

1.SPECIFICATION OF AUTOCLAVE-HORIZONTAL-180 L

- Should be microprocessor controlled double Door Horizontal steam sterilizer with capacity of 180 liter or more

(a) Door: The sterilizer supplied should be motorized double door with fully automatic vertical sliding movement along with door safety features.

Door Safety Systems:

1. Pressure sensor system should be available in the chamber to monitor the chamber pressure. Chamber should be completely depressurized before the door seal is retracted by vacuum.
2. Door chamber should not be opened when chamber is pressurized.
3. A cycle should not start if the door is open or not properly locked.
4. Double door safety is implemented through interlocks which prevent both doors from being opened simultaneously.
5. The door seal should be made of silicone rubber gasket & on commencement of the process the door gasket is pressed against the door by steam pressure to ensure that the door remains closed during the process.
6. The door should be pneumatically operated for trouble free operation

(b) Construction:

1. **Chamber & Doors:** The chamber and doors should be made of solid, high quality 316L Stainless steel. The chamber should be jacketed to ensure the temperature uniformity in chamber. The chamber floor is slightly sloped towards an internal drain to facilitate drainage. A stainless steel mesh strainer should be provided to protect the drain port from blockage by debris. The chamber is mounted on a stainless steel framework with height adjustable feet.
2. **Surface Treatment:** The internal surface should be electro-chemically treated for high quality smooth finish to facilitate cleaning. The resultant surface should be polished to less than 0.8 µm fineness to protect against corrosion. The internal corners should be rounded off to facilitate efficient cleaning.
3. **Insulation:** The sterilizer jacket and door should be completely insulated with mineral rock wool to keep the autoclave cool on the outside. The insulation should be completely encased in a rigid removable sheet housing.
4. **Jacket:** The jacket should be made of 316L quality stainless steel. The chamber should have a warranty for 10 years.

5. **Steam Generator:** The sterilizer should have inbuilt steam generator of adequate capacity. It should be mounted under the sterilizer chamber & should be made of 316 quality stainless steel. The steam generator should have insulation of thick chloride free mineral rock wool with rigid aluminium sheet housing. It should have a built in thermostat, pressure safety valve & water level glass gauge inspection device visible from service area. The heating element should also be made of stainless steel. It should also have the automatic blow down valve & degassing system for feed water to steam generator.

(c) PIPES VALVES & COMPONENTS:

1. The piping system should be made of S.S. 316 quality. All the process valves should be stainless steel & should be pneumatically operated piston valves for longer trouble free operations. All the non standard components should be non proprietary & should be easily sourced. All the hot pipes should be properly insulated. Only the safety valves should be made of brass.

2. Primary piping & fittings should be stainless steel threaded or stainless steel triclamp fittings.

3. Primary components: 316 quality triclamps or threaded fitting components like – Manual valve, non-return valve, pressure regulator, pneumatic valves, and steam trap etc.

4. Electrical Components: the terminals & contractors should be housed in a water tight cabinet while the other electrical component should be directly mounted on sterilizer.

(d) Air Filter : A disposable air filter should be provided for filtering the atmospheric air before entering inside the chamber. The filter separation efficiency should be higher than 99.998% for particle size less than 0.3µm. Two spare filter element should be enclosed with the supply.

(e) CONTROL SYSTEM:

1. The control system should be microprocessor based PLC system specially design for sterilization application. Control system should have colour display interface at operator loading side while it should have normal interface at unloading side. Apart from main PLC based control system the sterilizer should also have additional independent monitoring & documentation system which constantly cross checks the safety systems & time

2. Multiple password access levels (specify number) should be provided to control access/operation of the machine preventing unauthorized access. These access levels should be user selectable. The control system should have CPU processor with battery back-up & non volatile memories, Digital input/output controls, analog measuring inputs & COM ports for printer & PC connectivity should be provided.

(f) TEMPERATURE AND PRESSURE SENSORS:

1. The sterilizer should have atleast 2 temperature sensors one at chamber drain & one in Jacket. It should also have 1 pressure sensor in chamber.
2. The sensors should be PT100 sensors to confirm Class A of the IEC 571 standard, with accuracy of $\pm 0.1^{\circ}\text{C}$ while the pressure sensor should have the accuracy 1% over the range of 0-5 bar.
3. Each sensor circuit should be calibrated with individual constants to correct the deviation in manufacturing and aging.

(g) ALARMS:

Automatic process checking & failure correction should be possible by the control system. The range of alarm should include over Temperature , pressure sensor failure, phase time-out, doors not properly closed, power failure (less than 10 sec should be ignored), Continuous self checking of all the safety devices, low water level etc should be possible. All the alarms should be audio and visual.

(h) Loading/Unloading system:

Sterilizer should have the two rails for easy loading, shelf rack with shelves (carriage), two set of fixed height loading/unloading trolleys. The rails should be of removable type to have the flexible future loading options.

(i) CYCLE DOCUMENTATION - PRINTER:

The autoclave should be equipped with an alpha-numeric printer which prints the each cycle parameter performed by the sterilizer.

(j) WATER SAVING SYSTEM:

Sterilizer should have system for water saving to limit the water usage minimum. Specify water consumption levels.

(k) VACUUM PUMP:

High capacity liquid vacuum pump for removal of air within the chamber should be provided & mounted on vibration isolator for quite operations. It should be connected to series of condensers to assist air removal & protect it from high temperatures. It should also have low water level alarm to protect it from dry run. This vaccum pump should be efficient ,reliable and long lasting.

(l) Available Cycles:

The sterilizer should work with various programs which are user selectable. Apart from standard cycles,special cycle should be programmed by an authorized supervisor code only.

(m) Programs includes:

1. Wrapped Instruments, Porous load 134°C
2. Heat Sensitive material, rubber, plastic, porous load 121 °C
3. Rapid cycle for single open instrument
4. Heavy load cycle
5. Bowie & Dick test (7 Kg), PCD test
6. Leak test

(n) The sterilizer should meet the relevant AAMI, BIS or equivalent standards. Other applicable standards should be mentioned.

System should be FDA/CE/ISI/BIS compliant.

The manufacturer should have ISO 13485:2003 or EN 285 for Large Autoclaves (Europe) or USA: ST8 – Hospital Sterilizers

(l) Distillation Plant

Sterilizer should be supplied with suitable distillation plant