

English

**OWNER'S
MANUAL**
AUTOCLAVE BIOCLAVE
21 LITERS



PRESENTATION OF MANUAL

INSTRUCTIONS FOR USE

Technical Name: Autoclave

Trade Name: Autoclave

Model: Autoclave Bioclave 21L

Brand: Saevo

Manufacturer / Distributor:

Alliage S/A Indústrias Médico Odontológica
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Ribeirão Preto - SP - Brasil
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REF

77000001183 - Rev.: 04 - August/22

CAUTION

For improved safety:

Read and understand all the instructions contained in the Instructions for Use before installation or operation of this equipment.

Note: The Instructions for Use must be read by all persons that operate this equipment.

INDEX

02 PRESENTATION OF MANUAL

04 IDENTIFICATION OF EQUIPMENT

04 Indication of Equipment

04 Purpose of the equipment

05 Principles and fundamentals applied to the product functioning

05 Description of Equipment

06 MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION

09 TECHNICAL SPECIFICATIONS

09 General features

11 Dimensions

12 Symbology

13 INSTALLATION OF EQUIPMENT

17 EQUIPMENT OPERATION

20 PRECAUTIONS, RESTRICTIONS AND WARNINGS

20 Recommendations for preserving the equipment

20 Transportation, storage and operation

20 Sensitivity to predictable environmental conditions in ordinary situations of use

20 Precaution and warnings "during the installation" of the equipment

21 Precautions and warnings "during the use" of equipment

22 Precautions and warnings "after" the use of equipment

22 Precautions and warnings during the "cleaning and disinfection" of equipment

22 Precautions in case of alteration in the functioning of equipment

22 Precautions to be adopted against foreseeable or uncommon risks, related to the deactivation and abandoning of equipment

23 CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

23 Additional procedures for reuse

23 Cleaning

23 Disinfection

24 Internal cleaning (chamber and stainless steel trays sterilization)

24 Piping cleaning

24 Cleaning the filter

25 Wrapping types for sterilization by autoclave

25 Suggested method for wrapping instruments and materials

26 Control of the pressurized and saturated steam sterilization process

26 Maintenance of the qualification

26 Testing procedure using biological indicators

26 Attest biological monitoring system for steam sterilization process

26 Preventive Maintenance

26 Corrective Maintenance

27 UNFORESEEN EVENTS – SOLUTION OF PROBLEMS

27 EQUIPMENT'S WARRANTY

27 FINAL CONSIDERATIONS

IDENTIFICATION OF EQUIPMENT

Dear Customer

This manual is a general presentation of your product and it will give you important details to help you to solve possible problems.

Please, read it and keep this with you.



Indication of Equipment

This equipment is for dental use only. It must be operated and utilized by specialized professional (certified professional, according to the legislation of the country) and following the instructions of the manual. The operation of the equipment required, for the professional, the utilization of correct instruments and it should be in perfect conditions of the use, and to protect the professional, the patients and others, in the eventual danger situation.

Purpose of the equipment

Sterilization by autoclave has the purpose of destroying microorganism under high pressures and temperatures, aiming to prevent infections and contaminations.

IDENTIFICATION OF EQUIPMENT

Principles and fundamentals applied to the product functioning

Sterilization by autoclave consists of exposing the contaminated material to steam under high pressures and temperatures, for the time needed. Humidity and heat irreversibly denature structural enzymes and proteins, destroying microorganisms.

The process includes compression and decompression cycles as to provide easier contact between the steam and the contaminated material. The pressure value ranges from 1.3 to 2.1 kgf/cm² and temperatures from 123°C to 133°C.

Description of Equipment

It's an autoclave for sterilization by vapor, modern design, easy to operate, ideal for dentistry offices (general practice, endodontia, pediatric dentistry, orthodontics, prosthesis, operative dentistry and esthetics).

Its structure is made in carbon steel, with surface treatment through nanotechnology.

Smooth high gloss epoxy based paint polymerized at 250°C with corrosion resistant treatment and cleaning materials.

Its chamber is made of stainless steel* or aluminum*, offering long durability and resistance to the constant variance of temperature, with capacity for 21 Liters.

It's internally coated with heath isolating material, which optimizes its operation and reduces the energy consumption.

It features an anti-vacuum valve, which prevents the door and safety seal from blocking, and it's automatically activated if an excessive pressure was detected. The door's sealing system is made of high-performance silicone, resistant to temperature and pressure changes, and its flexibility allows the perfect sealing between surfaces in contact, preventing leakage.

The control panel contains LED and function buttons, graduated manometer for temperature and pressure, ergonomic handle with automatic depressurization safety system, which prevents accidents in case of unintentional opening.

Accompanied by a hose for outlet of steam, graduated cup, spare fuses and 3 trays made of stainless steel or aluminum totally pierced to allow a good circulation of heat, ensuring excellent quality in the sterilization.

Basic Principles of Autoclave's Operation:

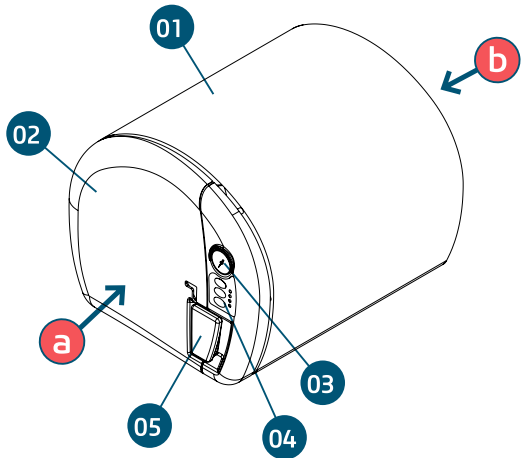
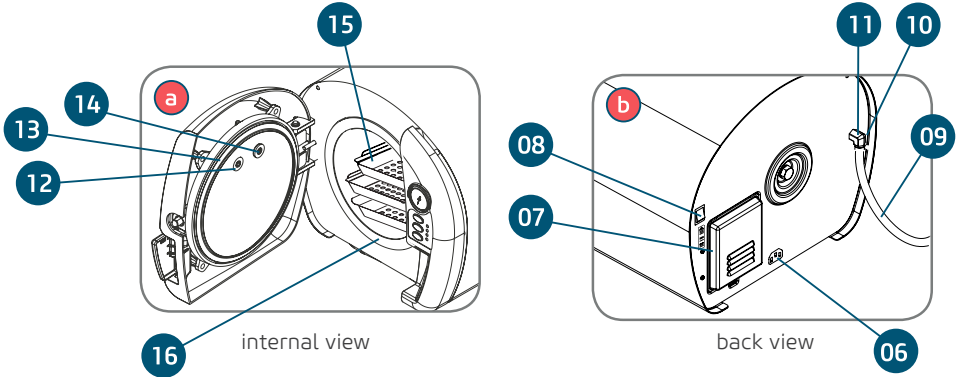
- Water supply for autoclave.
- Heating: Water steam followed by gradual increase of pressure.
- Sterilization: High pressures and temperatures through approximately 16 minutes.
- Depressurization: Steam release and relief of autoclave pressure.
- Drying: Material drying and cooling until achieving a temperature which allows handling.

* Optional

MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION



The contents of this page are of an informative nature, the equipment being able to differ from that illustrated. So, upon acquiring the product check the technical compatibility between equipment, coupling and accessories.

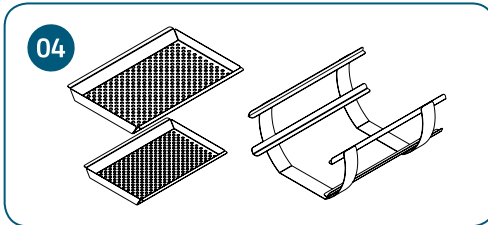
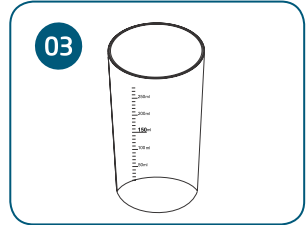
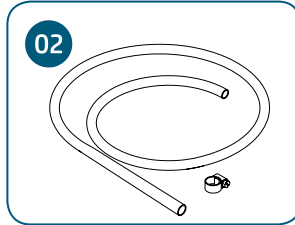
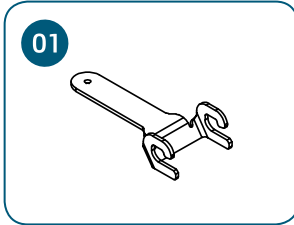


- 01 - Autoclave's body
- 02 - Front door
- 03 - Manometer
- 04 - Control panel
- 05 - Door latch
- 06 - Plug input power cable
- 07 - Fuse holder
- 08 - Master key
- 09 - Steam outlet hose
- 10 - Hose's fixing clamp
- 11 - Steam external outlet
- 12 - Anti-vacuum valve
- 13 - Sealing ring
- 14 - Safety seal
- 15 - Trays
- *16 - Sterilization chamber "available in stainless steel or aluminum"

* Optional

MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION

Accessories which accompany the Autoclave



01. Tray holder:

It's a device used to handle trays, avoiding direct contact with the operator.

02. External steam outlet's hose:

This accessory must be connected and fixed to the external steam outlet using a clamp. It takes steam out.

03. Graduated glass:

It's used to dose the quantity of distilled water needed for each sterilization cycle.

04. Trays and support:

Support with 3 trays, to keep materials to be sterilized from contact with chamber, bottom and water sidewalls

WARNING:

The material to be sterilized can't be in contact with any of the internal walls of the chamber.



Attention

- The use of any part, accessory or material not specified or provided in these use instructions is of entire responsibility of the user.

MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION

Characteristics and operation

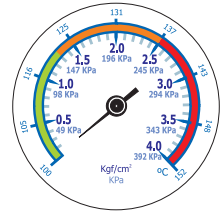
Manometer

It's used for temperature and pressure control, and its graduation range from 0 kgf/cm² to 4.0 kgf/cm² and from 100°C to 152 °C.

Manometer's tolerance variation

Divide the manometer's scale by three equal parts.

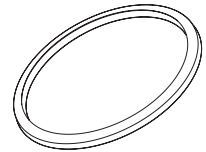
For the first part, the tolerance is 3%, for the second part is 2%, and for the third is 3%.



Sealing ring

Besides sealing the door, it also works as a safety device, relieving chamber's internal pressure in case of overpressure.

If the sealing ring were moved from its place, call a authorized technician to carry out the maintenance of the equipment.



Safety seal and anti-vacuum valve

Placed in the internal part of the door, they diminish the pressure in the chamber, in case it exceeds. The anti-vacuum valve has the same function, and it also reduces the pressure of the chamber if it were negative (vacuum).

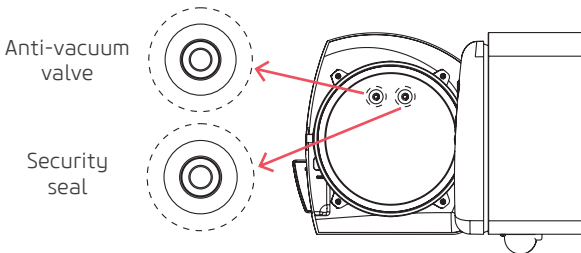
NOTE:

If during the sterilization procedure the valves were opened, the operator can reset them.

However, the appropriate cooling time must be observed in order to prevent accidents.

If the valves were opened repeatedly, call a authorized technician.

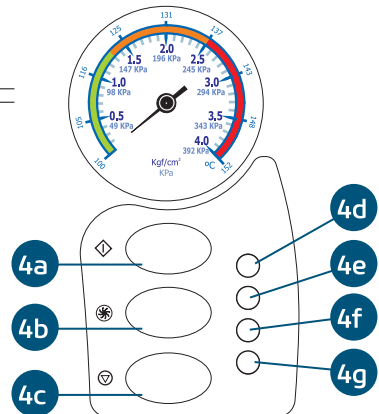
NOTE: Execute the replacement of the safety seal and anti-vacuum valve within the period "of 36 months". If it is necessary to do it before the period indicated, request the presence of an authorized technician.



Control panel

Found in the front part of the autoclave, it contains all controls necessary to operate the equipment.

- 4 A - Cycle start
- 4 B - Drying
- 4 C - Cancel
- 4 D - Equipment ON
- 4 E - Heating / Sterilization
- 4 F - Drying
- 4 G - Cycle end

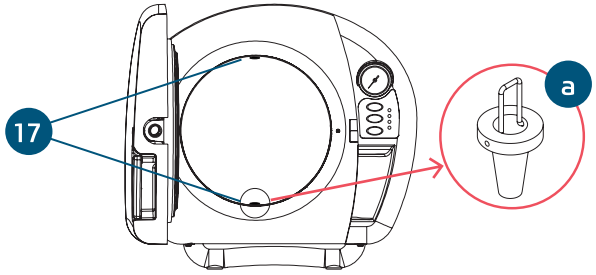


MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION

Characteristics and operation

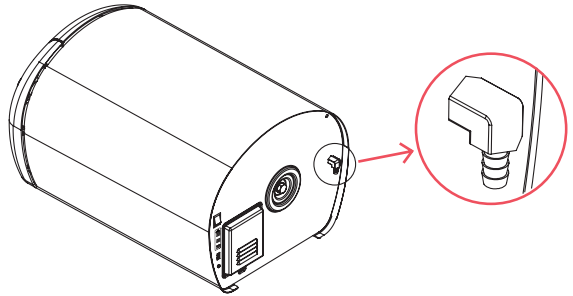
Steam internal outlets

They're holes in the rear wall of the internal chamber (17), they take the steam to the pressure control valve. Note: In the lower hole there's a protective filter (A), it prevents solid residues from entering the steam outlet.



External steam outlet

The 5/16" hose fitting, found in the autoclave rear part, takes the steam outside.



TECHNICAL SPECIFICATIONS

General features

Model

Autoclave 21L

Power Supply Voltage

127 / 220 V~ (Bivolt)

Frequency

50/60 Hz

Power

1700W

Mode of Operation

Continuous operation

Protection against harmful water penetration or particulate material

IPX0

TECHNICAL SPECIFICATIONS

Sterilization pressure

1,7 kgf/cm² ± 0,4 (1,3 to 2,1kgf/cm²)

Operation temperature

128 °C ± 5 (123 to 133°C)

Sterilization time

16 minutes

Volume

21 Liters

Diameter of the chamber

240mm

Chamber's depth

450mm

Water consumption per cycle

350 - 380ml

Net Weight / Gross Weight

30 Kg / 33 Kg

Fuse of Protection

(F1/F3) 127/220 V~ - T20A L 250V

(F2) 127/220 V~ - T0,5A L 250V

Full cycle time

60 minutes

These values are approximate, they may change depending on the material's type and volume, energy oscillation, etc.

Manometer's tolerance variation

Divide the manometer's scale by three equal parts. For the first part, the tolerance is 3%, for the second part is 2%, and for the third is 3%.



Warning

Pay attention while using this equipment together with other movable equipment, in order to avoid collisions.

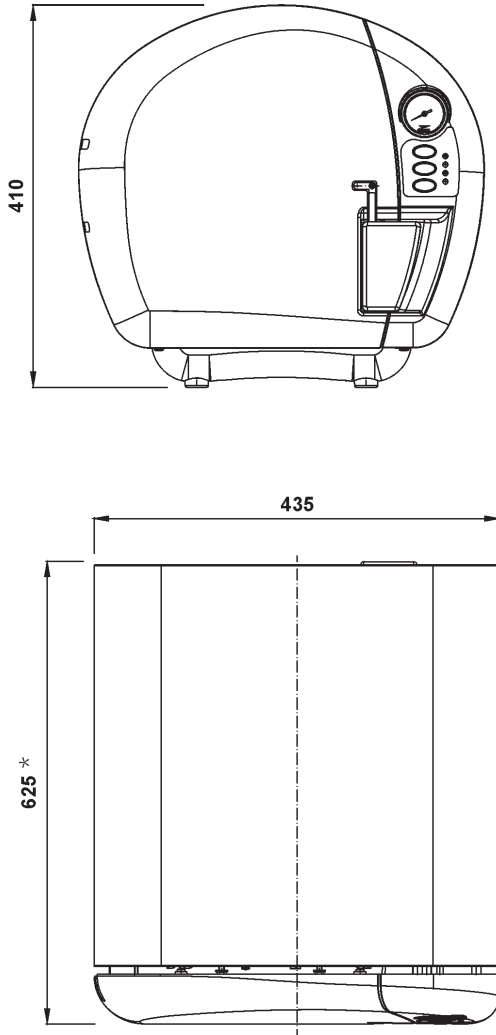


Attention

The materials used to produce the equipment are Biocompatible.

TECHNICAL SPECIFICATIONS

Dimensions (mm)



* For installation of the Autoclave in niches / cabinets, consider the addition of 50mm in the total length of the product.

TECHNICAL SPECIFICATIONS

SYMBOLGY

The following symbols are used both throughout this manual and on the product. Make sure you fully understand each symbol and follow the instructions that come with it.



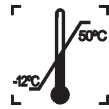
Fragile, handle with care



Maximum stacking



Protect from rain



Temperature limit



This side Up



Protect from sunlight



Attention



General warning



Protective ground wire



Catalog number



Model number



Model



Serial number



Manufacturer



Manufacturing date



Instructions for use

Autoclave

O.K.

Indicates cycle end



Indicates that the device is in heating mode



Indicates that the device is in sterilization mode



Indicates cycle cancellation



Indicates drying



Indicates cycle start



Indicates that the device is on



Applied part type B



Turned off position



Turned on position



Mandatory action



Fuse

INSTALLATION OF EQUIPMENT



The installation of this equipment requires the necessity of specialized technical assistance (Alliage). Ask for the presence of a Alliage representative technician at the nearest seller, or through the Alliage Service Center: + 55 (16) 3512-1212.

Important safety considerations

- Never touch the steam external outlet and, after the sterilization is finished, never touch the internal autoclave's surfaces. The inappropriate use may cause burns. Alliage may not be hold responsible for accidents caused by inadequate operation.
- Don't allow patients, and most specially children, to touch the autoclave.
- Periodically check that the door's door latch is correctly in place before operation. If this procedure were not observed, the sealing ring may come off.
- Before using the autoclave, verify that the internal chamber is clean, also check if the protection filter is completely clean, free of residues.
- When raising the door latch, the autoclave's door must open without difficulty.
- Always make sure that the depressurization is complete: the manometer's needle must be in the "0" (zero) position. Never use force to open the autoclave - If one of the safety devices were activated (unexpected steam leak) usually caused by the internal steam outlet blockage or by an obstruction in the pressure control valve, wait until the complete depressurization before switching the autoclave off.

INSTALLATION OF EQUIPMENT

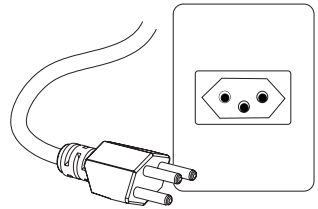
- Use only the hose supplied by Alliage, or one similar, so as to prevent it from melting when in contact with steam, which may cause the external steam outlet obstruction.
- We recommend you to read this manual entirely. Use is as consultation manual.

Protection against current overload

The equipment is protected from current overload by fuses.

Special precautions and installation conditions

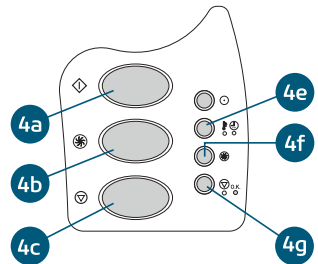
- Install the autoclave on a firm and leveled surface, approximately at 80 cm. from the floor. Leave enough space for handling the materials to be sterilized.
- Check if the grounding conductor is correctly connected.
- Never use cord extensions, connectors or voltage transformers.
- It is necessary to use a socket higher than 10A, in which a standardized plug will be connected to, according to ABNT NBR 14136 Regulation, as the picture below shows:



Operating altitude calibration

To perform altitude calibration, press keys (4a) and (4b) and turn on the autoclave. Press the keys simultaneously until the LEDs (4e) and (4f) light up. Remove all objects from inside the autoclave, including the trays. Place 200 ml of demineralized or distilled water inside the autoclave, through the measuring cup, and close the lid.

To start the calibration procedure, press button (4c). The calibration takes 50 minutes if the autoclave starts the procedure cold, and the process may take longer if the autoclave is hot. After the end of the calibration, beeps will be emitted and the led (4f) will light up. In case of calibration failure, beeps will be emitted and the led (4g) will light up.



INSTALLATION OF EQUIPMENT

Replacing the fuses

With a Phillips screwdriver, unscrew the lid (09) of the electronic board compartment, then remove the broken fuse and place the new fuse (19) in the position indicated.

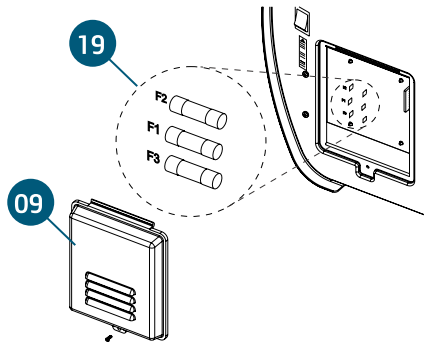
WARNING:

Before installing or replacing fuses, unplug the electric power cord. uses that come with the Autoclave:

- 2 20A fuses installed in the equipment (F1/F3) + 1 spare;
- 1 0.5A fuse installed in the equipment (F2) + 1 spare.

WARNING:

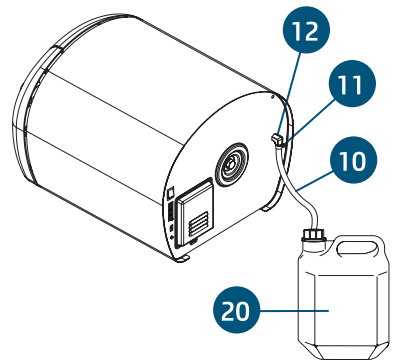
- After performing the first replacement, it is advisable to always have spare fuses at hand.
- All fuses must be installed independently from the grid voltage.



Preparing the autoclave

Connect and fix the rubber hose (10) using the clamp (11) to the external steam outlet (12) found in the autoclave's rear part. The other end must be placed in a water container (20) or in a drainage which can stand high temperatures.

In order to prevent the obstruction of water and steam flow, keep the hose straight, avoiding the formation of bends and siphons.



WARNING

Use only the hose supplied by Alliage, or one similar, so as to prevent it from melting when in contact with steam, which may cause the external steam outlet obstruction.

INSTALLATION OF EQUIPMENT

Open the front door raising the door latch, then push it to the left and check if the trays (16) are in their place. There must be three trays, and the biggest must be placed in the upper part.

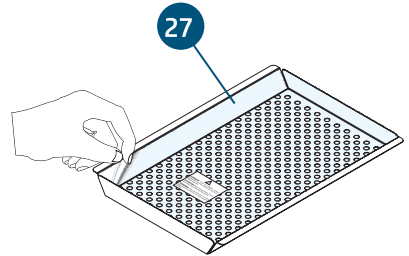
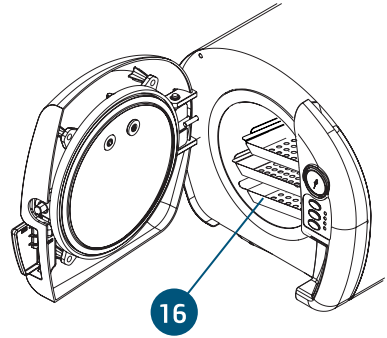


Warning

- Before first use, please remove the protector film, which wraps this tray (27).
 - The female outlet should be a grounded bipolar type - three prong (2 flat and 1 round).
- Verify that the ground wire is properly connected.

ATTENTION:

The ground connection is very important to the operator's safety and for the equipment's warranty. For this reason, the middle pin (ground) can't be removed or cut.



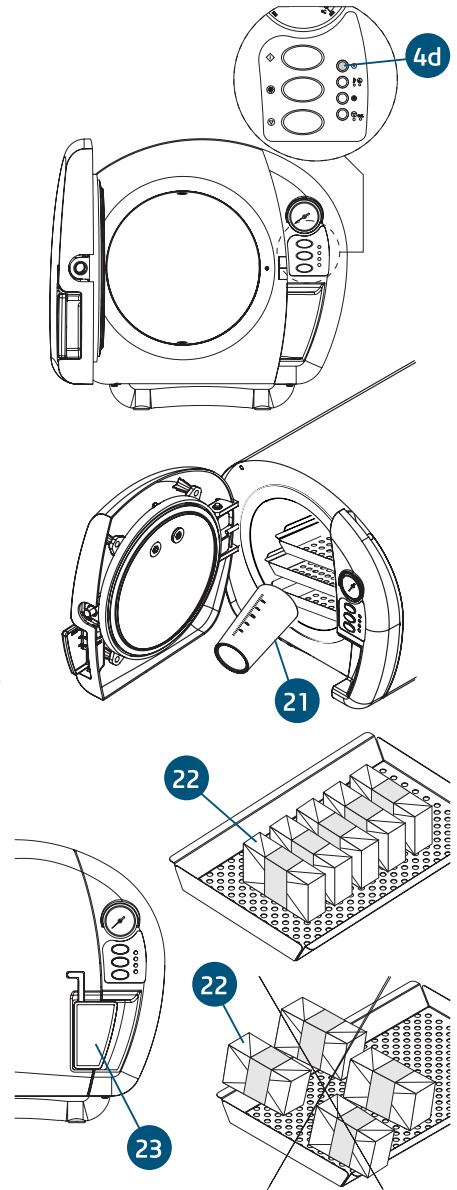
OPERATION OF EQUIPMENT

- 1) Connect the energy plug to the socket.
- 2) Raise the door latch, push it to the left, and check the cleanliness of the autoclave.
- 3) Using the dosing cup (21), pour inside the autoclave the following quantities of water:
Autoclave partially full - 150ml.
Autoclave completely full - 200ml.
Use only distilled water or demineralized. If you use other water than distilled, it may cause the obstruction of the internal valves and stain the instruments, and the warranty will not be applicable.
- 4) All material being sterilized must be previously washed, rinsed and dried.
- 5) Close the autoclave's door pushing it against the tank, pushing the door latch to the right and then lowering it. Check that it is correctly closed (23). In order to avoid accidents and burns, it's very important that the door is well closed.
- 6) Green led (4D) in the front panel will come on, indicating that the autoclave is on.

When turning on the Autoclave, an audible signal will be emitted, indicating the voltage that the Autoclave is on;
- 2 beeps: 127 V~.
- 1 beep: 220 V~.

WARNING:
Don't use "Kraft / TNT" paper for wrapping the materials to be sterilized (types of wrappings for autoclave sterilization, see page 25).
Observe each country's standards for preparation of material to be sterilized.
Distribute the wrappings at equal distances (22) leaving enough space between them so as to allow the steam to circulate.

ATTENTION:
The material to be sterilized (22) can't be in contact with any of the internal walls of the chamber.



OPERATION OF EQUIPMENT

7) Press the cycle start key (4A), the autoclave will automatically start to heat, and you will hear 2 beeps, and a green LED (V1) will come on. The heating time depends on the quantity of the material to be sterilized.

After the heating has reached a temperature of $128^{\circ}\text{C} \pm 5$, the autoclave will enter in the pressure sterilization mode, with a pressure from $1,7 \pm 0,4 \text{ kgf/cm}^2$ (24), the LED (4E) will change from green (V1) to yellow (A), and it will stay that way for 16 minutes.



Attention

If the cycle is started with the autoclave hot, the LED (4E) in green and the LED (4F) in blue will light up until the autoclave reaches the cycle start temperature, then the cycle starts automatically.

8) At the end of the sterilization cycle, the discharge valve will open automatically, depressurizing the Autoclave. After 3 minutes, 10 beeps will sound, the blue LED (4F) will light up, indicating the drying mode.



Attention

For drying the sterilized material, the door of the Autoclave can remain closed or ajar (25), but it should not be completely open due to high temperature, at which time the user will never be able to touch the internal areas of the Autoclave, avoiding the risk of accidents and burn.

The drying cycle is 20 minutes, for Autoclaves with aluminum tanks, the time is 18 minutes. At the end of drying, the Autoclave will sound 3 beeps, turning on the green LED (4G) (V2), indicating the end of the cycle.

If the material is not completely dry, you can opt for the extra drying function, press the key (4B), the blue LED (4F) will light up indicating the beginning of a new drying cycle. If the operator finds that the material is already dry, he can cancel the cycle by pressing the key (4C).

9) If it is necessary to interrupt the sterilization cycle, press the cycle cancellation key (4C). Wait for the autoclave to completely depressurize before opening the door.

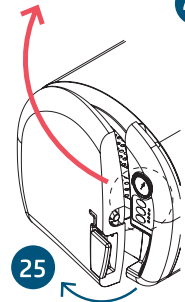
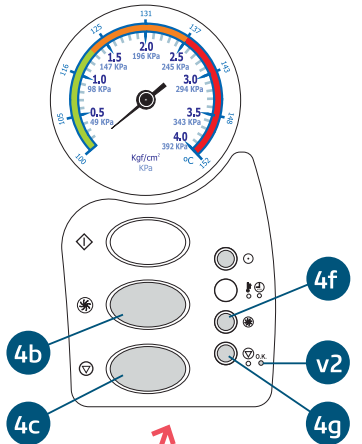
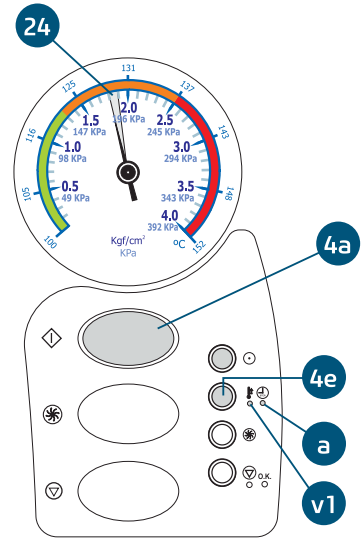


Warning

In case of power failure or involuntary shutdown of the equipment during the sterilization process, it is mandatory to restart the cycle to ensure proper sterilization. When the power is restored, the orange LED (4G) will light up, activating the discharge valve for 3 minutes, during this period no function will be available.

Press the key (4b) to release the use of the Autoclave, the orange LED (4G) will turn off.

When the power is restored, check the water level, if necessary, fill it up properly until it reaches the specified amount and restart the cycle.



OPERATION OF EQUIPMENT

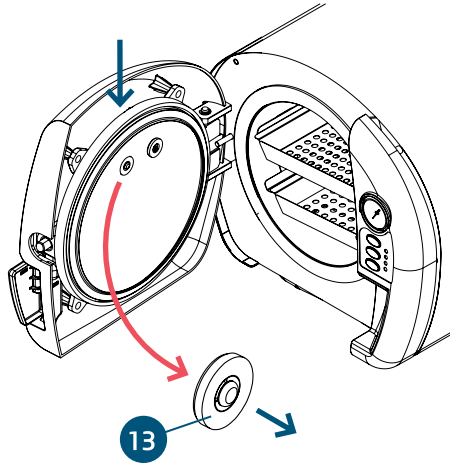
Resetting the valves (safety seal and anti-vacuum valve)

If the valve (13) were opened during the sterilization process, the operator can reset it. Open the autoclave's front door and wait until it's cold. Proceed as described in the drawing, pressing them until they go back to their original position.

If the valves were opened repeatedly, call a authorized technician.

WARNING:

HIGH TEMPERATURE, Before carrying out the procedure described above, wait until it's cold.



PRECAUTIONS, RESTRICTIONS AND WARNINGS

Recommendations for preserving the equipment

Your equipment has been designed and developed according to the standards of modern technology. Similarly to other kinds of equipment, it requires special care, which is many times neglected due to several reasons and circumstances. Therefore, here are some important reminders for your daily routine. Try to follow these simple rules, which will save you a lot of time and will avoid unnecessary expenses once they start making part of your working procedure.

Transportation, storage and operation

This equipment must be transported and stored observing the following directions:

- Avoid falls and impacts;
- Keep it dry, do not expose it to rain, water drops or wet floor;
- Keep it away from water and direct sunlight, and in its original wrapping;
- Don't move it over irregular surfaces, protect it from rain and observe the maximum stack quantity specified in the packaging;

Environmental condition for transportation or storage:

- Room temperature range for transportation or storage -29°C to +60°C.
- Relative humidity range for transportation or storage 20% to 90%.
- Atmospheric pressure range 500hPa to 1060 hPa (375 mmHg to 795 mmHg).

Environmental operation condition:

- Room temperature range for functioning +10°C to +40°C.
- Recommended room temperature range +21°C to +26°C.
- Relative humidity range for functioning 30% to 75%.
- Atmospheric pressure range 600 hPa to 1060 hPa (450 mmHg to 795 mmHg).
- Operation altitude: ≤4000m.

Attention

The Equipment maintains its condition of safety and efficacy, provided that it is maintained (stored) as mentioned in this instruction of use. Thus, the equipment will not lose or alter its physical and dimensional features.

Sensibility to predictable environmental conditions in regular use conditions

- The equipment has been planned not to be sensitive to interference such as magnetic fields, external electrical factors, electrostatic discharge, pressure or variance of pressure, provided that the equipment is installed, maintained, clean, preserved, transported and operated as per this instruction for use.

Precaution and warnings "during the installation" of the equipment

- This equipment can only be unpacked and installed by an Alliage authorized technician, under the penalty of losing the warranty, as only they possess the information, the proper tools and the required training for carrying out this task.
- Manufacturer does not take this responsibility for damage or accidents caused due to a bad installation performed by a technician non-authorized by Alliage.
- Only after the equipment is installed and properly tested by the Alliage authorized technician, it will be ready to start the working operations.
- Install the autoclave on a firm and leveled surface, approximately at 80 cm. from the floor. Leave enough space for handling the materials to be sterilized.
- Install the unit in a place where it will not be damaged by the pressure, temperature, humidity, direct sunlight, dust, salts.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

- The unit should not be submitted to inclination, excessive vibrations, or blows (including during transportation and handling).
- This equipment was not planned for use in an environment where vapors, anesthetic mixtures inflammable with air, or oxygen and nitrous oxide can be detected.
- Check that the socket in which the device will be connected has a ground connection. According to the ABNT standard, this is essential for the safe operation of the system.
- The equipment must be grounded correctly.
- Before the first use and/or after long interruptions from work such as vacations, clean and disinfect the equipment.

Precautions and warnings “during the use” of equipment

- The equipment should only be operated by duly enabled and trained technicians (Dental Surgeons, Capacitated Professionals).
- If any maintenance should be required, only use services of the Alliage Authorized Technical Assistance.
- Although this equipment has been planned in accordance with the standards of electromagnetic compatibility, it can, in very extreme conditions, cause interference with other equipment. Do not use this equipment together with other devices very sensitive to interference or with devices which create high electromagnetic disturbance.
- Do not expose the plastic parts to contact with chemical substances, use in the routines of dental treatment, such as: acids, mercury, acrylic liquids, amalgams, etc.
- Avoid spilling water or other liquids inside the equipment, which could cause short circuits.
- Never touch the steam external outlet and, after the sterilization is finished, never touch the internal autoclave’s surfaces. The inappropriate use may cause burns. Alliage may not be hold responsible for accidents caused by inadequate operation.
- Don’t allow patients, and most specially children, to touch the autoclave.
- Periodically check that the door’s door latch is correctly in place before operation. If this procedure were not observed, the sealing ring may come off.
- Before using the autoclave, verify that the internal chamber is clean, also check if the protection filter is completely clean, free of residues.
- When raising the door latch, the autoclave’s door must open without difficulty.
- Always make sure that the depressurization is complete: the manometer’s needle must be in the “0” (zero) position. Never use force to open the autoclave.
- Use only the hose supplied by Alliage.

The Alliage forbids:

1) The use of “kraft” paper for wrapping materials to be sterilized, because it isn’t manufactured with this purpose.

Its use has many disadvantages when compared to other materials, such as irregularities and uneven texture, what affects the resistance, turning it inadequate for its use as microbial barrier. Besides, it frequently contains starch, colorings and other toxic products that can stain the parts.

It can also contain Alkylthiophene, which, during the sterilization process may give off an unpleasant smell, which causes nausea and headache if breathed.

And besides all these disadvantages, during the sterilization process, this kind of paper releases pieces of fiber that can clog the autoclave’s valves and piping system.

Papel Kraft / TNT



PRECAUTIONS, RESTRICTIONS AND WARNINGS

2) Submit the autoclave sterilization process in the TNT tissue used as primary packaging material for sterile products and / or drapes. TNT is the acronym for (non-woven fabric), that is, a fabric produced from disoriented fibers that are bonded and fixed, not going through the most common textile processes that are spinning and weaving.

This tissue is not manufactures to be used in autoclaves, as TNT has polypropylene as the main raw material, which is similar to a thermoplastic.



Warning

Alliage is not responsible for any equipment damage or sterilization process due to the use of kraft and/or TNT paper.

Observe each country's standards related to wrapping preparation.



Attention

Alliage recommend the use of surgical paper, because the microbial barrier of this material is above 90%, and it permits the operator to visually check the state of the instruments. It also has chemical indicators of the process.

Alliage shall not be responsible for:

- Use of the equipment differing from that for which it is intended.
- Damages caused to the equipment, the professional and/or the patient by the incorrect installation and erroneous procedures of maintenance, differing from those described in these Instructions for use which come with the equipment or by the incorrect operation of it.

Precautions and warnings "after" the use of equipment

- Turn off the main switch of the dental set when it is not in use for an extended period of time.
- Always maintain the equipment clean for the next operation.
- Do not modify any part of the equipment. Do not disconnect the cable or other connections without need.

Precautions and warnings during the "cleaning and disinfection" of equipment

- Before cleaning the equipment, turn off the main switch.
- Avoid spilling water, even accidentally, or other liquids inside the equipment, which could cause short circuits.
- Do not use microabrasive material or steel wool when cleaning, or employ organic solvents or detergents which contain solvents such as ether, stain remover, etc.

Precautions in case of alteration in the functioning of equipment

- If the equipment has any abnormality, check if the problem is related to any item listed in the topic of unforeseen events (failures, causes and solutions). If it is not possible to resolve the problem, turn off the equipment, remove the power supply cable from the socket and contact your representative (Alliage).

Precautions to be adopted against foreseeable or uncommon risks, related to the deactivation and abandoning of equipment

In order to avoid environmental contamination or undue use of the Equipment after it has become useless, it should be discarded in the suitable place (as per the local legislation of the country). Pay attention to the local legislation of the country for the conditions of installation and disposal of residue.

CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

Additional procedures for reuse

The equipment can be reused in undetermined, i.e. unlimited, quantities, only needing to be cleaned and disinfected.

Cleaning

Important: In order to execute cleaning or any type of maintenance, ensure that the equipment is disconnected from the electrical network.



Attention

- In order to prevent risks and damages to equipment, make sure that the liquid does not enter into the equipment.
- For cleaning, use a clean, soft cloth dampened with mild soap and then dry with a clean, soft cloth or paper towel. The application of other chemical cleaning products based on solvents or sodium hypochlorite are not recommended, as they can damage the equipment.

Disinfection

For the equipment disinfection process, use disinfectant detergent foam containing active components based on didecyldimethylammonium chloride.

Apply the detergent foam on the surface or a clean cloth and spread over the surface to be treated. Respect the antimicrobial contact time indicated by the manufacturer.

After application, allow to dry. Do not rinse.

There is no limit on the cycles or application time that the equipment and its parts can tolerate during the cleaning and disinfection process, following the instructions in this manual.



Warning

For preventing contamination, use gloves and other protection systems during disinfection. Even that, during the procedures, gloves are used, after removing gloves the hands must be washed out.

CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

Internal cleaning (chamber and stainless steel trays sterilization)



Attention

Changing in visual appearance inner the autoclave tank is a normal feature of the product due to the heating of it.

Spots and oxidations signs may occur due to the continuous use and it is totally or partially removed according to the recommended procedure as below:

- To carry out the internal cleaning of your equipment, sterilization chamber and trays, we recommend the use of a descaling detergent product that has active components based on Linear Alkyl Sulfonate.

Clean according to the manufacturer's specifications (see package label).



Warning

After the cleaning procedure perform a complete cycle of autoclaving and then eliminate the water of the reservoir and dry the tub using a clean cloth.

Piping cleaning

Monthly it will be necessary to clean the internal components of the Autoclave.

To carry out the internal cleaning of components, pipes, valves and filters, we recommend the use of a monoacid sodium phosphate-based product.

Mix the product according to the manufacturer's specifications.

Place the solution in the chamber and perform 1 autoclaving cycle. Repeat the autoclaving operation using only distilled and demineralized water, after carrying out the cycles, remove the excess of the cleaning liquid with the aid of a clean cloth dampened with water.

Cleaning the filter

- The autoclave's filter shall be cleaned daily.
- In order to clean the filter, remove it via the handle, and then wash it in running water.
- Don't use sharp objects, which could damage the fabric.

CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

Wrapping types for sterilization by autoclave

The materials used for wrapping the pieces to be sterilized must keep the sterilization after the sterilization process and during storage.

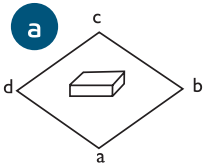
These materials must:

- allow the sterilization process;
- be appropriate for the material and the sterilization process;
- allow the drying, ventilation and dispersion of the sterilizing agents;
- not have lighter and darker parts;
- be resistant to wetness, be free of holes and scratches;
- don't release particles.

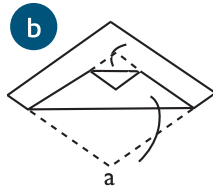
Suggested method for wrapping instruments and materials

The wrapping technique for wrapping instruments and/or materials before the sterilization process is described in the following sequence of illustrations.

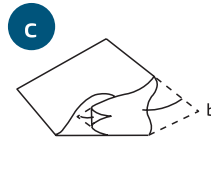
This folding sequence isn't unintentional. It makes its handling easier and it prevents contamination when the wrapping is opened.



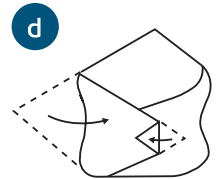
A. Place the piece diagonally and in the middle of the wrapping material.



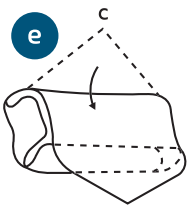
B. Hold the "a" corner, fold it and cover the piece.



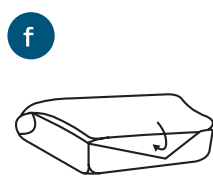
C. Hold the "b" corner and fold it over the piece, covering it and bending the end upwards.



D. Repeat the last step with the "d" corner.



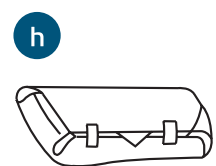
E. Fold the "c" corner in the direction of the operator.



F. Take the "c" corner and insert them under the folds made in C, D and E.



G. Let the "c" corner outside, in order to prevent the sterilized material from being contaminated and making the wrapping opening easier.



H. If necessary, seal the wrapping using cord or crepe.

CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

Control of the pressurized and saturated steam sterilization process

All Autoclaves are tested at the production line following a procedure that ensures the equipment's efficiency to provide safe and sterilized articles.

Maintenance of the qualification

In order to maintain the quality and the sterilization efficiency during the equipment's regular use, the BI test must be carried out routinely. To perform this test in the same place where the autoclave is installed, it must be used the ATTEST control system, which consists of BI test ampoules and an incubator, which allows the incubation of the test ampoule and the verification of the final result, 48 hours later.

Testing procedure using biological indicators

- 1) Make a test package that allows the steam to penetrate into it, place a BI inside it, and place the test package in the coldest part of the autoclave (in this case, the coldest part of the AUTOCLAVE is the upper part, near the door), with the load for a routine cycle.
- 2) Identify the test package that contains the BI, remember that this package shall be opened to remove the BI.
- 3) Once the cycle is finished, wait until the package is cold, then open it and remove the BI; break the BI ampoule inside the specified incubator and incubate it for 48 hours.
- 4) At the same time, place a BI ampoule (one that hasn't passed through the sterilization process) into the incubator, in order to verify the incubator operation and also to control the viability of the spores used in the test; check the BIs (both the positive control and the test ampoule), follow the directions provided by the manufacturer.
- 5) Record test data and its results in a record system
- 6) If the BI test's results were positive, don't use the equipment until it has been checked and repaired by the authorized technical service.

Attest biological monitoring system for steam sterilization process

For more information about biological and chemical control, access www.3M.com/br/hospitalar.

Preventive Maintenance

The equipment must suffer routinely measurements, following the current legislation of the country. But, never with a period superior to 3 years.
For protecting your equipment, look for a Alliage' technical assistance for periodic reviews as preventive maintenances.

Corrective Maintenance

The supplying of the circuits' diagram, Part lists or any other information that permits the technical assistance by the user, can be requested, since previously agreed.



Attention

In case of the equipment presents any abnormality; check if the problem is related to some of the listed items under the item unpredictable (situation, cause and solution).

If it's not possible to solve the problem, shutdown the equipment and demand the presence of a technician from the nearest resale, or ask through the Attendance Service Alliage: + 55 (16) 3512-1212.

UNFORESEEN EVENTS – SOLUTION OF PROBLEMS



Upon coming across any problem in operation, follow the instructions below to check and repair the problem, and/or get in touch with your representative.

Problem	Probable Cause	Solution
<ul style="list-style-type: none">- The autoclave doesn't switch on.	<ul style="list-style-type: none">- The cord is disconnected.- Power cut.- Burnt fuse(s).- Bad contact in the socket.	<ul style="list-style-type: none">- Connect the cord to the socket.- Wait until energy is back.- Replace fuse(s).- Replace socket.
<ul style="list-style-type: none">- The autoclave can't reach or maintain the pressure high.- Temperature range different from pressure based on the use of the gauge and thermometer indicative colors.	<ul style="list-style-type: none">- The voltage supplied is lower than the one required by the autoclave.- Leakage in the safety seal. - Problem with altitude calibration.- The door latch isn't in position, causing leakage.- Not enough water. - Overloaded chamber.	<ul style="list-style-type: none">- An electrician must check and adapt the electricity supply. - Disconnect the autoclave, and remove the safety seal and the anti-vacuum valve, clean them and place them again. If it were necessary, replace them.- Perform altitude calibration. - Place the door latch pushing it downwards.- Check that the volume of water is the specified.- Use up to 70% of the chamber, leaving spaces between the packages.
<ul style="list-style-type: none">- The autoclave's door can't be opened.	<ul style="list-style-type: none">- The autoclave isn't yet depressurized.	<ul style="list-style-type: none">- Wait the autoclave depressurization.

EQUIPMENT'S WARRANTY

This equipment is covered by the warranty periods, terms and conditions contained in the Warranty Certificate that comes with the product.

FINAL CONSIDERATIONS

Among the care you have to take with your equipment, the most important is regarding of the spare parts replacement.

To ensure the lifetime of your device, only replace original spare parts. They have the assurance of the standards and technical specifications required by the Alliage representative.

We call your attention to our authorized resellers' chain. Only this chain will keep your equipment constantly new, because it has trained technical assistant and specific tools for the correct maintenance of your device.

Whenever you need, demand the presence of a Alliage' technician from the nearest resale, or ask through the Attendance Service Alliage: + 55 (16) 3512-1212.

NUM. REG. ANVISA: 10069210082

