

# USER INSTRUCTION

## STEAM STERILIZER TYPE AS 66

 <sup>93/42/EEC</sup>  
2274

 <sup>2014/68/EU</sup>  
2274

SN



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## 1. RANGE OF MANUAL APPLICABILITY, EXPLANATIONS

This AS 66 range sterilizer operation manual describes the following types and versions of sterilizers:

| Sterilizer type | Version        |
|-----------------|----------------|
| AS 666          | A, WA, PA, WPA |
| AS 669          | A, WA, PA, WPA |
| AS 6612         | A, WA, PA, WPA |
| AS 6615         | A, WA, PA, WPA |
| AS 6618         | A, WA, PA, WPA |

Descriptions of version symbols:

**A** – denotes a sterilizer with an external source of steam, with a single-ended chamber (door on one side)

**WA** – denotes a sterilizer with an integral steam generator, with a single-ended chamber (door on one side).

**PA** – denotes a sterilizer with an external source of steam, with a double-ended chamber (door on both sides)

**WPA** – denotes a sterilizer with an integral steam generator, with a double-ended chamber (door on both sides)

**ABRIDGED OPERATING INSTRUCTION OF THE AS 66 TYPE STERILIZER** should be placed (hung) in the vicinity of the sterilizer either in a loading side or an unloading side.

Indications included in this manual and labelled **warning**, **important** and **attention** are very important and to draw attention to them. They are marked with the following graphical symbols.

### Warning



Failing to observe these warnings can cause injury and even death. This symbol also means that an operator must acquaint with a suitable passage in the manual.

### Important



This symbol denotes important indications for example to prevent sterilizer or load damage.

### Attention



Observing the texts marked with this symbol facilitates operation of the sterilizer

|   |   |
|---|---|
|  | <p><b>MANUFACTURER IS NOT RESPONSIBLE AND MAKES NO WARRANTY IF:</b></p> <ul style="list-style-type: none"> <li>• lack of or non-compliance with the timing of the routine maintenance of the sterilizer;</li> <li>• carrying out commissioning, maintenance and repairs of the sterilizer by not authorized by the manufacturer personnel;</li> <li>• usage sterilizer in conditions other than those specified in the User instruction;</li> <li>• make any changes in the design of a sterilizer (drilling additional holes, welding additional elements etc.);</li> <li>• mechanical, chemical and thermal damage of the sterilizer and its components;</li> <li>• change the setting of safety valves opening pressure, pressure gauges repairs and break their seals by unauthorized person;</li> <li>• sterilizer damage caused by extreme conditions or force majeure (fire, flood and other natural disasters)</li> </ul> |
|---|---|

|  |   |
|--|---|
|  | <p><b>FAILURE TO EVEN PART OF THE REQUIREMENTS OF THE MANUAL, MAY RESULT IN CANCELLATION OF ALL WARRANTIES AND LIABILITIES OF THE MANUFACTURER.</b></p> |
|--|---|

|   |   |
|---|---|
|  | <p><b>Access to sterilizer operations manual should be restricted only to persons authorized to operate a sterilizer.</b></p> |
|---|---|

|   |   |
|---|---|
|  | <p><b>During an installation of a sterilizer, after maintenance performed by technical staff and during power outlet exchange, the verification of null electric potential of the elements being touched by users should absolutely be performed by authorized staff.</b></p> |
|---|---|

## 2. APPLICATION OF A STERILIZER

Steam sterilizers of AS 66 type are used to sterilize medical products, one or more load units of packaged objects such as tools, textiles, rubber products etc. and porous load. Sterilizers can also be used in the process of industrial production of medical products. Other uses require consulting a sterilizer manufacturer and must be approved by the consent.

Steam sterilizers of AS 66 type are used mainly to equip sterilizer rooms. In case of lack of dedicated sterilizers (with rapid cooling) they can be installed in infusion solutions plants or milk kitchens.

|   |   |
|---|---|
|  | <p><b>Manufacturer does not take responsibility if a sterilizer is not used within its intended application area.</b></p> |
|---|---|

### 3. PROGRAMS

A sterilizer can perform sterilizing programs intended for different groups of material being sterilized and test programs: a Bowie-Dick test and a sterilization chamber air leakage test.

| №  | Name of the program | Factory settings  |
|----|---------------------|---|
| 1  | P01 Textile         | The program is used to sterilize heat-sensitive <b>packaged</b> products and textiles. Sterilization temperature <b>121°C</b> , exposure time <b>20 min</b> , drying time <b>20 min</b> .   |
| 2  | P02 Instruments     | The program is used to sterilize instruments and accessories <b>packaged</b> in paper-plastic bags. Sterilization temperature <b>134°C</b> , exposure time <b>5 min</b> , drying time <b>20 min</b> .                                   |
| 3  | P03 Test B-D        | Bowie-Dick test. Sterilization temperature <b>134°C</b> , exposure time <b>3.5 min</b> , drying time <b>8 min</b> .   |
| 4  | P04 Solutions       | The program is used to sterilize materials vacuum-sensitive and fluids in special containers. Sterilization temperature <b>121°C</b> , exposure time <b>20 min</b> , no dry.  |
| 5  | P05 Rubber          | The program is used to sterilize <b>packaged</b> rubber products (gloves, drain etc.) or low temperature resistant plastic. Sterilization temperature <b>121°C</b> , exposure time <b>20 min</b> , drying time <b>10 min</b> .          |
| 6  | P06 Prion           | The program is used to sterilize instruments and accessories packaged in paper-plastic bags. Sterilization temperature <b>134°C</b> , exposure time <b>18 min</b> , drying time <b>15 min</b> .   |
| 7  | P07 Flash           | The program is used to sterilize <b>non-packed</b> instruments and accessories. Sterilization temperature <b>134°C</b> , exposure time <b>5 min</b> , drying time <b>1 min</b> .  |
| 8  | P08 User Program    | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>121°C</b> , exposure time <b>30 min</b> , drying time <b>20 min</b> |
| 9  | P09 User Program 1  | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>121°C</b> , exposure time <b>30 min</b> , drying time <b>30 min</b> |
| 10 | P10 User Program 2  | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>121°C</b> , exposure time <b>30 min</b> , drying time <b>40 min</b> |
| 11 | P11 User Program 3  | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>134°C</b> , exposure time <b>5 min</b> , drying time <b>40 min</b>  |

| №  | Name of the program            | Factory settings  |
|----|--------------------------------|---|
| 12 | P12 User Program 4             | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>134°C</b> , exposure time <b>10 min</b> , drying time <b>30 min</b> |
| 13 | P13 User Program 5             | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>134°C</b> , exposure time <b>10 min</b> , drying time <b>40 min</b> |
| 14 | P14 User Program 6             | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>132°C</b> , exposure time <b>8 min</b> , drying time <b>20 min</b>  |
| 15 | P15 User Program 7             | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>121°C</b> , exposure time <b>25 min</b> , drying time <b>30 min</b> |
| 16 | P16 User Program 8             | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>121°C</b> , exposure time <b>25 min</b> , drying time <b>40 min</b> |
| 17 | P17 User Program 9             | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>134°C</b> , exposure time <b>7 min</b> , drying time <b>30 min</b>  |
| 18 | P18 User Program 10            | The program can be programmed by operator and used to sterilize different materials (which couldn't be sterilized in program P01-P07). Sterilization temperature <b>134°C</b> , exposure time <b>7 min</b> , drying time <b>40 min</b>  |
| 19 | P19 Solutions 1                | The program is used to sterilize materials vacuum-sensitive and fluids in special containers. Sterilization temperature <b>121°C</b> , exposure time <b>20 min</b> , no dry.  |
| 20 | P20 Solutions 2                | The program is used to sterilize materials vacuum-sensitive and fluids in special containers. Sterilization temperature <b>121°C</b> , exposure time <b>25 min</b> , no dry.  |
| 21 | <b>VACUUM TEST (LEAK TEST)</b> | The Leak Test of sterilization chamber. Stabilization time <b>5 min</b> , testing time <b>10 min</b> . Allowable pressure increase <b>1,3 kPa</b> .   |

## 4. THE DESCRIPTION OF THE STERILIZER

### 4.1. Technical description

Steam sterilizers of AS 66 type were designed in accordance with European Standards to work with standard load units: 300x300x600 mm. Our recommended packaging system (baskets, trays, boxes) and transport system (loading carts and transport trolleys) also meet these requirements.

Technical properties:

- double-ended – door are located on the opposite sides of the sterilizer chamber or single-ended – door located on one side of the chamber,
- Steam supply from an external or integral (built-in) steam generator,
- Sterilizing chamber, heating jacket, door(s) and steam generator are made of acid proof stainless steel AISI 316L,
- Casing made of stainless steel
- Venting phase consisting of fractionated vacuum,
- Automatic microprocessor control,
- Verification of particular phases of a sterilization cycle,
- Simple operation of 21 programs (including two test programs),
- Full colour LCD (liquid crystal) display with touch-screen to inform the operator about current status of the sterilizer (sterilizing cycle phase, failure etc.),
- Sterilization cycle parameters logger independent from control circuit,
- Built-in printer for sterilization cycle report (identification of the sterilizer, parameters of the selected program, temperature and pressure in a sterilization chamber, date and time etc.)
- Digital display of a pressure in the chamber and in the jacket,
- Double temperature sensor for independent verification of sterilizing cycle,
- Absolute pressure transmitter – indications independent of atmospheric pressure,
- Easy and comfortable operation,
- Simple installation.

### 4.2. Sterilizing chamber

Sterilizing chamber together with a heating jacket are made of stainless chrome-nickel-molybdenum steel. All the internal surfaces of the chamber and the doors were subject to special finishing.

The sterilizing chamber is equipped with a heating jacket ensuring uniform heating of the chamber walls to a sterilization temperature. Appropriately shaped nozzles placed at the steam intake allow for uniform and efficient distribution of steam inside the chamber and do not cause local overheating. The distribution of temperatures inside the chamber was frequently tested. Years of experience allowed us to build the chamber, where the temperature measured at different points do not differ by more than 1°C.

Chamber with a heating jacket is isolated by an appropriate layer of mineral wool, limiting the heat transfer to the exterior and guaranteeing safe operation of the device.

Versatility of a sterilizer is guaranteed by a separation of a sterilization chamber and a heating jacket from a steam generator or an external source of steam. The steam from a generator enters the heating jacket and through a cut-off valve into the chamber. This configuration allows for a good heating of the chamber before it is loaded and closed. This significantly reduces steam condensation on the walls during steam intake and moisturizing of sterilized objects which is connected with it.

Separation of the chamber from a heating jacket allows also for creating a fractionated vacuum before exposure phase. It secures good venting of loaded chamber and, after an exposure phase, it allows for creating negative pressure which causes rapid drying of loaded material. During drying process there is a working steam pressure in a steam generator and a heating jacket, which makes the device immediately ready for next sterilization cycle. Such a system ensures maximum efficiency of the device and an uninterrupted operation.

The sterilizing chamber is equipped with two measurement connectors. The connector for a measuring instrument: connector for pressure measuring instrument – pipe thread ISO 228-G $\frac{1}{2}$  A, and the connector for temperature probes – pipe thread ISO 228-G1 A.

### **4.3. Door**

Chamber door in form of a flat, rectangular ribbed plate are guided by rails with a mounted safety interlocks to prevent the doors from falling off in case of lack of pressure in the servo. Releasing a blockade in order to open the door is performed by using a compressed air. Doors open under its own weight after depressurizing the cylinder. Clamps on the blockade block the start of a program in case the doors are not fully closed.

Door stops in any position in case of pressing a safety bar located on their upper edge.

Opening and closing the door is performed automatically after pressing a key.

An o-ring gasket located in chamber groove is a main element to hermetize the door. After the program is activated, the gasket is pressed against the door by a pressure of compressed air present in a groove, which ensures the tightness between the door and a sterilization chamber.

### **4.4. Steam supply system**

Depending on a version the sterilizer can be supplied with an external source of steam or by an integral – built-in steam generator or combination.

#### **4.4.1. Steam filter**

In case of using an external source of steam, the sterilizer is equipped with a highly efficient steam filter (separator). Its task is to separate the drops of water from steam.

#### **4.4.2. Steam generator**

Steam generator is made of acid-proof steel and equipped with a sight-glass to gauge water level. The sight-glass with reflexive glass is led to the front panel of sterilizer case. There are 6 electric heaters installed in the boiler.

### **4.5. Vacuum generating system**

The AS 66 type sterilizer is equipped with a vacuum water ring pump. Operating fluid (water) forming the rotating ring is fed continuously seals the chambers between the blades and is removed from the deflated air chamber. In order to reduce the consumption of water working fluid is separated from the air and is reused.

The vacuum generating system allows to achieve negative pressure, which is equal or less than -93 kPa (7 kPa of the absolute pressure).

### **4.6. Air filter**

Programs, the sterilizing cycle of which is completed by a vacuum drying phase, require direct ambient air supply to the sterilizing chamber. For this purpose the AS 66 steam sterilizer is equipped with a filter (sterile air filter) able to capture not less than 99,999% of particles larger than 0,30  $\mu\text{m}$ .

### **4.7. Emergency switch**

On the sterilizer front panel, on the loading and unloading side, emergency switches of double function are mounted:

- while the door is in motion, pressing the button makes the door stop instantly and an alarm message is displayed,
- pressing the button during sterilization interrupts the process. All valves supplying media to the chamber will be closed and the generator heaters off.

## 4.8. Control and verification system

Work of the sterilizer and a steam generator is controlled by Siemens S7-1200 controller.

All the activities such as the following: supplying steam into the chamber, maintaining constant temperature during the exposure phase, course of the cycle, opening and closing the doors, automatic filling of the steam generator boiler with water, inspection of heating elements are monitored on an ongoing basis by the monitoring system. The controller stores sterilization and test programs: Bowie-Dick test and chamber Leak test.

The self-diagnosing system is able to detect a number of conditions of the sterilizer:

- supply status of the working media (air, water);
- proper opening and closing of the doors, control their status (whether they are opened or closed);
- mode of operation (manual or automatic);
- underpressure or overpressure in the chamber;
- monitoring the course of the sterilization cycle (temperature sterilization failure);
- condition of the device components such as the contactors (vacuum pump locking, emergency stop button pressed).

The response of the system to a defect depends on its location (i.e. which part of the system is at fault), time of detection (i.e. during the sterilization phase or at any other time), and the impact of the defect to the process. The control system of the sterilizer makes decisions automatically, and the messages are displayed on the panel.

The parameter change section can be accessed using the service menu access code.

The device is operated via the "smart keyboard": only the keys, which are necessary for control purposes are active, the other remain inactive. For example, "Start" and "Door" keys are inactive during the process.

The following items are to be found in the upper part of sterilizer casing in a loading side: sterilizer power switch (pos. 1<sup>1)</sup> – drawings 1, 2), loading side control panel (pos. 3), manovacuumeter displaying the pressure of the steam in a generator (pos. 5), manovacuumeter displaying the pressure of the steam inside the chamber (pos. 4), sterilizing cycle parameters printer (pos. 6) and the emergency switch (pos. 8).

A steam generator water level gauge is to be found in the lower part of the casing (pos. 7) – for a version with its own (built-in) steam generator.

The following items are to be found in the upper part of a sterilizer case in an unloading side – (double-ended sterilizers only) – manovacuumeter displaying the pressure of the steam inside the chamber (pos. 4), a control panel (pos. 9) and the emergency switch (pos. 8).

### 4.8.1 Control elements

#### 4.8.1.1 Control panel in a loading side (Fig 1).

The items to be found on a loading side control panel.

- LCD (liquid crystal) display with touch-screen (3),
- mains switch (1),
- emergency switch (8),
- printer (6),
- manovacuumeters (4 - Chamber, 5 - Generator).
- water level gauge (7)

<sup>1)</sup> All the pos. descriptions relate simultaneously to drawings 1 and 2

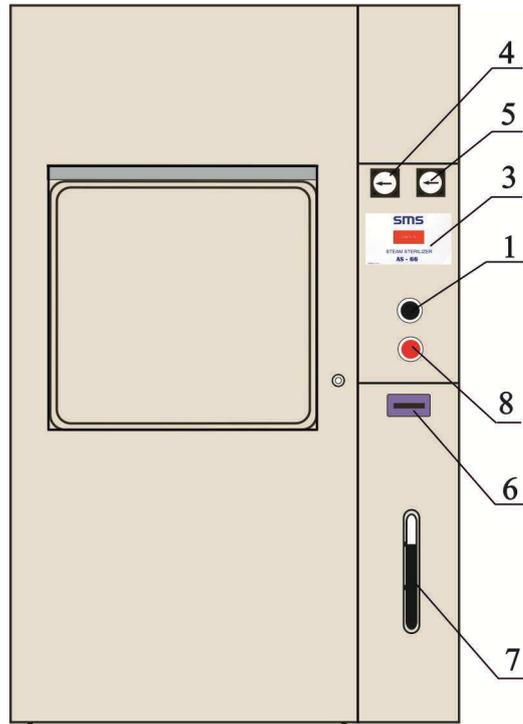


Fig. 1

#### 4.8.1.2 Control panel in an unloading side (Fig. 2a and Fig. 2b)

In an unloading side – (in double-ended sterilizers only), there is a control panel containing:

- control panel with four indicators and door control keys (9),
- emergency switch (8),
- manovacuumeter - pressure in the chamber (4).

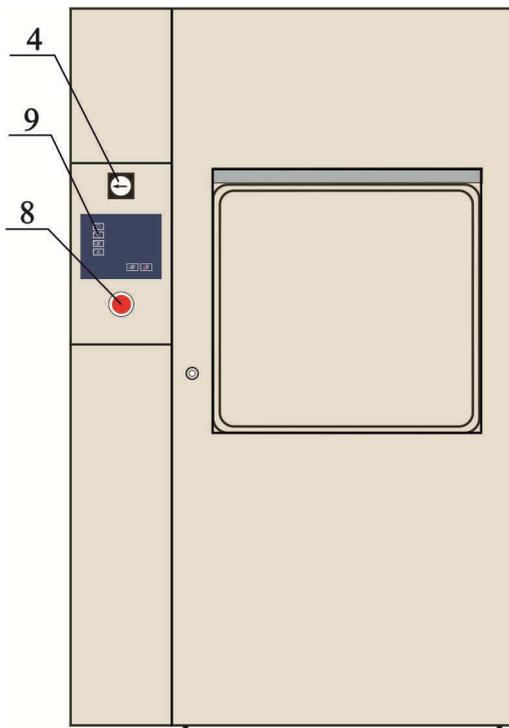


Fig. 2a

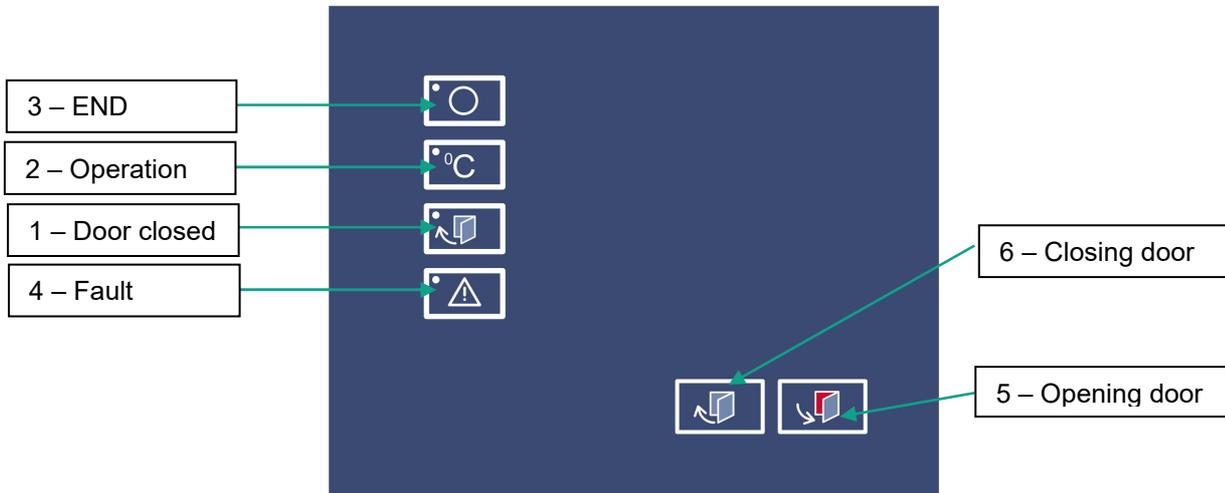


Fig. 2b

1 – "Door closed" indicator, which is lit when both doors are closed and flashes during the opening/closing operation of any door.

2 – "Operation" indicator, which is lit during the sterilization cycle.

3 – "End" indicator, which lights up at the end of the cycle. This is accompanied by a sound signal.

4 – "Fault" indicator, which lights up in the event of a fault. This is accompanied by a sound signal. The fault or the respective message is displayed on the control panel on the loading side.

5, 6 – back door control buttons. To close the door on the unloading side, press the button "6", to open the door on the unloading side press the button "5". An "Emergency Stop" button must not be pressed during this operation. The "6" button can be also used to clear the "End of cycle" message.

To ensure safe operation, the door unblock time is about 20 seconds.

- "Emergency Stop" button is designed to halt the selected sterilization mode and to lock the operation of all the sterilizer components. The button can be unlocked with a key and requires reset at the loading side.

## 4.9. Control elements – graphical user interface. Description

### 4.9.1. Introduction

The purpose of this chapter is to provide the user with information about the control system of AS 66 steam sterilizers. This section has the following:

- general description of the touch panel WEINTEK MT8073iE;
- explanation of the operation of the control system and of the manner of the performance of all the accessible graphical user interface actions;
- list of all displayable text and graphic messages, and signal lights caused by the system.

### 4.9.2. Description of the graphical user interface

WEINTEK MT8073iE touch panel with graphical user interface has the following features:

|                |                       |
|----------------|-----------------------|
| Screen size    | 7"                    |
| Resolution     | 800x480               |
| Brightness     | 400 cd/m <sup>2</sup> |
| Contrast       | 500:1                 |
| Colour palette | 16,7 mln              |
| Backlight      | LED                   |
| Matrix life    | >30000 h              |
| Sensor type    | 4-wire Resistive Type |

### Layout of the graphical user interface

The operator interface of the steam sterilizer comprises several screens. The current content of the display is referred to as a screen. There are several screens that display different information: temperature, pressure, text messages, icons representing switching on/off of the device components, buttons to navigate to other screens, etc. The operator may move to a different screen by pressing the appropriate button.

### Greening screen

Once the control system is switched, the monitor displays a splash screen as shown below.



Fig. 3

**Enter** – this button navigates to the main menu screen (Fig. 4).

**AS - 66** – sterilizer model.

**Software version** – the version of the installed software.

Press "Enter" to navigate to the main menu (Fig. 4).

## Main menu screen

The main screen displays the device status information (temperature, pressure, selected program, current step of the program, etc.), and the information about the start/stop of the sterilization process. It can also be used to navigate to other control screens.

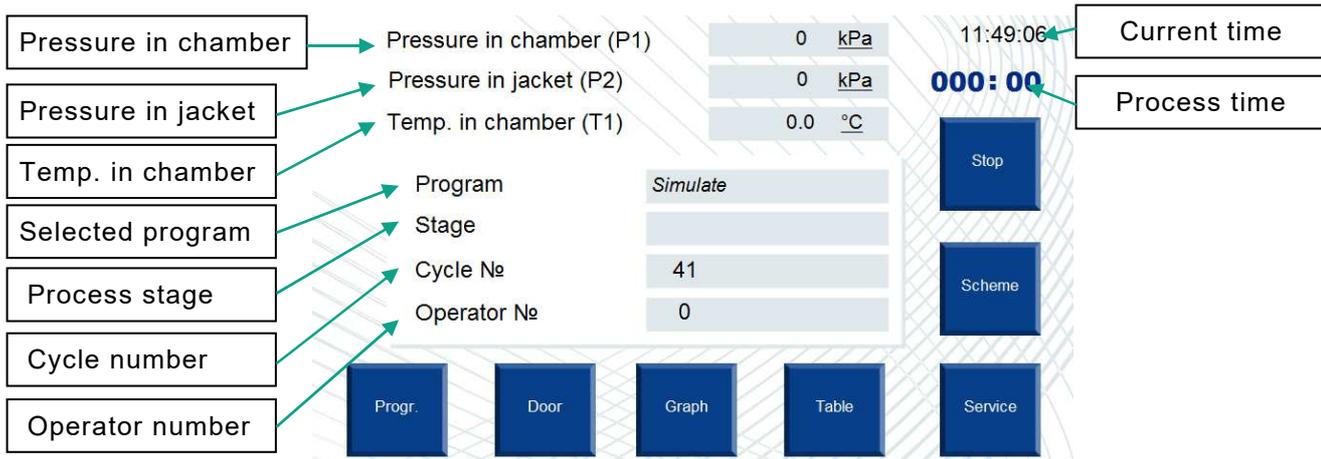


Fig. 4

If the device is in different modes, the windows display the relevant information.

**Pressure in chamber (P1)** – this window displays the current pressure in the chamber (kPa).

**Pressure in jacket (P2)** – this window displays the current pressure in the jacket (kPa).

**Temperature in chamber (T1)** – this window displays the current temperature in the chamber (°C).

**Note:** if the sensor T4 is chosen as a control sensor, Temperature in chamber (T4) will be displayed.

**Program** – this window displays the selected program. The following is displayed in the window, depending on the selected program:

- P01 Textiles;
- P02 Instruments;
- P03 Bowie-Dick;
- P04 Solutions;
- P05 Rubber;
- P06 Prion;
- P07 Flash;
- P08 User program;
- P09 User program 1;
- P10 User program 2;
- P11 User program 3;
- P12 User program 4;
- P13 User program 5;
- P14 User program 6;
- P15 User program 7;
- P16 User program 8;
- P17 User program 9;
- P18 User program 10;

- P19 Solutions 1;
- P20 Solutions 2;
- Simulation.

The „Simulation” message is displayed in this window during printer test. If no program is selected, this window is empty. To select the desired program, go to the program selection screen (Fig. 9) and press the respective button. The selected program is saved upon the completion of the cycle.

**Note: when the process starts, it is no longer possible to select a program. To choose a different program once the process has been started, stop the current process using the „Stop” button, confirm the termination of the program, and select a new program.**

**Stage** – this window displays the current stage of the program. The following stages are displayed, depending on the cycle:

- Pumping (deaeration, emptying, venting);
- Chamber heating;
- Sterilization (exposure);
- Steam pumping (exhaust, steam removing, decreasing);
- Drying;
- Cycle end (ending cycle, aeration).

At starting the work, the given window is empty.

**Cycle number**– this window displays the number of the performed cycle. The value decreases by one with each completed cycle. The counter is used to determine the status of the autoclave and is included in the printout.

**Operator number**– this window displays the number of the operator. The number is entered on the program selection screen (Fig. 9, 10).

**Current time** – the current time of the control system.

**Process time** – this window displays the time that has lapsed since the start of the process. Upon the completion of the process this value freezes until a new sterilization cycle starts.

**Program** – pressing this button navigates to the program selection screen (Fig. 9).

**Door** – pressing this button navigates to the front door control screen (Fig. 11). This button is not shown during the process. It is displayed only when the sterilizer is in the ready mode.

**Graph** – pressing this button navigates to the process graphs screen (Fig. 12).

**Table** – pressing this button navigates to the process table screens (depending of the selected program) (Fig. 14, 15).

**Service** – pressing this button navigates to the „Service” screen (Fig. 16). The „Service” screen can be accessed only after entering the password.



Fig. 5

**Scheme** – pressing this button navigates to the process flowchart screen (Fig. 17).

**Start** – pressing this button starts the process. The button is active only when the sterilizer is ready to run. The sterilizer is ready to run if the following conditions are met: the doors are closed, there is no emergency message, a sterilization program has been selected, pressure in the jacket reached Pmax for the selected sterilization program. Pressing this button displays the process start confirmation window (Fig.7).

If the number of the remained cycles to the maintenance is equal to 50, 25 or 0, or the maintenance deadline has expired, there will be a warning message about servicing. Service information may be different depending on the country of delivery:



Fig. 6

This message itself off after 10 seconds and will appear start the cycle window (Fig. 7)

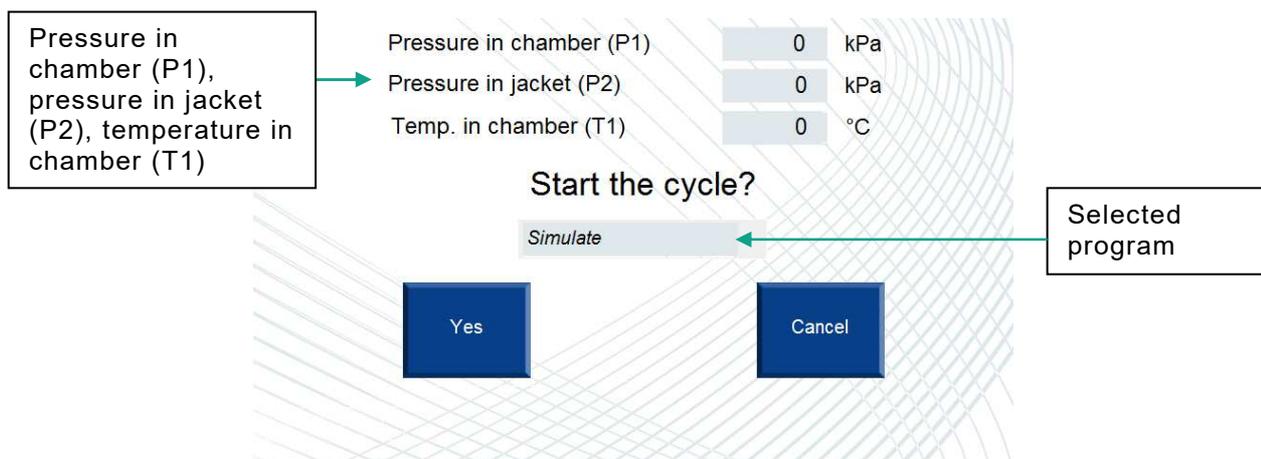


Fig. 7

The „Selected program” window displays the name of the program to be run.

Press „Yes” to start the cycle or „Cancel” to return to the previous menu.

**Stop** – pressing this button stops the process. When this button is pressed the cycle stop confirmation screen is displayed:

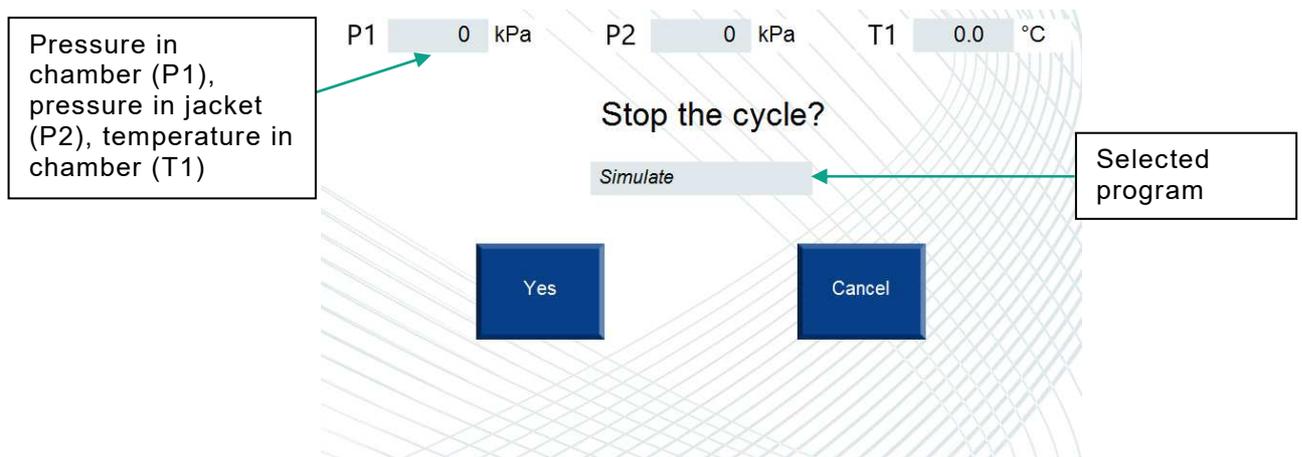


Fig. 8

The „Selected program” window displays the name of the current program. Press „Yes” to stop the cycle or „Cancel” to return to the previous menu.

## Program selection screen

The respective screen allows an operator to view the main settings of the sterilization programs, select the desired program and enter the operator number.

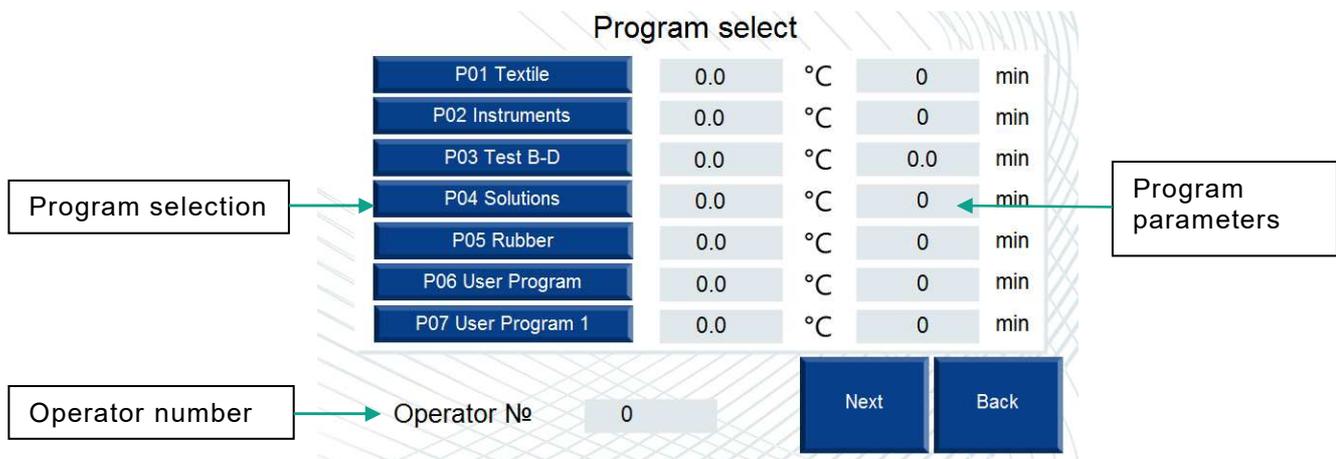


Fig. 9

**Program selection** – buttons to select desired programs. To select a program as the current program press its corresponding button.

**Operator number** – this window is used to enter the number of the operator (input range between 0 and 999). The operator number is used to identify the operator in the working process and is included in the printouts.

**Program parameters** – to facilitate the work, the boxes next to each program display the sterilization temperature and time.

**Next** – pressing this button navigates to the next program selection screen (Fig. 10).

**Back** – pressing this button returns to the main menu screen (Fig. 4).

### Program selection screen (Next)

This screen, as the screen Fig. 9 allows an operator to view the main settings of the sterilization programs, select the desired program and enter the operator number.

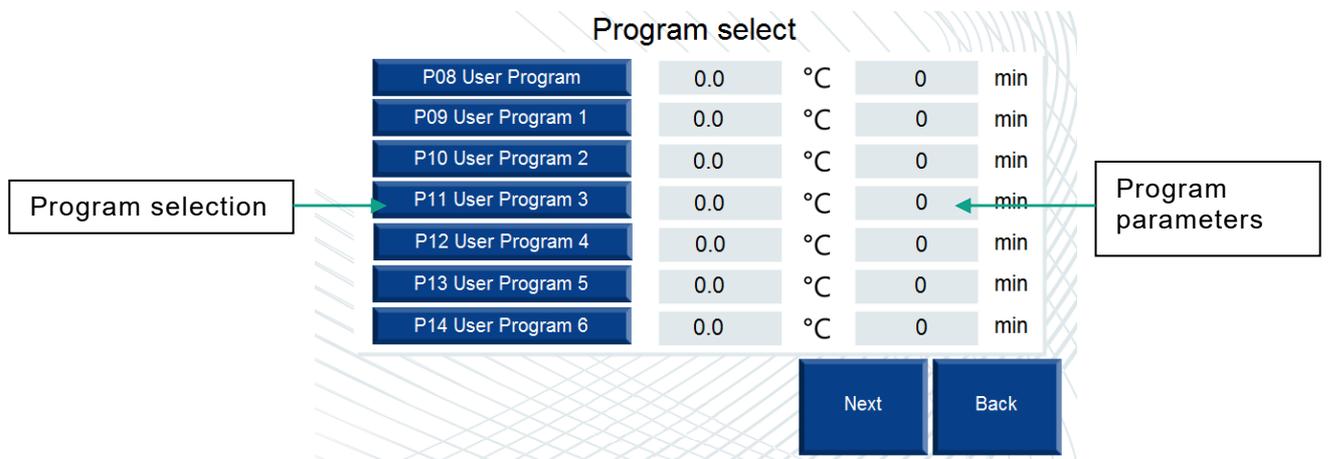


Fig. 10

**Program selection** – buttons to select desired programs. To select a program as the current program press its corresponding button.

**Operator number** – this window is used to enter the number of the operator (input range between 0 and 999). The operator number is used to identify the operator in the working process and is included in the printouts.

**Program parameters** – to facilitate the work, the boxes next to each program display the sterilization temperature and time.

**Next** – pressing this button navigates to the next program selection screen (Fig. 10a).

**Back** – pressing this button returns to the previous screen (Fig. 9).

### Program selection screen (Next)

This screen, as the screen Fig. 10 allows an operator to view the main settings of the sterilization programs, select the desired program and enter the operator number.

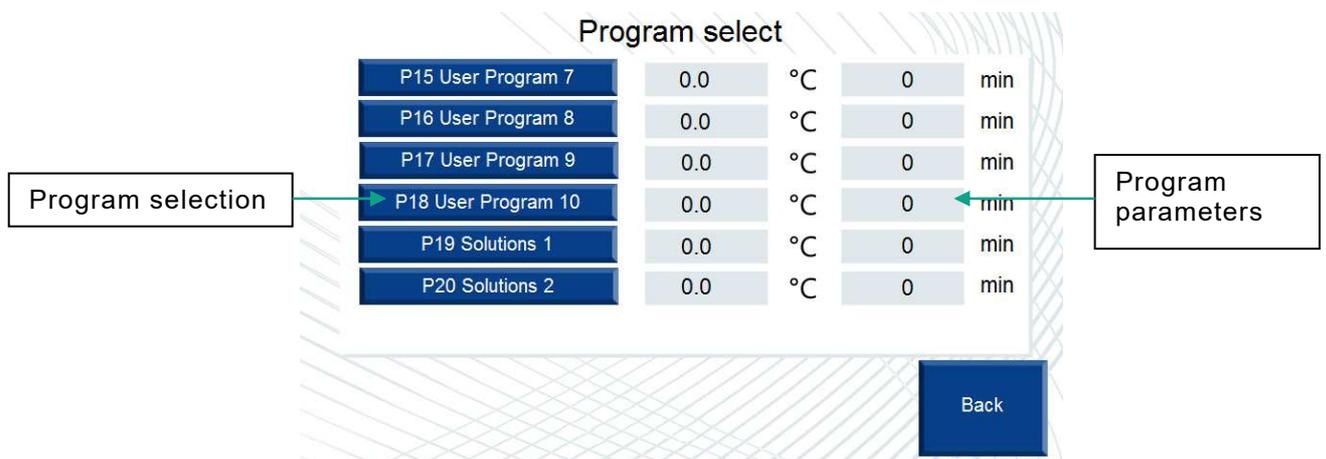


Fig. 10a

**Back** – pressing this button returns to the previous screen (Fig. 10).

## Front door control screen

This screen is used to operate (open/close) the front door and to check their status.

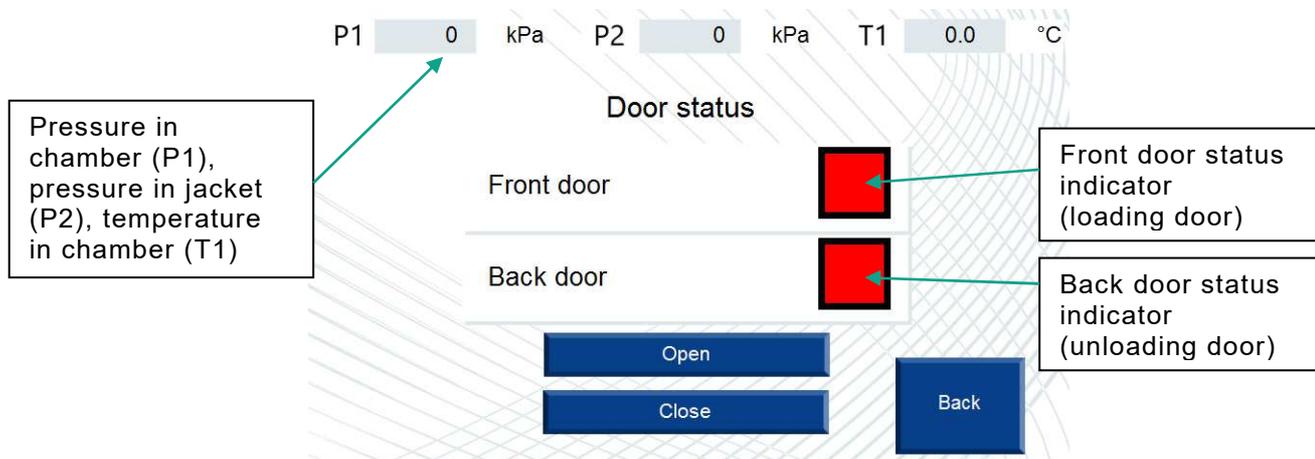


Fig. 11

**Front door** – this indicator signals the position of the front door. It is green if the front door is closed and red if it is open.

**Back door** – this indicator signals the position of the back door (only in sterilizer with double door). It is green if the back door is closed and red if it is open.

**Open** – pressing this button opens the front door.

**Close** – pressing this button closes the front door.

**Back** – pressing this button returns to the main menu screen (Fig. 4).

## „Graph” screen

This screen displays the chamber pressure and temperature as a graph. The graph allows the operator to monitor the process in real time.

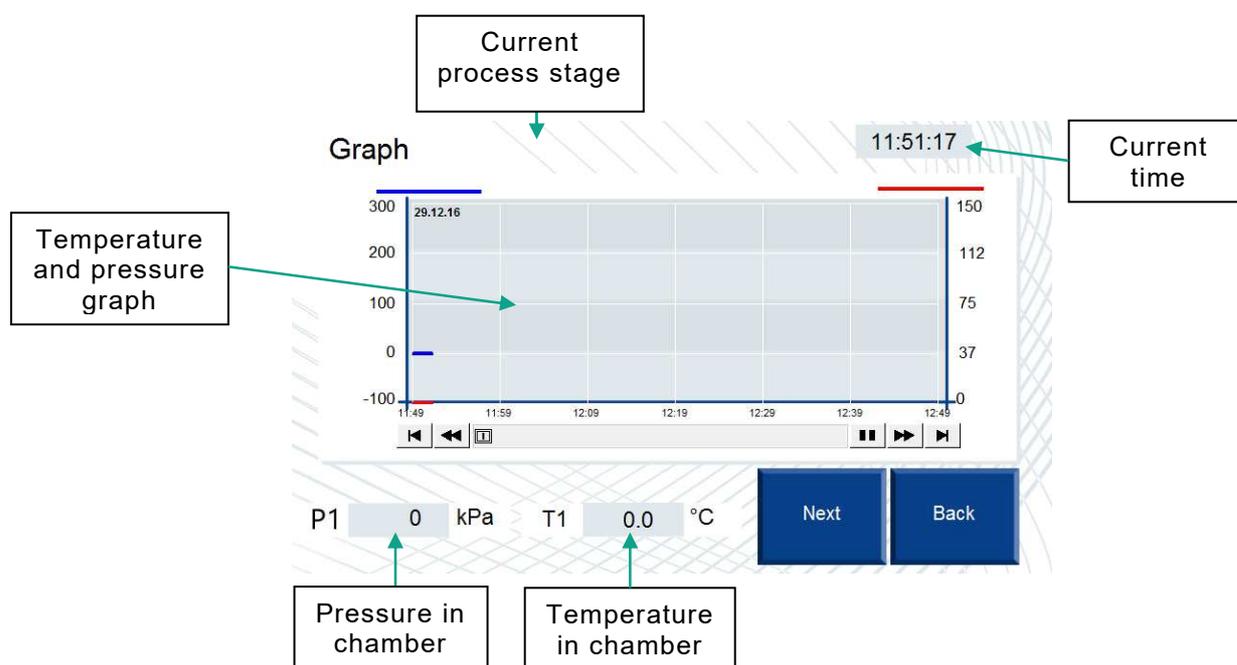


Fig. 12

**Pressure in chamber** – this box displays the current pressure in the sterilizer chamber, kPa.

**Temperature in chamber** – this box displays the current temperature in the sterilizer chamber, °C.

**Current time** – the current time of the control system.

**Stage** – this window displays the current stage of the program. The following stages are displayed, depending on the cycle:

- Pumping;
- Chamber heating;
- Sterilization;
- Steam pumping;
- Drying;
- Cycle end.

Upon starting the work, the given window is empty.

**Next** – pressing this button moves an operator to the Data Base screen (Fig. 13).

**Back** – pressing this button returns to the main menu screen (Fig. 4).

## „Data base” screen

This screen is intended for display of pressure and temperature in the chamber. The table allows an operator to watch process in real time and save data to HMI memory.

**Note:** the table will be filled in, if a process is started.

**Data base**

| Time     | Date     | Pressure | Temperature |
|----------|----------|----------|-------------|
| 18:53:33 | 26/12/16 | -200     | 25.0        |
| 18:53:32 | 26/12/16 | -200     | 25.0        |
| 18:53:31 | 26/12/16 | -200     | 25.0        |
| 18:53:30 | 26/12/16 | -200     | 25.0        |
| 18:53:29 | 26/12/16 | -200     | 25.0        |
| 18:53:28 | 26/12/16 | -200     | 25.0        |
| 18:53:27 | 26/12/16 | -200     | 25.0        |
| 18:53:26 | 26/12/16 | -200     | 25.0        |
| 18:53:25 | 26/12/16 | -200     | 25.0        |
| 18:53:24 | 26/12/16 | -200     | 25.0        |
| 18:53:23 | 26/12/16 | -200     | 25.0        |
| 18:53:22 | 26/12/16 | -200     | 25.0        |
| 18:53:21 | 26/12/16 | -200     | 25.0        |
| 18:53:20 | 26/12/16 | -200     | 25.0        |
| 18:53:19 | 26/12/16 | -200     | 25.0        |

**Back**

Fig. 13

**Time** – the current time of the panel of the operator. Selection of data is carried out with an interval of 5 sec.

**Date** – the current date of the control panel.

**Pressure** –the current pressure in the sterilizer chamber (P1 sensor, kPa) is displayed in this column;

**Temperature** –the current temperature in the chamber (T2 sensor, °C) is displayed in this column;

**Back** – the button to return to the “Graph screen” (fig. 12).

## „Table” screen

This screen displays the course of operation of the device. This menu displays the program settings and the degree of its completion.

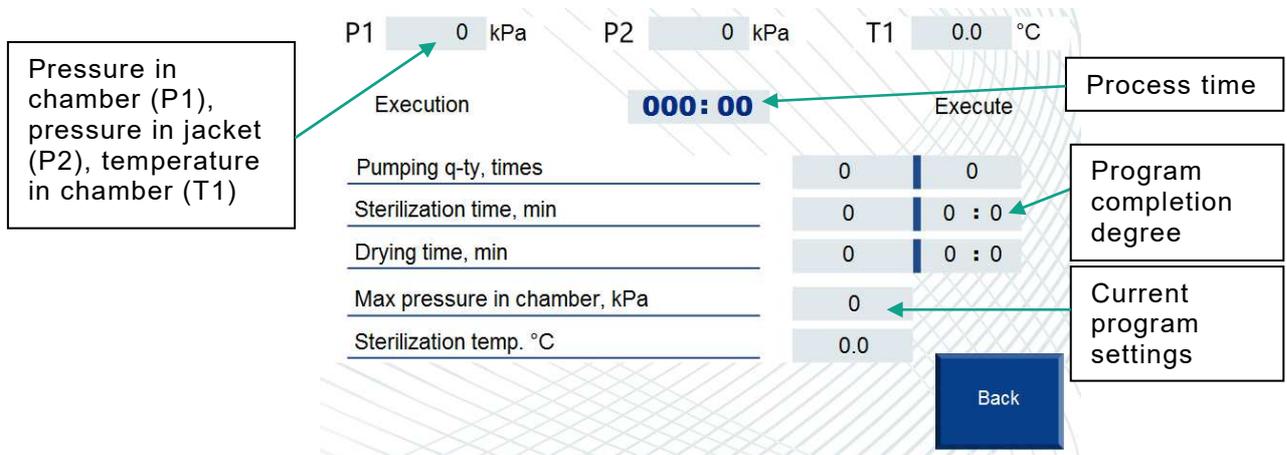


Fig. 14

**Current program settings** – in the cells of this column the settings of the selected program are displayed.

**Note:** all settings (except maximum pressure in the chamber) are available only for monitoring. The value of maximum pressure in the chamber can be changed during operation directly by the operator. To change the value, press the appropriate number and enter a new value using the appeared keyboard.

**Note:** when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!

**Program completion degree** – the boxes in this column display the information on the degree of completion of the program. The data is displayed in seconds.

**Process time** – the time that has lapsed since the start of the process.

**Back** – pressing this button returns to the main menu screen (Fig. 4).

## „Table of solution program” screen

This screen displays the course of operation of the device. This menu appears, a programs “P04 Solutions”, “P13 Solutions 1”, “P14 Solutions 2” are selected. This menu displays the program settings and the degree of its completion.

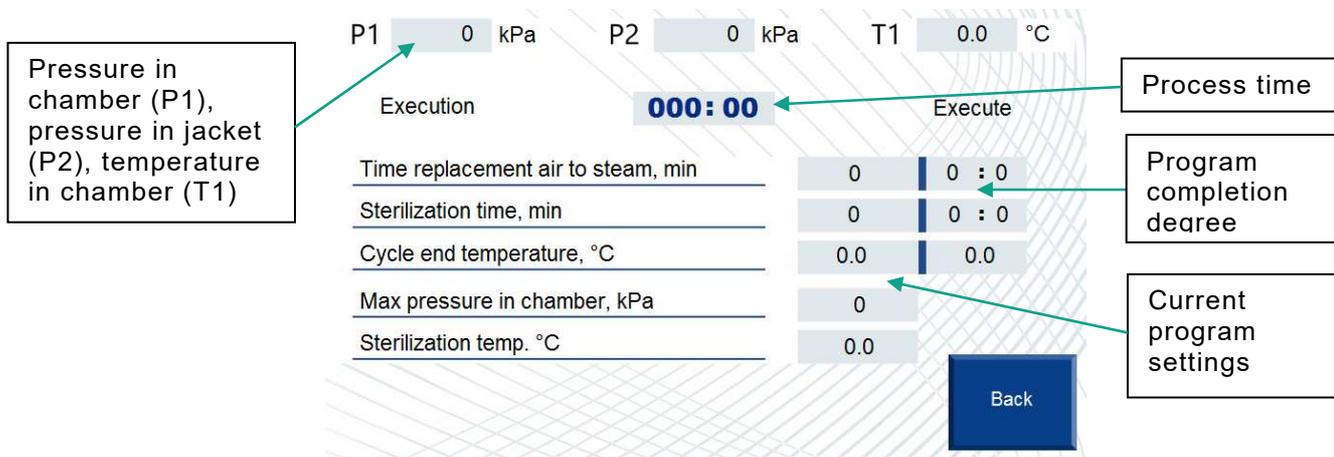


Fig. 15

**Current program settings** – in the cells of this column the settings of the selected program are displayed.

**Note:** all settings (except maximum pressure in the chamber) are available for monitoring only. The value of maximum pressure in the chamber can be changed during operation directly by the operator. To change the value, press the appropriate number and enter a new value using the keyboard.

**Note:** when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!

**Program completion degree** – the boxes in this column display the information on the degree of completion of the program. The data is displayed in seconds.

**Process time** – the time that has lapsed since the start of the process.

**Back** – pressing this button returns to the main menu screen (Fig. 4).

## „Scheme” screen

This screen is used for visual supervision of the control system. It allows the operator to monitor the process (completion of the respective stages) and the operation of the device components (valves, pumps, level sensors).

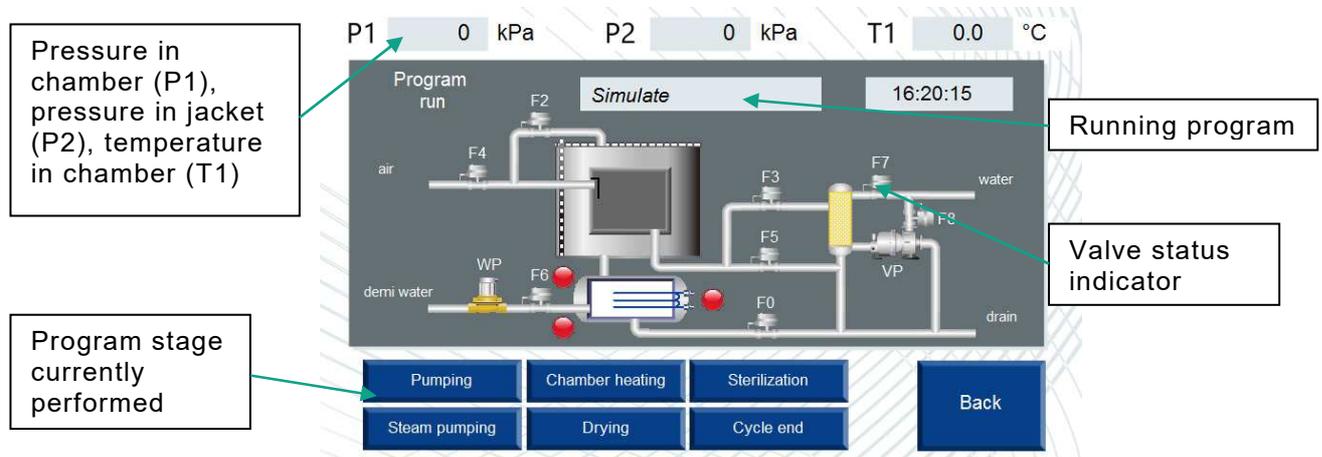


Fig. 16

**Running program** – this window displays the name of the currently running program.

**Indicator signalling the water level in the steam generator** – indicates the presence of water in the steam generator. If the top/bottom sensor level detects the presence of water, the indicator is blue; if no water is detected, the indicator is red.

**Performed stage** – indicator signalling the stage currently performed. The currently performed process stage is displayed in blue.

**Valves status indicator** – shows whether the valves, vacuum pump or water pump are switched on or off, the indicator is green if a component is switched on, and it is gray when a component is switched off.

**Back** – pressing this button returns to the main menu screen (Fig. 4).

## „Service” screen

This screen is used to navigate to the control system service screens.

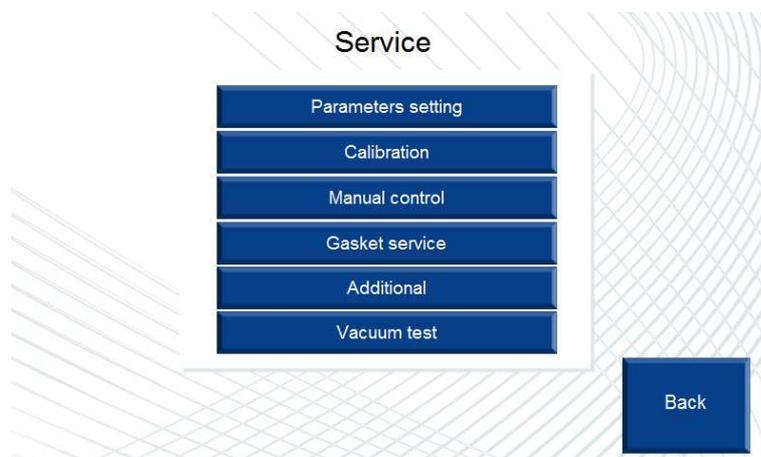


Fig. 17

**Parameters setting** – pressing this button moves to the parameter settings screen (Fig. 18).

**Calibration** – pressing this button moves to the sensor calibration screen (Fig. 30).

**Manual control** – pressing this button moves to the manual control screen (Fig. 31).

**Gasket service** – pressing this button moves to the door gasket service screen (Fig. 32).

**Additional settings** – pressing this button moves to the additional settings screen.

**Note: the screen of additional settings is only for service engineer's access and protected with a password.**

**Vacuum test** – pressing this button moves to the vacuum test screen (Fig. 33).

**Back** – pressing this button returns to the main menu screen (Fig. 4).

## „Parameters setting” screen

This screen is used to set the parameters common to all programs, and to navigate to the parameter settings screens of the respective programs. Once the parameters common to all programs are set, enter the values separately for each program.

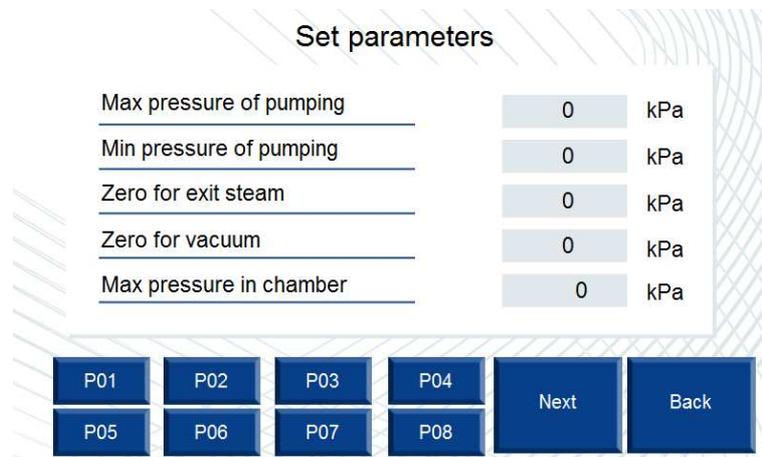


Fig. 18

**Maximum pressure of pumping** – this window is used to set maximum pressure in the chamber that can be reached during the "Pumping" stage, in which the air in the chamber is displaced by steam. **The value can be set in the range of -20 to 90 kPa. The default value is 30 kPa.**

**Minimum pressure of pumping** – this window is used to set minimum pressure in the chamber that can be reached during the "Pumping" stage, in which the air in the chamber is replaced with steam. **The value can be set in the range of -40 to -90 kPa. The default value is -90 kPa.**

**Zero for exit steam** – the pressure of the steam in the chamber, assumed to be zero, which, if reached, means that the steam has been evacuated from the chamber and the next operation may commence. **The value can be set in the range of -20 to 30 kPa. The default value is 10 kPa.**

**Zero for vacuum** – the pressure in the chamber at which the door of the sterilizer can be opened after supplying the air with the air tube once the drying stage has been completed. **The value can be set in the range of -50 to 10 kPa. The default value is -10 kPa.**

**Maximum pressure in the chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber. The range of 195-210 kPa (corresponding to the desired sterilization temperature) is adequate in case of the sterilization programs for textiles, instruments and the Bowie-Dick test. The pressure for sterilization of solutions is 110 kPa. These values may vary within  $\pm 15$  kPa.

**Note: when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!**

**P01** – pressing this button moves to the „Textile” program parameter settings screen (Fig. 20).

**P02** – pressing this button moves to the „Instruments” program parameter settings screen (Fig. 21).

**P03** – pressing this button moves to the „Bowie-Dick” program parameter settings screen (Fig. 22).

**P04** – pressing this button moves to the „Solutions” program parameter settings screen (Fig. 23).

**P05** – pressing this button moves to the „Rubber” program parameter settings screen (Fig. 24).

**P06** – pressing this button moves to the „Prion” program parameter settings screen (Fig. 25).

**P07** – pressing this button moves to the „Flash” program parameter settings screen (Fig. 26).

**P08** – pressing this button moves to the „User program” program parameter settings screen (Fig. 27).

**Next** – pressing this button navigates to the next screen (Fig. 19).

**Back** – pressing this button returns to the service screen (Fig. 17).

**„Parameters setting” “Next” screen**

This screen, as the previous screen is used to set the parameters common to all programs and navigate to the parameter settings screens.

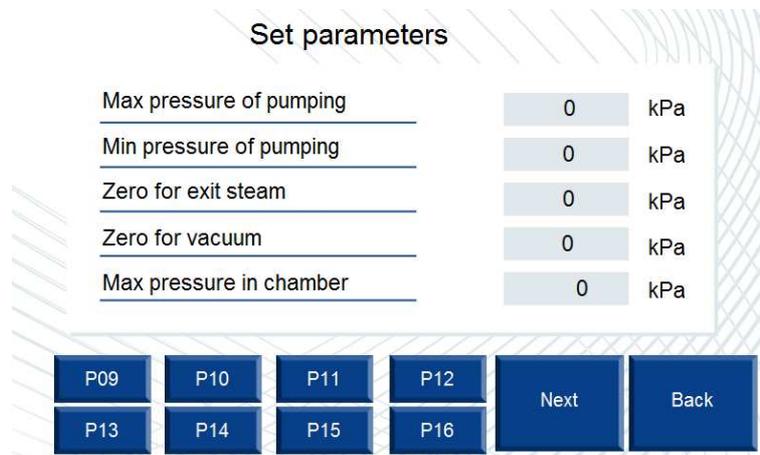


Fig. 19

**Maximum pressure of pumping, Minimum pressure of pumping, Zero for exit steam, Zero for vacuum, Maximum pressure in the chamber** – the same parameters as in the screen Fig. 18.

**P09** – pressing this button moves to the „User program 1” program parameter settings screen (Fig. 28).

**P10** – pressing this button moves to the „User program 2” program parameter settings screen (Fig. 28).

**P11** – pressing this button moves to the „User program 3” program parameter settings screen (Fig. 28).

**P12** – pressing this button moves to the „User program 4” program parameter settings screen (Fig. 28).

**P13** – pressing this button moves to the „User program 5” program parameter settings screen (Fig. 28).

**P14** – pressing this button moves to the „User program 6” program parameter settings screen (Fig. 28).

**P15** – pressing this button moves to the „User program 7” program parameter settings screen (Fig. 28).

**P16** – pressing this button moves to the „User program 8” program parameter settings screen (Fig. 28).

**Next** – pressing this button navigates to the next screen (Fig. 19a).

**Back** – pressing this button returns to the previous screen (Fig. 18).

## Parameters setting” “Next” screen

This screen, as the previous screen is used to set the parameters common to all programs and navigate to the parameter settings screens.

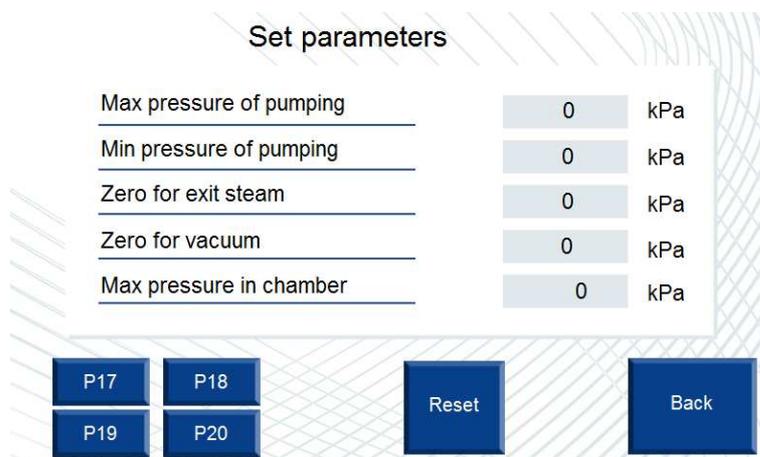


Fig. 19a

**Maximum pressure of pumping, Minimum pressure of pumping, Zero for exit steam, Zero for vacuum, Maximum pressure in the chamber** – the same parameters as in the screen Fig. 18.

**P17** – pressing this button moves to the „User program 9” program parameter settings screen (Fig. 28).

**P18** – pressing this button moves to the „User program 10” program parameter settings screen (Fig. 28).

**P19** – pressing this button moves to the „Solution 1” program parameter settings screen (Fig. 29).

**P20** – pressing this button moves to the „Solution 2” program parameter settings screen (Fig. 29).

**Reset** – pressing this button restores the default (manufacturer's) values of general parameters and program parameters.

**Back** – pressing this button returns to the previous screen (Fig. 19).

The following default values are set:

1. General parameters:
  - 1.1. Maximum pressure of pulsed discharge: +30 kPa;
  - 1.2. Minimum pressure of pulsed discharge: -90 kPa;
  - 1.3. Zero for exit steam: +10 kPa;
  - 1.4. Zero for vacuum: -10 kPa.
2. „Textiles” program parameters
  - 2.1. Number of pulses: 4;
  - 2.2. Sterilization temperature: 121°C;
  - 2.3. Sterilization time: 20 min;
  - 2.4. Drying time: 20 min;
  - 2.5. Maximum pressure in the chamber: +115 kPa.
3. „Instruments” program parameters
  - 3.1. Number of pulses: 4;
  - 3.2. Sterilization temperature: 134°C;
  - 3.3. Sterilization time: 5 min;
  - 3.4. Drying time: 20 min;
  - 3.5. Maximum pressure in the chamber: +215 kPa.
4. „Bowie-Dick” program parameters
  - 4.1. Number of pulses: 4;
  - 4.2. Sterilization temperature: 134°C;
  - 4.3. Sterilization time: 3,5 min;
  - 4.4. Drying time: 8 min;

- 4.5. Maximum pressure in the chamber: +215 kPa.
5. „Solutions” program parameters
  - 5.1. Time replacement air to steam: 10 min;
  - 5.2. Sterilization temperature: 121°C;
  - 5.3. Sterilization time: 20 min;
  - 5.4. Maximum pressure in the chamber: +115 kPa;
  - 5.5. Pressure difference: 10kPa;
  - 5.6. Interval of pressure relief: 30sec;
  - 5.7. Cycle end temperature: 95°C.
6. „Rubber” program parameters
  - 6.1. Number of pulses: 4;
  - 6.2. Sterilization temperature: 121°C;
  - 6.3. Sterilization time: 20 min;
  - 6.4. Drying time: 10 min;
  - 6.5. Maximum pressure in the chamber: +115 kPa.
7. „Prion” program parameters
  - 7.1. Number of pulses: 4;
  - 7.2. Sterilization temperature: 134°C;
  - 7.3. Sterilization time: 18 min;
  - 7.4. Drying time: 15 min;
  - 7.5. Maximum pressure in the chamber: +215 kPa.
8. „Flash” program parameters
  - 8.1. Number of pulses: 4;
  - 8.2. Sterilization temperature: 134°C;
  - 8.3. Sterilization time: 5 min;
  - 8.4. Drying time: 1 min;
  - 8.5. Maximum pressure in the chamber: +215 kPa.
9. „User program” program parameters
  - 9.1. Number of pulses: 4;
  - 9.2. Sterilization temperature: 121°C;
  - 9.3. Sterilization time: 30 min;
  - 9.4. Drying time: 20 min;
  - 9.5. Maximum pressure in the chamber: +115 kPa.
10. „User program 1” program parameters
  - 10.1. Number of pulses: 4;
  - 10.2. Sterilization temperature: 121°C;
  - 10.3. Sterilization time: 30 min;
  - 10.4. Drying time: 30 min;
  - 10.5. Maximum pressure in the chamber: +115 kPa.
11. „User program 2” program parameters
  - 11.1. Number of pulses: 4;
  - 11.2. Sterilization temperature: 121°C;
  - 11.3. Sterilization time: 30 min;
  - 11.4. Drying time: 40 min;
  - 11.5. Maximum pressure in the chamber: +115 kPa.
12. „User program 3” program parameters
  - 12.1. Number of pulses: 4;
  - 12.2. Sterilization temperature: 134°C;
  - 12.3. Sterilization time: 5 min;
  - 12.4. Drying time: 40 min;
  - 12.5. Maximum pressure in the chamber: +215 kPa.
13. „User program 4” program parameters
  - 13.1. Number of pulses: 4;
  - 13.2. Sterilization temperature: 134°C;
  - 13.3. Sterilization time: 10 min;

- 13.4. Drying time: 30min;
- 13.5. Maximum pressure in the chamber: +215 kPa.
14. „User program 5” program parameters
  - 14.1. Number of pulses: 4;
  - 14.2. Sterilization temperature: 134°C;
  - 14.3. Sterilization time: 10 min;
  - 14.4. Drying time: 40 min;
  - 14.5. Maximum pressure in the chamber: +215 kPa.
15. „User program 6” program parameters
  - 15.1. Number of pulses: 4;
  - 15.2. Sterilization temperature: 132°C;
  - 15.3. Sterilization time: 8 min;
  - 15.4. Drying time: 20 min;
  - 15.5. Maximum pressure in the chamber: +200 kPa.
16. „User program 7” program parameters
  - 16.1. Number of pulses: 4;
  - 16.2. Sterilization temperature: 121°C;
  - 16.3. Sterilization time: 25 min;
  - 16.4. Drying time: 30 min;
  - 16.5. Maximum pressure in the chamber: +115 kPa.
17. „User program 8” program parameters
  - 17.1. Number of pulses: 4;
  - 17.2. Sterilization temperature: 121°C;
  - 17.3. Sterilization time: 25 min;
  - 17.4. Drying time: 40 min;
  - 17.5. Maximum pressure in the chamber: +115 kPa.
18. „User program 9” program parameters
  - 18.1. Number of pulses: 4;
  - 18.2. Sterilization temperature: 134°C;
  - 18.3. Sterilization time: 7 min;
  - 18.4. Drying time: 30 min;
  - 18.5. Maximum pressure in the chamber: +215 kPa.
19. „User program 10” program parameters
  - 19.1. Number of pulses: 4;
  - 19.2. Sterilization temperature: 134°C;
  - 19.3. Sterilization time: 7 min;
  - 19.4. Drying time: 40 min;
  - 19.5. Maximum pressure in the chamber: +215 kPa.
20. „Solutions 1” program parameters
  - 20.1. Time replacement air to steam: 20 min;
  - 20.2. Sterilization temperature: 121°C;
  - 20.3. Sterilization time: 20 min;
  - 20.4. Maximum pressure in the chamber: +110 kPa;
  - 20.5. Pressure difference: 30kPa;
  - 20.6. Interval of pressure relief: 10sec;
  - 20.7. Cycle end temperature: 95°C.
21. „Solutions 2” program parameters
  - 21.1. Time replacement air to steam: 20 min;
  - 21.2. Sterilization temperature: 121°C;
  - 21.3. Sterilization time: 25 min;
  - 21.4. Maximum pressure in the chamber: +110 kPa;
  - 21.5. Pressure difference: 30kPa;
  - 21.6. Interval of pressure relief: 10sec;
  - 21.7. Cycle end temperature: 95°C.

## „Textiles program parameter setting” screen

This screen is used to set the parameters of the „Textiles” program to **sterilize clothes and underwear**.

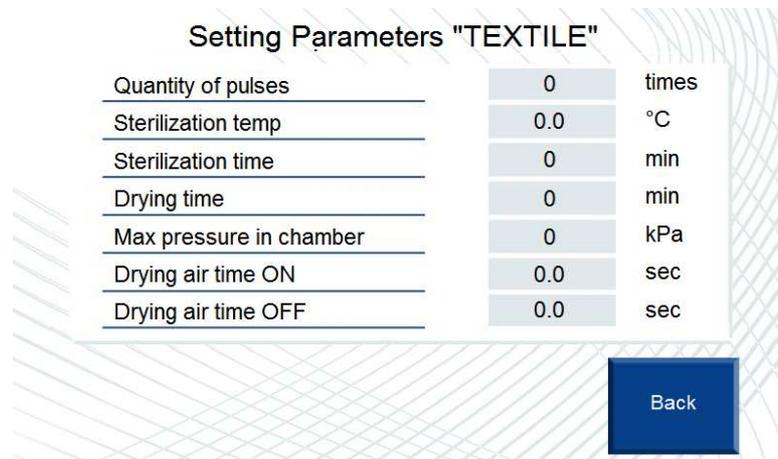


Fig. 20

**Quantity of pulses** – the number of pressure/vacuum pulses during the evacuation of air from the chamber. The acceptable values are in the range of 1-99 cycles. The default value is 4 pulses.

**Sterilization temperature** – this window is used to set the temperature of sterilization. The value can be set in the range of 100÷135°C. The default value for the "Textiles" program is 121°C.

**Sterilization time** – the time that lapses from reaching the set sterilization temperature as measured by the temperature sensor. The acceptable values are in the range of 0÷999 min.

The time and temperature of sterilization for textiles are set in compliance with the requirements of the national standards with respect to sterilization.

**Drying time** – the time required to remove moisture from the packages with sterilized clothes or underwear. It depends on the size of packages, properties of the sterilized material and the fill level of the chamber. The acceptable values are in the range of 0-999 min.

**Maximum pressure in chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber. The range of 195÷210 kPa (corresponding to the desired sterilization temperature) is adequate in case of the sterilization programs for textiles, instruments and the Bowie-Dick test. The pressure for sterilization of solutions is 110 kPa. These values may vary within  $\pm 15$  kPa.

**Note: when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!**

**Drying air time ON** – this window is used to set the periodic time for turning on air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The default setting is 0.0 (air drying function off). In case of difficulties with drying, it is recommended to set the value 3 to 6 seconds.

**Drying air time OFF** – this window is used to set the time for periodically turning off the air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The standard time is 25.0 (if air drying function enabled). In case of difficulties with drying, it is recommended to set the value 20 ÷ 60 seconds.

**Back** – pressing this button returns to the parameter settings screen (Fig. 18).

## „Instruments program parameter setting” screen

This screen is used to set the parameters of the „Instruments” program to sterilize instruments of various kinds. The parameters set for the "Instruments" program are the same as for the „Textiles” program.

One exception is the drying time, which depends on the rate of decompression of the chamber.

|                         |     |       |
|-------------------------|-----|-------|
| Quantity of pulses      | 0   | times |
| Sterilization temp      | 0.0 | °C    |
| Sterilization time      | 0   | min   |
| Drying time             | 0   | min   |
| Max pressure in chamber | 0   | kPa   |
| Drying air time ON      | 0.0 | sec   |
| Drying air time OFF     | 0.0 | sec   |

**Back**

Fig. 21

**Quantity of pulses** – the number of pressure/vacuum pulses during the evacuation of air from the chamber. The acceptable values are in the range of 1÷99 cycles. The default value is 4 pulses.

**Sterilization temperature** – this window is used to set the temperature of sterilization. The value can be set in the range of 100÷135°C. The default value for the "Instruments" program is 134°C.

**Sterilization time** – the time that lapses from reaching the set sterilization temperature as measured by the temperature sensor. The acceptable values are in the range of 0÷999 min.

**Drying time** – the time required to dry the tools. It depends on the size of packages, properties of the sterilized material and the fill level of the chamber. The acceptable values are in the range of 0-999 min.

**Maximum pressure in the chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber.

**Note: when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!**

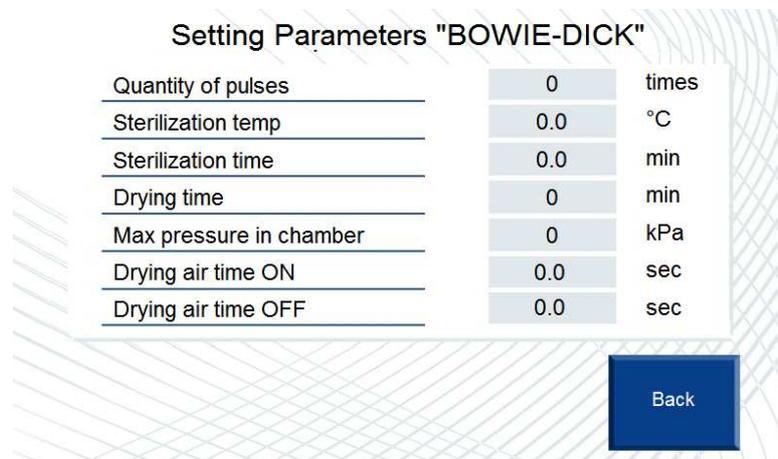
**Drying air time ON** – this window is used to set the periodic time for turning on air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The default setting is 0.0 (air drying function off). In case of difficulties with drying, it is recommended to set the value 3 to 6 seconds.

**Drying air time OFF** – this window is used to set the time for periodically turning off the air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The standard time is 25.0 (if air drying function enabled). In case of difficulties with drying, it is recommended to set the value 20 ÷ 60 seconds.

**Back** – pressing this button returns to the parameter settings screen (Fig. 18).

## "Bowie-Dick parameters" screen

This screen is used to display and set the parameters for the "Bowie-Dick Test", which is a standard program for testing steam sterilizers for steam tightness and the evacuation of air from the sterilization chamber.



The screenshot shows a screen titled "Setting Parameters BOWIE-DICK" with a list of parameters and their values. A blue "Back" button is located at the bottom right.

| Parameter               | Value | Unit  |
|-------------------------|-------|-------|
| Quantity of pulses      | 0     | times |
| Sterilization temp      | 0.0   | °C    |
| Sterilization time      | 0.0   | min   |
| Drying time             | 0     | min   |
| Max pressure in chamber | 0     | kPa   |
| Drying air time ON      | 0.0   | sec   |
| Drying air time OFF     | 0.0   | sec   |

Fig. 22

All the parameters of the Bowie-Dick test are set taking into account the requirements of the national standards. They should not be changed!!!

**Back** – pressing this button returns to the parameter settings screen (Fig. 18).

## "Solutions program parameter setting" screen

This screen is used to set the parameters of the "Solutions" program to sterilize solutions in bottles.

The solution sterilization program does not involve vacuum generation in the chamber so as to avoid any damage to the bottles with the sterilized solutions. The air is displaced by the steam supplied into the chamber. The air displacement time is a configurable parameter.

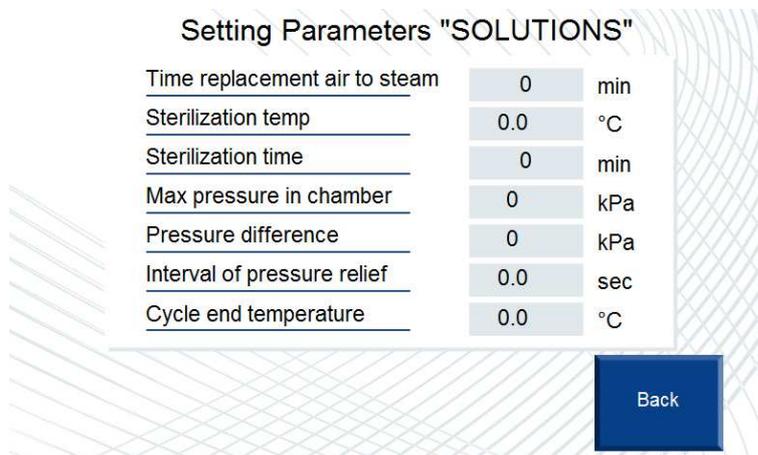


Fig. 23

**Time replacement air to steam** – the time during which the air in the chamber is displaced by steam. The acceptable values are in the range of 1÷999 min.

**Sterilization temperature** – this window is used to set the temperature of sterilization. The acceptable values are in the range of 100÷135°C.

**Sterilization time** – the time that lapses from reaching the set sterilization temperature as measured by the temperature sensor. This value is set taking into account the requirements of the national standard with respect to sterilization of pharmaceutical preparations. The value can be set in the range of 0 to 999 min.

The volume of the bottles with sterilized solutions should also be taken into consideration in the sterilization of solutions. The table shows approximate sterilization times of solutions depending on bottle volume.

| Bottle volume, ml       | 75 | 250 | 500 | 1000 | 1500 | 2000 |
|-------------------------|----|-----|-----|------|------|------|
| Sterilization time, min | 20 | 25  | 30  | 35   | 45   | 55   |

**Maximum pressure in the chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber. The acceptable values are in the range of 0÷230°kPa.

**Note: when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!**

**Pressure difference** – this window is used to set the value by which the pressure decreases when the pressure relief valve in the chamber is opened at the pressure decrease stage. The acceptable values are in the range of 0÷200°kPa.

**Interval of pressure relief** – this window is used to set the opening time of the pressure relief valve in the chamber at pressure decrease stage. The acceptable values are in the range of 0÷999°seconds.

**Note: the pressure difference parameters and the interval of pressure relief should be set taking into account the characteristics of the bottles (volume and wall thickness) and of the sterilized solutions. Any increase of the interval of pressure**

---

**relief extends the duration of the cycle, but reduces possible damage to the bottles at the chamber pressure decrease stage.**

**Cycle end temperature** – this window is used to set the temperature in the chamber which triggers the end of the process and allows the operator to open the doors.

**Back** – pressing this button returns to the parameter settings screen (Fig. 18).

## "Rubber program parameter setting" screen

This screen is used to set the parameters of the "Rubber" program to **sterilize rubber products**.

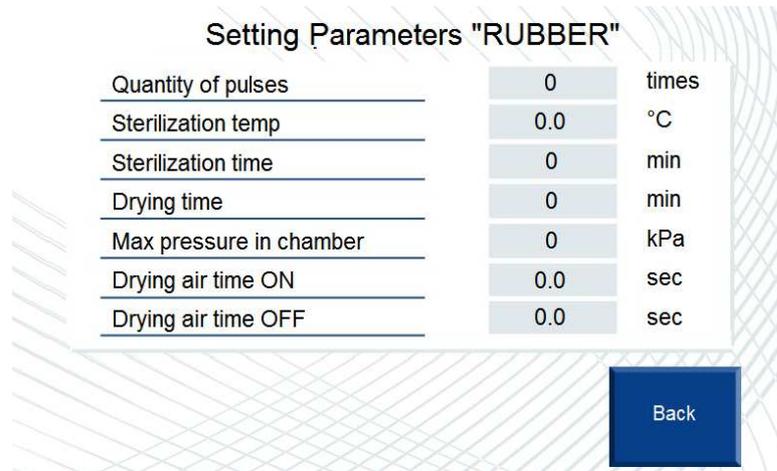


Fig. 24

**Quantity of pulses** – the number of pressure/vacuum pulses during the evacuation of air from the chamber. The acceptable values are in the range of 1÷99 cycles. The default value is 4 pulses.

**Sterilization temperature** – this window is used to set the temperature of sterilization. The value can be set in the range of 100÷135°C. The default value for the "Rubber" program is 121°C.

**Sterilization time** – the time that lapses from reaching the set sterilization temperature as measured by the temperature sensor. The acceptable values are in the range of 0÷999 min.

**Drying time** – the time required to dry the rubber. It depends on the size of packages, properties of the sterilized material and the fill level of the chamber. The acceptable values are in the range of 0÷999 min.

**Maximum pressure in the chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber.

**Note: when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!**

**Drying air time ON** – this window is used to set the periodic time for turning on air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The default setting is 0.0 (air drying function off). In case of difficulties with drying, it is recommended to set the value 3 to 6 seconds.

**Drying air time OFF** – this window is used to set the time for periodically turning off the air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The standard time is 25.0 (if air drying function enabled). In case of difficulties with drying, it is recommended to set the value 20 ÷ 60 seconds.

**Back** – pressing this button returns to the parameter settings screen (Fig. 18).

## "Prion program parameter setting" screen

This screen is used to set the parameters of the "Prion" program for sterilize products contaminated with prions.

|                         |     |       |
|-------------------------|-----|-------|
| Quantity of pulses      | 0   | times |
| Sterilization temp      | 0.0 | °C    |
| Sterilization time      | 0   | min   |
| Drying time             | 0   | min   |
| Max pressure in chamber | 0   | kPa   |
| Drying air time ON      | 0.0 | sec   |
| Drying air time OFF     | 0.0 | sec   |

**Back**

Fig. 25

**Quantity of pulses** – the number of pressure/vacuum pulses during the evacuation of air from the chamber. The acceptable values are in the range of 1÷99 cycles. The default value is 4 pulses.

**Sterilization temperature** – this window is used to set the temperature of sterilization. The value can be set in the range of 100÷135°C. The default value for the "Prion" program is 134°C.

**Sterilization time** – the time that lapses from reaching the set sterilization temperature as measured by the temperature sensor. The acceptable values are in the range of 0÷999 min.

**Drying time** – the time required to dry the product. It depends on the size of packages, properties of the sterilized material and the fill level of the chamber. The acceptable values are in the range of 0-999 min.

**Maximum pressure in the chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber.

**Note: when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!**

**Drying air time ON** – this window is used to set the periodic time for turning on air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The default setting is 0.0 (air drying function off). In case of difficulties with drying, it is recommended to set the value 3 to 6 seconds.

**Drying air time OFF** – this window is used to set the time for periodically turning off the air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The standard time is 25.0 (if air drying function enabled). In case of difficulties with drying, it is recommended to set the value 20 ÷ 60 seconds.

**Back** – pressing this button returns to the parameter settings screen (Fig. 18).

## "Flash program parameter setting" screen

This screen is used to set the parameters of the "Flash" program for sterilize **non-packed** instruments and accessories.

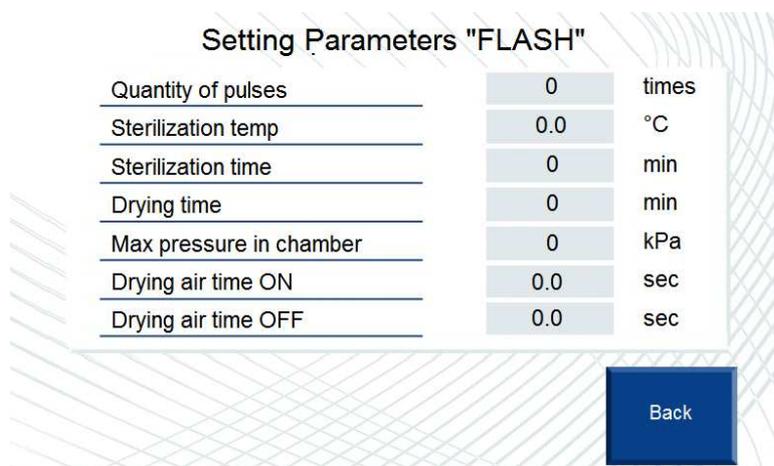


Fig. 26

**Quantity of pulses** – the number of pressure/vacuum pulses during the evacuation of air from the chamber. The acceptable values are in the range of 1÷99 cycles. The default value is 4 pulses.

**Sterilization temperature** – this window is used to set the temperature of sterilization. The value can be set in the range of 100÷135°C. The default value for the "Flash" program is 134°C.

**Sterilization time** – the time that lapses from reaching the set sterilization temperature as measured by the temperature sensor. The acceptable values are in the range of 0÷999 min.

**Drying time** – the time required to dry the instruments and accessories. It depends on the size of packages, properties of the sterilized material and the fill level of the chamber. The acceptable values are in the range of 0-999 min. The default value for the "Flash" program is 1 min.

**Maximum pressure in the chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber.

**Note: when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!**

**Drying air time ON** – this window is used to set the periodic time for turning on air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The default setting is 0.0 (air drying function off). In case of difficulties with drying, it is recommended to set the value 3 to 6 seconds.

**Drying air time OFF** – this window is used to set the time for periodically turning off the air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The standard time is 25.0 (if air drying function enabled). In case of difficulties with drying, it is recommended to set the value 20 ÷ 60 seconds.

**Back** – pressing this button returns to the parameter settings screen (Fig. 18).

## "User program parameter setting" screen

This screen is used to set the parameters of the "User program" used for **sterilization with user defined parameters**.

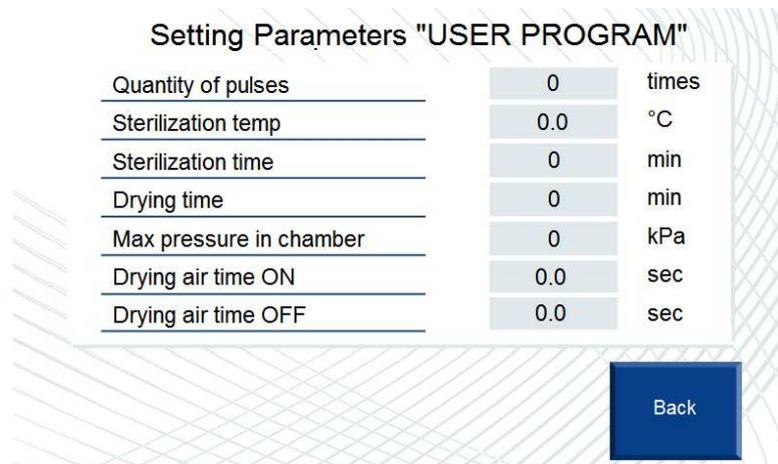


Fig. 27

**Quantity of pulses** – the number of pressure/vacuum pulses during the evacuation of air from the chamber. The acceptable values are in the range of 1÷99 cycles. The default value is 4 pulses.

**Sterilization temperature** – this window is used to set the temperature of sterilization. The acceptable values are in the range of 100÷135°C.

**Sterilization time** – the time that lapses from reaching the set sterilization temperature as measured by the temperature sensor. The acceptable values are in the range of 0÷999 min.

**Drying time** – the time required to dry. It depends on the size of packages, properties of the sterilized material and the fill level of the chamber. The acceptable values are in the range of 0÷999 min.

**Maximum pressure in the chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber.

**Note: when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!**

**Drying air time ON** – this window is used to set the periodic time for turning on air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The default setting is 0.0 (air drying function off). In case of difficulties with drying, it is recommended to set the value 3 to 6 seconds.

**Drying air time OFF** – this window is used to set the time for periodically turning off the air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The standard time is 25.0 (if air drying function enabled). In case of difficulties with drying, it is recommended to set the value 20 ÷ 60 seconds.

**Back** – pressing this button returns to the parameter settings screen (Fig. 18).

## "User program 1 parameter setting" screen

This screen is used to set the parameters of the "User program 1" used for **sterilization with user defined parameters**.

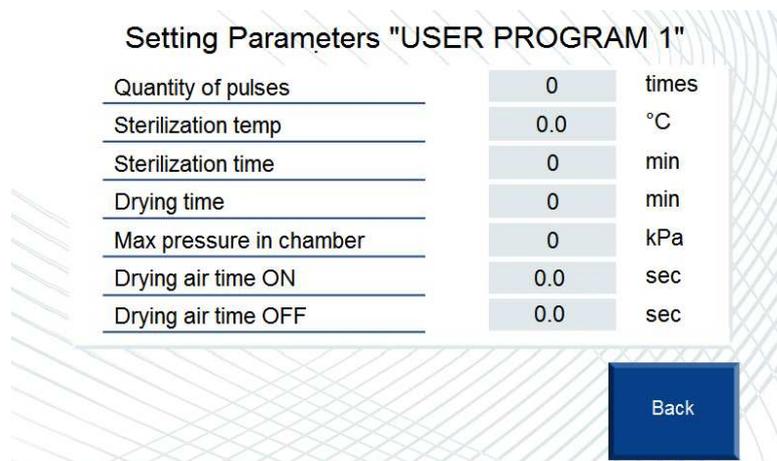


Fig. 28

**Quantity of pulses** – the number of pressure/vacuum pulses during the evacuation of air from the chamber. The acceptable values are in the range of 1÷99 cycles.

**Sterilization temperature** – this window is used to set the temperature of sterilization. The acceptable values are in the range of 100÷135°C.

**Sterilization time** – the time that lapses from reaching the set sterilization temperature as measured by the temperature sensor. The acceptable values are in the range of 0÷999 min.

**Drying time** – the time required to dry. It depends on the size of packages, properties of the sterilized material and the fill level of the chamber. The acceptable values are in the range of 0÷999 min.

**Maximum pressure in the chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber.

**Note: when changing the value of the maximum pressure in the chamber exercise extreme caution, as this may disrupt the sterilization process!!!**

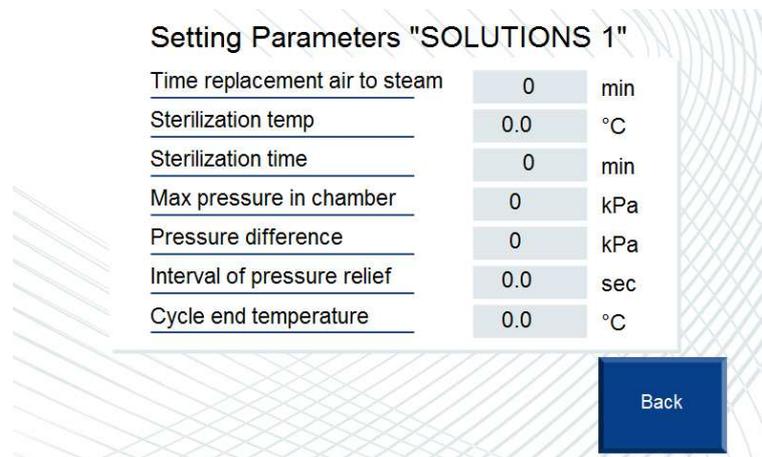
**Drying air time ON** – this window is used to set the periodic time for turning on air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The default setting is 0.0 (air drying function off). In case of difficulties with drying, it is recommended to set the value 3 to 6 seconds.

**Drying air time OFF** – this window is used to set the time for periodically turning off the air admission into the chamber (through a sterile filter) during the drying phase. The value can be set between 0.0 and 1000. The standard time is 25.0 (if air drying function enabled). In case of difficulties with drying, it is recommended to set the value 20 ÷ 60 seconds.

**Back** – pressing this button returns to the parameter settings screen (Fig. 18).

## "Solutions 1 program parameter setting" screen

This screen is used to set the parameters of the "Solutions 1" program to sterilize solutions in bottles **with used defined parameters**.



| Setting Parameters "SOLUTIONS 1" |     |     |
|----------------------------------|-----|-----|
| Time replacement air to steam    | 0   | min |
| Sterilization temp               | 0.0 | °C  |
| Sterilization time               | 0   | min |
| Max pressure in chamber          | 0   | kPa |
| Pressure difference              | 0   | kPa |
| Interval of pressure relief      | 0.0 | sec |
| Cycle end temperature            | 0.0 | °C  |

**Back**

Fig. 29

**Time replacement air to steam** – the time during which the air in the chamber is displaced by steam. The acceptable values are in the range of 1÷999 min.

**Sterilization temperature** – this window is used to set the temperature of sterilization. The acceptable values are in the range of 100÷135°C.

**Sterilization time** – the time that lapses from reaching the set sterilization temperature as measured by the temperature sensor. This value is set taking into account the requirements of the national standard with respect to sterilization of pharmaceutical preparations. The value can be set in the range of 0 to 999 min.

**Maximum pressure in the chamber** – this window is used to set the value of the maximum pressure in the chamber at the sterilization stage. It should correspond to the sterilization temperature! It is the maximum pressure in the chamber. The acceptable values are in the range of 0÷230°kPa.

**Pressure difference** – this window is used to set the value by which the pressure decreases when the pressure relief valve in the chamber is opened at the pressure decrease stage. The acceptable values are in the range of 0÷200°kPa.

**Note: the pressure difference parameters and the interval of pressure relief should be set taking into account the characteristics of the bottles (volume and wall thickness) and of the sterilized solutions. Any increase of the interval of pressure relief extends the duration of the cycle, but reduces possible damage to the bottles at the chamber pressure decrease stage.**

**Interval of pressure relief** – this window is used to set the opening time of the pressure relief valve in the chamber at pressure decrease stage. The acceptable values are in the range of 0÷999°seconds.

**Cycle end temperature** – this window is used to set the temperature in the chamber which triggers the end of the process and allows the operator to open the doors.

**Back** – pressing this button returns to the parameter settings screen (Fig. 19).

## "Calibration" screen

This screen is used to calibrate the pressure sensor and the temperature sensor. It is used when the displayed parameters differ from the actual ones.

For example, the pressure measurement system is configured by the manufacturer for the average above-sea-level pressure in Poland. If the sterilizer is used at high altitudes, the user should make an adjustment corresponding to the difference between the pressure at the sea level and the pressure at the place of operation.

The adjustment is 12,4 kPa at 1100 m above sea level and 24,1 at 2260 m.

If there is any discrepancy in the temperature readouts, the temperature should also be set in the appropriate active window.

To adjust the sensor place a reference sensor next to the adjusted one, and enter the adjustment value in the corresponding adjustment window.

| Calibration                     |     |     |     |
|---------------------------------|-----|-----|-----|
| Sensor pressure in chamber (P1) | 0   | 0   | kPa |
| Sensor temp. in chamber (T1)    | 0.0 | 0.0 | °C  |
| Sensor pressure in jacket (P2)  | 0   | 0   | kPa |
| Sensor temp. in tank (T3)       | 0.0 | 0.0 | °C  |
| Sensor temp. in chamber (T2)    | 0.0 | 0.0 | °C  |
| Sensor pressure in chamber (P3) | 0   | 0   | kPa |

**Back**

Fig. 30

**Sensor pressure in chamber (P1)** – this window is used to set the adjustment value for the pressure sensor in the chamber. The range of set values: from -999 kPa to +999 kPa.

**Sensor pressure in jacket (P2)** – this window is used to set the adjustment value for the pressure sensor in the jacket. The range of set values: from -999 kPa to +999 kPa.

**Sensor pressure in chamber (P3)** – this window is used to set the adjustment value for the pressure sensor in the chamber, used for printing out. The range of set values: from -999 kPa to +999 kPa.

**Sensor temp. in chamber (T1)** – this window is used to set the adjustment value for the temperature sensor in the chamber drain. The range of set values: from -500.0°C to +500.0°C.

**Sensor temp. in chamber (T2)** – this window is used to set the adjustment value for the temperature sensor in the chamber drain, used for printing out. The range of set values: from -500.0°C to +500.0°C.

**Sensor temp. in tank (T3)** – this window is used to set the adjustment value for the temperature sensor in the tank water. The range of set values: from -100.0°C to +100.0°C.

**Back** – pressing this button returns to the "Service" screen (Fig. 17).

## "Manual control" screen

This screen is used for visual supervision of the control system. It allows the operator to monitor the process (completion of the respective stages) and the operation of the device components (valves, pumps, level sensors).

The software of the sterilizer allows the operator to carry out a number of operations in the manual mode. This is particularly convenient in emergency situations (i.e. when it is necessary open the door of the pressurised chamber, etc.), as well as for testing and servicing.

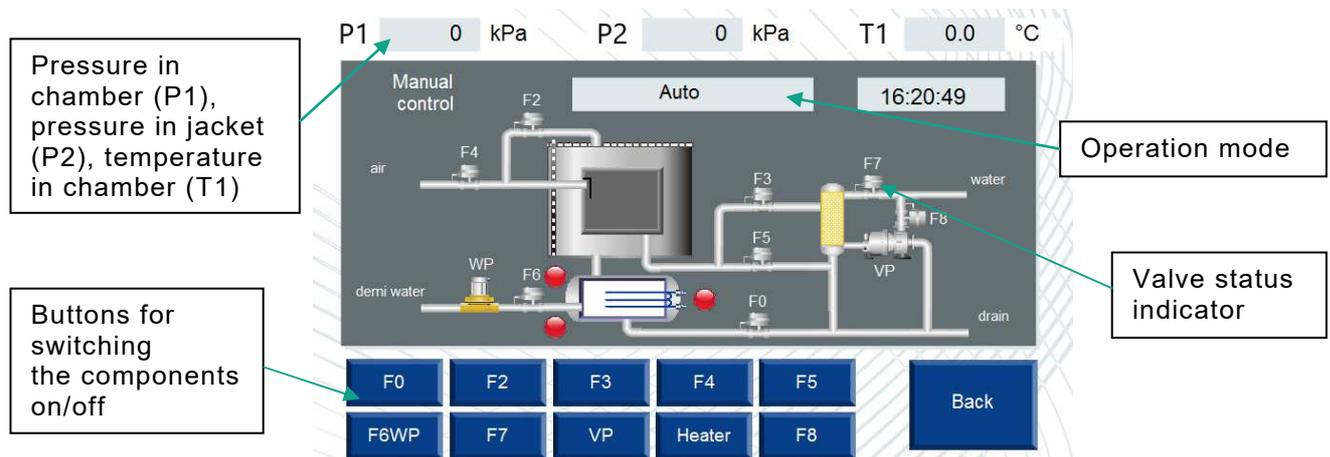


Fig. 31

**Operation mode** – pressing this button toggles the sterilizer operation mode (Auto/Manual).

Press the button to select the other mode. Manual operation of the valves is possible only in the "Manual" mode. To switch to automatic mode, switch the system to "Auto". After switching the operation to "Auto" all the components active in the manual mode switch off.

**Indicator signalling the water level in the steam generator** – indicates the presence of water in the steam generator. If the top/bottom sensor level detects the presence of water, the indicator is blue, and if no water is detected, the indicator is red.

**Component on/off buttons** – buttons for switching on/off of the valves, as well as the water pump and vacuum pump in the manual mode. To switch on a component press the respective button, to switch off a component press the button again. If a component is switched on, its button is blue, if the component is switched off, its button is red.

### Note:

- F0 valve can not be switched on in the manual mode if the printer test is running;
- F2 valve can not be switched on in the manual mode if the printer test is running or if the door is not closed;
- F3 valve can not be switched on in the manual mode if the printer test is running;
- F4 valve can not be switched on in the manual mode if the printer test is running or if the pressure in the chamber is above "zero for exit steam";
- F5 valve can not be switched on in the manual mode if the printer test is running;
- F6 valve and the water supply pump can not be switched on in the manual mode if the printer test is running;
- F7 and F8 valves can not be switched on in the manual mode if the printer test is running;

**Valves status indicator** – shows whether the valves, vacuum pump or water pump are switched on or off. If a component is switched on its respective indicator is bright-green.

**Back** – pressing this button returns to the "Service" screen (Fig. 17).

## "Gasket service" screen

This menu is used to operate the servicing and replacement of the gasket. It has two buttons: "Installing gasket" and "Remove gasket", and includes door position indicators.



Fig. 32

**Doors status indicator** – indicators of the door status. It is green if the door is closed and red if it is open.

### To remove the gasket:

- open a door;
- press the "Remove the gasket" button. The compressed air will be supplied to the groove. This will force the gasket from the groove;
- then press "Remove the gasket" again. This will stop the supply of the compressed air to the groove. Then pull the gasket out of the groove.

### To install the gasket:

- insert the gasket into the groove. The gasket insertion procedure is described in the "Maintenance" section;
- press the "Install the gasket" button. This will activate the vacuum pump, and the vacuum in the groove will suck the gasket into the groove;
- when the gasket is properly placed into the groove, press the "Install the gasket" button once again – this will deactivate the pump and close the valve.

**Back** – pressing this button returns to the "Service" screen (Fig. 17).

## "Vacuum test" screen

This menu is used to test the tightness of the sterilizer chamber.

The tightness is tested within the overall inspection or calibration of the device if the Bowie-Dick test results were unsatisfactory, as well as after transporting the device over long distances (the tubes may get damaged in transport). This test should be carried out with the empty chamber. The tightness of the chamber and the tubes is tested by generating a specific vacuum in the chamber and maintaining it for a specific duration (the test period).

The parameters of the tightness test are standardized and precisely specified in the software:

- generation of vacuum in the chamber during the tightness test: 10 minutes;
- vacuum level in the chamber – maximum level obtained during vacuum generation;
- test duration: 10 minutes;
- maximum acceptable decrease:  $\leq 1.3$  kPa.

If the vacuum in the chamber exceeds the pressure limit within the given time (the maximum acceptable decrease), the sterilizer chamber or tubes are not tight. Find and eliminate the cause of the lack of tightness.

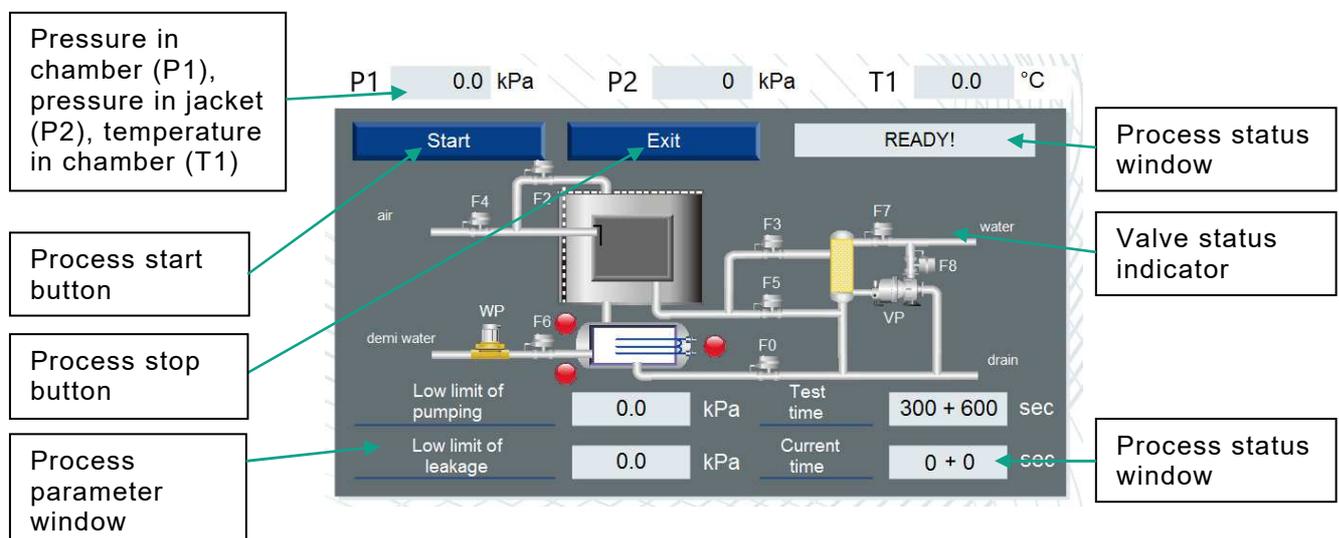


Fig. 33

**Start** – pressing this button starts the process. Pressing this button starts the process and the generation of vacuum in the chamber begins.

**Exit** – pressing this button stops the test. When this button is pressed, a process interruption confirmation window appears (see Fig. 34).

**Low limit of pumping** – this window shows the level of vacuum generated at the stage of generating vacuum in the chamber.

**Low limit of leakage** – this information window shows the maximum acceptable decrease of the vacuum during the test (the ability of the chamber to hold vacuum).

**Test time** – this information window shows the time of stabilization of the vacuum in the chamber (300 seconds) and the time during which the chamber holds vacuum (600 seconds).

**Current time** – this window shows the duration, the stabilization time (the number on the left) and the time during which the chamber holds vacuum (the number on the right). At each stage the respective value increases.

**Valves status indicator** – shows whether the valves, vacuum pump or water pump are switched on or off. If a component is switched on, its corresponding indicator lights up.

**Process status** – this window shows the status and outcome of the process. It provides the operator with the following information:

- READY!;
- Vacuum;

- Keeping;
- Test;
- Test passed!;
- Leak!

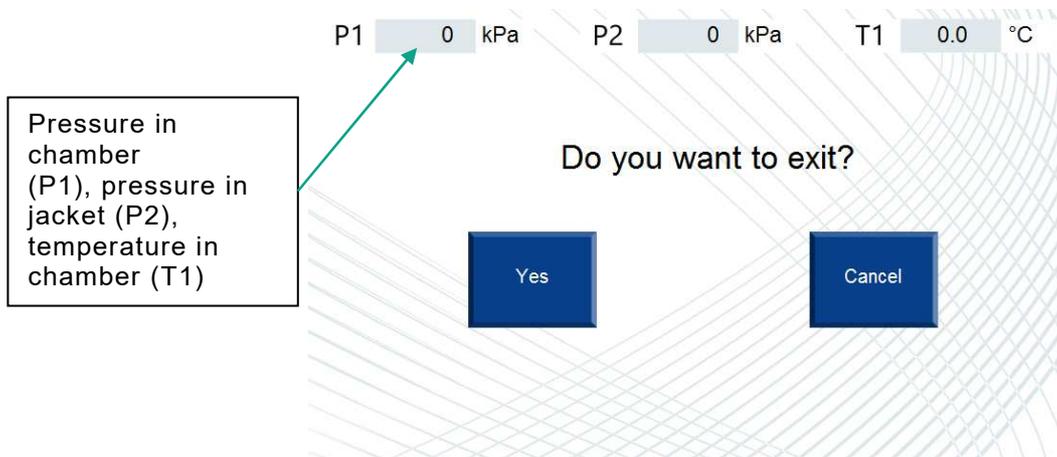


Fig. 34

Confirming the exit (by pressing "Yes") interrupts the test and navigates to the "Service" screen (Fig. 17). Pressing "No" navigates the system back to the vacuum test screen (Fig. 33).

The test can be started only if no other process is running and the window displays "READY!".

Once the test has been started, the vacuum pump activates and the display shows "Vacuum". When the vacuum reaches its lowest level (which will not change within the next 2 minutes), the duration of the stabilization time starts, and the window displays the "Holding" message. The current value of the vacuum in the chamber is displayed in the "Lowest value of generated vacuum" window.

When the hold time lapses (300 seconds), the test commences, the "Current time" shows the countdown, and the process status window shows the "Test" message.

During the test, the software compares the pressure difference and the set acceptable pressure decrease. If the change in pressure does not exceed the set limit, the display shows the "Test completed successfully!" message. If the acceptable value is exceeded, the "Leak!" message appears.

## "Additional" menu

This menu is used to navigate to other menus for setting the operating parameters of the sterilizer.

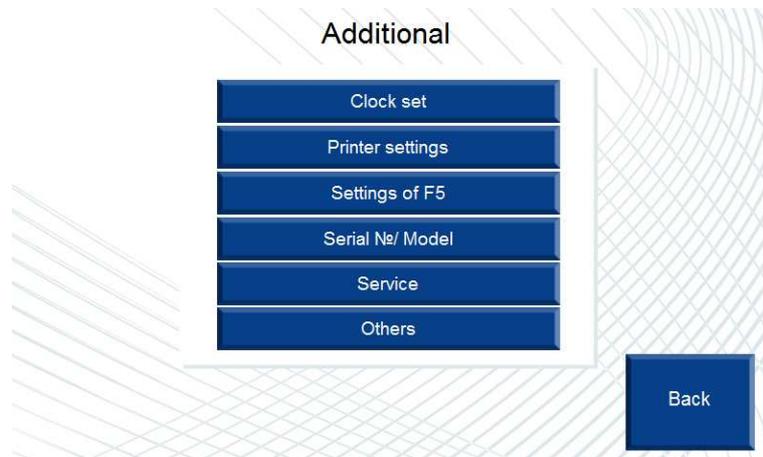


Fig. 35

**Clock set** – pressing this button moves to the system time settings screen (Fig. 36).

**Printer settings** – pressing this button moves to the printer settings screen (Fig. 37).

**Settings of F5** – pressing this button moves to the F5 valve operation settings screen (Fig. 38).

**Serial no./Model** – pressing this button moves to the serial number/model settings screen (Fig. 39).

**Service** – pressing this button moves to the "Service" screen used to restore the number of performed cycles by the service personnel (Fig. 40)

**Others** – pressing this button moves to the additional settings screen (Fig. 41).

**Back** – pressing this button returns to the "Service" screen (Fig. 17).

## "Clock set" ("System time") screen

This menu is used to set the system date/time. If necessary, this menu allows the user to set the time taking into account the time zone, and the desired date.



Fig. 36

**Year** – year setting window. The range of set values: 0÷999.

**Month** – month setting window. The range of set values: 0÷999.

**Day** – day setting window. The range of set values: 0÷999.

**Hour** – hour setting window. The range of set values: 0÷999.

**Minute** – minute setting window. The range of set values: 0÷999.

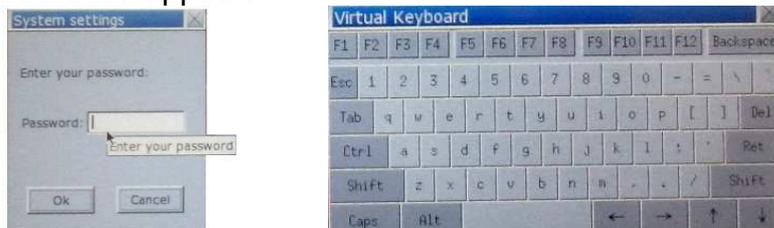
**Second** – second setting window. The range of set values: 0÷999.

Pressing the respective window displays a keypad for data entry.

**Note: make sure that the entered data is correct. If the data is incorrect, the desired values will not be set!**

**Back** – pressing this button returns to the "Additional" menu (Fig. 35).

**System** – press this button to move to the panel system settings menu. This menu can be used to set the panel system settings. Pressing this button displays the password entry screen and a keyboard will appear.



Enter "111111" to access the System settings menu.

## "Printer settings" ("Printer control") screen

This menu is used to monitor the operation of the printer and to select the printing interval.

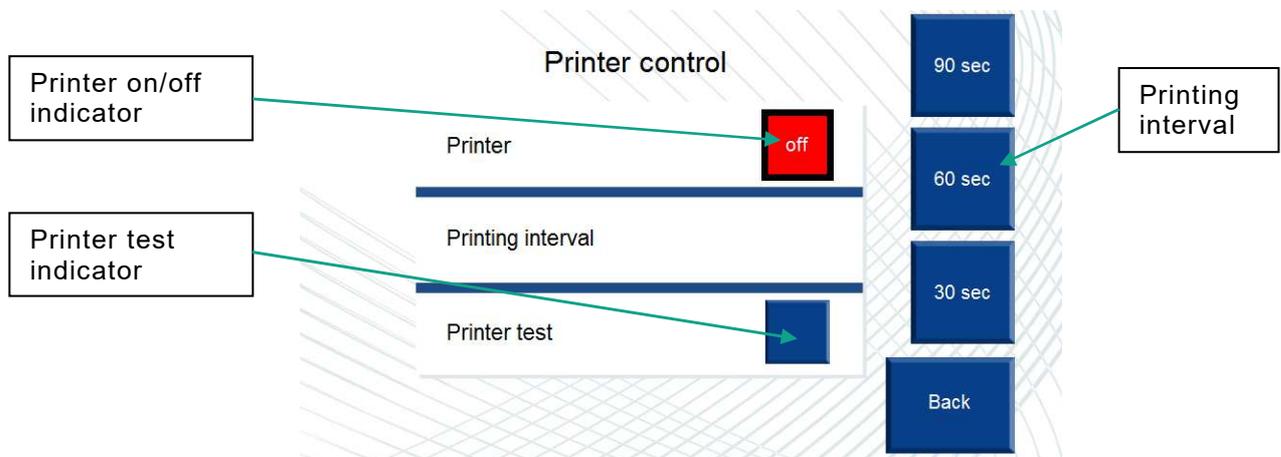


Fig. 37

**Printing interval** – pressing these buttons selects the printing interval (30, 60, 90 sec). This option is used to change the interval on the basis of which the current parameters are sent to be printed. This facilitates the recording of data during a time-consuming sterilization process and thus saves paper and ink.

The user can choose among the following printing intervals: 30 s, 60 s, 90 s. To print the data at intervals of 30 seconds, press "30 s" (the indicator will light up in blue). To print the data at intervals of 60 seconds, press "30 s" to cancel this interval (the led will light up in red), and press "60 s" (the led will light up in blue). A new interval will be set. Proceed in the same manner to set (replace) any interval. The default printing interval is 60 seconds.

**Printer** – use this button to activate/deactivate printing. To activate printing, press the button. Its status will change to "on". To deactivate printing, press the button once again. Its status will change to "off"). **If printing is deactivated, no data will be sent to the printer. When the system is loaded (default), the printer is active (the indicator is blue).**

**Printer test** – pressing this button runs the printer test. Use the "Printer test" to test the printer only if the printer, paper or cartridge has been replaced.

**Note: no other programs may run during the printer test!**

**Back** – pressing this button returns to the "Additional" menu (Fig. 35).

## "Settings of F5" ("Chamber drain valve F5") screen

This screen is used to configure the operation of the chamber drain valve (F5). In some cases it is necessary if the chamber is not being drained properly (stagnation of the condensate). If this is the case, extend the duration of the valve activity.

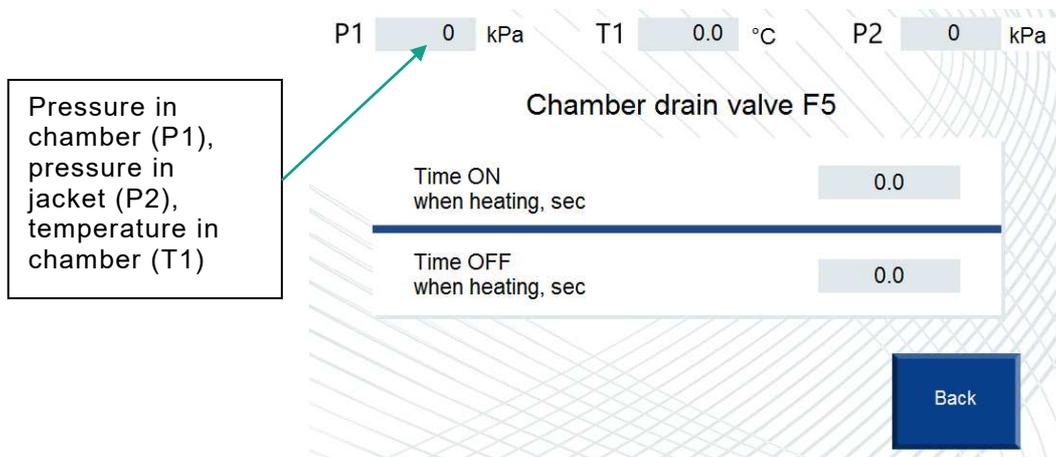


Fig. 38

**Time ON when heating** – this window is used to set the duration of the F5 valve activity at the heating stage. The value can be set in the range of 0.0÷1000. The default value is 4 seconds.

**Time OFF when heating** – this window is used to set the duration of the F5 valve inactivity at the heating stage. The value can be set in the range of 0.0÷1000. The default value is 17 seconds.

**Back** – pressing this button returns to the "Additional" screen (Fig. 35).

## "Serial No/Model" ("Sterilizer No") screen

This screen is used by a service engineer to enter the serial number and model of the sterilizer.



Fig. 39

**Sterilizer No** – this window is used by a service engineer to enter the serial number of the sterilizer. The serial number is included in the printouts together with the process data.

**Sterilizer model** – this window is used to enter the sterilizer model. The sterilizer model entered in this window is displayed on the Splash screen (Fig. 3).

**Back** – pressing this button returns to the "Additional" screen (Fig. 35).

## “Service” screen

This screen is used to restore the number of performed cycles by the service personnel.

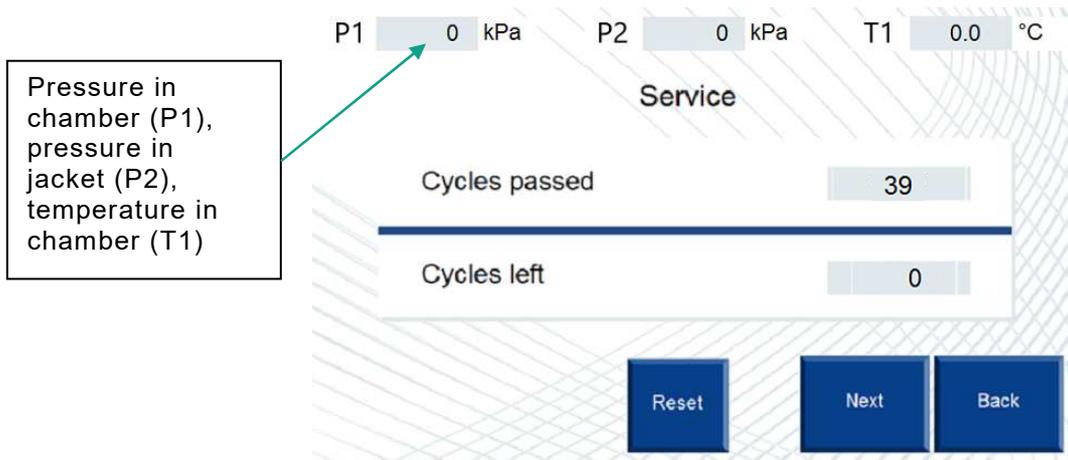


Fig. 40

**Cycles passed** – this window shows the number of cycles performed by the sterilizer since the last review. Input range 0÷500.

**Cycles left** – this window shows the number of cycles remaining to carry out a technical review. The value of this field is calculated as follows: 500 - "Cycles passed"

**Reset** – restores the specified number of cycles. Pressing this button will insert the value 0 in the "Cycles passed" and a value 500 in the "Cycles left".

**Next** – pressing this button navigates to the next screen (Fig. 40a).

**Back** – pressing this button returns to the "Additional" screen (Fig. 35).

This screen is used to enter the date of the next maintenance by the service personnel. If the next maintenance date expires, there will be a warning message about servicing. This function works independently of the cycle count function.

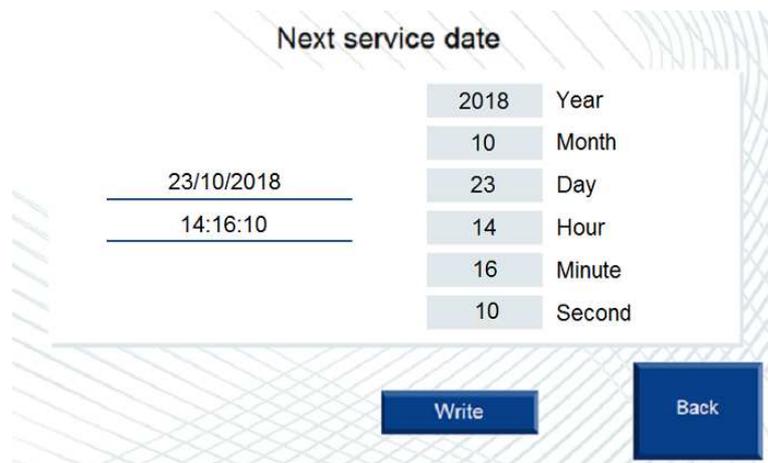


Fig. 40a

**Write** – pressing this button saves the next service date.

**Back** – pressing this button returns to the "Service" screen (Fig. 40).

## "Others" screen

This screen is used to enter additional operational parameters of the sterilizer.



Fig. 41

**Heating interval** – this window is used to set interval during which, at the heating stage, the pressure is maintained at the level of  $P1 = P1_{maks} - 18$  kPa. Increasing this value results in smoother (extended) heating of the chamber and in more even temperature distribution in the chamber. The range of set values is 0.0 to 1000 seconds.

**Cleaning time for SG** - the interval during at which the F0 valve (steam generator water drain) is open when starting the system at a generator pressure of 0 kPa. The range of set values is 0.0-1000 seconds.

**Temp. of F7 opening** – this window is used to enter the temperature at which the F7 valve opens (cooling the drain to the sewage system). The range of set values is 0-90 °C.

**Temp. of F7 closing** - this window is used to enter the temperature at which the F7 valve closes (cooling the drain to the sewage system).

**Vacuum time** – this window is used to enter the interval during which the minimum pressure is held at the vacuum generation stage. Increasing this value results in more even temperature distribution in the chamber. The range of set values is 0.0 to 9999 seconds.

**Control mode of pressure in jacket** – pressing this button toggles the pressure control modes in the jacket. The default value is "Auto". If the process is run in the "Auto" mode, the pressure held in the jacketed will be calculated automatically based on the desired sterilization temperature and the maximum pressure in the chamber for each program. Press the appropriate button to switch to the "manual" mode. In the manual mode, the desired value can be entered in the "Set jacket pressure" window. This value will be saved even if the power is turned off. When the process is started, the mode will automatically switch to "Auto".

**The set pressure in the jacket** – this window is used to enter the desired pressure value in the jacket and to enter the pressure value in the automatic mode. Enter a new value in this window if it necessary to change this value (the steam pressure is insufficient). This value is reset to the default value of 220 kPa when the sterilizer power is switched off.

**Note: entering incorrect values may disrupt the operation of the sterilizer and the sterilization process!**

**Polski** – button for switching the panel language. After pressing the button, the system switches to English, after pressing the button again, the system switches to Polish.

**Write** – after pressing this button, the changes are saved in the controller's memory.

**Back** – pressing this button returns to the "Additional" screen (Fig. 35).

## "Attention!" screen

This screen displays the current system messages. This screen appears regardless of the screen viewed by the user. All messages displayed in this screen are accompanied by a sound signal.



Fig. 42

**Text message field** – the field with the text of the current message and the time of message.

**Table 2 lists the system messages and their causes.**

**Reset** – message reset button. If the cause of the message is not eliminated, the message will appear again.

**Archive** – pressing this button navigates to the " Alarms Archive " (Fig. 43).

## "Alarms Archive" screen

This screen displays the messages that appear during the operation (both current and past messages).



Fig. 43

**Back** – returns to the "Attention!" screen (Fig. 32).

Table 2 –System Messages

| No | Name                        | Description  |
|----|-----------------------------|--|
| 1  | Program not finished!       | This message appears if, during the sterilization cycle, any of the following buttons has been pressed: "Open back door", "Open front door", "Start leakage test." |
| 2  | Close the door!             | This message appears if the operator selected the desired sterilization program and the door is open.  |
| 3  | Manual mode is activated!   | This message appears if the operator selected the sterilization program and the valve control manual mode is active.   |
| 4  | Emergency alarm activated!  | This message appears if the emergency stop button has been pressed.  |
| 5  | No water in the tank!       | This message appears if the low water level sensor in the steam generator tank has triggered.  |
| 6  | Compressed air low!         | This message appears if the compressed air monitoring sensor at the inlet has triggered.   |
| 7  | Pressure in chamber!        | This message appears if the pressure in the chamber exceeds "Zero for exit steam" and the button "Open back door" or "Open front door" has been pressed.           |
| 8  | Vacuum in chamber!          | This message appears if the pressure in the chamber is lower than "Zero for vacuum" and the button "Open back door" or "Open front door" has been pressed.         |
| 9  | Front door is open!         | This message appears if the front door is not closed and the operator has pressed the "Open back door" button.   |
| 10 | Back door is open!          | This message appears if the back door is not closed and the operator has pressed the "Open front door" button.   |
| 11 | Sterilization T alarm!      | This message appears if the temperature during the sterilization is 3°C above or below the sterilization temperature or is below Tster for more than 3 seconds.    |
| 12 | Program completed!          | This message appears when each sterilization cycle or the leakage test has been completed.   |
| 13 | Check for pure water!       | This message appears when the maximum water level in the generator is not reached for 2 minutes  |
| 14 | Max temp. in the water tank | The message appears if the temperature in the water tank exceeds 60 °C   |

#### 4.10. Recording the sterilization cycle parameters

On the insertion side there is a printer that records the sterilization cycle parameters.

All the standard parameters of the cycle are printed in a table.

The printout includes the following data:

- temperature in the chamber;
- date and time of the cycle start;
- sterilization cycle number;
- operator number;
- serial number;
- set sterilization program parameters (duration, temperature);
- name and start time of the process stage;
- temperature and pressure in the chamber;
- duration and end time of the cycle;
- minimum and maximum sterilization temperature;
- process outcome (sterilization or a tightness test) (positive/negative).

```

CYCLE START:2015-01-13 12:49
CYCLE COUNT:0013 OPERATOR ID: 0
PRO TYPE :P03 PULSE COUNT:0004
PURGE TIME :00005 STERI TIME :02105
DRY TIME :04805 STERI TEMP :134.0
STERILIZER ID: 152
STATE TIME TEMP PRE
PULSE 12:49:00 025.1 004kPa
12:49:35 040.1 -090kPa
12:49:47 041.8 040kPa
12:50:53 060.0 -090kPa
12:51:03 066.7 039kPa
12:52:16 060.3 -090kPa
12:52:23 065.0 042kPa
12:53:30 062.5 -090kPa
12:53:38 066.6 044kPa
HEAT 12:54:40 063.2 -090kPa
12:54:59 090.4 151kPa
12:55:59 130.2 190kPa
12:56:59 132.2 190kPa
12:57:59 132.3 192kPa
12:58:59 132.5 195kPa
12:59:59 134.0 201kPa
STERI 13:00:11 134.3 206kPa
13:00:59 134.9 208kPa
13:01:59 134.9 211kPa
13:02:59 134.9 211kPa
13:03:40 135.0 210kPa
EXHAUST 13:03:43 135.0 208kPa
13:03:59 133.5 097kPa
DRY 13:04:41 112.3 006kPa
13:04:59 099.0 -052kPa
13:05:59 071.6 -090kPa
13:06:59 083.2 -095kPa
13:07:59 087.6 -096kPa
13:08:59 089.5 -096kPa
13:09:59 088.3 -097kPa
13:10:59 085.5 -097kPa
13:11:59 082.5 -097kPa
ATR-IN 13:12:40 080.7 -097kPa
END 13:12:49 080.3 -006kPa
ACTUAL TIME
PULSE 00:05:41 HEAT 00:05:31
STERILIZE 00:03:33 EXHAUST= 00:00:59
DRY 00:08:00 TOTAL = 00:23:49
Tster. max. 135.0 Tster. min.134.3
CYCLE PASSED

```

Fig. 44

---

The recorder automatically prints the data starting from switching on the sterilizer. The operating personnel only need to replenish the paper and replace the printing tape when the print quality begins to decline (see the printer user guide).

Once any sterilization cycle or a test has started, the data printout is carried out online. The personnel is unable to interfere with the recording of the sterilization data.

The device does not require supervision during the work of the sterilizer – recording is done automatically.

The printout signed by the operator and together with the sterilization log, allows the user to follow the results of the sterilization of individual batches of materials. Printouts should be kept at the workplace for the time specified by the authorized person.

They are considered to have been sterilized only if the printout with the relevant summary has been produced.

## 5. PROGRAMS DESCRIPTION

In memory of controller is permanently saved all default sterilization programs and testing programs: Bowie and Dick Test and Leak Test.

Sterilization is carried out in clean, dry saturated steam. Jacket is heating chamber and reduce steam condensation inside the chamber. Steam is added from jacket to the chamber.

The sterilizer software, contain automatically realizing following operation:

- sterilization of textile materials and glasses at 121-134°C, followed vacuum drying (program "Textile").
- sterilization of instruments and equipment with vacuum drying (programs "Instruments") 121-134°C.
- sterilization of liquids at 121°C temperature (program "Solutions", "Solutions 1", "Solutions 2")
- sterilization of rubber at 121°C (program "Rubber").
- Bowie and Dick test for steam penetration in porous materials 134°C.
- automatic Leak Test (Vacuum test).

### 5.1 Description of the main programs

Sterilization cycles main programs "Textile", "Instruments", "Rubber", "User Programs" consists of the following phases:

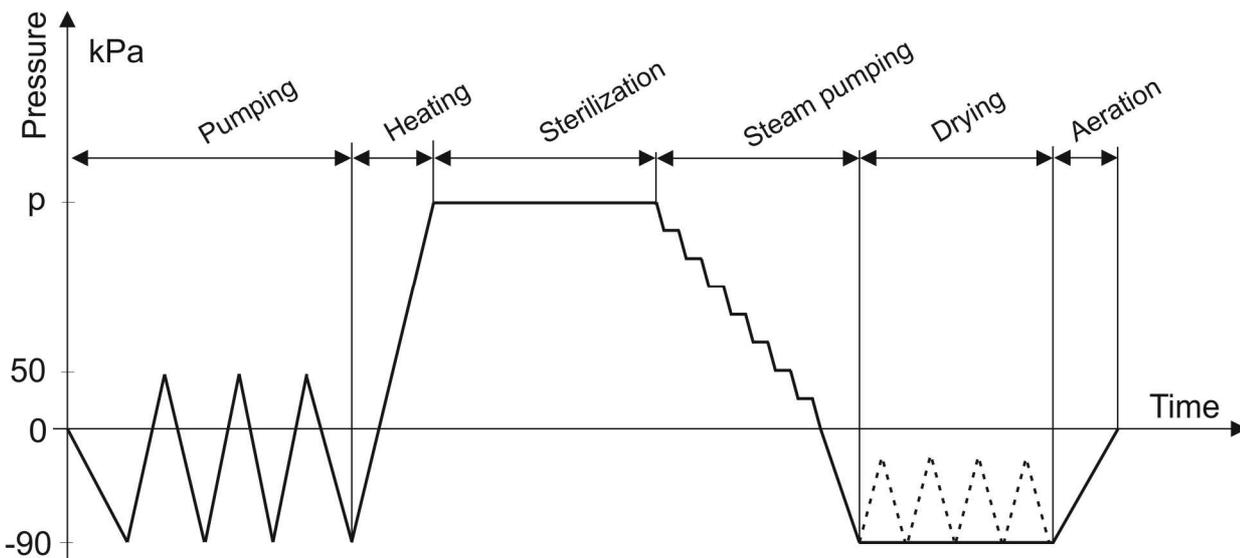


Fig. 45

- **Pumping (Venting)**

This phase is necessary to remove air from the chamber, channels and from load cavities, containers, from packages of porous materials, for better steam penetration and pre-heating of the load. Venting the chamber followed using vacuum pump with water ring. After reached the desired vacuum to the chamber is supplied steam. After obtained in the chamber desired pressure again is generated vacuum. The vacuum phase consists with three or four cycles. Each cycle is started by obtained the underpressure and then is supplied steam to the chamber (with each cycle, aeration level is increased) and finally in the chamber is only saturated steam. Removal 99% air from the chamber needs minimum 3 venting cycles. Software protection for cycle «Textile», «Instruments» and «Bowie and Dick Test» give us possibility to set 99 venting cycles. Depth of the vacuum during the venting phase can be set in range  $-40 \div -90$  kPa.

In the «Solutions» cycle, to sterilizing fluids in the chamber is not obtained the underpressure to protect glass bottle with fluids. Air from the chamber is replaced by steam, which is added to the chamber with simultaneous removing the steam-air mixture.

- **Heating**

The purpose of this phase to heat load up to a preset exposure temperature. This is accomplished by filling the chamber with steam to the Pchamb. max pressure. The p pressure depends on a selected temperature. The duration of this phase depends mainly on the size of load put into a sterilization chamber.

- **Sterilization (Exposure)**

After equilibration of a temperature selected inside load, specified by indication stationary temperature sensor Pt100, located in the drain tube countdown of the exposure time starts. After exposure (sterilization) end, saturated steam is removed from the chamber by heat exchanger and vacuum pump. Sterilization time we can set to 999 minutes. Sterilization temperature can be set by user in range 120÷134 °C.

- **Steam pumping (Exhaust, Decreasing)**

After the exposure phase is finished the pressure inside the chamber is lowered to the level required for a drying phase. Large pressure differential – between the end of exposure and beginning of drying – could cause in this phase damage to the packs (paper-foil packaging) and therefore it is extended in time.

- **Drying**

The aim of drying phase is achieve the required humidity of the sterilizing material. When the pressure in the chamber achieve the atmospherical pressure, is starting drying phase. Still in the chamber vacuum is generated and to the jacket is pulsatory added steam. Drying temperature doesn't increase - is determined by heat exchange between walls of chamber and jacket and is in the range 75÷85°C.

In "Instruments" and "Bowie and Dick Test" cycles drying time is set (in "Textile" cycle, during clothes drying, time can be set to 999 minutes, what guarantees removal of moisture, even with large packets).

In each program (except for the "Solutions" programs), you can set cyclic aeration of the chamber (through a sterile filter) during the drying phase to support the drying process (intensive drying).

- **Cycle end (Aeration)**

The chamber is aerated with dry and sterile air. Atmospheric air going through by sterile filter with pores less than 0,3 µm is sterilizing, and by the air pipeline (more part of them is located near the heating jacket) is supplied to the chamber.

## 5.2. Program «Solutions»

In program to sterilizing fluids, vacuum in the chamber is not realized to avoid breakage the bottle with sterilizing fluids. The air in the chamber is replaced by steam, which is added to the chamber.

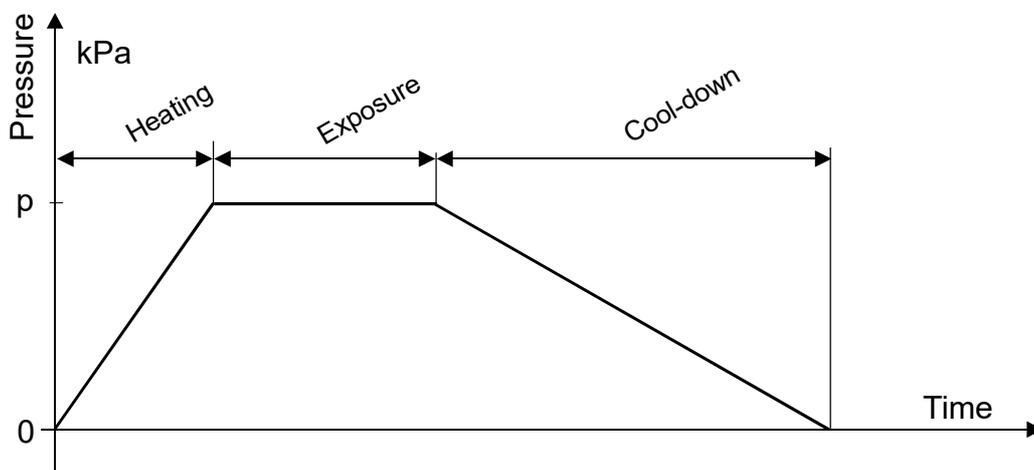


Fig. 46

**Replace time** - it is a time which is needed to remove air by steam from the chamber. Usually is set 10÷20 min.

**Sterilization temperature** - depending on sterilizing batch is set 120÷134°C. Usually is set 121°C.

**Sterilization time** - determined based on requirements of national standards to sterilizing of pharmaceuticals. Can be set up to 999 minutes.

#### **Block diagram of programs "Solutions":**

Replaced air in the chamber by steam → heating chamber → sterilization → slow exhaust of steam → provide air into the chamber → end of the program.

#### **Description and implementation of the stages of "Solutions" programs.**

Programs realize the following phases:

**Chamber heating phase.** This phase is begin of remove air from the chamber and heat chamber to the sterilization temperature. During removing air phase, steam to chamber valve F2 is open, and steam is begin provide to the chamber. The valve F7 on the pipeline supplying cold water to the heat exchanger opens and begin cooling the steam. The valve F3 on the creating vacuum pipeline opens, and steam begin remove air from the chamber. With opening valve F3, valve F7 opens and begins adding water to the heat exchanger. Valve F2 on the steam supply pipeline is open, in the chamber increases pressure and temperature. After reaching in the chamber defined sterilization temperature, program start countdown time of sterilization phase.

**Sterilization phase** - valve F2 which supply steam to the chamber, is periodically open and close, to keep before defined temperature in the chamber.

#### **"Slow steam exhaust" phase**

When cutdown time by processor will achieve sterilization time, steam exhaust phase starts. Valve F2 is close, supplying steam to the chamber stops. Valve F3 on the slow steam exhaust pipeline opens, valve F7 on the pipeline which added water to the heat exchanger opens, and in the heat exchanger is beginning vapor condensations.

After the pressure inside the chamber aligned with atmospheric, and defined end temperature of the cycle will be achieved, program will be ended.

### **5.3. Program P03 - Bowie and Dick test**

Program is used to check, whether venting of porous material and the following filling with steam is sufficient, and therefore whether the required temperature was reached and maintained during the whole exposure phase inside load.

Program consists of the same phases as others programs (with the exception of the "Solutions" programs). Exposure phase is executed with a temperature of 134°C for 3,5 minutes. Running this program is protected by the service code (200).

### **5.4. Vacuum Test (Leak Test)**

Program is destined to periodical check (once in a week) of leaking sterilization chamber. Access to the program is using the "Service" in Main menu after entering the code (100). The program sequence is shown on the below graph.

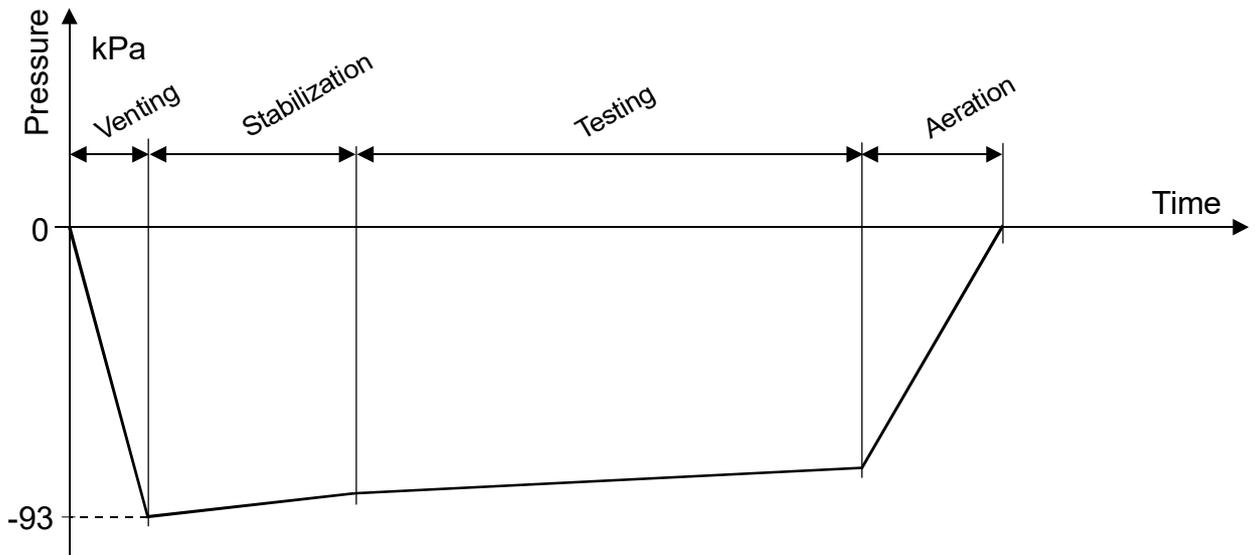


Fig. 47

This test consists of the following stages: creating vacuum in the chamber and monitoring it during defined period of time.

- **Venting (Vacuum)**

During that phase the air is removed from the chamber until the required negative pressure is reached.

- **Stabilization**

The purpose of this phase is to stabilize possible pressure changes caused by the presence of condensates in a sterilizing chamber. The duration of this phase is **5 min**.

- **Testing**

During that phase the value of the negative pressure is continuously controlled. The duration of this phase is **10 min**.

- **Aeration**

Aeration is the subsequent stage which completes the sterilization cycle. The pressure is then levelled (from the negative pressure) until there is atmospheric pressure inside the chamber ( $\pm 7$  kPa).

## 6. ACTIVATION AND MAINTENANCE OF A STERILIZER

Personnel operating the sterilizer should go through a documented post-related training concerning the sterilizer operated.



**Untrained personnel may not operate the sterilizer.**

### 6.1. Activation of a sterilizer

#### 6.1.1. Sterilizer supplied by an external source of steam

To prepare a sterilizer for daily operation you should:

- open the valves on pipework supplying steam (check the pressure on the manometer (pos. 5), it should reach a value of 2,5 bar) water and compressed air,
- turn the electric power on with a master switch located in the vicinity of the sterilizer,
- turn the sterilizer on with a power switch (pos. 1),
- enter to the main controller by pressing the button "Enter",  
Wait about 15 minutes to let the jacket heat up (this concerns the first time the sterilizer is turned on in a given day or after a long interruption of sterilizer's operation).
- to heat up the chamber and remove the remains of the air in supplying installation should be proceeded sterilization cycle **P02** (without load).

#### 6.1.2. Sterilizer supplied by an integral (built-it) steam generator

To prepare a sterilizer for daily operation you should:

- open the valves on pipework supplying water to a sterilizer, water (conditioned) to a steam generator and compressed air,
- turn on the electric power with a master switch located in the vicinity of the sterilizer,
- turn the sterilizer on with a power switch (pos. 1).
- enter to the main controller by pressing the button "Enter",
- wait about 20 min. until the pressure in the generator reaches 2,5 bar (pos. 5),
- to heat up the chamber and remove the remains of the air in supplying installation should be proceeded sterilization cycle **P02** (without load).

### 6.2. Operating the double-ended sterilizer

#### 6.2.1. Operating a sterilizer in a loading side

- place the transport trolley under the chamber entry. Place the transport trolley lever in a  position. Unblock the loading cart with a lever located on the left side of a transport trolley and move it into the chamber. Move a transport trolley away from the chamber after moving the lever to a position .



**Transport trolleys and loading carts are optional equipment of the sterilizer. If the sterilizer is not equipped with them - the chamber should be loaded and unloaded manually.**

- close the door in a loading side with a control key,
- if it is necessary, in menu "Settings" (fig. 18-29), set the appropriate parameters,
- select desired program from the menu "Set Program" (Fig. 9, 10).

After choosing the program, if the chamber is loaded and closed, pressure in the jacket achieve defined level, on the main screen of control panel (fig. 4) will show button "Start".

- if on the screen will not show alarm, can be pressed the button "Start" and run the program.

The process proceeds automatically according to one of the programs (see *program description*). During a process particular there will be cycle phases, pressure inside the chamber (**P1**), and pressure in a jacket (**P2**) displayed on a control panel LCD display. There will be the current chamber temperature (**T1**) and a time remaining to the end of a particular cycle phase displayed on LED. The pressure in a sterilization chamber can also be read out of a manovacuumeter (pos. 4).

### 6.2.2. Operating the sterilizer in an unloading side

- during the sterilization process,  indicator will light up on the control panel. After a sound signalling the end of the process and lighting the  indicator, the door can be opened with a  key,



**In case of the Bowie-Dick Test and Vacuum Test programs opening the door in a unloading side is impossible.**

- place the transport trolley under the chamber outlet. Place the levers of the transport trolley into  position and pull the loading cart with a hook to a blocked position on a transport trolley.



**While unloading the sterilizer a special care should be taken. Sterilized items, loading carts are too hot to be touched!**

- put a transport trolley away from the chamber after moving a lever to a  position and haul it to the place it will be unloaded.
- unload a loading cart.
- move a loading cart into a sterilizer chamber (see Operating the sterilizer in a loading side).
- close a sterilizer door with a  key.

### 6.3. Operating a sterilizer while sterilizing infusion solutions and culture media



**Sterilizer is designed to perform a sterilization cycle in open bottles only.**

In "P04 Solutions" program after the time of exposure there is a cool-down phase consisting of slow levelling of the pressure inside the chamber with an atmospheric pressure as a result of steam condensation and its escape through an opening in a drain system.

The condition to end the phase is lowering the temperature inside the chamber below 80°C and lowering the pressure to the level of an atmospheric pressure.

Sterilizer designed to sterilize liquids (ex. infusion solutions) is equipped with additional, movable temperature sensor located in the chamber (in a reference bottle).

Attention: the temperature sensor should be placed inside the reference bottle in such a way, that it is submersed in a sterilized liquid by at least min. 100 mm.

A reference bottle means a bottle of the same capacity and contents as the bottle containing a sterilized liquid. The reference bottle is not supplied with a sterilizer. In case of a need to sterilize a liquid in small bottles it is acceptable to use bottles of larger capacity, sufficient to accommodate a temperature probe.

In order to ensure comparable temperature measurement conditions in a reference bottle, it or its contents should be replaced with every sterilization cycle finished.

Reference bottle should be placed in a lower part of a sterilizing chamber. Bottles to be sterilized should be filled to two thirds of their capacity to avoid spilling the liquid they contain.



**Sterilizer is not designed to sterilize aggressive liquid that could cause corrosion of the sterilizer chamber.**

When using a program with the venting phase consisting of one vacuum application, the temperature of load placed in a sterilizer chamber should not be more than 25°C, and a sterilization cycle should be commenced immediately after load is placed inside the chamber.

#### 6.4. Emergency process termination

If for any reason, ex. when further operation of the device could be dangerous for its operators, it is necessary to terminate a process immediately. It can be done in every moment during a sterilization cycle.



**Executing a manual sterilization cycle phase change makes it impossible to treat that load cannot as a sterile one.**

To the begin the emergency process termination, press the button "**EMERGENCY STOP**", which is located in loading and the sterile side of control panel. The device emits intermittent sound signal. The LCD shown "**Emergency alarm activated!**"

#### 6.5. Turning the sterilizer off

After the sterilizer operation is finished you should:

- turn the sterilizer off with a power switch (pos. 1).
- turn off the sterilizer power supply with a master switch located in the vicinity of the sterilizer,
- turn off the power supply of the generator with a master switch located in the vicinity of the device – in case of integral (built-in) steam generator,
- close the valves on pipework supplying water to a sterilizer, water (conditioned) to a steam generator, compressed air and steam.

## 7. PROCEDURE IN CASE OF FAILURE, IRREGULARITIES OR A FIRE

### 7.1. Emergencies during sterilizer operation

One of the important functions of the controller is supervising and checking the executed programs. The controller continuously measures all the parameters and verifies their compatibility with the data stored in a controller memory (pre-programmed). Additionally the status of all control circuits and location of mechanical elements is verified. All the incompatibilities with a pre-programmed data are displayed as error messages on the control panel displays.

|   |   |
|---|---|
|  | <b>Please note, that emergencies are not (in majority of cases) failures of the sterilizer. These are conditions when operating parameters are unexpected ex. lack of water or compressed air supplied.</b> |
|---|---|

Messages displayed are intended to facilitate operation of a sterilizer and to inform the operators on the failure cause.

On the screen, message about the emergency is displayed together with the time of occurrence. Full list of messages are presented in Table 3.

### 7.2. Irregularities of a sterilizer operation

#### 7.2.1. Pressure rise or steam leaks

In case of pressure rise exceeding an allowed operating pressure level or if steam, water or air leaks are noticed or in case of any events that can be dangerous, the “**Emergency STOP**” button should be pressed.

After the procedure is finished, chamber doors should be opened, electric power should be turned off, and valves on pipework supplying steam, water and air should be closed. Then a maintenance professional should be called to eliminate a failure.

### 7.3. Conduct in case of fire

Turn off a sterilizer and a steam generator (in case it is a built-in one) with a master switch. Close a steam supply valve.

Extinguishing a fire is allowed only with extinguishers appropriate for extinguishing the fire of electric devices.

## 8. MAINTENANCE, CLEANING, INSPECTION



The warranty of the sterilizer does not include natural consumption of the device and consumable materials such as: door gasket, sterile air filter, paper and the cartridge to the printer.

### 8.1. Maintenance schedule

Activities to be performed on everyday basis:

- \* it is recommended that a „device log” with all information about tests, examinations, maintenance activities and repairs and the printouts of a program logs be maintained
- \* every day before commencing an operation you should:
  - check if there is a sufficient supply of paper in a printer and if the printing ribbon in a cartridge is not worn out. Replace when it is necessary (see *Printer maintenance*).
  - check a drain filter located in a lower part of the chamber (drain). Take a filter out and clean it when it is necessary (pos. 10).
- \* after the operation is finished and a cool-down completed, wipe the interior of a sterilization chamber with a soft cloth dampened with popular cleaning agents, again with a damp one, and then with a dry cloth.
- \* **in case of the first start up, after downtime, and periodically, not less frequently than once a month** check the safety valve for proper operation.  
In order to check the safety valve for proper operation, after the operation pressure of the generator of 2,5 bar is obtained, proceed as follows:



The exhaust handwheel is too hot to be touched. It is recommended to wear a protective glove and to pay attention to the escaping steam.

- a. open the front guard
- b. turn the exhaust handwheel counterclockwise as far as the steam is being blown out (do not turn the handwheel too far).
- c. turn the exhaust handwheel clockwise as far as it stops (closure)
- d. close the front guard



Should the valve operation be found defective (no or too small steam escape) switch the sterilizer off.

Activities to be performed periodically:

| SUBASSEMBLY  | Recommended period |          |         |         | COMMENTS  |
|--|--------------------|----------|---------|---------|---|
|  | 6 months           | 3 months | 1 month | 1 week  |   |
| <b>CHAMBER</b>   |                    |          |         |         |   |
| insides of a sterilization chamber   |                    |          |         | CL (O)  |   |
| external sterilizer walls  |                    |          |         | CL (O)  |   |
| door gasket *  | R (S)              |          |         | CHK (O) | <i>check the condition of doors gasket (without taking out), watch out for scratches and deformations, assess whether a whole surface of a gasket is covered with grease Use OKS grease</i> |
| drain filter of the chamber  |                    |          |         | CL (O)  |   |
| <b>INSTALLATION AND SUBASSEMBLIES</b>  |                    |          |         |         |   |
| boiler of a steam generator**  | CHK (S)            |          |         |         | <i>to remove scale use non-aggressive formulae such as KAMIX</i>  |
| water level electrodes in the steam generator**  | CHK (S)            |          |         |         | <i>check the length, adjust</i>   |
| water meter glass**  | CHK (S)            |          |         |         |   |
| (supplying) water pump **  | CHK (S)            |          |         |         |   |
| safety valve   |                    |          | CHK (S) |         |   |
| vacuum pump  | CHK (S)            |          |         |         |   |
| check valves   | CHK (S)            |          |         |         |   |
| sediment traps on entries of steam, water and compressed air supply installations  | CL (S)             |          |         |         | <i>a compressed air filter is equipped with an automatic dehydration system</i>   |
| connection tightness – leaks   |                    | CHK (S)  |         |         |   |
| sterile air filter   | R (O)              |          |         |         |   |
| <b>ELECTRIC CONTROL</b>  |                    |          |         |         |   |
| cables, electrical connections condition   | CHK (S)            |          |         |         | <i>especially in heating circuits **</i>  |
| <p>where CHK – check, CL – clean, R – replace.</p> <p>(S) - performed by the technical service<br/>(O) - performed by the user's operating or technical personnel</p> <p>* – replace as needed, no more seldom than once in half a year<br/>** – concerns versions with integral (built-in) steam generator.</p> |                    |          |         |         |   |

ATTENTION: The frequency of maintenance actions depends on the quality of water supplied to the device (see *Parameters of supplied water*).

## 8.2. Cleaning

|   |  |
|---|--|
|  | <b>Before cleaning, a sterilizer should be disconnected from electricity and cooled.</b> |
|---|--|

To clean the chamber and external walls the popular, non-aggressive stainless steel (chrome) cleaning agents ex. "HELIOS", causing no damage to the cleaned surfaces should be used.

Take care to avoid introduction of foreign objects into the chamber blowdown connection. After cleaning, cover the stainless steel external walls with a layer of silicate grease (spray).

To remove scale use only a dedicated agent ex. „KAMIX”.

|   |   |
|---|---|
|  | <b>In case of large sterilizers, when entering the chamber is required in order to clean it, electric power and steam, air and water supply should be unconditionally disconnected.</b> |
|---|---|

|   |                                      |
|---|--------------------------------------|
|  | <b>SMS sells maintenance agents.</b> |
|---|--------------------------------------|

### 8.3. Maintenance inspections

Regular maintenance inspections ensure safe and failure-free operation of a sterilizer.

Maintenance inspection should be conducted by authorized SMS representatives, after every 500 operation cycles of the sterilizer, but not more seldom than once every half a year. The results of each inspection should be recorded in a “device log”.

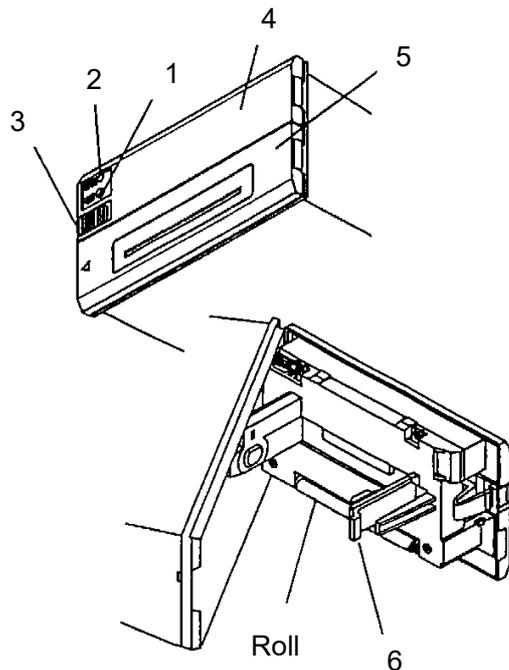
Within an inspection the following actions should be performed:

Within an inspection the following actions should be performed:

- check the operation of systems influencing safety:
  - check the operation of safety valves, opening threshold pressure,
  - check the operation of safety bar located in an upper edge of the doors, adjust as needed,
  - check the operation of a door block and clamps blocking the program start in case of incomplete door locking, adjust as needed,
  - check the electric connections, especially safety wiring, screw home,
- check the door tightening system:
  - check the condition of the gasket (wear, grease), replace as needed,
  - check the condition of a gasket groove in the chamber,
- check the tightness, clean the filters, steam trap, valves:
  - steam installation,
  - water installation,
  - compressed air installation,
  - drain installation,
- check the water level control system in a steam generator (minimum and maximum level), adjust as needed,
- check the operation of a pump (vacuum level, anti-cavitations valve setting)
- check the measuring and control instruments, calibrate as needed:
  - manovacuumeters,
  - PT100 temperature sensors,
  - pressure transmitters,
- check the emergency condition indicators,
- execute the Air leakage test,
- execute the Bowie&Dick test,
- check the operation of a sterilizer while executing programs
- commission a device to the user.

## 8.4. Printer maintenance

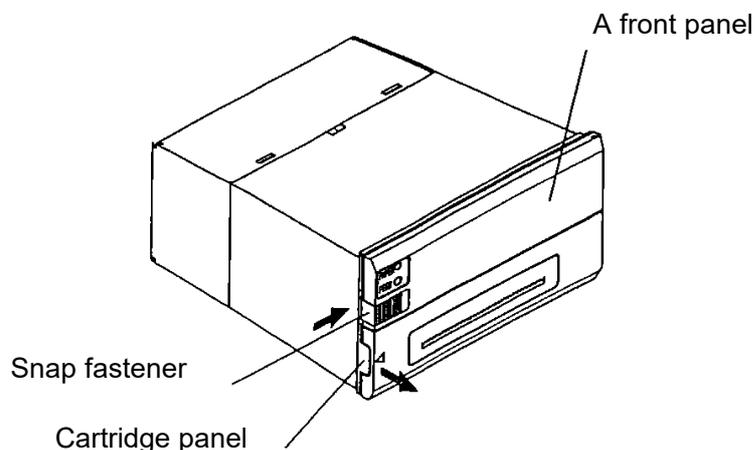
A CBM-920 printer is 40 – column dot-matrix printer characterized by an easy operation and high reliability.



1. Paper feed button FEED
2. Paper out detector PAPER
3. Snap fastener
4. Front panel
5. Cartridge panel
6. Paper grip

### Opening/closing a front panel

1. To open a panel press the snap fastener (3) on the left and pull it towards yourself. A 180° rotation of a panel is possible.
2. Close a panel by pressing it against the case until you hear a „click”. Watch out for paper being clamped.



### Opening/closing a cartridge panel

Check if the paper sticks out from a case. If so - cut it out.

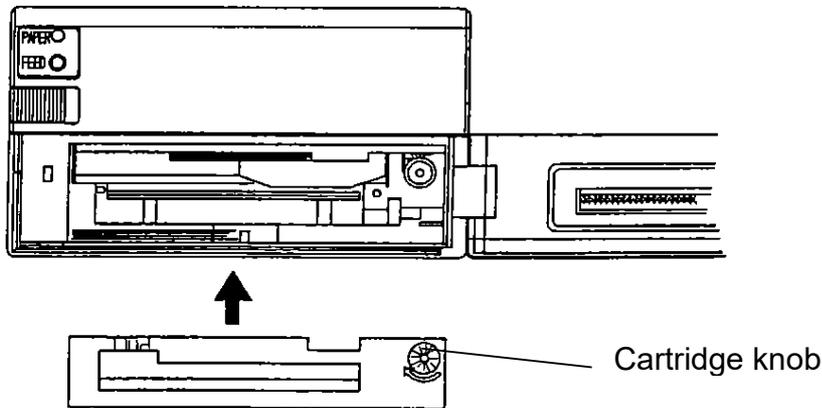
1. Grab a left side of a panel with a finger and pull it towards yourself. A 180° rotation of a panel is possible.
2. To close, press the panel.

### Paper feed

Pressing a FEED button once causes feeding a paper by one line. Holding a button for a longer time causes continuous paper feed. Use only a FEED button to feed paper. Paper feed is possible only when a printer is not printing.

### Installing/changing a cartridge

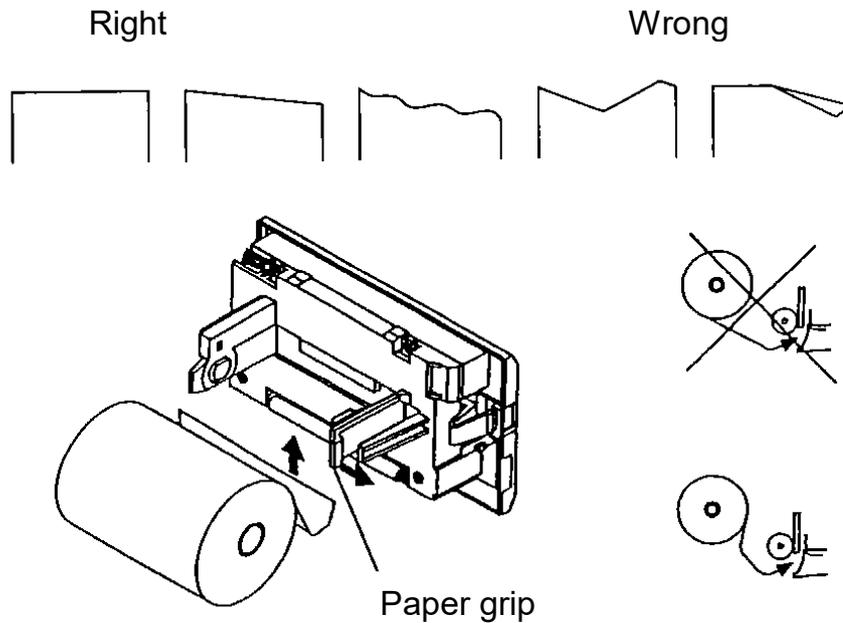
1. Open a cartridge panel. Remember to disconnect mains.
2. If the paper sticks out from a case cut (tear) it out.
3. Insert a cartridge between a printing head and a plate located opposite the printing head and press on a cartridge knob side. Pay attention to a correct direction of a cartridge.
4. Turn the cartridge knob lightly in the direction indicated by an arrow.
5. To take the cartridge out, pull it holding in a place indicated by PULL.



|   |  |
|---|--|
|  | <ul style="list-style-type: none"> <li>▪ <b>Leaving a cartridge in a printer can cause stains on paper in case of long intervals between printouts. Using a printer in a low temperature makes the printout lighter.</b></li> <li>▪ <b>Never start printing without a cartridge installed. It can damage a printing head.</b></li> <li>▪ <b>Replace a cartridge in case of wear.</b></li> <li>▪ <b>Use only quality cartridges.</b></li> </ul> |
|---|--|

### Installing/changing paper

1. Open a front panel.
2. Cut the end of paper roll according to a drawing.
3. Insert paper to a paper lead mechanism. If the automatic paper feed is enabled, paper will be loaded automatically. If not, press the FEED button until the paper is loaded into a mechanism.
4. Draw a paper grip aside (6) in the direction indicated by an arrow on the drawing, insert a paper roll, placing its core on a holder.
5. Wind the loose paper onto a roll and close a front panel.
6. To replace paper draw a paper grip aside in the direction indicated by an arrow and take a core out. Remove the paper which protrudes from a printer with a FEED button. Install a new paper roll and press FEED again. The printer will be ready to print in a while.



|   |   |
|---|---|
|  | <ul style="list-style-type: none"> <li>▪ <b>Carefully check the direction the roll is wound.</b></li> <li>▪ <b>While changing paper, printing is not allowed.</b></li> <li>▪ <b>After inserting paper into a feeding mechanism, never try to pull it back. This can cause a printing head damage.</b></li> <li>▪ <b>Skewed paper feeding can cause paper jamming or breaking. Turn a printer off immediately, and delicately pull the paper in a feed direction.</b></li> </ul> |
|---|---|

### A printer test

Turn the printer on while pressing a FEED button.

There will be available characters and a printer configuration printed among others. After the end of test a printer will switch to a 'ready' state.

### End of paper signalling

The end of paper is signalled by lighting a PAPER indicator. The printout is stopped. Resuming a printout is possible after replacing a paper roll.

Using different paper type is permitted if the paper meets the following conditions: roll width  $57 \pm 0.5$  mm, external diameter 50 mm, internal diameter of a core  $12 \pm 1$  mm, paper thickness 0,13 mm or less.

|   |   |
|---|---|
|  | <p><b>Supplies: paper rolls and cartridges can be purchased in SMS company store or via the sales department.</b></p> |
|---|---|

## 9. TECHNICAL INFORMATION

### 9.1. Technical data

| Type  |                        | AS 666                 | AS 669      | AS 6612      | AS 6615      | AS 6618      |
|---|------------------------|------------------------|-------------|--------------|--------------|--------------|
| Total capacity of a sterilization chamber<br>version <b>PA, WPA</b><br>version <b>A, WA</b> | dm <sup>3</sup>        | 334<br>375             | 459<br>499  | 605<br>646   | 756<br>796   | 897<br>938   |
| Dimensions of usable space<br>width×height×depth  | mm                     | 662x662x694            | 662x662x950 | 662x662x1250 | 662x662x1560 | 662x662x1850 |
| Usable capacity of a sterilization chamber  | dm <sup>3</sup>        | 304                    | 416         | 548          | 684          | 811          |
| Chamber capacity in standard load units (300x300x600)                                       | STE                    | 4                      | 6           | 8            | 10           | 12           |
| External dimensions   |                        |                        |             |              |              |              |
| width   | mm                     | 1170                   | 1170        | 1170         | 1170         | 1170         |
| height  | mm                     | 1900                   | 1900        | 1900         | 1900         | 1900         |
| depth – version <b>PA, WPA</b>  | mm                     | 970                    | 1225        | 1525         | 1835         | 2125         |
| depth – version <b>A, WA</b>  | mm                     | 1060                   | 1315        | 1615         | 1925         | 2215         |
| Weight  | ver. <b>A, PA</b>      | 710                    | 790         | 880          | 980          | 1060         |
|   | ver. <b>WA, WPA</b>    | 760                    | 840         | 930          | 1030         | 1130         |
| Sterilizer weight during a water test   | ver. <b>A, PA</b>      | 1060                   | 1250        | 1485         | 1735         | 1960         |
|   | ver. <b>WA, WPA</b>    | 1100                   | 1300        | 1535         | 1785         | 2030         |
| Utilities   |                        |                        |             |              |              |              |
| Steam – supply pressure 0,25 MPa*)  |                        |                        |             |              |              |              |
| max. consumption  | kg/min                 | 0,9                    | 1,2         | 1,5          | 1,7          | 1,8          |
| avg. consumption  | kg/cycle               | 8,5                    | 11          | 13           | 15           | 16           |
| Water – supply of a condenser and a vacuum pump – supply pressure 0,1÷0,6 MPa               |                        |                        |             |              |              |              |
| max. consumption  | dm <sup>3</sup> /min   | 25                     | 25          | 25           | 25           | 25           |
| avg. consumption  | dm <sup>3</sup> /cycle | 100                    | 100         | 150          | 170          | 200          |
| Water – supply of a steam generator – supply pressure 0,1÷0,6 MPa – version <b>WPA</b>      |                        |                        |             |              |              |              |
| max. consumption  | dm <sup>3</sup> /min   | 5                      | 5           | 5            | 7            | 10           |
| avg. consumption  | dm <sup>3</sup> /cycle | 10                     | 13          | 15           | 20           | 25           |
| Compressed air - supply pressure 0,5÷0,8 MPa  |                        |                        |             |              |              |              |
| efficiency  | Ndm <sup>3</sup> /h    | 600                    | 600         | 600          | 600          | 600          |
| Electricity - 3x380-400V; 50/60Hz   |                        |                        |             |              |              |              |
| Power installed   | ver. <b>A, PA</b>      | 2,5                    | 2,5         | 2,5          | 2,5          | 2,5          |
|   | ver. <b>WA, WPA</b>    | 36+2,5                 | 36+2,5      | 36+2,5       | 54+2,5       | 54+2,5       |
| Heat emission   |                        |                        |             |              |              |              |
| version <b>A, PA</b>  | kW                     | 3,2                    | 3,8         | 4,4          | 5,0          | 5,7          |
| version <b>WA, WPA</b>  |                        | 3,6                    | 4,2         | 4,8          | 5,2          | 6,3          |
| Average acoustic power level  | dB (A)                 | <65                    |             |              |              |              |
| Maximum allowable pressure  | bar                    | 2,8                    |             |              |              |              |
| Maximum allowable temperature   | °C                     | 142                    |             |              |              |              |
| Software version  | -                      | PLC - v1.2, HMI – v1.2 |             |              |              |              |

\*) a unit used in the description – MPa, can be replaced by bar or kPa – with a conversion 0,1 MPa = 1 bar = 100 kPa.

## 9.2. Measurement and control instruments

Measurement and control instruments table:

- Manovacuumeter, range  $-0,1 \div 0,5$  MPa, class 1,6.  
Measurement of a pressure inside the chamber and inside a generator boiler (in case of integral (built-in) steam generator). Measurement of a pressure inside a steam supply installation (in case of an external steam source).
- Pressure transmitter, range  $0 \div 4$  bar absolute pressure, precision class 0,15%.  
Measurement of steam pressure inside the chamber and inside a heating jacket
- Temperature sensor type  $2 \times$ PT100 A class.  
Measurement of temperature inside the chamber
- Temperature sensor type PT100.  
Measurement of temperature inside the water tank
- Sterilizing cycle parameters logger (temperature and pressure in the chamber, time).  
Basic technical data of a logger:  
Parameter logged: temperature in the chamber:
 

|                         |  |
|-------------------------|--|
| – line type             | resistance (PT100),                    |
| – measurement system    | 3 wire,                                |
| – resolution            | not worse than $0,1^{\circ}\text{C}$ , |
| – measurement range     | $0 \div 150^{\circ}\text{C}$ ,         |
| – measurement frequency | not worse than 200 ms.                 |

 Parameter logged: pressure in the chamber:
 

|                         |                           |
|-------------------------|---------------------------|
| – line type             | current measurement,      |
| – measurement range     | $4 \div 20\text{mA}$ ,    |
| – resolution            | not less than $0,1$ kPa , |
| – measurement scope     | $0 \div 400$ kPa,         |
| – measurement frequency | not worse than 200 ms.    |

Manovacuumeters and pressure converters are connected with drain trap pipes securing their measurement systems against steam and rapid pressure changes. Manovacuumeters and pressure converters are equipped with connectors for monitoring manometers.

## 9.3. Description and settings of safety devices

Safety devices table:

- Sterilizer is equipped with three proportional, spring safety valves. Two with threaded connectors G1/2" (opening pressure –  $0,28$  MPa ( $2,8$  bar)), one connected to the steam generator boiler, next to the sterilizing chamber and one with threaded connector G1/4" (opening pressure –  $0,45$  MPa ( $4,5$  bar)), connected to the door gasket grooves.
- Thermal switch  
In case of sterilizers with an integral (built-in) steam generator an additional safeguard against overheating has been mounted. A temperature limiter type (set to  $160 \pm 20^{\circ}\text{C}$ ), has been mounted on a boiler bottom. The limiter turns off the heater power in case when temperature on the surface of the boiler significantly exceeds permissible operating temperature.
- Emergency switch  
On the sterilizer front panel, on the loading and sterile side, emergency switches of double function are mounted:
  - while the door is in motion, pressing the button makes the door stop instantly and an alarm message is displayed,
  - pressing the button during sterilization interrupts the process. All valves supplying media to the chamber will be closed.

## 9.4. Parameters of steam (condensate) and water supplying a steam generator

Impurities in steam (condensate) and water supplying a steam generator

| Contents   | condensate                           | supplying water                      |
|--|--------------------------------------|--------------------------------------|
| Dry residue  | ≤1,0 mg/l                            | ≤10 mg/l                             |
| Silicon oxide, SiO <sub>2</sub>                      | ≤0,1 mg/l                            | ≤1 mg/l                              |
| Iron   | ≤0,1 mg/l                            | ≤0,2 mg/l                            |
| Cadmium  | ≤0,005 mg/l                          | ≤0,005 mg/l                          |
| Lead   | ≤0,05 mg/l                           | ≤0,05 mg/l                           |
| Other heavy metals except for iron, cadmium and lead | ≤0,1 mg/l                            | ≤0,1 mg/l                            |
| Chlorides (Cl <sup>-</sup> )                         | ≤0,1 mg/l                            | ≤0,5 mg/l                            |
| Phosphates (P <sub>2</sub> O <sub>5</sub> )          | ≤0,1 mg/l                            | ≤0,5 mg/l                            |
| Conductivity (at 20°C)                               | ≤4,3 μS/cm                           | ≤5 μS/cm                             |
| pH value (acidity)                                   | 5 to 7                               | 5 to 7,5                             |
| Colour   | colourless, clear without a sediment | colourless, clear without a sediment |
| Hardness (Σ alkaline earth ions)                     | <0,02 mmol/l                         | <0,02 mmol/l                         |

It is recommended that analysis of conformance with the values specified in a table was conducted in accordance with analytic methods generally recognized.

|   |   |
|---|---|
|  | <p><b>Using steam and water with impurity levels exceeding those found in an above table can significantly shorten a sterilizer operating life and lead to escalation of maintenance cost. Finally, it can reduce a warranty period or lead to warranty loss.</b></p> |
|---|---|

## 10. BASIC INFORMATION CONCERNING THE SAFETY OF STERILIZER OPERATION

A steam sterilizer is a pressure vessel and as such should be commissioned in accordance with a local law.

Maintenance activities, verifications and changes in parameters setpoints should be carried out by a person trained by a manufacturer.

|   |  |
|---|--|
|  | <p><b>IT IS FORBIDDEN TO:</b></p> <ul style="list-style-type: none"> <li>▪ entrust unauthorized persons with operation, service and maintenance of a sterilizer</li> <li>▪ make any changes in a pressure vessel design (the chamber, doors, a generator's boiler) ex. by drilling additional holes, welding additional elements etc.</li> <li>▪ executing any sterilization processes if the doors to an access room are locked (an easy access to safety valves must be secured)</li> <li>▪ touch the sterilizer fittings (especially electric appliances) when power is on</li> <li>▪ change the setting of safety valves opening pressure, break their seals or change the configuration of steam supply pipework</li> <li>▪ have unauthorized persons repair or replace manometers, pressure converters and temperature sensor and break their seals</li> </ul> |
|---|--|

|   |   |
|---|---|
|  | <p><b>IT IS OBLIGATORY:</b></p> <ul style="list-style-type: none"> <li>▪ to leave a sterilizer, when not in use that after the working hours, with steam, water and air valves closed, electric power turned off, and the doors to an access room locked. The lock an access room should be protected from unauthorized persons' access.</li> <li>▪ to press "Emergency STOP" button in case of excessive pressure rise (over 2,8 bar), failure, steam outflow, suspicious noise press an emergency button without switching the mains off</li> <li>▪ to disconnect immediately (with a master switch) the sterilizer from mains and activate a safety valve if after pressing an "Emergency STOP" button a vacuum pump was not started and pressure does not fall in the chamber.</li> <li>▪ that every reservation and remarks concerning sterilizer operation be immediately reported to a maintenance professional. Elimination of possible defects should be supervised personally.</li> </ul> |
|---|---|

## 11. APPENDIX

### 11.1. Sterilizer equipment

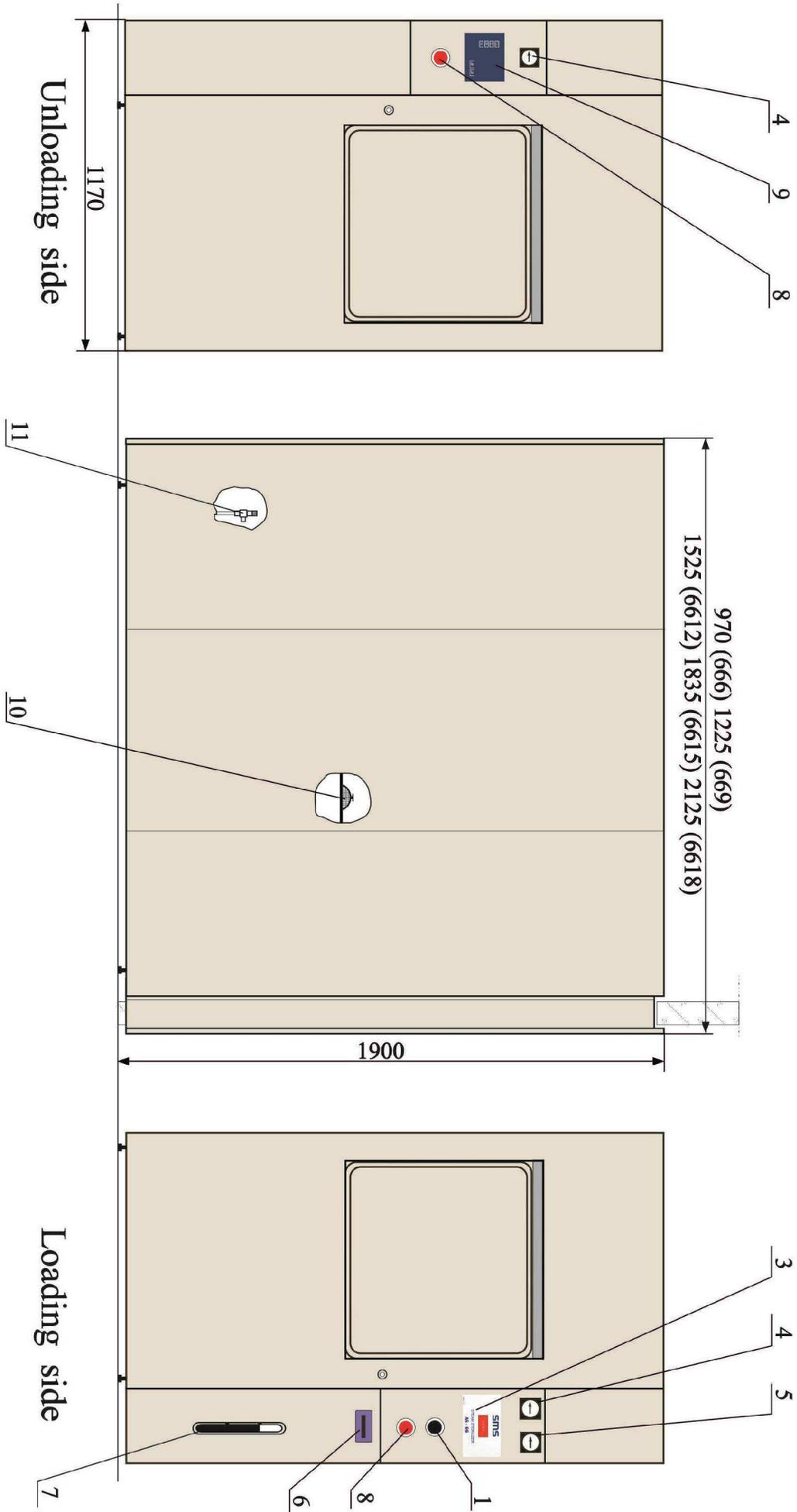
- Standard equipment:
  - loading cart **WWK666** or **WWP666** (with two shelves) – for AS 666 sterilizers,
  - loading cart **WWK669** or **WWP669** (with two shelves) – for AS 669 sterilizers,
  - loading cart **WWK6612** or **WWP6612** (with two shelves) – for AS 6612 sterilizers,
  - loading cart **WWKS669** or **WWPS669** (with two shelves) – for AS 6618 sterilizers - 2 pcs,
  - loading cart **WWK6618** or **WWPS6618** (with two shelves) – for AS 6618 sterilizers.
- Optional equipment:
  - transport trolley **WT666** – for AS 666, works with loading cart **WWK666**
  - transport trolley **WT669** – for AS 669 and AS 6618 sterilizers, works with loading cart **WWK669** and **WWKS669**
  - transport trolley **WT6612** – for AS 6612, works with loading cart **WWK6612**
  - transport trolley **WT6618** – for AS 6618, works with loading cart **WWK6618**
  - sterilizing basket **KS 6030**, dimensions 580×280×260 mm,
  - sterilizing basket **KS 6015**, dimensions 580×280×130 mm,
  - silent-running compressor – supplies sterilizers with a compressed air,
  - **WPT** steam generator (detached), capacity 108 kg/h – works with AS 66 type sterilizers,
  - RO station or ion exchange water conditioner and other.

### 11.2. Scraping the sterilizer

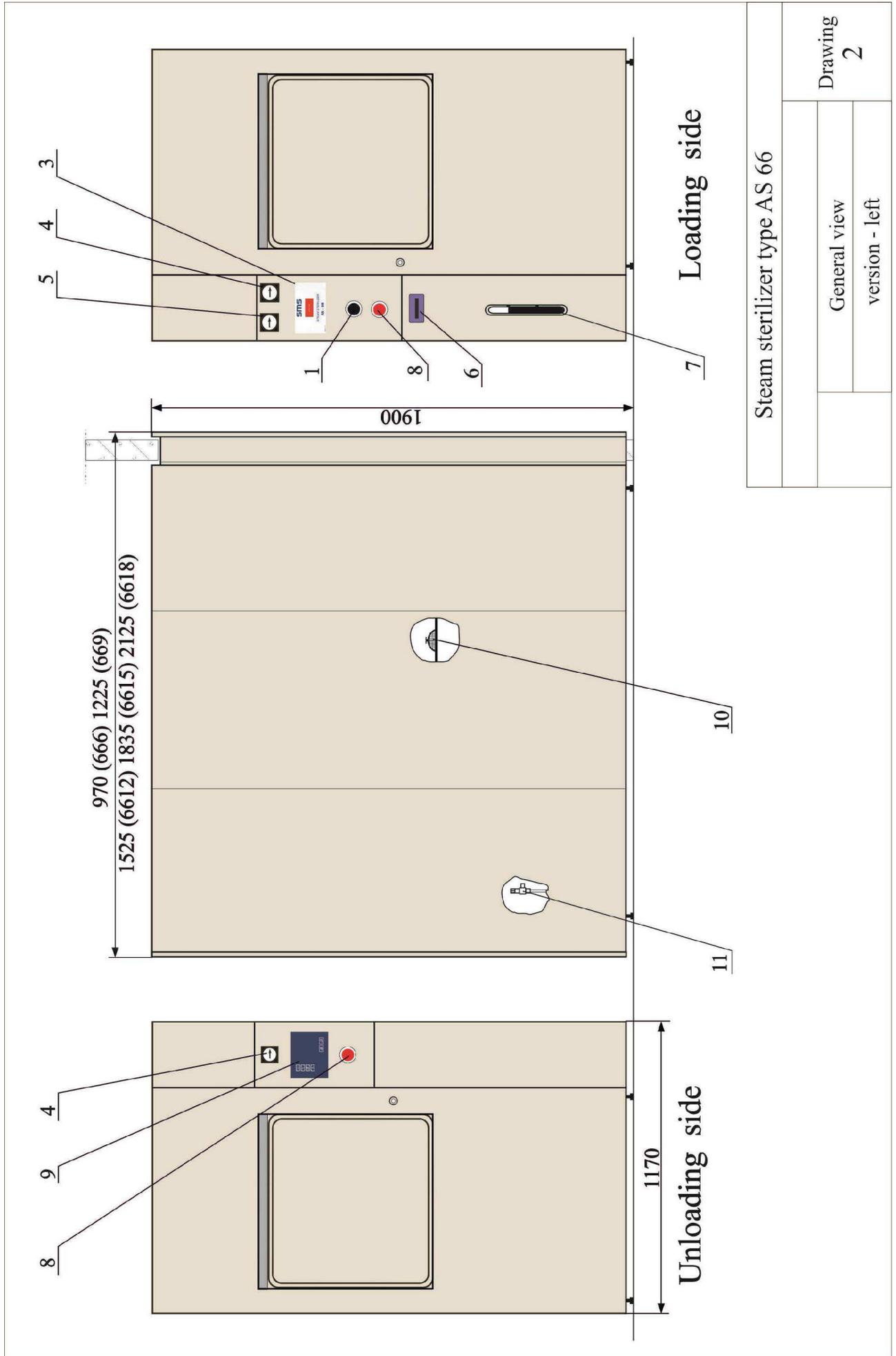
The sterilizer is composed of 94 % stainless steel, 4 % of non-ferrous metals and 2 % of other materials, which – after dismantling the unit by an authorised person – may be recycled.

### 11.3. Sterilizer type AS 66 – general view

On the following three pictures, the general views with basic dimensions and a layout of control and supervisory elements were shown.



|                             |  |              |
|-----------------------------|--|--------------|
| Steam sterilizer type AS 66 |  | Drawing<br>1 |
| General view                |  |              |
| version - right (standard)  |  |              |



Water-steam and compressed air installation scheme of sterilizer type AS 66

