M19 | MATERIAL INTELLIGENCE LAB

Introducing the Next-Generation
Bubble Point Integrity Tester

FILTER INTEGRITY ANALYZER
for superior sterility needs

Introduction

In the world of pharmaceuticals, maintaining product integrity and sterility is paramount. Our Next-Generation Advanced Filter Integrity Tester brings you a powerful solution for precisely assessing the reliability of your filtration systems. Let's explore how this cutting-edge technology can elevate your quality control processes.

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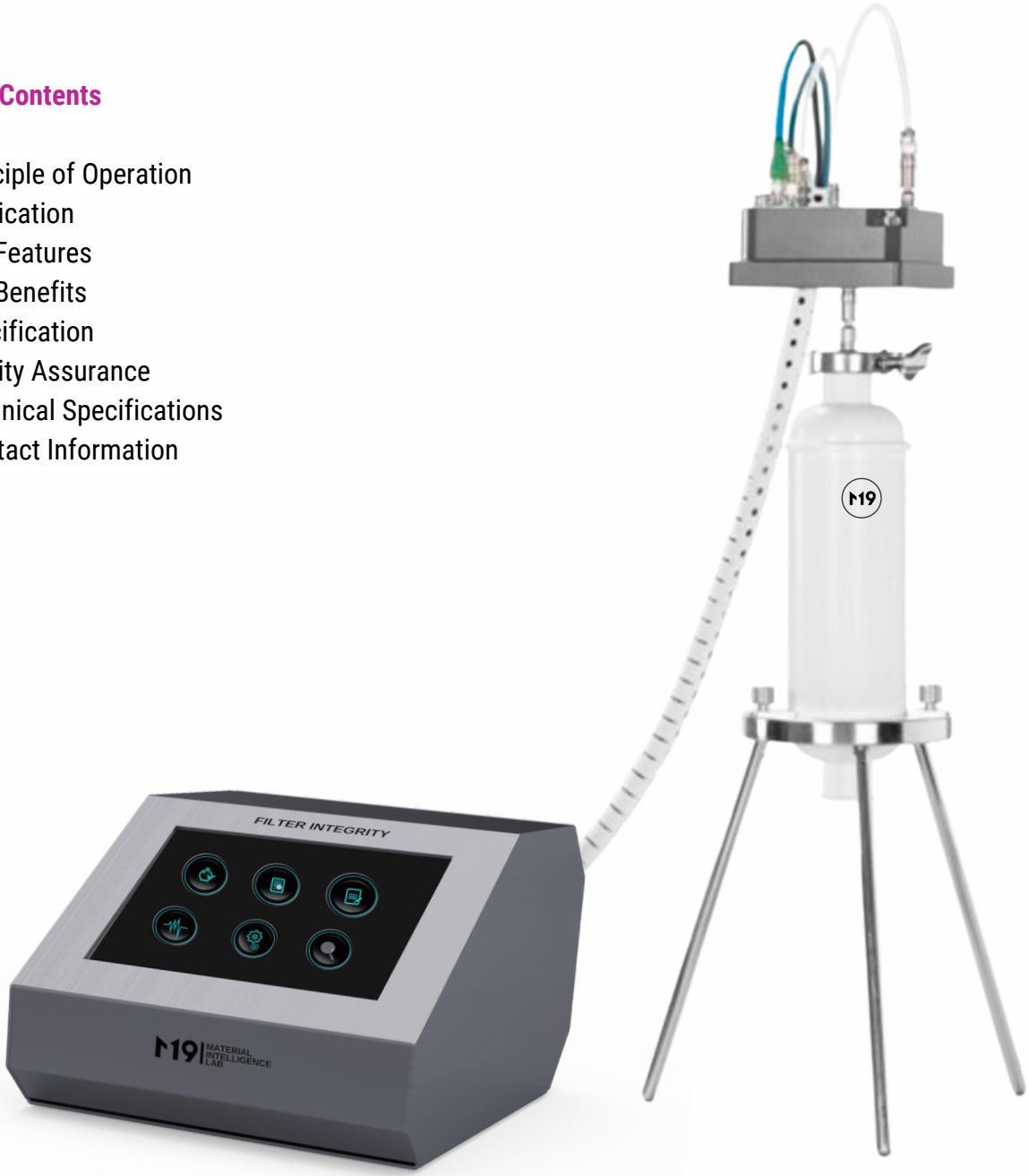
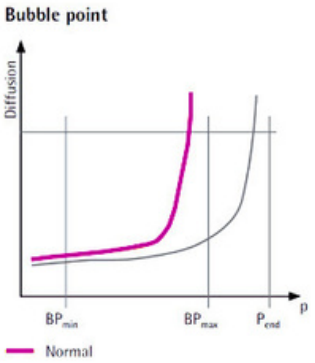
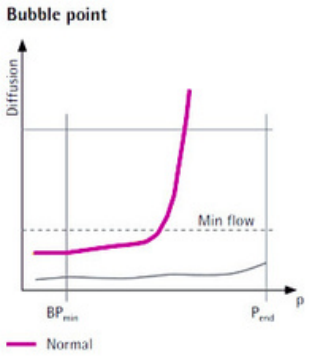


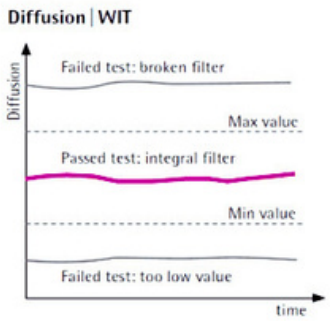
PRINCIPLE

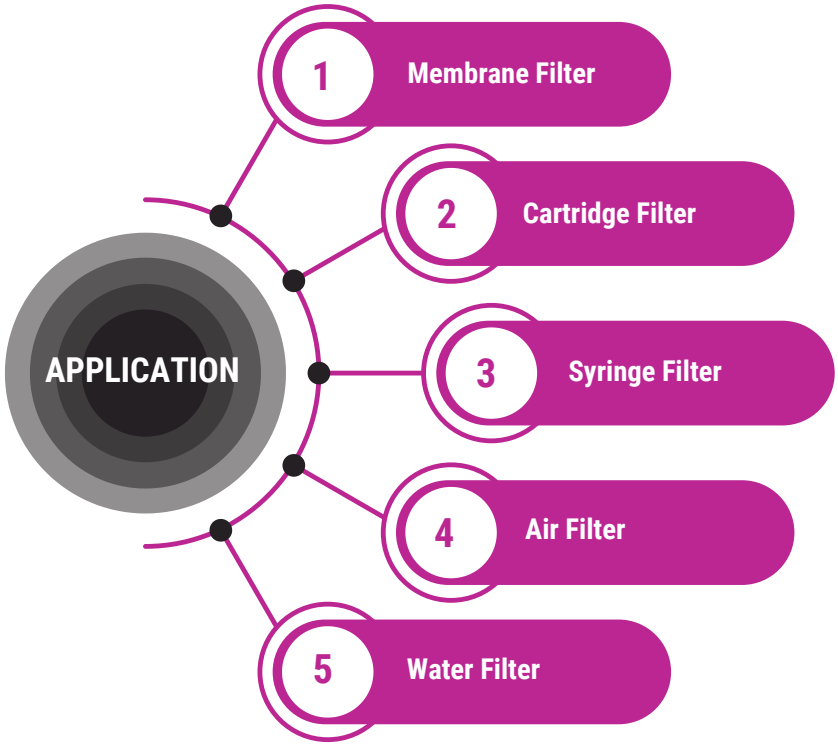
The Bubble Point/Integrity Analyzer is used to determine the pore size of a porous media. An inert gas such as nitrogen is used to force a wetting fluid through the pores of the specimen, in order to accurately predict the bubble point of the test specimen. Measurement of the steady state flow rate and the corresponding pressure drop across the media provides the necessary data for calculating the effective bubble point size in microns.

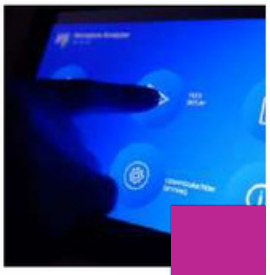
At its core, filter integrity testing relies on challenging the filter system with a controlled pressure or flow difference. This differential pressure creates conditions that mimic the real-world scenario where the filter is in use, allowing for a more accurate assessment of its performance. The goal is to detect any deviations in the expected filtration efficiency. There are several methods used in filter integrity testing, each based on distinct principles such as: Bubble Point Test, Forward Flow, Diffusional Flow, Pressure Decay and Water Intrusion Test.











TOUCH INTERFACE

EXTENDED MEASUREMENT RANGE

FASTER PROCESSOR

CUSTOM DESIGNED CHAMBER

IMPROVED SAFETY

KEY FEATURES

✓ Increased Focus on Reproducibility
Test recipes and parameters of sample references assures greater reproducibility.

✓ CFR Part 11 Compliance
The Advanced software meets the technical requirements of FDA regulations 21 CFR Part 11.

✓ Ease of Use
Samples are easy to load and unload eliminating user bias.

✓ Comprehensive Service & Support
Access services is available to conduct installation, calibration and validation on-site. M19 lab service representatives offer factory or on-site maintenance and repair services.

✓ Focus on Accuracy
Industry specific-customization in hardware and software control increases data accuracy to a whole new level.

KEY BENEFITS

✓ High Precision: Accurate detection of even the tiniest leaks in your filters.
✓ Rapid Testing: Expedite your quality control process without compromising accuracy.
✓ Versatility: Compatible with various filter types and sizes.
✓ Real-time Monitoring: Instantaneous feedback for immediate decision-making.
✓ Data Management: Seamless integration with your data management systems.
✓ User-Friendly: Intuitive interface for easy operation by both experts and newcomers.

TECHNICAL SPECIFICATION

Specification For Power & Compressed Gas	
Power Requirements	100 – 240 V AC at 50 | 60 Hz Average power usage
Max. Power Input	74W
Average Power Usage	66 W
Power Usage in Standby Mode	14.8 W
Max. Inlet Pressure	8,000 mbar/116 psi
Min. Inlet Pressure	4,000 mbar/58 psi
Compressed Gas Quality	Particles Free, Oil Free & Dry (recommended Dew Point: 20 °C
Measuring Ranges	
Diffusion, Intrusion & Pressure Drop Test Pressure	50-6,600 mbar/0.73- 95.7
Programmable Max Diffusion	0.01-4,800 ml/min flow
Programmable Max Intrusion Water Flow	0/005 ml/min- 60,000 ml/min
Max Measurable/Displayable Diffusion Flow	24,000 ml/min
Max Measurable/Displayable Intrusion Flow	300 ml/min
Programmable Min. Bubble Point	250-6,550 mbar/3.63-95.0 psi
Programmable Pressure Drop	0.5-6,600 mbar/0.007-95.7 psi (not higher than Pressure Test)
Sample Net Volume with Volume Measurement	
With Internal Reference Vessel	14 L
With External Reference Vessel	150 L
Max Sample Net Volume at Pressure Drop Test	1000 L
Dimension, Weight & Noise	
Dimensions in mm (WxDxH)	348 x 379 x 286
Weight	16.5 kg
Max. Noise at 1 m	70 dB (A)
Compliance & Conformity	
IP54	
Explosion Prone Areas (Device Only)	Class 1 Zone 2 Group II-B (USA,CA) / (IECEx, ATEX)
Explosion Prone Areas (Accessory Kit for Venting)	Class 1 Div. 1 Zone 1 Group II-B (USA,CA) / (IECEx, ATEX)
GAMPS	
21 CFR Part11	
Use in Class A Environment, if exhausts are connected to Tube	
USp Clss VI A	

Measuring Accuracy	
Measured Pressure	± 0.1% full scale (± 7.2 mbar |± 0.104 psi)
Measured Pressure Drop	± 0.2% before rounding
Net Volume Determination	± 4 %
Diffusion	± 5 %
Water Intrusion	± 5 %
Bubble Point	± 50 mbar | ± 0.7 psi
Accelerated Bubble Point	± 50 mbar | ± 0.7 psi from the starting pressure to one pressure step above the minimum bubble point. Beyond that the accuracy is pressure step dependent. C
Environmental Temperature for Integrity Testing	0 to 40 °C (32 – 104 °F)
Max Relative Humidity While	Conforming to IEC 61010-1 operating
Storage and transportation conditions	
From -10 °C to 60 °C (14 – 140 °F) at 90% RH non condensing humidity 8 T	
Touch Screen	
Size	14 L
Type	TFT LED-Backlit colour
Resolution	1280 × 800 pixels
Luminosity	400 CD/ m2 (Shock resistance: Thermally toughened glass DIN EN 12150-1; IEC 60068-2- 75)
Measuring Accuracy	
ModBus TCP	
Network RJ45	
USB (4 Ports)	

A) AMC (Annual maintenance contract) or technical support provided by M19 trained technicians.
B) A tubing kit and maintenance tool kit must be provided along with the system.
C) Installation and training will be provided by M19 technicians.

Note:
1. All certification of pressure transducer, gauges, sensors shall be provided.
2. Qualification Documents DQ, IQ, OQ and PQ including diagrams, electrical and manual shall be provided.
3. 1-year Warranty inclusive.

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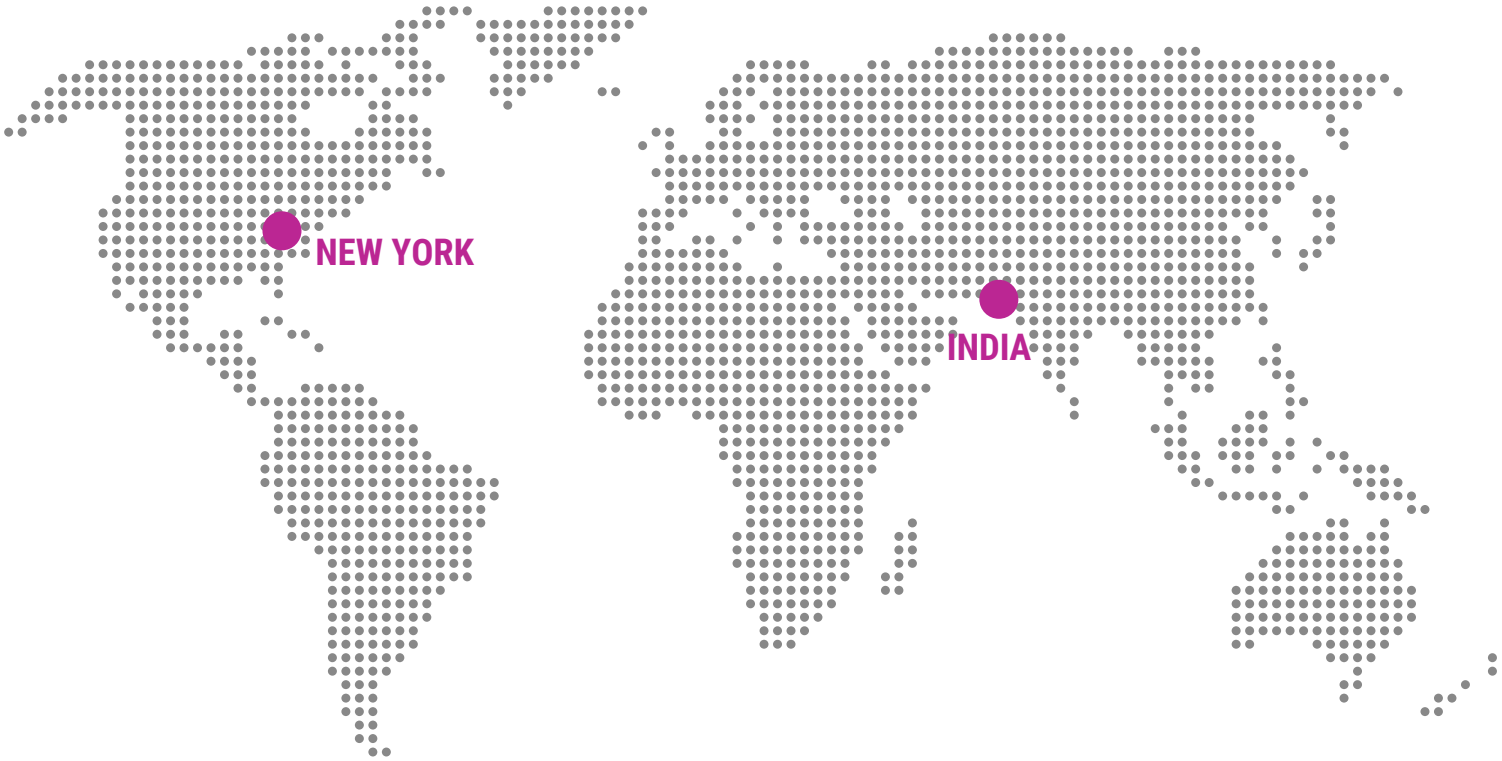

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