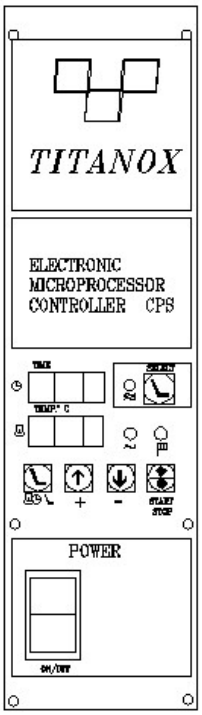
INSTRUCTIONS MANUAL

DRY HEAT STERILIZING UNIT MOD. PASTEUR ELECTRONIC



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TITANOX s.r.l.
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MEDICAL SANITARY ITEM FACTORY

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MD

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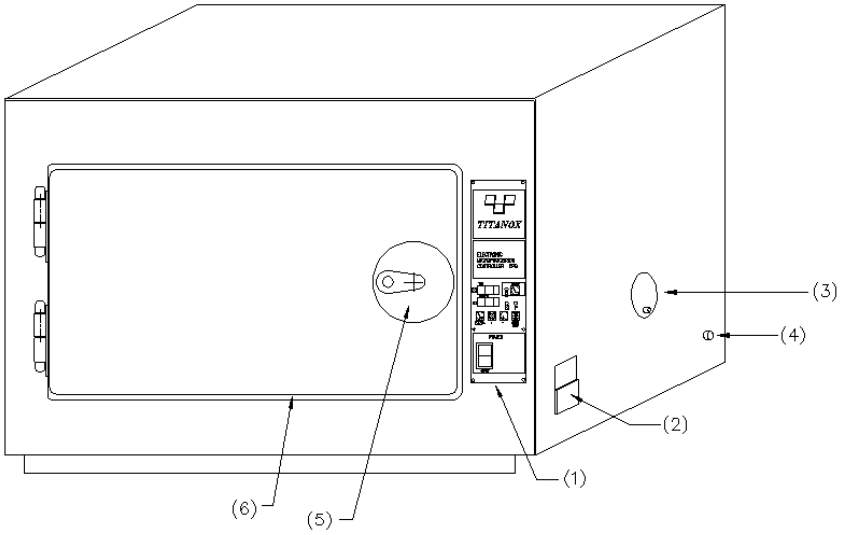
Summary

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 180º 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.

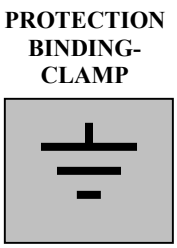
The device must be used only and exclusively by healthcare professionals (doctors, paramedics, nurses or similar) who are familiar with the principles of controlling sterilization processes in general and dry heat sterilization processes in particular



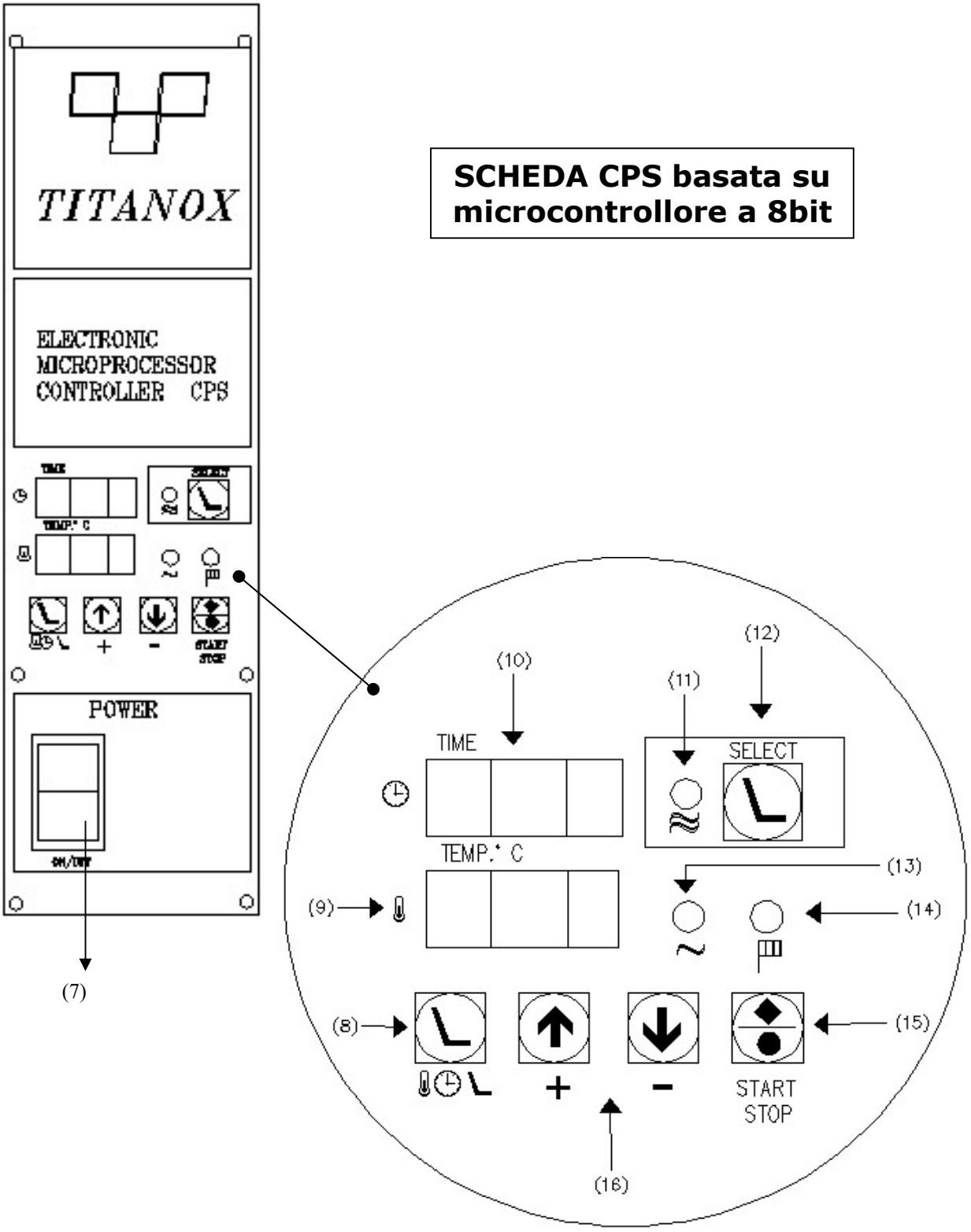
Index

Pos.1 – CPS Control Panel
Pos.2 – Connection plug with fuses
Pos.3 – Air-inlet for air circulation
Pos.4 – Security thermostat 260°C (±8°C)
Pos.5 – Closure with key
Pos.6 – Silicone gasket

1) SYMBOLS AND SAFETY WARNINGS



2) CPS CARD



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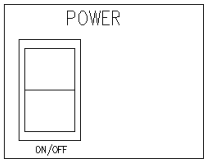
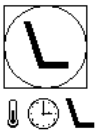
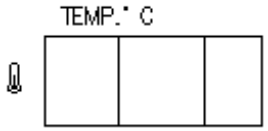
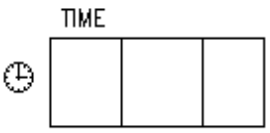
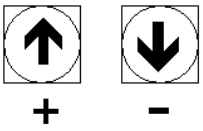
3) “CPS CONTROL PANEL” KEY

Pos. 7 Switch for starting and stopping device's working (ON/OFF)	
Pos. 8 Switch for setting time and temperature (SET)	
Pos. 9 Temperature Display (TEMP.°C)	
Pos. 10 Timer Display (TIME)	
Pos. 11 Led “CONTINUOUS CYCLE running”	
Pos. 12 Switch for setting “CONTINUOUS CYCLE running	
Pos. 13 Led “resistances”	
Pos. 14 Led “TIME-PROGRAMMED running”	
Pos. 15 Switch for starting and stopping “TIME-PROGRAMMED running”	
Pos. 16 Switch for setting time and temperature of the sterilization cycle.	

4) TECHNICAL SPECIFICATION

Models	**A3-216-400**	**A3-217-535**	**A3-218-670**
Loaded Chamber	3 kg	4 kg	5 kg
External size:			
Width mm	570	705	835
Height mm	400	475	555
Depth mm	345	450	565
Internal size:			
Width mm	405	535	670
Height mm	210	345	415
Depth mm	255	320	420
Weights:			
Net weight kg	13 kg	22 kg	36 kg
Gross weight kg	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	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 electronical devices wastes

Available operation:

TIME-PROGRAMMED: timer programmable up to 2 hours
CONTINUUOUS CYCLE: manual (without timer)

5) ENVIROMENTAL CONDITIONS

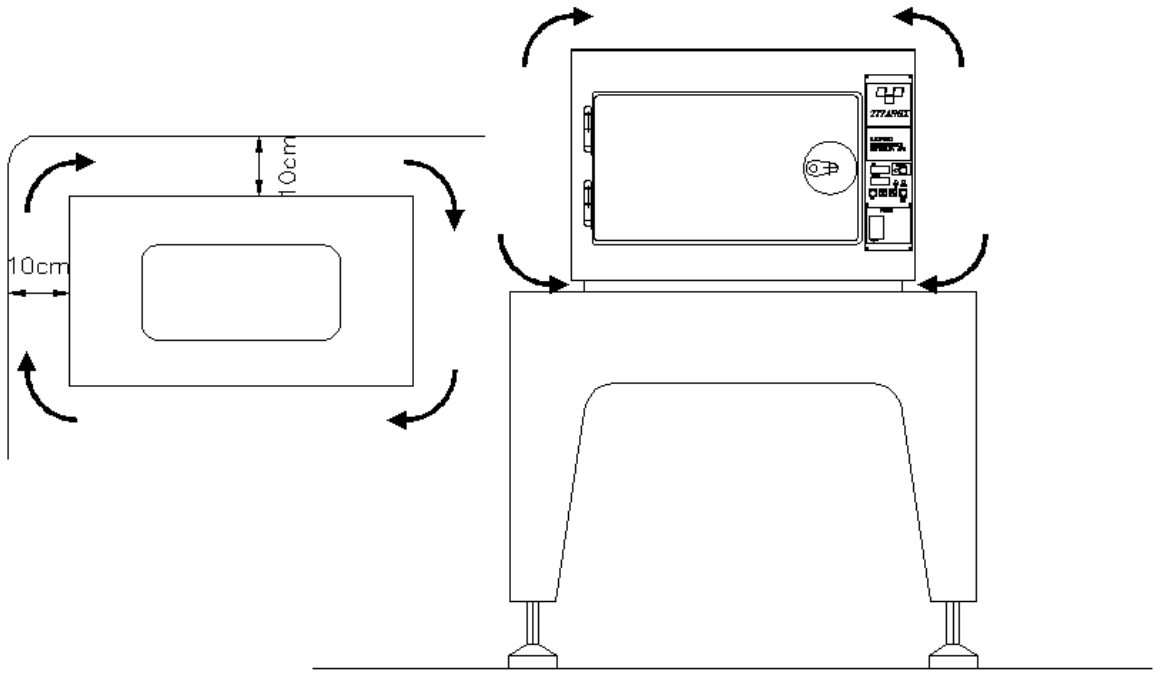
- Ambient temperature from 5 to 40° C.
- Relative humidity max. 80% for temperatures up to 31° C with linear decrease up to 50% at the temperature of 40° C condensing included.
- Atmospheric Pressure from 500 to 1060 hPa.
- Voltage supply variation not higher than ± 10%.
- Value of transitory over-voltage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

6) 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.

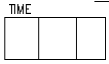
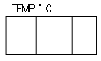
Once the device is correctly installed and power cable connected, it is ready for use.



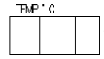
7) SAFETY WARNINGS

• 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 B Group 1; Insulation class: 1; IP20
• Always insist on original spare parts.
• 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

8) TIME – PROGRAMMED RUNNING

1. Insert the supplied connection socket of the mains cable in the plug of the device (Pos. 2) and the feeder- plug in the wall mains socket, after checking the voltage value.
2. Place materials to be sterilized inside the device.
3. Lock up the door. (Pos. 5)
4. Keep the air-inlets half-opened (Pos. 3) 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 to seal the device and to keep the material inside in temperature for a long time.
5. The device is switch on by pressing the button ON/OFF (Pos. 7). 
6. Once the device is on, the display TEMP.°C  (Pos. 9) shows the current internal temperature, while the display TIME  (Pos. 10) shows the last set timing for sterilization cycle.
7. For programming or changing sterilization time, press the button SET  (Pos. 8). In this way the display TIME  (Pos. 10) begin to blink. Use the buttons  (Pos. 16) to change the value shown, up to sterilization time required. The length, expressed in minutes, can be change from 1 to 250. At the end of blinking, the time shown shall be automatically memorized ⚠ (ATTENTION! Let the blinking end by itself).
8. To show the set heating temperature press the button SET  .
9. To set or change temperature press SET  for two consecutive times. In this way the temperature display TEMP.°C  will begin to blink. Use the buttons  to change the value shown, up to the temperature required. The temperature can be changed from 1 to 200°C. At the end of blinking, the temperature shown shall automatically be memorized and shall again be shown the current internal temperature ⚠ (ATTENTION! Let the blinking end by itself).

10. Activate the time-programmed sterilization running and press the key START/STOP 

. In this way the green LED  (Pos. 14) will light up and, for 1 second, the set temperature shall appear on the display TEMP.°C 

. If the key START/STOP 

is kept pressed, the temperature will remain visualized on the display until the key is released. After releasing the key START/STOP 

the green LED “resistances”  (Pos. 13) will light up and the display TEMP.°C 

will show the word ECL (Electronic-Compensation-Low). This indication shall remain until set temperature is reached.

11. On reaching the set temperature the display TEMP.°C 

will show the word ECH (Electronic-Compensation-High).
12. At the end of the internal compensation phase, the display TEMP.°C 

will show the current internal temperature and will begin the countdown, shown by the blinking of the decimal point (last value on the right) on the display TIME 

Once sterilization cycle time is finished, the green LED  shuts itself automatically.

ATTENTION

In the adjustment phase, the green LED  (Pos.13) shows the activation of the resistances for maintaining the temperature programmed. In case of abnormality of the driving system of the resistances, on display TIME 

(Pos. 10), the indication FAL is shown and the green LED  will remain off

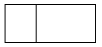
9) CONTINUOS – CYCLE RUNNING

The device has also a continuous cycle running. To use this kind of running proceed up to point 6 of the procedure for time-programmed running described above.

Then proceed as follows:

7. Press the key SELECT 

(Pos. 12). The display TIME 

will show the word OFF while the display TEMP.°C 

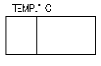
will show the set temperature during the last running.
8. On releasing the key SELECT 

the display TEMP.°C 

will show the word ECL (Electronic-Compensation-Low). If it is required to change the temperature (within ± 10°C), press the key SET  and then using the keys 

for setting the wished new value.
9. Once programmed the new temperature, on the display TEMP.°C 

will appear the word ECL that will remain shown on the display until the set temperature is reached.
10. When the set temperature is reached, on display TEMP.°C 

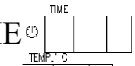
will appear the word ECH (Electronic-Compensation-High).
11. At the end of the internal compensation phase, on display TEMP.°C 

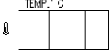
will appear the current internal temperature that persist with no time limit.
12. To finish the sterilization procedure in continuous cycle running press the key SELECT 

PLEASE NOTE

- If change of heating procedure is required, re-check each time set parameters since the two systems (time-programmed running and continuous cycle running) have memories independent from each other.
- In case of power cut-off while sterilization procedures have started, on return of power the system will compare the present temperature with the temperature at the time of power cut-off. If temperature has dropped more than 5°C, compensation procedure will automatically be restored and, in case of time-programmed running, pre-programmed time will be re-activated. If, on the other hand, the temperature has not dropped below 5°C, the procedure will re-start regularly as though nothing has happened.
- In the event sterilized materials cause eventual release of dangerous gasses, it will be necessary the use of suction system to neutralize unwanted fumes (check the point "consented uses" on page 9 regarding materials which can be sterilized and at any rate avoid use of soaked material with toxic or harmful substances).
- As the device heats up, avoid the introduction of substances or elements about which reaction to heat is unknown, in order to avoid explosions, implosions or emissions of toxic gasses.

10) ERROR IDENTIFICATION

WARNING! If on the display TIME 

appears the sign "ERR", a numerical code "xxx" will be shown on the display TEMP.°C 

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Numeric error code	Cause of the error
111	MCU error: error in the CRC check of the FLASH memory, or RAM memory or stack not working.
222	Triac Error: The triac is turned on when it should not or turned off when it should be on.
333	Temperature probe error: The temperature sensor has a reading outside the allowed limits.
444	Key error: One of the keys has been pressed for more than a minute.
555	Supply voltage error: One of the supply voltages (15V, 5V) is out of the allowed parameters
777	Non-volatile memory error (Eeprom). The eeprom memory is damaged and writing is unreliable
888	Voltage reference error 3V3

In all cases (except for the "444" error connected to the incorrect use of the keys), the sterilizer must be returned to Titanox for repairing the electronic card or the temperature probe, as these operations can only be carried out by Titanox S.R.L. specialized operators

11) 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.

12) 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.

13) 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.

14) 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.

15) DETACHABLE COMPONENT PARTS

2 Internal shelves
1 Main cable

16) 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.

17) **ATTENTION**

Laboratory tests following a cycle of 120 minutes at 180ºC 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.

18) 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.

19) 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.