

Engineering World Health: Projects That Matter

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Introduction

Engineering World Health is an extraordinary fusion of engineers, scientists and physicians who donate their time and talents to positively impact the quality of healthcare in disadvantaged areas around the world.

Our ultimate goal is to train local engineers and technicians in the developing world to maintain their own functional medical equipment. However, this aim is constantly frustrated by 1) the high cost of medical equipment, parts, and consumables; and 2) by the lack of adequate testing equipment. Even where the staff is adequately trained, they lack testing equipment which biomedical engineers in the developed world take for granted. In developing countries, biomedical technician training schools and ministry of health workshops have difficulties purchasing these expensive and specialized tools.

To meet these challenges, EWH is seeking designs for novel medical equipment that can offer significant impact at reduced cost. The objective of these projects is to design medical equipment or testing devices for the developing world. The designs could be manufactured by socially responsible companies, or turned into a EWH kit and used to educate BMETs in the developing world! Your design's legacy could be decades of well-trained technicians working in developing country hospitals -- a truly sustainable improvement in healthcare technology! Locally available materials may be best in many situations, to enhance the ability to do local repairs.

EWH Chapters, individuals, groups of students, senior design teams, BMES or IEEE chapters or just a bunch of friends can submit designs. Designs may be submitted at any time.

EWH chapters may also be interested in participating in the <u>EWH Design Competition</u>. Winning chapters will receive prizes, and participating design teams will be invited to present their work at an international conference. There is a design proposal due in the winter and a submission due in the summer, and registration fees are required.

We prefer that you write us before beginning your design, especially for a legacy project <u>chapters@ewh.org</u>. That way, we can give you any updates or clarifications on the design criteria. We may select your design for further investigation or manufacture if the final prototype testing data shows that it meets the specifications, and if its performance exceeds any design submission which we have previously received. If you write, we can inform you of any previous work we may have documented for the project.

Don't hesitate to write an e-mail to <u>chapters@ewh.org</u> if you have any questions. Your efforts can have a tremendous impact on the developing world.

Guidelines for projects submitted to EWH

Summary

By submitting your design you understand that it will be considered by Engineering World Health under the following guidelines:

- It must be well documented in Microsoft Word formatted documents. All documentation submitted must be readable and writeable on a Microsoft PC using standard Microsoft software products.
- You must agree your submission of your design to EWH constitutes a license to Engineering World Health to freely produce the final design non-exclusively, for use anywhere in the world as a kit, documentation, or in final form.
- Remember your finished design is not a viable or legally certified medical device. EWH does not design, certify or manufacture medical devices.
- We may or may not select your design for further study.

These points are covered in greater detail below. Please read them and if you have any questions contact EWH at: <u>chapters@ewh.org</u>

Documentation

Your design documentation must:

- Include a description of the theory of the device (approximately two pages) including the specifications (accuracy and such) that your device will meet;
- Include a detailed parts list, including source, quantity, part number, price and anything else that would be required for one to order the parts. Indicate if your design can be 'kit-able' (requiring no custom parts). Some projects require 'kitability';
- Include engineering drawings and construction drawings for the enclosure (if there is one), top and side views of the completed item (multiple if required);
- Include a cover letter stating your team members (name, address, telephone and email for each);
- include a list of any design changes required to produce an educational kit or changes required to donate your design to a local company in the developing world;
- include detailed construction or assembly instructions suitable for use by students in the developing world (sequence of drawings or photographs is highly recommended);
- include testing instructions so that another builder can confirm the design is working;
- include operating instructions to indicate how the design is operated; and
- include calibration data and testing data to show your design works as intended.

Additional documentation may be provided, at your discretion.

EWH considers designs to fall in to one of three possible categories for manufacture:

- 1) Locally manufacturable in the developing world.
- 2) EWH Kits program
- 3) Conventional manufacture.

Your cover letter must state if you are designing a locally producible item to be manufactured in the developing world (all parts on the parts list are from a developing world country of origin), or a kit (some parts may be ordered from a distributor and shipped to the developing world). You may choose conventional manufacturing with a patented technology incorporating components purchased and assembled before distribution to the developing world, however EWH will not be able to assist with the manufacturing of these types of devices. Preference is given to Kits and locally producible items.

License to EWH

Your submission to EWH constitutes an implied license to Engineering World Health to produce the final design non-exclusively, for use anywhere in the world as a kit, or engineering-documentation. Engineering World Health is licensed to publish all technical specifications on its web site, for general use.

Disposition of your project

The likely disposition of your project, if you are successful, is creation of an educational kit by EWH. EWH may use your documentation and design to train technicians and engineers internationally to provide a legacy of sustainable education throughout the World.

Another less likely alternative for a successful project is donation of the design to a socially responsible company in the developing world interested in product development. EWH student designs often result in proofs of concept. While this is a great achievement, it is a long way away from all of the work required to create a legally compliant device and a final product. Designing a medically compliant product requires teams of engineers and large investments.

You may choose to obtain start-up funding to pursue your product. Members of EWH working in industry might be able to provide collaboration or advice.

Projects

These items have been requested by personnel working with Engineering World Health in international hospitals. The project descriptions are intended to be used as guidelines. You should design your device to deliver the maximum possible performance while making sure the manufacturing costs are not prohibitive. Where superior performance specifications are given, they need not be followed for the design to be acceptable. Considerations of manufacture method and design are closely intertwined. Be sure to note if the design is for a kit, local production or traditional production.

We can accept suggestions for items to be added to the list. Feel free to suggest a new design project. If the project is accepted, it will be added to the list for everyone to see, and you will be able to submit your design as well. Write an e-mail describing your idea in one paragraph to <u>chapters@ewh.org</u> to find out if it is a project that we can support. Please include rationale as to why your suggestion is appropriate for the clientele of EWH.

There are three types of projects detailed in the list below. Legacy projects are those where some prior work has been done, which EWH can make available. Other solutions to these problems are welcome. Non-legacy projects have had no prior work, and research projects need more work prior to design.

Legacy Projects

These are projects where previous work has been done, and you can contact EWH at <u>chapters@ewh.org</u> for the files. For some of these projects, we have submitted designs, which might include a working prototype and may need more work and testing.

Sterilizer tester:

For medical instruments to achieve sterility, autoclaves commonly use steam heated to 121-134 C (250-273 F). Unwrapped instruments require a holding time of 15-20 minutes at 121 C (250 F) and instruments packed in layers of cloth require additional time. Flash sterilizing is usually done at a higher temperature, typically 134 C (273 F) for 3 minutes. To ensure that a sterilizer is thoroughly sterilizing its contents, the technician needs to know that the specific minimum threshold temperature was reached and for how long it was maintained during a particular sterilization cycle. Classic sterilizer testing techniques (such as Bowie-Dick test cards) are disposable and can, in addition to being too expensive, be very hard to find in resource poor settings. We are looking for a team which can design a reusable, reliable but low cost means of testing steam sterilizers. Over time, excessive heat can damage the items being sterilized so, as a bonus, the device would also measure the actual temperature reached inside the chamber as well as how long that temperature has been maintained.

Long-lifetime negatoscope (view box):

Negatoscopes are used to observe and examine x-ray photographs. They are very useful in clinical settings but also serve as an essential part of any mobile x-ray exam. Many older system's existing designs use fluorescent lamps that tend to break down, and appropriate replacement lamps are hard to find in resource-poor settings. Thus, we would like to determine if a long-lifetime negatoscope is feasible and develop it. A long-lifetime negatoscope would have a lifespan of 30,000 hours or more. Such a design would preferably be more power-efficient than current designs, hopefully reaching 60 lumens per Watt. This is a challenging project as negatoscopes require an evenly lighted field of adequate dimensions. The brightness of the field must be considerable but not so great as to cause blinding, while the chromaticity must be close to that of daylight. LED versions of this equipment are now available in volume at \$80 retail. Beating this price significantly or allowing for the design to be manufactured in a developing nation would be an important goal.

O₂ analyzer

A team of EWH design students has developed a proof of concept for an electronic O2 tester that will determine if an oxygen concentrator is indeed producing concentrated oxygen. Often there is no way to test for this in the developing world clinical setting, and the zeolite crystals used to create concentrated oxygen in these devices deteriorate over time. The proof of concept design used two zinc-air batteries in a simple electric circuit with an LED for indication. More design work needs to be done to develop a physical case that will interface with oxygen concentrator tubing and protect the batteries from over-exposure to air when they are not in use. More testing is also necessary to determine the functional range of the tester and the characteristics of the circuit with exposure to different oxygen concentrations over different time periods. Modifications might also be made to the circuit, or a different approach could be implemented.

Non-Legacy Projects

These are projects where no previous work has been done. Teams who take on one of these projects can choose whichever approach they see fit, keeping in mind that preference is often given to designs that are kit-able or can be locally produced.

Inexpensive multi-parameter tester:

Hospital equipment technicians (BMETs) have a frequent need to measure temperatures, pressures, and flow rates of both liquids and gasses. Commercial devices can cost over \$2000 and are out of the budget range of developing world technicians. This project would seek to develop transducers which could be manufactured locally in the developing world and function on an open source computer platform of extremely low costs (\$45 to \$75). Any team working on this research project would have to provide at least the design of low cost transducers and a method of calibration for each transducer which does not depend on an expensive metrology laboratory and national standards. The team would have to provide the means and methods description for manufacturing and calibration in a low technology manufacturing setting. Projects capable of measuring only one or two of the suggested parameters (temperature, pressure, or flow rate) will also be accepted.

Solar sterilization and distillation unit for water:

Using a multitude of mirrors and a pressure cooker, design a sterilization unit. Such a unit will have a dual purpose. The first will be to autoclave and sterilize surgical equipment. Temperature monitoring within the unit will ensure that appropriate temperatures are reached. A weight on the pressure cooker valve will ensure that appropriate pressures are reached, even when the atmospheric pressure is above sealevel. A second pressure cooker, without its valve can be used to generate steam that can be condensed in order to generate potable water. An inexpensive heat exchanger will allow the latent heat of steam (during condensation) to preheat the water.

Portable, inexpensive oxygen concentrator:

Oxygen concentrators use a material such as Zeolite to adsorb nitrogen. The goal of this project is to come up with cheap alternatives with reusable air filters. The concentrator should provide means to humidify the oxygen using distilled water prior to delivering to a patient.

Stand-alone surgical lamp:

A device which will use LEDs, Supercapacitors/Batteries (during power failures) Note: the initial cost of this device may be relatively expensive. Surgical lamps are often unavailable in developing countries and are expensive as bulbs need to be replaced. Power failures are common in these countries. Battery operated lamps have batteries with toxic materials. Today the price of supercapacitors is down to 2.5 cents/farad and these last for hundreds of thousands of charge/discharge cycles and are green. LEDs are at least 5 times as efficient as incandescent lamps. A 10 watt array of LEDs equates in luminance to a 50 Watt conventional bulb. For example, a 5V 1500 Farad stack can store as much as 15000 usable Joules. This would allow the operating field to have over 24 minutes of usable light at 10 Watts (LED). An inexpensive lens will allow the light to be focused onto the surgical field. The supercapacitors may be charged using PV cells or inexpensive batteries and be ready to use during surgery. A battery stack could also be used to charge the supercapacitors and operate in parallel. Evaluate charging these capacitors using a pedal powered generator.

Apparatus for evaluating hearing loss:

Audiometers are expensive and require a quiet room to conduct the tests. Using an inexpensive processor such as the Raspberry Pi, create an audiometer with conventional headphones. The frequency response of these can be calibrated using an inexpensive (calibrated) microphone. Sound is generated into the headphones. Using 3D printing or inexpensive methods, build a wrapper around the headphones in order to suppress ambient noise during the test. Alternatively, use the calibrated microphone to detect ambient noise and vary the sound levels appropriately into the headphones.

Inexpensive patient-bedside communication system:

Using an inexpensive processor, such as the Raspberry Pi and Wi-Fi module, create a VOIP system that allows two way communications between a patient and the nurse in an ICU. This system can also be used in a small clinic to communicate between departments.

Inexpensive LED-based otoscope:

Using multiple colored LEDs and inexpensive lenses create an otoscope for examination of ear infections using various color combinations.

NI myDAQ ECG simulator

The myDAQ from National Instruments is a measurement and instrumentation device designed especially for students. It has digital and analog I/O ports and there are many transducers and other plug-ins that would be useful for designing this and other projects through EWH. The goal of this project is to create an ECG simulator using the myDAQ that will output a reliable ECG signal from one of the ports. The design should allow the user of the simulator to modulate the cardiac frequency.

NI myDAQ Fetal Doppler Phantom

The myDAQ from National Instruments is a measurement and instrumentation device designed especially for students. It has digital and analog I/O ports and there are many transducer and other plugs-ins for myDAQ. Fetal Doppler units are available in the developing world, and there tend to be plenty of broken devices. The goal of this project would be to create an inexpensive (potentially electro-mechanical) phantom which could be used as a signal source for Fetal Doppler repair by developing world BMETs.

Smart Phone Based Toco Transducer and tocodynamometer

The tocodynamometer is a component of external monitoring in childbirth. The goal of this project is to use a smart phone with a built-in accelerometer and a software application to act as a toco transducer and recording tocodynamometer. The device would be used to record the duration of uterine contractions and the duration between them.

Research Projects

For these projects we are looking for a volunteer or group of students to find more information about a topic that might lead to a design project.

Inexpensive tester for plantar (foot) neuropathy:

Testing for nerve damage is done today with various filaments and training. Invent a device with variable tensions in order to test and quantify various stages of neuropathy. One embodiment may use springs. The device may be 3D printed and cleaned by isopropyl alcohol. The patient could rest his or her foot onto this device. Different forces may be applied using mechanical means to determine the extent of Neuropathy. Other approaches might also be considered.

Frequently Asked Questions

Is it necessary for the device to be simple to use?

No. Biomedical equipment technicians, clinical engineers and doctors in the developing world are just as capable as you and I. If you can figure it out, they can too. As in the US, clear documentation should accompany all project designs.

Does the device require maintenance?

If any maintenance is required, it must be something that itself does not require a specialized tool or part. If your design requires maintenance, you probably should write to us first (<u>chapters@ewh.org</u>).

What environmental conditions should the device meet?

Your design must not be damaged or destroyed even with extended exposure to temperatures down to -10 degrees centigrade and temperatures up to 40 degrees centigrade. It should be useable in environmental temperatures ranging from 0 degrees centigrade to 40 degrees centigrade. Your design should work well in the presence of dirt and dust. Additionally, if electronic, you can assume wide variance in power parameters and significant noise and spikes on the power line.

My design doesn't meet all the specifications, but it exceeds some. Should I send it in?

If your design doesn't meet all the specifications, EWH may decide not to pursue it. However, you may be able to make an argument that the added performance in one area is worth the missed specification in another.

How do I know what is locally available for production?

You should contact a clinical engineer and have a discussion. There is no substitute for a conversation with the clinical engineer who will use your design.

I have just one custom part. Will this affect your consideration of my design?

Assuming the question is for a project that is designated for local construction, yes it will! If you have one custom component, and that component cannot be manufactured in the developing world in single quantities (and those costs are included in your cost estimates), then your design might not be serviceable or producible.

What if a part is not locally available?

If you really need a component you can't find locally (a special plastic fitting for example), then consider making your design a kit.

What if the component requires programming?

Most PICs and FPGAs require programming. Most clinical engineers in the developing world may not have access to a computer or a device-programmer. Therefore, your project requires a special tool that is not available in the developing world. It is a conventional design and could perhaps be a kit, but it could not be locally produced.

The project I picked doesn't specify kit, local, or conventional. What do I do?

You have the choice. We prefer local construction and kits. If you choose conventional construction, EWH is not likely to be able to offer much assistance with manufacturing the device.

What is a reasonable price range for the device?

There is no set price range for the device you design. Inexpensive or low-cost simply means that the price reduction of your device should be significantly less than the current standard being used in developing world hospitals. It is your job to determine the upper threshold of the device cost and your target cost. We suggest that you consult knowledgeable parties in and outside of your institution as well as performing your own cost analysis before consulting EWH for assistance.