ITEA 2
INFORMATION TECHNOLOGY FOR EUROPEAN ADVANCEMENT

Mediate
Patient Friendly Medical Intervention

DELIVERABLE
D2.1.2
Technical report focused on the use cases

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V1.0	2011-Jul-26	Final Version (Approved by PMT)

Table of Contents

1 Introduction

1.1 Purpose

The purpose of this document is to deliver a first step towards the MEDIATE Architecture. This report focuses on Use Case needs, therefore providing the initial approach to be apply for later Architecture definition (D.2.1.3)

1.2 Scope

Due its technical nature, it will focus mainly on the definition of Architecture and its relationships with the clinical part. It is outside the scope of this document to go into clinical details of Use Cases.

1.3 Target Audience

The target audience of this deliverable are primarily technical partners involved in defining the MEDIATE architecture.

2 Executive summary

The use cases have been described taking into account three clinical areas: cardiovascular image guided interventions, oncological image guided interventions, orthopaedic interventions. Next to these three clinical areas generic use cases have been described for minimal invasive interventions. All the use cases are described in [6]. The table below show how the use cases are mapping on the clinical areas:

Clinical Area	Use Case
Cardiovascular	Use case 1 RF Ablation of cardiac arrhythmias Use case 2 Transcatheter Aortic Value Implantation Use case 3 Percutaneous Coronary Interventions
Oncological	Use case 4 Needle ablation of tumors Use case 5 Tumor treatment: MR-guided HIFU
Orthopaedic	Use case 6 Bone tumor navigation Use case 7 Corrective osteotomy
Generic minimal invasive interventions	Use case 8 Innovative user interfaces in minimally invasive treatment Use case 9 Single Incision Laparoscopic Surgery (SILS) for partial nephrectomy

Each use case posts constrains on the architecture. There are requirements that are common for all use cases, for example DICOM storage. And there are requirements that are specific per use case. These requirements have been described in this document.

Next to the focus on the use cases this document also focuses on the state of the art for certain technologies that are of interest for the MEDIATE architecture. As the list of technologies can be very broad a selection was made. The list of selected technologies is described in this document.

3 Context

3.1 Introduction

IGIT stands for Image Guided Intervention and Treatment, a new trend inside surgery that attempts to provide the surgeon with more information that can be used to take better decisions and so improving final results of surgery. This field is not only focused on real-time decision support, but it also affects pre-operation simulation and planning, for example.

During the last years, an increased interest about IGIT has been raised all over the world. The reasons behind this context are pretty straightforward: it provides an effective way to improve surgery, enhancing at the same time clinical needs and patient healthcare. Besides, it can reduce significantly the costs of surgery, on the long term, replacing long, exhausting surgeries by more accurate and less invasive operations.
The following picture shows the IGIT impact within Philips global Strategy

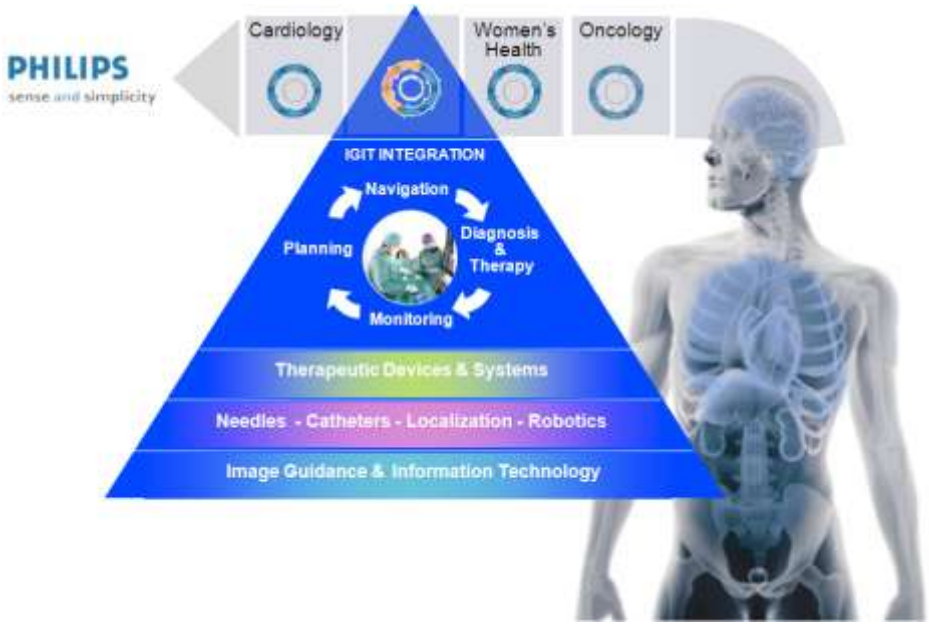

Figure 1: IGIT within Philips Global Strategy

3.2 Background

Patient data is stored, in modern Information systems, as a formatted, well-formed record called Electronic Health Record or **EHR**. This contains all patient-related data relevant for Health domain, as for example, patient data, diseases history, sanitary activity regarding those illness periods, and so on.
According to European Comittee for Standarization, the EHR is "*the persistent longitudinal and potentially multi-enterprise or multinational record of health and care provision relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform the subject's future health care and to provide a medico-legal record of care that has been provided*" [1].

Standardization of the architecture of electronic healthcare records is essential for two reasons: i) the records are being used to support shared care among clinicians with different specializations; ii) it should enable mobility within and among countries for people who give and receive healthcare. This approach has been supported by many working groups within different international initiatives:

- CEN/ISO **EN13606** is a norm designed to achieve semantic interoperability in EHR-related data communication among different Health Information Systems (HIS) [3]. Its main goal is to define a stable and reliable information structure in order to communicate EHR parts of the same patient. The first version of the 13606 four-part pre-standard was published in 1999-2000 but attempts to implement this pre-standard in software proved to be difficult and those implementations which were undertaken suffered from the "HL7 v2 problem" of too much optionality. In 2002 CEN made a decision to revise the 13606 pre-standard and upgrade it to a full normative European standard (EN 13606, also called **EHRcom**). One of the most important aspects of the revision project was a decision to adopt the openEHR two-level modelling approach, known as the 'archetype methodology'

- **HL7** is an international organization founded in 1987 and supported by ANSI with the goal of develops global standards related with eHealth [4]. This organization has already defined a set of standards for clinical information interchange, whose name are HL7 standards. Among them it is **HL7 CDA** (Clinical Document Architecture), which defines the Architecture of electronic documents used within Health domain and is HL7's current main strategy for EHR interoperability. Besides, HL7 supports **RIM** (Reference Information Model), a model of healthcare information as viewed within the scope of HL7 standards, which provides a static view of information needs along with use case models, interaction models, data type models, terminology models, and other types of models to provide a complete view of the requirements and design of HL7 standards, thus giving a valid starting point for any HL7-compliant Architecture Design.

- **OpenEHR** is a foundation that supports the development of an open and semantic-connected platform for eHealth systems [5]. It is based on 15 years research, focussed engineering design and real-world implementation experience, rather than being created as a formal consensus standard. However, over the last years it has had a significant influence on the development of EHR standards by the three main international ehealth standards development organisations: CEN, HL7 and ISO.

Following figure shows the relationships between some of these standards:

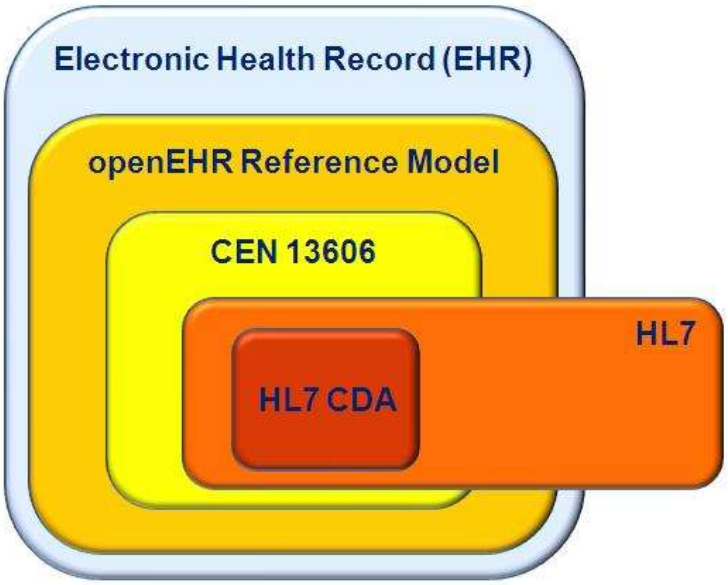

Figure 2: eHealth Standards

3.3 Conceptual view

As it will be mentioned in the following sections, most of Use Cases are supported by a wide range of tools, mostly related with imaging. On the next figure, representing an abstract Intervention Room, these can be divided into four sets: sensors, actuators, controllers and displays:

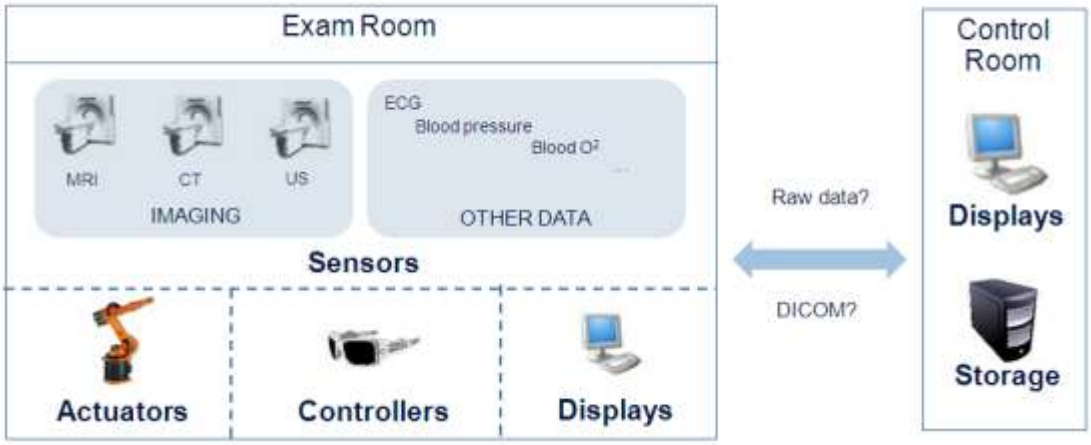

Figure 3: Exam room and Control Room

Each one of these elements plays a different role in the MEDIATE architecture, and although in some cases there are devices that are in two categories at the same time (as touch screens, which are both sensor and display), this view will be maintained all along the document in order to clearly separate inputs and outputs:

In a typical IGIT environment and from a highly abstract point of view, the surgeon receives signals and images data by means of a set of **displays**, which are fed by

several **sensors** located around, and inside the patient. Then, the doctor can execute several actions through **controllers**, which then transform surgeon motions into real movements of **actuators**, and so performing real actions over the patient. This flow of signals can be seen schematized in the following Figure:

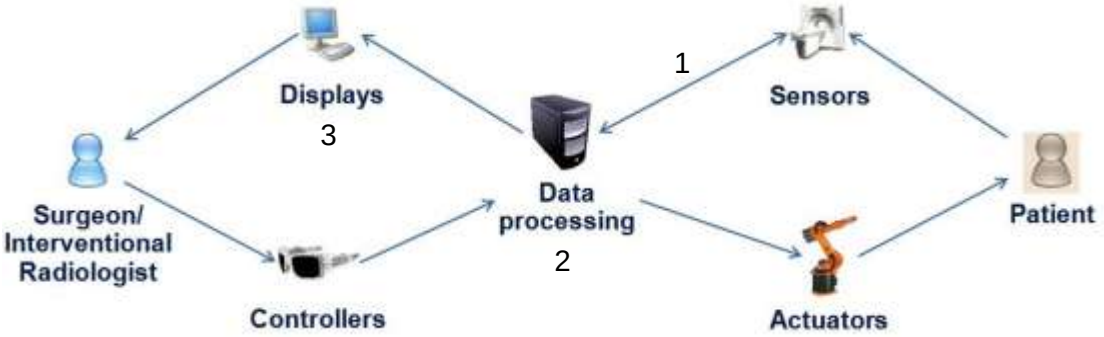

Figure 4: Ideal IGIT environment

Observe that:

1. Sensor input is used to steer the actuators. E.g. for Hifu, thermometry is used to actively control the ablation device (semi)autonomously
2. Data processing is used to control / steer the sensors (e.g. imaging planes that follow the needle tip)
3. By combining data the amount of display(s) can be reduced to show only relevant data for the part of the procedure, or smartly combine the different data sources. In an *ideal* IGIT environment, there would only be 1 display.

Each one of these elements can be described as follows: (for more detail, see D6.2.2 WP6 deliverable):

- **Displays**. Can be viewed as sources of information for surgeon. Screens and any kind of signal viewers fall into this category (and at the same time, also in others), but also HMM (Head mounted displays) or holography, for example.
- **Sensors**. They gather information from patient body and transmit it to the rest of systems involved, as displays, storage systems and so on. Examples of this goes from the simplest pulsioximeter to the most complex CT scanner.
- **Controllers**. Get commands from surgeon in several ways, being the most common hand (through haptic devices or touch screens) or eye motions (eyegaze tracking)
- **Actuators**. Execute surgeons commands received by means of controllers. A most innovate example of an actuator could be MrBot [2], developed by John Hopkins University research group, and that is specifically designed to work under MRI conditions, such as very high dense magnetic fields.

Definition of such peripherals is under the scope of WP6, while on WP2 their interface will be defined and applied. In order to achieve the objective, a key concept will be interoperability, and the main challenge will be to put all these different-vendors, heterogeneous devices working together.

Therefore, the MEDIATE architecture will provide a mechanism to make all these devices work together and will allow the communication between them. A first approach could be the **driver-by-device** philosophy. According to this, there would be a central controller connected to the storage system. Each new device that is

connected to the architecture is categorized in one or more of the sets already defined (display, sensor, controller or actuator). For each one of them, a specific driver must be built: this will serve as the communication bridge between the device and the core of architecture. This way, the addition of new devices is simple and straightforward and they will also share a common and homogeneous API (Application Program Interface) that simplifies their management from the core system:

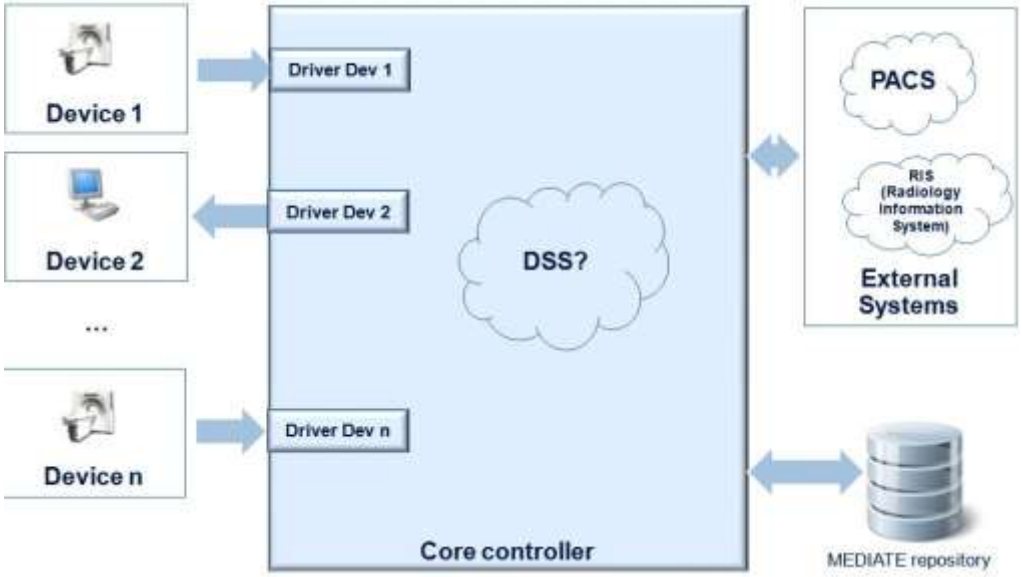

Figure 5: Driver-by-device approach

The drivers can transform the specific-commands and information produced by devices into a 13606-compliant message, which can be later used by the Decision Support System or any other architecture component. In some cases, specifically in early stages of the design, this message will be only given to another driver, thus enabling an almost direct communication between these two devices; for example, the outcome of a camera (sensor device) can be redirected without any transformation to a screen (display device), avoiding unnecessary delays.

Another advantage of this approach is that the architecture can be built using an iterative process: in the first iteration, with few devices connected, the core controller can be the simplest gather-input-from-sensor-and-show-it-in-display example. Then, as the project advanced and more devices are connected, the controller is evolved into a more complex structure, resulting during the final project stages in a fully operational Decision Support System.

The purpose of this document is to provide the architecture definition based on Use Cases, so merging it with the Driver-by-device approach showed in previous figure, results in the addition of each Use Case to Architecture global definition by means a new iteration:

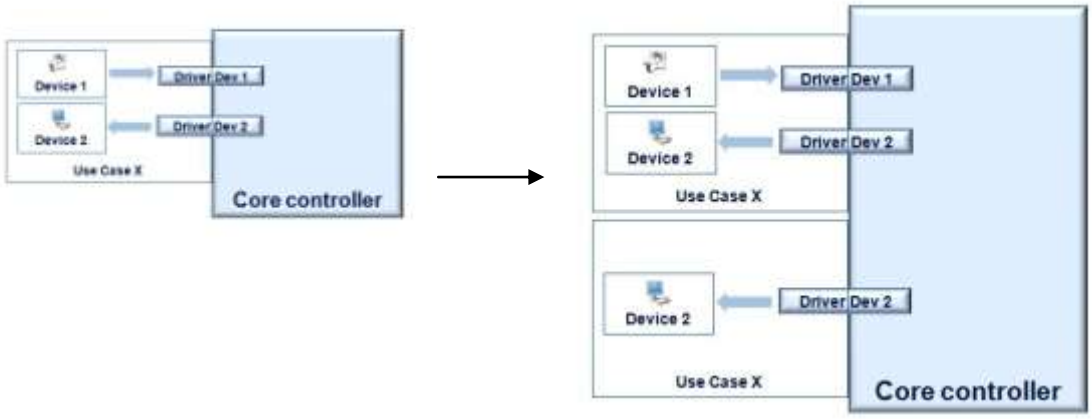

Figure 6: Iterative addition of Use Cases

4 Architectural requirements

4.1 Introduction

The Mediate architecture shall take the requirements dictated by the use cases as described in [6] into account. These requirements are captured from the use cases and described in this section.
Per use case the requirements on the architecture are described in separate sections. These per use case requirements are translated into an overall requirement set.

4.2 Use case view

In [6] 9 different use cases have been defined. Each use case is described in a separate section.
For each use case a visual view of the use case is given. This visual view is based on the description as described in section 3.3 of this document. In this visual view the in- and output are described. For each in- and output the characteristics are defined. The in- and output including their characteristics will form the basis of the requirements on the architecture.
The last section combines these architectural requirements per use case into one set of architectural requirements.

Table 1 gives an overview of the 9 use cases and their in- and outputs.

Use cases		Imaging					Generic data								
#	Name	MR	CT	US	X-ray	Fluoroscopy	ECG	Blood pressure	Blood oxygen	3D electro anatomical map	Anesthesia	Dose distribution	Dose registration	Robot control	Needle orientation
1	Image guided RF ablation of atrial fibrillation or ventricular tachycardia	X	X	X	X	X	X	X	X	X					
2	Image guided Transcatheter Aortic Valve Implantation (TAVI)	X	X	X	X	X	X	X							
3	Image guided Percutaneous Coronary Intervention	X	X		X		X								
4	Prostate cancer image guided minimal invasive, Robotic assisted therapy management (eg Brachy therapy) for low – intermediate patients groups	X	X	X								X	X	X	X
5	Segmentation of uterus myoma	X													
6	Bone Tumor navigation	X	X	X								X	X		
7	Corrective Osteotomy		X												
8	Innovative UI in minimally invasive procedures														
9	SILS –Partial Nephrectomy through a single incision using a robotized tool		X	X			X	X	X						

Table 1 Overview of inputs per use case

4.2.1 Use case 1 RF Ablation of cardiac arrhythmias

The figure below shows a visual view of use case 1 as described in [6].

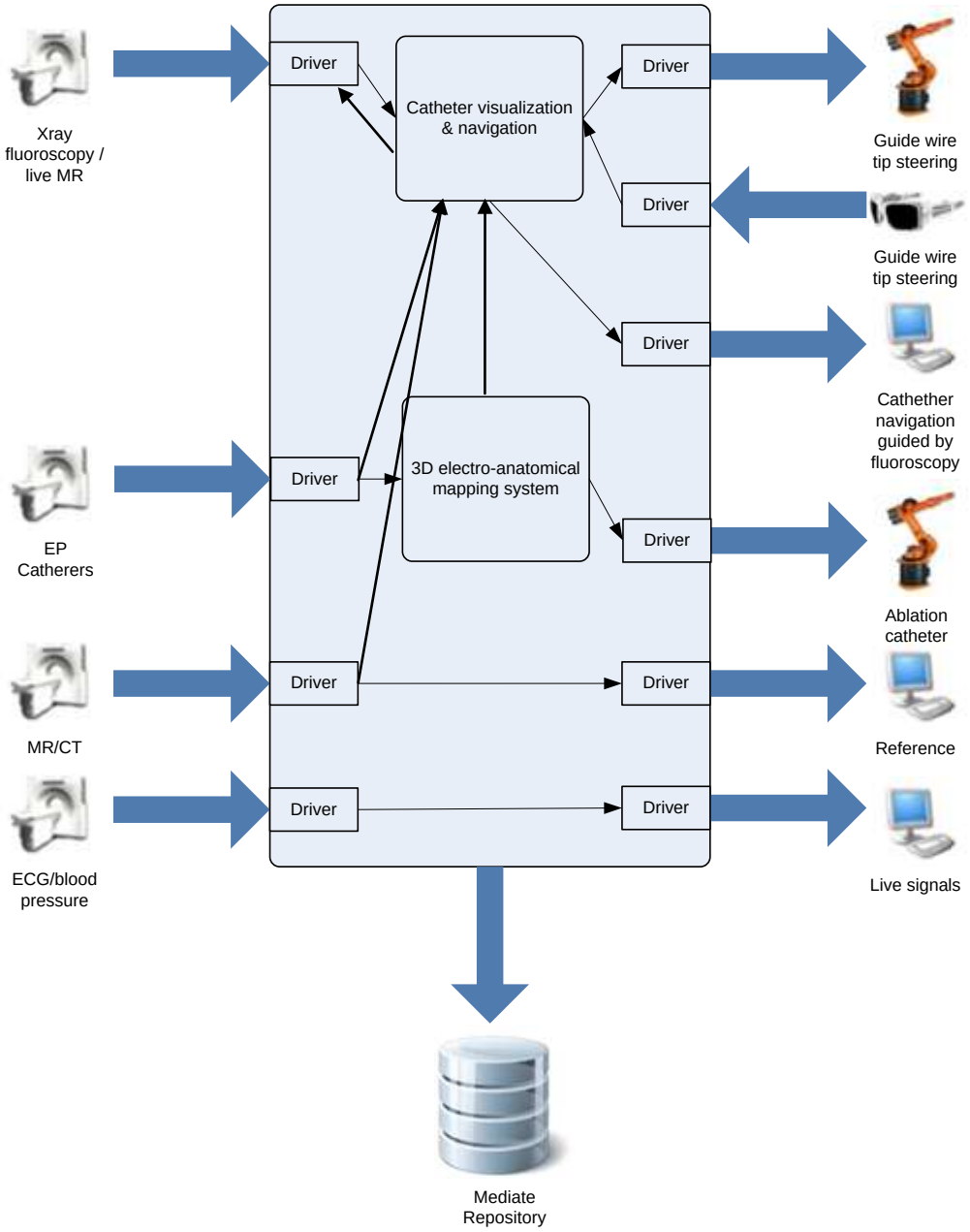

Figure 7: RF Ablation of cardiac arrhythmias

For this use case the following **sensors** are applicable:

Name	Description	Characteristics
CT/MR/Rotational X-ray	CT/MR images for pre-intervention diagnosis and decision.	• DICOM • Persistent • CT ○ Volume 512*512*512 pixels ○ 2 byte / pixel ○ Multiple datasets (20)

		• MR ○ Volume 180*180*180 pixels ○ 2 byte / pixel ○ Multiple datasets (3)
ECG/blood pressure	live signals of ECG, blood pressure etc.	• Data • Large sampling rate. • Not persistent
X-ray Fluoroscopy	Live X-ray fluoroscopy imaging	• 30 fps $1K^2$ image data • Latency < 150 ms • Not persistent • Image meta data needed for registration
MR Live imaging	MR live imaging (alternative for X-ray fluoroscopy). During MR live imaging the catheter positions are used to steer the MR Imaging device	• 10 fps 160*160 image data • Not persistent • Image meta data needed for registration
EP Catheters	Voltages, catheter position	• Data (including the time of ablation) • Low latency (< 100 ms) • Not persistent

For this use case the following **actuators** are applicable:

Name	Description	Characteristics
Guide wire tip steering	Equipment for steering the guide wire tip	• Control interface • Latency < 150 ms
Ablation Catheter	The actual ablation catheter	• Low bandwidth (only control signals like on/off)

For this use case the following **controllers** are applicable:

Name	Description	Characteristics
Guide wire tip steering	Control for controlling the actuator for steering the guide wire tip.	• Control interface • Latency <150 ms

For this use case the following **displays** are applicable:

Name	Description	Characteristics
Catheter navigation guided by fluoroscopy	Display	• DVI • Color • Low latency
Reference	Display	• DVI • Color
Live ECG	Display	• DVI • Color • Low latency

4.2.2 Use case 2 Transcatheter Aortic Value Implantation

The figure below shows a visual view of use case 2 as described in [6].

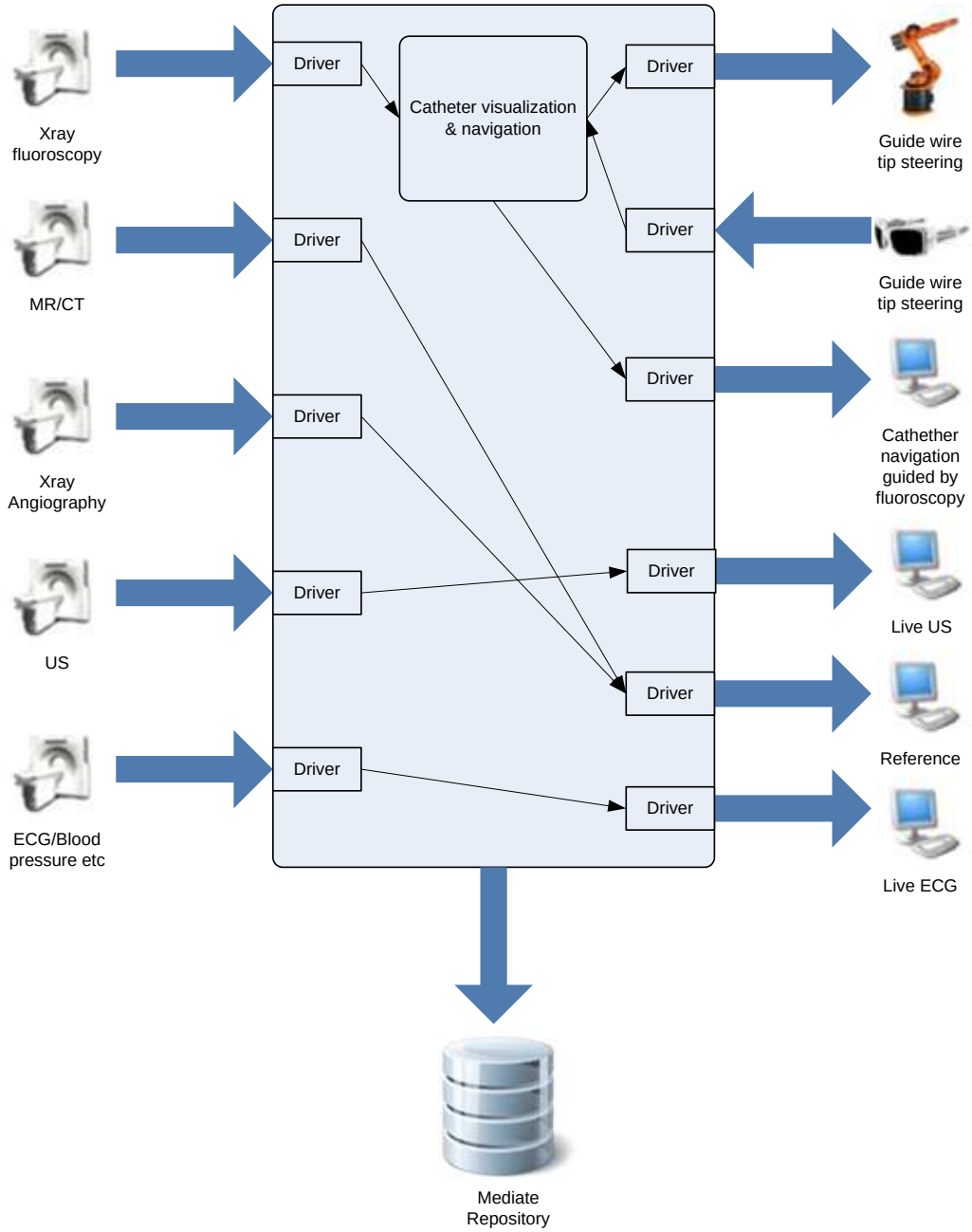

Figure 8: Transcatheter Aortic Value Implantation

For this use case the following **sensors** are applicable:

Name	Description	Characteristics
CT/MR	CT/MR images for pre-intervention diagnosis and decision.	• DICOM • Persistent • CT ○ Volume 512*512*512 pixels ○ 2 byte / pixel

		○ Multiple datasets (20) • MR ○ Volume 180*180*180 pixels ○ 2 byte / pixel ○ Multiple datasets (3)
ECG/blood pressure	live signals of ECG, blood pressure etc.	• Data • Large sampling rate. • Not persistent
X-ray Fluoroscopy	Live X-ray fluoroscopy imaging	• 30 fps $1K^2$ image data • Latency < 150 ms • Not persistent • Image meta data needed for registration
Live X-ray angiography	Live X-ray angiography	• 30 fps $1K^2$ image data • Persistent
X-ray angiography	X-ray Angiography images for pre-intervention diagnosis and decision.	• DICOM ○ Volume 1024*1024*180 pixels ○ 2 byte / pixel
US	Live ultrasound imaging	• 30 fps 512^2 image data • Latency < 150 ms • Persistent on demand

For this use case the following **actuators** are applicable:

Name	Description	Characteristics
Guide wire tip steering	Equipment for steering the guide wire tip	• Control interface • Latency < 150 ms

For this use case the following **controllers** are applicable:

Name	Description	Characteristics
Guide wire tip steering	Control for controlling the actuator for steering the guide wire tip.	• Control interface • Latency <150 ms

For this use case the following **displays** are applicable:

Name	Description	Characteristics
Catheter navigation guided by fluoroscopy/ Angiography	Display	• DVI • Color • Low latency
Reference	Display	• DVI • Color
Live ECG	Display	• DVI • Color • Low latency
Live US	Display	• DVI • Color • Low latency

4.2.3 Use case 3 Percutaneous Coronary Interventions

The figure below shows a visual view of use case 3 as described in [6].

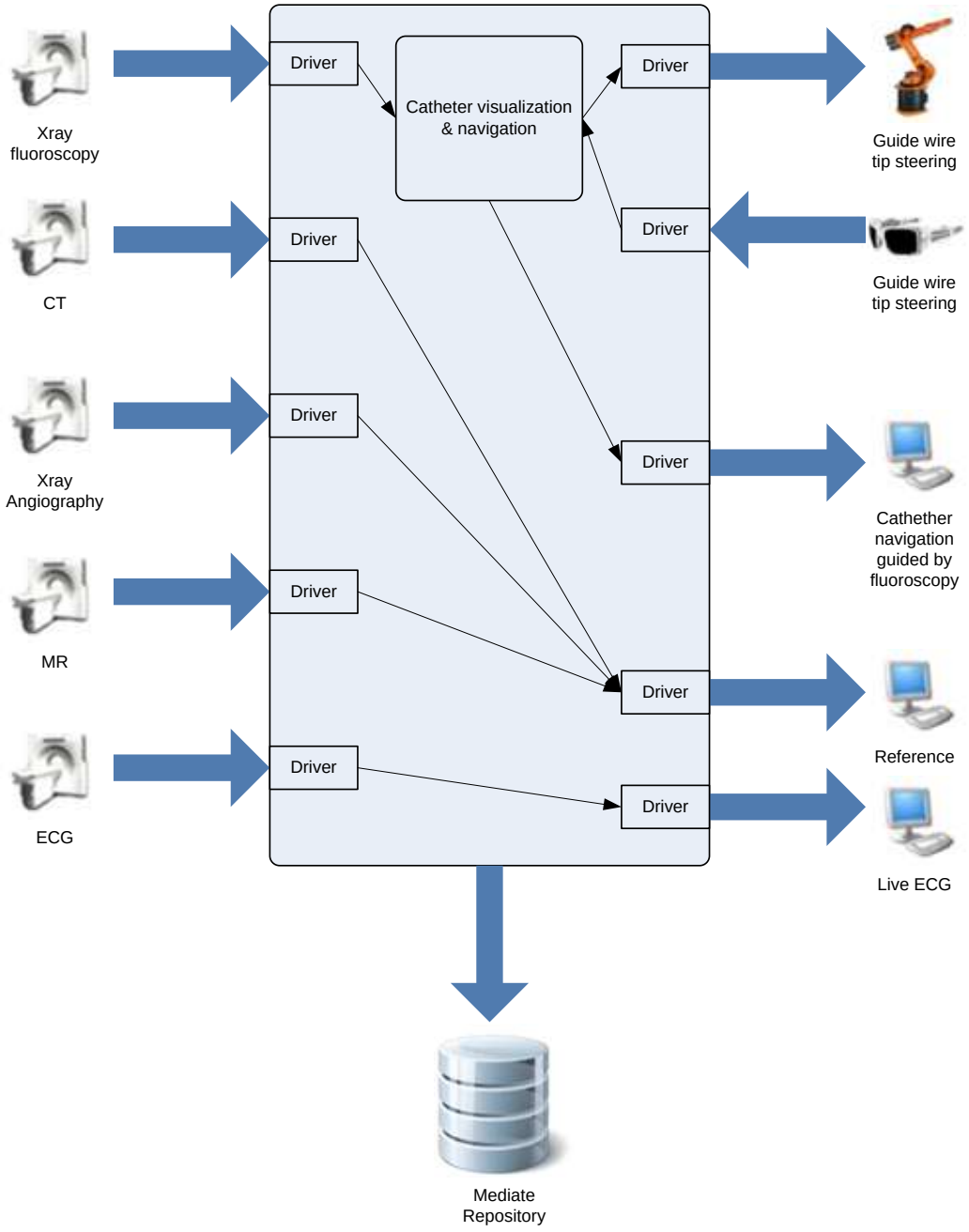

Figure 9: Percutaneous Coronary Intervention

For this use case the following **sensors** are applicable:

Name	Description	Characteristics

CT/MR	CT/MR images for pre-intervention diagnosis and decision.	• DICOM
		• Persistent
		• CT
		  ○ Volume 512*512*512 pixels
		  ○ 2 byte / pixel

		○ Multiple datasets (20) • MR ○ Volume 180*180*180 pixels ○ 2 byte / pixel ○ Multiple datasets (3)
Volumetric X-ray Angiography	Volumetric X-ray Angiography images for diagnosis and decision pre- or during the intervention.	• DICOM • Persistent ○ Volume 512*512*512 pixels ○ 2 byte / pixel ○ Multiple datasets (1-5) • Meta data from original Angio images needed • Calibration data needed
X-ray Angiography	X-ray Angiography images for pre-intervention diagnosis and decision.	• DICOM ○ Volume 1024*1024*180 pixels ○ 2 byte / pixel • Persistent
Live X-ray angiography	Live X-ray angiography	• 30 fps $1K^2$ image data • Persistent
IVUS	Live during intervention	• Live streaming data • 200 MB • Latency < 150 ms • Persistent on demand
OCT	Live during intervention	• Live streaming data • 200 MB • Latency < 150 ms • Persistent on demand
FFR	Pressure data	• Data stream
ECG	ECG signals	• Data • Large sampling rate. • Not persistent
X-ray Fluoroscopy	Live X-ray fluoroscopy imaging	• 30 fps $1K^2$ image data • Latency < 150 ms • Not persistent • Image meta data needed for registration

For this use case the following **actuators** are applicable:

Name	Description	Characteristics
Guide wire tip steering	Equipment for steering the guide wire tip Note: For CTO actuators like Stereotaxis will be used.	• Control interface • Latency < 150 ms

For this use case the following **controllers** are applicable:

Name	Description	Characteristics
Guide wire tip steering	Control for controlling the actuator for steering the guide wire tip.	• Control interface • Latency <150 ms

For this use case the following **displays** are applicable:

Name	Description	Characteristics
Catheter navigation guided by fluoroscopy	Display	• DVI • Color • Low latency
Reference	Display	• DVI • Color
Live ECG	Display	• DVI • Color • Low latency
All live modalities	Display	• DVI • Color • Low latency

4.2.4 Use case 4 Needle ablation of tumors

The figure below shows a visual view of use case 4 as described in [6].

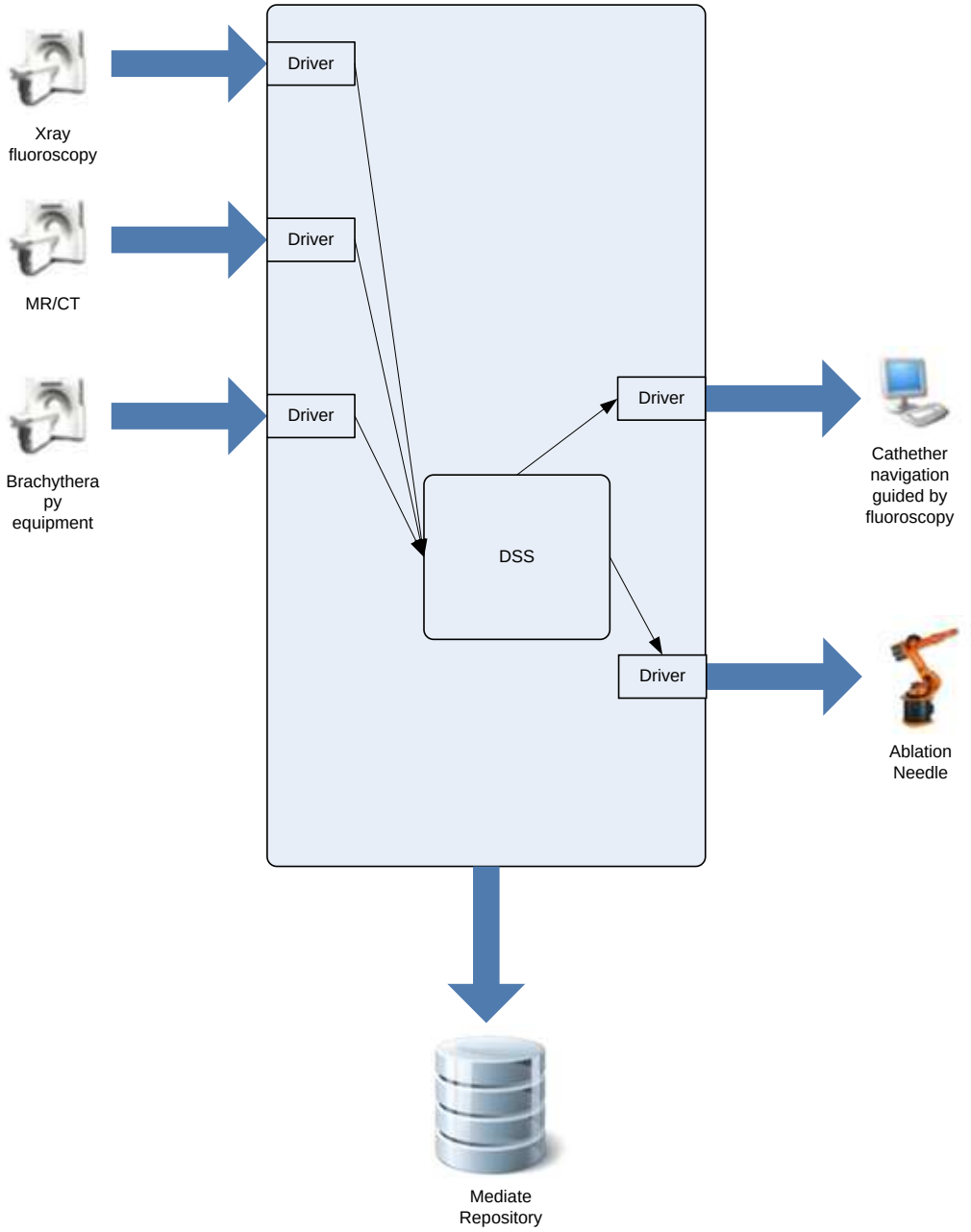

Figure 10: Needle ablation of tumors

For this use case the following **sensors** are applicable:

Name	Description	Characteristics
X-ray Fluoroscopy	Live X-ray fluoroscopy imaging	• 30 fps $1K^2$ image data • Latency < 150 ms • Not persistent • Image meta data needed for registration
US	Live ultrasound imaging	• 30 fps 512^2 image data

		• Latency < 150 ms • Persistent on demand
MR Live imaging	Alternative for Xray	• 10 fps 160*160 image data • Not persistent • Image meta data needed for registration
CT/MR	CT/MR images for pre-intervention diagnosis and decision.	• DICOM • Persistent • CT ○ Volume 512*512*512 pixels ○ 2 byte / pixel ○ Multiple datasets (20) • MR ○ Volume 180*180*180 pixels ○ 2 byte / pixel ○ Multiple datasets (3)

For this use case the following **actuators** are applicable:

Needle tip steering	Manual / robots	• Control interface

For this use case the following **controllers** are applicable:

Name	Description	Characteristics
Ablation	Controller	• Data interface

For this use case the following **displays** are applicable:

Name	Description	Characteristics
Catheter navigation guided by fluoroscopy	Display	• DVI • Color • Low latency

4.2.5 Use case 5 Tumor treatment: MR-guided HIFU

The figure below shows a visual view of use case 5 as described in [6].

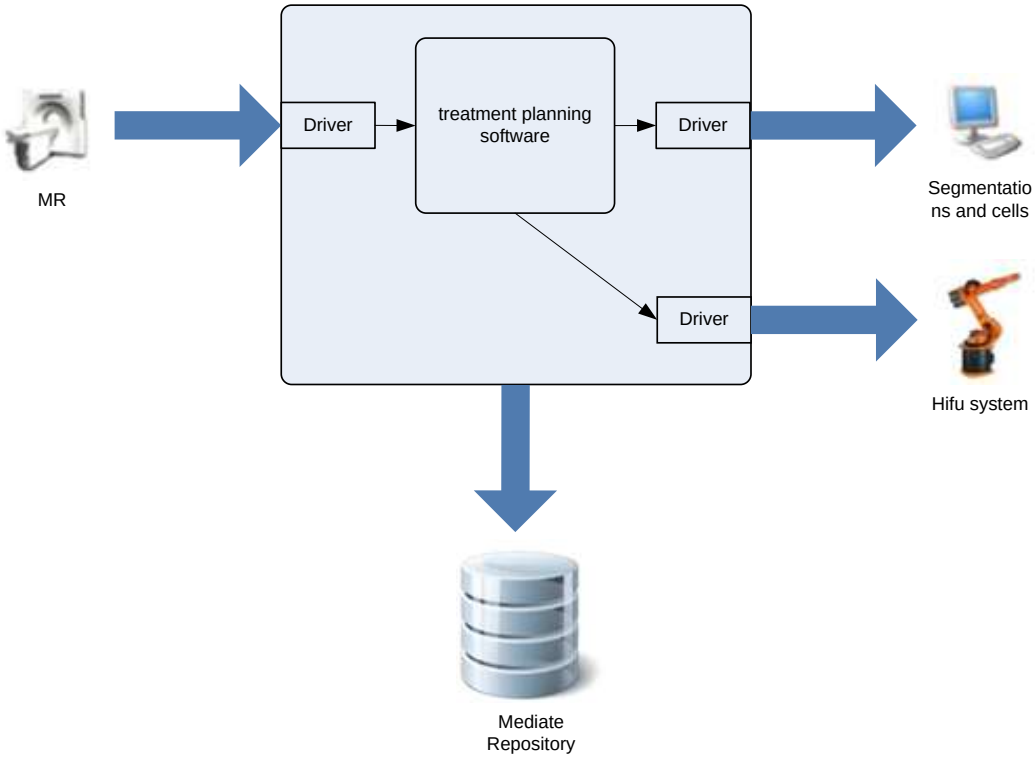

Figure 11: Tumor treatment: MR-guided HIFU

For this use case the following **sensors** are applicable:

Name	Description	Characteristics
MR Live imaging	Live MR imaging to measure temperature of ablation.	• 1 fps 160*160 image data • Not persistent • Image meta data needed for registration
MR	CT/MR images for pre-intervention diagnosis and decision.	• DICOM • Persistent • MR ○ Volume 180*180*180 pixels ○ 2 byte / pixel ○ Multiple datasets (3)

For this use case the following **actuators** are applicable:

Name	Description	Characteristics
Hifu system	High frequency US	• Data interface ○ Control (On/Off) ○ Data (position, size)

For this use case the following **displays** are applicable:

Name	Description	Characteristics
Segmentation and cells	segmentation of ablation area to plan location, number and type of treatment cells	• DVI • Color

4.2.6 Use case 6 Bone tumor navigation

The figure below shows a visual view of use case 6 as described in [6].

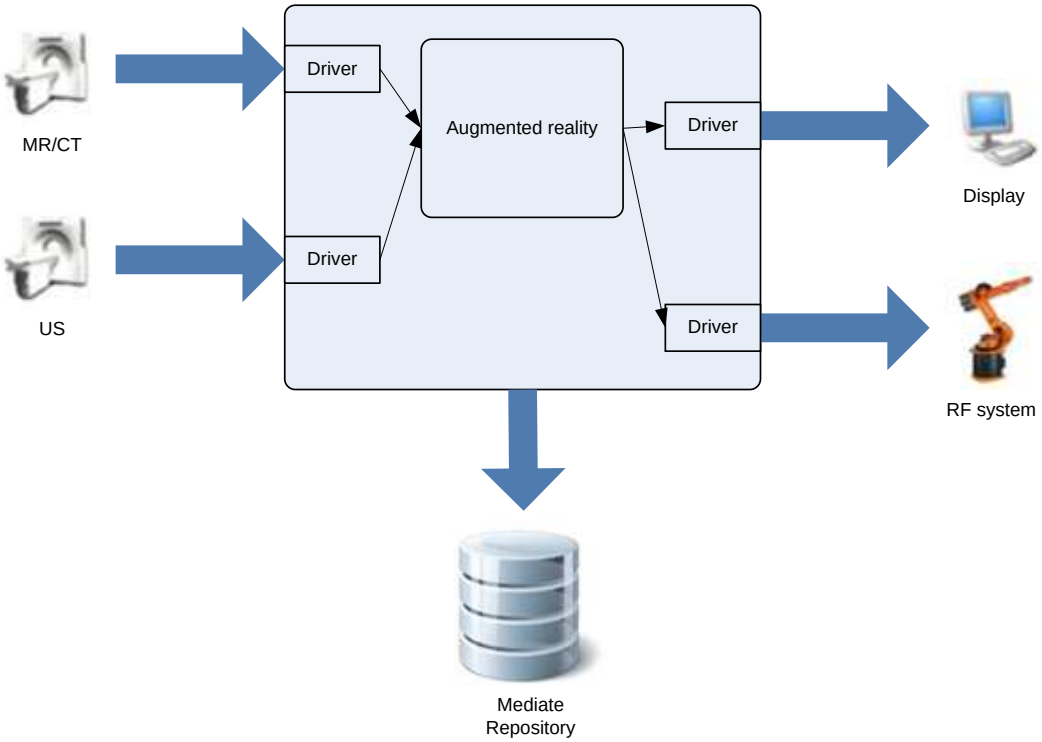

Figure 12: Bone tumor navigation

For this use case the following **sensors** are applicable:

Name	Description	Characteristics
CT/MR	CT/MR images for pre-intervention diagnosis and decision.	• DICOM • Persistent • CT ○ Volume 512*512*512 pixels ○ 2 byte / pixel ○ Multiple datasets (20) • MR ○ Volume 180*180*180 pixels ○ 2 byte / pixel ○ Multiple datasets (3)
US	Live ultrasound imaging	• 30 fps 512^2 image data • Latency < 150 ms • Persistent on demand
Optical tracking device	Optical tracking device for registration of US/MR images and needle.	• Low bandwidth • Low latency

For this use case the following **actuators** are applicable:

Name	Description	Characteristics
RF system	conversion of radio waves into heat	• Data interface ○ Control (On/Off) ○ Data (position, size)

For this use case the following **displays** are applicable:

Name	Description	Characteristics
Display	Display Diffusion (simulation based on the amount of RF power)	• DVI • Color • Low latency

4.2.7 Use case 7 Corrective osteotomy

The figure below shows a visual view of use case7 as described in [6].

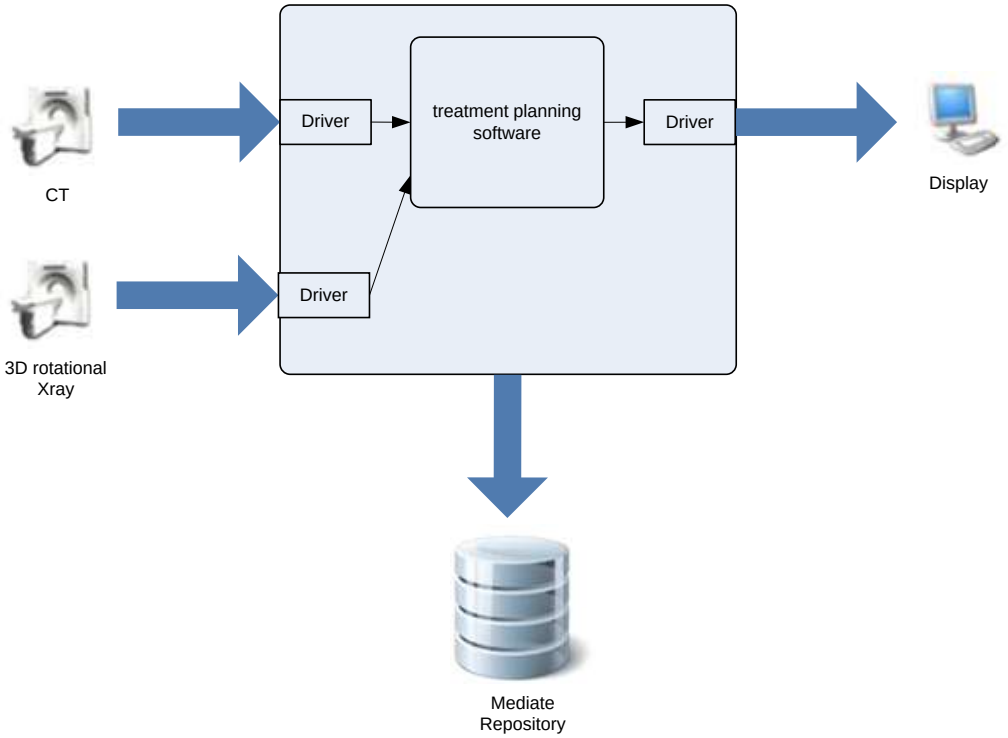

Figure 13: Corrective osteotomy

For this use case the following **sensors** are applicable:

Name	Description	Characteristics
CT	CT images for pre-intervention diagnosis and decision.	• DICOM • Persistent • CT ○ Volume 512*512*512 pixels ○ 2 byte / pixel
3D rotational XRay	Navigation for moving bone fragments. Fast volume reconstruction	• Volume ○ 512*512*512 pixels ○ 2 byte / pixel

For this use case the following **actuators** are applicable:

Name	Description	Characteristics
Fixator	Actuator	• Data interface

For this use case the following **displays** are applicable:

Name	Description	Characteristics
Display	Display	• DVI • Color

4.2.8 Use case 8 Innovative user interfaces in minimally invasive treatment

The figure below shows a visual view of use case 8 as described in [6].

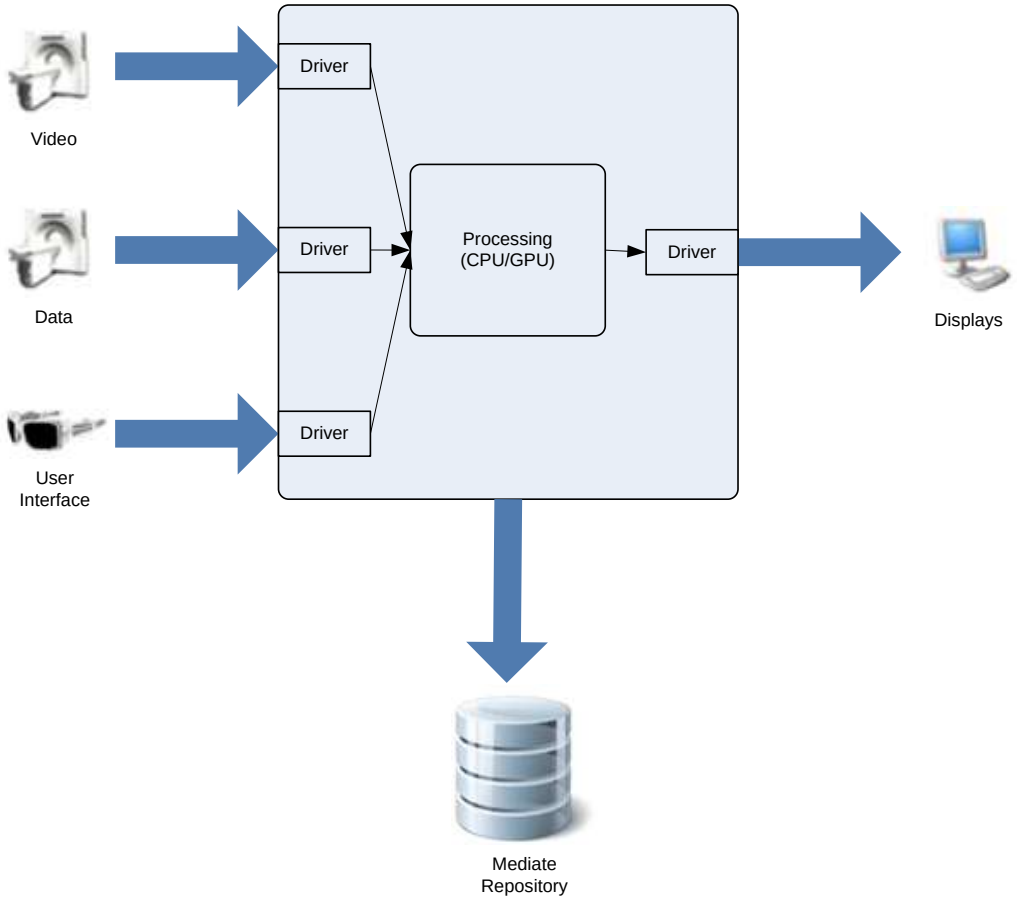

Figure 14: Innovative user interfaces in minimally invasive treatment

For this use case the following **sensors** are applicable:

Name	Description	Characteristics
Video	Video input source	• DVI, HD-SDI, 3G SDI, DISPLAY PORT, SERIAL PORT • Surgical: color high bit-rate signals (3+ Gbit/sec) • CathLab: 1280x1024 ab 60Hz • Raw streaming video. Maximum resolution is full HD 1080p 60Hz, although 1920x1200 at 60Hz is also found in some rare cases • Latency should be less than 100ms (end to end latency). • Format: - 30 bits per pixel, 10:10:10 format - 24 bits per pixel, 8:8:8 format - 16 bits per pixel, 5:6:5 format - 1024-grey scale format - 8 bits per pixel, 3:3:2, 3:2:3, 2:3:3 or 256-grey scale format

		- 4 bits per pixel, 16-grey scale format
Data	Data input source	• Next to image data also meta information is essential.

For this use case the following **controllers** are applicable:

Name	Description	Characteristics
User Interface	For example keyboard/mouse	• USB

For this use case the following **displays** are applicable:

Name	Description	Characteristics
Displays	Video output	• LCD flat panel displays • Full HD resolution • Color accuracy is key (ΔE color difference should be smaller than 3) • DICOM compliant display for DICOM reference images

4.2.9 Use case 9 Single Incision Laparoscopic Surgery (SILS) for partial nephrectomy

The figure below shows a visual view of use case 9 as described in [6].

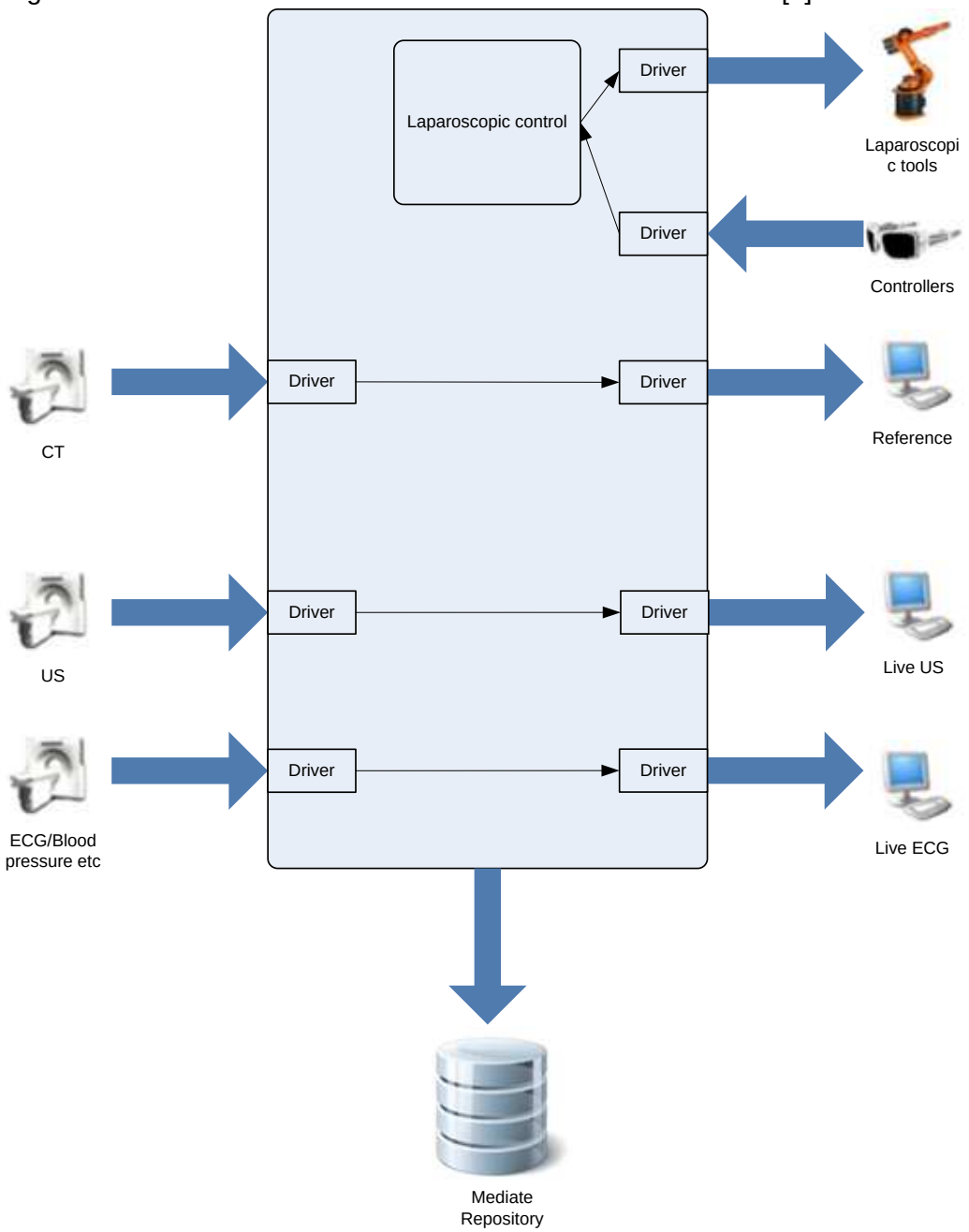

Figure 15: Single Incision Laparoscopic Surgery (SILS) for partial nephrectomy

For this use case the following **sensors** are applicable:

Name	Description	Characteristics
CT	CT images for pre-intervention diagnosis and decision.	• DICOM • Persistent • CT ○ Volume 512*512*512 pixels

		○ 2 byte / pixel
US	Live ultrasound imaging	• 30 fps 512^2 image data • Latency < 150 ms • Persistent on demand
ECG/blood pressure	live signals of ECG, blood pressure etc.	• Data • Large sampling rate. • Not persistent

For this use case the following **actuators** are applicable:

Name	Description	Characteristics
Laparoscopic tools	Actuator	• Data interface

For this use case the following **controllers** are applicable:

Name	Description	Characteristics
Controllers	Controller	• Data interface

For this use case the following **displays** are applicable:

Name	Description	Characteristics
Reference	Display	• DVI • Color
Live ECG	Display	• DVI • Color • Low latency
Live US	Display	• DVI • Color • Low latency

4.3 Requirements

The use cases have been described taking into account three clinical areas: cardiovascular image guided interventions, oncological image guided interventions, orthopaedic interventions. Next to these three clinical areas generic use cases have been described for minimal invasive interventions. All the use cases are described in [6]. The table below show how the use cases are mapping on the clinical areas:

Clinical Area	Use Case
Cardiovascular	Use case 1 RF Ablation of cardiac arrhythmias Use case 2 Transcatheter Aortic Value Implantation Use case 3 Percutaneous Coronary Interventions
Oncological	Use case 4 Needle ablation of tumors Use case 5 Tumor treatment: MR-guided HIFU
Orthopaedic	Use case 6 Bone tumor navigation Use case 7 Corrective osteotomy
Generic minimal invasive interventions	Use case 8 Innovative user interfaces in minimally invasive treatment Use case 9 Single Incision Laparoscopic Surgery (SILS) for partial nephrectomy

Each use case posts constrains on the architecture. These requirements are described in the following sub-sections. Each subsection focuses on a specific area.

Note that the requirements are based on the use cases. Other general requirements, for example security, safety, standards will not be covered in this report. These requirements are covered in D2.1.1 *Security and privacy requirements* and in D2.2.1 *Standard and interoperability*.

4.3.1 Requirements on visualization

Mediate.Visualization.Displays
The system shall allow visualizing multiple sources on multiple displays in a flexible way.

Mediate.Visualization.Locations
The system shall allow displays in- and outside the intervention room.

Mediate.Visualization.Quality
The system shall allow images to be displayed in HD video quality

Mediate.Visualization.Latency
The system shall not add more than 150 ms latency to imaging data (from source to display)
Rationale: needed for eye-hand coordination.

4.3.2 Requirements on user Interfaces

Mediate.UserInterface.Workflow
The system shall provide a user interface optimized for the workflow.

Mediate.UserInterface.Extendibility
The system shall provide mechanisms to connect multiple user interface devices

Mediate.UserInterface.Friendly
The ease of use and the simplicity to be used by clinical staff

4.3.3 Requirements on connectivity

Mediate.Connectivity.Archive
The system shall support DICOM for export and import of imaging data.

Mediate.Connectivity.ImageData
The system shall allow interconnectivity of image data with the outside world (e.g. hospital and internet)
Rationale: external consultancy and streaming to lecture rooms.

4.3.4 Requirements on Data inputs

Mediate.Inputs.Location
The system shall allow usage of input sources from outside the intervention room.

Mediate.Inputs.Images
The system shall combine image and meta data as one stream.

Mediate.Inputs.Sources
The system shall allow inputs from different sources (medical imaging equipment (e.g. MR, CR, X-ray), medical equipment (e.g. ECG), cameras (e.g. streaming to lecture rooms), etc)

Mediate.Inputs.Latency
The system shall provide different latency domains for data.
Rationale: Different inputs have different latency requirements. For example:

Live imaging used for navigation requires latency < 150 ms to allow eye-hand coordination.
Live imaging used for MR-guided HIFU requires latency < 10 ms
Haptic devices requires latency < 1ms

Mediate.Inputs.Sources
The system shall allow data to be stored persistently

4.3.5 Requirements on outputs

Mediate.output.reports
The system shall provide generic data reports which depend on the use case and the proposed solution. This kind of generic reports could have a double interest as kind of archive for clinical staff and logging module for engineers and development staff.

4.3.6 Requirements on Environment

Mediate.Environment.Sterile
The system shall allow usage in a sterile environment.

Mediate.Environment.OperatingRoom
The system shall allow usage in an operation room.

Mediate.Environment.XRay.Protection
The system shall provide protection for X-ray radiation.

Mediate.Environment.XRay.Monitoring
The system shall provide monitoring tools for the received X-ray radiation on patient and personnel.

5 State of the art on technologies

5.1 Introduction

The previous section (section 4) captures the requirements on the MEDIATE architectural based on the use cases. Whereas this section focuses on the state of the art on technologies. Each of the important technologies for architecture and for the use cases are described in separate sub-sections.

5.2 User interface concepts

Regarding User Interface issues, there are specific requirements Intervention room, which have been described in D6.2.1 WP6 deliverable. Some of the most important are:

- UI elements large and easy to read
- Easy access to UI elements from a medium distance (1.5 meters)
- UI controllers should be preferably handled hands-free or at least without looking at them (voice/gesture control, for example or eye/gaze tracking).
- Quick access and response, UI clear and ergonomic, due to the long and tiring operations, which can take several hours.
- Unified UI, providing a homogeneous aspect to all related applications

Regarding the Decision Support Systems (DSS), they are an innovative field with important applications in eHealth. In MEDIATE a Case Based Reasoning (CBR) will be developed in case the statistics about several clinical parameters proved to be insufficient to provide decision support.

Concerning architecture, the Decision Support System will be viewed as a separate module (see Figure 5: Driver-by-device approach), receiving input from sensors and repository and providing useful information to surgeon by means of displays. As the rest of systems, it will follow global UI principles of ergonomy and user-friendliness.

5.3 Visualization, Networking and Data distribution concepts

The integrated solution for the visualization of medical image, video and data sources is composed of a number of areas or technology zones:

1. Input zone: this zone contains various types of medical equipment that generate video, images or data that needs to be distributed across the network to various displays. These sources can be IP-based video sources, non-IP based (DVI, SDI, …) video sources, PACS images, patient data records, 3D-rendered images, etc.
2. Distribution zone: this zone is implemented via an IP network that interconnects all devices in the room or outside the room. The network can be composed of multiple interconnected networks and switches.
3. Room display zone: this zone contains the displays and image rendering tools to visualize the content from the input zone in the desired output format on the requested display. This display can be a 24” surgical display in an operation room, a 56” display in the cath lab or multiple smaller displays in the control room of the cath lab. In fact, it must be possible to display any input content on any output display.
4. External connectivity zone: this zone implements the interconnection of the intervention room (cath lab, EP lab, OR) with the rest of the hospital and potentially also the outside world.

These zones are visualized in the figure below.

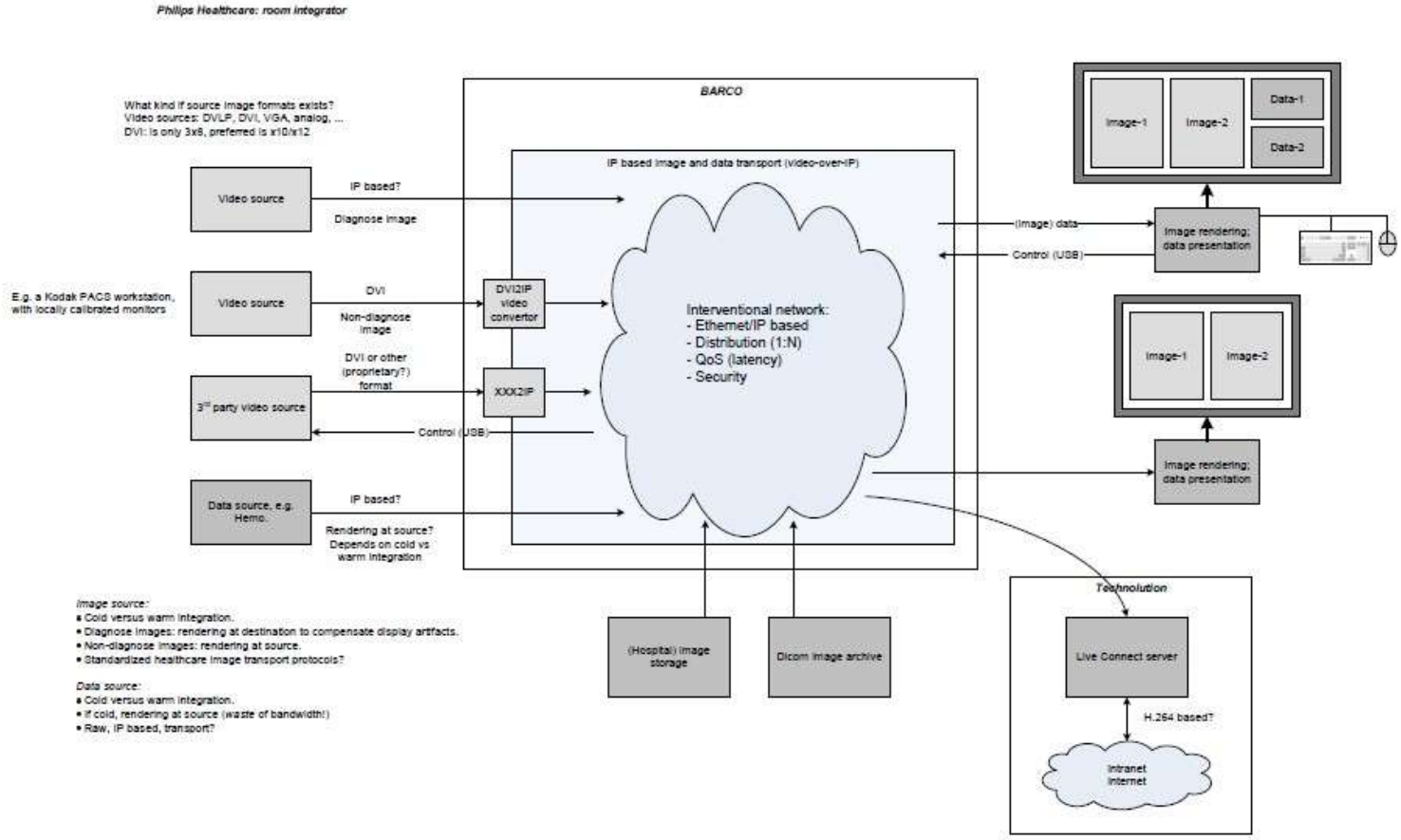

Figure 16: Technology zones overview

5.4 Image processing through physiological simulation techniques

According to the EC VPH[1] initiative, major diseases (cardiovascular diseases, neurological diseases, cancer, etc.) will benefit from computer models and in silico environments that will improve diagnosis and treatment planning. From a workflow perspective, this starts with sensors and image acquisition, is followed by physiological simulation, and finishes by summarizing result to feed pre-operative planning.

Physiological simulation permits the analysis of *whatif* scenarios. For instance, different stents may be tested in silico on top of the patient anatomy and physiology as part of preoperative planning. Accurate results demand:

- Image modalities adapted to each case, so that they provide the maximum information which is relevant for the planned intervention. Different combinations of MRI, CT, US and other image acquisition techniques provide the best capabilities in specific cases.
- Image curation, so raw images are used to reconstruct the 3D anatomy of the patient's region of interest, which may include parts of one or more organs. In some cases imaging techniques also provide already some physiological information, such as blood flow speed through Doppler (in US).
- Precise physical models of the region of interest. For instance, in the case of TAVI it is necessary to model the physiology of the ventricular and arterial walls, the aortic valve, and blood. At a mathematical level this is represented by partial differential equations (PDE) tailored to each tissue and possibly further tailored to the specific case of the patient's. For instance, the aortic valve is modelled through a viscoelastic equation, but exact parametrizations may depend on the specific properties of the patient's valve.
- Appropriate discretization schemes, which translate the abstract mathematical tissue model into a representation that implements an algorithm that runs on a computer. The discretization schemes work on meshes of points, which are mapped to the patient's anatomy. Discretization schemes are quite diverse and it is important to choose the right scheme for each tissue. For instance, blood flow is usually best resolved by using meshless methods, such as Smoothed Particle Hydrodynamics (SPH) or Lattice Boltzmann Methods (LBM). Solid rigid structures such as bone or stents are usually resolved through Finite Element Methods (FEM). Other methods include Finite Volume Methods (FVM) and Finite Difference Methods (FDM). It is quite important – and challenging - how different discretization methods representing neighbouring tissues are connected. In the case of solid-fluid interaction this is called FSI (fluid-solid interaction) and it is a very active field of research.
- A simulation platform on top of which such physical models and discretization schemas can be implemented. This platform needs to deliver in terms of scalability - using concepts such as MPI for parallelization - , security - integrating with the chosen IT architecture – and flexibility – so that any

[1] http://www.vph-noe.eu

required model or schema can be easily implemented and tailored to the use case needs.

- Visualization techniques that allow for the integration of the resulting simulation with the reconstructed patient anatomy and for the physician to navigate the region of interest both in space and time.

Research is quite active in all the points listed above, which constitute the workflow on which physiological simulation for pre-operative planning is built. Many techniques from other areas of knowledge, such as materials science or computational fluid dynamics, are being borrowed and adapted.

5.5 Integration concepts

5.5.1 Brachytherapy treatment systems

In Brachy therapy a treatment with a radioactive source or X-ray device is performed, by which the goal is to deliver radioactive radiation, gamma radiation or X-ray at the tumor and as less as possible radiation at the healthy tissue and organs at risk. In fact the user wants to irradiate the tumor with as much as possible dose and spare the organs and healthy tissue.

Integration of imaging and treatment planning
To execute this task, the user starts with a treatment planning, and the treatment planning is based mostly on 3D images of the patient. In 3D the tumor is indicated and organs at risks , and with optimization software the “best” dose distribution is calculated. In general this is a compromise between as much as possible dose on the tumor and as less as possible dose on the organs at risk.

Integration of imaging and navigation
This is still not reality, the user has to make an implant in the patient with catheters or applicators and needles to make the dose distribution as planned. To make the implant close to planned, the implant is mostly guided with real time imaging.
Most of the time the real time imaging is with X-ray fluoro, CBCT, Ultrasound or MRI
The implant guidance is based on 2D images and the trend will be real time 3D images if possible.
Next step is updating of the treatment planning since the implant is different than planned in the pre-planning. A new 3D image is made of the patient implant and with a short optimization the adapted dose distribution is calculated with a live planning.

Integration of imaging and treatment
The next task is to perform the live planning with the radioactive source or X-ray device as close as possible. Verification of the treatment according the planning is asked and “source tracking”, to verify the correct source position or “in vivo dosimetry” to verify at critical patient points the planned radioactive dose.

5.5.2 Treatment planning update by CT images

An important use case for integration of 3D imaging and treatment planning is the so called “advanced dose calculation” In Brachy planning is the dosimetry based on a patient of water. In reality the patient has different tissues, so the treatment planning will be much more accurate when the type of tissue is taken into account for the absorption of the radiation and the generated dose. With the 3D CT image a direct relation exist with the absorption of gamma rays, and in indirect relation for dose generation. The software module to adapt the dose planning by input of the 3D CT image will be developed. Improvements of 5-25% in dosimetry will be obtained dependent on the bodysite to treat.

5.5.3 MRI guided Brachy therapy

The most recommended imaging modality to perform Brachy treatments is MRI since the tumor and organs are very good visible. If possible a 3D MRI image is the basis for the Brachy planning and Brachy treatment. The goal is to develop a Brachy treatment by which the planning is based on 3D MRI and the implant is guided under MRI. The final plan is made directly after the implant, again supported by the 3D MRI image of the patient with the implant. This procedure must be real time in the MRI room and supported by real time 2D MRI imaging and rather fast static 3D MRI images.
Goal is to develop this MRI guided Brachy workflow in software and hardware, special problems to solve here are the MRI compatibility and visibility of catheters, needles and applicators which are needed for the Brachy implant.

5.5.4 Brachytherapy treatment navigation

Two use cases are in development to verify the correct dosimetry in the patient.
The first approach is to determine real time the position of the radioactive source in the patient. The patient is represented by the 3D image of the patient implant, and the radioactive source will be steered to the dwell positions in the implant, defined by the treatment planning. The source position will be tracked and final results of the real dwell positions and dwell times of the source are stored in a treatment record.
The actual dose delivered in the patient can be verified by these data in post planning
The second approach is “in vivo dosimetry” by which at some patient points the accumulated dose is measured. With the treatment planning some critical patient points are defined, and the planned dose is calculated. By positioning the dosimeters at the defined patient points the actual delivered dose is checked.

5.5.5 Brachytherapy treatment ergonomics

The Brachy treatment workflow is rather complex, since the radioactive source is controlled remote from a control room. High security requirements have to be fulfilled to perform a radioactive treatment. The patient and user must be safe during all phases of the workflow. The ergonomics,usability, and workflow will be optimized by which imaging of patient and visualization of the workflow in treatment room and control room are taken into account. Both hardware and software are developed on basis of workflow and usability starting from patient and user requirements.

5.6 Haptic devices

A “haptic device” is electromechanical equipment, used as an input/ouput interface for physical interaction with a computer-driven system. The most common haptic devices are arm-like robots equipped with a stylus or a handle at the tip instead of a gripper.

The aim of integrating haptic devices inside the operation room is to help the surgeon during his work. His interventions are performed using tools as scalpel, clamp, endoscope, laparoscope, milling tool, saw,…

Haptic devices can be used in two different ways:

- Force feedback Master/Slave system: The haptic device is a Controller to pilot the Actuator with force-feedback. The tools working on the patient are connected to the Actuator. The surgeon feels the interaction between the tools and the patient.
- Collaborative robot system (Cobot): The surgeon manipulates his tools as usual. The haptic device is also directly connected to the tools in order to guide and control the actions of the surgeon.

In both cases, a 3D simulation can run in parallel to monitor the real actions on the patient. The complexity of the simulation must be adapted to the use-case. For example, a simple 3D simulation can prevent the tool from entering a forbidden area. The forbidden area is defined by the surgeon from the database of the patient model. Another example of 3D simulation can be

- Simple viscosity simulation
- Simple virtual guide as prismatic constraints, planar constraints,…

The 3D simulation is updated in real-time based on the data coming from the haptic device, the slave robot and other external sensors.

A camera can be installed to track the task performed by the slave robot or the cobot. The position of the camera can be motorized in order to follow the tools of the surgeon.

The 3D simulation and the images from the camera can be visualized on a screen.

As the patient is able to move, it is useful to integrate external sensors (optical sensor for example) in order to track the position of the patient with respect to the position of the tools. The data from these external sensors can be used to update the simulation, for example the position of the forbidden area in the intervention zone.

To understand this architecture, it is very important to note that the haptic device, the slave robot, the simulation and the coupling module must be executed with a frequency greater than 300 Hz. The measurement from the external sensors can be integrated with a lower frequency.

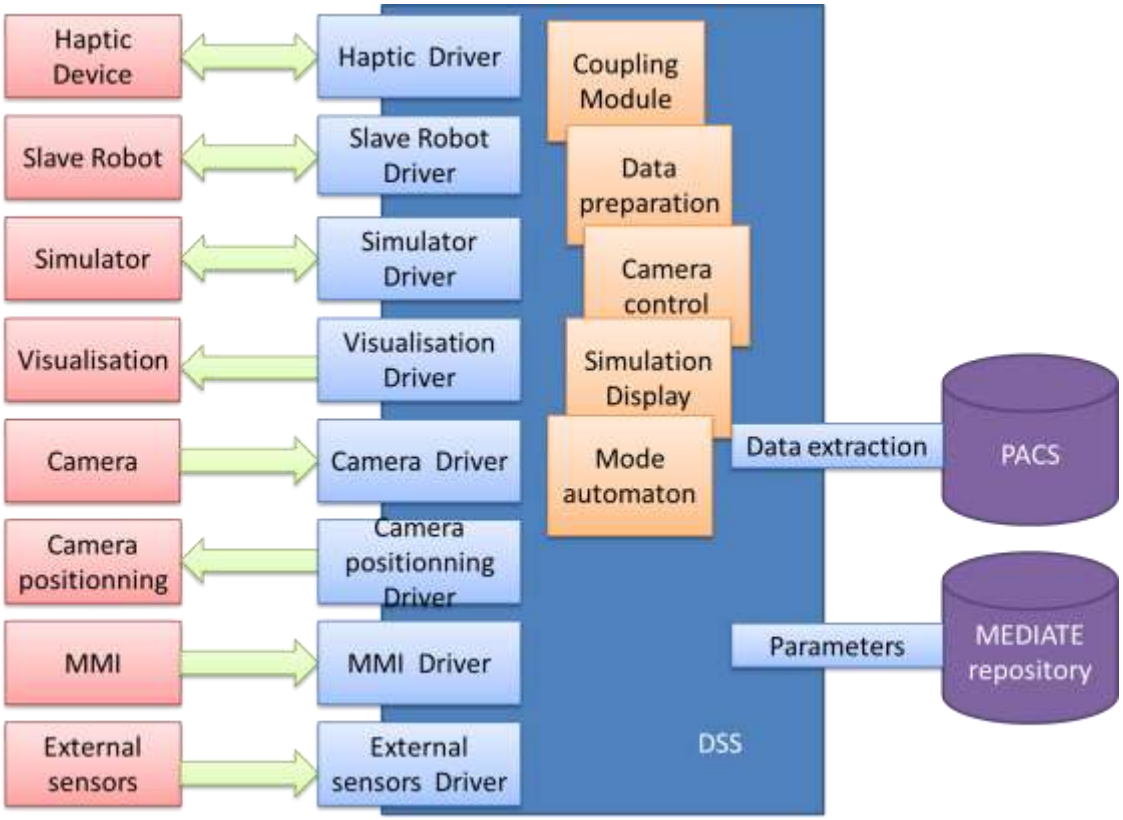

Figure 17: Haptic devices architecture

5.6.1 Haptic device and its driver

The haptic device is a force-feedback system. It provides:

i. Measurement of the movement of the surgeon's hands and/or sensing any forces he exerts;
ii. Presentation of the resultant forces to the surgeon's hands as appropriate.

The resultant force is calculated by the Coupling module based on the position and the speed of the haptic device, the slave robot and the simulation.

The Haptic device communicates to the DSS though the Haptic Driver by means of a real-time network connection. The network must be able to provide a high level of reliability in order to warranty the behavior of the system.

The Haptic Driver provides the state vector (position, speed, …) of the haptic device and sends commands (position and speed for admittance mode; force for impedance mode).

The Haptic Driver also provides functionalities to update other information, as the position of the observation frame (to get a coherent movement between the haptic device and the point of view used even if this point of view comes from a camera).

5.6.2 Components integrated in DSS

5.6.2.1 Coupling module

The coupling module binds together the haptic interface (Controller), the slave robot (Actuator) and the simulation.

The coupling module usually implements one of the two following strategies:

- Impedance mode: The coupling module reads the current position of haptic interface (Controller), of the slave robot (Actuator) and of the tool model in the simulation. After computation, it sends forces to the 3 entities.
- Admittance mode: The coupling module reads the current position of haptic interface (Controller), of the slave robot (Actuator) and of the tool model in the simulation. After computation, it sends new required positions to the 3 entities.

The Admittance mode provides a higher level of safety and the stability of the system can be proven. This mode should be selected for such applications.

For a cobot system, the coupling module has to deal only with 2 entities: the haptic device (acting as Controller and Actuator simultaneously) and the simulation.

The Coupling module is a part of the “Core Controller”. This module works with hard real-time constraints with a frequency greater than 300 Hz. The haptic device, the slave robot and the simulation must run with the same frequency.

The Coupling module needs the specific parameters of the Controller, the Actuator and the simulation.

5.6.2.2 Data preparation

The simulation is created with 3D models extracted from the patient database. Depending on the use-case, the model extracted can be simple or more complex. For example, the surgeon can define a forbidden area in the patient where the tool should not enter. The forbidden area can be modeled as a rigid object. As the tool is also a rigid object, the simulation can be made with well-known algorithms.

From the MEDIATE repository, the surgeon must be able to extract the model of an area of the patient. Using the Data preparation module, the surgeon can define a forbidden area or extract parts used in the simulation. He can also select a model of the tool(s) used during the intervention. The outputs of the module are parts integrated into the simulation.

In the simulation, the virtual tool is controlled by the position and the speed of the real tool known through the Coupling Module. Other components of the scene can be tracked by other sensor (optical tracking,…). The position of the corresponding virtual component can be upgraded in the simulator and impact the position of the virtual tool.

5.6.2.3 Camera control

The module calculates the position of the tools from the position of the slave robot (or from the cobot). The position of the camera can be controlled in order to follow the tools during the intervention.

This module sends orders to the Camera Positioning system.

5.6.2.4 Simulation display

The display of the simulation is not compulsory. Sometime the display of this simulation can provide helps to the surgeon. The physical simulation is then connected to a viewer. Thanks to this viewer, virtual camera can be added to give a new point of view to the surgeon.

These virtual points of view and the camera view can be display by the visualization device.

5.6.2.5 Finite-State Automaton

The surgeon can choose to connect the haptic device to the slave robot or to start the tracking of camera on the tools. These modes are activated with the Man Machine Interface when the automaton is updated.

The MMI must also provide the possibility to select a force factor and a position factor between the haptic device and the slave robot.

5.6.3 Frequency constraints

All the devices which can work in collaboration with a haptic device have their own constraints. Specifically, the frequency of the data transfer is an important feature.

Device	Cycle	Frequency
Haptic Driver	Asynchrony (Initialisation) Synchrony	None > 300 Hz
Slave Robot Driver	Asynchrony (Initialisation) Synchrony	None > 300 Hz
Simulation Driver	Asynchrony (Initialisation) Synchrony	None > 300 Hz
Visualization Driver	Synchrony	> 25 Hz
Camera Driver	Synchrony	> 25 Hz
Camera Positioning Driver	Synchrony	> 10 Hz
MMI Driver	Asynchrony	None
External Sensors Driver	Asynchrony (Initialisation) Synchrony	None > 60 Hz

The network of the full system must be compatible with these constraints.

6 Glossary

CBCT used in p.36, line 20
CBR Case Based Reasoning
CDA Clinical Document Architecture
CEN European Committee for Standardization
CT Computer Tomography
DICOM Digital Imaging and Communications in Medicine
DSS Decision Support Systems
DVI Digital Visual Interface
ECG ElectroCardioGram
FFR Fractional Flow Reserve
HER Health Electronic Record
HIFU High Intensity Focused Ultrasound
HIS Health Information Systems
HL7 Health Record 7
IGIT Image Guided Intervention and Treatment
ISO International Standard Organization
IVUS IntraVascular UltraSound
MMI Man–Machine Interface
MPI Message Passing Interface
MRI Magnetic Resonance Imaging
OCT Optical Coherence Tomography
PACS Picture Archiving and Communication System
RIM Reference Information Model
UI User Interface

7 References

[1] CEN/TC 251 (European Committee for Standardization / Technical Committee 251), 1999. EN13606. http://www.centc251.org/

[2] http://urobotics.urology.jhu.edu/projects/MrBot/

[3] http://www.en13606.org/

[4] http://www.hl7.org/

[5] http://www.openehr.org/

[6] D1.2.1 “End-user scenarios and requirements”
Mediate Deliverable, WP1

Appendix A: List of requirement tags