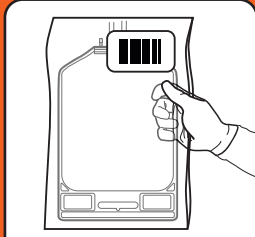
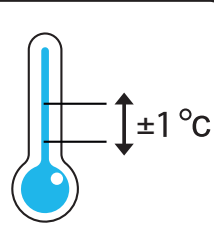


Point of Use Testing of Single-use Systems (SUS) Using the Palltronic® Flowstar LGR Instrument

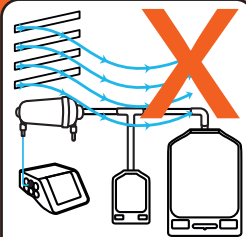
1 BEFORE YOU START



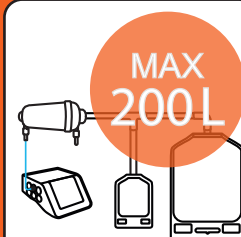
Retain outer packaging with part number bar code to identify correct test protocol.



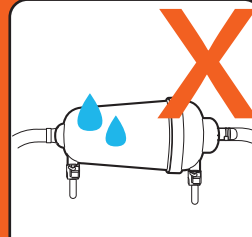
Environment temperature should be controlled within ± 1 degree celsius.



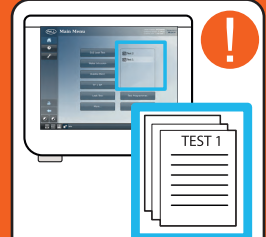
Ensure SUS is not under direct air flow. E.g. HVAC units.



Volume of the system to be isolated for testing is 200 L nominal or less.

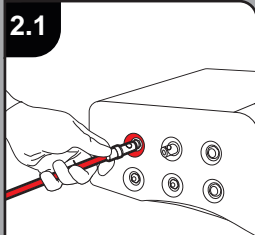


Leak test must be done before any filter integrity test to ensure filters are dry.

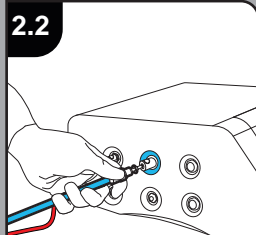


Ensure a test program has been created with the test program name matching the SUS part number.

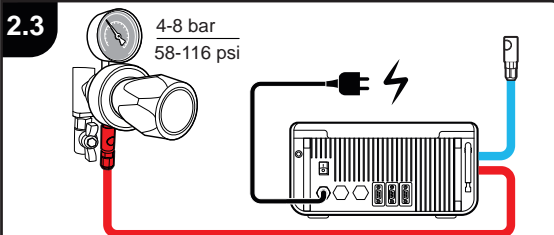
2 PALLTRONIC FLOWSTAR LGR INSTRUMENT



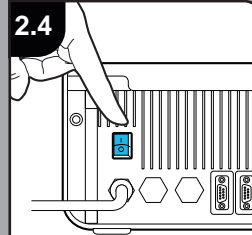
Connect the airline to the Palltronic Flowstar LGR Instrument 'IN' port.



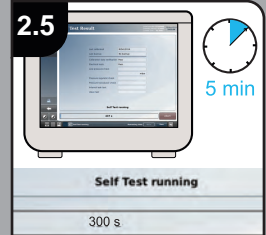
Connect the outflow to the Palltronic Flowstar LGR Instrument 'OUT' port.



Connect the airline to an air source and turn on the air flow. Check that pressure is between 4 and 8 bar (58 - 116 psi). Connect the Palltronic Flowstar LGR Instrument power cord.



Power on the Palltronic Flowstar LGR Instrument.



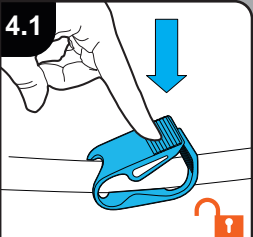
Auto test will take approx. 5 minutes to complete. If test fails, consult manual.

3 CHECK POINT

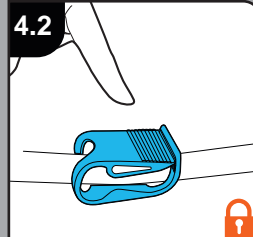


Volume of the system to be isolated for testing is 200 L nominal or less.

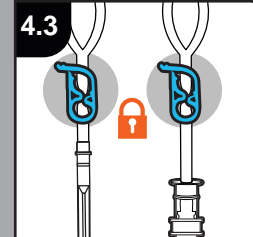
4 CLAMP OPERATION



Press down on clamp to close.

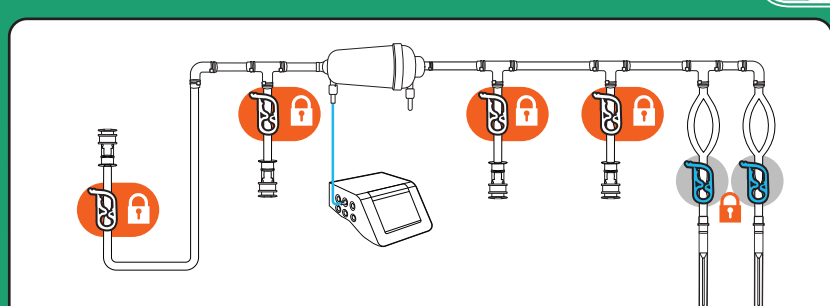


Make sure the clamp is fully closed.



All open ends must be clamped closed.

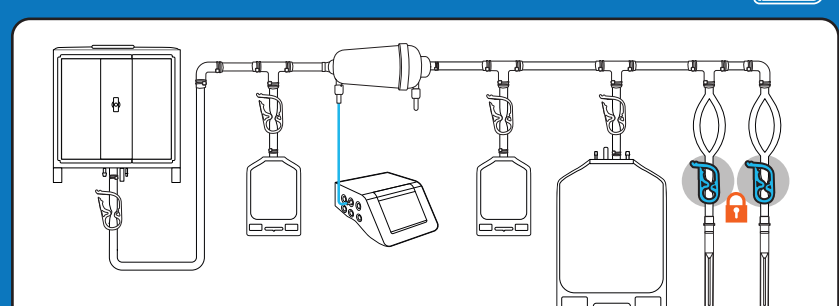
5A LEAK TEST / SYSTEMS WITHOUT BIOCONTAINERS



Close ALL blue clamps AND ensure ALL 2D and 3D biocontainers are clamped closed. Never perform a tubing only test without clamping off all biocontainers as a much higher pressure is used for this test.

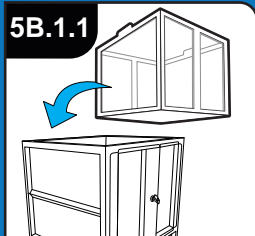
OR

5B SUS LEAK TEST / SYSTEMS WITH 2D AND OR 3D BIOCONTAINERS

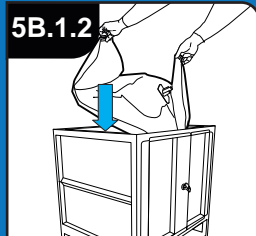


Close ALL blue clamps.

5B.1 3D ALLEGRO™ BIOCONTAINER SET UP

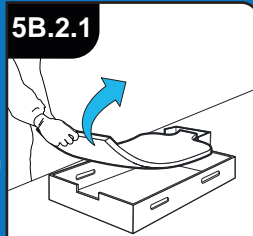


Place Allegro mesh in Allegro plastic tote.

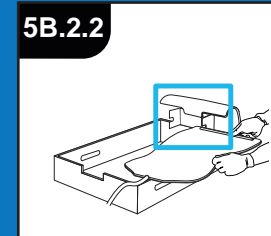


Each 3D biocontainer must be placed in an Allegro mesh for this test.

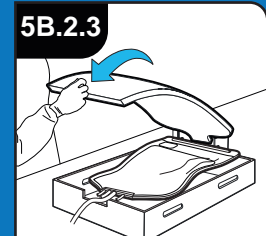
AND OR



Check 2D biocontainers (of 5-50 L ONLY) are placed within Allegro plastic trays.

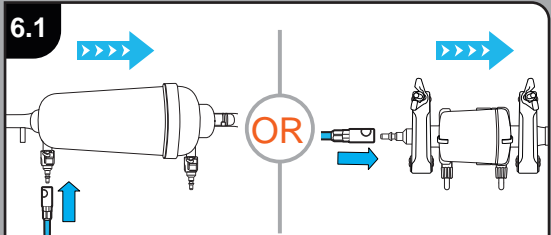


Lift up the silicone cover of the Allegro plastic tray. Slide the 2D biocontainer into the retention slot.

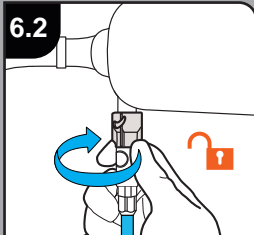


Place the silicone cover on top of the 2D biocontainer.

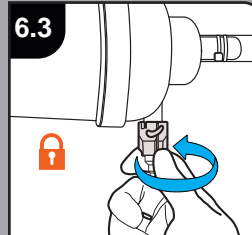
6 FILTER SET UP



Connect the Palltronic Flowstar LGR Instrument outflow line to the Stäubli fitting on the filter vent or inlet.

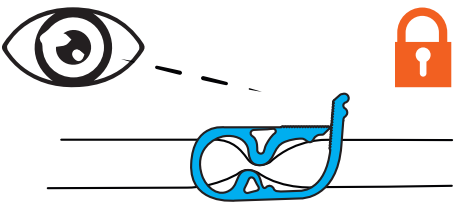


Open the filter vent valve.



Close all filter drain valve(s).

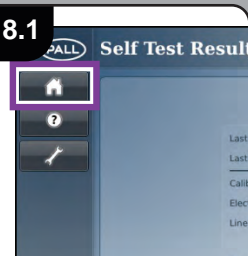
7 VISUAL CHECK



WARNING! Selecting the wrong test may damage the SUS or provide inaccurate results. Visually check to ensure clamping of the SUS is appropriate for the desired test.

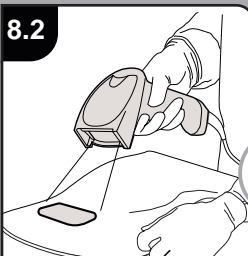
8 PALLTRONIC FLOWSTAR LGR USER INTERFACE SETUP

8.1




Press the home button to access the home screen.

8.2



Scan barcode located on SUS outer packaging.

8.3

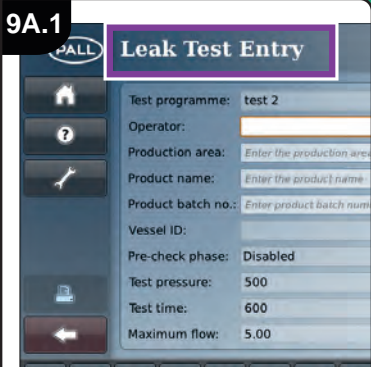


Manually select correct test program.

OR

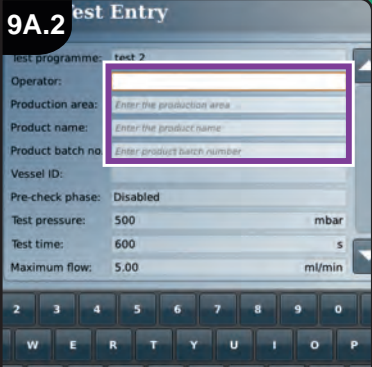
9A LEAK TEST / SYSTEMS WITHOUT BIOCONTAINERS

9A.1




Check test name. For a tubing only leak test this should read 'Leak Test Entry'.

9A.2




Enter user information.

9A.3



Press OK button.

9A.4

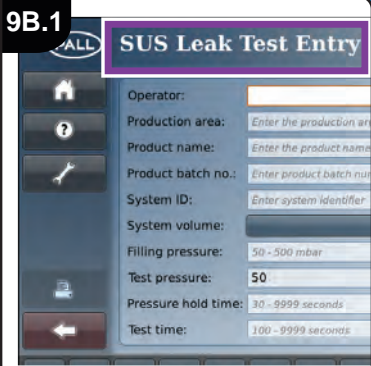


Review data entry.

OR

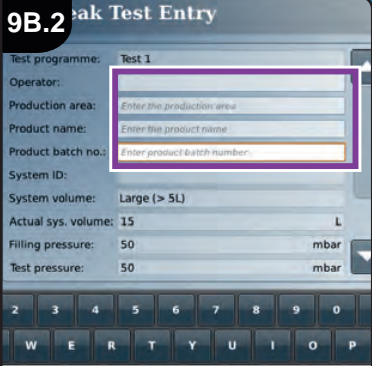
9B SUS LEAK TEST / SYSTEMS WITH 2D AND OR 3D BIOCONTAINERS

9B.1




Check test name. For a SUS leak test (2D, 3D biocontainers and tubing) it should read 'SUS Leak Test Entry'.

9B.2




Enter user information.

9B.3



Press OK button.

9B.4



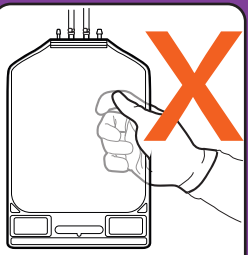
Review data entry.

10 START TEST

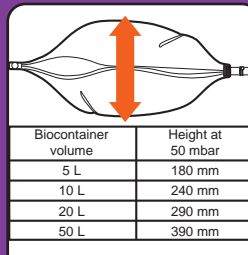


Press 'Start' to begin the test.

11 CHECK POINT



The test may take up to 30 minutes to complete. Do not touch the SUS during test.



Biocontainers may inflate to a considerable size during the test.

Biocontainer volume	Height at 50 mbar
5 L	180 mm
10 L	240 mm
20 L	290 mm
50 L	390 mm

12 REVIEW TEST RESULT

PASS

Pass: No leak detectable.

Pass: Flow within limits: X mL/min.

Pass indicates that no leak was detectable. Flow is less than the flow limit.

FAIL

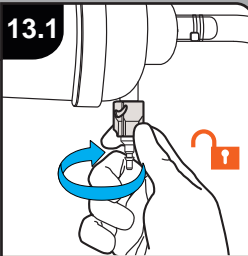
Fail: Flow outside limits: X mL/min.

Fail indicates that a leak was detected. Flow is above the flow limit.

If test fails check for obvious leaks and repeat the test. If the repeat result is also a fail please contact your Pall representative.

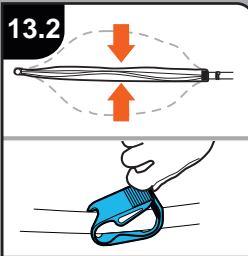
13 AIR EVACUATION

13.1



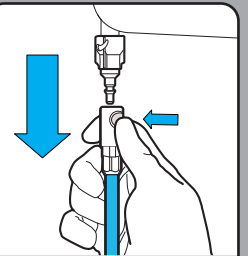
Open filter drain valve(s).

13.2



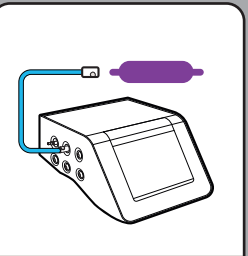
Open system section clamps as required. Allow air to evacuate until fully deflated.

14 DISCONNECT



Once air has evacuated, disconnect the Palltronic Flowstar LGR Instrument outflow from filter.

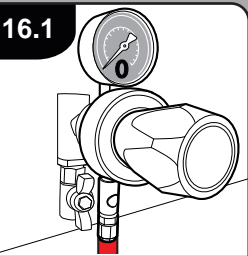
15 NEXT TEST



Connect Palltronic Flowstar LGR Instrument to another SUS for testing.

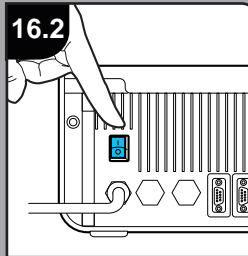
16 POWER OFF

16.1



Turn off the airflow to the Palltronic Flowstar LGR Instrument.

16.2



Switch off the Palltronic Flowstar LGR Instrument power switch.