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Local Wholesaler :

MEDICAL TRADING S.R.L.

Amministrazione / Administration / Administration / Verwaltung :
Via F. Reina, 133
21047 - **SARONNO** (VA) - ITALY

Stabilimento / Factory / Usine / Fabrikstätte :
Via S. Andrea, 32
22040 - **LURAGO D'ERBA** (CO)
Tel. **+39-031-697327** - Fax **+39-031-6940252**
E-Mail **info@medicaltrading.it** - http **www.medicaltrading.it**

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ENGLISH

MEDICAL TRADING

autoclave HYDRA 100
automatic

GB **INSTRUCTIONS FOR USE**

Dear Customer,

We thank you for having chosen a quality unit manufactured by MEDICAL TRADING S.r.l.

This unit has been planned according to the international Safety Regulations. There is no risk for the operator if this unit is used as instructed

IMPORTANT:

- read the instructions carefully and look at the pictures, then switch the unit on.
- keep these instructions always at hand.
- only use distilled water to avoid damages of the autoclave and of the instruments to be sterilized.
- follow carefully instructions in this handbook.

Warning:
this sign shows the necessity of reading the instructions carefully.

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MEDICAL TRADING
autoclave **HYDRA 100 automatic**
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CONTENTS

1

GENERAL DIRECTIONS

This handbook gives information about:

- the right assembly
- the safe and efficient working of the unit
- the continuous and regular maintenance

This unit must be used only as instructed.

The operator is legally responsible for installation and function of the unit itself.

Warning:
If the operator does not handle the unit correctly or does not service appropriately, the manufacturer cannot be considered responsible for any breakings, damages or wrong-functions.

GENERAL INFORMATION ON DELIVERY

On receiving the unit, check if packaging is not broken!

Open the box and examine if:

- the supply is in conformity with the order (see shipping document)
- there are any damages

In case of damages or missing parts, please inform the carrier, MEDICAL TRADING or their local distributors immediately and give details.

Don't destroy the box because it might be useful to send the autoclave back for any repairs and/or maintenance.

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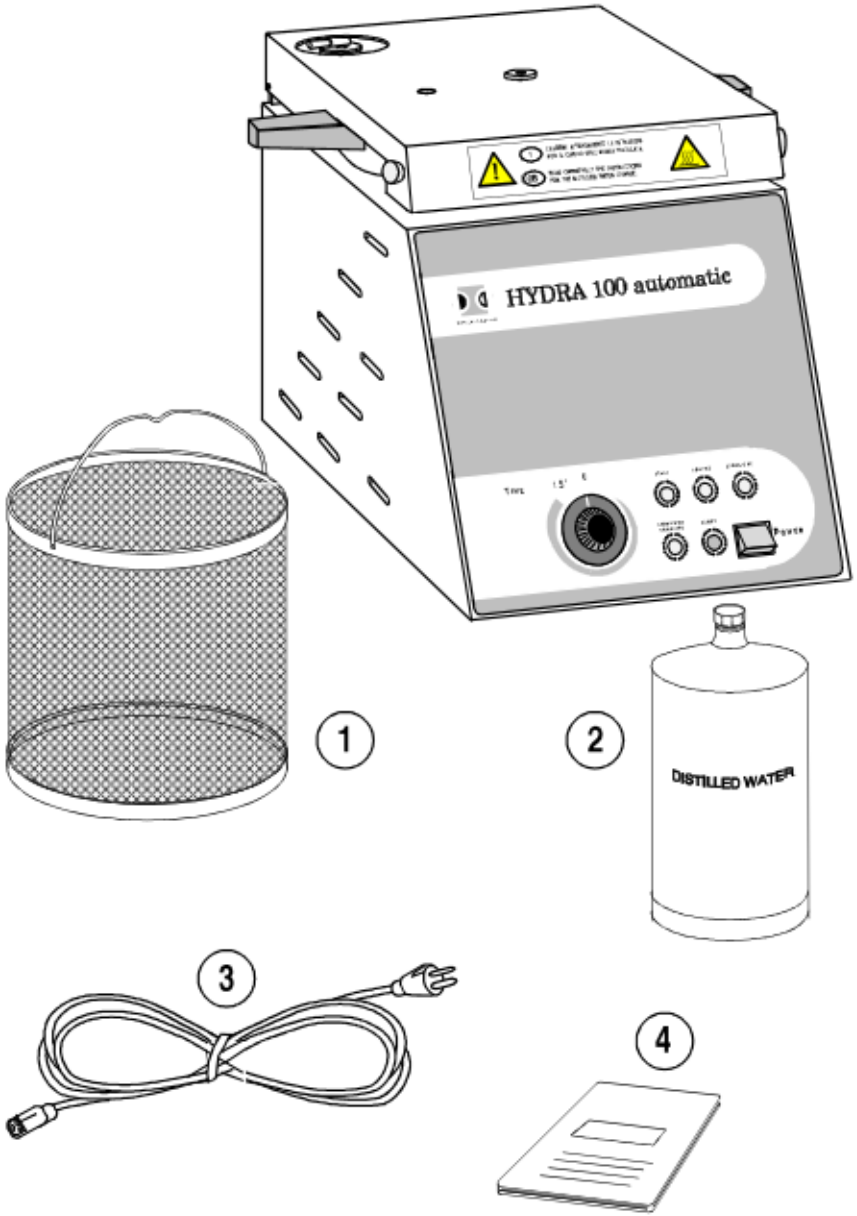
EQUIPMENTS AND EXTRA SUPPLIES

EQUIPMENTS (see picture no. 1)

1	1	perforated stainless steel basket (ø mm. 210, 215 mm h.)
2	1	litre of distilled water
3	1	cable with earthed plug
4	-	operator's handbook; warranty certificate; final inspection

EXTRA SUPPLIES :

- stainless steel instrument holder
- sterilization indicating tape
- biological indicator for sterilization control



Picture no. 1

autoclave **HYDRA 100 automatic** GB

ABBREVIATIONS USED IN ELECTRIC AND HYDRAULIC DIAGRAMS

V1	=	WORKING VALVE / STEAM BLEEDER
V2	=	PRESSURE SIGNAL VALVE / LID LOCK
SV	=	SAFETY VALVE
SC	=	STERILIZING CHAMBER
AR	=	AIR RELEASE
WT	=	WATER LEVEL
PR	=	TIME PROGRAMMER
RES	=	CIRCULAR ELECTRIC RESISTANCE
TR1	=	TEMPERATURE CONTROL THERMOSTAT
TRS	=	RECHARGING SAFETY THERMOSTAT
SCD	=	INTERCONNECTING BOARD
START	=	GREEN LIGHT
HEATING	=	GREEN LIGHT
STERILIZING	=	GREEN LIGHT
STERILIZING COMPLETE	=	GREEN LIGHT
ALARM	=	RED LIGHT
VPS	=	POWER LOCKER WITH FUSE
IG	=	MAIN POWER SWITCH
FR	=	ELECTRONIC FILTER

FUNCTION OF THE ELECTRIC AND HYDRAULIC COMPONENTS

	V1	V2	SV	RS	TIMER
OFF	Open	Open	Closed	OFF	OFF
ON	Open	Open	Closed	OFF	OFF
START	Open	Open	Closed	ON	OFF
PRESSURE 0,1 bar	Open	Closed	Closed	ON	OFF
AIR EJECTION - 100 °C	Open	Closed	Closed	ON	OFF
PRESSURE	Closed	Closed	Closed	ON	OFF
STERILIZATION	Closed	Closed	Closed	ON	ON
END (Steam recon-densing)	Open	Open	Closed	OFF	OFF
OFF	Open	Open	Closed	OFF	OFF

3

STERILIZATION WITH SATURATED STEAM: GENERAL CONCEPTS

After many years of application, experience has shown that all the different kinds of sterilization are reliable. But the most effective and safest way to obtain a complete asepsis is certainly the treatment in autoclave with water saturated steam (this is the common way used in hospitals).

The function of the autoclave is regulated by the Test of Boyle-Mariotte which binds pressure, temperature and volume.
The autoclaves with distilled water easily sterilize thanks to the perfect distribution of heat, the action of saturated steam, which brings about the heat exchange with the material to be sterilized (latent heat of water evaporation is extremely high: 539 Kcal/Kg at 100°C, 526 at 120°C, 519 at 130°C).

The essential reason for sterilizing through water saturated steam in pressure is that all the instruments, either liquid or solid, must be treated at the requested temperature for the right time. Pressure itself does not contribute to lethal process, but it just increases latent heat of water evaporation.

When vapour comes into contact with any other colder material or body, it yields its quantity of heat by condensing and then increasing the object temperature. In vapour condensing on microorganisms (due to the difference in temperature) this heat is integrally given with devastating effects on microbic cells. This action goes on till there is a thermal equilibrium, then there is no more heat exchange and further condensing. We can then say that sterilization takes place in an acqueus fluid. From this introductory statement two important factors come out: first, overheated steam must be avoided; second, all air must be excluded.

Overheated steam or steam heated over its usual temperature in connection with its pressure must be avoided for the following reason: although condensing takes place during the initial phase of heating it vaporizes again and the

sterilizing process becomes a process of dry heat, whose conditions are different,sterilizing temperature is higher and time is longer.

Air must be completely excluded, so that air pockets or layers are avoided, which compromize the effective steam penetration and the right heat exchange. In fact a content of 50% air increases seven times the necessary time to kill spores and time increases 11 times in presence of 100% air.

With water saturated steam heating process is not immediate in any case and time needed to reach thermal equilibrium varies according to the size of the autoclave, the quantity and quality of the material to be sterilized.

With liquids or materials for surgical dressing and glass articles, where penetration is difficult or heat capacity is high, time is important and you must consider it in the sterilizing cycle.

Scientific European and American Community have fixed and defined three temperatures, 115°C, 120°C and 134°C and relative exposures for different materials and their resistance to temperature. Treatment at 105°C has been recognized effective with appropriate exposure, to be used for disinfection of thermolabile materials which have obviously no direct contact with patients.

Cycle at 125°C for 15 minutes of sterilization is a middle cycle for sterilization of any metal instrument.

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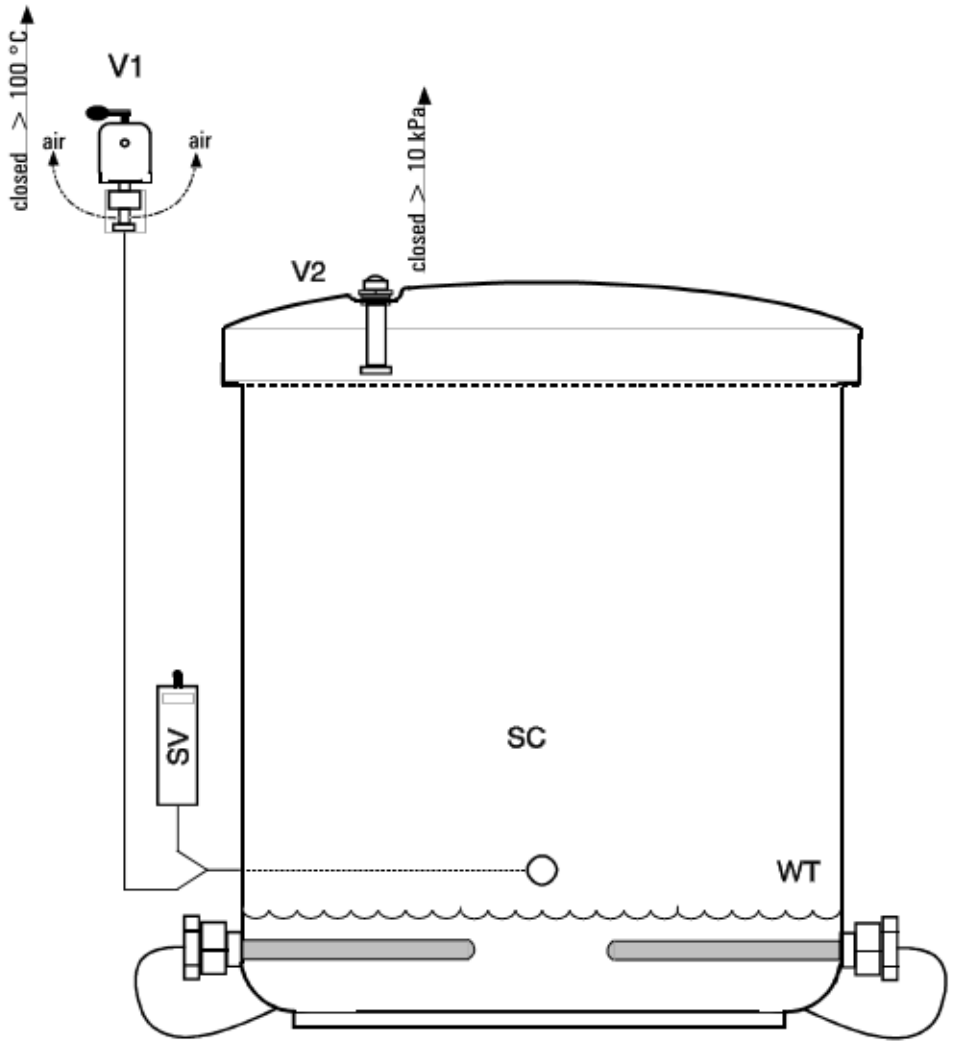
HYDRAULIC DIAGRAM



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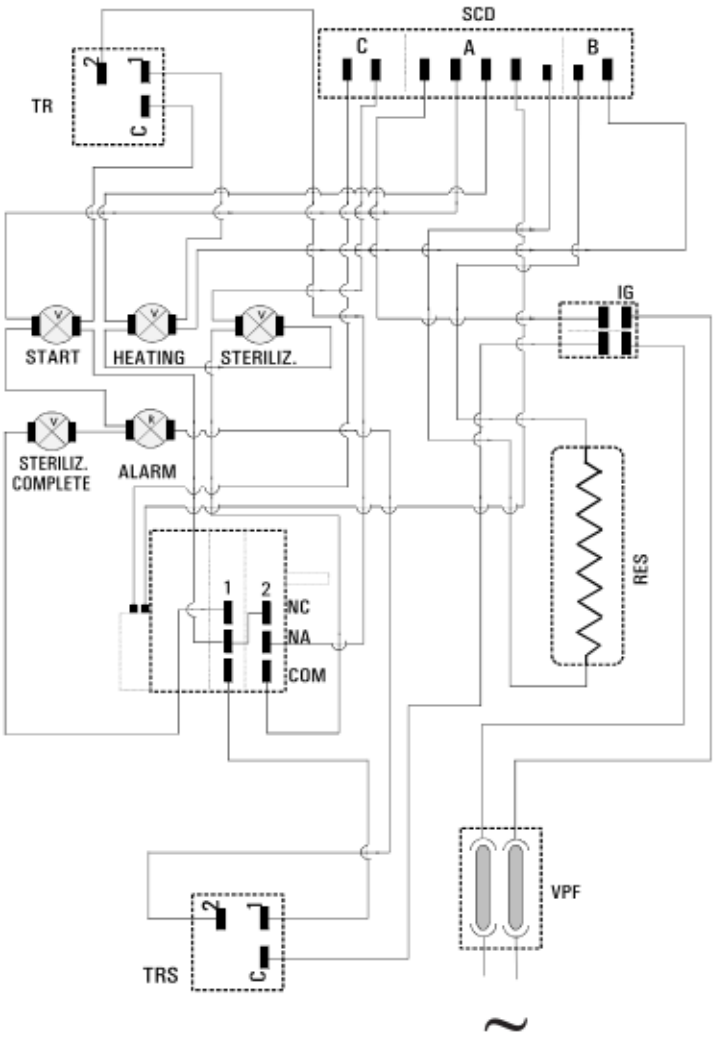
ELECTRIC AND HYDRAULIC DIAGRAM

ELECTRIC DIAGRAM



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THERMODYNAMIC VACUUM

When you push START the sterilizing chamber walls begins to heat, water becomes steam, rises and compresses cold air towards the bottom part of the chamber as it is lighter than water. Through the steam valve (see picture no. 10 on page 21) air vanishes almost completely. When there is no more air inside, the valve rises and pressure in the autoclave begins to raise.

RECOMMENDED OBJECTS FOR STERILIZING PROCESS

- Stainless steel instruments
- Stainless steel surgical instruments
- Carbon steel instruments
- Dynamic instruments (metallic hand-pieces and turbines)
- material in thermoresistant glass

PRESSURE TABLE/SATURATED VAPOUR TEMPERATURE

Temperature (°C)	Pressure (bar)	Temperature (°C)	Pressure (bar)	Temperature (°C)	Pressure (bar)
100	0.00				
101	0.05	116	0.75	131	1.79
102	0.10	117	0.80	132	1.87
103	0.14	118	0.88	133	1.95
104	0.17	119	0.92	134	2.05
105	0.21	120	0.98	135	2.14
106	0.25	121	1.06	136	2.23
107	0.30	122	1.11	137	2.32
108	0.35	123	1.17	138	2.41
109	0.39	124	1.25	139	2.51
110	0.44	125	1.32	140	2.72
111	0.48	126	1.40	141	2.81
112	0.52	127	1.46	142	2.83
113	0.58	128	1.54	143	2.95
114	0.64	129	1.62	144	3.05
115	0.70	130	1.71	145	3.16

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DESCRIPTION

This autoclave is an extremely simple and economic unit, it is equipped with a control panel and all necessary information for its proper use.

It has one sterilizing cycle which is optimized for a perfect and quick sterilization of the different materials used in hospital and/or surgery.

The unit is made of a boiler with electric heating resistance, a lid with rubber gasket, a timer to count sterilizing time and a microswitch to check temperature.

Electric resistance is electronically checked to obtain a quick increase of water temperature and keeping the steam at the set temperature.

Sterilizing cycle may be descripted in four phases:

1. Loading of materials to be sterilized and locking of the lid.
2. Heating of the chamber, thermodynamic vacuum of air and increasing of temperature and steam pressure to the set value.
3. Beginning of real sterilizing cycle, lasting for the set time (timer decrements).
4. Manual steam release or its condensation and bind on the bottom of sterilizing chamber.

Warning:
Never use disinfectants when cleaning the chamber.
Important:
Only use distilled water, otherwise calcareous deposits may obstruct valves

SUBSTITUTION OF THE GASKET

Open the lid and remove the gasket from its place. Clean the track of the gasket with a cloth and alcohol. Insert the new one, after pouring some talcum on the track of the gasket.

CLEANING OF THE WORKING AND SIGNAL VALVES

Regularly check that the working valve is always well cleaned and rises when achieving a 105°C temperature.

Warning:
The rare emission of water drops and a light venthole during the sterilizing cycle means that the valve is working correctly.

Check if the pressure signal is clean and runs freely in its place.

REPLACEMENT OF THE FUSES :

Unplug the power cable from the main power, move the power cable from the small container situated on the back side of the autoclave (**see detail no. 8, picture no. 11 on page 23**). With a small screwdriver unscrew the small drawer containing the fuses (**detail no. 9, picture no. 11 on page no. 23**).
Remove the fuses and replace both of them with two of the same kind and value. To determine their value see on the serial label (**detail no. 7, picture no. 11 on page no. 23**).

CLEANING OF THE LID GASKET

Clean either the gasket or the stainless steel lid with a cloth and water or vinegar to eliminate calcareous scales. Use a non-abrasive wet cloth and normal cleansing for stainless steel to clean shiny side of the lid.

Warning:
Do not accumulate calcareous or dirt residues on the gasket because they can cause its damaging or even breaking.

CLEANING AND DISINFECTION OF EXTERNAL SURFACES

Periodically clean every external side of the unit using a wet cloth and normal cleansing or simply water.

Use either denatured alcohol or cleansing with few hypoclorited sodium (or similar) to disinfect external sides.

Warning:
Do not wash the autoclave with direct or high pressure water jets. Any infiltration inside electrical or electronic components could damage the regular function of the unit and its safety system.

CLEANING OF THE STERILIZING CHAMBER, THE BASKET AND THE HOLDER

Accurately clean (every week) the sterilizing chamber, the basket and the holder with a non-abrasive cloth and water or cleansing for stainless steel objects. Then rinse with alcohol and later with water.

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Experience acquired in these years has brought to technological improvements for autoclave safety, expecially:

- Safety lock , which prevents the opening of the door during the sterilization cycle; the door can only be opened when pressure inside the chamber is levelled to the ambient one.
- Safety valve for steam exhaust in case of damage with inside overpressure > 2.5 bar.
- Safety thermostat which occurs if the inner temperature of the chamber rises over 135°C.
- Thermodynamic vacuum.

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SAFETY

- The unit has not been planned to be used in presence of gas or other explosives.

- You must not pour water or other liquids on the unit (only into the chamber) in order to avoid short circuits and corrosion.

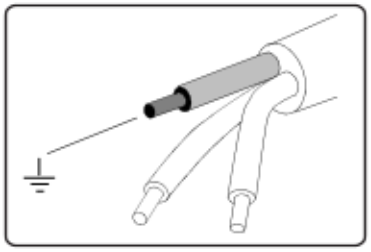
WARNING
If it is not possible to disconnect electric energy and the cutout is far or cannot be seen by the one who is servicing, you must put the sign **WORKING** on the cutout after positioning **OFF** (**see picture no. 2**).

Make sure that electrical system has an earthing according to the country safety regulations (**see picture no. 3**)

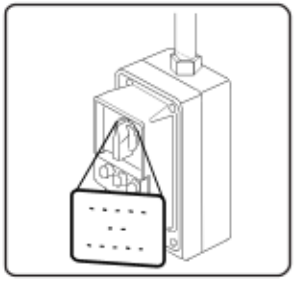
- Do not remove any labels or signs; in case of need ask for a new one.

- Only ask for original spare parts.

If you do not respect what has been said above, Medical Trading denies any responsibility.



Picture no. 3



Picture no. 2

- Do not use common abrasive cloth or metallic brushes to clean instruments.

PREVENTIVE MAINTENANCE

Warning !
Before making any maintenance, make sure that the line cord of the autoclave is not connected, in order to avoid electrical shocks or contacts with steam.

DAILY	Clean the gasket and the lid Clean the external surfaces Clean the internal surfaces
WEEKLY	Clean the sterilizing chamber Clean the basket and its bearing Clean and disinfect external surfaces
EVERY 10 DAYS OF AFTER 5/6 CYCLES	Empty the autoclave completely inclining it on one side, then pour some distilled water and cover the temperature control probe with water.
MONTHLY	maintenance of the working and pressure valves.
EVERY SIX MONTHS	check sterilizing effectiveness with the biological indicators
YEARLY	complete control by the technical assistance.
EVERY 2 YEARS	substitution of the lid gasket.

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MAINTENANCE AND CLEANING

Required controls are of ordinary maintenance made by the operator himself and of preventive and/or corrective measures made by the technical assistance.

Like any other electric appliances, this unit needs a proper use and maintenance or controls regularly.

This will grant you a continuous, safe and effective working of the unit. In order to prevent any risks to the operator, control and service the unit regularly.

WARNING:
In case of substitution of spare parts which have a direct influence on safety, please, only use original spare parts.

ORDINARY MAINTENANCE AND CLEANING

- For a good maintenance and cleaning of the autoclave, clean all the external parts periodically, using a wet cloth and normal neutral cleansing which is not corrosive and abrasive.
- Before beginning any cycle, clean the lid gasket accurately using a wet cloth.
- The formation of white spots or rust traces on the bottom of the sterilizing chamber depends on the use of distilled or demineralized water of bad quality (rust traces come from the ferrous minerals of water).

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- This electromedical equipment is manufactured according to current safety regulations and respects all protection requirements on electromagnetic compatibility (EMC); it's adviseable to take some precautions on EMC ; this equipment must be installed and operated in conformityt with EMC information, provided in this manual (see tables in the following pages).
- Portable and mobile radio communication equipments may influence the working of this ectromedical equipment .

WARNING:
For separation distances between portable and mobile radio communication equipments and this electromedical equipment, see **table 206 page 15**

- Guidance and manufacturer's declaration :electromagnetic emissions, see **table 201 page 12**.
- Guidance and manufacturer's declaration : electromagnetic immunity, see **tables 202** and **204**, pages **13** and **14**.

WARNING:
This electromedical equipment should not be used near other equipments or placed on top of them.
If used near other equipments or placed on top of them, it must be watched to ensure proper working.

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TABLE 201

Guida e dichiarazione del costruttore – emissioni elettromagnetiche Guidanceandmanufacturer'sdeclaration–electromagneticemissions		
L'apparecchio **HYDRA 100 Automatic** è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dell'apparecchio **HYDRA 100 Automatic** dovrebbe assicurarsi che esso venga usato in tale ambiente. *The equipment **HYDRA 100 Automatic** is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment **HYDRA 100 Automatic** should assure that it is used in such an environment.*		
Prova di emissione Emissionstest	Conformità Compliance	Ambiente elettromagnetico – guida Electromagneticenvironment-guidance
Emissioni RF *RF emissions* CISPR 11	Gruppo 1 *Group 1*	L'apparecchio **HYDRA 100 Automatic** utilizza energia RF solo per il suo funzionamento interno. Perciò le sue emissioni RF sono molto basse e verosimilmente non causano nessuna interferenza negli apparecchi elettronici vicini. *The equipment **HYDRA 100 Automatic** uses RF energy only for its internal function. Therefore, its RF emissions are very low and Are not likely to cause any interference in nearby electronic equipment.*
Emissioni RF *RF emissions* CISPR 11	Classe B *Class B*	L'apparecchio **HYDRA 100 Automatic** è adatto per l'uso in tutti i locali compresi quelli domestici e quelli collegati direttamente ad un'alimentazione di rete pubblica a bassa tensione che alimenta edifici usati per scopi domestici. *The equipment **HYDRA 100 Automatic** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.*
Emissioni armoniche *Harmonic emissions* IEC 61000-3-2	Classe A *Class A*	
Emissioni di fluttuazioni di tensione/flicker *Voltage fluctuations/ flicker emissions* IEC 61000-3-3	Conforme *Complies*	

PROBLEMS	CAUSES	REMEDIES
While the autoclave is working, the ALARM led lights on (6)	the safety thermostat has worked	-turn the autoclave **off** -wait till the autoclave is cold -unscrew the black plastic situated on the back side of the autoclave(**see detail no. 10 on page no. 23**). With a sharpened object push the red button that is placed under the cap. - check if the temperature control probe is completely covered with water - repeat sterilizing cycle
The autoclave heats but pressure does not increase	the lid is not correctly locked. the valve has its lever open (vertical). the gasket is faulty	switch the unit off and close the lid properly close the valve positioning its lever horizontally substitute it as it is shown in chapter **"Maintenance and Cleaning" - chapter 12 on page no. 40**.

If bad working goes on, call technical assistance and communicate the model of the unit and its serial number, which is on the label, on the back of the unit, or on the warranty.

PROBLEMS	CAUSES	REMEDIES
The autoclave does not switch on	Main cut-out switch of the unit and /or differential cut-out are **OFF.**	position the switches **ON**
	Lack of tension in the outlet where the unit is connected	check the cause of lack of tension in the outlet and find a remedy
	Mains fuses are interrupted	Replace them with new ones of the same value (**see "ways of replacement", chapter 12 "Maintenance and cleaning" on page no. 40.**)
	the plug of current is not connected	connect the plug.
START and HEATING leds do not light on when turning the programmer knob	check if the alarm led is on	If **ALARM** led is on you must push the safety thermostat button which is on the back of the autoclave
Heating led lights on but temperature does not increase	electric resistance is burnt	call technical assistance or send the autoclave back.
	electronic card is faulty	call technical assistance or send the autoclave back

If bad working goes on, call technical assistance and communicate the model of the unit and its serial number, which is on the label, on the back of the unit, or on the warranty.

TABLE 202

Guida e dichiarazione del costruttore – immunità elettromagnetica
Guidance and manufacturer'sdeclaration–electromagneticimmunity

L'apparecchio **HYDRA 100 Automatic** è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il Cliente o l'utilizzatore dell'apparecchio **HYDRA 100 Automatic** deve garantire che esso venga usato in tale ambiente.
*The equipment **HYDRA 100 Automatic** is intended for use in the electromagnetic environment specified below. The customer or the user of equipment **HYDRA 100 Automatic** should assure that it is used in such an environment.*

Prova di immunità *Immunità test*	Livello di prova *test level* IEC 60601	Livello di conformità *compliance level*	Ambiente elettromagnetico – guida *Electromagnetic environment -guidance*
Scarica elettrostatica (ESD) *Electrostatic discharge (ESD)* IEC 61000-4-2	±6 kV a contatto_*contact* ±8 kV in aria_*air*	±6 kV a contatto_*contact* ±8 kV in aria_*air*	I pavimenti devono essere in legno, calcestruzzo o in ceramica. Se i pavimenti sono ricoperti di Materiale sintetico, l'umidità rela - tiva dovrebbe essere almeno 30 %. *Floors should be wood, concrete or ceramic tile. If foors are covered with sntetic material, the relative humidity should be at least 30 %.*
Transitori/treni elettrici veloci *Electrical fast transient/burst* IEC 61000-4-4	±2 kV per le linee di aliment. di potenza_*for power supply lines* ±1 kV per le linee di ingresso/uscita_*for input/output lines*	±2 kV per le linee di aliment. di potenza_*for power supply lines* ±1 kV per le linee di ingresso/uscita_*for input/output lines*	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero *Mains power quality should be that of a typical commercial or hospital environment.*
Sovratensioni *Surge* IEC 61000-4-5	±1 kV modo differenziale _*differential mode* ±2 kV modo comune _*common mode*	±1 kV modo differenziale _*differential mode* ±2 kV modo comune _*common mode*	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero *Mains power quality should be that of a typical commercial or hospital environment.*
Buchi di tensione, brevi interruzioni e variazioni di tensione sulle linee di ingresso dell'alimentazione *Voltage dips, short interruptions and voltage variations on power supply input lines* IEC 61000-4-11	<5 % U_T (>95 % buco in_*dip in UT*) per_*for* 0,5 cicli_*cycle* 40 % U_T (60 % buco in_*dip in* U_T) per_*for* 5 cicli_*cycle* 70 % U_T (30 % buco in_*dip in* U_T) per_*for* 25 cicli_*cycle* <5 % U_T (>95 % buco in_*dip in* U_T) per_*for* 5 sec	<5 % U_T (>95 % buco in_*dip in* U_T) per_*for* 0,5 cicli_*cycle* 40 % U_T (60 % buco in_*dip in* U_T) per_*for* 5 cicli_*cycle* 70 % U_T (30 % buco in_*dip in* U_T) per_*for* 25 cicli_*cycle* <5 % U_T (>95 % buco in_*dip in* U_T) per_*for* 5 sec	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. Se l'utilizzatore di **HYDRA 100 Automatic** richiede un funzionamento continuato anche durante l'interruzione della tensione di rete, si raccomanda di alimen- tare **HYDRA 100 Automatic** con un gruppo di continuità (UPS) o con batterie. *Mains power quality should be that of a typical commercial or hospital environment. If the user of the **HYDRA 100 Automatic** requires continued operation during power mains interruptions, it is recommended that the **HYDRA 100 Automatic** be powered from uninterruptible power supply or a battery.*
Campo magnetico a frequenza di rete (50/60 Hz) *Power frequency (50/60 Hz) magnetic field* IEC 61000-4-8	3 A/m	3 A/m	I campi magnetici a frequenza di rete dovrebbero avere livelli carat- teristici di una località tipica in am- biente commerciale o ospedaliero. *Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.*

Nota_e U_T è la tensione di rete in c.a. prima dell'applicazione del livello di prova.
U_T is the a.c. mains voltage prior to application of the test level.

TABLE 204

Guida e dichiarazione del costruttore – immunità elettromagnetica

Guidanceandmanufacturer'sdeclaration–electromagneticimmunity

L'apparecchio **HYDRA 100 Automatic** è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dell'apparecchio **HYDRA 100 Automatic** deve garantire che esso venga usato in tale ambiente. *The equipment **HYDRA 100 Automatic** is intended for use in the electromagnetic environment specified below. The customer or the user of equipment **HYDRA 100 Automatic** should assure that it is used in such an environment.*

Prova di immunità *Immunity test*	Livello di prova *test level* IEC 60601	Livello di conformità *compliance level*	Ambiente elettromagnetico – guida *Electromagnetic environment - guidance*
			Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati più vicino a nessuna parte dell'apparecchio **HYDRA 100 Automatic** compresi i cavi, della distanza di separazione raccomandata calcolata con l'equazione applicabile alla frequenza del trasmettitore. *Portable and mobile RF communications equipment should be used no closer to eny part of the **HYDRA 100 Automatic**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.* **Distanza di separazione raccomandata** ***Recommended separation distance***
RF condotta *Conducted RF* IEC 61000-4-6	3 Vrms/Veff da 150 kHz a_*to* 80 MHz	3 Vrms/Veff	$d = 1,2\sqrt{P}$
RF irradiata *Radiated RF* IEC 61000-4-3			$d = 1,2\sqrt{P}$ da 80 MHz a_*to* 800 MHz $d = 2,3\sqrt{P}$ da 800 MHz a_*to* 2,5 GHz
	3 V/m da 80 MHz a_*to* 2,5 GHz	3 V/m	ove P è la potenza massima nominale d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore ed è la distanza di separazione raccomandata in metri (m). *Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).*

L'intensità di campo dei trasmettitori a RF fissi, come determinato da un'indagine elettromagnetica [a] del sito potrebbe essere minore del livello di conformità in ciascun intervallo di frequenza [b].
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less then the compliance level in each frequency range [b].

Si può verificare interferenza in prossimità di apparecchi contrassegnati dal seguente simbolo: 
Interference may occur in the vicinity of equipment marked with the following symbol:

Note_s:
(1) A 80 MHz e 800 MHz, si applica l'intervallo della frequenza più alto. *At 80 MHz and 800 MHz, the higher frequency range applies.*
(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone. *These guidelines may not apply in all situations Electromagnetic propagation reflection from structures, objects and people.*

a Le intensità di campo per trasmettitori fissi come le stazioni base per radiotelefoni (cellulari e cordless) e radiomobili terrestri, apparecchi di radioamatori, trasmettitori radio in AM e FM e trasmettitori TV non possono essere previste teoreticamente e con precisione. Per valutare un ambiente elettromagnetico causato da trasmettitori fissi RF fissi, si dovrebbe considerare un'indagine elettromagnetica del sito. Se l'intensità di campo misurata nel luogo in cui si usa l'apparecchio **HYDRA 100 Automatic**, supera il livello di conformità applicabile di cui sopra, si dovrebbe porre sotto osservazione il funzionamento normale dell'apparecchio **HYDRA 100 Automatic**. Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento o posizione dell'apparecchio **HYDRA 100 Automatic.**
*Field strengths from fixed transitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot bepredicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **HYDRA 100 Automatic** is used exceeds the applicable RF compliance level above, the **HYDRA 100 Automatic** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **HYDRA 100 Automatic.***
b L'intensità di campo nell'intervallo di frequenze da 150 kHz a 80 MHz dovrebbe essere minore di 3 V/m.
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

MEDICAL TRADING
autoclave **HYDRA 100 automatic**
GB

11

WORKING ANOMALIES AND THEIR REMEDIES

Warning:

Only use distilled or demineralized water. The use of not distilled water or water demineralized with chemical staff can cause:

1. : oxidation on sterilized instruments
2. : increase of calcareous residues on instruments, on holders and inside the sterilizing chamber
3. : pipes and valves scalings compromise the right working and the life of the autoclave.

If your autoclave does not work correctly, check as follows before calling the technical assistance:

(see next page)

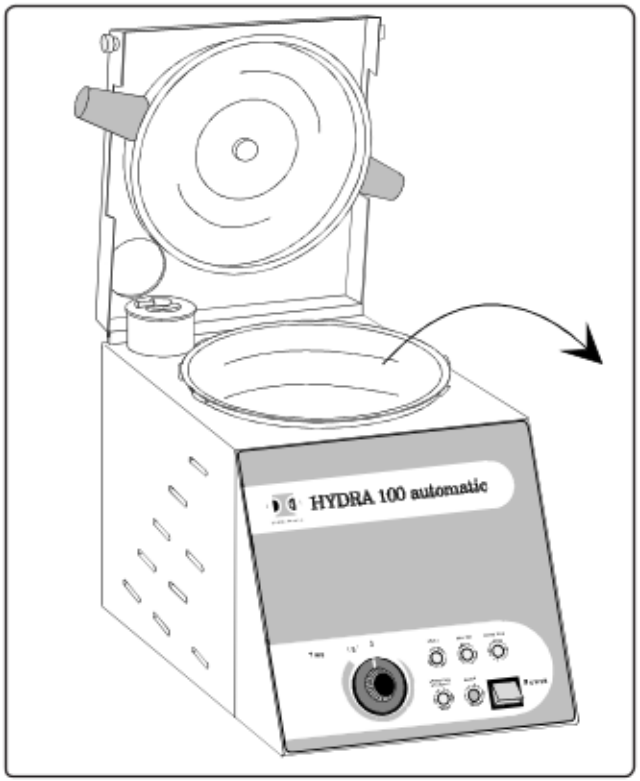
DISTILLED WATER TOPPING-UP

Before starting a new cycle it is necessary to check the distilled water level. **Make sure that the temperature control probe is always and completely covered with water**.

Warning :
When filling up the water please follow carefully the above mentioned instructions. In any case do not fill up over the upper hole (FS) of the chamber (see picture no. 14 on page 25).

USED WATER DISCHARGE

Every 10 days, or after 5/6 sterilizing cycles, empty the autoclave completely and incline it on one side.



Picture no. 23

TABLE 206

Distanze di separazione raccomandate tra apparecchi di radiocomunicazione portatili/mobili e gli apparecchi **HYDRA 100 Automatic**. *Recomended separation distances between bortable and mobile RF communications equipment and the equipment **HYDRA 100 Automatic**.*

L'apparecchio **HYDRA 100 Automatic** è previsto per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati RF. Il cliente o l'utilizzatore dell'apparecchio **HYDRA 100 Automatic**. possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e l'apparecchio **HYDRA 100 Automatic**. come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.
*The equipment **HYDRA 100 Automatic** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment **HYDRA 100 Automatic** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment **HYDRA 100 Automatic** as recommended below, according to the maximum output power of the communications equipment.*

Potenza di uscita massima del trasmettitore specificata *Rated maximum output power of transmitter* **W**	Distanza di separazione alla frequenza del trasmettitore *Separation distance according to frequency of transmitter* (m)		
	da 150 kHz a_to 80 MHz $d = 1,2\sqrt{P}$	da 80 MHz a_to 800 MHz $d = 1,2\sqrt{P}$	da 800 MHz a_to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,79	3,79	7,3
100	12	12	23

Per i trasmettitori specificati per una potenza massima di uscita non riportata sopra, la distanza di separazione raccomandata d in metri (**m**) può essere calcolata usando l'equazione applicabile alla frequenza del trasmettitore, ove **P** è la potenza massima nominale d'uscita del trasmettitore in Watt (**W**) secondo il costruttore del trasmettitore.
*For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (**m**) can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer.*

Note_s:

(1) A 80 MHz e 800 MHz, si applica l'intervallo della frequenza più alto.
At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.

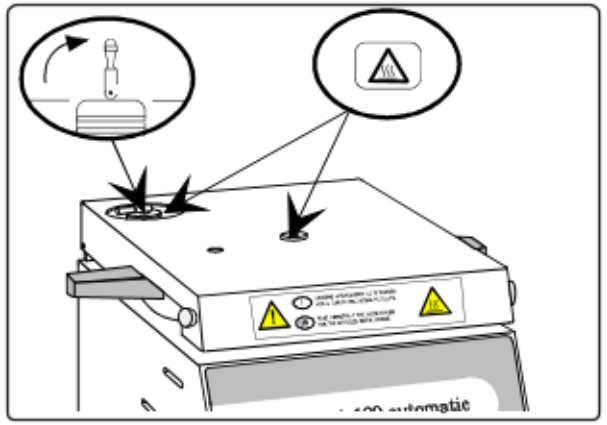
(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

6

TECHNICAL DATA

Type of unit	Autoclave **Hydra 100 Automatic**
Constructor	MEDICAL TRADING S.R.L. Via S. Andrea, 32 22040 - LURAGO D'ERBA (CO) - ITALY
Voltage	230 V. (or different, as requested)
Frequence	50/60 Hz.
Fuses	Type ø 6,3 x 32 mm. - 8 A.
Absorbed power	1500 W.
Sterilizing cycle	1 (one)
Sterilizing temperature	125°C
Maximum temperature	130 °C
Sterilizing time	15 minutes
Working pressure	130/160 kPa (1,3/1,6 bar)
Maximum pressure	220 kPa (2,2 bars)
External sizes	290 mm. l, 310 mm. h, 385 mm depth
Sizes of sterilizing chamber	ø mm. 210, 215 h.
Chamber capacity	9 litres
Weight	nett weight Kg 13,3 - gross weight Kg 18,8
Temperatureof transport / storage and function	+ 5 > + 40 °C
Maximal related humidity	80%
Altitude of function	0 > 2000 mt.

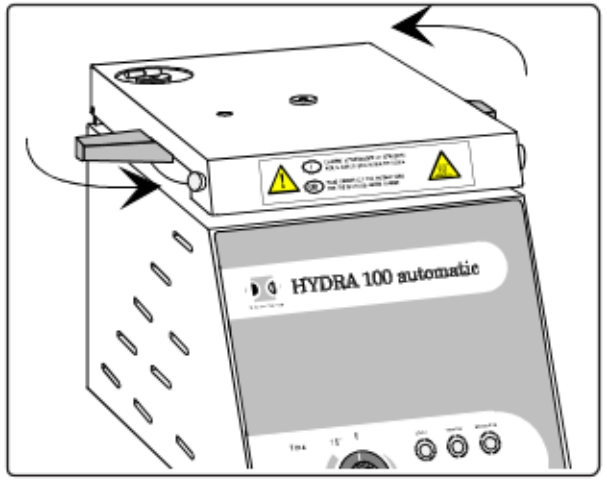
Picture no. 21



Attention :
Raise the lever very carefully in order to avoid being invested by high temperature steam.

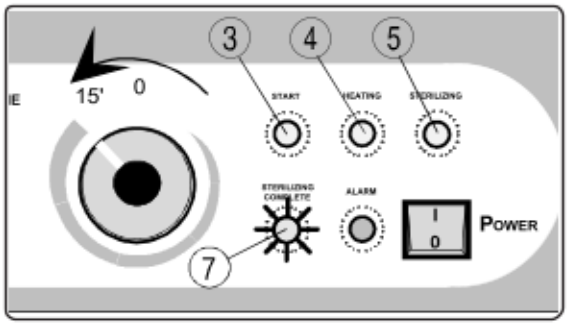
When all the steam is out and the pressure alarm device is back inside the autoclave, unlock the lid by turning the handles counterclockwise (see picture), let the left steam go out and leave the lid ajar for 10/15 minutes so that the sterilized instruments can dry well (**see picture no. 22**).

Picture no. 22



During this phase the green **"HEATING"** (**4**) led light turns on and off in order to keep temperature constant. After **15** minutes **START** (**3**) , **HEATING** (**4**) and **STERILIZING** (**5**) leds are off and the green **STERILIZING COMPLETE** led is on (**7**).

Picture no. 20



If something has been wrong during the cycle (lack of electric power, bad working) the green "**sterilization complete**" led indicating the complete sterilization will not light on. It is therefore necessary to repeat the sterilizing cycle.

END OF PROGRAM

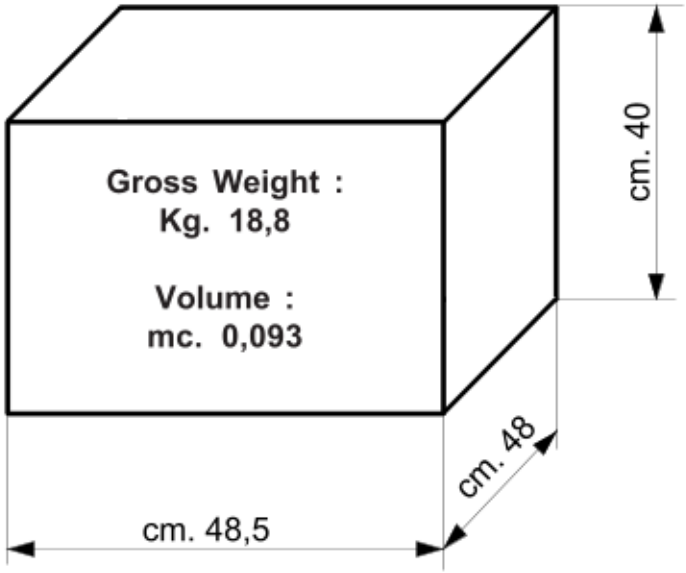
Raise the little lever of the valve vertically to exhaust all the steam (**see picture no. 21 on the next page**).

Attention :
Raise the lever very carefully in order to avoid being invested by high temperature steam.

7

DIMENSIONS AND PACKING WEIGHT

The unit is delivered in one packing with the following dimensions and weight :



Picture no. 4

8

INSTALLATION

The autoclave is tested and checked in the factory; so it does not need any other calibration before installing and for setting.

Unpack the unit and install it as instructed (**see picture no. 5**)

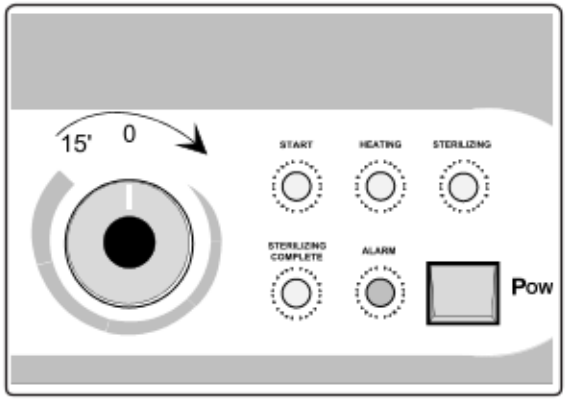
1. Put the autoclave on a level surface.
2. Leave at least cm 10 all around the autoclave to have enough airing.
3. Do not install the autoclave in places with poor ventilation.
4. Install the autoclave so that the supply cable is not folded and it can be free to socket.
5. Do not install the autoclave near sinks or other sources producing water sprinklings to avoid short circuits of the electrical system.
6. Do not install the autoclave near machines producing fumes or powders (ie. buffers, etc).

Attention
On the back of the autoclave there is a security valve : the autoclave has therefore to be put in a position where it cannot damage people or things in case of outputting hot steam.

Once installed and connected, the unit is ready for use.

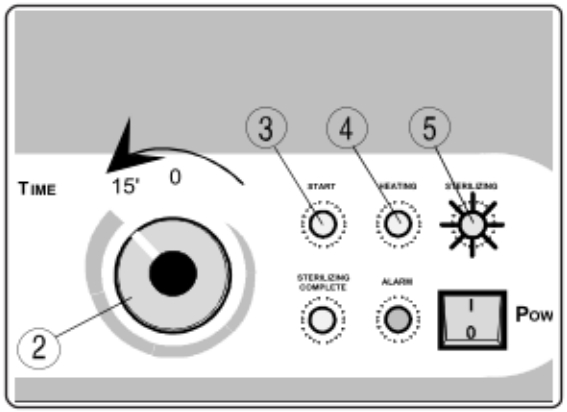
Turn the knob clockwise completely (15 minutes) (**see Picture no. 18**).

Picture no. 18



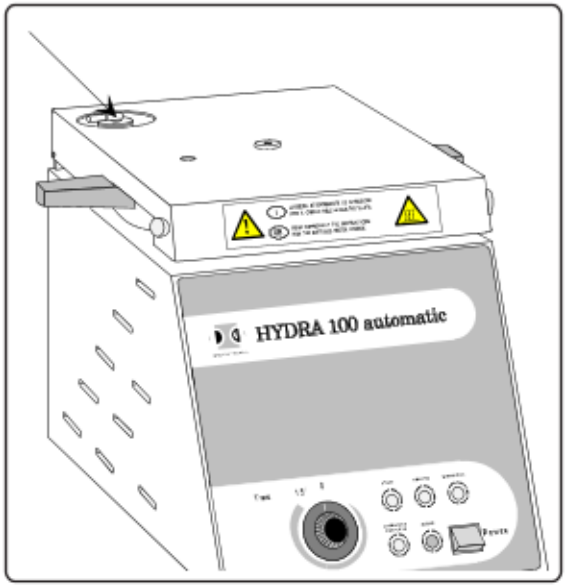
Now the automatic sterilization cycle begins and the green **START** light **(3)** togheter with the **"heating"** light (**4**) turn on. About two minutes after the pressure gauge (**1**) rises up (**picture no. 9 on page no. 70**) and from this moment on the lid cannot be opened any more.
When the pressure reaches the one corresponding to 100 °C the working valve rises up and closes the air bleeder.
At this moment the autoclave stats to rises its steam. When the temperature reaches 125 °C the real sterilizing cycle begins and therefore the green "**sterilizing**" gauge lights on (**5**). Now the programmer knob (**2**) begins automatically to turn conter-clockwise (**see picture no. 19**).

Picture no. 19



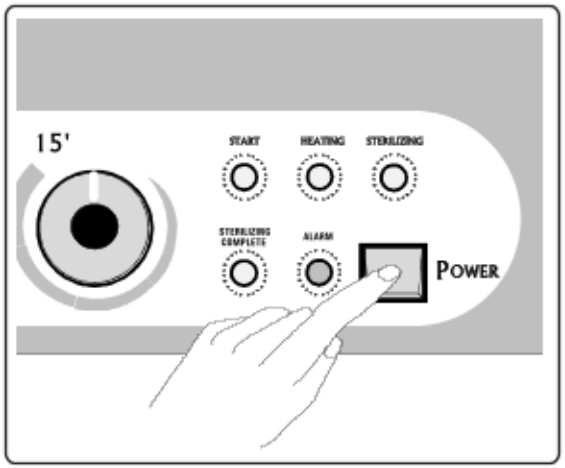
Check if the little lever of the working valve is in a horizontal position (**see Picture no. 16**).

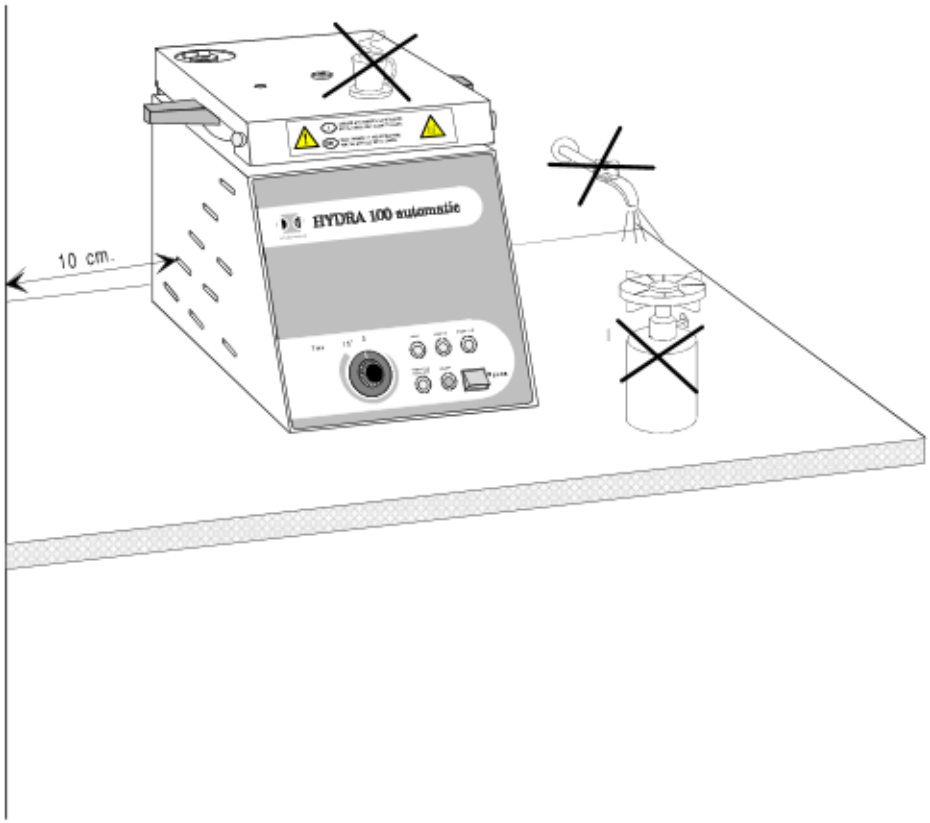
Picture no. 16



Switch the green cut-out on. (**see Picture no. 17**).

Picture no. 17





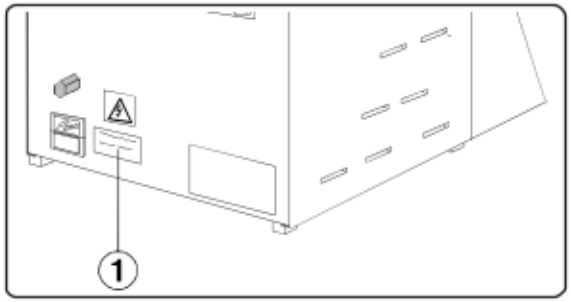
Picture no. 5

9

ELECTRIC CONNECTION

Check that supply voltage written on back label (**1**) corresponds to the one available in the installation place.

Picture no. 6



The autoclave must be connected by a protection switch to a system supplied with earthing according to the country safety regulations (**see picture no. 6**).

WARNING
Do not cause any foldings to the supply cable and do not leave anything on it.

NOTE VALID FOR ITALY:

The system must be executed according to the regulations CEI 64-4 and a differential switch (**3**) must be installed with the following characteristics before the socket for the autoclave (**4**):

- **nominal current** **10 A.**
- **differential sensibility** **0,03**

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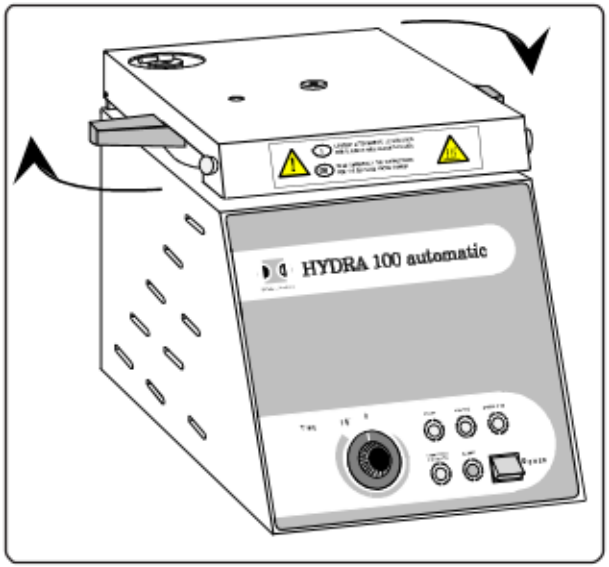
PROGRAM START

Close the lid, hold the two handles of the lid and turn them clockwise till perfect lock. Check if stainless steel lid is rightly hooked and locked (see Picture no. 15).

Picture no. 15



- use a biological indicating test to examine the lack of spores every six months.
- to have a perfect sterilization do not overload the basket with instruments.
- empty containers must be left upsidedown to avoid any presence of water inside.

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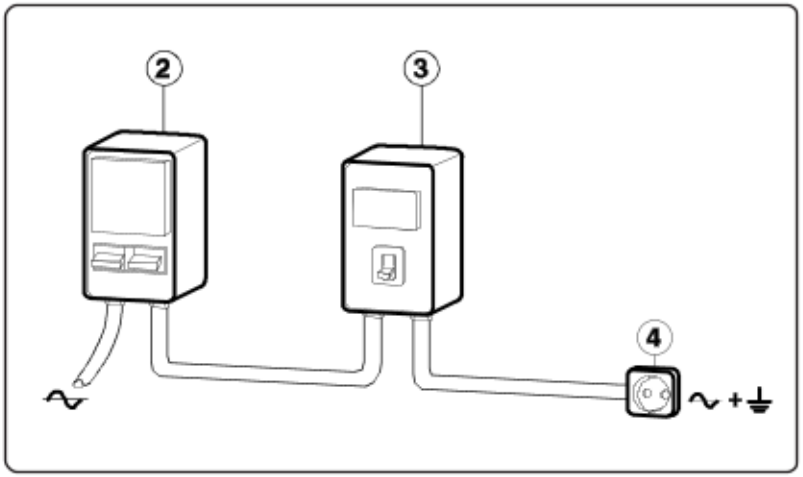


Picture no. 7

WARNING:

The unit is made according to the Safety regulations given by Security societies and it has a bipolaryzed plug with earth pole securing the complete earthing.

The as electric safety of this unit is only assured when it is properly connected to an efficient earthed system (according to laws), it is therefore important to check this foundamental security requirement.

Make sure that the carrying current of the system and the outlet are adequate to the unit max. power given on the identification label.

In case of doubts ask for a control of the unit by skilled staff.

The constructor denies every responsibilities for any damages caused to persons or things due to a non-connection to earth.

10

DIRECTIONS FOR USE

CONTROL PANEL: (see picture no. 8)

1. **MASTER SWITCH** : (green lighted)
switch **on/off**
Symbols printed :
- "0" = OFF
- "I" = ON

2. **STARTING KNOB** : To start the cycle of sterilization turn it clockwise following the increasing symbols printed on the panel till the end (15 minutes).

3. **"START" LIGHT** : (green)
it shows the beginning of sterilization cycle

4. **"HEATING" LIGHT** : (green)
it shows when electric resistance is working, which means that it heats water.

5. **"STERILIZING" LIGHT** : (green)
it shows that the autoclave has achieved 125°C temperature and that it is in sterilizing phase (lasting 15 minutes).

6. **"ALARM" LIGHT** : (red)
it shows that temperature achieved 135°C and safety thermostat has worked (for a new start of the autoclave

PREPARATION BEFORE THE FIRST STERILIZATION :

CLEANING OF INSTRUMENTS

The instruments to be sterilized must be cleaned without any residue, such as fragments, blood, plaster, resin, tampons, etc. These substances may cause damages to the objects in the basket or to the autoclave itself.

FOLLOW THE DIRECTIONS GIVEN BELOVE:

- clean the instruments after use to eliminate every residue.
- use, if possible, an ultrasound unit, with detergent solution with a basis of distilled water.
- follow suggested instructions on use of the products for cleaning and lubrication of instruments after using the ultrasound unit.
- check all the directions given by the constructor to know which instruments can be put into the autoclave.

SETTING INTO THE BASKET OR INTO THE INSTRUMENTS HOLDER (optional)

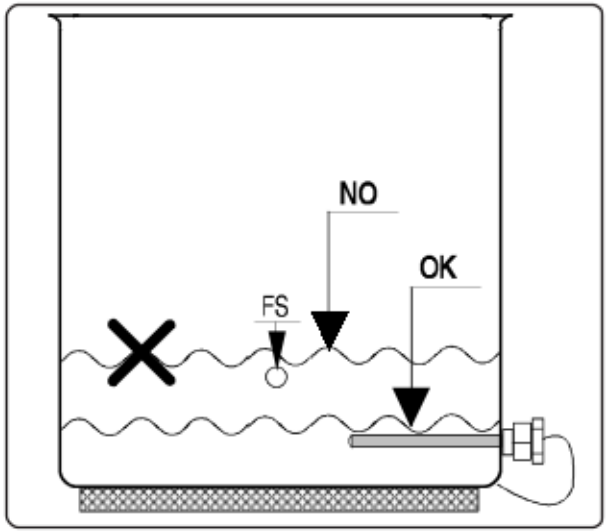
- Make sure that the instruments of different materials (stainless steel, carbon steel, etc.) are separated.
- in case of carbon steel instruments, put a paper napkin between the basket and the instrument, in order to avoid any contact of the two different materials.
- put the instruments in the special holder inside its holes according to their diameter (Optional).
- apply a piece of sterilizing indicating tape directly to the instruments or the basket (not on the bottom).

FIRST POURING OF DISTILLED WATER

Warning :
Use always and only distilled or demineralized water.

5. Pour distilled water inside the sterilizing chamber (it is usually given with the autoclave) and cover the temperature control probe completely: about l. 0.75 (**see picture no. 14**).

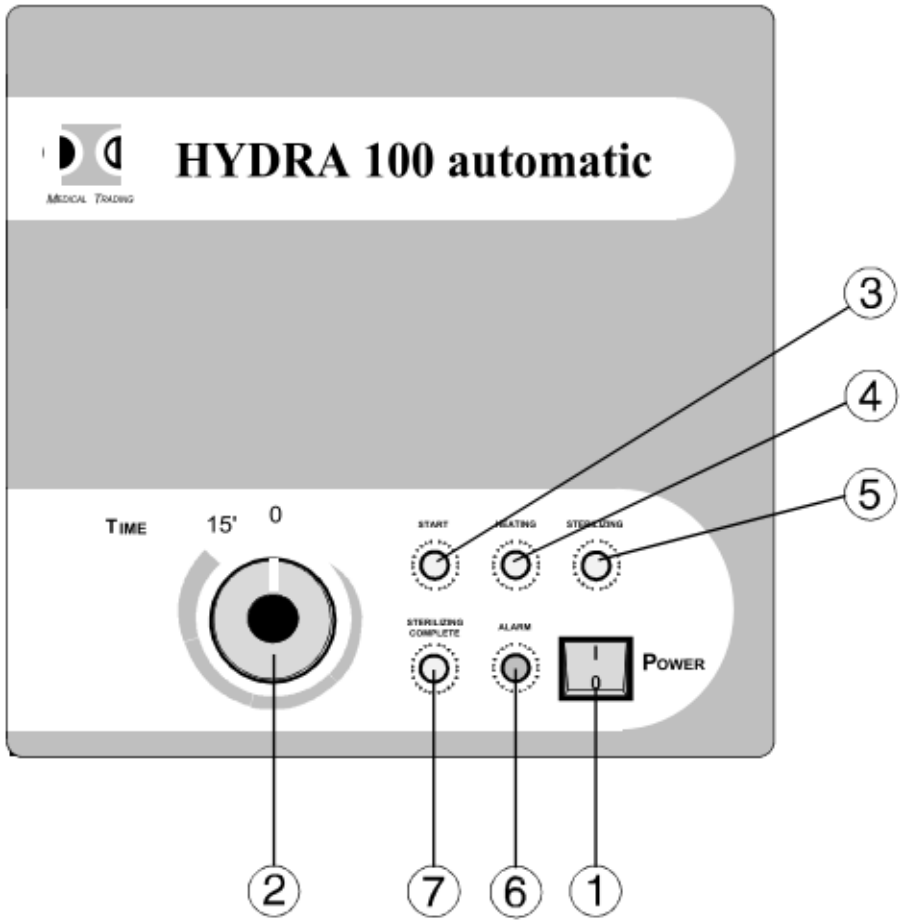
Picture no. 14



Warning :
When filling up the water please follow carefully the above mentioned instructions. In any case do not fill up over the upper hole (FS) of the chamber (see picture no. 14).

you must push the red button of safety thermostat). see **chapter 11, on page 36**.

7. "STERILIZING COMPLETE" LED : **When it is green**, it shows that sterilization cycle has finished (the knob of the timer has automatically come back to "0").

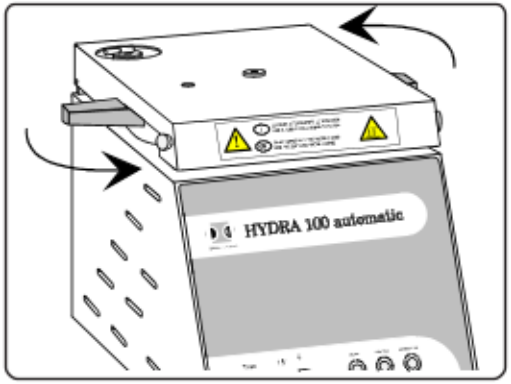


Picture no. 8

FIRST START

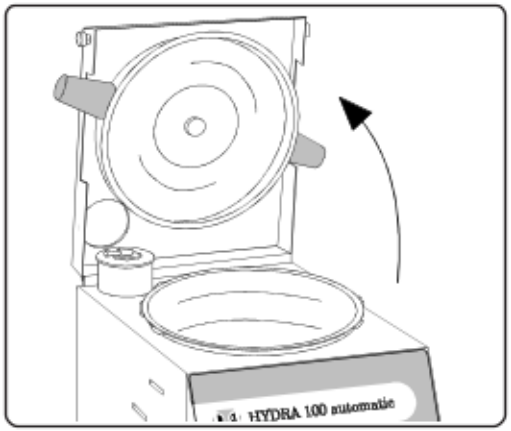
1. Release the lid turning counterclockwise the two handles with strength. (**see picture no. 12**).

Picture no. 12



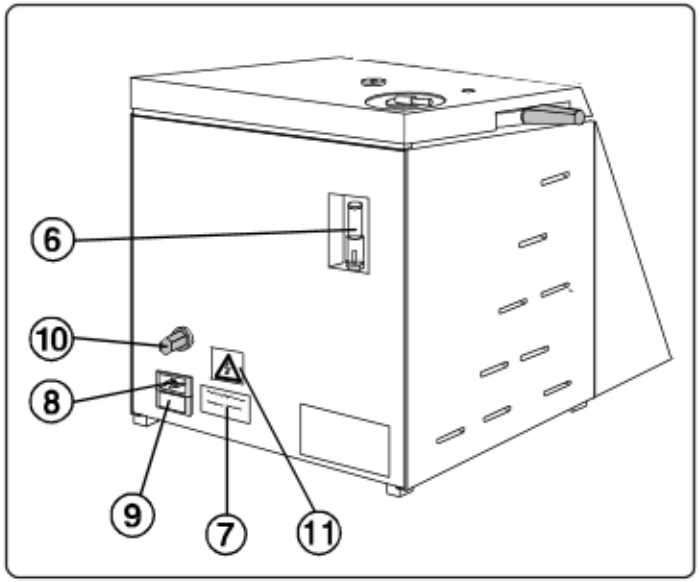
2. Lift the lid holding the white knobs on yhe two sides (**see picture no. 13**).

Picture no.13



3. Remove all accessories from sterilizing chamber.

4. Connect the current supply cable to an earthed safety outlet, as it is shown in chapter "**electric connection**" (**section 9 on page 15**).



Picture no. 11

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HIGHER DEVICES WITH LOCKED LID (see picture no. 9)

1. **Safety bolt and valve indicating pressure**

When pressure inside the sterilizing chamber reaches 10 kPa (0.1 bar) the device provided with a red-coloured sign moves from its seat, informing the operator that inside the autoclave there is presence of pressure and preventing the lid from being opened by chance.

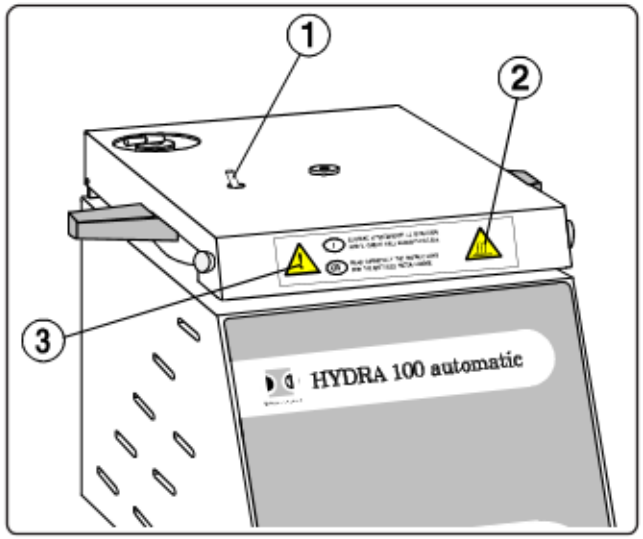
2. **Sticker** 

This sticker advises "High temperature"

Pay attention when opening the lid in order to avoid burnings.

3. **Sticker** 

The label recommends to read carefully the directions before filling up the distilled water.



Picture no. 9

HIGHER DEVICES WITH OPEN LID (see picture no. 10)

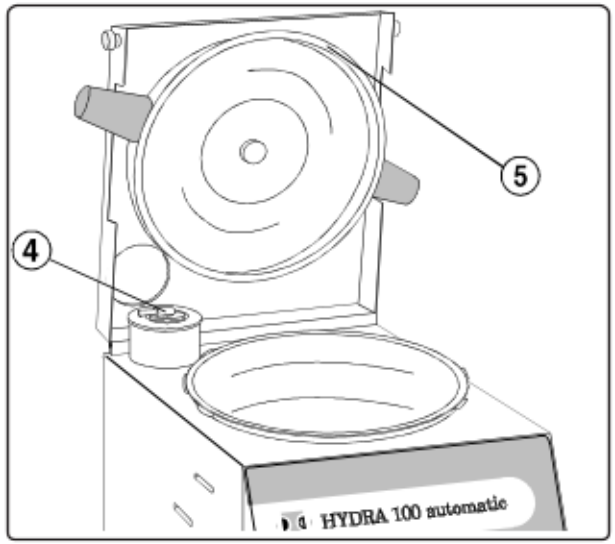
4. Working valve / vapour bleeder

Valve with double lock (patented) enables emission of air till the achievement of pressure corresponding to 105°C temperature.The valve closes after achieving this pressure. If pressure rises over 200 kPa, the valve escapes in order to keep pressure steady. At the end of the cycle you have a vapour exhaust by lifting the little lever on the valve.

5. Gasket

There is a silicone gasket for sealing the lid.

Picture no. 10



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DEVICES ON BACK PANEL (see Picture no. 11)

6. Safety valve

If the pressure of the autoclave comes up to over 2,5 bar, the valve allows to release steam in excess.

7. Identification label

This label contains the serial number, the year of the production, the catalogue number and all the data concerning the kind of power, the absorbed power, the type and amperage of the protective fuses, the maxi-mum temperature and working pressure of the autoclave.

8. Outlet for supply cable

Outlet for connection with the cable is in the equipments of the autoclave.

9. Grid fuses

It is possible to reach the protection fuses with a small screwdriver (indication on fuse type and amperage are on the identification label).

10. Button for safety thermostat

If during the sterilizing cycle the red Alarm light should go on, unscrew the black tap and push the red safety button.

11. Sticker 

This sticker advise " Voltage". Don't touch any parts connected with the electric current without switching off electricity.