


# Instructions for Use
# Tau Clave 3000 Fractionated Vacuum

CE 0426

DIRECTIVE 93/42 EEC and S.M.I.
MEDICAL DEVICES



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## *1 Warnings*

Tau Clave 3000 Fractionated Vacuum is an Autoclave. Carefully clean the sterilization chamber and the instruments to sterilize. USE ONLY DEMINERALIZED WATER.

## *2 Introduction:*

### *2.1 Normative References*

The autoclave Tau Clave 3000 Fractionated Vacuum is conforming to the essential requirements of the Directives of the Council: Medical devices 93/42/CEE and S.M.I., class II b it is conforming besides to the national norms that are translated in the harmonized norms:

EN 13060 ( Class S )
EN 61010-1
EN 61010-2-040
EN 61326 – 1
IEC 62304
EN 60601-1-6
IEC 62366
UNI CEI EN ISO 14971

The autoclave Tau 3000 Fractionated Vacuum complies with RoHS 2011/65 / EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

### *2.2 Expected use of materials to sterilize*

The equipment is used to sterilize surgical instruments in the medical-paramedical sector. The materials to be sterilized must **withstand** operating temperatures ranging from 105°C to 134°C.

**Do not load toxic materials into the autoclave. TAU STERIL shall not assume any responsibility in this respect.**

### *2.3 Manufacturer's Responsibility*

The equipment is manufactured in compliance with European regulations.
The use of this equipment is restricted to the functions for which it was originally designed and manufactured. **The user shall be responsible in case of any possible risks and dangers caused by an improper use of the autoclave.**
The product warranty is of twelve months starting from the date of purchase.



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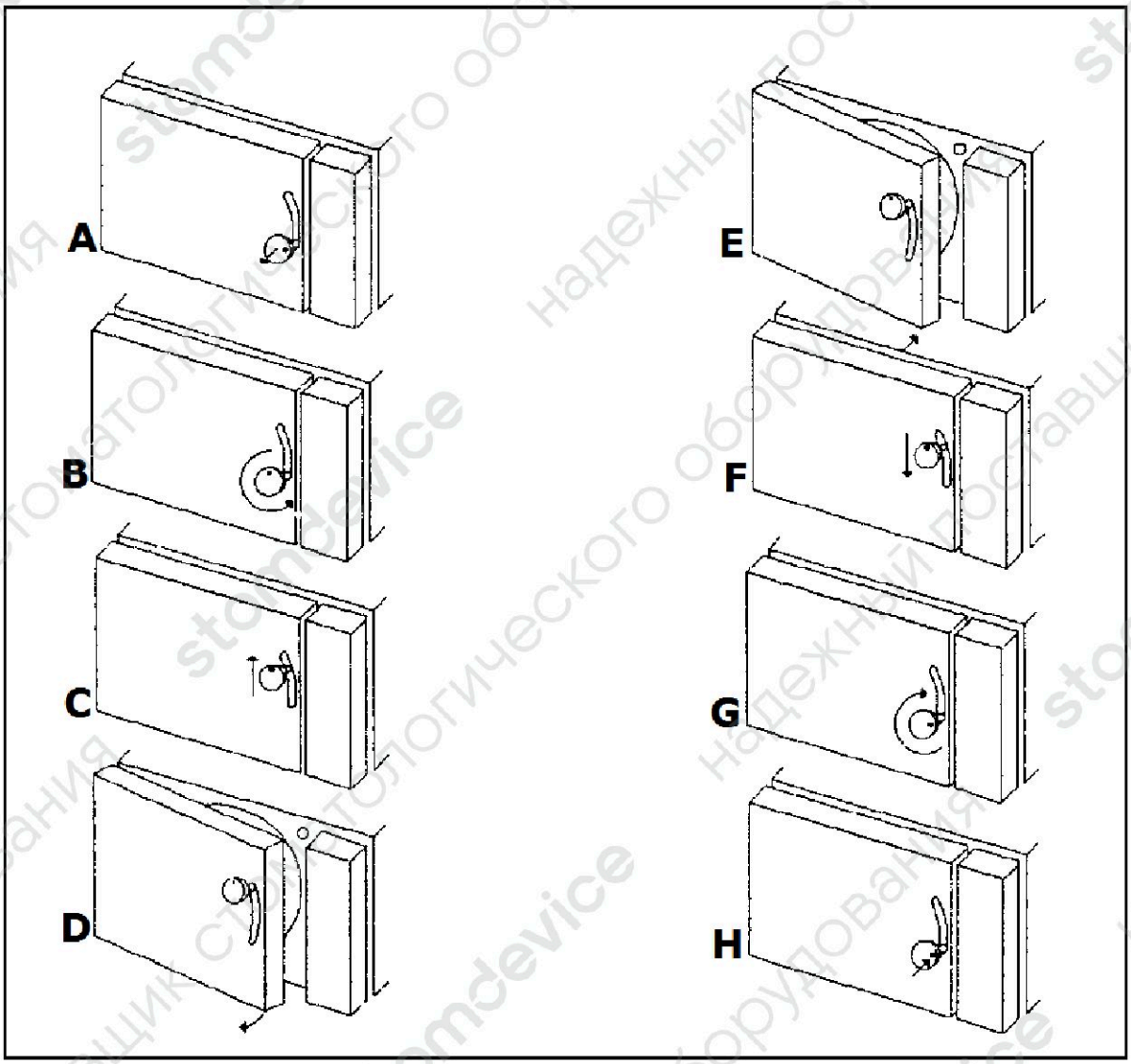
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### *2.4 Door opening and closure*

| OPENING MOVEMENT | CLOSING MOVEMENT |
|---|---|






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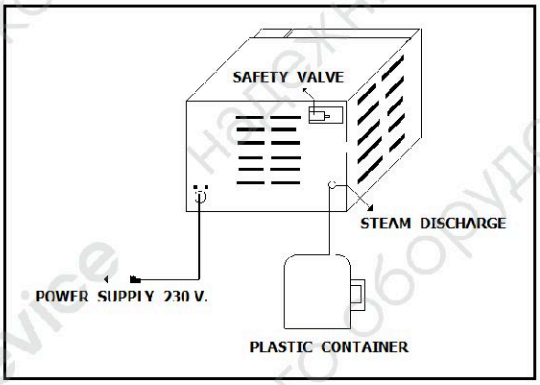
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## 3 *Installation*

Carefully remove the autoclave from its packing and make sure there are no signs of damage. Make sure earthing is correctly made. Put the autoclave on a flat and horizontal surface, to facilitate aeration. Always respect a distance of at least 10 cm from any wall or other equipment, to allow suitable ventilation.
Do not put objects or other items in the vicinity of the door, to prevent them from hindering opening of same.
To check that the tension of suitable feeding on the back label corresponds to that in hand in the place of installation (maximum variation of the tension of net: ± 10%).
To insert the thorn in the attack of the electric net. To press the general interrupter bringing him/it in position "I" and to verify the lighting of the same.
In case of missed observance of these dispositions TAU STERIL declines every liability.

**Fig. 2**




To give an inclination to the machine, it comes standard with two shims under the support legs front: it is important not to touch the shims. On the rear side of the machine is located in a pipe for the steam to exit.
**IMPORTANT: The tube must be positioned as shown in Figure 2.**

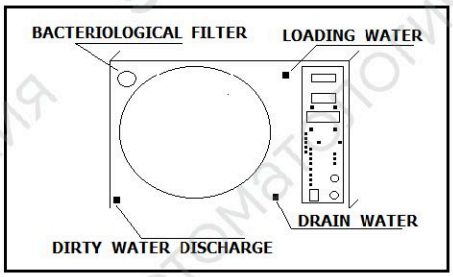



**Fig. 3**

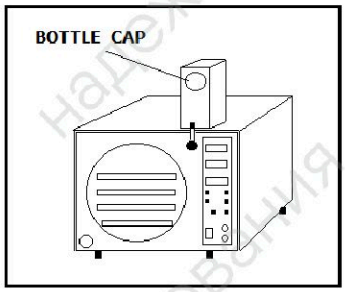



**Fig. 4**

- Fill the bottle with 2.5 liters of demineralized water, then close the bottle with the cap (see Fig. 4).
- Introduce the cannula orifice load autoclave. Unscrew the tap until the water begins to flow. The STOP appears on the display time, followed by a beep, it indicates that the machine is fully charged.
- When you turn on the red LED Lew level H2O, followed by the code A 01 (shown on the display time), it means the lack of water in the tank load.
- Fill the bottle with 1.5 l of demineralized water.
- Introduce the cannula orifice load the autoclave and unscrew the cap. The STOP appears on the display, which give you the completion of the load (about 1.5 l of the alarm activation A 01).
- **Tank drain recovery: Occurs alarm A 02 on the display of the time; It means that the machine must be emptied. Without this procedure, the same remains in the alarm condition, and therefore unusable. It is advisable for a better operation of the autoclave, the discharge of frequent recovery tank (dirty water).**
- **Caution: It is recommended before using the autoclave with load (first load water happened) of looping "Unwrapped" (empty chamber without load) in order to sterilize the chamber.**



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## *4 Characteristics*

### *4.1 Technical data*

**Weight**: 45 Kg.
**Outer dimensions**: Width cm. 44 – Height cm. 38 – Depth cm. 43
**Inner dimensions**: Diameter of chamber cm. 24 – Depth cm 35.
**Absorption**: 1250 Watt
**Power supply**: 230 V. 50 Hz

### *4.2 Environmental Conditions of Work*

- Temperature 5° - 40°
- Moisture (whit max T 31°) 80%
- Moisture ( whit max T 40°) 50%

### *4.3 Temperatures Times and Features programs*

The autoclave is equipped with five sterilization programs, and a cycle of Bowie & Dick test.All programs have the void before the sterilization step, and a step of vacuum during drying (DRY), alternating with phases of ventilation.To select the cycle BOWIE & DICK TEST as follows:Place the program cycle HOLLOW: before viewing (5 sec.) Of the cycle has finished, press the button decreases the time. Automatically displays the cycle 134 ° 3.5 'of BOWIE & DICK TEST.

| PROGRAM | FRACTIONATED VACUUM | STERILIZATION | DRYING AND VENTILATION | VACUUM FINAL |
|---|---|---|---|---|
| **UNWRAPPED**<br>(Instruments unwrapped) | **YES** | **134°**<br>**4 Minutes**<br>**2.11 Bar** | **15 Minutes** | **YES** |
| **WRAPPED**<br>(Tray wrapped) | **YES** | **134°**<br>**18 Minutes**<br>**2.11 Bar** | **15 Minutes** | **YES** |
| **POROUS**<br>(Synthetic fabrics) | **YES** | **121°**<br>**7 Minutes**<br>**1.08 Bar** | **15 Minutes** | **YES** |
| **Bowie & Dick Test** | **YES** | **134°**<br>**3 Minutes**<br>**2.11 Bar** | **-** | **NO** |
| **HOLLOW**<br>(Tools cables) | **YES** | **121°**<br>**15 Minutes**<br>**1.08 Bar** | **15 Minutes** | **YES** |
| **SPECIAL**<br>(suitable for delicate materials) | **YES** | **105°/135°**<br>**1 / 20 Minutes**<br>**0.20 / 2.25 Bar** | **15 Minutes** | **YES** |

WARNINGS: During the sterilization process TAU STERIL always recommended to insert in the sterilization chamber of the autoclave (with the material to be sterilized) an indicator of detection of the sterilization process (in compliance with current regulations).



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## 5 Terms of Use

### 5.1 General information

The controls and displays are shown in the drawing on page. 10 they are:
Control buttons:

| | | |
|---|---|---|
| 1 | **SELECT** | to select the program of sterilization |
| 2 | **START / STOP** | to start / stop the sterilization cycle |
| 3 | **TEMPERATURE DECREASE** | to decrease the temperature of the sterilization program Special. |
| 4 | **TEMPERATURE INCREASE** | to increase the temperature of sterilization in the program Special. |
| 5 | **DECREASE TIME** | to decrease the time in the program Special. |
| 6 | **INCREASE TIME** | to increase the time in the program Special. |

### 5.2 Views

| | | |
|---|---|---|
| 1 | **PRESSURE** | It indicates the pressure in bar. |
| 2 | **TEMPERATURE** | Shows the temperature of steam in the chamber, or by pressing the right button (+ TEMP) shows the temperature of the heating element. Also pressing the left button (-TEMP), you can see the selected temperature cycle. |
| 3 | **TIME** | Indicating the sterilization time of the selected program. They also bear the identification codes alarms, in addition to writing "FILL" indicates that the entry of water into the sterilization chamber. |

---

### . LED Operation (green)

They indicate the progress of the program:
- LED off: being not yet executed
- Flashing LED: phase running
- LED on steady: phase completed

They are:
READY = drying
FILL = filling (dose water)
VACUUM = vacuum
HEATING = heater
STERILIZE = sterilization
DRY = drying
END = end of the cycle
PRINT = print



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### . *LED Alarm (red)*

Report any anomalies:

they are: DOOR = door open
LOW H20 LEVEL = low level H2o
ALARM = generic alarm identified by the code on the display time

The front panel also has a cup connector (optional), suitable for the attachment of an external printer. It also has a switch with fuses (2x10A. 6.3x32).

## *5.3 Display mode alarm*

Each alarm is displayed in the machine in the following way:
- The time display shows the alarm code (ex: A01, A02 etc.).
- It has issued a long beep followed by 10 short, eventually silenced.
- In case of alarm A00 (door open) or A01 (insufficient water level) which are the most frequent, also they flash their LEDS and DOOR LOW LEVEL H20.
- In other cases, the ALARM LED flashes and the cause of the alarm must be obtained from the code on the display, or if present, from the printer that prints in detail the reason for alarm.
- The machine remains in this state until the occurrence of the condition of the termination / acknowledgment, specified individually for each alarm.
- If this (alarm) occurs during the cycle, the latter is interrupted and the pressure discharged.

### *5.3.1 Alarms and codes Summary*

| CODE ALARM | INDICATIONS |
|---|---|
| **A00** | **Door open: occurs if the start of the cycle, the door is open. Disappears by pressing any key or by closing the door.** |
| **A01** | **Low water: occurs if at the start of the cycle, the water level in the cargo tank is insufficient. Disappears by pressing any key or by resetting the level. If during the refueling operations is peaked, the time display shows "STOP" and the beeper sounds in the manner of an alarm. 2 ceased beeper "STOP" disappears, and returns to its normal state.** |
| **A02** | **Tank full exhaust: occurs when the level of water in the recovery tank is excessive. Disappears just emptying the tank.** |
| **A03** | **Black-Out: occurs in cases of abandoned cycle by Black-Out. Disappears opening the door or pressing any key. *** |
| **A04-A05** | **Long time for the heating is energized with any key. *** |
| **A06** | **High pressure: it excites with any key. *** |
| **A07** | **High temperature: energizes with any key. *** |
| **A08** | **Abnormal pressure: energizes with any key. *** |
| **A09** | **Abnormal temperature: energizes with any key. *** |
| **A10** | **Stage vacuum not successful. *** |
| **A12** | **High temperature PTV: it disappears by pressing any push button *** |
| **A13** | **High temperature PTC: it disappears by pressing any push button *** |

*** = Repeat cycle, the material to be sterilized <u>is not sterile</u>. If the problem persists, contact manufacturer.**

| **N.B: A00, A01, A02 do not cause (in the presence of printer) no print activity.** |
|---|



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There are also other alarms that are related to the components of the electronic board; they are:

| CODICE ALLARME | INDICAZIONI |
|---|---|
| **A 20** | **Data loss *** |
| **A 21** | **Watchdog malfunction *** |
| **A 22** | **Defective sensors *** |
| **A 23** | **Batteries Clock *** |
| **A 24** | **Software*** |

*** = Repeat cycle, the material to be sterilized is not sterile. If the problem persists, contact the manufacturer.**

### *5.4 Instruction Manual*

1 Clean the material to be sterilized.
2 Turn on the main switch.
3 Load the cargo tank (capacity 2.5 machine completely empty), until the message "STOP" on the display time. It occurs whenever the alarm Low H20 LEVEL add 1.5 liters of demineralized water. If you go over, it arises "STOP" that is tank full load, then pull the tube out of the oil cargo.
4 Whenever the alarm A02 occurs, download the recovery tank (better not wait for the alarm because nothing prevents you download it at any time) with the appropriate tube.
5 Load the media on the trays provided (without overlapping the pieces) and pull it into the sterilization chamber.
6 Select the program: to do this press the select button
A single press of the button does not change the program, but it serves the display shows the temperature of the temperature program: After five seconds the display temperature resumes its normal content. Within five seconds if the select button is pressed again, the program is changed (indicated by LED). If the selected program is special, the contents of the display temperature will flash to indicate that the sterilization temperature can be chosen between 105 ° - 134 ° with the + - temperature. The same applies to the time with the + - time.
These variations can be carried out simultaneously in both the time for which the temperature
7 Close the door after you have done so.
8 Press Start: starts the selected cycle.
9 Keep area within the opening of the door, to avoid (the opening of the door in hot machine) burns or other hazards:

**WARNING: DURING USE USE GLOVES.**

NOTE: At any time (ex: During sterilization or during DRY = dry) you can break the cycle by pressing the "STOP", a buzzer will sound and the beeper in the presence of pressure will be downloaded automatically.

### *5.5 Description cycle TAU CLAVE 3000 Fractionated Vacuum*

The phases of the cycle take place as follows:
At the start of the cycle we have the first vacuum phase (Cycle Unwrapped - Wrapped - Porous).
Follow the steps of fractionated vacuum with placing water cycle Hollow - Special).
This system is suitable for the sterilization of hollow bodies such as turbines, etc. autoclavable cannulas. etc.
The sterilization step takes place while maintaining the machine at a constant pressure. Then follows the drying phase is also composed of different phases of vacuum and ventilation. A sterilization cycle completed (END appears on the display "Temperature").
At this point part of the step of which consists in ventilation-condensation ventilate at intervals of 2 minutes (through the pump-vacuum) the interior of the sterilization chamber of the autoclave until the temperature read on the display "temperature" does not drop a degree below 70 degrees C °. This allows to obtain materials perfectly dry. The machine can still be open at any time by opening the door (see movement opening - closing the door 2.1 p. 3).



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## *6 Conditions for the Transport / Handling and Storage*

The autoclave is supplied with packaging that requires the usual precautions for transport fragile materials, as indicated on the packaging boxes himself. When returning for repair, use the original packaging. When storing, place the product in areas without humidity to protect the electrical components.
The device is packed in the following manner:
Two caps of polyethylene (above and below) protected by a box around the volcano in triple wave.
Do not lift the machine with violent jerks and not flip.
The device and the packaging are delicate, handle with care. Carry no shock, impact. Store in a dry and protected. The packaging should be stored. Using a different packaging, it could cause damage to the product during shipment.
The appliance must be extracted with the help of two people
- Remove the top cap.
- Extract the machine , taking care to keep it always in a horizontal position.
- Place the unit on the worktop.
- The device must be installed inside a laboratory accessible only to authorized personnel.
- Place the unit on a flat, horizontal surface.
- Leave a space of at least 20 cm around the apparatus for sufficient ventilation.
- Avoid placing the autoclave near sources of steam or splashing with water that may damage the internal electronics.
- Do not install in places with poor ventilation.
- Do not place it near heat sources.

## *7 Maintenance and Cleaning*

Each type of maintenance must be carried out with power wire off, and the machine completely cold.

**WARNING: Do not modify the equipment without the authorization of the manufacturer.**
In case of malfunction, contact the manufacturer.
For repairs to make the sterilizer manufacturer in its original packaging.

Cleaning the sterilization chamber (to be repeated on a daily basis):

- A cold machine using a sponge with vinegar to remove limestone from the chamber
- Wash the sponge with demineralized water and clean the chamber itself (several times)
- Pass a clean cloth with some isopropyl alcohol (90%) within the sterilization chamber.

Maintenance of the bacterial filter:

- Replace the filter every 6 months
- If dirt (sucks outside air during the sterilization cycle) to replace the first.

A cold machine monthly check that the door seal is accurate in the hard (steel) that contains: if withdrawn replace with a new one. We recommend replacing the gasket still every six months or after 200 sterilization cycles. Clean the seal on a daily basis (the machine is cold) with alcohol repositioning it in its proper housing.
Check monthly (or even if you move the device) the electric power cable is intact and in good condition.
In case of malfunction contact the manufacturer.
For repairs, it is recommended to make the autoclave to the manufacturer, using the original packaging


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It is always advisable to clean the instruments before putting it in the autoclave. Always clean the chamber (the machine is cold) with vinegar, then rinse with water and alcohol.
To safeguard against dirt components of the machine, it was put a small filter (unscrewable) on the tube at the side of the probe inside the sterilization chamber (see fig. 5).

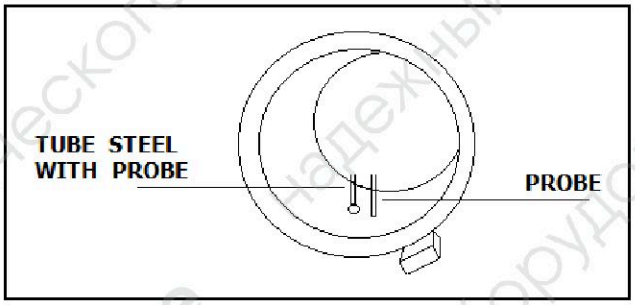



**Fig. 5**

**Dismantling: With the cold machine, turn from left to right the steel tube (with the help of pliers if necessary), paying attention to the probe closer.** Remove the piece from the chamber, unscrew the filter, clean it with vinegar or if too dirty replace it with a new one.
If you want you can avoid disassembling the tube with filter, pouring (machine cold) vinegar directly on the filter. To rinse well with water.
**Reassembly: repeat the contrary operations previously carried out, paying attention to the probe.**

**IMPORTANT: when you place the tube with the new filter, make sure that it is well established, keeping a distance from the probe equal to 2.5 cm.**


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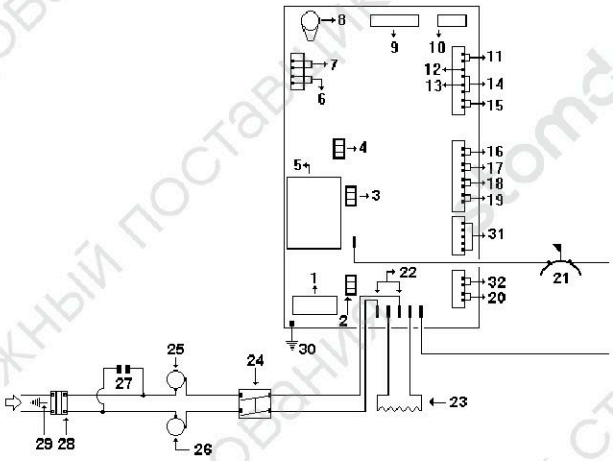
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## *8 Wiring Diagram*

### *LEGEND*

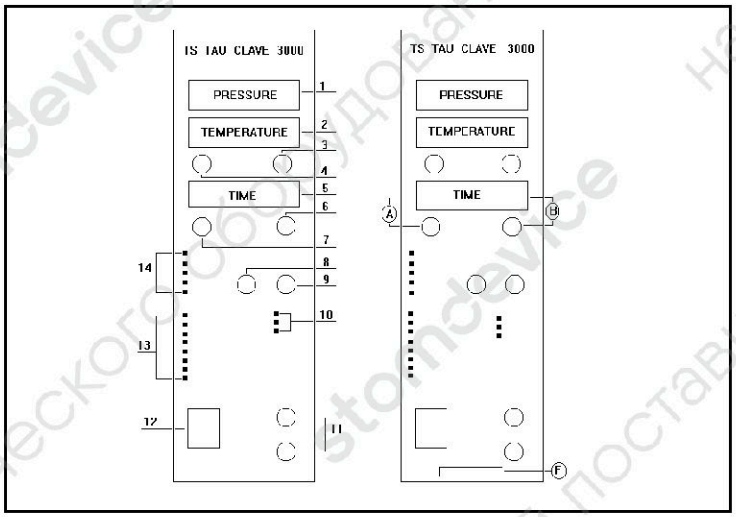



1. Line Filter
2. Fuse 5x20 extrafast 4 A.
3. Fuse 5x20 semi-delayed 3.15 A.
4. Fuse 5x20 semi-delayed 1.6 A.
5. Transformer
6. P.T.100 internal probe (temperature steam)
7. Probe P.T.100 external (temperature resistance)
8. pressure
9. Attack printer connector
10. Attack display connector
11. Floating maximum discharge
12. Floating minimum load
13. Floating maximum load
14. Floating common load connection
15. Micro-switch door
16. Electric valve N.A. (Normally open) 2 Way 24V DC.
17. Output optional 24V. cc.
18. Electric valve N.C. 2 Way 24V DC.
19. Electric valve N.C. 2 Way 24V DC.
20. 230 V power supply (feeding the vacuum pump and the electric valve nc 2 Vie)
21. Bimetallic security
22. Power supply 230 V 50 Hz.
23. Resistance 230V 1250 Watts.
24. switch
25. Fuse 6.3x32 quick 10 A.
26. Fuse 6.3x32 quick 10 A.
27. Capacitor 0.1 mF 250 VAC class x2
28. Cable clamp Power
29. Mass ground
30. Mass ground
31. Electric valve N.C. 2 Way 24V DC.
32. 230 V power supply (feeds the water pump)

---

## *9 Control Panel*

### *- LEGEND*




1 = Pressure Display
2 = temperature display
3 = + - Temperature
4 = Display time
5 = + - Time
6 = Selection Program
7 = START / STOP
8 = Led Alarms
9 = Fuses
10 = Switch General
11 = Led Operation
12 = Led Program



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### *- For Changing Printer Settings*

A = To change YEAR - MONTH - DAY - HOUR - MINUTES -
B = To move to the next parameter to be changed
F = Attack Printer

---

## *10 Rules and Safety Precautions*

• During use, wear gloves, to avoid sunburn (on the outer jacket is labeled precautionary "WARNING DANGER BURNS).

**The autoclave should be used only by authorized staff and informed about the techniques of "sterilization" of materials that can be sterilized and times and temperatures to be used.**

The equipment must be used exclusively for the use for which it was conceived: sterilization of surgical instruments in the medical and paramedical staff.
It's essential to take all necessary precautions to prevent misuse by unauthorized persons. It ' s forbidden to modify or alter in any way the security guards thermal and electrical equipment or put them out of order. It' s forbidden the operator to carry out repairs of any kind.
During cleaning and / or maintenance, it is absolutely essential to ensure that the equipment is disconnected from the power supply, and it is completely cooled.
In the case of sterilization of surgical instruments (eg scalpel or pointed instruments), we recommend the use of safety shoes.
Periodically check that the power cord is not damaged in any way.

**WARNING: There shall be no change in this unit.**
**In case of malfunction, contact the manufacturer.**
**For repairs to make the sterilizer manufacturer in its original packaging.**

## *10.1 Decommissioning and scrapping Device*

The autoclave Tau Clave 3000 Fractionated Vacuum is constructed of ferrous materials, electronic components and plastics. If the appliance is no longer repairable and running, separate the various components according to the material of which they consist, in order to simplify a possible re-use or disposal differentiated. When the unit is demolished there are no special instructions to be executed.
Do not leave the unit in an unguarded. Entrust scrapping to disposal companies. Scrapping always refer to the laws in force in the country of use


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### *10.2 Explanation of Symbols*

| | |
|---|---|
| WARNING: READ THE INSTRUCTIONS |  |
| WARNING: DANGER BURNS |  |
| CAUTION: RISK OF ELECTRIC SHOCK |  |
| WARNING: USE GLOVES FOR HAND PROTECTION |  |
| PRODUCT NOT COMPARABLE TO MUNICIPAL WASTE.<br>FOLLOW THE RULES FOR MUNICIPAL DISPOSAL |  |



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