

APPLICATION NOTE

Leak testing of Glove Boxes, RABS, Isolators, MSC and BSC

INTRODUCTION

This application note describes methods, technical challenges and the INFICON solution for leak testing of Glove Boxes, RABS (Restricted Access Barrier System), Isolators, MSC (Microbiological Safety Cabinets) and BSC (Bacteria Safety Cabinets).

APPLICATION

A glove box is a container designed to separate the contact between an inner and outer atmosphere, but still allows physical handling of objects inside the container. The purpose is to either prevent substances in the box from escaping and harming the environment or to protect the contents of the box from the environment.

Glove boxes are critical for personal safety as the content within the glove box often is harmful to humans or to the environment. There are many national as well as international standards specifying different safety levels, depending of the level of harmfulness. Typical standards are ISO 14644-7, ISO 10648-2, EN 12469. Different levels of safety are typically defined as different classes depending on the level of safety required.

Globe box names include RABS (Restricted Access Barrier System), Isolators, MSC (Microbiological Safety Cabinets) and BSC (Bacteria Safety Cabinets) and are used for similar devices. They are available in all sizes from small boxes up to huge rooms or even buildings.

DESCRIPTION OF TECHNICAL CHALLENGE

Standards describe a maximum allowed leak rate for each class. The leak rate is typically given as relative pressure drop per time. This is measured by pressurizing the glove box with air and checking the pressure drop over time or by a gas test like oxygen increase under negative pressure.

Example: ISO 10648-2 specifies a Class 1 glove box not losing more than 0.05% of its volume per hour at normal working pressure. In regulations and standards, the user is often required to do regular service and maintenance. Methods for finding the location of a leak are not specified, but there are some techniques commonly used. The challenge with all of them is to find



Glove boxes are critical for personal safety. It is important to find potential leaks quickly to minimize downtime.



leaks as quickly as possible with high precision, since every minute of downtime can be very costly.

TRADITIONAL LEAK LOCATING OF GLOVE BOXES

Ammonia test is sometimes used by injecting ammonia gas into the glove box and then searching for leaks by swiping an indication paper around suspicious leak points. This method requires no significant investment, but creates a need for cleaning the glove box afterwards which is time consuming, particularly in the pharmaceutical industry where each minute counts. Stopping the production line one hour for cleaning can easily mean a loss of production value of millions of dollars, as large systems like RABS must be closed down during leak location and this is costly. Additionally, personal safety must be considered since ammonia is harmful.

Soap spray can also be used to locate leaks. An operator sprays soap onto suspicious leak points and looks for bubbles. This method only allows leak location in places that are accessible and visible. The sensitivity of soap spray is not always enough to clearly indicate all leaks and therefore leaks sometimes are missed. Additional cleaning is always needed after the test.

Helium leak detectors can be used by injecting helium gas and searching for the leaks with a helium sniffer probe. However, these devices often get overexposed as a result of large leaks. A helium leak detector is typically a stationary device, difficult to move across glove boxes and RABS. The cost of helium will also be high when testing large glove boxes or RABS.

THE INFICON SOLUTION

The INFICON solution ensures high uptime of the system with quick leak localization at a minimum cost. INFICON suggests using the hydrogen method to locate the leaks. This is done by injecting a small amount of the inexpensive and conventional forming gas consisting of 5% hydrogen in nitrogen. Leaks are then located using the hand probe of the <u>Sensistor® Sentrac hydrogen leak detector</u>. The sensor placed in the probe tip reacts selectively to hydrogen, and makes a beeping sound that guides the operator to the leak position. Sensistor Sentrac has a locating capability over ten decades and its sensitivity is more than needed to find microbiological leaks.

This method can easily locate any leak in all classes of sealed glove boxes including the strict leak limit of US Class III biosafety cabinets: 1x10-5 cc/s at 3" of water column (8 mbar) overpressure. Investing in a hydrogen leak detector from INFICON will have a short return on investment thanks to the time saving potential this solution offers.



The Sensistor Sentrac hydrogen leak detector, battery operated model, has a weight of 4.8 kg (10.5 lb.) and is easily carried in the included case with a shoulder strap.



BENEFITS OF LEAK TESTING WITH THE HYDROGEN METHOD

- Fast pinpointing of leak location, minimizes down time
- High sensitivity to locate the smallest leaks
- Safe and clean method
- · Portable model as option, for large glove boxes and service operations
- Low cost of tracer gas

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