NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.

NC 100

VERTICAL STEAM STERILIZERS

USER'S MANUAL

CE 1984

Z14 K25 263 Rev.No: 22 Rev.Tarihi: 04 / 2021

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 you are receiving the product from the transportation company, make sure the package is intact. Take the device out of the box and please accept it after making sure device is intact. 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.

NÜVE
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İMALAT VE TİCARET A.Ş.

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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.

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"**.

ELECTROMAGNETIC COMPATIBILITIY DECLARATION

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
NC series are intended for use in the electromagnetic environment specified below. The customer or the user of this NC series should assure that it is used in such environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The NC series uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The NC series are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliance	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
NC series are intended for use in the electromagnetic environment specified below. The customer or the user of this nebuliser should assure that it is used in such environment.			
Immunity Test	**IEC 60101-1 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±4 kV contact ±8 kV air	±4 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<0 % UT (>100 % dip in UT) for 1 cycle	<0 % UT (>100 % dip in UT) for 1 cycle	Mains power quality should be that of a typical commercial and/or hospital environment.
	40 % UT (60 % dip in UT) for 10 cycles	40 % UT (60 % dip in UT) for 10 cycles	
	70 % UT (30 % dip in UT) for 25 cycles	70 % UT (30 % dip in UT) for 25 cycles	
	<0 % UT (100 % dip in UT) for 5 sec.	<0 % UT (100 % dip in UT) for 5 sec.	
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
NC series are intended for use in the electromagnetic environment specified below. The customers or the users of this nebuliser should assure that it is used in such environment.			
Immunity Test	**IEC 60101-1 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the NC series devices' including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommend separation distance:
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 Mhz	3 V_{rms}	d=1.2 √P 150 KHz to 80 MHz
Radiated RF IEC 61000-4-3	10 V_m 80 MHz to 1 GHz	10 V/m	d=1.2 √P 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V_m 1.4 GHz to 2 GHz	3 V/m	d=1.2 √P 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	1 V_m 2 GHz to 2.7 GHz	1 V/m	d=2.3 √P 800 MHz to 2.7 GHz

			Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NC series are used exceeds the applicable RF compliance level above, the NC series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NC series.			
[b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communications equipment and the NC series

NC series are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of these NC series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NC series as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in Watt	**Separation distance according to frequency of transmitter in Output Power of meter**		
	80 MHz - 1 GHz $d = 1,2 \sqrt{P}$	1.4 GHz - 2 GHz $d = 1.2 \sqrt{P}$	2 GHz - 2.7 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.17	2.33
10	3.79	3.69	7.37
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

CONTENT

1. INTRODUCTION

1.1. USE AND FUNCTION

NC 100 steam sterilizer is widely used in operating theatres and laboratories of hospitals; dentistry; biology, veterinary and agriculture departments of universities; microbiology and quality control laboratories of industry such as food.

NC 100 steam sterilizers are used to sterilize the wrapped or unwrapped solid products, porous products, small porous items, hollow load products, metal, glass, rubber material and liquid.

NC 100 steam sterilizers, which are suitable for the entire load mentioned above, have 5 preset programs for sterilization temperatures of 134°C and 121°C and 2 test programs. In addition, NC 100 has 10 special programs for sterilization temperatures of 105°C – 136°C, one program for drying and one program for liquid sterilization.

The steam is produced by the steam generator. The jacket system which is outside of the chamber provides homogeneous temperature homogeneity. Pre-heating system decreases the sterilization duration. All parts which are exposed to steam and water are made of stainless materials.

NC 100 operates automatically without user's interference.

NC 100 has 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 100V steam sterilizer is designed and manufactured in accordance with international directives EN 285, EN 61010-2-040, EN 61010-1, EN 60601-1-6, EN 61326-1, EN 62304, EN 62366-1, EN ISO 14971, EN 50419, EN ISO 15223-1, EN ISO 12100 and EN 13445 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 users 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

TEKNİK ÖZELLİKLER	NC 100
Sterilization Temperatures	105°C – 136°C
Number of Preset Programs	5 standard
Number of Special Programs	10 special, 1 liquid*, 1 drying
Sterilization Time	1-99 minutes
Special Program Temperature	105°C – 136°C
Maximum Pressure	3.0 Bar
Maximum Temperatures	144°C
Number of Pre-Vacuum	1-4
Drying Time	0-30 minutes
Standby	20-999 minutes / HOLD
Temperature Sensors	Pt-100
Test Programs	Vakum Test, Bowie&Dick Test
Chamber Material	304 Stainless Steel
External Surface Material	304 Stainless Steel
Power Supply	400VAC, 50 Hz, 3/N/PE
Power Rating	7500W
Control System	**N-SmArt™** Programmable Microprocessor
Display	Full-color LCD
Memory	29500 cycles + 500 detailed cycles
USB	Standard

Ethernet	Standard
RS 232	Standard
Wi-Fi	Standard
Chamber Volume (Liter)	104
Internal Dimensions (diameter x depth) mm	Ø 396x884
External Dimensions (WxDxH) mm	890x673x1115
Packed Dimensions (WxDxH) mm	970x730x1260
Net / Packed weight (kg)	180/190

There is no load (liquid) sensor because of the NC 100 is not a liquid autoclave. Maximum 1/3 of the chamber, flask and bottles should be filled against the risk of overflow in your liquid studies.The responsibility of the sterilization process for the liquid desired to be sterilized in special programs belongs to the user.

2.2. ACCESSORIES

2.2.1. FACTORY FITTED ACCESSORIES

- **NC 100 100Y** Panel type thermal printer
- **NC 100 100A** Automatic water supply unit
- **NC 100 100E** NuveLift

2.2.2. OPTIONAL ACCESSORIES

- **F 06 048** HEPA Filter
- **S 09 038** NC 100 sterilization basket (with handle) (Ø 360x242)
- **S 09 039** NC 100 sterilization basket (without handle) (Ø 360x242)
- **A 08 195** NüveCloser™ software

3. PRECAUTIONS AND LIMITATIONS ON USE

- Do not NC 100 operate the instrument for purposes NC 100 her than its main purpose.
- The set-up, installation, initial functioning, service and maintenance shall 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.
- The power line must be suitable for the power of the device and absolutely grounded.
- Do not NC 100 attempt to open the lid during the operation.
- The area to be installed must be heavyweight and insulated from vibration.
- NC 100 vertical steam sterilizer is suitable for the sterilization of the wrapped or unwrapped solid products, porous products, small porous items, hollow load products, metal, glass, rubber material and liquid. Materials NC 100 her than these and heat susceptible objects, explosive, flammable, adhesive and fusible materials shall not NC 100 be used.
- The liquid to be sterilized in the NC 100 sterilizer should have a boiling point of 100 ° C at sea level at 760 mmHg (1 atm) atmospheric pressure.
- Proper sterilization program shall be selected in accordance with the load type and the sterilization load shall be disinfected prior to being placed into the unit.
- When you are closing the lid, please be careful and do not NC 100 constrict your hand.
- Make sure that there is no anything on the lid gasket. If there is something, it will cause rising steam and can imperil the sterilization.
- When the lid is opened at the end of the operation, do not NC 100 approximate the lid, steam rising can cause burning of your hand or face.
- Do not touch the device during operation, it may be hot.
- Wear the protective gloves while taking the sample out after sterilization.
- Correctly grounded power supply should be used.
- Use only DISTILLED WATER.
- Installation, initial operation, maintenance, repair and transportation of the device must be performed by the manufacturer authorized persons.
- Be careful the warnings listed on the screen, any program must not be running or all of the work-energy and energy will be cut off when completed. Be sure the door is fully closed, door of the chamber in the closed position, if there is "DOOR OPEN" warning in the display.
- Only original spare parts and original accessories supplied by Nüve should be used.
- The personel who will use the device should have sufficient experience and knowledge. Incorrect interventions may cause damage to the device and malfunction.
- No dangerous gas is emitted from the device to the environment or atmosphere.
- If the process is terminated by the device or user due to error conditions during the process, the device and samples may be hot because the drying phase cannot be

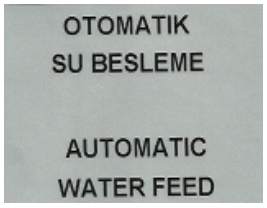
completed. Do not hold your hands or face close to the device when opening the door, taking samples, as steam from the cell can cause burns.

4. SYMBOLS AND LABELS

	Symbol in the operating instructions: Attention, general hazard area. This symbol refers to safety relevant warnings and indicates possibly dangerous situations. The non-adherence to these warnings can lead to material damage and injury to personal.
	Symbol in the operating instructions: This symbol refers to important circumstances.
	Notified Body: KİWA BELGELENDİRME HİZMETLERİ A.Ş. (İTOSB) İstanbul Tuzla Organize Sanayi Bölgesi Tepeören Mevkii 34957 Tuzla-İstanbul/TURKEY
	To identify the manufacturer of a product.
	To indicate the date on which a product was manufactured.
	This product is subject to the directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) of the European Parliament and of the EU Council of Ministers.

Before operating the instrument this manual should be read carefully.

Labels on the product:



Automatic water supply inlet is factory fitted accessories.

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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
- 1 ea. warranty
- 1 ea. HEPA filter
- 3 ea. Sterilization Basket
- 1 ea. 3-phase plug and socket
- 1 ea. Basket Carrying Handle
- 1 ea. Basket Carrying Grip
- 1 pair thermal gloves
- 1 ea. clamping ring
- 1 ea. Steam trap.

5.4. MAINS SUPPLY

The instrument requires 400 V, 50 Hz. (3-phases+N+G)

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 device is damaged or not.
- Check that the positioning is suitable for the usage purpose and users.
- Check that the instrument is stable on its four pedestals.
- Check that the user will be able to follow up the operation even when he deals with something else.
- Check that other devices are not occupied by the use of the device, that other devices are not being used, and that no damage will occur.
- Check that the positioning of the device prevents interference with other equipment in the near surrounding.(20cm space)
- Connect the waste line and the drain line as hot water and steam discharged from waste line.

5.6. GENERAL PRESENTATION

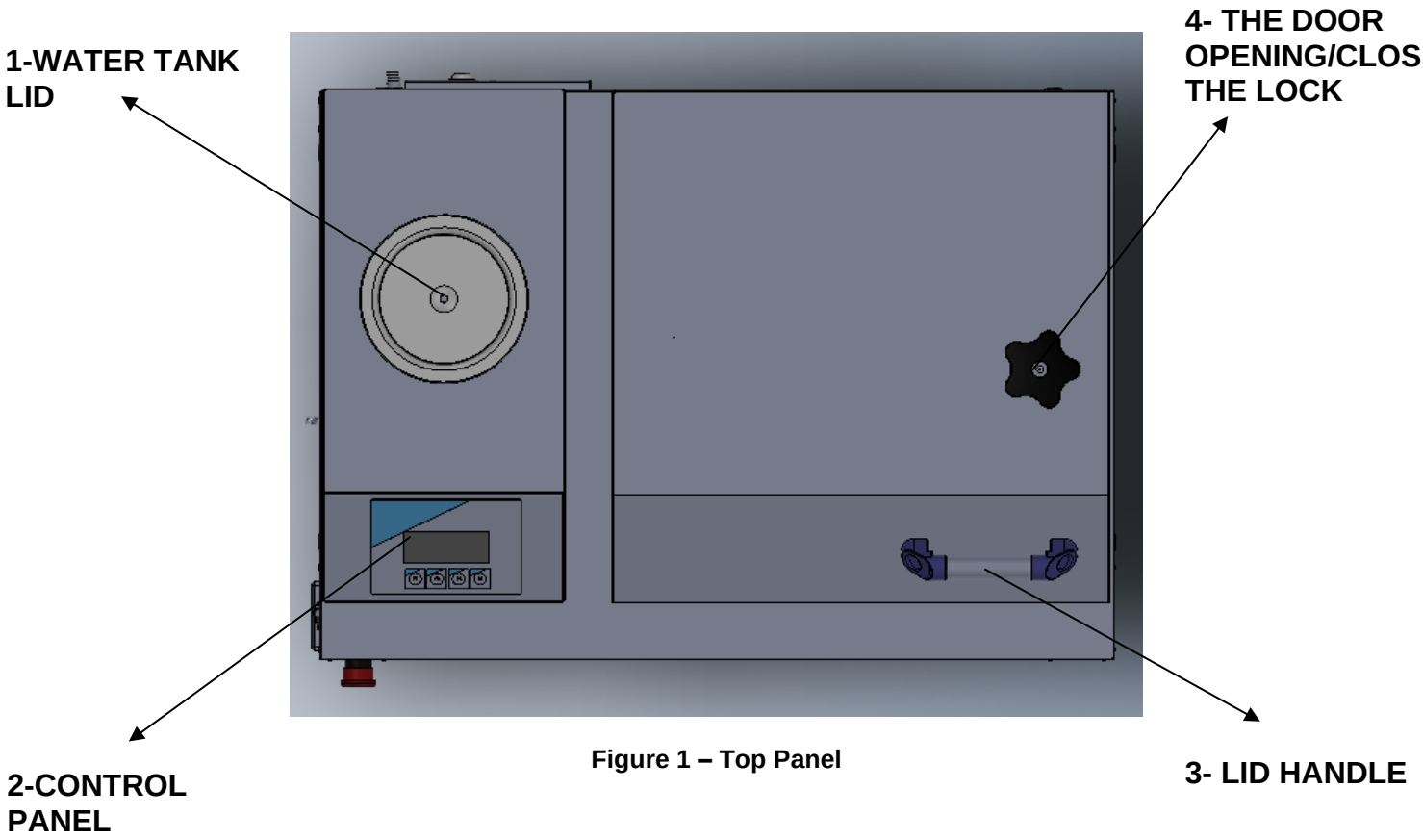


Figure 1 – Top Panel

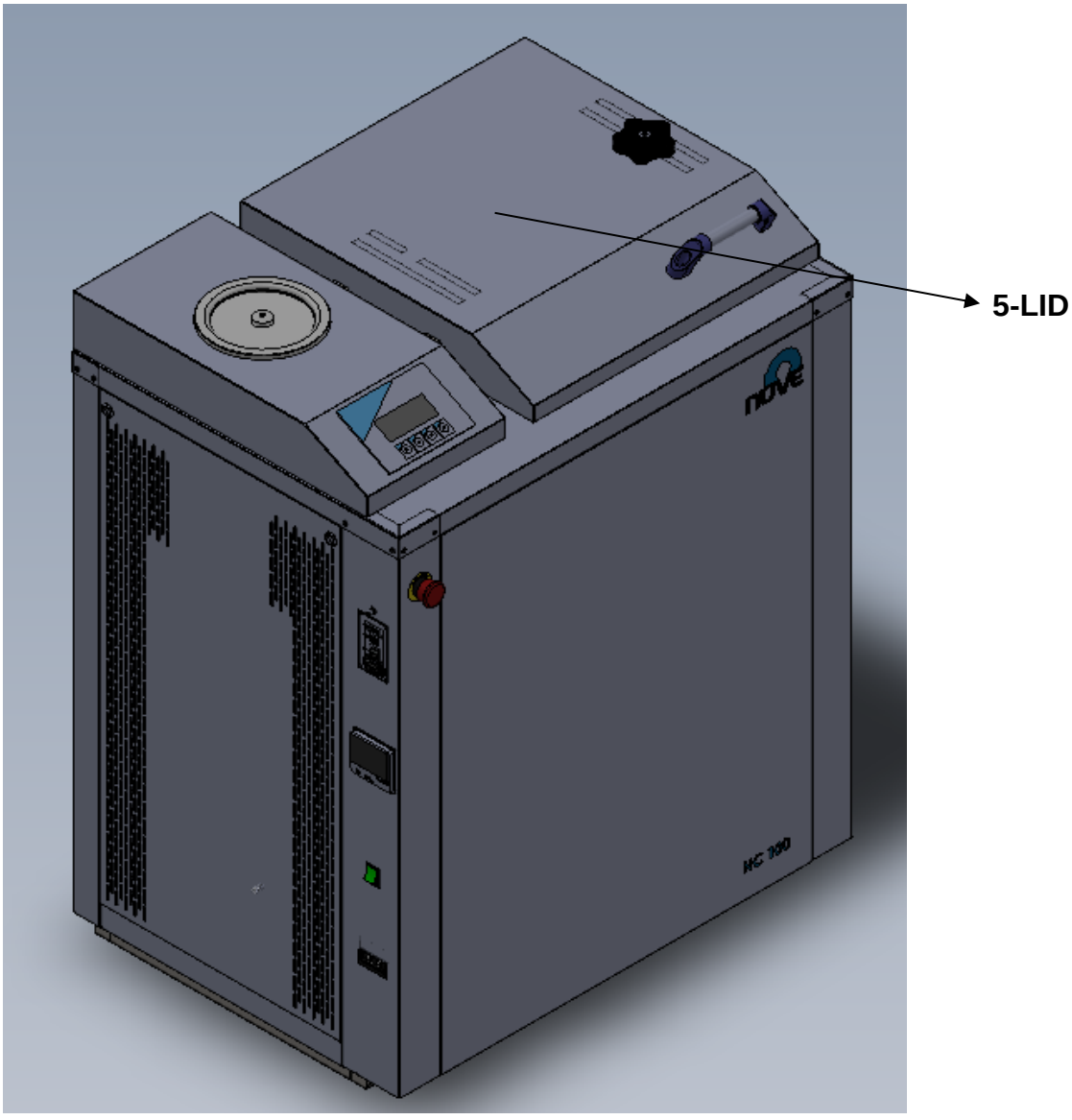


Figure 2 - NC 100

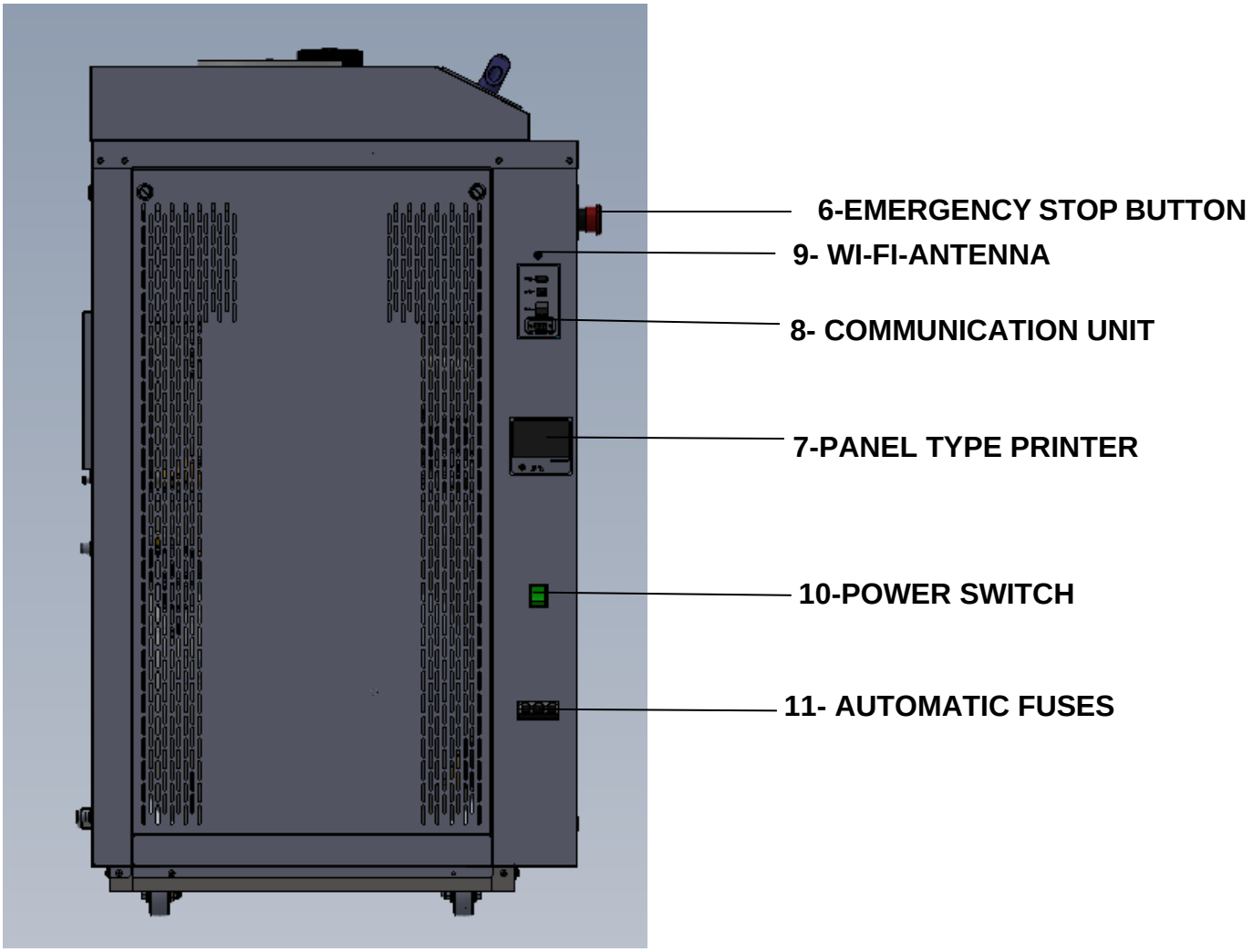


Figure 3 - Side Panel

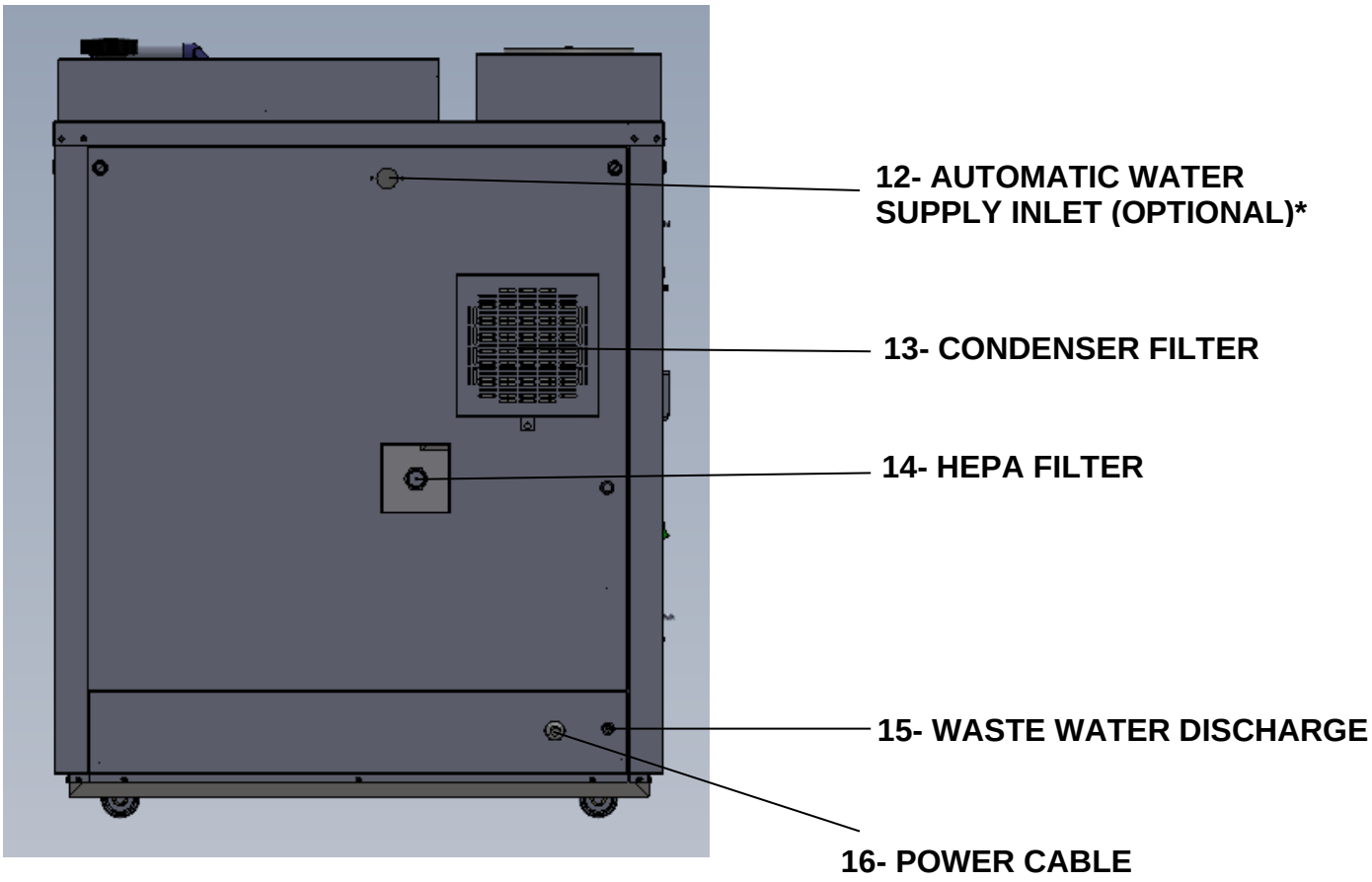


Figure 4 - Back Panel

☞ Automatic water supply inlet is factory fitted accessories.

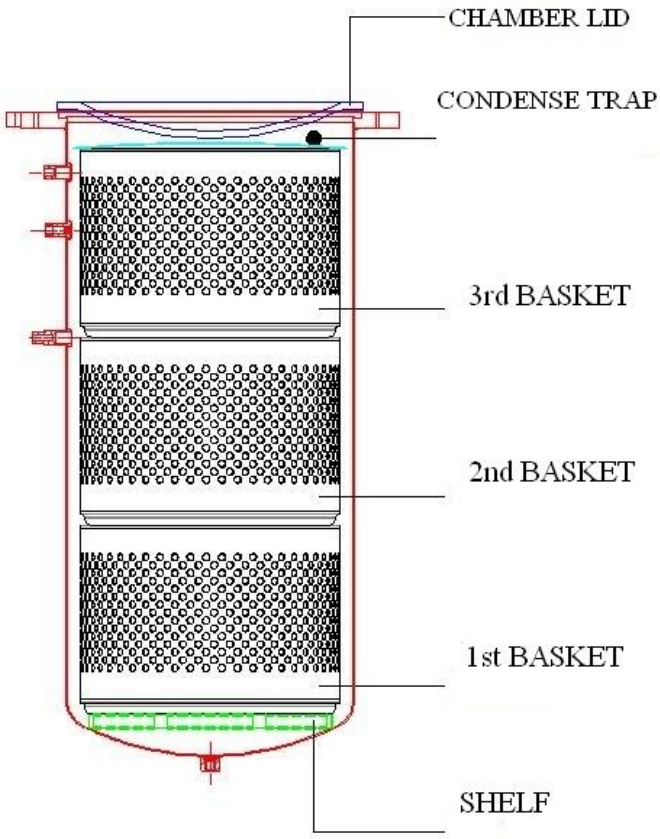


Figure 5 - Chamber

1. **Water Tank Lid:** Has to be opened to fill up the water tank.
2. **Control Panel:** Consists of an LC display and four touch buttons to scroll around, select and adjust the functions of the microprocessor control system.
3. **Lid Handle:** Helps the user to open and close the lid.
4. **Lid Locking Knob:** This knob locks and unlocks the lid.
5. **Lid:** Sterilization chamber lid.
6. **Emergency Stop Button:** Power cut-off button for stopping the entire autoclave when encountering any emergency that could compromise the safety of the job or disrupt the quality of the product being sterilized.
7. **Panel Type Printer:** A thermal printer that is used to print the completed program or any program recorded in the memory. The output involves parameters such as the sterilization phases, pressure-temperature data during sterilization phases' time and installation settings.
8. **Communication Unit:** Four outlets on communication unit can be used for saving data, remote control and software update.
    a. **USB Port-1:** It is used for data saving and software update via USB stick.
    b. **USB Port-2:** It is used to connect sterilizer to a computer for PC communication software.
    c. **Ethernet:** It is used for remote control and sending e-mail in case of any failure.
    d. **RS 232:** It is used to connect sterilizer to a computer for PC communication software. Optional GSM module is also connected to this port.

9. **Wifi-Antenna:** Connect N-Mobile and Nüve Kontrol.
10. **Power switch:** Used to power on and off the unit.
11. **Automatic Fuses:** Main fuses on the phase-neutral lines.
12. **Automatic Water Supply Inlet:** This inlet helps to get the water into the water tank automatically.
13. **Condenser Filter:** This filter protects the condenser from dust.
14. **HEPA Filter:** Used to sterilize the atmospheric air entering to the chamber.
15. **Waste Water Discharge:** Used to discharge the waste water.
16. **Power Cable:** It is the cable connected to the plug to power on the instrument.

5.7. CONTROL PANEL

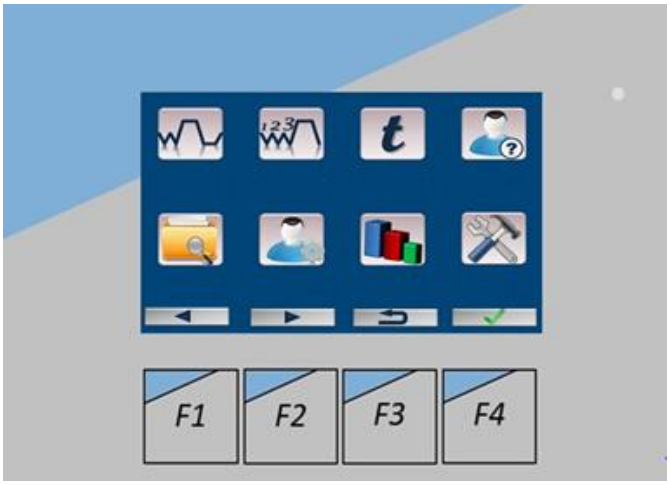


Figure 6 – Control Panel

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.

	This symbol denotes the menu. You can enter the menu by pushing the key corresponding to this symbol.
°C / Bar	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.
	This symbol denotes the graph screen. Temperature and pressure values of a sterilization cycle can be monitored on a graph by pushing the key corresponding to this symbol.
	This symbol denotes the door lock. On stand-by, door is unlocked when the key corresponding to this symbol is pushed.  The door is locked again 5 (five) seconds after unlocking. Press the button again to open it.

	This symbol denotes the start key. When the key corresponding to this symbol is pushed, the chosen sterilization program would start.
	This symbol denotes the stop key. When the key corresponding to this symbol is pushed, the chosen sterilization program would stop.
	This symbol denotes backspace. You can return the previous page or exit from the page by pushing the key corresponding to this symbol.
	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.
	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.
	This symbol denotes the left key. It appears on the main menu and graph screen. On main 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.
	This symbol denotes the right key. It appears on the main menu and graph screen. On main 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.
	This symbol denotes enter key. It is used for approval of adjustments.
	This symbol denotes the tab key. When the key corresponding to this symbol is pushed, next item would be selected.
	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 parameter is accessed.

5.8. PRIOR TO OPERATION

5.8.1. CONNECTION TO MAINS

- The unit is fed by 3-phased network supply.
- The panel board where the socket is connected shall be fuse protected.

5.8.2. WATER SUPPLY OPERATION

Open the water tank lid and add distilled water to tank up to maxımum point.

When any program is started or in stand-by position, if “unsufficient water” warning appears on the screen, it means that there is no water. Water should be filled. Do not operate any program whitout water supplement.

☞	Only distilled water should be used.

☞	If insuffient water is observed on the display, it means that there is no water in the tank, should be added water to tank.

⚠	Distilled water conductivity value to be used in the device must be at least 10 µS.

⚠	Irreparable damage may occur if water softening system is not used. In case of not using water softening unit, the damage occurred would be user’s responsibility.

5.8.3. ATTACHING REUSABLE HEPA FILTER

Mount the HEPA filter (Figure 7) provided with the device to the top of the device where the filter fitting point is.

Figure 7 – HEPA Filter

5.8.4. STERILIZATION PROGRAMS

NC 100 steam sterilizers, have 5 preset programs; **Universal, Solid, Prion, Quick, and Sensitive.** Loading methods is explained below. How to set preset and special programs is explained in Section 6.2.

Universal Program: Use for materials that are resistant to 134°C; materials with package (single-wrapped, double wrapped) or without package (unwrapped) tools (solid) (not gathering water, example: metals).

Solid Program: Use for materials that are resistant to 134°C; materials with package (single-wrapped, double wrapped) or without package (unwrapped) tools (solid) (not gathering water, example: metals).

Prion Program: Use for materials that are resistant to 134°C; materials with package (single-wrapped, double wrapped) or without package (unwrapped) or tools (solid) (not gathering water, example: metals)

Quick Program: When drying is not important, use for materials that are resistant to 134°C and without package (unwrapped) materials tools (solid)

Sensitive Program: Use at 121°C for materials which have low heat-resistance; materials with package (single-wrapped, double-wrapped) or without package (unwrapped) textile or tools (solid) (not gathering water, example: metals).

Before starting the device, pre-heating must be activated. Pre-heating helps to heat the load and prevent condensation. Do not forget put the condense trap onto the top basket

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 as containers: metal containers with lids or perforated bottoms with filters in paper, pouches in paper or polypropylene, medical paper or trays that are perforated or with grilles. Pouches in paper-polypropylene, packaging system gives good results only for the steam sterilization of instruments or small surgical instruments.

Medical grade paper and pouches in paper-polypropylene cannot be sterilized again and protection characteristics of life is not very long.

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

- Contents must not exceed ¾ 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.

Each packaged prepared must at least 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 each work-day without load.

The way in which the load to sterilize is arranged is also considerably important to sterility. Tested and valid methods are as followings:

⚠ Before sterilization process, to be sterile materials should be cleaned and disinfected. Used disinfectants effects should be cleaned carefully and thoroughly after the cleaning process. Uncleaned disinfectants can cause undesirable problems in the chamber during the sterilization phase.

⚠ 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 for the circulation of steam during the sterilization phase and then to facilitate drying.
- Load supports can be used 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.
- 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.
- Instruments made from different materials should be separated and placed to different baskets.
- To enable better drying, arrange such soft sterilization packages side-by-side and close to each other. Instruments should be placed to bags separately.
- Place the sterilization bags with the paper side down (in contact with the basket) and the transparent side up.
- 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 8 – Proper loading of the same size sterilization containers

- 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 place at the bottom(Figure 9).
    - Bigger bags should be placed at the bottom; smaller bags should be placed at the top.

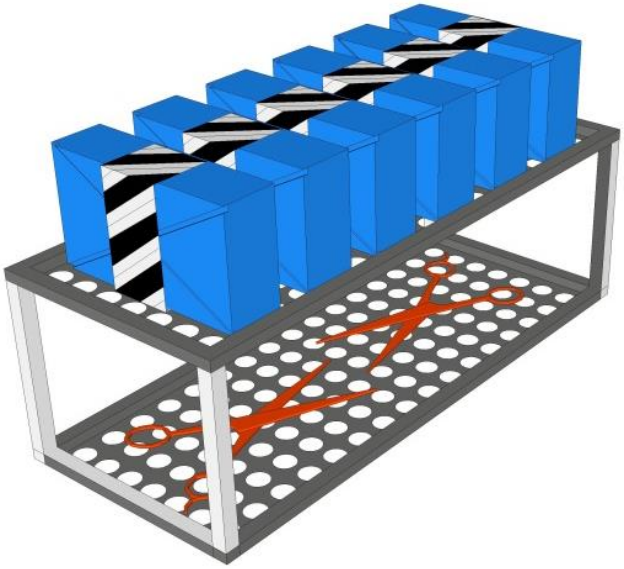


Figure 9 – Proper loading of instrument and sterilization packages at the same time

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.

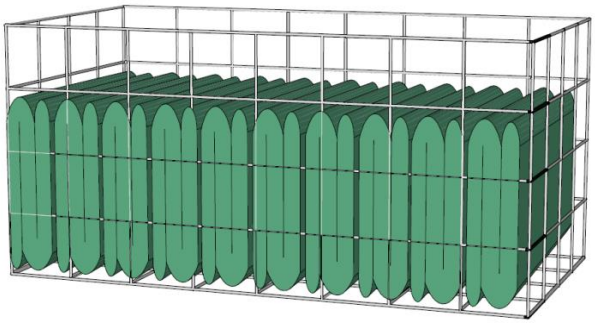


Figure 10 – Properly loading of textiles

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 made from different materials are separated and placed on different trays. Stainless steel instruments and carbon steel instruments should not be sterilized to touch each other.
- Position the instruments sufficiently distant from one another that they remain separate for the whole sterilization cycle.
- 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 so that steam can penetrate more efficiently.

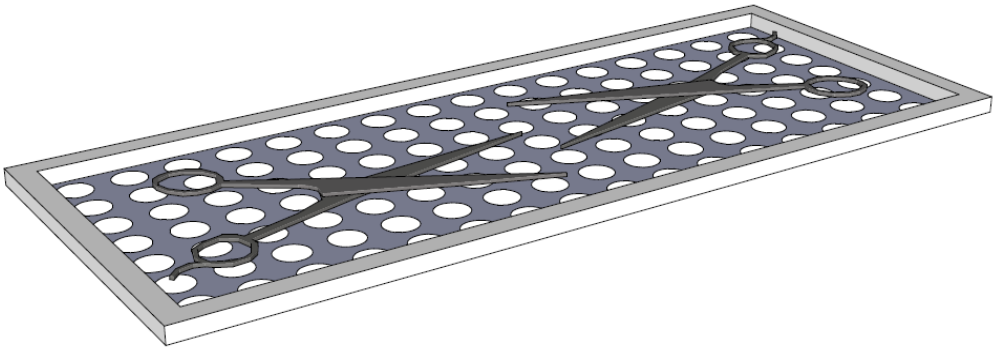


Figure 11 - Properly loading of instruments

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 possible 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 set steam temperature prior to sterilization.

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 decreases below ambient pressure and 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 start.

☞ When sterilization is completed, some 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 residual moisture on paper bags or transparent sterilization paper after sterilization: "..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...".

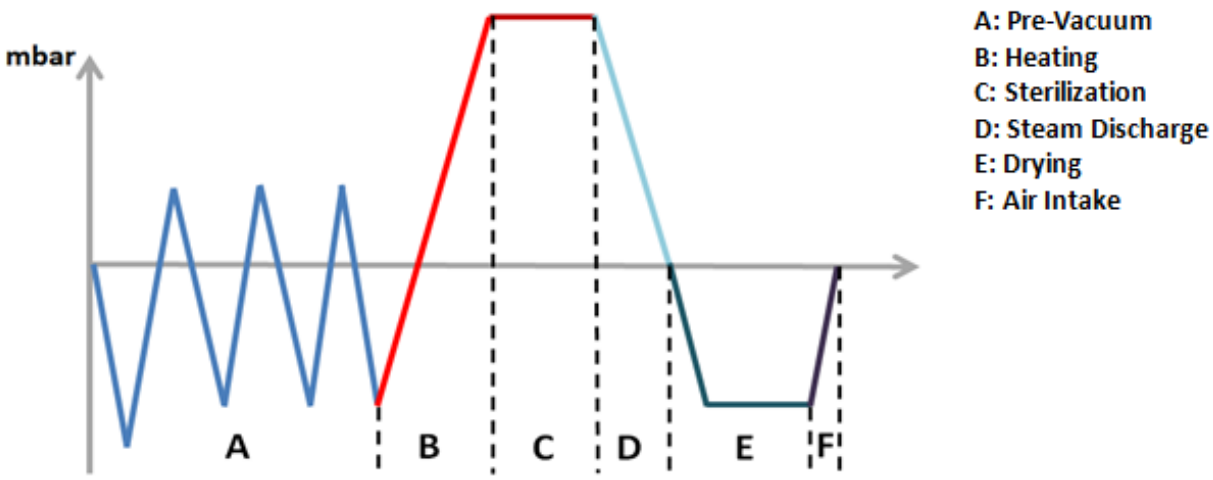
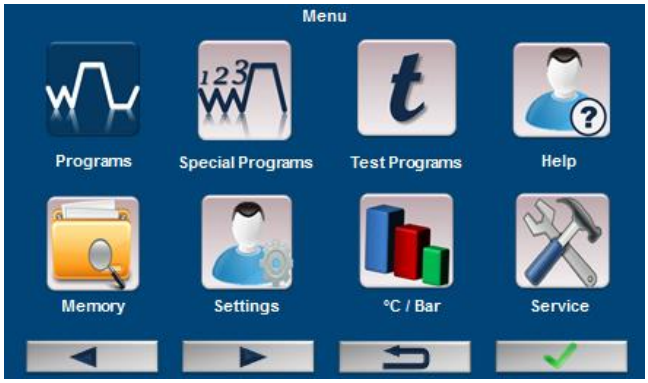
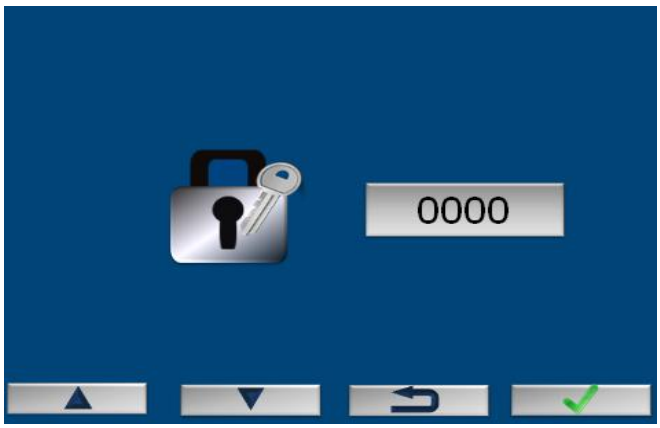


Figure 12 – Operation Phases

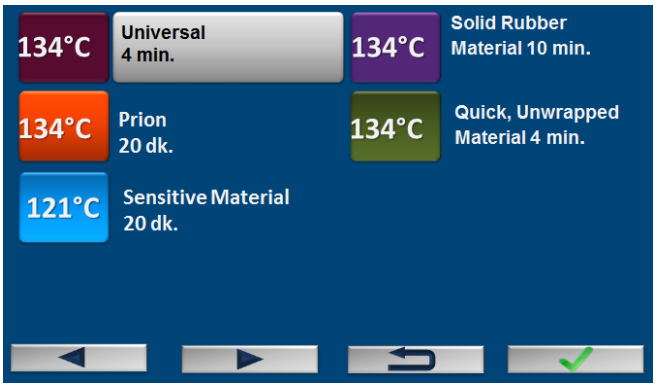
6.2. PROGRAMMING



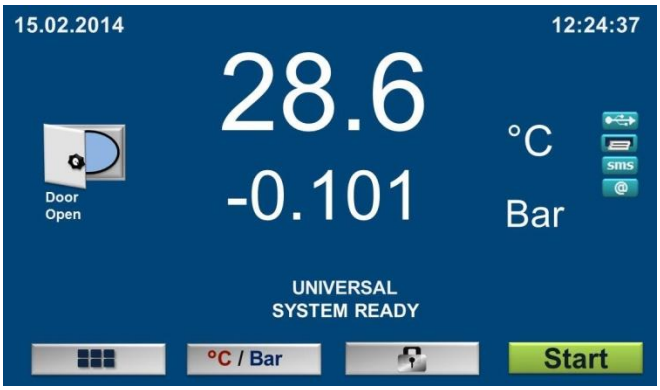
See that display and control panel activates when the device is powered on. Firstly, the screen on the left appears. Use left (F1) and right (F2) keys to select a menu item. Selected menu item color changes to blue and enter (F4) key is used to access the selected menu item.



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 is user password and it can be set on settings menu. 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.

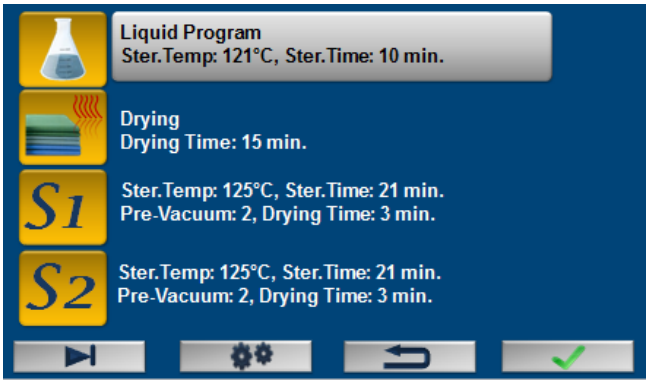


The screen on the left is working screen and on working screen sterilization chamber temperature and pressure values can be monitored. Current date and time are shown at the top line. Push enter (F4) key to start the selected program. When program starts to run, total sterilization cycle time and related sterilization cycle phase time appears at the top 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 on "°C / Bar" sub menu, 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. To change the selection to the next parameter, use tab (F3) key. After setting all parameters, push enter (F4) key to return special programs screen.

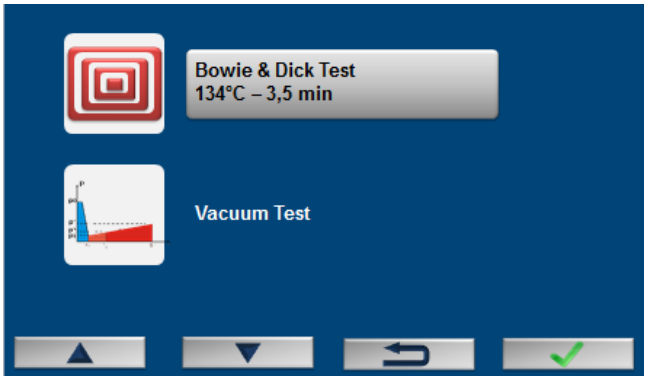
Working screen appears when enter (F4) key is pushed on the selected special program. Push start (F4) key on the working screen to start the selected program.

⚠ In liquid sterilization working, the sample temperature is not controlled by an external temperature sensor. Therefore, the sterilization parameters will be determined by the user. The assurance of product sterility in the special program is the responsibility of the user!

⚠ 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.

⚠ Only sterilization time can be changed from parameter page belong to liquid program. When liquid program is selected, sterilization temperature is adjusted as 121°C by device automatically.

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. DRYING PROGRAM

The NC 100 steam sterilizers provide very good drying standards for sterilized items. Particularly difficult drying tasks (e.g. double wrapping) can also be dried to very good standards with the help of the supplementary drying function and the automatic pre-heating.

Steam is obtained by heating the water in the sterilizer. The steam transfers heat to the instruments and sterilization container and warms these. This leads to steam condensing on the instruments and containers. Some of the condensation drops to the bottom of the sterilization container.

After sterilization, during the drying phase, all condensation must evaporate from the sterilization container and from the sterilized items. 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

6.4. COMPLETION OF THE OPERATION

When working program is completed successfully; if preset program is selected “LOAD IS STERILE” appears on the screen, if special program is selected “WORKING IS COMPLETED” appears on the screen.

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

6.4.1. 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.

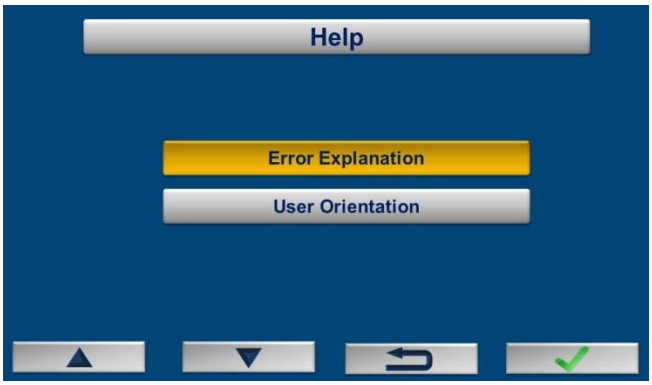
Type of material	Suggested time (days)
Combination of paper-polypropylene	30 (single) – 60 (double)
Metal containers, with standard-grade filters	28/30
Medical Grade with double orthogonal layer	28/30

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.

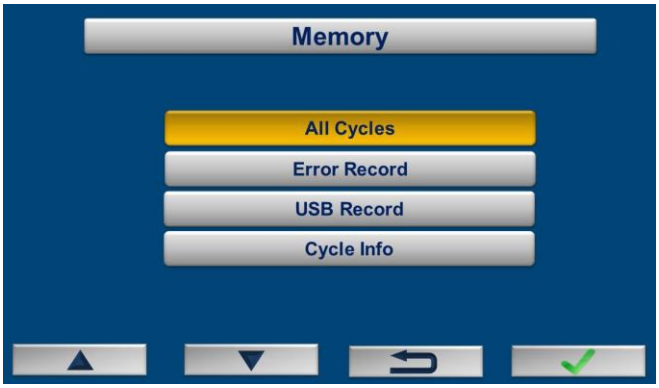
7. MENUS

7.1. HELP



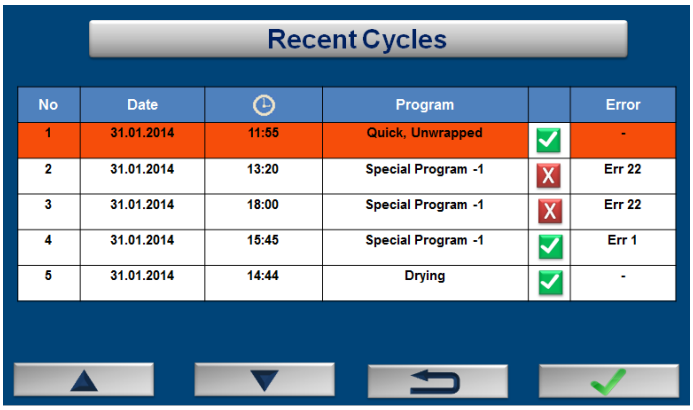
“Help” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access help page which contains submenus which includes failure explanations which user may encounter and some useful information for user.

7.2. MEMORY



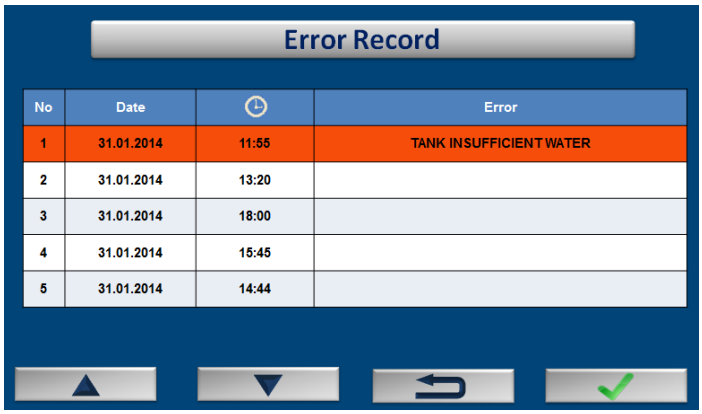
“Memory” menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access memory page. Use increase (F1) and decrease (F2) keys to select a submenu on memory page and push enter (F4) key to access the selected sub menu.

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 “Active Cycles” is selected on all cycles page, you are asked to enter a date to inquiry of a cycle. 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.

“Passive Cycles” page is similar to “Active Cycles” except it contains less detailed information regarding a cycle.



“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.

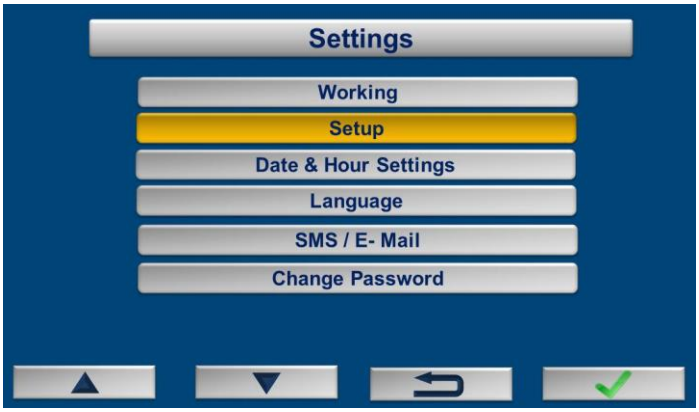
7.2.1. EXTERNAL MEMORY (USB STICK)

USB Stick is connected to USP port-1 of the communication unit. "⇠•⇢" appears on the working screen when the USB stick is identified by the microprocessor system.

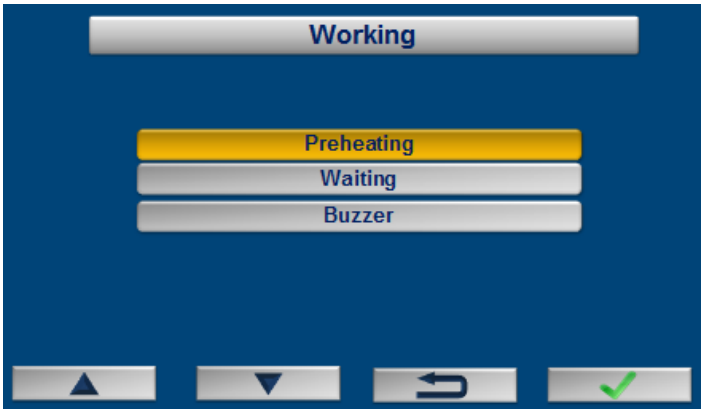
> ☞ If ⇠•⇢ does not appear on the screen, USB stick may be defective or may not be connected correctly.

When "USB Record" submenu is selected on the memory page, there are four options: "Active Cycles", "Passive Cycles", "Error", "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



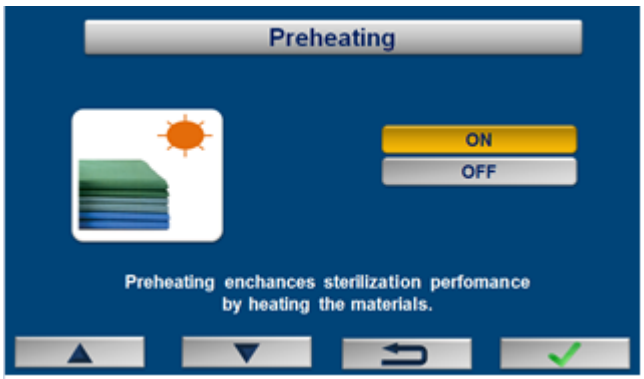
"Settings" menu is selected from the main menu by using left (F1) and right (F2) keys. Push enter (F4) key to access settings page on the left. Use increase (F1) and decrease (F2) buttons to select a submenu.



"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" and "Buzzer" submenus.

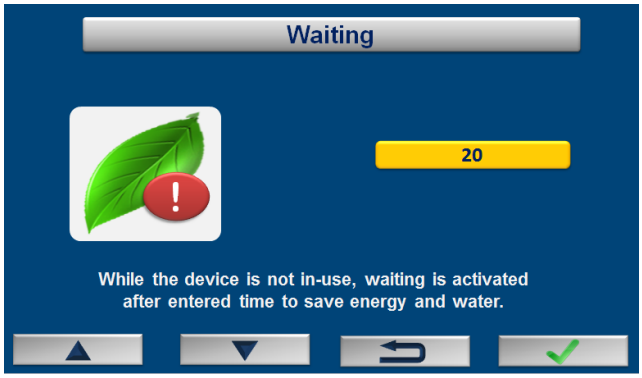
7.3.1. PREHEATING

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.



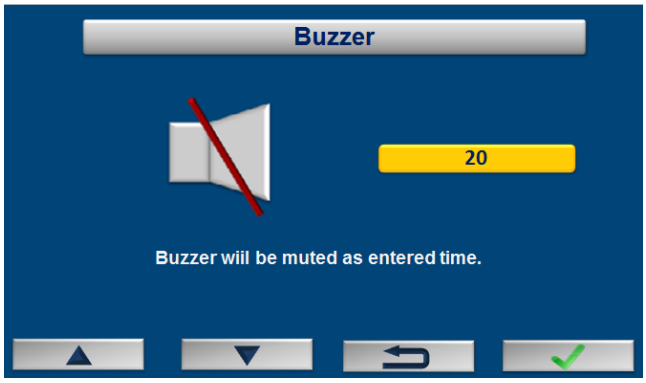
Select "Working" submenu on the settings page by increase (F1) and decrease (F2) keys and push enter (F4) key. On the next page, select Preheating by using increase (F1) and decrease (F2) keys and push enter (F4) key. Select ON and push enter (F4) key.

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. BUZZER

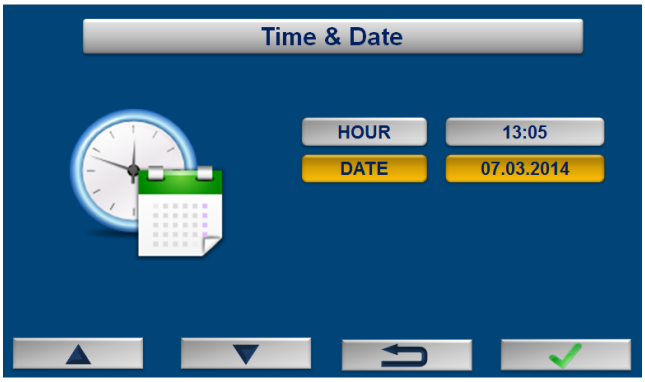


"Buzzer" submenu is selected on the working page by using the value increase (F1) and decrease (F2) keys. If the alarm condition continues after muting the alarm buzzer, "Buzzer" reactivates audible alarm at the end of the desired time (in minutes). If you want to exit this page without any change, push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

7.3.4. 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.

7.3.5. 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).

7.3.6. 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.

7.3.7. PASSWORD

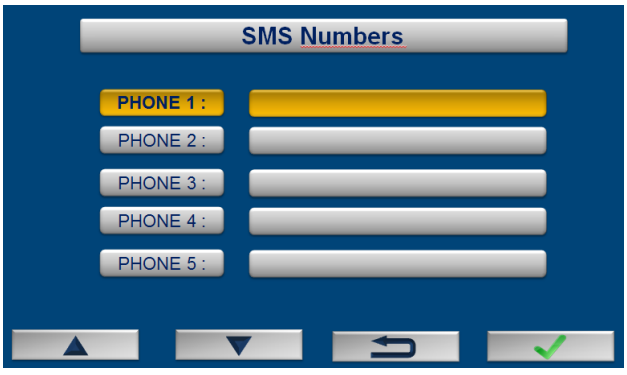
"Change Password" submenu is selected on the settings page by the value increase (F1) and decrease (F2) keys. The page on the left appears when enter key (F4) is pushed. After old password value is entered by pushing the value increase and decrease keys, push the enter key. New password value can be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

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.

7.3.8. SMS

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

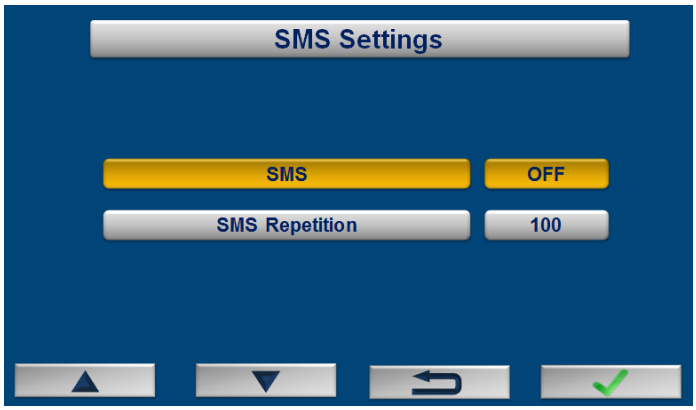
Select "SMS/E-mail" submenu on the settings page by increase (F1) and decrease (F2) keys and push enter (F4) key. On the next page, select SMS by using increase (F1) and decrease (F2) keys and push enter (F4) key.



"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.

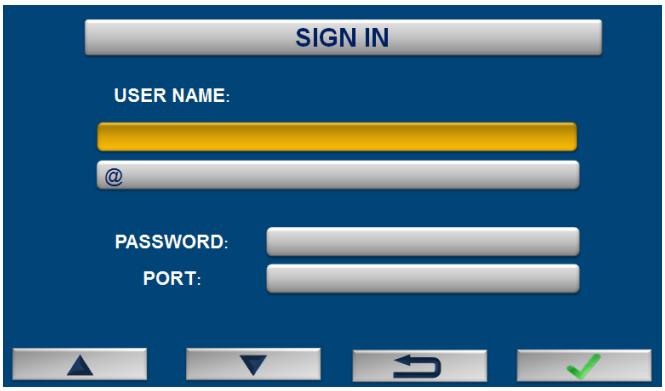
- Activation or deactivation of SMS function can be adjusted. If you want to activate this function, choose “on” by pushing the enter key (F4). If you want to deactivate SMS function, choose “Off” by pushing the enter key (F4).
- “Repeat time” is the frequency of sending SMS. The user is notified again 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).

7.3.9. 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.

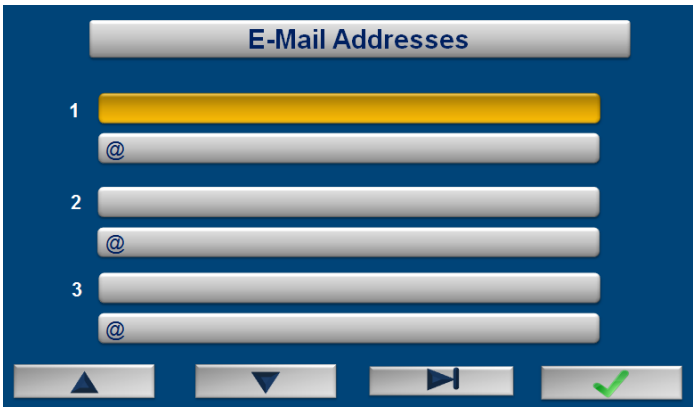


“Sign In” is selected on the e-mail page by the value increase (F1) and decrease (F2) keys. The page on the left appears when enter key (F4) is pushed. Each character of e-mail addresses is written one by one. The first character is entered by pushing value increase (F1) and decrease keys (F2) and tab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

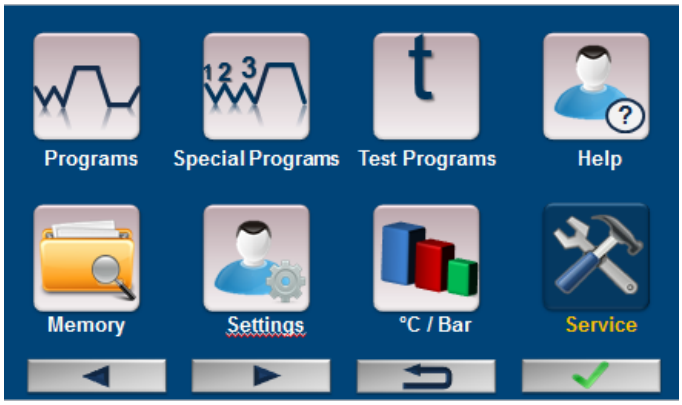
For Wi-Fi and NuveControl connection of N-Smart devices, follow these steps:

- Open a Wi-Fi broadcast.
- Download and register the N-Mobile app according to the phone's operating system (IOS, Android).
- Add device by typing the MAC address and Serial number of the device you are connecting to.
- Connect to the Wi-Fi broadcast to which the device is connected by phone.
- Set the Wi-Fi connection and Wi-Fi Auto-tuning to On from the Wi-Fi section on the Settings page of the device to be connected.
- Enter the password for the Wi-Fi broadcast connected to Wi-Fi Configuration in the settings section of the N-Mobile application and press the confirmation key.
- Check the connection from the icons on the Wi-Fi Settings page.

7.5. °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.

7.6. SERVICE



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

7.6.1. AUTOMATIC WATER SUPPLY UNIT (OPTIONAL)

⚠ Water tank should be placed above the water inlet; **if not there will not be any water inlet into the system!**

☞ Height should be adjusted according to water supply unit.

⚠ Only **DISTILLED WATER** must be used in the water tank. If distilled water is not used, there could be failures in the steam sterilizer.

⚠ When the water level is decreasing inside NC 100, additional water comes through the water tank. Therefore, water level inside the water tank should be checked regularly!

Automatic water supply unit connection should be done by authorized staff. The capacity of the water tank should be big enough to supply enough water to NC 100.

7.6.2. NuveLift (OPTIONAL)

Factory-mounted lift system allows the user; security and not having the extra power consumption which basket may guide.

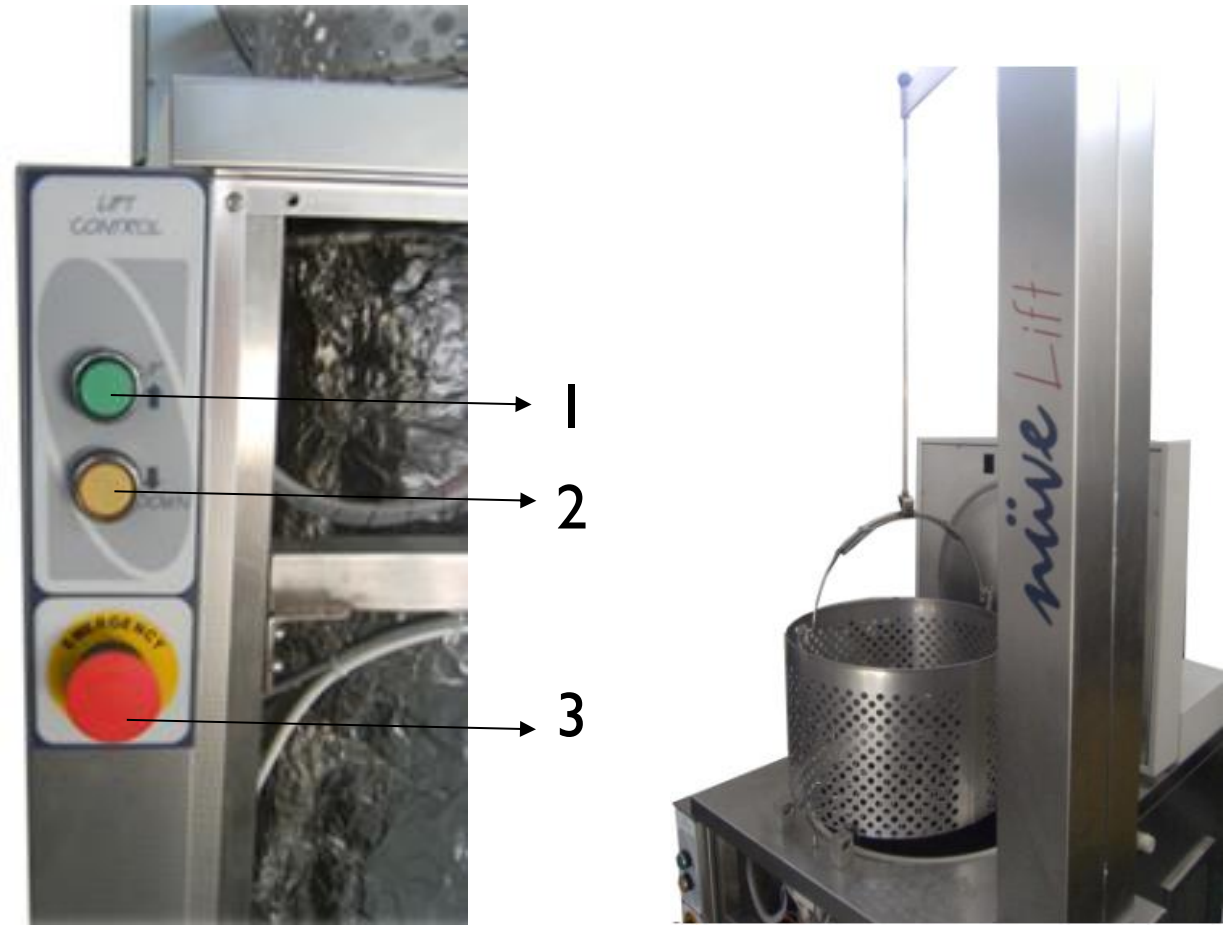


Figure 14 - NüveLift

1- Up button

2- Down button

3- Emergency Stop

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 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 Test shall be performed at the beginning of every working day, Vacuum Test shall be executed weekly while the chamber is not yet heated; to assure efficient functioning of the unit.

8.2. PERIODIC CONTROL

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.
- Cassette filter should be cleaned every week.

	*Used chemical materials effects for the chamber cleaning should be cleaned carefully and thoroughly after the cleaning process. Uncleaned chemical materials can cause undesirable problems in the chamber during the sterilization phase.
	Cleaning shall be performed while chamber is cold.
	It is recommended to run a cycle once after cleaning without load

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 dismounted 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.

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.

During a program run;

- In case of any failure before sterilization phase, the load would **not be sterile** since the sterilization phase is not started.
- In case of any failure after sterilization phase, 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 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 08: Door Locking : The duration for locking door has exceeded the preset time.

Error 09: Insufficient Water – Insufficient water in steam generator and water tank.

Error 10: Broken Sensor PT1, PT2, PT3, BT1 – Temperature and/or pressure sensors are 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 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 17: Heater Failure – Steam generator's heaters or grid phases are defective.

Error 18: Steam Generator High Pressure - Pressure in the steam generator exceeds acceptable limits during the cycle. Please contact with authorized Nüve Service.

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 48: Communication - There is no connection between main PCB and display.Please contact with authorized Nüve Service.

Error 49: SMS - SMS can not be sent SMS to user in case of any error situation. Please check whether GSM modul is connected with the device and SMS optional is selected as "OPEN".

Error 50: Modem - This message appears if the device can not send E-Mail to user in case of any error situation. Please check whether Ethernet cable is connected with the device and E-Mail option is selected as "OPEN".

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

11. OPTIONS

11.1. AlerText™ GSM MODULE

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

Figure 15 GSM Module

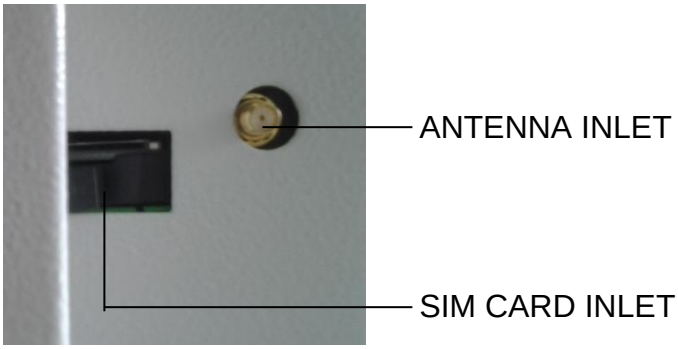


Figure 16

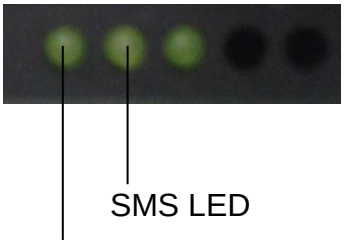


Figure 17

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

- Insert SIM card in the GSM module.

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 to the RS 232 port on the steam sterilizer.
- Ensure that power led is turned on (See Figure 16). 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.

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