

Dual Handheld and Video Otoscope - BME 400

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 and is designed to be able to create light pathways to go through and direct lights into the ear canal. The head of the otoscope is a box with a magnifying lens that projects a virtual enlarged image of the ear canal to the user. The tail of the otoscope is for holding and stores any essential extra components not mentioned yet, such as a battery. Video otoscopes vary greatly. Without the need of a magnifying glass, video otoscopes are much smaller in size, and usually integrate to combine the camera into the specula. 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. Digital camera is needed to feed live.

Client requirements:

- The otoscope should have components of a traditional handheld otoscope
- The otoscope has video live feed ability
- External Light Source
- Maintain expenses below the budget
- Suitable for 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. This is that when pictures taken through the lens, and on a digital device, both images show similar features and quality.
- 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. If not, the otoscope is expected to be plugged in at all times during use.
- 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. If batteries are used, the design should resemble similar features to allow change of battery.

- 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 Otoscope [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 400 to 900 grams 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 animals with it, as well as to better mimitate the handling of regular hand held otoscopes. Additionally, the weight distribution should also be similar to regular ones.
 - 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. Prototyping material will most likely be PLA, for its cheap price. Final product can be printed from resin, as it allows finer details but costs more. Other essential materials that will be used include: 9V battery (AAA), microLED, button switch, beam splitter, and magnifying lens. Additionally, for enhanced durability, it may be explored switching to metal for the outer surface in the final design. This would increase the product's resistance to wear and impact, ensuring a longer lifespan and more robust performance in demanding environments.
 - 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
 - b. *Target Product Cost:* Cost of a typical video otoscope on the market is relatively inexpensive, around \$25.99 to \$49.99 [6]. 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. Final prototype costs including all materials expenses are expected to be around \$350.

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. [7]
- 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 [8]. 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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[6] Soares, C., Clifton, W., & Freeman, W. D. (2019). Use of Handheld Video Otoscopy for the Diagnosis of Acute Otitis Media: Technical Note. *Cureus*, 11(9), e5547.
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