



Product Design Specification

Microscope Slide Scanner

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Client: Teri Stewart

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Function

The team has been tasked with finding a more efficient way to scan microscope slides using digital scanning. The client's department already has a scanner but it takes a while to scan one slide and the images are not of the best quality. Therefore, we must find a way to enhance the user quality of their digital scanner as well as the images themselves. The department has also asked our team to create software capable of housing the images. This project will benefit multiple labs who send in slides for processing including the primate lab and SMPH.

Client requirements

- Develop a method of digitally scanning slides that is more efficient
- Find a way to increase the quality of the scanned images
- Develop software capable of housing the slides once scanned
- Reduce the time it takes to scan one slide

Design requirements

1. Physical and Operational Characteristics

a. Performance requirements

- i. The method of scanning should produce images that are of notable quality when compared to the current method of scanning including a reduction in the blurriness seen around edges of cell clusters. This method should take less than 20 minutes, the current time it takes to scan one slide, with a goal of around 5 to 10 minutes. There should also be a software based method of housing the scanned slides.

b. Safety

- i. The scanner should follow basic FDA safety guidelines regarding medical related devices [11].
- ii. The scanner should not interfere, contaminate, or alter the slides.
- iii. The scanner should be properly insulated with no short circuit that could possibly lead to fires in the lab [12].
- iv. The scanner should have an emergency response in case of broken slides within the slider [10].

c. Accuracy and Reliability

- i. The method of scanning should produce consistent results across all slides and take less than 20 minutes to scan.

d. Life in Service

- i. The product will be used to scan five or more slides for around five days a week and must last for at least a year.

- e. **Shelf Life**
 - i. The product must be able to hold up for at least a year or until an updated scanner can be obtained by the lab.
 - f. **Operating Environment**
 - i. The scanner will be operating within a traditional lab.
 - ii. The scanner would be required to work efficiently indoors in a well ventilated area with an electrical outlet.
 - iii. The scanner must be able to operate remotely so that the user can access relevant scans from any location they may be in.
 - g. **Ergonomics**
 - i. The scanner must not interfere with other equipment in the lab either due to size or power surging.
 - ii. The scanner must be able to effectively scan the slides and notify the user once it finishes scanning a batch of slides.
 - iii. The scanner should be equipped with handles or a mechanism to move/transport between areas or buildings.
 - h. **Size**
 - i. The scanner must be able to fit into the clients lab without problem.
 - ii. The scanner must be able to hold the preferred amount of slides for scanning.
 - i. **Weight**
 - i. The scanner weight should not exceed 5 lbs, since the typical weight of the scanner is between 2-4lbs depending on existing models [9].
 - j. **Materials**
 - i. A scanner is usually made of a combination of sensors, specifically CCD, CMOS, and sCMOS sensors[9].
 - ii. Scanners also typically use LEDs and halogen lamps to properly maintain the illumination within the scanner[9].
 - iii. Scanners also use sensitive cameras, a possible improvement over the current camera is an Amscope digital camera or an Omax digital camera[7].
 - k. **Aesthetics, Appearance, and Finish**
 - i. The aesthetics of the scanner should not reduce efficiency of the scanner.
 - ii. The aesthetics of the scanner should not impede or interfere with the surrounding environment and maintain its safety standards
 - iii. The finished product's appearance and aesthetics are not as relevant provided that the scanner is effective and efficient meeting the clients needs and other requirements documented in this document.
2. **Production Characteristics**
- a. **Quantity**

- i. Only one method of scanning is needed at this time as well as one method of storage.
 - b. **Target Product Cost**
 - i. The client would prefer that edits are made to existing devices, however, if new devices or technology need to be purchased, it must be less than \$5000.
- 3. **Miscellaneous**
 - a. **Standards and Specifications**
 - i. eCFR 493.1274 Standard: Cytology clarifies that when cytology labs are using automated and semi-automated screening or scanning devices, the laboratory must follow the manufacturer's instructions for the machine [4]. Additionally, eCFR Standard 1254.80 specifies that when using a slide scanner, slides must be checked after scanning to ensure that no damage occurs when the slide is in the scanner. Automatic feeder devices on flatbed scanners are prohibited. Light sources in the scanner must not raise the surface temperature of the slide being scanned. Finally, no part of the equipment may come in contact with the slides in a way that will cause friction, abrasion, or any damage to the slides [5].
 - b. **Customer**
 - i. The customer for the slide scanner is Mrs. Teri Stewert. Working in the Cytotechnology program in the Wisconsin State Laboratory of Hygiene, she needs to digitally scan and upload slides for research and student purposes. Scanners on the market are either far too costly, or not permitting access to their resources. Her scanner is slow, outdated, and takes a long time with dated software.
 - ii. This product is being made with our client in mind, however, there is a large market for slide scanners and could be utilized by many researchers and or labs.
 - c. **Patient-related concerns**
 - i. The software used to store data must be able to keep the scanned slides confidential to those with access. Thus, it is important to ensure that there is a secure login feature in place to ensure confidentiality and protect sensitive information found in the scans.
 - d. **Competition**
 - i. There is a fast array of slide scanners currently being utilized in labs and on the market today. Some examples of which are, Motic Digital Pathology, Hologenic (genius system), Grundium, and others.
 - ii. Prices can reach upward of 250,000 making for unrealistic tools for lower budget labs.

References

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