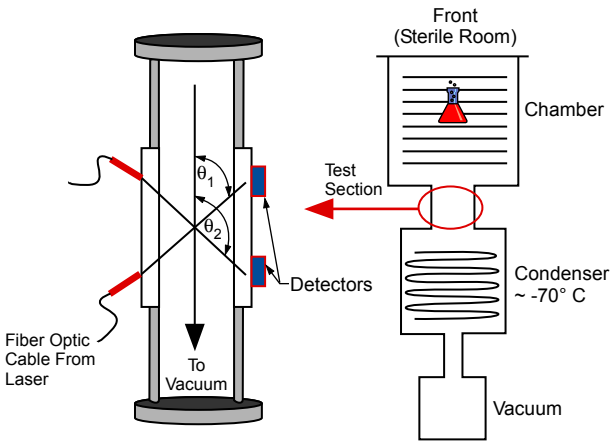
Physical Sciences Inc.

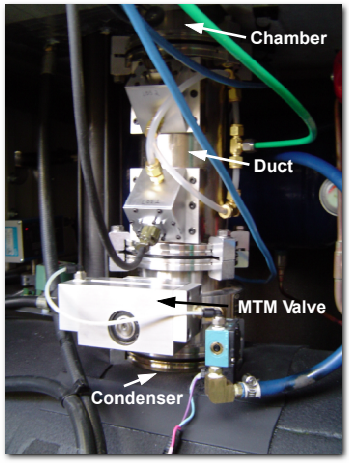
LyoFlux® – TDLAS Water Vapor Mass Flow Monitor

- Continuous, non-intrusive monitoring of lyophilization processes
- Applicable to lab, pilot and production dryers to monitor process scale-up

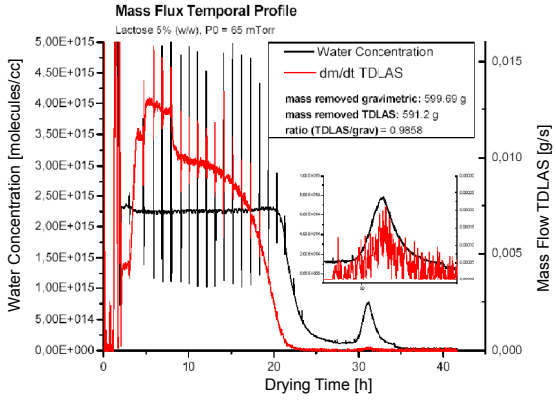
- Water vapor, [H_2O], flow velocity, (V) & water mass flow (dm/dt) measurements
- Continuous mass balance determination
- Determination of:
  - Primary & secondary drying endpoints
  - Average product temperature
  - Average product resistance
  - Vial heat transfer coefficients
  - Freeze dryer performance qualification

Tunable Diode Laser Absorption Spectroscopy Sensor Control Unit

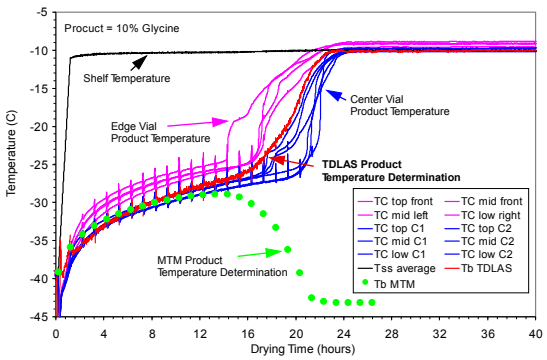




Freeze Dryer Measurement Interface



[H_2O] & Mass Flow Rate Measurements



Primary Drying Product Temperature Determination

Point of Contact: Bill Kessler, kessler@psicorp.com, t 978-738-8253

20 New England Business Center ♦ Andover, MA 01810-1077 ♦ t 978-689-0003 f 978-689-3232 ♦ www.psicorp.com

LyoFlux® – Specifications

A. Measurement Specifications

1. Detection method	: Near-IR Tunable Diode Laser Absorption Spectroscopy (TDLAS)
2. Measurement gas	: water vapor (H_2O)
3. Sample Gas (in spool)	: nitrogen (N_2) and water vapor (H_2O)
4. Sample Gas Pressure (in spool)	: <500 milliTorr
5. Measurement Gas Temperature	: -40°C - +40°C
6. Measurement Range (H_2O)	: ~3 - 500 mTorr
7. Measurement Range (velocity)	: ~1.5 - 300 meters/second
8. Mass Flow	: ~0.001 - 2.5 grams/second
9. Accuracy (3-shelf sublimation test)	: + 7% compared to gravimetric (average) (shelf temp: -10, -5, 0°C, chamber pressure: 65, 100, 200 mTorr)
10. Response Time	: < 60 seconds
11. Data Output	: [H_2O]: recorded in a comma
	: velocity: separated variable
	: mass flow: (CSV) data file

B. Measurement Spool Requirements

1. Four (4) optical access ports (2 lines-of-sight)
2. Mounting flanges for two (2) optical transmitters and two (2) receivers
3. Two (2) anti-reflection (AR) coated sight glass windows for the transmitter optical access ports
4. Flow valve downstream of the optical access for zero-flow measurement (typically included as a lyophilizer butterfly or mushroom isolation valve)
5. Wetted components: AR-coated BK7 glass, viton o-ring, 316 stainless steel

C. Sensor Inputs/Outputs

1. Optical output: FC/APC fiber optic bulkhead union (2)
2. Electrical I/O: 3-pin Lemo connector (detector bias/photocurrent) (2)
3. Nitrogen purge gas: SCU: ~ 1-2 SLPM, <10 PSIG, ¼“ compression fitting inlet: OMI: ~ 1-2 SLPM, <10 PSIG, ¼” compression fitting inlet (valves, tubing and flow meters for the purge gas must be provided by the customer; N_2 purge gas dewpoint <-60°C)

D. Software

1. LyoFlux 200A
2. TDLAS Sensor Control, Data Acquisition, Data Analysis, Display and Output
3. Graphical User Interface (GUI) Control
4. Automated System Startup
5. Automated system self check
6. Automated data acquisition and data processing
7. Continuous monitoring of a water vapor reference absorption cell located in the sensor control unit
    a. Diode laser wavelength reference
    b. System health monitor
8. Software electronic security
    a. Administrator access and control
    b. User sign-on required
    c. PSI system setup and diagnostic access

The LyoFlux sensor is a Class 1 laser device.

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