

Minipack Validated EtO Sterilization Parameters

Sterilization Chamber Stats		
	Items	Figures
1	Initial Temperature	46 to 56° C
2	Initial Vacuum	-40 kPa
3	Humidification	50 to 75% RH
4	Cycle Temperature	46 to 56° C
5	Operating Pressure	-40 kPa to +40 kPa
6	Gas Dwell time	8 hours
7	Gas Dwell time	50% EtO & 50% CO2
8	Gas Weight	13 Kg
9	Number of flushing cycles	3
10	Vacuum	-33 kPa to -6 kPa
11	Aeration Period	24 hours

EtO Cycle Parameters

1	PRE-CONDITIONING	Minimum	Maximum	Set Point
	Time	8 hours	9 hours	8.5 hours
	Temperature	46° C	56° C	50° C
	Relative Humidity	30%	70%	50%

2	INITIAL EVACUATION		
		Set Point	Range
	Rate	2.5 kPa/Minute	<6 kPa/Minute
	Termination	-40 kPa	-35 to -45 kPa

3	HUMIDIFICATION		
		Set Point	Range
	Pressure Rise	-35 kPa	-30 to -40 kPa

4.	HUMIDITY DWELL	Set Point	Range
	Time	120 min	110 to 130 min
	Humidity	60%	50 to 75%

5	STERILANT INJECTION (50%/50% Sterilant Gas Mixture)		
		Set Point	Range
	Weight	13 Kg	12.8 to 13.2 Kg
	Rate	1.4 kPa/min	<2 kPa/min
	Time	60 min	50 to 70 min

6	GAS DWELL (EXPOSURE)	Set Point	Range
	Time	Fraction cycle - 30 min Half cycle – 240 min Full cycle – 480 min	+/- 10 Min.
	Temperature	50° C	46 to 56° C
	Pressure	40 kPa	30 to 50 kPa

7	STERILANT REMOVAL		
		Set Point	Range
	Rate	2.5 kPa/Minute	<6 kPa/Minute
	Termination	-33 kPa	-30 to -37 kPa

8 to 10	AIR WASHES (3)		
		Set Point	Range
	Rate	2.5 kPa/Minute	<6 kPa/Minute
	Inbleed Termination	-6 kPa	-3 to -10 kPa
	Evacuation Termination	-33 kPa	-30 to -37 kPa

11	AERATION	Minimum	Maximum
	Time	24 hours	N/A
	Temperature	20° C	50° C