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Rev: 1.1.0004 **Washer Disinfecter Yearly Tests for Sugical Instruments**

Rev: 1.1.0012 **Washer Disinfecter Yearly Summary**

Authority			
Hospital			
Department	HSDU		
Date of Report	14/07/2007 14:53:08	Dates of Tests	14/07/2007
Machine	Manufacturer	Hamo	
	Serial Number	980000001017	
	Reference number	Number 3	
	Model	T 21	
	Usable Chamber Space	litres	
	Date of Manufacture	1999	
Service Provider	L.T.E. Scientific Ltd		

Results of Yearly Tests

Tests as Specified in HT2030	Ref	Pass/Fail	Comments
Safety Checks	7.10	Pass	
Water System-Chemical Purity	9.100	N/A	Estates to do tests
Water System-Bacterial Endotoxins	9.201	N/A	Estates to do tests
Drainage-Free Drainage	9.38	Pass	Tank draining ok
Drainage-Efficacy of Discharge	9.40	Pass	Test satisfactory
Door+Interlocks-Cycle Start	9.253	Pass	Pressing start closes door
Door+Interlocks-In Cycle	9.257	Pass	No door open in cycle-stop aborts cycle,password for door open
Door+Interlocks-On Sensor Failure	9.264	Pass	Sensors failing satisfactory
Door+Interlocks-Failed Cycle	9.271	Pass	Password required for dirty door open
Fault Interlock	9.274	Pass	Password required
Water Vapour Discharge Test	9.290	Pass	No visible signs of water vapour discharge
Aerosol Discharge Test	9.298	N/A	
Chemical Additive-Reproducibility	9.279	Pass	Detergent - 450ml/min
Chemical Additive-Low Level Detection	9.285	Pass	On pressing start error message appears, cycle does not start
Load Carriers	9.313	Pass	All free to rotate
Test for Air Quality	9.349	N/A	
Cleaning Efficacy Test	14.12	Pass	No soil residue left after Tests.
Over Temperature Cut Out Test	9.330	Pass	Temperature never exceeded 100°C approx
Load Dryness Test	9.336	Pass	Load was dry after tests
Process Residues-Chemical Additives	9.343	Pass	Test satisfactory

Rev: 1.1.0002 **Test Equipment**

	Manufacturer	Model	Serial No.	Test House	Cert No.	Renew
Data Logger	Fluke	NetDAQ	LTE-LOG16V	N/A	N/A	N/A
Millivolt Source	N/A	N/A	N/A	N/A	N/A	N/A
Temp Ref Source	Jofra	CTC-320A	LT313	N/A	N/A	N/A
Temp Ref Probe	Digitron	20006T	LT332	C.I.S Calibration	27349	20/04/08
Press Ref Unit	Druck	DPI103	DPVTG9	Druck Standards	MC24224001	18/06/08

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Rev. 1-1.0002 **Calibration Report**

Job Reference: 980000001017
Data file Reference: C:\logsys\98001017\data\00_1A.clb
Thermocouple Set: Calibration Set 2

Equipment	Logger	Temp. Ref. Source	Millivolt Source	Temp. Ref. Probe
Manufacturer	Fluke	Jofra	N/A	Digitron
Model	NetDAQ	CTC-320A	N/A	20006T
Serial Number	LTE-LOG16MB	LT313	N/A	LT332
Test House	N/A	N/A	N/A	C.I.S Calibration Laboratories
Cert. Number	N/A	N/A	N/A	27349
Renewal Date	N/A	N/A	N/A	20/04/08

Equipment	Pressure Ref. Unit
Manufacturer	Druck
Model	DPH103
Serial Number	DPVTG9
Test House	Druck Standards Laboratory
Cert. Number	MC24224001
Renewal Date	18/06/08

Setpoints	Programmed	Reference
Low	50 °C	49.90 °C
High	100 °C	99.90 °C
1st Check	90 °C	90.00 °C

Stability Set-up
 Thermocouple Stability: 0.15 Degrees per Minute for 2 Minute(s)
 Allowed deviation from reference: 1.5 Degrees
 Reference stability criteria: 0.05 Degrees for 2 Minute(s)
 Report after Calibration every: 15 Seconds for 2 Minute(s)
 Report maximum deviation allowed: 0.5 Degrees

Low Point 49.90 °C Stability Report
 Start at : 09:33:38 Stability requirements met at : 09:38:09 Elapsed Time : 00:04:31
 Reference Change : 0.00 °C Maximum sensor change over last minute : 0.11 °C

Channel	1	2	3	4	5	6	7
Change (°C)	0.07	0.09	0.11	0.09	0.07	0.09	0.05

Low Point 49.90 °C Qualification Report

Time	1	2	3	4	5	6	7
Time 09:38:09	49.99	49.96	49.90	50.01	49.96	49.99	50.04
Ref. 49.90 °C	49.99	49.96	49.90	50.01	49.96	49.99	50.04
Deviation (°C)	0.09	0.06	0.00	0.11	0.06	0.09	0.14

Low Point 49.90 °C Post Calibration Report

Time	1	2	3	4	5	6	7
Time 09:38:25	49.92	49.92	49.89	49.86	49.89	49.88	49.87
Ref. 49.90 °C	49.92	49.92	49.89	49.86	49.89	49.88	49.87
Deviation (°C)	0.02	0.02	-0.01	-0.04	-0.01	-0.02	-0.03
Time 09:38:40	49.94	50.00	49.95	49.92	49.95	49.96	49.91
Ref. 49.90 °C	49.94	50.00	49.95	49.92	49.95	49.96	49.91
Deviation (°C)	0.04	0.10	0.05	0.02	0.05	0.06	0.01
Time 09:38:55	49.98	49.97	49.91	49.89	49.94	49.91	49.92
Ref. 49.90 °C	49.98	49.97	49.91	49.89	49.94	49.91	49.92
Deviation (°C)	0.08	0.07	0.01	-0.01	0.04	0.01	0.02
Time 09:39:10	49.93	49.91	49.88	49.88	49.91	49.91	49.85
Ref. 49.90 °C	49.93	49.91	49.88	49.88	49.91	49.91	49.85
Deviation (°C)	0.03	0.01	-0.02	-0.02	0.01	0.01	-0.05
Time 09:39:25	49.95	49.92	49.92	49.92	49.93	49.96	49.91
Ref. 49.90 °C	49.95	49.92	49.92	49.92	49.93	49.96	49.91
Deviation (°C)	0.05	0.02	0.02	0.02	0.03	0.06	0.01
Time 09:39:40	49.95	49.95	49.97	49.90	49.98	49.97	49.93
Ref. 49.90 °C	49.95	49.95	49.97	49.90	49.98	49.97	49.93
Deviation (°C)	0.05	0.05	0.07	0.00	0.08	0.07	0.03
Time 09:39:55	49.93	49.97	49.90	49.90	49.93	49.92	49.92
Ref. 49.90 °C	49.93	49.97	49.90	49.90	49.93	49.92	49.92
Deviation (°C)	0.03	0.07	0.00	0.00	0.03	0.02	0.02
Max Deviation (°C)	0.08	0.10	0.07	-0.04	0.08	0.07	-0.05

High Point 99.90 °C Stability Report
 Start at : 09:40:15 Stability requirements met at : 09:51:14 Elapsed Time : 00:11:00
 Reference Change : 0.20 °C Maximum sensor change over last minute : 0.08 °C

Channel	1	2	3	4	5	6	7
Change (°C)	0.07	0.06	0.04	0.07	0.07	0.06	0.08

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Rev: 1.1.0002 **Calibration Report**

Job Reference: 980000001017
Data file Reference: C:\logsys\98001017\data\00_1A.cib
Thermocouple Set: Calibration Set 2

High Point 99.90 °C Stability Report

Start at : 09:40:15 Stability requirements met at : 09:51:14
 Reference Change : 0.20 °C Elapsed Time : 00:11:00
Maximum sensor change over last minute : 0.08 °C

Channel	1	2	3	4	5	6	7
Change (°C)	0.07	0.06	0.04	0.07	0.07	0.06	0.08

High Point 99.90 °C Qualification Report

Time 09:51:14	1	2	3	4	5	6	7
Ref. 99.90 °C	99.81	99.80	99.70	99.83	99.83	99.82	99.84
Deviation (°C)	-0.09	-0.10	-0.20	-0.07	-0.07	-0.08	-0.06

High Point 99.90 °C Post-Calibration Report

Time 09:51:30	1	2	3	4	5	6	7
Ref. 99.90 °C	99.93	99.93	99.94	99.90	99.93	99.92	99.90
Deviation (°C)	0.03	0.03	0.04	0.00	0.03	0.02	0.00

Time 09:51:45	1	2	3	4	5	6	7
Ref. 99.90 °C	99.92	99.96	99.92	99.88	99.91	99.93	99.94
Deviation (°C)	0.02	0.06	0.02	-0.02	0.01	0.03	0.04

Time 09:52:00	1	2	3	4	5	6	7
Ref. 99.90 °C	99.93	99.97	99.95	99.91	99.92	99.93	99.93
Deviation (°C)	0.03	0.07	0.05	0.01	0.02	0.03	0.03

Time 09:52:15	1	2	3	4	5	6	7
Ref. 99.90 °C	99.92	99.91	99.91	99.90	99.94	99.94	99.92
Deviation (°C)	0.02	0.01	0.01	0.00	0.04	0.04	0.02

Time 09:52:30	1	2	3	4	5	6	7
Ref. 99.90 °C	99.93	99.92	99.93	99.88	99.90	99.90	99.90
Deviation (°C)	0.03	0.02	0.03	-0.02	0.00	0.00	0.00

Time 09:52:45	1	2	3	4	5	6	7
Ref. 99.90 °C	99.90	99.93	99.92	99.88	99.89	99.92	99.92
Deviation (°C)	0.00	0.03	0.02	-0.02	-0.01	0.02	0.02

Time 09:53:00	1	2	3	4	5	6	7
Ref. 99.90 °C	99.90	99.94	99.95	99.93	99.93	99.93	99.92
Deviation (°C)	0.00	0.04	0.05	0.03	0.03	0.03	0.02

Max Deviation (°C)	1	2	3	4	5	6	7
	0.03	0.07	0.05	0.03	0.04	0.04	0.04

Calibration Factor and Offset Results

Ch. Num.	High Reference	High Measured	Low Reference	Low Measured	Status
1	99.90	99.81	49.90	49.99	Within Specification
2	99.90	99.80	49.90	49.96	Within Specification
3	99.90	99.70	49.90	49.90	Within Specification
4	99.90	99.83	49.90	50.01	Within Specification
5	99.90	99.83	49.90	49.96	Within Specification
6	99.90	99.82	49.90	49.99	Within Specification
7	99.90	99.84	49.90	50.04	Within Specification

First Calibration Check Point 90.00 °C Stability Report After Adjustment

Start at : 09:53:19 Stability requirements met at : 10:04:55
 Reference Change : 0.00 °C Elapsed Time : 00:11:36
Maximum sensor change over last minute : 0.09 °C

Channel	1	2	3	4	5	6	7
Change (°C)	0.07	0.05	0.09	0.07	0.04	0.04	0.07

First Calibration Check Point 90.00 °C Qualification Report

Time 10:04:55	1	2	3	4	5	6	7
Ref. 90.00 °C	90.02	90.04	90.00	90.00	90.02	90.03	90.00
Deviation (°C)	0.02	0.04	0.00	0.00	0.02	0.03	0.00

First Calibration Check Point 90.00 °C Report

Time 10:05:11	1	2	3	4	5	6	7
Ref. 90.00 °C	90.01	90.05	90.02	90.00	90.00	90.05	90.02
Deviation (°C)							

Time 10:05:26	1	2	3	4	5	6	7
Ref. 90.00 °C	90.02	90.04	90.04	90.01	90.02	90.03	89.98
Deviation (°C)							

Time 10:05:41	1	2	3	4	5	6	7
Ref. 90.00 °C	89.98	90.00	90.01	89.95	90.01	90.02	89.98
Deviation (°C)							

Rev. 1.1.0004	Washer Disinfecter Yearly Tests for Sugical Instruments
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Yearly Safety Checks		
Safety Check	Results	Comments
Check spray arm rotation for free movement	Pass	
Check spray nozzles for blockage	Pass	
Remove and clean strainers and filters	Pass	
Examine the door and seal(s)	Pass	
Check the security and performance of door safety devices	Pass	
Safety valves or pressure limiting devices are free to operate	N/A	
Other checks required with examination of pressure vessel	N/A	
Adequacy and safe connection of all engineering services	Pass	
Any additional checks as deemed necessary by ap's	N/A	
	N/A	
	N/A	
	N/A	
Record Test as PASS or FAIL	Pass	

Cleaning Efficacy Test				
Rev. 1.1.0002				
Test Soil Used	Brownes Test Soil			
Test	Cycle No	Expiry Date	Batch Number	Result
Chamber Wall/Load Carrier	N/A	2007-08	013751	Pass
Chamber Wall/Load Carrier	N/A	2007-08	013751	Pass
Reference Load	N/A	2007-08	013751	Pass
Performance Qualification	N/A	N/A	N/A	N/A
The Efficacy Tests where Satisfactory				

Automatic Control Test						
Rev. 1.1.0005						
Start time:	00:00:00	(hh:mm:ss)	Cycle Number:	N/A		
Date of test:	14/07/07		Serial Number:	980000001017		
Phase	Chemical Volume	Indicated Temperature		Recorded Temperature	Stage Time hh:mm:ss	
Cycle Started	N/A	End	29.10 °C	28.40 °C	00:00:00	
Prewash 1	N/A	End	29.40 °C	28.70 °C	00:05:20	
Mainwash 1	300 ml	End	62.10 °C	61.20 °C	00:16:28	
Neutralize	N/A	End	58.40 °C	57.60 °C	00:22:59	
Disinfection Up To 90	N/A	End	90.00 °C	88.20 °C	00:30:48	
		Start	90.00 °C	88.20 °C	00:30:48	
Disinfection Start	N/A	Middle	92.40 °C	91.60 °C	00:31:48	
		End	N/A °C	90.90 °C	00:33:11	
Drying	N/A	End	102.90 °C	85.40 °C	01:00:28	
Cooling	N/A	End	77.60 °C	81.60 °C	01:02:22	
Total cycle time	01:02:22	(hh:mm:ss)				

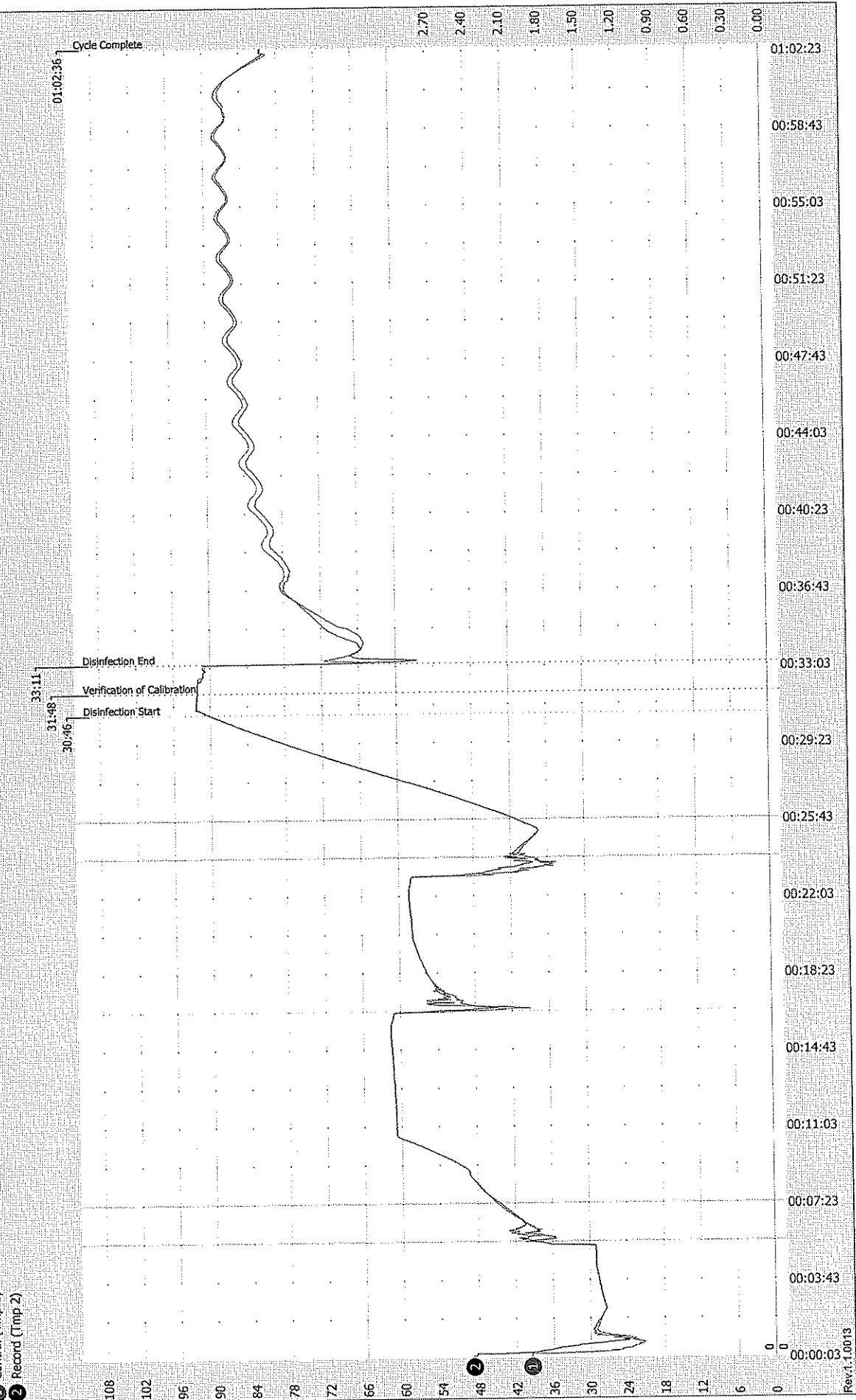
Operator: L.T.E.
 Test Date: 14/07/2007
 Test Name: HTM2030 Washer Calibration Verification

L.T.E. Scientific Ltd

Service Provider:
 Site Name:

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Control (Temp 1)
 Record (Temp 2)



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Rev: 1:1.0004 **Washer Disinfector Yearly Tests for Sugical Instruments**

Rev: 1:1.0006 **Thermometric Test 1**

Start time 16:57:02 (hh:mm:ss) **Cycle number** 03_1

Sensor	Sensor Location	Start	Middle	Max	End	
1	CONTROL	89.96	91.62	92.03	91.39	°C
2	RECORD	90.17	91.65	91.91	90.52	°C
3	INSTRUMENT MIDDLE SHELF	90.19	91.76	92.03	91.28	°C
4	INSTRUMENT BOTTOM SHELF	90.43	91.61	92.04	90.84	°C
5	TOP CARRIER	90.28	91.73	91.98	91.26	°C
6	MIDDLE CARRIER	90.16	91.63	91.88	90.85	°C
7	BOTTOM CARRIER	90.20	91.55	91.87	90.29	°C
8						°C
9						°C
10						°C
11						°C
12						°C
13						°C
14						°C
15						°C
	Machine Indicated	90.0	92.0	92.2	N/A	°C
	Machine Recorded	88.2	91.4	90.3	91.5	°C
Total time all above		90.0 °C	00:01:45 (hh:mm:ss)	Cycle time	01:02:11 (hh:mm:ss)	
Cycle meets the requirements of the Automatic Control Test		Pass				
Machine instrumentation Calibration is		Satisfactory				

Rev. 1.1.0004	Washer Disinfector Yearly Tests for Sugical Instruments
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Rev. 1.1.0004	Declarations
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DECLARATION OF TEST PERSON

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 machine is safe to use and that commissioning and performance qualification data collected during validation remain valid.

Test Person:	Name	Signature	Date 15/07/07
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DECLARATION OF USER

I have reviewed the records with the Test and Maintenance Person and declare that the Washer Disinfector is fit for use.

The next tests are due no later than:	Date
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User	Name	Signature	Date
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Rev. 1.1.0010	Washer Disinfector Chart Recorder Trace
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