

Product Bulletin

This document applies to the following products:

- ADVANTAGE PLUS™ 2.0 Endoscope Reprocessing System
- ADVANTAGE PLUS™ Pass-Thru Automated Endoscope Reprocessor
- DSD-201 Automated Endoscope Reprocessing System
- DSD EDGE™ Dual Basin Automated Endoscope Reprocessor
- CER OPTIMA™ Automated Endoscope Reprocessing System
- CER Automated Endoscope Reprocessing System

Date: March 23, 2020

Re: Clarification on Shut Down of Cantel/Medivators Automatic Endoscope Reprocessors

In acute circumstances, a need may arise to shut down an Automated Endoscope Reprocessor (AER) for an extended period of time. It is important to note that in extended dormancy of the water system, a stagnant environment is created and consequently develops conditions susceptible for microbial growth.¹ Such conditions may facilitate the growth of biofilm, a structure comprised of diverse microorganisms that adheres to surfaces and develops protection from harsh conditions in its environment. In healthcare settings, pathogens can persist in biofilms and inherently spread to patients through medical equipment.² Extensive biofilm colonization and maturation occurs over time and becomes challenging to remove and inactivate with standard disinfection treatments. As a result, mature biofilms and high microbial levels in an AER may potentially compromise successful reprocessing cycles by contamination of incoming water.

Failure to follow maintenance guidelines during extended AER dormancy will result in heavy microbial contamination in the system where waterline treatments become ineffective at removal. Cantel cannot guarantee the elimination of mature biofilm and would require the replacement of the AER should the recommissioning process fail to adequately remove mature biofilms. **In order to prevent microbial contamination of reprocessing cycles, Cantel does not recommend shutting down the AER.**

ISO 15883-4 document describes the guidance to qualify a washer/disinfector with a self-disinfection cycle in the event an AER has become contaminated. Confirmatory testing validates the efficacy of the self-disinfection cycle of the ADVANTAGE PLUS AER in the event the AER water treatment fails, or brief AER dormancy occurs.³ A self-disinfection cycle reduces microbial contamination to minimal levels in the AER system for at least seven days.⁴ Additionally, daily endoscope reprocessing cycles are recommended to disinfect AER basins. Recommendations for DSD and CER platforms are instituted based on ADVANTAGE PLUS AER data.

To reduce microbial contamination in the AER when not in clinical use, it is recommended that the following be performed:

1. Replace all water filters.
2. Perform a test reprocessing cycle without an endoscope once per weekday.⁵
3. Perform one self-disinfection cycle every seven days.⁴
 - a. Cycles can be automatically programmed in the ADVANTAGE PLUS™ AER. Consult Technical Service for programming instructions. It is recommended to periodically check the AER for water leakage or cycle failure if left unattended.
4. Replace water filters before initiating the first clinical reprocessing cycle.

If these recommendations are followed, no additional confirmation is necessary when resuming clinical use of the AER. Refer to the AER Instructions for Use (IFU) for procedural guidelines.

Cantel does not recommend shutting down the AER for any given period. In the severe circumstance that the AER must enter a period of non-use, please contact Cantel for further instruction on shutdown procedure. If unable to perform the recommended cadence of use, contact Cantel upon resumption of normal operations for the appropriate procedure to determine AER recommissioning. Cantel cannot guarantee adequate service of AERs after extended shutdown.

For additional support, contact Technical Service at: **1-800-444-4729 (option 2).**

1. Tsagkari E, Sloan WT (2018). Biofilm Growth in Drinking Water Systems under Stagnant Conditions. In: E-Proceedings. Protection and Restoration of the Environment XIV, Thessaloniki, Greece, 3-6 July 2018, pp. 707-717.
2. Kostakioti M, Hadjifrangiskou M, Hultgren SJ (2013). Bacterial biofilms: development, dispersal, and therapeutic strategies in the dawn of the postantibiotic era. Cold Spring Harb Perspect Med. Apr 1;3(4):a010306. doi: 10.1101/cshperspect.a010306.
3. Testing by Eurofins Biotech Germande, Marseille, France (report number 2601.Can.16.PT.6).
4. Testing by Cantel, Plymouth, Minnesota (QP202281)
5. Note: it is recommended to perform daily endoscope cycles to retain disinfection of the AER basin. Data from Eurofins Biotech Germande report 2601.Can.16.PT.6 indicate the reduction of microbial levels in the basin when a full cycle is performed every day, followed by self-disinfection cycles.

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