

# Tristel<sup>TM</sup> Rinse Assure

## HTM 01-06 compliant water management system for rinse water in Endoscope Washer Disinfectors (EWD)

Tristel Rinse Assure provides a continuous supply of rinse water that is compliant with HTM 01-06\*, the key factors of which are outlined in this document.

Tristel Rinse Assure doses low levels of Tristel's proprietary chlorine dioxide chemistry into the water used during a EWD decontamination process, ensuring that all water is of the highest quality.



## HTM 01-06 - PART B: DESIGN AND INSTALLATION

Table 3 EWD water chemistry requirements

Application	Requirement
Initial flush	Hardness less than 200 mg/L CaCO <sub>3</sub>
Intermediate flush	Hardness less than 200 mg/L CaCO <sub>3</sub>
Water for diluting disinfectants and detergents	Hardness less than 50 mg/L CaCO <sub>3</sub>
Final rinse-water (see also Table 1 in HTM 01-06 Part E – 'Testing methods')	Hardness less than 50 mg/L CaCO <sub>3</sub> TOC less than 1 mg/L Conductivity less than 40 µS/cm, unless disinfectant added

Note: If any of the above parameters for the final rinse-water are above the stated limits, additional water analysis will be required to determine the source of the problem (for example, pH, chloride, heavy metals etc).

The criteria and parameter limitations for other contaminants including salts not listed in this Table should accord with the rolling revision of the WHO guidelines for drinking water quality. In light of the use of variable supply quality through the recently established national water grid, it is appropriate for providers to periodically discuss this issue with their water supplier.

Tests for **hardness** and **electrical conductivity** are detailed in HTM 01-06 Part E – 'Testing methods'.

**2.11** The nature and extent of treatment will depend in part on the quality of the local water supply. Therefore when a new installation is being planned, analysis of the water supply will provide a useful guide for the plant and equipment required to treat the water [...] and may include at least the following steps:

- water softeners;
- pre-filtration to remove larger particulate matter (this may require one or two filtration stages but the final stage should be with a filter that will retain particles of 5 µm or larger) (see Table 3);
- filtration through pre-filter and a bacteria-retentive filter (0.22 µm);
- water deionisation;
- RO;
- addition of non-toxic disinfectant.

**2.12** For filtration, the operating system may include:

- means to monitor the integrity of the filter or warn of failure (for example, measurement of pressure differentials);
- means to disinfect the filter and the downstream water distribution system at the start of the working day. In addition, self-disinfection should be set up on the EWD to occur using a timer during periods when the EWD is not used. This should preferably be by exposure to moist heat;
- means to maintain the filter with a constant flow of water (not left wet in static water);
- means to inhibit microbial growth in water in the storage and distribution system downstream of the filter;
- means to measure the addition of disinfectant, if used.

**2.16** Knowledge of the mains water characteristics supplied to endoscope decontamination unit can be very useful. In many modern hospitals the water may be supplied via a storage tank. It is possible that this tank could give rise to high bacterial number or high chlorine levels. If water treatment is planned for the endoscope unit these properties can be allowed for. In areas where the mains water is of good quality, and the supply to endoscopy is taken from the incoming main, only a limited treatment may be required to obtain the quality described in this document for final rinse water. To adopt this procedure would meet the requirements of Best Practice.

**2.26** Water used in the cleaning and disinfection of flexible endoscopes should have a chloride concentration between 0 and 120 mg/L chlorine to avoid the risk of corrosion. Chloride concentrations greater than 240 mg/L can cause pitting of some stainless steel and plastic components.

**2.27** Water used for the final rinse should have a chlorine level no higher than 10 mg/L. Chlorine levels exceeding this level should be reduced using a carbon filter. (In some EWDs, a chlorine compound is added to the final rinse-water to prevent microbial contamination.)

**2.29** For final rinse-water that contains a disinfectant, conductivity may be greater than 40 µS/cm. Guidance from the manufacturer will be required to ensure damage to flexible endoscopes does not occur with multiple use.

**2.29** Some EWDs incorporate a disinfectant that will have a chloride concentration greater than 120 mg/L. Assurance from the manufacturer should be obtained regarding materials compatibility, both for the EWD and the endoscopes in use.

**2.44** There are generally six methods of water treatment available for use on water supplies to be used in EWDs. These can be used as individual treatments or in combination:

- water softeners;
- water deionisers;
- distillation;
- RO;
- filtration;
- disinfectant addition.

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**2.61** When water is treated by filtration (for example, through a 0.22 µm filter to remove microbial contaminants), rigorous controls are needed to ensure that the system works effectively. This should include:

- either maintaining the pressure drop across the filter throughout its working life – a decrease in differential pressure being cause for rejection of the process cycle and a change of filter – or a bubble point test (see BS 1752, ISO 4793). In the event of concerns in this area, a service agent should be consulted;
- a continuous recirculation system for RO water supplies. For a bank of filters, intermittent chemical disinfection is appropriate to prevent a bioburden build-up;

- treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited either by use of elevated temperature (for example, greater than 60°C), filtration through a suitable fine filter or by ultraviolet irradiation (wavelength 260 ± 10 nm; >2 J/m<sup>2</sup>) or chemical biocide.

## Note

Ultraviolet irradiation will only kill planktonic microbes; it has little effect on biofilm.

**2.62** If a chlorine-based disinfectant is used, some providers are allowing a non-toxic disinfectant to be present in the final rinse-water (see Chapter 4 in HTM 01-06 Part C – 'Operational management'). Confirmation is required to show these chemicals, in the concentrations used, are not toxic to the patient. Residual chlorine remaining in a reprocessed endoscope may reduce the possibility of biofilm formation and growth of contaminants.

**2.82** The addition of a non-toxic biocide to the final rinse-water may help prevent the formation of biofilm.

## HTM 01-06 - PART C: OPERATIONAL MANAGEMENT

**3.1** EWDs vary from manufacturer to manufacturer, but all have a similar operating cycle. The aim of the process is to meet Essential Quality Requirements and render the reprocessed endoscope:

- free of pathogenic microorganisms;
- clean and free of detectable protein free of any chemical residue from the decontamination process other than the disinfectant added to the final rinse-water as part of a controlled process.

See Chapter 3 in HTM 01-06 Part A – 'Policy and management' for further details of Essential Quality Requirements.

**3.37 (8) Final rinse.** The removal of chemical disinfectant after the disinfection stage is important and should be achieved without compromising the microbial quality of the product. The final rinse should remove any traces of process chemicals to prevent them coming into contact with patient tissue except EWDs that add disinfectants to the final rinse-water that have been validated as compatible with patient safety.

**4.59** An exception to the guidance are EWDs where diluted disinfectant is added to the final rinse-water. The rinse-water will then not support bacterial growth. The concentration of the chemical in the final rinse should be non-toxic to humans.

**4.61** If disinfectant is added to the final rinse-water, the EWD manufacturer will provide information on the chemical levels expected.

## HTM 01-06 - PART E: TESTING METHODS

**1.4** EWDs are characterised by a chemical disinfection stage because the endoscopes to be processed will not withstand the high temperatures required for thermal disinfection. It is necessary to ensure that the disinfectant is removed from the endoscope before it is used on a patient; this is achieved by a post-disinfection rinsing stage. Some EWD process cycles are available that add disinfectant to the final rinse-water. The level of disinfectant at this stage should be shown to be non-toxic to patients. The microbiological control of this stage is of critical importance to the microbial status of the reprocessed endoscope. A number of additional tests are required to ensure that this aspect of the process is properly controlled.

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