HIDEN ANALYTICAL

Monitor and Control Freeze Drying with the HPR-30 Vacuum Process Monitor

Topics

- ✓ HPR-30 System
- ✓ Sampling from a Freeze Dryer
- ✓ Applications of gas analysis
  - End Point Detection
  - Leak Detection
  - Contamination detection

HPR-30

Vacuum Process Gas Analyser

The HPR-30 system is a differentially pumped quadrupole mass spectrometer system with:

Re-entrant sampling orifice

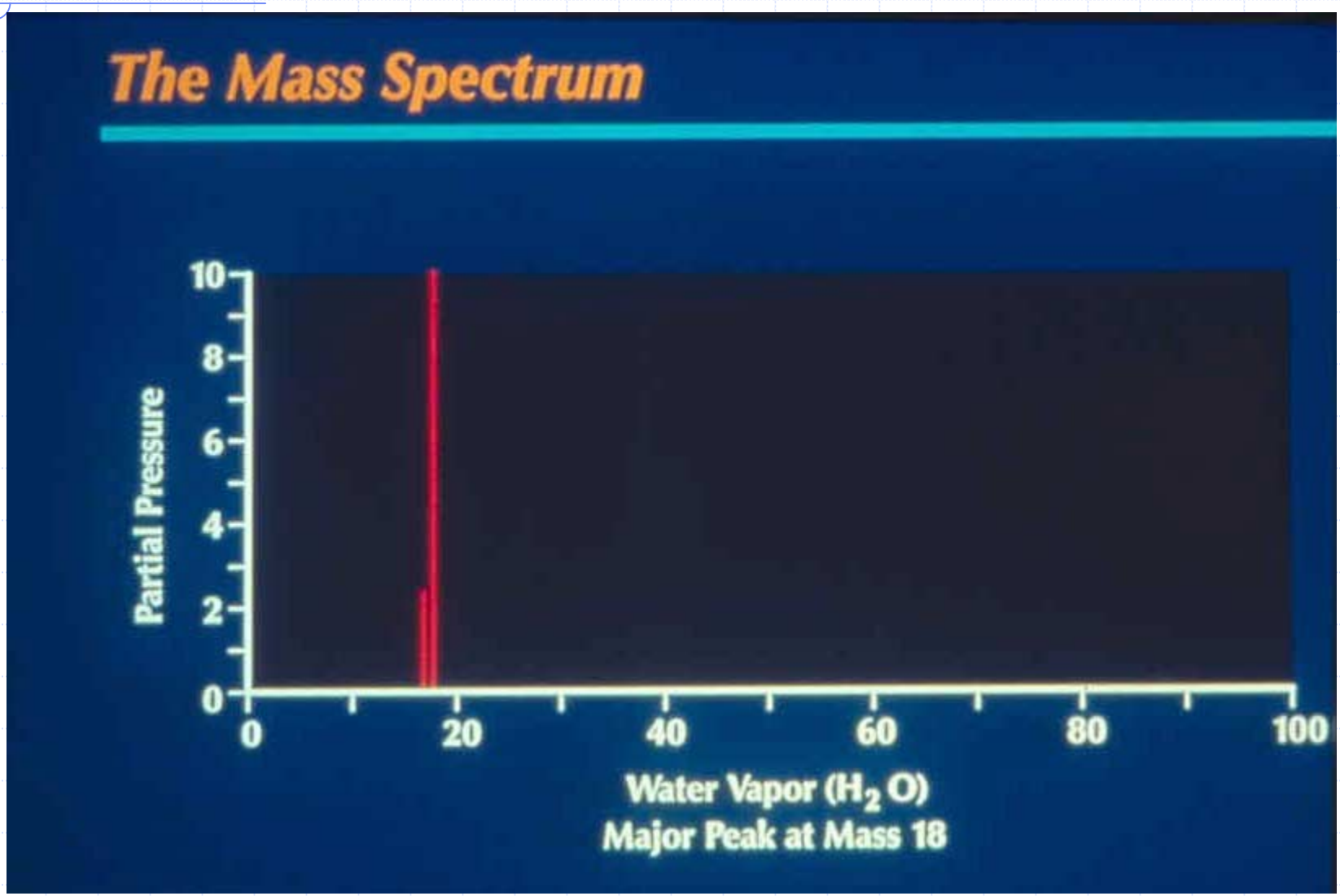
and

Fail-safe auto shut-off valve.

The HPR-30 system features:

- Fast response
- Wide dynamic range
- Real time analysis for water vapour, solvents and potential contamination

Re entrant orifice


The Mass Spectrum
Partial Pressure
10
8
6
4
2
0
0
20
40
60
80
100
Water Vapor (H_2O)
Major Peak at Mass 18

Simple Gases

Name	Major Peak
Helium	4
Water Vapor	18
Nitrogen	28
Oxygen	32
Argon	40
Carbon Dioxide	44

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Organic Vapors

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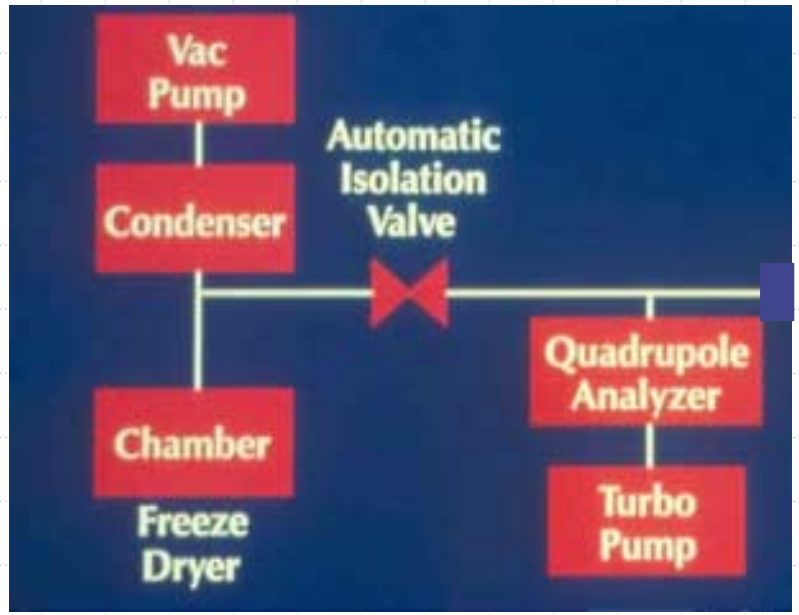
Hiden- HPR-30 Vacuum Process Analyser Connection to the Freeze Dryer

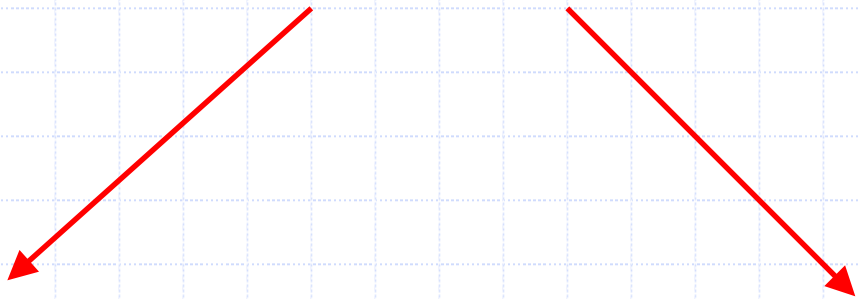
The HPR-30 system connects to the freeze dryer system with a KF type vacuum flange or similar. The connection is made to an available port on the main chamber or to a port between the main chamber and the condenser as shown on the schematic.



HPR-30 Applications

- ✓ End Point Detection
- ✓ Leak Detection
- ✓ Contamination detection

Monitor Water Vapour



Production

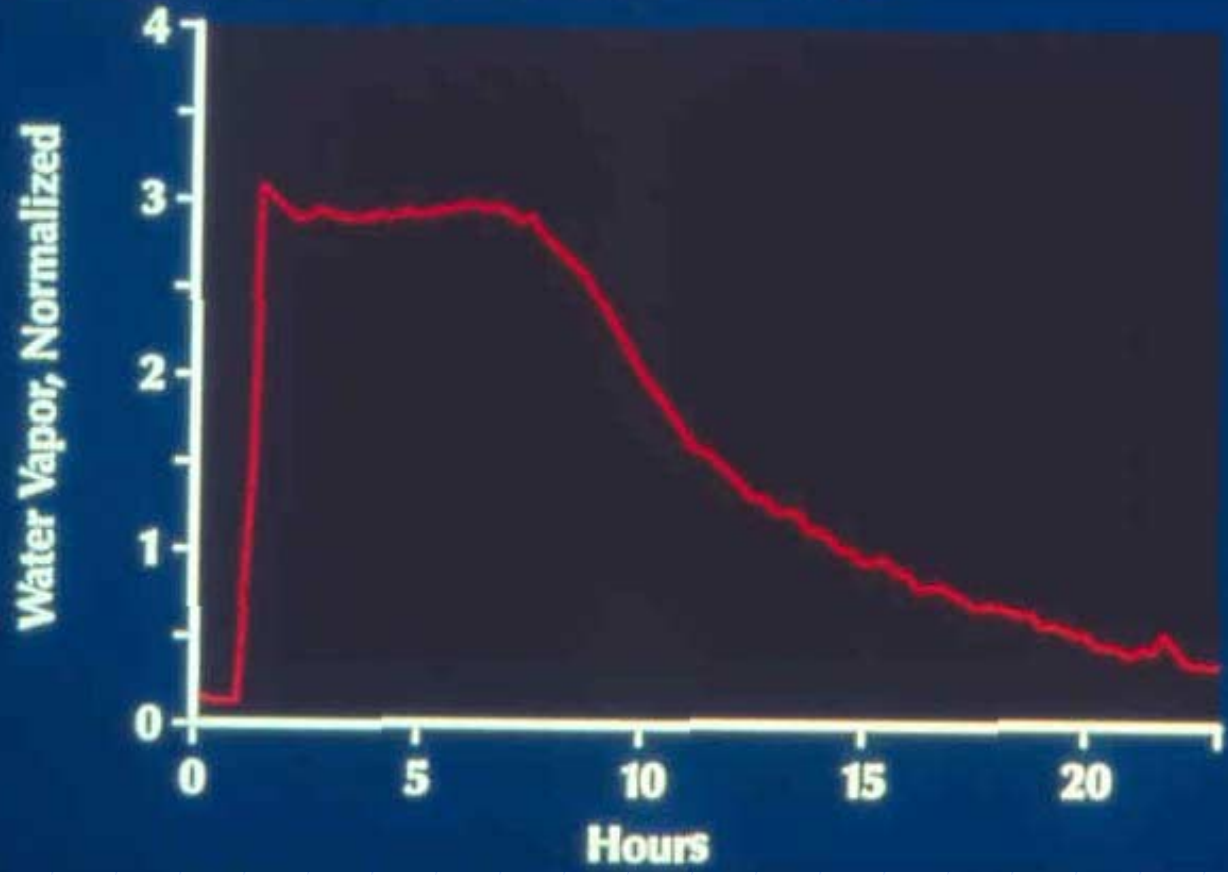
- Reduce Cycle Time
- On-Line Monitor
- Document Process

R&D

- Cycle development
- Optimize Cycle
- Validation

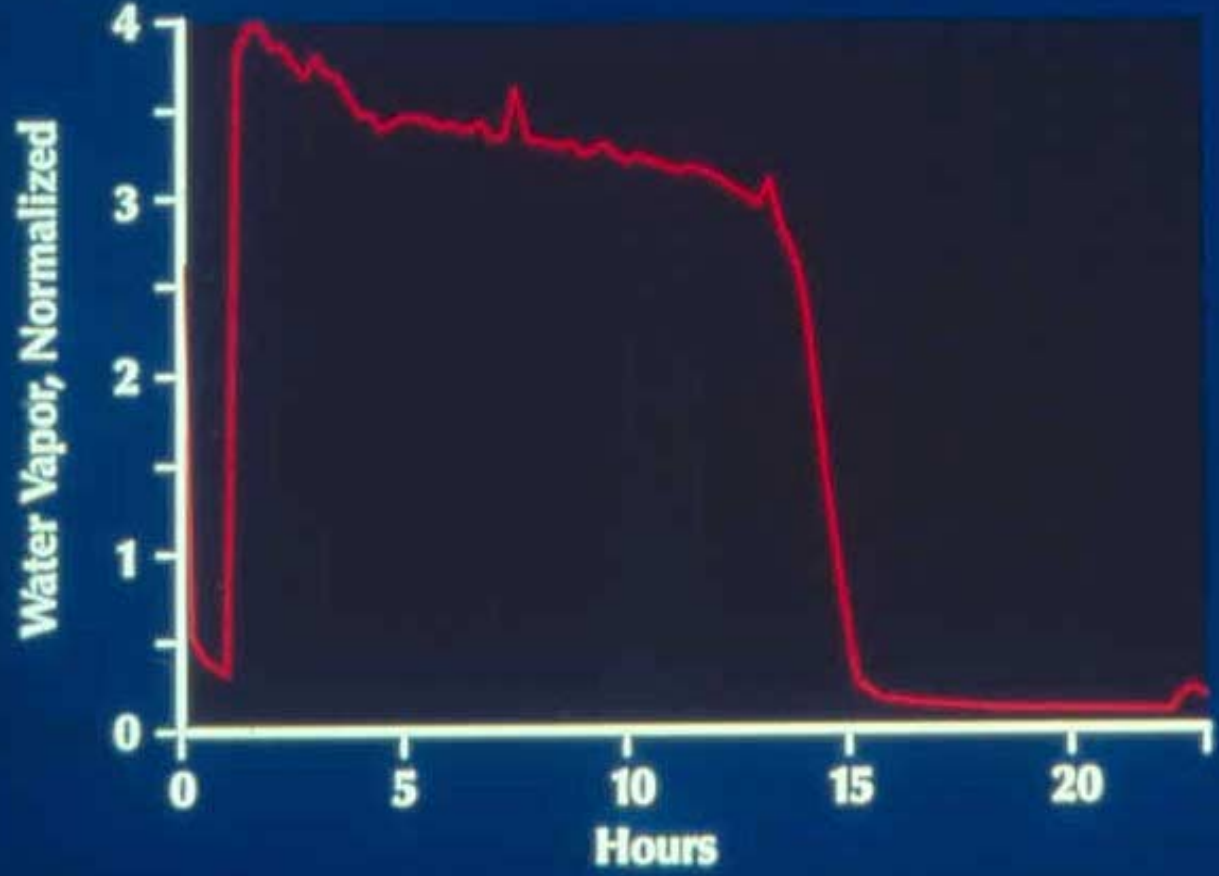
Lyophilization

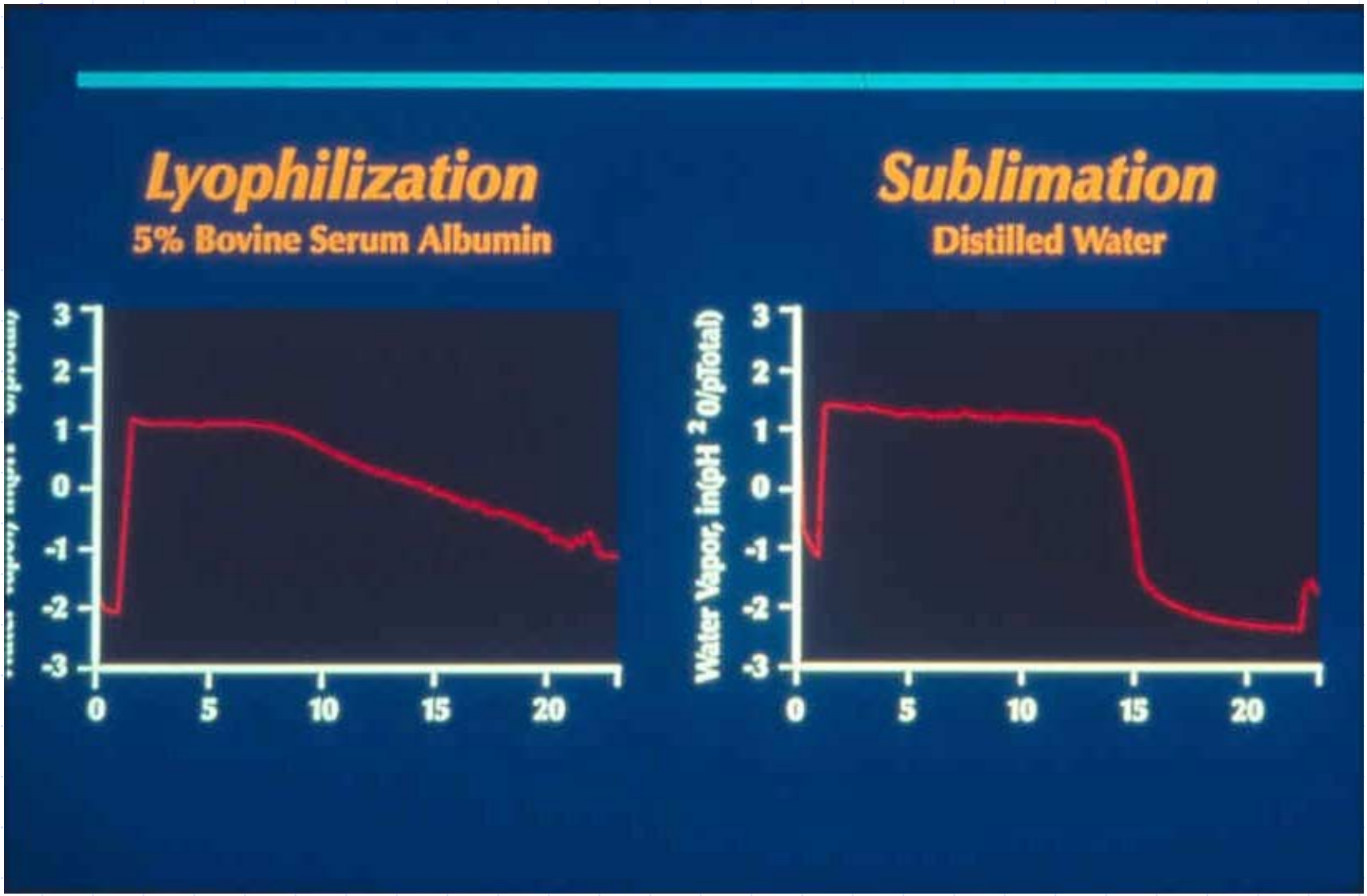
5% Bovine Serum Albumin



Sublimation

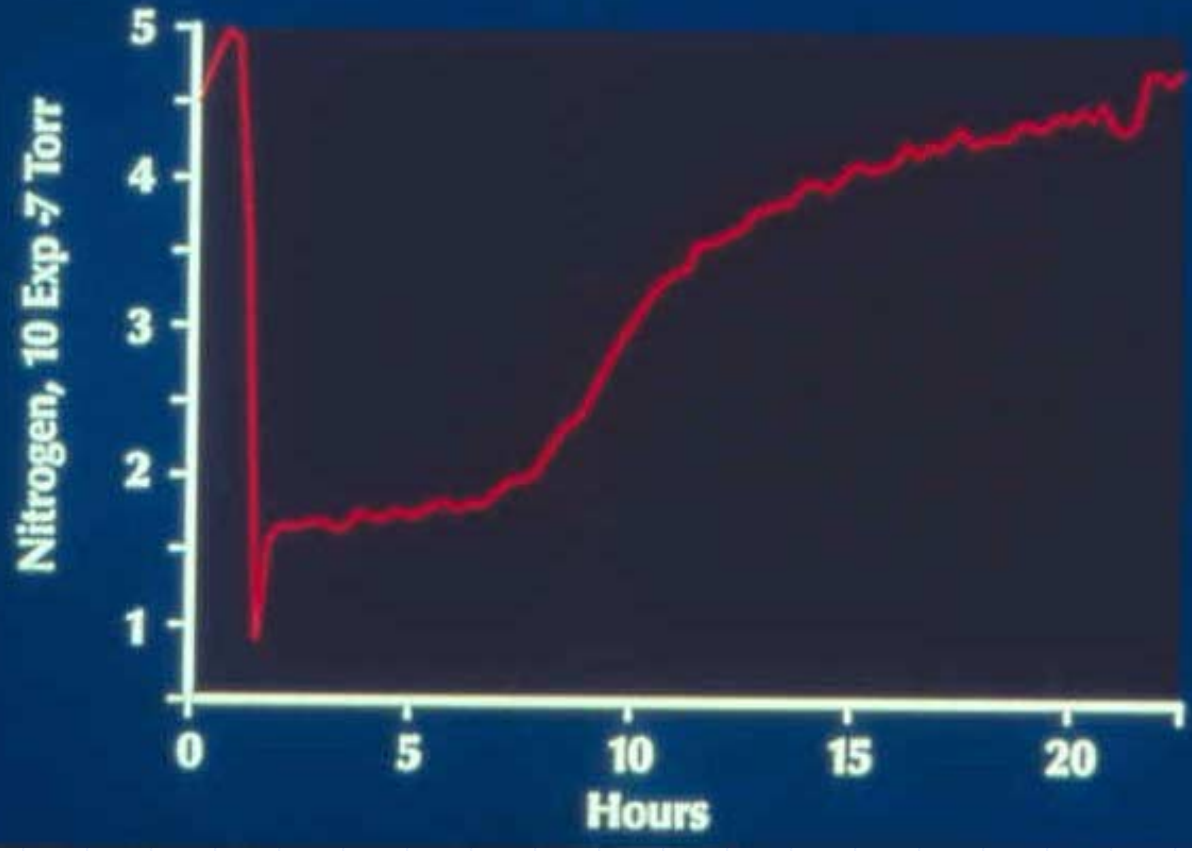
Distilled Water




Lyophilization
5% Bovine Serum Albumin
Sublimation
Distilled Water
Water Vapor, ln(pH 2 0/pTotal)
3
2
1
0
-1
-2
-3
0
5
10
15
20

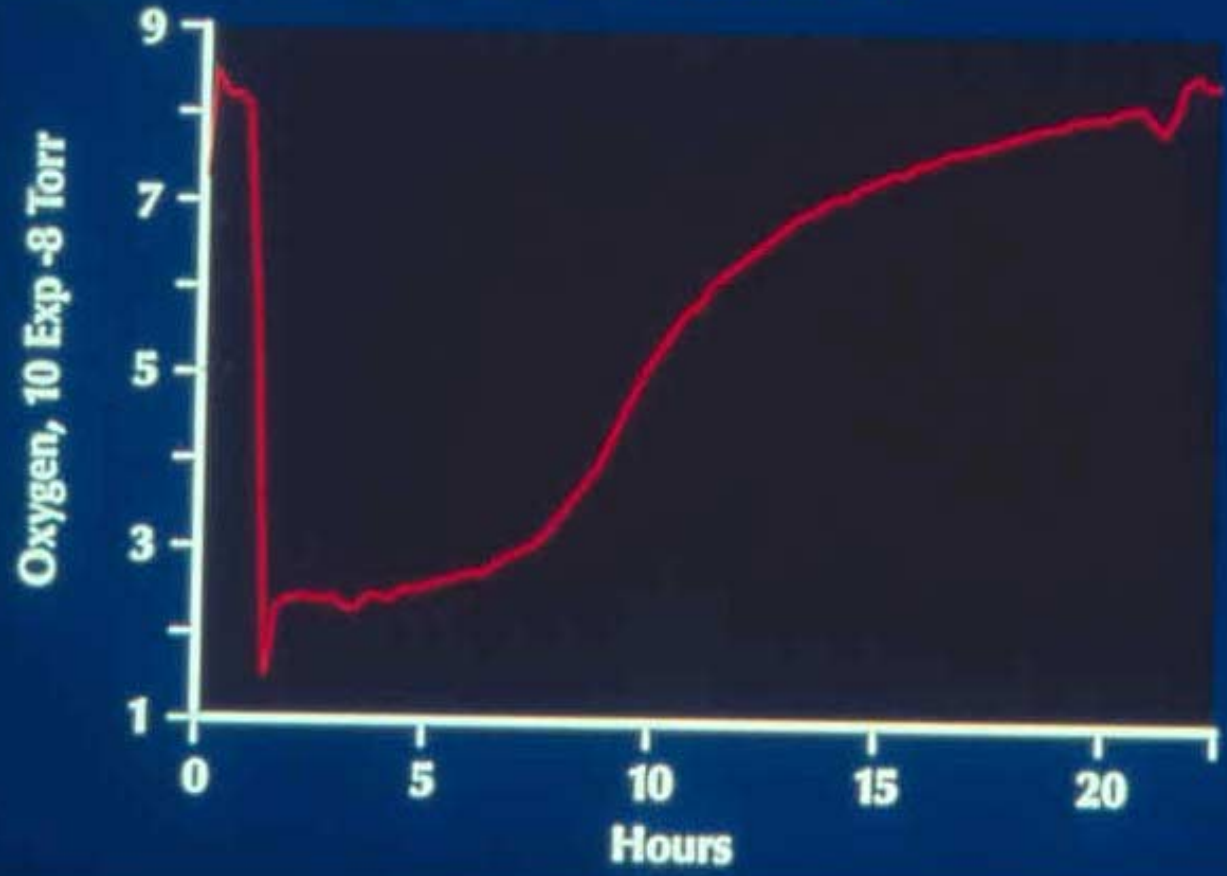
Lyophilization

5% Bovine Serum Albumin



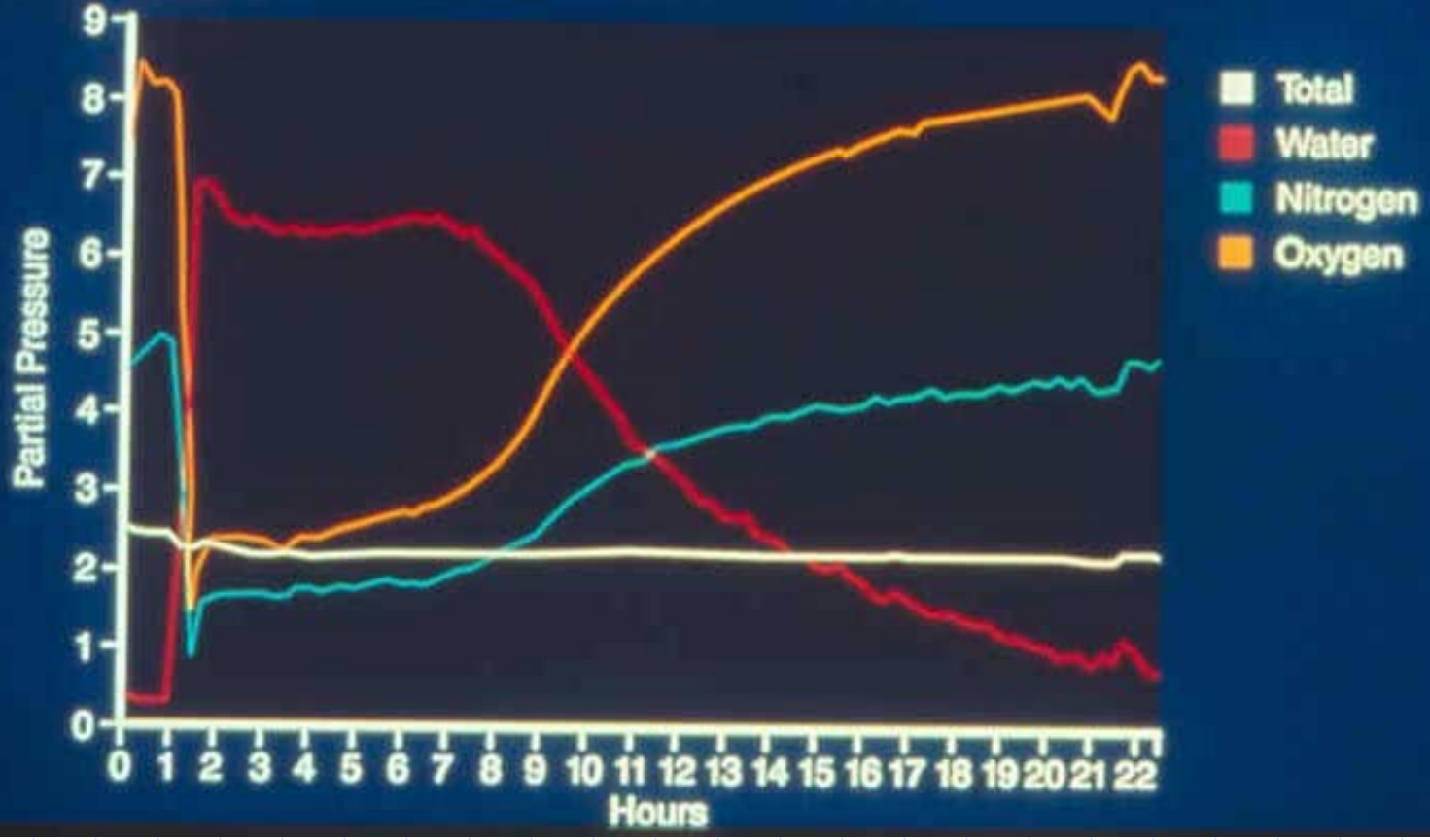
Lyophilization

5% Bovine Serum Albumin



Lyophilization

5% BSA



Leak Detection

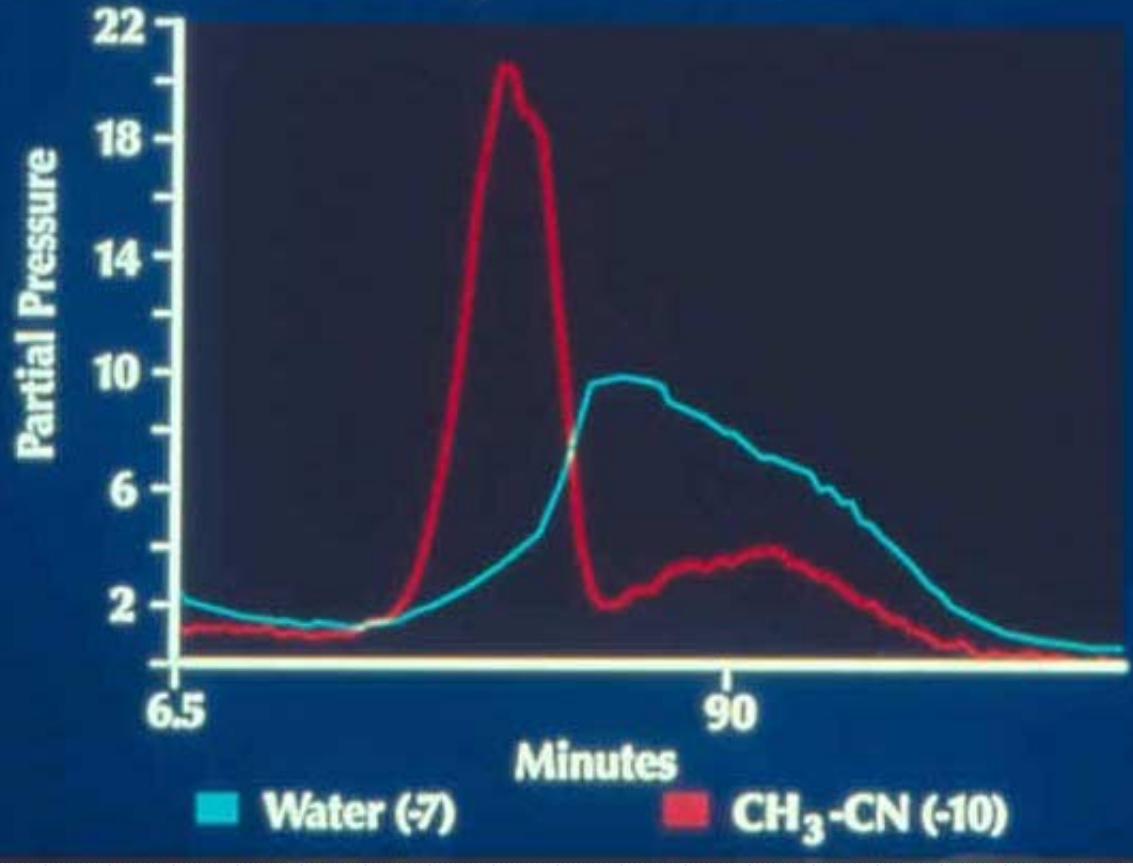
- Determine Real and Virtual leaks
- Helium and other tracer gas
- Process go / no go I/O.

Contamination Detection

- Heat Transfer (shelf and condenser)
- Oxygen and Nitrogen
- Cleaning solvents and Disinfectants
- HPLC Solvents
- Volatile Product Components

Lyophilization

5% BSA, 1% CH_3-CN, Aqueous



Summary

HPR-30 vacuum process analyser

Contamination Detection Insures Product Quality

Leak Detection

Keeps Freeze Dryer in Service

End Point Detection

Optimizes cycle – increases production