

PRODUCT SHEET

EndoHigh[®] PAA

HIGH-LEVEL DISINFECTANT FOR USE IN WASSENBURG[®] WASHER-DISINFECTORS FOR FLEXIBLE ENDOSCOPES – LIQUID CONCENTRATE

REFERENCE : MB 5239/2-9(DR. WEIGERT)
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Main fields of application

Automated high-level disinfection of flexible endoscopes in WASSENBURG[®] WD440, WD415, WD440 PT (pass through) and WD4200 washer-disinfectors for flexible endoscopes.

Properties

Active against bacteria (incl. MRSA and *Helicobacter pylori*), mycobacteria (incl. tuberculosis pathogen) fungi and viruses (incl. hepatitis A, B and C, HIV, rotaviruses, noroviruses, coronaviruses) and spores of *C. difficile*. The disinfecting action has been tested and confirmed according to the requirements of EN 14885. EndoHigh[®] PAA therefore complies with the demands on disinfectants for disinfecting flexible endoscopes according to ISO 15883-4. The automated reprocessing process with EndoHigh[®] Detergent and EndoHigh[®] PAA in WASSENBURG[®] WD440, WD415, WD440 PT (pass through) and WD4200 endoscope washer-disinfectors meets the demands of ISO 15883-4 regarding a germ reduction of > 9 log₁₀ steps in the entire process.

Based on peracetic acid. No activator necessary; just one component. Rapid activity, broad efficacy spectrum suitable for high-level disinfection, incl. activity against spores of *C. difficile* at 35 °C. Suitable for endoscopes of all leading manufacturers. Free of aldehydes and quaternary ammonium compounds.

Application and dosage

EndoHigh[®] PAA has been specially developed for use in WASSENBURG[®] WD440, WD415, WD440 PT (pass through) and WD4200 endoscope washer-disinfectors. The disinfectant is not suitable for use in WASSENBURG[®] AERclens washer-disinfectors. EndoHigh[®] PAA is dosed via the dosing system integrated in the endoscope washer-disinfector at the beginning of the disinfection step. To achieve the mentioned activity spectrum, the following parameters must be ensured:

bactericidal, fungicidal, mycobactericidal, virucidal
and sporicidal activity against
C. difficile

13 ml/l (1.3 %), 35 °C,
5 min

For the automated cleaning step the use of EndoHigh[®] Detergent is mandatory. A possible carry-over of the cleaning solution of EndoHigh[®] Detergent into the disinfection step does not interfere with the disinfecting performance of EndoHigh[®] PAA. Use suitable dosing devices for dosing. The content of chlorides in the water for disinfection must not exceed 50 mg/l.

The EndoHigh[®] PAA solution has to be rinsed off completely. For avoiding water stains the use of deionised water in the final rinse is recommended. Only dose from the original container. Do not use as a concentrate - only use as a working solution. Do not mix with other products. Do not let the concentrate come in contact with organic material (e.g. oil, grease/fat, rubber, paper, general soiling) or rust or metal abrasion. Rinse out dosing system including suction hose with water before changing product.

Flexible endoscopes are of complex construction and are made of high quality materials. The materials are to some extent very sensitive and can easily be damaged. Particular care must be taken when reprocessing flexible endoscopes. The endoscopes must be visually examined after each cycle to check for any material changes.

The suitability of disinfecting programmes using EndoHigh® PAA in WASSENBURG® WD440, WD415, WD440 PT (pass through) and WD4200 endoscope washer-disinfectors is checked and confirmed. No damage to the endoscopes is to be anticipated when EndoHigh® PAA is used as directed and our recommendations are observed.

The following surface changes, which do not influence the functionality or safety, cannot be ruled out:

- Chromium-plated or nickel-plated brass surfaces (e.g. light items/fibre optics) with mechanical damage (e.g. scratches) might be altered. We recommend that these surfaces are protected with a chemically resistant/impermeable protective cover during reprocessing.
- Discolouration might be observed with aluminium, in particular black anodised aluminium, e.g. on eyepiece rings, operating parts and biopsy inserts, during the course of their working life. This may be caused by certain types of water, e.g. softened water. This is a cosmetic change. It does not affect the function of the endoscope. We recommend replacing the aluminium parts with plastic or plastic covered parts, like for example an aluminium cap protecting electronic contacts.
- Individual adhesive bonds may show alterations during their life cycle. Color changes (due to the bleaching effect of peracetic acid) without dissolving or detaching the adhesive connections are not a hygiene risk. In case of doubt, we recommend contacting the endoscope manufacturer.

The above-mentioned application parameters temperature, concentration and contact time are to be observed.

Reprocessing must comply with all applicable laws and regulations for medical devices and should be performed with appropriate validated processes. Please observe the reprocessing recommendations of the medical device manufacturers according to the requirements of the DIN EN ISO 17664. The instructions given by the manufacturer of the washer-disinfector are to be observed. For professional use only. The above-mentioned conditions of use must be strictly adhered to. Otherwise the guarantee may be invalidated in the case of damage. If you have any questions about EndoHigh® PAA, please contact Wassenburg Medical B.V., Tel: +31 (0)488 700 500, before using it.

Expert Reports

The disinfecting action has been confirmed by certification.

Technical Data

pH-value	2.7 (1.3 %, determined in deionised water, 20 °C)
Viscosity	< 10 mPa s (concentrate, 20 °C)
Density	approx. 1.1 g/cm ³ (20 °C)

Ingredients

Disinfecting active substances in 100 g:
11.5 g peracetic acid

CE-mark



EndoHigh® PAA complies with European guidelines for medical devices.

If a serious incident occurs with the product, report it to the manufacturer and the relevant national authority.

Storage information

Always store at a temperature between 0 °C and 25 °C. Keep away from sunlight. Store locked up. Usable for 15 months when stored as recommended. For expiry date refer to the stamp mark on the label behind the hourglass symbol ⌚. In-use shelf life: 4 weeks

Hazard and precautionary statements

For safety information see Safety Data Sheets. Dispose only when container is empty and closed. For disposal of product residues, refer to the Safety Data Sheet.

Distribution

Distributed by: Wassenburg Medical B.V., Industrieweg 11, NL-6662 PA Elst, The Netherlands,
Tel: +31 (0)488 700 500, info@wassenburgmedical.nl, www.wassenburgmedical.com

Manufacturing

Manufactured by: Chemische Fabrik Dr. Weigert GmbH & Co. KG, Mühlenhagen 85,
20539 Hamburg, Germany, Tel + 49 (0)40 7 89 60-0, Fax + 49 (0)40 7 89 60-120

With the above information, which is appropriate to the current knowledge we describe our product regarding possible safety necessities, but we do not involve any quality description or promise certain properties.