

Technical Specifications for Steam Sterilization (Autoclave) System for Use in Ebola Treatment Units

Equipment:	One (1) autoclave for treatment of infectious waste using pressurized steam and one (1) waste collection trolley
Capacity:	About 175 liters per load
Working pressure:	200 kPa or higher (sterilizing mode)
Working temperature:	134°C (sterilizing mode)
Footprint:	Compact footprint: 1.1 m x 1.5 m x 2 m high
Pressure vessel standard	Complies with ASME Boiler and Pressure Vessel Code Section VIII and RSA/CI-OSHA-81-2010 A2011 – certificate to be provided
Outside steam jacket	Yes
Vacuum system and vacuum requirements	Steam ejector system capable of achieving -60 kPa; meets section 8.2.2 of EN 285:2006+A2:2009 (i.e., uniform color change throughout a Bowie-Dick indicator when tested on the empty autoclave)
Required sequential modes of operation	<p>Steam mode 1 up to 180 kPa</p> <p>Vacuum mode 1 to -50 kPa</p> <p>Steam mode 2 up to 180 kPa</p> <p>Vacuum mode 2 up to – 50 kPa</p> <p>Sterilizing mode for 15 minutes</p> <p>Drying mode for 10 minutes</p> <p>Door release mode</p>
Controls	The autoclave shall be operated by manual controls (mechanical wheel and cam system) to permit manual operation following the required sequential modes of operation specified above.
Safety feature – redundant overpressure features	Overpressure safety relief valve and pressure limiting control to keep the pressure below the maximum allowable pressure
Safety feature – door interlock	Door interlock system to prevent opening door while vessel is under pressure; safety feature shall also prevent start-up if the door is not properly closed
Safety feature – emergency shut-off	Shut-off as part of the manual control
Safety feature – protection from hot surfaces	External insulation to prevent workers from coming in contact with hot surfaces (exceeding 50°C)
Safety feature – accidental vacuum breaker	Vacuum breaker valve to introduce air when breaking the vacuum
Materials of construction:	Main shell – 304L stainless steel; jacket cells – A240 type 304L stainless steel
Microbiological inactivation efficacy:	Exceeds STAATT Level III microbial inactivation efficacy criterion using the specified sequential modes of operation

	<p>described above.</p> <p>Microbial inactivation efficacy demonstrated by challenge tests using biological indicators (required criterion: 5 log reduction or higher of heat-resistant <i>Geobacillus stearothermophilus</i> spores); sterilization efficacy shall also be demonstrated using Class 5 steam integrating indicators.</p> <p>Special challenge tests: the biological indicators and steam integrators shall be placed in sample carriers which in turn shall be placed as follows: (1) in the bottom, center and top of 85 liters of infectious waste; (2) in a closed plastic bag inside another closed plastic bag containing infectious waste inside another closed plastic bag containing infectious waste; (3) inside sealed plastic specimen collection tubes inside a closed plastic bag containing infectious waste; and (4) inside syringe barrels with capped needles and plungers in place and the syringes placed at the bottom of a full sharps container that is sealed. All biological indicators must demonstrate "no growth" and all moving front bars of the steam integrators must cover the entire PASS or ACCEPT window.</p>
Door:	Quick opening sliding door with expanding gasket
Electrical:	380-400 VAC, 3-phase, 50-Hz
Electrical safety:	Meets the requirements of IEC 61010-2-040, UL 61010A-2-041, or equivalent electrical safety standard
Display indicators:	Pressure gauge readable by normal vision from a distance of (1.00 ± 0.15) m
Other indicator displays:	Light indicating power on; other displays as needed
Indicator for temperature	± 1% accuracy or better over the scale range 50°C to 150°C
Indicator for pressure	± 1.6% or better over the scale range -1 bar to 3 bar
Recording:	Recording of temperature using a graph or printout; printed records should be readable for 3 years.
Decontamination of air:	Air removed during the vacuum cycle must be decontaminated by mixing with steam to prevent release of pathogens
Loading and unloading system:	Waste is collected inside a horizontal barrel (carriage) mounted on a trolley (see below); the barrel is locked to the trolley during transport and can be unlocked and pushed into the autoclave chamber for treatment
Markings:	Markings for safety shall comply with ASME BPV Code Section VIII
Required auxiliary equipment:	
Steam generator	24 kW steam generator (boiler) mounted under the autoclave chamber
Waste collection trolley with closed barrel	Autoclavable, stainless steel barrel (carriage) with cover; the barrel shall be mounted and locked onto a trolley; the trolley can be pushed up against the front panel of the autoclave

	<p>guided by floor rails; the trolley can hook onto a front panel rail on the autoclave; the barrel is designed to slide into the autoclave chamber; the barrel has a handle for removing it from the autoclave chamber</p>
<p>Other requirements:</p>	
	<p>Assistance in site preparation</p>
	<p>On-site installation</p>
	<p>Operating and service manual in English</p>
	<p>One (1) year warranty on parts and service after commissioning and acceptance</p>
	<p>On-site training provided to operators</p>