

# Department of the Navy SBIR/STTR Transition Program

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MCSC-PRR-4043

Topic # N182-096

Portable Ruggedized Energy Efficient Medical Sterilizer for Field Use  
Technology Holding, LLC

## WHO

**SYSCOM:** MARCOR

**Sponsoring Program:** Forward Resuscitative Surgical System (FRSS) – AMAL 645

**Transition Target:** Expeditionary Medical Systems

**TPOC:**  
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**Other transition opportunities:** In addition to the Army and Air Force, government organizations like the Department of Homeland Security and Federal Emergency Management Agency (FEMA), non-profits and non-governmental organizations that provide disaster relief operations and remote area medical clinics like the Red Cross and Doctors Without Borders are in dire need of this device.

**Notes:** The Portable Ruggedized Energy Efficient Medical Sterilizer (PREEMS) device will be an FDA 510(k)-certified commercial medical device that can be used in civil and industrial medical applications.



<https://media.defense.gov/2015/Jul/29/2001265119/-1/-1/0/150720-M-KE800-109.JPG>

## WHAT

**Operational Need and Improvement:** Sterilization of medical and surgical tools is a critical step in minimizing the risk of infection to combat casualties during far-forward medical interventions. Current field sterilizers are large, power-intensive systems that require large amounts of clean water to operate and present a logistical burden to forward-deployed resuscitative surgical facilities. There is a need for a low-cost, person-transportable medical sterilizer capable of sterilizing small surgical tools and trays in a Role 1-2 tactical environment.

**Specifications Required:** The system internal chamber volume must be capable of holding one standard USN perforated sterilizing container (23 x 12 x 7 inches, NSN 6530-01-500-9583). The system must be hand-transportable by no more than two persons per MIL-STD-1472 (Threshold (T)), one person (Objective (O)), and must have no single exterior dimension greater than 40 inches. The system must consume no more than 800 Watts of electrical power (T), 500 Watts (O); must consume no more than 5 liters of water per use (T), 0 liters of water per use (O); and must be capable of prolonged use in all Marine Corps operational environments and meet all Marine Corps transportation and storage requirements per MIL-STD-810G. The system shall comply with all Human Factors Engineering requirements per MIL-STD-1472, including noise requirements per indoor use, operations using gloves or MOPP gear, and comply with all safety factors therein. The system must operate using 120 VAC 60 Hz/210 VAC 50 Hz single phase power (T), be capable of operating for up to 2 hours on 24 VDC hot-swappable rechargeable battery power (O). The system must be capable of performing at a minimum 18 sterilizations within a 48 hour period (T) to meet FRSS surgical requirements. The system must achieve U.S. Food and Drug Administration (FDA) 510(k) certification prior to fielding.

**Technology Developed:** Field-ruggedized medical device for providing field sterilization of surgical instruments, tools, trays, and other reusable medical devices that come into contact with patients, which is a highly portable, efficient, and water independent sterilizer for Navy applications.

**Warfighter Value:** Will provide a new medical sterilizer for the austere far-forward Roles 1 & 2 that satisfies the portability, efficiency, and durability requirements that said demand.

## WHEN

**Contract Number:** M67854-20-C-6503 **Ending on:** August 31, 2023

Milestone	Risk Level	Measure of Success	Ending TRL	Date
Operational Alpha Prototype	Low	Demonstrated sterility assurance level in laboratory environment	5	2nd QTR FY21
Ruggedization of PREEMS System	High	Satisfactory Completions of MIL-STD-810H testing	6	4th QTR FY21
FDA 510(k) approval of PREEMS System	Med	Award of 510(k) status	6	3rd QTR FY22
Operational testing of Ruggedized PREEMS System	Low	Operational test of Final PREEMS System with fully loaded surgical tools to demonstrate sterility assurance	8	3rd QTR FY23

## HOW

**Projected Business Model:** Technology Holding LLC is a Research and Development company with a focus on Energy and Environmental Solutions. Researchers at Technology Holding are actively engaged in solving transformative problems for the government and commercial clients. We are working on a wide range of topics including but not limited to advanced battery technology, carbon dioxide (CO2) conversion to fuels/chemicals, advanced catalysis, new energy processes, biomass conversion, fuel cells and energy efficiency. We will partner with an established manufacturer to the military, which is already FDA Class II supplier. A lot of the components being used in the system are already procured as COTS products by the Marines to include the case, batteries, etc.

**Company Objectives:** Already partnered with an FDA Class II supplier to the military, Technology Holding seeks meetings with military and commercial hospitals, clinics, paramedics/EMTs, search and rescue teams, disaster relief organizations, and other industries requiring sterilization of surgical instruments, tools, trays, and other reusable medical devices.

**Potential Commercial Applications:** Potential private sector users include hospitals, clinics, paramedics/EMTs, search and rescue teams, disaster relief organizations, and other industries where infection from surgical tools is a common risk.

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