



PERSONNEL AND  
READINESS

UNDER SECRETARY OF DEFENSE  
4000 DEFENSE PENTAGON  
WASHINGTON, DC 20301-4000

The Honorable Thad Cochran  
Chairman  
Subcommittee on Defense  
Committee on Appropriations  
United States Senate  
Washington, DC 20510

JUL 8 2016

Dear Mr. Chairman:

Enclosed is the final report in response to House Report 114-139, page 285, which accompanied H.R. 2685, the Department of Defense Appropriations Bill, 2016, concerning the cost and benefits of alternative sterilization techniques and a plan for modernizing medical sterilization, including the potential use of portable hydrogen peroxide vapor sterilization technology for use in combat support hospitals (CSH), emergency humanitarian relief settings, and other austere military medical environments.

This report compares sterilization methods in terms of logistics, energy consumption, effectiveness, and the ability to enhance surgical capabilities of CSH. The CSH is a U.S. military field hospital that is normally transported to the battlefield, but not to the front lines of the battlefield. Sterilizers are needed in the Central Materiel Service of the CSH to sterilize surgical instruments, linen packs, and other items. Historically, wound infection due to ineffective sterilization techniques has been a significant cause of post-operative healing problems. The proper and effective sterilization of instruments, drapes, and supplies used in operating rooms, emergency treatment areas, and intensive care units significantly reduces the chance of infection.

Thank you for your interest in the health and well-being of our Service members and their families. A similar letter is being sent to the other congressional defense committees.

Sincerely,

A handwritten signature in black ink, appearing to be "Peter Levine", written over a large, stylized flourish.

Peter Levine  
Acting

Enclosure:  
As stated

cc:  
The Honorable Richard J. Durbin  
Vice Chairman



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The Honorable William M. "Mac" Thornberry  
Chairman  
Committee on Armed Services  
U.S. House of Representatives  
Washington, DC 20515

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Peter Levine  
Acting

Enclosure:  
As stated

cc:  
The Honorable Adam Smith  
Ranking Member



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The Honorable John McCain  
Chairman  
Committee on Armed Services  
United States Senate  
Washington, DC 20510

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cc:  
The Honorable Jack Reed  
Ranking Member



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WASHINGTON, DC 20301-4000

JUL 8 2016

The Honorable Rodney P. Frelinghuysen  
Chairman  
Subcommittee on Defense  
Committee on Appropriations  
U.S. House of Representatives  
Washington, DC 20515

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Peter Levine  
Acting

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As stated

cc:  
The Honorable Peter J. Visclosky  
Ranking Member

**REPORT TO THE CONGRESSIONAL DEFENSE COMMITTEES IN RESPONSE TO  
HOUSE REPORT 114-139, PAGE 285, WHICH ACCOMPANIED H.R. 2685, THE  
DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2016**

**“SURGICAL STERILIZATION IN AUSTERE MILITARY MEDICAL  
ENVIRONMENTS”**



**SUBMITTED BY THE OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE  
(HEALTH AFFAIRS)**

**June 2016**

The estimated cost of this report for the Department of Defense is approximately \$19,000. This includes \$0 in expenses and \$19,000 in DoD labor. Reference ID: 3-FC6D513.

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## **1.0 Introduction:**

This report responds to House Report 114-139, page 285, which accompanied H.R. 2685, the Department of Defense Appropriation Bill, 2016, directing the Assistant Secretary of Defense for Health Affairs to report on the costs and benefits of alternative sterilization techniques and provide a plan for modernizing medical sterilization, including potential use of portable hydrogen peroxide vapor sterilization technology for use in combat support hospitals (CSH), emergency humanitarian relief settings, and other austere military medical environments. This report compares sterilization methods in terms of logistics, energy consumption, effectiveness, and the ability to enhance surgical capabilities of CSH. The CSH is a U.S. military field hospital that is normally transported to the battlefield, but not to the front lines of the battlefield. Sterilizers are needed in the Central Materiel Service of the CSH to sterilize surgical instruments, linen packs, and other items. Wound infection due to ineffective sterilization techniques historically has been a significant cause of post-operative healing problems, which have the potential to result in death. The proper and effective sterilization of instruments, drapes, and supplies used in operating rooms, emergency treatment areas, and intensive care units significantly reduces the chance of infection.

## **2.0 Current Capability:**

The CSH currently uses large-chamber steam sterilizers manufactured by Environmental Tectonics Corporation (ETC). The ETC model P-138, widely known as the “Big Bertha,” has been in use since the 1960s, and the standard allocation is four sterilizers per CSH. While this sterilizer is still commercially available and operational, the “Big Bertha” lacks certain features commonly found with other more technologically-advanced sterilizers. Although this model performs well, upgrades and enhancements are needed to improve logistical supportability and meet state-of-the-art standards and Food and Drug Administration (FDA) regulations for safety and effectiveness. Desired improvements in sustaining the force with a future sterilizer include automated data logging; pre-vacuum cycles; improved sterilization safety, effectiveness, and throughput; and reduced power and water consumption.

Four models of potentially suitable sterilizers, including steam and hydrogen peroxide sterilizers, were purchased and subjected to environmental and operational testing. One purpose of testing was to determine which commercial sterilizer products on the market could meet the needs of the Department of Defense (DoD). Another purpose was to determine whether a DoD design and developmental effort was needed for a sterilizer before the medical acquisition process. The sterilizers were tested in both storage and simulated operational environmental conditions to enable a comprehensive technology comparison, and ensure adequate opportunity to determine the availability of safe and effective devices. The U.S. military will continue to engage in an era of persistent conflict, so key performance parameters and attributes were identified as described below for the selection of the next generation sterilizer.

### 3.0 Requirements for Evaluation:

There were 11 essential characteristics for requirements determination and evaluation selection of the sterilizer. The requirements evaluation rationale is listed below for each category which led to the sterilizer decision.

1. FDA Clearance: The FDA is the approving authority for uses of the sterilizer and clears the device for commercial distribution. All medical devices used in support of U.S. military personnel must be FDA-approved.
2. Chamber Size: Must be of adequate size to accommodate all current surgical instrument packs and instrument trays so that they can be completely sterilized.
3. Weight. Must not exceed weight of the existing sterilizer model used in the past to meet transportation and portability requirements.
4. Portability. Currently six soldiers are required to move the “Big Bertha” sterilizer into area where used. The modernized sterilizer should be moved by not more than six Service members.
5. Chamber Door Centerline Height. Center line of chamber door must be at least 36” above floor so that the operating room specialist can load trays and packs into sterilizer without unnecessary bending, stooping, or ergonomic stress.
6. Electrical Power. The sterilizer must operate from 230 VAC, 50/60 Hz, 3-Phase, electrical power. This is the type of electrical power available in the CSH, and there is no requirement for an auxiliary heating source (burner).
7. Footprint. Must not exceed foot print, area occupied, by the current work space, (i.e., 46" long X 25" wide X 39.8" high) in the Central Materiel Section of the CSH.
8. Operator Controls. The sterilizer must automatically cycle through the operation cycles in the proper sequence selected by an operator.
9. Sterilization Cycles. Various sterilization settings are needed to allow the processing of diverse objects, such as instrument trays and wrapped goods. The availability of a pre-vacuum cycle improves sterilization effectiveness and speed compared to a gravity cycle.
10. Data Recording. Visual display of the chamber internal temperatures reached, and the time at temperatures are required.
11. Water Use. The water use of the sterilizer will not exceed 3 liters per wrapped goods cycle. The control of the amount of water needed per cycle reduces the need for water resupply.



## **4.0 Process for Evaluation**

The U.S. Army Medical Materiel Agency oversaw testing to evaluate how candidate sterilizers would meet the essential characteristics for sterilization in an austere environment. The U.S. Army Medical Department Board conducted a customer assessment of sterilizers in an operational environment using typical operators and maintainers to assess functionality of the sterilizers in supporting the mission of the Central Materiel Services section in a CSH.

The sterilizers were evaluated to assess proper functioning of all cycles, determine power and water consumption for typical sterilizer cycles, and evaluate their ability to withstand climatic environmental extremes (during operation and in storage). Temperature and humidity tests were conducted because the field sterilizer may be used in geographic areas where climatic conditions would induce high or low temperatures or high humidity within the item, when operational or non-operational. These tests determine what sterilizers could operate under hot or cold climatic conditions and survive extreme variations in temperature or high humidity during transportation and storage without experiencing physical damage or deterioration of performance. High or low temperatures and high humidity can temporarily or permanently impair the performance of an item by changing the physical properties or dimensions of the material(s) from which it is made.

## **5.0 Candidates Tested**

The DoD identified four manufacturers and models of potentially suitable sterilizers for consideration: 1) Fort Defiance Industries (model P2131), 2) Tuttnauer (model 3870 EAP), 3) Fedegari Autoklaven AG (model H2000M2), and 4) Sterilucent (model PSD-85).

The Fort Defiance model is an automated field steam sterilizer with three components that work as an integrated system that includes: 1) Sterilizer, 2) Water Recovery System, and 3) Portable Water Softener. The Tuttnauer model is an automatic table top steam autoclave, featuring a closed-door, active drying system to maintain sterility and facilitate efficient drying of packs and pouches. The Fedegari model steam sterilizer is designed to treat solid and porous loads within compliance standards. It is composed of two modules that must be placed one on top of the other for operation, but can be split for transport. The Sterilucent model uses hydrogen peroxide to sterilize a variety of medical devices and instruments, and is self-contained in its own shipping container.

Test reports summarizing the outcomes of the customer assistance and environmental testing were prepared and distributed to members of the Sterilizer Integrated Product Team for review and analysis. Weaknesses of individual sterilizers were discussed with manufacturers to determine willingness to improve their equipment to meet the requirements. A high-level overview of sterilizer results is provided below with a subsequent detailed summary of the sterilizer test results.

## 6.0 Sterilizer Test Results

The Fort Defiance Industries Model, P2131 (Steam) model met all requirements based on the established criteria, and was most favored by users during the assessment. Users especially liked the similarity of the unit to the current system with regard to chamber size, simplicity of operation, and ease of setup/take down. There were minor problems during low temperature storage testing, but corrections were made by the manufacturer with minimal design changes. The water recovery system for this model is part of the steam sterilizer system and has to be transported to the CSH along with the instrument. However, because the water system is placed underneath the steam sterilizer, it does not increase the footprint of the steam sterilizer within the CSH. This model was considered easy to use, maintain, and had added features that included vacuum design, automated control and data logging, reduced power and water consumption, as well as simplicity.

The Tuttanauer Model 3870 EAP (Steam) also was FDA approved and although many users liked some aspects of the sterilizer, most felt the chamber was too small. Because it is a gravity type sterilizer, the unit does not meet the requirement for a having pre-vacuum cycle. The sterilizer did not sterilize its contents reliably even under normal ambient temperature and humidity conditions for reasons unknown. For this reason the environmental testing of the unit was suspended. The chamber size was smaller than the “Big Bertha” sterilizer. The unit had no handles for transport, and did not sterilize under baseline conditions 40 percent of the time. This sterilizer is by far the least expensive model of all sterilizers.

The Fedegari Model H2000M2 (Steam) was not FDA approved, and was complex and very difficult to use and maintain. Users felt this model was durable but was too complex for routine field use. The chamber size is smaller than the current sterilizer and there were repeated reliability problems in evidence throughout the customer assessment and environmental testing, only some of which were successfully corrected by the manufacturer. This sterilizer was the heaviest of all models and was complex to maintain. The operating and service manual was difficult to follow and the sterilizer failed 67 percent of cycles, and it repeatedly had problems with running and completing cycles. This model progressively worsened with leaks, and the safety release valve failed. In addition, there were problems achieving required vacuum level during high temperature/humidity operational test. This model was designed for military/field use, included vacuum design, low water consumption, automated control and data logging, but experienced numerous reliability challenges during testing.

The Sterilucent Model PSD-85 (Hydrogen Peroxide) was FDA approved, and users liked the simplicity of controls for this sterilizer. There were problems with prolonged drying cycles during the assessment and the unit could not operate at all of the required temperature levels. Users did not like the requirement to keep consumable supplies within a specified temperature range because that would impose an additional logistical burden. The chamber size is too small and the unit is too heavy, requiring more than six individuals to transport it. This model is unable to sterilize essentials such as linen and drapes because the sterilizer could not inactivate microorganisms within these products. This sterilizer exhibited problems with fault service messages, and users did not like having to wear gloves during use due to potential hydrogen peroxide exposure. During sterilization of all cycles, there was significantly lower power

consumption than with the steam sterilizer. However, this instrument exhibited problems with moisture, warm-up time, and with prolonged drying cycles. The sterilizer failed during operational testing at temperatures above 110 degrees Fahrenheit, and in high humidity. The hydrogen peroxide sterilizer (HPS) is heavy, though reportedly designed for military field use. It did feature automated controls, data logging capabilities, and used less power than steam sterilization. It had a lower sterilization temperature and did not require water. It was usable on materiel that could not withstand steam sterilization. A major issue with the HPS sterilizer was that it did not sterilize all required medical materiel. It had problems with operating temperature, reagent shelf life, storage temperature, and would have a greater operational expense.

The cost and effectiveness analysis of alternative sterilization techniques, such as the HPS, compared with modernized steam sterilization demonstrated the following:

<b>Cost and Effectiveness</b>		
<b>Characteristic</b>	<b>HPS</b>	<b>Steam</b>
Procurement Cost	\$120K each	\$105K each
Life Cycle Cost	\$78K	\$63K
Weight	440 pounds	310 pounds
Foot Print	2,160 square inches	900 square inches
Mobility	8 individuals to transport	6 individuals to transport
Chamber Size	2.91 cubic feet	4.13 cubic feet
Power – peak usage	1.7 KW	9 KW

HPS non-steam sterilizers may have a future role in austere environments, particularly for modalities that require conservation of resources and use fragile materials that are unable to withstand steam sterilization.

## Essential Characteristics and Specifications for Sterilizers Tested

☑ = Meets requirement

☒ = Does not meet requirement

Attribute	Threshold Requirement	Fort Defiance	Tuttnauer	Fedegari	Sterilucent
FDA Clearance (KPP)	FDA Clearance	☑	☑	☒	☑
Chamber Size	The sterilizer will have as a minimum an internal cylindrical chamber size of 16" in diameter x 36" deep.	☑	☒	☒	☒
Weight	The weight of the sterilizer will not exceed 325 pounds.	☑	☑	☒	☒
Portability	The sterilizer will be designed to be moved by six Soldiers.	☑	☑	☑	☒
Chamber Door Centerline Height	Center line of chamber door must be at least 36" above floor.	☑	☒	☑	☑
Electrical Power	The sterilizer must operate from 230 VAC, 50/60 Hz, 3-Phase, electrical power. An auxiliary heating source is not required.	☑	☑	☑	☒
Footprint	Have same "footprint" as existing sterilizer (i.e., 46" long X 25" wide X 39.8" high).	☑	☑	☑	☒
Operator Controls	Controls must automatically sequence the sterilizer through all selected cycles.	☑	☑	☑	☑
Sterilization Cycles	The sterilizer will have cycles for vacuum, flash, extended, programmable.	☑	☒	☑	☒
Data Recording	Visual display of the chamber internal temperature reached and the time at temperature are required.	☑	☑	☑	☑
Water Use	The water use of the sterilizer will not exceed 3 liters per wrapped goods cycle.	☑	☑	☑	Not Applicable. Doesn't Use Water

### 7.0 Findings by Criteria.

1. Food and Drug Administration (FDA) Clearance: Three of the four sterilizers were FDA approved. The FDA requested additional information for clearance of the Sterilucent model sterilizer and additional information was received for the clearance. There was no FDA clearance for the Fedegari model; the manufacturer planned to pursue FDA submission, but the government did not receive the paperwork for clearance.

2. Chamber Size Rationale: The Fort Defiance model sterilizer was the sole unit that met the chamber size necessary to accommodate current surgical instrument packs and instrument trays completely. The other sterilizers could not sterilize full instrument trays.
3. Weight Rationale. Two of the four sterilizers met the weight requirement between 260-325 pounds, Fort Defiance model weighed 220 lbs. and Tuttnauer model weighed 244 lbs. The Fedegari weighed 818 lbs. (system with two pieces) and Sterilicuent model weighed 443 lbs.
4. Portability. Three model sterilizers could be transported by 4-6 persons which were the objective; the Sterilicuent model required upwards of 7-8 persons for portability.
5. Chamber Door Centerline Height. Three of the four sterilizers met the threshold and/or objective of chamber door at least 36" - 50" above the floor. The Tuttnauer model did not meet the requirements.
6. Electrical Power Rationale. Three of the four sterilizers met the requirement to operate from 230 VAC, 50/60 Hz, which is the type electrical power available in the CSH. The Sterilicuent model uses 100-130 VAC or 200-250 VAC electrical power, single phase.
7. Footprint Rationale. Three of the four sterilizers met the threshold square footage requirement of 46" long X 25" wide X 39.8" high), which is the footprint of the current sterilizer. The Sterilicuent model did not meet the requirement and has a footprint of 2160 in<sup>2</sup>.
8. Operator Controls. All four sterilizers met this requirement.
9. Sterilization Cycles. The Tuttnauer and Sterilicuent models did not meet this requirement. The pre-vacuum cycle was not available for the Tuttnauer model, and for the Sterilicuent model, there are two cycles: lumen and non-lumen, and linen materials cannot be sterilized.
10. Data Recording. All four sterilizer models met this requirement.
11. Water Use. Three of the four models met this requirement. The Sterilicuent model was not applicable because the unit does not use water.

## **8.0 Conclusion, Selection and Rationale:**

Based on the analysis and comparison of four sterilizers, the Fort Defiance steam sterilizer met all the essential characteristics and specifications for the DoD and steam sterilization remains the industry's "gold standard." The rationale for selection of steam sterilization within a CSH was because steam sterilization could sterilize all materiel in medical equipment sets, kits, and outfits. As a result of the tests performed, a commercial steam sterilizer model was identified to meet the DoD requirements and results in greater reliability and efficiency and reduced logistical burden relative to the current sterilizer. Fort Defiance Industries was competitively awarded to deliver 11 certified steam sterilizer systems for initial operating capability and training. Though the Army took the lead on this analysis, the sterilizer project has Joint relevance, as other Services have expressed interest in the outcome of Army

sterilization efforts. Both the Army and the Air Force have procured Fort Defiance Industries steam sterilizers.

The DoD maintains an active technology watch program on emerging technologies in sterilization to enhance other surgical capabilities. The program includes hydrogen peroxide, ozone, ethylene oxide, plasma, and other sterilants.

## **9.0 Plans for Modernization**

There is a plan for modernizing medical sterilization in an austere environment. The plan was implemented through the evaluation of alternative sterilizers, which included environmental and operational testing of steam sterilizers and a hydrogen peroxide sterilizer. The modernization plan is supported by an acquisition strategy that provides four steam sterilizers per CSH. There is an acquisition strategy for the Army to acquire approximately 475 steam sterilizers to support the CSH acquisition strategy for full operational capability. In support of the modernization plan, a total of 29 sterilizers have been manufactured and delivered to date. The initial low rate of production for training and delivery within the MHS is as follows: May 2016 (6 sterilizers), July 2016 (6 sterilizers), September 2016 (8 sterilizers), December 2016 (10 sterilizers), and March 2017 (10 sterilizers). There is a subsequent plan with production capacity for 25-50 sterilizers per year with funding programmed through fiscal year 2021.