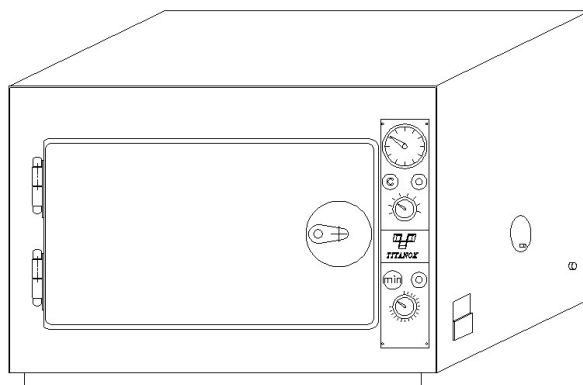


INSTRUCTIONS MANUAL

DRY HEAT STERILIZING UNIT MOD. PASTEUR ELECTRIC



TITANOX s.r.l.

FABBRICA ARTICOLI MEDICO SANITARI
MEDICAL SANITARY ITEM FACTORY

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0) INTENDED USE

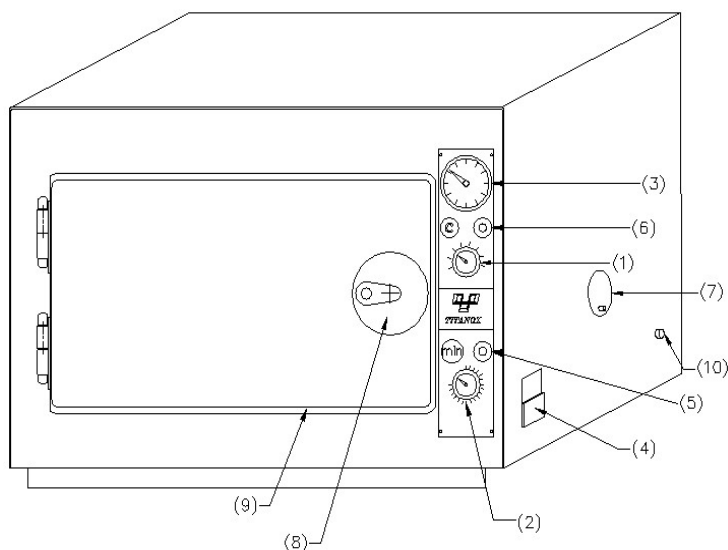
The device is designed to be used in sanitary environments for the purpose of sterilizing non-heat sensitive medical and surgical instruments. The process of disinfection is based exclusively on the thermal destruction of the microorganisms present upon the instruments at a typical temperature of about 180° C.

Effectively reaching a sterile state for the instruments inserted into the sterilizers depends upon multiple factors:

- The level of initial contamination of the instruments (total bacterial load);
- The type of contaminating microorganisms;
- The permeability of all the contaminated instrument parts by the hot air produced by the sterilizer.

For more information see the paragraph ****ATTENTION**** ahead.

The device must be used only and exclusively by healthcare professionals (doctors, paramedics, nurses or similar) who are familiar with the principles of controlling sterilization processes in general and dry heat sterilization processes in particular



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Pos.1 - Thermoregulator int. temp. 50÷210° C (±6°C)

Pos.2 – Prog. timer 2 hours or manual (±3°)

Pos.3 - Thermometer int. temp. 50÷200°C (±10°C)

Pos.4 - Connection plug with fuses

Pos.5 - Warning light “timer” or “manual” connected

Pos.6 - Warning light “resistances”

Pos.7 - Air-inlets for air circulation

Pos.8 - Closure with key

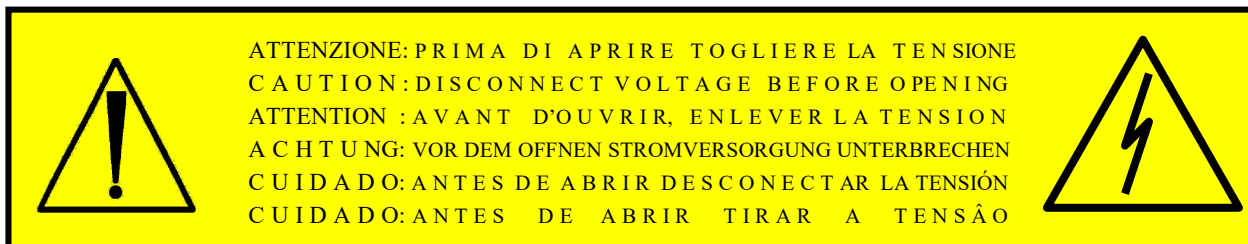
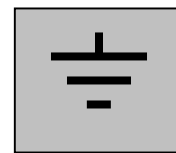
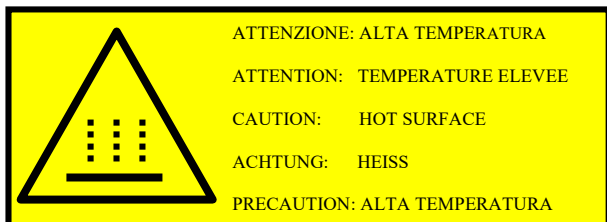
Pos.9 - Silicone gasket

Pos.10 - Security thermostat 232°C (±8°C)

1) SYMBOLS AND SAFETY WARNINGS

READ INSTRUCTIONS

PROTECTION BINDING- CLAMP



2) TECHNICAL SPECIFICATIONS

Models	A3-213-400	A3-214-535	A3-215-670
Loaded Chamber	3 kg	4 kg	5 kg
External sizes:			
Width mm	570	705	835
Height mm	400	475	555
Depth mm	345	450	565
Internal sizes:			
Width mm	405	535	670
Height mm	210	345	415
Depth mm	255	320	420
Weights:			
Net weight	13 kg	22 kg	35 kg
Gross weight	15 kg	25 kg	41 kg
Electrical Characteristics:			
Nominal tension (Voltage)	230 V	230 V	230 V
Nominal power (Watt)	450 W	950 W	1900 W
Nominal frequency (Hz)	50/60 Hz	50/60 Hz	50/60 Hz
Net's fuses (mm 5x20)	F5A-250 V	F5A-250 V	F10A-250V

The device is in conformity to electrical safety norms provided for by the normative institutes and supplied with bipolar plug which assures perfect electrical grounding.

NON-COMPLIANCE WITH INSTRUCTIONS DESCRIBED IN THIS BOOKLET SHALL FREE COMPANY TITANOX S.R.L. FROM ANY LIABILITY.

SYMBOLS	MEANING
	Warning!
	See the annexed documentation
	Use heat insulating gloves
	Caution! Hot surface (max. 210 °C)
	It points the Manufacturer's name
	This symbol, together with the year, points the production date
	Keep away from sunlight
	Keep in a cool, dry place
	Medical Device
	RAEE symbol to handle electrical and electronic devices wastes

Available operation:

TIME-PROGRAMMED: timer programmable up to 2 hours

CONTINUOUS CYCLE: manual (without timer)

3) ENVIRONMENTAL CONDITIONS

- Ambient temperature from 5 to 40° C.
- Relative humidity max. 80% for temperatures up to 31° C with linear decrease up to 50% at the temperature of 40° C condensing included.
- Atmospheric Pressure from 500 to 1060 hPa.
- Voltage supply variation not higher than $\pm 10\%$.
- Value of transitory over-voltage in conformity to the installation category (which provides for 2500V).

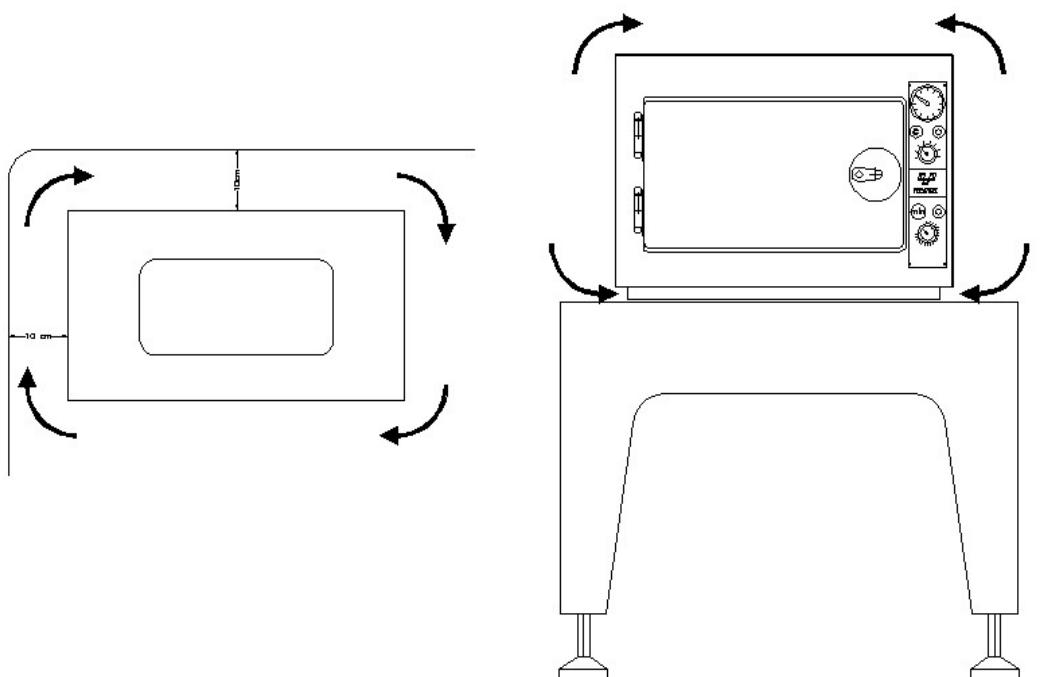
4) INSTALLATION

The device has been calibrated and tested at factory and as such does not require any further calibration or adjustments before installation and start-up.

Unpack the device and follow the next advices:

1. Position the device on a levelled flat, hard, and smooth surface, established with non-inflammable material.
2. Allow space not lower than 10 cm from walls and surrounding furniture.
3. Do not install the device nearby water sinks or similar to avoid contacts with water or substances which could cause electrical short-circuit to the system.
4. Install the device in a well aerated location, not near windows or external doors which could cause an unnatural circulation of the air inside the device and therefore compromise its correctly running.
5. Do not install the device nearby heat sources or near other electrical devices.
6. Install the device in such a way that the power cable is never twisted or bent, but it should connect to the socket free and unhindered. Avoid to positioning the power cable nearby heat sources or other devices that shall cause damage on it in a long run.
7. In the event the device is placed on a trolley, always check that the lower part of the device is not enclosed or hindered, as to allow continuous and sufficient ventilation.

Once the device is correctly installed and power cable connected, it is ready for use.



5) SAFETY WARNINGS

- The device is designed for use in internal locations.
- The device is not designed for use in presence of gasses or explosive vapours.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- No water or other liquids should be poured into device neither on its base.
- Before any cleaning or maintenance actions, the power cable must always first be removed.
- Make sure that the electrical system has electrical grounding and that it's in conformity to the safety norms in the country of installation.
- Do not remove any label or plate, in case of need, ask for more.
- Request only original spare parts cause in case of substitution with no original ones, there could be an increase of electromagnetic emissions or a decreased of electromagnetic immunity of this equipment. This may vary the performance and safety of the equipment.
- Portable RF communications equipment should be used no closer than 30 cm to any part of the sterilizer, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Emissions class and group: Class A Group 1; Insulation class: 1; IP20
- Do not open the door of the device until the thermometer of the internal temperature do not indicate a temperature lower than 30°C.
- Medical devices, before being placed in the sterilizer, should be washed and dried. The residual water steam may create deposits on the probes and resistances by altering the precision

6) TIME – PROGRAMMED RUNNING

1. Insert the supplied connection socket of the mains cable in the plug of the device (Pos. 4) and the feeder- plug in the wall mains socket, after checking the voltage value.
2. Turn the thermoregulator knob (Pos. 1) and set the desired temperature. This operation shall always be carried out when device is cold.
3. Place materials to be sterilized inside the device.
4. Lock up the door (Pos. 8).
5. Keep the air-inlets half-opened (Pos. 7) to allow a better circulation of the air inside the device and to distribute the heat even to the corners and hidden spaces. Close the above air-inlets only at the end of the sterilization cycle in order to seal the device and to keep the material inside in temperature for a long time
6. Set, by turning the timer knob (Pos. 2) anti-clockwise, the sterilization time adding necessary time in order to bring the device and the material inside to the desired temperature. The necessary time to reach the temperature of 180°C is about 30 minutes in case of empty chamber sterilizer, and about 60 minutes with Loaded Chamber well arranged on the trays. This operation switch on the warning light (Pos. 5) indicating that the device is working and the warning light “resistance” (Pos. 6) indicating that the resistances are turned on in the circuit. The graduated thermometer (Pos. 3) allows to check the progressive increase of the internal temperature. When the internal temperature has reached the programmed value, the warning light “resistance” (Pos. 6) is turned off for then, after brief time, again turned-on indicating the re-connection of the resistances in the circuit. This operation allows to keep inside the device a constant temperature up to the end of the sterilization cycle. After programmed time has elapsed, the device turns itself off automatically.

7) CONTINUOUS – CYCLE RUNNING

The device has also a continuous cycle running. For use this kind of running proceed up to point 5 of the procedure for time-programmed running described above. Turn, at this moment, the timer knob (Pos. 2) anti-clockwise. The indefinite-time manual continuous-cycle is inserted with a click. To turn off the device, turn back the timer knob to position 0.

8) ORDINARY MAINTENANCE

Before initiating any maintenance operation, make sure that:

- the device is not connected to the power source.
- the device is at ambient temperature.

Keep the internal parts and the grid perfectly clean. Even though they may change colour and become brownish, never use abrasive or inflammable products for cleaning them.

Keep the external parts perfectly clean that they must be always specular to prevent corrosion and dust.

9) PERIODIC MONTHLY MAINTENANCE

After removing the plug from the power socket, check that the fuses are not oxidised specially when the device is not used for a long time or kept in a humid ambient.

The power socket should not change colour or oxidise. If that happens, replace it immediately.

The power cable must be integral, and it should not show cuts, abrasions or bending.

The resistances and the internal electrical system do not require any maintenance.

10) PERIODIC ANNUAL MAINTENANCE

It is recommended to carry out at least annually the verification of the leakage currents and the verification of the earth conductor with an electrical safety tester in accordance with the requirements of EN 60601-1 or EN 62353. Even if it is advisable for the user to provide a method of physical validation of the device upon installation and routine checks (for example using biological indicators during each cycle), it is still recommended to check the status of the devices at least annually, to control systems of the sterilizer, in particular the temperature control system, to verify that the expected performance is maintained.

11) PERMITTED USES AND FORBIDDEN USES

The device must be used to sterilize metal materials whose point of melting is higher than 300°C (surgical instruments, plates, and metal screw).

Inside the sterilizer place only metal containers without plastic parts and without textile material.

It is forbidden to place in the device items whose temperature of melting is lower than 300°C or it is not known to the operator.

12) DETACHABLE COMPONENT PARTS

2 Internal shelves

1 Main cable

13) SELLING OFF

The sterilizing unit is made of various materials with mechanical, electro-mechanical and electronic parts.

The selling off has to be made according with the regulations in force in the utilizing Nation.

14) **ATTENTION**

Laboratory tests following a cycle of 120 minutes at 180°C on Bacillus subtilis var niger ATCC 9372 spores demonstrated the efficiency of the sterilizer.

Titanox does not guarantee and cannot ensure the effective achievement of the sterile state of the instruments placed in the sterilizer, according to the definition of sterile medical instruments foreseen by the EN 556 Norms. The user of the sterilizer therefore has the responsibility to conduct all of the confirmation procedures of the sterilization process and the necessary verifications in order to ensure the effective completion of every single sterilization cycle.

For this reason, in order to ensure a correct routine control of the sterilization cycle, it is recommended to use biological indicators in the load to be sterilized, as prescribed by ISO 20857. In any case, it is the user's responsibility to use a method that allows to unambiguously identify successfully sterilized and non-sterilized devices.

15) WARRANTY CONDITIONS

- 1) The device is warranted for a period of one year from date of purchase.
- 2) Warranty covers the substitution or repairs free-of-charge of components with manufacturing defects.
- 3) The device will be repaired only at our factory. Charges, risks arising from the transport of the device shall be on purchaser's account.
- 4) In the event of repairs at purchaser's home, purchaser shall be charged fixed call costs covering partial reimbursement of travel and professional visit by personnel.
- 5) Warranty coverage excludes internal lighting, damages caused by carelessness of purchaser, incorrect and improper uses and installations not conforming to warnings, indicated in these booklet instructions or in any case results from phenomenon unrelated to the normal working of the device.
- 6) The warranty expires when the device is tampered with or repaired by unauthorised personnel.
- 7) It is excluded the substitution and the extension of the warranty following a breakdown.
- 8) It is excluded any compensation for damages direct or indirect of any nature to persons or objects arising from use or suspension of use of the device.
- 9) The warranty expires immediately if the relative certificate shows alterations, erasing, or it is not issued or convalidated by us. The certificate must accompany the device or handed to maintenance personnel for home-repairs.

The manufacturing company Titanox S.r.l. is responsible for the safety, reliability, and performance of the device if:

- the assembly, the additions, the re-setting, the modification, or repairs are carried out by personnel of Titanox S.r.l.
- the electrical system to which it is connected conforms to safety norms in country of installation.
- the device is used in conformity to instructions of use and maintenance.

This liability expires immediately when the device is tampered with or repaired by unauthorised personal.

For any further requirements of spare parts, repairs or checks, it's necessary contact directly the manufacturer: TITANOX S.r.l. - Via Canove 2/A – Loc. Canove de' Biazzi – 26038 Torre de' Picenardi (CR) – Italia - Tel. (0039) 0375 394065 – Fax (0039) 0375 394067 communicating the registration number of the device to repair.

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and Competent Authority of the member State where your registered office is located.

16) USEFUL LIFE

The useful life of the device is established in years 5 from the commissioning. For this period Titanox S.r.l. guarantees the availability of spare parts and safe operation if the environmental and use conditions defined in the instructions for use are respected by the user.