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PHARMACEUTICAL EQUIPMENT

Leak Tester

Embedded Linux | Raspberry Pi 5 | Touchscreen GUI | Hardware Control Backend | Automated Report Generation | Audit & Compliance

CLIENT

A Mumbai-based supplier of precision pharmaceutical and laboratory equipment, serving major pharma companies across India and internationally. They required a complete embedded control and reporting system for their packaging leak tester, supplied in two variants: a standard version and an advanced audit-compliant version for regulated environments.

THE PROBLEM

Packaging integrity is a critical quality checkpoint in pharmaceutical manufacturing. Blister packs, strips, sachets, and bottles must be hermetically sealed — any breach means product degradation, contamination risk, or a failed regulatory audit. The standard test method places a sample inside a vacuum chamber, evacuates the chamber to a set pressure, and holds it there for a defined period; a drop in vacuum indicates a seal failure. Simple in principle, but the instrument needs to execute that sequence precisely and document every result. The client's existing setup relied on manual parameter entry and paper records, with no way to enforce consistent test conditions across operators or shifts, and no structured audit trail to satisfy quality reviewers. What they needed was an instrument that handled the test automatically from start to finish, and produced a traceable record of every run without any extra steps from the operator.

WHAT WE BUILT

We built the full control and data system for the instrument across two layers. The backend manages the vacuum pump, monitors chamber pressure throughout the hold period, compares the final reading against the pass/fail threshold, and returns the result to the application. The frontend — running on a Raspberry Pi 5 with a 7-inch touchscreen — gives the operator a clean interface to set test parameters, watch the test in progress, and review results. A method library handles the repetitive work: operators save standard configurations for each packaging type they test, so a routine run is a matter of selecting the method and loading the sample. After each test, a report is generated automatically with the method used, the pressure profile, the pass/fail verdict, and a full timestamp. All reports are stored on the instrument and searchable without a separate PC.

As with the client's other instruments in this programme, the system was built in two versions. The standard version covers the full test and reporting workflow. The audit-compliant version adds role-based access, electronic signatures, and a locked, tamper-evident audit trail — meeting the electronic records requirements that regulated pharmaceutical manufacturers and their contract packagers work under.

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WHAT IT DOES

- ✓ Operator selects a saved method for the packaging type being tested — or configures a new one — setting vacuum level, hold duration, and pass/fail threshold
- ✓ Backend controls the vacuum pump, evacuates the chamber to the target pressure, and holds it for the set duration while monitoring continuously
- ✓ Any pressure rise during the hold period is detected and recorded — the system automatically determines pass or fail against the method threshold
- ✓ Live test status shown on the touchscreen throughout: current pressure, elapsed hold time, and real-time pass/fail indication
- ✓ Test report generated automatically on completion: method used, pressure profile, result, operator, and timestamp — no manual recording required
- ✓ All reports stored on the instrument, searchable by date, product, or operator, and printable or exportable directly from the interface
- ✓ Full audit trail logs every user action and system event with a timestamp
- ✓ Audit-compliant version adds role-based access control, electronic signatures, and a tamper-evident audit trail for regulated pharmaceutical environments
- ✓ Backup and restore covers all saved methods, reports, and settings; admin functions kept in a separate area from the day-to-day test workflow

OUTCOME

The client received an instrument that executes the full leak test sequence automatically and produces a complete, traceable record of every run — with no manual data entry, no paper logs, and no reliance on operator memory for test parameters. The audit-compliant version gives regulated facilities a ready-to-inspect electronic records system built into the instrument, requiring nothing additional to satisfy quality reviewers.

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