Mediate
Patient Friendly Medical Intervention

DELIVERABLE
D2.2.1 – Standards & Interoperability

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- **Due date:** deliverable owner sends the final version of the deliverable to PM and co-reviewer

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1 General introduction

1.1 Introduction Standards & Interoperability

This section gives the reader an overview of the structure of this deliverable. This deliverable focuses on the standards and interoperability among the various components that compose the overall Mediate system.

The document is organized in terms of the interfaces that exist between the various components of the Mediate system. The overview and definition of these components is explained in section 1.2.

These interfaces are often video or data streams that are distributed among the Mediate components:

- Section 2 discusses the standard video streams within the Mediate system.
- Section 3 covers the standardization of video streams that go outside of the Mediate system.
- Section 4 dives into the live image streams that need processing in the IGIT box before becoming standard video streams

  Note: for more detailed information of the IGIT box we refer to the system architecture deliverable D213.

- Section 5 focuses on the DICOM images and their standards
- Sections 6 and 7 focus on the internal and external workflow standards

1.2 Mediate components

An overview of this philosophy for the Mediate system is shown below.

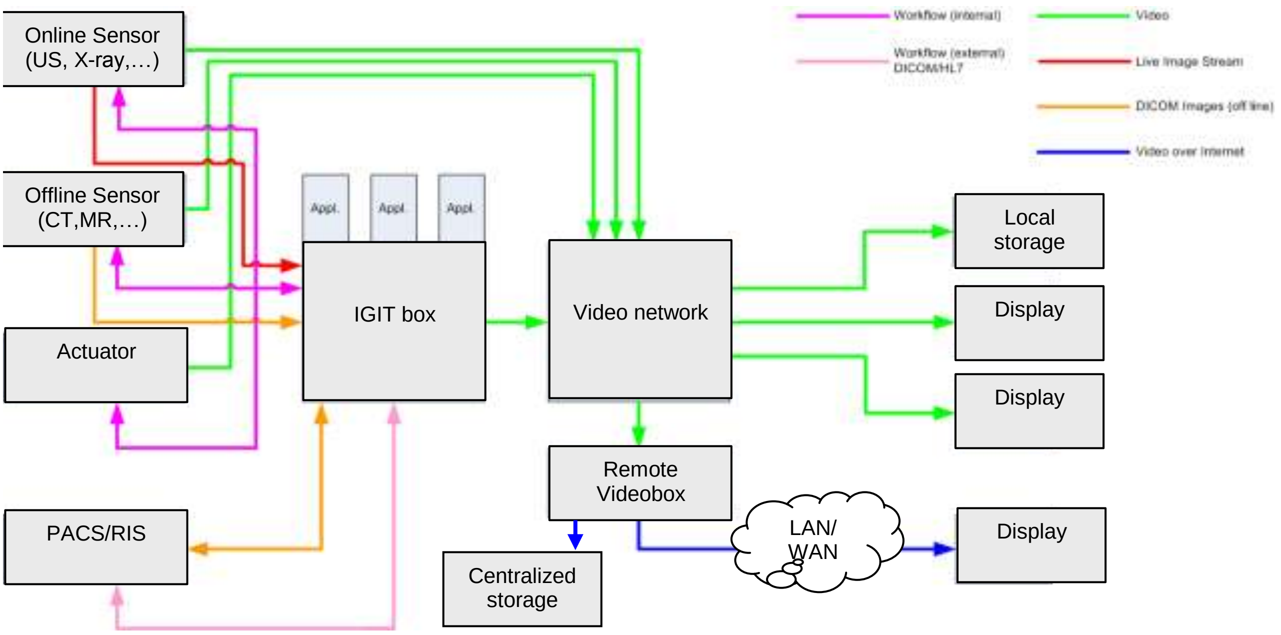


Figure 1. Mediate Philosophy

The following Mediate components are depicted in the figure above:

- Input components:
  - Sensors: The sensors are e.g. MR, CT, US and X-Ray devices, but can also be endoscopic cameras. As such the sensors are the visual aid to the physician. They can be subdivided in 2 types:
    - On-line sensors: these are the US, X-Ray devices and e.g. endoscopic cameras that generate live video of the patient.
    - Off-line sensors: these are the MR, CT, etc. devices that capture video or images that can be sent out afterwards (non-realtime) as images or video with medical information of the patient.
  - Actuators: The actuators are the tools used by the physician to perform the intervention on the patient. The actuators are quite diverse, e.g. guide wire tip steering, ablation catheter.
  - PACS/RIS: These systems store patient medical data in standardized formats that can be used to support the intervention.
- Video processing components:
  - IGIT: The "Image Guided Interventions and Therapy" is a central data processing and image rendering service. It is a platform on which various applications can perform their service-specific processing. The output of the IGIT is a video stream towards the network.
- Video distribution components:
  - Video network: The video network is the infrastructure that is responsible for distributing the video from the various sources to the right destinations, typically displays.
  - Remote videobox: The remote videobox is a service that makes the internal intervention-room video available outside this room and potentially even outside the hospital for external users to follow ongoing procedures.
- Output components:
  - Displays: The video needs to be visualized on the displays. This is done by dedicated medical displays for surgery and radiology.
  - Storage: The video can be recorded either locally in the intervention room or centralized in the hospital.

Between these components, the following types of interfaces can be distinguished:

- **Video-streams**: Systems will send video data to displays. In the Mediate system, these video streams will be sent to a video network. Inside the video-network, the streams will be converted to data that can be sent over networks. At the "other end" of the video network, the data will be converted back into plain video that can be sent to a display.

- **Remote Video-streams**: A node that can be connected to the video network will convert the video into a format that can be sent over the Internet for remote viewing

Live Image Streams: Medical Imaging Systems can send live image streams. These streams contain image data that needs to be processed before it can be used. The live image streams will contain, next to the image data, meta information. This meta information is needed by the clinical applications to process the information. Meta information consists of a wide variety of information, which is specific for a modality type (e.g. MR, CT, XRay). Examples of meta information is: geometry information (e.g. position of the XRay with respect to the patient), XRay dose information, patient information, acquisition settings. A live image stream cannot be sent to a display, since the data has not been rendered. The image data is rendered by the applications on the IGIT box. The output of the IGIT-box is a normal video stream that is fed into the video network.

- **DICOM Images**: Hospital PACS systems and modalilities that cannot send live data can send pre-recorded medical image data over a network. For this purpose, the DICOM standard is available.

- **External workflow**: Hospital RIS systems can send workflow data to medical systems. This can be a list of scheduled patients/studies/examinations and medical data for these patients. DICOM and HL7 provide standards for exchanging this type of data.

- **Internal workflow**: When building a system-of-systems, workflow information needs to be exchanged among these systems. A straightforward example is: synchronization of the selected patient to make sure that the same patient has been selected on all patients (without the operator having to do the same patient selection on all systems).
  Other types of workflow data exchange among the systems in the Mediate system-of-systems can be foreseen.

The standards that can be used for these interfaces in the Mediate system are elaborated in the next sections.

2 Video streams

2.1 Introduction

This section discusses the distribution system of the video streams inside the Mediate system. The input of the distribution system is a video signal from a source (IGIT box, actuator, sensor) and the output is the display or the remote video box.

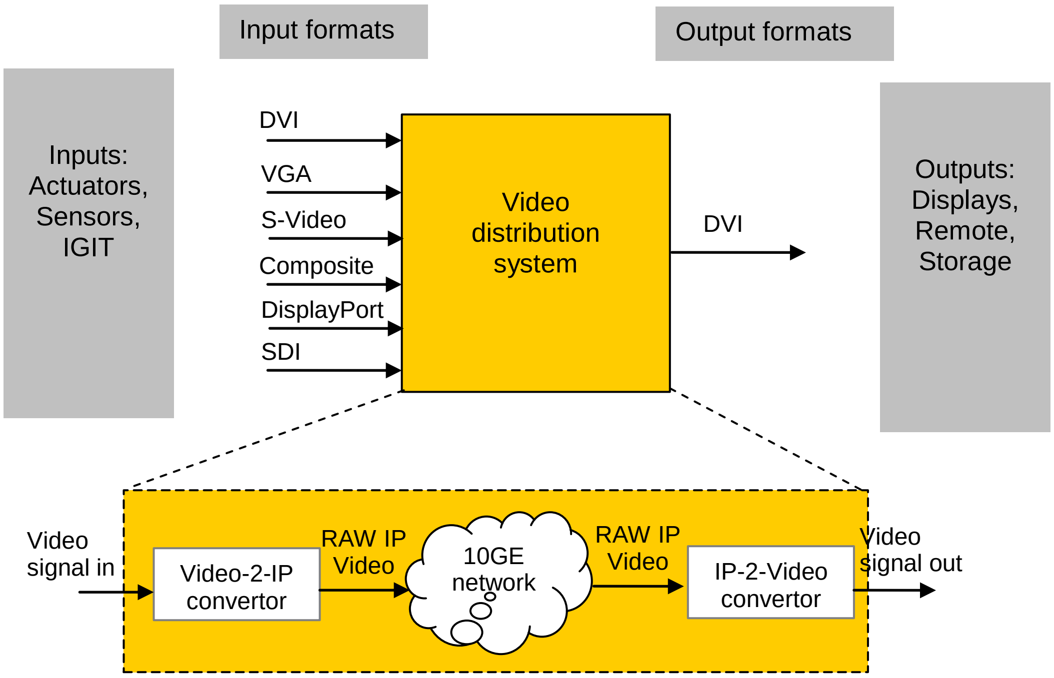
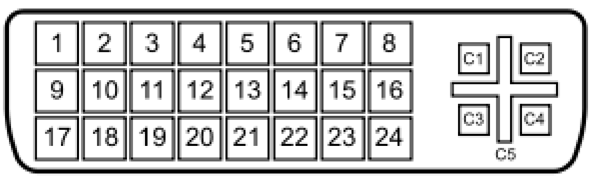


Figure 2. Video Distribution Interfaces

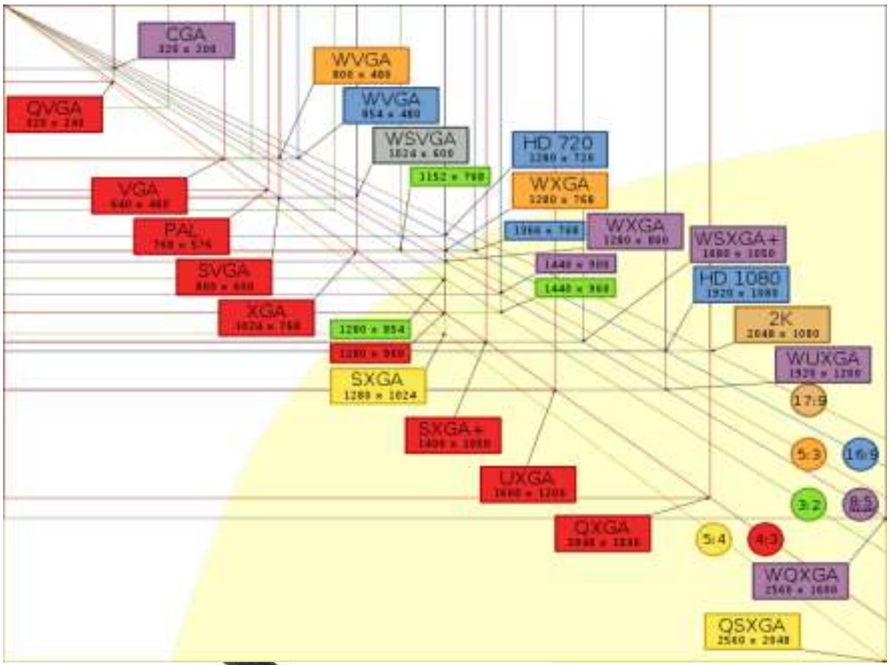
2.2 Video input standards

The video signals that are generated from the various input sources can be according to following video standards:

- DVI: Digital Visual Interface (DVI-D, *DVI-A*, DVI-I)
    - Uncompressed digital video stream up to 1,920 × 1,200 @ 60 Hz
    - Single-Link: WUXGA
    - *Dual-Link (Not to be used in Mediate System):* Limited by copper bandwidth limitations, DVI source limitations, and DVI sync limitations.



    -
- VGA: Video Graphics Array
    - Analog video signal
    - There are a lot of historically grown VGA formats as depicted below

- ○ 

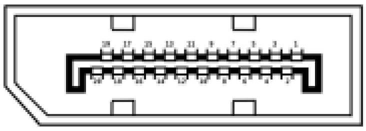
- ○ VGA connector: 

• S-Video: Super Video
  - ○ Analog video signal: NTSC, PAL, or SECAM video
  - ○ Connector: 

  - ○ Pin 1,2: Ground Y,C Pin 3: Y (Luminance), Pin 4: C (Colour)

• Composite video:
  - ○ Analog video signal: NTSC, PAL, or SECAM video
  - ○ Aka CVBS: Color, Video, Blanking, and Sync.
  - ○ 

• Display port:
  - ○ Developed by VESA
  - ○ Intended to replace VGA, DVI and LVDS
  - ○ Can be used for audio, video and data transfer
  - ○ V1.1a: up to 4Mpixel video

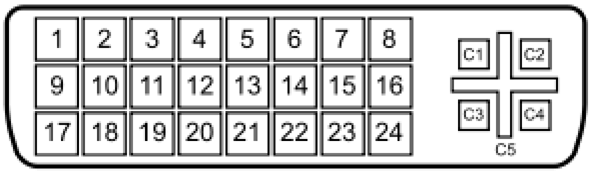



- SDI:
  - SD-SDI: SMPTE 259M
  - HD-SDI: SMPTE 296M and SMPTE 274M
  - 3G-SDI: SMPTE 424M and SMPTE 425M

2.3 Video output standards

The video signals that are used to drive the displays, the remote convertor and the local video storage are limited to DVI

- DVI: Digital Visual Interface (DVI-D, *DVI-A*, DVI-I)
  - Uncompressed digital video stream up to 1,920 × 1,200 @ 60 Hz
  - Single-Link: WUXGA
  - *Dual-Link (Not to be used in Mediate System):* Limited by copper bandwidth limitations, DVI source limitations, and DVI sync limitations. Dual-link is needed to drive 4MP displays. 8MP displays can be driven by 4x SL-DVI or 2x DL-DVI.

2.4 Video distribution network standards

This interface describes how the video signals are distributed between the endpoints, being the input and output interfaces of the video distribution system. The video distribution inside the intervention and control room area has very stringent latency requirements (1frame) at high refresh rates.

The video that is distributed to remote locations, outside the cathlab or even outside of the hospital, e.g. via internet have less stringent latency and quality requirements as they are not used for instantaneous medical decision on the patient. As there is also a physical bandwidth limitation to remote locations, the quality will be lower and/or latency will be higher. This is covered in section 3 on remote video streams

The video inside the intervention room has to meet diagnostic requirements w.r.t. quality and latency. In order to meet these requirements, the video has to be distributed in an uncompressed RAW video format.

2.4.1 Video Transport – RTP

To transmit the raw video streams between the different systems the Real-time Transport Protocol (RTP) (1) is used. The data stream will be packetized according to RFC4175 (Ref.[1]).

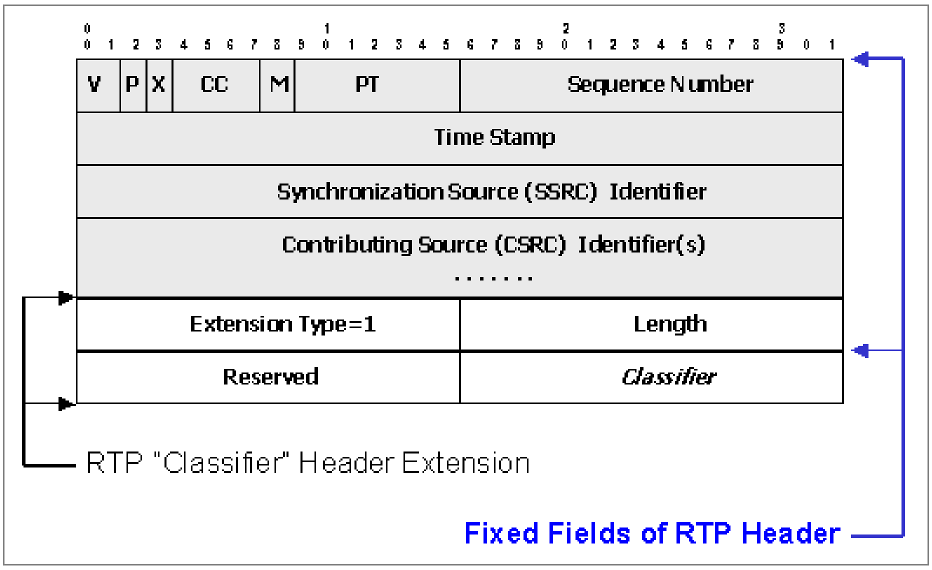


Figure 3: *RTP Header*

The RTP header has a minimum size of 12 bytes. After the header, optional header extensions may be present. This is followed by the RTP payload, the format of which is determined by the particular class of application. The contents of the payload will be the video from the inputs of the Mediate system. The different fields of this RTP header are explained in (1).

RTP provides end-to-end network transport functions for transmitting video, audio or simulation date over multicast or unicast network services. It doesn't guarantee Quality of Service (QoS) for these real-time services. As such another protocol will need to be used to assure this QoS.

On layer 2 Audio Video Bridging (AVB) (3) (4) (5) can be used to reserve a certain amount of bandwidth to ensure lossless end-to-end transport of a video stream. It also provides a precise timing protocol that enables synchronization of different sources and destinations to keep jitter to the absolute minimum.

A control protocol, RTCP, can be used in addition to RTP to monitor the data delivery in a manner scalable to large multicast networks. It also provides minimal control and identification functionality.

2.4.2 Real-Time Streaming Protocol: RTSP

To establish and to control media sessions between end points the Real Time Streaming Protocol (RTSP) (6) is used. This protocol provides commands to start, pause and stop media streams. This way client can send out VCR like commands to facilitate real-time control of playback of media files from the server. While similar in some ways to HTTP, RTSP defines control sequences useful in controlling multimedia playback. While HTTP is stateless, RTSP has state; an identifier is used when needed to track concurrent sessions. Like HTTP, RTSP uses TCP to maintain an end-to-end connection and, while most RTSP control messages are sent by the client to the server, some commands travel in the other direction (i.e. from server to client).

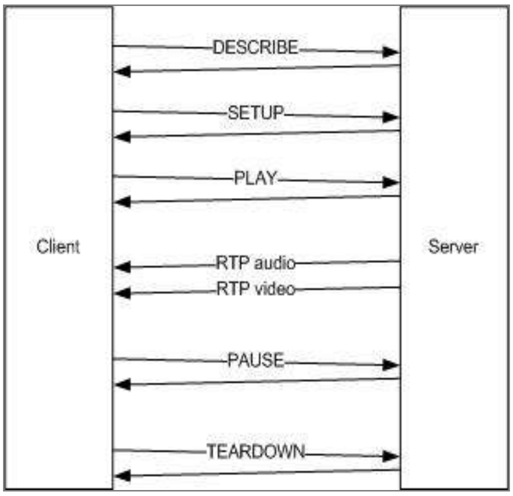


Figure 4: *RTSP communication between server and client*

2.4.3 TCP/UDP

The management communication between the components (like video encoders, decoders, mgt sw) in the video distribution network uses TCP for control communication. TCP is connection oriented and thus offers retransmission in case of lost packets.
The video traffic (RTP/RTCP) itself uses UDP for performance reasons. UDP is connection-less to make sure the optimal performance can be met. No retransmission or flow-control is done in UDP.

2.4.4 IP Unicast Routing

If there is more than one (V)LAN in the OR network connectivity between the VLANs is accomplished by configuring the switch(es) for unicast routing. Although there are many different unicast routing protocols, preferably standard routing protocols are configured such as OSPF (RFC 2328) or RIPv2 (RFC 2453).

2.4.5 IGMP (Internet Group Management Protocol) & Multicast Routing

IP multicast is the protocol to distribute media data like video data over the network. The destinations signal their interest in a particular multicast group by using IGMPv3, as described in RFC 3376.

2.4.6 VLAN Trunking

Some network topologies depend on VLAN based segmentation of the network. VLAN provide several features amongst which; segmentation of devices into smaller broadcast domains, reducing workload for STP and enforcing security when working with sensitive data.
In case VLAN's are used in the design of the network, the VLAN configuration should preferably be configured in a static manner. Although protocols exist to distribute VLAN configuration, like for example VTP[1], it is a best practice to avoid using these protocols and configure VLAN's manually on all switches and to avoid using VLAN 1. If VLAN trunking is required to span VLANs over multiple switches, the preferred protocol is IEEE 802.1Q.

2.4.7 Security – Port Based Admission Control

To secure the Digital OR network from unauthorized access, port based network admission control can be used via IEEE 802.1X. IEEE 802.1X defines how devices need to authenticate themselves before they are allowed access to the network. The standard defines three types of components:

1 Proprietary protocol to distribute VLAN configuration details like name and ID.

- Supplicants: devices that request to join the network
- Authenticator: the network switch that controls access to the network by blocking traffic from supplicants until they are authenticated
- Authentication server: the server that contains the database with credentials to make authentication decisions, a RADIUS server is an example of an authentication server

By applying port based admission control, using certificates, the Digital OR network will only allow authenticated devices access to the network hereby protected tampering with components of the system as well as protecting unauthorized access to patient related data.

2.4.8 Physical cable

Due to the need for galvanic separation and its native ability to span large distances for high bandwidths, an optical LC2 OM3 MM fiber cable is to be used as network cable inside the intervention room.

3 Remote video streams

The video outside the intervention room has lower requirements w.r.t. quality and latency. The main criterium now is the network bandwidth capacity. In order to meet these requirements, the video has to be compressed to a lower-bandwidth video format that allows video distribution over the 1G/100Mbps LAN or even outside the hospital at an even lower bandwidth. Typical compression algorithms are H.264 for video, JPEG2000 for images.

The remote convertor box takes video signal as input and sends out a compressed video network stream that can be used on a low-bandwidth network. This is illustrated in the figure below. Alternatively, the Remote convertor can also have a network input from the Mediate system and a compressed video output towards the LAN/WAN. This integrated convertor would then become part of the video distribution system. This architecture is not part of the Mediate demonstrator.

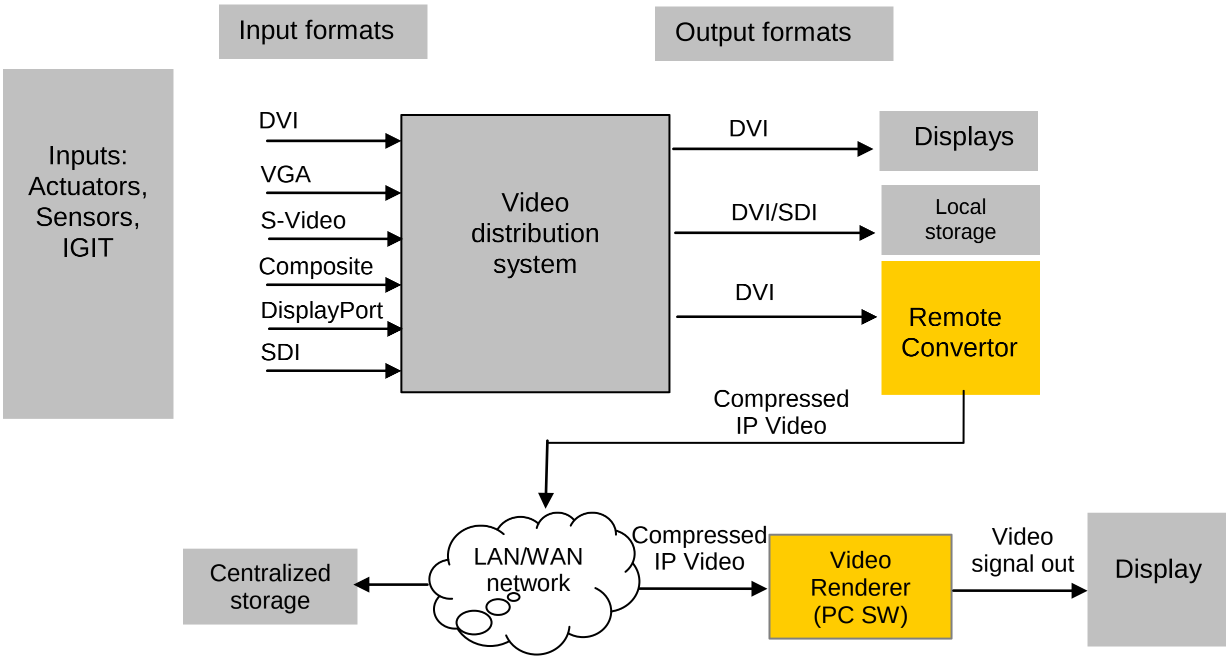


Figure 5. Remote video stream distribution

3.1 Video input standards

The video signals that come out of the video distribution system in the intervention room are DVI signals (see 2.3). These DVI signals need to be converted to compressed video streams.

3.2 Compressed video standards

The video is compressed when going outside the operation or intervention room environment. Preferred compression algorithms for video distribution over lower-bandwidth networks are standards like H.264/MPEG-4 AVC and its upcoming successor H.265/MPEG-H Part 2.

The compressed video streams can be made available to the various points on the network (laptops, pcs,... in the hospital) via a Media Streaming device. This will make the stream available in a point-to-point way via HTTP(S) or in a multicast way via RTP. The former can be simply shown in a standard web browser, the latter requires a standard video player like “vlc” to connect to the video stream and display it on the computer. Video can also be decoded and rendered inside web browsers like Mozilla Firefox and Google Chrome that support HTML5. HTML5 has a <VIDEO> tag that allows to view H264 AAC video streams natively inside the browser.

Depending on the available network bandwidth between the streaming server and the player device (external VPN@ 256kbps or hospital LAN at 100Mbps or 1Gbps with very low or very high network usage), different video quality levels need to be supported to avoid either high-quality, but continuously interrupted and delayed video on low-bandwidth connections or underperforming low-quality, fluent video on high-bandwidth connections.

It is therefore important that the streaming server and the endpoint player communicate to agree on the best possible video streaming setting (resolution & refresh rate vs network bandwidth).

In addition, the hospital LAN should support differentiated services with corresponding priorities to make sure critical traffic gets priority over lower-priority data traffic. DSCP at IP level and p-bits at Ethernet level can help in this prioritization.

3.3 Video distribution network

The same standards as described in section 2.4 apply here as well..

The physical connection of the distribution network inside the hospital is the standard CAT5 network cable.

The storage itself must be robust and reliable. Therefore RAID disk arrays [15] are advised. Ideally levels from RAID 5 onwards are deployed as they allow parts of the disks to get corrupted without actually loosing data.

In addition, the contents of the local Mediate repository should be duplicated on the remote hospital network storage systems as well. The local Mediate repository will keep the local, short term image and video storage while the remote storage is more longer term.

3.4 Video output standards

The video signals towards the remote displays or centralized storage are again any video of types listed in section 2.2. In case of a tablet or mobile device, the display is integrated with the video renderer and then there is no conversion from the IP video stream to the video signal via an external interface anymore.

4 Live image streams

Live image streams are streams that contain image data that needs to be processed before it can be used. A live image stream cannot be sent to a display, since the data has not been rendered. The image data is rendered by the applications on the IGIT box. The output of the IGIT-box is a normal video stream that is fed into the video network.

In addition to the image data itself, the data stream contains also metadata. This metadata (e.g. image geometry,…) is crucial for the correct rendering of video from the image data.

There exists some initiaties to standardize these streams like OpenIGTLink [16]. However, there is no official standard interface that describes the interface between the input devices and the IGIT box yet today. It is application specific. We may decide in the scope of the Mediate project that it makes sense to introduce standardization at this level. However, at the time of this writing it is too early to state whether or not this will actually be done in a later phase of the project.

5 DICOM Images

Hospital PACS systems and modalilities that cannot send live data can send pre-recorded medical image data over a network. For this purpose, the DICOM standard is available.

DICOM (Digital Imaging and Communications in Medicine) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format.
The DICOM standard has been and is still being developed by the DICOM Standards Committee, whose members are also partly members of the National Electrical Manufacturers Association (NEMA), which also holds the copyright to this standard. DICOM is also known as ISO standard 12052 “Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management”.

DICOM defines a set of services, of which the following are relevant to the Mediate IP video distribution system’s connection to remote systems:

- Store – to send images, waveforms, or other objects like reports.
- Storage commitment – to ensure persistency of stored objects.
- Query/Retrieve – to find information, and to retrieve it for further use.
- Printing – to make calibrated hard copies of information (e.g. on x-ray film).
- Off-line media – to store information on removable media (e.g. CD, DVD, USB).
- Modality worklist – to obtain information on scheduled examinations.
- Modality performed procedure step – to send information about the performed procedures, including data about the images acquired, beginning time, end time, and duration of a study, dose delivered, etc.
- Configuration – to obtain information about the way a system needs to be configured.

The latter service has been built instantiating another standard, the Lightweight Directory Access Protocol (LDAP) standard, which can serve the purpose of a plug-and-play way of DICOM network configuration.
On TCP/IP level DICOM leverages the Transport Layer Security (TLS) standard as defined in RFC 5246 to handle security aspects, and web services for data transfer in the internet world (allowing for both the SOAP/WSDL/UDDI and RESTful ways).
DICOM also leverages coding standards like LOINC and SNOMED to be able to consistently transfer data regarding clinical observations (e.g. blood values), diagnosis (mostly based on observations), and procedures (based on diagnosis).

DICOM is very explicit about the way data is transferred, using the notion of transfer syntaxes. In such a transfer syntax, the endianism as well as the pixel data compression is specified. With respect to compression, DICOM leverages existing standards like JPEG, JPEG 2000, and MPEG (for cine), RFC2557 MIME encapsulation and XML encoding.

A manufacturer of a system that supports DICOM may formalise that by issuing a DICOM Conformance Statement (DCS), which details quite extensively the services it provides, in what role (server or client), for what kind of data, and also configuration aspects, structured report content item mappings, use of other standards (IEEE, TLS, ISO character sets), and clinical applications. Given this information, potential buyers can verify the interoperability of this system with others.

6 External workflow

Hospital RIS systems can send workflow data to medical systems. This can be a list of scheduled patients/studies/examinations and medical data for these patients. DICOM (see 5) and HL7 provide standards for exchanging this type of data.

6.1 HL7

HL7 is both the name of a standard and the name of the standard defining organisation. The HL7 organisation has defined the following set of standards that apply to Mediate on the interface to remote systems[2]:

- Version 2.x Messaging Standard – an interoperability specification for health and medical transactions;
- Version 3 Messaging Standard – an interoperability specification for health and medical transactions, based on the Reference Information Model (RIM);
- Clinical Context Object Workgroup (CCOW) – an interoperability specification for the synchronisation of user applications;
- Clinical Document Architecture (CDA) – an exchange model for clinical documents, based on HL7 Version 3;

Especially the messaging standards will play a role, as these are meant to "send or receive patient admissions/registration, discharge or transfer (ADT) data, queries, resource and patient scheduling, orders, results, clinical observations, billing, master file update information, medical records, scheduling, patient referral, patient care, clinical laboratory automation, application management and personnel management messages. It does not try to assume a particular architecture with respect to the placement of data within applications. Instead, HL7 Version 2.6 serves as a way for inherently disparate applications and data architectures operating in a heterogeneous system environment to communicate with each other." [HL7 standard]

CCOW plays an important role in keeping the DSS and remote systems in sync on user (single sign-on), patient (who are we operating on today), study (what are we doing), and more. Keeping the remote systems synchronised with Mediate will give the clinicians a coherent view on all their systems, and will therefore rigorously increase the efficiency and safety of the entire clinical solution.

The CDA is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange, e.g. between healthcare providers and patients. A CDA can contain any type of clinical content – typical CDA documents would be a Discharge Summary, Imaging Report, Admission & Physical, Pathology Report and more.
Although the CDA is part of the third version of the messaging standard, it is worthwhile mentioning it separately, as the acceptance of this part of the standard is much higher than the acceptance of the messaging standard v3 in its entirety. This is due to the fact that this part is not only a side-step (not adding inherent value), but definitely adds something new.

[2] Other HL7 standards, like the Arden syntax and GELLO, apply to other Mediate connections.

A manufacturer of a system that supports HL7 may formalise that by issuing a HL7 Conformance Claim (HCC), which contains a quick and complete overview of all issues that are important when trying to decide the interoperability with other systems.

6.2 IHE

Next to HL7, there is also the IHE. Integrating the Healthcare Enterprise (IHE) is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. [IHE website] Although formally not defining a standard (it's called a framework), the IHE has created a multitude of integration profiles, which define the practical use of established standards, by making clear choices when alternatives or options are available, such that the practical integration is much easier to achieve.

Each integration profile describes a number of actors, which collaborate to achieve a certain goal (quite similar to use cases), by exchanging messages in a well-defined way, and with well-defined contents. Integration profiles belong to domains, and for the connection of the DSS to a remote system the anatomic pathology, cardiology, IT infrastructure, laboratory, and radiology domains are relevant. In these domains, DICOM and HL7 are the main healthcare-oriented standards that are being leveraged, but next to that also others like ICD-10, HIPAA, and IT-oriented standards like (S)NTP, Kerberos, and SysLog.

The IHE integration profiles can be categorized into four main categories, namely profiles for workflow (how to achieve the final goal), profiles for content (agreeing on the data that is being exchanged and used), profiles for presentation (how is something shown consistently over systems to the clinician), and profiles for infrastructure (agreeing on underlying data).

A manufacturer of a system that supports IHE may formalise that by issuing an IHE Integration Statement, which details in a short but precise way what integration profiles are supported (based on information in the DCS and the HCC).

6.3 Networking

Both HL7 and DICOM (and therefore also IHE) are in most cases deployed on TCP/IP, although other transport protocols are possible (e.g. HL7 on RS-232). Also, TSL and SSL are applied when TCP [17] is used as transport layer.

7 Internal workflow

When building a system-of-systems, workflow information needs to be exchanged among these systems. A straightforward example is: synchronization of the selected patient to make sure that the same patient has been selected on all patients (without the operator having to do the same patient selection on all systems).
Other types of workflow data exchange among the systems in the Mediate system-of-systems can be foreseen.

A standard for the internal workflow is CCOW which has been discussed in section 6.1.

8 References

[1] IETF. RTP: A Transport Protocol for Real-Time Applications. 2003. RFC3550.

[2] RTP Payload Format for Uncompressed Video. 2005. RFC4175.

[3] IEEE. 802.1AS - Timing and Synchronization.

[4] 802.1Qat - Stream Reservation Protocol.

[5] 802.1Qav - Forwarding and Queuing Enhancements for Time-Sensitive Streams.

[6] EtherCAT Technology Group (ETG) http://www.ethercat.org/

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