



# Microlit E-Burette Software

A robust software developed by team Microlit in compliance with FDA 21 CFR Part 11 for titration experiments conducted with Microlit E-Burette



ISO 17025



ISO 9001



UK  
ISO 13485

## What is FDA 21 CFR Part 11?

Considering the growing shift to digital record-keeping, the FDA (Food and Drug Administration, USA) introduced 21 CFR Part 11 (Code of Federal Regulations) in 1997 outlining guidelines on the usage of electronic documentation and electronic signatures. It was designed to help **pharmaceutical, healthcare and other biological & drug manufacturers** regulate the administration of their electronic records by:

- ◆ Knowing how to operate computer software and carry out basic troubleshooting
- ◆ Storing electronic records securely with indisputable electronic signatures
- ◆ Tracing data changes and preventing/detecting falsified records through audit trails

Microlit understands that electronic record-keeping is now a common industry practice. Therefore, it's critical to ensure the security and integrity of the stored data with the help of a software solution that complies with the strict regulations of FDA 21 CFR Part 11.

## Presenting the Microlit E-Burette Software

We've always upheld the importance of maintaining the validity, reliability and authenticity of the experiments conducted with our high precision liquid handling equipment. In line with this thinking, we're glad to present the all-new Microlit E-Burette Software developed in compliance with FDA 21 CFR Part 11 after 12 months of intensive R&D.

As users, you will now be able to create titration experiments as electronic records on the software and directly transfer E-Burette readings to it. Based on the inputs and the readings received, the software will automatically compute the molarity/normality of the analyte. Additionally, the integrity of the stored data will always stay protected as per the regulations laid down by the FDA.

# MICROLIT E-BURETTE

## with 3 Calibrated Pre-set Speeds

Microlit E-Burette, a state-of-the-art burette, offers sophisticated features like Motor Controlled Piston Movement, a touch-enabled Control Panel with Graphical User Interface (GUI), and 3 Calibrated Pre-Set Speeds to perform highly accurate titrations. For more product info, scan this QR code:



## Exciting Features & Benefits



### MULTI STEP AUTHENTICATION

*An additional layer of security*

In line with our intent to build infallible security mechanisms, a user is required to pass through a multi-step authentication process to operate the software and access the data.



### DATA SECURITY

*No falsified records ever*

Once recorded, the titration experiment data cannot be edited. This makes it 100% reliable, credible and authentic.



### AUDIT TRAIL

*An eye on every activity*

From user login/logout to the creation of a new experiment, the software records every user activity in an audit trail. It is completely secure and can only be accessed by permitted users.



### USER INTERFACE

*Intuitive and easy to grasp*

The software interface has been designed to maximise user convenience. With an intuitive design and easy navigation, you will understand how to operate it in no time.



### DATA AUTHENTICITY

*Complete safety and privacy*

The software keeps the data safe via a sturdy security mechanism involving multiple authentication checks, audit trails, non-editable electronic records, and more. Also, Microlit cannot access the data stored on your instance of the software: You have complete control over your organisation's database.



### TITRATION CHOICES

*Versatility at its best*

The software gives you the option to perform the titration experiment of your choice - Volumetric Titration or Assay Titration - further enhancing user comfort.

## Industrial Applications

The Microlit E-Burette Software designed in compliance with FDA 21 CFR Part 11 is immensely advantageous for **Pharmaceutical Companies** carrying out electronic record-keeping.

## System Requirements

- Currently compatible with Windows Operating System
- Require a reliable and secure LAN or wireless network

## ORDERING INFORMATION

S. No.	Description	Model No.
1	Server setup & one client licence	TI - SW - S
2	Additional client licence (required for each additional computer setup)	TI - SW - C

## OUR REACH



## YOUR SATISFACTION IS OUR PRIORITY

Microlit products follow GMP norms and are manufactured under comprehensive QA (Quality Assurance) and QC (Quality Control). However, if you are dissatisfied with the operation of any of our products, get in touch with us or call your nearest Microlit dealer for free replacement.

## CONTACT US

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