

Scottish Health Technical Memorandum 2010

(Part 6 of 6)

Testing and validation protocols

Sterilization

Disclaimer

The contents of this document are provided by way of guidance only. Any party making any use thereof or placing any reliance thereon shall do so only upon exercise of that party's own judgement as to the adequacy of the contents in the particular circumstances of its use and application. No warranty is given as to the accuracy of the contents and the Property and Environment Forum Executive, which produced this document on behalf of NHSScotland Property and Environment Forum, will have no responsibility for any errors in or omissions therefrom.

The production of this document was jointly funded by the Scottish Executive Health Department and the NHSScotland Property and Environment Forum.

NHSScotland, P&EFEx, June 2001



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

	A	SHTM 2010 Ref. Part 3
User / operator	Daily Test	
	 Warm Up Cycle Bowie-Dick test for steam penetration 	13.39
Test Person	Weekly tests	13.39
1651 1615011	Weekiy lesis	
	1. Weekly safety checks	5.7
	2. Vacuum leak test	11.2
	3. Air detector function test	11.60
	4. Automatic control test	12.1
	5. Bowie-Dick test steam penatration*	13.39
Test Person	Quarterly tests	
	1. Weekly savety checks	5.7
	2. Vacuum leak test	11.2
	 Vacuum leak test (temperature and pressure) 	
	sensor connected	11.2
	4. Automatic control test	12.1
	5. Verification of sterilizer instrum	ents* 12.2
	Thermometric test for a small load*	13.7
	7. Accuum leak test (sensors removed)	11.2
	8. Air detector tunction test	11.60
	9. Bowie Dick test for stream penetration	13.39
Test Person	Yearly and revalidation tests	
	1. Yearly safety checks	5.8
	2. Steam, mon-condensable gas test**	9.4
	3. Steam superheat rest**	9.20
	 Steam stryness test** 	9.30
	5. Vacuum leak test	11.2
	 Kacuum teak test (temperature and pressure sensors connected) 	e 11.2
	Automatic control test	12.1
	8. Wrification of calibration of sterilizer intsrum	
	Air detector performance test for a small loa	
	Air detector performance test for a full load	11.53
~	Thermometric test for a small load	13.7
	Tests for performance requalification as requestion to the user	uired 8.64
	Vacuum leak test (sensors removed)	11.2
	14. Air detector function test	11.60
	Bowie-Dick test for steam penetration	13.39
Test Person	Performance requalification test	
	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

INSTALLA	TION R	ECORD							Date	е				com	pleted
Oliant			Denentere				Data at 7	T	4-						
Client	o oturor		Departme				Date of T			~ *					
Sterilizer manu			Serial num	ber			Plant refe	erer	nce numb	er					
Type test file re			Date					1			Deset				La Martine I
	Task		3	cnea	ule Ref	erei	nce	_			Result				Initial
Preliminary che		eted (3.14)						_							-
Electrical check								_							-
Functional cheo	cks (3.16)														
Install	ation chec	ks (3.6)							Results						-
			Steam	Wat	ter C	omp	pressed	D	rainage	V	entilatior	ו E	Elect	trical	
_							air								
Pressure															
Pressure drop a		operating		-											
Flow rates are		<u>(()</u>													-
		effluent when all													
sterilizers are o Task	perating			Cure			Stort time			D	esults				
Vacuum leak te	ot (11.2)			Cyc	le No		Start time	9				r/min	. 1	Dooo	/ Fail
Automatic cont		1)								ie	akage pe		1		/ Fail / Fail
Automatic con		/		Inco	vrt data f	from	n each auto	omr	atic contro	l to	ct			газэ	/ 1 מו
Automatic con		2.1)		1130	n uala i	TUI	I Cacil auto				51				
		Negative p	ulsina					F	Positive	oule	sina				
Air Removal	Cycle	noguire p	Pulses					+	Contro		Pulses				
	Start time	Duration	Number	Pr	essure			1	Duration		Number	Pre	essi	ıre	-
					inimum		Maximum						nim		Maximum
Works tests				kF	°a		kPa					kP			kPa
Installation				kF	°a		kPa					kP	a		kPa
		Holding Tin	ne												
Sterilizing		Duration	Recorde	er							Indicate	ors			
			Tempera				Pressure	Э			Tempe	rature	e	Press	
			Minimur		Maximu	m	Minimum	า	Maximu	m	Maxim	um		Maxi	mum
Works Tests			°C		°C		kPa		kPa		°C			kPa	
Installation			°C	(°C		kPa		kPa		°C			kPa	
Drying & Vacuu			1 -								Vacuur		ak	-	
break	Finish Time	Duration	Pressur	e			emperature	Э			Duratio	n			
Works tests			kPa			°C									
Installation			kPa			°C)								
Verification of c	alibration s	terilizer instrume	nts (12.2)												
		Measured					Recorder E	Errc	or				ator	Error	
Chamber temp		°C					°C					°C			
Chamber press		kPa					kPa					kPa			
Jacket pressure		kPa				_	kPa					kPa			
Holding timer s	etting	SetM	ins	Secs.			Error								
Contractor															
		ation have been					•	e w	rith the sp	ecif	ication				
-) and they h					-								
Contractor sign	ature		Print nam	е					. Date		<u></u>				

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



POROUS LC	AD STE	RILIZER	S						Sheet	1 0	f 3	
COMMISSIO	NING R	FCORD						Week I	NO.			
		LOOND						HOOK I			•••	
Plant reference nu	mbor						Validatia	n file refere	200			
								serial num				
Date of tests							Sterilizer		ber			
	Task	(0.4.4)	SCI	nedule Refe	erence			Result			Initial	
Preliminary checks		(3.14)										
Electrical checks (Functional checks												
	· /						aaulta (2.6)					
Installation checks	(3.6)		Steam		Water		esults (3.6)	1			entilation	
			Stean	1	water		Compressed	sed Drainage Ventila				
Pressure						air						
Pressure drop all s	envices one	rating										
Flow rates are ade		ading										
Drains effectively r		ent when all										
sterilizers are oper												
	am tests		Scl	nedule Refe	erence	T	Result				Initial	
0.0			00				Result				initial	
NCG (9.4)												
Superheat (9.20)												
Dryness (9.30)												
Bry11000 (0.00)				Cycle num	her							
Vacuum leak test *	(11.2)							Leaka	Leakage per minute			
Vacuum leak test *		n sensors)							ge per r			
Automatic control t		reencercy						Lound	go por r	miato		
Air detector test (s	· · · /	(11.45)						l eaka	ge per r	ninute		
Air detector test (fu									ge per r			
Small load test (13								200.10	90 001			
Load dryness test								%	gain in	mass		
Full load test (13.1	5)							,,	3			
Load dryness test								%	gain in	mass		
Sound power test									0-			
Vacuum leak test *		n sensors						Leaka	ge per r	ninute		
removed)	. , .								01			
Air detector function	on test * (11	.60)					Setting:	.°C / Leaka	ge per r	ninute		
Bowie & Dick test		,						f test pack.				
Automatic contro	l test (12.1))	•		Insert data	fron	n each auto	matic con	trol test		-	
			Negativ	e pulsing				Positiv	e pulsin			
	Cycle			Pulses					Pul	ses		
Air Removal	Start	Duration	Number	Pre	essure		Duration	Number		Pres	sure	
	time				-							
				Minimum	Maximum	1			Minimu	ım	Maximum	
Commissioning				kPa	kPa				kPa		kPa	
Works				kPa	kPa				kPa		kPa	
			Holding Time Recorder Indicators									
Sterilizing		Duration			Recorder							
				perature			ssure	Tempe			ressure	
	1		Minimum	Maximu		ım	Maximum		านm		laximum	
Commissioning			°C °C kPa kPa °C				kPa					
Works	0		°C °C kPa kPa °C kPa				-1.					
Drying &	Cycle	Duration	Drying Vacuum break				ак					
Vacuum break	Finish	Duration	Pres	sure	ien	per	ature	Dura	ation			
Validation	Time		kPa		°C							
Validation Quarterly			kPa kPa		°C							
Quarterry	1	1	πα		0			1		1		

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



POROUS LOAD STERILIZ	ERS					Sheet	t 2 of	3
COMMISSIONING RECOR	D				Wee	ek No		
Plant reference		Ser	rial num	ber				
Oslikastisu								
Calibration								
		File	e referer	nce				
Test instruments		Cal	libration	date due				
Verification of the calibration of the s	sterilizer instrumen	nts						
	Measured		Record	er error		Indica	tor error	•
		Work	-	Commissi	oning	Works	Comm	hissionin
Jacket pressure	kPa k		kPa		kPa	kPa		kP
Chamber pressure	kPa		kPa		kPa	kPa		kP
Chamber temperature °C	°C		°C		°C	°C		٥
Time min,sec								
Readings to be noted when:- a b c		e standard t	est pac	k attains the	sterilizing te	-		
Small load test Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time	a Commissioning °C °C °C kPa Commissioning	Works °C °C °C kPa Works		b nissioning °C °C °C kPa	Works °C °C °C kPa	Commiss	С	Works °(°(°(kP
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time	Commissioning °C °C °C kPa	Works °C °C °C kPa		b nissioning °C °C °C	Works °C °C °C		C ioning °C °C °C	°(°(
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time	Commissioning °C °C °C kPa	Works °C °C °C kPa		b nissioning °C °C °C	Works °C °C °C		C ioning °C °C °C	°(°(
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time	Commissioning °C °C °C kPa	Works °C °C °C kPa		b nissioning °C °C °C	Works °C °C °C		C ioning °C °C °C	°(°(
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time Cycle finish time	Commissioning °C °C °C kPa	Works °C °C °C kPa		b nissioning °C °C °C	Works °C °C °C		C ioning °C °C °C	°(°(
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time Cycle finish time	Commissioning °C °C kPa Commissioning	Works °C °C °C kPa Works	Comn	b nissioning °C °C °C kPa	Works °C °C °C kPa	Commiss	C ioning °C °C c kPa	°(°(kP
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time Cycle finish time Full load test	Commissioning °C °C C kPa Commissioning	Works °C °C °C kPa Works	Comn	b nissioning °C °C °C kPa	Works °C °C °C kPa		C ioning °C °C c kPa	°(°(kP
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time Cycle finish time Full load test Temperature above the STP	Commissioning °C °C KPa Commissioning	Works °C °C °C kPa Works	Comn	b nissioning °C °C «C kPa b nissioning	Works °C °C °C kPa	Commiss	C ioning °C °C kPa kPa	°(°(
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time Cycle finish time Full load test Temperature above the STP Temperature in the drain/vent	Commissioning °C °C KPa Commissioning	Works °C °C kPa Works Works	Comn	b nissioning °C °C «C kPa b nissioning °C	Works °C °C °C kPa Works	Commiss	C ioning °C °C kPa kPa c ioning °C	۰ ۹۵ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time	Commissioning °C °C kPa Commissioning	Works °C °C °C kPa Works Works	Comn	b nissioning °C °C °C kPa b nissioning °C °C	Works °C °C °C kPa Works °C	Commiss	C ioning °C °C °C kPa kPa C ioning °C °C	۰ ۹ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time Cycle finish time Full load test Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP	Commissioning °C °C kPa Commissioning Commissioning Commissioning °C °C °C kPa	Works °C °C °C kPa Works Works °C °C «C kPa	Comn	b nissioning °C °C °C kPa b nissioning °C °C °C	Works °C °C °C kPa Works °C °C	Commiss	C ioning °C °C °C kPa KPa C ioning °C °C °C	۰ ۹ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time Cycle finish time Full load test Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure	Commissioning °C °C kPa Commissioning Commissioning Commissioning °C °C	Works °C °C °C kPa Works Works	Comn	b nissioning °C °C °C kPa b nissioning °C °C °C	Works °C °C °C kPa Works °C °C	Commiss	C ioning °C °C °C kPa KPa C ioning °C °C °C	۰ ۹ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴ ۴
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time Cycle start time Full load test Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time	Commissioning °C °C kPa Commissioning Commissioning Commissioning °C °C °C kPa	Works °C °C °C kPa Works Works °C °C «C kPa	Comn	b nissioning °C °C °C kPa b nissioning °C °C °C	Works °C °C °C kPa Works °C °C	Commiss	C ioning °C °C °C kPa KPa C ioning °C °C °C	୍ଦ୍ ବା ତା KP Works ଦା ଦା ଦା
Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure Total cycle time Holding time Cycle start time Cycle finish time Full load test Temperature above the STP Temperature in the drain/vent Temperature in the centre of the STP Chamber pressure	Commissioning °C °C kPa Commissioning Commissioning Commissioning °C °C °C kPa	Works °C °C °C kPa Works Works °C °C «C kPa	Comn	b nissioning °C °C °C kPa b nissioning °C °C °C	Works °C °C °C kPa Works °C °C	Commiss	C ioning °C °C °C kPa KPa C ioning °C °C °C	୍ଦ୍ ବା ତା KP Works ଦା ଦା ଦା



POROUS LOAD STERILIZERS

COMMISSIONING RECORD

Week No.....

Plant reference

Serial number

Sheet 3 of 3

Air detector tests :-

insert data from each air detector tests

Measurements (a) (b) are as for the automatic control test and are the values which causes the air detector to reject the process

Small load test	а		b		С		
	Commissioning	Works	Commissioning	Works	Commissioning	Works	
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			
Temperature difference	°C	°C	°C	°C			
					•		

Full load test	а		b		С	
	Commissioning	Works	Commissioning	Works	Commissioning	Works
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		
Temperature difference	٦°	°C	°C	°C		

controller setting..... sensor location.....

Comments

Data from the tests confirm conformity with the requirements detailed in SHTM 2010
Test Person signature date print name
Audited by:-
Authorised Person signature print name print name
I have reviewed the date from the tests with the Test Person and Authorised Person and I am satisfied that the sterilizer is fit for use
User signature date print name



POROUS LOAD STE	RILIZERS	;								S	heet 1	of 2		
PERFORMANCE QUALIFICATION RECORD (PQ)									v	Veek No	.			
Plant reference numb	oer				V	/alidatic	on file re	eferenc						
Date of tests					Sterilizer serial number									
Performance qualification reference Loading condition referen								erence.						
Task	Schedul	Schedule reference Result						Valid until						
Commissioning														
Yearly test														
Performance qualification														
microbiological *														
thermometric														
* Performance qualified by thermometric tests											ot be der	monstra	ated	
Test instruments														
File reference		Calibra	ation ce	ertificate	num	ber		Ca	libratio	n due				
Error at the sterilizin	ng tempera	ature:-					1	T		1	1	1		
Sensor number		1	2	3	4	5	6	7	8	9	10	11	12	
befor	re PQ test													
after	PQ test													
Data from the tests h reference the requirements are	for loa	ading c	conditio	n refere	nce.			It is c	confirm				with	
Test Person signature	e			print ı	name				d	late				
Audited by:-				•										
Authorised Person sig	gnature			print	name	ə			c	late				
I have compared this condition can be proc									am sa	atisfied	d that th	is loadi	ng	
User signature	datedate													



POROUS LOA	AD STERILIZE	RS					Shee	et 2 of 2	
PERFORMAN	CE QUALIFIC	ATION RECORD (PQ)					Wee	k No	
21									
				-					
Date of tests									
Performance qua	alification reference	æ	Loading	condit	ion reference	e			
Summary of the	rmometric tests								
ounnary or the			Test		Test 2		Test 3		
Cycle number									
		duration							
	Negative	number							
	pulsing	pressure minimum							
Air		pressure maximum							
removal		duration							
	Positive	number							
	pulsing	pressure minimum							
		pressure maximum							
Sterilizing temper	rature (ST) (Set)	procedie maximum							
Holding time (Set									
	()	Location of each sensor			Test ar	nd sen	sor number		
			1		2		3		
		drain/vent			2				
	Time when	fastest load item							
	ST is attained	slowest load item							
	Time when	drain/vent							
	temperature	fastest load item							
	falls below ST	slowest load item							
Sterilizing		drain/vent							
5		fastest load item							
		slowest load item							
	Holding	temperature maximum							
	time	pressure maximum							
		pressure minimum							
		actual ST							
Sanaara laastad	in the positions of	hown on the attached sheet re	oforonoo No						
Sensors localed			Test 2	1	Test 2	·····	Test 3		
		duration	1631		16312		1651.5		
Drying and	drying	pressure minimum							
Vacuum break	urying								
		pressure maximum							
	Vacuum	duration						<u> </u>	
	break								
Duration of the c	ycle	1							
	-					I		I	
Comments									
		ained during performance qua	alification for	loadin	g condition	referei	nce		
		r print nam				الم	ato		



Porous Load Sterilizers – User Daily Record

Tests to be carried out in accordance with SHTM	2010.	
Hospital/Location	Week beginning	Week No.
Department	Ref.No	Ser.No

	VACUUM	LEAK RATE	EST-EMPTY	CHAMBER				BOWIE-D	ICK TEST				
								Pack type 🛛 🖉 Indicator sheet ty					
	Cycle number	Pressure when pump stopped	Pressure below 50mbar	Pressure after 5 minutes P1	further 10	Leak rate per minute (P2-P1)/10	Leak rate <1.3 mbar/min	Cycle number	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	Xes/No		C	bar	Pass/Fail		
Tuesday		mbar	Yes/No	mbar	mbar	mbar	Yes/No			bar	Pass/Fail		
Wednesday		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C1	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	n nbar	Kes/No		°C	bar	Pass/Fail		
Retests													
day		mbar	Yes/No	mbar	mtar	f indbar	Yes/No		°C	bar	Pass/Fail		
day		mbar	Yes/No	mba	mbar	mbar	Yes/No		°C	bar	Pass/Fail		
						\mathbf{U}							

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



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	CHAMBE	R		Cycle number	
Pressure when pump stopped after	min	sec			millibar
Pressure below 50 millibar			YES/NO	A	
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 CON	ITROL /	BOWI	E DIC	K TEST		Pac	k / Indicator T	ype 🖌 <	/	
Start cycle t1=0	Cycle n	umber		Eva	cuation to	_	mpar in 🔪	enin 🗸	secon	ds
Pulse number	1	2	3	4	5 🖌		6	k	9	10
Time at peak	:	:		:	: / :	\sim		V :	:	:
Max ind. temp °C										
Max press. bar										
Min press. bar										
					Drair	n tem	perature	Chamb	per press	sure
Final evacuation a	t (t2)		min	sec			Recorded	Indicate	d Re	corded
Sterilizing temp at	(t3)		min	Sec		°C	° C		bar	bar
Instrument reading	gs (t3+1	1)	min	sec		°C	°C		bar	bar
Instrument reading	ys (t3+2	2)	min	sec		°C	°C		bar	bar
Instrument reading	ys (t3+3	3)	min (Sec		°C	°C		bar	bar
Drying stage starts	at (t4)	mip	\sim sec	Jacket pre	essur	e during sterili	izing	bar	
40 mbar reached	at (t	5)	min	sed	Minimum	press	sure		mba	ır
Air replacement sta	arts (t6) (min \	Sec /	Maximum	char	t temperature		О°	
Process complete	at (t7	7) <i>(</i>	(min	sec	Indicator s	sheet	result	PA	<u>SS / FAI</u>	L
Final evacuation to	o sterilizir		<u> </u>	√min∀	sec		removal time	(t2-t1)	min	sec
Time at sterilizing		<u></u> (t4-)	3)	min	sec	Ster	rilizing stage ti	me(t4-t2)	min	Sec
Time to reach 40m		<u>(</u>)(15-		min	sec		ing stage time	(t6-t4)	min	sec
Air replacement tir	ne 🖊 🖊	<u>(tz-t</u>	6)	min	sec	Tota	al cycle time	(t7-t1)	min	sec
AIR DETECTOR F	UNCTIC	N TES	ST		Pa	ack T	ype Shee	ts / Towels		
						-				

AIR DETECTOR FUNCTION I	251	Раск туре	Sneets / Towers	
Leak rate setting to reject cycle	millibar/min (fro	m Yearly test re	esults)	
Cycle number	Air detector setting		Air detector reached	
Result of test	REJECT / ACCEPT	SATISFACTO	RY / UNSATISFACTORY	

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

TEST RESULT SATISFACTORY/UN	SATISFACTORY	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.

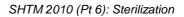
Hospital/Location	Date	Week
Department	Ref.No	Ser.No

VACUUM LEAK RATE TEST-EMPTY	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	

VERIFICATIO	N OF CALIBR	ATION OF ST	ERILIZER INS	TRUMEN	NTS/S	SMALL LOAD	TEST	
Verification of calibration of test instrument before tests ca							UNSATISFA	CTORY
Readings to be	e taken during	the sterilizing I	nold period		Cycl	le number		
	Indicate	d values	Recorde	d values		Mea	sured values	
Time	Chamber	Drain Temp.	Chamber	Drain Te	emp.	Chamber	Drain Temp	Load
	pressure		Pressure		-	Pressure		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	o.above pack		°C	Max.temp. above pack after 1 minute °C				
Calibration of i	nstruments wit	hin limits YES	S/NO	If not, then note inaccuracies below, and action.				
Outstanding in	accuracies							
If any calibration	on has been ch	nanged during	this quarterly	test,note l	below	/ with initial eri	or	
Equilibration tir	me less than 1	5 seconds YE	S/NO	Drying va	cuum	n below 40 m	illibar YES	S/NO
Drying stage m	Drying stage more than 3 minutes YES/NO					s sensibly dry a	after cycle Y	ES/NO
Verification of	calibration of te	est instrument	after tests car	ried out	SAT	ISFACTORY /	UNSATISFAC	TORY
Result of test	SATISFACTC	RY/UNSATIS	FACTORY					

VACUUM LEAK RATE TEST-EMPTY C	HAMBER			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/UNSA	ATISFACTORY	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	SATISFA	CTORY / 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/UNSA	Comments			

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

COMMENTS

-			
TEST RESULT SATISFACTORY/UNSATIS	SFACTORY	STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE



POROUS LOAD STERILIZERS Sheet 1 of 2													
PERFORMANCE REQUA	LIFIC	ΑΤΙΟ	N RECO	ORD (F	RQ)				W	eek No		
Plant reference number						Valid	Validation file reference						
Date of tests						Steri	Sterilizer serial number						
Performance qualification	ormance qualification reference						Loading condition reference						
Task			Sche	dule re	efer	ence		Res	ult	Valie	d until	Ini	itial
Commissioning													
Yearly test valid													
Performance qualification	on												
*microbiological													
thermometric													
Performance regualification													
* microbiological													
thermometric													
* is required if biological te	ests we	ere ca	rried du	uring va	lida	tion							
Test instruments													
File reference		Calit	oration of	certifica	atior	numb	er.			.Calibr	ation du	e	
Error at the sterilizing te	mpera	ature:	-										
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 to reference													วท
Test Person signature				. print n	am	e				dat	e		
Audited by:-				•									
Authorised Person signate	Jre			. print r	nam	e				dat	e		
I have compared the resu qualification reference with the Test Person, Main condition can be processe	Its fron	n thes	e tests erson ar	with th an nd Auth	e da nd I loris	ata in ti have a ed Per	he v also rsoi	validat o revie n. I am	ion file wed d satis	e for pe ata in t	erforma he bato	nce ch reco	
User Signature				print n	ame	ə				da	ate		



POROUS LOA	D STERILIZE	RS			Sheet 2	of 2		
PERFORMAN	CE REQUALIF	FICATION RECORD (PQ)		Week No	D		
Plant reference n	umber		Validation file	e reference				
Date of tests			Sterilizer serial number					
		e	Loading condition reference					
			0					
Summary of the	rmometric tests		Tast 4	Ta at 0	Te et 0			
Cycle number			Test 1	Test 2	Test 3			
		duration						
	Negative	number						
	pulsing	pressure minimum						
Air		pressure maximum						
removal		duration						
	Positive	number						
	pulsing	pressure minimum						
		pressure maximum						
Sterilizing temper	ature (ST) (Set)							
Holding time (Set								
	/	Location of each sensor		Test and sen	sor number			
			1	2	3			
		drain/vent	· ·					
	Time when ST is attained Time when temperature falls below ST	fastest load item						
		slowest load item						
		drain/vent						
		fastest load item						
		slowest load item						
Sterilizing		drain/vent						
		fastest load item						
		slowest load item						
	Holding	temperature maximum						
	time	pressure maximum						
		pressure minimum						
		actual ST						
Sensors located i	n the positions sl	hown on the attached sheet re	eference No			I		
			Test 1	Test 2	Test 3			
		duration						
Drying and	drying	pressure minimum						
Vacuum break		pressure maximum						
	-	duration						
	Vacuum							
	break							
Duration of the cy	vcle							
Comments								
		ained during performance qua			cation for loading	condition		
reterence		sterilized in sterilizer serial ne	umber					
Test Person sign	ature	print nam	ne		date			



Г

STERILIZER MODIFICATION AND REPAIR RECORD						
Service provider		Department				
Sterilizer		Plant ref. No				
Modification/repair	Rev	validation file reference	Maintenance Person/Contractor signature	Date completed		
	_					
1						
	_					
	_					



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

Fluids Sterilizer – Weekly Maintenance Schedule

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

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

AUTOMATIC CONT	ROL	TEST			MPR	Ref. No.				
Container type			Conta	iner size			Numb	er of cont	ainers	
Product in container	S								Glass/I	Plastic
Batch number			Cyc	le number		Tim	er setting/Pr	ofile num	ber	
	Ti	ime		Indicated v	alues			Recorded	l values	
Start t1=0	Mir	n:sec	Chamber	Spray			Chamber	Drain/	Load 1	Load 2
Load 1 at °C			Pressure.	Pressure	vent	Temp.	Pressure	vent	Temp.	Temp.
Load 2 at °C					Temp.			Temp		
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(t1		Load spi YES/NO	read max	/min /	°C Belo	ow 80/90 °C	C
MPR/Test compariso	on		MPR			Test		n Limits	Com	ments
	6-t2)		: +/- 209			:		S/NO		
Drain at 115/121 (t8-			: +/- 1			:		S/NO		
	3-t6)		:	+/- 1		:		S/NO S/NO		
	9-t8)		:	+/- 2		. :				
Calibration within lim		ES/NO			If not	, then not	te inaccuraci	es below	, and actio	n
Outstanding inaccur	acies									
Comments on test Result of test SATI	SEAC									
Result of test OAT										
HEAT EXCHANGER				plicable)						
Pressure 10 minutes	s after	closing	valves	bar	P	ressure a	fter further 1	0 minute	S	bar
Pressure drop			ba	bar Result of te SATISFAC			est CTORY/UNSATISFACTORY			
FAULTS-NEW OR E	XIST	ING-AI	SO ENTER	ΙΝ ΡΙ ΔΝΤ	HISTOR	Y RECO	RD			
TAULIS-NEW UR		NG-AL	JU ENTER		INSTOR	TRECO				

TEST RESULT SATISFACTORY/UNSAT	ISFACTORY	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 THERM	IOMET	RIC TE	ST		М	PR	Ref. No.				
Verification of calibra	ation of	test ins	trument b	efore tes	ts carried	lou	t SA	TISFACTO	RY / UNS	ATISFAC	CTORY
Container type			Con	tainer siz	е			Numb	er of cont	ainers	
Product in containers	S									Glass	s/Plastic
Batch number				ycle num				er setting/P			
Measured values in	shaded	boxes -	- Load 1 i	n positio	n slowest	to r	each ste	rilizing temp	erature a	nd Load	2 in
position slowest to reach 80°C(glass) or 90°C(plastic) during cooling.											
	Tim	е		Indicate	d values				Recorded	values	
Start t1=0	Min:s		hamber	Spray			Load	Chamber	Drain/	Load 1	Load 2
Load 1 at °C		P	ressure.	Pressur			Temp.	Pressure	vent	Temp.	Temp.
Load 2 at °C	(=)		-		Temp				Temp		
Load(s) at 80 ° C	(t2)	:	bar	ba	_	°C	°C	bar	•	°C	°C
Load(s) at 80 °C	(t3)	:	-	ba				bar	°C	°C	°C
Drain 115/121 ° C	(t4)	:	bar	ba		°C	°C	bar	°C	°C	°C
Drain 115/121 °C	(t5)	:		ba				bar	°C	°C	°C
Load at 115/121 °C	(t6)	:	bar	ba		°C	°C	bar	-	°C	°C
Load at 115/121°C	(t7)	:		ba				bar	°C	°C	°C
t6+5 minutes		:	bar	ba		°C	°C	bar	•	°C	°C
t6+5 minutes		:		ba	r			bar	•	°C	°C
t8-5 minutes		:	bar	ba	r	°C	°C	bar	-	°C	°C
t8-5 minutes		:		ba	ar			bar	°C	°C	°C
Sterilizing ends	(t8)	:	bar	ba	r	°C	°C	bar	°C	°C	°C
Sterilizing ends	(t8)	:		ba	r			bar	•	°C	°C
Load at 80/90°C	(t9)	:	bar	ba	r	°C	°C	bar	-	°C	°C
Load at 80/90° C	(t10)	:		ba	r			bar	-	°C	°C
Cooling ends (t11)	:	Cycle	complete((t12) :	Load YES/I		ead max/	/min /	°C Belo	ow 80/90	°C
MPR/Test compariso	on	MPR	ti Li	mits	Test	\	Within Li	mits	Measure	d values	Te st
	6-t2)	•	+/-	20%	:		YES/N		up stage		
Drain at 115/121 (t8-		:		10%			YES/N		n at 115/1) :
	3-t6)	:		10%			YES/N		lizing stag		
	9-t8)	:	+/-	20%	:		YES/N		ing stage	(t10-	
Calibration within lim		S/NO			lf	not,	then not	e inaccurac	ies below	, and act	ion
Outstanding inaccur											
If any calibration has	been o	changeo	d during ti	nis quarte	erly test, r	note	below w	lith initial eri	or		
Comments on test											
Verification of calibra	ation of	test ins	trument a	fter tests	carried c	ut	SA	TISFACTO	RY / UNS	ATISFAC	TORY
Result of test SATI											

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

TEST RESULT SATISFACTORY/UNSAT	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 C	HECK	S	Ti	ick if Sati	sfacto	ory				Additionation	al to weel	kly	
Drop below 115/121	°C duriı	ng sterilizii	ng sho	uld cause	e cycle	e fail [] Chamber safety li bar					r safety li	ft at	
Steam pressure low]] Wate	rpress	ure low]]	Air press	ure low]		er failure	[]	
							•						
PERFORMANCE REQUALIFICATION TEST MPR Ref. No.													
Container type			Con	tainer siz	e			1	Num	ber of co	ontainers		
Product in containers	S										Gla	ss/Plastic	
Batch number			С	ycle num	ber		Ti	imer sett	ing/l	Profile nu	umber		
Measured values in	shaded	boxes - L				vest t						d 2 in	
position slowest to re								0		•			
	Tim			Indicated					l	Recorde	d values		
Start t1=0	Min: s	sec Cha	mber	Spray	Dr	ain/	Load	Chamb	ber	Drain/	Load 1	Load 2	
Load 1 at °C		Pres	sure.	Pressur	e ve	ent	Temp.	Pressu	ire	vent	Temp.	Temp.	
Load 2 at °C					Те	mp.				Temp			
Load(s) at 80 ° C	(t2)		bar	ba	ar	°C	°C		bar	°C	°C	°C	
Load(s) at 80 °C	(t3)	:		ba	ar				bar	°C	°C	۵°	
Drain 115/121 ° C	(t4)	:	bar	r bar		°C	°C		bar	°C	°C	°C	
Drain 115/121 °C	(t5)	:		bar					bar	°C	°C	۵°	
Load at 115/121 °C	(t6)	:	bar	oar bar		°C	°C		bar	°C	°C	°C	
Load at 115/121°C	(t7)	:		ba	ar				bar	°C	°C	°C	
t6+5 minutes		:	bar	ba	ır	°C	°C		bar	°C	°C	°C	
t6+5 minutes		:		ba	ar			bar		°C	°C	°C	
t8-5 minutes		:	bar	ba	ar	°C	°C	bar		°C	°C	°C	
t8-5 minutes		:		ba	ar				bar	°C	°C	۵°	
Sterilizing ends	(t8)		bar	ba	ar	°C	°C		bar	°C	°C	°C	
Sterilizing ends	(t8)	:		ba	ar				bar	°C	°C	۵°	
Load at 80/90°C	(t9)	:	bar	ba	ar	°C	°C		bar	°C	°C	°C	
Load at 80/90° C	(t10)	:		ba	ar				bar	°C	°C	۵°	
Cooling ends (t11)	: Cy	cle comp	ete(t12	2): L	.oad s	prea	d max/mi	n /	°C	Below	80/90 °C	YES/NO	
MPR/Test compariso	on	MPR	Li	mits	Tes	st	Within	Limits		Measu	ed value	s Te st	
Heat up stage (te	6-t2)	:	+/-	20%			YES/	/NO		at up stag		-t3) :	
Drain at 115/121 (t8-	,	:		10%	:		YES/		Dra	in at 115	5/121 (t8-1	t5) :	
9 0 (8-t6)	:		10%			YES/			rilizing st		-t7) :	
	9-t8)	:	+/-	20%	:		YES/			oling stag		0-t8) :	
Calibration within lim		S/NO				lf n	ot, then n	ote inac	cura	icies belo	ow, and a	ction	
Outstanding inaccur													
If any calibration has	s been o	changed d	uring t	nis yearly	/ test,	note	below wi	tn initial	erro	r			
Commonte en test													
Comments on test Result of test SATI	SEACT			ΔΟΤΟΡΥ	,								
Result of test SATI													
COOLANT QUALIT							Carried of						
Result of test (resid	ue cono	centration)		mg/litre			Result le	ss than 4	40m	g/litre	YES/NO		
TEST RESULT SAT	ISFACT	ORY/UNS	SATISF	ACTOR	Y	ST	ERILIZEF	R IS FIT/	UNF	IT FOR	USE		

TEST PERSON

USER

DATE

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 sterili	•	Sterilizing		
		perio	d	hold Time		
	Cycle	Temperatur Pressure		min:sec	Result of test	Certified fit
	numbe	е				for use by
	r					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 Comments Water ch changed by									
	changeu		Бу							
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.

E	EO	MAINTENANCE SCHEDULES	1 st	2 nd	3 rd	4 th
			Q	Q	Q	Y
Q – Q	QUARTER	RLY				
Y – Y	EARLY I	NTERVALS				
		llowing items within the contract and at the frequency check for safe operation				
1.	Check f	uses and connections on the electrical mains or plug				*
2.	Replace	e faulty indicator lamps.	*	*	*	*
3.	Check t	he gauges and their calibrations. Recalibrate as required	*	*	*	*
4.	Examin	e the door seal(s) and replace if damaged	*	*	*	*
5.	Examin	e the door closure mechanism and lubricate.	*	*	*	*
6.	Check t	the door safety interlocks as required by the scheme of inspection	*	*	*	*
7.	Examin required	e all pipe work connections and components for leaks. Repair as	*	*	*	*
8.	Weekly	safety checks as SHTM 2010 Part 3	*	*	*	
9.	Yearly s	safety checks as SHTM 2010 Part 3				*
10.	Safety v	valve check	*	*	*	*
11.	Examin vent	e the condenser in the reservoir/ and discharge from chamber	*	*	*	*
12.	Examin	e electrical connections for security	*	*	*	*
13.	Examin	e timers and check their settings	*	*	*	*
14.		ut detailed periodic quarterly maintenance tasks in accordance scheme of inspection and manufacturer's instructions.	*	*	*	
15.		ut yearly maintenance tasks and check vessel in accordance with eme of inspection and the manufacturer's instructions				*
16.	Check t	he thermal sensor(s) and recorder and recalibrate if necessary				*
17.	Carry o	ut yearly tests in accordance with SHTM 2010 Part 3				*
18.	Refit all	covers & note the cycle count number	*	*	*	*
19.	CARRY REQUI	OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS RED	*	*	*	*
20.		Weekly Satisfactory Not satisfactory	*	*	*	*
21.		Quarterly Satisfactory Not satisfactory	*	*	*	*
22.		Yearly Satisfactory Not satisfactory				*
23.	Comple	te the log book and summary sheets	*	*	*	*
24.		ne user of any defect or safety hazard. Complete the service . 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/	ocation			Week nun	nber				4				
Departme	ent			Ref.No			Ser.	No					
				·									
Note:-Wh	nere the lo	bad probe cannot be placed in a load	item the "Cha	amber at T°C	C" time sl	nould be	used instead	d of "Sterjili zi r	g stage" (in	te for MPF	R comparisor	n.(See Yea	rly Test Form)
									∇			·	
Date	Batch	Product or load description	Container	Number of	Timer	Cycle	Time load	Load	Chamber	Heatup	Sterilizing	Cooling	Comments
	No.		type/size	containers	setting	counter	/chamber	▼ tenp	temp	time	time	time	and operator
							at	during	during	within	within	within	initials
							sterilizing	sterilizing	sterilizing	MPR	MPR	MPR	
							temp			limits	limits	limits	
					A			℃	°C	Yes/No	Yes/No	Yes/No	
						$\left(\cap \right)$	\ : \	<u>℃</u>	°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	
					$\land \land$:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
					\sim	~	:	°C	°C	Yes/No	Yes/No	Yes/No	
			\land	\cap			:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
			$\left(\begin{array}{c} \\ \\ \end{array} \right)$:	°C	°C	Yes/No	Yes/No	Yes/No	
			\mathbb{P}				:	°C	°C	Yes/No	Yes/No	Yes/No	
	1						:	°C	°C	Yes/No	Yes/No	Yes/No	
	1							°C	°C	Yes/No	Yes/No	Yes/No	
								°C	℃ ℃	Yes/No	Yes/No	Yes/No	
	1 1	\sim	 	l			•	Ŭ	0		100,110		
Roview o	f hatch ro	ecords for week by User and Test Pers	son If no pro	duction runs	have he	on carria	d out the To	et Parson of	ould carry	ut an Aut	omatic Contr	ol Test and	t fill in the
details at	I DAIGHTE				nave be	CITCAILLE		531 1 61 5011 51	iouiu carry (an Aut		UI I ESI dIII	
Weekly s		cks Door seal condition [] Do	oor temperat	ure interlock	[]								
WOORIY 3	arety one		oor temperat		LJ								

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



Dry Heat Sterilizer – Quarterly Maintenance Schedule

Tests to be carried	out in accordance	e with SHTM	<i>I</i> 2010.						
Hospital/Location			Date	Week					
Department Ref.No						Ser.No			
SAFETY CHECKS		Tick if S	Satisfactory						
Door Seal	[]	Cooling	interlock	[]	Door Clo	sed Inte	rlock	[]
AUTOMATIC CON	TROL TEST			Production	load.		Cycle n	umber	
Calibration SA	TISFACTORY/UI	NSATISFAC	CTORY	Fill in detai	ls on v	veekly test	t sheet D	HS1	
PERFORMANCE R	REQUALIFICATIO	N	М	PR Ref. No					
Load details							\boldsymbol{A}		
Container type		Container	· size			Number of	f contain	ers	
Product in containe	rs			<u>.</u>					
Batch number		cle number			ner set				
Sterilizing temperat	ure 160/170/180	°C =T°C	Te	emp control	ler set	ting(s)			
Measured values an	re in shaded boxe	es. Where the	he load prol	be of the ste	erilizer	cannot be	put into	the lo	bad,
use chamber at 80°	C for t2, leave the	e t6 row bla	nk, and use	e t4 and t7 ir	nstead	of t6 in th	e MPR/I	est	
comparison.	— ·	1				\downarrow			
01	Time		Indicated v				corded va		a d
Start t1=0	Min: sec	Chamber	Load	Pressure across fi		Chamber	temp.		bad
Load at 80°C	(t2) :	Temp.(B) °C	Temp.				°C	Te	mp. ℃
Load at 80°C	(t2) : (t3) :	°C				-	0°		0°
Chamber at T°C	(t3) :	0°C					<u> </u>		0°
Chamber at T°C	(t5) :	0°C					0°		0 O°
Load at T°C	(t6) :	°C	-				°C		°C
Load at T°C	(t7) :	°C					°C		°C
t6+5 minutes	:	\°C					°C		°C
t6+5 minutes	:	°C					°C		°C
t8-5 minutes	:			·			°C		°C
t8-5 minutes	:	°C	°C				°C		°C
Sterilizing ends	(t8) :	3 ° 1					°C		°C
Sterilizing ends	(t8) :	°C	-				°C		°C
Load at 80°C	(t9) :	$ \land \ \circ $	°C				°C		°C
Load at 80°C	(t10) :	°C	0	•			°C		°C
Cooling ends (t11)		Cycle con	plete (t12)	:	l	_oad belov	<u>v 90°C `</u>	YES/N	10
MPR/Test comparis		MPR	Limits	Test		Result			
	(t6- 12)or(t4	↓ :	+/- 20%	:		Yes/No			
t2)									
	8-t4)	:	+/- 10%	:		Yes/No			
Sterilizing stage (I		:	+/- 10%			Yes/No			
		:	+/- 20%	:		Yes/No			
Calibration within lin	mits YES/NO		C	omments					
Comments on test	HSFACTORY/UN		TODY						
Result of test SA	ROFACIURY/UN	ISA IISFAC	IUKI						

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

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



Dry Heat Sterilizer – Yearly Maintenance Schedule

Hospital/Location										
Department			Ref	ef.No Ser.N				Ser.No	No	
SAFETY CHECKS		Tick if	Satisfactory	/						
Door Seal	[]	Coolir	g interlock		[]	Door (Closed Ir	terloc	k []
			•							
AUTOMATIC CONT	ROL TEST			Proc	duction	load.		Cycle n	umber	
Calibration SAT	ISFACTORY/	JNSATISFAC	TORY	Fill i	in detai	ls on	weekly test	sheet DI	IS1	
PERFORMANCE RE	EQUALIFICAT	ION		MPR R	Ref. No.					
Load details			L.							
Container type		Containe	er size				Number of	containe	ers	
Product in containers	S	•					<u> </u>			
Batch number		Cycle numbe	r		Tin	ner se	etting			
Sterilizing temperatu	ire 160/170/18	$30^{\circ}C = T^{\circ}C$		Temp o	controll	er set	tting(s)			
Measured values are	e in shaded bo	xes. Where th								
chamber at 80°C for		<u>6 row blank, a</u>				of t6 i	n the MPR/T	est com	pariso	n
	Time		Indicated					corded v		
Start t1=0	Min:sec	Chambe			essure		Chamber	Temp.	Load	Temp.
		Temp(B			cross fi	lter	(A)			
Load at 80°C	(t2) :			°C				°C		°C
Load at 80°C	(t3) :			°C				°C		°C
Chamber at T ^o C	(t4) :			°C				°C		°C
Chamber at T°C	(t5) :			°C				°C		°C
Load at T ^o C	(t6) :			°C				°C	C °(
Load at T⁰C	(t7) :			°C				°C		°C ℃
t6(or t7)+5 minutes	:			°C				°C		°C
t6(or t7)+5 minutes	:			°C				°C		°C
t8-5 minutes	:			°C				°C		°C
t8-5 minutes	:			°C				°C		°C
Sterilizing ends	(t8) :			°C				°C		°C
Sterilizing ends	(t8) :			°C				°C		°C
Load at 80°C	(t9) :			°C				°C		°C
Load at 80°C	(t10) :			°C				°C		°C
Cooling ends (t11)	:		mplete (t12)		:		Load below	<u>/90°C Y</u>	ES/NC	D C
MPR/Test compariso		MPR	Limits		Test		Result			
	6-t2)or(t4-t2)	:	+/- 20%				Yes/No			
	3-t4)	:	+/- 10%		:		Yes/No			
Sterilizing stage (t8-		:	+/- 10%		:		Yes/No			
· ·	9-t8)	:	+/- 20%		:		Yes/No			
Calibration within lim	its YES/NO			Comm	ents					
Comments on test										
Result of test SAT	ISFACTORY/L	INSATISFACT	ORY							
FAULTS-NEW OR E	XISTING-ALS	O ENTER IN	PLANT HIS	TORY	RECO	RD				

CHAMBER OVERHEAT CUT-OL	JT TEST	Maximum cha	mber temperature	°C (should be <200 °C)
AIR FILTER INTEGRITY TEST	Result	%	(should be <0.001%)	
			_	
TEST RESULT SATISFACTORY	UNSATI:	SFACTORY	STERILIZER IS FIT	/UNFIT FOR USE
Test Person	D	ate	User	Date



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

LT	LTS.F MAINTENANCE SCHEDULES							
D =	DAILY W = WEEKLY	D	W					
	ce the following items within the contract and at the frequency ated. Check for safe operation & correct readings			U	М			
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	SMTW ThF 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	SMTW ThF Sa						
13.	Weekly safety checks as per HTM 2010 Part 3	SMTW ThF 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	S M T W Th F Sa						
	Weekly tests satisfactory Not Satisfactory							
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.

L	LTS.F MAINTENANCE SCHEDULES		1 st	2 nd	3 rd	4 th
			Q	Q	Q	Y
Q – (QUARTERL	Y.				
	EARLY IN			1		
		owing items within the contract and at the frequency indicated safe operation				
1.	Check fu	ses and connections on the electrical mains or plug				*
2.	Replace	faulty indicator lamps.	*	*	*	*
3.	Check th	e 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 th	e door safety interlocks as required by the scheme of inspection	*	*	*	*
7.	Examine required	all pipe work connections and components for leaks. Repair as	*	*	*	*
8.	Weekly s	afety checks as SHTM 2010 Part 3	*	*	*	
9.	Yearly sa	fety checks as SHTM 2010 Part 3				*
10.	Safety va	lve check and formalin container vent	*	*	*	*
11.	Examine	the condenser	*	*	*	*
12.	Examine	electrical connections for security	*	*	*	*
13.	Examine	timers and check their settings	*	*	*	*
14.		t detailed periodic quarterly maintenance tasks in accordance with the of inspection and manufacturer's instructions.	*	*	*	
15.		yearly maintenance tasks and check the pressure vessel in the with the scheme of inspection and the manufacturer's instructions				*
16.	Check th	e thermal sensor(s) and recorder and recalibrate if necessary				*
17.	Carry out	yearly tests in accordance with SHTM 2010 Part 3				*
18.	Refit all c	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	e the log book and summary sheets	*	*	*	*
24.		e user of any defect or safety hazard. Complete the service records.	*	*	*	*

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.

E	0	MAINTENANCE SCHE	EDULES			
D =	DAIL	Y W = WEEKLY	D	w		
		following items within the contract and at the frequency check for safe operation & correct readings			U	М
1.		All sterilizer services are turned on and correct readings dicated on controls & gauges	S M T W Th F Sa			
2.		the log book & production records together with the routine biological test for each production cycle. Complete as ed	S M T W Th F Sa			
3.		the chart recorder or data logger. Fit new chart; replenish fit new ink cartridge as required	S M T W Th F Sa			
4.		the chamber & clean as detailed for the type of material ber is constructed from.	S M T W Th F Sa			
5.	Check requir	the chamber discharge strainer. Remove & clean as ed.	S M T W Th F Sa			
6.	Clean	the door system as required by the scheme of inspection. the door seal & its contact surface. Report any damage to aintenance Person	S M T W Th F Sa			
7.		out detailed periodic daily tests in accordance with HTM Part 3 Table 4f.	S M T W Th F Sa			
8.		the ethylene oxide cylinder(s) & monitoring equipment. ge as required. Report defects to the Maintenance Person.	S M T W Th F Sa			
9.		c gauges, digital indicator(s) & indicator lamps. If faulty or change as required.	S M T W Th F Sa			
10.		the door safety interlocks & control systems, lubricate the closure mechanism as required by the scheme of inspection.	S M T W Th F Sa			
11.		ine all pipe work connections & components for leaks. r as required.	S M T W Th F Sa			
12.	Exam	ine door seal(s). Replace if damaged	S M T W Th F Sa			
13.	Week	ly safety checks as per HTM 2010 Part 3	SMTW ThF Sa			
14.		out weekly maintenance tasks & check the pressure vessel ordance with the scheme of inspection and manufacturer's ctions	S M T W Th F Sa			
15.		RY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS JIRED. INSPECT RECORDS WITH USER	SMTW ThF Sa			
16.		Daily tests Satisfactory Not Satisfactory	S M T W Th F Sa			
		Weekly tests satisfactory Not Satisfactory				
17.	Comp	lete the log book.	S M T W Th F Sa			
18.		the user of any defect or safety hazard. Complete the e 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				3 rd	4 th
			Q	Q	Q	Y
	UARTERL					
	EARLY IN		r	r		,
		owing items within the contract and at the frequency indicated afe operation				
1.	Check fu	ses and connections on the electrical mains or plug				*
2.	Replace	faulty indicator lamps.	*	*	*	*
3.	Check the	e 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	e door safety interlocks as required by the scheme of inspection	*	*	*	*
7.	Examine required	all pipe work connections and components for leaks. Repair as	*	*	*	*
8.	Weekly s	afety checks as SHTM 2010 Part 3	*	*	*	
9.	Yearly sa	fety checks as SHTM 2010 Part 3				*
10.	Safety va	lve 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.		detailed periodic quarterly maintenance tasks in accordance with the of inspection and manufacturer's instructions.	*	*	*	
15.		yearly maintenance tasks and check the pressure vessel in ce with the scheme of inspection and the manufacturer's instructions				*
16.	Check the sensor(s)	e temperature sensor(s), humidity sensor(s), and the pressure) & recalibrate if necessary				*
17.	Carry out	yearly tests in accordance with SHTM 2010 Part 3				*
18.	Refit all c	overs & note the cycle count number	*	*	*	*
19.	CARRY	DUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED	*	*	*	*
20.	,	Weekly Satisfactory Not satisfactory	*	*	*	*
21.		Quarterly Satisfactory Not satisfactory	*	*	*	*
22.	,	Yearly Satisfactory Not satisfactory				*
23.	Complete	e the log book and summary sheets	*	*	*	*
24.		e user of any defect or safety hazard. Complete the service records. For 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 READ	INGS DUR	ING FIRST PRC	DUCTION CY	CLE OF THE DA	Y	
	Cycle	During sterilizin	g hold period	Sterilizing hold	Result of test	Certified fit
	number	Temperature	Pressure	time min:sec		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	

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 TE	ST	Cycle counter number				
The cycle selected should b	e rotated	between those in ro	outine use.			
Description of cycle selected	d(include	number if applicable	e)			
Description of load						
Sterilize temperature		Sterilize time		Sterilize pressure		
Temperature controller setting		olicable)				
Timer settings (if applicable)						
Position of load probe (inclu	de type o	f bottle and conten	ts for fluids cycles)			
Start t1=0						
Sterilizing achieved	Ste	erilizing ends	Cooling/drying	g ends Cycle complete		complete
(t2) :	(t3)	:	(t4) :		(t5)	:
Take readings during steriliz	ing hold p	period				
	Indicate	d values		Recorded values		alues
Drain/vent temp. Load	temp.	Chamber	Jacket pressure	Record	ed temp	Recorded
		pressure				pressure
⊃°C	°C	bar	bar		°C	bar
Sterilizing hold period (t3-t2		:	Sterilizing condition		YES/NO	
8	YES/NO		If not, then note ina	accuracie	s below, a	nd action
Outstanding inaccuracies						
For fluids loads , load temp	below 80/	90°C at end of cycl	e YES/NO			
Comments on test						
Result of test SATISFACTO	ORY/UNS	SATISFACTORY				

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

TEST RESULT SATISFACTORY/UNSA	TISFACTORY	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 C	HAMBER			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 C		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			

VACUUM LEAK RATE TEST-EMPTY O		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

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/UNSA	ATISFACTORY	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.

Hospital/Location				Date Week					
Department					Ref.No			Sei	r.No
AUTOMATIC CO	NTROL T	EST			Cycle co	unter num	nber		
Description of cyc	le selecte	ed(inclu	ide number if applic	able	e)				
Description of load									
Sterilize temperature Sterilize time Sterilize pressure Temperature controller settings (if applicable) Sterilize time Sterilize pressure									
			f applicable)						
Timer settings (if a	applicable	∋) udatum	be of bottle and con	4	to for fluido qual				
Position of load pl	iobe (inci	ude typ	be of bottle and con	ten	ts for fluids cycle	es)			
Start t1=0									
Sterilizing achi	eved	5	Sterilizing ends		Cooling/drying	ends	Cv	cle co	omplete
(t2) :	0104	(t3)	:	(t	(4) :	, 0110.0	(t5)	0.0 00	:
Take readings du	ring steril	izing ho			,				
			ted values				Recorde		
Drain/vent temp.	Load te	mp. (Chamber pressure	Ja	acket pressure	Recorde	ed temp		Recorded pressure
°C		°C	bar		bar		°C		bar
Sterilizing hold pe	riod (t3-t	2)	:	Ste	erilizing conditior	ns 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 SA	TISFACT	FORY/L	JNSATISFACTORY						
AUTOMATIC CO						unter num	nber		
		ed(inclu	ide number if applic	able	e)				
Description of load			Ctoriling times						
Sterilize temperat Temperature cont		tingo (if	Sterilize time			5	terilize pr	essur	е
Timer settings (if a			applicable)						
			be of bottle and con	ten	ts for fluids cycle	es)			
						/			
Start t1=0									
Sterilizing achi	eved		Sterilizing ends		Cooling/drying) ends	Су	cle co	omplete
(t2) :		(t3)	:	(t	:4) :		(t5)		:
Take readings du	ring steril								
Ducin has not to see	1		cated values				Recor		
Drain/vent temp.	Load	temp.	Chamber pressu	re	Jacket pressu	re Rec	orded ter	mp	Recorded pressure
°C		° (C k	bar	l	bar		°C	bar
Sterilizing hold pe	riod (t3-t		:		Sterilizing cond	litions me	t YES/	NO	
Calibration within	limits	YES/N			Comments				
				N/OL	e YES/NO				
			80/90°C at end of c	yui					
			80/90°C at end of c JNSATISFACTORY	ycn					
Result of test SA	TISFACT	FORY/L	JNSATISFACTORY						_
Result of test SA	TISFACT	FORY/L			STERILIZER	R IS FIT/U	INFIT FO	RUS	E 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

Hospital/Location				Date			Week	
Department			F	Ref.No			Ser.No	
THERMOMETRIC 1	EST FO	R SMALL I	OAD	C۱	cle counter n	umber		
Small plastic discar							(A)	
Description of cycle						on autocia	vo).	
Description of load	36160160)				
Sterilize temperatur	<u>_</u>	C+	erilize time		Storil	izo procour		
					Stern	lize pressur	е	
Temperature controller settings (if applicable)								
Timer settings (if applicable) Position of load probe (include type of bottle and contents for fluids cycles)								
Position of load pro	be (inclu	de type of t	bottle and contents	s for fluic	is cycles)			
Start t1=0	<u> </u>	0		<u> </u>	· · · ·			
Sterilizing achie			zing ends		g/drying ends		Cycle com	plete
(t2) :		(t3)		4)	:	(t5)		
Take readings durin	ig steriliz			alues in s	shaded boxes.			
		Indicated					orded va	
Drain/vent temp.	Load	temp.	Chamber	Jack	et pressure	Recorded	d temp	Recorded
			pressure					pressure
°C		°C	ba	ar	bar		°C	bar
°C		°C	ba	ar	bar		°C	bar
Sterilizing hold period	od (t3-t2)	:	Sterili	zing condition	s met YE	S/NO	
Calibration within li		/ES/NO			then note ina		elow, and	d action
Outstanding inaccu				,			,	
For fluids loads , loa		helow 80/90	°C at end of cycle	YES/N	0			
Result of test SAT								
Result of test OAT								
	FOLIALI	FICATION				umbor		
PERFORMANCE R				,	cle counter n			
Fluid discard, or cul	ture mec	lia, or free s		first cycle			clave).	
Fluid discard, or cul Description of cycle	ture mec	lia, or free s		first cycle			clave).	
Fluid discard, or cul Description of cycle Description of load	ture mec selectec	lia, or free s d(include nu	mber if applicable	first cycle		ble on autoo		
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur	ture mec selectec e	dia, or free s d(include nu	mber if applicable Sterilize time	first cycle				
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro	ture mec selectec e ller settir	dia, or free s d(include nu ngs (if applic	mber if applicable Sterilize time	first cycle		ble on autoo		
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap	ture mec selectec e ller settir plicable)	dia, or free s d(include nu ngs (if applic	mber if applicable Sterilize time cable)	first cycle)	e in list availat	ble on autoo		
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro	ture mec selectec e ller settir plicable)	dia, or free s d(include nu ngs (if applic	mber if applicable Sterilize time cable)	first cycle)	e in list availat	ble on autoo		
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap	ture mec selectec e ller settir plicable)	dia, or free s d(include nu ngs (if applic	mber if applicable Sterilize time cable)	first cycle)	e in list availat	ble on autoo		
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0	ture mec selectec e Iler settir plicable) be (inclue	dia, or free s d(include nu ngs (if applic	mber if applicable Sterilize time cable)	first cycle)	e in list availat	ble on autoo		
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro	ture mec selectec e Iler settir plicable) be (inclue	dia, or free s d(include nu ngs (if applic de type of t	mber if applicable Sterilize time cable)	first cycle) s for fluic	e in list availat	Sterilize pr	ressure	complete
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0	ture mec selectec e Iler settir plicable) be (inclue	dia, or free s d(include nu ngs (if applic de type of t	mber if applicable Sterilize time cable) pottle and contents	first cycle) s for fluic	e in list availat	Sterilize pr	ressure	complete :
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Sterilizing achie	ture mec selected e Iller settir plicable) be (inclue	dia, or free s d(include nu ngs (if applic de type of t de type of t t ste	mber if applicable Sterilize time cable) pottle and contents rilizing ends	first cycle) s for fluic c (t4)	e in list availat ls cycles) cooling/drying	Sterilize pr	essure	complete :
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Sterilizing achie (t2) :	ture mec selected e Iller settir plicable) be (inclue be (inclue eved	dia, or free s d(include nu ngs (if applic de type of t de type of t total de type of t de type of t	mber if applicable Sterilize time cable) pottle and contents erilizing ends : iod : measured va	first cycle) s for fluic c (t4)	e in list availat ls cycles) cooling/drying	Sterilize pr	essure Cycle c (t5)	:
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Start t1=0 Sterilizing achie (t2) : Take readings durin	ture mec selected e Iller settir plicable) be (inclue be (inclue eved	dia, or free s d(include nu ngs (if applid de type of t de type of t (t3) ing hold per Indicated	mber if applicable Sterilize time cable) pottle and contents erilizing ends : tiod : measured va d values	first cycle) s for fluid c (t4) alues in s	e in list availat ls cycles) ooling/drying : shaded boxes.	Sterilize pr	Cycle c (t5)	: lues
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Sterilizing achie (t2) :	ture mec selected e Iller settir plicable) be (inclue be (inclue eved	dia, or free s d(include nu ngs (if applic de type of t de type of t total de type of t de type of t	mber if applicable Sterilize time cable) pottle and contents erilizing ends : tiod : measured va d values Chamber	first cycle) s for fluid c (t4) alues in s	e in list availat ls cycles) cooling/drying	Sterilize pr ends	Cycle c (t5)	: lues Recorded
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Start t1=0 Sterilizing achie (t2) : Take readings durin Drain/vent temp.	ture mec selected e Iller settir plicable) be (inclue be (inclue eved	dia, or free s d(include nu ngs (if applie de type of t de type of t ttap (t3) ing hold per Indicated t temp.	mber if applicable Sterilize time cable) pottle and contents erilizing ends : tod : measured va d values Chamber pressure	first cycle) s for fluid (t4) alues in s	e in list availab ls cycles) cooling/drying shaded boxes. et pressure	Sterilize pr ends	Cycle c Cycle c (t5) corded va d temp	lues Recorded pressure
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Start t1=0 Sterilizing achie (t2) : Take readings durir Drain/vent temp. °C	ture mec selected e Iller settir plicable) be (inclue be (inclue eved	dia, or free s d(include nu ngs (if applic de type of t de type of t (t3) ing hold per Indicated t temp. °C	mber if applicable Sterilize time cable) pottle and contents erilizing ends : tiod : measured va d values Chamber pressure ba	first cycle) s for fluic (t4) alues in s Jack	e in list availab ls cycles) cooling/drying shaded boxes. et pressure bar	Sterilize pr ends	Cycle c Cycle c (t5) corded va d temp	lues Recorded pressure bar
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Sterilizing achie (t2) : Take readings durin Drain/vent temp. °C	ture mec selected e ller settir plicable) be (inclue eved g steriliz Load	dia, or free s d(include nu ngs (if applid de type of t (t3) ing hold per Indicated t temp. °C	mber if applicable Sterilize time cable) pottle and contents erilizing ends : tod : measured va d values Chamber pressure	first cycle) s for fluic (t4) alues in s Jack ar	e in list availab ls cycles) cooling/drying shaded boxes. et pressure bar bar bar	ends (Recorded	Cycle c (t5) corded va d temp °C °C	lues Recorded pressure
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Sterilizing achie (t2) : Take readings durin Drain/vent temp. °C Sterilizing hold perio	ture mec selected e ller settir plicable) be (inclue eved g steriliz Load	dia, or free s d(include nu ngs (if applid de type of t (t3) ing hold per Indicated t temp. °C °C	mber if applicable Sterilize time cable) pottle and contents erilizing ends : tiod : measured va d values Chamber pressure ba	first cycle) s for fluid (t4) alues in s Jack ar ar Sterili	e in list availab is cycles) cooling/drying shaded boxes. et pressure bar bar jung condition	Sterilize pr Sterilize pr ends (Recorded s met YE	essure Cycle c (t5) corded va d temp °C °C S/NO	: Recorded pressure bar bar
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Sterilizing achie (t2) : Take readings durin Drain/vent temp. C Sterilizing hold perio Calibration within li	ture mec selected e ller settir plicable) be (inclue eved g steriliz Load bd (t3-t2 mits	dia, or free s d(include nu ngs (if applid de type of t (t3) ing hold per Indicated t temp. °C	mber if applicable Sterilize time cable) pottle and contents erilizing ends : tiod : measured va d values Chamber pressure ba	first cycle) s for fluid (t4) alues in s Jack ar ar Sterili	e in list availab ls cycles) cooling/drying shaded boxes. et pressure bar bar bar	Sterilize pr Sterilize pr ends (Recorded s met YE	essure Cycle c (t5) corded va d temp °C °C S/NO	: Recorded pressure bar bar
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Sterilizing achie (t2) : Take readings durin Drain/vent temp. C Sterilizing hold perio Calibration within li Outstanding inaccu	ture mec selected e ller settir plicable) be (inclue eved g steriliz Load bd (t3-t2 mits N racies	dia, or free s d(include nu ngs (if applid de type of t de type of t (t3) (t3) ing hold per Indicated t temp. °C °C) fES/NO	mber if applicable Sterilize time cable) pottle and contents rilizing ends : riod : measured va d values Chamber pressure ba ba i	first cycle) s for fluid (t4) alues in s (t4) alues in s Jack ar Jack ar If not,	e in list availab is cycles) cooling/drying shaded boxes. et pressure bar bar jung condition then note inac	Sterilize pr Sterilize pr ends (Recorded s met YE	essure Cycle c (t5) corded va d temp °C °C S/NO	: Recorded pressure bar bar
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Start t1=0 Sterilizing achie (t2) : Take readings durin Drain/vent temp. °C Sterilizing hold peric Calibration within li Outstanding inaccu For fluids loads , loa	ture mec selected e Iller settir plicable) be (inclue eved g steriliz Load d (t3-t2 mits) racies ad temp l	dia, or free s d(include nu ngs (if applid de type of t de type of t (t3) ting hold per Indicated t temp. °C °C) YES/NO	mber if applicable Sterilize time cable) pottle and contents rilizing ends : iod : measured va d values Chamber pressure ba : ba chamber pressure ba	first cycle) s for fluid (t4) alues in s (t4) alues in s Jack ar Jack ar If not,	e in list availab is cycles) cooling/drying shaded boxes. et pressure bar bar jung condition then note inac	Sterilize pr Sterilize pr ends (Recorded s met YE	essure Cycle c (t5) corded va d temp °C °C S/NO	: Recorded pressure bar bar
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Sterilizing achie (t2) : Take readings durin Drain/vent temp. C Sterilizing hold perio Calibration within li Outstanding inaccu	ture mec selected e Iller settir plicable) be (inclue eved g steriliz Load d (t3-t2 mits) racies ad temp l	dia, or free s d(include nu ngs (if applid de type of t de type of t (t3) ting hold per Indicated t temp. °C °C) YES/NO	mber if applicable Sterilize time cable) pottle and contents rilizing ends : iod : measured va d values Chamber pressure ba : ba chamber pressure ba	first cycle) s for fluid (t4) alues in s (t4) alues in s Jack ar Jack ar If not,	e in list availab is cycles) cooling/drying shaded boxes. et pressure bar bar jung condition then note inac	Sterilize pr Sterilize pr ends (Recorded s met YE	essure Cycle c (t5) corded va d temp °C °C S/NO	: Recorded pressure bar bar
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Start t1=0 Sterilizing achie (t2) : Take readings durin Drain/vent temp. Calibration within li Outstanding inaccu For fluids loads , loa Result of test SAT	ture mec selected e ller settir plicable) be (inclue be (inclue)be (inclue be (inclue)be	dia, or free s d(include nu ngs (if applid de type of t de type of t (t3) ing hold per Indicated t temp. °C °C) (ES/NO below 80/90 DRY/UNSAT	mber if applicable Sterilize time cable) Dottle and contents rilizing ends : riod : measured va d values Chamber pressure ba : "C at end of cycle TISFACTORY	first cycle irst cycle first cycle control control	e in list availat ls cycles) cooling/drying : shaded boxes. et pressure bar bar bar jing condition then note inac	Sterilize pr Sterilize pr ends (Recorded s met YE ccuracies b	essure Cycle c (t5) corded va d temp °C °C S/NO elow, and	: Recorded pressure bar bar
Fluid discard, or cul Description of cycle Description of load Sterilize temperatur Temperature contro Timer settings (if ap Position of load pro Start t1=0 Start t1=0 Sterilizing achie (t2) : Take readings durin Drain/vent temp. °C Sterilizing hold peric Calibration within li Outstanding inaccu For fluids loads , loa	ture mec selected e ller settir plicable) be (inclue be (inclue)be (inclue be (inclue)be	dia, or free s d(include nu ngs (if applid de type of t de type of t (t3) ing hold per Indicated t temp. °C °C) (ES/NO below 80/90 DRY/UNSAT	mber if applicable Sterilize time cable) Dottle and contents rilizing ends : riod : measured va d values Chamber pressure ba : "C at end of cycle TISFACTORY	first cycle irst cycle first cycle control control	e in list availab is cycles) cooling/drying shaded boxes. et pressure bar bar jung condition then note inac	Sterilize pr Sterilize pr ends (Recorded s met YE ccuracies b	essure Cycle c (t5) corded va d temp °C °C S/NO elow, and	: Recorded pressure bar bar



Laboratory Sterilizer – Yearly Maintenance Schedule

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

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 ste	rilizing 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 TE	Cycle counter	number						
The cycle selected sh	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	pressure					
Temperature controlle	ler settings (if	applicable)						
Timer settings (if app								
Position of load probe	e (include typ	e of bottle and conte	ents for fluids cycle	es)				
Start t1=0	I							
Sterilizing achieve		Sterilizing ends	Cooling/drying			complete		
(t2) :	(t3)	:	(t4) :		(t5)	:		
Take readings during			d values in shaded					
		ted values		Recorded values				
Drain/vent temp. L	_oad temp.	Chamber pressure	Jacket pressure	Record	ed temp	Recorded		
					-	pressure		
۵°	°C	bar	bar		°C	bar		
٦°	°C	bar	bar		°C	bar		
Sterilizing hold period	· · ·	:	Sterilizing condition					
Calibration within lim		0	If not, then note in	naccuraci	es below,	and action		
Outstanding inaccuracies								
For fluids loads , load			/cle YES/NO					
Result of test SATIS	SFACTORY/L	JNSATISFACTORY						

TEST RESULT SATISFACTORY/UN	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	Product	Volume	Timer	Cycle	Time	Indicated	Recorded	Sterilizing	Comments
	No.			setting	counter	chamber at	temp	temp	time within	and
						sterilizing	during	during	limits	operator
						temp	sterilizing	sterilizing		initials
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	C°	°C	Yes/No	
						:	0°	0°	Yes/No	
						:	0°	°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	С°	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	
						:	<u> </u>	°C	Yes/No	
			L			:	<u>0°</u>	°C	Yes/No	
						:	<u>0</u> 0°	0 ℃	Yes/No	
						:	<u>0</u> 0°	0 ℃	Yes/No	
							<u>0</u> 0°	0 ℃	Yes/No	
						· ·	0 0°	0 ℃	Yes/No	
							<u>℃</u> ℃	⊃°C	Yes/No	
							 ℃	⊃°	Yes/No	
						•	 ℃	ວ ົ	Yes/No	
							<u></u> 0°	℃ ℃	Yes/No	
						:	-U	÷ل	Tes/INO	

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 SATISFACTOR	RY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE		
Test Person	Date	User	Date	



Culture Media Preparator Sterilizer Yearly Maintenance Schedule

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[]							
Chamber safety lift at bar	Jacket safety lift at ba	Power failure []					

THERMOMETRIC TEST FOR FULL LOAD				Cycle counte	r number		
Type of culure med	dium			Volume of liquid			
Sterilize temperatu	ire			Sterilize time			
Temperature controller settings (if applicable)							
Timer settings (if a	Timer settings (if applicable)						
Start t1=0							
Sterilizing achi	eved	Ste	rilizing ends	Cooling e	nds	Cycle	complete
(t2) :		(t3)	:	(t4) :		(t5)	:
Take readings duri	ng steriliz	zing hold p	eriod : measured v	alues in shaded	ooxes.		
		Indicated	d values		Recorded values		
Load temp.	Load	temp.	Chamber	Jacket pressure	Record	ed temp	Recorded
			pressure				pressure
°C		°C	bar	ba	ar	°C	bar
۵°		°C	bar	ba	ar	°C	bar
Sterilizing hold per	iod (t3-t2	<u>')</u>	:	Sterilizing condit	ions met	YES/NO	
Calibration within limits YES/NO				If not, then note inaccuracies below, and action			
Outstanding inaccu	uracies						
Door safety hood ι	unable to	be opened	d until load temps b	elow 80°C at end	of cycle	YES/NO	
Result of test SA	TISFACT	ORY/UNS	ATISFACTORY				

REHEAT AND DIS	PENSING TEST		Cycle counter number			
Type of culture me	dium		Volume of liquid			
Reheat temperatur	e setting	°C	Dispensing temper	rature setting	°C	
Start t1=0						
Take readings at s	tart, middle and end	d of dispensing per	iod.			
	Indicated	d values		Recorded v	alues	
	Load temp.	Chamber	Jacket pressure	Recorded temp	Recorded	
		pressure			pressure	
Start	°C	bar	bar	°C	bar	
Middle	°C	bar	bar	°C	bar	
End	°C	bar	bar	°C	bar	
Indicated temp with	hin 2 °C of set temp	YES/NO	Indicated chamber pressure zero YES/NO			
Medium does not solidify YES/NO						
Outstanding inaccu	Outstanding inaccuracies					
Result of test SA	TISFACTORY/UNS	ATISFACTORY				

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