HTM2010 Porous Load - Quarterly Tests

Header			
Authority	Example Health Authority		
Hospital	Example Hospital		
Department	CSSD		
Date of Report	07/09/2004	**Dates of Tests**	07/09/2004
Sterilizer	**Manufacturer** Unknown		
	Serial Number No. 01 /014567 1995		
	Plant reference number None		
	Model Model 2		
	Usable Chamber Space N/A litres	**Date of Manufacture**	
Service Provider	Isopharm Systems Ltd		
Validation File Ref.		**Data File Ref.**	

Quarterly Safety Checks

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

Record Test as PASS or FAIL **PASS**

Vacuum Leak Test

	Before insertion of test Instruments.	After insertion of test Instruments.	After removal of test Instruments.
Cycle Counter Number	328	329	331
Start time	00.15.00 hh.mm.ss	00.15.12 hh.mm.ss	00.15.15 hh.mm.ss
Absolute Gauge Reading (Pump stopped)	25 mbar	28 mbar	30 mbar
Absolute Gauge Reading after 5 minutes	30 mbar	33 mbar	35 mbar
Absolute Gauge after further 10 minutes	35 mbar	38 mbar	40 mbar
Rise in Pressure between Readings	5 mbar	5 mbar	5 mbar
Vacuum Leak Rate	1 mbar/min	1 mbar/min	1 mbar/min
State PASS/FAIL	**PASS**	**PASS**	**PASS**

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Automatic Control Test

Cycle No. 000330 **Start time** 12:32:39 hh.mm.ss

Air Removal Stage

Pre-Vacuum

Pulsing

Vacuum Switch Point N/A bar Time to Vacuum Switch Point mins.secs

Vacuum Hold Time mins.secs 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	49.2	-25	00:00:06	43.1	-980	00:03:11	92.7	-78	00:03:32
2	92.7	-78	00:03:32	73.1	-756	00:03:50	94.5	-74	00:04:04
3	94.5	-74	00:04:04	74.2	-749	00:04:22	94.7	-182	00:04:34
4	94.7	-182	00:04:34	43.1	-750	00:04:52	92.6	-148	00:05:05
5	92.6	-148	00:05:05	74.6	-735	00:05:21	92.2	-142	00:05:33
6	92.2	-25	00:05:33	73.0	-746	00:05:49	122.4	1452	00:06:31
7	122.4	1452	00:06:31	112.9	407	00:06:37	120.8	1435	00:06:52
8	120.8	1435	00:06:52	113.6	416	00:06:58	121.3	1482	00:07:13
9	121.3	1482	00:07:13	114.3	471	00:07:19		Not Set	
10									
11									
12									
13									
14									
15									

Duration of Pulsing 0:07:07 h:mm:ss Number of Pulses 9

Steam Admission Stage Time to Attain Sterilizing 00:31 mins.secs Sterilization temp (ST) selected 134.0 °C

Sterilizing Stage

	Start	**1 minute(s)**	**2 minutes**	**3 minutes**
Indicated Pressure (barA)	3.100	3.180	3.220	3.230
Recorded Pressure (barA) (Digital**)	3.060	3.190	3.220	3.220
Recorded Pressure (barA) (Analogue*)				
Test Pressure Bar	2.0149	2.1844	2.2030	2.2109
Indicated Temperature (°C)	134.0	136.0	136.0	136.0
Recorded Temperature (°C) (Digital**)	134.0	135.9	136.0	136.0
Recorded Temperature (°C) (Analogue*)				
Test Temperature °C	134.1	135.8	136.0	136.1

Hold Time 00:03:39 h.mm.ss **Equilibration Time** 00:00 mins.secs **Stage Time** 00:03:39 h.mm.ss

Drying Stage

Time to Switch Point 1.16 mins.secs Vacuum Switch Point N/A bar

Vacuum Hold Period 0.31 mins.secs Extended Drying Period 1.00 mins.secs

Maximum Vacuum Attained -0.9781 bar Stage Time 3.45 mins.secs

Air Admission Stage Time to Atmospheric Pressure N/A mins.secs

Cycle Complete Time 12:49:26 hh.mm.ss **Total Cycle Time** 00:16:47 hh.mm.ss

Bowie - Dick Test **PASS** Cycle meets requirements of Automatic Control Test **Yes**

** 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. 000330 **Start time** 12:32:39 hh:mm:ss **Start of Plateau Period** 00:07:50 hh.mm.ss **Drain** 134.1 °C

Holding Time Temperature 134.0 °C

Channel	Location	Start	1 minute(s)	2 minutes	3 minutes	Time Above
Sensor no. 1	Drain	134.1 °C	135.7 °C	135.9 °C	136.0 °C	00:03:39 h:mm:ss
Sensor no. 4	Load	134.1 °C	135.8 °C	136.0 °C	136.1 °C	00:03:39 h:mm:ss
Indicated	Drain	134.0 °C	135.8 °C	136.0 °C	136.1 °C	00:04:02 h:mm:ss
Recorded	Drain	134.0 °C	135.9 °C	136.1 °C	136.1 °C	00:04:02 h:mm:ss

Equilibration Time	00:00 hh:mm:ss	Drain Fluctuation	2.0 °C
Max. difference Drain - Free Space 1st min. hold time	2.2 °C	Load Fluctuation	2.1 °C
Max. difference Drain - Free Space remainder of hold time	0.4 °C	Max. difference Drain - Load	0.3 °C

Holding Time Pressure

Channel	Location	Start	1 minute(s)	2 minutes	3 minutes	
Sensor no. 13	Chamber	2.0149 bar	2.1844 bar	2.2030 bar	2.2109 bar	
Indicated	Chamber	2.050 bar	2.220 bar	2.230 bar	2.250 bar	
Recorded	Chamber	2.060 bar	2.230 bar	2.240 bar	2.250 bar	

Post Vacuum (Drying) Stage

Stage Time 3.45 mm.ss Pressure at end of vacuum hold -0.9708 bar Load sensibly dry **PASS**

Total Cycle Time 00:16:47 hh:mm:ss	Cycle meets requirements of Automatic Control Test **PASS**
Applicable section of HTM 2010	Applicable HTM 2010 requirements met **Yes**

HTM 2010 - 13.7

Air Detector - Function Test

Cycle No.	**Start time** hh:mm:ss
Air Detector Setting to Fail Cycle mbar/°C	Automatic Controller Triggering Point mbar/°C
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*

HTM 2010 - 11.60

Bowie - Dick Test for Steam Penetration

Cycle No. 000330 **Start time** 12:32:39 hh:mm:ss **Complete time** 12:49:26 hh:mm:ss **Total time** 00:16:47 hh:mm:ss

Indicated sterilizing temperature 135 °C	Indicated sterilizing pressure 2.250 Bar
Sterilizing Hold Time 00:03:39 mins.secs	Plateau time 00:03:39 mins.secs
Maximium Temperature difference between Centre Pack and Drain during Hold Time 0.3 °C	
Maximum recorded Pressure during Hold Time 2.2119 Bar	Type of test pack
Uniform Colour change throughout Indicator **PASS**	System indicates that Bowie - Dick has been run Yes

HTM 2010 - 13.39

HTM2010 Porous Load - Quarterly Tests

Comments

HTM2010 Porous Load - Quarterly Tests

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

DECLARATION OF USER

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

User:	Name	Signature	Date

Calibration Report

Job Ref.: Thermocouple: Calibration Set 1

Date: 07/09/2004 dd/mm/yyyy Time: 15:50:03

Test Person Russell Baker Sign:VALID ESIG Date: 09/09/2004 dd/mm/yyyy Time: 11:13:13

Reviewed Russell Baker Sign:VALID ESIG Date: 09/09/2004 dd/mm/yyyy Time: 15:38:06

EQUIPMENT	Logger / Recorder	Temp. Ref. Unit
Manufacturer	Agilent	Isotech
Model	34970A	907
Serial No.	MY41030455	34567
Test House		N.T.P.L
Cert. No.		GRD25082
Renew Date		23/06/05

EQUIPMENT	Temp. Ref. Source	Pressure Ref. Unit
Manufacturer	Isotech	SI Instruments
Model	907	TP1-40
Serial No.	34567	5467
Test House	N.T.P.L	RS
Cert. No.	GRD25082	254156
Renew Date	23/06/05	26/04/05

STABILITY SET-UP

0.2 Degrees per minute for 2 minutes. Allowed deviation from Reference 2.0 degrees.

Reference stability criteria 0.05 degrees for 1 minute. Report after Calibration for 2 minutes every 15 seconds.

Report max deviation allowed 0.5 degrees.

		Programmed	**Reference**
Setpoints	Low	100 °C	100.22 °C
	High	130 °C	130.25 °C
	1st Check	121 °C	121.17 °C

LOW Point 100.22 °C STABILITY REPORT

Start Time: 15:54:21 Time when stability requirements met: 16:01:22 Elapsed time: 00:07:02

Reference change: 0.03 °C Maximum sensor change over last minute: 0.06 °C

	Chan1	**Chan2**	**Chan3**
Change (°C)	0.06	0.06	0.04

LOW Point 100.22 °C QUALIFICATION REPORT

Time	Ref.	**Chan1**	**Chan2**	**Chan3**
16:01:22	100.22 °C	100.34	100.41	100.45
Deviation (°C)		0.12	0.19	0.23

LOW Point 100.22 °C POST CALIBRATION REPORT

Time	Ref.	**Chan1**	**Chan2**	**Chan3**
16:01:38	100.20 °C	100.20	100.20	100.22
Deviation (°C)		0.00	0.00	0.02
16:01:53	100.20 °C	100.18	100.19	100.20
Deviation (°C)		- 0.02	- 0.01	0.00
16:02:08	100.19 °C	100.16	100.18	100.19
Deviation (°C)		- 0.03	- 0.01	0.00
16:02:23	100.20 °C	100.21	100.24	100.26
Deviation (°C)		0.01	0.04	0.06
16:02:38	100.20 °C	100.24	100.22	100.24
Deviation (°C)		0.04	0.02	0.04
16:02:53	100.21 °C	100.22	100.23	100.23
Deviation (°C)		0.01	0.02	0.02
16:03:08	100.20 °C	100.16	100.19	100.19
Deviation (°C)		- 0.04	- 0.01	- 0.01
MAX DEV. (°C)		0.04	0.04	0.06

HIGH Point 130.25 °C STABILITY REPORT

Start Time: 16:03:26 Time when stability requirements met: 16:16:22 Elapsed time: 00:12:57

Calibration Report

Job Ref.: Thermocouple: Calibration Set 1

Date: 07/09/2004 dd/mm/yyyy Time: 15:50:03

Test Person Russell Baker Sign:VALID ESIG Date: 09/09/2004 dd/mm/yyyy Time: 11:13:13

Reviewed Russell Baker Sign:VALID ESIG Date: 09/09/2004 dd/mm/yyyy Time: 15:38:06

Reference change: 0.03 °C Maximum sensor change over last minute: 0.11 °C

	Chan1	**Chan2**	**Chan3**
Change (°C)	0.10	0.11	0.08

HIGH Point 130.25 °C QUALIFICATION REPORT

Time	Ref.	**Chan1**	**Chan2**	**Chan3**
16:16:22	130.25 °C	130.53	130.62	130.67
Deviation (°C)		0.28	0.37	0.42

HIGH Point 130.25 °C POST CALIBRATION REPORT

Time	Ref.	**Chan1**	**Chan2**	**Chan3**
16:16:38	130.24 °C	130.24	130.25	130.24
Deviation (°C)		0.00	0.01	0.00
16:16:53	130.25 °C	130.23	130.23	130.23
Deviation (°C)		- 0.02	- 0.02	- 0.02
16:17:08	130.26 °C	130.31	130.28	130.29
Deviation (°C)		0.05	0.02	0.03
16:17:23	130.24 °C	130.30	130.29	130.29
Deviation (°C)		0.06	0.05	0.05
16:17:38	130.22 °C	130.24	130.25	130.25
Deviation (°C)		0.02	0.03	0.03
16:17:53	130.23 °C	130.23	130.25	130.23
Deviation (°C)		0.00	0.02	0.00
16:18:08	130.23 °C	130.22	130.24	130.23
Deviation (°C)		- 0.01	0.01	0.00
MAX DEV. (°C)		0.06	0.05	0.05

CALIBRATION FACTOR AND OFFSET RESULTS

Channel Number	Status	High Ref.	High Measured	Low Ref.	Low Measured
1	IN SPEC.	130.25	130.53	100.22	100.34
2	IN SPEC.	130.25	130.62	100.22	100.41
3	IN SPEC.	130.25	130.67	100.22	100.45

FIRST CALIBRATION CHECK Point 121.17 °C STABILITY REPORT AFTER ADJUSTMENT

Start Time: 16:18:26 Time when stability requirements met: 16:25:12 Elapsed time: 00:06:47

Reference change: 0.02 °C Maximum sensor change over last minute: 0.10 °C

	Chan1	**Chan2**	**Chan3**
Change (°C)	0.09	0.08	0.10

FIRST CALIBRATION CHECK Point 121.17 °C QUALIFICATION REPORT

Time	Ref.	**Chan1**	**Chan2**	**Chan3**
16:25:12	121.17 °C	121.28	121.28	121.28
Deviation (°C)		0.11	0.11	0.11

FIRST CALIBRATION CHECK Point 121.17 °C_ REPORT

Time	Ref.	**Chan1**	**Chan2**	**Chan3**
16:25:28	121.18 °C	121.22	121.24	121.24
Deviation (°C)		0.04	0.06	0.06
16:25:43	121.16 °C	121.21	121.22	121.22
Deviation (°C)		0.05	0.06	0.06
16:25:58	121.15 °C	121.22	121.23	121.23
Deviation (°C)		0.07	0.08	0.08
16:26:13	121.16 °C	121.27	121.27	121.26
Deviation (°C)		0.11	0.11	0.10

Calibration Report

Job Ref.: Thermocouple: Calibration Set 1

Date: 07/09/2004 dd/mm/yyyy Time: 15:50:03

Test Person Russell Baker Sign:VALID ESIG Date: 09/09/2004 dd/mm/yyyy Time: 11:13:13

Reviewed Russell Baker Sign:VALID ESIG Date: 09/09/2004 dd/mm/yyyy Time: 15:38:06

16:26:28	121.17 °C	121.30	121.29	121.28
Deviation (°C)		0.13	0.12	0.11
16:26:43	121.16 °C	121.28	121.28	121.27
Deviation (°C)		0.12	0.12	0.11
16:26:58	121.16 °C	121.23	121.24	121.23
Deviation (°C)		0.07	0.08	0.07
MAX DEV. (°C)		0.13	0.12	0.11

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Cycle No. 000330 **Example Hospital** **15/09/2004**

Serial No. No. 01 /014567 1995

Porous Load Demo **C:\logsys\AC000001\data\000330.mbf**

Test Person: **Sign** **Date** *dd/mm/yyyy*

Reviewed By: **Sign** **Date** *dd/mm/yyyy*

Test Details

Cycle Number 000330 **Comments**

Date 15/09/2004

Start Time: 12:32:39 **End Time:** 12:49:26 **Operator** Russell Baker

Batch **Product**

Operating Cycle Ref User

Logger Serial No. MY41030456

Manufacturer Agilent **Model** 34970A

Cert. No. **Renew Date**

Test House

Test Specification General Porous Load Demo

Sterilising temperature 134.0 °C

Scan Interval (secs) 1 **Version:** **Date of last revision:**

Auto stop logging after: dd:hh:mm **Log off temperature** °C **Log off channel**

Stage Analysis ON

Test Specification Lethality Porous Load Demo

Base temperature: 0.0 °C **Z Value:** 5.0

Selected Channels

Start lethality on: 0.00 °C

End lethality on:

CHANNEL CONFIGURATION Simulation

No.	Label:	Channel Type:	Units:	Chart Colour:	Location:
1	Tmp 1	Type T range: 100mV	°C	Light Red	Drain
4	Tmp 4	Type T range: 100mV	°C	Light Blue	Pack
7	Tmp 7	Type T range: 100mV	°C	Light Cyan	Top
11	Tmp11	Type T range: 100mV	°C	Light Magenta	Bottom
12	Tmp12	Type T range: 100mV	°C	Light Green	Free Space
13	Press	+/- 10V range: 10V	Bar	Black	Pressure

Calibration Calibration Set 1

No.	Date	Time	Measured 1	Reference 1	Measured 2	Reference 2		
1	07/09/2004	16:25:14	130.53	130.25	100.34	100.22	°C	
4							°C	
7							°C	
11							°C	
12							°C	
13							Bar	

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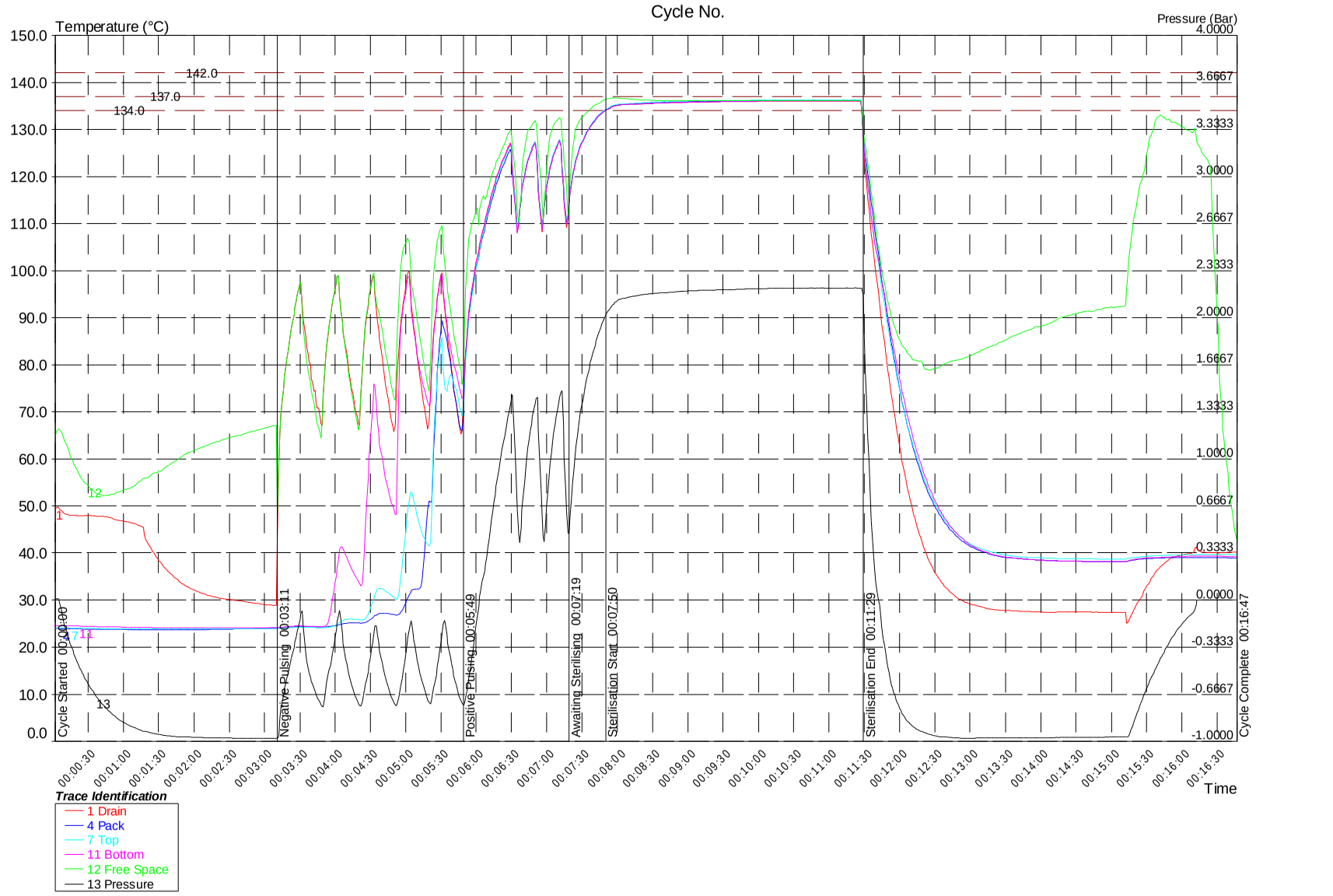
Example Hospital

Cycle No. 000330
Serial No. No. 01 /014567 1995

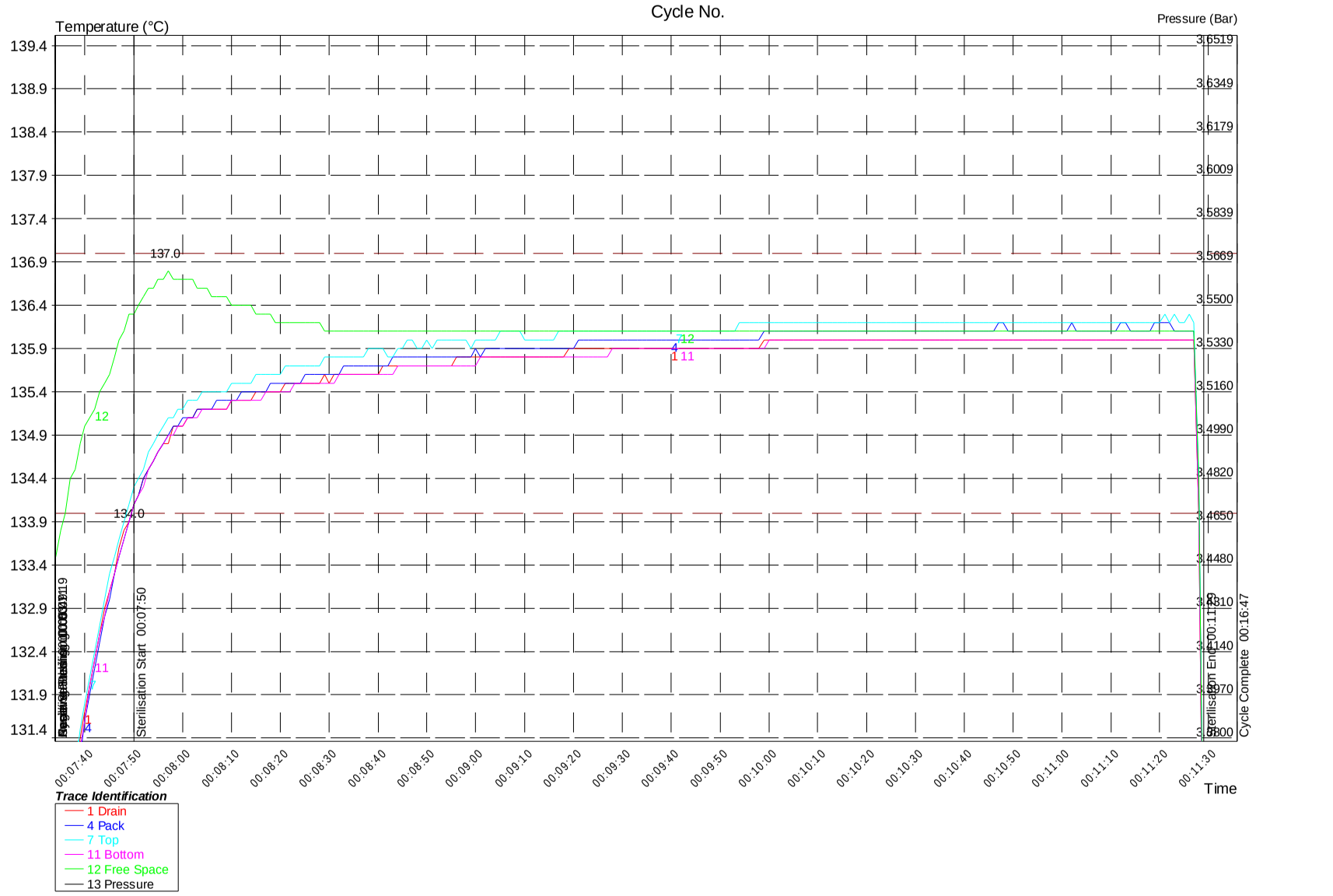
C:\logsys\AC000001\data\000330.mbf
15/09/2004
Porous Load Demo



Isopharm Systems Ltd
Example Hospital

Cycle No. 000330
Serial No. No. 01 /014567 1995

C:\logsys\AC000001\data\000330.mbf
15/09/2004
Porous Load Demo



Calibration Check Report

Job Ref.: Thermocouple: Calibration Set 1

Date: 15/09/2004 dd/mm/yyyy Time: 12:50:24

Operator: Sign: Date:

Reviewed By: Sign: Date:

EQUIPMENT	Logger / Recorder	Temp. Ref. Unit
Manufacturer	Agilent	Isotech
Model	34970A	907
Serial No.	MY41030456	34567
Test House		N.T.P.L
Cert. No.		GRD25082
Renew Date		23/06/05

EQUIPMENT	Temp. Ref. Source	Pressure Ref. Unit
Manufacturer	Isotech	SI Instruments
Model	907	TP1-40
Serial No.	34567	5467
Test House	N.T.P.L	RS
Cert. No.	GRD25082	254156
Renew Date	23/06/05	26/04/05

STABILITY SET-UP

0.2 Degrees per minute for 2 minutes. Allowed deviation from Reference 2.0 degrees.

Reference stability criteria 0.05 degrees for 1 minute. Report after Calibration for 2 minutes every 15 seconds.

Report max deviation allowed 0.5 degrees.

		Programmed	**Reference**
Setpoints	1st Check	134 °C	134.02 °C

FIRST CALIBRATION CHECK Point 134.02 °C STABILITY REPORT AFTER ADJUSTMENT

Start Time: 12:50:31 Time when stability requirements met: 12:52:33 Elapsed time: 00:02:03

Reference change: 0.02 °C Maximum sensor change over last minute: 0.03 °C

	Chan1	**Chan2**	**Chan3**
Change (°C)	0.03	0.03	0.03

FIRST CALIBRATION CHECK Point 134.02 °C QUALIFICATION REPORT

Time	Ref.	**Chan1**	**Chan2**	**Chan3**
12:52:33	134.02 °C	134.06	134.02	134.00
Deviation (°C)		0.04	0.00	- 0.02

FIRST CALIBRATION CHECK Point 134.02 °C REPORT

Time	Ref.	**Chan1**	**Chan2**	**Chan3**
12:52:49	134.02 °C	134.06	134.04	133.99
Deviation (°C)		0.04	0.02	- 0.03
12:53:04	134.02 °C	134.08	134.03	133.98
Deviation (°C)		0.06	0.01	- 0.04
12:53:19	134.02 °C	134.07	134.03	133.99
Deviation (°C)		0.05	0.01	- 0.03
12:53:34	134.02 °C	134.07	134.03	133.99
Deviation (°C)		0.05	0.01	- 0.03
12:53:49	134.02 °C	134.06	134.04	134.00
Deviation (°C)		0.04	0.02	- 0.02
12:54:04	134.02 °C	134.07	134.04	133.98
Deviation (°C)		0.05	0.02	- 0.04
12:54:19	134.02 °C	134.06	134.03	134.00
Deviation (°C)		0.04	0.01	- 0.02
MAX DEV. (°C)		0.06	0.02	- 0.04