



STEAM STERILIZERS

SST2200B - SST1700B

Safe Sterilization for GP's,
dental and medical clinics

Technology and design made in Italy





CBM

History

CBM

1943

CBM has been founded in **1943** by Cav. Busatti in Milan. Since the beginning, the company specialized in medical devices.



CBM

1962

In the 1962 it has been moved to Torre de' Picenardi.
CBM is focused in the sterilization field, manufacturing
high quality and trustable medical devices.



CBM

2015

Nowaday CBM develops over an area of 30.000 m².
CBM manufacturing capabilities allow the quick and precise managment of **more that 4000 articles.**





CBM

Products

Sterilization
Containers

Perforated
Baskets

Hospital
furniture

Steam
Sterilizers

Hollowares

Hot air
sterilizers

Bed pan
washers

Lab
equipments

During such long story, CBM technical department developed a very wide range of products for many different applications..

Company management has created important business opportunities in many different countries all around the world.

CBM

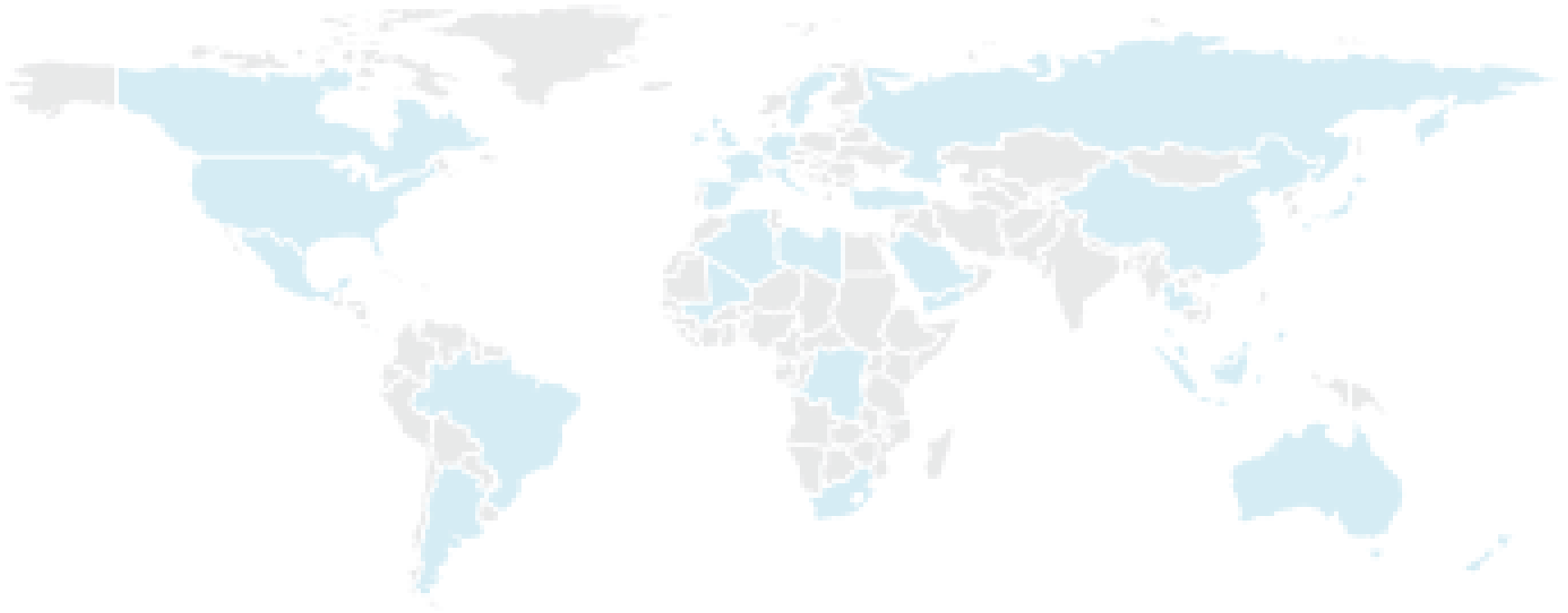
Products



CBM

In the World

CBM delivers its products and services in **more than 100 countries** .



Mercati CBM



CBM

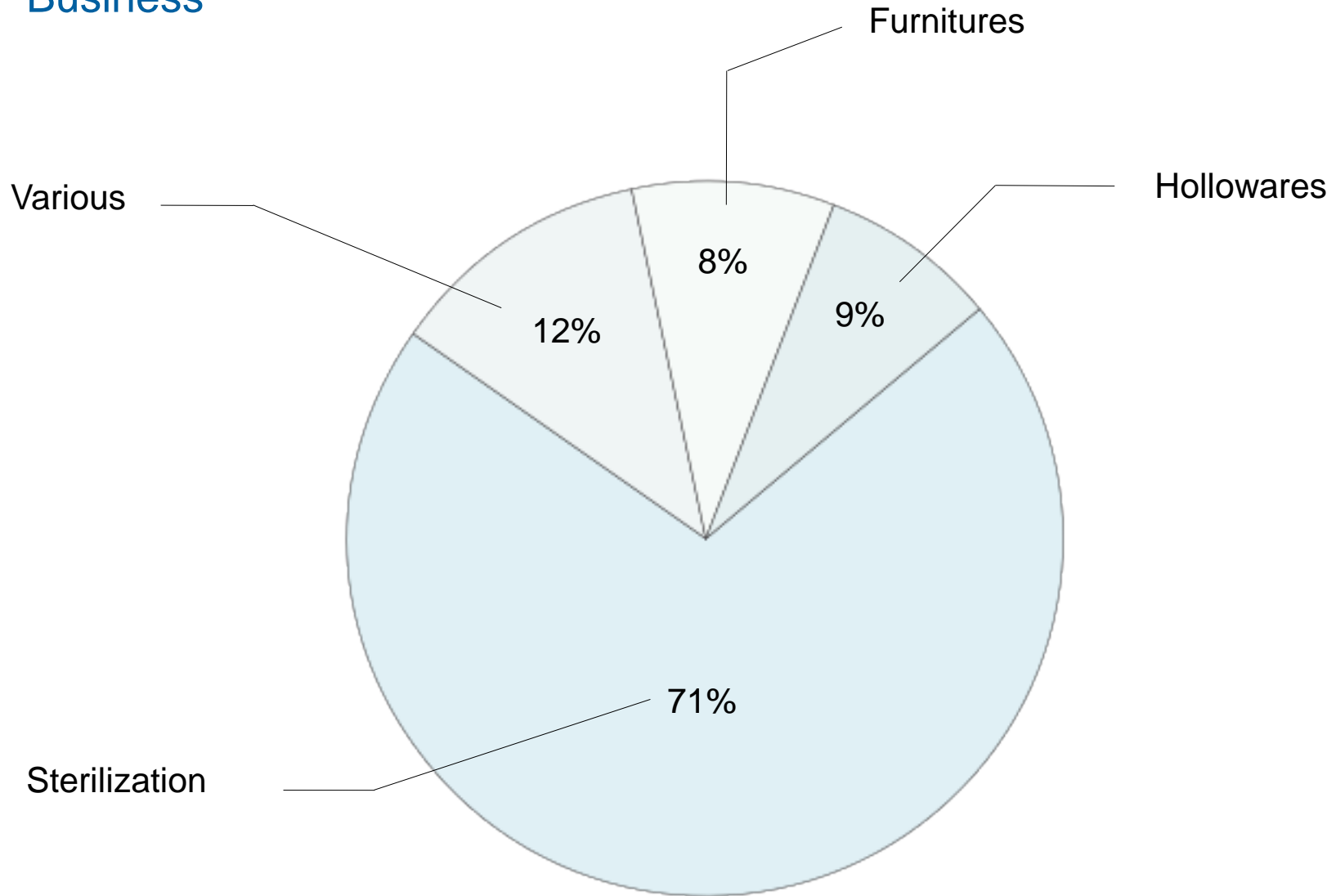
In the World

CBM delivers its products and services in **more than 100 countries**

Andorra	Danimarca	Korea	Porto Rico	Ukraina
Afghanistan	Ecuador	Kuwait	Portogallo	Ungheria
Albania	Egitto	Lettonia	Qatar	Uruguay
Algeria	Emirati Arabi Uniti	Libano	Regno Unito	Vietnam
Angola	Eritrea	Libia	Rep. de Panama	Yemen
Arabia Saudita	Estonia	Lituania	Repubblica Ceca	
Argentina	Finlandia	Lussemburgo	Repubblica del Congo	
Australia	Francia	Macedonia	Repubblica Slovacca	
Austria	Georgia	Madagascar	Romania	
Azerbaijan	Germania	Maldiva	Russia	
BAHRAIN	Ghana	Malesia	Senegal	
Bangladesh	Giappone	Malta	Serbia	
Belgio	Gibilterra	Marocco	Singapore	
Benin	Giordania	Mauritania	Siria	
Bosnia Erzegovina	Gran Bretagna	Mauritius	Slovenia	
Brasile	Grecia	Messico	Spagna	
Bulgaria	Guatemala	Moldavia	Sri Lanka	
Burkina Faso	Hong Kong	Nigeria	Sudafrica	
Cambogia	Ile de la Reunion	Norvegia	Sudan	
Cameroon	India	Nuova Caledonia	Svezia	
Canada	Indonesia	Nuova Zelanda	Svizzera	
Cile	Iran	Olanda	Tanzania	
Cina	Iraq	Oman	Thailandia	
Cipro	Irlanda	Pakistan	Tunisia	
Corea del Sud	Israele	Palestina	Turchia	
Costa d'Avorio	Italia	Perù	U.S.A.	
Croazia	Kenya	Polonia	Uganda	

CBM

Business



CBM

From the first Formaldehyde Sterilizer to Hot Air



➤ CBM
Formaldehyde
sterilizer
60's



➤ CBM Hot air
sterilizer
60's



➤ Water boilers
70's



➤ CBM Hot air
sterilizer
«Panacea»
70's

CBM

From the first Formaldehyde Sterilizer to Hot Air



> CBM Hot air
sterilizer
80's



> CBM Hot air
sterilizer
«electronic»
90's

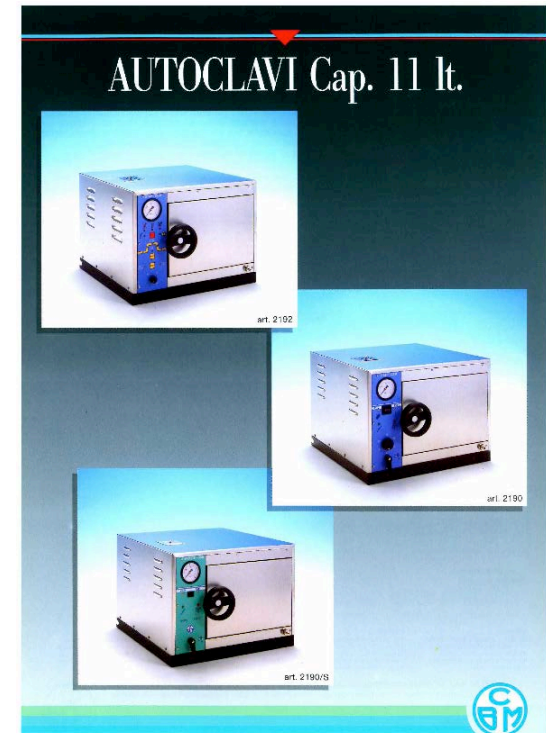


> CBM Hot air sterilizer «electronic»
with Microprocessor
2000

CBM

Steam Sterilizers

- Simple electromechanic
Steam Sterilizers of 11
and 20 liters
80's



CBM

Steam Sterilizers

- First 20 liters
microprocessor
controlled
1988



CBM

Steam Sterilizers

- 20 and 11 lts. With vacuum pump
1997



CBM

Steam Sterilizers

- > 15 & 18 liters
- type B** conforming to
- EN 13060**
- 2001



**EGLE
EGLE 20**




**Steam sterilizers
Fractionated vacuum
CYCLES B**



EGLE
fractionated vacuum
CBM

Technologie della sterilizzazione • Sterilization technologies • Technologies de la stérilisation • Technologien der Sterilisierung

CBM

Steam Sterilizers

- New autoclaves 17 & 23 liters **EN 13060** with **advanced electronic control**
2013



Stainless
Steel
Steam
Sterilizer

SST2200^B
SST1700^B

Le tue nuove asSiSTenti





CBM

Directives and Norms

EU Directive 93/42 and Small Steam Sterilizers

➤ Classification.



Class IIB

➤ Essential requirements and harmonized norms



UNI EN 13060

➤ Third party conformity assesment



For CBM is Det Norke Veritas

➤ CE marking



CE
0434

CBM in technical working groups

- CBM is member of different working groups focused on sterilization. This give us the possibility to have always the latest know-how on sterilization. EN 13060 has been developed by CEN (European Committe for Standardization) Wg5, in which CBM actively partecipated. Wg5 has just completed the last revision of EN 13060.



International
Organization for
Standardization



European
Committe
for Standardization



Ente
Italiano
di unificazione

EN 13060 European Norm on Small Steam Sterilizers

**NORMA
EUROPEA**

Piccole sterilizzatrici a vapore

UNI EN 13060

APRILE 2015

Small steam sterilizers

Versione italiana
dell'aprile 2015

La norma specifica i requisiti prestazionali e i metodi di prova per piccole sterilizzatrici a vapore e per i cicli di sterilizzazione che sono utilizzati per scopi medici o per materiali che possono venire in contatto con sangue o liquidi fisiologici.

Scope and application

The standard is addressed to small steam sterilizers having the following characteristics.

- Automatically controlled.
- That generate steam using electrical heaters or use steam that is generated by a system external to the sterilizer.
- Dedicated to medical devices sterilization.
- Equipped with a chamber volume of less than 60 l and unable to accommodate a sterilization module (300 mm × 300 mm × 600 mm).

This European Standard does not apply to small steam sterilizers that are used to sterilize liquids or pharmaceutical products.

Types of load

➤ **Solid**

Product that is not made from porous material and which has no recesses or features which present a greater or equal challenge to steam penetration than a simple hollow item



➤ **Porous**

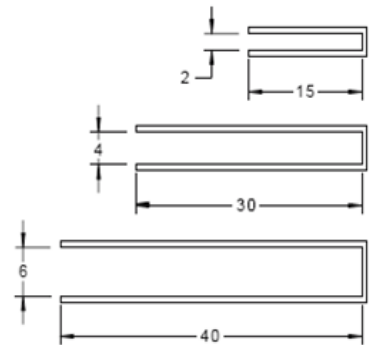
Permeable to water, air or other fluids.



Types of load

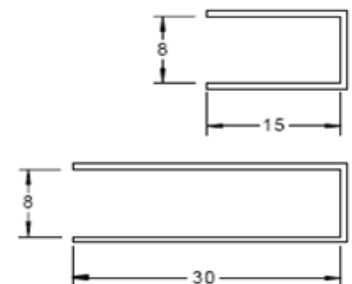
➤ **Narrow lumen** [prev. Hollow A]

hollow device which is beyond the range defined for a simple hollow item, and which is neither solid nor porous)



➤ **Simple hollow item.** [prev. Hollow B]

single-ended open-space items where the ratio of length to diameter of the cavity is greater than or equal to 1 and less than/or equal to 5 ($1 \leq L/D \leq 5$) and where the diameter is greater than or equal to 5 mm ($D \geq 5$ mm) or double-ended open-space items where the ratio of length to diameter of the cavity is greater than/or equal to 2 and less than/or equal to 10 ($2 \leq L/D \leq 10$) and where the diameter is greater than or equal to 5 mm ($D \geq 5$ mm)



Types of load

➤ Wrapped «**single layer**».



➤ Wrapped «**multiple layer**».



Sterilization Cycle Types

Manufacturers shall carry out «work tests» in order to grant that the sterilizers achieve the performance requirements for the correct sterilization of each type of in each available cycle.

- **Cycle type B**

- **Cycle type S**

- **Cycle type N**

Sterilization cycle

Type B

Sterilization cycle tested and dedicated to all the types of load defined in the EN13060:

- Wrapped or not Wrapped products.
- Narrow lumens .
- Solid and porous products.

Sterilization cycle

Type S

Sterilization cycle tested and dedicated to :

- ⑤ Non wrapped solid products.
- ⑤ The sterilization of products as specified by the manufacturer of the sterilizer including at least on of the following:
 - Porous product
 - Small porous items
 - Lumen devices
 - Bowls and receivers
 - Single-layer wrapped products
 - Multiple-layer wrapped products



Sterilization cycle

Type N

Sterilization cycle tested and dedicated to :

- Non wrapped solid products.



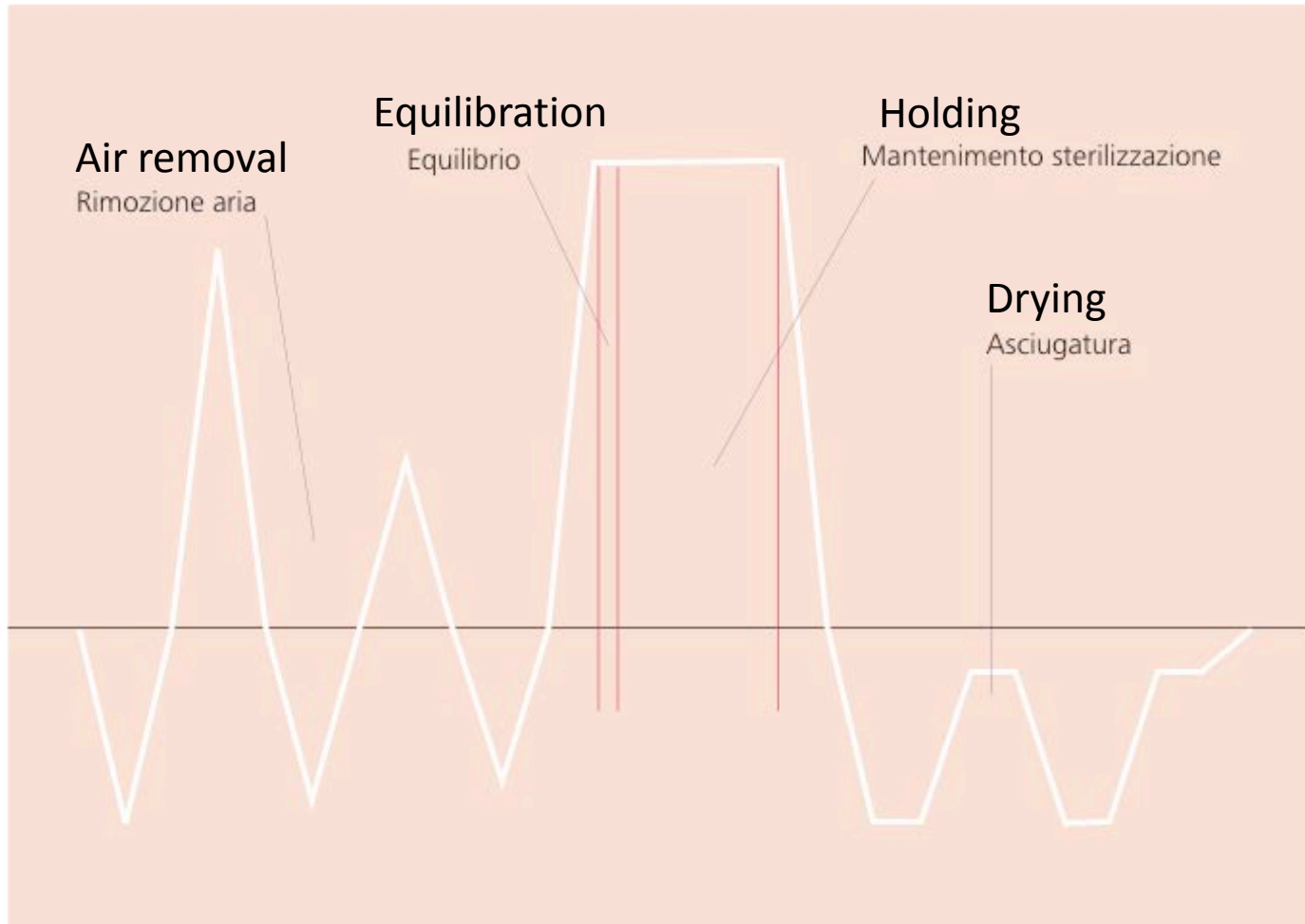
Performance requirements

EN 13060

- Achieving and maintaining of the sterilization condition for saturated steam..
- For moist heat sterilization using steam as the sterilant it is essential that all surfaces to be sterilized are subjected to saturated steam at a predetermined temperature for a predetermined period of time. Proper steam penetration into the load and — if applicable into the individual items — therefore is essential.
- Steam penetration requires adequate air removal.

Type B cycle Pressure – Temperature chart

Fractionated vacuum



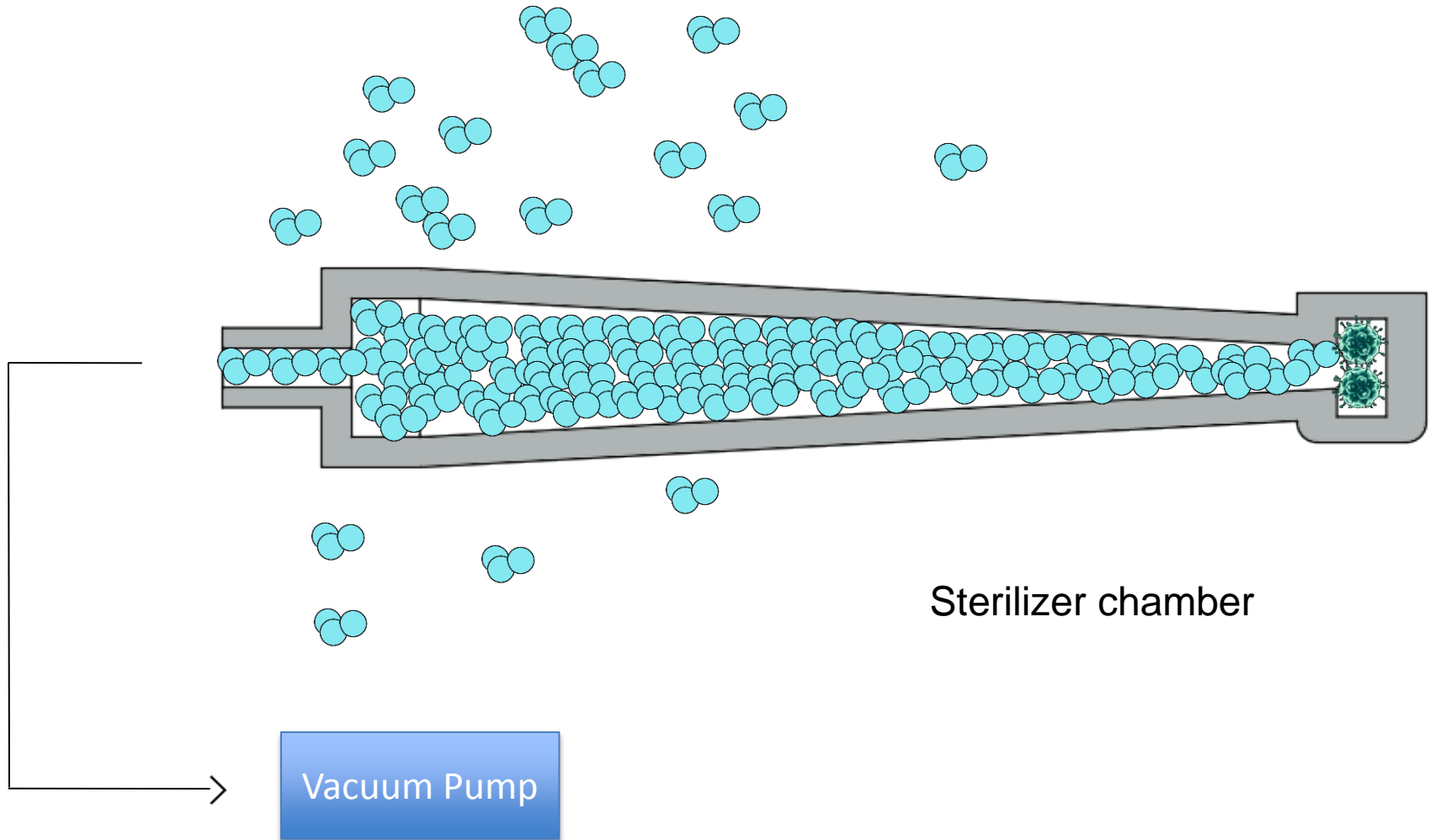


Fractionated Vacuum

Fractionated vacuum system, by means of using thermodynamic effect of alternation between vacuum phases and steam injection, removes the air from the more complex items.

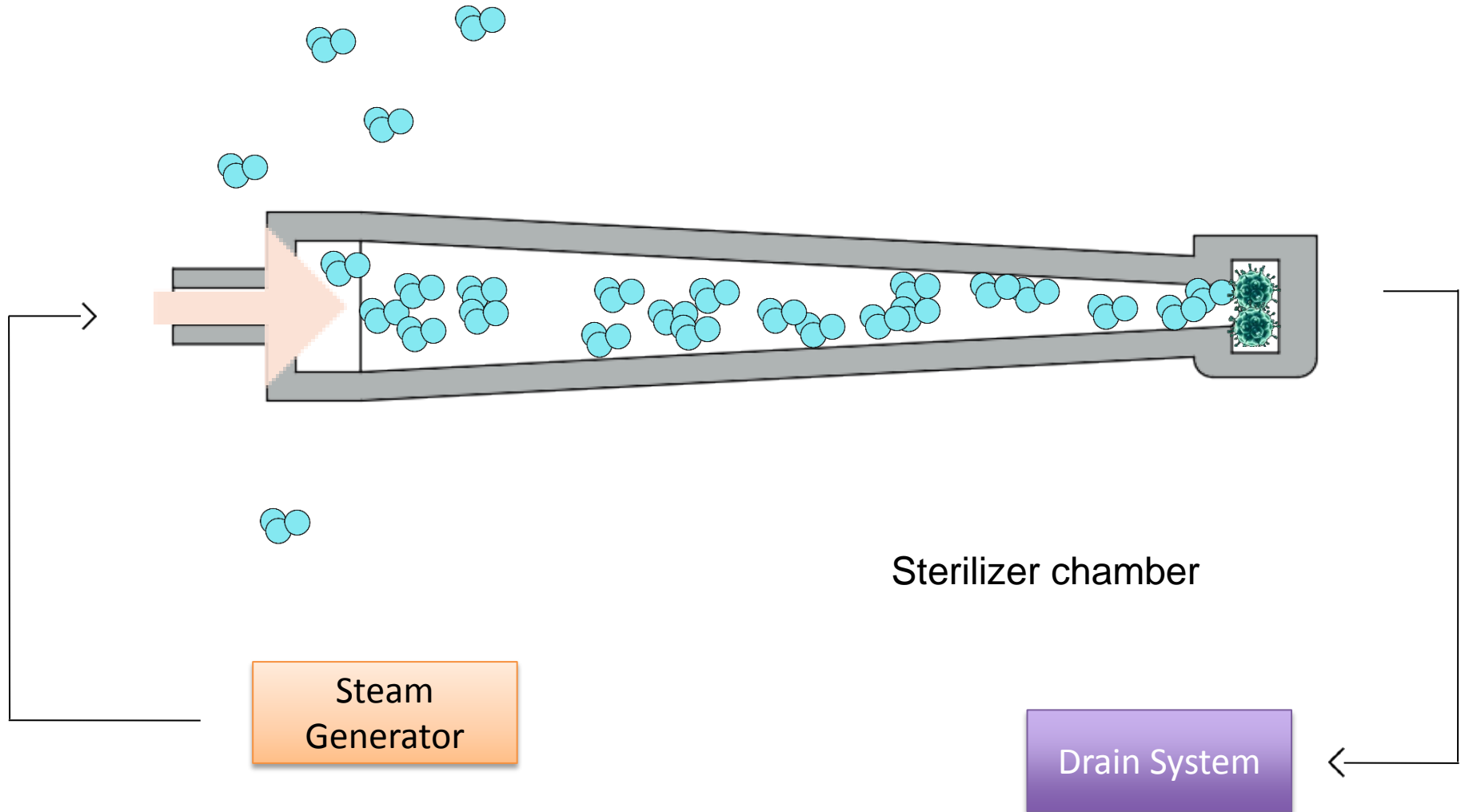
Fractionated Vacuum

Phase 1 – 1st vacuum = remove a big quantity of air using vacuum pump



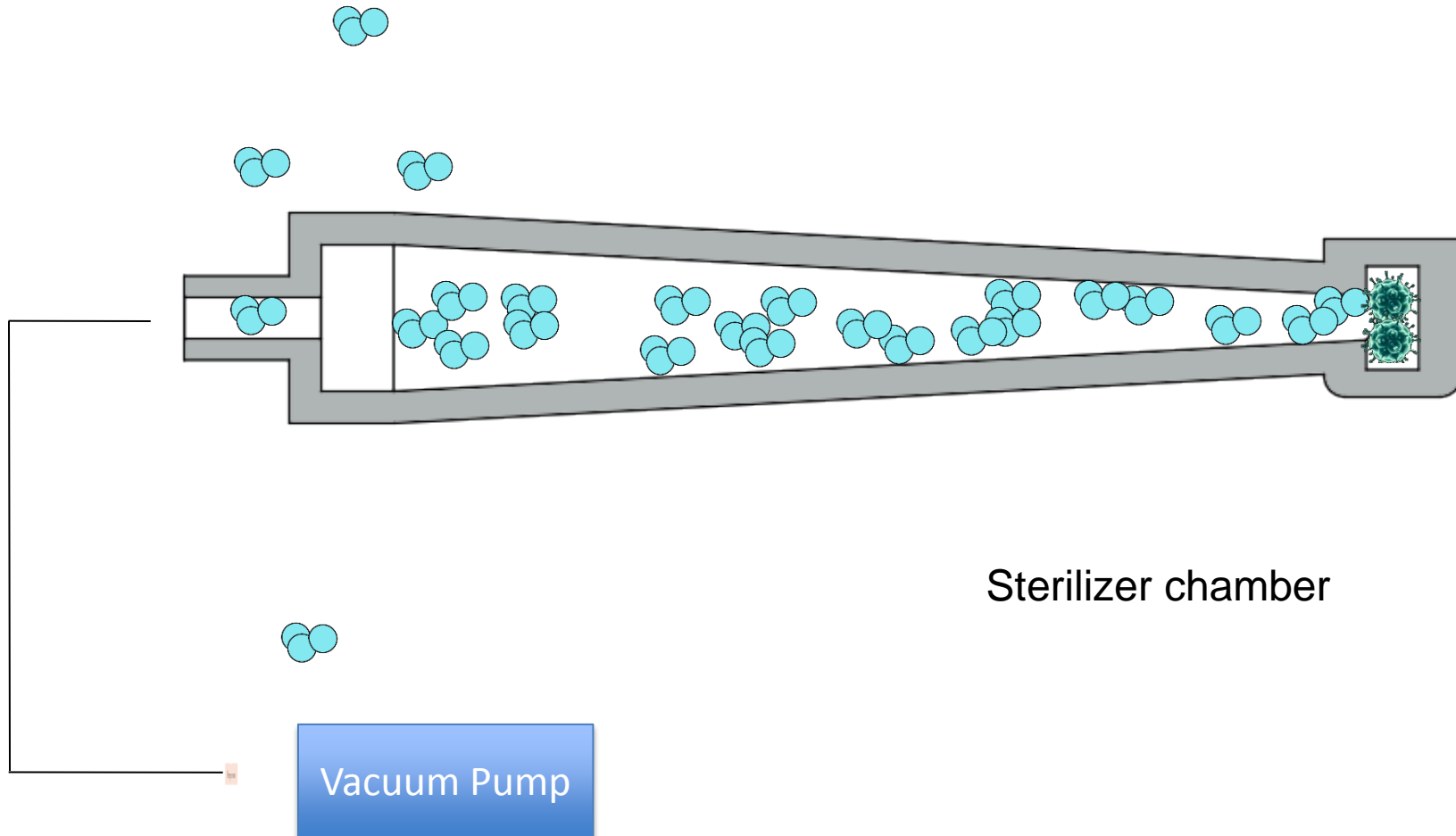
Fractionated Vacuum

Phase 2 – 1st steam injection and drain = Warm, compress the air and drain it



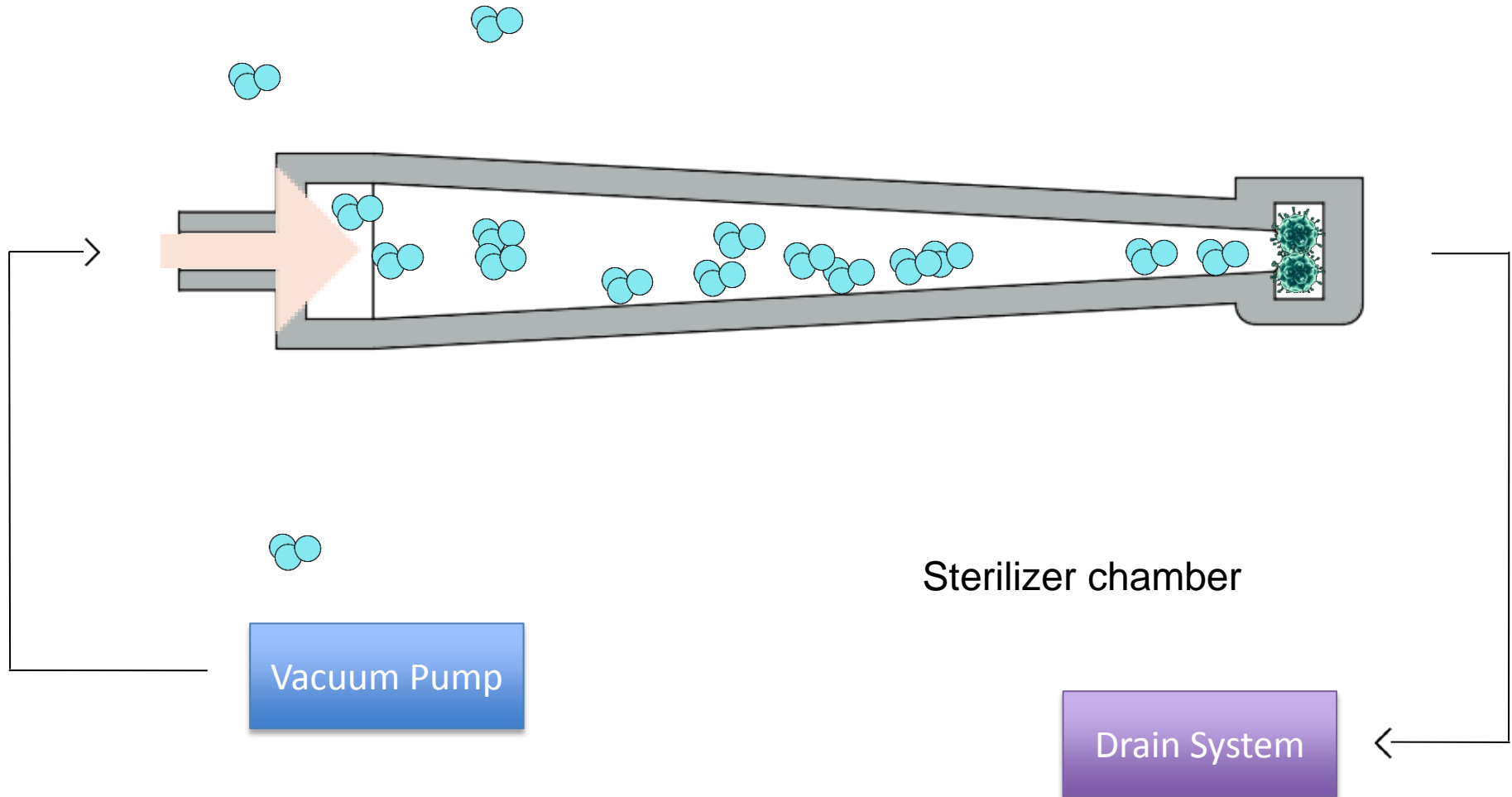
Fractionated Vacuum

Phase 3 – 2nd vacuum = remove again air using vacuum pump



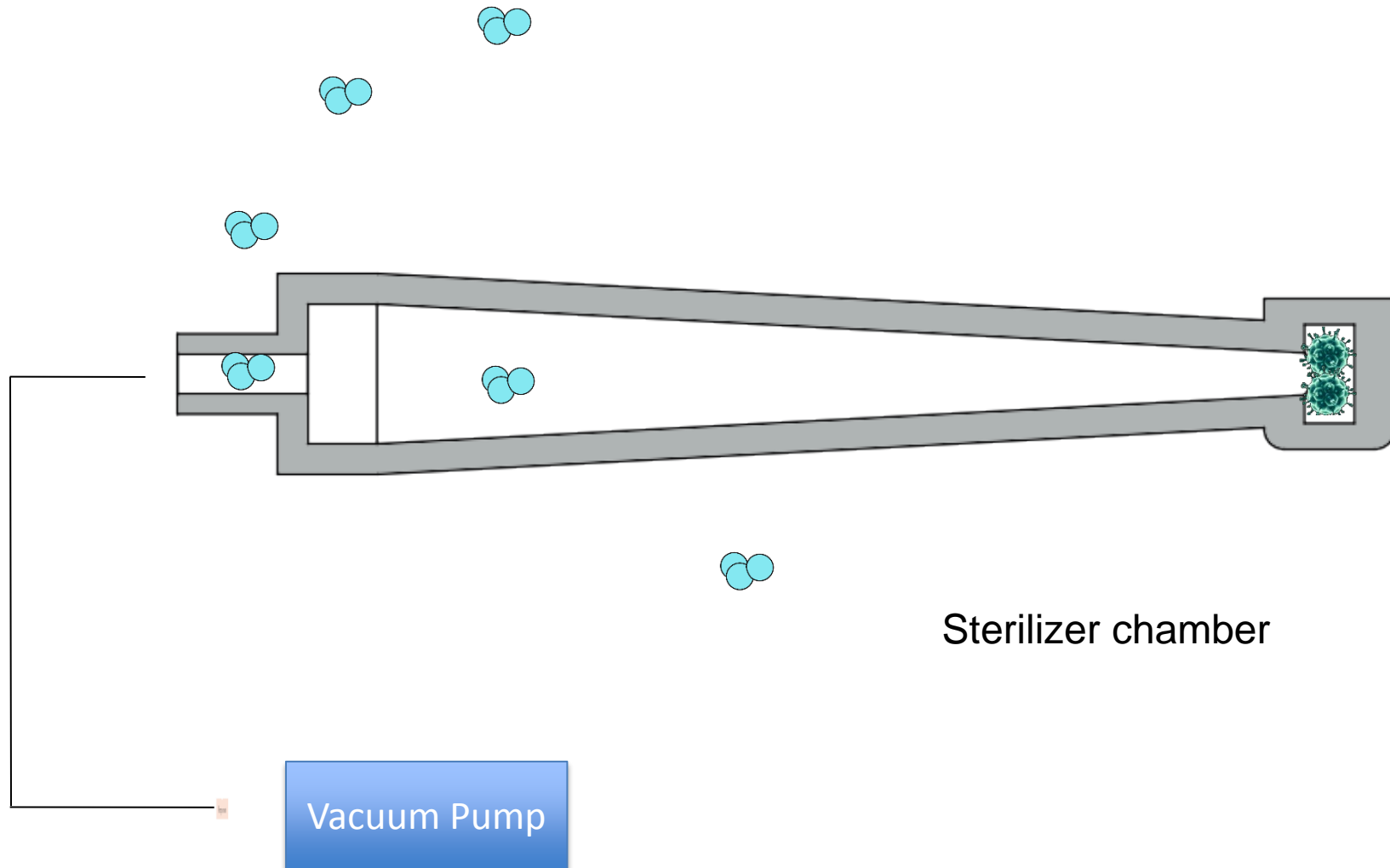
Fractionated Vacuum

Phase 4 – 2nd steam injection and drain = Warm, compress the air and drain it



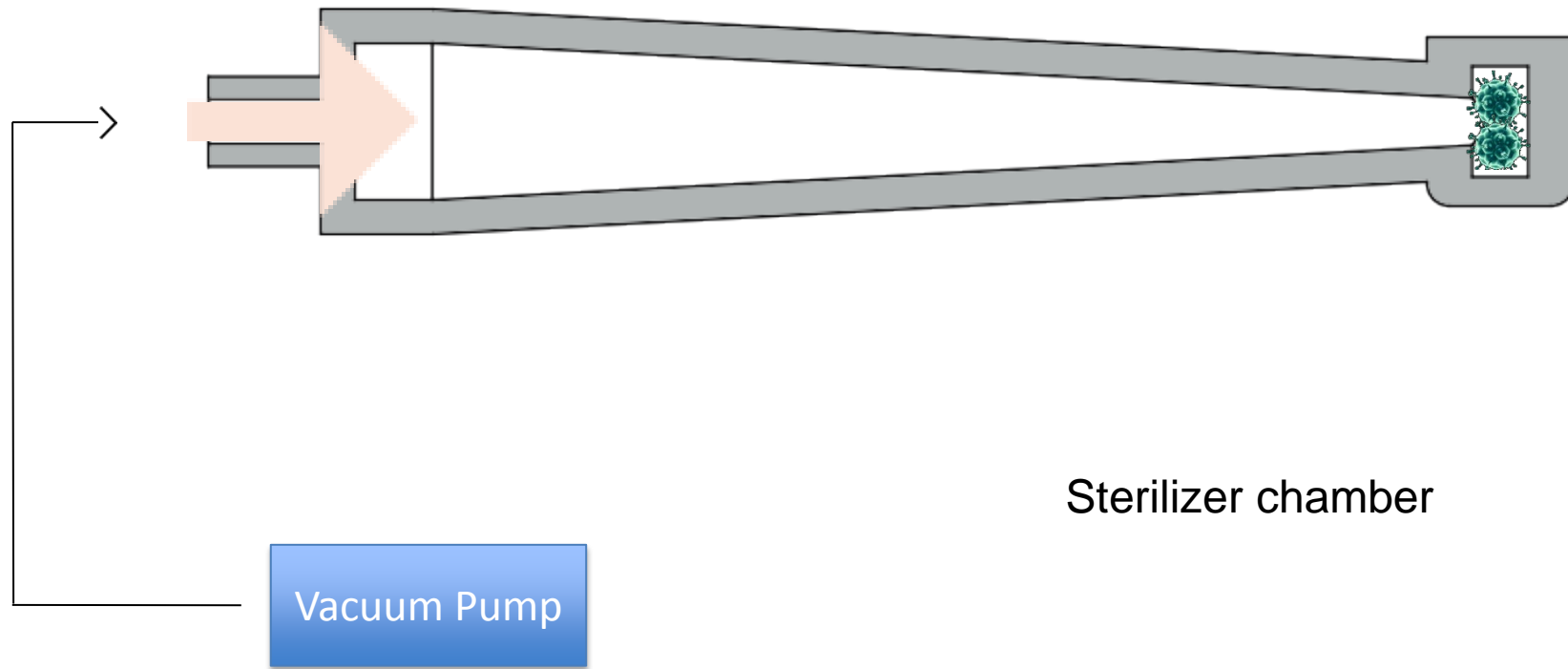
Fractionated Vacuum

Phase 5 – 3rd vacuum = remove again air using vacuum pump



Fractionated Vacuum

Phase 6 – sterilization



Controls during sterilization phase

The correct transfer of energy between the steam and the load takes place only in the presence of saturated steam. The standard defines the limits of the temperature changes, which may have place in the various points of the chamber and the load, during the sterilization phase. The pressure variations are also defined.

The proper sterilization conditions are achieved if, during the holding time, the temperatures inside the chamber and the load:

- are not lower than the sterilization temperature
- are not more than 3 K above the sterilization temperature (3°C).[prev.4°C]
- Do not differ from each other by more than 2 K(2°C).

Controls during sterilization phase

Temperatura di Sterilizzazione (°C)	Tempo Minimo di Mantenimento (min.)
121	15
126	10
134	3
143	1

The norm consider two methods for the evaluation of the correct sterilization conditions achievement through out the holding time:

- By the user, from readings obtained by the recording system and the
➤ sterilizer indicating devices..
- Automatically be means of a **“Process evaluation system”**.

Drying

The packaging materials, used for maintaining sterility of the loads processed in small steam sterilizer, are affected by the percentage of residual humidity in the load at the end of the cycle. So it is necessary that the sterilizers ensure proper drying of loads after sterilization. The EN13060 defines the maximum residual moisture content of the loads.

- For solid loads, residual moisture content shall not exceed 0,2%
- For porous loads, residual moisture content shall not exceed 1%

Water quality

The standard indicates, in an informative and therefore not binding, which is the quality of water to be used for steam generation.

Annex C (informative)

Suggested maximum limits of contaminants in and specification for water for steam sterilization

Table C.1 — Contaminants of condensate and feed water

	Feed water	Condensate
Evaporate residue	≤ 10 mg/l	≤ 1,0 mg/l
Silicium oxide, SiO ₂	≤ 1 mg/l	≤ 0,1 mg/l
Iron	≤ 0,2 mg/l	≤ 0,1 mg/l
Cadmium	≤ 0,005 mg/l	≤ 0,005 mg/l
Lead	≤ 0,05 mg/l	≤ 0,05 mg/l
Rest of heavy metals, excluding iron, cadmium, lead	≤ 0,1 mg/l	≤ 0,1 mg/l
Chloride	≤ 2 mg/l	≤ 0,1 mg/l
Phosphate	≤ 0,5 mg/l	≤ 0,1 mg/l
Conductivity (at 20 °C)	≤ 15 µS/cm	≤ 3 µS/cm
pH value	5 to 7,5	5 to 7
Appearance	colourless, clean, without sediment	colourless, clean, without sediment
Hardness	≤ 0,02 mmol/l	≤ 0,02 mmol/l
NOTE The condensate is produced from steam that has been taken from the empty sterilizer chamber.		

Compliance should be tested in accordance with acknowledged analytical methods. The use of water for steam generation with contaminants at levels exceeding those given in this Table can greatly shorten the working life of a sterilizer.

ISO17665

Protocols of washing, packaging, sterilization and verification of performances of the process can be carried out by applying all or part of the information contained in the following norm.

NORMA EUROPEA	Sterilizzazione dei prodotti sanitari Calore umido Parte 1: Requisiti per lo sviluppo, convalida e il controllo di routine di un processo di sterilizzazione per dispositivi medici	UNI EN ISO 17665-1
		GENNAIO 2007

ISO17665

The ISO17665-1 requires that each steam sterilizers equipped with a **dynamic** air removal (vacuum pump) shall be daily checked with:

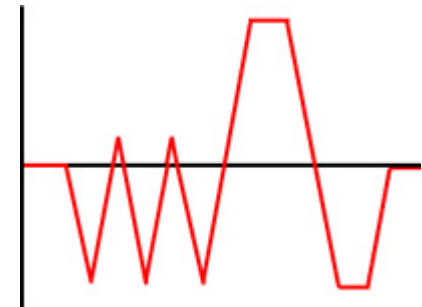
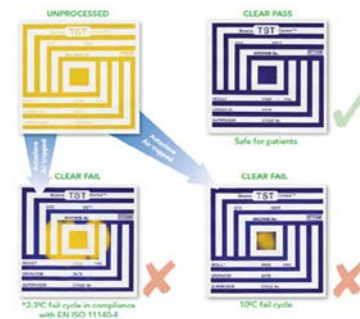
➤ Air Leackage test.



➤ Steam penetration test (Helix test or Bowie & Dick test).



The sterilizer shall be also annually validated according to the ISO 17665.





SST2200B & SST1700B

Main characteristics

—

Deep drawn stainless steel chamber

The sterilization chamber, made of **austenitic stainless steel Aisi304**, is manufactured in a seamless piece by means of **deep drawing**.

This process allows the use of a smaller thickness, **reducing the total mass** of pressure vessel, thus **avoiding the waste of time and energy** used to merely warm up the chamber.

Moreover the chamber is **electropolished**. This treatment enhances the **corrosion resistance and improves the cleaning procedures**.



Automatic door locking system

SST2200B and **SST1700B** are equipped with an **automatic door locking system** microprocessor controlled.

Two sturdy stainless steel hooks, activated by a gearbox, hang firmly the door and **avoid the opening of the door until the pressure is inside the chamber.**

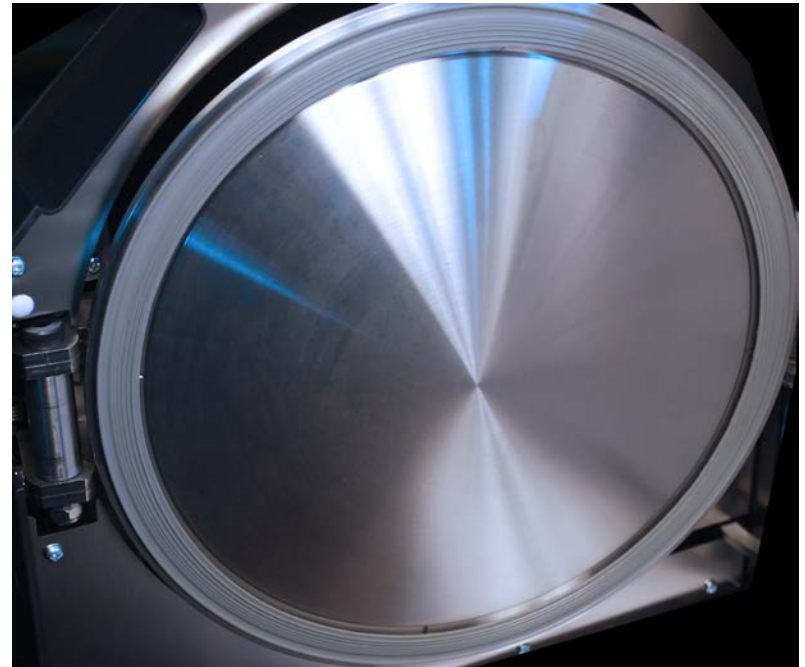


Automatic door locking system

The door plate is equipped with a not glued **gasket easily replaceable**.

The door gasket is never compressed before the beginning of the cycle, this improves the shelf life of the component.

The correct door closure is continuously controlled during sterilization cycle by means of **3 sensors**.

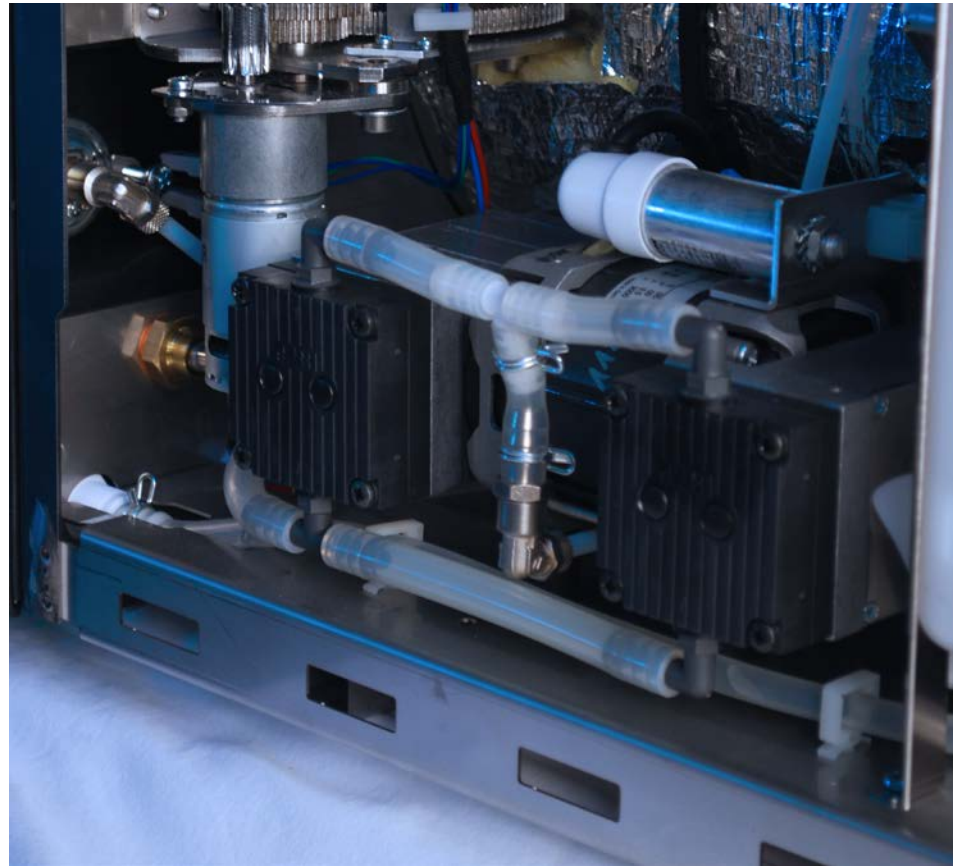


Air removal system

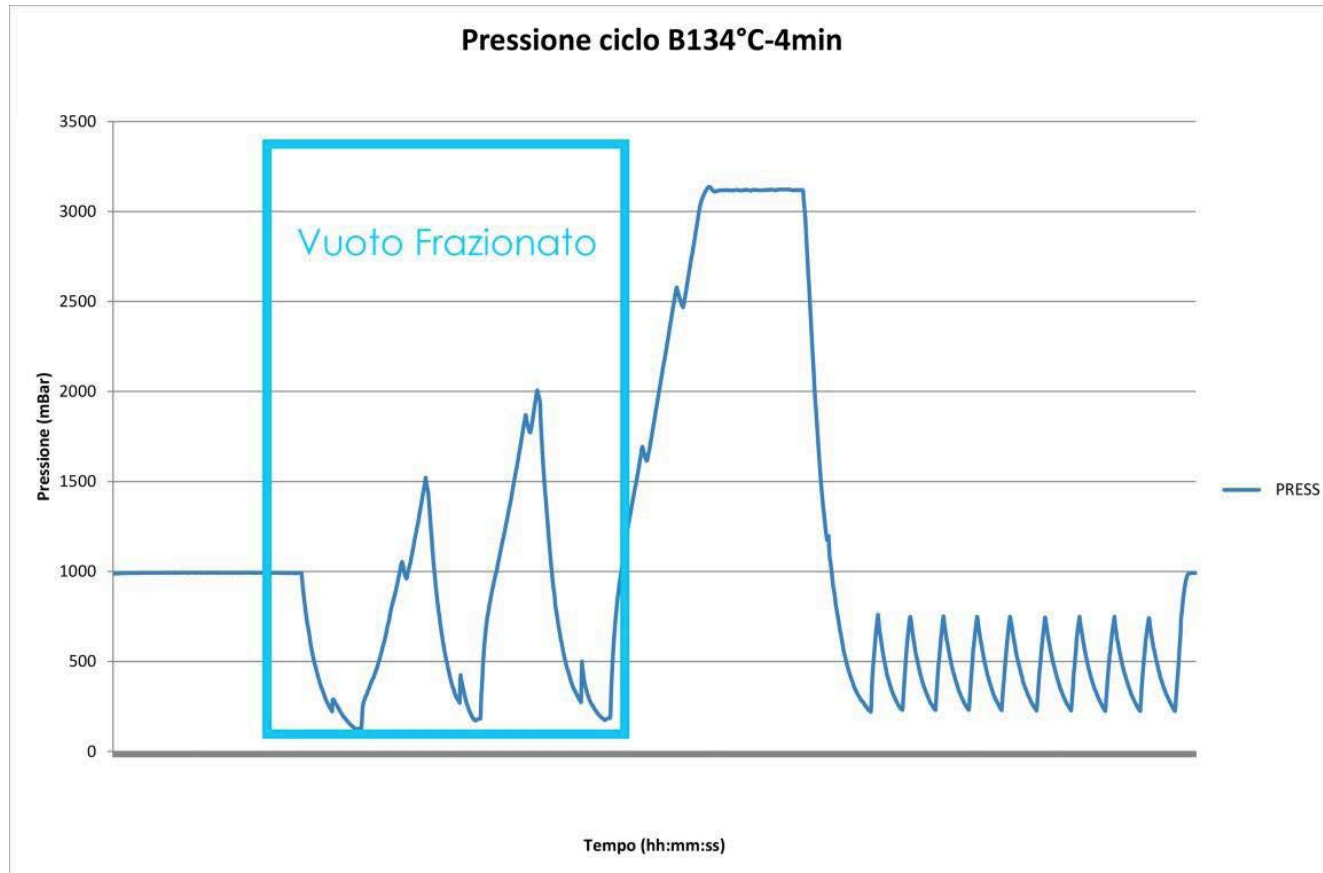
In order to assure the proper air removal from the load, the fractionated vacuum process is carried out by means of using a **triple head membrane pump**.

The hydraulic circuit has been designed in order to assure the maximum vacuum pump performances, that is never affected by water or steam passing through its heads.

.



Air removal system



The 28 lt/min vacuum pump allows the completion of a standard cycle in 35 minutes*

*Cycle 134°C – 4 minutes - B=25 air removal and sterilizzazione +10 minutes ECO drying (average load)

Steam generator

CBM steam sterilizers are equipped with a **2000 Watt dedicated steam generator**, connected to the sterilization chamber by the hydraulic circuit. In order to avoid limestone deposit into the generator, heating elements are placed outside.

The **water quantity** in the steam generator is **continuously monitored** by the microprocessor by means of a dedicated sensor. The steam generator is preheated in order to reduce the cycle time.



Cooling system

In order to improve the vacuum pump performances, condense the drained steam and lower the sterilizer internal temperature, CBM sterilizers are equipped with a **double fans cooling system**.



In order to **lower the fans noise**, they turn at maximum speed only when needed.



Cooling system

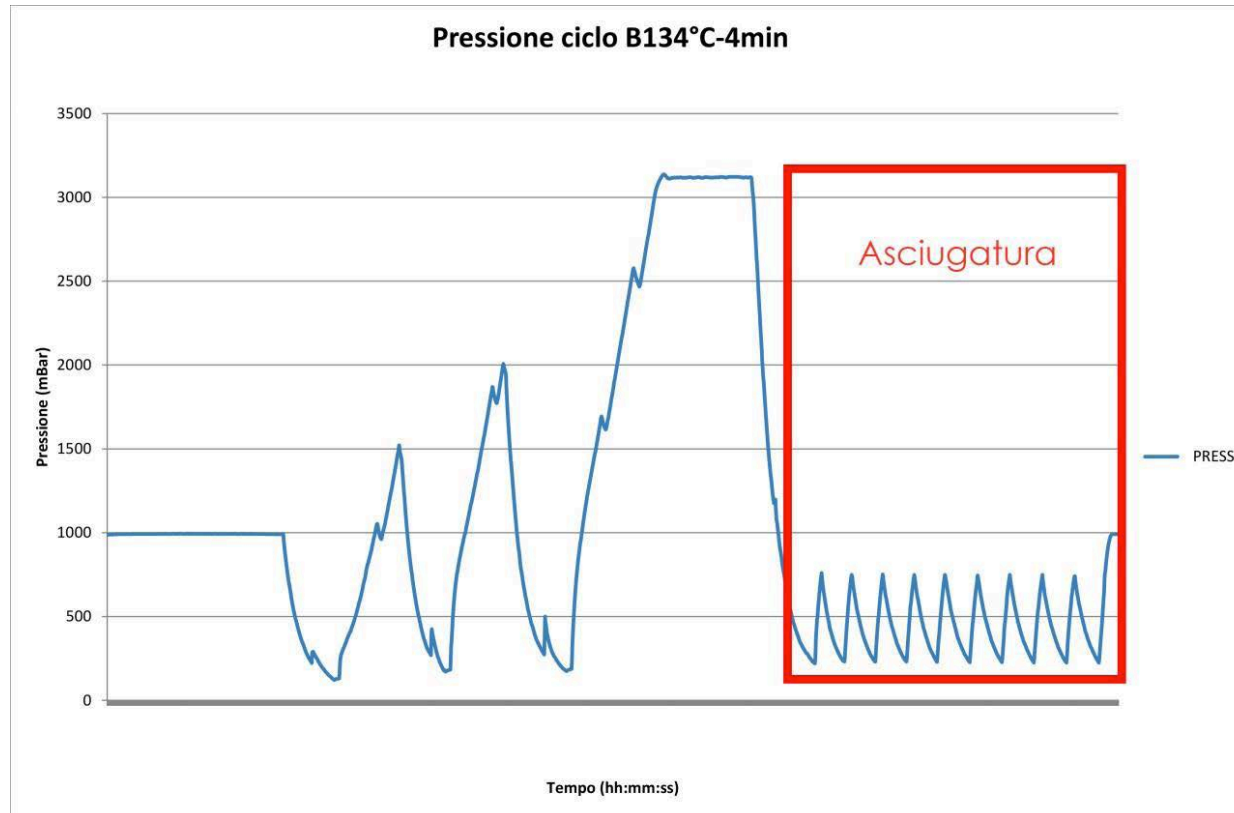
In other situation fans turn slower or are switched off..

The cooling air entering into the sterilizer is filtered .

In this manner **dust deposit are avoided** into the chassis and the cooling system remain efficient.



Drying.



The drying of loads is carried out under vacuum. The negative pressure created by the pump let the residual moisture evaporate because of the load residual temperature and because of the band heating element .

Drying

The pre-set drying phase can be :

- Removed
- Double
- Self evaluating (**ECO mode**)

Anyhow the standard drying is able to grant the achieving of residual moisture content percentages requested by the EN13060:

Maximum 0,2% for solid load

Maximum 1% for porous load

The air admitted to return into the chamber at the end of the drying phase is filtered by the **bacteriological air filter** . The filter is placed in the front panel in order to be **easy replaceable**.



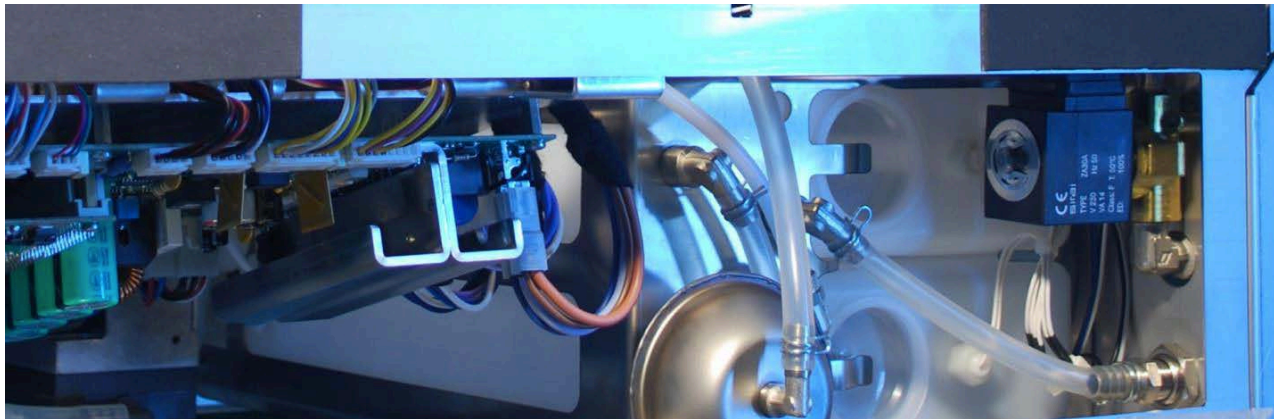
Water management system

Double tanks

CBM sterilizers are equipped with internal double tanks of about 3 litres each one.

One tank is dedicated for clean demineralized water and the second one is for the used water.

The sterilization cycle **always use clean water in order to protect instruments** and the apparatus itself from deposit.

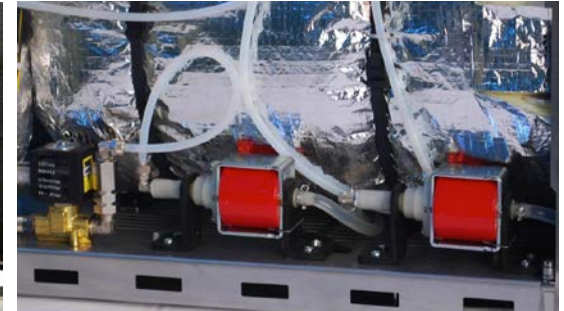


Water management system

Filling system

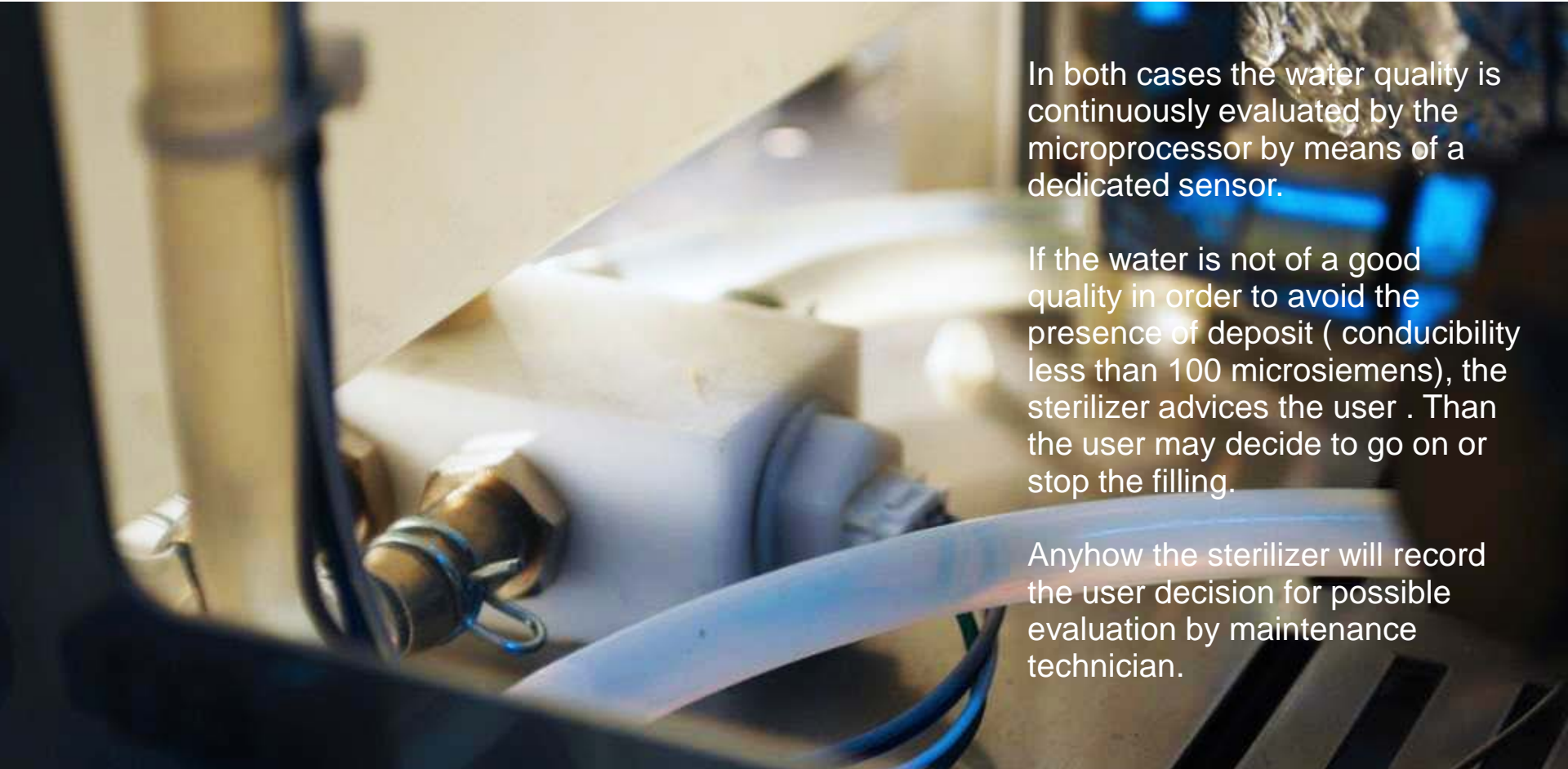
The water filling inside the tank can be done in two ways:

- **Interactively** by means of the dedicate software utility and the tap in the front panel
- **Automatically** by means of connecting the sterilizer to a source of demineralized or osmotized water.



Water management system

Water quality evaluation system



In both cases the water quality is continuously evaluated by the microprocessor by means of a dedicated sensor.

If the water is not of a good quality in order to avoid the presence of deposit (conductivity less than 100 microsiemens), the sterilizer advises the user. Then the user may decide to go on or stop the filling.

Anyhow the sterilizer will record the user decision for possible evaluation by maintenance technician.

Water management system

Water quantity

CBM sterilizers have been designed in order to **reduce as much as possible the water usage.**

The generator is in fact always filled with **just the amount strictly necessary for one cycle.**

With a full tank it is possible to make an average of 6 to 8 sterilization cycle.



Electronic and electricity waste reduction system

Electronic control boards

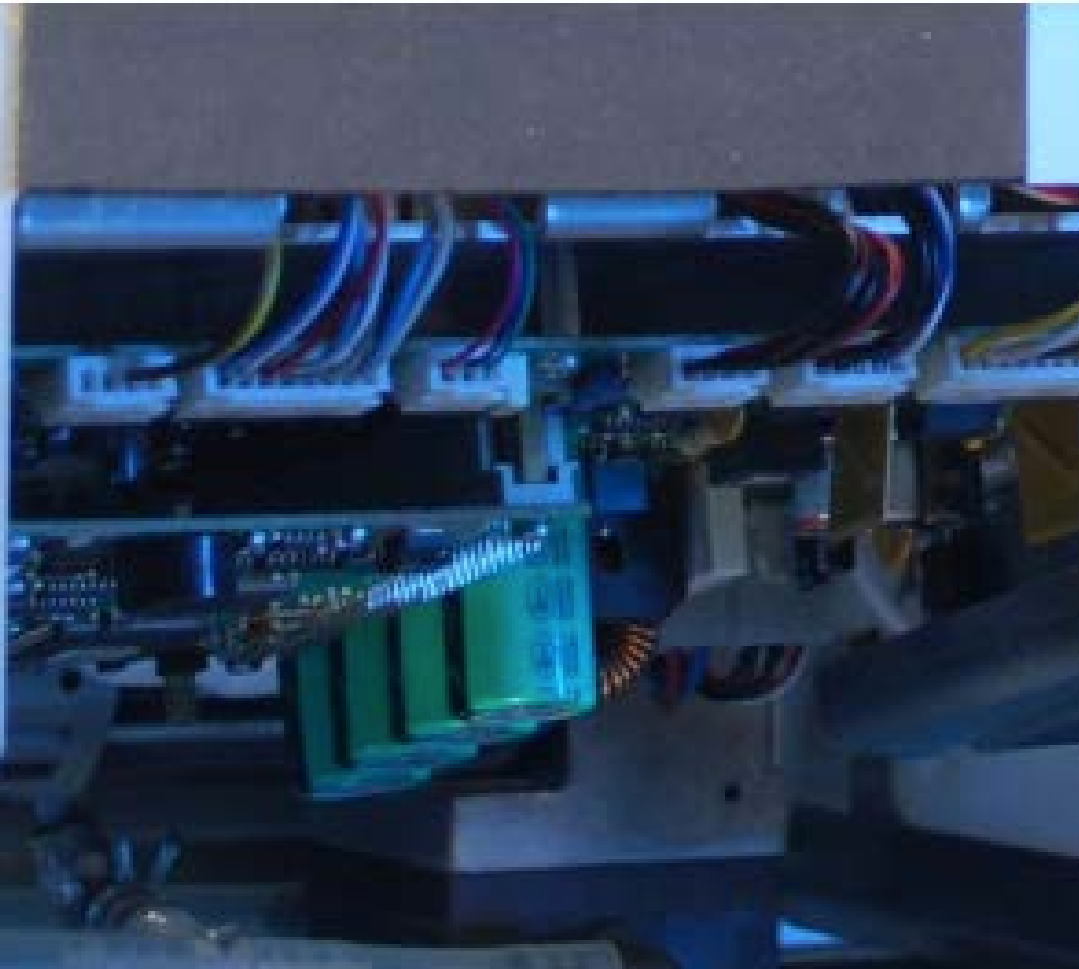
The autoclaves are equipped with an **electronic control of the latest generation** managed through a user interface with graphical 5.7 "resistive" **touch screen display**, that can be used even when wearing gloves.

The control system consists of 3 dedicated cards , manufactured with SMT technology. The electronics designed by CBM is absolutely free from problems due to electromagnetic interference.



Electronic and electricity waste reduction system

Electronic control boards

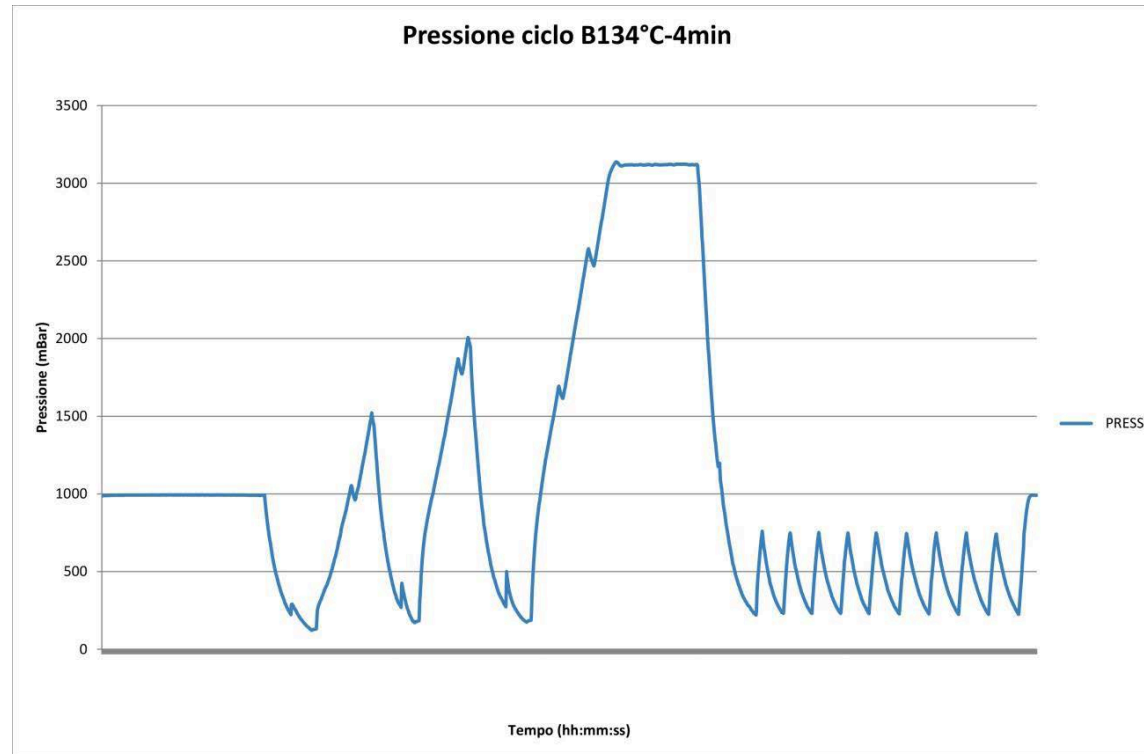


Hardware and firmware have been designed with great care for energy saving. The system power control is able to modulate the voltage supplied to the various components.

In this way it is possible to provide power in proportion to the actual need. For example it is possible to feed the steam generator and the band, without let the power exceeds 2050 watts.

Elettronic and electricity waste reduction system

P.I.D. and process evaluation system



The achievement and maintenance of the correct sterilization conditions is obtained thanks to the control software that uses a sophisticated algorithm **PID (Proportional Integral Derivative)**.

Electronic and electricity waste reduction system

P.I.D. and process evaluation system

The efficacy of sterilization cycle is **automatically verified by the process evaluation system** integrated into the software.

The microprocessor read the real temperature by means of PT1000 chamber sensor and compare it with the theoretical saturated steam temperature (Molier chart), derived from the absolute pressure chamber sensor.

In any case, both temperatures must not be below the sterilization temperature or be over it by more than 3°C . In the same time temperatures must not differ for more than 2°C.

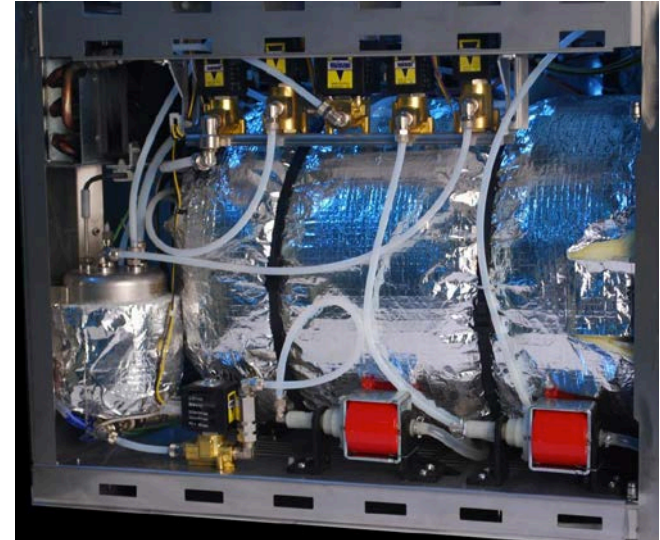


Chassis and easyness of maintenance

Both models have a **frame entirely manufactured in stainless steel Aisi304**.

The sterilizer has been designed in order to **easy the access of technicians**.

Hydraulic and electric parts are grouped and **clearly identified** for a quick identification.



Models and optionals

Sterilizers are available in two capacities, **17 and 23 litres**, having the same external dimensions.

Autoclaves can be sold with or without **integrated printer**.

It is also possible, for model without integrated printer, to use an external printer connected to the RS232 port placed in the back of the sterilizer.

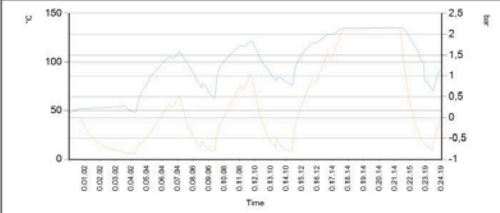


Data recording software

All models are equipped with a **USB integrated port** and are sold together with a 1Gb USB **pen-drive** that is able to record up to **10000 cycles**.

Autoclave registers in the external memory the data of each executed sterilization cycle. The sterilizer is supplied together with “**CBM-Sterireport**” software that is used to download data from USB pen and to create traceability reports. Reports can be printed or stored in electronic format.

RAPPORTO CICLO DI STERILIZZAZIONE					
DATI UTENTE:					
Nome Azienda	CBM srl a socio unico				
Indirizzo	via Castello 10/A				
Telefono	+39 0375 394095				
e-mail	tecnico@cbm-srl.com				
Responsabile	laboratorio				
DATI APPARECCHIATURA:					
Modello	SST2200				
Numero di Serie	563				
Nr.di Cicli	103				
CICLO:					
Nome File:	05630103.CBM				
Data	venerdì 9 maggio 2014 11:28				
Pressione Atmosferica	1,013				
Conducibilità H2O	---				
Ciclo	Helix test				
Asciugatura	Drying				
Risultato del Ciclo Ciclo completo!					
DATI CICLO:					
Fase nr.	Descrizione	Temperatura Camera (C°)	Pressione Camera (Bar)	Start Fase	Fine Fase
1	riscaldamento	51,28	0,003	11:28:44	11:29:23
2	vuoto	48,59	-0,858	11:29:23	11:33:03
3	iniezione vapore	109,18	0,49	11:33:03	11:35:53
4	vuoto	63,81	-0,809	11:35:53	11:38:15
5	iniezione vapore	120,44	0,99	11:38:15	11:40:33
6	vuoto	76,2	-0,811	11:40:33	11:43:18
7	iniezione vapore	135,23	2,128	11:43:18	11:46:45
8	sterilizzazione	135,54	2,136	11:46:45	11:50:17
9	scarico	122,3	0,187	11:50:17	11:51:10
10	asciugatura	91,86	-0,036	11:51:10	11:53:07
11	fine ciclo				11:53:07

RAPPORTO CICLO DI STERILIZZAZIONE	
STATISTICHE DEL CICLO	
Temperatura Camera Min. (°C)	135,30
Temperatura camera Max. (°C)	135,55
Pressione camera Min. (Bar)	2,119
Pressione camera Max. (Bar)	2,134
Temperatura teorica del vapore Min. (°C)	135,1
Temperatura teorica del vapore Max. (°C)	135,2
Tempo totale del ciclo	00:24:23
GRAFICO DEL CICLO:	
	
APPROVATO:	
Responsabile	laboratorio
Data	
Commenti	
Firma	

Accessories

The autoclave is sold with a standard shelves support that can accept up to 4 trays or 2 minicontainers.

Each sterilizer is supplied with 4 stainless steel trays, one handle for tray removal.



Optional packaging system

CBM manufacture a very wide range of reusable packaging systems, that represent the more skillful solution for:

- Reduce the cost of disposables
- Handle safely the instruments.
- Protect very delicate intruments.





SST2200B & SST1700B

Performance



Performance







Cycles

	SST2200 (23 litri)	SST1700 (17 litri)
Carico metallico massimo cicli tipo B	6 Kg	4,5 Kg
Carico poroso massimo cicli tipo B	2 Kg	1,5 Kg
Carico metallico massimo ciclo tipo S – imbustato	2 Kg	1,5 Kg



Performance

Cycles

										
Tipo ciclo EN13060	B	B	B	S	Test	Test				
Temperatura di Sterilizzazione	121°C	134°C	134°C	134°C	134°C	-				
Pressione di Sterilizzazione	1.1 Bar	2.15 Bar	2.15 Bar	2.15 Bar	2.15 Bar	-				
Tempo di Sterilizzazione	18 minuti	4 minuti	20 minuti	4 minuti	3.5 minuti	-				
Numero fasi di vuoto	3	3	3	2	3	1				
Asciugatura	ECO	ECO	ECO	ECO	nessuna	nessuna				
SST2200 (23 litri)										
	Partenza da Freddo	Partenza da Caldo	Partenza da Freddo	Partenza da Caldo	Partenza da Freddo	Partenza da Caldo	26	22		
Totale ciclo Carico minimo (minuti)	43	37	31	25	47	41			23	17
Totale ciclo Carico medio (minuti)	53	47	41	35	57	51			28	22
Totale ciclo Carico massimo (minuti)	63	57	51	45	67	61			35	29
SST1700 (17 litri)										
	Partenza da Freddo	Partenza da Caldo	Partenza da Freddo	Partenza da Caldo	Partenza da Freddo	Partenza da Caldo	Partenza da Freddo	Partenza da Caldo	24	22
Totale ciclo Carico minimo (minuti)	41	35	28	22	44	38	22	16		
Totale ciclo Carico medio (minuti)	50	44	37	31	53	47	26	20		
Totale ciclo Carico massimo (minuti)	60	54	47	41	63	57	30	24		



THANK YOU FOR THE ATTENTION!!



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