

Attachment 1

Critical Operational Device Specification (CODS)

Critical Specifications: The below are critical specifications and the minimum must be met in order for the device to be considered acceptable by the government. They are separated by “minimum” and “desired” columns.

Instructions: Indicate “yes” or “no” under both minimum and desired columns below. Additional comments may be added.

1. Critical Operational Device Specifications

Number	Operational Characteristic	Minimum Required	Desired Characteristics	Meets Minimum Y/N?	Meets Desired Y/N?	Comments
1	Food and Drug Administration (FDA) Regulatory Oversight	The sterilizer shall be cleared by the FDA with a 510(k) approval if it is a Class II medical device. If the system is a Class I medical device, it shall be registered with the FDA for human use.	Minimum Requirement		N/A	
2	Core Function	The Sterilizer shall be able to sterilize all surgical instrumentation s necessary to perform clinical procedures and surgeries.	Minimum Requirement		N/A	
3	Chamber Size	The sterilizer shall have a chamber size of 12.0" dia. x 23.5" long 1.6 ft(3)	Desired Characteristics size of the chamber is 13.5" dia. x 24" long 2.0 ft(3)			
4	Operating Temperature range	The sterilizer shall have an operating temperature range of 35°F to 130°F (1.7°C to 54°C)	Minimum Requirement		N/A	

5	Sterilization Temperature	The Sterilizer shall have an exposure temperature Range of (°F/°C) 250/121-275/135	Minimum Requirement		N/A	
6	Tray Dimensions	The sterilizer shall fit standard wrapped sterilization trays with outside dimensions of 6.7" x 16.3" x 0.8"	Desired Characteristics of the sterilizer fits full-length rigid sterilization containers with outside dimensions of 23.1" x 12.4" x 8.4"			
7	Tray material	The tray shall be made of stainless steel	Minimum Requirement		N/A	
8	Indicator Light	The sterilizer shall have a power light, heat light and dry light.	Minimum Requirement		N/A	
9	Power	The power supply shall provide a balanced power source for the device, supporting both 110-120 VAC, 60Hz, and 220-240 VAC, 50Hz. It must include auto-detection and simultaneous switching capability between both voltage ranges. Additionally, if battery charging is necessary, the device must support charging for both voltage ranges.	Minimum Requirement		N/A	
10	Operational Cube and Weight:	The system shall have operational dimensions of 4 cu ft, 35 lbs.	Desired characteristic of the system dimensions 9 cu ft, 95 lbs.			

11	Water quality/ conservation	Unit requires a Distilled Water Generator	Minimum Requirement		N/A	
12	Maximum relative humidity	The sterilizer shall have a relative humidity 80%, non- condensing.	Desired characteristic sterilizer has relative humidity least than 90%, non- condensing			
13	Trade Agreements Act (TAA) Compliance	The Sterilizer and parts shall be compliant with TAA regulations.	Minimum Requirement		N/A	

2. Critical Logistic Specifications

Number	Operational Characteristic	Minimum Required	Desired Characteristics	Meets Minimum Y/N?	Meets Desired Y/N?	Comments
1	Repair Parts Support	Contractor shall provide a full listing of repair parts and distinguish the items to be considered high- failure repair parts (identified by OEM and Government Subject Matter Experts). The country of origin, availability, proprietary parts, and procurement accessibility of each item shall be provided on the list.	Minimum Requirement		N/A	
2	Warranty	The contractor shall provide a warranty for at least (1) year. This warranty shall include all parts, In-House labor, and technical support during the warranty period	Desired the contractor provides a warranty for at least 3 years. This warranty shall include all parts, In- house labor, and technical support during the warranty period.			
3	Manuals	The vendor shall provide 1 physical and 1 digital User and Operator Service Manuals with each system	Minimum Requirement		N/A	
4	Reusable Harden Transport Case	A.) The system and all accessories should be	Minimum Requirement		N/A	

		<p>securely contained in harden reusable transport cases (e.g. Hardigg, Pelican, ECS Case or Equivalent).</p> <p>B.) The system should be designed to withstand MILSTD testing in accordance with (IAW) the following paragraphs:</p> <p>501.7 High Temperature 502.7 Low Temperature 507.6 Humidity 511.7 Explosive Atmosphere 514.8 Vibration 516.8 Shock 517.3 Pyroshock 528.1 Mechanical Vibrations of Shipboard Equipment (Type I- Environmental and Type II- Internally Excited)</p>				
5	Training	<p>The vendor shall provide video training on the use of the surgical sterilizer and</p>	<p>The vendor provides service and maintenance training at 3 training events for 5 people</p>			

(End of CODS)