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1 Packaging And Product Symbols



Fragile



Protect from sunlight



Humidity Limits



Attention



Lot number



Back / Menu



Confirm / Start



This side Up



Keep in a dry place.



Atmospheric pressure limits



See instructions for use



Serial number



Lower Selection



Door lock



Temperature limits



Maximum stacking



Fuse



Date of Manufacture



Recyclable



Superior Selection



Attention hot surface

2. Introduction

2.1 Congratulations!

The equipment you just purchased was designed to give you the best performance.

This has come to you after being fully passed the factory quality tests and is the result of experience and know-how in the manufacture of peripheral dental equipment.

Before starting the equipment, carefully read the instructions contained in this manual, so you will avoid errors in operation and ensure the perfect performance of your AUTOCLAVE LINEA N.

2.2 Essential Performance

The instructions for use contained in this manual are of utmost importance to users, where they must understand and respect the contents for the sake of patient and professional safety.

The operation of AUTOCLAVE LINEA N is intended to sterilize heat-resistant articles and / or instruments using pressure saturated steam.

If in doubt of the application, the user should contact with Fomos. The user is responsible for the equipment and its use.

3. Presentation

This manual is intended to clarify the operation of this equipment, as well as the precautions necessary for its longer life.

Specifications and information contained in this manual are based on data existing at the time of publication.

We reserve the right to make changes at any time without notice.

The manual is available in print and digital form. If you want to access the digital format, just download it from the site www.fomos.cn and in the Products link, select the corresponding template.

3.1 Equipment life

The life of the AUTOCLAVE LINEA N is not possible except for the lid and the stainless steel chamber which is 8 (eight) years for normal use, provided they are subject to regular preventive maintenance and are NOT used. and installed third party components in the equipment without being approved by Fomos.

4. Recommendations and Warnings

→ Read all the information in this manual before using your autoclave.

Improper use may result in sterilization failures or accidents;

To avoid electric shock, disconnect the equipment from the power supply before performing any maintenance procedures;

Do not allow patients and children to approach the autoclave; And install the autoclave in exclusive and appropriate rooms;

Never use or heat food in the autoclave;

Never conduct any animal experiments in the autoclave;

→ Before starting any sterilization program, make sure that the material can be sterilized or is autoclavable;

→ During the sterilization, it is normal to hear some noises which are generated by the internal components of the autoclave in normal operation;

→ When moving the autoclave door opener, the operator should do it easily, and never use too much force in this process;

→ When releasing the lock, the autoclave door should open easily. Never force open the door;

When opening the autoclave at the end of the cycle in order to cool the sterilized material, it is normal to vent some steam through the door;

Never perform any procedure not described in this manual;

→ This equipment is not designed for use in environments where vapors, flammable anesthetic mixtures with air, or oxygen and nitrous oxide can be detected;

→ Do not cover or block the autoclave door, ventilation or cooling openings;

→ Do not place heavy items or reservoirs with liquids that may spill on the autoclave.

4.1 Sensitivity to foreseeable environmental conditions under normal use

The equipment is designed not to be sensitive to interference such as magnetic fields, external electrical influences, electrostatic discharge, pressure, or pressure variation, provided that the equipment is installed, kept clean, maintained, transported, and operated in accordance with the instructions for use.

4.2 Environmental Protection

To avoid environmental contamination or improper use of the equipment after it has been disposed of, it must be disposed of in an appropriate location (in accordance with local country legislation).

Check the local legislation of the country for the conditions of installation and disposal of waste.

5 Warranty terms

This equipment is covered by the warranty terms from the date of purchase invoice, provided that the defect occurred under normal use.

Warranty Time is one year from the invoice date of purchasing.

6 General specifications

6.1 Graphics

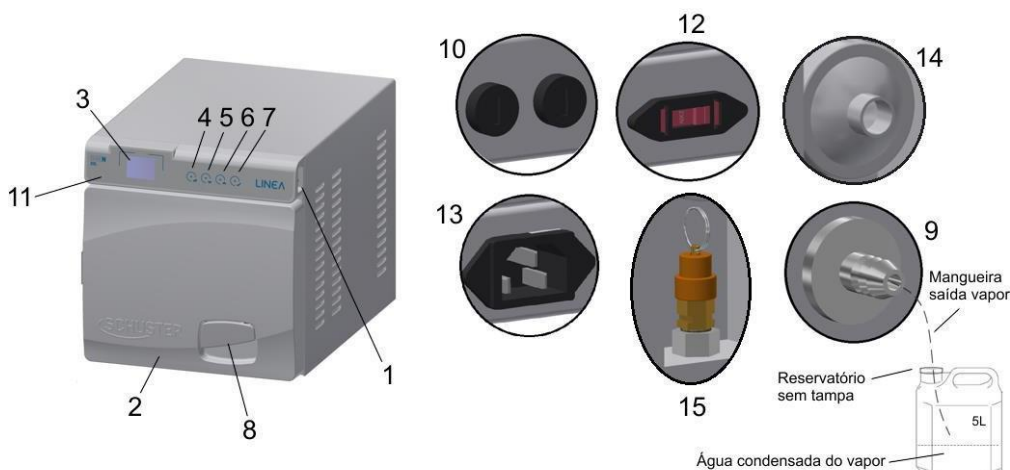


Fig. 1

1. Power switch	9. Steam Outlet
2. Door	10. Power Input Fuses
3. LCD display	11. Control Panel
4. Back / Menu Button	12. Voltage selector switch
5. Bottom Selection Button	13. Power Input Connector
6. Top Selection Button	14. Air Intake Filter
7. Confirm / Start Button	15. Safety Valve
8. Closing	

Table 1

6.2 Control panel



Fig. 2

1. Back / Menu Button:

When pressed for 5 seconds will enter the Restricted Access menu directly.Navigate through programs using the Bottom / Top Select buttons to choose the desired program.To return to the last screen, press the Back / Menu button again.To abort the program in progress press it for 5 seconds.

2. Bottom Selection Button:

When pressed for 3 seconds, it will enter the Select Cycle menu directly.In addition, it is used to navigate the lower submenu options.

3. Top Selection Button:

When pressed for 3 seconds, it will enter the Setup Languages menu directly.In addition, it is used to navigate the upper submenu options.

4. Confirm / Start Button:

Press to confirm chosen sterilization program, press again to start cycle.

5. LCD display:

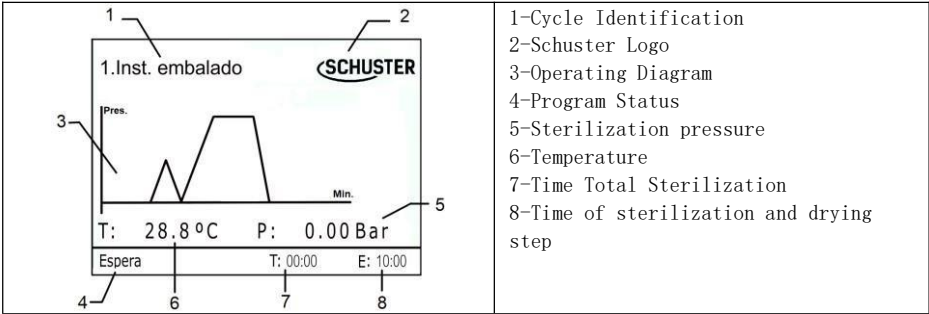


Table 2

6.3 Description

High performance surface treatment carbon steel frame sterilization equipment front cover and high impact ABS panel.Modern design and easy handling.

Surface treatment resistant to corrosion and cleaning products, special epoxy-based paint, curable at 250°C;

It has solenoid valves that control the internal flows of steam;Electronic and mechanical security systems;

Drying pump that optimizes the drying time and therefore the total cycle;

Easy-to-clean, high-strength, one-piece stainless steel chamber;

Stainless steel lid with exclusive and fully secure locking system; Automatic deaeration and depressurization;
LCD display, digital control;
Keyboard with precise activation;
Easy interaction interface
Allows adjustment for different altitudes;
Drying with closed door;

Sterilization Programs: Packed Instruments - Unpacked Instruments - Plastics and Cotton - Surgical Kit - Fabrics - Liquids

22L capacity;
Support for 2-stage multi-stage trays - 3 instrument trays.

6.4 Indications for use

This equipment is suitable for general sterilization of materials in dental clinics, veterinary, beauticians and certain hospital and laboratory procedures.

7 Installation

7.1 General Procedures Before Installation

- Due to the weight of the equipment it is recommended that the transportation be done by two people, thus avoiding falls and accidental shocks;
- The furniture where the equipment will be arranged must bear the weight of the same;
- It is recommended to install the autoclave in an exclusive room for sterilization;
- The surface to which the equipment will be installed must be flat, level and at an ergonomically correct height to the operator (close to 80cm from the floor);
- The necessary space around the equipment is at least 12cm, frontally the access must be free;
- Make sure that the equipment voltage is in accordance with the local network;
The voltage selector switch is located at the rear of the equipment and, for your safety, it leaves the factory positioned at 220V. If the local network is 127V, invert the selector switch;
- Grounding is mandatory, only in this way will the operator be completely safe.
The operator is solely responsible for non-grounding, resulting in the loss of warranty;
- Install the autoclave where the power cord can be easily disconnected from the mains.

The above items are of paramount importance for the perfect functioning of the LINEA AUTOCLAVE N, otherwise the equipment will be subject to loss of your guarantee.

7.2 Electrical installation

Fomos will not be liable for improper facilities / services not in accordance with the guidelines described in this owner's manual.

- The AUTOCLAVE LINEA N is a manual double voltage, and it is necessary to check the mains voltage first and then make the correct adjustment on the voltage selector switch on the back of the equipment (Fig.1-12);
- Use a three-prong grounded plug (2P + T - 20A), always grounding at the center pin;
- Never use adapters, voltage transformers or extensions;
- For proper autoclave operation it is essential that the voltage of the mains is stable, the oscillation may compromise the equipment. It is also necessary to install an exclusive circuit breaker for the socket where the autoclave will be connected.

Technical data for circuit breaker sizing and wiring are given in Table 2 below.

Never connect ground to neutral. Grounding is critical to ⚠ operator safety, so operator protection and product warranty will be maintained. If this point is not observed, the autoclave may be damaged.

Equipment	Nominal chain	Circuit breaker	Voltage	Wiring diameter (breaker distance to outlet)		
LINEA N 22L-127V	15A	25A	127VAC (100-150V)	Up to 5m: 2.5mm wiring.	From 5 to 35m: 6.0mm wiring.	From 35 to 50m: 8.0mm wiring.
LINEA N 22L-220V	8,6A	20A	220VAC (200-254V)	Up to 5m: 2.5mm wiring.	From 5 to 15m: 4.0mm wiring.	From 15 to 50m: 6.0mm wiring.

Table 3

220V Network Regions:

FF (phase to phase): use bipolar circuit breaker.

FN (phase-neutral): use unipolar circuit breaker.

7.3 Hydraulic installation

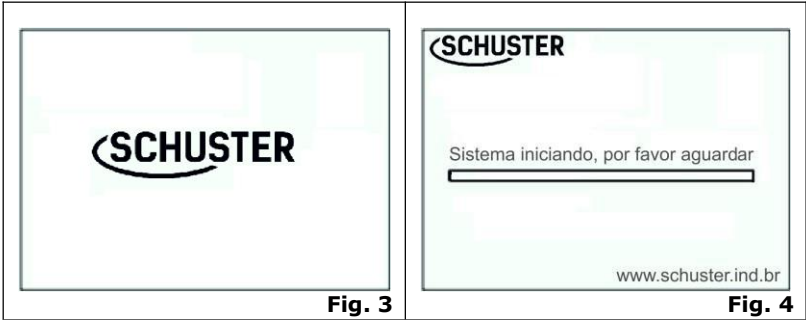
Connect the hose supplied with the autoclave to the rear external steam outlet of the equipment (Fig.1-9), check that it is properly connected and secure with a metal clamp that comes with the accessories. The other end of the hose should be connected to a sewer pipe that supports a temperature of 100°C or placed inside an empty plastic canister without a cap, making a "V" cut at the end of the hose. Position the same 40cm below the autoclave level. Empty the reservoir when water reaches the hose.

Only replace the hose with one of the same gauge and heat resistance.

⚠ **Do not submerge the hose end in water, the outlet should be free of obstructions.**

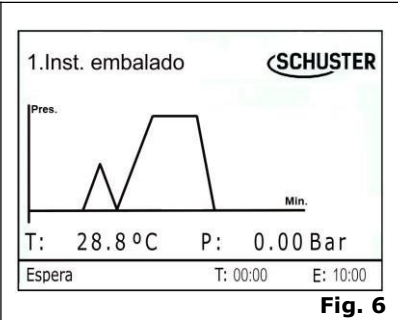
8 Operation instruction

- Turning the power switch on the right side of the front panel (Fig.1-1) will turn on the display (Fig.1-3). The system will be started by starting the self test which lasts about 5 seconds (Fig.3 and Fig.4).



Then the equipment unlock screen will appear (Fig.5). For safety and traceability issues of the Schuster Quality System the Linea autoclaves line has an electronic lock system. To unlock the product you will need to access the Fomos website (www.fomos.cn) and locate the "Unblock Equipment" option. At this time, follow the instructions on the page. Some information will be required to create the customer profile and at the end of the

In this process, the system sends the release code by email.The release code may also be requested from Schuster Technical Support (P.17).
After unlocking the autoclave will go directly to the first program (Fig.8).



- In the main screen (Fig.6), press the lower selection button  for 3 seconds to go to the cycle selection menu (Fig.7).In this screen you can choose one of the 6 available programs.Use the bottom selection buttons  or top selection  to navigate between options.Choose the cycle according to the type of sterilization.At the end, press the confirm / start button  to activate the chosen cycle.Press the confirm / start button  once more to start autoclave operation.

8.1 Performing the first cycle

- Open the autoclave door (Fig.1-2) by sliding the latch (Fig.1-8) upwards and using the measuring cup that comes with the equipment, place the correct amount of distilled water directly in the chamber before each cycle, follow the table below for volume orientation;

Amount of distilled water per cycle	
LINEA N 22L	350ML

Table 4

Only use distilled water for sterilization.If this recommendation is not  If the equipment is complied with, its hydraulic system may be obstructed, the instrument may be stained and the warranty will be lost.The water to be used must meet the specifications of NBR11817: 2001 according to the table below:

Poisoning	Limit value
Evaporation Waste	≤ 15 mg/L
Silicon	≤ 2 mg/L
Iron	≤ 0.2 mg / L
Cadmium	≤ 0.005 mg / L
Lead	≤ 0.05 mg / L
Heavy metal waste	≤ 0.1 mg / L
Chlorides	≤ 3 mg/L
Phosphates	≤ 0.5 mg / L
Conductivity	≤ 50 μS/cm
pH	6.5 to 8
Appearance	Colorless, clear, no residue
Toughness	≤ 0.1 mmol / L

Table 5

- Place the instrument tray correctly in the tray holder;
- Load the autoclave with the materials to be sterilized. Take care that they do not come into contact with the camera or between themselves. Do not obstruct any autoclave hydraulic connections. Do not overload the autoclave. Always load envelopes with the paper side facing up, making it easy to steam and dry later. Boxes and trays should be fully perforated allowing for better vapor circulation as well. Never overlap packages;

 Use a maximum of 70% of the internal space of the camera, considering a maximum weight of 3.5 kg. Maintain a minimum clearance of 1.0cm between packages to allow better vapor circulation.

- Close the autoclave door (Fig.1-2) by pressing it against the chamber and move the lock (Fig.1-8) forward;
- While in the first program screen (Fig.8), press and hold the lower selection button  to access the menu with the 6 available programs.



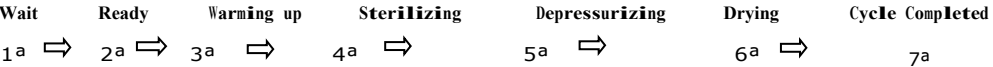
Fig 7

The specific characteristics of each available program are in the table below:

Program	Average warm up time (min)	Sterilization temperature and pressure	Sterilization Time (min)	Drying Time (min)	Total Time (min)
Wrapped instruments	15-30	134°C - 214kPa	10	35	60-75
Unwrapped instruments	15-30	134°C - 214kPa	6	40	61-76
Plastic And Cotton	8-30	121°C - 110kPa	30	30	68-90
Fabrics	8-30	121°C - 110kPa	30	40	78-100
Surgical kit	8-30	121°C - 110kPa	30	50	88-110
Liquids	8-30	121°C - 110kPa	30	-	38-60

Table 6

- After choosing the desired program by navigating the selection buttons, press the confirm / start button  to select the chosen program.
 - If the door is not closed properly, the program will not start. To cancel the cycle at any time, press the  back / menu button for 5 Seconds.
- The progress steps for all programs are as follows (except for the Liquids program, which does not require drying):



- At the end of sterilization, the display will show the message "open the door" and an alarm will sound. At this time it is necessary to open the door and wait for 3 minutes for the initial cooling, after which time the waiting message will clear and it will be possible to unload the material using the tray removal support;



At the end of sterilization, the display will show the message "open the door" and sound a Alarm. At that time it is necessary to enter the door and wait three minutes for the initial cooling, after that time the waiting message will delete and be possible unload the material using the trays removal medium;

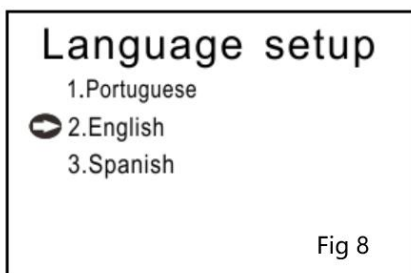
Never remove trays without using the removal medium accompanying the

Therefore, due to high temperature, after the cycle there is a high risk that the Burn victim.

Never try to open the door to the autoclave until the pressure indicator is clear, showing 0.0.

It is not recommended to start a further cycle if the temperature inside the chamber is above 70°C, this prevents the evaporation of part of the distilled water and the heat shock between the heated surface of the chamber and cold water.

- To change the language of the equipment while in the first program screen (Fig.6), press and hold the upper selection button  to access the menu with the 3 available languages (Fig.8). Select the desired one with the selection buttons and confirm with the confirm / start button.



9 Safety systems and devices

- **Protective fuse:** Its purpose is to protect the equipment against overcurrent. Two of them are located at the autoclave power input at the rear of the autoclave and another fuse located on the electronics board. Fuses should be replaced only by Accredited Service Person;
- **Sealing ring:** Serves to seal the lid with the stainless steel chamber. Used as a safety device, allowing air / vapor to escape if pressure exceeds 260kPa;
- **Alert Messages:** These are intended to alert the user to any important equipment operation information;
- **Double door lock safety system:** There are two devices, one mechanical and one that is driven by the steam generated in the chamber, which prevent opening if there is pressure inside the chamber;
- **Temperature Sensor Resistance:** Device that limits overheating of the resistance;
- **Temperature sensor:** Device that monitors the excessive heating of the chamber;
- **Pressure Sensor:** A device that monitors the internal pressure in the chamber and, if necessary, sends a signal to the electronics that will cancel the cycle;
- **Safety Valve:** Device responsible for relieving pressure inside the chamber, if it reaches levels outside the established;
- **Electronic power stabilization system:** System that acts on the power oscillation of the power grid, adjusting whenever necessary, which makes this oscillation not affect the power and operation of the autoclave.

10 Maintenance

The AUTOCLAVE LINEA N requires little care from the professional, but of great importance for the best operation and durability of the equipment.

The table below serves to assist the operator in performing maintenance procedures and their periodicity:

Maintenance	Daily	Weekly	Monthly	Yearly	Semester	03 years	08 years
External cleaning	•						
Tray and Chamber Cleaning	•						
O-ring cleaning		•					
Drain filter cleaning		•					
Monitoring gives sterilization (chemical test)	•						
O-ring replacement				•			
Solenoid valve check, heater, temperature sensor, drying pump, safety sensors, internal hoses				•			
Air Inlet Filter Inspection			•				
Cover and chamber replacement							•
Air Inlet Filter Replacement					•		
Replacement of protector thermal thermostat						•	
Monitoring gives sterilization (biological test)		•					
General service maintenance				•			

Table 7

- **External cleaning:** Use a soft cloth with water and neutral biodegradable detergent, then wipe with a cloth moistened with 70% alcohol;
- **Cleaning the trays and chamber:** Use a soft non-abrasive sponge with biodegradable neutral detergent and distilled water. Finish cleaning with 70% alcohol. Do not use any descaling agent for cleaning as this will seriously damage the chamber, trays and internal piping;
- **Sealing ring cleaning:** Remove the sealing ring. With a soft cloth and distilled water clean the ring and its seat in the cap;
- **Drain filter cleaning:** Use running water and soft bristle brush to remove impurities from the filter micro holes;
- **Sterilization monitoring (chemical testing):** This should be performed daily to monitor and evaluate sterilization cycles. Indicators, integrators and emulators may be used according to the monitoring plan defined by the operator. They should be used according to the tester manufacturer's manual;
- **O-ring replacement:** Autoclave cover O-ring replacement should be performed annually, but if any anomaly is found, it may be replaced earlier. Use the spare ring shipped with the equipment, always cleaning the new ring and the ring seat in the autoclave cover before installation;
- **Solenoid valve , Heater , Temperature sensor , Drying pump, Safety sensors, Internal hose , these items should be evaluated by Accredited technical assistant annually ;**
- **Inspection of air inlet filter:** Must be performed monthly, if any stains of moisture, yellowish color, dirt, tears or holes are observed, replace the filter immediately;
- **Lid and Chamber Replacement:** Required to maintain high product safety and reliability rating;
- **Air Inlet Filter Replacement:** The air filter should be replaced every six months so that the air allowed during the sterilization cycle is as pure as possible;

- **Thermal protector replacement - thermostat:** Responsible for physical temperature control. It needs to be correctly calibrated for perfect operation;
- **Sterilization monitoring (biological test):** Should be performed weekly. They monitor the sterilization process for greater reliability and use heat-resistant bacterial spores. They should be used according to the tester manufacturer's manual;
- **General maintenance on Accredited Technical Assistance:** Once a year, it is recommended that the autoclave undergo a more thorough evaluation by a Accredited Technical Assistance for an overall assessment of physical parameters (sealing and safety components, thermal grease of the autoclave). resistance, internal piping, drainage, valves and door system) and equipment electronics (sensors, keypad and circuit boards).

10.1 Protection fuse

To replace the power input protection fuses on the back of the autoclave, turn off the power and unplug the power cord. Unscrew the fuse holder cover and replace the blown fuse. Use ceramic fuses 6X30 20A 250V.

10.2 Sealing ring

First, turn off the autoclave and wait for it to cool to avoid burns. Using a flat-bladed screwdriver, hold the ring in one hand and insert the screwdriver under the inner side of the ring with the other, carefully pulling it out. When one part is out and possible, remove the rest of the ring by hand. Clean the ring groove and carefully reassemble the new part, observing the correct side of the assembly. We aim for the ring to be fixed manually at four points of the cover slot first and then to adjust the entire remaining area. The tendency of the rubber will not be easy to get in because it is fair, in which case the screwdriver handle can be used carefully to assist in the process.



Note:

The equipment should be routinely checked for protective fuse verification, cover ring sealing and door closing.

To avoid electric shock, disconnect equipment from the power source before performing any maintenance procedures.

The power cord may only be replaced by a Accredited Service Center.

The equipment should not undergo any preventive or corrective maintenance during operation, and if there is any problem with the equipment, it is recommended to check if there is a solution in item 10 of this manual. If not immediately resolvable, the customer should contact Accredited Technical Assistance.

We do suggest a Periodic Maintenance Plan with its Accredited Technical Assistance for general verification of equipment operation, and a period longer than 12 months is not advised.

No modifications that change the original design specifications on this equipment are permitted. Unauthorized modifications may affect safety when using the equipment. Never perform unauthorized repairs under any circumstances.

11 Technical data

Technical data	Linea N 22 liters
Capacity	22 liters
Protection against electric shock:	Class II Equipment
Degree of protection against electric shock:	Applied Part Type B
Degree of protection against liquid penetration:	IPX 0
Operation mode:	Continuous Operation
Net weight:	37.6Kg
Gross weight:	49.3kg
Chamber / Cover Material:	Stainless steel
Inner Dimensions of Chamber (DxP):	24.9x45.0cm
Autoclave External Dimensions (WxHxD):	43.9x47.5x57.0cm
Tray Dimensions (WxHxD):	19.5x17.0x38.3cm
Voltage (Manual Bivolt):	127VAC(95-150V) 220VAC(200-254V)
Frequency:	50/60Hz
Power:	1800W
Fuse (x2):	Ceramic 6X30 20A 250V
Electric Consumption:	127VAC / 220VAC: 1.8kWh
Operating pressure:	214kPa (2.18 kgf / cm ²)
Drained Water Temperature:	100°C
Suitable working environment temperature:	15°C-40°C
Noise level (1 meter away)	<45dB
Appropriate working altitude:	Up to 3500m

Table 8

11.1 Standards applied

This product has been tested and approved to the following standards:

ABNT NBR 16035-1: 2012-Boilers and pressure vessels-Minimum requirements for construction- Part 1: General;

ABNT NBR 11817: 2001 – Sterilization – Steam Sterilizer – Small Sterilizers– Requirements

EM 13060:2014-Small steam sterilizers;

EN 980:2008(Ed. 2)-Symbols for use in the labeling of medical devices;

NR 13-Boilers, Pressure Vessels and Pipes.

11.2 Content of accessible tags



Removal of the identification label/Nameplate will automatically void the warranty.

12 Altitude change

The working altitude detection process for the LINEA N Autoclave occurs automatically without operator interference. Each time the product is turned on it checks the correct ambient pressure and makes the necessary adjustments to internal parameters.

13 Operating graphs (time x pressure)

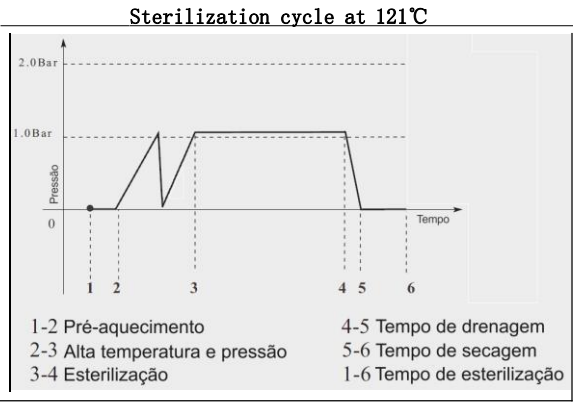


Fig. 9

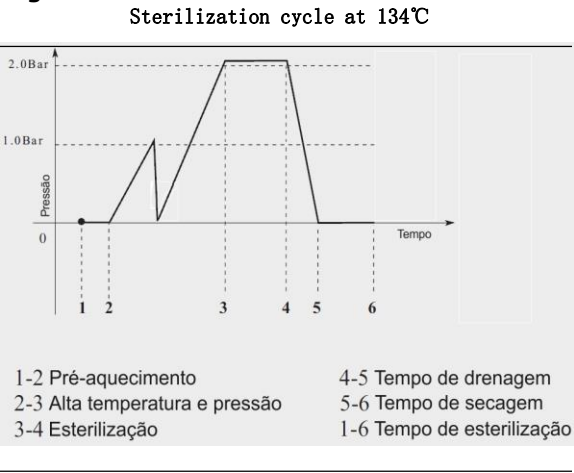


Fig. 10

14 Exclusive use accessories for LINEA N

Accompany the equipment:

- 01 Tray removal support;
- 03 Trays;
- 01 power cord;
- 01 Hose drain water outlet;
- 01 Tray removal holder;
- 01 Silicone door seal ring;
- 02 Power input fuses;
- 01 Measuring Cup;
- 01 Chamber drain filter.

15 Failures ,possible causes and solutions

Before consulting Accredited Technical Assistance, check the possible causes and their solutions in the table below:

failure	possible cause	solution
• The autoclave does not turn on	• Plug disconnected from network • Blown fuse (s) • Oscillations in electrical voltage • Power switch not engaged	• Plug in the plug • Replace fuse (s) • Contact the power company • Turn on the power switch, the indicator LED will light
• Autoclave starts but does not start cycle	• With program selected key not pressed • There is no activation when press the key	• Press key • Likely on pushbutton failure, call Schuster Accredited Service
• E1 - Cycle aborted by operator	• Manual cycle stop	• Start a new cycle
• E2 - Door opens during the cycle	• Faulty door lock key	• Call Accredited Technical Assistance
• E3 - Pressure sensor error	• Defective pressure sensor	• Call Accredited Technical Assistance
• E4 - Excessive temperature	• Lack of water in the chamber	• Correct the water level
	• Defective resistance • Exhaust Valve Failure	• Call Accredited Technical Assistance
• E5 - Pressure output failure	• Exhaust Valve Failure	• Call Accredited Technical Assistance
	• Clogged steam outlet hose	• Unclog hose
• E6 - Temperature sensor error	• Defective temperature sensor	• Call Accredited Technical Assistance

16 Storage and transportation

- Ambient temperature (operation): 5°C to 40°C;
- Ambient temperature (transport and storage): -10°C to 55°C;
- Relative humidity (operation): ≤ 80%;
- Relative air humidity (transport and storage): 0% to 100%;
- Atmospheric pressure: 70kPa to 106kPa;
- Maximum Stack: 3 units.

Special cares:

- MPacking with arrow side up;
- Store in a moisture-free , cool and sun free place;
- Take care of falls or bumps.

Notes

[illegible]