Frameless Stereotactic Navigation
Product Design Specifications
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Group Members: Stephen Monette, Alex Yueh, Matthew Boyer, Jake Levin, Alex Nguyen

Advisor: Dr. John Puccinelli

Function:

Computerized frameless stereotaxy is used routinely for neurosurgical and spine surgeries. This technology makes it possible to determine the 3D location of the surgical tools in relation to the patient, which is invaluable for the removal of tumors or the placement of instrumentation. However, this technology is quite expensive due to its reliance on the use of high definition feature recognition software and hardware, so its application has been limited to expensive, in-patient surgical procedures. Frameless stereotactic navigation could be used to perform smaller interventional radiology procedures and pain procedures if a less expensive alternative could be developed. The goal of this project is to create a frameless stereotactic navigation system using an inexpensive Wii or Kinect system in order to spread the availability of the tool.

Client requirements:

- Design must be accurate up to one millimeter
- Constructed using off the shelf software and hardware (i.e. Kinect, Wii motion software)
- Conformable with pre-existing x-ray prints taken of the patient to track tooling
- Final design should be smaller than existing machine (current are quite large)
- Budget: $1000 (negotiable)

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: Device must be able to locate the surgeon's tools within one millimeter accuracy on the patient readouts. The stereotactic navigation system must also have a high refresh rate with a minimum of 20 FPS for data acquisition.

b. *Safety*: The end design must comply with medical standards in both sanitation and reliance. It must be able to handle sanitation cycles and be free of unnecessary faces, which facilitate bacterial growth. Any location identifying stickers/markers placed on the patients or tools must also be safe and free of any possible products that may affect the patient (I.E. latex-free, hypoallergenic materials). Stickers/markers must also comply with the data acquisition protocols used in the stereotactic system, i.e. discernible, high contrast colors. Errors in precision may not exceed 1 mm.

c. *Accuracy and Reliability*: The device must have an accuracy minimum of 1 mm, and it must maintain this level of accuracy while the system is anywhere between 1-1.5 m from the patient.

d. *Life in Service*: The life of the product should be 5 years, operating 5 times per week at most for 12 hours at a time.

e. *Shelf Life*: While in storage the device should be kept at normal room temperatures, the device will use power from the computer display.

f. *Operating Environment*: The device could come into contact with small amounts of water or other liquids found in operating rooms, such as blood. It should work at any climate and conditions acceptable for an operating room.

g. *Ergonomics*: The system should not interfere with the surgical process. The locators on the patient should provide minimal discomfort to the patient.

h. *Size*: The device should be able to accommodate maintaining a three dimensional visual field the size of 0.028 m^3 around the surgical site. The system will be designed in order to rest at the foot of the 1 meter high surgical table and extend over the patient lying on the table. As a result, the system will consist of a base, and a collapsible arm with the data acquiring cameras attached. The entire system should be able to collapse down to a carrying case or rolling stand that occupies no more than 0.042 m^3, as specified by the client.

i. *Weight*: The system should be easily transportable between operating rooms with/without the use of a wheeled cart. The total collapsed system should weigh no more than 18 kg.

j. *Materials*: The portion of the device coming into contact with the patient should be easily cleaned or disposable and should not cause harm to the patient.

k. *Aesthetics, Appearance, and Finish*: Because it will be used in the clinical setting, the product must be easy to use, and the display must be easy to read. The system should not be distracting to the patient or surgeon. Focus should be kept on the utility of the design rather than the aesthetics.

2. Production Characteristics

a. *Quantity*: We are designing one system to be used on multiple subjects.

b. *Target Product Cost*: The target product cost is $750.

3. Miscellaneous

a. *Standards and Specifications*: If marketed, the product will require approval from the FDA.

b. *Customer*: The system should be able to track all movements and recognize the instruments being used while taking up minimal room and not interfering with the surgical procedures. The project should be easy to use and inexpensive.

c. *Patient-related concerns*: The information from the fluoroscopic x-rays should be accessed in the system and protected during the procedure, but afterwards discarded. All equipment must be able to be sterilized.

d. Competition: *Brainlab* and *Stealth* are some current models of this technology, but they are too expensive for smaller interventional radiology and pain procedures. Students at the University of Washington have developed a program for the Kinect, which maps the body so that when surgeons use robotic tools they can receive tactile feedback to aid them in navigation.