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The case of an intravascular medical device

Modeling the Mission Dimension

MBSE Lightning Round

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Agenda

- The Intravascular Medical Device (IMD) project
- The three dimensions of ISE&PPOOA MBSE methodology
- The IMD mission dimension goals
- Application of the ISE&PPOOA Mission dimension subprocess
  - IMD context diagram
  - IMD mission use cases and scenarios
  - IMD operational needs
  - IMD interfaces
- To conclude

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The Intravascular Medical Device (IMD) project

- This research aims to develop a **micrometric-size robotic joint**, enabling the creation of micro-robotic complex mechanisms for minimally invasive micro-surgery techniques and in-vivo health treatments.
- The robotic joint will contain a micro-motor connected to a new type of long-lasting gearbox.
- A very important issue is that the robotic joint (motor + gear) will be **wireless powered**, thus providing long endurance to any tool or micro-robot activated by it

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The three dimensions of ISE&PPOOA MBSE methodology

Mission

Context+scenarios+needs

System

Sys. requirements+functions+parts

Software

Sw requirements+sw components

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The IMD mission dimension goals

- Based on how the system is **used in a context**
- Identify the **operational needs** of the diverse actors
- Identify the **external interfaces**

Out-In Approach

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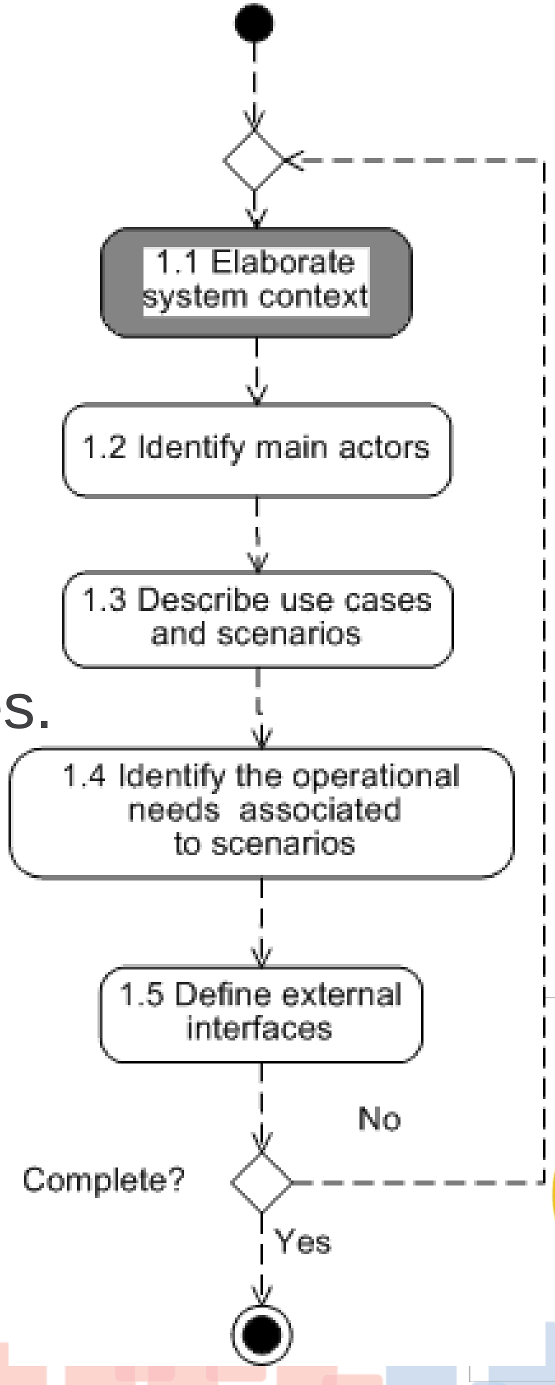
ISE&PPOOA Mission dimension subprocess
Step 1. Elaborate system context

- The system operates in a context consisting of the environment and other systems.
- The Context may be considered as external users, external systems, natural environment, threats, and resources.
- Next slide shows the context of the system represented as an SysML IBD (internal block diagram) where the diverse entities of the context are represented as blocks
- The main external interfaces are represented as well



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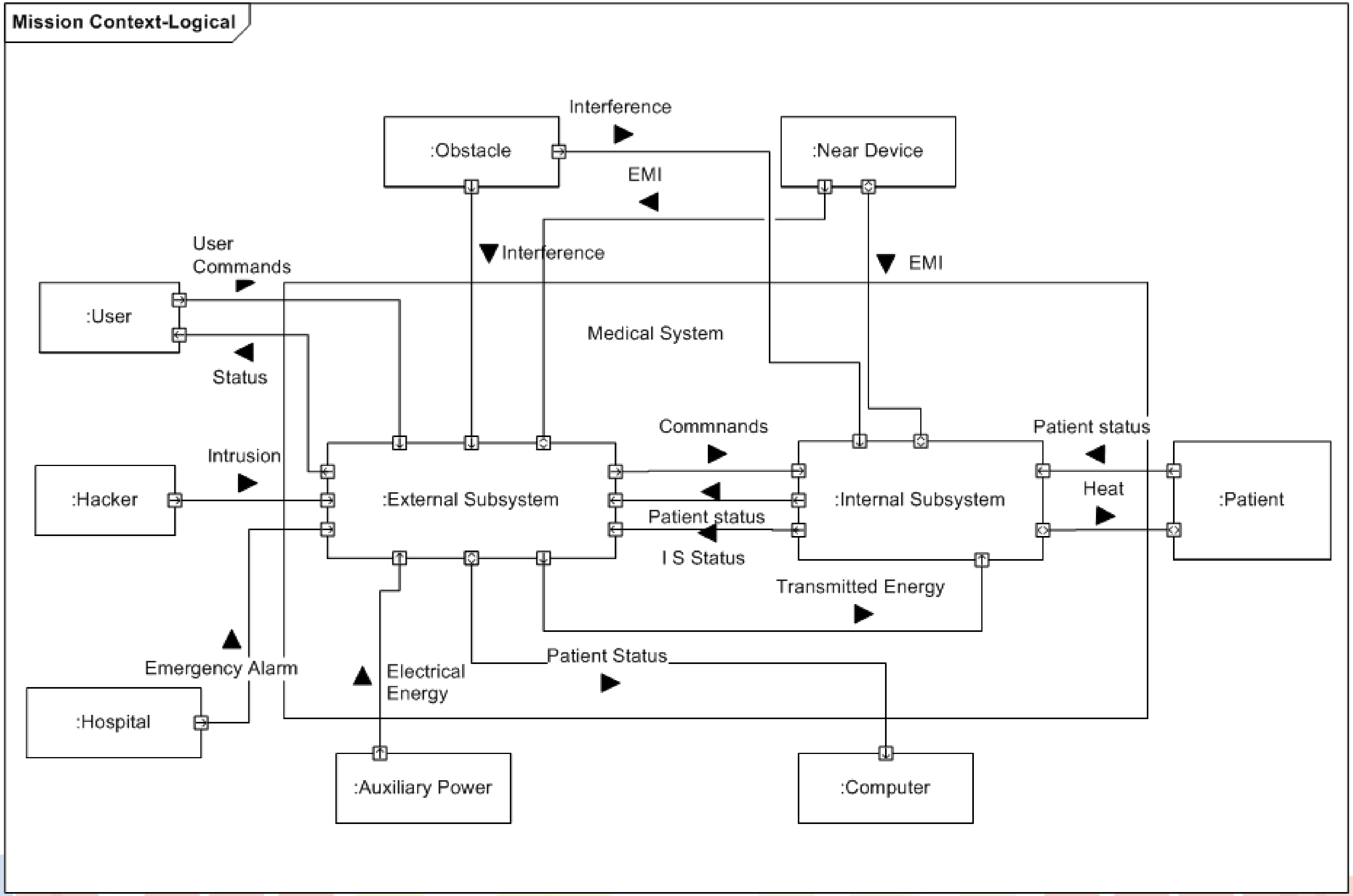
IMD Context Diagram



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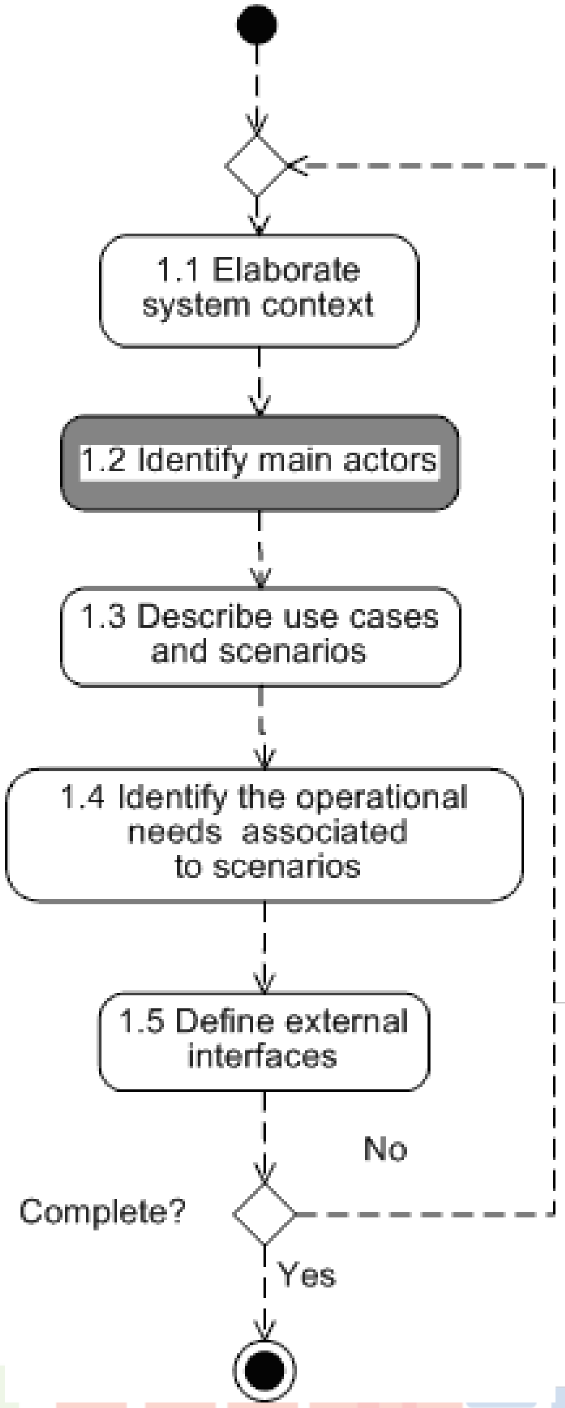
ISE&PPOOA Mission dimension subprocess
Step 2. Identify main actors

- Based on the context diagram, the main actors (external entities) interacting with the system are identified.
- Actors are not only human roles but devices, other systems and the environment



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IMD-Actors

- User
- Hacker
- Hospital
- Auxiliary power
- Computer
- Patient
- Near device
- Obstacle

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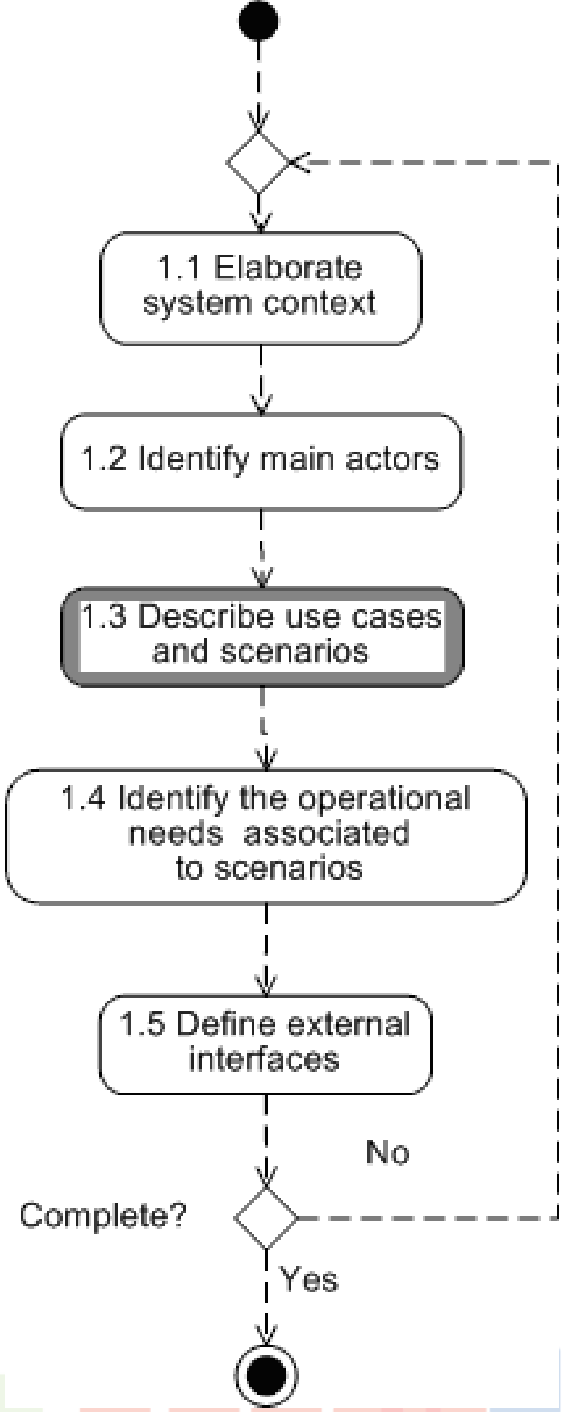
ISE&PPOOA Mission dimension subprocess
Step 3. Describe use cases and scenarios

- Use cases represented in next slides are the main interactions of the system and the external actors.
- Use cases representing safety and security concerns are considered as well. They are labelled CUM (Misuse cases)
- A use case may have more than one scenario
- Here use cases and their scenarios are described textually using a template.
- Other representations such as sequence diagrams or activity diagrams are allowed.



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IMD use and misuse cases

- Operate on the patient
- Diagnose the patient
- Communicate patient results
- Manage and store results
- Prepare the surgical intervention
- Report system status
- Report system location
- Manage power
- Report periodically about the implanted system status

- Harm the patient
- Cause EMI
- Prevent communication
- Prevent energy transfer
- Harm the user
- Hack the system
- A non-system related medical emergency arises

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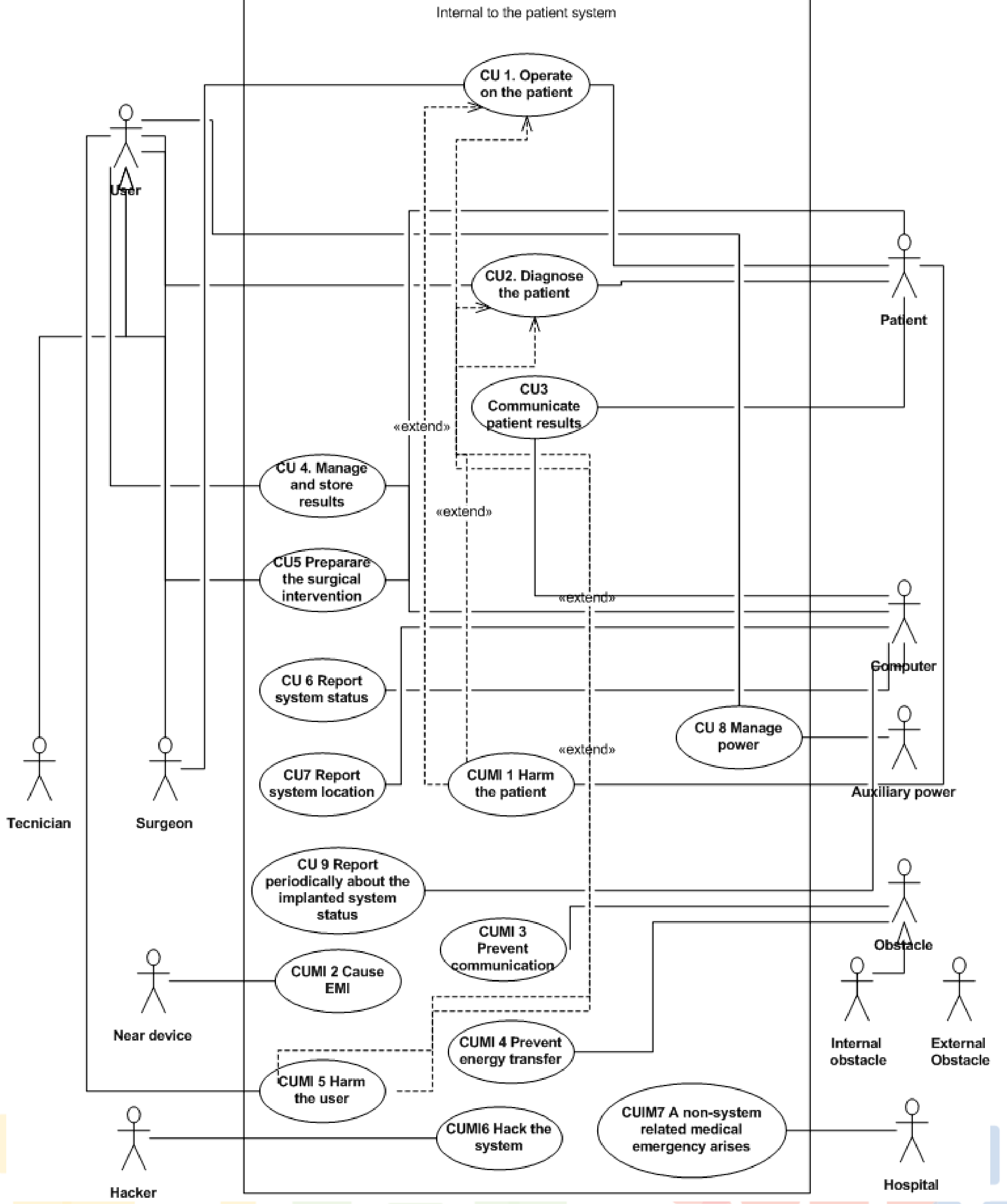
IMD Use cases diagram



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IMD- Use Case UC1: Operate on the patient

- **Scenario 1**: The physician perform a surgery only with the system
- **Scenario 2**: Surgery performed using a combination of systems
- **Scenario 3**: (Semi) permanent implantation of the system inside the patient's body.

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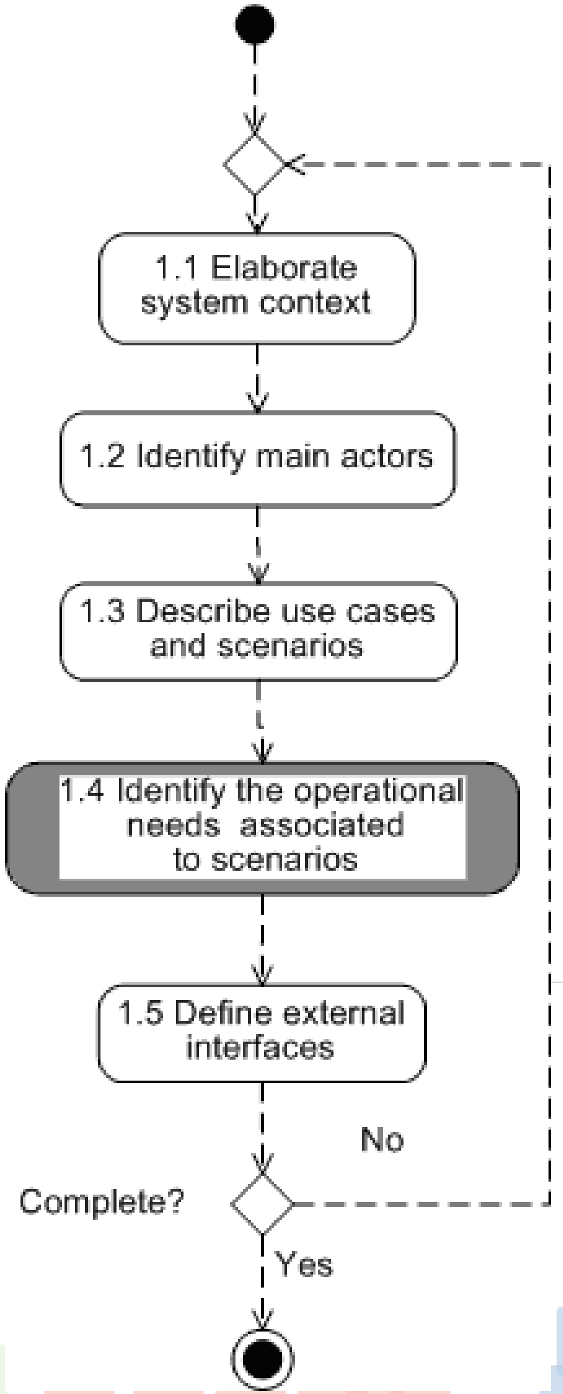
IMD- Use Case UC1: Operate on the patient- Scenario 1. The physician perform a surgery only with the system

1. The physician inserts the system inside the patient's body.
2. The physician guides the system inside the patient's body.
3. The system transmit its status and position to the physician.
4. The system transmits that it has arrived at the surgery point.
5. The physician commands the system to operate.
6. The system transmits the end of the surgery.
7. The physician commands the system to comeback to the extraction point.

ISE&PPOOA Mission dimension subprocess Step 4. Identify the operational needs associated to scenarios

- Here operational needs are defined in the answer to the question “What problem are we trying to solve with the new system operating in a particular context?”
- Some authors call them user or stakeholder needs
- An operational need may appear in multiple scenarios
- Identify MoEs related to the mission



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Operational needs related to UC 1 scenario 1 (1 of 3)

- ON1.1_1. The surgeon can insert the system inside the patient's body by means of a needle whose diameter is less than 1 +/- 0.1 mm
- ON1.1_2. The surgeon can inject the system immersed in saline or other suitable fluid
- ON1.1_3. The surgeon can inject the system inside an artery
- ON1.1_4. Patient's tissues pressure will not affect the system performance
- ON1.1_5. Patient's tissues will not affect chemically the system performance
- ON1.1_6. The electrical properties of the patient's tissues will not affect the system performance
- ON1.1_7. Patient's temperature will not affect the system performance
- ON1.1_8. The surgeon can activate the system motion immediately after the insertion inside the patient's body
- ON1.1_9. The surgeon can command the system to move autonomously
- ON1.1_10. The surgeon is informed if there is any obstacle which affects the system motion

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Operational needs related to UC 1 scenario 1 (2 of 3)

- ON1.1_11. The surgeon can command the system to rotate.
- ON1.1_12. The surgeon can guide the system manually.
- ON1.1_13. The surgeon will know the system position inside the patient's body with an accuracy of 0.1 mm and a precision of 0.1 mm.
- ON1.1_14. The surgeon will know the system rotation state using the symmetry axes of the device as reference with an accuracy of 1 degree and a precision of 1 degree.
- ON1.1_15. The surgeon can verify the correct functioning of the system at any time.
- ON1.1_16. The surgeon can verify that the system has achieved the surgery point with an accuracy of 0.1 mm and a precision of 0.1 mm.
- ON1.1_17. The surgeon can stabilize the system motion with an accuracy of 0.1 mm and a precision of 0.1 mm.
- ON1.1_18. The surgeon can stabilize the system rotation with an accuracy of 1 degree and a precision of 1 degree.
- ON1.1_19. The surgeon can command the autonomous stabilization of the system motion with an accuracy of 0.1 mm and a precision of 0.1 mm.
- ON1.1_20. The surgeon can command the autonomous stabilization of the system rotation with an accuracy of 1 degree and a precision of 1 degree.

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Operational needs related to UC 1 scenario 1 (3 of 3)

- ON1.1_21. The surgeon can command the activation or deactivation of the system sensors at any time.
- ON1.1_22. System data transmission will have a minimum bandwidth of 50 kHz.
- ON1.1_23. Surgeon commands to the system will have a minimum bandwidth of 50 kHz.
- ON1.1_24. The surgeon can command the activation or deactivation of the system actuators at any time.
- ON1.1_25. The surgeon can measure the system surgery duration with an accuracy better than 0.01 s and a precision better than 0.01 s.
- ON1.1_26. The surgeon can command the system to shut down its actuators after the surgery is finished.
- ON1.1_27. The surgeon can command the system to detect the surgery completion automatically using its sensors.
- ON1.1_28. The surgeon can guide the system manually towards the extraction point with an accuracy of 0.1 mm and a precision of 0.1 mm.
- ON1.1_29. The surgeon can command the system to go the extraction point in an autonomous way.
- ON1.1_30. The system must be biocompatible with the patient's tissues.
- ON1.1_31. The surgeon can fix the duration of the surgery.
- ON1.1_32. The surgeon can use the system continuously without any interruption during the whole duration of the surgery.

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Measure of Efficiency (MoE)

- An MoE represents a stakeholder expectation that is critical to the success of the system/mission, and failure to attain its critical value, attribute or feature will cause the stakeholder to judge the system/mission a failure (Expanded Guidance for NASA Systems Engineering, 2016)
- Example of MoE we identified related to IMD energy:

Availability of energy to the device for performing navigation and other functions during the patient intervention time

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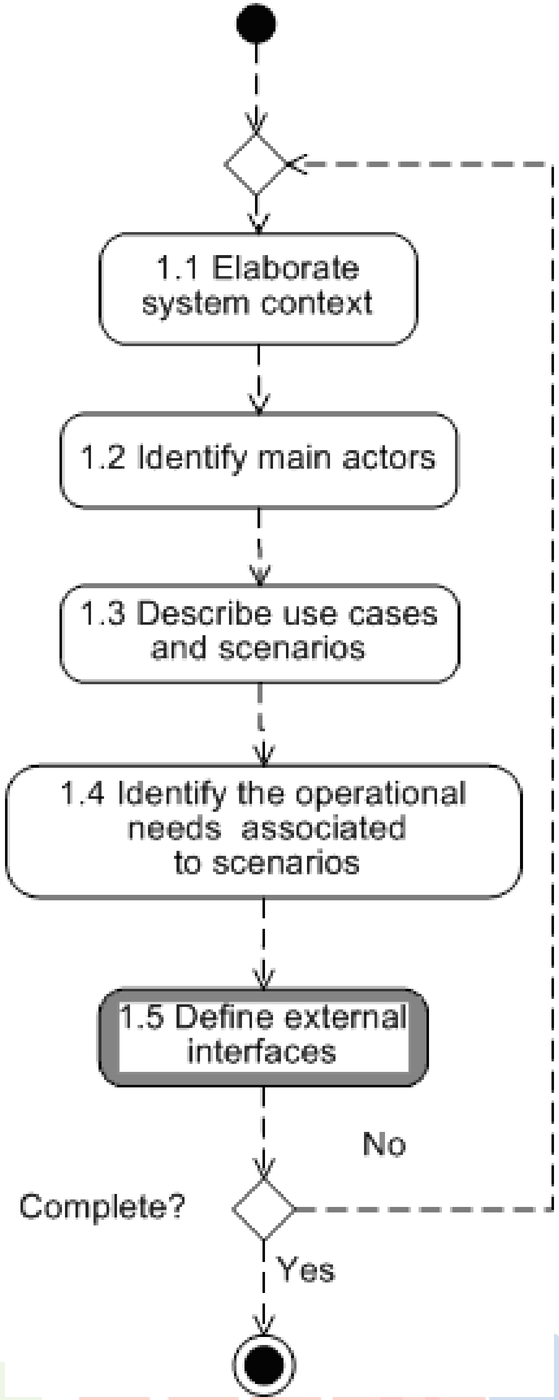
ISE&PPOOA Mission dimension subprocess
Step 5. Define external interfaces

- The external interfaces identified in the context diagram are described
- For data external interfaces we recommend the use of a data dictionary
- For mass and/or energy external interfaces we use a template to describe them



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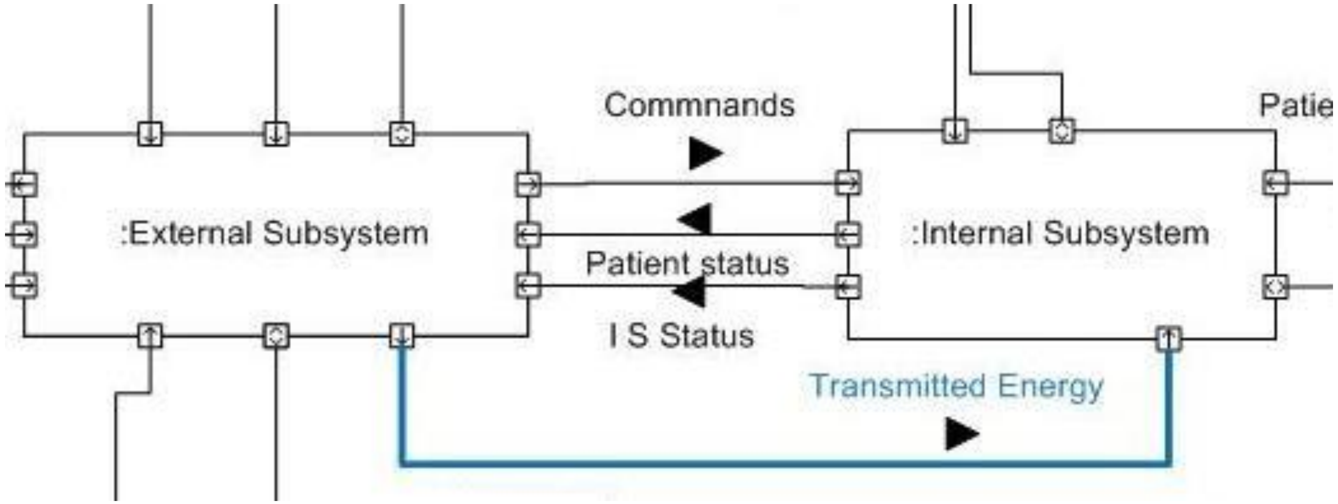
Example of interface- Transmitted Energy 1/2



Transmitted energy interface description: electromagnetic radiation in the range of 2,5 GHz or less with a beam dispersion on the patient's skin no larger than 1 cm in diameter.

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Example of Interface-Transmitted Energy 2/2

- Frequency : 2.45 ± 0.05 GHz
- Electric field: 100 ± 0.1 V/m
- Beam diameter on skin: 10 ± 1 mm
- Signal properties: TBD
- Electromagnetic effects: TBD
- Electromagnetic compatibility: TBD
- Electromagnetic interference: TBD

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To conclude

- To conclude, we emphasize that a good model of the mission dimension is critical for an **"out-in" modeling** of a customer-oriented system.
- Technology, for example energy transfer and energy harvesting, is an important issue
- but in domains as medical applications the users and the patients are more important so "**out-in" approaches** to the system modeling are the best option.

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