

lock

**Password** 

expiration period







Enter admin

password



Read &

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

# 3. User Management

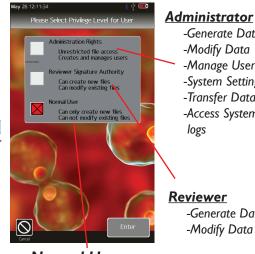




User Management Options

### **User Roles**

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



-Generate Data -Modify Data -Manage Users -System Settings -Transfer Data

logs

-Access System

#### Reviewer -Generate Data

-Modify Data

**Normal User** -Generate Data only

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

Secure Mode - On/Off

Toggle

Expiration: 3 month

**✓** 

0

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



### **Electronic Signatures & Data Output**

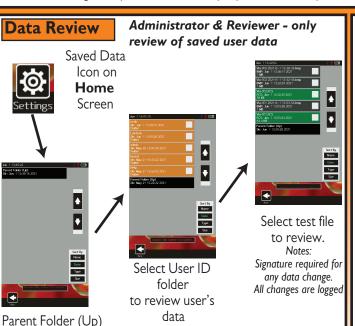




Auto - BMP output for all data events = permanent results & signature snapshot/log Results Signature

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

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





Administrator - only access

\*older data in "Test-Files" folder \*Secure data in /Users sub-folder

Connect System

to PC with USB

power cable

\*.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 V 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 V is a research use only (RUO) instrument, not for use in diagnostic procedures

