

VirTis Benchmark Production Freeze Dryers

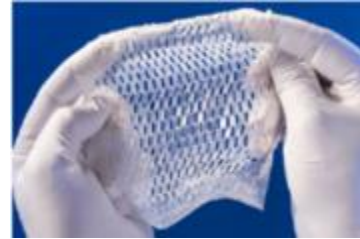
John Barley, Product Manager



- Manufactured in our Warminster, PA & Gardiner NY, USA factories
- All major components are completely built in the USA, including:
 - Product Chamber
 - Shelves
 - Condenser
- Installed base of over 200 units worldwide, with over 20 years of continuous dependable operation



- Production Freeze Dryers designed for a variety of life sciences applications:
 - Diagnostic Kits & Bulk Reagents
 - Bulk Collagen & Tissue Products
 - Nutraceuticals
 - API (Active Pharmaceutical Ingredients)





- Industrial-grade 316L SS commercial construction – built to last
- Shelf area available from 2m² to 20m²
- Either bulk fixed-shelves, or, stoppering configuration option

SP Scientific Benchmark Lyophilizers - Shelf Area and Clearance						
Model		3000	3500	4000	4500	5000
Shelf Size	millimeters	610 x 915	610x 1220	610x 915	610x 1220	915 x 1220
	Inches	24 x 36	24 x 48	24 x 36	24 x 48	36 x 48
5	Area (square meters) (square feet)	2.79 (30.0)	3.72 (40.0)			
	Clearance (millimeters)	95	95			
6	Area (square meters) (square feet)	3.34 (36.0)	4.46 (48.0)			
	Clearance (millimeters)	77	77			
7	Area (square meters) (square feet)	3.9 (42.0)	5.2 (56.0)	3.9 (42.0)	5.2 (56.0)	
	Clearance (millimeters)	64	64	120	120	
8	Area (square meters) (square feet)	4.46 (48.0)	5.95 (64.0)	4.46 (48.0)	5.95 (64.0)	8.92 (96.0)
	Clearance (millimeters)	54	54	105	105	125
9	Area (square meters) (square feet)			5.02 (54.0)	6.69 (72.0)	10.03 (108.0)
	Clearance (millimeters)			92	92	110
10	Area (square meters) (square feet)			5.57 (60.0)	7.43 (80.0)	11.15 (120.0)
	Clearance (millimeters)			82	82	95
11	Area (square meters) (square feet)			6.13 (66.0)	8.18 (88.0)	12.26 (132.0)
	Clearance (millimeters)			72	72	85
12	Area (square meters) (square feet)			6.69 (72.0)	8.92 (96.0)	13.38 (144.0)
	Clearance (millimeters)			65	65	75
13	Area (square meters) (square feet)			7.25 (78.0)	9.66 (104.0)	14.49 (156.0)
	Clearance (millimeters)			60	60	70

- Standard Benchmark Shelf Sizes, Total Area & Clearances
- Other sizes available

Design Flexibility - Configuration Options Available

- Standard Round, or Square Product Chamber
- External or internal ice condenser
- Redundant refrigeration & vacuum systems
- Rotary-vane oil vacuum pumps, or, dry scroll option
- CIP (Clean-In-Place)

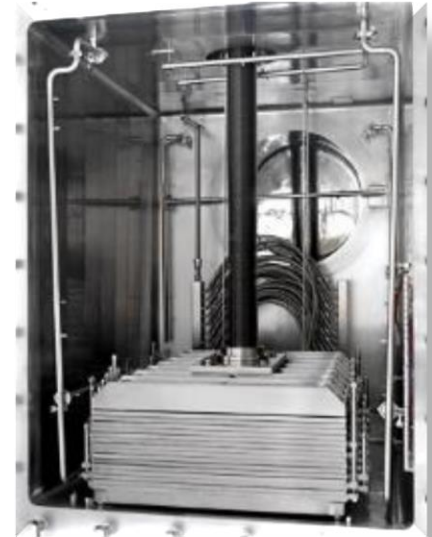


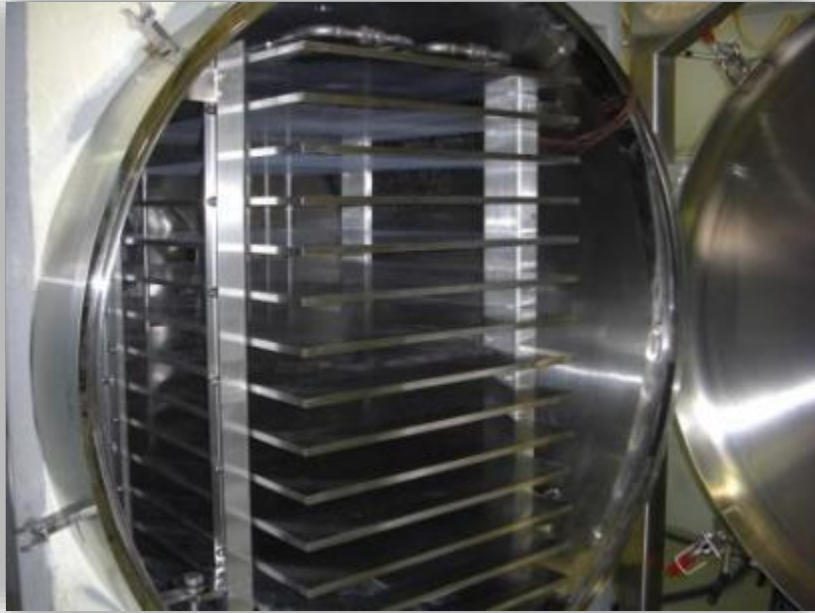


Clean room wall installation with 316L SS wall flange. Designed for easy accessibility to major components and maintenance points on the service/technical side.

Superior Shelf Performance

- Shelf Temperature Uniformity of $\pm 1^{\circ}\text{C}$
- 316L Stainless Steel Construction
- Ra 25 standard interior finish
- Radiant shelf above first usable shelf
- Shelf Latching option for flexible processing

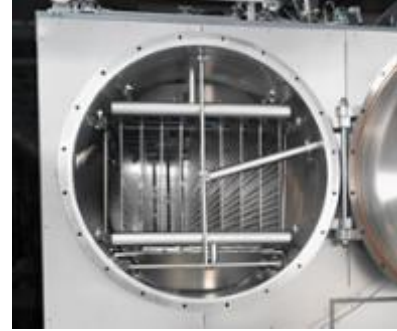




- Optimized shelf configurations provide maximum processing capacity = large product batch sizes with small equipment footprint
- Shelf area from 2m² to 20m²

Condenser Configurations Available

- Standard External Ice Condenser with condensing plate design
- Internal Ice Condenser option to save space
- Condenser temperatures
 - - 70°C standard design
 - - 65°C redundant (fluid) design
 - - 80°C cascade option





- Dependable 2-stage Reciprocating Refrigeration Compressors
- Option for N+1 Redundancy
- Option for cascade refrigeration



- Complete chamber coverage – riboflavin test verified
- Dependable spray nozzle approach
- CIP Skid - Heated Storage Tank option



- Isolation valve
- H2O2 VHP Ready
- Solvent Traps
- Shelf Latching
- Dry Scroll Vacuum Pump
- Validation Port



LyoS™ 2.0
Serial Number: XXXXXX

Cycle	Cycle Time (min)
None Active	0
Phase	Phase Time (min)
Ready	0
Step	Step Time (min)
0	0

Shelf SP (°C)	0.0
Shelf Inlet (°C)	22.8
Shelf Outlet (°C)	23.3
Condenser (°C)	26.5
Probe Avg (°C)	21.1 !
Vacuum SP (mTorr)	0
Vacuum CM (mTorr)	2100
Vacuum PVG (mTorr)	1042
Rough Vac (mBar)	625
Condenser CM (mTorr)	2100
Ambient Temp (°C)	20.4
Voltage (VAC)	L1 210

PVG/CM Diff (mTorr)	0
Pressure Rise (mTorr)	0
Hydr. Press. (PSIG)	0.85

SYSTEM ADMINISTRATOR 2020-09-30 09:30:43

Recipe Synoptic Test Semi-Auto Historical Data



LyoS™ 2.0

PLC Version LyoS2.0_2.0

SP Scientific
A Division of SP Industries

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All systems are equipped with Lyos 2.0 control system:

- Process Data stored indefinitely in a secure format
- Robust GE iFIX SCADA
- Secure Login ID & PW
- Allen Bradley PLC
- Pirani & MKS Capacitance Manometer
- Minimum 8 Product Probes
- Comprehensive suite of over 25 process alarms to protect valuable product

Benchmark – Controls



Serial Number: AlphaS10

SYSTEM ADMINISTRATOR
2018-11-12
16:08:38

SP SCIENTIFIC

Serial Number: AlphaS10

Cycle: Cycle Time [min]
Semi-Auto: 106

Phase: Phase Time [min]
0

Step: Step Time [min]
0

Shell SP [°C]: 15.0

Shell Inlet [°C]: 22.9

Shell Outlet [°C]: 22.5

Condense [°C]: -31.4

Probe Avg [°C]: 99.9

Vacuum SP [mTorr]: 0

Vacuum CM [mTorr]: 158

Vacuum PVC [mTorr]: 104

Condense CM [mTorr]: 225

Pressure Rise [mTorr]: 0

PVC/CM Diff [mTorr]: 0

Condenser Drain [°C]: 21.4

Chamber Drain [°C]: 22.7

Filter Drain [°C]: 19.7

Chamber Press. [PSIA]: -0.1

Condenser Press. [PSIA]: 0.0

Hydr. Press. [PSI]: 1.00

Recipe
Synoptic
Test
Semi-Auto
Historical Data
Cycle

Freeze Dry

Current Batch

Batch ID: XXXXXX

Recipe Name: DRYRUN

Product Name: XXXXXX

Shell Load

Shell SP [°C]: 0.0

Cycle Control

Control With CM:

Product Driven Freeze:

Freezing

	1	2	3	4	5	6	7	8	9	10	11	12
Temperature SP [°C]	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Ramp Time [min]	0	0	0	0	0	0	0	0	0	0	0	0
Hold Time [min]	0	0	0	0	0	0	0	0	0	0	0	0

Freeze / Evacuate

Shell SP [°C]: -60.0

Hold Time [min]: 60

Condenser Check [°C]: -50.0

Initial Vac SP [mTorr]: 100

Pressure Rise Data

Pressure Rise Enable:

Closure Time [sec]: 60

On Demand Pressure Rise:

Drying

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Temperature SP [°C]	-90.0	-85.0	-80.0	-75.0	-70.0	-70.0	10.0	10.0	10.0	21.0	21.0	30.0	40.0	50.0	60.0	70.0	80.0
Ramp Time [min]	0	60	0	0	300	210	0	0	0	120	120	70	0	0	0	0	0
Hold Time [min]	4000	20	30	60	30	30	70	30	60	30	60	50	60	5	5	5	60
Vac. SP [mTorr]	20	300	500	100	100	600	200	500	50	125	100	100	75	75	75	75	150
Vac. Ramp Time [min]	0	30	30	0	0	20	0	30	30	0	0	0	0	0	0	0	0
PVC/CM Diff [mTorr]	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Press. Rise SP [mTorr]	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Product Storage

Shell SP [°C]: 0.0

Vacuum SP [mTorr]: 0

End Cycle:

Process Control Action

PVC/CM:

Pressure Rise:

Retest Time [min]: 2

Recipe Management

Edit Recipe:

Backfill / Stopping

Backfill (PSIA): 1

Stopping:

End Cycle:

Save

Save As...

Load...

Lyos-2.0 SCADA Controls - Additional Options

- Automatic Batch Reports
- UPS
- 21CFR11 audit trail



Freeze Dry Cycle Report

Freeze Drying Cycle Start: 2019-02-05 08:04:03
 Freeze Drying Cycle End: 2019-02-06 07:13:58
 Freeze Drying Cycle Duration: 0:23:09:55

Serial Number:
 Batch ID:
 Package Name:
 Product Name:

S24825
 SN S24825
 DR15LN
 Architectural Environments

Events

Date and Time	Code	Description	Event Type
2019-02-05 8:04	SPLYO	[SPLYO] 1 RW32.SPLYO.CYCLE.F.CV set to 1 by SPLYO\SYSTEM ADMINISTRATOR	OPERATOR
2019-02-06 7:08	SPLYO	[SPLYO] 1 RW32.SPLYO.FD.11Z.CONTINUE.RELEASE.F.CV set to 1 by SPLYO\SYSTEM ADMINISTRATOR	OPERATOR

- GAMP 5 Approach
- Design Specifications
- Lifecycle Documents with Material & Surface Finish Certifications
- As-Built Drawing Package
- FAT
- SAT
- IQOQ

