Secure Mode (21 CFR, Part 11)
Quick Start Guide

Moxi GO II

1. Activate Secure Mode

⚙ Settings

Touch to toggle ON

Secure Mode — On

Security Feature
Are you sure you want to implement CFR-21 Part II Signatures?
✓ Yes   ⊘ No

Password = "reset"

☑

Licensed Feature
Contact Gemini Bio-Products to upgrade. Press Cancel or press OK to sign in.
✓ OK   ⊘ Cancel

Contact GemBio for license code.

Enter

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

Enter admin user first name and last name

Enter

New Administrator Required
Please update the admin account. If you are not the admin, press cancel.
✓ OK   ⊘ Cancel

Enter admin password

Enter

Read & acknowledge warning

*** WARNING ***

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

😊 Users

User Management under new "Users" Icon on Home Screen

User Profiles
- Add a User
- Remove a User
- Edit User Account
- Sign Out

ORFLO

Current User: admin

User Management Options

Add a User

Please Select Privilege Level for User

Administration Rights
Unrestricted file access
Creates and manages users

Reviewer Signature Authority
Can create new files
Can modify existing files

Normal User
Can only create new files
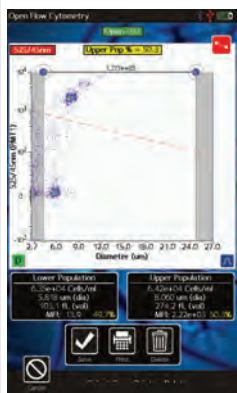Can not modify existing files

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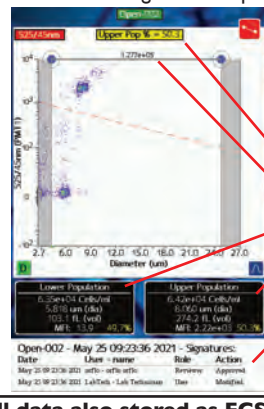
Reviewer
- Generate Data
- Modify Data

Normal User
- Generate Data only

Electronic Signatures & Data Output

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

Results

Signature

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)

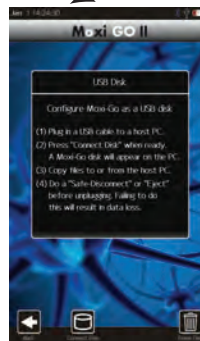Select User ID folder to review user's data

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 revelant 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

Complete User Manual can be downloaded at www.GEMBIO.com

GeminiBio
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