



**HANGZHOU BOCON MECHANICAL
& ELECTRICAL EQUIPMENT Co.ltd**



HZBOCON – a professional in EO sterilization

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GROUP OVERVIEW

Our history
Experience
Companies

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STERILIZATION HARDWARE

EO Sterilization
Parameters
Sterilizer chamber
Preheating &
Aeration rooms
Scrubber
Auxiliaries

3

STERILIZATION SOFTWARE

Controls systems
Special data report
system
Network Data
connection

4

CASE HISTORIES & OUR AWARDS

Factory sterilization
Sterilization service
as business



HZBOCON – a professional in EO sterilization

Founded in Hangzhou from industrial control system assembling and programming



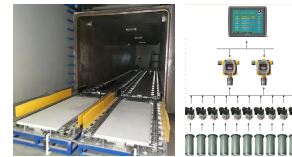
Local control box for sterilizer was developed



Steam generator and Circulation fan were developed



EO monitor system and Conveyor system were developed



Temperature & humidity combined sensor developed



2006

2007

2009

2011

2013

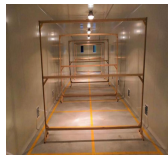
2015

2016

2018

2021

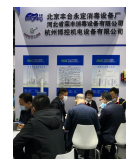
2023-24



Sterilizer components development started



Door controller, EO vaporizer
Water tank are developed



Supply of sterilizers to International markets



Finish the 1st round of standardization



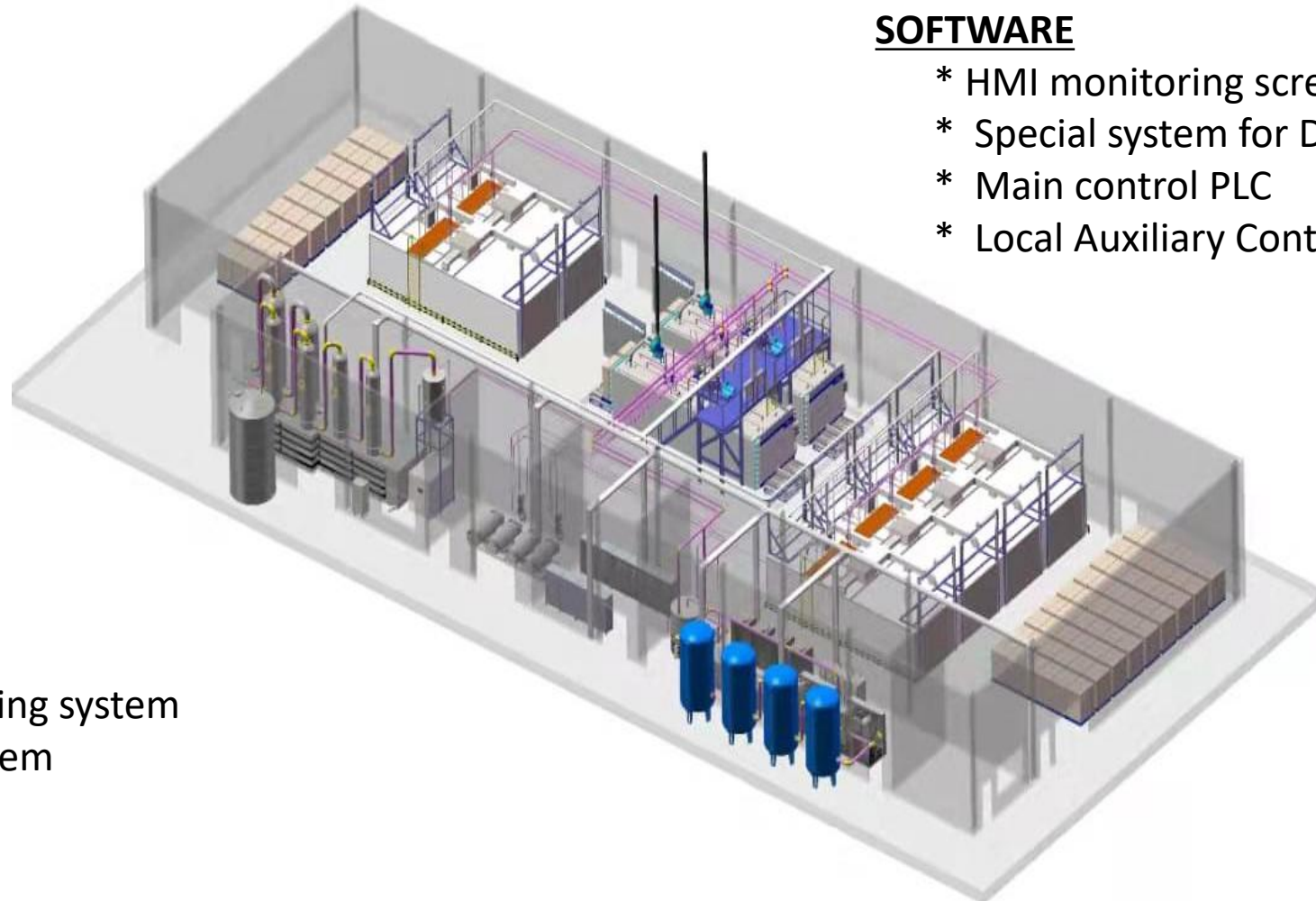
New markets
Update of soft- & hardware



EO Sterilizer as a Turn Key Solution

HARDWARE

- * ETO sterilizer chamber
- * preheating room
- * Aeration Room
- * Scrubber
- * Conveyor
- * control system cabinet
- * local control box
- * Door controller
- * Water tank
- * EO vaporizer
- * Medical steam generator
- * Internal circulation fan
- * workshop EO gas monitoring system
- * Sterilization conveyor system



SOFTWARE

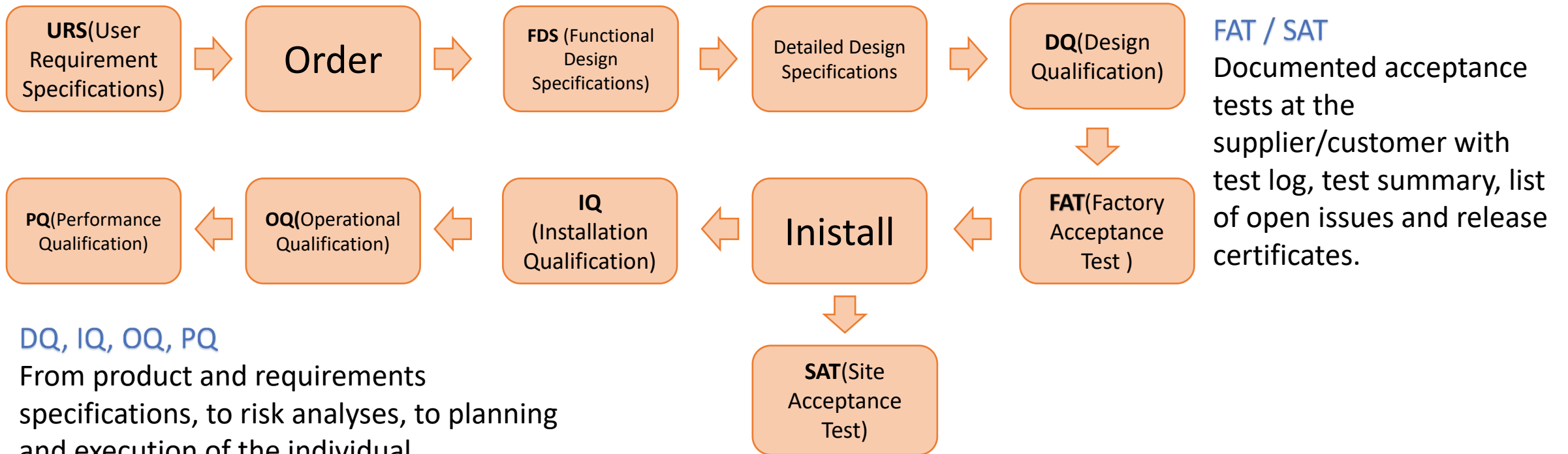
- * HMI monitoring screen
- * Special system for Data Reporting
- * Main control PLC
- * Local Auxiliary Control PLC



With you every step of the way

DESIGN SPECIFICATION (DS)

Specification of the technical basis and specification of the limiting factors that are to be considered during development, construction and assembly. DS ensures that all customer requirements and current valid standards from cGMP, EU, EN ISO and the FDA are satisfied.

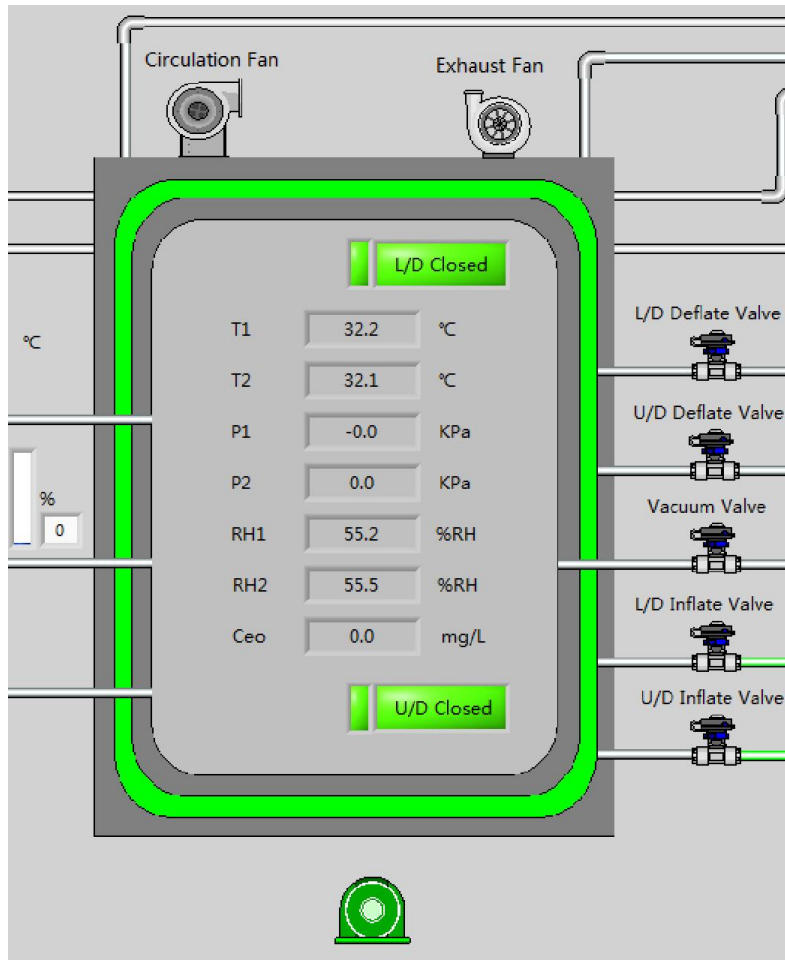


DQ, IQ, OQ, PQ

From product and requirements specifications, to risk analyses, to planning and execution of the individual qualification steps, we takes care of everything implementation requires.



Parameters control is the core of sterilization



Temperature uniformity

achieve $t^{\circ}\text{C}$ value after 1 h, $\Delta T = T_{\text{max}} - T_{\text{min}} \leq 3^{\circ}\text{C}$

Proper sealing (Pressure test)

loss of ≤ 2 kPa from - 95 kPa in 10h

loss of ≤ 2 kPa from + 85 kPa in 10h

Thermal insulation, energy saving:

Sterilizer main body heat preservation

Outsourcing plate & environmental temperature -
no obvious heat dissipation



Parameters control is the core of sterilization

Uniformity

Ideal equilibrium of temperature, humidity, sterilization agent concentrations due to the reasonable gas flow design

Safety & reliability

Plenty of stress calculation enables the sterilizer to meet the technological requirements of the continuous pressure

EO Sterilization Process Record 灭菌过程记录							
Sterilization Lot# 灭菌批号		S1-20150910-25N5					
Sterilizer Operator 操作员		a					
ETO Tank # 钢瓶号		a					
Cycle# 灭菌工艺号		test1					
Sterilizer# 灭菌机编号		Sterilizer #1					
Sterilization Process 灭菌过程		Start time 开始时间	End time 结束时间	Time elapsed(min) 耗时			
Heating 加热		2015-09-17 21:32	2015-09-17 22:45	73			
Keeping warm 保温		2015-09-17 22:45	2015-09-17 22:55	10			
Prevacuum 初始真空		2015-09-17 22:55	2015-09-17 23:05	10			
Leak test 泄漏检测		Beijing FengTai YongDing Disinfectant Equipment Factory Hangzhou Bocon Electrical & Mechanical Co., LTD					
Nitrogen replacement 氮气置换		Sterilizer					
Steam injection 加湿		EO Sterilization Process Record					
Humidity dwell 加湿平衡		Sterilization Lot# 灭菌批号					
EO injection 加药		20161228					
N2 injection 氮气填充		Customer Name 客户名称					
EO dwell 灭菌		shenzhen					
nitrogen washing 氮气清洗		Sterilizer Operator 操作员					
air washing 空气清洗		xinyi					
flushing 通风		EO Tank# EO钢瓶号					
ETO Engineer Reiew(signature/date):		chen					
QA Manager(signature/date):		1					
		Sterilizer# 设备编号					
		BCNST1#					
Process Parameters		Set Value	Actual Value min max		Allowed Value min max		Pass/Fail
Chamber Temperature starting vacuum (°C)		50.0	51.0	0	50	Fail	
Vacuum Value (KPa)		50.0	51.3	20	50	Fail	
Vacuum process times (Mins)		-50.0	-50.1	20	15	Fail	
Leak test time (Mins)		---	10	40	-68	Fail	
Pressure rise in leak test (ΔKPa)		90	90	8	12	Fail	
Total humidity injection rise (ΔKpa)		---	0.8	0	3	Pass	
Humidity dwelling time (Mins)		---	1	0	5	Pass	
EO pressure injected (ΔKpa)		---	5	-12	-8	Fail	
EO weight injected (ΔKg)		0.5	5.4	-72	-68	Fail	
EO injection temperature (°C)		0.5	0.0	0	5	Pass	
Temperature during EO exposure (°C)		91.8	91.9	0	10	Fail	
Pressure of EO exposure (KPa)		---	9	20	50	Fail	
Humidity of EO exposure (%RH)		50.0	51.3	54.5	20	50	Fail
EO Concentration during EO exposure (mg/l)		50.0	51.5	54.5	20	60	Pass



Sterilizer chamber

Size: 1m³, 2m³, 5m³, 8m³, 11m³, 12m³, 15m³, 20m³, 26m³, 30m³, 50m³, 100 m³

Stainless steel SUS304, $\delta=8\text{mm}$ welded body

Stainless steel SUS430, $\delta=1.5\text{mm}$ outer cover

Highly effective Aluminum silicate fiber thermal insulation

All pipes, which contact EO gas, are made of SUS304





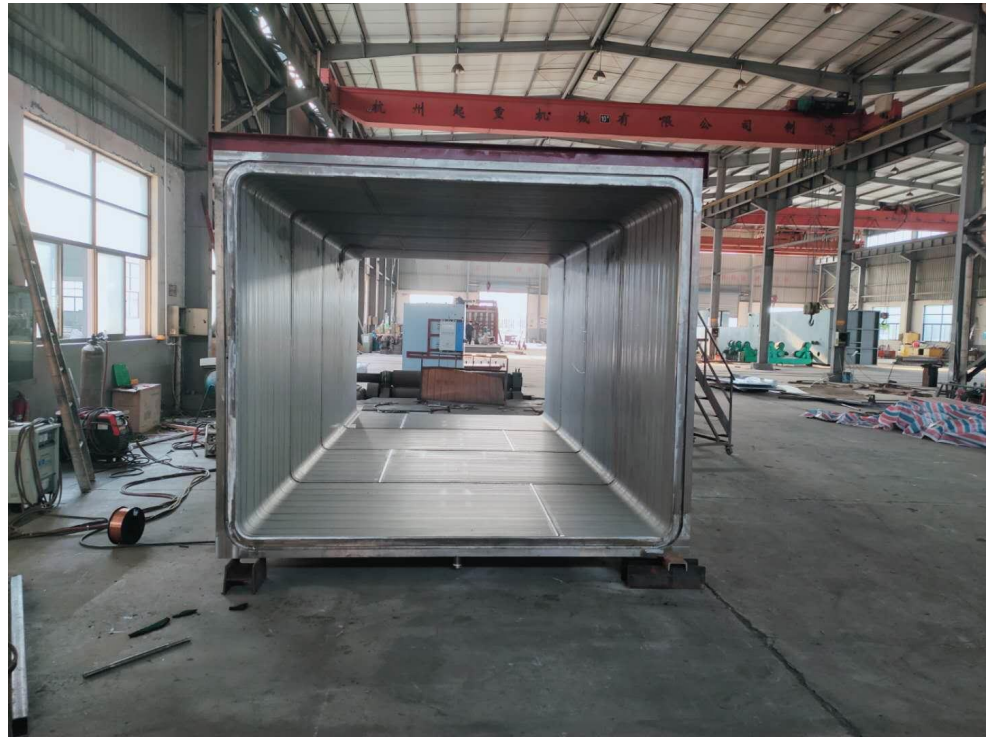
Sterilizer chamber size



Volume	(L*W*H)	Sliding door (L*W*H)		Revolving door (L*W*H)		Lifting door (L*W*H)	
	Internal Size	Outer size	Shipment size	Outer size	Shipment size	Outer size	Shipment size
1m3	1400*700*1000	N/A	N/A	1750*1270*1520	1750*1270*1520	N/A	N/A
2m3	1650*1000*1200	2070*2520*1720	2070*1360*1720	2000*1570*1720	2000*1570*1720	N/A	N/A
3m3	1400*1350*1700	1820*3220*2270	1820*1710*2270	1750*1920*2220	1750*1920*2220	1820*1910*3950	1820*1910*2220
4.5m3	2000*1350*1700	2420*3220*2270	2420*1710*2270	2350*1920*2220	2350*1920*2220	2420*1910*3950	2420*1910*2220
5m3	2250*1350*1700	2670*3220*2270	2670*1710*2270	2600*1920*2220	2600*1920*2220	2670*1910*3950	2670*1910*2220
6m3	2700*1350*1700	3120*3220*2270	3120*1710*2270	3050*1920*2220	3050*1920*2220	3120*1910*3950	3120*1910*2220
8m3	3500*1350*1700	3920*3220*2270	3920*1710*2270	3850*1920*2220	3850*1920*2220	3920*1910*3950	3920*1910*2220
10m3	4500*1350*1700	4920*3220*2270	4920*1710*2270	4850*1920*2220	4850*1920*2220	4920*1910*3950	4920*1910*2220
15m3	5500*1350*2000	5920*3220*2570	5920*1710*2570	5850*1920*2520	5850*1920*2520	5920*1910*4550	5920*1910*2520
20m3	7500*1350*2000	7920*3220*2570	7920*1710*2570	7850*1920*2520	7850*1920*2520	7920*1910*4550	7920*1910*2520
26m3	9600*1350*2000	10020*3220*2570	10020*1710*2570	9950*1920*2520	9950*1920*2520	10020*1910*4550	10020*1910*2520
30m3-1	11300*1350*2000	11720*3220*2570	11720*1710*2570	11650*1920*2520	11650*1920*2520	11720*1910*4550	11720*1910*2520
30m3-2	5600*2700*2000	6060*6260*2580	6060*3280*2580	6060*3450*2580	6060*3450*2580	6060*3380*4730	6060*3380*2580
35m3-1	13000*1350*2000	13420*3220*2570	13420*1710*2570	13550*1920*2520	13550*1920*2520	13420*1910*4550	13420*1910*2520
35m3-2	6550*2700*2000	7010*6260*2580	7010*3280*2580	7010*3450*2580	7010*3450*2580	7010*3380*4730	7010*3380*2580
48m3-1	12850*1400*2700	13270*3320*3270	13270*1760*3270	13200*1970*3220	13200*1970*3220	13270*1960*3950	13270*1960*3220
48m3-2	6550*2700*2700	7010*6260*3280	7010*3280*3280	7010*3450*3280	7010*3450*3280	7010*3380*6130	7010*3380*3280
52m3	13900*1400*2700	14320*3320*3270	14320*1760*3270	14250*1970*3220	14250*1970*3220	14320*1960*3950	14320*1960*3220
55m3	7500*2700*2700	7960*6260*3280	7960*3280*3280	7960*3450*3280	7960*3450*3280	7960*3380*6130	7960*3380*3280
63m3	8650*2700*2700	9110*6260*3280	9110*3280*3280	9110*3450*3280	9110*3450*3280	9110*3380*6130	9110*3380*3280
70m3	9700*2700*2700	10160*6260*3280	10160*3280*3280	10160*3450*3280	10160*3450*3280	10160*3380*6130	10160*3380*3280
78m3	10750*2700*2700	11210*6260*3280	11210*3280*3280	11210*3450*3280	11210*3450*3280	11210*3380*6130	11210*3380*3280
86m3	11800*2700*2700	12260*6260*3280	12260*3280*3280	12260*3450*3280	12260*3450*3280	12260*3380*6130	12260*3380*3280
93m3	12850*2700*2700	13310*6260*3280	13310*3280*3280	13310*3450*3280	13310*3450*3280	13310*3380*6130	13310*3380*3280
101m3	13900*2700*2700	14360*6260*3280	14360*3280*3280	14360*3450*3280	14360*3450*3280	14360*3380*6130	14360*3380*3280



Sterilizer chamber



Strengthen carbon steel U-bars

Process testing nozzles with s/s handball valve

Comfortable lighting for loading /unloading operation

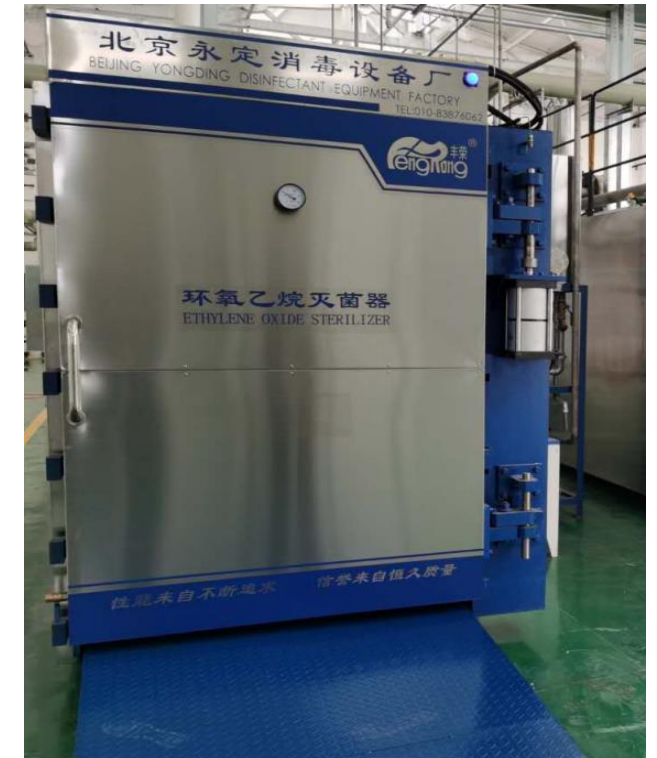
Sealing gaskets and seals, which would contact EO gas are made of polytetrafluoroethylene or silicone rubber

Door seal is made of silicone rubber nitrogen filling , with a non-return valve during power off, avoiding the gas leaking



Sterilizer chamber door system

Normally there are 3 kinds of doors: siding door , lifting door and revolving door.
no need to vacuum when open the door, door system has the pressure test function





Preheating room



Temperature (± 3 °C) and humidity (5 ÷ 10%) uniformity

Forced air circulation and positive pressure inside the room to speed up heat transfer and heat penetration

Precise control, high level of automation, parameters records

Relatively simple construction and fast installation

Easy operation and convenient maintenance

Low investments, low use cost and energy consumption

Preheating room and ETO sterilizer volume ratio is normally 1:1



Aeration room

Forced hot air cleaning and negative pressure keeping accelerates the residual ethylene oxide parse out

Stop heating, exhaust fan running to avoid inhaling EO during loading and unloading for more safety

Temperature uniformity of ± 5 °C , exhaust temperature control for maximum energy saving

Low investments, low energy consumption and use cost, easy operation and convenient maintenance

Preheating room and ETO sterilizer volume ratio is normally 1:1, 3:1 or 4:1





Scrubber

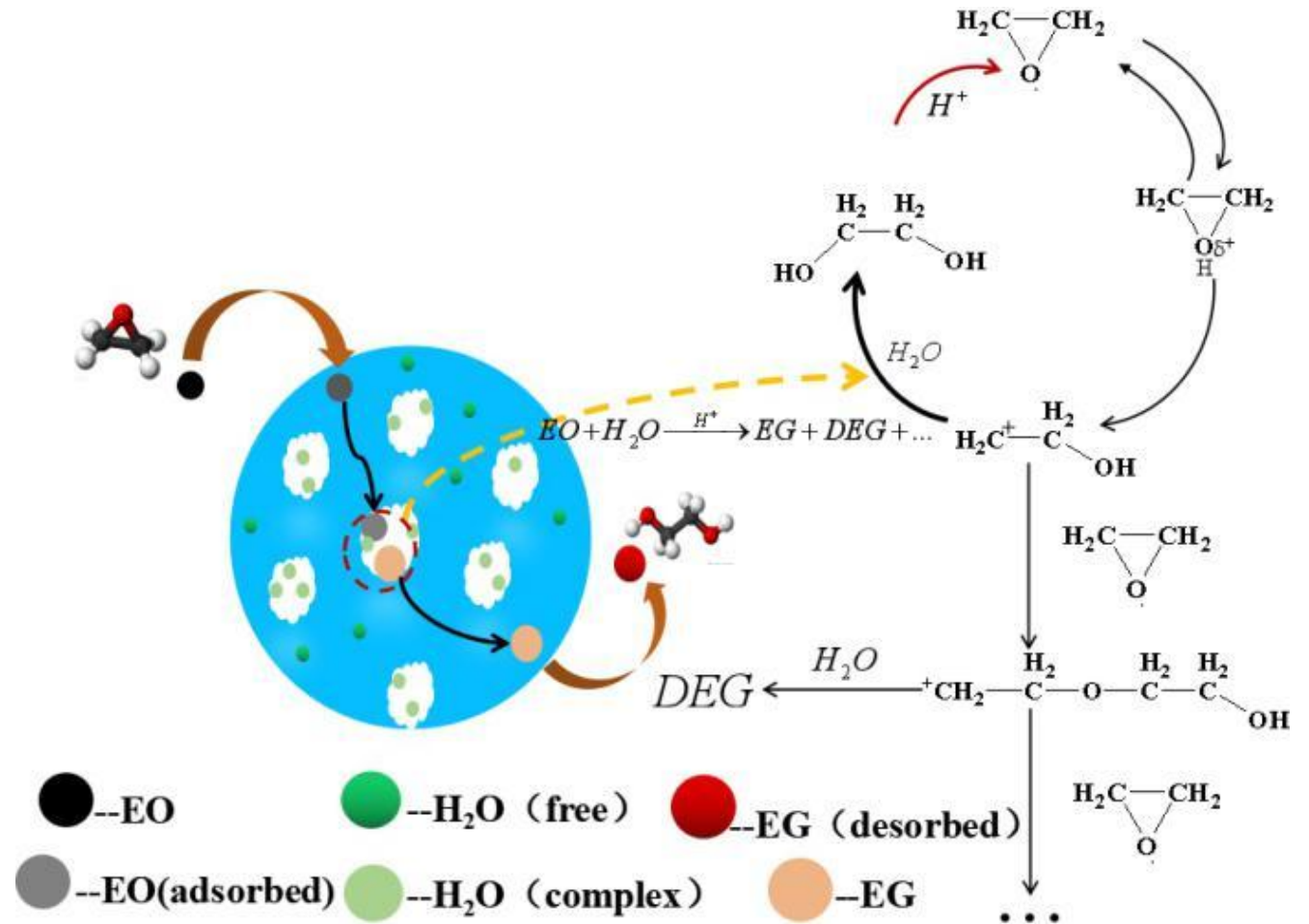




Scrubber

The process principle is that EO and water can react under the catalytic action of acid to generate ethylene glycol (EG), diethylene glycol (DEG), triethylene glycol (TEG), little polyethylene glycol and trace polyester polyol

The EO and water can dissolve in any proportion, then EO tail gas can be treated by reaction absorption tower





Scrubber



Can meet two kind of Emission standard :
 $\text{NMHC} \leq 40\text{mg/m}^3$ or $\text{NMHC} \leq 80\text{mg/m}^3$

All explosion-proof anticorrosive equipment, DII BT4, and the protection rating is IP55

Motors, pressure transmitters & temperature sensors are of flame-proof type, and explosion-proof grade

Siemens PLC control with touch screen on-line monitoring system with simple operation

Micro negative pressure operation

Easy maintenance, low energy consumption

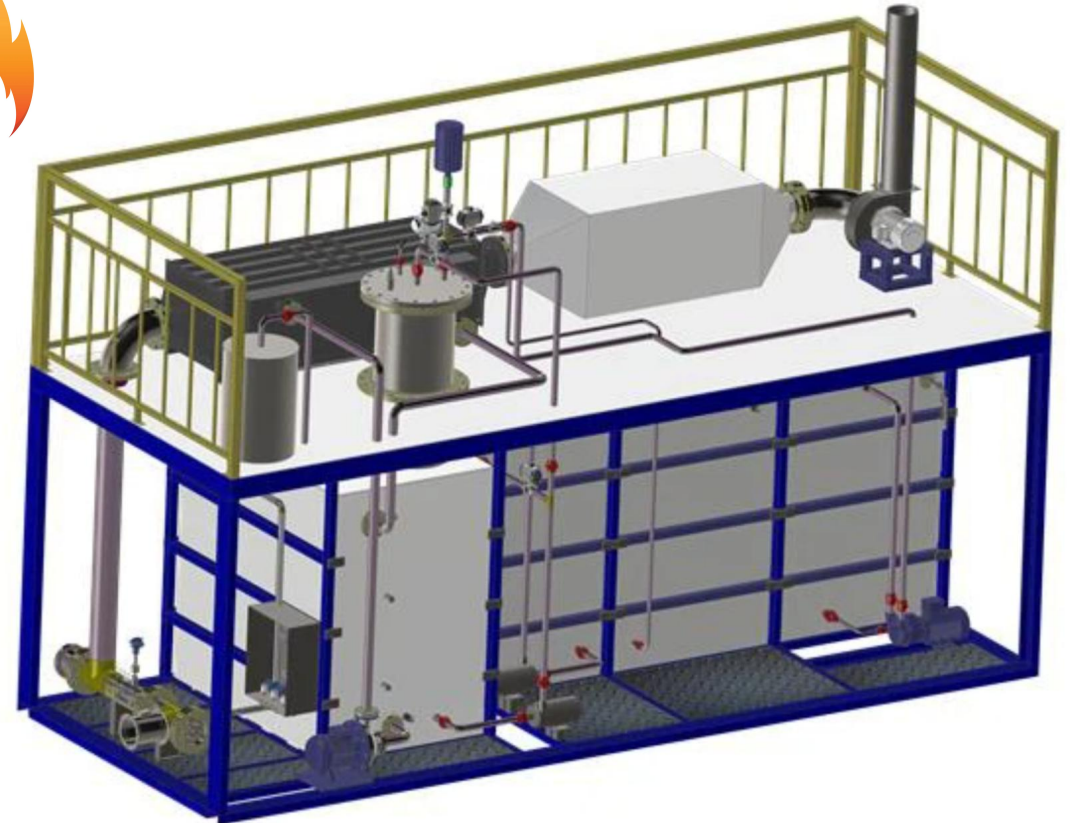


BEGCL Sterilizer EO Energy Recycling

Patent No. ZL20172 0292727/0

Scrubber produces ethylene glycol, Chemical pump pumps it to energy recovery device, by burning energy recovery device, the heat generated by the recycling in a heat exchanger, saves a lot of energy for water heating

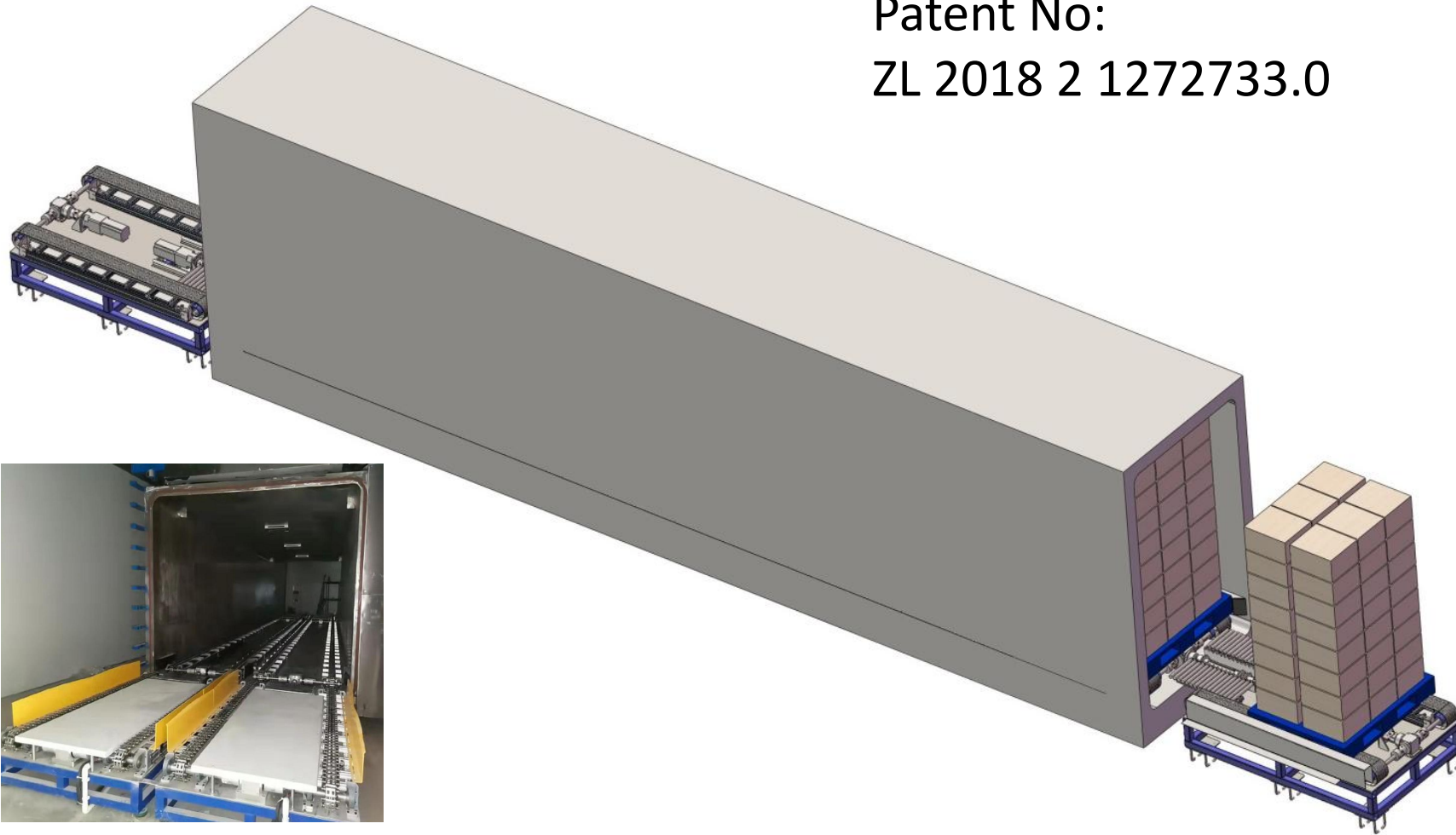
EO toxic ingredients in tail gas is removed completely, lto 100%





Sterilizer chamber conveyor

Patent No:
ZL 2018 2 1272733.0





Sterilizer chamber conveyor



Ensures high precision at loading and unloading
Stainless steel rollers, ATEX type motors

Option 1: Passive EO Sterilizer transmission mode, which mainly relies on the operator to transfer the products in or out by means of tray , pushing into or outside of the chamber.

Option 2: Pneumatic EO Sterilizer Automatic Transmission Device

Option 3: Tracked ETO Sterilizer Automatic Transmission Device

Option 4: Fully automatic based on AGV solution



Sterilizer control system

Split type composition: separate power cabinet +Local control box+ computer desk

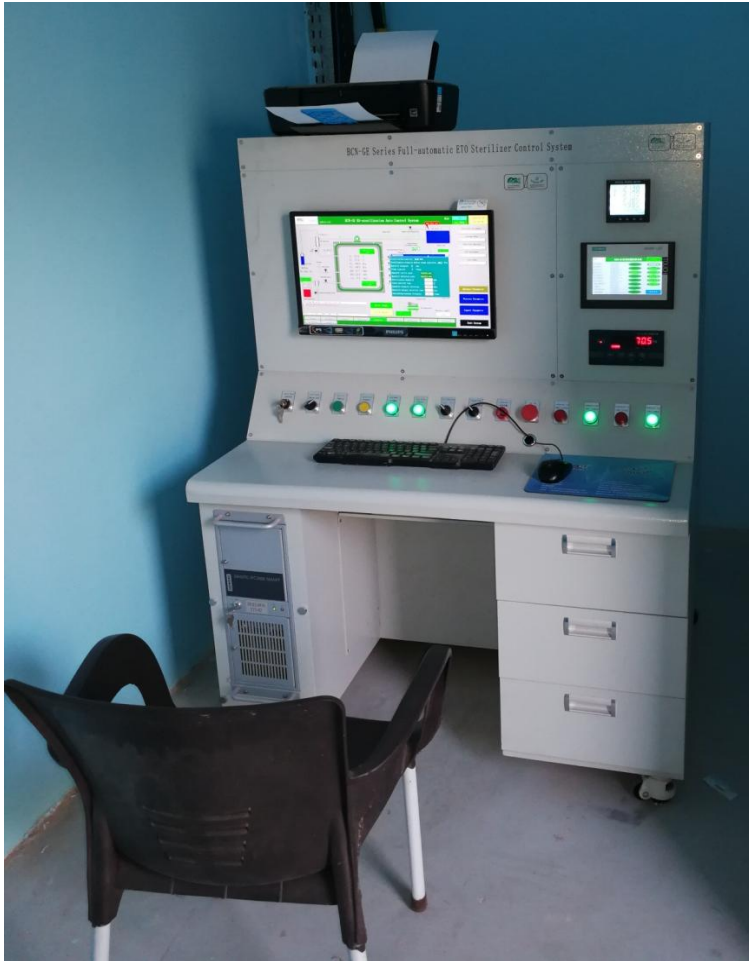
The split cabinet is suitable for the occasion where the power cabinet needs to be separated from the computer due to local regulations etc.

When power cabinet needs to be centralized in the power room, but the control computer needs to be centralized in the central control room





Sterilizer control system



Integrated type composition: Power cabinet with IPC +Local control box

It is suitable for occasions where there is not enough space to use, because the integrated cabinet integrates the functions of computer desk, document cabinet and power cabinet.

It is especially suitable for single control system layout, and will not appear inconsistent.



Local control box

Strong anti-interference ability:

The signal wire directly enter into local control box, it avoids effectively the interference of power cable to signal cable.

Distributed design:

It's easy to install on site, save a lot of signal wires, labor and time expenses for installation workers.

Modular design:

The local box does not involve any control of power components, so it is very convenient to realize the standardization of the whole sterilization control system and realize the modular design and production





Sterilizer door controller



Patent No.: 201xxxx73506.6

Conforms to the latest ISO11135-2014 standard

One door controller controls one door independently, basically without the control of other PLCs or devices

The gate can be operated as an independent device or as a slave station controlled by the central control

Stop and maintaining any position of the door function

Touch screen display, showing the door status, temperature, pressure, humidity, other sterilization operation parameters inside the sterilization chamber





Water heating tank

Multi-function heating mode:

Heat Exchange Heating Mode: by hot water or hot air

Steam mixing heating mode: steam is mixed into heated water by steam mixer for heating mode

Hot water mixing heating mode: high temperature water mixes with heated water for heating mode

Electric heating mode: water can be heated directly through an electric heating tube

Wall hanging type, to be installed on the side wall of the chamber or other convenient walls





EO vaporizer



Two installation modes : ground based and wall mounted

Mainly is stainless steel, avoid easy to get rusted

Easy maintenance : the heat exchange core inside the body can be taken out, cleaned and repaired separately



Steam generator



Pure water generator to prevent scale, provide easy cleaning and maintenance, energy saving and improve product reliability

Automatic cleaning function

Core components are made of stainless steel

Steam pressure, liquid level display, automatic control of water level and the pressure in the furnace

The electronic control and mechanical parts are integrated to facilitate installation and connection, and the electronic control parts are sealed and isolated

Modular assembly design for easy expansion and maintenance



Internal circulation fan

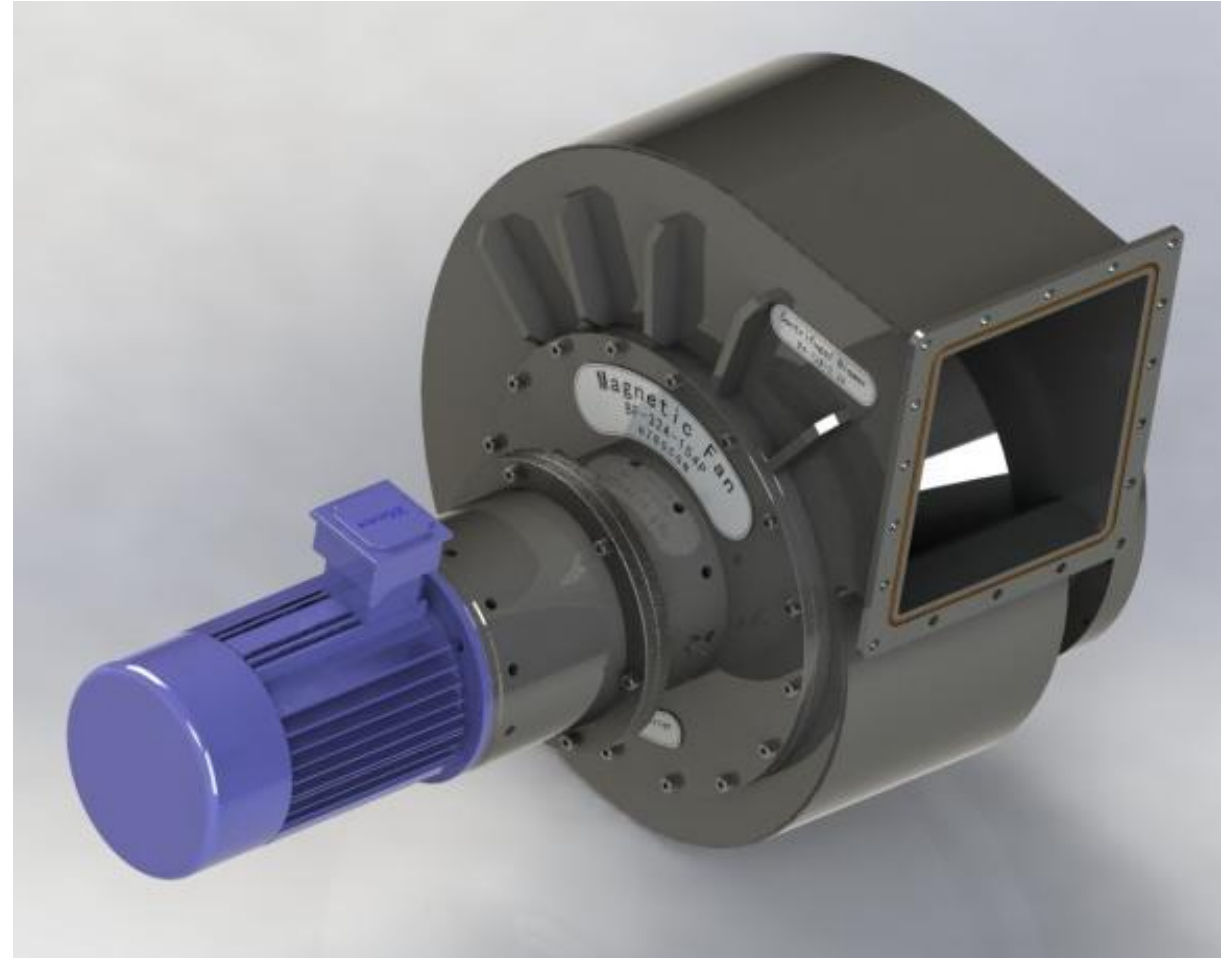
BZBOCON design

SUS304 Stainless steel shell and impeller is pure aluminum

Magnetic coupled structure

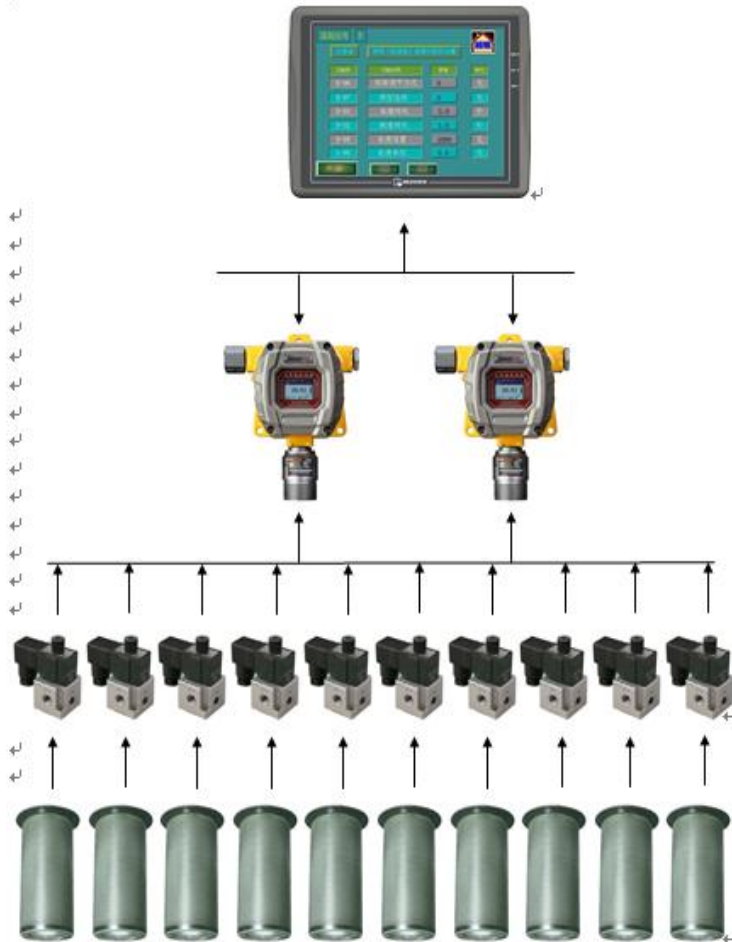
Design life is at least 5 years.

Continuous working time is two years





Workshop EO gas monitoring system



The system tests the EO concentration of the monitoring points by sampling pump polling, to establish the EO concentration system for the whole workshop.

Less EO sensors are needed, 4 sensors at most, 2 of PEL and 2 of LEL for the whole workshop, with inspection of many points. Normally : 8 points, 32 points

The chamber above 50m³ meets GMP standard and 21 CFR Part 11 standard

Compliance with EN1422-2014, YY0503-2016

Compliance with ISO11135-2014, ISO13485-2016



Control composition

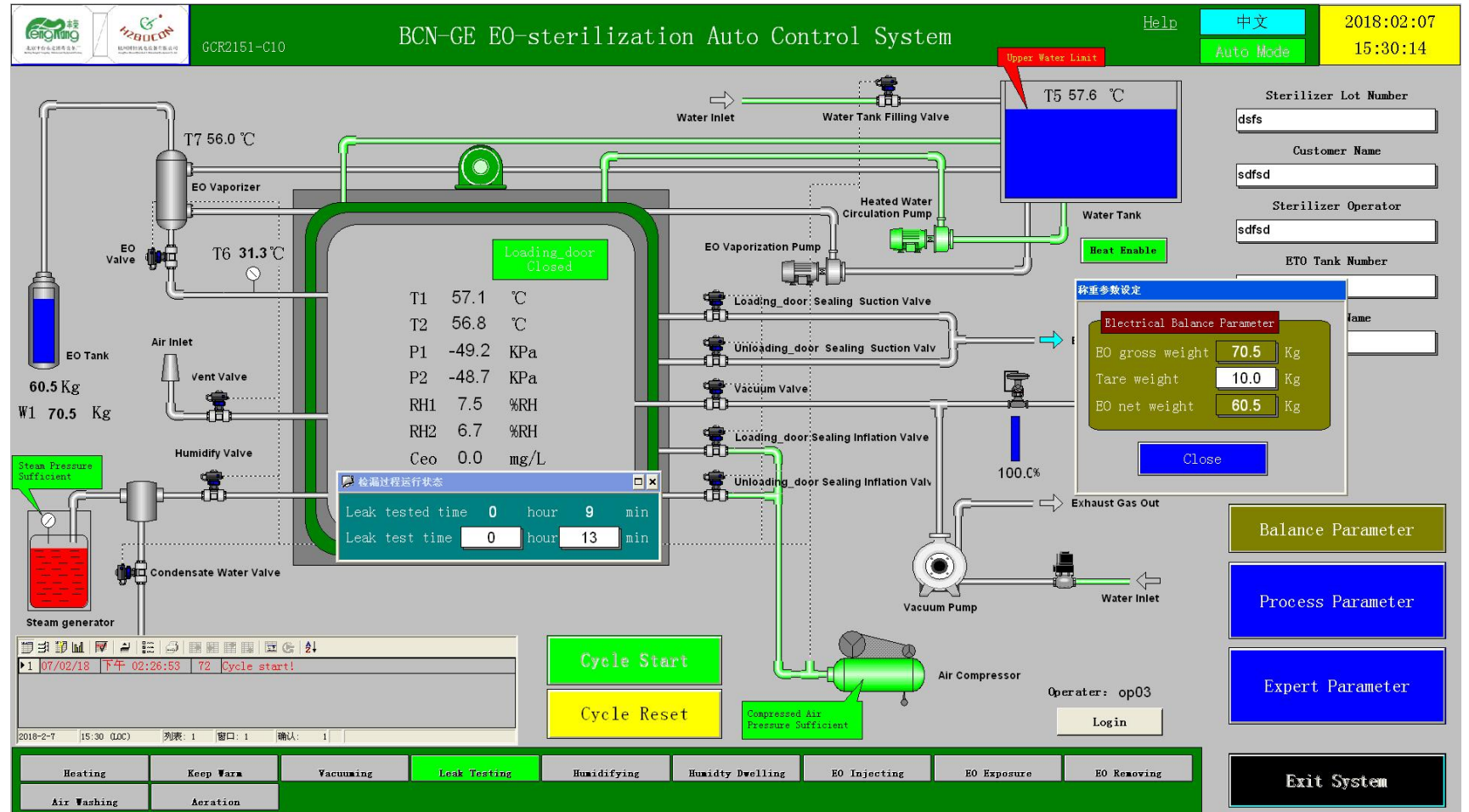
Monitoring screen
HMI

Special System for
Data Reporting

Main control PLC

Local Auxiliary
control PLC

Local operation box





Special Data Report System



Historical curve software

Management function of process formulation

Dynamic device operation status display support

Process pop-up window function support to make system running process clear at a glance

Query and print function of historical curve support



Special Data Report System

Beijing FengTai YongDing Disinfectant Equipment Factory
Hangzhou Bocon Electrical & Mechanical Co.,LTD Sterilizer

EO Sterilization Process Record						
Sterilization Lot# 灭菌批号	20221228					
Customer Name 客户名称	shenzhen					
Sterilizer Operator 操作员	xinyi					
EO Tank# EO钢瓶号	chen					
Cycle Name# 灭菌工艺号	1					
Sterilizer# 设备编号	BCNST1#					
Process Parameters	Set Value	Actual Value		Allowed Value		Pass/Fail
		min	max	min	max	
Chamber Temperature starting vacuum (°C) 真空起始温度 (°C)	50.0	51.0		0	50	Fail
Vacuum Value (KPa) 真空深度 (Kpa)	50.0	51.3		20	50	Fail
Vacuum process times (Mins) 抽真空时间 (Mins)	-50.0	-50.1		20	15	Fail
Leak test time (Mins) 泄漏检测时间 (Mins)	—	10		40	-68	Fail
Pressure rise in leak test (ΔKPa) 总泄漏压力变化量 (ΔKPa)	90	90		8	12	Fail
Total humidity injection rise (ΔKpa) 加湿压力变化量 (ΔKpa)	—	0.8		0	3	Pass
Humidity dwelling time (Mins) 加湿驻留时间 (Mins)	—	1		0	5	Pass
EO pressure injected (ΔKpa) 加药压力变化量	—	5		-12	-8	Fail
EO weight injected (ΔKg) 加药重量变化量	0.5	5.4		-72	-68	Fail
EO injection temperature (°C) EO注入温度	0.5	0.0		0	5	Pass
Temperature during EO exposure (°C) EO暴露阶段EO温度	91.8	91.9		0	10	Fail
Pressure of EO exposure (KPa) EO暴露阶段柜内压力	—	9		20	50	Fail
Humidity of EO exposure (%RH) EO暴露阶段柜内湿度	50.0	51.3	54.5	20	50	Fail
EO Concentration during EO exposure (mg/l) EO暴露阶段柜内EO浓度	50.0	51.5	54.5	20	60	Pass

Process Data Auto-Sum Function

Up to 80 automatic summary items are currently supported

Completely liberates operators from data auditing and summary work

Predefined automatic summary function depending of customers' needs

The automatic Pass/Fai judgment function of the system (can automatically judge the result of sterilization in each batch, which greatly facilitates the requirement of parameter release)



Special Data Report System

Sterilizer

XXX Co., Ltd. XXX有限公司 Sterilization Process Parameters Record 灭菌过程参数记录							
Sterilization Cycle No. 灭菌工艺号		cycle#		Sterilization Lot# 灭菌批号	Lot Number		
Date 日期	2022/4/26	Operator 操作员	Operator	Sterilizer# 设备编号	BCNST35#		
No. 序号	Order No. 订单号	Product REF 产品代号	Product Name 产品名称	Product Specification 产品规格	Lot No. 批号	Quality(Cases) 数量(箱)	Remark (备注)
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

Material Management Function

Data report system support manual type in, Two-Dimensional Code Scanning and import through excel reports.

The actual production materials and sterilization data are managed together, which is both formal and well managed

Complete digital management is provided by software



Special Data Report System

Network Data Connection

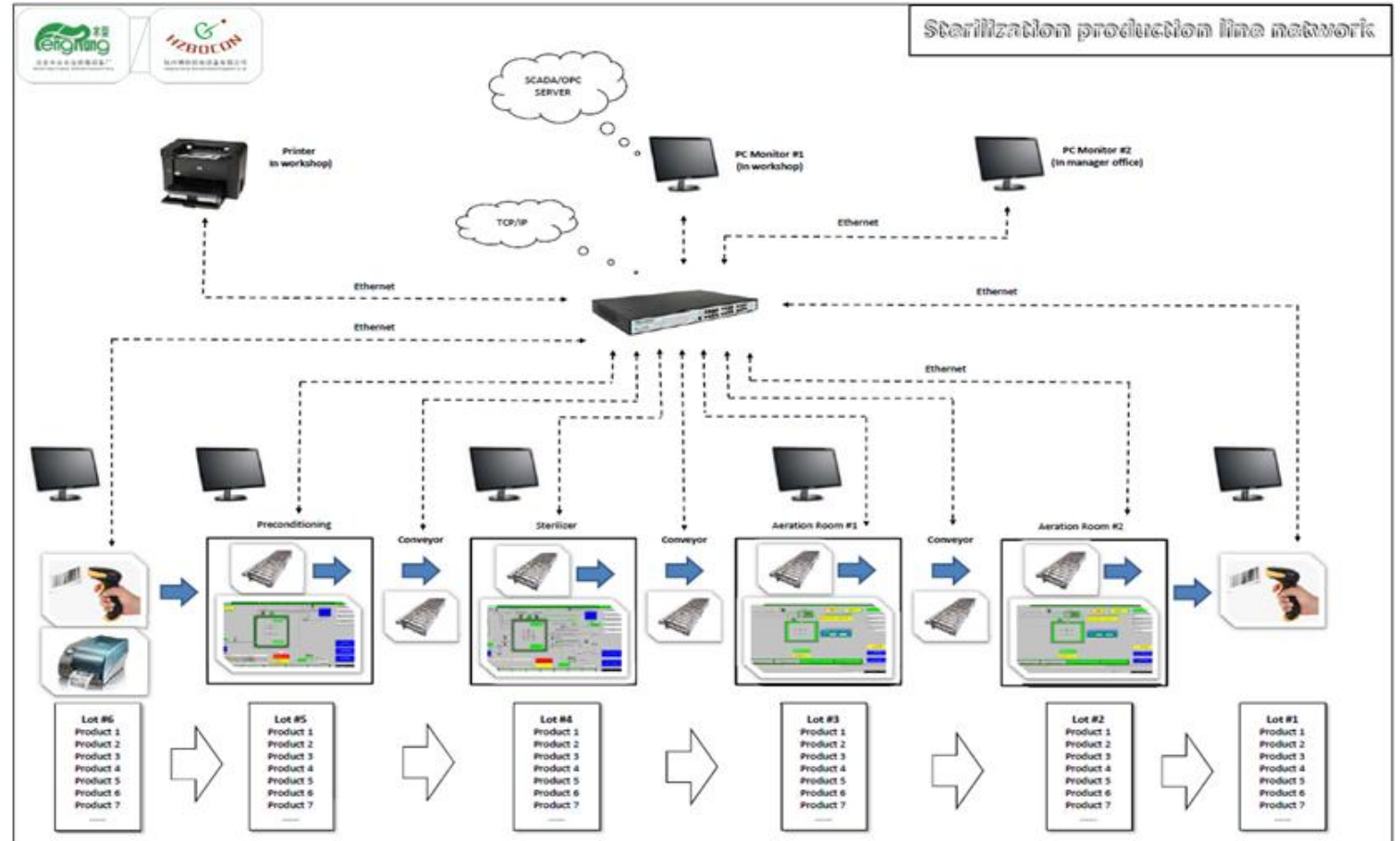
The central server structure according to the idea of IoT

ERP, MES, MRP integration

Remote connection to HZBOCON server optionally

Other equipment monitoring with connection to a remote terminal

Meet 21 CFR P.11 standard



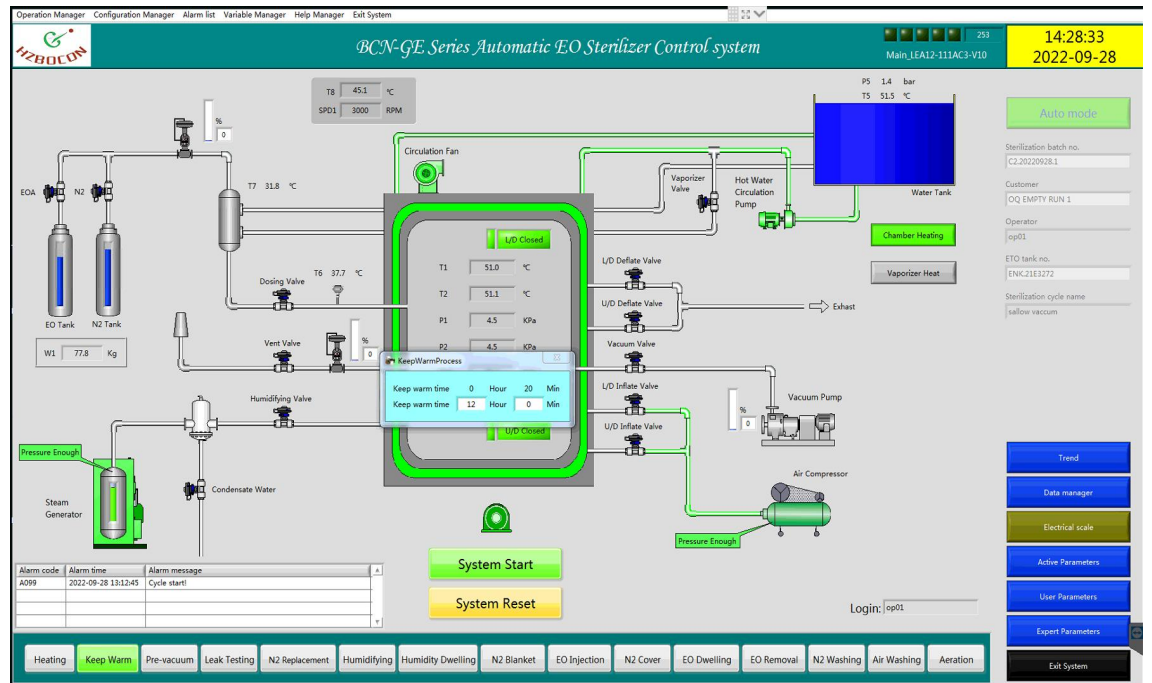


Software functions, training of staff



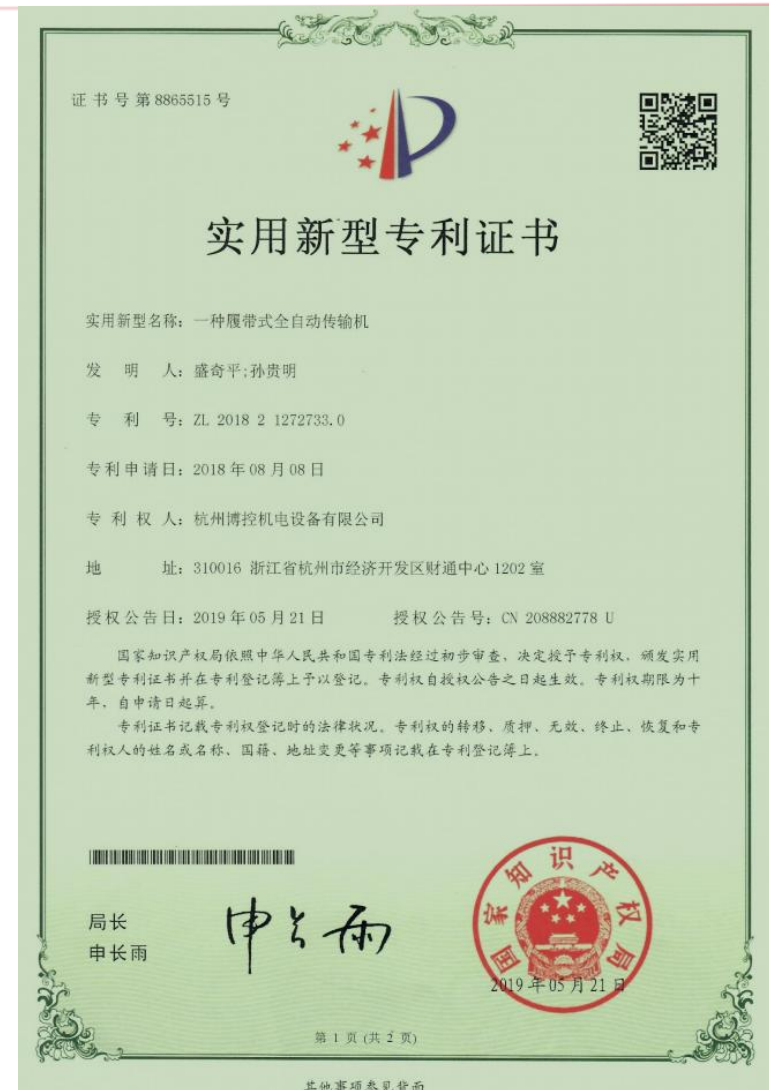
Training of customer staff is provided during commissioning, additional training at the manufacture factory is available

Control system software main and advanced functions are presented in technical documentation



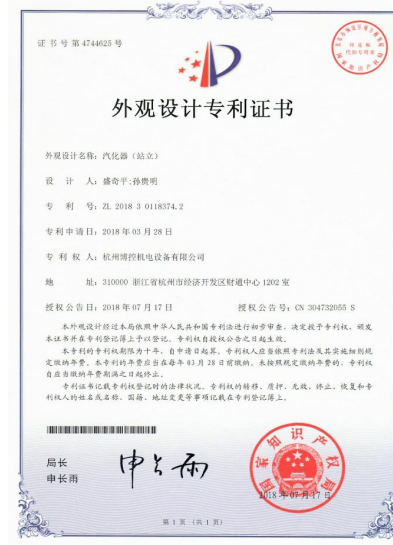
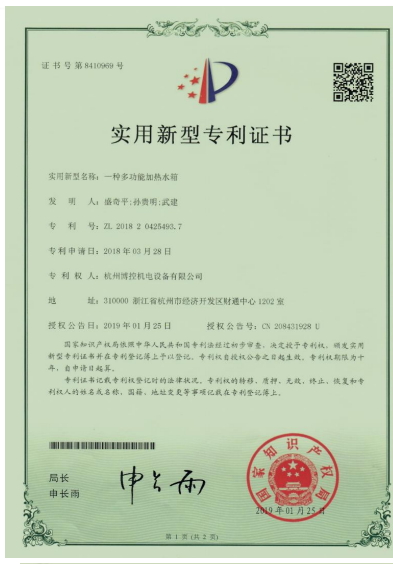
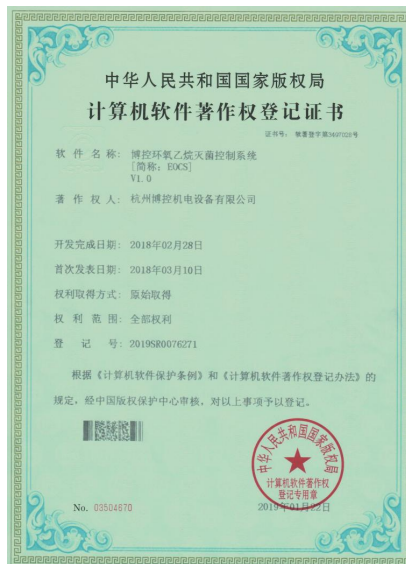


Certificates of honor





Certificates of honor





Our services

Supply installation **drawings**.
Equipped **installation and testing** service.
Supply **technical support** all time.
Training how to operate the machine.
Engineers available to service machinery overseas

Software and hardware upgrades

Upgrades to improve the performance of equipment

Process optimization for current and future customer's product





HZBOCON - WE KNOW WHAT IS STERILIZING



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