CORIS® System Training Guide

This document serves as a training guide to support training users of the CORIS System with the CORIS System Training Checklist. This training guide does not replace the User Manual provided with the CORIS System. All users must read the User Manual.

Instructions

Important messages are indicated in **bold orange text**. Additional instructions in relevant sections of the User Manual are indicated with **bold blue text**. Training should be conducted interactively with trainees with an installed CORIS System as much as possible so that participants can learn hands-on. Following training, trainees should demonstrate competence following the CORIS System Training Checklist.

	Introduction
	This training will introduce you to the CORIS System, its use and operation. Review the relevant sections of the User Manual as we progress through each section. Following this training we will conduct a Competency Assessment so you can demonstrate that you can use the CORIS System safely and effectively.
	Training Guide
1	**Training** **The CORIS System is intended to be operated by properly trained users only. All users of the CORIS System should be trained in its use, safety procedures and potential hazards as outlined in the User Manual.** **Refer to the User Manual and Quick Reference Guide during training and when using the CORIS System.**
2	**CORIS System** • The CORIS System replaces the manual cleaning of endoscope channels with an automated cleaning cycle. **Cleaning of the external surfaces of the endoscope is still required, as well as standard precleaning and leak testing according to device IFUs and your facility procedures.** **After cleaning the endoscope internal channels with CORIS, high level disinfection is still required according to device IFUs and your facility procedure.** **Review sections 1.1 and 1.2 of the CORIS User Manual.**
3	**Endoscope Compatibility** **Only compatible endoscopes can be used with CORIS. Refer to the CORIS Compatible Endoscope List on the regional Nanosonics website.**
4	**CORIS System parts and accessories** The CORIS System includes the following parts and components: • CORIS Device, including the door, touch screen display, barcode reader, RFID reader, adaptor port, side door, power socket, network connections, power switch, Self-Disinfection Input Tube port, air, water and drain ports. • CORIS QUANTUM Cleaning Agent, including the cap and foil. • CORIS Adaptor: Model O1, including the port and connectors: (1) Dark Blue: suction air/water, (2) Pink: biopsy, (3) Green: auxiliary, (4) Yellow: suction. • CORIS Smart Drain. • CORIS Smart Drain Adaptor: Model OA, including the connectors: (5) Light Blue: air pipe, (6) Orange: air/water supply, the Smart Seal connector, and Smart Drain lock. • CORIS Smart Seal: Model type and QR code. This accessory must be discarded after 24 hours. • CORIS Maintenance Kit, including the Adaptor Plug, Bottle Plug, and Self-Disinfection Input Tube. • CORIS Adaptor Reprocessing Hub. • CORIS Flushing Accessory, including the CORIS Adaptor plate, Smart Drain plate, syringe, inlet tube, dial and channel indicators. • Optional: CORIS Printer, CORIS Operator ID **Inspect all components and accessories for damage before use. Do not use damaged components or accessories.**

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5	**CORIS Validated High-Level Disinfectant**
	Review section 4 of the User Manual, as well as the Revital-Ox® RESERT® High Level Disinfectant instructions.
	Only Revital-Ox® RESERT® High Level Disinfectant (Steris®) is validated for use with CORIS.
	• Ensure that you use a bottle with at least 1,000mL of HLD before starting a Self-Disinfection Cycle.
	• Automated reprocessing of adaptors:
	  ○ Ensure that you use a bottle with at least 1,000mL of HLD before starting an Adaptor Reprocessing Cycle.
	• Manual reprocessing of adaptors:
	  ○ Ensure that you have enough HLD to fully submerge all connectors during disinfection of the CORIS accessories.
	• Follow all Revital-Ox® RESERT® High-Level Disinfectant instructions provided by the manufacturer. For example, the temperature of the disinfectant must be 20°C or higher, the disinfectant must be used undiluted, the contact time is 8 minutes, and the solution concentration must be verified with a test strip.
	Read the Revital-Ox® RESERT® High Level Disinfectant (Steris®) directions for use.

6	**Wearing PPE** **Always wear appropriate PPE (Personal Protective Equipment), including gowns, gloves, protective face wear and mask, during endoscope reprocessing.** **Refer to your facility's documentation on PPE requirements.**
7	**Administration – User Management** • Users can be registered with CORIS as an operator or an administrator. Administrators are required for some functions like adding new users. • To register a user, go to Menu, User Management, and select the plus symbol to add a new user. Scan the ID in via RFID. Select either Operator or Administrator. • To remove obsolete user IDs, archive them. **Administration – Endoscope Management** • Endoscopes must be registered with the CORIS Device. If your endoscope has an RFID, it will automatically register when you scan it, or you can manually register it in Endoscope Management. • If you use your own Internal ID barcode for the endoscope, it must be manually added to CORIS. • To register a new endoscope, go to Menu, Endoscope Management, and select add a new endoscope. • Scan the endoscope's Internal ID barcode or the endoscope RFID. If you scan a barcode, you must select the model type associated with that Internal ID barcode. • To remove obsolete endoscopes, archive them. **You must select the correct endoscope model. Failure to do so may lead to ineffective cleaning and damage to the CORIS System and endoscope.**
8	**QUANTUM Cleaning Agent Replacement** **Review section 3.2.2 of the User Manual.** • On the home screen, CORIS will show you how many cycles are left on the current QUANTUM Cleaning Agent. When there is no QUANTUM remaining, CORIS will prompt you to load a new bottle, and you will not be able to run a cleaning cycle until a new bottle is loaded. • To change a QUANTUM bottle at any time, go to Menu, Maintenance, and select "Change QUANTUM Cleaning Agent". The existing bottle will be emptied before it can be removed. This may take a few minutes to complete. • All steps are shown on the touchscreen. Open the door, unlock and remove the empty bottle. • Wipe the surfaces of the exposed bottle port, including the 3 round features, using a wetted wipe. • Note that now the door is open, this is the best time to clean and wipe the surfaces behind the door. This is covered in the Maintenance section. • Retrieve a new bottle of QUANTUM Cleaning Agent and scan the large QR code on the bottle by holding it a bottle's width away from the scanner.

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	• Remove the cap and foil from the QUANTUM bottle and place the bottle into the CORIS Device with the alignment key facing towards you. • Rotate the bottle lock ring and close the door. • The new bottle will be hydrated automatically before it can be used. • Each bottle contains enough QUANTUM for 10 cleaning cycles.
9	**Running a Cleaning Cycle** **Review section 3 for instructions on completing a cleaning cycle.** • All steps are shown on the touchscreen. You will not be able to run a Cleaning Cycle if there is no QUANTUM Cleaning Agent remaining, or if a Self-Disinfection Cycle is overdue. • Your endoscope must have gone through all standard reprocessing steps up to the point that it is ready for internal channel cleaning. For example, you must have completed pre-cleaning and leak testing before using CORIS. Refer to your facilities procedure for endoscope reprocessing. • Press the start button on the home screen and scan your operator ID. • Scan the endoscope RFID, or if you have registered the internal endoscope ID barcode, scan your internal ID barcode. • Retrieve the CORIS Adaptor shown on screen and inspect it for damage. • Insert the CORIS Adaptor into the adaptor port and rotate the lock. CORIS will detect if a valid Adaptor has been inserted and locked. • The screen will show each connection of the CORIS Adaptor to the endoscope. Note the colours and numbers. • You can repeat an animation by selecting the number on the screen. They otherwise play through automatically. • ① Suction Air/Water: Align the connector pins so the shorter pin is in the suction channel, and the longer pin is in the air/water channel. At the same time, push down firmly and twist the connector body clockwise to engage the lock of the connector to the suction and air/water channels. The alignment dots should be rotated from the unlocked to the locked position. The connector must be flush against both channels. Gently pull the connector to ensure that it's properly attached. • ② Biopsy: Push the connector down until it clicks. Note: the two outer clips remove the connector. Do not press clips while attaching. • ③ Auxiliary: Align the thread and twist the connector body clockwise to lock the thread into place. • ④ Suction: Push the connector fully down. • Retrieve the Smart Drain Adaptor shown on screen and inspect it for damage. • Insert the Smart Drain Adaptor into the Smart Drain port and rotate it clockwise to lock. Note the Smart Drain Adaptor lock. • ⑤ Air Pipe: Align the connector with the air pipe and push down. Rotate the clip on to the light guide arm. • ⑥ Air/Water Supply: Align the pins of the connector with the endoscope air/water channels and push down until it clicks. • Retrieve the required Smart Seal and inspect it for damage. CORIS will detect if a valid QR Code has been scanned. • Wet the seal before use. Submerge the seal in water or run under a tap to ensure it is wet. • Attach the Smart Seal to Smart Drain Adaptor, push it on and rotate to lock noting the alignment markers. • Carefully insert the endoscope distal end fully into Smart Seal. • Check all connections are correct and secure before confirming. • Press the start button to begin the cleaning cycle. The cycle takes approximately 15 minutes to complete. It may take longer if needed. **Do not disconnect the endoscope or accessories until the cycle has completed.** • At the end of the cycle CORIS will display the cycle result. **If the cycle fails for any reason, or the screen does not display Pass, the endoscope is not clean and must be cleaned again. Refer to the User Manual for information on specific errors.** • Remove the endoscope from the seal and detach the seal from the Smart Drain. **If the seal has been used for 24 hours, it must be discarded and a new Smart Seal used for the next cleaning cycle.**

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	• Disconnect the endoscope from the connectors. • The Adaptor and Smart Drain Adaptor can be left attached for the next cycle. • The cycle summary is shown to review. • If you have a CORIS Printer installed, the cycle result will print out for your records. • After a cycle pass, continue reprocessing the endoscope according to the endoscope manufacturer's IFU and your facility procedure.
10	**Cleaning Cycle Fail Errors** **Review section 5 of the User Manual for details of cycle errors messages.** **A failed Cleaning Cycle means the endoscope has not been cleaned and must be recleaned.** • If for any reason the Cleaning Cycle fails, the screen will inform you of a failed cycle. • Refer to the error code displayed and consult the User Manual for instructions. You may need to refer to the endoscope manufacturer's instructions and your facility procedures for certain errors.

11	**Maintenance of the CORIS System**
	Review section 4 of the User Manual.
	• Regular maintenance of the CORIS Device and accessories must be performed to enable safe and proper use of the CORIS System.
	Review the Maintenance Schedule in section 4.1.1 of the User Manual.
	Review the compatible chemicals in section 4.2.1 of the User Manual.
	Only use compatible cleaning and disinfectant products.
	• Use of cleaning and disinfectant wipes must be done according to the wipe manufacturer's instructions for use. Thoroughly clean all surfaces as directed. Ensure all surfaces are visually clean after the cleaning process. Ensure the surface remains wetted for the full contact time for disinfection according to the wipe manufacturer's IFU.
	• Wear PPE, such as gloves, while using cleaning and disinfectant products.
	• At least once per day when in use, thoroughly clean and disinfect the CORIS Device with a wipe, including all external surfaces, the touchscreen, adaptor lock and Cleaning Agent bottle lock. Note: the best time to access the bottle lock area is during a QUANTUM bottle change or when performing the CORIS Self-Disinfection Cycle.
	• At least once per day when in use, thoroughly clean and disinfect the Smart Drain port and housing with a wipe.
	• At least once per day when in use, thoroughly clean and disinfect the CORIS Adaptor and Smart Drain Adaptor exterior surfaces, including the handles, tubes and connectors.
	• Automated reprocessing of adaptors:
	  ○ Following external cleaning and disinfection of the CORIS Adaptor and Smart Drain Adaptor, disinfect the interior surfaces using the CORIS Adaptor Reprocessing Hub, Self-Disinfection Input Tube and Revital-Ox® RESERT® High-Level Disinfectant.
	  ○ After Adaptor Reprocessing Cycle, clean and disinfect the exterior surfaces of the CORIS Adaptor Reprocessing Hub and the Self-Disinfection Input Tube with a wipe.
	• Manual reprocessing of adaptors:
	  ○ Following external cleaning and disinfection of the CORIS Adaptor and Smart Drain Adaptor, disinfect the interior surfaces using the CORIS Flushing Accessory and Revital-Ox® RESERT® High-Level Disinfectant.
	  ○ After using the CORIS Flushing Accessory, clean and disinfect the exterior surfaces with a wipe.
	• The CORIS Device internals must be disinfected with a Self-Disinfection Cycle at least twice per week, with a maximum of 4 days between each Self-Disinfection Cycle within a week.
	• The Self-Disinfection Cycle uses the CORIS Maintenance Kit and a bottle of Revital-Ox® RESERT® High-Level Disinfectant with at least 1,000mL of disinfectant.
	• After using the Maintenance Kit, clean and disinfect the exterior surfaces of the Adaptor Plug, Bottle Plug and Self-Disinfection Input Tube with a wipe.

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12	**Disinfection of the CORIS Adaptor and Smart Drain Adaptor with the CORIS Adaptor Reprocessing Hub** **Review section 4.4.3 of the User Manual for instructions on using the CORIS Adaptor Reprocessing Hub.** • The CORIS Adaptor and Smart Drain Adaptor must be reprocessed once per day when in use. • The internals of the CORIS Adaptor and Smart Drain must be disinfected by running the Adaptor Reprocessing Cycle. • The Adaptor Reprocessing Cycle circulates Revital Ox® RESERT® High Level Disinfectant through the CORIS Adaptor and Smart Drain Adaptor using the Adaptor Reprocessing Hub and the Self-Disinfection Input Tube. • Ensure the sink is empty and preferably dry for reprocessing. • To begin the Adaptor Reprocessing Cycle, navigate to Menu > Maintenance > Reprocess CORIS Adaptors. • Retrieve the CORIS Adaptor and insert it into the adaptor port and rotate the lock. • Retrieve the Adaptor Reprocessing Hub and place it into the sink. • Follow the on-screen animations and attach each connector to the Adaptor Reprocessing Hub, ensuring the correct connector is matched to the correct port: • ① Suction Air/Water: push down and twist to lock • ② Biopsy: push until it clicks • ③ Auxiliary: align threads and twist clockwise to lock • ④ Suction: push firmly onto the port • Retrieve the Smart Drain Adaptor. Insert it into the Smart Drain port and rotate clockwise to lock. • ⑤ Air Pipe: push onto the air pipe and clip into position • ⑥ Air/Water Supply: align both pins and push down until it clicks • ⑦ Smart Seal connector: aligning the markings, pushing on, and rotate clockwise to lock **Confirm each connector is securely attached.** • Before using Revital-Ox® RESERT® High Level Disinfectant, follow all Revital-Ox® RESERT® High-Level Disinfectant instructions provided by the manufacturer. For example, the temperature of the disinfectant must be 20°C or higher, the disinfectant must be used undiluted, and the solution concentration must be verified with a test strip. • Retrieve a bottle of Revital-Ox® RESERT® High Level Disinfectant with at least 1000 mL remaining. **Only use undiluted Revital-Ox® RESERT® High Level Disinfectant for the Adaptor Reprocessing Cycle.** • Screw the Self-Disinfection Input Tube onto the disinfectant bottle. Keep the disinfectant bottle cap for storage. • Connect the Self-Disinfection Input Tube to the port on the right side of the CORIS Device. • Press the start button to begin the adaptor reprocessing cycle. The cycle takes approximately 16 minutes. • Observe the system for leaks or errors. If a leak occurs, cancel the cycle. **If the cycle fails for any reason, the CORIS Adaptor and the Smart Drain Adaptor have not been reprocessed, and the Adaptor Reprocessing Cycle must be run again. Refer to the User Manual for information on specific errors.** • When the cycle has finished, remove the Self-Disinfection Input Tube from the CORIS Device and disinfectant bottle. Replace the disinfectant bottle cap and set the tube aside for reprocessing. • Disconnect all connectors from the Adaptor Reprocessing Hub. • Unlock and remove the CORIS Adaptor from the CORIS Device, and the Smart Drain Adaptor from the Smart Drain. • Store by hanging the adaptors in a clean dry area away from potential contamination or damage until required. • The CORIS Adaptor Reprocessing Hub and the Self-Disinfection Input Tube should be cleaned and disinfected with a wipe after use and stored in a clean and dry location.
13	**Adaptor Reprocessing Cycle Fail Errors** **Review section 5 of the User Manual for details of cycle errors messages.** • If for any reason the Adaptor Reprocessing Cycle fails, the screen will inform you of a failed cycle. • Refer to the error code displayed and consult the User Manual for instructions. You may need to refer to your facility procedures for certain errors. **A failed Adaptor Reprocessing Cycle means the CORIS Adaptor and the Smart Drain Adaptor have not been reprocessed, and the** Adaptor Reprocessing Cycle **must be run again.**

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14	**Disinfection of the CORIS Adaptor and Smart Drain Adaptor with the CORIS Flushing Accessory** **Review section 4.4.3 of the User Manual for instructions on using the CORIS Flushing Accessory.** • The interior surfaces of the CORIS Adaptor and Smart Drain Adaptor must be disinfected once per day. Use the Flushing Accessory to flush Revital-Ox® RESERT® High Level Disinfectant into all connected channels. The Flushing Accessory inlet tube draws liquid up to pump through the channels using the syringe and dial. • Wear appropriate PPE, such as gloves. • Attach the large plate to the CORIS Adaptor and the small plate to the Smart Drain Adaptor by aligning the arrow to the large key on each adaptor. Push to attach. • Place the adaptors, Flushing Accessory adaptor plates and inlet tube in a clean container with the connectors on the bottom. Do not place the Flushing Accessory body in the container. • Before using Revital-Ox® RESERT® High Level Disinfectant, follow all Revital-Ox® RESERT® High-Level Disinfectant instructions provided by the manufacturer. For example, the temperature of the disinfectant must be 20°C or higher, the disinfectant must be used undiluted, and the solution concentration must be verified with a test strip. • Pour into the container enough undiluted Revital-Ox® RESERT® High Level Disinfectant to fully submerge all adaptor connectors and the inlet tube. Ensure that all connectors and the inlet tube are below the surface of the disinfectant. • Rotate the Flushing Accessory dial to position A. Pump the syringe fully at least 5 times. • Rotate the Flushing Accessory dial to the next position and pump the syringe fully at least 5 times. Complete for all dial positions (A, B, C, D, E) to fill the adaptor tubing with disinfectant. • Ensure that all connectors are fully submerged and leave for the full contact time for disinfection according to the Revital-Ox® RESERT® High Level Disinfectant instructions for use (8 minutes). • Fill a clean basin with enough potable water to fully submerge all adaptors and the inlet tube. • After the disinfectant contact time has completed, transfer the adaptors, Flushing Accessory adaptor plates and inlet tube out of the disinfectant and into the water. Ensure that all adaptors and the inlet tube are below the surface of the water. • Rotate the Flushing Accessory dial to position A. Pump the syringe fully at least 5 times. • Rotate the Flushing Accessory dial to the next position and pump the syringe fully at least 5 times. Complete for all dial positions (A, B, C, D, E) to flush the adaptor tubing with water. • Move the adaptors and Flushing Accessory adaptor plates into a clean basin. Ensure that the inlet tube remains outside in open air. • Rotate the Flushing Accessory dial to the position A. Pump the syringe fully at least 5 times. • Rotate the Flushing Accessory dial to the next position and pump the syringe fully at least 5 times. Complete for all dial positions (A, B, C, D, E) to purge water out with air. • Move the adaptors and Flushing Accessory adaptor plates to a clean, dry surface and disconnect the adaptors from the Flushing Accessory adaptor plates. • Thoroughly dry all exterior surfaces of the adaptors and Flushing Accessory with a sterile, low-lint soft wipe. Store by hanging the adaptors in a clean dry area away from potential contamination or damage until required.
15	**Disposal of Smart Seals** **The Smart Seal is 24 hours use only.** • After 24 hours, the Smart Seal must be disposed of according to your facility procedures.

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16	**Running a CORIS Self-Disinfection Cycle** **Review section 4.5.1 of the User Manual for instructions on the Self-Disinfection Cycle.** • The CORIS Device must be internally disinfected by running the CORIS Self-Disinfection Cycle. The CORIS Self-Disinfection cycle circulates Revital-Ox® RESERT® High Level Disinfectant through the CORIS Device using the Maintenance Kit (Adaptor Plug, Bottle Plug, Self-Disinfection Input tube). • The Self-Disinfection Cycle must be run twice a week, with a maximum of 4 days between each cycle within a week, • To run a CORIS Self-Disinfection Cycle, go to the Menu, Maintenance and select CORIS Self-Disinfection Cycle. • If there is any QUANTUM remaining in the bottle it will be emptied. • Following the instructions on the touchscreen, open the door, unlock and remove the empty bottle. • Retrieve and inspect the accessories from the Maintenance Kit: the CORIS Adaptor Plug, Bottle Plug, and Self-Disinfection Input Tube. • Insert the Bottle Plug, lock it and close the door. Take note of the alignment pins for the correct orientation. • Remove the Adaptor if it is still attached and insert the Adaptor Plug. • Before using Revital-Ox® RESERT® High Level Disinfectant, follow all Revital-Ox® RESERT® High-Level Disinfectant instructions provided by the manufacturer. For example, the temperature of the disinfectant must be 20°C or higher, the disinfectant must be used undiluted, and the solution concentration must be verified with a test strip. • Retrieve a bottle of Revital-Ox® RESERT® High Level Disinfectant with at least 1,000mL remaining. **Only use undiluted Revital-Ox® RESERT® High Level Disinfectant for the Self-Disinfection Cycle.** • Screw the Self-Disinfection Input Tube onto the disinfectant bottle. Keep the disinfectant bottle cap for storage. • Connect the Self-Disinfection Input Tube to the port on the right side of the CORIS Device. • The cycle will run for approximately 60 minutes. **If the cycle fails for any reason, the CORIS Device has not been disinfected, and the Self-Disinfection cycle must be run again. Refer to the User Manual for information on specific errors.** • When the cycle has finished, remove the Adaptor Plug, Bottle Plug and Self-Disinfection Input Tube. Place the disinfectant bottle cap back onto the bottle. • Note, this is the best time to wipe down the external surfaces of this part of the CORIS Device. • A new QUANTUM Cleaning Agent bottle must now be loaded. • All accessories in the Maintenance Kit should be cleaned and disinfected with a wipe after use and stored in a clean and dry location.
17	**Self-Disinfection Cycle Fail Errors** **Review section 5 of the User Manual for details of cycle errors messages.** • If for any reason the Self-Disinfection Cycle fails, the screen will inform you of a failed cycle. **A failed Self-Disinfection Cycle means the CORIS Device has not been disinfected, and the Self-Disinfection Cycle must be run again.** • Refer to the error code displayed and consult the User Manual for instructions. You may need to refer to your facility procedures for certain errors.
18	**Nanosonics Service** **Review the User Manual for Nanosonics contact information.** • If you have repeated cycle failures, or if you have any questions or require additional information on how to use the CORIS System, contact your Nanosonics customer service team.

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