Engineering World Health 2015 Design Competition

Multi-coloured LED Otoscope

Designed by

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May, 2015

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1 PROBLEM DEFINITION

A prominent issue facing poorer countries is that medical professionals lack access to essential resources due to a lack of financial and technological support. A major factor in this problem is the prohibitive design of medical technologies, due to expensive and difficult to find components, such as batteries and alternative power sources. The accumulated effect of these problems in the medical industry is that preventable illnesses go undiagnosed and untreated.

One such area of concern is the diagnosis and treatment of infections and ear injuries such as otitis media, which can complicate into injury or deafness that might have otherwise been preventable. The instrument used to examine the eardrum and auditory canal is the ÒotoscopeÓ, a universal tool in general practices in richer states. The otoscope is a complex electronic device must be maintained in proper condition (sterility, power, replaced parts) to perform properly - a lack of funds for maintenance, therefore, will quickly render the device useless. Considering the disadvantages associated with the otoscope, we are confident that this technology can be engineered in a more cost-effective manner to maximise its efficiency and effectiveness in poor regions, ultimately improving the health and wellbeing of patients.

Specifically, we aim to produce an otoscope design that:

1. Can be used independently of power sources such as mains electricity or batteries.

- 2. Is economically viable and has the potential be readily available for clinics and services internationally (it should have lower initial costs and ongoing maintenance costs than budget otoscopes commercially available for around US\$40)
- 3. Provides a level of diagnostic capability comparable to existing products on the market. In particular, we aim to use low-power LEDs to produce a variety of colour combinations that can provide an extra diagnostic capability at a minimum of cost.

There exists a number of more recent technologies that could be brought together to satisfy these design goals, including the use of dynamos and super capacitors to provide battery-independent use, and coloured LEDs to provide a robust, long-lasting and diagnostically effective light source. The use of coloured LEDs allows the user to choose from several colours of light to view the eardrum and auditory canal, which can make diagnosis easier by increasing the visibility of certain structures (such as the bones of the middle ear). These technologies have been implemented to some success in products such as survival flashlights and bicycle indicators. Therefore, we are confident in proposing that an effective solution to this problem is both attainable and feasible.

2 IMPACT IN THE DEVELOPING WORLD

The otoscope is an important diagnostic tool in modern medicine. As is clear from its ubiquity in the clinics of the developed world, the otoscope is universal in its use for the identification of ear disease. Furthermore, for countries with restricted access to advanced facilities and treatments, preventative diagnosis is one of the most efficient and effective ways to lower both disease rates and pressure on local medical systems. By creating a more accessible, cheaper and more readily usable tool at this key point in the treatment process, significant impact can be made at minimal cost.

Ear disease is a recognized problem in developing countries, with one report estimating a cumulative prevalence of up to 23% in the first two years of life for a group of Indian children. [1] In particular, otitis media has been identified by the World Bank and the World Health Organization as a significant disease. The 1993 World Bank World Development report states otitis media as the cause of 52,000 deaths per year associated with children under 5 years of age in a demographically developing group. It also accounts for over 25 DALYs (Disability-Adjusted Life Years) in men and women; a value comparable with diseases such as syphilis (29.1 in women and 34.1 in men) and meningitis (31.1 in women and 49.8 in men). [2] The 2004 WHO publication "Chronic Suppurative Otitis Media: Burden of Illness and Management Options" stated that diagnostic examination "requires adequate illumination through a head mirror, head light, otoscope or otomicroscope, suction apparatus and small instruments'. [3] This demonstrates not only the significance of auditory disease, but that the otoscope plays a critical role in the diagnosis of auditory disease worldwide. Combined with the significance of auditory disease, it follows that greater availability of otoscope tools will be associated with improved detection and treatment rates of diseases.

Current otoscopes start at about \$100 (pocket-sized) with full-sized ones used by medical professionals being \$250 or more. [4] As it has been demonstrated that local health providers are in the possession of, or can effectively be taught, otoscope skills, [5] the limiting factor becomes the availability and affordability of otoscopes. Our proposed design uses different coloured LEDs to highlight different structures within the auditory canal. [6] It also will be of much lower cost compared to current otoscopes and completely independent of batteries or main power. It is clear that the development of a cheap, effective and self-contained otoscope system for developing countries has the strong potential to improve the quality of life for patients with aural disease, and reduce the burden of undiagnosed and untreated diseases on the medical system itself.

| ID | Requirements | References/Standards |
|----|--|---|
| 1 | The device shall toggle through specific light wavelengths in order to highlight different ear abnormalities. These wavelengths are: • White • 352 nm (Green) • 450 nm (Blue) • 405 nm (Violet) | Otolaryngology - Head and Neck Surgery, Vol.145, no.2, pp.96. |
| 2 | The device shall be affordable for purchase and maintenance by an operating hospital in a developing country and the expected annual maintenance and use costs of the device shall not exceed that of existing market products. | Emergency Items Catalogue (ICRC) |
| 3 | Any markings on the device shall withstand cleaning, washing and/or sterilization processes for the lifetime of the instrument. | ISO 11135 (Ethylene Oxide Sterilization) ISO 11137(Radiation Sterilization) |
| 4 | The device's light shall be sufficiently bright to allow a physician to make a diagnosis for the duration of 2 to 3 minutes. | |
| 5 | The device will comply with medical ISO standards applicable in Cambodia and most of the world. In particular, the device shall comply with ISO 8600, which outlines the requirements of medical endoscopes. The device shall be marked with information as outlined in ISO 8600. | ISO 11135 (Ethylene Oxide Sterilization) ISO 11137(Radiation Sterilization) ISO 8600 (Endoscopes) ISO 10993 (Materials for inserted portion) |
| 6 | The device shall be of a similar performance, weight, size, and shape to existing otoscopes. | |
| 7 | The device will fit standard specula available on the market. The specula will attach/detach with ease and should attach securely for both use and cleaning (e.g. with an alcohol wipe) while on the device. | |
| 8 | The device must not cause harm, or increase the risk of harm to users as indicated in ISO 8600. | ISO 8600 (Endoscopes) |

3 REQUIRED PERFORMANCE SPECIFICATIONS

Table 1: Required performance specifications

4 IMPLEMENTATION OF PROTOTYPE

Our prototype otoscope is constructed of off-the-shelf PVC piping pieces, electrical components assembled onto a prototype board and small 3D printed components. The casing can be separated into the head and handle, with the majority of the electrical assembly sitting within the handle. A technical drawing of the outer casing has been appended in Appendix 8.3.3.

The head is primarily a 20mm PVC T-piece, which forms the 'optic chamber' into which a clinician will look. The speculum is attached onto this using a custom 3D printed adapter piece, shown in Appendix 8.3.7, while a loupe lens is attached on the opposite end of the PVC T-piece. Both these components are press-fit or glued into the head. Another 3D printed part is inserted through the bottom hole of the T-piece, and holds the ?25mm mosaic mirror tile and RGB LED, so that light is reflected down the speculum and into a patient's auditory canal. It is also mounted in a way so it does not obstruct the field of view. The inside of the optic chamber has been painted a matte black to avoid any reflection or escape of light from the normally glossy and translucent PVC material - this also helps protect it from external solar degradation.

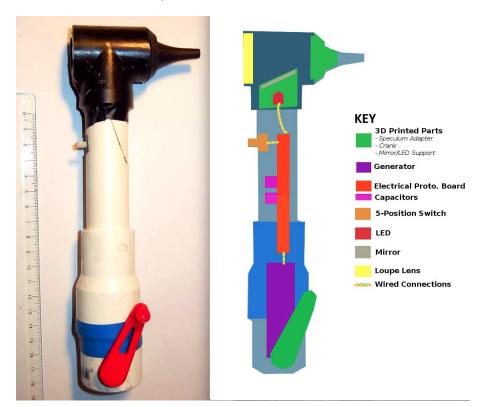


Figure 1: Otoscope Components

The handle casing is made from three pieces of PVC pipe sections; an 85mm length of 20mm diameter pipe, a 20 to 25mm diameter adapter and a 25mm diameter end cap. This casing holds all of the electrical components except for the single RGB LED, which is wired into the mirror-support. This single LED can produce different colours depending on the voltages applied to its four pins. The generator is inserted into the end cap and glued in as a safety precaution against any impact forces, which may otherwise dislodge it. For the prototype, all electrical circuits were soldered onto a prototype

board, and positioned within the central handle, above the generator and associated crank; however, for production, a PCB (attached in Appendix 8.1.2) will simplify both the circuit and the amount of soldering required - improving the robustness of the product.

The electrical component for the otoscope consists of four main parts, the AC generator, AC-DC converter, the charging/storage unit and the colour selection unit. Each component plays a key role in our prototype.

Firstly, the AC generator is placed at the bottom of the otoscope and is charged by turning the crank. It is used for charging up the supercapacitors (Power storage). However, the generator produces an alternating current (AC) signal. Therefore, it cannot charge up the power storage directly.

In order to charge the power storage, the AC-DC converter is used. The AC-DC converter is a full bridge rectifier (Appendix 8.1.1 PCB of AC-DC generator), which is an arrangement of 4 diodes in a bridge circuit connection. This ensures that the input to the supercapacitors is a stable DC signal.

The power storage consists of a pair of supercapacitors in series, which are used to store the output of the AC-DC converter and act similarly to a rechargeable battery. In our otoscope, we used two 5 Farad supercapacitors to store the electrical power from the generator. When fully charged, we observed that the supercapacitors required approximately 30 minutes to completely discharge, providing about seven and a half minutes of useful illumination. The use of supercapacitors rather than batteries removes the need for maintaining or replacing batteries as a power source, allow the otoscope to be used at any time in any location. In addition, the capacity of a capacitor does not decrease as it goes through many charge-discharge cycles.

Finally, the colour selection circuit selects the desired colour mode of the RGB LED. The circuit consists of a 5 position rotary switch and a LED drive (Appendix 8.1.2 PCB of LED drive). The rotary switch allows the user to change the mode (and therefore the output colour) of the otoscope by simply twisting the switch. Finally, the LED drive circuit protects the RGB LED from blowing up by preventing too much current from passing through the RGB LED, thus increasing its lifetime.



Figure 2: System diagram of the electrical components of the otoscope

5 PROOF OF PERFORMANCE

The primary test used to determine the effectiveness of the prototype was qualitative testing by three physicians. In order to maintain an unidentifiable submission for judging purposes, their names have been omitted.

- A lecturer for our University Medical Education program, Convenor of the Clinical Skills Element and Clinical Transition Course, and Chair of the Clinical Learning and Assessment Committee for our University
- 2. A Medical Doctor and General Practitioner from our University Health Service

- 3. A Medical Doctor and General Practitioner from our University Health Service
- 4. A graduate with a Bachelor of Medicine

The performance of the otoscope was compared to both those generally used by the aforementioned physicians as well as that of the Dr Mom otoscope (an existing low cost otoscope intended for amateur use by nonprofessionals).

Additional technical testing of the otoscope was also performed. This involved using the prototype to examine objects such as fine print and barcodes. This testing determined that the prototype provides a clear view of the objects examined across the entire field of view. It also determined that the plane of focus of the lens was a suitable distance from the tip of the speculum. In some otoscopes (particularly low cost ones such as the Dr Mom otoscope), the field of view is not circular, but D-shaped due to the presence of the mirror obstructing part of the field of view. The prototype made visible the whole circular field of view.

The prototype provides four times magnification of the view through the speculum. This is the same magnifications used in professional otoscopes. The prototype's field of view is limited by the size and shape of the speculum and is therefore similar to that of professional otoscopes

The prototype successfully produces white, green, blue and violet light. We did not have access to the equipment required to determine the peak wavelengths produced by the prototype. The prototype design is such that altering the wavelengths of the coloured light produced can be done without significant change to the overall design.

Testers reported that the required cranking time and illumination time were acceptable. Cranking time from a fully discharged state to a full charge takes approximately two minutes. A standard clinical otoscope examination takes approximately one minute, but can be longer [7]. The prototype produces illumination for approximately seven and a half minutes from a full charge, with slight variation depending on the colour used. The testers were happy with the cranking action, naturally using the required speed and force to charge the otoscope.

The prototype can successfully mount the specula used by "Dr mom" otoscope as well as more commonly used specula. These specula can be easily attached to and detached from the otoscope. The prototype holds the speculum securely for use or for cleaning (such as with an alcohol wipe). The testers couldn't identify any potential hazards to themselves or to the patient. Testers found the otoscope small and light enough to comfortably hold with the same 'pencil grip' or 'hammer grip' that they were used to using.

In initial testing, the brightness of the coloured illumination was inadequate for a proper clinical examination. The testers expressed a preference for white light as it is what they accustomed to using in a clinical examination. In response to this, the effectiveness of the white light was prioritised over that of the other colours. The white light was made brighter, which allowed for an effective clinical examination to take place.

Importantly, the cost of manufacture of this design (assuming a production run of 1000 units) is only USD\$19.33, which is significantly less than even the Dr Mom otoscope (4th generation) - a cheap otoscope available online for home use which is available for about USD\$39.92. For a more detailed cost breakdown, see the Business Plan for Manufacture and Distribution. Expected annual use costs are less than that of existing otoscopes, as our design does not require replacement batteries or light bulbs.

5.0.1 Future Work

Possible future prototypes could feature brighter green, blue and violet lights in order for them to be seen as equally useful as the white light. More thorough discussion with clinicians is required in order to determine whether clinicians would make use of illumination colours other than white if these additional colours are made available to them. Comments from the testers suggested that they don't see additional colours as being entirely necessary.



Figure 3: Otoscope producing white light

6 BUSINESS PLAN FOR MANUFACTURE AND DIS-TRIBUTION

The product's target market is initially rural Cambodian hospitals and medical centres, however this business plan would also be appropriate for many developing countries. Rural clinicians have limited access to expensive diagnostic tools. They may be unable to initially afford, or be able to maintain, existing market cost instruments. The market can be extended to include NGOs such as the Red Cross, who require access to affordable and easily maintainable but effective diagnostic tools.

With the product aimed at maximizing health in rural communities rather than creating profit, the enterprise would ideally remain not-for-profit. However, in order to create a sustainable business model, some net profits are required. This will keep the selling price cheaper than competitor products on the market. The profit should be reinvested to facilitate improvement of production methods, improving the supply chain and funding further research. The summary of material costs for our device is shown in Table 2. The figures stated indicate the cost per unit. The cost per unit assumes the production of 1000 units, in order to offer a more realistic set of figures.

As a point of comparison, the 2009 International Federation of Red Cross (IFRC) Emergency Items Catalogue [6], a guide for those in need of or supplying emergency medical tools, indicates an otoscope priced at 67 CHF (Swiss Francs), equivalent to \$70 USD as of May 30th 2015. Our device is evidently less than half of this with an estimated manufacturing cost of only USD\$19.33. Our otoscope can perform the essential tasks of commercially available otoscopes, providing clinical utility for a low cost. We have detailed in the previous section the effectiveness of the design. Due to these considerations, there is a clear and persistent market for the device as part of emergency relief, or as a replacement or supplement to existing tools.

| Component | Quantity | Unit price for 1000 units (USD) | Overall component price (USD) | rice Distributor | |
|---|----------|------------------------------------|----------------------------------|------------------|--|
| 5F Supercapacitor | 2 | 1.03522 | 2.07044 | Digikey | |
| 5 position rotary switch | 1 | 1.90791 | 1.90791 | Digikey | |
| Diodes | 9 | 0.06049 | 0.54441 | Digikey | |
| Resistor (390 Ohms) | 5 | 0.008 | 0.04 | Digikey | |
| Resistor (330 Ohms) | 3 | 0.00992 | 0.02976 | Digikey | |
| AC generator | 1 | 0.92 | 0.92 | Alibaba | |
| RGB LED | 1 | 0.69850 | 0.69850 | Digikey | |
| 25mm PVC end cap | 1 | 0.4325 | 0.4325 | Bunnings | |
| 25mm Reducing coupling | 1 | 0.6 | 0.6 | Bunnings | |
| 25mm PVC pipe | 0.02 | 0.7 | 0.014 | Bunnings | |
| 20mm PVC pipe | 0.05 | 0.55 | 0.0275 | Bunnings | |
| 20mm PVC T piece | 1 | 0.3625 | 0.3625 | Bunnings | |
| 3D printed speculum holder | 1 | 3.4 | 3.4 | | |
| Disposable surgical plastic ear speculum | 1 | 0.02 | 0.02 | Alibaba | |
| Printed Circuit Board | 1 | 1.442 | 1.442 | Itead Studio | |
| Component handling cost (per component) | 20 | 0.2 | 4 | | |
| Total Manufacturing Cost | | \$15.363 | | | |

Table 2: Costs of components

An inexpensive diagnostic device is vital in developing countries. The World Health Organization's Health Spending fact sheet [9], outlines the distribution of medical spending globally. 84% of the world's medical spending is done in Organisational of Economic Co-operation and Development (OECD) countries, which comprise only 18% of the world's population. The largest spender, the US, spends over \$8000 USD per capita per year on health. The lowest spender, Eritrea, spends \$12 USD per capita per year. The WHO estimates that the minimum expenditure for medical essentials would be \$44 USD per capita per year. This incredible disparity between countries means that even relatively inexpensive medical tools are extremely expensive in comparison to the money available; if a country requires \$44 USD per capita per year to cover all medical basics, a \$70 USD tool could be thought of as meaning a choice between the tool, or medical services

for a person. It is clear from this that even a small reduction in cost has the potential to improve medical conditions in economically disadvantaged countries.

Due to the low cost of the device, it is hoped that a sustainable production can be developed from money gained in sales. The design of the device allows it to be manufactured locally in Cambodia in order to simplify the supply chain. Medical device regulatory requirements should allow this to occur. If manufacturing oversight requirements cannot be met locally, this device could be produced as a kit to be assembled by volunteers in a developed country.

The medical device regulatory requirements in Cambodia are being developed by the Medical Device Product Working Group under the the Association of Southeast Asian Nations. [11 12] The Group is developing a directive called the ASEAN Medical Device Directive to link the medical device requirements of the region to the Global Harmonization Task Force. [11 13 14] The harmonised directive should match the regulatory burden of the United States Food and Drug Administration. Under the Food and Drug Administration, an otoscope is in the least severe class (class 1) [15] . For an otoscope good manufacturing practises have to be met. No premarket notification or 510(k) is required. [16] This should reduce the cost. [10] The regulatory requirements for marketing an otoscope in Cambodia should be minimal.

Initial funds for further research and product development will stem from the university and their facilities. Further prototyping will be conducted by the team, exposing undergraduates and schools to the process of device development, establishing a device market profile within the educational sector. Through this platform we can apply for further funding through various community design or development grants. We will seek medical institutional support for greater access to testing facilities to refine our device. At this stage we will focus on passing regulatory requirements for the use of our device in Cambodia.

Through further product development, this initial commercialisation stage will be maintained throughout the marketing process in hopes of developing product kits to be sent to clinics within developing countries. This will reduce manufacturing costs and thus decrease the device cost price for consumers. These kits can be tested and sold within the university's high school development programs for additional funding, and thus it is essential our education start-up profile be maintained. The assembly of the device can lead students through important electrical and optical concepts and therefore provide some value for those assembling the device.

As the mass manufacture and distribution of the otoscope device involves a large amount of capital, the project will be divided into three phases. The first phase involves the distribution of the otoscope kit to universities and schools near our university for assembly of the device. By conducting workshops at local institutions, production costs are significantly reduced whilst enabling the development of new skills for students. Profits from the first phase can then be used to improve production methods for the second phase. This phase includes the hiring of locals in Cambodia for the assembly of the device from kit form. As result, unemployment rates in the area can be lowered and local distribution networks developed. The final stage involves mass production of the device from a local factory from local or imported raw materials. This would further support the local economy. To obtain initial manufacturing funds, after further design refinement within the university, we will seek investors in the medical device industry. The funding obtained from this avenue will be primarily focused on developing greater manufacturing sustainability and obtaining regulatory approval. Passing regulatory tests and policies is essential to the marketing and distribution of our device to developing countries such as Cambodia.

7 REFERENCES

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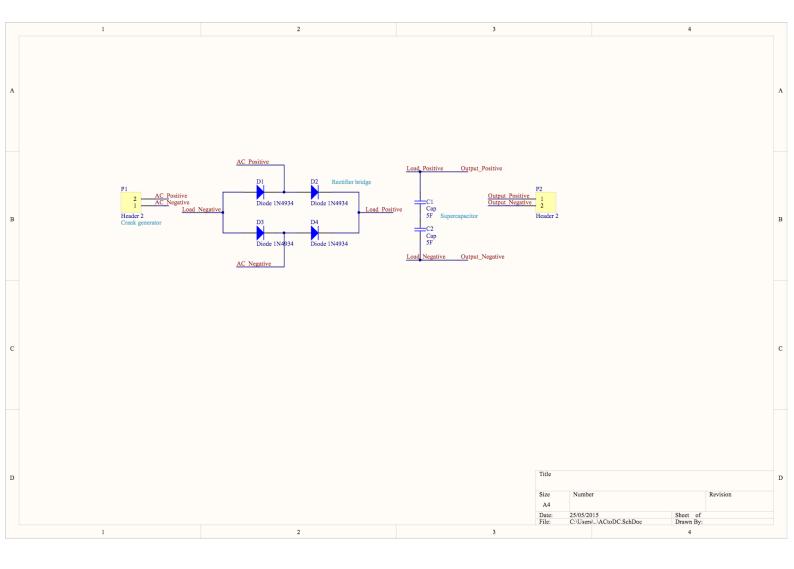
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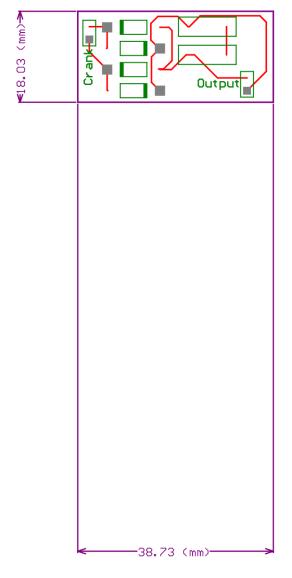
[16] Food and Drug Administration, May 2015, Medical Device Exemptions 510(k) and GMP Requirements

8 APPENDICES

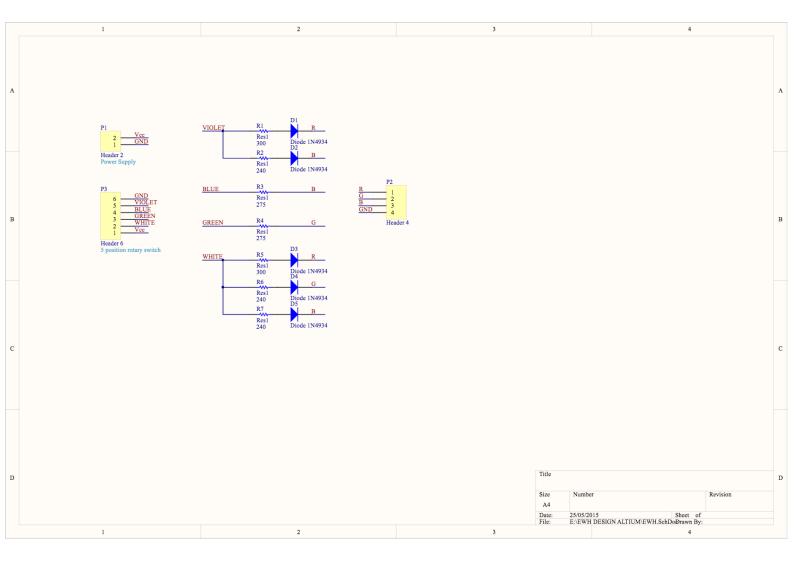
8.1 Electrical Components

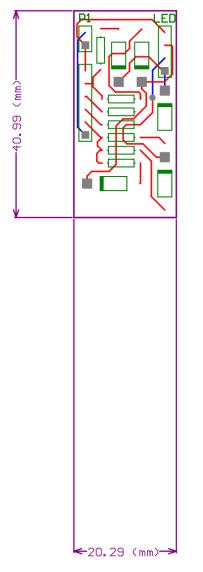
8.1.1 PCB of AC-DC generator





8.1.2 PCB of LED drive





8.2 Bill of Materials

Startup Costs.

Assigning administrative and startup costs of \$4500;

Cost Estimation:

Accommodating all the raw materials costs, as well as printed PCB costs of \$1.44 we get our total material cost:

Total!"# =\$ 6.21102 + 1.442 + 3.71 = \$11.36302

To account for other indirect costs, we add a 20% margin to the costs identified above. Therefore,

we get: Total Manufacturing cost

= \$ 11.36302×1.2 = \$13.64

The median hour rate for factory worker in Cambodia is currently \$0.5/hour. However, assuming a substantially more generous pay rate of \$1.13 per hour (that could also be considered to include operational and administrative costs, or supporting a larger or more skilled workforce) and that a worker team contains 25 people - the predicted time to manufacture one otoscope is 30 minutes, at a consequent pay-rate of around \$5 per otoscope.. Estimated cost for producing 1000 otoscopes:

Cost for the worker team = \$(10.13*0.5)*(1000) = \$565 to produce 1000 instruments

Total cost = \$ 0.565 for workers

= \$ 4.500 for startup costs

= 5.064 per otoscope

Total Manufacturing cost = \$ 13.64 + 5.064 = *USD*\$18.704

h) Packaging and shipping of the product

Due to the fact that shipping in Cambodia is difficult and expensive, the shipping fee for our device will be varied. In May 2015, the shipping fee from United State to Cambodia is \$5.481 perkg from DHL. [http://www.myus.com/en/ship-to-cambodia/]

We expect our final product's weight is 0.5kg (k =0.5kg). Therefore, we get:

Packaging and shipping cost = \$5.481×0.5 = \$2.7405

The shipping fee will be varied due to the currency and other factors. This amount is excluded deom the total manufacturing cost, as our product may export to other countries.

i) Profit of the Product

Comparing to other existing products on the market, we concluded that the market price for the otoscope is \$20.

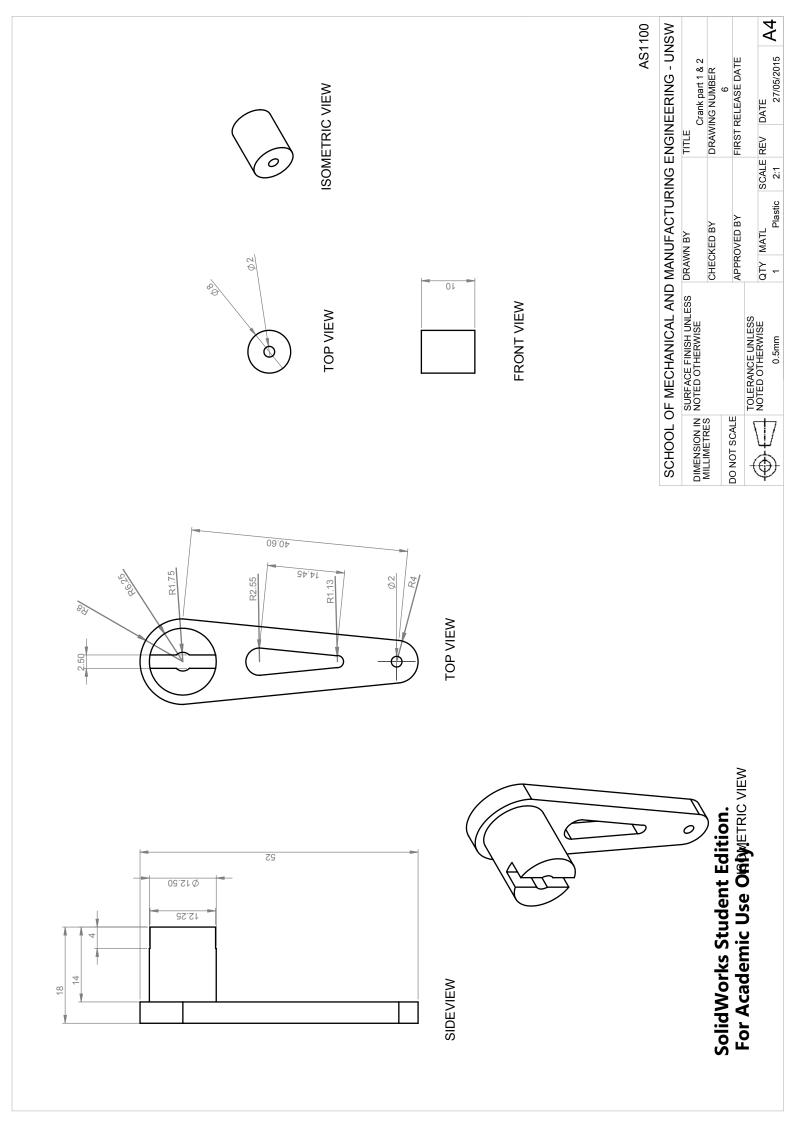
In ideal case, each of our products can earn:

Profit = \$20 - 18.704 = \$1.296

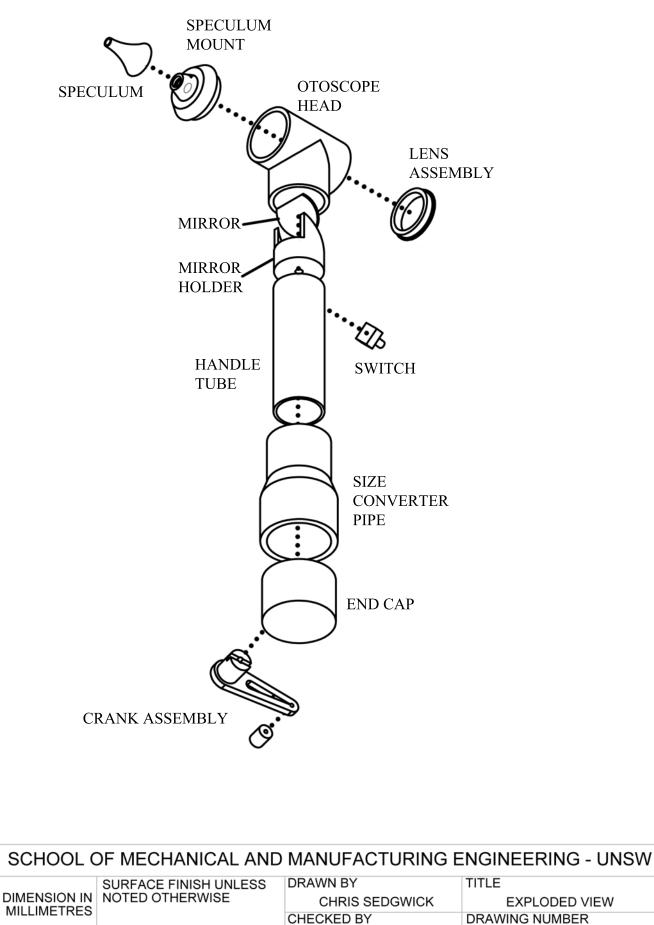
This is a 7% profit on each product, ideally to be spent on its development.

8.3 Mechanical Componets

8.3.1 Crank



8.3.2 Otoscope Exploded



| | CHEC | RED DI | | DRAM |
|-------------------------------|------|-------------|-------|------|
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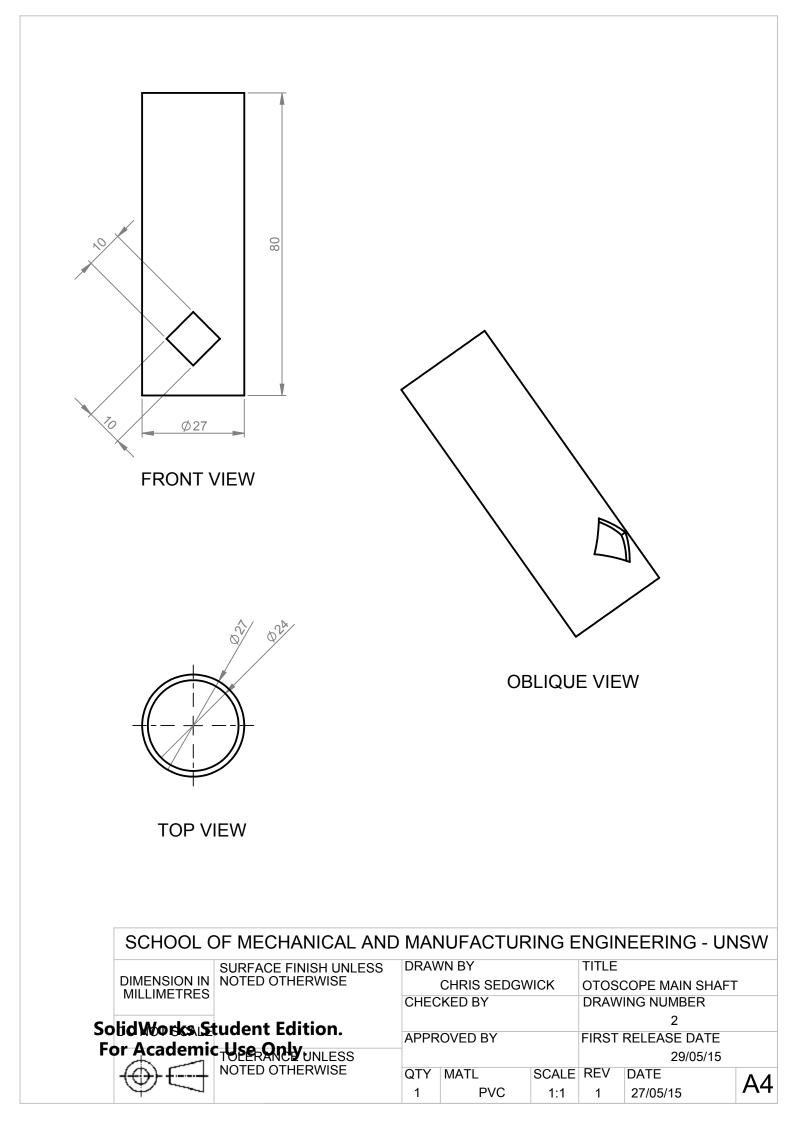
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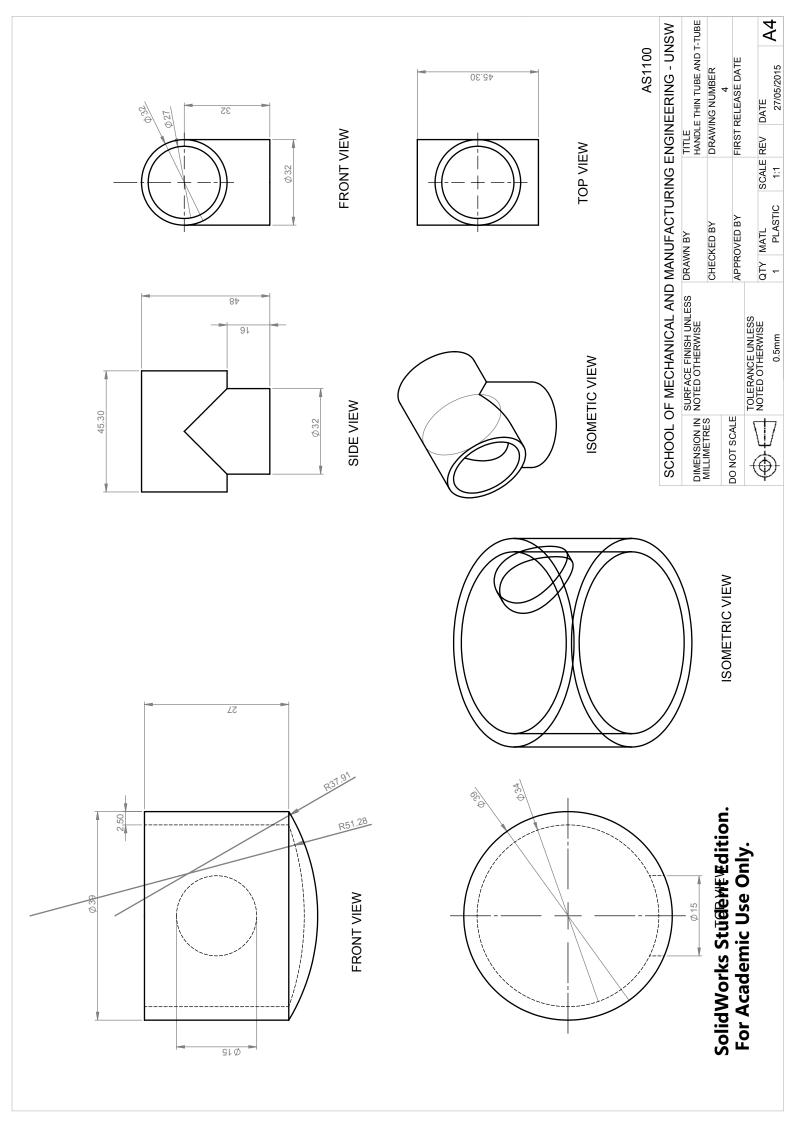
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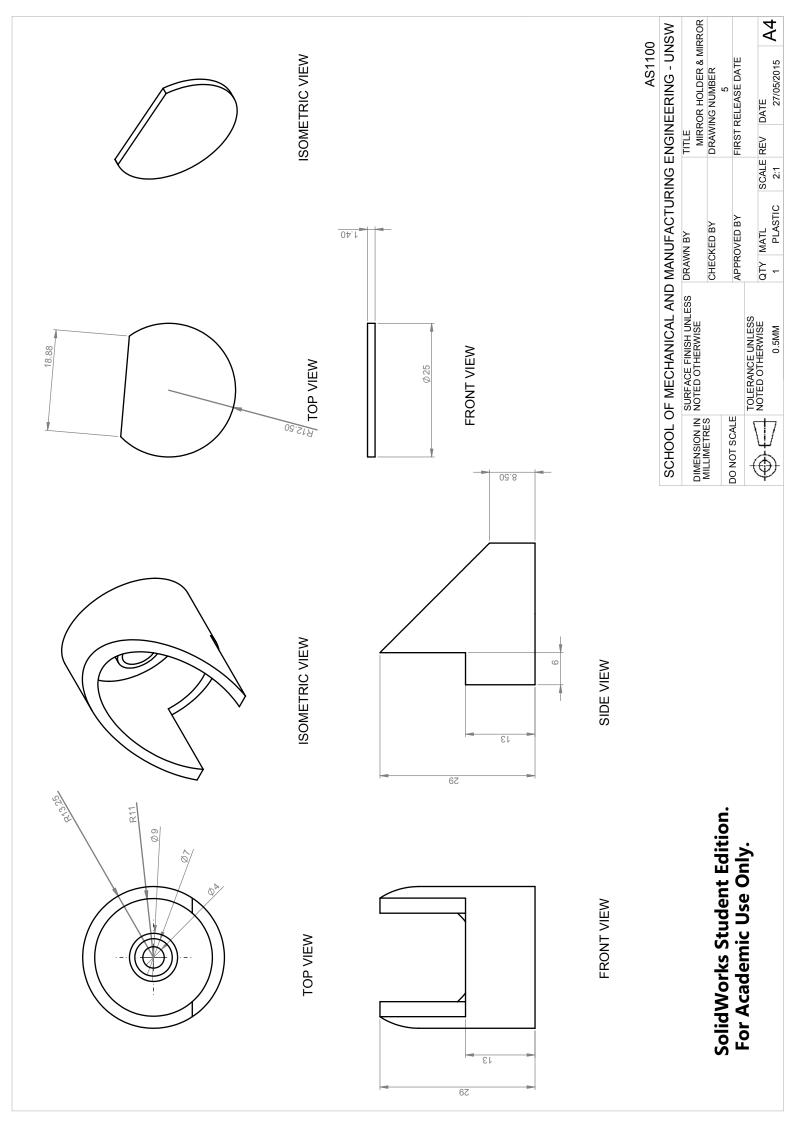
8.3.3 switch Hole



8.3.4 Handle and T-tube



8.3.5 Mirror holder and Mirror



8.3.6 Spectra Mount

