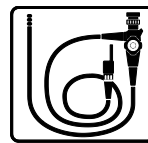




neodisher[®] Septo PAC



High-level disinfectant for
the automated reprocessing
of flexible endoscopes



Liquid concentrate

Fields of application:

- Disinfection of flexible endoscopes in endoscope washer disinfectors

Performance spectrum:

- Bactericidal, fungicidal, mycobactericidal, sporicidal (*C. difficile*) and virucidal activity confirmed by experts according to European standards
- In the cleaning step the detergent neodisher MediClean forte is recommended
- The automated reprocessing process with neodisher MediClean forte and neodisher Septo PAC complies with the requirements for disinfectants for disinfecting flexible endoscopes according to DIN EN ISO 15883-4.
- On the IHO¹ list of disinfectants

Special properties:

- Based on peracetic acid
- No activator necessary, just one component
- Rapid and comprehensive activity at 25 °C and at 35 °C
- The disinfecting activity has been tested according to EN 14885
- Corresponds to the requirements of EN 15883-4
- Excellent material compatibility – proved in several thousand reprocessing cycles – suitable for endoscopes of all leading manufacturers
- Free of aldehydes, formaldehyde and quaternary ammonium compounds

Application and dosage:

neodisher Septo PAC is used in washer disinfectors for flexible endoscopes. neodisher Septo PAC is dosed via the dosing system integrated in the endoscope washer disinfectant at the beginning of the disinfecting step. The content of chlorides in the water for the disinfection must not exceed 50 mg/l. The following parameters must be observed when using neodisher Septo PAC:

bactericidal,
fungicidal,
mycobactericidal,
virucidal, sporicidal
against *C. difficile*

10 ml/l (1.0 %), 25 °C, 10
min.
or
10 ml/l (1.0 %), 35 °C, 5 min.

- The above-mentioned application parameters temperature, concentration and contact time are to be observed.
- We recommend using the alkaline-enzymatic detergent neodisher MediClean forte in the cleaning step. The product neodisher MediClean forte is optimally matched with neodisher Septo PAC: A possible carry-over of neodisher MediClean forte solution into the disinfecting step does not lead to an inhibited disinfecting performance of neodisher Septo PAC.

Important notes on application:

Flexible endoscopes are intricate instruments 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 endoscope surfaces must be visually examined after each cycle to check for any material changes.

If applied according to the instructions of neodisher Septo PAC and if our recommendations are observed no damage to endoscopes is to be expected.

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 ducts) with mechanical damage (e.g. scratches) might be altered. In order to avoid this, we recommend covering it with a protective cap during reprocessing.
- Aluminium, especially black anodised aluminium, e.g. on ocular rings, controlling parts, biopsy inserts, can lose colour in the course of the operating life, which is caused solely by certain water qualities, e.g. softened water. This is a cosmetic change. The function of the endoscope is not inhibited by this. We recommend replacing the protective cap for the



neodisher® Septo PAC

electronic contacts made of aluminium with a protective cap with a plastic coating.

- 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 following types of endoscope washer disinfectors have been tested successfully by the manufacturers for use with neodisher Septo PAC:

- Wassenburg WD 440 (25 °C)
- BHT Innova E3, Innova E4, Innova E5 (25 °C und 35 °C)
- Belimed: WD 420 Series 99993..., 99994... and WD 425 Series 99998.... (from 2001 onwards), WD 430 (25 °C)
- Steelco EW1 and EW2 (25 °C und 35 °C)

Prior to the first application of neodisher Septo PAC the endoscope washer disinfectant manufacturer must be informed, in order to make slight changes to the endoscope washer disinfectant and/or the endoscope washer disinfectant program. This should be done via our neodisher Application Engineering department. Before using neodisher Septo PAC, check the compatibility of other endoscope washer disinfectants with our neodisher Application Engineering department.

- Reprocessing should comply with all ordinances pursuant to the regulations on medical devices and should be performed with appropriate validated processes.
- The neodisher Septo PAC working solution has to be rinsed off completely with water (preferably deionised water).
- 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.
- Rinse out dosing system including suction hose with water before changing product.
- Do not mix with organic material (e.g. oil, grease, rubber, paper, general soiling) or rust or metal abrasion.
- 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 disinfectant 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 event of an accident.

Experts' reports:

The disinfecting activity has been confirmed by certification. Experts' reports are available on request.

Technical data:

pH-value	3.0 (10 ml/l, determined in deionised water, 20 °C)
Viscosity	< 50 mPa s (concentrate, 20 °C)
Density	approx.. 1.1 g/cm ³ (20 °C)

Ingredients:

Active substances in 100 g:
15.0 g peracetic acid



neodisher Septo PAC 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. Usable for 1 year when stored as recommended. For expiry date refer to the stamp mark on the label behind the hourglass symbol. The shelf-life of the opened canister is 3 months.

Hazard and precautionary statements:

Observe the information sheet "Safety Recommendations for Handling Products Containing Peracetic Acid" available at www.drweigert.com under the category "Service/Downloads".

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

For further safety information see Safety Data Sheets.

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¹ Industrieverband Hygiene und Oberflächenschutz [German Association for Hygiene and Surface Protection]

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



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