

PHAZIR R_xTM Handheld NIR Material Analyzer

Overview

The Polychromix PHAZIR R_xTM is the first of its kind handheld NIR material analyzer engineered to provide an innovative solution for portable raw material identification testing and at-line process monitoring applications for the pharmaceutical industry.

Near Infrared has never been this portable and this easy. Just select the application, point and shoot, and see the results in seconds. Designed for the expert and non-technical user alike, the PHAZIR R_xTM unleashes the power of near-infrared spectroscopy enabling real time, on-site analysis with minimal training.

Features

- Rugged portable handheld solution
- Lightweight 4 lbs. device
- Intuitive Color LCD screen
- Rechargeable Li-Ion batteries
- 10+ hours battery life
- Minimal training required
- Rugged design
- Safe for use



Applications

- Incoming raw material inspection
- Quality control and assurance
- Counterfeit product Identification
- At-line Process Analytical Technology Control (PAT)
- Process troubleshooting

Speed and Power

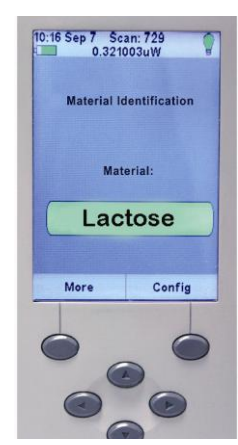
- Qualitative and quantitative material analysis including material ID and concentration level measurements
- Liquids, pastes, solids powders, gels
- Fully programmable via PC software
- Instantaneous (1-2 seconds) results

Regulatory Compliance

- 21 CFR Part 11 Compliant
- IQ/OQ/PQ Documented
- USP 1119 Verification Protocol
- Traceable Standards available
- Validation Services available

Ease of use

- Non destructive measurement
- Results logged in database
- Minimal training required



Typical raw material Identification result

Polychromix, Inc.
30 Upton Drive
Wilmington, MA 01887
www.polychromix.com
Phone: (978) 284-6000
Fax: (978) 284-6060





PHAZIR R_x™ Handheld NIR Material Analyzer

Validation PHAZIR R_x™ was designed with modern good laboratory practices and regulatory compliance requirements in mind. The PHAZIR R_x™ compliance system includes 21 CFR Part 11 electronics records and signatures, comprehensive IQ/OQ/PQ procedures, and support for traceable standards. PHAZIR R_x™ provides system administrators with the necessary multi-level user permission controls to ensure system security. PHAZIR R_x™ has built-in self diagnostics including system qualification checks based on USP 1119 NIR Qualification Protocol. The PHAZIR R_x™ GLP features monitors scheduled OQ/PQ test intervals, guides the operator through qualification processes thus ensuring complete confidence in every result.

Method & Method Generation A comprehensive raw material library is available for PHAZIR R_x™ so you can use the system right away or build your own custom library. The Polychromix PHAZIR R_x™ Method Generator software makes NIR method generation easier than ever. Method libraries can be extended for new materials in just a few easy clicks. Methods can also be generated using Camo's unscrambler software.

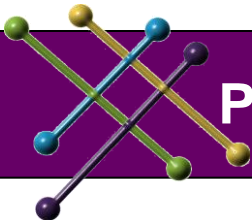
Robustness PHAZIR R_x™ was engineered as a robust industrial strength analytical testing tool with proven reliability successfully performing millions of analysis in very harsh environments. PHAZIR is designed to go where you need it including laboratories, loading docks, warehouses, and even onto your manufacturing floor.

Optional Accessories Optional PHAZIR R_x™ accessories include a holster, spare batteries, liquid vial sampling adapter, solids vial adapter. IQ/OQ/PQ manual, training and validation qualification services.

Reports, Archive, and LIMS Compatibility PHAZIR R_x™ is a high performance NIR system with typical analysis time of about 2 – 3. Results are instantaneously displayed to the user on the color LCD display. PHAZIR Rx also logs records in an integrated database. Users can connect to the USB port in order to generate printed reports or to upload records from the PHAZIR database to LIMS system or data archiving networks.

| Specifications | |
|-------------------------------|---|
| Principle of Operation | Non-destructive chemical analysis via Near Infrared Spectroscopy |
| Weight | 4.0 lbs |
| Dimensions | 10 x 11.5 x 6 inches (254 x 292 x 152 mm) |
| Light Source | Tungsten light bulb, safe for operators and sample integrity |
| Spectral Resolution | 12 nm |
| Spectral Range | 1600 – 2400 nm (including the complete near-infrared combination region) |
| Measurement time | User-definable. Typical 1-2 seconds. |
| Internal data storage | All readings stored in internal memory and can be offloaded to PC |
| Data Download | Transfer data in text based files to a PC via USB connection. Easily transfer data to all types of applications. |
| Security | User selectable password protection with multiple security levels. |
| Operating conditions | Temperature range 40° to 115° F (5° to 45° C°) |
| Batteries | Interchangeable, rechargeable 10+ hours lithium-ion battery pack. AC battery charger included. Battery pack recharge time <4 hours. |
| Housing | High-strength, dust proof/splash proof plastic housing |
| Standard accessories | <ul style="list-style-type: none">▪ Rugged waterproof carrying case, 110/220 VAC battery charger/adapter▪ PC Interface cable, Documentation CD, Safety Lanyard |

Polychromix, Inc. 30 Upton Drive, Wilmington, MA 01887
Phone: (978) 284-6000 Fax: (978) 284-6060 www.polychromix.com



PHAZIR R_x™ Handheld NIR Material Analyzer