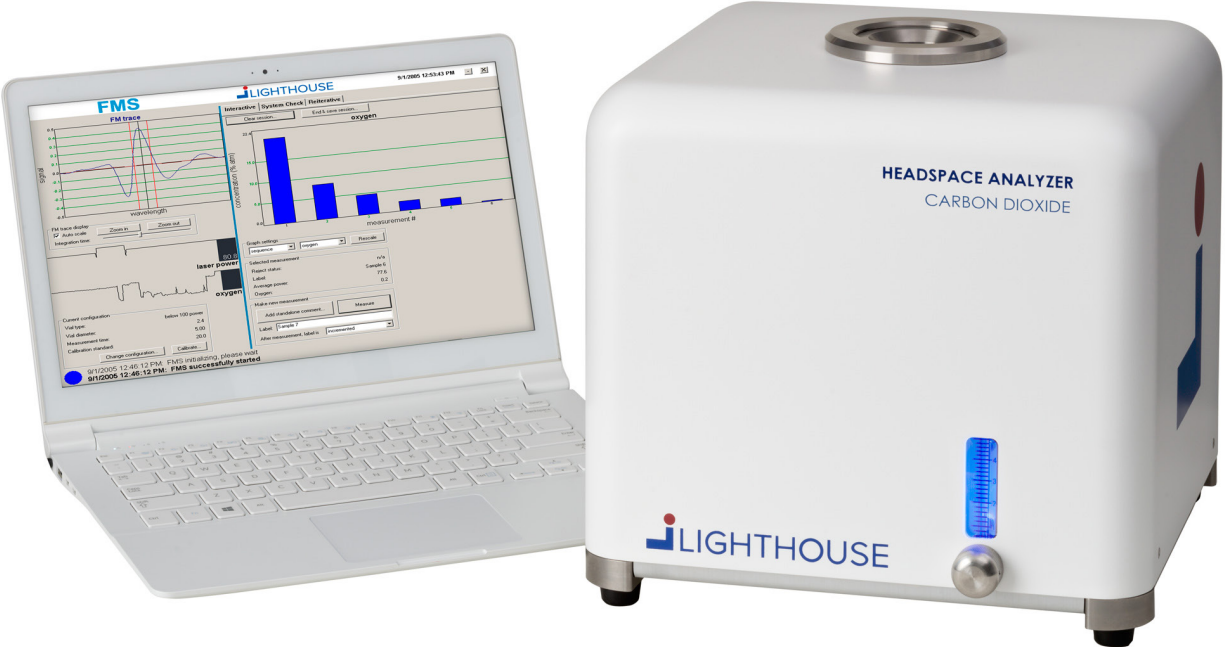


PRODUCT NOTE

FMS GxP Database Software ●



PRODUCT DESCRIPTION

The FMS GxP Database software package brings enhanced compliance features and centralized data management to the FMS family of nondestructive headspace analyzers. Data collected with the FMS 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. With password-protected user access and a full audit trail, the FMS GxP Database software represents a comprehensive solution to address the current data integrity concerns of the industry.

MAIN 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
- Includes a complete system audit trail with time & date stamp and user attribution.
- Compliant with Title 21 CFR Part 11

All FMS analyzers are provided with the basic software package, which includes the following software modes: FMS Open, FMS GxP Print, and FMS GxP File. The FMS GxP Database software package is available as a software add-on for new or existing FMS systems when additional data management features are required. 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