Product Requirements

for

Electromagnetic Tracking of Endovascular Catheters

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I. Hardware Requirements

For the catheter design, the following requirement should be considered:

1. Accuracy: The catheter must be accurate enough. It should have a high positional accuracy of at least ±3 mm.

2. Size: The catheter must be small enough to navigate through the blood vessels, typically with a diameter of less than 3 mm.

3. Electromagnetic Tracking: The catheter should be equipped with electromagnetic tracking sensors that provide real-time guidance for the operator during the procedure.

4. Flexibility: The catheter should be flexible enough to navigate through the vessel. It should also be able to curve and bend without breaking or kinking.

5. Biocompatibility: The catheter must be biocompatible to minimize any potential adverse reactions or complications.

6. Ease of Use: The catheter should be easy to use and manipulate

7. Durability: The catheter must be durable enough to withstand the stresses and strains of navigating through the blood vessels. It should also be able to withstand multiple uses without degradation or failure.

II. Software Requirements

2.1. Registration Requirements

1. Accuracy: The software must be accurate in registering the EM tracker path with the CT data. It should have a high positional accuracy of at least ±3 mm.

2. Speed: The registration process should be performed quickly and efficiently, with minimal delays or interruptions.

3. User-friendly Interface: The software should have a user-friendly interface that allows for easy navigation and manipulation of the registration process. It should also provide visual feedback to the operator to confirm the accuracy of the registration.

4. Integration: The software should be able to integrate with 3D Slicer.

5. Flexibility: The software should be flexible enough to accommodate different registration scenarios. It should have the ability to switch between fiducial points registration and path-based registration.

2.2 Visualization Requirements

1. Real-Time Visualization: The software must provide real-time visualization of the EM tracking catheter position and orientation during the procedure. It should be able to display the position and orientation of the catheter on a 3D model of the patient's anatomy.

2. Accuracy: The software must be accurate in displaying the position and orientation of the catheter in relation to the patient's anatomy. It should have a high positional accuracy of at least ±3 mm.

3. Integration: The software should be able to integrate with other medical imaging systems, such as CT or MRI, to provide additional information about the patient's anatomy.

4. User-Friendly Interface: The software should have a user-friendly interface that allows for easy manipulation and visualization of the catheter's position and orientation.

5. Customization: The software should allow the operator to customize the visualization parameters, such as color, transparency, and size of the catheter.