

# OLYMPUS

## FIELD SAFETY INFORMATION

Dear Customer,

Olympus has become aware of an issue that requires your attention. This letter pertains to the

### Dosing of EndoDis in ETD2 with PAA upgrade kit

In 2009 we informed you about the necessity of routine checks when operating ETD2 machines with our Information Letter to customers of ETD2, ETD2 Plus and mini ETD "Recommended daily routine checks on Endoscope Washers / Disinfectors ETD2, ETD2 Plus and miniETD" (October 19th 2009). Due to a recent incident with an ETD2 PAA, where EndoDis had not been dosed in the disinfection step, we would like to raise your attention again to these routine checks. Reduced or no disinfection increases the risk for a potential contamination of endoscopes and patients.

In order to assure a safe and reliable reprocessing, we request your assistance to verify the correct dosage of process-chemicals as follows:

- check your notes of canister replacements for EndoDis
    - if your notes show that in the recent past the replacement of canisters took place for every 20 cycles, no recheck is necessary
    - if your notes do not indicate a replacement every 20 cycles or you have difficulties in counting the cycles between the replacements, please perform the following test:
1. Make sure the EndoDis container has at least a fill level of 5 cm.
  2. Mark the fill level of the chemistry in the container with a black pen.
  3. Run five standard cycles of the ETD2 PAA. You can run these cycles in your normal operation while continuously reprocessing endoscopes.
  4. Mark the fill level of the canister.
  5. Measure the distance between the upper and the lower level.
  6. If the distance between the upper and the lower marking indicates a clear decrease of the fill level, the pump of your machine is installed correctly. No further action is necessary.

Canister	Required distance after 5 cycles
EndoDis	~ 3 cm

7. If you do not note any decrease of the fill level, immediately contact your Olympus service and do not operate the machine any longer.

Olympus regrets if the implementation of these measures might cause inconveniences and fully appreciates your prompt cooperation in addressing this situation. In case of any questions, please do not hesitate to contact your local Olympus partner who will be delighted to support or make the necessary arrangements.

Please return the completed reply form to

Olympus Subsidiary / Distributor {by end on [month]}  
Contact person xxxxxxxxx  
Address xxxxxxxxx

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Tel xxxxxxxxxxxxxxxx

Yours sincerely,

Enclosures:

- Appendix 1: Reply Form
- Appendix 2: Instruction on monitoring of chemical dosage in ETD2 with PAA upgrade kit
- Appendix 3: Check list for daily routine checks of correct dosage by the ETD2 with PAA upgrade kit

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## **REPLY FORM**

Olympus Subsidiary/Distributor  
[Dept/Attn]  
[Street No.]  
  
[ZIP City]

Date  
Ref No.  
EXT-xxx

**Field Safety Information: ETD2 with PAA Upgrade Kit**

Dear Sirs and Madams,

We herewith confirm the receipt of your customer letter. We will share this information with the relevant departments. If we do not note any decrease of chemistry, we will immediately contact the Olympus service and not operate the machine any longer.

Name \_\_\_\_\_

Hospital \_\_\_\_\_

Department \_\_\_\_\_

Street \_\_\_\_\_

Postal Code/ City \_\_\_\_\_

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Date                      Signature

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## Appendix 2: Instruction on monitoring of chemical dosage in ETD2 with PAA upgrade kit

The dosage system of ETD2 includes sensors, which comply with accuracy and safety requirements of former standards. They do not comply with recently released, more stringent EN 15883 standards. Therefore, the decrease of level of chemicals in the chemical containers should be verified regularly.

We recommend marking the chemical level of the disinfectant and detergent at the beginning of each working day. Alternatively, you can measure the weight of the container each working day and calculate the consumption of chemicals.

**If the level of chemicals remains unchanged, although the machine has been used, please call the Olympus technical service!**

Alternatively for the chemicals with opaque containers the following method can be used:

- Create a log book for each machine
- Note the date and time of exchange for each chemical container
- Take a note for each reprocessing cycle that has been successfully run. Please note the cycle not at the beginning of a cycle but at the end.
- Check the correct consumption of chemicals by adding up the number of cycles run since the last reprocessing cycle
- If a machine runs more than the allowed number of cycles between two replacements of the chemical container, please call the Olympus service

The machine uses the following quantities of chemicals per cycle and allows the following maximum number of reprocessing cycles per container:

Chemical	Content of container	Consumption per reprocessing cycle	Maximum cycles per container
Olympus Detergent EndoDet	4 Liters	65 ml	58-65*
Olympus Disinfectant Endodis	2,8 Liters	130 ml	20**
Olympus Activator EndoAct	4 Liters	130 ml	29-33*

\*A small quantity of chemicals can remain in the container.

\*\* Add. Consumption by daily refill of dosing system



**Appendix 3: Check list for daily routine checks for the correct dosage of process-chemicals for the ETD2 with PAA upgrade kit**

ETD Type: \_\_\_\_\_

Serial number: \_\_\_\_\_

**Inspection of Dosage System**

<b>Inspection</b>	<b>Result (ok/ not ok)</b>	<b>Measure</b>
Liquid level Detergent		
Liquid level Disinfectant		
Liquid level Activator (if ETD2 plus PAA)		
Comments		

\_\_\_\_\_

Place

\_\_\_\_\_

Date

\_\_\_\_\_

Signature of user

\_\_\_\_\_

Title