Isolator Technology
Cytotoxic Dispensing Isolators (CMR)
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ENVAIR Group
Much more than clean air

The ENVAIR Group is on the markets since more than 40 years. As an installations specialist for Life Science / Biotechnology, Pharmacy and Chemistry ENVAIR produces in their own factory. ENVAIR Deutschland GmbH is in charge of the German-speaking market and organizes sales of the complete ENVAIR product range. The palette of clean-air and containment installations reaches from smallest Work Benches up to most complex Isolators. Cleanroom Technology at its best.

1972: Foundation ENVAIR Ltd. (GB)
1979: Development of Microbiological Safety Cabinets
1986: Development of Isolators for hospitals and pharmacies
1992: Development of complex pharmaceutical Isolators for Industry
2000: Honouring with the “Awarded Design Council Millennium Products” for the development of Micro-Isolators
2006: ENVAIR Ltd. becomes subsidiary of Bassaire Ltd. (www.bassaire.co.uk)
2009: Foundation of ENVAIR Deutschland GmbH
2009: Re-design of Cytotoxic Dispensing Isolators CMR
2009: Options enhancement for Isolators e.g. vertical material lock doors
2011: Re-Design Stent Line
2012: New development Botox production line
High-Tech for your laboratory – Cytotoxic Dispensing Isolators of the latest generation

- Energy save blowers for energy saving of 50%
- Siemens HMI Touch Panel with connection to Building Management System (display size 6“)
- Remote control function (remote maintenance)
- Timer for programmable start/stop
- Vertical lock door for extended space in the work chamber (no swivel doors)
- Foot switch operation of the inner lock door
- Lock door opening towards the Isolator for better charge/discharge
- Button operation of the outer lock door
- Automatic pressure decay test lid
- HEPA H14 main filter, space-saving installation, attached ergonomically for maximum legroom – 300 mm

Cytotoxic Dispensing Isolator (white epoxy-powder coated)
New lock design
Remote control connection (remote maintenance)
Cytotoxic Dispensing Isolator (CMR)

Application range:

Processing of:
- Cytotoxic drugs (CMR)
- Antiviral drugs
- Capsules
- Hazardous material (hazmat) under TRGS 525
- Any toxic agents

The Isolator has the following features:

- Air quality of cleanroom class A (unidirectional laminar flow) as per EU-GMP guide within the whole working space
- Easy cleaning inner and outer surfaces
- SIEMENS control easy to clean
- Automatic pressure decay test with data storage
- Remote control function. If need be the Envair service department is able to log in from externally for failure detection. Therefore reasonable saving of cost.
- Safe and consistent separation of operator and process due to a closed system
- Negative pressure (-85Pa) operation under laminar flow
- Sterile glove exchange system
- Easy supervision, check and maintenance
- Ergonomically designed for simple operation, good visibility and high personnel comfort
- Selectable display of internal pressure with delayed disjunction time, automatic pressure decay test and display of pressure decay
- Electro-polished stainless steel work tray, easy to clean
- High air change rate in the working area and in the material locks for rapid clean-up of contaminated air and rapid discharge of disinfectants
- Locks with transfer trays, foot switches for the doors and electro-magnetic counter lock
- SIEMENS PLC control S7 200 with HMI touch panel (size 6”)
- Stand-by operation
- Tested and documented quality (IQ/OQ)
- Reasonable price/performance relation compared to tailor-made Isolators
- Standards conformity to DIN EN IASO 14644-7, EN 61010 (electrical safety), VDE / DIN 57789 (tests), VDI 2083-1 and VDI 2083-3 (qualification)
- Air quality cleanroom class A as per EU-GMP guide and DIN EN ISO 14644-1 class 5

Cytotoxic Dispensing Isolator 1.5 m useful width with vertical inner lock doors, no swivel doors

Ø 300 mm glove port
Optional equipment for all Isolator models

- Connections for air, vacuum, N₂
- H₂O₂ gassing, H₂O₂ lock
- Electrically driven support frame
- 2 Isolators (double version) with central 3-way lock
- Isolator with 1 lock
- Vertical inner lock doors
- Activated charcoal filters
- Suspension bar in the work zone
- Isokinetic sensor for particle monitoring
- Water proof electric socket IP 56
- Connection for air sampler

- Lock pressure display
- Camera for documenting the process
- Test disk with manometer for glove testing
- Cleanroom monitor 12” or 19” with touch screen
- Work surface for utilizing a balance
- Interface RJ 45 / RS 232 / USB
- Temperature and humidity supervision
- Complete manufactured in stainless steel 1.4301 <0,8µ
- Active 2-hand disinfection lock
- 3-way lock with attached Safety Cabinet
- Further options on request
State of the Art – for safe work

Description Isolator:

The Isolator is basically manufactured in powder-coated steel sheet but can be manufactured entirely in stainless steel 1.4301 upon request. The work zone is made of stainless steel 1.4404, the work surface is removable. The system is filtered with a unidirectional laminar airflow via HEPA H14 filters.

The front visor offers a number of practical and reliable features. It is fitted with either 2 or 4 integrated glove ports which allow comfortable work due to a wide diameter of 300 mm.

It is hinged for easy cleaning works and held open by gas struts. During operation the front visor seal is pressed against the Isolator body by means of 7 locking levers.

The Isolator is connected to the material locks with a static gasket.

The rear wall holds optionally a 17” or 19” touch screen monitor which is level with the wall. In order to avoid reflections during operation there is no additional glass screen in front of the monitor.

The Isolator can be operated in seated as well as in standing position. The 100% legroom is granted by the construction of the main filter housing which is situated towards the back.

The Isolator is fitted with transfer locks at both sides for charging / discharging the treated material. Each transfer lock has an inner and outer door as well as a pull-out transfer table from out the lock into the work zone. Every lock is ventilated via a pre-filter G4 and 2 HEPA H14 filters.

The air which enters the work zone is always filtered by a HEPA H14 filter, regardless from one of the lock doors to be open. For safety reasons the inner and outer doors of the locks are electro-magnetically interlocked which means, only one door can be opened at a time. All other doors remain locked and cannot be opened.

If the door is closed an adjustable delay time will count down, then one of the other doors can be opened. This guarantees that no particles will enter the work zone or will escape to the environment (rinsing phase). Each lock is fitted with a foot switch to open the inner lock doors.

Isokinetic sensor for permanent particle monitoring, the placement inside the work zone is free as long as it is in conformity to the standards.

17” cleanroom monitor in the rear wall with touch-screen function. This monitor has been developed specially for cleanrooms.
Transfer lock doors (swivel doors):

The outer and inner transfer lock doors are swivel-type doors. The outer doors open from the bottom to the top. Optionally they can be opened from the left to the right or vice versa by attaching a lateral door catch. The mechanism is operated by a push-button at the lock and a second switch at the display. The inner lock doors open from the front to the back, operated by a foot switch or a second switch at the display.

Remark: You don’t lose any space in the work zone. As soon as the transfer tray is in use or pulled out there will be enough space left.

Optional vertical lock doors:

The inner vertical lock doors open with the foot switch. When pressing the switch the prevailing lock door will open automatically. The door moves vertically to the top. When the door is to be closed again, the foot switch must be pressed again, the door moves vertically downwards automatically. The doors are fitted with a counter-pressure sensor in order to avoid fingers to be squeezed. The inner doors must no longer be opened by hand due to this new function. Cross-contamination via the doors can be avoided in this way. Even the complete work flow will become more economic.

Remark: Fail-safe by compressed air function, no electric motor drives.

Outer lock doors: Opening function via SIEMENS control or push-button at the lock

Inner lock doors: Opening function via SIEMENS control or foot switch

Exhaust air piping with customer’s fix connection (no blind)

View the lock door function under:
http://www.youtube.com/watch?v=FpnV2TkK3JM

View the glove exchange under:
http://www.youtube.com/watch?v=3UNsJ7SFCqI

Media connections in the work zone for: electric sockets, RJ45, RJ32, USB, gas, vacuum, etc.
**Airflow:**

Air from the environment enters the work zone after double-filtration. Firstly via a pre-filter and HEPA H14 lock filter from the top into the transfer lock, then via a second HEPA H14 filter at the rear wall. From there on it is guided through the main HEPA H14 filter which is installed in the work zone and 30% of the volume is directed back to the environment via another HEPA H14 exhaust air filter. The remaining 70% portion of the volume is recirculated through the HEPA H14 circulating filter vertically, laminar to the work zone and the main HEPA H14 filter at the bottom respectively. The air circulation starts again from the beginning.

**Due to the main HEPA H14 filter underneath the work surface only the work zone and the space underneath the work surface will be contaminated. Other contamination of the air guidance system is not possible which eases maintenance and enhances safety.**

**Exhaust air:**

The exhaust air is directed via a gas-tight valve and the anti-blowback flap to the exhaust air flange. The delivered exhaust air piping must be connected to customer’s exhaust air system.

**Control system:**

SIEMENS HMI Touch Control.
Optional free interface to customers exhaust air system and alarm system.

**Password protection at the control:**

Changes of the interlock time of the lock doors or alarm limits are only accessible with password.

**Power breakdown:**

An acoustic alarm will be generated in case of power breakdown. The alarm is independent from the mains by an UPS (Uninterruptable Power Supply). Optionally a strong UPS is available which allows further works for about 10-20 minutes.

**Separate switches:**

- Foot switch left to open the left inner lock door
- Foot switch right to open the right inner lock door
HMI Touch Panel

The Isolator is fitted with a digital SIEMENS HMI Touch Panel to display all measured values, with scroll-down function. The Isolator does not have any analogue differential pressure indications.

The menu offers a number of features:

- Operation hours counter (hours, minutes)
- Last power breakdown (Date, time)
- Last service (date, time, password protected)
- Last pressure decay test (date, time, pass or fail)
- Pressure decay test values (value 1, value 2, etc.)
- Locking time left inner lock door (seconds, password protected)
- Locking time left outer lock door (seconds, password protected)
- Locking time right inner lock door (seconds, password protected)
- Locking time right outer lock door (seconds, password protected)

Status of the lock doors with indication of rinsing time.

Alarms at the display of the PLC control:

- Air change rate
- Work zone pressure
- Main filter – differential pressure monitoring

All alarms are free adjustable
Automatic pressure decay test:

The Isolator carries out a pressure decay test by itself in order to make sure that Isolator and locks are completely gastight. Automatic build-up of -250Pa negative pressure, then the hold time starts.

Automatic measuring start when the negative pressure has reached -180Pa. Measuring are taken every 90 seconds, the values are stored by the PLC, total 3 measuring. All measured values can be read from the display.

**Acceptance criteria: max. 25Pa pressure drop per minute.**
In case the pressure drop will exceed 25Pa per minute the display will show "pressure test fail".
In case the pressure drop will be less than 25Pa per minute the display will show "pressure test passed".
Envair criteria: 25Pa during 90 seconds measuring time.

Gloves/Sleeves:

Separately exchangeable glove/sleeve combination. Gloves can be changed without breaking the cleanroom atmosphere of the work zone.

The advantage of a large sleeve port is the advanced mobility. This makes it easy to work with the Isolator for personnel of different body size.

Filter:

All filters (except the pre-filters) are HEPA filters with a nominal separation rate of 99.995% and comply with DIN EN 1822 in terms of separating rates of filter class H14.

The pre-filters on top of the transfer lock filters are coarse dust filters of class G4 as per DIN EN 779 and they are a deciding factor in terms of lifetime of the transfer lock HEPA filters.

Exchanging the pre-filters is done by simple pull-out from the filter frame and replace by a new filter. No tools needed and the filters are not contaminated.

**DEHS-Test/Filter test:**

The Isolator is fitted with a number of test openings to allow filter testing in terms of separating rate and leakage. All test pass-through are accessible from the front. All HEPA filters are tested (main filter H14, circulation filter H14, exhaust air filter H14 and transfer lock filter H14).
Air classification:
The classification of air in the complete work zone is standardized:
• EU GMP, Grade A
• BS 5295 (1989) Class F
• ISO Class 5 as per DIN EN ISO 14644-1

Air pressure:
On drop or exceeding of pre-set alarm values an alarm is generated (optical and acoustical).

Air velocity:
Vertical, unidirectional laminar airflow (LF) inside the work zone of approx. 0.45 m/s air speed. The air speed rises to ≥0.7 m/s in case of leakage, for instance an “open” glove port (0.7 m/s is prescribed by DIN EN 14644-7).
The air speed inside the work chamber is in limits adjustable by adjusting the r.p.m. of the circulation blowers (vertical flow blower).

Support frame:
Metal support frame, fixed height 850 mm
Option: complete stainless steel

Double glove system
Biogel Eclipse Indicator – the criterion in protection and safety.
The innovative Biogel Eclipse™ Indicator consists of two gloves, one green inner glove and one straw-coloured outer glove. The inner glove is half a size bigger than the outer glove. The advantage is pressure reduction to the hand and less fatigue of the hand.
If the outer glove gets perforated the air from the work zone remains between both gloves. A green dot indicates the perforation. Besides the quick perforation indication the Biogel Eclipse™ convinces by an optimal fit, better comfort and increased sense of touch. Biogel Eclipse™ gloves are thinner and smoother than other gloves. The special Biogel inner lining allow easy slip-in even with sweaty hands.

Why double glove system?
• Glove perforations remain undetected during work.
• 97% of perforations are detected with the patented Biogel Eclipse™ indicator system.
• Double glove systems reduce the perforation risk from 34.7% to 3.8%.
• Double glove systems reduce the contamination risk of hands from 13% to 2%. 

Iso-Footrest

Biogel Eclipse™Indicator
Particle monitoring in the Isolator:

The outstanding features of the particle counters of PZG-series are: user-friendly, versatile data-technical linkable, easy to transport and with enormous capacity.

The compact particle counters in their elegant stainless steel housing and the large touch-screen colour display are the favourite expert tools in the field of filter integrity testing in semi-conductor and pharmaceutical industries, for hospitals and pharmacies as well as in various other clean production processes.

Precision and flexibility are outstanding features of the PZG-series. At a flow rate of 28.3 l/min the particle counters measure from 0.2 µm on and with a flow rate of 100 l/min from a particle size of 0.3 µm. The two model-types can display up to 8 different particle sizes simultaneously.

The PZG units are fitted with 2 interfaces (USB and ETHERNET) and generate data reports according to all important standards: DIN EN ISO 14644-1, DIN 1946-4, CFM, GMP at rest and GMP in operation. The particle counters are not only independent measuring instruments but also fully usable as components of a particle monitoring system.

Particle measuring unit connected to an existing monitoring system:

The remote-series are the "specialists" for monitoring in cleanrooms. They cover the measuring methods and standards in the pharmaceutical industry, semi-conductor production, biotechnology and many other clean production processes.

Concerning a continuous particle monitoring, the remote-series offers considerable advantages against common monitoring systems. All units are fitted with RS 485 interface and one 4-20 mA analogue outlet and can easily be integrated in an existing cleanroom system. Since each sensor has its internal vacuum pump the installation of vacuum networks is not necessary.
Quality Assurance Concepts for Cytotoxic Dispensing Isolators / SOP templates

We have prefabricated SOPs which can be adopted to your work flow with only little expenditure

SOP templates

Cleanroom
• Cleanroom and climate engineering
• Isolators and Cabinets
• Monitoring

Personnel
• Basics
• Briefing, training, further education
• Personnel validation
• Personal protective clothing

Cleaning
• Cleaning personnel
• Assistant
• Compounder

Production
• Goods flow
• Goods transfer
• Working instruction assistant
• Working Instruction compounder
• Substantial working instruction
• Production flow

Quality control
• Validation of open packs
• Microbiological production validation
• Microbiological ambient monitoring
• Cleanroom monitoring

Documentation
• Cleanroom and Climate Technology, Isolators and Cabinets
• Personnel
• Cleaning
• Production
• Quality control

Malfunction and Accidents

Iso-Chair ergonomic
Iso-assistant
### Cytotoxic Dispensing Isolator (CMR)

<table>
<thead>
<tr>
<th>Isolator dimensions:</th>
<th>CDC‘F’ 2G2D 1.2 m work zone width 1.2 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.5 m work zone width 1.5 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.8 m work zone width 1.8 m 4 gloves, 2 locks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer dimensions (mm) WxHxD complete</td>
<td>2432 x 2200 x 720</td>
<td>2750 x 2200 x 720</td>
<td>3030 x 2200 x 720</td>
</tr>
<tr>
<td>Inner dimensions (mm) WxHxD</td>
<td>1180 x 690 x 520</td>
<td>1495 x 690 x 520</td>
<td>1780 x 690 x 520</td>
</tr>
<tr>
<td>Outer dimensions (mm) WxHxD Isolator w/o locks</td>
<td>1340 x 2200 x 720</td>
<td>1660 x 2200 x 720</td>
<td>1940 x 2200 x 720</td>
</tr>
<tr>
<td>Working height (mm)</td>
<td>690</td>
<td>690</td>
<td>690</td>
</tr>
<tr>
<td>Volume (litre)</td>
<td>423</td>
<td>536</td>
<td>639</td>
</tr>
<tr>
<td>Inner door dimensions material lock (mm)</td>
<td>305 x 310</td>
<td>305 x 310</td>
<td>305 x 310</td>
</tr>
<tr>
<td>Outer door dimensions material lock (mm)</td>
<td>450 x 310</td>
<td>450 x 310</td>
<td>450 x 310</td>
</tr>
<tr>
<td>Sleeves</td>
<td>Polyurethane with textile lining</td>
<td>Polyurethane with textile lining</td>
<td>Polyurethane with textile lining</td>
</tr>
<tr>
<td>Dimensions at wrist 90 mm, glove port Ø 300 mm</td>
<td>Polyurethane with textile lining</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Electric connection and weight

<table>
<thead>
<tr>
<th>Connected values</th>
<th>CDC‘F’ 2G2D 1.2 m work zone width 1.2 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.5 m work zone width 1.5 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.8 m work zone width 1.8 m 4 gloves, 2 locks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (approx. kg)</td>
<td>420</td>
<td>450</td>
<td>480</td>
</tr>
<tr>
<td>Lighting work surface (lux)</td>
<td>≥ 1200</td>
<td>≥ 1200</td>
<td>≥ 1200</td>
</tr>
<tr>
<td>Noise level</td>
<td>≤ 56 dB(A)</td>
<td>≤ 58 dB(A)</td>
<td>≤ 60 dB(A)</td>
</tr>
</tbody>
</table>

### Filter

<table>
<thead>
<tr>
<th>Pre-filter G4 (mm)</th>
<th>CDC‘F’ 2G2D 1.2 m work zone width 1.2 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.5 m work zone width 1.5 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.8 m work zone width 1.8 m 4 gloves, 2 locks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply air lock filter H14 (mm)</td>
<td>320 x 460 x 20</td>
<td>320 x 460 x 20</td>
<td>320 x 460 x 20</td>
</tr>
<tr>
<td>Exhaust air lock filter H14 (mm)</td>
<td>320 x 460 x 69</td>
<td>320 x 460 x 69</td>
<td>320 x 460 x 69</td>
</tr>
<tr>
<td>Main filter H14 (mm)</td>
<td>1130 x 456 x 66</td>
<td>1450 x 456 x 124</td>
<td>2x 860 x 456 x 124</td>
</tr>
<tr>
<td>Circulation filter (mm)</td>
<td>1220 x 508 x 66</td>
<td>1560 x 508 x 66</td>
<td>1828 x 508 x 66</td>
</tr>
<tr>
<td>Exhaust filter (mm)</td>
<td>860 x 456 x 124</td>
<td>860 x 456 x 124</td>
<td>860 x 456 x 124</td>
</tr>
</tbody>
</table>

### Materials

<table>
<thead>
<tr>
<th>Isolator chamber</th>
<th>CDC‘F’ 2G2D 1.2 m work zone width 1.2 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.5 m work zone width 1.5 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.8 m work zone width 1.8 m 4 gloves, 2 locks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work surface</td>
<td>Electro-polished stainless steel 1.4404</td>
<td>Electro-polished stainless steel 1.4404</td>
<td>Electro-polished stainless steel 1.4404</td>
</tr>
</tbody>
</table>

### Air changes

<table>
<thead>
<tr>
<th>Air change rate work zone /h</th>
<th>CDC‘F’ 2G2D 1.2 m work zone width 1.2 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.5 m work zone width 1.5 m 2 gloves, 2 locks</th>
<th>CDC‘F’ 2G2D 1.8 m work zone width 1.8 m 4 gloves, 2 locks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air change rate material lock /h</td>
<td>1800</td>
<td>1800</td>
<td>1800</td>
</tr>
<tr>
<td>Exhaust air Isolator</td>
<td>3400</td>
<td>3400</td>
<td>3400</td>
</tr>
<tr>
<td>Exhaust air volume m³/h</td>
<td>860</td>
<td>860</td>
<td>860</td>
</tr>
<tr>
<td>Temperature increase work zone (constant ambient temperature 20°C)</td>
<td>3-5°C depending on filter condition</td>
<td>4-6°C depending on filter condition</td>
<td>4-6°C depending on filter condition</td>
</tr>
<tr>
<td>Air flow (Laminar Flow) m/s</td>
<td>0.45</td>
<td>0.45</td>
<td>0.45</td>
</tr>
<tr>
<td>Negative pressure</td>
<td>-85 Pa</td>
<td>-85 Pa</td>
<td>-85 Pa</td>
</tr>
</tbody>
</table>
Envair offers service in pure culture. We do not simply sell our units to you but will assist you gladly from A to Z.

**Delivery:**
We deliver all units ex works. Set-up service and packaging disposal are included upon request.

**Service:**
- 24h at site service and 24h free of charge phone hotline
- 7 days a week

**Spare parts guaranty:**
- 10 years
- Availability within 24h
- Ex stock Emmendingen

**Qualification:**
- IQ/OQ
- GMP
- GAMP
- 21 CFR Part 11

**Decontamination:**
We carry out microbiological decontaminations with most modern H2O2 generators or Formalin units in Cleanrooms, Isolators and Safety Cabinets

**Maintenance:**
- Microbiological Safety Cabinets DIN 12469
- Cytotoxic Dispensing Cabinets with KI-discus test DIN 12980
- Product Protection Cabinets
- Laboratory Fume Hoods
- Cytotoxic Dispensing Isolator EN 14644-7
- Isolator EN 14644-7
- Cleanrooms

Service by professional staff. All works are carried out by service technicians qualified by TÜV Nord

**Maintenance contract:**
Regular terms of maintenance increase your safety. With a maintenance contract we guarantee the complete check of all functions of your units. We will contact you reliably in regular terms.

**Guaranty and Warranty:**
Combined with an ENVAIR maintenance contract we offer a 2-year warranty to all units. Excepted are consumables and wearing parts as well as compressed air components.
### Excerpt of our product portfolio

**Life Science/Biotechnology**
- Microbiological Safety Cabinets
- Incubators/CO2-Incubators
- Laminar Flow Cabinets Horizontal/Vertical
- PCR Cabinets

**Pharmacy**
- Isolators
- Cytotoxic Dispensing Safety Cabinets
- Cleanroom Cabinet
- Special Constructions

**Chemistry**
- Laboratory Fume Hoods circulating