

MEDIVATORS
ADVANTAGE™
Endoscope Reprocessor

***Safety, Efficacy and
Microbiological
Considerations***

Endoscope Disinfection System
for Multiple Use Chemistry

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50096-777 REV B

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1. Device Name:	Medivators ADVANTAGE for Endoscope Reprocessing
2. Device Classification Name:	Washer washer/disinfector
3. 510(k) Number:	K063876
4. 510(k) Decision Date:	June 14, 2007
5. Regulation Number:	876.1500
6. Predicate Device:	Medivators DSD-91E™ Endoscope Disinfector
7. Applicant:	Medivators Reprocessing Systems A Minntech Corporation Business Group
8. Contact Person:	Lynn Lueders Director, Regulatory Affairs
9. Type:	Substantially equivalent
10. Classification Advisory Committee:	Gastroenterology/Urology
11. Relevant Patents:	US 6,260,560, US 6,641,781

12. Intended Use:

The ADVANTAGE Endoscope Reprocessor from Medivators Reprocessing Systems is cleared by the Food and Drug Administration (FDA) to test, disinfect, and rinse flexible endoscopes, such as fiberoptic and video endoscopes, between patient uses. The ADVANTAGE is indicated to provide high level disinfection of heat sensitive and semi-critical endoscopes. It is indicated for use with FDA cleared, liquid high level disinfectants in accordance with all of the disinfectant label requirements.

The ADVANTAGE does not replace manual cleaning of endoscopes. They must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing in the ADVANTAGE.

13. Description:

The ADVANTAGE is an electro-mechanical system intended to test, disinfect and rinse flexible fiberoptic and video endoscopes between uses. It is not intended for reprocessing rigid endoscopes. ADVANTAGE can asynchronously reprocess two endoscopes at a time.

Prior to reprocessing in the ADVANTAGE, users must perform manual cleaning of the endoscope to remove debris from the outside and all lumens by following their clinic's internal guidelines and procedures. Scopes are connected to the ADVANTAGE to test for channel connectivity blockage and outer sheath leaks. Upon successful completion of the connectivity, blockage and leak tests, the system proceeds to rinse the instrument and start the disinfection cycle.

The system is designed to use currently marketed, reusable high-level disinfectants including glutaraldehyde (such as Rapicide Disinfectant manufactured by Medivators) or *ortho*-phthalaldehyde (Cidex® OPA manufactured by Advanced Sterilization Products) packaged at use concentration. In order to show the machine effectiveness with both types of germicides, both Rapicide and Cidex OPA were evaluated. Any enzymatic or non-enzymatic neutral pH detergent may be used in the detergent step of the cycle according to its labeled instructions for use. During testing, Intercept™ Detergent (distributed in the U.S. by Medivators) was used at 0.5% final concentration. The ADVANTAGE also has the ability to perform a 70% isopropyl alcohol flush with subsequent air purge to assist drying of endoscope channels.

Prior to the disinfection cycle, the disinfectant is heated to the manufacturer's recommended use temperature. The disinfectant is then transferred to the reprocessing basin where it is recirculated through the endoscope lumens, and also fills the basin to fully immerse the endoscope in disinfectant. The scope remains submerged for the chemical manufacturer's recommended contact time. The disinfectant is then drained from the basin into the onboard chemical reservoir. Following disinfection, the endoscopes are rinsed and dried by the machine, either by filtered air or an optional alcohol rinse, and then removed from the machine for the next use.

Each ADVANTAGE must be properly set up at the endoscopy facility by trained Medivators Field Service Engineers. At that time, settings specific to the germicide being used, and individual scope reprocessing parameters will be activated. It is important for the customer to use the correct connections (hookups) for connecting the scope to the machine. Medivators provides a complete list of connectors which have been tested with all major scope manufacturers' devices. Users will be provided this list during installation and in-service, and can access updates on the Medivators' website (www.medivators.com).

14. ADVANTAGE Features

- Asynchronous operation of two large independent basins
- A dedicated personal computer (PC) for cycle recording, powerful quality assurance reporting, easy backups, networking availability, and remote diagnostics
- Hook-up blocks dedicated to a family of endoscopes to ensure correct connectivity and flow rates to meet manufacturers' specifications
- Individual channel identification and blockage monitoring
- Continuous endoscope leak testing throughout entire reprocessing cycle
- Remote diagnostics for operator assistance and troubleshooting
- Ability to use heated disinfectant chemistry
- Easy-to-fill detergent and alcohol reservoirs, and no separate water tank needed

15. Summary of Simulated In-use Testing Under Worst Case Conditions:

The interior channels of an Olympus-brand bronchoscope, colonoscope and gastroscope were inoculated with $>10^8$ colony forming units (CFU) of *Mycobacterium terrae* and disinfected with Rapiocide High-Level Disinfectant and Sterilant under worst case conditions for both the ADVANTAGE and disinfectant conditions. The endoscope models were selected as the most complex and difficult to reprocess in order to provide the maximum challenge and demonstrate that the ADVANTAGE can disinfect these specific endoscopes as well as those of less complex and less challenging design. Each scope was tested three times. In these tests, the pre-rinse and detergent flush cycles were disabled so the machine would start with the disinfection cycle. Worst case conditions were defined as the disinfectant at a lower temperature than recommended for use, disinfectant concentrations at MRC or below and disinfectant at the end of its shelf life. All testing was carried out according to the requirements listed in FDA Guidance Documents.

The data in Table 1 demonstrate that all endoscopes were processed with a greater than the required 10^6 CFU reduction. These studies show that the ADVANTAGE can effect high-level disinfection of endoscopes that are connected via the recommended hook-up and parameter set.

Table 1. High-level Disinfection of Endoscopes in the ADVANTAGE Under Worst Case Conditions.

Endoscope	Inoculum (CFU)	Average log ₁₀ reduction
Bronchoscope	1.51×10^{10}	> 8.18
Colonoscope	1.42×10^8	> 7.6
Gastroscope	1.35×10^8	> 7.6

16. Summary of Clinical in-use Testing:

In-use testing of clinically used scopes was performed by acquiring gastroscopes, bronchoscopes and colonoscopes from clinical facilities. Five scopes of each type were reprocessed in the ADVANTAGE using the same worst case conditions as the simulated use testing. The data summarized in Table 2 shows that under worst case conditions the ADVANTAGE successfully disinfected endoscopes sourced from a number of actual clinical environments.

Table 2. High-level Disinfection of Clinically Used Endoscopes in the ADVANTAGE.

Endoscope	Controls % recovery	CFU Recovered from processed scopes
Bronchoscope	92	0
Colonoscope	92	0
Gastroscope	88	0

17. Disinfectant Residue Evaluations

Residual disinfectant levels on endoscopes were determined after completion of the ADVANTAGE rinse cycles, in order to determine the level of actual residues relative to safe amounts allowed for patients and health care workers. Colonoscopes were selected for this study because they are the most difficult to rinse due to construction with long channels and large surface areas, and subsequent potential to retain the highest levels of disinfectant. Residues on the exterior surfaces and interior channels were analyzed. Table 3 summarizes the range of residual glutaraldehyde from Rapicide and the residual *ortho*-phthalaldehyde from Cidex OPA extracted from three colonoscopes. Safe levels of disinfectant in this study, including a ten-fold safety factor of maximum allowable residues using LD₅₀ values, are 250 mg for glutaraldehyde and 1000 mg for *ortho*-phthalaldehyde. The studies show that residual disinfectant levels on endoscopes were significantly below acceptable safety levels after processing in the ADVANTAGE.

Table 3. Total Residues Extracted from Colonoscopes After ADVANTAGE Processing

Disinfectant	Safe residual level (mg)	Range of total extracted residuals from 3 endoscopes (mg)	Required Endoscope Rinses
Glutaraldehyde	250 mg	1.5 - 3.4	2
<i>Ortho</i> -phthalaldehyde	1000 mg	0	3

18. Electrical Safety Testing

All electrical safety aspects of the ADVANTAGE have been tested by an outside testing service (Intertek Testing Services) for compliance with UL-61010-1 Standard for Safety Requirements for Electrical Equipment. It has also been tested for emissions that may affect other devices, and for immunity to the effects that other devices may have on the reprocessor. These test data meet the requirements of IEC 60601-1-2. Testing on file with Medivators Reprocessing Systems shows the machine meets all required standards and will be safe under its labeled conditions.

19. Reprocessor Self-Disinfection

The ADVANTAGE needs to be sanitized at regular intervals to ensure that water pathways and filters do not become contaminated. Testing was performed on the ADVANTAGE using the self-disinfection cycle with both Rapicide and Cidex OPA. Concentrations of both disinfectants relative to the MRC in the water filter were determined in three replicate runs during the self-disinfection hold period. Results in Table 4 demonstrate that both glutaraldehyde and *ortho*-phthalaldehyde disinfectant concentrations are within the normal use concentration and well above the MRC during the disinfection hold period.

Table 4. Disinfectant Concentrations During ADVANTAGE Self-Disinfection Cycles

Disinfectant	MRC	Range of baseline disinfectant (%)	Range during disinfection (%)
Glutaraldehyde	1.5%	2.33-2.33	2.22-2.24
<i>Ortho</i> -phthalaldehyde	0.3%	0.48-0.48	0.47-0.50

20. Material Compatibility

Material compatibility testing has been performed on all components of the ADVANTAGE that will be contacted by the labeled disinfectants. Metals, ceramics, plastics, composites and elastomers were exposed to both Rapicide and Cidex OPA at full strength at manufacturers' recommended use temperatures. Components were exposed for 325 hours to meet the equivalent of 1.5 years of field use. All materials had parameter changes less than the 5% criterion and are acceptable for use with disinfectants under labeled use conditions.

21. Software Verification

Laboratory studies were conducted to verify that the ADVANTAGE will perform its specified functions. Each system and sensor has been studied, and the complete integrated system has been shown to perform in an effective manner.

Software system parameter verification testing included:

- Variable contact times (based on disinfectant used)
- Control of machine draining
- Control of the pre-rinse and final rinse requirements
- Control of the reservoir heater settings
- Execution of the proper self-disinfection cycle

Software detection of error conditions verification testing included:

- Compromised endoscope sheath (leak detection)
- Disconnected or improperly connected channels
- Endoscope channel blockage
- Reservoir temperatures above or below labeled parameters
- Open/ajar basin lids
- Low water or disinfectant level in basin
- Deviation from maximum/minimum cycle step times
- Disinfectant overflow sensor
- Disinfectant low level sensor
- Electrical power supply at incorrect cycle phase
- Disinfection contact times inadequate
- Unsatisfactory completion of self-disinfection phase

22. Installation Requirements:

Electrical: The ADVANTAGE must be connected to a single electrical outlet capable of supplying 10 amps at 230/240 ± 10% volts AC, 50/60 Hz, single phase, 2300 Watts. The outlet must be properly grounded.

Drain: For optimal performance the ADVANTAGE should be connected to a vented sanitary drain system capable of draining at a minimum rate of 5 gallons per minute (19 liters/min).

Water: Potable water is the minimum standard. For optimum performance, water must be delivered at a minimum flow rate of 5 L/min (1.32 gpm) at a dynamic pressure of 30 psi (2 bar) during the basin fill. A back siphonage prevention device must be purchased separately and installed between the water line and the machine to prevent contamination of the water supply in the event of a sudden drop in water pressure.

Room Ventilation: The ADVANTAGE must be installed in a room with a ventilation system capable of delivering a minimum of 10 air exchanges per hour.

The reprocessor is supplied with a factory installed fan which can be connected to a duct system capable of handling an air flow of 60 m³/hour (35 CFM). Connection of this fan does not change the requirement for adequate room ventilation.

An optional vapor management system is available for ductless fume removal.

Air: The Medivators ADVANTAGE System must be connected to an air supply for proper operation. The air supply must be capable of delivering house compressed air (dry/oil free) at a minimum of 40 L/min (10.57 gpm) at 87 psi (6 bar).



Manufactured in the USA by:

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REPROCESSING SYSTEMS

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