

CORIS®



User Manual

nanosonics
Infection Prevention. For Life.

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Read this User Manual before operating the CORIS® device to determine the correct procedures.

For further information, contact your customer service representative or visit the Nanosonics website.

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FCC RF Exposure Statement

This equipment complies with the FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and all persons during normal operation.

Notice

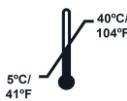
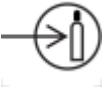
This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Warning

Any changes or modifications not expressly approved by Nanosonics could void the user's authority to operate this equipment.

Symbols used in this document

	Warning. Dangerous outcome possible, including death or serious injury		Caution. Undesirable outcome possible, including minor or moderate personal injury or potential equipment damage
	Information. Important information or reminders. Ignoring such information may result in failed outcomes (e.g. cleaning cycle failures)		EU Importer
	Manufacturer		EU Representative
	Product Number		Batch Number

SN	Serial Number		Date of Manufacture
	Expiry Date		This Way Up
	Consult Instruction for Use		Separate Collection for Electrical and Electronic Equipment
	Environmental Conditions: Storage and Transport Conditions: Temperature range: 5 °C to 40 °C / 41 °F to 104 °F		Conforming to EU MDR 2017/745
	Conforming to UK MDR 2022, UK Electrical Equipment Safety Regulations 2016 (SI 2016/1101) and UK Electromagnetic Compatibility Regulations 2016 (SI 2016/1091)		Conforming to the Australian Communications Media Authority (ACMA)
MD	Medical Device		Heavy goods – Team or mechanical lift recommended
	24 hour use only. Discard after 24 hour use		Single Use
	Inlet for gas (air)		Inlet for liquid (water)
	Draining		

Standards Compliance

CORIS® is designed to meet the requirements of the following Acts:



Health Insurance Portability and Accountability Act of 1996



EU General Data Protection Regulation

Disclaimer

Whilst all commercially reasonable efforts have been taken to prepare this CORIS User Manual, to the fullest extent permitted by law, Nanosonics will not be liable for any loss or damage (including any consequential, incidental, special or indirect damages) whatsoever or for any loss of data, loss arising from interruption to business, loss of profits or other losses of any third party arising out of or in any way relating to errors, omissions, or inaccurate or out-of-date information in this document.

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1 This Document

This document, together with the CORIS Installation Guide, comprise the Nanosonics CORIS user documentation suite.

Updates to this document will be identified by Version Number and Publication Date, as listed on page [2](#) of this document. Updates may reflect updated software, which will also be identified on page [2](#) of this document.

1.1 Reading this document

CORIS is the commercial name of Nanosonics' Endoscope Channel Cleaner (CORIS) device.

NOTE: This document makes extensive use of cross-referencing to simplify access to relevant material. If you are reading an electronic copy, click the [hyperlink](#) to access the relevant information and use [ALT] < to get back to the location of the hyperlink.

Features in a graphic highlighted with a **red bounding box** will be mentioned in the text.

1.2 References

#	Source	Document Name
[1]	Nanosonics	CORIS Installation Guide
[2]		

1.3 Terms and Acronyms

Table 1: Table of Terms or Acronyms

Term or Acronym	Definition
CORIS	Nanosonics' endoscope channel cleaner, whose commercial name is CORIS.
CORIS QUANTUM	The CORIS Cleaning Agent product used for running endoscope channel cleaning cycles.
IFU	Instructions for Use, or User Manual.
SOP	Standard Operating Procedure
WI	Work Instruction
WIQ	Work Instruction for Quality

2 Cautions

This section provides a list of all warnings and cautions in this document. Each warning is also found in the section where the warning is either required or likely to be useful.



This Manual does NOT replace your Facility documentation that covers endoscope reprocessing. Refer to your Facility SOP, Work Instruction or other document for information on how to reprocess endoscopes in your Facility.



The procedures described in this document should not be used as-is to reprocess relevant parts of endoscopes unless reviewed and integrated with your Facility reprocessing workflow.



It is expected that the information in this document (and any additional information supplied by Nanosonics) will be used to modify your Facility documentation (SOP/WI/WIQ) for reprocessing of endoscopes.



Dispose of Splash Guard Seals responsibly. Please follow your Facility guidelines.



Only compatible endoscopes should be cleaned by CORIS. Use of CORIS to reprocess endoscopes that are not compatible, may potentially be ineffective, unsafe, and could result in damage to CORIS and/or the endoscope.



If you are unsure of the manufacturer and model of your endoscope seek help from your supervisor. Use of the CORIS to reprocess endoscopes that are not validated, may potentially be ineffective, unsafe, and could result in damage to the CORIS and/or the endoscope



Only validated endoscopes should be cleaned by the CORIS.

Refer to Section [3.2 Indications for Use](#) on page [13](#) for endoscopes that can be used with the CORIS.

Use of the CORIS to reprocess endoscopes that are not validated, may potentially be ineffective, unsafe, and could result in damage to the CORIS and/or the endoscope



Appropriate personal protective equipment (PPE) (including gowns, gloves, protective face wear and masks) should be worn for protection against biological contamination during endoscope reprocessing.



The CORIS Splash Guard Seal (see 5.7.3) is single-use and should be disposed of immediately after use. Follow your Facility procedures on disposal of infected items.



Refer to your Facility documentation (SOP/WI/WIQ) for information on how to proceed with endoscope reprocessing after a cleaning cycle has been completed.



When you abort a cleaning cycle the attached endoscope channels are considered untreated. You must perform a new cleaning cycle on that endoscope.



The CORIS and its accessories cannot be refurbished or repaired by users or third parties and must be replaced by new, validated Nanosonics replacement parts.

3 Introduction

3.1 Intended Use

The Nanosonics Endoscope Channel Cleaner (CORIS) System is intended to clean the channels of endoscopes, when used in accordance with its labelling. The CORIS is an electro-mechanical system that replaces manual cleaning of endoscope channels with an automated, verified and traceable cleaning process. Manual cleaning of endoscope channels is not required prior to cleaning with the CORIS.

3.2 Indications for Use

The Nanosonics CORIS is indicated for cleaning of the channels of the Olympus endoscope CF-HQ190L. Cleaning of external surfaces of the endoscope is still required. Endoscopes must be high-level disinfected or sterilised after cleaning with the CORIS according to the manufacturer's instructions. The CORIS is suitable for use in healthcare settings by trained healthcare workers.

3.3 Mode of Operation

The CORIS Cleaning Agent is hydrated to create a slurry that is composed of undissolved particles and saturated solution. During the cleaning cycle, the CORIS delivers discrete portions of this slurry, called slugs, to the target endoscope channels at predefined conditions to generate a physical mode of action to achieve cleaning.

The CORIS controls the critical cleaning parameters for each endoscope model, including the number and size of slugs, applied pressure, and slug flow rate. Critical cleaning parameters are verified with an independent process to ensure that they are within acceptable ranges throughout the cleaning cycle. The CORIS also logs endoscope and cycle information to enable traceability of the cleaning process for users.

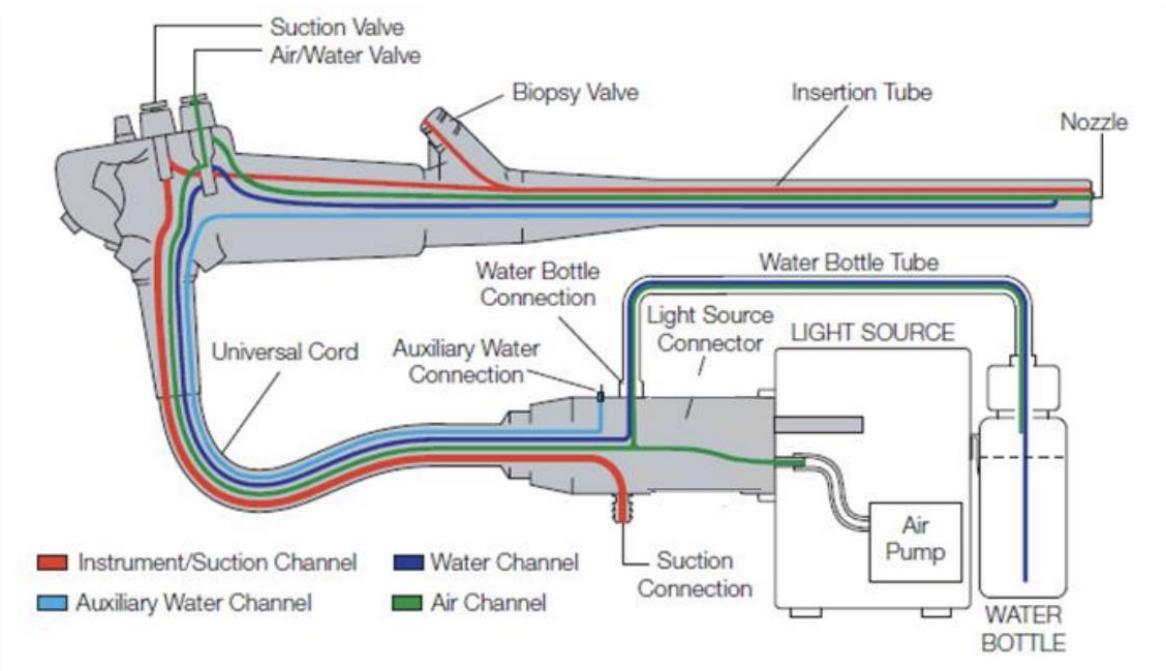
With a water/air mixture flush at the beginning of each cleaning cycle, the CORIS removes the process residuals from the upstream reprocessing steps i.e. bedside pre-cleaning and external cleaning. Similarly, the CORIS removes the cleaning agent residuals from the endoscope channels with a water/air mixture at the end of each cleaning cycle to prevent interference with the subsequent reprocessing steps such as high-level disinfection (HLD).

4 The CORIS and Your Endoscope Reprocessing Workflow

4.1 What the CORIS Cleans

An indicative picture of an endoscope is shown here in [Figure 1](#).

Figure 1: Olympus CF-HQ190L



The CORIS cleans the following internal surfaces of endoscopes:

- the Suction/Biopsy Channel
- the Air/Water Channel
- the Auxiliary Channel
- the internal surfaces of ports, cylinders, connectors, inlets, and Air Pipe.

The CORIS does NOT clean ANY external surfaces, specifically the external surfaces of:

- the endoscope body
- the handle
- endoscope ports, cylinders, connectors, outlets, and Air Pipe
- components of the distal end, including the Instrument channel outlet, Objective lens, Air/water nozzle, Auxiliary water nozzle.

[Figure 2](#) gives an example of the types of features cleaned by the CORIS.

NOTE: [Figure 1](#) pictures the CF-HQ190L with valves attached. When being reprocessed using the CORIS these valves will be removed and will need to be reprocessed separately.

Figure 2: Showing Endoscope Features Cleaned by the CORIS



DRAFT

5 The CORIS System



The CORIS and its accessories cannot be refurbished or repaired by users or third parties and must be replaced by new, validated Nanosonics replacement parts.

TBA

This section describes the Nanosonics CORIS system hardware and software components.

The Nanosonics CORIS system comprises the following:

- 1 x CORIS main body device
- 1 x (or more) CORIS Adaptor
- 1 x CORIS Splash Guard
- 1 x power supply
- 1 x regional mains connector
- Tubing as required
- Software

The Nanosonics CORIS package may also include:

- n x Nanosonics CORIS Operator Card (purchased separately)

To be provided by the client:

- Ethernet cabling to connect the Nanosonics CORIS device to the Facility Ethernet ports
- Further networking devices, as necessary, for Wi-Fi connectivity of the CORIS device (e.g. switches, routers, Wi-Fi access points)
- 1 x computing device with compatible Web browser to access the Internet.

The following sections describe these components in more detail.

5.1 CORIS Device

See below for overview of CORIS features.

Figure 3: CORIS Features (front and left side)

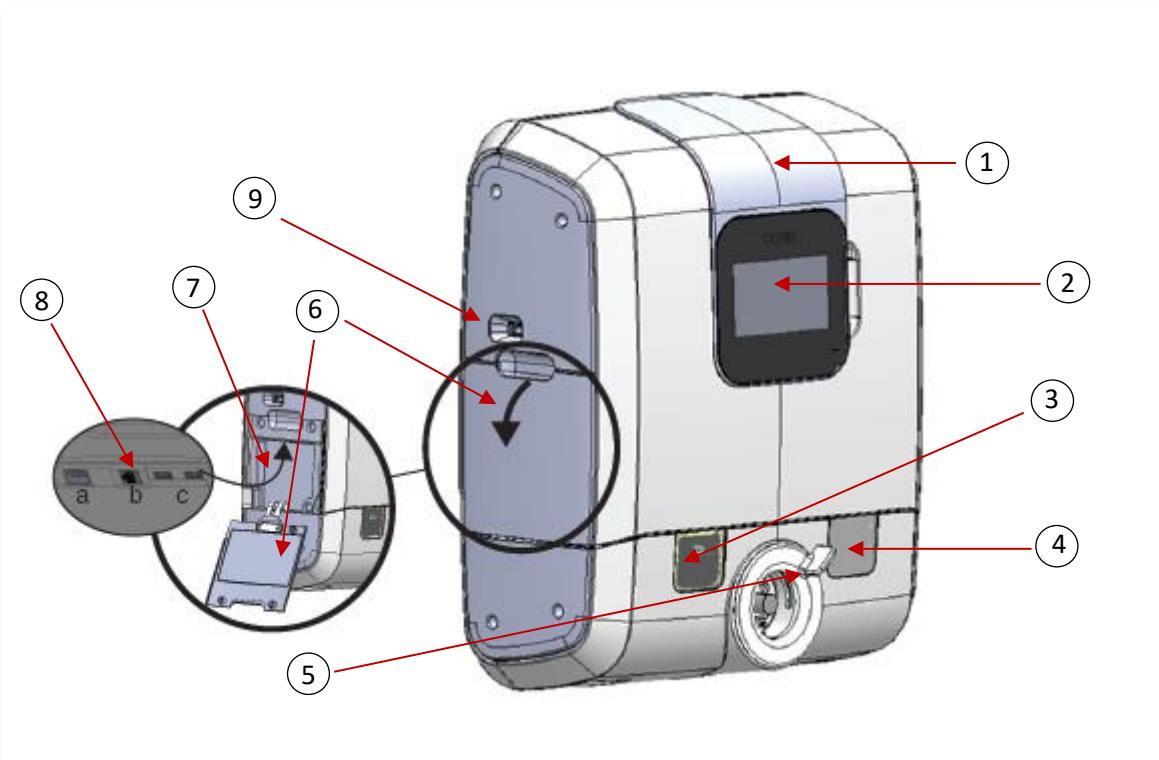
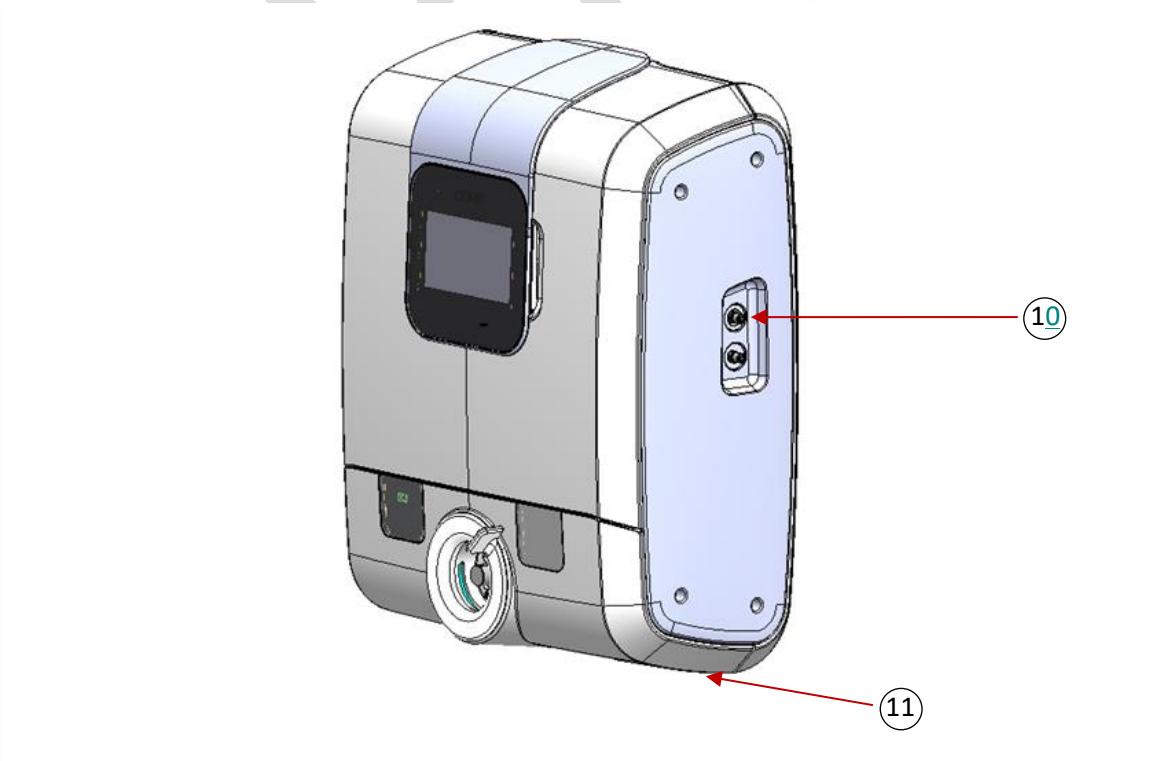


Figure 4: CORIS Features (right side)



- | | |
|---|--|
| 1. CORIS main door | 8. a. Power socket |
| 2. Touch screen | b. Ethernet |
| 3. Barcode reader | c. 2 x USB port |
| 4. RFID reader | 9. Power switch |
| 5. Adaptor lock lever (in locked position) | 10. Self-disinfection port |
| 6. Side door of power socket and device label | 11. Location of air, water and drain ports |
| 7. Device label* | |



* Please refer to the device label located underneath the side door for the applicable regulatory and electrical markings, Nanosonics contact details and the device model and serial number.

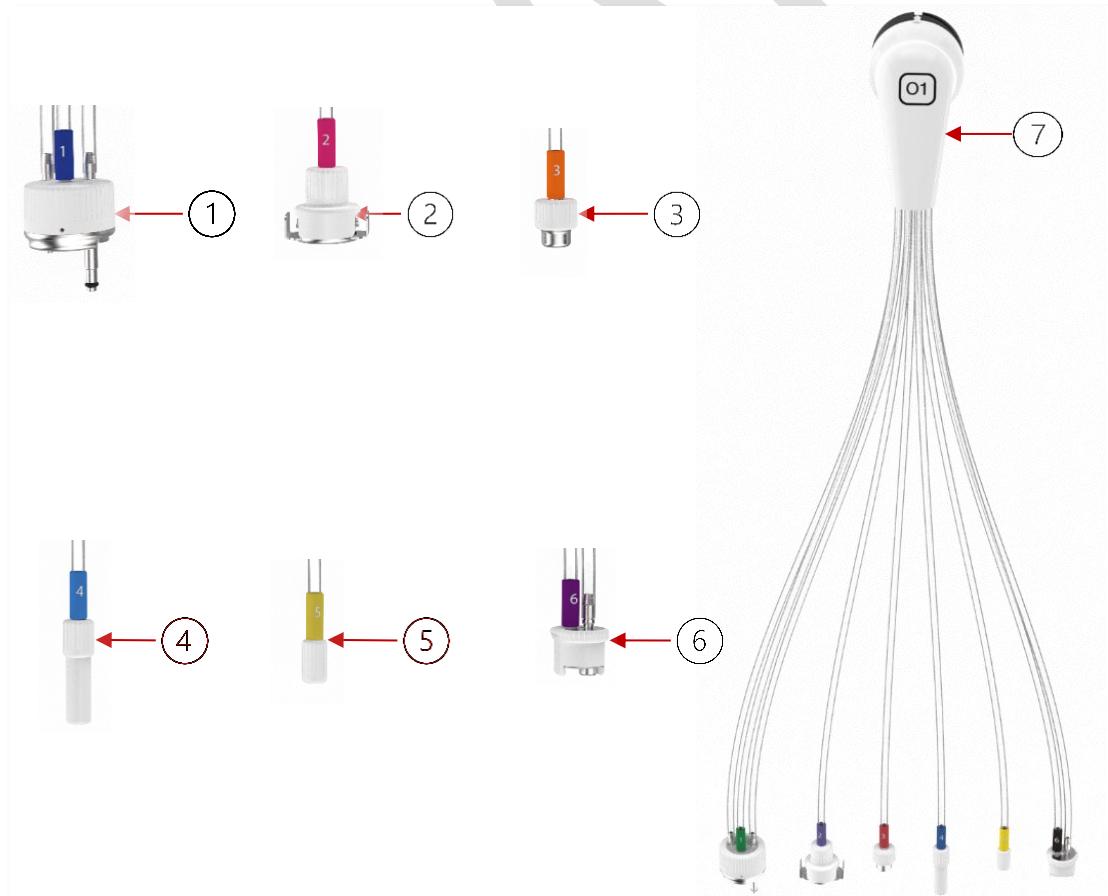
5.2 CORIS Adaptor

The function of the CORIS Adaptor is to connect an endoscope to the CORIS device.

The Adaptor (see [Figure 5 ⑦](#)) consists of a handle ([Figure 6-A](#)) which will connect to the CORIS Adaptor port ([Figure 6-B](#)) and several tubes ending in connectors ([Figure 5 ① to ⑥](#)), which will connect to the appropriate sites on the endoscope.

NOTE: The CORIS Adaptor must be replaced every 24 hours (i.e. daily). See Section [9](#) on page [62](#).

Figure 5: CORIS Adaptor O1



1. Suction air/water connector

2. Biopsy connector

- | | |
|------------------------|--|
| 3. Auxiliary connector | 6. Air/water supply connector |
| 4. Suction connector | 7. Adaptor O1 handle and tubes with connectors. |
| 5. Air pipe connector | |

[Figure 6-A](#) shows close-ups of the Adaptor handle.

[Figure 6-B](#) shows the location of the Adaptor port on the CORIS and the position of the lock lever when open and ready for attachment of the CORIS Adaptor. Do not force the lever anti-clockwise / down from this position. When the CORIS Adaptor is connected, gently slide the lock lever clockwise to the lock position shown in [Figure 6-C](#).

[Figure 6-C](#) shows the CORIS with Adaptor **O1** connected and the position of the lock lever when locked.

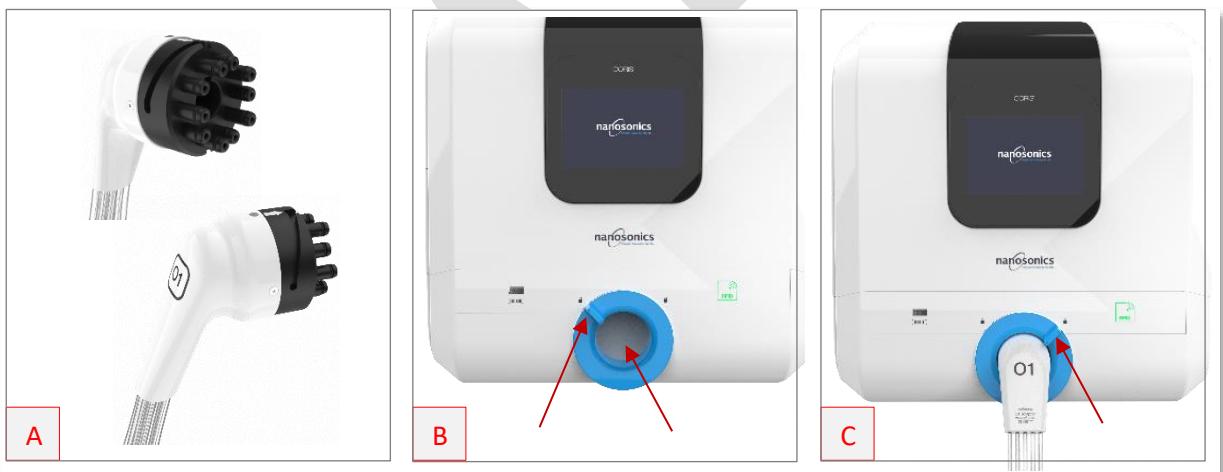


Take care to clear all fingers of the CORIS Adaptor handle interface when attaching to the CORIS Adaptor Port, to avoid pinch point.



The CORIS Adaptor is 24-hour use only. Discard after 24 hours. See Section [9](#) on page [62](#). Dispose of responsibly. Please follow your Facility guidelines.

Figure 6: Adaptor O1 Handle (A), CORIS Adaptor Port (B) and CORIS with Adaptor O1 Connected (C)



Adaptor **O1** connects to the Olympus CF-HQ190L endoscope.

As more endoscopes are validated for the CORIS more adaptors will be provided, along with a list of the validated endoscope models that they will connect to.

5.3 CORIS Self-Disinfection Adaptor

The CORIS Self-Disinfection System Adaptor (SD Adaptor) is used to ensure the disinfectant liquid will traverse all fluidic paths in the CORIS during a Self-Disinfection cycle. It replaces the endoscope Adaptor for the duration of the Self-Disinfection cycle.

Figure 7: CORIS SD System Adaptor



See Section [8.4 CORIS Self-Disinfection Cycle](#) on page [56](#) for information on how and when to use the SD Adaptor during the CORIS Self-Disinfection cycle.



Take care to clear all fingers of the CORIS Adaptor handle interface when attaching to the CORIS Adaptor Port, to avoid pinch point.



The CORIS Self-Disinfection Adaptor is 24-hour use only. Discard after 24 hours. See Section [9](#) on page [62](#). Dispose of responsibly. Please follow your Facility guidelines.

5.4 CORIS Self-Disinfection Plug

The CORIS Self-Disinfection plug is used during the CORIS Self-Disinfection cycle. It replaces the CORIS Cleaning Agent bottle for the duration of the cycle.

Figure 7: CORIS Self Disinfection Plug



See Section [8.4 CORIS Self-Disinfection Cycle](#) on page [56](#) for more information on how Self Disinfection plug is used during the CORIS Self-Disinfection cycle.



The CORIS Self-Disinfection Plug is 24-hour use only. Discard after 24 hours. See Section [9](#) on page [62](#). Dispose of responsibly. Please follow your Facility guidelines.

5.5 CORIS Splash Guard

The endoscope is connected to the Splash Guard to direct effluent to the drain.

The Splash Guard (see [Figure 8](#)) is attached to the CORIS via the CORIS discharge tube ① and to the endoscope via the Splash Guard Tube ④.

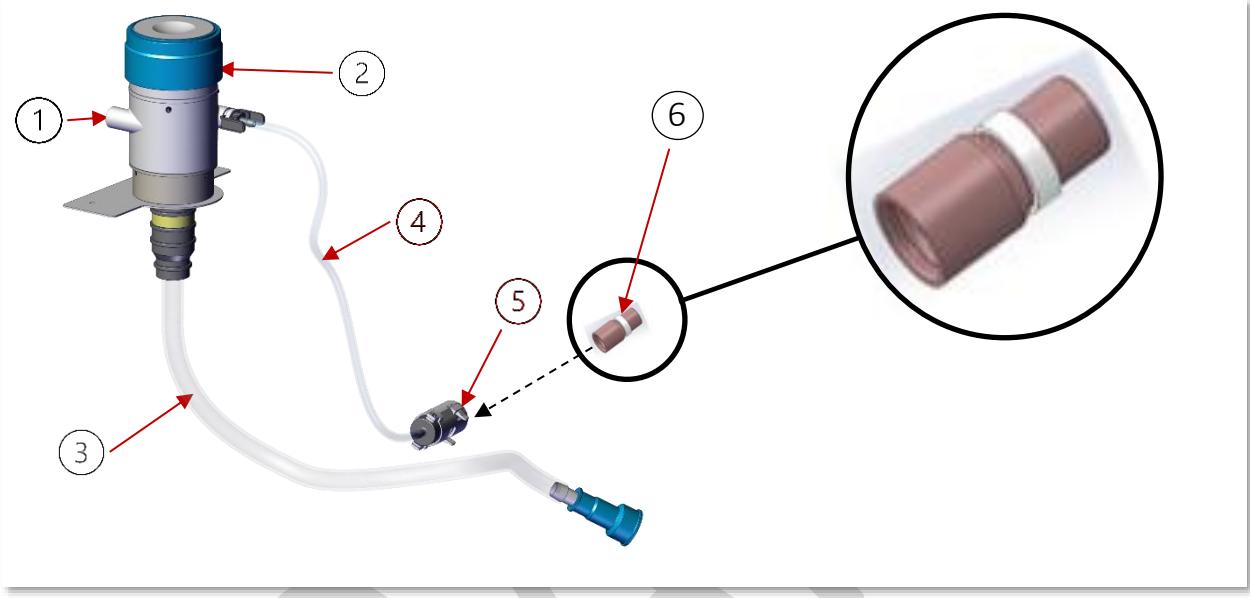
Note that a seal in a clip ⑤ is used to attach the endoscope distal end to the Splash Guard tube. See Section [5.7.2](#) on page [24](#) for more information.

Filtered waste liquid is discharged via the Splash Guard drain tube ③, which must be inserted into an appropriate fluid disposal container.

See Section [5.7.2](#) on page [24](#) for more information on the Splash Guard Tube.

See Section [5.1](#) on page [17](#) for more information on the CORIS discharge tube.

Figure 8: CORIS Splash Guard



- 1. Splash Guard device drain input
- 2. CORIS Splash Guard
- 3. Splash Guard drain
- 4. CORIS Splash Guard Tube
- 5. Splash Guard Tube clip
- 6. CORIS Splash Guard Seal

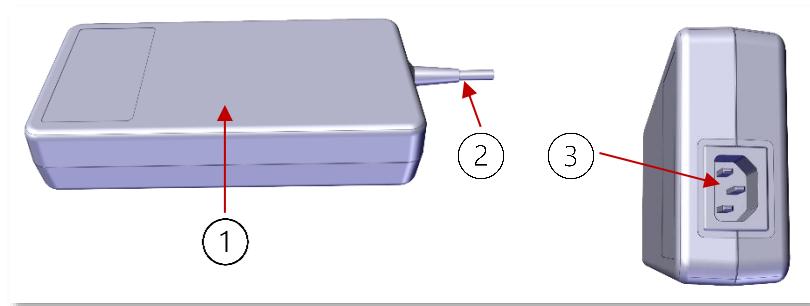


* Single use only product. The CORIS Splash Guard Seal inserts into the Splash Guard Tube clip and should be replaced every cleaning cycle. See [5.7.3](#).

5.6 CORIS Power Adaptor

The CORIS will already be connected to the mains power.

The CORIS Power Adaptor is supplied with your CORIS and will be packaged with a mains power cable suitable for your Facility. Its function is to regulate mains power and provide 24DC current to the CORIS. It consists of the power adaptor (see *Figure 9 - ①*) with attached cable for connection to CORIS, (see *Figure 9 - ②*). This will attach to the CORIS power socket, located under the side door of power socket and device (see Figure 3). The mains power cable should be attached to the universal AC socket on the Power Adaptor (see *Figure 9 - ③*).

Figure 9: CORIS Power Adaptor

1. Power Adaptor
2. CORIS Connector cable (fixed)
3. Universal Input Socket

5.7 CORIS Consumables

CORIS consumables are bought separately from the CORIS and are provided with their own Instructions For Use (IFU). Currently these consist of:

- *Cleaning Agent (packaged in a bottle)*
- *CORIS Splash Guard Tube*
- *CORIS Splash Guard Seal*
- *CORIS Operator Card*
- *Disinfectant*
- *SD Spout*
- *Disinfectant Cleaning Wipes*

5.7.1 CORIS QUANTUM Cleaning Agent

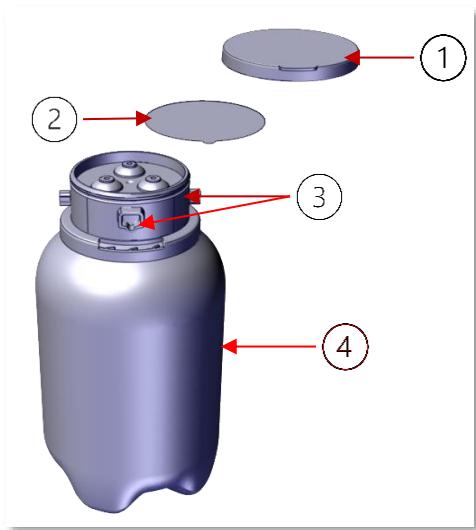


The CORIS QUANTUM has been specially designed for use with CORIS. Only the cleaning agent CORIS QUANTUM supplied by Nanosonics, is suitable for use for cleaning endoscopes with CORIS. No other cleaning agent has been validated for use with CORIS and use of other cleaning agents may result in damage to CORIS and the endoscope and/or reduced effectiveness of cleaning.

CORIS QUANTUM cleaning agent is supplied in bottles as shown in [Figure 10](#). Each cleaning agent bottle contains enough cleaning agent to perform 10 cleaning cycles. New bottles are sealed with both a removable foil and a cap, as shown in [Figure 10](#).

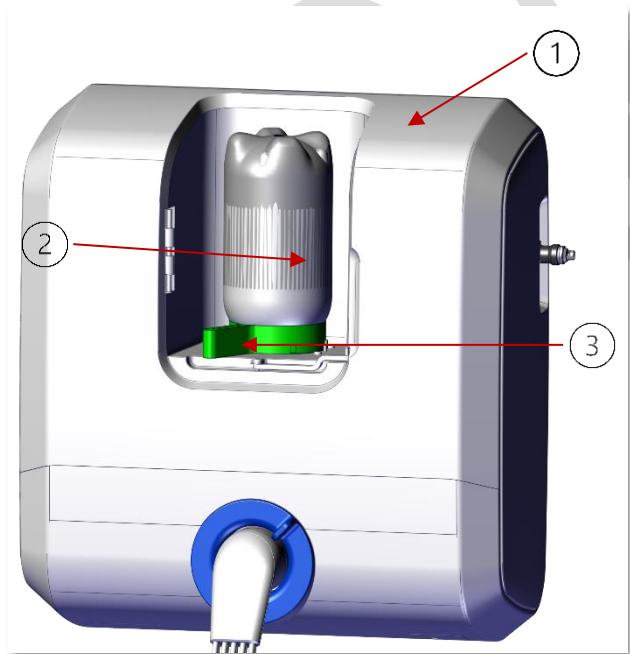


The CORIS QUANTUM Cleaning Agent is single use only. Discard immediately after the bottle is empty or expired. Dispose of responsibly. Please follow your Facility guidelines.

Figure 10: CORIS Cleaning Agent Bottle

- | | |
|-------------------|---------------------|
| 1. Bottle Cap | 3. Locking features |
| 2. Removable Foil | 4. Bottle |

When in use, cleaning agent bottles are housed behind a door and locked in place via a lock lever. See [Figure 11](#) (CORIS Door not shown). For information on replacing empty bottles see Section [10.1](#) on page [63](#).

Figure 11: Cleaning Agent Bottle in CORIS

- | | |
|--------------------------|---------------------------------------|
| 1. CORIS | 3. Locking lever (in locked position) |
| 2. Cleaning Agent Bottle | |

5.7.2 CORIS Splash Guard Tube

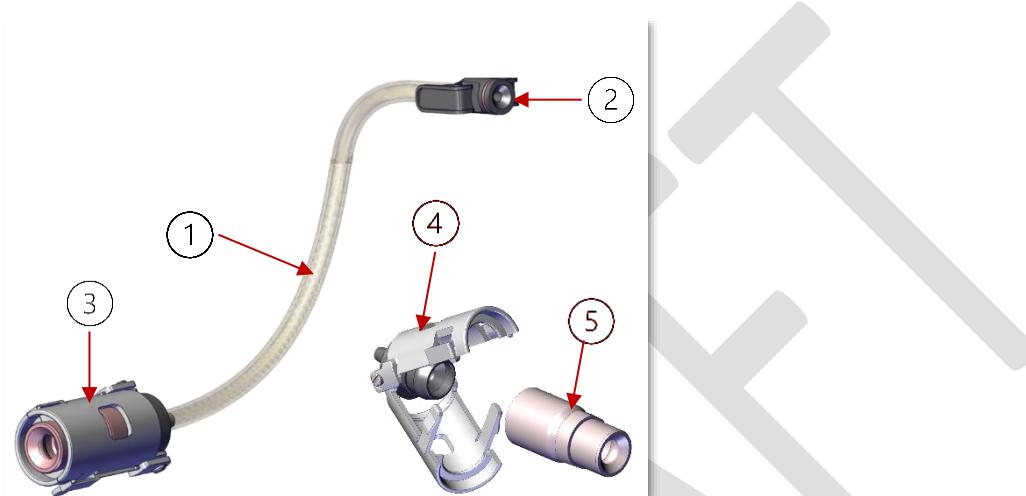


The CORIS Splash Guard Tube is 24-hour use only. Discard after 24 hours. Dispose of responsibly. Please follow your Facility guidelines.

The CORIS Splash Guard Tube (see [Figure 8](#)) attaches on one end to the Splash Guard via the Splash Guard Tube Connector ② and the other end attaches to the endoscope distal end via the Splash Guard Seal and clip ③.

The seal is also a consumable item. For more information see [Splash Guard Seal](#).

Figure 12: CORIS Splash Guard Tube



1. CORIS Splash Guard Tube
2. CORIS Splash Guard Tube connector
3. CORIS Splash Guard Tube clip (shut) containing CORIS Splash Guard Seal
4. CORIS Splash Guard Tube clip (open)
5. CORIS Splash Guard Seal

5.7.3 CORIS Splash Guard Seal

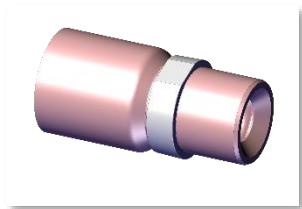


The CORIS Splash Guard Seal is single use only. Discard immediately after use. Dispose of responsibly. Please follow your Facility guidelines.

The CORIS Splash Guard Seal is a consumable item and is supplied separately from the CORIS. It is used to connect the Splash Guard to the distal end of the endoscope (see [Section 5.5](#) on page [20](#)).

See [Section 8.2.2](#) step [5](#) on page [51](#) for more information on how this component is used during an endoscope cleaning cycle.

Figure 13: Splash Guard Seal



Contact your Nanosonics supplier for further information on replacements.

5.7.4 CORIS User ID Card

User cards with Operator and Admin level access can be provided (see Section [7.3 on page 35](#)). These cards may contain an RFID chip or a barcode.

Figure 14: CORIS User ID Cards



Where requested, Nanosonics can provide CORIS Operator Cards to uniquely identify operators during the operation of the CORIS device. These cards feature an embedded RFID card which can be programmed with a pointer to a unique User ID in a protected facility employee database, preserving employee anonymity. Alternatively, to fit in with your Facility ID cards, the Nanosonics ID cards can be furnished with an appropriate barcode.

Cards can provide either Admin or Operator level access to the CORIS, depending on how they are programmed.

For information on

- programming cards see Section TBA
- Operator and Admin level access see Section [7.3 on page 35](#).



Traceability requires unique ID cards for each User.

5.7.5 Disinfectant Bottle for SD Cycle

Periodically the internal components of the CORIS will need to be disinfected. To perform this disinfection Nanosonics recommends the use of Steris® Revitalox™ Resert® High Level Disinfectant (see [Figure 15](#)).

Figure 15: Steris® Revitalox™ Resert® High Level Disinfectant Used in CORIS SD Cycle



For more information on the self-disinfection cycle see Section [8.4 CORIS Self-Disinfection Cycle](#) on page [56](#).



Revitalox™ is a hazardous substance and PPE is required for use. Refer to the Steris® Revitalox™ Resert® High Level Disinfectant IFU and SDS for more information.

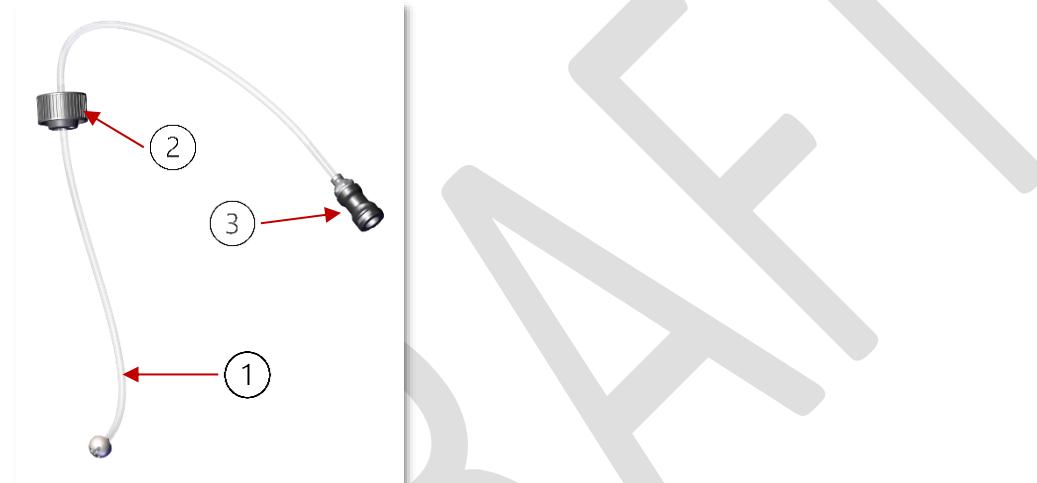
5.7.6 SD Spout

The Self-Disinfection Spout consists of a tube, connector and a cap (see [Figure 16](#)) which will replace the cap of the disinfectant bottle for the SD cycle (see Section [5.7.5 above](#)). For more information on the SD cycle see Section [8.4](#) on page [56](#).

NOTE: This spout assembly is to be replaced after every SD cycle.

Contact your Nanosonics supplier for further information on replacements.

Figure 16: SD Spout



1. SD Tube

2. SD Cap

3. SD connector Coupling



The disinfectant bottle and SD spout should be used with the CORIS Self-Disinfection Adaptor and Plug (see section 5.3 and 5.4) to complete the CORIS Self-Disinfection cycle.

5.7.7 Disinfectant Cleaning Wipes

External surfaces of the CORIS device should be wiped down with Quat wipes at the end of each day, as required by the End of Day Procedure (see Section [8.5](#) on page [61](#)). Appropriate disinfectant cleaning wipes may be provided by Nanosonics in the form of tropon Companion Cleaning Wipes.

Figure 17: trophon Companion Cleaning Wipes



Contact your Nanosonics supplier for further information.

5.8 CORIS Software

TBA.

6 The CORIS User Interface

The CORIS is equipped with a touch screen which is used extensively to guide you through the cleaning cycle, setting system options and executing maintenance and self-disinfection tasks. This section covers the user interface, the iconography and its functions as well introducing you to the top-level Power Standby, Home and Menu screens.

6.1 Symbols and Icons

Some symbols are just informative, whilst others are touch-sensitive and will launch some task when tapped, as listed in [Table 2](#) below.

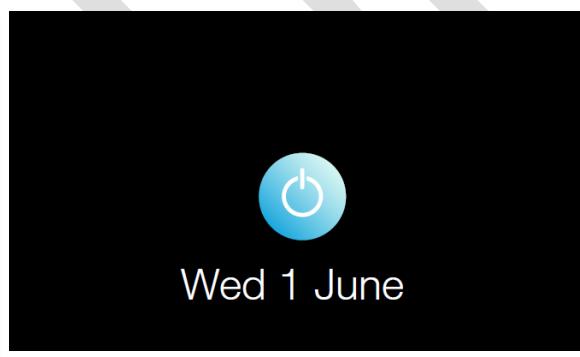
Table 2: Symbols and Icons

Symbol or Icon	Name	Informative or Active	Information or Action
	Home	Active	Action: Access the Home screen (see Section 6.3 below)
	Home	Informative	Indicates the Home button is inactive (e.g. when on the Home screen)
	Menu	Active	Action: Access the Menu screen (see Section 6.4 below)
	Wi-Fi	Informative	Indicates the CORIS is connected to the local Wi-Fi network
	Ethernet	Informative	Indicates the CORIS is connected to the local Ethernet via cable
	Cloud	Informative	Indicates the CORIS is connected to the Internet
	User	Active	Action: Aborts current User Management procedure
	Endoscope	Active	Action: Aborts current Endoscope Management procedure

6.2 Power Standby Screen

The Power Standby screen is displayed automatically after a powered CORIS has been left unused for nn minutes.

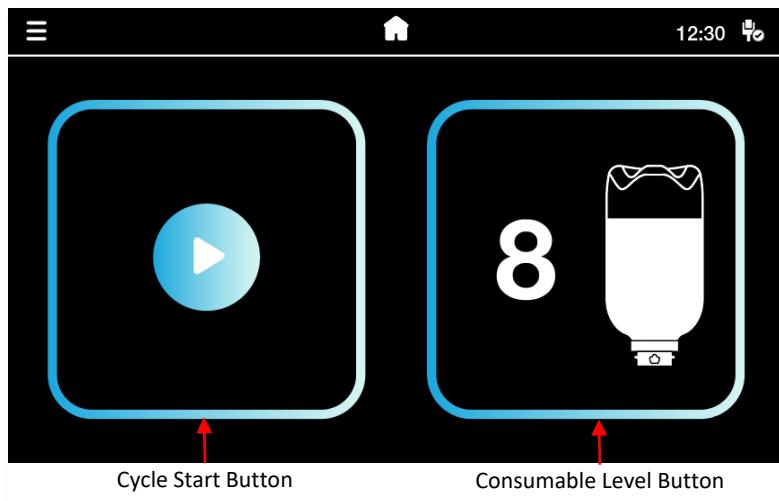
Figure 18: The CORIS Power Standby Screen



Tap the Power symbol  in the Power Standby screen to access the Home screen (see [Figure 19](#)).

6.3 Home Screen

This screen is used to start a cleaning cycle and to indicate any errors encountered by the CORIS. To access this screen tap the Home icon  on any screen (or the Power symbol in the Power Standby screen, as mentioned above).

Figure 19: The CORIS Home Screen

The Cycle Start button is used to commence a cleaning cycle. See Section [8.2](#) on page [48](#) for further information.

The Consumable Level button is informative only. It displays the number of cleaning cycle before the Cleaning Agent Bottle is to be replaced. For further information on changing the Cleaning Agent Bottle see Section [10.1](#) on page [63](#).

When the CORIS encounters an error this screen will change the color of either one or both buttons, as shown in [Figure 20](#). In some cases the cause of the error may also appear as a message, below the buttons.

Figure 20: The CORIS Home Screen Showing Active Errors

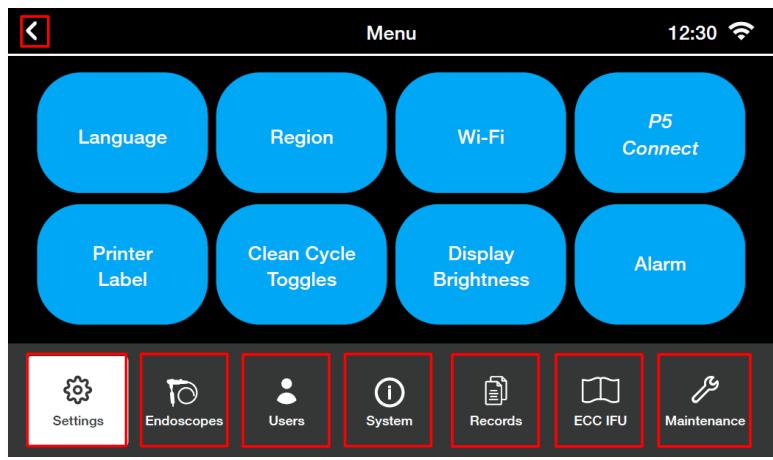
For a complete list of errors see Section [11](#) on page [67](#).

6.4 Menu Screen

To access this screen tap the Menu icon  on any screen. The Menu screen displays a set of buttons and icons which provide access to all the available functions of the CORIS software, as listed below.

Use the Back button  to return to the Home screen.

Figure 21: The CORIS Menu Screen



Buttons

Language	Use this button select another language. The default language will be selected by the CORIS based on your geographical location. See Section 6.4.1.1 on page 31 for more information.
Region	TBA. See Section 6.4.1.2 on page 31 for more information.
Wi-Fi	Use this button to set and modify Wi-Fi connection parameters. See Section 6.4.1.3 on page 31 for more information.
P5 Connect	This button will allow you to set up or modify access to the Nanosonics <CORIS Connect> service. See Section 6.4.1.4 on page 31 for more information.
Printer Label	?? See Section 6.4.1.5 on page 31 for more information.
Clean Cycle Toggles	CORIS clean cycles can be varied by switching these toggles ON or OFF. For further information See Section 8.2 on page 48 for more information.
Display Brightness	This allows you to change the brightness of the CORIS display.
Alarm	TBA. See Section 6.4.1.8 on page 31 for more information.

Tabs – at the bottom of the screen

Settings	TBA. See Section 6.4.2.1 on page 31 for more information.
Endoscopes	Tap to access the endoscope management functions. See Section 6.4.2.2 on page 31 for more information.
Users	Tap to access the user management functions. See Section 6.4.2.3 on page 32 for more information.
System	Tap to access all system management functions. See Section 6.4.2.4 on page 32 for more information.
Records	Tap to view and manage all CORIS records. See Section 6.4.2.5 on page 32 for more information.
CORIS IFU	Tap to view the CORIS IFU document (this User Manual) on your screen
Maintenance	Tap to access all maintenance functions. See Section 6.4.2.7 on page 32 for more information.

6.4.1 Buttons

The following buttons are currently inactive.

6.4.1.1 *Language*

The Language tab has been provided for use where more than one language may be in use in a specific region. For example in countries like Switzerland or Canada.

6.4.1.2 *Region*

TBA

6.4.1.3 *Wi-Fi*

TBA

6.4.1.4 *CORIS Connect*

TBA

6.4.1.5 *Printer Label*

TBA

6.4.1.6 *Clean Cycle Toggles*

The CORIS cleaning cycle can be adapted to suit your specific use of the software by selecting toggles. These can modify the amount of data recorded during the cycle or provide information about optional output devices. They are:

- **Patient Identifier:** turning this toggle ON indicates you wish to record patient data in this cycle.
- **Cleaning Cycle Parameters:** turning this toggle ON indicates you wish to record cleaning time and flow rate parameters in this cycle.
- **Printer Present:** this should be switched ON only when a printer has been connected.

To select these toggles tap the **Clean Cycle Toggles** button.

6.4.1.7 *Display Brightness*

TBA

6.4.1.8 *Alarm*

TBA

6.4.2 Tabs

6.4.2.1 *Settings*

TBA

6.4.2.2 *Endoscopes*

TBA

6.4.2.3 *Users*

TBA

6.4.2.4 *System*

TBA

6.4.2.5 *Records*

TBA

6.4.2.6 *CORIS IFU*

TBA

6.4.2.7 *Maintenance*

TBA

DRAFT

7 Getting Ready to Use the CORIS

Test instructions will be provided by your Nanosonics contact.

7.1 Installation and Connectivity Prerequisites

The CORIS will already be installed and all connectivity requirements will have been completed.

This section includes guidelines for setting up your devices to enable communication between the hardware, the Facility Intranet and the Internet, a mandatory requirement for proper functioning of the system.

NOTE: You will need to involve your IT department when connecting any new device to the facility network

7.2 Unpacking the CORIS Device



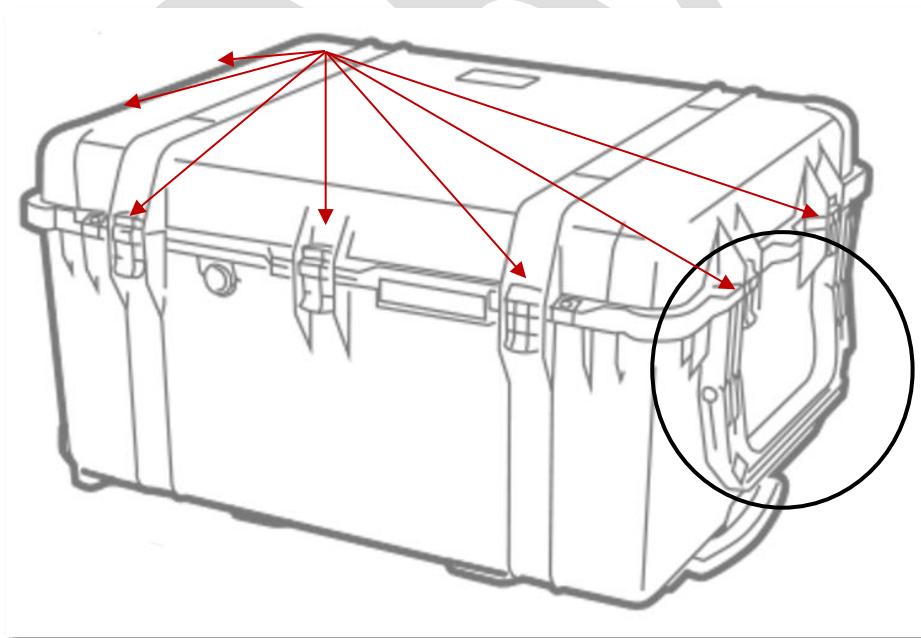
The unpacked CORIS device weighs approximately 45kg (99.2 lbs). Follow your facility's manual handling procedures for guidance on lifting heavy objects.

The packaged CORIS weighs approximately 65kg (143.3 lbs). If required to move prior to installation, multi-person lifting is required to lift the packaged CORIS 65 kg (143.3 lbs), using the handles at each end (see circled in Figure 22).

To open the package:

1. Unclip the seven fastenings on the packaging (indicated by the arrows in Figure 22) and lift the lid open.
2. Using a team or mechanical lift, gently lift the CORIS device out of the packaging, using the straps (pics to be provided and referenced here with description).

Figure 22: The CORIS Package and the multi-person lift handle position



7.2.1 Connecting the CORIS to your Facility Network

There will be no CORIS connectivity requirements.

Figure 23: A Networked CORIS



7.3 User Management

There are two types of users known to the CORIS software:

Admins: (or Administrators), are users that can access all functions of the CORIS software via the Menu screen, including performing the cleaning cycle.

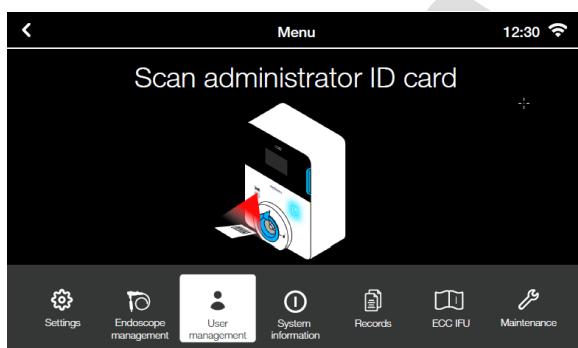
Operators: are users that can only perform cleaning cycles. All other actions accessible via the Menu screen are prohibited.

When your CORIS is newly installed, an initial Admin user will be registered in the CORIS database, and an Admin card will be supplied. Use this Admin ID card to perform any user management functions until new Admin users have been added.

Before you can manage the user database you need to:

1. Tap the Menu icon  on the top left of the Home screen ([Figure 19](#)) to bring up the Menu screen.
2. In the Menu screen tap the User Management tab  on the bottom (see [Figure 21](#)). A Scan Administrator ID Card animation will be shown (see [Figure 24](#)).
3. Follow the animation and scan your Admin card using the RFID or Barcode Reader on the CORIS. The CORIS now checks that the scanned card has administrative rights.

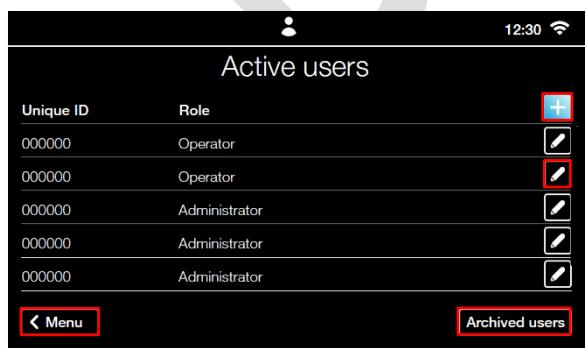
Figure 24: Scan Administrator ID Card Animation



If the scanned card does not have administrative rights, a warning message is displayed (see Section [11](#) on page [67](#) for a list of errors), and the display reverts to the previous animation.

When your ID has been accepted, the Active Users screen will be displayed ([Figure 25](#)).

Figure 25: Active Users Screen



From this screen you can:

- register a new user (see Section [7.3.1](#) on page [36](#))
- archive a user (see Section [7.3.2](#) on page [37](#))

- view all archived users (see Section [7.3.3 on page 38](#))
- change a user role (see Section [7.3.4 on page 39](#))
- exit by tapping Menu.

7.3.1 Registering a User

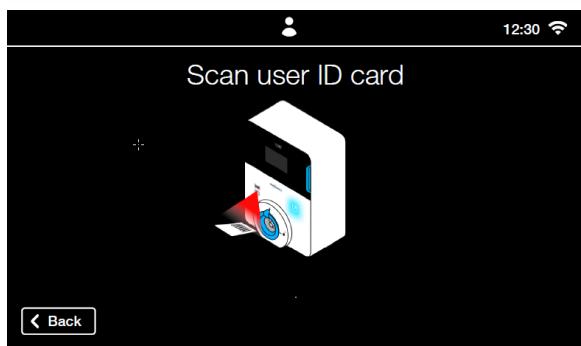
To register a new user:

1. Tap the Add button  in the Active Users screen (see [Figure 25](#)).

The Scan User ID card animation will be shown ([Figure 26](#)), prompting you to scan a new user ID card using the appropriate reader (barcode or RFID).

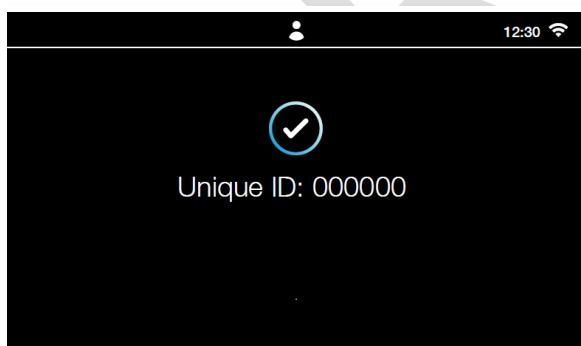
Any errors will briefly display a warning screen and then revert to the animation screen. See Section [11](#) on page [67](#) for a list of errors.

Figure 26: Scan User ID Card Animation

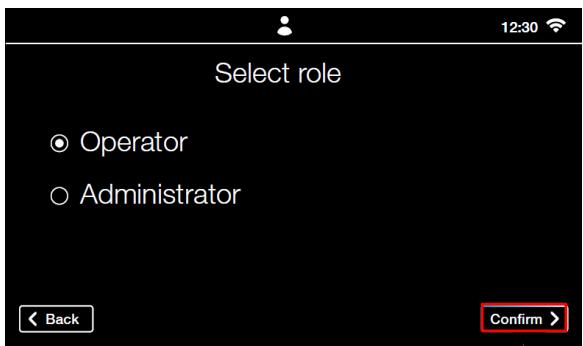


2. When the unique ID of the new user card is recognized a screen similar to [Figure 27](#) will be briefly displayed.

Figure 27: User ID Recognized



3. You are now asked to select a role for the new user. Tap **Operator** or **Administrator** to select. The associated option button will be highlighted.

Figure 28: Select User Role Screen

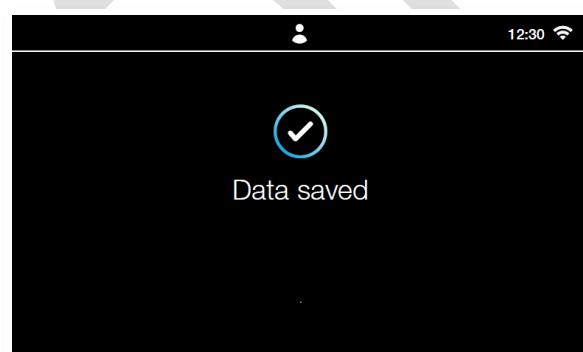
Tap **Confirm** to continue.

4. The New User profile screen will be displayed, showing the Unique ID and Role of the new user.

Figure 29: New User Profile Screen

To finish tap **Confirm** to continue. Else tap **Back** to access the previous screen.

The CORIS will briefly display a Data Saved screen to confirm the new user information has been saved locally.

Figure 30: Data Saved Screen

The Active Users screen will then be displayed ([Figure 25](#)), listing the new user at the top of the user list.

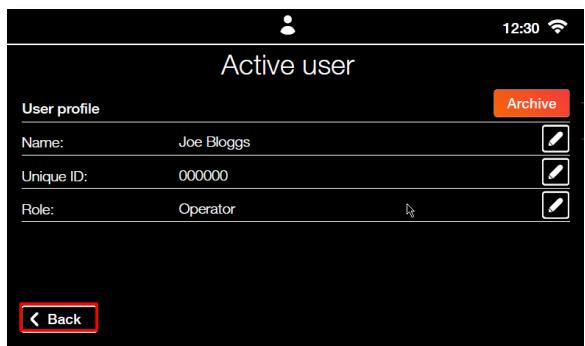
To abort the procedure at any time click the User icon  at the top of the screen. See Section [7.3.4.1](#) on page [39](#).

7.3.2 Archiving a User

When existing users no longer need access to the CORIS they can be archived, so they no longer appear in the list of current users. To archive any current user:

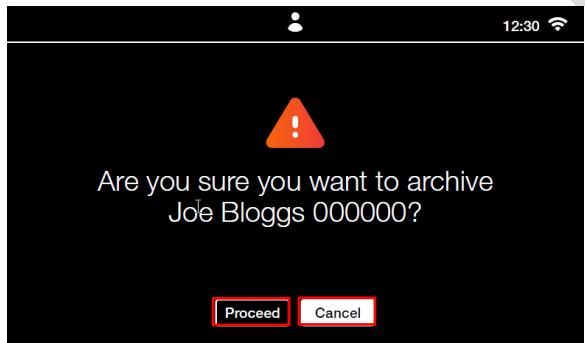
1. In the Active Users screen tap the Edit icon  on the row containing the user to be archived (see [Figure 25](#)). This will display the Active User Profile screen ([Figure 31](#)).

Figure 31: Active User Profile Screen



2. Tap **Archive** to archive the listed user. This will display the User Archive warning screen ([Figure 32](#)). If you have chosen the wrong user tap **Back** to return to the previous screen.

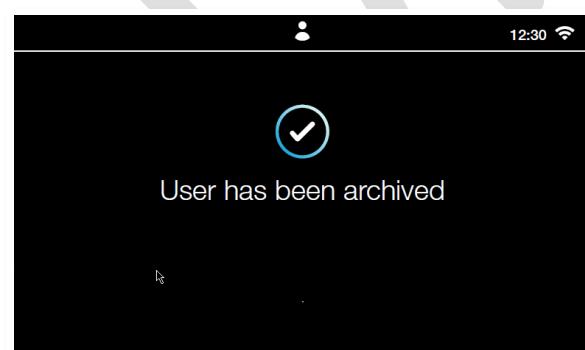
Figure 32: User Archive Warning Screen



3. To confirm tap **Proceed**, otherwise tap **Cancel**.

Tapping **Proceed** will briefly display the user archive confirmation screen ([Figure 33](#)), before reverting to the Active Users screen ([Figure 25](#)), which will now no longer list the user as being active.

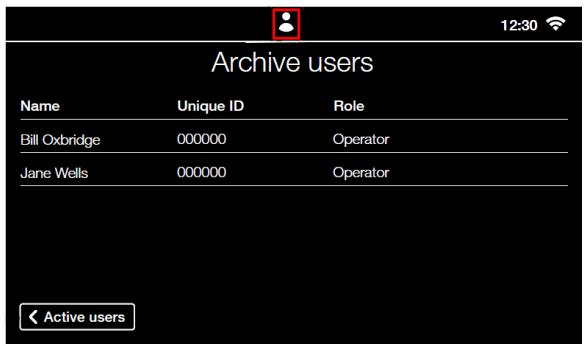
Figure 33: User Archive Confirmation Screen



7.3.3 Viewing Archived Users

To view archived users:

1. In the Active Users screen ([Figure 25](#) on page 35) tap **Archived Users**. This will bring up the Archived Users screen ([Figure 34](#)), showing all users that have been archived.

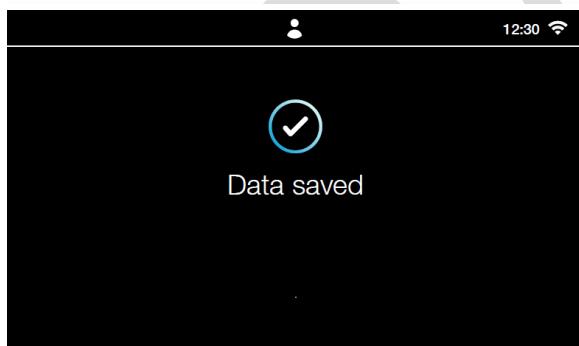
Figure 34: Archived Users Screen

Tap **Active Users** to return to the Active Users screen.

7.3.4 Changing a User Role

To change a user role:

1. In the Active Users screen (*Figure 25*) tap the Edit icon  on the row containing the user to be archived. This will display the User Details screen (*Figure 28*).
2. Select **Operator** or **Administrator** by tapping on the word. The associated option button will be highlighted.
3. Tap **Confirm** to save your change. A Data Saved screen will be briefly displayed to confirm your action (*Figure 35*).

Figure 35: Data Saved Confirmation Screen

The screen will then revert to the Active Users screen.

7.3.4.1 Aborting a User Procedure

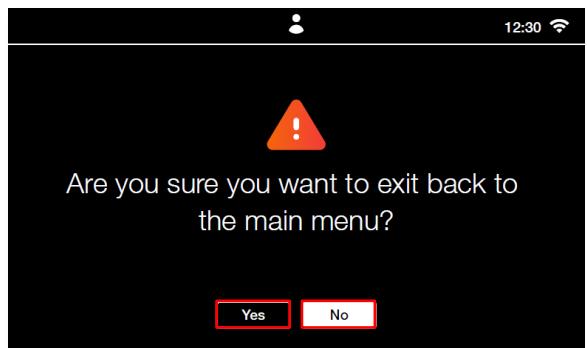
You can abort any user procedure at any time when the User icon  is showing at the top of the screen.

To abort a User procedure:

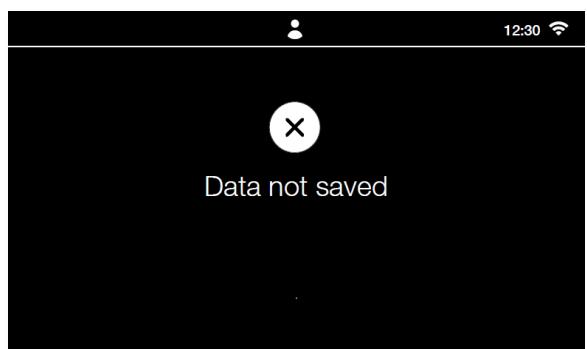
1. Tap on the User icon  at the top of the screen.

A confirmation screen will be displayed asking you to confirm your choice (*Figure 36*).

2. Tap **Yes** to confirm or **No** to return to the previous screen.

Figure 36: Exit Confirmation Screen

Selecting **Yes** will briefly display a Data Not Saved confirmation screen ([Figure 37](#)).

Figure 37: Data Not Saved Confirmation Screen

The CORIS will then display the Scan Administrator ID Card screen ([Figure 24](#) on page [35](#)).

7.4 Endoscope Management

NOTE: Only users with administrative rights can manage endoscopes for the facility. See Section [7.3 User Management](#) for further information about administrative rights.

Before you can use the endoscope management tools you need to:

1. Tap the Menu icon  on the top left of the Home screen ([Figure 19](#) on page [29](#)) to bring up the Menu screen.
2. Tap the Endoscopes tab  at the bottom of the Menu screen (see [Figure 21](#) on page [30](#)).

The Endoscopes screen will be displayed ([Figure 38](#)) showing a list of endoscopes registered with this CORIS.

From this screen you can:

- register new endoscopes (see Section [7.4.1](#) below)
- archive endoscopes (see Section [7.4.2](#) on page [44](#))
- change endoscope details (see Section [7.4.3](#) on page [45](#))
- view archived endoscopes (see Section [7.4.4](#) on page [46](#))
- exit by tapping **Menu**, which will take you back to the Menu screen.

7.4.1 Registering Endoscopes

Endoscopes must be registered on the CORIS before you can use the CORIS to clean them.

This allows the CORIS to identify which CORIS Adaptor should be used to connect that endoscope and to select the correct cleaning parameters when cleaning that endoscope.

Only validated endoscopes should be cleaned by the CORIS.

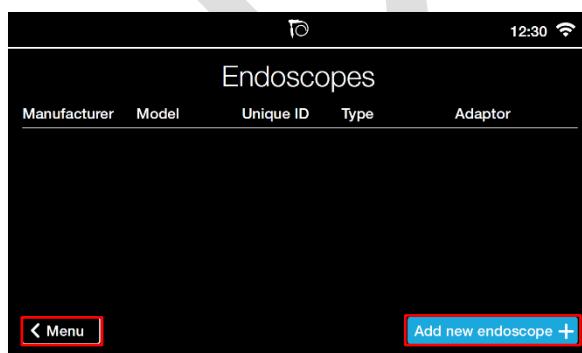
Refer to Section [3.2 Indications for Use](#) on page [13](#) for endoscopes that can be used with the CORIS.

 Use of the CORIS to reprocess endoscopes that are not validated, may potentially be ineffective, unsafe, and could result in damage to the CORIS and/or the endoscope.

To register a new endoscope to your CORIS:

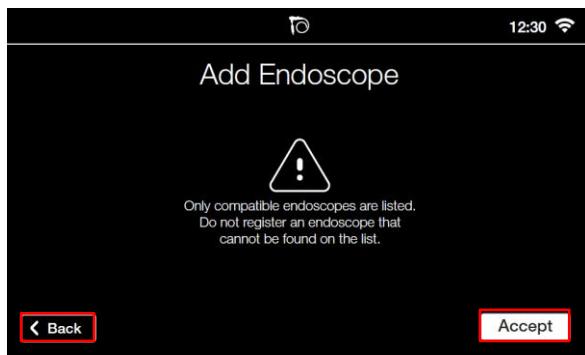
1. Tap **Add new endoscope** in the Endoscopes screen (see [Figure 38](#)).

Figure 38: Endoscope Management Screen



The Add Endoscope screen will be displayed (see [Figure 39](#)).

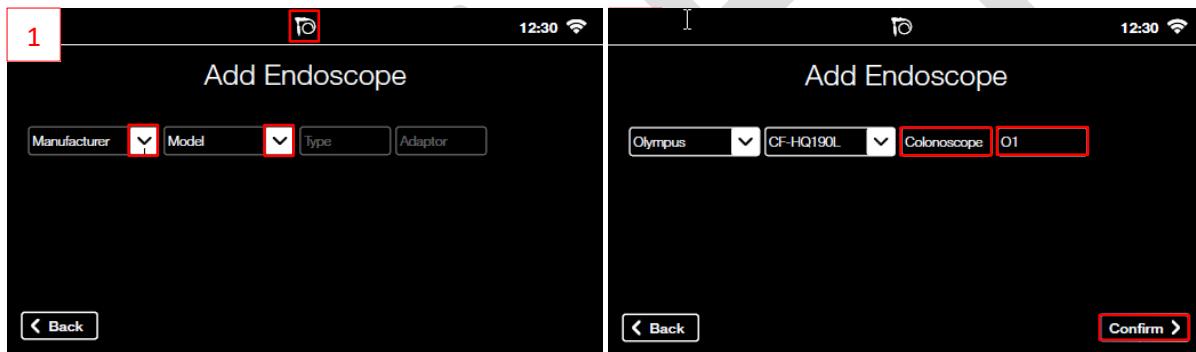
2. Take note of the warning message that is displayed about compatible endoscopes ([Figure 39](#)).

Figure 39: Add Endoscope Screen Showing Warning Message

To proceed tap **Accept**.

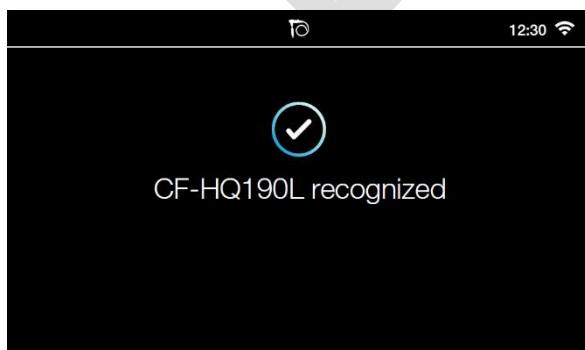
3. Tap the **Manufacturer** and **Model** arrows in the new screen (see [Figure 40-1](#)) and select your endoscope make and model from the drop-down lists. If your endoscope does not appear tap  to abort this procedure (see Section [7.4.1.1](#) on page [43](#)).

The endoscope **Type** and **Adaptor** fields will be auto-filled, and the **Confirm** button will appear (see [Figure 40-2](#)).

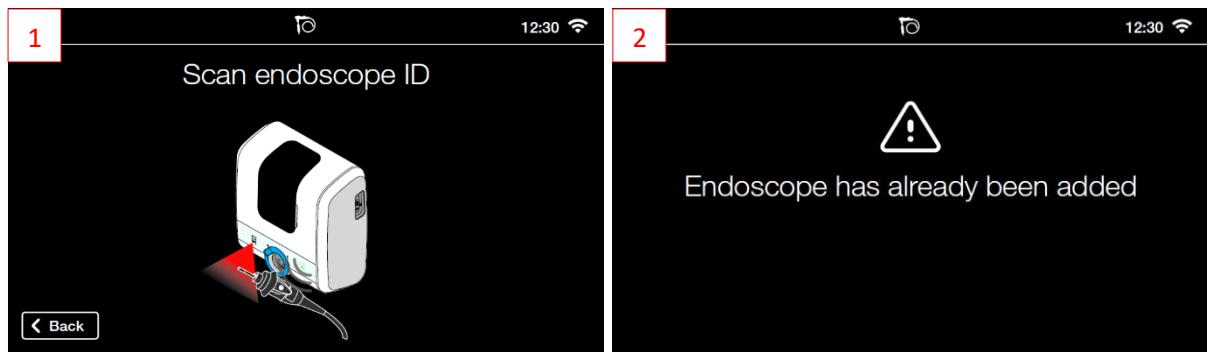
Figure 40: Add Endoscope Screen

4. Click **Confirm** to continue.

An audio prompt will sound, and a confirmation screen will be briefly displayed, showing the selected endoscope. (see [Figure 41](#)).

Figure 41: Confirmation of Endoscope Selection

5. The Scan Endoscope ID animation will be displayed ([Figure 42-1](#)). Scan the endoscope using either the RFID scanner or the barcode scanner.

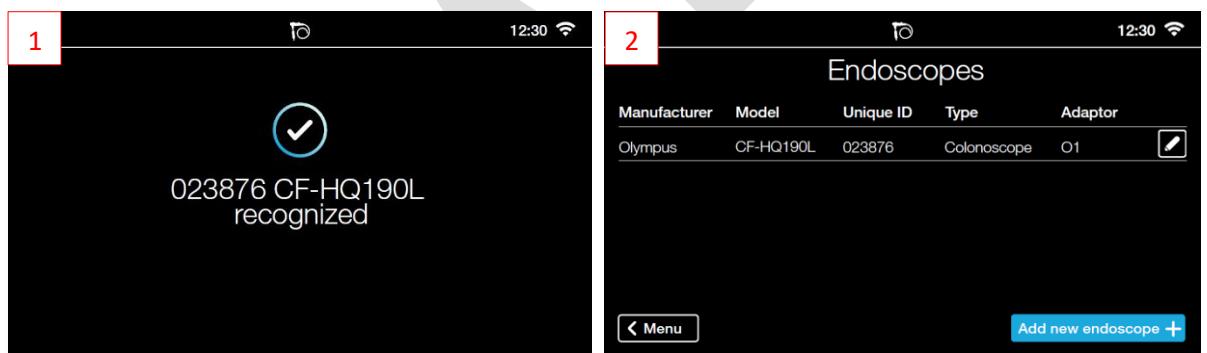
Figure 42: Scan Endoscope ID Animation

If the scanned endoscope has already been registered a brief message will be displayed ([Figure 42-2](#)) and the animation will be replayed.

For a complete list of errors see Section [11](#) on page [67](#).

6. An audio prompt will sound, and a confirmation screen will be briefly displayed, showing the unique ID of your newly registered endoscope ([Figure 43-1](#)).

The Endoscope Management screen will then be displayed, which will show the newly registered endoscope ([Figure 43-2](#)).

Figure 43: New Endoscope Registration Confirmation

You have successfully registered a new endoscope. Tap **Menu** to access the Menu screen (see [Figure 21](#) on page [30](#)).

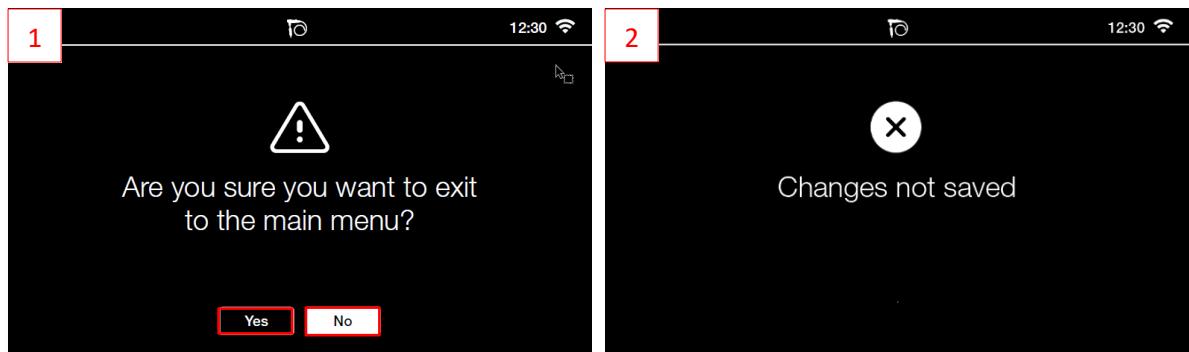
7.4.1.1 *Aborting an Endoscope Registration*

You can exit any endoscope procedure at any time when the endoscope icon  is displayed at the top of the screen. To do so:

1. Tap the endoscope icon .

You will be presented with the confirmation screen shown in [Figure 44-1](#).

2. Tap **Yes** to continue or **No** to go back to the previous screen.

Figure 44: Exit Confirmation Screen and Message

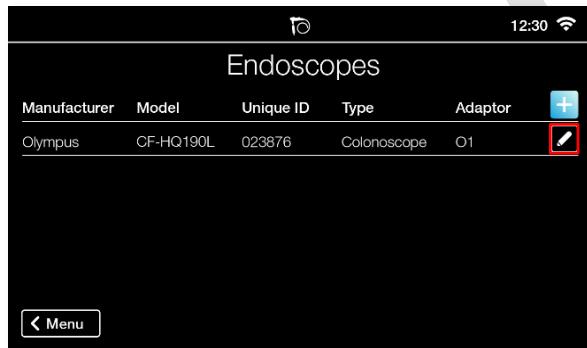
Tapping **Yes** will briefly display a screen ([Figure 44-2](#)) informing you that the registration changes have not been saved.

7.4.2 Archiving Endoscopes

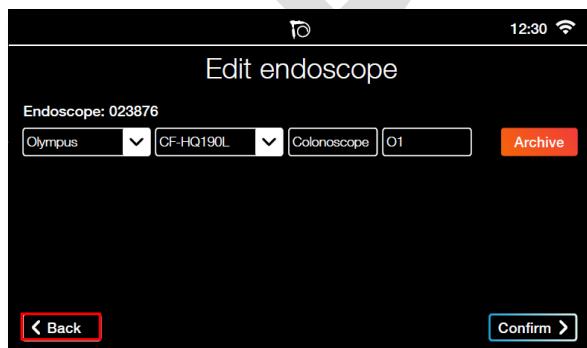
When registered endoscopes are no longer to be used in your facility you may archive them to ensure they will be de-registered and no longer listed in the registered endoscopes list.

To archive a registered endoscope:

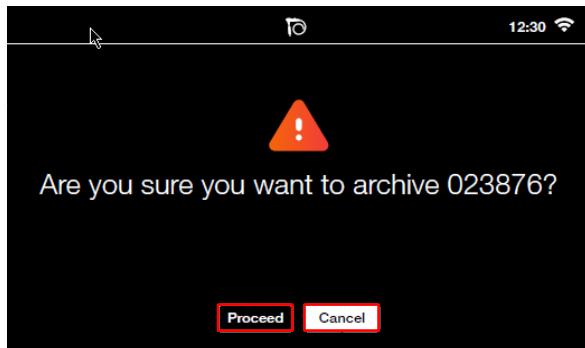
1. Access the Endoscopes screen following steps [1](#) and [2](#) of Section [7.4 Endoscope Management](#).
2. Tap the Edit icon  on the row containing the endoscope to be archived (see [Figure 45](#)).

Figure 45: Endoscopes Screen

This will display the Edit Endoscope screen ([Figure 46](#)).

Figure 46: Edit Endoscope Screen

3. In the Edit Endoscope screen tap **Archive**. A warning screen will be displayed, asking you to confirm the archiving of the selected endoscope. See [Figure 47](#).

Figure 47: Endoscope Archiving Warning Screen

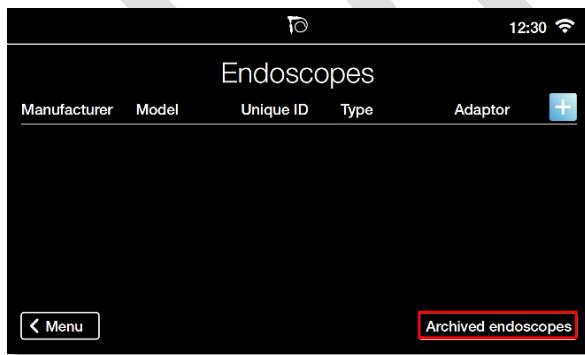
EITHER – Tap **Proceed** to archive the endoscope, an audio prompt and a confirmation screen will indicate the endoscope has been archived. (see [Figure 48](#)).

OR – Tap **Cancel** to return to the previous screen.

Figure 48: Endoscope Archived Screen

The endoscope will be saved in the Archived Endoscopes database. See Section [7.4.4](#) on page [46](#) for further information.

After a brief time the Endoscopes screen will be redisplayed ([Figure 49](#)) showing a new button labelled **Archived Endoscopes** and the archived endoscope will no longer be listed as a registered endoscope.

Figure 49: Endoscopes Screen Showing Archived Endoscopes Button

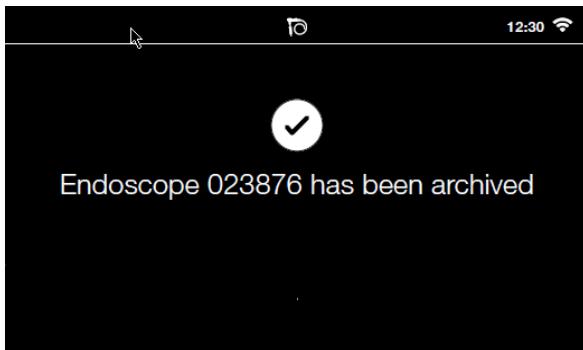
You have successfully archived the endoscope.

7.4.3 Changing Endoscope Details

If you wish to change the details of a registered endoscope (i.e. Manufacturer or Model):

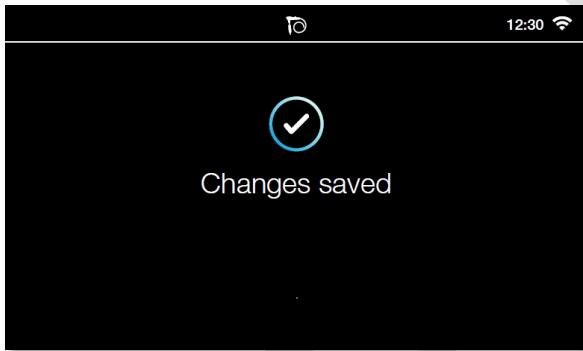
1. Access the Edit Endoscope screen following steps 1 and 2 of Section 7.4.2 Archiving Endoscopes.
In Step 2 you will be selecting the endoscope to be edited.

Figure 50: Edit Endoscope Screen



2. Tap the arrows and select a new Manufacturer and/or Model from the drop-down lists.
3. Tap **Confirm** when you have made the required changes. A confirmation screen will be briefly displayed.

Figure 51: Changes Saved Screen



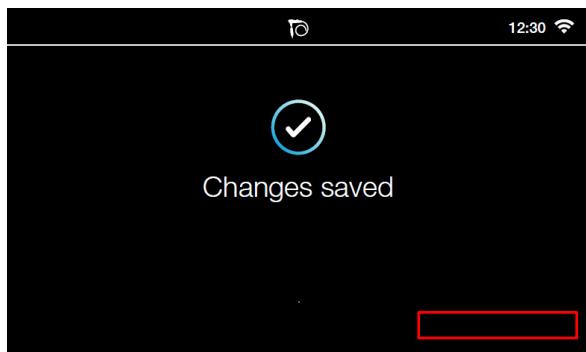
The Endoscopes screen will then be displayed (see Figure 38 on page 41).

7.4.4 Viewing Archived Endoscopes

Archived endoscopes are never deleted from the CORIS database, merely moved from the registered endoscopes list to the archived endoscopes list.

To view archived endoscopes:

1. Access the Endoscopes screen following steps 1 to Error! Reference source not found. of Section 7.4 Endoscope Management. If any endoscopes have been archived, you will see the Archived Endoscopes button, as shown in Figure 52.

Figure 52: Endoscopes Screen Showing Archived Endoscopes Button

2. Tap **Archived Endoscopes** to bring up the Archived Endoscopes screen (*Figure 53*), showing details of all endoscopes that have been archived.

Figure 53: Archived Endoscopes Screen

Tap **Back** to return to the Endoscopes screen.

8 Operating the CORIS

Only validated endoscopes should be cleaned by the CORIS.

Refer to Section [3.2 Indications for Use](#) on page [13](#) for endoscopes that can be used with the CORIS.



Use of the CORIS to reprocess endoscopes that are not validated, may potentially be ineffective, unsafe, and could result in damage to the CORIS and/or the endoscope.

The CORIS is indicated to clean the internal channels of endoscopes (Section [3.2 Indications for Use](#), page [13](#)).



Endoscopes must be high-level disinfected or sterilised after cleaning with the CORIS according to the manufacturer's instructions (Section [3.2 Indications for Use](#), page [13](#)).

Refer to the endoscope manufacturer's instructions for the overall reprocessing requirements.



Appropriate personal protective equipment (PPE) (including gowns, gloves, protective face wear and masks) should be worn for protection against biological contamination during endoscope reprocessing.

8.1 Endoscope Leak Testing

Perform leak testing according to the endoscope manufacturer's instructions.

8.2 The CORIS Cleaning Cycle

During the cleaning cycle, a number of screens and animations will appear on the CORIS touch screen display to help guide you through the workflow.

For animations only the initial screens are shown in this document.

8.2.1 Cleaning Cycle Summary

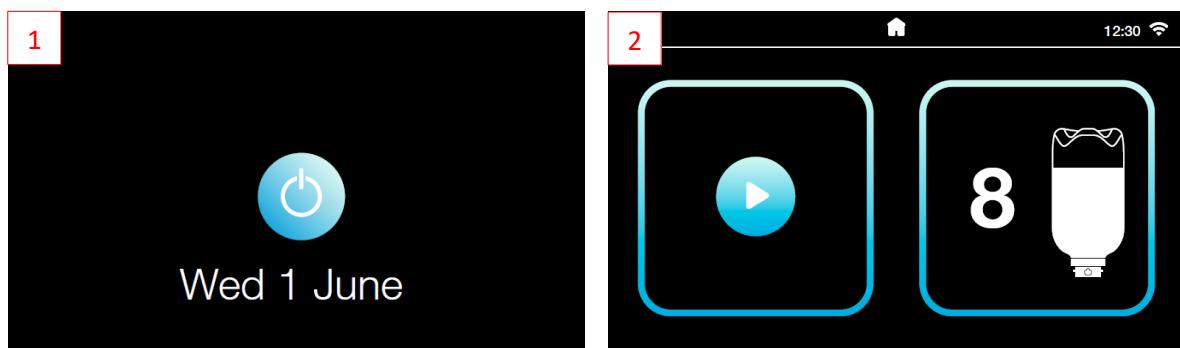
In summary the CORIS cleaning cycle consists of the following main steps:

1. Scan the endoscope (let the CORIS know what endoscope you are cleaning).
2. Attach the scanned endoscope to the CORIS and the Splash Guard.
3. Start the cleaning cycle.
4. Remove the endoscope from the CORIS and the Splash Guard.

8.2.2 Performing a Cleaning Cycle

You can only start a cleaning cycle from the Home screen (see [Figure 54-2](#)).

Figure 54: Power-on Standby [1] and Home [2] Screens



1. If your CORIS is displaying the Power-on Standby screen ([Figure 54-1](#)) tap the Power button  to display the Home screen.
2. On the Home Screen tap the Start Cycle button  to launch an animation on the CORIS touch screen. Scan the endoscope ID using the barcode or RFID reader on the front of the CORIS as shown in the animation ([Figure 55-1](#)). A successful scan will result in your endoscope ID being displayed briefly on the CORIS screen, as shown in [Figure 55-2](#), before moving on to the next step.

See Section [11 Error Messages](#) for a list of possible errors and how to deal with them.

Figure 55: Scan Endoscope ID Animation and ID Recognized Screen



3. If:
 1. **There is no Adaptor in the CORIS** – insert and lock the adaptor identified in the animation on the screen ([Figure 56-1](#)). Once the adaptor has been recognized a confirmation screen will be briefly displayed ([Figure 56-2](#)). Continue with step [4 below](#).
 2. **There is an Adaptor in the CORIS (left from the previous cleaning cycle)** – [Figure 56-2](#) will be briefly displayed on the screen. Continue with step [4 below](#).

Figure 56: Insert Adaptor and Lock it in Place Animation

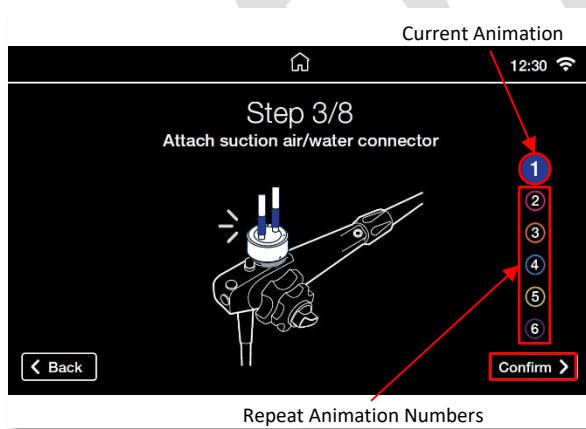
4. Attach the endoscope to the following Adaptor connectors:

- ① suction air/water connector
- ② biopsy connector
- ③ auxiliary connector
- ④ suction connector
- ⑤ air pipe connector
- ⑥ air/water supply connector

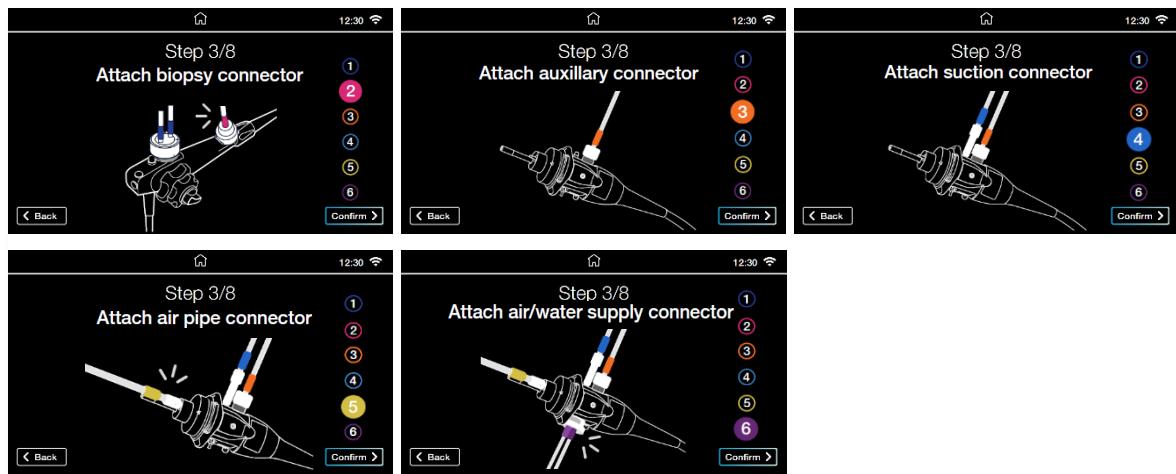
A different animation will be displayed for each connector, continuing to the next when finished.

The current animation will be highlighted on the screen, as shown in [Figure 57](#). To view an animation again tap its Repeat Animation number.

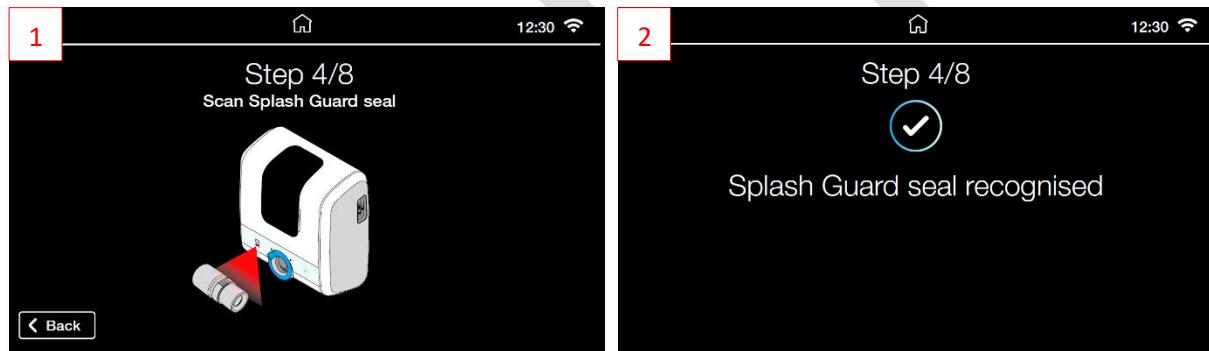
NOTE: Tap **Confirm** at any time, to proceed to the next step (see step [5 below](#)).

Figure 57: Attach all CORIS Connectors to the Endoscope

Initial screens of animations ② to ⑥ are shown in [Figure 58](#).

Figure 58: Individual Connector Attachment Animations 2 to 6

5. Source a new Splash Guard Seal and scan it using the appropriate scanner as shown in the animation ([Figure 59-1](#)).

Figure 59: Scan Splash Guard Seal Animation and Recognition Screen

A recognition screen will confirm a successful scan ([Figure 59-2](#)).

6. Connect the endoscope to the CORIS Splash Guard.

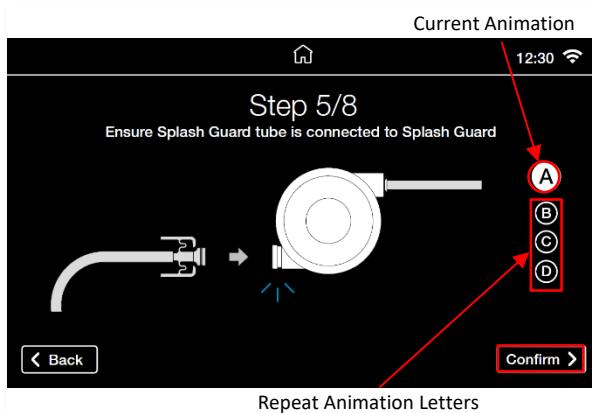
To do so you will be prompted by a set of animations, **A** to **D**. A different animation will be displayed for each step, continuing to the next animation automatically. The current animation will be highlighted on the screen, as shown in [Figure 60](#).

To view an animation again tap its Repeat Animation letter.

NOTE: Tap **Confirm** at any time, to proceed to the next step (step **7** on page [53](#)).

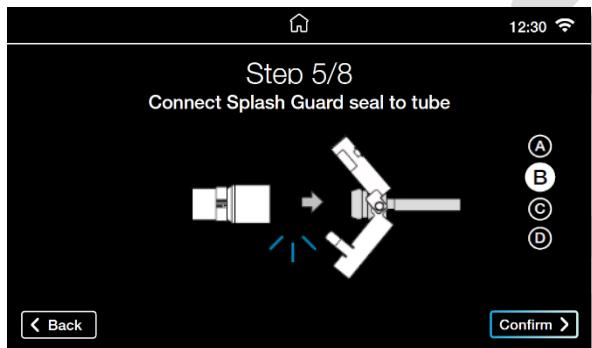
1. Clip the Splash Guard Tube to the Splash Guard as shown in the animation ([Figure 60](#)).

Figure 60: Connect Splash Guard Tube Animation



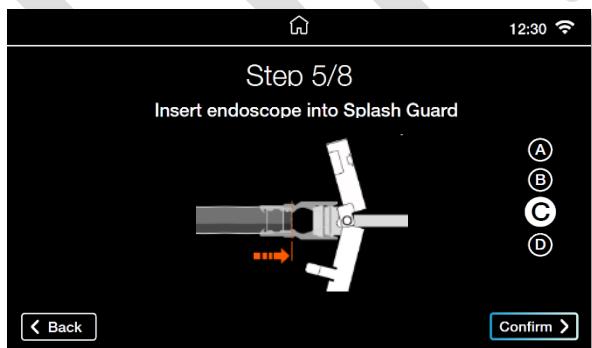
2. Connect the Splash Guard Seal to the Splash Guard Tube. Follow the animation shown in [Figure 61](#).

Figure 61: Connect Splash Guard Seal Animation

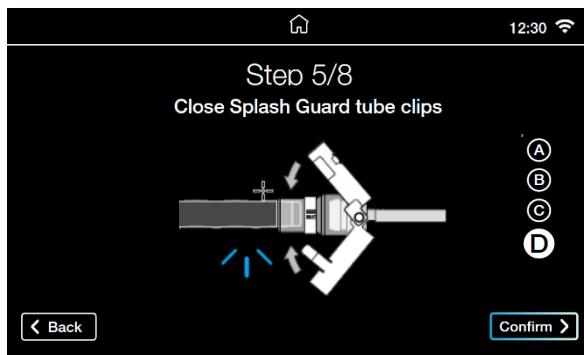


3. Insert the endoscope distal end into the Splash Guard Seal up to the mark as shown in the animation ([Figure 62](#)).

Figure 62: Insert Endoscope Distal End Animation



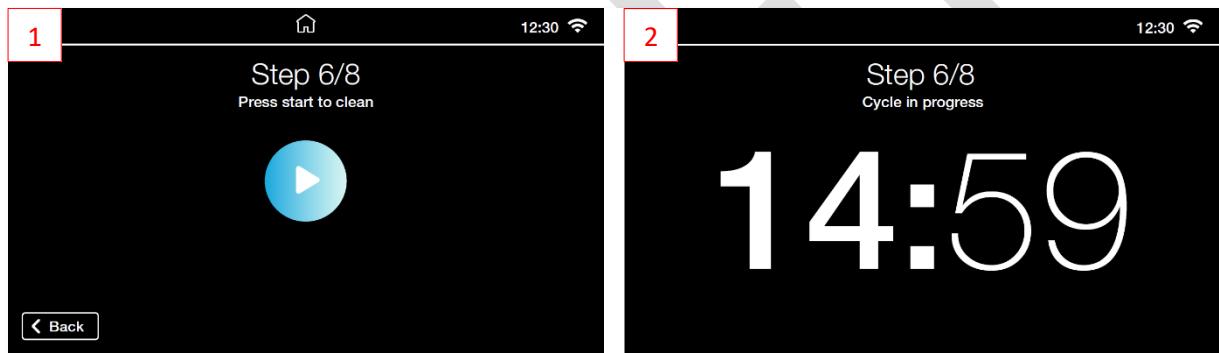
4. Finally, snap the Splash Guard Tube Clip shut to firmly engage the Splash Guard Seal to the endoscope distal end, as shown in the animation ([Figure 63](#)).

Figure 63: Close Splash Guard Tube Clip Animation

You have now prepared the endoscope and the CORIS, and are ready to launch the cleaning cycle. Tap **Confirm** to proceed to the next step.

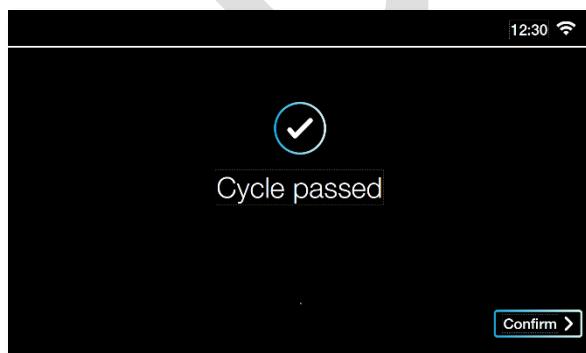
7. The CORIS is now displaying [Figure 64-1](#). Tap the Start Cycle button  to launch the cleaning cycle.

NOTE: This screen is the last point at which you can exit this procedure by tapping the Home icon . See Section [8.2.2.1 Aborting the Cleaning Cycle](#) on page [56](#) for more details.

Figure 64: CORIS Cleaning Cycle Ready to Start (left) and Under Way (right)

Once the cleaning cycle is underway a countdown timer is displayed (see [Figure 64-2](#)). The CORIS will inform you with an audio prompt when your presence is required.

8. When the cleaning cycle has finished a message to that effect is displayed and an audio prompt will sound every minute until you press **Confirm**.

Figure 65: Cleaning Cycle Passed

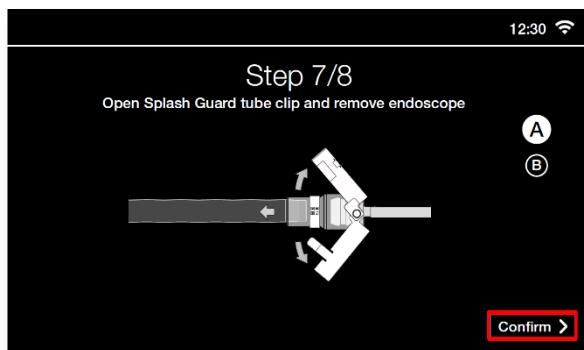
NOTE: Any errors that occur during the cleaning cycle will cause the CORIS to display an error message. For information on how to deal with these errors see Section [11.1.1](#).

9. Disconnect the endoscope from the Splash Guard.

To do so:

1. Open the Splash Guard clip and disconnect the endoscope distal end as shown in the animation ([Figure 66](#)).

Figure 66: Remove Endoscope Animation



2. Remove Splash Guard Seal from the Splash Guard Tube as shown in the animation ([Figure 67](#)).

Figure 67: Remove Seal from Splash Guard Tube Animation



Tap **Confirm** to continue.



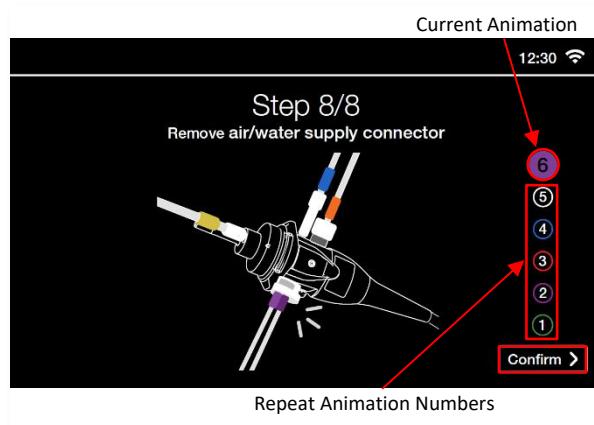
The seal is single-use and should be disposed of immediately after use. Follow your Facility procedures for disposal.

10. Remove all the Adaptor connectors from the endoscope as shown in the animations:

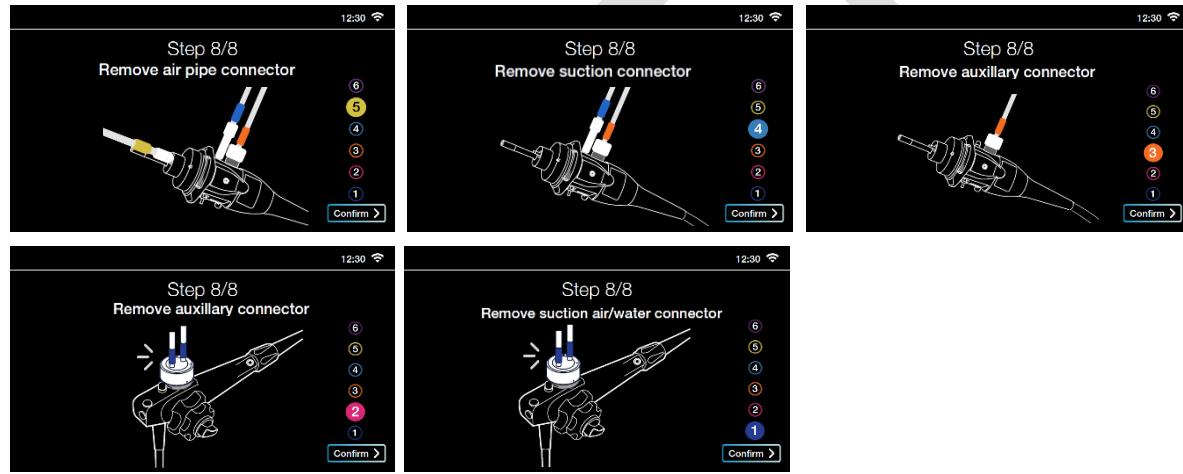
- ⑥ air/water supply connector
- ⑤ air pipe connector
- ④ suction connector
- ③ auxiliary connector
- ② biopsy connector
- ① suction air/water connector

A different animation will be displayed for each connector, continuing to the next when finished.

The current animation will be highlighted on the screen. Tap a Repeat Animation number at any time to view that animation again (see [Figure 68](#)).

Figure 68: Remove all Adaptor Connectors from the Endoscope

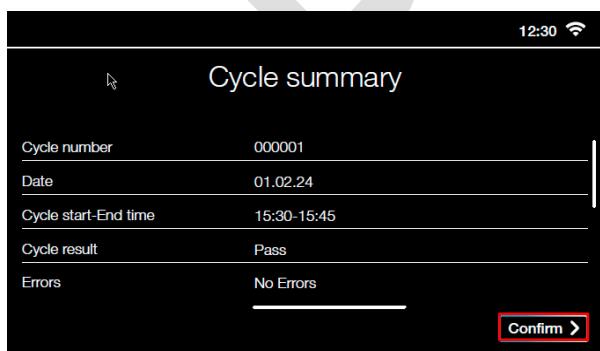
Initial screens of animations ⑤ to ① are shown in [Figure 69](#).

Figure 69: Individual Detachment Animations 5 to 1

Tap **Confirm** at any time to continue to the next step.

NOTE: The CORIS Adaptor can remain attached to the CORIS device for the next cleaning cycle.

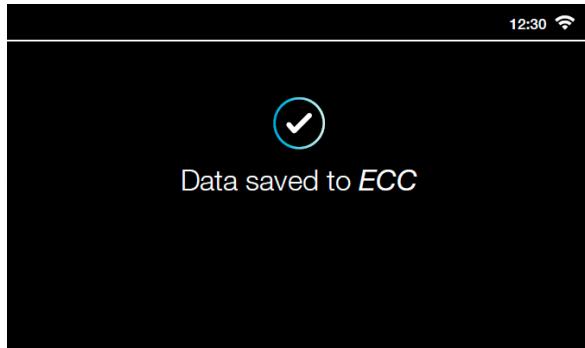
11. You will now be presented with a screen containing a summary of cleaning cycle parameters. You can scroll up or down, left and right to view all parameters.

Figure 70: Cleaning Cycle Parameters Summary Screen

Tap **Confirm** on the screen to continue.

12. An audio prompt and a final screen will confirm that all data has been saved to the CORIS. You have completed the cleaning cycle.

Figure 71: Data Saved



This screen will be replaced with the [Home](#) screen after a few seconds.



Continue reprocessing as recommended by the endoscope manufacturer.

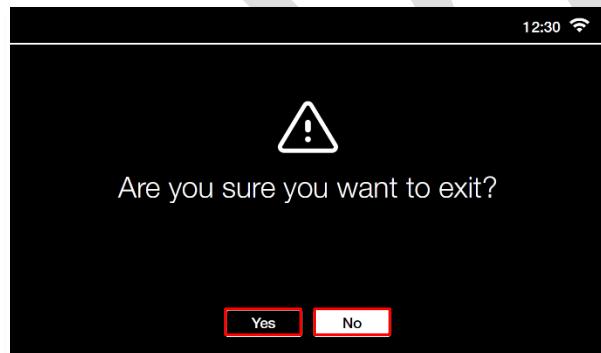
8.2.2.1 *Aborting the Cleaning Cycle*



When you abort a cleaning cycle the attached endoscope channels are considered untreated. You must perform a new cleaning cycle on that endoscope.

You can abort the cleaning cycle at any time by tapping the Home icon  when it appears at the top of any screen. A confirmation screen will be displayed when you do so, as shown below.

Figure 72: Abort Confirmation Screen



Tap **NO** to go back to the previous screen. Tap **Yes** to exit the current cleaning cycle. The Home screen will be displayed (see [Figure 19](#)).

NOTE: Aborting a cleaning cycle will cause the CORIS to perform a purge cycle before it is ready to clean another endoscope.

8.3 CORIS Reprocessing

TBA

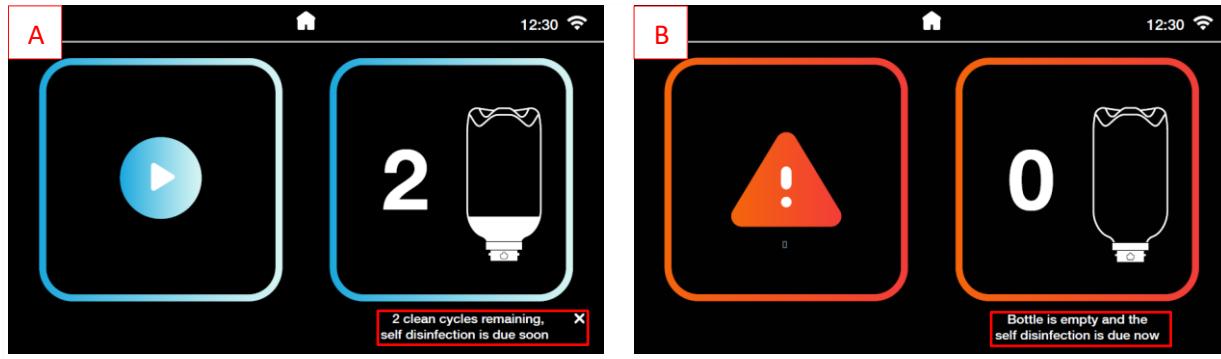
8.4 CORIS Self-Disinfection Cycle

Regular disinfection of the internal components of the CORIS is required. This is achieved by performing CORIS self-disinfection (SD) cycles.

The CORIS will indicate when a SD cycle is due:

- By displaying a warning on the Home screen a few cleaning cycles before the SD cycle becomes mandatory (see [Figure 73-A](#))
- By changing the status of the Home screen when the SD cycle must be performed (see [Figure 73-B](#)).

Figure 73: Self-Disinfection Cycle Warnings



Once the Home screen looks like [Figure 73-B](#) you will not be able to continue to use the CORIS until a SD cycle is performed.

To perform a SD cycle you will need to have access to:

- A bottle of approved disinfectant with **at least 600ml of disinfectant**. See Section [5.7.5 Disinfectant Bottle for SD Cycle](#) on page [25](#) for more information
- SD Spout (provided by Nanosonics). See Section [5.7.6 SD Spout](#) on page [26](#) for further information.
- The CORIS Self-Disinfection Adaptor (supplied with the CORIS). See Section [5.3 CORIS Self-Disinfection Adaptor](#) on page [19](#) for more information
- The CORIS Self-Disinfection plug (supplied with the CORIS). See Section [0](#)

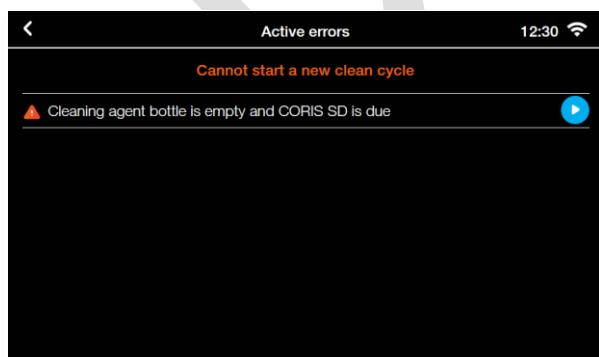
C The CORIS Self-Disinfection Adaptor is 24-hour use only. Discard after 24 hours. See Section [9](#) on page [62](#). Dispose of responsibly. Please follow your Facility guidelines.

- CORIS Self-Disinfection Plug on page [20](#) for more information.

To proceed with a SD cycle:

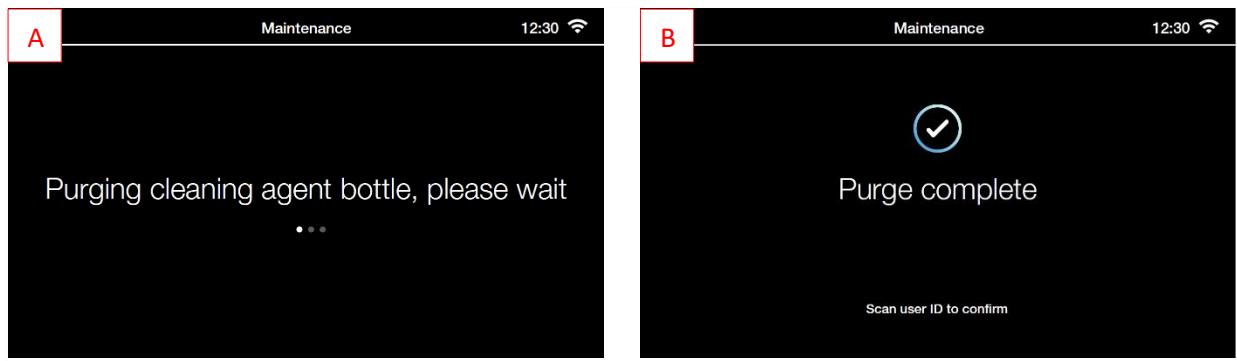
1. Tap anywhere on the Home screen ([Figure 73-B](#)) to bring up the error screen (shown in [Figure 74](#)).

Figure 74: Error Screen Indicating SD Cycle is Due



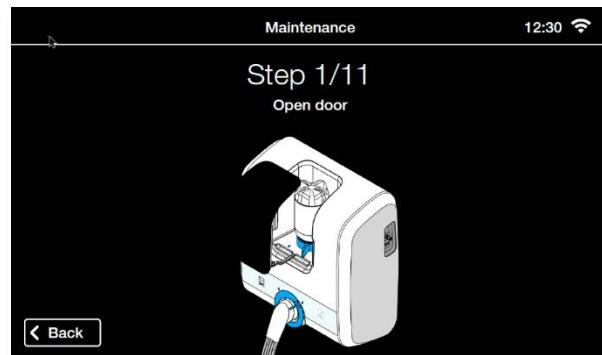
2. Tap the blue arrow  at the end of the error message (in [Figure 74](#)) to launch a purge of the cleaning agent bottle. The start and end of the purge cycle will be indicated on the CORIS display as shown in [Figure 75-A](#) and [Figure 75-B](#). A confirmation audio sound will play when the purge is complete.

Figure 75: Cleaning agent Bottle Purge Cycle Start and End



3. When the purge is complete scan your Operator card to acknowledge.
4. Open the CORIS door as shown in the animation ([Figure 76](#)).

Figure 76: Open CORIS Door Animation



5. Unlock the cleaning agent bottle and remove it as shown in the animation ([Figure 77](#)).

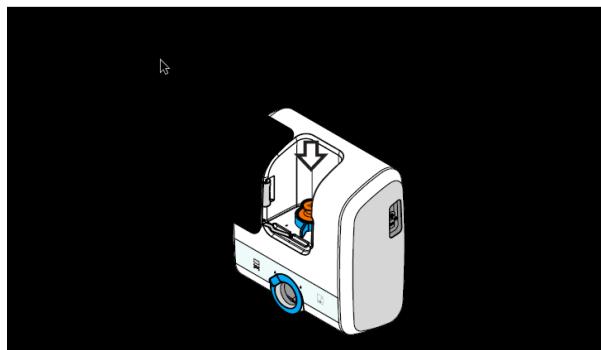
Figure 77: Unlocking and Removing Cleaning Agent Bottle



6. Insert the Self-Disinfection plug, lock it and close the door, as shown in the animation ([Figure 78](#)).

NOTE: If the door is not locked properly the CORIS will display an error. See Section [11](#) on page [67](#).

Figure 78: Insert CORIS Self-Disinfection Plug



7. If the Self-Disinfection plug is recognized (see [Figure 79-A](#)) a confirmation audio sound will play. Continue with the next step.

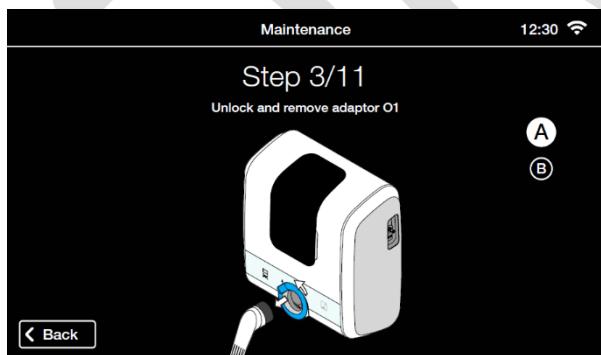
If an error has occurred (see [Figure 79-B](#)), the animation requesting you to insert a Self-Disinfection plug will be re-displayed (see [Figure 78](#)).

Figure 79: Self-Disinfection Plug Recognized (A) and Not Recognized (B)



8. If Adaptor 01 is still connected to the CORIS unlock and remove it as shown in the animation ([Figure 80](#)).

Figure 80: Unlock and Remove Adaptor 01 (if connected)

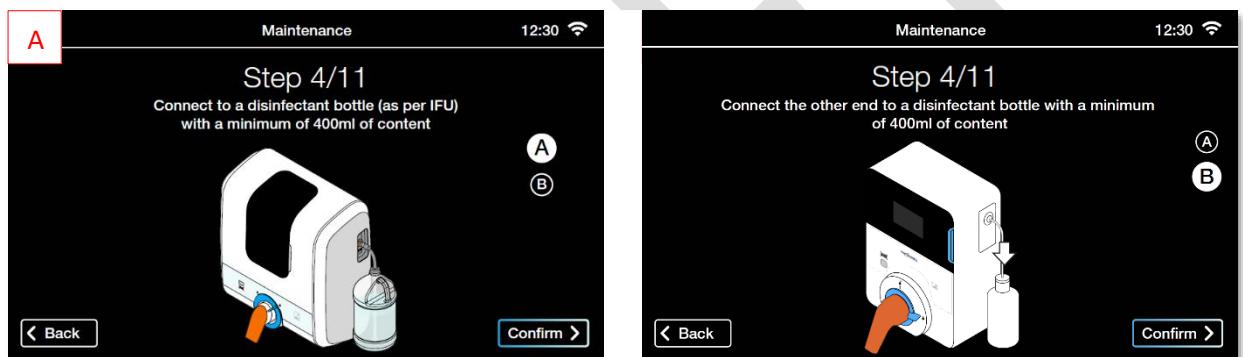


9. Insert and lock Self-Disinfection Adaptor as shown in the animation ([Figure 81-A](#)). Correct insertion is denoted by a confirmation audio sound and message (see [Figure 81-B](#)).

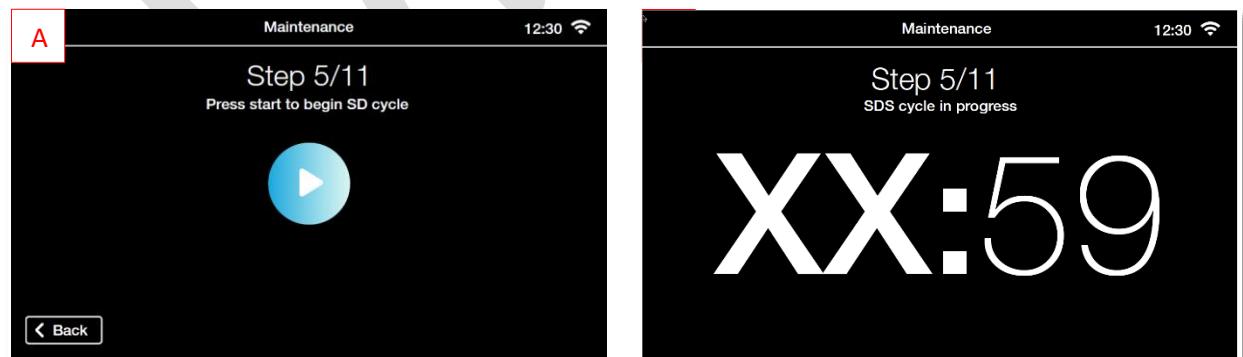
Figure 81: Insert and Lock Self-Disinfection Adaptor

10. Connect the disinfectant bottle to the CORIS. To do so:

1. Connect the disinfectant tube into the CORIS as shown in the animation ([Figure 82-A](#)) and tap **Confirm >**
2. Connect the other end of the tube to the provided disinfectant bottle as shown in the animation ([Figure 82-B](#)) and tap **Confirm >**.

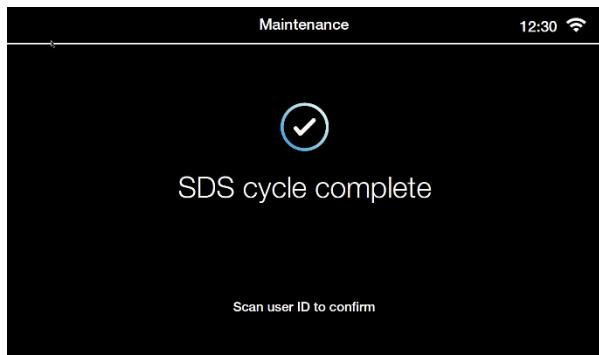
Figure 82: Connecting the Disinfectant Bottle to the CORIS

11. You are now ready to perform a Self-Disinfection cycle on the CORIS. Press Start  ([Figure 83-A](#)) to commence SD cycle. After launch, a countdown timer commences (see [Figure 83-B](#)).

Figure 83: Ready to Launch SD Cycle (A) and Launched (B).

12. When the disinfection cycle has finished you will be notified on the display (see [Figure 84](#)) and by an audio prompt repeating every minute. To stop the sound and continue scan your Operator card.

NOTE: Any errors occurring during the SD cycle will be reported on the screen. See Section [11 Error Messages](#) on page [67](#) for further instructions.

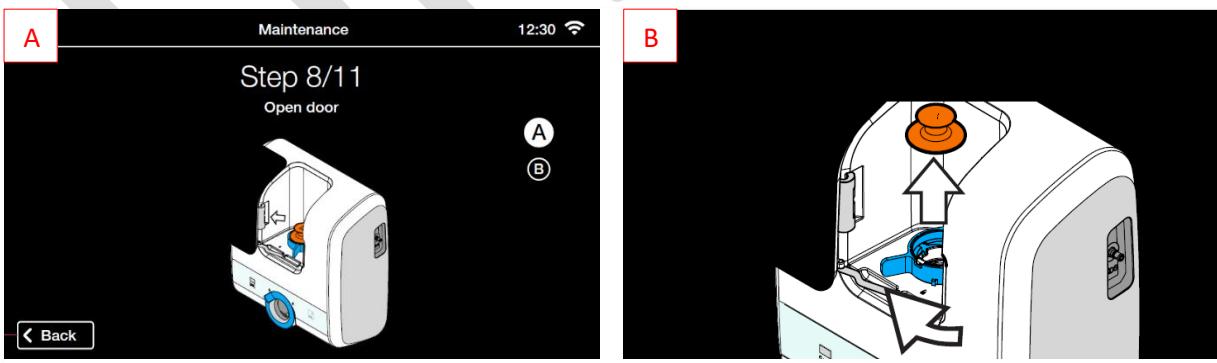
Figure 84: SD Cycle Finished

13. Remove disinfectant tubes and Self-Disinfection Adaptor from CORIS. To do so:

1. Remove disinfectant tube from the CORIS ([Figure 85-A](#))
2. Unlock and remove Self-Disinfection Adaptor from CORIS ([Figure 85-B](#)).

Figure 85: Remove Disinfection Tube and SD Cycle Connector from CORIS

14. Open CORIS door and unlock and remove CORIS Self-Disinfection plug. See animations [Figure 86-A](#) and [Figure 86-B](#).

Figure 86: Open CORIS door (A), Unlock and remove SD Cycle Bypass Plug (B)

You have completed the CORIS self-disinfection cycle.

To get the CORIS ready for a cleaning cycle you now need to insert a new cleaning agent bottle. To do so follow the instructions given in Section [10.1 Replacing the Cleaning Agent Bottle](#) on page [63](#), starting from Step [2](#). As there is no empty cleaning agent bottle in the CORIS, you can ignore Step [3-2](#).

8.5 Splash Guard Reprocessing

TBA

9 End of Day Procedure

At the end of each day:

- Discard the Adaptor (see Section [.0](#) on page [18](#))
- Discard the Splash Guard Tube (see Section [5.7.2](#) on page [24](#))
- Discard the Self-Disinfection Adaptor (see Section [5.3](#) on page [19](#))
- Discard the Self-Disinfection Plug (see Section [0](#) on page [20](#))
- Discard the SD Spout (see Section [5.7.6](#) on page [26](#))
- Wipe all the external surfaces of the device and Splash Guard with trophon Companion Cleaning Wipes (from Nanosonics).

NOTE: The CORIS should be left powered up at all times. DO NOT power down the device.

DRAFT

10 CORIS Maintenance

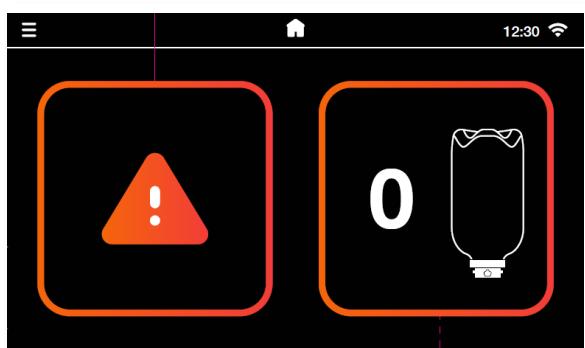
10.1 Replacing the Cleaning Agent Bottle

The Cleaning Agent Bottle. Is described in detail in Section [5.7.1](#) on page [21](#).

It is housed in a covered compartment on top of the CORIS, behind a locked door.

When the Home screen looks similar to [Figure 87](#) your Cleaning Agent Bottle needs replacing.

Figure 87: Home Screen Warning (Cleaning Agent Bottle Empty)



To replace an empty Cleaning Agent Bottle:

1. Tap the consumable level button  on the Home screen to bring up the animation ([Figure 88](#)). Tapping the error  button will display an Active Errors screen. See Section [11](#) on page [67](#) for a list of all errors.
2. Scan the Cleaning Agent Bottle QR code as shown in the animation.

Figure 88: Scanning Cleaning Agent Bottle QR Code Animation



For a list of possible errors see Section [11](#) on page [67](#).

3. When the QR code is accepted you will be asked to replace the CORIS Cleaning Agent Bottle.

The five steps required to replace the cleaning agent bottle have been animated and labelled A to E. These animations will run sequentially. To view any animation again tap on the labelled button.

1. Open the CORIS door.

Figure 89: Animation A – Open Door Animation

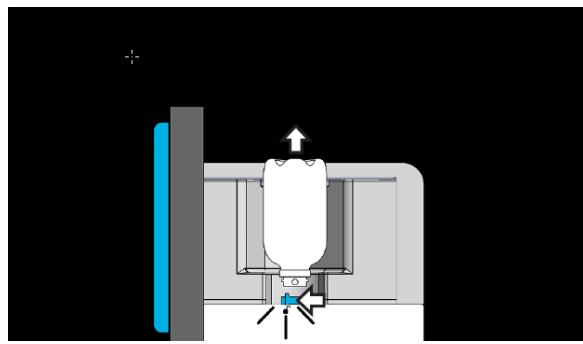


2. Unlock and remove empty Cleaning Agent Bottle.



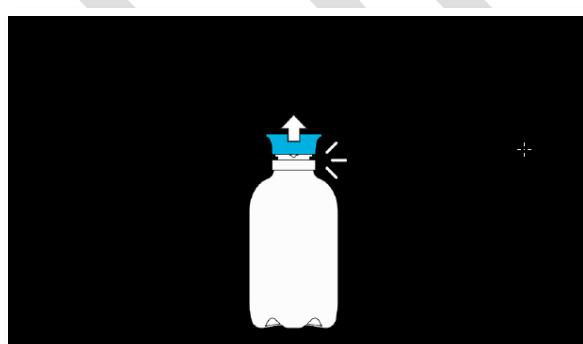
Dispose of the empty cleaning agent bottle responsibly. Please follow your Facility guidelines.

Figure 90: Animation B – Remove Bottle Animation.



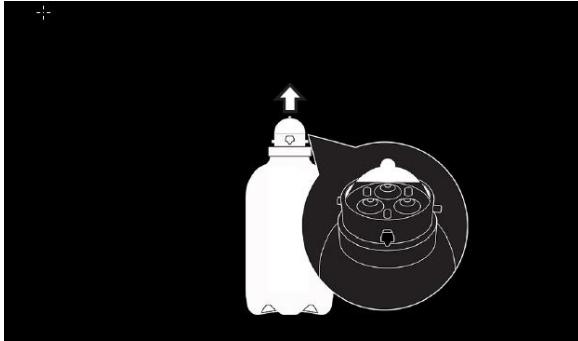
3. Remove travel cap from Cleaning Agent Bottle.

Figure 91: Animation C – Remove Cap Animation



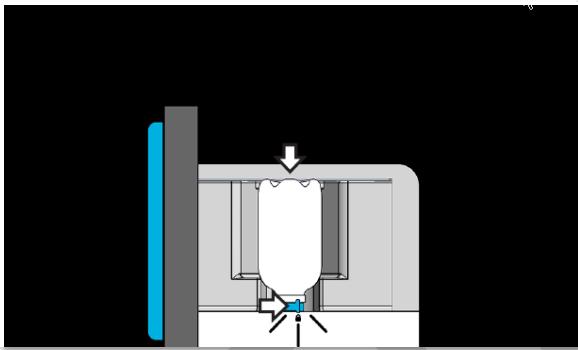
4. Remove foil from cleaning agent bottle

Figure 92: Animation D – Remove Foil Animation



5. Correctly orientate the CORIS QUANTUM bottle into the CORIS device bottle interface to insert and lock new the bottle.

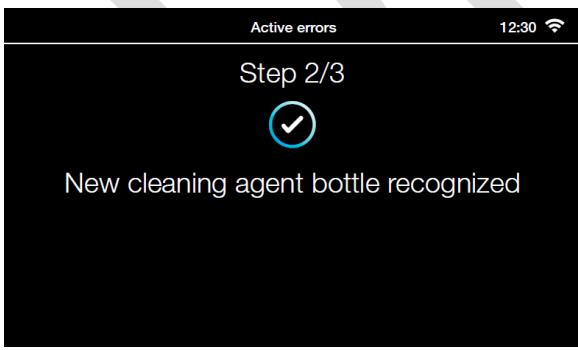
Figure 93: Animation E – Insert new Bottle Animation



4. IF the CORIS Cleaning Agent Bottle has been inserted and latched correctly, an audio prompt and a confirmation screen will indicate it has been inserted correctly (see [Figure 94](#)).

Should this screen not appear, remove the cleaning agent bottle and re-insert it, then lock it securely (see [step 5 above](#)).

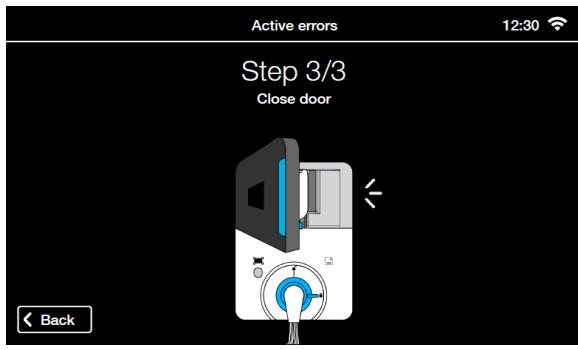
Figure 94: New CORIS Cleaning Agent Bottle Recognized



5. Close the CORIS door.

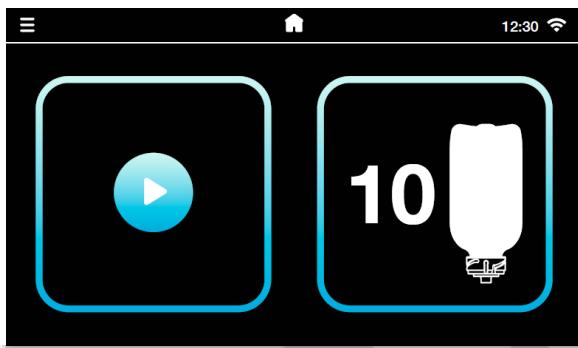
NOTE: If the door is not locked properly the CORIS will display an error. See Section [11](#) on page [67](#)).

Figure 95: Close the CORIS Door Animation



After the CORIS door has been closed the CORIS will prepare the cleaning agent for use and The Home screen will then change to that shown in [Figure 96](#).

Figure 96: Home Screen, Showing Cleaning Agent Bottle is Full.



You are now ready to proceed with a cleaning cycle.

10.2 Software Updates

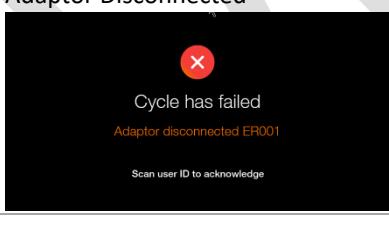
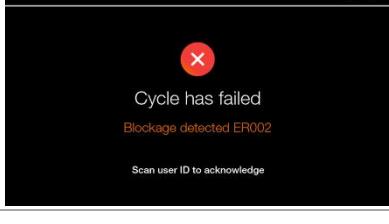
TBA

11 Error Messages

Following is a list of error messages you may encounter in the day-to-day operation of your Nanosonics CORIS software. For each, an explanation of the message is given, along with suggested remediation actions.

All Active Errors detected by the CORIS will be highlighted on the Home screen, and the Cycle Start Button (see [Figure 19](#) on page [29](#)) will be replaced with a Warning or Error button, as shown in [Figure 19](#) and [Figure 20](#).

Table 3: Table of Errors

Code	Description	Action Required
Endoscope Management		
	User does not have access 	You have scanned an Operator card, not an Admin Card. Only Admins can access the procedure. Scan an Admin card to continue
	Endoscope already registered 	The endoscope you are trying to register already exists in the CORIS database. Register another endoscope or terminate this task.
Cleaning Cycle		
ER0001	Adaptor Disconnected 	Operator interaction required, see Section 11.1.1 below
ER0002	Blockage Detected 	Operator interaction required, see Section 11.1.1 below

Code	Description	Action Required
SD Cycle		
	QR Code not recognized  QR code is not recognized Scan a Nanosonics SDS plug	
ER004	SD Cycle has failed  SDS cycle has failed Disinfectant error [ER004] Scan user ID to acknowledge	Operator interaction required. See Section ??? below
	Door open	The CORIS door need to be closed and locked before continuing.
Replace Cleaning Agent Bottle		
	Cleaning Agent Bottle is empty	
	QR Code not recognized	
	Cleaning Agent Bottle has expired	
	Cleaning Agent Bottle has been used	
	Door open	The CORIS door need to be closed and locked before continuing.

Table 4: Table of Warnings

Code	Description	Action Required

11.1 Errors Requiring Operator Interaction

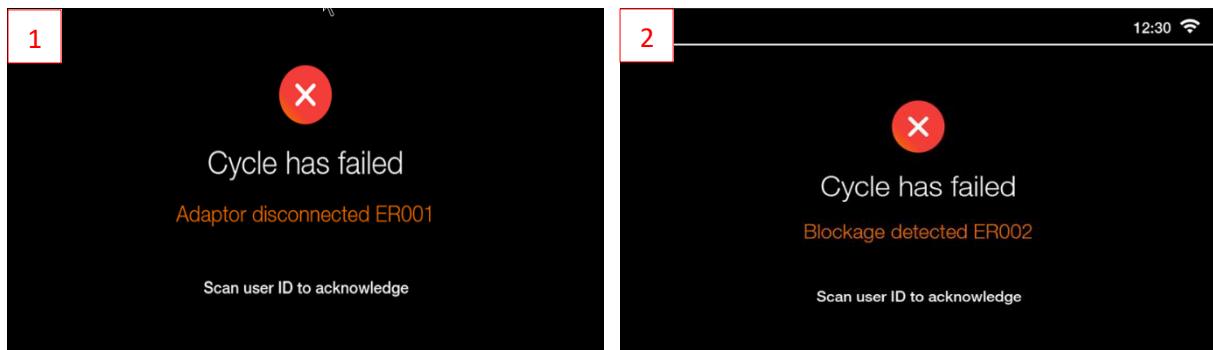
Although the CORIS can recover autonomously from most errors, some will require operator interaction.

This section lists all the errors that require such interaction and describes the steps required to be performed by operators.

11.1.1 Cleaning Cycle Failures

If an error occurs which causes the current cleaning cycle to abort, a cleaning cycle failure is logged and the error code and reason for the failure is shown on the CORIS screen.

Examples of errors which fall into this category are listed in [Table 3](#).

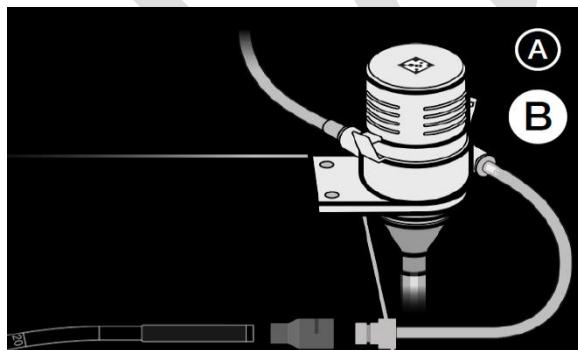
Figure 97: Some Cleaning Cycle Failures

Typical errors are:

- Adaptor Disconnected (*Figure 97-1*)
- Blockage Detected (*Figure 97-2*)

To restore the CORIS to an operable condition:

1. Scan your User ID card to acknowledge the error. The CORIS will sound an alarm at regular intervals until you do so.
2. Follow the animation to remove the seal from the Splash Guard and the distal end from the seal.

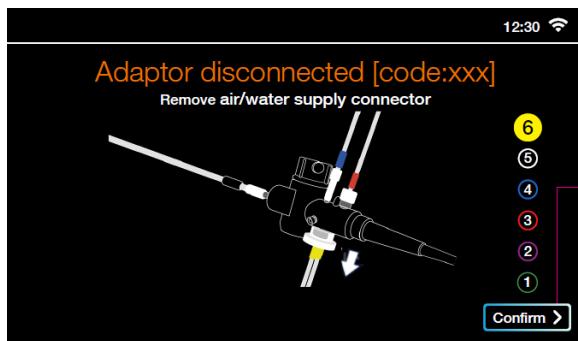
Figure 98: Remove Seal from Cone Tube Adaptor (Animation)**Figure 99: Remove Distal End from Seal (Animation)**

Tap **Confirm** to continue.



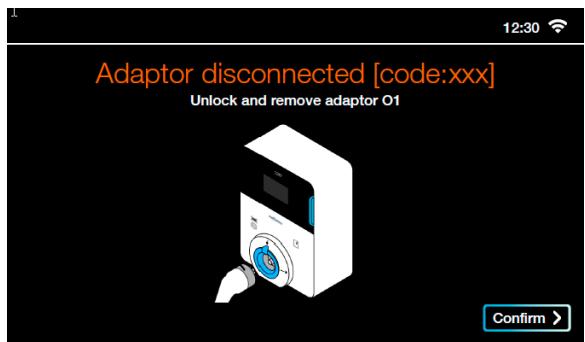
The seal is single-use and should be disposed of immediately after use. Consult with your local environmental and government agencies to confirm how the seal should be disposed.

3. Remove all the connectors from the endoscope.

Figure 100: Remove All Endoscope Connectors (Animation)

Tap **Confirm** to continue.

4. Unlock and remove the endoscope adaptor.

Figure 101: Unlock and Remove Adaptor

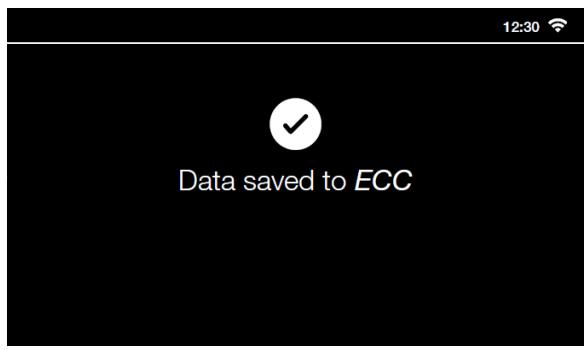
Tap **Confirm** to continue.

5. A cleaning cycle failure screen will be displayed.

Figure 102: Cleaning Cycle Summary

Tap **Confirm** to continue.

6. An audio prompt will sound, and a screen will be briefly displayed informing you the failure has been registered locally ([Figure 103](#)).

Figure 103: Data Saved Screens

The Home screen will then be displayed. The CORIS is now ready for a new cleaning cycle.

12 Security

TBA

12.1 Hardware

TBA

12.2 Software

TBA

DRAFT

13 Device Replacement

TBA

TBA

DRAFT

14 Help and Support

If you have any questions or require additional information on how to use the device, contact your customer service team or access the websites below:

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DRAFT

15 Technical Specifications

Coris Electrical Specification	<p>Rated mains input to the power supply unit (PSU): 100–240 V AC ~ 4 Amp, 50–60 Hz. Input connector: IEC type C14. PSU Output: 24 V = 10.42 A.</p> <p>DC Power Input Rated voltage: 24V. Rated Frequency: DC. Rated Input Current: 10.42 A.</p> <p>Class II (Double Insulated).</p> <p>PSU to Coris cord length (low voltage): 2 m. Equipment must be connected to an earthed outlet using the power adaptor supplied with the Coris. No other adaptor must be used.</p>
Operating System	<p>Wittenstein's SafeRTOS</p>
Environmental Specification	<p>Indoor use only. The Coris and the supplied PSU must not be placed in a wet area. Please refer to local regulatory standards for the minimum distance between the PSU and the wet area for compliance.</p>
Physical Characteristics	<p>Unpacked Weight of Coris: Dry: 45kg (99.2 lbs). Wet (with cleaning agent and wall mount): 52kg (114.6 lbs). Dimensions of Coris: 684 mm high × 550 mm wide × 293 mm depth. (26.92" high × 21.65" wide × 11.54" depth).</p> <p>Packed Weight: 65 kg (143.3 lbs). Dimensions: 849 mm high × 721 mm wide × 448 mm depth. (33.43" high × 28.40" wide × 17.65" depth).</p>

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