sartorius

# Sartocheck® 3

The easy-to-use, production-safe filter integrity tester

**Sartocheck® 3**

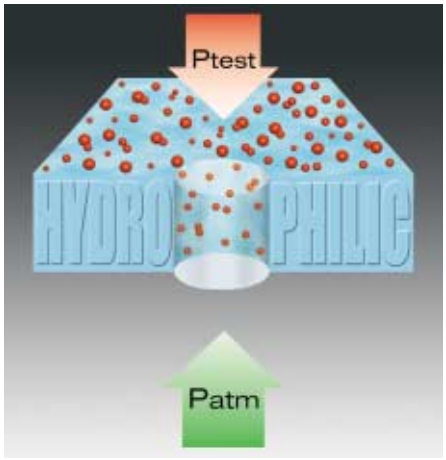
# Test a filter's integrity your way

Back in 1992 Sartorius was the first to validate the Water Intrusion Test (WIT) for integrity testing of hydrophobic filters, in-situ without alcohol. This test became so popular that at present, most filter manufacturers have paid tribute to our innovative thinking by creating their own version of our water intrusion test. More important to Sartorius is that we provide our customers with the flexibility to choose what's best for them and to offer innovative solutions to make their life easier and their processes more efficient.

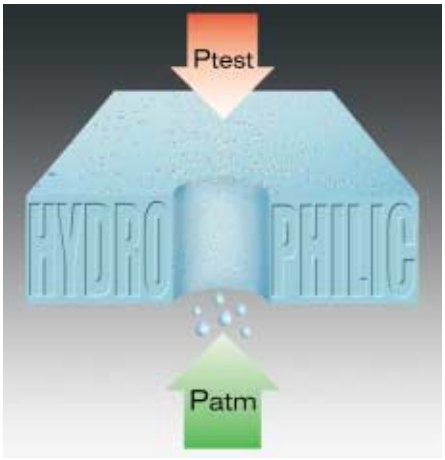
**Know no boundaries in integrity testing.**
Bubble point, diffusion, multi-point diffusion, water intrusion, pressure drop... whatever test suits your process our Sartocheck 3 systems know no boundaries.

Following is a sampling of the three most commonly used integrity test methods and a description of how they work.

**Diffusion Test.**
The Diffusion Test measures the diffusive gas flow across a wetted membrane. The test method detects very precisely whether or not a filter will deliver a sterile filtrate.



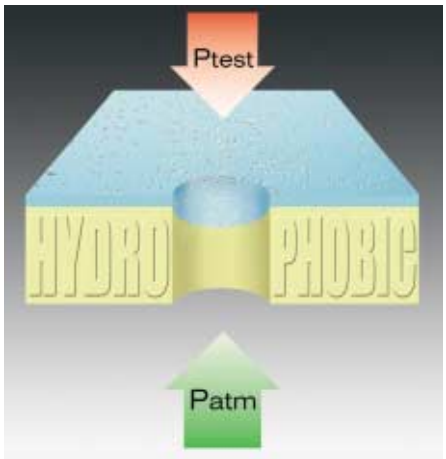

**Bubble Point Test.**
The Bubble Point detects the biggest pore in a membrane structure. During the measurement, test pressure is gradually increased until water is expelled through the largest pore.




**Water Intrusion Test (WIT)**
**Water Flow Test (WFT)**
Sartorius WIT is based on the same principle as the mercury intrusion test. Water is introduced to the inlet side of the housing and pressurized. Since the membrane is PTFE, it is highly hydrophobic. The pressure at which it will permit water to intrude is inversely proportional to the pore size.

In the test, the pressure is held constant at a value below the penetration point and any flow of the pressurized water into the membrane is measured.

The Sartorius Water Intrusion Test (WIT) not only eliminates the need for downstream manipulation and preflushing, but most importantly it eliminates the need to wet the membrane with solvents. Thus, eliminating the inherent disadvantages of solvents.



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# Integrity testing – an integral part of pharmaceutical filtration

There's nothing worse in pharmaceutical manufacturing than starting to process a batch of product only to find that the integrity of your filters is in question. That's why, back in 1981 we invented the first integrity tester for membrane filters. Since then, we've come a long way. This pioneering achievement laid the groundwork for assuring the highest level of process safety and security. Today, our Sartocheck 3 is a third generation improvement on what we started over 18 years ago. It's very symbolic of our founder's original intentions and dedication to focus on what we do best. To continuously research ways to improve our products and processes. At Sartorius we call this our think smart, think small philosophy.

Like anything in life, you get out of it what you put into it. At Sartorius, we've made it our life's work to help advance the technology in pharmaceutical and food and beverage processing. Rather than try to be all things to all people, we focus on what we do best. We are separation specialists in the filtration of vaccines, cell cultures, blood products and fermentation products via membrane filtration. By concentrating our R & D efforts in these areas we can work a lot smarter and achieve better results.

**When the pressure's on to integrity test lab-scale filter devices, down to 1 mbar!**
We aren't kidding when we say our Sartocheck 3 filter integrity tester knows no boundaries. This versatile unit can integrity test any filter we manufacture regardless of filter area or pressure limitations. From our Minisart syringe filters to our crossflow filter cassettes, even our 98-round filter cartridge housing systems for processing beer and wine – no filter is too small or too large.

And filter efficiency testing and the selection of the proper filter combinations has never been easier. During validation testing, all tests (incl. integrity testing) can be performed with small surface area pleated devices so data from small scale validation testing can be used for fulfillment of regulatory requirements necessary for cGMP production.

## Sartocheck® 3

# Optimized for top performance

**Simple, safe, and secure.**
Sartocheck 3 units are specifically designed for use in "real-world" pharmaceutical production environments. In the real-world things get wet. Not to worry, a little water won't hurt the Sartocheck 3 due to its splash-proof IP54 rating.

Other safety and security features include:
- Password protection for programs on an individual basis
- Storage of up to 240 testprograms via the built-in PCMCIA card

**Document everything.**
In the regulated world we live in, it's not enough to take all the proper steps to ensure the safety and security of your process. You have to prove it.

So we think small to include as many little details as possible to help you document the safety and security of your integrity testing process. From our unit's serial number, program number and test method selected, to a printed pressure drop curve for quick identification of temperature fluctuations which may affect test results.

In addition, we provide a state-of-the-art, comprehensive validation guide including IQ and OQ checklists, installation and operating instructions along with complete descriptions of all hardware and software.

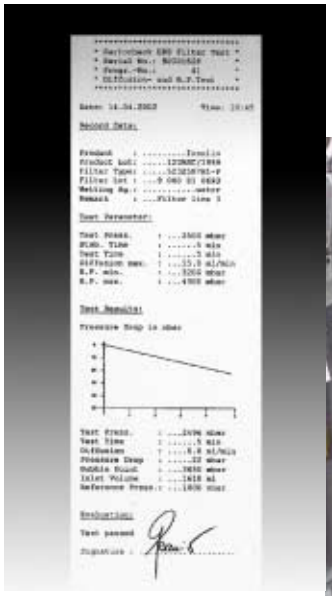
For a complete review of all data generated from our Sartocheck 3 for every test – refer to the sample printout below.

**Know no boundaries.**
Due to the expansion and contraction of air in a normal pneumatic system, most units have a distance limitation between the integrity testing unit and the filter housing. The result was the Sartocheck 3 EPS version. EPS stands for External Pressure Sensor. This new feature converts the system from pneumatics to electronics thereby eliminating the distance limitation found with other integrity testers.

**Built for speed and convenience.**
Building from our latest EPS innovation, we sought to take our integrity testing innovation mobile. The result: a turnkey integrity testing station on wheels. We call it our WIT Trolley System.

You'll call it the fastest most convenient way to ensure the integrity of your membrane filtration process.

The WIT Trolley System pictured below is equipped with a 20 liter water container, pressure tank and all necessary software and electronics to conduct integrity tests at filter housing sites throughout your facility. Simply hook up the external pressure sensor and valve assembly to the filter housing to be tested and hit the start button. You're now free to do other tasks. The intelligent WIT Trolley System will complete the test, drain the housing and stand idle waiting for further instructions.



New WIT Trolley System is a turnkey mobile integrity testing station for fast, convenient integrity testing of membrane filters.

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