



## Containment Testing of a Modern Flexible Film Isolator in a Commercial Laboratory Setting

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### Abstract

Offering the same containment as rigid glove boxes, isolators constructed of flexible film have been used in a variety of industries with great success. Commonly referred to as "glove bags", these isolators have improved since early versions were introduced. The Purair® Flex is a portable, cost effective flexible film isolator sold by Air Science.

In early 2015, BioVectra, Inc., a CMO with substantial experience in handling and containment of highly potent compounds, performed an OHS qualification test on the Purair Flex to determine the particulate containment capabilities of the isolator. It was hypothesized that under normal-use conditions operators would be protected from dangerous levels of released particulates. The study was designed to closely approximate typical use conditions for the Purair Flex flexible film isolator.

Overall, the containment results for the Purair Flex film isolator in this study indicated a high level of protection from contaminants. The isolator provided good containment of the naproxen sodium powder during each packaging job and final cleaning.

The findings of this study indicate that the Purair Flex isolator provides a high level of containment capability and can help ensure operator safety while manipulating contaminated equipment.



## Origins of the Glove Box

Glove boxes are rigid, fixed-location containment solutions that feature fully sealed gloves to allow manipulation of equipment and items inside of the workspace without exposing researchers and technicians to harmful contaminants. Glove boxes have long been used in laboratory settings to provide protective containment and an inert working environment for highly delicate and potentially dangerous procedures<sup>1</sup>. Common uses include forensic investigation and evidence processing, containment of biological contaminants, and for the repair or manipulation of contaminated equipment.

## Issues with Glove Boxes

The rigid nature of glove boxes work well in a laboratory setting, yet there are additional procedures and applications outside of the laboratory in which having access to a contaminated surface or piece of equipment is impossible without the use of flexible film isolators. Film isolators are constructed of impermeable film to isolate users from contaminated equipment, but are easily collapsed and portable, allowing use in almost nearly environment<sup>2</sup>.

## Adoption of the Flexible Film Isolator

Offering the same containment as rigid glove boxes, flexible film isolators have been used in a variety of industries with great success throughout history. One of the most notable instances of use was in 1983 in a study by P.C. Trexler and A.M. Gilmour in the *Journal of Clinical Pathology*<sup>3</sup>. This was one of the first instances found in the literature in which the effectiveness of a containment system was tested against biological contaminants. Trexler and Gilmour performed necropsies on cadavers that were infected with potentially hazardous diseases and used large flexible film isolators to protect researchers from exposure. The research was largely focused on determining the practicality of using flexible film isolators in the laboratory while not affecting manual skill and vision. Trexler and Gilmour found that a high degree of safety was provided by flexible film isolators with negligible effects on the manual skill and vision of researchers during necropsies<sup>4</sup>. Essentially, all processes, including the sterilization of tools, could safely and easily be performed inside of the film isolator while keeping the laboratory clean and free of contaminants.

## The Modern Glove Bag

Modern flexible film isolators, commonly referred to as "glove bags", have added a number of improvements compared to their early predecessors. The Purair® Flex is a portable, cost effective flexible film isolator sold by Air Science that offers a number of important features compared to other isolators on the market today<sup>5</sup>:

- **More Volume.** The Purair Flex Film Isolator features an innovative curved film design that provides more working volume than any other glove bag on the market.
- **Versatile Tapered Sleeve / Glove Options.** Unlike other glove bags, the double O-ring design on the standard polyurethane cuffs allow users to change gloves quickly and easily to meet a variety of dexterity needs.
- **Easy Setup.** Semi-rigid support rods make the Purair Flex easy to setup up and provide increased stability, even if the bag is not inflated to full pressure.
- **Safety Options.** HEPA filter availability, Bag-in / Bag-out Port, and optional Nitrogen purge inlet connections offer the reliability and safety today's analysts need.
- In early 2015, an independent test laboratory, BioVectra, Inc., performed an OHS qualification test on the Purair Flex to determine the particulate containment capabilities of the film isolator. The results are found herein and provide valuable insight into the effectiveness of film isolators in providing protection in variable environments from numerous contaminants.

## Hypothesis

BioVectra, Inc. performed a surrogate study with minimal concentration testing of the product in air surrounding the Purair Flex units. Based on the intended containment capabilities for the Purair Flex, it was hypothesized that under normal-use conditions operators would be protected from dangerous levels of released particulates<sup>6</sup>.

1 [http://www.coleparmer.com/Assets/manual\\_pdfs/04408-38.pdf](http://www.coleparmer.com/Assets/manual_pdfs/04408-38.pdf)

2 <http://airscience.com/purair-flex-portable-isolators>

3 Trexler, P.C. and AM Gilmour. 1983. *Use of flexible plastic film isolators in performing potentially hazardous necropsies.*

4 Trexler, P.C. and AM Gilmour. 1983. *Use of flexible plastic film isolators in performing potentially hazardous necropsies.*

5 <http://airscience.com/purair-flex-portable-isolators>

6 BioVectra, Inc. 2015. *OHS Qualification of Purair Flex 30. Internal Publication.* <http://www.biovectra.com>

## Methods<sup>7</sup>

The study was designed to closely approximate typical use conditions for the Purair Flex flexible film isolator. Two experienced research and development chemists (herein referred to as operators) carried out a packaging instruction using naproxen sodium within the isolator. The main operator manipulated the naproxen sodium, scale, and other equipment through the isolator glove ports. The helper stood at the right side of the isolator, close to the zipper, and recorded weights and provided general support during the packaging. The roles were switched in the second packaging task so the isolator was tested by different individuals.

The packaging instruction was to weigh twenty 1g ( $\pm 0.1$ g) samples of naproxen sodium powder from a 50 g bottle into twenty 30 mL vials within the isolator. Following the weigh task, the main operator wiped bottles and the inside of the isolator with highly purified water. The final cleaning of the isolator involved a more thorough wipe down of the isolator and packaging equipment/materials with highly purified water and then with acetone.

A total of 17 air samples and one blank (to be used as a control) were collected. The samples were collected in the following locations (Figure 1):

1. Main operator's collar, breathing zone sample (Location 1, 2)
2. Helper operator's collar, breathing zone sample
3. Beside zipper of isolator,
4. Top of enclosure, between glove ports,
5. Immediately beside the HEPA filter,
6. In front of enclosure (approximately 1 m behind the main operator).

Figure 1: Sample cassette locations



Air samples were collected using air sampling pumps attached to filter cassettes. The pumps were calibrated pre- and post-sampling using a flow rate calibrator. The pump flow rate was set to 2.0 Lpm. A field blank cassette was included in the analysis. The field blank was carried with the other cassettes, but the plugs were not removed and no air was drawn through the cassette. The analysis requested was naproxen sodium and the laboratory limit of quantification was 0.0002  $\mu$ g.

<sup>7</sup> BioVectra, Inc. 2015. OHS Qualification of Purair Flex 30. Internal Publication.

## Results<sup>a</sup>

Concentrations of up to 0.00506 µg/m<sup>3</sup> of naproxen sodium were detected outside of the containment area during the study, however the vast majority of readings were well below 0.0029 µg/m<sup>3</sup> with many readings even reaching levels below the detectable level.

**Table 1. Concentration of naproxen sodium in air samples taken in several locations around Purair Flex film isolator.**

	First Packaging Job		Second Packaging Job		Isolator Clean	
	Duration (min.)	Naproxen sodium (µg/m <sup>3</sup> )	Duration (min.)	Naproxen sodium (µg/m <sup>3</sup> )	Duration (min.)	Naproxen sodium (µg/m <sup>3</sup> )
Personal sample, (Operator 1) Main operator, 1st job	43	<0.00229	31	<0.00318	34	<0.0029
Personal sample, (Operator 2) Main operator, 2nd job & cleaning	43	<0.00229	31	<0.00318	-	-
Area, zipper right side of isolator	48	<0.00204	36	<0.00272	50	<0.00196
Area, top of isolator between glove ports	48	0.00506	38	0.00415	51	<0.00193
Area, HEPA Filter, top of enclosure	47	0.00459	37	0.00375	50	<0.00196
Area, in front of enclosure	46	<0.00211	36	0.00466	49	<0.00198
Blank	n/a	<0.0002	-	-	-	-

**Table 2. Concentration of naproxen sodium on exposed surfaces as tested on locations on and around the Purair Flex film isolator.**

	Area Swabbed (µg/cm <sup>2</sup> )	Concentration (µg/cm <sup>2</sup> )
Side zipper, outside plastic	100	BQL
Stainless steel scale top surface	100	0.000511
Isolator glove plastic, inside out	50	BQL
Blank	n/a	BQL

<sup>a</sup> BioVectra, Inc. 2015. OHS Qualification of Purair Flex 30. Internal Publication.

## Discussion

Overall, the containment results for the Purair Flex film isolator in this study were impressive and indicated a high level of protection from contaminants<sup>9</sup>.

The isolator provided good containment of the naproxen sodium powder during each packaging job and final cleaning. The personal air samples on the main operator and helper had no detectable naproxen sodium (Table 1).

The area sample at the zipper (Location 3) was non-detect for naproxen sodium during both packaging jobs (Table 1). The zipper was not opened during either packaging job, only during the final isolator clean. The weakest areas of the unit appeared to be between the glove ports (Location 4) and at the HEPA filter (Location 5). Area samples at these locations during both packaging jobs had concentrations of naproxen sodium (Table 1). The highest concentration was **0.005 µg/m<sup>3</sup> (5 ng/m<sup>3</sup>)** (Table 1). These findings could be attributed to small amounts of powder escaping from the HEPA filter, the nitrogen line, or possibly the isolator glove area. The isolator was under positive pressure for the duration of the packaging job, so any weak part in the plastic or seals could have resulted in a small leak.

The room sample (in front of enclosure, behind the chemists, (Location 6) was non-detect in the first packaging job and during the cleaning. However, a small amount was detected during the second packaging job (Table 1). The second packaging job was done more quickly than the first, and less care was taken when handling the samples within the isolator. This gave the isolator a good challenge, but could have potentially led to more naproxen escaping the containment.

## Caveats

The variables in this study were monitored and controlled as closely as possible, however as with any scientific study, small caveats existed<sup>10</sup>.

For instance, there was considerable variability between operator weighing and packaging techniques. One operator was observed to work more slowly and diligently at the task. The other operator worked quickly and less carefully. Regardless of technique, the isolator contained during both packaging jobs<sup>11</sup>.

Additionally, typically the HEPA filter would have been tested prior to use as part of an equipment qualification. Since this was a surrogate test though, a full engineering check was not performed. A compromised HEPA filter could have resulted in a small leak. Another explanation may be the lack of an attachment port for the nitrogen line. In order to package in an oxygen-free environment (which is often a pharmaceutical packaging requirement) a small slit was made at the lower back of the isolator to insert a nitrogen line and then securely taped. A leak in this area is less likely though, because no naproxen sodium was found in the Location 3 sample (zipper) which was closest to the nitrogen line.

## Conclusions

The findings of this study indicate that the Purair Flex film isolator provides a high level of containment capability and can help ensure operator safety while manipulating contaminated equipment. In addition to the containment capabilities of the Purair Flex, there are additional, unquantifiable benefits that include<sup>12</sup>:

- **High Quality Materials:** The Purair Flex is constructed of ArmorFlex film from DoverPac® Containment Systems which offers complete visual clarity and excellent solvent resistance across a range of chemicals.
- **Large Workspace:** At 30 inches wide and an internal volume of 85L, the Purair Flex provides a large work area with a gas tight zippered access (12.5" zipper with an effective opening of 6" in diameter). Zipper also features a redundant sealing system to serve as secondary containment in the case of zipper failure.
- **Puncture Resistant Construction:** The pliable film material used to construct the Purair Flex is 8 millimeters thick to prevent accidental punctures from internal and external equipment.
- **Pharmaceutical Grade Materials:** The Purair Flex is constructed with pharmaceutical grade vinyl that is FDA approved and anti-static / ESD safe.
- **HEPA Filtration:** HEPA Filtration is now standard on the Purair Flex to maintain atmospheric pressure and allow safe deflation and disposal of a contaminated system.
- **Oxygen-free Work Zone:** A nitrogen barb is a standard feature to allow users to create oxygen-free workspaces. Additionally, the Purair Flex can typically be purged quicker than a rigid glove box and with less gas, making adaptation to your specific application easy and economical.
- **Simple Support Rod Design:** The internal support rod structure helps keep the unit stable and features a built in carry handle.
- **Disposable:** It is economical enough to be used once and discarded, if contaminated, but it's durable and it can be used repeatedly if desired.

Overall, the Purair Flex has been shown to be effective at protecting operators from contaminants while offering some of the most robust product features on the market. As with any containment situation, the chemicals and materials in use should be thoroughly evaluated by a qualified Safety Manager to ensure all practices adequately maintain user safety<sup>13</sup>.

9 BioVectra, Inc. 2015. OHS Qualification of Purair Flex 30. Internal Publication.

10 BioVectra, Inc. 2015. OHS Qualification of Purair Flex 30. Internal Publication.

11 BioVectra, Inc. 2015. OHS Qualification of Purair Flex 30. Internal Publication.

12 <http://airscience.com/purair-flex-portable-isolators>

13 <http://airscience.com/purair-flex-portable-isolators>

### About the Author: Andre Chambre

Andy Chambre is the founder and CEO of Air Science, LLC and has been associated with the ductless fume hood industry for more than 25 years. He was formerly the US Vice President for Captair Labx and President of Astec Microflow US. He was named President of Filco Corporation in 2003 and currently also serves as a Director of Air Science Technologies Ltd. in the UK. Mr. Chambre has written numerous articles on fume hood safety and assisted in the development of safety standards by serving on various committees such as the Canadian Standards Association subcommittee on fume hoods and the SEFA 9 Ductless Enclosures Committee.

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*Disclaimer: BioVectra performed the Occupational Health and Safety qualification on the isolator for internal use. BioVectra acted independently and was not contracted by Air Science LLC. BioVectra makes no representations, warranties or guarantees with respect to the Flex30 isolator system, including without limitation warranties of merchantability or fitness for a particular purpose. Data provided by BioVectra is for reference only and should not be considered a substitute to internal use studies on containment efficacy by the Flex30 isolator system. BioVectra is a CMO with substantial experience in handling and containment of highly potent compounds.*

### Sources

- Air Science, Purair Flex Product Page. Accessed March 20, 2015. Online: <http://airscience.com/purair-flex-portable-isolators>
- BioVectra, Inc. 2015. OHS Qualification of Purair Flex 30. Internal Publication
- Glas-Col. Glove Bag Tips and New Uses. Accessed March 20, 2015. Online: [http://www.coleparmer.com/Assets/manual\\_pdfs/04408-38.pdf](http://www.coleparmer.com/Assets/manual_pdfs/04408-38.pdf)
- Trexler, P.C. and AM Gilmour. 1983. Use of flexible plastic film isolators in performing potentially hazardous necropsies. *Journal of Clinical Pathology*. 36: 527-529.



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