

**OXYGEN ANALYSER & INERTING CONTROL SYSTEMS**

Focus on

## Oxygen Monitoring & Inerting of Glove Boxes and Isolators

APPLICATION FOR OXYGEN ANALYSIS

The ever increasing demands of potent compound manufacturing and handling has meant that custom designed containment solutions are now the norm in most API manufacturing plants today.

Today's Health and Safety regulations along with the requirements of cGMP must be complied with meaning complete protection for the operator and the product.

### General

The primary concern when installing this type of equipment is towards that of eliminating the risk of exposure to the operator from the product or process. Once this is complete the design engineer must also consider the risks associated with the use and operation of the Glove Box or Isolator from the types of operations and processes that will be carried out by the equipment when in normal day to day use.

This barrier isolation must be uncompromising at all stages of product handling from Charging to Sampling to Drying to Packing to Cleaning etc. During many of these operations the atmosphere within the Isolator will need to be controlled and on many of these circumstances this involves the Inerting of this atmosphere.

### Inerting

Inerting is the reduction or displacement of the oxygen in the atmosphere by the flushing or purging of the space with an inert gas like nitrogen.

This reduction in the oxygen content may be for a number of design engineering reasons like :

- Oxygen sensitive products.
- Safety from explosions by reducing the oxygen level below the RMOc. Flammable atmospheres can exist during the use of flammable liquids during production or cleaning after use.
- The Isolator is connected to another inerted vessel, which may have their connection open during various stages of the process.



## Air Flow and Ventilation

The air handling in Isolators can be carried out by a number of different methods depending on the process operation and the level of containment required within. These can include:

- ◆ Constant re-circulation (downflow) with limited vent. The atmosphere is HEPA filtered with 90% recycled and 10% is released to vent
- ◆ Continuous extraction and ventilation for secondary containment with or without filtration. (HEPA)
- ◆ Constant re-circulation with vent only on purge.

For containment reasons most units have some type of filtration system employed on the ventilation line from the Isolator. This filtration forms an integral part of the system and its operation.

One of the most common forms of Isolator is a Glovebox which will operate under a negative pressure of  $-100$  to  $-250$  Pa with reference to the room pressure, this cancels any possibility of outward leakage of product but can be more complicated to control.

## Oxygen Monitoring and Control

When oxygen monitoring of Isolators is deemed a requirement then there are a number of options available to the application engineer. The final choice of Oxygen Analyser system is decided based on a couple of criteria.

- ◆ How safety critical is the measurement.
- ◆ What access to the sensor will be available when the system is installed.
- ◆ What level of automation and output is required.



