

SterOx System V-Series

steriLux

Ozone Sterilizer Instruction for Use



CE

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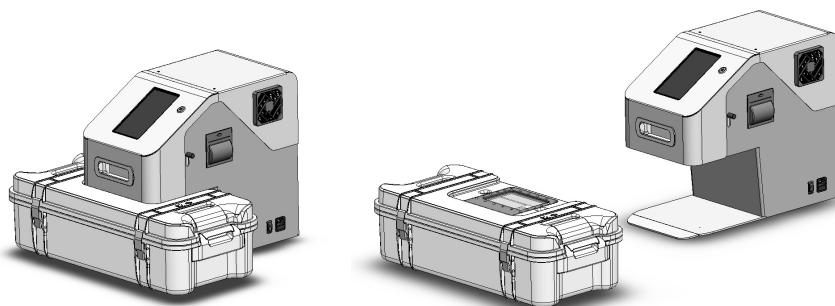
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1 Introduction



Congratulations on selecting the SterOx System V-Series. The SterOx System V-Series is a compact, environmentally-friendly sterilization device based on ozone as sterilizing agent composed of two components: the SteriBase V-Series and the SteriBox V-Series.























The details of installing, operating, and maintaining your SterOx System V-Series are all contained within these instructions for use manual. Please read these instructions before starting to operate this device and keep them for future reference. Calibration tests were performed at the factory; the sterilizer does not require any special commissioning settings.

Operational, maintenance and replacement instructions must be followed.

The SterOx System V-Series is suitable for terminal sterilization of devices and materials compatible with ozone sterilization. The SterOx System V-Series has not been designed to sterilize liquids, textile fabrics, powders, bio-medical waste or any other materials not compatible with ozone sterilization. The processing of such loads may result in incomplete sterilization and / or damage to the load and / or to the sterilizer. For more information about instruments compatibility with ozone sterilization, please contact SteriLux SA directly.

2 Symbols


The following table displays the different symbols used in the margins of this manual and/or on the product and summarizes their meaning.

	Serial number
	Catalogue number
	Batch code
	Date of manufacture
	Manufacturer
	Use-by date
	CE marking
	Consult instructions for use
	Caution, consult the instructions for use for important cautionary information
	Keep away from sunlight
	Keep dry
	Temperature limit
	Humidity limitation
	Fragile, handle with care
	Waste Electrical and Electronic Equipment
	Caution, hot surface
	Caution, UV radiation
	Direct Current
	Alternative current
	Stand-by / Switch button
	Protective Conductor Terminal
	Potential hazard to the operator

3 Important information

3.1 Disclaimers

The protection provided by the equipment may be impaired if the operator does not use the SterOx System V-Series in a manner specified in the present document. Failure to follow the present document instructions and recommendation may lead to machine malfunction and serious injuries. Do not permit any person other than certified personnel to supply parts for service or maintain your SterOx System V-Series. SteriLux SA shall not be liable for incidental, special or consequential damages caused by any maintenance or services performed on the SterOx System V-Series by a third party, or for the use of equipment or parts manufactured by a third party, including lost profits, any commercial loss, economic loss, or loss arising from personal injury.

 Never attempt to dismantle the SteriBase V-Series. Doing so may damage the device and/or pose a hazard to the operator.

The use of this sterilizer is limited to the range of application indicated in this technical document and must only be operated with fully functional accessories, consumables and spare parts recommended or supplied by SteriLux SA. SteriLux SA shall not be liable for incidental, special or consequential damage caused by the use of products, accessories, consumables or spare parts not recommended or supplied by SteriLux SA and/or damaged or suspected of damage.

The operations of preparation and sterilization of devices must be carried out by qualified personnel only.

It is imperative to sterilize only instruments and other devices that are specified as sterilisable by the manufacturer.

3.2 Declaration of Conformity

The SterOx System V-Series falls into the definition of a Low Voltage Device, as defined by Article 1 of 2014/35/EU.

The manufacturer declares under its sole responsibility, that the SteriBase V-Series is in conformity with:

- 1) Safety Objectives referred to in Article 3 and set out in Annex I of European Directive 2014/35/EU, as amended.
- 2) The relevant Essential Requirements of Article 3 of European Directive 2014/53/EU, as amended, and that Annex III (Module B on EU-type Examination) has been followed for their conformity assessment.
- 3) The relevant Essential Requirements of Article 4 of European Directive 2011/65/EU, as amended.

3.3 Field of application

This sterilizer has been designed for indoor use only in veterinary settings.

3.4 Warning

Careful monitoring of the shelf-life and/or the maximum allowable number of cycles of the different components of the SterOx System V-Series is essential to ensure the required sterility assurance level (SAL) at the end of the cycle. Never use components that have an expired shelf-life.


Do not remove or erase labels and markings present on individual products.

Always allow the sterilizer to cool down to room temperature before transporting and use a suitable transport packaging.

Avoid pouring or splashing of water or liquids on the SteriBase V-Series as this may cause short circuits. Do not place any liquid or liquid container of any type on the SteriBase V-Series or close to it.

When using the SterOx System V-Series, ensure that the power cable port remains accessible and removable at all times.

Keep the SterOx System V-Series away from children and pets at all times.

 In case of malfunction or failure, the operator may be exposed to high ozone concentration. In case of suspected malfunction, shut the device down using the power switch, ventilate and evacuate the room for at least 30 minutes.

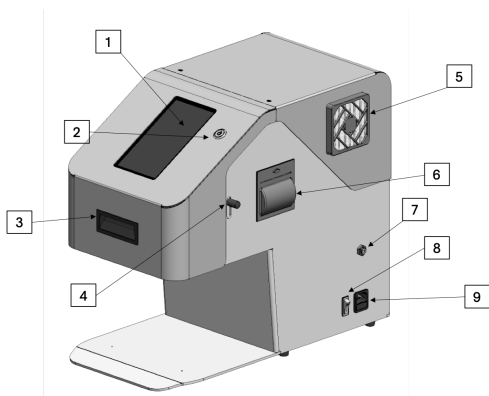
Any person suspected to have come in contact with high ozone concentration or who has effectively been in contact with high ozone concentration shall seek medical assistance and follow-up as soon as possible.

The SteriBase V-Series contains lamps that emit ultraviolet (UV) radiations.

4 Products overview

4.1 SteriBase V-Series (SKU-0006)

- 1 Touchscreen
- 2 Start button
- 3 Handle
- 4 Manual levers (of the Lamp Unit)
- 5 Cooling fan
- 6 Thermal printer
- 7 Nitrogen plug
- 8 Power switch
- 9 Power cable port

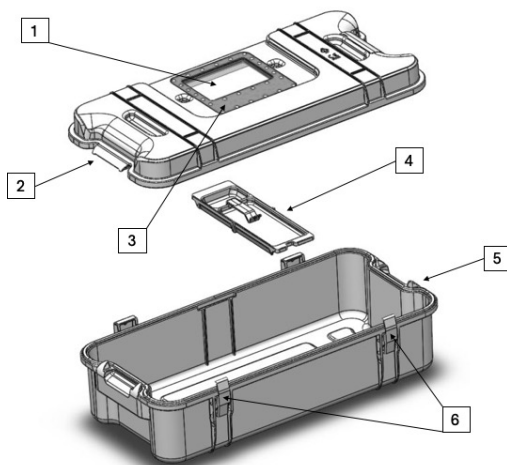


When you receive your SteriBase V-Series, the items listed below should be included. If any of the items are missing or damaged, contact your supplier immediately.

- SteriBase V-Series
- Power cord
- Back door access key
- Instructions for use
- Short user guide

4.2 SteriBox V-Series (SKU-0007)

- 1 Quartz window
- 2 Lid
- 3 Incorporated RFID tag
- 4 Module and clip
- 5 Bottom
- 6 Locks



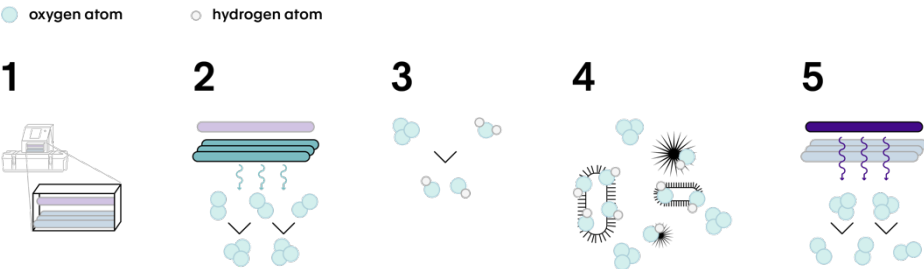
When you receive your SteriBox V-Series, the items listed below should be included. If any of the items are missing, contact your supplier immediately.

- SteriBox V-Series Lid
- SteriBox V-Series Bottom
- SteriBox V-Series Module and clip
- Instructions for use

Always use parts belonging to the same serial number of a SteriBox V-Series assembly (Lid, Bottom, Module and clip).

5 Principles of operation

The SterOx System V-Series is an ozone-based sterilizer. 172 nm UV lamps contained in the Lamp Unit inside the SteriBase V-Series [1] transform oxygen (O_2) from ambient air into ozone (O_3) [2]. Ozone further reacts with water (H_2O) to form hydroxyl and hydroperoxyl radicals [3] which are responsible for the inactivation of micro-organisms causing infections and disease transmissions [4]. At the end of the sterilization process, a 254 nm UV lamp also contained in the Lamp Unit transforms remaining ozone back into oxygen [5].



6 Setting up your SteriBase V-Series

6.1 Installing your device

There are several factors that may affect the performance of your SteriBase V-Series. Please review these factors and select a suitable location in which to install the device. After each relocation of the sterilizer, installation must be carried out according to the protocol.

Safety of any system incorporating the device is the responsibility of the assembler of the system.

When transporting the SteriBase V-Series, never carry the SteriBase V-Series alone. Two persons shall carry it by using the specific handles present on the SteriBase V-Series. Always keep the SteriBase V-Series vertical when out of its packaging.

The SterOx System V-Series is conceived for use outside patient surroundings. Neither the SteriBase V-Series nor the SteriBox V-Series should be in direct contact with the patient.

• Temperature and Humidity

Avoid installing your SteriBase V-Series in direct sunlight or close to a heat or cold source (e.g. vents or radiators). The operating temperatures have to be between 20 – 30°C with relative humidity of 20 – 70%. Ideal room temperature is 23°C.

• Spacing

The cooling fans and vents of the SteriBase V-Series should remain uncovered and unobstructed. It ensures proper ventilation and facilitates removal of power supply if necessary. The main power switch acts as a disconnecting device and must remain easily accessible all the time in case the device needs to be shut down.

• Venting

The SteriBase V-Series should be operated indoor in a clean, dust-free environment, with a good ventilation system.

• Work surface

The sterilizer must be placed on a flat and horizontal surface that can support the total weight of the SteriBase V-Series (~20 kg), the SteriBox V-Series (~6 kg) and the instruments placed in the SteriBox V-Series. Do not install the sterilizer near water sources.

• Altitude and pressure

The SteriBase V-Series and the SteriBox V-Series cannot be used in altitude superior to 2'000 m above sea level. The system must be used in an environment with atmospheric pressure of 1 atm \pm 0,095. The SteriBox V-Series must not undergo pressure changes exceeding 5'000 Pa.

• Electromagnetic environment

The SteriBase V-Series has been tested and meets applicable standards for electromagnetic emissions (class A product). In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures. For more information on electromagnetic compatibility, please refer to chapter 17.

• Electrical requirements

The SterOx System V-Series has been designed to be powered from the power cable port. Connect the sterilizer to an AC power supply, properly grounded and fused power sources

with the following voltage rating: single phase 110/240 V – 50/60 Hz – 3 A. The system must be used within $\pm 10\%$ of the nominal voltage (110/240 V). Do not plug into multiple outlet receptacles.

The SteriBase V-Series has been designed to withstand transient overvoltage up to levels of Overvoltage category II.

⚠ The SterOx System V-Series must be connected to a mains socket outlet with a protective earthing connection. The manufacturer will not be responsible for damages to the operator caused by an unsuitable electrical installation or missing of the protective earth connection. Always observe the electrical instructions, standards and regulations for the electrical connection of the sterilizer. In case of doubt, please consult a qualified technician. It is important to never modify, bend or twist the power cord. Never place heavy objects on the cable or place it near a heat source. Do not use staples or nails to secure the cable. In case of damage to the plug or cable, immediately disconnect the power supply. To completely disconnect the power supply from the SteriBase V-Series, pull the separable power cord out of the device and turn off the power switch.

6.2 Powering your device

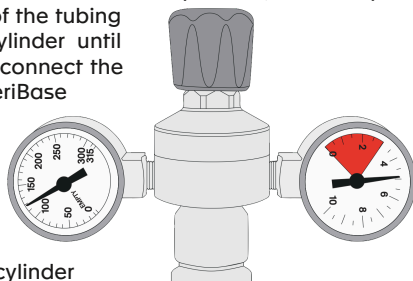
To power your SteriBase V-Series, connect the power cord to the power cable port (AC inlet receptacle on the right side of the device). Ensure the power switch is in the OFF position and connect the device to your power source. Turn the power switch in the ON position and click on the start button.

6.3 Installing nitrogen supply

To function properly, your SteriBase V-Series requires a nitrogen gas supply (purity >99.999%). SteriLux SA proposes a turnkey solution that includes:

- re-usable nitrogen cylinders 110 bar 1.34L
- 1 reusable pressure regulator
- 1 m tubing external diameter 4 mm

To install it, ensure that pressure regulator is closed (knob towards “–” position) and firmly secure it on the nitrogen cylinder. Connect one end of the tubing to the pressure reducer and open the nitrogen cylinder until feeling a weak flow coming out of the tube. Quickly connect the other end of the tube to the nitrogen plug on your SteriBase V-Series. Check that the tubing is well connected by gently pulling it at both ends. Keep opening the nitrogen cylinder until the needle on the right dial reaches 5 bar (see photo). The left dial of the pressure regulator indicates the amount of nitrogen remaining. When the bottle is nearly empty (i.e. needle on the right is below 3 bar) change the cylinder following the same procedure.



The cylinders supplied by SteriLux SA remain the property of SteriLux SA. Once empty, they need to be shipped back to SteriLux SA.

Never use device without nitrogen supply or on an empty cylinder as this can permanently damage the device and may impede the sterilization process.

Note: It is possible to use other commercially available nitrogen supply cylinders. However, if you decide to go with another alternative, you must have SteriLux SA written approval prior to installing it on your SteriBase V-Series.

6.4 Setting the nitrogen flow

1. Open the SteriBase V-Series back door using the access key provided with the device
2. From the menu PARAMETERS click on *Nitrogen flow setting* - this will activate nitrogen flow for 2 minutes
3. While the flow is activated, set it to 1.2 l/min (see photo)

Note: If the flow is not activated the ball will always be on 0.



6.5 Nitrogen purging

At device installation and if the device has not been used for more than 4 weeks, a nitrogen purging should be performed. The goal of this program is to remove all traces of oxygen from the Lamp Unit. Traces of oxygen in the Lamp Unit cause formation of ozone inside the Lamp Unit thus preventing efficient irradiation of the UV lamps inside the SteriBox and increasing the risk of cycle errors and damage of the device.

1. From the menu MAINTENANCE click on *Nitrogen purging*
2. This program lasts 17 minutes

6.6 Connecting your device to a Wireless Network

1. Go to the menu WIFI
2. Click on the three dots button and click on *Connect to a Wi-Fi network*
3. Select Wi-Fi, enter login details and press OK

Note: Connecting your device to a Wireless Network is essential for quick troubleshooting from SteriLux SA.

6.7 Setting the time and date

1. From the menu PARAMETERS click on *Date and time*
2. Use the up and down buttons to set the date and time
3. Press the tick button to save your changes

Note: The date and time are automatically set if the device is connected to a Wireless network

6.8 Setting the language

1. From the menu PARAMETERS click on *Language*
2. Select your desired language from the list – your selection will automatically be saved

6.9 Setting the users/contents

1. From the menu PARAMETERS click on *User/Content settings*
 - a. Create a new user/content by clicking on *Add user/content*
 - b. Edit existing users/contents by clicking on the user/content you want to modify
 - c. Delete existing users/contents by clicking on the user you want to delete
2. When creating a new user/content or editing existing users/contents, a touchscreen keypad will appear allowing you to create and modify your entries at any time - to save your entries press Save, to discard press Cancel.

6.10 Managing email addresses

Provided the device is connected to a stable Wi-Fi network, you can inform one or more email addresses to which the device will send a detailed PDF report at the end of each cycle.

1. In the menu PARAMETERS click on *Email addresses*
 - a. Enter new email address by clicking on *Add email address*
 - b. Edit existing email address by clicking on the email address you want to modify
 - c. Delete existing email address by clicking on the email address you want to delete
2. When adding a new email address or editing existing email addresses, a touchscreen keypad will appear allowing you to create and modify your entries at any time - to save your entries press Save, to discard press Cancel
3. Be careful not to add any blank space when typing the email address

7 Using the SteriBox V-Series and preparing instruments

7.1 Using the SteriBox V-Series

Opening the SteriBox V-Series in a sterile manner

1. Disengage both locks
2. Stand behind the SteriBox V-Series and grab the handles on both sides of the lid
3. Pull the lid towards yourself
4. Rest the lid on its outer surface
5. Take the module out with sterile gloves and place it inside the lid

Closing the SteriBox V-Series

1. Place module in the dedicated SteriBox V-Series notches
2. Align the lid with the bottom of the SteriBox V-Series
3. Engage the locks
4. Push the locks downward until they are secured

Inserting the SteriBox V-Series into the SteriBase V-Series

1. Slide the SteriBox V-Series inside the SteriBase V-Series with the locks facing you
2. Verify that the SteriBox V-Series is inserted all the way in
3. The touchscreen will automatically display the pop-up message *SteriBox # inserted*

Removing the SteriBox V-Series from the SteriBase V-Series

1. If the Lamp Unit manual levers are in upward position, simply slide the SteriBox V-Series out of the device
2. If the Lamp Unit manual levers are in downward position, grab both levers and pull them up to upward position. Then slide the SteriBox V-Series out of the device
3. When removing the SteriBox V-Series from the SteriBase V-Series, exercise caution as the quartz window area may be hot

Important information

The module is a highly important piece of the SteriBox. It serves not only to hold the blotting paper with the 5 mL of water but also to measure the ozone concentration throughout the cycle. The upper part of the module should always be clean and nothing should be placed on top of it.

Never force the lid to close as this might alter the physical integrity of the SteriBox V-Series. Always handle the lid with care as the quartz window is very fragile, it has been tested to withstand 1 Joule of Impact, corresponding to a normalized impact rating IK06.

The SteriBox V-Series shall be stored in a clean and dry environment. Do not stack more than 3 SteriBox V-Series on top of each other. The SteriBox must be stored on a flat surface that can support at least 20 kg.

7.2 Preparing and loading instruments in the SteriBox V-Series

Before loading any instruments in the SteriBox V-Series, consult the instructions for use or SteriLux SA directly to check for instruments compatibility. The maximum load to be sterilised – including the weight of any sterilization basket, rack or other accessories – must not exceed 7.5 kg, otherwise SteriLux SA cannot guarantee sterility of the load.

SteriLux SA guarantees the performance of its products only when their physical integrity has not been altered. In the event of leaks, cracks or other damage, or suspected damage, the equipment should not be used. Therefore, an inspection must be carried out before each use. In case the quartz window presents a crack, do not use as the airtightness of the SteriBox V-Series may be altered and the operator risks being exposed to high ozone concentration.

Clean Instruments

Clean, rinse and dry all instruments before loading them into the SteriBox V-Series. Disinfectant residues and solid debris may inhibit sterilization and damage the instruments. Lubricated instruments must be wiped thoroughly, and any excess lubricant should be removed before loading. Improper cleaning, rinsing or drying can cause the sterilization cycle to malfunction. Breach of the appropriate preparation instructions can lead to non-sterility of the instruments. Sterility cannot be guaranteed if the material to be sterilized is dirty, contains dust, residues or biofilms.

Avoid glutaraldehyde- and peracetic acid-based disinfectants. Here is a list of preferred commercially available disinfectants to disinfect medical devices to be sterilized in the SterOx System V-Series:

1. STABIMED® FRESH – B BRAUN
2. GIGASEPT® INSTRU AF – SCHÜLKE
3. NEODISHER® SEPTO PRECLEAN – DR. WEIGERT
4. BOMIX® PLUS – HARTMANN

Unwrapped instruments

You can arrange unwrapped instruments either directly in the SteriBox V-Series as it is, or in a sterilization basket (the SteriBox V-Series has been designed to fit with standard size sterilization baskets). Avoid stacking or piling of instruments in the SteriBox V-Series, as this might impede the sterilization process.

Wrapped instruments

Place the instruments into single or double sterilization pouches. Stick an Ozone Strip Type 1 inside each pouch. Ensure there is enough space around the indicator and make sure the plastic side does not touch the indicator. Tyvek® sterilization pouches have been cleared for use and are recommended for use with the SterOx System V-Series¹. Place the wrapped instruments in the SteriBox V-Series or on a rack and arrange them to avoid overlap. Always ensure that porous side of the pouches are facing upwards. Avoid compressing of the pouches as this might impede the sterilization process.

Add distilled water on the HUMIDIFY Blotting Paper

For effective sterilization, it is mandatory to add 5 mL of distilled water on the HUMIDIFY Blotting Paper provided by SteriLux SA. If there is any doubt about the amount of water added, remove the HUMIDIFY Blotting Paper and dispose of it. Dry the module and repeat the operation with a new HUMIDIFY Blotting Paper. A smaller or larger amount of water

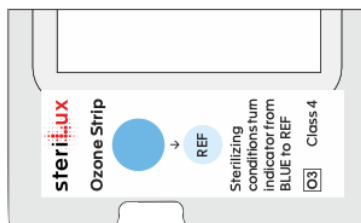
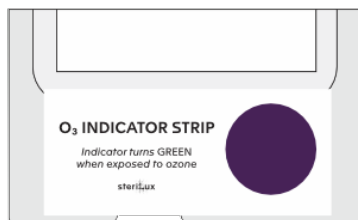
¹ Paper-plastic, SMS and crepe paper have also been tested and validated for ozone sterilization

might not guarantee effective sterilization. Refer to the HUMIDIFY Blotting Paper Instructions for Use for detailed instructions.

Add chemical indicators on the module

For any Speed cycle, stick one Ozone Strip Type 1 on the module as shown on the picture below on the left.

For any Standard or Pouch cycle, stick one Ozone Strip Type 4 on the module as shown on the picture below on the right.



Compatibility of materials

The following materials are compatible with the ozone sterilization process (non-exhaustive list).

PLASTICS	METALS
Polybutylene terephthalate (PBT)	Stainless steel
Polyvinylchloride (PVC)	Titanium
Polypropylene (PP)	Anodized aluminum
Polycarbonate (PC)	Gold plating
Polysulfone (PSU)	ELASTOMERS
Polyethylene (PE, HDPE, UHMWPE)	Silicone
Polyoxymethylene	Fluorosilicone
Polyether etherimide	Viton (FKM)
Polyether ether ketone (PEEK)	Santoprene
Polytetrafluoroethylene (PTFE, Teflon)	Tygon
Polyvinylidene difluoride (PVDF, Kynar)	Ethylene propylene (EPDM)
Acrylonitrile butadiene styrene (ABS)	OTHER
Acrylic (PMMA, Plexiglas)	Ceramic
	Glass

The following materials ARE NOT compatible with the ozone sterilization process (non-exhaustive list):

PLASTICS	ELASTOMERS	OTHER
Polyurethane (PU)	Natural rubber	Textiles
Nylon	Nitrile rubber	Powders
METALS	Butyl rubber	Bio-medical waste
Untreated steel	Polychloroprene	Liquids
Zinc	Acetal (Delrin®)	
	Latex	

Use of these materials may lead to instrument or equipment damage. If you are unsure of your instrument's material or construction, do not load into your SterOx System V-Series until you have checked with the instrument manufacturer and/or SteriLux SA.

All instruments

The SterOx System V-Series has not been designed to sterilize liquids, textile fabrics, powders, bio-medical waste or any other materials not compatible with ozone sterilization. Instruments will remain sterile after a successful cycle until the locks of the SteriBox V-Series are disengaged (maximum storage of sterile instruments: 1 year). Unwrapped instruments, once exposed to ambient or external conditions, cannot be maintained in a sterile state. If sterile storage is desired, either leave the SteriBox V-Series securely closed, or wrap the instruments to be sterilized in sterilization pouches.

ⓘ It is proscribed to reprocess tools that came in contact with a patient suffering or suspected to suffer from any form of prion-related diseases (e. g. Creutzfeldt-Jacob disease (CJD), the new variant of CJD, Gerstmann-Sträussler-Scheinker syndrome, Kuru's disease, Fatal Familial Insomnia, Scrapie, Feline spongiform encephalopathy). Complete destruction of all prions cannot be guaranteed.

Routine Monitoring

SteriLux SA provides two types of chemical indicators to monitor the sterilization process:

- Ozone Strip type 1 Chemical indicator – to be used in all cycles (Speed, Standard and Pouch) as an external or internal pack process indicator to exposure to ozone in the SteriOx System V- Series
- Ozone Strip type 4 Chemical indicator – to be used exclusively in Standard and Pouch cycles as a multi-variable indicator responding to all variable parameters

For more information regarding both chemical indicators refer to their related instructions for use.

Note for hollow instruments

Ozone, generated within the SteriBox V-Series beneath the quartz window, diffuses throughout the container. However, it's important to note that hollow instruments pose a particular challenge, requiring additional time for ozone diffusion.

All the cycles have been designed for instruments made of any compatible materials. These instruments can be either packaged in single or double pouches, which are permeable to ozone, or left unwrapped within the SteriBox V-Series.

The efficacy of SteriBox V-Series against a broad spectrum of microorganisms, known to be causative agents of infections, has been rigorously tested. This includes various instrument geometries, as outlined in the table below. Furthermore, the effectiveness against the most resistant micro-organism to ozone, *Geobacillus stearothermophilus* spores, has also been thoroughly examined and is detailed in the table below.

	Speed cycle	Standard cycle	Pouch cycle
Bacteria <ul style="list-style-type: none">· <i>Staphylococcus aureus</i>· <i>Enterococcus hirae</i>· <i>Acinetobacter baumannii</i>· <i>Escherichia coli</i>· <i>Proteus hauseri</i> Yeast and moulds <ul style="list-style-type: none">· <i>Candida albicans</i>· <i>Aspergillus Brasiliensis</i> Mycobacteria <ul style="list-style-type: none">· <i>Mycolicibacter terrae</i>	Reduction of $>10^6$ (6 \log_{10}) inside geometries up to: 0.5 cm long, 1 mm \emptyset 1.0 cm long, 2 mm \emptyset 1.5 cm long, 3 mm \emptyset 2.0 cm long, 4 mm \emptyset	Reduction of $>10^6$ (6 \log_{10}) inside geometries up to: 50 cm long, 1 mm \emptyset 100 cm long, 2 mm \emptyset 150 cm long, 3 mm \emptyset 200 cm long, 4 mm \emptyset	
Bacterial spores <ul style="list-style-type: none">· <i>Geobacillus stearothermophilus</i>	Reduction of $>10^1$ (1 \log_{10}) inside geometries up to: 1.5 cm long, 3 mm \emptyset	Reduction of $>10^6$ (6 \log_{10}) inside geometries up to: 10 cm long, 3 mm \emptyset	Reduction of $>10^{12}$ (12 \log_{10}) inside geometries up to: 10 cm long, 3 mm \emptyset

8 Using your SterOx System V-Series

8.1 Preparing device for use

Once the device is installed and before any cycle is launched, clean the lid, bottom and module of the SteriBox V-Series (see chapter 11 for further details). Pay special attention to thoroughly clean the quartz windows, both on the SteriBox V-Series and the SteriBase V-Series, using any commercially available glass cleaner and a clean soft cloth.

8.2 Launching a cycle

The SterOx System V-Series proposes three cycles.

The **Speed** cycle is designed for maximum flexibility. This cycle was validated on all common pathogens encountered in the veterinary setting for wrapped and/or unwrapped simple geometry devices only. The cycle takes place at room temperature and ambient pressure and lasts 3 hours.

The **Standard** cycle is designed for devices with complex geometry. This cycle was validated on all common pathogens encountered in the veterinary setting for wrapped and/or unwrapped complex geometry devices (details available on chapter 7.2). The cycle takes place at room temperature and ambient pressure and lasts 16 hours.

The **Pouch** cycle is designed for maximum security. This cycle was validated on *Geobacillus stearothermophilus* spores, which are the most resistant micro-organism to ozone, where a reduction of 12 log₁₀ is achieved. The cycle takes place at room temperature and ambient pressure and lasts 22 hours.

To launch any of these three cycles:

1. Insert SteriBox V-Series inside the SteriBase V-Series
2. From the HOME menu press START NEW CYCLE
3. Select the cycle of your choice by pressing *Select cycle*
4. Optional: Select the user and content
5. Click on the start icon button

After clicking on the start icon button, the Lamp Unit will automatically drop down securing the SteriBox V-Series inside the SteriBase V-Series.

During the first 15 minutes of each cycle, sounds of nitrogen under pressure being released at regular intervals should be heard. If this is not the case, check that nitrogen supply is well connected and not empty.

8.3 Course of the cycle

Throughout the whole cycle, the cycle phase, time remaining and general information related to the cycle are displayed on the screen.


Every cycle will display three different phases:

1. GENERATION – Build-up of biocide gas (ozone, O₃) generated from air and slow increase of relative humidity
2. EXPOSURE – Maintaining high biocide gas concentration and high humidity – monitoring of the ozone concentration to guarantee process efficiency
3. VALIDATION – Active removing of remaining biocide gas by converting it back to oxygen

You should never touch or remove the SteriBox V-Series during the whole duration of a cycle. When the cycle is running, the display will automatically switch to standby mode. To exit the standby mode simply touch the screen anywhere.

Once the cycle is complete, cycle label is printed, cycle report is emailed if an email address was entered and the device automatically shuts down within 10 minutes (this is important to avoid software bugs in future cycles).

The printed label should always read CYCLE COMPLETED – a chemical indicator that has changed color is not sufficient on its own to validate a cycle. If the printed label reads CYCLE FAILED, refer to chapter 12. In case the label could not be printed, you can always access past cycles in the menu HISTORY as explained in chapter 9.

 Be careful. In any case, the quartz window areas on both the SteriBox V-Series and the SteriBase V-Series may be hot. Do not place your hands or body parts near these areas.

8.4 Interrupting a Cycle

To stop a cycle in progress, press the INTERRUPT CYCLE button. Interruption of a cycle will automatically launch a 45-minutes interruption phase to remove all remaining ozone. The device can also detect a problem while operating and automatically stop the cycle. See chapter 12 for more information on potential errors.

In any case, if the cycle is stopped before the end, the content of the SteriBox V-Series is not sterile and should not be used.

9 Storing and retrieving cycle information

The SteriBase V-Series has an internal Data Logger capable of storing all cycle data of every past cycle, whether successful or incomplete, for the lifetime of the device. You can access this information through the touchscreen or using a USB storage device.

9.1 Retrieving cycle information from the history

1. Go to the menu HISTORY
2. Scroll down using your finger to display older cycles
3. Select a cycle from the list to display cycle information
4. Click on the three dots button to reprint the cycle label or resend the cycle report via email

9.2 Retrieving cycle information using a USB stick

The data contained in the SteriBase V-Series can only be retrieved on an empty NTFS formatted USB stick with at least 1 GB of storage capacity and USB 2.0 technology or higher.

The USB port delivers 5 volts of electricity and maximum voltage 5 W (insulation: 3'660 VAC).

1. Open the SteriBase V-Series back door using the access key provided with the device
2. Plug your USB storage device into the USB port as shown on the picture. A pop-up message USB inserted will appear on the screen.
3. Go to the menu USB
4. Click on *All cycles* if you wish to download all cycles or on *Last 10 cycles* if you wish to download the last 10 cycles.



10 Shutting device down

10.1 Normal shutdown

To switch off your device click on SHUTDOWN at the bottom of the menu and confirm. The process takes a few seconds during which a waiting screen appears. Once the screen has shutdown, turn the power switch in the OFF position.

Never switch off the machine by unplugging the power cord from the power cable port unless otherwise specified in this Instructions for Use manual.

10.2 Emergency shutdown

Shut the device down by switching the power switch to OFF position and unplug the power cord from the power cable port.

11 Maintaining your SteriOx System V-Series

11.1 Cleaning the SteriBox V-Series

Keeping the SteriBox V-Series clean is good clinical practice and assists good functioning of the device. SteriLux SA recommends that the interior surface be cleaned regularly. Use a soap compatible with materials embedded in the SteriBox V-Series and its components to scrub the inside of the SteriBox V-Series with a cleaning pad to remove all traces of residues, dust, organic materials, lubricant, etc. After scouring, rinse thoroughly with clean water to remove all traces of detergent and dry using a clean soft cloth. Use commercially available glass cleaner to clean the quartz window. Keep the SteriBox V-Series closed to prevent deposition of dust inside.

Cleaning your SteriBox V-Series and its various components (module and clip) is very important. Improper cleaning, rinsing or drying may interfere with the ozone sterilization process.

11.2 Cleaning the SteriBase V-Series and exterior surface of the SteriBox V-Series

With the device switched off, use isopropyl alcohol (IPA) or a commercially available glass cleaner to clean all exterior surfaces. Do not use harsh cleaning chemicals or disinfectants.

11.3 Preventive maintenance

To ensure trouble-free performance, it is recommended to perform a preventive maintenance once a year. This preventive maintenance has to be done only by certified personnel from SteriLux SA.

Note: Please refer to your National, Regional, State of Safety laws for any additional reoccurring user testing that may be required.

Operator		
Every cycle	SteriBox V-Series	<ul style="list-style-type: none">• Check quartz window and seal for damage• Verify cleanliness
Monthly	SteriBase V-Series	<ul style="list-style-type: none">• Clean fan filters
Technician		
Once a year	SteriBox V-series	<ul style="list-style-type: none">• Airtightness check• Check lid, module, bottom and seal for damage• Replace seal if necessary
	SteriBase V-Series	<ul style="list-style-type: none">• UV irradiation check• Lamp Unit airtightness check• Measuring system verification• Functional testing of all peripherals• Replacement of defective parts if necessary• Electrical circuits check

Always unplug the power cord before servicing or working on the device.

12 Troubleshooting your SteriOx System V-Series

After each failed cycle, the SteriBox should always be opened, dried up and the blotting paper changed before launching a new cycle.

Cycle related problems	Solution
201 – 202 – 204 SteriBase turned off during Phase 1/2/3	The SteriBase V-series switched off while a cycle was running thus interrupting the cycle. When switching back on, the device will launch a 45-minutes safety program to remove all remaining ozone in the box. Once this is over, you will be able to relaunch a new cycle.
221 – 222 – 224 Lamp Unit moved up during Phase 1/2/3	The Lamp Unit has been manually moved up while a cycle was running thus interrupting the cycle. If the SteriBox is left inside the SteriBase, the device will launch a 45-minutes safety program to remove all remaining ozone in the box. Once this is over, you will be able to relaunch a new cycle. If the error occurred during phase 3, you can contact SteriLux to check whether or not the content is sterile. If the Lamp Unit was not manually moved up, contact SteriLux for assistance.
411 – 412 UV calibration measure too low/high	Verify that the module of the SteriBox V-Series is in place, clean and that nothing is obstructing the space between the SteriBox quartz and the module. Clean quartz and module and try relaunching a cycle. If the problem persists, contact SteriLux SA for assistance.
427 – Last ozone concentration measure above threshold	Check that you have correctly added the 5 mL of water on the blotting paper. If not, the content is not sterile and you should relaunch a cycle. If you did not forget to add the water, contact SteriLux for assistance.
429 – Insufficient ozone dose 433 – Ozone concentration measure too low	These two errors can happen for several reasons: <ul style="list-style-type: none"> • Room temperature is too high (above 30°C) and/or there is a heat source close to the SteriBox • Too much content in the SteriBox • Nitrogen supply not connected or empty • Relative humidity too high in the SteriBox when launching the cycle • The SteriBox was not correctly inserted <p>In case the room temperature is too high and there is nothing you can do about it or in case there is too much content in the SteriBox, try relaunching a cycle with less content.</p> <p>In case the nitrogen supply was not connected or empty, follow steps 6.3 to 6.5, then try relaunching a cycle.</p> <p>Relative humidity in the SteriBox can be too high if the SteriBox was prepared a while before launching a cycle. If this was the case, simply open the box, dry up the SteriBox and change the blotting paper before relaunching a cycle.</p> <p>In case the SteriBox was not correctly inserted all the way into the SteriBase, try relaunching a cycle paying extra attention to this.</p> <p>If the problem persists, contact SteriLux SA for assistance.</p>
431 – UV reference fetching failed	Software bug, try relaunching a cycle after the device has shutdown. If the problem persists, contact SteriLux SA for assistance.
432 – Ozone computation from UV signal failed	Software bug, try relaunching a cycle after the device has shutdown. If the problem persists, contact SteriLux SA for assistance.

434 – Ozone concentration measure too high	Check that you have correctly added the 5 mL of water on the blotting paper. If water has not been added, open the SteriBox V-Series and place 5 mL as described in chapter 7.2, then launch a new cycle. If water was added, try relaunching a cycle after the device has shutdown. If the problem persists, contact SteriLux SA for assistance.
451 – Ozone dose computation failed	Try relaunching a cycle after the device has shutdown. If the problem persists, contact SteriLux SA for assistance.

Other problems	Solution
Repeated malfunction	Follow the emergency shutdown process described in chapter 10.2 and switch back on. If the problem persists, contact SteriLux SA for assistance.
Touchscreen displays OVERHEAT and a red thermometer icon	The temperature sensor in the Lamp Unit has detected a temperature higher than 38°C. Verify that the device is installed in a suitable location as described in chapter 6. This can also happen after running a cycle if the room temperature is high, in this case just wait for the device to cool down. This may be the case if the Lamp Unit did not have time to cool down to room temperature after a previous cycle.
Device is unresponsive	Follow the emergency shutdown process described in chapter 10.2 and switch back on. If the problem persists, contact SteriLux SA for assistance.
The printer does not work	Check if there is still paper and replace paper if necessary. If the problem persists, contact SteriLux SA for assistance.
Device does not power ON	Check that the device is plugged into a properly grounded outlet and that the power cord is firmly seated at the rear of the machine. Check the power switch is ON. Try another circuit. Power device OFF for 10 seconds and then power ON again. Check the condition of the line circuit breaker or fuse. If the problem persists, contact SteriLux SA for assistance.
Device is stuck on loading screen	Force the unit to shut down by holding down the power button.
Device keeps rebooting	Follow the emergency shutdown process described in chapter 10.2 and switch back on. If the problem persists, contact SteriLux SA for assistance.
Device does not recognize SteriBox V-Series	Make sure the SteriBox is inserted all the way into the SteriBase. If it is, follow the emergency shutdown process described in chapter 10.2 and switch back on. If the problem persists, contact SteriLux SA for assistance.
Time and date are incorrect	The time and date have not been set. See chapter 6.7 for time and date instructions.
Device does not recognize USB / USB upload failed / USB software update failed	USB name should not include special characters or space in the name. Verify that there is enough storage space on your USB. Delete all files from the USB key, restart device and try again. If the problem persists, change USB key. If the problem persists, contact SteriLux SA for assistance.
Wi-Fi connection failed / Wi-Fi not found	Verify that your router is within range. Verify that you chose the right Wi-Fi and entered the correct password. Try forgetting Wi-Fi and restarting device. Check that your network fits the following requirements: <ul style="list-style-type: none"> • WiFi 2.4GHz or 5GHz • Cipher TKIP or CCMP • Password PSK or 802.1x

13 SterOx System V-Series Consumables

SKU-0006	SteriBase V-Series <i>Ozone sterilizer</i>
SKU-0007	SteriBox V-Series <i>Sterilization container</i>
SKU-0004	Ozone Strip <i>Type 4 chemical indicator x90pcs.</i>
SKU-0005	Humidify <i>Blotting paper x60pcs.</i>
SKU-0019	Ozone Strip <i>Type 1 chemical indicator x200pcs.</i>
SKU-0023	Thermal paper roll
SKU-0026	N2 Pressure regulator <i>Pressure regulator for reusable cylinders</i>
SKU-0031	UltraPure™ Nitrogen 8 cylinders <i>Reusable nitrogen cylinder 110 bar 1.34L x8pcs.</i>
SKU-0032	UltraPure™ Nitrogen 12 cylinders <i>Reusable nitrogen cylinder 110 bar 1.34L x12pcs.</i>

14 Recycling and disposal

The SterOx System V-Series is mainly built from polymers, metals and electric/electronic components.

In case of disposal:

- 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.

15 Warranty

Limited warranty

For a period of one (1) year, SteriLux SA guarantees that the SterOx System V-Series, when manufactured by SteriLux SA in new and unused condition, will not fail during normal service due to defects in material and workmanship that are not due to apparent abuse, misuse, or accident.

The one-year warranty will cover the performance of all components of the device, provided that the product is being used and maintained according to the description in the user's manual.

In the event of failure due to such defects during this period of time, the exclusive remedies shall be repair or replacement, at SteriLux SA's option and without charge, of any defected part(s), provided SteriLux SA is notified in writing within seven (7) days of the date of such a failure and further provided that the defective part(s) are returned to SteriLux SA prepaid.

This warranty shall be considered to be validated, if the product is accompanied by the original purchase invoice from the authorized SteriLux SA supplier, and such invoice identifies the item by serial number and clearly states the date of purchase. No other validation is acceptable. After one year, all SteriLux SA's warranties and other duties with respect to the quality of the product shall be conclusively presumed to have been satisfied. All liability therefore shall terminate, and no action or breach of any such warranty or duty may thereafter be commenced against SteriLux SA.

Any express warranty not provided hereon and any implied warranty or representation as to performance, and any remedy for breach of contract which, but for this provision, might arise by implication, operation of law, custom of trade or course of dealing, including any implied warranty or merchantability or of fitness for particular purpose with respect to all and any products manufactured by SteriLux SA, is excluded and disclaimed by SteriLux SA. If you would like to learn more about SteriLux SA products and features, contact us directly.

The use of SteriLux SA products implies that you have read and accepted its Standard Terms and Conditions of Sales.

16 Specifications

SteriBase V-Series dimensions:	Length:	518 mm
	Width:	296 mm
	Height:	437 mm
SteriBase V-Series weight:		18.5 kg
SteriBox V-Series size (External):	Length:	630 mm*
	Width:	318 mm*
	Height:	194 mm*
SteriBox V-Series size (Internal):	Length:	554 mm*
	Width:	260 mm*
	Height:	104 mm*
SteriBox V-Series weight:		4.5 kg*
Sterilization capacity volume:		20 L*
Clearance required:	Top:	200 mm
	Sides:	200 mm
	Back:	200 mm
	Front:	400 mm
Electrical rating:	Nominal voltage:	110 / 240 V
	Fluctuations:	110 V \pm 10%
	Nominal frequency:	50 / 60 Hz 3 A
Power:	Nominal	50 W
	Peak	200 W
Pollution degree (IEC 61010-1):		2
Protection:		Covered (indoor use only)
Ambient operating Temperature, Humidity and Pressure limits:		20°C to 30°C 20% to 70% 1 atm \pm 0,095
Ambient storing Temperature and Humidity:		5°C to 40°C 20% to 80%
Max. altitude:		Up to 2'000 meters

* is dependent of the SteriBox version

17 Appendix

17.1 Electromagnetic compatibility – Environment

The equipment under test is intended for industrial electromagnetic environment. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.

Verification of all devices in simultaneous operation are required to ensure the electromagnetic compatibility and co-existence of all other devices prior to use of SteriBase V-Series.

The product is intended for use in the electromagnetic environment specified in the table here below. The customer or the user of the product should assure that it is used in and identical environment.

Immunity tests	Applicable Standard	Test Levels	Expected Criteria	Observed Criteria
Electrostatic Discharges (ESD)	EN 61000-4-2 (2009)	± 4kV Contact Discharges ± 8kV Air Discharges	B	B
Radiated immunity to RF field	EN 61000-4-3 (2006+A1/2008+A2/2010)	10V/m AM 80% @ 1kHz, 80MHz to 1GHz 3V/m AM 80% @ 1kHz, 1.4GHz to 2GHz 1V/m AM 80% @ 1kHz, 2GHz to 2.7GHz 3V/m AM 80% @ 1kHz, 80MHz to 6GHz Performed at: 10V/m AM 80% @ 1kHz, 80MHz to 1GHz 3V/m AM 80% @ 1kHz, 1GHz to 6 GHz	A	A
Electrical Fast Transient (TRS)	EN 61000-4-4 (2012)	± 2kV: AC power supply port ± 2kV: DC power supply port (1) ± 2kV: signal and telecommunication lines directly connected to main supply ± 1kV: signal and telecommunication lines	B	A
Immunity to surges AC power supply port	EN 61000-4-5 (2014)	± 1kV for differential mode ± 2kV for common mode	B	A
RF conducted immunity	EN 61000-4-6 (2014)	3V AM 80% @ 1kHz 150kHz to 80MHz	A	A
Immunity to power frequency magnetic field	EN 61000-4-8 (2010)	30 A/m at 50Hz/60Hz	A	A
Voltage dips and short interruptions	EN 61000-4-11 (2004)	0% nominal during 1 period 40% nominal during 10/12 periods 70% nominal during 25/30 periods 0% nominal during 250/300 periods At 50Hz/60Hz	B C C C	A A A A

Emission Test	Limits			Applicable Standards
Limits for conducted disturbance at mains ports 150kHz-30MHz	Frequency	Quasi-peak value (dBµV)	Average value (dBµV)	EN 61326-1 (2013) EN 55011 (2009) and A1 (2010)
	150-500MHz	79	66	
	0.5-30MHz	73	60	
Radiated emissions 30MHz-1GHz	Frequency	Quasi-peak value (dBµV) @ 10 meters		
	30-230 MHz	40		
	230MHz-1GHz	47		
Harmonics current emission	According to standard EN 61000-3-2			EN 61000-3-2 (2014)
Voltage fluctuation and flickers test	According to standard EN 61000-3-3			EN 61000-3-3 (2013)

17.2 Electromagnetic compatibility – Performance Levels

For each internal function, a set of criteria has been defined to evaluate performance loss during immunity tests session. These criteria are listed per function in the table here below. Please note that these tests were performed on a device specifically designed for tests, presumed representative of the final product and its behaviour.

Function/Item to be tested	Parameter	Success criterions-A	Success criterions-B	Success criterions-C
UV analog measure	Analogic ozone sensor value (before computation) mean over 100 acquisition	Value between 0 and 1023	N/A	N/A
		Standard deviation of dataset less than (1% of mean value or 2)	Standard deviation of dataset less than (2% of mean value or 4)	N/A
RFID reading	RFID tag value (a SteriBox should be inserted in the SteriBase)	Only SteriBox ID	Connection lost (-1 or -2) for less than 5% of time	N/A
Thermometer	Lamp Unit temperature value	Floating point values	N/A	N/A
		Step between two measurements must be less than 5 degrees, except if one of them is the default value	Step between two measurements must be less than 15 degrees, except if one of them is the default value	Values must be between 5 and 90 degrees
		No default values	Measure is correct after a default value	Measure remains the default one
Raspberry Pi	Internal data writing	Log exists	Raspberry Pi shutdowns unexpectedly and reboots	User must press the ON/OFF button to either power it on or shut it down
	State of Shutdown Command, detect falling edge	Commands are detected, but the SteriBase must not reboot/turn off		

Function/Item to be tested	Parameter(s)	Success criterions-A	Success criterions-B	Success criterions-C
172 nm UV Lamp	State of Generation Control Pins	State of Generation Control Pin must be LOW for at least 99% of time	State of Generation Control Pin must be LOW for at least 50% of time	N/A
254 nm UV Lamp	State of Destruction Control Pin	State of Destruction Control Pin must be LOW for at least 99% of time	State of Destruction Control Pin must be LOW for at least 50% of time	N/A
Printer	State of Printer connectivity	Printer must be connected for at least 99 % of measurement	Printer must be connected for at least 50 % of measurement	Printer must be connected for at least 10 % of measurement
Clock	Date must be superior to latest registered value Date must be superior to 1. Jan.2017 Date must be superior to 1. Jan.1970	Each of the parameters are respected	One of the conditions on the left is not respected during one measurement, and correct itself on the next measurement	More than one of the conditions on the left is not respected during one measurement, and correct itself on the next measurement
USB	Check if USB stick is available	USB stick is always available	USB Stick state goes from "unavailable" to available	USB Stick remains unavailable

17.3 Accessories replacement

Fuse

Manufacturer	Bel Fuse Inc
Manufacturer Reference	5MF 4-R
Nominal Current	4A
Nominal Voltage	125VAC

Power cord

Manufacturer	Schurter Inc.	Schurter Inc.	Qualtek
Manufacturer Reference	6011.0215	6004.0215	370001-E01
Nominal Current	10A	10A	10A
Nominal Voltage	250VAC	250VAC	250VAC
Cross Section	1 mm ² (or AWG 18)	1 mm ² (or AWG 18)	1 mm ² (or AWG 18)

