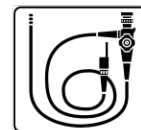




# neodisher endo<sup>®</sup> SEPT PAC



## High-level disinfectant for the automated reprocessing of flexible endoscopes



### Liquid concentrate

#### Fields of application:

- Disinfection of flexible endoscopes in washer disinfectors (WD-E)

#### Performance spectrum:

- Active against bacteria (incl. MRSA, tuberculosis bacteria and Helicobacter pylori), fungi, mycobacteria, spores (incl. C. difficile) and viruses (incl. hepatitis A, B and C, HIV, rota viruses, noro viruses)
- 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 reprocessing 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 steps in the entire process.
- On the list of the IHO for disinfectants with virucidal activity.

#### Special Properties:

- Suitable for endoscopes of all leading manufacturers.
- Rapid and extensive activity incl. sporicidal 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 (WD-E). neodisher endo SEPT PAC is dosed via the dosing system integrated in the 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, sporicidal and virucidal activity	10 ml/l (1.0 %), 25 °C, 10 min or 10 ml/l (1.0 %), 35 °C, 5 min
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- The above-mentioned application parameters, especially the combination of temperature and contact time are to be observed. Higher temperatures must be avoided!
- We recommend using the alkaline-enzymatic cleaning agent 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



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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 reprocessing.
- Aluminium, especially black anodized 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 electronic contacts made of aluminium with a protective cap with a plastic coating.
- The following washer disinfector 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)
  - Steelco EW 1 and EW2 (at 25 °C and 35 °C)

Prior to the first application of neodisher endo SEPT PAC the washer disinfector manufacturer must be informed, in order to make slight changes to the washer disinfector and/or the washer disinfector program. This should be done via the neodisher Application Technology Department. Please inquire about the compatibility of other washer disinfectors for flexible endoscopes at the neodisher Application Technology 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).

- Reprocessing should comply with all ordinances pursuant to the Medical Device Directive and should be performed with appropriate validated processes.
- Please observe the instrument manufacturer's recommendations for use according to the requirements of DIN EN ISO 17664.
- The instructions given by the manufacturer of the washer disinfector 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 trade units.
- 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/Listings:

The disinfecting activity has been tested and confirmed by certification. We will be pleased to provide certificates on request.

## Technical Data:

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

## Ingredients:

Disinfecting substances in 100 g:  
15.0 g peracetic acid

**CE-mark:** 

neodisher endo SEPT PAC conforms to the European directive 93/42/EEC, Annex I, concerning medical devices.

## Storage information:

Always store at a temperature between 0 and 5 °C. Do not expose to direct sunlight.

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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Usable for 1 year when stored as recommended.  
For expiry date refer to the stamp mark on the label behind the hourglass symbol ⌚.

## Hazard and precautionary statements:

Observe the information sheet "Safety Advice Peracetic Acid" available at [www.drweigert.com](http://www.drweigert.com) under the category "Service".

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

For further safety information see EC Safety Data Sheets. These are available at [www.drweigert.com](http://www.drweigert.com) under the category "Service".

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

<sup>2</sup>Industrieverband Hygiene und Oberflächenschutz  
[German Association for Hygiene and Surface Protection]

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