Instructions for Use

lexa

MN-111

MN-111 Med - ENG - Rev15

Table of contents

Conformity

CONFORMITY TO EUROPEAN AND AMERICAN REGULATIONS, STANDARDS AND DIRECTIVES

Sterilizer conforms with the following Regulations, Standards and Directives:

Standards and Directives	Description
CE 0051	Medical Device Regulation (MDR) / Regulation (UE) n. 2017/745 for medical devices. Class IIb devices, in accordance with the Rule 16 – ANNEX VIII of the above Regulation
CE	For Device in compliance with Machinery Directive (2006/42/EC), Low Voltage Directive (2014/35/EU) and Electomagnetic Compatibility Directive (2014/30/EU)
CE 0497 **2014/68/EU**	Pressure Equipment Directive (PED) / Directive 2014/68/EU (PED – Pressure Equipment Directive) for every sterilization chamber designed and manufactured in conformity to the ANNEX 1 and to the procedure described in the moduleD1 Annex III
2012/19/EU	Waste Electrical and Electronic Equipment Directive (WEEE)
CSA C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use, general requirements
UL 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use, general requirements
ASME	Boiler and pressure vessel code
EN 13060	Small steam sterilizers
ANSI/AAMI ST55	Table-top steam sterilizers
IEC 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use, general requirements
IEC 61010-2-040	Safety requirements for electrical equipment for measurement, control and laboratory use; particular requirements for sterilizers and washer-disinfectors used to treat medical materials
IEC 61326-1	Electrical equipment for measurement, control and laboratory use - EMC requirements; general requirements
IEC 61770	Electric appliances connected to the water mains - Avoidance of backsiphonage and failure of hose-sets

Note: every new sterilizer is delivered with a Declaration of Conformity and a Warranty Card.

Symbols and messages

SAFETY SYMBOLS USED IN THIS MANUAL

WARNING: indicates a hazardous situation that, if not avoided, could result in death or serious injury.

Related to a sterilizer, these warnings indicate hazardous situations that could result in non-sterile conditions (e.g. non-sterile instruments) which could lead to fatal personal injury.

CAUTION: indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

SYMBOLS DISPLAYED ON THE PRODUCT

Hot surfaces!
Risk of burns.

Hot steam!
Risk of burns.

Consult the Instructions for Use for important cautionary information.

Do not use drinking water to fill the clean water tank; use distilled or demineralized water only.

Consult the Instructions for Use.

Disposal / Do not dispose of with normal waste.

PROPERTY DAMAGE MESSAGES

Notice: indicates information considered important, but not hazard-related. Typically to avoid damage to the product.

STORAGE	Storage
TRANSPORTATION	Transportation
MD	Medical Device Only for MDR devices
SN	Serial Number
REF	Catalogue number
Max. P	Max. pressure / Max. allowable working pressure (MAWP)
	Temperature between XX °C and XX °C
	Manufacturing date (YYYY-MM-DD)
	Country of manufacture

	Manufacturer
UDI	Unique Device Identification
HIBC	Health Industry Bar Code in accordance with HIBC Standard
SMALL STEAM STERILIZER	Small Steam Sterilizer
	This side up
	Fragile, handle with care
	Keep dry
	The sterilizer must be transported by two authorized technicians due to its heavy weight
	ON (supply) IEC 60417-5007

	OFF (supply) IEC 60417-5008
	IN-position of bistable push control IEC 60417-5268
	OUT- position of bistable push control IEC 60417-5269
	USB connection
GS1 Logistic	GS1 datamatrix for logistic purpose
#	Sterilizer type or model
TC	Test connection

Introduction

CONTENTS

This section deals with the following subjects:

About this manual

FOR YOUR SAFETY AND THE SAFETY OF YOUR PATIENTS

The purpose of this manual is to provide information about Lexa sterilizers to ensure:

- proper installation and set-up
- optimal use
- safe and reliable operation
- compliance with regular maintenance and servicing requirements

Please carefully read the safety information (see "Safety warnings" on page 12).

OBLIGATIONS WITH REGARD TO THIS MANUAL

This manual is an integral part of the product and accompanies it for its entire working life. It must be consulted in all situations related to the life cycle of the product, from its delivery through to decommissioning. For this reason, it should always be accessible to operators both online and offline.

Contact customer service in the event the manual is unavailable. If the device is transferred, always attach the manual for the new owner.

MANUAL CONTENT

This manual contains the Instructions for Use and for maintenance of the following sterilizer versions:

- MN-111 Med 100–125 V ac
- MN-111 Med 200–240 V ac

DISCLAIMER

All pictures, graphics and illustrations provided in this manual are for the comprehension of the text. They are not meant to be an accurate representation of product details. Thus, they should be taken as indicative only, and may differ from the actual product.

For any suggestions or remarks please send an email to office.sterilization@wh.com.

COPYRIGHT NOTICE

The information contained in this document is subject to change without prior notice.

Use restrictions

INTENDED USE

For Medical Device in accordance with Regulation EU 2017/745:

The small steam sterilizers are intended for the sterilization of invasive and non-invasive medical devices. The devices are intended for professional use by trained people only.

For other purposes out of the scope of Regulation EU 2017/745:

The small steam sterilizers are intended for the sterilization of devices other than invasive and non-invasive medical ones. The small steam sterilizers are intended for the sterilization in veterinary practices. They are also intended to be used for materials and equipment which are likely to come into contact with blood or body fluids, e.g. implements used by beauty therapists, tattooists, body piercers and hairdressers.
The devices are intended for professional use by trained people only.

For North American market:

The Lexa is designed for pressurized steam sterilization of medical and pouched dental instruments, including dental handpieces, porous and hollow loads.

Key program features, including sterilization time, temperature and recommended load type are listed in the following table:

Program	Type of Load and Load weight	Sterilization Temperature	Sterilization Time	Drying Time (recommended)
Pouches Medium Load	Instruments and dental handpieces, up to 3 lbs (1.4 kg).	270 °F (132 °C)	4 minutes	25 minutes
Pouches Large Load	Instruments and dental handpieces, up to 6 lbs (2.7 kg).	270 °F (132 °C)	4 minutes	30 minutes
Wrapped Cassettes	Instruments and dental handpieces, up to 14 lbs (6.3 kg).	270 °F (132 °C)	4 minutes	40 minutes
Low Temperature	Textiles, up to 4.4 lbs (2 kg), or instruments and dental handpieces requiring low temperature, up to 5 lbs (2.3 kg).	250 °F (121 °C)	30 minutes	30 minutes
Unwrapped	Instruments and dental handpieces, up to 18 lbs (8.1 kg). Unwrapped, naked.	270 °F (132 °C)	4 minutes	8 minutes

See "Sterilization programs" on page 83 for the full list of key program features, including sterilization time, temperature, drying time and recommended load type.

USER QUALIFICATION

The users who may operate the sterilizer are the following.

User qualification	Competences
Head of the clinic/practice	Legally responsible for: ■ the efficiency of the hygiene protocol in place ■ the sterilization process ■ the operators' training and training documentation ■ the correct operation and maintenance of the equipment
Trained operators	■ Regularly attend the training for operating and using the sterilizer safely. ■ Use the sterilizer according to the Head of the clinic/practice's instructions.

Safety information

CONTENTS

This section deals with the following subjects:

Safety warnings

THERMAL HAZARDS

- The chamber automatically begins to heat to high temperature as soon as the sterilizer is switched on – risk of burns!
- The trays and the sterilization load are hot at the end of each cycle. Use tray or cassette holders to empty the sterilization chamber.
- Always wear appropriate PPE during use of the sterilizer (e.g. gloves for cleaning, maintenance, etc...).

ELECTRICAL RISKS

- Do not pour water or any other liquids over the sterilizer (risk of electrical short circuits).
- Switch off the sterilizer and unplug the mains cable before inspecting, carrying out maintenance or servicing the sterilizer.
- Ensure that the power receptacle the sterilizer is connected to is properly grounded.
- All electric devices connected to the sterilizer shall be of Insulation Class II (double insulated) or higher.
- Use only the power cord provided by the manufacturer.

IMPROPER USE OF THE STERILIZER

- The sterilizer must not be used in presence of explosive or flammable gases, vapors, liquids or solids.
- The sterilizer has not been designed for the sterilization of foodstuff or waste.
- Do not exceed the maximum load weight limits as specified in this manual (see "Run a sterilization cycle" on page 49).
- Do not drink any water that has been inside the sterilizer.

TAMPERING

- Do not remove the name plate or labels from the sterilizer.
- Repairs, maintenance or service must be carried out by authorized service providers always using genuine spare parts.

REQUIREMENTS

- All accessories connected to the sterilizer shall be FDA cleared.
- Use only the power cord set and accessories provided by the manufacturer.
- Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.
- In case of malfunction of the sterilizer, contact an authorized technician or the manufacturer.

CYBERSECURITY

1) Device connectivity

The accessible external ports of the device are:

- Ethernet port, where present
  Intended use:
  - Network services (see description below)
- USB ports
  Intended use:
  - mass storage device, such as a pen drive, for cycle report saving;
  - mass storage device, such as a pen drive, for software update;
  - report printer
  - label printer
  - QR code reader (seen as a keyboard), for EliTrace functionality, where present;
  - Wi-Fi dongle key, for network services (see description below);
  - USB to Ethernet adapter for network services (see description below).

Network services are:

- remote data storage;
- label printer sharing;
- device user management;
- cloud communication for sending cycle data and device status and for software update.

Please note that the device functionality does not require connecting to the Internet.

Recommendation for cybersecurity

- All the listed ports and uses are available for both the device users and the service personnel, except for the software update that can be performed only by authorized personnel only (W&H partners or technicians).
- Update the device software to the latest version as recommended by the manufacturer.
- Use only trusted USB mass storage devices for report saving.
- Regularly backup the cycle reports to ensure to have a copy in case of cybersecurity events or incidents.

- Don't access the device web server functionality through links in e-mails.
- Ensure the mail service provider has a spam filter.

2) Device protective features for cybersecurity

The device is designed in such a way that a cyber attack or software failure does not compromise the safety in relation to the intended use. A successful cyber attack cannot result in direct patient harm: in fact, the device is not in contact with patients.

The device does not share any data (sensible and not sensible data) related to patients.

To further protect the device and minimize successful cyber attacks, the following precautions were taken:

- the access to the device operating system is not possible (user access to the operating system is disabled);
- a firewall is active on the device; all the device network connections (to and from the external world) are managed by the firewall which, following specific rules, filters them and blocks everything that is not strictly necessary for the device;
- the update/install operations are only possible using signed and encrypted software, provided by W&H;
- during the normal use, the operating system and the application (responsible for the device functionalities) are located in a read-only memory to avoid intentional corruption;
- all the cycle data are secured by means of checksum controls.

3) Cycle data storage

The device saves cycle data on the USB pen drive. Each file contains a control code that allows to check the file integrity.

4) Cloud secure communication

A secure communication (with authentication and authorization) can be established between the device and the cloud server for the following functionalities:

- remote software update;
- setting management;
- device monitoring;
- cycle data acquisition.

The user and authorized technicians can interact with the cloud server by means of a generic device (e.g.: PC, tablet, smartphone) with a web browser and proper authorization and authentication.

5) Infrastructure requirements

In order to minimize the possibility of cyber attacks, it is user responsibility to apply the following measures:

- software update/install shall be done by authorized and trained personnel only;
- it is recommended to activate a firewall on the router/modem used for the Internet connection.

Note: further security information is mentioned in the MDS2 document, which is available on request.

6) Software Bill of Material (SBOM)

The device provides the possibility to download the SBOM to the USB pen drive, by accessing the “System Info” menu page.

7) Events possibly caused by a cyberattack detectable by the user

The following situations, visible by the user, could by caused by cybersecurity events:

- frozen screen;
- black screen;
- significant slowdown when navigating the menus;
- malfunctioning or blocked network services (such as: remote data storage, label printer sharing, etc...).

8) Instructions for users on how to respond if a cybersecurity event or incident occurs

If a cybersecurity event or incident occurred, or in case of a suspect, the following indication shall be followed to minimize the impact and prevent further damage:

- to disconnect the device from the network (Ethernet cable and/or Wi-Fi dongle) to prevent spreading the damage to other devices;
- to disconnect the USB pen drive to reduce the possibility to corrupt stored data, like cycle reports;
- to inform the IT department and an authorized technician (or device manufacturer) and follow the indications they would provide to secure the affected device.

Responsibility

USER RESPONSIBILITY

- The user is responsible for the proper installation, the correct use and maintenance of the sterilizer in accordance with these Instructions for Use.
- The safety devices of the sterilizer are impaired when the product itself is not installed, used and serviced in accordance with these Instructions for Use.
- The Instructions for Use updated to the latest version is always available at med.wh.com.
- Keep these Instructions for Use for future reference.

MANUFACTURER RESPONSIBILITY

- The manufacturer can only accept responsibility for the safety, reliability and performance of the product when the product itself is installed, used and serviced in accordance with the Instructions for Use.
- Servicing by unauthorized persons invalidates all claims under warranty and any other claims.

Getting started

CONTENTS

This section deals with the following subjects:

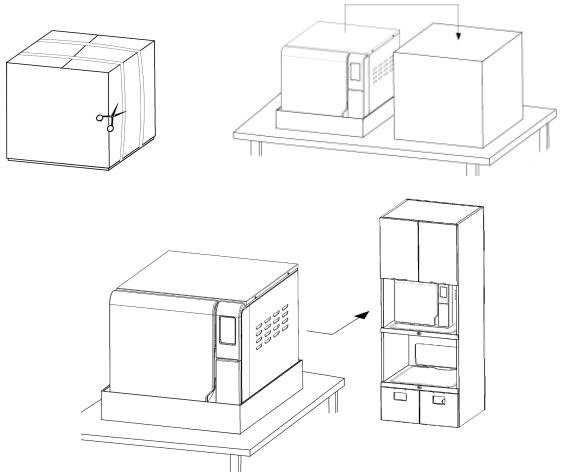
Unpacking

UNPACK THE STERILIZER

CAUTION! Heavy product. The sterilizer must be removed from the box and transported by two authorized technicians.

Weight with box: 121.5 lbs (55.1 kg)

Weight without box: 110.2 lbs (50 kg)

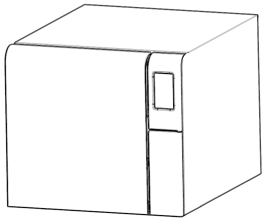


WARNINGS

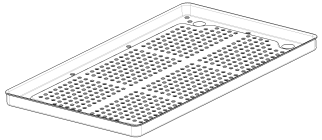
Notice: check the external conditions of the box and the sterilizer. In case of any damage, immediately contact the dealer or shipping agent that has carried out the transport. Keep the packaging for shipping or transporting the sterilizer in the future.

Note: the packaging of the product is environmentally friendly and can be disposed of by industrial recycling companies.

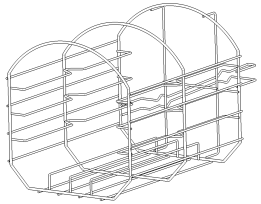
CONTENTS OF THE PACKAGING



Sterilizer

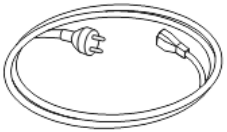


Trays (four)

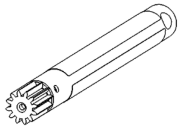


Chamber rack

Tray holder

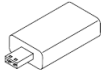


Power cord

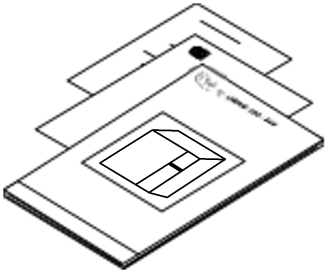


Emergency door opening tool

Drain tube



USB pen drive loaded with Instructions for Use



This manual, declaration of conformity, warranty card, work test report

ITEMS NOT PROVIDED WITH THE STERILIZER

The following items are not provided:

- Water container to capture waste water during manual tank draining (volume larger than 1.84 gal (7 l)).
- LAN cable for connecting the sterilizer to a network (optional).

See "Accessories, spare parts, consumables" for a full list of optional accessories.

Handling

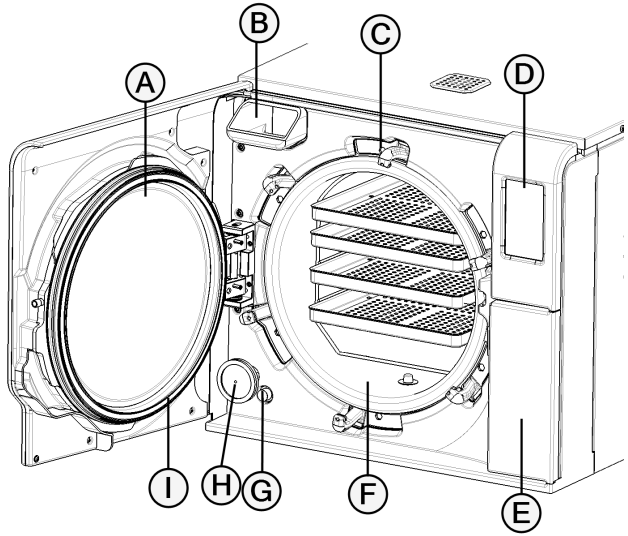
HOW TO RELOCATE THE STERILIZER

Before transport:

- Completely drain both water tanks (see "Draining the used and clean water tank" on page 67).
- Allow the sterilization chamber to cool down.
- Use original packaging when shipping or transporting the sterilizer. Replacement packaging materials are available from Service W&H.

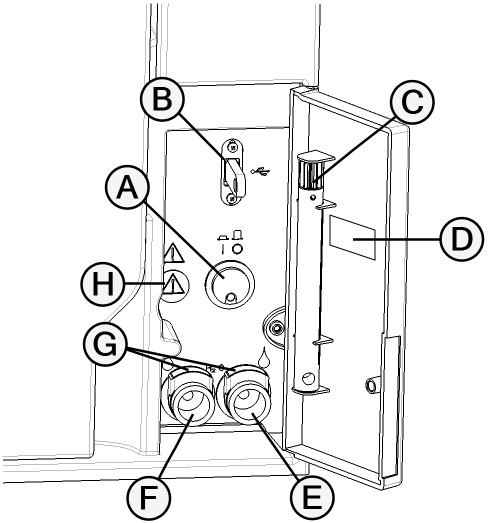
Product description

FRONT VIEW



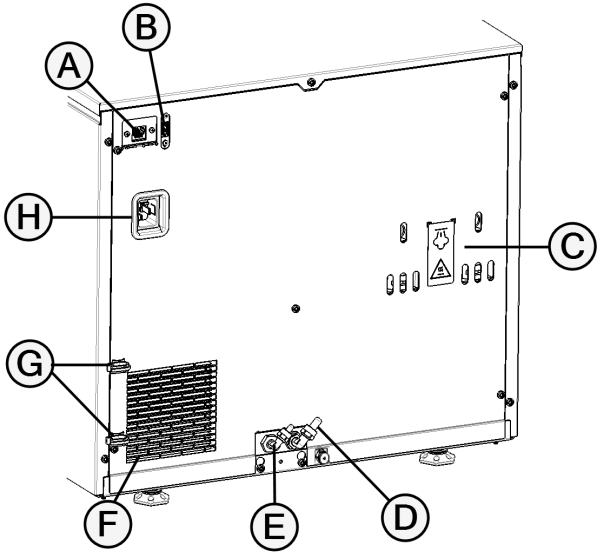
Part	Description
A	Chamber door
B	Clean water tank
C	Door locking system
D	Touch screen
E	Service door
F	Sterilization chamber
G	Safety thermostat reset
H	HEPA filter
I	Door gasket

COMPONENTS BEHIND THE SERVICE DOOR



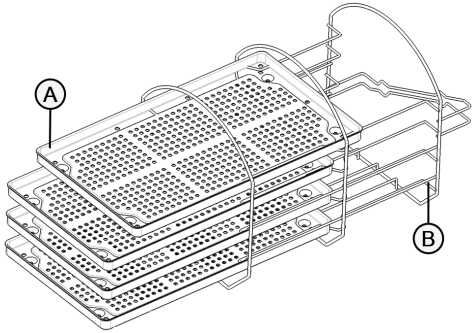
Part	Description
A	Mains switch
B	USB port
C	Emergency door opening tool
D	Identification label
E	Used water drain connection (grey)
F	Clean water drain connection (blue)
G	Drain tube release buttons
H	Port for emergency door opening tool

REAR VIEW



Part	Description
A	LAN port (KIT)
B	USB port
C	Pressure safety valve cover
D	Used water drain (optional)
E	Water supply inlet (optional)
F	Condenser grid
G	Power cord guides
H	Power cord socket

CHAMBER ACCESSORIES



Part	Description
A	Tray
B	Chamber rack. It can host trays or cassettes inserted horizontally or vertically.

Installing the sterilizer

LOCATION REQUIREMENTS

Notice:

Do not place the sterilizer so that it is difficult to operate the controls behind the service door. Do not place the sterilizer so that it is difficult to disconnect the power cord.

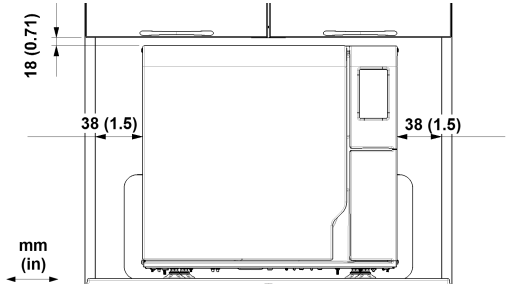
Leave the condenser grid (rear side of the sterilizer) free from anything that might obstruct the air passage.

Surface materials should be water resistant. If sterilization cycles will be continuous, pay attention to the surrounding materials: steam can damage them.

The sterilizer must operate in absence of explosive atmospheres. The sterilizer must operate in a well ventilated room (indoor), far from sources of heat and from flammable materials.

Place the sterilizer on a flat and level surface.

Clearance requirements to ensure proper air circulation:



ELECTRICAL CONNECTIONS

All the cables and tubes connected on the rear side of the sterilizer must be placed far from the condenser grid (e.g. using the available guides).

Notice:

Connect the sterilizer to a dedicated line. Do not use cable extensions nor multiple sockets/adapters.

Ensure that external and internal surfaces are free from moisture or condensation before connecting to power.

The installation of the sterilizer shall be performed by two authorized technicians using PPE (Personal Protective Equipment) according to applicable standards.

The electrical power supply of the sterilizer must fulfill all applicable standards in the country of use, and must comply with the data label on the back of the sterilizer.

WATER CONNECTIONS

The sterilizer clean water tank can be filled manually by the user or automatically with a water supply system . The water supply system must deliver demineralized or distilled water meeting the specifications listed in these instructions. Do not add any chemical/additive to the water.

The manufacturer's warranty is void if the sterilizer was used with water containing either chemical additives, or contaminant levels exceeding those listed in these instructions. See "Feed water specifications (ANSI/AAMI and AAMI TIR34)" on page 95.

Notice: the maintenance of the external water filling system must be done in exact accordance with the Instructions for Use given with the relevant system.

WATER TANKS

At every cycle the sterilizer uses new fresh water and, at the end of the cycle, discharges it. Thus, the sterilizer is fitted with two water tanks : the clean water tank and the used water tank.

For this reason is necessary to periodically fill the clean water tank and draining the used water tank.

FILLING THE CLEAN WATER TANK

Notice:

Before carrying out the following steps, make sure that the sterilizer has completed the cycle in progress.

Always wear appropriate PPE during use of the sterilizer (e.g. gloves for cleaning, maintenance, etc...).

1. If switched-off, switch the sterilizer ON. If the clean water tank is almost empty, an alert appears on the display.
2. Open the chamber door.
3. Fill the clean water tank with a water container (app. 1.7 gal (6.4 l)).
   Notice: the water must be demineralized or distilled meeting the specifications listed in these instructions (see "Feed water specifications (ANSI/AAMI and AAMI TIR34)" on page 95). Do not add any chemical / additive to the water.

   Notice: take care not to pour the clean water out of the tank.
4. Once the clean water tank is almost full, an audible tone sounds; stop filling.

DRAINING THE USED AND CLEAN WATER TANKS

Notice:

Before carrying out the following steps, make sure that the sterilizer has completed the cycle in progress.

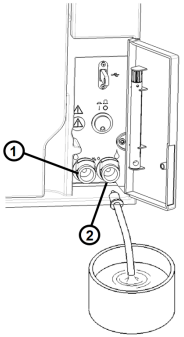
Always wear appropriate PPE during use of the sterilizer (e.g. gloves for cleaning, maintenance, etc...).

1 If the used water tank is almost full, an alert appears on the display.

2 Open the service door at the front of the sterilizer.

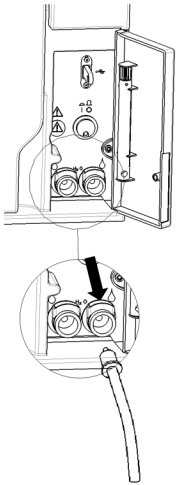
3 Put a container (1.84 gal (7 l) min) below the sterilizer and insert into it the free end of the drain tube.

4 Plug the other end of the drain tube into the drain connector until it clicks. Make sure that the connector is firmly engaged.
Use left connector (blue, **1**) for the clean water and the right connector (grey, **2**) for the used water.

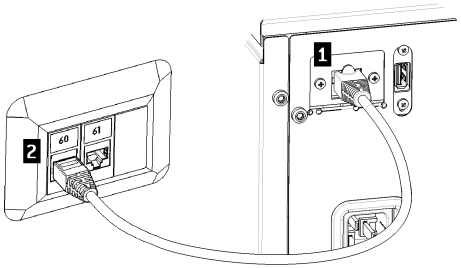


5 Let the water flow from the tank completely.

6 Press the push-button on top of the quick connector to dislodge the drain tube.



LAN CONNECTION (OPTIONAL)



1 Insert a standard Ethernet cable in the LAN port of the sterilizer.

2 Insert the other end of the cable in the LAN port of your computer or computer network: when the sterilizer will be switched on it will connect automatically to the LAN.

WI-FI CONNECTION

For the Wi-Fi connection proceed as follows:

1 Insert the Wi-Fi dongle key in the USB port.

2 Read the Instructions for Use provided with the Wi-Fi dongle key.

INSTALLING THE STERILIZER

WARNING! In case of sterilizer malfunctions immediately unplug the sterilizer and call for service. Do not attempt to repair the sterilizer by yourself.

Notice:
Please ensure that all installation requirements are met before plugging the sterilizer. See "Connection diagrams" on page 94.
No other devices should be connected to the sterilizer power panel circuit.

1 Place the sterilizer on a sturdy, flat and level surface.

2 Open the chamber door, remove all items from the sterilizer chamber except the chamber rack. Remove all plastic covers from trays.

3 Connect the auto-fill and auto-drain tubes in the rear of the sterilizer (optional).

4 Connect the Ethernet cable or the Wi-Fi dongle key in the rear of the sterilizer (optional).

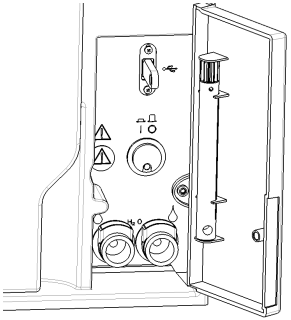
5 Attach the power cord to the socket in the rear of the sterilizer and route the cord through the cable guides.

6 Connect the power cord to a wall outlet. For power supply requirements, see "Technical data" on page 92.

Operating the sterilizer

POWER THE STERILIZER ON/OFF

1 Press the power switch behind the service door: once switched ON, the visual indicator on the power switch turns green.

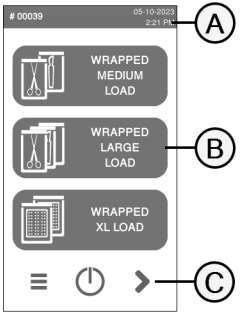


2 After a quick autotest the sterilizer automatically enters Standby mode. See "Standby mode" on page 38.

Note: at the first start-up of the sterilizer, the Guided Configuration procedure automatically appears; see "Sterilizer setup" on page 35.

3 Tap ⏻. The homepage appears with the enabled sterilization cycles.

HOMEPAGE DESCRIPTION



Part	Description
A	Title/purpose of the screen, or the cycle number and the current date and time.
B	Available cycles and tests.
C	Additional buttons used to navigate the menu.

User interface menu

MAIN MENU FUNCTIONS

Note: this section describes the device functions. Please note that the availability of them depends on the device model and some of them might not be available for this model.

Icon	Label	Function
	**Menu**	Opens the menu.
	**System Info**	■ Shows the system information. ■ During a cycle, shows the cycle parameters.
	**Device Settings**	Opens the pages to sterilizer management.
	**Traceability**	Opens the pages to: ■ monitor the performed cycle data. ■ manage users. ■ set the label printing options.
	**Accessories**	Opens the pages to accessories management.
	**Maintenance**	Carries out the maintenance procedure.

DEVICE SETTINGS MENU FUNCTIONS

Icon	Label	Function
	**Device**	Opens the pages to set the device.
	**Language**	Sets device language.
	**Date & Time**	Sets date and time format, current date and time and time zone.
	**Sterilizer Name**	Sets the sterilizer name.
	**Energy Management**	Changes the standby mode delay.
	**Display**	Sets the display brightness.
	**Audio**	Manages the sterilizer sounds.
	**Cycle**	Opens the pages to manage cycles.

Icon	Label	Function
	**Cycle Exclusion**	Sets the cycles menu.
	**Measurement Units**	Sets the unit of measure (temperature, water conductivity and pressure).
	**Daily Cycle Program**	Programs a sequence of cycles to be run on daily basis.
	**Connectivity**	Opens the pages to manage the network connection.
	**Ethernet**	Manages the Ethernet network.
	**WI-FI**	Allows wireless network selection and configuration.
	**Network Status**	Only with a network connection set. Provides information about the network status.
	**IoDent**	Only if this service is supported in the country of use, and if the sterilizer is connected to it. Shows the status of the connection with the W&H monitoring server.
	**Akidata status**	

Icon	Label	Function
	**Remote Data Storage**	Only with a network connection set. Opens the page to manage the remote storage.
	**Settings**	Only with a network connection set. Sets the parameters of the network location.
	**Save all**	Only with a network connection set. Copies all the files in the specified location in the network.
	**Test**	Only with a network connection set. Checks if the files can be copied to the specified location.
	**USB options**	Enables/disables USB warning messages.
	**Traceability Settings**	Chooses if the sterilizer is master or slave.
	**Guided Configuration**	Allows to start the configuration of: ■ language. ■ network connection. ■ time zone settings. ■ date & time settings. ■ sterilizer name.

TRACEABILITY MENU FUNCTIONS

Icon	Label	Function
	**Cycle History**	Shows all the sterilization cycles and tests and prints reports and labels.
	**Save**	Saves all the sterilization cycle reports in the USB pen drive.
	**User Management**	Optional, activated with an activation code. Permits managing the users.
	**Add User**	Administrator only. Adds a user.
	**Delete User**	Administrator only. Deletes a user.
	**Reset user PIN code**	Administrator only. Resets a user PIN code.
	**Change your PIN code**	Changes the PIN code.
	**Options**	Optional, activated with an activation code. Administrator only. Permits the following: ■ Identifies and saves the operator who starts the cycle and releases the load. ■ Protects with a password the cycle start, the cycle stop and the load release.

Icon	Label	Function
	**EliTrace**	Allows to manage the instrument database.
	**Label Printer**	Optional, activated with an activation code. ■ Enables/disables the printing of the labels. ■ Sets the automatic or manual printing of the labels. ■ Sets the maximum storage time of the wrapped sterilized items.

ACCESSORIES MENU FUNCTIONS

Icon	Label	Function
	**USB Pen Drive**	Opens the formatting page of the USB pen drive.
	**Format**	Formats the USB pen drive.
	**Label Printer**	Optional, activated with an activation code. Permits to select the label printer and sets the printout layout.
	**Local Printer**	Selects a printer connected to the sterilizer.
	**Shared Printer**	Selects a printer connected to another sterilizer (connected via local network).

Icon	Label	Function
	**Calibration**	Adjusts the label printer to the edge of the label.
	**Test**	Prints a test label.
	**Printer**	Selects the printer model connected to the sterilizer. The icon appears disabled if the printer/Ethernet cable/Wi-Fi dongle key is not connected.
	**Special Codes**	Saves the codes issued by the manufacturer to activate special functions. **Note**: only for technical support.

MAINTENANCE MENU FUNCTIONS

Icon	Label	Function
	**Bact. Filter**	■ Shows the status of the consumables. ■ Resets the cycle counter. ■ Displays the consumable replacement procedure videos.
	**Door Gasket**	
	**Water**	Shows the water information (conductivity, clean water tank level and dirty water tank remaining capacity).
	**Chamber Cleaning**	■ Shows the status of the cleaning operations. ■ Resets the cycle counter. ■ Displays the cleaning procedure videos.

Icon	Label	Function
	**System Update**	Installs and upload the software.

COMMON COMMANDS AND ICONS

Icon	Function
	Enters/exits the standby mode.
	Moves to the previous/next screen.
	Indicates that the chamber door is locked.
	Indicates that the chamber door is locking/unlocking.
	Indicates that the chamber door is unlocked and can be open.
	Copy the error log/reports to the USB pen drive.

Icon	Function
	Gives information about the current function.
	Opens the homepage.
	Accesses to the sub-menus.
	Opens a screen with other settings/options.
	Provides access to the SETTING screen of a specific area.
	Shows the list of all operating parameters of the sterilizer.
	Shows a sterilization summary.
	Indicates the value that may be changed and appears by clicking on it.
	Confirms the active option and saves a setting or a parameter.

Icon	Function
	■ Aborts the action/function. ■ Moves to the previous screen without confirming/making any changes nor saving any parameters.
	Indicates that the option is ON and allows to set it OFF by touching it.
	Indicates that the option is OFF and allows to set it ON by touching it.
	Shows the error log.
	Confirm the active option. Saves a setting or a parameter. Answers YES to a question.
	Aborts the action/function. Moves to the previous screen without confirming/making any changes nor saving any parameters. Answers NO to a question.

Icon	Function
	Increases/decreases the value.
	Indicates that the option is active/not active.
	Indicates that the option is enabled/disabled.
	Show an animation about the replacement procedure.

Sterilizer setup

GUIDED CONFIGURATION

At the first start-up of the sterilizer, the Guided Configuration procedure automatically appears; this procedure allows to set some parameters of the unit, such as:

- Language
- Network connection (where applicable)
- Time zone settings
- Date & time settings
- Sterilizer name

At any time, to force the Guided Configuration:

1. On the homepage, tap ☰ > ⚙ > › > 🪄.
2. Follow the Guided Configuration on the sterilizer screen.

SET THE DATE AND TIME

To change the date and time format, current date and time and time zone:

1. On the homepage, tap ☰ > ⚙ > 🌐.
2. Tap the value you want to change (format, time, date and/or time zone).
3. Tap the desired value.
4. Tap ‹ to confirm and return to the previous page.

SET THE STERILIZER NAME

To change the sterilizer name that appears in the cycle reports:

1. On the homepage, tap ☰ > ⚙ > › > 🪪.
2. Tap the text box: a keyboard appears.
3. Enter the new sterilizer name.
4. Tap ✓ to confirm.

SET THE DISPLAY BRIGHTNESS

To change the display brightness:

1. On the homepage, tap ☰ > ⚙ > ☀.
2. Tap ⌃ or ⌄ to change the value.
3. Tap ✓ to confirm.

CONNECT TO A NETWORK

If you connect through an Ethernet cable, in most cases the sterilizer will connect to the network automatically. If it does not connect automatically, or if you are using a Wi-Fi dongle key, follow the procedure below under supervision of your IT manager / network administrator.

1. On the homepage, tap ☰ > ⚙ > › > ((•)).
2. If the connection is through the Ethernet cable, tap ▭: the TCP/IP screen appears.
3. If the connection is through the Wi-Fi dongle key, tap ((•)): after a while, the sterilizer shows the available networks found. Choose the network, enter the credentials in the following screen, then tap ✓ to confirm: the TCP/IP screen appears.

Note: the ▭ and ((•)) icons are disabled if the connectivity means (cable or Wi-Fi dongle key) are not properly plugged.

Note: in the TPC/IP screen, the ✓ icon is visible only if you make any change. The Wi-Fi icon at the bottom isn't visible if you connect through Ethernet cable.

4. If your network supports dynamic IP addresses (ask your IT manager), enable the options **Dynamic** both in **IP Configuration** and in the **DNS Configuration** fields, then tap ✓ to confirm: all entry fields are disabled.
5. If your network does not support dynamic IP addresses (ask your IT manager), enable the options **Static** both in **IP Configuration** and in the **DNS Configuration** fields. Tap on each entry field and enter the IP addresses (ask your IT manager for details). Then tap ✓ to confirm.

ioDent

DESCRIPTION

It allows to save the data securely and automatically on the cloud and it ensures intelligent and networked reprocessing of instruments, with a wide selection of smart solutions and options.

ACCESS TO IODENT

For the ioDent access proceed as follows:

1. On the homepage, tap ☰ > ⚙ > › > ((•)) > ioDent.

Note: for more information see the dedicated documentation .

User authentication (optional)

FUNCTION AVAILABILITY

To access the user management functions the **User Management** activation code must be entered. The activation code is required only at the first access to the **User Management** (👥) or the **Options** (▤) menus: after the code was entered, the function is enabled and there is no need to enter the code again.
To acquire the activation code please refer to the Activation code instructions.

PIN MANAGEMENT

PIN “0000” is assigned as default to each new user. It has to be changed at the first login. When the PIN is reset the default value “0000” is reassigned.

CHANGE YOUR PIN

Change your PIN the first time you use the sterilizer and if your PIN has been reset. This will prevent other users from accessing your account.

1. On the homepage, tap ☰ > › > > .
2. Tap your user name.
3. Enter your current PIN and tap to confirm.
4. Tap .
5. Enter your new PIN and tap to confirm: a confirmation message with your new PIN appears.
6. Tap and then ‹ to return to the previous page.

WHAT TO DO IF YOU FORGET YOUR PIN

If...	Then...
you are a common user	contact the administrator
you are the administrator	contact your authorized service provider

USB pen drive

DESCRIPTION

A USB pen drive is available to be installed in order to automatically record all the sterilization cycle reports. The USB pen drive can be inserted equally into the front or rear port.

Notice: periodically remove the USB pen drive to save the cycle data on a computer or on another safe support.

FORMAT THE USB PEN DRIVE

1. Insert the USB pen drive in one USB port.
2. On the homepage, tap ☰ > > › > ☰ > > .
3. Tap .
4. Tap to confirm: all data will be erased.
5. Tap ‹ to confirm and return to the previous page.

Notice: formatting erases all data from the pen drive. Be sure you have already saved your data on a safe support before formatting.

Standby mode

DESCRIPTION

When in Standby mode, the sterilizer display remains dark and the sterilizer chamber is not heated to save energy. If the sterilizer is not used for three hours, it automatically switches to Standby mode.

ENTER THE STANDBY MODE MANUALLY

1. Homepage
2. Tap ⏻.

EXIT THE STANDBY MODE

Tap ⏻ or open or close the chamber door.

CHANGING STANDBY MODE DELAY TIME

1. On the homepage, tap ☰ > ⚙ > 🔌.
2. Tap ⌄ or ⌃ to change the delay time.
3. Tap ‹ to confirm and return to the previous page.

Administrator

CONTENTS

This section deals with the following subjects:

User management (optional)

FUNCTION AVAILABILITY

To access the user management functions the **User Management** activation code must be entered. The activation code is required only at the first access to the **User Management** ( ) or the **Options** ( ) menus: after the code was entered, the function is enabled and there is no need to enter the code again.
To acquire the activation code please refer to the Activation code instructions.

WHO CAN MANAGE USERS AND RESET THEIR PIN

Only a user with administrator rights can create and delete users and reset the PIN code of a user to "0000".

ADD A USER

1. On the homepage, tap > > > .
2. Tap your user name.
3. Enter the PIN and tap to confirm.
4. Tap .
5. Tap the text box: a keyboard appears.
6. Enter the new user name and tap to confirm.
7. If desired, tap to give the administrator authority to the new user.
8. Tap to confirm: the PIN of the new user is set to "0000" and a confirmation message appears.
9. Tap and then to return to the previous page.
10. Tap to return to the homepage.

DELETE A USER

1. On the homepage, tap ≡ > › > > .
2. Tap your user name.
3. Enter the PIN and tap to confirm.
4. Tap .
5. Tap the user name you want to delete.
6. Tap to confirm.

RESET A USER PIN

1. On the homepage, tap ≡ > › > > .
2. Tap your user name.
3. Enter the PIN and tap to confirm.
4. Tap and the user name for which you want to reset the PIN.
5. Tap to confirm: the PIN is set to "0000" and a confirmation message appears.
6. Tap to return to the homepage.

Note: remember the user to change its PIN before reusing the sterilizer (≡ > › > > >).

Traceability options (optional)

FUNCTION AVAILABILITY

To access the user management functions the **User Management** activation code must be entered. The activation code is required only at the first access to the **User Management** ( ) or the **Options** ( ) menus: after the code was entered, the function is enabled and there is no need to enter the code again.
To acquire the activation code please refer to the Activation code instructions.

WHO CAN SET THE TRACEABILITY OPTIONS

Only a user with administrator rights can set the traceability options.

SET THE TRACEABILITY OPTIONS

1. On the homepage, tap ≡ > › > > .
2. Tap your user name.
3. Enter your PIN and tap to confirm.
4. Tap the information to be requested to the users at the beginning and at the end of the cycle.
5. If you want the user to check the load and release it as valid at the end of the cycle, tap .
6. Tap ‹ to confirm and return to the previous page.

Hide/Unhide a cycle

WHO CAN HIDE/UNHIDE A CYCLE

Only a user with administrator rights can hide a cycle or make it available to users on the homepage.

HIDE/UNHIDE A CYCLE

1. On the homepage tap ☰ > ⚙ > › >  .
2. Tap your user name.
3. Enter your PIN and tap ✓ to confirm.
4. Tap  to hide a cycle from the homepage.
5. Tap  to unhide a cycle from the homepage.
6. Tap ‹ to confirm and return to the previous page.

Managing printers

CONTENTS

This section deals with the following subjects:

Printer selection (optional)

SELECT THE PRINTER

Note: the sterilizer only supports the specific printer models available through the manufacturer/distributor.

1. On the homepage, tap ☰ > ⚙ > › > 🖨.
2. Tap the model of the printer to use.
3. Tap ‹ to confirm and return to the previous page.

Label printer selection (optional)

FUNCTION AVAILABILITY

The first time you access the **Label Printer** (🖨) menu, you will be requested to enter an activaction code. To require the activation code, please refer to the activation code instructions provided with the label printer.

LABEL PRINTER SETUP

Labels can be printed by a local label printer or (only with a LAN connection set) a shared label printer. The local label printer is connected to the sterilizer, while the shared label printer is connected to another sterilizer in the network.

SELECT AND CALIBRATE A LOCAL LABEL PRINTER

1. On the homepage, tap ☰ > ⚙ > › > 🖨.
2. Tap 🖨: the local printer is located automatically.
3. Tap ⇥⇤ to center the printout properly in the label area.
4. Tap TEST to print a test label.
5. If the printout is not duly centered, tap ⌃ or ⌄ to center it horizontally (x) and vertically (y).
6. If necessary, tap TEST to print another test label and repeat step 4.
7. Tap ‹ to confirm the settings and return to the previous page.

SELECT A SHARED LABEL PRINTER

Note: function available only if the LAN/Wi-Fi connection has been activated (optional).

1. Ensure the sterilizer to which the printer is physically connected is ON and no cycle is running.
2. From that sterilizer, tap ☰ > i .
3. Depending on the LAN connection, take note of the Ethernet or Wi-Fi IP address.
4. Do not switch OFF the sterilizer until the whole procedure is complete.
5. From the sterilizer to which the printer is not physically connected, tap homepage > ☰ > ⚙ > › > 🖨.
6. Tap 🖨.
7. Tap the text box and enter the IP address previously noted.
8. Tap TEST to confirm.
9. From the sterilizer to which the printer is connected, confirm the printer sharing.
10. Tap TEST again to print a test label.

Label printer usage (optional)

CAUTION! For your safety and the safety of your patients use a storage time compliant with the recommendations of the manufacturers of the containters/packaging used, and with applicable norms and rules.

FUNCTION AVAILABILITY

The first time you access the **Label Printer** (🖨) menu, you will be requested to enter an activaction code. To require the activation code, please refer to the activation code instructions provided with the label printer.

AUTOMATIC PRINTING OPTION

The automatic printing option permits to automatically print a preset number of labels after a successful sterilization cycle. The labels are

printed only after the user has identified him/herself (with password if required) and the load has been checked and released, if these options have been enabled by the administrator.

For the automatic label printing, a maximum storage time in weeks can be set. This value is used to calculate the expiry date to be printed on the labels (see "Label content description" on the next page).

SET THE AUTOMATIC LABEL PRINTING

1. On the homepage, tap ☰ > › > > .
2. Activate **Automatic printing**.
3. Tap  or  to set the maximum storage time and the number of labels to be printed automatically.
4. Tap ‹ to confirm and return to the previous page.

SET THE MANUAL LABEL PRINTING

The manual printing option permits the user at the beginning of a sterilization cycle to set manually the number of labels to print.

1. On the homepage, tap ☰ > › >  >  .
2. Activate **Manual printing**.
3. Tap ‹ to confirm and return to the previous page.

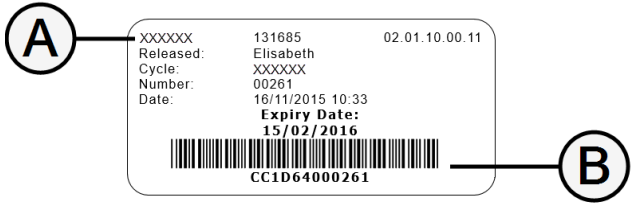
DISABLE THE LABEL PRINTING

If the label printing is disabled, no label can be printed at the end of a sterilization cycle.

1. On the homepage, tap ☰ > › >  >  .
2. Activate **Disabled**.
3. Tap ‹ to confirm and return to the previous page.

Label content description

STRUCTURE



Part	Description
A	■ Sterilizer model ■ Serial number ■ Software release
B	Traceability code (alphanumerical and bar code)
Released	Depending on the traceability settings, this field may contain one of the following elements: ■ the user who released the cycle ■ the user who started the cycle ■ the sterilizer ID
Cycle	Cycle name
Number	Cycle number
Date	Date and time of cycle start
Expiry date	■ Expiry date of the bag/package. ■ The cycle outcome if a storage time is not set.

Sterilization cycles

CONTENTS

This section deals with the following subjects:

Load maintenance and preparation

WARNINGS

WARNING! Any residual of chemicals (like cleaning and disinfection products), could affect the purity of the steam and consequently the whole sterilization process. If necessary, the load shall be cleaned and lubricated in accordance with the instrument manufacturer's instructions.

Notice: any residual of chemicals could seriously damage the sterilizer. The manufacturer's warranty is void in case of damage caused by chemicals.

CLEANING THE INSTRUMENTS

Clean all instruments thoroughly prior to sterilization. If possible, clean instruments immediately after use; always follow the instrument manufacturer 's instructions. Remove all traces of disinfectants and detergents. Rinse and dry carefully all instruments.

The instruments and tubes must be carefully rinsed and dried prior to sterilization.

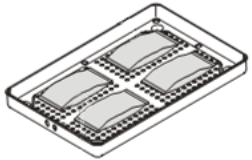
CORRECT LOAD PLACEMENT

WARNING! Do not overload trays and the chamber. Adhere to the maximum load weight limits (see "Sterilization programs" on page 83).

Wrap items with porous wrapping materials to facilitate steam penetration and drying (e.g. sterilization bags for autoclaves).

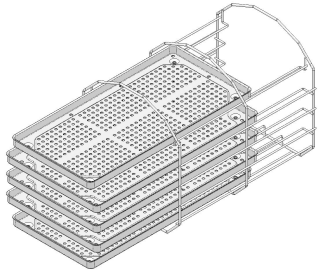
WARNING! Always use the chamber rack. Failing to use the chamber rack can damage the unit and could affect adequate steam circulation.

Follow these requirements:

Load type	Placement
Hinged instruments (e.g., forceps, extraction pliers, etc.)	In open position.
Tubes	Place tubes on a tray allowing the ends to remain open. Do not bend tubes.
Cassettes	Cassettes can be placed vertically or horizontally into the chamber rack (vertical placement enhances drying). When placing cassettes horizontally, slide them into the rack position without putting them on trays (if size allows) to enhance drying. When sterilizing double-decker cassettes, place them in the lowest rack position as there is more space height-wise.
Pouched items	On trays allowing adequate space in-between bags. Ensure that packs do not touch the walls of the chamber. Place sterilization pouched items with the paper side facing up. 
Items made from different materials (stainless steel, carbon steel, aluminium, etc.)	On separate trays or wrapped/pouched.
Instruments manufactured from carbon steel	Place paper among them and the trays to avoid rusty spots.
Chemical/biological indicator and Helix strip/s	For more information see the dedicated documentation.

PARTIAL LOAD

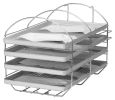
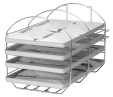
If the chamber is only partially loaded, place the load in such a way that the space in-between the trays is maximized. Spread items evenly on multiple trays. Below is an example with five trays.



Typical loads

EXAMPLES

An example of a typical load used during the tests performed by W&H is reported below:

Program	Load example
Wrapped Medium Load	
Wrapped Large Load	
Pouches & Wrapped Cassettes	
Wrapped XL Load	

Prepare the sterilizer

WARNINGS

Notice: use only distilled or demineralized water (see "Water quality" on page 95 for technical requirements). Do not add any chemical / additive to the water.

FILLING THE CLEAN WATER TANK

If no water system is connected you have to fill the tank:

1. Switch the sterilizer ON and open the chamber door.
2. Fill the clean water tank with distilled or demineralized water until the sterilizer makes a sound. See "Technical data" on page 92 for the tank volume.

INSERTING THE CHAMBER RACK INTO THE STERILIZER

CAUTION! Risk of burns. Before touching the chamber rack or contents, ensure the sterilization chamber is not hot.

1. Open the chamber door and align the chamber rack at the center/bottom of the chamber.
2. Push the chamber rack gently into position until it clicks into place.
3. Insert cassettes horizontally or vertically, or insert trays. See "Load maintenance and preparation" on page 46 for load requirements .
4. Close the door.

5 Turn the sterilizer ON: after the initialization the homepage appears.

GENERAL RECOMMENDATIONS

Follow these recommendations to obtain the most from the drying:

- Ensure the paper side of the sterilization bags faces up, and that the space in-between bags is enough.
- To enjoy the full benefit of short cycle times when only one tray is used, always place the load on the upper tray of the chamber rack and remove all other trays from the chamber.

Sterilization cycle management

RUN A STERILIZATION CYCLE

Note: if the user management and the label printer functions are enabled, you might be requested to enter your PIN code during the following procedure.

1 On the homepage, tap the desired cycle.

Tap › to display further cycles on the next page, if any.

2 Check the cycle requirements.

3 Tap ⚙ to set a different start time. See "Delay the sterilization cycle start" on the next page.

4 Tap ▶: the door locks. If you have not set a different start time, the cycle starts immediately.

5 Tap ℹ to view the cycle information. See "View the cycle parameters" on page 51.

6 The sterilization is completed. Tap 🗎 to view the cycle summary (to check the cycles values manually, see "STERILIZATION CYCLE MONITORING" on the next page) or tap ℹ to view the cycle information. See "View the cycle parameters" on page 51.

7 Tap **OPEN**: the door unlocks and the homepage appears.

8 If required, enter your credentials and confirm the load release.

Note: the load release is possible only if the cycle is completed successfully.

Note: the user visually checks that pouches are intact and dry. It is even possible to identify the user who releases the load, accepts the cycle plateau time, cycle minimum temperature and cycle minimum pressure.

Note: during the load release it is also possible to accept or reject the Helix strip, biological indicator and chemical indicator results (for more information see the dedicated documentation).

STERILIZATION CYCLE MONITORING

Even if the sterilization process is automatically monitored by the software and the values of temperature, pressure and duration are controlled, there is the possibility to check the values manually. See the table below for the correct values of the temperature, pressure, and duration in order to confirm manually the proper execution of the cycle.

US - Canada version

	270 °F (132 °C) cycles	250 °F (121 °C) cycles
Duration (minutes)	4	30
Min. temperature	270 °F (132 °C)	250 °F (121 °C)
Max. temperature	275 °F (135 °C)	255 °F (124 °C)
Min. pressure	26.68 psi at 270 °F (1.84 bar) at (132 °C)	14.9 psi at 250 °F (1.028 bar) at (121 °C)
Max. pressure	30.45 psi at 275 °F (2.1 bar) at (135 °C)	17.83 psi at 255.2 °F (1.23 bar) at (124 °C)

Standard version

	269.6 °F (132 °C) cycles	249.8 °F (121 °C) cycles
Duration (minutes)	4	30
Min. temperature	269.6 °F (132 °C)	249.8 °F (121 °C)
Max. temperature	275 °F (135 °C)	255.2 °F (124 °C)
Min. pressure	26.68 psi at 269.6 °F (1.84 bar) at (132 °C)	14.9 psi at 249.8 °F (1.028 bar) at (121 °C)
Max. pressure	30.45 psi at 275 °F (2.1 bar) at (135 °C)	17.83 psi at 255.2 °F (1.23 bar) at (124 °C)

DELAY THE STERILIZATION CYCLE START

You may schedule the start of the sterilization cycles at a certain date and time (e.g., if you want to load the sterilizer in the evening and run standard sterilization cycle early the next morning before office hours). You can set the cycle start date and time and enable or disable it for each cycle.

1. On the homepage, tap the cycle and ⚙.
2. Tap **Start cycle at**.
3. If you want to change the start time, tap the time or the date: a settings page opens.
4. Tap the number you want to change and tap ^ or v to increase it or decrease it.
5. Tap ‹ to confirm. This date and time become the scheduled default start time for all next sterilization cycles.
6. Tap ▶ to lock the door; a new page appears.

Note: if nothing else is pressed, the cycle will start at the programmed time. The page allows also to start the cycle immediately ("Start now") or to delete the operation and the programmed cycle ("Stop").

SET THE DRYING TIME

Drying time is set by default for each sterilization program. The default drying time for each sterilization program can only be increased from the default value.

1. On the homepage, tap the cycle and ⚙.
2. Tap the drying time: a settings page opens.
3. Tap ^ or v to increase the minutes or decrease them.
4. Tap ‹ to confirm and return to the previous page. If **Remember next time** is selected, this becomes the new fixed value.

Note: for the minimum value of the drying time for each cycle see Sterilization cycles.

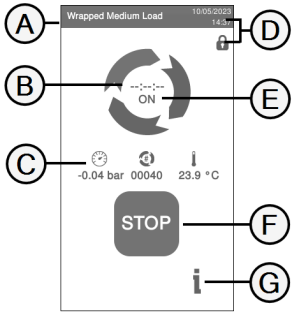
VIEW THE CYCLE PARAMETERS

You can check the real-time cycle parameters or the cycle parameters at the end of the cycle. Following is an example:

1. While the sterilization cycle is running or when cycle ends tap i : the cycle information page opens.
2. Tap ‹ or › to scroll the pages.

STERILIZATION CYCLE PAGE

Following are the information displayed while a cycle is running:



Part	Description
A	Sterilization cycle name
B	Countdown clock (time until the cycle completion)
C	: chamber pressure : cycle counter : chamber temperature
D	Date and time and door securely locked symbol
E	Current cycle phase
F	Stop button
G	Button to open the cycle information page

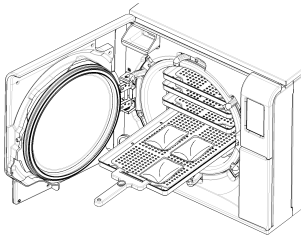
END OF A STERILIZATION CYCLE

When a cycle is successfully finished, the "Cycle completed" message appears on the screen. To end the cycle:

1. Tap to view the cycle summary or tap to view the cycle parameters. See "View the cycle parameters" on the previous page.
2. Tap **OPEN** to open the door: the door unlocks and the home page appears.

Note: if an error message appears see "Troubleshooting" on page 74

CAUTION! Hot surfaces. Burnings. Do not touch the chamber, the internal side of the door and the internal fittings. Use the tray holder or cassette holder or gloves for high temperatures or adequate protection to remove the load!



3. Open the chamber door.
4. Remove the load and stock it.

STOP A STERILIZATION CYCLE

WARNING! You can stop the cycle at any time. Instruments must not be considered sterile if this occurs before the DRY phase.

A cycle can be manually aborted at any time. To stop a cycle:

1. Tap **STOP**: a confirmation request appears.
2. Tap ✗ to abort the stop command. The cycle continues as programmed.
3. Tap ✓ to abort the cycle: the sterilizer starts a reset phase.

Notice: do not switch off the sterilizer during the reset phase: it takes some time to reset the system and reach safe conditions in the sterilizer chamber.

4. Check the message. See "Messages of a stopped sterilization cycle" below.
5. Tap i to view the cycle parameters. See "View the cycle parameters" on page 51.
6. Open the chamber door.
7. Reprocess the load if necessary.

CAUTION! Hot steam. Wait the steam to dissipate before opening the door.

Note: water could be present in the chamber when opening the door. To prevent spilling place a towel below the chamber door.

MESSAGES OF A STOPPED STERILIZATION CYCLE

The following are the messages:

- Load not sterile: Do not use items on patients!
- Drying interrupted: The load might be wet. Don't use wet items!

Unloading

WARNINGS

CAUTION! Risk of burns. Before touching, ensure the sterilization chamber is cold. Always use the tray holder.

Sterilization cycle report

WHERE CYCLE DATA ARE STORED

The sterilizer stores in its memory the summarized reports of the last 400 cycles and the analytical reports of the last 5 cycles. All reports can also be saved on the USB pen drive or in a specific remote folder in the network if the sterilizer is connected to a LAN (optional) A minimum of 10000 cycles are storable in the provided USB.

STORED REPORT FORMAT

The summarized reports are stored in HTML format and the analytical reports in SCL format. All parameters are recorded every second.

WHAT HAPPENS WITH UNSAVED CYCLES

If for any reason (e.g. USB memory full, USB pen drive disconnected, etc.) some cycles cannot be saved, no alert is shown. If still stored in memory, the unsaved cycles will be copied to a working USB pen drive connected to the sterilizer as soon as a new cycle starts.

VIEW CYCLE HISTORY

To view the sterilization cycle history:

1. On the homepage, tap ☰ > : all the sterilization cycles are listed with number, date, time and sterilization program. The interrupted sterilization cycles appear in red.
2. Scroll the list and tap the desired sterilization cycle: the report opens.

PRINT OR SAVE A CYCLE REPORT ON THE USB PEN DRIVE

1. On the homepage, tap ☰ > .
2. Scroll the list and tap the desired sterilization cycle: the report opens.
3. Tap ••• .
4. Tap to print the report, or tap to save the report on the USB pen drive.

PRINT LABELS FOR A SPECIFIC CYCLE

Note: function available only with the Label printer activation code.

1. On the homepage, tap ☰ > .
2. Scroll the list and tap the desired sterilization cycle: the report opens.
3. Tap ••• .
4. Tap to print traceability labels for the selected cycle.
5. Tap or to increase or decrease the number of label to be printed.
6. Tap to save the set number for the next time.
7. Tap to print the labels required.

SAVE ALL THE CYCLE REPORTS ON THE USB PEN DRIVE

The number of reports that can be saved on the USB pen drive depends on upon the USB capacity. To save all the cycle reports:

1. On the homepage, tap ☰ > .
2. Tap : after the confirmation all sterilization cycle reports are stored in the USB.

SET THE REMOTE FOLDER FOR SAVING THE REPORTS

To activate the remote storage and set the necessary parameters do the following:

1. On the homepage, tap ≡ > ⚙ > › > 🖥 > 🖥⚙.
2. Tap ◯✕ to enable the remote data storage: the first four fields in the page and the check box turn dark grey.
3. In **Path** enter the name of the shared folder followed by the sub-folder name, if any, where to save reports. Do not enter the full path.

Note: The folder name must include letters and numbers only. Do not use other characters like space-bar, slash, accent, etc.

4. Enter the host name or the IP address: if the data are complete, the fields highlight.
5. Not mandatory. Enter the domain name.
6. Tap ☐ to require the authentication credentials to access the remote storage folder and enter the username and password.
7. Tap ✓ to save.
8. Tap ‹ to return to the previous page.
9. To check if the parameters entered are valid, see "Test the data storage " below.

TEST THE DATA STORAGE

Note: the test function is available only if the remote data storage is enabled. See "Set the remote folder for saving the reports" above.

1. On the homepage, tap ≡ > ⚙ > › > 🖥.
2. Tap TEST: a sequence of tests is automatically performed.
3. If a test fails, check the relevant settings and tap ↻ to repeat the test sequence. If the error persists, contact your IT manager.
4. Tap ‹ to return to the previous page.

SAVE ALL THE CYCLE REPORTS IN A REMOTE FOLDER

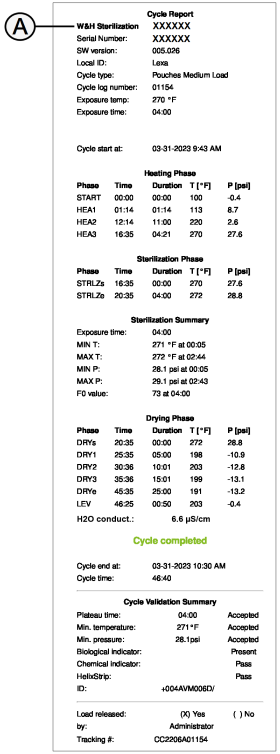
Note: the save all function is available only if the remote data storage is enabled. See "Set the remote folder for saving the reports" above.

Only the last 400 cycles in HTML and 5 cycles in SCL in the sterilizer memory can be saved in the remote folder.

1. On the homepage, tap ≡ > ⚙ > › > 🖥 > 🖥.
2. Tap ✓ to start the remote saving.

CYCLE REPORT STRUCTURE

Following the structure of a cycle report:



Cycle Report

A — W&H Sterilization XXXXXX
Serial Number: XXXXXX
SW version: 005.026
Local ID: Lexa
Cycle type: Pouches Medium Load
Cycle log number: 01154
Exposure temp: 270 °F
Exposure time: 04:00

Cycle start at: 03-31-2023 9:43 AM

Heating Phase

Phase	Time	Duration	T [°F]	P [psi]
START	00:00	00:00	100	-0.4
HEA1	01:14	01:14	113	8.7
HEA2	12:14	11:00	220	2.6
HEA3	16:35	04:21	270	27.6

Sterilization Phase

Phase	Time	Duration	T [°F]	P [psi]
STRLZs	16:35	00:00	270	27.6
STRLZe	20:35	04:00	272	28.8

Sterilization Summary

Exposure time: 04:00
MIN T: 271 °F at 00:05
MAX T: 272 °F at 02:44
MIN P: 28.1 psi at 00:05
MAX P: 29.1 psi at 02:43
F0 value: 73 at 04:00

Drying Phase

Phase	Time	Duration	T [°F]	P [psi]
DRYs	20:35	00:00	272	28.8
DRY1	25:35	05:00	198	-10.9
DRY2	30:36	10:01	203	-12.8
DRY3	35:36	15:01	199	-13.1
DRYe	45:35	25:00	191	-13.2
LEV	46:25	00:50	203	-0.4

H2O conduct.: 6.6 µS/cm

Cycle completed

Cycle end at: 03-31-2023 10:30 AM
Cycle time: 46:40

Cycle Validation Summary

Plateau time:	04:00	Accepted
Min. temperature:	271 °F	Accepted
Min. pressure:	28.1psi	Accepted
Biological indicator:		Present
Chemical indicator:		Pass
HelixStrip:		Pass
ID:	+004AVM006D/	

Load released: (X) Yes ( ) No
by: Administrator
Tracking #: CC2206A01154

Data	Description
A	Sterilizer brand and model
Serial Number	Sterilizer serial number
SW version	Software version number
Local ID	Surgery – practice – doctor name
Cycle type	Name of the executed cycle
Cycle log number	Cycle counter
Exposure temp	Programmed exposure temperature
Exposure time	Programmed exposure time
Cycle start at	Cycle start date and time
Heating Phase	Phase: conditioning phases (steam pressure pulses). See "Sterilization program phases" on page 89. ■ Time: phase duration ■ Partial: xxxxxxx ■ T [F°]: maximum temperature ■ P [psi] : maximum pressure
Sterilization phase	Phase: sterilization phase. See "Sterilization program phases" on page 89. ■ Time: phase duration ■ Partial: xxxxxxx ■ T [F°]: maximum temperature ■ P [psi] : maximum pressure

Data	Description
Sterilization Summary	Exposure time ■ MINT: Min. temperature ■ MAX T: Max. temperature ■ MIN P: Min. pressure ■ MAX P: Max. pressure ■ F0 value
Drying Phase	Phase: Exhausting drying phase. See "Sterilization program phases" on page 89 ■ Time: phase duration ■ Partial: xxxxxxx ■ T [F°]: maximum temperature ■ P [psi] : maximum pressure
H2O conductivity	Cycle water conductivity
"Cycle completed"	Cycle end conditions (Cycle outcome)
Cycle end at	Cycle end date and time
Cycle time	Cycle duration
Cycle Validation Summary	Cycle validation (you can choose to accept or reject the results): ■ Plateau time ■ Min. temperature ■ Chemical indicator ■ Biological indicator ■ Helix strip/s
Signature	Operator signature
Tracking	Tracking code for traceability

Maintenance

CONTENTS

This section deals with the following subjects:

Warnings for maintenance operations

WARNINGS

WARNING! Turn the sterilizer OFF and remove the power cord before beginning any maintenance. Follow all health, safety, cross-infection and cross-contamination protocols.
Maintenance operation shall be done at illumination level of 215 lx (±15 lx) to 1500 lx (±15 lx).
Before making any operation, ward off unauthorized personnel from the working area.

CAUTION! Before accessing the chamber and the connected parts, be sure that the sterilizer is cold.

Notice: follow the instructions in this chapter when carrying out any maintenance on the sterilizer.

User maintenance

MAINTENANCE BY THE USER

Frequency [1]	Cycles [1]	Operation
Monthly	50	Cleaning the door gasket and the chamber face side. See "Cleaning the door gasket and the chamber face side" on the next page. Clean the chamber, trays and the rack. See "Cleaning the chamber and the chamber accessories" on page 61. Cleaning the chamber filters. See "Cleaning the chamber filters" on page 62. Cleaning the external surfaces of the sterilizer. See "Cleaning the external surfaces of the sterilizer" on page 62.
Yearly [2]	1200 [2]	Replace the door gasket. See "Replacing the door gasket" on page 63. Replace the HEPA filter. See "Replacing the HEPA filter" on page 65.
5 years [3]	7000 [3]	General check and service. See "7000-cycle or five-year maintenance (not mandatory)" on page 66.

1: whichever occurs first.

2: even if the maximum cycle number is not reached, it is recommended to replace the consumable parts every year, or if they appear worn or damaged, or if the filters are clogged or discolored.

3: not mandatory.

EXPIRED MAINTENANCE

The sterilizer monitors the wear of consumables by counting the number of cycles executed since the last replacement.

When the number of cycles is close to the maximum, a pre-alert about the concerned consumable is displayed. Please check that you have the requested spare part available, buy one if not. When the maximum number of cycles has been met, a message to replace the consumable will be displayed.

1. Tap to see an animated replacement procedure.
2. When you have replaced the consumable tap to confirm: the executed cycle counter is reset.

REPLACE THE CONSUMABLE BEFORE THE MAINTENANCE DUE DATE

If you replace the consumables before the request of replacement appears, you should manually reset the counters through the following procedure.

1. On the homepage, tap >
2. Select the consumable you want to replace: a message appears showing the current worked hours of the part.
3. Tap to see an animated replacement procedure.
4. When you have replaced the consumable tap to confirm: the executed cycle counter is reset.

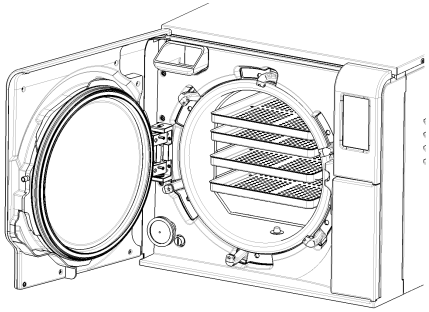
50-cycle or monthly maintenance

CLEANING THE DOOR GASKET AND THE CHAMBER FACE SIDE

Proceed as follows:

1. Clean the door gasket and the outer edge of the chamber with a non-abrasive cloth moistened with clean water.
   Notice: do not use abrasive products, cutting tools or sharp objects.
1. Rinse with clean water.

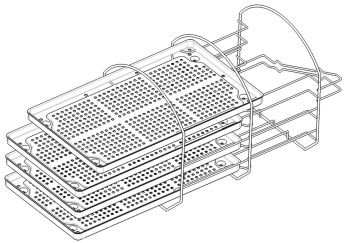
Note: when the seal is new it might be necessary to hold the door gently closed at the sterilization start.



CLEANING THE CHAMBER AND THE CHAMBER ACCESSORIES

Proceed as follows:

1. Remove the trays and the chamber rack.
2. Clean the chamber with a damp sponge and a mild detergent solution paying attention not to bend or damage the temperature probe inside the sterilizer chamber.
3. Rinse with water.
4. Clean the trays and the chamber rack with a damp sponge and a mild detergent solution.
5. Rinse with water.
6. Reposition all pieces of the chamber accessories properly.



Note: tap to see the animated cleaning procedure.

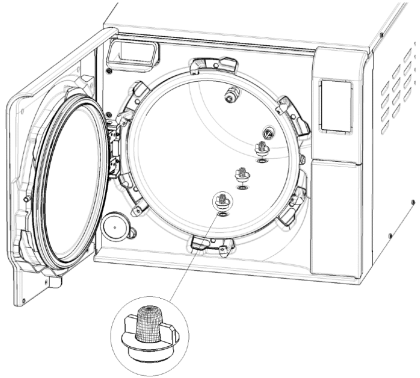
Note: the trays and the tray holder may also be cleaned in a washer disinfector.

CLEANING THE CHAMBER FILTERS

Proceed as follows:

1. Allow the sterilization chamber to cool down.
2. Empty the sterilizer chamber by removing the trays and the rack.
3. Remove the filters at the bottom of the chamber (bottom/center) by unscrewing them.
4. Rinse the filters with tap water.
5. Insert the filters in their original position, screwing them into place.

Note: tap to see the animated cleaning procedure.



CLEANING THE EXTERNAL SURFACES OF THE STERILIZER

Proceed as follows:

1. Clean all external sterilizer covers with a slightly damp cloth moistened with water. For better cleaning results, clean with W&H MC-1000 cleaning solution.
   Note: for cleaning operations, do not dilute the W&H MC-1000 cleaning solution.
   Notice: never use any other disinfectant, detergent or abrasive product, as they might result aggressive for the external covers and damage them.

1200-cycle or yearly maintenance

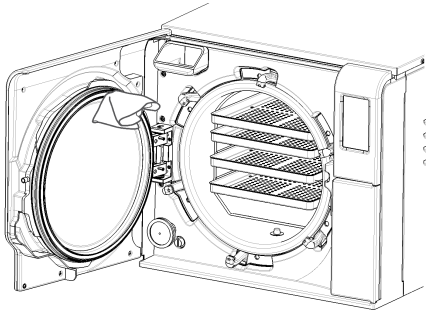
REPLACING THE DOOR GASKET

Notice: the door gasket needs to be replaced every 1200 sterilization cycles or once a year, whichever come first. A replacement message alerts when replacement is due. If the consumables is replaced prior to the message, you have to reset the consumable cycle counter.

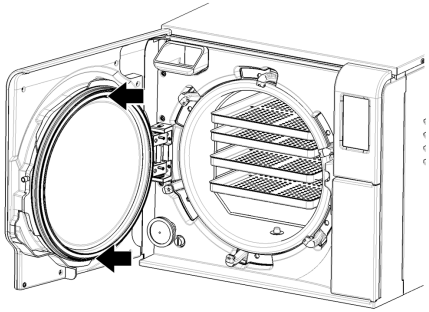
Proceed as follows:

1. Open the chamber door.
2. Remove the used door gasket by hand.
3. Carefully clean the seal seat and the inside face of the chamber door.

Note: tap to see the animated replacement procedure.

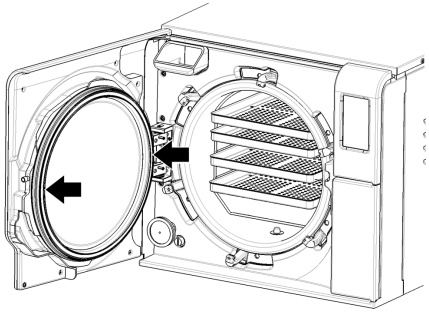


4 Insert the new seal and press first up and down.



5 Press left and right.

6 Make sure the door gasket is seated evenly.



REPLACING THE HEPA FILTER

Notice: the HEPA filter needs to be replaced every 1200 sterilization cycles or once a year, whichever come first. A replacement message alerts when replacement is due. If the consumables is replaced prior to the message, you have to reset the consumable cycle counter.

Proceed as follows:

1. Open the sterilizer door.
2. Unscrew the HEPA filter by hand (counter-clockwise).
3. Screw on the new HEPA filter (clockwise) and tighten it snug.

Note: tap to see the animated replacement procedure.

7000-cycle or five-year maintenance (not mandatory)

GENERAL CHECK AND SERVICE REQUIRED

Note: performing 7000-cycle or five-year maintenance as per the instructions below, the device can run 28.000 cycles on its product life cycle.

A general check and service should be carried out every 7000 cycles or five years by an authorized service technician. The service required includes the following:

- the replacement of consumables and other important internal components
- a check of the entire sterilizer with special care for the safety systems
- the cleaning of areas and components that cannot be accessed by the user.

ACTIONS REQUIRED FOR EACH ELEMENT

For each element, the actions to carried out are the following:

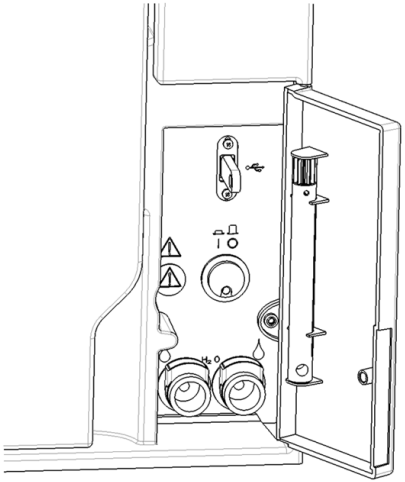
Element	Replace	Clean	Check
Sterilization chamber, door gasket and external surfaces	-	x	-
Chamber filters	-	x	-
Condenser and fan	-	x	-
Electro valves	x	-	-
Tube line filter	x	-	-
Water pump	x	-	-
Steam generator	x	-	-
Chamber integrity	-	-	x
Pneumatic connections	-	-	x
Electrical connections	-	-	x
Pressure safety valve/s	-	-	x
Safety systems	-	-	x

Extraordinary maintenance

DRAINING THE USED AND CLEAN WATER TANK

If you left accidentally the tanks full for more than seven days or if you plan not to use the sterilizer for at least seven days, you have to drain the tanks.

1. Open the sterilizer service door.
2. Put a container below the sterilizer (1.84 gal (7 l) minimum) and place the end of the drain tube in it.
3. To drain the used water, insert the drain tube connector in the grey connection.
4. To drain the clean water, insert the drain tube connector in the blue connection.
5. When the water has been completely drained, press the release button to remove the drain tube and close the service door.



Disposal

DISPOSAL RESPONSIBILITY

- Separate the various components according to the materials they are made of
- Drop the sterilizer with a company that specializes in the recycling of related products
- Do not abandon the sterilizer in unsecured places
- Always refer to current/applicable laws and rules in the country of use

The same instructions apply to disposal of all used consumable parts.

MATERIALS

The sterilizer is mainly built from fiber-reinforced polymers, metals and electric / electronic components.

Diagnostics

CONTENTS

This section deals with the following subjects:

Errors

CHECKS AND ACTIONS

Notice: for any error not listed in this table, contact technical service.

Code	Description	Actions
0xx	Load cannot be considered sterile. See "End of a sterilization cycle" on page 52.	Repeat the cycle. If the problem persists, contact technical service.
	Check if the mains switch or network circuit breaker is OFF.	
	Check if the mains cable is properly connected.	
	Switch the sterilizer OFF and ON.	
	Set date and time, then switch the sterilizer OFF and ON.	
	Ensure that the sterilizer fan is not blocked.	
10x	See error "13x to 16x" on the next page.	Repeat the cycle. If the problem persists, contact technical service.

Code	Description	Actions
12x	Wait before opening the chamber door. Allow the sterilization chamber to cool down.	Repeat the cycle. If the problem persists, contact technical service.
	Switch the sterilizer OFF and ON.	
	Clean the chamber and the chamber furniture from residuals of detergents, disinfectants and other chemicals. Replace the clean water if it is suspected to be contaminated with chemicals. Ensure all the load is clean rinsed and free from any chemicals before sterilizing.	
13x to 16x	Switch the sterilizer OFF and ON.	Repeat the cycle. If the problem persists, contact technical service.
	Clean the door gasket and the chamber face side.	
	Check if the load placed in the sterilization chamber complies with the MAXIMUM WEIGHT LIMITS.	
	Clean the chamber and the chamber furniture from residuals of detergents, disinfectants and other chemicals. Replace the clean water if it is suspected to be contaminated with chemicals. Ensure all the load is clean rinsed and free from any chemicals before sterilizing.	
18x	Chamber filters clogged. Remove and clean the chamber filters. See error "13x to 16x" above.	Repeat the cycle. If the problem persists, contact technical service.
	HEPA filter clogged. Check and replace if necessary.	
2xx	Switch the sterilizer OFF.	Repeat the cycle. If the problem persists, contact technical service.
	Wait for the chamber to cool down. Reset the safety thermostat (see "Extraordinary maintenance" on page 67).	
3xx	Check the door gasket. Clean or replace it if necessary.	Repeat the cycle. If the problem persists, contact technical service.
	Clean the chamber face side.	
	Check the load does not exceed the MAXIMUM WEIGHT LIMITS.	

Code	Description	Actions
4xx	Clean water error (bad quality, clean tank low level, high consumption of water).	Repeat the cycle. If the problem persists, contact technical service.
	Drain and/or refill the clean water tank.	
	Check the door gasket. Clean or replace it if necessary.	
5xx	Check if there are hurdles on the door locking area (chamber rack, loads, objects, …).	Repeat the cycle. If the problem persists, contact technical service.
	Check the door gasket (wrong placed).	
	Check if the door can move freely without touching the trays or the load when closing.	
	Switch the sterilizer OFF and ON.	
990	The cycle has been aborted by the user.	Re-process the load.

MESSAGES AND ALERTS

Notice: for any message/alert not listed in this table, contact technical service.

Note: this section describes messages and alerts. Please note that the availability of them depends on the device model and some of them might not be available for this model.

Message/Alert	Description	Action
Fill clean water tank.	There is not enough water in the tank to perform a cycle.	Fill the water tank as requested.
Drain used water tank.	The used water tank is full.	Drain the water tank as requested.
Please close the door.	The door must be locked, but you didn't close it.	Close the door so it can be locked.
Non-conform water	The clean water quality is bad (conductivity between 15 and 50 µS/cm).	You may run a cycle but the water must be replaced soon, otherwise the unit will automatically lock-out to prevent damage.
Poor water quality detected. Replace with higher quality water, or equipment damage may occur.	The clean water quality is very bad (conductivity more than 50 µS/cm).	Running a cycle is inhibited to prevent damage. Replace the clean water.
Door Gasket must be replaced in ... cycles. **Do you want to replace it now?**	These are pre-alerts advising that one of the consumables has to be replaced within a small number of cycles.	Tap ✔ if you have the consumable available for replacement. Tap ✘ if you do not have the consumable in stock and must order one. In this case, the pre-alert will appear again after some cycles. See "Maintenance" on page 58.
HEPA Filter must be replaced in ... cycles. **Do you want to replace it now?**		

Message/Alert	Description	Action
Door Gasket replacement is due. **Do you want to replace it now?**	These messages advise that one consumable must be replaced.	Replace the consumable and tap ✔ to reset the counter (See "Maintenance" on page 58). If you do not replace the consumable, tap ✘. In this case, you may still use the sterilizer but the message will appear again after some cycles. ⚠ **CAUTION!** Operating the sterilizer with expired consumables could be dangerous and could damage the sterilizer.
Have you replaced the door gasket? **Press YES to reset the counter.**		
Have you replaced the HEPA filter? **Press YES to reset the counter.**		
HEPA Filter replacement is due. **Do you want to replace it now?**		
Possible leak detected. **Please run Vacuum Test.**	Air was detected in the chamber: a vacuum leak is suspected. The cycle was completed but a vacuum test is required.	Run a vacuum test. Call for service if an anomaly is detected.
Please check: **- Not to overload the sterilizer** **- The door gasket** **If the problem persists contact the service.**	This message advises you that the pressure inside the chamber did not drop as expected in the first 30 seconds of drying phase.	Check the door gasket correct positioning and make sure do not overload the sterilizer chamber. If the problem persists, contact technical service.

Troubleshooting

MANAGING ERRORS

If during a sterilization cycle an error occurs do the following:

1. Wait until the **OPEN** button appears.
2. At the end of the reset phase, you may open the door. A pop appears requiring a confirmation.
3. Tap to open the door.

CAUTION! Do not switch off the sterilizer during the reset phase: it takes some minutes to reset the system and reach safe conditions in the sterilizer chamber.

Notice: water could be present in the chamber when opening the door: prevent spilling (e.g., place a towel below the chamber door).

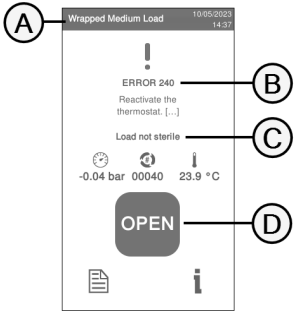
VIEW AND SAVE THE ERROR LOG

1. On the homepage, tap > > : a list of the recent errors appears.
2. Tap to save the list in the USB pen drive.

ERROR PAGE

During the sterilization cycle, the sterilizer is continuously monitored by a control system. If an anomaly is detected, the cycle is aborted automatically, and the sterilizer starts a reset phase.

The following page appears:



Part	Description
A	Current sterilization cycle
B	Error number, See "Errors" on page 69.
C	Warning messages.
D	Open button that appears after the reset phase had finished.

WARNING MESSAGES

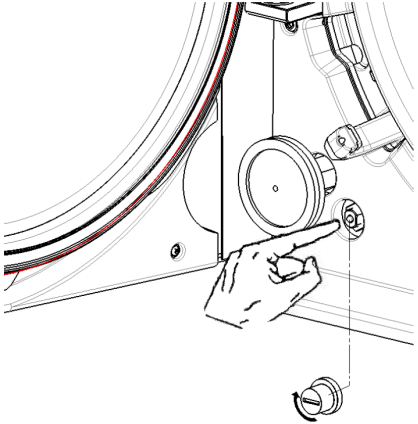
Message	Description
Load not sterile	The load is not sterile.  **WARNING! Do not use items on patients!**
Drying interrupted	The load might be wet.  **WARNING! Don't use wet items!**

RESET THE SAFETY THERMOSTAT

The sterilizer is fitted with a safety thermostat to prevent it from overheating. If the safety thermostat operates because of too high temperatures, the error 240 or a timeout error is displayed. The thermostat must be reset manually. Proceed as follows:

1. Switch the sterilizer OFF and remove the mains cable.
2. Wait for the sterilizer to cool down.
3. Open the sterilizer door.
4. Unscrew the cap and push on the reset button of the thermostat switch; a click sound indicates that the thermostat switch has been reset.
5. Screw the cap.
6. Connect the mains cable and switch the sterilizer ON.

   Note: if the thermostat operates repeatedly, contact technical service.
7. Wait for the sterilizer to finish the error reset phase and follow the instructions on the display.



TROUBLESHOOTING TABLE

Note: if your problem is not resolved, call your authorized service provider.

Notice: before sending the sterilizer for technical service, remove the mains cable, empty both water tanks and use the original or appropriate packaging.

Problem	Possible cause	Solutions
The sterilizer remains switched OFF.	The mains switch or network circuit breaker is OFF.	Activate the mains switch or network circuit breaker (ON).
	No voltage at the socket.	Check the electric circuit.
	The power cord is not connected properly.	Check and connect the power cord properly.
Water is leaking at the front of the sterilizer.	Leaks through the chamber door gasket.	Clean or replace the door gasket. Clean the chamber face side.
	Internal leak.	Contact technical service.
The cycle commences but there is no pressure/temperature rise.	The safety thermostat switch is open.	Reset the safety thermostat switch. See "Extraordinary maintenance" on page 67.
	Electric - electronic fault.	Contact technical service.
At the end of the cycle, there is residual water in the chamber.	Sterilizer not properly leveled.	Properly level the surface the sterilizer is placed on.
	Overloaded chamber.	Comply with the maximum load weight limits for each type of load. Always use the chamber rack for trays and cassettes. See "Load maintenance and preparation" on page 46.
	Chamber filters clogged.	Remove and clean the chamber filters.
	One or more chamber filter caps not well-positioned.	Mount the chamber filter caps properly (see "User maintenance" on page 59).
	Load incorrectly placed.	See "Load maintenance and preparation" on page 46.

Problem	Possible cause	Solutions
Corrosion or spots on instruments.	Tap water on instruments when placed in the sterilizer.	Ensure that instruments are dry before they are placed in the sterilizer.
	Use of water of poor quality or water containing chemical substances.	Drain both water tanks. Use water of good quality. See "Water quality" on page 95.
	Organic or chemical residues on the instruments.	Clean, rinse and dry instruments before placing them in the sterilizer. See "Load maintenance and preparation" on page 46.
	Chamber, trays, chamber rack dirty.	Clean the chamber and wash the chamber furniture.
	Contact between instruments of different materials.	Ensure that instruments of different materials do not touch (aluminium, carbon or stainless steel, etc.); place them on different trays or cassettes or pouch them. See "Load maintenance and preparation" on page 46.
	Scale deposits on the chamber.	Clean the chamber and use water of good quality. See "Water quality" on page 95.
Instruments are turning brown or black.	Incorrect temperature selected.	Select a sterilization cycle featuring a lower sterilization temperature. Follow the instructions of the instrument manufacturer.
The cycle report printer does not work.	Printer not properly connected or not powered on.	Check the data and the power connection to the printer.
No cycles are stored in the cycle history menu.	An electronic board was replaced by service.	None. The memory of the old board cannot be restored. Save periodically the history on the USB pen drive and on another safe support.
When starting a cycle, the chamber door locks but re-opens immediately. The “Open the door” message appears.	Door gasket not properly placed; seal sticking out.	Ensure that the door gasket is evenly inserted on the entire circumference.
	Door jammed by external objects or by the load itself.	Remove any objects interfering with the chamber door. Check the door does not force against the load or the chamber furniture.

Problem	Possible cause	Solutions
When the sterilizer is connected to an automated water supply system: there is no clean water in the tank, but the automatic water filling does not fill the water.	Water fill system not connected.	Connect the water fill system to the sterilizer. See "Water quality" on page 95.
	When the water fill system attempted to fill the tank, water was temporarily unavailable.	Since water tank filling is attempted only once in-between cycle execution, this event inhibits water feeding. Switch the sterilizer OFF and then ON again. Check the external water supply system. Check for water leaks from the sterilizer.
	Faulty MIN water level sensor in the clean water tank.	Contact service.
The sterilizer enters the standby mode immediately after opening the chamber door.	The chamber door has not been opened after the previous cycle had finished and the standby mode delay has expired.	Press the standby button to exit.
At the end of the cycle the display reads “Open the door” but opening the door is impossible.	The HEPA filter is clogged.	See ““Emergency door opening" on the next page”. Contact technical service if the problem persists. Remove the HEPA filter to get the pressure released. Replace the filter. **Note**: The HEPA filters need to be replaced every 1200 cycles.
The sterilization process phase of a sterilization cycle was longer than expected.	The chamber temperature dropped below the minimum threshold and the software performed a successful recovery.	Wait for cycle completion. If the problem occurs frequently, contact technical service.
Warning about USB saving (HTML and SCL files).	The USB pen drive is not connected or not properly connected to the sterilizer.	Check presence and connection of the USB pen drive. If the problem persist, contact service.
Warning about programmed maintenance.	A component shall be replaced for the programmed maintenance of the sterilizer.	Contact service to order the requested component (door gasket, HEPA filter…). See "User maintenance" on page 59

Emergency door opening

WARNING ABOUT OPENING THE DOOR IN EMERGENCY

WARNING! High pressure. Risk of explosion, jet of hot steam, sudden opening of the door. Carry out the following procedure only if necessary and only when NO RESIDUAL PRESSURE IS IN THE CHAMBER. Any attempt to open the door while the unit is still hot or under pressure could expose the operator and the surrounding personnel to serious risk.

CAUTION! High temperature. Risk of burns. Carry out the following procedure only when the sterilizer has completely cooled down. The sterilizer should be unplugged from the mains power supply for at least 3 hours before executing this procedure.

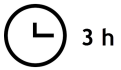
Notice: carry out this procedure only as indicated and with the sterilizer in the indicated conditions. Any attempt to open the door in a different way can seriously damage the sterilizer.

OPENING TOOL

The door locking system is electrically activated. In case the door remains locked due to a black-out or an electric fault, an auxiliary unlocking procedure is available.

OPEN THE DOOR IN EMERGENCY

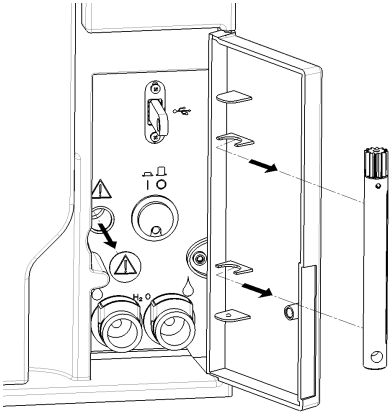
1. Switch off the sterilizer and wait at least three hours until the pressure has naturally decreased to the environment pressure.



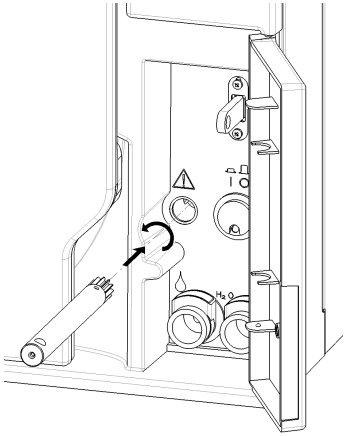
2. Unplug the mains cable (back side).

3 Extract the opening tool placed behind the service door.

4 Remove the cap.



5 Insert the opening tool into the hole and then turn it counterclockwise until the door is unlocked (proceed slowly until it stops).



Technical data

CONTENTS

This section deals with the following subjects:

Sterilization programs

WARNINGS

WARNING! For your safety and for the safety of your patients:
Never process objects different from those specified in the cycle program table and never exceed the maximum load weight limits specified in it. Such actions could result in non-sterile conditions at the end of the cycle, could expose people to the hazard of cross-infections, are considered as an improper use of the sterilizer for which the manufacturer cannot be hold responsible.
An improper use of these profiles will result in wet load at the end of the cycle, exposing the load to a contamination due to improper storage.
The display reminds the maximum permitted load before starting a cycle. All indications of sterile load or successful completion of the cycle that are given on the display at the end of the cycle are not valid if the type and quantity of the load are not complied with.

STANDARD STERILIZATION PROGRAMS

The sterilizer offers five preset FDA cleared sterilization programs that comply with the American National Standard ANSI/AAMI ST55.

Program	Ref. intended use	Recommended use	Sterilization Temperature	Load example [1]
Wrapped Medium Load	**Pouches Medium Load**	Instruments and dental handpieces, up to 3 lbs (1.4 kg). Pouches, wrapped, unwrapped and naked.	270 °F (132 °C)	40 pouched instruments (probes, explorers, mirrors, etc.), 4 pouched dental handpieces.
Wrapped Large Load	**Pouches Large Load**	Instruments and dental handpieces, up to 6 lbs (2.7 kg). Pouches, wrapped, unwrapped and naked.	270 °F (132 °C)	80 pouched instruments (probes, explorers, mirrors, etc.), 8 pouched dental handpieces.
Wrapped XL Load	**Wrapped Cassettes**	Instruments and dental handpieces, up to 14 lbs (6.3 kg). Pouches, wrapped, unwrapped and naked.	270 °F (132 °C)	4 wrapped Hygiene cassettes (8" x 5.5" | 20.3 mm x 13.8 mm), 2 wrapped Restorative cassettes (8" x 11" | 20.3 mm x 27.9 mm), 4 wrapped Exam cassettes (8" x 3" | 20.3 mm x 7.6 mm)
Low Temperature	**Low Temperature**	Textiles, up to 4.4 lbs (2 kg), or instruments and dental handpieces requiring low temperature, up to 5 lbs (2.3 kg). Pouches, wrapped, unwrapped and naked.	250 °F (121 °C)	65 pouched instruments (probes, explorers, mirrors, etc.), 6 pouched dental handpieces.
Unwrapped	**Unwrapped**	Instruments and dental handpieces, up to 18 lbs (8.1 kg). Unwrapped, naked. The instruments sterilized with this cycle cannot be stored: they must be used immediately after being sterilized.	270 °F (132 °C)	80 unwrapped instruments (probes, explorers, mirrors, etc.), 8 unwrapped dental handpieces.

1: mixture of instruments and/or packages within each program may vary. Not to exceed maximum load weight.

CUSTOM STERILIZATION PROGRAMS

WARNING! The custom programs are not FDA cleared and it is the responsibility of the user to validate these programs.

The sterilizer provides the following custom programs. These programs are disabled by default.

Program	Sterilization Temperature	Sterilization Time (settable)	Drying time (settable)
Custom A [1]	250 °F (121 °C)	15–60 minutes	30–60 minutes
Custom B [1]	270 °F (132 °C)	4–30 minutes	3–60 minutes
Custom C [1]	273 °F (134 °C)	3–30 minutes	3–60 minutes

[1]: these are profiles defined by ANSI/AAMI ST55 as dynamic-air-removal (steam-flush pressure-pulse). These profiles can be enabled by the user. Some of the parameters can be adjusted by the user according to his needs (Plateau/Sterilization phase, dry time, etc.). These cycles are not FDA cleared.

STERILIZATION PROGRAM OPTIONS (200–240 V AC VERSION)

WARNING! The sterility of items processed unwrapped is compromised on exposure to non-sterile environments. Ensure that items are dry when removed from the sterilizer. If the default drying time is not adequate for the load to be sterilized, additional drying time can be added (see "Sterilization cycle management" on page 49). To load properly the sterilizer see "Prepare the sterilizer" on page 48.

		Unwrapped	Wrapped Medium Load	Wrapped Large Load	Wrapped XL Load	Low Temperature
Sterilization temperature		270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	250 °F (121 °C)
Sterilization program type according ANSI/AAMI ST55		Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Gravity displacement
Sterilization program type according EN 13060		Class S	Class S	Class S	Class S	Class S
Sterilization time (minutes)		4'	4'	4'	4'	30'
Drying time (minutes)		Range: 8–99' Recommended: 8'	Range: 25–99' Recommended: 25'	Range: 30–99' Recommended: 30'	Range: 40–99' Recommended: 40'	Range: 30–99' Recommended: 30'
Total program duration (min) [1] *Full loaded including drying time*		26–30'	43–46'	48–52'	58–63'	73–76'
Load type	**Pouched, wrapped instruments and dental handpieces**	No	Yes	Yes	Yes	Yes
	Unwrapped instruments and dental handpieces	Yes	Yes	Yes	Yes	Yes

		Unwrapped	Wrapped Medium Load	Wrapped Large Load	Wrapped XL Load	Low Temperature
	Textiles	No	No	No	No	Yes
Maximum load weight (excluding trays)		instruments: 18 lb (8.1 kg)	instruments: 3 lb (1.4 kg)	instruments: 6 lb (2.7 kg)	instruments: 14 lb (6.3 kg) included cassettes	instruments: 5 lb (2.2 kg) included trays or textile: 4.4 lb (2 kg)

1: The total cycle time may vary depending on the type of load (solid or porous), the load weight, and other factors.

STERILIZATION PROGRAM OPTIONS (100–125 V AC VERSION)

WARNING! The sterility of items processed unwrapped is compromised on exposure to non-sterile environments. Ensure that items are dry when removed from the sterilizer. If the default drying time is not adequate for the load to be sterilized, additional drying time can be added (see "Sterilization cycle management" on page 49). To load properly the sterilizer see "Prepare the sterilizer" on page 48.

	Unwrapped	Wrapped Medium Load	Wrapped Large Load	Wrapped XL Load	Low Temperature
Sterilization temperature	270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	250 °F (121 °C)
Sterilization program type according ANSI/AAMI ST55	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Gravity displacement
Sterilization program type according EN 13060	Class S	Class S	Class S	Class S	Class S
Sterilization time (minutes)	4'	4'	4'	4'	30'
Drying time (minutes)	Range: 8-99' Recommended: 8'	Range: 25–99' Recommended: 25'	Range: 30–99' Recommended: 30'	Range: 40–99' Recommended: 40'	Range: 30–99' Recommended: 30'

		Unwrapped	Wrapped Medium Load	Wrapped Large Load	Wrapped XL Load	Low Temperature
Total program duration (min) [1] *Full loaded including drying time*		30–39'	47–53'	52–58'	62–71'	75–79'
Load type	**Pouched, wrapped instruments and dental handpieces**	No	Yes	Yes	Yes	Yes
	Unwrapped instruments and dental handpieces	Yes	Yes	Yes	Yes	Yes
	Unwrapped cassettes	Yes	Yes	Yes	Yes	Yes
	Textiles	No	No	No	No	Yes
Maximum load weight (excluding trays)		instruments: 18 lb (8.1 kg)	instruments: 3 lb (1.4 kg)	instruments: 6 lb (2.7 kg)	instruments: 14 lb (6.3 kg) included cassettes	instruments: 5 lb (2.2 kg) included trays or textile: 4.4 lb (2 kg)

1: the total cycle time may vary depending on the type of load (solid or porous), the load weight, and other factors.

Sterilization program phases

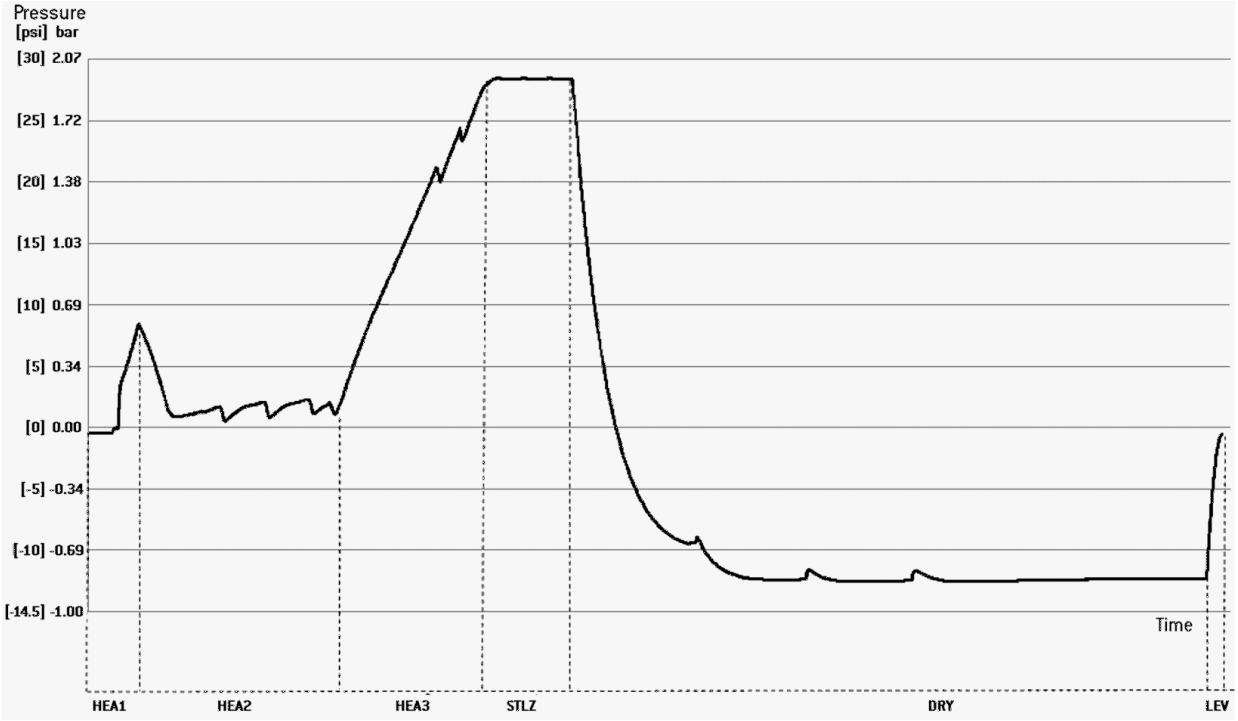
LEGEND OF THE STERILIZATION PROGRAM PHASES

Following is the description of the sterilization phases.

Code	Phase	Description
PHE	**Pre-heating phase**	Pre-heating of the sterilizer steam generator and chamber. This phase is not considered a part of the cycle.
HEA1 **HEA2**	**Heating phase (steam pressure pulses)**	Initial heating phase to remove the air from the sterilization chamber. Air is removed using pressure pulses followed by discharge phases. The iteration of these phases reduce the percentage of air inside the chamber and determinates the correct sterilization conditions.
HEA3	**Pressure rise**	Heating phase to achieve the sterilization conditions (pressure and temperature) for the selected cycle.
STLZ	**Sterilization phase**	Sterilization condition (pressure and temperature) maintained for the time specified for the selected cycle. During this phase the unit controls the theoretical temperature (pressure converted in temperature, because of physical behaviour of water) and the steam temperature inside the chamber. The value must be between the sterilization temperature band, and the difference between them must be lower than 3.6 °F (2 °C). If the temperature drops below the sterilization temperature band a restart process procedure is automatically executed by the sterilizer (according to ST55). The sterilizer controls the sterilization condition through steam generation. The steam generation is controlled by a PID, that modulates the electrical power using as feedback the instant average between theoretical and internal temperature.
DRY	**Exhausting drying phase**	The objective of this phase is to dry the load placed in the sterilizer chamber. The drying phase is divided in two step: ■ The first step is the depressurization phase, when most of the steam is removed from the chamber. The second step is the drying of the load. ■ Duration of the DRY phase depends on the selected profile.
LEV	**Levelling phase**	Pressure inside the sterilization chamber is leveled to the atmospheric pressure.

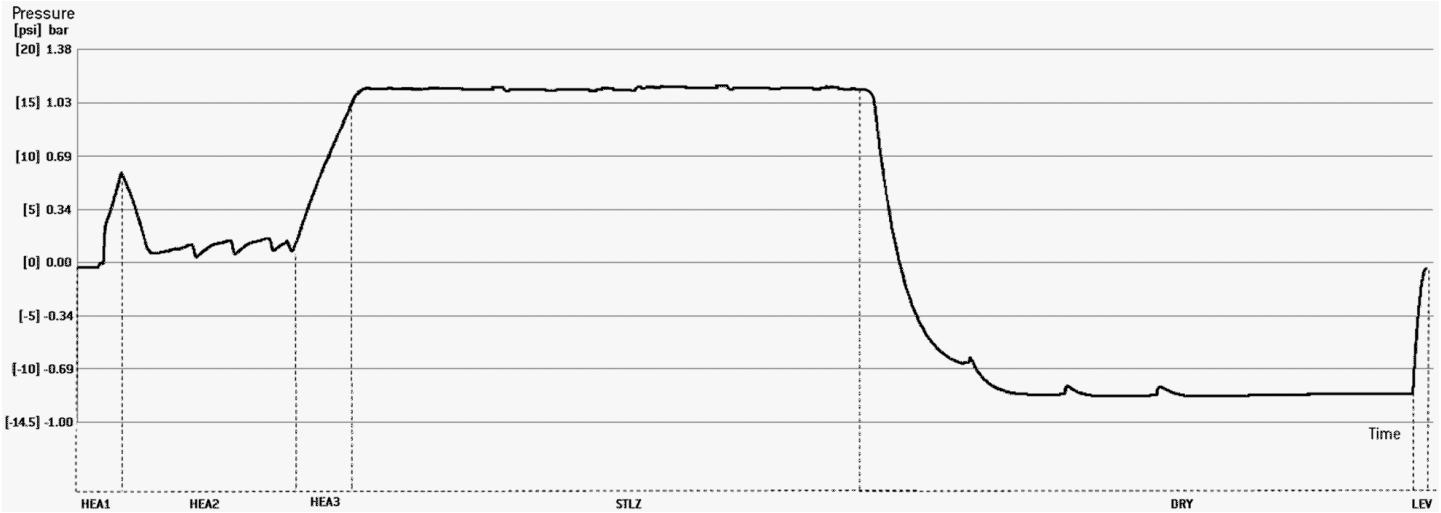
HIGH TEMPERATURE PRESSURE PROFILE

All programs with the sterilization phase at 270 °F (132 °C) feature the same basic pressure profile. The duration of the drying phase differ between the various programs.



LOW TEMPERATURE PRESSURE PROFILE

Low Temperature sterilization program features the following pressure profile 250°F (121 °C).



Technical data

WATER SUPPLY SYSTEM

Temperature	max. 95 °F (35 °C)
Pressure	min. 29 psi - max. 124.7 psi (min. 2 bar – max. 8.6 bar)
Flow	min. 0.066 - max. 0.132 gal/min (min. 0.25 – max. 0.5 l/min)

POWER SUPPLY SYSTEM

Nominal voltage and Max. current	200–240 V ac (±10%), 50/60 Hz, 10 A, single-phase 100–125 V ac (±10%), 50/60 Hz, 12 A, single-phase
Overvoltage category	II
Protection required	Suitable circuit breaker and a Ground Fault Circuit Interrupter (GFCI). All protection devices must be certified according to applicable standard. A grounded connection is essential.
Communication with other devices	2 USB ports - 1 LAN port (optional)
Features	Fully micro-processor controlled, process evaluation system according to EN13060. Programmable standby mode.
Max. heat output	3000 kJ/h

INSTALLATION REQUIREMENTS

Working temperature	From +41 °F to +104 °F (from +5 °C to +40 °C)
Working relative humidity	Max. RH 80% up to 88 °F (31 °C), linearly decreasing to 50% at 104 °F (40 °C)
Storage temperature / rel. humidity	From -4 °F to +140 °F (from -20 °C to +60 °C) / 0–90 % (with empty tanks)
Max altitude	9843 ft asl (3000 m)
Min. atmospheric pressure	8.7 psi (0.6 bar)
Overall dimensions	W: 19.3"/H: 17.9"/D: 24.2" (W: 49 cm/H: 46 cm/D: 62 cm)
Min. space required (feet in forward position)	W: 22.5"/H: 18.9"/D: 20.1" (W: 57 cm/H: 48 cm/D: 51 cm)
Size of the door movement	W: 21.5"/H: 16.4"/D: 15.6" (W: 55 cm/H: 42 cm/D: 38 cm)
Weight empty	105.8 lbs (48 kg)
Max. weight (fully loaded)	155 lbs (70.3 kg)
Weight per support area	41.5 kN/m2
Environment pollution	Degree 2
Usage environment	Indoor

STERILIZER CHAMBER

Pressure safety valve	37.7 psi (2.6 bar)
Safety thermostats	356 °F (180 °C)
Total volume	~7.4 gal, Ø: 11"/D: 18" (~28 l, Ø: 279.5 mm/D: 456.8 mm)
Usable space *	W: 9.05"/H: 9.05"/D: 15.35" (W: 230 mm/H: 230 mm/D: 390 mm)
HEPA filter	0.3 µm

STEAM GENERATOR

Pressure safety valve	72.51 psi (5 bar)
Safety thermostats	446 °F (230 °C)

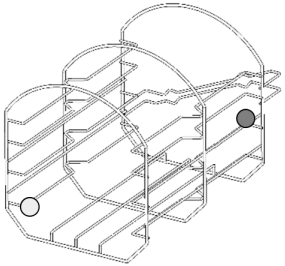
DISTILLED OR DEMINERALIZED WATER

Water quality	See the Test Instructions service book (conductivity : < 10µS/cm, Total Dissolved Solids: < 6.5 ppm)
Average water consumption	0.17 to 0.2 gal/cycle (0.65 to 0.75 litres/cycle)
Tank volume	Clean water 1.7 gal (6.4 l) Min. water charge (clean water): 0.29 gal (1.1 l) Used water 1.77 gal (6.7 l)

*: usable space with standard rack and trays. With optional racks and trays, see Accessories, spare parts, consumables.

Recommendations for validation

TEST VALIDATION POINTS

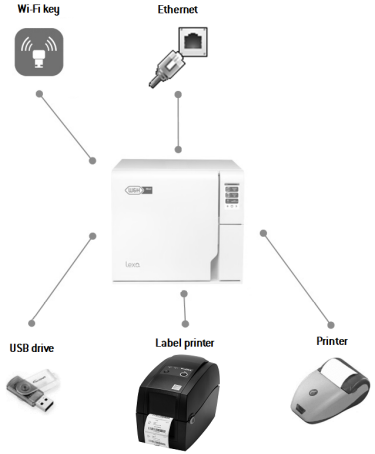


Part	Description
	Hottest points
	Coldest points

Diagrams

CONNECTION DIAGRAMS

Data communication



Water system

(*): for water requirements see "Water quality" on the next page.

Water quality

FEED WATER SPECIFICATIONS (ANSI/AAMI AND AAMI TIR34)

The table below lists the specifications for the water used for steam sterilization according ANSI/AAMI ST55 and AAMI TIR34. Following is the Table 1 AAMI TIR34.

	Units	Utility water [1] flushing/ washing/ rinsing	Critical water finale rinse[2] /steam
Hardness	mg/L	< 150[3]	< 1
Conductivity	µS/cm	< 500	< 10
Total Dissolved Solids	ppm	< 350	< 6.5
pH[4]		6 – 9	5 – 7
Chlorides	mg/L	< 250	< 1
Bacteria	cfu/mL	n/a, <10[5]	< 10
Endotoxin	EU/mL	n/a, <20[5]	< 10

Note 1: this is the quality of water that might come from the tap but might need some form of treatment to achieve these specifications.

Note 2: if this is the final rinse prior to sterilization of a critical device.

Note 3: if hardness is greater than 150 mg/L, a water softener is recommended unless used for washing and the cleaning chemistry is capable of handling higher levels of hardness.

Note 4: for boiler-treated steam, most boilers are treated to maintain a pH of 7.5 or 8.5. Any treatment of water that goes into boilers should be in accordance with the sterilizer and boiler manufacturers' written IFU.

Note 5: after high-level disinfection.

Notice:

The use of water with a conductivity greater than 10µS/cm (6.5 ppm) may affect the sterilization process and damage the sterilizer.

The use of water with a conductivity greater than 50µS/cm, or not complying with the specifications in the table above, may strongly affect the sterilization process and seriously damage the sterilizer.

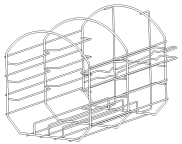
The manufacturer's warranty is void if the sterilizer was used with water containing contaminant or chemical levels exceeding those listed in the table above.

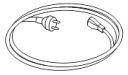
Accessories, spare parts, consumables

Note: use only accessories, spare parts and consumables recommended by W&H.

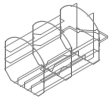
Note: before purchasing, check that the accessories fulfill all applicable standards in the country of use.

LIST OF PARTS PROVIDED WITH THE STERILIZER

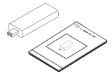
Picture	Part	Part number
	**Standard chamber rack**	F523030X
	**Large aluminium tray** 8.5" x 0.77" x 14.9" (215 x 19.5 x 379 mm)	F523211X
	**Tray holder**	F523001X
	**Emergency door opening tool**	S520009X

Picture	Part	Part number
	**Drain tube**	S230903X
	**Mains cable (125 V)** **Mains cable (250 V)**	U380119X U380120X
	**USB pen drive**	V000004X

LIST OF ACCESSORIES AND SPARE PARTS

Picture	Part		Part number
	**Optional chamber rack for 3 trays / 3 taller cassettes or 4 standard cassettes** Usable space - Tray / Cassette size: ■ 8.5" x 2" x 15" (215 x 50 x 380 mm) ■ 8.5" x 2" x 15" (215 x 50 x 380 mm) ■ 8.5" x 2" x 15" (215 x 50 x 380 mm)		F523036X
	Optional chamber rack for 1 cassette Usable space - Tray / Cassette size: ■ 6.7" x 7.1" x 15" (170 x 180 x 380 mm)		
	**Drain tube kit with fittings**		A812110X
	**Network data cable RJ45 (3 m)**		A801500X
	**USB hub (4 ports)**		19721129
	**Report printer**		19721141

Picture	Part	Part number
	**USB-serial converter**	A801503X
	**Label printer (label printer only)**	19721109
	**Label printer USB connection kit** ■ USB connection cable ■ 1 roll of 2100 labels ■ 1 wax/resin ribbon ■ activation code instructions	19721131
	**Roll of thermal paper**	A810504X
	**Label printer consumable kit** ■ 2 rolls of 2100 labels ■ 2 wax/resin ribbons	A810513X
	**QR code / Bar code reader for labels**	19721132
	**Multidem C27 water demineralizer**	19723112
	**Multidem resin cartridge**	A812016X

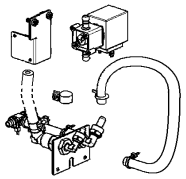
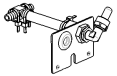
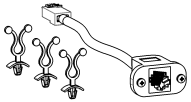
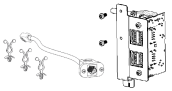
Picture	Part	Part number
	**Osmo water demineralizer (220 V)** **Osmo water demineralizer (110 V)**	19721134 19721135
	**Wi-Fi dongle key**	19721137
	**Lifting strap**	F602001X

CONSUMABLES

Picture	Part	Part number	When replace it
	**HEPA filter (bagged)**	W322400X	Every 1200 cycles
	**Door gasket**	F460535X	Every 1200 cycles
	**Maintenance kit** Components: ■ 1 HEPA filter ■ 1 door gasket ■ Chamber filter (set of 3 pieces)	X050334X	-

OPTIONAL KITS

Notice: the kits must be installed by service technicians authorized by the manufacturer.

Picture	Part	Part number
	**Auto-fill kit with valve**	X051302X
	**Auto-fill kit with pump (110 V)** **Auto-fill kit with pump (220 V)**	X051303X X051304X
	**Auto-drain kit**	X051331X
	**LAN cable kit**	X051301X
	**USB-Ethernet socket hub assembly**	X051337X

Activation code	Description	Part number
Traceability	Activates the **User Management** and **Options** menus.	19730072

Authorized W&H service partners

A list and a map with your nearest W&H service partner are available at med.wh.com.

Documentation forms

CONTENTS

This section deals with the following subjects:

W&H installation check-list

QUESTIONS

N.	Question	Answer	
	Responsibility		
1	Was the head of the clinic/practice present during all the in-service?	Yes	No
	Packaging and content		
2	Is the packaging of the sterilizer undamaged?	Yes	No
3	When unpacked, is the sterilizer undamaged?	Yes	No
4	Are all the contents of the package available (sterilizer ship-with)?	Yes	No
5	Are all the ordered accessories available with the sterilizer?	Yes	No
6	Have you removed all the protection covers from the sterilizer and from all the ship-with?	Yes	No
	Completeness of the Instructions for Use		
7	Were all sections of the Instructions for Use of the sterilizer covered and explained during the in-service?	Yes	No
	Workplace suitability		
8	Is the allocated countertop for the sterilizer levelled and flat?	Yes	No
9	Are the recommended ventilation indications of the allocated area for the sterilizer respected?	Yes	No
10	Are the required minimum clearances respected?	Yes	No
11	Have you explained which water quality is required for the use of the sterilizer? Check and measure the µS/cm of the water.	Yes	No
	Involvement of the Head/personnel of the clinic/pratice		
12	Have you shown to the Head/personnel of the clinic/practice the procedure for filling and draining the main and used water tanks?	Yes	No
13	Have you shown to the Head/personnel of the clinic/practice how to program the sterilizer?	Yes	No
14	Have you shown to the Head/personnel of the clinic/practice the cycle options?	Yes	No
15	Have you shown to the Head/personnel of the clinic/practice what the messages and alarms mean?	Yes	No

N.	Question	Answer	
16	Have you shown to the Head/personnel of the clinic/practice how to manually abort a cycle?	Yes	No
17	Have you shown to the Head/personnel of the clinic/practice the maintenance program and procedures?	Yes	No
18	Have you shown to the Head/personnel of the clinic/practice how to use all of the accessories?	Yes	No
19	Have you shown to the Head/personnel of the clinic/practice the advantages of having a USB connection for a pen drive?	Yes	No
20	Have you suggested to the Head/personnel of the clinic/practice to periodically backup the data, stored on the USB pen drive and/or in a PC, on another safe support?	Yes	No
21	Have you shown to the Head/personnel of the clinic/practice the advantages of having a Ethernet connection (remote data saving)?	Yes	No
22	Have you explained to the Head/personnel of the clinic/practice the correct load type for each available sterilization program?	Yes	No
23	Have you shown to the Head/personnel of the clinic/practice how to prepare and place the load in the sterilizer chamber?	Yes	No
24	Have you explained to the Head/personnel of the clinic/practice to use only original parts and accessories on the sterilizer?	Yes	No
25	Have you shown and explained to the Head/personnel of the clinic/practice the safety advise section?	Yes	No
26	Have you explained to the Head/personnel of the clinic/practice the cybersecurity information?	Yes	No

N.	Question	Answer	
	Check		
27	Have you executed a Pouches & Wrapped Cassettes 270 °F (132 °C) with the tray rack and trays inserted?	Yes	No
28	Are all connections to the sterilizer well positioned and plugged (accessories, etc…)?	Yes	No

INSTALLATION INFORMATION

MN-111 Serial Number:	
Date:	
Purchased from:	
Installed by:	
Dr./Clinic name:	
Address:	
Phone:	
Receiver's signature:	
Installer's signature:	

ADDRESSES FOR SENDING THE INSTALLATION CHECK-LIST

Send a copy of the installation check-list duly filled-in to both of the following addresses:

Fax:	+43 6274 6236-55
Mail:	Ignaz-Glaser-Straße 53, Postfach 1 5111 Bürmoos Austria

W&H Sterilization Srl
via Bolgara, 2
Brusaporto (BG)
Italy
med.wh.com
+39 035 66 63 000

MN-111 Med
Instructions for Use
ENG
Rev15
21/05/2025
Subject to changes