Gator™ Part11 Software

## 21 CFR Part 11 Compliant BLI software

Introduction

The FDA's code of Federal Regulations (CFR) Title 21 is critical in ensuring safe and ethical drug administration. Gator™ Part11 Software enables users in GMP or GLP laboratory environments to comply with 21 CFR Part 11 regulations.

Data integrity is a primary consideration of Gator™ Part11 Software. All data acquired is time-stamped and traceable. Features such as account management, enhanced audit trails and recorded user sessions comply with FDA guidance. It is appropriate for users to review an audit trail, as it reveals unauthorized intent to tamper with data or modify results.

Gator™ Part11 Software

The Gator™ Part11 Software portfolio is a client-server architecture for managing digital records created with Gator™ systems and the Gator™ GatorOne Software application. A default Part11 Software administrator is responsible for configuring user accounts for users of the Part11 Software.

The 21 CFR Part 11 editions of the Gator™ system applications enforce user logins prior to performing any operations with the software. During the user session, the GatorOneRS Server records all system, software, and user events. User sessions are closed when the user logs out or after a set period of inactivity is reached. A new session starts each time a user accesses the software.
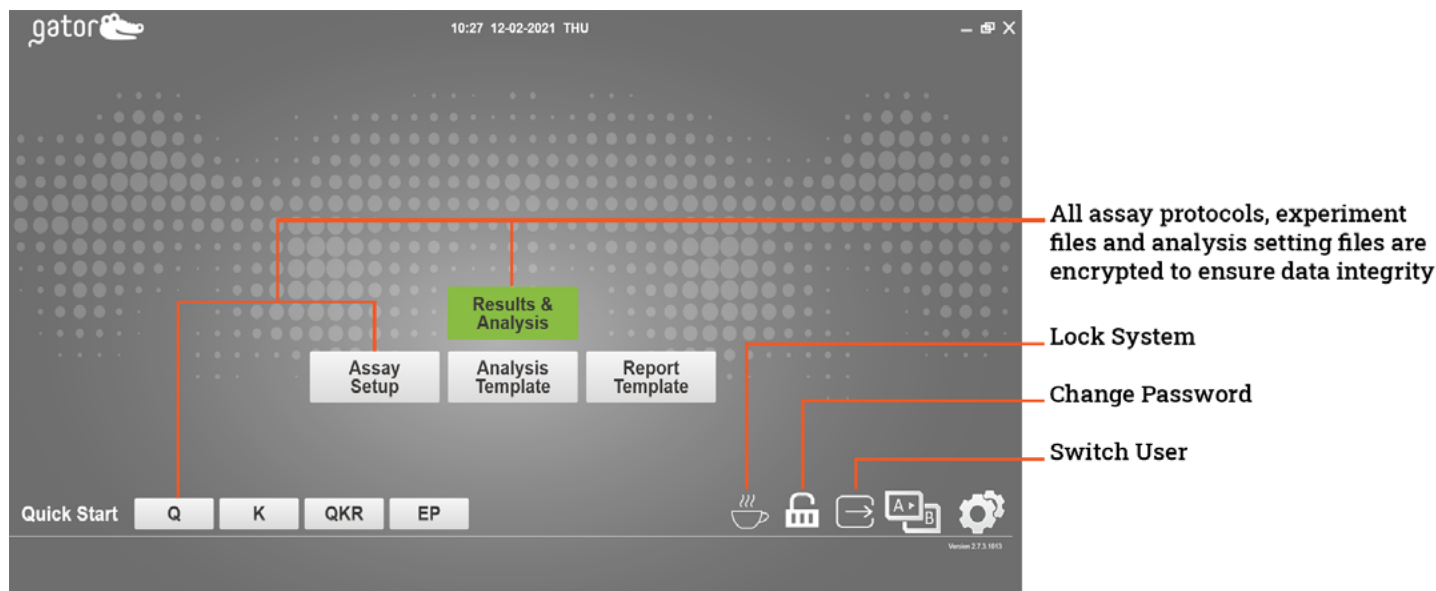
Customized Reports

Once users complete their experiments, Gator™ Part11 Software provides the capability to customize experiment reports by combining various items including graphs, data tables, and customized sensor-grams. The workspace in Gator™ GatorOne Software can then be printed and saved as a PDF file, while the customized reports can be exported as Excel files, which can be stored in the company cloud database for records.

Controlled User Level Permission

Gator™ Part11 Software controls the access of all features with which users can create, acquire, modify and analyze data, including exporting and saving results. The Administrator manages all users and sets user permissions based on their authorization level. Four user-level groups—Administrator, Supervisor, Developer and Lab User—are available with default permissions. Each user or user-level group may be customized according to the organization's requirements.

Primary Data Integrity

The integrity of raw data is a primary design consideration of Gator™ Part11 Software. All data acquired using Gator™ Part11 Software is time-stamped and traceable to the user who initiated data acquisition. All assay protocols, experiment files and analysis-setting files are encrypted to ensure data integrity. Any modification or tampering outside of the Gator™ Part11 Software environment invalidates the encryption. The Gator™ Part11 Software performs integrity checks any time methods, experiment files, or analysis settings are accessed, and alerts the user if unauthorized modification has occurred. Event logs of all activities performed in Gator™ Part11 Software are stored in the Gator™ Part11 Server database.

Experiment files created using Gator™ Part11 Software are strictly bound to features that comply with FDA 21 CFR Part 11 regulations. As a result, these files cannot be opened or modified by the non-CFR version of Gator™ GatorOne Software, to ensure the integrity of the acquired data.

Fig. 1

Gator™ Part11 Software records Audit Trail details, including user, activities, and timestamp.

Biopharma Total Solution

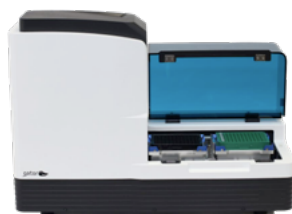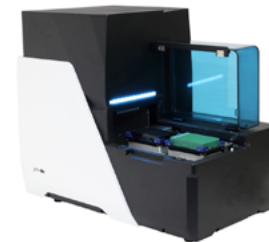**Gator™ Probes**   **GatorPrime™**   **GatorPlus™**   **Gator™ Part11 Software**

+   OR   +

Ordering Info

Catalog No. 600002: Gator™ Part11 Software