

FREQUENTLY ASKED QUESTIONS FOR THE *ADVANTAGE*

What is an Automated Endoscope Reprocessor ?

An Automated Endoscopes Reprocessor (AER) performs all the cycle steps (fresh water pre-flush, rinsing, disinfection, leak test, alcohol flush, drying) established by a pre-set program, which the operator cannot change, to high-level disinfect endoscopes when used in combination with an approved liquid chemical germicide. The program parameters include disinfection chemistry temperature, use concentration, and contact time. This ensures consistent and effective reprocessing, while minimizing the chance of human error. All cycle steps and operational parameters are documented by either hard copy printout or data download to a PC.

What types of endoscopes can be reprocessed in the *ADVANTAGE*?

*The *ADVANTAGE* is suitable for reprocessing most makes and models of flexible endoscopes used for diagnostic or therapeutic examinations. Included among these endoscopes are those manufactured by Fujinon, Olympus and Pentax. Select Karl Storz endoscopes have also been tested for use with the *ADVANTAGE*. Although the number of channels varies with different types of endoscopes, the number of channel connections required can be met with hookups specially designed and tested for use with the *ADVANTAGE*. Even small flexible endoscopes can be rinsed and disinfected in this reprocessor. The *ADVANTAGE* has programming capabilities enabling the effective reprocessing of a wide range of endoscopes. The custom program parameters are based on the configuration and internal dimensions of the channels. The *ADVANTAGE* should only be used to reprocess fully immersible instruments that can be internally and externally disinfected. If there are any questions, the device supplier should be contacted.*

How many endoscopes can be disinfected in the *ADVANTAGE* at one time?

*The *ADVANTAGE* has two asynchronous basins. In the standard version, one endoscope can be reprocessed in each basin. An option to simultaneously reprocess two endoscopes in each basin is under development. This double endoscope disinfection option will be suitable for endoscopes with up to three channels, no elevator lift channel and rigid endoscopes with a length less than 40 cm. The double endoscope option will also enable the disinfection of up to four endoscopes with one channel per connector block.*

What is asynchronous reprocessing?

Each basin of the ADVANTAGE operates completely independently. The operator doesn't have to wait for the cycle to finish in one basin before loading an endoscope into the empty side, reducing turnaround time.

What disinfectants can be used with the ADVANTAGE?

The ADVANTAGE reprocessor has been tested and validated with the following disinfectants:

- 1. Rapicide High Level Disinfectant and Sterilant*
- 2. Cidex OPA High Level Disinfectant and Sterilant*

Other disinfectants may be used with the ADVANTAGE after evaluation in the system. The disinfectants are heated to a pre-set temperature (if required) in dedicated reservoirs, automatically circulated through all endoscope channels and around the exterior of the endoscope, and thoroughly rinsed from all surfaces of the endoscope at the end of the cycle. The rinse process has been thoroughly evaluated and validated with the disinfectant formulations to insure the lowest level of residual.

How many endoscopes channels are separately reprocessed by the ADVANTAGE?

The ADVANTAGE rinses and disinfects all of the endoscopes channels separately, with the exception of a very small number of endoscopes fitted with large diameter independent channels. This means that all channels are monitored throughout the whole process for flow, leaks, channel blockage, and hookup connectivity

What is a typical reprocessing cycle, and how long does it take?

The general process includes:

A leak test; pre-rinse; detergent flush (if programmed); disinfection step; 2-3 post-rinses (depending on disinfectant used); alcohol flush; air purges follow each fluid step (water, detergent, disinfectant, alcohol); endoscope channel blockage monitoring and connectivity are conducted throughout the cycle.

A complete disinfection cycle takes approximately 30 minutes.

The actual cycle time varies with incoming water pressure, drain capacity, cycle selected, number of channels in the endoscope, among other factors.

How much detergent, disinfectant, and water are used for an average cycle?

Detergent: *The actual detergent dispensed will depend upon the requirements of the detergent manufacturer. If the detergent (INTERCEPT, for example) is used at a 0.25% concentration, approximately 9 ml of detergent will be dispensed each cycle.*

Water: *The actual water consumption will vary depending upon the actual cycle programmed. Typical cycles utilizing a pre-flush, rinse, disinfect, and final rinse will use approximately 24 liters (6 gallons) of water.*

Disinfectant: *Five gallons of disinfectant are required for each reservoir of the unit at time of filling (10 gallons total). A minimal amount of disinfectant will be lost with each reprocessing cycle, so additional disinfectant must be added as required.*

How does the ADVANTAGE self-disinfect?

Disinfectant is pumped into the filtration system and through all internal wetted components as well as the basin. The system design eliminates any “dead legs”, which could interfere with the chemical disinfection process. Chemical disinfection of the machine should be carried out regularly. This is intended to reduce the incidence of bacterial growth (including Mycobacterium) and prevent the subsequent development of biofilm in the valves, tubings, fittings and pumps.

How do I know my endoscope has been properly reprocessed?

All reprocessing cycle step functions, from pre-rinse through air dry are stored in a data file, and the entire cycle can be monitored in real time via the flat panel display. Faults which would lead to improper disinfection and potential damage to the endoscopes will be reported to the operator through an error message on the monitor and an audible alarm. Monitoring of the cycle’s operational parameters is conducted at critical points of the process; these include: continuous leak test; basin fill volume; connectivity of hookups to endoscopes channel; individual channel flow/blockage detection.

Features and benefits of the **ADVANTAGE**

What is the function of the connector block?

Use of the connector block assures proper hookup connectivity and flow to the endoscope. Each type of endoscope has a special connector block. Each block is clearly labeled to indicate which endoscope it should be used with. The number and configuration of connections on the block are unique for each endoscope type, so improper connection is avoided.

What are the various options for data entry in the **ADVANTAGE**?

The options are:

1. Barcode reader – reads barcodes on specific endoscopes, operators, patients and physicians. Cycle will only start after identification details have been recorded, assuring maximum traceability.
2. Keyboard / pre-programmable cycle parameters -- even without a bar-code reader, the **ADVANTAGE** is simple to operate. Numerous standard programs for a wide variety of endoscopes are available and the operating parameters can be modified by an authorized operator to meet facility-specific needs or to accommodate new endoscopes models.

What are the **ADVANTAGE** system's benefits to the operator?

1. Ergonomic design – the height of the system, angle of basin access and convenient touch-pad location assures minimal operator fatigue or injury. Foot pedal-controlled lid release minimizes contact with reprocessor exterior.
2. Easy to use – Program parameters are pre-set, and the bar code technology enables the **ADVANTAGE** to initiate the appropriate program for a particular endoscopes quickly and automatically.

What are the benefits to the endoscopy facility?

1. Certified procedure – the performance of every cycle step is saved to the PC-based operating system, enabling data analysis and outstanding recordkeeping
2. Remote diagnostics/software upgrades – **ADVANTAGE** performance can be monitored, adjusted, and enhanced either remotely or during a visit by a certified Medivators Field Service Engineer
3. Easy access for maintenance – removal side panels enable quick entry to the **ADVANTAGE** interior for repair and service
4. Networking capability – several **ADVANTAGE** units can be linked electronically within the same facility or from various remote locations

Reprocessor specifications

What are the dimensions of the **ADVANTAGE**?

Width: 45 in (115 cm)

Height including computer: 57 in (145 cm)

Depth including computer: 35 in (89 cm)

What is the weight of the reprocessor?

The empty reprocessor (without water, detergent, or disinfectant) weighs 180 kg (400 lbs).

Operational Parameters

Is manual pre-cleaning still necessary?

Manual pre-cleaning of the endoscopes channels and exterior surfaces must be performed in accordance with the endoscope manufacturer's recommendations.

Can multiple rinses be programmed into the unit?

Yes. All steps of the program can be adjusted to meet specific disinfectant manufacturer and/or endoscopy facility requirements.

Is a compressed air supply required to operate the **ADVANTAGE**?

*Yes; a compressed air supply is necessary to operate air-actuated valves and the pumps. The **ADVANTAGE** can be supplied with an optional air compressor, or connected to house air in the facility.*

How are software upgrades installed?

Software upgrades can be installed from a CD, by email file (downloaded) or by remote PC file transfer when performed by a Medivators Field Service Engineer.

Is there a pre-filtration system included with the ADVANTAGE? What are the membrane pore sizes of the filters?

The ADVANTAGE has a specially designed three-stage water filtration. There is a 1.0 micron and a 0.45 micron pre-filter, and a 0.2 micron bacteria-retentive filter system included in the system.

What are the data management capabilities of the ADVANTAGE?

Comprehensive reprocessor operation and cycle recording is achieved in the ADVANTAGE using the PC-based operating system. Cycle performance, as well as operator, patient, physician, and endoscope ID are tracked throughout the cycle. The data can then be downloaded into a database or spreadsheet for analysis.

Service / maintenance / training requirements:

What type of warranty is provided with the ADVANTAGE?

All parts and service for 12 months after installation date are provided at no charge, once it has been verified that the ADVANTAGE machine has been properly installed and is being correctly operated. Items not covered by warranty include:

- water filters*
- disinfectant filter*
- air filters*

Regulatory Considerations and Clearances

Is the ADVANTAGE cleared for use in the United States?

Yes; Minntech received clearance for FDA on June 14 2007 to market the ADVANTAGE in the US for the reprocessing of flexible endoscopes.

Is the ADVANTAGE CE-marked?

The ADVANTAGE is CE marked (by NSAI - 0050) under the Medical Device Directive. Minntech's Quality System is registered under ISO 13485.

In what countries has the ADVANTAGE been installed and is operational?

The ADVANTAGE is currently in use in the Netherlands, Switzerland, the United Kingdom, Germany, Kuwait, Denmark, Ireland, Italy and France.

What number and type of connections are required for channel irrigation for each device and/or device family?

See application guide for connector block per endoscope type recommendations.

What is the maximum pressure of fluids delivered through each channel during processing in the *ADVANTAGE*?

The maximum pressure for most channels is 25 PSI; the elevator channel may reach 45 PSI

What restriction of flow through each channel will indicate a blockage fault?

The system will detect completely and partially blocked channels. The percentage of partially blocked channel detection is dependent on the type of endoscope, as well as the diameter of the channel.

How is the flow of process fluids through each channel verified?

A pressure switch is activated when sufficient flow is detected.

Which parts of the *ADVANTAGE* are disinfected during the self-disinfection cycle?

All wetted parts of the unit, water-line and 0.2 micron filter. Automated, programmable disinfection of the 1.0 and 0.45 micron pre-filters will be added soon.

What is the method and frequency for disinfection of the connection between the *ADVANTAGE* and the water supply for post-disinfection rinse water?

This is a manual process and needs to be performed consistent with the facilities needs.

How are samples of final rinse water collected from the basin?

Rinse water samples for testing purposes, can be collected from the incoming water spout in the basin.

Will the temperature sensors in the *ADVANTAGE* monitor the lowest (worst case) temperature in the system?

The temperature of the fluid in the basin is monitored in as the fluid exits the bottom of the basin.

For additional questions on the *ADVANTAGE* reprocessor or other Medivators products, please visit us online at www.minntech.com, call Medivators Customer Support at 1-800-444-4729, or contact your local Medivators sales representative.