

I. Activate Secure Mode

Settings Password = "reset" Contact GemBio for license code. Enter admin user first name and last name Enter admin password Read & acknowledge warning

Touch to toggle ON

Provide Bluetooth ID and Date/Time (shown on screen)

New Administrator Required
Please update the administrator if you are not the admin, press cancel.

Secure mode requires the purchase of a separate license to activate. Contact Gemini/Orflo sales or Customer Service for a quote.

2. System Settings

Set system settings that are key to 21 CFR, Part 11

Default data gating behavior (auto vs. manual)

Set timeout for screen lock

Password expiration period

Secure Mode - On/Off Toggle

3. User Management

User Management under new "Users" Icon on Home Screen

User Roles
All Users must be assigned one of three roles when created. Brief overview below.

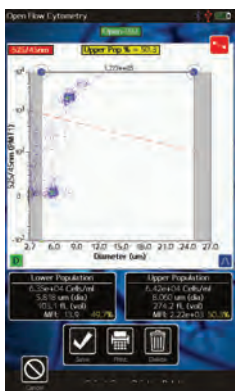
Administrator
-Generate Data
-Modify Data
-Manage Users
-System Settings
-Transfer Data
-Access System logs

Reviewer
-Generate Data
-Modify Data

Normal User
-Generate Data only

User Management Options

Electronic Signatures & Data Output

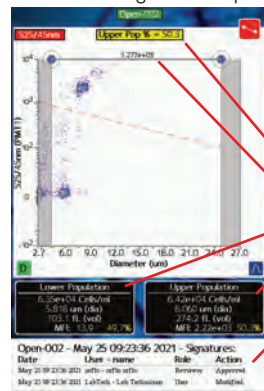


Official User Signature

**** WARNING ****
By entering your user ID and password information and clicking on "Accept", you are applying a legally binding signature to the file created when saving the data. Further password entries will constitute an equivalent, legal signature event.

Accept Decline

Auto - BMP output for all data events = permanent results & signature snapshot/log



Signature (User ID and Password) required for all data operations

All data also stored as FCS 3.1 data file with checksum protection & signature log

Data Review

Administrator & Reviewer - only review of saved user data

Saved Data Icon on Home Screen



Parent Folder (Up)



Select User ID folder to review user's data



Select test file to review.
Notes:
Signature required for any data change.
All changes are logged

USB Data Transfer

USB Disk Icon on Home Screen



Connect System to PC with USB power cable

Administrator - only access
-User Data

- *older data in "Test-Files" folder
- *Secure data in /Users sub-folder under UserID of owner
- *FCS, .BMP, and .CSV data
- System Logs (2 week's logs per file) in /Users/admin folder - logs of all relevant system events

The Moxi GO II software does not ensure 21 CFR, Part 11 compliance, by itself, as proper procedures, training, and internal controls (e.g cGMP/GLP) are also required by companies in conjunction with the firmware in order to be 21 CFR, Part 11 compliant.

The Moxi GO II is a research use only (RUO) instrument, not for use in diagnostic procedures