

## Selection Guide

### Selecting a Filter Integrity Test Instrument

Selecting a filter integrity test instrument can be a complex task. Several departments can ask for different requirements and set different priorities on the same features on an instrument. Since most instruments that are available offer the most important types of filter integrity test procedures that are accepted by authorities, the instrument can be chosen independent of the filter or housing manufacturer.

The required features of an integrity test instrument can be very different depending whether the instrument will be used independently to produce paper documentation, if the instrument will be linked to a network and produce electronic records, or if the instrument will be remotely controlled from process control equipment.

We have listed a sequence of tests to evaluate an integrity test instrument. To give you a better idea of which features are important for the different operation methods, we have listed the general requirements in the section “Basic Requirements”, the requirements for use of electronic records in the section “Electronic Data Handling” and the requirements for remote control of the instrument in the section “Automation”.

#### Basic Requirements

Ease of Use	Obtain demonstration units for evaluation – a salesperson can demonstrate for you, but it is important to use the instrument yourself. Try out the types of tests you expect to do in production and let one or more actual operators perform the tests. Ideally, very few steps should be necessary to get to the actual integrity test. The instrument should not require input of unnecessary parameters, and should give hints on fields with mandatory data entry or entry limits.
Accuracy	Make sure the instrument is accurate. Accuracy claims can vary from 3% to 10% and do sometimes depend on the test type that is used. Compare also the lower accuracy boundaries; they can range from 0.02 mL/min to up to 1 mL/min. Accuracy can only be confirmed if it can be verified against a reference. There are calibrated references available for gas flow measurement ranges from roughly 1 mL/min to 1000 mL/min. You can use those to verify the accuracy claims given by the instrument manufacturers. References for Bubble Point tests are not available and accuracy claims on those tests are only mathematical functions. Find out if the instrument offers safeguards to prevent false pass results (and false failures). There are methods available to assure that the differential pressure over the tested filter is not impaired by elevated pressure on the downstream side of the filter, or to prevent a pass result if the integrity test is run against a closed valve.
Speed	Compare how quickly the units perform their functions, especially the functions you expect to use routinely. If you compare the test speed also compare if higher speed has an impact on test accuracy.
Simple to Validate	Which tools and resources the vendor provides to assure that the instrument will be successfully validated. In addition to a published validation guide, you will want to know specifics about IQ, OQ and PQ procedures and services. According to the GAMP5 guideline, an integrity test instrument can usually be rated as Class 3. It is acceptable to use generic documents from the instrument manufacturer. Such documents and appropriate guideline for PQ should be available.
Properly Calibrated	Find out how the instrument is calibrated. An instrument should be calibrated against references of the units it reports. For integrity test instruments this should be a calibration with pressure and flow references to assure accurate results. What is the accuracy transfer ratio between the calibration reference and the instrument under calibration? Are proper calibration certificates issued? Calibration needs to be performed by trained personnel. Find out what calibration equipment, training or calibration service is offered for your instrument by the vendor.
Design	An instrument that is made for use in pharmaceutical production will typically be used in a cleanroom. There should be no ventilation on the instrument and it should not generate particles. Check that the instrument is dust and splash-proof. Can the instrument be cleaned externally and internally by appropriate methods? What methods are used to avoid process liquid to drain back into the instrument? An internal diagnosis program can help to check the internal hardware and software in regular intervals. Find out if all critical components like sensors, valves, volumes and data are checked and what needs to be done in case of failures.

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### Basic Requirements

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Service	What service structure does the instrument vendor have? It can be an advantage if the instrument can be calibrated and serviced on site. Shipping instruments back to the manufacturer is time consuming, expensive and risky. Find out if you can get a replacement instrument if your instrument needed to be repaired. Does the instrument manufacturer also have the facility to help handle failed filters, to recommend installations and procedures and to find root causes for failed tests?
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### Electronic Data Handling

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Data Safety	For electronic records, the instrument should offer the controls for compliance with 21 CFR Part 11. Some of the controls needed for that purpose should be validated on the instrument and protocols should be available from the manufacturer. There might be a document where all the controls are described and linked to the respective part of the regulation. Does the instrument offer methods to check for data integrity? Filter integrity test results are part of the batch records and are critical documents.
Data Transfer Options	There must be an option to create a backup of the electronic test results and to store them in a safe place. There should also be an option to test for data integrity on the backup file. Find out what options there are to transfer data in a safe way from the integrity test instrument to your data storage system and if the instrument does support your required data format.

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### Automation

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Automation Protocols	Some integrity test instruments can be integrated into automated process control equipment and can be remotely controlled. If you consider this option find out what interfaces the instruments offer and which automation protocols can be used. It might be helpful if the instrument supplier can assist in choosing the right automation option and give recommendations on filter wetting and draining procedures.
Customization	You might not find the perfect integrity test solution for your process from any supplier. Find out how flexible they are in modifying hardware or software to your needs.

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Third Party References	Obtain references and published reports about the instruments. Seek out others in your company (perhaps in a different location), who have experience that they can share. If you look at all these criteria and get feedback from other users, you will be on the right track for any filter integrity test instrument for your process.
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