

Northern Ireland addendum to HTM 01-01

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Title	Periodic testing of Sterile Services Department (SSD) Washer Disinfectors (WD), Ultrasonic cleaners (UC) and Porous load sterilizers (PLS).	
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Washer Disinfectors – (Thermal)

Daily tests - User

Test No:	Description of test	HTM 01-01	Comments
1	Check spray arm rotation for free movement	n/a	As per manufacturer's instructions
2	Check spray arm nozzles for blockage (Pay particular attention to those fitted to carriages for cannulated instruments)	n/a	As per manufacturer's instructions
3	Remove and clean strainers and filters etc.	n/a	As per manufacturer's instructions
4	Ensure that sufficient additives is available and that the dosing system is functioning	n/a	As per manufacturer's instructions
5	Process challenge device	Part: D Washer disinfectors - section 2.279	Process challenge device to be approved by AE (D), AP (D) and User.

Weekly tests – User or CP (D)

Test No:	Description of test	HTM 01-01	Comments
1	Weekly safety check	Part: D Washer disinfectors - section 2.66	
2	Carry out daily tests	Table 3	
3	Water hardness (all process stages)	Part: D Washer disinfectors - section 3.7	Reference should also be made to Document Number: NI/Testing Requirements/01 – (September 2016)
4	Water conductivity (final rinse stage)	Part: D Washer disinfectors - section 3.106	Reference should also be made to Document Number: NI/Testing Requirements/01 – (September 2016)
5	Automatic control test	Part: D Washer disinfectors - section 2.294	Every cycle available to the User

Quarterly tests –CP (D)

Test No:	Description of test	HTM 01-01	Comments
1	Weekly safety checks	Part: D Washer disinfectors - Section 2.66	
2	Automatic control test	Part: D Washer disinfectors - Section 2.294	Every cycle available to the User
3	Verification of calibration of WD instruments	Part: D Washer disinfectors - Section 2.181	Temperature - $\pm 2^{\circ}\text{C}$ Pressure - $\pm 100\text{mbar}$ Conductivity - $\pm 5\mu\text{S}$ To include independent monitoring system(s)
4	Thermometric test for thermal disinfection Thermal disinfection test	Part: D Washer disinfectors - Section 2.281 to 2.293	Periodic test to be carried out once on each loading condition or as per agreed AE (D) testing schedule.
5	Cleaning efficacy test:	Part: D Washer disinfectors - Section 2.30	Periodic test: Load carrier and Reference load – <i>test to be carried out once using loading condition as per agreed AE (D) testing schedule.</i> Test soil used must meet requirements of ISO/TS 15883-5, Annex N or equivalent. NB: Anaesthetic accessories require ISO/TS 15883-5, Annex O A minimum of 30 minutes to a maximum of 2 hours drying time (for applied test soil) is required for this test.

Annual tests –CP (D)

Test No:	Description of test	HTM 01-01	Comments
1	Yearly safety checks	Part: D Washer disinfectors - Section 2.68	
2	Automatic control test	Part: D Washer disinfectors - Section 2.294	Every cycle available to the User
3	Verification of calibration of WD instruments	Part: D Washer disinfectors - Section 2.181	Temperature - $\pm 2^{\circ}\text{C}$ Pressure - $\pm 100\text{mbar}$ Conductivity - $\pm 5\mu\text{S}$ To include independent monitoring system(s)
4	Water system	Part: D Washer disinfectors - Section 3.59	Reference should also be made to Document Number: NI/Testing Requirements/01 – (September 2016)
5	Drainage:	Part: D Washer disinfectors -	

Test No:	Description of test	HTM 01-01	Comments
	<ul style="list-style-type: none"> - Free draining - Efficacy of discharge through the trap 	Section 2.83 Section 2.88	
6	Door and door interlocks <ul style="list-style-type: none"> - Cycle start interlocks - In-cycle interlocks - Failed cycle interlocks - On sensor failure 	Part: D Washer disinfectors - Section 2.132 Section 2.136 Section 2.151 Section 2.144	
7	Fault indication on sensor failure	Part: D Washer disinfectors - Section 2.154	To be carried out on each sensor fitted to the WD.
8	Water vapour discharge test	Part: D Washer disinfectors - Section 2.173	By visual examination
9	Chemical additive dosing tests: <ul style="list-style-type: none"> - Reproducibility of volume admitted. - Low level detection 	Part: D Washer disinfectors - Section 2.159 Section 2.168	Requirements of BS EN ISO 15883-2, 4.1.6 to be met ($\pm 5\%$)
10	Load carriers	Part: D Washer disinfectors - Section 2.183	
11	Air quality	Part: D Washer disinfectors - Section 2.217	Due to the difficulties involved in conducting this test, a copy of the test certificate included with the hepa filter should be included in the test report.
12	Cleaning efficacy test:	Part: D Washer disinfectors - Section 2.30	Periodic test: Load carrier and Reference load <i>– test to be carried out once using loading condition as per agreed AE (D) testing schedule.</i> Test soil used must meet requirements of ISO/TS 15883-5, Annex N or equivalent NB: Anaesthetic accessories require ISO/TS 15883-5, Annex O A minimum of 30 minutes to a maximum of 2 hours drying time (for applied test soil) is required for this test.
13	Over temperature cut out test	Part: D Washer disinfectors - Section 2.202	Advice should be sought from the WD manufacturer as to how this test should be conducted.
14	Thermometric test for thermal disinfection <ul style="list-style-type: none"> - Thermal disinfection test 	Part: D Washer disinfectors - Section 2.281 – 2.293	Periodic test to be carried out once on each loading condition or as per agreed AE (D) testing schedule.
15	Load dryness test	Part: D Washer disinfectors - Section 2.57	May be carried out on completion of the automatic control test
16	Process residue test	Part: D Washer disinfectors -	Test to be carried out using twice the normal dose of chemical

Test No:	Description of test	HTM 01-01	Comments
		Section 2.49 Part: D Washer disinfectors - Section 2.211	additive. Chemical manufacturer to provide safe working limits for this test. Final rinse water & simulated product to be tested.

Ultrasonic Cleaners

Daily tests - User

Test No:	Description of test	HTM 01-01	Comments
1	Remove and clean strainers or filters	Part: D Washer disinfectors - Section 2.303	As per manufacturer's instructions

Weekly tests – User or CP (D)

Test No:	Description of test	HTM 01-01	Comments
1	Carry out the daily test	Part: D Washer disinfectors - Section 2.303	As per manufacturer's instructions
2	Weekly safety checks	Part: D Washer disinfectors - Section 2.66	
3	Automatic Control Test	Part: D Washer disinfectors - Section 2.294	Every cycle available to the User
4	Cleaning efficacy by residual soil	Part: D Washer disinfectors - Section 2.268	Visual inspection

Quarterly tests – CP (D)

Test No:	Description of test	HTM 01-01	Comments
1	Weekly safety checks	Part: D Washer disinfectors - Section 2.66	
2	Automatic Control Test	Part: D Washer disinfectors - Section 2.294	Every cycle available to the User
3	Verification of calibration	Part: D Washer disinfectors - Section 2.181	Temperature - $\pm 2^{\circ}\text{C}$ Pressure - $\pm 100\text{mbar}$
4	Cleaning efficacy with test soil	Part: D Washer disinfectors - Section 2.231	Periodic test: Load carrier and Reference load – test to be carried out once using loading condition as per agreed AE (D) testing schedule. Test soil used must meet requirements of ISO/TS 15883-5, Annex N or equivalent

Annual tests – CP (D)

Test No:	Description of test	HTM 01-01	Comments
1	Automatic Control Test	Part: D Washer disinfectors - Section 2.304	Every cycle available to the User
2	Verification of calibration	Part: D Washer disinfectors - Section 2.181	Temperature - $\pm 2^{\circ}\text{C}$ Pressure - $\pm 100\text{mbar}$
3	Chamber walls temperature (if applicable)	Part: D Washer disinfectors - Section 2.187	
4	Chemical additive dosing tests: - Reproducibility of volume admitted. - Low level detection	Part: D Washer disinfectors - Section 2.159 Section 2.168	Requirements of BS EN ISO 15883-2, 4.1.6 to be met ($\pm 5\%$)
5	Cleaning efficacy with test soil	Part: D Washer disinfectors - Section 2.231	Periodic test: Load carrier and Reference load – test to be carried out once using loading condition as per agreed AE (D) testing schedule. Test soil used must meet requirements of ISO/TS 15883-5, Annex N or equivalent
6	Door and door interlocks - Cycle start interlocks - In-cycle interlocks - Door opening force - On sensor failure	Part: D Washer disinfectors - Section 2.132 Section 2.136 Section 2.146 Section 2.144	
7	Load carriers	Part: D Washer disinfectors - Section 2.183	
8	Load dryness	Part: D Washer disinfectors - Section 2.57	May be carried out on completion of the automatic control test
9	Over temperature cut out test	Part: D Washer disinfectors - Section 2.202	Advice should be sought from the WD manufacturer as to how this test should be conducted.
10	Test for ultrasonic activity	Part: D Washer disinfectors - Section 2.305	
11	Water hardness	Part: D Washer disinfectors - Section 3.7	Manufacturer to specify water hardness limits.
12	Water over flow test	Part: D Washer disinfectors - Table 4	As per manufacturer's instructions
13	Water supply temperature	Part: D Washer disinfectors - Section 3.82	
14	Volume of water used per stage	Part: D Washer disinfectors - Section 2.124	

Test No:	Description of test	HTM 01-01	Comments
15	Drainage: - Free draining	Part: D Washer disinfectors - Section 1.187 & 2.83	

Porous load sterilizers

Daily tests - User

Test No:	Description of test	HTM 01-01	Comments
1	Bowie-Dick test for steam penetration	Part: C Steam sterilisation - Section 1.40 and 2.80	Test pack must conform to EN ISO 11140-4.

Weekly tests – CP (D)

Test No:	Description of test	HTM 01-01	Comments
1	Weekly safety checks	Part: C Steam sterilisation - Section 2.104	
2	Air leakage test	Part: C Steam sterilisation - Section 2.69	
3	Air detector function test <i>To be carried out on the cycle with the longest sterilising hold time.</i>	Part: C Steam sterilisation - Section 2.71	
4	Automatic control test	Part: C Steam sterilisation - Section 2.60	To be carried out on each cycle available for use by the User
5	Bowie-Dick test for steam penetration <i>(Only required if not already carried out by the User - 'Daily tests – User')</i>	Part: C Steam sterilisation - Section 1.40 & 2.80	Test pack must conform to EN ISO 11140-4

Quarterly tests – CP (D)

Test No:	Description of test	HTM 01-01	Comments
1	Weekly safety checks	Part: C Steam sterilisation - Section 2.104	
2	Air leakage test	Part: C Steam sterilisation - Section 2.69	
3	Air leakage test (temperature and pressure sensors connected)	Part: C Steam sterilisation - Section 2.69	
4	Automatic control test	Part: C Steam sterilisation - Section 2.60	To be carried out on each cycle available for use by the User.

Test No:	Description of test	HTM 01-01	Comments
5	Verification of calibration of sterilizer instruments*	Part: C Steam sterilisation - Table 4	Temperature - $\pm 1^{\circ}\text{C}$ Pressure - $\pm 50\text{mbar}$ To include independent monitoring system(s)
6	Thermometric test for a small load*	Part: C Steam sterilisation - Section 2.73	Total of 7 No: thermocouples to be used for this test. <ul style="list-style-type: none"> 5 No: thermocouples to be placed within the standard test pack at the locations indicated in figure 1. 1 No: thermocouple to be placed in the drain of the sterilizer. 1 No: thermocouple placed in free space above test pack.
7	Air leakage test (sensors removed)	Part: C Steam sterilisation - Section 2.69	
8	Air detector function test <i>To be carried out on the cycle with the longest sterilising hold time.</i>	Part: C Steam sterilisation - Section 2.71	
9	Bowie-Dick test for steam penetration	Part: C Steam sterilisation - Section 1.40 & 2.80	Test pack must conform to EN ISO 11140-4

*May be carried out simultaneously with the preceding test.

Annual tests – CP (D)

Test No:	Description of test	HTM 01-01	Comments
1	Yearly safety checks	Part: C Steam sterilisation - Section 2.105	
2	Non-condensable gas test	Part: C Steam sterilisation - Section 3.29	Reference should also be made to Document Number: NI/Testing Requirements/01 – (September 2016)
3	Steam superheat test	Part: C Steam sterilisation - Section 3.223	Reference should also be made to Document Number: NI/Testing Requirements/01 – (September 2016)
4	Steam dryness test	Part C – Steam sterilisation - Section 3.233	Reference should also be made to Document Number: NI/Testing Requirements/01 – (September 2016)
5	Steam chemical purity tests	Part: C Steam sterilisation - Section 3.295	Reference should also be made to Document Number: NI/Testing Requirements/01 – (September 2016)
6	Air leakage test	Part: C Steam sterilisation - Section 2.69	

Test No:	Description of test	HTM 01-01	Comments
7	Air leakage test (temperature and pressure sensors connected)	Part: C Steam sterilisation - Section 2.69	
8	Automatic control test	Part: C Steam sterilisation - Section 2.60	To be carried out on each cycle available for use by the User.
9	Verification of calibration of sterilizer instruments*	Part: C Steam sterilisation - Table 4	Temperature - $\pm 1^{\circ}\text{C}$ Pressure - $\pm 50\text{mbar}$ To include independent monitoring system(s)
10	Air detector performance test for a small load <i>To be carried out on the cycle with the longest sterilising hold time.</i>	Part: C Steam sterilisation - Table 4 & Section 2.71	Total of 7 No: thermocouples to be used for this test. <ul style="list-style-type: none"> • 5 No: thermocouples to be placed within the standard test pack at the locations indicated in figure 1. • 1 No: thermocouple to be placed in the drain of the sterilizer. • 1 No: thermocouple placed in free space above test pack.
11	Air detector performance test for a full load <i>To be carried out on the cycle with the longest sterilising hold time.</i> NB: Additional tests may be required by enabling/disabling the air detector to demonstrate functionality of the air detector settings.	Part: C Steam sterilisation - Table 4 & Section 2.71	Total of 7 No: thermocouples to be used for this test. <ul style="list-style-type: none"> • 5 No: thermocouples to be placed within the standard test pack at the locations indicated in figure 1. • 1 No: thermocouple to be placed in the drain of the sterilizer. • 1 No: thermocouple placed under the top sheet of the test pack.
12	Thermometric test for a small load*	Part: C Steam sterilisation - Section 2.73	Total of 7 No: thermocouples to be used for this test. <ul style="list-style-type: none"> • 5 No: thermocouples to be placed within the standard test pack at the locations indicated in figure 1. • 1 No: thermocouple to be placed in the drain of the sterilizer. • 1 No: thermocouple placed in free space above test pack.
12a	Bowie-Dick test for steam penetration (thermometric test).	Part: C Steam sterilisation - Table 2 Section 1.40 Section 2.80 DoH requirement	Thermometric temperature within the test pack to be $134 - 137^{\circ}\text{C}$ for not less than 3.3 and not more than 3.5 minutes Total of 7 No: thermocouples to be used for this test. <ul style="list-style-type: none"> • 5 No: thermocouples to be placed within the standard test pack at the locations indicated in figure 1. • 1 No: thermocouple to be

Test No:	Description of test	HTM 01-01	Comments
			placed in the drain of the sterilizer. <ul style="list-style-type: none"> 1 No: thermocouple placed in free space above test pack.
13	Thermometric test for a full load.	Part: C Steam sterilisation - Section 2.74	Total of 7 No: thermocouples to be used for this test. <ul style="list-style-type: none"> 5 No: thermocouples to be placed within the standard test pack at the locations indicated in figure 1. 1 No: thermocouple to be placed in the drain of the sterilizer. 1 No: thermocouple placed under the top sheet of the test pack.
13a	Load dryness test for a metal load (See BN EN 285)	N/A	Only required if deemed necessary by the Designated User to investigate wet loads.
14	Test for PRQ as required by the User. <i>NB: Must be carried out using a test load that represents normal production loads processed within the department</i>	Part: C Steam sterilisation - Table 4 & 2.26	A minimum of 12 No: thermocouples to be employed for this test.
15	Air leakage test (sensors removed)	Part: C Steam sterilisation - Section 2.69	
16	Air detector function test. <i>To be carried out on the cycle with the longest sterilising hold time.</i>	Part: C Steam sterilisation - Section 2.71	
17	Bowie-Dick test for steam penetration	Part: C Steam sterilisation - Section 1.40 & 2.80	Test pack must conform to EN ISO 11140-4
18	Hollow load test	Part: C Steam sterilisation - Section 2.81	This is a test for steam penetration into (a) medical device(s) containing lumens.

*May be carried out simultaneously with the preceding test.

At the Frequency defined by the manufacturer.

Test No:	Description of test	HTM 01-01	Comments
1	Dynamic pressure test	Part: C Steam sterilisation - Section 2.83	Only required if damage is being caused to the instrument tray wrap(s). Advice should be sought from the sterilizer manufacturer on how to conduct this test.

