

LYOSENSING

Telstar In-line process analyzer



GET A GOOD LYOPHILIZED PRODUCT



Freeze drying is removal of water (or other solvents) from a product by freezing and a combination of sublimation and desorption.

Controlling the process is a challenge with the objective of keeping the product in perfect condition without external contamination. In addition there is the need to have concise knowledge of the whole process involved.

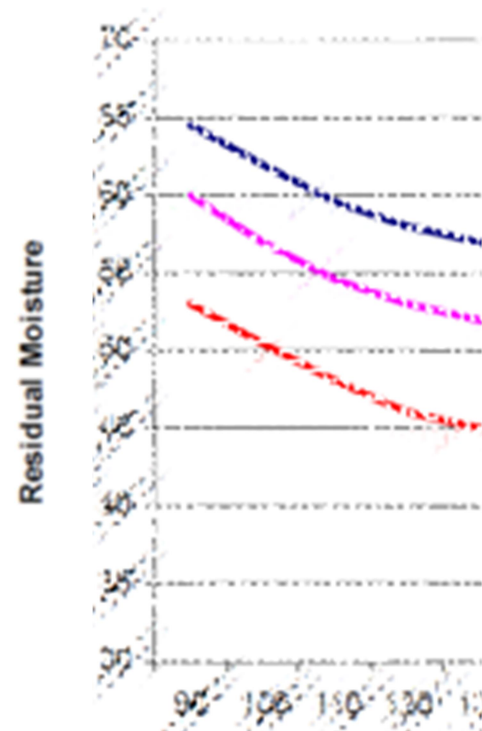
There are several ways to monitor the freeze-drying process: temperature of probes, pressure, and temperature of the condenser...

But there are still some needs:

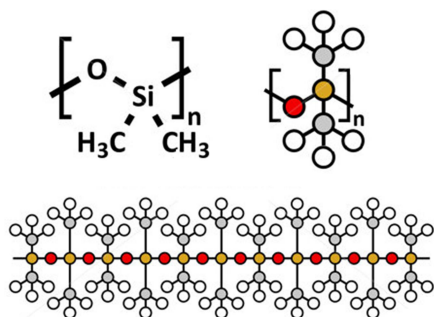
- to detect the end of primary and secondary drying monitoring.
- to improve process monitoring (PAT), as recommended by the FDA.
- to know the presence of external agents in the work environment.

Monitoring and control the agents (humidity, gases, silicon oil...) that are present during the cycle is a solution for those needs.

The instrument used to monitor these gases is the RGA (Residual Gas Analyser).



The majority amount of gas comes from the sublimation water. Nevertheless other gases are present from the controlled leak, real or virtual leaks, as well as backstreaming from the vacuum pumps...



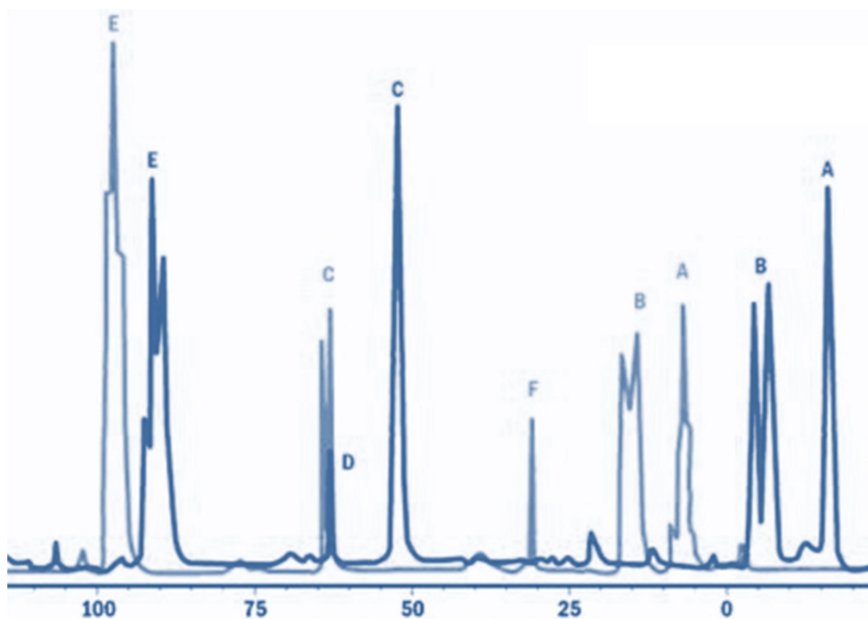
THE INSTRUMENT TO MEASURE THESE GASES

Quadrupole Mass Spectrometer System

Mass range: 1-100 (100 AMU)

Typical detection limit: 0.5 ppm

Implemented as stand-alone or integrated on SCADA using the MV2 ASCII protocol



What is a quadrupole mass spectrometer?

An instrument that measures the gas composition in a chamber based on the formation of ions and detection of their mass to charge ratio.

A small fraction of the gas molecules are ionized (+ ions), and the resulting ions are separated, detected and measured according to their molecular masses.

USES OF AN RGA

- Determine the gas composition
- Process cycle monitoring

Monitoring a process

End-point detection
(chamber? clean)

Indicating if the process
is out of specification

Analysis of process
gases

- Leak detection & identification of leak source - real & virtual

Leaks in welds, flanges, valves,
etc.

Elastomer outgassing

Water desorption

Detection of other contaminants

DRYING POINTS ANALYSIS AND END POINT VERIFICATION

Process endpoints are typically determined by pressure and temperature readings.

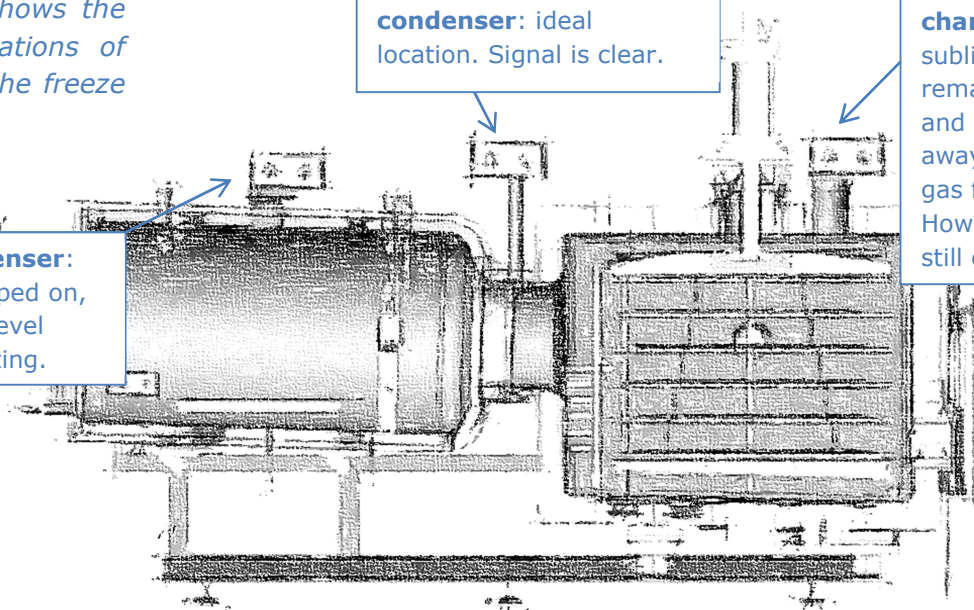
The RGA is providing more accurate data about the drying endpoint by monitoring the water concentration.

The figure shows the different locations of the RGA in the freeze dryer

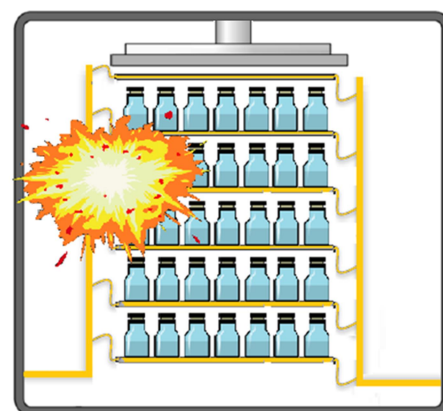
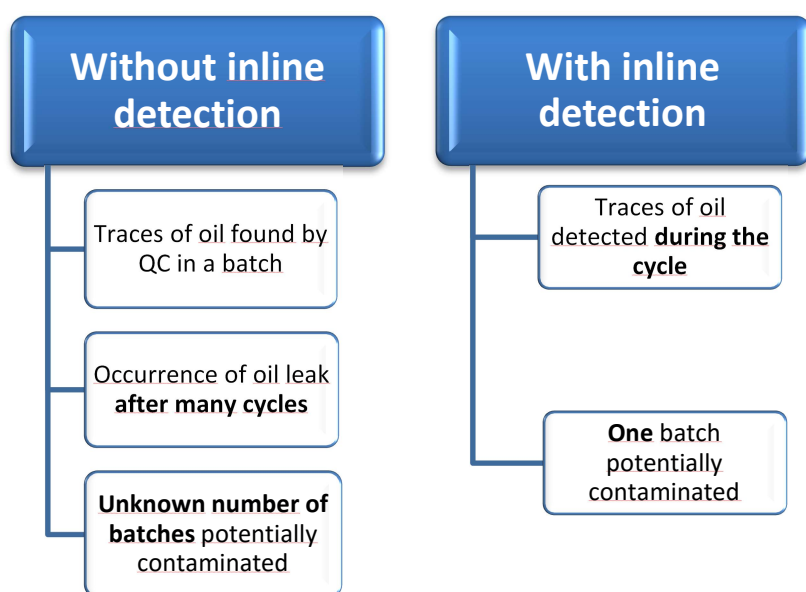
On the condenser:
vapour is trapped on,
constant low level
signal is resulting.

Between chamber and condenser: ideal location. Signal is clear.

On the chamber:
sublimated vapor remains on walls and is not swept away by the main gas flow.
However signal is still clear.

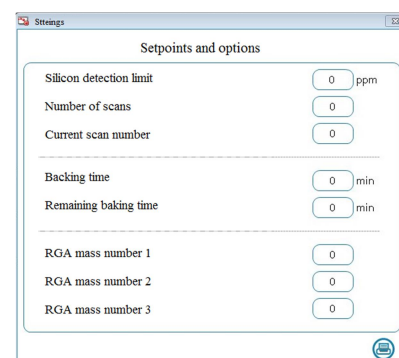
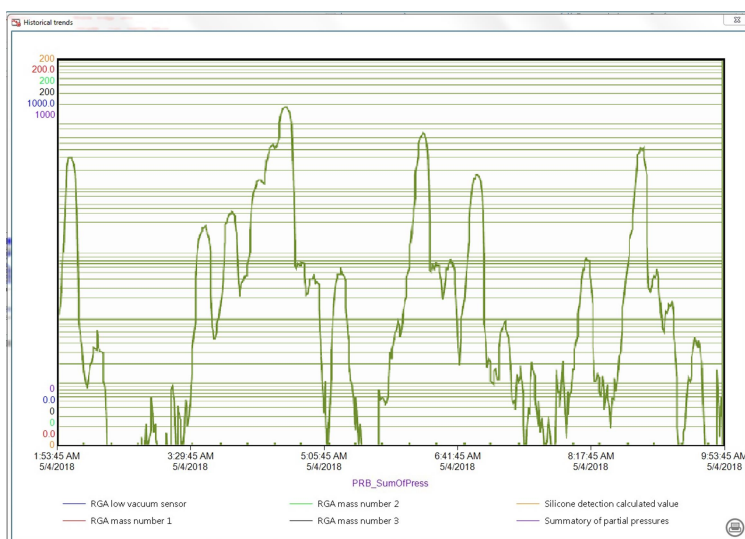
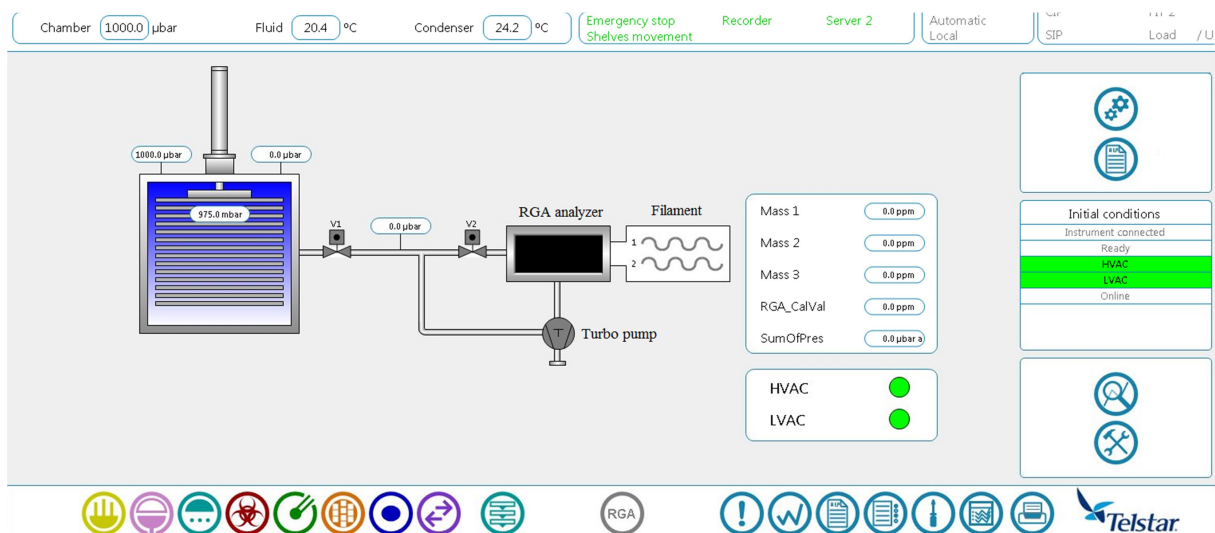
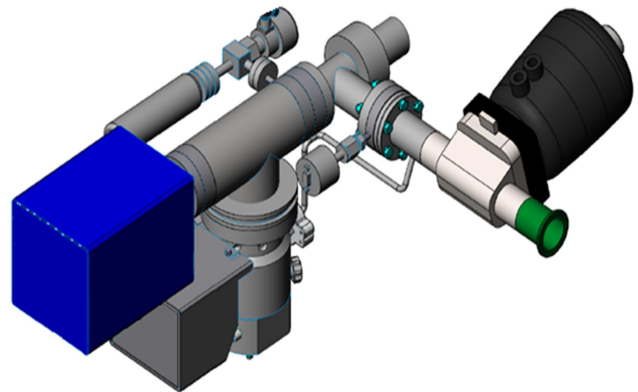


SILICON OIL DETECTION in case of LEAKAGE



TELSTAR LYOSENSING BENEFITS AND VERSATILITY

- Robust and efficient
- Ease of user interaction
- Independent of the freeze dryer layout
- Stand-alone or integrated on SCADA
- Easily upgradeable to existing units
- Available to all freeze dryer sizes from 1m²



Figures shows screens of Telstar SCADA with RGA integrated on the freeze dryer.

OEM PMS INTEGRATION

Full integration into the equipment control system (PMS/SCADA) including:

- Fail-safe operation
- Calibration against on-board references
- Validation and verification with an embedded sensor on the control system

Telstar offers its customers more than 50 years' experience in the development of Freeze Dryers equipment and processes.

Training and recipe development

Introduction which will include basic lyophilisation, end of primary drying and leak detection concepts.

Determine recipe parameters for the customer's product

Sensitive monitoring of the water concentration for optimizing the process and verification of the endpoint

Reliable identification of critical silicon oil contaminations during the primary and secondary phase and after the drying process

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Telstar reserves the right to improvements and specifications changes without notice.

