Equipment Validation in CSSD: Experience Sharing in Hong Kong

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Content

- Validation: Definition and Scope
- Experience Sharing: Steam Sterilizer Validation Tests
- Experience Sharing: Washer Disinfector Validation Tests

What is Validation?

"documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications" (ISO 17665-1: 2006)

What is the predetermined specification of a sterile product?

EN 556-1:2001. Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices

Why?

"……for certain processes used in manufacturing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely and the equipment is maintained" (ISO 17665-1: 2006)

Standards

- International Standards:
  - ISO 17665-1 2006: Sterilization of Healthcare Products – Moist heat
  - EN 285 2006+A2 2009: Steam sterilizers - large sterilizers
  - ISO 14937 2009: Sterilization of healthcare products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
  - EN ISO 15883 2009 Parts 1 to 6: Washer-disinfectors
  - ISO 17664- Sterilization of medical devices- Information to be provided by the manufacturer for the processing of resterilizable medical devices

Standards

- Local/National Standards:
  - AS/NZS 4187:2003 Reprocessing of reusable medical devices in health service organisations
  - ANSI/AAMI ST79:2013 Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities
  - DH, UK: 2016. Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care- Part D: Washer-disinfectors
  - DH, UK: 2016. Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care- Part C: Steam sterilization

Two Approaches to Validation

- Parametric Validation
  - Evaluation of a sterilization process primarily based on the measurement of physical parameters
- Biological Validation
  - Evaluation of a sterilization process primarily based on biological inactivation

Biological Validation

- All steam sterilizers should be tested using PCDs (BI challenge test packs or BI challenge test trays) after sterilizer installation, relocation, malfunctions, and major repairs, and after sterilization process failures
- Three consecutive test runs with negative results from the test BIs, along with appropriate CI results and cycle printout records demonstrating correct and complete sterilization cycles

(ANSI/AAMI ST79:2010)

ANSI/AAMI ST79:2010

Routine load release (see 10.5 and 10.6)		Routine sterilizer efficacy monitoring (see 10.7)	Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 10.8)	Periodic product quality assurance testing (see 10.9)
Nonimplants	**Implants**			
Physical monitoring of cycle External and internal chemical indicator monitoring of packages Optional monitoring of the load with a PCD containing one of the following: • a BI • a BI and a Class 5 integrating indicator • a Class 5 integrating indicator • a Class 6 emulating indicator	Physical monitoring of cycle External and internal chemical indicator monitoring of packages Monitoring of every load with a PCD containing a BI and a Class 5 integrating indicator	Physical monitoring of cycle External and internal chemical indicator monitoring of packages Weekly, preferably daily (each day the sterilizer is used), monitoring with a PCD containing a BI. (The PCD may also contain a CI.) For sterilizers larger than 2 cubic feet and for table-top sterilizers, monitoring is done in a fully loaded chamber. In IUSS cycles, monitoring is done in an empty chamber. For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber	Physical monitoring of cycle External and internal chemical indicator monitoring of packages For sterilizers larger than 2 cubic feet and for IUSS cycles, monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack	Physical monitoring of cycle Placement of BIs and, CIs within product test samples

HA Guidelines on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre

- Sterilization process is suggested to be validated and monitored routinely with reference to relevant standards including ISO 17665 for steam sterilization……Validation provides the evidence to support the process conformity that may allow parametric release of the load.
- The load can be released for use provided that the values of the cycle variables as shown on the batch process record are within the permitted tolerance marked on the master process record established during performance qualification……

Parametric Validation

- Four parts:
  - Equipment specification
  - Installation qualification (IQ)
  - Operational qualification (OQ)
  - Performance qualification (PQ)

IQ

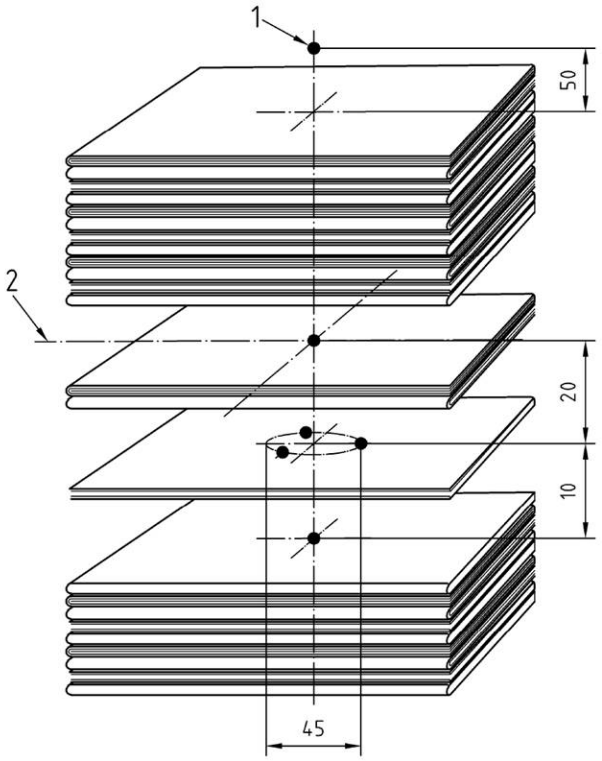
- Equipment has been provided and installed in accordance with its specification
- Upon delivery provide evidence that the sterilizer is installed and works as it should:
  - It turns on
  - It is safe
  - There are no leaks
  - It runs a cycle
  - It is calibrated (Verification of calibration test)

OQ

- Installed equipment operates within predetermined limits when used in accordance with its operational procedures
- Provide evidence that it can process the **standard load** types:
  - The chamber has an even temperature profile with no cold spots
  - Map out the worst and best places (chamber temperature profile)
  - It can run a standard cycle (Automatic control Test)
  - Check it works with a standard/reference load by using thermocouples
  - Check it washes/disinfects/sterilizes
  - Check it fails safely (produce faults)

Thermometric Tests – Standard Test Pack (EN285)

Dimensions in millimetres



Key

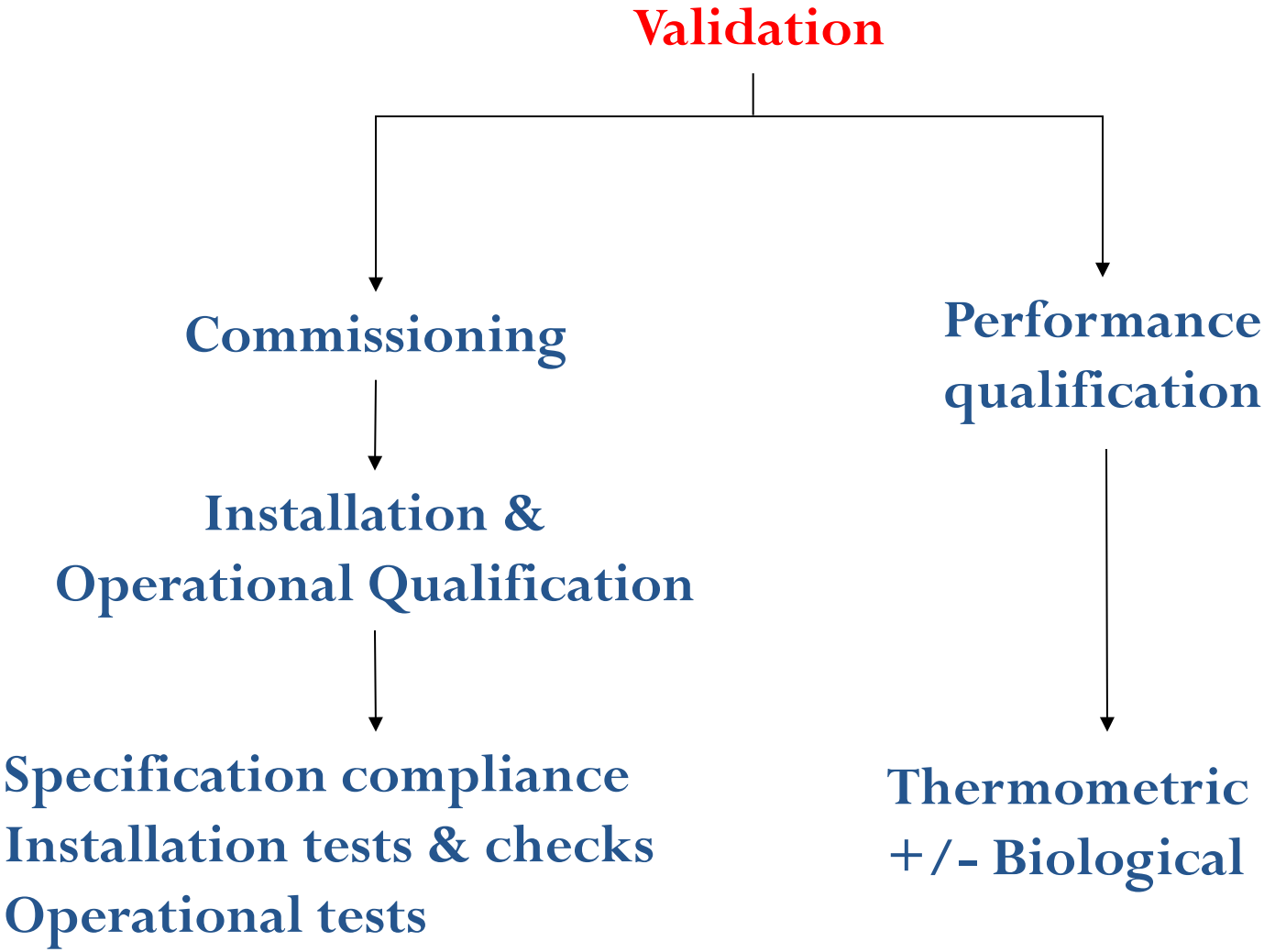
1 position of sensor

2 centre layer

Figure 6 — Location of temperature sensors

PQ

- Provide evidence that it can process the **production load**:
  - Identify product groups based on their challenge to the process
  - Define your test load (worst case):
    - Which are the worst to heat and cool
    - Which are the biggest challenge to the washing/disinfection/sterilization process
    - Whether any of them are more of a challenge than the standard test loads


Validation
Commissioning
Installation &
Operational Qualification
Specification compliance
Installation tests & checks
Operational tests
Performance
qualification
Thermometric
+/- Biological

Summary
IQ, OQ and PQ

- Define your equipment specification
- OQ: Know what the equipment is expected to comply with (e.g. standard test packs for sterilizer; reference load for WD)
- PQ: Define your production load- the worst case

IQ and OQ for Steam Sterilizer EN 285: 2015

Test	Requirements according to clause	Test according to clause	Installation Qualification	Operational Qualification
Safety Tests and checks	11		XX	—
Steam quality tests				
- Non-condensable gases	13.3.1	21.1	X	X
- Dryness value	13.3.2	21.2	X	X
- Superheat	13.3.3	21.3	X	X
- Contaminants	Table 4	a	X	X
Thermometric tests				
- Small load	8.2.1.2	16.1	—	XX
- Full load	8.2.1.3	16.2	—	XX
Hollow load test [b]	8.2.5	15	—	XX
Bowie and Dick test	8.2.2	17	—	XX
Rate of pressure rise caused by air leakage	8.2.3	18	—	XX
Air detector[c]				
- Small load	8.2.4.2	19.2	—	XX
- Full load	8.2.4.3	19.3	—	XX
- Function	8.2.4.4	19.4	—	XX
Load dryness tests				
- Small load, textiles	8.3.1	20.1	—	X
- Full load, textiles	8.3.2	20.2	—	XX
- Metal	8.3.3	20.3	—	X
Rate of pressure change	10	22	—	X

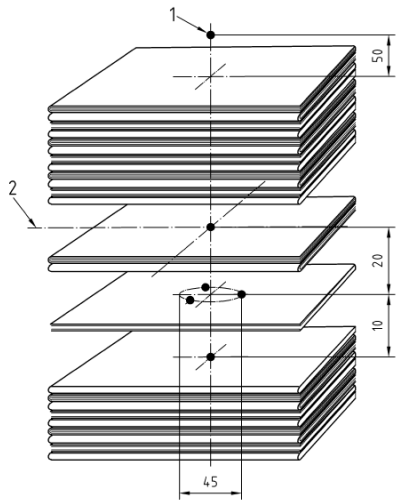
Thermometric Tests

- Demonstrate sterilizing conditions are obtained within the sterilizer chamber and standard test pack after air removal stage
- Small load and Full load
- Temperature probes (thermocouples) are introduced into the test pack and the chamber drain

OQ: Standard test pack

- EN 285 provides the specification of the standard test pack
- It is used for the Bowie and Dick test, the small/full load test, air detector tests, load dryness test (textiles) and can be used with other materials to form a full load

Dimensions in millimetres



Key

1 position of sensor
2 centre layer

Thermometric Test- Small Load

7. Automatic control test and verification of calibration

7.2 High Temperature Cycle (134°C)

UNIT MODEL:	**V160H**
UNIT SERIAL:	**0323408-05 (steri No.2)**
DATE:	**25/8/2015**
TEST RUN #:	**1**
CYCLE SELECTED:	**PREVAC 134**
CYCLE COUNT:	**19625**

Cycle Record

Phase	Cycle Settings	**Indicated Chamber temperatur (℃)	Recorded Chamber temperatur (℃)	Measured Chamber temperatur (℃)	**Indicated Chamber pressure (psig)	Recorded Chamber pressure (psig)	Measured Chamber pressure (psig)	Stage time (h:mm:ss)
Purge	**1 min**	--	**112.3**	**115.3**	--	**15.1 P**	**15.38 P**	**0:01:23**
VAC 1	**>10.0V**	--	**86.6**	**83.69**	--	**15.1 V**	**15.09 V**	**0:03:07**
Pulse 1	**26.0P ± 0.7P**	--	**130.8**	**130.21**	--	**26.1 P**	**26.38 P**	**0:04:27**
VAC 2	**>10.0V**	--	**88.1**	**85.84**	--	**16.4 V**	**16.45 V**	**0:06:08**
Pulse 2	**26.0P ± 0.7P**	--	**131.1**	**130.63**	--	**26.1 P**	**26.36 P**	**0:07:18**
VAC 3	**>13.0V**	--	**88.8**	**84.79**	--	**17.6 V**	**17.61 V**	**0:08:58**
Pulse 3	**26.0P ± 0.7P**	--	**131.6**	**130.57**	--	**26.1 P**	**26.16 P**	**0:10:05**
VAC 4	**>14.0V**	--	**90.8**	**86.48**		**17.9 V**	**17.94 V**	**0:11:45**
Sterilize (mid)	**134-137 °C 20m00s**	**134.9**	**134.9**	**135.1**	**31 P**	**30.6 P**	**30.31 P**	**0:23:47**
Exhaust	**4.0P ± 0.7P**	--	**105.9**	**107.71**	--	**3.6 P**	**3.37 P**	**0:26:02**
Dry	**>26.0V 30m00s**	--	**30.1**	**102.66**	--	**28.2 V**	**28.08 V**	**1:11:03**
Air break	**2.0V ± 0.7V**	--	**31.7**	**86.3**	--	**2 V**	**1.92 V**	**1:13:46**
							Cycle START time	9:48:40
							Cycle END time	11:02:26
							Holding time	0:03:27

**Remarks:

1) Indicated temperature : temperature reading copy from screen

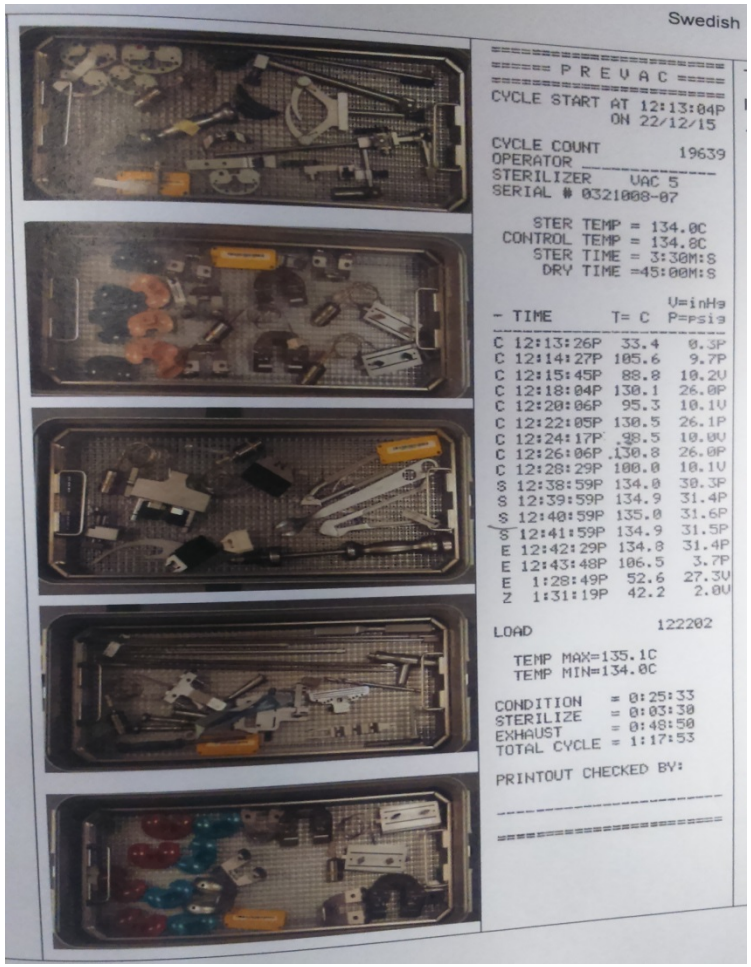
2) Indicated pressure : Pressre reading copy from screen

Thermometric PQ Tests

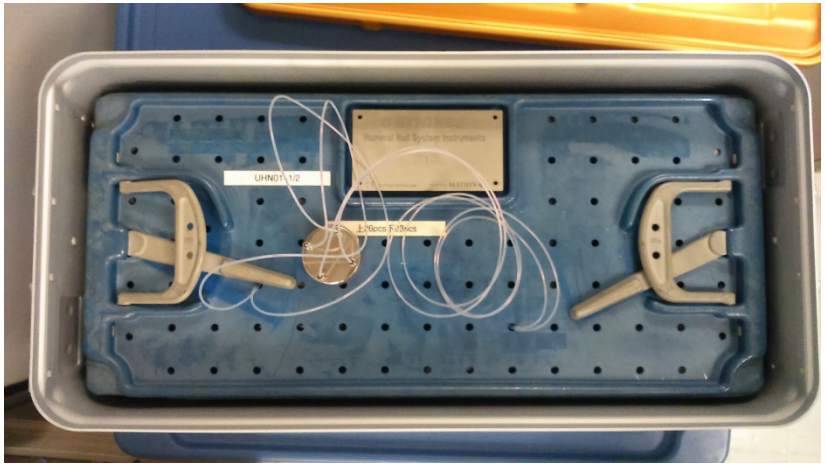
- Standard test pack used for small load and full load thermometric tests
- PQ if load configurations present greater challenge to the process than standard test pack
- Items that present a large challenge to air removal processes e.g. :
  - Narrow lumen devices and tubing
  - Sets with complex layouts such as graphic trays
  - Complex multilayer packs
  - Multilayers of wraps

Thermometric PQ Tests

- Items that may be difficult to dry e.g.:
  - Large sets in graphic trays
  - Heavy sets
  - Containerized sets
  - Sets with a large amount of non-metal content
  - Complex shapes that retain water



Thermometric PQ Tests



	Drain	1	2	3	4	
2015/10/07 11:03:20	133.39	133.14	133.18	124.69	133.78	
2015/10/07 11:03:30	133.76	133.38	133.44	125.01	134.07	
2015/10/07 11:03:40	134.24	133.67	133.88	125.99	134.56	Start of Plateau Period
2015/10/07 11:03:50	134.6	133.98	134.18	126.79	134.84	
2015/10/07 11:04:00	134.78	134.28	134.5	126.92	135.15	
2015/10/07 11:04:10	134.46	134.46	134.37	127.02	134.85	
2015/10/07 11:04:20	134.57	134.58	134.45	127.18	134.96	
2015/10/07 11:04:30	134.68	134.68	134.58	127.37	135.1	
2015/10/07 11:04:40	134.75	134.78	134.67	127.58	135.17	
2015/10/07 11:04:50	134.59	134.83	134.61	127.78	135.01	
2015/10/07 11:05:00	134.76	134.91	134.7	127.99	135.12	
2015/10/07 11:05:10	134.71	134.95	134.76	128.2	135.16	
2015/10/07 11:05:20	134.64	134.94	134.69	128.4	135.04	
2015/10/07 11:05:30	134.8	135.03	134.83	128.58	135.21	
2015/10/07 11:05:40	134.67	135.02	134.8	128.77	135.14	
2015/10/07 11:05:50	134.68	135.05	134.82	128.94	135.12	
2015/10/07 11:06:00	134.81	135.08	134.9	129.12	135.24	
2015/10/07 11:06:10	134.65	135.05	134.84	129.29	135.12	
2015/10/07 11:06:20	134.68	135.06	134.85	129.44	135.11	
2015/10/07 11:06:30	134.81	135.09	134.93	129.58	135.24	
2015/10/07 11:06:40	134.66	135.07	134.86	129.74	135.12	
2015/10/07 11:06:50	134.69	135.09	134.9	129.87	135.14	
2015/10/07 11:07:00	134.8	135.11	134.99	130.02	135.23	End of Plateau Period (3:20)
2015/10/07 11:07:10	128.79	131.56	131.33	130.18	131.26	

	Drain	1	3	2	4	
2015/10/07 14:14:30	133.76	132.63	126	133.4	133.79	
2015/10/07 14:14:40	134.11	132.91	126.15	133.76	134.13	Start of Plateau Period
2015/10/07 14:14:50	134.42	133.19	126.39	134.04	134.41	
2015/10/07 14:15:00	134.43	133.44	126.64	134.25	134.57	
2015/10/07 14:15:10	134.15	133.6	126.88	134.04	134.28	
2015/10/07 14:15:20	134.31	133.76	127.13	134.14	134.42	
2015/10/07 14:15:30	134.4	133.91	127.37	134.29	134.55	
2015/10/07 14:15:40	134.47	134.04	127.59	134.37	134.63	
2015/10/07 14:15:50	134.37	134.12	127.82	134.36	134.57	
2015/10/07 14:16:00	134.4	134.2	128.04	134.35	134.58	
2015/10/07 14:16:10	134.44	134.26	128.24	134.44	134.64	
2015/10/07 14:16:20	134.51	134.34	128.45	134.51	134.72	
2015/10/07 14:16:30	134.45	134.38	128.65	134.49	134.67	
2015/10/07 14:16:40	134.31	134.39	128.82	134.38	134.53	
2015/10/07 14:16:50	134.49	134.44	129	134.51	134.68	
2015/10/07 14:17:00	134.57	134.5	129.18	134.6	134.77	
2015/10/07 14:17:10	134.51	134.52	129.36	134.6	134.75	
2015/10/07 14:17:20	134.34	134.49	129.52	134.45	134.56	
2015/10/07 14:17:30	134.44	134.53	129.67	134.55	134.67	
2015/10/07 14:17:40	134.53	134.57	129.82	134.65	134.79	
2015/10/07 14:17:50	134.38	134.56	129.96	134.56	134.66	
2015/10/07 14:18:00	134.41	134.54	130.09	134.51	134.6	End of Plateau Period (3:20)
2015/10/07 14:18:10	128.02	130.4	130.32	130.1	129.86	

Summary:

- IQ: Installation and checks as per manufacturer's instruction
- OQ: Use a standard test pack as per EN285
- PQ: Define your Production Load
  - The sterilizer load and load configuration should be as proposed for routine production.
  - A load configuration and the least favourable combination of products should be used.
  - Packaging that will be used routinely.

Validation Tests: Washer Disinfector ISO 15883-1 (Annex A)

	Brief description of test	Requirements subclause	Test subclause	Type test	Works test	Operational qualification	Performance qualification	Routine test
1	Cleaning efficacy							
1.1	Chamber	4.2.1.1	6.10.2	X	B	X	B	B
1.2	Load carrier	5.1.10	6.10.2	X	B	X	B	B
1.3	Load	4.2.1.1	6.10.2	X	B	X	B	X(Q)
			6.10.3	B	B	B	X	X(D)
			(visual)					
			6.10.3			O	X	O
			(Annex C)					
2	Thermometric							
2.1	Thermal disinfection							
—	Chamber walls	4.3.1.2, 4.3.1.3, 4.3.3.2 and 5.9.2	6.8.3	X	X	O	X	O
—	Load carrier	4.3.1.1, 4.3.1.3	6.8.2	X	X	X	B	O
—	Final rinse water tank	5.3.2.5	6.8.4	X	B	X	B	O
—	Load	4.3.1.1, 4.3.1.3, 4.3.3.1, 5.9.1	6.8.2	X	X	X	X	X(Q)
2.2	Temperature control							
—	Rate of rise	4.1.4	6.8.2	X	B	X	B	X(Q)
—	Flushing stage	4.2.2	6.8.2	X	B	X	B	X(Q)
—	Washing stage	4.2.3	6.8.2	X	B	X	B	X(Q)
2.3	Over-temperature cut-out	5.8.3	6.8.5	X	X	X	B	B
2.4	Chemical disinfection[a]							
—	Chamber walls and load carrier	4.3.2	6.8.2	X	X	B	X	O
—	Calorifier and tanks	4.3.3	6.8.3					
—	Load	5.3.2.3	6.8.4	X	X	B	X	X(Q)
		4.3.2, 4.3.3	6.8.3	X	X	B	X	X(Q)
3	Load dryness	4.5.1, 4.5.2	6.12	X	X	O	X	O
4	Fluid emission							
—	Chamber leak proof	5.1.7, 5.1.8	6.5.3	X	X	X	B	B

	Brief description of test	Requirements subclause	Test subclause	Type test	Works test	Operational qualification	Performance qualification	Routine test
5	Doors and interlocks							
5.1	Cycle start	5.4.1.8	6.3.1	X	X	X	B	X(Q)
5.2	Loading/unloading	5.4.3.1	6.3.4	X	X	X	B	X(Q)
		5.4.3.3	6.3.3	X	X	X	B	X(Q)
		5.4.1.4	6.3.4	X	X	X	B	X(Q)
			6.3.7					
5.3	On fault condition	5.4.1.5	6.3.5	X	B	X	B	O
		5.22	6.3.6	X	B	X	B	O
—	Door interlock	5.4.3.2	6.3.7	X	B	X	B	O
6	Process residuals	4.4.1, 4.4.2	6.10.4	X	B	B	X	B
7	Chemical dosing							
7.1	Accuracy and repeatability	5.7.5	6.9.1	X	X	X	B	X(Q)
7.2	Low level indicator	5.7.6	6.9.2	X	X	X	B	X(Q)
8	Water quality	4.4.1	6.4.2	X	B	X[b]	B	O
8.1	Rinse water	4.4.2, 4.4.3	6.4.2	X	B	X	B	O
		4.2.1.2	6.4.3	X	B	B	B	B
8.2	Prior to OQ and PQ	8.2 b)	6.4.3	X	B	O	B	B
8.3	Volume per stage	8.2 b)	6.4.4					
9	Air quality	4.5.3, 4.5.4	6.11	X	X	X	B	O
10	Pipework							
10.1	Dead volume	5.5.1.3	6.5.1	X	B	O	B	B
10.2	Free draining	4.1.7	6.5.2	X	B	O	B	B
		5.1.10	6.5.2	X	B	O	B	B
		5.3.1.1 a)	6.5.4	X	B	O	B	B
		5.5.1.2	6.5.4	X	O	O	B	B
			6.5.5	X	B	X	B	B
10.3	Venting system	5.24.2	6.5.6	X	B	O	B	B
		5.8.4, 5.24.6	6.5.6	X	B	B	B	B
11	Instrumentation							
11.1	Legibility	5.12.3	6.6.2	X	B	B	B	B
11.2	Calibration	5.11	6.6.1	X	X	V	B	v(Q)
		5.14		X	X	V	B	v(Q)
		5.15						
12	Load carriers – internal							
12.1	Stability	5.27.1 a), b)	6.7.1	X	B	B	B	B
12.2	Alignment	5.27.4	6.7.1	X	B	B	B	B
		5.1.10	6.7.1	X	B	B	X	B
12.3	Fitting	5.27.5	6.7.1	X	B	B	B	B
12.4	Force to move	5.27.1 b)	6.7.1	X	B	B	B	B

Cleaning Efficacy Test – Artificial Soil

- Prepare the test load:
  - Paint a freshly formulated test soil compliant with ISO/TS 15883 Part 5 onto the test load and leave to dry
  - A suitable soil for the type of loading encountered within the department
  - Leave the load to dry more than 0.5 hours and maximum 2 hours
  - Drying time should be consistent with the departments instrument collection times from Theatres
  - The load should be a worst case (PQ)

Cleaning Efficacy Test- Artificial Soil

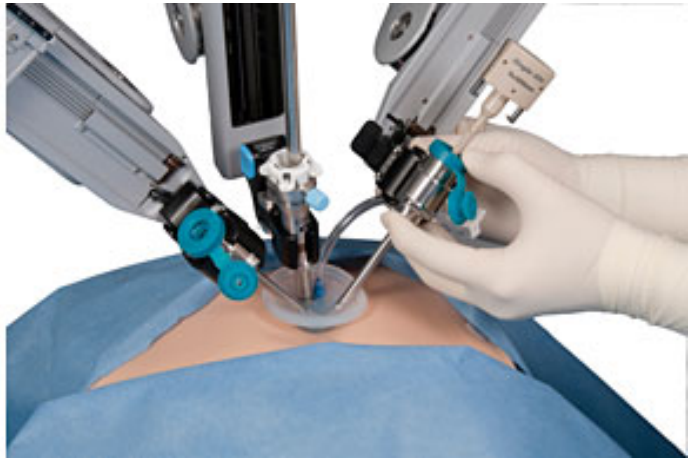
- Wash the test load in WD:
  - Place the load is placed in the chamber and start a cycle
  - Interrupt the cycle after the first rinse stage
  - Examine results visually and/or with a residual protein test

Reference Load (UK)

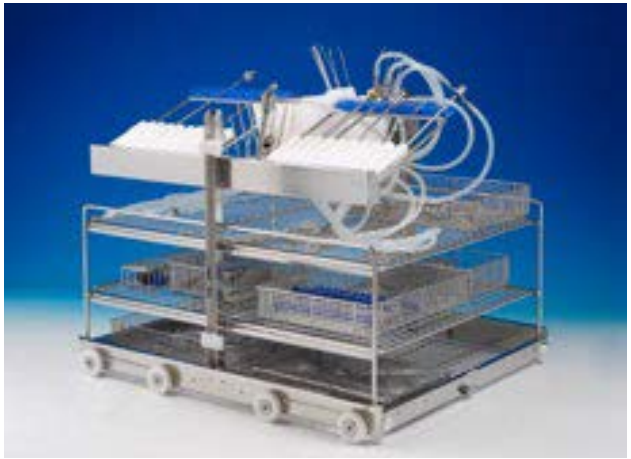
- 3 x Vaginal speculum
- 3 x Artery forceps with box joints
- 3 x No. 3 scalpel handles;
- 3 x Yankauers or Pooles suction tubes
- Sufficient additional instruments to make up a full load

Cleaning Efficacy PQ Test

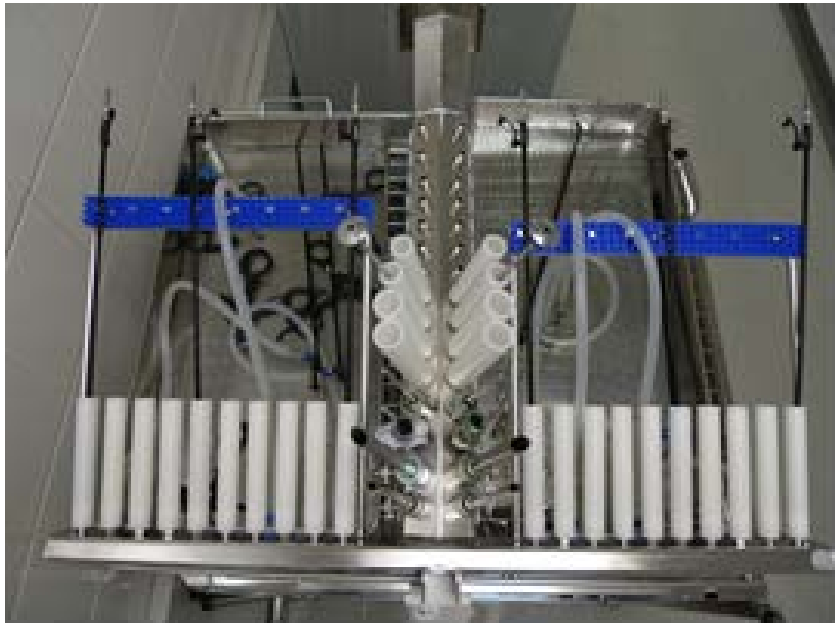
- PQ if items that present a great challenge to the cleaning processes e.g.
  - Narrow lumen devices and tubing
  - Sets with complex layouts
  - Instruments with pulley and cable pathways
  - Burrs and drills
  - Small optical instruments
  - Laryngeal airways



Cleaning Efficacy PQ Test- Loading Equipment

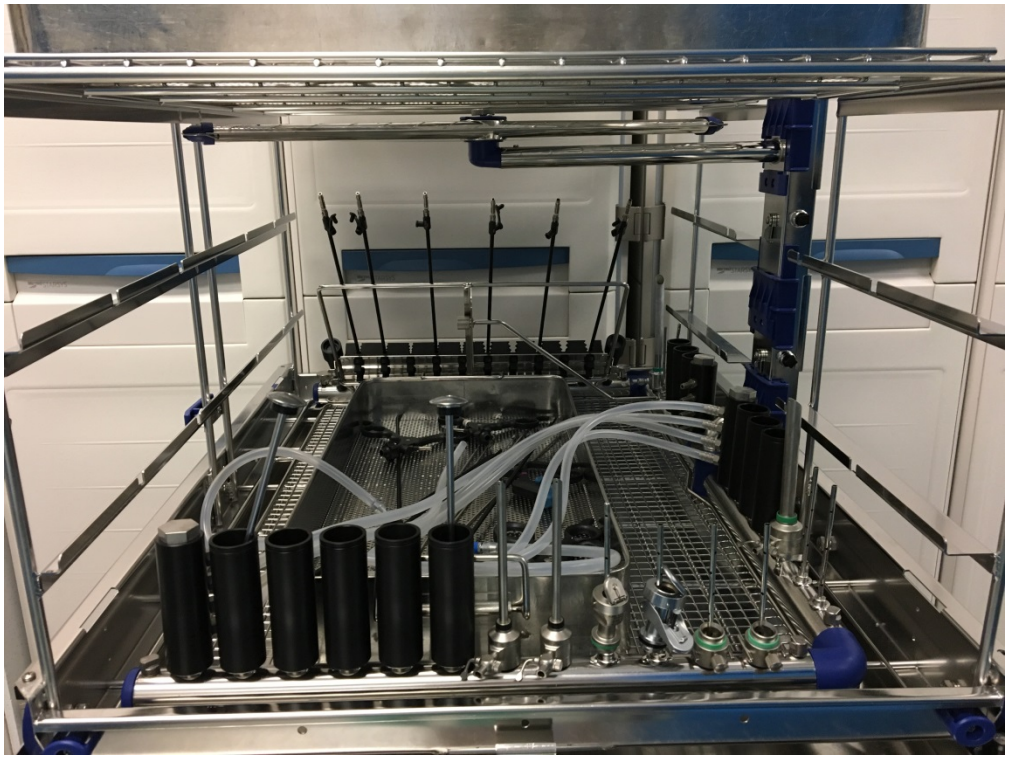


Cleaning Efficacy PQ Test- Loading Equipment (Old)



Cleaning Efficacy PQ Test-Loading Equipment (New)

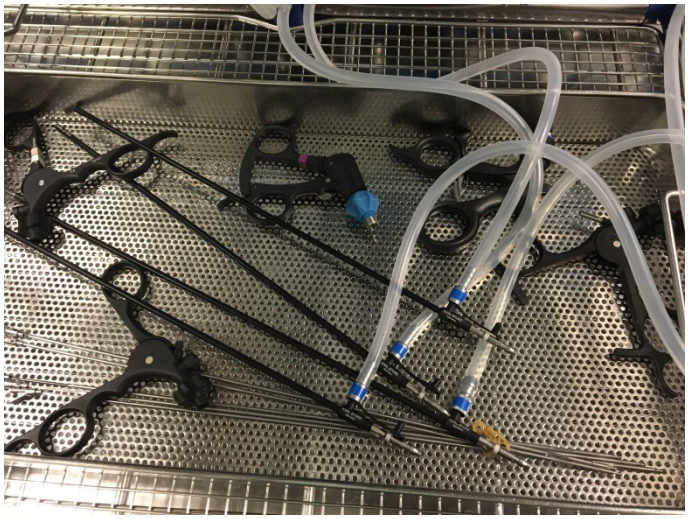
Cleaning Efficacy PQ Test- Loading Equipment



Load content
On MIS ramp, it includes:

a. Lap. Forceps sheaths x 6
b. Lap. Cannula x 4
c. Lap. Functional valves x 2
d. Hassan stoppers w/ detachable cap x 2
e. Lap. Trocars (tip removed) x 2

Cleaning Efficacy PQ Test- Loading Equipment



Load content

<u>Instruments on the first (top) & second level of rack:</u>

<u>each cleaning tray contains:</u>

a. Vaginal speculum x 3

b. Artery forceps x 3

c. No. 3 scalpel handles x 3

<u>Instruments on the third (bottom) level of rack,</u>

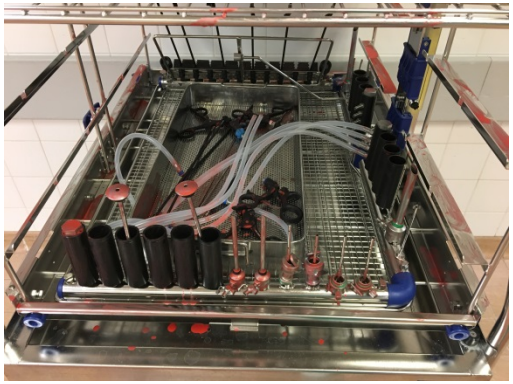
a. Lap. Ring handles x 5

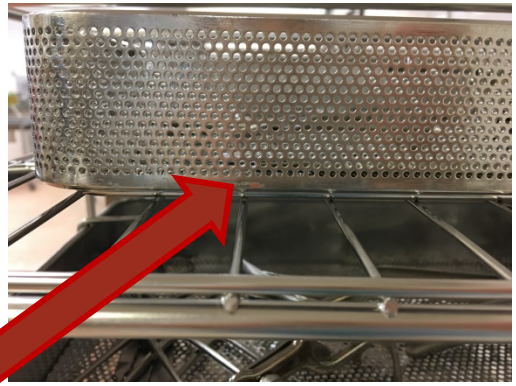
b. Lap. Forceps sheaths x 4

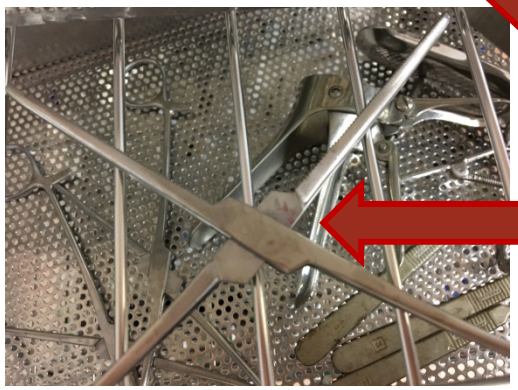
c. Lap. Grasping forceps x 4

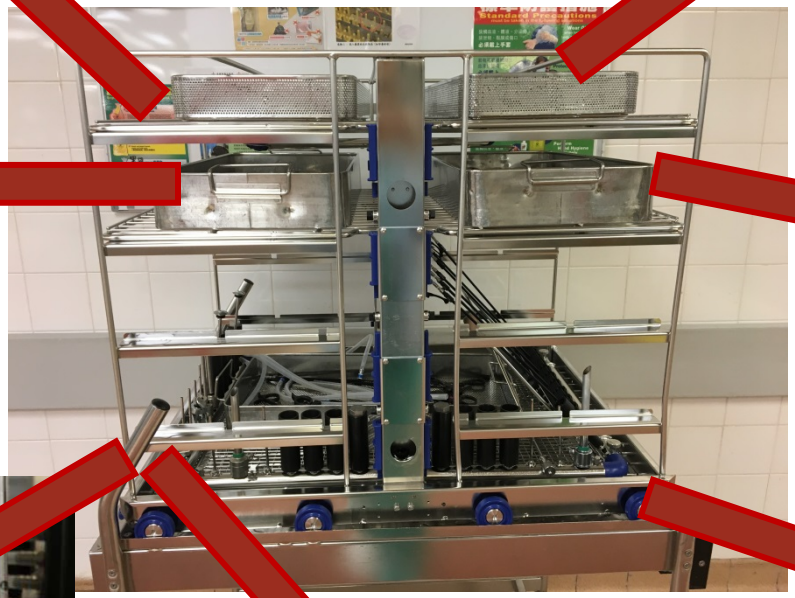
d. Lap. Scissors x 1

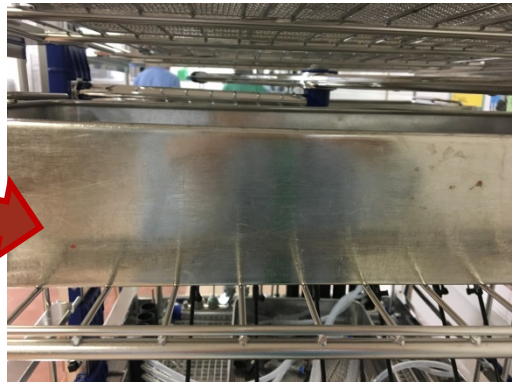
Cleaning Efficacy PQ Test- Loading Equipment



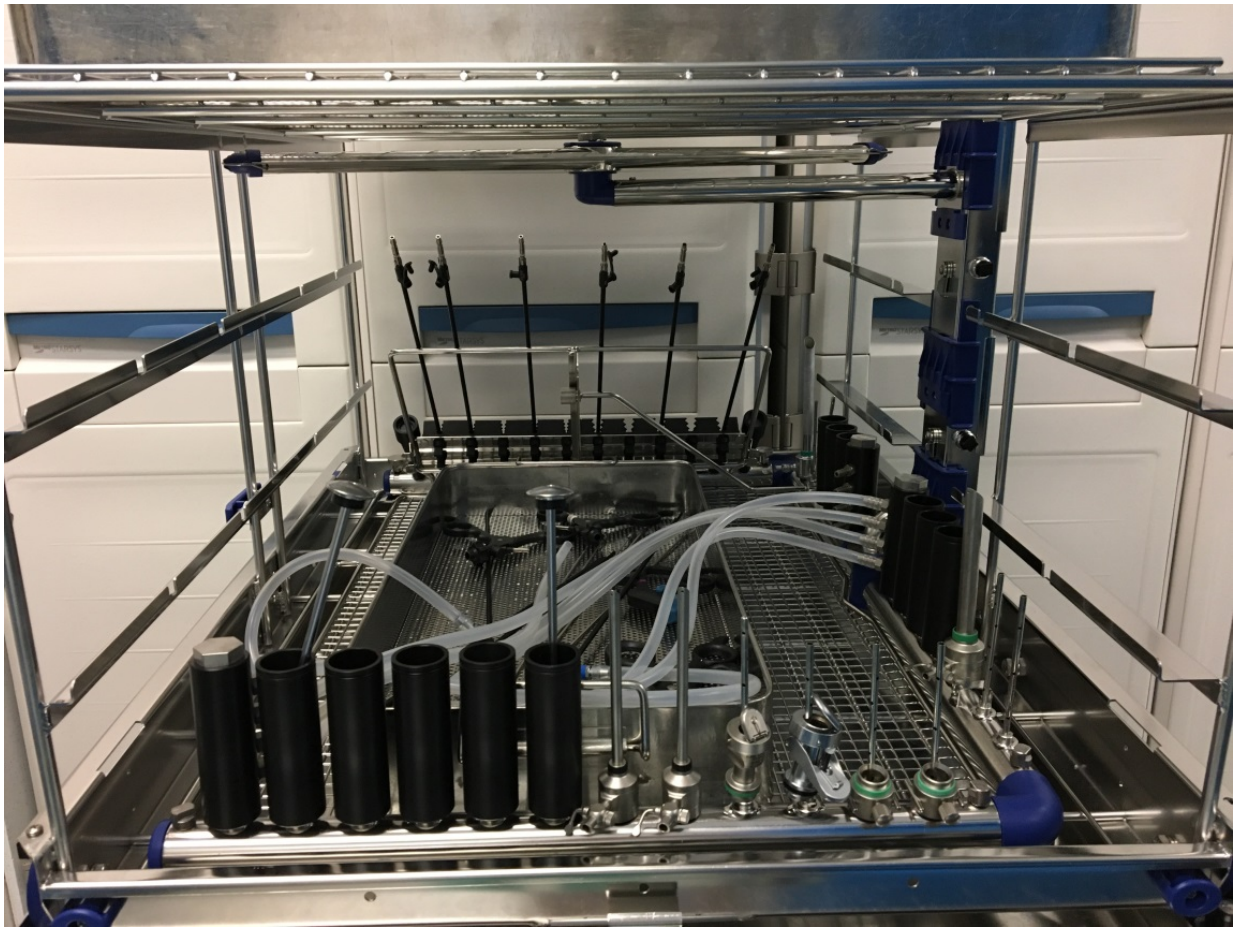








Solution?



Thermometric Test For Thermal Disinfection

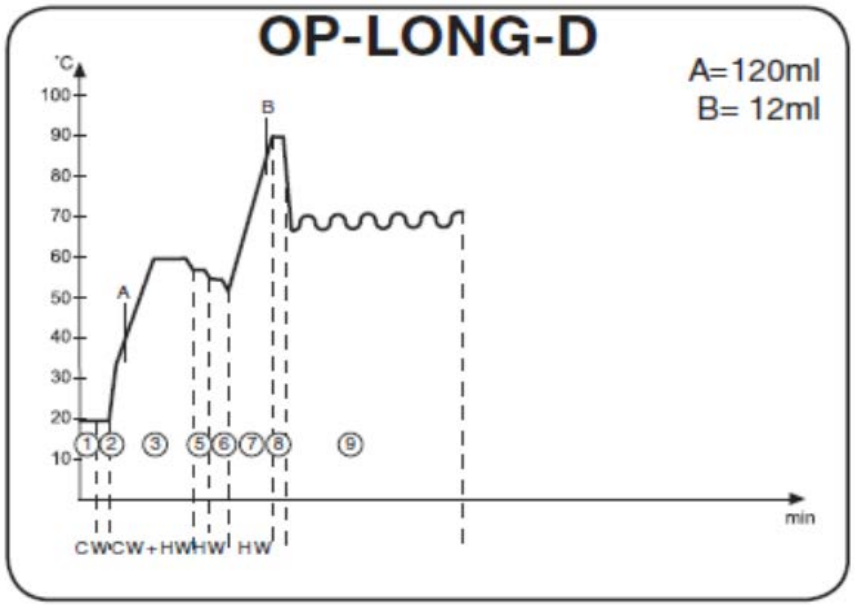
- Thermometric tests are carried out to verify the attainment of adequate disinfection temperatures throughout the chamber and load ($A_0 = 600$).
- With multi-chamber WDs, they can be tested using self-contained data loggers that can be processed through the WD.
- To avoid pre-heating the load, the washing stages need to be disabled or the controlled temperature at the start of the disinfection stage reduced to be at or below the lowest temperature specified for the washing stage.

Thermometric Test For Thermal Disinfection

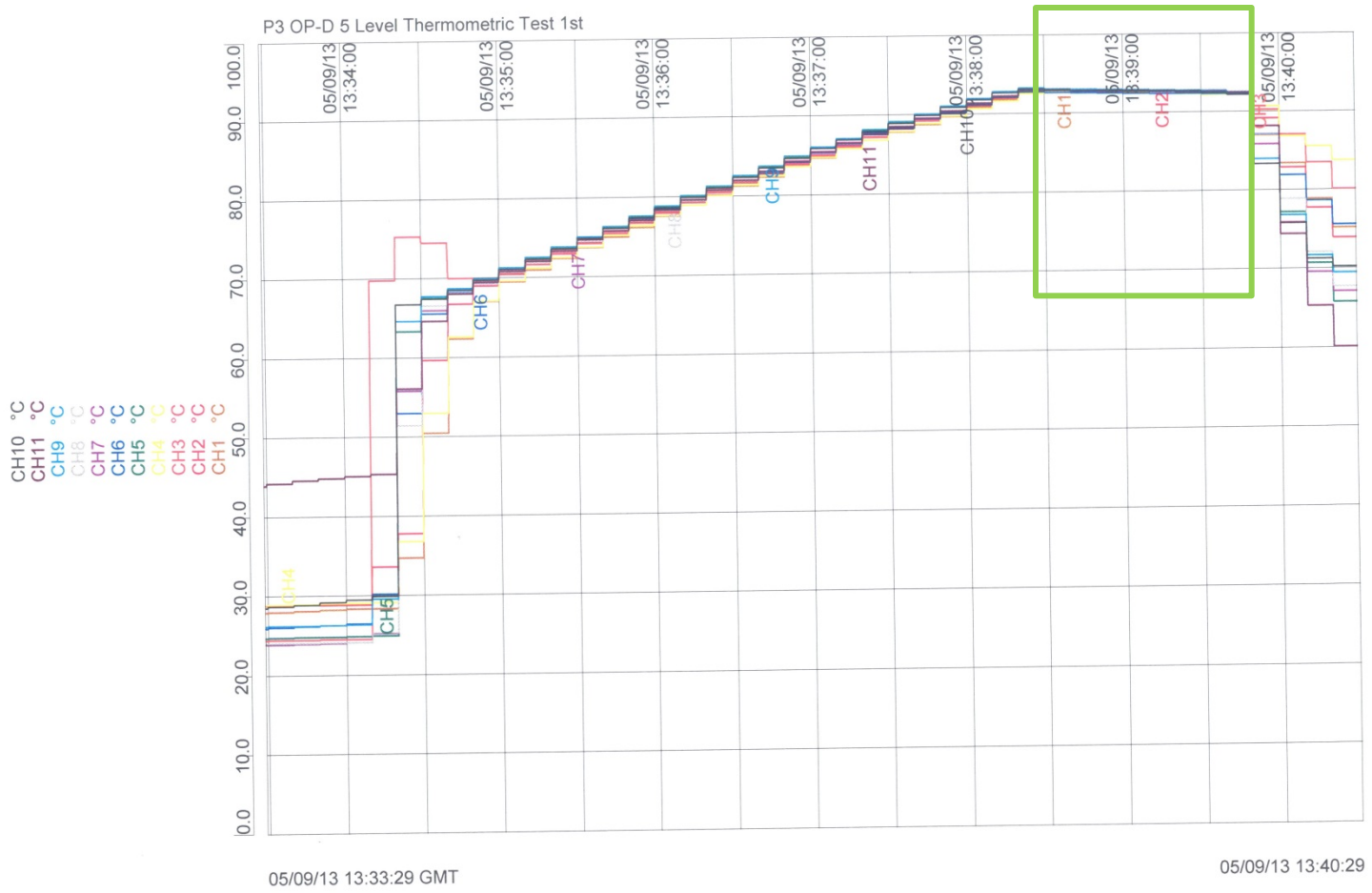
- Locate the temperature sensors as follows:
  - on the load carrier at two diagonally opposite corners and in the approximate geometric center;(3)
  - on items in the load with at least one on an item at each level in the load carrier (up to a maximum of three if the load carrier accommodates load items on more than one level);(3)
  - one on an item in the region known to be slowest to attain the disinfection temperature;(1)
  - one on an item in the region known to be fastest to attain the disinfection temperature;(1)
  - one adjacent to the automatic control temperature sensor;(1)
  - one adjacent to the process recorder or indicator sensor (if fitted) in each chamber or compartment.(1)

Thermometric Test (Sample)

```
PROCESS OK
00:07:47   57.5    7.4
00:07:46   57.7    7.6
ENDING
00:07:00   85.4    6.3
00:06:39   91.8   -0.8
DRYING
LOWEST TEMP        91.1C
HIGHEST TEMP       92.3C
DISINF STOP
00:06:14   91.9   41.1
00:06:00   92.1   40.5
00:05:30   92.1   41.2
DISINF START
00:05:13   90.9   40.7
00:05:00   89.6   41.5
00:04:00   83.5   39.4
DOS3 AMOUNT        42.0ml
DOS STOP
00:03:36   80.7   47.0
DOS START
00:03:29   79.9   53.8
00:03:00   76.4   55.7
00:02:00   68.5   57.1
00:01:00   45.4   -0.6
00:00:32   44.7   -0.5
FINAL RINSE
00:00:00   44.4   -0.5
START
PROGTIME   AI07   AI01
-------------------------
PROGRAM: P3  OP-LONG-D3
```



Thermometric Test (Sample)



Cleaning Efficacy Test by Residual Soil Detection

- Cleaning efficacy tests are used to demonstrate the ability of the WD to remove or reduce natural soiling and contamination to acceptable level
- ISO 15883-1 recommends Ninhydrin method or two alternatives to detect the presence of residual proteinaceous contamination
- Commercial kits are available for protein detection

Cleaning Efficacy Test by Residual Soil Detection

- Alternative residual soil detection method chosen should be at least as sensitive as the ninhydrin method.
- Able to detect protein to a level of 2 μg.
- Some kits require incubation to get full sensitivity (ninhydrin based).
- About 10 cm^2 of an instrument is swabbed with water-wetted swabs for a few minutes.

Summary:

- IQ: Installation and checks as per manufacturer's instruction
- OQ: Use a reference load
- PQ: Define your Production Load
  - The washer-disinfector load and load configuration should be as proposed for routine production.
  - A load configuration and the least favourable combination of products should be used.
  - A new PQ is required if change in loading equipment

Reference

- Association for the Advancement of Medical Instrumentation (AAMI) (2014). ANSI/AAMI ST79:2010. Arlington: AAMI.
- DH, UK: 2016. Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care- Part D: Washer-disinfectors
- DH, UK: 2016. Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care- Part C: Steam sterilization
- EN 285 2006+A2 2009: Steam sterilizers - large sterilizers
- ISO 15883-1:2006. Washer-disinfectors- Part 1: General requirements, terms and definitions and tests.
- ISO 17665-1 Sterilization of health care products- Moist heat.
- Spencer W (2015). Notes of Central Commissioned Training Program 2014/15 on Advanced Course on Decontamination Sciences.