

FilterCheck 06

Integrity Test Equipment



Integrity Testing of
Critical Sterilizing Filters

FilterCheck 06

Integrity testing of sterilizing grade filters in aseptic processes is critical as undetected filter integrity failure may compromise drug product sterility and have huge regulatory and financial implications.

Process engineers are looking for accurate and reliable non destructive integrity testing of sterilizing filters. Online integrity testing of sterilizing filters is even more demanding as integrity test equipment are required to be aseptic area compatible and should be easy to move from one filter location to another. The high incidence of sterilizing filters in a pharmaceutical or biopharmaceutical process requires faster test times in order to meet process demands.

Current testers are unable to meet one or the other need. **mdi** FilterCheck 06 fulfils all the above needs.

FilterCheck 06 is a fully automatic, compact, 21 CFR part 11 compliant integrity tester for reliable testing of your critical filters.

It uses the latest mass flow measurement technology for real time flow measurement to deliver accurate and precise test results. The user friendly, easy to use validated software and calibrated sensors ensure test reliability.

SS 316 L body and a light weight compact design, allows it to be stationed within the aseptic process area for online integrity testing of sterilizing filters. It then wirelessly transfers test results to the laboratory network as well as to a printer.

mdi FilterCheck 06 with fast integrity testing (~15 minutes/test) delivers high productivity. It is supported by extensive documentation including COQ, IQ, OQ, OQ software, PQ, calibration report and user manual.

Unique Performance Advantages



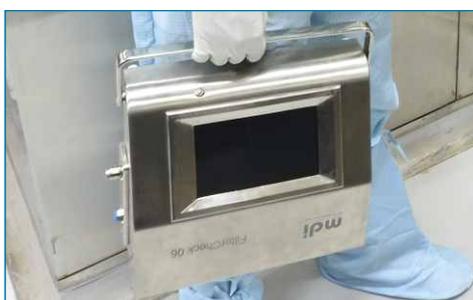
Linear Mass Flow Sensor

Latest Technology for High Precision and Accuracy

- Direct Mass Flow Measurement
- Independent of Temperature and Pressure Variation

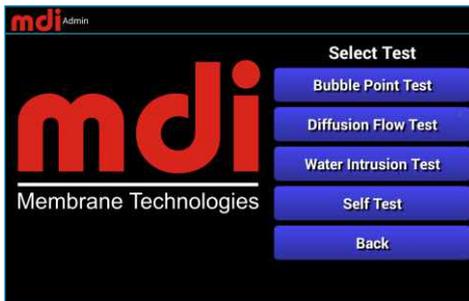
Compatibility with Sterile Processing Areas

- Electropolished SS 316L Surface
- No Instrument Cooling Fan
- Wireless and Paperless to minimize particle generation in sterile areas



Easy Portability

- Smallest Integrity Tester on the Market
- Weight: 9kg



All types of Integrity tests

- For Hydrophilic as well as Hydrophobic Filters
- Option for QuickTest for Higher Productivity

21 CFR part 11 Compliance for Data Reliability and Security

- Three Access levels with Password Security
- System Audit Trail

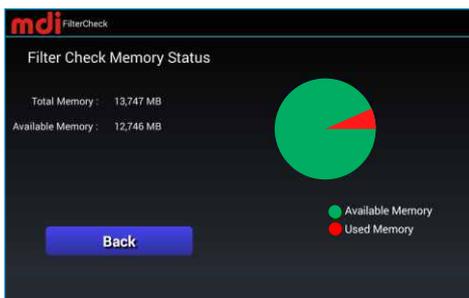
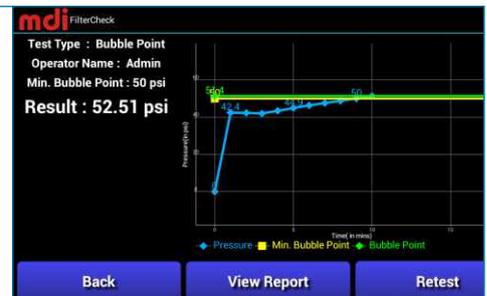


Self Diagnosis

- Internal Leakages
- External Leakages to ensure Test Filter Connectivity

Shows Real Time Test Status

- Graphical representation of test results
- PDF report generation



Large Storage Space > 10GB for

- Test Templates
- Test Reports

Inbuilt Equipment Safety with separate Hydrophobic Filters for

- Entrained moisture in Inlet Air
- Inadvertent back flow of test fluids



Wi-Fi Connectivity and Data Back Up

FilterCheck 06 connects with the external printer (with inbuilt Wi-Fi Router) and a remote back up data repository.

The remote back up data repository for test reports can be set up with an optional software specially designed for reliability and security.



Validation and Calibration

FilterCheck 06 uses a completely validated software.

The pressure and mass flow sensors are calibrated with instruments traceable to national reference standards.

Each instrument is supplied with a calibration report.

Equipment Supplied

- FilterCheck 06: Main Integrity Test Unit
- Outlet tubing connections with:
 - SS Quick Connector to connect to the main test unit, and 1.5" TC connector to connect to the test filter inlet
 - SS Quick Connector to connect to the main test unit, and Staubli Female (RBE03) connector to connect to the test filter housing
 - SS Quick Connector to connect to the main test unit, and 1/8" Stepped Hose Barb connector to connect to the test capsule filter inlet
- Laser Printer with inbuilt Wi-Fi router
- Power Cord

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Specifications

Dimensions	
Dimensions(Main Test Unit)	35cm X 32cm X 12cm
Weight	9 Kg

Electrical data	
Voltage	100-240V AC
Input Frequency	50 Hz
Battery Pack	14.4V - 4.5 AH
Battery Charger (in-built)	Yes
Power Backup	6 hours

Operating Range	
Minimum Inlet Pressure	≥70psi
Maximum Inlet Pressure	100psi
Operating Temperature	5°-35° C
Storage Temperature	8°-30° C
Relative Humidity	10-80 %

Measuring Range	
Diffusion Flow	0.2-100 ml/min
Bubble Point	15-80psi
Water Intrusion Test	0.03-10 ml/min

Accuracy	
Diffusion Flow	±5% or ±1 ml whichever is greater
Bubble Point	± 0.7psi
Water Intrusion Test	±5% or ±0.02ml whichever is greater

Report Printing	
External Laser Printer with Inbuilt Wi-Fi Router	

Support Documents

FilterCheck 06 comes with full documentation which is easy to follow.

Certificate of Quality		Yes
Calibration Report		Yes
User Manual		Yes
IQ		Yes
OQ	Test Equipment	Yes
	Application Software	Yes
PQ		Yes

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