PROJECT SPECIFICATIONS REPORT

Project Title: SurgeVision

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1. Introduction

1.1 Description

The SurgeVision project is an advanced surgical navigation system specifically designed to optimize the accuracy and safety of hip replacement surgeries.

It allows surgeons to view real-time 3D MRI images of the patient's anatomy, which can be viewed on a monitor or using augmented reality (AR) glasses.

One of the system's key features is the synchronization between the surgeon's physical points of contact on the patient and corresponding areas in the MRI image, ensuring real-time guidance and better alignment.

By integrating real-time imaging with point-of-contact synchronization, SurgeVision aims to improve surgical accuracy, reduce risk, and reduce overall procedure time.

The AR glasses provide an additional layer of visual support for surgeons, allowing them to have better situational awareness.

This flexibility ensures that the system can adapt to a variety of surgical styles and preferences.

1.2 Constraints

1.2.1 Economic Constraints

The project faces a number of economic constraints, including the cost of purchasing specialized equipment such as computers, augmented reality glasses, and sensors.

There is also ongoing maintenance costs associated with keeping the equipment in good working order.

Development budgets may be limited, affecting various phases of the project including research, development, testing, and deployment.

Additionally, surgeons and medical staff may need specialized training to use the system effectively, increasing the overall cost.

1.2.2 Social Constraints

The system may encounter some resistance from healthcare professionals who are hesitant to adopt new technologies due to the learning curve involved.

Additionally, patient trust may be an issue, as some may feel uncomfortable with the use of advanced technology during critical procedures.

Overcoming these barriers will require efforts to communicate the safety and effectiveness of the system to healthcare professionals and patients.

1.2.3 Political Constraints

Policy constraints include regulatory approval processes for medical devices, which can vary significantly between countries.

Compliance with international health policies and regulatory agencies (such as FDA approval in the United States) can result in delays or additional costs.

Changes in health policy or insurance coverage can also impact system adoption in different regions.

1.2.4 Ethical Constraints

Ethically, the system must adhere to strict guidelines regarding patient confidentiality and data security.

Processing MRI images and sensitive patient information requires compliance with data protection regulations such as HIPAA in the United States and GDPR in the European Union.

Additionally, if the system uses machine learning algorithms, the developer must ensure that these systems are bias-free and provide accurate results for all patient demographics.

1.2.5 Health and Safety Constraints

From a health and safety perspective, the system must ensure surgical precision, as any errors in real-time feedback can lead to serious complications during surgery.

The AR glasses must be designed to avoid any obstruction of the surgeon’s vision and avoid distractions.

1.3 Professional and Ethical Issues

1.3.1 Patient Data Privacy and Security

The SurgeVision project must comply with the ACM Code of Ethics and the IEEE Code of Ethics, ensuring that patient data is handled securely.

All MRI images and sensitive medical information must be encrypted and stored securely, with strict controls on who can access this data.

1.3.2 Informed Consent and Transparency

The project must ensure that surgeons and patients are fully informed about how the system works, including risks, limitations, and features such as AR glasses.

There must be clear communication about the system’s capabilities to establish trust and realistic expectations.

1.3.3 Safety and Reliability

Safety is paramount and the system must provide accurate, real-time feedback during surgery to ensure accuracy.

Additionally, it must be reliable and minimize any risk of failure or malfunction that could compromise patient safety.

1.3.4 Avoidance of Bias in the System

If using AI or machine learning components, the developer must ensure that the system is bias-free, ensuring that the system's accuracy is applied equally to all patient demographics.

1.3.5 Professional Competence and Lifelong Learning

Developers involved in the project must maintain professional skills and continuous training to stay up to date with the latest technological and medical advances.

Collaboration with healthcare professionals will be essential to ensure the system is adapted to current surgical practices.

2. Requirements

2.1 Functional Requirements

• Real-time 3D MRI image viewing: The system shall display a 3D MRI image of the patient's anatomy in real time during surgery.

• Contact point synchronization: It shall synchronize the surgeon's physical contact points on the patient's body with corresponding locations in the MRI image.

• Real-time guidance: The system shall provide real-time feedback to help the surgeon navigate the surgical site.

• AR integration: Support for AR glasses to improve the surgeon's situational awareness.

• Alignment function: This function is provided to mark reference points on the patient's body, ensuring alignment between the MRI image and the patient's anatomy.

• System control interface: The system shall have an intuitive control interface for adjusting parameters, viewing images and AR functionality.

2.2 Non-Functional Requirements

Performance: The system must respond to surgeon input updates and display in real time with minimal latency (less than one second) to ensure precise synchronization between the patient's physical contact points and the MRI image.

3D image rendering must be smooth and maintain at least 30 frames per second to avoid visual lag during surgery.

• Reliability: The system must maintain high reliability, especially during surgery, to avoid interruptions or failures.

• Scalability: The system must be able to handle different types of MRI data and patient anatomy, ensuring that it can be expanded to a variety of use cases beyond hip replacement, including other types of surgery in the future.

• Security: Patient data must be encrypted and stored securely to prevent unauthorized access.

• Ease of use: The system's user interface must be easy to navigate, allowing healthcare personnel to use it without extensive training.

• Regulatory compliance and safety: The system must comply with medical device regulations and safety standards required for surgical equipment.

3. References

1. ACM Code of Ethics and Professional Conduct

2. Software Engineering Code of Ethics (IEEE Computer Society)

3. IEEE Code of Ethics