

## Reprocessing of Flexible Endoscopes Olympus Compatibility Statement

### 1. Reprocessing with the Olympus ETD System

Based on the Olympus Tokyo test reports and our practical experience, we herewith state that below listed automatic processes for endoscope reprocessing have been found compatible with Olympus flexible endoscopes. The processes have been tested for the following machines: ETD4, ETD3, ETD2, miniETD2, miniETD, ETD Double.

The hygienic efficacy of the ETD processes has been thoroughly tested by independent hygienic institutes. For details on test methods and results, please ask for the ETD certificates.

Product Name	Distributor	Major Ingredient
<b>ETD PAA Process with</b> - Olympus EndoDet - Olympus EndoDis - Olympus EndoAct	OLYMPUS	Peracetic Acid
<b>ETD GA Process with (*)</b> - Olympus CLEANER (CETD) - Olympus DISINFECTANT (DETD)	OLYMPUS	Glutaraldehyde

(\*) not for ETD Double

### REMARKS

It is known from our field experience that applying a combination of different processes for the reprocessing of endoscopes might accelerate damages to materials of the instruments. The above information is only valid for the exclusive influence of the mentioned process using the products named above.

## 2. Detergents for PreCleaning & Manual Reprocessing

For precleaning or manual endoscope cleaning purposes the use of suitable products with the following main characteristics shall be considered:

- Detergents classified by the manufacturer as Medical grade class I products
- Products with low foaming characteristics
- Products which are pH neutral
- Products mainly based on tenside or enzymatic functional compounds

Please consult your local detergent manufacturer if the above criteria are met.

## 3. Disinfectants for Manual Reprocessing

Based on the Olympus Tokyo test reports we herewith state that the below listed disinfectants for manual endoscope reprocessing have been found compatible with Olympus flexible endoscopes.

Product Name	Manufacturer/Distributor	Major Ingredient
CIDEX	Johnson & Johnson	Glutaraldehyde
CIDEX OPA <sup>(1)</sup> <sup>(2)</sup>	Johnson & Johnson	Ortho-phthalaldehyde
GIGASEPT	Schulke & Mayr	Glutaraldehyde + Formaldehyde
Nu-CIDEX	Johnson & Johnson	Peracetic acid
SEKUSEPT Aktiv	Ecolab GmbH & Co.	Peracetic acid
SEKUSEPT Forte S	Ecolab GmbH & Co.	Glutaraldehyde + Formaldehyde
SEKUSEPT Plus <sup>(2)</sup>	Ecolab GmbH & Co.	Glucoprotamine
SEKUSEPT Pulver +Aktivator	Ecolab GmbH & Co.	Peracetic acid
STERANIOS 2%	Anios	Glutaraldehyde

<sup>(1)</sup> Slight cosmetic changes may be observed ( transparency at tubes and glue / greyish colours).

<sup>(2)</sup> Products are compatible with Olympus miniature probes.

### REMARKS

- Compatibility for manual reprocessing only. Reprocessing process by WD (Washer Disinfector) is **not** involved.
- For chemicals not supplied by OLYMPUS, OLYMPUS is unable to make any recommendations in relation to the microbiological efficacy of a disinfection agent. An such request should be addressed to the chemical manufacturer or should be investigated and reviewed by the hospital's Infection Control Committee or equivalent authority in conjunction with other relevant hospital departments. The information

provided here only addresses the material and functional compatibility of OLYMPUS flexible endoscopes against these agents.

- The result of the compatibility test is closely related to the product lot that was supplied to Olympus. Any changes to the recipe of the agent that might be made afterwards by the chemical manufacturer may lead to different material compatibility results.
- The test result and conclusions are only valid for the protocol undertaken with the specific working condition of the agent according to its label instructions (i.e. concentration, temperature and contact time, etc.)
- It is known from our field experience that applying a combination of different processes for the reprocessing of endoscopes might accelerate damages to materials of the instruments. The above information is only valid for the exclusive influence of the products named above.

## NOTE

In the above list, no differentiation has been made between fully compatible and functionally compatible. Products listed can be either fully compatible or functionally compatible:

### - Fully Compatible

No functional and no cosmetic changes were observed with tested instruments.

### - Functionally Compatible

No functional changes were observed with tested instruments however some cosmetic changes (i.e. staining, discoloration, etc.) might be observed in use. For disinfectants not listed, Olympus is neither in a position to grant material compatibility nor to accept liability or guarantee claims.

## 4. Disinfectants not tested by Olympus

The products listed in the previous chapter (3. **Disinfectants for Manual Reprocessing**) have been tested by OLYMPUS for material compatibility. However, there is a broad range of products in the different European countries available and applied for manual endoscope reprocessing, which had not been tested by OLYMPUS for material compatibility with OLYMPUS flexible endoscopes. Based on customer feedback information, such products may be used for endoscope reprocessing purposes. It is up to the hospital service provider to decide for using such products on their own risk. OLYMPUS can not be liable in case of any material compatibility problems on OLYMPUS flexible endoscopes.

Product Name	Manufacturer / Distributor	Comment
SEKU EXTRA	Ecolab GmbH & Co.	Successor Product of Sukucid N which was formerly approved for compatibility by Olympus Tokyo
KORSOLEX extra	BODE	Aldehyde based disinfectant which is comparable to previous Kohrsolin recipes. There is no indication for critical feedback about material compatibility.

Product Name	Manufacturer / Distributor	Comment
GIGASEPT PA	Schuelke & Mayr	Peracetic acid based products! Applied by numerous users and no concrete evidence about compatibility concerns
Anioxyde 1000	Anios	
MEDDIS	MediChem	Product based on non-oxidising compounds. Only limited practical experience when used on OLYMPUS endoscopes

## REMARKS

- The above listed products were **not** proven by OLYMPUS for material compatibility aspects.
- OLYMPUS is unable to make any recommendations in relation to the microbiological efficacy of a disinfection agent. Any such request should be addressed to the chemical manufacturer or should be investigated and reviewed by the hospital's Infection Control Committee or equivalent authority in conjunction with other relevant hospital departments.
- It is important to acknowledge that detergents and disinfectants which are applied outside neutral pH range (pH < 6,5 and pH >7,5) may cause increased wear and tear to endoscopes. The manufacturer of such detergent or disinfectant should be asked for clear endoscope compatibility statement.
- The above listed overview is not representative for all products in the market and specified for endoscope reprocessing by their manufacturers or distributors.

## 5. Reprocessing with other washer-disinfectors

Washer-disinfectors which have passed the type and works testing requirements according to the EN ISO 15883 standards, should be equipped with suitable compliance statements, demonstrating sufficient reprocessing performance and sufficient material compatibility. According the EN ISO 15883-4, the manufacturer of such devices is obliged to provide statements about which reprocessing chemicals are compatible and which endoscopes can be reprocessed. Users shall ask the manufacturer of such products for written statements.

Olympus will be not able to evaluate such systems for material compatibility

Hamburg, July 2015

Product Management Endoscope Reprocessing Systems

Annette Rittich

Reinhard Blum