

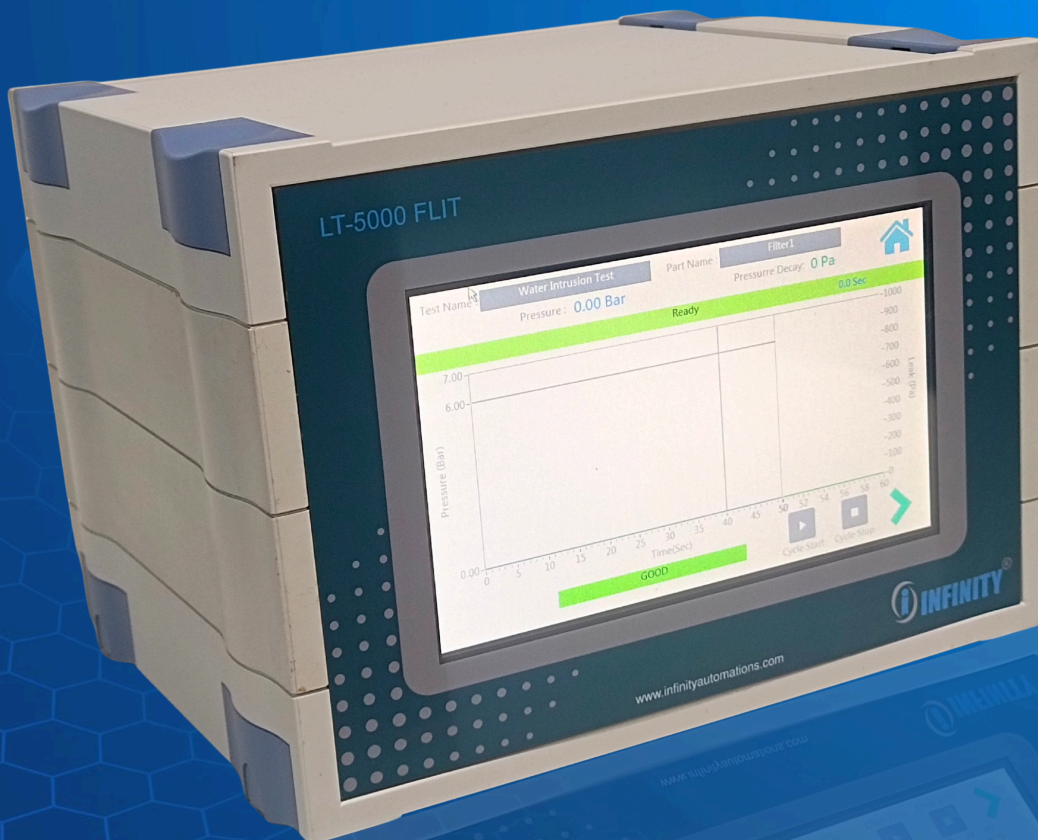


Infinity Automation Systems Pvt. Ltd.

Filter Integrity Tester

LT-5000 FLIT

Integrity Assured, Intelligence Built In..!



SINCE
2
DECADES

150+
EMPLOYEES

PAN
India



EMA
ANNEX 11

WWW.INFINITYAUTOMATIONS.COM

Introduction

The LT-5000 FLIT Filter Integrity Tester is a compact, high-precision system designed for reliable filter integrity measurement with advanced security and automation features.

Key Points

- Operates from 50–9000 mbar
- Supports Bubble Point, Diffusion Flow, and Water Intrusion tests
- Includes Ethernet & USB communication
- Built-in password protection, authority control, and e-signature
- Equipped with an automatic sterilization control system



As per **ASTM, FDA 21CFR Part11, USP 1207, NABL, CE, ISO 9001:2008, EMA ANNEX 11** guidelines

TECHNICAL SPECIFICATIONS

SPECIFICATIONS	MICRO LEAK DETECTION
Input power	100 to 260 VAC, 50 Hz, 120W
Environmental Condition	Ambient Temperature: +5°C to +40°C Relative Humidity: 10 to 80%
Unit	m bar/kpa/pa
Test Scope	BP: 50 to 9000 mbar DF: up to 1000 ml/min WI: 0.01 to 150ml/min
Test Accuracy	0.075%
Modes	Bubble Point Test, Diffusion Flow Test, Water Intrusion Test
Print Function	Compatible
Internal Memory	Stores upto 5 years of data
Test Report	In-built non-editable, printable PDF format
Display Screen	7"/10" color touch screen - resistive/capacitive
Connectivity	Serial Ethernet & USB
Weight	6.5 Kg

FEATURES

Offers a wide range of integrity testing, compatible with all existing test methods.

Integrated security framework offering password protection, permission control, hierarchical authority grading, and electronic signature support.

Compatible with SAP, ERP communication with various protocols like Profinet, UDB, OPC etc.

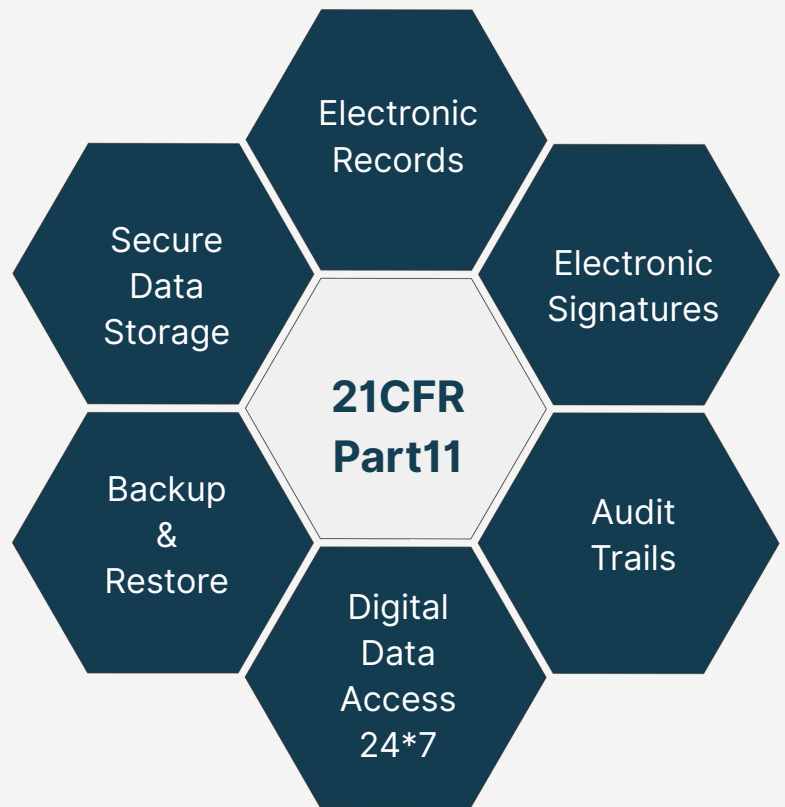
Dedicated development team for customization

APPLICATIONS

Filter Integrity Testers play a vital role precisely in the food and pharmaceutical industries, where-in the product ranges from capsule filter housings, industrial filter cartridges, membrane filtration systems, Syringe Filter etc., to name a few

21CFR PART11 COMPLIANT LT-5000 FLIT

- To keep pace with the increasing use of electronic systems and technology in FDA-regulated industries, 21CFR Part11 was introduced, ensuring the same level of data integrity, authenticity, and reliability as paper-based systems
- Basically, 21CFR Part11 is a regulation established by the U.S. Food and Drug Administration (FDA) that outlines the requirements for the use of electronic records and electronic signatures in FDA-regulated industries, including pharmaceuticals.
- Adhering to these guidelines, the introduction of Information Technology (IT) in compliance was a milestone.
- It establishes requirements for the security, integrity, and availability of electronic records and the validation of electronic systems used for GxP (Good Laboratory Practices, Good Clinical Practices, Good Manufacturing Practices) activities.



Audit Trail:

- Tamperproof and Non-Editable Audit Trail Data Format.
- The time stamp of the change of the parameter value and the user making the change
- The audit trail records the following details-
- User Creation
- User Login/ Logout
- Wrong attempts at login
- User Block / Unblock by Administrator
- Old value and new value of the parameter change
- The time stamp of each event

Electronic signatures:

- Through 3/4 user level validation & authentication

System Data and Data Backup:

HMI offers basic connectivity for data exchange with Central SCADA / MES / ERP by following the means:

- Through OPC UA
- Through Data file transfer
- Through USB / SD Card Backup

Electronic Data Record and Data Storage:

- Review of the reports on the HMI Screen for Production, Alarms, and Audit Trail.
- Storage limit can be interlocked in terms of the number of batches produced or % of the memory consumed.

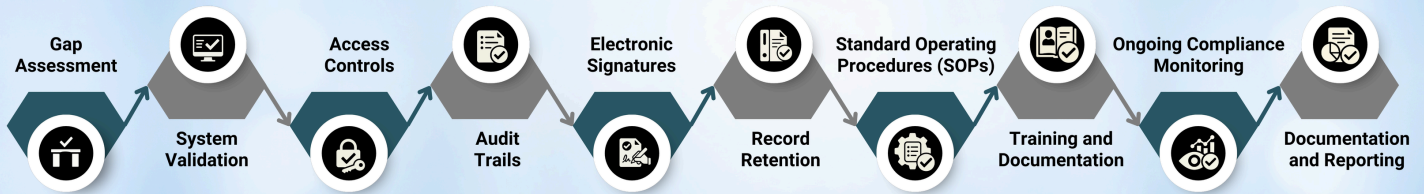
User Management Functionalities:

- Password-protected individual Unique user account.
- Password Complexity.
- Minimum 8 Character password length.
- Configurable Number of Wrong Attempts
- User Block/Unblock Facility
- Password Validity
- Multiple User Levels as per the User Rights

Report Generation and Printing:

- Batch data is stored in a secure database format, and the Batch Report can be generated using this data.
- The report printing has been offered in multiple ways
- Online printing of Alarms, Events, and Logged data through Serial Printer

IMPLEMENTATION OF 21CFR PART11

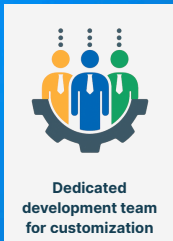


SERVICES FOR CCIT METHOD SETUP

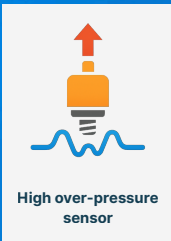
- PAN India service support
- Dedicated development team for customization
- High over-pressure sensor
- Accuracy to detect up to 0.5 μm
- Method setup:
- Micro drilling services
- Micro-calibrated leak
- Master (solid dummy)
- Positive control (1 μm , 5 μm , 10 μm , 20 μm)



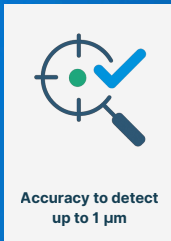
PAN India service support



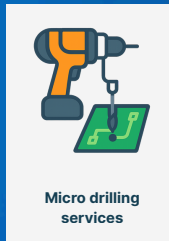
Dedicated development team for customization



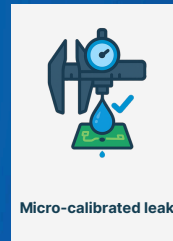
High over-pressure sensor



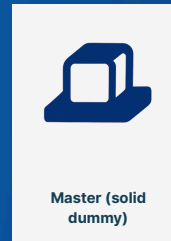
Accuracy to detect up to 1 μm



Micro drilling services



Micro-calibrated leak



Master (solid dummy)



Positive control (1 μm , 5 μm , 10 μm , 20 μm)



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