Selecting the Right Filter Integrity Test Instrument for the Food and Beverage Industry: 20 Tips

Overview

As a key part of the Food & Beverage manufacturer's HACCP (Hazard Analysis Critical Control Points) program, the performance of microbial controls, such as final membrane filters, should be monitored.

Integrity testing provides assurance of filter performance of your process, through a non-destructive test which is directly correlated to the ability of a filter to retain microorganisms.

An integrity test therefore helps manufacturers avoid costly issues such as:

Product Contamination	Product Losses	Reprocessing	Production Delays	Not Satisfying Auditor Requirements

Consequently, selecting the right filter test instrument is a very important task, not only because the instrument will become an essential tool to prevent the costly issues enlisted above; but also, because to select the best-in-class integrity test device, multiple requirements must be considered to make an informed decision regarding which device is best for you and your operation.
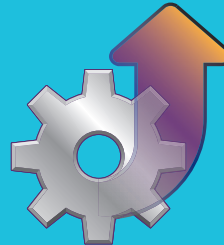
Core Requirements

Design
- Ease of use
- Suitability and reliability

Function
- Accuracy
- Speed
- Automation

Compliance
- Data storage
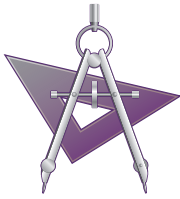- Data export
- Data security

Service
- Servicing
- Accessories and spare parts
- Warranty terms

Design

Ease of use

Ease of use is often cited by operators as the primary factor that affects their selection of an instrument. This is a significant aspect to consider when deciding on the right choice for any application. Instruments that are easy to use also tend to be quick to learn, quick to adopt, and reduce deviations by minimizing operator errors. Easy to use instruments also simplify the training and routine re-training burdens demanded in any GMP process, saving operator time and reducing training costs.

QUICK TIP *If possible, obtain a demonstration instrument for evaluation and allow a cross-section of users to experience the instrument and perform each of the tests that the instrument is expected to run. In case a knowledgeable operator requires more than basic direction, this may be an indication that the instrument takes some time to master and may continually present usability challenges throughout its lifetime.*

QUICK TIP *Ask about options to reduce transcription errors by using technology such as barcode readers for the entry of test data.*

QUICK TIP *Operation is easier if the instrument interface, and the accompanying documentation is available in multiple languages. Some integrity test instruments have multiple operating languages (i.e. English, German, Chinese, Japanese, Spanish, etc.) available that can be readily selected in the settings screen without the need of software updates.*

Suitability and reliability

Food & Beverage operating environments and conditions can be demanding to any instrument. Risk of damage due to water ingress, dust exposure and continuous handling must be considered. It is also important to understand the operating and storage conditions (i.e. temperature, humidity) that the device can withstand over continuous or cyclical exposure.

QUICK TIP *Ask if there are protective accessories that can extend the life of the product, such as protective and carrying cases.*

QUICK TIP *Enquire how the device's enclosure is rated, and whether it complies with any specific guidelines to measure the device's capabilities to protect. For example, IP Ratings (or "Ingress Protection") ratings are defined international standards EN 60529 (British BS EN 60529:1992, European IEC 60509:1989) used to define levels of sealing effectiveness of electrical enclosures against intrusion from foreign bodies (tools, dirt, etc.) and moisture.*

Function

Accuracy

As the accuracy of any instrument increases, the process risk resulting from the potential for a filter integrity test providing a false result decreases. Both false passes and false failures impact your process' safety or efficiency, and are highly undesirable.

The claimed accuracy and measuring range of the integrity test instrument might vary, as well as the methodology used for its validation.

QUICK TIP *Find out what safeguards are provided to prevent false pass results and false failures for any instrument you are considering. For example, methods are 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.*

QUICK TIP *Ask if there are any devices that might assist in reducing any residual risks by identifying issues before they lead to batch deviations. Consider using a flow check device to monitor accuracy between calibrations.*

Speed

Some flow measurement technologies, when coupled with validated algorithms, may be able to shorten the filter test times without any compromise of the measurement accuracy.

Shorter test times release valuable resources for other process tasks and speed the progress of process operations. Compare how quickly each instrument performs each test, especially those you expect to do routinely. This is key, as the second most important benefit of integrity testing (other than accurate results), is fast test results that allow you to measure filtration efficacy in almost real time. Some instruments commercially available can provide integrity test results in just a few minutes.

QUICK TIP *While comparing test speeds, also check that instruments that offer the highest speed of testing still maintain the test accuracy.*

QUICK TIP *For users that need to test large numbers of filters, even more time can be saved by using instruments and extensions that can support the testing of multiple filters without the operator returning to the instrument during testing.*

QUICK TIP *Check to see if the instrument can be used to support the testing of multiple filters without increasing the number of units that require calibration.*

QUICK TIP *If the device is portable, ask how fast can the battery be fully charged.*

Automation

Some integrity test instruments might be integrated into automated process control equipment and can even be remotely controlled. If you consider this option, it is important that your chosen instrument offers an automation protocol that works for you.

QUICK TIP — Before purchasing, ask for an operating and installation manual, to understand how to adapt or connect the integrity test device with your process control equipment. In many cases only a competent electrician should attempt the electrical connections detailed in the manual. Make sure that your company has internal technical resources, or that the supplier offers installation services that guarantee a safe and successful installation.

QUICK TIP — There are many types of communication ports (USB, Ethernet, CAN Bus, Profi Bus, etc.). Ensure the integrity test instrument has communication ports that suit your current process control equipment. Also, ask about the differences, advantages and disadvantages of the different communication ports.

Compliance

Data storage

Integrity test data, depending of your quality control protocols, is likely to be collected frequently and regularly. Therefore, large volumes of valuable integrity test results are likely to be generated over time.

QUICK TIP — Understand how many test results can be stored in the device as well as the device's installed storage space/memory. Make sure it is sufficient to limit the frequency at which data must be backed up, downloaded or transferred.

Data export

It is likely that for internal or external auditing purposes, or to run data analytics; that you will want to export historical results. Best-in-class integrity test devices should allow you to download or export data via Ethernet or USB. In some of them, it should also be possible to print results directly from the device with a portable printer.

QUICK TIP — Chose an instrument capable of exporting data in a file format that can be readily read, formatted and edited by your team (e.g.: .xls) for subsequent data analytics, and reporting.

Data security

For electronic records, the instrument needs to offer the controls for use in environments subject to 21 CFR Part 11 regulations on electronic signatures and records. Some of the controls required for these purposes should be validated on the instrument.

QUICK TIP — For peace of mind, ask if the manufacturer can provide a document where all the controls are described and linked to the respective part of the regulation.

QUICK TIP — It is also very important to understand if the instrument settings allow for different levels of access (e.g. administrative versus user access). That way different levels of security can be created to prevent unauthorized or non-compliant data manipulations such as deletion or editing of results.

Service

Servicing

It is very important, that you ensure the ongoing consistency, functionality and accuracy of your integrity test device. Most devices will require software upgrades, regular calibration, preventive maintenance and occasional repairs.

QUICK TIP — Make sure that the suppliers offer optional Service Packages, regional support, on-site calibration.

Accessories & spare parts

Portable printers, spare pneumatic tubes, replacement valves, additional batteries or external power adaptors are some of the most common accessories or spare parts that you may need in the future. Some suppliers have regional sales representatives, or online shops that carry the most essential accessories or spare parts in stock.

QUICK TIP — Being able to readily purchase accessories or spare parts is very important to keep your integrity test device performing as intended, and your filtration process compliant with auditor requirements.

Warranty items

Make sure you understand and agree with the manufacturing warranty terms included with your purchase. Understand what is covered with the standard manufacturing warranty versus what needs to be covered with an optional service plan.

QUICK TIP — Finally, make sure the supplier explains how software updates can be communicated and downloaded after purchase. It is likely that various newer versions of the software will be published after your purchase. New software versions typically include software bug fixes, as well as upgrades and functional improvements that you want to benefit from after purchase.

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