FISPM 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:

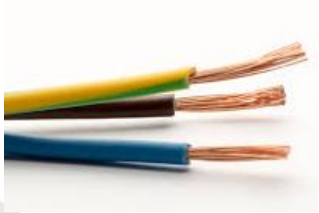
1. Verify correct installation of connections

Water

Compressed Air

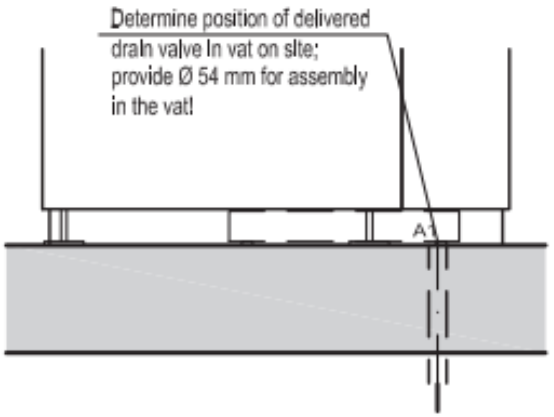
Steam

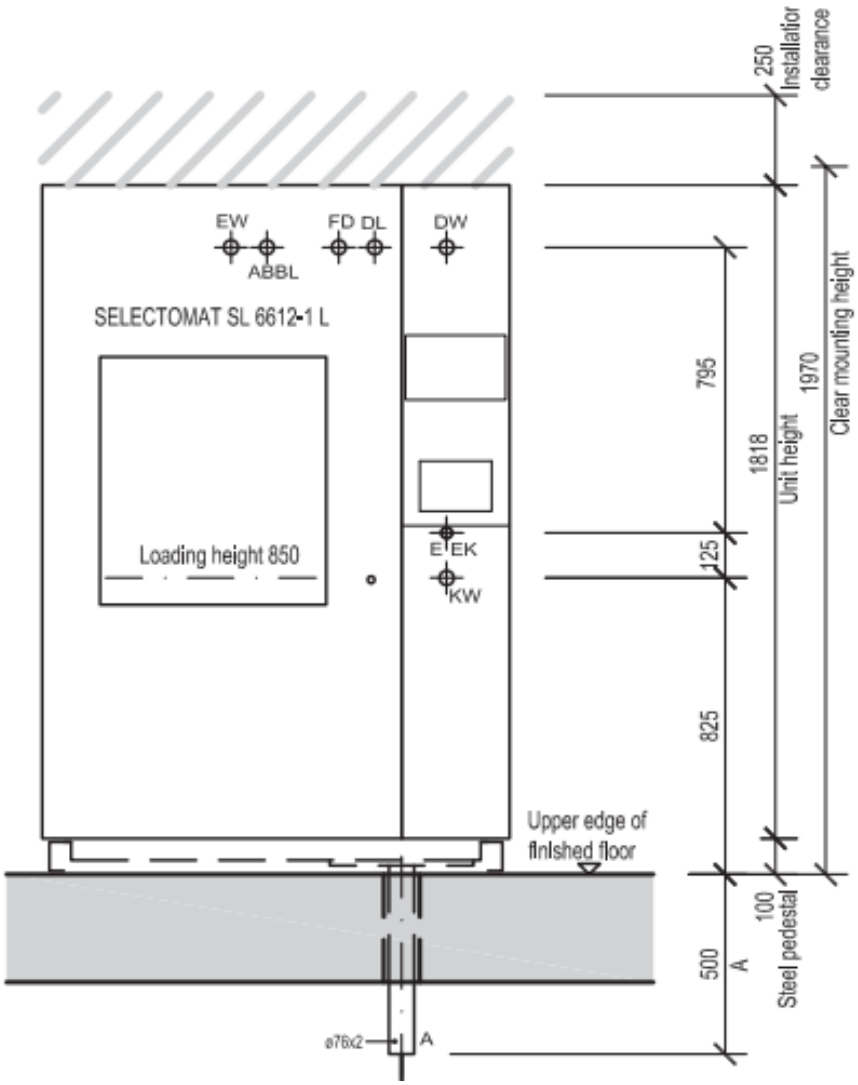
Ventilation

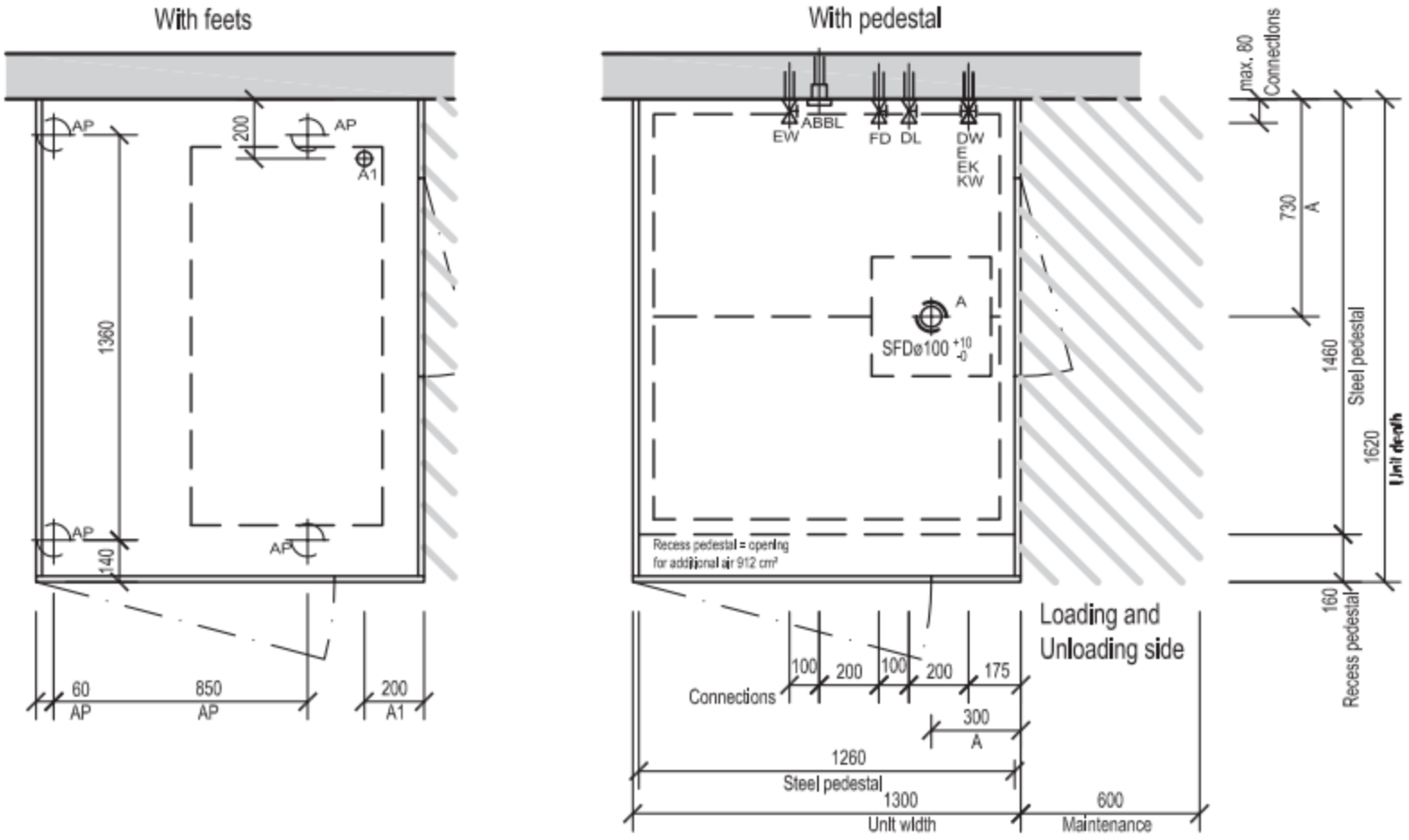


Electrical Wiring

Technical Data Sheet







Integrated steam supply, steel pedestal or feets and side panelling are accessoires

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	Softenend 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
	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

Compressed air PA 5-10 bar

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 Comsumption 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	SIGNALS	
PROCESS START	: 12:34:56	AI03	CHAMBER PRESSURE
STERILIZER NAME	: L20074	AI27	S CHAMBER PRESSURE
STERILIZER NUMBER: 1		AI00	CHAMBER TEMP
CYCLE COUNTER	: 200	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***:**

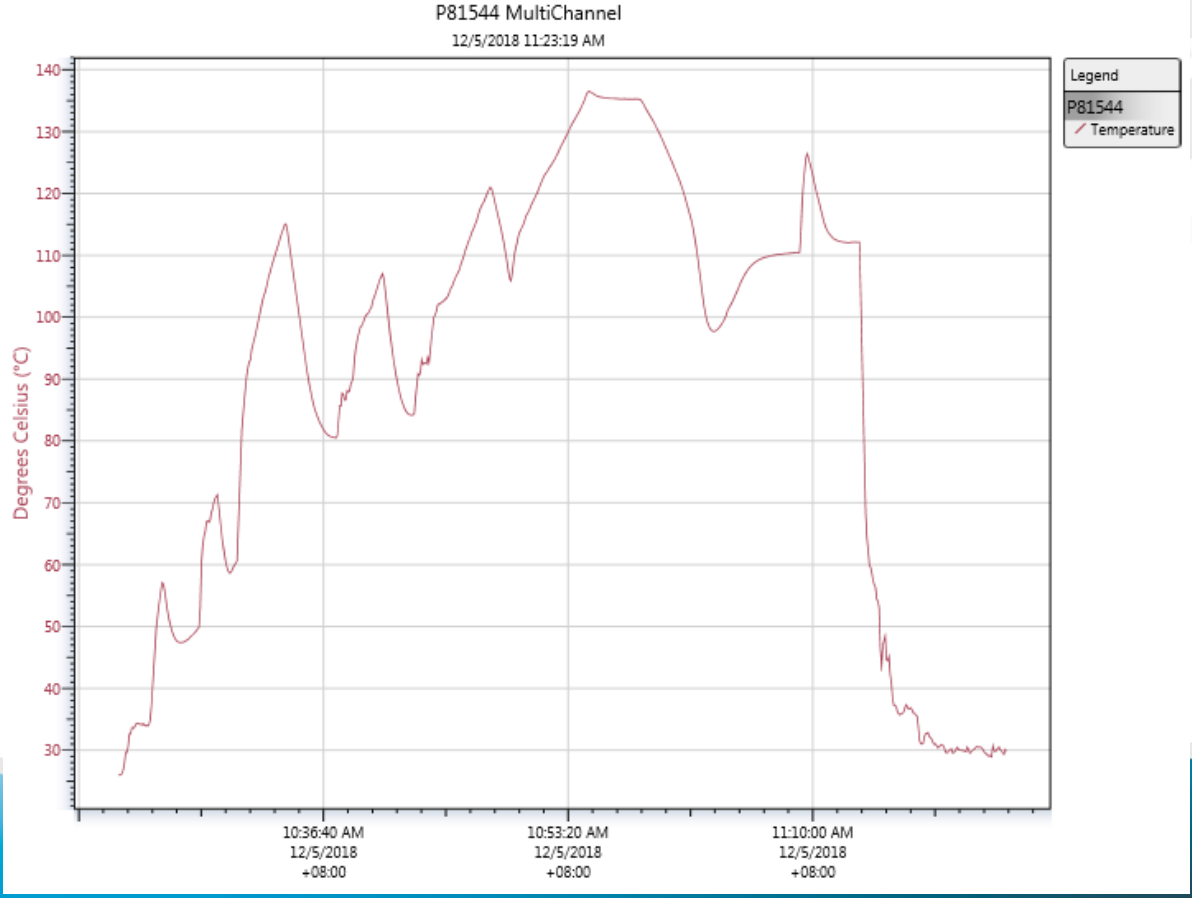
2. Carry out a cycle with the vacuum test.

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!