



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.

# MB3600-PH FT-NIR Analyzer for the Life Sciences and Pharmaceutical Industries



## 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 AIRS/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-mean-square at peak response (16  $\text{cm}^{-1}$  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  $\text{cm}^{-1}$ ).

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.

## 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 (analysis of liquids and waxes in disposable vials with 5 mm, 8 mm and 12 mm outer diameter)
- Rotating diffuse reflectance accessory with large sample area for scintillation vials (granulates, powder formulations, lyophilisates)
- Transflectance cup (creams, gels)
- Hand-held "pen" probe (powders)
- Fiber-optic launcher to interface with flow-through 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 and qualification) and for at-line PAT applications.

# Implementation made easy

## Simple and rugged software interface

The MB3600-PH is equipped with the PLSPlus/IQ chemometrics package for univariate and multivariate calibration model development. It also includes the AIRS/MB3600 analytical software, a rugged platform for instrument qualification, routine data acquisition and analysis. It offers password-protected multi-level access and two user modes:

- Development mode (unprotected, for method development or non-GMP operations)
- Operation mode (password protection, method and result encryption, audit log for regulated activities)

Performance Qualification tests for different instrument configurations are pre-loaded and can be run at any time by operators as required by major pharmacopoeia guidelines. The AIRS/MB3600 software supports methods and procedures developed on previous generations of ABB FT-NIR instruments (MB160 series, FTLA2000 series), which ensures a smooth transition for customers who wish to upgrade their instrumentation while minimizing the development effort.



## Documentation and services for regulatory compliance

The MB3600-PH is supplied with a full set of IQ-OQ documents and a CD with software validation records and user manuals. Installation and on-site instrument qualification are performed by factory qualified specialists for installations in regulated environments. In addition, ABB's international team of application specialists can provide a wide range of services to assist customers with the implementation of the MB3600-PH:

- Custom calibration development
- Training for raw material qualification procedures and model development
- On-site application support
- Remote application support
- Calibration maintenance
- Spectroscopy training

ABB also provides extensive, globally-distributed after-sales support and engineering services:

- Preventive maintenance
- Extended warranty services
- Tailor-made service contracts
- Process analyzer start-ups
- Laboratory analyzer installations
- Analyzer & software exchanges / upgrades



# MB3600-PH Technical Specifications

## Spectroscopic performance (typical at 25 °C)

- Spectral range:
  - 3,700 to 15,000  $\text{cm}^{-1}$  with DTGS detector
  - 3,900 to 11,000  $\text{cm}^{-1}$  with extended-InGaAs detector
- Resolution better than 0.7  $\text{cm}^{-1}$
- Apodized resolution adjustable 1  $\text{cm}^{-1}$  to 64  $\text{cm}^{-1}$ , in increments of 2
- Root-mean-square signal-to-noise ratio (60 s, 16  $\text{cm}^{-1}$ , 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  $\text{cm}^{-1}$ ): < 0.09 %
- Temperature stability (@ 8000  $\text{cm}^{-1}$ ): < 1 % per °C
- Frequency repeatability (@ 7300  $\text{cm}^{-1}$ ): < 0.006  $\text{cm}^{-1}$
- Frequency accuracy (@ 7300  $\text{cm}^{-1}$ ): < 0.06  $\text{cm}^{-1}$
- Absorbance reproducibility (measured on spectroscopic grade toluene): < 0.002 AU

## Application software (computer not included)

- Operating system compatibility: Windows XP Professional
- Standard software:
  - Grams/AI: instrument control and data acquisition
  - PLSPlus/IQ: chemometrics modeling
  - AIRS3/MB3600: operator interface for routine analysis

## 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, center focus
- Sample compartment dimensions: 20 cm x 14 cm plate, 8.7 cm beam height
- Sample compartment mounting: 3-point positioning guide or 3-point kinematic adjustable

## Data communication

- Hardware port: Ethernet, 10/100 Mbps

## Instrument enclosure

- Casting: rugged all-metal with integral handles
- Size: 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

- cGMP IQ-OQ protocol templates
- User manual
- Quick-start guide
- CD-ROM with software validation records

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 warranties

## Contact us

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