# LyoConstellation<sup>™</sup> S20

# **Pilot Lyophilizer**



## **Key Features**

- Unmatched process accuracy and reliability
- Deliver Line of Sight™ approach in cycle development & scale up using same technologies from R&D to production
- Designed to conform to good instrumentation practices
- Optional LyoFLux\*TDLAS instrument with integrated communication with SP Hull LyoS™2.0 controls system software
- Optional ControLyo® Nucleation Technology for improved product homogeneity and process efficiency

## **Specifications**

Lowest Shelf Temperature (50 Hz / 60 Hz)	-60 °C
Shelf Temperature Control Range	-55 °C To 65 °C
Shelf Temperature Control Accuracy	± 0.5 °C
Shelf Pull-Down From 20 °C To -40 °C	≤ 25 minutes
Shelf Temperature Uniformity <sup>1</sup>	± 1.0 °C
Lowest Condenser Temperature	-65 °C
Condenser Surface Area	1.85 m <sup>2</sup> (19.4 ft <sup>2</sup> )
Condenser Pull-Down From 20 °C To -45 °C	≤ 20 minutes
Maximum Sublimation Rate <sup>2</sup>	2,050 g/hour
Compressor Horsepower	10 hp (7.45 kW)
System Refrigerant	R410A (CFC free)
Vacuum Time To 100 mTorr <sup>3</sup>	≤ 20 minutes
Vacuum Rate Of Rise <sup>3</sup>	≤ 30 mTorr/hour
Volume-Based Leak Rate <sup>3</sup>	≤ 0.010 mbar • L/sec (7.5 mTorr • L/sec)
Lowest System Vacuum <sup>3</sup>	≤ 15 mTorr

**Note:** Performance specifications are based on SP test data from clean, dry and empty (CDE) units operating at an ambient room temperature of approximately 20° C. SP recommends an optimum operating range of 15-25 °C (59-77 °F) with an RH of  $\leq 80$  % at sea level.

# **Electrical Requirements**

Voltage	200–250 VAC	360-440 VAC	420-500 VAC
Hertz	60 Hz	50 Hz	60 Hz
Phase	3 Φ (4 wire)	3 Φ (5 wire)	3 Φ (4 wire)
Breaker Amperage	70 A	40 A	40 A



# **Utility Requirements**

Compressed Air	5.5 barg (80 psig)
Cooling Water <sup>4</sup>	19-30 Lpm (5-8 gpm)
Inert Gas For Backfilling	0.21-0.34 barg (3-5 psig)
Inert Gas For VLC/Vacuum Release	0.21-0.34 barg (3-5 psig)
Inert Gas Consumption (Full Vacuum Release)	860 L @ 1 ATM
Inert Gas For Controlyo®	3.45-4.14 barg (50-60 psig)
Steam For Sterilization In Place (SIP)	40.82 kg/hour (90 lbs/hour) @ 1.38-1.72 barg (20-25 psig)
Clean In Place (CIP) Water / Media	150 Lpm (40 gpm) @ 4.14 barg (60 psig)
Cooling Water Heat Removal	41.03 kW/hr (140,000 BTU/hr)
Heat Output (Room), Peak	2.93 kW (10,000 BTU/hr)

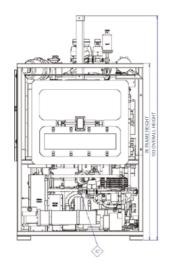
## **ControLyo® Requirements (Optional)**

Volume To Vent Percentage Ratio (Vv/V <sub>R</sub> )	< 6.5 %
--	---------

**Note:** Vent Volume (Vv) is the product chamber volume multiplied by 10. The volume of a standard SP Hull LyoConstellation S20 chamber is 0.51  $\,\mathrm{m}^3$  (18  $\,\mathrm{ft}^3$ ). VR is the volume of the room in which the lyophilizer is located.







#### **Dimensional Data**

Width	147 cm (58 in)
Length	277 cm (109 in)
Height	199 cm (78 in)
Height of Stoppering Ram	262 cm (103 in)
Maximum Weight	3175.1 kg (7,000 lb)

**Note:** LyoFLux\* TDLAS installation increases overall length by 61.0 cm (24 in). SP recommends a 60.7 cm (24 in) clearance around all sides of the unit for serviceability.

#### **Materials of Construction**

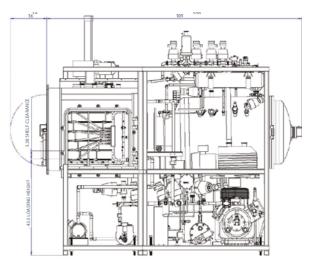
Product Chamber	AISI 316L stainless steel
Shelf	AISI 316L stainless steel
Condenser Chamber	AISI 316L stainless steel
Isolation Valve Disc	AISI 316L stainless steel

#### **Surface Finish**

Product Chamber Interior	Ra 0.635 micrometers (25 micro-inches)
Shelves	Ra 0.635 micrometers (25 micro-inches)
Condenser Chamber Interior	Ra 0.813 micrometers (32 micro-inches)

#### **Additional Information**

Stoppering	Top-down hydraulic
Defrost Type	Hot water/steam (optional)
Noise Level <sup>5</sup>	≤ 85 dB
Vapor Port Inner Diameter	30.5 cm (12 in)
Loading / Unloading Door to Cleanroom	Automatic/Autolocking
Chamber Inspection Door to Machine Room	Manual locking
Locking For Condenser Door	Manual locking
Protection Rating	IP20
CE Compliant	



## **Shelf Configuration**

Number of Shelves	Shelf Area	Shelf Clearance
5 Usable Shelves (1 Radiant)	1.93 m <sup>2</sup> (20.8 ft <sup>2</sup> )	85 mm (3.35 in)
Shelf Dimensions $(W \times L)$	762 mm × 508 mm (30 in × 20 in)	_
Shelf Loading Height	1105 mm (43.5 in)	_

## **Refrigeration Information**

F Gas	R410A
Charge (Kg)	Approximately 20 lbs
GWB	2088
Total CO <sub>2</sub> e (tonnes)	18.9

### **Options / Other Considerations**

ControLyo® Nucleation Technology
LyoFlux* 200 TDLAS Mass Flow Sensor
Independent CIP Skid
Tempris* Wireless Temperature Sensors
Virtual Servers & Thin Clients



<sup>&</sup>lt;sup>1</sup> Shelf temperature deviations shall not exceed the specification relative to the mean of the highest and lowest temperature readings

<sup>&</sup>lt;sup>2</sup> The specified Maximum Sublimation Rate at 40 °C, 100 mTorr using a 0.001" thickness plastic lined trays

 $<sup>^3</sup>$  Vacuum specifications are based on SP test data from similar units equipped with a two-stage rotary vane vacuum pump. Units equipped with other vacuum pumps may yield different results (e.g. a dry pump shall yield a Lowest System Vacuum of ≤ 50 mTorr)

 $<sup>^4</sup>$  Cooling water temperatures should not exceed 24  $^{\circ}$ C

<sup>5</sup> Noise from the equipment under normal operating conditions shall not exceed 85 dB when measured at any point 91 cm (3 feet) away from the equipment. Lyophilizers equipped with ControLyo® shall exceed the specified noise level rating for approximately 3 to 5 seconds during depressurization and SP recommends the use of both hearing and eye protection during the ControLyo® process