SAMPLE PROCEDURES for use of Revital-Ox™ RESERT® High Level Disinfectant

I. PURPOSE:

To establish a procedure for the safe and effective use of Revital-Ox RESERT High Level Disinfectant. **The procedures contained in this document are only intended to provide a foundation for developing specific policies and procedures for your facility. It is the responsibility of the healthcare facility to ensure compliance with applicable laws, regulations, standards and industry recommended practices.**

II. SCOPE:

This sample procedure applies to all locations with Health Care Facility's (HCF) Name making use of Revital-Ox RESERT High Level Disinfectant.

III. EXCEPTIONS:

None

IV. CROSS REFERENCES:

Cite the following references deemed applicable in the work instruction:

a. Revital-Ox RESERT High Level Disinfectant – Instructions for Use (IFU)
b. Revital-Ox RESERT High Level Disinfectant – Technical Data Monograph
c. Revital-Ox RESERT High Level Disinfectant – Safety Data Sheet (SDS)
d. Revital-Ox™ RESERT™ R60 Solution Test Strips – Instructions for Use (IFU)
e. Current ANSI/AAMI ST58 and ST 91 Standards
f. Current Society for Gastroenterology Nurses and Associates Guidelines (SGNA)
g. Current AORN Recommended Practice & Standard
h. Current OSHA Guidelines
i. Device Manufacturer's Instructions for Use
j. AER Manufacturer's Instructions for Use (if applicable)
k. HCF's Infection Control Manual (Include as applicable)

V. DEFINITIONS:

a. **HLD – High-level Disinfectant:** Disinfection is a process that reduces the level of microorganisms on a device or surface. A high level disinfectant is expected to inactivate most forms of microbial life, including mycobacteria and some bacterial spores (although this may require extended time).

b. **AER – Automated Endoscope Reprocessor:** Automated equipment designed to reprocess flexible endoscopes. The minimum process should include disinfection and rinsing; some AERs also clean the endoscope prior to disinfection.
c. **MRC – Minimum Recommended Concentration:** Minimum concentration at which the manufacturer tested the product and validated its performance.

VI. POLICY STATEMENTS:

a. All reusable devices to be disinfected shall be compatible with Revital-Ox RESERT High Level Disinfectant.
b. All reusable devices shall be cleaned in preparation for further processing in Revital-Ox RESERT High Level Disinfectant.
c. Written departmental guidelines and/or manufacturers' written instructions regarding the care and cleaning of medical devices must be available and followed.
d. All reusable devices shall be rinsed, handled, and stored in compliance with the manufacturer's instructions, departmental guidelines and the HCF's Infection Control Manual.
e. Personnel will demonstrate competency and knowledge in the safe and proper use of all cleaning equipment and chemicals, and must adhere to established dress codes, Universal Precautions policy and the HCF's Infection Control Manual (include as applicable).
f. Hospital personnel will utilize appropriate PPE when using product per manufacturer's written instructions.

VII. PROCEDURE(S):

1. **Preparation for Disinfection**
   a. Follow instrument manufacturer's instructions for disassembly and leak testing (if appropriate) as prescribed by the device's labeling and Instructions for Use.
   b. Clean the device as directed by the device manufacturer.
   c. Flush, rinse, and dry the device thoroughly as instructed by the device and cleaning chemistry manufacturer prior to immersion in Revital-Ox RESERT High Level Disinfectant solution. Thorough drying will reduce subsequent dilution of the HLD solution concentration.

2. **Preparation of Revital-Ox RESERT High Level Disinfectant**
   a. Verify expiration date on disinfectant bottle.

b. Open bottle and pour the necessary amount of Revital-Ox RESERT High Level Disinfectant (HLD) from its original container into a secondary container e.g. soaking basin or AER reservoir.
c. Record date solution was dispensed and expiration date of 21 days in an HLD reprocessing log and/or the secondary container, provided the 21 day does not extend past the expiration date on the original Revital-Ox RESERT HLD container.
d. If there is solution remaining in the original container, date the bottle with date opened and expiration date of 90 days, provided the 90 days does not extend past the expiration date on the container. Store remaining solution in its original container.
e. Verify the minimum recommended concentration (MRC) of Revital-Ox RESERT High Level Disinfectant using a Revital-Ox RESERT R60 Solution Test Strip prior to every use in reprocessing devices (see section 3).
f. Ensure that the temperature of the Revital-Ox RESERT HLD solution in the secondary container is ≥ 20°C /68°F before use.
g. Ensure the secondary container is covered to prevent spillage or contamination of the solution.

3. **Use of Revital-Ox™ RESERT™ R60 Solution Test Strips**
   a. Verify the expiration date on the bottle of solution test strips.
   b. Ensure that a quality control procedure has been conducted on one bottle of each new batch of the test strips (see Section 8 - Quality Control Procedure for Revital-Ox™ RESERT™ Solution Test Strip).
   c. Remove one solution test strip from the bottle.
   d. Ensure the high level disinfectant solution temperature is 20°C/68°F at a minimum.
   e. Manual Soaking:
      1. Dip the strip in the secondary solution container for 2 seconds.
      2. Remove the strip and start 60 second time.
      3. Remove excess fluid by touching the short edge of the strip to a paper towel.
      4. Lay the strip on the paper towel with the viewing window facing up.
      5. At 60 seconds compare the strip pad (through the viewing window) to the color references on the strip's bottle. Note: The strip must be read at 60 seconds to observe an accurate reading. Reading the strip before 60 seconds may result in false passing.
      6. Identify the color change as "PASS" if the strip pad is completely blue/purple, indicating the solution is > 1.5% hydrogen peroxide concentration.

7. Identify the color change as “FAIL” if pink appears on the strip pad or the pad is not a complete blue/purple. NOTE: Do not read the pad after 60 seconds may result in false failing
8. If a fail result is achieved, do not use the solution and dispose of it according to the instructions for use.
9. Record strip results in the HLD reprocessing log (See VERDOC® RESERT High Level Disinfectant Solutions log form.

f. Minimum Concentration Requirement (MRC)Confirmation in an AER:
   1. Test solution and identify “PASS” or “FAIL” following the same steps as for manual soaking (e) above. If the solution cannot be reached in an AER reservoir, remove a small amount of Revital-Ox RESERT High Level Disinfectant per the AER instruction into a ~30ml specimen bottle and proceed to test solution per instructions.

4. Manual Device Disinfection using Revital-Ox RESERT High Level Disinfectant

a. Verify and record that the Revital-Ox RESERT High Level Disinfectant is within expiration date.
b. Ensure the solution is ≥ 20°C /68°F.
a. Verify the MRC of Revital-Ox RESERT High Level Disinfectant using a Solution Test Strip prior to every use and record the result (see section 3). Record the temperature and the result of the test in HLD reprocessing log.
c. Place the device to be disinfected in the solution, ensuring complete immersion of the device, and follow the device manufacturer’s instructions for filling all channels/lumens.
d. Set a timer for 8 minutes and allow the device to be immersed in the solution for the entire 8 minutes.
e. Cover the soak container to prevent spills or contamination of the solution.
f. Upon completion of 8 minutes immersion, follow the device manufacturer’s instructions of purging channels/lumens prior to rinsing.

5. **Manual Rinsing after High Level Disinfection**

a. Thoroughly rinse the device by immersing it completely in a separate clean soaking basin using water of the appropriate quality.
b. Keep the device immersed for a minimum of one minute, flushing all lumens per the device manufacturer’s instructions.
c. Remove device and discard rinse water, ensuring water is not reused.
d. Thoroughly dry device prior to use or storage. Consult manufacturer’s instructions for recommended drying using alcohol and/or medical grade air purge of lumens.

6. **AER Reprocessing (if applicable)**

b. Verify and record that the Revital-Ox RESERT High Level Disinfectant is within expiration date.
c. Verify the minimum recommended concentration (MRC) of Revital-Ox RESERT High Level Disinfectant using a Revital-Ox RESERT R60 Solution Test Strip prior to every use and record the result (see section 3). Record the temperature and the result of the test in HLD reprocessing log.
d. Position and connect the device per manufacturer's instructions to ensure all required surfaces and lumens are contacted, using the correct connectors and tubing as identified in the AER labeling.
e. Conduct a reprocessing cycle per manufacturer's instructions for use, ensuring that the AER cycle parameters (time and temperature of exposure, followed by rinsing) meet Revital-Ox RESERT High Level Disinfectant label instructions.

7. **Post-Processing Handling and Storage**
   a. Store disinfected reusable devices in a manner to minimize re-contamination and device damage.
   b. Refer to the reusable device manufacturer's labeling for additional storage and/or handling instructions.

8. **Quality Control Procedure for Revital-Ox RESERT Solution Test Strip**
   a. Verify and record expiration date of Revital-Ox RESERT High Level Disinfectant and the solution test strip.
   b. Verify that the disinfectant solution temperature is at 20°C /68°F minimum when tested.
   c. Perform a positive and negative control on one bottle from each new batch of test strips received. Note: If multiple lots are received within the batch, one bottle from each lot much be tested. See Instructions for Use for Revital-Ox RESERT R60 Solution Test Strip
   d. Positive Control:
      1. Dispense ~30ml Revital-Ox RESERT High Level Disinfectant from an unopened bottle into a clean plastic container.
      2. Dip the strip in the solutions container for 2 seconds.
      3. Remove the strip and start a 60 second timer.
      4. Remove excess fluid by touching the edge of the strip to a paper towel.
      5. Lay the strip on the paper towel with the strip viewing window facing up.
      6. At 60 seconds compare the strip pad to the color references on the bottle.

7. Identify the color change as “PASS” if the strip pad is completely blue/purple.
8. Identify the color change as “FAIL” if pink appears on the strip pad or the pad is not a complete blue/purple. NOTE: Do not read the pad after 60 seconds may result in false failing
9. Repeat procedure for a total of 3 strips. All 3 strips must demonstrate “PASS” results. If one strip fails, DO NOT USE any strips from the bottle and dispose of as normal waste.
10. Records strip results in HLD reprocessing record-keeping log.

e. Negative Control:

1. Dispense ~15ml of Revital-Ox RESERT High Level Disinfectant from an unopened bottle into a clean plastic container and add ~15ml of tap water to the bottle. Gently mix.
2. Dip the strip into the solution in the container for 2 seconds.
3. Remove the indicator strip and start a 60 second timer.
4. Remove excess fluid by touching the edge of the strip to a paper towel.
5. Lay the strip on the paper towel with the strip pad facing up.
6. At 60 seconds, compare the strip pad to the color references on the bottle.
7. Identify the color change as “PASS” if the strip pad is completely blue/purple. NOTE: Reading the strip before 60 seconds may result in false passing.
8. Identify the color change as “FAIL” if pink appears on the strip pad or the pad is not a complete blue/purple. NOTE: Reading the pad after 60 seconds may result in false failing
9. Repeat procedure for a total of 3 strips. All 3 strips must demonstrate “FAIL” results. If one strip passes, DO NOT USE any strips from the bottle. Dispose of as normal waste.
10. Records strip results in HLD reprocessing record-keeping log.

9. **Record Keeping**

a. Complete documentation of work performed, including but not limited to (see VERDOC® RESERT High Level Disinfectant Solutions log form as example):

1. Date/Time
2. Patient Name/ID Medical Record Number or Load Number
3. Item description including model and serial number
4. Exposure temperature/time
5. Expiration Date of Solution Test Strip
6. Solution Test Strip Results (PASS or FAIL)

7. Operator's Signature

10. **Disposal**
    a. At 21 days or upon Solution Test Strip failure, discard solution into drain, in accordance with facility policy.
    b. Flush drain thoroughly with water.

VIII. RESPONSIBILITY:

The department manager and or the clinical educator is responsible for assuring that proper training is conducted with all employees responsible for use and application of this product in compliance with this procedure.

The department management team is responsible for developing and or revising this procedure in accordance with manufacturer's recommendations, recommended practices, and regulatory standards.

IX. APPROVAL BODY:

Designated HCF Committee

X. APPROVAL SIGNATURES:

Name/Title: _____

Date:_____

Name/Title: _____

Date:_____

XI. DATE(s):

Approval Date: _____Month-Day-Year

Effective Date: _____Month-Day-Year

Review/Revision Date: _____Month-Day-Year

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