Summox One

Instructions for use

the first all-in-One

Summox Dental B.V.
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1. TABLE OF CONTENTS

2. CONTACT INFORMATION

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SRN: NL-MF-000000057

3. WARRANTY

A warranty period of 12 months is given for the Summox One System starting on the date of delivery. The warranty covers production and material defects, provided that the Summox One System is used according to the Instructions for Use and indications provided by the manufacturer.

Notice: All maintenance actions, other than those described in this manual must be executed by a Summox certified service engineer. Failure to use a Summox Certified Service Engineer for any maintenance activities will **void the warranty** on the Summox One System.

A warranty period of 12 months or 250 cycles, whichever comes first, is given for Summox Smart Containers starting on the date of delivery. The warranty covers production and material defects, provided that the Summox Smart Containers are used according to the Instructions for Use and indications provided by the manufacturer.

4. REPORTING A SERIOUS INCIDENT

If a serious incident has occurred in relation to the device, it should be reported to the Legal Manufacturer Log10 B.V. and the Competent Authority of the Member State in which the user and/or patient is established. A serious incident means any incident that directly or indirectly led, might have led or, in case of recurrence, could lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's, foetus or other person's state of health, or a serious public health threat.

5. SAFETY WARNINGS AND PRECAUTIONS

These Instructions for Use hold safety remarks. Pay extra attention to these remarks and follow the given instructions.

5.1 WARNING SIGNS AND MEANING

	Warning: Indicates a hazard with a moderate level of risk which, if not avoided, could result in injury or impairment requiring medical or surgical intervention of the user or patient.

5.2 PERSONAL PROTECTION EQUIPMENT SYMBOLS

The following personal protection materials are prescribed in these Instructions For Use.

	Protection gloves.
	Safety goggles.

5.3 OTHER SYMBOLS

	Indicates information that does not describe an action or a risk but requires extra attention.

5.4 SAFETY REMARKS IN THIS DOCUMENT

5.4.1 General safety remarks

	Warning: Do not place liquids and/or objects on top of the Summox One System. If liquids flow into the device, system failure may be the result, causing a possible health risk for patient and user.
	Warning: Always perform maintenance according to schedule. Not doing so may lead to a health risk for patient and user. It may also damage the machine and voids the warranty.
	Warning: Do not process instruments when these are contaminated with Prions. Processing instruments contaminated with prions may cause a health risk for patient and user.
	Warning: Do not sterilize hollow instruments, e.g. handpieces, canulas, syringe tips, suction tubes etc. Processing hollow instruments for sterilization may cause a health risk for patient and user.

5.4.2 When programming the RFID tag

	Warning: Always select the correct decontamination program: not selecting the correct decontamination program can lead to improperly decontaminated instruments, causing a possible health risk for patient and user.

5.4.3 When working inside the Summox One System

When recovering lost instruments, when opening the Handpieces chamber, when cleaning the Summox One internally, when cleaning filters in the chambers:

	Warning: Hot surfaces. Risk of skin burn. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: Sharp edges. Risk of injury. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: User health risk (biohazard). Wear protection gloves.

5.4.4 While placing and removing Summox Smart Containers

	Warning: Process instruments within 2 hours after use. After this time, the effectivity of decontamination is reduced, causing a possible health risk for patient and user.
	Warning: Moving parts. Risk of entrapment. Do not put hands in the input or output.
	Warning: Do NOT use Summox Smart Containers when these are manually removed from system during power cut or error recovery. Even when the Summox Smart Seal is on the Container (and might even show discoloration). The container might not be properly decontaminated, and the instruments may cause a health risk for patient or user.

5.4.5 While loading instruments into Summox Smart Containers

	Warning: Do NOT prepare Containers other than described in the instructions for use. For example, overloading, wrong orientation, wrong instruments, disposables in container etc. This may lead to improper decontamination of instruments, causing a possible health risk for patient and user.
	Warning: Do not load Containers with instruments that are contaminated with anything other than blood and saliva, e.g., Gutta Percha, cement, composites, etc. This may lead to improperly decontaminated instruments, causing a possible health risk for patient and user.
	Warning: do NOT add instruments made of materials that are not corrosion resistant, like aluminum, brass, copper etc. Processing these materials may lead to instrument damage and a health risk for patient and user.
	Warning: Do not sterilize instruments containing anodized aluminum. Sterilizing these instruments may lead to instrument damage and a health risk for patient and user.
	Warning: do NOT add instruments that cannot withstand temperatures up till 102ºC. Processing these materials may lead to instrument damage and a health risk for patient and user.
	Warning: Do not place handpieces and cannulas in the Wirebasket. This may lead to improper decontamination of instruments, causing a possible health risk for patient and user.
	Warning: Do not place instruments that contain a hollow part with the opening facing upwards while placing them in the container. Droplets may stay behind. These droplets may contain irritating substances that may cause skin damage for patient or user.

5.4.6 When opening a Summox Smart Container

	Warning: Do NOT use instruments with visible droplets after sterilization. These droplets may contain irritating substances that may cause skin damage for patient or user.
	Warning: Use safety goggles and wear protection gloves when opening a Container that has droplets inside. The droplets within the Container are irritating and may cause skin and eye damage.
	Warning: Do NOT use Containers when a hissing sound is not heard when removing the Summox Smart Seal, or when a correctly printed Summox Smart Seal is not present. The container is possibly not properly decontaminated, and the instruments may cause a health risk for patient or user.
	Warning: Do NOT use instruments from Summox Smart Containers after the expiry date. This may cause a health risk for patient and user.

5.4.7 When replacing consumables

	Warning: Risk for irritating substances. Wear protection gloves.
	Warning: Do NOT use consumables after the expiry date. This may cause a health risk for patient and user.
	Warning: Only use Summox consumables. Using other than Summox consumables may cause a health risk for patient and user and voids the warranty of the Summox One System.

6. SUMMOX ONE SYSTEM DESCRIPTION

The Summox One System is intended to decontaminate reusable dental instruments that are carried in a Summox Smart Container. All types of instruments are cleaned, disinfected, dried, and cooled; non-hollow instruments may additionally be sterilized, and dental handpieces may be lubricated. Furthermore, the Summox One System is intended to close and seal Summox Smart Containers, which allows storage of the dental instruments, in a sterile manner where applicable.

The Summox One System is to be used in dental healthcare facilities.

The primary users of the Summox One System are dental professionals—including but not limited to dentists, dental specialists, dental assistants, and other dental staff—who will work in accordance with the Instructions for use guidelines.

The expected clinical benefit of the Summox One System is that it is certain that several required processes are executed for decontamination of re-processable dental instruments. Properly decontaminated instruments minimize the risk of contamination that can affect the patient during dental treatment. In the Summox One System, decontamination is ensured to the endpoints “Disinfected” for all types of instruments, and (if required) “Sterile’” for non-hollow instruments. Through the automation of multiple decontamination processes in one device, the Summox One system ensures that risks resulting from human error during instrument reprocessing are highly unlikely to occur.

6.1 DEVICE OVERVIEW

The Summox One System is shown in Figure 1.

Figure 1 The Summox One System with Summox Smart Containers stacked on top

References Figure 1		
Item	Name	Function
A	Input stack	Position at which Summox Smart Containers are stacked before loading into device.
B	Front door	Gives access to the interior of the device for periodic maintenance. Door is locked for safety, and can be opened by using the Graphical user interface.
C	Consumables door	Gives access to the consumables.
D	Graphical user interface	Allows user control over some functions of the Summox One System, including but not limited to, (re)programming of the decontamination program in the RFID tag on the Summox Smart Container, view consumable statistics, view historic data from previously processed Summox Smart Containers, Troubleshoot warnings.
E	Printer door	Gives access to the labelling module for replenishing Summox Smart Seals.
F	Output stack	Position at which Summox Smart Containers are stacked after processing.

6.2 DECONTAMINATION PROGRAMS

The type of instruments and the way they will be used determines which decontamination program needs to be performed. The combination of the different processes in the process chambers classify as decontamination programs. The Summox One System offers five distinct decontamination programs.

1. General instruments: Washing + Disinfection
2. General instruments: Washing + Disinfection + Sterilization
3. Handpieces: Washing + Disinfection [internal + external] + Lubrication
4. Handpieces: Washing + Disinfection [internal + external]
5. Handpieces: Washing + Disinfection [external]

Module			Handpieces										Sterilization		
Function			Internal washing	External washing	Internal disinfection	External disinfection	Lubrication	Ultrasonic cleaning	Spray washing	Disinfection	Drying	Cooling	Sterilization	Closing & Sealing	Labelling
Program	1	General Instruments Disinfection						✓	✓	✓	✓	✓		✓	
	2	General instruments Sterilization						✓	✓		✓	✓	✓	✓	✓
	3	Hollow Handpieces Disinfection and Lubrication	✓	✓	✓	✓	✓				✓	✓		✓	✓
	4	Hollow Handpieces Disinfection	✓	✓	✓	✓					✓	✓		✓	✓
	5	Solid Handpieces Disinfection		✓		✓					✓	✓		✓	✓

6.2.1 Performance characteristics

For use within the intended purpose, performance characteristics can be defined for all five decontamination programs of section 6.2.

Cleaning performance:

- The ultrasonic module cleans surface contamination by using cavitation bubbles, in a mixture of Summox One Detergent and water of 37°C, created by piezo electric ultrasonic transducers that operate on a frequency of 40 kHz.
- The spray module washes the instruments with water at 73°C and Summox One Detergent.
- Cleaning is validated for worst case contamination and tested for protein and hemoglobin residues in accordance with EN ISO 15883-1 and EN ISO 15883-5.

Disinfection performance:

- For disinfection, the Container carrying dental instruments is completely submerged in hot water of ≥93°C.
- Disinfection is successful when an A0 value of ≥3000 is reached. A0 = 3000 means the item has been disinfected to a high medical standard — it's safe to use and nearly all harmful microbes have been destroyed.
- The water is continuously circulated with a circulation pump to ensure an even temperature distribution, and to rinse off all detergent residue from the previous washing processes.
- Disinfection is validated in accordance with EN ISO 15883-1, and EN ISO 15883-2
- The disinfection process is compatible with instruments made from commonly used materials in dental instruments, such as stainless steel, silicone, anodized aluminium, titanium and temperature resistant polymers.

Processes with endpoint sterilization additionally have the following performance characteristics:

- The sterilization process achieves a sterilization assurance level of 10-6 for most difficult to inactivate microorganism (i.e. spore of the Geobacillus stearothermophilus). This means a probability of one in one million that an instrument may be non-sterile.
- The sterilizing agent comprises controlled concentrations of ozone, nitrogen dioxide, nitrous oxide and nitric acid. The agent is generated on-site and on demand by the Dielectric Barrier Discharge plasma-reactor.
- End point sterilization is achieved by the sterilization agent that induces lethal oxidative stress on microorganisms during the defined sterilization process under the specified process conditions.
- Sterilization can be achieved when the following process parameters are within the boundaries: chamber pressure between Atm-40 mBar and Atm-60 mBar, specific humidity between 11,5 g/kg and 13,5 g/kg, chamber temperature between 23°C and 30°C, Power DBD reactor between 110W and 120W, and air flow between 9 and 11 Ln/min.
- Sterilization is validated in accordance with the conservative overkill approach described in Annex D of the EN ISO 14937:2009.
- After use, all reactive molecules in the sterilization agent are neutralized in a special filter.
- The sterilization process is compatible with dry, non-hollow instruments, made from commonly used materials in dental instruments, such as stainless steel, silicone, titanium and polymers.

Handpieces disinfection and lubrication performance:

- Cleaning of external surfaces and internal channels is performed with water of 40°C and Summox One Detergent, after which internal channels are purged with pressurized medical grade air.
- Internal and external disinfection is performed with steam. The steam has a temperature of ≥97 ˚C, disinfection is successful when an A0 value of ≥3000 is reached. A0 = 3000 means the item has been disinfected to a high medical standard — it's safe to use and nearly all harmful microbes have been destroyed.
- Internal drive channels are lubricated with Summox One Oil.

Closing and sealing of Summox Smart Containers

- The Summox One System closes and seals Summox Smart Containers at a sub-atmospheric pressure, which allows storage of the dental instruments, in a sterile manner where applicable.
- The Summox Smart Seal shows relevant information such as decontamination status, processing date, and expiry date if applicable.

Input water and air:

- Input air is pressurized and of medical grade
- Input water is softened (<0.5dH) and the quality is in accordance with the drinking water directive EU 2020/2184.
- The Summox One System creates reverse osmosis water from the input water to be used for final rinsing, disinfection and sterilization.

Process monitoring:

- The decontamination progress and process control are monitored by software.
- A container is released from the Summox One System when all parameters are within bounds during all phases of the decontamination process.
- Process data is kept by the Summox One System with a time stamp for each Container.
- Process data is available for review and parametric release on the Graphical User Interface.

6.3 SUMMOX SMART CONTAINERS & SUMMOX SMART SEAL

The Summox Smart Containers are available in two sizes.

A full-sized and half-sized Summox Smart Container are shown in Figure 2.

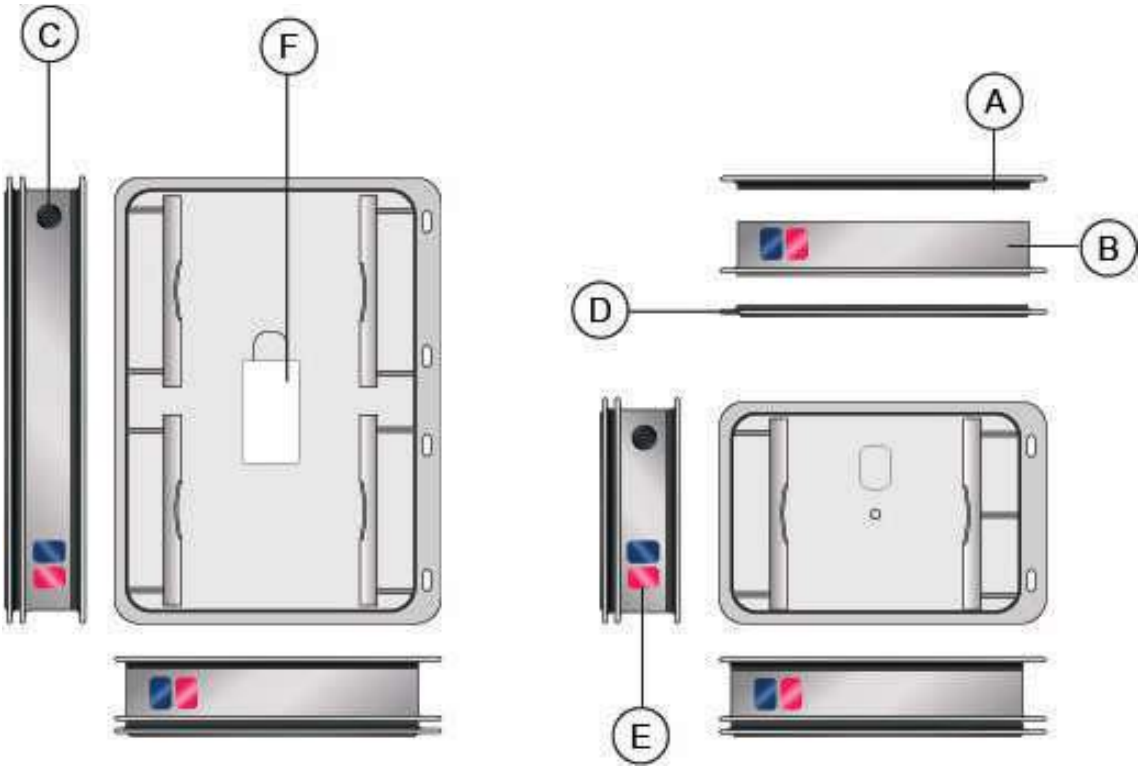


Figure 2 Full-sized Summox Smart Container (left) and half-sized Summox Smart Container (right)

References Figure 2		
Item	Name	Function
A	Cover	Functions as a barrier between the reprocessed instruments and the environment and allows closing and sealing of the Container at the end of the decontamination process.
B	Inlay	Holds the inserts, which in turn hold the instruments.
C	RFID Tag	Holds all Summox Smart Container and program information.
D	Bottom	Functions as a barrier between the reprocessed instruments and the environment and allows closing and sealing of the Container at the end of the decontamination process.
E	Summox Color Tag	Helps the user to quickly identify the Summox Smart Container.
F	Summox Smart Seal	A self-adhesive label that seals the Summox Smart Container after processing. Moreover, the Summox Smart Seal shows relevant Container information such as the Container type, decontamination status (e.g., disinfected or sterilized) and expiration date. Additionally, the Summox Smart Seal functions as a tamper evident and sterilization indicator.

6.3.1 Container types & inserts

You can configure your own containers, but not all combinations of container type and inserts are possible. Allowed combinations are indicated in Figure 3.

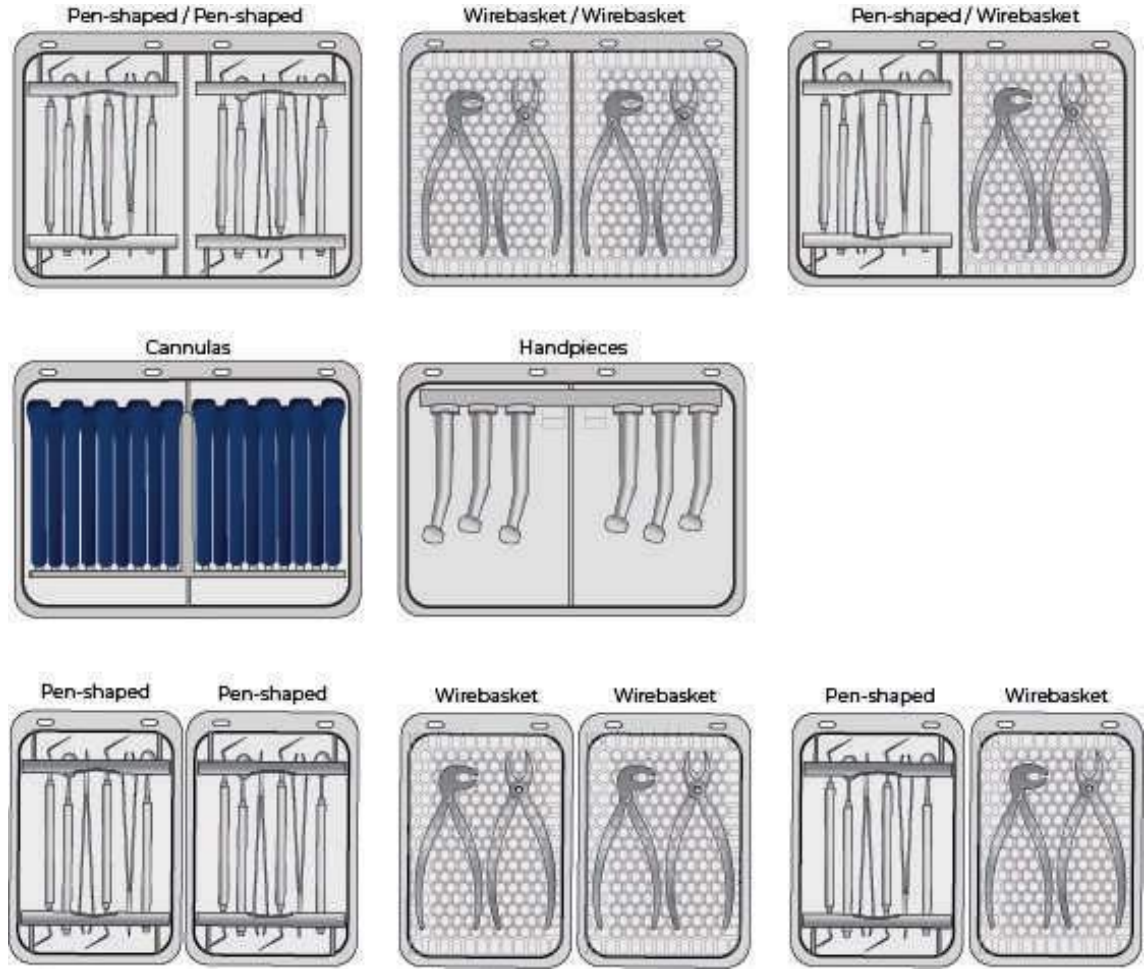


Figure 3 Container with different inserts

Allowed configurations of Summox Smart Containers			
Container type	Size in mm (l x w x h)	Allowed insert types	Configurations
General instruments full-sized	208 x 294 x 51.5	Pen-shaped (PS) half-sized Wirebasket (WB) half-sized	Can be mixed, maximum 2 per full-sized container
		Cannulas (CA) full-sized	One Cannula insert per full-sized container
General instruments half-sized	208 x 149,5 x 51.5	Pen-shaped (PS) half-sized Wirebasket (WB) half-sized	One insert per half-sized container
Handpieces full-sized	208 x 294 x 51.5	Handpieces (HP) full-sized	One insert per full-sized container

The reconfiguration of container inserts is described in section *Reconfiguring Summox Smart Containers.*

6.3.2 Summox Smart Seal

Only original Summox Smart Seals may be used in the Summox One System. Figure 4 below shows the Summox Smart Seal.

Figure 4 Summox Smart Seal

References Figure 4		
Item	Name	Function
A	Sterilization Indicator	Helps the user to quickly identify the program that was used for the Summox Smart Container. (it remains white in disinfection programs, it changes color to a shade of green in sterilization programs)
B	Sterile Symbol	Provides information to the user on the program that was used for the Summox Smart Container, in this case sterilizing.
C	Expiry date	Provides information to the user until which date the instruments in the Summox Smart Container remain sterile.
D	Processing date	Identifies at which date and time the Summox Smart Container was processed in the Summox One System.
E	Container name	Helps the user to quickly identify the Summox Smart Container if a name was given to this Summox Smart Container. See *Scanning and (re)programming a Summox Smart Container.*
F	Insert code	Provides information on which inserts are part of this container. See *Container types and Inserts.*
G	Non-sterile Symbol	Provides information to the user on the program that was used for the Summox Smart Container in this case disinfection.

6.3.3 Color tags

Colors that are available are shown below.

Figure 5 Color tags

It is up to the user to decide how to code any Summox Smart Container with the use of the Summox Color Tags.

Installing or changing color tags is described in *Adding or changing Summox Color Tags.*

6.4 APPROVED ACCESSORIES AND CONSUMABLES FOR THE SUMMOX ONE SYSTEM

The Summox One System requires the use of accessories and consumables. Only those accessories and consumables with which the Summox One System is validated may be used to operate the device. These accessories and consumables are:

Approved accessories* and consumables**		
Item code	Description	Item name
60110	Summox Smart Container	Summox Smart Container for General Instruments - full-sized
60120	Summox Smart Container	Summox Smart Container for Handpieces - full-sized
60150	Summox Smart Container	Summox Smart Container for General Instruments - half-sized
70101	Summox One Detergent	Summox One Detergent – Suma® Med Super LPH – 5L
70201	Summox One Oil	*Summox One Oil – 0,5L*
70401	Summox Smart Seal	*Summox Smart Seal*

* The Summox Smart Container for General Instruments is a configurable device. 7 Configurations can be created with 4 types of Summox Inserts.

** Suma® Med Rinse is used in the device which will be refilled by Summox Service Engineers during preventive maintenance, it is not for sale to users.

6.5 SUMMOX ONE SYSTEM PROCESS CHAMBERS

The Summox One System processes the Summox Smart Containers in dedicated process chambers. These process chambers are usually called chambers.

The chambers become visible after opening the front door. One of the reasons for opening the front door is the need to clean the inside of the device as is explained in Periodic Maintenance. Figure 6 shows the different process chambers.

If we discuss a process chamber and include all related equipment, like hoses, pumps, control system, etc. the name module is preferred, as a functional part of the Summox One System. The user interface may use module and chamber interchangeably.

Figure 6 The Summox One System process chambers visible with opened front door

References Figure 6		
Item	Process chamber	Function
A	Handpiece chamber	Decontamination and lubrication of handpieces.
B	Ultrasonic chamber	Ultrasonic cleaning of general instruments.
C	Spray washing chamber	Spray washing of general instruments.
D	Disinfection chamber	Thermally disinfecting of general instruments.
E	Drying chamber	Drying of general instruments.
F	Sterilization chamber	Plasma activated air sterilization of general instruments and closing of all Summox Smart Containers.
G	Cooling chamber	Cooling of general instruments and handpieces.

6.5.1 Handpieces chamber

This chamber combines spray washing, disinfection, and lubrication, while the Handpieces are connected to a flow manifold for effective internal processing including lubrication.

6.5.2 Ultrasonic chamber

In this chamber, ultrasonic cleaning takes place with the Container fully submerged in water measuring 37 ˚C. To enhance cleaning, Summox One Detergent is added to the water.

6.5.3 Spray washing chamber

Spray washing uses water measuring 73 ˚C. To enhance cleaning, Summox One Detergent is added to the water. Spray washing is performed with rotating nozzles.

6.5.4 Disinfection chamber

For disinfection, the Container carrying dental instruments is completely submerged in hot water measuring ≥93 ˚C.

6.5.5 Drying chamber

Drying of the Container and instruments takes place at 82.5 ˚C. It uses clean hot dry air to evaporate the water from the Container parts and dental instrument's surfaces.

6.5.6 Sterilization chamber

Sterilization is achieved by exposing the instruments to plasma activated air (PAA) at a temperature of 25 - 40 ˚C. Closing of containers is achieved by applying vacuum.

6.5.7 Cooling chamber

Cooling is performed at 11-22 ˚C using two cooling fans.

6.5.8 Automatic self-disinfection program

During shutdown (automatically by the timer or manually by selecting the shutdown button), the system will automatically run the self-disinfection program. This program needs to run at least once per 24 hours. It contains a disinfection step similar to the step in the washing and disinfection process. The self-disinfection program is used to disinfect the washer and associated components (including pumps and piping) and guarantees a biologically safe operation of the system.

7. OPERATING THE SUMMOX ONE SYSTEM

⚠	Warning: Do not place liquids and/or objects on top of the Summox One System. If liquids flow into the device, system failure may be the result, causing a possible health risk for patient and user.
⚠	Warning: Do not process instruments when these are contaminated with Prions. Processing instruments contaminated with prions may cause a health risk for patient and user.

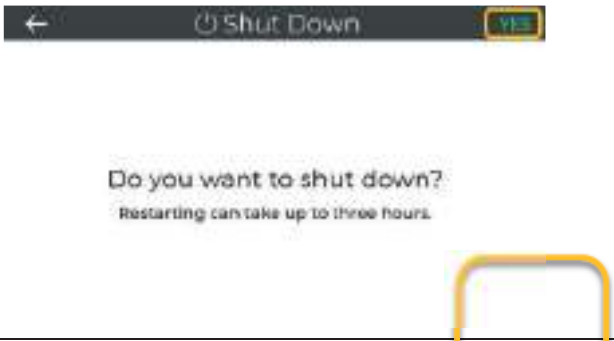
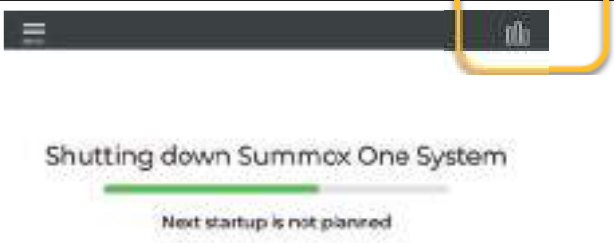
7.1 MACHINE SHUTDOWN AND STARTUP

During normal operation, the timer will do the shutdown and startup according to the timer schedule. Setting the timer can be found in section Timer settings.
However, the timer schedule can be overruled by the user by giving startup and shutdown commands in the user interface.

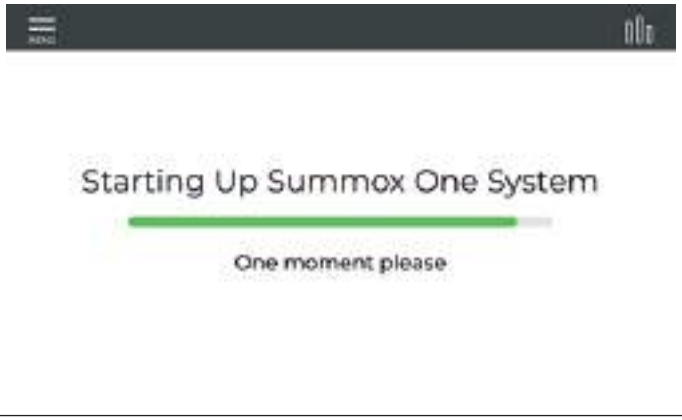
Note that each shutdown includes a self-disinfection program, see *Automatic self-disinfection program*.

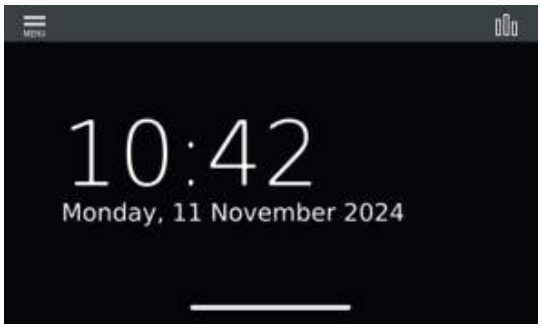
7.1.1 Manual shutdown using the user interface

Step	Reference
1. Make sure that all Summox Smart Containers are processed, and the device is in stand-by state.	N.A.
2. On the stand-by screen, press the menu button. *The Menu window becomes visible.*	
3. In the menu window, press **Shut Down**. *The Shut Down window becomes visible.*	

4. Press **YES** to confirm the Shutdown. The device will do a self-disinfection program and then shut down. This may take more than one hour.	
The Shut Down window is visible during the shutdown process. 5. Wait until the shutdown is completed.	

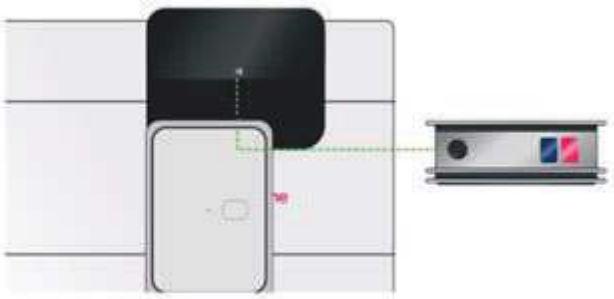
7.1.2 Manual startup using the user interface

Step	Reference
1. Tip the user interface with a finger. *The startup acknowledge window becomes visible.*	N.A.
2. Press **YES**.	
The start-up screen is visible during start up. *The start-up time from cold start to standby will be ≤ 60 min.*	

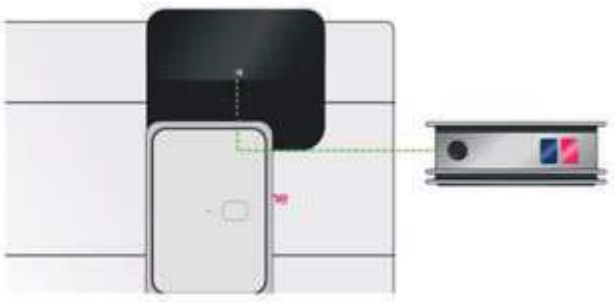
3. Wait for the Standby screen to show.	
4. The Summox One System is now ready for use.	

7.2 SCANNING AND (RE)PROGRAMMING A SUMMOX SMART CONTAINER

	Warning: Always select the correct decontamination program: not selecting the correct decontamination program can lead to improperly decontaminated instruments, causing a possible health risk for patient and user.
	The default program setting of every Smart Container is disinfection. The default setting can be changed after reading the RFID tag.

Step	Reference
1. Hold the RFID tag of the Container close to the Graphical user interface. (the screen) *The Container Info window becomes visible after a few seconds.*	
2. For general instruments containers 2.1. Press the **Insert** line to select the type from the pop-up list: 2.1.1. None 2.1.2. Pen-shaped 2.1.3. Wirebasket 2.1.4. Cannula rack 3. At **Program**, select **Sterilization** or **Disinfection** (default).	 
4. For Handpieces containers, 4.1. Switch **Internal cleaning** on if the handpieces need to be internally cleaned. 4.2. Switch **Lubrication** on/off according to the specific user instructions delivered by your instrument's supplier. *Disinfection is automatically selected.* 5. Activate Alert in case a audible sound is required when a Container is ready. 6. Scroll up or down to select Name. *The Change Name field becomes visible.*	

7. Type the new Summox Smart Container name. 8. Press **SET**.	
9. Select **Color Tags.** *The Edit Color Tags window becomes visible.*	
10. Change the color for Tag1 and Tag2 10.1. Select the color 10.2. Select the first box for no color 11. Press **SET**. 12. Make sure the set colors match with the actual colors of the Summox Color Tags on the Container, change the tags if required, see below subsection *Adding or changing Summox Color Tags*	
13. In the Container info window, Press **SET**.	
The message to hold the container below the display appears.	

14. Hold the RFID tag of the Container close to the user screen for a few seconds until the screen changes its message. *The RFID tag will be programmed to hold the program data and Container name and colors.* 15. In the Programming Container window, press **FINISH**.	

7.3 PROCESSING A SUMMOX SMART CONTAINER TO DECONTAMINATE INSTRUMENTS

	Warning: Process instruments within 2 hours after use. After this time, the effectivity of decontamination is reduced, causing a possible health risk for patient and user.

Pre-cleaning of instruments may be warranted, for example when the instruments are extensively soiled or have complex tips.

To process a Summox Smart Container, place the Summox Smart Container(s) on the input stack.
The containers may be stacked on top of each other but no more than 6 containers may be on the input stack at any given point. The Summox One System reads the RFID tag on the Summox Smart Container, automatically selects the program required, opens the safety door input and the device will proceed with the selected program delivering a correctly processed Summox Smart Container on the output stack.

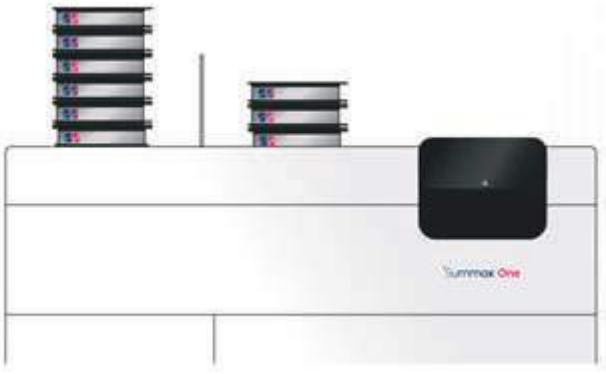
7.4 ATTACHING TWO HALF-SIZED CONTAINERS

Half-sized containers can only be processed in twos.
To process 2 half-sized Summox Smart Containers, you need to connect them before placing them on the input stack of the Summox One System. How to attach them is described below.

Step	Reference
1. Put the two half-sized Containers on a flat surface. 2. Push the containers together to join the interlocking latches. This way the two half-sized Containers are connected.	

7.5 ADDING A CONTAINER TO THE INPUT STACK

	Warning: Moving parts. Risk of entrapment. Do not put hands in the input or output.

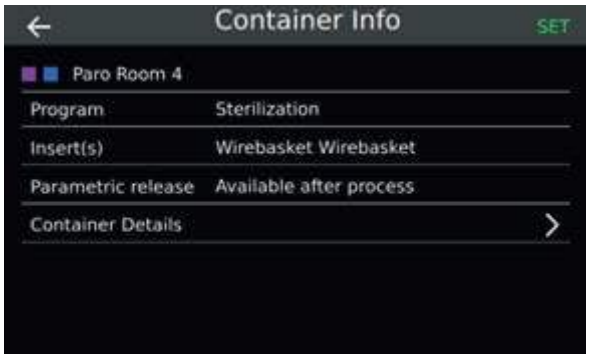
Step	Reference
1. Make sure that the Container is correctly prepared for processing, see *Closing the Summox Smart Container.* 1.1. If present, the Summox Smart Seal must be removed. 1.2. The Container must be correctly closed. 1.3. Instruments must be clamped or resting in the basket.	N.A.
2. Make sure that half-sized Summox Smart Containers are always grouped into couples, see 3. Attaching two half-sized Containers. 4. Make sure the input stack holds no more than 6 Summox Smart Container layers. wait until the next Container is processed and the stack is less than 6. 5. Make sure the Container output stack holds less than 6 Summox Smart Containers, if needed, remove Containers to lower the stack.	

7.6 CHECKING THE PROCESS

	The added Container will automatically start the process when it enters the device.

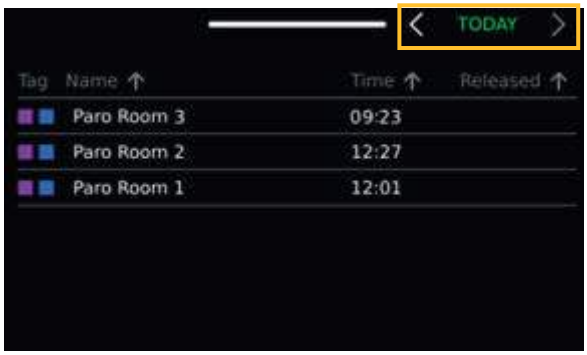
The Summox One System is fully automatic, there is no need for manual action while the instruments in the Summox Smart Containers are being decontaminated. In case you would like to know the progress of a specific Summox Smart Container or see which Containers are in progress, you can see this on the status screen.

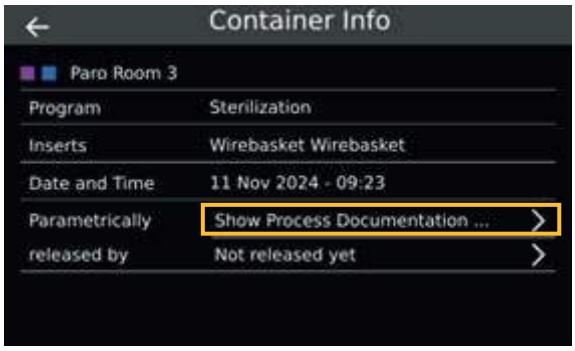
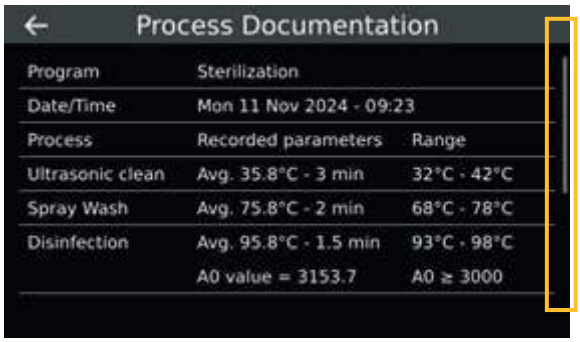
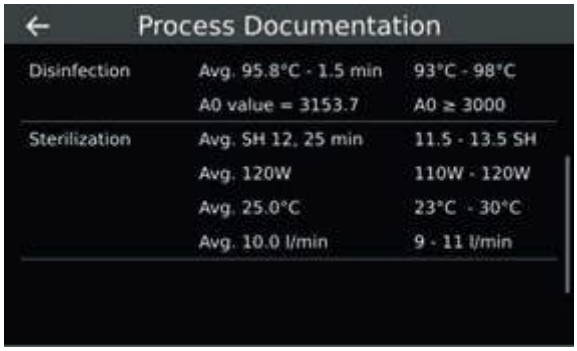
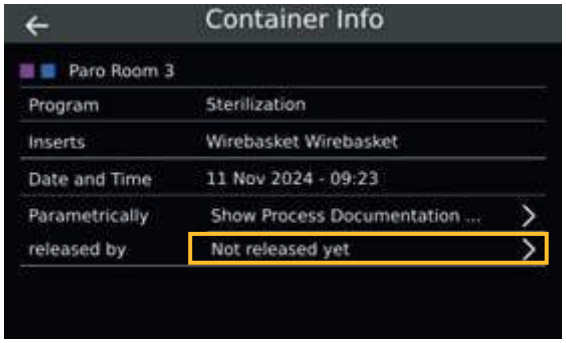
Step	Reference
1. Check the Container process progress on the process status screen: 1.1. The **Time left** column gives the remaining time for a Container until the end of the process. 1.2. The **Alert** column shows if an alert is activated at the end of the process. 2. Press on a specific Container line to see process details. *The Container Info window opens.*	

3. At **Program**, the Container program is shown. 4. At **Inserts**, the insert(s) present in the container is show. 5. At **Position**, (only visible in case of half-sized) front or back position 6. **Alert** can be switched on to give an alert when this Container is processed. 7. **Validation** shows when validation (option) is ready 8. Select **Container details**, to view the Container Details window.	
8.1. **Unique ID** is the unique Container ID that was chosen while programming the RFID tag. 8.2. For **Container Type**, see Reconfiguring Summox Smart Containers. 8.3. **UDI-DI** is Unique Device Identifier for the used container type 8.4. **UDI-PI** is production batch number 8.5. **Process Cycles** history of total number of times that this container was processed 8.6. After checking, press ←	

7.7 SHOW HISTORY AND RELEASE SUMMOX SMART CONTAINERS

It is possible to manually approve the parametric release of each individual Summox Smart Container. This is option “parametric release” in the container info window.

Step	Reference
1. Swipe up the white bar at the bottom of the process progress screen.	
2. Select a day by pressing **<** or **>** at the right top of the window. 3. Sort the information per column by pressing **Name**, **Time** or **Released**. 4. Press the Container of your preference to see the process details *The Container Info window opens.*	

5. If required, select **Show Process Documentation** to see the process values. *The Process Documentation window will become visible.*	
6. In the **Process Documentation** window, check the process values, see appendix, section *Summox* Smart Container release requirements. 7. After checking, press .	 
8. If process validation is enabled (see 9. Change process validation setting), select **Not Validated yet**. *The Container Info window will become visible.*	

10. Select the name of the user that is validating. 11. Press **SET**.	

	The validation cannot be changed or deleted.

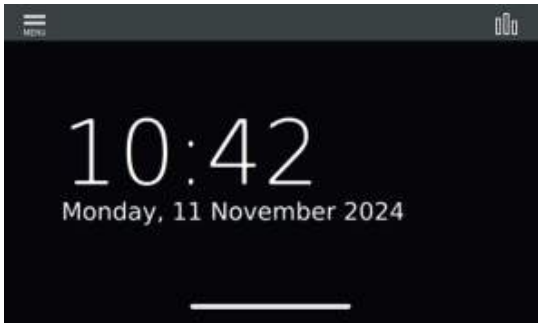
7.8 TAKING A PROCESSED SUMMOX SMART CONTAINER FROM THE SUMMOX ONE SYSTEM

	Warning: Moving parts. Risk of entrapment. Do not put hands in the input or output.

Step	Reference
1. Wait for the Summox Smart Container to have fully ascended from the Summox One System and the Safety door output has closed.	
2. Remove the Container from the output stack.	
3. If needed, you may remove a container from a position within the stack.	

7.9 CHECK PROCESSED SUMMOX SMART CONTAINERS' EXPIRY DATES

After decontamination some Summox Smart Containers might move to stock for future use. To make sure the instruments in a specific Summox Smart Container may still be used in the treatment room (only relevant for instruments that were sterilized), the expiry date on the Summox Smart Seal needs to be checked. Information on all sterilized containers is also available in the Graphical user interface by following the below steps.

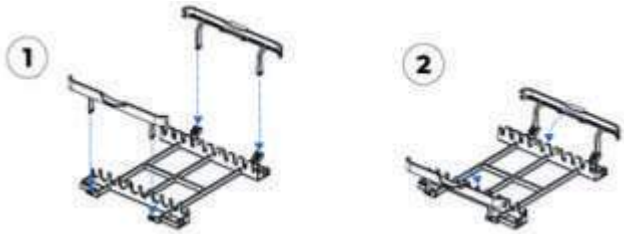
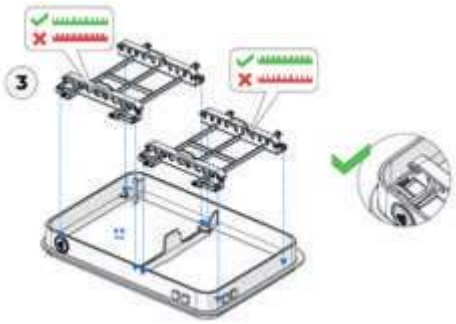
Step	Reference
1. Wait until the device is in standby mode. 2. Do not add new Containers to the input stack.	

3. In the **Menu** window, select Maintenance. *4. The **Maintenance** window becomes visible.*	
5. Select **Expiry date list**.	
6. Check the expiry date in the Container list. *The list only shows sterilized Containers close to the expiry date.*	

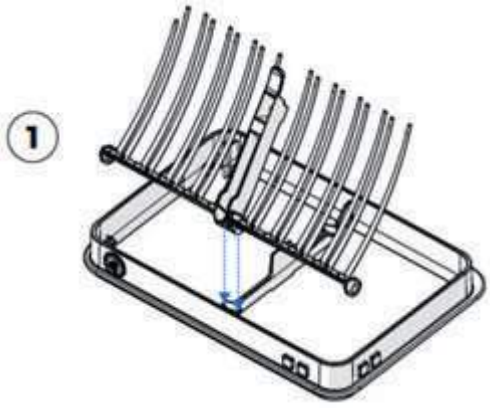
8 CONFIGURING SUMMOX SMART CONTAINERS

Summox Smart Containers come in two sizes: half-sized and full-sized. A full-sized Summox Smart Container can hold up to two inserts, a half-sized Summox Smart Container can hold just one insert. See also *Container types and Inserts*. Configuring the Summox Smart Containers is described in the next sections.

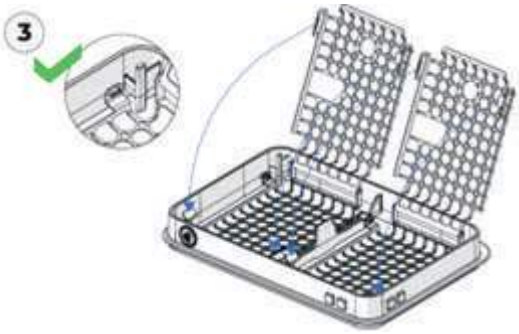
8.1 INSTALL A PEN-SHAPED INSERT

Step	Reference
1. Put the inlay with the pen-shaped insert on a flat surface. Push the pen-shaped inserts in the bracket. 2. Close the inserts before installing.	
3. Connect the four corner supports to the container per insert. Be sure the corner supports are in the right place.	

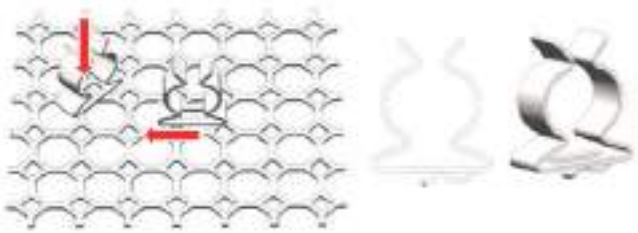
8.2 INSTALL A CANNULA INSERT

Step	Reference
1. Put the Inlay on a flat surface and push the middle of the Cannula insert in the container.	
2. With some force connect the left and right insert to the Container. 3. When properly installed, the insert closes easily and securely.	

8.3 INSTALL A WIREBASKET INSERT

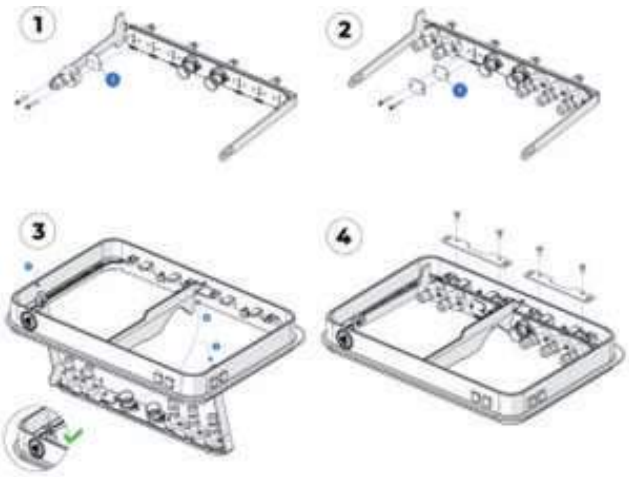
Step	Reference
1. Put the Inlay on a flat surface. Attach the two panels by aligning the clips with the slots, ensuring a secure fit.	
2. Place the top frame over the panels, sliding them into the correct slots (as shown by the blue arrows). Avoid misalignment (red example).	
3. Ensure the side clips lock the panels in place (green check), confirming proper assembly.	

8.4 INSTALL A WIREBASKET TOOL CLAMP

Step	Reference
1. Open the Wirebasket.	N/A
2. Install the clamp: 2.1. Position the clamp into a hole. 2.2. Move the clamp sideways and click it in position.	
3. Close the Wirebasket.	N/A

8.5 INSTALL A HANDPIECE ADAPTER

	The Summox Smart Container for handpieces is compatible with adapters that fit Dentsply Sirona's DAC Universal lids for the reprocessing of straight and contra-angle handpieces and turbines (i.e. standard/blue/pink lid). The adapters are not included with the Summox Smart Container for handpieces and must be purchased separately.

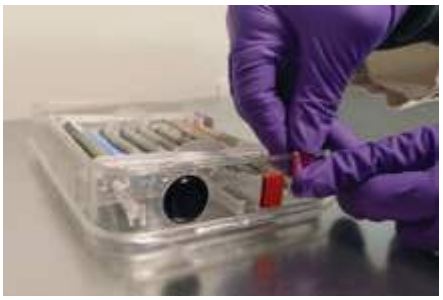
Step	Reference
1. Ensure you have the correct handpiece adapters	N/A
2. Install the adapters: a. Screw the adapters to the manifold. b. Ensure that the gasket is positioned between the manifold and the adapter.	

8.6 ADDING OR CHANGING SUMMOX COLOR TAGS

For easy recognition of the Summox Smart Containers, Summox Color Tags are available.

Summox Smart Containers hold a maximum of 2 Summox Color Tags.

It is up to the user to decide how to code any Summox Smart Container with the use of the Summox Color Tags. Below is explained how to place and remove the Summox Color Tags.

Step	Reference
1. Make sure that the Container is processed.	N/A
2. Select color tags, see the available colors.	
3. Replace color tags by sliding them off and on the Container side.	
4. Make sure to reprogram changed colors in the RFID tag, see *Scanning and (re)programming a Summox Smart Container.*	N/A

9 OPENING, FILLING AND CLOSING SUMMOX SMART CONTAINERS

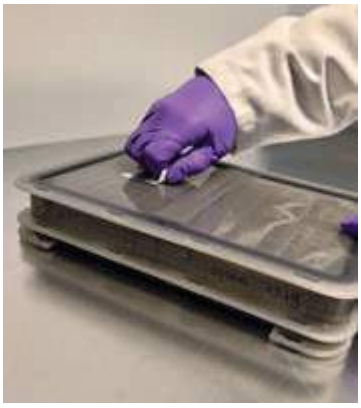
9.1 OPENING A PROCESSED SUMMOX SMART CONTAINER

	Warning: Do NOT use instruments with visible droplets after sterilization. These droplets may contain irritating substances that may cause skin damage for patient or user.
	Warning: Do NOT use instruments from Summox Smart Containers after the expiry date. This may cause a health risk for patient and user.

Step	Reference
1. Check Container before opening: 1.1. Check that the Container looks dry on the inside and outside. 1.2. If the Container appears dry, continue with the check of the Summox Smart Seal at step 2. 1.3. If the Container does not appear dry: 1.3.1. Do NOT open the Container 1.3.2. Remove the Smart Seal. 1.3.3. Reprocess the Container by putting it on the input stack. 1.3.4. If, after reprocessing, the container still does not appear dry: do NOT use the instruments. 1.3.5. Store the Container and inform the manufacturer within seven days	N/A

	Warning: Do NOT use Containers when a hissing sound is not heard when removing the Summox Smart Seal, or when a correctly printed Summox Smart Seal is not present. The container is possibly not properly decontaminated, and the instruments may cause a health risk for patient or user.

2. For sterilized Containers (see the STERILE symbol, in the middle of the seal), check the Summox Smart Seal: 2.1. Check the expiry date on the Smart Seal (next to hourglass). 2.2. If the expiry date has passed, do NOT use the instruments from the Summox Smart Container. 2.3. Check if the top part of the Summox Smart Seal is colored, if not, do NOT use the instruments from the Summox Smart Container.	

3. Remove the Smart Seal: 3.1. Place the Smart Container on a flat surface. 3.2. Place the index finger or thumb in the cavity under the seal. 3.3. Carefully pull off the seal. 3.4. If you hear a hissing sound, continue with the opening of the Container at step 4. 3.5. If you do NOT hear a hissing sound and the Smart Seal indicates the instruments were sterilized: 3.5.1. Reprocess the Container by putting it on the input stack. 3.5.2. If, after reprocessing, you still do NOT hear a hissing sound when opening the seal, do NOT use the instruments, 3.5.3. Store the Container and inform the manufacturer within seven days.	

	The user can remove the Summox Smart Seal in the presence of the patient, to show the cleanliness of the instruments.
	When opening a Summox Smart Container that has droplets inside, wear safety goggles and protection gloves. The droplets within the Container are irritating and may cause skin and eyes damage.

4. Open the Container 4.1. Pull at a corner of the Top Cover to open it. *The bottom is NOT removed by the user.* 4.2. Use the Cover and Inlay edges to separate the Cover from the Inlay.	
5. Check if any Container part is damaged. 5.1. Check the thermoplastic rubbers (A, D) and counterparts (B, C). 5.2. Check that the air orifice (F) is clean. 5.3. On cover and bottom, check if the cut outs (E) are undamaged. *The cut outs are used to open the Container during processing.* 5.4. If any part is damaged: 5.4.1. Do NOT use, store the faulty Container and inform the manufacturer within seven days.	

6. Inspect the dental instruments (according to best practice guidelines for dental professionals): 6.1. Ensure they do not contain droplets. 6.2. Ensure the instruments are free from debris, stains, or visible material. 6.3. If not clean or if there are droplets visible: 6.3.1. Close the Container 6.3.2. Ensure the Summox Smart Seal was indeed removed. 6.3.3. Reprocess the Container by putting it on the input stack. 6.3.4. If the Container still does not look dry, store the faulty Container and inform the manufacturer within seven (7) days. 6.3.5. If needed, process the instruments in another container.	N.A.

9.2 CONTAINER SPECIFIC LOADING INSTRUCTIONS

	Warning: Do NOT prepare Containers other than described in the instructions for use. For example, overloading, wrong orientation, wrong instruments in container, no disposables etc. This may lead to improper decontamination of instruments, causing a possible health risk for patient and user.

9.2.1 General loading remarks

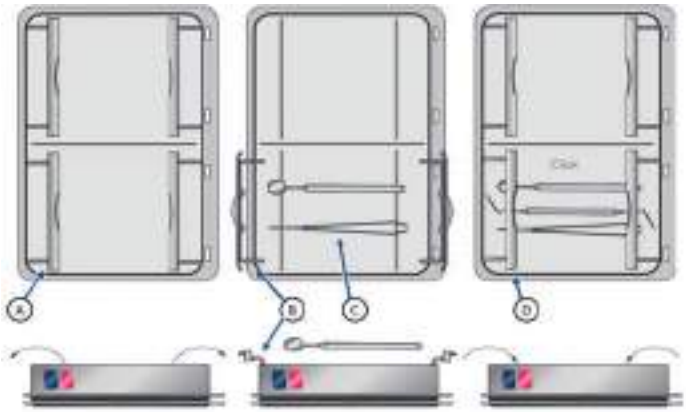
Ensure that the bottom cover (D, Figure 2) is connected to the inlay (B, Figure 2) before loading the instruments into the Summox Smart Container.

Remove 'hard' contaminations such is Gutta Percha, cement, composites, etc. **before** loading into the Summox Smart Container. These contaminations cannot be removed by the Summox One System.
Pre-cleaning of instruments may be warranted, for example when the instruments are extensively soiled or have complex tips.

	Warning: Do not load Containers with instruments that are contaminated with anything other than blood and saliva, e.g., Gutta Percha, cement, composites, etc. This may lead to improperly decontaminated instruments, causing a possible health risk for patient and user.
	Warning: do not add instruments that are not corrosion resistant, like aluminum, brass, copper etc. Processing these materials may lead to instrument damage and a health risk for patient and user
	Warning: Do not sterilize instruments containing anodized aluminum. Sterilizing these instruments may lead to instrument damage and a health risk for patient and user.
	Warning: do not add instruments that cannot withstand temperatures up till 102°C. Processing these materials may lead to instrument damage and a health risk for patient and user.
	Warning: Do not sterilize hollow instruments, e.g. handpieces, canulas, syringe tips, suction tubes etc. Processing hollow instruments for sterilization may cause a health risk for patient and user.
	Warning: Do not place instruments that contain a hollow part upright in the container. Droplets may stay behind. These droplets may contain irritating substances that may cause skin damage for patient or user.

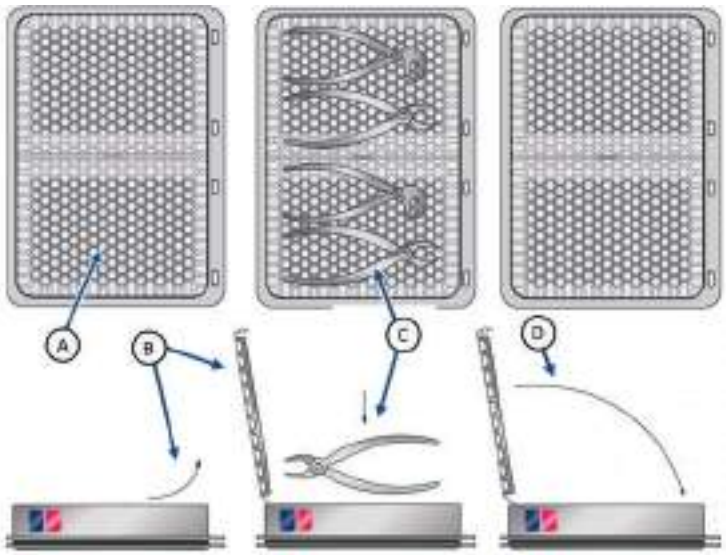
9.2.2 Loading instruments into a Pen-shape insert

The Pen-shape Summox Smart Containers hold pen shaped instruments. These are for instance mirrors, scalers, curettes, explorers, and tweezers.

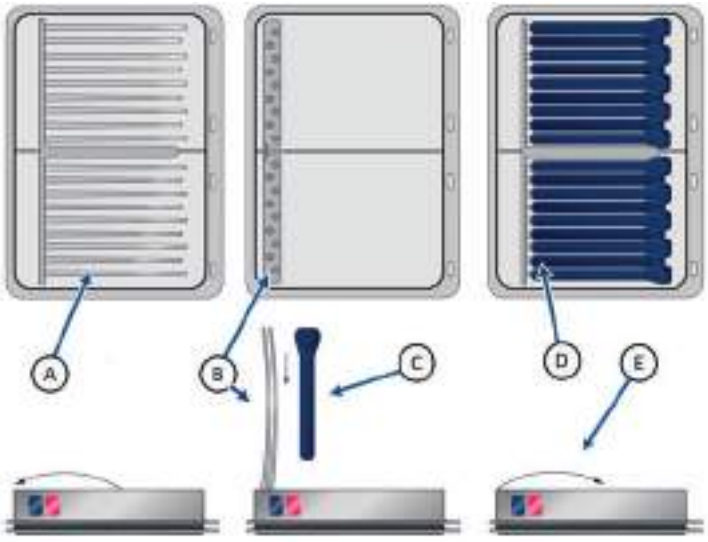
Step	Reference
1. Precheck: make sure the instruments are between 150mm and 180mm, otherwise they will not fit 2. Push & lift to open the locks (A). 3. While the locks are open (B), add the instruments (C). 4. Close the locks until they snap into position. 5. If a lock does not snap into position, check the instruments for length and thickness, if needed retry adding the instrument that blocks the locking. 6. If locking into snap position for a specific instrument is not possible, load the instrument into a Wirebasket Container.	

9.2.3 Loading instruments into a Wirebasket insert

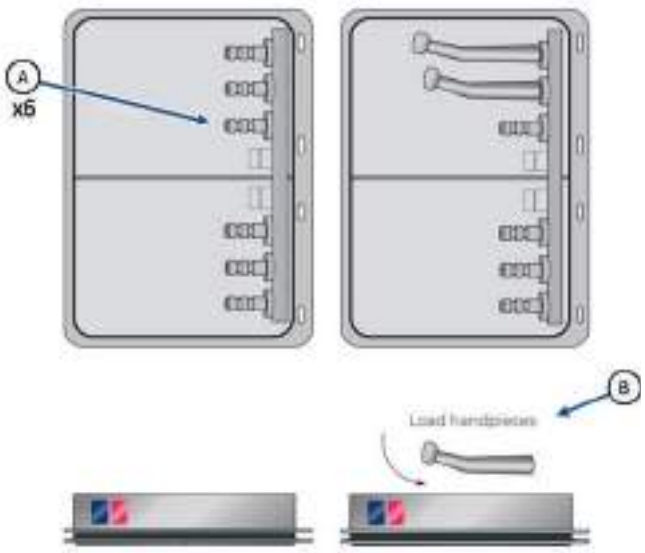
	Warning: Do not place handpieces and cannulas in the Wirebasket. This may lead to improper decontamination of instruments, causing a possible health risk for patient and user.

Step	Reference
1. Open the Wirebasket top cover by placing a finger through the opening (A) of the wire and pull it upwards (B). 2. Check that the Wirebasket is not damaged, if needed, replace it, see Exchange a Wirebasket insert. 3. Place the instruments in the Wirebasket (C). 3.1. Make sure that the instruments do NOT stick through the wire basket. 3.2. Make sure instruments are not overlap each other to not overload the wire basket. 3.3. Make sure instruments are placed such that water cannot stay behind during the processing. Mind that the Container side with the cut-outs will be on top during processing. 3.4. Do NOT overload the Wirebasket. 4. Securely close the Wirebasket top cover (D) until it clicks into position. If not closed correctly, instruments may fall out of the Container during processing, causing unwanted recovery delays, see ***Retrieve lost instruments.***	

9.2.4 Loading Cannulas into a Cannula Insert

Step	Reference
1. Rotate the Cannula clamping part (A) upward (B). 2. Place the cannulas (C) the turned-up clamping part (B). 3. Make sure all cannulas are pushed down on the clamping part (D). 4. After filling, rotate the clamping part downwards (E) and snap it in place.	

9.2.5 Loading Handpieces into a Handpieces Container

Step	Reference
1. Make the correct combination of handpieces: 1.1. Combine mechanical handpieces and air driven handpieces. 1.2. Decontaminate prophylactic handpieces separately from mechanical and air driven handpieces. 2. Load each Handpiece (B) by pushing it onto a connector (A). 3. Make sure all connectors (A) are occupied.	
4. Make sure that the handpieces are turned such that they do not stick out above the Container. 5. Remove handpieces that do not properly fit to the connecter, as they may fall off while processing the Container.	N.A.

9.3 CLOSING THE SUMMOX SMART CONTAINER

Step	Reference
1. Make sure that all instruments are placed correctly in the inserts. 2. Make sure all disposable materials are removed from the Summox Smart Container. 3. Visually check that dental instruments do not stick out of the Wirebaskets or above the inserts.	N.A.
4. For Pen-shaped inserts, check if instruments are correctly inserted: 4.1. Put the inlay in an upright position 4.2. Check if the instrument placement is correct when gently shaking the Smart Container. 4.3. Replace instruments, that fell out, correctly until they stay in place while holding the open Summox Smart Container upright. 5. Remove instruments that do not stay fixed in the insert.	
6. Check if any Container part is damaged. 6.1. Check the thermoplastic rubber (A, D) and counterparts (B, C). 6.2. Check that the air orifice (F) is clean, free from debris, or visible staining, material. 7. Ensure cut outs (E) are undamaged on both top and bottom cover. The cut outs are used to open the Container during processing.	
8. Position the cover on the inlay. *The cover can only be mounted in one orientation.*	N.A.
9. Push every corner of the cover to fit the cover on the inlay. 10. Visually inspect if the Container is properly closed.	N.A.

9.4 CARRYING SUMMOX SMART CONTAINERS

Whether Summox Smart Containers are filled with contaminated or clean instruments you have to make sure you carry them by always supporting the bottom cover.

Summox Smart Containers may be carried individually or stacked on top of each other.

9.5 MALFUNCTION SUMMOX SMART CONTAINERS

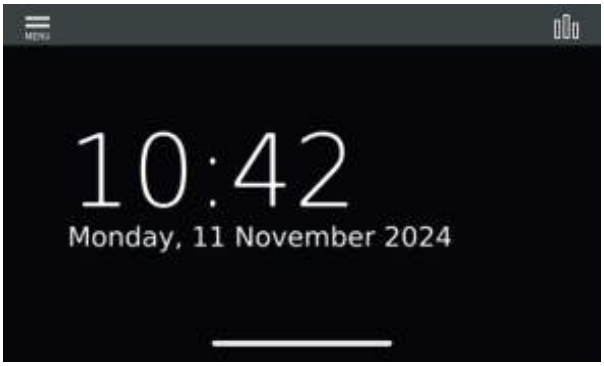
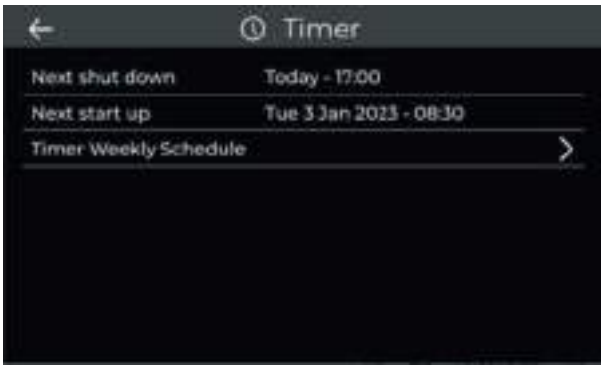
Sterilized Containers can be stored under normal ambient conditions as long as the expiry date on the Summox Smart Seal allows.

Non-sterilized containers can be stored under normal ambient conditions as long as needed.

10 TIMER SETTINGS

The Summox One System has a built-in timer function. With the timer function, an option can be selected to automatically start the device before office hours, to ensure that the device reaches operation temperature and is ready for use when the first patient arrives. During automatic switch off after office hours, the self-disinfection program will be automatically executed.

10.1 OPEN TIMER MAIN WINDOW

Step	Reference
1. In the standby screen, select the **MENU** button. *The Menu window opens.*	
2. Select **Timer**. *The Timer window opens.*	
3. **Next Shutdown:** The moment of the next device shutdown sequence. 4. **Next Start up:** The moment Summox One System is ready to use. 5. Select **Timer Weekly Schedule** to adjust the weekly schedule. *The Timer Weekly Schedule window will become visible.*	

10.2 SET TIMER WEEKLY SCHEDULE

The Summox One System can start up automatically according to a weekly schedule. In this way, the system is always ready at the times selected.

Step	Reference
1. At the days of your preference, press **>** to adjust the schedule for that day. *The window for a specific day will become visible.*	
2. To have no device operation, select **Monday's Timer Off**. 3. If device operation is required, select **Operation hours**. 4. At **Start**, select the time at which you want the device to be ready for use. 5. At **End**, select the time to switch off the device. 6. Press **SET**. *This Timer setting is now active. When the timer is shutting down the device, all Containers in the input stack will first be processed, even if this is outside office hours. Before the shutdown is completed, the self-disinfect program will run.* 7. If you do NOT want to make changes, press the back button ← to go back to the Timer Weekly Schedule window.	

11 MAINTENANCE

	Warning: Always perform maintenance according to schedule. Not doing so may lead to a health risk for patient and user. It may also damage the device and voids the warranty.
	Warning: Do not place liquids and/or objects on top of the Summox One System. If liquids flow into the device, system failure may be the result, causing a possible health risk for patient and user.

11.1 REPLACE CONSUMABLES

	Warning: Only use Summox consumables. Using other than Summox consumables may cause a health risk for patient and user and voids the warranty of the Summox One System.
	Warning: Do NOT use consumables after the expiry date. This may cause a health risk for patient and user.

The use of unauthorized consumables is prohibited by the European Union Medical Device Regulations EU MDR 2017/745).

11.1.1 Check consumable levels

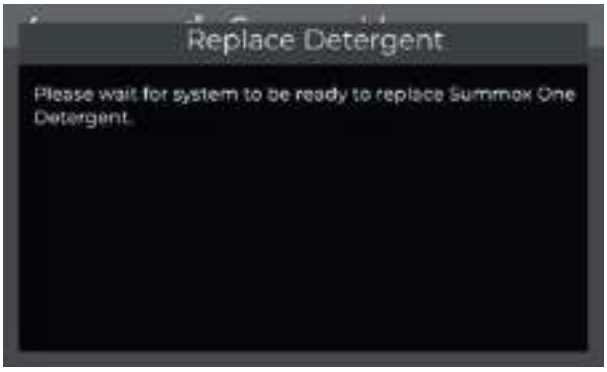
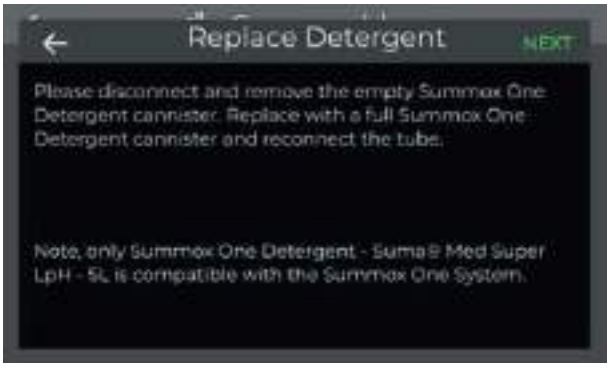
	When consumable levels are within working range, it is NOT possible to do a replace via the Graphic User Interface (GUI).

Step	Reference
1. If a consumables warning message occurs, press the consumables icon  *The consumables icon is also present in the startup screen* (Figure 12), *the Standby screen* (Figure 13) *and the process status screen* (Figure 26) *The Consumables window becomes visible.*	
2. Check the status of the consumables.	
3. At first occasion, replace consumables that have an orange-colored status bar.	N.A.

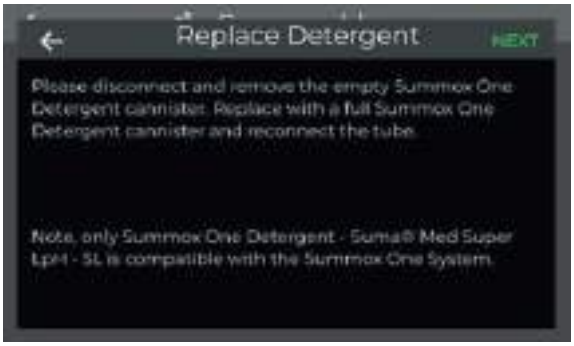
	When above messages are ignored, and the Summox One System runs out of detergent, oil or Smart Seals, an error appears on the screen and the system is not able to process any Summox Smart Container until the consumable is replaced. The user interface will then lead you through the replacement.

11.1.2 Replace Summox One Detergent

Step	Reference
1. If you are going to replace the detergent pro-actively, (caution: Low level of Summox One Detergent) wait until all Containers are processed and the system is in stand-by mode. If you are replacing the detergent reactively (Orange screen: Out of Detergent) push NEXT on the orange screen and start at step 3.	N.A.
2. At **Detergent**, press the replace button **>**. *The system automatically prepares for the detergent replacement.*	

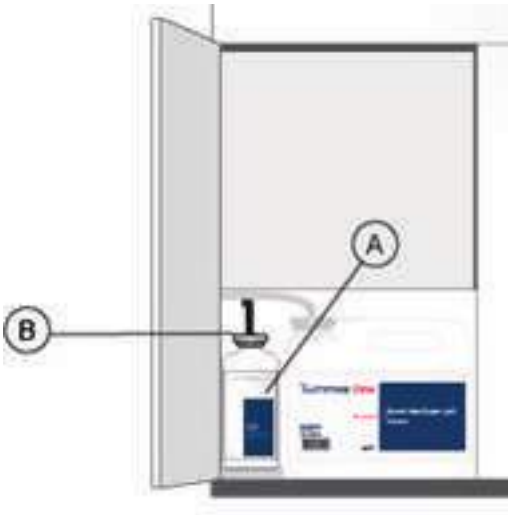
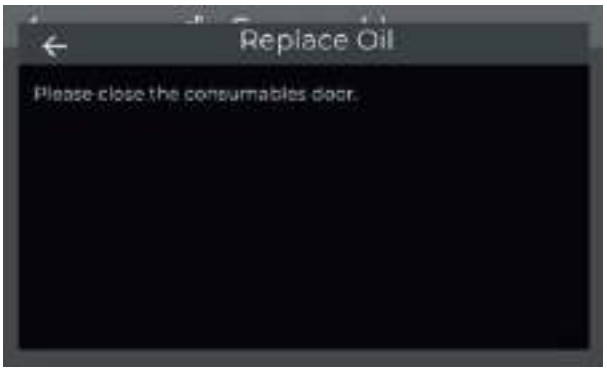
3. The Summox One System prepares for Detergent replacement.	
4. The message 'Please open consumables door' appears.	
5. Press the consumables door (B) and open it.	
6. The message to replace the detergent canister appears.	

	Warning: Risk for irritating substances. Wear protection gloves.

7. Use the handle (A) to take the canister out of the device. 8. Remove the section tube (B) by pulling it from the canister.	
9. Open the new Summox One Detergent canister. 10. Install the suction tube into the canister. 11. Place this new canister into the device. 12. Close the consumables door. 13. Dispose of the old detergent canister according to local regulations.	N.A.
14. Press **NEXT** in the Replace detergent window (Figure 71). If not yet closed, the message 'Close the consumables door' appears.	 
15. Press **FINISH** in the message Replace detergent screen. The software will automatically reset the fluid level and registers the date of the detergent replacement.	

11.1.3 Replace Summox One Oil

Step	Reference
1. Wait until all Containers are processed, and the system is in stand-by mode.	N.A.
2. At **Oil**, press the replace button **>**. *The system automatically prepares for the oil replacement.*	
3. The Summox One System prepares for Summox One oil replacement.	
4. Wait until the screen shows the message: 'Please open consumables door'.	
5. Press the consumables door B and open it.	

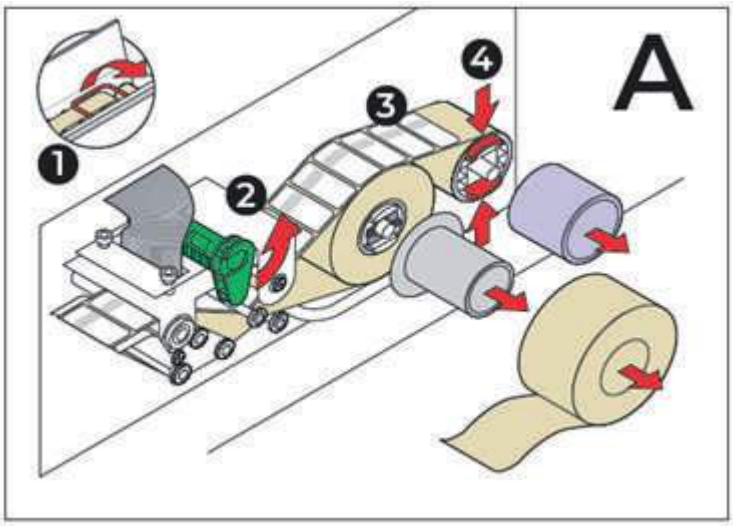
6. The message to replace the Summox One Oil bottle appears.	
7. Take the empty oil bottle out of the device. (A) 8. Remove the section tube (B) from the bottle.	
9. Open the new Summox One Oil bottle. 10. Install the suction tube into the top opening. 11. Place this new bottle into the device. 12. Close the consumables door. 13. Dispose of the old bottle according to local regulations.	N/A
14. Press **NEXT** in the Replace Oil window (Figure 78). *If not yet closed, the message 'Close the consumables door' appears.*	
15. Press **FINISH** in the message Replace Oil window. *The software will automatically reset the fluid level and registers the date of the detergent replacement.*	

11.1.4 Replace Summox Smart Seal roll

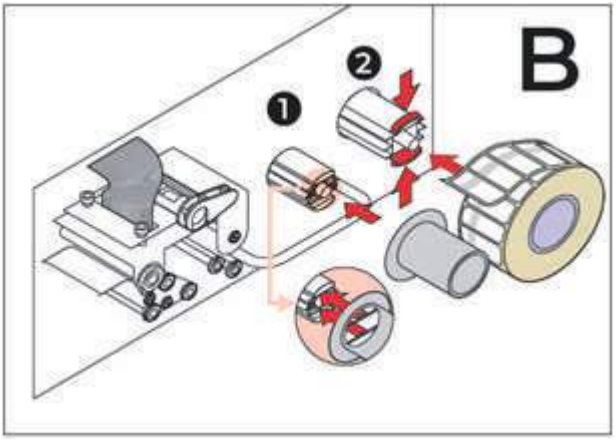
Step	Reference
1. Wait until all Containers are processed, and the system is in stand-by mode.	N.A.
2. At **Seals**, press the replace button **>**. *The system automatically prepares for the Summox Smart Seal roll replacement.*	
3. Wait until the screen shows the message: 'Please open the printer door'	
4. Press the printer door (C, Figure 70) and open it.	
5. The message to replace the Summox Smart Seal roll appears.	

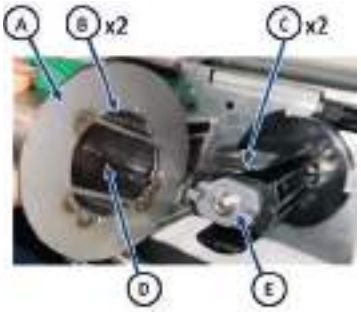
For clarity, the illustrations include annotations that are used on the label inside the printer door.

6. Use the handle (1) to pull the printer out of the Summox One System (printer will remain fixed) to get access to the Summox Smart Seal roll mechanism.
7. Turn the lever (2) counter clockwise.
8. Remove the used roll:
   8.1. Push the two clamps (4) towards the middle position.
   8.2. Pull and remove the used roll.
9. Pull and remove the used roll (3).
10. Remove the remaining pieces of the ribbon from the printer.
11. Remove the ribbon of the used roll from the holder and dispose of it according to local regulations.

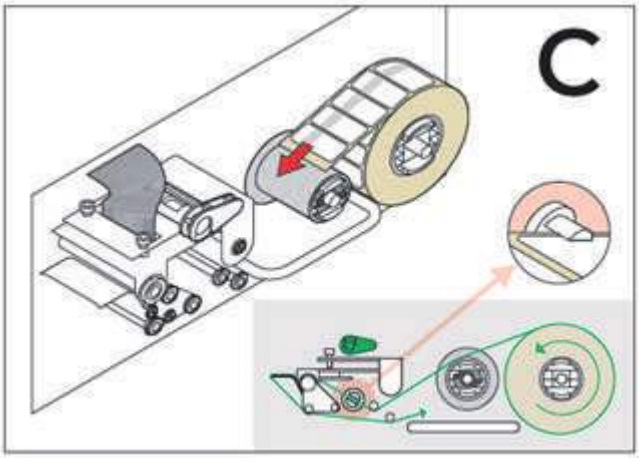


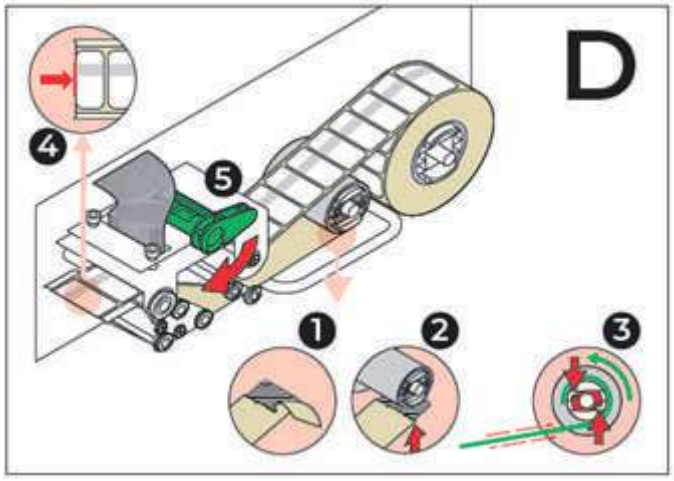
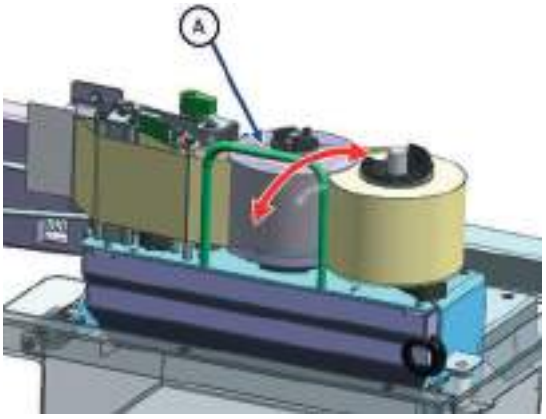
12. Re-Install the used roll holder (1).
   12.1. Make sure that the two openings (B) match with the clamps (C).
   12.2. Make sure that the central hole (D) matches with the grey part (E).
13. Install the new Summox Smart Seal roll over the holder (2):
   13.1. Push the two clamps (2) towards the middle position.
   13.2. Install the new roll.





14. Guide the new seal ribbon through the printer as depicted in Figure 86.



15. Press **NEXT** in the Replace Seals window (Figure 84). *The message to remove extra seals and close the smart seal lid appears.*	
16. Remove the first 10 seals from the ribbon. 17. Use one of the removed Smart Seals to attach the ribbon to the empty roll holder. 18. Turn the empty roll holder (3) until the ribbon is under tension. 19. Make sure the last Seal is 2-3mm right of the edge (4). 20. Turn down the lever (5).	
21. Use the handle (A) to turn the printer into the device. 22. Close the printer door.	
23. Press **FINISH**. *The software will automatically reset the fill level and registers the date of the Summox Smart Seal roll replacement.*	

11.2 PERIODIC MAINTENANCE

To use the Summox One System without unnecessary delays and risks, ensure correct maintenance is performed on:

- your own utilities like water supply and compressed air supply.
- the Summox One System, internally and externally by the user.
- the Summox One System, by a qualified service engineer.

Below the periodic maintenance to be performed by the user is described.

11.2.1 Check/clean Handpiece Container manifold

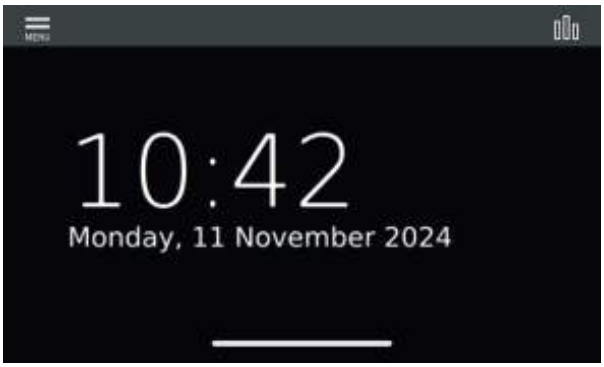
Interval: 2 weeks

The manifold of the Handpieces Container needs to be checked visually every week for blockages, clogging holes and irregularities to the gasket, to guarantee a proper internal cleaning and lubrication of handpieces.

Step	Reference
1. Use a regular syringe filled with potable water. 2. Put the syringe on each manifold connector and flush it. 3. Check that the water flows out through the manifold outputs.	

11.2.2 Clean the Summox One System externally

Interval: 2 weeks

Step	Reference
1. Wait until the device is in standby mode. 2. Do not add new Containers during cleaning.	
3. Dampen a soft cloth in a pH neutral surface disinfection solution that does not contain phenols. 4. Clean in the following order: 4.1. Safety door output (B) 4.2. Printer door (C) 4.3. Graphical user interface (D) 4.4. All other reachable doors and covers (E) 4.5. Safety door input (A) 5. Do not spray disinfection solution directly on the device and display.	

11.2.3 Safety remarks while working inside the Summox One System

Some chambers may still be hot when you open and work behind the front door:

	Warning: Hot surfaces. Risk of skin burn. Wear protection gloves. Check the warning signs at specific locations inside the device.

In the space behind the front door, above the chambers, there may be objects with sharp edges:

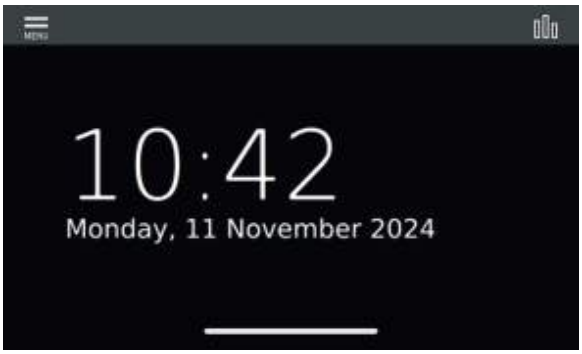
	Warning: Sharp edges. Risk of injury. Wear protection gloves. Check the warning signs at specific locations inside the device.

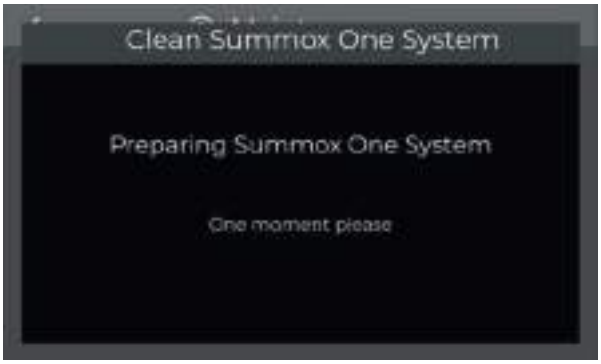
When you work on any part or chamber behind the front door, work clean:

	Warning: User health risk (biohazard). Wear protection gloves.

11.2.4 Clean the Summox One System internally

Interval: 2 weeks.

Step	Reference
1. Wait until the device is in standby mode. 2. Do not load new Containers during cleaning.	
3. In the **Menu** window, select **Maintenance**. *The Maintenance window becomes visible.*	
4. Select **Clean Summox One.**	

5. Wait for the system to prepare. *Power will be withdrawn from all modules and component that may cause a risk. Water remains in the chambers and may be hot.*	

	Warning: Hot surfaces. Risk of skin burn. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: Sharp edges. Risk of injury. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: User health risk (biohazard). Wear protection gloves.

6. Open the front door.	
7. Dampen a soft cloth in a pH neutral surface disinfection solution that does not contain phenols. 8. Check and clean the Cooler (B) and the Sterilizer (A) 8.1. Clean the top side of the lid. 8.2. Manually open the lid, by pulling it towards you. 8.3. Check if the seal of the lid is attached and not damaged. 8.4. Clean the seal. 8.5. Clean the top edge of the chamber where the seal touches when the lid closes. 8.6. Manually close the lid. 9. Press **NEXT**.	

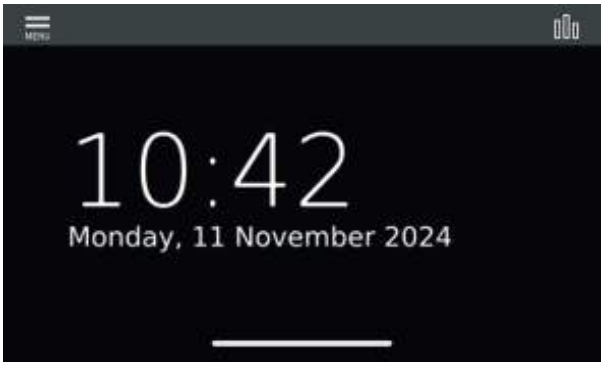
10. Close the front door.	
11. Wait for the system to prepare. *The handler moves to the other side. Next, power will be withdrawn from all modules and components that may cause a risk.*	

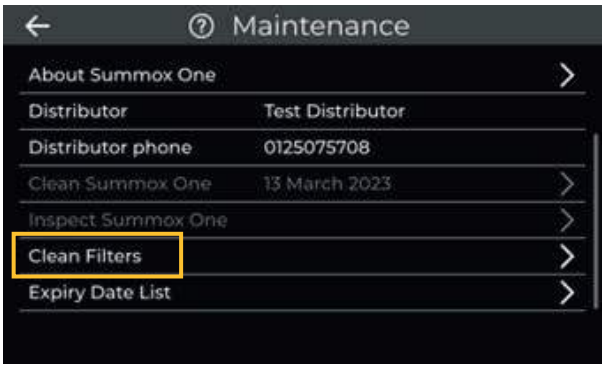
	Warning: Hot surfaces. Risk of skin burn. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: Sharp edges. Risk of injury. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: User health risk (biohazard). Wear protection gloves.

12. Open the front door.	

13. Dampen a soft cloth in a pH neutral surface disinfection solution that does not contain phenols. 14. Check and clean the lids of the Drying chamber (E), Disinfection chamber (D), Spray washing chamber (C), Ultrasonic chamber (B) and Handpieces chamber (A). 14.1. Clean the top side of the lid. 14.2. Manually open the lid by pulling it towards you. 14.3. Check if lid seal is attached and not damaged. 14.4. Clean the seal. 14.5. Clean the top edge of the chamber where the seal touches when the lid closes. 14.6. Manually close the lid. 15. Press **NEXT**.	
16. Close the front door.	

11.2.5 Clean the filters inside Handpieces, Spray washing and Ultrasonic chambers
Interval: 2 weeks

Step	Reference
1. Wait until the machine is in standby mode. 2. Do not load new Containers during cleaning.	
3. In the **Menu** window, select **Maintenance**. *The **Maintenance** window becomes visible.*	

4. Scroll down to the bottom part of the window. 5. Select **Clean Filters.**	
6. Wait for the system to prepare.	

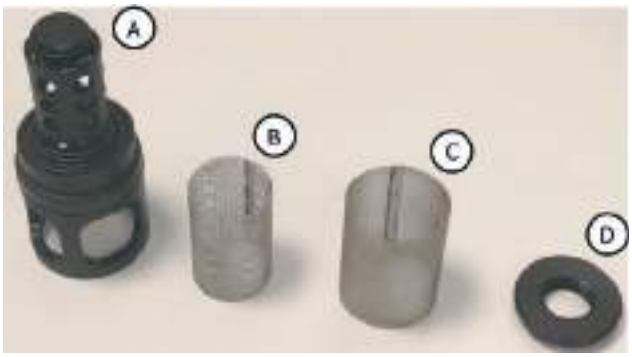
	Warning: Hot surfaces. Risk of skin burn. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: Sharp edges. Risk of injury. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: User health risk (biohazard). Wear protection gloves.

7. Open the front door.	

8. Clean the filters in the Handpieces chamber (A) and Spray washing chamber (C) as explained in 11.3.6. 9. Clean the filters in Ultrasonic chamber (B) as explained in 11.3.7. 10. Close the front door. 11. Press **NEXT**.	

11.2.6 Clean filters inside Handpieces and Spray washing chambers

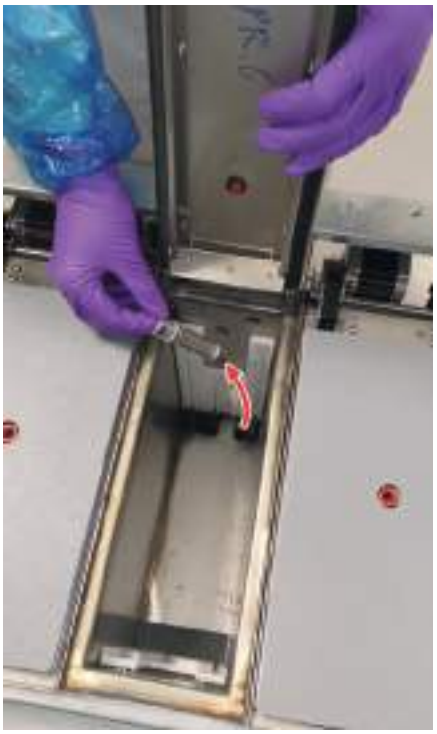
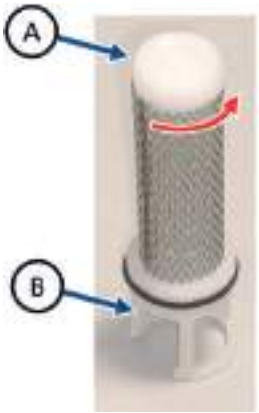
Step	Reference
Execute below steps for chamber A & C (Figure 111). 1. Open the lid, by pulling it towards you: 2. Hold lid with one hand. 3. With the other hand, go into the chamber and pull-out the filter. *The action can be compared to the removal of the filter in a dish washer.*	
4. Disassemble the filter: 4.1. Hold the filter upside down over a dustbin and shake it to remove larger particles. 4.2. Turn the filter cap (A) counter clockwise and remove it. 4.3. Take the filter apart.	

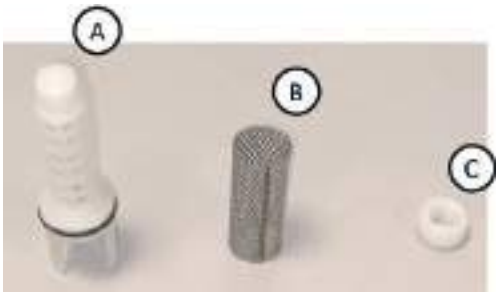
5. Clean the filter parts by rinsing in tap water: 5.1. The filter holder (A). 5.2. The coarse filter element (B). 5.3. The fine filter element (C). 5.4. The filter cap (D). 6. Assemble the filter: 6.1. Take filter holder (A). 6.2. Install the coarse filter element (B). 6.3. Install the fine filter element (C). 6.4. Install the filter cap (D). 6.5. Turn the end cap until the fine filter (B) on the outside has no more play and it is finger tight.	
7. Install the filter back into the chamber, by pushing it into the drain. 8. Close the chamber lid.	N.A.

11.2.7 Clean filter in the Ultrasonic chamber

Interval: 2 weeks

Safety: see the above section Safety remarks for working in the machine.

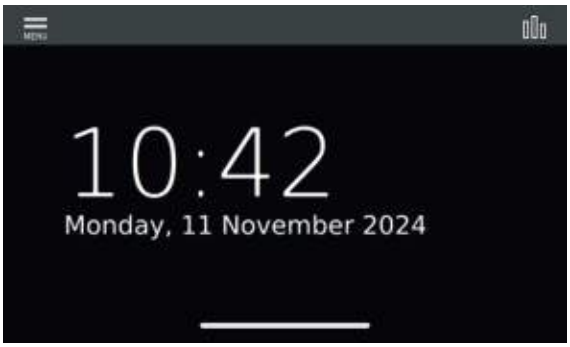
Step	Reference
Execute below steps for chamber B (Figure 111). 1. Open the lid, by pulling it towards you: 2. Hold lid with one hand. 3. With the other hand, go into the chamber and full out the filter. *The action can be compared to the removal of the filter in a dish washer.*	
4. Disassemble the filter: 4.1. Hold the filter upside down and shake above a dustbin it to remove larger particles. 4.2. Turn the filter cap (A) counter clockwise and remove it. 4.3. Take the filter apart.	

5. Clean the filter parts, by rinsing under tap water: 5.1. The filter holder (A). 5.2. The filter element (B). 5.3. The filter cap (C). 6. Assemble the filter: 6.1. Take filter holder (A) 6.2. Install the filter element (B). 6.3. Install the cap (C). 6.4. Turn the end cap until the fine filter (B) on the outside has no more play and it is finger tight.	
7. Push the filter back into the chamber. 8. Close the front door.	N.A.

12 PROBLEMS AND SOLUTIONS

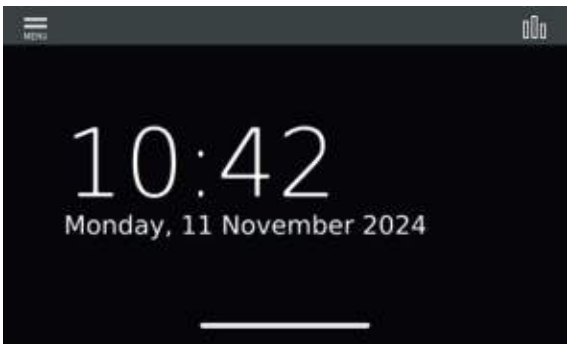
Errors can be viewed in the active warning/error list. Some errors can be solved by users, for all other problems not described below please call the Summox certified field service engineer.

12.1 CHECKING FOR ERRORS AND WARNINGS

Step	Reference
1. Do not load new Containers. 2. Wait until the machine is in standby mode. (Figure 118) 3. Press Maintenance. 4. Select Active Warnings. 5. Active warnings can also be seen by touching the error logo ⚠ on the screen.	
6. Check for active warnings/errors.	

12.2 RETRIEVE LOST INSTRUMENTS

When Instruments fell out of a Summox Smart Container, you can retrieve them by following the next steps.

Step	Reference
1. Wait until the machine is in standby mode. 2. Do not load new Containers during the instrument retrieval.	
3. In the **Menu** window, select **Maintenance**. 4. *The **Maintenance** window becomes visible.*	

5. Scroll down to the bottom of the window. 6. Select Inspect Summox One. *All chambers are drained automatically.*	
7. Wait for the system to prepare	

	Warning: Hot surfaces. Risk of skin burn. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: Sharp edges. Risk of injury. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: User health risk (biohazard). Wear protection gloves.

8. Open the front door.	

9. Inspect the Cooler (B) and the Sterilizer (A) 9.1. Manually open the lid. (Sterilizer lid (A) opens automatically. 9.2. Inspect the chamber. 9.3. Take out any dental instruments you find. 9.4. Manually close the lid of the cooler (B). 10. Press **NEXT**.	
11. Close the front door.	
12. Wait for the system to prepare. *The handler moves to the other side. Next, power will be removed from all devices that may cause a risk.*	

	Warning: Hot surfaces. Risk of skin burn. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: Sharp edges. Risk of injury. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: User health risk (biohazard). Wear protection gloves.

13. Open the front door.	
14. Inspect the lids of Drying chamber (E), Disinfection chamber (D), Spray washing chamber (C), Ultrasonic chamber (B) and Handpieces chamber (A). 14.1. Manually open the lid by pulling it towards you. Lid may be hot. 14.2. Inspect the chamber. 14.3. Take out any dental instruments you find. 14.4. Manually close the lid. 15. Press **NEXT**.	
16. Close the front door. 17. Wait for the Summox One System to recover.	

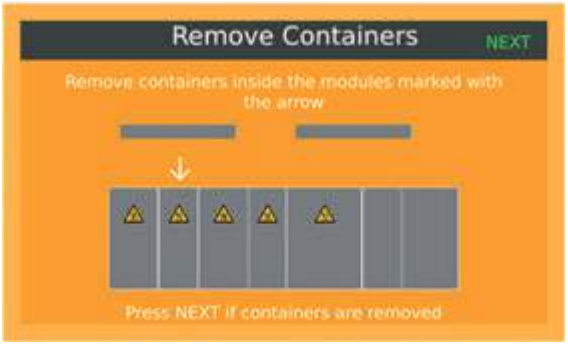
12.3 RETRIEVE SUMMOX SMART CONTAINER(S) AFTER POWER CUT OR ERROR RECOVERY

To retrieve Summox Smart Containers after a power cut or error recovery, follow the below steps.

Step	Reference
When the Summox One System is restarting after a power cut or an error recovery, an error message appears.	

The system automatically prepares for Container removal.	

	Warning: Hot surfaces. Risk of skin burn. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: Sharp edges. Risk of injury. Wear protection gloves. Check the warning signs at specific locations inside the device.
	Warning: User health risk (biohazard). Wear protection gloves.
	Warning: Do NOT use Summox Smart Containers when these are manually removed from system during power cut or error recovery. Even when the Summox Smart Seal is on the Container (and might even show discoloration). The container might not be properly decontaminated, and the instruments may cause a health risk for patient or user.

1. Open the front door.	
2. Remove Container ONLY from the locations indicated with a white arrow on the Graphical user interface. 2.1. If needed, manually open chamber lids. *The Summox One System knows where containers are located.* 3. Press **NEXT**.	

4. Close the front door.	
If there are still containers in the Summox One System, a new sequence Prepare - Open door - Remove containers - Close door will start. *If all containers are removed, the machine will recover and go to standby state.* 5. Reprocess the manually removed Summox Smart Containers: 5.1. Do NOT open the Container 5.2. Remove the Smart Seal (if present) 5.3. Reprocess the Container by putting it on the input stack. Use Container once processed and ready for use at output stack.	 

13 CHECK NEXT SUPPLIER SERVICE DATE

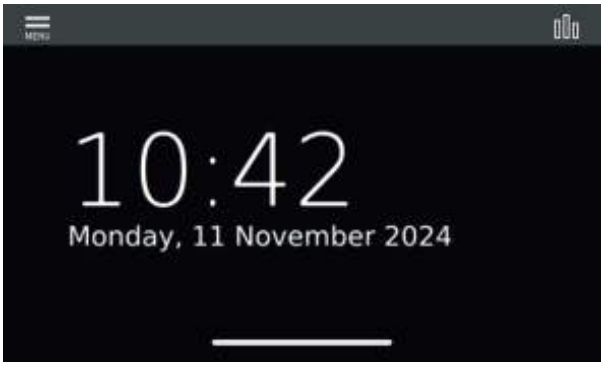
Based on a semi-annual schedule, a Summox certified service engineer will perform preventive maintenance on the Summox One System. In case of device failure, this engineer will diagnose the problem and perform repair actions.

Step	Reference
1. In the **Menu** window, select **Maintenance**. *The **Maintenance** window becomes visible.*	
2. At **Next Service Date**, read the next service date.	

14 CHANGE SETTINGS

14.1 OPEN DEVICE SETTINGS WINDOW

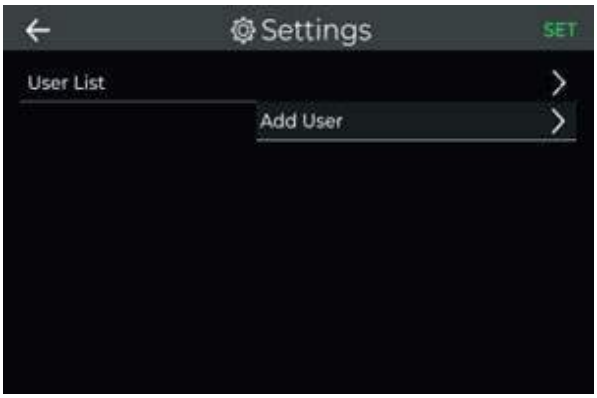
To change machine settings, open first the machine settings window.

Step	Reference
1. In the standby screen, select the **MENU** button. *The Menu window will open.*	
2. Select **Settings**. *The Settings window will open.*	
3. Select **Display Brightness** to change the brightness of your screen, see *Change brightness of the display.* 4. Select **Sound Settings** to change the type of signaling sound, see *Change sound settings.* 5. Select **Language** to change the language of your screen. 6. Select **Time 12h-24h** if you want to change time system that the machine uses. 7. Select **User list** if you want to change the list of users that can operate the machine, see *Change default user and users list.* 8. Select **Validation** if you want to change your process validation settings, see *Change process validation setting.*	

14.2 CHANGE BRIGHTNESS OF THE DISPLAY

Step	Reference
1. Select the preferred brightness. The brightness automatically changes as a preview when selecting another brightness option. 2. Press **SET**. 3. If you do NOT want to make changes, press the back button ← to go back to the Settings overview window.	

14.3 CHANGE DEFAULT USER AND USERS LIST

Step	Reference
1. At **User List**, press **>** to go to the actual list of users.	
2. To change the user, click on the user of preference and ☆ will appear next to this user. 3. To remove a user, click on 🗑 4. To add a user, in the **Add User** line, press **>**.	
4.1. Type the name. 4.2. Press **SET**.	
5. Press **SET**. 6. If you do NOT want to make changes, press the back button ← to go back to the Settings overview window.	N.A.

14.4 CHANGE PARAMETRIC RELEASE SETTING

Step	Reference
1. Select the **Parametric release off** button. 2. Press the back button ← to go back to the Settings overview window.	

15 APPENDICES

15.1 SUMMOX ONE SYSTEM SPECIFICATIONS

Summox One System Specifications	
General Specifications	
Product Name	Summox One System
Classification	Medical Device, class IIb EU MDR 2017/745
Item Code	50 101
Basic UDI-DI	87202992747 50101 PA
IP classification	IP20
Use location	Indoor use only, dry location only
Altitude above sea level	≤1000m
Ambient temperature (Operation)	15-25 °C
Relative humidity (Operation)	30-80 %
Ambient temperature (Storage & Transportation)	0-40 °C
Relative humidity (Storage & Transportation)	10-80%
Electrical	
Input Voltage	230V/400V AC, 50 Hz, 3 phase
Maximum current	16A per phase
Maximum voltage unbalance	2%
Appliance class	I
Internal fuse(s)	230V PCA and 24V PCA
Maximum power usage	11kW
Max average power consumption during a run.	6kW
Max standby power consumption	500W
Power cable length	1,7m
Maximum energy consumption for typical use	40kWh/day
Earth leakage max current	30mA
Power cable connector	CEE 4p + PE 16A/400V IP54
RFID reader frequency	866 MHz
Overvoltage category	IEC Category II
Mechanical	
Dimensions	1197 x 620 x 1436 mm (lxwxh)
Weight	Summox One System empty: approx. 330 kg
	Summox One System incl. liquids: approx. 350 kg
Input stack size (max)	6 layers of Summox Smart Containers
Input stack weight (max)	12 kg
Output stack size (max)	6 layers of Summox Smart Containers

Noise level	
Noise level	Average 60 dB(A), max 70 dB(A)
Max noise (peak) measured during a full sterilization run	<70dB(A)
Average noise measured during a full sterilization run	<60dB(A)
Average noise standby	<40dB(A)
Temperature inside machine	
Maximum temperature generated inside	<102 °C
Airflow	
HEPA filter air input and air output	H12
HEPA filter sterilizer input	H12
Water supply to Summox One System	
Water quality	Potable quality (in accordance with Drinking Water Directive EU 2020/2184)
Water hardness	<0.5dH
Minimal flow	>10 l/min
Average water consumption per cycle (typical)	9± 2 l
Water inlet hose	Outer diameter 15mm, inner diameter 9mm
Drain hoses	
Water drain Temp	<90 °C
Water drain pH	pH <10
Minimal pressure from drain	15 kPa
Drain hose (warm)	Outer diameter 17mm, inner diameter 10mm
Drain hose (cold)	Outer diameter 11.5mm, inner diameter 6.3mm (1/4”)
Compressed air connection	
Air quality	Compressed air quality is in accordance with regulations regarding compressed air for medical/dental application (e.g. EN ISO 8573-1, EN ISO 22052, EU pharmacopoeia 1238)
Compressed air hose	Outer diameter 6mm, inner diameter 4mm
Pressure	Min 6 bar overpressure
Flow	Min 60 normal l/min
Summox Smart Containers	
Container closing pressure (after disinfection / sterilization program)	200mBar Under Atmospheric Pressure
Container output conditions - max temp	55 °C

15.2 MACHINE DIMENSIONS

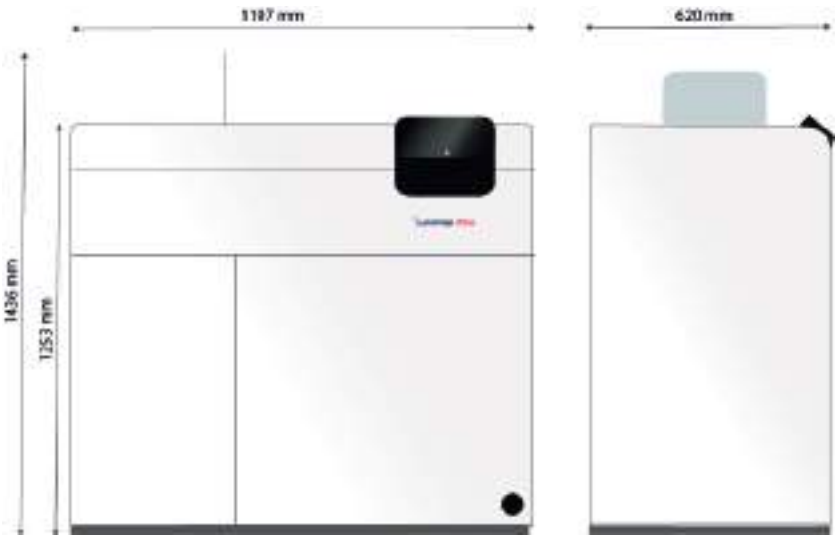


Figure 7 Summox One System dimensions

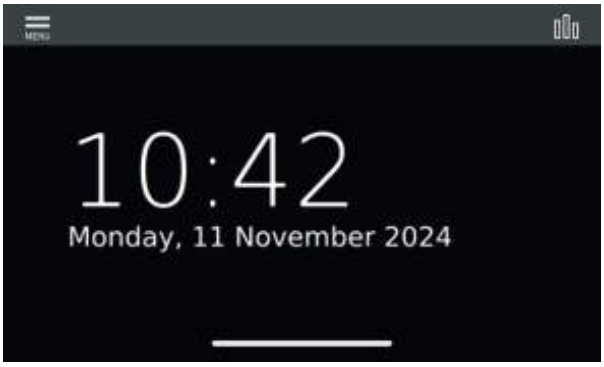
15.3 POWERING OFF AND ON THE SUMMOX ONE SYSTEM

15.3.1 Powering off

Step	Reference
1. Shut down the machine, either by the timer function or by giving the shutdown command on the user interface, see *Manual shutdown using the user interface*. 2. Turn switch (A) anti-clockwise to the OFF position.	

15.3.2 Power on

Step	Reference
1. Check that your local supplies are active: · Compressed air. · Electrical power. · Tap water.	N.A.
2. Make sure that the front door (A), the consumables door (B), and the printer door (C) are closed.	

3. If the electrical power of the machine was switched off, turn the switch (A) clockwise to the ON position to start the device	
4. Wait for the Standby screen to show.	

15.4 SUMMOX SMART CONTAINER RELEASE REQUIREMENTS

Validation requirements			
Process	Value GUI	Description	Release range
Ultrasonic cleaning	Avg. xxxoC	Average temperature during the process	32-42 °C
		Process step duration in minutes	3 min
Spray wash	Avg. xxxoC	Average temperature during the process	68-78 °C
		Process step duration in minutes	2 min
Disinfection	Avg. xxxoC	Average temperature during the process	93-98 °C
		Process step duration in minutes	0.5 -2.5 min
	A0 value = xxxx,x	Indicates the effectiveness of the disinfection, depends on disinfection time and temp (temp curve).	>3000
Sterilization	Avg. SHxx	Humidity in gram per kg air	11.5-13.5
	Avg. Watt	Power DBD reactor	110-120W
		Process step duration in minutes	25 min
Handpieces cleaning	Avg. xxxoC	Average temperature during the process	35-45 °C
		Process step duration in minutes	3 min
Handpieces disinfection	Avg. xxxoC	Average temperature during the process	70-102 °C
		Process step duration in minutes	1 - 6 min
	A0 value = xxxx.x	Indicates the effectiveness of the disinfection, depends on disinfection time and temp (temp curve).	>3000

15.5 TAKING THE DEVICE OUT OF SERVICE AND DISPOSAL

In case the machine must be taken out of service, contact the supplier.
Summox Smart Containers that are no longer used, empty Summox One Detergent cannisters, and empty Summox One Oil bottles, may be disposed of as household or plastic waste according to your country's requirements.

15.6 DECLARATIONS

This medical device conforms with the applicable requirements set out by the European Union, as demonstrated in the Declaration of Conformity.

15.7 SYMBOLS LIST

Symbols used on the Summox One System and in these Instructions For Use		
	Manufacturer	Indicates the medical device manufacturer.
	Country of Manufacture	Indicates the country where the medical device was manufactured. The date of manufacture shall be placed adjacent to this symbol YYYY-MM.
	Consult Instructions for Use or consult electronic Instructions For Use.	Indicates the need for the user to consult the Instructions For use.
	Caution/Warning	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's Serial number so that a specific medical device can be identified.
	Unique device identifier	Indicates a carrier that contains unique device identifier information.
	Medical device	Indicates the item is a medical device.
	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.

16 ABBREVIATIONS & DEFINITIONS

Abbreviations & Definitions	
Abbreviation	Description
RFID	Radio-frequency identification tag
Module	System that executes one or multiple primary or secondary processes
Chamber	Closed compartment of a process module in which primary processes are performed