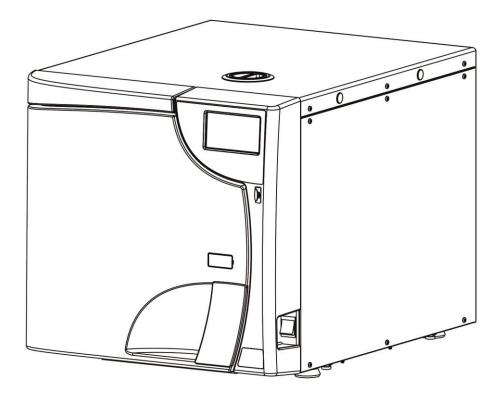
# BRAVO<sup>™</sup> G4

Chamber Autoclave



**Operator's Manual** 



Distributed by: SciCan Ltd. A Coltene Group Company 1440 Don Mills Rd., Toronto, ON, Canada, M3B 3P9 T +1-416-445-1600 TF +1-800-667-7733 customerservice@scican.com

Manufactured by: CEFLA s.c. Headquarter: Via Selice Provinciale 23/A 40026 Imola (BO) IT

### Contents

1.	FOREWORD	
	1.1. STMBOLS USED	
	1.3. RELEVANT EUROPEAN DIRECTIVES	5
	1.4. CLASSIFICATION 1.5. INTENDED USE	
	1.5. INTENDED USE	-
	1.6. GENERAL WARNINGS	-
	1.7. RESIDUAL RISKS	
	1.8. INFORMATION ON MITIGATION OF RESIDUAL RISKS	
	PACKAGE CONTENT	
	2.1. DIMENSION AND WEIGHT	
	2.3. PRODUCT HANDLING	-
	2.4. CONDITIONS FOR STORAGE AND TRANSPORT	
3.	GENERAL DESCRIPTION - PRODUCT PRESENTATION	11
	3.1. GENERAL CHARACTERISTICS	
	3.2. TECHNICAL SPECIFICATIONS	
	3.3. SAFETY DEVICES	
	3.4. WATER SUPPLY CHARACTERISTICS	15
	3.5. FRONT	
	3.6. REAR	
	3.8. EXAMPLE OF WORKING CYCLE	
4.	SETTING UP THE DEVICE	20
	4.1. OVERALL DIMENSIONS	21
	4.2. COMPARTMENT DIMENSIONS FOR BUILT-IN INSTALLATION	
	<ul> <li>4.3. GENERAL PRECAUTIONS FOR INSTALLATION</li></ul>	
	4.5. ELECTRICAL CONNECTIONS	23
	4.6. DIRECT CONNECTION TO A CENTRALISED DRAINING POINT	
	4.7. ANTI-DUST FILTER INSTALLATION	
5.	FIRST START-UP	
	5.1. STARTING	
	5.3. FILLING DEMINERALISED / DISTILLED WATER	27
	5.3.1. MANUAL FILLING	27
	5.3.2. AUTOMATIC FILLING	
6.	CONFIGURATION	
	6.1.1. LANGUAGE	20 28
	6.1.2. DATE AND TIME	29
	6.1.3. REMINDER	-
	6.1.4.1. USERS	
	6.1.5. PREFERENCES	32
	6.1.5.1. UNIT OF MEASUREMENT	
	6.1.5.2. DISPLAY	
	6.1.5.4. PREHEATING	
	6.1.6. SERVICE	36
	PREPARATION OF THE MATERIAL	
	7.1. TREATING THE MATERIAL BEFORE STERILISATION	-
	<ul> <li>7.2. ARRANGING THE LOAD</li> <li>7.3. POSITIONING AND USE OF TRAY HOLDER SUPPORT</li> </ul>	
	STERILISATION CYCLES	
ø.	8.1. EXTRA DRYING	
	8.2. DELAYED START	43
	8.3. EXECUTION OF THE CYCLE	
	<ul> <li>8.4. CYCLE OUTCOME</li></ul>	
	8.6. USER-DEFINED CYCLE	
9.	MATERIAL STORAGE	45
	. TEST PROGRAMS	
10	10.1. HELIX TEST / B&D CYCLE	
	10.2. VACUUM TEST CYCLE	47
	EN	3

10.3. VACUUM TEST + HELIX TEST/B&D CYCLE	48
10.4. H2O TEST	
10.5. DOOR OPENING	
10.6. MANUAL INTERRUPTION	
11. USED WATER DRAIN	
12. DATA MANAGEMENT & CONNECTIVITY	
12.1. USB MANAGEMENT	-
12.1.1. DIRECT DOWNLOAD	
12.2. WIFI	
12.3. PRINTERS	56
12.4. ETHERNET	58
12.5. G4 CLOUD	58
13. APPENDIX – PROGRAMS	
13.1. SUMMARY TABLE OF 17 220 V - 240 V CYCLES	60
13.2. SUMMARY TABLE OF 22 220 V - 240 V CYCLES	62
13.3. SUMMARY TABLE OF 28 220 V - 240 V CYCLES	-
13.4. STERILISATION PROGRAM DIAGRAM	
13.5. DIAGRAMS OF THE TEST PROGRAMMES	
13.6. EXAMPLES OF PRINTED REPORTS	-
14. APPENDIX - MAINTENANCE	
14.1. REGULAR MAINTENANCE PROGRAMME	
14.2. SCHEDULED MAINTENANCE MESSAGES	
14.3. DESCRIPTION OF MAINTENANCE INTERVENTIONS 14.3.1. DOOR GASKET AND THE INTERNAL PART OF THE DOOR CLEANING	
14.3.2. STERILISATION CHAMBER AND ACCESSORIES CLEANING	
14.3.3. EXTERNAL SURFACE CLEANING	-
14.3.4. CHAMBER FILTER CLEANING	-
14.3.5. DOOR LOCK LUBRICATION	-
14.3.6. ANTI-DUST FILTER CLEANING	
14.3.7. REPLACE THE BACTERIOLOGICAL FILTER	74
14.3.8. DOOR GASKET REPLACEMENT	
14.3.9. INTERNAL WATER RESERVOIR CLEANING	
14.4. PERIODIC STERILISER VALIDATION	
14.5. DEVICE USEFUL LIFE	
15. APPENDIX - GENERAL PROBLEMS	
15.1. TROUBLESHOOTING	77
16. APPENDIX – ALARMS	
16.1. ALARM INTERVENTION	79
16.2. ALARM DURING A CYCLE	
16.3. SYSTEM RESET	79
17. ALARM CODES	
17.1. ERRORS (CATEGORY E)	
17.2. ALARMS (CATEGORY A)	82
17.3. HAZARDS (CATEGORY H)	
17.4. SYSTEM ERRORS (CATEGORY S)	
17.5. TROUBLESHOOTING	
17.5.1. ERRORS (CATEGORY E)	
17.5.2. ALARMS (CATEGORY A)	
17.5.3. HAZARDS (CATEGORY H)	
18. USER PIN RESET	
19. APPENDIX - ACCESSORIES	
20. PRINTER CONNECTION	
21. APPENDIX - SPARE PARTS AND ACCESSORIES	
22. APPENDIX - TECHNICAL SERVICE	
23. APPENDIX - WARNINGS AND LOCAL REGULATIONS	

#### FOREWORD 1.

The instructions inform the user on how to properly operate the device. It is extremely important to read this manual carefully and thoroughly before using the device.

This publication must not be reproduced, copied or transferred in any manner (electronically, mechanically, via photocopies, translations or other means) without the prior written consent of the manufacturer.

The manufacturer has a company policy of continual development. Therefore, some of the instructions, specifications and figures given in this manual may slightly differ from the purchased product. The manufacturer reserves the right to make changes to this manual without giving prior notice. The original text is in Italian; this is a translation from the original in Italian.

#### 1.1. SYMBOLS USED



Pay particular attention to the paragraphs marked with the symbol shown.

Potential danger for people, environment and property. Follow the procedures indicated in the manual to prevent potential damage to materials, devices and/or property.

#### 1.2. SYMBOLS ON THE DEVICE



Potential danger due to high temperature.



Disposal symbol in accordance with Directive 2012/19/EU.



Device in compliance with essential requirements of Directive 93/42/EU and subsequent modifications. Notified body: IMQ spa

Device compliant with the requirements set out in the Directive

0474

Notified body: Rina Services S.p.A. Switch ON / OFF. 1/0

2014/68/EU (PED).

Fuses 2xT15A 250V. 

Refer to the user manual.

2xT15A 250V

#### **1.3. RELEVANT EUROPEAN DIRECTIVES**

The product described in this manual is manufactured in accordance with safety standards and doesn't represent any danger for the operator if used according to the following instructions. The product is complying with the following European Directives as applicable:

93/42/EEC, and subsequent amendments and additions, concerning medical devices. 2011/65/EU, (Rohs II) on restriction of hazardous substances in electrical and electronic devices. 2014/68/EU, (PED).

The product complies with Standard EN 13060:2014 + A1:2018.

#### 1.4. CLASSIFICATION

Classification of the device according to the rules indicated in Annex IX of Directive 93/42/EEC and subsequent modifications and integrations: CLASS IIB.

#### 1.5. INTENDED USE

The product described in this manual is only intended for sterilisation of reusable surgical instruments and materials.

#### DEVICE INTENDED FOR PROFESSIONAL USE



The use of the device is strictly reserved to qualified personnel. It must never be used or handled by untrained and/or unauthorised persons.

The device must not be used for the sterilisation of fluids, liquids or pharmaceutical products. The steriliser is not a mobile or portable device.

#### 1.5.1. IMPORTANT NOTES

Information contained in this manual is subject to change without notice. The manufacturer is not responsible for direct, indirect or accidental damage resulting from or relating to the provision or use of this information. This document may not be reproduced, adapted or translated, in part or in full, without the prior written permission of the manufacturer.

#### 1.6. GENERAL WARNINGS

When using this product, always follow the instructions in the manual and never use it for anything other than its intended purpose.



The user is responsible for any legal requirements relating to the installation and use of the product. The manufacturer will not be held responsible for any breakage, malfunction, property damage or injury to people in the event that the product is not installed or used correctly, or proper maintenance is not carried out.

Please observe the following precautions in order to avoid injury or property damage:

• Use ONLY demineralised / distilled water of high quality (IF THE DEMINERALISATION FILTER IS NOT PRESENT IN THE FILLING TANK).

The use of water of inadequate quality can severely damage the device. See technical characteristics appendix in this regard.

- Do not pour water or other fluids on the device.
- · Do not pour flammable substances on the device.
- Do not use the system in the presence of flammable or explosive gases or vapours.
- · Before performing any maintenance or cleaning intervention, ALWAYS DISCONNECT power supply.



Whenever it is not possible to disconnect the power supply from the device, or if the external mains switch is distant or not visible to the maintenance technician, place a "work in progress" sign on the external mains switch after having turned it off.

- Make sure the electrical system is grounded according to current laws and/or standards.
- Do not remove any label or nameplate from the device; request new ones, if necessary.
- · Use only original spare parts.



Failure to comply with the above exempts the manufacturer from all liability.





#### 1.7. RESIDUAL RISKS

#### FOR THE USER

- · Contamination due to improper handling of the load.
- Burn by contact with hot surfaces or fluids.

#### FOR THE PATIENT

- · Contamination due to unsterilised material caused by incorrect cleaning treatment before sterilisation.
- Contamination due to implementation of incorrect reprocessing procedures.
- · Contamination due to material unsuitable for sterilisation or not compliant with instructions for use.
- · Contamination due to unsterilised material caused by incorrect final assessment of sterilisation process.
- Contamination due to missing or incorrect scheduled maintenance.
- Contamination due to missing periodic validation.

#### **1.8. INFORMATION ON MITIGATION OF RESIDUAL RISKS**

#### FOR THE USER

#### Contamination due to improper handling of the load.

See chapter PREPARING THE MATERIAL.

#### Burn by contact with hot surfaces or fluids.

To extract the sterile material, once the sterilisation process has been completed with saturated steam at 121°C or 134°C, proceed as follows:

- Always wear PPE suitable for the handling of hot material and gloves of appropriate material and thickness.
- Clean your gloved hands with a germicide detergent.
- Always use the special tray extractor, supplied as standard, to extract the trays from the sterilisation chamber.
- · Avoid any contact of trays and material with contaminated and/or non-heat-resistant surfaces.
- · Handle the sterile material making sure not to damage any packages, bags and containers serving as a barrier.

#### FOR THE PATIENT

**Contamination due to unsterilised material caused by incorrect cleaning treatment before sterilisation.** See chapter TREATING THE MATERIAL BEFORE STERILISATION.

#### Contamination due to implementation of incorrect reprocessing procedures.

Make sure to use sterile material.

#### Contamination due to material unsuitable to sterilisation or not compliant with instructions for use.

- · Check that the contaminated material is compatible with the selected sterilisation process.
- Immediately separate the materials to be sterilised from those that must not be subjected to such process or are not able to withstand it.

#### Contamination due to unsterilised material caused by incorrect final assessment of sterilisation process.

The sterilisation process electronic control system monitors the various phases, at the same time checking that the various parameters are respected; if any type of anomaly is encountered during the cycle, the program is immediately interrupted, generating an alarm identified by a code, with a relative message explaining the nature of the problem.

Furthermore, the sterilisation process can be checked by means of:

#### CHEMICAL INDICATORS

That monitor the sterilisation process by providing information, together with the control of physical and biological parameters, on the conditions occurred in the sterilisation chamber during the process.

The final toning of the process indicator does not certify that the product is sterile but only that the device has been subjected to a sterilisation process. If the toning does not occur, the operator in charge of releasing the sterile material, that must not be used, must put all actions to avoid the use of the treated material.

#### PHYSICAL INDICATORS

They include the reading of machine data and the execution of specific tests indicated during the validation phase for that specific cycle/load/autoclave. This control system can include:

- Direct reading of the synoptic system (thermometer, pressure gauge, recorder, etc.).
- · Reading of prints/labels/files on which the data detected by the synoptic system are stored (parameters).
- Execution of specific tests (Vacuum test, Bowie&Dick test, Helix test) according to local guidelines.

The operator in charge of the process certifies the validity of the load at the end of every cycle by means of the parametric release.

#### Contamination due to missing or incorrect scheduled maintenance.

The steriliser, based on a preset programming, displays a warning message relating to the scheduled maintenance necessary to ensure the good operation of the device.

#### Contamination due to missing periodic validation.

See chapter PERIODIC STERILISER VALIDATION.

### 2. PACKAGE CONTENT

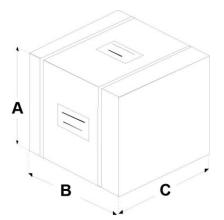
Check the integrity of the product package upon receipt.

#### 2.1. DIMENSION AND WEIGHT

Once the package is opened, check that:

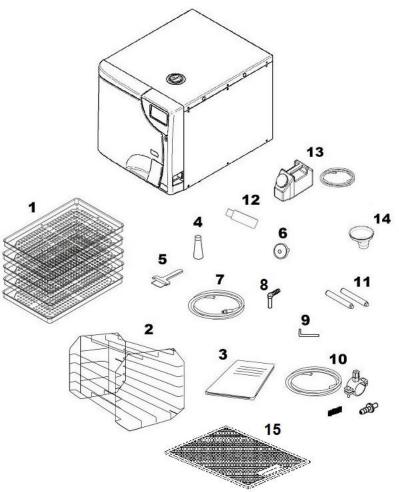
- The supply matches the specifications of the order (see the delivery note).
- There is no visible damage to the product.

Dimensions and weight	
A Height	600 mm
B Width	600 mm
C Depth	700 mm
Total weight	68 kg



In case of wrong delivery, missing parts or any type of damage, immediately inform in detail the reseller and the carrier that made the delivery.

### 2.2. DESCRIPTION OF THE CONTENT



In addition to the steriliser, the package contains:

- 1 Instrument trays:
  - 5 pcs for 17 and 22
    - 6 pcs for 28
- 2 Tray holder support
- **3** Operator's documentation and safety valve's EC Declaration of Conformity
- 4 Lubricant for door locking mechanism
- 5 Tray extractor
- 6 Additional bacteriological filter
- 7 Transparent silicone hose with quick coupling, for manual water drainage

- 8 Elbow hose connector
- **9** Allen wrench (for manual door unlocking)
- **10** Grey plastic tube for direct drainage, with fastening clamp, gasket, straight fitting
- 11 Rear spacers
- 12 USB key, containing user's manual
- **13** Bottle complete with silicone transparent tube and quick coupling, for manual water filling
- **14** Water filling funnel
- 15 Anti-dust filter

#### 2.3. PRODUCT HANDLING

The packed product must be handled using, where possible, suitable mechanical means (lift truck, pallet truck, etc.) and following the indications on the package.

In case of manual handling, the product must be lifted by two people using the suitable available means.

Lift the product from the underneath on the sides.

Do not lift / hold the device by applying force to the door and its hinge.

Once the steriliser has been removed from the package, it must be lifted by two people using the suitable available means and handled, if possible, using a truck or similar.



We recommend to transport and store the device at a temperature not below 5°C. Extended exposure to low temperatures may damage the product.

Store the original package and use it for any transport of the device. Using a different package may damage the product during shipping.

Before transport, leave the device turned off for about 30 minutes after the last program finishes and drain the filling and discharge tanks so that all the internal parts will have time to cool down.

#### 2.4. CONDITIONS FOR STORAGE AND TRANSPORT

TEMPERATURE: between +5°C and +70°C HUMIDITY: between 20% and 80% PRESSURE: between 50 and 110 kPa

#### **GENERAL DESCRIPTION - PRODUCT PRESENTATION** 3.

#### 3.1. GENERAL CHARACTERISTICS

The device is an electronic steam steriliser, entirely operated by a micro-processor, with a large, moulded stainless steel sterilisation chamber. It is characterised by an advanced fractionated vacuum system for the complete removal of air, even from hollow, porous materials, and an effective final vacuum drying phase capable of eliminating all traces of humidity from any load.

The exclusive steam generation system, the effective hydraulic circuit and the electronic management (integrated by high-precision sensors) ensures high execution speed of process and an excellent stability of thermodynamic parameters. Moreover, its Process Evaluation System constantly monitors all the machine's "vital" parameters in real-time, guaranteeing absolute safety and a perfect result.

The device offers users 6 sterilisation programs (one of which completely programmable), all equipped with customisable, optimised drying for the effective sterilisation of the various types of load (instruments and materials) used in a medical environment. All the cycles can be selected on the clear LCD screen, which also allows extensive configuration of the device according to the user's needs.

Like in the best tradition, the new range of autoclaves feature the most complete and advanced safety systems available today, to ensure the user against any operation, electrical, mechanical, thermal or functional fault.

For the description of safety devices, refer to Technical Characteristics appendix.

### 3.2. TECHNICAL SPECIFICATIONS

### 3.2.1. SUMMARY TABLE

Device	STEAM STERILISER			
	Bravo G4 17	Bravo G4 22	Bravo G4 28	
Class (according to Directive 93/42/EEC and subsequent amendments)		llb		
Manufacturer	CEFLA s.c. Sede legale - Headquarter Via Selice Provinciale 23/A – 40026 Imola (BO) IT			
Input voltage	220 V - 240 V~ 50 Hz 220 V - 240 V~ 60 Hz			
Network fuses				
(6.3 x 32 mm)		2x T15A 250V		
Electronic board fuses (5 x 20 mm)	F1: T3.15A 250V (tra	ansformer primary 220/240 V~ 50 Hz	z 220/240 V~ 60 Hz)	
Nominal power		2300 W		
Insulation class		Class I		
Installation category (according to EN 61010)		Cat. II		
Operational environment	(EN 6	Indoor use HUMID LOCATION 1010 extended environmental condi	tions)	
A-weighted sound power level (ISO 3746)	(	< 67 db (A)		
Degree of protection (IP Code) (EN 60529:1991+A1:2000+A2:2013)		IP21		
Environmental operating conditions	Relative humi	Temperature: +15°C ÷ +35°C dity: between 20% and 80% max. no	n-condensing	
External dimensions (HxWxD)		456 x 480 x 600 mm		
(rear connections excluded) Net weight:				
unladen	approx. 49.60 kg	approx. 51.30 kg	approx. 53.40 kg	
unladen, with tray holder support and trays	approx. 51 kg	approx. 53 kg	approx. 56 kg	
unladen, with tray holder support, trays and water at MAX. level	approx. 56.50 kg	approx. 58.50 kg	approx. 61.50 kg	
Sterilisation chamber dimensions (D x D)	250 x 350 mm	250 x 450 mm	280 x 450 mm	
Sterilisation chamber total volume	approx. 17 l (0.017 cu. m)	approx. 22 l (0.022 cu. m)	approx. 28 l (0.028 cu. m)	
Sterilisation chamber usable				
volume (with tray holder support inserted)	approx. 10 l (0.010 cu. m)	approx. 13 l (0.013 cu. m)	approx. 19 l (0.019 cu. m)	
Sterilisation chamber usable dimensions	17 l (1.38x1.55x2.97) dm / 6.4 cu. dm	22 l (1.38x1.55x3.97) dm / 8.5 cu. dm	28 I (1.72x1.66x3.96) dm 11.3 cu. dm	
Water tank capacity (filling)	0.4 cu. um	approx. 5.5 I (water at MAX. level) approx. 1 I (water at MIN. level)	11.0 cu. um	
Sterilisation programs	5 standa	rd programs + 1 program defined by	the user	
		Helix/B&D Test		
Test programs		Vacuum Test Vacuum Test+Helix/B&D Test		
Pre-heating time (from cold)		approx. 10 min.		
USB connection	Key capacity lowe	r than or equal to 4GB: FAT formattin Keys capacity higher than 4GB: FAT32 formatting with 16K/sector	ng with 16K/sector	
Printer connection*	Seria	I RS232 (printer cable max. length 2	.5 m)	
Printer insulation class:	Class I or Class II			

Device	STEAM STERILISER			
Device	Bravo G4 17	Bravo G4 22	Bravo G4 28	
Printer power supply standard:	ard: Compliant with Standard EN 60950. (The safety of the steriliser may be compromised in case of uncertified printer power supply unit)			
220-240 V 50 Hz Main power cord       3x1.5 sq.mm cable from -         C19 connector according to IEC 6032         BS1363 plug 250V-13A         220-240 V 60 Hz Main power cord:       3x1.5 sq.mm cable from -		Plug CEE 7 / VII IEC 250V-16A 50 H 3x1.5 sq.mm cable from -25 to 70°C ctor according to IEC 60320 UL 498,	;	
		BS1363 plug 250V-13A 50/60 Hz 3x1.5 sq.mm cable from -25 to 70°C C19 connector according to IEC 6032		
Ethernet connection	RJ45 (max. cable length 29 m)			
WiFi	802.11 b/g/n (2.4 Ghz); WEP / WPA / WPA2-PSK encryption			
Bacteriological filter (filter element in PTFE)		Porosity: 0.027 microns Connection: male connector 1/8" NP	т	
Maximum flow of drained water Temperature of drained water Maximum temperature of drained water	1 l/min. 50°C 90°C			
Total heat in Joule sent by the steriliser to the surrounding air in 1 hour of continue operation	17 l = 3.6 MJ	22 I = 4 MJ	28 I = 5.4 MJ	
Manoeuvre/handling space	1 m x 1 m			

Device	Bravo G4 17	Bravo G4 22	Bravo G4 28
Class (according to Directive 2014/68/EU PED)	Category I	Category II	Category II
Working pressure	-0.8 ÷ 2.4 barg	-0.8 ÷ 2.4 barg	-0.8 ÷ 2.4 barg
Safety device set	2.4 barg	2.4 barg	2.4 barg
PT	500 kPa (abs)	500 kPa (abs)	500 kPa (abs)
PS	2.4 barg	2.4 barg	2.4 barg
TS	10 ÷ 140 °C	10 ÷ 140 ℃	10 ÷ 140 ℃
Fluid Group	2	2	2

\* Only the optional external printer Ref. M7D200012 is compatible with the BRAVO G4.

Please contact Customer Service to confirm other printer compatibility. Refer to the printer manual for startup and paper loading.

#### 3.3. SAFETY DEVICES

The steriliser is equipped with the following safety devices for which we provide a brief description of their function:

· Mains fuses (see data in summary table)

Protection of the whole device against possible failures of heating elements. Action: power supply interruption.

#### Electronic circuit protection fuses (see data in summary table)

Protection against possible failures of the primary circuit of the transformer and of low voltage users. Action: interruption of one or more low voltage circuits.

#### · Thermal circuit-breakers on mains voltage windings

Protection against possible overheating of pump motors and of transformer primary winding. Action: temporary cut-off (until cooling) of the winding.

#### Safety valve

Protection against overpressure in the sterilisation chamber. Action: release of the steam and restoration of the safety pressure.

### Safety thermostat with steam generator manual reset

Protection against steam generator overheating.

Action: cut-off of the electricity to the steam generator.

#### • Safety thermostat with chamber heating element manual reset

Protection against overheating of the heating elements of the container under pressure.

Action: cut-off of the electricity to the chamber heating element.

#### Door position safety microswitch

Confirmation of the correct closing position of the door of the container under pressure. Action: signalling of wrong door position.

#### · Motor-driven door lock mechanism with electromechanical protection (pressure switch)

Protection against accidental opening of the door (even in a blackout). Action: prevents accidental opening of the door during a program.

#### Door locking mechanism safety microswitch

Striker for the correct closing position of door locking system. Action: signalling of failed or wrong operation of door locking mechanism.

#### Self-levelling hydraulic system

Plumbing system structure for the spontaneous levelling of the pressure in the case of a manual interruption of the cycle, alarm or blackout. Action: automatic restoration of atmospheric pressure in the sterilisation chamber.

#### Integrated system for evaluating the sterilisation process

Continuous verification of the sterilisation process parameters entirely managed by microprocessor. Action: immediate interruption of the program (in case of malfunction) and generation of alarms.

#### Steriliser operation monitoring

Real-time oversight of all significant parameters when the machine is powered. Action: generation of alarm messages (in the case of anomaly) with possible interruption of the cycle.

#### 3.4. WATER SUPPLY CHARACTERISTICS

Only use demineralised / distilled water having the following characteristics to supply the steriliser.

DESCRIPTION	VALUES IN THE WATER SUPPLY	VALUES INSIDE RESIDUAL
DRY CONDENSATE	< 10 mg/l	< 1 mg/l
SILICONE OXIDE SiO2	< 1 mg/l	< 0.1 mg/l
IRON	< 0.2 mg/l l	< 0.1 mg/
CADMIUM	< 0.005 mg/l	< 0.005 mg/l
LEAD	< 0.05 mg/l	< 0.05 mg/l
HEAVY METAL RESIDUES (iron, cadmium and lead excluded)	< 0.1 mg/l	< 0.1 mg/l
CHLORIDES	< 2 mg/l	< 0.1 mg/l
PHOSPHATES	< 0.5 mg/l	< 0.1 mg/l
CONDUCTIVITY AT 20°C	< 15 µS/cm	< 3 µS/cm
pH VALUE	5 - 7	5 - 7
ASPECT	colourless, transparent, without sediment	colourless, transparent, without sediment
HARDNESS	< 0.02 mmol/l	< 0.02 mmol/l



When buying demineralised / distilled water, make sure that the quality and characteristics declared by the manufacturer are compatible with those specified in the table.

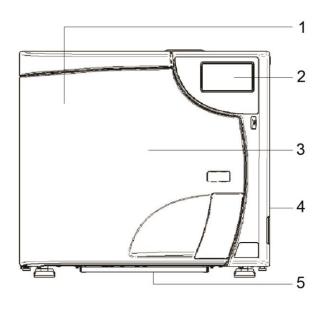
The use of water for steam generation with presence of contaminants with levels exceeding those indicated in the above table can greatly shorten steriliser lifetime.

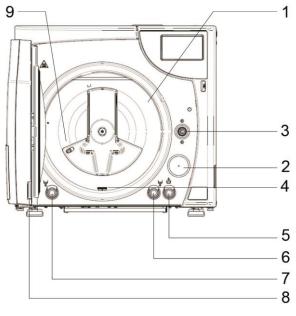
This could also result in an increase of oxidation in the most sensitive materials as well as in an increase of limescale residues on generator, boiler, internal supports, trays and instruments.

### 3.5. FRONT

- Model
- Control panel and LCD screen
- 1 2 3 4 5 Door
- Power switch
- Anti-dust filter

- Sterilisation chamber
- Bacteriological filter
- Door locking system
- Water drainage filter
- Front filling quick connector
- Clean water reservoir drainage quick connector
- Waste water drainage quick connector
- 123456789 Door
  - Steam diffuser



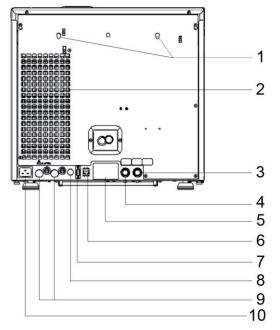


#### 3.6. REAR

- 1 Fastening slots for rear spacers
- 2 Heat exchanger
- 3 Connection for direct water drainage
- 4 Connection for automatic demineralised / distilled water filling (only for PURE 100 / 500, H<sub>2</sub>O AUX EV Kit (AUX SV) and Automatic Filling Accessory Kit)
- 5 Data plate

SERIAL NUMBER LABEL (See image \*)

- 6 Ethernet cable connection (max. length 29 m)
- 7 Serial cable connection
- 8 Automatic filling electrical connection (only for PURE 100 / 500 H<sub>2</sub>O AUX EV Kit (AUX SV) and Automatic Filling Accessory Kit)
   9 Network fuses
- 9 Network fuses10 Power cable connection



	MANUFACTU	JRER		
MOI	DEL	REF	TYPE	CODE
MAD	E IN			
TEC	HNICAL DATA			SYMBOLS
TEC	HNICAL DATA			STIVIDULS
TEC	HNICAL DATA			

EN 17

### 3.7. LCD ICONS

The screens in the following pictures may vary in shapes and colours, but their contents are the same as shown on the steriliser display.

-----

m.

Α Selection for data management & connectivity Α в С D BCDEF Selection of sterilisation and test cycles Time and date 18/12/2019 14:15 Button for quick download of new cycles System info selection Door unlock G Selection of the steriliser settings (Setup) Info CLES & TEST G Ε F

The screens in the following pictures may vary in shapes and colours, but their contents are the same as shown on the steriliser display.

#### 3.8. EXAMPLE OF WORKING CYCLE

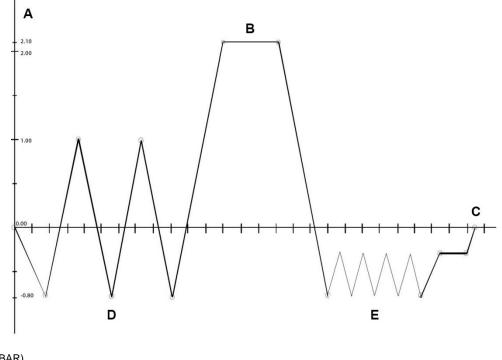
The sterilisation program can be effectively described as a succession of phases, each one with a very precise objective.

For example, the Universal program (cycle B, 134°C – 4 minutes): after loading the material in the chamber, closing the door, selecting the program and starting the cycle (after locking the door opening mechanism), the following sequence will occur (see the graph below):

- **1** Generator and sterilisation chamber pre-heating.
- 2 Air removal and steam penetration in the material through a series of vacuum (extraction of air and fluid from the sterilisation chamber) and pressure (injection of steam into the chamber) phases.
- 3 Pressure rises with the consequent increase in the temperature of the steam, until reaching the conditions required for sterilisation (in the example, 134°C).
- 4 Pressure and temperature stabilisation.
- 5 Load sterilisation for the required time (in the example, 4 minutes).
- 6 Sterilisation chamber depressurisation.
- 7 Vacuum drying phase.
- 8 Load ventilation, by means of sterile air.
- 9 Pressure levelling, bringing the sterilisation chamber back to the atmospheric pressure level.

Having reached this last phase, you can unlock the door and remove the load from the sterilisation chamber.

It should be emphasised that phases 1, 3, 4, 6 and 9 are identical in all cycles, with slight variations of duration that are solely dependent on the quantity and consistency of the load and the heating conditions of the steriliser while phases 2, 5, 7 and 8 clearly vary their configuration and/or duration on the basis of the cycle selected (and, as a consequence, the type of load) and the choices made by the user.



- A PRESSURE (BAR)
- B PROCESS
- C TIME (MIN)
- **D** FRACTIONATED VACUUM
- E VACUUM DRYING

Please refer to the Programs appendix for more details on programs.

#### EN 19

#### SETTING UP THE DEVICE 4.



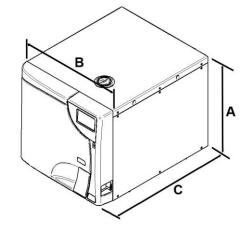
#### The safety of every system which integrates the device is the responsibility of the system assembler.

The first and essential step for the proper operation of the steriliser, its durability over time and complete use of its features, is a correct and careful commissioning. Moreover, this precaution will avoid the danger of physical injury or property damage, not to mention malfunctions and damage to the device.

#### Please meticulously follow the instructions contained hereafter in this chapter.

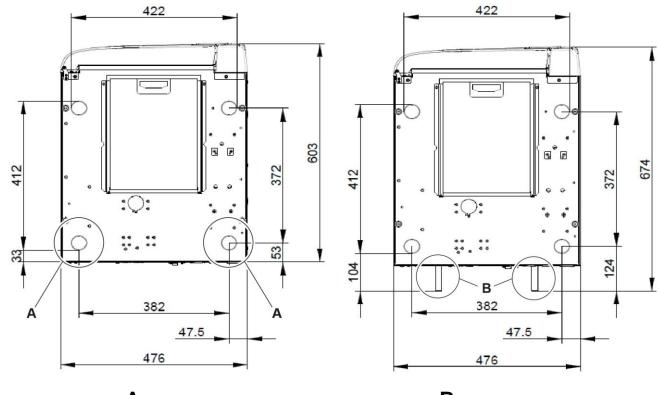
Technical Service department (see appendix) is available for further information. The steriliser is placed on the market only after having passed all the checks required. It does not require any additional calibration for commissioning.

D	imensions and weight	17 I	22	28 I
Α	Height (total)	456 mm		
в	Width (total)	480 mm		
С	Depth (excluding rear connections)			
	Note: the steriliser can be positioned on a surface only 550mm deep	<b>n</b> 600 mm		
Total weight (device only, no trays or holder, no water)		49.60 kg	51.30 kg	53.40 kg
<b>Total weight</b> (max. load, including trays & holder, max. clean water)		62.50 kg	66 kg	70.50 kg



#### 4.1. OVERALL DIMENSIONS

Centre distance and maximum overall dimensions of the steriliser feet, with and without rear spacers.



A Feet

**B** Rear spacers

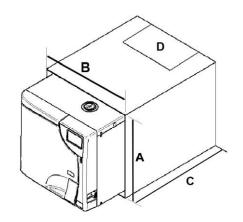
#### 4.2. COMPARTMENT DIMENSIONS FOR BUILT-IN INSTALLATION

When installing the steriliser inside a cabinet, you must provide adequate space all around the device to provide effective ventilation as well as an opening in the back (D) - 180 sq.cm - that, in addition to allowing the passage of the power cord, will also provide an adequate air flow and the optimum cooling of the heat exchanger.

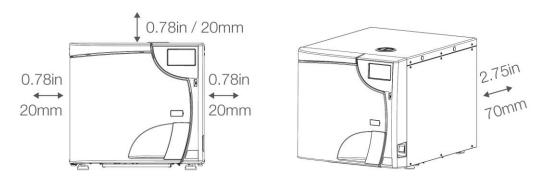
Mount the rear spacers supplied to ensure that the steriliser is placed at the correct distance from the wall.

The compartment where the steriliser will be installed must have the following minimum dimensions:

COMPARTMENT DIMENSIONS		CHAMBER VOLUME 17-22-28 L
Α	Height	470 mm
В	Width	520 mm
С	Depth	670 mm



Compartment dimensions lower than those shown may compromise the correct circulation of air around the device and may not provide adequate cooling, with the consequent deterioration of performance and/or possible damage.



If the main switch is inaccessible when installed in the compartment, use an electric plug that incorporates an on/off switch. Do not remove the upper cover nor any other external part. The device must be completely installed in the compartment. Please refer to appendix "Technical Characteristics" for complete technical data.

#### 4.3. GENERAL PRECAUTIONS FOR INSTALLATION

To ensure a correct operation of the device and/or avoid risky situations, respect the following warnings:

- Install the steriliser on a flat and perfectly horizontal surface.
- Make sure that the support surface is strong enough to support the device weight (about 90 kg, complete with water in hydrostatic test configuration);
- · Leave adequate space for ventilation all around the steriliser, in particular in the rear area.
- If the device is built into a cabinet, be sure to respect the warnings in the previous paragraph, avoiding any obstructions of the air intakes.
- Do not install the steriliser too close to tubs, sinks or similar places, avoiding contact with water or liquids. This could cause short circuits and/or potentially dangerous situations for the operator.
- · Do not install the steriliser in excessively humid or poorly ventilated environments.
- · Do not install the machine in environments with flammable and/or explosive gasses or vapours.
- Install the device so that the supply cable is not bent or crushed.
- Supply cable must freely run all the way to the electrical outlet.
- Install the device so that any external filling/drainage tubes are not bent, crushed or obstructed.

#### 4.4. POWER SUPPLY

The electrical system to which the steriliser will be connected must match the electrical characteristics of the device. Plate data are shown in the TECHNICAL CHARACTERISTICS table and on the back of the machine.

#### 4.5. ELECTRICAL CONNECTIONS

#### This information is shown on the back of the machine.

The steriliser must be connected to a socket of the electric system having adequate capacity for the device and properly grounded, in accordance with laws and/or regulations in force.

The socket must be properly protected through magneto-thermal and differential circuit breakers having the following characteristics:

 Rated current In 16 A 0.03 A

Residual current I<sub>Dn</sub>



1

2

(P

The manufacturer is not responsible for any damage caused by the installation of the steriliser with unsuited and/or not properly grounded electric systems.

Always connect the power cord directly to the power outlet.

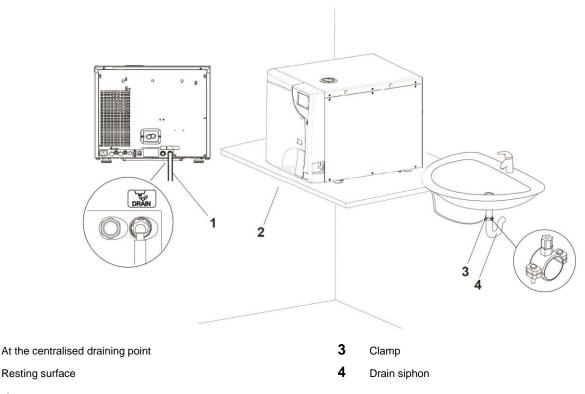
Do not use extensions, adapters or other accessories.

#### 4.6. DIRECT CONNECTION TO A CENTRALISED DRAINING POINT

- · Remove the cap holding clip and the cap on the rear of the autoclave;
- Fit the plastic tube on the elbow union (supplied).
- · Fit the union and then refit the clip.
- Fasten the clamp (supplied) to the drain siphon.
- · Cut the tube to the right length and insert its free end into the centralised draining point union locking it with the dedicated ring nut.

Make sure that the tube is not bent, crushed or obstructed in any way.

The following diagram provides an arrangement of the components:



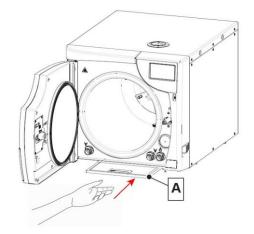
E. The position of the union of the centralised draining point must be lower than the resting surface of the steriliser. Otherwise, the tank may not be emptied correctly.

If an automatic filling system (external pump or H<sub>2</sub>O AUX EV Kit (AUX SV), Pure 100, Pure 500) is connected the use of the direct drain connection is required.

In case of fault or failure, this system allows any excess water produced by the Automatic Filling System to flow into the centralised draining point, thus preventing flooding.

#### 4.7. ANTI-DUST FILTER INSTALLATION

Complete the autoclave positioning and install the anti-dust filter (A) by inserting it into the guides in the lower part of the device. Insert the filter until it is flush with the front of the unit and cannot be pushed further back.

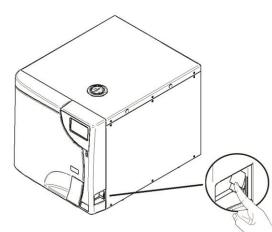


### 5. FIRST START-UP

The time required to start the steriliser is approximately 30 seconds.

#### 5.1. STARTING

Once the steriliser has been correctly installed, turn it on with the main switch on the right-hand side of the machine.



Do not turn on the steriliser if USB key is inserted. The unit scans for new software updates anytime a USB key is inserted and the machine is turned on. Only insert the USB key when you need to download cycle reports and when performing software updates.

#### Step 1 - LANGUAGE setting

When the device is first turned on, the display shows the selection of LANGUAGE, DATE and TIME settings.

Select the field with  $\blacktriangle \lor$  and confirm using ENTER. Use buttons  $\blacktriangle \lor$  to adjust the values. Confirm using ENTER and adjust the other fields.





Step 2 - DATE setting

#### Step 3 - TIME setting

#### Step 4 - PREHEATING setting

Once LANGUAGE, DATE and TIME have been set, the PREHEATING screen appears.

See User Manual, paragraph SETTINGS, section PREHEATING to set the relevant parameters.

If the device is already connected to Ethernet and IP address is already acquired, the First Start Up procedure will proceed to **Step 8**.

#### Step 5 - WiFi networks research

The device automatically searches for WiFi networks (max. 60 s). If the device has an Ethernet connection but IP address not acquired, refer to **Step 9** to complete the setup steps for connecting the device to Ethernet.

#### Step 6 - Wi-Fi networks selection

Select the WiFi network name and confirm by pressing ENTER. If connecting the unit to WiFi at a later date, use the SKIP button to move to the next startup step.

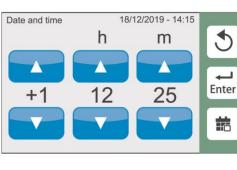
#### Step 7 - WiFi networks access

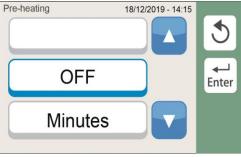
Insert the WiFi network access password and press ENTER to confirm.

#### Step 8 - CLOUD connection

Then the cloud connection page is displayed. Refer to **G4 Cloud** paragraph (12.5).

Complete the online access activation by visiting <u>www.scican.com/online-access/</u> and enter the activation code, or by scanning the QR code. Once finished, press "Home" to complete the first start procedure. The G4 Cloud Online Access Activation screen can be displayed at any time by clicking the Cloud icon.













#### Step 9 - ETHERNET connection

Refer to this step when connecting the unit to Ethernet and the IP address is not automatically acquired.



BRAVO G4's WiFi-enabled G4 technology allows connection and access to cycle data from any computer or smart device with browser capabilities, allowing staff to focus on the most important thing in a dental practice, the patients. Maintenance reminders, instructions and software updates keep your BRAVO G4 in good working order. Should your unit experience an error, G4 technology can connect your unit to specialised technicians who can provide remote support that can minimise unnecessary downtime.

#### 5.2. MAIN MENU

At the end of starting procedure the main menu is displayed on the side.

The steriliser waits for the program selection (see "Program Selection" Chapter).



#### 5.3. FILLING DEMINERALISED / DISTILLED WATER

Only use demineralised / distilled water having the following characteristics to supply the steriliser.

DESCRIPTION	VALUES IN THE WATER SUPPLY	VALUES INSIDE RESIDUAL
DRY CONDENSATE	< 10 mg/l	< 1 mg/l
SILICONE OXIDE SiO <sub>2</sub>	< 1 mg/l	< 0.1 mg/l
IRON	< 0.2 mg/l l	< 0.1 mg/
CADMIUM	< 0.005 mg/l	< 0.005 mg/l
LEAD	< 0.05 mg/l	< 0.05 mg/l
HEAVY METAL RESIDUES (iron, cadmium and lead excluded)	< 0.1 mg/l	< 0.1 mg/l
CHLORIDES	< 2 mg/l	< 0.1 mg/l
PHOSPHATES	< 0.5 mg/l	< 0.1 mg/l
CONDUCTIVITY AT 20°C	< 15 µS/cm	< 3 µS/cm
pH VALUE	5 - 7	5 - 7
ASPECT	colourless, transparent, without sediment	colourless, transparent, without sediment
HARDNESS	< 0.02 mmol/l	< 0.02 mmol/l

#### 5.3.1. MANUAL FILLING

**1.** When filling the steriliser for the first time during installation, fill the reservoir until you hear the audible beep and the LCD displays the message that Max Water Level has been reached

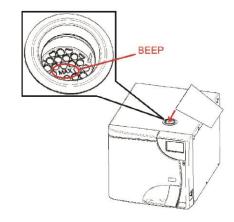
**2.** After running cycles, if the LCD screen displays a Water Level Low warning, fill the reservoir until you hear the audible beep and the LCD displays the message that Max Water Level has been reached.

Remove the cap from the top cover.

Pour in water taking care not to exceed the maximum level indicated inside the tank (MAX.).

Put the cap back in the top cover.

Pay attention <u>not</u> to spill water on the machine; if water is spilled, promptly dry.



The tank must be filled before the cycle starts or after its completion (if the LCD screen display a Low Water Level warning). Do not open the tank doors during the cycle execution in order to prevent hot water leaks.

#### 5.3.2. AUTOMATIC FILLING

Refer to the "ACCESSORIES" appendix.

### 6. CONFIGURATION

The sterilisers offer a wide range of customisable options. The user can thus configure the device according to their own needs, adapting the performance based on, for example, the type of activity carried out, the type of material to be sterilised and the frequency of use.

The CONFIGURATION menu offers the user a wide possibility to customise various device functions, by means of a user-friendly interface.

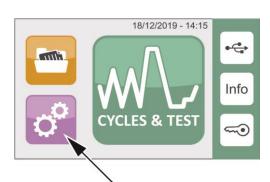


Use the configuration program whenever necessary. A correct customisation of the device provides the best performance.

The Technical Service department (see appendix) is available to help users by providing suggestions or advices on the best way to use the options in the configuration program.

#### 6.1. SETTINGS

To enter the configuration program, select the icon shown on the side.



#### 6.1.1. LANGUAGE

Select the LANGUAGE option.

	/		
	18/	/12/2019 - 14:15	
Language	Date and Time	Reminder	
Users	Preferences	Service	Â
Language	18/	/12/2019 - 14:15	
It	aliano		5

Enter

English

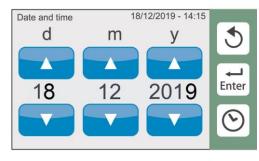
Deutsch

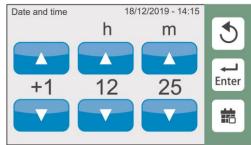
Select the desired language scrolling the list with arrows ( $\blacktriangle$  and  $\bigtriangledown$ ) and confirm by pressing ENTER.

#### 6.1.2. DATE AND TIME

ENTER.

Select DATE AND TIME option.







This function allows the user to set a specific interval for the display of a message recalling the execution of the relative test.

Select the field to be modified using the arrows and confirm by pressing

Select the REMINDER option.

Select if and when the Test reminders (Vacuum - Helix/B&D - Vacuum + Helix/B&D) should be enabled, using the available options.

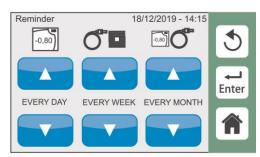
Once the fields have been set, by pressing ENTER.

Reminders activate at 8 a.m. of the selected day or upon switching ON the unit (if it occurs after 8 a.m.).

The user can choose between:

- · Starting the test
- · Postponing the test (the reminder appears again the next day)
- · Ignoring the test (the reminder appears again at the next interval)





#### 6.1.4. USERS

The users list can be edited with 30 users max. Press USERS button to enter the menu.

18/12/2019 - 14:15 Language Date and Time Date and Time Preferences Description Service

18/12/2019 - 14:15			
User_			3
!?'/@ 1	ABC 2	DEF 3	
GHI 4	JKL 5	MNO 6	Enter
PQRS 7	TUV 8	WXYZ 9	
	□ 0	×	





When using the device for the first time create the ADMIN user (identified by \*) following the steps outlined below.

Fill in the fields inserting ADMIN user name and PIN. Press ENTER to confirm.

The first user entered is given administrator rights.

If the user enters the pin incorrectly 3 times, it is necessary to use the unlocking procedure described in APPENDIX - USER PIN RESET.

After you have entered the PIN, you can access the reserved administrator menu.

The ADMIN user can decide whether the steriliser will ask for the generic user PIN at the cycle start (PIN Start) and/or at the end of the cycle (PIN End).

It is possible to activate either one of the two options or both.

By activating "PIN Start" the system requests the user to enter the PIN when the sterilisation cycle starts.

By activating "PIN End" the system requires to enter the PIN at the end of the cycle before unlocking the door.

If PIN request is set at cycle start, press START to select the user and the relevant PIN.

Once the PIN is confirmed, the cycle starts automatically.

To create a new user, press the "+ User" button. Fill in the fields inserting user name and PIN. Press ENTER to confirm.

#### 6.1.4.1. USERS LIST

Press USERS button to enter the menu.

Select the desired user.

You will access the screen containing data of the selected user.

Once entered, a generic user can see only a summary of their data, or change their PIN (see entering PIN - the following is requested in sequence: current PIN, new PIN, new PIN confirmation).

The ADMIN can instead:

- Give a generic user administration rights.
- Delete the user (a pop-up will be displayed to confirm the deletion).
- · View Info on users.
- · Select the cycles that the selected user is enabled to perform, by pressing the related icons.











#### 6.1.5. PREFERENCES

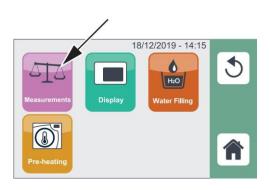
- Press PREFERENCES button to enter the menu and set:
- UNITS OF MEASUREMENT
- DISPLAY
- WATER FILLING
- PREHEATING

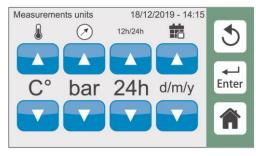


'n

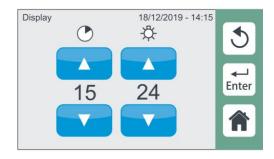
#### 6.1.5.1. UNIT OF MEASUREMENT

Press the MEASUREMENTS icon to set the desired units of measurement (temperature, pressure), the time (12 or 24 hours) and the date format using the cursors shown in the figure. Press ENTER to confirm the settings.





# 18/12/2019 - 14:15 Measurements Display Water Filling Pre-heating



#### 6.1.5.2. DISPLAY

Press the DISPLAY icon to select the screen settings.

The two cursors respectively adjust:

Screen Saver activation time-out

Screen brightness

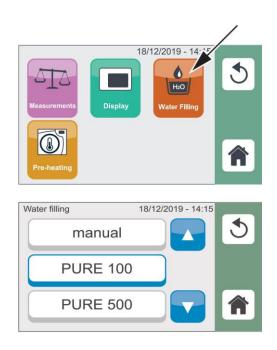
Press ENTER to confirm the settings.

#### 6.1.5.3. WATER FILLING

Press the H2O FILLING icon to choose the type of water filling.

Available options include:

- Manual filling
- Pure 100
- Pure 500
- Automatic Filling Kit (External Pump)
- H<sub>2</sub>O AUX EV kit (AUX SV)



The device should be turned on when connecting the water system. The unit's factory default fill setting is set to manual. When you plug one of the external automatic water filling devices into the rear port, the LCD will automatically display the water filling option screen so you can select the appropriate device.

If connecting the filling system when the steriliser is off, access the menu via the configuration program and manually select the correct option.

This menu can also be used to temporarily deactivate the automatic filling system (filters exhausted, fault, etc.) and go to manual tank filling, keeping the automatic filling system connected.



J.

#### 6.1.5.4. PREHEATING

Select the relevant icon to activate  $\ensuremath{\mathsf{PREHEATING}}$  in the sterilisation chamber.

The preheating max temperature settings are:

- 50°C/122°F with door open
- + 100°C/212°F with door closed

Keep the door closed, when not running the sterilisation cycle, in order to ensure the preheating achieves the max. temperature level.

Use the arrows to scroll the PREHEATING available values:

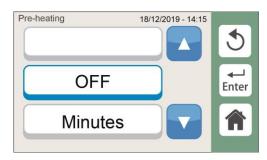
- OFF
- Minutes
- Schedule

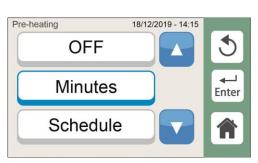
The current selection in shown inside the blue box. Confirm by pressing ENTER

The preheating menu is displayed when the sterilizer is started for the first time, after selecting the language and date/time options. The preheating is OFF by factory default.

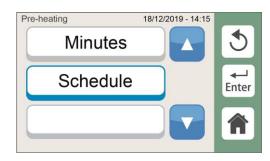
Select Minutes, confirm by pressing ENTER











EN 35

The arrows allow setting the maximum operating time, after which the PREHEATING is disabled.

Confirm by pressing ENTER.

The user can set preheating time up to 720 minutes (12 hours).

Select Schedule, confirm by pressing ENTER

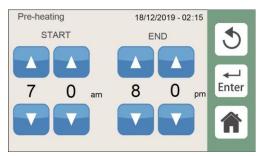
Set the PREHEATING power on time by means of START counters.

Set the PREHEATING power off time by means of END counters.

Confirm by pressing ENTER







12H format

#### 6.1.6. SERVICE

This menu is intended for the Technical Service department. It can be used only by an authorised technician.



#### PREPARATION OF THE MATERIAL 7.



Always use personal protective equipment.



Clean and rinse all instruments before loading them into the steriliser. Disinfectant residues and solid debris may inhibit sterilisation and damage the instruments and the BRAVO G4.

Unwrapped instruments, once exposed to ambient or external conditions, cannot be maintained in a sterile state. If sterile storage is desired, wrap the instruments to be sterilised according to the instrument manufacturer's instructions, select the appropriate wrapped cycle and allow it to run to completion.

To promote drying and enable effective sterilisation, wrapped or pouched instruments must not touch each other.

SciCan recommends the final user carefully choose the most appropriate sterilisation cycle according to the recommendations of their leading infection control authorities and local regulatory guidelines / recommendations.



User should select the appropriate sterilization wrap depending on the sterilization program chosen.

#### 7.1. TREATING THE MATERIAL BEFORE STERILISATION

An effective cleaning consists of the following:

Separate metal instruments by type of material (carbon steel, stainless steel, brass, aluminium, chromium, etc.), to avoid electrolytic oxidation-1 reduction



Solutions containing phenols or quaternary ammonia compounds can cause corrosion on instruments and on the metal parts of the ultrasonic device. Follow instrument IFU for effective cleaning.

- 2 If using an ultrasonic cleaner, ensure instruments are thoroughly rinsed and dried.
- If using an automated washer, verify the dry cycle of the automated washer was completed. 3

For handpieces (turbines, contra-angles, etc), in addition to the above listed procedure, follow the Manufacturer instructions.

At the end of the sterilisation program, remember to lubricate the internal handpiece mechanisms. By taking this precaution, the instrument life time will not be reduced in any way.



Consult the instructions provided by the manufacturer on the instrument/material to be sterilised before placing into the autoclave.

As regards textile materials (porous), such as lab coats, napkins, caps and other, carefully wash and dry them before treating them in the autoclave.

Do not use detergents with a high content of chlorine and/or phosphates. Do not bleach with chlorine-based products. These substances can LA. damage the tray supports, trays and any metal instruments that may be present in the sterilisation chamber.



### 7.2. ARRANGING THE LOAD



Always use personal protective equipment.



To get the best effectiveness of the sterilisation process and preserve the material over time, increasing its useful life, follow the instructions below.

#### General notes for the positioning on trays:

- When arranging unwrapped instruments made with different metals (stainless steel, hardened steel, aluminum, etc.) use different trays (whenever possible).
- In case of instruments not made of stainless steel, put a sterilisation paper napkin or a muslin cloth between instrument and tray, avoiding direct contact between the two different materials.
- In any case, arrange the objects sufficiently spaced from each other, so that they can remain in such position for the whole sterilisation cycle.
- Make sure that all instruments are sterilised in an open position.
- Position cutting instruments, (scissors, scalpels, etc.) so they can not come into contact with each other during sterilisation; if necessary, use a cotton cloth or a gauze to isolate and protect them.
- Arrange recipients (glasses, cups, test tubes, etc.) resting on their side, or upended, thus avoiding pooling water.
- Do not load trays beyond the limit indicated (see Appendix).
- Do not stack trays one on top of the other and do not put them in direct contact with the walls of the sterilisation chamber.
- Always use the supplied tray support.
- To insert and remove trays from the sterilisation chamber, always use the special supplied extractor.





Use chemical process monitors suitable for steam autoclaves/sterilizers at the indicated cycle temperatures and times in or on each package or load being sterilized.

Only use chemical and biological indicators that are designed for the particular sterilization cycle temperature and exposure time being monitored.

#### Note for rubber and plastic hoses:

- Always rinse before use with demineralised / distilled water, then dry properly.
- Arrange hoses on tray so that their ends are not obstructed or bent.
- Do not bend or twist hoses, but leave them as linearly stretched as possible.

#### Notes for packages:

- Arrange packages next to each other, duly spaced and not stacked, avoiding their contact with chamber walls.
- Should it be necessary to wrap special objects, always use a suitable porous material (sterilisation paper, muslin napkins, etc.), closing the package with adhesive tape suitable for autoclave.





#### Notes for packed material:

- Individually pack the instruments or, in case more than one instrument is placed inside the same pouch, make sure they are made of the same metal.
- Do not use metal staples, needles or the like, as sterility could be affected.
- Position pouches in such a way to leave the paper side up and the plastic side down (tray side) .
- In any case, make sure that this position proves effective, reverting it, if necessary.
- Never stack pouches one on top of the other.



Always pack instruments if they are going to be stored. Refer also to the indications given in chapter "Sterilised Material Storage".

Program selection is an essential operation for the correct performance of the sterilisation process.

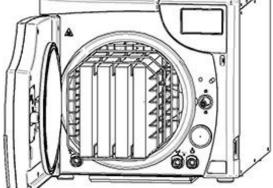
Since all instruments, or material in general, have a different structure, consistency and properties, the **most suitable program must be identified**, both to preserve the physical characteristics (avoiding or, in any case, limiting its alterations) and to ensure the best effectiveness of the sterilisation process.

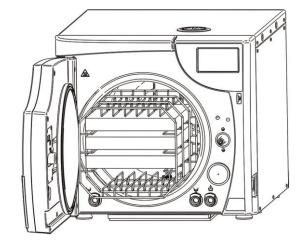
A guide for the selection of the correct program based on the load is present inside Programs Appendix.



### 7.3. POSITIONING AND USE OF TRAY HOLDER SUPPORT

Tray holder support can be used in "tray" version (5/6 compartments based on the steriliser model).





It can be used to house special "cassettes" (3/4 compartments based on steriliser model) vertically or horizontally.

### 8. STERILISATION CYCLES

A sterilisation cycle consists of a determined number of phases.

The number and duration of the phases can differ for the various cycles, based on the type of air extraction, sterilisation process and drying methods:

- B 134°C Universal
- B 121°C Universal
- B 134°C Prion
- S 134°C Hollow
- S 134°C Solid
- · Custom (User-defined)

The electronic control system monitors the various phases, at the same time checking that the various parameters are respected; if any type of anomaly is encountered during the cycle, the program is immediately interrupted, generating an alarm identified by a code, with a relative message explaining the nature of the problem.

With this type of control, when you select a suitable sterilisation program, effective sterilisation will be achieved.

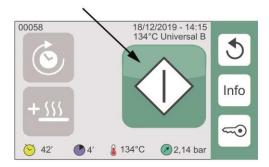
After inserting the load in the sterilisation chamber (taking the precautions described in the section **PREPARATION OF THE MATERIAL**).

Press CYCLES & TEST button to display the cycle selection buttons.



Press the button corresponding to the cycle chosen.





Start the cycle by pressing the indicated START button. The cycle counter appears in the upper left corner.

The following data are shown at the bottom:

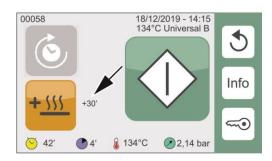
- · Total cycle time
- Process time
- · Rated process temperature
- Rated process pressure

### 8.1. EXTRA DRYING

To set parameters, press and **hold** the following button until the screen changes to the Extra Drying settings listed below.

00058 18/12/2019 - 14:15 134°C Universal B ↓ 134°C Universal B Info ∞ 42' • 4' § 134°C ∞ 2,14 bar

00058 18/12/2019 - 14:15 134°C Universal B + 555 30 ▼ ■



Set the minutes of drying you want to add to the standard drying time and confirm by pressing ENTER.

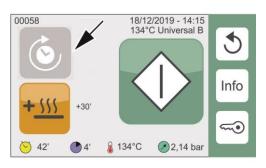
The selected value appears near the button. Activate the cycle by pressing the START button.

At next use, press the Extra Drying button to activate the values previously set.

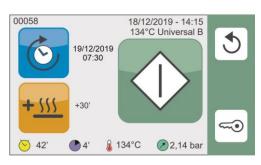
Extra drying can be activated independently for each cycle.

#### 8.2. DELAYED START

To set parameters, press and **hold** the following button until the screen changes to the Delayed Start settings listed below.



00058 18/12/2019 - 14:15 134°C Universal B 07:30 19/12/2019 - 07:30



Set the time you want to start the cycle and confirm by pressing  $\ensuremath{\mathsf{ENTER}}$  .

The selected time appears near the button.

Press the START button; the cycle will automatically start at the set time.

At next use, press the Delay Start button to activate the values previously set.

#### 8.3. EXECUTION OF THE CYCLE

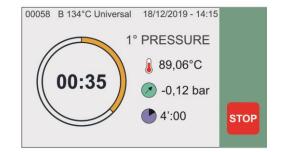
Taking as an example the most <u>complete</u> and <u>significant</u> sterilisation cycle, i.e. the **B 134°C UNIVERSAL** program, characterised by fractionated pre-vacuum, the cycle sequence is as follows:

WARMING UP FIRST VACUUM PHASE FIRST PRESSURE RISE SECOND VACUUM PHASE SECOND PRESSURE RISE THIRD VACUUM PHASE THIRD PRESSURE RISE STERILISATION STEAM DISCHARGE DRYING VENTILATION CYCLE COMPLETION

#### 8.4. CYCLE OUTCOME

At the end of the cycle it is important to check the sterilisation process outcome.

If the message "**COMPLETED**" is displayed, it means that the cycle correctly completed without any alarm interruptions and that **complete asepsis** of the material is guaranteed.





### 8.5. DOOR OPENING AT THE END OF THE CYCLE

To open the steriliser door, press the DOOR UNLOCK button shown in the figure:



#### 8.6. USER-DEFINED CYCLE

To set the Custom, User-Defined cycle parameters, select the following button:

Hold down the following button to access settings:

Select the type of pre-vacuum (fractionated or single), the process temperature, the exposure time and total drying time.

Once you have made the selections, press the ENTER button to save the settings and go back to the previous screen.

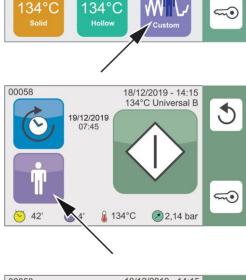
Press the START button to start the User-Defined cycle.

## 9. MATERIAL STORAGE

The sterilised material must be adequately treated and stored to maintain its sterility over time until its use.

Follow your local guidelines for proper material storage requirements.

Consult the specifications provided by the manufacturer of the packaging material relative to the maximum allowed storage time.



R

121°C

Universal

S

134°C

Universal

4

18/12/2019 - 14:15

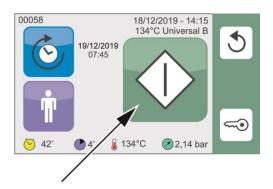
134°C

Prie

3

Test



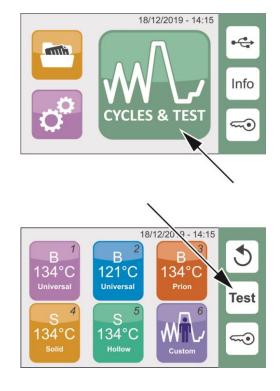


#### **10. TEST PROGRAMS**

To protect the safety of users and patients, a fundamental process like sterilising medical devices should be periodically checked.

The device offers the possibility of easily and automatically executing two distinct test cycles:

- HELIX TEST / B&D TEST
- VACUUM TEST
- A program that executes the two tests combined VACUUM + HELIX TEST / B&D TEST
- There is also a test to check the water quality:  $\ensuremath{\text{H}_2\text{O}}\xspace$  TEST



#### 10.1. HELIX TEST / B&D CYCLE

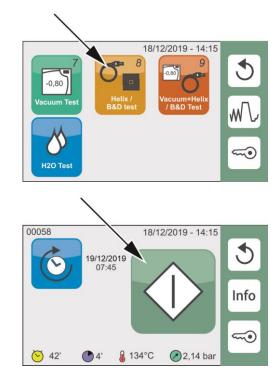
Helix / B&D Test is a cycle run at 134°C characterised by a sterilisation phase that lasts a specific time (3.5 minutes); the cycle comprises of the fractionated vacuum phases similar to those used in the sterilisation cycles.

Using an appropriate device, you can assess correct steam penetration into hollow loads (Helix Test).

The cycle is also suitable to measure steam penetration into porous loads (Bowie & Dick test pack).

Load the appropriate Helix or B&D Test pack (see the section below for proper use of the test packs)

To use the **Helix / B&D Test cycle**, press the corresponding button and then press Start.



The HELIX test device (in accordance with EN 867-5 specifications) consists of a 1.5 m-long PTFE tube, with an inside diameter of 2 mm to which a small hermetically-sealed screw cap is fastened, able to contain an appropriate chemical indicator.

The other end of the tube is left free so that the steam can penetrate and you can assess its effectiveness.

To conduct the test (with reference to standard EN 13060:2014 + A1:2018), insert the chemical indicator, consisting of a paper strip with a special reagent ink in the device cap (always to be used perfectly dry). Tighten the cap in such a way that seepage through the gasket is <u>not</u> possible.



P The test device and the chemical indicators to execute the helix/b&d test cycle are <u>not</u> provided with the device.

For information in this regard, contact Technical Service department (see appendix).

Place the device roughly in the middle of the central tray. Do not insert other material in the chamber. Close the door and start the cycle.

The test cycle takes place with a succession of phases similar to those described for a normal sterilisation cycle. At the end of the cycle, remove the test device from the chamber, open the cap and remove the indicator from its housing. If the steam has correctly penetrated, the ink will have completely changed its original colour over the entire length of the strip; if not (insufficient penetration), there will only be a partial colour change or even no change at all.

The same cycle can be used for the Bowie & Dick test at the same time by placing the test device next to the HELIX test device.

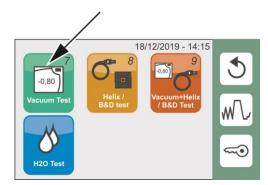
J.

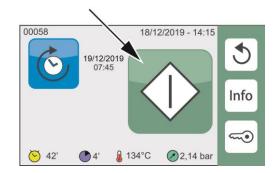
Toning usually occurs from a light colour (beige, yellow, etc.) to a dark colour (blue, violet or black). In any event, strictly follow the instructions and any additional technical details provided by the indicator manufacturer.

### **10.2. VACUUM TEST CYCLE**

The VACUUM TEST cycle allows testing perfect seal of the steriliser hydraulic system. Measuring the variation of the degree of vacuum in a defined time-frame and comparing it with pre-established limit values, you can determine how good the seal of the sterilisation chamber, tubes and the various interception devices is.

To select the VACUUM TEST cycle, press the corresponding button and then press START.





The cycle must run with the sterilisation chamber empty, and only the trays and their supports inserted.

We suggest running this test at the beginning of each working day with chamber at ambient temperature.

A high chamber temperature affects the variation in the vacuum value measured during the test; the system is therefore programmed to prevent execution of the test when the operating conditions are inadequate.

Close the door and start the program.

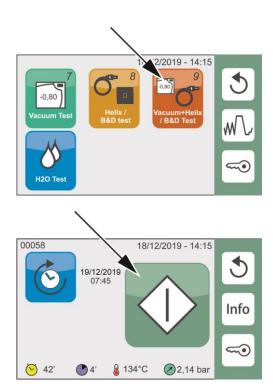
The vacuum phase starts immediately and the pressure value (bar) and the countdown from the start of the test cycle are shown on the display.



If the pressure variation exceeds the limit defined, the program is interrupted and an alarm message generated. For the complete description of the alarms refer to the appendix.

#### 10.3. VACUUM TEST + HELIX TEST/B&D CYCLE

Select this option to run a VACUUM TEST cycle and a Helix Test/B&D cycle in sequence.



To this end, place the test device on the central tray without inserting other material.

Close the door and start the cycle.

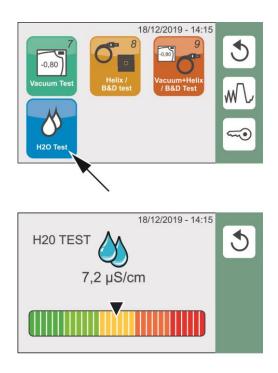
The program will execute the two cycles in succession.

Check the results as described in the previous paragraphs.

The presence of the Helix test device and/or of the Bowie & Dick test device does not alter the execution and the result of the Vacuum test cycle.

#### 10.4. H2O TEST

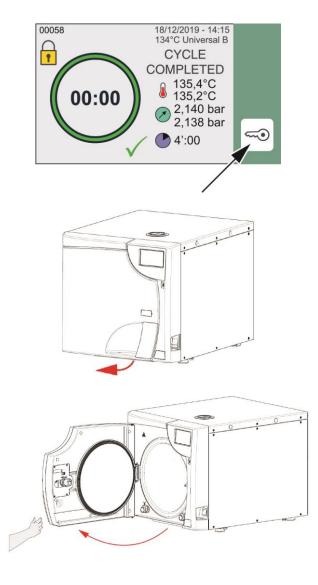
Select this option to test the water quality.



The water conductivity is automatically measured at each sterilisation or test cycle start and the relative value is indicated in the cycle report.

### **10.5. DOOR OPENING**

To open the autoclave door, press and hold the button shown in the figure.



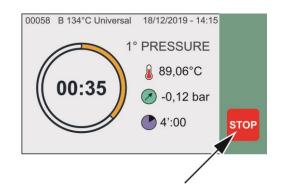
The door opens and stays ajar.

Now you can manually open the door.

Keep the door closed, while not running the sterilization cycle, in order to ensure preheating achieves the max. temperature level.

#### **10.6. MANUAL INTERRUPTION**

The cycle can be interrupted by the operator in any time, by holding down the STOP button indicated in the figure for about 3 seconds.

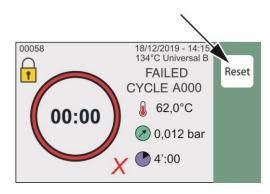


The command generates E999 error since the cycle could not finish correctly. Press ENTER to proceed.



If the cycle is interrupted during certain phases, an automatic cleaning procedure of the internal hydraulic circuit starts. For the complete description of the alarms refer to "Alarms" appendix.

Press and hold RESET for about 3 seconds to open the door.



After a manual interruption of the program, the load must not be used since the sterilisation is not ensured.

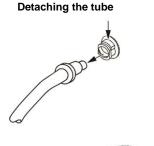
### 11. USED WATER DRAIN

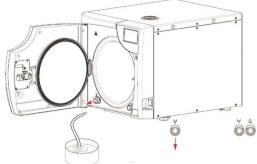
The unit is equipped with an internal waste water tank that collects the drainage water after each cycle. When the maximum water level is reached, a specific message is displayed. Proceed with draining the water tank by following the instructions listed below.

Open the door and continue as follows:

- **1** Prepare a basin with a capacity of at least 4 litres in proximity to the steriliser; place the free end of the drain tube provided in the basin.
- **2** Insert the other end of the tube in the female union beneath the chamber inlet (connector on the left) pushing down until you hear a click.
- **3** Completely empty out the tank and then press on the upper part of the union and detach the tube quick coupling.

Do not open the tank doors during the cycle execution in order to prevent hot water leaks or spurts.

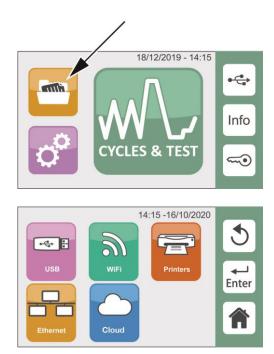




The unit can be directly connected to a centralized draining point for automatic direct drainage (ref. paragraph 4.6).

## **12. DATA MANAGEMENT & CONNECTIVITY**

To access DATA MANAGEMENT & CONNECTIVITY section press the relevant icon.



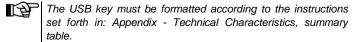
DATA MANAGEMENT & CONNECTIVITY offers access to:

- USB management
- WIFI
- PRINTERS management
- ETHERNET
- CLOUD connection

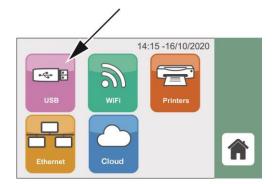
#### **12.1. USB MANAGEMENT**

Before carrying out the following operations insert the USB key. It is possible to copy data about the cycles carried out, stored in the internal memory of the steriliser, onto a USB key.

To download the sterilisation cycles/tests files (in PDF format) select the following button:



Insert the USB key into the front port as shown in the figure.





Before proceeding with the download you are required to select the report type and to choose the format:

Report (standard version)

· Extended report

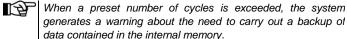
The sterilisation / test cycle report files are in PDF format.

It is possible to select the number of cycles to download onto the external storage device:

- New
- Last 10
- Last 50
- Last 100 · Custom Mode

If Custom Mode is selected, you will be prompted to enter the number of the first and last cycle to download.

At the end of the download remove the key.



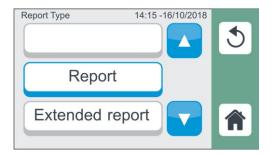
generates a warning about the need to carry out a backup of data contained in the internal memory. To delete the warning displayed, download the cycle reports

using the "New" option.



Do not turn on the steriliser if USB key is inserted.

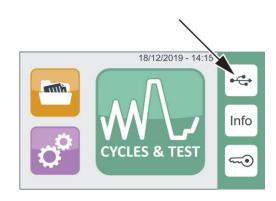
The unit scans for new software updates anytime a USB key is inserted and the machine is turned on. Only insert the USB stick when you need to download cycles and when performing software updates.





#### 12.1.1. DIRECT DOWNLOAD

This control performs the download of NEW cycle reports, as PDF file, by means of a USB key. NEW indicates the cycle reports have not been previously dowloaded.



#### 12.2. WIFI

Select WiFi to connect the steriliser to a local WiFi network.

Select ON/OFF to enable or disable WiFi connection. Confirm by pressing ENTER. Select SETTINGS button to configure the WiFi network.

WiFi SETTING offers access to:

NETWORKS SEARCHMANUAL ENTRY

SETUP







NETWORKS SEARCH automatically searches for available WiFi networks, displayed as a list. Scroll the list to select the WiFi network and confirm by pressing ENTER.

Following the selection of the network name, enter the network PASSWORD and confirm by pressing ENTER. SHIFT button allows special characters keyboard.

MANUAL ENTRY allows manually editing the WiFi network SSID and

PASSWORD, and confirm by pressing ENTER. Pressing SSID or PSW button displays the editing keyboard.

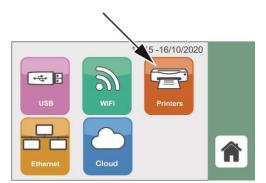
\*26 abc ghi def jkl pqrs mno Enter wxyz .,àèòiù tuv ABC X

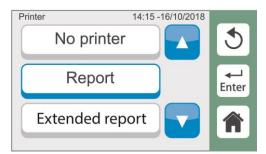
14:15 -16/10/2018



	1	4:15 -16/10/2018	-
	Network 11		3
abc	def	ghi	
jkl	mno	pqrs	Enter
tuv	wxyz	.,àèòìù	
<b></b>	ABC	×	

WiFi			14:15 -16	6/10/2018	
IP	192	168	1	3	3
Mask	255	255	255	0	-
Gate	0	0	0	0	Enter
DNS	0	0	0	0	Manual DHCP





DHCP can be set as Automatic or Manual.

In Automatic DHCP mode, the network configuration parameters are automatically assigned.

In Manual DHCP mode, the network configuration parameters must be set manually.

Confirm the selected mode by pressing ENTER.

### 12.3. PRINTERS

To set parameters select the following item:



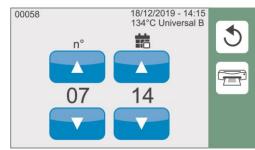
The optional external printer Ref. M7D200012 is compatible with the BRAVO G4. Please contact Customer Service to confirm other printer compatibility.

Select PRINTERS to choose the mode from the following options:

- NO PRINTER deactivates the printer.
- · REPORT prints a compact version of the cycle summary report at the end of the process.
- EXTENDED REPORT prints an extended version of the cycle summary report at the end of the process.
- BARCODE LABELS prints the labels bearing the cycle data and the barcode.

#### At the end of the cycle, press the DOOR UNLOCK button.





If the BARCODE LABELS mode is selected, the following screen is displayed from which it is possible to set the number of labels and the interval (in days) between the cycle execution date and the sterilised material expiry date.

Use the arrows to adjust the value.

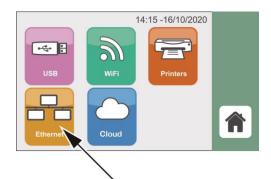
Press the PRINTER button to print the labels complete with barcode.

In case of an unsuccessful cycle or test cycle, only one label will be automatically printed.

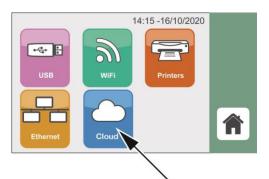
If the printer is connected to the autoclave and REPORT option is set, the steriliser automatically prints the summary report at the end of the cycle.

#### 12.4. ETHERNET

Select ETHERNET to connect the steriliser to a local Ethernet network



WiFi			14:15 -16	/10/2018	
IP	192	168	1	3	3
Mask	255	255	255	0	-
Gate	0	0	0	0	Enter
DNS	0	0	0	0	Manual DHCP





DHCP can be set as Automatic or Manual.

In Automatic DHCP mode, the network configuration parameters are automatically assigned.

In Manual DHCP mode, the network configuration parameters must be set manually.

Confirm the selected mode by pressing ENTER.

#### 12.5. G4 CLOUD

The BRAVO G4 Cloud web portal is a direct connection to the BRAVO G4 on your local area network. It is protected by your firewall and not accessible to outside users (unless they have a Remote Access Code). For more information, please contact the Technical Service Department for retrieving Remote Access Code.

The G4 Cloud web portal provides real-time cycle information and archived sterilisation records unique to this unit. From here, you can print reports, set up email notifications and search cycle histories.

To set up the web portal, please follow the below instructions; additional information is available on the portal's 'HELP' tab.

Once network connection is complete, select the Cloud icon to setup SciCan Online Access. The Online Activation Code or QR Code will automatically display on the screen.

Using the Online Access Activation Code, please follow the instructions listed on <u>www.scican.com/online-access</u> or use the QR-Code for faster URL access.

Online Access can be completed at any time (the unit must be connected to WiFi or Ethernet network).

## 13. APPENDIX - PROGRAMS

Steam sterilisation is suitable for almost all the materials and instruments, provided that they can bear without damage a minimum temperature of 121°C (if this is not the case, other low-temperature sterilisation systems must be used).

- The following material can normally be sterilised with steam:
- Stainless steel surgical/generic instruments
- Carbon steel surgical/generic instruments
- · Rotating and/or vibrating instruments driven by compressed air (turbines) or mechanical transmission (contra angles, tooth scalers)
- Glass items
- Mineral-based items
- Heat-resistant plastic items
- Heat-resistant rubber items
- Heat-resistant textiles
- Medication materials (gause, pads, etc.)
- · Other generic material suitable for autoclave treatment

Depending on the material (solid, hollow or porous), on any package containing it (paper/plastic pouch, paper for sterilisation, container, muslin napkins, etc.) and on its resistance to heat, it is essential to choose the suitable sterilisation program, referring to the table in the next page.

The device must not be used for the sterilisation of fluids, liquids or pharmaceutical products.



#### "Prion" cycle

The reference standard for this device, EN 13060:2014 + A1:2018, does not lay down any requirements for inactivation processes that cause spongiform encephalopathies as scrapie, bovine spongiform encephalopathy and creutsfeldt-jakob disease.

The cycle named "prion" (18 min at 134°C) applies national regulations, which indicate this modified steam sterilisation process as part of a prion decontamination program.

## 13.1. SUMMARY TABLE OF 17 220 V - 240 V CYCLES

	Ν	OMINA	L VALUE	ES			SIC CY RAMET			STERILISABLE		RIALS		NOTES
CYCLE DESCRIPTION	Temperature (°C)	Pressure (bar)	Holding time (min.)	Cycle type (EN 13060:2014 + A1:2018)	Pre-vacuum (F=fractionated; S=single)	Standard drying (min.) ***	Total cycle time (Load Max.)	Max. H <sup>2</sup> O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	ТҮРЕ	MAX. TOTAL MASS (kg)	MAX. MASS PER TRAY (kg) **	MAX. MASS PER ITEM (kg)	
										Unwrapped porous materials	1.00	0.30	0.30	
										Porous materials in single pack	0.75	0.25	0.25	
										Porous materials in double pack	0.60	0.20	0.20	
134°C UNIVERSAL	134	2.1	4(*)	В	F	13	42	550	0.75	Solid and hollow materials in single pack	3.00	1.00	0.50	
										Unwrapped solid and hollow materials	6.00	1.20	0.25	
										Solid and hollow instruments in double pack	1.50	0.50	0.25	
										Unwrapped porous materials	1.00	0.30	0.30	
										Porous materials in single pack	0.75	0.25	0.25	For wrapped materials and instruments
										Porous materials in double pack	0.60	0.20	0.20	(single and double pack), it is
134°C PRION	134	2.1	18	В	F	13	56	600	0.85	Solid and hollow materials in single pack	3.00	1.00	0.50	advisable to use the 3-tray configuration
										Unwrapped solid and hollow materials	6.00	1.20	0.25	, , , , , , , , , , , , , , , , , , ,
										Solid and hollow instruments in double pack	1.50	0.50	0.25	
										Unwrapped porous materials	1.00	0.30	0.30	
										Porous materials in single pack	0.75	0.25	0.25	
										Porous materials in double pack	0.60	0.20	0.20	
121°C UNIVERSAL	121	1.1	20	В	F	13	58	600	0.75	Solid and hollow materials in single pack	3.00	1.00	0.50	
										Unwrapped solid and hollow materials	6.00	1.20	0.25	
										Solid and hollow instruments in double pack	1.50	0.50	0.25	
134°C HOLLOW	104	0.4	A/*)	c	F	4	25	FEO	0.65	Unwrapped hollow instruments	6.00	1.20	0.50	
UNWRAPPED	134	2.1	4(*)	S	Г	4	35	550	0.0	Unwrapped solid instruments	6.00	1.20	0.50	

60 EN

	N	OMINA		ES			SIC CY			STERILISABLE		RIALS		NOTES
CYCLE DESCRIPTION	Temperature (°C)	Pressure (bar)	Holding time (min.)	Cycle type (EN 13060:2014 + A1:2018)	Pre-vacuum (F=fractionated; S=single)	Standard drying (min.) ***	Total cycle time (Load Max.)	Max. H <sup>2</sup> O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	ТҮРЕ	MAX. TOTAL MASS (kg)	MAX. MASS PER TRAY (kg) **	MAX. MASS PER ITEM (kg)	
134°C SOLID WRAPPED	134	2.1	4(*)	S	s	13	33	350	0.55	Solid instruments in single pack	3.00	1.00	0.25	It is advisable to use the 3-tray configuration
										materials	6.00	1.20	0.50	
XXX°C USER	134	2.1	4÷30	n.a.	F/S	5÷30	n.a.	n.a.	n.a.	Unwrapped solid instruments (other load types are possible	n.a.	n.a.	n.a.	Variable parameters
(see note)	121	1.1	20÷30							depending on the user settings)				depending on the settings made
HELIX/BD TEST	134	2.1	3.5	-	F	1	20	-	-	Test device only (without another load)	-	-	-	
VACUUM TEST	-	-0.8	-	-	-	-	18	-	-	Empty chamber	-	-	-	
VACUUM + HELIX/BD TEST (executable in sequence)	-	-	-	-	-	-	42	-	-	-	-	-	-	

(\*) To set a sterilisation time of 5.5 minutes, contact the Technical Service.

Single Pre-Vacuum = 1 pre-vacuum; -0.8 bar (see figures in the following pages).

Fractionated Pre-Vacuum = 3 pre-vacuum; -0.8 bar each (see figures in the following pages).

Definition of hollow loads in accordance with standard EN 13060:2014 + A1:2018.

The term "hollow loads" in this manual refers both to "narrow lumen" elements (paragraph 3.18 EN 13060:2014 + A1:2018) and "simple hollow" elements (paragraph 3.30 EN 13060:2014 + A1:2018).

The term "hollow load B" refers ONLY to the elements defined as "simple hollow" (paragraph 3.30 EN 13060:2014 + A1:2018).

(\*\*) The Max. Mass per Tray means the maximum load to be placed on each tray, while respecting the MAX. TOTAL MASS as device load limit.

(\*\*\*) Depending on the type of load, it may be necessary to optimise drying using the extra drying function (8.1).

## 13.2. SUMMARY TABLE OF 22 220 V - 240 V CYCLES

	Ν	OMINAI		ES			SIC CY			STERILISABLE		RIALS		NOTES
CYCLE DESCRIPTION	Temperature (°C)	Pressure (bar)	Holding time (min.)	Cycle type (EN 13060:2014 + A1:2018)	Pre-vacuum (F=fractionated; S=single)	Standard drying (min.) ***	Total cycle time (Load Max.)	Max. H <sup>2</sup> O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE	MAX. TOTAL MASS (kg)	MAX. MASS PER TRAY (kg) **	MAX. MASS PER ITEM (kg)	
										Unwrapped porous materials	1.20	0.40	0.30	
										Porous materials in single pack	1.00	0.30	0.25	
										Porous materials in double pack	0.75	0.25	0.20	
134°C UNIVERSAL	134	2.1	4(*)	В	F	15	46	700	0.8	Solid and hollow materials in single pack	4.00	1.25	0.50	
										Unwrapped solid and hollow materials	7.50	1.20	0.25	
										Solid and hollow instruments in double pack	2.00	0.60	0.25	
										Unwrapped porous materials	1.20	0.40	0.30	
										Porous materials in single pack	1.00	0.30	0.25	For wrapped materials and
										Porous materials in double pack	0.75	0.25	0.20	instruments (single and double pack), it is
134°C PRION	134	2.1	18	В	F	15	60	750	0.9	Solid and hollow materials in single pack	4.00	1.25	0.50	advisable to use the 3-tray configuration
										Unwrapped solid and hollow materials	7.50	1.20	0.25	
										Solid and hollow instruments in double pack	2.00	0.60	0.25	
										Unwrapped porous materials	1.20	0.40	0.30	
										Porous materials in single pack	1.00	0.30	0.25	
										Porous materials in double pack	0.75	0.25	0.20	
121°C UNIVERSAL	121	1.1	20	В	F	15	63	750	0.8	Solid and hollow materials in single pack	4.00	1.25	0.50	
										Unwrapped solid and hollow materials	7.50	1.20	0.25	
										Solid and hollow instruments in double pack	2.00	0.60	0.25	
134°C HOLLOW	134	2.1	4(*)	S	F	5	39	750	0.7	Unwrapped hollow instruments	7.50	1.50	0.50	
UNWRAPPED	104	<i>ב</i> . י	r( <i>)</i>	0		Ŭ	00		5.7	Unwrapped solid instruments	7.50	1.50	0.50	

	N	OMINA	L VALUE	ES			SIC CY			STERILISABLE		RIALS		NOTES
CYCLE DESCRIPTION	Temperature (°C)	Pressure (bar)	Holding time (min.)	Cycle type (EN 13060:2014 + A1:2018)	Pre-vacuum (F=fractionated; S=single)	Standard drying (min.) ***	Total cycle time (Load Max.)	Max. H <sup>2</sup> O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	ТҮРЕ	MAX. TOTAL MASS (kg)	MAX. MASS PER TRAY (kg) **	MAX. MASS PER ITEM (kg)	
134°C SOLID WRAPPED	134	2.1	4(*)	S	s	15	39	400	0.6	Solid instruments in single pack	4.00	1.00	0.25	It is advisable to use the 3-tray configuration
										Unwrapped solid materials	7.50	1.20	0.50	
XXX°C USER	134	2.1	4÷30	n.a.	F/S	5÷30	n.a.	n.a.	n.a.	Unwrapped solid instruments (other load types are possible	n.a.	n.a.	n.a.	Variable parameters
(see note)	121	1.1	20÷30							depending on the user settings)				depending on the settings made
HELIX/BD TEST	134	2.1	3.5	-	F	1	24	-	-	Test device only (without another load)	-	-	-	
VACUUM TEST	-	-0.8	-	-	-	-	18	-	-	Empty chamber	-	-	-	
VACUUM + HELIX/BD TEST (executable in sequence)	-	-	-	-	-	-	46	-	-	-	-	-	-	

(\*) To set a sterilisation time of 5.5 minutes, contact the Technical Service.

Single Pre-Vacuum = 1 pre-vacuum; -0.8 bar (see figures in the following pages).

Fractionated Pre-Vacuum = 3 pre-vacuum; -0.8 bar each (see figures in the following pages).

Definition of hollow loads in accordance with standard EN 13060:2014 + A1:2018.

The term "hollow loads" in this manual refers both to "narrow lumen" elements (paragraph 3.18 EN 13060:2014 + A1:2018) and "simple hollow" elements (paragraph 3.30 EN 13060:2014 + A1:2018).

The term "hollow load B" refers ONLY to the elements defined as "simple hollow" (paragraph 3.30 EN 13060:2014 + A1:2018).

(\*\*) The Max. Mass per Tray means the maximum load to be placed on each tray, while respecting the MAX. TOTAL MASS as device load limit.

(\*\*\*) Depending on the type of load, it may be necessary to optimise drying using the extra drying function (8.1).

## 13.3. SUMMARY TABLE OF 28 220 V - 240 V CYCLES

	N	OMINAI		ES			SIC CY			STERILISABLE	E MATEI	RIALS		NOTES
CYCLE DESCRIPTION	Temperature (°C)	Pressure (bar)	Holding time (min.)	Cycle type (EN 13060:2014 + A1:2018)	Pre-vacuum (F=fractionated; S=single)	Standard drying (min.) ***	Total cycle time (Load Max.)	Max. H <sup>2</sup> O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE	MAX. TOTAL MASS (kg)	MAX. MASS PER TRAY (kg) **	MAX. MASS PER ITEM (kg)	
										Unwrapped porous materials	1.50	0.50	0.50	
										Porous materials in single pack	1.25	0.35	0.35	
										Porous materials in double pack	0.90	0.30	0.30	
134°C UNIVERSAL	134	2.1	4(*)	В	F	17	56	900	0.8	Solid and hollow materials in single pack	5.00	1.50	0.75	
										Unwrapped solid and hollow materials	9.00	1.40	0.25	
										Solid and hollow instruments in double pack	2.50	0.70	0.25	
										Unwrapped porous materials	1.50	0.50	0.50	
										Porous materials in single pack	1.25	0.35	0.35	For wrapped materials and instruments
										Porous materials in double pack	0.90	0.30	0.30	(single and double pack), it is
134°C PRION	134	2.1	18	В	F	17	70	950	1	Solid and hollow materials in single pack	5.00	1.50	0.75	advisable to use the 3-tray configuration
										Unwrapped solid and hollow materials	9.00	1.40	0.25	Ŭ
										Solid and hollow instruments in double pack	2.50	0.70	0.25	
										Unwrapped porous materials	1.50	0.50	0.50	
										Porous materials in single pack	1.25	0.35	0.35	
										Porous materials in double pack	0.90	0.30	0.30	
121°C UNIVERSAL	121	1.1	20	В	F	17	69	950	0.9	Solid and hollow materials in single pack	5.00	1.50	0.75	
										Unwrapped solid and hollow materials	9.00	1.40	0.25	
										Solid and hollow instruments in double pack	2.50	0.70	0.25	
134°C HOLLOW	134	2.1	4(*)	S	F	6	44	950	0.8	Unwrapped hollow instruments	9.00	1.50	0.50	
UNWRAPPED	101	£.1	r( <i>)</i>	Ŭ		Ŭ	<b>T</b> - <b>T</b>	000	0.0	Unwrapped solid instruments	9.00	1.50	0.50	

64 EN

	N	OMINA		ES			SIC CY			STERILISABLE		RIALS		NOTES
CYCLE DESCRIPTION	Temperature (°C)	Pressure (bar)	Holding time (min.)	Cycle type (EN 13060:2014 + A1:2018)	Pre-vacuum (F=fractionated; S=single)	Standard drying (min.) ***	Total cycle time (Load Max.)	Max. H <sup>2</sup> O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	ТҮРЕ	MAX. TOTAL MASS (kg)	MAX. MASS PER TRAY (kg) **	MAX. MASS PER ITEM (kg)	
134°C SOLID WRAPPED	134	2.1	4(*)	S	S	17	45	500	0.7	Solid instruments in single pack Unwrapped solid	5.00	1.00	0.25	It is advisable to use the 3-tray configuration
										materials	9.00	1.20	0.50	
XXX°C USER (see note)	134	2.1	4÷30	n.a.	F/S	5÷30	n.a.	n.a.	n.a.	Unwrapped solid instruments (other load types are possible	n.a.	n.a.	n.a.	Variable parameters
(see note)	121	1.1	20÷30							depending on the user settings)				depending on the settings made
HELIX/BD TEST	134	2.1	3.5	-	F	1	24	-	-	Test device only (without another load)	-	-	-	
VACUUM TEST	-	-0.8	-	-	-	-	18	-	-	Empty chamber	-	-	-	
VACUUM + HELIX/BD TEST (executable in sequence)	-	-	-	-	-	-	46	-	-	-	-	-	-	

(\*) To set a sterilisation time of 5.5 minutes, contact the Technical Service.

Single Pre-Vacuum = 1 pre-vacuum; -0.8 bar (see figures in the following pages).

Fractionated Pre-Vacuum = 3 pre-vacuum; -0.8 bar each (see figures in the following pages).

Definition of hollow loads in accordance with standard EN 13060:2014 + A1:2018.

The term "hollow loads" in this manual refers both to "narrow lumen" elements (paragraph 3.18 EN 13060:2014 + A1:2018) and "simple hollow" elements (paragraph 3.30 EN 13060:2014 + A1:2018).

The term "hollow load B" refers ONLY to the elements defined as "simple hollow" (paragraph 3.30 EN 13060:2014 + A1:2018).

(\*\*) The Max. Mass per Tray means the maximum load to be placed on each tray, while respecting the MAX. TOTAL MASS as device load limit.

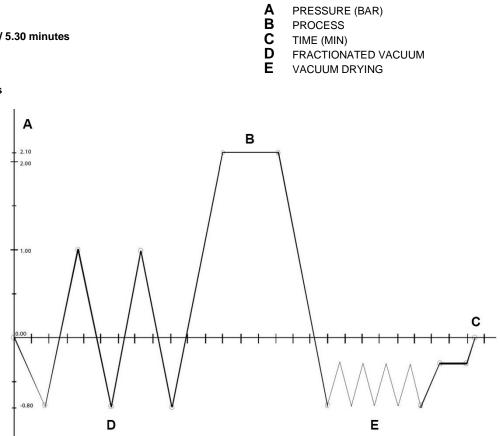
(\*\*\*) Depending on the type of load, it may be necessary to optimise drying using the extra drying function (8.1).

		PRESSUR n compliance with EN	RE, TIME AND TEMP		25				
134°C cycles									
EN 13060:2014 + A1:2018		Time (minutes)	Min. temperature	Max. temperature	Min. pressure (bar)	Max. pressure (bar)			
1	CS								
t1	1PV				-0.81	-0.79			
t2	1PP				+0.97	+1.03			
t3	2PV				-0.81	-0.79			
t4	2PP				+0.97	+1.03			
t5	3PV				-0.81	-0.79			
t6	SS	4 / 5.5	+134	+137	+2.04	+2.31			
t7	SE	4 / 5.5	+134	+137	+2.04	+2.31			
t8	DS				-0.81	-0.79			
t9	DE								
2	CE				-0.02	+0.02			
			121°C cycles						
EN 13060:2014 + A1:2018		Time (minutes)	Min. temperature	Max. temperature	Min. pressure (bar)	Max. pressure (bar)			
1	CS								
t1	1PV				-0.81	-0.79			
t2	1PP				+0.97	+1.03			
t3	2PV				-0.81	-0.79			
t4	2PP				+0.97	+1.03			
t5	3PV				-0.81	-0.79			
t6	SS	20	+121	+124	+1.05	+1.25			
t7	SE	20	+121	+124	+1.05	+1.25			
t8	DS				-0.81	-0.79			
t9	DE								
2	CE				-0.02	+0.02			

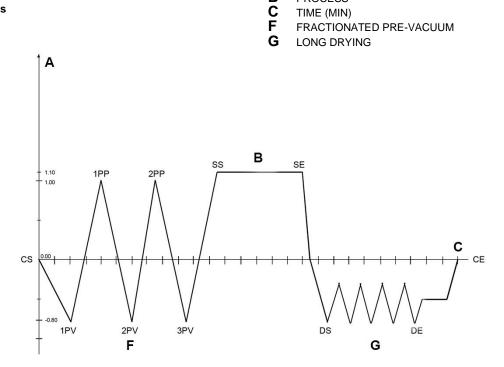
### **13.4. STERILISATION PROGRAM DIAGRAM**

PROGRAM 134°C UNIVERSAL 134°C - 4 minutes / 5.30 minutes

PROGRAM 134°C PRION 134°C – 18 minutes







Α

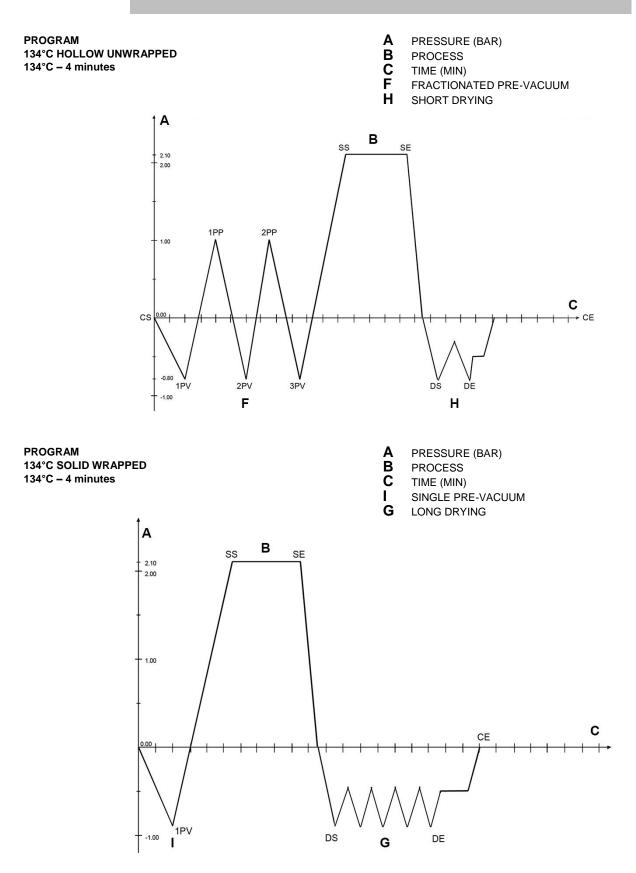
В

PRESSURE (BAR)

PROCESS

TIME (MIN)

EN 67



#### **13.5. DIAGRAMS OF THE TEST PROGRAMMES**

1.00

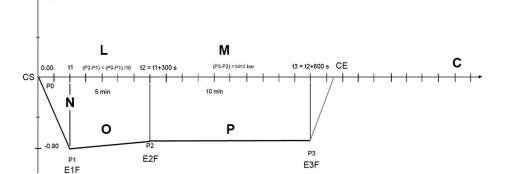
PROGRAM HELIX B&D TEST 134°C – 3.5 minutes

PROGRAM

-0.80 bar

VACUUM TEST

A B PRESSURE (BAR) PROCESS С TIME (MIN) F FRACTIONATED PRE-VACUUM Н SHORT DRYING Α в SS SE 2.10 2.00 2PP 1PP 1.00 С CE cs 0.00 -0.80 1PV 2PV 3PV DS DE -1.00 F Н A C PRESSURE (BAR) TIME (MIN) L INTERMEDIATE CONDITION TO CONTINUE THE TEST Μ FINAL CONDITION TO PASS THE TEST Ν VACUUM PHASE O P STANDBY LOSS MEASUREMENT Α



EN 69

#### **13.6. EXAMPLES OF PRINTED REPORTS**

#### (WITH OPTIONAL PRINTER)

Machine model Serial Number FW Version Current cycle Cycle Counter Program Temperature Pressure Process time Standby Prevacuum

Prevacuum Drying time Measuring H2O

CYCLE START

CS CSV 1PV 1PP 2PV 2PP 3PV ET SS

SE DS SPD EPD

DE CE

OPERATOR:

Time

00:00 11:00 15:53 19:54 22:46 25:26 27:55 32:24 32:39 33:38 34:38 35:38 36:39 38:39 39:47 56:47 57:47

58:08

33:38 32:58

CYCLE:

OPERATOR:

Drying pulse CYCLE END

#### **PROGRAM PRINTING (STANDARD)**

°C

Bravo G4 28 AJxxxxxx

ON FRACTIONATED

17.00 min 2.0 uS/cm

02/04/2021 14:34

bar

 C
 bar

 37.0
 0.015

 55.0
 0.018

 58.0
 -0.802

 119.3
 1.016

 64.7
 -0.804

 129.8
 1.022

 72.9
 -0.806

 134.7
 2.140

 135.0
 2.156

 135.0
 2.158

 135.0
 2.154

 135.0
 2.002

 85.8
 -0.802

 95.6
 -0.622

 98.6
 -0.092

 99.7
 0.014

MAX 135.1 °C MIN 134.9 °C

11 02/04/2021 15:32

PASS

AJXXXXXX 1.11/J001 01044 00947/01046 134°C Universal B 134°C 2.10 bar 4 min ON

PROGRAM	PRINTING	HEL	IX/BD	TEST
111001174			1000	

°C

 $\begin{array}{c} 22.1\\ 55.0\\ 57.5\\ 119.2\\ 76.5\\ 119.9\\ 75.7\\ 134.8\\ 134.9\\ 135.0\\ 135.0\\ 135.0\\ 135.0\\ 135.0\\ 82.9\\ 84.0\\ 92.7\\ 95.5 \end{array}$ 

Bravo G4 28 **AJXXXXXX** 1.11/3001 01046 00947/01046 Helix/BaD Test 134 °C 2.10 bar 3.5 min ON FRACTIONATED 1.00 min 1.6 uS/cm

06/04/2021 10:31

bar

-0.000 0.002 -0.807 1.011 -0.806 1.021 -0.806 2.140 2.158 2.158 2.159 2.156 2.158 -0.000 -0.807 -0.697 -0.211 -0.002

MAX 135.0 °C MIN 134.8 °C

06/04/2021 11:17

PASS

Machine model Serial Number FW Version Current cycle Cycle Counter Program Temperature Process time Standby Prevacuum Drying time

Drying time Measuring H2O

CS CSV 1PV 1PP 2PV 2PP 3PV ET SS

SE DS SPD EPD DE CE

CYCLE START

OPERATOR:

Time

00:00 16:14 20:37 24:49 27:10 29:50 32:03 36:46 37:01 38:01 39:01 40:01 40:01 40:30 43:24 43:24

45:24 45:47

37:55 37:51

CYCLE:

OPERATOR:

Drying pulse CYCLE END

#### **PROGRAM PRINTING VACUUM TEST** Machine model Serial Number FW Version Current cycle Cycle Counter Program Bravo G4 28 Bravo G4 28 AJxxxxxx 1.11/J001 01045 00947/01046 Vacuum Test 06/04/2021 10:10 CYCLE START OPERATOR: Time °C bar 21.1 -0.001 21.2 -0.001 21.0 -0.803 21.3 -0.803 21.4 -0.801 22.3 -0.002 00:00 00:03 04:08 09:08 19:08 CS CSV E1F E2F E3F CE 20:06 06/04/2021 10:30 CYCLE END VACUUM TEST: PASS OPERATOR:

LA.

The text printed on the receipt remains for a couple of years, if correctly stored (away from any source of heat and in a cool, dry place). Store thermal receipts using cellulose envelopes, do not use plastic bags.

### 14. APPENDIX - MAINTENANCE

In addition to correct use, the user needs to perform regular maintenance in order to guarantee safe, efficient operation over the device's entire life.



Always use personal protective equipment.



For better quality of maintenance, supplement routine checks with regular periodic check-ups that can be performed by Technical Service Department (see Appendix).

It is also fundamental to perform a **periodic steriliser validation**, i.e. a check of process thermo-dynamic parameters and their comparison with the reference values detected by duly calibrated tools. Refer to 'Steriliser Periodic Validation'' in the next part of the Appendix.

The regular maintenance described below consists of easy manual operations and preventative interventions involving simple tools.

In the event of replacement of components or parts of the device, request and/or use original spare parts only.

#### 14.1. REGULAR MAINTENANCE PROGRAMME

The table summarises the maintenance interventions required to maintain the steriliser in good working order.

In case of *heavy use*, we recommend *shortening* maintenance intervals:

DAILY	Clean the door gasket and the internal part of the door (14.3.1)	
	Clean the chamber drain filter (14.3.4) Clean external surfaces (14.3.3)	
WEEKLY	Clean the sterilisation chamber and its accessories (14.3.2)	
	Clean the anti-dust filter (14.3.6)	
MONTHLY	Clean the internal water tank (14.3.9)	
	Warnings related to Scheduled Maintenance are displayed with the follow	wing frequency (14.2):
	WARNING MESSAGE	FREQUENCY
	CHAMBER FILTER CLEANING (14.3.4)	250 CYCLES or 3 MONTHS
PERIODICALLY	DOOR LOCK LUBRICATION (14.3.5)	250 CYCLES or 3 MONTHS
PERIODICALLI	ANTI-DUST FILTER CLEANING (14.3.6)	500 CYCLES or 6 MONTHS
	BACTERIOLOGICAL FILTER REPLACEMENT (14.3.7)	500 CYCLES or 6 MONTHS
	DOOR GASKET REPLACEMENT (14.3.8) *	1000 CYCLES or 1 YEAR
	GENERAL SERVICE	3000 CYCLES or 3 YEARS
YEARLY	Validate steriliser (14.4) **	
IEARLI	Replace the door gasket (14.3.8) *	

\* Replacement every 1000 cycles or 1 year, whichever is first.

\*\* Based on local guidelines or regulations.

1P

 $\mathbf{P}$  A regular maintenance is essential to achieve the best performance of the device.

Periodically, a message will be displayed requesting that the above maintenance operations are performed.

For further information or in case of doubt, contact Technical Service if they have performed regular maintenance on the device the technician might have already carried out some of these operations (e.g. Replacement of the bacteriological filter or of the door gasket).

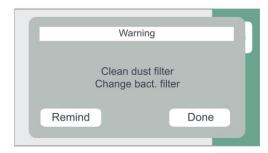
#### **14.2. SCHEDULED MAINTENANCE MESSAGES**

The steriliser periodically displays warning messages relevant to "routine" maintenance operations that must be carried out in order to ensure the proper operation of the device.

Press DONE to confirm that the required maintenance operation has been completed.

Press REMIND button to postpone the operation.

In this case, the warning message will reappear the next time the steriliser is used.



Always keep in mind the following general warnings:

after turning it off.

- <u>Do not</u> wash the steriliser with direct jets of water, neither under pressure nor sprinkled. Seepage into electrical and electronic components could irreparably damage the functioning of the device or its internal parts.
- <u>Do not</u> use <u>abrasive cloths</u>, <u>metal brushes</u> (or other aggressive materials), <u>or products for metal cleaning</u>, both solid and liquid, to clean the device and the sterilisation chamber.
- Do not use unsuitable chemical products or disinfectants to clean the sterilisation chamber. In fact, these products can cause irreparably damage.
- Do not allow limescale or residues of other substances to accumulate in the sterilisation chamber, on the door and on the gasket, and remove them periodically. In fact, such residues may damage these parts and compromising the operation of the hydraulic circuit components.

The formation of white spots on the base of the internal wall of the chamber means that you are using poor quality demineralised water.

Before performing regular maintenance, make sure that the power cord plug is removed from the mains socket. If this is not possible, move the external switch of the device's power supply line to Off. If the external switch is distant or not visible to the maintainer, place a "work in progress" sign on the switch,



#### **14.3. DESCRIPTION OF MAINTENANCE INTERVENTIONS**

Let's now look at the various operations to be carried out.

#### 14.3.1. DOOR GASKET AND THE INTERNAL PART OF THE DOOR CLEANING

To eliminate any traces of limescale, clean the gasket of the chamber and the door porthole with a clean cotton cloth soaked in a soft solution of water and vinegar (or a similar product, checking the contents on the label before using).

Dry the surfaces and remove any residues before using the device.



#### 14.3.2. STERILISATION CHAMBER AND ACCESSORIES CLEANING

Clean the sterilisation chamber, support and trays (and internal surfaces in general) with a clean cotton cloth soaked in water, and possibly the addition of a small amount of neutral detergent.

Carefully rinse with demineralised / distilled water, taking care not to leave any type of residue in the chamber or on accessories.



 $\square$  Do not use pointed or sharp tools to remove scale from the sterilisation chamber.

Should there be evident deposits, immediately check the quality of the demineralised / distilled water used (see Technical Characteristics appendix).

#### 14.3.3. EXTERNAL SURFACE CLEANING

Clean the external surfaces using appropriate product (i.e. Ethyl alcool, 50% diluted with water). Apply product with a soaked cloth, then dry.



#### Do not spray or vaporise any product directly on device surfaces. Inflammable liquid.

#### 14.3.4. CHAMBER FILTER CLEANING

With use it is likely that various residues accumulate in the filter and with time obstruct the lower drain duct.

To clean the filter, open the steriliser door and remove the cap using a coin or another suitable tool.

Loosen the union that contains the filter.

Remove the filter from its support and thoroughly clean it under a jet of running water, if necessary using a sharp tool to remove any large foreign bodies (if possible use a jet of compressed air).

#### If it is impossible to recover the filter, replace it with a new one.

Refit everything operating in reverse order and making sure to screw the union in such a way that the drain holes are positioned at the level of the boiler wall.



Properly fit the filter in its housing.

A partial fitting may damage the component.

#### 14.3.5. DOOR LOCK LUBRICATION

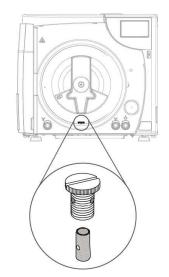
Using a clean cloth, remove any residues from the bushing and the screw.

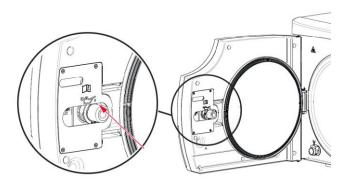
Lubricate the inside of the bushing on the steriliser door with a film of the silicone-based grease provided (as shown in the figure).

Wear single-use gloves before application.

Essentially, the lubricant is not an irritant to the skin; nevertheless, it may cause unpleasant effects if it accidentally comes into contact with eyes.

In case of contact with eyes, rinse with plenty of water.

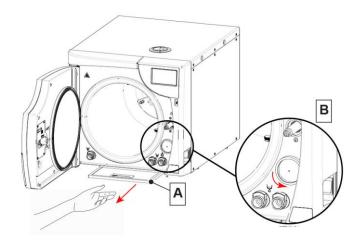




#### 14.3.6. ANTI-DUST FILTER CLEANING

Remove the filter (A) from the lower part of the autoclave, thoroughly rinse it with water and dry it before refitting it.

The filter can be cleaned using a jet of compressed air, making sure not to disperse any dust into the environment.



#### 14.3.7. REPLACE THE BACTERIOLOGICAL FILTER

When filter maintenance is due or every time you notice visible clogging of the filter (indicated by the filter markedly turning grey), unscrew the bacteriological filter ( $\mathbf{B}$ ) from its support and replace it with a new one, screwing it fully down on the union.



A spare bacteriological filter is provided with the device. If you need spare parts of this component, refer to APPENDIX – TECHNICAL SERVICE.

#### 14.3.8. DOOR GASKET REPLACEMENT

The door gasket needs to be replaced by an authorised technician. Contact Technical Service (see A**PPENDIX – TECHNICAL SERVICE**).

## 14.3.9. INTERNAL WATER RESERVOIR CLEANING



Do not run cycles during the following operations.

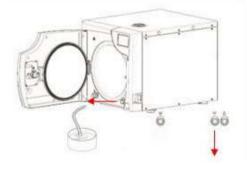
#### Step 1

With the device ON, proceed to:

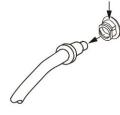
- · Open the door.
- · Arrange an empty container with minimum capacity of 5 l.
- Insert the manual drainage tubing with quick connector into the front port.
- Fully drain the internal water reservoir by means of the front quick connector.

#### Step 2

Once the internal water reservoir is empty, disconnect the drainage tube from the quick connection port.



#### Detaching the tube

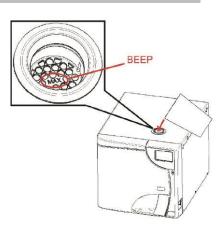


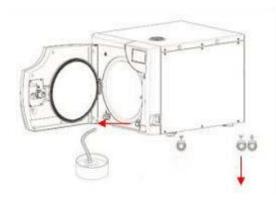
#### Step 3

- Remove the cap from the top cover and manually fill with 70% ethyl alcohol + demineralised/distilled water solution (4 I in equal parts).
- Pour the 70% ethyl alcohol + demineralised/distilled water solution up to the MAX level, signalled by an audible warning.
- Leave the solution to sit for 30 minutes.

#### Step 4

Repeat STEP 1 to drain the solution from the tank by means of the front quick connector.





#### Step 5

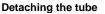
Once the internal water reservoir is empty, disconnect the drainage tube from the quick connection port.



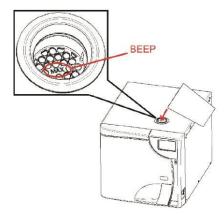
- Rinse the internal water reservoir with clean, demineralised/distilled water by again removing the cap from the top cover and manually
- filling up to the MAX level, signalled by an audible warning.
- · Leave the clean, demineralised/distilled water to sit for 5 minutes.

#### Step 7

- Repeat STEP 1 to fully drain the internal water reservoir.
- Once the reservoir has been rinsed and drained, it is important to fill the internal water reservoir with demineralised/distilled water before starting a cycle.
- Resume normal operation of the unit, and fill the reservoir using one of the suitable manual or automatic fill options available.







#### **14.4. PERIODIC STERILISER VALIDATION**

As happens with all devices, it is possible, and sometimes inevitable, to have a decrease in performance and the effectiveness of components along their lifespan, in a period of time dependent on its frequency of use.

To guarantee the safety of the process over time, it is periodically (depending on local guidelines or regulations) necessary to verify, the thermodynamic process parameters (pressure and temperature), to check if they continue to remain within allowed limits or not.

The requalification of the steriliser's performance is the **responsibility of the user** of the product.

The reference European standards **EN 17665** (Sterilisation of the medical devices - Method for the validation and systematic control of the steam sterilisation) and **EN 556** (Sterilisation of the medical devices – Requirements for the medical devices marked with "STERILE" indication) supply an effective guide tool for carrying out the verifications on the steam sterilisers.

Since, in addition to specific experience and training, these controls require the use of special equipment (high-precision sensors and probes, data loggers, dedicated software, etc.) suitably verified and calibrated, it is necessary to contact a **company specialising** in these activities.

Customer Service department (see Appendix) is available to provide any information relative to the periodic validation of steam sterilisers.

#### 14.5. DEVICE USEFUL LIFE

Steam steriliser service life is of 10 years (average use: 5 cycles/day, for 220 days/year). For normal use, it is expected that the device is used and maintained according to the instructions provided by the manufacturer.

The expected useful life of the device is subject to risk analysis carried out in compliance with requirements of standard ISO 14971.

#### 14.6. DISPOSING THE EQUIPMENT WHEN NO LONGER USED

According to Directive 2012/19/EU concerning waste disposal, the units must not be disposed of as municipal waste, but must be separated. When purchasing a new device of an equivalent type, one for one, the device that has come to the end of its lifetime should be returned to the dealer for disposal.

Regarding reuse, recycling and other forms of recovery of the above mentioned waste, the manufacturer carries out the functions defined in the individual national legislations.

Appropriate differentiated waste collection for subsequent recycling treatment and environmentally friendly disposal contributes to preventing possible negative effects on the environment and health, and encourages recycling of the materials of which the device is made up. The symbol indicating separate collection for electrical and electronic equipment consists of the crossed out bin marked on the device.

Under national legislation, fines can be imposed if the product is disposed in an illegal manner.

### **15. APPENDIX - GENERAL PROBLEMS**

If while using the device a problem or an alarm occurs, this **DOES NOT** mean that the device is out of order. It may not, in fact, be related to a breakdown but more probably to an anomalous situation, often merely transitory (such as a blackout), or incorrect use.

In any case, it is important to first identify the cause of the failure and then take suitable corrective actions, either autonomously or with the intervention of the **Technical Service Department** (see Appendix).

For this purpose, we provide instructions for diagnosing and resolving general problems, in addition to a precise description of the alarm codes, their meaning and their solution.

#### **15.1. TROUBLESHOOTING**

If your steriliser is not working correctly, please make the following checks before contacting the Technical Service Department:

PROBLEM	POSSIBLE CAUSE	SUGGESTED SOLUTION
	The power cable is not plugged-in.	Plug it in.
The starilizer data not power on	Lack of voltage at the power supply socket.	Check the cause of the lack of voltage at socket and fix it.
The steriliser does not power-on.	The main switch and/or differential switch are turned to OFF.	Turn the switch to ON.
	The mains fuses are blown.	Contact Technical Service.
After pressing START, the sterilisation cycle does not start.	The device is preheating.	Wait for the steriliser to reach the proper operating conditions for starting the program. Under standard conditions, the Average Preheating Time is about 10-15 Minutes.
The safety valve has triggered.	Locking ring loosened. Presence of anomalous overpressure in the chamber.	Contact Technical Service.
Water presence on the steriliser	The water automatic filling system hose (optional) is not correctly connected.	Check the tightness of the fittings and, if necessary, reassemble them more carefully. Check that the hoses are completely inserted on the fittings; check the presence of hose clamps.
resting surface.	Steam leak from door gasket.	At the end of the cycle clean the gasket and the closing porthole with a dampened cloth. Check the presence of any gasket damage. Perform a new verification cycle.
	Excessive load in the sterilisation chamber.	Check that the load does not exceed the maximum values allowed (See the Summary Table in Appendix "Technical Characteristics").
Excessive humidity on the material and/or instruments at the end of the program.	Load not correctly positioned.	Position the load, in particular the wrapped one, as per the indications. (See <u>Chapter</u> "Preparing the material").
	Wrong selection of the sterilisation program.	Choose the sterilisation program suitable for the type of material to be treated. (See the Summary Table in " <b>Programs</b> " <u>Appendix</u> ).
	Clogged chamber drainage filter.	Clean or replace the drainage filter. (See <u>Appendix</u> "Maintenance").

PROBLEM POSSIBLE CAUSE		SUGGESTED SOLUTION	
	Quality of the instruments not adequate.	Check the quality of instruments, making sure that the material they are made of is suitable to tolerate the steam sterilisation.	
Traces of oxidation or spots on	Organic or inorganic residues on the instruments.	Carefully clean the material before subjecting it to the sterilisation cycle. (See Chapter "Preparing the material").	
instruments.	Contact between instruments made of different metals.	Separate instruments made of different metals. (See Chapter "Preparing the material").	
	Presence of limescale residues on the wall of the chamber and/or accessories.	Clean the chamber and the accessories as prescribed. (See <b>Appendix "Maintenance").</b>	
Blackening of the instruments or damage to the material.	Wrong selection of the sterilisation program.	Choose the sterilisation program suitable for the type of material to be treated. (See the <b>Summary Table in "Programs" Appendix).</b>	

### 16. APPENDIX – ALARMS



If the problem persists, contact Technical Service (see APPENDIX) communicating the steriliser model and serial number. This data is indicated on the registration plate on the rear side of the device, on the declaration of conformity and can also be viewed by means of the "steriliser information" command.

Every time an anomalous condition occurs during the operation of the steriliser, an alarm is generated, identified by a specific code (consisting of a letter followed by a 3-digit number).

Alarm codes are divided into four categories:

#### E = ERROR/WARNING

Incorrect handling and/or use or a cause outside the device. The problem can normally be solved by the user. Code format: (xxx = identification number 000 ÷ 999) Exxx

#### A = ALARM

First level fault The problem can normally be solved on site by a specialised technician. Code format: Axxx (xxx = identification number 000 ÷ 999)

#### H = HAZARD

Second level fault The problem can normally be solved by the Technical Service Centre. (xxx = identification number 000 ÷ 999) Code format: Hxxx

#### S = SYSTEM ERROR

Electronic system error (HW-FW).

(xxx = identification number 000 ÷ 999) Code format: Sxxx

In case of alarm, switch off the device only after having followed the indications displayed and having carried out the reset (see "Resetting the system" paragraph).

#### **16.1. ALARM INTERVENTION**

The alarm intervention causes the cycle interruption (or the normal operation interruption), the display of the relevant alarm code and message and an audible warning.

#### **16.2. ALARM DURING A CYCLE**

The alarm procedure is designed to ensure the user does not confuse an anomalous cycle with an efficiently carried out one, and therefore to eliminate the unintentional use of unsterilised materials; it is structured to guide the user to RESET the steriliser and follow the instructions below.

#### 16.3. SYSTEM RESET

The system can be reset in two alternative ways, depending on the type of alarm (see the List of alarm codes below in this appendix):

- · Pressing the OK button.
- · Following the instructions displayed and holding down the RESET button for about 3 seconds.

Press the RESET button for approx. 3 seconds to go back to the main menu.



After the RESET and any technical operation necessary to eliminate the fault, the device will be ready to perform a new program.



Never turn off the device before carrying out the reset.

### **17. ALARM CODES**

The list of alarm codes, the relevant messages displayed and RESET modes are indicated in the following table:

### 17.1. ERRORS (CATEGORY E)

The alarm codes in the list can refer to functions that are not present in the models concerned in this Operator's Manual.

CODE	ALARM DESCRIPTION	MESSAGE ON THE DISPLAY	RESET MODE
E000	Black-out	POWER OUTAGE CONTACT TECH. SERVICE	2
E001	Voltage of power supply line too high	OVERVOLTAGE CONTACT TECH. SERVICE	1
E002	Water conductivity threshold 1 exceeded	INSUFFICIENT H2O QUALITY	1
E003	Water conductivity threshold 2 exceeded	QUALITY H2O BAD CHANGE WATER	1
E004	Error in electrical mains frequency reading	LINE FREQ. ERROR CONTACT TECH. SERVICE	1
E007	One of the two fans is not working properly	FAN PROBLEM CONTACT TECH. SERVICE	1
E008	Water conductivity threshold 1 exceeded	FILTERS NEARLY EXHAUSTED	1
E009	Water conductivity threshold 2 exceeded	QUALITY H2O BAD CHANGE WATER	1
E010	Door open	DOOR OPEN CLOSE DOOR	1
E020	Door lock system (closing) activation time-out exceeded	DOOR CLOSING ERROR CONTACT TECH. SERVICE	1 (then reattempt or turn off)
E021	Door lock system (opening) activation time-out exceeded	DOOR OPENING ERROR CONTACT TECH. SERVICE	1 (then reattempt or turn off)
E022	Door lock microswitches failure.	DOOR LOCK PROBLEM CONTACT TECH. SERVICE	2
E030	The water in the feed tank is at minimum level (MIN.)	LOAD TANK MINIMUM LEVEL FILL TANK	1
E031	Maximum level of water in the drainage tank (MAX.)	DISCHARGE TANK MAXIMUM LEVEL EMPTY TANK	1
E042	The MAX. water level in the filling tank has been reached	LOAD TANK MAXIMUM LEVEL	1
E050	Reminder to run the Vacuum Test cycle	TEST REMINDER RUN VACUUM TEST	1
E060	The autoclave cannot connect to LAN network	ETHERNET CONFIG. ERROR CHECK SETTINGS	1
E061	The autoclave cannot connect to WiFi network	WIFI CONFIG. ERROR CHECK SETTINGS	1
E070	Activation of preheating with door open	PREHEATING ON IS RECOMMENDED TO CLOSE THE DOOR	1
E126	Cloud firmware is being updated	CLOUD FW UPDATING WAIT	1
E141	The cloud firmware version is not the correct one with respect to the firmware process. There may be malfunctions in the connection with WiFi / ethernet or cloud	INCORRECT FW VERSION CLOUD PLEASE UPDATE THIS FW	1
E900	Vacuum test failed (during TEST PHASE)	TEST FAILED SECOND STEP CONTACT TECH. SERVICE	2

CODE	ALARM DESCRIPTION	MESSAGE ON THE DISPLAY	RESET MODE
E901	Vacuum test failed (during STAND-BY PHASE)	TEST FAILED FIRST STEP CONTACT TECH. SERVICE	2
E902	Vacuum test failed (vacuum pulse time-out exceeded)	TEST FAILED VACUUM NOT ACHIEVED CONTACT TECH. SERVICE	2
E998	Remote maintenance activity in progress	REMOTE SERVICE ACTIVE	1
E999	Manually interrupting the cycle	MANUAL INTERRUPTION	2

1 = OK (warning) 2 = OK + door unlocking + RESET (if in cycle)

## 17.2. ALARMS (CATEGORY A)

CODE	ALARM DESCRIPTION	MESSAGE ON THE DISPLAY	RESET MODE
A032	Problem with the level sensor of the filling tank	FILL. WATER LEVEL SENSOR PROBLEM CONTACT TECH. SERVICE	1
A040	The tank has not been filled (only with automatic filling system)	FAILED WATER INLET CHECK AUTOMATIC LOAD	1
A042	The MAX. water level in the filling tank has been reached abnormally (automatic filling)	WATER FILLING MAXIMUM LEVEL CHECK TANK	1
A101	Temperature sensor PT1 broken (sterilisation chamber)	CHAMBER PROBE PT1 OPEN CIRCUIT CONTACT TECH. SERVICE	1
A102	Temperature sensor PT2 broken (steam generator)	GENERATOR PROBE PT2 OPEN CIRCUIT CONTACT TECH. SERVICE	1
A103	Temperature sensor PT3 broken (heating element)	HEATING BAND PROBE PT3 OPEN CIRCUIT CONTACT TECH. SERVICE	1
A105	Temperature sensor PT5 broken (conductivity measurement compensation)	CONDUCTIVITY SENSOR PT5 OPEN CIRCUIT CONTACT TECH. SERVICE	1
A111	Temperature sensor PT1 short-circuited (sterilisation chamber)	CHAMBER PROBE PT1 SHORT-CIRCUIT CONTACT TECH. SERVICE	1
A112	Temperature sensor PT2 short-circuited (steam generator)	GENERATOR PROBE PT2 SHORT-CIRCUIT CONTACT TECH. SERVICE	1
A113	Temperature sensor PT3 short-circuited (heating element)	HEATING BAND PROBE PT3 SHORT-CIRCUIT CONTACT TECH. SERVICE	1
A115	Temperature sensor PT5 short-circuited (conductivity measurement compensation)	CONDUCTIVITY SENSOR PT5 SHORT-CIRCUIT CONTACT TECH. SERVICE	1
A116	ADC error	PROCESS BOARD ERROR CONTACT TECH. SERVICE	1
A117	Motor door overcurrent	MOTOR DOOR OVERCURRENT	2
A120	Reference heating element acquisition chain fault	PROCESS BOARD ERROR CONTACT TECH. SERVICE	1
A121	Reference heating element acquisition chain fault	PROCESS BOARD ERROR CONTACT TECH. SERVICE	1
A122	Reference heating element acquisition chain fault	PROCESS BOARD ERROR CONTACT TECH. SERVICE	1
A126	Connection error with WiFi module	WIFI MODULE ERROR CONTACT TECH. SERVICE	1
A131	Solenoid valve 1 failed	SOLENOID VALVE 1 ERROR CONTACT TECH. SERVICE	2
A132	Solenoid valve 2 failed	SOLENOID VALVE 2 ERROR	2
A133	Solenoid valve 3 failed	CONTACT TECH. SERVICE SOLENOID VALVE 3 ERROR	2
A134	Solenoid valve 4 failed	CONTACT TECH. SERVICE SOLENOID VALVE 4 ERROR	
A135	Solenoid valve 5 failed	CONTACT TECH. SERVICE SOLENOID VALVE 5 ERROR	2
A135	Solenoid valve 6 failed	CONTACT TECH. SERVICE SOLENOID VALVE 6 ERROR	2
		CONTACT TECH. SERVICE	
A140 A145	Firmware update error Faulty current draw detected	FW CLOUD UPDATE ERROR FAULTY CURRENT DRAW CONTACT TECH. SERVICE	2
A146	Door motor control driver fault	DOOR MOTOR DRIVER ERROR CONTACT TECH. SERVICE	2
A147	Faulty current draw detected	FAULTY CURRENT DRAW CONTACT TECH. SERVICE	2

CODE	ALARM DESCRIPTION	MESSAGE ON THE DISPLAY	RESET MODE
A201	Pre-heating not executed within time-out (steam generator)	STEAM GENERATOR RESISTOR OPEN CIRCUIT CONTACT TECH. SERVICE	2
A202	Pre-heating not executed within time-out (tube bundle heating element)	HEATING BAND OPEN CIRCUIT CONTACT TECH. SERVICE	2
A250	1st pulse with vacuum not achieved within time out	1PV TIMEOUT CHECK LOAD CHECK CHAMBER FILTER	2
A251	1st rise back up to atmospheric pressure not reached within the time- out	ATM1 UPSTROKE TIMEOUT CONTACT TECH. SERVICE	2
A252	1st pressure pulse not reached within the time-out	1PP UPSTROKE TIMEOUT CONTACT TECH. SERVICE	2
A253	2nd pulse with vacuum not achieved within time out	2PV TIMEOUT CHECK LOAD CHECK CHAMBER FILTER	2
A254	2nd rise back up to atmospheric pressure not reached within the time- out	ATM2 UPSTROKE TIMEOUT CONTACT TECH. SERVICE	2
A255	2nd pressure pulse not reached within the time-out	2PP UPSTROKE TIMEOUT CONTACT TECH. SERVICE	2
A256	3rd pulse with vacuum not achieved within time-out	3PV TIMEOUT CHECK LOAD CHECK CHAMBER FILTER	2
A257	3rd rise back up to atmospheric pressure not reached within the time- out	ATM3 UPSTROKE TIMEOUT CONTACT TECH. SERVICE	2
A258	3rd pressure pulse not reached within the time out	3PP UPSTROKE TIMEOUT CONTACT TECH. SERVICE	2
A260	Chamber depressurisation not reached within time out	ATM3 DOWNSTROKE TIMEOUT CHECK LOAD CHECK CHAMBER FILTER	2
A261	Chamber levelling not reached within time out	PRESSURE LEVELLING TIMEOUT CONTACT TECH. SERVICE	2
A262	Vacuum pulsation during drying not executed within time-out	PD PRESSURE UPSTROKE TIMEOUT CONTACT TECH. SERVICE	2
A353	1st drop to atmospheric pressure not completed within the time-out	ATM1 DOWNSTROKE TIMEOUT CHECK LOAD CHECK CHAMBER FILTER	2
A356	2nd drop to atmospheric pressure not completed within the time-out	ATM2 DOWNSTROKE TIMEOUT CHECK LOAD CHECK CHAMBER FILTER	2
A360	Vacuum pulsation after maintenance step not executed within time- out	SPD PRESSURE DOWNSTROKE TIMEOUT CONTACT TECH. SERVICE	2
A362	Chamber depressurisation during drying not reached within time-out	PD PRESSURE DOWNSTROKE TIMEOUT CONTACT TECH. SERVICE	2

1 = OK (warning) 2 = OK + door unlocking + RESET

## 17.3. HAZARDS (CATEGORY H)

CODE	ALARM DESCRIPTION	MESSAGE ON THE DISPLAY	RESET MODE
H150	MPX pressure sensor broken/not connected	PRESSURE SENSOR OPEN CIRCUIT CONTACT TECH. SERVICE	3
H160	MPX pressure sensor short-circuited	PRESSURE SENSOR SHORT-CIRCUIT CONTACT TECH. SERVICE	3
H400	Pconv/T ratio not balanced (Pconv>T) (STERILISATION phase)	INCORRECT P/T RATIO CHECK LOAD	3
H401	T/Pconv ratio not balanced (T>Pconv) (STERILISATION phase)	INCORRECT T/P RATIO CHECK LOAD	3
H402	Temperature over the MAX. limit (STERILISATION phase)	TEMPERATURE BEYOND MAXIMUM LIMIT CONTACT TECH. SERVICE	3
H403	Temperature below the MIN. limit (STERILISATION phase)	TEMPERATURE BELOW MINIMUM LIMIT CONTACT TECH. SERVICE	3
H404	Floating temperature over the limit (STERILISATION phase)	ERRATIC TEMPERATURE CONTACT TECH. SERVICE	3
H405	Pressure over the MAX. limit (STERILISATION phase)	PRESSURE BEYOND MAXIMUM LIMIT CONTACT TECH. SERVICE	3
H406	Pressure below MIN. limit (STERILISATION phase)	PRESSURE BELOW MINIMUM LIMIT CONTACT TECH. SERVICE	3
H410	Time measurement error	INTERNAL TIMER ERROR CONTACT TECH. SERVICE	3
H411	Sterilisation time error	STERILIZATION TIME ERROR	3
H990	Excessive pressure (sterilisation chamber, MPX)	PRESSURE BEYOND MAXIMUM LIMIT CONTACT TECH. SERVICE	3
H991	Overheating (sterilisation chamber, PT1)	PT1 OVERHEATING CHECK LOAD	2
H992	Overheating (steam generator, PT2)	PT2 OVERHEATING CONTACT TECH. SERVICE	2
H993	Overheating (layer resistance, PT3)	PT3 OVERHEATING CONTACT TECH. SERVICE	2

1 = OK (warning) 2 = OK + door unlocking + RESET 3 = Cycle failed + OK + door unlocking + RESET

## 17.4. SYSTEM ERRORS (CATEGORY S)

CODE	ALARM DESCRIPTION	MESSAGE ON THE DISPLAY	RESET MODE
S001	Flash memory 1 on process board failed	FLASH MEMORY NOT ACCESSIBLE CONTACT TECH. SERVICE	2
S002	Flash memory 2 on process board failed	FLASH MEMORY NOT ACCESSIBLE CONTACT TECH. SERVICE	2
S005	USB key not accessible	PROBLEM WITH USB KEY CHANGE KEY	2
S006	USB key not accessible	USB KEY NOT ACCESSIBLE CHANGE KEY	2
S007	USB key full	USB KEY FULL CHANGE KEY	2
S009	Printer not connected or incompatible printer	PRINTER DISCONNECTED CHECK CONNECTION	2
S010	Printer: there is no paper or there might be a configuration error	PRINTER PAPER OUT CHECK PAPER	2
S011	Printer cover open	PRINTER: DOOR OPEN	2
S012	Probable printer configuration error	PRINTER: NOT READY TRY AGAIN	2
S020	Cycle backup not done	RUN BACKUP DOWNLOAD NEW CYCLES	2
S021	Cycle storage limit exceeded	CYCLE MEMORY FULL START OVERWRITING	2
S030	Check, using a watchdog, that one of main tasks is not in crash condition	SYSTEM ERROR CONTACT TECH. SERVICE	2 (off-cycle) 3 (in cycle)
S031	Check, using a hardware watchdog, that one peripheral is not in lock condition.	SYSTEM ERROR CONTACT TECH. SERVICE	2 (off-cycle) 3 (in cycle)
S032	Check, using a watchdog, that one of main tasks is not in lock condition (e.g. infinite loop)	SYSTEM ERROR CONTACT TECH. SERVICE	2 (off-cycle) 3 (in cycle)
S034	SW malfunction	SYSTEM ERROR CONTACT TECH. SERVICE	2
S035	SW malfunction in solenoid valve management	SYSTEM ERROR CONTACT TECH. SERVICE	2
S040	Check the log saving in the Flash memory	SYSTEM ERROR CONTACT TECH. SERVICE	2 (off-cycle) 3 (in cycle)
S041	Cycle performed with 4 minutes sterilisation time at 134°C	4-MINUTE STERILISATION COMPLETED	1
S042	Cycle performed with standard drying	4-MINUTE STERILISATION COMPLETED	1
S099	Error during cycle report creation	STANDARD DRYING CHECK LOAD DRYING	1
S100	SW malfunction	PROBLEM IN CREATING CYCLE REPORT CONTACT TECH. SERVICE	2

1 = OK (warning) 2 = OK + door unlocking + RESET 3 = Cycle failed + OK + door unlocking + RESET

### **17.5. TROUBLESHOOTING**

According to the type of alarm occurred, please find below the indications to detect the possible causes and restore the proper operation:

### 17.5.1. ERRORS (CATEGORY E)

The alarm codes in the list can refer to functions that are not present in the models concerned in this Operator's Manual.

CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
	Sudden power failure (blackout).	Wait for the power to be restored and do a RESET following the instructions.
E000	The main switch has accidentally been turned off and/or the power plug pulled from the socket.	Reconnect the plug and/or turn the device on again and RESET according to the instructions.
	Network fuses blown.	Contact Technical Service (see <u>Appendix</u> ).
E001	Abnormal voltage peak on the mains.	Reset according to the instructions. If the problem occurs again, have the mains electric system checked by a technician.
E002	The filling tank contains water of inadequate quality.	RESET according to the instructions. Empty the filling tank and refill it with demineralised / distilled water of adequate quality (<15µs/cm).
		RESET according to the instructions. IMMEDIATELY empty the filling tank and refill it with demineralised / distilled water of adequate quality (<15µs/cm).
E003	The filling tank contains water of very poor quality.	In these conditions, the steriliser allows a maximum of 5 cycles, after which it locks until the tank is filled with demineralised / distilled water of adequate quality (<15 µs/cm). This precaution is necessary to prevent damage to the device.
	Failure to main board.	RESET according to the instructions. Contact Technical Service (see Appendix).
E004	Disturbance on the electrical mains.	RESET according to the instructions. If the problem occurs again, have the electrical mains checked by a technician. If the electrical mains is equipped with a Continuity system, have the system checked by a technician.
E007	One or more rear fans failed.	RESET according to the instructions. Check the operation of rear fans and contact Technical Service (see Appendix).
E008	The filling/discharge tank contains water of inadequate quality.	RESET according to the instructions. Empty the filling tank and refill it with demineralised / distilled water of adequate quality (<15 µs/cm). If an automatic filling system is present, empty the external container and fill it with water of adequate quality. If a Pure100/500 demineraliser is present, replace the filter elements.
E009	The filling/discharge tank contains water of very poor quality.	RESET according to the instructions. Empty the filling tank IMMEDIATELY and refill it with demineralised / distilled water of adequate quality (<15 µs/cm). If an automatic filling system is present, IMMEDIATELY empty the external container and fill it with water of adequate quality. If a Pure100/500 demineraliser is present, replace the filter elements IMMEDIATELY.
	Door open (or not properly closed) at program start (START).	RESET according to the instructions. Properly close the door and restart the program.
E010	Door position microswitch failure.	Contact Technical Service (see Appendix).
	Door position microswitch failure.	
	Door lock mechanism limit microswitch failure.	RESET according to the instructions. Contact Technical Service (see Appendix).
E020	Door lock system lack of lubrication.	RESET according to the instructions. Lubricate the door system.
	Door lock mechanism limit microswitch failure.	
E021	Door lock system gearmotor failure.	RESET according to the instructions. Contact Technical Service (see Appendix).
E022	Door lock microswitches failure.	RESET according to the instructions. Contact Technical Service (see Appendix).

CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
E030	Water level in the filling tank below minimum.	RESET according to the instructions. Top up with water up to the MAX. level (or at least over the MIN. level).
	MIN. water level sensor failure.	Contact Technical Service (see Appendix).
E031	Water level in the drain tank over the MAX. level.	RESET according to the instructions and empty the tank. Completely drain the tank.
	MAX. water level sensor failure.	Contact Technical Service (see <u>Appendix</u> ).
E042	Warning that the maximum water level in the tank has been reached (manual filling).	Interrupt the filling operation to prevent water spillage.
E060	The autoclave cannot connect to Lan network.	Make sure that configuration parameters of the LAN network are correct. Check that the LAN network chosen for the connection is working properly. Contact Technical Service (see Appendix).
E061	The autoclave cannot connect to WiFi network.	Make sure that configuration parameters of the WiFi network are correct. Check that the router managing the WiFi network is on and that the WiFi network chosen for the connection is working properly. Contact Technical Service (see Appendix).
E070	Activation of preheating with door open	Always keep the door closed when the steriliser is not in cycle
E126	Cloud firmware is being updated	Wait for the message to disappear and restart the machine
E141	The cloud firmware version is not the correct one with respect to the firmware process. There may be malfunctions in the connection with WiFi / ethernet or cloud.	Contact Technical Service (see <u>Appendix</u> ).
E900	Air seepage through the gasket.	RESET according to the instructions. Thoroughly clean the gasket with a clean cotton cloth moistened with water. Restart the program.
	Problem in the hydraulic circuit.	Contact Technical Service (see <u>Appendix</u> ).
	Excessive humidity in the sterilisation chamber.	RESET according to the instructions. Thoroughly dry the inside of the chamber and restart the program.
E901	Air seepage through the gasket.	RESET according to the instructions. Thoroughly clean the gasket with a clean cotton cloth moistened with water. Restart the program.
	Problem in the hydraulic circuit.	Contact Technical Service (see <u>Appendix</u> ).
	Excessive humidity in the sterilisation chamber.	RESET according to the instructions. Thoroughly dry the inside of the chamber and restart the program.
E902	Air seepage through the gasket.	RESET according to the instructions. Thoroughly clean the gasket with a clean cotton cloth moistened with water. Restart the program.
	Vacuum pump failure.	
	Problem in the hydraulic circuit.	Contact Technical Service (see <u>Appendix</u> ).
E998	Service maintenance in progress.	Service maintenance in progress. If you were not informed, contact IMMEDIATELY the manager of the network to which the steriliser is connected. Contact Technical Service (see <u>Appendix</u> ).
E999	Manual interruption of the sterilisation or test cycle.	RESET according to the instructions.

## 17.5.2. ALARMS (CATEGORY A)

CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
A032	Connector of water level sensors in the filling tank not connected.	Contact Technical Service (see Appendix).
	Failure of water level sensor(s) in the filling tank.	
	Lack of water in the external container (automatic filling).	RESET according to the instructions. Fill the container with a sufficient quantity of water (check the level at regular intervals).
A040	Automatic filling system not properly installed.	RESET according to the instructions. Check that the filling tube is properly connected. Remove any obstruction along the tube path.
	Automatic filling system failure.	Contact Technical Service (see Appendix).
A042	Possible problem with the automatic loading system.	Contact Technical Service (see Appendix).
A101	Chamber temperature sensor failure (PT1).	
A102	Steam generator temperature sensor failure (PT2).	
A103	Heating element temperature sensor failure (PT3).	
A105	Temperature sensor PT5 failed (conductivity measurement compensation).	
	Incorrect temperature sensor connection (sterilisation chamber).	
A111	Temperature sensor short-circuit (sterilisation chamber).	
A112	Incorrect temperature sensor connection (steam generator).	Contact Technical Service (see Appendix).
	Temperature sensor short-circuit (steam generator).	
A113	Incorrect temperature sensor connection (heating element).	
-	Temperature sensor short-circuit (heating element).	
A115	Temperature sensor PT5 short-circuited (conductivity measurement compensation).	
A116	ADC error.	
A117	Door lock system lack of lubrication.	Lubricate the door system.
A120	Reference heating element acquisition chain fault.	
A121	Reference heating element acquisition chain fault.	Contact Technical Service (see Appendix).
A122	Reference heating element acquisition chain fault.	
A126	Connection error with WiFi module.	
A131	Solenoid valve 1 failed.	
A132	Solenoid valve 2 failed.	
A133	Solenoid valve 3 failed.	
A134	Solenoid valve 4 failed.	
A135	Solenoid valve 5 failed.	
A136	Solenoid valve 6 failed.	Contact Technical Service (see Appendix).
A140	Firmware update error.	
A145	Faulty current draw detected.	
A146	Solenoid valves control driver fault.	
A147	Door motor control driver fault.	
A201	Steam generator safety thermostat triggered.	
A201	Steam generator or heating element malfunction.	
A202	Heating element safety thermostat triggered.	Contact Technical Service (see Appendix).
~2UZ	Heating band or heating element malfunction.	
	Water or condensate in the sterilisation chamber.	RESET according to the instructions. Thoroughly dry the inside of the sterilisation chamber and restart the cycle. Do <u>not</u> insert material impregnated with water or in general with liquids into the chamber.
	Drain filter obstructed.	Clean the chamber drain filter. (See <u>Appendix</u> Maintenance).
A250	Air seepage through the gasket.	RESET according to the instructions. Thoroughly clean the gasket with a clean cotton cloth moistened with water.
	An scopage through the gasket.	Restart the cycle.
	Vacuum pump failure.	

88 EN

CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
	Water injection pump malfunction.	
A 051	Problem in the hydraulic circuit.	
A251	Steam generator safety thermostat triggered.	Contact Technical Service (see <u>Appendix</u> ).
	Steam generator malfunction.	
	Steam seepage through the gasket.	RESET according to the instructions. Thoroughly clean the gasket with a clean cotton cloth moistened with water. Restart the cycle.
A252	Excessive load.	RESET according to the instructions. Check that the load does not exceed the maximum values permitted. (See the Summary Table in <u>Appendix</u> Technical Characteristics).
	Problem in the hydraulic circuit.	
	Steam generator safety thermostat triggered.	Contact Technical Service (see Appendix).
	Steam generator malfunction.	
	Water or condensate in the sterilisation chamber.	RESET according to the instructions. Thoroughly dry the inside of the sterilisation chamber and restart the program Do <u>not</u> insert material impregnated with water or in general with liquids into the chamber.
A253	Air seepage through the gasket.	RESET according to the instructions. Thoroughly clean the gasket with a clean cotton cloth moistened with water. Restart the program.
	Vacuum pump failure.	
	Problem in the hydraulic circuit.	Contact Technical Service (see <u>Appendix</u> ).
	Water injection pump malfunction.	
	Problem in the hydraulic circuit.	
A254	Steam generator safety thermostat triggered.	Contact Technical Service (see <u>Appendix</u> ).
	Steam generator malfunction.	_
	Steam seepage through the gasket.	RESET according to the instructions. Thoroughly clean the gasket with a clean cotton cloth moistened with water. Restart the program.
A255	Excessive load.	RESET according to the instructions. Check that the load does not exceed the maximum values permitted. (See the Summary Table in <u>Appendix</u> Technical Characteristics).
	Problem in the hydraulic circuit.	
	Steam generator safety thermostat triggered.	Contact Technical Service (see <u>Appendix</u> ).
	Steam generator malfunction.	
	Water or condensate in the sterilisation chamber.	RESET according to the instructions. Thoroughly dry the inside of the sterilisation chamber and restart the program Do <u>not</u> insert material impregnated with water or in general with liquids into the chamber.
A256	Air seepage through the gasket.	RESET according to the instructions. Thoroughly clean the gasket with a clean cotton cloth moistened with water. Restart the program.
	Vacuum pump failure.	Contact Technical Service (see <u>Appendix</u> ).
	Problem in the hydraulic circuit.	
	Water injection pump malfunction.	
A 267	Problem in the hydraulic circuit.	Contact Technical Service (acc Aspendix)
A257	Steam generator safety thermostat triggered.	Contact Technical Service (see <u>Appendix</u> ).
	Steam generator malfunction.	
	Steam seepage through the gasket.	RESET according to the instructions. Thoroughly clean the gasket with a clean cotton cloth moistened with water and restart the program.
A258	Excessive load.	RESET according to the instructions. Check that the load does not exceed the maximum values permitted. (See the Summary Table in <u>Appendix</u> Technical Characteristics).
	Problem in the hydraulic circuit.	
	Steam generator safety thermostat triggered.	Contact Technical Service (see <u>Appendix</u> ).
	Steam generator malfunction.	
A260	Drain filter obstructed.	Clean the chamber drain filter (see Maintenance Appendix).
, 200	Problem in the hydraulic circuit.	Contact Technical Service (see Appendix).

EN 89

CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
A261	Drain filter obstructed.	Clean the chamber drain filter (see Maintenance Appendix).
	Problem in the hydraulic circuit.	Contact Technical Service (see Appendix).
A262	Drain filter obstructed.	Clean the chamber drain filter (see Maintenance Appendix).
	Problem in the hydraulic circuit.	Contact Technical Service (see Appendix).
A353	Drain filter obstructed.	Clean the chamber drain filter (see Maintenance Appendix).
	Problem in the hydraulic circuit.	Contact Technical Service (see Appendix).
A356	Drain filter obstructed.	Clean the chamber drain filter (see Maintenance Appendix).
	Problem in the hydraulic circuit.	Contact Technical Service (see Appendix).
A360	Drain filter obstructed.	Clean the chamber drain filter (see Maintenance Appendix).
	Problem in the hydraulic circuit.	Contact Technical Service (see Appendix).
A362	Drain filter obstructed.	Clean the chamber drain filter (see Maintenance Appendix).
	Problem in the hydraulic circuit.	Contact Technical Service (see Appendix).

## 17.5.3. HAZARDS (CATEGORY H)

CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
H150	Pressure sensor failure (MPX).	
H160	Pressure sensor (MPX) not properly connected to the connector.	Contact Technical Service (see Appendix).
	Pressure sensor short-circuit (MPX).	
H400	Problem in the hydraulic circuit.	
H401	Problem in the hydraulic circuit.	
H402	Steam generator malfunction.	
	Problem in the hydraulic circuit.	
11400	Steam generator malfunction.	
H403	Problem in the hydraulic circuit.	
11404	Problem in the hydraulic circuit.	
H404	Steam generator malfunction.	
	Problem in the hydraulic circuit.	
H405	Steam generator malfunction.	
11400	Problem in the hydraulic circuit.	
H406	Steam generator malfunction.	
H410	Timer problem.	
H411	Sterilisation time error.	
H990	General operating problem.	
H991	General operating problem.	
H992	General operating problem.	
H993	General operating problem.	

## 17.5.4. SYSTEM ERRORS (CATEGORY S)

CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
S001	Error of Flash memory 1 on process board. Flash memory 1 on process board failed.	Contact Technical Service (see Appendix).
S002	Error of Flash memory 2 on process board. Flash memory 2 on process board failed.	Contact Technical Service (see Appendix).
S005	USB key not correctly formatted. Damaged USB key.	Check USB key correct formatting (FAT32). As an alternative, use another correctly formatted USB key. If the problem persists, contact Technical Service (see Appendix).
S006	USB key not correctly formatted. Damaged USB key.	Check USB key correct formatting (FAT32). As an alternative, use another correctly formatted USB key. If the problem persists, contact Technical Service (see Appendix).
S007	USB key full.	Download data from USB key or use another USB key. If the problem persists, contact Technical Service (see Appendix).
S009	Printer off. Data cable not correctly connected to serial ports RS- 232.	Make sure that printer is on. Check correct connection of the printer cable. Check printer compatibility. If the problem persists, contact Technical Service (see Appendix).
S010	No paper inside printer. Paper setting configuration not correctly done.	Make sure that paper is correctly loaded. Check correct connection of the printer cable. Make sure that paper settings are correct. If the problem persists, contact Technical Service (see Appendix).
S011	Printer lid open.	Make sure that printer lid is correctly closed. Check correct connection of the printer cable. If the problem persists, contact Technical Service (see Appendix).
S012	Printer not ready for use.	Make sure that paper is correctly loaded. Check correct connection of the printer cable. Make sure that paper settings are correct. If the problem persists, contact Technical Service (see Appendix).
S020	Cycle back-up not done after 250 cycles.	Perform cycle back-up. See paragraph Sterilisation cycle back-up. If the problem persists, contact Technical Service (see Appendix).
S021	Cycle storage limit exceeded after 7000 cycles.	Perform cycle back-up. See paragraph Sterilisation cycle back-up. If the problem persists, contact Technical Service (see Appendix).
S030	Malfunction of the control software.	RESET according to the instructions. Try restarting the program a second time. If the problem persists, contact Technical Service (see the Appendix).
S031	Malfunction of control board or software.	RESET according to the instructions. Try restarting the program a second time. If the problem persists, contact Technical Service (see the Appendix).
S032	Malfunction of the control software.	RESET according to the instructions. Try restarting the program a second time. If the problem persists, contact Technical Service (see the Appendix).
S034	Malfunction of the control software.	RESET according to the instructions. Try restarting the program a second time. If the problem persists, contact Technical Service (see the Appendix).
S035	Control software malfunction in solenoid valve management.	RESET according to the instructions. Try restarting the program a second time. If the problem persists, contact Technical Service (see the Appendix).
S040	Malfunction of the control software.	RESET according to the instructions. Try restarting the program a second time. If the problem persists, contact Technical Service (see the Appendix).
S041	Malfunction of control board or control software.	Contact Technical Service (see Appendix).
S042	Malfunction of control board or software.	Contact Technical Service (see Appendix).
S099	Malfunction of control board or control software.	Try restarting the program a second time. Try replacing the USB key. If the problem persists, contact Technical Service (see the Appendix).
S100	Malfunction of control board or control software.	Contact Technical Service (see Appendix).

### **18. USER PIN RESET**

If the user enters the pin incorrectly 3 times, it is necessary to enter the following unlock pin on the fourth consecutive time when you are prompted to enter pin again:



## **19. APPENDIX - ACCESSORIES**

Only use spare parts and accessories that meet the manufacturer's specifications.

**DEMINERALISER PURE 100** 

**DEMINERALISER PURE 500** 

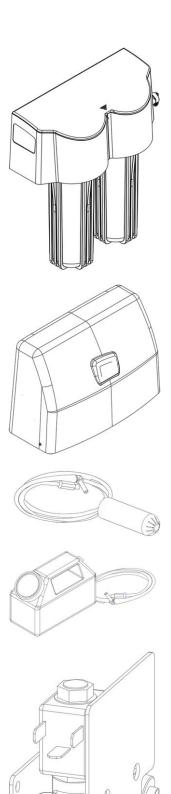
AUTOMATIC FILLING KIT (External Pump)

FRONT FILLING KIT

H2O AUX EV kit (AUX SV)

Auxiliary solenoid valve kit includes:

- 2 way water solenoid valve, NC 24 V DC
- · Steel support and fastening screws
- Connection cable with plug
- · Silicone hose with connector
- · Control valve
- 1-way valve





For the management of automatic filling accessories, refer to the manual of the relevant accessory.

EXTERNAL PRINTER

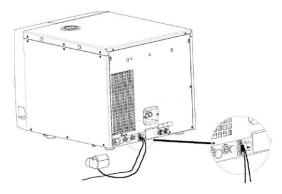


### **20. PRINTER CONNECTION**

Connect the printer to the RS232 serial port located on the rear of the autoclave (see figure).

Load the desired type of paper and turn on the printer.

Set the type of paper loaded (see the paragraph PRINT MANAGEMENT).



R.

The optional external printer Ref. M7D200012 is compatible with the BRAVO G4. Please contact Customer Service to confirm other printer compatibility. Refer to the printer manual for printer startup and paper loading.

## 21. APPENDIX - SPARE PARTS AND ACCESSORIES

Only use spare parts and accessories that meet the manufacturer's specifications.

DESCRIPTION	CODE
Bacteriological filter	97290160
Door gasket (17/22 I)	97400145
Door gasket (28 I only)	97467176
Chamber drain filter	97290210

### 22. APPENDIX - TECHNICAL SERVICE

FOR ANY REQUEST FOR TECHNICAL INTERVENTION ON THE PRODUCT, BOTH UNDER WARRANTY AND OUT OF WARRANTY, DIRECTLY CONTACT THE DEALER OR RESELLER THAT SUPPLIED THE AUTOCLAVE.

We will gladly provide any information you may need on the product as well as give you suggestions and advice on the steam sterilisation procedures.

In this regard, please refer to the following address:

Head Office: **SciCan Ltd.** 1440 Don Mills Rd. Toronto, ON, Canada, M3B 3P9 T +1 416 445 1600 TF +1 800 667 7733 <u>customerservice@scican.com</u> <u>www.scican.com</u>

Distributed by: **SciCan GmbH** Wangener Strasse 78 88299 Leutkirch, Deutschland T +49 (0)7561 98343 0 F +49 (0)7561 98343 699 customerservice eu@scican.com www.scican.com

#### 23. APPENDIX - WARNINGS AND LOCAL REGULATIONS

Before carrying out any technical service operations, consult the Technical Service Manual containing the above instructions.