

Report Test

M/C : Henan Sanqiang Medical Equipment Liability Co. Ltd
Model : SQ-H220
Serial No : HNSQ2020050063

LOT No : 0639/2023
Date : 04 July 2023

Determination of Sterilization Operation Specification

Item Detail	Specification	Setting	Result
Chamber Setting Temperature	40.0-55.5 °C	45.0 °C	
Vacuum pressure	40-60 kPa	60 kPa	
Vacuum Time	50-60 min	60 min	
Humidification			
Humidity	50.0-90.0%	20.2 %	
Sterilization			
Sterilization Temperature	40.0-55.5 °C	43.5 °C	
Gas Injection			
Final pressure	0-10 kPa	4 kPa	
Final temperature of vaporizer	40.0-55.5 °C	44.8 °C	
Exposure			
Temperature at start point of Exposure time period	40.0-55.5 °C	43.3 °C	
Temperature at finish point of Exposure time period	40.0-55.5 °C	46.0 °C	
Exposure Time	120-240 min	180 min	
Exhaust			
Exhaust Time	60-80 min	75 min	
First Vacuum pressure	0-2 kPa	1.5 kPa	
Second Vacuum pressure	0-2 kPa	1.5 kPa	
Third Vacuum pressure	0-2 kPa	1.5 kPa	
Fourth Vacuum pressure	0-2 kPa	1.5 kPa	
Fifth Vacuum pressure	0-2 kPa	1.5 kPa	
Storage			
Storage Time	≥ 48 hour	≥ 48 hour	
Chemical Test			
EO sterilization temperature 40-55°C, Time Sterilization by EO 3hours	Blue	Red	Pass
Biological Test			
EZ Test Biological Indicator	Green	Green	Pass


 (.....)
 Mr. Jutha Liammukda
 Research and Development Engineer


Keep pressure qualified
Temperature: 43.5℃
Humidity: 20.2RH
Pressures: -58.7KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 0:41

Evacuation
Temperature: 42.3℃
Humidity: 20.1RH
Pressures: -3.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 0:29

Heating-up:
Temperature: 25.4℃
Humidity: 20.1RH
Pressures: -3.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 0:0

Setting:
Temperature: 45.0℃
Humidity: 55.0RH
Pressures: -60.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 0:0

Sterilization:
Temperature: 45.6℃
Humidity: 20.2RH
Pressures: -0.0KPa
Sterilization time: 0Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 4:48

Sterilization:
Temperature: 44.1℃
Humidity: 20.2RH
Pressures: -0.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 1:49

Sterilization:
Temperature: 44.1℃
Humidity: 20.1RH
Pressures: -2.7KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 1:47

Add EO gas
Temperature: 44.1℃
Humidity: 20.2RH
Pressures: -4.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 1:47

Evacuation
Temperature: 44.5℃
Humidity: 20.1RH
Pressures: -0.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 1:42

Keeping Temp
Temperature: 44.6℃
Humidity: 20.2RH
Pressures: -1.6KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 0:42

END Lot 139 A-766

Air replacement:
Temperature: 45.3℃
Humidity: 20.2RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 1
round time: 0min(s)

2001-1-1 6:14

Air replacement:
Temperature: 45.8℃
Humidity: 20.1RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 2
round time: 0min(s)

2001-1-1 5:54

Air replacement:
Temperature: 45.0℃
Humidity: 20.2RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 3
round time: 0min(s)

2001-1-1 5:34

Air replacement:
Temperature: 45.0℃
Humidity: 20.2RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 4
round time: 0min(s)

2001-1-1 5:13

Air replacement:
Temperature: 45.9℃
Humidity: 20.1RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 5
round time: 15min(s)

2001-1-1 4:53



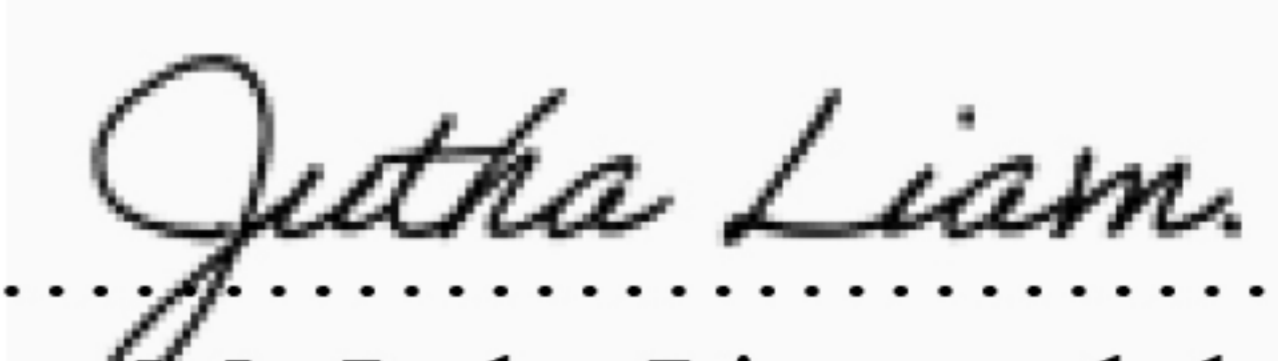
Report Test

M/C : Henan Sanqiang Medical Equipment Liability Co. Ltd
 Model : SQ-H220
 Serial No : HNSQ2020050063

LOT No : 0653/2023
 Date : 04 August 2023

Determination of Sterilization Operation Specification

Item Detail	Specification	Setting	Result
Chamber Setting Temperature	40.0-55.5 °C	45.0 °C	
Vacuum pressure	40-60 kPa	60 kPa	
Vacuum Time	50-60 min	60 min	
Humidification			
Humidity	50.0-90.0%	20.2 %	
Sterilization			
Sterilization Temperature	40.0-55.5 °C	43.5 °C	
Gas Injection			
Final pressure	0-10 kPa	4 kPa	
Final temperature of vaporizer	40.0-55.5 °C	44.8 °C	
Exposure			
Temperature at start point of Exposure time period	40.0-55.5 °C	43.3 °C	
Temperature at finish point of Exposure time period	40.0-55.5 °C	46.0 °C	
Exposure Time	120-240 min	180 min	
Exhaust			
Exhaust Time	60-80 min	75 min	
First Vacuum pressure	0-2 kPa	1.5 kPa	
Second Vacuum pressure	0-2 kPa	1.5 kPa	
Third Vacuum pressure	0-2 kPa	1.5 kPa	
Fourth Vacuum pressure	0-2 kPa	1.5 kPa	
Fifth Vacuum pressure	0-2 kPa	1.5 kPa	
Storage			
Storage Time	≥ 48 hour	≥ 48 hour	
Chemical Test			
EO sterilization temperature 40-55°C, Time Sterilization by EO 3hours	Blue	Red	Pass
Biological Test			
EZ Test Biological Indicator	Green	Green	Pass


 (.....)
 Mr.Jutha Liammukda
 Research and Development Engineer

Air replacement:
Temperature: 45.4℃
Humidity:20.2RH
Pressures:-1.5KPa
Sterilization time:0Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 4:54

Sterilization:
Temperature: 45.6℃
Humidity:20.2RH
Pressures:-0.0KPa
Sterilization time:0Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 4:48

Sterilization:
Temperature: 43.8℃
Humidity:20.1RH
Pressures:-0.0KPa
Sterilization time:3Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 1:50

Sterilization:
Temperature: 43.6℃
Humidity:20.1RH
Pressures:-1.6KPa
Sterilization time:3Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 1:48

Add EO gas
Temperature: 43.6℃
Humidity:20.2RH
Pressures:-4.0KPa
Sterilization time:3Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 1:48

Evacuation
Temperature: 44.3℃
Humidity:20.1RH
Pressures:-0.0KPa
Sterilization time:3Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 1:43

Keeping Temp
Temperature: 44.3℃
Humidity:20.1RH
Pressures:-1.6KPa
Sterilization time:3Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 0:43

Keep pressure qualified
Temperature: 43.4℃
Humidity:20.1RH
Pressures:-59.0KPa
Sterilization time:3Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 0:41

Evacuation
Temperature: 42.2℃
Humidity:20.2RH
Pressures:-3.0KPa
Sterilization time:3Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 0:30

Heating-up:
Temperature: 24.9℃
Humidity:20.1RH
Pressures:-3.0KPa
Sterilization time:3Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 0:0

Setting:
Temperature: 45.0℃
Humidity:55.0RH
Pressures:-60.0KPa
Sterilization time:3Hour
Air replace rounds:5
round time:15min(s)

2000-1-9 0:0

END

4/8/06
lot 653

Air replacement:
Temperature: 44.9℃
Humidity:20.2RH
Pressures:-1.5KPa
Sterilization time:0Hour
Air replace rounds:1
round time:0min(s)

2000-1-9 6:15

Air replacement:
Temperature: 45.1℃
Humidity:20.2RH
Pressures:-1.5KPa
Sterilization time:0Hour
Air replace rounds:2
round time:0min(s)

2000-1-9 5:55

Air replacement:
Temperature: 45.4℃
Humidity:20.2RH
Pressures:-1.5KPa
Sterilization time:0Hour
Air replace rounds:3
round time:0min(s)

2000-1-9 5:34

Air replacement:
Temperature: 45.8℃
Humidity:20.1RH
Pressures:-1.5KPa
Sterilization time:0Hour
Air replace rounds:4
round time:0min(s)

2000-1-9 5:14