REA VERIFIER

REA Audit Trail Software

Optional software extension for REA VeriCube
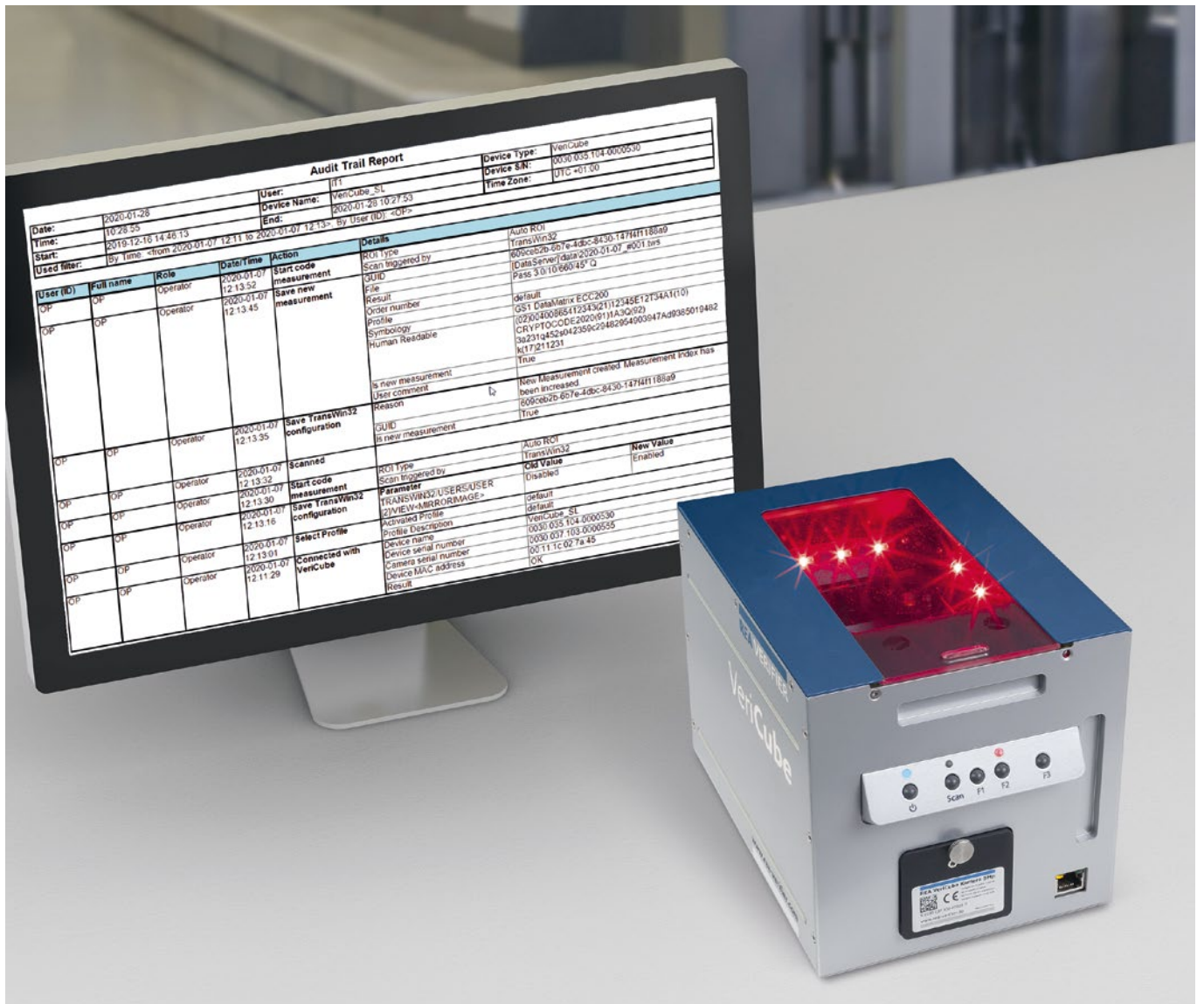
REA Audit Trail Software

The REA Audit Trail Software is an optional software extension for the REA VeriCube.

Audit Trails are required for applications in healthcare industry (pharmaceuticals and medical devices). In health industry, work must be carried out under strictly controlled conditions (GxP compliant) both in production and in laboratory areas. This is monitored by the supervisory authorities through audits. Background for this is the American law 21 CFR Part 11 as well as the GMP /GAMP requirements of the European Union and the United States.

All actions relevant to measurement results are monitored and documented in an Audit Trail, available for reviews. This allows following up who has performed, saved and printed measurements with appropriate settings. In addition other actions and configuration changes on the system can be tracked.

Acquired data shall be protected against manipulation. For this reason, all relevant data and configurations are stored and retrieved by the aid of a system called "Data server". Only the Data server has access to the "repository" where user data, measurement data and the Audit Trail log data are stored.

User management

To make sure that only known and authorized personnel can access the system it is protected by a user management. The local user management has a capacity of 1024 users. In case of connection to Active directory audit trail user roles are assigned to active directory groups.

User Roles

Depending on duties users are assigned to roles. Each role has different rights. For example, a user in the role "operator" can only measure and print reports but cannot change any settings. He can just select predefined measuring profiles.

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Features

- Data repository protected against unauthorized access
- Configurable automatic backup of entire data
- Full Audit Trail view which logs any event including system events like automatic log off. The view for Audit Trail can be filtered (actions, users, date etc)
- Archiving of data including closing of current Audit Trail
- Protection against data manipulation:
  - printout is only possible for saved reports
  - export and import of data is blocked.
- Automatic closing of the application by user logoff and by Windows screensaver
- Templates for IQ/OQ forms are available for free

Local User management

- User management with 4 user roles
- User password history (12)
- Password validity: 90 days
- Password security – min 8 characters: upper case, lower case, number and special characters (3 of 4 categories are mandatory)

User management by active directory

- User management with 3 roles
- Password strength and management is handled entirely via the active directory system

System requirements

- Windows 10, 64-bit
- Memory ≥ 8 GB
- ≥ 1 TB HDD for repository a local SSD Hard disk is recommended
- Processor Intel i5 / AMD Ryzen or better
- Separate 1Gb/s Ethernet Port for REA VeriCube
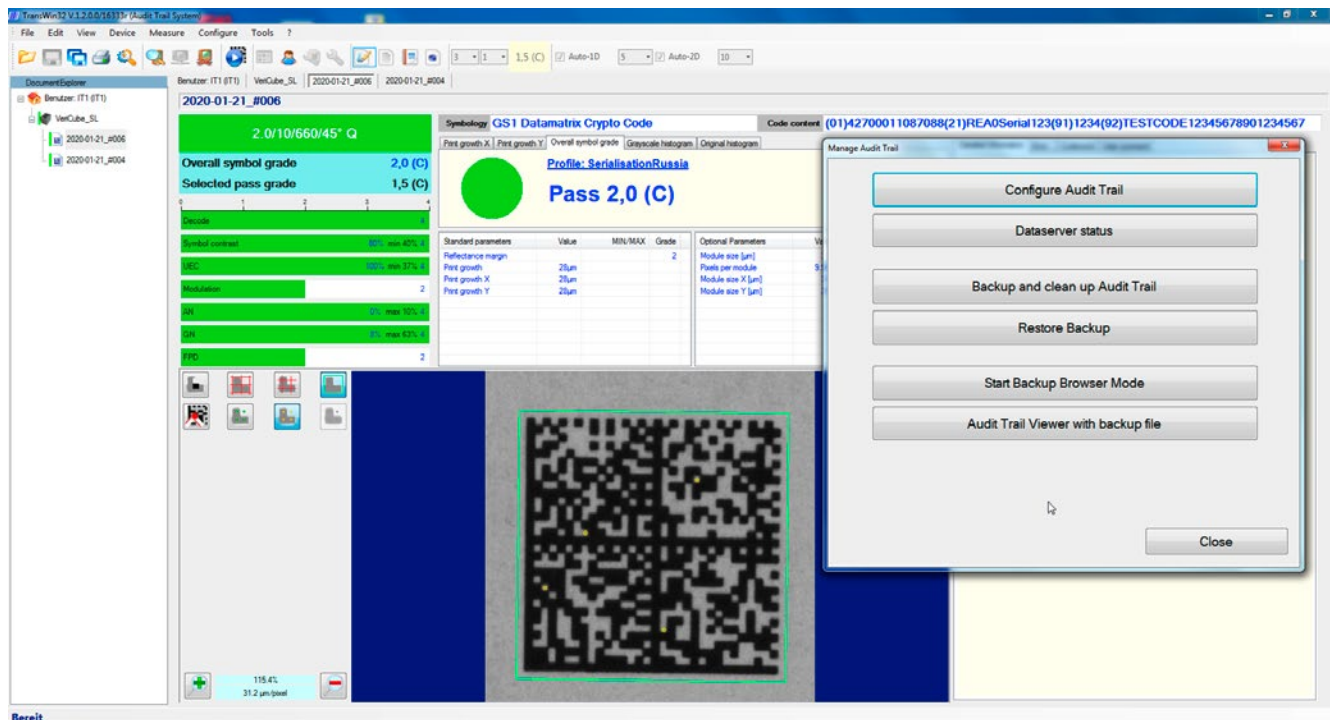
Specifications and features explained here are subject to change without notice

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