

Engineering World Health 2017 Design Competition

# Solaleo

Low-cost Vacuum Sterilization



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<b>Problem Definition</b>	2
<b>Impact on the Developing World</b>	2
<b>Performance Requirements</b>	3
<b>Prototype Implementation</b>	4
Design	4
Methods of Construction	4
Methods of Operation	5
<b>Proof of Performance</b>	5
Cycle Time Test	6
Insulation Test	6
Bowie-Dick Test	7
Stress Test	7
<b>Further Improvements</b>	7
<b>Business Plan</b>	8
Cost	8
Funding, Manufacturing, and Distribution	9
Regulatory Considerations	9
Intellectual property considerations	9
Commercialization Timeline	10
<b>Conclusion</b>	11
<b>Appendix</b>	11
<b>References</b>	13

## Problem Definition

Sterilization of medical equipment and consumable materials is crucial for the prevention of healthcare-associated infection. Healthcare-associated infections include surgical-site infections, ventilator-associated pneumonia, catheter-associated urinary tract infection, and other types of infection. Each type of infection is caused by a variety of types of bacteria and other pathogens present on medical equipment or in a medical facility.<sup>1</sup> Sterilization is the removal of all such microorganisms, including heat- and chemical-resistant bacterial spores, from an instrument. Any item that enters sterile tissue or the vascular system, from surgical instruments to urinary catheters, must be sterilized.<sup>2</sup>

Proper sterilization is a challenge at rural clinics in the developing world due to limited funds for equipment, chronic understaffing, inconsistent power sources, and dirty conditions.<sup>3,4,5</sup> Steam sterilization in an autoclave is dependable and inexpensive,<sup>2</sup> and thus it is appropriate for resource-limited settings. A steam autoclave must meet required temperatures and pressures for sterilization. To meet the needs of rural clinics, it should be cheap and rugged, function with multiple energy sources including solar energy, complete its cycle quickly, and require minimal training. The pre-vacuum autoclave is a promising solution for rural clinics because the vacuum step allows for shorter cycle times and vaporization with lower energy input.

## Impact on the Developing World

Recent studies show healthcare-associated infections are more frequent in resource-limited settings than in developed countries. Overall, hospital-transmitted infection is 5% to 20% more prevalent in developing countries.<sup>1</sup> Surgical site infection, the leading infection in the general patient population in undeveloped regions, affects up to one third of operated patients with a frequency up to nine times higher than in developed countries.<sup>6</sup>

Volunteers in Guatemalan clinics explained that autoclaves are currently used in some areas.<sup>4</sup> However, due to improper use and poor maintenance of autoclaves, as well as inconsistent power and the dusty environment, the effectiveness of sterilization is highly questionable.<sup>3,4</sup> Commonly, instruments are not sterilized at all. Instead, they are disinfected by boiling or washing with various chemical agents, which leave bacterial spores behind.<sup>7</sup>

Solaleo, a low-cost vacuum autoclave, is designed to meet the needs of resource-limited clinics in providing reliable sterilization in undeveloped regions. Solaleo was designed for use with a solar concentrator that focuses light onto the bottom of the autoclave, like those developed for similar solar sterilization projects,<sup>9</sup> but it can also be heated on a gas burner or electric stove when sunlight is not available or a faster cycle time is required. Solaleo is low-cost, and its simple structure and user-friendly design lower maintenance and repair requirements of the device in clinics that suffer from money and personnel shortages.

Solaleo overcomes limitations of existing solar autoclaves.<sup>9,10,11,12</sup> Some such devices are expensive,<sup>10</sup> rely on hard-to-come-by parts such as nanoparticles<sup>12</sup> or they do not meet temperature and pressure requirements for sterilization.<sup>11</sup> A group at MIT and the University of Dayton developed Solarclave, a similarly low-cost, high-performance, easy-to-use device. Like Solaleo, the Solarclave contains few parts and is designed to be heated with a mirror or an alternative heat source.<sup>4,9</sup> In contrast, our device includes an air removal mechanism. The addition of vacuum pump and valve on the side of autoclave allows the air inside the device to be exhausted out, which lowers the required energy input and shortens the sterilization cycle without significantly raising costs. The pre-vacuum autoclave can reduce the sterilization time,<sup>2</sup> which is desirable for understaffed rural clinics. Pre-vacuum autoclaves tend to perform better than gravity displacement autoclaves at sterilizing porous heat and moisture stable materials.<sup>13</sup>

## Performance Requirements

1. The device shall comply with applicable standards for safety and reliability
  - 1.1. The device shall meet Center for Disease Control and Prevention (CDC) recommendations for pre-vacuum autoclaves; i.e. it shall maintain or exceed a temperature of 132° Celsius for four minutes to ensure eliminations of all microbial life from instruments.<sup>2</sup>
  - 1.2. The vacuum pressure shall be low enough for the device to be considered a pre-vacuum autoclave; i.e. the device shall pass the Bowie-Dick test, which indicates whether air has been sufficiently evacuated from the sterilization device.<sup>14</sup>
  - 1.3. To ensure safety and reliability, and to allow for commercialization, the device shall meet or exceed the standards for CE marking of medical devices.<sup>15,16</sup>
  - 1.4. To ensure safety and reliability, and to allow for commercialization, the device shall comply with regulations set forth in the EU pressure equipment directive.
  - 1.5. To ensure safety and reliability, and to allow for commercialization, the device shall comply with regulations set forth in standard EN 13060 for small steam sterilizers.
2. The device shall meet the needs of low-resource clinics
  - 2.1. The device shall cost less than \$100.
  - 2.2. To enable consistent sterilization despite unreliable energy sources, the device shall operate safely and effectively on multiple heat sources, including solar concentrator, electric stove or hot plate, and gas burner.<sup>4</sup>
  - 2.3. The size constraints of the particular facilities are unknown, so the device dimensions shall be minimized while still allowing for a sufficient daily volume of sterilization.<sup>3</sup>
  - 2.4. As the autoclave may be operated by health personnel unfamiliar with the autoclave process, so the device should be usable for personnel who lack formal training.

- 2.5. The device shall consist of few vital components to minimize the risk of system failure. Any critical component that could fail must be locally available, or a surplus the component must be provided to clinics upon delivery of the autoclave.<sup>3,4</sup> Specifically, small air leaks may compromise the efficacy of the device, but may not be apparent to the untrained user. The device shall be leak-proofed wherever possible, and replacement gaskets should be included with the device.
- 2.6. The device shall be uncomplicated so that repair personnel can restore operability with basic repair tools.<sup>3</sup>
- 2.7. As the device will be used outdoors, the intrusion of dust and other elements is a concern, both to the system integrity as well as device sterility.<sup>3</sup> The device shall allow for the insertion and removal of medical equipment without contamination. Cleaning the device components must also be straightforward to reduce the possibility of error or dereliction.

## Prototype Implementation

### Design

The body of the autoclave consists of an off-the-shelf, 6-quart (5.68 liter) pressure cooker. The existing steam valve on the lid of the device is modified to release steam at the required pressure. A pressure gauge and thermometer are also added. To achieve rapid sterilization, the device includes a small vacuum pump used to remove most of the air from the pressure cooker prior to heating. Inside the pressure cooker, hanging from the lid, is an aluminum cage that holds instruments above the boiling water.

The pressure cooker is heated from the bottom with focused sunlight or another of the aforementioned energy sources. To improve heat absorption from the solar concentrator, the bottom of the device is painted black. To prevent heat loss, a removable insulation layer made of ceramic wool and aluminum tape covers the sides and top of the pressure cooker.

### Methods of Construction

A 6-quart pressure cooker is used as the body of the autoclave. The pressure cooker has a very small footprint, as described in requirement 2.3, but more research is needed to confirm whether this size is sufficient for clinics that would use the device. Each of the three safety valves on the off-the-shelf pressure cooker is modified (Figure 1A in the appendix). The first, a rubber-stoppered hole, is widened into  $\frac{1}{4}$  inch diameter with a drill press. A copper pipe fitting is inserted on the interior side of the autoclave lid, and a pressure gauge is attached to the exterior of the autoclave lid (Figure 1B). On a separate position on the autoclave lid, a safety valve, along with a ball valve and a vacuum fitting is attached (Figure 1C). A temperature probe was added to the valve in the center of the lid for testing purposes. All other holes and fittings were sealed to be airtight with silicone sealants (Figure 1D). The

bottom of the pressure cooker is painted black with a matte spray paint. Finally, a removable insulation is constructed from ceramic wool covered with aluminum tape.

The vacuum pump is a modified bicycle tire pump. A Bell Air Attack 350 pump is used for the prototype. The hose assembly (Figure 2A in the appendix) and base (Figure 2B) are removed and the top plastic assembly unscrewed (Figure 2C), allowing the entire pump rod to be pulled from its shaft. At the end of the shaft is a rubber and plastic assembly that pushes air through the shaft (Figure 2D). The rubber and plastic assembly is forcibly removed and the rubber piece flipped, held in place with a tape wrapping (Figure 2E). The base and shaft are reassembled. The lever valve is cut from the end of the hose (Figure 2F) and the hose widened to the size of the autoclave fitting. The one-way ball valve that attaches to the base of the pump is removed and reversed (Figure 2G), which also requires widening the hose. The hose is reattached (Figure 2H).

Figure 3 in the appendix shows the completed prototype ready for pre-vacuum and sterilization on a gas burner.

## Methods of Operation

Fill the device with water to the fill line, then position over the heat source. Prior to sterilization, wash instruments and wrap in paper or cloth, then insert into the aluminum cage. Also insert one Class 5 indicator strip wrapped like the instruments. Close the pressure cooker by lining up the two arrows indicated along the lid and the handle, rotating the lid to seal and locking the device. Open the ball valve located on the top of the autoclave and attach the vacuum pump. Pump repeatedly to create a vacuum. The stronger the vacuum, the faster the sterilization cycle, but an incomplete vacuum will still improve steam penetration and cycle time. Upon heating, the ball valve is closed and the vacuum pump is removed.

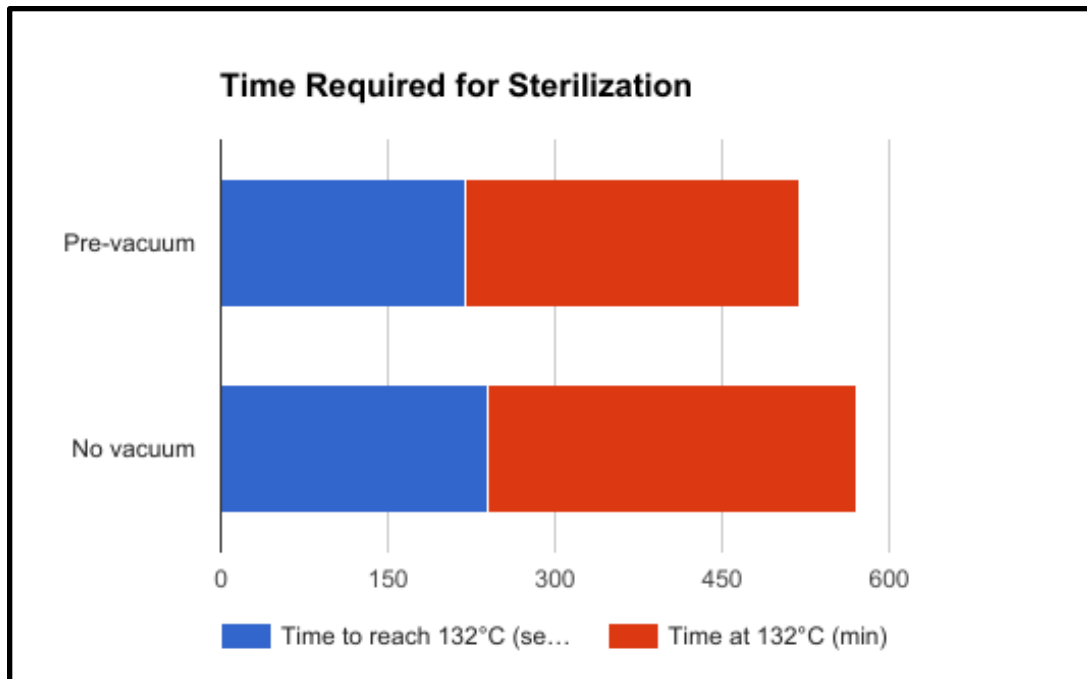
The sterilization cycle ends four minutes after steam begins to escape through the safety valve. If the heating source is reliable, it is not necessary to monitor the device during the sterilization cycle. If solar power is used, stay with the device and watch to ensure steam is escaping for six full minutes. After six minutes, or longer, open the ball valve to release pressure. Use the handles, which remain relatively cool throughout the process, to remove the lid. Check the class 5 indicator strip to ensure a complete cycle. If the cycle did not complete, repeat the cycle and check the device for leaks. Allow a few minutes for the instruments inside to cool, then remove them.

## Proof of Performance

For reduced environmental variables, testing was performed over a gas burner on low heat. When heated over a gas burner, the device reaches the required 132°C and can be held at that temperature without damage or deformation. Thus, requirement 1.1 is met.

## Cycle Time Test

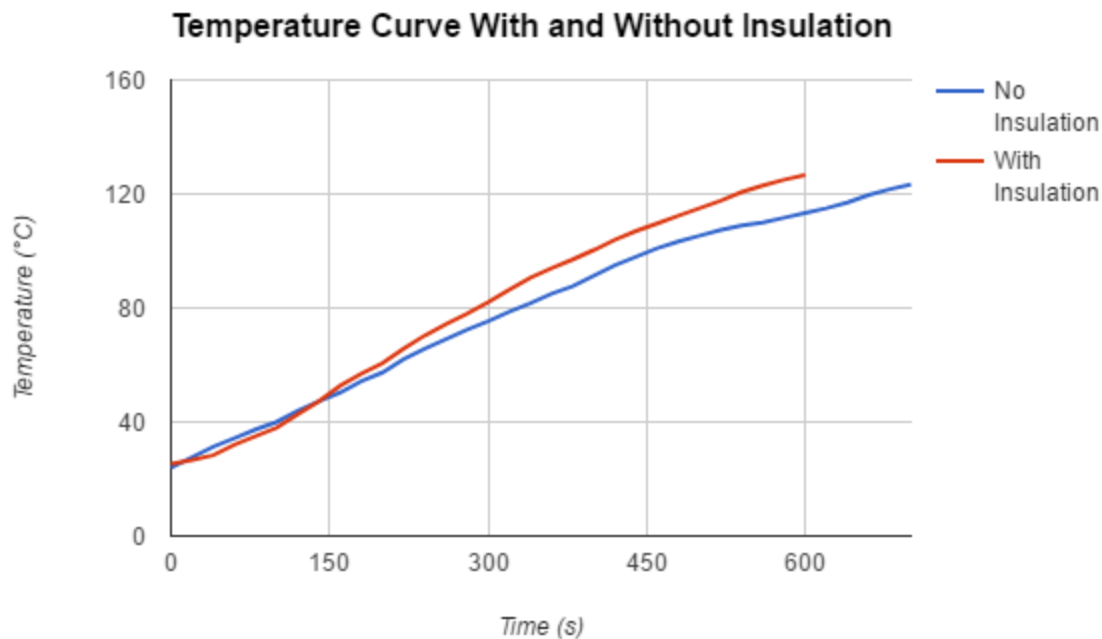
Lightly wrapped class 5 indicator strips were used to determine the required cycle time at 132°C with and without a vacuum, as shown in Figure 4. These trials were performed with a gas burner on medium heat. Time to reach 132°C depends entirely on the rate of heat transfer from the heat source. Time at 132°C is the same regardless of heat source, barring significant leaks.



**Figure 4.** Recommended cycle time at 132°C

## Insulation Test

To test the effectiveness of the insulation, the device was heated on a gas burner on low heat with and without insulation. Low heat was used to simulate solar power. If the insulation is effective on a gas burner on low heat, this indicates the device can likely be used with a solar concentrator or other slow heat source. Thus it meets requirement 2.2.



**Figure 5.** Temperature vs. time with and without insulation, averaged over 3 trials.

### Bowie-Dick Test

The current prototype does not pass the Bowie-Dick test as described in requirement 1.2.

Given the high cost of a stronger vacuum pump however, if the vacuum is incomplete but still speeds sterilization, then the existing pump may be sufficient, as it lowers the total energy necessary to heat the device. The insufficient vacuum still decreases the pressure within the device which reduces the heat necessary for liquid water to vaporize.

### Stress Test

The safety valve on the device was closed, then it was heated until the pressure in the chamber reached 41 PSI. This pressure was then maintained for 5 minutes. There was no evidence of deformation or damage at that pressure. Stress testing is an important component of the safety testing required for regulatory approval.

### Further Improvements

The following modifications should be made to the existing design so that it better meets the needs of low-resource clinics.



Leaking occurred at multiple silicon seals, requiring several rounds of sealing to create a leak-proof device (requirement 2.5). Components should be welded in place for safety and to prevent leaks.

For usability (requirement 2.4), a fill line should be etched into the inside of the pressure cooker so the device can be filled to the appropriate level without accurate measuring equipment. An instruction sheet should be included with the device and should be in the user's native language. Before full-scale manufacturing, the device should be tested with workers at rural clinics in Guatemala. Future users should also be consulted to confirm that the device is easily repaired (requirement 2.6) and maintained (requirement 2.7).

All components chosen withstand high temperatures and moisture, and the pressure cooker and valves withstand appropriate pressures. However, frequent and extreme fluctuations in temperature, pressure, and humidity may degrade components quickly. The final device should be rigorously tested for longevity. It should undergo many sterilization cycles on an electric stovetop and be examined for signs of failure.

Extensive testing on the final product will be required to ensure all regulatory requirements (requirements 1.3-1.5) are met. As described below, the manufacturer will manage regulatory requirements.

## Business Plan

### Cost

The cost of materials used in the prototype is shown in table 1 below. As the prices in the third column indicate, a manufacturer could acquire materials for as low as \$45 per unit, plus shipping costs, if the number of units produced is sufficient. Using the methods described above, one worker could easily assemble a device in under 2 hours. Thus the cost per unit if manufactured in bulk would be under \$100 (requirement 2.1).

Part	Quantity	Retail price	Wholesale/bulk price
Presto 6-Quart Pressure Cooker	1	\$33	\$17
Ceramic Wool	250 in <sup>3</sup>	\$27	\$0.47
Aluminum foil tape	1000 in <sup>2</sup>	\$3	\$0.33
Pressure Safety Valve	1	\$13	\$1
Brass CA360 Fitting, Tee, 1/4" NPT Female	2	\$7	\$7
Brass Hose Fitting, Adapter, 1/4" Barb x 1/4" NPT Female	1	\$4	\$1
Brass Mini Ball Valve, Lever, 1/4" NPT Male x NPT Female	1	\$7	\$7

Brass Pipe Fitting, Hex Nipple, 1/4" x 1/4" NPT Male Pipe	2	\$6	\$2
Silicone Aquarium Sealant	1.4 oz	\$2	\$0.53
Silicone Auto/Marine Sealant	0.3 oz	\$1	\$0.003
Metal bucket (small)	1	\$8	\$6
Bicycle pump	1	\$16	\$8
<b>Total</b>		<b>\$127</b>	<b>\$45</b>

**Table 1.** Retail and wholesale/bulk cost of materials, shipping not included

## Funding, Manufacturing, and Distribution

Our team will seek a partnership to get additional funding for prototypes and regulatory fees, as well as expertise on manufacturing and regulation. We are considering partnering with UL<sup>18</sup> or with an established for-profit manufacturer in the US that takes on service projects for global health, as Rice 360 does.<sup>3</sup> The manufacturing partner will help with finalizing the design, testing onsite, and CE marking. The clinics most in need of this device are those with very few resources, so rather than market directly to the clinics, it will be marketed to charities and nonprofit organizations. One such organization is the Caputo Children's Fund,<sup>20</sup> which seeks to improve health and sanitation in low-resource areas, or directly to clinics that have some funds available to purchase the device.

## Regulatory Considerations

The World Health Organization includes in its definition of medical devices “any instrument [...] for the specific medical purpose of [...] disinfection of medical devices.”<sup>21</sup> The WHO drives medical device regulation in developing nations.<sup>22</sup> Thus, autoclaves are considered medical devices for regulatory purposes and are subject to regulation in many developing countries.

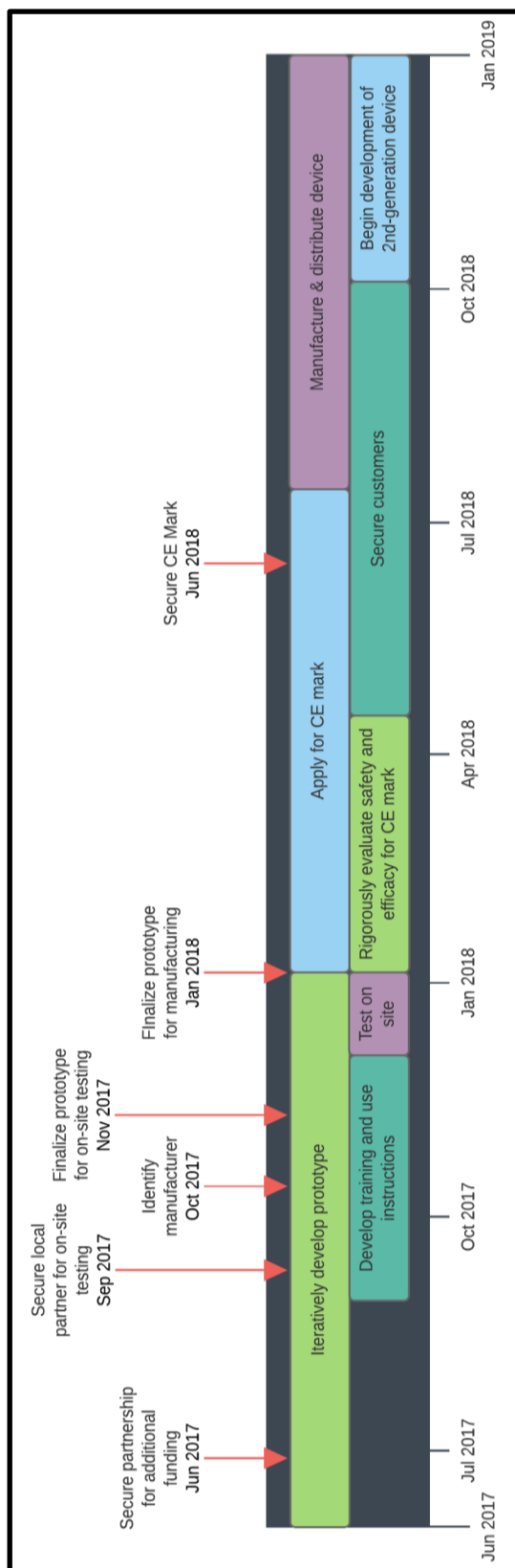
Though medical device regulations are very poorly enforced Guatemala,<sup>23</sup> we plan to minimize liability by complying with all requirements. Guatemala's has medical device regulations require a certificate to foreign government for the distribution of autoclaves to clinics,<sup>23</sup> so we plan to seek a CE mark before large-scale distribution. The manufacturing partner will manage the CE marking process.

## Intellectual property considerations

Though Solaleo will be the first marketed device that uses solar power for vacuum sterilization, the mechanisms of the vacuum pump and the solar concentrator are not new, nor is the concept of the pre-vacuum autoclave or the solar autoclave. Therefore patent claims would be limited. Furthermore, the device will likely face little competition in the low-profit market for global health technologies. Finally, patent enforcement in developing countries is poor if it exists at all. Thus, it would be unwise to spend tens of thousands of dollars on US or international patents for this device.

## Commercialization Timeline

A projected timeline for commercialization of the device is shown in Figure 6. Distribution of the device could begin as early as the summer of 2018, though the CE marking process could introduce delays, as could slow communications with rural clinics.

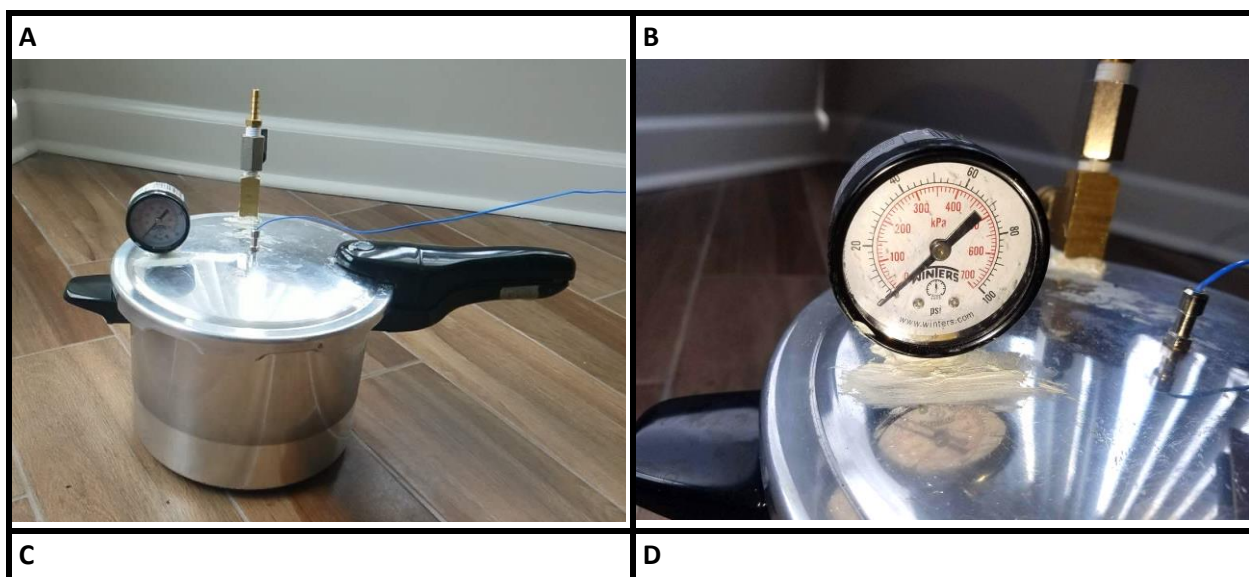


**Figure 6.** Commercialization timeline

## Conclusion

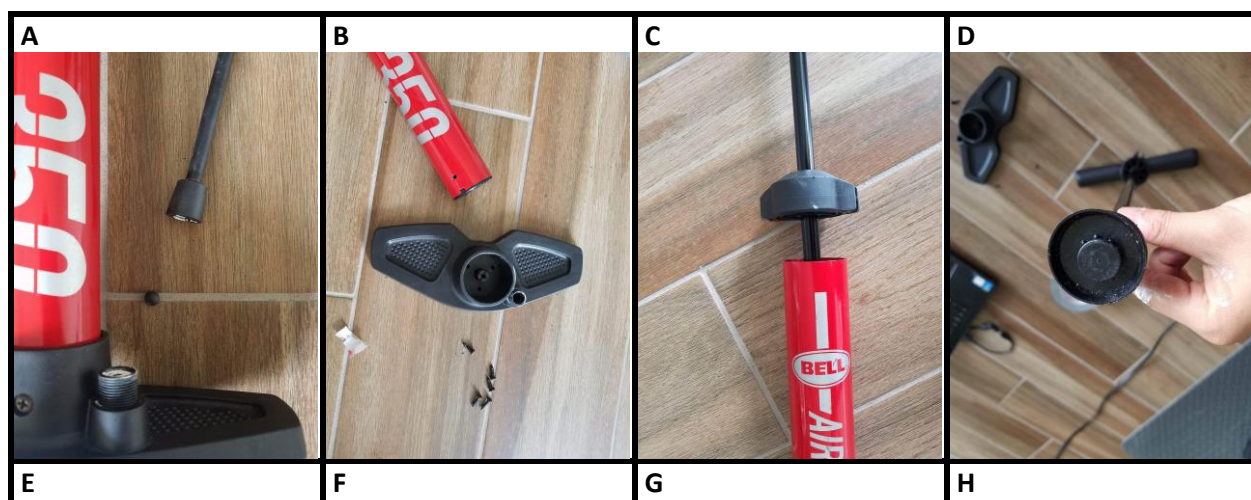
The low-cost vacuum autoclave described in this report can alleviate the burden of surgical-site infections and nosocomial infections in the developing world. The device offers improved reliability of sterilization to clinics with unreliable power sources, and it offers fast cycle times to understaffed clinics. The low cost of this device will appeal to clinics in resource-poor areas and to the various NGOs and nonprofit organizations dedicated to improving lives in those areas.

## Appendix





**Figure 1.** The autoclave, built from a modified pressure cooker (A) Modified pressure cooker (B) Pressure gauge attached to the lid of the autoclave (C) Safety valve, ball valve, and vacuum fitting attached to the lid of the autoclave (D) Silicone sealants used on the underside of the lid to prevent air leaks







**Figure 2.** The vacuum pump, built from a modified bicycle pump (A) Hose is removed (B) Base is removed (C) Top is unscrewed (D) Plastic and rubber assembly is removed (E) Rubber piece is reversed and reattached (F) hose is cut (G) ball valve is reversed (H) Ball valve is reinserted.



**Figure 3.** Completed autoclave with insulation and vacuum pump.

## References

1. Benedetta A, Bagheri NS, Christophe C, et. al. Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis. *Lancet*. 2016; 377(9761): 228-241. doi:10.1016/S0140-6736(10)61458-4.
2. Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008. Centers for Disease Control and

- Prevention Website. t. Published 2008. Updated December 29, 2009. Accessed December 15, 2016.
3. M.K. Hardy, BE, oral communication, October, 10, 2016.
  4. A. Young, BS, oral communication, October 10, 2016.
  5. Perry L, Malkin R. Effectiveness of medical equipment donations to improve health systems: how much medical equipment is broken in the developing world? *Med Biol Eng Comput.* 2011; 49: 719. doi:10.1007/s11517-011-0786-3
  6. Health care associated infections. World Health Organization Website. [http://www.who.int/gpsc/country\\_work/gpsc\\_ccisc\\_fact\\_sheet\\_en.pdf](http://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf). Published December 10, 2010. Accessed December 15, 2016.
  7. Stevens S, Cox I. Sterilization and disinfection: a reference for ophthalmic practice in developing countries. International Centre for Eye Health Website. <http://s160131.gridserver.com/wp-content/uploads/sterilization-and-disinfection-in-developing-countries.pdf>. Accessed December 15, 2016.
  8. Solar Irradiance. Solar Electricity Handbook Website. <http://www.solarelectricityhandbook.com/solar-irradiance.html>. Accessed December 15, 2016.
  9. Young A. Distributed surgical instrument sterilization using solar powered autoclaves in low resource settings. World Health Organization Website. [http://www.who.int/medical\\_devices/poster\\_a18.pdf](http://www.who.int/medical_devices/poster_a18.pdf). Accessed December 15, 2016.
  10. Jones RH, Brown I, Przybylko J, Fisher S, Tracey J, Russel N. Portable solar-powered autoclave [Health Care Without Harm competition winner]. Sydney, AU: Sydney University. [http://www.builditsolar.com/Projects/OddProjects/AutoClaveFirstplace\\_2.pdf](http://www.builditsolar.com/Projects/OddProjects/AutoClaveFirstplace_2.pdf)
  11. Lawrence B, Brettner E, Liu Y, Godwin K, Compton A. Solar autoclave for rural areas. [capstone project]. Flagstaff, AZ: Northern Arizona University; 2013.
  12. Stromberg J. This new device can sterilize medical tools using solar power alone. Smithsonian.com. <http://www.smithsonianmag.com/science-nature/this-new-device-can-sterilize-medical-tools-using-solar-power-alone-8046495/?no-ist>. Published July 8, 2013. Accessed December 15, 2016.
  13. Butler G. Steam Sterilization cycles for lab applications. Presented at: Steris Life Sciences; August 2009; Lincoln, NE. [https://ehs.unl.edu/training/colloquium/2009-09\\_Presentation.pdf](https://ehs.unl.edu/training/colloquium/2009-09_Presentation.pdf). Accessed December 15, 2016.
  14. Lin C. Premarket notification [510(k)] submissions for chemical indicators: guidance for industry and FDA staff. Food and Drug Administration Website. <http://www.fda.gov/RegulatoryInformation/Guidances/ucm072613.htm>. Published December 19, 2003. Updated June 26, 2015. Accessed December 15, 2016.

15. G. Spiegel, BE, personal communication, November 18, 2016.
16. Medical devices directive. European Commission Website. [https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices\\_en](https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en). Published 1993. Updated 2016. Accessed December 15, 2016.
17. C. Paschal, PhD, oral communication, September 29, 2016.
18. UL Website. <http://www.ul.com/aboutul/>. Accessed December 15, 2016.
19. Adecavic. WE Guatemala Website. <http://weguatemala.org/en/ngo/adevacic-asociaci%C3%B3n-de-ayuda-para-el-desarrollo-y-vida-comunitaria>. Accessed December 15, 2016.
20. Caputo Children's Fund Website. <http://www.caputo-children-fund.org/>. Accessed December 15, 2016.
21. Global Harmonization Task Force. Definition of the terms 'medical device' and 'in vitro diagnostic (IVD) medical device'. Kyoto, JP: Global Harmonization Task Force; 2012:71.
22. Medical Device Regulations. World Health Organization Website. [http://who.int/medical\\_devices/safety/en/](http://who.int/medical_devices/safety/en/). Accessed December 15, 2016.
23. Medical Device Regulatory Requirements for Guatemala. US Department of Commerce. <http://www.trade.gov/td/health/guatemalaregs.html>. May 2, 2005. Accessed December 15, 2015.