Lunatic hooks micro-volume biologics quantification up with compliant features

Are you in a GxP lab and require proper electronic record keeping and data security? The Lunatic has your back with its straight, out-of-the-box, unique 21 CFR Part 11 special add-on, including all features that allow you to make your system compliant with the 21 CFR Part 11 regulations. This implies assurance of audit trail functionality, electronic signatures, security, and data integrity. This makes the Lunatic unique in its capability to analyze micro-volume samples in 96-well plates ensuring full sample tracking, data integrity and traceability.

Lunatic makes batch quantification of biologics and nucleic acids a no brainer. Combining high speed UV/Vis spectral analysis with micro-volume Lunatic Plates (Figure 1), Lunatic offers the unique possibility of quantifying 96 droplets at once in only 5 minutes. No need to worry about sample dilutions nor contamination, the Lunatic Plate takes care of your samples upon loading them by hand or using a liquid robot. Just drop, load and read.

Key features of the Lunatic 21 CFR Part 11 add-on

21 CFR Part 11 main screen

The main 21 CFR Part 11 screen can be opened at any time from the drop-down menu on the home page (Figure 3).

Here 3 items are available:

- **Setting password options.** The administrator can adjust the password requirements for new users.
- **Audit trail.** This database gives an overview of all events and changes (actions) performed by users on the system and tracks the general history of your Lunatic software (user settings, experiments and reports).
- **Experiments integrity.** This button activates a general check of all experiments in the experiment list. If one of the experiments in your list has been corrupted or altered without authorization, the experiments integrity check will fail and you'll be notified about which experiment has been altered.
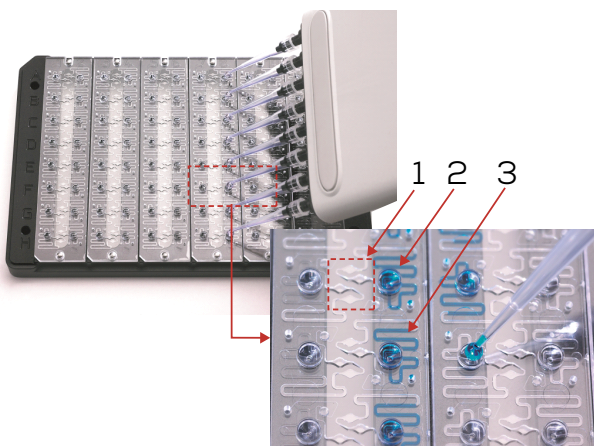

Figure 1: Lunatic Strip features: Lunatic Strips have a unique structure including: (1) dual micro-cuvettes for stable sample read-out; (2) Input wells fit for manual or robotic sample dispensing; (3) storage meander for temporary sample protection from evaporation and cross contamination. Lunatic Strips come as a single 16-well strip or as a SBS-standardized 96-well Lunatic Plate.

Figure 2: Lunatic instrument fit for manual or robotic sample processing.
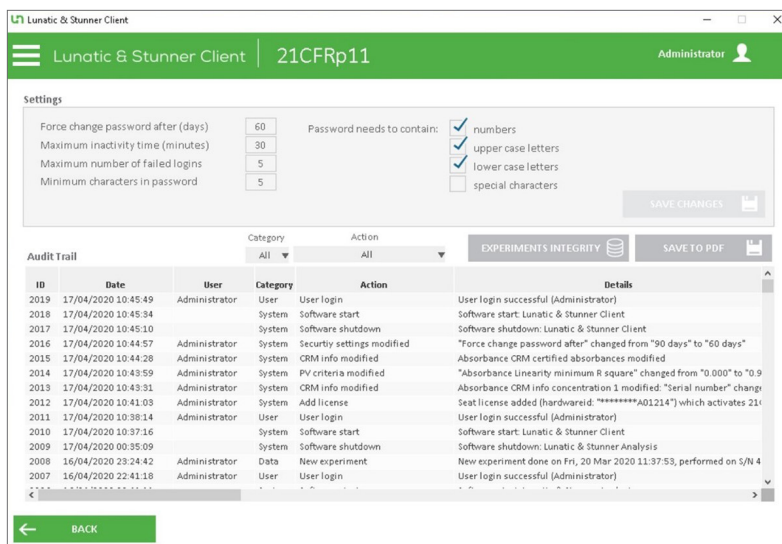
Figure 3: Main 21 CFR Part 11 screen.

System	User	Data
Software start	New user created	New experiment
Software shutdown	User login	New revision
Security settings modified	User login (failed)	Add signature
Add license	User logout	Report created
Database integrity check	User info modified	Report integrity check (success)
CRM info modified	User password changed	Report integrity check (success for other experiment)
PV criteria modified	User password reset	Report integrity check (failed)
New analyte created	User password reset (failed)	
Analyte changed	User enabled	
Analyte removed	User disabled	
Homebrew application changed	Password recovery code requested	
Blanks stored	User account recover attempt	
Stored blanks removed	Account level changed	

Table 1: Filtering options.

At the bottom of this screen, an overview of the audit trail is given. You can scroll within this audit trail and get a better overview by applying the filters shown in Table 1.

With the "Save to PDF" button, you can get a complete or a filtered overview of the audit trail.

Experiment-specific information and audit trails

Upon opening the Lunatic and Stunner Analysis software, an overview of all experiments is given. This overview displays all experiment revisions and concomitant signature history.

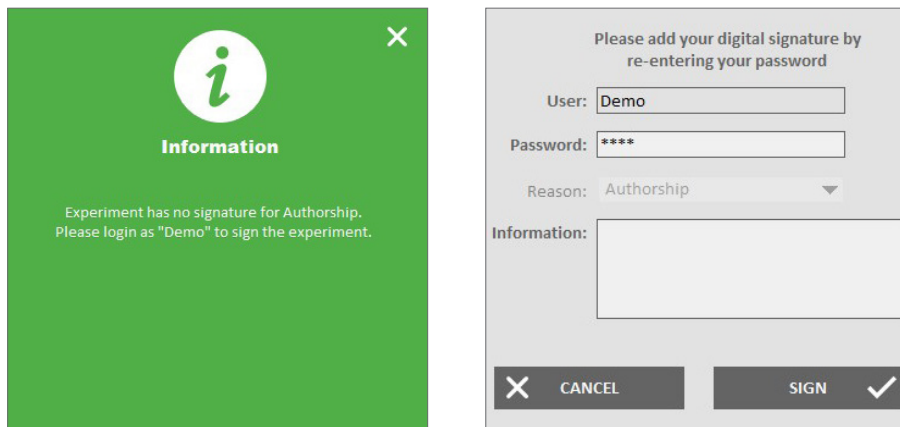Figure 4: Experiment list in the Lunatic & Stunner Analysis software.

Figure 5: Digital signature request screens.

There are two actions that will lead to a new revision number:

• A user renames and saves the experiment.

• A user re-calculates the data using a different application.

When an experiment gets a new revision number, the old revision will remain stored in the experiment list.

Whenever a user or administrator performs an experiment, an authorization signature is requested. Non-signed experiments are indicated by an orange colored figure instead of a gray figure next to the experiment date in the overview (Figure 4).

When an experiment hasn't been signed, the experiment cannot be opened until the user completes the sign-off process (Figure 5). All experiments can be signed for review, approval and responsibility, by users and administrator.

An experiment specific audit trail can also be generated. First, open the experiment by double clicking on an experiment in the database (Figure 6). Then, click on the "21CFRp11 button" to go to the 21 CFR Part 11 page for this experiment.

Similar to the main 21 CFR Part 11 screen, you get an audit trail specific for the experiment.

Extra features are also available, such as integrity checks of created reports (XLS, TXT, etc.) (Figure 7). You have to select the report for the experiment and click "Check integrity." An automatic pop-up screen will display the result of your report integrity check.
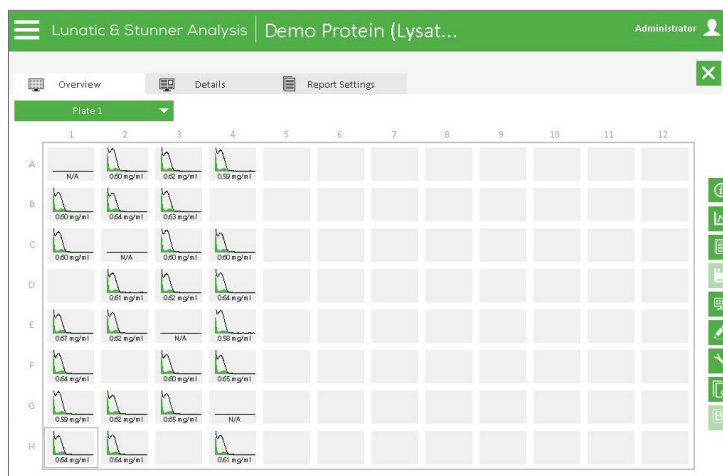
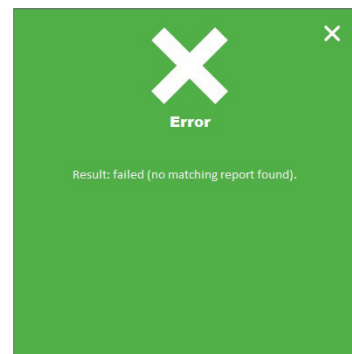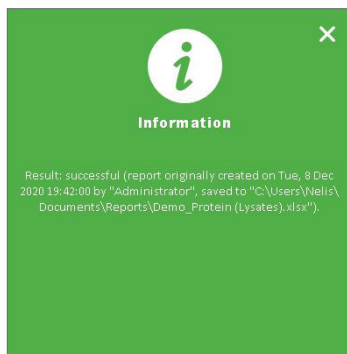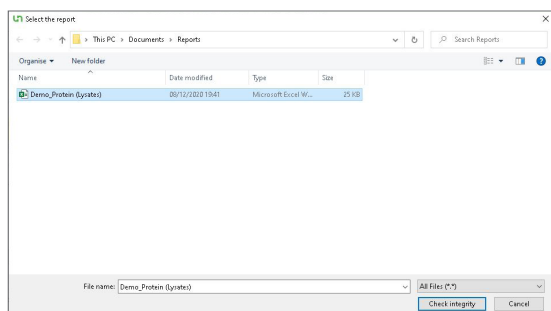Figure 6: Possibility to perform experiment specific audit trails.

Figure 7: Checking report integrity.

Conclusion

To meet GxP laboratory requirements the Lunatic software offers out-of-the-box features designed to meet 21 CFR Part 11 regulations. These features include saving data as electronic records (bin files). From this electronic record, the customer can create reports at any time. Both the measurements and reports are logged in an audit trail, allowing integrity checks of both. The software also includes an advanced user management system, full audit trail capacities and signature procedures on the electronic records.

Rev B