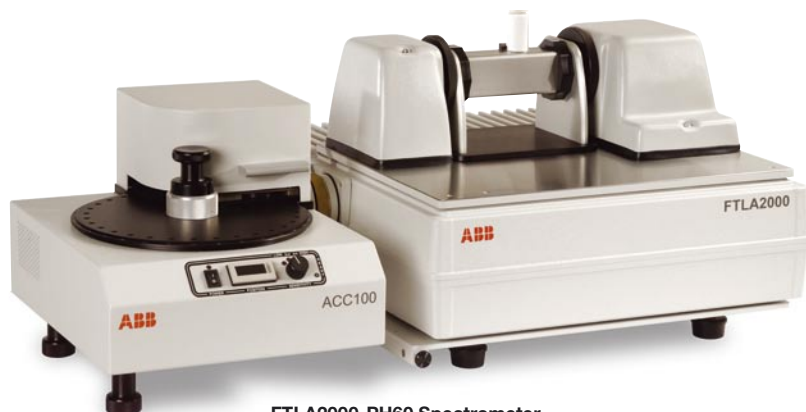


Tablet Samplir



FTLA2000-PH60 Spectrometer

Performance

- Spectral range: 3800 to 12000 cm^{-1}
- Wavenumber reproducibility: 0.04 cm^{-1} at 7300 cm^{-1} ($\pm 2\sigma$)
- Wavenumber repeatability $\pm 0.002 \text{ cm}^{-1}$ ($\pm 2\sigma$)
- Calibration transferability test: All NIR models will reproduce the absorbance spectrum of toluene (4100-6000 cm^{-1}) in a 0.5 mm cell at $28^\circ\text{C} \pm 1^\circ$ to within 0.002 A when compared with any other NIR unit.
- Near IR RMS-noise absorbance at peak response is typically 4 micro-A for 1 min scan time, 16 cm^{-1} resolution, open beam.
- 100% line reproducibility is within 0.1% in the 8000 to 4500 cm^{-1} range for NIR models, for 2 consecutive measurements.
- 100% line long-term stability is affected only by temperature change. Temperature coefficient of change in 100% line is 1% / 1°C at 8000 cm^{-1} .
- Resolution selectable from 2 cm^{-1} (NIR mode) to 64 cm^{-1} (apodized resolution) in steps of 2x.
- Arid-Zone main sample compartment with "Open-architecture" provides free space for accessories.
- Overall dimensions (WDH): 20 in. x 22 1/4 in. x 12 in. (50.8 cm x 56.5 cm x 30.4 cm)
- Weight: 96 lb. (44 kg)

Interferometer

- Four port optical design. Eliminates retro-modulation induced artifacts. Patented Michelson-type interferometer with 2-cube corner retro-reflectors mounted on a "wishbone" swing arm.

- Factory pre-aligned interferometer and input/output optics; does not require adjustment by user.
- Scanning is performed by rotating the swing arm on a flex pivot bearing, driven by an induction motor. This provides smooth, constant-velocity, perturbation-free scanning. The scanning mechanism has a lifetime warranty against breakage and wear-out. Swing arm is balanced to permit operation in any orientation.
- Self-compensating, single-plate beam-splitter/compensator.
- He-Ne reference laser for digital sampling, mirror velocity control, quadrature detection of scan direction, and fringe counting for path difference determination.
- Diagonal mirror with flipper mechanism to switch to side port beam.

Accessories

ACC100 Whole tablet NIR transmission accessory for content uniformity analysis

- Universal 30 tablet removable carousel for spherical-shaped samples
- Universal 30 tablet removable carousel for cylindrical-shaped samples (capsules, etc.)
- Custom carousels for samples with special shapes can be ordered optionally.
- Automated analysis and reporting for up to 30 tablets. Sampling position controlled through software.
- Fixed Spectralon transmission reference disk
- Side port connection
- InGaAs 1.9 μm TE-Cooled detector
- Must be mounted on an FTLA200-160 series spectrometer
- Dimensions (WDH): 12 in. x 14 in. x 8 3/4 in. (31 cm x 35 cm x 22 cm)
- Weight: 29 lb. (13 kg)

ACC101 Powder Samplir diffuse reflectance accessory for solids and powders analysis

- Universal 30 tablet removable carousel for

Computer

- Uses standard 20 ml scintillation glass vials (quantity of 100 supplied with the accessory)

- Sampling area: 60 mm²
- Supplied with removable rotating mechanism to rotate standard 20 ml vials at 5 RPM (110-240 VAC, 50-60 Hz)
- PTFE sample in 20 ml vial supplied for reference
- InAs TE-Cooled detector
- Other sample presentations can be used: bottles, Petri dishes, PE bags, etc.

Computer

- Pre-loaded Pentium 4 desktop Computer
- Two Ethernet interfaces
- Windows 2000 Service Pack 4 or Windows XP Service Pack 1
- 256 MB RAM minimum
- 20 GB Hard Drive minimum
- CD-ROM 48X, 15" flat panel monitor or better
- Consult factory for updated specifications

Software

- GRAMS-AI7 version 7.00 data acquisition and spectroscopic package
- PLSPlus/IQ version 5.10 chemometrics package
- AIRS version 3.12 QA/QC data acquisition and reporting package

The software package includes functions that facilitate the use of the system in a 21 CFR Part 11 compliant environment. Complete software validation documentation is available as an option.

Options

- Accessories for temperature-controlled liquids analysis
- Validation standards
- Installation
- Modeling and Application support
- Documentation
- Preventive maintenance contracts

Operating environment

- AC input: 120 or 240 V manually selectable
- Power consumption: 150 W
- Ambient temperature: -15° to 50°C non-operating, 5° to 30°C operating stable within ±5°C

- Relative humidity (operating): 0% to 95% non-condensing.

Performance

- Spectrometric technique: Fourier Transform near-infrared
- Sampling: diffuse transmission measurement
- Scan rate: 137 spectra/min at 32 cm⁻¹
- The calibration spectra are generally acquired at a resolution of 32 cm⁻¹ and 128 co-added scans (56 s acquisition time). Lower acquisition time can be used.
- Typical concentration limit for aromatic API content uniformity or assay determination with performance comparable to compendial techniques: 1% w/w. Applications with lower concentrations can be submitted to a feasibility study performed by ABB using customer samples.

Calibration

A tablet content uniformity preliminary model can be built with a minimum of 25 to 50 calibration samples, each sample consisting of a NIR spectrum and corresponding reference values. The calibration set should be representative of all process variations that can be expected in practice. To develop the calibration, we recommend using samples of at least five different concentrations covering the entire range of the property to be measured. There should be five to ten samples for each concentration, which gives a minimum of 25 to 50 samples in the calibration set. Note that it is often necessary to use composite samples to cover the entire range. In order to model process-specific variations, it is also important to include samples obtained from the process in the calibration set.

Operating environment

- AC input: 120 or 240 V manually selectable
- Power consumption: 150 W
- Ambient temperature: -15° to 50°C non-operating, 5° to 30°C operating stable within ±5°C.
- Relative humidity (operating): 0% to 95% non-condensing.



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FTLA2000-PH60 Spec B4239 2005-03

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