# **TECHNICAL SPECIFICATION**

**PRODUCT NAME:** Pulsating vacuum sterilizer

MODEL: <u>YG-0.36 (360L)</u>



### 1.General

Pulsating vacuum sterilizer is strictly designed and manufactured in accord with GMP technical Standard. It has passed ISO9001 quality management qualification standard and ISO13485:2003 Certificate of Quality Management System for Medical Devices.

The relevant data can be saved and printed automatically.

This autoclave is suitable for pharmaceutical factory, hospital, scientific research institute and other units to sterilize and dry asepsis clothes, instruments, culture medium, etc.

### 2.Size & Utilities

Design Pressure	0.245Mpa	Vacuum	-0.095Mpa
Working Pressure	0.22Mpa	City Water supply pressure	0.2-0.3Mpa
Design Temperature	139℃	Compressed Air supply pressure	0.6-0.8Mpa
Working Temperature	<b>134</b> ℃	Steam pressure	0.4-0.8Mpa
Heat equilibrium	≤±1°C		

Model	Overall Size W*H*D (mm)	Inner Size W*H*D(mm)	Steam (kg/cycle)	•	City water (kg/cycle)		
YG-0.36	1195*1220*1720	1000*600*600	25	0.1	150	1.5	760

## 3.Structure and performance features

- (1) Adopting the jacketed structure, a full dimpled jacket shall be provided wrapping around the chamber in order to avoid steam condensation and facilitate, and proper temperature distribution. which can be peripherally heated uniformly, preventing material from non-uniform heating.
- (2) Chamber: the chamber is made of SUS316L, According to mechanical and chemical treatment, the chamber surface is bright, beautiful and corrosion resistant. Two stainless steel rail guides in the chamber shall be provided as tracks for the loading cart.
- (3) The insulating layer is made by aluminium silicate which is the best insulating material, and the equipment is rectangular, having stainless steel decorating cover

- (4) Doors: The autoclave is designed as pass-through (double door) autoclave.
  - Both doors cannot be opened simultaneously.
  - > The door seal is the inflatable type, pressurized with compressed air, and can withstand the chamber temperature and pressure.
  - > The doors shall have a safety mechanism to prevent opening of the door when the chamber is hot or pressurized or when the autoclave is in operation.
  - > Sterilization cycle can start only after the door is fully closed and locked.
- (5) Pipeline system is consisted of air filter, vacuum pump, pneumatic valve, etc.
  - Air filter for is using PALL company brand. The performance is excellent with no medium break or contamination unload.
  - Angle type of pneumatic valve: strong switch valve, without any mistake, remote compressed gas control. with the inner chamber of interlinked valve for stainless steel clamp type seat.
  - > Vacuum pump:The autoclave include a liquid ring vacuum pump to obtain vacuum in the chamber.
- (6) Control system: PLC+ HMI control + Micro-printer. a timely data printing, should be able to default one or more sterilization cycle. Electric apparatus system adopts domestic or imported components whose performance is stable and reliable.
  - When automatic controller in the failure of the circumstances, the security device makes the sterilization indoor pressure safety in the pressure of the atmosphere to the back of the state, and allow the loading door can be opened.
  - In order to maintenance, test and emergency needs, manual operation can be through the use of access control tools to complete.
  - The master controller system: can set the user name and password, also can set up different user access. A manager, users, maintainers triple interface function. Managers can be used according to different level, set on use of a password, ensure use safety, prevent that due to improper operation or modify the program brings experiment.
  - > Touch screen: display work process parameters, control is simple, the operation is convenient. Interface has the following functions:

Display shows the process of sterilization cycle state, time,pressure,temperature,two-door airtight state, the running records, printing, etc.

## (7) Material Loading System

Loading cart (Rack):

Sterilization cart made of SUS 316L stainless steel is provided for loading, sterilization and unloading the items. The cart have support guides at different levels in order to place the product support trays.

Transfer trolley:

Transfer trolley made of SUS 304 stainless steel is provided for transporting and loading/unloading the sterilization cart to and from the chamber. For proper operation of a double door autoclave, 2 units are recommended.

- (8) The system have an E-Stop mechanism designed to stop all physical movement of the equipment immediately.
- (9) The GMP confirming connecter fixed can provide the GMP validation for the customer freely.

#### 4.Process flow

The autoclave control with optional automatic operation or manual operation.

We will preset many programs for customers.

All these programs are editable by users.

- Bowie Dick test
- Chamber leak test
- Sterilizing program for textiles, such as clothes and medical packages.
- Sterilizing program for instruments

## Dynamic pre-vacuum:

Pulling vacuum in the chamber, and then while still pumping out air, allowing steam into the chamber. This way, the air is removed from the chamber with no heat build-up on the material.

#### Pressure pulsing:

The aim is to provide rapid removal of non-condensable gases and condensates and to pre-heat the material prior to sterilization.

# Sterilization:

Steam injection into the chamber until sterilization temperature is achieved. When the working pressure and temperature are obtained in the chamber, sterilization time begins. If the temperature falls below the minimum sterilizing temperature.

# > Drying:

Pulling vacuum in the chamber, and then start drying time count while vacuum is still being made.

Throughout the drying process, the jacket is kept at working pressure with hot steam. In this way, the high vacuum and heat radiation from the chamber walls helps drying the material.

## Cooling:

Once sterilization is done, slow vacuumize made until pressure drops to 1.100 mbar. After that, while the vacuum system is still working, vacuum break valve opens preventing drop of pressure and thus accelerating the cooling process. The phase ends when cooling ending temperature is reached.

# **CONFIGURATION LIST**

No.	Name	Model	Manufacturer	Remark
I	Main body	01-00		
1	Chamber	01-01	WANROOEMED	Made of SUS316L
2	Door sealing ring	01-03	Runde China	Medical used silicon rubber
I	Door	02-00		
1	Door board	02-01	WANROOEMED	Made of SUS304
2	Door proximity switch	CLJ series	CoRon China	Sharp,easy to install
3	Safety interlock device	02-02	WANROOEMED	High temperature resistance
ш	Control system	03-00		
1	Sterilizing software	03-01	WANROOEMED	

2	PLC	FX series	MITSUBISHI, Japan	Reliable running, high stability,	
3	Touch screen	TP106	TRE	LCD Color touchscreen for easy operation	
4	Micro printer	WH40-SA	Weihuang, China	Stable performance	
5	Temperature sensor	902350-22	JUMO, Germany	Pt100,A level precision, temperature equilibrium $\leq 0.15^{\circ}\mathrm{C}$	
6	Pressure transmitter	MBS-3000	DANFOSS, Denmark	High control accuracy, and reliability	
7	Pressure controller	SNS series	TOKYO Japan	Reliable, performance, accurate control	
8	Solenoid valve	2V025-06	AMISCO Italy	Integration installation with manual operation, good performance	
9	Data recorder	ARS2101	ARS China	Stable performance	
IV	Pipe system	04-00			
1	Air filter	KA series	PALL USA	Diameter 0.2μm	
2	Angle pneumatic valve	514 series	GEMU Germany	Stable performance in practical operation	
3	Vacuum pump	SK series	YUHUAN China	Quiet, high vacuum rate	
4	Steam trap	CS47H series	ZHUANGFA	Quality is stable, good technical performance	
5	Pressure gauge	YTF-98ZK	Brighty, China	Simple structure and good reliability	
6	Safety valve	A28-16P	Guangyi China	High sensitivity, unlock pressure 0.1-0.3Mpa	
V	Loading system	05-00			
1	Loading cart	05-01	WANROOEMED	Made of SUS316L	
2	Transfer trolley	05-02	WANROOEMED	Made of SUS304	