Operating Instructions
Tau Steril Portatile Automatic

CE 0426

DIRETTICTIVE 93/42 EEC E S.M.I.
MEDICAL DEVICE

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1. Warnings

Tau Steril Portatile automatic is a **Dry Sterilizer. Do not load wet material into the sterilization chamber of the unit to avoid <u>the risk of short circuits.</u>**

2. Introduction

2.1 Normative References

The Dry-sterilizer Tau Steril Portatile automatic is conforming to the essential requirements of the Directives of the Council: Medical Devices 93/42/CEE e s.m.i., class II b
it is conforming besides to the national norms that are translated in the harmonized norms:

EN 61010-1
EN 61010-2-040
EN 61326 – 1
EN 60601-1-6
EN 62366
UNI CEI EN ISO 14971

"For the date of validity of the aforementioned standards, refer to the Technical File to be requested from the manufacturer".

The Dry-sterilizer Tau Steril Portatile automatic 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 0°to 200°C. **Do not load toxic materials into the sterilizer. TAU STERIL <u>shall not assume any responsibility</u> 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 sterilizer.
The product warranty is equal to twelve months starting from the date of purchase.

3. Installation

To verify that the transport has happened under conditions of acceptable damp not to jeopardize the safety of the dry-sterilizer To preserve and to install the instrument in deprived environments of damp (<u>Tau Steril assumes no responsibility for the safety of the equipment is kept, on occasions, not appropriate).</u>
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 "The" and to verify the lighting of the same.
In case of missed observance of these dispositions TAU STERIL declines every liability.
To verify some correct mass to earth of the general plant. To position the sterilizer on a plain surface, to facilitate the ventilation of the same one. Don't approach the sterilizer to less than 10 cm. from walls or other equipments to allow a fit ventilation, and to avoid the contact with surfaces to risk of fire e/o issue of smoke.
Don't approach objects or other in proximity of the ray of opening of the door of the instrument with the purpose to allow the correct opening of the same one.

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4. Characteristics

4.1 Technical data

Weight: 8 kg
Outer dimensions: Width cm. 49.5 – Height cm. 22 – Depth cm. 31
Inner dimensions: Width cm. 38,5 – Height cm. 9 – Depth cm 17
Absorption: 400 watt
Power supply: 230 V – 50Hz

4.2. Environmental working conditions

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

4.3 Recommended times and temperatures

The temperatures that can be programmed depend on the specific characteristics stated by the manufacturer and/or on the instrument to be sterilized. The recommended temperatures for dry sterilization range from 150° to 180°. **IMPORTANT: The personnel using the sterilizer must respect above-mentioned temperatures. Maximum programmable temperature: 200°C**
The recommended sterilization times range from a minimum of 30 minutes to a maximum of 45/60 minutes. Maximum programmable time: 120 minutes. The sterilizer can also work indefinitely (by turning the thermostat knob counterclockwise, as indicated on the nameplate placed on the sterilizer).

5 Operating modes

ATTENTION: The Surety of the Sterilization is completely submitted to the operator, as a very simple device being, it doesn't foresee alarms of any kind. The operator always has to be present during the operation of the equipment verifying possible lacks of net that could jeopardize the phase of sterilization

- Carefully clean and wipe the instruments to sterilize
- Turn on the switch
- **To program the temperature:** Turn the thermostat knob and set the pointer on the temperature you wish to reach.
- Turn the timer knob **clockwise** and set the pointer on time needed (max. 120 minutes).

After completion of these operations, the two-colors pilot lamps will show you the operating status of the sterilizer (green pilot lamp = operation, yellow pilot lamp = thermostat). Before stabilizing on the temperature programmed, the yellow pilot lamp will blink every now and then (to indicate that temperature is rising).
If you want to disconnect the timer and make the sterilizer operate indefinitely, turn the timer knob **counterclockwise** and set in to "manual".
For a correct use of the machine, we recommend not to overload the trays, to enable a good heat circulation.
To control temperature the sterilizer is equipped with a thermometer visualizing the programmed temperature.

6 Transport and storage conditions

The sterilizer is equipped with packing requiring normal transport precautions necessary for fragile materials, as indicated on the packing container itself. Make sure you retain the packaging materials for future shipment or should the machine need repairing. In case of storage, put the sterilizer in a moisture-free area to protect electrical parts.

7 Maintenance and cleaning

Any maintenance must be executed after disconnecting the feeding cable and when the machine is completely cold.
Operations of cleaning of the room of sterilization (to be repeated himself/herself/themselves with daily frequency):

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- To sterilizer with disconnected cable to use a rag with denatured alcohol (90%) and to clean the room of the dry – sterilizer.

Operations of cleaning of the gasket of the counter (to be repeated himself/herself/themselves with weekly frequency):

- To sterilizer with disconnected cable to use a rag with denatured alcohol (90%) and to clean the gasket of the dry - sterilizer posts next to the counter and of black color black .

ATTENTION: Do not modify the machine without the manufacturer's permission.
In case of malfunction contact the manufacturer.
If repairs are recommended to make the sterilizer to the manufacturer, using the original packaging.

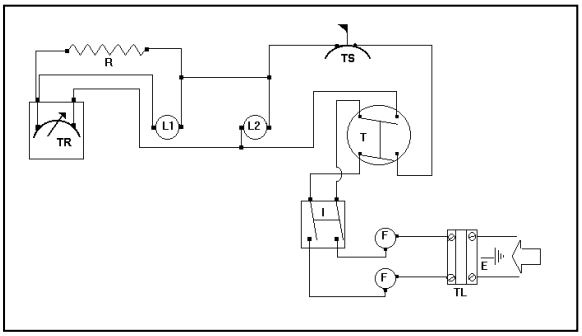
Do not use sprays or jets of water. Do not let water drip inside: short circuit danger.
Monthly check that the electrical power cord is in good condition.

Periodically check (in case there are problems) the correct functioning of the safety device (thermostat).
If the safety thermostat trips, unplug the power plug and reset the red button on the thermostat

8 Wire diagram

LEGEND

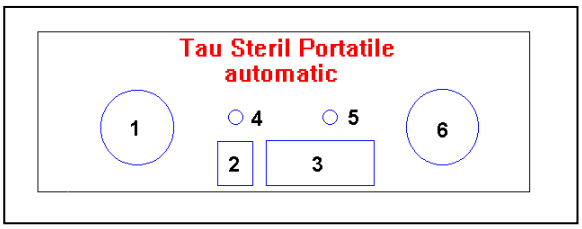
TR= Thermostat
T = Timer
L1= Thermostat Pilot lamp
L2= Operation Pilot lamp
R= Resistor 230 V. 400 Watt
I = Switch
F= Fuses (2) 5 x 20 quick 3.15A
TL= Line terminal
E= Earthing
TS = Safety thermostat



9 Control panel

LEGEND

1= Timer
2 = Main switch
3= Termometer
4= Operation pilot lamp
5= Thermostat pilot lamp
6= Thermostat



10 Safety rules and precautions

- When operating the sterilizer always wear protective gloves to avoid possible burns (a precautionary nameplate "WARNING: DANGER OF BURNS" can be found on the outer frame of the sterilizer)
- **PAY ATTENTION WHILE EXTRACTING THE INSTRUMENTS FROM THE STERILIZER: DANGER OF BURNS — WEAR PROTECTIVE GLOVES.**

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The sterilizer must be used only by an expressly authorized personnel, informed about the "Sterilization techniques", the materials that can be sterilized and the recommended times and temperatures to follow.

This equipment must be used uniquely for the purpose for which it was originally designed and manufactured: sterilization of surgical instruments to be used in the medical and paramedical field.

All precautions must be **absolutely** taken to avoid an improper use of the machine by **unauthorized** people. Modification, removal or disconnection of existing thermal and electric protections is strongly forbidden. The operator must not perform any repairs on the machine. Always disconnect the sterilizer during cleaning and maintenance of same. Moreover it must always be completely cold.
When sterilizing surgical instruments (such as scalpels or pointed instruments) safety shoes should be preferably worn.
Check periodically that the feeding cable is not damaged.

ATTENTION: Do not modify the machine without the manufacturer's permission.
In case of malfunction contact the manufacturer.
If repairs are recommended to make the sterilizer to the manufacturer, using the original packaging.

10.1 Decommissioning and scrapping of the appliance

The dry-sterilizer Tau Steril Portatile automatic are built with material ferrous, component electronic and plastic subjects. In the case the instrument is not more repairable and running, to separate the different components according to the material of which they are constituted, so that to simplify a eventual reuse or the diversified disposal. When the instrument is demolished there are no particular instructions to perform.
Don't remise the instrument in places not guarded. To submit the scrapping to enterprises of disposal.
Entrust an enterprise disposal. Always refer to scrap the laws of the country of use

10.2 Legend of symbols

WARNING: READ OPERATING INSTRUCTIONS	
WARNING: DANGER OF BURNS	
WARNING: DANGER OF ELECTRIC SHOCKS	
WARNING: WEAR PROTECTIVE GLOVES	
NOT TREATED AS MUNICIPAL WASTE. FOLLOW RULES FOR MUNICIPAL DISPOSAL.	

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