BIOTECH

Palltronic® Flowstar LGR Test Instrument

USD3015a

Fast Fully Traceable Testing of Single-Use Systems (SUS) at Point-Of-Use

Single-use technologies in formulation and filling applications are gaining fast market acceptance both in clinical and manufacturing operations. This has led to an increase in requirements in validation and robustness of SUS. As a result, point-of-use testing of SUS is quickly becoming a requirement. At Pall, we set up very high standards with regards to the design and validation of the manufacturing process of Allegro® SUS and operators should be well-trained in unpacking, handling, and installing SUS. There is still a requirement in the biopharmaceutical industry to confirm the absence of leaks prior to or after use from a risk management perspective. The availability of an easy and reliable point-of-use leak test provides end users with the confidence that the SUS they are going to use is leak-free and has not been damaged during the installation, and/or use or storage process.

The Palltronic Flowstar LGR test instrument enables point-of-use leak testing of SUS up to 200 L nominal volume and provides the ability to test the integrity of the filters within the SUS. This technology has an extremely small footprint, is easy to use, and is compliant with current regulatory standards. The instrument allows end users to test endless configurations of SUS and filters, with one device, without compromising the sterility of the system. Designed for use in the vaccines, biotech, and pharmaceutical markets and with a specific focus on formulation and filling applications where sterility of the SUS needs to be maintained, the Palltronic Flowstar LGR instrument meets all of the key user needs such as:

- Robust true point-of-use test to confirm the absence of damage to SUS during transportation, installation and/or use
- Safe: test can be done without breaching the sterility of the tested system
- Fast: leak testing of SUS can be achieved within 15 minutes
- Flexible: ideal for both pre and post-use integrity tests of filters integrated in SUS
- Compliant: full traceability of the system data and the testing data according to CFR 21 Part 11

Features and Benefits

Features	Benefits
Technology	
All configurations of SUS (nominal volume < 200 L) can be tested	Very high degree of flexibility, can test systems with or without biocontainer
Leak detection is based on flow measurement	■ Exact volume of the systems does not need to be calculated or measured ■ Easy input of threshold values for any configuration of a SUS
Different leak test pressures can be used	■ High pressure testing for SUS without biocontainers provides increased test sensitivity ■ Low pressure testing prevents damage to 2D and 3D biocontainers in tested systems
Sterilizing filters integrated into reducing equipment requirements	Test unit has multiple functions - the filter can be checked for integrity and tested pre and post use, single-use systems can be leak tested, maximizing footprint usage in the cleanrooms
Test can be carried out with air or nitrogen	Nitrogen can be used for pre-use testing of systems for oxygen sensitive products in final filling applications
Ease of Use	
True point-of-use test unit	Test is performed on the single-use system as it will be used during the process, this removes additional risks due to extra handling
Storage of individual recipes for the testing of SUS	Test parameters are stored in test programs that are aligned with system part number
Barcode reader supplied for selection of test program and input of system part number and batch number	Prevents transcription errors
Short test times - less than or equal to 15 mins	Avoids impact on cycle time of the manufacturing process
Small footprint for test unit	Minimizes impact on layout of the manufacturing suite
Quality and Regulatory	
Fully validated and CFR 21 Part 11 compliant software	■ Full audit trail of tests provided with electronic signatures ■ Test data can be recorded, printed or downloaded and stored in a compliant manner
Easy and secure connection of the test unit to the single-use system	■ Quick connection through Stäubli fitting ■ Connection of the instrument on the non-sterile side of a 0.2 µm gas filter in the SUS allows for *in-situ* leak testing and filter integrity testing without breaching the sterility of the SUS flow path.

Direct Flow Measurement

The Palltronic Flowstar LGR integrity test instrument utilizes a method that was developed by Pall for use in integrity test instruments and patented as “volume-dosed flow measurement technology”. Unlike pressure hold or pressure decay based tests, Pall’s volume dosed flow measurement method is independent of the tested volume and offers clear advantages in terms of reduced overall test time, accuracy, reliability, and test reproducibility.

Testing Capabilities of the Palltronic Flowstar LGR Instrument

Test Function	Measurement	Technical Specification	Notes
SUS leak test	Flow	Test pressure range: 50 – 500 mbar Measuring range: 0.1 – 1000 mL/min	
Leak test	Flow	Test pressure range: 50 – 6500 mbar Resolution: 0.1 mL/min Measuring range: 0.1 – 1000 mL/min	
Forward flow test	Flow	Accuracy: ± 3% of value or ± 0.05 mL/min whichever is greater Resolution: 0.1 mL/min (0.01 mL/min for flows below 10 mL/min) Measuring range: 0.1 – 1000 mL/min	Recommended test for integrity testing filters integrated in SUS
Water intrusion test	Flow	Accuracy: ± 3% of value or ± 0.02 mL/min whichever is greater Resolution: 0.01 mL/min Measuring range: 0.03 – 50 mL/min	Hydrophobic filter test only

Unique Design

- Built to GAMP 5 guidelines
- LAN and WLAN networking capabilities
- USB connectivity – can be used with flash drives, barcode readers, printers
- Intuitive user interface with color touch screen

Electronic Data Handling and Remote Control

Range of automation options including:

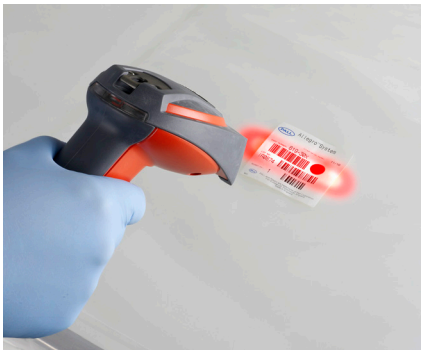
- OPC UA
- ProfiBUS DP (optional)
- DeviceNET (optional)

The Palltronic Flowstar LGR instrument can synchronize with network clocks and can export test results directly to a Windows◆ shared folder. Electronic print options include compatibility with network printers and automatic file generation (PDF and/or XML format) on a USB flash drive or Windows shared folder.

Leak Testing of SUS Containing Flexible Biocontainers

Systems containing 2D biocontainer

When testing a SUS with a 2D biocontainer(s), the test gas must be completely vented when the test is complete. Pall's air evacuation device (patent pending) is designed to fit directly into the Allegro tray that is already used as biocontainer bag supporting hardware. Simply place the air evacuation device in the tray, lift the silicon cover, insert the 2D biocontainer bag handle into the retaining clasp, and lay the silicone cover over the top face of the biocontainer bag. As the single-use system leak test runs, the biocontainer bag will inflate and lift the silicone cover with it. When the test is complete the weight of the cover will result in full evacuation of the air from the bag without any operator handling. The full system can remain in place and does not have to be removed from the air evacuation device prior to further processing.



Systems containing 3D biocontainer(s)

Unlike systems containing 2D biocontainer(s), systems containing 3D biocontainer(s) can remain inflated prior to use, provided an air vent filter is present at the top of the 3D biocontainer bag.

Point-of-Use Testing of SUS

Unpack the single-use system

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Install the system how it will be used during processing so that it does not need to be handled after the test. When applicable, position the 2D biocontainer within the air evacuation device and/or tote.

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Connect the Palltronic Flowstar LGR instrument directly to the upstream side of the SUS vent or liquid filter. This ensures the sterile boundary is maintained.

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Scan the part number and batch number barcode of the Allegro single-use system with the Palltronic Flowstar LGR bar code scanner. Enter the operator name and any other necessary information for record keeping and press the start button on touch screen.

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The leak test will be completed in approximately 15 minutes, after which the test result will be displayed. A successful test will result in the message PASS- NO LEAK DETECTED.

Technical Specifications

Physical Dimensions (nominal)
Weight: 10 kg (21.6 lbs)
Width, height, depth: 348 mm x 205 mm x 483 mm (13.7 in. x 8 in. x 19 in.)

Testing Capabilities
SUS leak test (for volumes up to 200 L nominal)
Leak test (for volumes up to 200 L nominal)
Forward flow test
Water intrusion test

Function Tests
Self test
Flow check test
Printer test
Network test
Other functions
Cleaning function
Test program transfer function
Configuration transfer function
Access management transfer function
Test result export function
Back-up function

Language Options
English, Japanese
Language files on the instrument are constructed such that other languages may be added as necessary.

Communication Ports
USB
Ethernet
Wireless ethernet network

Accuracy
Forward flow test: ± 3% of reading or ± 0.05 mL/min, whichever is the greater
Water intrusion test: ± 3% of reading or ± 0.02 mL/min, whichever is the greater

Measuring Range
SUS leak test: 0.1 – 1000 mL/min
Leak test: 0.1 – 1000 mL/min
Forward flow test: 0.1 – 1000 mL/min
Water intrusion test: 0.03 – 50 mL/min

Resolution
SUS leak test: sensitivity up to 30 µm (volume dependent)
Leak test: 0.1 mL/min
Forward flow test: 0.1 mL/min (0.01 mL/min for flows below 10 mL/min)
Water intrusion test: 0.01 mL/min

Calibration
The calibration of the Palltronic Flowstar LGR instrument includes a calibration of the pressure transducers and the flow measurement calibration limits:
Pressure measurement: ± 0.33% of full scale
Flow measurement: ± 3% of measurement

Electrical Data
Voltage: automatically adjusted between 100 – 240 V AC
Input frequency: 50 Hz / 60 Hz
Power: typically 75 W (peak 150 W)
Fuse: 3.15 A slow blow
External vent valve: 24 V DC

Screen
Size: diagonal 264 mm (10.4 in.)
Resolution: 1024 x 768 pixels
Features: color, illuminated background, adjustable contrast, touch screen

Pneumatic Connections
Compressed air inlet: Stäubli nipple
Compressed air outlet: Stäubli coupling
Vent: hose connection 8 mm outer diameter

Pneumatic Specifications
Maximum gas supply pressure: 8000 mbar (116 psi)
Minimum gas supply above test pressure (Standard):
– Flow range: 0.01 – 150 mL/min 1000 mbar (14.5 psi)
– Flow range: 150 – 1000 mL/min 2000 mbar (29.0 psi)
Test pressure range: 50 – 6500 mbar (0.7 – 94 psi)

Internal Printer
Thermal printer
Printer resolution: 832 dots/line
Lifetime of printout: 10 years depending on storage conditions
Printer speed: 12 mm/sec (0.5 in./sec) printout with graphic
Paper width: 112 mm (4.4 in.)
Paper roll diameter: 50 mm (1.9 in.)

External Printing Function
External USB printer
External network printer (The printer should be capable of handling the printer language PCL5e)
Virtual printing to PDF or XML file format

Environmental Conditions
Splash proof: IP54
Operating temperature: +5 °C to +50 °C
Storage temperature: -20 °C to +70 °C
Humidity: 95% RH (no condensation)

Operating System
Linux◆ (The source code which falls under the GNU, general public license stored on the USB flash drive supplied with the instrument)

Ordering Information

Part Number	Description
FFS04R-LGR	Palltronic Flowstar LGR instrument for testing single-use assemblies
AEDLGR005	Air evacuation device for a 5 L biocontainer bag to fit an Allegro tray with part number LGRTPE20L
AEDLGR010	Air evacuation device for a 10 L biocontainer bag to fit an Allegro tray with part number LGRTPE20L
AEDLGR020	Air evacuation device for a 20 L biocontainer bag to fit an Allegro tray with part number LGRTPE20L
AEDLGR050	Air evacuation device for a 50 L biocontainer bag to fit an Allegro tray with part number LGRTPE50L

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