be described in high detail to inform a remote consumer about the precise semantics.

Furthermore, the CCU has one or more image output capabilities, which may present to the user a composition of frames, overlays, a picture-in-picture mode, or a menu. It therefore includes into its containment tree an *output* ModSpec that describes the individual display elements together with a layout configuration. Another ModSpec used herein is the *documentation* VMD that allows for snapshots or video capture to be triggered; the image files are then communicated through other means such as DICOM. Finally, it includes a *specialty* VMD enabling sets of presets for device settings that can be applied in the context of a specific procedure or for a specific operator.

B. Observation modes and image enhancement

Endoscopic camera systems offer two important categories of mechanisms that influence the images being displayed to the operator. *Observation modes* are employed early in the imaging chain, e.g., to filter light of specific wavelengths emitted by fluorophores that accumulate in a certain type of tissue. This can be used, for example, to highlight anatomical structures or malignant tissue. In contrast, *software enhancements* are applied after image acquisition and modify the output algorithmically, e.g., in order to reduce image noise or smoke, or to enhance edges or colours.

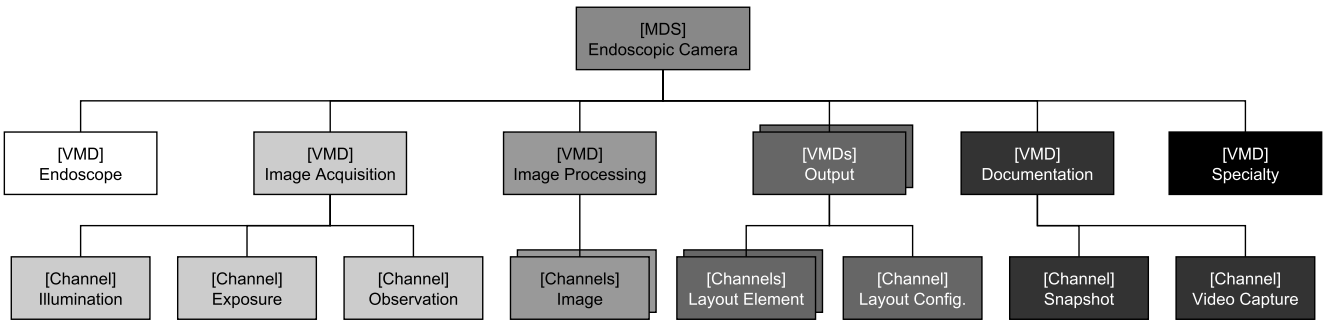

Fig. 1. Containment tree structure of an endoscopic camera, Metrics are not shown.

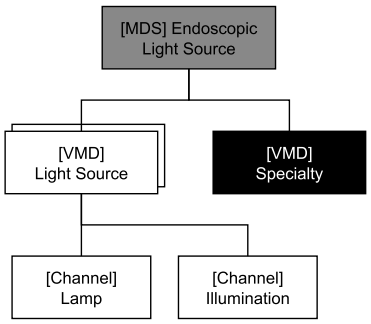

Fig. 2. Containment tree of an endoscopic light source without Metrics

IV. ENDOSCOPIC LIGHT SOURCE

The illumination of the surgeon's field of view is provided by an endoscopic light source – typically a device on its own that is connected to the scope through an optical fibre, but integrated solutions are available. Proprietary interconnection with the CCU is a common feature in order to (automatically) control the light source using the camera interface.

A. Containment Tree

For each (physical) lamp of the device, the MDS provides a light source VMD, see Fig. 2. Its *lamp* Channels contains information about the type of technology, such as halogen, xenon, LED, or laser. Especially in the case of LEDs or for specific excitation modes (see Sec. IV-B), multiple lamps can be part of one device. In addition, lifecycle management information such as operating cycles/hours and maximum life time should be made available.

The other Channel comprises Metrics that describe the actual *illumination*, including the intensity and means for external (automatic) control. It furthermore includes information about the physical properties of the emitted light, e.g. the spectrum, colour rendering index and temperature, and – if applicable – pulse length.

B. Fluorescence Endoscopy

Many endoscopic light sources can be set to emit light of specific wavelengths in order to excite fluorophores such as 5-aminolevulinic acid or indocyanine green [6]. Whereas the precise spectrum remains optional in the device's capability description, the intended use of the light must be represented on the network as the *excitation mode*.

Whenever light with special properties is employed, there may be additional low level background illumination of the situs. Similarly, LEDs of different colours may be adjustable individually for changing the overall light colour. In addition to the individual controls for changing the light intensity of each lamp, the device should thus offer a composite intensity control to change the overall illuminance.

V. ENDOSCOPIC INSUFFLATOR

An endoscopic insufflator is used to create a pneumatosis in a cavity inside the patient using gas (usually CO_2) to open up a field of view for the operator.

A. Containment Tree

The *insufflation* normally operates pressure-controlled with an additional *flow* limit. Especially at the beginning of insufflation, when connected to a veress needle, most devices operate on flow control. Next to target and actual values for these parameters, total gas usage is modelled as well as a *venting valve* that opens when both a pressure threshold and delay are exceeded. Some devices provide additional capabilities like *gas heating* or *humidification* – either integrated or as separate devices.

B. Modular Specification: Gas Supply

The *gas supply* VMD serves as an example for a modular specification that is used herein but not unique to insufflators. Many other devices such as ventilators, anaesthesia machines, or argon plasma coagulators have a similar component. Multiple supplies – typically gas bottle or central supply – can be represented in the model together with configuration information such as input pressure expectancy.

VI. ENDOSCOPIC PUMP

There is a large variety of surgical pumps. Peristaltic irrigation pumps provide an adjustable flow of liquid. In many kinds of procedures, they provide a regulated amount of irrigation for a clean situs, cooling of instruments, and a clear (endoscopic) view. In procedures such as arthroscopy, pumps are also used to provide dilation of the operation area.

The simplest suction pumps provide only a constant negative pressure. The resulting suction pressure is controlled

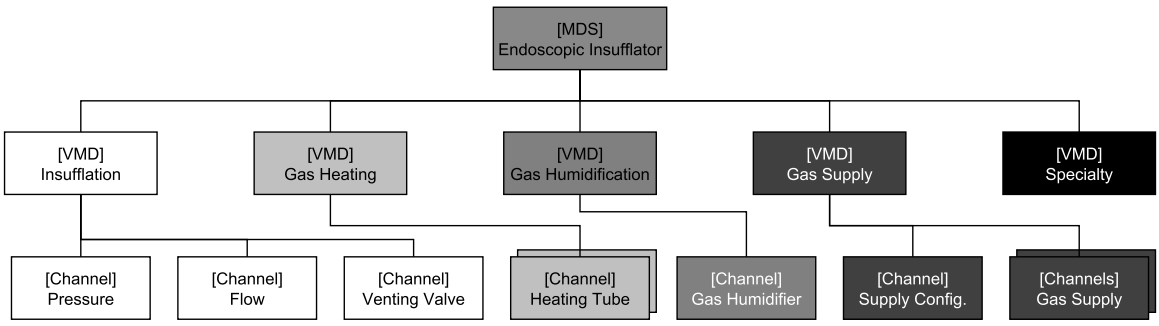

Fig. 3. Containment tree structure of an endoscopic insufflator, Metrics are not shown.

through partially covering a hole at the handheld by the operator. These are used, for example, to remove liquids or contamination such as small pieces of tissue from the situs.

For complex interventions, double peristaltic pumps are used. These pumps control flow and pressure for inflow and outflow separately. This allows well-defined conditions for the surgical procedure as well as additional useful features like automated fluid balancing.

The pump model therefore has to cover the whole range of surgical pumps described above. It has to provide for the core functionalities, like flow and pressure, as well as optional supporting features, like fluid bag characteristics.

A. Containment Tree

The surgical pump MDS is divided into the two basic functionalities: irrigation and suction (see Fig. 4).

The *irrigation pump* VMD covers *inflow* and *outflow* parameters, *fluid supply*, and (if applicable) different *fluid* balancing properties. Operator adjustable parameters such as flow rate and pressure are represented with both their target and actual values. In addition to these common parameters, the pump may provide features for a temporarily increased flow, e.g., to perform wash and/or cooling functionalities.

The fluid supply system is parametrised, among others, by nominal and current fluid bag volume, kind of fluid (typically saline or glucose solution), the difference in height between fluid bag and pump, etc. The latter parameter may help an internal control system to better adjust its algorithms.

High-end pumps may also provide a fluid balancing system. Therefore, inflow and outflow volume are measured. For a highly accurate balance, the *leakage* volume has to be considered, too. This is typically achieved using a scale that weighs the leaked liquids.

Depending on both the device and the use case, the *suction functionality* may provide target and actual values for the current (negative) pressure, or even simply inform about whether suction is currently on or off.

B. Smart connected pumps

For comprehensive assistance of the caregivers in the OR, communication between the surgical pump and other devices is useful. For example, if an HF surgical device or a shaver is used, a higher wash flow may be desired by the surgeons to flush ablated pieces of tissue away and for the purpose of cooling. Additionally, other devices might introduce flows into the situs, like the wash and cooling irrigation of a shaver.

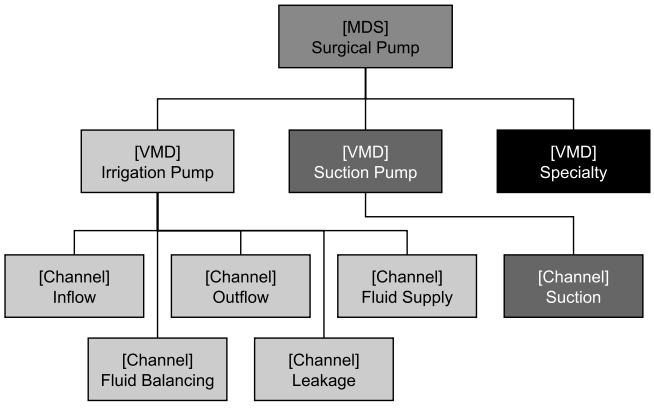

Fig. 4. Containment tree of a surgical pump without Metrics

For optimal control, the pump should be aware of these environmental influences. Therefore, the pump can additionally implement *service consumer* functionalities to get this and other information from the device ensemble. For use cases like the activation of a wash flow, the OR integration system or the HF generator may use remote control functionalities of the pump to trigger the desired behaviour for a certain duration. Smart surgical pumps will additionally optimise their control algorithms by taking preoperative patient and procedure information into account or by consuming current vital signs of the patient [2].

VII. CONCLUSION

The draft models discussed in this work will further promote medical device interoperability using the open communication protocol standard IEEE 11073 SDC. They allow for functionally similar devices to have a similar network representation and therefore ease the burden on the communication partners. Features and operating modes of present devices devices are covered by these models and extension points allow for the inclusion of future functionality.

The availability of compliant devices is going to support integration solutions and innovative assistive systems built on a manufacturer-independent interoperability architecture. All experts are hence encouraged to participate in the development of these and further Device Specialisation standards.

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