



FSPM Inc.
Fil-International Sterile Processing Management Inc.

INSTRUMENT TO PATIENT SAFETY

New Standards of Validation Equipment

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Objectives:

At the end of the session, participants will be able to...

- ☐ Understand what is validation
- ☐ Know the ways of validation the sterilization equipment.

Validation

A process that consists of systematically carrying out the process in a specific manner in order to improve by planning.

Usually applies to equipment or procedures used for reprocessing medical devices.

Establish temporary programmes and checklists, validation protocols with criteria for acceptance/rejection, resource needs and risk analysis.

Validation should consist of the following:

1. Installation Qualification (IQ)
2. Operational Qualification (OQ)
3. Performance Qualification (PQ)
4. Documentation
5. Microbiological Performance Qualification (MPQ)
6. Validation report and certificates



Installation Qualification (IQ)

A process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.



Steps of IQ:

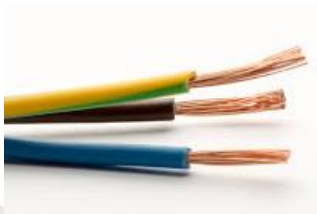
1. Verify correct installation of connections



Water



Steam



Electrical Wiring

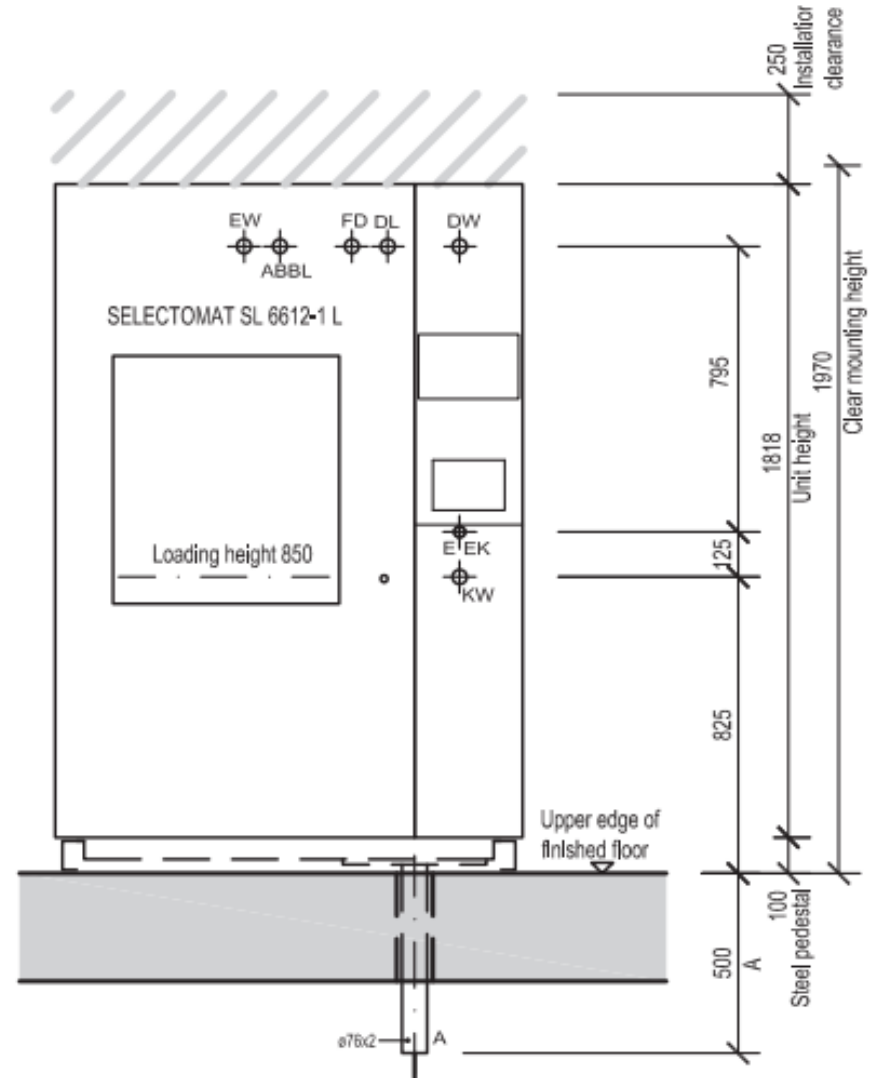
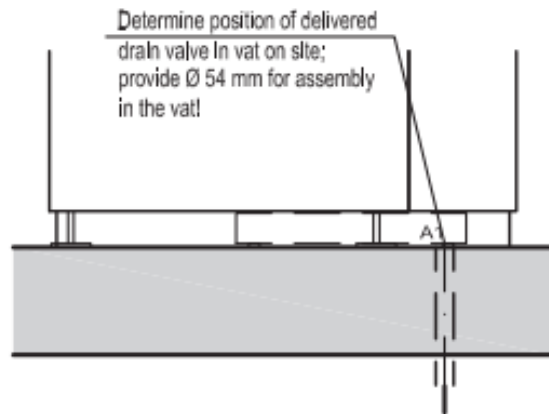


Compressed Air



Ventilation

Technical Data Sheet



Technical drawing of a room layout. The room dimensions are 1360 (vertical) and 850 (horizontal). The layout includes a dashed rectangle representing a bed or sofa, and a solid rectangle representing a desk or table. Equipment locations are marked with symbols: AP (Access Point) and A1 (Antenna 1). The AP locations are at the top-left, top-right, bottom-left, and bottom-right corners. The A1 location is at the top-right corner. Dimensions for the equipment placement are 60 (horizontal distance from left wall to AP), 850 (horizontal distance between APs), and 200 (horizontal distance from right wall to A1). A vertical dimension of 1360 is shown for the room height. A horizontal dimension of 200 is shown for the distance from the top wall to the AP at the top-right corner. A horizontal dimension of 60 is shown for the distance from the left wall to the AP at the bottom-left corner. A horizontal dimension of 850 is shown for the distance between the AP at the bottom-left and the AP at the bottom-right. A horizontal dimension of 200 is shown for the distance from the right wall to the A1 at the top-right corner. A vertical dimension of 1360 is shown for the room height. A horizontal dimension of 60 is shown for the distance from the left wall to the AP at the bottom-left corner. A horizontal dimension of 850 is shown for the distance between the AP at the bottom-left and the AP at the bottom-right. A horizontal dimension of 200 is shown for the distance from the right wall to the A1 at the top-right corner. A vertical dimension of 1360 is shown for the room height. A horizontal dimension of 60 is shown for the distance from the left wall to the AP at the bottom-left corner. A horizontal dimension of 850 is shown for the distance between the AP at the bottom-left and the AP at the bottom-right. A horizontal dimension of 200 is shown for the distance from the right wall to the A1 at the top-right corner.

The technical drawing illustrates the SFD 100 unit, a rectangular air conditioning unit with a width of 1300 mm and a height of 1620 mm. The top view shows a central circular fan grille labeled 'SFD Ø100 +10 -0' with a diameter of 100 mm. The unit is mounted on a steel pedestal, which is recessed into the ceiling. The side view shows the unit's profile with a total height of 1620 mm, including a 160 mm recess pedestal. The unit is connected to the ceiling via four connections, each with a diameter of 100 mm. The unit is labeled 'SFD 100' and 'Unit width 1300'. The side view also shows the 'Loading and Unloading side' and the 'Unit depth 1620'. The unit is shown in a shaded area, indicating it is a standard unit.

Top view labels: EW, ABBL, FD, DL, DW, EK, KW.

Side view labels: max. 8, Connect, 730, A, 1460, Steel pedestal, 1620, Unit depth, 160, Recess pedestal.

Bottom view labels: Connections, 100, 200, 100, 200, 175, 300, A, 1260, Steel pedestal, 1300, Unit width, 600, Maintenance.

Text inside unit: Recess pedestal = opening for additional air 912 cm².

Text on side: Loading and Unloading side.

Active

Data for the dimensioning of the sanitary and electrical installations on site

A	Drain with pedestal	Temp. max. 55° C (in case of failure 100° C for a short period of time) With integrated steam generator	Connection Discharge Discharge	DN 70 15 l/min 45 l/min
A1	Drain with feet	Temp. max. 55° C (in case of failure 100° C for a short period of time) With integrated steam generator	Connection Discharge Discharge	DN 50 15 l/min 45 l/min
DL	Compressed air	PA 5-10 bar With integrated steam generator	Connection Design capacity Consumption appr. Consumption appr.	DN 15 15 Nm³/h 0.2 Nm³/h 0.4 Nm³/h
E	Electric mains Not applicable in case of connected steam generator	3/N/PE 400 V AC, 50 Hz Connecting cable Ölflex (YSLY-J) 5x2,5 mm². Main switch to be provided on site	Power Fuse protection Consumption/h appr.	3.0 kW 10 A 1.2 kWh
EW	Softened Water Opt. jacket cooling	PA 3-5 bar, Remaining hardness <0.1° d Temp. max. 15° C	Connection Design capacity	DN 15 1.2 m³/h

Compressed air

PA 5-10 bar

	steam generator	equivalent device: Noncondensable gases	Percentage	≤ 3.5%
KW	Fresh water	Temp. max. 15° C, 3-15° d, PA 3-5 bar	Connection Design capacity Consumption appr.	DN 15 1.4 m³/h 0.2 m³/h

Additional data concerning electric steam generator (optional)

ABBL	Blow-off pipe for safety valve	Galvanized steel pipe for blowing the steam off into the open up to 0.35 bar max. back pressure at 185 kg/h flow	Connection	DN 40
DW	Demineralized fresh water	1-5 µS/cm, PA 1-5 bar	Connection Design capacity Consumption appr.	DN 15 0.25 m³/h 0.028 m³/h
EK	Electric mains	3/N/PE 400 V AC, 50 Hz Only flexible cable allowable Ölflex (YSLY-J) 5x25 mm² Provide load break switch on site close to the unit. We recommend a load break switch with remote disconnection, potential free contact provided in the unit.	Power Fuse protection Consumption/h appr.	48 kW 80 A 12 kWh
	Remote disconnect.	Connecting cable	1x YSLY-0	2x0.75 mm²

Steps of IQ:

2. Verify the correct operation of the equipment's different security functions, according to standards.

DATE : 06/02/09
PROCESS START : 12:34:56
STERILIZER NAME : L20074
STERILIZER NUMBER: 1
CYCLE COUNTER : 200

SIGNALS
AI03 CHAMBER PRESSURE
AI27 S CHAMBER PRESSURE
AI00 CHAMBER TEMP
AI24 S CHAMBER TEMP
AI01 JACKET TEMP

PARAMETERS
STERIL TEMP 121.0 C
STERIL TIME 00:20:00
POST VACUUM TIME 00:05:00

PROGRAM: P1 POROUS LOAD

PROGTIME	AI03	AI27	AI00	AI24	AI01
START					
00:00:00	1.008	1.007	45.0	45.1	118.9
00:00:10	1.011	1.010	45.1	45.1	118.5
00:00:20	1.016	1.015	45.2	45.2	118.2
PREVACUUM					
00:00:20	1.016	1.015	45.2	45.2	118.2
00:00:30	0.855	0.781	48.6	50.2	117.9

Steps of IQ:

3. Confirm that the machine is equipped with technical documentation.

Installation plans

Technical/Operational User Manual



Operational Qualification (PQ)

A process of obtaining and documenting evidence that the installed equipment operates within predetermined limits when used accordance with its operational procedures.



Aim:

1. To verify that the sterilizer's different measurement and control element function correctly and within the ranges specified by the manufacturer.
2. To verify that the temperature distribution in the chamber is uniform and within the parameters designated by the country standards.

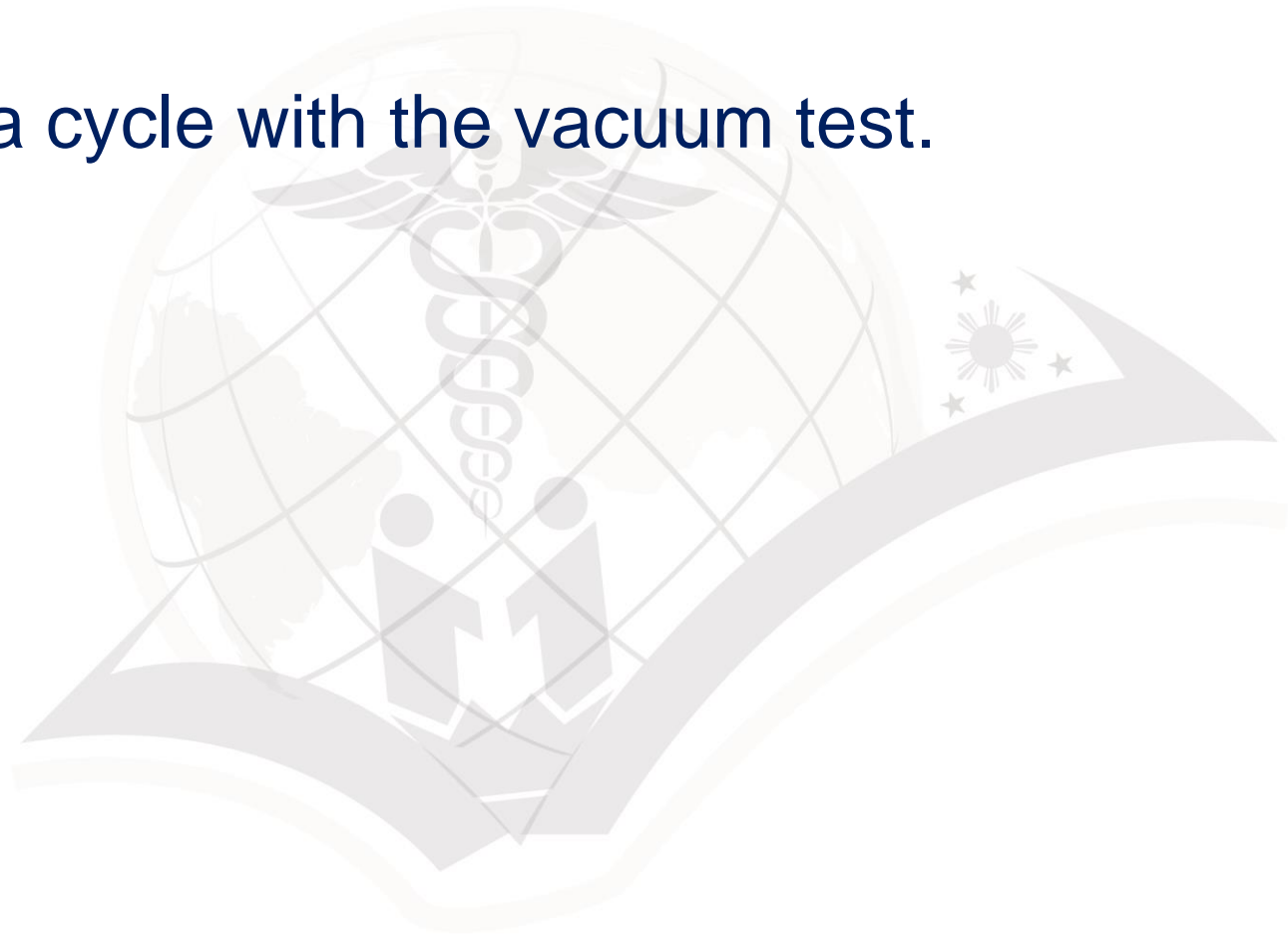
Steps of OQ on *Pre-Vacuum Steam Sterilizer*:

1. Calibration of the regulation and control elements



Steps of OQ on *Pre-Vacuum Steam Sterilizer*:

2. Carry out a cycle with the vacuum test.



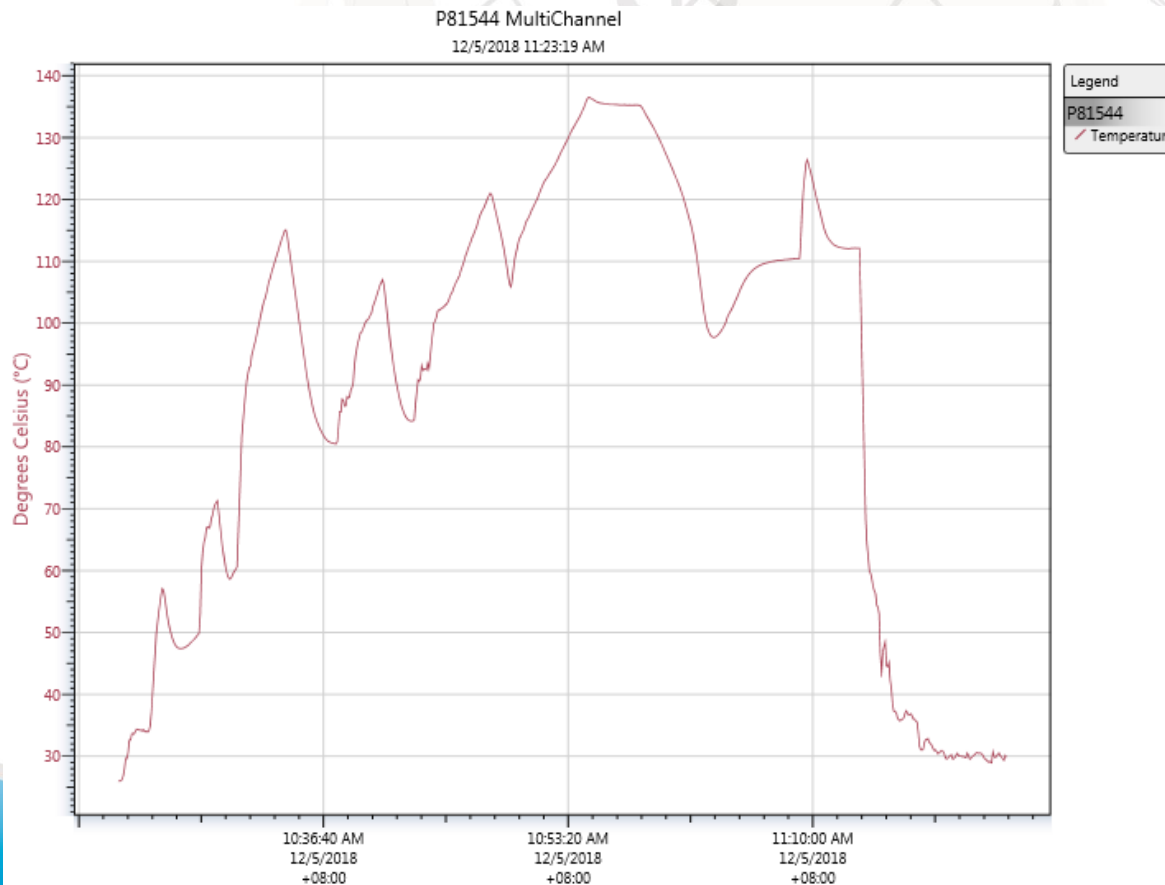
Steps of OQ on *Pre-Vacuum Steam Sterilizer*:

3. Carry out a cycle with the Bowie-Dick Test



Steps of OQ on *Pre-Vacuum Steam Sterilizer*:

4. Implement three thermometric tests in an empty chamber in order to obtain the temperature profile at all points of the chamber



Performance Qualification (PQ)

A process of obtaining and documenting evidence that the equipment as installed and operated is in accordance with operational procedures consistently performs in accordance with predetermined criteria and thereby yields a product meeting its specification.



Tests must include:

- 1. Reference load** that corresponds to the routine load.
- 2. Packaging systems** that corresponds to the routine packaging system.
- 3. Load configuration** specified and known to be the most difficult to sterilize- worst case.
- 4. Volume and weight.**

Qualification	Responsible Person
1. Installer Qualification	The installer
2. Operational Qualification	The installer/ User/Operator
3. Performance Qualification	User/Operator



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Thank you!

