

Measurement & Analytics | Measurement made easy

# MB3600-PH

Versatile FT-NIR analyzer for the life sciences and pharmaceutical industries Designed for QA/QC, research and development and at-line PAT applications



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#### Perpetuating the heritage

Since 1997, ABB has supplied the life sciences and pharmaceutical industries with high performance analytical instruments that have an established reputation for performance and reliability. This heritage is now being continued with the MB3600-PH, a versatile Fourier transform near-infrared (FT-NIR) benchtop analyzer that can be fitted with a variety of accessories for accurate measurements on a broad range of applications in the pharmaceutical and life science industries. It is the optimal solution for applications such as:

- Laboratory QA/QC analysis
- Raw material identification and qualification
- Research and development
- NIR method development
- At-line PAT measurements

The MB3600-PH is virtually maintenance-free and features a user friendly software interface that enables operations in a 21 CFR Part 11-compliant mode. The MB3600-PH represents the ultimate combination of performance, reliability and ease of use.

#### Reliability by design

The MB3600-PH is built with dependable components integrated in a system requiring minimal moving parts. While the exceptional stability of the wishbone principle with corner cube mirrors ensures reproducible data, the interferometer design has been further refined with the introduction of an innovative double-pivot concept derived from our aerospace technology, offering outstanding robustness. To illustrate this, the materials of the interferometer flex pivots are designed for several decades of continuous use. In addition, the permanently aligned optics do not require dynamic alignment and the interferometer comes

with a lifetime warranty. The MB3600-PH aluminum casting provides the level of protection needed for intensive use of an analytical instrument in an industrial environment. Each user can be confident that the MB3600-PH will provide consistent analytical results for years to come.

#### Ease of use, a must for modern analytical instrumentation

The sampling compartment of the MB3600-PH is designed to accommodate a variety of accessories to address all the needs of a modern analytical laboratory and minimize the number of movable mechanical elements. The MB3600-PH software package Horizon/MB3600 offers a very simple and robust interface for data acquisition and routine analysis. In addition, a complete set of cGMP IQ-OQ protocols and templates is included in the package. With the MB3600-PH, the implementation of NIR instrumentation in a regulated environment has never been easier.

#### An exceptionally low cost of ownership

While the MB3600-PH novel vertical design provides a minimal footprint, it is also the FT-NIR analyzer with the lowest cost of ownership. Our engineers have designed the modular components of the MB3600-PH to provide the longest product life on the market according to the following key principles:

- No maintenance
- No adjustments
- No wear of the scan mechanism

As a result, the pre-aligned source module with electronic stabilization is designed to operate for 10 years without replacement, and the new solid state laser-based metrology module has a 20 year lifespan. All MB3600-PH optics are non-hygroscopic so that no instrument purging is necessary for optical protection.

## MB3600-PH: features

#### The best performance on the market

A brand new interferometer design is at the core of the MB3600-PH. This new design is extremely modular and compact and is combined with a unique patented 24-bit sampling algorithm for optimal dynamic range. The MB3600-PH has a single output port for optical efficiency maximization. As a result, it offers an outstanding spectroscopic performance characterized by a signal-to-noise ratio that is simply the best on the market: > 100,000:1 root-meansquare at peak response (16 cm<sup>-1</sup> resolution, 60 s acquisition) for the DTGS detector, > 600,000:1 for the InGaAs detector. The permanently aligned optics with a Jacquinot stop in the interferometer output beam ensure an accurate and stable line shape as well as wavelength and resolution stability. The 100% line spectral repeatability permits reliable determination of small spectral features down to below 10 micro-absorbance with the DTGS detector and 2 micro-absorbance with the InGaAs detector. The MB3600-PH is provided with a highly accurate internal wavelength calibration standard and exhibits an outstanding frequency accuracy (< 0.06 cm<sup>-1</sup>).

Overall, the level of quality of the MB3600-PH for the key analytical figures of merit enable ABB application specialists to provide stringent guarantees of performance for transfer of calibrations, not only to another MB3600-PH, but also to other ABB FT-NIR analyzers (laboratory or process). The instrument delivers consistent, precise and reproducible results year after year, from unit to unit. Because we know that in a highly regulated environment, reproducible spectroscopy is the key.



## MB3600-PH: features

#### A flexible and complete line of accessories

The MB3600-PH is a versatile analyzer that can be fitted with a variety of easily accessories that do not require alignment to accommodate all kinds of samples. Among others, the MB3600-PH can accommodate the following accessories:

- Universal heatable vial holder with electronic recognition via USB port (analysis of liquids and waxes in disposable vials with 5 mm, 8 mm and 12 mm outer diameter)
- Rotating diffuse reflectance accessory with electronic recognition via USB port and large sample area for scintillation vials (granulates, powder formulations, lyophilisates)
- Transflectance cup (creams, gels)
- Hand-held "pen" probe (powders)
- Fiber-optic launcher with electronic recognition via USB port to interface with flow-though cells (liquids), transmission probes (liquids), transflectance probes (opaque liquids) or diffuse reflectance probes (powders, lyophilisates)
- Fiber-optic coupled disposable temperature controlled vial (liquids)
- Temperature controlled transmission cell (liquids).

The MB3600-PH analyzer can be used as a benchtop instrument (QA/QC or research laboratory) but also as a mobile unit on a stainless steel movable cart - with an uninterrupted power supply option for applications in the warehouse or dispensary (raw material identification





# Implementation made easy





#### Intuitive and modern software interface Horizon

The MB3600-PH is equipped with the Horizon Suite software package that provides complete flexibility for development and execution of methods in total compliance with regulatory guidelines. It also includes complete validation and regulatory compliance documentation

#### Horizon MB FT-IR

#### Intuitive software for daily operations.

The Horizon MB FT-IR module facilitates the acquisition, processing and analysis of samples. With Horizon MB FT-IR, managing analytical results has never been easier.

#### **Horizon MB Security**

#### Enabling 21 CFR Part 11 compliance.

The Horizon MB Security module offers 2 selectable security setting levels ("Computer" or "Windows"). It provides distinctive access control to software functions based on permission schemes, hierarchical access control based on data access roles, electronic signatures, activity logging and traceability of all data manipulations.

#### Horizon MB Quantify

#### The modern chemometrics toolbox.

The Horizon MB Quantify module incorporates univariate and multivariate algorithms for data analysis and quantification. It also incorporates enhanced mathematical functions, 3-D capabilities, extended import/export functions and enables automated execution and reporting of the instrument verification tests described in pharmacopoeia guidelines.

#### Horizon QA

#### The modern software for routine analysis and QA/QC

The Horizon QA module makes running QA/QC and routine applications simple and reliable for laboratory staff by providing intuitive workflow along with integrated spectrometer and accessory control. The software guides the user in every step from collecting reference data to designing QA/QC applications and implementing turnkey methods. Horizon QA also enables plant connectivity by automatically generating a tab-separated file with detailed results and parameter information for each sample analysis performed with a procedure. This can file can then be imported by a LIMS system.

# MB3600-PH technical specifications

#### Spectroscopic performance (typical at 25 °C)

- Spectral range:
- 3,700 to 15,000 cm<sup>-1</sup> with DTGS detector
- 3,900 to 11,000 cm<sup>-1</sup> with extended-InGaAs detector
- Resolution better than 0.7 cm<sup>-1</sup>
- Apodized resolution adjustable 1 cm<sup>-1</sup> to 64 cm<sup>-1</sup>, in increments of 2
- Root-mean-square signal-to-noise ratio (60 s, 16 cm<sup>-1</sup>, at peak response):
  - -> 100,000:1 with DTGS detector
  - -> 600,000:1 with extended-InGaAs detector
- Signal sampling: 24-bit ADC
- Short-term stability (@ 8000 cm<sup>-1</sup>): < 0.09 %
- Temperature stability (@ 8000 cm<sup>-1</sup>): < 1 % per °C
- Frequency repeatability (@ 7300 cm<sup>-1</sup>): < 0.006 cm<sup>-1</sup>
- Frequency accuracy (@ 7300 cm<sup>-1</sup>): < 0.06 cm<sup>-1</sup>
- Absorbance reproducibility (measured on spectroscopic grade toluene): < 0.002 AU</li>

#### Application software (computer not included)

- Horizon MB FTIR: basic instrument operations and validation
- Horizon MB Quantify: chemometrics, calibration development, regulatory qualification
- Horizon MB Security: configurable settings for securized access control, electronic records protection and traceability
- Horizon QA: Intuitive operator interface for routine analysis and QA/QC operations

#### Optical

- Beamsplitter material: ZnSe (non-hygroscopic)
- Patented double pivot high throughput Michelson interferometer, fully jacketed
- Optical path fully purgeable
- Source: quartz halogen with electronic stabilization (10 year expected lifespan)
- Metrology: solid-state laser (no scheduled maintenance required)
- Detector module: DTGS
- Optional extended-InGaAs detector module with integrated cooling
- Open sample compartment configuration: Arid-Zone, centerfocus
- Sample compartment dimensions: 20 cm x 14 cm plate,8.7 cm beam height
- Sample compartment mounting: 3-point positioning guide or3-point kinematic adjustable

#### **Data communication**

- Hardware port: Ethernet, 10/100 Mbps

#### Instrument enclosure

- Casting: rugged all-metal with integral handlesSize: 43.5 cm (W) x 28.0 cm (D) x 37.2 cm (H)
- Weight: 24 kg Instrument enclosure

#### Environmental

- Universal power supply: 120-240 VAC, 50/60 Hz
- Power consumption: 65 W
- Operating temperature: 10 °C to 35 °C
- Operating relative humidity: 5 % to 80 %, non-condensing
- Regulatory certification and compliance: TÜV and CE

#### **Documentation**

CD-ROM with user manual and complete validation documentation addressing Design Qualification, Installation Qualification, Operational Qualification and regulatory compliance with pharmacopoeia guidelines, 21 CFR Part 11 requirements and ISO standards.

# ABB Analytical

ABB Analytical is one of the major ABB manufacturing centers for laboratory and process analytical systems with more than 35 years of experience in developing FT-IR and FT-NIR spectrometers for industrial, military and space applications.

As part of our portfolio of products and services for process optimization, we are able to offer a full range of custom calibration modeling services and application support for industrial applications.

ABB also provides extensive, globally distributed after-sales support and engineering services, as well as a full customer training program.

#### IR & NIR Spectroscopy **Knowledge Management**

- Application support and spectroscopy training
- Calibration and chemometrics development training
- On-site services including hardware and calibration maintenance

### **Up-Time Insurance Program**

- Preventive maintenance
- Extended warranty services
- Tailor-made service contracts
- Chemometrics services

#### Installations / Start-ups & Analyzer Life Cycle Program

- Process spectrometer start-ups
- Laboratory spectrometer installations
- Spectrometer and laboratory / process software exchanges / upgrades
- Extended process and lab spectrometer warrantees

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