

WARRANTY CERTIFICATE

Name

Address

City State Country

Phone Pin

Invoice Issue Date.....

Dealer

ModelSerial No.

Batch Manufacturing Date



DENTAL PRODUCT

Manufactured By
Dibya Industries (India)

A-2/34, Site-IV, Sahibabad, Industrial Area, Ghaziabad
Mobile : 9891814441, 9711118437, 9811330727
sales.dibyaindustries@gmail.com | gdpdental@gmail.com



User Manual

ENCLAVE

FRONT LOADING AUTOCLAVE



Dear doctor,

We thank you for your confidence demonstrated by the purchase of our Front Loading Autoclave-Enclave.

As an owner-run and operated family concern founded in 1997, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and continuous improvement in operational reliability has established GDP as the most trusted manufacturers of Autoclave in India.

You, our customer are justified in your demand for the best products, quality and reliability Providing 'Competence in Hyglene" and "Quality-Made in India", we guarantee that these demands will be met.

- Depending on the time of the program abort, it is possible that the load is unsterile. Observe the clear instructions shown on the display of the steam sterilizer. If necessary, sterilize the affected objects after re-wrapping.

REMOVING THE STERILIZED EQUIPMENT

- Never use force to open the door.
- Use a tray jack to remove the tray. Never touch the sterilized items, the chamber or the door with un-protected hands. The components are hot.

MAINTENANCE

- Have the maintenance done only by authorized persons.
- Only original Enclave spare parts may be used.

MALFUNCTIONS

- Only have the device repaired by authorized persons.

PERFORMANCE SPECIFICATIONS

INTENDED USE

The steam sterilizer is designed for use in a general medical environment in which the instruments used and their packaging do not require a class B steam sterilizer. This steam sterilizer is a Class B sterilizer. As a universal steam sterilizer, it is suitable for the sterilization of unwrapped or wrapped solid instruments, hollow body articles and smaller quantities of textiles

WARNING

Any attempt to sterilize liquids can result in a delay in boiling. This can result in damage of the steam sterilizer and burns

- Never use this steam sterilizer to sterilize any fluids. It is not licensed for the sterilization of fluids

NOTICE

Failure to comply with these safety instructions can result in damage or can compromise safety.

- Only ever use the steam sterilizer for the applications as foreseen in the technical documentation and only in connection with the devices and components as recommended by GDP.
- When conducting sterilization procedures, only use instruments, packaging and textiles which the manufacturer has cleared for steam sterilization

GENERAL GUIDELINES

Please read this user manual carefully before commissioning the device. The user manual includes important safety information. The functionality and value-retention of this device depends on the care accorded to it. Please store these user manuals carefully and in close proximity to your device. It represents a component of the product.

Should the user manual no longer be legible, damaged or lost, please obtain a new copy from the sales personnel. State the device type and your address in an e-mail.

The manual contains the operating procedure for the GDP range of autoclaves

- B-Class Pro Supreme
- B-Class Supreme (Touch)
- B-Class Supreme
- B-Class Elite
- B-Class Enclave

DESCRIPTION OF THE DEVICE

Scope of delivery

Please check the scope of delivery before setting up and connecting the device.

- Standard scope of delivery
- Enclave/Elite/ Supreme/ Pro Series
- User manual
- Warranty certificate
- Drain Pipe
- Knob for emergency release of the door
- Water Measuring Mug
- Tray lifter

Optional

- Trays
- Water treatment unit (Water Distiller)
- Standard tray cassettes and lifter
- Additional mounts

LOADING THE STEAM STERILIZER

PREPARING THE STERILIZATION MATERIAL

Cleaning and disinfection must always have been performed before sterilization. Only in this way is it possible to guarantee the subsequent sterilization of the sterilization material. The materials used, the cleaning fluid and treatment procedures used are of decisive significance

NOTICE
Only ever operate the steam sterilizer with a sterile filter inserted.

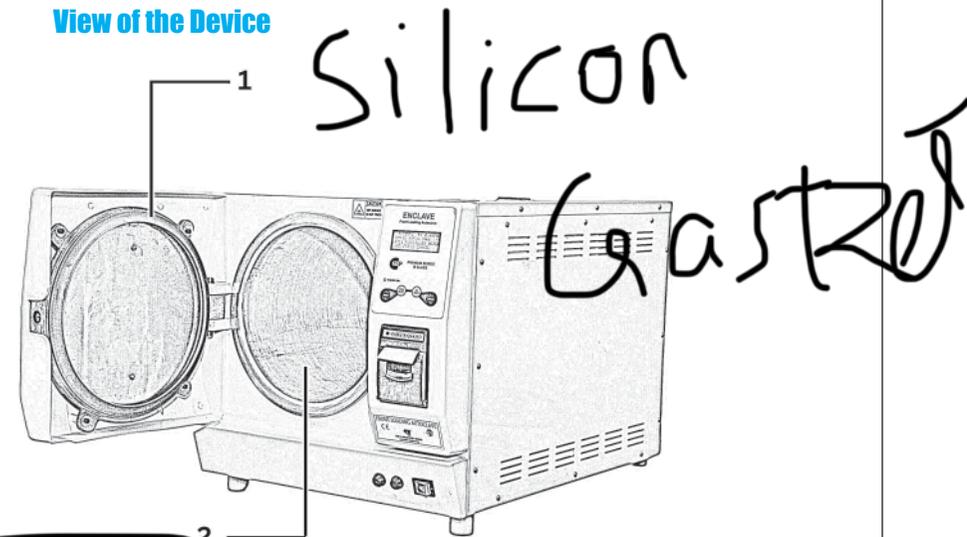
WARNING
The incorrect decontamination of textiles, e.g., a textile package can prevent steam penetration and/or produce poor drying results. The textiles could not be sterilized.

Please comply with the following points when treating textiles and putting the textiles in sterilization containers :

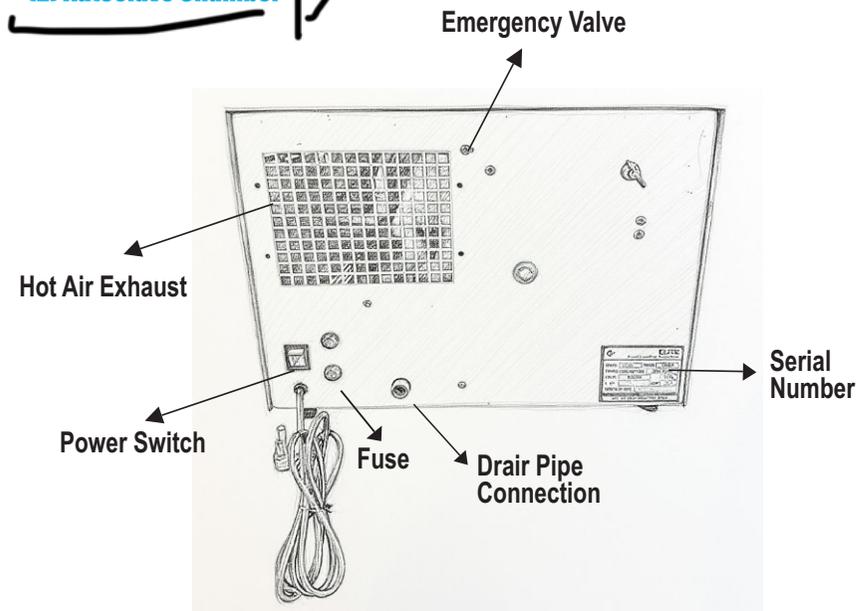
- Arrange the folds in the textiles parallel to each other.
- Stack textiles vertically wherever possible and not too closely together in the sterilization container
- This enables the development of flow channels.
- Retain the vertical stacking system when packing textiles in the sterilization container.
- If textile packages do not remain together, wrap the textiles in sterilization paper
- Only ever sterilize dry textiles.
- The textiles may not be permitted to come into direct contact with the sterilization chamber; otherwise they will become saturated with condensate.
- The perforations of one-sided perforated sterilization containers should be at the top of any containers
- Wherever possible, please ensure that sterilization containers are only stacked on top of those of identical size, so that the condensate can run down their sides.
- Ensure that the perforations are not covered when stacking the containers.

DESCRIPTION OF THE DEVICE

View of the Device



(2) Autoclave Chamber



STERILIZATION

Selecting the program (Only in SUPREME / Touch Pro SUPREME)

You can switch between the initial state and the desired program using the cycle selection button

Now select the sterilization program according to how and whether the sterilization material is packed. It is also necessary to take into account the temperature resistance of the sterilization material,

The following table shows which program is to be selected for which sterilization material.

Table 4: Overview of the sterilization programs

	Universal Program	Quick Program	Normal Program	Prion Program
Sterilization temperature	121 °C	134 °C	121 °C	134 °C
Sterilization pressure	1.1 bar	2.1 bar	1.1 bar	2.1 bar
Sterilization time	16 min.	8.00 min.	16:30 min	2:00 min
Operating time*)	c. 40 min.	c. 15 min.	c. 40 min.	60 min.
Drying	25 min.	c. 10 min.	25 min.	25 min.

*) without drying, depending on the load and installation conditions (such as supply voltage)

Table 5: Overview of the use of the sterilization programs

Program name	Packaging	Especially suitable for	Load*
Universal-Program	Single and multiple wrapping	Mixed loads; transmission instruments, simple hollow bodies	4 Kg
Quick-Program	Only unwrapped (no textiles)	Single massive instruments; simple hollow bodies	4 Kg
Normal-Program	Single and multiple	Textiles, thermo-unstable items (e.g. plastic, rubber articles)	Textiles 0.6 Kg Thermo-unstable equipment 4kg
Prion-Program	Single and multiple wrapping	Instruments under suspicion of carrying the danger of infection through abnormally altered proteins	4 Kg

*) This applies massive loads (e.g. instruments) including the weights of mounts, trays, sterilization containers and standard tray cassettes. This applies porous loads (eg. textiles) excluding the weights of mounts, trays, sterilization containers and standard tray cassettes.

CLOSED STERILIZATION CONTAINERS

CAUTION



The use of unsuitable sterilization containers results in insufficient steam penetration and even failure of the sterilization. This can also prevent condensate drain-off.

This produces poor drying results. This can result in unsterile instruments and thus endanger the health of patient and practice team.

CAUTION



Incorrect stacking of the sterilization containers can result in the dripping condensate being unable to drain off to the chamber floor. This can saturate sterilization material directly underneath it

This produces poor drying results. This can result in unsterile instruments and thus endanger the health of patient and practice team.

- Do not cover the perforations when stacking the sterilization containers.

Please comply with the following when using closed sterilization containers for sterilization material:

- Closed sterilization containers must be either perforated or have a valve on at least one side-optimally the bottom.

LOGGING

BATCH DOCUMENTATION (Only In Elite & Supreme / Pro Series)

The batch documentation acts as proof of the successful conclusion of the program and represents an obligatory part of quality assurance. The device internal log memory saves such data as the program type, batch and process parameters of all the programs completed

To obtain the batch documentation, you can output the internal log memory and transfer its data to various output media. This can be performed immediately at the end of every program or at a later point, such as at the end of the day.

PLEASE NOTE

An abort during log output on the log printer is only possible through deactivation of the device using the power switch or by interrupting the power supply to the printer.

When switching off the device via the power switch, wait three seconds before switching it back on.

DISPLAYING THE LOG MEMORY

If a printer or other output medium is connected and initialized (only in ELITE & SUPREME model), you can check how many logs have already been saved in the steam sterilizer log memory.

Fig. 5: Example for a text log of a successfully completed program.

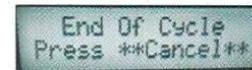
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Dibya Industries India
Elite S-Class
Autoclaves
Cycle - Count : 5
Date : 1/2/21
Time : 15 hr 3 min
Vacuum Cycles At
1 At 0 Psi
2 At 11 Psi
3 At 12 Psi
Sterilization At
124C-18Psi
Sterilization 18 min
Post Sterilization
Vacuum Cycle 3 min
Sterilization Over
At 37 min
Dry-Cycle Start
At 12PsiC
Dry-Cycle 1: 8 min
Mid Dry
Vacuum Cycle 2 min
Dry-Cycle 2: 8 min
Final Vacuum 3 min
Total Cycle Time
0 hour 58 min
-----END OF CYCLE-----

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PROGRAM END

When the program has been completed successfully, the display shows:



End of Cycle is displayed on the LCD. Now the instruments are now completely dry and sterilized. They are being kept in a vacuumized chamber and as long as they are in the chamber they are sterilized.

PRESS CANCEL and wait for 60Secs to normalize the chamber pressure. Open the door and remove the trays through the tray holder. Switch off the Enclave Autoclave.

Total Cycle-Time ~1 hour 5 mins.

MANUAL PROGRAM ABORT

You can abort a current program in all phases. If you end the program before drying begins, the sterilization material remains unsterile.

PROGRAM ABORT BEFORE THE START OF DRYING



WARNING

Danger of infection from early program abort

Aborting a program before the drying phase begins means that the load is unsterile. This endangers the health of your patients and practice team.

- If necessary, repack the load and repeat the sterilization for the sterilization material affected.

PROGRAM ABORT AFTER THE START OF DRYING

You can abort the program during the drying phase by pressing "CANCEL" key without the steam sterilizer registering a fault.

Should you abort a program after drying has started, the sterilization is having been completed successfully. You should expect insufficient drying, especially in the case of wrapped sterilized equipment and a full load. Sterile storage requires sufficient drying.

REMOVING THE STERILIZED EQUIPMENT



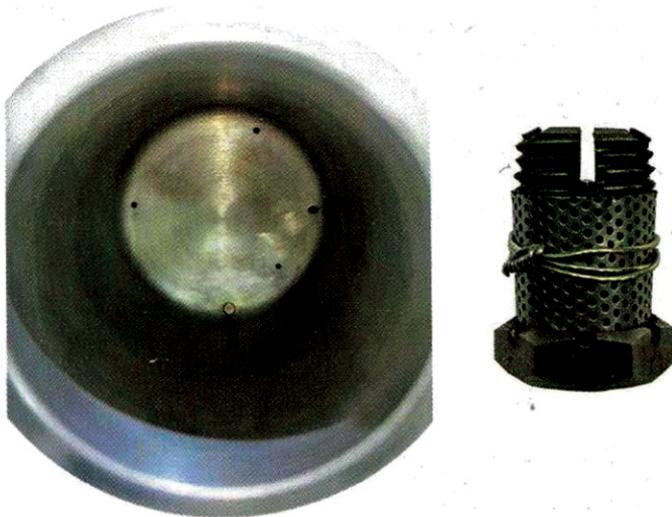
CAUTION

Danger of burns from hot metal surfaces

Allow the device to cool sufficiently before opening.

Do not touch any hot metal parts.

CLEANING THE FILTER IN THE CHAMBER



1. Unscrew the filter in the sterilization chamber (using your hand or plier)
2. Rinse the filter (a and b) for cleaning with water
3. Fasten the Filter in the sterilization chamber with clockwise rotation until it seals off.

MAINTENANCE

NOTICE

Continuing operation beyond the maintenance interval can result in malfunctions in the device.

- Maintenance should only be performed by trained and authorized customer services technicians, or stockist technicians.
- Maintain the specified servicing intervals.

Regular maintenance is vital to ensure reliable operation and value retention of the steam sterilizer. All function and safety-relevant components and electrical units must be checked during maintenance and replaced where necessary. Maintenance is performed in accordance with the maintenance instructions pertinent to this steam sterilizer

Arrange for regular maintenance in 24 months intervals or after 1000 program cycles. The steam sterilizer will issue a maintenance message at the relevant time.

AVOIDING STAINING

Only after cleaning instruments properly prior to sterilization is it possible to avoid residue from the load or the instrument decontamination from being released during sterilization. Loosened dirt residue can clog the filter, nozzles and valves of the steam sterilizer and deposit themselves on the instruments and chamber as deposits and stains.

All steam-conducting parts of the steam sterilizer consist of non-rusting material. This rules out the possibility of stain or rust development being caused by the steam sterilizer. The development of rust is always extraneous rust

Incorrect instrument decontamination can result in the accretion of rust even on stainless steel instruments of leading manufacturers. Often, an instrument which drops rust can suffice to cause the development of rust on another instrument or in the steam sterilizer.

The extent of stain accretion on the instruments is also dependent on the feed water used for steam generation.

REPLACING THE DOOR SEAL

The door seal may not be greased or oiled. It should be kept clean and dry. If the door seal becomes worn or loses form, it must be replaced. Otherwise, this could result in leaks and the egress of steam. The door seal is only inserted in the groove of the round blank and can be changed as follows:

1. Open the steam sterilizer door and remove the old door seal.



FAULT MESSAGES

ERROR CODES

- Error 1- During 2nd Vacuum Cycle, The pressure is less than 5 PSI & temperature goes above 115 C
- Error 2- At the end of the first vacuum cycle, if the pressure is greater than 7 psi
- Error 3- During 134C cycle i.e. (134 pouch, 134 solids, Bowie and Dick, Prion). if the pressure is greater than 33 PSI
- Error 4- During DRY-CYCLE if the pressure goes above 3 - PSI
- Error 5- During 134C cycle i.e. (134 pouch, 134 solids, Bowie and Dick, Prion), if the pressure drops below 10 PSI
- Error 6- During Vacuum Cycle- 3 i.e. (134 Pouch, 121 Pouch, Prion, Bowie and Dick cycle), if the temperature is above 115 C and pressure is less than 7
- Error 7- At the end of the Second vacuum cycle, if the pressure is greater than 7psi
- Error 8- At the end of the Third vacuum cycle, if the pressure is greater than 7 psi
- Error 9- Contact Support Personal
- Error 10- RTD Sensor Issue, Temperature above 150C or drops below 60C after second Vacuum Cycle
- Error 11- During 121C Cycle, if the pressure exceeds 29 PSI
- Error 12- During preheating for 121 C Cycle, if the temperature goes above 127 C
- Error 13- During preheating for 134 C Cycle, if the temperature goes above 139 C

MALFUNCTIONS

Warnings

Warnings are not malfunction messages. They help to ensure malfunction-free operation and to recognize undesirable situations. Comply with these warnings early in order to avoid malfunctions.

Malfunction messages

Malfunction messages are issued on the display with an event number. This number serves identification purposes. Malfunction messages are issued when it is not possible to ensure safe operation or safety of sterilization. These can appear on the display shortly after activating the steam sterilizer or during a program run. If a malfunction occurs during a program run, the program will be aborted.

**WARNING****Danger of infection from early program abort**

Aborting a program before the drying phase begins means that the load is unsterile. This endangers the health of your patients and practice team.

If necessary, repack the load and repeat the sterilization for the sterilization material affected

Before contacting customer services

Ensure that you have complied with all instructions relating to a warning or malfunction message issued by the display of the device. The following table contains a summary of the most important events. The events contain possible causes and the corresponding operator information.

**CAUTION****Danger of burns from hot metal surfaces**

Allow the device to cool sufficiently before opening.
Do not touch any hot metal parts.

Opening the door in an emergency following a power outage



WARNING

The steam sterilizer must be completely pressure free. Failure to observe this provision can result in scalding/Injury.

- No steam may be permitted to leave from between the sterile filter and the rear panel of the steam sterilizer.
- The slide seal grip must be easy to actuate
- It must be possible to push the door c. 2 mm to the rear with light pressure.
- It is imperative that you allow the steam sterilizer to cool. Metal parts such as the door and chamber can be hot

Should it not be possible to open the door e.g. following a power outage, taking into account the safety information specified above, proceed as follows:

1. Switch off the steam sterilizer at the mains and remove the plug from the socket



2. To effect emergency release of the door, position long side of the lever between the door and the side wall of the steam sterilizer. The curve points forwards; the lever is at the level of the slide seal grip. If the lever is in the guide, pull it forwards with your right hand. Push the slide locking grip upwards with your other hand.



3. Open the door.

TECHNICAL DATA

Device type	Enclave 23
Device dimensions (H x W x D)	49 x 42.5 x 70 cm
Chamber diameter/depth	0 25 cm 45 cm
Chamber volume	22.6 litres
Empty weight	45 kg
Operating weight ⁽¹⁾⁽²⁾	55 kg
Max. Floor loading (hydraulic ressure test) ⁽²⁾	67.6 Kg
Electricity supply	220-240 V, 50/60 Hz, 1500W (16, 18ltrs), 2000 W(23ltrs)
Building fuses	16 A fuse, FI protection 30 mA
Waste heat (with maximum load)	0.9 kWh
Noise emission	64 dB (A)
Ambient temperature	5-40 °C (ideal range 16-26 °C)
Relative humidity	max. 80% at 31 °C. decreases in a linear fashion up to max. 50% relative humidity at 40 °C
Max, height	2000 m
Length of the power cable	1.5 m
Degree of protection (following IEC 60529)	Ip20
Water quality	Distilled or demineralized feed water
Recommended flow pressure	1.5 at 3 l/ min.
Max, water pressure (static)	10 bar
Max, water consumption ⁽⁴⁾	500ml

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PAUSE TIMES

FREQUENCY OF STERILIZATION

Pause times between individual programs are not necessary. After the end/abort of the drying time and removal of the sterilized equipment, you can load the steam sterilizer again and start a new program.

OPERATING PAUSES

Depending on the duration of the operating pauses, the following measures must be maintained:

Duration of the operating pause	Measure
Short pauses between two sterilization processes	<ul style="list-style-type: none"> Keep the door closed to save energy
Pauses which last longer than an hour	<ul style="list-style-type: none"> Switch off the steam sterilizer
Longer pauses e.g. overnight or the weekend	<ul style="list-style-type: none"> Switch off the steam sterilizer Push the door to, to prevent premature wear and the sticking of the door seal. If present, shut off the water inflow of the water treatment unit
Longer than two weeks	<ul style="list-style-type: none"> Switch off the steam sterilizer Push the door to, to prevent premature wear and the sticking of the door seal. If present, shut off the water inflow of the water treatment unit <p>Upon re-commissioning:</p> <ul style="list-style-type: none"> Perform an empty sterilization run in Quick-Programs

DECOMMISSIONING

When decommissioning the steam sterilizer for a long pause (e.g. due to holiday or planned transport), proceed as follows:

1. Switch off the steam sterilizer at the power switch
2. Disconnect the power plug from the socket.
3. Close the water inflow if you are using a water treatment unit.

ENCLAVE AUTOCLAVE

MALFUNCTIONS

Incident	Possible causes	What you can do
Door Wont Open	Negative Pressure generated during cooling of the Enclave	Remove the hose at the drainage exit from the back. Check the drainage pipe for any bends, obstructions. Check weather the pipe is in any stagnant water. Check if the pipe/hose are blocked. Clean the pipe and hose, reattach and check again.
	Check the drainage pipe for any bends, obstructions	
Autoclave: Not Turning On	Tripped MCB	Power on MCB at the back of the autoclave
	Poor Contact on Power Cord	Check Power Outlet
	Defective PC Board	Consult Technical Personnel
Taking longer than usual to reach the desired pressure	Overloaded Chamber	Only use upto 80% of the chamber capacity
	Leakage in Safety Seal	Turn Off Autoclave, Change the Safety Seal
	Leakage in Door	Polish the edge of the chamber using water sand paper grade 400 to ensure all scratches are removed.
	Insufficient Amt of Water	Ensure adequate amount water is there
Overpressure Inside Autoclave	Obstruction in Steam Discharge in the tubing/ pipe at the back of the Autoclave	Check the pipe attached at the back of the autoclave and clear off any dirt or debris
	Blockage in Solenoid Valve	Contact Service Personnel
Carry out maintenance	The maintenance message is activated. The device has reached the set number of batches or the running time of 2 years.	PLEASE NOTE: The maintenance counter is reset by the customer services.

MAINTENANCE

Servicing Intervals

Interval	Measure	Device components
Weekly	Check for soiling, deposits or damage	Chamber inc. door seal and chamber sealing face, mount for the load
After 24 months 1000 cycles	Maintenance	By the authorized customer services working in accordance with the maintenance instruction
As required	Cleaning the surfaces	Housing Parts



NOTICE

Inappropriately performed cleaning can lead to the scratching of and damage to surfaces and the development of leaks in sealing surfaces. This also favors the development of soiling deposits and corrosion in the sterilization chamber.

Comply with all information regarding cleaning of the part affected.

DOOR SEAL, CHAMBER, CHAMBER SEALING FACE, MOUNT, TRAYS

Check the chamber, door seal, chamber sealing face and the load mount once a week for soiling, deposits or damage.

If you find any impurities, remove the trays or cassettes from the chamber from the front. Clean the soiled components.

When cleaning the chamber, load mount and chamber seal face, please comply with the following :

- Switch off the steam sterilizer before cleaning and remove the power plug from the socket.
- Ensure that the chamber is not hot.
- Use a soft, non-fuzzing cloth.
- First soak the cloth with the cleaning alcohol or spirit and attempt to wipe away impurities.
- Use a chlorine and vinegar-free cleaning fluid
- Use a neutral liquid cleaning agent to clean the door seal.
- You should not allow cleaning fluid to enter the piping coming from the chamber.
- Do not use any hard objects such as a metal saucepan cleaner or a steel brush.

2. Insert the door seal in the groove of the round blank.



PLEASE NOTE

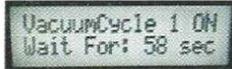
Make sure that the broad seal face faces the chamber when inserting. The door can only be shut correctly and the chamber sealed, if the door seal sits correctly in the groove.

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PROGRAM RUN

After starting the program, you can follow the program run in the display. It shows the chamber temperature and pressure as well as the time until the end of sterilization / the drying time which has passed.

- A) 1st Vacuum Cycle will start to create cold vacuum in the chamber. Reverse Timer displays the amount of time left in the cycle.



VacuumCycle 1 ON
Wait For: 58 sec

- B) 2nd Vacuum Cycle is started at 95 C to purge out remaining air and steam, At this point all the air is purged out.
- C) 3rd Vacuum Cycle is started at 110 C to saturate steam inside the instruments. Any air pockets left inside are completely erased.

STERILIZATION PHASE

The display enables you to see whether the sterilization phase has already been completed successfully. The remaining time of the sterilization phase is displayed in alternation with pressure and temperature specifications.



Sterilization 121
Wait For: 16 MIN

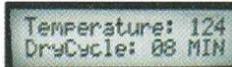
At the end of Sterilization, a buzzer sound is made to indicate the end of sterilization cycle. All the water and steam, is purged out through the drainage. A message for Sterilization Completion will be displayed.

Buzzer Time: 30Secs.

Note: If you don't need Dry Cycle, then you can press CANCEL here to take out the Sterilized instruments.

DRYING PHASE

The regular drying time amounts to cis 25 minutes. The display will show the corresponding message during the drying phase.



Temperature: 124
DryCycle: 08 MIN

The steam sterilizer provides excellent drying of the sterilization material. If difficult-to-dry items require better drying, you can undertake the following steps to improve drying:

- Load the steam sterilizer properly. Stand e.g., the transparent and paper sterilization packaging upright. Observe the contents of the section Loading the steam sterilizer.

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WARNING

Unsterile instruments resulting from damaged or burst packaging. This endangers the health of your patients and practice team.

Should the packaging be damaged or have burst, re-pack the sterilization material and re-sterilize it

If you remove the sterilized equipment from the device directly after the end of the program, it is possible that the instruments can be partially damp. "In practice, residual moisture in the form of a few drops of water capable of evaporating within 15 minutes is tolerated, but actual pools of water are not acceptable." Comply with the following specifications when removing the sterilized equipment:

- Never use force to open the door. This could damage the device and/or result in the emission of hot steam.
- Use a tray lifter to remove the tray.
- Never touch the sterilized equipment, the device interior or the inside of the door with unprotected hands. The components are hot.
- Check the packaging on the sterilized equipment for damage when removing it from the device.
- Should the packaging be damaged, re-pack the sterilization material and re-sterilize it.

STORING STERILE INSTRUMENTS

The maximum storage time is dependent on the packaging and the storage conditions. For standard- conform packaged sterilized equipment- (if protected from dust) it can amount to up to six months.

- Comply with the maximum storage duration in accordance with the packaging type.
- Do not store the sterilized equipment in the decontamination room.
- Store the sterilized equipment in a dust-protected environment e.g. in a closed instrument cabinet
- Store the sterilized equipment in a moisture-protected environment (e.g. alcohol, disinfectant).
- Store the sterilized equipment in an environment protected against excess temperature variations

DECONTAMINATING THE INSTRUMENTS

WARNING



The incorrect decontamination of instruments could result in any dirt residue being loosened by the steam pressure during sterilization.

The use of unsuitable care agents e.g. water repellent agents or oils impermeable to steam could result in unsterile instruments. This represents a danger to the health of both patients and yourself.

Please ensure the following when treating used and brand-new instruments:

- Clean the instruments exceptionally thoroughly eg. using an ultrasonic device or washer-disinfector.
- Rinse the instruments after washing and disinfecting, wherever possible with demineralized or distilled water and then dry the instruments thoroughly with a clean, non-fuzzing cloth.
- When using ultrasound devices, care equipment for hand pieces and washer-disinfectors, please comply with the manufacturer's treatment instructions

Loading the steam sterilizer

Effective sterilization and good drying is only possible if the steam sterilizer has been loaded correctly. Ensure the following during loading:

- Insert trays or cassettes in the chamber only with their appropriate mount.
- Use perforated trays. Only in this way can condensate drain off. The use of a non-perforated base or half-shell to accommodate the sterilization material can result in poor drying results.
- The use of paper tray inserts can also result in poor drying results.
- Wherever possible, please ensure the separate sterilization of textiles and instruments in separate sterilization containers or sterilization packaging. This leads to better drying results.

SOFT STERILIZATION PACKAGING

Soft sterilization packaging can be used in both sterilization containers and on trays. Please comply with the following when using soft sterilization packaging

- 1 Arrange soft sterilization packaging in a perpendicular position and at narrow intervals.
- 2 Do not place multiple soft sterilization packages flat on top of each other on a tray or in a container.
- 3 If the seal seam tears during sterilization, the packaging could be too small or the sealing pulse too low. Re-pack the instruments and if necessary, extend the sealing pulse on the film sealing device or make a double seam. Sterilize the sterilization material again.

Multiple wrapping

The steam sterilizer works with a fractionated flow procedure. This permits the use of multiple packaging.

Mixed Loads

Please observe the following when sterilizing mixed loads:

- 1 Always place textiles at the top.
- 2 Place the sterilization containers at the bottom.
- 3 Place unwrapped instruments at the bottom.
- 4 Place the heaviest loads at the bottom.
- 5 Place transparent sterilization packaging and paper bags at the top except in combination with textiles. In this case, place them at the bottom.
- 6 Place transparent sterilization packages on their edge wherever possible and with the paper side facing downwards.

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OVERVIEW OF THE STERILIZATION PROGRAMS

The results in this table show which inspections were performed on the steam sterilizer. The marked fields demonstrate compliance with all the applicable sections of the standard DIN EN 13060.

Table 1: Overview of the sterilization programs

Type Tests	Universal Program	Quick-Program B	Normal Program	Prion Program
Program type in accordance with DIN EN 13060	Type B	Type B	Type B	Type B
Sterilization temperature	134 °C	134 °C	121 °C	134 °C
Sterilization pressure	2.1 bar	2.1 bar	1.1 bar	2.1 bar
Sterilization time	5:30 min.	3:30 min.	20:30 min.	20:30 min.

X = Complies with all applicable sections of the standard DIN EN 13060

PROGRAM SEQUENCES

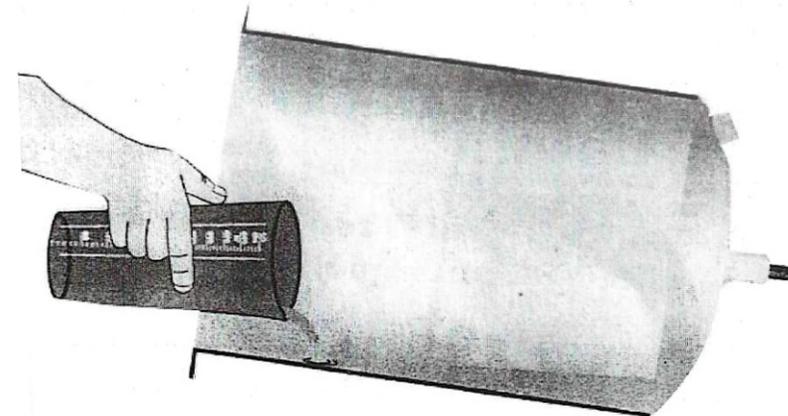
Regular sterilization program

After program start, you can follow the program run on the display. It shows the chamber emperature and pressure as well as the time until the end of sterilization/the drying.

Program phase	Description
1. Air removal phase	The fractionated flow procedure removes the air from the chamber through pulsing repeated steam injection and removal. Depending on the program selected and the current chamber temperature upon program start, further fractionation can also follow.
2. Heating phase	The heating phase follows the air removal phase. The pressure and temperature increase until the program-specific sterilization parameters have been reached.
3. Sterilization phase	If the pressure and temperature correspond to the program-dependent nominal values, the sterilization phase begins. The sterilization time is indicated on the display
4. Pressure release	The end of the sterilization phase is followed by pressure release with simultaneous emptying.
5. Drying phase	The drying phase begins after the pressure release.

ENCLAVE AUTOCLAVE

OPERATING INSTRUCTIONS- ENCLAVE



**WARNING ! USE ONLY DISTILLED WATER
IN THE STERILIZED PROCESS**

WATER QUANTITY CHART

Enclave 12 L

250 ML

Enclave 18 L

450 ML

Enclave 23 L

500 ML

- 1 Prior to use, ensure the chamber is clean and internal hole for steam discharge is not clogged.
- 2 Pour distilled water, load the Autoclave with materials to be sterilized.
- 3 Close the door, Double check to ensure the door is completely locked

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SAFETY



When operating the device, comply with the following safety instructions as well as those contained in subsequent chapters. Use the device only for the purpose specified in these instructions. Failure to comply with the safety instructions can result in injury and/or damage to the device.

QUALIFIED PERSONNEL

- As with the preceding instrument decontamination, the sterilization of instruments and textiles using this steam sterilizer may only be carried out by competent personnel.

SET-UP, INSTALLATION AND COMMISSIONING

- Check the device for any damage suffered during transport after unpacking.
- The connections for electrical provision and effluent must be set-up by trained personnel.
- In accordance with current VDE specifications, the device is unsuitable for operation in explosive atmospheres.
- Install and operate the device in a frost-free environment.
- The device is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.
- Observe all the information contained in the technical manual during commissioning.

POWER CABLE AND POWER PLUG

- Comply with all legal requirements and locally-specified connection conditions.
- Never operate the device if the plug or power cable are damaged.
- The power cable and plug should only be replaced by authorized personnel.
- Never unplug by pulling on the power cable. Always take a grip on the plug. Ensure that the power cable does not become jammed in.

DECONTAMINATION AND STERILIZATION

- Follow the manufacturer instructions of your textile articles and instruments regarding their sterilization.
- Only ever use packaging material and systems which have been approved by their manufacturer for steam sterilization (consult the manufacturer's instructions).

PROGRAM TERMINATION

- Please observe that depending on the time of the program abort, opening the door following a program abort can lead to hot steam leaving the chamber.