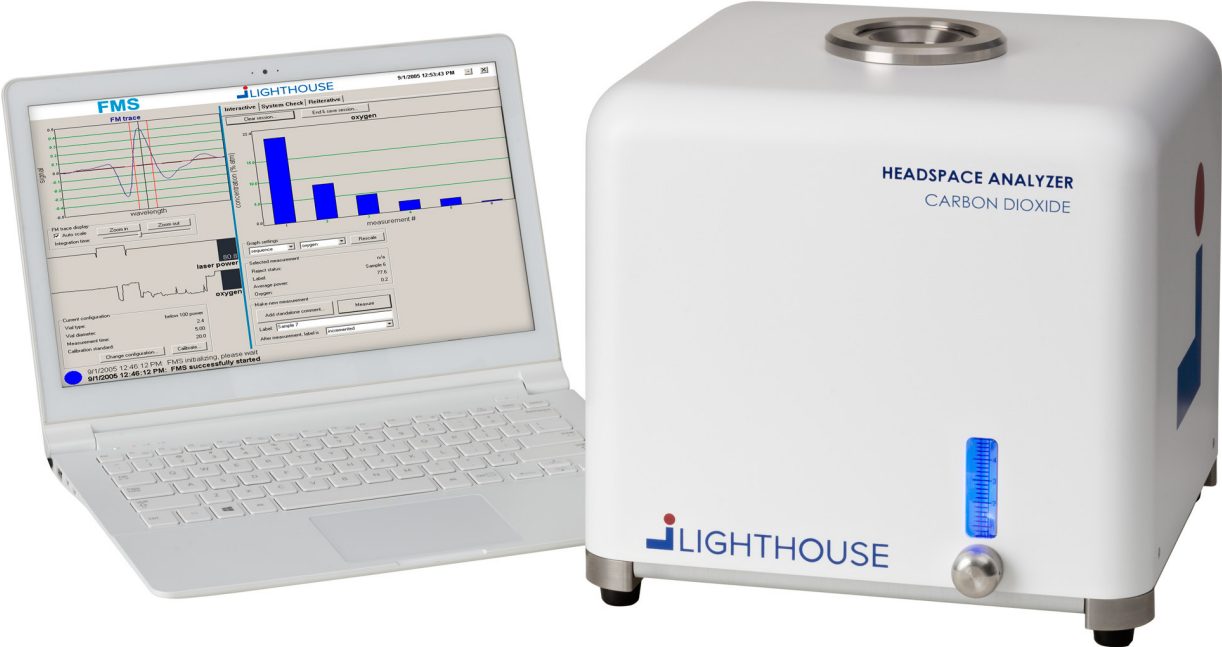


PRODUCT NOTE

FMS Software Package ●



FMS DATA INTEGRITY AND COMPLIANCE

With applications spanning sterile product development, quality control, and manufacturing, the FMS series of Headspace Analyzers must meet the current regulatory requirements on data integrity. The FMS software package includes a GxP mode to support the collection of compliant analytical data. A GxP measurement method guides the user through a sequence of steps to calibrate and verify the FMS analyzer before analysis can begin. All raw data and metadata collected during the session are stored according to the method parameters — in a printed report, as an electronic file, or in a secure database. The FMS software package enables full compliance with data integrity regulations while limiting the need for procedural controls.

FMS SOFTWARE FEATURES

All FMS analyzers are provided with the basic software package, which includes the following operating modes:

- Open offers flexibility when performing measurements that do not require strict compliance
- GxP Print uses predefined methods to collect compliant data in a printed record
- GxP File uses predefined methods to collect compliant data in an electronic data file

The addition of the GxP Database package introduces a fourth operating mode to the FMS software package, bringing enhanced compliance features and centralized data management to the FMS system. Data collected with the GxP Database software is stored in a secure database and accessed from any networked computer through the included FMS Database Viewer software, which incorporates new tools to filter, review, approve, print or export data from a single user interface.

The GxP Database package is available as a software add-on for new or existing FMS systems and includes the following additional features:

- Password-protected software access with multi-tiered user privileges
- Data stored in the secure database can not be modified or deleted
- Results logged to the database at the time of measurement
- Stand-alone database viewer provides access to raw data and batch reports
- Searchable database allows for easy retrieval of measurement data or user events
- Electronic signatures for review & approval
- Complete system audit trail with time & date stamp and user attribution

A comparison of the complete set of features for each software mode is presented in the table on the next page.

● *natively supported* ○ *requires external controls and/or policies*

FEATURES DESCRIPTION	FMS OPEN	FMS GxP PRINT	FMS GxP FILE	FMS GxP DATABASE
Password-protected user access		○	○	●
Support for Windows Active Directory				●
Multi-tiered access to functions based on user group				●
User-generated measurement method definitions		●	●	●
User-defined pass/fail configuration	●	●	●	●
Enforced sequence of calibration and verification		●	●	●
Minimal operator training required	●	●	●	●
Measurements presented in human-readable form	●	●	●	●
Data stored as electronic record	●		●	●
Data stored at the time of measurement		●		●
Time/date stamp of measurements and events	●	●	●	●
Data cannot be overwritten	●	●	●	●
Restricted data storage location			●	●
Data protected from modification		○	○	●
Secure data viewer software				●
Data accessible on local network	●		●	●
Electronic signatures for review & approval				●
Searchable database of measurement sessions				●
Export data to Excel	●		●	●
Export data to PDF				●
Audit trail of measurement activity		●	●	●
Audit trail of all system activity				●
Full validation package available	●	●	●	●

Please contact us or visit our website for more information: www.lighthouseinstruments.com

Corporate Headquarters

Lighthouse Instruments, LLC
2020 Avon Court, Suite #2
Charlottesville, VA 22902
Telephone: +1 (434) 293-3081
E-mail: info@lighthouseinstruments.com

European Support Center

Lighthouse Instruments B.V.
Science Park 408
1098 XH Amsterdam, The Netherlands
Telephone: +31 20 7051 050
E-mail: euinfo@lighthouseinstruments.com