Product Bulletin

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Subject: **Protocol to validate the antimicrobial effectiveness of a Medivators AER (DSD-91E, SSD-100, DSD-201, SSD-102) utilizing an Endoscope.**

Introduction

The purpose of an Automated Endoscope Reprocessing (AER) system is to high level disinfect endoscopes, destroying all non-spore forming microbes that might have contaminated the endoscope from previous use with a patient, or in storage. In other words, to produce an endoscope that is ready for patient use. An AER system might not be able to achieve this purpose if the bacteria-retentive filters malfunction or are not used, or if biofilms develop within the tubing or surfaces of the system, or clogged endoscope channels prevent disinfectant flow and contact, for example. A regular quality assurance program for an AER will assure the intended performance of the system, or allow potential problems to be detected and corrected.

Definitions

This voluntary protocol is designed for use with Medivators AER systems that are connected to a potable water source, include highly-recommended bacteria-retentive filters, and use a high-level disinfectant. The microbiological quality of potable water is defined by the World Health Organization as water that contains no coliform bacteria, and not more than about 20,000 colony forming units of heterotrophic bacteria per 100 ml. Standards for non-coliform bacteria in potable water may vary from geographic location to location, and users are encouraged to check with their local health officials for their standard for potable water. Although outside of the AER system, the quality of water is very important to such matters as the use-life and function of the bacteria-retentive filters. Colony forming units (CFU) of bacteria are single or multiple cells of bacteria that grow into a colony visible to the naked eye that can be counted as a measurement of the numbers of viable bacteria present. Heterotrophic bacteria are bacteria that will grow in air (oxygen). Considering that this protocol is intended for an AER system with a bacteria-retentive filter, the action standard for this protocol is an arbitrary number set at equal to or greater than 10 CFU per 100 ml of sampling solution, designed to detect system malfunctions. A system with a functioning bacteria-retentive filter and no biofilm may in fact produce lower numbers of bacteria, and will produce 10 CFU per 100 ml or greater only if there is some filter, biofilm, disinfectant, endoscope, or sampling technique failure. Aseptic sampling technique is a method that does not contaminate the test sample with bacteria from any other than the test source. Failure to maintain aseptic techniques during this quality assurance test may lead to false results. Consult with a microbiologist if you have questions regarding aseptic technique.

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MEDIVATORS
REPROCESSING SYSTEMS

Materials

Fundamentally this procedure passes about 100 ml of rinse water through a 0.45 µ membrane, places this membrane onto a nutrient medium, and incubates the membrane at 35±1ºC to count the colonies of bacteria that might have been present in the rinse water. This can be done by several different methods. A microbiology laboratory will be equipped with a filter apparatus (beaker, membrane support, clamp, membranes, and pump), incubator, and nutrient medium in petri plates. Otherwise various companies offer simple prepared disposable apparatus to test water for bacteria. The following materials are available from Fisher Scientific (800-766-7000), or other scientific supply companies:

Incubator capable of 35±1ºC:	Lab-Line incubator, 1ft.^{3}, capable of ambient to 40ºC. Fisher catalog # 11-695-1
Membrane filters, 0.45 µ, steril:	Pall Gelman GN-6 Metricel, 47 mm i.d. Fisher catalog # 09730102
Filter Unit:	Nalgene, 0.45µ membrane included, sterile, Fisher catalog # 09-740-21B
Petri plates with absorbent pads:	Fisherbrand, 50x11 mm, sterile. Fisher catalog # 09-753-53C
R2A broth:	Pall Gelman, 2 ml ampoules. Fisher catalog # 09761172
Sterile glass or plastic containers:	Fisherbrand, 5oz, graduated, with lid, Fisher catalog # 11-838-16

Procedures

1. **Test the rinse water from an endoscope for CFU of bacteria:**

   In a Medivators AER system (DSD-91E, SSD-100, DSD-201, SSD-102) with a 0.2 micron bacteria-retentive filter and pre-filters, test the rinse water for CFU of bacteria per 100 ml of rinse water. Follow the instructions in the Medivators Service Manual to disable the lid interlock/sensor to allow access to the endoscope chamber without interrupting the reprocessing cycle. Wear sterile gloves to aseptically direct the flow of about 100 ml of rinse water from the distal tip of the endoscope into a sterile container. Collect this rinse water sample toward the end of the final rinse cycle while the rinse water is flushing through the endoscope channels. Test the rinse water immediately after collection, or refrigerate to test later, by filtering 100 ml through a 0.45 micron sterile membrane filter. Rinse the filter with 50 ml of sterile water. Use sterile flamed forceps to place the filter onto nutrient agar in a petri plate. Incubate the petri plate for 48 hrs and count the colonies of bacteria, if any. The action standard is equal to or greater than 10 CFU per 100 ml of water, i.e. equal to or greater than 10 colonies of bacteria on the petri plate. Correctly installed and functioning filters can remove 99.999% of the bacteria from water. Thus the test may show zero bacteria per 100 ml. Ten or more CFU of bacteria per 100 ml indicates a problem. If there is a problem, then examine and maintain the AER system as follows, and re-test the system:

   (a) The bacteria-retentive filter of the AER system may be torn or clogged: Change the filter.

   (b) The filter may not be correctly installed: Correctly install the filter.

   (c) The filter housing may be contaminated: Sanitize the filter housing.

   (d) A biofilm may have developed in rinse water lines after the filter: Disinfect the water lines within the AER.

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(e) The potable water supply may contain more than 20,000 CFU per 100 ml: Consult with your building engineer or local health department to bring the quality of the water supply into compliance with standards.

(f) Are all of the endoscope channels open to allow contact with the disinfectant?

(g) Test the disinfectant to determine that it is at or above the minimum recommended concentration. Does the high-level disinfectant need to be changed?

(h) Are the disinfectant/AER system label directions for exposure time and temperature being followed?

(i) Have the endoscopes been thoroughly cleaned according to protocol before placed into the AER?

2. Test the AER basin and lid surfaces for bacteria:

Use a sterile packaged swab moistened with sterile water or sterile saline solution to swab approximately a 10 X 10 cm (4 X 4 in) surface area of the AER basin or lid. Swab an area of the basin or lid that does not contact disinfectant during the AER cycle. Cut off the swab with sterile scissors into 100 ml of sterile water. Shake/agitate the swab to dislodge bacteria. Assay the 100 ml of water as described above for CFU of bacteria. If there are 10 or more CFU per 100 ml, sanitize the surfaces with an approved chlorine sanitizer, and repeat the quality assurance test. Consider these results together with the rinse water results. If the rinse water is contaminated, then the basin and lid surfaces might also be contaminated.

3. Test the incoming water supply for bacterial contamination:

The sample collection may have to be performed with the assistance of the facility plumber or/and engineer. If the incoming water supply pipe to the AER is fitted with a drain or sampling tap, this can be utilized to aseptically obtain the sample. Samples are acceptable from devices plumbed directly into the same pipeline (i.e. an adjacent cold water tap) provided that an aseptic technique is used to collect the sample. Culturing techniques should follow the instructions above.

This test can be used as a comparison to the results obtained from the endoscope sample detailed above. It can also provide informative data on water quality, which can used to determine pre-filtration requirements in difficult cases.

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