

with superior engineering

comes instrument matching and method transferability



Antaris II FT-NIR analyzer

solve industrial quality problems on a common near-infrared platform

The Thermo Scientific Antaris II Fourier transform near-infrared (FT-NIR) analyzer sets the standard for process and quality control analytics through its intuitive operation and unique combination of performance, power, and support. This analyzer is designed for use at production lines and on factory floors, loading docks or warehouses, while retaining the performance and flexibility necessary for method development work.



Antaris[™] II defines the standard for the design and manufacture of full spectral range, near-infrared analyzers including:

- High performance combined with rugged design
- Reproducible regardless of configuration, maintenance, user, or environment
- Regulatory traceability incorporated into every facet of the system, from the ground up
- Suitable platform for each point in your product-development lifecycle, facilitating method development, deployment, transfer, and routine operation

Total Solutions

The Antaris II analyzer was developed to meet the unique needs of the pharmaceutical, food and beverage, chemical, and polymer industries. The instrument's design and extensive support programs were developed with input from industry market leaders to offer a solution to your specific problem. The Antaris II analyzer provides:

- System-to-system repeatability for method transfer
- Easy software setup via dedicated validation and application programs
- A regulatory and validation-ready instrument
- Complete worldwide support programs
- Low cost of ownership

Why FT Near-infrared?

FT-NIR spectroscopy offers a practical alternative to time-consuming, solvent-intensive, wet-testing methods and liquid chromatography techniques. Its ability to test materials quickly in their production state allows routine analyses to be carried out at the line, rather than in the lab.

the right software

for the right environment

The Antaris II analyzers can be used with a complementary choice of software matched to the end user and environment. Whether used for spectroscopic analysis, method development, routine use or process analysis, there is no need to force fit software into a use for which it was not designed.

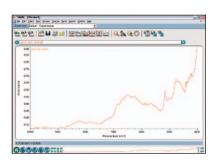
RESULT Analysis Software

Routine operation of the Antaris II industrial analyzer is accomplished with Thermo Scientific RESULT software. The revolutionary design of RESULT™ provides easy-to-use tools, method development, method transfer, and operational setup. RESULT includes the powerful predictive model builder Thermo Scientific TQ Analyst.

- Complete regulatory and validation-compliant software package for GMP environments (including 21 CFR Part 11)
- Method and workflow developed to create automated SOPs without programming
 - Intuitive, flexible, easy-to-use graphical interface
 - Workflow-based operation allows SOP control of analysis, report generation and data archival

OMNIC™ Software

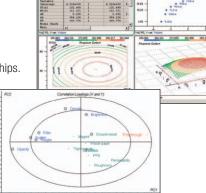
Thermo Scientific OMNIC software has been the industry benchmark for molecular spectroscopy work for over twenty years, and now it's available for the Antaris II. It provides a data work environment for even the most demanding, raw-data analysis and provides seamless data portability to any of the four chemometric packages available for sample prediction, with full 21 CFR Part 11 compliance tools.



The Unscrambler Software by Camo

We offer The Unscrambler® software for users performing extensive investigation and modeling. The Unscrambler is the standard in chemometric software for near-infrared spectroscopy and can be used to discover, understand, and capitalize on complex sample relationships. In today's race for process

understanding, this software tool provides a powerful component to applying analytics to operational problems in industry.



Advantages of NIR Analysis Over Traditional Techniques

NIR is ideal for quick, reliable raw-material identification and is a powerful tool used for multi-component quantitative analysis. Remote sampling with an NIR fiber optic probe is also an ideal option for process monitoring.

- No sample preparation sampling can be done through glass and other packaging materials
- Non-destructive measurement
- Accurate, reliable analysis
- Reduced cost
- Increased sample throughput
- Remote sampling with low-cost fiber optics

Advantages of FT-NIR Analysis

FT-NIR provides several clear advantages over dispersive NIR techniques:

- Fast all frequencies are measured simultaneously
- Mechanical simplicity for improved reliability the moving mirror is the only continuously moving part
- Internally calibrated for better accuracy and precision based on the HeNe laser as an internal wavelength calibration standard
- High spectral resolution resolution is determined by the stroke length of the moving mirror, so there is no degradation to optical throughput or system sensitivity
- Fewer standards and less complex methods are required due to superior resolution, precision and accuracy of FT-NIR data; methods are more robust and easier to develop

Antaris II FT-NIR method development sampling system

Bridge the gap between method development and analyzer deployment with the NIR platform that does it all.

When you have to solve a problem, selecting the correct sampling tool is crucial. The Antaris II MDS system provides a simple solution. It contains all the tools you need to analyze solids, liquids, powders, pastes, and tablets. More importantly, the system allows you to select the best technique for your environment, without reconfiguring the analyzer or changing accessories. It offers everything you need to run any sample, without compromising repeatability or ease of use:

- Integrating sphere module for diffuse reflectance sampling
- Automated transmission sampling
- · Fiber optic sampling with the Thermo Scientific SabIR probe
- Optional Tablet Analyzer module

After choosing a sampling technique, it is simple to transfer the method to any Antaris II analyzer, regardless of location. Additional Antaris II systems are configured with only the specific sampling techniques required for the method you developed, for streamlined deployment into at-line QC operations. Because every module uses the same beam path, each Antaris II system has identical alignment and performance results, making method and calibration transferability achievable. This not only saves you time and money, it provides you with systems that are dedicated for your operations.





Liquids and Films: Transmission Sample Compartment

- · Automated, three-position holder
- Dual-load sampling
- · Automatic background handling with samples in position
- · Automatic backgrounds with matrix or reference material
- Heating with automatic temperature control

Building an Analyzer for the Lab and the Plant

Rugged Design for **Working Environments**

- · Heavy-duty, aluminum housing and cover protects the system while, accommodating permanently aligned precision optics
- Best-in-class thermal stability
- Source is replaced from the outside without opening the cover

Internal Beam Path Use

- Internal background handling eliminates operator error
- Elimination of external references reduces sampling variability
- United States Pharmacopoeiarecommended performance testing is both internal and automated

Design Qualification

- Quality system design consistent with CFR 820 quality system rules
- Performance and design traceable to specification for intended use
- · Documentation of product development process
- Project documentation, including change control, verification and validation plans, ensures quality design

Design for Method Development

- Optical matching between Antaris II MDS and dedicated systems facilitates calibration transfer
- Dedicated optimal choice of sampling for intended task and location



Tablet Transmission Analysis: Antaris II Tablet Detector

- · Allows cross-sectional assay of solid dosage cores or coated tablets
- · True simultaneous measurement of transmission and reflection data in conjunction with integrating sphere
- · Optimized detection maximizes tablet signal and rejects stray light
- · Sensitivity and spectral range can be optimized for tablets or softgels
- Tablets of all shapes and sizes accommodated



This dedicated analyzer is a powerful, fast and easy-to-use tool for tablet uniformity verification.

Taking the Analysis to Remote or In-situ Samples: SabIR™ Fiber Optic Sampling

- · Trigger operation makes complete analysis simple
- Integrated indicator lights communicate pass, fail, prompt
- · Adapts quickly between solids and liquids with a single probe
- · Ideal for material identification at point-of-use



Methods can be transferred to the compact Antaris MX process analyzer for mobile field analysis.

Reflection Sampling of Solids, Powders, Pastes, and Suspensions: Integrating Sphere

- Ultra high-efficiency light collection
- · Sample materials directly or through glass containers
- · High-sensitivity, high-stability detection system
- Automated internal background collection with samples in position
- · Wide range of options for different sample types, shapes, and sizes



This dedicated system is ideal for measuring solids and powders.

Dedicated Antaris II Configurations



Reflectance Sampling



Liquids and Transmission Analysis



Tablet Analysis



Liquids and Solids

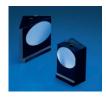
method transferability

through precision engineering and manufacturing

Every Antaris II instrument is a high-performance FT-NIR spectrometer. The design excellence and manufacturing precision of every Thermo Scientific analyzer allows for reproducible results for method transferability. Permanently aligned, pinned-in-place optics, and state-of-the-art hardware components make the Antaris II an instrument you can rely on.

The Optics

Method transferability is made possible with the Antaris II because every system is manufactured using exactly the same process, and to very tight specifications.



- Pinned-in-place, permanently aligned optics ensure that every instrument we manufacture uses the same optical path
- All components are housed in a sealed and desiccated enclosure, allowing operation in the harshest industrial environments

The Source

Internally, the Antaris II uses a long-life, high-intensity NIR source.

- Pinned-in-place, pre-aligned holder ensures accurate and continuous instrument operation
- Pre-aligned to filament image level repeatability to ensure calibration continuity
- Hassle-free replacement (no need to open the instrument, and the source has a lock-and-key fit)

The Interferometer

At the heart of the Antaris II is the Thermo Scientific MagnaFlex interferometer offering:

- Best scan-to-scan repeatability of any highresolution NIR technology available today
- Stability, long life, and fast scanning capabilities

The Laser

The HeNe laser is the source of the Antaris II's high wavenumber accuracy and precision.



- Ensures you never need to calibrate the Antaris II – it uses a HeNe reference laser to calibrate itself
- Permits reproducible spectral measurements, enables fewer standards needed for method development, and reduces development time
- Ensures simpler, more transferrable qualitative and quantitative models

High Throughput Automation and Specialized Sampling

The Antaris II analyzer features several dedicated automation options to facilitate large-volume sampling. These tools allow the system to analyze up to 120 samples per hour.

Autosampler RS

Ideal for sampling powders through vials. Analyze bulk solids: pellets, beads, powders.



MultiPro Autosampler

Designed for tablet analysis, the MultiPro Autosampler can be optimized for opaque or softgel tablets. It allows rapid, simultaneous sampling (reflection and transmission) for maximum sample information in minimal time. It can also be used for reflection sampling of vials, bottles, and other sample types.



Sample Cup Spinner

Obtain bulk or average information from inhomogeneous samples quickly and reliably. The Sample Cup Spinner is ideal for powders, grains, pellets, and other granular samples.



the standard

for analyzer qualification and validation tools

Product specifications traceable to use in regulated manufacturing environments require qualification and validation support. The Thermo Scientific ValPro system qualification package was developed in conjunction with the design of the analyzer and software platform it supports, ensuring a truly integrated and comprehensive qualification tool. ValPro™ is not a software package or an instrument test. It is an integrated approach to system qualification traceable to the manufacture and original design of the product.

Development and Manufacturing Procedures

Our contribution to your DQ processes begin with strictly controlled processes in product development and production. All project records are available for on-site audit at the factory.

Extensive Documentation

ValPro's documentation set covers design qualification (DQ, including documentation of the product development process), IQ and OQ procedures, and PQ guidance.



USP General Chapter <1119>

ValPro provides the full USP NIR test suite, as well as additional tests for performance.

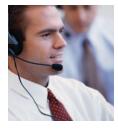
Internal and External Fully Traceable Standards

We provide standards and test limits that are fully traceable, both internal and external to the system.



Qualification Services

Certified service engineers provide qualification test services that can be used to satisfy initial and ongoing analyzer-use requirements.



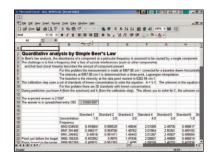
Use-specific Testing

ValPro allows workflow-based authoring and implementation of your own PQ or suitability tests.

ValPro TQ Analyst[™] Algorithms

Calibration equations used for prediction of traits from near-infrared data are a critical part of near-infrared deployment. However, the generation of these equations, and the execution of a calibrated method, is rarely understood beyond what appears in the software application interface. Validation of and proof statements about chemometrics with the ValPro TQ Algorithms system goes beyond, the "black box" approach. For the first time, near-infrared chemometrics can be backed up by documentation and traceability. Components of ValPro's traceable approach to algorithm and method validation:

- Fully documented algorithms, as implemented in the software
- A set of open, user-accessible reference calculations for all algorithms
- Reference calculations applied to known calibration problems using standard data sets and predict known samples (in spreadsheet format)
- Calibrations implemented in the software using the same data sets
- Known samples can be predicted and compared with reference calculations



About the Antaris Line of Analyzers and Sensors



Solving industrial analytical challenges requires bringing the right tools to the job. The cumulative years of reliable spectroscopic technology from Thermo Fisher Scientific have been combined with the knowledge of experts and everyday users in industry to produce a range of analyzers that set a new standard in task suitability. We are pleased to offer a full line of analyzers with common platform elements in software, validation tools, methodology, support, and implementation. The Antaris product line represents an industry-driven migration of spectroscopy from science to industry, in a solution that connects the lab and the plant for the first time.

Our Pledge of Support: A Fundamental Analyzer Requirement

The Antaris analyzer product family is backed by our worldwide applications and process support team. With dedicated support for most countries and regions around the world, our customer support organization is the best in the industry. We provide:

- Applications Assistance
- Qualification Support
- Preventive Maintenance
- 24/7 Services

We offer a full suite of product and customer services tailored to near-infrared and process analysis. Let us recommend a support configuration, or ask us how we can customize these services specifically to your requirements:

Feasibility and Site Survey

We will work with you to evaluate the feasibility of near-infrared as a solution to your process analytical challenge. A Thermo Scientific NIR specialist will visit your intended use site to gather key information related to process analyzer integration and the necessary components, services, and preparations. We will provide a thorough proposal to ensure a smooth implementation.

2 Installation

Our certified field-service engineers ensure proper installation and operation of the analyzer. Prior to installation, we provide a site-readiness form to synchronize installation preparedness between your site and our engineers.

Qualification Services

We offer a full line of installation and operation qualification services and annual requalification services, which can be used in conjunction with the ValPro system, to demonstrate proper performance and suitability.

4 Training

Our team of Antaris support specialists can provide:

- . On-site or factory-based training on the use of the system
- Customized training to ready your staff or plant
- Service training and certification to your plant personnel

5 Method Development Services

If you do not have the time or resources to model your process parameters using near-infrared, let us provide calibration services for you:

- Method Development
- Maintenance
- Transfer Services

6 Repair and Technical Support Services

From depot repair to critical support, we offer repair and technical support services that include 24/7 options to help meet the uptime requirements of your application.

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