

## Northern Ireland addendum to HTM 01-01 & HTM 01-06

### Document Number: NI/Testing Requirements/01 – (September 2016)

<b>Title</b>	Water testing requirements specific to Endoscope Washer Disinfectors (EWD), Washer Disinfectors (WD) & Reverse Osmosis (RO) water treatment plants - HTM 01-06 / HTM 01-01.  Microbiological testing of Endoscope Washer Disinfectors (EWD) and Controlled Environment Storage Cabinets (CESC)  Steam quality and clean steam analysis testing requirements to HTM 01-01	
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## Endoscope Washer Disinfectors (EWD)

Table 1.

Description of Test	Frequency of test	Result required	HTM 01-06	Comments
Conductivity	Weekly	<40µS* @ 25°C	Part E Testing methods section 6	Sample to be taken from the EWD chamber
Total hardness	Weekly	<50mg/litre	Part E Testing methods section 6	Sample to be taken from the EWD chamber
Total viable count	Weekly	<10 cfu/100ml (Incubate for 5 days at 28-32°C)	Part E Testing methods section 6 (Also see table 3 in HTM 01-06 Part B)	Sample to be taken from the EWD chamber
Environmental Mycobacteria	Quarterly	No recovery	Part E Testing methods section 6	Sample to be taken from the EWD chamber
Pseudomonas aeruginosa	Quarterly	Non detected in 100ml samples	Part E Testing methods section 6	Sample to be taken from the EWD chamber
Appearance	Annual	Clear, bright & colourless.	Part E Testing methods section 6	Sample to be taken from the EWD chamber
Total organic carbon	Annual	<1mg/litre	Part E Testing methods section 6	Sample to be taken from the EWD chamber.
pH	Annual	5.5 – 8.0	Part E Testing methods section 6	Sample to be taken from the EWD chamber
Bacterial endotoxin	Annual	<0.25EU/ml	BS EN ISO 15883 - 4 Section 4.5.3	Sample to be taken from the EWD chamber

## Washer Disinfectors – (Thermal)

### Other Processes

Table 2.

Description of Test	Frequency	Result required	HTM 01-01	Comments
Total hardness	Weekly	<210mg/litre – other processes	Part D Testing methods section 3 table 6	Sample to be taken from the water supply to the WD.
Chloride	Annual	<120mg;/litre – other processes	Part D Testing methods section 3 table 6	Sample to be taken from the water supply to the WD.
Silicate	Annual	<2.0mg/litre – other processes	Part D Testing methods section 3 table 6	Sample to be taken from the water supply to the WD.

**Final Rinse Water**

Table 3.

Description of Test	Frequency	Result required	HTM 01-01	Comments
Conductivity	Weekly	<30µS @ 25°C	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD
Total hardness	Weekly	<50mg/litre	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD
Appearance	Annual	Clear, bright & colourless.	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD
pH	Annual	5.5 – 8.0	Part D Testing methods section 3.100	Sample to be taken from the RO loop supplying the WD
Total dissolved solids	Annual	<4mg/100ml	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD
Chloride	Annual	<10mg/litre	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD
Heavy metal, determined as Lead, Ph (mg/L)	Annual	<10mg/litre	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD
Iron	Annual	<2mg/litre	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD
Phosphate	Annual	<0.2mg/litre	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD
Silicate	Annual	0.2mg/litre	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD
Bacterial endotoxin	Annual	<0.25EU/ml	Part D Testing methods section 3 table 6	Sample to be taken from the RO loop supplying the WD

## Reverse Osmosis water treatment plant

Table 4.

Description of Test	Frequency	Result required	HTM 01-01 / HTM 01-06	Comments
Appearance	Annual	Clear, bright & colourless.	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
pH	Annual	5.5 – 8.0	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Conductivity	Annual	<30µS @ 25°C	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Total hardness	Annual	<50mg/litre	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Chloride	Annual	<10mg/litre	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Heavy metal, determined as Lead, Ph (mg/L)	Annual	<10mg/litre	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Iron	Annual	<2mg/litre	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Phosphate	Annual	<0.2mg/litre	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Silicate (only required if the RO plant supplies thermal SSD washer disinfectors)	Annual	0.2mg/litre	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Total viable count	Annual	<10 cfu/100ml (Incubate for 5 days at 28-32°C)	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Total organic carbon	Annual	<1mg/litre	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop
Bacterial endotoxin	Annual	<0.25EU/ml	HTM 01-06 Part E Testing methods section 6	Sample to be taken from the RO loop

\*The results for the Reverse Osmosis water treatment plant (where applicable) may be superseded by the tests results obtained from the Washer Disinfectors.

## Microbiological Testing of Endoscope Washer Disinfectors

Table 5.

Description of Test	Frequency	Result required	Comments
EWD self-disinfection test <i>(only applies to chemically disinfected EWDs)</i>	Annual	No recovery	For EWDs that utilise chemical disinfection systems a microbiological test will be required. The test is designed to ensure that the self-disinfection cycle will disinfect the EWD. The EWD self-disinfection test is to be carried out using contaminated tubing containing <i>Pseudomonas aeruginosa</i> . Reference should also be made to HTM 01-06 Testing methods section 18
Microbiological test of disinfection efficacy	Annual	There should be not less than a log reduction (as noted below) for each of the following organisms.  <ul style="list-style-type: none"> <li>• <i>Pseudomonas aeruginosa</i> - <math>10^6</math></li> <li>• <i>Staphylococcus aureus</i> - <math>10^6</math></li> <li>• <i>Mycobacterium terrae</i> – <math>10^5</math></li> <li>• <i>Candida albicans</i> – <math>10^4</math></li> </ul>	Disinfection efficacy should be verified using the test method described in EN15883 (2009) part 4 section 4.4.2.4 This test should not be carried out until the adequacy of the WD self-disinfection cycle has been established.  The following 4 No: organisms are to be used for this test. <ul style="list-style-type: none"> <li>• <i>Pseudomonas aeruginosa</i></li> <li>• <i>Staphylococcus aureus</i></li> <li>• <i>Mycobacterium terrae</i></li> <li>• <i>Candida albicans</i></li> </ul>

## Microbiological Testing of Controlled Environment Storage Cabinets (CESC)

Table 6.

Description of Test	Frequency	Result required	Comments
Determine the contamination levels on the inside surfaces of the cabinet.	Quarterly	The contamination levels identified shall be less than 25 cfu/25 cm <sup>2</sup> . EN 16442 – Section 6.5	Reference should be ne made to EN 16442 – Section 6.5  NB: Pathogenic organisms to be identified.
Check that the cabinet is capable of maintaining the quality of the endoscopes.	Annual	The acceptable result for the test is <1 cfu/lumen. It is recommended that an alert is instigated where results are between 1 and 5 cfu/lumen, and the unit is removed from service where results are >5 cfu/ lumen.	Irradiated scope to be fitted to the endoscope drying cabinet and left for a period of no less than what was established during commissioning.
Evaluate airborne microbial contamination.	Annual	Reference should be made to BS EN 16442 Annex C	

**Steam Quality Tests – (Physical qualities)**

Table 7.

Description of Test	Frequency	HTM 01-01 Part C – Steam sterilisation	Result required
Dryness value <sup>1</sup>	Annual	Section 3.74	≥ 0.95
Non-condensable gasses <sup>1</sup>	Annual	Section 3.74	≤ 3.5%
Super heat <sup>1</sup>	Annual	Section 3.74	≤ 25°C

<sup>1</sup> Sterilisers supplied from a centralised steam boiler plant require the above tests to be carried out in triplicate during periods of minimum, average and peak demand.

**Clean Steam Analysis – (Particulate qualities)**

Specification for contaminants in condensate collected according to the method described in EN285

Table 8.

Description of Test	Frequency	HTM 01-01 Part C – Steam sterilisation	Result required
Appearance	Annual	Section 3.74	Clear & Colourless
Silicate	Annual	Section 3.74	≤0.1 mg/L
Heavy metals	Annual	Section 3.74	≤0.1 mg/L
Cadmium	Annual	Section 3.74	≤0.005 mg/L
Lead	Annual	Section 3.74	≤0.05 mg/L
Chloride	Annual	Section 3.74	≤0.1 mg/L
Phosphate	Annual	Section 3.74	≤0.1 mg/L
Conductivity	Annual	Section 3.74	≤35 µS/cm
pH	Annual	Section 3.74	5–7
Hardness	Annual	Section 3.74	≤0.02 mmol/L
Bacterial endotoxin	Annual	Section 3.74	≤0.25 EU/mL
Ammonium	Annual	Section 3.74	≤0.2 mg/L
Nitrate	Annual	Section 3.74	≤0.2 mg/L
Sulphate	Annual	Section 3.74	Ra
Oxidisable Sub	Annual	Section 3.74	Ra
Evap Residue	Annual	Section 3.74	≤30 mg/L
Calcium & magnesium	Annual	Section 3.74	Ra

Note: This table is a combination of tables A1 (re:corrosion) and A2 (re:load) in BS 17665 and BS EN 285.

Note: Ra signifies methods and reagents specified in the European Pharmacopoeia.