

## **Design of an Efficient Sterilisation System**

**Gifty Tetteh**

*Department of Biomedical Engineering, Faculty of Engineering Sciences  
University of Ghana, Accra, Ghana*

**Elsie Effah Kaufmann**

*Corresponding Author, Department of Biomedical Engineering  
Faculty of Engineering Sciences, University of Ghana, Accra, Ghana  
E-mail: eek@ug.edu.gh  
Tel: +233 244 621 935*

### **Abstract**

Sterilisation, a key method for reducing the transfer of communicable diseases, is an extermination method for microorganisms from the surface of devices, culture media, fluids and reagents. In a developing country such as Ghana, electricity is often unavailable and supply when available is frequently unreliable. High cost of existing sterilisation systems, inefficient microbe elimination by improvised methods and material degradation were identified as major inadequacies associated with sterilisation systems, currently being employed. Using a formal engineering design process, a sterilisation system satisfying objectives of user safety, high operational efficiency, competitive cost, and an aesthetically pleasing appearance was developed for hospitals, clinics, traditional birth attendants and beauty parlours. The affordable steriliser resolves the aforementioned limitations by operating without the use of electricity and attains sterility without material degradation. The design may be modified to obtain sterilisers of varying capacity to satisfy different categories of users, both small and large scale. The mediation of designing a non-electrical steriliser, with an operational efficiency of 83%, is meant to promote the practice of sterilisation among healthcare providers and beauticians, so as to reduce disease transfer resulting from the use of contaminated equipment.

**Keywords:** Sterilisation, Microbes, Non-Electrical, Efficiency, Disease Transmission

### **1. Introduction**

Sterilisation has been defined as any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses, protozoa and prions) from a surface, equipment, foods, medications, or biological culture medium (Block, 2001). This process in practice is achieved by exposure of the object to be sterilised, to a chemical or physical agent for a specified time (Sultana, 2007). Sterility, the product of any successful sterilization process can thus be achieved by applying the proper combinations of heat, chemicals, irradiation, high pressure, and filtration (Dempsey and Thirucote, 1988). The effectiveness of any sterilisation process depends on time, adequate contact, temperature and with steam sterilisation, high pressure (Tietjen et al, 1992). The nature and amount of microorganisms to be sterilised also affects the effectiveness of a sterilisation process.

Transmissible agents are human parasites which cause diseases such as tuberculosis, typhoid fever, amoebiasis, ebola, avian influenza and Creutzfeldt - Jakob disease (Farmer, 2001; Fouchier et al, 2004; Rutala and Weber, 2001; Sanchez et al, 1995). The prevalence of the aforementioned diseases necessitates the practice of sterilisation of devices such as medical and surgical instruments, surgical gloves and other items, (Spaulding, 1939) that come into direct contact with the body. In addition, the Centre for Disease Control and Prevention recommends that heat stable reusable medical devices that enter the blood stream or enter normally sterile tissue should always be reprocessed using heat-based methods of sterilization(CDC, 2008); hence the need for the design of an efficient sterilisation system.

In developing countries like Ghana where access to high level health care services is limited and patients have to resort to less advanced and ill-equipped health centres (Salisu and Prinz, 2009) the use of sterilisation processes poses a major challenge. These challenges arise as a result of the high cost involved in the procurement of sterilisation devices and their attendant maintenance costs. The price of an autoclave ranges from about \$800-\$12,000 (Twenga, 2010; Nextag, 2010); however, the actual price of an autoclave is dependent on the capacity of the autoclave in terms of spatial requirement and function specification. In addition, the availability of electricity is a privilege in many communities and even in the urban centres, reliability of supply is of concern. The electrical requirements of an autoclave range from 1050 W to 2700 W in terms of power consumption, a voltage of about 220 V and a frequency range of 50-60 Hz, (Tuttnauer, 2012). These requirements make it expensive to replace the normal hydro-power with alternate energy forms such as the use of fuel generators.

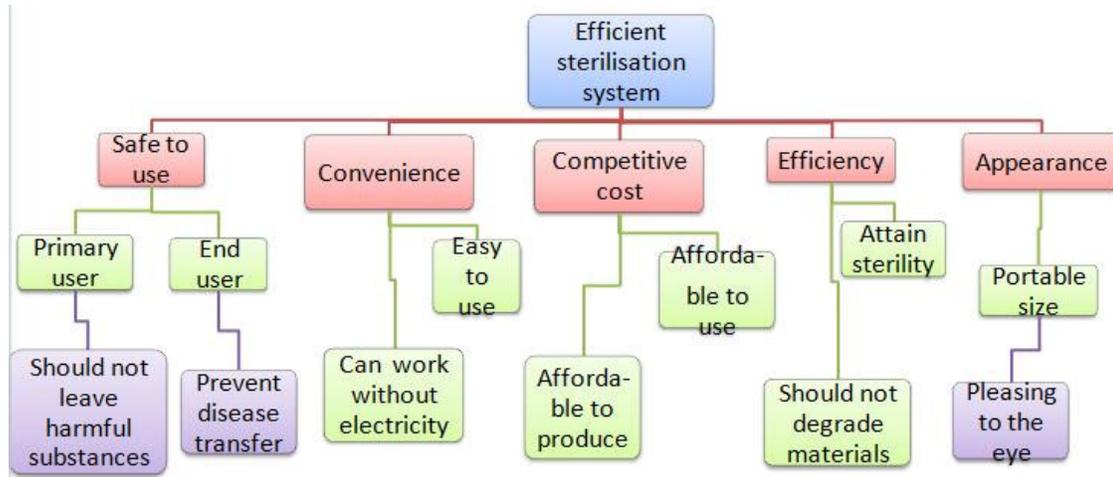
The need for sterilization is not limited to just the healthcare setting as other service providers such as tattoo parlours, hair dressing and barbering salons, as well as traditional birth attendants engage in activities which necessitate the use of sterilization processes. The high cost of efficient sterilisation methods, coupled with the unfavourable electrical requirements pushes some of these service providers to adopt alternate sterilisation forms of varying efficiency such as high level disinfection and boiling. These processes have been found to be inefficient against some viruses and endospores of some transmissible bacteria (Drummond and Skidmore, 1991; Elkarim et al, 2004; Huezo, 2003). Sterilisation systems are used in Hospitals, Clinics, Tattoo Parlours, Hair Dressing and Barbering Saloons and by Traditional Birth Attendants; these organisations form the clientele for the project. Interviews with nurses, technicians and beauticians in some of these institutions yielded an in-depth understanding of some of the challenges faced with regard to this problem. The challenges included material degradation in the form of corrosion, and the dulling of sharp edges of instruments resulting from the practice of High Level Disinfection, eventually leading to an increase in operational cost, since degraded instruments require replacement.

The authors have designed an efficient sterilization system that addresses the unreliable or unavailable electrical power supply, high cost of procuring and running existing sterilisation systems, inability of improvised sterilisation methods to attain sterility, and material degradation resulting from corrosion. The affordable non-electrical steriliser designed is meant to promote the practice of sterilisation with the aim of reducing the risk of disease transfer resulting from the use of contaminated equipment. Improving sterilisation among traditional birth attendants, in particular, would go a long way to contribute towards the attainment of Millennium Development Goal five, which seeks to reduce maternal mortality.

A formal engineering design process (Haik, 2003; Khandani, 2005) was used in designing the steriliser. The iterative process consisted of several stages including Problem Identification, Background Search, Functional Analysis, Development of Specifications, Concept Generation, Analysis and Selection of Components, Component Implementation, Integration and Testing, and finally Product Presentation.

The objectives of the design were set as part of Problem Identification. The major objectives of the project were efficiency, competitive cost, aesthetic appearance, safety and convenience. These major objectives together with other supporting objectives were organized into an objective tree as shown below:

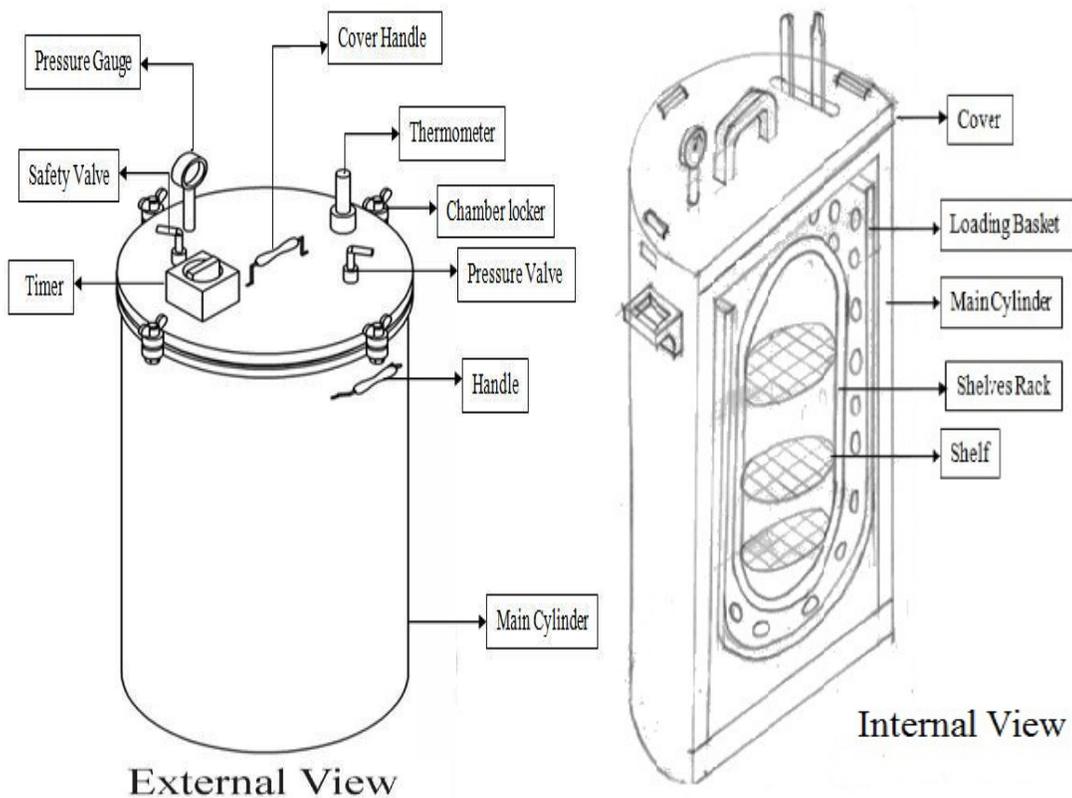
**Figure 1:** Objective Tree for the Design of an Efficient Sterilisation System



**2. The Design**

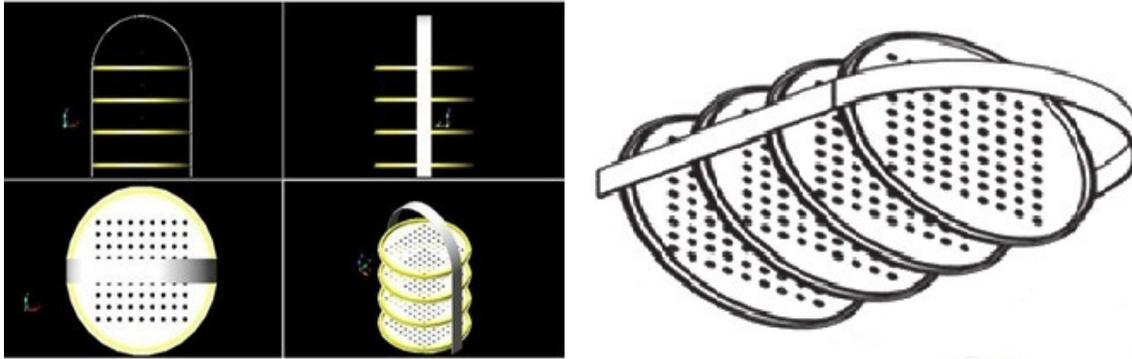
**2.1 Steriliser:** It consists of four main parts, namely, the shelf rack, loading basket, cover and main cylinder. The main cylinder and its cover, houses the loading basket which contains the shelf rack, as shown below:

**Figure 2:** External and Internal Views of the Efficient Sterilisation System



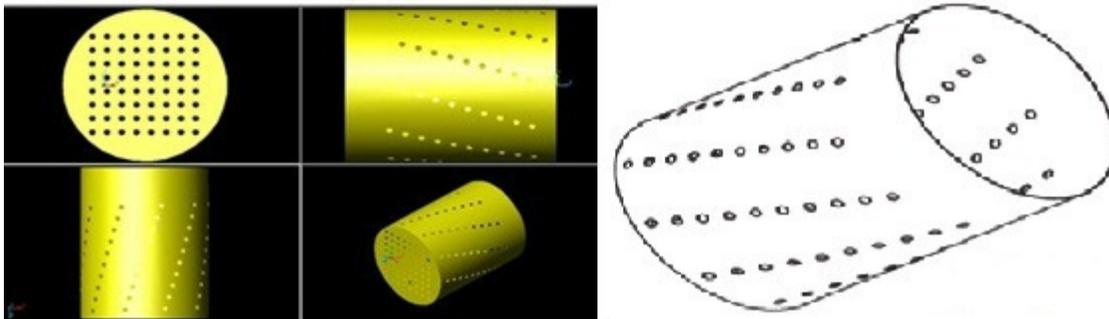
**2.2 Shelf Rack:** It consists of four circular and perforated shelves suspended on a riveted rack. Each shelf is made of a 0.8 mm thick aluminium sheet and has several perforations that enhance steam transfer. With a diameter of 300 mm, each shelf can accommodate about eight wrapped scalpels and forceps or about five medium sized instruments.

**Figure 3:** Shelf Rack Containing Wrapped Instruments during sterilisation



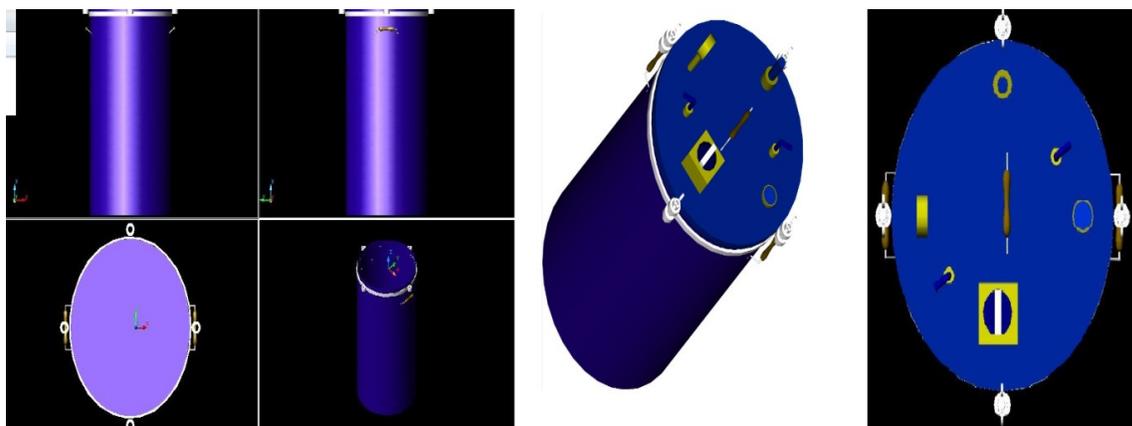
**2.3 Loading Basket:** It is fabricated out of a 0.8 mm thick aluminium sheet, with a height of 500 mm and a diameter of 400 mm. Steam generated from water in the main cylinder is effectively transported to items on the shelf rack through the diagonally drilled perforations of the loading basket. Supported by an inner support system, the cylindrical container separates the shelf rack from the main cylinder, and prevents instruments from contact with water.

**Figure 4:** Loading Basket which Houses the Shelf Rack of the Sterilisation System



**2.4 Main Cylinder:** Fabricated with a grooved seam joint, the 1 mm thick aluminium cylinder houses an inner support system, made up of four riveted aluminium stands that suspend the loading basket. It has a water storage capacity of 21 L and has attached insulated handles at both ends. The handles are made of threaded metals inserted into wooden holders, and attached using bolts and nuts. Four butterfly wing nuts have also been attached around the cylinder to serve as chamber locks.

**Figure 5:** Main Cylinder and Cover of the Sterilisation System



**2.5 Cover:** The cover of the steriliser is made of a 1 mm aluminium sheet, with four extension slots for chamber locking. A 400 kPa pressure gauge, thermometer (-20 °C to 320 °C), 60 minute timer, pressure and safety ball valves, and a wooden handle are incorporated into the cover by means of bolts and nuts, nipple rings and washers. The cover is firmly placed on the main cylinder and locked prior to use.

**Table 1:** Bill of Materials for the Steriliser

NUMBER	PART	QUANTITY	DESCRIPTION	UNIT SIZE / MASS
1	1 mm Aluminium Sheet	1	Sheet metal used for the fabrication of the main cylinder and cover as well as loading basket support.	1.22 * 2.44 m
2	0.8 mm Aluminium Sheet	1	Sheet metal used for the fabrication of the shelves, shelf rack and loading basket.	1.22 * 2.44 m
3	0.15 m Ball Valve	2	Pressure stopcock and emergency steam escape valve.	250 g
4	0.15 m Nipple Rings	3	Aids in the fixation of valves and pressure gauge.	50 g
5	400 kPa Pressure Gauge	1	For pressure measurement during a sterilisation cycle.	400 g
6	Size 6 Butterfly Wing Nuts	3	Locks the steriliser to prevent steam escape.	10 g
7	-20°C to 320 °C Thermometer	1	For temperature measurement during a sterilisation cycle.	150g
8	60 Minute timer	1	For keeping time during a sterilisation cycle.	100g
9	Wooden Cover Handle	1	Rounded wooden knob used in opening the steriliser and lifting the cover.	20 g
10	Metallic and Wooden Cylinder Handles	2	Attached firmly to the sides of the steriliser and used in carrying the steriliser.	80 g
11	Bolts and Nuts	7	Used to fasten handles, pressure gauge, and safety ball valves to the steriliser.	5 g
12	Riveting Pins	14	Used to fasten the shelf rack and the support of the loading basket.	1 g
13	Screws	2	Used to fasten the wooden handle to the cover of the steriliser.	2 g
14	Washers	14	Aid the fastening of handles, pressure gauge and safety ball valves to the steriliser.	5 g

## 2.6. Mode of Operation

The system works in conjunction with a heat source, preferably a gas or firewood stove. The already washed and disinfected thermostable items to be sterilised, are double wrapped with muslin paper and sterility indicator tapes. An average of about twenty five (25) medium sized items are loaded onto the shelves allowing enough space for steam penetration and contact; bearing in mind the total surface area of the shelves at 0.4 m<sup>2</sup> and the volume of the loading basket at 0.6 m<sup>3</sup>. The main cylinder is filled with 21 litres of water at room temperature; the loading basket is then suspended in the main cylinder by means of the inner support system and the shelves rack containing the wrapped items to be sterilised immersed into the loading basket.

Initial parameters of pressure and internal temperature are recorded. Pressure and temperature are measured at ten (10) minute intervals throughout the process. Heating is commenced and the pressure valve is partially opened to allow air escape as pressured steam is being generated. After

attaining an internal temperature of 121 °C and a pressure of 150 kPa, the timer is set to thirty (30) minutes whilst still heating, so as to cause inactivation of all pathogens contained on and within the wrapped items. After this period the heat source is turned off, final temperature and pressure values are recorded, both valves are opened to allow steam to escape and cooling to take place within a period of thirty (30) minutes. The items are then removed from the shelves and kept in a sterile environment for future use.

In the event of an emergency, where the temperature or pressure exceeds tolerable limits of over 250 °C or 400 kPa, respectively both the pressure and safety valves should be opened and the heat source turned off, in order to avoid the occurrence of an accident.

## 2.7. Advantages of the Design

The system:

- Operates without the use of electricity
- Attains sterility and prevents material degradation
- Is affordable to produce and use
- Is about 83% efficient
- Is expected to eliminate or significantly reduce the incidence of disease transfer
- Does not leave harmful substances such as radiation after sterilisation
- Is user friendly hence requires minimal attention during operation
- Is portable in size and pleasing to the eye

## 3. Discussion

Using quantitative parameters as criteria the design was evaluated, to determine whether the stated objectives had been achieved. The design prevents disease transfer and does not utilise any form of radiation. Effective energy penetration mechanisms, shape and dimensions of the various components that relate to steam generation, and operating the system at a pressure of 150 kPa and a temperature of 121 °C for 30 minutes, are standards set to prevent disease transfer and eliminate radiation. User safety is further enhanced with the inclusion of insulators, to impede heat transfer from the system to the user, and the use of safety valves as emergency stop buttons during system failure.

The system provides operational convenience by being non electrical and user friendly. Energy generated from an external heat source is conducted through the main cylinder (made of aluminium sheets), to convert water to steam for sterilisation. The user friendly steriliser requires few instructions and minimal attention during operation, and incorporates a pressure gauge and thermometer with legible calibrations.

Simple fabrication methods and the use of durable components that are readily available on the local market make the steriliser affordable to produce, whilst the use of water and sterility indicators as the only consumables makes the system, affordable to use. The steriliser is priced at GH¢600 (approximately \$300).

Efficiency of the system is dependent on the attainment of sterility, and the prevention of material degradation. Material degradation in the form of corrosion results mostly from contact of medical instruments with water and the harsh chemicals used in High Level Disinfection. The inner support system of the main cylinder, the loading basket and the wrapping of items before sterilisation, eliminates water contact and therefore prevents material degradation. Additionally, no harsh chemicals are required. Initial prototype testing yielded excellent results; a change in colour of sterility indicator tapes upon sterilisation confirms sterility. Additionally, the shiny and silvery nature of portable aluminium steriliser makes the steriliser aesthetically pleasing to the eye.

The steriliser has an operational efficiency of 83% from heat energy calculations. Although all the objectives and design specifications were achieved, it is recommended that the design be developed

further. Iterating the material selection process can aid in improving safety by specifying thicker aluminium sheets for fabrication and incorporating automatic safety valves to improve user friendly and safety operations. Also, subsequent development could include the production of different sizes of the steriliser, to suit the various categories of clients ranging from small to large scale organisations.

#### 4. Conclusion

The designed system after testing and evaluation meets the requirements for an efficient sterilisation process and is capable of ameliorating the challenges associated with the use of sterilisation systems in terms of using an alternative source of power to electricity, providing a low cost option to currently available but expensive systems and minimizing the risk of disease transmission due to ineffective sterilisation methods.

#### Acknowledgment

Acknowledgement is hereby accorded to Mrs. Vivian Yeboah of the La General Hospital, Mrs. Hannah Owusu of the Osu Maternity Home, and Mrs. Millicent Tandoh of the Nyaho Medical Centre, all in Accra, Ghana for partaking in interviews regarding the project.

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