ISOMate

BIOAIR
a TECNIPLAST company

Positive & Negative Pressure Isolators

A safe and secure environment for your processes

Isolation technology is becoming widespread in several applications in the pharma and life sciences world. The ability to provide a **physically separated environment** from the lab in which to perform various kind of processes makes isolators the preferred goto solutions for different realities:

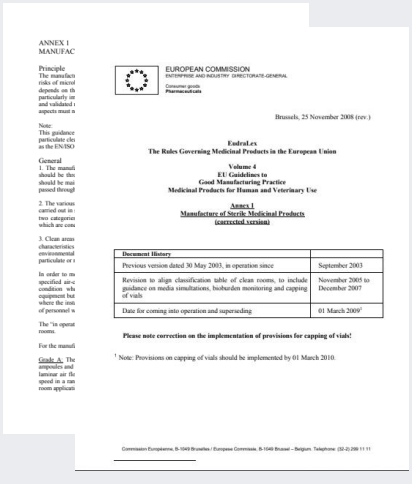
- Small & medium labs
- Pharmaceutical production
- Pharmacy departments in hospitals

Isolators allow to **fulfill the needs of GMP production without the need to provide a class B cleanroom**, reducing both the initial investment and the total running costs, both in terms of time and money. Moreover isolators provide a **scalable solution** allowing to start with a relatively lower investment and increase the total throughput over time if needed.

BioAir range of isolators covers many application scenarios, from **Advanced Therapy** with the **ISOCellPRO**, to hospital **pharmacy drugs preparation** with the **Isomate** series which is presented in this document.

GMP RECOMMENDS THE USE OF ISOLATORS

European Commission



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Consumer goods
Pharmaceuticals

Brussels, 25 November 2008 (rev.)

EudraLex
The Rules Governing Medicinal Products in the European Union

Volume 4
EU Guidelines to
Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use

Annex 1
Manufacture of Sterile Medicinal Products
(corrected version)

Document History	
Previous version dated 30 May 2003, in operation since	September 2003
Revision to align classification table of clean rooms, to include guidance on media simulations, bioburden monitoring and capping of vials	November 2005 to December 2007
Date for coming into operation and superseding	01 March 2009[1]

Please note correction on the implementation of provisions for capping of vials!

[1] Note: Provisions on capping of vials should be implemented by 01 March 2010.

"Restricted Access Barrier Systems (RABS) and isolators are beneficial in assuring the required conditions and minimizing the microbial contamination associated with direct human interventions in the critical zone. Their use should be considered in the CCS [Contamination Control Strategy]. Any alternative approaches to the use of RABS or isolators should be justified". (EudraLex Volume 4 – Annex 1 – Par. 4.3)

"The utilisation of isolator technology to minimize human interventions in processing areas may result in a significant decrease in the risk of microbiological contamination of aseptically manufactured products from the environment." (EudraLex Volume 4 – Annex 1 – Par. 21)

ISOMATE Steri – Positive pressure isolator

Applications

Sterile Galenic Preparations

Parenteral feeding solutions preparation

Aseptic manipulation of non-toxic products

GMP/pharmacological processes for hospital/lab

Configuration/
more options

2 or 4 gloves

Additional gloves for Pass-box

Painted or full stainless steel external surface

Control Systems/
optional

VHP Sterilization system

Particle and microbial counter

Panel PC – SCADA module

Glove leakage test system

Leak Rate Class/4
ISO 14644-7:2004 & ISO 10648-2:1994

ISOMATE Steri has been designed to provide protection to products/processes requiring a sterile environment without external contaminants.

Product protection is achieved via a sealed work area with an inner pressure higher than the surrounding environment; the only access to the work area, when in operation, is through the lateral pass-boxes.

Product manipulation is done via gloves installed in the front window.
All three areas (work area and two pass-boxes) are provided with a unidirectional airflow and HEPA filters.

The additional integrated **hydrogen-peroxide vaporization system** allows full sterilization of the working chamber and both passboxes.

TECHNICAL SPECIFICATIONS

- Two (2) interlocked pass-boxes, with unidirectional air-flow, more than 100 air changes per hour and an inner pressure higher than the external environment but lower than the working area; both are equipped with a manual sliding tray and tempered glass doors to allow entrance and exit of the products from two different sides;
- Front window made in tempered, layered glass with oval flanges for the gloves; the flanges are compatible with glove testing systems;
- Inner working area will be in AISI316 stainless steel;
- Outer structure will be in epoxy painted steel (optionally in stainless steel);
- HEPA H14 filters both for air inlet and for exhaust;
- Inner cleanliness classification: ISO3 according to EN14644-1 (Class A GMP EU);
- 2 inner sockets in working area;
- Power supply: 230V 50/60Hz single phase
- Pressure transducers to control the differential pressure between the various environments;
- Cam-lock connector in all the chambers to allow connection with a VHP generator for sterilization;
- Touch-panel interface;

Standard Sizes

	2 GLOVES	4 GLOVES
External Size - mm	2.798 x 841 x 2.390h mm	3.408 x 841 x 2.390h mm
Inner working area size - mm	1.228 x 590 x 690h mm	1.838 x 590 x 690h mm
Pass-box	2	2
HEPA filters	4	4
Motorblowers	2	3
Gloves	2	4
Working area classification	ISO 3	ISO 3
Power supply	230V-50 Hz	230V-50 Hz

ISOMATE Cyto – Negative pressure isolator

Applications

Cytotoxic/CMR substances manipulation

Oncology pharmacy unit

GMP/pharmacological processes for hospital/lab

Configuration/ more options

2 or 4 gloves

Additional gloves for Pass-box

Painted or full stainless steel external surface

Control Systems/ optional

VHP Sterilization system

Panel PC – SCADA module

Glove leakage test system

Leak Rate Class/4

ISO 14644-7:2004 & ISO 10648-2:1994

ISOMATE Cyto has been designed to provide protection to operators, environment and products during processes requiring **the manipulation of cytotoxic and mutagen (CMR) substances**.

Operator and environment protection is achieved via a sealed work area with an inner pressure lower than the surrounding environment; the only access to the work area, when in operation, is through the lateral pass-boxes.
Product manipulation is done via gloves installed in the front window.

All three areas (work area and two pass-boxes) are provided with a unidirectional airflow and HEPA filters. Two centrifugal motor-blowers will take care of ventilation and pressure management. An additional set of HEPA filters below the working surface collects all the CMR contaminated aerosols preventing them to reach the non-cleanable surfaces in the technical areas of the isolator (plenum, airflow channels, main and exhaust filters).

The ISOMATE Cyto is designed and built according to the **DIN 12980:2017** normative, the leading standard for CMR safe manipulation.

The **patended BagIn-BagOut** procedure ensures that, during the replacement of the first stage HEPA filters, there is never exposure of environment and personnel to potentially contaminated surfaces both on the filters and in the working area, making sure that **safety is always granted**.

TECHNICAL SPECIFICATIONS

- Inner cleanliness classification: ISO3 according to EN14644-1 (Class A GMP EU);
- Inner work area airflow: unidirectional, self-regulated with average speed 0.45m/s;
- Inner work area pressure: -75Pa with respect to outer environment, self-regulated;
- Partially recirculated airflow with three (3) filtration stages equipped with HEPA H14 (EN1822-1) filters;
- First filtering stage (recirculated air, below work surface) with bag-in/bag-out filter removal system;
- Two (2) interlocked pass-boxes, with turbulent air-flow, more than 500 air changes per hour and an inner pressure between -30Pa and -50Pa with respect to the external environment (+25Pa and + 45Pa with respect to inner working chamber); cleanliness level ISO5 (EN14644-1);
- Dynamic air-barrier when opening the passbox inner door: the differential pressure creates a slight airflow toward the inner chamber avoiding contaminants to leave the working space. The air barrier is created by ad-hoc slots which prevent the contamination of the working area as well;
- Both passboxes are equipped with a manual sliding tray and tempered glass doors to allow entrance and exit of the products from two different sides;
- Front window made in tempered, layered glass with oval flanges for the gloves; the flanges are compatible with glove testing systems;
- Inner working area will be in AISI316 stainless steel;
- Outer structure will be in epoxy painted steel (optionally in stainless steel);
- HEPA H14 filters both for air inlet and for exhaust;
- 2 inner sockets in working area;
- Power supply: 230V 50/60Hz single phase
- Pressure transducers to control the differential pressure between the various environments;
- Cam-lock connector in all the chambers to allow connection with a VHP generator for sterilization;
- Touch-panel interface;

Standard Sizes

	2 GLOVES	4 GLOVES
External Size - mm	2.798 x 841 x 2.390h mm	3.408 x 841 x 2.390h mm
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Gloves	2	4
Working area classification	ISO 3	ISO 3
Power supply	230V-50 Hz	230V-50 Hz

ISOMATE CONTROL SYSTEM

All the functions of the isolator, including ventilation and doors interlock, is managed by a **PLC system** with a graphical touchscreen interface.

Optionally it is possible to integrate a panel PC acting as a local SCADA module interfacing with the isolator control system, allowing control, monitoring and data recording in compliance with **GAMP and FDA CFR21 part 11** requirements.

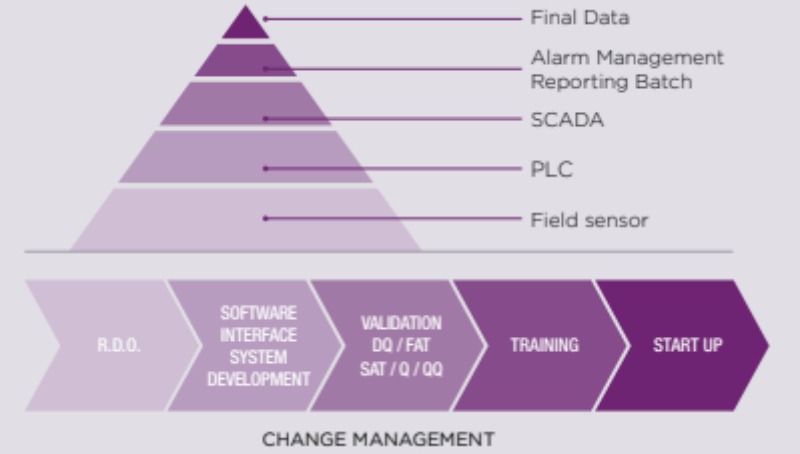
The main software functions are:

Monitoring of:
- Inner chamber pressure;
- Air tightness;
- Passbox doors interlocking and status;
- Front window opening (for cleaning/maintenance only);
- Air flows and HEPA filters status;

Generation and recording of alarms;

It is also possible to interface the isolator with **BMS systems** using ModBus or TCP/IP protocols.
If needed other interfaces and protocols can be evaluated as custom options.

An optional SCADA system can be connected to the ISOMATE to make it fully GAMP and FDA CFR21 part 11 compliant



Applications

Leak testing for isolator's gloves

Specifications

Color Touchscreen interface

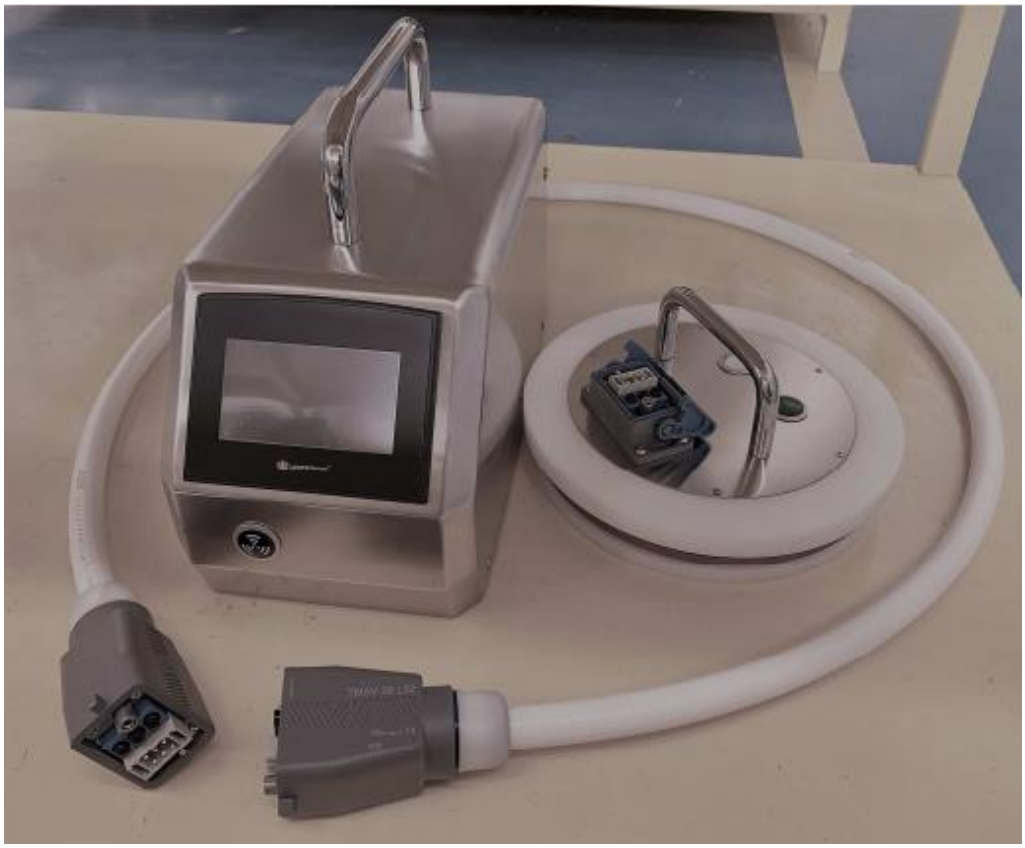
Integrated printer

Full stainless steel body

SAFEGLOVE - Gloves leak test device

SafeGlove is a **leak test system** for "Access devices" (i.e. gloves) for isolators and similar closed systems.

SafeGlove is an equipment that allows to check the tightness of a glovebox, according to the method described in **Annex E of ISO 14644-7**.
The pump, installed in the main body of the machine, conveys the air to the flange through the connection cable. The air inflates the flange seals, allowing it to adhere completely to the glove box, sealing the opening.
At this point, air is pumped inside the glovebox until a set point pressure is reached and its decrease is monitored to detect any leaks.



3 Different operational modes

Pre-stretching: this test is used to repeatedly inflate and deflate the glove to allow the elastomer to relax, making the test reproducible in case of a new glove;
ISO Test: This mode allows a leak test to be carried out as described in ISO 14644-7, Annex E, paragraph 2.1.2;
Custom Test: this mode allows to set up custom parameters.

Reference normatives

SAFETY:
IEC 61010-1:2010 + A1:2016 / EN 61010-1:2010 + A1:2019
Electrical insulating protection class [IEC 61140]: I
ELECTROMAGNETIC COMPATIBILITY (EMC):
IEC 61326-1:2012 / EN 61326-1:2013
IP Protection Degree [IEC 60529]:
Common equipment (xxB)

ISOMATE
Positive & negative
pressure isolators

WE ARE

Bioair's history of research and development is characterized by more than 50 years of innovation. When, in 1972, the company, under the Gelaire brand, first launched in Europe what today is called a "Biological Safety Cabinet" or BSC, the very name of this equipment was not yet in common use. Then, in the 1980s, with the entry into force of the first International Standards for this type of product, our R&D department revolutionized the BSC control system of the time, designing the Compusafe, the first microprocessor developed specifically for Biological Safety Cabinets. Always one step ahead of the competition. Over the years, always in line with the most significant developments in Environmental Contamination Control technology, always trying to "plan the future" and keeping faith with the company motto: your safety is our commitment, Bioair enters in increasingly sophisticated sectors and, in 2012, produces its first isolator for Advanced Cell Therapies.

Contacts

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