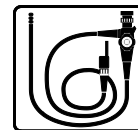




neodisher endo[®] SEPT PAC



Disinfectant for the
automated processing of
flexible endoscopes



Liquid concentrate

Fields of application:

Disinfection of flexible endoscopes in washer
disinfectors for endoscopes

Performance spectrum:

- Activity against bacteria (incl. MRSA, tuberculosis bacteria and *Helicobacter pylori*), fungi, mycobacteria, spores of *C. difficile* and viruses (incl. hepatitis A, B and C, HIV, rota viruses, noro viruses) confirmed by experts according to European standards
- The disinfecting efficacy has been tested and confirmed according to DIN EN 14885. Therefore, neodisher endo SEPT PAC complies with the requirements for disinfectants for disinfecting flexible endoscopes according to DIN EN ISO 15883-4
- The automated processing with neodisher endo CLEAN and neodisher endo SEPT PAC fulfils the requirements of the DIN EN ISO 15883-4 regarding a germ reduction of $> 9 \log_{10}$ -steps in the entire process.
- On the IHO¹ list of disinfectants

Special Properties:

- Suitable for endoscopes of all leading manufacturers
- Rapid and extensive activity at 25 °C and at 35 °C.
- Based on peracetic acid – free of aldehydes, formaldehyde and quaternary ammonium compounds.
- No activator necessary, only one component.

Application and dosage:

neodisher endo SEPT PAC is used in washer disinfectors for flexible endoscopes. neodisher endo SEPT PAC is dosed via the dosing system integrated in the endoscope washer disinfectant at the beginning of the disinfection step. The chloride content of the water must not exceed 50 mg/l. To achieve the stated performance spectrum, the following parameters are to be observed:

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.
- Use suitable dosing systems for dosing neodisher endo SEPT PAC.
- We recommend using the alkaline-enzymatic detergent neodisher endo CLEAN in the cleaning step.
- The products neodisher endo CLEAN and neodisher endo SEPT PAC are optimally matched: A possible carry-over of neodisher endo CLEAN solution into the disinfecting step does not lead to an inhibited disinfection performance of neodisher endo SEPT PAC.

Important notes on application:

Flexible endoscopes are intricate instruments and are made of high-quality materials. Some of these materials are very sensitive and can be easily damaged. Therefore, flexible endoscopes must be reprocessed with special care and visually checked for material changes after every cycle.

If applied according to the instructions of neodisher endo SEPT PAC and if our recommendations are observed no damage to endoscopes is to be expected. The following surface changes, which do not inhibit functionality and safety cannot be excluded:

- When using light ducts made of chromed or nickel-plated brass with a mechanically pre-damaged surface the brass matrix material can be changed. In order to avoid this, we recommend covering it with a protective cap during processing.
- 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

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of the endoscope is not inhibited by this. We recommend replacing the protective cap for the electronic contacts made of aluminium with a protective cap with a plastic coating.

- Individual adhesive bonds may show alterations during their life cycle. Colour 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 endoscope washer disinfectant types have been successfully tested by the manufacturer for the application of neodisher endo SEPT PAC:
 - Wassenburg WD 440 (at 25 °C)
 - BHT Innova E3, Innova E4, Innova E5 (at 25 °C and 35 °C)
 - Belimed: WD 420 series 99993..., 99994... and WD 425 series 99998... from 2001 (year of manufacture) onwards, WD 430 (at 25 °C)
 - MMM Uniclean PLE 3 (35 °C)

Prior to the first application of neodisher endo SEPT 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 the neodisher Application Engineering department. Please inquire about the compatibility of other washer disinfectants for flexible endoscopes at the neodisher Application Engineering Department before using neodisher endo SEPT PAC.

- The neodisher endo SEPT PAC solution has to be rinsed off completely with water (preferably with deionised water).
- For avoiding water stains the use of deionised water in the final rinse is recommended.
- Processing should comply with all ordinances pursuant to the regulations on medical devices and should be performed with appropriate validated processes.
- Please observe the processing 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.
- Rinse out dosing system including suction hose with water before changing product.
- Do not mix with other products.
- For professional use only!

- Only dose from factory-sealed containers.
- Do not use the product as a concentrate – only as a working solution.
- Do not let the concentrate come in contact with organic substances (e.g. oils, grease/fat, rubber, paper, general soiling) or with rust or metal abrasions.
- The stated application conditions must be observed. Otherwise, we cannot be held liable for any warranty claims in the case of damage.

Experts' reports:

The disinfecting activity has been tested and 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 endo SEPT 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. Canisters are usable for 1 year, drums for 2 years, 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 Advice 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 the Safety Data Sheet.

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For further safety information see Safety Data Sheets. These are available at www.drweigert.com under the category "Service/Downloads".

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¹ Robert-Koch-Institut / Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten
[Robert Koch Institute / German Association for the Control of Viral Diseases]

² Industrieverband Hygiene und Oberflächenschutz
[German Association for Hygiene and Surface Protection]

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