Instructions for Use

CE 0051

MN-111 - ENG - Rev13

lexa

MN-111

Table of contents

Conformity

CONFORMITY TO EUROPEAN AND AMERICAN STANDARDS AND DIRECTIVES

STERILIZER featuring sterilization cycles conform with the following standards:

Standards and Directives	Description
CE 0051 93/42/EEC	Medical Device Directive (MDD). Medical Device Directive 93/42/EEC for devices class IIb, in accordance with the Rule 15 – ANNEX IX of the above Directive.
CE 0497 2014/68/EU	Pressure Equipment Directive (PED). Directive 2014/68/EU (PED – Pressure Equipment Directive) for every sterilization chamber designed and manufactured in conformity to the ANNEX 1 and to the procedure described in the module D1 Annex III.
2012/19/EU	Waste Electrical and Electronic Equipment (WEEE).
CSA C22.2 No. 61010-1-12	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.

Don't use drinking water to fill the clean water tank; use only distilled or demineralized water.

Consult the Instructions for Use.

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.

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 MN-111 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 10).

OBLIGATIONS WITH REGARD TO THIS MANUAL

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

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

MANUAL CONTENT

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

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

Versions differ only for nominal voltage and maximum current (e.g. they have the same hydraulic circuit, software menu, sterilization programs, etc.).

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

The MN-111 is designed for pressurized steam sterilization of medical and pouched dental instruments, including dental handpieces, porous and hollow loads.

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

Program	Type of Load and Load weight	Sterilization Temperature	Sterilization Time	Drying Time (recommended)
Pouches Medium Load	Instruments and dental handpieces, up to 3 lbs (1.4 kg).	270 °F (132 °C)	4 minutes	25 minutes
Pouches Large Load	Instruments and dental handpieces, up to 6 lbs (2.7 kg).	270 °F (132 °C)	4 minutes	30 minutes
Pouches & Wrapped Cassettes	Instruments and dental handpieces, up to 11 lbs (5 kg).	270 °F (132 °C)	4 minutes	35 minutes
Wrapped Cassettes	Instruments and dental handpieces, up to 14 lbs (6.4 kg).	270 °F (132 °C)	4 minutes	40 minutes
Unwrapped	Instruments and dental handpieces, up to 18 lbs (8.2 kg).	270 °F (132 °C)	4 minutes	8 minutes
Low Temperature	Textiles, up to 4.4 lbs (2 kg), or instruments and dental handpieces requiring low temperature, up to 5 lbs (2.3 kg).	250 °F (121 °C)	30 minutes	30 minutes

See "Sterilization programs" on page 88 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 52).
- 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.

CYBER SECURITY

In order to improve the IT security of the system, a firewall (iptables) is installed in the system and protects the security of the device from external attacks.

It is recommended not to leave the machine unattended.

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

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

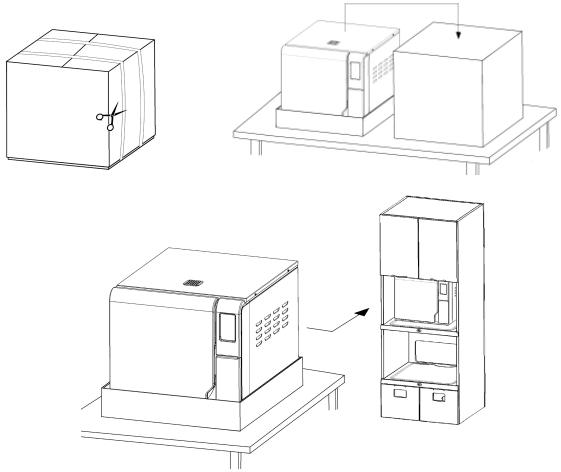
This section deals with the following subjects:

Unpacking

UNPACK THE STERILIZER

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

Weight: 105.8 lbs (48 kg)



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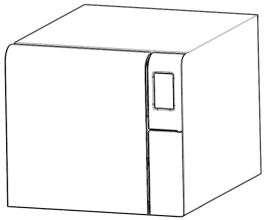
WARNINGS

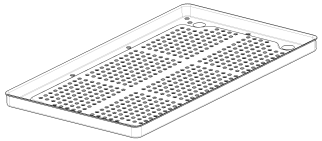
Notice: Check the external condition of the box and the sterilizer. In case of any damage, immediately contact the dealer or shipping agent that has carried out the transport. Keep the packaging for shipping or transporting the sterilizer in the future.

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

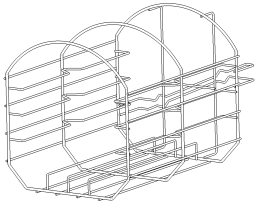
CONTENTS OF THE PACKAGING



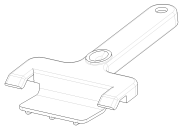
Sterilizer



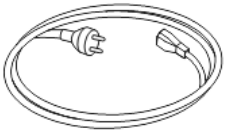
Trays (four)



Chamber rack

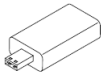


Tray holder

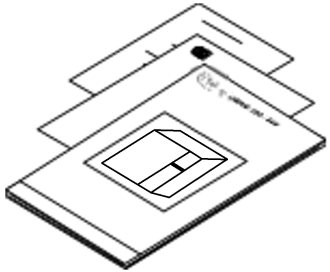


Power cord

Drain tube



USB pen drive loaded with Instructions for Use



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

ITEMS NOT PROVIDED WITH THE STERILIZER

The following items are not provided:

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

See "Accessories, spare parts, consumables" on page 102 for a full list of optional accessories.

Handling

HOW TO RELOCATE THE STERILIZER

Before transport:

- Completely drain both water tanks (see "Draining the used and clean water tank" on page 74).
- 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.

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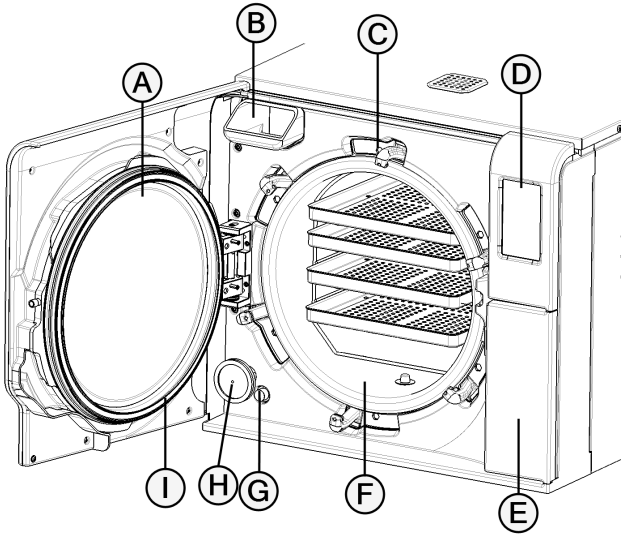
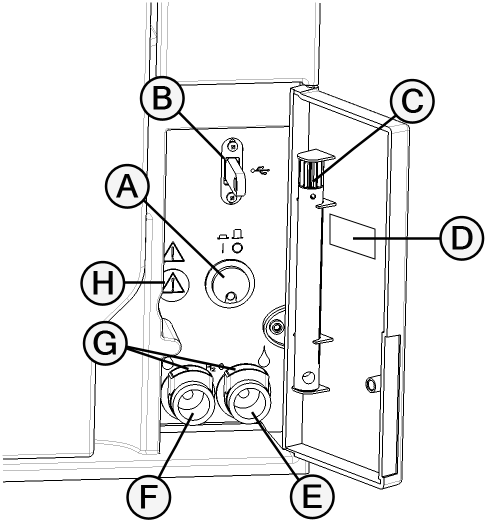
Product description

FRONT VIEW



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

COMPONENTS BEHIND THE SERVICE DOOR



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

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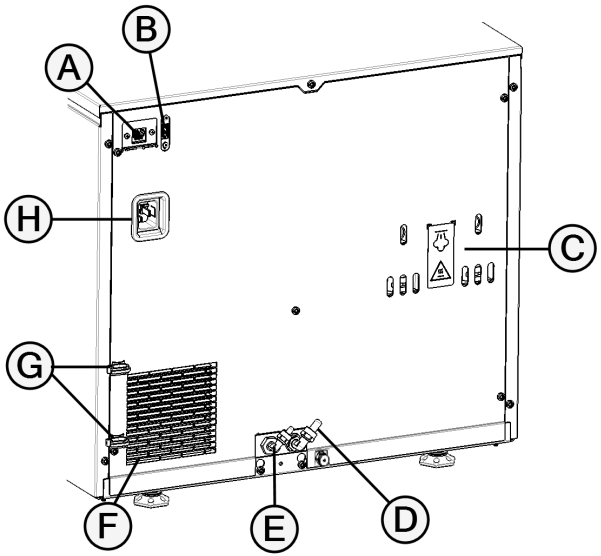
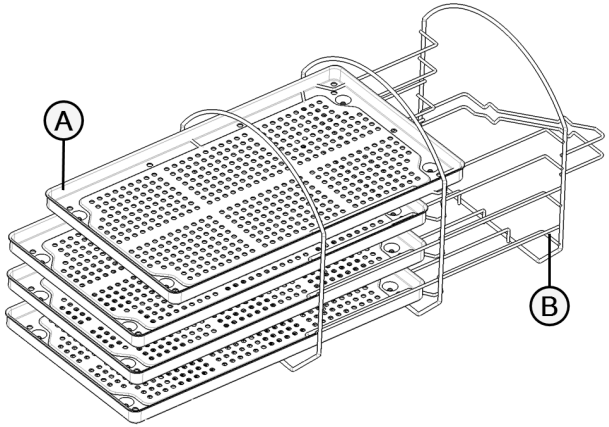
REAR VIEW



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

CHAMBER ACCESSORIES



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

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Installing the sterilizer

LOCATION REQUIREMENTS

Notice:

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

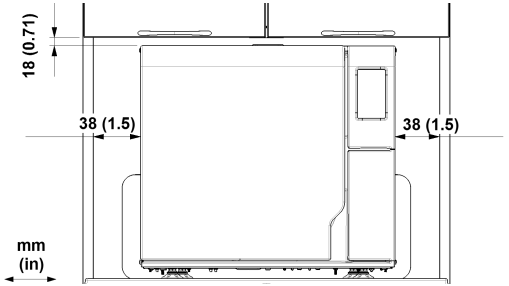
Leave the condenser grid (rear side of the sterilizer) free from anything that might obstruct the air passage.

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

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

Place the sterilizer on a flat and level surface.

Clearance requirements to ensure proper air circulation:



ELECTRICAL CONNECTIONS

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

Notice:

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

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

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

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

WATER CONNECTIONS

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

The manufacturer's warranty is void if the sterilizer was used with water containing either chemical additives, or contaminant levels exceeding those listed in these instructions. See "Feed water specifications (EN 13060)" on page 100 and "Feed water specifications (ANSI/AAMI and AAMI TIR34)" on page 101.

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

WATER TANKS

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

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

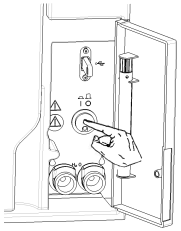
FILLING THE CLEAN WATER TANK

Notice:

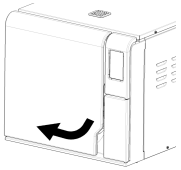
Before carrying out the following steps, make sure that the sterilizer has completed the cycle in progress.

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

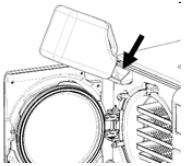
1 If switched-off, switch the sterilizer ON. If the clean water tank is almost empty, an alert appears on the display.



2 Open the chamber door.



3 Fill the clean water tank with a water container (app. 1.7 gal (6.4 l)).
Notice: The water must be demineralized or distilled meeting the specifications listed in these instructions (see "Feed water specifications (EN 13060)" on page 100 and "Feed water specifications (ANSI/AAMI and AAMI TIR34)" on page 101.). Do not add any chemical / additive to the water.



Notice: Take care not to pour the clean water out of the tank.

4 Once the clean water tank is almost full, an audible tone sounds; stop filling.

DRAINING THE USED AND CLEAN WATER TANKS

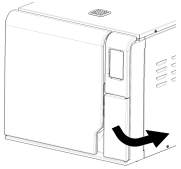
Notice:

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

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

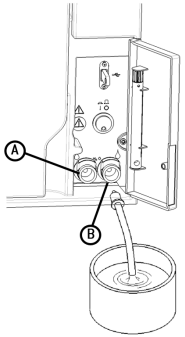
1 If the used water tank is almost full, an alert appears on the display.

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



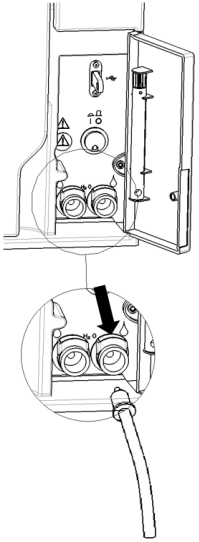
3 Put a container (1.84 gal (7 l) min) below the sterilizer and insert into it the free end of the drain tube.

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

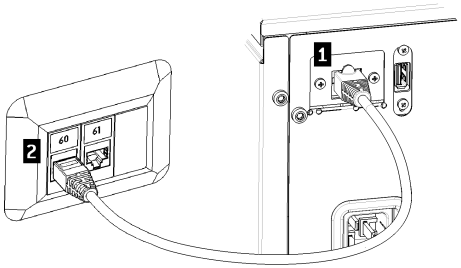


5 Let the water flow from the tank completely.

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



LAN CONNECTION (OPTIONAL)



1 Insert a standard Ethernet cable to 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 key in the USB port.

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

Note: for details see also the "Wi-Fi key & APP - Quick start".

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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.

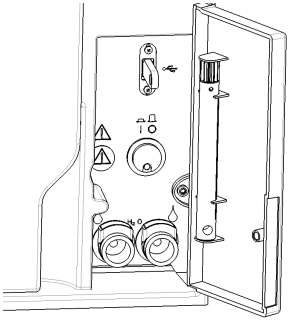
Notice:
Please ensure that all installation requirements are met before plugging the sterilizer. See "Connection diagrams" on page 99.
No other devices should be connected to the sterilizer power panel circuit.

1. Place the sterilizer on a sturdy, flat and level surface.
2. Open the chamber door, remove all items from the sterilizer chamber except the chamber rack. Remove all plastic covers from trays.
3. Connect the auto-fill and auto-drain tubes in the rear of the sterilizer (optional).
4. Connect the Ethernet cable or the Wi-Fi key in the rear of the sterilizer (optional).
5. Attach the power cord to the socket in the rear of the sterilizer and route the cord through the cable guides.
6. Connect the power cord to a wall outlet. For power supply requirements, see "Technical data" on page 97.

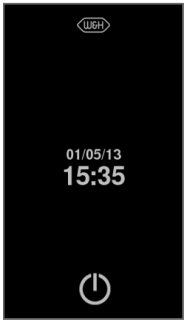
Operating the sterilizer

POWER THE STERILIZER ON/OFF

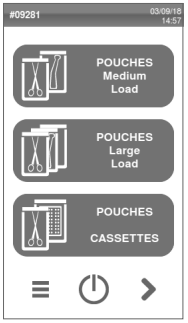
1. Press the power switch behind the service door: once switched ON, the visual indicator on the power switch will turn green.



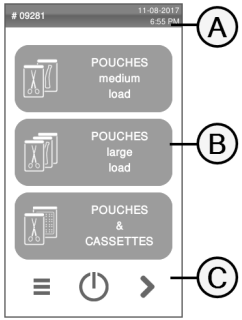
2 After a quick autotest the sterilizer automatically turns in standby mode. See "Standby mode" on page 35.



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



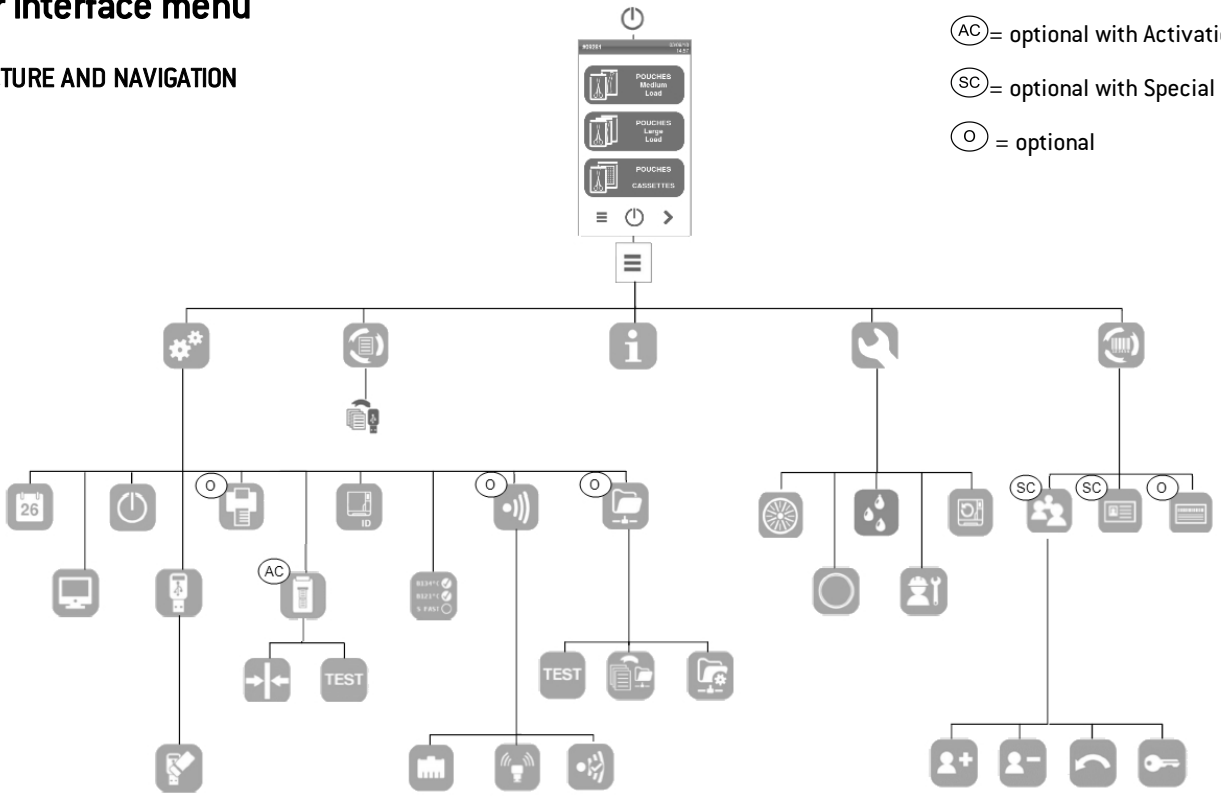
HOMEPAGE DESCRIPTION



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

User interface menu

STRUCTURE AND NAVIGATION



(AC) = optional with Activation code

(SC) = optional with Special code

(O) = optional

MAIN MENU FUNCTIONS

Icon	Label	Function
	**Menu**	Opens the menu.
	**Device Setting**	Sets the device.
	**Cycle History**	Shows all the sterilization cycles.
	**Save**	Saves all the sterilization cycle reports in the USB pen drive.
	**System Info**	■ Shows the system information ■ During a cycle, shows the cycle parameters.
	**Maintenance**	Carries out the maintenance procedure.
	**Traceability**	Opens the pages to: ■ monitor the performed cycle data; ■ manage users; ■ set the label printing options.

DEVICE SETTING MENU FUNCTIONS

Icon	Label	Function
	**Date & Time**	Sets time and date values and format.
	**Display**	Sets the display brightness.
	**Standby**	Changes the standby mode delay.
	**USB Pen Drive**	Opens the formatting page of the USB pen drive.
	**Format**	Formats the USB pen drive.
	**Printer**	Selects the printer model connected to the sterilizer. The icon appears disabled if the printer/Ethernet cable/Wi-Fi key is not connected.
	**Label Printer**	Optional, activated with an activation code. Permits to select the label printer and sets the printout layout.
	**Calibration**	Adjusts the label printer to the edge of the label.

Icon	Label	Function
	**Test**	Prints a test label.
	**Sterilizer Name**	Sets the sterilizer name.
	**Cycle Exclusion**	Sets the cycles menu.
	**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.
	**Remote Folder**	Only with a network connection set. Opens the page to manage the remote storage.
	**Test**	Only with a network connection set. Checks if the files can be copied to the specified location.

Icon	Label	Function
	**Save all**	Only with a network connection set. Copies all the files in the specified location in the network.
	**Settings**	Only with a network connection set. Sets the parameters of the network location.
	**USB options**	Enables/disables USB warning messages.
	**Traceability settings**	Chooses if the sterilizer is master or slave.

MAINTENANCE MENU FUNCTIONS

Icon	Label	Function
	**Bact. Filter**	■ Shows the status of the consumables; ■ Resets the cycle counter.
	**Door Gasket**	
	**Water**	Accesses and checks the water conductivity.
	**Service**	Opens the **Service** menu.

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

TRACEABILITY MENU FUNCTIONS

Icon	Label	Function
	**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 an activation code. Administrator only. Permits the following: ■ Identify and save the operator who starts the cycle and releases the load. ■ Protect with a password the cycle start, the cycle stop and the load release.

Icon	Label	Function
	**Label Printer**	Optional, activated with an activation code. ■ Sets the maximum storage time of the wrapped sterilized items. ■ Sets the automatic or manual printing of the labels.

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.

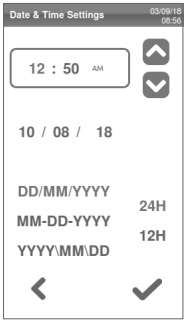
Icon	Function
	Increases/decreases the value.
	Indicates that the option is active/not active.
	Indicates that the option is enabled/disabled.
	Show an animation about the replacement procedure.

Sterilizer setup

SET THE DATE AND TIME

To change the current date and time:

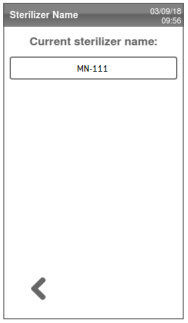
1. On the homepage tap ☰ > ⚙ > 📅
2. Tap the value you want to change (time, date, format): the highlighted value can be changed.
3. Tap ⌃ or ⌄ to change the value.
4. Tap ✓ to confirm.



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.

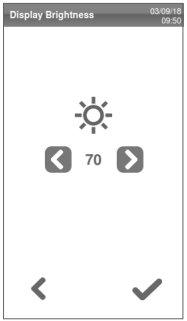


3. Enter the new sterilizer name.
4. Tap ✓ to confirm.

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.



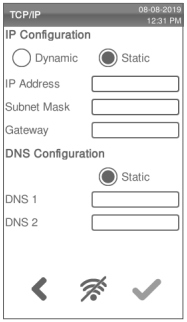
CONNECT TO A NETWORK

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.

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 key, tap 📶: after a while, the sterilizer shows the available networks found. Choose the network, enter the credentials in the further screen, then tap ✓ to confirm: the TCP/IP screen appears.

Note: the 🔌 and 📶 icons are disabled if the connectivity means (cable or Wi-Fi 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 will not be 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.

User authentication (optional)

FUNCTION AVAILABILITY

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

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

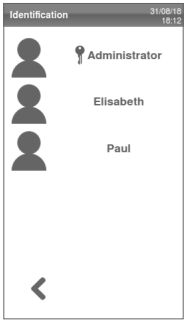
Change your PIN the first time you use the sterilizer and if your PIN has been reset. This will prevent other users to use your account.

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

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

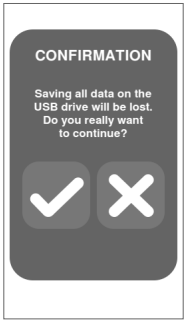
1 On the homepage tap ☰ > ⚙ > › > 🖴

2 Insert the USB pen drive in one of the two USB ports.

3 Tap 🖴 .

4 Tap ✓ to confirm: all data will be erased.

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



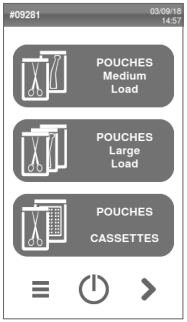
Standby mode

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.

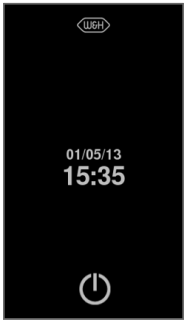
ENTER THE STANDBY MODE MANUALLY

1. Homepage
2. Tap ⏻.



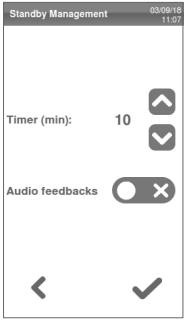
EXIT THE STANDBY MODE

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.



Administrator

CONTENTS

This section deals with the following subjects:

User management (optional)

FUNCTION AVAILABILITY

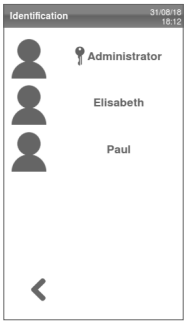
To access the user management functions the suitable special code (USERSON) must be entered. The special code is required only at the first access to the **User Management** ( ) or the **Options** ( ) menus: after the code was entered, the function is enabled and there is no need to enter the code again.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

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".

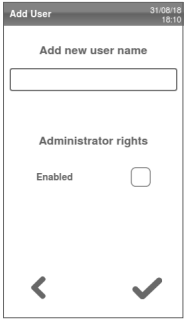
ADD A USER

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.



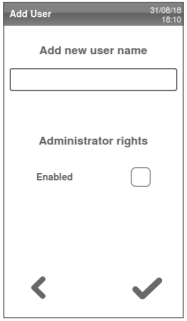
6 Enter the new user name and tap ✔ to confirm.

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.

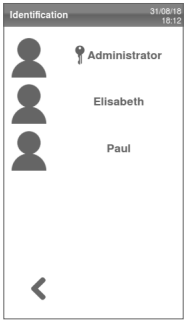


DELETE A USER

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.

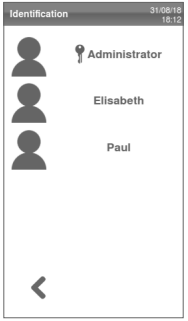
6 Tap to confirm.

RESET A USER PIN

1 On the homepage tap > > > >

2 Tap your user name.

3 Enter the PIN and tap to confirm.

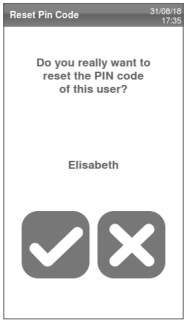


4 Tap and the user name for which you want to reset the PIN.

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 their PIN before reusing the sterilizer.



Traceability options (optional)

FUNCTION AVAILABILITY

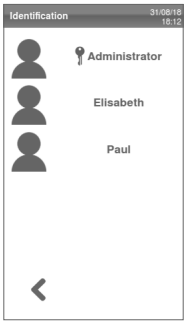
To access the user management functions the suitable special code (USERSON) must be entered. The special code is required only at the first access to the **User Management** ( ) or the **Options** ( ) menus: after the code was entered, the function is enabled and there is no need to enter the code again.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

WHO CAN SET THE TRACEABILITY OPTIONS

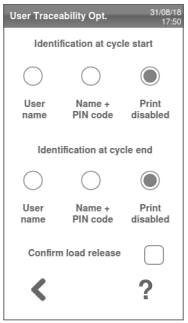
Only a user with administrator rights can set the traceability options.

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.



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Hide/Unhide a cycle

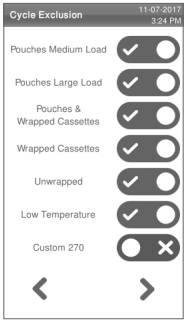
WHO CAN HIDE/UNHIDE A CYCLE

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/importer.

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.

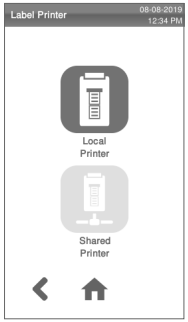
LABEL PRINTER SETUP

Labels can be printed by a local label printer or (only with a LAN connection set) a shared label printer. The local label printer is

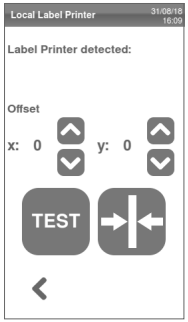
connected to the sterilizer, while the shared label printer is connected to another sterilizer in the network.

SELECT AND CALIBRATE A LOCAL LABEL PRINTER

1. On the homepage tap ☰ > ⚙ > › > 🖨
2. Tap 🖨: the local printer is located automatically.



3. Tap ⇥⇤ to center the printout properly in the label area.
4. Tap TEST to print a test label.
5. If the printout is not duly centered, tap ⌃ or ⌄ to center it horizontally (x) and vertically (y).
6. If necessary, tap TEST to print another test label and repeat step 4.
7. Tap ‹ to confirm the settings and go back to the previous page.



SELECT A SHARED LABEL PRINTER

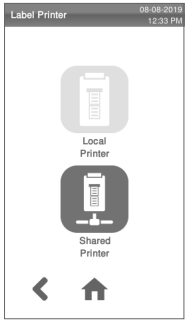
Note: Function available only if the LAN/Wi-Fi connection has been activated (optional).

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 from which the printer is not physically connected, tap homepage > ☰ > ⚙ > › > 🖨.

6 Tap 🖨.



7 Tap the text box and enter the IP address previously noted.

8 Tap TEST to confirm.

9 From the sterilizer to which the printer is connected, confirm the printer sharing.

10 Tap TEST again to print a test label.

Label printer usage (optional)

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

FUNCTION AVAILABILITY

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

AUTOMATIC PRINTING OPTION

The automatic printing option permits to automatically print a preset number of labels after a successful sterilization cycle. The labels are printed only after the user has identified him/herself (with password if required) and the load has been checked and released, if these options have been enabled by the administrator.

For the automatic label printing, a maximum storage time in weeks can be set. This value is used to calculate the expiry date to be printed on the labels (see "Label content description" on page 47).

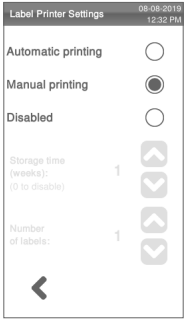
SET THE AUTOMATIC LABEL PRINTING

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.

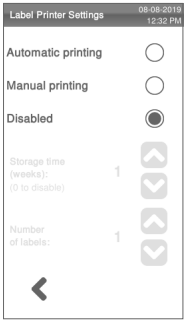
1. On the homepage tap ☰ > › > > >
2. Activate **Manual printing**.
3. Tap ‹ to confirm and go back to the previous page.



DISABLE THE LABEL PRINTING

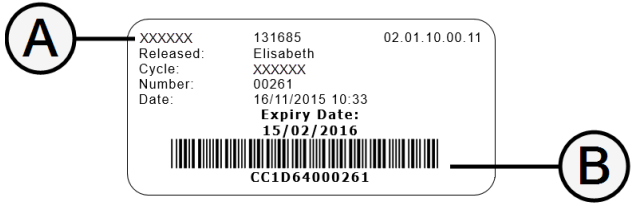
If the label printing is disabled, no label can be printed at the end of a sterilization cycle.

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.

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 HANDPIECES 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.)

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DENTAL HANDPIECES 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 HANDPIECES 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.

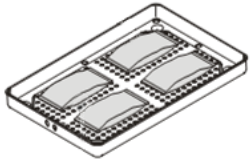
CORRECT LOAD PLACEMENT

WARNING! Do not overload trays and the chamber. Adhere to the maximum load weight limits (see "Sterilization programs" on page 88).

Wrap items with porous wrapping materials to facilitate steam penetration and drying (e.g. sterilization bags for autoclaves). Always use the chamber rack to allow adequate steam circulation.

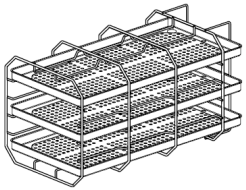
Follow these requirements:

Load type	Placement
Hinged instruments (e.g., forceps, extraction pliers, etc.)	In open position
Tubes	Place tubes on a tray allowing the ends to remain open. Do not bend tubes.
Cassettes	Cassettes can be placed vertically or horizontally into the chamber rack (vertical placement enhances drying). When placing cassettes horizontally, slide them into the rack position without putting them on trays (if size allows) to enhance drying. When sterilizing double-decker cassettes, place them in the lowest rack position as there is more space height-wise.

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. 
Empty containers or non-perforated trays	Upside down to prevent accumulation of water
Items made from different materials (stainless steel, carbon steel, aluminum, etc.)	On separate trays or wrapped/pouched
Instruments manufactured from carbon steel	Place paper among them and the trays to avoid rusty spots

PARTIAL LOAD

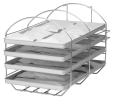
If the chamber is just partially loaded, place the load in such a way that the space in-between the trays is maximized. Spread items evenly on multiple trays. Below is a example with three trays.



Typical loads

EXAMPLES

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

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

Prepare the sterilizer

WARNINGS

Notice: Use only distilled or demineralized water (see "Feed water specifications (EN 13060)" on page 100 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 97 for the tank volume.

INSERTING THE CHAMBER RACK INTO THE STERILIZER

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

1. Open the chamber door and align the chamber rack at the center/bottom of the chamber.
2. Push the chamber rack gently into position until it clicks into place.
3. Insert cassettes horizontally or vertically, or insert trays. See "Load maintenance and preparation" on page 48 for load requirements .
4. Close the door.

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

GENERAL RECOMMENDATIONS

Follow these recommendations to obtain the most from the drying:

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

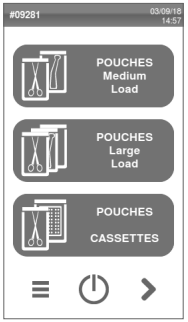
Sterilization cycle management

RUN A STERILIZATION CYCLE

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

1 On the homepage tap the desired cycle.

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

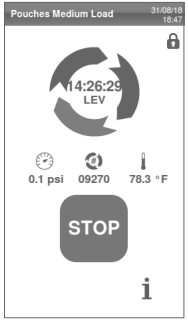


2 Check the cycle requirements.

3 Tap ⚙ to set a different start time. See "Delay the sterilization cycle start" on page 54.

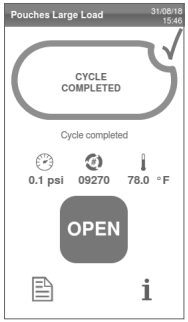
4 Tap ▶: the door locks. If you have not set a different start time, the cycle starts immediately.

5 Tap i to view the cycle information. See "View the cycle parameters" on page 56.



6 The sterilization is completed. Tap to view the cycle summary (to check the cycles values manually, see "STERILIZATION CYCLE MONITORING" below) or tap i to view the cycle information. See "View the cycle parameters" on page 56.

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



STERILIZATION CYCLE MONITORING

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

US - Canada version

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

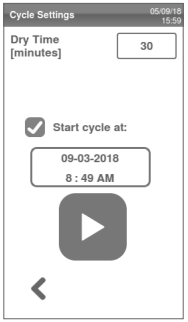
Standard version

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

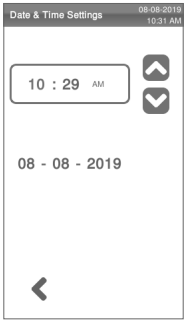
DELAY THE STERILIZATION CYCLE START

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

1. On the homepage tap the cycle and ⚙.
2. Tap **Start cycle at**.
3. If you want to change the start time, tap the time or the date: a settings page opens.



4. Tap the number you want to change and tap ⌃ or ⌄ to increase it or decrease it.
5. Tap ‹ to confirm. This date and time become the scheduled default start time for all next sterilization cycles.



6 Tap ▶ to start the countdown for the current cycle.

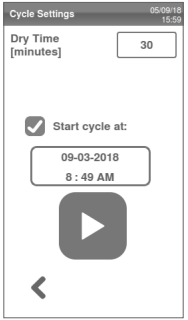
Note: You can decide to start the cycle immediately or stop the countdown at any time.

SET THE DRYING TIME

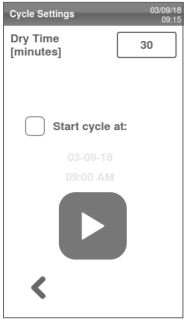
Dry time is set by default for each sterilization program. The default drying time for each sterilization program can only be increased from the default value.

1 On the homepage tap the cycle and ⚙.

2 Tap **Dry time**.



3 Enter the value and tap ✔ to confirm. This becomes the default dry time for the current sterilization program.

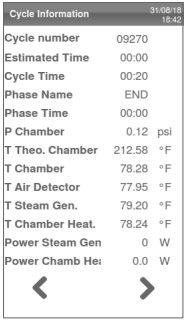


VIEW THE CYCLE PARAMETERS

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

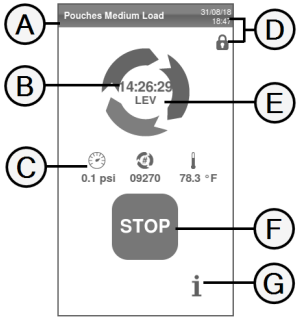
1 While the sterilization cycle is running or when cycle ends tap ℹ: the cycle information page opens.

2 Tap ‹ or › to scroll the pages.



STERILIZATION CYCLE PAGE

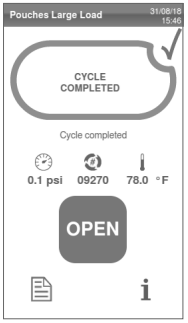
Following are the information displayed while a cycle is running:



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

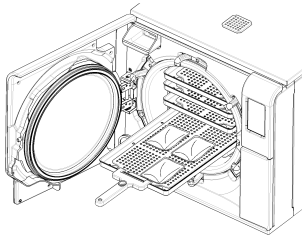
When a cycle is successfully finished, the "Cycle completed" message appears on the screen. To end the cycle:



1. Tap to view the cycle summary or tap i 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.

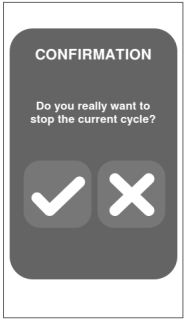
A cycle can be manually aborted at any time. To stop a cycle:

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" below.

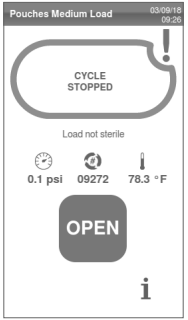
5 Tap i to view the cycle parameters. See "View the cycle parameters" on page 56.

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 200 cycles and the analytical reports of the last 100 cycles. All reports can also be saved on the USB pen drive or in a specific remote folder in the network if the sterilizer is connected to a LAN (optional). A minimum of 10000 cycles are storable in the provided USB.

STORED REPORT FORMAT

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

WHAT HAPPENS WITH UNSAVED CYCLES

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

VIEW CYCLE HISTORY

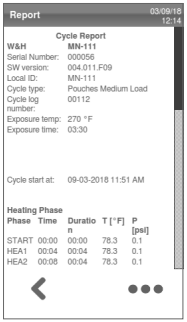
To view the sterilization cycle history:

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 •••.



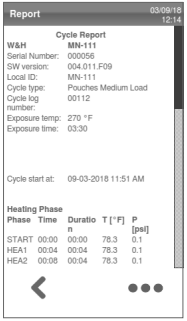
4. Tap  to print the report, or tap  to save the report on the USB pen drive.

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 ≡ > .

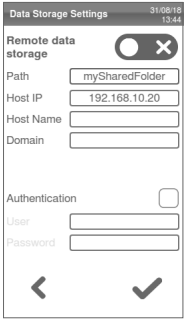
2 Tap : after the confirmation all sterilization cycle reports are stored in the USB.

SET THE REMOTE FOLDER FOR SAVING THE REPORTS (OPTIONAL)

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.

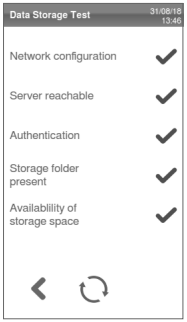


5. Not mandatory. Enter the domain name.
6. Tap ☐ to require the authentication credentials to access the remote storage folder and enter the user name and password.
7. Tap ✔ to save.
8. Tap ‹ to go back to the previous page.
9. To check if the parameters entered are valid, see "Test the data storage (optional)" on the next page.

TEST THE DATA STORAGE (OPTIONAL)

Note: The test function is available only if the remote data storage is enabled. See "Set the remote folder for saving the reports (optional)" 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.
4. Tap ‹ to go back to the previous page.

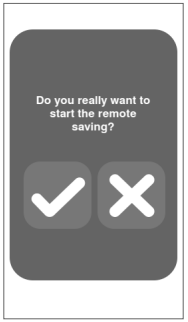


SAVE ALL THE CYCLE REPORTS IN A REMOTE FOLDER (OPTIONAL)

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

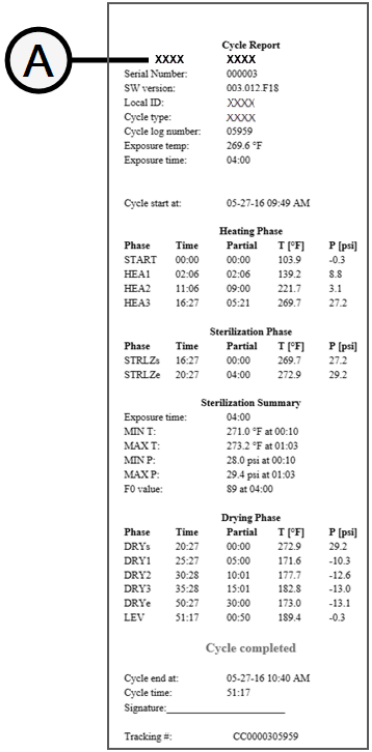
Only the last 400 cycles in HTML and 100 cycles in SCL in the sterilizer memory can be saved in the remote folder.

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



CYCLE REPORT STRUCTURE

Following the structure of a cycle report:



Data	Description
A	Sterilizer brand and model
Serial Number	Sterilizer serial number
SW version	Software version number
Local ID	Surgery – practice – doctor name
Cycle type	Name of the executed cycle
Cycle log number	Cycle counter
Exposure temp	Programmed exposure temperature
Exposure time	Programmed exposure time
Cycle start at	Cycle start date and time
Heating Phase	Phase: conditioning phases (steam pressure pulses). See "Sterilization program phases" on page 93. ■ Time: phase duration ■ Partial: xxxxxxx ■ T [F°]: maximum temperature ■ P [psi] : maximum pressure
Sterilization phase	Phase: sterilization phase. See "Sterilization program phases" on page 93. ■ Time: phase duration ■ Partial: xxxxxxx ■ T [F°]: maximum temperature ■ P [psi] : maximum pressure

Data	Description
Sterilization Summary	Exposure time ■ MINT: Min. temperature ■ MAX T: Max. temperature ■ MIN P: Min. pressure ■ MAX P: Max. pressure ■ F0 value
Drying Phase	Phase: Exhausting drying phase. See "Sterilization program phases" on page 93 ■ Time: phase duration ■ Partial: xxxxxxx ■ T [F°]: maximum temperature ■ P [psi] : maximum pressure
"Cycle completed"	Cycle end conditions (Cycle outcome)
Cycle end at	Cycle end date and time
Cycle time	Cycle duration
Signature	Operator signature
Tracking	Tracking code for traceability

Maintenance

CONTENTS

This section deals with the following subjects:

Warnings for maintenance operations

WARNINGS

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

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

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

User maintenance

MAINTENANCE BY THE USER

Frequency [1]	Cycles [1]	Operation
Monthly	50	Cleaning the door gasket and the chamber face side. See "Cleaning the door gasket and the chamber face side" on page 68 Clean the chamber, trays and the rack. See "Cleaning the chamber and the chamber accessories" on page 69 Cleaning the chamber filters. See "Cleaning the chamber filters" on page 70 Cleaning the external surfaces of the sterilizer. See "Cleaning the external surfaces of the sterilizer" on page 70
Yearly[2]	1200[2]	Replace the door gasket. See "Replacing the door gasket" on page 71 Replace the HEPA filter. See "Replacing the HEPA filter" on page 73

Note [1]: Whichever occurs first.

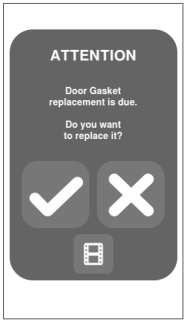
Note 2: Even if the maximum cycle number is not reached, it is recommended to replace the consumable parts every year, or if they appear worn or damaged, or if the filters are clogged or discolored.

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.

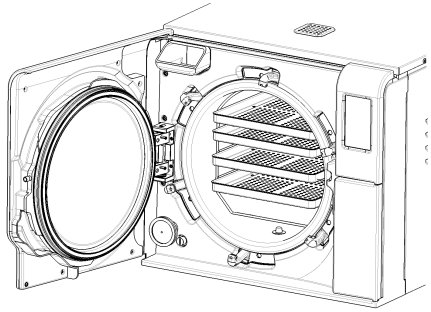
Monthly or 50-cycle maintenance

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.
2. Rinse with clean water.

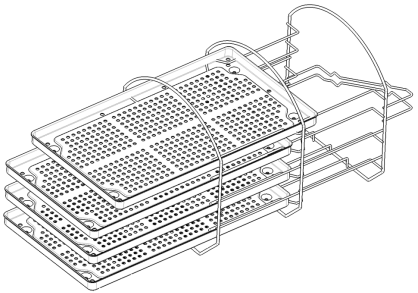
Note: when the seal is new it might be necessary to hold the door gently closed at the sterilization start.



CLEANING THE CHAMBER AND THE CHAMBER ACCESSORIES

Proceed as follows:

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

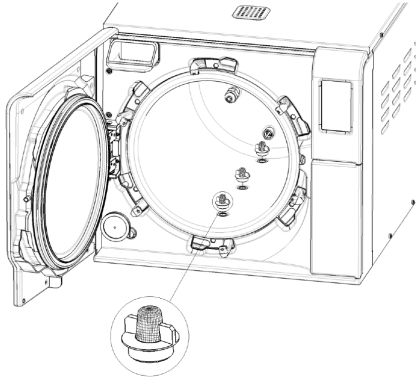


Note: The trays and the tray holder may also be cleaned in a washer disinfector.

CLEANING THE CHAMBER FILTERS

Proceed as follows:

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



CLEANING THE EXTERNAL SURFACES OF THE STERILIZER

Proceed as follows:

1. Clean all external sterilizer covers with a slightly damp cloth moistened with water.
   Notice: Never use disinfectants, detergents or abrasive products.

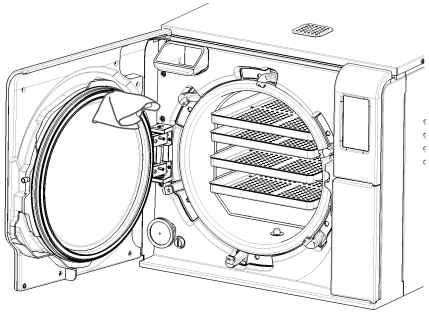
1200-cycle or yearly maintenance

REPLACING THE DOOR GASKET

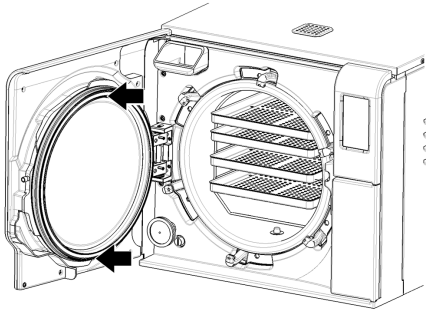
Notice: The door gasket needs to be replaced every 1200 sterilization cycles or once a year, whichever come first. A replacement message alerts when replacement is due. If the consumables is replaced prior to the message, you have to reset the consumable cycle counter.

Proceed as follows:

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

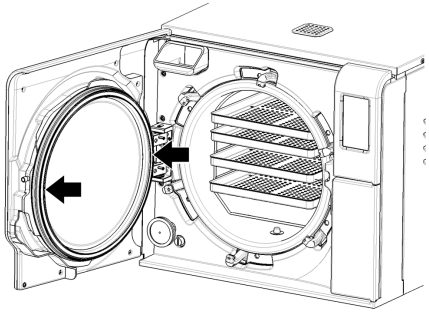


4 Insert the new seal and press first up and down.



5 Press left and right.

6 Make sure the door gasket is seated evenly.

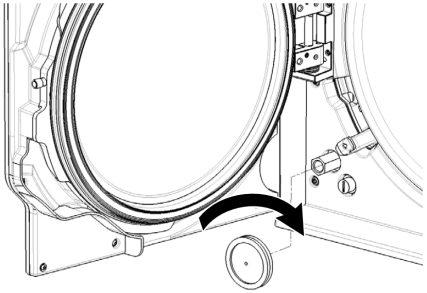


REPLACING THE HEPA FILTER

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

Proceed as follows:

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

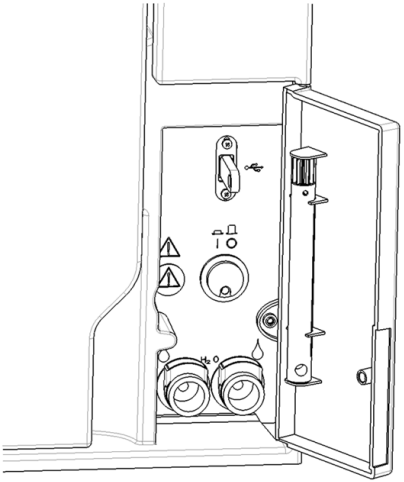


Extraordinary maintenance

DRAINING THE USED AND CLEAN WATER TANK

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

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



Disposal

DISPOSAL RESPONSIBILITY

- Separate the various components according to the materials they are made of.
- Drop the sterilizer with a company that specializes 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, call technical service.

Code	Description	Actions
0xx	Load cannot be considered sterile. See "End of a sterilization cycle" on page 57	Repeat the cycle. If the problem persists, call 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, call 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, call 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, call 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.	
18x	Chamber filters clogged. Remove and clean the chamber filters. See error "13x to 16x" above.	Repeat the cycle. If the problem persists, call service.
	Bacteriological filter clogged. Check and replace if necessary.	
2xx	Switch the sterilizer OFF and ON.	Repeat the cycle. If the problem persists, call service.
	Wait for the chamber to cool down. Reset the safety thermostat (see "Extraordinary maintenance" on page 74).	
3xx	Check the door gasket. Clean or replace it if necessary.	Repeat the cycle. If the problem persists, call service.
	Clean the chamber face side.	
	Check the load does not exceed the MAXIMUM WEIGHT LIMITS.	

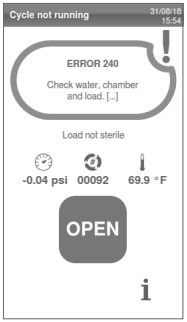
Code	Description	Actions
4xx	Clean water error (bad quality, clean tank low level, high consumption of water).	Repeat the cycle. If the problem persists, call service.
	Drain and/or refill the clean water tank.	
	Check the door gasket. Clean or replace it if necessary.	
5xx	Check if there are hurdles on the door locking area (chamber rack, loads, objects, ...).	Repeat the cycle. If the problem persists, call 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.

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 will appear 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).

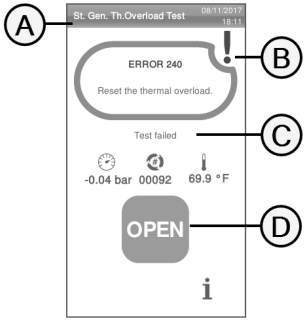
VIEW AND SAVE THE ERROR LOG

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 76.
C	Warning messages.
D	Open button that appears after the reset phase had finished.

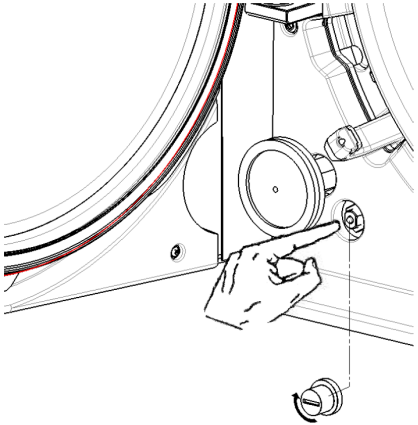
WARNING MESSAGES

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. Wait for the sterilizer to finish the error reset phase and follow the instructions on the display.
2. Switch the sterilizer OFF and remove the mains cable.
3. Wait for the sterilizer to cool down.
4. Open the sterilizer door.
5. Unscrew the cap and push on the reset button of the thermostat switch.
6. A click sound indicates that the thermostat switch has been reset.
7. Screw the cap.
8. Connect the mains cable and switch the sterilizer ON.



Note: If the thermostat operates repeatedly, call technical service.

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.	Call 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 74.
	Electric - electronic fault.	Call technical service.
At the end of the cycle, there is residual water in the chamber.	Sterilizer not properly leveled.	Properly level the surface the sterilizer is placed on.
	Overloaded chamber.	Comply with the maximum load weight limits for each type of load. Always use the chamber rack for trays and cassettes. See ."Load maintenance and preparation" on page 48
	Chamber filter clogged.	Remove and clean the chamber filter.
	One or more chamber filter caps not well-positioned.	Mount the chamber filter caps properly (see "User maintenance" on page 66)
	Load incorrectly placed.	See "Load maintenance and preparation" on page 48

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 100.
	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 48
	Chamber, trays, chamber rack dirty.	Clean the chamber and wash the chamber furniture.
	Contact between instruments of different materials.	Ensure that instruments of different materials do not touch (aluminum, carbon or stainless steel, etc.); place them on different trays or cassettes or pouch them. See "Load maintenance and preparation" on page 48
	Scale deposits on the chamber.	Clean the chamber and use water of good quality. See "Water quality" on page 100.
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.
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 100.
	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 into 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”. Call technical service if the problem persists. Remove the HEPA filter to get the pressure released. Replace the filter. **Note**: The HEPA filters need to be replaced every 1200 cycles.
The sterilization process phase of a sterilization cycle was longer than expected.	The chamber temperature dropped below the minimum threshold and the software performed a successful recovery.	Wait for cycle completion. If the problem occurs frequently, call 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 66

Emergency door opening

WARNING ABOUT OPENING THE DOOR IN EMERGENCY

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

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

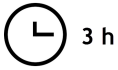
Notice: Carry out this procedure only as indicated and with the sterilizer in the indicated conditions. Any attempt to open the door in a different way can seriously damage the sterilizer.

OPENING TOOL

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

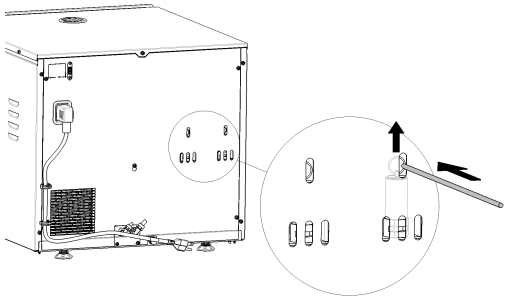
OPEN THE DOOR IN EMERGENCY

1 Unplug the sterilizer and wait at least three hours.



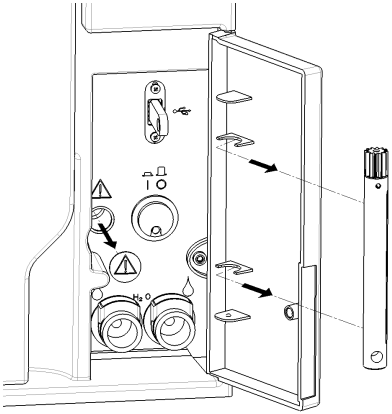
2 Remove the power connection (back side)

3 Release the chamber pressure through the ring of the safety valve (sterilizer rear side) or wait three hours until the pressure has naturally decreased to the environment pressure.

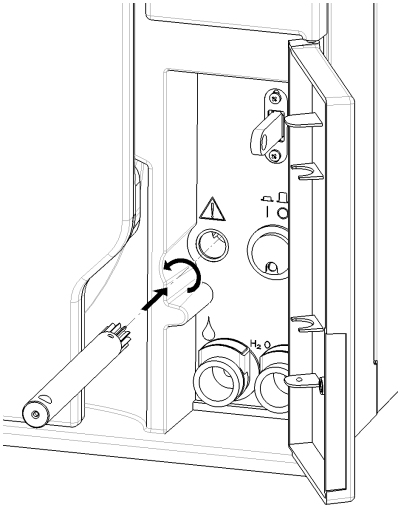


4 Extract the opening tool placed behind the service door

5 Remove the cap



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



Technical data

CONTENTS

This section deals with the following subjects:

Sterilization programs

WARNINGS

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

STANDARD STERILIZATION PROGRAMS

The sterilizer offers six preset FDA cleared sterilization programs that comply with the American National Standard ANSI/AAMI ST55:2010.

Program	Recommended use	Sterilization Temperature	Load example [1]
Pouches Medium Load	Instruments and dental handpieces, up to 3 lbs (1.4 kg). Pouches, wrapped, unwrapped and naked.	270 °F (132 °C)	40 pouched instruments (probes, explorers, mirrors, etc.), 4 pouched dental handpieces.
Pouches Large Load	Instruments and dental handpieces, up to 6 lbs (2.7 kg). Pouches, wrapped, unwrapped and naked.	270 °F (132 °C)	80 pouched instruments (probes, explorers, mirrors, etc.), 8 pouched dental handpieces.
Pouches & Wrapped Cassettes	Instruments and dental handpieces, up to 11 lbs (5 kg). Pouches, wrapped, unwrapped and naked.	270 °F (132 °C)	40 pouched instruments (probes, explorers, mirrors, etc.), 8 pouched dental handpieces, 2 wrapped Hygiene cassettes (8" x 5.5" | 20.3 mm x 13.8 mm), 1 wrapped Restorative cassette (8" x 11" | 20.3 mm x 27.9 mm), 2 wrapped Exam cassettes (8" x 3" | 20.3 mm x 7.6 mm).
Wrapped Cassettes	Instruments and dental handpieces, up to 14 lbs (6.4 kg). Pouches, wrapped, unwrapped and naked.	270 °F (132 °C)	4 wrapped Hygiene cassettes (8" x 5.5" | 20.3 mm x 13.8 mm), 2 wrapped Restorative cassettes (8" x 11" | 20.3 mm x 27.9 mm), 4 wrapped Exam cassettes (8" x 3" | 20.3 mm x 7.6 mm)

Program	Recommended use	Sterilization Temperature	Load example [1]
Unwrapped	Instruments and dental handpieces, up to 18 lbs (8.2 kg). Unwrapped, naked.	270 °F (132 °C)	80 unwrapped instruments (probes, explorers, mirrors, etc.), 8 unwrapped dental handpieces.
Low Temperature	Textiles, up to 4.4 lbs (2 kg), or instruments and dental handpieces requiring low temperature, up to 5 lbs (2.3 kg). Pouches, wrapped, unwrapped and naked.	250 °F (121 °C)	65 pouched instruments (probes, explorers, mirrors, etc.), 6 pouched dental handpieces.

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

CUSTOM STERILIZATION PROGRAMS

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

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

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

STERILIZATION PROGRAM OPTIONS (200–240 V AC VERSION)

WARNING! The sterility of items processed unwrapped is compromised on exposure to non-sterile environments. Ensure that items are dry when removed from the sterilizer. If the default drying time is not adequate for the load to be sterilized, additional drying time can be added (see "Sterilization cycle management" on page 52). To load properly the sterilizer see "Prepare the sterilizer" on page 51.

		Unwrapped	Pouches Medium Load	Pouches Large Load	Pouches & Wrapped Cassettes	Wrapped Cassettes	Low Temperature
Sterilization temperature		270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	250 °F (121 °C)
Sterilization program type according ANSI/AAMI ST55:2010		Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Gravity displacement
Sterilization program type according EN 13060		Class S	Class S	Class S	Class S	Class S	Class S
Sterilization time (minutes)		4	4	4	4	4	30'
Drying time (minutes)		Range: 8–99 Recommended: 8	Range: 25–99 Recommended: 25	Range: 30–99 Recommended: 30	Range: 35–99 Recommended: 35	Range: 40–99 Recommended: 40	Range: 30–99 Recommended: 30
Total program duration (min) [1] *Full loaded including drying time*		26–30	43–46	48–52	53–58	58–63	73–76
Load type	**Pouched, wrapped instruments and dental handpieces**	No	Yes	Yes	Yes	Yes	Yes
	Unwrapped instruments and dental handpieces	Yes	Yes	Yes	Yes	Yes	Yes
	Wrapped cassettes	No	Yes	Yes	Yes	Yes	Yes
	Unwrapped cassettes	Yes	Yes	Yes	Yes	Yes	Yes
	Textiles	No	No	No	No	No	Yes
Maximum load weight (excluding trays)		instruments: 18 lb (8.1 kg)	instruments: 3 lb (1.4 kg)	instruments: 6 lb (2.7 kg)	instruments: 11 lb (5 kg) included cassettes	instruments: 14 lb (6.3 kg) included cassettes	instruments: 5 lb (2.2 kg) included trays or textile: 4.4 lb (2 kg)

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

STERILIZATION PROGRAM OPTIONS (100–125 V AC VERSION)

WARNING! The sterility of items processed unwrapped is compromised on exposure to non-sterile environments. Ensure that items are dry when removed from the sterilizer. If the default drying time is not adequate for the load to be sterilized, additional drying time can be added (see "Sterilization cycle management" on page 52). To load properly the sterilizer see "Prepare the sterilizer" on page 51.

		Unwrapped	Pouches Medium Load	Pouches Large Load	Pouches & Wrapped Cassettes	Wrapped Cassettes	Low Temperature
Sterilization temperature		270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	270 °F (132 °C)	250 °F (121 °C)
Sterilization program type according ANSI/AAMI ST55:2010		Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Dynamic-air-removal: SFPP	Gravity displacement
Sterilization program type according EN 13060		Class S	Class S	Class S	Class S	Class S	Class S
Sterilization time (minutes)		4	4	4	4	4	30'
Drying time (minutes)		Range: 8-99 Recommended: 8	Range: 25–99 Recommended: 25	Range: 30–99 Recommended: 30	Range: 35–99 Recommended: 35	Range: 40–99 Recommended: 40	Range: 30–99 Recommended: 30
Total program duration (min) [1] *Full loaded including drying time*		30–39	47–53	52–58	57–64	62–71	75–79
Load type	**Pouched, wrapped instruments and dental handpieces**	No	Yes	Yes	Yes	Yes	Yes
	Unwrapped instruments and dental handpieces	Yes	Yes	Yes	Yes	Yes	Yes
	Wrapped cassettes	No	Yes	Yes	Yes	Yes	Yes
	Unwrapped cassettes	Yes	Yes	Yes	Yes	Yes	Yes

		Unwrapped	Pouches Medium Load	Pouches Large Load	Pouches & Wrapped Cassettes	Wrapped Cassettes	Low Temperature
	Textiles	No	No	No	No	No	Yes
Maximum load weight (excluding trays)		instruments: 18 lb (8.1 kg)	instruments: 3 lb (1.4 kg)	instruments: 6 lb (2.7 kg)	instruments: 11 lb (5 kg) included cassettes	instruments: 14 lb (6.3 kg) included cassettes	instruments: 5 lb (2.2 kg) included trays or textile: 4.4 lb (2 kg)

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

Sterilization program phases

LEGEND OF THE STERILIZATION PROGRAM PHASES

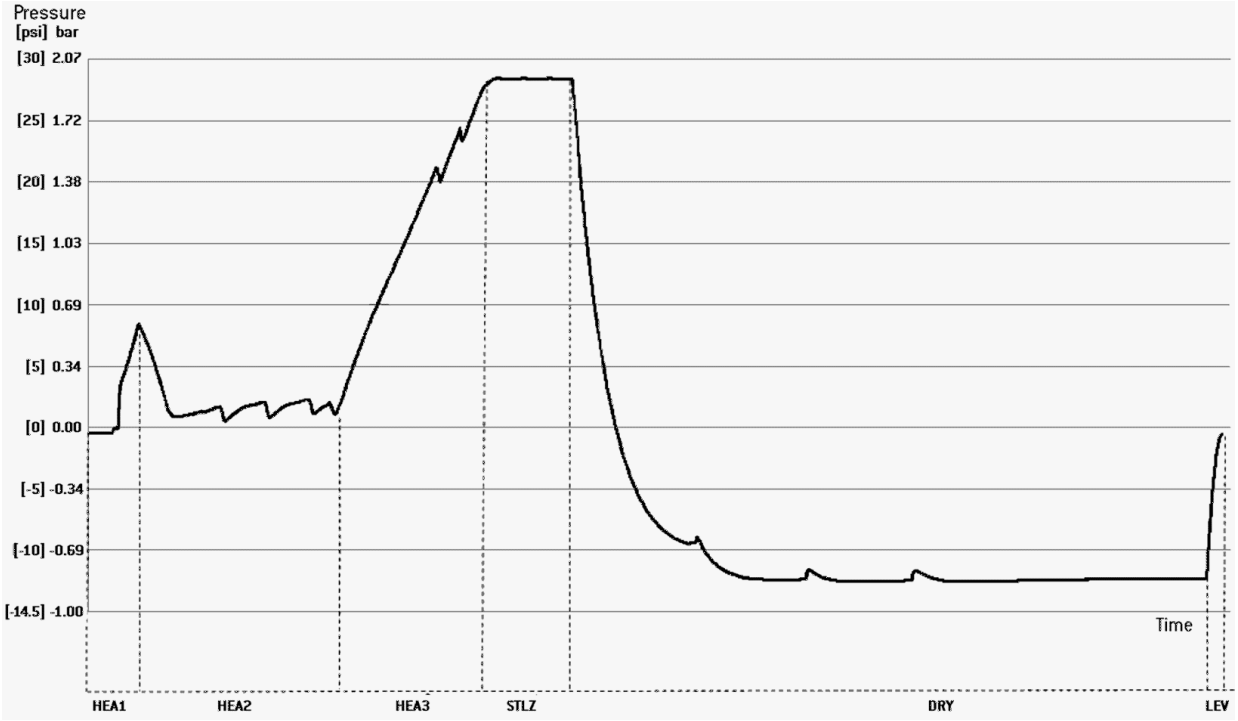
Following is the description of the sterilization phases.

Code	Phase	Description
PHE	**Pre-heating phase**	Pre-heating of the sterilizer steam generator and chamber. This phase is not considered a part of the cycle.
HEA1 **HEA2**	**Heating phase (steam pressure pulses)**	Initial heating phase to remove the air from the sterilization chamber. Air is removed using pressure pulses followed by discharge phases. The iteration of these phases reduce the percentage of air inside the chamber and determinates the correct sterilization conditions.
HEA3	**Pressure rise**	Heating phase to achieve the sterilization conditions (pressure and temperature) for the selected cycle.

Code	Phase	Description
STLZ	Sterilization phase	Sterilization condition (pressure and temperature) maintained for the time specified for the selected cycle. During this phase the unit controls the theoretical temperature (pressure converted in temperature, because of physical behaviour of water) and the steam temperature inside the chamber. The value must be between the sterilization temperature band, and the difference between them must be lower than 3.6 °F (2 °C). If the temperature drops below the sterilization temperature band a restart process procedure is automatically executed by the sterilizer (according to ST55). The sterilizer controls the sterilization condition through steam generation. The steam generation is controlled by a PID, that modulates the electrical power using as feedback the instant average between theoretical and internal temperature.
DRY	Exhausting drying phase	The objective of this phase is to dry the load placed in the sterilizer chamber. The drying phase is divided in two step: ■ The first step is the depressurization phase, when most of the steam is removed from the chamber. The second step is the drying of the load. ■ Duration of the DRY phase depends on the selected profile.
LEV	Levelling phase	Pressure inside the sterilization chamber is leveled to the atmospheric pressure.

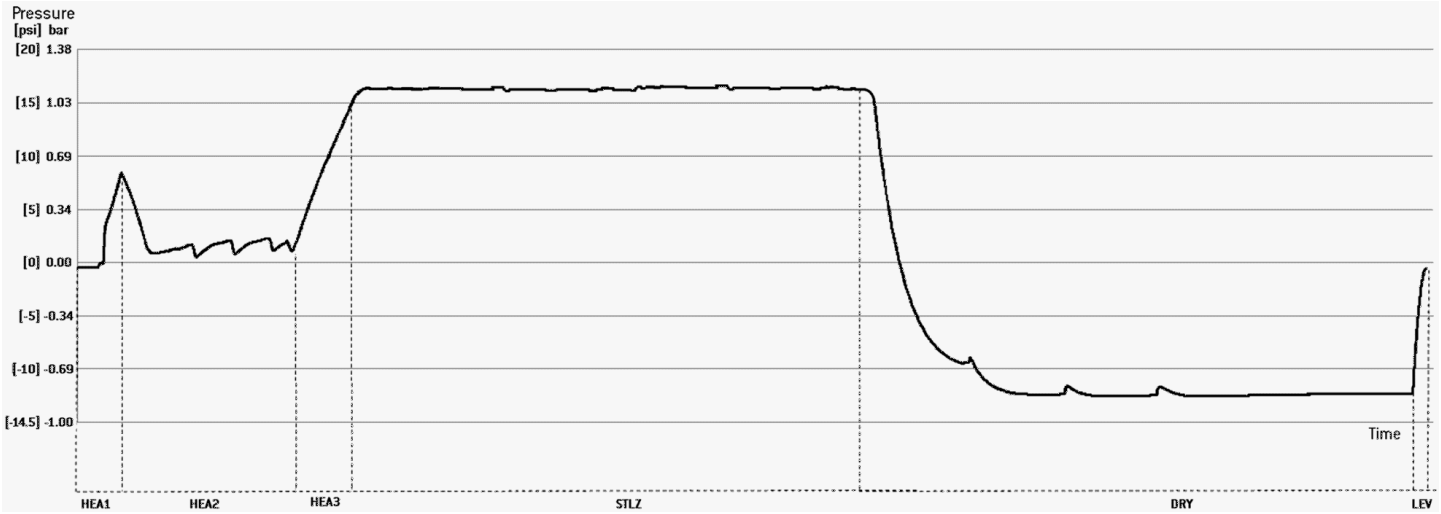
HIGH TEMPERATURE PRESSURE PROFILE

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



LOW TEMPERATURE PRESSURE PROFILE

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



Technical data

WATER SUPPLY SYSTEM

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

POWER SUPPLY SYSTEM

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

INSTALLATION REQUIREMENTS

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

STERILIZER CHAMBER

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

Note*: Usable space with standard rack and trays. With optional racks and trays, see "Accessories, spare parts, consumables" on page 102.

STEAM GENERATOR

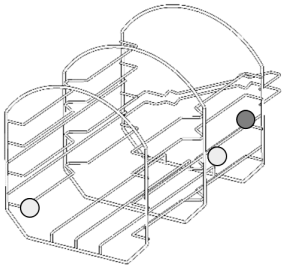
Pressure safety valve	72.51 psi (5 bar)
Safety thermostats	446 °F (230 °C)

DISTILLED OR DEMINERALIZED WATER

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

Recommendations for validation

TEST VALIDATION POINTS

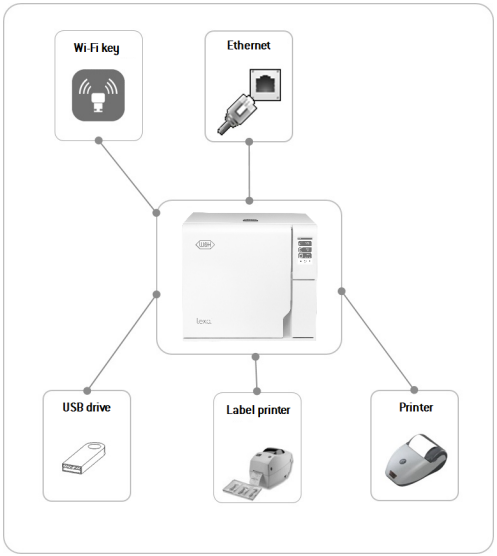


Part	Description
	Hottest points
	Coldest points

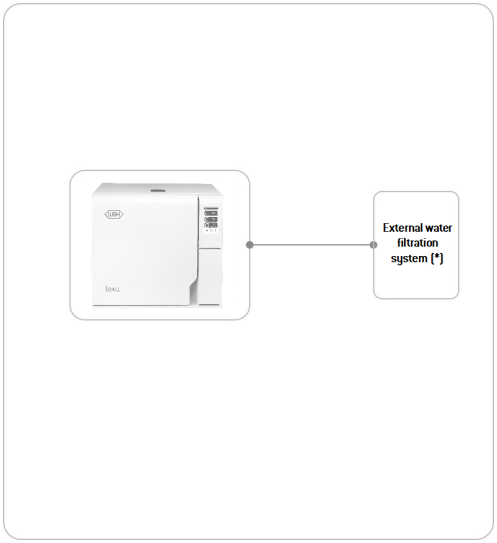
Diagrams

CONNECTION DIAGRAMS

Data communication



Water system



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

Water quality

FEED WATER SPECIFICATIONS (EN 13060)

Notice: Do not use rust inhibitor or any other agents in the clean water tank.

This sterilizer uses distilled or demineralized water to generate steam for the sterilization process. The table below lists the maximum content of minerals and the specifications for the water used for steam sterilization according to EN13060 ANNEX C.

Contaminants/minerals/qualities	Value/Specification
Total Dissolved Solids	< 10 mg/l
Silicon oxide, Si02	< 1 mg/l
Iron	< 0.2 mg/l
Cadmium	< 0.005 mg/l
Lead	< 0.05 mg/l
Heavy metals (excl. iron, cadmium, lead)	< 0.1 mg/l
Chloride	< 2 mg/l
Phosphate	< 0.5 mg/l
Conductivity (at 20°C)	< 15 µs/cm
pH value	5–7

Contaminants/minerals/qualities	Value/Specification
Appearance	colorless, clean, free from sediment
Hardness	< 0.02 mmol/l
Chemical additives	**No chemicals or additives must be added to the water used for the steam sterilization process**, even if they are specifically claimed for use in steam generators, or for steam production, or as additives for sterilization, disinfection, cleaning or corrosion protection.

FEED WATER SPECIFICATIONS (ANSI/AAMI AND AAMI TIR34)

The table below lists the specifications for the water used for steam sterilization according ANSI/AAMI ST55:2010 and AAMI TIR34:2014. 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:

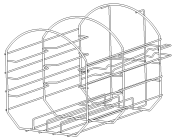
The use of water with a conductivity greater than 10µS/cm (6.5 ppm) may affect the sterilization process and damage the sterilizer.

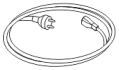
The use of water with a conductivity greater than 50µS/cm, or not complying with the specifications in the table above, may strongly affect the sterilization process and seriously damage the sterilizer.

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

LIST OF PARTS PROVIDED WITH THE STERILIZER

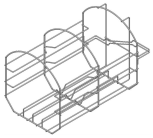
Picture	Part	Part number
	**Standard chamber rack**	F523030X
	**Aluminium tray (x4)**	F523211X
	**Tray holder**	F523001X
	**Emergency door opening tool**	S520009X
	**Drain tube**	S230903X

Picture	Part	Part number
	**Mains cable**	U380119X (120 V) U380120X (230 V)
	**USB pen drive**	V000004X

CONSUMABLES

Picture	Part	Part number	When replace it
	**HEPA Filter**	W322400X	Every 1200 cycles
	**Door gasket**	F460535X	Every 1200 cycles

LIST OF ACCESSORIES AND SPARE PARTS

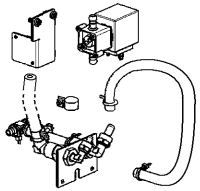
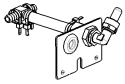
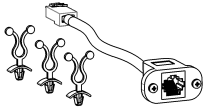
Picture	Part		Part number
	**Optional chamber rack for 3 trays / 3 taller cassettes or 4 standard cassettes** Usable space - Cassette size (mm): ■ 207x48x48		F523036X
	**Ethernet cable, 3 m**		A801500X
	**USB hub**		19721129
	**Cycle report printer**		19721108
	**USB-serial adapter (for the connection of the cycle report printer)**		A801503X
	**Label printer (label printer only)**		19721109
	**Label printer connection kit** ■ USB connection cable ■ 1 roll of 2100 labels ■ 1 wax/resin ribbon ■ activation code instructions		19721131

Picture	Part	Part number
	**Label printer consumable kit** ■ 2 rolls of 2100 labels ■ 2 wax/resin ribbons	A810513X
	**Roll of thermal paper**	A810504X
	**QR code / Bar code reader for labels**	19721132
	**Multidem C27 - water demineralizer**	19723112
	**Multidem resin cartridge**	A812016X

Note: use only accessories recommended by W&H.

OPTIONAL KITS

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

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

Authorized W&H service partners

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

Alternatively please contact:

A-dec Inc.
2601 Crestview Dr
Newberg, OR 97132 USA
Phone: 1-800-547-1883 (within U.S.), 1-503-538-7478 (outside U.S.)
Fax: 1-503-538-0276
Website: www.a-dec.com

Documentation forms

CONTENTS

This section deals with the following subjects:

W&H installation check-list

QUESTIONS

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

N.	Question	Answer	
17	Have you shown the Head of the clinic/practice the maintenance program and procedures?	Yes	No
18	Have you shown the Head of the clinic/practice how to use all of the accessories?	Yes	No
19	Have you shown the Head of the clinic/practice the advantages of having a USB connection for a pen drive?	Yes	No
20	Have you suggested to the Head of the clinic/practice to periodically backup the data, stored on the USB pen drive and/or in a PC, on another safe support?	Yes	No
21	Have you shown the head of the clinic/practice the advantages of having a Ethernet connection (remote data saving)?	Yes	No
22	Have you explained to the head of the clinic/practice the correct load type for each available sterilization program?	Yes	No
23	Have you shown the head of the clinic/practice how to prepare and place the load in the sterilizer chamber?	Yes	No
24	Have you explained to the head of the clinic/practice to use only original parts and accessories on the sterilizer?	Yes	No
25	Have you shown and explained to the head of the clinic/practice the safety advise section?	Yes	No
Check			
26	Have you executed a Wrapped/Pouched 270 °F (132 °C) with the tray rack and trays inserted?	Yes	No
27	Are all connections to the sterilizer well positioned and plugged (accessories, etc…)?	Yes	No

INSTALLATION INFORMATION

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

ADDRESSES FOR SENDING THE INSTALLATION CHECK-LIST

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

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

Importer
A-dec Inc.
2601 Crestview Dr
Newberg, OR 97132
USA

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

MN-111
Instructions for Use
ENG
Rev13
31/08/2020
Subject to changes

CE 0051