Testing Management Plan Document

Motorized Fixation to Tubular Retractor

Project for EN.601.456 Computer Integrated Surgery II

Group 1:

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1. Introduction

A Test Plan is a document describing the testing scope and activities that will be completed by the team to control the quality of our motorized tubular retractor f after it has been developed and before it is placed in production. It serves as the basis for formal testing for devices.

A. Purpose

The Test Plan documents the strategies that will be used to ensure testing activities are effectively implemented within the CIS II 2021 Group 1 Project team. The plan defines the testing scope, milestones, requirements, dependencies, risks, and procedures that support the project deliverables, team members, and contributors

2. Objective and Tasks

A. Objectives

The objective of the Test Plan is to outline the project testing activities and responsibilities that will ensure a continuous end-to-end quantitative evaluation of the quality of project deliverables and processes throughout the life cycle of the project.

B. Roles and Responsibilities

Name	Role	Test Responsibility
Mark Shifman	Designee (Mechanical)	Identification, review, monitoring, and control of project nonconformities as they relate to the mechanical design
Caroline Hoerrner	Designee (SW)	Identification, review,

Robby Waxman	Designee (SW)	monitoring, and control of project nonconformities as they relate to the software design

3. Scope

The scope of this test plan highlights the activities that will be covered in testing. For this project, we will be performing software unit testing for software including: orientation estimation code, motor actuation code, and data analysis code. We will also be conducting ease of use testing (human factors) to see how efficiently surgeons and other users can operate the device and to check whether there is confusion in directions or use. We will also be testing accuracy and repeatability of our movements and estimations. Lastly, we will be performing benchtop testing and then testing with animal models.

4. Testing Strategy / Levels of Testing

A. Unit Testing

The project team will develop and use unit testing to demonstrate functionality of software. This will be done with the Python library “unittest” which is a popular unit testing framework based off of JUnit. The project team and major stakeholder (CortiTech) will then agree up front on when each major software deliverable is complete and correct.

B. System Testing

The project team will perform benchtop testing with surgeons to ensure that the device can reach the desired resolution of movement, as well as efficiently work

with the surgeon's workflow and not disrupt any portions of a procedure. In this case, that will mean determining whether we can reach 1 degree of resolution in movement and orientation accuracy, as well as operate within a 15 degree range effectively.

C. Performance Testing

Performance testing will be conducted by the project team with the assistance of practicing neurosurgeons. This performance testing will take place inside of an animal model (pig brain) and force sensing measurements will be taken throughout the procedure to measure the stress we are causing on the brain.

5. Testing Procedure

A. Environment

Unit testing can be executed locally on group member’s personal devices. The testing will occur in an environment as close to the development environment as possible.

System testing shall also be performed in a similar environment to development, using group members personal devices to interface with the microcontroller. As these tests do not require a phantom, they have no strict physical environment restrictions.

Performance testing needs to be required in designated lab space, which will be coordinated with surgeon mentors at a later date. Virtual environment will be identical to that of the system testing.

B. Features to Test

Testing should confirm the validity of all orientation estimation algorithms, as well as proper sensor and motor functionality. Precision testing should determine the error margin of orientation estimation as well as actuator performance.

System testing should ensure adequate performance of the repositioning software when presented with anomaly input data as well as incomplete input data. Testing should determine if the speed of readjustment is appropriate, as well as gauge maximum resistance force endured by the motors.

Performance testing will simulate the surgical workflow of the system. This will gauge the effectiveness of operation, and the ability to sustain the resistance force of simulated brain tissue. If time allows, further testing and analysis will be done to determine forces exerted by the device onto the brain tissue to assess potential damage caused.

6. Schedule

A tentative testing schedule is as follows.

Test	Timeframe
IMU sensor and orientation accuracy testing	3/22 - 3/29
Motor precious testing	3/22 - 3/29
Software unit testing	Continuous
System general functionality testing	4/26 - 5/3
Performance testing and phantom trials	4/29 - 5/5