

# MEDICAL DEVICES SECTOR

# □ USER MANUAL AND MAINTENANCE □

Language: English Cod. 9041



**STEAM STERILIZER** 



"THE NEW GENERATION"





# IMPORTANT (1)





#### ≺THE MACHINE IS FOR PROFESSIONAL USE ONLY ➤

## ≺THE USE IS PERMITTED ONLY QUALIFIED PERSONNEL TO DO>

 $\prec$  CONTACT THE QUALIFIED INSTALLER FOR THE IMPLEMENTATION OF THEEQUIPMENT  $\succ$ 

≺THE MACHINE CANNOT BE PUT IN WORK IN A ENVIRONMENT AT RISK OF EXPLOSION>

- Read carefully the instructions when buying the machine and before storing / installing / using it.
- This Manual, that provides useful information regarding the safety during the IMPLEMENTATION OF THE EQUIPMENT, INSTALLATION, USE, etc., is part of the product itself and it must be delivered to the user, who has to store and carefully read it before starting each step of the service provided by the machine.
- Do not remove, tear or rewrite neither partly this Manual.
- Keep the Manual in areas protected from moisture and heat for future reference.
- This Manual contains the "CE" Declaration of conformity.



# THE MACHINE MUST BE INSTALLED AND USED ONLY ACCORDING TO THE **RULES LAID DOWN BY THE MANUAL** U.M.M.



# NOTE:

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1	INTRODUCTION	
	1.1 USER'S PROFILE	
	1.2 EUROPEAN STANDARDS AND DIRECTIVES APPLICABLE	
	1.3 EXPECTED USAGE	
	1.4 SYMBOLS SHOWN ON THE STERILIZER	
	1.5 CAUTIONS, WARNINGS, PROHIBITIONS	
	1.6 WARRANTIES AND LIABILITY	
	1.7 WARRANTIES CONDITIONS	
	1.9 ILLUMINATION IN THE WORKPLACE	
	1.10 USE NOT PERMITTED	
	1.11 RECOMMENDATIONS AND GENERAL SAFETY	
	1.12 SAFETY DEVICES	
	1.13 DEVICES FOR PERSONAL PROTECTION	
	TO BE USED TO PREVENT THE ONSET OF RESIDUAL RISKS	
	1.14 EMERGENCY STOP AUTOCLAVE	
	1.15 CONDUCT OF MACHINE BY USER	
	1.16 RESIDUAL DANGERS INFORMATION	13
	1.17 FAILURES, MALFUNCTIONS OR OTHER INCONVENIENCES	13
2	UNPACKING	14
	2.0 SUPPLIED ACCESSORIES (STANDARD)	
3		
_	3.0 KEYBOARD	_
	3.1 FRONTAL SIDE	
	3.2 DESCRIPTION OF INTERIOR WATER TANKS	
	3.3 QUALITATIVE WATER TABLE	
	3.5 CLEAN WATER LOAD	
	3.7 AUTOMATIC LOADING	
	3.8 DRAINIG WATER USED	22
	3.9 DIRECT CHARGING AND DISCHARGING WATER CONNECTIONS	23
	3.10 TRAYS SUPPORT FOR THE STERILIZATION CHAMBER	
4	INSTALLATION	24
	4.0 POSITIONING	24
	4.1 POWER SUPPLY	
	4.2 CONNECTION TO THE PRINTER M9004 OR TO THE PC	
	4.3 CONNECTION TO THE PRINTER (on demand)	
	4.4 CONNECTION TO THE LABELLER M9006 (on demand)	
	4.5 USING SD CARD	
5		
	5.0 CLEANING OF TOOLS	
	5.1 PREPARATION OF THE TRAYS	
6	START OF STERILIZER	_
	6.0 EXECUTION OF A STERILIZATION CYCLE	
	6.1 AVAILABLE PROGRAMMS	
	6.1.1 UNIVERSAL CYCLE TYPE B	
	6.1.2 SPECIAL CYCLES	
	6.1.3 STERILIZATION CYCLES GRAPHS, TEST AND TYPE OF TEST	
	6.1.4 SPECIAL CYCLE	
	6.1.5 TEST CYCLES	
7	OPTIONS	
	7.0 PRINT LABELS LAST CYCLES	
	7.1 DRYING ONLY	
	7.2 EXTRA DRYING	
	7.3 LABELS EXPIRY DATE	
	7.4 START POSTPONED CYCLE	
	7.5 NIGHT CYCLE	
_	7.6 OPENING DOOR	47
•	CETTINGS	/19

Screna GB NOS acror GO 17	
8.0 PRE HEATING	48
8.1 DRYING TEMPERATURE	48
8.2 DATE FORMAT:	49
8.3 DATE/TIME	49
8.4 OPENING DOOR	50
8.5 MAINTENANCE	50
8.5.1 BACTERIAL FILTER	50
8.5.2 WASHER	51
8.5.3 WATER FILTER	
8.5.4 HAVE THE AUTOCLAVE SERVICED	
8.6 TOTAL N° OF CYCLES:	
8.6.1 VALID CYCLES:	
8.6.2 CYCLES NOT VALID:	53
8.6.3 VACUUM TEST	
8.6.4 B&D/HELIX TEST	53
8.6.5 SPORE TEST	54
8.7 COUNTERS	54
8.7.1 WORKING HOURS	
8.7.2 N° OF CYCLES PERFORMED	
8.7.3 CONFORMABLE WATER LITRES	
8.7.4 unconformable water litres	
8.7.5 PRINTED LABELS:	
8.8 CYCLES HISTORY:	
8.9 CONFIGURATION:	
9 ALARMS	
9.0 ALARM CODEs	
9.1 TABLE OF STERILIZATION PROGRAMS AVAILABLE	
10 MAintenance	62
10.0 NATURE AND FREQUENCY OF CLEANING, INSPECTION AND MAINTENANCE	
10.0.1BACTERIOLOGICAL FILTER REPLACEMENT (USER) CODE 1067	63
10.0.2PINS LUBRICATION (USER)	63
10.0.3WATER TANK CLEANING (LICENSED TECHNICIAN)	
10.0.4 REPLACEMENT OF THE VAPORIZER GROUP (AUTHORIZED TECHNICIAN) CODE 5177	64
10.0.5 REPLACEMENT OF THE ELECTROVALVES GROUP (AUTHORIZED TECHNICIAN) CODE 5181	64
10.0.6 REPLACEMENT PUMP LOAD (AUTHORIZED TECHNICIAN) CODE 5154	
10.0.7MAINTENANCE OF VACUUM PUMP (AUTHORIZED TECHNICIAN) CODE 5153	
10.0.8 REPLACEMENT OF THE GASKET(LICENSED TECHNICIAN) CODE 5030	
10.0.9 REPLACEMENT OF THE TRANSDUCER (LICENSED TECHNICIAN) CODE 5186	
10.0.10 REPLACEMENT OF THE ELECTRONIC BOARD(LICENSED TECHNICAL) CODE 5189	
10.0.11 REPLACEMENT OF THE BATTERY OF THE ELECTRICAL CARD (AUTHORIZED TECHINICIAN) CODE 5279	
10.0.12 REPLACEMENT OF DISPLAY (AUTHORIZED TECHINICIAN)	
10.0.13 REPLACE PRINTER PAPER ROLL (USER)	
10.0.14 REPLACEMENT PIN DOOR (AUTHORIZED TECHINICIAN) COD.5040	
10.1 SCHEDULED MAINTENANCE SUMMARY TABLE	
10.2 RECOMMENDED SPARE PARTS LIST	
11 EMERGENCY - HOW TO COPE	
11.0 FIRE	
12 SOLUTION to FAILURES	72
13 TECHNICAL FEATURES	74
14 APPeNDIXES	75
14.0 HYDRAULIC DIAGRAM	
14.1 ELECTRICAL	_
14.1.1 NEW SOFTWARE INSTALLATION – PROCEDURE	_
14.2 LABELLING	
14.3 EXPLODED	
14.4 TEST	
14.5 SCHEDULED MAINTENANCE COUPONS	
14.6 FORM TO FILL IN FOR THE RETURN OF THE EQUIPMENT	90
14.8 WARRANTY CERTIFICATION	91

14.	.9 VARIOUS FORMS	92
15	DECLARATION OF INSTALLATION	97

# 1 INTRODUCTION

We thank you for choosing a REVERBERI sterilizer.

The User and Maintenance Manual (U.M.M.) has been realized in order to provide general knowledge of the machine and to give the transport, use and maintenance instructions and all the necessary details for the installation, for the correct use and for the proper functioning.

We ask you kindly to CAREFULLY readthe manual BEFORE CARRYING OUT ANY OPERATION ON THE MACHINE.

In caseyou need another copy of the Use and Maintenance Manual (U.M.M.) you are invited to forward your motivated request to the CONSTRUCTOR, quoting the serial number on the title of this post or on the name plate on the back of the machine.

## 1.0 PURPOSE OF THE USER MANUAL AND MAINTENANCE

The following Manual aims to provide user all the information about SERENA 18/23 sterilizers in order to warrant:

- √ the correct installation and implementation of the SERENA 18/23 steam sterilizer.
- ✓ the optimal use.
- ✓ a safe and reliable functioning.
- ✓ the requirements for proper and regular maintenance and for the periodic replacement operations of the components.

## 1.1 USER'S PROFILE

The user, who has the responsibility for operation of the equipment, must be a person previously well trained by the Employer (or whoever takes his place), that person must MANDATORY read/UNDERSTAND all the instructions in this U.M.M.



The manufacturer is not liable for any direct or indirect damages caused by people who had used the device without having received adequate instruction and relevant qualifications to conduct the same and consequently have made bad use.

Three kinds of profiles can use the sterilizer and have to read carefully this Manual:

#### The Administrator

The administrator is the responsible for the clinic or doctor's office, or rather the person responsible for the protocol of hygiene and sterilization process.

The administrator is also responsible for the OPERATORS' training and for the proper operation and maintenance of the equipment. Must have adequate training for all operations to be performed and for safe use.

#### The Operators

The operators are those who use the sterilizer according to the instructions received from the ADMINISTRATOR.

# **Enabled technicians**

All the ordinary and extraordinary maintenance, qualified, controls, cleanings and registrations should be performed only by authorized personnel and/or instructed to do so and when the equipment is not working (state of zero energy). The qualified personnel must have attended a technical training from the manufacturer. At the end of the course will receive a certificate of training.



The manufacturer shall make available to operators and technical managers, training at the headquarters of Bibbiano (RE). For information on course dates contact number. Tel 0522 875 159.

# 1.2 EUROPEAN STANDARDS AND DIRECTIVES APPLICABLE

SERENA 18/23 sterilizer complies with the following European Directives:

Serena GB-R03 del 07-06-17

- 93/42/CEE and s.m.i. Medical Devices Directive, IIb Class, in accordance with the rule 15 Appendix IX of the above Directive.
- 2014/68/UE (PED Pressure Equipment Directive) on the sterilization chambers projected and realized in accordance with Category I with evaluation form A.
- 2002/96/CEE (RAEE) on the disposal of shares from electrical or electronic components.
- EN13060 current edition concerning performance requirement for small steam sterilizers
- EN 61010-1 and 61010-2-40 current edition concerning safety requirements for small steam sterilizers.
- EN 62304 Software certification current edition
- EN 61326 Electromagnetic Compatibility current edition

## 1.3 EXPECTED USAGE

Sterilizers SERENA are "steam sterilizers" fully automatic, which generate steam by heating elements. SERENA sterilizers are used for the sterilization of surgical instruments

The load types that can be sterilized by the sterilizer SERENA are described in Table 1 of the reference technical standard EN 13060. These loads include solid, porous, hollow type A and B, unwrapped, wrapped in single and double envelope. They are also used for materials and tools that can come into contact with blood and / or body fluids.

Usage environments may be: hospitals, education or medical clinics, dental offices, veterinary. Sterilizers REVERBERI can not be used to sterilize liquids or pharmaceutical products.



Do not use the machine for purposes other than those for which it was created. It is important to ensure that the value of ground resistance is efficient and well coordinated with the electrical protections of the implant, in order to avoid electrical interferences to the autoclave.

# 1.4 SYMBOLS SHOWN ON THE STERILIZER

Consult the following table whenever a symbol below appears on the sterilizer or on the Manual.

	WARNING	It shows a notice or a warning about the key functions or about useful information. Pay close attention to blocks of text indicated by this symbol.
•	OBSERVATION	The User is required to detect a measure value, to check an alert, etc.
	PROHIBITION	Any procedures that staff must not perform because, otherwise, might endanger his own safety and that of others
0	OBLIGATION	Any procedures that staff must perform because, otherwise, might endanger his own safety and that of others
	CAUTION, IT IDENTIFIES A SOURCE OF HEAT, THERE MAY BE AN UNSAFE TEMPERATURE	
Ŵ	CAUTION, IT IDENTIFIES A GENERIC DANGER, THERE MAY BE A DANGEROUS SITUATION	
	IT IDENTIFIES THE PI	ROTECTIVE EARTH TERMINAL
<ul> <li>This symbol indicates that the product is covered by 2002/96/CE European Directive.</li> <li>Please inform yourself about the local separate collection system for electrical and electronic products.</li> <li>Comply with local rules and do not dispose of your old products with your normal household waste. Proper disposal of the product will help prevent potential negative consequences for the man's health and for the environment.</li> </ul>		

THE MANUFACTURER DO NOT PROVIDE WARRANTIES ABOUT THE SUITABILITY OF THE TECHNICAL / LEGAL ROOM WHERE THE EQUIPMENT IS INSTALLED AND ALL THE SUPPORT SERVICES AT THE SAME, ALTHOUGH THE U.M.M. OFFERS IMPORTANT INFORMATION FOR A PROPER INSTALLATION.

REGARDING THIS ASPECT THE USER IS RECOMMENDED TO USE THE ADVICE OF QUALIFIED PERSONNEL EXPERT IN THE FIELD, FOR THE RESPECT OF EVENTUAL LAWS AND/OR REGULATIONS TOO.

#### DO NOT ALLOW ANYONE TO USE THE INSTRUMENT WITHOUT FIRST:

- READ AND UNDERSTAND ALL THE INDICATIONS INCLUDED IN THE U.M.M.
- RECEIVE SUITABLE INSTRUCTION FOR THE SAME CONDUCTION BY A PERSON AUTHORIZED.

THE MACHINE IS BUILT IN COMPLIANCE WITH CURRENT STANDARDS. PLEASE BEFORE PROCEEDING WITH THE INSTALLATION, USE, MAINTENANCE AND REPARATION (AND RELATED), READ CAREFULLY THIS USER AND MAINTENANCE MANUAL BECAUSE IT CONTAINS ALL THE NECESSARY INFORMATION FOR A PROPER USE AND OPERATION, DESIGNED TO PREVENT ACCIDENTS.

THIS U.M.M. MUST BE CONSIDERED PART OF THE PRODUCT ITSELF AND IT MUST REMAIN PART OF IT FOR ALL THE PRODUCT LIFE.

The frequencies of monitoring and maintenance, prescribed by the U.M.M., refer to the minimum necessary to ensure efficiency, safety, and duration of the equipment in normal working conditions. Surveillance will still be constant and will act promptly in cases of anomalies.

All our equipment are subject to continuous technological development. We must therefore, from time to time, subject to the possibility of making changes regarding the construction and endowment, which can modify the operating features.

The electrical system, as well as the continuity of the protective circuit, has been tested by REVERBERI at the factory so it is general and guaranteed perfect and functioning.

Any damage caused by the buyer for incorrect links, automatically excludes any warranty on the unit. The position of the CE plaque is visible EC.

# 1.5 CAUTIONS, WARNINGS, PROHIBITIONS

- 1°. LIQUIDS OR DUSTSHOULD NOT FALL/ENTER INTO THE APPARATUS. SEEK TO MAKE INSTALLATION THAT AVOID THESE PROBLEMS.
- PLAMMABLE LIQUIDS OR POWDERS SHOULD NOT BE USED NEAR THE MACHINERY.
- 3°. IT IS FORBIDDEN TO EVERYONE AND / OR TO OPERATORSWITH HEART DISORDERS AND PACEMAKERS, TO APPROACH THE MACHINERY WITHOUT FIRST CONSULTING THE DOCTOR.
- 4°. BEFORE USING THE DEVICE, IT IS NECESSARY TO KNOW ALL THE OPERATIONS AND CONTROL DEVICES. LEARNING CONCEPTS OF THIS SHOULD BE MANDATORY BEFORE BEGINNING. PEOPLE NOT ATTACHED AND WITHOUTTHE APPROPRIATE CONCEPTS ARE NOT ALLOW USING THE STERILIZER.
- 5°. READ ALL SAFETY INFORMATION CONTAINED HEREIN AND UNDERSTAND ALL THE PLATES (REPORTS SECURITY) ON THE UNITS. THE SIGNS ON THE UNIT MUST ALWAYS BE READ WELL, REPLACE THEM IN CASE THEY GET WORN OR DAMAGED.
- 6°. NO WARRANTIES PROVIDED ON GOOD FUNCTIONAL OR ON SAFETY OF THE USER AND / OR ENABLED PERSON AND / OR ANY OTHER PERSON AND / OR THE ENVIRONMENT, IN THE EVENT THAT:
  - THE PROVISION OF ELECTRICITY NOT COMPLY WITH THE REQUIREMENTS OF THIS LAW AND U.M.M.;
  - THE EQUIPMENT ONCE INSTALLED AND PUT IN SERVICE NOT COMPLY WITH THE REQUIREMENTS STATED IN THIS U.M.M.:
  - THE DEADLINES SET MAINTENANCE ARE NOT RESPECTED.
- 7°. THE OPERATING SAFETY EQUIPMENT ALLOWS IT TO BE INSTALLED AND PUT INTO SERVICE BY QUALIFIED PERSONNEL RESPONSIBLE TO FOLLOW THE INSTRUCTIONS GIVEN IN THIS U.M.M. AND RULES.
- 8°. THOSE WHO ARE NOT ABLE TO INSTALL, START UP OR USE SAFETY ALONE OUR PRODUCT, BECAUSE OF PHYSICAL, SENSORY OR MENTAL INABILITY, OR THROUGH INEXPERIENCE OR NO KNOWLEDGE, THEY MAY CARRY OUT THE BUSINESS SPECIAL SUPERVISION ONLY IF INSTRUCTED BY COMPETENT PEOPLE, WHO TAKE FULL RESPONSIBILITY.
- 9°. YOU MAY NOT USE WATER TO WASH THE MACHINE PARTS (EXCEPT FOR SOME ACCESSORIES, NOT EXPRESSLY REPORTED)
- 10°.IT IS FORBIDDEN TO REMOVE AND / OR TAMPER WITH THE LABELLING AND SYMBOLS FROM ORIGINALLY AFFIXED REVERBERI.

- 11°.DO NOT PUT ANY OBJECT OVER EQUIPMENT,
- 12°.DO NOT TOUCH THE DEVICE WITH BODY PARTS WET AND / OR BARE FEET.
- 13°.DO NOT PULL THE ELECTRICAL CABLES OR THE SHEATHS OF THE ELECTRICAL INSTALLATION
- 14°.DO NOT START BEFORE CHECKING DIRECTLY AND VISUALLY THAT IN OR ON THE MACHINERY THERE IS NO FOREIGN BODY.
- 15°.IN ANY SPECIFIC CIRCUMSTANCES ALWAYS USE APPROPRIATE PROTECTIVE CLOTHING OR TOOLS.
- 16°.NEVER INSERT THE HANDS OR OTHER PARTS OF THE BODY IN COMPONENTS NOT PERFECTLY FIXED OR IN PARTS NOT COMPLETELY VISIBLE FROM THE PERSON WHO IS OPERATING.
- 17°.KEEP THIS U.M.M. ALWAYS AT HAND AND AT DISPOSAL OF THE ENABLED USER AND DURING INSTALLATION AND / OR MORE VISITS AND USE.
- 18°.THE U.M.M. DUPLICATION IS RECOMMENDED (AUTHORIZED BY THE MANUFACTURER FOR THE INTERNAL USE ONLY) AND IT IS AVAILABLE FOR THE PERSONAL AND ENABLED USER, KEEP THEN THE ORIGINAL COPY IN A SAFE AND EASY AVAILABILITY.



# DURING THE OPERATION OF THE MACHINE, THE SURVEILLANCE OPERATOR MUST BE CONTINUED





ANY TOOLS FOR THE OPENING OF ELECTRICAL PANEL OR PROTECTIONS
MUST BE STORED AND / OR ACCESS ONLY TO AUTHORIZED PERSONS
AND EDUCATED.





# 1.6 WARRANTIES AND LIABILITY

The MANUFACTURER ASSUMES NO LIABILITY FOR DAMAGES CAUSED ON THEMACHINE, ON THINGS, ANIMALS AND / OR PERSONS, MAKING ANY KIND OFWARRANTY INVALIDATE IMMEDIATELY IF:

- THE INSTALLATION OF THE APPLIANCE IS NOT DONE BY QUALIFIED
- PERSONNEL IN ACCORDANCE WITH THE RULES AND MAY BE REPORTED ASIN THE DECLARATION OF CONFORMITY
- THE START UP OF THE EQUIPMENT IS NOT PERFORMED BY A QUALIFIED
- QUALIFIED PERSONNEL AND / OR USER NOT COMPLY WITH THE INSTRUCTIONS GIVEN IN THIS
  USER AND MAINTENANCE MANUAL OR AS RESULT OF ANY OPERATION NO SPECIFICALLY
  DESCRIBED.
- VERIFY CAREFULLY DURING THE READING OF U.M.M. THE CORRESPONDENCE WITH THE PARTS OF THE EQUIPMENT, CHECKING:
  - THE PARTS HAVE NOT BEEN DAMAGED DURING THE TRANSPORTATION AND HAVE BEEN DELIVERED INTEGRA,
  - THERE ARE ALL THE SAFETY SYMBOLS.

DO NOT PROCEED TO USE THE STERILIZER IF ALL ITEMS DESCRIBED ABOVE DO NOT EXIST:

- THE MANUFACTURER ASSUMES NO RESPONSABILITY FOR DAMAGES CAUSED TO THE SAME DEVICE ON PEOPLE, ANIMALS AND / OR PROPERTY, IF ANY ANOMALIES IS NOT REPORTED WITHIN 30 DAYS OF RECEIPT OF GOOD TO MANUFACTURER. IN THESE CASES ANY TYPE OF WARRANTY BECOME INVALID AUTOMATICALLY.
- TO COMPLY WITH THE TRACEABILITY OF THE STERILIZER ANY CHANGE OF ADDRESS OF THE SAME MACHINE MUST BE COMMUNICATED TO THE MANUFACTURER / DEALER.

ANY CHANGES MADE ON ITS DEVICE or safety devices, WHICH MAY AFFECT THE FUNCTIONS PROVIDED BY THE MANUFACTURER and the risks of the risk analysis, included in the "Technical Construction File",

WILL BE FULL RESPONSIBILITY OF THE RUN. AS CHANGE IS MEANT ALSO THE FAILURE OF THE INSTRUCTIONS, REPRESENTATIONS AND EFFORT NONCONFORMING AND THE USE OF PARTS NOT ORIGINAL.

Any change, even if not substantial, must be communicated by registered post and also approved by the MANUFACTURER, THAT will approve THE CHANGES only if, such amendment, shall not constitute

implementations of risk analysis AND THE risks of the machine.

Any change made without notice to the MANUFACTURER, will constitute CANCELLATION OF the "CE" Declaration of Conformity, making void any warranty and guarantee by the same.

The manufacturer is not responsible for:

- The placement of a protection mechanisms against overcurrent for power conductors of the electrical equipment, which must be placed upstream of the apparatus and duly reported.
- The installation of a power plug to be placed between the electrical panel and the electrical appliance in place of the existing installation.

#### 1.7 WARRANTIES CONDITIONS

This appliance is guaranteed for one year (12 months) from the date of purchase, on the whole territory of the European Union; the date of the delivery note / invoice will be the authentication

The device is used for professional use.

During this period, the manufacturer will repair or replace for free those pieces that, at its own sole discretion, were to be originally defective, with only the reimbursement of travel expenses incurred by the technicians of the "Service Centre", at doorstep or totally free if the equipment is delivered to BARCO di Bibbiano (RE).

Defective parts replaced become the property of the manufacturer.

If the defect is not repaired, the manufacturer may avoid the termination of the contract by the customer by offering free replacement of the property.

Are not covered by the warranty the damaged parts for transport / shock for bad or improper installation / use, through neglect or misuse, tampering by unauthorized persons, damages weather or other natural events or other causes not dependent on REVERBERI, supplies and / or subjected to wear / low.

Further or other claims for damages, in addition to those provided by law, are excluded.

The manufacturer will charge the cost of repair if the returned product is not covered under warranty.

Interventions for alleged defects or casual checking shall be borne by the customer.

Any repair of transport to and from the "Technical Assistance Centre" of BARCO di Bibbiano (RE) is done at the expense and responsibility of the customer.

The technical staff, when called to repair, will be sent in time only compatible with the business needs of the manufacturer.

Any use bans imposed by the Health Authority or by other competent bodies, do not entitle the buyer to demand the surrender or to ask for damages.

Any difference on the exterior colour or colour effects of the various parts making up the unit are not considered defects: the differences may be e.g. due to the manual workers.

The inability to ensure substitutability of parts that make up the set with pieces from standard / freshmen / supplies purchased specifically different and not as a replacement is not considered a defect.

In case of repair / replacement of defective parts or replacement of the equipment during the warranty period, the warranty remains unchanged: it always starts from the original date of purchase of the unit.

As nothere reported The Terms and Conditions listed on the commercial documentation / sales catalogue in force at the time of purchase remain valid.

# 1.8 ENVIRONMENTAL CONDITIONS ALLOWED

TEMPERATURE, HUMIDITY AND ALTITUDE

#### **ELECTROMAGNETIC COMPATIBILITY**

Install the unit where electromagnetic interference comply with the limits permitted by the rules and with the presence of electric and electronic equipment.

#### RADIATION EXPOSURE

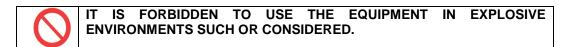
The appliance is not intended to be used to direct exposure to:

- Non-ionizing radiation of the sun, being the same to be placed indoor and / or repaired
- X-ray radiation, microwave radiation, laser radiation, etc...

In the event that, in the environment where the unit is placed, there is a risk of radiation directly on it, specific measures to protect exposed areas must be taken by the purchaser.

#### USE IN EXPLOSIVE ENVIRONMENT

The device cannot be used in any way in the environment where there is a risk of explosion or in a potentially explosive environment.



## 1.9 ILLUMINATION IN THE WORKPLACE

The environment in which the sterilizer is installed must meet the requirements listed on the Directive 89/654/EEC concerning the workplace and the requirements of the RULES FORCE THE INSTALLATION SITE.



Proper lighting can, in some cases, avoid or limit an injury to the operator.

#### REQUIREMENTS OF THE LOCAL WHERE THE EQUIPMENT IS INSTALLED. THE LOCAL SHOULD:

- Be free of debris and / or residues of various kinds of flammable or potentially dangerous operation;
- Provide a specific room for sterilization, away from the patient.
- Have doors (accesses) appropriate to the size of the machine, ensure a suitable floor for the mass flow of the machine, ensure a perfectly level floor, be free, at the area of installation, strong drafts or substantial temperature changes:
- ensure good ventilation and air exchange with the provision of specific natural ventilation openings.

#### 1.10 USE NOT PERMITTED

it is not allowed:

- THE USE of the machine if you have not INSTALLED in accordance with APPLICABLE RULES and BY AUTHORIZED PERSONNEL.
- the use of the appliance by USERS not authorized by the superior role (or employer),
- the use of the appliance by USERS not trained to manage it.
- the use the equipment for purposes other than those expected and stated in the Declaration of Conformity,
- the use the equipment in environments with explosive atmosphere or where there are similar risks,
- · elaborate or otherwise alter the unit cycles and performance
- use or use accessories other than the original operation.
- use replacement parts other than original
- alter the electrical system and safety devices connected to them.
- NOT TO COMPLY WITH THE INSTRUCTIONS, THE OBLIGATIONS AND PROHIBITIONS CONTAINED IN THIS MANUAL AND ON THE UNIT ITSELF.

# 1.11 RECOMMENDATIONS AND GENERAL SAFETY

- The user is responsible for installation, proper use and maintenance of the sterilizer in accordance with the instructions in this manual. If necessary, contact your local Technical Support.
- The sterilizer is not designed for the sterilization of liquids.
- The sterilizer should not be used with flammable gases or vapors.
- For the sterilization of materials, carefully follow the instructions provided by the manufacturer of the materials.
- For the preservation of sterilized materials, we recommend the use of special cabinets equipped with ultraviolet lamps, which are perfect for this specific use.
- The support trays and trays must be always present In the room
- At the end of the cycle, the load will be hot. Use the appropriate key for the extraction of the trays or cassettes.
- Do not exceed load limits specified in this manual
- Do not remove the identification number or any other labels from the serial number or other sterilizer.
- To prevent electrical short circuits, do not spill water or other liquids on the sterilizer.
- Turn off the sterilizer and unplug the power cord before inspecting, make operations, maintenance or repairs of the sterilizer.
- Never turn off the machine with the door closed.
- · Keep the original packaging carefully for any transport.
- The repairs should be made by individuals authorized by the manufacturer and using only original parts.

# 1.12 SAFETY DEVICES

- SAFETY VALVE 2.5 bar
- FUSE 10 A security
- o manual reset safety THERMOSTAT calibrated 230°

In case of transport:

- · Fully discharge both water tanks.
- · Leave to cool the sterilization chamber.
- · Use the original packaging or other suitable packaging.
- Use a reliable transporter



Any intervention on, determined by a malfunction, must mandatory be performed by qualified personnel to do so.



In case of replacements of equipment parts, use original spare parts, to avoid causing variations in performance and / or reduce the level of safety.



Each cleaning, checking and / or maintenance must be performed by authorized personnel and authorized to do so in accordance with the requirements described in this U.M.M.



Failure to follow the instructions in this manual may cause danger to the user.

## 1.13 DEVICES FOR PERSONAL PROTECTION

TO BE USED TO PREVENT THE ONSET OF RESIDUAL RISKS

According to legal requirements dictated by the regulations on this subject it is the duty of Head of Hygiene and Safety to analyse the potential risks people are exposed to and to wear appropriate Personal Protective Equipment (P.P.E.) in the Studio where the equipment is installed. Regardless of the risk analysis of Hygiene and Safety Manager, in all cases mentioned in this Section are shown the MANDATORY P.P.E. that the exposed personnel must use while approaching the machine. The use of additional D.P.I. is at the discretion of the Head of the Hygiene and Safety in the Studio where the equipment is installed.

#### Use:

- 1. safety shoes to ensure a sufficient level of electrical / mechanical isolation /
- 2. flame retardant protective clothing.
- 3. appropriate gloves



IN NORMAL CONDITION OPERATIONS NEVER STOP THE DEVICE REMOVING THE POWER SUPPLY DIRECTLY FROM THE GENERAL SWITCH BUT STOP THE CONTROL PANEL FIRST.

# 1.14 EMERGENCY STOP AUTOCLAVE

Serena GB-R03 del 07-06-17

In case of emergency there is a need to stop THE equipment the operator must take prompt action on the connection socket / plug off, grabbing the plug WITHOUT pulling the cable. In this regard it should be noted that the plug must always be free of any material or furniture and always visible.

# 1.15 CONDUCT OF MACHINE BY USER

The user's tasks are:

- monitor the operation of the appliance, acting promptly in case of malfunctions;
- check the constancy of performance and integrity of the devices used and promptly shut down the device in case of malfunctions.



It is FORBIDDEN to leave the unit without first having switched it off at the end of the work



The intervention of the user will always be subject to compliance with the symbols placed on the machine and the requirements dictated by this U.M.M.

## 1.16 RESIDUAL DANGERS INFORMATION

**RESIDUAL DANGERS AND SIGNALS** 

To highlight to the user, to those exposed and to the authorized personnel all the residual risks to which attention must be paid, it was decided to affix to the machine standardized symbols highlighted in the following pages.

The dangers to which it could not apply a total protection, because it would make the machine difficult to use, inhibiting their intended use, are as follows:



1 Electrical dangers inside the control panel or any derivations of the unit.



Thermal dangers resulting from the contact of the user's arms when the respective electrical resistance is operating.

# 1.17 FAILURES, MALFUNCTIONS OR OTHER INCONVENIENCES

In case of failures, malfunctions or other problems not covered in this U.M.M., call the manufacturer directly. The address is as follows.

# **REVERBERI ARNALDO S.R.L.**

Via Don L. Sturzo, 6 – 42021 BARCO di Bibbiano (RE) – ITALIA Tel. +39 (0) 522 875159 Fax.+39 (0) 522 875579 e-mail: reverberisrl@gmail.com



Any work on the machine, determined by a malfunction, must necessarily be performed by qualified personnel.



In case of replacements of equipment parts, use original spare parts, to avoid causing variations in performance and / or reduce the level of safety



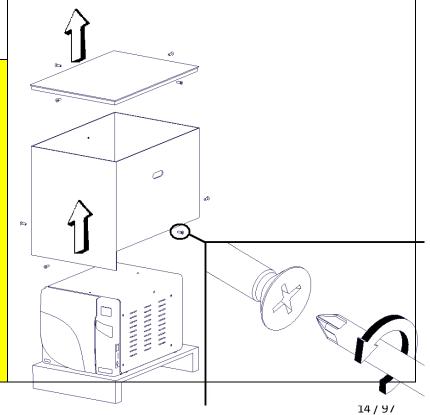
Each cleaning, checking and / or maintenance must be performed by authorized personnel and authorized to do so in compliance with the requirements given in this U.M.M.

# **2 UNPACKING**

# **UNPACKING OF THE STERILIZER**



If the sterilizer has been kept in temperature and humidity conditions different from those of the installation, wait for an appropriate period of time before installing it and turn it on. The sterilizer that comes from a cold place could accumulate inside moisture an condensation which could cause a danger if turned on immediately. The sterilizer should be removed from the packing box and transported by two people.



Serena GB-R03 del 07-06-17

Total weight dry: SERENA 18 = 45kg 441.5N SERENA 23 = 50kg 490.5N

#### NOTES:

Check the external condition of the carton box and of the sterilizer. In case of damage, contact the retailer, the shipper and the carrier that have delivered the product.

# 2.0 SUPPLIED ACCESSORIES (STANDARD)

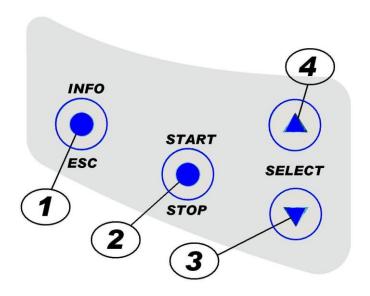
The autoclave has the following standard accessories: ACCESSORIES CONTAINED IN THE CHAMBER

Key for adjustment door and extraction trays, 4 trays made of anodized aluminium, stainless steel support for 4 trays or 2 boxes, SD card, exhaust pipe, water supply hose, funnel for filling water in emergency, support phials for spores, 2 sterilization indicators, a sponge for cleaning.

DOCUMENTATION CONTAINED IN THE PACKAGING

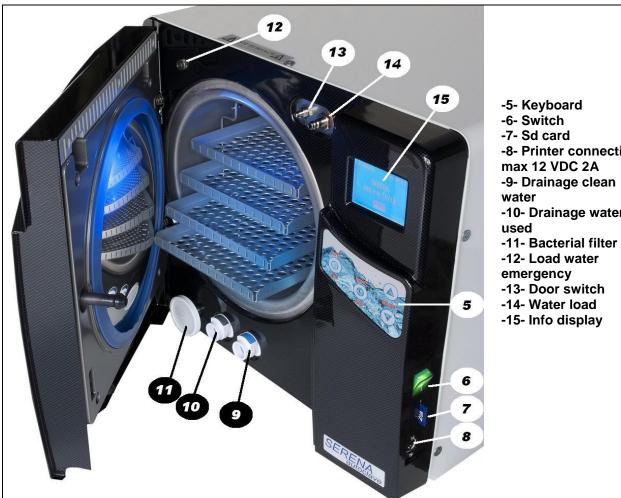
Use and maintenance manual containing the CE Declaration of Conformity

# **3 STERILIZER DESCRIPTION** 3.0 KEYBOARD



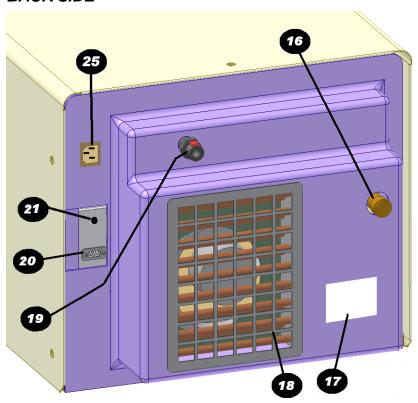
- -1- Info / Exit
- -2- Start / Stop
- -3- Reduction / Menu
- -4- Increase / Menu

# 3.1 FRONTAL SIDE



- -8- Printer connection
- -9- Drainage clean
- -10- Drainage water

# **BACK SIDE**

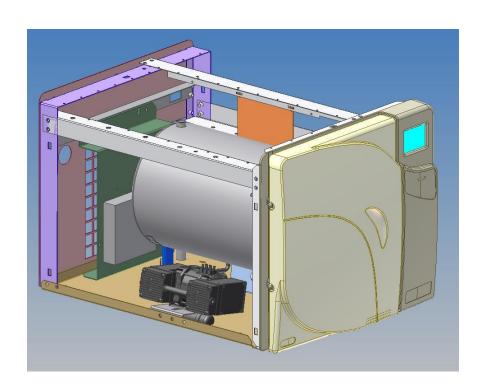


- -16- Safety valve
- -17- CE plate
- -18- Heat exchanger
- -19- Vent
- -20- Labeller connection 9 PIN max 12VDC

**1A** 

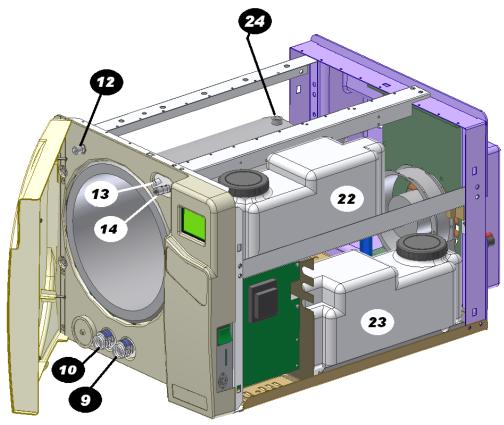
- -21- Power cord
- -22- Clean water tank
- -23- Water USED tank
- -24- Connection test
- -25- 230V/50Hz 10A power outlet for

connection to the cleaner



Vacuum pump

# 3.2 DESCRIPTION OF INTERIOR WATER TANKS



The autoclave is equipped with two independent water tanks, respectively, for pure water and that used (each tank has a usable capacity of 3.5 litres). The drainage port for the water used is grey.

The upper tank (22) is called "clean water tank" and must be filled with distilled or demineralized water required for the sterilization process. Please find below the quality table of the water to be used.

The tank has a minimum (0.8 litres) and maximum level sensor (3.5 litres). When the water level falls below the minimum threshold and you are choosing a sterilization cycle, the display shows a message of request for water.

It is then necessary to connect the supplied tube to the quick connection (14) and press the START button (2). During this phase it is important that the container of clean water is at the same height of the autoclave.

Just in case of emergency, the tank can be filled manually from the junction (12), or automatically through an automatic external water treatment system connected to the attack (9) on the front of the autoclave. Use quick connection (9) to download the clean water tank.

The lower tank (23) is called "water tank used" and contains the used water collected at the end of each cycle. The tank is equipped with a sensor-level maximum (3.5 litres).

Use the quick (10) to get the water tank.

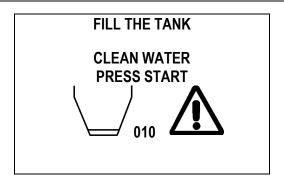


- Water consumption per cycle varies depending on the type and weight of the load. The clean water tank capacity is enough for 6 to 8 cycles of sterilization.
- Never reuse the water used!

# 3.3 QUALITATIVE WATER TABLE

CEN STANDARD DIN EN 285	MAXIMUM VALUE
Evaporation residue	10mg/l
Silicon oxide (SiO <sup>2</sup> )	1mg/l
Iron	0,2mg/l
Cadmium	0,005mg/l
Lead	0,05mg/l
Remains heavy metal (excluded iron cadmium and lead)	0,01mg/l
Chloride	2mg/l
Phosphate	0,5mg/l
Conductivity (at 20° C)	15 μ s/cm
Ph Value	From 5 to 7
Aspect	colourless, clean and free of sediment
Hardness	0,02 mmol/l

NOTE: the use of feed water containing concentrations higher than those indicated in the table above may significantly reduce the life of the device causing serious damages to its components and determining the loss of the warranty



#### 3.5 CLEAN WATER LOAD

# FILLING THE TANK WITH CLEAN WATER



Use only distilled water of high quality! Follow the qualitative water table!

# 3.6 MANUAL FILLING

Place the tank of distilled water (standard 5 lt.) on the right side of the autoclave at about the level of the car door.

- Connect the water hose supplied to the hose connection (14) by inserting the other end into the tank
- Press START
- In this way the pump is activated and starts filling water
- If the water is non-compliant (> 15µS), the pump stops and the message of dirty water appears on the display.
- The filling takes place in two or three times since the command is timed. The pump will stop automatically when the tank is full and on the display will appear the screen and then the filling.
- If you notice that during the filling in the tank the water is running out, the pump stops as you press START.
   Provide for a new tank and re-press START to continue and complete the filling.
- Disconnect the water supply hose and keep it for the next filling.



To clear the message of dirty water you must empty it and fill with water quality.

Serena GB-R03 del 07-06-17

Proceed as follows:

- Insert the supplied drain hose into the blue speed connection
- · Proceed automatically empting the tank of clean water
- Fill the tank with water quality

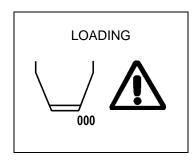
# 3.7 AUTOMATIC LOADING

In the SETTINGS choose AUTOMATIC LOADING:

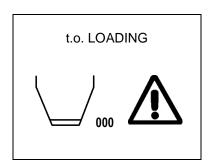
AUTOMATIC LOADING

99 MIN.

It is recommended to set about 20-30 minutes if the water supply system has no less than 2 atmospheres.



The valve of the water purifier starts working for the set minutes pressing the START button.

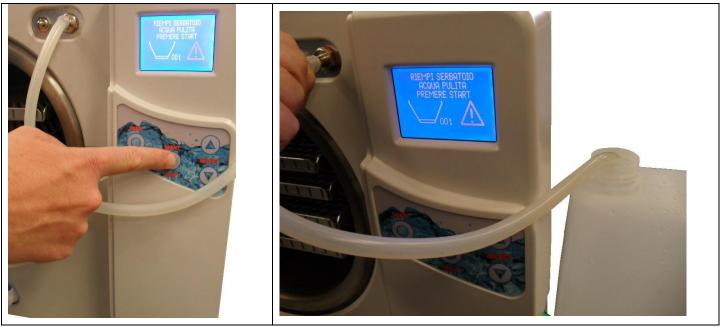


T.o. LOADING means TIME OUT LOADING. It's a valve opening timer of the purifier with sufficient time for refilling the tank with clean water to a minimum. The three zeros indicate that no passage of water has been found therefore the quality has not been checked. In case of normal water passage numbers instead of zeros attest to the quality of the water.

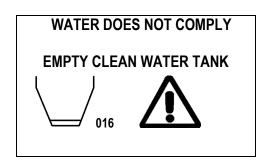
- 1. Make sure the tap of the cleaner is opened.
- 2. The technician must verify the correct operation of the filling device present in the autoclave.
- 3. For the detailed calibration, refer to the instruction manual of our cleaner.
- Insert the attack provided to the front of the sterilizer purifier (9).
- Connect the plug of the purifier into the plug to the back of the sterilizer

	For the first functioning of purifier, check the pressure gauge. The pressure must be at least 2 bars.  Otherwise, extend the filling T.O.  After replacing the cartridges, turn off and then switch on the sterilizer.
(F	Just in case is selected the automatic filling, it is the task manager, to provide the sterilizer a check valve conforms to IEC61770.

#### Serena GB-R03 del 07-06-17



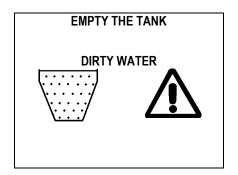
If the water is used is of low quality, ie more than 15 microsiemens, the following message appears:



Proceed to empty the water tank clean as follows:

- 1. Set the MANUAL LOADING (Menu -> Settings-> Manual loading)
- 2. Insert the drain hose (red) provided in the slot blank. Will come out of the water present in the clean water tank.
- 3. When all the water is output, remove the exhaust pipe (red).
- 4. Insert the inlet hose (white-transparent) in the graft load water at the top right of the sterilizer (see photo 1).
- 5. Press START. Fill up with pure water NOT EXCEEDING 15 microsiemens

# 3.8 DRAINIG WATER USED



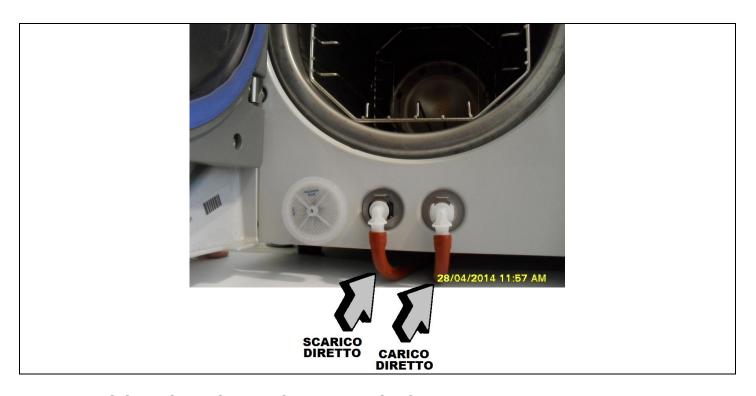




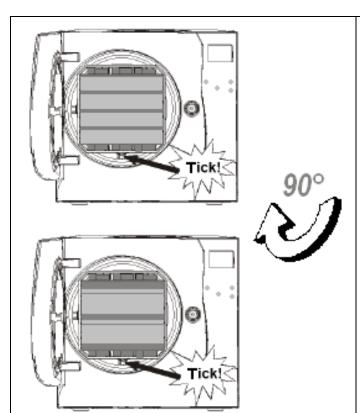


Warning! The drain water of the sterilizer must be conveyed in a <u>clearly visible</u> labelled container with the words "DIRTY WATER DERIVED FROM THE AUTOCLAVE". Empty it immediately!

## 3.9 DIRECT CHARGING AND DISCHARGING WATER CONNECTIONS



# 3.10 TRAYS SUPPORT FOR THE STERILIZATION CHAMBER



Insert the support into the sterilization chamber, align it with the centre / bottom of the chamber andgently push it until a click warns the connection has been established.

The support is reversible and can be used for: 4 trays or, once entered and rotated to 90  $^{\circ}$ , for 2 horizontal cassettes.

# Usable space of the sterilization chamber

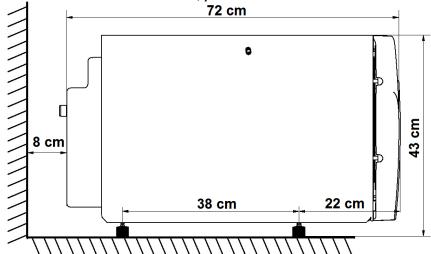
The usable space of the chamber is the maximum volume load and it is identical for all types of loading and sterilization cycle.

Serena 18 lt - (axlxp) mm 195x195x360 volume 13.69 lt Serena 23 lt. - (axlxp) mm 195x195x490 volume 18.63 lt

# 4 INSTALLATION

## 4.0 POSITIONING

Install the autoclave in a well-ventilated area and away from sinks, heat sources, mole, and any other machinery. Possibly use as a separate room as sterilization room. Carefully place the autoclave on a perfectly flat surface with a minimum height of 70 cm and maximum 130 cm, making sure to leave an area of about 8-10 cm and 5-6 cm on the back side around the machine to allow proper ventilation. It is not recommended to install the machine inside a cabinet. In the event, the cabinet must have the back side completely open and the side walls provided with air intakes. Before the construction of a custom furniture, please contact the manufacturer.





• Check with a "bubble" or "levelling" the plane in which the device should be supported to be perfectly flat, both in length and width.



Observe the following environmental conditions:

Operating temperature +10° C to +25 ° C / relative humidity: 0 - 90%

Storage temperature +3 ° C to +35 ° C / relative humidity: 0 - 90%

The maximum weight of the sterilizer is:

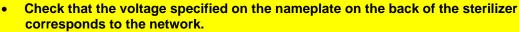
SERENA 18 - 45kg = 441.5N

SERENA 23 - 50kg = 490.5N

## 4.1 POWER SUPPLY

The electrical system for the sterilizer shall conform to the rules in force in the country of installation, and must have the following features: Voltage 230 V  $\pm$  10%, 50 Hz, 10A (single phase). Installation category / class of overload power = II Differential switch 10A with a sensitivity of 30mA. The power switch must be a certified typo according to current regulations. Maximum Power Consumption: 2000-2400 W (10A)

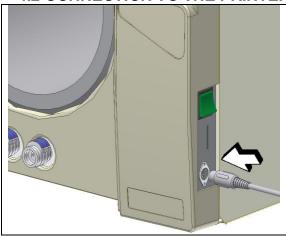
It is essential an efficient ground connection.



- The complete electrical safety is guaranteed only if the electrical connection is provided with proper connection to the ground according to current regulations.
- If necessary make electrical circuit checked by a qualified electrician.
- Do not connect other equipment to the same power.
- Do not bend or twist the power cord.
- Use only the original cables supplied with the sterilizer.
- Do not use extension cords.



# 4.2 CONNECTION TO THE PRINTER M9004 OR TO THE PC





# 4.3 CONNECTION TO THE PRINTER (ON DEMAND)



Do not connect printers different from the Rever-Print! The use of other printers relieve the autoclave manufacturer from any liability under warranty or any other claim or damage caused by the printer itself.

- Connect the printer cable to the serial attack pin9 on the back of sterilizer.
- Use only the supplied cable (length up to 2 meters)
- Connect the network cable to the printer
- Turn the printer

# 4.4CONNECTION TO THE LABELLER M9006 (ON DEMAND)



**Use only our labeller UNION PRINT!** 

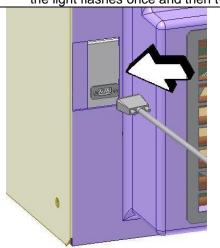
The use of other labellers relieves the manufacturer of the autoclave from any liability under warranty or any other claim or damage caused same label.

- Use only thermal labels supplied by us Place the roll as shown in the drawing visible when you open the door
- Close the door until it clicks leaving a label outside
- Press the button to place the label.
- Flashing red light -> NOT operational
- Flashing green light -> WAITING positioning
- Solid green light -> READY

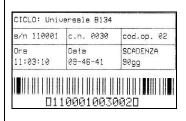
To do a test print (p. 44 Instruction Manual): OPTIONS -> LABEL PRINTING LAST CYCLE

In the case of incorrect printing, too high or too low, the light is solid green, press and hold the button and wait until

the light flashes once and then twice more, then release the button.









Use only original rolls and place them in the right way!

#### 4.5USING SD CARD



SERENA sterilizers are equipped with an integrated digital recording cycles.

The cycle data are automatically recorded and saved as a file on a removable SD memory card / rewritable.

This filecan be downloaded and run on a PC or MAC. Insert the SD card in the appropriate space (7) designed in the lateral side of the autoclave, enter it oriented with the bevel up, and press gently until it stops.

**NOTE 1** To avoid damage to the SD memory card, it is recommended to insert and remove (7) SD card, only when the machine is off.

**NOTE 2** It is recommended to periodically download the data from the card to a computer. Do not format! **NOTE 3** The manufacturer assumes no responsibility for any damage to the SD card or loss of data both during and after the warranty period.

**NOTE 4** AND 'mandatory for the validity of the warranty, to keep an SD card inserted.

To remove the SD card, pull it out directly.

The card supplied has a storage capacity of at least 1-2GB. Be careful not to bend the package and remove the SD card with the help of scissors. Leave it in the lock up position.

## READ OF THE MEMORY CARD WITH PC / MAC

The data on the card can be directly read, copied and printed via PC or Macintosh equipped with a USB 1.1 (or higher) with a card reader or SD card input. The MAC must be able to format in FAT32.

# MINIMUM HARDWARE REQUIREMENTS FOR A PC / MAC

PC / MAC 1-Port USB 1.1 (or higher) free PC / MAC CD-ROM

Operating system PC Windows 98SE, 2000, ME, XP or higher

Mac OS 9.1.x, OS X v10.1.2 +.

The autoclaves SERENA record all data of sterilization on a digital SD card that can be recorded, saved or printed directly on a standard PC.





When you turn on the sterilizer if you do not have an SD card, the display shows an error message. If during the cycle, the SD card is removed, at the end of the cycle the display shows the error.

# CONNECTIONS TO DEMINERALIZERS KIARA-TEC (ON DEMAND)

The manufacturer offers the possibility of automatic feeding of SERENA autoclaves with demineralized water. Once installed the system, the tank of clean water is automatically kept full without any operator intervention.

# **CONTINUOUS DRAIN CONNECTION (ON DEMAND)**

The autoclave can be connected to an external drain to allow the automatic discharge of water used.



The length the drain hose must not exceed 5 meters!

The discharge point must be at least 20-30 cm below the plane of the autoclave!

# 5 LOADING PREPARATION 5.0 CLEANING OF TOOLS

The objects to be sterilized must be perfectly clean, carefully dried and without any residue of blood, soap, plaster. These substances can cause irremediable damage to both the objects to be sterilized and either to the components of the autoclave as well as compromising the autoclave sterilization. In cleaning, always use protective gloves.

- 1. Immediately after the use, immerse the instruments in a bowl with disinfectant solution. Strictly follow what is indicated by the manufacturer of the disinfectant for the times and the percentages of solution. After this preliminary decontamination proceed with a thorough rinsing.
- Continue with cleansing by using ultrasound machines and washer machine. If you use ultrasound machines, it
  is essential a thorough rinsing with demineralised water if possible. Follow the manufacturer's instructions. We
  recommend using a WASHER-DISINFECTOR and disinfection that in addition to cleaning, rinse and dry
  automatically.
- Before the sterilization, make sure that the instruments are perfectly dry (use a paper towel, TNT or cloth of low release) and without any residual disinfectant, since these residues may cause corrosion during the sterilization. For the drying of hollow instruments use a compressed air gun.
- 4. Make a final check of the tools and eliminate those with cracks, stains, rust and friction between the parties (it may be useful a magnifying glass). Then proceed with the enveloping.
- 5. For dynamic tools, lubricate according to the instructions provided by the manufacturer of the instruments.
- 6. Snippy or cutting materials should be protected with rubber tubes resistant to high temperatures.
- 7. For the cleaning of dental manipulates, proceed as follows:
  - Always use protective gloves
  - Follow the instructions provided by the manufacturer of the tools
  - Do not use abrasive cleaners nor chlorine-based disinfectants neither similar
  - •Do not immerse instruments in the disinfectant
  - Clean, rinse and dry with extreme care, taking care not to scratch the fibre optic
  - · Lubricate the instrument before the sterilization according to the manufacturer's instructions
  - · Wrap the instrument in



- Do not use sharp objects for cleaning or Disinfectants
- Carefully clean the bottom of the chamber, taking care not to damage the sensors
- Use non-abrasive cloth and light detergent.
- Rinse thoroughly



WARNING! DO NOT introduce sensitive materials in the autoclave!

## 5.1 PREPARATION OF THE TRAYS



Pay close attention to the preparation of the trays. It is recommended to use always the porttrays and trays for sterilization.

Warning! Use always the trays and the tray holder.

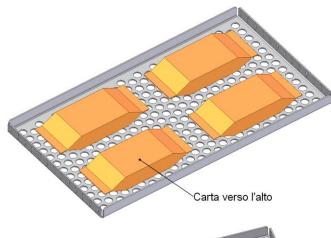
Never place the material to be sterilized directly on the bottom of the chamber!



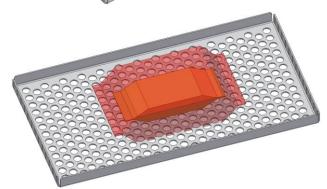
During the cleaning and maintenance of instruments, always use protective gloves!

- a) Adhere to the weight of the load limits set by the manufacturer
- b) Always use the trays and hold-trays
- c) Do not overload individual trays
- d) Leave space between the envelopes placed on travs. in this way the steam circulates better.
- s) Please note that the envelopes do not touch the walls of the sterilization chamber
- f) Empty containers or bowls not drilled must be placed in the inverted position to prevent the accumulation of water inside
- g) The instruments of different material (stainless steel, carbon steel, aluminium, etc..) must be placed on separate trays and wrapped in separate envelopes
- h) The instruments of carbon steel should be isolated from the tray with a specific sheet of paper and wrapped with a special double envelope by inserting an indicator of sterilization.
- i) Instruments with joints, such as forceps, scissors, etc... must be sterilized in the open position.
- j) Always use proper sterilization pouches that allow good penetration of steam and a good drying. It's better to use sealed envelopes with HEAT.
- k) The envelope must be placed on the tray with the paper side facing up.
- I) Place the tubes in order to keep the open ends. Make sure there are no kinks.
- m) To prepare the trays containing dental manipulates, follow instructions provided by the manufacturer of the handpiece. Proceed as follows:
- Wrap the tray for sterilization in the cleaning cloth and proceed to pack it
- Place the handpiece on a tray NOT drilled to prevent a possible spill of oil that could contaminate the pipes of the autoclave.
- At the end of the cycle immediately remove the handpiece
- n) For the preparation of the trays containing rotary instruments (drills, etc.) always use a <u>double envelope</u> and indicate the type of sterilization. In the case <u>of double wrapped</u>, at the end of cycle wait <u>about 5 minutes</u> before removing the trays.

# Disposition of the envelopes on the tray (put the paper up)



Trays containing cutters or other tools inside two sealed envelopes



# **6 START OF STERILIZER**

To turn on the autoclave, press the main switch (6), on the right side of the sterilizer.

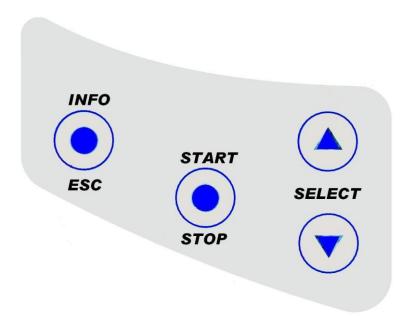
Only the first time you will turn on the autoclave, the display screen appears as below: it warns that the sterilizer will not start if the water will not be in the tank (22) (clean water).

CLEAN WATER PRESS START

Normally at the starting of the autoclave the following screen appears:



Use the keyboard to navigate through the menu:



# **INFO**

Pressing the info button when the machine is running and the door closed, the following technical data will appear:

- 1. Temperature probes
- 2. Four other temperatures
- 3. The chamber pressure
- 4. Quantity of water
- 5. the voltage
- 6. Water quality expressed in microns
- 7. Door status and levels

It allows to go to the previous menu or to exit any situation. **ESC** 

**START** 

It allows to:

**STOP** 

1. Close the door

- 2. Interrupt a cycle
- 3. Confirm a menu item
- 4. Enter the menu item
- 5. Open the door
- 6. Trigger the pump that fills the tank (with door open)

# **SELECT**

It allows to:

- 1. Go up / down in a menu item
- 2. Pressed together take off any alarms.

## 6.0 EXECUTION OF A STERILIZATION CYCLE

Place the load inside the chamber and press "START" to enter the main menu:

# UNIVERSAL CYCLES B

SPECIAL CYCLES
TEST CYCLES
OPTIONS
SETTINGS

# UNIVERSAL CYCLES B

Press "START" to choose the B cycle you want to start:

# UNIVERSAL CYCLE B134

**PRIONE CYCLE B134** 

**UNIVERSAL CYCLE B121** 

Use the arrows to move up and down:

**UNIVERSAL CYCLE B134** 

**PRIONE CYCLE B134** 

**UNIVERSAL CYCLE B121** 

**UNIVERSAL CYCLE B134** 

**PRIONE CYCLE B134** 

UNIVERSAL CYCLE B121

In case of choosing the B134 UNIVERSAL CYCLE: position the cursor on this item and pressSTART

UNIVERSAL B134
OPERATOR CODE 01
N° LABELS 00
START

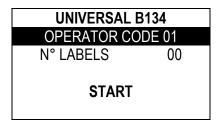
To change the "OPERATOR CODE "press" START ".

**UNIVERSAL B134** 

OPERATOR CODE 01 The following screen will appear, if you want to change the operator code you have to press the arrow keys (the top if you want to increase and the bottom if you want to decrease).

Press "ESC" (each operator within of the studio will be marked with a number, so that at the time of sterilization of the material you can find out who made the sterilization). We recommend keeping on hand a list of the codes of the various operators of the studio. We enclose an example in the last pages of this U.M.M.

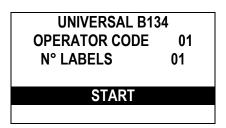
To return to the previous screen press "ESC".



By using the arrow you move to the item below, once placed on the selected item press "START" will appear as the following screen:

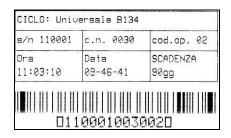
UNIVERSAL B134
OPERATOR CODE
01

The same applies for labels, increase / decrease the numbers by using the arrows, then "ESC" to exit.



Move the arrow down until you highlight the word "START" and press "START" approaching the door atclosing time.

# LABEL EXAMPLE

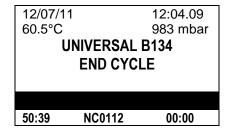


We recommend that you print a number of labels equal to the number of STERILIZED bags because each LABEL will be attached to AN ENVELOPE. Moreover, if you do not possess a bar code reader, YOU NEED TO print as many labels THAT will be associated with that patient. Another label will be printed for filing.

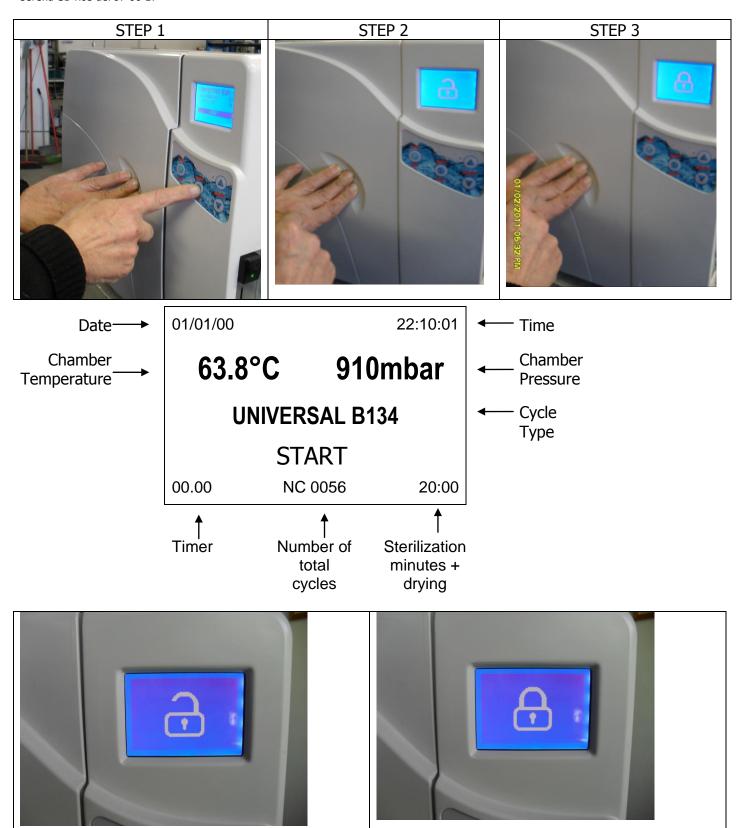
If you own a bar code reader, you only need to print the labels to be attached to the envelope as they will then proceed through the reader to the association to the patient.

Another label will always be printed for filing.

At the END OF THE CYCLE the following screen appears:



To return to the menu, press START. Pressing ESC / INFO the information related to the ended cycle will be displaied.



#### 6.1 AVAILABLE PROGRAMMS

## 6.1.1 UNIVERSAL CYCLE TYPE B

The following three universal cycles differ in the temperature, in the time of sterilization and in the minutes of drying.

**B134 UNIVERSAL CYCLE** This sterilization cycle of Type B is suitable for any load, solid, porous, unwrapped and packed in a single envelope or double, for hollow type A and B.

**PRION CYCLE B134** Type B sterilization cycle is suitable for any load, solid, porous, unwrapped and packed in a single envelope or double, for hollow type A and B.

<u>UNIVERSAL CYCLE B121</u> Type B sterilization cycle is suitable for any load, solid, porous, unwrapped and packed in a single envelope or double, for hollow type A and B.



Follow the instructions provided by the manufacturer of the materials to be sterilized.

Pay close attention to weight limits for maximum the load and to dispose the load in the trays as per detailed instructions of the manufacturer's autoclave,

Only in full respect of the above information, the sterilization is guaranteed

# 6.1.2 SPECIAL CYCLES

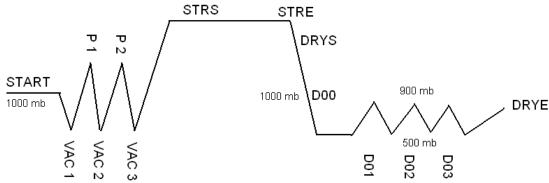
The special cycles allow to increase the sterilization time, drying time (10 minutes is default), the number of hollows (default is two) Once you set up data they are automatically stored

# SPECIAL CYCLE 1 SPECIAL CYCLE 2

NOTE: If you leave set the two predefined hollows and the ten minutes of drying, the load should only be UNWRAPPED and SOLID.

# 6.1.3 STERILIZATION CYCLES GRAPHS, TEST AND TYPE OF TEST

## PHASES OF THE CYCLE OF STERILIZATION



-----

SERENA 23 ONLY B CYCLE

Ver. 0.27

S/N 000000

Nr. CYCLE 0000 CYCLE: UNIVERSAL B 134

OPERATOR CODE 04 DATE 00-00-00

TIME 00:00:00

**PHASE** TIME TøC P mbar **START** 00:00:03 1013 93.3 VAC1 00:03:12 98.6 199 00:04:02 106.7 1301 VAC2 00:06:40 97.4 168 P2 00:07:59 110.5 1300 VAC3 00:10:36 96.9 180 PPH 00:11:11 101.6 1004 STRs 00:16:12 135.6 3151 00:18:19 MINt 134.8 MAXt 00:16:28 136.0 MINp 00:18:19 3043 ---.-MAXp 00:16:32 3164 STRe 00:21:12 135.4 3080 DRYs 00:21:12 135.4 3078 D00 00:22:34 117.9 1096 D01 00:22:55 111.6 493 D02 00:25:36 107.8 901 D03 00:26:22 104.1 498

D04 00:27:37 101.8 901 D05 00:28:24 98.7 498 00:29:36 D06 96.6 901 D07 00:30:24 94.0 497

D08 00:31:36 92.6 901 00:32:24 D09 90.5 499 D10 00:33:32 901 89.3 D11 00:34:22 88.3 496

D11 00:34:22 88.3 496 D12 00:35:27 90.7 901 D13 00:36:17 90.6 497 DRYe 00:37:12 91.1 895

CYCLE OK

PHASE	DESCRIPTION
START	START
VAC1	FIRST ACHIEVED MAXIMUM
	VACUUM
P1	FIRST PRESSURE ACHIEVED
VAC2	MAXIMUM ACHIEVED IN VACUUM
P2	SECOND PRESSURE ACHIEVED
PPH	REPORT TEMPERATURE /
	PRESSURE
VAC3	THIRD ACHIEVED MAXIMUM
	VACUUM
STRS	STERILIZATION MAINTENANCE
STRE	END OF STERILIZATION
DRYS	DRYING TIME START
D01	VACUUM PULSATIONS IN
D02	DRYING
D03	
DRYE	END OF DRYING

# VT-0 VT-0 300s 600s

SERENA 23

ONLY B CYCLE
Ver. 0.27
S/N 000000
Nr.CYCLE 0000
CYCLE: VACUUM TEST
OPERATOR CODE 01

00-00-00 DATE TIME 00:00:00 **PHASE** TøC P mbar TIME VT-0 00:00:03 19.7 992 VT-1 00:03:30 19.6 47 VT-2 00:08:30 20.1 45 VT-3 00:18:30 21.1 45

CYCLE OK

PHASE	DESCRIPTION
VT-0	PRESSURE ENVIRONMENT
VT-1	TIME IN WHICH THE MAXIMUM
	DEPRESSION IS REACHED .
VT-2	START TIME COMPENSATION
VT-3	START LEAK PERIOD







Sterilization cycle								
UNIVERSAL B134	UNIVERSAL B121							
х	х							
х	х							
х	х							
х	х							
х	х							
х	х							
х	Х							
х	x							
х	х							
	x x x x x x x x x x x x x x x x x x x	UNIVERSAL B134         UNIVERSAL B121           X         X           X         X           X         X           X         X           X         X           X         X           X         X           X         X           X         X						

#### 6.1.4 SPECIAL CYCLE

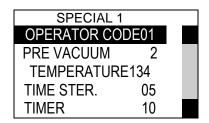
In special cycles the features are:

- ✓ Possible empties from 2 to 5 (default is two)
- ✓ Sterilization from 5 min. to 99 min.
- ✓ Dry from 10 min. to 99 min.
- ✓ Temperature 121 ° or 134 °

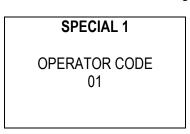
Note: when set to manual water filling, the sterilizer automatically asks filling of clean water. Choosing SPECIAL CYCLE: Press "START" to confirm.



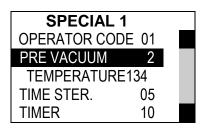
If you decide you want to continue with the SPECIAL CYCLE 1 press "START":



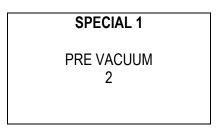
**OPERATOR CODE** press START to enter and use the arrows to change the numbers



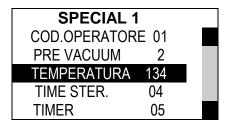
Press "ESC" to exit.



PRE VACUUM -to confirm press "START"



#### **TEMPERATURE**

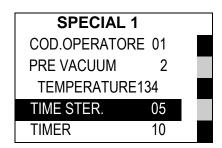


Press "START" to access and modify the data;

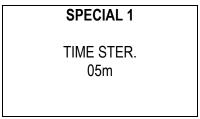
SPECIAL 1
TEMPERATURE
134 °C

Press "ESC" to exit.

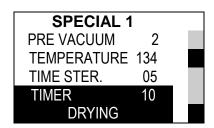
#### STERILIZATION TIMER



Once you press the "START" button will open the following screen:



Use the arrows to increase or decrease the time, when finished press "ESC".

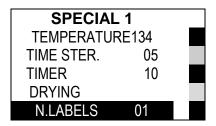


#### **TIMER DRYING**

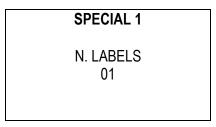
to enter press "START".

# SPECIAL 1 TIMER DRYING 10m

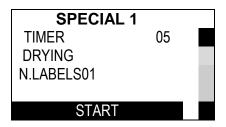
Once you set the timer, press "ESC". Use the arrow keys to move down to enter the item below.



N. LABELS: to enter press "START".



Once you set the timer, press "ESC" to return to the previous screen.



PRESS START to start the cycle.
PRESSING ESC to return to the main menu.

#### TO UNLOCK AN ALARM



#### TO UNLOCK AN ALARM

Simultaneously press the up arrow and down arrow until the disappearance of the alarm (about 20 seconds).



Then MENU, OPTIONS, OPEN DOOR and press start twice. The door will open automatically.

The procedure has been studied for safety reasons.











**INTERRUPTION OF A STERILIZATION CYCLE:** HOLD the "START" button until the beep. After a few seconds the door will open automatically (even if the opening is set to manual) in total safety.

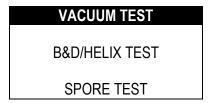
#### 6.1.5 TEST CYCLES

Use the arrows to move the item below and press START to access this item

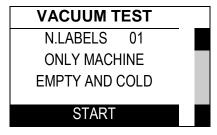


#### 6.1.5.1 VACUUM TEST

Once you press the "START" button the following screen will be open:



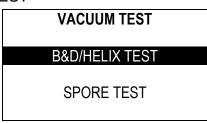
Press "START" in order to change the parameters within this code:



Press "START" to access the screen for changing the number of labels, then press "ESC", move down with the arrow and press "START".

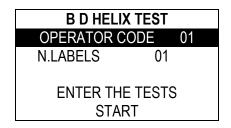
Press ESC to exit.

#### 6.1.5.2 B&D/HELIX TEST



Moving with the arrow you switch to the next item. When you choose the cycle B & D / Helix and water filling is set manually, automatically the sterilizer calls for the filling of clean water. For this test the temperature is  $121^{\circ}$ .

Press ESC to exit. B & D / HELIX TEST: by pressing "START" and the use of arrows to access the modification of the following data:



Once set the data, by using the arrows go to the "START" button and press "ESC" to exit.

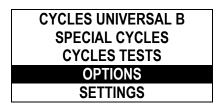
#### 6.1.5.3 SPORE TEST

The spores must be introduced into a normal sterilization cycle. After the cycle the vials must be removed, broken and incubated for 48 h at 53 ° into the cycle spores (insert an integrated vial for better test). Follow the instructions of the manufacturer of spores to a correct reading of the result.





#### 7 OPTIONS



Pressing START the following screen will appear:

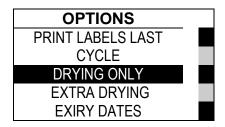


#### 7.0 PRINT LABELS LAST CYCLES

Only missing labels of the last cycle are printed (e.g. if the card is over, to forget, etc). The print is a label at a time



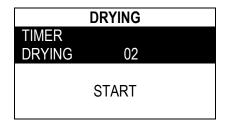
Pressing the "START" you will have access to change information.



#### 7.1 DRYING ONLY

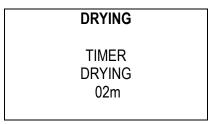
Drying cycle only

Pressing the "START" you will have access to change information.

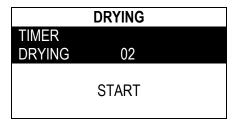


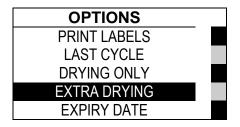
With the arrow move down after selecting the timer drying, the drying is a minimum of 1 additional minute, to a maximum of 99 minutes.

Then press START



Press ESC to exit

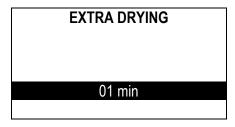




#### 7.2 EXTRA DRYING

With this menu the standard drying sterilization cycle is increased from 1 to 99 minutes.

Pressing the "START" you will have access to change information. This drying is indicated in the presence of multiple packaging (double envelope). Continuing with the arrows you can access the other sub-menu OPTIONS

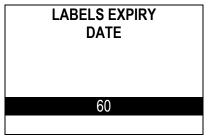


Press ESC to exit and return to the main menu



#### 7.3 LABELS EXPIRY DATE

Pressing the "START" you will have access to change information. And 'the expiry date printed on the labels has to be attached to the envelopes containing the sterilized instruments. After this date the instruments is no longer considered sterilized.

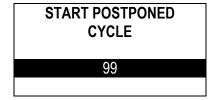


Press "ESC" to exit



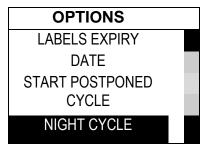
#### 7.4 START POSTPONED CYCLE

Pressing the "down arrow-up arrow" you should program a delayed start of the sterilization cycle up to 99 hours.

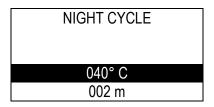


The next screen will appear all the cycles. Select the cycle and close the door.

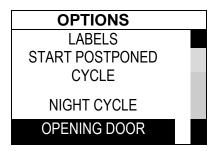
#### 7.5 NIGHT CYCLE



Pressing the "START" you will have access to change information.



The programming of the night cycle is only possible if you have set the opening of the door in manual mode. The display shows the storage temperature of the instruments and the minutes of storage (up to 999 minutes).





See section 1.5 PRECAUTIONS, WARNINGS AND RESTRICTIONS!
DURING THE OPERATION OF THE AUTOCLAVE, THE SURVEILLANCE OF THE
OPERATOR MUST BE CONTINUE!

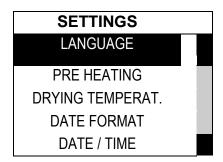
#### 7.6 OPENING DOOR

"Pressing the "START" you will have access to change information. With this option you can open the door safely in case of error or interrupted cycle.

OPENING DOOR START

Press START and open the door

#### 8 SETTINGS



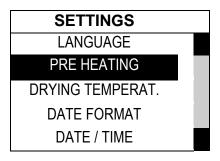
Press START to access and modify the followings: Then the below display will appear:



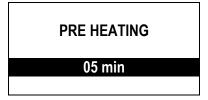
After selecting the item, press START and press ESC to exit. Navigate with the arrow keys to access the item in the SETTINGS menu.

#### 8.0 PRE HEATING

Press START to access and modify the followings:



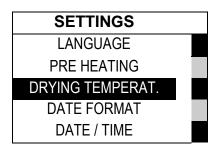
The below display will appear:

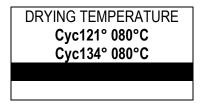


Use the arrows to increase or decrease the timer. Press ESC to exit.

#### 8.1 DRYING TEMPERATURE

Press START to access and modify the data:

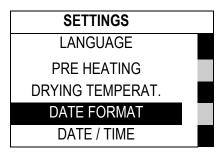




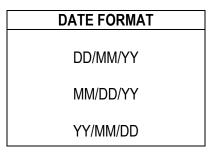
It is possible to modify the drying temperature with the arrows UP and DOWN

#### 8.2 DATE FORMAT:

Press START to access and modify the data:



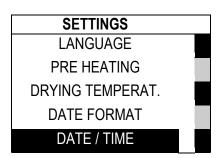
The below display will appear:



Press ESC to exit.

#### 8.3 DATE/TIME:

Press START to access and modify the data:



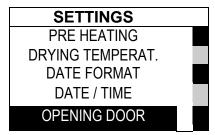
The below display will appear:

DATA ORA	
11/02/16	
16:34:47	

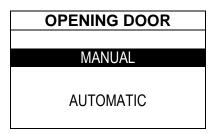
Use arrows to modify the data.

#### **8.4 OPENING DOOR**

Press START to access and modify the data:



The below display will appear:

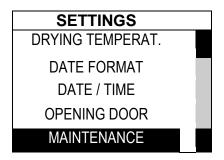


If you set the opening of the door manually, once the sterilization cycle finish the door remains closed and you cannot print any labels. By pressing START the door will be open and automatically will print the labels.

If you set the automatic door opening, once the sterilization cycle is finished, the door opens automatically and the labels are automatically printed.

#### **8.5 MAINTENANCE**

Press START to access and modify the data:



#### 8.5.1 BACTERIAL FILTER

Press START to access and modify the data:

BACTERIAL FILTER
WASHER
WATER FILTER
HAVE THE AUTOCLAVE
SERVICED

The below display will appear:

BACTERIAL FILTER
MAX. 0400
N° CYCLES
0121

0400 INDICATES THE MAXIMUM STERILIZATION CYCLES WITH A BACTERIAL FILTER.

#### 8.5.2 WASHER:

Press START to access and modify the data:

BACTERIAL FILTER

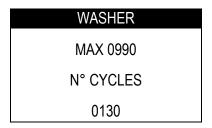
WASHER

WATER FILTER

HAVE THE AUTOCLAVE

SERVICED

The below display will appear:



0990 INDICATES THE MAXIMUM STERILIZATION CYCLES WITH A WASHER.

#### 8.5.3 WATER FILTER:

Press START to access and modify the data:

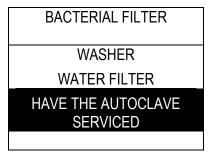


Press START to access and modify the data:

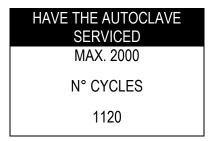
WATER FILTER
MAX. 2000
N° CYCLES
0036

2000 INDICATES THE MAXIMUM STERILIZATION CYCLES WITH A WATER FILTER.

#### 8.5.4 HAVE THE AUTOCLAVE SERVICED:

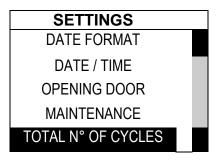


The below display will appear:



2000 IT MEANS THAT ONCE ARRIVED TO THE 2000 CYCLES THE AUTOCLAVE HAS TO BESERVICED.

#### 8.6 TOTAL N° OF CYCLES:

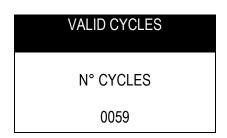


#### 8.6.1 VALID CYCLES:

Press START to access and modify the data:

VALID CYCLES	
CYCLES NOT VALID	
VACUUM TEST	
B&D/HELIX TEST	
SPORE TEST	

The below display will appear:



Press ESC to exit.

#### 8.6.2 CYCLES NOT VALID:

Press START to access and modify the data:

VALID CYCLES
CYCLES NOT VALID
VACUUM TEST
B&D/HELIX TEST
SPORE TEST

The below display will appear:

N° OF CYCLES
0000

#### 8.6.3 VACUUM TEST

Press START to access and modify the data:

VALID CYCLES
CYCLES NOT VALID
VACUUM TEST
B&D/HELIX TEST
SPORE TEST

The below display will appear:

VACUUM TEST

N° OF CYCLES

0201

Press ESC to exit

#### 8.6.4 B&D/HELIX TEST

Press START to access and modify the data:

VALID CYCLES
CYCLES NOT VALID
VACUUM TEST
B&D/HELIX TEST
SPORE TEST

The below display will appear:

B&D/HELIX TEST

N° OF CYCLES

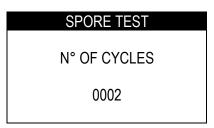
0071

#### 8.6.5 SPORE TEST

Press START to access and modify the data:

VALID CYCLES
CYCLES NOT VALID
VACUUM TEST
B&D/HELIX TEST
SPORE TEST

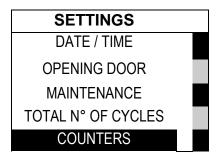
The below display will appear:



Press ESC to exit

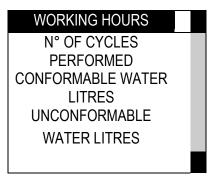
#### **8.7 COUNTERS**

Press START to access and modify the data:



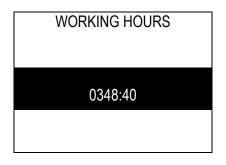
#### 8.7.1 WORKING HOURS

Press START to access and modify the data:



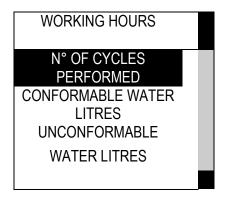
The below display will appear:

The hours indicate the period in which the sterilizer has been turned on (ON).

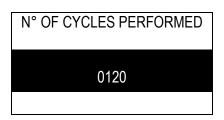


#### 8.7.2 N° OF CYCLES PERFORMED

Press START to access and modify the data:

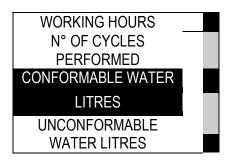


The below display will appear:

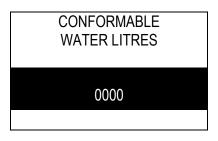


Press ESC to exit

#### 8.7.3 CONFORMABLE WATER LITRES



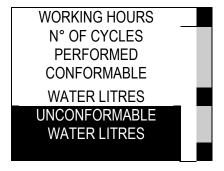
The below display will appear:

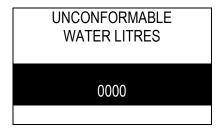


Press ESC to exit.

#### 8.7.4 UNCONFORMABLE WATER LITRES

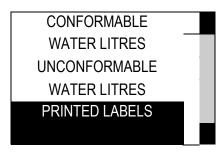
Press START to access and modify the data:



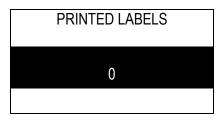


#### 8.7.5 PRINTED LABELS:

Press START to access and modify the data:



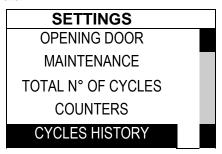
The below display will appear:



Press ESC to exit.

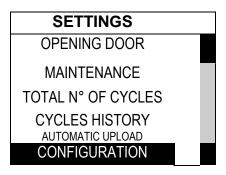
#### 8.8 CYCLES HISTORY:

Press START to access and modify the data:

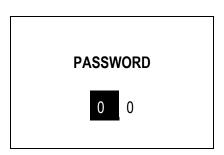


The historical cycles contains the last ten cycles performed successfully (it does not contain cyclesconcluded with alarms).

#### **8.9 CONFIGURATION:**



The below display will appear:



Consult the manufacturer to access the menu that require PASSWORDS.

#### 9 ALARMS

During the course of the cycle, the autoclave SERENA, constantly monitors a set of parameters to ensure a perfect sterilization. If during this check there is an error of one parameter, the cycle is interrupted and appears on the display a warning message. The display shows the message even if sterilization has had a positive exist, or if you have to repeat the cycle.

If the alert occurs during sterilization, the display shows:

UNIVERSAL B134
93.3° C 963 mbar
INTERRUPTED CYCLE
LOAD NOT STERIL

If the alert occurs after the sterilization phase, for example during the drying phase, the display shows:

UNIVERSAL B134
93.3° C 963 mbar
INTERRUPTED CYCLE
LOAD NOT STERIL
DRYING INTERRUPTED

STERILE LOAD: If drying is not sufficient (see UNI EN13060, 5.5,10.11,10.12), perform a drying cycle only. Once the operator has read the error message, you can unlock the alarm by pressing simultaneously on the down arrow and up arrow.

#### 9.0 ALARM CODES



Warning! Never turn off the machine during ALERT! To remove the alarms simultaneously press the Down and the UP arrow - for at least 5 seconds!



To open the door, proceed going to the OPTIONS menu and select OPEN DOOR. Then press START twice.

ALARM CODE	DESCRIPTION	CAUSES	ACTIONS
AL0002 Load not sterile	Lack of networking with sterilization cycle in progress	-Interruption of the cycle in progress in a voluntary manner -Lower-voltage below 190v	-Check that the plug of the studios is efficient -Check the power behind the equipment -Repeat-the sterilization
AL0002 sterile load, drying interrupted	Lack of networking during the drying phase	-Defective switch	-Check that the plug of the studios is efficient -Check the power behind the equipment -Repeat-the sterilization
AL0003	Door open during the sterilization cycle	Micro-control defective door - see attached picture	-Check the efficiency of micro- 1-2-3 with a tester -Only authorized technicians
AL0004	Lack of water during the cycle Resistance is not working Injection pump is not working	-Volumetric dispenser broken -Cable not properly connected -Excessive consumption of waterGroup-filter obstructed evaporator -Drop-pump performance -Cable-resistance is not connected -Resistance burned -Electrovalve-vaporizer is not working	-Replace the dispenser -Connect the cable properly -Check for water leaks Replace the filter -Repeat the sterilization  -Check if the problem occurs both in the cycle and in the 134° 121°. If it does not occur in the cycle 121°, replace the pumpConnect the cable resistance -Replace the resistance if was burned
AL0005	The compensation time between depression maximum and minimum is higher than 1 minute	-Bacterial filter obstructed -Electrovalve bacterial filter not working	-Replace the bacterial filter no. 20 with an original one -Replace the electrovalve no. 7
AL0006	Excessive consumption of water during the cycle	Connections with any loss Electro valves with losses Resistance to external band interrupted	-Check and / or replace fittings - Check and / or replace electrovalves - Check that the resistance is not burned
AL0017 AL0018 AL0022 AL0023	Excessive temperature during sterilization. t1 Low temperature during sterilization. t1 Excessive temperature during sterilization. t2 Low temperature during sterilization. t2	-Loss of steam during the sterilization phase -Breakage of the electronic card-Triac	-Check if inside probes are intact, or if they touch the material present in the chamber -If the problem persists, contact your service centre -Only authorized technicians
AL0027	Excessive pressure during the sterilization	-Presence of air in the chamber	-Check that drains are not blocked

Serena GB-R03 (			
AL0028	Insufficient pressure during the sterilization	-Steam generator with burned resistant -Safety thermostat activated - the support surface is not perfectly flat	-Check actuators and verify the heating -Only authorized technicians - Install the machine on a flat surface (see p. 24)
AL0041	Gap between the temperature readings higher of two degrees during the sterilization	-Presence of air in the chamber -Probes T1 and T2 are not aligned -Breakage of one of the two probe	-Ensure the Safety electric valve and vacuum pump -Align the temperatures through configuration, and proceed with the calibration -Replace the defective or broken sensor -Only authorized technicians
AL0101 AL0111	Problem self diagnosis temperature sensor T1 Problem self diagnosis temperature sensor T2 Self diagnosis Pressure Problem	-Element inside the probe broken -The transducer has values not aligned	-Replace the transducer -Only authorized technicians
AL0121 AL0102 AL0112 AL0122 AL0132 AL0142 AL0152 AL0162 AL0103 AL0113 AL0123 AL0133 AL0143 AL0143 AL0153 AL0163	T1 temperature sensor open T2 temperature sensor open Pressure sensor open Evaporator temperature sensor open Metal temperature sensor open Band temperature sensor open Radiator temperature sensor open Short-circuit temperature sensor T1 Short-circuit temperature sensor T2 Short-circuit pressure sensor Short-circuit temperature sensor steamer Short circuit temperature sensor metal Short-circuit temperature sensor band short circuit temperature sensor radiator	-Cables not connected or defective transducer -Transducer elements in the fused or attached -Wait at least 5 minutes	-Replace the transducer -Only authorized technicians -Replace the transducer -Only authorized technicians
AL0201 AL0202 AL0203 AL0204 AL0205	Failure fractionated vacuum, first vacuum Failure fractionated vacuum, second vacuum Failure fractionated vacuum, third vacuum Failure fractionated vacuum, fourth vacuum Failure fractionated vacuum, fifth vacuum	- Fuses Nr. 2 and 3 burned.  - Check the micro door  -The vacuum pump does not provide sufficient vacuumVentilator condenser not activated	Replace the fuse (identify the cause) and verify with the control actuators  -Check if inside the chamber the ducts are free -Replace the pump . If you do not install a pump functioning, the alarm does not stop.
AL0209	Insufficient vacuum in drying	-It does not reach the minimum values of peaks and venting -Drain valve no. 5 not working -It does not perform the vacuum in drying vacuum drying - Maximum depression is not reached	-Check if inside the chamber the ducts are free -Check configurations in DRYING -Only authorized technicians -Replace the valve no. 5 -Check if the vacuum pump works -Perform Vacuum Test for control

Serena GB-NOS (	<u> </u>	I to the second	T -
AL0301 AL0302 AL0303 AL0304	Failure thermodynamic pressure 1st impulse Failure thermodynamic pressure 2nd impulse Failure thermodynamic pressure 3rd impulse Failure thermodynamic pressure 4th impulse	-It has not reached the temperature -Resistance steamer burned -Resistance band burned	-Through INFO check if Tr is higher than 110° -Through INFO check if Tr is higher than 130°
AL0309	Failure final slope	-Pump water injection steamer decreased of pressure. Electric valve 1 - 1B	-Pump Replacement -Only authorized technicians
AL0401 AL0402 AL0403 AL0404	Failure discharge after 1st thermodynamic Failure discharge after 2nd thermodynamic Failure discharge after 3rd thermodynamic Failure discharge after 4th thermodynamic	-Electric valve 5 burned -Electric valve 4 burned	-Check and / or replace electric valves 5-4 -Only authorized technicians
AL0409	Failure discharge during the drying	-Electrovalve 5 defective	-Replace the Electric valve 5 -Warning door opening, there may be presence of water -Only authorized technicians
AL0901	VACUUM TEST excessive changes of pressure during the stabilization	-Loss of air from electric valves 6-5-1B -Loss door gasket	-Check and/or replace the gasket and electric valves -Only authorized technicians
AL0902	VACUUM TEST excessive changes of pressure during the maintenance	-Loss of air from electric valves 6-5-1B -Loss door gasket	-Check and/or replace the gasket and electric valves -Only authorized technicians

See page 41 to Release Alarms in detail

#### 9.1 TABLE OF STERILIZATION PROGRAMS AVAILABLE

				STERILIZATION CYCLE					TES	ST CYCL	ES		
				UNIVERSAL B134	PRIONE B134	UNIVERSAL B121	SPECIAL 1 **	SPECIAL 2 **	Helix B&D	Vacuum	Spore		
TEMF	PERA	ATURE		134°	134°	121°	121°/134°	121°/134°	135.5° 5		54°		
PRES	SUR	RE		3050 mb	3050 mb	2060 mb	2060/3050 mB	2060/3050 mb	3185 mb				
	DURATION OF		5' 18' 15' 5'-99'			5'-99'	3'30''	15'					
STERILIZATION PHASE * DURATA TION DRYING PHASE		15'	15'	15'	1-99'	1-99'	4'						
DURA	DURATION TOTAL CYCLE		18 LT	40'	53'	43'	VARIABLE	VARIABLE	60'	19'	2910'		
	23 LT		23 LT.	45'	58'	48'	VARIABLE	VARIABLE	65'	21'	2910'		
		TWEEZ	ZERS,	YES	YES	YES	YES	YES		<u> </u>			
	MILLS  POROUS  SMALL OBJECTS SUCH AS GAUZES, COTTON  POROUS  80% USABLE SPACE		OUS BJECTS GAUZES,	YES	YES	YES	NO	NO					
LOADS			SABLE	YES	YES	YES	NO	NO	EMF	PTY CHAMB	BER		
OF			H AS S, PLIERS,	YES	YES	YES	NO	NO	OR				
TYPE	ŀ	HOLLOV TYP SURG SUCT	SERY	YES	YES	YES	NO	NO	TEST				
		UNWR	APPED	YES	YES	YES	YES	YES	]				
		WRAF	PPED	YES	YES	YES	NO	NO					
		DOU ENVE		YES	YES	YES	NO	NO					
	3LT.		RAPPED OLID	3 KG.	3 KG.	3 KG.	3 KG.	3 KG.					
ΦD	SERENA 18L		APPED OLID	3 KG.	3 KG.	3 KG.	NO	NO					
JM LO	SEF	РО	ROUS	1 KG.	1 KG.	1 KG.	NO	NO					
MAXIMUM LOAD	23 LT.		RAPPED OLID	4 KG.	4 KG.	4 KG.	4 KG.	4 KG.					
2	SERENA 2		APPED OLID	4 KG.	4 KG.	4 KG.	NO	NO					
	SE	РО	ROUS	1.2 KG.	1.2 KG.	1.2 KG.	NO	NO					

<sup>\*</sup> COLD CHAMBER: Add 5 minutes - MACHINE FULL LOAD: Add 5 minutes

<sup>\*\*</sup> SPECIAL CYCLES: If you leave vacuums two set and five minutes of drying, the load should only be unwrapped and SOLID

#### **10 MAINTENANCE**



- Carry out maintenance with the machine off, having pulled the plug from the wall outlet, when the various components are not at high temperature.
- The declaration of conformity to standards in force has no effect if the below maintenance have not been performed.
- In case of replacement of one or more components you need to verify the integrity of the safety of the machine.
- In response of all maintenance indicated it is declared a useful life of the device of 8 years.
- Depending on the application of existing rules will require the user to perform all maintenance indicated. This is to ensure that the device maintains the level of performance and security declared by the manufacturer.
- The operations and maintenance checks must be made on time and procedures indicated. Otherwise the guarantee will no longer be 'valid and the manufacturer will not be liable for any damages.
- It is required by those who perform maintenance to communicate the manufacturer the operations carried out.
- In the maintenance phase should be used only parts supplied by the manufacturer.

#### GENERAL MAINTENANCE BY THE USER

The machine requires special maintenance, so it is good practice to follow the instructions below:

- Periodically check the electrical system with particular attention to the connection cable. In case of damage please contact our technical support or service assistant.
- Clean periodically the door, the gasket and with particular care the inside of the chamber from any of calcification using the supplied wet sponge. Proper cleaning maintenance of these parts of the machine makes optimal the performance of the sterilization cycle.
- In the event of prolonged inactivity switch off the machine leaving the door not completely closed, keep it in an environment with a temperature >8 ° C and empty both tanks.
- To clean the fairing is necessary to use a wet cloth. Never use flammable liquids case.
- It is recommended to replace at least once every 6 months or when the machine signals, the bacterial filter.

#### DAILY CARE BY THE USER

Clean the door / clean the porthole / general cleaning of internal or external surfaces.

Clean the black silicon gasket of the door, the outer edge, and the internal support of the sterilization chamber on which the gasket is sealed.

For this cleaning, use the sponge that comes, the soft part will be used to clean the seal and the rough to clean the edge of the chamber.

This clean should be performed regularly to remove any impurities that may cause loss of pressure.

Also check that the gasket has no cuts or incisions, or imperfections.

#### **WEEKLY MAINTENANCE BY THE USER**

Cleaning the chamber sterilization / cleaning trays and plate trolley.

As specified in section "General Maintenance", you must eliminate any deposits on the bottom of the chamber. Use the rough part of the supplied sponge for this operation trying to eliminate all traces of limestone. Rinse everything with the same water used for sterilization. This cleaning should also be extended to the tray and the tray door.

#### MONTHLY MAINTENANCE BY THE USER

Clean with a barely wet sponge all over the furniture of the autoclave, including the cover of the door.

Lubricate the pins and locking mechanisms with silicone spray.

Check the movement of the hinge pin and door locks; lubricate with silicone spray.

Check the adjustment black silicon gasket of the door: if it appears very slow use the special wrench to adjust.

#### 10.0 NATURE AND FREQUENCY OF CLEANING, INSPECTION AND MAINTENANCE

To proceed with this operation:

- Wear appropriate clothing.
- Use only vacuum cleaners where possible,
- If the use of compressed air is forced: also wear masks, goggles, protective gloves and always close the sleeves with elastic,
- Dispose of waste deposits and respecting the environment and laws.

It is FORBIDDEN to use jets of water or other liquids on the unit.

Water splashing generated by atmospheric pressure and pressure jets generated by pressure washer for industrial cleaning are both seen as jets of water.

For a smooth operation and good maintenance of the machine, it is recommended to perform, by the technician, the regular operations. Scheduled maintenance can be limited to a few interventions that can save you from UNDESIRED STOPS DURING THE USE AND MUST BE PERFORMED IN COMPLIANCE WITH THE TERMS ESTABLISHED OTHERWISE BY APPLICABLE RULES.

#### 10.0.1BACTERIOLOGICAL FILTER REPLACEMENT (USER) CODE 1067

- Open the door
- Unscrew the bacterial filter manually in a counterclockwise direction
- Install new filter in a clockwise direction



#### The new bacterial filter should be new and in its original envelope

#### 10.0.2 PINS LUBRICATION (USER)

- Only use silicone spray
- Use the spray in small quantities in the direction of closing hinges

#### 10.0.3WATER TANK CLEANING (LICENSED TECHNICIAN)

AUTHORIZED BY THE TECHNICAL



#### Disconnect the network cable! Only authorized technicians!

- Remove the fairing
- Empty both tanks through the drain hose supplied
- Unhook the springs that hold the tanks
- Disconnect the tubes connected
- Disconnect the wires connected paying attention to the colours
- Remove the caps from the tanks
- Wash carefully with water and mild detergent tanks. Rinse and dry carefully.
- In case of persistent impurities, use for cleaning a dishwasher detergent tablet, chopped, and placed in tanks with about 500 cc of warm water. Shake to try to remove the dirt residues.
- Rinse thoroughly and dry carefully.
- Be careful during reassembly of the original positions of the coloured wires.



To prevent algae growth or other deposits, empty both tanks if the sterilizer is not used for more 'than three days! When the sterilizer is turned off, keep always the door not completely closed!

At the end check that everything is ok CHECK ACTUATORS.

#### 10.0.4 REPLACEMENT OF THE VAPORIZER GROUP (AUTHORIZED TECHNICIAN) CODE 5177

- Remove the casing
- Empty the tanks
- Remove the two lower springs of the water used tank
- Disconnect the three tubes of rubber holder and remove the tank, being careful NOT to remove the wires of the level
- Unscrew the vaporizer
- Disconnect the wires and tubes connecting the vaporiser
- Remove and replace the old with the new vaporizer
- Replace the wires and tubes in the original position
- Replace the water tank used taking care to check that inside is perfectly clean
- Try the sterilizer without the casing (keeping a safe distance) to check any loss
- Replace the casing and perform a Vacuum Test

#### 10.0.5 REPLACEMENT OF THE ELECTROVALVES GROUP (AUTHORIZED TECHNICIAN)

**CODE 5181** 

- Remove the casing
- Disconnect wires and tubes
- Remove the old bar and replace the new pre-assembled and complete
- Replace wires and tubes as originally
- Check without reassembling the casing the presence of any loss (maintain safe distance)
- Run the Vacuum Test



Remove the network cables! Only authorized technicians!

#### 10.0.6 REPLACEMENT PUMP LOAD (AUTHORIZED TECHNICIAN) CODE 5154

- Remove the casing
- Empty the tank of clean water
- Replace the pump and filter making sure to reconnect all tubes and cables in the original position
- Check for loss
- Check the efficiency of conducting

#### 10.0.7MAINTENANCE OF VACUUM PUMP (AUTHORIZED TECHNICIAN) CODE 5153 TWO HEADS

#### TYPE Sterilizer 23lt.:

- Remove the casing
- Unscrew the pump placed under the camera
- Disconnect tubes and cables
- Remove the pump and replace the membrane and valves of the three heads
- Replace the pump with cables and tubes in the original position
- Perform a vacuum test

#### TYPE Sterilizer 18lt.:

- Remove the casing
- Unscrew the two heads of the pump without removing the pump
- Replace the valves and the two membranes
- Replace the casing
- Perform a vacuum test

#### FOR BOTH TYPES:

- By using an indelible pen mark each head
- Remove the four screws
- Take the two heads
- Remove the two centre screws (two plugs are hidden by blacks) and replace the two valves
- Replace the two heads respecting the sign made with the indelible pen
- Replace the membranes taking the two ends and unscrew
- Put the new membranes and screw all the way down
- Replace the heads
- Turn the motor fan by hand (full cycle) checking that nothing has hardness

#### SEE PUMP EXPLODED



# USE ONLY ORIGINAL SPARE PARTS PROVIDED BY THE MANUFACTURER!

# 10.0.8 REPLACEMENT OF THE GASKET (LICENSED TECHNICIAN) CODE 5030 OF THE DOOR BY THE AUTHORIZED TECHNICIAN

- Open the door of the sterilizer
- Remove the 4 screws on the door
- Use a wrench of 10 to unscrew the central nuts
- Remove the gasket along with stainless steel cover
- Replace the old seal with a new one along with the stainless steel cover making sure that the central spring must be in its original position.
- Tighten the central nut (MODERATELY) along with its lock washer using a wrench of 10.
- Start a sterilization cycle at 134 ° universal. When it is in the sterilization phase (STR), tighten the nut and put silicone gel for fixing.
- Replace the plastic cover and tighten the 4 screws carefully when the cycle is finished and the autoclave is cold



To tighten the central nut, always use a wrench of 10!



Pay close attention to replace the door gasket to prevent leakage. It must be entered perfectly to fit without swelling or warping.

## 10.0.9 REPLACEMENT OF THE TRANSDUCER (LICENSED TECHNICIAN) CODE 5186 OF THE DOOR BY THE AUTHORIZED TECHNICIAN

- Remove the casing of the sterilizer
- Remove the PAKER connector that is attached to the transducer
- Unscrew the connection of the Teflon pipe Teflon
- Unscrew the fixing screw of the transducer support
- Assemble the new transducer that will be featured with ring
- Verify by the menu OPTIONS -> OPEN DOOR > info button if the pressure corresponds to the ambient temperature

# 10.0.10 REPLACEMENT OF THE ELECTRONIC BOARD(LICENSED TECHNICAL) CODE 5189 BY THE AUTHORIZED TECHNICAL

- Remove the cowling of the sterilizer
- Begin to remove the connectors on the left side of the card. With a coloured pen mark their original position, paying particular attention to the transducer and probe connectors
- Remove the other connectors using an appropriate tweezers
- Unscrew with a wrench of 5 the five nuts of 3 MA
- Unscrew the screw of 5 MA that holds fixed the heat sink (top right)
- Replace the card with a new one
- It is advisable, once changed the card, to update the software using a new SD card and carefully storing the old
- It is then necessary to arrange the SETTING, CONFIGURATIONS and the OPTIONS of the
  autoclave and taking care to restore the original choices of the studio. It is important to apply to the
  manufacturer's the factory settings file (according to the serial number of the machine)



Always use a paste of White type transmission under the heatsink!

Give full attention to securing the heatsink and the box! In case of incorrect fixation it may burn the triaks of the electronic board!

65 / 97



#### The trimmer on the board controls the display REVERSE.



After replacing the electronic board, REGISTER YOUR TRIMMER tab to enhance the contrast!

# 10.0.11 REPLACEMENT OF THE BATTERY OF THE ELECTRICAL CARD (AUTHORIZED TECHINICIAN) CODE 5279

- Remove the cowling of the sterilizer
- Remove the existing stack and replace it with a new ORIGINAL
- Be careful putting it back in same position as the original
- Do not use pliers or metal
- The battery must not come into contact with metal parts

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#### 10.0.12 REPLACEMENT OF DISPLAY (AUTHORIZED TECHINICIAN)

- Disconnect from electronic card brown connector with blue wires connected and release it (for the moment do not disassemble display from the machine)
- Take the new display and connect the new brown connector to the electronic card
- Check that the new display work correctly. If everything is ok, proceed to remove the old display and replace with the new display.

#### 10.0.13 REPLACE PRINTER PAPER ROLL (USER)

- See its manual



Use only original rolls and place them in the right way!

#### 10.0.14 REPLACEMENT PIN DOOR (AUTHORIZED TECHINICIAN) COD.5040

- Obtain key 8/9 and Phillips screwdriver.
- With the machine's door open remove the 4 screws that support the front plastic
- Unscrew the stop pin
- Remove the pin and replace it with the new pin
- During the fixing make sure that the pin is soft, but it must not get out of its seat
- Screw the stop pin
- Try closing the door
- Replace the plastic front, moderately, with screw, washer, grommet

#### 10.1 SCHEDULED MAINTENANCE SUMMARY TABLE

C. I GOILE DELLE MAINTENANCE GOMMAN TABLE												
SUMMARY TABLE												
DESCRIPTION	Cat. INTERVALS											
	lubrica nts	At each start	Every 8 hours	Every 40 hours	Every 100 hours	Every 200 hours	Every 500 hours	Every 1000 hours	Every 6 month s	Every 2000 hours	Every 2 years	Every N° cycles
			,	<b>☆Electric</b> a	l safety te	est☆						
Visual inspection (any subsidence of isolation, burns)	-											2000 or 2 years
Check continuity of the earth												2000 or 2 years
Control of leakage currents (1)												2000 or 2 years
Functional test with the receipt issued												2000 or 2 years

(1) If the leakage is
At the limit of acceptability, it is necessary to provide as soon as possible... to the replacement of the filter code.

rena GB-R03 del 07-06-17												
			S	<i>UMMA</i>	<u>RY TAI</u>	BLE_						
DESCRIPTION	Cat.	INTERVALS										
	lubrica nts	At each start	Every 8 hours	Every 40 hours	Every 100 hours	Every 200 hours	Every 500 hours	Every 1000 hours	Every 6 month s	Every 2000 hours	Every 2 years	Every N° cycles
			☆N	<b>Mechanica</b>	l Mainten	ance☆						
Cleaning water filter	-											2000 or 2 years
Clean door gasket	-		*									
General cleaning of exterior and interior surfaces	-		*									
Cleaning the sterilization chamber	-			*								
Cleaning support for trays and cleaning trays	-			*								
Lubrication of hinges and locking mechanism	-					*						
Bacteriological filter replacement	-											400
Control door regulation	-											2000 or 2 years
Replacing door gasket and pin	-											990
		7	Electr	ical / elect	ronic Ma	intenand	ce 🖈					
Control actuators	-											2000 or 2 years
Check the integrity of the flexible cable and of the plug power supply (in case of damage replace)	-			*								

**☆** Guarantee Slips**☆** 

40.0			1	1	l	l		1
1° Guarantee slip with replacement and/or								
control of:								
<ul><li>membrane gaskets of vacuum</li></ul>								
pump								
group Vaporizer								
drain valve								
• 3-way valve								2000
• control door lock	-							or 2
<ul> <li>Control ACTUATORS</li> </ul>								years
<ul><li>cleaning tanks</li></ul>								
<ul> <li>Water filters</li> </ul>								
<ul><li>metal filter</li></ul>								
<ul><li>micro switch</li></ul>								
<ul> <li>Pump group of tanks loading</li> </ul>								
<ul><li>valve purifier</li></ul>								
2° Guarantee slip with replacement and/or								
control of:								
<ul><li>membrane gaskets of vacuum</li></ul>								
pump								
<ul><li>group Vaporizer</li></ul>								
<ul><li>drain valve</li></ul>								
<ul><li>3-way valve</li></ul>								
<ul><li>control door lock</li></ul>	-							4000
<ul><li>Control ACTUATORS</li></ul>								
<ul><li>cleaning tanks</li></ul>								
<ul><li>Water filters</li></ul>								
<ul><li>metal filter</li></ul>								
<ul><li>micro switch</li></ul>								
<ul><li>Pump group of tanks loading</li></ul>								
<ul><li>valve purifier</li></ul>								
<ul> <li>3° Guarantee slip with replacement</li> </ul>								
and/or control of:								
<ul> <li>same as 2° guarantee slip</li> </ul>								
■ fan								
<ul> <li>Pressure Transducer</li> </ul>								
<ul><li>valve bacterial filter</li></ul>								6000
<ul><li>By-pass valve</li></ul>								UUUU
<ul> <li>temperature sensors T1 and T2</li> </ul>								
<ul><li>drain pipes</li></ul>								
<ul><li>Replace the batteries of the</li></ul>								
electronic board model. CR2032								
					<u> </u>			
		 		- 1	•	•	•	

#### 10.2 RECOMMENDED SPARE PARTS LIST

You should keep in your service area for the spare parts the details listed below that in case the sterilizer stops working, the details below may be useful to the TECHNICAL AUTHORIZED qualified during maintenance, avoiding the downtime lasts more than necessary, an event that in some cases can cause substantial damage to your business.

RECOMMENDED SPARE PARTS					
n°	denomination	quantity	s/n.	s/n. 70ommle	
1	Door Gasket	1	5030	-	
2	Bacteriological Filter	1	1067	-	
3	Power Cable	1	4404	-	
4	Pressure Transducer	1	5125	-	
5	Probe Double T1 T2	1	5123	-	
6	SD Card	1	4490	-	
7	Label Roll	1	K800262	-	
8	Float Tank Range	1	3907	-	
9	Water Filter	1	1484	-	
10	Bowie-Dick Test	1	3606	-	
11	Strip Test	1	4263	-	
12	Phials Spores	1	4344	-	
13	3-Way Complete Valve	1	3246	-	
14	Entry fuses	1	1542	-	
15	Cartridges for connecting water supply	1	4839	-	
16	Vaporizer group	1	5177	-	
17	Electro valve group	1	5181	-	
18	Load pump	1	5154	-	
19	Vacuum pump 18 lt	1	5104	-	
	Vacuum pump 23 lt.	1	5237		
20	Electronic card	1	5189	-	
21	Battery of the electronic card	1	5279	-	
22	Safety thermostat	1	5093	-	
23	Door pin	1	5040	-	



Use only original spare parts supplied by the manufacturer! It is required by those who perform maintenance to communicate the manufacturer the operations carried out.

#### 11 EMERGENCY - HOW TO COPE

#### 11.0 FIRE

#### FIRE EQUIPMENT

Water must not be used to extinguish fires, because it may react with materials with which it would meet, causing the significant increase in temperature or the emission of flammable gases and / or dangerous.

#### Use, unless contraindicated, powder extinguishers CO2.

In close proximity to the machine, it must always be prepared, at least one extinguisher of approved type and of sufficient size:

• features and minimum requirements for fire equipment have to be evaluated in relation to the environment where the machine is placed and in relation of the user or users' risk factors.

Features and requirements of fire equipment specified in this U.M.M., are minimal and are not binding and do not release the buyer (in the country of use), from any obligations arising from standard regulations and/or laws, in prevention and fire protection.

The fire equipment must be maintained in efficient and periodically inspected by qualified and authorized personnel, according to the deadlines prescribed by the relevant rule.



Present fire extinguishers must be inspected once every law (in Italy at least every six months).

#### NOXIOUS EMISSIONS IN CASE OF FIRE

Noxious emissions released from the machine, in case of fire, are caused by the combustion of (non-exhaustive list):

- Paints,
- Textiles.
- Plastic materials
- Electrical equipment in general.
- The precautions are those normal in the event of a fire and dictated by the specific case.

### **12 SOLUTION TO FAILURES**

PROBLEM	CAUSES	ACTION				
The autoclave does not turn on	<ul><li>The main switch is off</li><li>No power outlet</li><li>Faulty cable</li></ul>	<ul> <li>Turn on the power switch</li> <li>Check the installation</li> <li>Replace the cable</li> </ul>				
Loss of water in front of the machine during the cycle	<ul> <li>Gasket worn</li> </ul>	Replace the gasket				
Presence of water within the chamber at the end of the sterilization cycle	<ul> <li>Problem inside the machine</li> </ul>	Contact authorized service centre				
Sterilized instruments with spots or rust	<ul> <li>Tools are not perfectly dry</li> <li>Chemical residues on the tools</li> <li>Tools are not perfectly clean</li> <li>Tools made of different materials wrapped together</li> <li>Sterilization chamber not clean</li> <li>Load water of poor quality see paragraph "water quality"</li> <li>Cutters or similar tools not properly wrapped</li> </ul>	<ul> <li>Dry thoroughly the tools before the sterilization</li> <li>Rinse carefully the tools</li> <li>Clean tools carefully</li> <li>Place on several trays the tools of different material</li> <li>Always keep the chamber clean - see paragraph "cleaning and maintenance"</li> <li>Use water with features referred to paragraph "water quality"</li> <li>See paragraph "load preparation"</li> </ul>				
Tools that change colour	<ul> <li>Choice of the wrong cycle</li> <li>Tools fallen in the bottom of the chamber</li> </ul>	<ul> <li>Always follow the tools manufacturer's instructions</li> <li>Ensure the correct conditions to restore load water</li> </ul>				
The display does not light	<ul><li>Fuse no. 1 burned</li><li>Flat cable not connected</li></ul>	Replace the fuse (identify the cause)     Connect the flat cable				
The door will not open.	<ul> <li>The device is delivered with the locked door</li> </ul>	Options     Opening door  If the door does not open, contact the service center.				
Error message on the display	<ul> <li>Operating error</li> </ul>	Press the up arrow and down arrow keys simultaneously for at least 20 seconds				
To break the cycle	<ul> <li>Various reasons</li> </ul>	Press the start button until it beeps				

#### INTERRUPTION OF THE STERILIZATION CYCLE

#### **VOLUNTARY INTERRUPTION** during the depression phase without introduction of water in the chamber:

- 1. Acoustic signal with the writing on the display CYCLE INTERRUPTED
- 2. Opening of the valve of the bacterial filter (no.7). The sterilizer comes to ambient pressure.
- 3. Starting of the vacuum pump (No.3) and electrovalve drain ignition (no.5) for a few minutes.
- 4. Opening of the three-way valve (number 6) up to 600 mbar
- The sterilizer stops and the bacterial filter is activated .At ambient pressure, the door opens automatically and the display will show the message CYCLE INTERRUPTED - LOAD NOT STERILE
- 6. Press START to remove the warning message.

#### > LACK OF POWER TO THE STERILIZER:

- 1. Acoustic signal with a message on the display showing ALARM a0002 LOAD NOT STERILE
- 2. Opening of the valve of the bacterial filter (no.7). The sterilizer reaches the ambient pressure.
- 3. Starting of the vacuum pump (No.3) and electrovalve drain ignition (no.5) for a few minutes.
- 4. Opening of the three-way valve (number 6) up to 600 mbar.
- 5. The sterilizer stops and the bacterial filter is activated. To open the door go in the MENU, OPTIONS and select OPEN DOOR START -START.
- 6. The display will show PLEASE WAIT. After a few seconds the door will open.
- 7. In the event that the sterilizer fails to fall below 600 mbar, e.g. for a pump problem, after 4 minutes the door will open automatically, because the water inside the chamber will already have been eliminated.

#### VOLUNTARY INTERRUPTION during the SPECIAL cycle1

- 1. Acoustic signal with a message on the display showing ALARM CYCLE INTERRUPTED PLEASE WAIT
- 2. See points as described above
- 3. In the event the power failures to work while the sterilizer is being emptied (PLEASE WAIT) and returns the current, the machine returns to the MENU '. It will open the door manually as in step 5.

#### > VOLUNTARY INTERRUPTION during the SPECIAL cycle1 during the sterilization phase

- 1. Acoustic signal with a message on the display showing ALARM INTERRUPTED CYCLE-PLEASE WAIT
- 2. Opening of the valve (no.5) and valve (No.4), the fan starts working, (no. 19).
- 3. Discharge water up to 1100 mbar
- 4. Starting of the vacuum pump (No.3) and opening of the valve (number 6) with the creation of vacuum inside the chamber for a few minutes
- 5. On the display-CYCLE INTERRUPTED LOAD NOT STERILE
- 6. Door opens automatically when achieving 600mbar.

#### > VOLUNTARY INTERRUPTION during the SPECIAL cycle1 during the drying phase

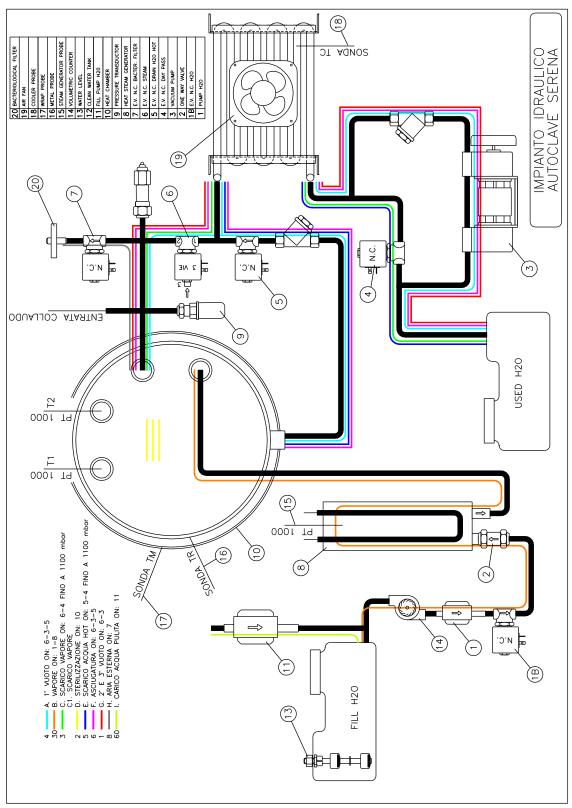
- 1. Acoustic signal with a message showing on the display CYCLE INTERRUPTED
- 2. Opening the valve of the bacterial filter (no.7). The sterilizer comes to ambient pressure.
- 3. Starting of the vacuum pump (No.3) and ignition of the electrovalve drain (no.5) for a few minutes. The fan starts working nr.19).
- 4. Opening the three-way valve (number 6) up to 60 mbar.
- 5. The sterilization stops and the bacteriological filter starts working. At ambient pressure, the door opens automatically and the display will read-CYCLE INTERRUPTED LOAD NOT STERILE
- 6. Press START to remove the warning message.

NOTE: ALL TRANSACTIONS DESCRIBED ABOVE HAVE BEEN STUDIED TO PREVENT RELEASE OF WATER FROM THE STERILIZATION CHAMBER.

3 TECHNIC	AL FEATURES	AUTOCLAVE "SERENA"		U.M
		SERENA 18 LT.	SERENA 23 LT.	
<u>Sterilizer</u>	L L	2200	2200	W
	Power sterilization chamber	1250	1250	W
	Working pressure	2,1 – 1,1 3100-2100 (absolute)	2,1 - 1,1 3100-2100 (absolute)	Bar mBar
<u>Steam generator:</u>	Electrical power	230 Vca ~ 50Hz monophase – 10 A	230 Vca ~50Hz monophase – 10 A	~
	Max. power consumption	1050/1100	1050/1100	W
terilization chamber		2,1 – 1,1 3100-2100(absolute)	2,1 - 1,1 3100/2100(absolute)	Bar mBar
	Max. temperature	180°	180°	°C
	Voltage	230	230	~
	Max. pressure	2,5 3500 (absolute)	2,5 3500 (absolute)	Bar mBar
	Max. temperature	140°	140°	°C
	Safety valve	2,5 3500 (absolute)	2,5 3500 (absolute)	Bar mBar
	Bacteriological filter	0,027	0,027	μm
	Temperature / Operating humidity	Da +5° a +29° C / 0-90%	Da +5° a +29° C / 0- 90%	-
	Max. altitude	2800 slm	2800 slm	m
	Minimum atmospheric pressure	0,5	0,5	Bar
	FLEXIBLE ELECTRIC CABLE LENGTH	2	2	m
	PLUG POWER EQUIPMENT	si	Si	-
	Power commands	24	24	V
AXIMUM NOISINESS E	QUIPMENT	62	66	dB
	TOTAL WEIGHT (NET)	(45) 441,5	(50) 490,5	(Kg) N
	TOTAL WEIGHT (GROSS)	(51) 500,3	(56) 549,4	(Kg) N
	PREDOMINANT COLOUR	Varnish RAL 9010	Varnish RAL 9010	
	BOILER	Ø 236 P. 360	Ø 236 P. 530	mm
MENSIONS	STERILIZER	L470Xh400XP630	L470Xh400XP700	mm
	PACKAGE	L580XH530XP760	L580XH530XP760	mm
	<u>Distilled water</u> WATER QUALITY	European standard EN13060 <15 μS/cm	European standard EN13060 <15 µS/cm	-
	MIN/MAX CONSUPTION	0,32L/0,57L POROUS LOAD	0,42L/0,62L POROUS LOAD	-

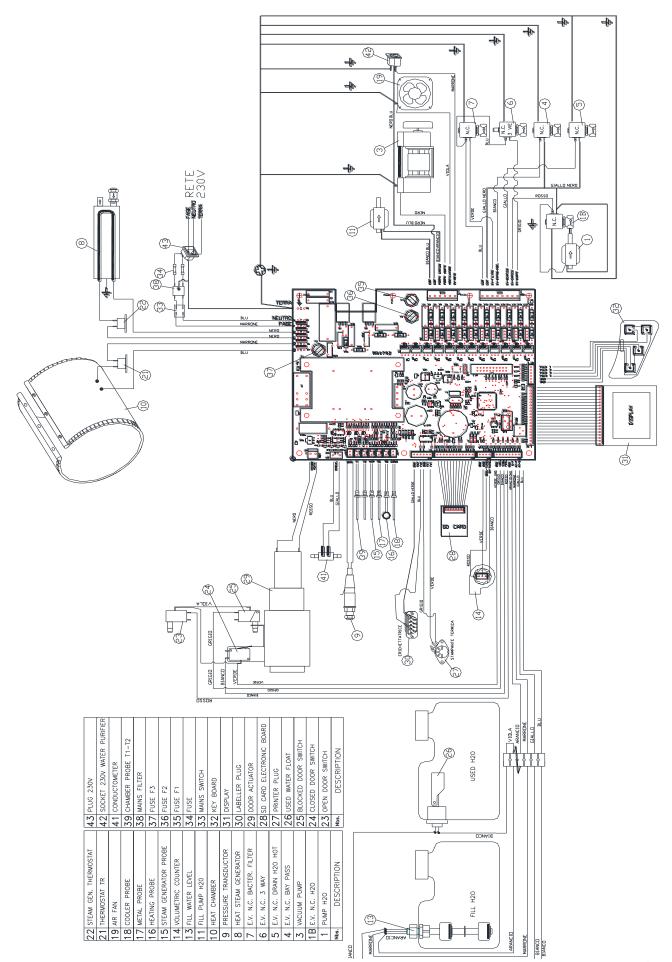
#### 14 APPENDIXES

#### 14.0 HYDRAULIC DIAGRAM



- 4 = A. 1st. VACUUM ON: 6-3-5 /  $\emph{30}$  =  $\emph{B}$  . STEAM ON: 1-8 3 = C. STEAM DISCHARGE ON: 6-4 UP TO 1100 mbar / C.1STEAM DISCHARGE
- 2 = D. STERILIZER ON: 10  $\,/\,$  5 = E. HOT WATER DISCHARGE ON: 5-4 UP TO 1100 mbar
- 6 = F. DRYING ON: 6-3-5 / 1 = G. 2° AND 3° VACUUM ON: 6-3
- 8 = H. EXTERNAL WATER ON: 7 / 60 = I. CLEAN WATER LOAD ON: 11

#### 14.1 ELECTRICAL





If the display does not light, check the fuse near the transformer because it could be burned!

#### 14.1.1 NEW SOFTWARE INSTALLATION - PROCEDURE



It is recommended to use a new SD card of the same type! The old card must be downloaded on a PC and stored!



- Extract the SD card from the sterilizer
- 2. Save the SD card data on your computer
- 3. After saving the data, proceed with formatting the SD card (The formatting window must contain FAT 32)
- 4. Close the formatting
- 5. The new software will be sent by e-mail, so ensure to open the message in your inbox
- 6. Save the attachment. A window will open. Save on SD card.
- 7. Remove the SD card from the computer and move the small button of the SD card on LOCK
- 8. With the sterilizer OFF, insert the SD card
- 10. The display turns on automatically when the machine has loaded the new software
- 11. Wait a few minutes before turning off the machine or start a sterilization cycle.
- 12. To verify the successful update of the software, check directly on the SD card or control the printing of labels
- 13. If the software installation is successful, remember to remove from the SD card the LOCK (otherwise the card will not be recorded data sterilization) or insert a new SD card without LOCK.
- 14. For assistance, call 0039 522 875159 from 8 am to 12.30pm.

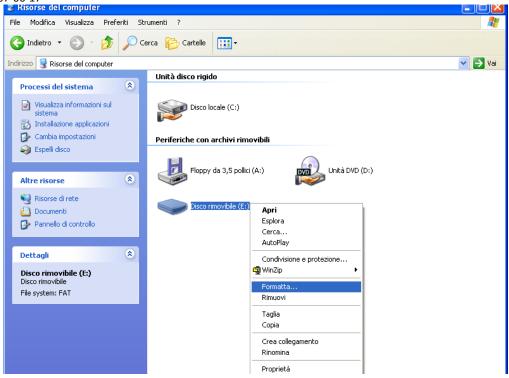
#### FORMATTING SD CARD



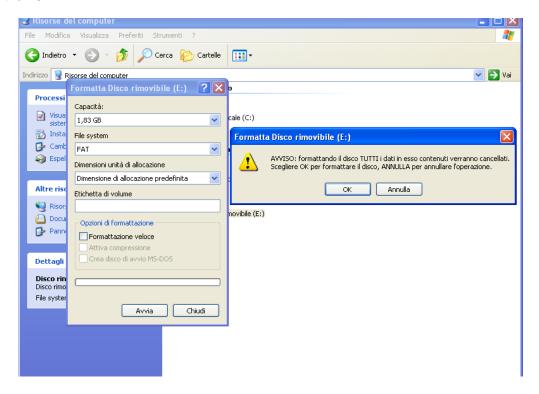
Warning! By formatting the SD card all presented data will be automatically deleted.

After entering the SD card to read, highlight the Removable Disk (E:) and by the right bottom highlight to format. show format

Serena GB-R03 del 07-06-17



#### Press START then OK



Once the formatting is complete, is it possible to enter the SD card in the autoclave .To copy a new software or for updates to the same, after formatting, using copy-paste, and copy on a removable disk (E:)



Warning! When you insert a new software or for updates and the SD card is removed, it is important that the machine is turned off After inserting the card, turn on the machine and make sure it does not lack the electrical system for at least one or two minutes.

#### 14.2 LABELLING

The following is an example, accompanied by brief description of the labelling that you will find on the device.



COMMERCIAL NAME MODEL CODE SERIAL NUMBER YEAR OF CONSTRUCTION

# 14.3 EXPLODED VACUUM PUMP KNF118279 4629 KNF016741 PM 21157-816.3 ESPLOSO CON CODICI DEI COMPONENTI

**EXPLODED WITH CODES OF THE COMPONENTS** 

#### 14.4 TEST

# TEST BOWIE & DICK



IT IS THE SPECIFIC TEST FOR MEASURING THE EFFICIENCY OF STERILIZATION LOADS FOR TEXTILE.

TIME OF TEST

Sterilization phase 3.5.minutes Drying phase 4 minutes

#### PERFORMANCE OF THE TEST

- The test should be run with empty chamber but leaving the port trays and all trays inside.
- Place the test package on the lower tray
- Select the program CYCLE B & D / HELIX
- TEST CYCLES -> B & D / HELIX
- At the end of the cycle, remove the test paying attention because it could still be very hot.
- Open the package and remove the chemical indicator. For a correct interpretation of results, follow the instructions of the manufacturer of the test package.

#### **TEST RESULT**

The result is positive if all radial strips of the test are toned getting dark.

You should keep STORED all test results in a register.

#### **TEST HELIX**



It is 'THE SPECIFIC TEST FOR MEASURING THE EFFICIENCY OF STERILIZATION FOR LOADS OF HOLLOW OBJECTS OF TYPE A

TIME OF THE TEST
Sterilizing Phase ....minute
Drying phase ... minutes

Important Note: There are two types on the market of the Helix test. Be sure to purchase one specifically for dentists.

#### PERFORMANCE OF THE TEST

- The test should be run with empty chamber but leaving the port trays and all trays inside.
- Place a test strip within the capsule and close carefully according to the instructions provided by the manufacturer of the test.
- Select the program CYCLE B & D / HELIX
- At the end of the cycle, remove the test paying attention because it could still be very hot.
- Open the capsule and remove the chemical indicator. For a correct interpretation of results, follow the instructions provided by the manufacturer of the test.

#### **TEST RESULT**

The result is positive if the indicator is tacked completely to black.

You should keep STORED all test results in a register.

#### **PROCESS INDICATORS**

Class	Description	Precision	Cycle
1	- Tape to close packages Small Tiles-on envelopes		Normal sterilization cycle
2	-Bowie & Dick Specific for porous loads		Appropriate test cycle
3	- Indicators that measure a parameter and monitor only the point where they are located.	2° on temperature 25% on time	Normal sterilization cycle
4	Indicators that measure two parameters, time and temperature.	1° on temperature 15% on time	Normal sterilization cycle
5	Indicators that measure three parameters, time, temperature and humidity.	1° on temperature 15% on time	Normal sterilization cycle
6	Helix-test. Measures three parameters,	1° on temperature 5% on time	Dedicated test cycle
	- Spore Test The spores must be placed inside the chamber. At the end of the sterilization cycle they must return to the chamber temperature and incubated for at least two days. Incubation of spores can take place directly in the sterilizer Serena using the appropriate SPORE TEST cycle		Normal sterilization cycle

The indicators specified above should be used at each sterilization cycle

The belonging class is written on the packaging of the indicator

Test results should be archived and stored

If the tone is not correct, repeat the test. Contact the technical support if the tone is still wrong.

ISO 11140-1

SERENA 18 ONLY B CYCLE Ver. 0.27

> S/N 000000 Nr.CYCLE 0000 CYCLE: HELIX - BOWIE & DICK OPERATOR CODE 04 DATE 00-00-00 TIME 00:00:00

PHASE TIME TøC P mbar 00:00:03 108.2 START 960 VAC1 00:03:45 106.2 138 P1 00:04:09 111.5 1315 VAC2 00:07:08 105.6 139 P2 00:07:56 113.9 1301 VAC3 00:11:27 98.5 139 00:11:43 102.2 PPH 1004 STRs 00:15:45 137.0 3254 MINt 00:17:42 135.8 MAXt 00:15:47 137.1 MINp 00:17:39 3085 ---.-MAXp 00:15:47 3256 00:19:15 136.7 STRe 3180 DRYs 00:19:15 136.7 3181 D00 00:20:47 121.3 1099 D01 00:21:09 115.5 498 D02 00:23:45 111.4 901 DRYe 00:24:15 109.0 609 CYCLE OK

SERENA 23 ONLY B CYCLE Ver. 0.27

\_\_\_\_\_

S/N 000000 Nr.CYCLE 0000 CYCLE: HELIX - BOWIE & DICK OPERATOR CODE 04 DATE 00-00-00 TIME 00:00:00

PHASE TIME TøC P mbar 00:00:03 27.3 START 967 VAC1 00:04:21 35.4 144 P1 00:10:22 102.2 1323 VAC2 00:17:16 62.0 168 P2 00:20:58 106.0 1304 VAC3 00:28:28 67.2 172 PPH 00:31:06 98.2 1002 STRs 00:38:45 136.3 3277 MINt 00:39:50 136.2 00:39:06 136.6 MAXt MINp 00:40:02 3265 ---.-MAXp 00:40:54 3299 STRe 00:42:15 136.4 3286 DRYs 00:42:15 136.4 3286 D00 00:44:19 104.8 1095 D01 00:44:41 89.9 498 D02 00:46:55 72.5 901 DRYe 00:47:15 70.2 687 CYCLE OK

#### 14.5 SCHEDULED MAINTENANCE COUPONS



FOR THE AUTHORIZED TECHNICIAN

Form 93/A

# SPARE PARTS KIT

#### Serena

To activate the warranty of the equipment and the proper functioning of the same, in addition to the bulletin installation, it is necessary to perform the scheduled maintenance. In this respect below you will find coupons for periodic maintenance.

For every action made by you, the coupon at the bottom must be completed and returned to us, .

#### SCHEDULED MAINTENANCE WITHIN THE FIRST 1000 CYCLES

Coupon within the first 1000 cycles:

Check if the daily maintenance are run, such as:

✓ Cleaning the door

WITHIN THE FIRST 1000 CYCLES

- ✓ Cleaning of the chamber, trays and port trays
- ✓ Check that the water used is distilled, clear and not recycled
- ✓ Check the quality of the water with the appropriate tool
- ✓ Check that the clean water tank is in a good condition and that inside there is clear water without algae and other impurities
- ✓ Replace the door gasket and check the regulation
- ✓ Replace the bacteriological filter
- ✓ Check the integrity of cables and plugs
- ✓ Check the metal filter inside the chamber
- ✓ Replace the door pin

Please complete	Please complete and mail to our address or fax number 0039 (0) 522 875579. Thank you.					
COUPON WITHIN 1000 CYCLES						
Date	Date Serial Number					
Model of autoclave	At the studio of					
Address:						
Post Code: City:	Post Code: City:					
		reverberi				
STAMP AND SIGNATURE OF THE STUDIO	STAMP AND SIGNATURE OF THE TECHNICIAN	Via Don Luigi Sturzo, 6-42021 BIBBIANO ( Reggio Emilia ) ITALY				

83 /97



#### FOR THE AUTHORIZED TECHNICIAN

**SPARE PARTS KIT** 

#### Serena

## **SCHEDULED MAINTENANCE WITHIN TWO YEARS OR 2000 CYCLES**

#### Coupon on Payment:

	Quantity	Code	Components description	REPLACED	REVISED	CONTROLLED
	4 per 5104 6 per 5237	KNF118279	Gasket vacuum pump			
	1	5695	Vaporizer group			
	1	5104	Vacuum pump 18 lt.			
	1	5237	Vacuum pump 23 lt.			
	1	3028	Discharge electro valve			
	1	3246	3-ways electro valve			
	1	3028	Purifier electro valve			
	1	5158	Door micro switch			
WITHIN 2000 CYCLES	1	5040	Door pin			
00 C	Registration	and control doc	or pressure			
V 20	Replaceme	nt water filter				
IHH.	Cleaning ta	nks				
3	Lubrication door plug					
	Control acti	uators				
	Control tem	perature param	eters / pressure and test cycles			
	Control me	tallic filter inside	the chamber			
	Electrical sa	fety test				
	Replaceme	nt of <b>SAFETY THE</b>	RMOSTATS of the heaters			
		-	nce are performed, such as:			
	✓ CI	neck the water q eaning the door, eaning the exter	uality the gasket and the sterilization chamber ior of the sterilizer			
	Send a copy of the revised delivery note to the manufacturer.					

Please complete and mail to our address or fax number 0039 (0)522 875579 Thank you.

COUPON W	ITHIN 2000 CYCLES OR T	WO YEARS
Date	Serial Number	
Model of autoclave	At the studio of	
Address:		
Post Code: City:		
STAMP AND SIGNATURE OF THE STUDIO	STAMP AND SIGNATURE OF THE TECHNICIAN	reverberi Via Don Luigi Sturzo, 6 42021 BIBBIANO ( Reggio Emilia ) ITALY



#### FOR THE AUTHORIZED TECHNICIAN

**SPARE PARTS KIT** 

#### **SERENA**

#### **SCHEDULED MAINTENANCE WITHIN 4000 CYCLES**

#### Coupon on Payment:

	Quantity	Code	Components description	REPLACED	REVISED	CONTROLLED
	1	5695	Vaporizer group			
	1	5104 5237	Vacuum pump 18 lt. Vacuum pump 23 lt.			
	1	3028	Discharge electro valve			
	1	3246	3-ways electro valve			
	1	3028	Purifier electro valve			
	1	5158	Door micro switch			
ES	1	5040	Door pin			
WITHIN 4000 CYCLES	Registration and control door pressure					
000	Replacement water filter					
1N 4	Cleaning tar	nks				
MHIN	Lubrication door plug					
_	Control actuators					
	Control temperature parameters / pressure and test cycles					
	Control metallic filter inside the chamber					
	Electrical sa	fety test				
	Replacemer	nt of <b>SAFETY TH</b>	HERMOSTATS of the heaters			
	✓ Cł ✓ Cl ✓ Cl	neck the water eaning the doc eaning the exte	quality or, the gasket and the sterilization chamber erior of the sterilizer delivery note to the manufacturer.			

Please complete and mail to our address or fax number 0039 0522 875579 Thank you.

COUPON WITHIN 4000 CYCLES				
Date	Serial Number			
Model of autoclave	At the studio of			
Address:				
Post Code: City:				
STAMP AND SIGNATURE OF THE STUDIO	STAMP AND SIGNATURE OF THE TECHNICIAN	reverberi Via Don Luigi Sturzo, 6 42021 BIBBIANO ( Reggio Emilia ) ITALY		



#### FOR THE AUTHORIZED TECHNICIAN

**SPARE PARTS KIT** 

#### **SERENA**

### **SCHEDULED MAINTENANCE WITHIN 6000 CYCLES**

#### **Coupon on Payment:**

	Quantity	Code	Components description	SUBSTITUTED	REVISED	CONTROLLED
	4 per 5104 6 per 5237	KNF118279	Gasket vacuum pump			
	2 per 5104 3 per 5237	KNF052066	Membrane vacuum pump			
	1	5695	Vaporizer group			
	1 1	5104 5237	Vacuum pump 18 lt. Vacuum pump 23 lt.			
	1	3028	Discharge electro valve			
	1	3246	3-ways electro valve			
	1	3028	Purifier electro valve			
	1	5158	Door micro switch			
	1	4361	Fan 18 lt.			
	1	5192	Fan 23 lt.			
	1	5125	Pressure transducer			
S <sub>T</sub> TES	1	1067	Bacteriological filter electro valve			
CXC	1	3028	Bypass electro valve			
2000	1	5123	Temperature sensors T1 and T2			
WITHIN 6000 CYCLES	1	5244	Discharge pipes			
ΗV	1	5279	Batteries electronic card mod. CR2032			
_	1	5040	Door pin			
	Registration	and control do	or pressure			
	Replaceme	nt water filter				
	Cleaning ta	nks				
	Lubrication	door plug				
	Control acti	uators				
	Control tem	nperature param	eters / pressure and test cycles			
	Control me	tallic filter inside	the chamber			
	Electrical sa	fety test				
	Replaceme	nt of <b>SAFETY THE</b>	ERMOSTATS of the heaters			
	Check if the	daily maintenar	nce are performed, such as:			

- Check the water quality
- Cleaning the door, the gasket and the sterilization chamber
- Cleaning the exterior of the sterilizer

Send a copy of the revised delivery note to the manufacturer. **IMPORTANT! AFTER 6000 CYCLES, CONTACT THE MANUFACTURER FOR THE FUTURE MAINTENANCE.** 

STAMP AND SIGNATURE OF THE STUDIO STAMP AND SIGNATURE OF THE TECHNICIAN

reverberi
Via Don Luigi Sturzo, 6
42021 BIBBIANO ( Reggio Emilia ) ITALY

#### 14.6 FORM TO FILL IN FOR THE RETURN OF THE EQUIPMENT



REVERBERI ARNALDO S.R.L Via Don Luigi Sturzo n°6 42021 Barco di Bibbiano Reggio Emilia – ITALY Tel. 0039 522 875159 Fax. 0039 522 875159 E-mail: reverberisrl@gmail.com

Numero REA: 180051 C.C.I.A.A di Reggio Emilia Partita IVA, CodiceFiscale e reg. imprese di R.E. 01363800358 FORM FOR THE RETURN FOR THE REPARATION OF AUTOCLAVES MODEL SERENA Mod. 94/B

To be filled by the technician or an authorized person

Autoclave model		Serial Number				
Purchase Ir	nvoice Nbr	Dated				
REASON FO	OR RETURN TO THE MANUFACTURER:					
☐ REPAIR F	FEE	☐ EXTRAORDINARY MAINTE (According to regulation E	ENANCEWITH SAFETY TESTING (N61010)			
.□ PERIOD	IC INSPECTION	□ OTHER				
According t	to regulation EN 13060					
PROBLEM	FOUND: Which message appears on the display	/?				
	· , ,					
ISTRUCTIO	NS FOR THE RETURN OF THE AUTOCLAVE :					
	efore sending back the machine please send us	this form filled by fax to the n	umber 0039 522 875579 and Inlease			
	ait the authorization for the shipment that mus					
	nauthorized or not agreed shipments won't be					
	efore sending back the machine, empty both wa	•	ter) Remove the travs and travs-holder			
	nd keep them.	(				
	nd back the autoclave packed in the original pa	ckaging in which it was purch	ased. In absence of the original			
	acking please pack the machine in a suitable pa					
1	e intervention on the machine will follow our in					
-	cludes a control and a possible update for a per		4			
6) Af	ter taking vision of the machine, will be sent youtened to a sent youtened to sent youtened to sent your charge with payment on deliver	ou a detailed quote. The quote ed tacitly rejected and the ma	chine will be sent back to you NOT			
	case of non-acceptance of the quote, we will p					
	anaging of the appliance.	<u> </u>				
8) Re	equest for machines in loan use, will be carried 50,00.	out according to availability a	and, with a monthly charge for use of			
	andard repairs time: 3 weeks					
-	gent repairs time: 7 working days with a price i	ncrease of € 50.00 for the ur	gency.			
	s mentioned above are NET		5667.			
	te: any unforeseen events that may occour du	ring repair (not foreseen in t	he quotation) will be quantified at the			
time of inv		( ( )				
□ACCEPTA	ANCE OF THE REPAIR AND WAITING FOR THE C	QUOTE	EPAIR			
Date:	Stamp and	I signature				

#### 14.8 WARRANTY CERTIFICATION



Hereby certify the correct construction of the equipment.

The device that within the warranty period manifests irregularities in the running for manufacturing defects will be repaired at the sole discretion of the house.

The sterilization chamber is covered by a period of 60 months from date of purchase and must be evidenced by returning the attached coupon, duly stamped and signed by the technician who took pat to the installation course. In case of dispute will be valid the delivery note / sale invoice or delivery invoice.

The electric and electronic parts, screws, are guaranteed for a period of 12 months.

The warranty is limited to the replacement or refurbishment of spare parts or parts that prove defective manufacturing, excluding expenses, or call.

Any particular replaced must be returned prepaid. Any piece that is not returned will be billed to the payer.

#### • THE WARRANTY IS NO MORE VALID:

- 1. If the equipment is repaired, modified or tampered with by the purchaser or unauthorized third parties
- 2. If the customer does not perform the proper and constant maintenance on this manual
- 3. If the buyer does not talk to the dealer or authorized service centre
- 4. After 12 months from date of purchase proven by the sales document
- 5. If the customer delays or suspends payments
- 6. If the equipment shows damages caused by exposure to fire, spilled liquids, natural disasters, falls, however, causes not attributable to manufacturing defects
- 7. If the guarantee has been not duly completed, signed and returned in a timely manner
- **8.** If the customer makes improper use of the equipment, does not administer the ordinary maintenance or neglects elements principles of good maintenance

#### 14.9 VARIOUS FORMS

# 

Operator Code	Operator name	Date of assignment
01		
02		
03		
04		
05		
06		
07		
08		
09		
10		

#### DOCUMENTATION STERILIZATION CYCLES

# DOCUMENTATION STERILIZATION CYCLES

At the end of each sterilization cycle the form must be filled in attacking the chemical indicator used in the Helix test to the specific column.

The success of the sterilization process is documented by the colour of the indicator that from yellow is toned to a dark colour.

Date	Label	Helix indicator	Signature
	1		I

**UPDATE** 

# Control System Table

## STANDARD IEC 61010-2-040:2005

FUNCTIONS	FIGURES THAT CAN PERFORM THE FUNCTION	SIGNATURE
START OF THE OPERATIVE CYCLE	OPERATOR	
SELECTION OF THE OPERATIVE CYCLE	OPERATOR / SUPERVISOR	
MODIFICATION OF THE PARAMETERS OF THE OPERATION CYCLE	OPERATOR / SUPERVISOR	
MANUAL ADVANCEMENT THROUGH THE OPERATING CYCLE	NOT APPLICABLE	
MAINTENANCE	TECHNICIANS WITH TRAINING	
OPERATING CYCLE PROGRAM	MANUFACTURER	

**ORAGENT** 

#### 15 DECLARATION OF INSTALLATION

# WARRANTY CERTIFICATE AND STATEMENT OF SERVICE INSTALLATION

Copy for the medical.

INSTALLATION DATE	
-------------------	--

#### Technical course of installation, repair and maintenance

The technician who has carried out the installation of the sterilizer has previously attended the technical course and has been authorized by the manufacturer's for the installation and repair of such equipment

#### Installation according to the manual of use and maintenance

The technician who has carried out the installation of the sterilizer claims to have complied with all conditions that allow the correct installation of the device according to theuse and installation manual.

#### Instruction to the user, functioning and maintenance

The technician further declares to have properly instructed the user on the functioning of the machine with the support of the instruction manual and he declares to have explained the timing of scheduled and daily maintenance. See paragraph 11 MAINTENANCE.

#### Instructions to the user on the warranty conditions

The technician has also shown the warranty conditions as described in the use and maintenance manual.

#### Warranty form

The technician declares to have attached to this form the warranty model, which has been carefully filled in.

## WARRANTY CERTIFICATION



**EQUIPMENT:** 

Incollare etichetta matricola

The undersigned dealer certifies that the warranty conditions have been read and that the autoclave has been delivered and operated in accordance with the provisions of the manufacturer.

Installation date:	To the Doct:
Address:	Post Code
City:	Country

STAMP AND SIGNATURE OF THE DEALER

STAMP AND SIGNATURE OF THE DOCTOR/MANAGER

To be completed by the technician who has made the installation of sterilizer according to the DDM 93/42/CE replaced by Directive 2007/47/CE-D.lgs. 25.01.2010 n°37, attachment I. Copy for the medical.

INICTALL ATION DATE

#### 15 DECLARATION OF INSTALLATION

# WARRANTY CERTIFICATE AND STATEMENT OF SERVICE INSTALLATION

Copy to be sent to manufacturer.

INSTALLATION DATE	 

#### Technical course of installation, repair and maintenance

The technician who has carried out the installation of the sterilizer has previously attended the technical course and has been authorized by the manufacturer's for the installation and repair of such equipment

#### Installation according to the manual of use and maintenance

The technician who has carried out the installation of the sterilizer claims to have complied with all conditions that allow the correct installation of the device according to theuse and installation manual.

#### Instruction to the user, functioning and maintenance

The technician further declares to have properly instructed the user on the functioning of the machine with the support of the instruction manual and he declares to have explained the timing of scheduled and daily maintenance. See paragraph 11 MAINTENANCE.

#### Instructions to the user on the warranty conditions

The technician has also shown the warranty conditions as described in the use and maintenance manual.

#### Warranty form

The technician declares to have attached to this form the warranty model, which has been carefully filled in.

# WARRANTY CERTIFICATION



**EQUIPMENT:** 

Incollare etichetta matricola

The undersigned dealer certifies that the warranty conditions have been read and that the autoclave has been delivered and operated in accordance with the provisions of the manufacturer.

nstallation date:	To the Doct:
Address:	Post Code
City:	Country

STAMP AND SIGNATURE OF THE DEALER

STAMP AND SIGNATURE OF THE DOCTOR/MANAGER

To be completed by the technician who has made the installation of sterilizer according to the DDM 93/42/CE replaced by Directive 2007/47/CE-D.lgs. 25.01.2010 n°37, attachment I. Copy to be sent to manufacturer.