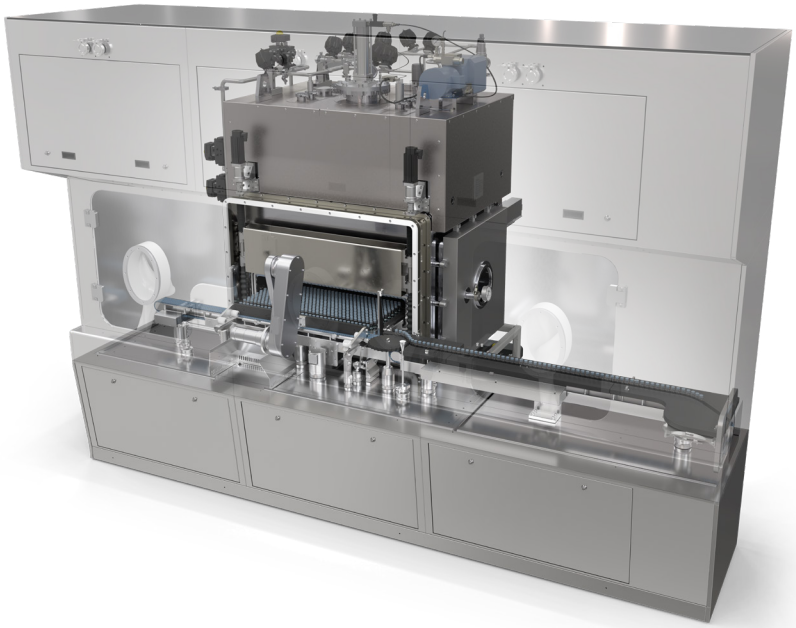
Small-Scale Aseptic Freeze Dryer

with Autoloading System

SP Hull



The newest addition to the LyoConstellation family, these aseptic small-scale freeze-dryers are designed to seamlessly integrate with an aseptic autoloader for use in isolators and oRABS environments.

With its specialized loading system, the autoloader enhances line sterility assurance while maintaining a reduced footprint.

Its compact design fits easily into existing cleanroom layouts and eliminates manual intervention, helping your team work more efficiently without adding complexity.

Key Features & Benefits

- **Fully Automated Operation**
  Enables consistent, efficient row-by-row vial loading and unloading while **reducing manual intervention** and human error.
- **Bellows-Free Loading Pusher**
  Eliminates hidden contamination risks by removing hard-to-clean components and preventing non-sterile parts from entering the process chamber.
- **First-Air Optimized Sub-Door**
  Enhances sterility assurance by fully exposing critical surfaces during decontamination and **minimizing contamination** at transfer points.
- **Compact Footprint**
  Maximizes valuable cleanroom space with an **integrated design** ideal for small-batch production. For redundant configurations (compressors and vacuum circuits), a specially integrated frame optimizes space, **reducing the footprint** even within the freeze dryer technical area.
- **Seamless Aseptic Integration**
  Designed for isolators and oRABS systems, **enabling smooth connection** with small-scale freeze dryers and fill-finish lines.
- **Compliance-Ready Design**
  Supports cGMP (FDA & EU Annex 1), 21 CFR Part 11, GAMP5, and ASME-BPE requirements for regulatory confidence.

Designed for Reliable Small-Batch Production

- Enhance sterility assurance across your process by minimizing risk in critical aseptic zones and increasing confidence during periodic line qualification.
- Lower total cost of ownership by minimizing cleanroom space requirements and reducing supporting infrastructure.
- Accelerate time to production through streamlined automation that enables faster setup and efficient batch handling.
- Improve batch consistency with controlled, repeatable processes that reduce variability.
- Enable flexible small-batch manufacturing to support clinical trials and high-value, low-volume production
- Future-proof your facility by staying aligned with evolving regulatory expectations.

LINE OF SIGHT ENABLED

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Freeze Dryer Specifications

Lowest shelf temperature (50 Hz / 60 Hz)	-60°C
Shelf Inlet Temperature Control Range Accuracy*	-55 to 65°C / +/- 1.0 °C
Vacuum Level Control Range	0.067 – 0.67 mbar (50 – 500 mTorr)
Volume-Based Leak Rate	≤ 0.02 mbar·L/ sec
Lowest System Vacuum	0.026 mBar (≤ 20 mTorr)

Shelf Configuration

Model	Number of Shelves (+1 Radiant)	Shelf Area (m^2)
S20-A	3 Shelves	2 m^2 (19.9 ft^2)
S30-A	5 Shelves	3 m^2 (33.2 ft^2)
S50-A	8 Shelves	5 m^2 (53.2 ft^2)

Useable Shelf dimension: (W x D) 650 mm x 900 mm
Loading height: 950 mm

Vial Capacity (estimated)

Vial Size	S20-A	S30-A	S50-A
2R	7,308	12,180	19,488
6R	3,906	6,510	10,416
10R	3,234	5,390	8,624
20R	2,013	3,355	5,368
30R	2,013	3,355	5,368
50H	945	1,575	2,520

Specifications note:

Performance specifications are based on SP test data from units operating at an ambient room temperature of approximately 20°C. SP recommends an optimum operating range of 15-25°C (59-77°F). For full specifications please contact your regional product specialist.

* Shelf luid inlet temperature controlled to within ± 1.0°C of the setpoint within the Shelf Temperature Control Range when at I00 mTorr.

Autoloader Configuration

Loading and Unloading from Same Side (left or right)
Loading in One Side and Unloading to the Other
Liquid By-pass Configuration (for multiple freeze dryers)

Additional Information

Construction	316L stainless steel shelves, product chamber and condenser chamber
Defrost type	Clean Steam
Standard Refrigerant	R449
Certifications	PED / ASME

Options / Other Considerations

CIP with Recirculation and/or Additional Cleaning Media
Independent CIP Skid with Accumulation Tank
Bellows for Subdoor Driving Screws (standard without)
Mycom Screw Compressors (standard with reciprocating)
Full Redundant Pack (vacuum, compressors and pumps)
Frame Extension to Integrate the Redundant Configuration
Potent and/or Solvent Products
Additional Certifications (CE, NRLT, Atex)
LyoLogic® HMI, compliant to 21 CFR Part 11.

Process Analytical Technology (PAT) Tools

- **ControLyo® Nucleation Technology:** enables controlled, simultaneous nucleation across all vials, ensuring consistent product quality and reduced drying times.
- **LyoFlux® 200 TDLAS Mass Flow Sensor:** NIR-based technology that provides real-time monitoring of water vapor mass flow, supporting process optimization, consistent product quality.
- **Tempris® Wireless Temperature Sensors:** replace traditional thermocouples with wireless, real-time temperature monitoring to enhance freeze-drying precision.

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