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Patient Safety in Robotic Surgery

Safety Principles: the Safros Stance on Patient Safety

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Consortium Composition

ÉCOLE POLYTECHNIQUE FÉDÉRALE DE LAUSANNE

center for biorobotics

Karlsruhe Institute of Technology

HOLOGRAFIKA Holographic display technology

DLR

FONDAZIONE CENTRO S. RAFFAELE DEL MONTE TABOR

Force Dimension

World Health Organization

SCHOOL OF PEDAGOGICAL AND TECHNOLOGICAL EDUCATION

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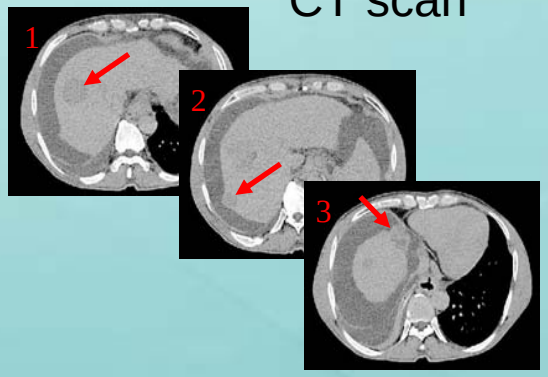
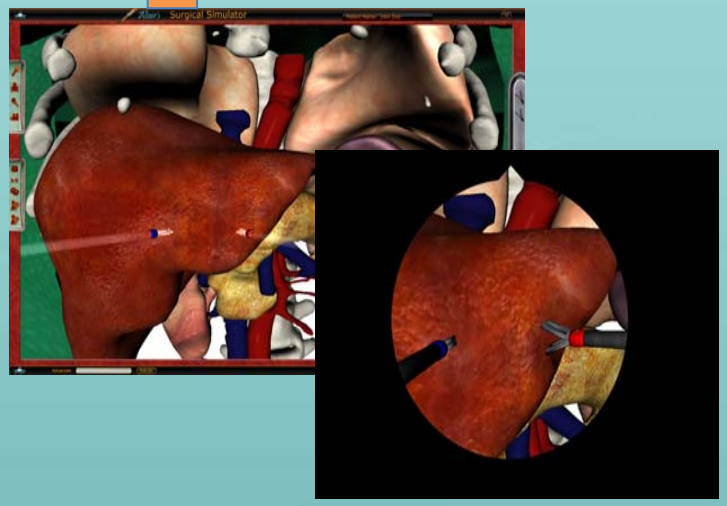
Approach

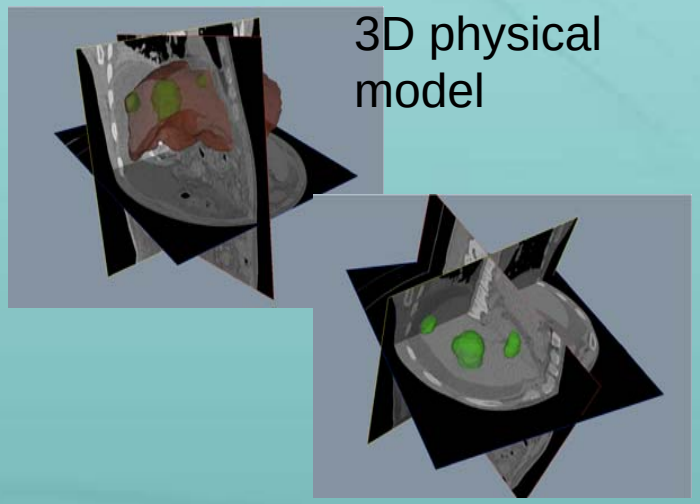
Robotic execution

CT scan





3D interactive virtual reality



3D physical model

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Initial Safety Concepts:

1.Safety of pre- and intra-operative 3D model reconstruction.
2.Safety of deformable organ models and surgical simulator.
3.Safety of surgical planning.
4.Safety of the surgery execution.
5.Safety of surgical robots and their models.
6.Safety of the operator interface.

Project Workflow

1. Develop swine phantoms (physical models) and computer models
2. Carry out virtual interventions
3. Repeat the interventions on the phantoms
4. Repeat the interventions on the animal (two robots, two anatomies)
5. Collect data on accuracy, errors, etc. and generalize

1. Develop human phantoms (physical models) and computer models
2. Carry out virtual interventions
3. Repeat the interventions on phantoms
4. Extrapolate the effects (safety, accuracy, precision, etc) on human interventions from the animal data

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Hardware Support

Need a robot that could support the data flow

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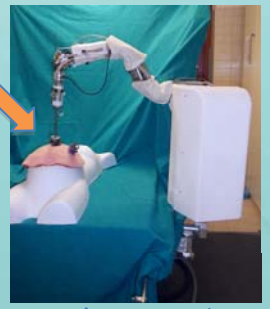
Hardware Support



Need technologies related to the use of the robot

- Telepresence Operator Interface
- Robot Modeling and Diagnostics
- Operating Room Workflow
- Training and Education

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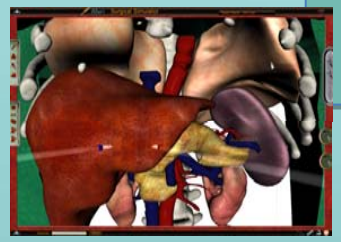
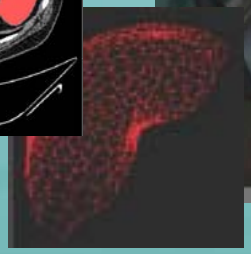
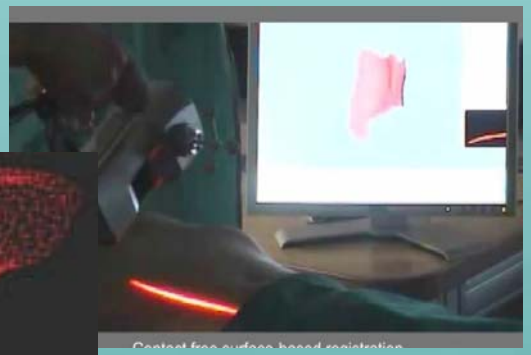
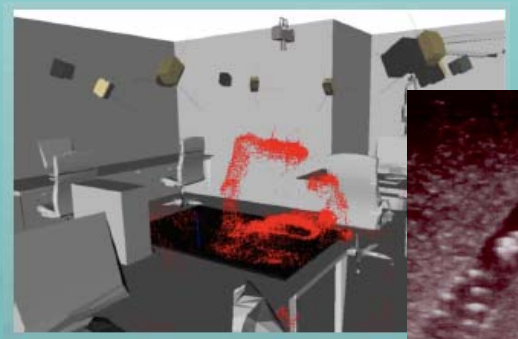
Software Support

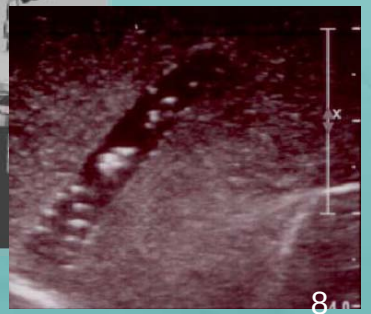


Need modeling and registration software

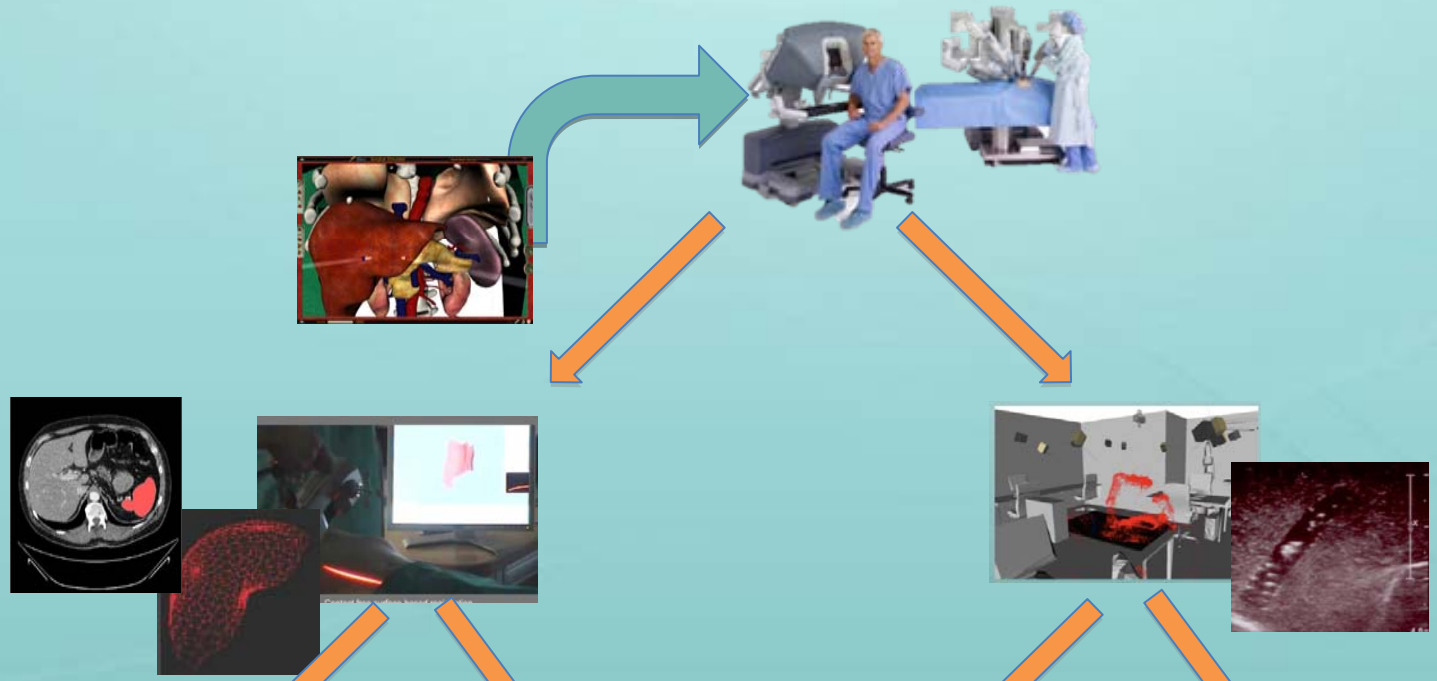








Software Support



Phantoms and virtual models

Medical image segmentation and validation

Object tracking and 3d modeling

Ultra sound image processing

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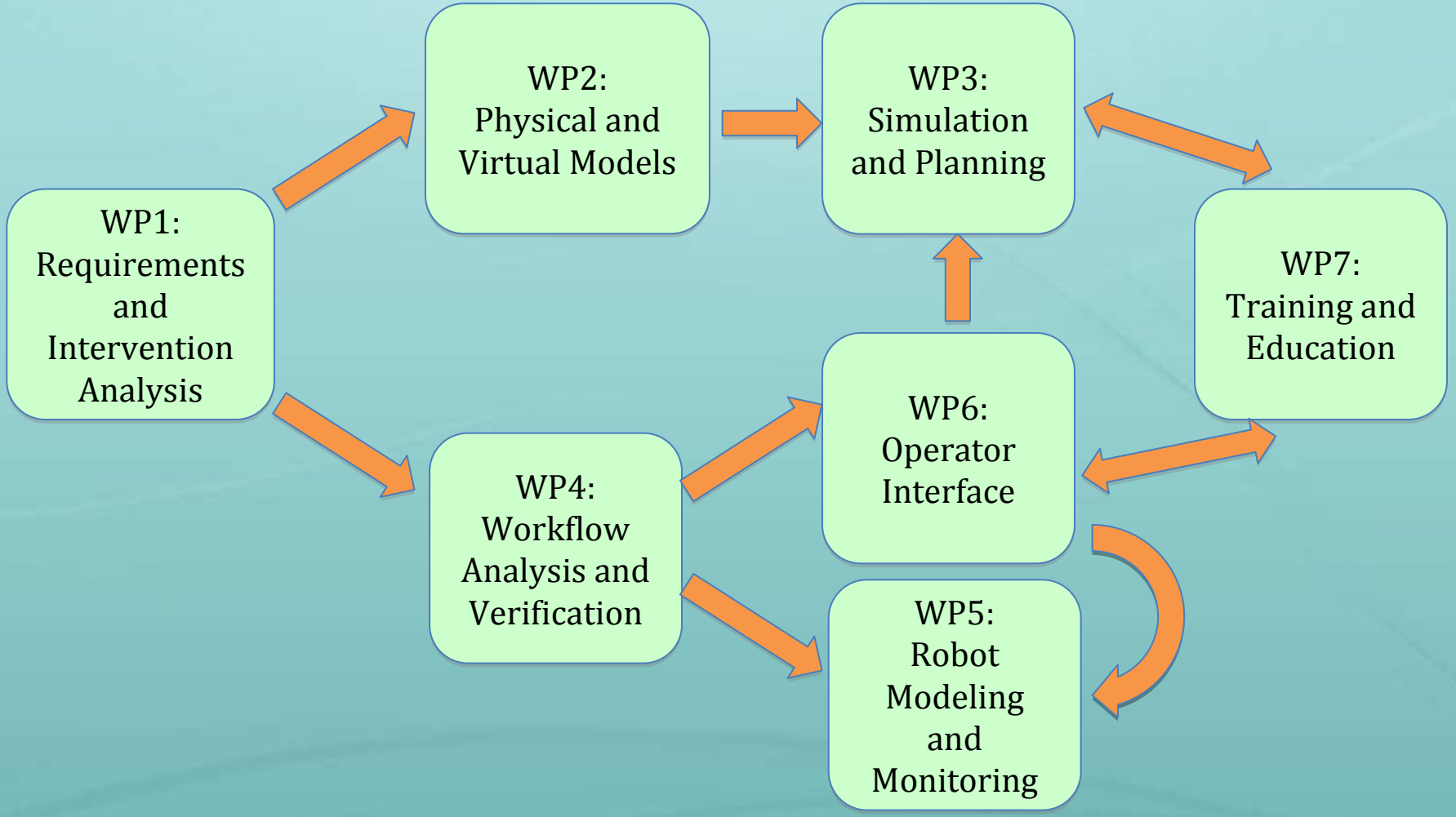
WP Structure



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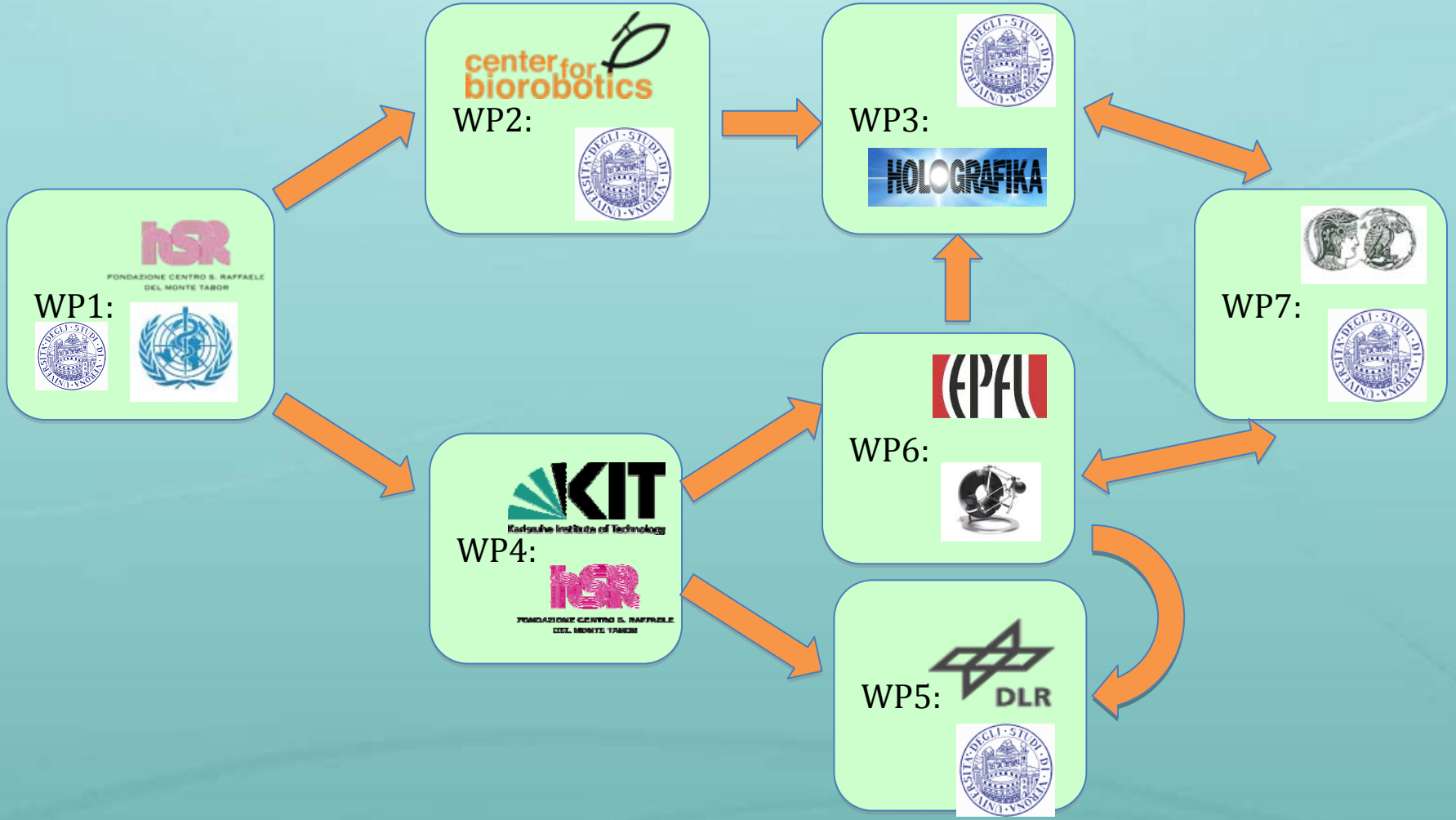
WP Structure



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The MIRO Robot

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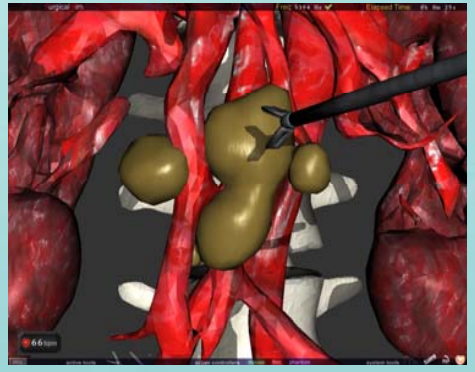
EVENTH FRAMEWORK PROGRAMME

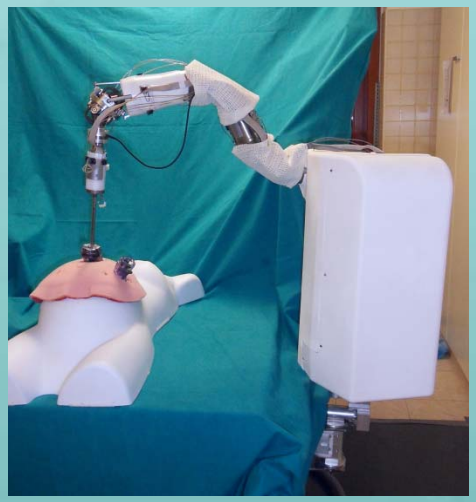
UNIVERSITÀ · DEGLI · STUDI · DI · VERONA

SURGICAL ROBOTICA
Medical Technology Solutions

JPL

NASA





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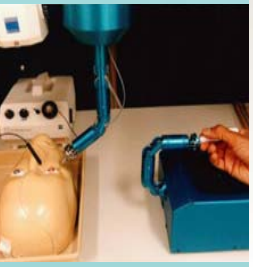
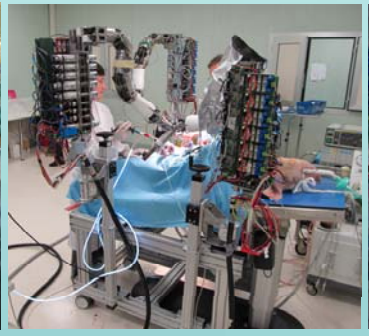
RAMS | Alfa | Beta.0 | Beta.1 | Gamma




Design phase

NASA R&D → Universita' di Verona R&D → Alpha design and fabricaiton → Beta design and fabricatiion → Validation → CE Mark

90's | 2009 | 1Q2010 | 3Q2010 | 1Q2011

SURGICA ROBOTICA established

Less than 1 year per design / fabrication / validation cycle

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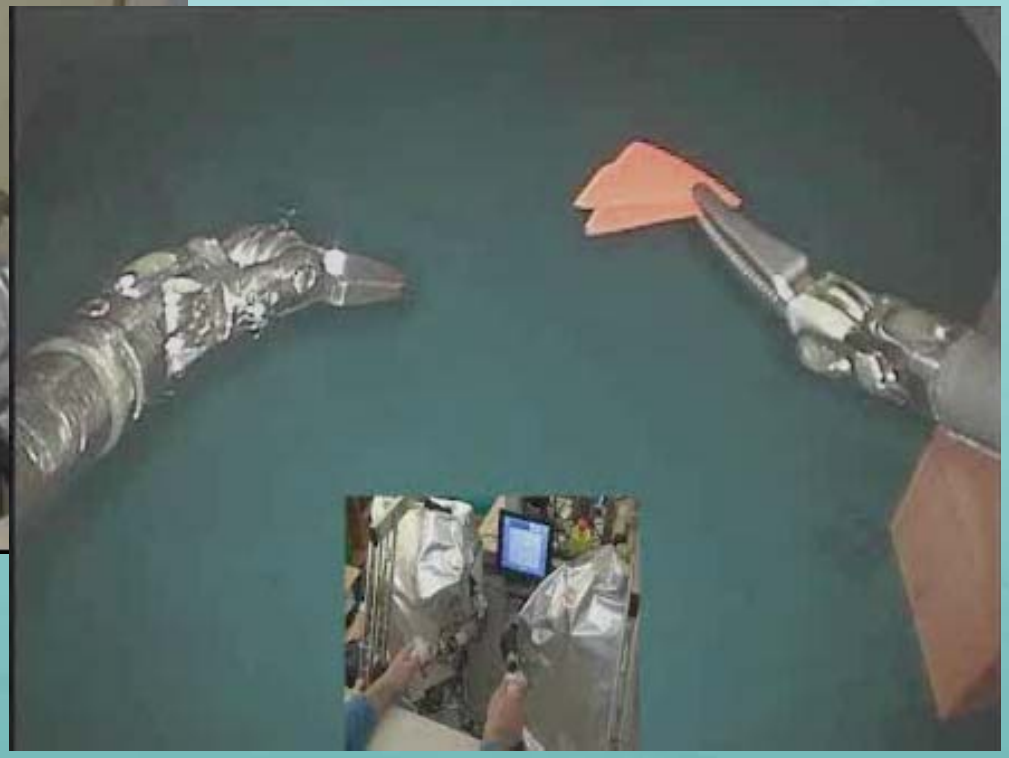
The Surgenius surgical robot



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During the first project year, we realized how complex the problem really is

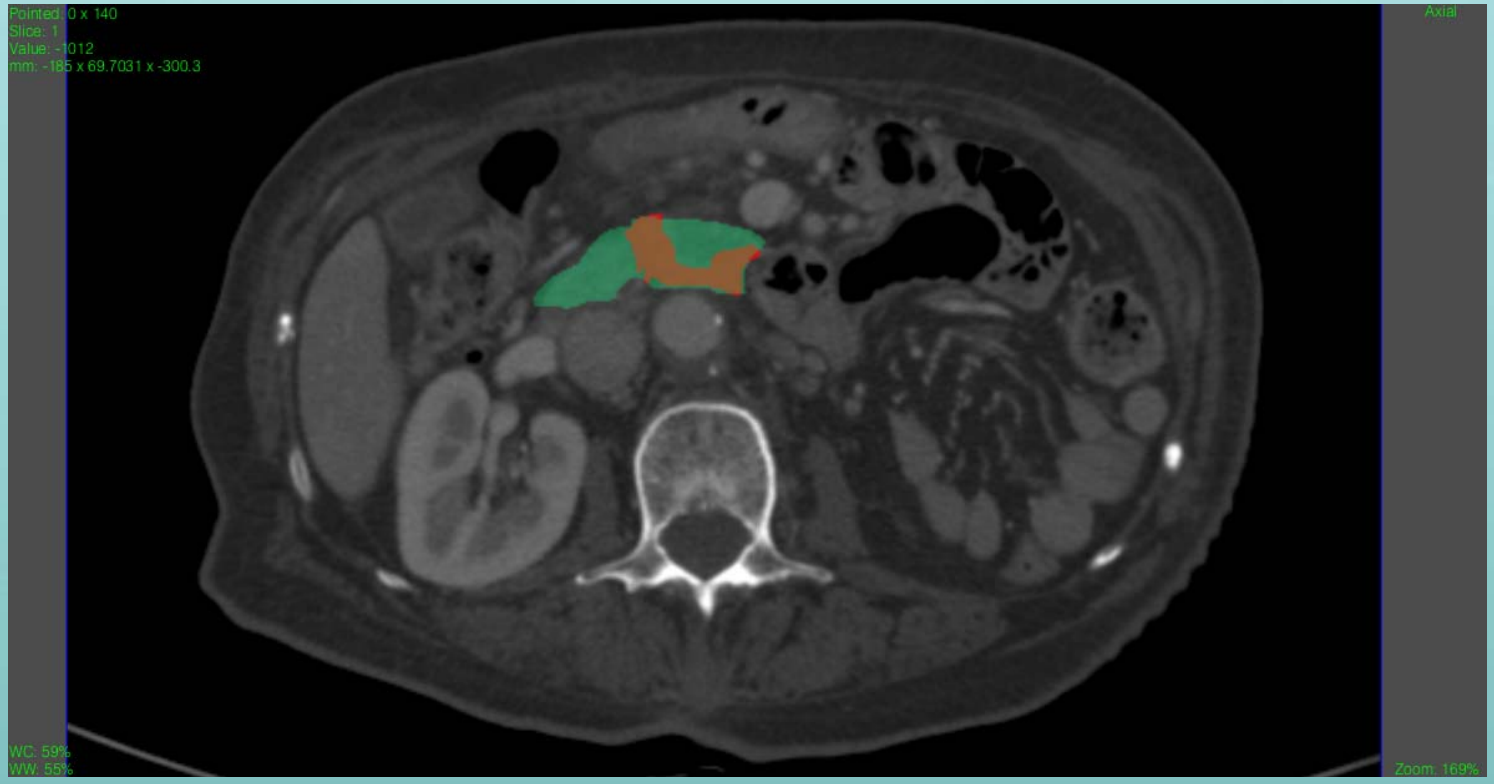
Surgical robotic "system"

- Overall paradigm should be **patient safety**
- Medical image processing: segmentation and validation
- Model computation: techniques, calibration, hardware
- Training: skills, rules and knowledge
- Diagnosis and planning: virtual fixtures
- Perception: haptics, 3D vision, acoustic
- Execution: new surgical robots, automation & control

Patient Safety motivates a Systemic Approach

- The notion of patient safety: the medical concept.
- What does “preventable error” actually mean?
- What emerges from prior studies: this notion is intrinsically **systemic**
- Systemic properties vs. modular/reductionist engineering: local performance improvement can admit global performance degradation.
- Non-integrated innovation can (and does) lead to iatrogenesis
- Computer-assisted healthcare: potential technological iatrogenesis

Medical image processing: segmentation and validation

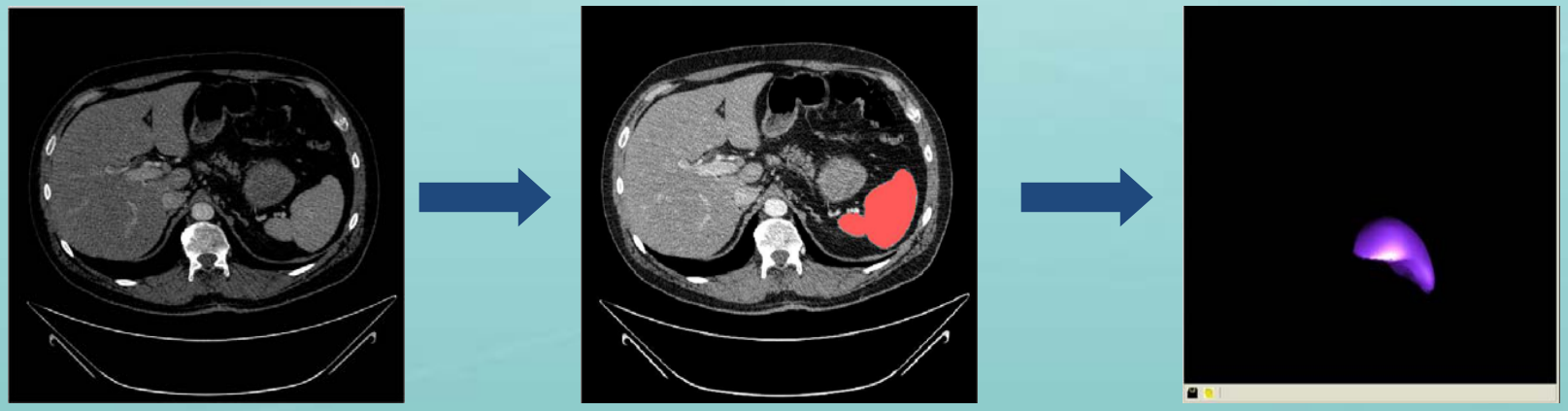


Task: contour healthy pancreatic parenchyma

(same radiologist)

Virtual model creation

Each step corresponds to a software module



DICOM dataset

Segmented image

3D model

Repeat for each organ of interest

Image with the complete reconstruction

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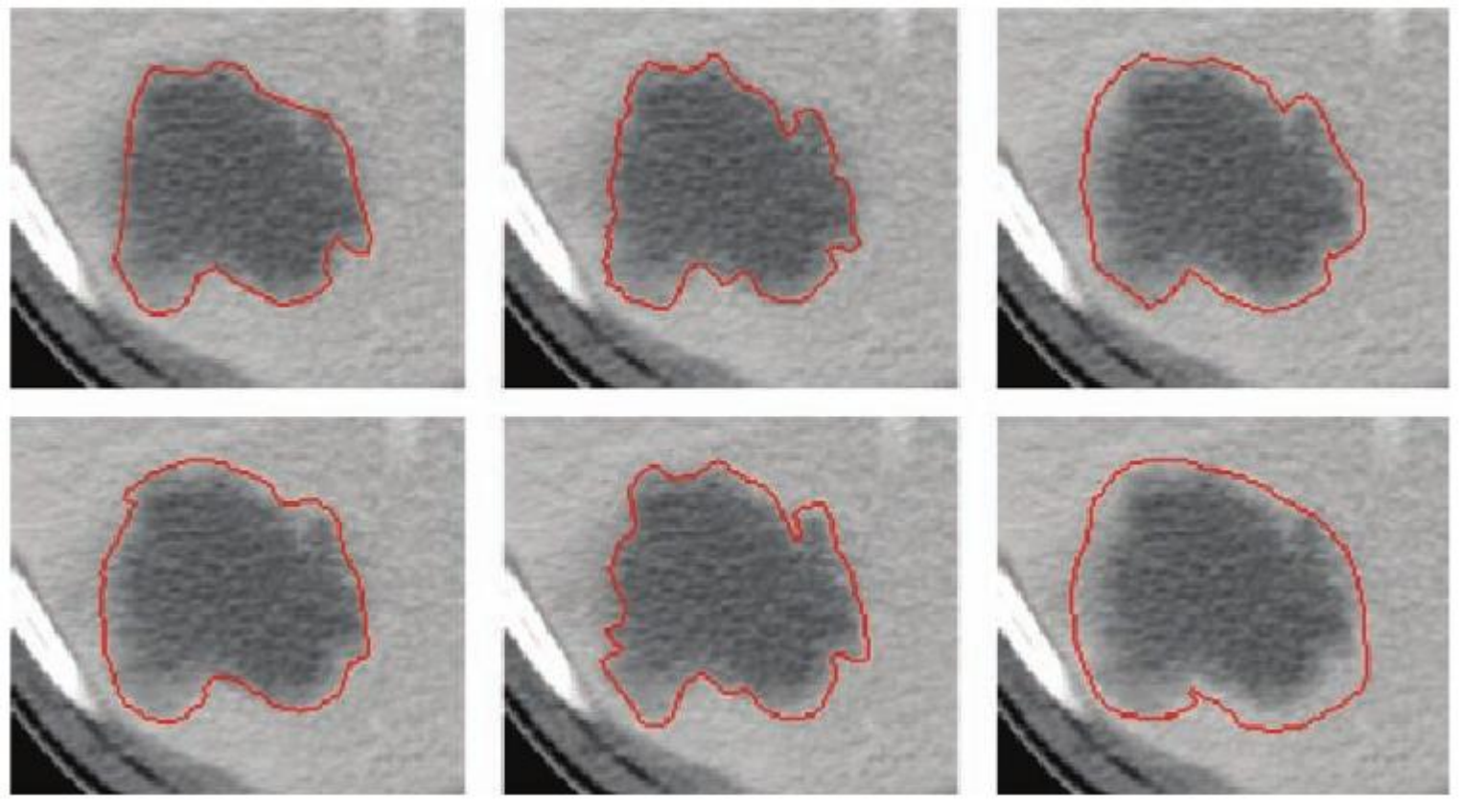
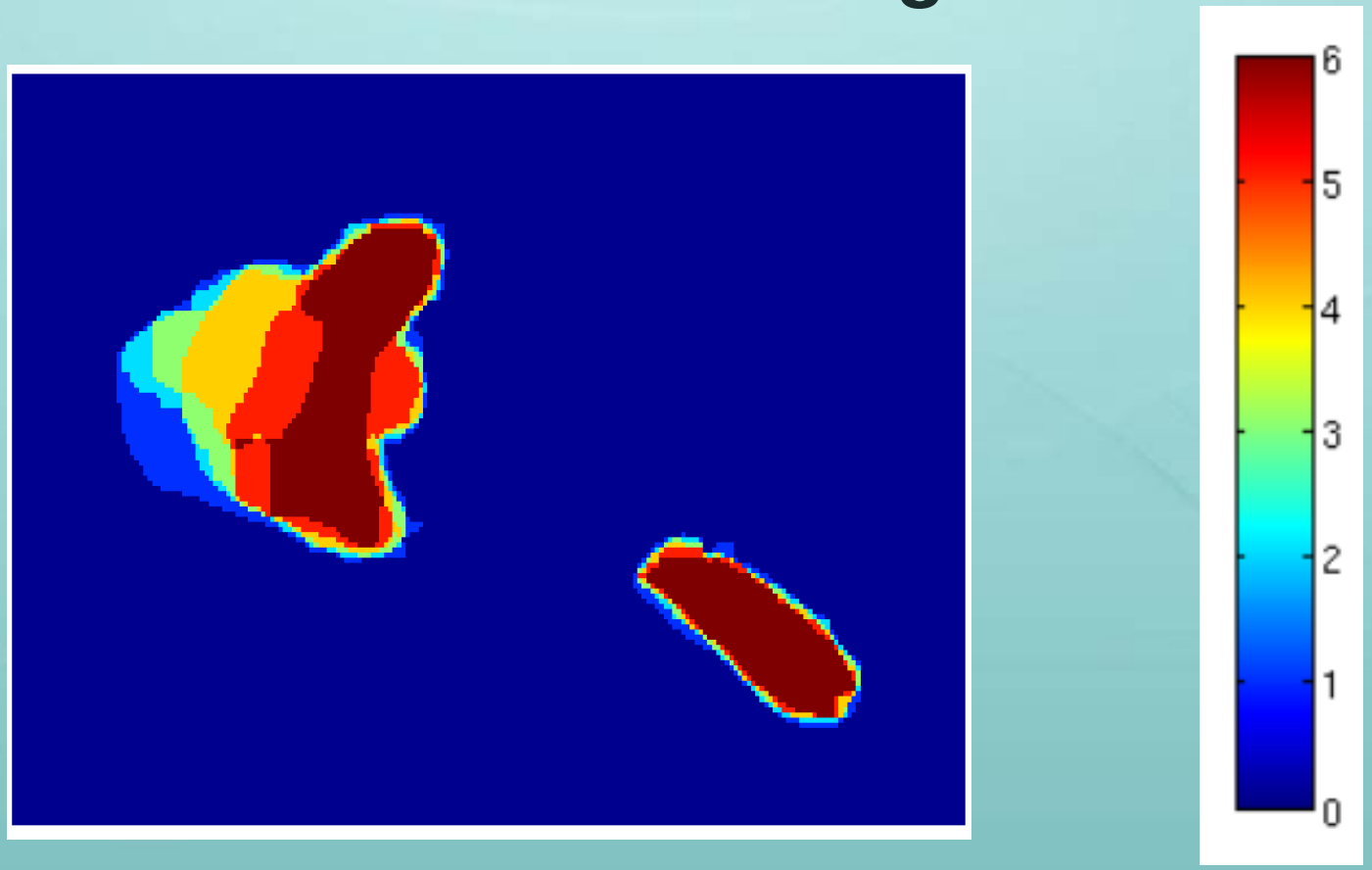
Typical performance: easy environments



Task: countour an epatic tumor

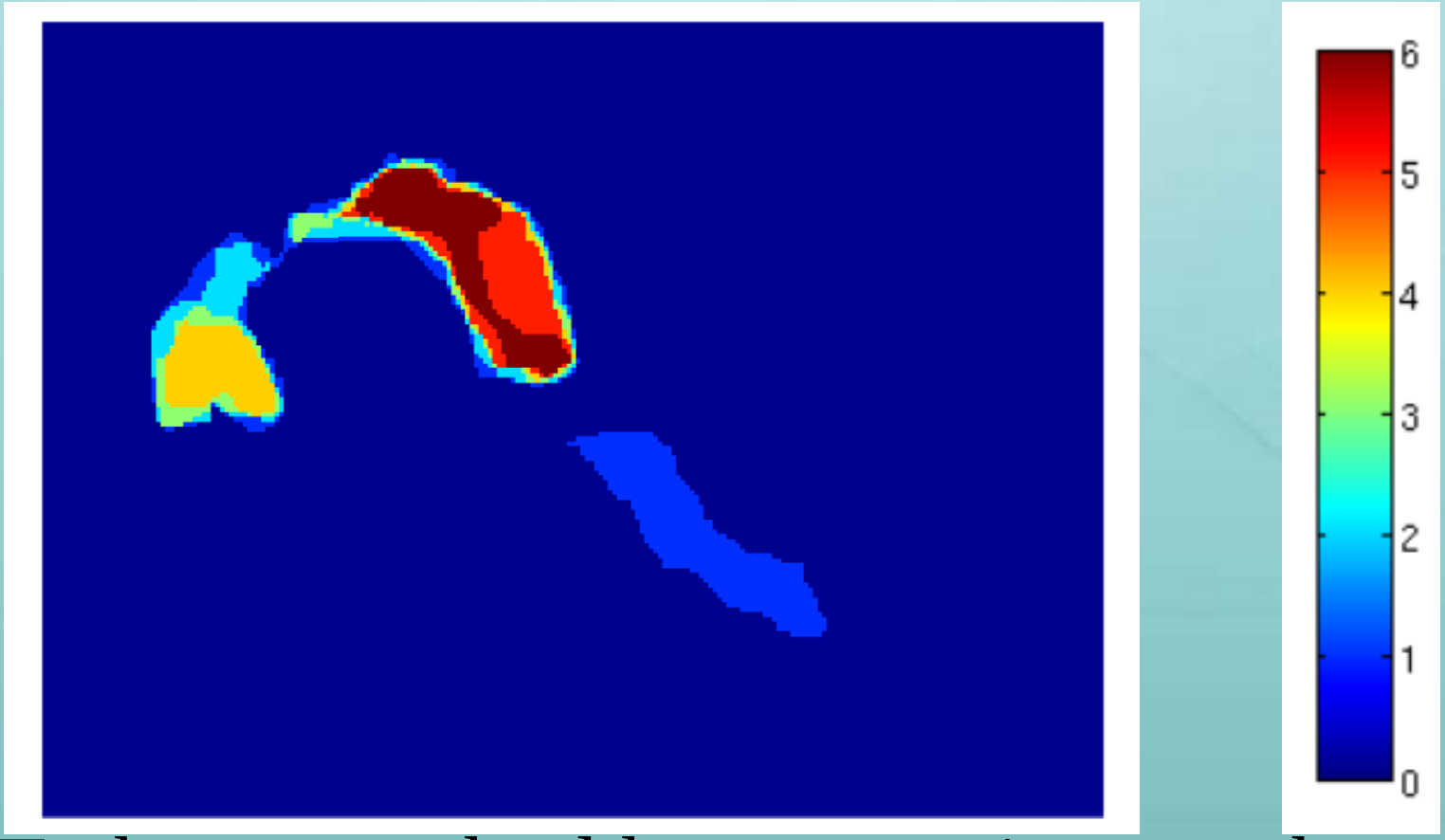
Consensus on healthy organs



Task: contour healthy pancreatic parenchyma

(6 different radiologists)

Consensus on pathological organs



Task: contour healthy pancreatic parenchyma

(6 different radiologists)

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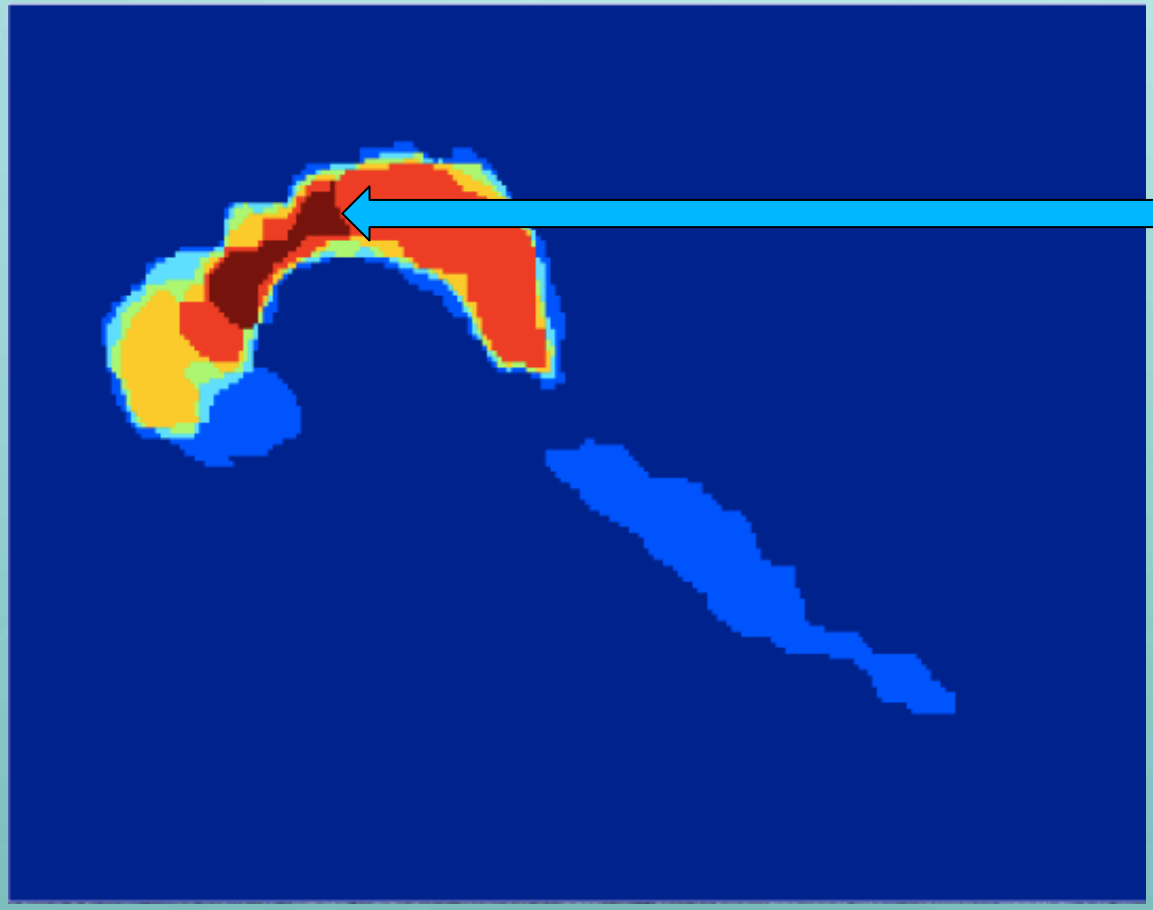
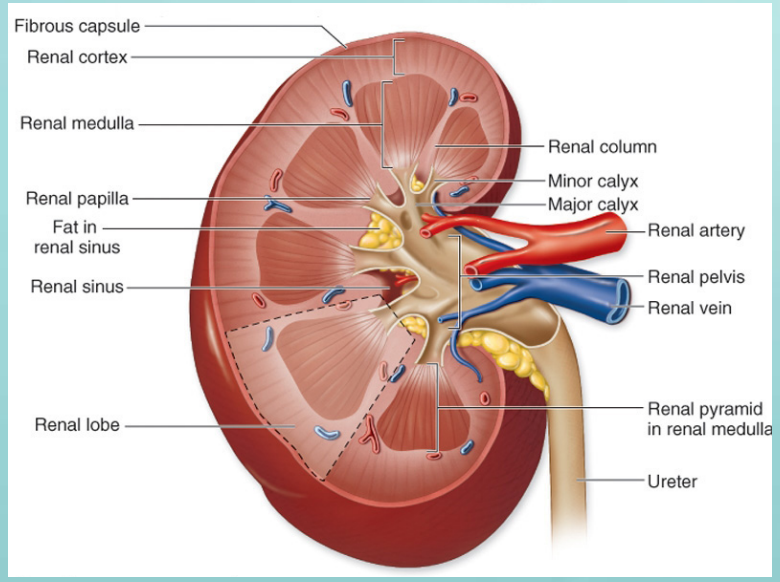
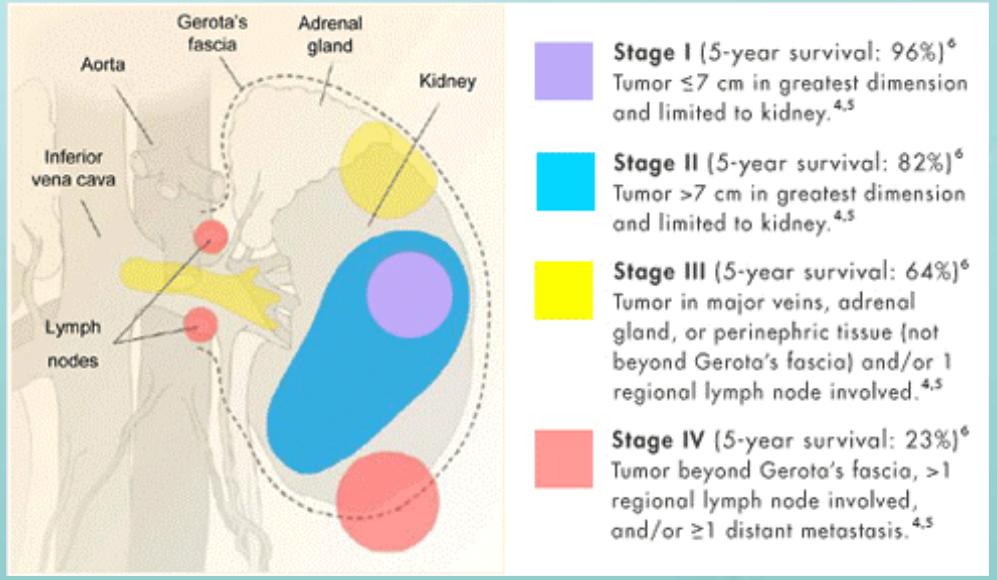
What we found

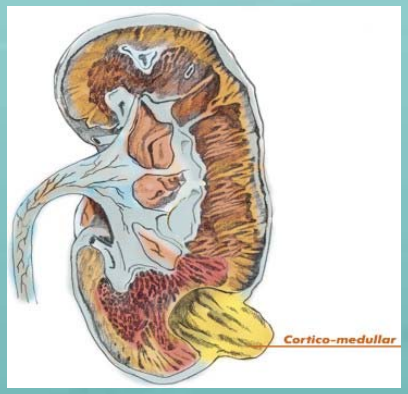


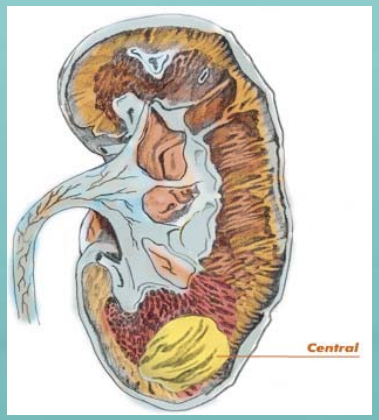
This is the only area that all 6 radiologists agreed to be healthy

The Anatomy of Kidney Tumors



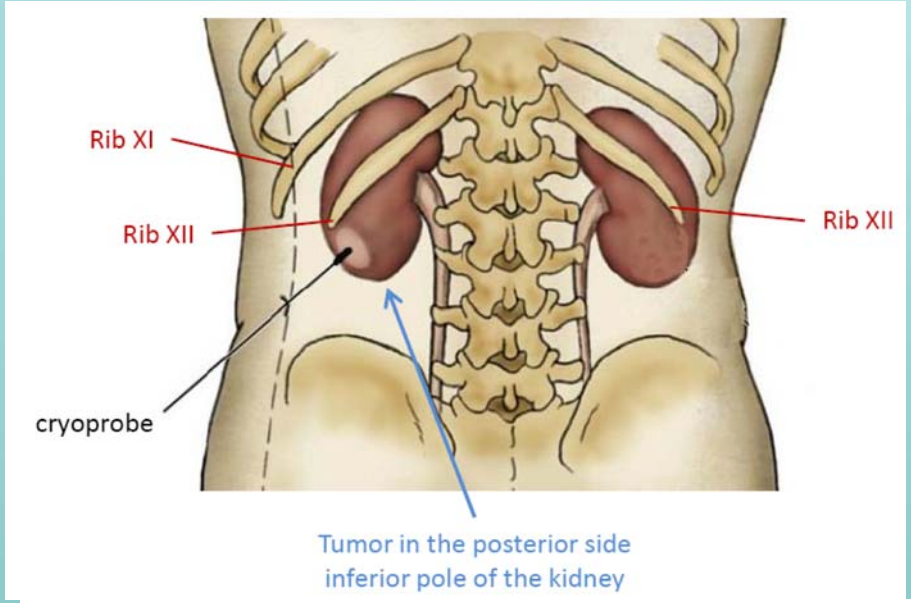


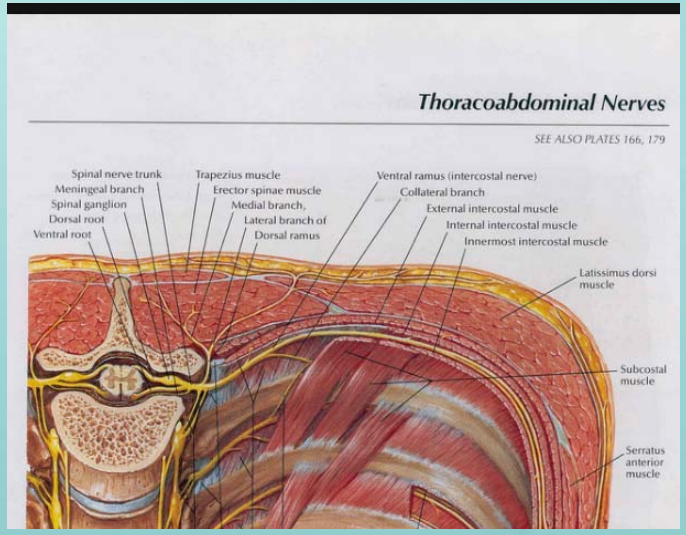


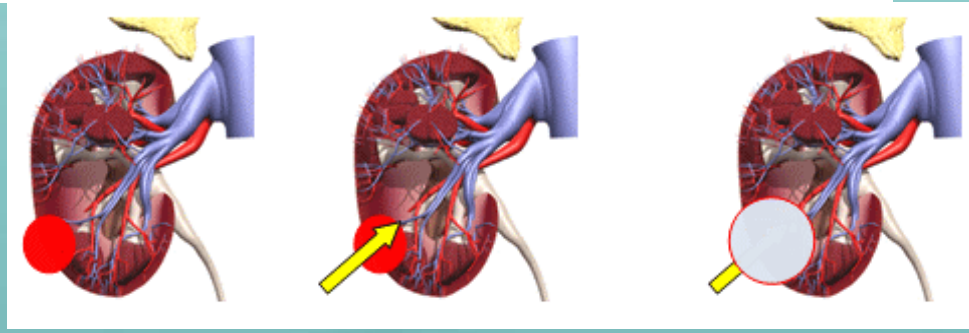


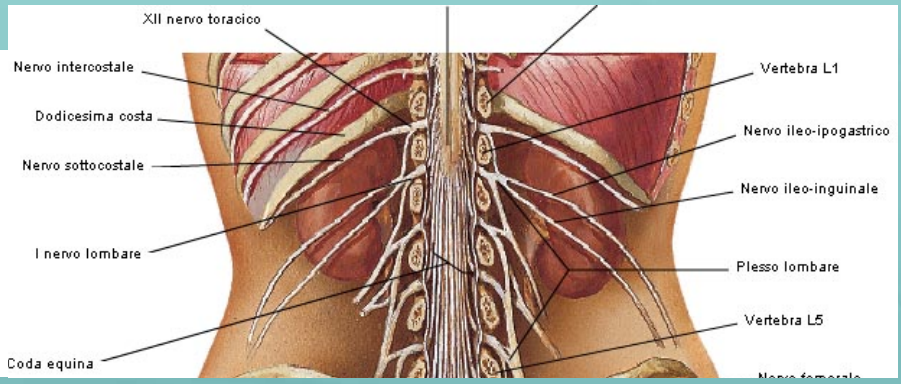
- Kidney tumors are characterized by small size, confined area, and easier percutaneous access.
- They are good candidates for ablation procedures.

Access Routes and Constraints



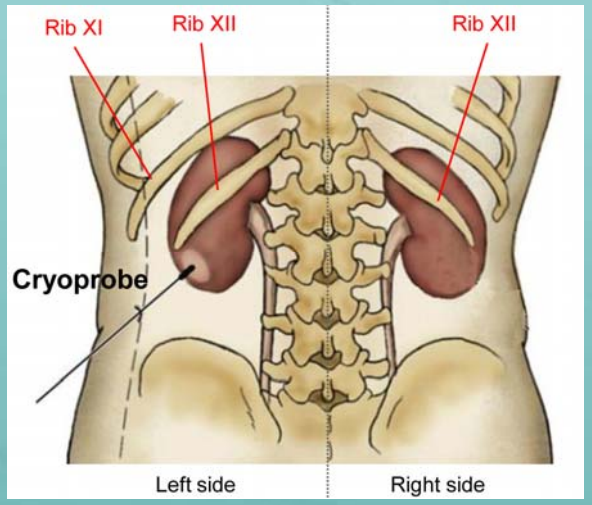






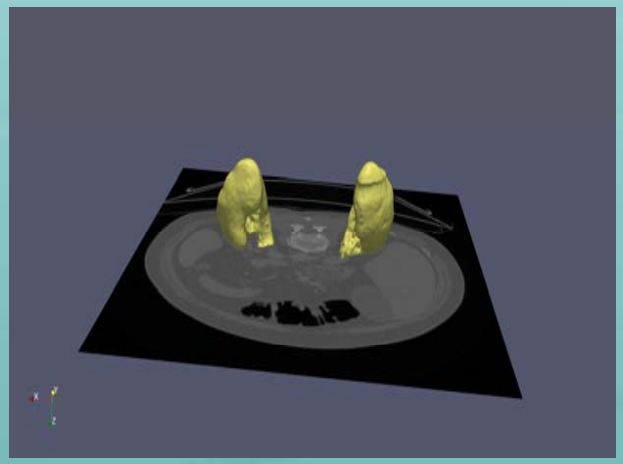
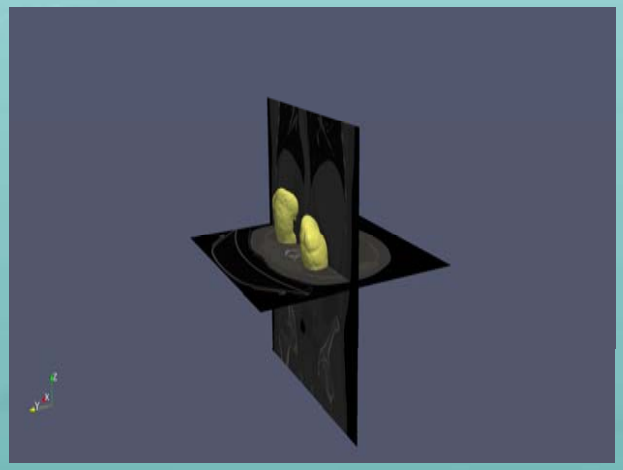
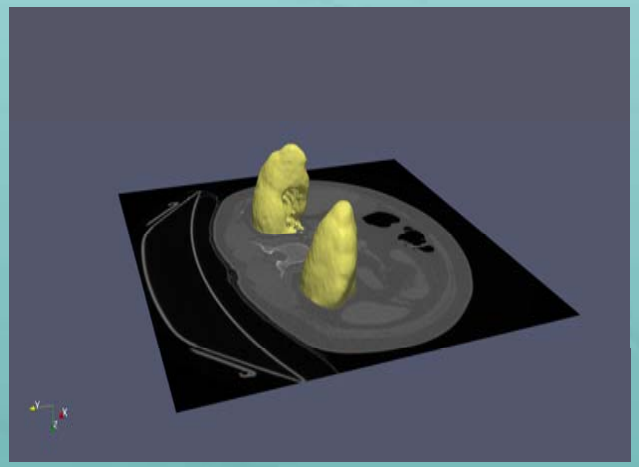
Cryoablation Procedure

- Cryoablation is usually applied for patient with small tumours with a diameter < 4 cm and in which the tumour is placed in superficial position
- **Forbidden regions (kidneys crioablation)**
  - Ribs XI –XII
  - intercostal nerves, iliohypogastric and ilioinguinal nerves
- **Pre-surgical examination**:
  - CT or MRI images
  - definition of target area and sorroundings



Pre operative data analysis

- Pre operative data have better image quality → easier to diagnose the lesion
- Usually a CT acquisition with contrast medium is available for the patient
- Easy to evaluate anatomical relationship and critical area for the procedure, and to define the target point and entry region.

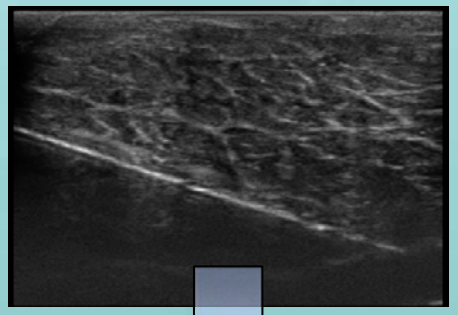
Intra operative data: RGBD

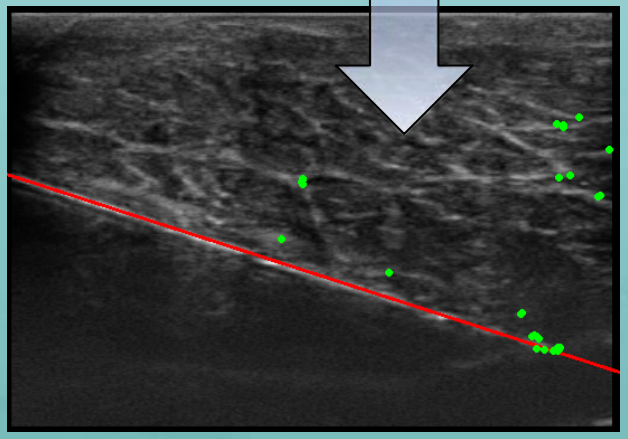
- Surface reconstruction
- Markers segmentation
- Initial registration with CT surface (markers + surface CT- surface RGBD)
- Continous registration to update data (surface RGBD - surface RGBD)

=>Patient monitoring: skin deformation, breathing motion, patient movement.

Intra operative data: Ultrasound

- Real time update of planning data
  - Patient is awake (under local anesthesia) during the surgery → need to track motions of the target region due to breathing and tissue deformation (RGBD+US)
  - Blood flow to the kidney is not blocked during surgery → need to monitor the flow (US?)
  - Needle tip position could be measured and compensated (US+RGBD?)





Tool calibration and tracking

- US calibration

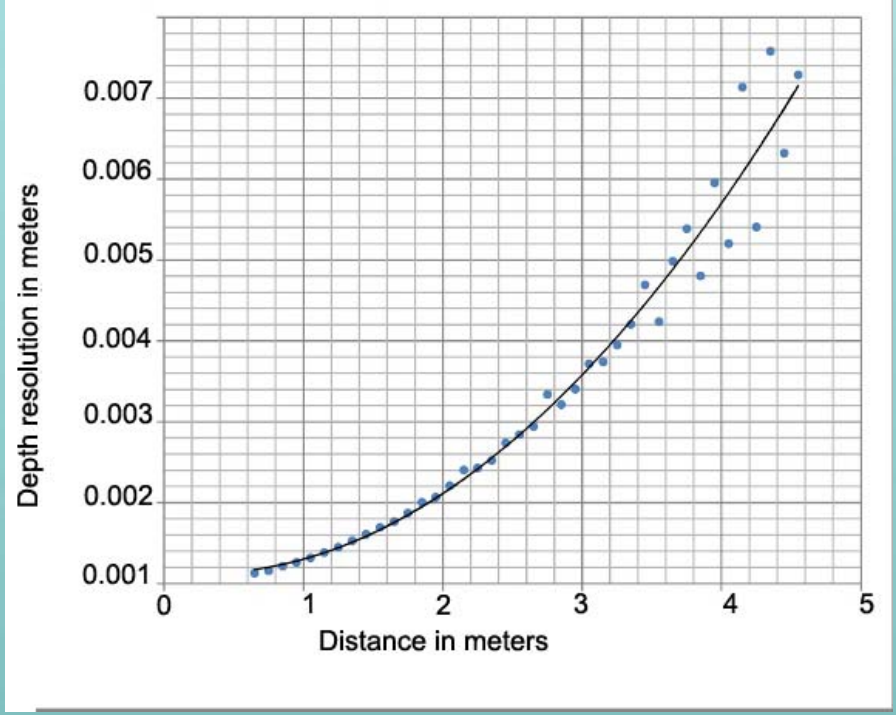
	D.	Mean	STD	Median	RMS	Global
US Calibration Error	x	-0.873	2.893	-1.002	**0.559**	**0.645**
	y	-0.113	1.428	-0.351		
	z	0.950	2.165	-0.806		

- Needle calibration

Position	RMS Error	Needle 1 16G	Needle 2 18G	Needle 3 18G	All
Accuracy	Mean	0.6561	0.7117	0.8002	**0.7226**
	STD	0.1674	0.3125	0.215	**0.2316**
Precision	STD	0.3254	0.8613	0.9361	**0.7076**

Tool calibration and tracking

- Kinect calibration



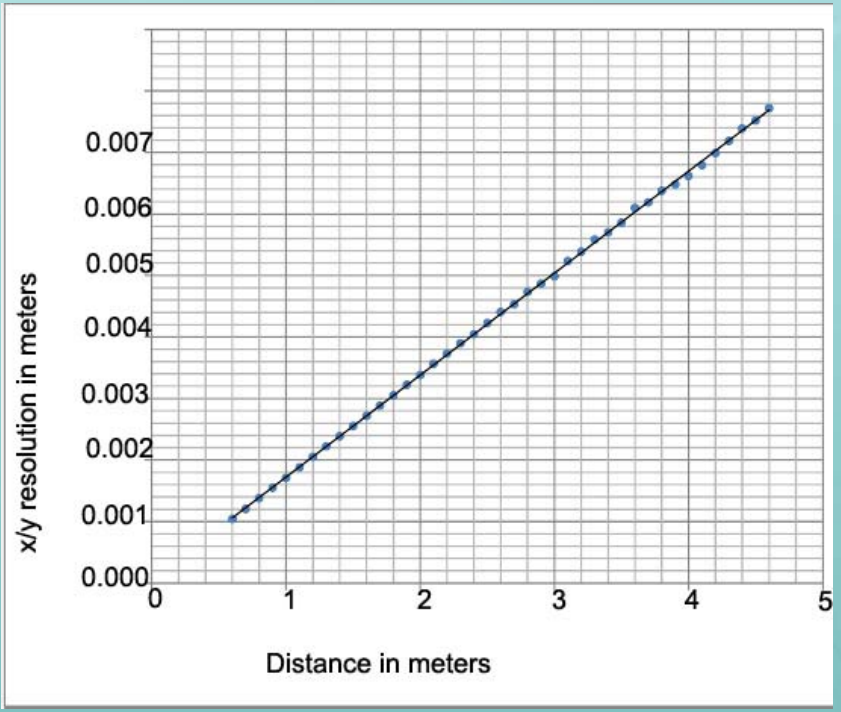


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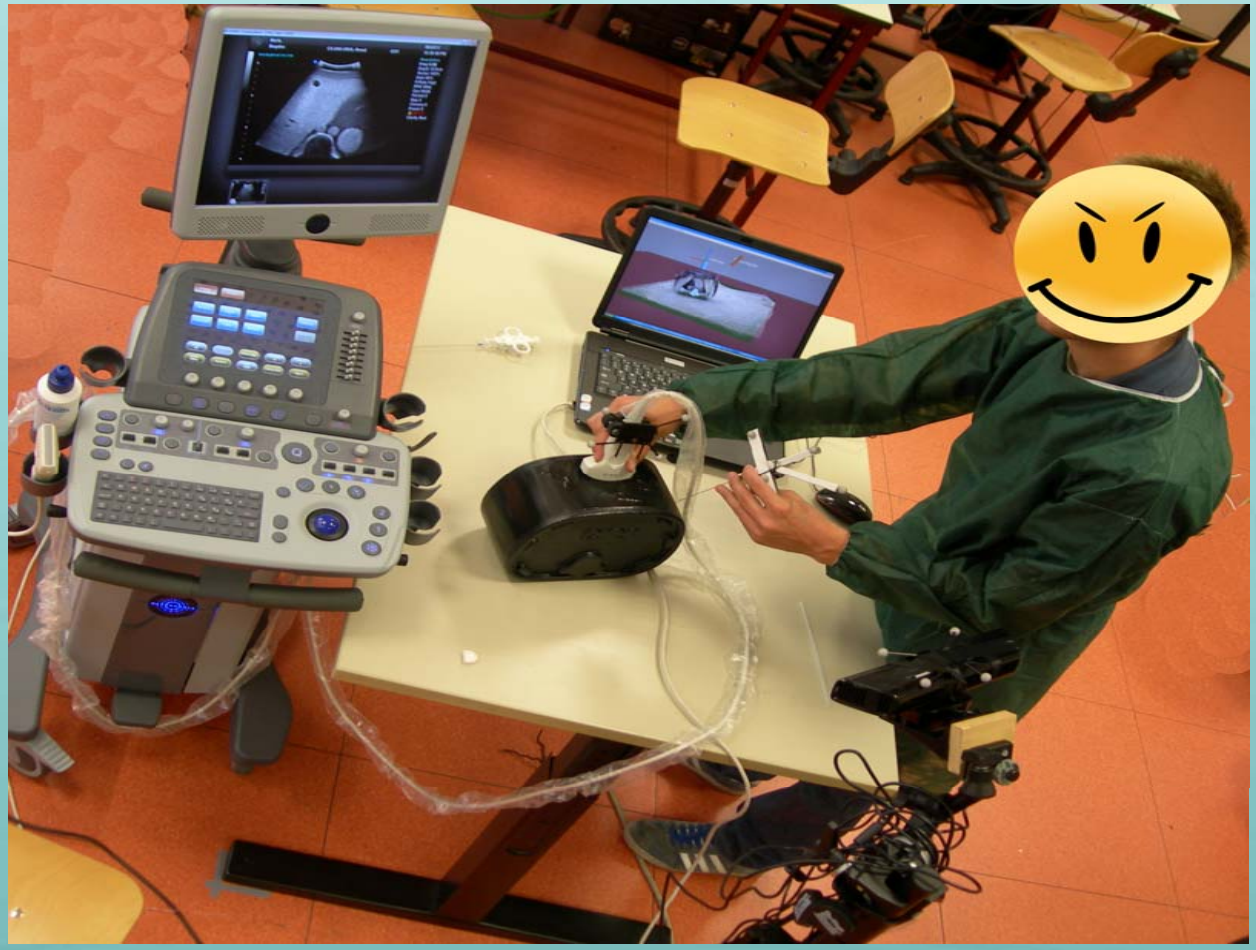
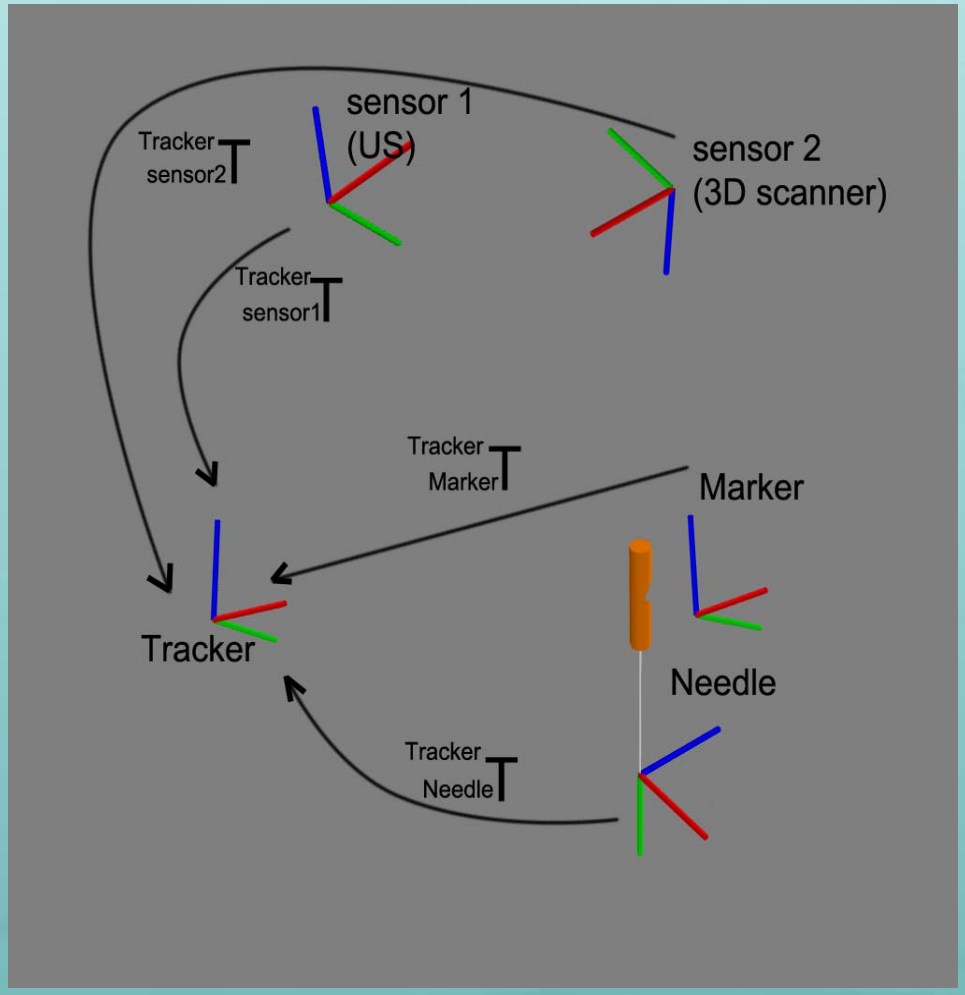
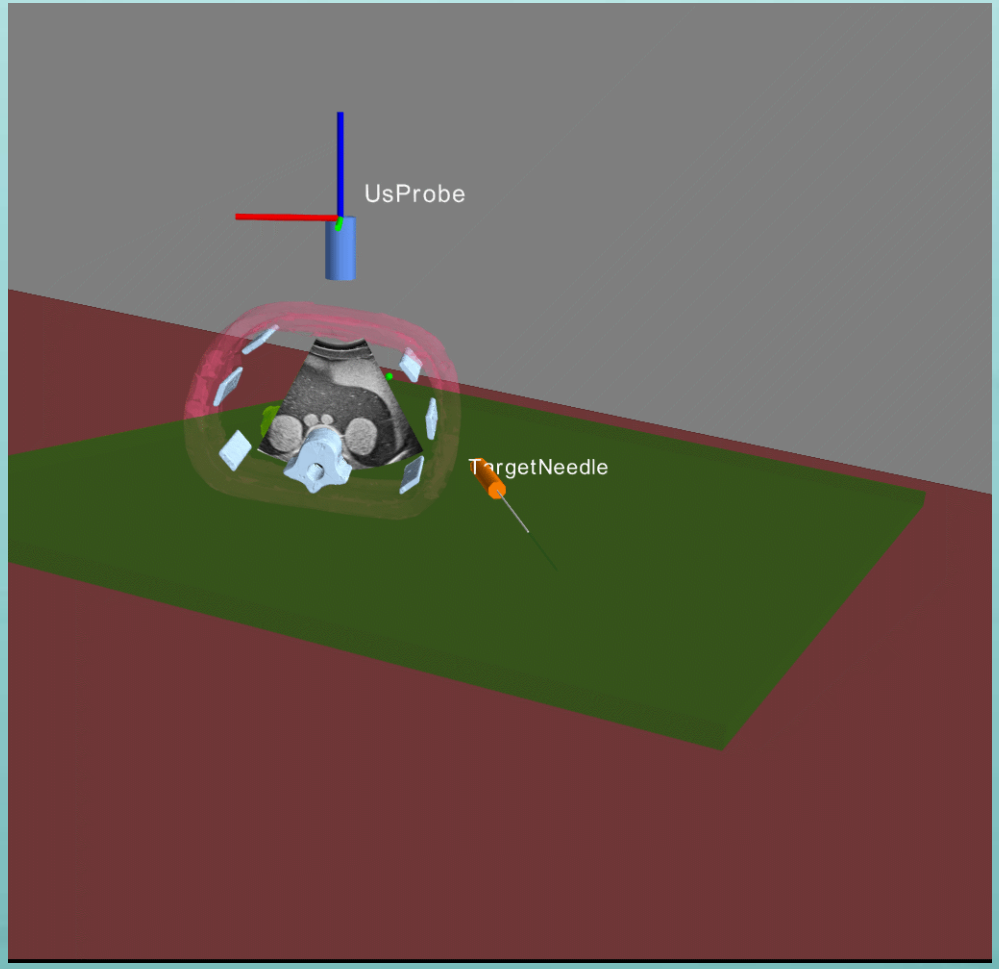
Image guided surgery: test set-up



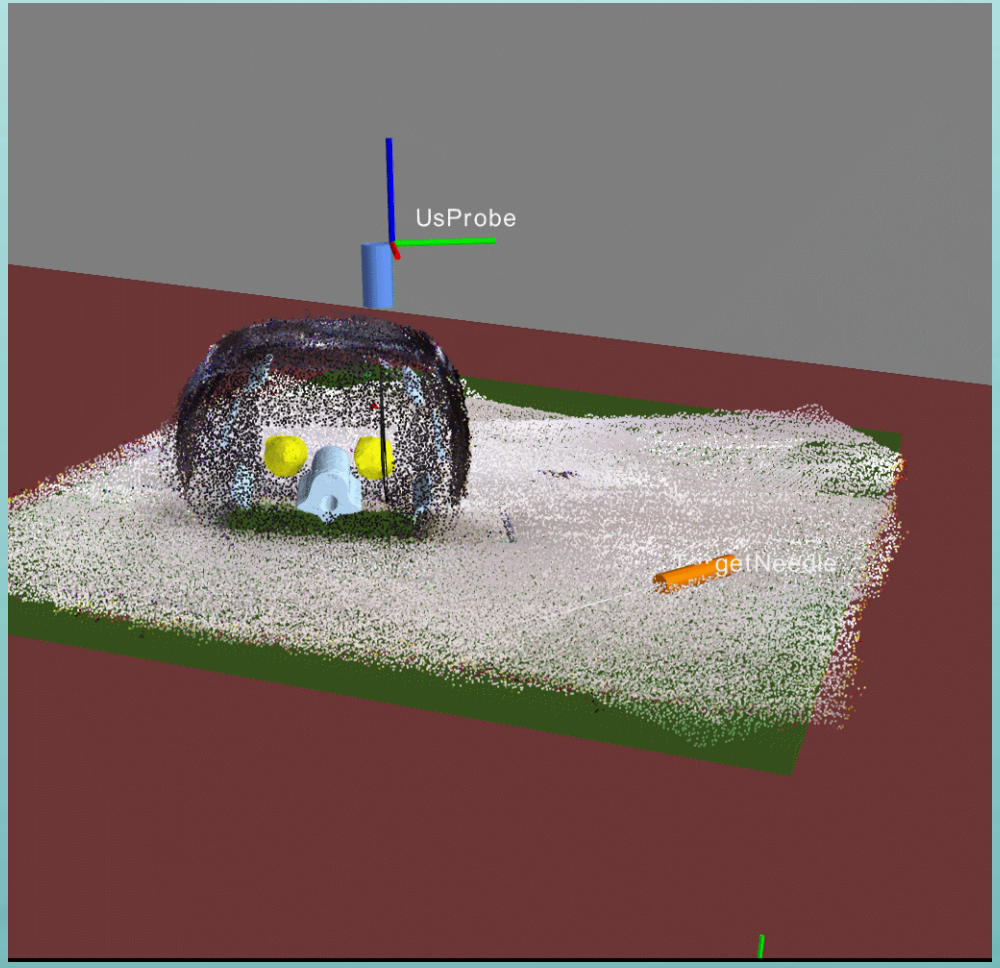
Registration reference frames



Data fusion: US-CT-3D models



Data fusion: US-CT-Kinect



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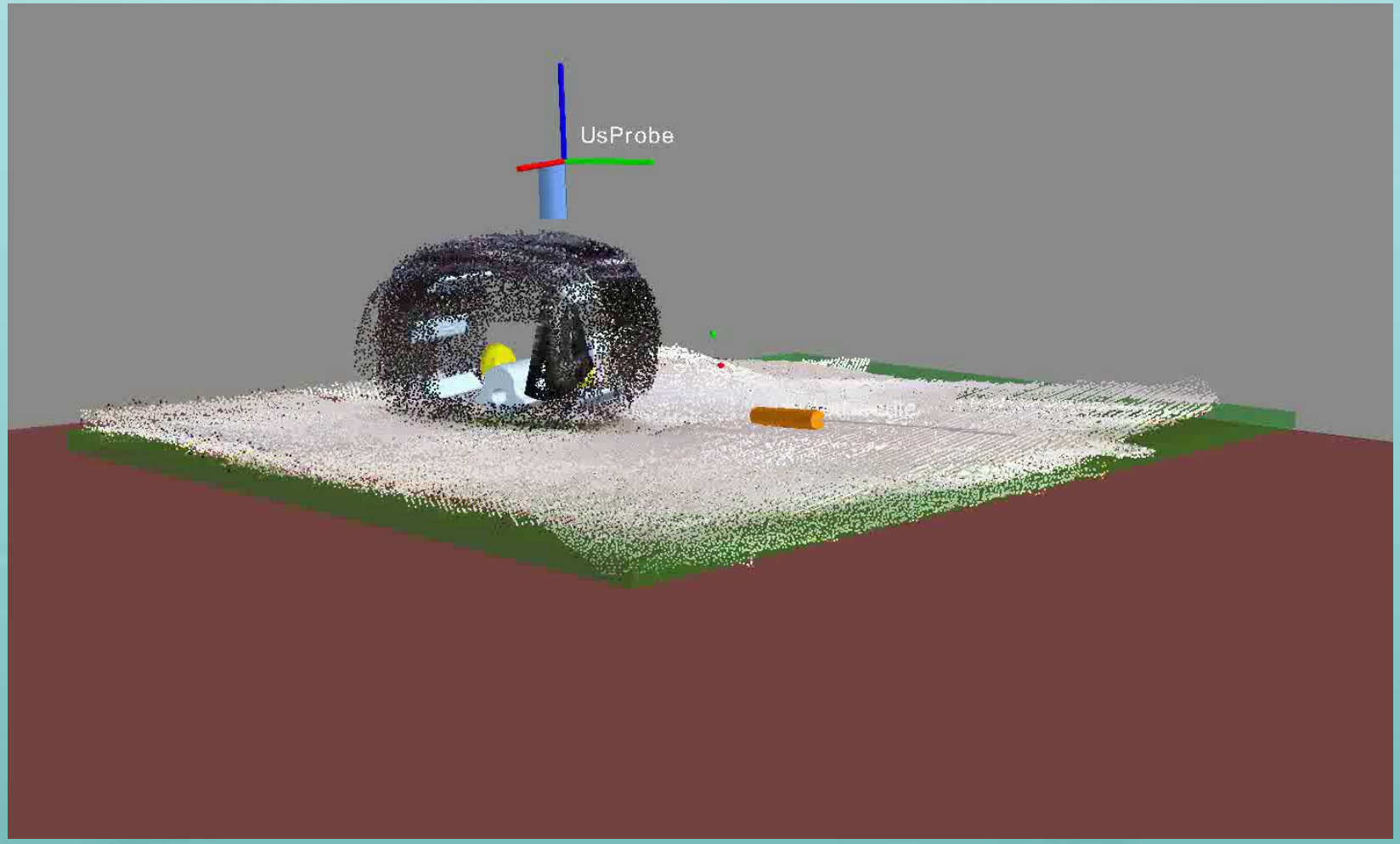
Example of navigation procedure



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Minimally Invasive Surgery Simulator

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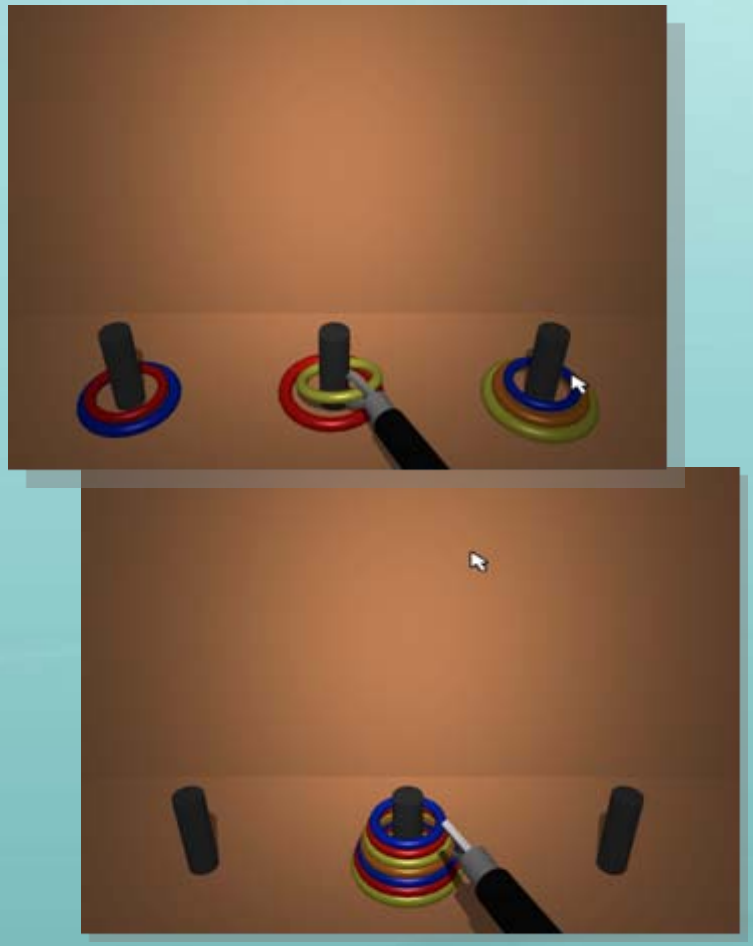
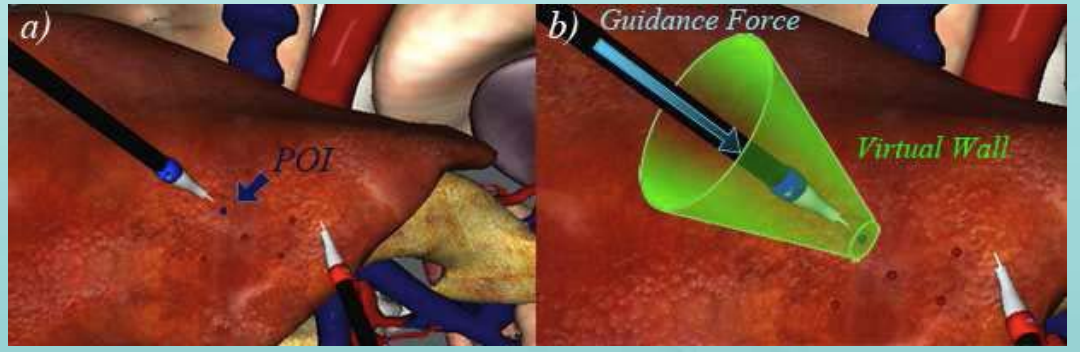
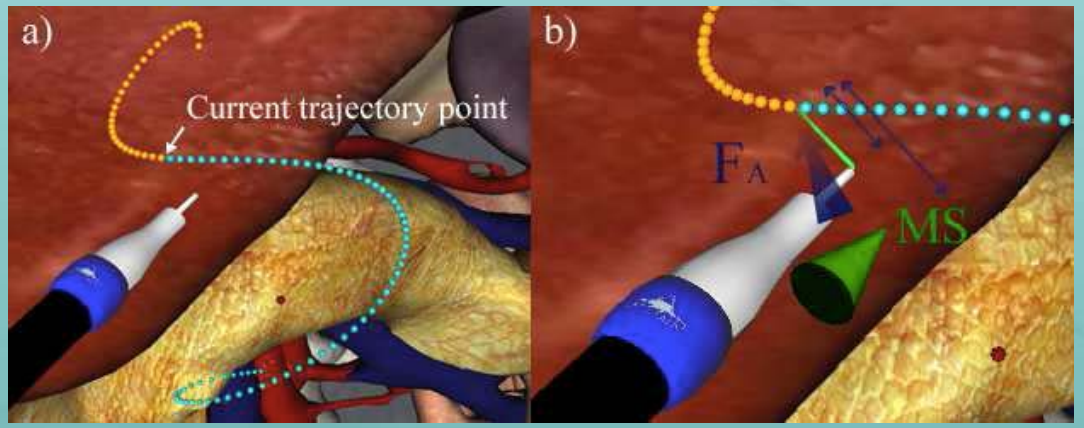
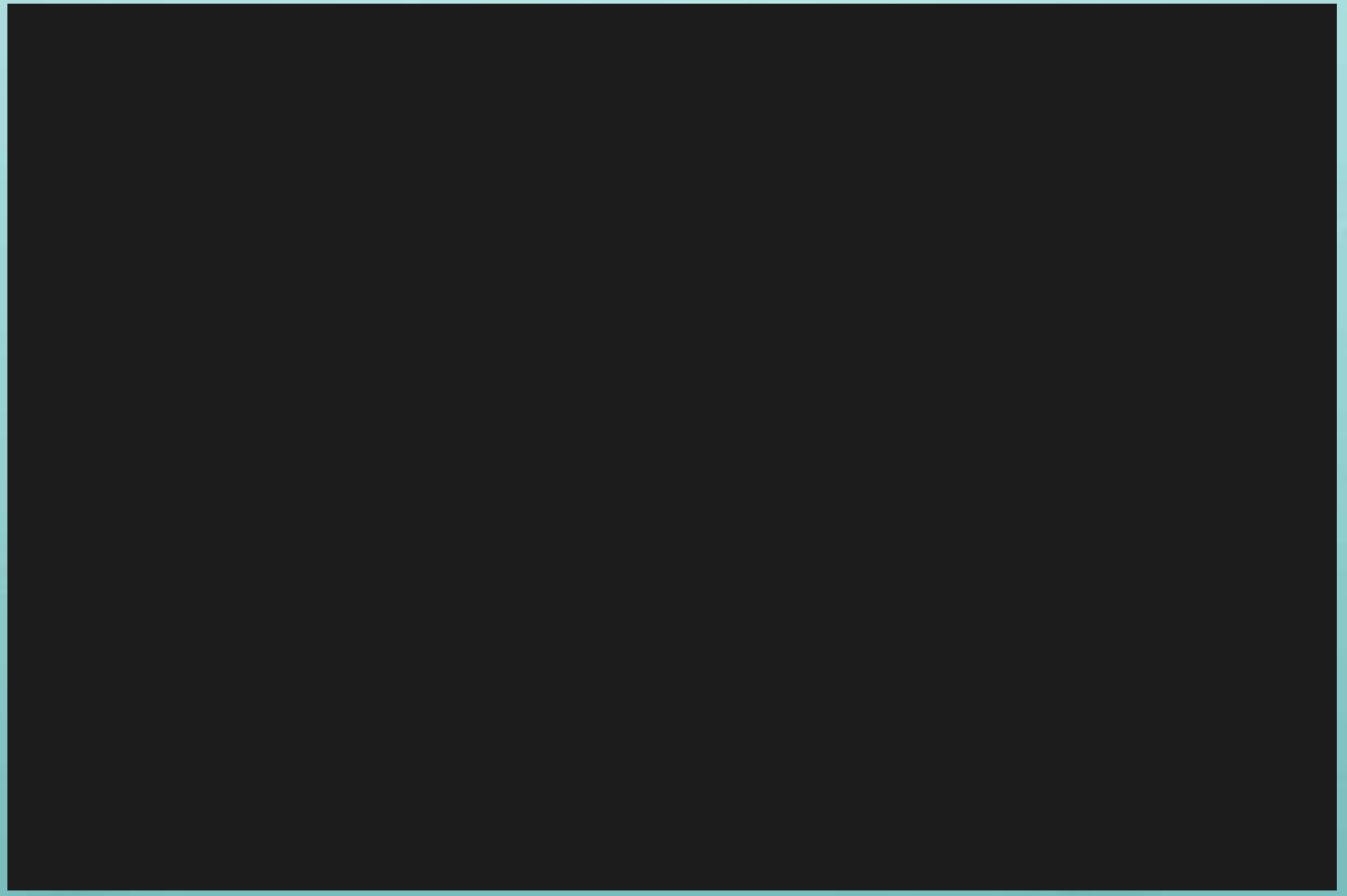
Skill training with virtual fixtures







Perception training: cutting



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Perception training: clamping

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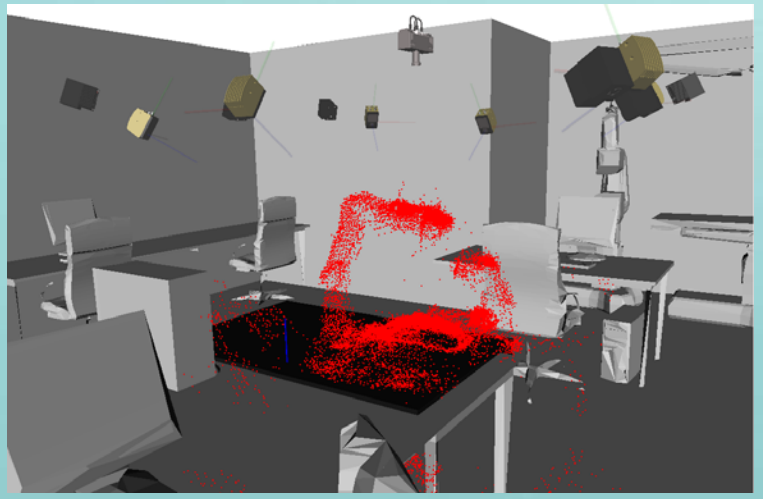
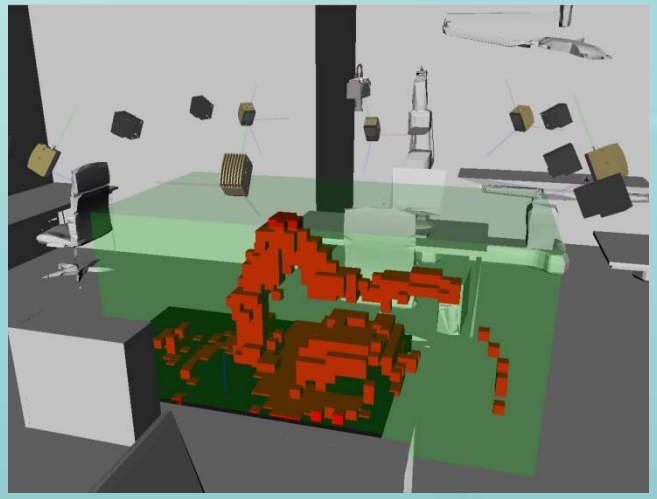
Operating Room and WorkFlow Monitoring



Voxel Carving



- Scene interpretation by voxel carving
- Combination of the point cloud data and oriented bounding boxes (OBB) of the CAD models will be used for real-time path-planning and collision detection/avoidance

In Summary

- Technology evolves fast and technology for surgery/healthcare involves a large number of components.
- Foresight of innovation is necessary in order to avoid conceptual clashes between components developed at different times.
- Inconsistent systems notoriously lead to error.
- Design according to general organizational principles: avoid introducing unnecessary constraints.
- State organizational principles and design principles that can be instantiated on a particular technological module

Patient-Safety-driven design

- Safety-driven design paradigm: it has to be based on **information-related** principles
- Accuracy/precision are useful measures only when related to **decision-relevant** information
- Information reduction to lighten **cognitive overload**
- Decisions and performance analysis are **intrinsically contextual**
- Attention to **error-awareness** and error tracking.
- Benchmark different phases of the processing pipeline to get **error estimates** at different phases of the pipeline/workflow.

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Thanks for your attention