



NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.

NC 23B

BENCH TOP STEAM STERILIZERS

USER'S MANUAL



Dear Nüve User,

We would like to take this opportunity to thank you for preferring this Nüve product. Please read the operating instructions carefully and keep them handy for future reference.

Please detain the packing material until you see that the unit is in good condition and it is operating properly. If an external or internal damage is observed, contact the transportation company immediately and report the damage. According to ICC regulations, this responsibility belongs to the customer.

While you are operating the instrument please;

1. obey all warning labels,
2. do not remove warning labels,
3. do not operate damaged instrument,
4. do not operate instrument with a damaged cable,
5. do not move instrument during operation.

In case of a problem contact your Nüve agent for an authorized service or maintenance.

The validity of the guarantee is subject to compliance with the instructions and precautions described in this manual.

Nüve reserves the right to improve or change the design of its products without any obligation to modify previously manufactured products.

Information contained in this document is the property of Nüve. It may not be duplicated or distributed without our permission.

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WARRANTY CERTIFICATE

1. Nüve warrants that the equipment delivered is free from defects in material and workmanship. This warranty is given for a period of two years. The warranty period begins from the delivery date.
2. Warranty does not apply to parts normally consumed during operation or general maintenance or any adjustments described in the operating instructions provided with the instrument.
3. Nüve does not accept any liability in case where the goods are not used in accordance with their proper intent.
4. The warranty may not be claimed for damages incurred during the shipment, for damages resulting from improper handling or use, abuse, fire, liquid spillage, tampering or unauthorized repairs by any persons, use of defective or incompatible accessories, exposure to abnormally corrosive conditions, use of the product in non-standard environmental conditions, including but not limited to failure to meet requirements of ambient temperature, lubrication, humidity or magnetic field influences, from the defects in maintenance, negligence, bad functioning of auxiliary equipment, in the case of force majeure or accident and incorrect power supply.
5. Any injury, loss or damage caused; due to a failure resulting from negligence of the instructions given in this manual; is beyond the scope of the warranty conditions.



BEFORE OPERATING THE INSTRUMENT THIS MANUAL SHOULD BE READ CAREFULLY.



THE VALIDITY OF THE GUARANTEE IS SUBJECT TO THE OBSERVATION OF THE INSTRUCTIONS AND PRECAUTIONS DESCRIBED IN THIS MANUAL.

INFORMATION CONTAINED IN THIS DOCUMENT IS THE PROPERTY OF NÜVE. IT MAY NOT BE DUPLICATED OR DISTRIBUTED WITHOUT PERMISSION.

PLEASE REGISTER ONLINE TO VALIDATE YOUR WARRANTY:

To register your warranty online, please visit our webpage www.nuve.com.tr and fill in the “Warranty Registration Form”.

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I. INTRODUCTION

I.1. USE AND FUNCTION

NC 23B Bench Top Steam Sterilizers are widely used for sterilization of appliances utilized in general medical applications, dentistry, acupuncture and veterinary sciences. These equipment are also appropriate for the sterilization of tools and instruments that are directly in contact with blood or other body fluids (e.g. tools and instruments used at beauty clinics, tattoo centers, hair-dressers etc.)

NC 23B Steam Sterilizers are manufactured in accordance with EN 13060 standard, which outlines the general rules for small steam sterilizers and determines the sterilization methods for specific sterilization loads. According to EN 13060 standard, unwrapped solid loads, solid porous loads, hollow A type loads, hollow B type loads, single and double wrapped loads can be sterilized in small steam sterilizers.

NC 23B Steam Sterilizers, come with 5 operating programs for sterilization temperatures of 134°C and 121°C, 2 special programs, 1 drying program and 2 test programs. They can be used for wrapped or unwrapped, porous textile or hollow loads, metal, glass and rubber materials that can be sterilized using pressurized and saturated water vapor. NC 23B are not compatible with liquid sterilization.

The steam is produced by the steam generator. The jacket system which surrounds outside of the chamber provides temperature homogeneity. Jacket system is also used for pre-heating which helps to decrease total sterilization cycle duration.

All programs operate full-automatically without user's interference.

NC 23B steam sterilizers have several safety functions with its integrated safety thermostat, safety valve and surface thermostat in addition to the safety features of the control system (i.e. high pressure, high temperature).

NC 23B Steam Sterilizers are designed and manufactured in accordance with international directives and EN 13060, EN 61010-1, EN 61010-2-040, EN 60601-1-6, EN 61326-1, EN 62304, EN 62366-1, EN ISO 14971, EN 50419, EN 13445 and EN ISO 15223-1 standards under the supervision of total quality management systems ISO 9001 and ISO 13485.

This device is in compliance with WEEE Regulation.

Do not operate the instrument for purposes other than main purpose.

This instrument is only to be used by authorized people after the user manual has been read.

If the warnings mentioned in this manual are not considered, NUVE will not be responsible from their results.

2. TECHNICAL SPECIFICATIONS

2.1. TECHNICAL SPECIFICATIONS TABLE

Technical Specifications	NC 23B
Sterilization Temperatures	121 °C – 134 °C
Number of Preset Programs	5
Number of Special Programs	2 special programs + 1 drying
Test Programs	Vacuum Test, Bowie&Dick/Helix Test
Maximum Chamber Pressure	2.60 Bars
Maximum Temperature	140 °C
Sterilization Time	1 – 20 minutes
Number of Pre-Vacuum	1 – 4
Drying Time	1 – 60 minutes
Stand-by	20 – 999 minutes / OFF
Temperature Sensors	Pt-100
Chamber Material	304 Stainless Steel
Steam Generator Material	304 Stainless Steel
Chamber Volume (Liters)	23
Power Supply	230 V, 50-60 Hz
Power Consumption	2500W
Control system	N-SmArt™ Programmable Microprocessor
Display	Full-color LCD
Memory	30000 cycles
USB	Standard
Ethernet	Standard
RS 232	Standard
Chamber Dimension (diameter x depth) mm	∅ 260 x 420
External Dimension (W x D x H) mm	570 x 729 x 525

2.2. ACCESSORIES

2.2.1. OPTIONAL ACCESSORIES




F 06 048	Microbiological Filter
S 09 026	Basket (300x600x300mm)
A 08 104	Printer paper
A 08 191	AlerText™ GSM alarm module
A 08 195	NuveCloser™ Software CD with 3 m.RS 232 cable
Y 07 009	Thermal Printer

3. PRECAUTIONS AND LIMITATIONS ON USE

The user shall pay attention to the following:

- Do not operate the instrument for purposes other than its main purpose.
- Handling, transportation, installation, first operation, service and maintenance should be handled by authorized personnel appointed by the manufacturer.
- The instrument should only be used by authorized and trained staff after the instruction manual has been read carefully. Only authorized technical staff can handle the product in case of a failure.
- Correctly grounded power supply should be used.
- NC 23B steam sterilizers are suitable for the sterilization of the textiles, rubber, glass, plastics; all of which are resistant to high pressure and temperature. Materials other than these and heat susceptible objects, explosive, flammable, adhesive and fusible materials shall not be used.
- The liquid to be sterilized in the NC 23B sterilizer should have a boiling point of 100 ° C at sea level at 760 mmHg (1 atm) atmospheric pressure.
- Prior to sterilization, items which would be sterilized should be cleaned and disinfected.
- The load which would be sterilized should withstand to the applied sterilization temperature. Proper sterilization program shall be selected in accordance with the load type.
- Be careful and do not constrict your hand, while closing the door.
- Do not attempt to open the door during the operation.
- Do not touch the body of sterilizer during operation as it can be hot.
- At the end of the operation, do not get too close to the door while opening it, steam can cause scalds and wait for 10 minutes before unloading the sterilizer for temperature to decrease.
- Wear the protective gloves while taking the sample out after sterilization.
- If there is "OPEN DOOR" warning on the display when the door is closed, ensure that the door is fully closed.
- Only original spare parts and original accessories supplied by Nüve should be used.
- The instrument should only be used by authorized and trained staff. Incorrect attempts may cause severe damages.

4. SYMBOLS AND LABELS

	<p>Symbol in the operating instructions:</p> <p>Attention, general hazard area.</p> <p>This symbol refers to safety relevant warnings and indicates possibly dangerous situations.</p> <p>The non-adherence to these warnings can lead to material damage and injury to personal.</p>
	<p>Notified Body:</p> <p>KİWA BELGELENDİRME HİZMETLERİ A.Ş.</p> <p>(İTOSB) İstanbul Tuzla Organize Sanayi Bölgesi Tepeören Mevkii 34957 Tuzla-İstanbul / TURKEY</p>
	<p>Symbol in the operating instructions:</p> <p>This symbol refers to important circumstances.</p>

Labels on the product:



DO NOT OPERATE BEFORE READING THE INSTRUCTION MANUAL!..
KULLANMA KILAVUZUNU OKUMADAN ÇALIŞTIRMAYINIZ!..
Z14.E 02 016

CAUTION!
Always use earthed wall sockets.
DİKKAT!
Cihazı mutlaka topraklı prizde çalıştırınız.
Z14.E 02 022

WARNING !.. DISCONNECT THE MAIN SUPPLY BEFORE REMOVING THE COVER.
DİKKAT !.. BU KAPAĞI AÇMADAN FİŞİ MUTLAKA PRİZDEN ÇIKARINIZ.
Z14.E 02 015

ONLY AUTHORIZED TECHNICAL SERVICE CAN OPEN.
SADECE YETKİLİ TEKNİK SERVİS AÇABİLİR.
Z14.E 02 032

WARNING! HOT SURFACE
DİKKAT! SICAK YÜZEY
Z14.E 02 097

F2x16A 250V ~
FUSES (2X16A)

Earthed Plug



5. INSTALLATION

5.1. ENVIRONMENTAL CONDITIONS

The instrument is designed to operate safely under the following conditions:

- Indoor use only
- Ambient temperature: 5°C to 40°C
- Maximum relative humidity for temperature up to 31°C: 80%
- Maximum altitude: 2000 m
- Temperature for maximum performance: 15°C / 25°C

5.2. HANDLING AND TRANSPORTATION

All handling and transportation must be carried out by using proper equipment and experienced staff. The instrument must be supported underneath and never be turned upside down.

5.3. UNPACKING

Remove the cardboard box packing and the second nylon wrapping around the instrument. Ensure that no damage has occurred during transportation. The below mentioned are provided with the instrument, please check them;

- 1 ea. user's manual and warranty
- 1 ea. microbiological filter
- 3 pieces of shelves
- 1 piece shelf carrier
- 1 piece of shelf support
- 1 ea. PC Communication software CD
- 1 ea. PC communication cable

5.4. MAINS SUPPLY

The instrument requires 230 V, 50/60 Hz.

Please make sure that the supplied mains matches the required power ratings which are written on the name of plate of the instrument located at the back of the instrument.



Always plug-in the instrument to correctly grounded sockets.



A supply fitted with a circuit breaker should be used for protection against indirect contact in case of isolation fault.

5.5. POSITIONING

- Check that the positioning is suitable for the usage purpose and users.
- Check that the instrument is stable on its four pedestals.
- The bench where the instrument is positioned should be resistant to the weight of the instrument and vibration free.
- Check that the user will be able to follow up the operation even when he deals with something else.
- Check that the positioning of the device prevents interference with other equipment in the near surrounding.
- Leave at least 20 cm free space between the device and wall.

5.6. GENERAL PRESENTATION



Figure 1

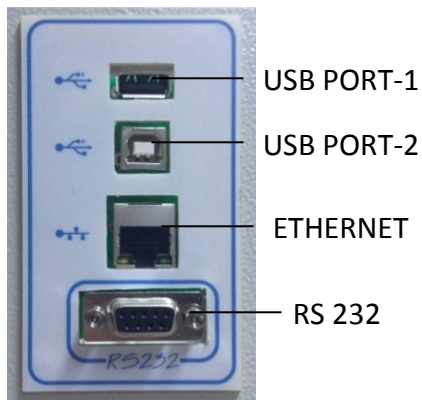


Figure 2 - Communication Unit



Figure 3

- 1- **Control Panel:** Consists of an LC display and four control buttons to select and adjust the equipment functions.
- 2- **Lid Handle:** Opens and closes the front lid with a vertical movement.
- 3- **Fuses:** Main fuses on the phase-neutral lines.
- 4- **On-Off Switch:** Puts the unit on and off power.
- 5- **Thermal Printer:** After operation is completed, printer provides hard copy of sterilization parameters.
- 6- **Water Storage Discharge Connector:** Connector is used to empty the water storage tank. To empty the water storage tank, the silicon stopper shall be removed and the hose shall be pulled out.

- 7- **Waste Water Discharge Connector:** Connector is used to empty the waste water tank. To empty the waste water tank, the silicon stopper shall be removed and the hose shall be pulled out.
- 8- **Communication Unit:** Unit provides USB-1, USB-2, Ethernet and RS 232 inputs for recording, software updating and remote connection.
- 9- **Safety Valve:** Releases the excess steam automatically from the unit in case the inside pressure surpasses 3 Bars. Also used to manually release the chamber pressure or to break vacuum.
- 10- **Microbiological Filter:** Used on the vacuum break connection to sterilize the atmospheric air entering the unit.
- 11- **Condenser:** The water vapor is condensed herein.
- 12- **Water Tank Lid:** Has to be opened to fill up the water tank.

5.7. CONTROL PANEL

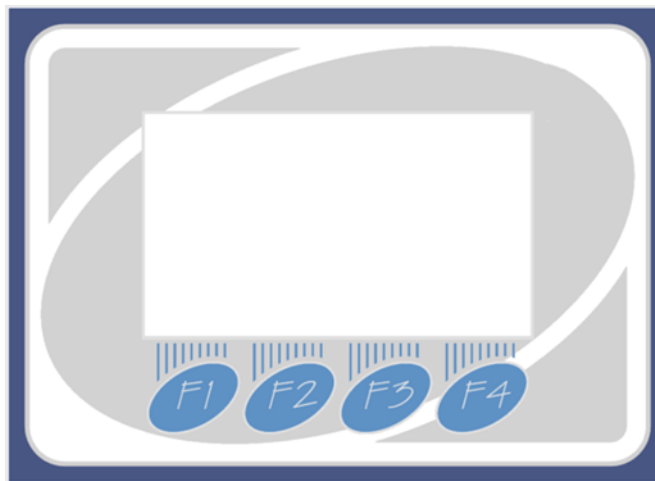















Figure 4

The functions of F1, F2, F3 and F4 keys depend on the meaning of the corresponding symbol appearing on the display. The following table shows the meaning of these symbols.

	<p>This symbol denotes the menu. You can enter the menu by pushing the key corresponding to this symbol.</p>
	<p>This symbol denotes temperature and pressure. When the key corresponding to this symbol is pushed, the screen which shows temperature and pressure values of all sensors in sterilizer.</p>
	<p>This symbol denotes the graph screen. Temperature and pressure values of current or last sterilization cycle can be monitored on a graph by pushing the key corresponding to this symbol.</p>
	<p>This symbol denotes the start key. When the key corresponding to this symbol is pushed, the chosen sterilization program would start.</p>

	<p>This symbol denotes the stop key. When the key corresponding to this symbol is pushed, the chosen sterilization program would stop.</p>
	<p>This symbol denotes backspace. You can return the previous page or exit from the page by pushing the key corresponding to this symbol.</p>
	<p>This symbol denotes the value increase key. You can increase the value by pushing the key corresponding to this symbol while adjusting the numerical values such as temperature or password. It is also used to select next menu item.</p>
	<p>This symbol denotes the value decrease key. You can decrease the value by pushing the key corresponding to this symbol while adjusting the numerical values such as temperature or password. It is also used to select previous menu item.</p>
	<p>This symbol denotes the left key. It appears on the Main menu, Programs and Graph screen. On Main menu and Programs menu, previous menu item is chosen when the key corresponding to this symbol is pushed. On graph screen, the previous graph appears when the key corresponding to this symbol is pushed.</p>
	<p>This symbol denotes the right key. It appears on the Main menu, Programs and Graph screen. On Main menu and Programs menu, next menu item is chosen when the key corresponding to this symbol is pushed. On graph screen, the next graph appears when the key corresponding to this symbol is pushed.</p>
	<p>This symbol denotes enter key. It is used for approval of adjustments.</p>
	<p>This symbol denotes the tab key. When the key corresponding to this symbol is pushed, next item would be selected.</p>
	<p>This symbol denotes settings and it appears only on special programs page. When the key corresponding to this symbol is pushed, the page to set special program parameters is accessed.</p>

5.8. PRIOR TO OPERATION

5.8.1. CONNECTION TO MAINS

- Plug-in the device to correctly grounded socket.



The panel board where the socket is connected shall be fuse protected.

5.8.2. CONNECTION TO WATER SUPPLY

- Open the water tank lid on top of the unit and fill distilled water into the larger tank at the left side, up to the maximum level.
- The smaller tank at the right side is the waste water tank and shall remain empty.
- The water storage tank and the waste water tank are emptied from the discharge connectors situated at the front of the unit (see Figure 1).



Please use only distilled water.



If you see “Insufficient Water” warning, when you attempt to start a program, it means that there is no enough water in the water tank. Add water to the water tank.

5.8.3. ATTACHING MICROBIOLOGICAL FILTER



Figure 5

Mount the microbiological filter (Figure 5) provided with the device to the top of the device where the filter fitting point is.

5.8.4. STERILIZATION PROGRAMS

/23B steam sterilizers, have 5 preset programs; **Universal, Quick, Sensitive Material, Prion** and **Flash**. These programs features and loading methods is explained below. How to set preset and special programs is explained in Section 6.2.2.












Universal Program: Wrapped (single wrapped or double wrapped) or unwrapped materials that are resistant up to 134°C can be loaded up to 1,8 kg textile or 5 kg tools(solid) , if resistant universal program is chosen.


Quick Program: When drying is not important, 1 kg unwrapped tools(solid) materials(as metals on which water do not accumulate) that are resistant up to 134°C can be loaded, if quick program is chosen.


Sensitive Program: Wrapped (single wrapped or double wrapped) or unwrapped materials that are resistant up to 121°C can be loaded up to 1,8 kg or 5 kg tools(solid) materials(as metals on which water do not accumulate).

Prion: Wrapped (single wrapped or double wrapped), or unwrapped materials that are resistant up to 134°C can be loaded up to 1 kg textile or 2 kg tools(solid) materials(as metals on which water do not accumulate), if prion program is chosen.

Flash Program: Unwrapped solid materials that are resistant up to 134°C can be loaded up to 1 kg tools(solid materials as metals on which water do not accumulate).

PROGRAM NAME	Program Temperature	LOADING WAY		MATERIAL TYPE	
		Wrapped Load	Unwrapped Load	Textile	Solid Material
UNIVERSAL	134°C			Max.1,8kg	Max.5kg
QUICK	134°C				Max.1kg
SENSITIVE	121°C			Max.1,8kg	Max.5kg
PRION	134°C			Max.1kg	Max.2kg
FLASH	134°C				Max.1kg

 Before starting the device, pre-heating must be activated (See Section 6.3.4.1). Pre-heating helps to heat the load and prevent condensation.

 Follow the instructions for loading, otherwise the efficiency of the device decreases and this situation may cause error.

5.8.5. PACKAGING

In order to store sterile items for a long time, items should be packed prior to sterilization. Correct packaging of the materials is essential in ensuring that sterility is maintained.

The followings can be used for packaging: metal containers with lids or perforated bottoms with filters in paper, pouches in paper or polypropylene, medical grade paper.

For packaging, observe the following recommendations (for pouches in paper-polypropylene):

- Contents must not exceed $\frac{3}{4}$ of the volume of the pouch.
- The instruments must be positioned so that they can be extracted by their handle.
- The sealing strip on the pouch must be continuous with a height of at least 6 mm.



Use materials that comply with EN 868-1 for packaging the materials to sterilize.

Each packaged prepared must indicate the date of sterilization, the type of cycle performed and the date in which the preservation of sterility expires. This latter value must be established considering the length of preservation of sterility as indicated by the manufacturer of the packaging material, the internal procedure used and stocking conditions of the sterilized material itself.

Instruments packaged in individual pouches have a life (in terms of sterility) of 30 days, those in double pouches of 60, if kept in closed cabinets. These values are, in any case, to be considered indicative, in that the date of preservation is influenced by various factors, as the environmental microbic level, the granulometry of environmental dusts (that act as carriers of micro-organism), as well as the temperature, pressure and ambient humidity parameters.

5.8.6. LOADING



It is suggested to run a cycle at the beginning of daily work without load.

The way in which the load to sterilize is arranged is also considerably important to sterilization process. Always observe the explanations indicated in this manual.



The materials to be sterilized shall be disinfected prior to sterilization process.



Do not stack instruments on tray or in basket. Overloading could compromise sterilization.

- It is necessary to leave space between materials to be sterilized to allow the circulation of steam during the sterilization phase and then to facilitate drying.
- Use the load supports, to facilitate the circulation of steam.
- Place a chemical sterilization indicator on each basket or tray.
- Position the instruments sufficiently distant from chamber walls and from one another that they remain separate for the whole sterilization cycle.
- It is preferable that the sterilization container be made of aluminum, as this metal stores and conducts heat well, ensuring faster drying than other materials.

- When arranging sterilization containers, care should be taken that drops of condensate do not wet items being sterilized beneath, but can flow away to the base of the chamber. The best arrangement is a stack of sterilization containers of the same size, so that condensate can flow down the sides.

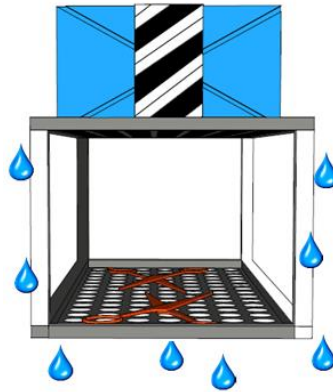


Figure 6 - Stacked Sterilization Trays

- Textiles and instruments should not be sterilized together in one sterilization container. However, where this is unavoidable, the following rules should be observed:
 - Instruments and sterilization containers should be placed at the bottom.
 - Textiles should always be placed at the top.
 - If sterilization bags and instruments are loaded together, then instruments should be placed at the bottom (Figure 7).
 - Bigger bags should be placed at the bottom; smaller bags should be placed at the top.

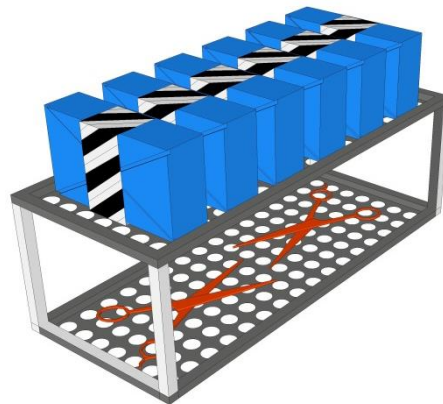


Figure 7

5.8.6.1. TEXTILES

When preparing textiles for treatment in the autoclave, care must be taken that the folds in the textiles are arranged in parallel, and that the items are packed side by side. This vertical configuration ensures that channels can form between the textile folds for the air to flow out and steam to flow in.

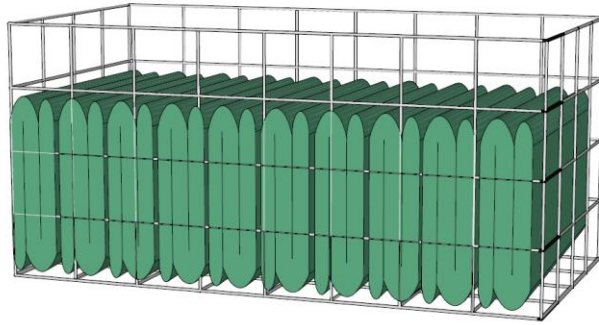


Figure 8 – Properly Loaded Textiles

When loading sterilization containers with textile items, care should be taken ensure that they retain their vertical orientation. This would prevent the formation of flow channels for air and steam.



Do not stack textiles on the top each other as this hinders the penetration of steam into the packages of textiles.

5.8.6.2. INSTRUMENTS

- Ensure that instruments of different materials are separated and placed on different trays. Stainless steel and carbon steel should not be sterilized touch to each other.
- Position the instruments sufficiently distant from one another that they remain separate.
- Pay attention to the guidance of the manufacturer of the instrument.
- Where appropriate, instruments should be disassembled before placing them in the autoclave, as this will improve the drying results.
- Lubricants in the instruments (as instrument oil) can be hydrophobic and these are impenetrable for steam. In case of sterilization of these instruments, the sterilization may fail. Prior confirmation should be obtained from the manufacturer of such agents that they are in fact suitable for steam sterilization.
- Place the instruments in open position and demounted so that steam can penetrate more efficiently.

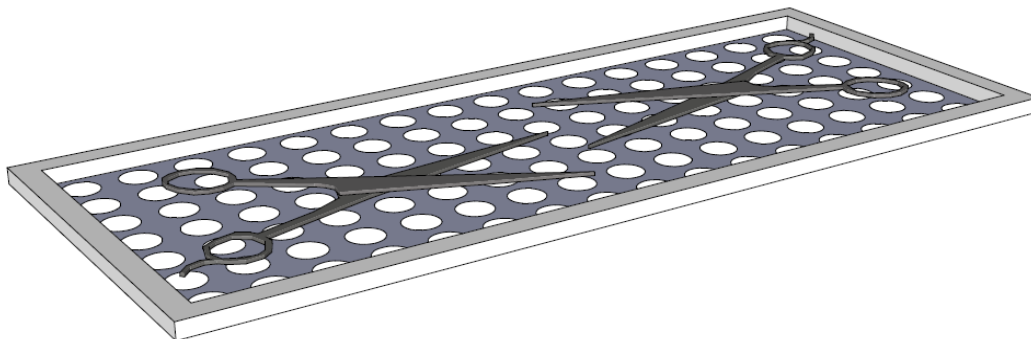


Figure 9

5.8.6.3. STERILIZATION BAGS

Sterilization packages can be sterilized either in sterilization containers or sterilization baskets. To enable better drying,

- Arrange soft sterilization packages vertically and side-by-side. This allows condensation to penetrate to the packages, while at the same time preventing possibly bursting at the seams.
- Do not allow bags and chamber inside touch each other.
- Do not arrange packages as stacked.
- Insert tools into separate bags.
- While loading paper/plastic sterilization bags, place paper side of a paper/plastic bag towards paper side of the other bag. Place plastic side of paper/plastic bag toward plastic side of other bag.
- Ensure that space shall be left between sterilization bags.

6. OPERATING PRINCIPLES

6.1. OPERATION PHASES

PRE-VACUUM: As soon as the program is started, the pre-vacuum phase starts to operate. Pressure in the chamber decreases below ambient pressure by vacuuming the air in the chamber and steam is blown in to replace the volume of vacuumed air. This phase is repeated several times depending on the selected program.

HEATING: Steam is charged to the chamber to reach sufficient steam temperature before sterilization phase.

STERILIZATION: The chamber temperature is kept at the required sterilization degree all through the sterilization phase.

STEAM DISCHARGE: The pressure in the chamber is decreased to the ambient pressure by discharging the steam in the chamber after the sterilization phase.

DRYING: Following the steam discharging, the pressure in the chamber is decreased below ambient pressure. Thus the humidity within the chamber is eliminated throughout the drying phase.

AIR INTAKE: Following the drying phase, ambient air passing through the filter is taken into the chamber to break the vacuum and raise the chamber pressure to ambient pressure.



If the lid is not opened after the program is over, another program cannot be started.



When sterilization is completed, condensate may be observed on the sterilized items. However, it does not show that the sterilization is unsuccessful. The German standard 'DIN 58953' Part 7 Section 7 comments on: "...Small amounts of water on the surface of packages do not represent a cause for concern if they dry completely within thirty minutes after removal from a steam sterilization system..."

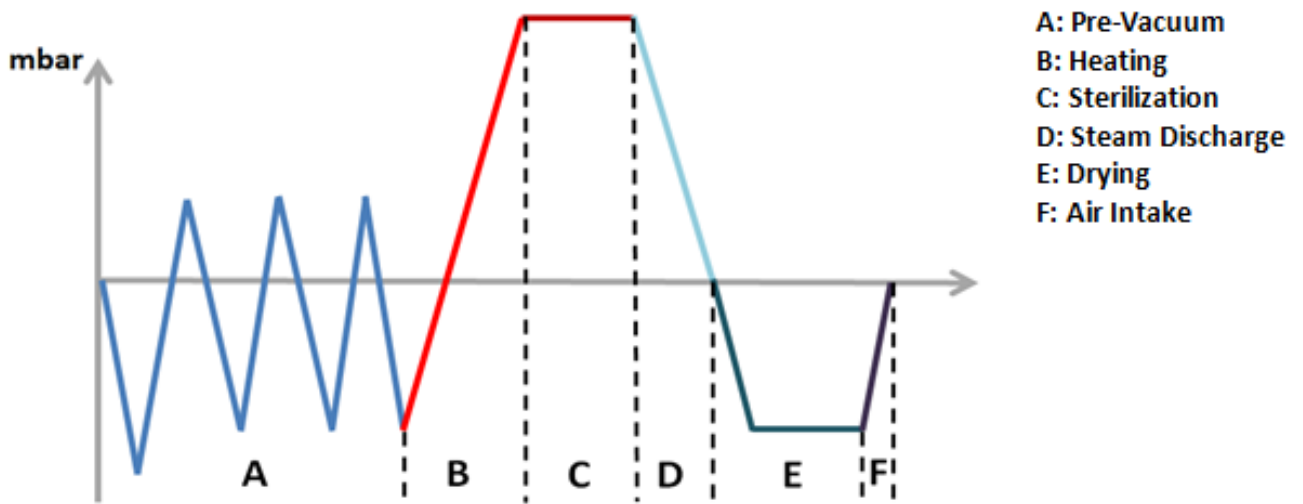


Figure 10

6.2. PROGRAMMING

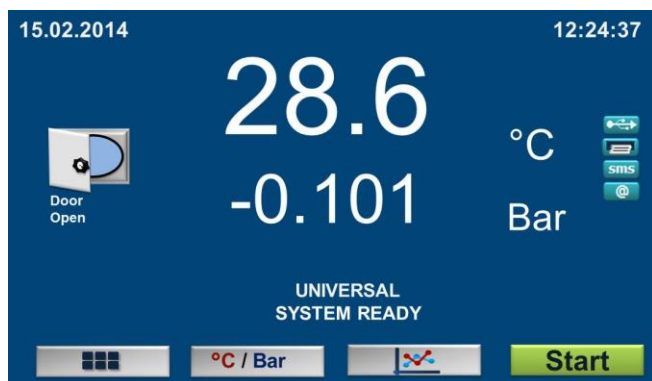


See that display and control panel activates when the device is powered on. Firstly, the screen on the left appears. Use left (F1) and right (F2) keys to select a menu item. Selected menu item color changes to blue and enter (F4) key is used to access the selected menu item.

Password query screen on the left appears, while accessing to “Programs, Special Programs, Test Programs and Settings”. Enter password by using increase (F1) and decrease (F2) keys and push enter key (F4). The password should be changed on settings menu to activate password query screen (See Section 6.4.3). The password is 0000 for the first use.



“Programs” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access programs page on the left. Use left (F1) and right (F2) keys to select the program to operate. Working screen appears when enter (F4) key is pushed on the selected program.



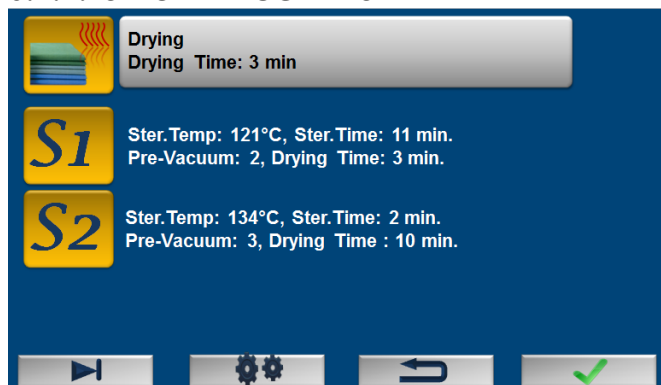
The screen on the left is working screen and on working screen sterilization chamber temperature and pressure values can be monitored. Current date and time are shown at the top line. Push enter (F4) key to start the selected program. When program starts to run, total sterilization cycle time appears at the top left corner and related sterilization cycle phase time appears at the top right line.



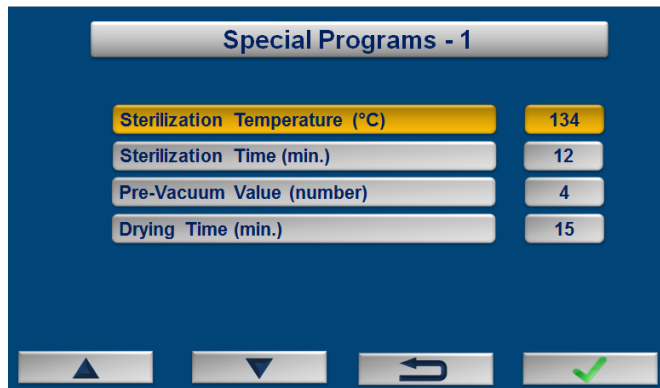
Push “°C / Bar” key (F2) on the working screen to see the temperature and pressure sensor values which are placed in the different parts of the sterilizer. Back key (F3) is used to exit the screen. You may also access this page by using “°C / Bar” sub menu on main menu.


When the graph button (F3) is pushed during the operation, the graph page showing pressure and temperature values appears on the screen.

6.2.1. SPECIAL PROGRAMS




“Special Programs” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access special programs page on the left. Use tab (F1) key to select the program to operate. Working screen appears when enter (F4) key is pushed on the selected program.

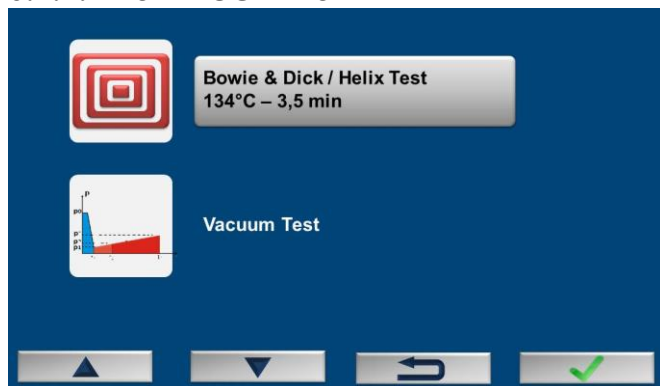


Use the key (F2) corresponding to “” symbol to set the parameters of a special program. The screen on the left is special program parameter settings page. Use increase (F1) and decrease (F2) keys to change the value of the selected parameter. Push enter key (F4) to set other parameter values. After setting all parameters, push enter (F4) key to return special programs screen.

Working screen appears when enter (F4) key is pushed on the selected special program. Push start (F4) key on the working screen to start the selected program.

	The parameters of a special program shall be set by user who should be authorized and have knowledge about sterilization and its phases. Incorrect setting of a special program may cause irreparable damages on the sterilizer and on sterilized items.
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6.2.2. TEST PROGRAMS



“**Test Programs**” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access test programs page on the left. Use increase (F1) and decrease (F2) keys to select the test program to operate. Working screen appears when enter (F4) key is pushed on the selected test program. Push start (F4) key on the working screen to start the selected program.

6.3. COMPLETION OF THE OPERATION

When program is completed, audible alarm starts on the device and “Loads are sterilized” appears on the screen.

- See that the program is over.
- Push stop key (F4) to stop the running program at any time.
- Take the samples out. Be careful while handling the samples after the operation as they can be hot.
- Wipe the chamber surface if needed when the chamber is cold enough.
- You may leave the sterilizer at the stand-by position or switch it off.

6.3.1. UNLOADING AND PRESERVING

The material is at the greatest risk of contamination while it is still hot, because the barrier capabilities of the packaging materials are much lower in the presence of residual humidity, compared to an ambient temperature situation. Wait for temperature of material to drop to room temperature before stocking it: before stocking, make sure that the packages are intact

and check the chemical indicator color change; if the package is broken or torn, the load can only be used immediately, in that preservation of sterility cannot be guaranteed.

The indicative times for preserving the material are shown below, considering that the material itself is kept in closed cabinets away from light, heat and humidity.

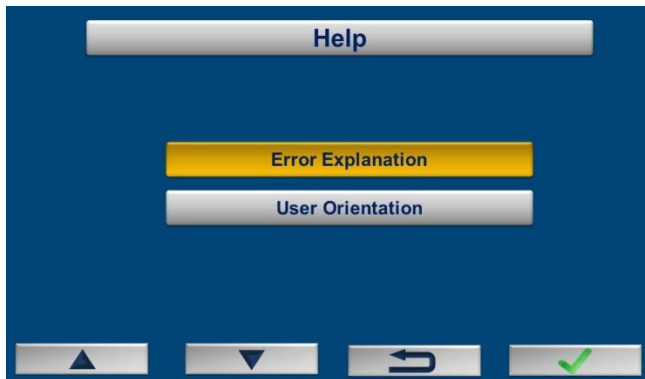
Type of material	Suggested time (days)
Combination of paper-polypropylene	30 (single) – 60 (double)
Metal containers, with standard-grade filters	28/30
Medical Grade with double orthogonal layer	28/30

We emphasize the fact that the times indicated in the table above are indicative, in that the preservation of sterility depends on numerous factors, as ambient microbic level, size of the dust particles, ambient conditions of temperature, pressure and humidity, as well as the degree of handling of the sterilized materials themselves.

The material should be stocked in sealed cabinets, 30 cm away from the floor and 5 cm from the ceiling; if this is not possible protect the material in nylon bags.

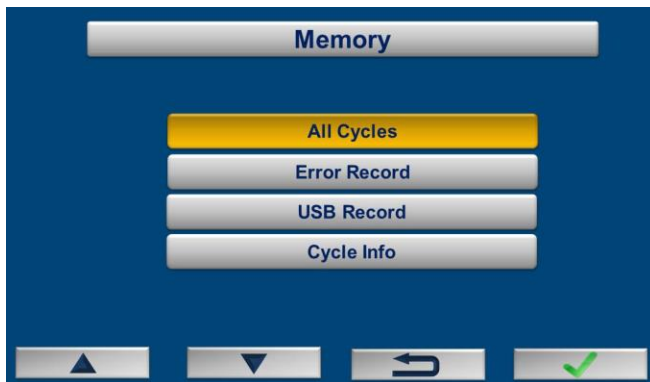
7. MENUS

7.1. HELP



“Help” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access help page which contains submenus which includes failure explanations which user may encounter and some useful information for user.

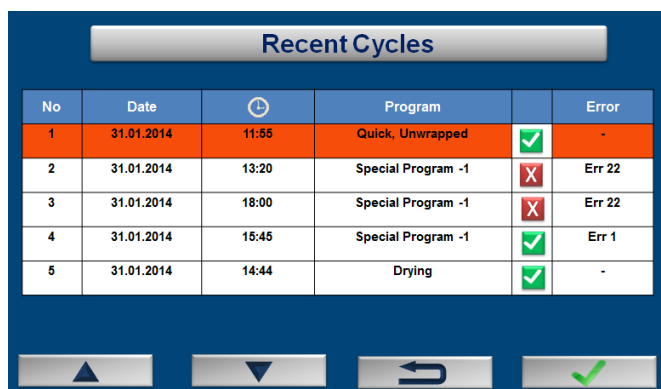
7.2. MEMORY



“Memory” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access memory page. Use increase (F1) and decrease (F2) keys to select a submenu on memory page and push enter (F4) key to access the selected sub menu.



When you select “All Cycles” on memory page by using increase (F1) and decrease (F2) keys and push enter (F4) key, the page on the left appears.



When “Recent Cycles” is selected on all cycles page, date query screen for requested program appears on the screen. After entering the date and time by using increase (F1) and decrease (F2) keys and pushing enter (F4) key, a page consisting of records of cycles appears as on the left. Choose a cycle by using increase (F1) and decrease (F2) keys and push enter (F4) key to see detailed record of cycle. Push print (F4) key to print out the record.


“Older Cycles” page contains program name, date, time and sterilization result. “Recent Cycles” displays more detailed information regarding cycle than “Older Cycles”.




“Error Record” submenu is selected on the memory page by the value increase (F1) and decrease (F2) keys. The page on the left appears when enter key (F4) is pushed. Failures are listed from the current date to the earlier. Push the value increase (F1) and decrease (F2) keys to pass the other page. Push the backspace key (F4) in order to exit the page.

Select “Cycle Info” submenu on memory page by using value increase (F1) and decrease (F2) keys and push enter (F4) key. The page consisting of number of daily cycles and number of total cycles appears. Total number of cycles left to next replacement of gasket and filter are also shown on this page. Push the backspace key (F4) in order to exit the page.

7.2.1. EXTERNAL MEMORY (USB STICK)

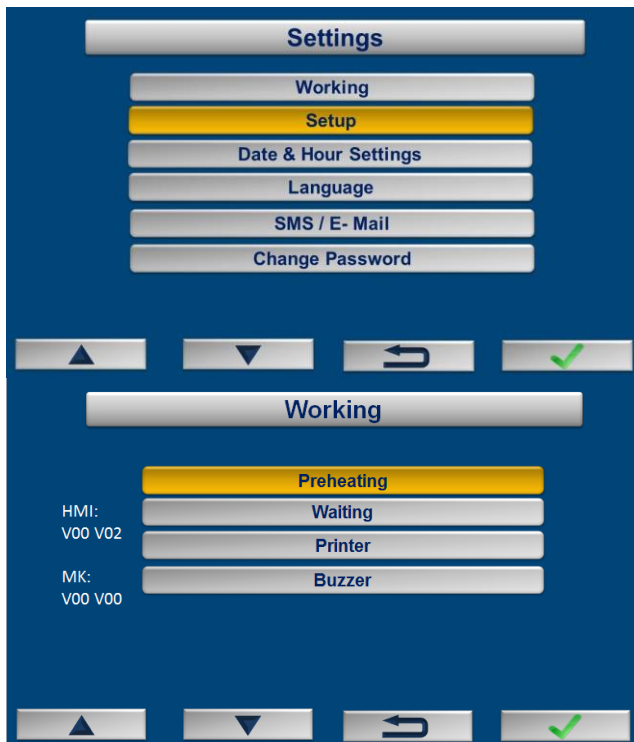
USB Stick is connected to USB port-1 of the communication unit (Figure 2). “” appears on the working screen when the USB stick is identified by the microprocessor system.



If  does not appear on the screen, USB stick may be defective or may not be connected correctly.

When “USB Record” submenu is selected on the memory page, there are four options: “Recent Cycles”; “Older Cycles”; “Error Record”; and “All”. Use increase (F1) and decrease (F2) keys to select one of the options and push enter (F4) key to transfer to USB stick.

7.3. SETTINGS

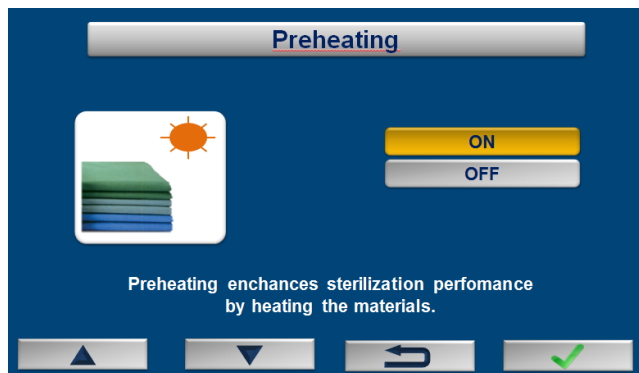


“Settings” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access settings page on the left. Use increase (F1) and decrease (F2) keys to select a submenu.

“Working” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access settings page on the left. Use increase (F1) and decrease (F2) buttons to select “Preheating”, “Waiting”, “Printer” and “Buzzer” submenus.

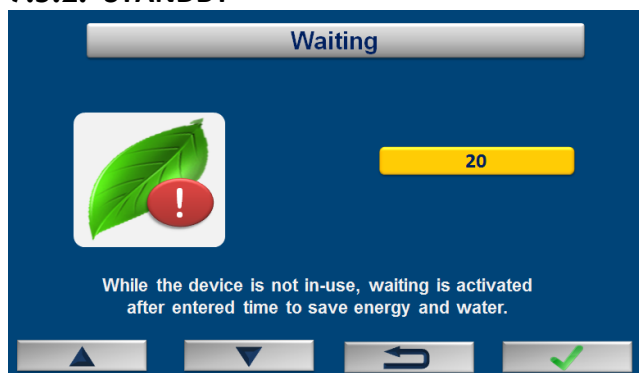
7.3.1. PREHEATING

Steam is produced by heating water in steam sterilizers. The steam penetrates to materials and heats materials to be sterilized. This may lead to steam condensing on the instruments and containers. Condensation forms on the objects being sterilized, and some of the condensation drops to the bottom of the sterilization container. After sterilization, during the drying phase, all the condensation is eliminated from the sterilization container and from the sterilized items themselves. Activate ‘preheating’ section for better drying result.



Select “Working” submenu on the settings page by increase (F1) and decrease (F2) keys and push enter (F4) key. On the next page, select Preheating by using increase (F1) and decrease (F2) keys and push enter (F4) key. Select ON and push enter (F4) key.

7.3.2. STANDBY

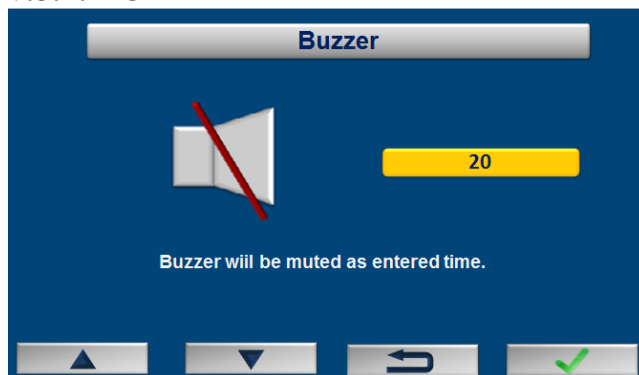


Standby is for energy saving while the sterilizer is not in use. Select “Working” submenu on the settings page by increase (F1) and decrease (F2) keys and push enter (F4) key. On the next page, select Standby by using increase (F1) and decrease (F2) keys and push enter (F4) key. Adjust the time (in minutes) when to activate standby by using increase (F1) and decrease (F2) keys and push enter (F4) key.

7.3.3. PRINTER

Sterilization parameters can be printed as alphanumeric via Thermal Printer that is optional accessories. Printer should be selected as “ON” from printer settings page to take printout via Thermal Printer.

7.3.4. BUZZER



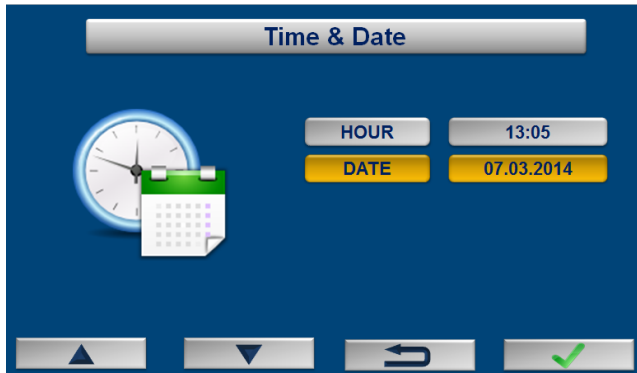
“Alarm Repeat Time” submenu is selected on the working page by using the value increase (F1) and decrease (F2) keys. If the alarm condition continues after muting the alarm buzzer, “Alarm Repeat Time” reactivates audible alarm at the end of the desired time (in minutes). If you want to exit this page without any change, push the backspace key (F3).

7.3.5. SETUP

Select “Setup” by using increase (F1) and decrease (F2) buttons and push enter (F4) button to access the page where the company name, address and phone number can be entered. This information is to be used in print outs and memory. Each character of data is entered one by one. Enter first character by using increase (F1) and decrease keys (F2) and push tab key (F3) to

enter next character. After all characters of the data is entered completely, push enter (F4) key to enter next data.

7.3.6. TIME/DATE



“Date/Time Settings” submenu is selected on the settings page by the value increase (F1) and decrease (F2) keys. The page shown on the left appears when enter key (F4) is pushed. Time is shown in the format of “hour:minute” and the cursor is on hour part when “Date/Time Settings” page comes to the screen. Hour is adjusted by pushing the value increase (F1) and decrease (F2) keys. In order to continue to adjust, push enter key.

If you want to exit this page without any change, push the backspace key (F3).

7.3.7. LANGUAGE



“Select Language” submenu is selected on the settings page by using the value increase (F1) and decrease (F2) keys. The page on the left appears when enter key (F4) is pushed. The language of the control panel can be set as Turkish, English, French, Russian or Spanish. Push the value increase (F1) and decrease (F2) keys to select the language and then push the enter key (F4) to save the selection. If you want to exit this page without any change, push the backspace key (F3).

7.3.8. PASSWORD



“Change Password” submenu is selected on the settings page by the value increase (F1) and decrease (F2) keys. The page on the left appears when enter key (F4) is pushed. After old password value is entered by pushing the value increase and decrease keys, push the enter key. New password value can be entered in the “New Password” and “Retype New” sections.

If you want to exit this page without any change, push the backspace key (F3). Password query page provides to access to “Programs”, “Test Programs”, “Special Programs” and “Settings” pages. If “New Password” is selected “0000”, Password query page does not appear to access these pages.

7.3.9. SMS



In order to use SMS, optional GSM module is mandatory to have. Refer to Section 11.1 for information regarding GSM module connection.

Select “SMS/E-mail” submenu on the settings page by increase (F1) and decrease (F2) keys and push enter (F4) key. On the next page, select SMS by using increase (F1) and decrease (F2) keys and push enter (F4) key.



“SMS Numbers” is selected on the SMS page by using the value increase (F1) and decrease (F2) keys. The page on the left appears when enter key (F4) is pushed. The phone numbers can be entered in this page and SMS notifications are delivered to these phone numbers in case of any failure.

- SMS can be sent to 5 different mobile phones.
- Enter country code before the phone numbers.
- A cursor flashes under a digit which means you can set this digit of the number. Each digit of phone numbers is entered one by one. The first digit of the phone number is entered by pushing value increase (F1) and decrease keys (F2) and tab key (F3) is pushed to enter the second digit. The second number is entered pushing value increase (F1) and decrease keys (F2) and tab key (F3) is pushed to enter the next digit. After all digits of the phone number are entered completely by this way, push the enter key (F4) to enter the next phone number.
- Tab key (F3) is used for changeover from one digit of phone number to another.
- After all phone numbers from “Phone 1” to “Service 2” is entered as mentioned above, push the enter key (F4) and return to main page.



Use increase (F1) and decrease (F2) keys to select “SMS settings” on SMS page and push enter (F4) key to access the page.


- Activation or deactivation of SMS function can be adjusted. If you want to activate this function, choose “on” by pushing the enter key (F4). If you want to deactivate SMS function, choose “Off” by pushing the enter key (F4).

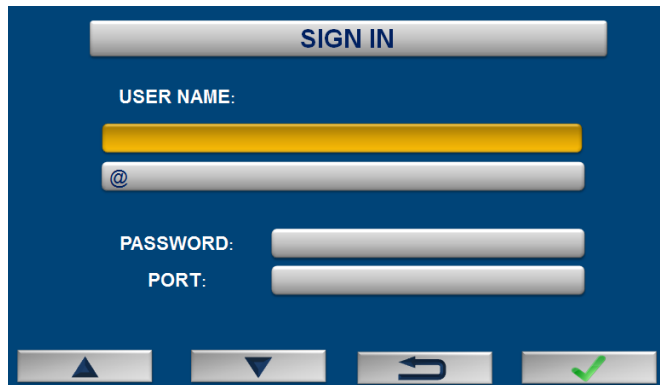
- “Repeat time” is the frequency of sending SMS. The user is notified again by sending SMS if the failure still continues. Repeat time can be adjusted to 8 hours, 16 hours and 24 hours by pushing enter key (F4).

7.3.10.E-MAIL

Select “SMS/E-mail” submenu on the settings page by increase (F1) and decrease (F2) keys and push enter (F4) key. On the next page, select “E-Mail” by using increase (F1) and decrease (F2) keys and push enter (F4) key.

- Activation or deactivation of e-mail function can be adjusted from “E-mail” submenu. If you want to activate this function, choose “on” by pushing the enter key (F4). If you want to deactivate e-mail function, choose “off” by pushing the enter key (F4).

 Ethernet settings should be adjusted by technical service staff for the first usage. Otherwise, this function does not work.



“Sign In” is selected on the e-mail page by the value increase (F1) and decrease (F2) keys. The page on the left appears when enter key (F4) is pushed. Each character of e-mail addresses is written one by one. The first character is entered by pushing value increase (F1) and decrease keys (F2) and tab key (F3) is pushed to enter the next character. The second character is entered by pushing value increase (F1) and decrease keys (F2) and tab key (F3) is pushed to enter

the next character. After all characters of user’s name are entered by this way, push enter key (F4) to enter the mail server of the e-mail address. After mail server is entered in the same way, push enter key (F4) to pass the “password” submenu.

Enter the password and push enter key (F4).

The port provided by internet server is entered on the part of “Port”. After port is entered, enter key (F4) is pushed to return the main menu. Tab key (F3) is used for changes from one character of address to another.



“E-Mails” is selected on the e-mail page by the value increase (F1) and decrease (F2) keys. The page on the left appears when enter key (F4) is pushed. The e-mail addresses can be typed in this page and e-mail is sent to these addresses in case of any failure.

- Each character of e-mail addresses is typed one by one. The first character is entered by pushing value increase (F1) and decrease keys (F2) and tab key (F3) is pushed to enter the

second character. The second character is written by pushing value increase (F1) and decrease keys (F2) and tab key (F3) is pushed to enter the next character. After all characters are written completely in this way, push the enter key (F4) to enter the mail server. After mail server is written in the same way, push the enter key (F4) to write next e-mail address.

- After all e-mail addresses from 1 to 5 are written as mentioned above, push enter key (F4) and return to main page.
- Tab key (F3) is used for changeover from one character of address to another.

7.4. °C/BAR

“°C / Bar” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to monitor temperature and pressure sensor values which are placed in the different parts of the sterilizer. Back key (F3) is used to exit the screen. You may also access this page by using “°C / Bar” (F3) key on working screen.

7.5. SERVICE

“Service” menu is selected from the main menu by using left (F1) and right (F2) keys and push enter (F4) key to access. Service menu is password protected and it is for authorized technical staff.

8. PERIODIC MAINTENANCE AND CLEANING

8.1. PERIODIC MAINTENANCE



Cleaning and periodical maintenance operations should be performed the manometer pressure is 0 bar, the lid is open position and the chamber is cold. During cleaning and maintenance operation, remove the plug from the outlet.

- Security valves which are in direct contact with pressure shall be replaced in every 5 years by authorized personnel.
- After each 2000 runs the instrument should be controlled by authorized technical service personnel.
- The door gasket shall be replaced by the authorized personnel after each 500 cycles or in every six months.
- The air filter shall be replaced after in every 300 cycles.
- It is recommended that the Bowie&Dick/Helix Test shall be performed weekly, while the Vacuum Test shall be executed at the beginning of every working day while the chamber is not yet heated; to assure efficient functioning of the unit.

8.2. PERIODIC CONTROL

The service technician shall perform the following preliminary checks before operating the autoclave.

NO	TEST PARAMETERS	CONTROL RANGE
1.	Check the safety valve by operating it.	2 months
2.	Remove the cover of the autoclave, check and tighten the ports and valves.	6 months
3.	Check the lid gasket.	6 months
4.	Check that the autoclave is leveled.	Annual
5.	Check the continuity of the grounding connections.	Annual
6.	Check the safety elements (safety valve, safety and cut-off thermostats and lid locking mechanism).	Annual
7.	Check the water reservoir, piping and plastic parts of autoclave.	Annual
8.	Run the sterilization programs of autoclave and check the operational/ sterilization parameters.	Annual
9.	Check the precise operation of the earth leakage relay and electrical control systems.	Annual
10.	Check and tighten all screw connections in the control box, valves and instrument.	Annual
11.	Check the temperature sensor calibration.	Annual
12.	Validate autoclave effectiveness (loading/ unloading).	6 months/ Annual
13.	Observe the closing device for excessive wear.	5 years
14.	All safety valves exposed to direct steam pressure must be checked.	5 years



Safety tests (pressure vessel, efficiency, electrical) shall be performed in accordance with local rules or regulations, by an authorized inspector.



According to calculations, number of allowable cycles for the operation conditions are 10.000 at pressure fluctuation between 0 bar to 2,05 bar and 20.000 at pressure fluctuation between 0 bar to 1,05 bar.

8.3. CLEANING

- Weekly cleaning should be performed if the sterilizer operates daily. Use liquid detergent to remove tough dirt. Take precautions while handling chemical cleaners. Please be aware of the undesirable effects of the chemicals and be careful while applying them.
- A soft washcloth shall be used not to cause any detriment in the chamber.
- The chamber shall be checked before loading sterilizer; and shall be immediately cleaned if needed.
- The sterilization load should be disinfected prior to loading sterilization chamber.



Cleaning shall be performed while chamber is cold.

9. DISPOSAL MANAGEMENT CONCEPT

The currently valid local regulations governing disposal must be observed. It is in the responsibility of the user to arrange proper disposal of the individual components.

All parts which may comprise potentially infectious materials have to be disinfected by suitable validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal have to be carefully observed.

The instruments and electronic accessories (without batteries, power packs etc.) must be disposed off according to the regulations for the disposal of electronic components. Batteries, power packs and similar power source have to be dismantled from electric/electronic parts and disposed off in accordance with applicable local regulations.

10. TROUBLESHOOTING

If the device fails to operate, please check the followings:

- The power switch is on;
- The plug is plugged-in properly;
- The plug is not defective;
- The mains supply is present.

10.1. ERROR CODES

Error Codes may appear immediately after the sterilizer is turned on or following a time lag after the unit is turned on, before any program is started.

Error Codes may appear immediately after a program is started or during any program execution.

These messages are accompanied by an alarm tone which can be shut down by the “stop” button.

In case of any failure during a program run; the program is interrupted and the sterilizer either releases steam or vents the chamber according to the pressure condition in the chamber.



In case of any failure before sterilization phase during a program run, the load would **not be sterile** since the sterilization phase is not started.



In case of any failure after sterilization phase during a program run, the load would be **sterile**. However, loads could be **wet**, since drying phase would be interrupted.

Failures which may be encountered during operation is listed below:

Error 01: Vacuum Time Exceeded – The chamber pressure does not drop to the required vacuum value within preset duration.

Error 02: Air Detector – During sterilization, difference between two temperature sensors in the chamber is more than 3 degree.

Error 03: Steam Discharge – The steam in the chamber is not released within the preset time following the sterilization phase.

Error 04: Air intake – Following the drying phase, the airflow rate is below the preset value.

Error 06: Door Open – Door lock has been released during operation.

Error 07: Steam Generator Over Heating – Steam generator is overheated.

Error 10: Sensor Failure PT1, PT2, PT4, BT2 – Sensor is broken.

Error 11: Pre-Heating – The duration for pre-heating has exceeded the preset time.

Error 12: Pre-Heating High Temperature – The maximum pre-heating temperature has been exceeded.

Error 13: Water Pump Failure – Water pump is defective or filling pipe is clogged.

Error 14: Door Lock Failure – Door lock activating time exceeds the time allowed after the program beginning.

Error 16: Power Failure – The mains supply has interrupted during a cycle. If chamber is pressurized in case of power failure, pressurized air is released. Thus, the filter on the air release line should be sterilized by running quick program after power failure.



In case of power failure during sterilization phase, chamber temperature is checked when the power is on again. Program continues to run if the temperature is in the safe limits. Otherwise, it stops. If the power failure occurs before or after the sterilization phase, the operation stops and audible and visual alarm appears.

Error 19: Low Temperature – The temperature in the chamber remains below the preset temperature after the sterilization phase has started.

Error 20: High Temperature – The sterilization temperature exceeds the maximum permitted temperature.

Error 21: Low Pressure – The pressure in the chamber remains below the preset pressure after the sterilization phase has started.

Error 22: High Pressure – The sterilization pressure exceeds the maximum permitted pressure.

Error 23: Door Lock Cannot Open - This message appears on the screen when door lock could not open. Ensure that lid handle is closed properly.

Error 30: Steam supply – This message appears when required for temperature and pressure values are not reached at Preheating phase which is preparation phase before sterilization.

WARNINGS

Waste Water Tank Full : New operation is not started unless waste water tank is not discharged.

Insufficient Water: Before starting to program, add distilled water to water storage tank.

High Temperature for Vacuum Test: This message appears if Vacuum Test Program is started when the chamber is hot. Vacuum Test Program should be started before sterilization phase and the chamber is cold.



If an error occurs, please contact with an authorized Nüve agent to seek technical help.

10.2. FUSE REPLACEMENT

The fuses shall always be replaced by the authorized personnel.

II. OPTIONS

II.1. AlerText™ GSM MODULE

In case of error, DF series can send SMS to five different phone numbers by GSM module as an option.



Figure 11

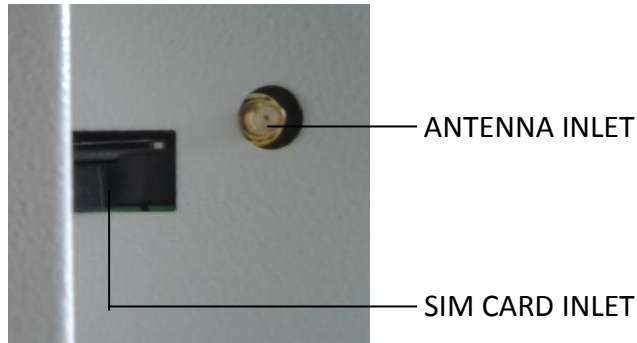


Figure 12

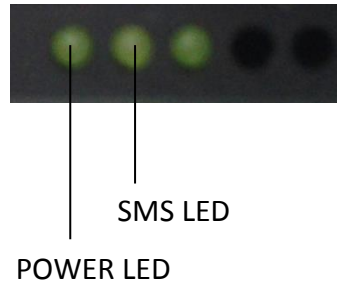




Figure 13

Please carry out the following steps for connection of GSM module:


- Insert SIM card in the GSM module (See Figure 14).

 SIM card is provided by the user. The cost of SIM card and SMS differs according to the GSM providers and all the charges will be covered by the user.

 SIM card which will be used for GSM module should not have PIN code.

- Plug-in the GSM module to correctly grounded sockets.
- Connect the end of RS 232 cable of GSM module (See Figure 13) to the RS 232 port on the ultra-low freezer (See Figure 2).
- Ensure that power led is turned on (See Figure 15). Power led is on when energy is supplied to the GSM module. SMS led starts to flash while the module sending SMS.
- Connect the antenna cable to antenna inlet on the GSM module (See Figure 14).

Antenna has magnet to place it easily. Place the antenna on a place where the signal of GSM module is high.

 If the GSM module is not connected or does not send messages although it is connected, “modem” error code appears in the error history. If the GSM module is connected and cannot send messages, “SMS” error code appears in the error history. Modem and SMS errors do not appear when SMS submenu on the SMS page is selected as “off”.

12. ELECTRICAL CIRCUIT DIAGRAM

