

Dual Handheld and Video Otoscope - BME 200/300 Section 301

Product Design Specifications

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Function:

A typical handheld otoscope consists of three main parts: head, tail, and the speculum. The speculum is a thin tube that inserts into the ear canal of animals with a light source at the tip. This part of the otoscope is designed to be able to comfortably create light pathways to go through and direct lights into the head component of the otoscope. The head of the otoscope is a box with a magnifying lens, which is usually convex, that projects a virtual enlarged image of the ear canal to the observer. The tail of the otoscope is for holding, and storage for camera and other essential processing components of the otoscope. Video otoscopes come in a variety of designs. Without the need of a magnifying glass, a video otoscope can be smaller in size. The Dual Handheld and Video Otoscope is needed to integrate functions of video otoscope to a typical handheld otoscope for distant viewers. While maintaining the features and the three main parts of a handheld otoscope, a digital camera is needed to feed live.

Client requirements:

- The otoscope resembles features of a traditional handheld otoscope (lenses)
- The otoscope has video relay ability
- External Light Source
- Maintain expenses below the budget
- Capable for using currently existing speculums

Design Requirements:

1. Physical and Operational Characteristics
 - a. *Performance requirements:* The redesign of the handheld otoscope must meet basic otoscope features, this includes: allow light to emit, reflect, and gather back to the viewer. The video relay to a distant viewer must be stable, smooth.

Although no requirements from the client, the resolution and framerate of the camera should maintain industry specification for a video otoscope at a sensor resolution of 1280 x 1024 and frame rate of 30 FPS [1].

- b. *Safety*: During student examination, a trained handler or veterinary technician should also be present all the time of the examination to assist with collecting data and analysis on performance. This can be the exam instructor as the distant viewer or someone who is familiar with the process and the device. This is to avoid injuries for both students and the animal subject during the process. The otoscope should also not consist of exposed electrical components and potentially sharp edges that could cause harm to both student and animal subject [2]. Users or students need to check the basic functions and each part of the otoscope to make sure the otoscope is in functional shape and each component on the otoscope is working to their intended function only, prior to the use of animal subjects and handled with care to avoid animal abuse. Users or students also need to consider examination duration to avoid overheating from the light source and possible damage to camera functions.
- c. *Accuracy and Reliability*: Magnifying lenses of the otoscope should accurately enlarge the real image. Image through the lens should resemble similar details to the camera captured images. A minimum of 50 percent accuracy should be achieved when two images overlap and are compared.
- d. *Life in Service*: Oscopes tend to have long lives in service, the product should run 10,000 exams without major failures. The battery life should be sustained one day in a vet clinic each time fully charged if batteries are used.
- e. *Shelf Life*: Power off, disconnect all electrical connections when not in use and store properly. If batteries are used, store them in a dry environment. Storage temperature limitation between -20°C and 55°C , humidity limitation of 10% and 95% [3].
- f. *Operating Environment*: The otoscope operates between the temperature limitation of 10°C and 49°C , humidity limitation of 30% and 90%, atmospheric pressure limitation of 500hPa and 1060hPa [3].
- g. *Ergonomics*: The device will feature a comfortable grip, intuitive controls, and an optimally balanced weight distribution to reduce strain on the user's hand and wrist. The product should not be bulky and avoid sharp edges and corners for user comfort. Additionally, the ergonomic design will take into account the ease of

cleaning and maintaining the otoscope to uphold the highest standards of hygiene in clinical settings.

- h. *Size:* The size of the otoscope will be based on the size of the otoscope gifted to us by the client. The brand of the otoscope is Welch Allyn Veterinary Pneumatic Oscope [4]. Its measurements are 196.48 mm in length, 24.5 mm long on the top head, and 30.92 mm in diameter. Different sized ear speculum are placed at the front of the otoscope. This device will be portable because it will be used for everyday use.
 - i. *Weight:* This device will range from 0.453592 to 0.907185 kilograms based on the materials chosen for the camera and video transmission to the monitor. This device needs to be lightweight due to students having to carefully examine dogs with it.
 - j. *Materials:* 3D printers from the UW maker space will be used to print 3D prototypes of the product [5]. The printing method chosen will most likely be FDM/FFF methods. A laser cutter from the maker space will be used ideally. The laser cutter will be the Universal ILS9.150D [6]. A ESP-32 CAM module along with a 75mm OV2640 is the current solution for the replacement of the digital camera portion of the tail [7].
 - k. *Aesthetics, Appearance, and Finish:* The appearance and finish should remain mostly similar to currently in used ones for recognizability.
2. Production Characteristics
- a. *Quantity:* One or two. More upon request by client.
 - b. *Target Product Cost:* Cost of a typical video otoscope on the market is relatively inexpensive, around \$25.99 to \$49.99 [8]. Although the client does not have a target cost of the product, maintaining the cost relatively close to the market price is ideal and friendly to all labs and teaching faculties.
3. Miscellaneous
- a. *Standards and Specifications:* The product will not be mass produced, so there's no manufacturer-required standards. According to the FDA otoscopes fall into the generic category and do not need FDA clearance. Manufacturers are required to register their device. [9]

- b. *Customer*: There is a slight preference for the camera feed to be wirelessly connected to the monitor/viewing device, however it is completely adequate to have a wired connection for the video feed. Additionally, a recording function to be able to review footage is desirable. Lastly, there is a preference for having the viewing experience be on a monitor rather than a cellular device.
- c. *Patient-related concerns*: The otoscope cannot harm the patient in any way and must be as comfortable as possible for the user and patient while being used. The patient should react the same way as it reacts to previously used otoscopes.
- d. *Competition*: Many video otoscopes and handheld otoscopes are available to purchase online. Their price varies based on functionality. However, these designs are often for human use, options for animal otoscopy are not often available to pick and choose from. Out of those available, some are either handheld otoscopes with no video feature, or video otoscopes that aren't handheld for student examination. One competing design is the Wispr Digital Otoscope [10]. This video otoscope is a close replacement for the handheld otoscope, and comes with video function in replacement for the lenses. However, this does not satisfy the lens requirements and is extremely costly considering the teaching faculty and budget for animal exams.

References:

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[3] 3.5 V Diagnostic Otoscope and Ophthalmoscope, User Manual, Multi-Language <https://www.hillrom.com/en/products/pneumatic-otoscope-veterinary/>

[4] "Welch Allyn Pneumatic Otoscope," *MedicalDeviceDepot.com*. https://www.medicaldevicedepot.com/Welch-Allyn-Pneumatic-Otoscope-p/20260.htm?dfw_tracker=3918-15657&gclid=Cj0KCQjwrs2XBhDjARIsAHVymmRxW4csdg1rOvKVI3eqJ1oMAlgI Bif8N3RJeI2STa3oPLInxopudMsaAkf4EALw_wcB (accessed Sep. 22, 2023).

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[6] “Ils9.150D Platform.” *ULS*, <https://www.ulsinc.com/products/platforms/ils9150d>.

[7] ESP32 CAM Camera Module With OV2640 Kit DIY 2.4 GHz WiFi Development Module 8MB
PSRAM 66 2MP ESP32-S ESP32-CAM

[8] Soares, C., Clifton, W., & Freeman, W. D. (2019). Use of Handheld Video Otoscopy for the
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[10] Wispr Digital Otoscope.
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