



Amity PAA 5 System

A Peracetic Acid based High Level Disinfectant for Flexible Endoscopes & Medical Devices Technical Information

Description & Application:

Amity PAA 5 is a powerful peracetic acid based high level disinfectant concentrate for use in Automated Endoscope Reprocessors (AERs) and other automated decontamination systems. It is an acidic disinfection concentrate for flexible endoscopes and medical devices.

Amity PAA 5 Solutions A and B are combined to produce a single use solution for HLD (High Level Disinfection) of flexible endoscopes with Peracetic Acid.

Amity PAA 5 Part A and Part B are registered as Class IIB Medical Device

Primary features attributable to Amity PAA 5 solutions are;

- Active ingredient: Peracetic Acid (PAA);
- PAA concentration: 1,000 – 1,200 ppm;
- Minimum Effective Concentration (MEC): 850 ppm
- Reuse Period: Single use;
- HLD claim: 5 minutes at 30°C;
- Dilution Required: 1:1 to 48 water;
- Activator Required: No;
- Corrosion Inhibitors: Yes.
- Tested to EN 14885 for disinfectant properties;
- Tested to EN 15883-4.

Amity PAA 5 System is a single use liquid chemical HLD solution with PAA in the concentration range 1,000 – 1,200 ppm. Amity PAA 5 System contains corrosion inhibitors and water softeners.

Applications

Amity PAA 5 System is intended for HLD of critical and semi-critical, heat sensitive medical flexible endoscopes and medical devices in AERs. Amity PAA 5 System is intended for single use at 30°C or until the PAA is below the MEC of 850ppm.

Amity PAA HLD Test Strips must be used by trained staff to monitor MEC.



**Infection
Controlled**

Please read and follow the instructions for use and precautionary statements contained on the label and MSDS.

Compatibility

Amity PAA 5 System HLD is suitable for use on all types of flexible endoscopes, heat sensitive instruments and medical devices.

List of compatible materials:

Metals	Plastics	Elastomers
301 Stainless Steel	Acetal	Aflas
304 Stainless Steel	Nylon	EPDM
316 Stainless Steel	PETG	Santaprene
Hastelloy	Polycarbonate	Silicone Rubber
Inconel	Polyester	EPDM
	Polyethylene	
	Polypropylene	
	Polysulphone	
	PVC	
	Polyurethane	
	PTFE	
	PVDF	

The compatibility of Amity PAA 5 has been carried out by conducting intensive exposure tests with the use solution. In addition biocompatibility testing has been conducted in order to demonstrate the rinsing of the chemical components from the flexible endoscopes.

No damage to endoscopes is to be anticipated when using Amity PAA 5 System provided Amity PAA 5 System is used as directions for use.

As with all Peracetic Acid products some cosmetic effects may be noticed, such as bleaching of the colour from black adhesives and anodised surfaces.

- These Aluminium parts can be replaced with plastic or plastic covers.
- Chromium-plated or Nickel plated brass surfaces (e.g. light sources) with mechanical damage (e.g. scratches) must be protected with a resistant protective cover during reprocessing.

Health and Safety

Amity PAA 5 solutions are classed as biodegradable in accordance with OECD criteria.

Amity PAA 5 Part A is classed as being Oxidising, Harmful and Corrosive. Amity PAA 5 Part B is classed as being Corrosive. Always wear proper eye protection and chemical resistant gloves when handling Amity PAA 5 solutions.

Contact with skin and eyes should be avoided.

Avoid breathing or ingesting mist, vapour or liquid droplets. Prepare and use Amity PAA 5 System only in well ventilated areas.

See relevant Material Safety Data Sheets for details.

Typical Properties Amity PAA 5 System

	Part A	Part B
Appearance	Transparent, Colourless liquid	Clear colourless liquid
Odour	Pungent odour	odourless
pH,	< 2.0 units (Neat solution)	12.6 units (Neat solution)
Density, g/cm ³ @ 20 °C	1.10 (neat)	1.04
Solubility in water	Completely miscible	Completely miscible
Flash Point (Abel closed cup)	Flammable vapours may occur above SADT	Non-flammable

SADT = Self-Accelerating Decomposition Temperature

Shelf Life: Concentrate – Not less than 12 - 18 months in unopened original containers when stored between 5 °C and 25 °C out of direct sunlight.

Test Compliance

- EN 13704 Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas
- EN 13727 Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics
- EN 13624 Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area
- EN 14347 Chemical disinfectants and antiseptics - Basic sporicidal activity
- EN 14348 Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants
- EN 14476 Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine
- EN 14561 Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area
- EN 14562 Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area
- EN 14563 Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area

Directions for Use

Amity PAA 5 System Solutions are supplied as a concentrated products that requires dilution prior to use.

Application:

For Cleaning of Endoscopy instruments and equipment in Automated Endoscope Reprocessors:

Amity PAA 5 Solutions A and B are injected together, diluted to 2% (20ml/L) each at 30°C for 5 minutes in AER and then rinse with water.

A recommended cleaning cycle is set out below and ideally RO water should be used for all phases:

Phase	Time	Temp.	Solution	Dosage
Rinse	3 min	-	-	-
Wash	5 min	35-55°C	Viruzyme or Virudet N	5ml/L or 0.5%
Rinse	3 min	-	-	-
Disinfection	5 min	30°C	Amity PAA 5 Solutions A and B	20 ml/L or 2% of each
Rinse	3 min	-	-	-
Rinse	3 min	-	-	-
Dry				

Drying time and temp according to the machine manufacturer

General Notes:

Do not add other chemicals to the Amity PAA 5 solutions as they can seriously impair the performance.

Containers and basins used to contain the cleaning process must be resistant to acids as must be the sinks and pipes, through which the working solutions of Amity PAA 5 solutions A and B are discharged.

After HLD, instruments must be rinsed thoroughly with water, dried and then stored correctly.

CONTACT DETAILS:

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For any further information, please contact your distributor or Amity.

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Packaging Details:

Amity PAA 5 Solutions A and B are available in the following packaging.

- 4 x 5 L box