

HTM2010 Porous Load - Quarterly Tests

Header		
Authority		
Hospital		
Department		
Date of Report		Dates of Tests
Sterilizer	Manufacturer	
	Serial Number	
	Plant reference number	
	Model	
	Usable Chamber Space	litres
Service Provider		
Validation File Ref.		Data File Ref.

Quarterly Safety Checks		
Safety Check	Completed	Notes
Check condition of Door Seal:		
Check condition of Closure Mechanism and Limit Switches correctly set:		
Check that the Door is fully engaged by clamps in the locked position:		
Check that the Door Steam Safety interlock is working correctly:		
Check that the Door Safety Edge is working correctly:		
Check that the Door Pressure interlock is working correctly:		
Check that the Chamber Safety Valve is free and discharges at correct press.:		
Check that the Jacket Safety Valve is free and discharges at correct pressure:		
Check condition of Services and test for correct functioning of failure modes:		
Additional checks listed by Competent Person regarding the Pressure Vessel:		

Record Test as PASS or FAIL

Vacuum Leak Test			
	Before insertion of test Instruments.	After insertion of test Instruments.	After removal of test Instruments.
Cycle Counter Number			
Start time	hh.mm.ss	hh.mm.ss	hh.mm.ss
Absolute Gauge Reading (Pump stopped)	mbar	mbar	mbar
Absolute Gauge Reading after minutes	mbar	mbar	mbar
Absolute Gauge after further minutes	mbar	mbar	mbar
Rise in Pressure between Readings	mbar	mbar	mbar
Vacuum Leak Rate	mbar/min	mbar/min	mbar/min
State PASS/FAIL			

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Automatic Control Test													
Cycle No.			Start time			hh.mm.ss							
Air Removal Stage Pre-Vacuum Pulsing	Vacuum Switch Point			Time to Vacuum Switch Point			mins.secs						
	Vacuum Hold Time			Total Vacuum Duration			mins.secs						
	Pulse		Start			Peak			Finish				
		Temp (°C)	Press mB	Time		Temp (°C)	Press mB	Time	Temp (°C)	Press mB	Time		
	1												
	2												
	3												
	4												
	5												
	6												
	7												
	8												
	9												
	10												
	11												
	12												
13													
14													
15													
Duration of Pulsing			h:mm:ss			Number of Pulses							
Steam Admission Stage	Time to Attain Sterilizing			mins.secs			Sterilization temp (ST) selected						
Sterilizing Stage	Start			minute(s)			minutes		minutes				
	Indicated Pressure (barA)												
	Recorded Pressure (barA) (Digital**)												
	Recorded Pressure (barA) (Analogue*)												
	Test Pressure												
	Indicated Temperature (°C)												
	Recorded Temperature (°C) (Digital**)												
	Recorded Temperature (°C) (Analogue*)												
	Test Temperature												
	Hold Time			h.mm.ss			Equilibration Time		mins.secs		Stage Time		h.mm.ss
Drying Stage	Time to Switch Point			mins.secs			Vacuum Switch Point						
	Vacuum Hold Period			mins.secs			Extended Drying Period		mins.secs				
	Maximum Vacuum Attained			mbar			Stage Time		mins.secs				
Air Admission Stage	Time to Atmospheric Pressure			mins.secs									
Cycle Complete Time	hh.mm.ss			Total Cycle Time			hh.mm.ss						
Bowie - Dick Test	Cycle meets requirements of Automatic Control Test												

** Digital - taken from Sterilizer digital data log (where fitted). *Analogue - taken from Sterilizer analogue recorder (where fitted)

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Thermometric Test for a Small Load

Cycle No.	Start time	hh:mm:ss	Start of Plateau Period	hh:mm:ss	Drain	
Holding Time Temperature						
Channel	Location	Start	minute(s)	minutes	minutes	Time Above
Sensor no.	Drain					h:mm:ss
Sensor no.	Load					h:mm:ss
Indicated	Drain					h:mm:ss
Recorded	Drain					h:mm:ss
Equilibration Time			hh:mm:ss	Drain Fluctuation		
Max. difference Drain - Free Space 1st min. hold time				Load Fluctuation		
Max. difference Drain - Free Space remainder of hold time				Max. difference Drain - Load		
Holding Time Pressure						
Channel	Location	Start	minute(s)	minutes	minutes	
Sensor no.	Chamber	bar	bar	bar	bar	
Indicated	Chamber	bar	bar	bar	bar	
Recorded	Chamber	bar	bar	bar	bar	
Post Vacuum (Drying) Stage						
Stage Time	mm:ss	Pressure at end of vacuum hold		bar	Load sensibly dry	
Total Cycle Time	hh:mm:ss	Cycle meets requirements of Automatic Control Test				
Applicable section of HTM 2010			Applicable HTM 2010 requirements met			

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Air Detector - Function Test

Cycle No.	Start time	hh:mm:ss
Air Detector Setting to Fail Cycle	mbar/°C	Automatic Controller Triggering Point
Pressure/Temperature attained by Air Detector	mbar/°C	Leak Rate for Depression dT = Reject* for Small Load
		mbar/min
Failed Cycle indicated at end of Test		

* As determined during small load Air Detector Performance Test

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Bowie - Dick Test for Steam Penetration

Cycle No.	Start time	hh:mm:ss	Complete time	hh:mm:ss	Total time	hh:mm:ss
Indicated sterilizing temperature		Indicated sterilizing pressure				
Sterilizing Hold Time		mins.secs	Plateau time		mins.secs	
Maximum Temperature difference between Centre Pack and Drain during Hold Time						
Maximum recorded Pressure during Hold Time			Type of test pack			
Uniform Colour change throughout Indicator			System indicates that Bowie - Dick has been run			

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Comments

Declaration Section

DECLARATION OF TEST PERSON (STERILIZERS)

1. All test instruments have current calibration certificates.
2. Calibration of the thermometric test instruments has been checked before and after the thermometric tests
3. The periodic checks and tests have been completed and confirm that the sterilizer is safe to use and that commissioning and performance qualification data collected during validation remain valid.

Test Person:	Name	Signature	Date
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DECLARATION OF USER

The sterilizer is fit for use. The next periodic tests are due no later than:

User:	Name	Signature	Date
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