Product Design Specification (PDS)

Title: iPhone Virtual Reality Training Model for Microsurgical Practice.

Henry Plamondon, Nicholas Jacobson, Haochen Wang, Frida Albiter, Emma Kupitz, Kenzie Germanson

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Function:
This training model will make microsurgical training less expensive and more accessible to a wide range of users. It eliminates the need for an expensive surgical microscope by replacing it with a smartphone equipped with the model. The prototype will utilize the zoom functionality of the smartphone for the surgeon to clearly see sutures and tissues up close. By using a smartphone, it is also possible to stream the training to Zoom or a similar platform so training can occur virtually. The design will minimize lag time between the recording phone and projecting device for simultaneous view of both the trainee and observers, while increasing spatial awareness and depth perception via binocular live video.

Client requirements:
- Must allow for depth perception with regard to where the trainee's hands are in relation to the work site.
- Must create an image with high enough zoom and resolution to see sutures (0.070 mm in diameter) clearly [1]
- Must remain inexpensive so it is widely accessible to training surgeons
- Must produce a streaming resolution of at least 10.2 megapixels
- Must have a stream delay of no more than 0.5 seconds
- Should utilize full magnification power of the smartphone

Design requirements:

1. **Physical and Operational Characteristics**

    a. **Performance requirements:**
        i. The device must be able to provide a clear image of the subject in a clinical environment. The device must be able to handle daily use and must be able to handle a load of at least 400g, the weight of the heaviest available smartphones.

    b. **Safety:**
        i. The device should be out of the way of the surgeon to prevent interference during practice. The device also needs to be able to be sterilized in an efficient manner before and after each use.

    c. **Accuracy and Reliability:**
        i. The device should be able to consistently maintain a magnification of 5x and the displayed magnification should be accurate with repeated trials. The device should display an accurate and clear image of the surgery area with minimal latency.

d. Life in Service:

i. The device should withstand continued use over the duration of the training process, the longest of which can last up to 12 hours. The device should be able to withstand this use everyday over its lifespan, as many different trainees may use the device.

e. Shelf Life:

i. The device should be stored in normal interior conditions. After six months without use, a lithium ion battery may begin to degrade. With continued use, the team would expect the smartphone being the limiting factor for the whole design. Thus, the final product should have at least one year of lifespan, which matches the lithium battery warranty provided by Apple. [2]

f. Operating Environment:

i. The product will most likely be used in a domestic or indoor environment, so the device will not be exposed to extreme conditions.
ii. 0-35 ° C operating temperature, - 20-45 ° C nonoperating temperature, 5-95% non-condensing, relative humidity (the specification of iPhone 8, and more restriction may be applied as other hardware is introduced to the final product) [3]
iii. The person who will use this will be the trainee, which is the person who is practicing surgery using the iphone, and the trainer(s) who is/are watching the trainee on the headset.
iv. Potential splash of food dye, blood, in vitro tissues, etc. [4]
v. Components that are exposed to the operation station shall not be malfunctioned upon such splash
vi. Potential scratches from the surgical equipment, such as tweezers or needles.
vii. The final product should at least endure accidental damage from the aforementioned scenarios, while maintaining the resolution to recognize the suture

g. Ergonomics:

i. The product can involve somewhat delicate technology, such as smart phones and laptops, so the same restrictions of force that cause those devices not to be damaged or break apply here.
ii. For the iPhone 8, do not submerge in water greater than 1 meter and for longer than 30 minutes. [3]
iii. The device should be comfortable to use for over 1 hour
iv. Should not cause any unnecessary strain to the surgeon

h. Size:

i. Should be able to be set up in an indoor living space (i.e. 10 x 10 sqft, approximately 3 x 3 meters)

i. Weight:

i. Optimum weight: < 10lbs (approximately 4.5 kg). Must be easily transportable

j. Materials:

i. No restrictions on material mechanics
ii. Cannot be toxic upon skin contact or inhalation
iii. Shall have minimal degradation resistance, such as from sunlight

k. Aesthetics, Appearance, and Finish:

i. The color of the product should be dull so that it doesn't distract from the microsurgical practice it is intended for. The shape and form should be adjustable so that each user/consumer can place it into alternate positions to get a better and more comfortable practice for themselves. The texture of the finish should be flat and soft in order for it to be comfortable for the user and in order for it to not be a distraction.
ii. Should simulate the working condition of an operation room with microscopes

iii. Must not interfere with the operation and training performance of the user

2. Production Characteristics

a. **Quantity:**
   i. One final prototype as deliverable
   ii. Tens of thousands of units for mass production after approval, replacing all current expensive training mechanisms for microsurgical practice for medical residents.

b. **Target Product Cost:**
   i. The target cost of the product is undetermined, but shall be less than our clients budget of $500
   ii. Cost for an iPhone, a stand, and any attachment that is necessary to put over the camera to replicate microsurgery practice are not considered as part of the budget for this project. Since the existing products cost at least $100,000 [5] which is drastically greater than the target cost. The prototype, even considering the cost for the equipment listed above, will be a cheap alternative for medical students to use for remote training, using materials that are commonly owned.

3. Miscellaneous

c. Standards and Specifications:
   i. ISO 10936-1:2017
      - Specifies the requirements for microscopes used during surgical procedures, so the team must adhere to these specifications when creating a design. However, since this prototype will be used for practice purposes, the requirements many not all apply [6]
   ii. Code of Federal Regulations Title 21, Volume 8, Sec. 882.4525 Microsurgical instrument [7]
      - The final deliverable will fall into the Class I medical device category, which is exempt from the premarket notification procedures 510(k)
   iii. Code of Federal Regulations Title 21, Volume 8, Sec. 878.4700 Surgical microscope and accessories [8]
      - The final deliverable, under definition of this section, will be a Class I device. However, since the recording device in this design will be a DC powered smartphone, no more actions shall be made upon this regulation

d. **Customer:**
   i. The customer would prefer the delay of relaying the image to the headset to be minimized for enhance practicing technique (less than 0.5 s)
   ii. The quality of the camera while zooming should be clear enough to clearly see the material being worked upon. 2x zoom using an iPhone 11 Pro was tested to be the most practical. The requirement is that the trainee is able to see the suture, which is 0.070 mm [1]
   iii. The camera should be able to show the depth of the workspace in order to help determine the distance between the instruments being utilized and the suture on the workbench. This may require the use of two lenses to allow for a binocular view
   iv. The device should be comfortable to wear for extended periods of time

e. **Patient-related concerns:**
   i. As this is a device used for practice, there will be no requirements for patient confidentiality.
   ii. Sterilization should not be an issue with regard to the camera setup. However, it may be practical to clean the headset with a wipe between uses.

f. **Competing designs**:

i. Augmented Reality (Mixed Reality)
The Microsoft Hololens is a very complex device which allows for similar types of practice. However, the Hololens is much less accessible and much more expensive. This will be an alternative that is possible to use from many different remote locations. Meanwhile, mixed reality provided by Hololens is rather redundant for the purpose of the clients. [9]

ii. Exoscopic Platforms
Zeiss, Olympus and Mitaka are well known medical device providers for exoscopes, featuring high definition images of the field with 8x to 30x magnifying capability. However, the price varies from 0.2 to 1.5 million dollars, resulting in limited access for trainees from less developed regions [5].

Reference

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[4] "Dr. Sam POORE and team featured ON BTN LiveBIG Wisconsin," Department of Surgery, 13-Jul-2020. [Online]. Available: https://www.surgery.wisc.edu/2020/07/13/dr-sam-poore-and-team-featured-on-btn-livebig-wisconsin/. [Accessed: 24-Sep-2021].
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[8] CFR - Code of Federal Regulations Title 21 Sec. 878.4700, vol. 8. 2020.
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