AUTOCLAVE

Model: FVA2 – FVA3

THIS MANUAL'S INFORMATION REFERS TO THE MACHINE, COMPLETE WITH ALL OPTIONAL FITTINGS. THE MACHINE CONFIGURATION DESCRIBED BELOW DEFINES THE OPTIONS AVAILABLE DURING FINAL TESTS, BEFORE DELIVERY.

MACHINE CONFIGURATION:

● BASIC MACHINE
  ○ K10 STEAM GENERATOR
  ○ K20 VACUUM PUMP
  ○ K30 EFFLUENT COOLER
  ○ K40 INTERNAL AIR ELECTROCOMPRESSOR
  ○ K43 EXTERNAL AIR ELECTROCOMPRESSOR
  ○ K50 AIR STERILIZING FILTER
  ○ K51 NETWORK COMPRESSED AIR SUPPLY UNIT
  ○ K52 QUICK COOLING UNIT
  ○ K53 SPONTANEOUS COOLING
  ○ K61 CHAMBER PRESSURE LEAK TEST
  ○ K62 DECONTAMINATION CYCLE
  ○ K70 STEAM SUPPLY DEFLECTION UNIT
  ○ K80 ADDITIONAL HEAT PROBE
  ○ K81 PROCESS PRINTER
  ○ K82 KIT EN285–DATALOGGER
  ○ HW1 SECONDARY RS232 SERIAL OUTPUT
  ○ SW1 CONTROL FUNCTION FO
  ○ T30 DEIONIZER
  ○ SW2 CYCLE REPETITION

FEDEGARI Autoclavi S.p.A.

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Model:  FVA–HT

MACHINE CONFIGURATION:

- K10  STEAM GENERATOR
- K30  EFFLUENT COOLER
- K50  AIR STERILIZING FILTER
- K51  NETWORK COMPRESSED AIR SUPPLY UNIT
- K52  QUICK COOLING UNIT
- K61  CHAMBER PRESSURE LEAK TEST
- K62  DECONTAMINATION CYCLE
- K80  ADDITIONAL HEAT PROBE
- K81  PROCESS PRINTER
- HW2  HIGH PATHOGEN
- SW2  CYCLE REPETITION

This sterilizer is designed in such a way as to prevent any contamination hazard to the environment and the operators. For this reason, the sterilizer operates as follows:

1. It does not extract the air from the chamber, since all filters, even high–retention ones, are useless in the presence of small agents, such as prions.
2. It keeps in the chamber the condensate that forms during the process, until the sterilization has been completed; however, the first condensate which may be produced is not sterile.

The steam + air mixture forming in the sterilization chamber is kept homogeneous by a fan positioned inside the chamber. As a matter of fact, the air density (at the same temperature and pressure) is approximately 1.7 times higher than the water steam density, and without this measure the air would stratify on the bottom of the chamber, resulting in intolerable temperature gradients.

The temperature of the steam + water mixture forming in the chamber will depend on the selected sterilization temperature.

The mixture pressure will consist of the addition of two factors:

1. The water steam pressure at the selected sterilization temperature.
2. The air pressure at the selected sterilization temperature.

If, for example, the sterilization process is carried out at 140°C:

- factor 1 is 3,61 absolute bar (water steam pressure 140°C);
- factor 2 can be calculated as follows: when the sterilizer is closed at room temperature (approx. 20°C), the pressure of the air closed in the chamber is about the room pressure, i.e. 1.0 absolute bar. The air, however, heats up at 140°C, increasing its pressure in the ratio of initial to final heating temperatures, and accordingly pressure becomes:

\[
1,0 \times \frac{140 + 273}{20 + 273} = 1,0 \times \frac{413}{293} = 1,41 \text{ absolute bar}
\]

- The total pressure of the steam + air mixture in the chamber will be 138°C: 3,61 + 1,41 = 5,02 absolute bar.

The sterilizer is therefore designed to operate up to 4.70 rel. or manometric bar (i.e. above the atmospheric pressure), up to 5.70 absolute bar.
# ADDITION AND CHANGE REGISTRATION

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1. **FOREWORD**

1.1. **PUBLICATION IDENTIFICATION**

The "OPERATING MANUAL" is an official document issued by FEDEGARI AUTOCLAVI S.p.A. (hereinafter referred to as FEDEGARI) and forms and integral part of the machine. It is identified by a document code printed on the cover, to allow for its identification, traceability and reference. FEDEGARI reserves the right to change this manual at any time and without notice.

1.1.1. **Allied documentation**

Main manuals and documents

- Technical reference documents, including:
  - Installation drawing;
  - P&ID drawing;
  - Instrument legend;
  - Wiring diagrams.

1.2. **PUBLICATION OBJECTIVE**

This manual is addressed to the users of sterilizers belonging to the series mentioned in the heading. It includes the information required to use the machine properly. Good performance and durability of this machine, as well as operators’ safety and processed product protection, depend on compliance with this manual’s rules and instructions. Read it carefully and comply with its requirements and instructions. Its information is updated to the printing date.

1.3. **REFERENCES TO RULES AND STANDARDS**

This manual has been prepared in conformity with:

- Enclosure "I" to directive 89/392/CEE and amendments thereof.

1.4. **USING THE MANUAL**

**NOTE**

Keep this manual as long as the machine is used. Make sure that all updates are promptly included in the manual. As it forms an integral part of the machine, it should always follow it, inside the firm where the machine is used or elsewhere.

This manual consists of two sections. The first section, the pages of which are identified by Roman numerals (e.g. I, II, III, IV...etc.), is composed by:
the Title Page;
- the addition and change registration;
- the Table of Contents.

Through this section, the user can identify the publication and its update level. The table of contents allows to find the desired topic in the manual.

The second section, the pages of which are identified by Arabic numerals (e.g. 1,2,3,...n), provides the sterilizer operating and maintenance instructions. Read all this manual, page after page. Learn and remember all warnings. As the operator should be qualified for using sterilizers, all general information and instructions they are acquainted with have been omitted.

All operations require great care and caution. Throughout this manual, the following "warnings" inform the user about difficult and dangerous operations.

NOTE
Indicates important information pointed out outside the text.

WARNING
Indicates a condition in which lack of caution or wrong procedures are likely to damage – also irreparably – the sterilizer.

CAUTION!
Indicates a dangerous situation for people.

In addition to these general warnings, this manual includes other special symbols, printed throughout its pages, similar to the symbols applied to the machines by means of plates and/or decalcomania in order to indicate dangerous areas and behavior.

Before approaching the machine to start any operations and maintenance jobs, carefully read the above mentioned warnings and instructions and understand them.

Carefully keep this manual. Handle it with care and do not damage its content, even partially.

The operator must promptly replace the manual or any lost, damaged or completely/partially illegible plates, stickers etc. applied to the machine.

NOTE
Do not remove, tear or re-write this manual or its sections. In case of operations or situations other than those described in this manual, do not hesitate to contact the manufacturer for any updates. Keep the manual in a dry and cool place.

1.5. UPDATES

Any updates may be communicated to the machine owner using single sheets, complete with all instructions required to add them to the manual.

Should the sterilizer be sold, its owner must notify FEDEGARI about all related references, so that the manufacturer will be able to deliver any additions/updates to the new owner.
2. INTRODUCTION

2.1. IDENTIFICATION

Figure 2.1 shows the facsimile of the sterilizer CE identification plate.

```
STERILIZER
MODEL
SERIAL NUMBER
YEAR OF FABRICATION

MODEL              Voltage       V
Frequency          Hz
CHAMBER VOLUME     I
MAX OPERATING
PRESSURE          bar

0123

NOTIFIED BODY’S INITIAL
(MARKED ONLY IF THE MACHINE
IS A MEDICAL DEVICE)
```

Figure 2.1 – CE identification plate

2.2. SERVICING

FEDEGARI is always at its customer’s disposal, whether directly or indirectly through its agents/local dealers, for any operations required. Suitable equipment and specialized personnel are available for overhaul and servicing. Please ask FEDEGARI AUTOCLAVI S.p.A SS.235, km 8 – 27010 Albuzzano (PAVIA) – Italy, for the names and address of FEDEGARI SERVICE CENTERS in Italy and abroad.

This machine is guaranteed according to the Sales Agreement General Conditions. The guarantee will no longer be valid:

- if the machine is repaired without the consent of the manufacturer or of FEDEGARI Service Centers;
- when using spare parts other than the original ones;
- should the machine be used for any operations other than those recommended;
- in case of non-compliance with this manual’s instructions.

WARNING

FEDEGARI cannot be held liable for any failures and operational faults due to non-compliance with preventive maintenance suggested by the manufacturer and indicated in this manual.
2.3. **RISKS DERIVING FROM USING THE SOFTWARE**

The use of the software supplied by Fedegari together with its products is licensed to the customer, who will be fully responsible for it (see also the General Terms of Sale).

---

**CAUTION!**
Fedegari or its representatives cannot be held liable for direct/indirect damage deriving from using the software, from its failures or the above mentioned license.

---

2.4. **SAFETY WARNINGS**

2.4.1. **General warnings**

---

**CAUTION!**
Most labor accidents are due to non-compliance with safety rules.
All operators using the sterilizer must know and comply with the rules mentioned in this manual and on warning plates.
Always observe the rules recommended below.

---

**CAUTION!**
Some electrical circuits of the machine remain supplied also when the master switch is off (in the "0" position). These circuits are located inside the electrical board and are adequately indicated.

---

**CAUTION!**
Do not inhibit the machine safety devices. When safety is not assured, all operations are allowed only to FEDEGARI's personnel, or, with the manufacturer's authorization, to the user's trained staff.

---

**CAUTION!**
Before using the sterilizer, ALWAYS check that the materials to be processed are compatible with the cycles and steps of the sterilization program to be started.
Make sure that the materials are free of molecular instability risks which, during product handling or processing, are likely to cause explosions.

---

**CAUTION!**
Do not perform any kind of jobs and changes on the machine and its fittings.
Do not modify the sterilizer parts in order to fit other devices.
In case of malfunctioning/accidents due to non-compliance with the above mentioned instructions,
FEDEGARI shall not be liable for the related consequences. 
Do not hesitate to contact FEDEGARI whenever changes to the machine are required.

CAUTION!
CAREFULLY position the heat probe used also as a safety device for chamber opening temperature, according to the following instructions.
Pay attention to the temperature displayed as:

* when the heat probe is placed between – not inside – the bottles of one of the lowest batch layers, the heat probe can detect the sterilization chamber temperature.
Therefore, always TAKE INTO ACCOUNT that the time required by bottle liquid to reach the temperature displayed by the heat probe is directly proportional to the bottle volume.
For 50 cc bottles, the safety margin is 30°C (for larger bottles, this margin is to be increased) and the chamber must be cooled at a temperature not below 40°C, so that the bottle internal temperature is 70°C, which is an acceptable value.

* When placing the heat probe inside a bottle, plunged in its liquid, safety limits are not needed, although the sample bottle could be broken during its processing.
In this case, the heat probe will indicate the chamber temperature instead of the bottle temperature. Therefore, before opening the sterilizer, the operator MUST check that the heat probe placed inside the chamber is indicating the temperature based on the safety margin mentioned in the previous section (about 40°C).

CAUTION!
When extracted from the machine, bottles having an internal temperature of more than 70°C could explode, thus jeopardizing the operators.
The maximum safety temperature allowing to open the cover must be set at <70°C and parameter "CHECK FINAL T" must be enabled by setting value "1".

CAUTION!
Thermal sterilization in the presence of low–boiling liquids (i.e. with steam tension higher than the water tension at the same temperature) and/or liquids flammable in the air (i.e. characterized by a ceiling of concentration in the air above which a fire may propagate) involves two kinds of hazard.

* At the temperatures typical of thermal sterilization (i.e. at least 105°C) a low–boiling liquid can develop such a high pressure that the safety valve opens, letting any gas and/or steam out of the sterilizer, or preventing the correct performance of the sterilization process. For example, the presence of alcohol in a closed room causes a partial pressure, in the aeriform phase, of approx. 4.5 absolute bar at the traditional temperature of 121°C. This pressure depends only on temperature and is not affected by the quantity of alcohol. When the regulation of a saturated steam sterilization occurs "in temperature", at 121°C, the pressure tends to reach approx. 6.5 absolute bar, and the safety valve opens well before reaching this value. When the sterilization is regulated "in pressure", the pressure developed by the low–boiling liquid simulates the
reaching of the regulation pressure, preventing the supply of steam to the chamber; the temperature reached at the regulation pressure (3.50 absolute bar in case of decontamination cycles with Fedegari FOB and FVA sterilizers) is not 121°C, being just above 100°C. The process may indefinitely stop in the heating phase. Therefore, the presence of any low-boiling liquid may result in the hazardous release of contaminated material from the chamber or in the impossibility to carry out the sterilization.

* The eventual flammability of the liquid involves, of course, a fire hazard. The concentration of flammable vapors in the air, as necessary for ignition, decreases based on temperature, while the true concentration increases according to it. In most cases, a fire may break out due to the level (even negligible) of static electricity entering with the vapor or, most frequently, with the cooling air. Also in those cases that, at present, are well-known, the damage has been limited to the interior of the sterilizer (that, of course, is shut-down), though it cannot be denied that the possible opening of the safety valve may propagate fire also outside it. A similar hazard is present when vacuum is applied at the end of the sterilization process. The flammable mixture is sucked by a machine not meant for it and any cause of firing may have serious consequences, that cannot be calculated.

⚠️ CAUTION!
Before starting a sterilization cycle, make sure that the manual pressure relief valve is perfectly closed.

⚠️ CAUTION!
C02 fire-fighting means are recommended in order to provide preventive protection.

⚠️ WARNING
Always assure that:

* the supply voltage to the sterilizer is constantly kept within ±10% of the nominal value required.

* The compressed air pressure to the sterilizer pneumatic circuits is stable, within ±10% of the nominal value required.

* the saturated steam pressure oscillation for the sterilization chamber is kept within ±10% of the nominal values required.

* the pressure of water feed line to the sterilizer is kept within ±10% of the nominal values required.

Failure to comply with these recommendations may cause malfunctions during the sterilization cycles and damage the machine.

⚠️ WARNING
Do not use alcohol, petrol, other solvents or acid reaction substances for cleaning or washing the chamber or the sterilizer components, as they are likely to attack stainless steel surfaces and
elastomer parts. Use water, also slightly diluted with neutral detergents, according to this manual’s maintenance instructions.

**CAUTION**
To avoid cuts during maintenance of the air circulation fan in the sterilization chamber, do not disassemble the fan and motor protections unless the plant is completely isolated from power supply sources.

**WARNING**
For any kind of processes, especially in case of manual operations or dangerous processes (e.g. decontamination), Fedegari guarantees the sterilization carried out by its machines provided the process manager authorizes proper performance of all cycle phases envisaged for the product, by signing the document printed by the sterilizer control system for approval.

**CAUTION!**
Do not use the sterilizer and its fittings to perform jobs other than those permitted and specified in this manual.

**CAUTION!**
These sterilisers are not electromedical devices. If they are installed near medical or surgical operation areas, they must never be placed at less than 2.0 metres from the patient for the entire period of the operation.
Figure 2.2 shows the warning plate position on the machine, pointing out any potential dangers.

<table>
<thead>
<tr>
<th>Symbol/Plate name</th>
<th>Plate position</th>
</tr>
</thead>
</table>
| **General danger** | 1 USERS  
2 SAFETY VALVE(S) VENT PIPE  
3 COVER OPENING/CLOSING KNOB –  
4 MASTER SWITCH  
5 MANUAL PRESSURE RELIEF VALVE OF THE CHAMBER  
6 CHAMBER'S PRESSURE RELIEF PIPE |
| **heck safety valve on a periodical basis** | 1 INSIDE THE TECHNICAL CABINET PANEL  
2 AT THE REAR OF THE ELECTRICAL BOARD  
3 REAR PANEL NEAR THE SAFETY VALVE(S) VENT PIPE |
| **Hot surfaces** | 1 MACHINE CASING  
2 AUTONOMOUS STEAM GENERATOR (with option K10) |
| **Electrical hazard** | 1 ELECTRICAL BOARD |

**Figure 2.2 – Plates indicating potential dangers**

### 2.4.2. Machine state

This machine allows for three different operating modes. The first one (USE) allows to give the machine simple orders, while checking it in full safety, from its starting to process completion, as well as to obtain the reports and/or messages confirming successful process performance.

The second operating mode (CONFIGURATION) allows to reconfigure the machine applications (sterilization programs), while defining the general parameters controlling the activities and functions common to all sterilization processes.
The third operating mode (MAINTENANCE) includes all operating modes allowing to service and/or control (also "ON LINE") several software functions and the functional operating logics controlling the sterilizer.

2.4.3. Operators

When analyzing the works described in this manual, concerning the machine life cycle steps, FEDEGARI has taken into account the operator’s qualities.

2.4.3.1. Operators’ qualification

Please find below a profile about the professional qualities required to each operator using the sterilizer.

The operator:

- Must know the physical and chemical principles concerning gas, fluid and liquid dynamics during sterilization processes;

- Must be acquainted with environmental and behavioral problems, to protect the environment and other products from microbiological and particulate contamination;

- Must thoroughly know the operating principles of the machine, its structure, main blocks as well as the allocation of the control units allowing to disconnect the machine from its main supply sources;

- Must be properly trained for all operations required to start and control the plant and able to record the sterilization data, also referring to the workmanlike manufacture rules in force in the country where the machine is used;

- Must be properly trained to evaluate all events occurring during the sterilization cycle;

- Must be properly trained to evaluate any alarms activated during the cycle;

- Must be properly trained for stopping the machine in case of an emergency (also concerning the batch);

- Must be properly trained and able to perform the preventive and corrective maintenance required for operator interface performance.

CAUTION!

This recommended profile is to be integrated with other professional skills required by the rules in force in the country where the machine is used.
2.4.3.2. Personal protection means

Based on the batch to be processed, the operator must protect his body against the direct or indirect influence of chemicals (whether organic or not) or microbiological elements (e.g. viruses, bacteria), forming the batch to be sterilized or aggregated to it. These substances can be noxious by contact, inhalation or contamination.

Always wear suitable protection means, such as masks, suits, gaberdines, gloves, protective glasses, footwear, boots etc...

![CAUTION!]
The operator MUST be allowed to check the batch before its delivery, to verify the type of material included.

![CAUTION!]
The operator must wear suitable work clothing, to be protected against chemical, physical and/or microbiological risks, deriving from contact with a wide range of materials, including gases and liquids.

The work clothing material and structure must be fit for protecting the operator against any contact/contamination dangers.

The buyer is responsible for the use of highly protective means suitable for the type of product to be processed, in compliance with the rules in force in the country where the machine is used.

![WARNING]
All personal protection means must permit the operator to move freely in order to carry out the necessary operations and to properly see with the best angulation and limited sight distortion. Use only certified protection means. All protection means must be carefully used and kept (e.g. wear them correctly, tighten the related closing systems, replace mask filters etc.).

![WARNING]
Personal protection means are sometimes recommended in order to protect the processed product against contamination (e.g., during unloading operations).

To treat products free of chemical or microbiological risks:

- Wear a waterproof cotton one-piece suit or other work clothing, allowing for good transpiration and covering the whole body, except for your face;
- Wear suitable, comfortable shoes, for proper mechanical protection from spilled liquids;
- Wear light, protective glasses against sprays. They should not be made of glass, without fragmentation danger, transparent with the best refractive index, visual angulation and low distortion.
2.4.4. Recommendations and precautionary measures to be adopted by the user

The user must fit the installation area with suitable lighting devices, complying with safety and accident prevention rules.

The user must assure that the area before the sterilizer is provided with an antislip flooring, in aggregate or polymeric materials, easy to wash and fit for chemical and thermal disinfection.

The floor must be fit for any processing, according to the products to be sterilized.

Clear and legible warnings must be installed near the work station, to prevent unauthorized personnel from entering the work area.

Before delivery, the user must train its operators and make sure that they are acquainted with the machine and able to carry out the necessary operations, according to the skill profile mentioned in section 2.4.3.1.

2.4.5. Emergencies

The user must fit the area with proper fire-fighting stations.

⚠️ **CAUTION!**

**CO2 fire-fighting means are recommended in order to provide preventive protection.**

In an emergency, the operator must be free to reach the main switch and the primary feed shut-off valves.

**Electric system black-out**

In case of black-out, the main switch is activated to isolate all downstream elements.

All processes started before the black-out will be stopped.

When the electric power is restored, after resetting the main switch, the sterilizer enters an emergency state, waiting to receive a manual control which brings the sterilization process to the cycle end phase or to the Emergency–Decontamination phase, after an electrical blackout has occurred, during the "Heating" or "Sterilization" phases, in the Decontamination Program.

The sterilization chamber features a pneumatic cover seal and the related devices, which assures chamber tightness also in case of pneumatic or power failure.

Depressurizing the door pneumatic seal takes more than depressurizing the chamber.

The atmospheric pressure inside the chamber, caused by sealing failure due to a black-out, is reached after at least 20 hours, based on the machine maintenance level.

**Pneumatic, steam and water supply failure**

All supply line failures are detected by proper sensors and could considerably increase the time required to complete the steps of the process in progress.

The sterilizer enters an emergency state, waiting for the reset of suitable parameters.
Emergency stop

Press the "EMERGENCY" mushroom-head push-button to stop power supply to the machine by means of the main switch. Refer to the instructions of item "Electric system black-out".
3. GENERAL INFORMATION

3.1. GENERAL DESCRIPTION

3.1.1. Foreword

FVA vertical steam sterilizers are flexible and high-performance small-sized semiautomatic machines for sterilization processes to be carried out in laboratories and hospitals (where they are not used as production equipment).

3.1.2. Main components

The sterilizer (see Figure 3.1) consists of the following main components:

- Sterilization chamber;
- Cover and related sealing system;
- Technical cabinet complete with a shutter covering the electrical board;
- Electric system;
- Hydraulic and pneumatic installations;
- Operator panel;
- PLC electronic process controller console;
- Additional components (optional);
- Fittings for product loading/unloading;
Figure 3.1 – Main components of the sterilizer
3.1.2.1. Sterilization chamber

The pressurized sterilization chamber features a cylindrical section and a vertical axis, and houses the material to be processed. The purge system on its bottom collects the condensate to be drained. The chamber is in AISI 316Ti gloss finished steel with Ra < 0.19 mm surface roughness.

3.1.2.2. Cover and Sealing system

Cover

The horizontally rotating cover (see Figure 3.2), in position "Closed door" is coupled with the chamber through a "C" band which, even under minimum pressure inside the chamber prevents the cover from rotating and opening. The chamber cover is fitted with a horizontally rotating knob (pos. 1) for easy opening and closing. When closing the cover, a safety lever (pos. 2) positioned on its top, is moved by the operator with both hands, to prevent damaging his fingers. Once closed, the cover can be opened by lowering the lever (pos. 3), which releases a safety device. The particular profile of the cover allows you to install a special (optional) fan, with magnetic joint (pos. 4), to be used for specific phases of batch cooling.

LEGEND

1. Knob
2. Safety lever
3. Cover release lever
4. Fan (optional)

Figure 3.2– Cover closing system
Sealing system

The sealing system consists of a silicone rubber seal. To seal the sterilization chamber when the cover is closed, supply the seal housing with compressed air. The seal is pushed outwards and pressed against the cover.

3.1.2.3. Technical cabinet

The external cabinet, in polyurethane resin and featuring an AISI 304 stainless steel frame, includes the hydraulic, electric and pneumatic installations, the process electronic controller components and, according to the machine configuration, the autonomous steam generator, the vacuum pump and other optionals.

3.1.2.4. Electric system

The sterilizer electric system complies with EN61010–1, EN61010–2–041, EN60204–1 European standards. The electric circuit is fitted into a suitably ventilated box, which can be easily reached from the machine front.

The plant includes all control lines of electrohydraulic or electropneumatic actuators of the motors, of the electronic process controller, of the autonomous steam generator, if any. The plant connects the process controller to all sensors and transducers (e.g. pressure switches, heat probes etc.), as well as to the operator interface devices. It also provides for the primary feed line and its protection plant.

3.1.2.5. Electric board

The electric board is located in front of the machine cabinet and lodges the main electric and electronic feeding/disconnecting devices, as well as the distribution equipment, including the main switch. This switch features a release coil allowing to open it, should the protection devices be activated, and to disconnect power supply to the machine.

3.1.2.6. Plumbing and pneumatic plant

The plumbing and pneumatic plant (see the P&ID scheme) consist of pipes, solenoid valves, pneumatic and electropneumatic valves. The hydraulic plant is in AISI 316L stainless steel and is fitted with small sanitary flanges, with the related closing clamps for connecting each element and suitable elastomer seals.

3.1.2.7. Operator panel

The Operator Panel, located on the top of the cabinet, consists of a LCD 4 lines, 20 columns display and of a membrane keyboard, through which the operator manages the interactive dialogue with the machine. It also features RAM, with emergency power supply and FLASHEPROM for the user program, a serial port for the printer interface and a RS 232 serial port for PLC interfacing.
3.1.2.8. Electronic process controller

The electronic process controller consists of a programmable logic controller (PLC) which, together with specific hardware blocks and other electronic equipment, controls the machine as well as all operations regarding the interactive dialog with the operator.

It features 16 digital inputs/outputs, RS232 serial port for interfacing with the operator’s panel, RAM with emergency power supply. The controller can use EPROM or EEPROM and features another RS232 serial port to transmit the cycle data to an outer system (master), with a well–defined ASCII protocol.

The control software is certified according to IEC1131–3 standards.

The controller:

– manages the dialogue with the operator through the interface devices;

– controls the hydraulic/pneumatic plant actuators;

– detects the system logics from the field (electric and hydraulic/pneumatic plant), based on the confirmation of set activations;

– detects the analog values of pressure and temperature measurements carried out, through specific modules converting the analog signal from temperature and pressure sensors into a PLC–readable digital signal.

The process controller consists of the following units:

A PLC Matsushita FP–M–C32TC 5K–DC24V;

B Operator panel EXOR R&D T–line TCP01R–04–0245;

C Printer CUSTOM FT190SP;

D Module TECNA ADPLC/F32, converting analog signals into digital signals, with a minimum of 2 digital input and output lines, for the direct reading of a 4÷20 mA sensor and of two 4–wire heat probes Pt100.

E Expansion card provided with 12 inputs and 8 digital outputs;

F Datalogger CUSTOM FT190DL (K82).

Figure 3.3 shows the functional connections between the main blocks forming the process controller.
3.1.2.9. Main additional components (optional)

Main optional components:
- Steam generator;
- Vacuum pump;
- Effluent cooler;
- Air electrocompressor;
- Air sterilising filter;
- Network compressed air supply unit;
- Quick cooling unit;
- Spontaneous cooling;

Figure 3.3 – Process electronic controller—functionals connections
- Pressurized chamber leak test;
- Decontamination cycle;
- Steam supply deflection unit;
- Additional heat probe;
- Process printer;
- Control function F0;
- Secondary RS232 serial output;
- Datalogger;
- Deionizer.

**Steam generator (K10)**

The steam generator is installed when no saturated steam is available to feed the sterilizer, or when the quality of the available steam is poor. The steam generator consists of pressurized reservoir D001, in AISI 316 stainless steel, supplied with deionized water evaporating by means of three electric heating elements RX02 fitted on the top of the reservoir. The loading of deionized water, supplied by the feed network and by a proper container through an electric pump PA01, is controlled by solenoid valve E009, which opens pneumatic valve S009. Check valve R004 prevents water from flowing to the pump. Pressure switch P004 detects pressure inside the generator, checks the heating element power supply and warns the process controller when the pressure reached allows to supply the chamber. Sensors L001 and L002 detect the water level inside the pressurized body.

The steam generator is also fitted with the following devices, for the pressurized reservoir operational safety:

- Manual discharge valve V004;
- Safety valve Y002;
- Pressure gauge M003 detecting reservoir D001 pressure, clearly visible to the operator;
- Thermostat T002, controlling the heating element temperature and signaling dry operation;
- Thermostat T003, if required, checking the generator maximum temperature (TÜV).

**Vacuum pump unit (K20)**

It consists of a liquid ring pump PV01, fed by the network water. Water enters the pump through solenoid valve E011 and is regulated by valve V003. Valve V007 adjusts the air ballast necessary to the vacuum pump through the air intake. Solenoid valve E011 opens when the motor is energized.

The pump is used to create continuous as well as discontinuous (impulse) vacuum in the sterilizer chamber. This pump is required whenever air cushions in the batch could prevent its sterilization, as well as for product drying.

**Effluent cooler (K30)**

Effluent cooler W001 consists of a small mixing reservoir, fed by network water. The drain line condensate and gases are sent to the reservoir before being discharged outside the machine. The cooling system is regulated by thermostat
T004 and solenoid valve E001, located on the network water feeding line. The cooler is used in order to lower the effluent temperature (up to 60°C) before letting it outside the sterilizer. The cooling unit must be fitted whenever low temperature effluent is required, e.g. when the regulations of the installation site do not allow for high-temperature effluent, or when the drain lines connected to the sterilizer are in plastic material, which is likely to be damaged by high temperature.

**Internal air electrocompressor (K40)**

It can be fitted into the machine cabinet, to be used when no network compressed air is available. The electrocompressor model and the related plenum chamber must be chosen based on the machine configuration. If the sterilizer is not used to process liquids, compressed air is only needed to feed the cover seal and the pneumatic valves. A 2 liters plenum chamber is sufficient to guarantee proper operation.

**External Air electrocompressor (K43)**

When the machine is used to carry out sterilization processes requiring compressed air, an external compressor must be installed featuring a plenum chamber with more than 10 liters capacity.

**Sterilizing filter for air (K50)**

The air filtering unit consists of a filter F007 which can be sterilized in the sterilizer, with 0,22 mm retention, fitted in a plastic container.

**Network compressed air supply unit (K51)**

This unit consists of solenoid valve E010 and pressure reducer VR02, which supplies the chamber with sterile compressed air. This unit must be installed on the sterilizer when the batch to be sterilized requires an air counter-pressure on completion of the sterilization process.

**Quick cooling unit (K52)**

The quick cooling unit basically consists of a magnetic fan CV12 and a heat exchanger located in the cover concavity. They are installed so that the sterilization chamber volume is not reduced. The fan coupled to the motor ME12 through a suitable magnetic joint must assure air circulation inside the chamber. Air is cooled when coming into contact with the surface of the heat exchanger, supplied by network water. This procedure allows to reduce the liquid cooling time and to increase the sterilizer performance. The quick cooling unit is recommended whenever the sterilizer is used to process heat-sensitive liquids, in particular when they are stored in large bottles.

**Spontaneous cooling (K53)**

This option allows the “Slow spontaneous cooling” of the load. It requires the use of load interception electro-valve E007, that during the “Spontaneous cooling” phase remains closed until the pressure inside the chamber is lower than/equal to the average of maximum and minimum balancing pressures. The opening of the valve allows the discharge of the condensate produced during the cooling phase. The phase ends
as soon as the target Temperature is reached.
During the "Spontaneous cooling" phase, the pressure inside the chamber reaches balancing pressure values spontaneously, without creating a pressure drop that is likely to damage the batch, if consisting of liquids contained in reservoirs.

**NOTE**

The presence of option K51 "Newtork compressed air supply unit" or option K52 "Quick cooling unit" (including K51), disables the effect of option K53 "Spontaneous cooling", that in these cases is not enabled.

**Pressurized chamber leak test (K61)**

This option is used to perform the pressurized chamber leak test. It consists in shutting–off the discharge, usually connected to the chamber through a calibrated orifice. This test can be performed as an alternative to vacuum leak test in sterilizers lacking the necessary equipment. To carry out the pressure leak test, the machine must be fitted with the air supply unit in counterpressure (K51).

**Decontamination cycle (K62)**

This cycle is installed on the machine in order to sterilize products involving microbiological pollution risks. During the sterilization phase, start solenoid valve E071 to let saturated steam in, either through the chamber purge system or directly through S008. The chamber and the purge system must have the same temperature. Solenoid valve E007 is closed until completion of the sterilization process. Therefore, the sterilization chamber batch must not be removed until the process is completed, i.e. when the chamber content has been sterilized. The maximum allowed temperature is 121°C, equal to a 3.4 bar pressure with air/steam mixture.

**Steam supply deflection unit (K70)**

This device allows to selectively feed a sterilizer featuring an autonomous steam generator (K10), also with network steam. The operator enters a process controller parameter for manually deviating a three–way valve V009 inside the sterilizer technical cabinet.

**Additional heat probe (K80)**

This Pt 100 heat probe T005 is identical to that fitted on the sterilizer chamber. It can be connected to the process controller, which will provide for the second temperature measurement, to be printed with the first one, or to an optional external recorder.

**Process printer (K81)**

It is an alphanumeric printer installed next to the operator interface, in order to print detailed process documents. The printer is provided with a 200 dpi thermal printing mechanism, uses 57.7mm wide paper and is connected to the controller through a RS232 serial output.

**Secondary RS232 serial output (HW1)**

This option consists of a special software version loaded on the process controller, which enables the second PLC RS232 serial output. It can be used to download in real time all data of the process in progress to a remote PC, in ASCII format, or to connect a remote PC featuring the Fedegari software CVB–LINK.
Control function F0 (SW1)

For all applications requiring a handling of the F0 value accumulated during the process, instead of regulating sterilisation based on a fixed time; you may obtain a handling of the F0 value accumulated during the process, through the selection of proper parameters. The software begins calculating the Fo values starting from 100°C.

Datalogger (K82)

This device is used for the digital recording of analog signals, and is installed as an option for printing process data (time, temperature and pressure) on thermal paper. Both the data loaded through the serial port and the data acquired by the datalogger through its sensors (heat probe Pt100 and pressure transducer – optional), in recording mode, are considered for printing.

Deionizer (T30)

If the network water available for supplying the steam generator is too hard, in order to ensure better performance and less frequent maintenance jobs, we recommend that you install a deionizer. This group is mainly made up of a cartridge of mixed bed resin (8.5 l), that can change its tone based on its progressive emptying. Once empty, the cartridge must be replaced with a new one, containing regenerated resin; the replacement takes a few minutes and does not require any specific experience. This model allows the treatment of approx. 750 l of water (with a new cartridge), for an output of 30 l/h; if the water pressure at the inlet exceeds 0.8 bar install a pressure reduced fitted with a pressure gauge on the network, upstream of the deionizer.

Cycle repetition (SW2)

This option allows the repetition of a cycle up to a maximum of 20 consecutive times.

3.1.2.10. Loading/unloading devices

The machine loading/unloading system uses baskets in steel plate, fitted with folding handles (see Figure 3.4).

Figure 3.4- Loading/unloading devices
3.2. SAFETY SYSTEMS

3.2.1. Opening/closing system

Initial system state

Before closing the chamber, until the cover has reached the recommended position, limit switch Z001, checking the system correct operation, is kept pressed by a spring, and breaks the circuit for compressed air supply to the seal housing, thus preventing pressurized fluids from entering the chamber.

Starting closing operations

For safety reasons, both hands are required to manually turn the sterilizer cover from position A to position B (see Figure 3.5).

When the cover has reached the position required for closing, limit switch Z001 changes its state and activates the control for compressed air supply to the seal housing.

Closing the chamber

When the limit switch has selected the cover correct position, the operator must press the closing push-button in order to let compressed air in the seal housing. The chamber starts closing and the cover is blocked.

Sealing system operation

The compressed air pushes the seal upwards and presses it against the cover perimeter, which is lifted from its rest position held by two semicircular brackets.

The seal is pressed against the cover for perfectly closing the sterilizer, thus assuring tightness against pressurized fluids entering the chamber.

Letting fluids into the chamber

Air pressure in the chamber is detected by pressure switch P002. When pressure has reached the set value, the pressure switch warns that the chamber is closed and perfectly tight, thus enabling the process cycle and letting fluids into the chamber.

Starting opening operations

The sterilizer can be opened only when:

- the process cycle is completed;
- pressure transducer P001 connected to the sterilizer control system and electro-mechanical safety pressure
switch P005 indicate that the chamber internal pressure and atmospheric pressure have the same value again;
- the chamber temperature measured by the probe T001 is lower than the set value, so that the temperature of the liquids to be sterilized in glass containers inside the sterilizer is less than their boiling temperature at atmospheric pressure.

Exhausting air from the seal housing

After the above mentioned steps, the operator presses the opening push-button to exhaust compressed air from the seal housing.

Opening the sterilizer manually

After automatic air exhausting from the seal housing, the sterilizer can be manually opened.

LEGEND

1. POS. A: Open chamber
2. POS. B: Cover in closing position

Figure 3.5 – Chamber closure
3.2.2. Safety valves

For the operator protection, the sterilizer features the following devices:

- a safety valve to let out excessive chamber pressure;
- a safety valve to let out admitted excessive pressure (working pressure value).

The valve is mechanically regulated on the maximum allowed value (design pressure value).
3.3. DATA SHEET

3.3.1. Main dimensions and weights

The main dimensions of the vertical steam sterilizer (models FVA2 and FVA3) are shown in the figure below: (see Figure 3.7).

<table>
<thead>
<tr>
<th>DIMENSIONS (mm)</th>
<th>WEIGHT (kg)</th>
<th>CAPACITY (l)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(*)</td>
<td>(**)</td>
</tr>
<tr>
<td>FVA2</td>
<td>173</td>
<td>248</td>
</tr>
<tr>
<td>FVA3</td>
<td>188</td>
<td>328</td>
</tr>
</tbody>
</table>

* With all the options
** With all the options and chamber full of water under hydrostatic testing conditions.

Figure 3.7– Main dimensions and weights
3.3.2. Operational data and main performance

**DATA SHEET:**

- Installation class: II
- Pollution degree: 2
- Sterilization process: saturated steam
- Process control: automatic, through PLC
- Operator interface: keyboard and 4-line x 20-character displays
- Pressure measurement: piezoelectric transducer
- Temperature measurement: heat probe Pt100
- Chamber closing: horizontally rotating cover with pneumatic seal
- Sound pressure level: < 64 dBA (EN ISO 11202)
- Max. operating pressure: 3.5 bar abs.
- Working pressure (Model FVA–HT): 6.2 abs. bar
- Working temperature: 139°C
- Working temperature (Model FVA–HT): 155°C
- Voltage: 400V triphase + N + PE (standard version)
- Frequency: 50 Hz
- Protection of drive components: IP54
- Installed power:
  - without steam generator: 1.5 kW
  - with steam generator: 10.5 kW
- Absorption:
  - without steam generator: 3A
  - with steam generator: 18A
- Materials:
  - chamber: AISI 316Ti
  - valves and piping: AISI 316L

**NOTE**

In compliance with the requirements of standard EN61010–par. 5.1.3.(C), the power load value indicated on the CE plate refers to the most complete steriliser model, equipped with all optional accessories.

<table>
<thead>
<tr>
<th>USERS</th>
<th>MODEL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FVA2</td>
</tr>
<tr>
<td>Steam</td>
<td>12</td>
</tr>
<tr>
<td>D.I water for generator</td>
<td>15</td>
</tr>
<tr>
<td>Network water</td>
<td>(Max. 20°F)</td>
</tr>
<tr>
<td>- for drain cooling</td>
<td>20</td>
</tr>
<tr>
<td>- for vacuum pump</td>
<td>200</td>
</tr>
<tr>
<td>- for forced cooling</td>
<td>50</td>
</tr>
<tr>
<td>Compressed air</td>
<td></td>
</tr>
<tr>
<td>- for actuators</td>
<td>10</td>
</tr>
<tr>
<td>- for back-pressure</td>
<td>210</td>
</tr>
</tbody>
</table>

 (): this value may change depending on the cycle configuration and on the type of the load.
3.4. RECOMMENDED USE

CAUTION!
Do not use the sterilizer and its fittings to perform jobs other than those permitted and specified in this manual.

This sterilizer can process both solid and liquid materials, according to the selected configuration, using different sterilization processes.

The machine configuration allows to process:
- Empty glassworks;
- Stainless steel tools;
- Parts of machines;
- Small stainless steel reservoirs;
- Different products, manufactured using materials suitable for this type of processing;
- Liquid and semiliquid culture media (agar) in unsealed reservoirs;
- Several solutions in unsealed reservoirs.

Sterilizers featuring vacuum pumps can process not only the above mentioned materials, but also:
- Porous substances;
- Various packed instruments;
- Solids to be extracted dry;
- Empty containers fitted with filters;
- Filters.

3.5. FORBIDDEN USE

All applications excluded from the previous section are forbidden. Do not use a sterilization program fit for a specific material for processing another type of material. Wet heat processing must be avoided in case of:
- Flammable or explosive substances;
- Non-flammable liquids, with high vapor pressure (halogenated hydrocarbons and similar substances), also in closed containers;
- Bottled/spray cylinder gas (also empty);
- Substances which, when decomposing due to wet heat could generate noxious, flammable, explosive gases or vapors as well as hazardous and flammable residues and solids.

As sterilization is assured by direct or indirect steam contact with the surfaces to be processed, wet heat sterilization processes are not fit for:
- Closed containers, steam–tight, to be sterilized inside (e.g. closed empty vials);
- Closed containers, steam–tight, containing an anhydrous material to be sterilized (e.g. vials containing oily anhydrous solutions and anhydrous powders).

If in doubt, do not hesitate to contact FEDEGARI.
4. TRANSPORT, HANDLING, STORAGE

4.1. GENERAL WARNINGS

CAUTION!
Always disconnect the machine from its power supply before moving it.
Do not move the machine unless it is perfectly stable.

4.2. TRANSPORT

4.2.1. General information

To transport the machines described in this manual, always comply with the following rules.

4.2.2. Transport instructions

4.2.2.1. Packaging

To transport the machine, use the packaging system adopted for its delivery, provided the same carrier is used. In this case, keep the original packaging or replace it if it is no longer available or in poor condition.

The packaging system includes a board to fasten the machine.

Two types of packaging are available, to meet all requirements:

- Paperboard protection box;
- Wooden box.

4.2.3. Specific procedures

4.2.3.1. Warnings

CAUTION!
The machine must not be turned over or inclined during lifting operations.

CAUTION!
Before starting lifting operations, make sure that the means used capacity is sufficient, compared with the required carrying capacity and radii.
4.2.3.2. Lifting the machine packaging

The machine packaging must be lifted in order to load/unload the carriers charged with the sterilizer transportation. These operations require suitable lifting equipment, fitted with forks to handle the board.

**CAUTION!**
During lifting operations, access to the surrounding area is strictly forbidden.

**CAUTION!**
Use only suitable and certified lifting means. In Europe, they should feature the EC marking.

**Loading**

1. Lift the machine packaging with suitable equipment. Check that it is perfectly balanced during these operations and be careful to place it on the horizontal plane of the vehicle used for transportation, without dangerous tilting and shaking.

2. Fasten the board to the vehicle platform by means of suitable ropes, and protect it, as it could be damaged when touching such ropes, or using other suitable means.

**Unloading**

- With a machine fitted with suitable forks, lift the sterilizer packaging. Make sure that it is always balanced during this operation and be careful to place it on a horizontal plane of the unloading area, without dangerous tilting and shaking.

4.2.3.3. Handling on the installation site

Due to its small size, the sterilizer can be transported using a manual lift truck, inside the installation building, in order to reach the chosen position.

The machine is generally positioned by two operators.

Follow this procedure:

1. Unpack the machine by taking it away from the board forming the packaging base. Keep the packaging, which could be used for other transport operations;

2. Transport the machine, which is still forming part of the packaging, to the installation place, and place it on the room floor;

3. Remove the fastening devices;

4. Lift the machine, and remove pallets.
CAUTION!
Before transporting the machine to the installation site using lifts, check their carrying capacity, by taking into account the following weights:

- Machine weight (see the data sheet, section 3.3.1.);
- Board weight (max. 20 kg);
- Truck weight;
- Operator’s weight.

CAUTION!
As regards handling, when the machine must be lifted, check that all ropes and lifting equipment comply with the required capacity and, in Europe, with EEC regulations.

4.3. STORAGE

Before its final installation the machine can be stored, for a short time, in a closed and dry place, at a temperature ranging from 4°C to 50°C, relative humidity lower than 80%.

If no suitable rooms are available please ask FEDEGARI to deliver the machine equipped with welded mixed case for boxes by sea.

WARNING
The sun’s rays are likely to damage the plastic and rubber components of the sterilizer. Avoid prolonged exposure to direct sunlight.

4.3.1. Short shut-downs

No problems are involved for shut-downs of up to two months.

4.3.2. Prolonged shut downs

In case of shut-downs of more than two months, apply silicone oil on seals to prevent gluing and quick wear. After prolonged shut-downs, check whether seals must be replaced.
5. INSTALLATION AND DISMISSION

5.1. ENVIRONMENTAL CONDITIONS FOR USE

The installation site must be well lighted and aerated. The machine and its control system require the following environmental conditions:

- Room temperature: \(10^\circ\pm 40^\circ\text{C}\);
- Max. relative humidity: \(85\%\) con \(T \leq 40^\circ\text{C}\);

**CAUTION!**

If the installation site is artificially lighted, check the related devices for compliance with the characteristics required by the law in force in the country where the machine has been installed, as to operators’ safety and health. The machine features a LCD display. Align and position the display so as to avoid reflections and reverberations on the operator’s visual plane.

5.2. SPACE REQUIRED FOR USE AND MAINTENANCE

The available space surrounding the machine must allow the operator to perform:

- the necessary movements to use the control devices without difficulty;
- the necessary movements for loading/unloading operations with the accessories supplied;
- the ordinary maintenance, such as cleaning and processing operations;
- the extraordinary maintenance operations.

5.3. PACKING REMOVAL

Special containers (packaging) are used to transport the machine, wrapped in materials assuring protection against bad weather during transportation and short-term storage.

All packaging materials must be carefully removed, without damaging the machine structure and surface. The sterilizer external cabinet is painted. Keep it with care, to avoid scuffing its surface.

**NOTE**

When using the machine in another site, keep the original packaging container.
5.4. POSITIONING THE MACHINE

**CAUTION!**
When installing the sterilizer, carefully follow the instructions of the installation drawing, as well as this manual’s instructions.

Do not forget that:

* the installation room floor must comply with the required capacity, including the additional weight resting on its structure, due to scheduled hydraulic tests.

* the connections to the floor must bear a 80°C temperature at least.

* all technical safety measures recommended for seismic areas must be adopted in conformity with the related regulations.

* All pipes and accessories used for draining the sterilizer service fluids, the lines and fittings for connecting to the control panel and to other sterilizer components must comply with the regulations of the applicable law.

**NOTE**
The hydraulic test required by the regulations of the country where the machine is used, to be performed when the sterilizer has been installed with its user, might increase the load and reduce the stability of the sterilizer supporting structure. The installation scheme indicates the machine weight and size.

**CAUTION!**
When installing the machine DO NOT create structural links with surfaces or elements subject to stress or dynamic load outside the sterilizer. Should such links exist in the installation area, please let FEDEGARI know the related problems before buying the machine.

1. Position the machine, so that it rests on a perfectly flat surface;

2. The sterilizer must be placed on a flat surface, near a fume hood;

3. Place the machine according to the instructions given in FEDEGARI’s drawings and installation documents (see Section 1.1.1., allied publications).
5.5. CONNECTIONS TO POWER SOURCES AND SERVICE NETWORKS

5.5.1. Hydraulic connections of the users

1. The hydraulic connection to the users is made by means of flexible hoses (see Figure 1.1).

   This system also requires:
   * hose adapters (Ø16 mm) for the purge system;
   * quick–connection Ø 6 mm for network water;
   * quick–connection Ø 4 mm adapters for other users (demineralized water, steam and compressed air).

   **CAUTION!**
   It is recommended to connect the sterilizer purge system to the drains, taking into account ventilation requirements. Network backflows can result from non–compliance with these instructions and the sterilization chamber might be contaminated/polluted. A simple check valve is not considered to be an effective microbiological barrier according to international standards CGMP/CGLP.

   To prevent dangers of pollution to the water supply network, it is recommended that suitable back–flow prevention devices and barriers be installed on the intake line of the vacuum pump. To carry out the connections to the users and the trap, all pipes must be kept at atmospheric pressure. Make sure that all fittings feature their specific tag.

   **WARNING!**
   The deionized water, required with option K10 Steam Generator, must have precise conductivity characteristics. Conductivity can change according to the type of plant by which it is obtained and the maintenance conditions of the plant. With modern plants you can obtain water with a conductivity lower than 5 µS/m, an optimum value for this application. Water with a conductivity above 5 µS/m can be used, though, of course, maintenance jobs on the generator will be more frequent. We recommend that you avoid using water having a conductivity above 30 µS/m. Finally, the following information can be summed up:

   Recommended conductivity: 2 to 15µS/m, inspecting the generator every year.
   Admitted conductivity: up to 30 µS/m, inspecting the generator every six months.

   **CAUTION!**
   The machine is equipped with safety valves calibrated and checked by FEDEGARI AUTOCLAVI at its factory, at an ambient pressure of 1 bar. If the machine is installed in a place where the ambient pressure is notably different from 1 bar (≥ 0.1 bar), FEDEGARI recommends you to have the valves re–calibrated by qualified personnel and/or by the engineers selected for installing the machine, according to the new ambient pressure and before starting the work cycle. This trick ensures safety and proper conditions of use.
5.5.1.1. DEIONIZER options (T30)

If the deionizer has been installed (option T30), connect it as follows (cf. Figure 5.2):

1. Connect pipe A to the water to be deionized (Ideal pressure: 0.3 bar – 0.8 bar max.; if the water pressure at the inlet is higher, install a pressure reducer with pressure gauge on the network, upstream of the deionizer.
2. Connect pipe B to the deionized water load, on the sterilizer.
3. Open the network water cock slowly.
4. The resin in the cartridge becomes progressively blue, from top to bottom. When the blue resin reaches an height of approx. 15 cm from bottom, this will indicate that the cartridge is empty and must be replaced with a new one.
WARNING!
The deionizer’s reservoir is designed for a max. pressure of 2 bar. Any higher pressure would cause the reservoir collapse, resulting in uncontrolled water spillage.

5.5.2. Wiring

WARNING!
The sterilizer is delivered with a five–pole feeder cable, featuring a suitable section, without plug and cable terminal.

The customer must complete all machine connections to power supply. These connections must take into account the power required by the machine (see section 3.3.2. as well as the user plant conditions), so that their are fully compatible, in compliance with safety rules.

WARNING!
The connection of the sterilizer to the electrical network requires the installation of a protection system on the supply electrical panel. To ensure safety, the installer should use a magnetothermal switch of a suitable size, based on the equipment’s electrical absorption (cf. see paragraph 3.3.2.).

WARNING!
The equipment has a single serial output for connection to any external equipment. This output is characterised by a net separation through the double insulation of the power and control circuits. Make sure that the equipment connected to this output is characterised by an equivalent insulation class.

When carrying out such connections, always take into account the conductor colors inside the cables, according to IEC standards:

- **BLACK**: phases (R, S, T);
- **BLUE**: neutral (N);
- **YELLOW/GREEN**: earth.

Therefore:

1. **IF A VACUUM PUMP IS NOT AVAILABLE**: the connection has been completed.

2. **IF A VACUUM PUMP IS AVAILABLE**: slowly turn the pump and check its direction of rotation to make sure that the phase sequence is correct. If the pump is rotating in the wrong direction, invert the two phase conductors, as the only three–phase motor (requiring a correct sequence) has been installed on the vacuum pump.
5.6. INSTALLATION MONITORING

**WARNING!**
In conformity with the laws current in the Country of destination, pressure equipment must be checked on the responsibility of the User by a competent inspection body.

Before using the machine, carry out a short running-in, consisting of at least two complete no-load cycles. During this period, check the sterilizer for any failures. The machine can start its usual production cycles only on test completion, if no problems have occurred. In case of failures, do not hesitate to contact the manufacturer.

5.7. DISMISSION

To dismiss the machine, follow the procedures listed above, but in reverse.

**WARNING!**
The eventual demolition of the machine must be carried out according to the laws current in the Country of destination.
6. USING THE STERILIZER

6.1. OPERATION DESCRIPTION

6.1.1. General information

The most important operations dealing with materials to be processed and sterilized, are defined "sterilization process", or "sterilization cycle" or "cycle". These operations also concern the presetting/preparation of the sterilizer sub-systems and components, as well as the batch and materials to be processed.

The sterilization process consists of the following main steps:

- Sterilizer preparation;
- Product sterilization;
- Product cooling or drying;
- Final phase.

Each operation also includes other operating processes, the "phases", which might change, based on the programs selected by the operator through the menu, their sequence and size, with different physical parameters of processed liquids/liquids.

The machine operation (i.e. the sequence of operations performed on fluids/liquids and on power requirements during the process) is examined below, starting from the most important activities required to process the batch.

The following explanations also describe the physical/functional blocks controlling the above mentioned operations.

The most important activities and the related operations are the following:

- **Sterilizer preparation**
  - Starting the machine;
  - Loading the product and starting the cycle;

- **Batch sterilization**
  - Chamber heating;
  - Initial air exhausting;
  - Sterilization using saturated steam;

- **Cooling or drying**
  - Spontaneous cooling;
* Convection cooling, with forced air circulation using a fan;
* Drying, using a vacuum pump;

- **Final phase**
  including:
  * Atmospheric pressure reset;
  * Cycle completion;

The machine operation during the above mentioned steps will be also described.

### 6.2. CONTROLS

#### 6.2.1. General information

The sterilizer is controlled through a system consisting of a dedicated microprocessor card. The microprocessor manages the main drives, monitors and controls the machine hardware and enables the operating sequences (phases) of the specific sterilization "cycle" programmed.

The microprocessor, hereinafter the "process controller", also controls the operator dialogue, through proper peripherals.

The machine is fitted with control elements which, independently of the microprocessor, integrates its tasks for several control functions.

#### 6.2.2. Control desks

The sterilizer features functional control elements and units located partly on the front cabinet paneling and partly on the Operator Panel.

The machine is equipped with the following control devices (see Figure 6.1):

- LCD display (pos. 1);
- Keyboard (pos. 2);
- Main switch (pos. 7);
- Printer (optional K81) or Datalogger (optional K82) (pos. 3);
- Emergency push–button (pos. 4);
- Control pressure–vacuum gauge (pos. 5);
- Manual purge valve (not available for model FVA–HT) (pos. 6).
The operator can stand in front of the panel lodging the control elements in order to work without problems and to immediately identify warnings and messages.

LEGEND

1. LCD Display
2. Keyboard
3. Printer or Datalogger
4. Emergency button
5. Pressure-vacuum gauges
6. Manual pressure relief valve of the chamber
7. Main switch
8. Technical cabinet key
9. Effluent duct

![Figure 6.1 – Position of the control elements](image)

6.2.3. Display

It is the most important display device (see Figure 6.2) used by the operator. It is a monochrome, LCD model, consisting of 4 lines x 20 columns.

It displays all menus which can be selected by the operator as well as the most important commands given to the machine. In particular, it displays both pressure and temperature parameters of the sterilization cycle in progress. The parameters related to the sterilization cycle in progress and all warnings are also displayed.
6.2.4. Keyboard

The keyboard (see Figure 6.2) is directly managed by the process controller. It is the most important equipment used by the operator to dialog with the machine and to give it the operating commands required.

It is a diaphragm keyboard, featuring 24 keys and 5 LED indicators. Press the keys to control the process, while interacting with the controller to carry out operations.

![Figure 6.2 — Display/keyboard unit](image)

Table 6.1 — Keyboard: controls

<table>
<thead>
<tr>
<th>SIMB. / Nr. POS.</th>
<th>DEVICE/FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>F1</strong></td>
<td>Key &quot;Start/Step-by-Step&quot;: it is a double function key.</td>
</tr>
<tr>
<td><img src="image" alt="F1 START" /></td>
<td>1) It allows to start the program selected during the preparation phase;</td>
</tr>
<tr>
<td></td>
<td>2) During the sterilization program execution, press it in order to enter the next operating phase, while blocking the controls related to the operating phase in progress without waiting to reach the preset end-of-phase value.</td>
</tr>
<tr>
<td><img src="image" alt="←" /></td>
<td>Key &quot;Left Arrow&quot;: allows to scroll in reverse the pages of the process software menus.</td>
</tr>
<tr>
<td><img src="image" alt="↑" /></td>
<td>Key &quot;Up Arrow&quot;: It is a double function key. It allows to scroll upwards the selected page, if it has more than 4 lines. Press it after pushing key &quot;INS&quot; to move the cursor on the parameter numeric fields.</td>
</tr>
<tr>
<td>SIMB. / Nr. POS.</td>
<td>DEVICE/FUNCTION</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------</td>
</tr>
<tr>
<td><img src="image" alt="Down Arrow" /></td>
<td>Key &quot;Down Arrow&quot;: it is a double function key. It allows to scroll downwards the selected page, if it has more than 4 lines. Press it after pushing key &quot;INS&quot; to move the cursor on the parameter numeric fields.</td>
</tr>
<tr>
<td><img src="image" alt="Right Arrow" /></td>
<td>Key &quot;Right Arrow&quot;: allows the sequential scrolling of the pages of the process software menus.</td>
</tr>
</tbody>
</table>
| ![STOP](image) | **F2** – Stop: this key has three functions.  
1) It allows to return to the main menu from the selected program preparation phase.  
2) During the program execution, press it to enter the emergency phase immediately. In the Emergency phase, but not in Decontamination Emergency, pressing the "STOP" keys again allows you to terminate the program, entering the "Pressure Balancing" and "Cycle End" phases.  
3) During the end–of–cycle phase, press this key to conclude it and to deactivate the acoustic signal. |
| ![7](image) | Key 7: allows to enter number "7" in the selected field. |
| ![8](image) | Key 8: allows to enter number "8" in the selected field. |
| ![9](image) | Key 9: allows to enter number "9" in the selected field and to print through the function identical to key **F3**. |
| ![PRINT](image) | **F3** – Key "Print image": allows to print the displayed image, when the printer is configured and without processes in progress. |
| ![Decimal Point](image) | Key ".": allows to enter the decimal point in the number keyed in. |
| ![4](image) | Key 4: allows to enter number "4" in the selected field. |
| ![5](image) | Key 5: allows to enter number "5" in the selected field. |
| ![6](image) | Key 6: allows to enter number "6" in the selected field. |
| ![Open Cover](image) | **F4** – Key "Open cover": press it only when no sterilization processes are in progress. It controls the cover safety devices and compressed air exhaust from the cover seal. |
### 6.2.5. Main switch

The main switch, located on the rear of the operator panel, allows to enable the process controller. It also allows to enable the related peripherals, which form, together with the controller, the main machine hardware. Switch it to the <O> position to disable the process controller and the peripherals connected to it.
6.2.6. Printer (optional)

The machine is equipped with a printer (see Figure 6.4), featuring a 200 dpi thermal printing device, RS232 interface. It can support the following transmission protocols:

The printer is directly connected to the process controller and must document in real time the development of the sterilization program in progress.

It is also used to obtain parameter reports and data on the sterilization cycle completed. The operator must feed it with new paper and remove the reports printed on the sterilization process completion.
Table 6.2 – Thermal printing: commands and controls

<table>
<thead>
<tr>
<th>SYMBOL /POS. No.</th>
<th>DEVICE/FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>POWER</td>
<td>Green Led: if lit, the printer is supplied.</td>
</tr>
<tr>
<td>STATUS</td>
<td>Red Led: if continuously lit, indicates the presence of an error (excessive/insufficient head supply or excessive head temperature), if blinking, there is no more paper.</td>
</tr>
<tr>
<td>Print</td>
<td>Push–button: not enabled.</td>
</tr>
<tr>
<td>Feed</td>
<td>Push–button: if pressed, the paper is fed.</td>
</tr>
</tbody>
</table>

6.2.7. Datalogger – Kit EN285 (optional K82)

The DATALOGGER (cf. Figure 6.5) is provided with a 200 dpi thermal printing device, RS232 interface.

![Figure 6.5 – Datalogger](image)

For Printing, it considers the external data, entered through the serial port, and detects temperature and pressure signals with double-detection heat probe Pt100 and a pressure transducer (provided in the Kit).

The Recording can be controlled either manually or automatically:

- **Manually** with key START STOP.
- **Automatically** with an external digital signal corresponding to "CYCLE IN PROGRESS".

The two operating modes can be selected in the set–up menu; if automatic operation is selected, the key START STOP is disabled.
The Recording frequency is set, in the set-up, as rate time ("synchronous" recording).
When the recording starts (and, then, according to the rate), the following data is printed (cf. Figure 6.6):
- Recording time/duration (hh:mm:ss);
- Temperature (T----.--);
- Pressure (P--.--).

Figure 6.6 – Printing of "Start recording" data

Among "synchronous" rates, some "asynchronous" recordings may occur that, activated through an external signal from the second digital input, are marked by an asterisk.
At the end of the recording (end of cycle), you can print a chart representing the temperature/pressure curves. The curve can include up to 255 samplings. The temperature/pressure range that can be represented is 0 to 150°C and 0 to 5 bar.

Table 6.3 – Datalogger: led functions

<table>
<thead>
<tr>
<th>SYMBOL /POS. No.</th>
<th>DEVICE/FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>POWER</td>
<td>Green Led: if lit, the Datalogger is supplied.</td>
</tr>
<tr>
<td>START</td>
<td>Green Led: if blinking, the recording is in progress.</td>
</tr>
<tr>
<td>STATUS</td>
<td>Red Led: if continuously lit, indicates the presence of an error (excessive/insufficient head supply or excessive head temperature), if blinking, there is no more paper.</td>
</tr>
</tbody>
</table>

Table 6.4 – Datalogger: keys’ functions

<table>
<thead>
<tr>
<th>KEY</th>
<th>ACTIVATED ON START-UP</th>
<th>ACTIVATED DURING OPERATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print</td>
<td>CALIBRATION MENU: sensor calibration.</td>
<td></td>
</tr>
<tr>
<td>Feed</td>
<td>Auto–test.</td>
<td>Print date/time (just press the key); Paper feed (press the key and hold it down);</td>
</tr>
<tr>
<td>START STOP</td>
<td>Recording start, if enabled in configuration and if sensors are calibrated. If unset sensors are detected, the Datalogger immediately prints the part of the calibration menu relating to the unset sensor.</td>
<td>If enabled in configuration:– Start recording (press the key once);– Stop recording (press the key twice).</td>
</tr>
<tr>
<td>Print + Feed</td>
<td>SET–UP Menu</td>
<td>SET CLOCK CALENDAR Menu: date/time setting.</td>
</tr>
</tbody>
</table>
In the CONFIGURATION menus the keys have a dedicated function described in the following table.

Table 6.5 – Datalogger: keys’ function in the CONFIGURATION menus

<table>
<thead>
<tr>
<th>KEY</th>
<th>MENU</th>
<th>FUNCTION</th>
</tr>
</thead>
</table>
| ![Print] | 1. AUTOTEST  
2. SET--UP  
3. CALIBRATION MENU  
4. SET CLOCK CALENDAR | 1. CONTINUE  
2. INCREMENT  
3. CALIBRATION  
4. INCREMENT |
| ![Feed] | 1. AUTOTEST  
2. SET--UP  
3. CALIBRATION MENU  
4. SET CLOCK CALENDAR | 1. EXIT  
2. CONFIRM  
3. EXIT  
4. CONFIRM |
| ![START STOP] | 1. AUTOTEST  
2. SET--UP  
3. CALIBRATION MENU  
4. SET CLOCK CALENDAR | 1. –  
2. SKIP  
3. –  
4. EXIT |

The TEST and CONFIGURATION menus, in English, are listed in the following table.

Table 6.6 – Datalogger: TEST and CONFIGURATION menus

<table>
<thead>
<tr>
<th>MENU</th>
<th>FUNCTION</th>
</tr>
</thead>
</table>
| AUTOTEST | Displays: – the make, model and version of the device’s firmware;  
– the configuration parameters;  
– the set date/time;  
– the characters of the available fonts.  
Performs: – the DOT TEST. |
| SET--UP | Parameters: – PRINT MODE  
– SERIAL MODE  
– REAL TIME CLOCK |
| CALIBRATION MENU | For the initial setting/creation of the high and low points for analog inputs’ R/T (ohm/°C) and I/P (ampere/bar) conversion characteristics. These are set by connecting analog inputs to precision potentiometer in order to obtain the requested resistances and currents. N.B. The recorder activates this menu automatically if the characteristics are lost, e.g. after the back-up battery has run down. After calibration, the analog signals must be calibrated with the OFFSET and GAIN functions in the SET--UP menu. The OFFSET can be set by carrying–out the calibration at a low point; the characteristics are thus increased or decreased by entering a positive or negative value, within the range. Then, the GAIN can be set by carrying–out the calibration at a high point; if the reading is too low, set a value above 1, if it is too high, set a value below 1, within the range. The R/T and I/P characteristics can be adjusted properly. |
| SET CLOCK CALENDAR | To set the date and time operating through the Datalogger’s internal clock. |
Table 6.7 – Datalogger: parameters of the SET-UP menu

<table>
<thead>
<tr>
<th>PARAMETERS</th>
<th>OPTIONS</th>
<th>DESCRIPTION</th>
<th>DEFAULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>FINAL GRAPH</td>
<td>ENABLED</td>
<td>Graph at the recording end.</td>
<td>ENABLED</td>
</tr>
<tr>
<td></td>
<td>DISABLED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OFFSET TEMP</td>
<td>−9.9°C +9.9°C</td>
<td>Translation of the R/T characteristic</td>
<td>0.0°C</td>
</tr>
<tr>
<td></td>
<td>−0.99 bar +0.99 bar</td>
<td>Translation of the I/P characteristic</td>
<td>0.0 bar</td>
</tr>
<tr>
<td>GAIN TEMP</td>
<td>0.667 1.500</td>
<td>Rotation of the R/T characteristic</td>
<td>1.0</td>
</tr>
<tr>
<td>GAIN PRESS</td>
<td>0.667 1.500</td>
<td>Rotation of the I/P characteristic</td>
<td>1.0</td>
</tr>
<tr>
<td>START/STOP</td>
<td>PRINT KEY EXT. INPUT</td>
<td>Manual recording (activated with the START/STOP key). Automatic recording (digital input).</td>
<td>EXT. INPUT</td>
</tr>
<tr>
<td>TIMER</td>
<td>10,20,30,40,50 SEC., 1,2,3,4,5,6,7,8,9,1 0,15,20,25,30,40,50 MIN., 1 HOUR</td>
<td>Printing rate during recording.</td>
<td>10 sec</td>
</tr>
<tr>
<td>LANGUAGE</td>
<td>IT EN DE FR NL</td>
<td>Translation of the final graph heading in: – Italian – English – German – French – Dutch</td>
<td>IT</td>
</tr>
<tr>
<td>COLUMNS</td>
<td>24–FONT 16x24 40–FONT 9x24</td>
<td>Normal dimensions (24 columns). Small (40 columns).</td>
<td>24</td>
</tr>
<tr>
<td>PRINT</td>
<td>NORMAL REVERSE</td>
<td>Legible after the tear or legible on the printer.</td>
<td>NORMAL</td>
</tr>
<tr>
<td>MODE</td>
<td>LITTLE DOUBLE WIDTH DOUBLE HEIGHT EXPANDED</td>
<td>– normal – double width – double height – large characters</td>
<td>LITTLE</td>
</tr>
<tr>
<td>FONT</td>
<td>1 2</td>
<td>Type of characters</td>
<td>1</td>
</tr>
<tr>
<td>CR–LF</td>
<td>HONOR CR IGNOR CR</td>
<td>In printing mode the return (carriage return) is honored or ignored.</td>
<td>HONOR</td>
</tr>
<tr>
<td>PARAMETERS</td>
<td>OPTIONS</td>
<td>DESCRIPTION</td>
<td>DEFAULT</td>
</tr>
<tr>
<td>------------</td>
<td>------------------</td>
<td>--------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>DENSITY</td>
<td>NORMAL, DARK,</td>
<td>Black density:</td>
<td>NORMAL</td>
</tr>
<tr>
<td></td>
<td>VERY DARK, VERY LIGHT</td>
<td>- normal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LIGHT</td>
<td>- dark</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- very dark</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- very light</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- light</td>
<td></td>
</tr>
<tr>
<td>SECONDS</td>
<td>ENABLE, DISABLE</td>
<td>Enables the printing of seconds.</td>
<td>ENABLE</td>
</tr>
</tbody>
</table>
Figure 6.7 shows an example of the recording printing in a sterilization cycle.

Figure 6.7 – Example of recording printing
6.2.8. Emergency button

Press this button to stop the machine immediately (EMERGENCY STOP) and to switch on the master switch. Once pressed, this button must be reset manually by pulling it horizontally (see Fig. 6.8).

![Emergency push-button](image)

*Figure 6.8 – Emergency push-button*

6.2.9. Control pressure–vacuum gauges

The machine mechanical analog pressure–vacuum gauges (see Figure 6.9) display pressures in the sterilizer pressurized components.

One of these devices measures the sterilization chamber pressure.

The other one indicates the steam generator pressure, if it has been installed, or the steam supply line pressure.

These gauges feature a scale for reading pressure (bar).

They continue to detect pressure and vacuum even when the sterilizer is deactivated and the chamber is not operating.

![Control pressure-vacuum gauges](image)

*Figure 6.9 – Control pressure–vacuum gauges*
6.2.10. Manual pressure relief valve of the chamber (not available on FVA–HT model)

It is a diaphragm valve (Fig. 6.10) located on the front panel of the machine, near the vacuum–pressure gauges, and connected to the sterilizer chamber. If the machine cannot run in automatic mode, the operator can use this valve for manually checking whether any pressure is left in the chamber on the sterilization process completion. This valve is also used to let out the pressure generated in the chamber when the cover must be opened for new loading operations.

⚠️ CAUTION !

Risk of scalding! Opening the manual valve may cause hot steam to be expelled from the release duct located at the bottom of the front panel of the machine.

**Figure 6.10 – Manual pressure relief valve of the chamber and effluent duct**

**Table 6.8 – Manual purge valve (see Figure 6.11)**

<table>
<thead>
<tr>
<th>DEVICE/FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knob:</strong> Turn it clockwise until it stops, in order to intercept the pipe for purging the sterilization chamber. To purge the chamber, turn the knob anticlockwise from the CLOSE position. To obtain maximum draining section turn the knob anticlockwise until it stops.</td>
</tr>
</tbody>
</table>

**Figure 6.11 – Manual purge valve: operations**

**a. Valve closing**

**b. Valve opening: drainage**
6.3. ACCESS LEVELS AND OPERATING MODES

6.3.1. Access levels

To protect the system and to guarantee a proper hierarchy, according to all identified tasks, access is allowed only for different authorization levels, by typing in a code, also known as "password". Access is allowed according to 5 levels (0 to 4).

Each level allows to access other levels, by typing in a specific password.

The first 2 (0 and 1) of the 5 access levels (3 and 2), defined "FEDEGARI DEVELOPER" and "FEDEGARI PERSONNEL" respectively, are reserved to Fedegari's engineers, the other levels (2, 3 and 4), defines "User supervisor", "User : user" and "Stand–by" are reserved to the sterilizer personnel.

Table 6.9 below shows the operating functions associated to every level.

<table>
<thead>
<tr>
<th>ACCESS LEVELS</th>
<th>OPERATING FUNCTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 STAND–BY</td>
<td>Displaying of the alarms list (EVT)</td>
</tr>
<tr>
<td></td>
<td>– Enter password (PSW)</td>
</tr>
<tr>
<td></td>
<td>– Control of the Operator Panel’s operation (SYS)</td>
</tr>
<tr>
<td></td>
<td>– Exit from the Operator Panel Functions menu (EXT)</td>
</tr>
<tr>
<td></td>
<td>– Displaying of program Parameters</td>
</tr>
<tr>
<td></td>
<td>– Displaying of digital Inputs/Outputs state</td>
</tr>
<tr>
<td></td>
<td>– Displaying of analog inputs</td>
</tr>
<tr>
<td></td>
<td>– Displaying of TE1, TE2 and PT calibration data</td>
</tr>
<tr>
<td></td>
<td>– Displaying of System Parameters</td>
</tr>
<tr>
<td></td>
<td>– Displaying of sterilizer Data and Options</td>
</tr>
<tr>
<td></td>
<td>– System Displaying</td>
</tr>
<tr>
<td></td>
<td>– Displaying of the Alarms List</td>
</tr>
<tr>
<td>3 USER: USER</td>
<td>All &quot;STAND BY&quot; functions plus:</td>
</tr>
<tr>
<td></td>
<td>– Program selection and running</td>
</tr>
<tr>
<td></td>
<td>– Print the Alarms List</td>
</tr>
<tr>
<td></td>
<td>– Current Alarm Acknowledgement</td>
</tr>
<tr>
<td></td>
<td>– “Print Screen” function (keys: “PRN” or “F3”)</td>
</tr>
<tr>
<td>2 USER SUPERVISOR</td>
<td>All &quot;USER&quot; functions plus:</td>
</tr>
<tr>
<td></td>
<td>– Change the system’s date/time (TIM)</td>
</tr>
<tr>
<td></td>
<td>– Change Program Parameters</td>
</tr>
<tr>
<td></td>
<td>– Change the programs’ names (4 to 10)</td>
</tr>
<tr>
<td></td>
<td>– Force Digital Outputs state</td>
</tr>
<tr>
<td></td>
<td>– Change TE1, TE2 and PT calibration data</td>
</tr>
<tr>
<td></td>
<td>– Change System Parameters</td>
</tr>
<tr>
<td></td>
<td>– Cancel the Alarms List</td>
</tr>
<tr>
<td></td>
<td>– Select language</td>
</tr>
<tr>
<td></td>
<td>– Change password</td>
</tr>
<tr>
<td></td>
<td>– Invert doors</td>
</tr>
<tr>
<td></td>
<td>– Delayed start of a program</td>
</tr>
</tbody>
</table>
### Access Levels

<table>
<thead>
<tr>
<th><strong>FEDEGARI PERSONNEL</strong></th>
<th><strong>Operating Functions</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>This password allows access to the main System functions, including Configuration.</td>
<td>All &quot;USER SUPERVISOR&quot; functions plus:</td>
</tr>
<tr>
<td></td>
<td>- System Configuration (PGS) ♦</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>FEDEGARI DEVELOPER</strong></th>
<th><strong>Operating Functions</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>This password allows access to all System functions, including the SW configuration and loading on the Operator Panel.</td>
<td>All &quot;FEDEGARI PERSONNEL&quot; functions plus:</td>
</tr>
<tr>
<td></td>
<td>- SW loading on the Operator Panel (CFG) ♦</td>
</tr>
</tbody>
</table>

**NOTE**
The functions with the z symbol are part of the Operator Panel menu. For further information, refer to paragraph 6.4.5.2. Panel functions and operation enabling.

**NOTE**
The USER SUPERVISOR password allows the modification of the USER SUPERVISOR and USER USER passwords through an appropriate operation in the main menu. The changed passwords will be always reset at their original value, after the SW downloading.

**NOTE**
The "Step–by–step", "Cycle Stop" and release of the "Contamination Lock" functions can be implemented only at USER SUPERVISOR, FEDEGARI PERSONNEL and FEDEGARI DEVELOPER access levels.

**NOTE**
For safety reasons, the user must always disable his/her password (entering the STAND–BY password = 0000) when the machine is no longer used and, in any case, before turning it off.

### 6.3.2. Operating modes

The interface software has three main operating modes.

The first allows to use the machine, while controlling safety from its start until cycle completion (operating mode: "USE").

The second allows to reconfigure the machine application units (sterilization programs) and to define the general parameters controlling all activities and functions common to sterilization processes (operating mode: "CONFIGURATION").

The third sums up all operating modes allowing to service and/or control, also "ON LINE", several software functions, as well as the operating and functional logics (operating mode : "MAINTENANCE").
The following information on operating procedures, is addressed to the operator authorized to work in the use mode, as well as to the operator/maintenance engineer who, thanks to his training and knowledge of the machine, corresponds to the professional indicated in section 2.4.3.

6.4. OPERATING PROCEDURES

6.4.1. Warnings

Most labor accidents are due to non-compliance with the most important safety regulations. All operators working with the machine must know and comply with the rules of this manual (also refer to section 2.4. "Safety warnings").

6.4.2. General information

The most important activities concerning product processing in order to sterilize it is known as "sterilization process", or "sterilization cycle" or "cycle".

To carry out a sterilization process, a specific program must be developed on the process controller, which, through its operating system and the above mentioned program, manages a series of operations related to the components and elements controlling fluid temperature and pressure.

Therefore, thermal energy is properly transferred to the batch, according to its physical characteristics. Based on its configuration, the sterilizer exploits one or several sterilization programs which can be selected according to the product to be processed.

6.4.3. Sterilization programs

Every program consists of a sequence of elementary modules named phases. To develop a program the following phase must be sequentially carried out. They control the sterilizer elements so that the sterilization chamber pressure and temperature are compliant with the set functions.

The programs has a set structure of sequential phases, to be enabled by the operator through proper parameters. The phase trend can be modified through the related parameters. A program family can be implemented to meet all requirements, by loading the above mentioned parameters (the "program parameters"), as well as a series of general parameters concerning activities and functions common to each program.
6.4.3.1. Working parameters

The sterilizer applications (see Figure 6.12, 6.13 and Figure 6.14) consist of a group of specific use programs and of a group, consisting of the same phase sequence, to be used for sterilizing the product.

The above mentioned applications include the following programs:

- **Prg.1 – Vacuum test**
  It allows to verify the sterilizer vacuum seal. Of course, this program should be used only if the machine is fitted with a *vacuum pump unit* (option K20).

- **Prg. 2 – Pressure leak test**
  It allows to check the pressure seal. It can be used only when the sterilizer features a *sterilizing filter for air* (K51) and the pressurized chamber *leak test* (option K61).

- **Prg. 3 – Decontamination (FVA2/FVA3) High Pathogen (FVA-HT)**
  It is fit for sterilizing products coming from environments with microbiologic pollution.

- **Prg. 4 – Bowie and Dick Test**
  Allows you to check the proper removal of the air from porous batches, as required by European standards for Hospitals EN285. The parameter selection is subject to the machine configuration.

- **Prg. 5 +10 – Sterilization programs**
  The six sterilization programs (5 to 10) have the same structure and can be completely configured by the user. The phase sequence can be modified, by selecting suitable *program parameters*. Their selection is subject to the machine configuration.

To enable the above mentioned programs, enter their identification number in a specific mask (*SELECT PROGRAM* activated from the main menu).

The system enters the initial cycle phase (Preparation), common to all applications. During this phase, the program does not activate any sterilizer elements or components, thus allowing the operator to complete the sterilizer preparation (product loading in the chamber, cover closing).

To start the sterilization cycle, press key **START**.

**NOTE**

All programs are supplied with the default value of every parameter, which will be acquired by the system unless the operator changes it.
Before going on, the program checks the cover system logic, in order to assure that the operations carried out are compliant with the chamber safety conditions.

When running, the program can be stopped before the sterilization process completion only through a manual emergency control (cycle stop), by an activated alarm (due to a failure occurring during the sterilization process) or when the machine is restarted after a black-out. In this case, the sterilizer enters an “emergency” phase, providing a wait state which protects the machine, the personnel and any loaded products. The sterilizer is no longer in the emergency state and immediately reaches the cycle final phases (pressure balancing and end-of-phase), by pressing key \[\text{STOP}\].

The operator will be permitted to execute specific programs (1, 2, 3) and to select some phase sequences of the sterilization programs only if the sterilizer features one or several of the following additional systems (Table 6.10):

### Table 6.10 – Additional component program phase

<table>
<thead>
<tr>
<th>PROGRAMS/PHASES</th>
<th>DESCRIPTION</th>
<th>Phase No.</th>
<th>K20</th>
<th>K51</th>
<th>K52</th>
<th>K61</th>
<th>K62</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prg. N.1</td>
<td>VACUUM TEST</td>
<td>–</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prg. N.2</td>
<td>PRESSURE TEST</td>
<td>–</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prg. N.3</td>
<td>DECONTAMINATION (FVA2/3)</td>
<td>–</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>HIGH PATHOGEN (FVA-HT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase</td>
<td>INITIAL VACUUM</td>
<td>3+4</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase</td>
<td>STEAM PULSES</td>
<td>5</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase</td>
<td>FINAL VACUUM</td>
<td>10+11</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase</td>
<td>COOLING FORCED</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Phase</td>
<td>AIR PULSES</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

**NOTE**
Option K62 includes option K61.

**NOTE**
The operator must set up sterilization programs compatible with the machine components, fit for the product to be sterilized. The sterilizer software will prevent the operator from select phases, programs or functions which are not allowed by the machine P&ID configuration.
Figure 6.12–Flow chart of the sterilizer cycles (1st part)
Figure 6.13 – Flow chart of the sterilizer cycles (2nd part)
Figure 6.14 – Flow chart of the sterilizer cycles (3st part)
6.4.3.2. Program parameters

The operator can select the desired phase sequence (v1, v2, ...v22) or modify some phase parameters in order to choose the operating configuration required by simply setting proper "program parameters". Program parameters are available in display and adjust mode, when accessing suitable software pages from the main menu (see 6.5.2.). These 10 pages, one for each program, consist of two types of parameters:

- Phase selection parameters, allowing to enable the corresponding phase(s);
- Phase parameters allowing to set target times and values for the phase.

The four tables below describe the program parameters of the sterilizer applications. In particular, program parameters (5-10) mentioned in Table 6.16 are supplied with their default values for special uses:

- Prg. 5 – Solid materials
- Prg. 6 – Porous materials
- Prg. 7 – Rubber materials
- Prg. 8 – Closed box for sterilization
- Prg. 9 – Liquid forced cooling
- Prog.10 – Spontaneous–cooling liquids

The meaning of the table fields is the following:

- NO: parameter identification number;
- DESCRIPTION: parameter name;
- FUNCTION: description of the activities managed by the parameter;
- MIN: minimum parameter value;
- DEF: parameter Default value for every program;
- MAX: maximum parameter value;

Units of measurement of the parameter: bar (bar), centigrades (°C), minutes (min).
Table 6.11 – Program parameter list: **VACUUM TEST**

<table>
<thead>
<tr>
<th>No.</th>
<th>DESCRIPTION</th>
<th>FUNCTION</th>
<th>MIN</th>
<th>DEF</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1</td>
<td>TEST PRESSURE</td>
<td>bar Target pressure during the initial vacuum phase.</td>
<td>0.01</td>
<td>0.20</td>
<td>1.00</td>
</tr>
<tr>
<td>V2</td>
<td>STABILIZ. TIME</td>
<td>min Duration of the pressure stabilization phase in the chamber.</td>
<td>0</td>
<td>2</td>
<td>480</td>
</tr>
<tr>
<td>V3</td>
<td>VACUUM TEST TIME</td>
<td>min Target time of vacuum test in the chamber.</td>
<td>0</td>
<td>10</td>
<td>480</td>
</tr>
<tr>
<td>V4</td>
<td>MAX. PRESS. RISE</td>
<td>bar Max. pressure rise allowed during the vacuum test in the chamber.</td>
<td>0.001</td>
<td>0.013</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Table 6.12 – Program parameter list: **PRESSURE TEST**

<table>
<thead>
<tr>
<th>No.</th>
<th>DESCRIPTION</th>
<th>FUNCTION</th>
<th>MIN</th>
<th>DEF</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1</td>
<td>TEST PRESSURE</td>
<td>bar Target pressure of the pressurization phase</td>
<td>1.00</td>
<td>2.00</td>
<td>3.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Values for FVA–HT model</td>
<td>1.00</td>
<td>5.00</td>
<td>5.00</td>
</tr>
<tr>
<td>V2</td>
<td>STABILIZ. TIME</td>
<td>min Duration of pressure stabilization phase in the chamber.</td>
<td>0</td>
<td>2</td>
<td>480</td>
</tr>
<tr>
<td>V3</td>
<td>VACUUM TEST TIME</td>
<td>min Target time of the pressure test in the chamber.</td>
<td>0</td>
<td>10</td>
<td>480</td>
</tr>
<tr>
<td>V4</td>
<td>MAXIMUM PRESSURE LACK</td>
<td>bar Max. pressure rise or drop allowed during the chamber leak test.</td>
<td>0.001</td>
<td>0.013</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Table 6.13 – Program parameter list: **HIGH PATHOGEN – SPECIFIC FOR THE FVA–HT MODEL**

<table>
<thead>
<tr>
<th>No.</th>
<th>DESCRIPTION</th>
<th>FUNCTION</th>
<th>MIN</th>
<th>DEF</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>V10</td>
<td>STER. T. TEMP.</td>
<td>ºC It is the temperature that, being added to 0.2ºC represents the heating phase final target. It is also the minimum temperature allowed during the sterilization phase. When the chamber temperature drops below this value, the alarm “STER. TEMP. LACK.” is displayed and the sterilization time is no longer counted.</td>
<td>105.0</td>
<td>140.0</td>
<td>140.0</td>
</tr>
<tr>
<td>V14</td>
<td>STER. TIME</td>
<td>min Duration of the sterilization phase.</td>
<td>0</td>
<td>10</td>
<td>3000</td>
</tr>
</tbody>
</table>
### Table 6.14 – Program parameter list: DECONTAMINATION

<table>
<thead>
<tr>
<th>No.</th>
<th>DESCRIPTION</th>
<th>FUNCTION</th>
<th>MIN</th>
<th>DEF</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>V10</td>
<td>STER. T. TEMP.</td>
<td>°C It is the temperature that, being added to 0.2°C represents the heating phase final target. It is also the minimum temperature allowed during the sterilization phase. When the chamber temperature drops below this value, the alarm &quot;STER. TEMP. LACK,&quot; is displayed and the sterilization time is no longer counted.</td>
<td>105.0</td>
<td>121.0</td>
<td>122.0</td>
</tr>
<tr>
<td>V14</td>
<td>STER. TIME</td>
<td>min Duration of the sterilization phase.</td>
<td>0</td>
<td>10</td>
<td>3000</td>
</tr>
<tr>
<td>V16</td>
<td>COOLING</td>
<td>0/1 It allows to enable/disable the spontaneous or forced cooling phase.</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V17</td>
<td>SPONT. COOL. TEMP.</td>
<td>°C Spontaneous cooling phase target temperature.</td>
<td>50</td>
<td>110</td>
<td>140</td>
</tr>
<tr>
<td>V18</td>
<td>FORCED COOL TEMP.</td>
<td>°C Forced cooling phase target temperature.</td>
<td>50</td>
<td>80</td>
<td>140</td>
</tr>
<tr>
<td>V19</td>
<td>COOL. PRESS.</td>
<td>bar Forced cooling phase target pressure.</td>
<td>1.00</td>
<td>3.60</td>
<td>3.60</td>
</tr>
<tr>
<td>V20</td>
<td>DRYING VACUUM</td>
<td>0/1 It allows to enable/disable the product drying phases (final vacuum and drying vacuum).</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V21</td>
<td>PRESSURE</td>
<td>bar Drying vacuum phase target pressure.</td>
<td>0.01</td>
<td>0.20</td>
<td>1.00</td>
</tr>
<tr>
<td>V22</td>
<td>TIME</td>
<td>min Drying vacuum duration.</td>
<td>0</td>
<td>10</td>
<td>480</td>
</tr>
</tbody>
</table>
### Table 6.15 – List of Bowie & Dick program parameters

<table>
<thead>
<tr>
<th>No.</th>
<th>DESCRIPTION</th>
<th>FUNCTION</th>
<th>MIN</th>
<th>DEF</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>V3</td>
<td>INITIAL VACUUM</td>
<td>0/1 It allows the enabling/disabling of the initial vacuum condition.</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V4</td>
<td>PRESSURE</td>
<td>bar End-of-phase target pressure value for letting air out of the chamber.</td>
<td>0.01</td>
<td>0.20</td>
<td>1.00</td>
</tr>
<tr>
<td>V5</td>
<td>TIME</td>
<td>min Indicates the duration of the vacuum phase inside the chamber, with steam injection and air extraction.</td>
<td>0</td>
<td>3</td>
<td>480</td>
</tr>
<tr>
<td>V6</td>
<td>STEAM PULSES</td>
<td>0/1 It allows the enabling/disabling of the steam pulse phase.</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V7</td>
<td>PULSES NUMBER</td>
<td>n. Indicates the number of steam vacuum pulses.</td>
<td>0</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>V8</td>
<td>PRESSURE UPPER</td>
<td>bar Indicates the increasing pulse pressure value.</td>
<td>0.10</td>
<td>1.50</td>
<td>3.00</td>
</tr>
<tr>
<td>V9</td>
<td>PRESSURE LOWER</td>
<td>bar Indicates the decreasing pulse vacuum value.</td>
<td>0.10</td>
<td>0.50</td>
<td>3.00</td>
</tr>
<tr>
<td></td>
<td><strong>STERILIZATION</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>V10</td>
<td>STER. T. TEMP.</td>
<td>°C It is the temperature that, being added to 0.2°C represents the heating phase final target. It is also the minimum temperature allowed during the sterilization phase. When the chamber temperature drops below this value, the alarm “STER. TEMP. LACK.” is displayed and the sterilization time is no longer counted.</td>
<td>65.0</td>
<td>133.0</td>
<td>136.0</td>
</tr>
<tr>
<td>V11</td>
<td>STER. T. TOLER.</td>
<td>°C It is the temperature value based on which the sterilization phase is regulated. The sterilization tolerance determines the sterilization range by adding to sterilization temperature V10 its value.*</td>
<td>1.0</td>
<td>2.0</td>
<td>5.0</td>
</tr>
<tr>
<td>V14</td>
<td>STERILIZ. TIME</td>
<td>min Duration of the sterilization phase.</td>
<td>0.0</td>
<td>3.5</td>
<td>900.0</td>
</tr>
<tr>
<td>V20</td>
<td>DRYING VACUUM</td>
<td>0/1 Allows the enabling/disabling of the product drying phases.</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V21</td>
<td>PRESSURE</td>
<td>bar Pressure target during the 1st vacuum phase for drying.</td>
<td>0.01</td>
<td>0.20</td>
<td>1.00</td>
</tr>
<tr>
<td>V22</td>
<td>TIME</td>
<td>min Duration of the drying phase.</td>
<td>0</td>
<td>10</td>
<td>480</td>
</tr>
<tr>
<td>No.</td>
<td>DESCRIPTION</td>
<td>FUNCTION</td>
<td>MIN</td>
<td>DEF</td>
<td>MAX</td>
</tr>
<tr>
<td>-----</td>
<td>---------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>V23</td>
<td>AIR PULSES</td>
<td>Allows the enabling/disabling of the air pulse phase inside the chamber.</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V24</td>
<td>PULSES NUMBER</td>
<td>Number of air pulses.</td>
<td>0</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>V25</td>
<td>UPPER PRESSURE</td>
<td>Increasing pressure of air pulses.</td>
<td>0.10</td>
<td>0.95</td>
<td>3.00</td>
</tr>
<tr>
<td>V26</td>
<td>LOWER PRESSURE</td>
<td>Decreasing pressure of air pulses.</td>
<td>0.08</td>
<td>0.20</td>
<td>3.00</td>
</tr>
</tbody>
</table>

Table 6.16 – Program parameter list (PROGRAMS 5 ÷ 10)

<table>
<thead>
<tr>
<th>No.</th>
<th>DESCRIPTION</th>
<th>FUNCTION</th>
<th>Prg 5</th>
<th>Prg 6</th>
<th>Prg 7</th>
<th>Prg 8</th>
<th>Prg 9</th>
<th>Prg 10</th>
<th>MIN</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1</td>
<td>PREHEATING</td>
<td>Allows the enabling/disabling of the pre-heating phase.</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>V2</td>
<td>TIME</td>
<td>Pre-heating phase duration</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>0</td>
<td>480</td>
</tr>
<tr>
<td>V3</td>
<td>PREVACUUM</td>
<td>Allows the enabling/disabling of the initial vacuum phase.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V4</td>
<td>PRESSURE</td>
<td>It is the end-of-phase target pressure of air extraction from the chamber.</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.20</td>
<td>0.20</td>
<td>0.01</td>
<td>1.00</td>
</tr>
<tr>
<td>V5</td>
<td>TIME</td>
<td>Duration of the vacuum phase inside the chamber, with steam injection and air extraction.</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>480</td>
</tr>
<tr>
<td>V6</td>
<td>STEAM PULSES</td>
<td>Allows the enabling/disabling of the steam pulse phase.</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V7</td>
<td>PULSES NUMBER</td>
<td>Indicates the steam pulses number.</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>V8</td>
<td>PRESSURE UPPER</td>
<td>Upper pressure of steam pulses.</td>
<td>1.50</td>
<td>1.20</td>
<td>1.20</td>
<td>1.20</td>
<td>1.50</td>
<td>1.50</td>
<td>0.10</td>
<td>3.00</td>
</tr>
<tr>
<td>V9</td>
<td>PRESSURE LOWER</td>
<td>Lower pressure of steam pulses.</td>
<td>0.50</td>
<td>0.10</td>
<td>0.20</td>
<td>0.10</td>
<td>0.50</td>
<td>0.50</td>
<td>0.10</td>
<td>3.00</td>
</tr>
</tbody>
</table>

STERILIZATION

<p>| V10 | STER. T. TEMPER. | It is the temperature which (added to 0.2°C indicates the pre-heating phase final target. It is also the minimum temperature allowed during the sterilization phase. When the chamber temperature drops below this value, the alarm &quot;STER. TEMP. LACK.&quot; is displayed and the sterilization phase time is suspended. | 133  | 133  | 120  | 133  | 120  | 120  | 65  | 136 |</p>
<table>
<thead>
<tr>
<th>No.</th>
<th>DESCRIPTION</th>
<th>FUNCTION</th>
<th>Prg 5</th>
<th>Prg 6</th>
<th>Prg 7</th>
<th>Prg 8</th>
<th>Prg 9</th>
<th>Prg 10</th>
<th>MIN</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>V11</td>
<td>STER. T. TOLER.</td>
<td>°C</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
<td>1.0</td>
<td>5.0</td>
<td></td>
</tr>
<tr>
<td>V13</td>
<td>CONTROL BY F0</td>
<td>°C</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V14</td>
<td>STER. TIME</td>
<td>min</td>
<td>10</td>
<td>10</td>
<td>20</td>
<td>10</td>
<td>15</td>
<td>15</td>
<td>0</td>
<td>3000</td>
</tr>
<tr>
<td>V15</td>
<td>F0 TARGET</td>
<td>min</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>0</td>
<td>9999</td>
</tr>
<tr>
<td>V16</td>
<td>COOLING</td>
<td>0/1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V17</td>
<td>SPONT. COOL. TEMP.</td>
<td>°C</td>
<td>115</td>
<td>110</td>
<td>110</td>
<td>110</td>
<td>120</td>
<td>80</td>
<td>50</td>
<td>140</td>
</tr>
<tr>
<td>V18</td>
<td>FORCED COOL. TEMP.</td>
<td>°C</td>
<td>80</td>
<td>80</td>
<td>80</td>
<td>80</td>
<td>80</td>
<td>80</td>
<td>80</td>
<td>50</td>
</tr>
<tr>
<td>V19</td>
<td>COOL. PRESS.</td>
<td>bar</td>
<td>2.20</td>
<td>2.20</td>
<td>2.20</td>
<td>2.20</td>
<td>2.20</td>
<td>2.20</td>
<td>1.00</td>
<td>3.40</td>
</tr>
<tr>
<td>V20</td>
<td>DRYING VACUUM</td>
<td>0/1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V21</td>
<td>PRESSURE</td>
<td>bar</td>
<td>0.20</td>
<td>0.10</td>
<td>0.10</td>
<td>0.20</td>
<td>0.20</td>
<td>0.20</td>
<td>0.01</td>
<td>1.00</td>
</tr>
<tr>
<td>V22</td>
<td>TIME</td>
<td>min</td>
<td>15</td>
<td>20</td>
<td>20</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>480</td>
</tr>
<tr>
<td>V23</td>
<td>AIR PULSES</td>
<td>0/1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>V24</td>
<td>PULSES NUMBER</td>
<td>n.</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>V25</td>
<td>PRESSURE UPPER</td>
<td>bar</td>
<td>0.95</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.95</td>
<td>0.95</td>
<td>0.10</td>
<td>3.00</td>
</tr>
<tr>
<td>V26</td>
<td>PRESSURE LOWER.</td>
<td>bar</td>
<td>0.20</td>
<td>0.20</td>
<td>0.10</td>
<td>0.10</td>
<td>0.20</td>
<td>0.20</td>
<td>0.08</td>
<td>3.00</td>
</tr>
</tbody>
</table>
* The sterilization range (ranging between $T_{ster_{\text{min}}}$ and $T_{ster_{\text{max}}}$) and the Treg Regulation temperature are defined using only two parameters:

<table>
<thead>
<tr>
<th>No.</th>
<th>DESCRIPTION</th>
<th>MIN</th>
<th>DEF</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>V10</td>
<td>STER. T. TEMP. (Tster)</td>
<td>65.0</td>
<td>120.0 / 133.0</td>
<td>136.0</td>
</tr>
<tr>
<td>V11</td>
<td>STER. T. TOLER. (Ttoll)</td>
<td>1.0</td>
<td>2.0</td>
<td>5.0</td>
</tr>
</tbody>
</table>

| REGULATION TEMPERATURE (Treg) | 65.5 | 121.0 / 134.0 | 137.5 |

\[
T_{reg} = T_{ster_{\text{min}}} + \frac{T_{toll}}{2}
\]

\[
T_{ster_{\text{max}}} = T_{ster_{\text{min}}} + T_{toll}
\]

\[
T_{toll} = T_{reg} - \frac{1}{2} (T_{ster_{\text{max}}}-T_{ster_{\text{min}}})
\]

6.4.3.3. General system parameters

During the execution of the sterilization program, the machine is managed by specific parameters, as well as by a series of general parameters (SYSTEM PARAMETERS) controlling the activities and functions common to every sterilization process.

Table 1.10 below shows the general parameter list and includes a short description of their functions.

The meaning of the table fields is the following:

- **NO:** parameter identification number
- **DESCRIPTION:** parameter name
- **FUNCTION:** description of the activities managed by the parameter
- **MIN:** minimum parameter value
- **DEF:** parameter Default value
**Table 6.17 – General system parameters**

<table>
<thead>
<tr>
<th>No.</th>
<th>DESCRIPTION</th>
<th>FUNCTION</th>
<th>MIN</th>
<th>DEF</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>STERIL. –P TOLER.</td>
<td>During the product heating and sterilization, the chamber pressure is regulated according to the value of these 2 parameters and of the program parameter “STER. TEMP.”, allowing to obtain the regulation pressure.</td>
<td>0.02</td>
<td>0.03</td>
<td>0.10</td>
</tr>
<tr>
<td>1b</td>
<td>STERIL. +P TOLER.</td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.10</td>
</tr>
<tr>
<td>2</td>
<td>MIN. P. BALANCE P_{max}b</td>
<td>It is the minimum pressure inside the chamber during pressure balancing and end–of–cycle phases, to enable the cover opening.</td>
<td>0.50</td>
<td>0.95</td>
<td>1.00</td>
</tr>
<tr>
<td>3</td>
<td>MAX. P. BALANCE P_{max}b</td>
<td>It is the maximum pressure inside the chamber during pressure balancing and end–of–cycle phases, to enable the cover opening.</td>
<td>0.55</td>
<td>1.05</td>
<td>1.10</td>
</tr>
<tr>
<td>4</td>
<td>CYCLE END TIME</td>
<td>It indicates the cycle end phase duration, in seconds.</td>
<td>0</td>
<td>10</td>
<td>999</td>
</tr>
<tr>
<td>5</td>
<td>STEAM GENER.</td>
<td>It can take only values 0 and 1. Number 1 must be set when the machine features an autonomous steam generator.</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>PRINTER</td>
<td>It enables printing of the cycle data during the sterilization program execution. Value 1 is set only if the machine is equipped with a printer.</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>7a</td>
<td>PRINTER INTERVAL</td>
<td>It allows to set the printing interval for the cycle data during the execution of the sterilization program. Operating only if the machine is provided with a printer and the &quot;PRINTER&quot; general parameter is set to 1.</td>
<td>30</td>
<td>60</td>
<td>9999</td>
</tr>
<tr>
<td>7b</td>
<td>PRINTING INTERVAL IN STERILIZATION</td>
<td>It allows to set the printing interval for the cycle data during the execution of the sterilization program. Operating only if the machine is provided with a printer and the &quot;PRINTER&quot; general parameter is set to 1.</td>
<td>30</td>
<td>999</td>
<td>9999</td>
</tr>
<tr>
<td>8</td>
<td>POWER RESET</td>
<td>On the cycle end phase completion, the machine can be automatically switch off only if this parameter is set to 1.</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>CHECK FINAL T</td>
<td>Value to be set to 1 in order to enable the control of system parameter &quot;FINAL TEMPERAT.&quot; on heat probe T001.</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>FINAL TEMPERAT.</td>
<td>°C</td>
<td>0</td>
<td>70</td>
<td>95</td>
</tr>
<tr>
<td>11</td>
<td>DOOR INVERSION.</td>
<td>°C</td>
<td>Not applicable</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12</td>
<td>REPEAT CYCLE.</td>
<td>°C</td>
<td>If this option is enabled, the cycle can be repeated up to 20 times.</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
6.4.4. Operating phases

The operator manages the sterilization process according to the following main operating phases:

- Switching on and initial controls;
- Operation enabling;
- Product loading;
- Program starting;
- Process control;
- Product unloading;
- Disabling or switching off.

To process the product, these operating phases must be carried out in sequence. Of course, to execute these operating phases, the operator must be acquainted with a series of auxiliary functions, such as:

- Logic of access to the menu pages;
- Cover opening logic;
- Printing functions;
- Step–by–step and cycle stop functions;
- $F_0$.

6.4.4.1. Menu page access logic

The main menu is automatically displayed when the controller has been fed. Other pages can be accessed:

- by entering the number corresponding to the option selected through the main menu or another menu;
- by pressing key

To return to the previous menu:

- Press key

6.4.4.2. ”Step–by–step” and ”Cycle stop” functions

During the sterilization program execution, until the process is over, the operating interaction is inhibited, except for monitoring the chamber parameters. In case of failures, the operator is allowed to intervene in the process in progress through the specific functions (STEP–BY–STEP and CYCLE STOP) described below.

**STEP–BY–STEP Function**

To enable it, at the 3 highest password levels.
It allows to have access to the next operating phase, by blocking the controls related to the operating phase in progress, without waiting to reach the end-of-phase set value. The alarm "PHASE STEP UTILIZED" is displayed and printed.

**CYCLE STOP function**

To enable it, at the 3 highest password levels, press key [STOP].

It allows to enter the emergency phase. The alarm "MANUAL PROGRAM–STOP" is displayed and printed. When pressing key [STOP], the system has access to the Pressure Balancing and Cycle End functions.

**CAUTION !**

Pressing this key is likely to damage the batch in all cases in which, during sterilization of liquids kept in tight containers, a pressure differential dangerous for containers is caused when reaching atmospheric pressure.

The pressure differential makes liquids boil even though they are kept in containers which are not tight, but feature protective filters.

Press key [STOP] only after having checked that the chamber pressure has spontaneously reached atmospheric pressure, and when the product temperature is < 70°C.

STEP–BY–STEP and CYCLE STOP functions will be enabled in all phases except for the cases mentioned in the following Table

<table>
<thead>
<tr>
<th>PHASE</th>
<th>PRG.</th>
<th>STEP–BY–STEP</th>
<th>CYCLE STOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>all</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Pressure balancing</td>
<td>all</td>
<td>yes (*)</td>
<td>no</td>
</tr>
<tr>
<td>Cycle end</td>
<td>all</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Phase emergency</td>
<td>all</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Black Out emergency</td>
<td>all</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Decontamination program emergency</td>
<td>3</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Decontamination program heating</td>
<td>3</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Decontamination program sterilization</td>
<td>3</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Spontaneous cooling</td>
<td>3–10</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Forced cooling</td>
<td>3–10</td>
<td>no</td>
<td>yes</td>
</tr>
</tbody>
</table>

(*) When forced exit is required, having pressed [STOP] during the EMERGENCY phase, if no pressure balance is reached.

**6.4.4.3. F₀**

This parameter is the sterilization time at 121,11°C or, better, the time related to a sterilization process carried out at another temperature and duly calculated for a 121,11°C process, so that it has an equivalent lethal thermal power, i.e.
it proves effective in killing microbes (probability of finding 1 non sterile unit out of a certain number of PNSU units).
The calculated F0 is totalled by processing the temperature values measured by the heat probe if the measured
temperature is ranging from 100°C to 143, 9°C.
F0 value is updated every second, displayed and printed when the cycle is over in order to check the lethal doses
applied in the point monitored by T001.
F0, value is also used to regulate the sterilization phase through proper program parameters.

6.4.4.4. Opening/closing logic of the cover

Opening system

To open the sterilizer:
- No process cycle must be in progress;
- Both the pressure transducer connected to the sterilizer control system and the electromechanical safety
  pressure switch must indicate that pressure inside the chamber is equal to atmospheric pressure again;
- The heat probe located inside the chamber measures a temperature lower than the safety set value (this is
  possible only if the system parameter "CHECK FINAL T" has been set);

If the above mentioned conditions have been met, the operator can enable compressed air exhausting from the
seal housing. The "Opened cover" LED on the operator panel will indicate that the cover can be turned to unload
the batch.

Closing system

Manually turn the cover in order to close it, while pressing the safety lever which releases it.
When the cover has reached the closing position, its hooking lever is released. The cover cannot turn and the safety
limit switch is pressed.
The limit switch allows the system to send the control required to the solenoid valves allowing to supply compressed
air to the seal housing of the sealing system.
The cover being properly positioned, a control sent by the operator enables the compressed air supply to the seal
housing, in order to close the chamber and to lock the cover.

When the chamber is closed, the LED located near the key switches on.
If the cover is not perfectly closed and the cycle is in progress, a specific alarm message (OPEN DOOR IN CYCLE) is
displayed causing the cycle to be stopped.

6.4.4.5. Printing function (if a printer is available)

The machine is equipped with a printer to print cycle data.
The preset printing enabling and intervals are shown in the general parameter page.
The printing report includes the following information:
1. HEADING
   - FEDEGARI AUTOCLAVI
   - Program start–up DATE AND TIME
   - STERILIZER NF (serial number entered by FEDEGARI’s engineers through a reserved menu)
   - Message about the number of repetitions set
   - Notes on the sterilized product
   - Notes on the batch program

2. PROGRAM NUMBER AND PROGRAM PARAMETER LIST

3. CYCLE DATA
   Displayed data are printed according to set intervals, calculated based on the phase time.

4. ALARM MESSAGES:
   - ALARM NAME
   - detected ALARM STATE (ON, OFF, ACK)
   - ACK (acknowledgment request), if activated by the alarm
   - Data recording DATE and TIME

5. FINAL DATA
   - CYCLE NUMBER (progressive program time)
   - PROGRAM TIME (overall program time)
   - STERILIZATION TIME (time of exposure to correct temperatures during the sterilization phase)
   - Fo CALCULATED (Final $F_0$ value)
   - Message about the test or sterilization result
   - Message about the number of repetitions set
   - DATE AND TIME (Program end time)
   - SIGNATURE (Space for the operator’s signature)

When no cycles are in progress, the page displayed can be printed through the command.

6.4.5. Operating procedures and warnings

CAUTION!
The operator must work so that all controls are easy to reach and suitably positioned from an ergonomic viewpoint. Keep the working place free from any equipment, other than the tools required to control the sterilizer. Before starting the machine, do not allow unauthorized people to stay near the sterilizer.
Procedures
The main operating phases mentioned in the previous section thoroughly identify the sequence of procedures carried out by the operator in order to use, step–by–step, the sterilizer according to its functions.
Every operating phase consists of several sections, based on the above mentioned sequence.

NOTE
Should the graphic representation of the menus and pages supporting these instructions include more than 4 lines, the remaining text will be in a shadow area.

To display the whole text, use keys ↑ and ↓.

NOTE
Some pages displayed to support the manual instructions show information, values and parameters by way of example. They could not be installed on your sterilizer.

Instructions for use
This section provides useful information and warnings for operating procedures. However, these procedures will also include specific warnings, whenever it is required by the type of procedure to be carried–out.

WARNING!
The emergency stop mushroom–head button must not be used improperly. Use it carefully, without forcing it, to avoid damaging it.

NOTE
All characters inconsistent with selectable options cannot be entered, as they are not accepted by the controller.

6.4.5.1. Switching on and initial checks

Lighting the workplace
Check that the workplace is properly lighted (if possible, with natural light), to allow the operator to identify the machine command and control devices.

Checking supply systems
Check that the main switch is in the “I” position. If this switch is in the”O” position, feed the machine by turning its lever until it is in the “I” position.

Control enabling and acquisition
Turn on the master switch located on the front side of the machine. A message (in English) is displayed for a few seconds (see Figure 6.15) showing the panel software version, followed by the main menu (see Figure 6.16) with the list of operating and maintenance selectable options.
To select the main menu options, press the key corresponding to the number displayed next to the option. Table 6.19 shows the selectable options, corresponding to the sections dealing with the selection topics.

<table>
<thead>
<tr>
<th>OPTION</th>
<th>RELATED SECTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>SELECT PROGRAM</td>
<td>6.4.5.3. Program start</td>
</tr>
<tr>
<td>MODIFY PROGRAM</td>
<td>6.5.2. Program parameter configuration</td>
</tr>
<tr>
<td>AUTODIAGNOSE</td>
<td>6.6.4. Self-diagnosis</td>
</tr>
<tr>
<td>SYSTEM PARAMETERS</td>
<td>6.5.3. Changing general parameters</td>
</tr>
<tr>
<td>AUTOCLAVE DATA</td>
<td>6.6.6. Sterilizer data</td>
</tr>
<tr>
<td>AUXIL. FUNCTIONS</td>
<td>6.7. Auxiliary functions</td>
</tr>
</tbody>
</table>

6.4.5.2. Panel functions and operation enabling

Starting from the main menu, press key ENTER for at least 2 seconds to have access to the function menu of man/machine interface, known as "PANEL FUNCTIONS" (see Figure 6.17).
Through their enabling the operator can:

- enter the password (PSW);
- check the operator panel performance and adjust the display brightness (SYS);
- set the system date and time (TIM);
- Enter configuration data (PGS);
- Alarm list (EVT);
- Load the SW on the operator panel (CFG);
- Exit from the menu (EXT)

Functions ACC and ALM are not used.

The table below shows the password level required to have access to every panel function as well as the section dealing with it.

### Table 6.20 – PANEL FUNCTIONS, access levels and related paragraphs

<table>
<thead>
<tr>
<th>OPERATOR PANEL FUNCTIONS</th>
<th>ACCESS LEVELS</th>
<th>REFERENCE SECTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSW</td>
<td>all</td>
<td>6.4.5.2 . Panel functions and operation enabling</td>
</tr>
<tr>
<td>SYS</td>
<td>all</td>
<td>6.6.3. Monitoring the operator panel</td>
</tr>
<tr>
<td>TIM</td>
<td>FEDEGARI DEVELOPER - FEDEGARI PERSONNEL - USER SUPERVISOR</td>
<td>6.6.2. Changing date and time</td>
</tr>
<tr>
<td>PGS</td>
<td>FEDEGARI DEVELOPER - FEDEGARI PERSONNEL</td>
<td>6.6.6. Sterilizer data</td>
</tr>
<tr>
<td>EVT</td>
<td>all</td>
<td>6.6.5. Alarm list</td>
</tr>
<tr>
<td>CFG</td>
<td>FEDEGARI DEVELOPER</td>
<td>-</td>
</tr>
<tr>
<td>EXT</td>
<td>all</td>
<td>-</td>
</tr>
</tbody>
</table>

### Operation enabling

To use the machine, the operator must enter his code (password) as follows:
1. From the main menu, press key ENTER for at least 2 seconds. The PANEL FUNCTION menu is displayed (see Figure 6.17);

2. Move with the keys, \( \rightarrow \) and \( \leftarrow \) light function PSW;

3. Press ENTER to confirm the selected option. A page is displayed to enter the access code;

4. Key in your password consisting of four numeric characters;

5. Press key CLR to confirm the password and to return to the main menu.

**NOTE**

For your privacy, the controller does not display the numeric characters entered and the code does not appear on the screen.

**NOTE**

When entering password 0000 or another password that is not recognized as programmed in the PASSWORD MODIFICATION function, the system will automatically configure at STAND–BY level. To return to the condition of use provided for the machine, re–insert one of the programmed keys, such as USER or SUPERVISOR.

### 6.4.5.3. Program start

1. Press key 1 to select option "SELECT PROGRAM" from the main menu. The page "SELECT PROGRAM" is displayed (see Figure 6.18) and you are required to enter a number corresponding to the program to be run.

   If option ### Cycle repetit. is disabled

   ![SELECT PROGRAM](image1)

   If option ### Cycle repetit. is enabled

   ![SELECT PROGRAM](image2)

   *Figure 6.18 – SELECT PROGRAM menu*

2. Press 0 (the numeric field is blinking) and key in the number corresponding to the program selected. Press
3. If option ### Repeat Cycles is enabled, select the “Repeat Cycle” field with keys ↑ and ↓. Digitare il
   Enter the desired number of repetitions (max. 20). Press the ENTER key to confirm.

The controller will start the program, having checked that:

- The selected program is enabled by the machine software configuration;
- The printer, if any, is available, for cycle printing (general parameter PRINTER set to 1).

After the above mentioned checks, the controller displays the page corresponding to the first program phase, the "PREPARATION" (see Figure 6.19).

The operator must make sure that the batch has been loaded in the chamber. If it is not so, he will load it (see Section 6.4.5.4.) and close the cover as follows:

- Turn the cover while pressing the safety lever which keeps it released until the cover is closed (the microswitch controlling the cover closing is triggered);
- Press key on the keyboard, to let compressed air in the seal housing. When the LED located next to the key lights up , the system receives the message that the chamber is closed and tight.

If option ### Cycle repetit. is disabled

![Preparation Message](image1)

If option ### Cycle repetit. is enabled

![Preparation Message](image2)

Figure 6.19 – PREPARING the sterilization cycle
4. Press key \[ \text{START} \] to complete the “PREPARATION” phase and to start the sterilization process, with register “progressive program number” increasing and printed when the cycle is over (provided a printer has been installed and enabled). From now on, until the sterilization process is over, operating interactions other than chamber parameter monitoring are inhibited, except for CYCLE STOP and STEP–BY–STEP functions (enabled by Password).

NOTE
To return to main menu, without starting the sterilization program selected and increasing the progressive instruction register, press key \[ \text{STOP} \] instead of key \[ \text{START} \] .

NOTE
After the machine has been prepared, the operator can enable the sterilization program only if the cover is closed and the autonomous steam generator, properly installed, has given the controller the signal “generator ready”.

NOTE
The machine can be loaded at any time after cover opening, also before its starting.

CAUTION!
To avoid pouring and/or stacking the product, check that its containers are perfectly fitted into the machine chamber before closing the cover.

6.4.5.4. Batch loading

1. Remove the heatprobe(s) from the sterilization chamber;
2. Place the baskets with the product to be processed inside the chamber;
3. Position the flexible heat probe T001 and the auxiliary heat probe, if any, in the upper basket, so that their metal points touch the product.

NOTE
If the product to be sterilized consists of a liquid solution inside tightened bottles, the heat probe must be placed inside a sample bottle filled with deionized water. The sample bottle, positioned inside the chamber, in the upper basket, must be prepared according to the product characteristics.

CAUTION!
When extracted from the machine, bottles with more than 70°C internal temperature are likely to explode, thus endangering the operators. Therefore, to sterilize solutions kept in tightened bottles,
select only sterilization processes providing a suitable final cooling phase and sterile air counterpressure, which guarantee safety during the product extraction. The maximum safety temperature allowing to open the cover must be set at <70°C and the parameter "CHECK FINAL T" must be activated by setting value "1".

CAUTION!
To sterilize heat-sensitive products use containers with homogeneous size.

CAUTION!
If product containers have different sizes, place the heat probe in the largest container.

CAUTION!
Check that the heat probe cable(s) have been properly fitted in the chamber before closing the cover.

6.4.5.5. Process control

The operator can check the sterilization process in progress by reading the dedicated page displayed, i.e. the "process page".

This page includes and shows information based on two main categories: the first, known as "control parameters", supplies useful information (data allowing to identify the program and the phase in progress, set threshold values – pressure, temperature, time – as well as their related values, measured and processed in real time inside the sterilization chamber.

The second category concerns information named "alarm messages" and auxiliary messages.

Control data

During every phase, the control page informs the operator about:

- the number of the run program;
- the name of the phase in process;
- the preset threshold value (pressure, temperature or time), representing the target value of the phase in progress, starting the next phase;
- the temperature (°) measured in the sterilization chamber by heat probe T001;
- the pressure (bar) measured by pressure transducer P001;
- the phase time;
- $F_0$ ($F_0$ value, totalled by processing the temperatures measured by heat probe T001). It is calculated only if the machine features the option "calculation and control with $F_0$".
  
  If it is not so, $F_0$ is given value 0);
- the temperature (°) measured in the sterilization chamber by heat probe T005 (if Option K80 is available);
- sterilization time “ts” (only during the sterilization phase);

By way of example, Figure 6.20 shows the process page of the HEATING phase.

If the machine is equipped with a printer enabled, the above mentioned process information can be displayed and printed at the beginning of every phase, according to the printing intervals set in the general parameters.

![Figure 6.20 – Control page concerning the HEATING phase](image)

**NOTE**

Press key [START] at the 3 highest levels to enable the STEP–BY–STEP function. This function allows to pass from the phase in progress to the next one. Alarm ”PHASE STEP UTILIZED” is displayed and printed.

Press key [STOP] at the 3 highest levels to enable the CYCLE STOP function. This function allows to enter the emergency phase. Alarm ”MANUAL PROGRAM–STOP” is displayed and printed. When key [STOP] is pressed, the system enters the pressure balancing and cycle end phase.

**Alarm messages**

The sterilizer features up to twenty different alarms, displayed together with their short description and printed in real time if a printer is available.

All alarms raised generate visual and acoustic warnings which can be deactivated by pressing the [ENTER] key.
If the activated alarm must be acknowledged (ACK) the operator must hold the \( \text{ENTER} \) key down for a few seconds.

Such alarms are defined as system alarms when they concern general safety tools or conditions or as phase alarms when they are related to the execution of specific phases.

Top level alarms, e.g. the alarm indicating that the cover is not perfectly closed during the process, stop the cycle. Therefore, the autoclave enters the emergency phase, during which it is stopped in full safety.

In this EMERGENCY phase, key \( \text{STOP} \) allows the operator to enter the pressure balancing and cycle end phase.

The machine described in this manual can enable, based on its configuration, all (full optional machine) or part of the alarms listed in Table 7.1 (see Section 7.1).

⚠️ **CAUTION!**

The operator must be perfectly acquainted with the meaning and importance of the machine alarms.

**Auxiliary messages**

Auxiliary messages consist of short text lines that are displayed in some screens to inform the operator about the machine and door state, as well as about the sterilization/test result.

The tables listing possible auxiliary messages and the relative screens are the following:

<table>
<thead>
<tr>
<th>MAIN MENU FOR CYCLE END PREPARATION</th>
<th>FINAL DATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>READY TO START</td>
<td>TEST FAILED</td>
</tr>
<tr>
<td>CYCLE IN PROGR.</td>
<td>STERILIZATION FAILED</td>
</tr>
<tr>
<td>DOOR OPENING OK</td>
<td>TEST OK</td>
</tr>
<tr>
<td>DOOR OPEN</td>
<td>STERILIZATION OK</td>
</tr>
<tr>
<td>GENERATOR NOT READY!</td>
<td>DECONTAMINAT. FAILED</td>
</tr>
<tr>
<td>CONTAMINATION--LOCKED !</td>
<td>DECONTAMINATION OK</td>
</tr>
<tr>
<td>DELAY!</td>
<td></td>
</tr>
<tr>
<td>REP --/--</td>
<td></td>
</tr>
</tbody>
</table>

**Emergency phase**

The sterilizer enters the emergency phase when one or several failures take place during the sterilization process, or when the machine is restarted after a black–out or through a manual command.

The emergency makes all valves close and stops all motors, with the sterilizer on stand–by.
This state protects the machine, the personnel and the batch.
The events causing the emergency phase, as well as the messages displayed for every phase and the procedures to exit from the emergency state are listed below.

**Black–out emergency**

The system enters the emergency phase when the sterilizer is restarted after a black–out.

Black–out starting and end time is displayed together with the sterilization chamber temperature, pressure and phase time.

Press key [STOP] to enter the pressure balancing and cycle end phase or the decontamination emergency phase.

**CAUTION!**

Before entering the pressure balancing phase, check that temperature and pressure conditions allow for the operations required without damaging the batch.

In particular, let liquid products cool before pressing the key [STOP].

**Decontamination program emergency**

During the sterilization program execution, when function CYCLE STOP is activated during heating or sterilization, or when the cycle in progress is stopped by an alarm before decontamination (heating and sterilization phases), the sterilizer enters the emergency phase.

The sterilization chamber temperature and pressure as well as the phase time and the progressive cycle number are displayed. The operator can only switch the machine off.

When the machine is turned on again, the operator panel’s display shows the "CONTAMINAT. LOCK!" message, that indicates that the valves involved in the pressure balancing in the chamber (E003 when the pressure in the chamber is below the minimum balancing pressure and E006 when the pressure in the chamber exceeds the maximum balancing pressure) are locked to prevent any microbiologic contamination hazard for the rooms and the products. Therefore, after solving the problem that has caused the decontamination Emergency, the operator can relaunch the cycle, being sure that no contaminated product has been in contact with the exterior of the chamber.

If the emergency causes result in the opening the chamber cover, the operator can manually remove the lock on the chamber’s pressure balancing.

Press the keys in the AUXILIARY FUNCTIONS menu. The following message is displayed:

![CONTAMINATION LOCK message](image)
Press 7 INS: the lock is removed. To return to the main menu, press the CLR key.

Phase emergency

The system enters the emergency phase when function CYCLE STOP is selected or whenever an alarm stops the cycle in progress.

The sterilization chamber temperature and pressure are displayed together with the phase time.

Press key 9 STOP to enter the pressure balancing and cycle end phase.

End of process

When the program has reached the last phase, “CYCLE END”, the sound signal is activated and the LED, positioned on the display side, starts blinking. After a set time (end of phase target) or when key 9 STOP is pressed, the sterilization program is over, the MAIN MENU is displayed and, if the printer is enabled, cycle end data are printed.

NOTE

The alarm message “AUTOMATIC POWER OFF” is displayed after the cycle end phase; it indicates for 5 seconds that the machine is going to be manually switched off.

6.4.5.6. Batch unloading

CAUTION!

When extracted from the machine, bottles having an internal temperature of more than 70°C could explode, thus jeopardizing the operators. Therefore, to sterilize solutions kept in tightened bottles, select only sterilization processes providing a suitable final cooling phase and sterile air counterpressure, which guarantee safety during batch unloading. The maximum safety temperature allowing to open the cover must be set at <70°C and the parameter “CHECK FINAL T” must be activated by setting value ”1”.

1. Open the cover as follows:
   - Press the proper key 9 on the keyboard to automatically exhaust air from the seal housing;
   - Check that the key 9 LED switches on;
   - Press the lever which releases the cover from the mechanical locking system;
- Turn the cover until it is completely open;
- Transfer the batch, by removing the flexible(s) heat probe(s);
- Place heat probe T001 and auxiliary heat probe T005, if any, inside the empty sterilization chamber.

6.4.5.7. Deactivation or switching off

Usual or automatic stop

**NOTE**
Before turning the machine off, do not forget to enter the STAND–BY password (0000).

1. The sterilizer is usually shut–down by placing the master switch on the front panel of the machine in the <O> position.
2. To shut–down the machine automatically, use system parameter POWER RESET.
3. Check that the process controller is OFF (the LCD display must be switched off).

Emergency stop

**WARNING!**
Pressing the emergency push–button is likely to damage the sterilizer batch. The operator cannot restart the machine if this button has been pressed. Refer to the competent manager.

Press the mushroom–head emergency button located on the front panel of the machine to stop it immediately through the main switch. In this state, the machine works as in case of electric system black–out.

For further information, refer to Section 2.4.5. 

Emergency stops take place:
- when safety thermostats T002 and T003 (TÜV) of the autonomous steam generator are activated;
- when the cycle end “AUTOMATIC POWER OFF” option is activated.

Restarting the machine after an emergency stop

**CAUTION**
To avoid damaging the machine and jeopardizing the operators, check and remove the emergency cause before starting the sterilizer.

- Pull the emergency mushroom–head button to release it;
To restart the machine, reset the main switch.

6.5. CONFIGURATION

6.5.1. General Information

The process controller features software functions to redefine and modify the machine sterilization and service programs, as well as to set a series of general parameters controlling operations and functions common to all cycles. Two configuration modes are available:
- Program parameter configuration;
- System parameter configuration.

The operations required to configure these parameters are described below.
The operator can modify these functions only if password level “USER SUPERVISOR” is available.

6.5.2. Program parameter configuration

To modify program parameters (phase parameters and phase selection):
- Select option "MODIFY PROGRAM" from the main menu by pressing key $\uparrow$;

A message (see Figure 6.22) is displayed, introducing the program parameter pages;
- Press the alphanumeric key corresponding to the program whose parameters must be modified to have access to the new page. Figure 6.23 shows program 5;
- Scroll the selected page using keys $\uparrow$ and $\downarrow$, until the parameter to be modified is displayed;
- Press $\uparrow$ to enter data;
- Select the desired parameter using keys $\uparrow$ and $\downarrow$;
- Key in the desired value in the lighted numeric field;
- Press $\uparrow$ to store the modification on the process controller;
- Press $\uparrow$ to return to the main menu.
**Figure 6.22 – Program Parameter Modification menu**

<table>
<thead>
<tr>
<th>MODIFY PROGRAM</th>
<th>Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>VACUUM TEST</td>
</tr>
<tr>
<td>2.</td>
<td>PRESSURE TEST</td>
</tr>
<tr>
<td>3.</td>
<td>DECONTAMINATION</td>
</tr>
<tr>
<td>4.</td>
<td>TEST BOWIE DICK</td>
</tr>
<tr>
<td>5.</td>
<td>***************</td>
</tr>
<tr>
<td>6.</td>
<td>***************</td>
</tr>
<tr>
<td>7.</td>
<td>***************</td>
</tr>
<tr>
<td>8.</td>
<td>***************</td>
</tr>
<tr>
<td>9.</td>
<td>***************</td>
</tr>
<tr>
<td>+.</td>
<td>***************</td>
</tr>
</tbody>
</table>

**Figure 6.23 – Program Parameter page (e.g. program 5)**

<table>
<thead>
<tr>
<th>P5-***************</th>
<th>Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREHEATING (Y/N)</td>
<td>0</td>
</tr>
<tr>
<td>time</td>
<td>3</td>
</tr>
<tr>
<td>PREVACUUM (Y/N)</td>
<td>1</td>
</tr>
<tr>
<td>pressure</td>
<td>0.10</td>
</tr>
<tr>
<td>time</td>
<td>5</td>
</tr>
<tr>
<td>STEAM PULSES (Y/N)</td>
<td>0</td>
</tr>
<tr>
<td>pulses number</td>
<td>3</td>
</tr>
<tr>
<td>pressure upper</td>
<td>1.50</td>
</tr>
<tr>
<td>pressure lower</td>
<td>0.50</td>
</tr>
<tr>
<td>STERILIZATION</td>
<td></td>
</tr>
<tr>
<td>steril. temp.</td>
<td>133.0</td>
</tr>
<tr>
<td>ster. T. tolleran.</td>
<td>2.0</td>
</tr>
<tr>
<td>control by F0 (Y/N)</td>
<td>0</td>
</tr>
<tr>
<td>ster. time.</td>
<td>10</td>
</tr>
<tr>
<td>F0 target</td>
<td>8</td>
</tr>
<tr>
<td>COOLING (Y/N)</td>
<td>1</td>
</tr>
<tr>
<td>spont. cool. temp.</td>
<td>115</td>
</tr>
<tr>
<td>forced cool. temp.</td>
<td>80</td>
</tr>
<tr>
<td>cool. press.</td>
<td>2.20</td>
</tr>
<tr>
<td>DRYING VACUUM (Y/N)</td>
<td>1</td>
</tr>
<tr>
<td>pressure</td>
<td>0.20</td>
</tr>
<tr>
<td>time</td>
<td>15</td>
</tr>
<tr>
<td>AIR PULSES (Y/N)</td>
<td>0</td>
</tr>
<tr>
<td>pulses number</td>
<td>3</td>
</tr>
<tr>
<td>pressure upper</td>
<td>0.95</td>
</tr>
<tr>
<td>pressure lower</td>
<td>0.20</td>
</tr>
</tbody>
</table>
6.5.3. Changing general parameters

During the sterilization program execution, the machine operation is controlled by specific parameters as well as by a series of general parameters, controlling operations and functions common to all sterilization processes.

To set system parameter values:

- Press key 4 to select option "SYSTEM PARAMETERS" from the main menu. The general parameter page (Figure 6.24) is displayed with current values;

- Scroll the selected page using keys ↑ and ↓, until the parameter to be modified is displayed;

- Press INS to enter data;

- Press keys ↑ and ↓ to select the desired parameter field;

- Enter the desired value in the numeric field next to the parameter;

- Press ENTER to store the modification on the process controller;

- Press CLR to return to the main menu.
SYSTEM PARAMETERS
Steril. P Toler. -0.03
Steril. P Toler. +0.00
MIN P Balance 0.95
MAX P Balance 1.05
Cycle End time 10
Steam Generat. (0/1) 0
Printer (0/1) 1
Print interval 9999
Interval Steril 30
Power Reset (0/1) 0
Check final T (0/1) 0
Final temperat. T 70
Doors invers. (0/1) 0
Cycle Repetitions 0

Figure 6.24 – System parameters

NOTE
To cancel parameter modifications, press key CLR instead of key ENTER.

NOTE
Press key INS to enter data and to lock scrolling of the selected page. Arrow keys ↑ and ↓ allows the operator to move inside the displayed parameter fields. To scroll pages again, press key ENTER.

6.6. CONTROL SYSTEM MAINTENANCE

6.6.1. General information

Maintenance includes all operating modes allowing to service and/or control several software functions as well as operating logics.

Three maintenance procedures are available:
Checking the operator panel performance;
Programming the clock/internal calendar (date and time);
Self-diagnosis and calibration operating procedures.

Function maintenance and control operations will be described below.

6.6.2. Changing date and time

The operator panel features an internal clock supplied by a battery which constantly updates date and time, even in case of black-out.

Then operator can set or modify current date and time:

- From the main menu, press ENTER for at least 2 seconds.
  The panel function menu is displayed;
- Select parameter TIM using keys → and ←;
- Press ENTER to confirm your choice, the system date and time fields are displayed (see Figure 6.25);
- Enter the desired numeric value in the lighted field, using the keyboards;
- Press ENTER to reach the next field and to repeat the previous operation, if required;
- Press CLR to return to the main menu.

![Figure 6.25 – Programming date and time](image)

6.6.3. Monitoring the operator panel

The machine features a software device to check ON LINE the Operator Panel performance. This check allows to monitor the performance of the operator panel battery, of LEDs, of panel communication with PLC and printer (if any) and to adjust display brightness.
To check the operator panel:

- From the main menu, press \[ \text{ENTER} \] for at least 2 seconds. The panel function menu is displayed;

- Press keys \[ \rightarrow \] and \[ \leftarrow \] to light function "SYS";

- Press \[ \text{ENTER} \] to confirm the selected option: the panel AUTODIAGNOSE page is displayed (see Figure 6.26);

- Press keys \[ \uparrow \] and \[ \downarrow \] to select different options;

- Select line "DISPLAY". To modify the display brightness press keys \[ \rightarrow \] and \[ \leftarrow \];

- Light the battery line and check its performance;

- Light line "PLC" and check, through the related message, the panel/PLC connection;

- Light line "PRINTER" and check, through the related message, the printer/panel connection;

- Press \[ \text{CLR} \] to return to the main menu.

![Operator Panel Autodiagnose menu](image)

**Figure 6.26 – Operator Panel Autodiagnose menu**

### 6.6.4. Autodiagnose

The process controller features a self-diagnosis device "AUTODIAGNOSE", in order to check:

- digital input/output parameter values;
- system analog inputs;

Calibrate temperature and pressure measured in the sterilization chamber (see Sections 8.3.4.10. and 8.3.4.11.).
6.6.5. Alarm List

Start function "EVT", from the panel function menu, to display a specific page which shows, through a keyboard control, all activated alarms, starting from the last one.

For each alarm, this page displays:

- its progressive number;
- the type of transition "STATUS" of the detected situation:
  * "ON" = alarm activated;
  * "OFF" = alarm deactivated;
  * "ACK" = alarm acknowledged.
- The alarm description:
- the alarm starting date and time.

To display the page "alarm list":

- Start from the main menu;
- Press \[ \text{ENTER} \] (for at least two seconds): the panel function menu is displayed;
- Press keys \[ \text{ } \text{ } \leftarrow \text{ and } \rightarrow \] to select function "EVT";
- Press key \[ \text{ENTER} \] to confirm your choice. The latest alarm activated is displayed;
- Press key \[ \rightarrow \] to display recorded alarms.

**NOTE**

Press key \[ \text{PRN} \] to print all detected alarms, starting from the first one. The operator cannot access the alarm list page if no alarms have been stored.

6.6.6. Sterilizer data

Press key \[ \text{ } \] from the main menu to select option "AUTOCLAVE DATA" and to access the page showing the sterilizer general data (see Figure 6.27).
6.7. AUXILIARY FUNCTIONS

1. Select the “AUXILIARY FUNCTIONS” option in the main menu, by pressing the key on the keyboard.

2. Use the and keys to select the various options.

---

**AUTOCLAVE DATA**

- Autoclave : NF0000AA
- SW Panel : VD0M02..4
- SW PLC : VC0002..9
- Cycles No. : 0

**SYSTEM OPTION**

- K10. Steam Generat. : 0
- K20. Vacuum System : 0
- K51. Pressurization : 0
- K52. Cooling System : 0
- K53. Spont. Cooling : 0
- K61. Pressure Test : 0
- K62. Decontaminat. : 0
- K80. TE2 probe : 0
- K81. Printer : 0
- K82 Datalogger : 0
- K90 Second door : 0
- --- High Pathogen : 0

**SW OPTION**

- # # #.F0 calculation : 0
- # # #.RS232 protocol : 0
- # # #.Cycle repetit. : 0

---

Figure 6.27 – AUTOCLAVE DATA menu

---

**Fig. 6.28 – AUXILIARY FUNCTIONS menu**
6.7.1. Transferring system regulation data

1. Select option "INITIALIZATION" from the AUXILIARY FUNCTIONS menu, by pressing the key on the keyboard. A confirm message is displayed to proceed with this operation.

2. On request the displayed message press . After about one minute, i.e. the time required to complete data transfer, the main menu is displayed again.

NOTE
The “INITIALIZATION” must be carried out during the installation phase only. However, system performance is not damaged if this function is initialized by fault.

Figure 6.29 – Message displayed during data transfer

6.7.2. Managing the stored alarm list

Press key in the AUXILIARY FUNCTIONS menu. The "ALARMS MANAGEMENT" option is selected and you can have access to the page showing the alarm management option list (see Figure 6.30).

Figure 6.30 – ALARM MANAGEMENT Page

- Press keys and to select the available options;

1. Press key to display the alarm list.

- Scroll the selected page through key and .
2. Press key 2 to print the alarm list.

3. Press key 3 to cancel the alarm list content (only with password, in USER SUPERVISOR mode).

### 6.7.3. Language select

Press key 3 from the AUXILIARY FUNCTIONS menu to select option "LANGUAGE SELECT" and have access to the page allowing to choose the message language (see Figure 6.31).

![LANGUAGE SELECT Page](image)

- To choose the desired language, press keys 0 INS followed by key 1 or 2 or 3 or 4 or 5.

**NOTE**
The selection of language No. 5 (DUTCH) is implemented only upon specific request.

### 6.7.4. Modify password

Press key 4 from the AUXILIARY FUNCTIONS menu to select the "PASSWORD MODIFY" option and access the page in which it is possible to modify the "user" level password (see Figure 6.32).

The "user" passwords (Supervisor and User) may be modified by user only at the supervisor level. When loading the software, "user" passwords will be reset at the initial values. Moreover, when forgetting the modified password, it is necessary to remove the battery from the operator panel for at least 10 minutes, so that initial "user" passwords may be reset (enter all values previously set, such as, for example, program, calibration, date and time values etc.). The original password USER SUPERVISOR" (cf. para. 6.3.1.) of Step–by–Step and Stop functions, cyclically used, shall remain always the same, since it is managed by the Controller and not by the Operator Panel.
6.7.5. Delayed start

Press the \( \text{INS} \) key in the AUXILIARY FUNCTIONS menu to select the "PROGRAM START DELAY" option and to access the page from which you can select the delayed start of a program (cf. Figure 6.33).

**Figure 6.33 – PROGRAM START DELAY page**

1. Press the \( \text{INS} \) key and, then, the \( \\downarrow \) key to activate the "PROGRAM START DELAY" parameter (0/1).
   - Press the ENTER key to confirm.

2. Press the \( \text{INS} \) key; use keys \( \uparrow \) and \( \downarrow \) to position on the "Day" field and enter the number of the day on which the program will start.
   - Press the ENTER key to confirm.

3. Repeat this operation for the "Month", "Year", "Hours" and "Minutes" field, entering the date and time for the delayed start of the program.

4. Press \( \text{START} \) to go to the program selection; use keys \( \uparrow \) and \( \downarrow \) to position on the "Progr. No." field and enter the number of the selected program.
   - Press the ENTER key to confirm.

After entering the program number ("Progr. No.") the process controller will check that:
- the selected program is enabled by the machine’s SW configuration;
- the printer, if any, is available, if activated by the operator for cycle printing ("PRINTER" system parameter set to 1).

After these checks, the process controller displays the page corresponding to the first phase of the program, known as "PREPARATION" (cf. Figure 6.34).

The operator must insert the product in the chamber (cf. Para. 6.4.5.4.), unless this operation has already been performed, and must close the cover.

Once the Date/time set for the delayed start is reached, the "PREPARATION" phase is over and the sterilization cycle is automatically started.

The "progressive program number" counting increases and will be printed at the end of the cycle (if the printer is enabled).

All operations are inhibited until completion of the cycle, apart from the monitoring of chamber parameters, and the Step–by–Step and Cycle Stop functions.

**NOTE**

The program number must be entered the last, because it may provide access to the "PREPARATION" phase even if the other parameters have not been entered.

**NOTE**

If you don’t want to run the "delayed" program, simply press the [STOP] key or turn the machine off in the "PREPARATION" phase.

**NOTE**

If, in the "PROGRAM START DELAY" menu, the "Start delay" parameter is set at 1 and a preceding date or hour (or both) is/are set, the controller enter the "PREPARATION” phase and doesn’t live it until aborted by pressing the [STOP] key or turning the machine off.

The [START] key, if pressed, doesn’t run the program.
If, in the "PROGRAM START DELAY" menu, the "Start dealy" menu is set at 0, regardless of the date and hour values, the controller enter the "PREPARATION" phase and doesn't live it until aborted by pressing the START key, starting the program.

If, when the date/hour set for the start are reached the door is still open, the program doesn't start. The program will be run only after closing the door.

If, when the date/hour set for the start are reached, the steam generator is "not ready", the program doesn't start. The program will be run only with the generator's permission.
7. ALARMS AND FAULT FINDING

7.1. ALARMS

The sterilizer has up to 20 alarms, displayed together with a short description and printed (if a printer is available). The operator is informed about activated alarms by visual and acoustic warnings.

System alarms concern safety tools and conditions. Phase alarms relate to specific phases to be carried out. Top-level alarms (e.g. cover not perfectly closed during the process) stop the cycle in progress. The sterilizer enters the emergency phase and is kept in full safety.

Press key \( \text{STOP} \) and key in the required password in order to enter pressure balancing and cycle end phase.

All alarms refer to temporary failures or to other failures which might require engineers’ assistance.

Based on its configuration, the sterilizer described in this manual can enable all (machine full optional) or part of the alarms listed in Table 7.1.

The meaning of the Table fields is the following:

- **No.** : alarm number
- **ALARM** : alarm message
- **IN CYCLE** : period in which an alarm may be triggered.
- **CAUSE** : description of failures detected by the controller
- **TYPE** : Alarm type
- **DELAY** : delay in the alarm activation;
- **RESULT** : How the alarm affect the sterilizer
- **CIC** : Acoustic warning
- **PRINT ON** : Print (alarm activated)
- **PRINT OFF** : Printing alarm disabling.
- **ACK** : Acknowledgment request

**NOTE**

Symbols TE1, TE2 and PT of alarm messages correspond to thermal probes T001 and T005 and pressure transducer P001 respectively.

**NOTE**

Several alarms require the operator’s acknowledgment (ACK message blinking).

Press key \( \text{ENTER} \) for at least 5 seconds to erase the “alarm acknowledgment” message.
<table>
<thead>
<tr>
<th>N.</th>
<th>ALARM</th>
<th>IN CYCLE</th>
<th>CAUSE</th>
<th>TYPE</th>
<th>DELAY</th>
<th>RESULT</th>
<th>CIC</th>
<th>PRINT ON</th>
<th>PRINT OFF</th>
<th>ACK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>VACUUM PUMP ALARM</td>
<td>X</td>
<td>The Controller has sent the vacuum pump the starting signal (PV01), but does not receive any return signal (TPPV).</td>
<td>System</td>
<td>10</td>
<td>Display</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>STER. TEMP. EXCESS</td>
<td>X</td>
<td>During the sterilization phase, the chamber temperature exceeds the sterilization temperature plus the sterilization tolerance (V10+V11).</td>
<td>Phase (STER.)</td>
<td></td>
<td>Display</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>STER. TEMP. LACK</td>
<td>X</td>
<td>During the sterilization phase, the chamber temperature is lower than the sterilization temperature (V10).</td>
<td>Phase (STER.)</td>
<td></td>
<td>Display and susp. steriliz. time</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>TE1 UNSERVICEABLE</td>
<td>X</td>
<td>The chamber temperature measured by the process controller exceeds the measuring range of heat probe TE1 (T001) or the process controller does not receive any signals from TE1 (T001).</td>
<td>System</td>
<td>5</td>
<td>Display and EMERG.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>PT UNSERVICEABLE</td>
<td>X</td>
<td>The chamber temperature measured by the process controller exceeds the measuring range of pressure transducer PT (P001) or the process controller does not receive any signals from PT (P001).</td>
<td>System</td>
<td>5</td>
<td>Display and EMERG.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>STEAM WATER LACK</td>
<td></td>
<td>The controller receives from level sensor (L002) the signal which indicates a lack of water in the autonomous steam generator. Note: this alarm is enabled only if the optional heat probe is working (Opt. K10 = 1 and system param. S5=1)</td>
<td>System</td>
<td>60</td>
<td>Display</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>TE2 UNSERVICEABLE</td>
<td>X</td>
<td>The chamber temperature measured by the process controller exceeds the measuring range of heat probe TE2 (T005) or the process controller does not receive any signals from TE2 (T005). Note: this alarm is enabled only if the optional heat probe is working (Opt. K80 = 1)</td>
<td>System</td>
<td>5</td>
<td>Display and EMERG.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>N.</td>
<td>ALARM</td>
<td>IN CYCLE</td>
<td>CAUSE</td>
<td>TYPE</td>
<td>DELAY</td>
<td>RESULT</td>
<td>CIC</td>
<td>PRINT ON</td>
<td>PRINT OFF</td>
<td>ACK</td>
</tr>
<tr>
<td>----</td>
<td>------------------------</td>
<td>----------</td>
<td>-----------------------------------------------------------------------</td>
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<td>-----</td>
<td>----------</td>
<td>-----------</td>
<td>-----</td>
</tr>
<tr>
<td>8</td>
<td>LEAK TEST ALARM</td>
<td>X</td>
<td>During the sterilizer leak test, the controller detects a chamber pressure exceeding the programmed limits. Note: the variation in pressure is referred to the initial pressure value of the phase.</td>
<td>Phase (VACUUM TEST and PRESS TEST)</td>
<td></td>
<td>Display and test failure</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>OVERTEMPERATURE</td>
<td>X</td>
<td>The process controller measures the chamber temperature, which is higher than the set limit (141°C, 155°C for the FVA-HT model). Note: to avoid any false alarms if TE1 is unserviceable, this alarm is activated only for values below 150°C (200°C for the FVA-HT model).</td>
<td>System</td>
<td></td>
<td>Display and EMERG.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>OPEN DOOR IN CYCLE</td>
<td>X</td>
<td>During the cycle, the process controller warns the operator that the cover is not perfectly closed. (Signal P002 not available)</td>
<td>System</td>
<td></td>
<td>Display and EMERG.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>AUTOMATIC POWER OFF</td>
<td>X</td>
<td>Displayed and printed on CYCLE completion, when the machine automatic switch off has been required.</td>
<td>System</td>
<td></td>
<td>Display</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>MANUAL PROGRAM–STOP</td>
<td>X</td>
<td>Displayed and printed, during a cycle, after selecting CYCLE STOP function.</td>
<td>Phase (all phases with stop enabled)</td>
<td></td>
<td>Display and EMERG.</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>PHASE STEP UTILIZED</td>
<td>X</td>
<td>Displayed and printed, during a cycle, after selecting STEP–BY–STEP function</td>
<td>Phase (all phases with P–P enabled)</td>
<td></td>
<td>Display and Phase end</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>BLACK OUT DETECTED</td>
<td>X</td>
<td>Alarm displayed or printed, when a new cycle is started after a Black Out</td>
<td>System</td>
<td></td>
<td>Display and EMERG. B.O.</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>PRINTER ERROR</td>
<td></td>
<td>When starting a cycle, after selecting the program No., check that the printer is available. (Opt. K81 = 1 and system Param. S6 = 1). If it is not so, the alarm is activated and the cycle is not selected.</td>
<td>System (cycle selection)</td>
<td></td>
<td>Display and progr. sel. denied</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
The process controller detects an operating anomaly on inputs (limit stops and pressure switches of the door system).

System Display and EMERG X X X

Activated in case of a autodiagnose error.

System Display X X X

Activation in case of discharged or missing battery. The alarm is activated before the battery is completely discharged. Replace the battery to avoid losing all the data contained in the RAM.

System Display X X

Activation in case of discharged or missing battery. The alarm is activated before the battery is completely discharged. Replace the battery to avoid losing all the data contained in the RAM.

System Display X X

CAUTION!
The operator must be perfectly acquainted with machine alarms which could be activated.

7.2. FAULT FINDING

This section provides information on fault finding (e.g. alarms activated, vibrations, unusual noise).
To this end, the operator can use a diagnostic device ("AUTODIAGNOSE"), allowing to check system/computer performance, through analog and digital input/output channels.

CAUTION!
All jobs on the machine, including the access to live elements and main feed lines, must be carried out by FEDEGARI’s skilled personnel, or must be authorized by the manufacturer.
7.3. FAULT DETECTION PROCEDURES

Table 7.2 shows the commonest failures which might take place during the sterilizer operation. The following table identifies their possible causes as well as the related troubleshooting.

<table>
<thead>
<tr>
<th>ALARM NO.</th>
<th>DESCRIPTION</th>
<th>POSSIBLE CAUSES</th>
<th>TROUBLESHOOTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The controller has sent the vacuum pump PV01 the start signal (PV01) without receiving the return signal (TMPV). The alarm message “VACUUM PUMP ALARM” is displayed.</td>
<td>a) Pump PV01 feed circuit failure.</td>
<td>a) Based on wiring, try to identify and repair such failure. Check relay K1 performance.</td>
</tr>
<tr>
<td>2</td>
<td>During the sterilization phase, the chamber internal temperature exceeds the sterilization temperature added to the sterilization tolerance (V10 + V11). The alarm message “STER. TEMP. EXCESS” is displayed.</td>
<td>a) The sterilizer is fed with overheated steam. b) Faulty heat probe T001 or pressure transducer P001 c) Heat probe T001 or pressure transducer P001 are not properly calibrated. d) The conversion module of sensor signals does not work properly.</td>
<td>a) Reset pressure in the saturated steam supply line. b) Identify the faulty element and replace it. c) Calibrate the system based on the signal coming from heat probe or transducer. d) Identify the faulty element and replace it.</td>
</tr>
<tr>
<td>3</td>
<td>During the sterilization phase, the chamber temperature drops below the minimum sterilization temperature (defined as system parameter). The alarm message “STER. TEMP. LACK” is displayed.</td>
<td>a) The sterilizer is fed with low pressure steam. b) Faulty heat probe T001 or pressure transducer P001. c) Heat probe T001 or pressure transducer P001 are not properly calibrated. d) The conversion module of sensor signals is not working properly.</td>
<td>a) Reset pressure in the saturated steam supply line. b) Identify the faulty element and replace it. c) Calibrate the system on the signal coming from the probe or transducer. d) Identify the faulty element and replace it.</td>
</tr>
<tr>
<td>ALARM NO.</td>
<td>DESCRIPTION</td>
<td>POSSIBLE CAUSES</td>
<td>TROUBLESHOOTING</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------</td>
<td>-----------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>4</td>
<td>The internal chamber pressure measured by the process controller is higher than the measuring range of heat probe T001. - The alarm message “TE1 UNSERVICEABLE” is displayed. The cycle stops and the system enters the emergency phase.</td>
<td>a) Faulty heat probe T001 or conversion module of the detected signal.</td>
<td>a) Identify the faulty element through the self-diagnostic functions, repair or replace it.</td>
</tr>
<tr>
<td>5</td>
<td>The chamber pressure measured by the process controller exceeds pressure transducer P001 measuring range. - The alarm message “ PT UNSERVICEABLE” is displayed. - The cycle stops and the system enters the emergency phase.</td>
<td>a) Faulty pressure transducer P001 or conversion module of the signal detected by the transducer.</td>
<td>a) Identify the faulty element through the self-diagnostic functions, repair or replace it.</td>
</tr>
<tr>
<td>6</td>
<td>Level sensor L002 indicates that the autonomous steam generator D001 is empty. The alarm message “ STEAM WATER LACK” is displayed.</td>
<td>a) No water is available. A possible cause, apart from the lack of water, may be the presence of air bubbles in the pump suction duct. In this case, let the pressure out of the generator, by opening manual valve V004 (that must be closed once the generator is empty). After this operation, the deionized water supply can be restored. b) Faulty autonomous steam generator water pump PA01. c) Dirty or faulty supply valves. d) Faulty level sensor L002.</td>
<td>a) Reset demineralized water supply. b) Repair or replace the water feed pump PA01 to the autonomous steam generator. c) Check water feed line to the autonomous steam generator. d) Identify the faulty element, repair or replace it. Replace the level sensor L002.</td>
</tr>
<tr>
<td>ALARM NO.</td>
<td>DESCRIPTION</td>
<td>POSSIBLE CAUSES</td>
<td>TROUBLESHOOTING</td>
</tr>
<tr>
<td>-----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>7</td>
<td>The chamber temperature measured by the process controller exceeds the measuring range of heat probe <strong>T005</strong>.</td>
<td>a) Faulty heat probe <strong>T005</strong> or conversion module of the detected signal.</td>
<td>a) Identify the faulty element using the AUTODIAGNOSE function, repair or replace it.</td>
</tr>
<tr>
<td></td>
<td>- The alarm message “TE2 UNSERVICEABLE” is displayed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>During the leak test, the sterilization chamber pressure measured by the controller exceeds set limits. The message &quot;LEAK TEST ALARM&quot; is displayed.</td>
<td>a) Faulty or dirty fluid loading/unloading valves.</td>
<td>a) Identify faulty valve(s), clean or repair it/them.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Valves</strong> Function</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>S003</strong> Air inlet <strong>S008</strong> Steam inlet <strong>S006</strong> Drain <strong>E071</strong> Steam inlet (K62) <strong>E007</strong> Steam control (K61)</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>The chamber temperature measured by the process controller exceeds the set limit (141°C): (155°C for the FVA–HT model):</td>
<td>a) Faulty solenoid valve loading steam inside the chamber <strong>E008</strong>. **b) Saturated steam supply valve open <strong>S008.</strong></td>
<td>a) Repair or replace solenoid valve <strong>E008</strong>. **b) Repair or replace supply valve <strong>S008.</strong></td>
</tr>
<tr>
<td></td>
<td>- The alarm message &quot;OVERTEMPERATURE&quot; is displayed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- The cycle stops and enters the emergency phase.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>During the cycle, the process controller warns that the cover is not perfectly closed:</td>
<td>a) Faulty pressure switch <strong>P002</strong> detecting &quot;high pressure&quot; in the cover seal. <strong>b) No compress air available in the cover seal.</strong></td>
<td>a) Replace pressure switch <strong>P002</strong>. **b) Check the compressed air supply circuit. Identify the faulty element and replace it.</td>
</tr>
<tr>
<td></td>
<td>- The alarm message &quot;OPEN DOOR IN CYCLE&quot; is displayed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- The cycle is stopped and enters the emergency phase.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>During forced cooling, the fan <strong>CV12</strong> does not start.</td>
<td>a) Mechanical heating element in the system. <strong>b) Short–circuiting fan.</strong></td>
<td>a) Repair or replace the fan <strong>CV12</strong>. **b) Repair or replace the motor <strong>ME12.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Water leaks in the vacuum pump <strong>PV01</strong> or in the autonomous generator feed pump <strong>PA01.</strong></td>
<td>a) Faulty seals.</td>
<td>a) Replace seals.</td>
</tr>
<tr>
<td>ALARM NO.</td>
<td>DESCRIPTION</td>
<td>POSSIBLE CAUSES</td>
<td>TROUBLESHOOTING</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------</td>
<td>-----------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>15</td>
<td>After selecting the sterilization program, the message &quot;PRINTER ERROR&quot; is displayed.</td>
<td>a) The printer has been activated (system parameter PRINTER = 1), but is not available on the sterilizer. b) The printer is not fed.</td>
<td>a) Switch printer off. b) Check printer connection to the controller and the electric mains.</td>
</tr>
<tr>
<td></td>
<td>The sterilizer cannot be started because the main switch trips several times.</td>
<td>a) Internal short-circuit. b) The electric cubicle is open. c) The generator safety thermostat T003 (TÜV) is activated. d) Thermostat T002, protecting the generator heating elements is activated.</td>
<td>a) Identify and remove failure, according to the wiring diagram. b) Close the electric cubicle by means of its key. c) Remove the cause of dry operation, which has made heating elements work with low water level.</td>
</tr>
<tr>
<td></td>
<td>The vacuum pump PV01 does not start.</td>
<td>a) No activation signal of the process controller. b) Opening of the magnetothermal power switch. c) Faulty pump PV01.</td>
<td>a) Identify the failure through self–diagnostic functions. b) Identify the circuit failure downstream the magnetothermal power switch. c) Repair or replace the pump PV01.</td>
</tr>
<tr>
<td></td>
<td>When the cycle is in progress, the controller does not receive the ready generator signal.</td>
<td>a) Faulty regulation pressure switch P004. b) Faulty autonomous generator heating system.</td>
<td>a) Replace pressure switch P004. b) Check performance of electric heating elements and of their electric feed circuit.</td>
</tr>
</tbody>
</table>

### 7.3.1. Autodiagnose functions

The process controller features a diagnostic instrument, known as "AUTODIAGNOSE". This tool allows to check digital input/output channels as well as analog inputs. To access this tool:

1. Press key [3] to select option “AUTODIAGNOSE” from the main menu. The following menu will be displayed
(see Figure 7.1):

**AUTODIAGNOSE**
1. Digital Input
2. Digital Output
3. Analog Input
4. TE1 Calibration
5. TE2 Calibration
6. PT Calibration

*Figure 7.1 – AUTODIAGNOSE menu*

2. Select the desired option by pressing the key corresponding to the number displayed next to the option, on the main menu.

- Press **1** to access the page displaying the digital input state (see Figure 7.2). The state of the corresponding channel (0 = OFF, 1 = ON) is displayed below line 0123456789ABCDEF.

  *Figure 7.2 – DIGITAL INPUT menu*

- Press key **2** to access the page for displaying and modifying digital outputs state (see Figure 7.3). The state of each channel (0 = OFF, 1 = ON) is displayed below line 0123456789ABCDEF.

  *Figure 7.3 – DIGITAL OUTPUT menu*
To modify a channel state:

* Press \[\text{INS}\] to enter data;

* Select channels using keys \[\rightarrow\] and \[\leftarrow\]; activate the channel by selecting key \[\text{↑}\] or deactivate it through key \[\text{INS}\];

* Press key \[\text{ENTER}\] to store the modification.

**NOTE**
The channels related to solenoid valves for the seal compressed air and analog module outputs cannot be modified.

- Press key \[3\] to access the page displaying the chamber Temperature and Pressure (see Figure7.4);

![ANALOG INPUT]

**Table 7.3 – PLC input/output digital channels and related field devices**

<table>
<thead>
<tr>
<th></th>
<th>OUTPUT</th>
<th>INPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Letters</td>
<td>Description</td>
</tr>
<tr>
<td>0</td>
<td>RESET</td>
<td>● main switch reset</td>
</tr>
<tr>
<td>1</td>
<td>E071</td>
<td>● decontamination steam and fan</td>
</tr>
<tr>
<td>2</td>
<td>CIC</td>
<td>● buzzer</td>
</tr>
<tr>
<td>3</td>
<td>E003</td>
<td>○ chamber air valve</td>
</tr>
<tr>
<td>4</td>
<td>FREE</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>E005</td>
<td>● cooling valve (H2O+fan)</td>
</tr>
<tr>
<td>6</td>
<td>E006</td>
<td>○ drain valve and PV vacuum</td>
</tr>
<tr>
<td>7</td>
<td>E007</td>
<td>● condensate purge valve</td>
</tr>
<tr>
<td>8</td>
<td>E008</td>
<td>● chamber steam supply valve</td>
</tr>
<tr>
<td>9</td>
<td>FREE</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>E010</td>
<td>● chamber compressed air valve</td>
</tr>
</tbody>
</table>

*Figure 7.4 – ANALOG INPUTS menu*
<table>
<thead>
<tr>
<th>N</th>
<th>Letters</th>
<th>Description</th>
<th>Opt</th>
<th>Letters</th>
<th>Description</th>
<th>Opt</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>PV01</td>
<td>vacuum pump</td>
<td>K20</td>
<td>TMPV</td>
<td>vacuum pump return</td>
<td>K20</td>
</tr>
<tr>
<td>C</td>
<td>E012</td>
<td>door seal press. valve</td>
<td>--</td>
<td>FREE</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>D</td>
<td>E013</td>
<td>door seal depress. valve</td>
<td>--</td>
<td>FREE</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>E</td>
<td>YE</td>
<td>ENABLE module ADPLC/F32</td>
<td>--</td>
<td>FREE</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>F</td>
<td>YF</td>
<td>CLOCK module ADPLC/F32</td>
<td>--</td>
<td>XF</td>
<td>SDATA module ADPLC/F32</td>
<td>--</td>
</tr>
<tr>
<td>+0</td>
<td>E014</td>
<td>&quot;out-of-cycle&quot; signal</td>
<td>--</td>
<td>FREE</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>+1</td>
<td>E015</td>
<td>&quot;cycle-in-progress&quot; signal</td>
<td>--</td>
<td>FREE</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

● = digital outputs that can be manually activated in SELF–DIAGNOSIS and are reset to OFF when a program is run.
○ = digital outputs that can be manually activated/deactivated in SELF–DIAGNOSIS, and that are reset to OFF when a program is run. Their forced deactivation can be overwritten by the automatic control. Therefore, if the system activates this output automatically, any deactivation attempt is useless (even though the system displays that the “forced” state of the output has been reset to OFF).
X = digital outputs continuously and automatically controlled by the process controller; they cannot be activated/deactivated manually in SELF–DIAGNOSIS.
8. MAINTENANCE AND SERVICING

8.1. GENERAL WARNINGS

**WARNING**
Correct and timely maintenance allows to prevent most failures and to assure proper performance and durability of the machine.

**CAUTION!**
Always CARRY OUT scheduled maintenance suggested in this manual.
Perform periodical top level maintenance and related overhauls as recommended by FEDEGARI. The machine must be checked at least every year or after no more than 400 cycles. The manufacturer shall not be liable for any failure or damage due to total or partial non-compliance with the above mentioned scheduled times and procedures.

**NOTE**
Electric motors overloads are usually due to mechanical failures, causing vibrations and unusual noise, which deserve the operator's attention from the beginning. If in doubt, do not hesitate to contact FEDEGARI’s Service Centers.

8.2. FOREWORD

Maintenance jobs indicated in this section have been defined after a careful exam of average machine performance and use. For different needs, please contact the manufacturer.

This chapter identifies preventive maintenance (sections 8.3. and 8.4.) as well as troubleshooting.

8.3. PREVENTIVE MAINTENANCE

8.3.1. General information and warnings

This section explains ordinary preventive maintenance procedures, based on different steps. It informs the operator about any warnings, maintenance schedules, tools, materials and equipment to be used for maintenance.

These procedures are organized according to the following topics:

- Visual inspection;
- Cleaning;
Scheduled performance tests.

**CAUTION!**
Be careful to carry out maintenance with suitable work clothing, fit to protect the operator from contusions, abrasions and burns deriving from contact with hot fluid jets.

**CAUTION!**
Before maintenance of the sterilizer, ALWAYS stop it, unless otherwise provided, by disconnecting the master switch and the equipment from the power supply network.

### 8.3.2. Visual inspection
Check the plant and its main components every week, according to the instructions of the following sections.

#### 8.3.2.1. Preliminary operations
1. Check work reports to make sure that the last sterilization cycle has been successfully completed.

**CAUTION**
Do not carry out maintenance if you are not sure that the working environment is free from chemicals, bacteria and microbes, i.e. until successful completion of the previous sterilization cycle, when the batch has been sterilized without any leaks (broken or open vials, bags, containers etc.). All maintenance jobs carried out in environments with chemicals, bacteria or microbes MUST BE authorized by the competent bodies of the sterilizer owner and performed using suitable protective equipment, in conformity with the safety rules of the country where the machine is used.

2. Check that the machine cover is open;

3. The cover being closed, check that the chamber pressure corresponds to atmospheric pressure and that temperature corresponds to room temperature (10%);

4. Check that the machine and the process controller are switched off. If it is not so, switch the machine off and comply with safety rules for isolation from power supply sources.

#### 8.3.2.2. Inspection

**CAUTION!**
When operated, some machine parts feature high-temperature components and surfaces. The operator MUST AVOID to approach them without wearing suitable protective garments.
**Off-line check**

If necessary, have access to the technical cabinet to check components every month. In particular:

1. Check that hydraulic pipes and pneumatic lines are not cracked or strained; that they have no dripping, leaks or pressurized fluid jets;

2. Check warning, supply and control electric lines. They must not have non-insulated sections, cutting or coils with narrow radii of curvature;

3. Check internal sterilization chamber surfaces. They must be smooth, without any dents, abrasions or procks;

4. Check the magnetic fan, if any: the shaft blades must turn freely and without problems;

5. Check the paneling and cabinet external surfaces. Their form and painting must be in good state;

6. Check the supply line and plant fittings. They must be fastened to the machine pipes, without cracks, deformations, dripping, leaks or pressurized fluid jets, especially on primary line shut-off valves, set by the user;

7. Check all plant components (solenoid valves, filters, sensors, electropneumatic actuators). The external containers must be in good state, the identification plates must be readable, the core hitches and tight connectors must be free from mechanical failures and/or isolation losses;

8. Check the integrity of heat probes. In particular, check the sensor head for scale, strain or breaks. The signal conductor sheath must bear bending, without cracks or isolation losses;

9. Check the autonomous generator, if any, and other auxiliary systems;

10. Start the emergency stop device several times (red mushroom-head button) to make sure that no failures and strange noise occur. The device form and color must be in good state;

11. Check the control devices (keyboard, display, pressure-vacuum gauges). Their surface must be free from cracks, abrasions and breaks. In particular, key and button serigraphs must be clearly readable, their colors in good state;

12. Check that all warning and danger plates are properly fitted and positioned on the machine surface and make sure that they are in good state, with unchanged colors.

**On-line check**

During any cycle or sterilization phase, access, if necessary, the technical cabinet every month to carry out the following check:
CAUTION!
When the machine is running, carry out VISUAL inspections only, using suitable personal protection means. Do not touch any machine parts.

1. Check that hydraulic pipes have no dripping, leaks or pressurized fluid jets;
2. Check that the machine is free from noise or failures deriving from pneumatic circuit leaks;
3. Check the primary supply line fittings. No dripping, leaks or pressurized fluid jets must be detected on primary line shut-off valves set by the user;
4. Check operating equipment noise (e.g. fan, vacuum pump, water pump, if any). It must not exceed usual levels, without intensity and/or tone changes.

8.3.3. Cleaning

CAUTION!
Before any cleaning operations, according to the instructions given in the previous section, carry out all steps explained in section 8.3.2.1. “Preliminary operations”.

WARNING
All parts in contact with process fluids in Fedegari sterilising machines are manufactured using austenitic stainless steel. When properly maintained, this material offers excellent corrosion resistance properties.

It is recommended to carry out maintenance cleaning of all internal surfaces at regular intervals. Unless otherwise provided, do not use abrasive tools or cloth. Always use soft natural or artificial sponges and rags without fraying.

CAUTION!
Austenitic stainless steel surfaces may lose their corrosion resistance properties and be irreversibly damaged if they come in contact with chlorine or chlorine compounds. When operating and cleaning the steriliser, avoid the use of solutions and detergents containing chlorine or chlorides.

8.3.3.1. Cleaning the chamber

Ordinary cleaning
Wash and rinse the chamber every month.
1. Wash it with a solution of hot demineralized water and mild detergent for metals;
2. Carefully rinse it with water.

**Cleaning surface dirt**

Wash and rinse dirty chamber surfaces in order to clean them.

1. Wash them demineralized hot water and non–acid and non–abrasive detergents usually available on the market;
2. Carefully rinse with much water.

**Cleaning dirt layers (oxide spots and rust)**

If the chamber surface is encrusted or covered with dirt deposits with oxides, wash and rinse with slightly aggressive detergents for metals; in the presence of scale, use descaling solutions.

### 8.3.3.2. Cleaning the chamber filter

Make sure that the filter is clean every day. If necessary, clean it as follows:

1. Pull the filter body out of its housing by means of its grip;
2. Remove all macroscopic residues from the metal filter (glass pieces, organic fragments etc.);
3. Wash the filter with a solution of hot water and mild detergent for metals, using a soft horsehair or synthetic brush;
4. Carefully rinse it and, if necessary, dry the metal filter mesh with a low pressure compressed air jet (1.5 bar);
5. Fit the filter in its housing inside the chamber.

![Figure 8.1 -- Cleaning the chamber filter](image)

**WARNING**

Do not pull out the filter if fragments, glass and other substances (e.g. agar etc.) are found on the chamber bottom..
Remove all solid substances and make sure that they do not fall in the drain trap during filter extraction, as they might clog and damage the sterilizer valves.

8.3.3.3. Cleaning the heat probe

Make sure every week that the heat probe is clean. If necessary, clean it as follows:

1. Take the heat probe out of the chamber and clean the sensor head with a solution of water and neutral detergent and a cotton cloth;
2. Use this solution and a non-abrasive sponge to clean the sheath. Dry the head and sheath using a clean cloth without fraying.

![Figure 8.2 – Heat probe](image)

8.3.3.4. Cleaning the operator interface devices

Clean these devices every week as follows:

**Cleaning the operator interface and the pressure–vacuum gauges**

1. With a vacuum cleaner, suck dirt on device reflective surfaces;
2. Clean the surface with a natural sponge soaked with clean water;
3. Dry surfaces with clean cotton cloth without breaking or a wet non-abrasive cloth.

8.3.3.5. Cleaning the cover and the external cabinet

Wash and rinse the cover and the external cabinet every month, with a wet cloth.

8.3.3.6. Cleaning the batch transport baskets

Wash and rinse the reservoirs every week to clean them.

1. Wash them with hot water and non-abrasive/non-acid detergents available on the market;
2. Carefully rinse them with water.

8.3.3.7. Cleaning line filters

Make sure every month that the line filters on the air, water and steam supply lines are clean.
8.3.4. Scheduled performance tests

8.3.4.1. Checking the chamber safety valves and the steam generator, if any

Check chamber safety valves and steam generator performance (if any) every month. The machine must be switched on and the process controller activated with a sterilization cycle in progress, with chamber under pressure at 1.5 bar. To check performance:

1. During a sterilization cycle with chamber pressure higher than atmospheric pressure and lower than maximum operating pressure, unscrew the collar located on the top of the safety valve;
2. Soon after, check that steam is let out of safety valve drain gathering lines. Screw the collar again and make sure that the steam flow immediately stops.

NOTE
This check simply allows to verify that no gluing or deposits between the shutter and the valve housing prevent the operator from opening it, without ensuring that calibration is observed.

CAUTION!
The safety valves for pressurized reservoirs must be submitted to specific testing cycles, according to the rules in force in the country where the machine is used. In time, gaskets may lose their seal. Check their correct operation periodically.

RING NUT

Figure 8.3 – Safety valve

8.3.4.2. Checking the chamber manual pressure relief valve

Carry out this check every day. The machine must be switched on and the process controller activated. Perform this test on completion of a "CHAMBER VACUUM TEST" cycle.

NOTE
The valve is located on the sterilizer front paneling, near the emergency button.

1. During the "vacuum seal" or "pressure seal" phases, slightly open the valve and make sure that chamber pressure
is changing.

Figure 8.4 – Chamber manual pressure relief valve

8.3.4.3. Checking chamber sealing (if vacuum pump is available)

**WARNING**
The sterilizer basic model, without vacuum pump and “pressure test”, does not allow for chamber seal cycles.

This check, to be performed every week, allows to verify the chamber vacuum tightness. To carry out this procedure:

1. Start the machine and enable process controller; select option “SELECT PROGRAM” from the main menu. Select program “VACUUM TEST” on the page displayed;

2. Press key “START” to run the program;

3. Make sure that the test program is successfully executed and completed. Switch the machine off, unless further operations are required.

**WARNING**
If, during the test, the message “LEAK TEST ALARM” is displayed by the process control page, repair the failure, which is often due to dirty/faulty chamber loading/unloading valves or cover seal.

8.3.4.4. Checking chamber pressure (if pressurization with compressed air is available)

This check, to be performed every week, allows to verify the pressurized chamber tightness. To carry out this procedure:
1. Start the machine and enable process controller; select option “SELECT PROGRAM” from the main menu.

2. Select program “PRESSURE TEST”;

3. Press key [START] to run the program;

4. Make sure that the test program is successfully executed and completed. Switch the machine off, unless further operations are required.

**WARNING**

If, during the test, the message “LEAK TEST ALARM” is displayed by the process control page, repair the failure, which is often due to dirty/faulty chamber loading/unloading valves or cover seal.

### 8.3.4.5. Checking the cover grommet

This check allows to verify the closing system performance and should be carried out every month.

**Checking the seal**

1. Follow the steps mentioned in section 8.3.2.1. “Preliminary operations”

2. Check the cover seal for wear and flexibility as follows:
   
   * Open the machine cover;
   
   * Check that the seal is not glued (e.g. due to improper use of chemicals for cleaning the machine);
   
   * Check that the seal is not broken or cracked;
   
   * Check that the seal body is free from metal particles and other materials (e.g. glass etc.).

### 8.3.4.6. Checking compressed air plant tightness

This check must be performed every month:

1. Close the sterilizer cover;

2. Close the compressed air supply outside the machine;

3. Check that the dedicated pressure gauge indicates that the plant pressure loss after a 1.5 h. shut–down is lower than 1.5/bar.

### 8.3.4.7. Checking heat probe (Pt100)

This check concerns the heat probe performance and should be carried out every week:
1. Check the heat probe state as follows:
   - Check that the heat probe enclosure has no holes and cuts;
   - Make sure that the sheath is not broken in the sealing point.

2. Check heat probe performance as follows:
   - Press key 3 to select option "AUTODIAGNOSE" from the main menu;
   - Press key 3 to select the page displaying the chamber Pressure and Temperature;
   - Bend the heat probe and check on the monitor that the temperature measured does not suddenly change.

8.3.4.8. Temperature check of the cover opening safety system

This check aims to verify the performance of the system which prevents the cover from opening when the chamber temperature is higher than a set value, corresponding to system parameter “FINAL TEMPERAT.”. This check can be performed only if system parameter “CHECK FINAL T” is set to 1.

To carry out this test:
   - Close the cover;
   - Set system parameter “CHECK FINAL T” to 1;
   - Give system parameter “FINAL TEMPERAT.” a value lower than the one measured by heat probe T001 before closing the cover;
   - Check that the cover does not open;
   - Give system parameter “FINAL TEMPERAT.” a value higher than the one measured by heat probe T001 before closing the cover;
   - Open the cover to make sure that it can be opened;

8.3.4.9. Checking the compressed air reducer (if the solenoid valve for compressed air inlet is available)

This check should be carried out every week to verify the compressed air reducer state. To carry out this check:
   - Slightly turn the knob clockwise and anticlockwise;
   - Check whether pressure is increasing or decreasing on the dedicated pressure gauge.

8.3.4.10. Calibrating the heat probe

1. Press key 3 to select option “AUTODIAGNOSE” from the main menu. The following menu will be displayed
(see Figure 8.5):

![Figure 8.5 – Self-diagnosis menu](image)

1. Digital Input
2. Digital Output
3. Analog Input
4. TE1 Calibration
5. TE2 Calibration
6. PT Calibration

**Figure 8.5 – Self-diagnosis menu**

2. Press key [4] to display the calibration page for heat probe TE1 (T001) (see Figure 8.6).

![Figure 8.6 – TE1 calibration page](image)

This page shows 4 numeric fields (I1, I2, O1, O2). Enter temperatures to set up the calibration table used by the process controller to correct the value measured in the sterilization chamber.

As results from the field names, the calibration table consists of the temperatures obtained through the identification of two calibration points, according to the following procedure:

* Take the heat probe out of the chamber and plunge it in a thermostatic bath, at a temperature of approx. 100°C;
* Wait until the heat probe is balanced, i.e. its temperature no longer changes;
* Enter the value displayed in field (I1) and enter the thermostatic bath temperature in field (O1) as follows (see Figure 8.7):
  a) Press [INS] to enter data;
  b) Use keys [RIGHT] and [LEFT] to select the field;
  c) Type in the numeric value;
  d) Press key [ENTER] to store entered data.
* Repeat this procedure after having fixed the thermostatic bath temperature at a value of approx. 140°C and enter values in field I2 or O2 (see. 8.8).

![Image of TE1 CALIBRATION °C](figure87.png)

**Figure 8.7 – Temperatures related to calibration low point**

![Image of TE1 CALIBRATION °C](figure88.png)

**Figure 8.8 – Temperatures related to calibration high point**

**NOTE**

Enter two different temperatures in fields I1 and I2. If such temperatures are the same (I1 = I2) a PLC error occurs (red LED lights up). To correct the error, change I1 or I2, switch off the sterilizer and switch it on again.

3. Press key 5 to access heat probe TE2 (T005) calibration page. Follow instructions of section 2.

If the above mentioned procedures do not allow to service failures mentioned in this paragraph, or in case of unexpected failures, it is strongly recommended to contact FEDEGARI’s Service Centers.

### 8.3.4.11. Calibrating the pressure transducer

1. Press key 3 to select option “AUTODIAGNOSE” from the main menu. The following menu will be displayed
2. Press key 6 to access pressure transducer PT (P001) calibration page (see Figure 8.10).

This page shows 4 numeric fields (I1, I2, O1, O2). Enter pressures to set up the calibration table used by the process controller to correct the value measured in the sterilization chamber.

As results from the field names, the calibration table consists of the pressures obtained through the identification of two calibration points, according to the following procedure:

* Connect the transducer to an environment with known and constant pressure, ranging from 0.01 to 6 bar;

* Wait until the transducer is balanced, i.e. its pressure no longer changes;

* Enter the value displayed in field (I1) and enter calibration environment pressure in field (O1) as follows (see Figure 8.11):

  a) Press 0 INS to enter data;
b) Use keys → and ← to select the field;

c) Type in the numeric value;

d) Press key ENTER to store entered data.

* For TP calibration high point, pressurize the transducer at a pressure ranging from 0.1 and 5 bar (e.g. 3 bar.); interface with a certified control instrument to obtain I2 and O2 (see 8.12).

---

**CAUTION**
The pressure transducer must be calibrated on the bench.

**NOTE**
Enter two different pressures in fields I1 and I2. If I1 = I2 a PLC error occurs. To correct the error, change I1 or I2, switch off the sterilizer and switch it on again.

If the above mentioned procedures do not allow to service failures mentioned in this paragraph, or in case of unexpected failures, it is strongly recommended to contact FEDEGARI’s Service Centers.
8.3.4.12. Checking instruments with a control pressure gauge

This check allows to monitor the machine pressure gauges and pressure transducer. Connect a precision pressure gauge to the related connection provided on the sterilizer (see 8.13) or on the steam generator (see 8.14). Measure pressure and vacuum, while comparing the control pressure gauge data to the data indicated by the machine instruments.

Figure 8.13 – Precision pressure gauge connected to the sterilizer

Figure 8.14 – Precision pressure gauge connected to the steam generator
8.3.4.13. Checking the chamber internal temperature with control sensors

The sterilizer can be fitted with control sensors through a suitable TT connection (see Figure 8.15). Fit the thermocouples or, if necessary, the heat probes, through this connection and place them in the chamber according to the temperature map to be carried out.

Carry out all measurements and recordings using the control instruments and performing the cycles to be monitored.

![Figure 8.15 - Validation sensor connection](Image)

8.3.4.14. Checking print quality, paper amount and feed (if a printer is available)

Every day, before starting the machine:

1. Make sure that paper is available. To this end, check the paper roll. Printer paper must be properly aligned and the roll must have enough paper. The roll diameter must allow to complete a sterilization cycle printing. If paper is lacking, feed the printer with new paper, according to the following procedure, i.e. replace the old roll with a new one.
   - Open the printer cover;
   - Press the up–and–over support of the printing device (where the PUSH message is indicated);
   - Fit the paper edge in the feed slot;
   - Load the new roll;
   - Press the up–and–over support of the printing device (where the PUSH message is indicated);
8.4. TROUBLESHOOTING

8.4.1. Replacing the operator panel battery

1. Switch the sterilizer off;
2. Remove the rear cover screw using a screw–driver;
3. Remove the rear cover, without damaging the flat cable connecting the serial interface module to the controller;
4. Remove the battery from its housing;
5. Install the new battery (3V lithium type DL2430 or equivalent);
6. Reassemble the rear cover and screw it (check that the flat cable is properly positioned);
7. Switch on the machine (check that the operator panel self–diagnosis page warns that the battery is charged).

8.4.2. Clearing paper jams (if a printer is available)

1. Open the printer cover;
2. Remove jammed paper from the feed slot;
3. Cut and remove jammed and damaged paper from the roll;
4. Fit the paper edge in the feed slot and press the paper feed button to make it protrude on the opposite side.
8.4.3. **Replacing the sterile filter**

1. Loosen the quick connection clamp connecting the compressed air unit to the chamber inlet unit;
2. Unscrew the filter of the two inlet and outlet fittings;
3. Screw the new filter to the fittings;
4. Fit the unit in the quick connection and tighten the clamp.

![Sterile Filter](image)

**Figure 8.17 – Sterile filter**

8.4.4. **Replacing the PLC battery**

When the sterilizer being activated, the “ERR” led located on the PLC control card is lighted (see Figure 8.18) the PLC RAM battery might be discharged.

To replace it:

1. Switch the sterilizer off;
2. Power off the machine. Wait one minute, and replace the battery within three minutes;
3. Remove the upper screws of the rear cover of the console/electronic process controller;
4. Check that led “ERR” on the PLC control card is lighted;
5. With a flat screwdriver, lift the battery and take it out of the battery holder (see Figure 8.19);
6. Install the new battery (3V lithium type BR2032/CR2032/DL2032 or equivalent) in the battery holder, by sliding it on its side, with the positive face (+) facing upwards (see Figure 8.20);
7. Check that LED “RUN” is lighted;
8. Close the rear cover and screw it;
9. Turn on the sterilizer again.

**NOTE**
Before fitting a new battery, make sure that its surface is free from foreign matters.
Figure 8.18 – Control card

Figure 8.19 – Discharged battery removal

Figure 8.20 – Fitting a new battery
8.4.5. Replacing the power cable

To replace the power cable, proceed as follows:

1. Turn the steriliser off;

   CAUTION
   Before carrying out any maintenance operation, ALWAYS turn OFF the main power switch of the steriliser and disconnect the equipment from power supply network, except if otherwise specifically indicated.

   NOTE
   All cables used in the electrical board must be suitable to withstand a working temperature above 70°C.

2. Using a recessed head wrench (Allen), release the strain release clamp located on the bottom at the rear of the machine and free the cable;
3. Open the electrical board door;
4. Remove master switch from the relative guide (see Figure 8.21);
5. Remove the terminal board covers on the upper part of the master switch of the device;
6. Loosen the lugs and free the wires;
7. Loose the connection nut of the protection wire [PE] on the earth bar in the lower part of the electrical board and free and remove the cable;
8. Insert the new cable, and install it like the old cable;

   ATTENZIONE!
   Keep the length of the protection wire [PE] at least the double compared to the other wires. In this way it is possible to avoid, in case the protection wire is accidentally pulled, that it is stressed before wires R–S–T–N.

9. Connect the protection wire to the [PE] lug on the earth bar and tighten the nut securely;
10. Tighten the power supply cables onto the terminal board of the power cut-out switch, ensuring that the phases and the neutral wires are connected to the correct positions R–S–T–N (see Figure 8.21);
11. Replace the terminal covers;
12. Insert master switch into the relative guide and close the electrical board;
13. Secure the cable in the strain relief clamp by tightening the nuts.

---

Figura 8.21 – Replacing the power cable: Power cut-out switch.
8.4.6. Replacing fuses

**NOTE**
The fuses positioned inside the electrical board must be replaced by a qualified personnel. The operator must not carry out this type of maintenance.

The electrical board's fuses are shown in Figure 8.22 while the relevant types, dimensions and quantities are indicated in Table 8.1.

*Figure 8.22 – Electrical board – fuses’ arrangement*
Table 8.1 – Fuses’ identification

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To replace fuses, proceed as follows:

1. Turn off the sterilizer;

**CAUTION!**

Before carrying out any maintenance job on the sterilizer, ALWAYS TURN IT OFF, unless otherwise indicated, by switching off the master switch and disconnecting the equipment from the network supply.

2. Open the electrical board’s door;

3. To access fuses F1 – F2 – F3 – F4 – F5 – F6 – F7 – F8 – FCP – FPA – FV open the cover of the relevant fuse–holder, as shown in Figure 8.23;

4. Remove the damaged fuse from its seat and replace it with a new fuse;

5. Re–close the fuse–holder cover.

*Figure 8.23 – Replacing fuses F1 – F2 – F3 – F4 – F5 – F6 – F7 – F8 – FCP – FPA – FV*
6. To access fuses F10 open the cover of the relevant fuse–holder, as shown in Figure 8.24;
7. Remove the damaged fuse from the relevant seat and replace it with a new one;
8. Re–close the fuse–holder cover.

![Image of F10 fuse holder]

**Figure 8.24 – Replacing fuses F10**

9. To access fuses Q1 open the cover of the relevant fuse–holder, as shown in Figure 8.25;
10. Remove the damaged fuse from the relevant seat and replace it with a new one;
11. Re–close the fuse–holder cover;

![Image of Q1 fuse holder]

**Figure 8.25 – Replacing fuses Q1**

12. Close the electrical board.
## ENCLOSURES

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POSITION OF CONNECTION IS INDICATIVE IN ORDER TO LET CUSTOMER DEFINE AREA WHERE UTILITIES SHOULD BE AVAILABLE ONCE STERILISATOR IS INSTALLED IT IS CUSTOMER DUTY TO CONNECT UTILITIES PIPINGS TO EACH SPECIFIC EQUIPMENT INSIDE THE STERILIZER.

ALLACCIMENTO UTENZE — UTILITIES HOOK-UP

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PESSO INDICATIVO AUToclave VUOTA
EMPTY AUToclave APPROX. WEIGHT

MACHINE FVA3

GROUP LAY OUT

DESCRIPTION

INSTALLATION DRAWING

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Written by: PIB
Issue date: 24/05/01
Issued by: ING
File: TD-65216 Rev.1
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* A ISPESL 400 V 50 Hz  C ASIT 400 V 50 Hz  F ASME 460/480 V 60 Hz
A1 ISPESL 220 V 50 Hz  D TUEV/A 400 V 50 Hz  F1 ASME 220 V 60 Hz
B TUEV/D 400 V 50 Hz  E APAVE 400 V 50 Hz  H MOL 200 V 60 Hz

Approved by: FAF  Written by: PIB
Issue date: 24/05/01  Issued by: ING
File: TD-65216  Rev.1  Page 3 of 3
### Terminal board: -XG

Total 2 terminals

- G1E1 -0# T 1 /1.7 SGV05 G1E 1
- G1E2 -0# H 2 /1.7 SGV05 G1E 2

### Terminal board: -XG

Total 15 terminals

- G1E 1 ME13 3 1 /1.5 SGV05 XG 3
- G1E 2 ME13 2 2 /1.5 SGV05 XG 2
- G1E 3 ME13 1 3 /1.5 SGV05 XG 3
- G1E 4 -E006 4 4 /1.5 SGV05 XG 4
- G1E 5 -E006 5 5 /1.5 SGV05 XG 5
- G1E 6 /1.6 SGV05 XG 6
- G1E 7 /1.6 SGV05 XG 7
- G1E 8 -P004 1 8 /1.7 SGV05 XG 8
- G1E 9 -P004 3 9 /1.7 SGV05 XG 9
- G1E 10 -L001 10 /1.7 SGV05 XG 10
- G1E 11 -L001 11 /1.7 SGV05 XG 11
- G1E 12 -L001 12 /1.7 SGV05 XG 12
- G1E 13 -L002 13 /1.8 SGV05 XG 13
- G1E 14 -L002 14 /1.8 SGV05 XG 14
- G1E 15 -L002 15 /1.8 SGV05 XG 15

### Terminal board: -J2

Total 4 terminals

- SBV04 J2-1 1 /1.7 SGV05 J2-1
- SBV04 J2-2 2 /1.7 SGV05 J2-2
- SBV04 J2-3 3 /1.8 SGV05 J2-3
- SBV04 J2-4 4 /1.8 SGV05 J2-4

### Terminal board: -PV

Total 6 terminals

- 70 -A2 13 1 /2.6 SPV01 PY-1 70
- 37 -A2 12 2 /2.6 SPV01 PY-2 37
- 37 -K1 A3 3 /2.6 SPV01 PY-3 37
- 0 -K2 A2 4 /2.6 SPV01 PY-4 0
- 10 -K2 13 5 /2.7 SPV01 PY-5 10
- 0 -K1 14 6 /2.7 SPV01 PY-6 0

### Terminal board: -XPV

Total 2 terminals

- SPV01 -E031 1 /2.5 SPV01 XPV 1
- SPV01 -E031 2 /2.5 SPV01 XPV 2

### Terminal board: -J3

Total 3 terminals

- SBV05 J3-1 1 /2.7 SPV01 J3-1
- SBV05 J3-2 2 /2.7 SPV01 J3-2
- SBV05 J3-3 3 /2.7 SPV01 J3-3

### Terminal board: -X

Total 3 terminals

- X1 -F1 18V 1 /3.2 SBV05 X 1
- X2 -F2 0V 2 /3.2 SBV05 X 2
- X3 -F3 18V 3 /3.2 SBV05 X 3
- X4 -F4 0V 4 /3.2 SBV05 X 4

### Terminal board: -XP

Total 5 terminals

- XP1 -0# 5 1 /3.2 SBV05 XP 1
- XP2 -0# 5 2 /3.2 SBV05 XP 2
- XP3 -0# 5 3 /3.2 SBV05 XP 3
- XP4 -0# 5 4 /3.2 SBV05 XP 4
- XP5 PE 5 /3.2 SBV05 XP 5
<table>
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<tr>
<th>Wire description</th>
<th>Start terminal</th>
<th>Wiring List</th>
<th>Stop terminal</th>
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**Terminal board: -XA**
Total 15 terminals

- X41 P001 1
- X42 P001 2
- X43 P001 3
- X44 P001 4
- X45 P001 5
- X46 P001 6
- X47 P001 7
- X48 P001 8
- X49 P001 9
- X50 P001 10
- X51 P001 11
- X52 P001 12
- X53 P001 13
- X54 P001 14
- X55 P001 15

**Terminal board: -X2**
Total 26 terminals

- X2-1 E005 1
- X2-2 E005 2
- X2-3 E005 3
- X2-4 E005 4
- X2-5 E005 5
- X2-6 E005 6
- X2-7 E005 7
- X2-8 E005 8
- X2-9 E005 9
- X2-10 E005 10
- X2-11 E005 11
- X2-12 E005 12
- X2-13 E005 13
- X2-14 E005 14
- X2-15 E005 15
- X2-16 E005 16
- X2-17 E005 17
- X2-18 E005 18
- X2-19 E005 19
- X2-20 E005 20
- X2-21 E005 21
- X2-22 E005 22
- X2-23 E005 23
- X2-24 E005 24
- X2-25 E005 25
- X2-26 E005 26
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### Terminal Board: -XPL

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### Terminal Board: -XPR

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### Terminal Board: -XPR1

**Total 2 terminals**

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### Terminal Board: -XVE

**Total 4 terminals**

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<th>SB/VOS</th>
<th>XVE 1</th>
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<tr>
<td>XVE2</td>
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<td>XVE3</td>
<td>ME12</td>
<td>BK</td>
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### Terminal Board: -X3

**Total 4 terminals**

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<th>SB/VOS</th>
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### Terminal Board: -X1

**Total 16 terminals**

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