

# Safety Issues

## Background Information / Data to Consider:

Olympus created the OER-Pro because no one understands the intricacies of our endoscopes better than we do. Since the OER-Pro eliminates a significant number of steps in the manual cleaning process, you can overcome common user errors and provide faster turnaround times.

Because of our intimate knowledge of Olympus endoscope design, we can provide guaranteed material compatibility of our high level disinfectants and detergents. In addition, you can be assured that endoscopes repaired by Olympus maintain their reprocessing validation, this also includes our CPO, used and demo equipment. This is not the case for Olympus endoscopes repaired with third party components. This intimate knowledge and continuous component validation allow us to bring you efficiencies such as eliminating 7 of the 11 recommended manual cleaning steps.

The OER-Pro features also provide the following safety values:

- Optimizes infection control efforts
- Tracks scopes to patient, OER-Pro, and reprocessing technician
- Mitigates risk
- OER-Pro with the Acecide-C cartridge system minimizes staff exposure to chemicals

### The OER-Pro currently records the following:

- Serial Number / Endoscope ID
- AER ID
- Reprocessing Staff Member
- Errors
- Other details as shown on the left

### The OER-Pro with IN10 Reprocessing Management Module\*\*\* also records:

- Patient Name
- Medical Record Number
- Procedure Type
- Endoscopist

\*\*\*The IN10 Reprocessing Management Module (an additional product to be launched in early 2013) exceeds ALL of the documentation requirements noted in any of the new Guidelines.

The diagram shows the OLYMPUS OER-Pro interface with various data fields and labels. The interface is divided into several sections:

- Serial number of this equipment**: Points to the 'Serial No : xxxxxxxx' field.
- Total accumulated process count**: Points to the 'Total Count : xxxxxxxx' field.
- Year/Month/Day and Hour/Minute of the start of process**: Points to the 'Process Started: 2012/04/01 14:30' field.
- Year/Month/Day and Hour/Minute of the end of process**: Points to the 'Process Completed: 2012/04/01 15:00' field.
- Setting details**: Points to the 'Wash', 'Dis', 'Temp', 'Leak', and 'Alc' fields.
- Serial number of scope**: Points to the 'Scope SN: 0123456' field.
- Model name of scope**: Points to the 'Model name of scope' field.
- Serial number of scope (when two scopes were reprocessed)**: Points to the 'Scope SN: 0123456' field.
- Model name of scope (when two scopes were reprocessed)**: Points to the 'Model name of scope' field.
- User number**: Points to the 'User ID : 2222222' field.
- User name**: Points to the 'User name' field.
- User check columns**: Points to the 'Preclean', 'Tube', and 'MRC' check columns.

The interface also includes a 'Note:' section at the bottom.

# ALDAHOL High-Level Disinfectant

**Safety:** Ease of use & minimal staff exposure when changing cartridges (as opposed to pouring other liquid chemical germicides) as shown below:



## Step 1

Remove the empty cassette bottles from the disinfectant bottle drawer.

## Step 2

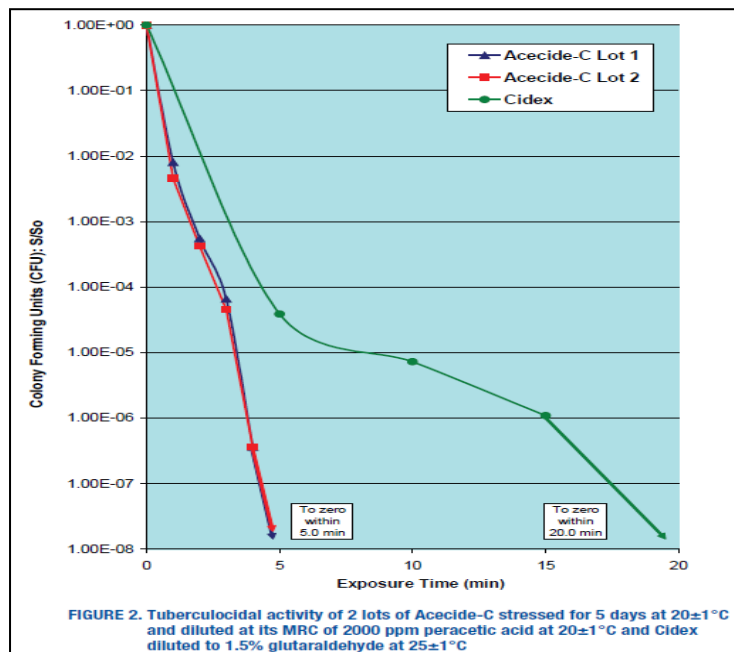
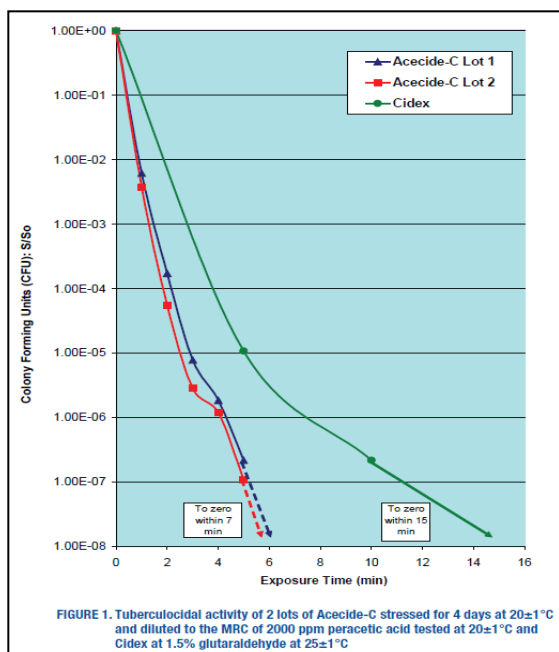
Hold the new disinfectant cassette bottles together and place them on the disinfectant bottle drawer so that the bottle with the purple cap is on the right.

## Step 3

Lift the disinfectant bottle drawer so that it is level, and insert it all the way. The buzzer should beep, the drawer should lock, and the disinfectant cassette bottles should open automatically.

Acecide-C is an aldehyde-free, liquid chemical germicide that provides an easier, safer, more efficient reprocessing solution – proven for material compatibility by Olympus for Olympus endoscopes.

**Superior Efficacy:** Faster tuberculocidal activity than Cidex as shown below. Refer to Acecide-C brochure for complete details:



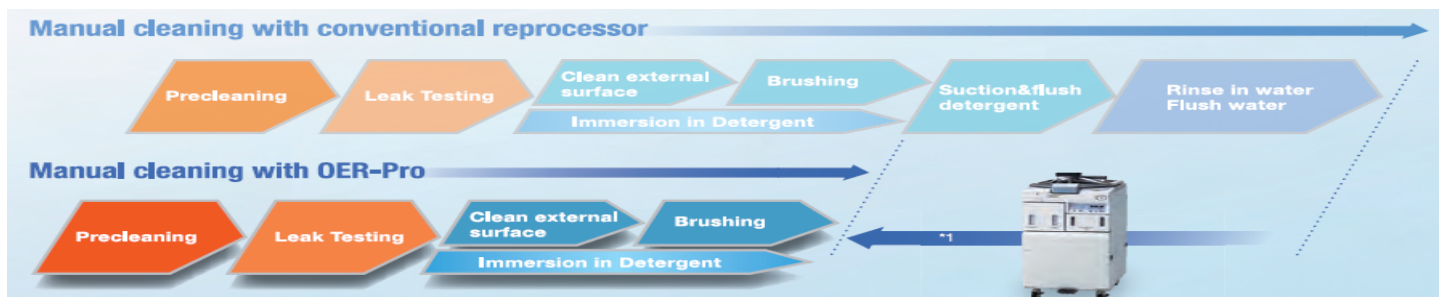
## ALDAHOL High-Level Disinfectant (Con't)

**Superior Efficacy:** Faster tuberculocidal activity than Cidex as shown below. Refer to Acecide-C brochure for complete details:

- Delivered in easy-to-handle cassette bottles that minimize staff exposure.
- Achieves high-level disinfection in 7 minutes resulting in a short, 26-minute OER-Pro cycle time.
- Validated by Olympus to maintain the exceptional performance you expect day after day.

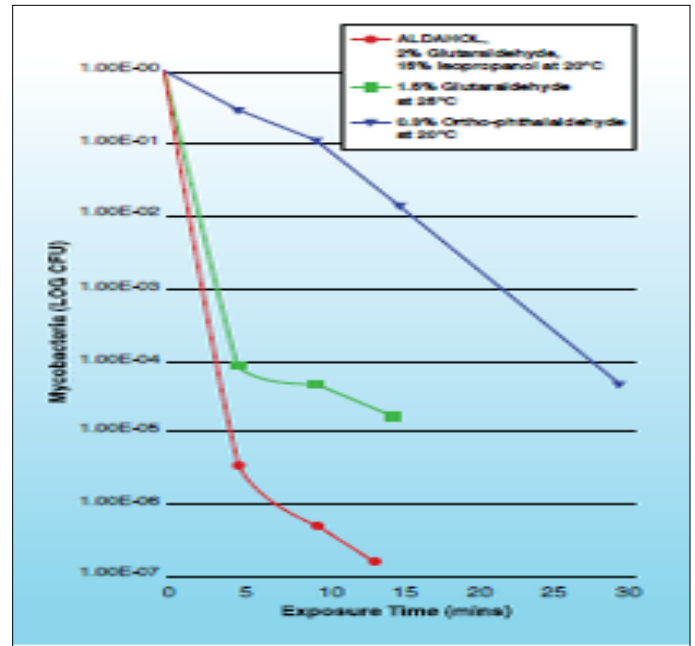
Features and Benefits	
1	Unique, easy-to-handle cassette bottles allow for quick and easy chemical loading while minimizing exposure to the disinfectant—enhancing safety for the user.
2	Fast acting PAA delivers high-level disinfection in 7 minutes resulting in a short 26-minute OER-Pro <sup>1</sup> cycle time.
3	Time-saving test strip verifies efficacy in just 13 seconds—changing from white to black for clear interpretation of results.
4	Convenient room-temperature (20°C) use protects equipment while saving on utility costs.
5	Only PAA available that has been validated for material compatibility with Olympus endoscopes by the endoscope manufacturer.

### Time Savings:



# ALDAHOL High-Level Disinfectant

ALDAHOL is the result of a groundbreaking scientific discovery. Scientists discovered that low concentrations of isopropanol greatly enhance the mycobactericidal activity of glutaraldehyde. ALDAHOL was created to provide fast-acting, room-temperature, high-level disinfection for reprocessing.



## HLD Kill-Rate Comparison

With a kill rate exceeding glutaraldehyde and OPA at the same time and temperature, you can ensure confident, efficient reprocessing with ALDAHOL.

### Features and Benefits:

- Fast Acting:** ALDAHOL is rapidly active against all vegetative bacteria, fungi, virus types, mycobacteria, and spore-forming bacteria. When used manually at just 10 minutes, it is the fastest high-level disinfectant on the market.
- Energy Efficient:** Used at room temperature (68 degrees F), ALDAHOL frees your facility from the time and expense of having to continuously heat chemicals, using less energy overall.
- Simple To Use:** ALDAHOL has a convenient 14-day maximum use life, and an easy-to-use liquid activator that changes ALDAHOL to red for visual confirmation. Additionally, it rinses easily from all surfaces.
- Widely Compatible:** Unlike some other aldehyde-based solutions, ALDAHOL is ideal for all Olympus and Gyrus ACMI flexible endoscopes.

## OER-Pro Service

**Preventative Maintenance (PM) Procedure:** The PM is a recommended service performed annually (or after 2500 machine cycles, whichever occurs first) that proactively replaces critical components. This 3-5 hour process is expertly performed by trained Olympus personnel. Components replaced include: Alcohol/Disinfectant pump, Disinfectant and Pump Heads, Silencer in compressor, Mesh filter and Hoses in disinfectant solution tank, Water leakage pump relief valve, and Ring gaskets on all internal connections.

**Disinfectant Change Procedure:** This service must be performed whenever a different formulation of Disinfectant Chemical is to be used (i.e. changing from Aldahol to Acecide-C). This 3 hour process is performed by trained Olympus personnel and consists of software programming changes, cleaning of disinfectant reservoir, testing of reprocessing cycle and customer instruction related to the disinfectant change.

**Full Service Agreement:** The Full Service Agreement is a comprehensive protection program that includes all needed PM and Disinfectant Change Procedures described above, and provides unlimited repairs for the term of the agreement, regardless of the cause of the damage. In addition, Full Service Agreement customer receive priority dispatch of field service personnel for the term of the agreement. When repairs are required on-site, a fully-trained Olympus Service representative will bring repairs within 2 days of customer notification.

- Includes ALL PMs and Disinfectant Change Procedures
- Maximize Up-Time & Minimize Unexpected Equipment Failure
- Expedited Response times for field service
- Olympus Quality Service to ensure proper parts installation
- Fixed Annual Service Costs

