NXperience TRUST ✓

| Inviolable information |
| Data security |
| Flexibility of configuration |
| GMP Compliance (21CFR Part 11) |

HARDKEY
More Reliability
in the data record

NXperience Trust is validating software specially designed for the pharmaceutical, food and health market segments for the configuration and data collection of data loggers for the environment variables to be monitored.

These segments require a reliable, simple and intuitive system to use, as complete data analysis and visualization, user authentication, and information security features.

The **NXperience Trust** connectivity allows it to be used as a central data management tool, and can handle information from all devices in networked installations, with more than one workstation and with centralized server data.

The **NXperience Trust** complies with the technical requirements of FDA 21 CFR Part 11 for validation of computer systems. The user has an electronic record of encrypted data, a strong authentication mechanism with password validity, and an application event log for traceability and audit trail.

Protocols and execution of validation are optional and offered separately, in order to complement the solution.

DATA MANAGEMENT

DEVICE DIAGNOSTICS

ANALYTICAL REPORTS

SETTING PARAMETERS
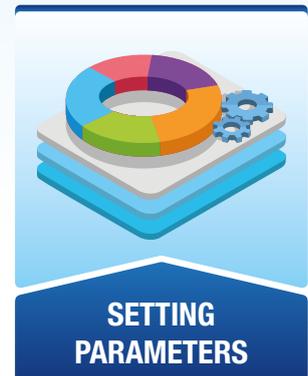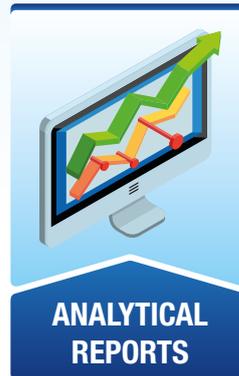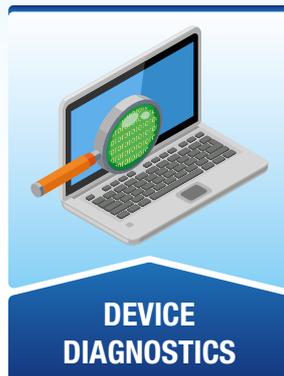
VALIDATION FDA 21 CFR PART 11

- Controlled access to software
- Automatic user logout
- Encryption of electronic data records
- Presentation of the data in a readable format
- Backup of the electronic records in the network server
- Detection of change of electronic records
- Records of occurrences (for Audit Trail)
- Electronically signed reports

VERIFICATION AND VALIDATION

SPECIFICATION

PLANNING

FUNCTIONAL SPECIFICATION

SOFTWARE AND HARDWARE DESIGN

VERIFICATION

ACCEPTANCE OF USER

OPERATION QUALIFICATION

INSTALLATION QUALIFICATION

www.novusautomation.com/en/NXperienceTrust

NOVUS
We Measure, We Control, We Record

REQUIREMENTS FROM FDA 21 CFR PART 11

Secure Access

Allows creating users to access software with different predefined permission levels - user profiles - to features and data. Password creation features with rules and expiration period, automatic logout of user by inactivity and user blocking by password expiration or consecutive login attempts with invalid password.

Audit Trail

Record of all actions performed by the user in the software, logging information such as the user identification and the action timestamp. It allows to generate track report and apply filters per user, by event and by date/time.

Data Security and Devices

Metadata file from process is encrypted, making it unreadable. In addition, the files have a protection hash key, which allows detecting file modification attempts, ensuring the integrity and reliability of the device data.

Devices configured by the **NXperience Trust** are protected and marked electronically, preventing access to configuration and data by means other than the software itself, ensuring controlled access to the device.

Reports with Unique Identification

Each report has a unique and visible electronic identification, guaranteeing the uniqueness, integrity and inviolability of the report when in electronic or printed form.

DATA LOGGER

HUMIDITY AND TEMPERATURE

DIFFERENTIAL PRESSURE

PORTABLE DATA LOGGER

FEATURES NXPERIENCE TRUST

CONFIGURATION

CHARTS

MAPS

REPORTS

- **Device Configuration**
  - Operation parameters
  - Input and output calibration
  - Simulation of signals
  - Custom input signals

- **Data Management**
  - Data collection
  - Import/export of metadata
  - Data visualization (list, chart and/or map)

- **User Control**
  - Creation of users with different access profiles
  - Password with rulesand expiration
  - Automatic logoff
  - User blocking

- **Data Integrity and Reliability**
  - Encrypted validated data
  - Hash key against data file violation

- **Audit Trail**
  - Record of actions taken
  - Report of actions taken

- **Device Diagnostics**
  - Monitoring of variables
  - Status and alarm display

- **Device Connectivity**
  - USB
  - RS485
  - Ethernet / WiFi

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