



System requirements

The PC must fulfill the following requirements:

Operating System	Windows 7 Professional / Enterprise / Ultimate (32-bit or 64-bit) SP1, 3 GB RAM Windows 8 Pro (64-bit), .NET 3.5 recommended, 3 GB RAM
Central Processing Unit	Intel Core i3 or higher and 1.4 GHz or faster
RAM	3 GB or higher
Harddisk	15 GB free hard disk space
Display resolution	1280 x 1024
LAN	1 x 100 Mbit/s LAN (2 x 100 Mbit/s LAN recommend)
Others	DVD-ROM drive

Licenses

NIRWare Basic	Consists of Operator Interface, Application Designer, Sample Manager, Security Designer and Administrative Tools (registration required).
NIRWare Advanced	Includes all software modules of NIRWare Basic. In addition the Library Designer and NIRWare Regulatory Kit (registration required)

Order code

Choose the configuration according to your needs:

N 5 5 0 - 0 1

- 1 NIRWare CD incl. Basic License
- 3 NIRWare CD incl. Advanced License
- 5 NIRWare CD incl. Multilicense Basic (3 Licenses)
- 6 NIRWare CD incl. Multilicense Advanced (3 Licenses)

Optional modules

N 5 5 5 - 1 0 3

License NIRWare Library Designer 1

N 5 5 5 - 1 0 4

License NIRWare Regulatory Kit 1

1 1 0 5 6 9 3 0

NIRWare 2EX CD

NIR Network Solutions

1 1 0 5 6 9 2 8

NIRAnywhere Server Solution

1 1 0 5 6 9 2 9

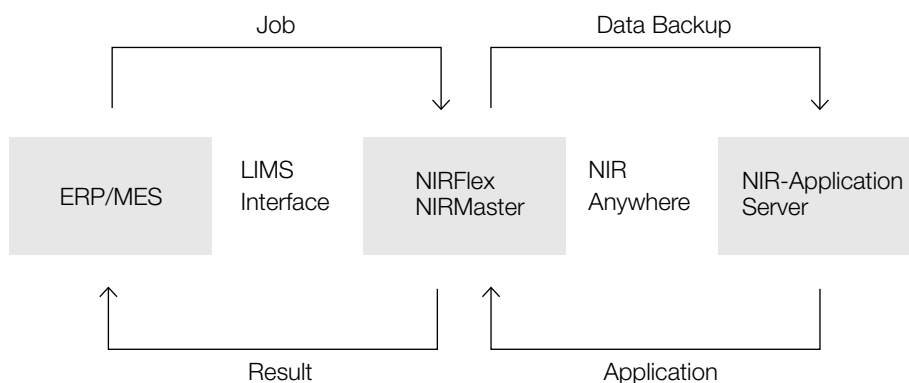
NIRAnywhere Client CD

N 5 5 0 - 0 3 1

NIRWare LIMS Interface 1 CD incl. License

N 5 5 0 - 0 3 2

NIRWare LIMS Interface 1 CD - 3 Licenses

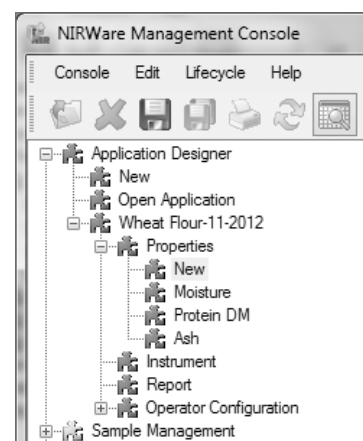


Description

NIRWare Management Console

The NIRWare Management Console is a centralized tool providing all configuration functions in a well structured design.

Application Designer:	Combines application specific configuration of instrument parameters, calibration and NIRWare Operator.
Sample Manager:	Management of reference values and samples, as well as result review.
Administrative Tools:	Management of system settings and data exchange.
Security Designer:	User management and administration of access rights.
Library Designer:	Development of spectral libraries.
LIMS Interface:	Flexible data exchange of job files and measurement results with customer's existing LIMS/MES systems.

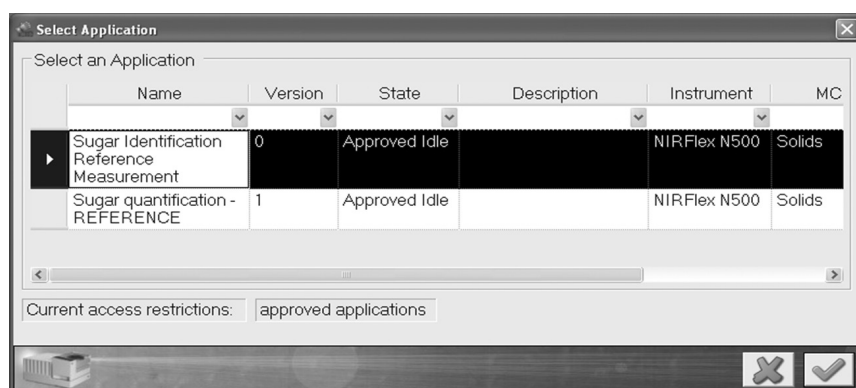


NIRWare Operator

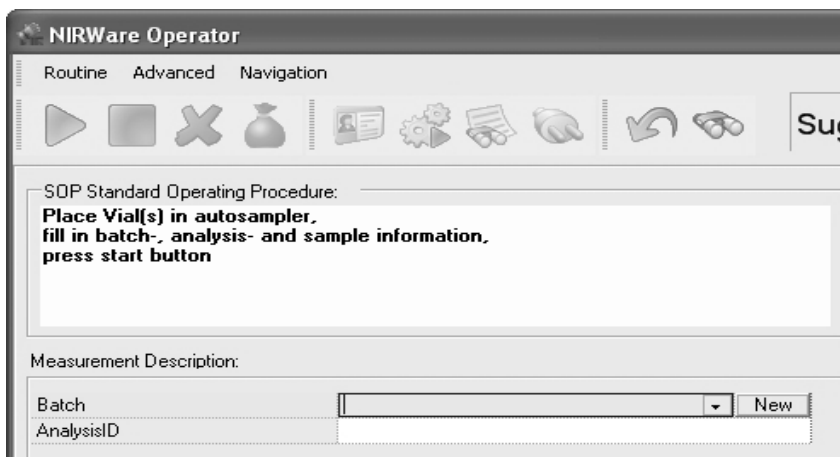
The NIRWare Operator is a simplified user interface. Displaying only parameters and options needed for routine use helps to prevent errors. Therewith operator skills requirements are kept to a minimum.

Example for routine use of operator interface:

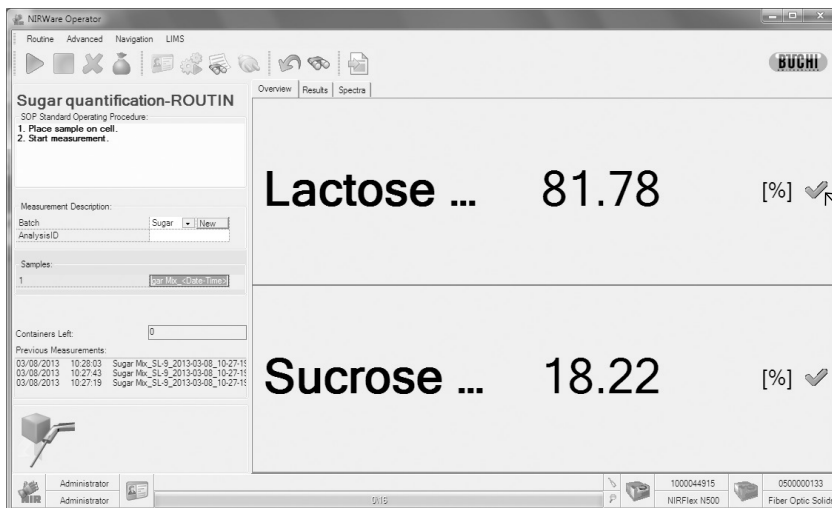
1. Application selection



2. Input of sample information



3. Sample measurement and configurable result display. Example: Results of a quantitative analysis displayed in large fonts.



Details can be accessed
with one mouse click

Example: Results of a quantitative analysis displayed as a detailed report.

Overview

Results

Spectra

Main Report

1

Sugar Mix_SL-9_2013-03-08_10-27-19

Value

Residual

1

81.30 % ok

0.000263 ok

2

81.65 % ok

0.000262 ok

3

82.40 % ok

0.000263 ok

Lactose Gehalt

81.78 % ok

ok

1

18.70 % ok

ok

2

18.35 % ok

ok

3

17.60 % ok

ok

Sucrose content

18.22 % ok

ok

Calibration

Lactose Gehalt

Calibration name:

Lactose QN-02-13

Version:

2

Calibration range:

0.00 - 100.00 [%]

Method:

PCR

Action range:

0.00 - 100.00 [%]

SEP:

2.650098

Training range:

0.00 - 100.00 [%]

Star:

0.000000

Max. Residual:

0.000361

Slope:

1.000000

SUID:

(3BAE4B8-70F3-4F9A-8CFB-36C36E93122F)

Sucrose content

Calibration name:

CalculatedValue = 100-AgProperty [Lactose Gehalt] Value

Version:

Calculated

Calibration range:

0.00 - 100.00 [%]

Method:

SEP

Action range:

0.00 - 100.00 [%]

Star:

0.000000

Max. Residual:

0.000000

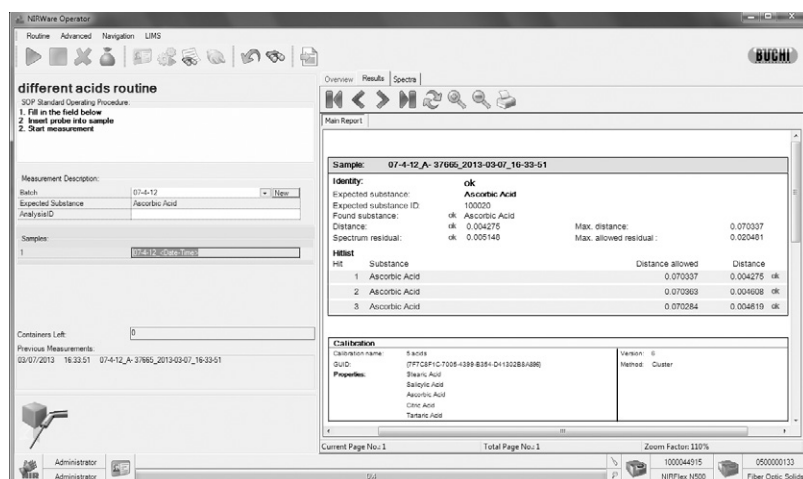
Slope:

1.000000

SUID:

Calibration information is
optionally shown

Example: Results of a qualitative analysis displayed as detailed report.



NIRWare Regulatory Kit

The Regulatory Kit is a license for optional tools like electronic records and electronic signatures for full compliance with FDA CFR 21 Part 11.

NIRSolutions Pharma - Regulatory Compliance

This document details the compliance of BUCHI's NIRSolutions with regulatory requirements. Main aspects: Product development, instrument and software validation, electronic records and signatures and BUCHI's quality system.

NIRWare 2EX

This tool extracts selectable data records from the NIRWare database for export to MS-Excel files. Current as well as historical data can be displayed to assess product quality trends.

NIRAnywhere Server Solution

NIRAnywhere is a software tool for global networking of multiple NIRFlex N-500 and NIRMaster spectrometers. Using a client-server setup based on a MS SQL-Server the NIRAnywhere software handles data management and centralized backup.

Functional principle

Workflow

The following table depicts the typical workflow from data generation over calibration development to routine use. This workflow is compliant to Pharmaceutical guidelines for NIR application's lifecycle.

Task	Lifecycle	NIRWare Operator	NIRWare Management Console	NIRCal
Setup reference application Set application to „approved“	•		•	
Record spectra of reference samples	•	•		
Define sample properties and values	•		•	
Calibrate Set calibration to „approved“	•			•
Copy application as template for routine use Define SOP	•		•	
Assign calibration to application Set application to „approved“	•		•	
Use for prediction / routine measurement	•	•		