

Urgent – Medical Device Field Safety Corrective Action
EVOTECH® Endoscope Cleaner and Reprocessor (ECR), P/N: 50004 and P/N: 50004-002

14th May 2015

Please distribute this information to appropriate personnel at your facility.

Dear Valued Customers,

This communication is to notify you that Advanced Sterilization Products (ASP) recently determined, as part of its routine quality program, that the EVOTECH® Endoscope Cleaner and Reprocessor (ECR) may not detect an improper endoscope connection on two channels, and subsequently pass the cycle without cancellation if there is a disconnected scope. The likelihood of this occurrence is low, and ASP has not received complaints or reports of adverse events related to this issue.

The EVOTECH® ECR is designed to verify endoscope connections for each cycle. If an improper connection is detected, the system is designed to stop and cancel the cycle. This system detection, along with a user verification step stated in the User's Guide to verify the connections of the endoscope channels before and after the completion of a cycle, help to ensure that an endoscope has been processed properly.

DESCRIPTION OF ISSUE

ASP has discovered a fault condition on the interface board which may cause an anomaly in some cycles, preventing the ability to detect improper connections of Channels 3 and/or 4, allowing the cycle to complete without cancelling. The EVOTECH® ECR is susceptible to this issue when all three (3) of the following circumstances take place during the same cycle:

1. The EVOTECH® ECR is affected by the fault condition on the interface board, and causes an anomaly within a cycle.
2. The endoscope is improperly connected to Channels 3 or 4.
3. The user does not inspect all connectors and adapters during loading and unloading of the scope as stated in the User's Guide.

As a reminder, ASP has not received complaints or reports of adverse events related to this issue.

PRODUCTS AFFECTED

Product Code	Product Description
50004, 50004-002	EVOTECH® Endoscope Cleaner and Reprocessor (ECR)

WHAT ACTIONS ARE RECOMMENDED?

Please note this is not a removal of the EVOTECH® ECR and customers may continue to use the product in accordance with the User's Guide. ASP is in the process of correcting this issue; your system will be updated when the correction is available. ASP advises the customer to follow the below precautions until your system has been updated:

- Ensure that the steps below in the User's Guide for the EVOTECH® ECR are followed completely and accurately as per Chapter 3, *Processing Endoscopes*, of the *EVOTECH® Endoscope Cleaner and Reprocessor (ECR) User's Guide* (Product Code 99902-07):
 1. **Loading and Connecting an Endoscope, Step 5:** Attach the appropriate tubing set to the scope being reprocessed. Attach the leak test tubing first. Then proceed to attach the tubing set designed to be used with the particular endoscope. The tubes are color-coded and numbered. They fasten onto the system connections and onto the endoscope. Make sure all connections are tight and the tubing sets are correctly attached. Double-check the connectors and adapters for correct placement and secure attachment.
 2. **Unloading an Endoscope, Step 3:** Inspect all connectors and adapters prior to removing the scope. Make sure they are still correctly attached and undamaged. If they are not attached or if they are damaged, reattach them and reprocess the scope. If they are correctly attached and undamaged, proceed to the next step to disconnect the scope.
- Appendix A includes these instructions from the latest version of the User's Guide (Product Code 99902-07) for "Loading and Connecting an Endoscope" and "Unloading an Endoscope."

ACTION REQUIRED FROM YOU

You are receiving this letter because our records indicate that you have received an EVOTECH® ECR. To report any complaints or suspected problems with your EVOTECH® ECR related to this letter, please contact your ASP Representative.

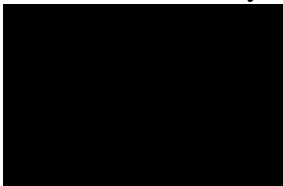
1. Read this notice carefully.
2. Ensure anyone in your facility impacted by this notification reads this letter carefully. Please retain this document with EVOTECH® ECRs in your facility.
3. Complete the **Customer Acknowledgement Form** and pass it to your ASP Representative or fax it to **6720 0750 within 2 business days.**
4. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

The U.S. Food and Drug Administration (FDA) has been notified and is aware that ASP is voluntarily communicating this information.

We know that you place a high value in our products. We appreciate your cooperation in this matter and value you as our customer. ASP is committed to maintaining your confidence in the safety and quality of our products.

Thank you for your cooperation and patience.

Yours sincerely,



Cherie Yip
Regulatory Affairs Specialist

Appendix A

Processing Endoscopes 3

Loading and Connecting an Endoscope

This section contains detailed information on the correct way to load and connect an endoscope into the EVOTECH® ECR. It is important to note how the endoscope is held, the placement of the distal end of the endoscope and the umbilicus, and the correct connection of the tubing sets and soaking caps. This procedure also assumes that in step 2 you have logged in or started the system according to the procedures set by your facility (see Chapter 1 and Chapter 4 for details on system operation and running cycles). Please follow all steps in order.

WARNING! YOU MUST WEAR PROPER PPE WHEN HANDLING THE ENDOSCOPE, REGARDLESS OF THE CLEANING PROCEDURES THAT HAVE BEEN USED.

Obtain the recommended tubing sets for the endoscope you are processing. Inspect them for tears prior to using them for processing scopes. Tubing sets are stored according to your facility's protocol.

WARNING! NEVER REPROCESS A DAMAGED ENDOSCOPE, AN ENDOSCOPE WITH RESTRICTIONS OR BLOCKAGES, OR AN ENDOSCOPE WITH A DEFECTIVE CONNECTION SET, AS THIS MAY RESULT IN INADEQUATE HIGH-LEVEL DISINFECTION.



Figure 41. This figure shows both the Tubing Set Diagram on the front panel and the color-coded channel information shown on the display screen.

The above graphic details the color-coded and numbered tubing sets' connections to the endoscope. The connection information is shown in the control panel. The diagram appears on the front panel.

Appendix A (Continued)

3 Processing Endoscopes

The following figure shows a typical tubing set with all the tubes connected. It is for sample purposes only to demonstrate the correct connections. Requirements for tubing sets used with your endoscopes will vary with the model and type of endoscope.

Caution: *Only touch the screen with uncontaminated hands or gloves.*

1. Open the lid of the basin by stepping on the foot pedal for one second. To open the lid using the touch screen; touch the open lid button with uncontaminated hands or gloves for one second.
2. Make sure the appropriate tubing set is in place or is ready to be used; e.g., inspected for tears, cracks, etc. When you connect the tubing set to the reprocessor connectors, make sure you hear an audible click. This ensures that the connectors are firmly seated and correctly attached to the system.



Figure 42. Tubing set attached to color-coded and numbered connections.
Shown without a scope for clarity.

Note: *The red leak test connector is not used for scopes qualified for disinfection only.*

3. Hold the distal end of the endoscope in one hand and the umbilicus gently coiled in the other. Position the endoscope so that the umbilicus is loosely coiled and resting on the basin ledges.

Caution: *Make sure that no small parts are near the basin or they may fall into the insertion tube housing and a service call may be required to remove them. See the routine maintenance chapter for information on how to remove items from the coarse screen below the insertion tube.*

Appendix A (Continued)

Processing Endoscopes **3**

WARNING! DO NOT ALLOW THE SCOPE TO TOUCH THE EDGE SEAL. BE SURE TO CLEAN THE EDGE SEAL AFTER THE LAST CYCLE OF THE DAY. SEE THE INFORMATION ON CLEANING THE SEALS IN THE ROUTINE MAINTENANCE SECTION.

4. Carefully slide the distal end of the endoscope over the rail and into the insertion tube housing.



Figure 43. Slide the distal end of the endoscope into the insertion tube housing.

5. Attach the appropriate tubing set to the scope being reprocessed. Attach the leak test tubing first. Then proceed to attach the tubing set designed to be used with the particular endoscope. The tubes are color-coded and numbered. They fasten onto the system connections and onto the endoscope. Make sure all connections are tight and the tubing sets are correctly attached according to the connection diagram. Double-check the connectors and adapters for correct placement and secure attachment.



Figure 44. Attach the appropriate tubing set.

6. With the manufacturer's soaking cap in place, attach the channel separator, and/or suction plug where needed. (Use of channel separators and suction plugs is determined by the type of scope being processed.)

Appendix A (Continued)

3 Processing Endoscopes

Note: Channel sets and separators should not be mixed, or interchanged between different endoscope types/families/manufacturers. Inspect the channel sets and separators periodically to ensure integrity.

Note: All connections on the basin must have a tube connected, even for endoscopes having fewer than 6 channels. You may wish to use the tubes from the self-disinfect tube set for those tubes that are not connected to an endoscope. This is to ensure that contaminants are not trapped in the tubing.

7. After attaching the color-coded and numbered tubing set to all the connections, observe the endoscope and the tubes. Make sure the endoscope and the tubing set are not tangled or kinked. Make sure all connectors at the endoscope and basin are firmly seated. The tubing set and the endoscope should be inside the basin in such a way that they do not protrude above the rail. The following figure shows proper placement of an endoscope and tubing set.



Figure 45. Make sure no tubing sets protrude above the rail.

Note: Tubes not connected to the scope should be placed along the top ledge.

8. After manual cleaning, place small accessories in an accessory basket. Place the basket in the basin.
9. When you have verified that the endoscope and tubing are properly placed, remove your gloves.

Caution: Do not touch the display screen with contaminated hands or gloves.

10. Simultaneously touch the close lid button on the touch screen and the close lid button on the front panel for the basin in use. The lid should close completely. Verify that all connector tubes are below the spray arm guard.

Appendix A (Continued)

Processing Endoscopes **3**

If any connectors are above the spray arm guard, put on chemical resistant gloves, open the lid, reposition the endoscope, and re-close the lid. Remove your gloves before touching the screen again.



Figure 46. Simultaneously press BOTH Buttons To Close The Lid.

11. Follow the steps in Chapter 4 to log in and/or start a cycle.

Unloading an Endoscope

WARNING! WEAR NEW CHEMICAL RESISTANT GLOVES BEFORE TOUCHING THE CONTENTS OF THE BASIN OR REMOVING THE SCOPE.

1. At the completion of a successful cycle, open the lid by stepping on the foot pedal for at least 1 second or touch the Open Basin Lid button on the control panel for one second.

Note: You may have to log in to activate the basin lid button on the control panel.

2. Remove the accessory basket, if used.
3. Inspect all connectors and adapters prior to removing the scope. Make sure they are still correctly attached and undamaged. If they are not attached or if they are damaged, reattach them and reprocess the scope. If they are correctly attached and undamaged, proceed to the next step to disconnect the scope.
4. Disconnect the channel connection set, channel separators, soaking caps, and suction plug from the endoscope as applicable.
5. If you will not be processing more endoscopes using the same tubing set, carefully remove the tubing set and store it according to your facility's protocol.

Appendix A (Continued)

3 *Processing Endoscopes*

WARNING! DO NOT ALLOW THE SCOPE TO TOUCH THE EDGE SEALS. THE EDGE SEALS ARE NOT DISINFECTED DURING THE CYCLE. SEE THE ROUTINE MAINTENANCE SECTION FOR INFORMATION ON CLEANING THE EDGE SEALS.

6. Remove the endoscope and store or use according to your facility's protocols.