Sr No.	Feature	Regular Software (Not 21-CFR-11 Compliant)	Vantage Software (21-CFR-11 Compliant)
1	User Login	No Login. Any user can access the software.	Unlimited Users with individually configurable privileges

Incorrect Logins are logged. If user enters 3 wrong passwords, user is SUSPENDED and cannot login again even with correct password. Event is logged as Critical. Only an admin (or user with appropriate privileges can Un-Suspend the suspended user.

Auto - Logout after 15 mins of inactivity. (Timeout period can be defined)

Auto - Shutdown (software) on inactivity. (Auto-Logout will also trigger Auto-Shutdown) |
2	User Rights / Privileges	Any user can : 1) Perform Test 2) Search Test 3) Calibrate Machine 4) Configure Software	Software Admin or any user (with Modify user privileges) can create unlimited users with any of following privileges. 1) Perform Test 2) Search Test 3) Calibrate Machine 4) View Audit Trail 5) Add / Edit / Delete users (User Management privilege) 6) Configure Software 7) Review and Approve Test / Calibration reports
3	User Levels	NA	Unlimited Users with Unlimited variable privileges. User List (summary or detailed) can be printed.
4	Software Configuration Options	1) Change Header	1) Change Test Folder 2) Change Backup Folder 3) Set Auto Backup On/Off 4) Set Auto Backup Frequency 5) Set Password Expiry On/Off 6) Set Password Expiry Time (Days) 7) Change Header
5	User Password Expiry / Change	NA	Upon user first login, user has to change password immediately. User can change his/her own password anytime. Users must change password after expiry date. Password expiry time can be defined in software config.

6	Password Complexity	NA	Password should be 1) 8-20 characters long 2) Has to contain alphabets, numbers and &%#$@. 3) Password should contain atleast 1 uppercase, 1 lower case and 1 special character 4) New password cannot be same as previous 3 passwords.
7	User Addition / Deletion	NA	User can be added or deleted by Software Admin or anyone who has User Management privilege. User cannot delete himself. No one can delete the SUPER USER.
8	User Suspension	NA	User can be suspended/un-suspended by Software Admin or anyone who has User Management privilege. Suspended user cannot login to software. If he tries to login, a Critical Audit Trail entry will be passed.
9	Data Storage	NA	Data is stored in an internal database. PDF reports are generated as and when demanded.
10	User Signature	User must type or select his / her name when the software starts.	User's details captured from the login is posted on the report "analysis done by" section.
11	Reviewer Signature	NA	Reviewer can login with his credentials, review and approve Test and Calibration Data. Once approved, the report will carry his E-Sign.
12	Backup Data	NA	If Autobackup is ON, software will automatically backup all configuration files and test data as per frequency chosen in Software Configuration. Note : Backup Location has to be a local drive or a network location mapped as a Local Drive.
13	Audit Trail Data	NA	Software captures important events and logs them in the audit trail log. A PDF report can be generated as and when required. Critical Events will be flagged separately. Audit Trail Report can be pulled for a date range or user or event.

14	Aborted Tests / Calibrations	NA	Aborted Tests and Calibrations are saved. These events are logged in Audit Trail as "Critical".
15	Ignore a Test Value	NA	No test result can be avoided from being reported. But the user can mark a particular result as abnormal. Abnormal results are not considered in statistical calculations but will still be shown in report. User needs to justify the Abnormal values (if any) in the remarks section. A test report can have 10 normal samples + up to 5 abnormal samples. Only normal tests will be used for statistical calculations.
16	Test / Calibration Report Format	Report Format is fixed in software. Not changeable by user.	
17	Report Header	Text Header with 3 lines of Text.	Image Header with Logo or Text Header with 3 lines of Text.
18	Other Features	NA	Incorrect Shut Downs are logged in Audit Trail. Equipment ID is printed on all Test / Calibration / Audit Trail Reports Automatic Pre-Calibration Diagnostics of communication. Option of Pre-Analysis Diagnostics (10-15 seconds) to prevent communication errors. Enhanced data handling and communication with equipment.

FDA 21 CFR Part 11 COMPLIANCE with **VANTAGE Software**

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