



Scottish Health Technical Memorandum 2010

(Part 6 of 6)

Testing and validation protocols

Sterilization

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Contents

1. **Sample log-book for porous load sterilizers.** *page 3*
2. **Procedures for the procurement, validation, revalidation and operational management of sterilization.** *page 17*

NOTE: We acknowledge the support of Scottish Healthcare Supplies in providing the Test Forms. Complete Test Log books containing the Forms are available from Scottish Healthcare Supplies, Trinity Park House, South Trinity Road, Edinburgh, EH5 3SH. Telephone 0131 552 6255. The Forms marked Sample Copy are copyright of Scottish Healthcare Supplies.

1. Sample log-book for porous load sterilizers.

Schedule of periodic tests

Log book report(s) periodic tests for porous load

		SHTM 2010 Ref. Part 3
User / operator	Daily Test	
	<ol style="list-style-type: none"> 1. Warm Up Cycle 2. Bowie-Dick test for steam penetration 	13.39
Test Person	Weekly tests	
	<ol style="list-style-type: none"> 1. Weekly safety checks 2. Vacuum leak test 3. Air detector function test 4. Automatic control test 5. Bowie-Dick test steam penetration* 	5.7 11.2 11.60 12.1 13.39
Test Person	Quarterly tests	
	<ol style="list-style-type: none"> 1. Weekly safety checks 2. Vacuum leak test 3. Vacuum leak test (temperature and pressure sensor connected) 4. Automatic control test 5. Verification of calibration of sterilizer instruments* 6. Thermometric test for a small load* 7. Vacuum leak test (sensors removed) 8. Air detector function test 9. Bowie-Dick test for stream penetration 	5.7 11.2 11.2 12.1 12.2 13.7 11.2 11.60 13.39
Test Person	Yearly and revalidation tests	
	<ol style="list-style-type: none"> 1. Yearly safety checks 2. Steam, non-condensable gas test** 3. Steam superheat test** 4. Steam dryness test** 5. Vacuum leak test 6. Vacuum leak test (temperature and pressure sensors connected) 7. Automatic control test 8. Verification of calibration of sterilizer instruments* 9. Air detector performance test for a small load 10. Air detector performance test for a full load 11. Thermometric test for a small load 12. Tests for performance requalification as required by the user 13. Vacuum leak test (sensors removed) 14. Air detector function test 15. Bowie-Dick test for steam penetration 	5.8 9.4 9.20 9.30 11.2 11.2 12.1 12.2 11.45 11.53 13.7 8.64 11.2 11.60 13.39
Test Person	Performance requalification test	
	<ol style="list-style-type: none"> 1. Performance Requalification 	8.64

* May be done at the same time as the preceding test

** Subject to agreement between the User and Authorised person these test may be omitted providing there is no evidence of a steam quality problem.



POROUS LOAD STERILIZERS									
INSTALLATION RECORD						Date		completed	
Client			Department			Date of Tests			
Sterilizer manufacturer			Serial number			Plant reference number			
Type test file reference			Date						
Task		Schedule Reference				Result		Initial	
Preliminary checks completed (3.14)									
Electrical checks (3.15)									
Functional checks (3.16)									
Installation checks (3.6)			Results						
			Steam	Water	Compressed air	Drainage	Ventilation	Electrical	
Pressure									
Pressure drop all services operating									
Flow rates are adequate									
Drains effectively remove effluent when all sterilizers are operating									
Task		Cycle No		Start time		Results			
Vacuum leak test (11.2)						leakage per/min		Pass / Fail	
Automatic control test (12.1)								Pass / Fail	
Automatic control test (12.1)			Insert data from each automatic control test						
Air Removal	Negative pulsing					Positive pulsing			
	Cycle	Pulses			Pulses		Pulses		
	Start time	Duration	Number	Pressure		Duration	Number	Pressure	
				Minimum	Maximum			Minimum	Maximum
Works tests				kPa	kPa			kPa	kPa
Installation				kPa	kPa			kPa	kPa
Sterilizing		Holding Time							
		Duration	Recorder				Indicators		
				Temperature		Pressure		Temperature	Pressure
				Minimum	Maximum	Minimum	Maximum	Maximum	Maximum
Works Tests				°C	°C	kPa	kPa	°C	kPa
Installation				°C	°C	kPa	kPa	°C	kPa
Drying & Vacuum break	Cycle	Drying					Vacuum break		
	Finish Time	Duration	Pressure		Temperature		Duration		
Works tests				kPa	°C				
Installation				kPa	°C				
Verification of calibration sterilizer instruments (12.2)									
		Measured			Recorder Error			Indicator Error	
Chamber temperature		°C			°C			°C	
Chamber pressure		kPa			kPa			kPa	
Jacket pressure		kPa			kPa			kPa	
Holding timer setting		Set.....Mins.....Secs.....			Error.....				
Contractor									
The sterilizer and its installation have been checked for safety and for compliance with the specification (schedule reference.....) and they have been found to be satisfactory									
Contractor signature Print name Date									

Note:- The holding time is deemed to start when the chamber temperature attains the pre-set sterilizing temperature



POROUS LOAD STERILIZERS						Sheet 1 of 3			
COMMISSIONING RECORD						Week No.....			
Plant reference number.....				Validation file reference.....					
Date of tests.....				Sterilizer serial number.....					
Task		Schedule Reference			Result		Initial		
Preliminary checks completed (3.14)									
Electrical checks (3.15)									
Functional checks (3.16)									
Installation checks (3.6)		Results (3.6)							
		Steam	Water	Compressed air	Drainage	Ventilation			
Pressure									
Pressure drop all services operating									
Flow rates are adequate									
Drains effectively remove effluent when all sterilizers are operating									
Steam tests		Schedule Reference			Result		Initial		
NCG (9.4)									
Superheat (9.20)									
Dryness (9.30)									
		Cycle number							
Vacuum leak test * (11.2)					Leakage per minute				
Vacuum leak test * (11.2) (with sensors)					Leakage per minute				
Automatic control test (12.1)									
Air detector test (small load) * (11.45)					Leakage per minute				
Air detector test (full load) (11.53)					Leakage per minute				
Small load test (13.7)									
Load dryness test (13.25)					% gain in mass				
Full load test (13.15)									
Load dryness test (13.25)					% gain in mass				
Sound power test (10.1)									
Vacuum leak test * (11.2) (with sensors removed)					Leakage per minute				
Air detector function test * (11.60)					Setting:°C / Leakage per minute				
Bowie & Dick test * (13.39)					Type of test pack.....				
Automatic control test (12.1)				Insert data from each automatic control test					
Air Removal	Cycle	Negative pulsing				Positive pulsing			
		Start time	Duration	Pulses		Duration	Number	Pulses	
				Pressure				Pressure	
				Minimum	Maximum			Minimum	Maximum
Commissioning			kPa	kPa			kPa	kPa	
Works			kPa	kPa			kPa	kPa	
Sterilizing	Duration	Holding Time							
		Recorder				Indicators			
		Temperature		Pressure		Temperature	Pressure		
		Minimum	Maximum	Minimum	Maximum	Maximum	Maximum	Maximum	
Commissioning		°C	°C	kPa	kPa	°C	kPa		
Works		°C	°C	kPa	kPa	°C	kPa		
Drying & Vacuum break	Cycle	Drying					Vacuum break		
	Finish Time	Duration	Pressure	Temperature		Duration			
Validation			kPa	°C					
Quarterly			kPa	°C					

Note:- The holding time is deemed to start when the chamber temperature attains the pre-set sterilizing temperature



POROUS LOAD STERILIZERS				Sheet 2 of 3		
COMMISSIONING RECORD				Week No.....		
Plant reference			Serial number			
Calibration						
			File reference.....			
Test instruments			Calibration date due			
Verification of the calibration of the sterilizer instruments						
	Measured	Recorder error		Indicator error		
		Works	Commissioning	Works	Commissioning	
Jacket pressure	kPa	kPa	kPa	kPa	kPa	
Chamber pressure	kPa	kPa	kPa	kPa	kPa	
Chamber temperature °C	°C	°C	°C	°C	°C	
Time min,sec						
Small load test						
Insert data from each small load test						
Readings to be noted when:-						
a. drain/vent temperature attains the sterilizing temperature b. the centre of the standard test pack attains the sterilizing temperature c. when the vent/drain temperature falls below the sterilizing temperature						
Small load test	a		b		c	
	Commissioning	Works	Commissioning	Works	Commissioning	Works
Temperature above the STP	°C	°C	°C	°C	°C	°C
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa	kPa	kPa
	Commissioning	Works				
Total cycle time						
Holding time						
Cycle start time						
Cycle finish time						
Full load test						
	a		b		c	
	Commissioning	Works	Commissioning	Works	Commissioning	Works
Temperature above the STP	°C	°C	°C	°C	°C	°C
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa	kPa	kPa
	Commissioning	Works				
Total cycle time						
Holding time						
Cycle start time						
Cycle finish time						



POROUS LOAD STERILIZERS					Sheet 1 of 2								
PERFORMANCE QUALIFICATION RECORD (PQ)					Week No.....								
Plant reference number.....					Validation file reference.....								
Date of tests.....					Sterilizer serial number.....								
Performance qualification reference.....					Loading condition reference.....								
Task					Schedule reference		Result		Valid until		Initial		
Commissioning													
Yearly test													
Performance qualification													
microbiological *													
thermometric													
* Performance qualification using microbiological methods if a sterilizing environment cannot be demonstrated by thermometric tests. Data from the microbiological test are attached to this log sheet													
Test instruments													
File reference.....				Calibration certificate number.....				Calibration due.....					
Error at the sterilizing temperature:-													
Sensor number		1	2	3	4	5	6	7	8	9	10	11	12
before PQ test													
after PQ test													
Data from the tests have been compared with the requirements for sterilization detailed in specification reference.....for loading condition reference..... It is confirmed that compliance with the requirements are obtained using operating cycle reference.....													
Test Person signature..... print name.....date.....													
Audited by:-													
Authorised Person signature..... print name.....date.....													
I have compared this data with the requirements given in the specification and I am satisfied that this loading condition can be processed in sterilizer serial number.....													
User signature..... print name.....date.....													



POROUS LOAD STERILIZERS				Sheet 2 of 2					
PERFORMANCE QUALIFICATION RECORD (PQ)				Week No.....					
Plant reference number.....				Validation file reference.....					
Date of tests.....				Sterilizer serial number.....					
Performance qualification reference.....				Loading condition reference.....					
Summary of thermometric tests									
				Test 1		Test 2		Test 3	
Cycle number									
Air removal	Negative pulsing	duration							
		number							
		pressure minimum							
		pressure maximum							
	Positive pulsing	duration							
		number							
		pressure minimum							
		pressure maximum							
Sterilizing temperature (ST) (Set)									
Holding time (Set)									
		Location of each sensor		Test and sensor number					
				1		2		3	
Sterilizing	Time when ST is attained	drain/vent							
		fastest load item							
		slowest load item							
	Time when temperature falls below ST	drain/vent							
		fastest load item							
		slowest load item							
	Holding time	drain/vent							
		fastest load item							
		slowest load item							
		temperature maximum							
		pressure maximum							
	pressure minimum								
actual ST									
Sensors located in the positions shown on the attached sheet reference No.....									
				Test 1		Test 2		Test 3	
Drying and Vacuum break	drying	duration							
		pressure minimum							
		pressure maximum							
	Vacuum break	duration							
Duration of the cycle									
Comments									
.....									
.....									
This is a summary of the data obtained during performance qualification for loading condition reference..... sterilized in sterilizer serial number.....									
Test Person signature..... print name date.....									



Porous Load Sterilizers – User Daily Record

Tests to be carried out in accordance with SHTM2010.

Hospital/Location	Week beginning	Week No.
Department	Ref.No	Ser.No

VACUUM LEAK RATE TEST-EMPTY CHAMBER								BOWIE-DICK TEST				
Cycle number	Pressure when pump stopped	Pressure below 50mbar	Pressure after 5 minutes P1	Pressure after further 10 minutes P2	Leak rate per minute (P2-P1)/10	Leak rate <1.3 mbar/min	Pack type		Indicator sheet type			
							Drain temp. sterilizing	Chamber pressure sterilizing	Indicator sheet result	Tested by (initials)	Certified fit for use by User	
Monday	mbar	Yes/No	mbar	mbar	mbar	Yes/No	°C	bar	Pass/Fail			
Tuesday	mbar	Yes/No	mbar	mbar	mbar	Yes/No	°C	bar	Pass/Fail			
Wednesday	mbar	Yes/No	mbar	mbar	mbar	Yes/No	°C	bar	Pass/Fail			
Thursday	mbar	Yes/No	mbar	mbar	mbar	Yes/No	°C	bar	Pass/Fail			
Friday	mbar	Yes/No	mbar	mbar	mbar	Yes/No	°C	bar	Pass/Fail			
Saturday	mbar	Yes/No	mbar	mbar	mbar	Yes/No	°C	bar	Pass/Fail			
Sunday	mbar	Yes/No	mbar	mbar	mbar	Yes/No	°C	bar	Pass/Fail			
Retests												
day	mbar	Yes/No	mbar	mbar	mbar	Yes/No	°C	bar	Pass/Fail			
day	mbar	Yes/No	mbar	mbar	mbar	Yes/No	°C	bar	Pass/Fail			

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

Sample Copy



Porous Load Sterilizers – Weekly Record

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS	Tick if Satisfactory	Door Pressure Interlock []
Door Seal []	Door Safety Edge []	Door Closed Interlock []

VACUUM LEAK RATE TEST-EMPTY CHAMBER		Cycle number
Pressure when pump stopped after	min sec	millibar
Pressure below 50 millibar		YES/NO
Pressure after 5 minutes	P1	millibar
Pressure after further 10 minutes	P2	millibar
Leak rate per minute (P2-P1)/10		millibar
Leak rate <1.3 millibar/min		YES/NO PASS / FAIL

AUTOMATIC CONTROL / BOWIE DICK TEST		Pack / Indicator Type					
Start cycle t1=0	Cycle number			Evacuation to	mbar in	min	seconds
Pulse number	1	2	3	4	5	6	7
Time at peak	:	:	:	:	:	:	:
Max ind. temp °C							
Max press. bar							
Min press. bar							
				Drain temperature		Chamber pressure	
Final evacuation at	(t2)	min	sec	Indicated	Recorded	Indicated	Recorded
Sterilizing temp at	(t3)	min	sec	°C	°C	bar	bar
Instrument readings	(t3+1)	min	sec	°C	°C	bar	bar
Instrument readings	(t3+2)	min	sec	°C	°C	bar	bar
Instrument readings	(t3+3)	min	sec	°C	°C	bar	bar
Drying stage starts at	(t4)	min	sec	Jacket pressure during sterilizing		bar	
40 mbar reached at	(t5)	min	sec	Minimum pressure		mbar	
Air replacement starts	(t6)	min	sec	Maximum chart temperature		°C	
Process complete at	(t7)	min	sec	Indicator sheet result		PASS / FAIL	
				Air removal time (t2-t1)		min sec	
				Sterilizing stage time(t4-t2)		min sec	
				Drying stage time (t6-t4)		min sec	
				Total cycle time (t7-t1)		min sec	

AIR DETECTOR FUNCTION TEST		Pack Type	Sheets / Towels
Leak rate setting to reject cycle	millibar/min (from Yearly test results)		
Cycle number	Air detector setting	Air detector reached	
Result of test	REJECT / ACCEPT	SATISFACTORY / UNSATISFACTORY	

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
TEST PERSON	DATE
USER	DATE



Porous Load Sterilizers – Quarterly Record

To be filled in along with Weekly Test Sheet to complete a Quarterly Test.
 Tests to be carried out in accordance with SHTM2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

VACUUM LEAK RATE TEST-EMPTY CHAMBER				Cycle number	
Test carried out after connection of temperature and pressure sensors					
		Indicated		Measured	
Pressure when pump stopped after	min	sec			millibar
Pressure below 50 millibar			YES/NO	YES/NO	
Pressure after 5 minutes		P1			millibar
Pressure after further 10 minutes		P2			millibar
Leak rate per minute (P2-P1)/10					millibar
Leak rate <1.3 millibar/min			YES/NO	YES/NO	PASS / FAIL

VERIFICATION OF CALIBRATION OF STERILIZER INSTRUMENTS/SMALL LOAD TEST							
Verification of calibration of test instrument before tests carried out					SATISFACTORY / UNSATISFACTORY		
Readings to be taken during the sterilizing hold period					Cycle number		
	Indicated values		Recorded values		Measured values		
Time	Chamber pressure	Drain Temp.	Chamber Pressure	Drain Temp.	Chamber Pressure	Drain Temp	Load Temp
Start	bar	°C	bar	°C	bar	°C	°C
+1 minute	bar	°C	bar	°C	bar	°C	°C
+2 minutes	bar	°C	bar	°C	bar	°C	°C
+3 minutes	bar	°C	bar	°C	bar	°C	°C
Maximum temp.above pack °C				Max.temp. above pack after 1 minute °C			
Calibration of instruments within limits YES/NO				If not,then note inaccuracies below, and action.			
Outstanding inaccuracies							
If any calibration has been changed during this quarterly test,note below with initial error							
Equilibration time less than 15 seconds YES/NO				Drying vacuum below 40 millibar YES/NO			
Drying stage more than 3 minutes YES/NO				Sheets/Towels sensibly dry after cycle YES/NO			
Verification of calibration of test instrument after tests carried out					SATISFACTORY / UNSATISFACTORY		
Result of test					SATISFACTORY/UNSATISFACTORY		

VACUUM LEAK RATE TEST-EMPTY CHAMBER				Cycle number	
Test carried out after removal of temperature and pressure sensors					
Pressure when pump stopped after	min	sec			millibar
Pressure below 50 millibar			YES/NO		
Pressure after 5 minutes		P1			millibar
Pressure after further 10 minutes		P2			millibar
Leak rate per minute (P2-P1)/10					millibar
Leak rate <1.3 millibar/min			YES/NO		PASS / FAIL

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE



Porous Load Sterilizers – Yearly Record

To be filled in along with Weekly and Quarterly Test Sheets to complete a Yearly Test. Tests to be carried out in accordance with SHTM 2010

Hospital / Location	Date	Week
Department	Ref.No	Ser.No

YEARLY SAFETY CHECKS	Tick if Satisfactory	Additional to weekly checks.
Drop below 134°C during sterilizing should cause cycle fail	[]	
Chamber safety valve free YES / NO	Jacket safety valve free YES / NO	Power failure []
Steam pressure low []	Water pressure low []	Air pressure low []

AIR DETECTOR PERFORMANCE TEST SMALL LOAD		Pack Type Sheets / Towels
Leak rate setting up to max of 10 millibar/min to give 2°C depression		millibar/min
Cycle number	Air detector disabled.	Air detector reached
Cycle number	Air detector enabled/set at	Air detector reached
Result of cycle REJECT / ACCEPT	Result of test SATISFACTORY / UNSATISFACTORY	

AIR DETECTOR PERFORMANCE TEST FULL LOAD		Pack Type Sheets / Towels
Leak rate setting to give less than 2°C depression and reject cycle		millibar/min
Cycle number	Air detector disabled.	Air detector reached
Cycle number	Air detector enabled/set at	Air detector reached
Result of cycle REJECT / ACCEPT	Result of test SATISFACTORY / UNSATISFACTORY	

THERMOMETRIC SMALL LOAD TEST	Cycle number	SHTM 2010 Pt.3 Para 13.14 met YES/NO
Comments		

THERMOMETRIC FULL LOAD TEST	Cycle number	SHTM 2010 Pt.3 Para 13.24 met YES/NO
Comments		

PERFORMANCE REQUALIFICATION TESTS AS REQUIRED BY USER		
Load Details		
Thermocouple locations		
Cycle number	Sterilizing conditions met YES/NO	
Dryness of load SATISFACTORY/UNSATISFACTORY	Comments	

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD		

COMMENTS		

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE		
TEST PERSON	DATE	USER	DATE



POROUS LOAD STERILIZERS											Sheet 1 of 2	
PERFORMANCE REQUALIFICATION RECORD (PRQ)											Week No.....	
Plant reference number.....											Validation file reference.....	
Date of tests.....											Sterilizer serial number.....	
Performance qualification reference.....											Loading condition reference.....	
Task	Schedule reference					Result	Valid until	Initial				
Commissioning												
Yearly test valid												
Performance qualification												
*microbiological												
thermometric												
Performance requalification												
* microbiological												
thermometric												
* is required if biological tests were carried during validation												
Test instruments												
File reference.....Calibration certification number.....Calibration due.....												
Error at the sterilizing temperature:-												
Sensor number	1	2	3	4	5	6	7	8	9	10	11	12
before PRQ test												
after PRQ test												
Data from the tests have been compared with the data in the validation file performance qualification reference..... and it is confirmed as being comparable within the limits specified.												
Test Person signature..... print name..... date.....												
Audited by:-												
Authorised Person signature..... print name..... date.....												
I have compared the results from these tests with the data in the validation file for performance qualification reference and I have also reviewed data in the batch records with the Test Person, Maintenance Person and Authorised Person. I am satisfied that this loading condition can be processed in sterilizer serial number.....												
User Signature..... print name..... date.....												



POROUS LOAD STERILIZERS				Sheet 2 of 2					
PERFORMANCE REQUALIFICATION RECORD (PQ)				Week No.....					
Plant reference number.....				Validation file reference.....					
Date of tests.....				Sterilizer serial number.....					
Performance qualification reference.....				Loading condition reference.....					
Summary of thermometric tests									
				Test 1		Test 2		Test 3	
Cycle number									
Air removal	Negative pulsing	duration							
		number							
		pressure minimum							
		pressure maximum							
	Positive pulsing	duration							
		number							
		pressure minimum							
		pressure maximum							
Sterilizing temperature (ST) (Set)									
Holding time (Set)									
		Location of each sensor		Test and sensor number					
				1		2		3	
Sterilizing	Time when ST is attained	drain/vent							
		fastest load item							
		slowest load item							
	Time when temperature falls below ST	drain/vent							
		fastest load item							
		slowest load item							
	Holding time	drain/vent							
		fastest load item							
		slowest load item							
		temperature maximum							
		pressure maximum							
	pressure minimum								
actual ST									
Sensors located in the positions shown on the attached sheet reference No.....									
				Test 1		Test 2		Test 3	
Drying and Vacuum break	drying	duration							
		pressure minimum							
		pressure maximum							
	Vacuum break	duration							
Duration of the cycle									
Comments									
.....									
.....									
.....									
This is a summary of the data obtained during performance qualification and performance requalification for loading condition reference..... sterilized in sterilizer serial number.....									
Test Person signature..... print name date.....									



STERILIZER MODIFICATION AND REPAIR RECORD			
Service provider		Department	
Sterilizer		Plant ref. No.	
Modification/repair	Revalidation file reference	Maintenance Person/Contractor signature	Date completed



2. Procedures for the procurement, validation, revalidation and operational management of sterilization.

Fluids Sterilizer – Weekly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS	Tick if Satisfactory	Door Pressure Interlock []
Door Seal []	Door Safety Edge []	Door Closed Interlock []

AUTOMATIC CONTROL TEST					MPR Ref. No.				
Container type			Container size			Number of containers			
Product in containers								Glass/Plastic	
Batch number			Cycle number		Timer setting/Profile number				
	Time	Indicated values				Recorded values			
Start t1=0	Min:sec	Chamber Pressure.	Spray Pressure	Drain/vent Temp.	Load Temp.	Chamber Pressure	Drain/vent Temp	Load 1 Temp.	Load 2 Temp.
Load 1 at °C									
Load 2 at °C									
Load(s) at 80 °C	(t2) :	bar	bar	°C	°C	bar	°C	°C	°C
Drain 115/121 °C	(t4) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 115/121 °C	(t6) :	bar	bar	°C	°C	bar	°C	°C	°C
t6+5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
t8-5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
Sterilizing ends	(t8) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 80/90 °C	(t9) :	bar	bar	°C	°C	bar	°C	°C	°C
Cooling ends (t11) :	Cycle complete(t12) :	Load spread max/min / °C Below 80/90 °C			YES/NO				
MPR/Test comparison		MPR	Limits	Test	Within Limits	Comments			
Heat up stage (t6-t2)		:	+/- 20%	:	YES/NO				
Drain at 115/121 (t8-t4)		:	+/- 10%	:	YES/NO				
Sterilizing stage (t8-t6)		:	+/- 10%	:	YES/NO				
Cooling stage (t9-t8)		:	+/- 20%	:	YES/NO				
Calibration within limits YES/NO				If not, then note inaccuracies below, and action					
Outstanding inaccuracies									
Comments on test									
Result of test SATISFACTORY/UNSATISFACTORY									

HEAT EXCHANGER INTEGRITY TEST (if applicable)	
Pressure 10 minutes after closing valves bar	Pressure after further 10 minutes bar
Pressure drop bar	Result of test SATISFACTORY/UNSATISFACTORY

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE		
TEST PERSON	DATE	USER	DATE



Fluids Sterilizer – Quarterly Maintenance Schedule

To be filled in along with Weekly Test Sheet to complete a Quarterly Test.
 Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SIMPLIFIED THERMOMETRIC TEST						MPR Ref. No.			
Verification of calibration of test instrument before tests carried out						SATISFACTORY / UNSATISFACTORY			
Container type		Container size		Number of containers					
Product in containers								Glass/Plastic	
Batch number		Cycle number		Timer setting/Profile number					
Measured values in shaded boxes - Load 1 in position slowest to reach sterilizing temperature and Load 2 in position slowest to reach 80°C(glass) or 90°C(plastic) during cooling.									
	Time	Indicated values				Recorded values			
Start t1=0	Min:sec	Chamber Pressure.	Spray Pressure	Drain/vent Temp.	Load Temp.	Chamber Pressure	Drain/vent Temp	Load 1 Temp.	Load 2 Temp.
Load 1 at °C									
Load 2 at °C									
Load(s) at 80 °C	(t2) :	bar	bar	°C	°C	bar	°C	°C	°C
Load(s) at 80 °C	(t3) :		bar			bar	°C	°C	°C
Drain 115/121 °C	(t4) :	bar	bar	°C	°C	bar	°C	°C	°C
Drain 115/121 °C	(t5) :		bar			bar	°C	°C	°C
Load at 115/121 °C	(t6) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 115/121 °C	(t7) :		bar			bar	°C	°C	°C
t6+5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
t6+5 minutes	:		bar			bar	°C	°C	°C
t8-5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
t8-5 minutes	:		bar			bar	°C	°C	°C
Sterilizing ends	(t8) :	bar	bar	°C	°C	bar	°C	°C	°C
Sterilizing ends	(t8) :		bar			bar	°C	°C	°C
Load at 80/90°C	(t9) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 80/90°C	(t10) :		bar			bar	°C	°C	°C
Cooling ends (t11) :	Cycle complete(t12) :	Load spread max/min / °C Below 80/90 °C				YES/NO			
MPR/Test comparison	MPR	Limits	Test	Within Limits	Measured values			Test	
Heat up stage (t6-t2)	:	+/- 20%	:	YES/NO	Heat up stage (t7-t3)			:	
Drain at 115/121 (t8-t4)	:	+/- 10%	:	YES/NO	Drain at 115/121 (t8-t5)			:	
Sterilizing stage (t8-t6)	:	+/- 10%	:	YES/NO	Sterilizing stage (t8-t7)			:	
Cooling stage (t9-t8)	:	+/- 20%	:	YES/NO	Cooling stage (t10-t8)			:	
Calibration within limits YES/NO					If not, then note inaccuracies below, and action				
Outstanding inaccuracies									
If any calibration has been changed during this quarterly test, note below with initial error									
Comments on test									
Verification of calibration of test instrument after tests carried out						SATISFACTORY / UNSATISFACTORY			
Result of test SATISFACTORY/UNSATISFACTORY									

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE		
TEST PERSON	DATE	USER	DATE



Fluids Sterilizer – Yearly Maintenance Schedule

To be filled in along with Weekly Test Sheet to complete a Yearly Test. May require more than one PRQ Test. Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

YEARLY SAFETY CHECKS	Tick if Satisfactory	Additional to weekly checks.
Drop below 115/121°C during sterilizing should cause cycle fail	[]	Chamber safety lift at bar
Steam pressure low	[]	Water pressure low
	[]	Air pressure low
	[]	Power failure
	[]	

PERFORMANCE REQUALIFICATION TEST						MPR Ref. No.			
Container type			Container size			Number of containers			
Product in containers						Glass/Plastic			
Batch number			Cycle number			Timer setting/Profile number			
Measured values in shaded boxes - Load 1 in position slowest to reach sterilizing temperature and Load 2 in position slowest to reach 80°C(glass) or 90°C(plastic) during cooling.									
	Time	Indicated values				Recorded values			
Start t1=0	Min: sec	Chamber Pressure.	Spray Pressure	Drain/vent Temp.	Load Temp.	Chamber Pressure	Drain/vent Temp	Load 1 Temp.	Load 2 Temp.
Load 1 at °C									
Load 2 at °C									
Load(s) at 80 °C	(t2) :	bar	bar	°C	°C	bar	°C	°C	°C
Load(s) at 80 °C	(t3) :		bar			bar	°C	°C	°C
Drain 115/121 °C	(t4) :	bar	bar	°C	°C	bar	°C	°C	°C
Drain 115/121 °C	(t5) :		bar			bar	°C	°C	°C
Load at 115/121 °C	(t6) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 115/121°C	(t7) :		bar			bar	°C	°C	°C
t6+5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
t6+5 minutes	:		bar			bar	°C	°C	°C
t8-5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
t8-5 minutes	:		bar			bar	°C	°C	°C
Sterilizing ends	(t8) :	bar	bar	°C	°C	bar	°C	°C	°C
Sterilizing ends	(t8) :		bar			bar	°C	°C	°C
Load at 80/90°C	(t9) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 80/90°C	(t10) :		bar			bar	°C	°C	°C
Cooling ends (t11) :	Cycle complete(t12) :	Load spread max/min		/ °C		Below 80/90 °C		YES/NO	
MPR/Test comparison	MPR	Limits	Test	Within Limits	Measured values		Test		
Heat up stage (t6-t2)	:	+/- 20%	:	YES/NO	Heat up stage (t7-t3)		:		
Drain at 115/121 (t8-t4)	:	+/- 10%	:	YES/NO	Drain at 115/121 (t8-t5)		:		
Sterilizing stage (t8-t6)	:	+/- 10%	:	YES/NO	Sterilizing stage (t8-t7)		:		
Cooling stage (t9-t8)	:	+/- 20%	:	YES/NO	Cooling stage (t10-t8)		:		
Calibration within limits YES/NO				If not, then note inaccuracies below, and action					
Outstanding inaccuracies									
If any calibration has been changed during this yearly test, note below with initial error									
Comments on test									
Result of test SATISFACTORY/UNSATISFACTORY									

COOLANT QUALITY TEST	Carried out by
Result of test (residue concentration) mg/litre	Result less than 40mg/litre YES/NO

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
TEST PERSON	DATE
USER	DATE



Unwrapped Instrument and Utensils Sterilizer – Daily/Weekly Maintenance Schedule

Tests to be carried out in accordance with SHTM2010.

Location	Week beginning	Week
Department	Ref.No	Ser.No

AUTOMATIC CONTROL TESTS SHTM2010 recommends an empty chamber but in order to reduce testing time it is now considered acceptable that a production load of instruments can be used instead.

		During sterilizing hold period		Sterilizing hold Time		
	Cycle number	Temperature	Pressure	min:sec	Result of test	Certified fit for use by User
Monday		°C	bar	:	PASS/FAIL	
Tuesday		°C	bar	:	PASS/FAIL	
Wednesday		°C	bar	:	PASS/FAIL	
Thursday		°C	bar	:	PASS/FAIL	
Friday		°C	bar	:	PASS/FAIL	
Saturday		°C	bar	:	PASS/FAIL	
Sunday		°C	bar	:	PASS/FAIL	
		°C	bar	:	PASS/FAIL	

RESERVOIR WATER CHANGES (where applicable). See SHTM 2031- Drain, rinse and refill with Sterilized Water for Irrigation.

	Cycle number when water changed	Comments	Water changed by
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

WEEKLY SAFETY CHECKS	Tick if Satisfactory	Door Pressure Interlock []
Door Seal []	Door Safety Edge []	Door Closed Interlock []
TESTED BY	Date	SATISFACTORY /UNSATISFACTORY

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD



PLANNED PREVENTATIVE MAINTENANCE
Unwrapped instrument and utensil sterilizer
Quarterly/Yearly Maintenance Schedule

The User or maintenance Person should tick each task when it has been completed.

EO	MAINTENANCE SCHEDULES	1 st Q	2 nd Q	3 rd Q	4 th Y
Q – QUARTERLY					
Y – YEARLY INTERVALS					
Service the following items within the contract and at the frequency indicated and check for safe operation					
1.	Check fuses and connections on the electrical mains or plug				*
2.	Replace faulty indicator lamps.	*	*	*	*
3.	Check the gauges and their calibrations. Recalibrate as required	*	*	*	*
4.	Examine the door seal(s) and replace if damaged	*	*	*	*
5.	Examine the door closure mechanism and lubricate.	*	*	*	*
6.	Check the door safety interlocks as required by the scheme of inspection	*	*	*	*
7.	Examine all pipe work connections and components for leaks. Repair as required	*	*	*	*
8.	Weekly safety checks as SHTM 2010 Part 3	*	*	*	
9.	Yearly safety checks as SHTM 2010 Part 3				*
10.	Safety valve check	*	*	*	*
11.	Examine the condenser in the reservoir/ and discharge from chamber vent	*	*	*	*
12.	Examine electrical connections for security	*	*	*	*
13.	Examine timers and check their settings	*	*	*	*
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions.	*	*	*	
15.	Carry out yearly maintenance tasks and check vessel in accordance with the scheme of inspection and the manufacturer's instructions				*
16.	Check the thermal sensor(s) and recorder and recalibrate if necessary				*
17.	Carry out yearly tests in accordance with SHTM 2010 Part 3				*
18.	Refit all covers & note the cycle count number	*	*	*	*
19.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED	*	*	*	*
20.	Weekly Satisfactory Not satisfactory	*	*	*	*
21.	Quarterly Satisfactory Not satisfactory	*	*	*	*
22.	Yearly Satisfactory Not satisfactory				*
23.	Complete the log book and summary sheets	*	*	*	*
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the user	*	*	*	*

Tasks to be undertaken at frequency indicated by * and as appropriate by

Maintenance Person sterilizers, Manufacturer, Service contractor



Dry Heat Sterilizer – Weekly Maintenance Schedule

Hospital/Location	Week number	
Department	Ref.No	Ser.No
Note:-Where the load probe cannot be placed in a load item the “Chamber at T°C” time should be used instead of “Sterilizing stage” time for MPR comparison.(See Yearly Test Form)		

Date	Batch No.	Product or load description	Container type/size	Number of containers	Timer setting	Cycle counter	Time load /chamber at sterilizing temp	Load temp during sterilizing	Chamber temp during sterilizing	Heat up time within MPR limits	Sterilizing time within MPR limits	Cooling time within MPR limits	Comments and operator initials
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	
:	:	:	:	:	:	:	:	°C	°C	Yes/No	Yes/No	Yes/No	

Review of batch records for week by User and Test Person. If no production runs have been carried out, the Test Person should carry out an Automatic Control Test and fill in the details above.
 Weekly safety checks Door seal condition [] Door temperature interlock []

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
Test Person _____	User _____
Date _____	Date _____



Dry Heat Sterilizer – Quarterly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS			Tick if Satisfactory		
Door Seal	[]	Cooling interlock	[]	Door Closed Interlock	[]

AUTOMATIC CONTROL TEST		Production load.	Cycle number
Calibration	SATISFACTORY/UNSATISFACTORY	Fill in details on weekly test sheet DHS1	

PERFORMANCE REQUALIFICATION				MPR Ref. No.		
Load details						
Container type		Container size		Number of containers		
Product in containers						
Batch number		Cycle number		Timer setting		
Sterilizing temperature 160/170/180 °C =T°C				Temp controller setting(s)		
Measured values are in shaded boxes. Where the load probe of the sterilizer cannot be put into the load, use chamber at 80°C for t2, leave the t6 row blank, and use t4 and t7 instead of t6 in the MPR/ Test comparison.						
	Time	Indicated values			Recorded values	
Start t1=0	Min: sec	Chamber Temp.(B)	Load Temp.	Pressure drop across filter	Chamber Temp. (A)	Load Temp.
Load at 80°C	(t2) :	°C	°C		°C	°C
Load at 80°C	(t3) :	°C	°C		°C	°C
Chamber at T°C	(t4) :	°C	°C		°C	°C
Chamber at T°C	(t5) :	°C	°C		°C	°C
Load at T°C	(t6) :	°C	°C		°C	°C
Load at T°C	(t7) :	°C	°C		°C	°C
t6+5 minutes	:	°C	°C		°C	°C
t6+5 minutes	:	°C	°C		°C	°C
t8-5 minutes	:	°C	°C		°C	°C
t8-5 minutes	:	°C	°C		°C	°C
Sterilizing ends	(t8) :	°C	°C		°C	°C
Sterilizing ends	(t8) :	°C	°C		°C	°C
Load at 80°C	(t9) :	°C	°C		°C	°C
Load at 80°C	(t10) :	°C	°C		°C	°C
Cooling ends (t11)	:	Cycle complete (t12)		:	Load below 90°C YES/NO	
MPR/Test comparison		MPR	Limits	Test	Result	
Heat up stage (t6-t2) or (t4-t2)	:		+/- 20%	:	Yes/No	
Chamber at T°C (t8-t4)	:		+/- 10%	:	Yes/No	
Sterilizing stage (t8-t6) or (t8-t7)	:		+/- 10%	:	Yes/No	
Cooling stage (t9-t8)	:		+/- 20%	:	Yes/No	
Calibration within limits		YES/NO		Comments		
Comments on test						
Result of test		SATISFACTORY/UNSATISFACTORY				

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
Test Person	Date
User	Date



Dry Heat Sterilizer – Yearly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS			Tick if Satisfactory		
Door Seal	[]	Cooling interlock	[]	Door Closed Interlock	[]

AUTOMATIC CONTROL TEST		Production load.	Cycle number
Calibration	SATISFACTORY/UNSATISFACTORY	Fill in details on weekly test sheet DHS1	

PERFORMANCE REQUALIFICATION				MPR Ref. No.		
Load details						
Container type		Container size		Number of containers		
Product in containers						
Batch number		Cycle number		Timer setting		
Sterilizing temperature 160/170/180 °C =T°C				Temp controller setting(s)		
Measured values are in shaded boxes. Where the load probe of the sterilizer cannot be put into the load, use chamber at 80°C for t2, leave the t6 row blank, and use t4 and t7 instead of t6 in the MPR/Test comparison..						
	Time	Indicated values			Recorded values	
Start t1=0	Min:sec	Chamber Temp(B).	Load Temp.	Pressure drop across filter	Chamber Temp. (A)	Load Temp.
Load at 80°C	(t2) :	°C	°C		°C	°C
Load at 80°C	(t3) :	°C	°C		°C	°C
Chamber at T°C	(t4) :	°C	°C		°C	°C
Chamber at T°C	(t5) :	°C	°C		°C	°C
Load at T°C	(t6) :	°C	°C		°C	°C
Load at T°C	(t7) :	°C	°C		°C	°C
t6(or t7)+5 minutes	:	°C	°C		°C	°C
t6(or t7)+5 minutes	:	°C	°C		°C	°C
t8-5 minutes	:	°C	°C		°C	°C
t8-5 minutes	:	°C	°C		°C	°C
Sterilizing ends	(t8) :	°C	°C		°C	°C
Sterilizing ends	(t8) :	°C	°C		°C	°C
Load at 80°C	(t9) :	°C	°C		°C	°C
Load at 80°C	(t10) :	°C	°C		°C	°C
Cooling ends (t11) :		Cycle complete (t12) :		Load below 90°C YES/NO		
MPR/Test comparison		MPR	Limits	Test	Result	
Heat up stage (t6-t2)or(t4-t2)		:	+/- 20%	:	Yes/No	
Chamber at T°C (t8-t4)		:	+/- 10%	:	Yes/No	
Sterilizing stage (t8-t6)or (t8-t7)		:	+/- 10%	:	Yes/No	
Cooling stage (t9-t8)		:	+/- 20%	:	Yes/No	
Calibration within limits YES/NO				Comments		
Comments on test						
Result of test SATISFACTORY/UNSATISFACTORY						

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

CHAMBER OVERHEAT CUT-OUT TEST Maximum chamber temperature	°C (should be <200 °C)
AIR FILTER INTEGRITY TEST Result	% (should be <0.001%)

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
Test Person	User
Date	Date



Low Temperature Steam and Formaldehyde Sterilizer – Daily/Weekly Maintenance Schedule

LTS.F	MAINTENANCE SCHEDULES				
D = DAILY W = WEEKLY					
Service the following items within the contract and at the frequency indicated. Check for safe operation & correct readings		D	W	U	M
1.	Check all sterilizer services are turned on and correct readings are indicated on controls & gauges	S M T W Th F Sa			
2.	Check the log book & production records together with the routine microbiological test for LTSF. Complete as required	S M T W Th F Sa			
3.	Check the chart recorder or data logger. Fit new chart; replenish ink or fit new ink cartridge as required	S M T W Th F Sa			
4.	Check the chamber & clean as detailed for the type of material chamber is constructed from.	S M T W Th F Sa			
5.	Check the chamber discharge strainer. Remove & clean as required.	S M T W Th F Sa			
6.	Check the door system as required by the scheme of inspection. Clean the door seal & its contact surface.	S M T W Th F Sa			
7.	Carry out detailed periodic daily tests in accordance with HTM 2010 Part 3 Table 4.	S M T W Th F Sa			
8.	Replace faulty indicator lamps	S M T W Th F Sa			
9.	Check gauges & digital indicator(s). If faulty repair or change as required.	S M T W Th F Sa			
10.	Check the door safety interlocks & control systems as required by the scheme of inspection. Lubricate the closure mechanism as required.	S M T W Th F Sa			
11.	Examine all pipe work connections & components for leaks. Repair as required.	S M T W Th F Sa			
12.	Examine door seal(s). Replace if damaged	S M T W Th F Sa			
13.	Weekly safety checks as per HTM 2010 Part 3	S M T W Th F Sa			
14.	Carry out weekly maintenance tasks & check the pressure vessel in accordance with the scheme of inspection and manufacturer's instructions	S M T W Th F Sa			
15.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED. INSPECT RECORDS WITH USER	S M T W Th F Sa			
16.	Daily tests Satisfactory Not Satisfactory Weekly tests satisfactory Not Satisfactory	S M T W Th F Sa			
17.	Complete the log book.	S M T W Th F Sa			
18.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User.	S M T W Th F Sa			

User and Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at frequency indicated by U = User M = Maintenance person



PLANNED PREVENTATIVE MAINTENANCE

Low temperature steam and formaldehyde sterilizer

Quarterly/Yearly Maintenance Schedule

The Maintenance Person should tick each task when it has been completed.

LTS.F	MAINTENANCE SCHEDULES	1 st Q	2 nd Q	3 rd Q	4 th Y
Q – QUARTERLY					
Y – YEARLY INTERVALS					
Service the following items within the contract and at the frequency indicated and check for safe operation					
1.	Check fuses and connections on the electrical mains or plug				*
2.	Replace faulty indicator lamps.	*	*	*	*
3.	Check the gauges and their calibrations. Recalibrate as required	*	*	*	*
4.	Examine the door seal(s) and replace if damaged	*	*	*	*
5.	Examine the door closure mechanism and lubricate.	*	*	*	*
6.	Check the door safety interlocks as required by the scheme of inspection	*	*	*	*
7.	Examine all pipe work connections and components for leaks. Repair as required	*	*	*	*
8.	Weekly safety checks as SHTM 2010 Part 3	*	*	*	
9.	Yearly safety checks as SHTM 2010 Part 3				*
10.	Safety valve check and formalin container vent	*	*	*	*
11.	Examine the condenser	*	*	*	*
12.	Examine electrical connections for security	*	*	*	*
13.	Examine timers and check their settings	*	*	*	*
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions.	*	*	*	
15.	Carry out yearly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and the manufacturer's instructions				*
16.	Check the thermal sensor(s) and recorder and recalibrate if necessary				*
17.	Carry out yearly tests in accordance with SHTM 2010 Part 3				*
18.	Refit all covers & note the cycle count number	*	*	*	*
19.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED	*	*	*	*
20.	Weekly Satisfactory Not satisfactory	*	*	*	*
21.	Quarterly Satisfactory Not satisfactory	*	*	*	*
22.	Yearly Satisfactory Not satisfactory				*
23.	Complete the log book and summary sheets	*	*	*	*
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User	*	*	*	*

*Tasks to be undertaken at frequency indicated by * and as appropriate by Maintenance Person sterilizers, Manufacturer, Service contractor*



Ethylene oxide sterilizer – Daily/Weekly Maintenance Schedule

The User or Maintenance Person should tick each task when it has been completed.

EO		MAINTENANCE SCHEDULES			
D = DAILY W = WEEKLY		D	W	U	M
Service the following items within the contract and at the frequency indicated. Check for safe operation & correct readings					
1.	Check all sterilizer services are turned on and correct readings are indicated on controls & gauges	S M T W Th F Sa			
2.	Check the log book & production records together with the routine microbiological test for each production cycle. Complete as required	S M T W Th F Sa			
3.	Check the chart recorder or data logger. Fit new chart; replenish ink or fit new ink cartridge as required	S M T W Th F Sa			
4.	Check the chamber & clean as detailed for the type of material chamber is constructed from.	S M T W Th F Sa			
5.	Check the chamber discharge strainer. Remove & clean as required.	S M T W Th F Sa			
6.	Check the door system as required by the scheme of inspection. Clean the door seal & its contact surface. Report any damage to the Maintenance Person	S M T W Th F Sa			
7.	Carry out detailed periodic daily tests in accordance with HTM 2010 Part 3 Table 4f.	S M T W Th F Sa			
8.	Check the ethylene oxide cylinder(s) & monitoring equipment. Change as required. Report defects to the Maintenance Person.	S M T W Th F Sa			
9.	Check gauges, digital indicator(s) & indicator lamps. If faulty repair or change as required.	S M T W Th F Sa			
10.	Check the door safety interlocks & control systems, lubricate the door closure mechanism as required by the scheme of inspection.	S M T W Th F Sa			
11.	Examine all pipe work connections & components for leaks. Repair as required.	S M T W Th F Sa			
12.	Examine door seal(s). Replace if damaged	S M T W Th F Sa			
13.	Weekly safety checks as per HTM 2010 Part 3	S M T W Th F Sa			
14.	Carry out weekly maintenance tasks & check the pressure vessel in accordance with the scheme of inspection and manufacturer's instructions	S M T W Th F Sa			
15.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED. INSPECT RECORDS WITH USER	S M T W Th F Sa			
16.	Daily tests Satisfactory Weekly tests satisfactory	Not Satisfactory Not Satisfactory	S M T W Th F Sa		
17.	Complete the log book.	S M T W Th F Sa			
18.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User.	S M T W Th F Sa			

User and Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at frequency indicated by U = User M = Maintenance person



PLANNED PREVENTATIVE MAINTENANCE

Ethylene Oxide Sterilizer Quarterly/Yearly Maintenance Schedule

The Maintenance Person should tick each task when it has been completed.

EO	MAINTENANCE SCHEDULES	1 st Q	2 nd Q	3 rd Q	4 th Y
Q – QUARTERLY					
Y – YEARLY INTERVALS					
Service the following items within the contract and at the frequency indicated and check for safe operation					
1.	Check fuses and connections on the electrical mains or plug				*
2.	Replace faulty indicator lamps.	*	*	*	*
3.	Check the gauges and their calibrations. Recalibrate as required	*	*	*	*
4.	Examine the door seal(s) and replace if damaged	*	*	*	*
5.	Examine the door closure mechanism and lubricate.	*	*	*	*
6.	Check the door safety interlocks as required by the scheme of inspection	*	*	*	*
7.	Examine all pipe work connections and components for leaks. Repair as required	*	*	*	*
8.	Weekly safety checks as SHTM 2010 Part 3	*	*	*	
9.	Yearly safety checks as SHTM 2010 Part 3				*
10.	Safety valve check	*	*	*	*
11.	Examine the heat exchanger and the discharge vent from the chamber	*	*	*	*
12.	Examine electrical connections for security	*	*	*	*
13.	Examine timers and check their settings	*	*	*	*
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions.	*	*	*	
15.	Carry out yearly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and the manufacturer's instructions				*
16.	Check the temperature sensor(s), humidity sensor(s), and the pressure sensor(s) & recalibrate if necessary				*
17.	Carry out yearly tests in accordance with SHTM 2010 Part 3				*
18.	Refit all covers & note the cycle count number	*	*	*	*
19.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED	*	*	*	*
20.	Weekly Satisfactory Not satisfactory	*	*	*	*
21.	Quarterly Satisfactory Not satisfactory	*	*	*	*
22.	Yearly Satisfactory Not satisfactory				*
23.	Complete the log book and summary sheets	*	*	*	*
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User	*	*	*	*

*Tasks to be undertaken at frequency indicated by * and as appropriate by Maintenance Person sterilizers, Manufacturer, Service contractor*



Laboratory Sterilizer – Daily Test Sheet

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Week beginning	Week
Department	Ref.No	Ser.No

TAKE READINGS DURING FIRST PRODUCTION CYCLE OF THE DAY						
	Cycle number	During sterilizing hold period		Sterilizing hold time min:sec	Result of test	Certified fit for use by User
		Temperature °C	Pressure bar			
Monday		°C	bar	:	PASS/FAIL	
Tuesday		°C	bar	:	PASS/FAIL	
Wednesday		°C	bar	:	PASS/FAIL	
Thursday		°C	bar	:	PASS/FAIL	
Friday		°C	bar	:	PASS/FAIL	
Saturday		°C	bar	:	PASS/FAIL	
Sunday		°C	bar	:	PASS/FAIL	
		°C	bar	:	PASS/FAIL	

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD



Laboratory Sterilizer – Weekly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS			Tick if Satisfactory		
Door Seal	[]	Door Safety Edge	[]	Door Closed Interlock	[]
Chamber Safety Valve Free	[]	Jacket Safety Valve Free	[]	Door Pressure Interlock	[]

VACUUM LEAK RATE TEST-EMPTY CHAMBER				Cycle number	
Pressure when pump stopped after	min	sec		millibar	
Pressure below 50 millibar				YES/NO	
Pressure after 5 minutes	P1			millibar	
Pressure after further 10 minutes	P2			millibar	
Leak rate per minute (P2-P1)/10				millibar	
Leak rate <1.3 millibar/min				YES/NO	
				PASS / FAIL	

AUTOMATIC CONTROL TEST				Cycle counter number	
The cycle selected should be rotated between those in routine use.					
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature		Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling/drying ends	
(t2)	:	(t3)	:	(t4)	:
				(t5) :	
Take readings during sterilizing hold period					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :			Sterilizing conditions met YES/NO		
Calibration within limits YES/NO			If not, then note inaccuracies below, and action		
Outstanding inaccuracies					
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Comments on test					
Result of test SATISFACTORY/UNSATISFACTORY					

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD					

TEST RESULT SATISFACTORY/UNSATISFACTORY			STERILIZER IS FIT/UNFIT FOR USE		
Test Person	Date	User	Date		



Laboratory Sterilizer – Quarterly Maintenance Schedule (Sheet A)

To be filled in along with Quarterly Test Sheets B and C to complete a Quarterly Test.

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS	Tick if Satisfactory	
Door Seal []	Door Safety Edge []	Door Closed Interlock []
Chamber Safety Valve Free []	Jacket Safety Valve Free []	Door Pressure Interlock []

VACUUM LEAK RATE TEST-EMPTY CHAMBER	Cycle number	
Pressure when pump stopped after min sec		millibar
Pressure below 50 millibar	YES/NO	
Pressure after 5 minutes	P1	millibar
Pressure after further 10 minutes	P2	millibar
Leak rate per minute (P2-P1)/10		millibar
Leak rate <1.3 millibar/min	YES/NO	PASS / FAIL

VACUUM LEAK RATE TEST-EMPTY CHAMBER	Cycle number	
Test carried out after connection of temperature and pressure sensors		
Pressure when pump stopped after min sec	Indicated	Measured
Pressure below 50 millibar	YES/NO	YES/NO
Pressure after 5 minutes	P1	millibar
Pressure after further 10 minutes	P2	millibar
Leak rate per minute (P2-P1)/10		millibar
Leak rate <1.3 millibar/min	YES/NO	YES/NO
		PASS / FAIL

VACUUM LEAK RATE TEST-EMPTY CHAMBER	Cycle number	
Test carried out after removal of temperature and pressure sensors		
Pressure when pump stopped after min sec		millibar
Pressure below 50 millibar	YES/NO	
Pressure after 5 minutes	P1	millibar
Pressure after further 10 minutes	P2	millibar
Leak rate per minute (P2-P1)/10		millibar
Leak rate <1.3 millibar/min	YES/NO	PASS / FAIL

THERMAL DOOR LOCK OVERRIDE TEST	SATISFACTORY/UNSATISFACTORY
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CALIBRATION : If any calibration has been changed during this quarterly / yearly test, note below with initial error	
Verification of calibration of test instrument before tests carried out	SATISFACTORY / UNSATISFACTORY
Verification of calibration of test instrument after tests carried out	SATISFACTORY / UNSATISFACTORY

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
TEST PERSON	DATE
USER	DATE



Laboratory Sterilizer – Quarterly Maintenance Schedule (Sheet B)

To be filled in along with Quarterly Test Sheets A and C to complete a Quarterly test
 This sheet to be used for any other cycles available but not tested on Quarterly Sheet C.

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

AUTOMATIC CONTROL TEST				Cycle counter number	
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature		Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling/drying ends	
(t2) :		(t3) :		(t4) :	
:		:		:	
Take readings during sterilizing hold period					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :				Sterilizing conditions met YES/NO	
Calibration within limits YES/NO				Comments	
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

AUTOMATIC CONTROL TEST				Cycle counter number	
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature		Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling/drying ends	
(t2) :		(t3) :		(t4) :	
:		:		:	
Take readings during sterilizing hold period					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :				Sterilizing conditions met YES/NO	
Calibration within limits YES/NO				Comments	
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE



Laboratory Sterilizer – Quarterly Maintenance Schedule (Sheet C)

To be filled in along with Quarterly Test Sheets A and B to complete a Quarterly test

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

THERMOMETRIC TEST FOR SMALL LOAD				Cycle counter number	
Small plastic discard, or fabrics, or glassware (choose first cycle in list available on autoclave).					
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature		Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling/drying ends	
(t2)	:	(t3)	:	(t4)	:
Take readings during sterilizing hold period : measured values in shaded boxes.					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2)			:	Sterilizing conditions met YES/NO	
Calibration within limits			YES/NO	If not, then note inaccuracies below, and action	
Outstanding inaccuracies					
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

PERFORMANCE REQUALIFICATION				Cycle counter number	
Fluid discard, or culture media, or free steaming (choose first cycle in list available on autoclave).					
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature		Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling/drying ends	
(t2)	:	(t3)	:	(t4)	:
Take readings during sterilizing hold period : measured values in shaded boxes.					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2)			:	Sterilizing conditions met YES/NO	
Calibration within limits			YES/NO	If not, then note inaccuracies below, and action	
Outstanding inaccuracies					
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE		
TEST PERSON	DATE	USER	DATE



Laboratory Sterilizer – Yearly Maintenance Schedule

To be filled in along with Quarterly Test Sheets A, Band C to complete a Yearly test.

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

YEARLY SAFETY CHECKS	Tick if Satisfactory	Additional to weekly checks.
Drop below 134/121/115°C during sterilizing should cause cycle fail	[]	
Chamber safety lift at _____ bar	Jacket safety lift at _____ bar	Power failure []
Steam pressure low []	Water pressure low []	Air pressure low []

THERMOMETRIC TEST FOR FULL LOAD		Cycle counter number	
The cycle selected should be rotated between those in routine use.			
Description of cycle selected(include number if applicable)			
Description of load			
Sterilize temperature		Sterilize time	Sterilize pressure
Temperature controller settings (if applicable)			
Timer settings (if applicable)			
Position of load probe (include type of bottle and contents for fluids cycles)			
Start t1=0			
Sterilizing achieved	Sterilizing ends	Cooling/drying ends	Cycle complete
(t2) :	(t3) :	(t4) :	(t5) :
Take readings during sterilizing hold period : measured values in shaded boxes.			
Indicated values			Recorded values
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure
Recorded temp	Recorded pressure		
°C	°C	bar	bar
°C	°C	bar	bar
Sterilizing hold period (t3-t2) :		Sterilizing conditions met YES/NO	
Calibration within limits YES/NO		If not, then note inaccuracies below, and action	
Outstanding inaccuracies			
For fluids loads , load temp below 80/90°C at end of cycle YES/NO			
Result of test SATISFACTORY/UNSATISFACTORY			

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE		
TEST PERSON	DATE	USER	DATE



Culture Media Preparator Sterilizer – Weekly Maintenance Schedule

Hospital/Location		Week number	
Department		Ref.No	Ser.No

Date	Batch No.	Product	Volume	Timer setting	Cycle counter	Time chamber at sterilizing temp	Indicated temp during sterilizing	Recorded temp during sterilizing	Sterilizing time within limits	Comments and operator initials
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	

The Test Person should carry out an Automatic Control Test and fill in the details above, in addition to the weekly safety checks. The time at sterilizing temperature should be checked with a stopwatch.
 Weekly safety checks Seal condition [] Lid temperature interlock [] Lid closed interlock []
 Safety Valve free []

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
Test Person	Date	User	Date



Culture Media Preparator Sterilizer Yearly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

YEARLY SAFETY CHECKS	Tick if Satisfactory	Additional to weekly checks.
Drop below 121/115°C during sterilizing should cause cycle fail or timer reset[<input type="checkbox"/>]		
Chamber safety lift at <input type="text"/> bar	Jacket safety lift at <input type="text"/> bar	Power failure [<input type="checkbox"/>]

THERMOMETRIC TEST FOR FULL LOAD				Cycle counter number	
Type of culture medium			Volume of liquid		
Sterilize temperature			Sterilize time		
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling ends	
(t2)	:	(t3)	:	(t4)	:
Take readings during sterilizing hold period : measured values in shaded boxes.					
Indicated values				Recorded values	
Load temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2)			Sterilizing conditions met YES/NO		
Calibration within limits YES/NO			If not, then note inaccuracies below, and action		
Outstanding inaccuracies					
Door safety hood unable to be opened until load temps below 80°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

REHEAT AND DISPENSING TEST				Cycle counter number	
Type of culture medium			Volume of liquid		
Reheat temperature setting °C			Dispensing temperature setting °C		
Start t1=0					
Take readings at start, middle and end of dispensing period.					
Indicated values				Recorded values	
	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
Start	°C	bar	bar	°C	bar
Middle	°C	bar	bar	°C	bar
End	°C	bar	bar	°C	bar
Indicated temp within 2 °C of set temp YES/NO			Indicated chamber pressure zero YES/NO		
Medium does not solidify YES/NO					
Outstanding inaccuracies					
Result of test SATISFACTORY/UNSATISFACTORY					

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
Test Person <input type="text"/>	User <input type="text"/>
Date <input type="text"/>	Date <input type="text"/>