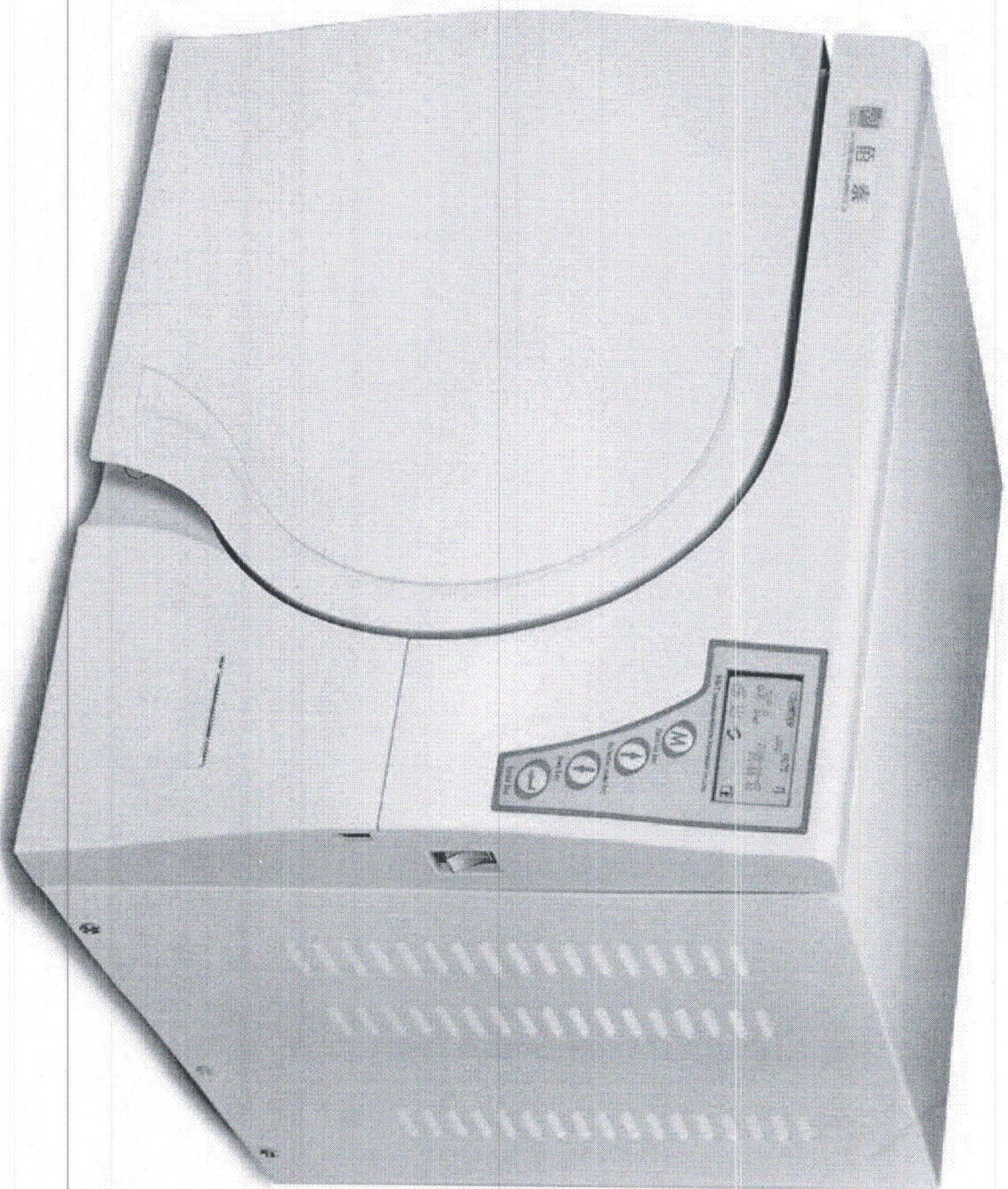


# Bench-top Autoclave/Steam Sterilizer B Class





## *What is Bench-top Autoclave/Steam Sterilizer?*

- ❖ Steam Sterilization is the most practicable method for sterilizing reusable medical devices in healthcare premises because it has high lethality, it is rapid and non-toxic.
- ❖ Bench-top steam sterilizers contribute to the prevention of cross infection, especially in primary healthcare, but also in non-medical practices such as tattooing, body piercing and beauty treatment on the condition that in the absence of a central sterilizing services.



## Sterilization temperature bands, holding times and pressures for steam sterilization

Sterilizing temperature range (°C)		Approximate pressure(bar)	Minimum hold time(minutes)
Minimum	Maximum		
134	137	2.25	3
126	129	1.50	10
121	124	1.15	15

**Recommendation:** Use the highest temperature compatible with the load item.



## What is Class B (Types of sterilization cycle)?

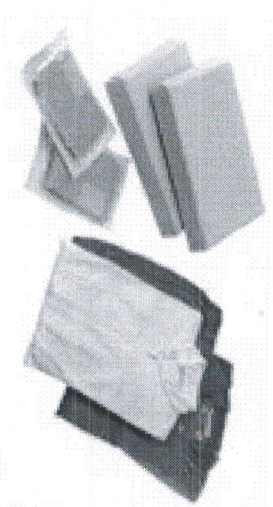
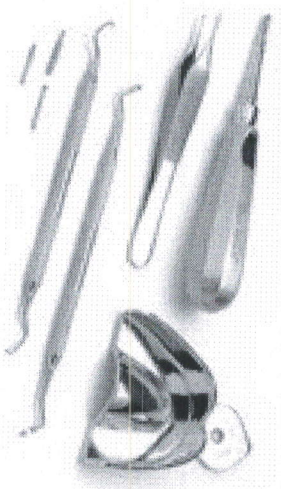
Cycle Type	Air removal	Classification	Load type
Class N	Passive (gravity displacement)	Sterilization exclusively of Naked solid products.  No transportation, no storage, for immediate use only.	Non-wrapped solid items. Not to be used for: Hollow devices or those with lumens.
✓ Class B	Active (forced air removal)	Provides medical grade sterilization, processing any load a <u>Big</u> sterilizer(En 285) can process	<p>Wrapped or non-wrapped solid items.(e.g. forceps, dental probes)</p> <p>Wrapped or non-wrapped hollow items.(e.g. cannulae within dimensions specified by sterilizer manufacturer)</p> <p>Porous Loads (e.g. fabrics, swabs, dressings)</p>
Class S	Active (forced air removal)	Sterilization of Specific products as specified by the manufacturer.	It is essential that this cycle is used only for the types of load it was designed for.



## Why Class B?

❖ Class B Steam Sterilizer is fully automatic high-speed pre&post vacuum, designed for sterilization of wrapped materials, hollow instruments and porous loads in hospitals, private clinics, dental offices, beauty therapists, tattooists, body piercers and hairdressers.

❖ Widest Application: stainless steel surgical instruments; stainless steel generic tools; carbon steel generic tools; glass articles; mineral basis articles; heat-proof plastic articles; heat-proof rubber articles; heat-proof textile articles; treatment material (gauze, tampons); Dynamic instruments(turbines, contra angles, ablation tools).





## Why fractionated pre vacuum (Air remove type)?

Air remove Type	Description
Gravity displacement type	Displace air passively from the chamber and load by steam generated within the sterilizer chamber or in a separate boiler within the sterilizer's casing. This is known as a 'Type N'.
Vacuum air remove type	Have a pump or some other active method to remove air from the chamber and load.
✓ Fractionated pre vacuum air remove type	<p>A pre vacuum pump removes the air from the chamber and then use a succession of steam pulse, in which the chamber is alternately pressurised and then depressurised to below atmospheric pressure. This process is repeated 1 to 4 times (Optional). With each cycle of vacuum and steam-pulse, the air fraction decreases. This ensure the complete air removal and steam could penetrate throughout the entire load much more efficiently.</p> <p>The effectiveness of air removal contribute to the sterilization effect as spores and bacteria are found to be survive at 134 °C (273 °F) in air pockets, which will be remain in hollow, porous, wrapped and fabrics items.</p>



## What is Bowie and Dick Test?

The Bowie & Dick test is prescribed in the type test procedure for steam sterilizers that are built in compliance with EN285. The B&D test pack, also called steam penetration test pack, is representative of the small porous type load that is often considered to be "the most difficult to sterilize object". If the sterilizers is capable of providing sufficient steam penetration into this test pack one tends to assume that the sterilizer is capable of sterilizing all types of loads and items. It comprises several sheets of paper wrapped in a small packet in the middle of which there is a chemical heat-sensitive indicator sheet.

The Bowie & Dick test was conceived as a test for successful air removal from high vacuum porous load sterilizer. A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack. The presence of air within the pack, due either to an inefficient air removal stage, an air leak during this stage or non-condensable gases in the steam supply, are circumstances which can lead to a failure of the test.

Test result:

- \* Test passed: the entire surface of the indicator sheet has changed color
- \* Certain areas of the indicator sheet have not changed color. Any unexpected color change, such as the center of the indicator sheet being paler or of a different color than the edges, indicates that there was an air pocket present during the cycle due to sterilizer malfunction.



## What is Helix Test?

The Helix Test , is representative of the type A hollow load. It consists of a 1500mm long tube that is open on one side and closed with a capsule on the other side. An indicator strip is placed inside of the capsule.

The test is used to validate the sterilizer performance in terms of hollow A load sterilization, that is:

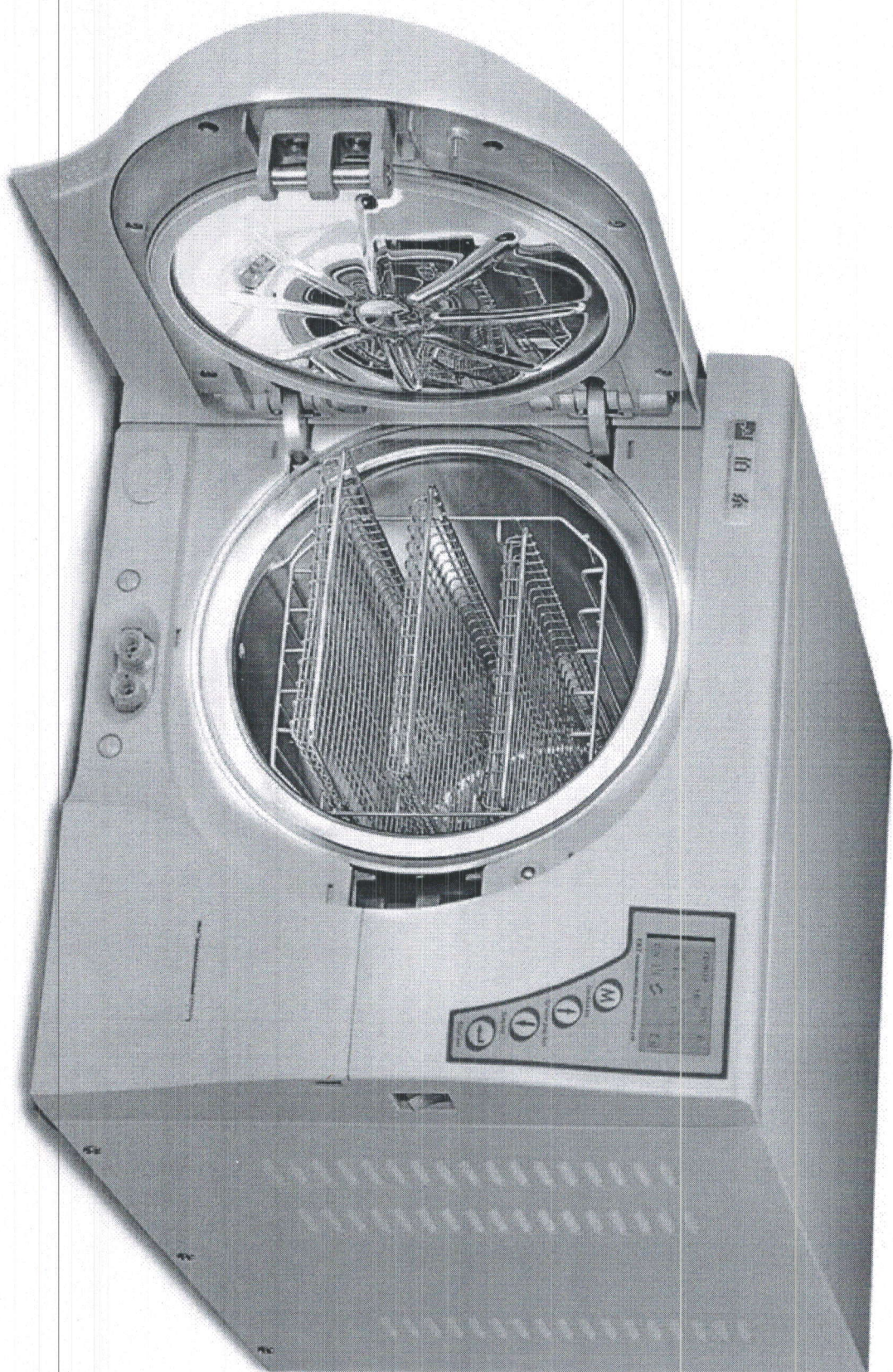
- \* Pre-vacuum efficiency; rapid and uniform steam penetration.
- \* Temperature and pressure of saturated steam achieved during the holding phase.

Test result:

- \* Test passed: the chemical indicator of strip from the capsule has turned dark.
- \* Test Failed: part of the chemical indicator has not turned dark, due to residual air inside the capsule. Insufficient color change of the indicator strip indicates that there was an air pocket present during the cycle due to sterilizer malfunction.



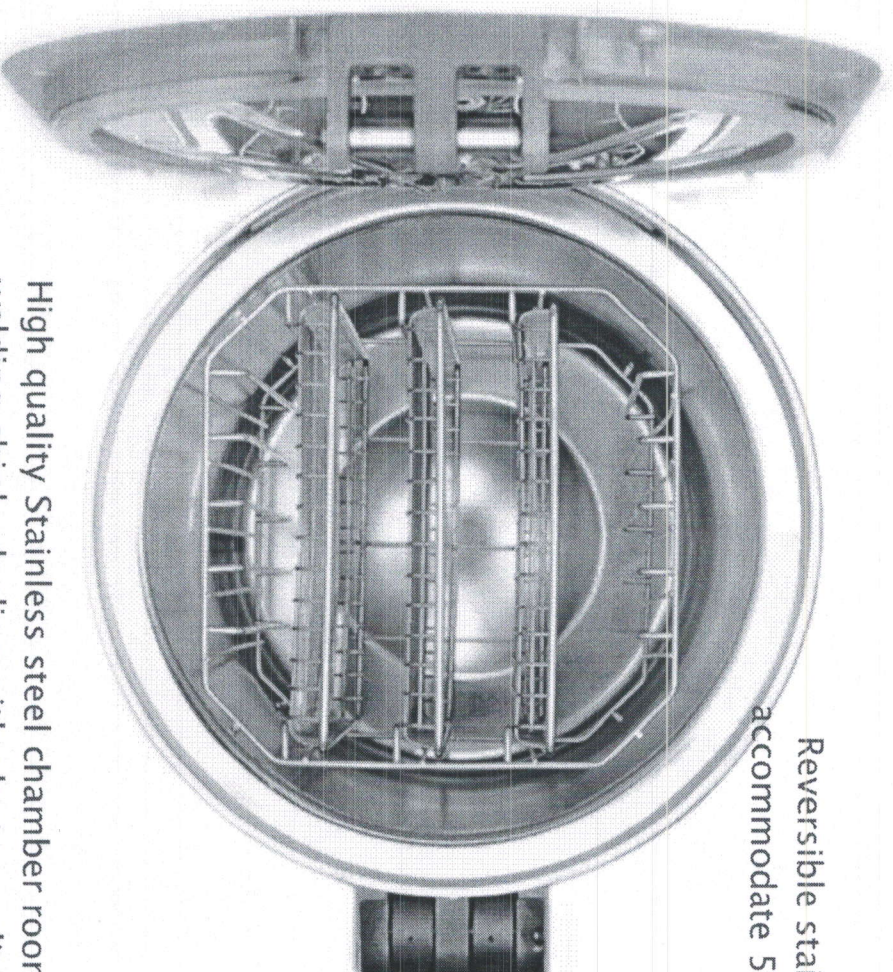
БТД17/БТД23





БТД17/БТД23

Reversible stainless steel rack to  
accommodate 5 trays or 3 cassettes



High quality Stainless steel chamber rooms without  
welding chink, dealing with electro-polish finish  
OEM for many a lot of world-wide famous autoclave  
suppliers



CE Certificate

# Notified Body No: 1293



**EVPU**

NOTIFIED BODY No. 1293

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical devices, Annex II (with the exemption of section 4),  
transposed into Slovak government decree No. 572/2001 Coll. of Laws as amended

No. 40052/101/1/2008/CE

We hereby declare that an examination of the product mentioned in the quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing into Slovak law the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive. Identification of the products covered by this certificate is given in the Appendix.

**Manufacturer and Facility**

P&T (Ningbo) Medical Equipment Co., Ltd.  
Houcang Section, Yinxian Avenue, Ningbo 315153, China

**Applicant**

P&T (Ningbo) Medical Equipment Co., Ltd.  
Houcang Section, Yinxian Avenue, Ningbo 315153, China

**Product(s)**

Steam Sterilizer

**Product type(s)**

BT017-A, BT023-A

**Classification  
of medical device**

Medical Devices - Class IIa

**Scope of quality system**

Quality of design, production, storage and distribution

**Final report number**

40052/2008

**Date of issue**

December 8<sup>th</sup>, 2008

**Date of the end of validity**

December 7<sup>th</sup>, 2013



The **CE** Marking may only be used if all relevant and effective Directives of EC and Council are complied with.



Karel Giamos

The Notified Body has audited the quality system in accordance with the Directive 93/42/EEC Annex II (3), and found that the quality system meets the requirements of the Directive 93/42/EEC Annex II.  
The manufacturer must inform EVPU of any change in the design, construction of the products or the quality system of production or other information which may affect the conformity of the products with the scope of this Certificate.  
This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive 93/42/EEC may require the Certificate to be amended. The product safety rests with the manufacturer of the equipment in accordance with the Directive 93/42/EEC.  
016002 EVPU A.S. JO ILO 1293, Trnávská 15, 010 01, Bratislava, Slovak Republic



## BTD17/BTD23 Features

**B Class**

European B standard, up to 4 time pre-vacuum preceding vacuum drying for directly sterilization.

**Automatic Door**

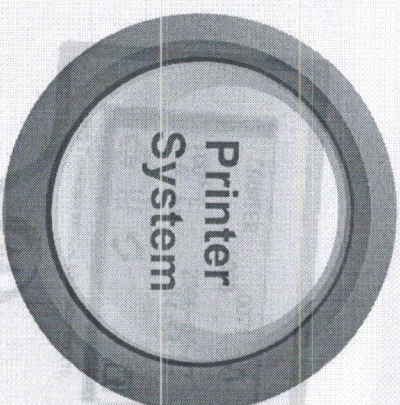
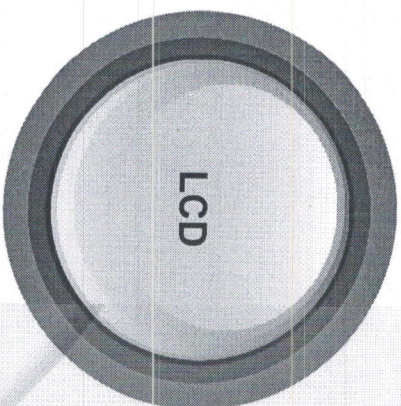
A double inter-locking robotized mechanism with triple-protection system which ensures complete safety and usability

**Pre-vacuum**

Vacuum measurement reaches -0.80bar. Double head robust high - volume vacuum-pump for fast and efficient air-removal.



## BTD17/BTD23 Features



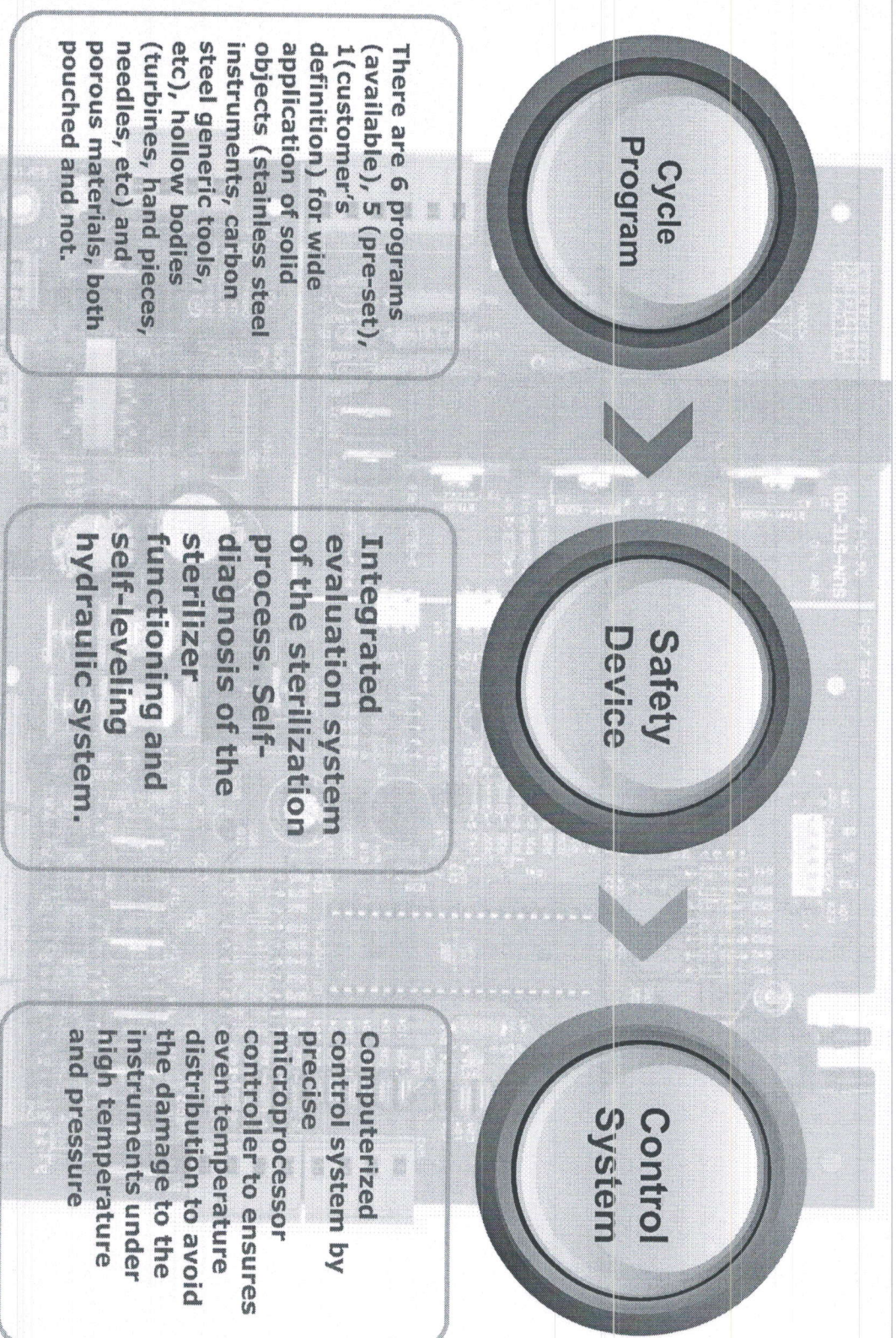
The four lines of characters and the included symbols guide the users throughout their navigation in the various cycle phases.

Equipped with an integrated thermal printer which allows the complete recording of all the cycle data about temperature, pressure and time consumption.

Formed deep-stretched shape stainless steel 304 sterilization chamber ensures higher durability, quality and easy-cleaning

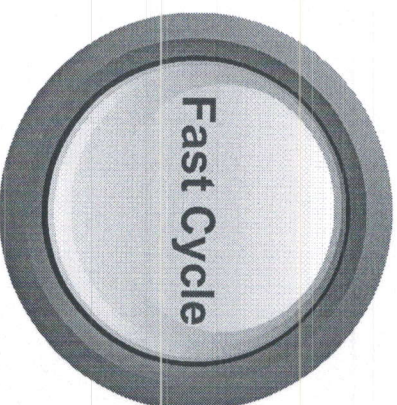


## BTDP17/BTD23 Features





## BTD17/BTD23 Features



**Automatic**  
(behind ports)  
and manual (front  
ports) distilled  
water feeding and  
drainage are both  
available for  
easily handling

**Very fast cycle** as  
steam is always  
ready for fast  
sterilization.

**Pure and waste**  
water bottle  
ensure the  
internal  
circulation of  
vapor and water.



#



# | Vacuum Steam Sterilizer | BTD17 | BTD23 | |--------------------------|---|-------| | Sterilization cycles | 3 preset+1 customer definition | | | Test cycles | Vacuum Test/Leakage Test | | | Drying | Post vacuum drying | | | Printer & interface | integrated thermal printer/USB Interface | | | Bacteriologic filter | 0.22µm debris filter | | | LCD | four line of characters and included symbols LCD screen | | | Operation language | English, Chinese (other language could be translated) | | | Water tank | distilled water and used water tanks | | | Water feeding & drainage | automatically and manually | | | Door & Lock | auto-locking door | | | Sterilization Chamber | 304Stainless steel without welding chink | | | Miscellaneous | fully micro-processor controlled | | | Rack | 1PC reversible rack | | | Tray | 5PCs stainless steel wire trays | | | Tray holder | 1PC tray holder for removing trays from the sterilization chamber | | | Warranty | 18months | | 17



# Sterilization Cycles

Vacuum Steam Sterilizer	Sterilization Cycles					Test Cycles	
	134°C Porous	121°C Porous	134°C Hollow	Customer definition	Helix B&D	Air leakage	
Temperature (°C)	134	121	134	105-134	134	\	
Pressure(Bar)	2.1	1.1	2.1	1-2.1	2.1	-0.8	
Pre-vacuum Times	3	3	1	0-4	3		
Holding Duration time(M)	5	25	4	4-40	3.30		
Total cycle time for small load including drying time (M)	30	50	25	\			
Total cycle time for full load including drying time (M)	45	60	35	\	20	18	
Load Type	Max Load (Kg)		Max Load (Kg)		Max Load (Kg)		
	BTD17	BTD23	BTD17	BTD23	BTD17	BTD23	
	Unwrapped Porous	1.00	1.50	1.00	1.50	6.00	7.50
	Single/Dual Wrapped Porous (cotton, gauze)	0.65	1.1	0.65	1.1	\	\
	Single-wrapped solid (probes, tweezers, burs)	3.00	3.75	3.00	3.75	\	\
	Single-wrapped hollow(hand pieces, forceps, scissors,	3.00	3.75	3.00	3.75	\	\
	Dual-wrapped solid(probes, tweezers, burs)	1.50	1.80	1.50	1.80	\	\
	Dual-wrapped hollow(hand pieces, forceps, scissors,	1.50	1.80	1.50	1.80	\	\
	For emergency and follow the instructions provided by the instrument manufacturer						
	Empty Chamber without any load or test pack only						

Empty Chamber without any load or test pack only