Instructions for Use

lexa MINI

RIS-303 RIS-305

RIS-303 RIS-305 - ENG - Rev01

Table of contents

Conformity

CONFORMITY TO EUROPEAN AND AMERICAN REGULATIONS, STANDARDS AND DIRECTIVES

Sterilizer was developed according to 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 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 module A 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 way up
	Fragile, handle with care
	Keep dry
	The sterilizer must be transported by two authorized technicians due to its heavy weight
	Stand-by IEC 60417-5009

	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 MINI 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:

- RIS-303/RIS-305 100–125 V ac
- RIS-303/RIS-305 200–240 V ac

Versions differ for nominal voltage, maximum current and chamber volume.

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.

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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:

Lexa MINI is a dynamic-air-removal (pre-vacuum) table-top steam sterilizer intended for use by a healthcare provider to sterilize medical products by means of pressurized steam. It is suitable for the sterilization of medical and dental instruments that are validated to be sterilized by steam.
The Lexa MINI has not been designed to sterilize liquid loads, biomedical waste or materials not compatible with steam sterilization. The processing of such loads may result in incomplete sterilization and/or damage to the autoclave.

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

Program	Type of Load and Load weight	Steriliz. Temp.	Steriliz. Time	Drying Time (recom.)
Wrapped & Porous	All types of load; wrapped items: ■ Lexa MINI 3 - 2.2lbs (1.0 kg). ■ Lexa MINI 5 - 3.3lbs (1.5 kg). Wrapped porous/textile load: 0.22 lbs (< 100 g).	270 °F (132 °C)	4'	10'
Wrapped	All types of load, except porous/textile load; wrapped items: ■ Lexa MINI 3 - 2.2lbs (1.0 kg). ■ Lexa MINI 5 - 3.3lbs (1.5 kg).	270 °F (132 °C)	4'	10'
Low Temperature	All types of load; wrapped items: ■ Lexa MINI 3 - 2.2lbs (1.0 kg). ■ Lexa MINI 5 - 3.3lbs (1.5 kg). Wrapped porous/textile load: 0.22 lbs (< 100 g).	250 °F (121 °C)	30'	10'
Unwrapped	All types of load, except porous/textile load; unwrapped items: ■ Lexa MINI 3 - 2.2lbs (1.0 kg). ■ Lexa MINI 5 - 3.3lbs (1.5 kg).	270 °F (132 °C)	4'	1'

See "Sterilization programs" on page 86 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 55).
- 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 www.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

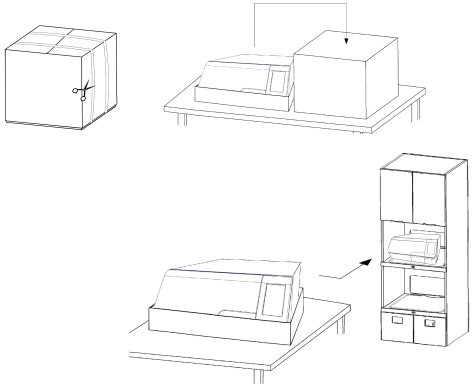
CAUTION! Heavy product. The sterilizer must be removed from the box and transported by two authorized technicians.

Weight with box:

- Lexa MINI 3: 63.9 lbs (29 kg)
- Lexa MINI 5: 70.6 lbs (32 kg)

Weight without box:

- Lexa MINI 3: 50.7 lbs (23 kg)
- Lexa MINI 5: 57.3 lbs (26 kg)

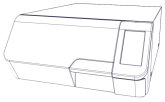


WARNINGS

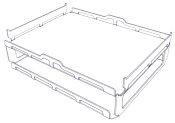
Notice: check the external conditions of the box and the sterilizer. In case of any damage, immediately contact the dealer or shipping agent that has carried out the transport. Keep the packaging for shipping or transporting the sterilizer in the future.

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

CONTENTS OF THE PACKAGING

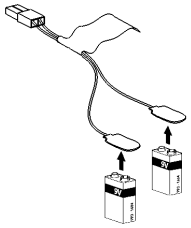


Sterilizer

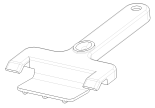


Trays (two)

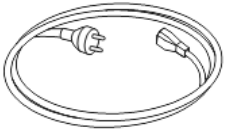
Drain tube



Emergency door opening tool

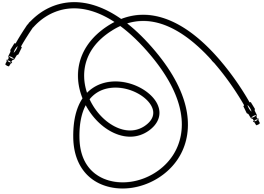


Tray holder

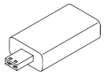


Power cord

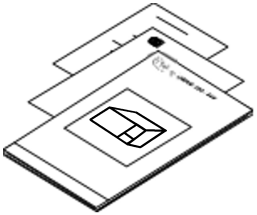
Tube for drain connection



Compressed air tube (only for Lexa MINI equipped with ejector)



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 / external used water tank to capture waste water during manual tank draining (volume larger than 0.16 gal (0.6 l)).
- LAN cable for connecting the sterilizer to a network (optional).

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

Handling

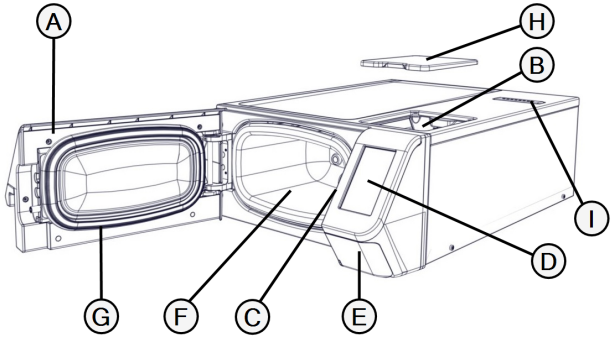
HOW TO RELOCATE THE STERILIZER

Before transport:

- Completely drain both water tanks (see "Draining the clean water tank" on page 72).
- 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.

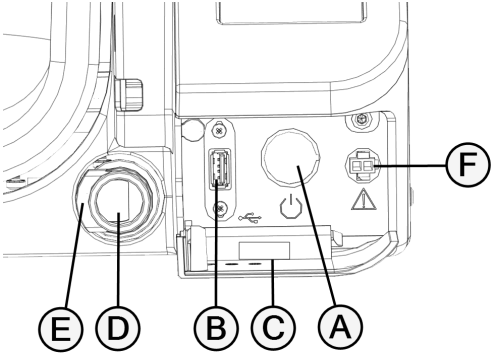
Product description

FRONT VIEW



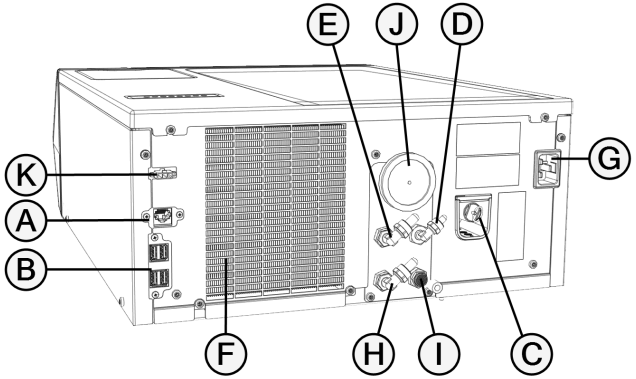
Part	Description
A	Chamber door
B	Clean water tank
C	Door locking system
D	Touch screen
E	Service door
F	Sterilization chamber
G	Door gasket
H	Water filling cover
I	Tank venting cap

COMPONENTS BEHIND THE SERVICE DOOR



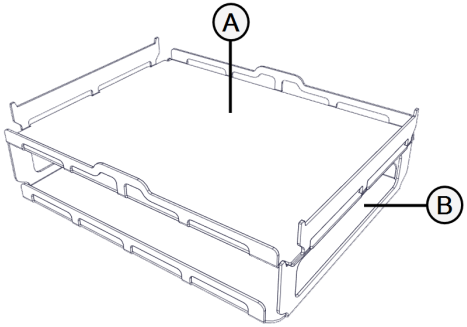
Part	Description
A	Mains switch
B	USB port
C	Identification label
D	Clean water drain connection (blue)
E	Drain tube release button
F	Port for emergency door opening tool

REAR VIEW



Part	Description
A	LAN port
B	USB ports
C	Pressure safety valve ring
D	Water supply inlet
E	Condensate drain in external tank
F	Condenser grid
G	Power cord socket
H	Used water drain
I	■ Compressed air connection (only for Lexa MINI equipped with ejector) ■ Air filter (only for Lexa MINI equipped with vacuum pump)
J	HEPA Filter
K	External used water tank connection

CHAMBER ACCESSORIES



Part	Description
A	Upper tray
B	Lower tray

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.

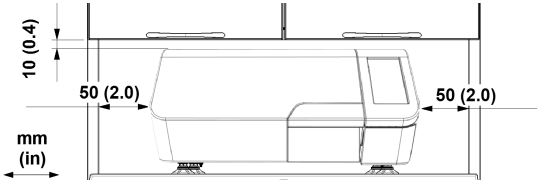
Leave the condenser grid (rear side of the sterilizer) free from anything that might obstruct the air passage.

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.

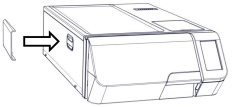
Clearance requirements to ensure proper air circulation:

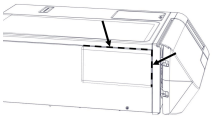


AIR CONVEYOR INSTALLATION (OPTIONAL)

If you need to install the sterilizer into a cabinet or into a confined space (see image below) it is necessary to install the air conveyor (optional).

1. Place the sterilizer on a flat surface.
2. Place the air conveyor on the left side panel of the sterilizer, aligning the upper and right side to the corner of the left side panel, as show on the right image.





Note: the air conveyor is fixed through magnets.

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 99.

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.

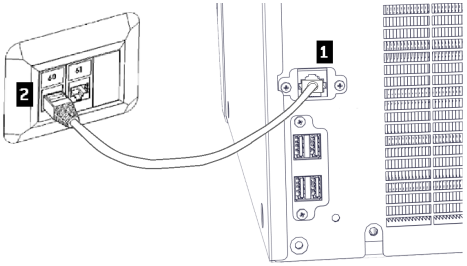
COMPRESSED AIR CONNECTION

Note: only for Lexa MINI equipped with ejector.

The compressed air tube connected on the rear side of the sterilizer must be placed far from the condenser grid.

The compressed air supply must comply with the data label on the back of the sterilizer.

LAN CONNECTION



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.

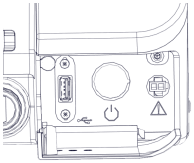
Notice:
Please ensure that all installation requirements are met before plugging the sterilizer. See "Connection diagrams" on page 98.
No other devices should be connected to the sterilizer power panel circuit.

1. Place the sterilizer on a sturdy, flat and level surface.
2. Open the chamber door and remove all items from the sterilizer chamber. Remove all plastic covers from trays.
3. Connect the auto-fill and auto-drain tubes in the rear of the sterilizer.
   Note: make sure the drain tube is vertically positioned, as straight as possible and without any portions in horizontal position.
4. It's possible to connect the auto-drain tube to an external used water tank (optional).
   Note: make sure the external used water tank is installed in a lower position compared to the position of the machine.
5. Connect the Ethernet cable or the Wi-Fi dongle key in the rear of the sterilizer.
6. Attach the power cord to the socket in the rear of the sterilizer and route the cord through the cable guides.
7. Connect the power cord to a wall outlet. For power supply requirements, see "Technical data" on page 95.
8. Connect the compressed air tube (Ø 6 mm) in the rear of the sterilizer (only for Lexa MINI equipped with ejector).
   Note: make sure the tube is inserted correctly into the quick fitting to avoid leaks.
9. Connect the tube to the compressed air plant. For air supply requirements, see "Technical data" on page 95.
   Note: once the connection has been completed, check that the compressed air tube was not damaged and that there are no leaks; otherwise, replace it.

Operating the sterilizer

POWER THE STERILIZER ON/OFF

1. Press the power switch behind the service door.

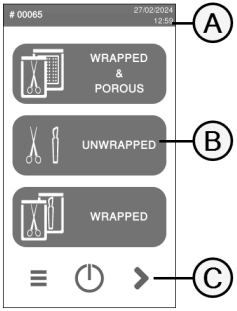


2 After a quick autotest the sterilizer automatically turns in Standby mode. See "Standby mode" on page 38.

Note: at the first start-up of the sterilizer, the Guided Configuration procedure automatically appears; see "Sterilizer setup" on page 34.

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 some functions that might not be available on this product.

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 a special code. Permits manage 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 a special 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).

Icon	Label	Function
	**Chamber Cleaning**	■ Shows the status of the cleaning operations. ■ Resets the cycle counter. ■ Displays the cleaning procedure videos.
	**Tank Cleaning**	
	**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 LANGUAGE

1. On the homepage, tap ☰ > ⚙ > 🌐 > 🇬🇧.
2. Tap the language you prefer.
3. Tap ‹ to confirm and go back to the homepage.

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 go back 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 following procedure under supervision of your IT manager / network administrator (refer also to "Cybersecurity" on page 13).

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 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 (refer also to "Cybersecurity" on page 13).

User authentication (optional)

FUNCTION AVAILABILITY

To access the user management functions a special code must be entered. The special code is required only at the first access to the **User Management** (👥) menu: after the code was entered, the function is enabled and there is no need to enter the code again. If you want to disable the function another special code must be entered.

Note: for more information contact your dealer.

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 to use 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 go back 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

EliTrace (optional)

FUNCTION AVAILABILITY

To access the EliTrace functions a special code must be entered. The special code is required only at the first access to the **EliTrace**( ) menus: after the code was entered, the function is enabled and there is no need to enter the code again.
If you want to disable the function another special code must be entered.

Note: for more information contact your dealer.

DESCRIPTION

EliTrace allows to know exactly which instruments were sterilized and link them to a specific cycle.

ACCESS TO ELITRACE

For the EliTrace access proceed as follows:

1. On the homepage tap ≡ > › > > .

Note: for more information see the dedicated documentation.

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 go back 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 go back to the previous page.

Administrator

CONTENTS

This section deals with the following subjects:

User management (optional)

FUNCTION AVAILABILITY

To access the user management functions a special code must be entered. The special code is required only at the first access to the **User Management** ( ) menu: after the code was entered, the function is enabled and there is no need to enter the code again. If you want to disable the function another special code must be entered.

Note: for more information contact your dealer.

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 go back 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)

To access the user management functions a special code must be entered. The special code is required only at the first access to the **Options** ( ) menus: after the code was entered, the function is enabled and there is no need to enter the code again.
If you want to disable the function another special code must be entered.

Note: for more information contact your dealer.

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 go back 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 go back 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 manufacturer/distributor.

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

SELECT A SHARED LABEL PRINTER

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

Note: refer also to "Cybersecurity" on page 13.

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.

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 v to set the maximum storage time and the number of labels to be printed automatically.
4. Tap ‹ to confirm and go back 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 go back to the previous page.

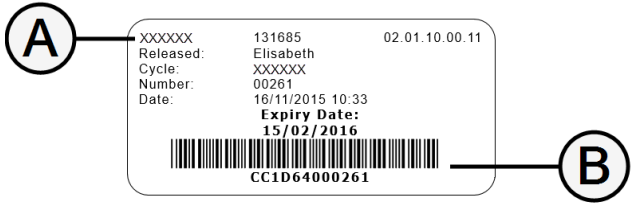
DISABLE THE LABEL PRINTING

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 go back 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.

Sterilizer tests

CONTENTS

This section deals with the following subjects:

Sterilizer performance tests

TESTS THAT CAN BE PERFORMED ON THE STERILIZER

Test	Purpose	Reference
Bowie and Dick test	Validate the sterilizer performance for textile load sterilization.	See "Bowie and Dick test" on the next page.
Vacuum test	Validate the sterilizer performance in terms of: ■ efficiency of the vacuum pump ■ tightness of the pneumatic circuit	See "Vacuum test" on page 50.

Bowie and Dick test

CAUTION! Follow local/national guidelines on the frequency of testing.

PURPOSE OF THE TEST

The test is used to validate the sterilizer performance for textile load sterilization.

DESCRIPTION

It consists of several sheets of paper wrapped in a small packet with a chemical heat-sensitive indicator sheet in the middle. The colour assumed by this indicator sheet at the end of the sterilization cycle gives the result of the test.

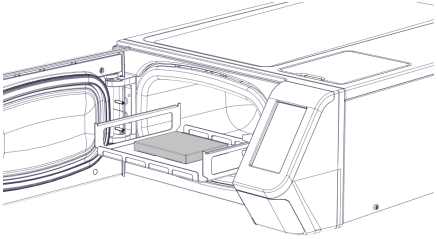
CARRY OUT THE TEST

Note: carry out the test according to the local Regulations and the instructions of the PCD manufacturer.

Note: the test can be performed either with hot or cold sterilization chamber.

Note: to take advantage of the traceability benefits, a W&H test must be used.

1. On the homepage, tap **B&D test**.
2. Tap to see an animated description of the test steps.
3. Empty the sterilization chamber to ensure no load is present. Remove all trays from the sterilization chamber, except the lowest one.
4. *Optional*: scan the QR code of the B&D test pack and tap ✔ to confirm the scanned test (only with QR code / Bar code reader for labels connected).
5. Place the B&D test pack in the center of the lower tray and close the chamber door.



6 To set the duration of the Plateau/Sterilization phase and other settings, tap ⚙.

7 Tap ▶ and enter your credentials if required: the chamber door locks. If you have not set a different start time (see "Set the sterilization cycle start" on page 56), the test starts immediately.

8 Wait until the end of the test and tap **OPEN**: the chamber door unlocks.

9 Enter your credentials if required.

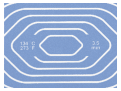
10 Open the chamber door, extract the tray using the tray holder and take the test pack. The test pack can be wet outside.

CAUTION! Risk of burns. The test pack is very hot at the end of the cycle. Wear appropriate PPE (e.g. gloves).

11 Remove the indicator sheet from the center of the test pack and check the change in colour. See "Bowie and Dick test" on the previous page.

12 *Optional*: to validate the result, scan the QR code on the test sheet (only with QR code / Bar code reader for labels connected); the test report is saved in the HTML file.

Note: for more information on test traceability, see the dedicated documentation.

Outcome of the test	Outcome of the test	Explanation	Action
 The indicator sheet has changed colour (a uniform pink pattern).	PASSED	It represents an acceptable cycle.	None.
 The indicator sheet has changed colour (a uniform blue pattern).	FAILED	it represents an unexposed test sheet.	Repeat the test. If it fails repeatedly, contact technical service.
 A part of the indicator sheet has not changed colour (a pink pattern with a dark blue area).	FAILED	it represents an unacceptable air removal condition.	
 The indicator sheet has changed colour (a uniform dark blue pattern).	FAILED	It represents a low temperature condition.	

Note: for interpreting the test result follow the instructions of the PCD manufacturer.

Vacuum test

CAUTION! Follow local/national guidelines on the frequency of testing.

Notice: if a drainage period of the Unwrapped cycle is still operating, wait the drainage to be finished and the sterilizer to be both cold and dry. Otherwise, a false negative outcome could occur.

PURPOSE OF THE TEST

The test is used to validate the sterilizer performance in terms of:

- efficiency of the vacuum pump.
- tightness of the pneumatic circuit.

DESCRIPTION

It consists of a vacuum phase, followed by a stabilization period of 5 minutes and a testing period of 10 minutes. The internal pressure is monitored during the testing period. The pressure rise must be less than 0.013 bar (0.19 psi).

CARRY OUT THE TEST

1. Empty the sterilization chamber to ensure no load is present.
2. Close the chamber door and ensure the sterilization chamber is completely dry and cold to avoid any false negative outcome.

3 On the homepage, tap **Vacuum test**.

4 Tap to see an animated description of the test steps.

5 Tap and enter your credentials if required: the chamber door locks. If you have not set a different start time (see "Set the sterilization cycle start" on page 56), the test starts immediately.

6 Wait until the end of the test and tap **OPEN**: the chamber door unlocks.

7 Enter your credentials if required: a message informs if the test passed or failed. If the test failed, see "What to do when the test failed" below.

WHAT TO DO WHEN THE TEST FAILED

1 Check, clean or replace the door gasket (see "User maintenance" on page 64).

2 Clean the chamber face side and the chamber filter (see "User maintenance" on page 64).

3 Repeat the Vacuum test. See "Carry out the test" on the previous page.

4 If the test fails repeatedly, contact technical service.

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.

DENTAL HANDPIECE EXTERNAL DISINFECTION

This procedure reduces the risk of infection during cleaning and maintenance of the dental handpieces.

- Wear protective gloves during disinfection.
- Avoid using abrasive disinfectants (pH-value 2.5 – 9; no chlorine based disinfectants).
- Use disinfectant wipes rather than spray disinfection.
- Do not immerse handpieces in disinfectants.
- Residual disinfectants on handpieces can cause extensive damage to your instrumentation during sterilization (oxidation, alteration of technical characteristics of seals, rubbers, fiber optics, etc.).

DENTAL HANDPIECE EXTERNAL CLEANING

This procedure involves the removal of residues (blood, dentine, etc.) that adhere to critical areas such as spray outlets, light ports, knurling etc.

- Wear protective gloves during cleaning.
- Refer to the instructions of the instrument manufacturer.
- Use a soft, damp brush and take care not to scratch the surface of the light ports.

DENTAL HANDPIECE LUBRICATION

Once the dental handpieces has been disinfected, cleaned and dried (free from residues), it must be lubricated prior to sterilization. Follow manufacturer's instructions for proper lubrication.

PACKAGING

In order to preserve sterility, rotating instruments should be wrapped/bagged prior to sterilization. Follow the manufacturer's packing instructions when using sterilization packaging.

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.

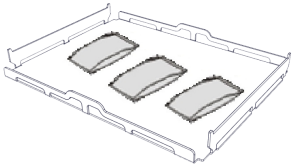
CORRECT LOAD PLACEMENT

WARNING! Do not overload trays and the chamber. Adhere to the maximum load weight limits (see "Sterilization programs" on page 86).
Risk of burns. Before touching, ensure the sterilization chamber is cold.

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

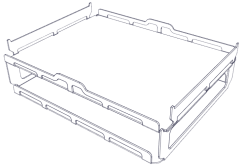
Follow these requirements:

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 only be placed horizontally on the trays. When placing cassettes, slide them into the chamber putting them on trays.

Load type	Placement
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 just partially loaded, place the load in such a way that the space in-between the trays is maximized. Spread items evenly on two trays. Below is an example with two 5 l trays.



Prepare the sterilizer

WARNINGS

Notice: use only distilled or demineralized water (see "Water quality" on page 99 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 95 for the tank volume.

INSERTING THE TRAYS INTO THE STERILIZER

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

1. Open the chamber door and insert the trays horizontally (one above the other)See "Load maintenance and preparation" on page 52 for load requirements and "Chamber accessories" on page 23.
2. Close the door.
3. 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.

Sterilization cycle description

AVAILABLE STERILIZATION CYCLES

See "Sterilization programs" on page 86 for the full list of key program features, including sterilization time, temperature and recommended load type.

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. If the door gasket is new, hold the door gently closed until the beginning of the cycle.
4. Tap ▶ and enter your credentials if required: the door locks. If you have not set a different start time, the sterilization starts immediately.

7. 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 57.

8. The sterilization is completed. Tap 🗎 to view the cycle summary or tap i to view the cycle information. See "View the cycle parameters" on page 57.

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

10 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)

SET 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. To change the start time, tap **Start cycle at**.
3. 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 and go back to the previous page. 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").

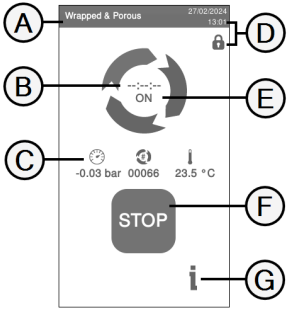
VIEW THE CYCLE PARAMETERS

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 79

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 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" on the next page.
5. Tap to view the cycle parameters. See "View the cycle parameters" on the previous page.
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

Following are the messages:

- Load not sterile: Do not use items on patients!
- Drying interrupted: The load might be wet. Wet items are for immediate use only!

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 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 .

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 in 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 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 user name and password.
7. Tap ✓ to save.
8. Tap ‹ to go back to the previous page.
9. To check if the parameters entered are valid, see "Test the data storage " on the next page.

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" on the previous page.

1. On the homepage, tap ☰ > ⚙ > › > 🖥.
2. Tap TEST: a sequence of tests is automatically performed.
3. In case a test fails, check the relevant settings and tap ↻ to repeat the test sequence, if the error persists call your IT manager (refer also to "Cybersecurity" on page 13).
4. Tap ‹ to go back to the previous page.

SAVE ALL THE CYCLE REPORTS IN A REMOTE FOLDER

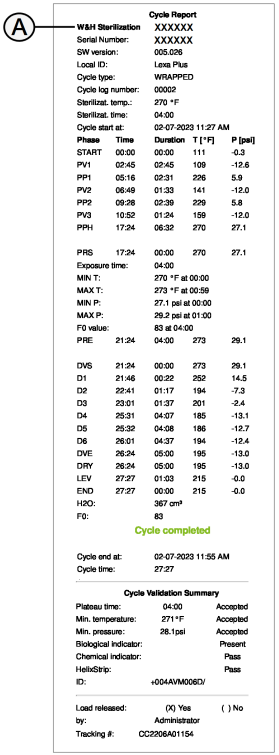
Note: the save all function is available only if the remote data storage is enabled. See "Set the remote folder for saving the reports" on the previous page.

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

W&H Sterilization XXXXXX
Serial Number: XXXXXX
SW version: 005.026
Local ID: Lexa Plus
Cycle type: WRAPPED
Cycle log number: 00002
Sterilizat. temp.: 270 °F
Sterilizat. time: 04:00
Cycle start at: 02-07-2023 11:27 AM

Phase	Time	Duration	T [°F]	P [psi]
START	00:00	00:00	111	-0.3
PV1	02:45	02:45	109	-12.6
PP1	05:16	02:31	226	5.9
PV2	06:49	01:33	141	-12.0
PP2	09:28	02:39	229	5.8
PV3	10:52	01:24	159	-12.0
PPH	17:24	06:32	270	27.1
PRS	17:24	00:00	270	27.1

Exposure time: 04:00
MIN T: 270 °F at 00:00
MAX T: 273 °F at 00:59
MIN P: 27.1 psi at 00:00
MAX P: 29.2 psi at 01:00
F0 value: 83 at 04:00

PRE	21:24	04:00	273	29.1
DVS	21:24	00:00	273	29.1
D1	21:46	00:22	252	14.5
D2	22:41	01:17	194	-7.3
D3	23:01	01:37	201	-2.4
D4	25:31	04:07	185	-13.1
D5	25:32	04:08	186	-12.7
D6	26:01	04:37	194	-12.4
DVE	26:24	05:00	195	-13.0
DRY	26:24	05:00	195	-13.0
LEV	27:27	01:03	215	-0.0
END	27:27	00:00	215	-0.0

H2O: 367 cm³
F0: 83

Cycle completed

Cycle end at: 02-07-2023 11:55 AM
Cycle time: 27:27

Cycle Validation Summary

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

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

Data	Description
A	Sterilizer model
SN	Sterilizer serial number
Software rev.	Software revision number
Sterilizer Name	Surgery – practice – doctor name
Cycle	Name of the executed cycle
Number	Cycle counter
Sterilizat. temp.	Programmed sterilization temperature
Sterilizat. time	Programmed Plateau/Sterilization
Date	Cycle start date and time
START	Cycle start
	Pressure and vacuum pulses
PPH	Phase of pressure rise to sterilization conditions
PRS	Plateau/Sterilization phase start: ■ MIN, MAX temperature ■ MIN, MAX pressure
PRE	Plateau/Sterilization phase end
DVS	Drying phase start
DVE	Drying phase end
SEP	Chamber venting phase
LEV	Pressure leveling phase
END	Cycle end conditions

Data	Description
Cycle end at	Cycle end date and time
H2O	Cycle water consumption
F0	F0 value
Cycle time	Cycle time
Signature	Operator signature
"Cycle completed"	Cycle outcome
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
Tracking	Tracking code for traceability management

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 page 66. Clean the chamber and trays. See "Cleaning the chamber and the chamber accessories" on page 67. Cleaning the chamber filter. See "Cleaning the chamber filter" on page 68. Cleaning the external surfaces of the sterilizer. See "Cleaning the external surfaces of the sterilizer" on page 68.
Yearly[2]	400[2]	Replace the HEPA filter. See "400-cycle maintenance" on page 69.
Yearly[2]	800[2]	Replace the door gasket. See "Replacing the door gasket" on page 70.

[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.

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.

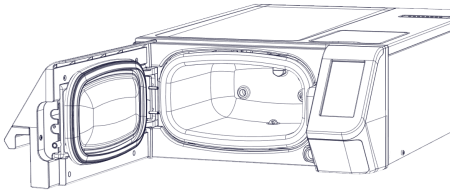
50-cycle or monthly maintenance

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.

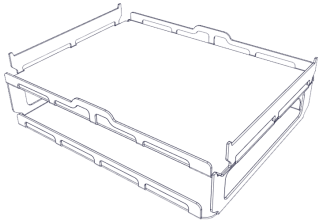
Note: when the seal is new it might be necessary to hold the door gently closed at the sterilization start.



CLEANING THE CHAMBER AND THE CHAMBER ACCESSORIES

Proceed as follows:

1. Remove the trays.
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 with a damp sponge and a mild detergent solution.
5. Rinse with water.
6. Reposition all pieces of the chamber accessories properly.



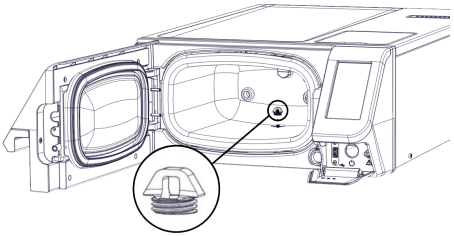
Note: tap to see the animated cleaning procedure.

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

CLEANING THE CHAMBER FILTER

Proceed as follows:

1. Allow the sterilization chamber to cool down.
2. Empty the sterilizer chamber by removing the trays.
3. Remove the filter at the bottom of the chamber by unscrewing it.
4. Rinse the filters with tap water.
5. Insert the filter in its original position, screwing it 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.

400-cycle maintenance

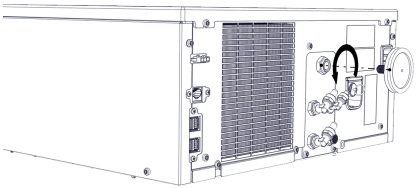
REPLACING THE HEPA FILTER

Notice: the HEPA filter needs to be replaced every 400 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. Unscrew the HEPA filter by hand (counter-clockwise).
2. Screw on the new HEPA filter (clockwise) and tighten it snug.

Note: tap to see the animated replacement procedure.



800-cycle or yearly maintenance

REPLACING THE DOOR GASKET

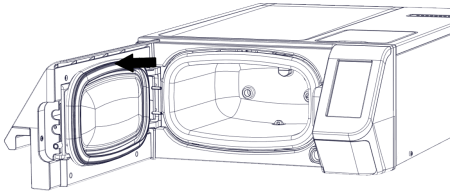
Notice: the door gasket needs to be replaced every 800 sterilization cycles or once a year, whichever come first. A replacement message alerts when replacement is due. If the consumables is replaced prior to the message, you have to reset the consumable cycle counter.

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.

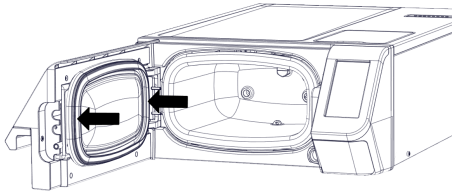
Note: tap to see the animated replacement procedure.

4. Insert the new seal and press it starting from the central-upper point.



5 Press left and right.

6 Make sure the door gasket is seated evenly.

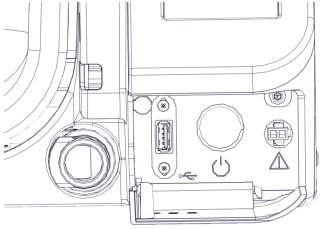


Extraordinary maintenance

DRAINING THE 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 clean water tank.

1. Open the chamber door.
2. Put a container below the sterilizer (0.16 gal (0.6 l) minimum) and place the end of the drain tube in it.
3. To drain the water, insert the drain tube connector in the blue connection.
4. When the water has been completely drained, press the release button to remove the drain tube and close the chamber door.



Disposal

DISPOSAL RESPONSIBILITY

- Separate the various components according to the materials they are made of
- Drop the sterilizer with a company that specializes on 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 58.	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	Check water level in the clean water tank. Reset the safety thermostat..	Repeat the cycle. If the problem persists, contact technical service.
	Switch the sterilizer OFF and ON.	
	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.	
	Start a vacuum test to check the tightness of the pneumatic circuit.	
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 and ON.	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 72).	

Code	Description	Actions
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.	
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 (trays, 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 error not listed in this table, contact technical service.

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 64.
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 64). 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?**		
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.
Not defined.	This message advises you that the device reached a high temperature and it can't do other sterilization cycles.	Ensure proper air circulation (See "Installing the sterilizer" on page 24). Allow the sterilization chamber to cool down and restart the cycle.

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).

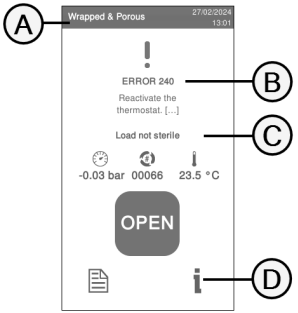
VIEW AND SAVE THE ERROR LOG

1. On the homepage, tap > > : a list of the last 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 74.
C	Warning messages.
D	Open button that appears after the reset phase had finished.

WARNING MESSAGES

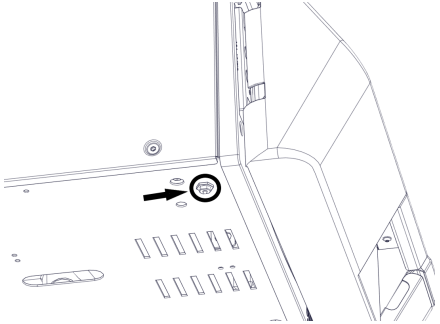
Message	Description
Load not sterile	The load is not sterile. **WARNING! Do not use items on patients!**
Drying interrupted	The load might be wet. **WARNING! Wet items are for immediate use only!**

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. Lift the sterilizer and push on the rest button of the thermostat switch; a click sound indicates that the thermostat switch has been reset.
4. Reposition the sterilizer.
5. Connect the mains cable and switch the sterilizer ON.

   Note: if the thermostat operates repeatedly, contact technical service.
6. 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 72.
	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. See "Load maintenance and preparation" on page 52.
	Chamber filter clogged.	Remove and clean the chamber filter.
	Chamber filter cap not well-positioned.	Mount the chamber filter cap properly (see "User maintenance" on page 64).
	Load incorrectly placed.	See "Load maintenance and preparation" on page 52.

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 99.
	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 52.
	Chamber, trays 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 52.
	Scale deposits on the chamber.	Clean the chamber and use water of good quality. See "Water quality" on page 99.
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.	Check the data and the power connection to the printer.
	Shared label printer doesn't work due to a cybersecurity event.	See "Cybersecurity" on page 13.
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 99.
	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.	Call 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 400 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, call service.
Warning about programmed maintenance.	A component shall be replaced for the programmed maintenance of the sterilizer.	Call service to order the requested component (door gasket, HEPA filter…). See "User maintenance" on page 64

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.

For this reason, two 9V batteries size PP3 or 1604 are required.

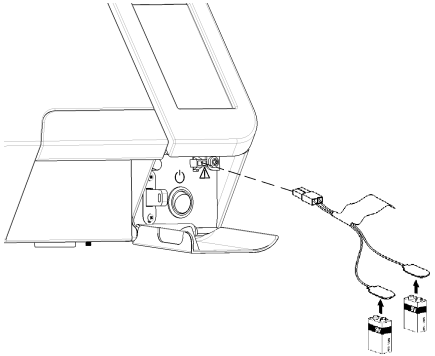
OPEN THE DOOR IN EMERGENCY

1. Unplug the sterilizer and wait at least three hours.
2. Take the emergency door opening tool included in the sterilizer box.
3. Firmly open the service door.

4 Plug two batteries into the connectors.

5 Holding the service door pulled, plug the plastic connector into the socket.

6 As soon as the door opens, unplug the plastic connector to prevent system overload and consequent damage.



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 three preset FDA cleared sterilization programs that comply with the American National Standard ANSI/AAMI ST55.

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]: for enabling these profiles contact technical service. Some of the parameters can be adjusted according to your needs (Plateau/Sterilization phase and dry time). These cycles are not FDA cleared.

STERILIZATION PROGRAM OPTIONS

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, the duration of the drying time can be modified (see "Set the sterilization cycle start" on page 56). To load properly the sterilizer see "Prepare the sterilizer" on page 54.

	Sterilization cycles							
	Wrapped & Porous		**Wrapped**		**Low Temperature**		**Unwrapped**	
Sterilization temperature	270 °F (132 °C)		270 °F (132 °C)		250 °F (121 °C)		270 °F (132 °C)	
Duration of the Plateau/Sterilization phase	4'		4'		30'		4'	
Minimum duration of the drying phase (set by the user)	10'		10'		10'		1'	
Total program duration (min) [1] *Full loaded including drying time*	Empty	Full	Empty	Full	Empty	Full	Empty	Full
Lexa MINI 3	21'00"	25'30"	18'45"	20'45"	46'45"	50'30"	09'45"	11'45"
Lexa MINI 5	22'45"	31'15"	19'30"	23'00"	48'00"	56'45"	10'30"	14'00"
Load type	All types of load *		All types of load, except porous/textile load *		All types of load * / [2]		All types of load, except porous/textile load *	
Packaging type	Wrapped		Wrapped		Wrapped		Unwrapped	
Maximum load weight [3]	Wrapped items: ■ Lexa MINI 3 2.2 lbs (1.0 kg). ■ Lexa MINI 5 3.3 lbs (1.5 kg). Wrapped and porous/textile load: 0.22 lbs (< 100 g).		Wrapped items: ■ Lexa MINI 3 2.2 lbs (1.0 kg). ■ Lexa MINI 5 3.3 lbs (1.5 kg).		Wrapped items: ■ Lexa MINI 3 2.2 lbs (1.0 kg). ■ Lexa MINI 5 3.3 lbs (1.5 kg). Wrapped and porous/textile load: 0.22 lbs (< 100 g).		Unwrapped [4] items: ■ Lexa MINI 3 2.2 lbs (1.0 kg). ■ Lexa MINI 5 3.3 lbs (1.5 kg).	

*: the liquids are excluded.

1: the total cycle time may vary depending on the type of load (solid or porous), the load weight, the vacuum generation, the duration of the drying phase and other factors. Value and cycle names could be different depending on country requirement.

2: designed for all items that cannot withstand the high temperatures of the 270 °F (132 °C) cycles, such as textiles, plastics and delicate items.

3: the weight of trays in the standard configuration is included.

4: the manufacturer suggests to use unwrapped load immediately after the sterilization cycle.

Sterilization cycle phases

COMMON LEGEND OF THE STERILIZATION CYCLE PHASES

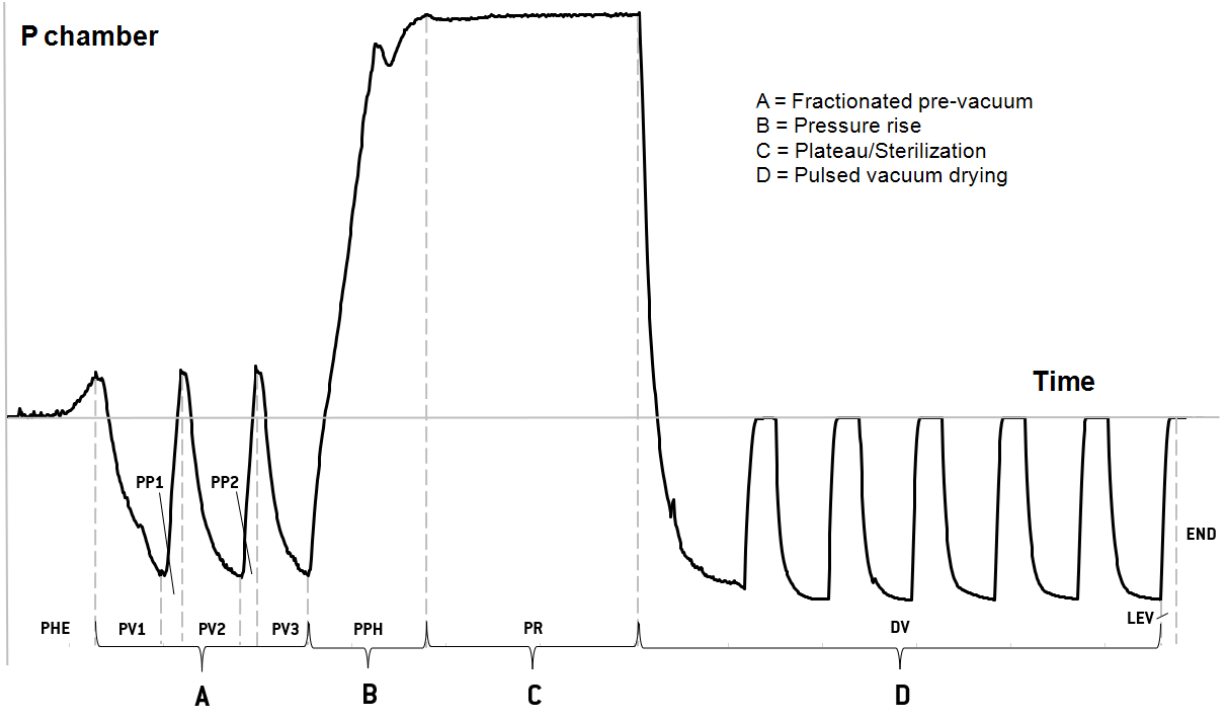
Following is the description of the sterilization phases.

Code	Description
PHE	Pre-heating of the sterilizer. This phase is not considered a part of the cycle.
PV1 - PV3	Vacuum pulse (removal of air from the sterilizer chamber/load).
PP1 - PP2	Pressure pulse (steam generation).
PPH	Rise to the Plateau/Sterilization phase.
PR	Process (Plateau/Sterilization phase).
DRY	Vacuum drying.
LEV	Leveling. Pressure inside the sterilization chamber is leveled to the atmospheric pressure.
END	End of the cycle.

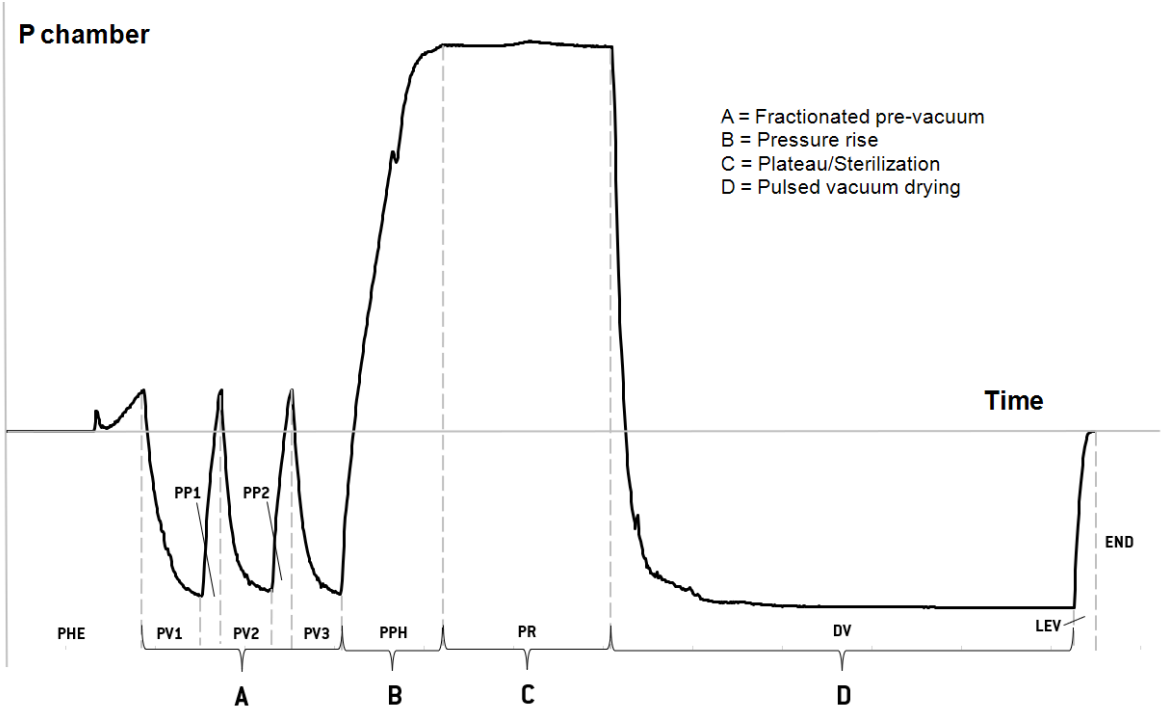
STERILIZATION CYCLE PHASES

Wrapped & Porous and Low Temperature sterilization cycles feature the same basic pressure profile as shown in the graph below. The duration and the temperature of the sterilization phase differ between the various cycles.

Note: only for Lexa MINI equipped with ejector.

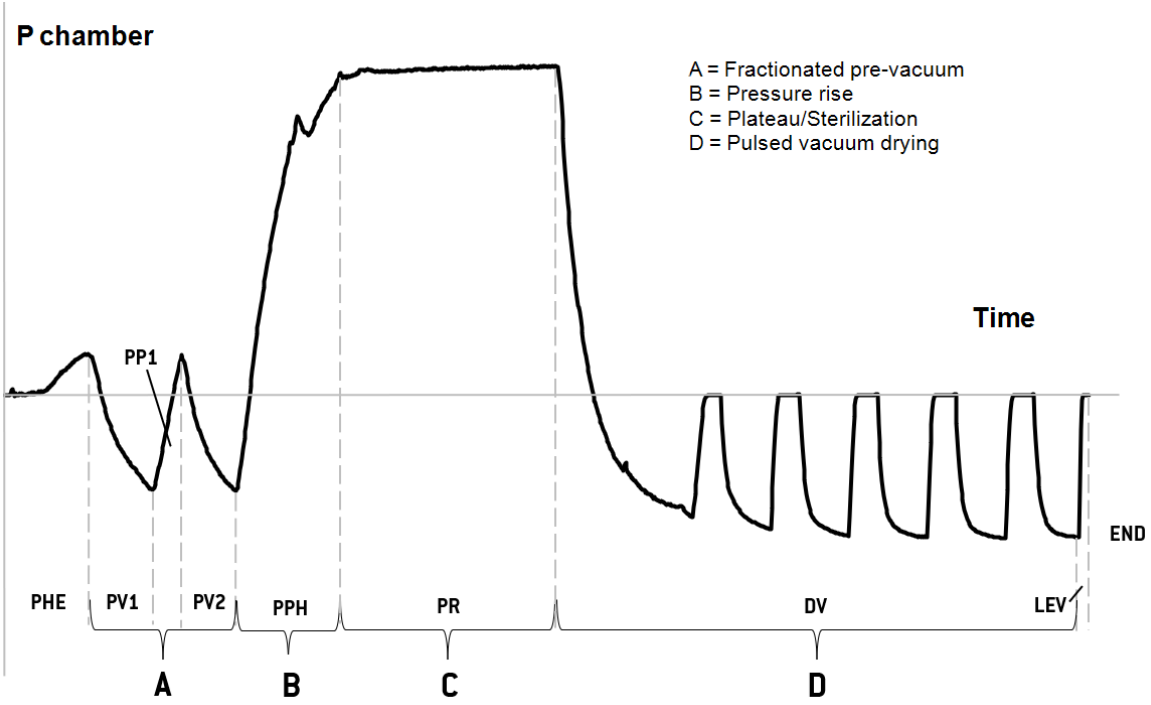


Note: only for Lexa MINI equipped with vacuum pump.

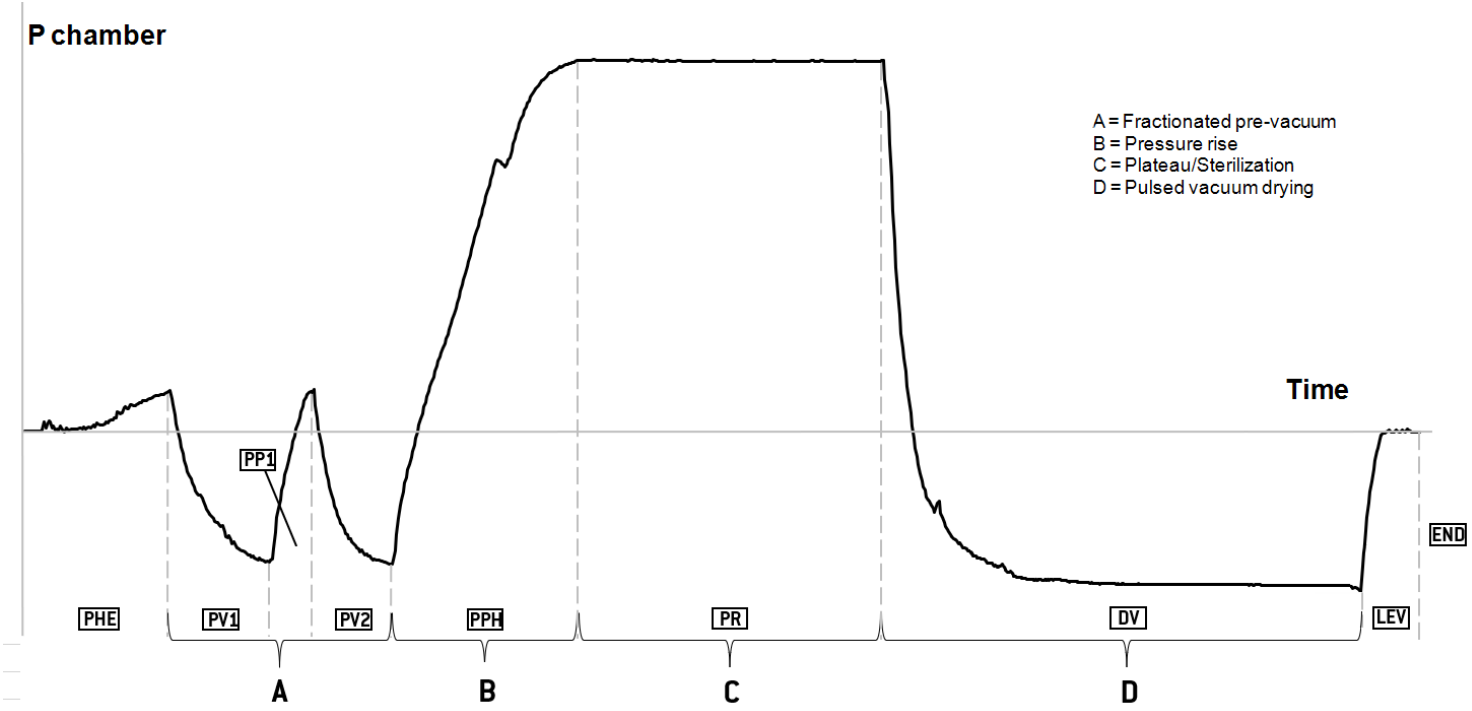


Wrapped and Unwrapped cycles feature the same pressure profile as shown in the graph below. The temperature and the duration of the sterilization phase, and the duration of the de-aeration and evaporation (drying) phases are different from cycle to cycle.

Note: only for Lexa MINI equipped with ejector.



Note: only for Lexa MINI equipped with vacuum pump.



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	1 USB port at the front 4 USB ports - 1 LAN port at the rear
Features	Fully micro-processor controlled, process evaluation system according to EN13060. Programmable standby mode.
Max. heat output	3000 kJ/h
Residual-current device	30 mA or less, if required by local regulations

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	3000 m asl
Min. atmospheric pressure	8.7 psi (0.6 bar)
Overall dimensions	Lexa MINI 3 - W: 17.3”/H: 7.9”/D: 22.9” (W: 44 cm/H: 20 cm/D: 58 cm) Lexa MINI 3 - with air conveyor - W: 17.8”/H: 7.9”/D: 22.9” (W: 45 cm/H: 20 cm/D: 58 cm) Lexa MINI 5 - W: 17.3”/H: 7.9”/D: 26.2” (W: 44 cm/H: 20 cm/D: 67 cm) Lexa MINI 5 - with air conveyor - W: 17.8”/H: 7.9”/D: 26.2” (W: 45 cm/H: 20 cm/D: 67 cm)
Min. space required (feet in forward position)	Lexa MINI 3 - W: 17.3”/H: 7.9”/D: 16.5” (W: 44 cm/H: 20 cm/D: 42 cm) Lexa MINI 3 - with air conveyor - W: 17.8”/H: 7.9”/D: 16.5” (W: 45 cm/H: 20 cm/D: 42 cm) Lexa MINI 5 - W: 17.3”/H: 7.9”/D: 19.7” (W: 44 cm/H: 20 cm/D: 50 cm) Lexa MINI 5 - with air conveyor - W: 17.8”/H: 7.9”/D: 19.7” (W: 45 cm/H: 20 cm/D: 50 cm)
Min. space required (feet in rearward position)	Lexa MINI 5 - W: 17.1”/H: 7.9”/D: 16.5” (W: 44 cm/H: 20 cm/D: 42 cm) Lexa MINI 5 - with air conveyor - W: 17.5”/H: 7.9”/D: 16.5” (W: 45 cm/H: 20 cm/D: 42 cm)

Min. space required (overall dimensions + clearance)	Lexa MINI 3 - W: 21.3"/H: 8.3"/D: 22.9" (W: 54 cm/H: 21 cm/D: 58 cm) Lexa MINI 3 - with air conveyor - W: 21.7"/H: 8.3"/D: 22.9" (W: 55 cm/H: 21 cm/D: 58 cm) Lexa MINI 5 - W: 21.3"/H: 8.3"/D: 26.2" (W: 54 cm/H: 21 cm/D: 67 cm) Lexa MINI 5 - with air conveyor - W: 21.7"/H: 8.3"/D: 26.2" (W: 55 cm/H: 21 cm/D: 67 cm)
Size of the door movement	W: 20.2"/H: 7.9"/D: 12.6" (W: 51 cm/H: 20 cm/D: 32 cm)
Weight empty	Lexa MINI 3: 48.3 lbs (21.9 kg) Lexa MINI 5: 53.8 lbs (24.4 kg)
Max. weight (fully loaded)	Lexa MINI 3: 53.8 lbs (24.4 kg) Lexa MINI 5: 62.4 lbs (28.3 kg)
Weight per support area	Lexa MINI 3: 14.4 kN/m² Lexa MINI 5: 16.7 kN/m²
Environment pollution	Degree 2
Usage environment	Indoor

STERILIZER CHAMBER

Pressure safety valve	37.7 psi (2.6 bar)
Safety thermostats	302 °F (150 °C)
Total volume	Lexa MINI 3 - 0.75 gal (2.84 l) Lexa MINI 5 - 1.31 gal (4.94 l)
Usable space *	Lexa MINI 3 - 0.54 gal (2.06 l) Lexa MINI 5 - 1.06 gal (4.03 l)
HEPA filter	0.3 µm

STEAM GENERATOR

Safety thermostats	536 °F (280 °C)

AIR EJECTOR

Average air consumption	13.2-15.8 (N) gal/min (50-60 (N)l/min)
Working pressure	73-145 psi (5-10 bar)

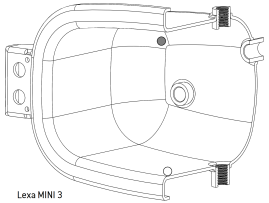
DISTILLED OR DEMINERALIZED WATER

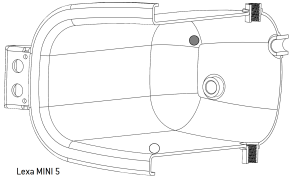
Water quality	See the Test Instructions service book (conductivity : < 10µS/cm, Total Dissolved Solids: < 6.5 ppm)
Average water consumption	0.05 to 0.2 gal/cycle (0.2 to 0.76 litres/cycle)
Tank volume	Lexa MINI 3 0.42 gal (1.6 l) 0.27 gal (1 l) with air gap Min. water charge 0.17 gal (0.65 l) Lexa MINI 5 0.66 gal (2.5 l) 0.45 gal (1.7 l) with air gap Min. water charge 0.27 gal (1 l) Used water 0.16 gal (0.6 l)

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

Recommendations for validation

TEST VALIDATION POINTS


Lexa MINI 3

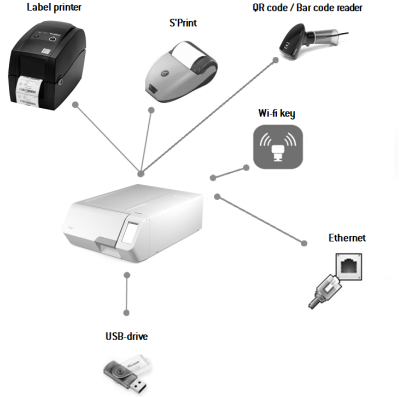

Lexa MINI 5

Part	Description
	Hottest points
	Coldest points

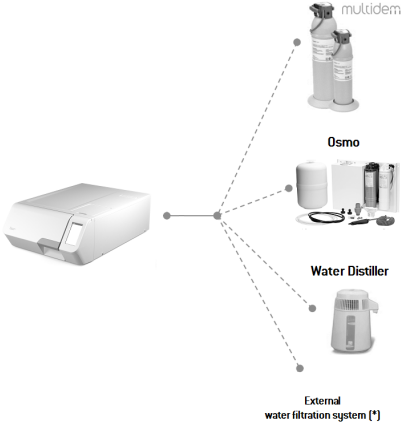
Diagrams

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.

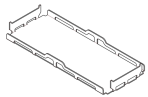
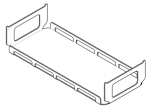
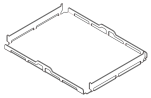
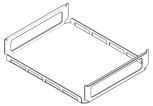
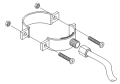
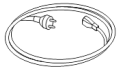
The manufacturer's warranty is void if the sterilizer was used with water containing contaminant or chemical levels exceeding those listed in the table above.

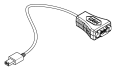
Accessories, spare parts, consumables

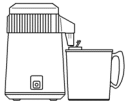
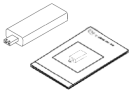
Note: use only accessories, spare parts and consumables recommended by W&H.

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

LIST OF ACCESSORIES AND SPARE PARTS

Picture	Part	Part number
	**Upper tray Lexa MINI 3** (227 x 23.5 x 94 mm)	F523213X
	**Lower tray Lexa MINI 3** (218 x 44.5 x 94 mm)	F523215X
	**Upper tray Lexa MINI 5** (227 x 23.5 x 175 mm)	F523212X
	**Lower tray Lexa MINI 5** (224 x 44.5 x 175 mm)	F523214X
	**Tray holder**	F523001X
	**Drain tube kit with fittings**	A812110X
	**Drain tube**	S230903X
	**Permanent drain tube (3 m)**	W230009X
	**Compressed air tube**	W230000X
	**Mains cable**	U38012XX

Picture	Part	Part number
	**Network data cable RJ45 (3 m)**	A801500X
	**USB pen drive**	V000004X
	**Report printer**	19721141
	**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

Picture	Part	Part number
	**QR code / Bar code reader for labels**	19721132
	**Water Distiller**	19723101
	**Multidem C27 water demineralizer**	19723112
	**Multidem resin cartridge**	A812016X
	**Osmo water demineralizer (220 V)** **Osmo water demineralizer (110 V)**	19721134 19721135
	**Wi-Fi dongle key**	19721137

Picture	Part	Part number
	**Lifting strap**	F602001X
	**Emergency door opening tool**	F372106X
	**B&D test pack**	T800003X
	Air conveyor	F540668X
	**External used water tank**	X051700X

CONSUMABLES

Picture	Part	Part number	When replace it
	**HEPA filter (bagged)**	W322400X	Every 400 cycles
	**Door gasket**	F460550X	Every 800 cycles

Authorized W&H service partners

A list and a map with your nearest W&H service partner are available at www.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	Is the minimum air inlet pressure respected?	Yes	No
12	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		
13	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
14	Have you shown to the Head/personnel of the clinic/practice how to program the sterilizer?	Yes	No
15	Have you shown to the Head/personnel of the clinic/practice the cycle options?	Yes	No

N.	Question	Answer	
16	Have you shown to the Head/personnel of the clinic/practice what the messages and alarms mean?	Yes	No
17	Have you shown to the Head/personnel of the clinic/practice how to manually abort a cycle?	Yes	No
18	Have you shown to the Head/personnel of the clinic/practice the maintenance program and procedures?	Yes	No
19	Have you shown to the Head/personnel of the clinic/practice how to use all of the accessories?	Yes	No
20	Have you shown to the Head/personnel of the clinic/practice the advantages of having a USB connection for a pen drive?	Yes	No
21	Have you shown to the Head/personnel of the clinic/practice the advantages of having a LAN connection?	Yes	No
22	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
23	Have you shown to the Head/personnel of the clinic/practice the advantages of having a connection (remote data saving)?	Yes	No
24	Have you explained to the Head/personnel of the clinic/practice the correct load type for each available sterilization program?	Yes	No
25	Have you shown to the Head/personnel of the clinic/practice how to prepare and place the load in the sterilizer chamber?	Yes	No
26	Have you explained to the Head/personnel of the clinic/practice to use only original parts and accessories on the sterilizer?	Yes	No
27	Have you shown and explained to the Head/personnel of the clinic/practice the safety advise section?	Yes	No
28	Have you explained to the Head/personnel of the clinic/practice the cybersecurity information?	Yes	No
29	Have you explained to the Head/personnel of the clinic/practice how to perform the B&D test?	Yes	No
	Check		
31	Have you executed a Vacuum test?	Yes	No
32	Have you executed a Wrapped & Porous 270 °F (132 °C) with the trays inserted?	Yes	No
33	Are all connections to the sterilizer well positioned and plugged (accessories, etc…)?	Yes	No

INSTALLATION INFORMATION

RIS-303 RIS-305 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 / email:	Ignaz-Glaser-Straße 53, Postfach 1 5111 Bürmoos Austria office.sterilization@wh.com

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

RIS-303 RIS-305
Instructions for Use
ENG
Rev01
04/03/2024
Subject to changes