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

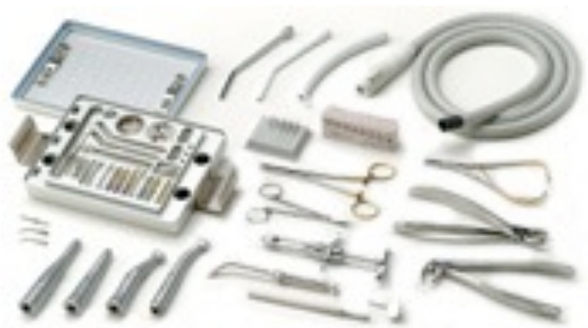
Recommendation: Use the highest temperature compatible with the load item.

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 Big sterilizer(En 285) can process	Wrapped or non-wrapped solid items.(e.g. forceps, dental probes) Wrapped or non-wrapped hollow items.(e.g. cannulae within dimensions specified by sterilizer manufacturer) Porous Loads (e.g. fabrics, swabs, dressings)
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 fractioned 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.
✓ Fractioned pre vacuum air remove type	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. 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.

What is Bowie and Dick Test?

The Bowie & Dick test is prescribed in the type test procedure for steam sterilizers that are build 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.

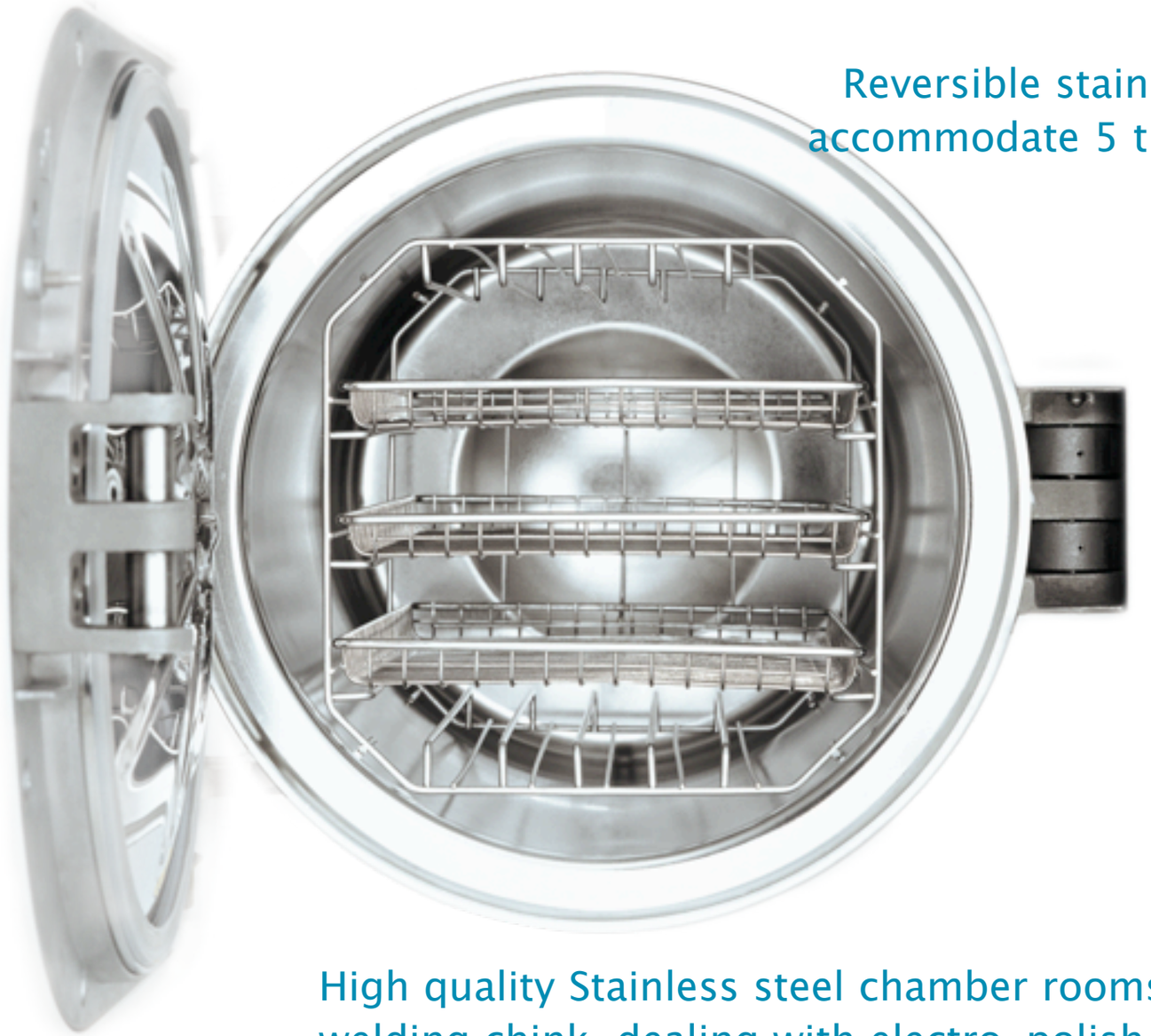
Test result:

✳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.

BTD17/BTD23

BTD17/BTD23



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

EVPÚ®

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 under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with 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)	**BTD17-A, BTD23-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 8th, 2008**
Date of the end of validity	**December 7th, 2013**

EVPÚ, a.s. NOVÁ DUBNICA Notified Body

Karol G l a m o š

The CE 1293 **Marking may only be used if all relevant and effective Directives of EP and Council are complied with.**

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 meet the requirements of the Directive 93/42/EEC Annex II.

The manufacturer must inform EVPÚ a.s. of any plan for substantial changes in the design, construction of the products or the quality system of production in order to examine whether this Certificate remains valid. Annual Surveillance Audits will be held to verify the validity 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 render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with the Directive 85/374/EEC.

016002 *EVPÚ a.s., NB No. 1293, Trenčianska 19, 018 51 Nová Dubnica, Slovak Republic*

BTD17/BTD23 Features

B Class

European B standard, up to 4 time pre-vacuum preceding vacuum drying for directly using after 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

LCD

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

Printer System

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

Chamber

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

BTD17/BTD23 Features

Cycle Program

There are 6 programs (available), 5 (pre-set), 1(customer's definition) for wide application of solid objects (stainless steel instruments, carbon steel generic tools, etc), hollow bodies (turbines, hand pieces, needles, etc) and porous materials, both pouched and not.

Safety Device

Integrated evaluation system of the sterilization process. Self-diagnosis of the sterilizer functioning and self-leveling hydraulic system.

Control System

Computerized control system by precise microprocessor controller to ensures even temperature distribution to avoid the damage to the instruments under high temperature and pressure

BTD17/BTD23 Features

Water feeding and drainage

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

Fast Cycle

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

Water Tank

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

BTD17/BTD23 Specification

Vacuum Steam Sterilizer	BTD17	BTD23
Nominal voltage	220/240 V	
Frequency	50HZ~60HZ	
Nominal power	1800W	2000W
Sterilization temperature	121℃ & 134℃ & Customer Definition Between 105℃-134℃	
Rated working pressure	0.21Mpa	
Classification	IIa(as per 93/42/CEE)	
Sterilization type	B Class(as per EN 13060)	
Air Removal	Fractioned pre Vacuum (1-4 times)	
Chamber volume	17L	23L
Chamber dimension (Diameter × Depth)	250mm×350mm	250mm×450mm
Net weight	52KGS	57KGS
Gross weight	70KGS	75KGS
Overall dimension (L ×W ×H)	572×443×475mm	632×443×475mm
Packing dimension(L ×W ×H)	670×600×680mm	730×600×680mm
Packing condition	Carton box/around 198PCS in a 40 Feet Container	

BTD17/BTD23 Specification

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	

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	\	20	18
Total cycle time for full load including drying time (M)		45	60	35	\		
Load Type		Max Load (Kg)		Max Load (Kg)		Max Load(Kg)	Load
		BTD17	BTD23	BTD17	BTD23	BTD17	BTD23		
	Unwrapped Porous	1.00	1.50	1.00	1.50	6.00	7.50	For emergency and follow the instructions provided by the instrument manufacturer	Empty Chamber without any load or test pack only
	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	\	\		

Suggestion for good sterilization

- Never place instruments made of different materials on the same tray.
- Thorough cleaning of all items prior to sterilization is imperative to ensure effective sterilization.
- Never overload the sterilization tray as this may cause inadequate steam circulation and sterilization.
- Place the empty containers with the upper part facing downward to prevent water from accumulating inside.
- Place pouched items on trays with the paper side facing up.
- Sterilize the instruments in the open position.
- If instruments are manufactured from carbon steel, paper or towel should be placed between them and the stainless steel tray.
- Place cassettes in the vertical position to enhance drying.
- Sterilize pouches put them on the tray in the vertical position, side by side. The pouches should not touch the sides of the chamber walls.
- Wrap items with porous wrapping materials to facilitate steam penetration and drying.
- Clean tubes with alcohol in order to enable internal and external drying and then place them on a tray with both ends open, without bended or twisted.
- There are, however, difficulties in achieving thorough cleaning and sterilization of the difficult to access internal mechanisms and fine lumens of hand pieces.
- The sterilizer should be installed on a level surface for drying.

Decontamination of dental turbines, hand pieces and their attachments

- Two types of air-driven hand pieces are used in current dental practice. High-speed units usually consist of a bur, turbine and drill head, attached to air and water lines. Low speed units usually consist of a bur (or other device), drill head, hand piece or shank (which may be angled) and motor. These units a re complex instruments, with fine lumens and deep recesses inherent in their design.
- Although not in direct contact with intra-oral surface, the internal parts of these instruments can become contaminated with patient material form the spinning bur, and this material may subsequently be sprayed into the oral cavity.
- There are, however, difficulties in achieving thorough cleaning and sterilization of the difficult to access internal mechanisms and fine lumens of hand pieces.

Step one: External disinfection
(can not be immersed)

↓

Step two:External cleaning
(this procedure involves the removal of residues, blood, dentine that adhere to critical ares, such as spray outlets, light ports, knurling et.)

↓

Step three: Lubrication
(Must be lubricated prior to sterilization)

↓

Step four: packing
(Ensure preserving sterility)

↓

Step five: sterilization
(Choose appropriate cycle and ensure load)

Decontamination of burs and polishing cups

- Burs and polishing cups will frequently come into contact with patient's blood or body fluid and therefore need to be thoroughly cleaned and appropriately sterilized in order to prevent patient material being expelled intra-orally during subsequent use.
- There are a number of burs and polishing cups, that cannot be easily manually cleaned because they have recesses.

Step one:External cleaning
(Ultrasonic cleaning/Thermal disinfector be considered for these items)

↓

Step two: Rinse and dry
(Remove all traces of disinfectants from the instruments as this may cause corrosion during the sterilization process)

↓

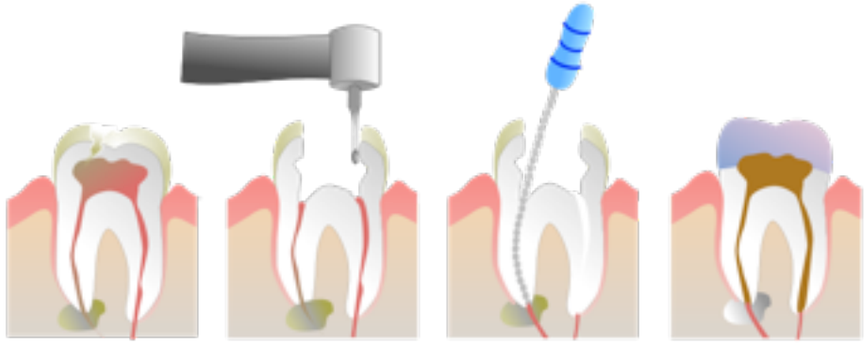
Step three: packing
(Ensure preserving sterility)

↓

Step four: sterilization
(Choose appropriate cycle and ensure load)

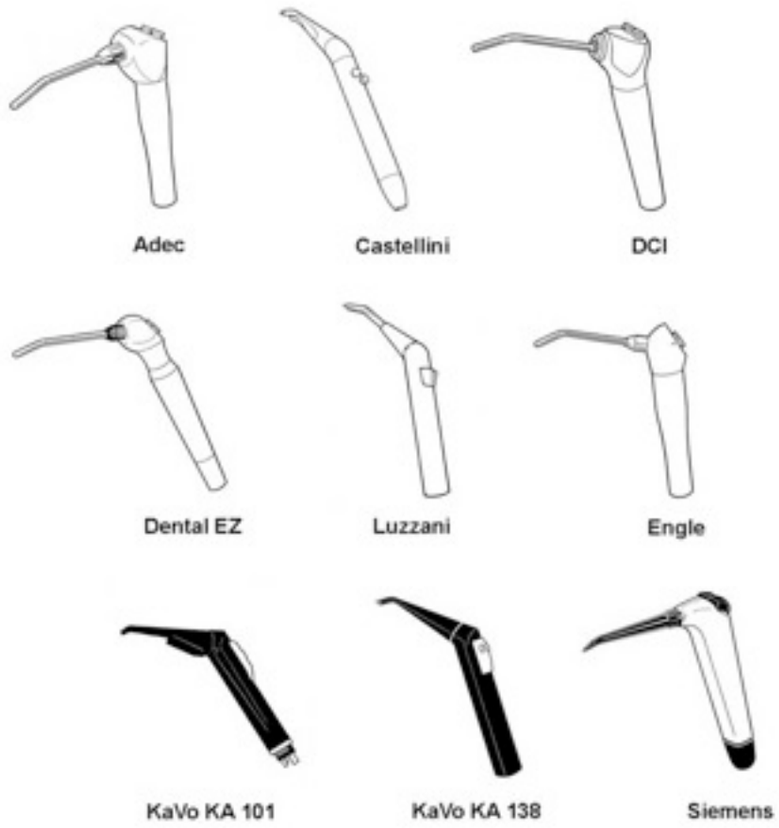
Decontamination of Endodontic instruments

- Root Canal treatment(endodontic treatment) can involve instruments becoming contaminated with dental pulp and peripheral branches of the trigeminal nerve, which may therefore theoretically pose a risk of prion transmission, but this is thought to be at least 10 times lower than that for tonsillectonmy.
- Nevertheless, these instruments are difficult to clean, even after ultrasonication, and the use of single-use endodontic files should be considered.



Decontamination of Air/Water Syringes (Three way)

- These units supply air and water through push button valves, which are then sprayed into the patient's mouth. Disposable tips are available which carry individual channels for air and water.Disposable sheaths, which these tips puncture, provide protection to the external surfaces of the instrument. The tips and sheaths are for single patient use.
- Autoclavable tips are also available, their fine lumens need to be cleaned by automated washing methods, such as ultrasonic cleaner and sterilized in a vacuum steam sterilizer.
- The body of the instrument may be routinely decontaminated with a solution of 1000 ppm available chlorine in detergent after each patient. If chlorine is incompatible with the materials from which the instrument is made, an alternative virucidal agent, such as 70% isopropylalcohol wipes, should be used or as recommended by the manufacturer.



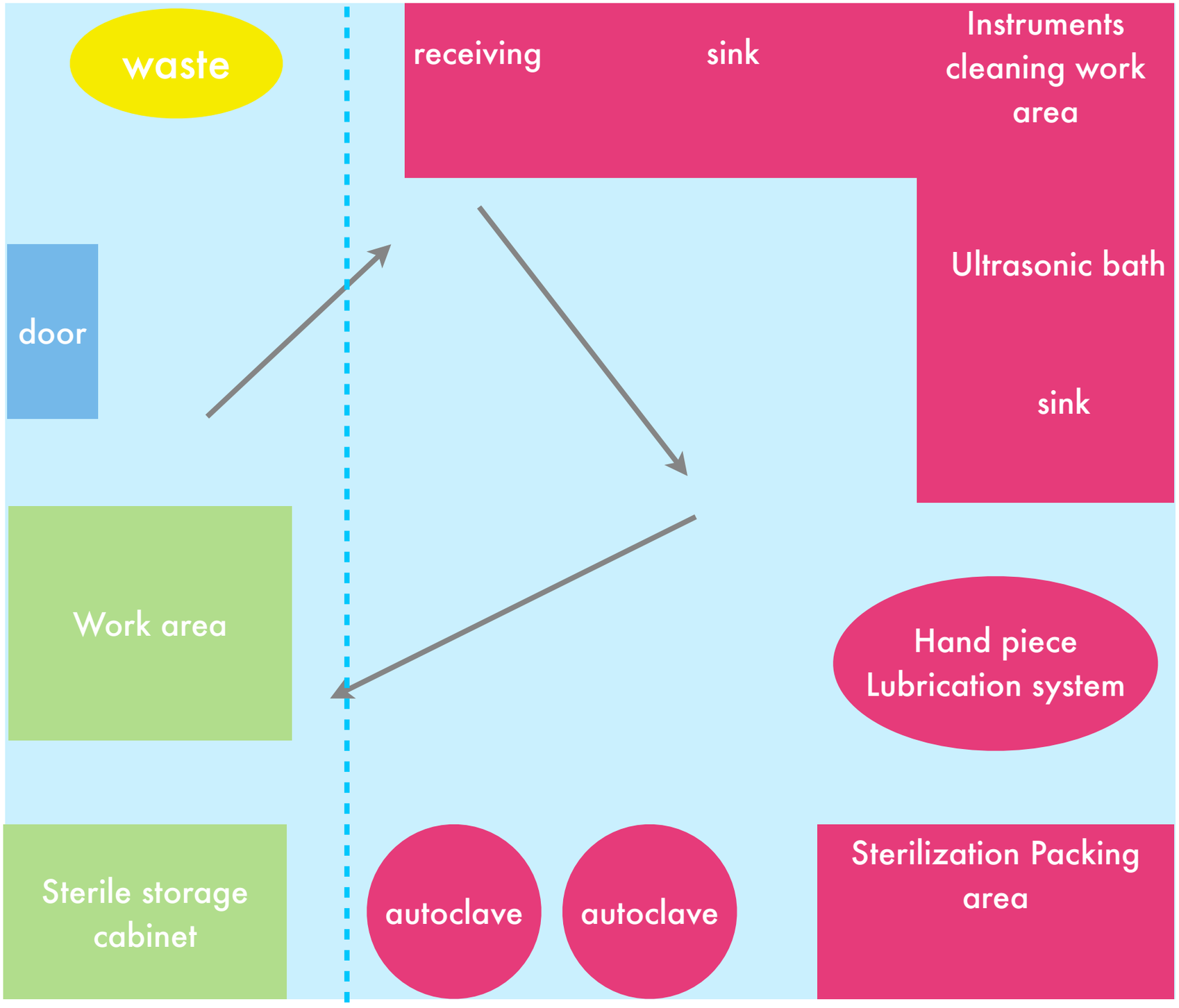
Decontamination of Saliva ejectors

- Attached to aspirating units are suction lines to which aspirating tips (Saliva ejectors) are connected. Aspirating tips/ Ejectors are available as single-use disposable items and should be discarded as clinical waste after each patient use.
- Autoclavable tips may also be used which is difficulty in cleaning inside the lumens, which means single-use versions are preferred and automatic machine cleaning method are necessary.
- The external surfaces of the lines may be wiped with a solution of 1000ppm available chlorine in detergent or 70% isopropylalcohol (if compatible) after each patient.

Factors of purchasing

- Quantities of instruments you are likely to reprocess per load and per day
- whether the loads are solid
- if you want to process hollow items, what the limitations are for their length and diameter
- whether you intend to process porous loads
- they types and numbers of layers of wrapping that you expect to use
- whether you wish to store sterile devices in packs or wrapping for future use.
- the running cost
- ease of use
- cycle time
- the routine maintenance

Layout of infection control center



Infection Control Center