

ATONARP

LyoSentinel™ Molecular Sensor

Real Time Process Control for
Lyophilization Applications



*Robustness
Reliability
Repeatability
Accuracy
Sensitivity*

Cloud Ready

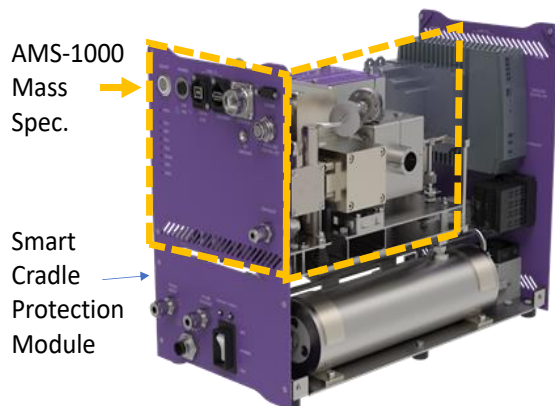
Designed for Pharma Lyophilization Process Monitoring, Protection & Control

The LyoSentinel™ is a turnkey process monitor solution tailored for pharma lyophilization applications using freeze-dryers(FD). The LyoSentinel value offering includes:

- Tool qualification prior to the start of the lyophilization process to ensure vacuum integrity and absence of contaminants e.g. Silicone oil & air leaks.
- Monitoring of water vapor and aqueous solvents for accurate drying endpoint detection.
- Detection and identification of traces of silicone oil leaks emanating from compromised heat transfer fluid conduits during lyo process.
- Process cycle development and process production transfer tool.

LyoSentinel Description

A modular system consisting of a smart cradle protection module nesting the AMS-1000 mass spectrometer.



LyoSentinel Process Monitoring Features & Benefits

- Designed for lyophilization process monitoring
- Unique miniature mass spectrometer design
- Detect & Protect: Silicone oil detection and protection system
- Designed for standalone or integration operation.
- On board use cases – Primary and secondary drying endpoint
 - Fast silicone oil detection
 - Baseline chamber health – leak and contaminates checking
 - Process transfer
 - User customizable
- Smart cradle docking system
- Edge device/ cloud-ready integration for Lyo system machine learning
- Field serviceable
- Endorsed by major pharma PAT professionals.
- 21CFR part 11 full compliance
- Real-time process monitoring

Smart Cradle Filter Module

- Consists of an integrated sampling system intended for direct connection to the freeze dryer.
- Includes a heat-controlled dual sample path manifold, with the primary path featuring a proprietary filter design for continuous monitoring of the drying process and its endpoint detection.
- The chamber gas sample is drawn through the heated filter while high molecular weight contaminants are removed based on permeation rates.

AMS-1000

- The AMS core platform is a compact system featuring the MS sensor and its associated electronics, vacuum manifold, and vacuum pumps.

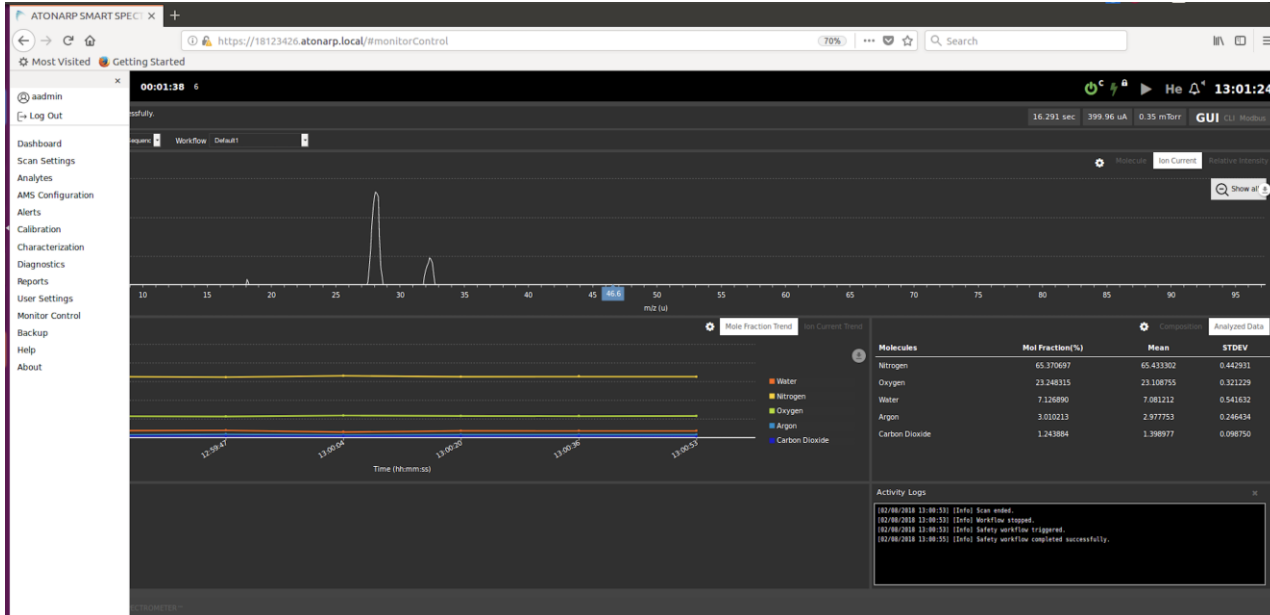
- The enabling MS sensor technology is a miniature array of quadrupole mass filters operating in parallel to achieve high-sensitivity performance with fast response time.
- The sensor covers 100 amu of mass range and is compatible with high pressure process chamber operation.

Software

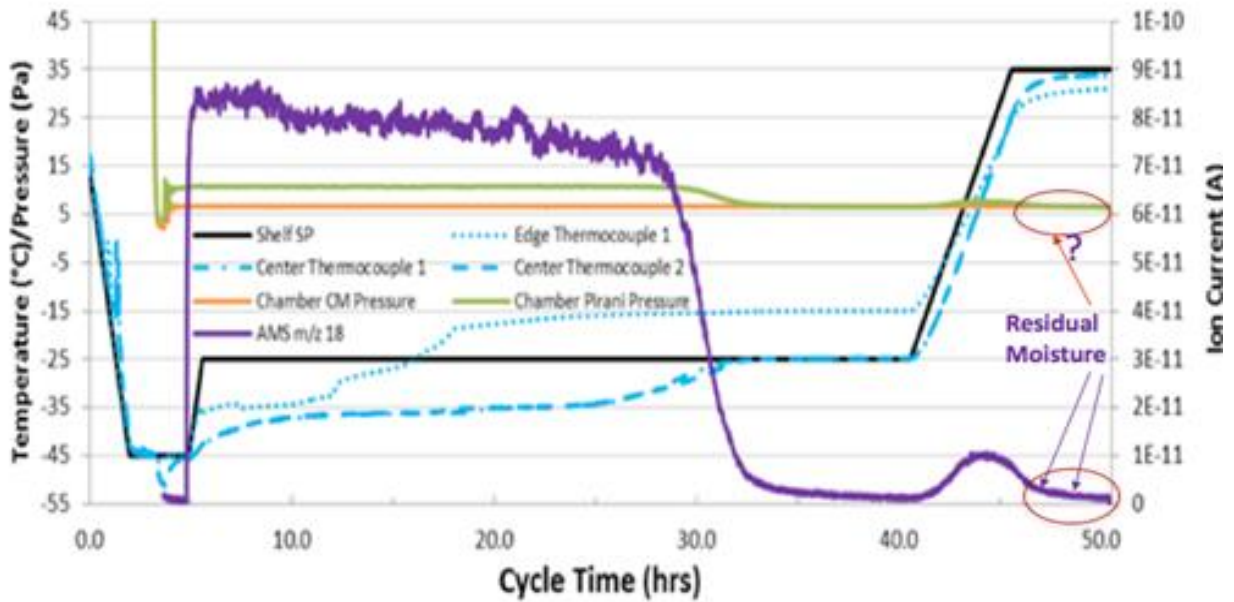
The LyoSentinel™ is controlled via a web-browser based application (Atonlab™). The dashboard is the primary user interface (UI) view for control, data acquisition, and system health monitoring and diagnostics display.

- UI provides instrument customization and displays many user defined configuration parameters.

- UI allows users to switch between various “recipes” to suit specific application requirements.
- Datasets generated from perpetual scans are time stamped and stored allowing the system to run autonomously.
- Process spectral information, pressure and vacuum diagnostics, preventative maintenance schedule, and operational control are all supported in Atonarp’s Cloud Services.
- Additional data analytics, multiple system access and machine learning algorithm solutions for process standardization among dryer tools are also available



View of the LyoSentinel User Interface (UI)



Plot of cycle data including AMS water signal for 5% w/v sucrose solution

LyoSentinel Specifications

Parameter	Conditions	Min	Typ	Max	Units
Mass Range		2		100	amu
Sampling pressure range		10×10^{-3}	200×10^{-3}	1	Torr
Ambient temperature	80% relative humidity non-condensing	0		40	°C
Inlet pump	A dry pump able to establish low mTorr pressure	100			l/min
Power consumption	24VDC			240	W
Weight			22		kg
Size	Length x Width x Height	408 x 204 x 316			mm

Ordering Information

Instruments:	Part number
LyoSentinel 120VAC	ASM-900-0011
LyoSentinel 240VAC	ASM-900-0012

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