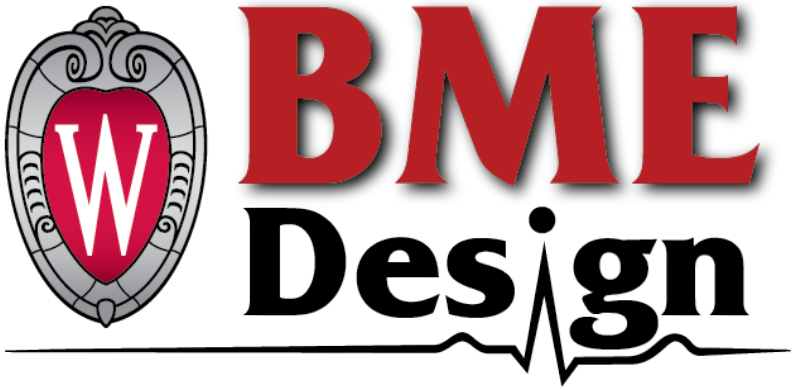


# iPhone Virtual Reality Training Model for Microsurgical Practice

## Preliminary Product Design Specifications

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# Table of Contents

**Function:**

The clients' current model is combining virtual reality glasses with a computer, two cell phones, and a lightning cable connection to perform microsurgery. However, there is too much delay and the team is expected to design a simple streamlined iPhone-VR system to create a home microsurgery simulation tool that could be used as a resource for resident surgeons to practice microsurgery.

**Client Requirements:**

- Magnification: 1:12.
- Ensures an immersive experience for the entire surgical team due to its big-screen 3D imaging.
- Minimize the delay of real-time 3D imaging (currently around 1 ms)
- Make the model more streamlined with fewer devices. The expectation is to use a single iPhone for recording and casting to the Macbook screen so that surgeons could use VR glasses to directly look at the screen.

**Design Requirements:**

- *Performance Requirements:*
    - The device should be as fast as possible to improve the VR viewing experience
        - Minimize display lag between the smartphones and the MacBook
- *Safety:*
    - The device should minimize unnecessary visuals to the user's eyes
        - Not overly bright, no sudden flashes, reduce motion blur
- *Accuracy and Reliability:*
    - The ratio of the original camera image to the one seen should be maintained
- *Life in Service:*
    - The device should be able to be used multiple times for as long as the shelf life
- *Shelf Life:*
    - The device should ideally last as long as the smartphone/MacBook in use remains functional
- *Operating Environment*
    - The device will be exposed to normal conditions, such as room temperature, and will be used by resident surgeons

- *Ergonomics:*
    - The device should be fairly portable as it will likely be worn by the user
- *Size:*
    - The device should minimize the number of devices, such as smartphones and MacBooks, used.
- *Weight:*
    - The device currently consists of an iPhone XR (194g [1]), an iPhone 8(148g [2]), 1 Macbook 13" with retina display computer (1551g [3]), lightning cables (negligible), and an articulating arm phone mount stand (440g with a maximum load of 500g [4]). Therefore, the total amount of weight is estimated to be 2333g.
- *Materials:*
    - The device does not have certain materials that should be used for fabrication. However, the material used in the VR set should be considered. The current model is using google cardboard as our VR headset, and the material from the google cardboard such as the head strap may cause some uncomfortableness according to some customer reviews.
- *Aesthetics, Appearance, and Finish:*
    - The device aims to perform a mock surgery at home, so it should use as many materials available at home as possible. In this case, this platform will result in an iPhone clamped on the mount and connected to a MacBook Pro, and another iPhone will wirelessly be connected to the MacBook and placed in the google cardboard.

**Production Characteristics:**

- *Quantity:*
    - Nowadays, in developing countries, the demand for microsurgery, especially in the field of plastic surgery, has increased tremendously. It is estimated that in Zimbabwe there are only 0.03 plastic surgeons in every 100,000 people, which is a very low number compared to 1.98 plastic surgeons per 100,000 people in the United States [5]. Additionally, the lack of facilities for surgeons to practice will also cause high demand for experienced surgeons. In this case, the development of a VR platform that mimics the surgical situation with depth perception will help surgeons in developing countries.
- *Target Product Cost:*
    - The current model requires two smartphones, one computer, a connection cable, and a smartphone stand mount, but in the future, we may reduce the smartphones or computers used in the product. We would assume that the user already has at least one smartphone and a cable. Thus, although the total cost of the product may

vary, the maximum cost for this platform is to buy another smartphone, a computer, and a smartphone stand mount.

**Miscellaneous:**

- *Standards and Specifications:*
    - The device, similar to its current professional version used by surgeons, is a class 1 device and is exempt from requiring FDA Premarket Approval. To receive a CE mark for EU approval for a class I medical device, the device needs a Declaration of Conformity registered with a Competent Authority. ISO 10936-1:2017 specifies requirements and refers to test methods for operation microscopes used for observation during surgical operation and treatment of patients, but it does not apply to accessories, e.g. photographic cameras. [6]
- *Customer:*
    - The customer has a preference for the components of the device to be cheap and easy to obtain. There is potential to market the device in underdeveloped countries where there are limitations in money and technology available. The device should be able to hook up to external monitors for the potential viewing of students in a teaching environment. For better ease of use, the operator of the device should have the ability to adjust the zoom and move the optics of the device as needed without any trouble. The device needs a depth of field such that the operator is able to effectively wield instruments while using the device - however, the distance required is short, less than 30 centimeters in practice, and no peripheral vision is required. The client is considering between two iterations of the device, one iteration being stand-mounted, and the other being a form of headset the user wears, and both routes for the design still need to be evaluated for their practicality and performance.
- *Patient-Related Concerns:*
    - Whether it is used for training or for a real operation, the device comes into contact with its user and must be cleaned after every use. It should not, however, come into contact with a potential patient. The device does take footage of the operation, which requires the user's consent, and if it were to be used to operate on a patient, it would need the patient's consent.
- *Competition:*
    - The competition to this device is not an already used professional device such as what the client uses (MM51 YOH Surgical Microscope System, MSRP $310,000), but any proposed cheapened alternative that offers great magnification and resolution for microsurgical practices using as few components as possible. [7]

- eoSurgical has microsurgery simulations using your own devices such as phones, tablets, and tv screens, but their cheapest product, the eoMicro, costs £82.50 ($106.84 USD). It has its own stand, which is rather bulky and cannot be used outside of training. [8]
- Pocket Suture has a Pocket Microsurgery Trainer for $145.00. It is too simplistic for the client's needs by only requiring a phone and does not solve the client's problem with their current proposed device (the lag between devices). It is also only for individual training. [9]

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