STANDARD SOLUTIONS

UNIDIRECTIONAL AIRFLOW
STANDARD ASEPTIC ISOLATOR

RECIRCULATED UNI-DIRECTION AIRFLOW ACHIEVING A GRADE A ENVIRONMENT

FLEXIPHARM
IDEAL FOR R&D OR SINGLE USE APPLICATIONS

STANDARD CONTAINMENT ISOLATOR

ACHIEVABLE OPERATOR PROTECTION TO <1 µG/M³

TURBULENT FLOW
STANDARD ASEPTIC ISOLATOR

POSITIVE PRESSURE ENVIRONMENT COMPLETE WITH INTEGRATED HYDROGEN PEROXIDE GENERATOR

MOBILE AUTOMATED GLOVE TESTER

TESTING UP TO 6 GLOVES AT ONE TIME FULL CYCLE IN UNDER 5 MINUTES!
Whatever you look for in an aseptic solution, you will want it to be proven, tested and guaranteed. Extract Technology’s Isolators deliver all these things and more.

AS PART OF THE STANDARDISED PRODUCT RANGE STERIPHARM IS A USER AND MAINTENANCE FRIENDLY SYSTEM PROVIDING A COST EFFECTIVE ALTERNATIVE SOLUTION FOR ASEPSTIC PROCESSING OR STERILITY TESTING

STERIPHARM TURB
SteriPharm TURBulent is designed to offer increased protection and quality assurance of process integrity by utilising single pass turbulent flow.

IDEAL FOR STERILITY TESTING
ACHIEVING A ISO 5 (AT REST) ENVIRONMENT.

DESIGN FEATURES
- EU GMP compliant design with controls system to GAMP 5 (cat 4)
- Full process equipment integration within a ISO5 environment in both working and transfer chambers
- Energy efficient
- Fully integrated VPHP Generator
- Fully integrated dehumidification unit.
- Rapid gassing transfer hatch (Sub 30mins with small load)
- Manufactured at Extract Technology HQ to accredited ISO9001 operating procedures
- DOP scanning probes for full exhaust filter face leak detection
- Specifically designed to be disassembled and to fit through a standard single width doorway
- Automatic pressure decay and leak detection
- Positive pressure cascade between each chamber and room environment.
- Integrated H₂O₂ room monitor
- Integrated High/Low level H₂O₂ Monitor
- Comprehensive validation package FAT/FS/GA/P&ID/IQ/OQ & Data Book with O&M manual and full certification package

AVAILABLE OPTIONS
- Viable and Non-viable particle monitoring
- Paperless touch screen chart recorder (validated to 21CFR-Part11),
- Fully customised product racking
- RTP
- Cycle development at Extract Technology’s dedicated testing facility + many more

POWER SUPPLY
- 3PH 50/60HZ
- 400v N+E

Technical requirements
The SteriPharm Bio-decontamination process ensures a **6 log reduction in bacterial spore** population with inclusive safety features to guarantee operator and plant safety.

Increased protection from contamination is achieved by:
- reducing human interventions
- physical barrier technology
- using ergonomically designed sloping visor and large oval Pharmaport gloveports
- differential pressure cascade
- routine Hydrogen Peroxide Vapour Phase Decontamination

**STERIPHARM UDAF**

SteriPharm UDAF is designed to offer increased protection and quality assurance of process integrity by utilising **Recirculated Uni-Directional AirFlow achieving a grade A environment**

**IDEAL FOR STERILITY TESTING OR OPEN PROCESS MANUFACTURING WITHIN A VALIDATED FULLY STERILE ENVIRONMENT.**

### STERIPHARM UDAF

**EU GMP compliant design with controls system to GAMP 5 (cat 4)**
- Full process equipment integration within a grade A environment in all chambers
- Energy efficient
- Fully integrated VPHP Generator
- Fully integrated dehumidification unit
- Rapid gassing transfer hatch
- Manufactured at Extract Technology HQ to accredited ISO9001 operating procedures
- Safe-Change Exhaust H14 grade HEPA filters
- DOP scanning probes for full exhaust filter face leak detection
- Specifically designed to be disassembled and to fit through a standard single width doorway
- Automatic pressure decay and leak detection
- Positive pressure cascade between each chamber and room environment
- Integrated H₂O₂ room monitor
- Integrated High/Low level H₂O₂ Monitor
- Comprehensive validation package FAT/FS/GA/P&ID/IQ/OQ & Data Book with O&M manual and full certification package

### DESIGN FEATURES

**UNIDIRECTIONAL AIRFLOW STERIPHARM**

<table>
<thead>
<tr>
<th>Overall Height</th>
<th>2,320 - 91 3/8&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Width</td>
<td>3,180 - 125 1/8&quot;</td>
</tr>
<tr>
<td>Overall Depth</td>
<td>880 - 34 5/6&quot;</td>
</tr>
<tr>
<td>Chamber Width</td>
<td>1,840 - 72 1/2&quot;</td>
</tr>
<tr>
<td>Chamber Height</td>
<td>850 - 33 1/2&quot;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chamber Depth</th>
<th>600 - 23 3/8&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chamber Height</td>
<td>850 - 33 1/2&quot;</td>
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**STERIPHARMS’ DIMENSIONS :**

<table>
<thead>
<tr>
<th>SteriPharm Isolator</th>
<th>Overall Height</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Glove with Airlock (TURB)</td>
<td>2,475 - 97 1/2&quot;</td>
</tr>
<tr>
<td>4 Glove single chamber (TURB)</td>
<td>2,320 - 91 3/8&quot;</td>
</tr>
<tr>
<td>4 Glove with Airlock (UDAF)</td>
<td>2,320 - 91 3/8&quot;</td>
</tr>
</tbody>
</table>

**Overall Width**
- 3,180 - 125 1/8"
- 2,170 - 85 3/8"
- 3,180 - 125 1/8"**

**Overall Depth**
- 880 - 34 5/6"**
- 880 - 34 5/6"**
- 1,219 - 48"**

**Chamber Width**
- 1,840 - 72 1/2"**
- 1,840 - 72 1/2"**
- 1,840 - 72 1/2"**

**Chamber Depth**
- 600 - 23 3/8"**
- 600 - 23 3/8"**
- 740 - 29 1/8"**

**Chamber Height**
- 850 - 33 1/2"**
- 850 - 33 1/2"**
- 850 - 33 1/2"**
Standard Containment Solutions are based around our innovative range of Isolators bringing different features and benefits to your application. But all have one thing in common: they provide Guaranteed Product and Operator Protection.

**DESIGN FEATURES**

- Provide operator protection to <1µg/m³
- Negative operating pressure to –25pa/0.1”wc in the chamber
- Low noise levels
- Single chamber design complete with bag out port
- 3 off connections for mechanical services
- Isolator frame and optional table made from 304 stainless steel
- Large gas-tight zip on the main chamber for the loading of process equipment
- Open loop control and green/red visual indication of isolator pressure and exhaust filter condition
- Safe change H14 “push- push” exhaust HEPA filters within a stainless steel housing
- 150mm / 6” Waste bag out port

**FLEXIPHARM**

**FLEXIPHARM’S DIMENSIONS :**

<table>
<thead>
<tr>
<th>FlexiPharm</th>
<th>Overall Width</th>
<th>Overall Depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Glove</td>
<td>1,380 - 54 3/4&quot;</td>
<td>670 - 26 1/4&quot;</td>
</tr>
<tr>
<td>3 Glove</td>
<td>1,880 - 74&quot;</td>
<td>670 - 26 1/4&quot;</td>
</tr>
<tr>
<td>4 Glove</td>
<td>2,380- 93 3/4&quot;</td>
<td>670 - 26 1/4&quot;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall Height</th>
<th>Working Chamber Width</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,300 - 90 1/2&quot;</td>
<td>1,000 - 39 3/4&quot;</td>
</tr>
<tr>
<td>2,300 - 90 1/2&quot;</td>
<td>1,500 - 59 3/4&quot;</td>
</tr>
<tr>
<td>2,300 - 90 1/2&quot;</td>
<td>2,000 - 78 3/4&quot;</td>
</tr>
</tbody>
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**AVAILABLE OPTIONS**

- Alternative glove material
- Bench mounted or supplied with a stainless steel table with adjustable support frame
- IQ/OQ Documentation
- Marble Base for Scales
- Weighing Scales
- Replacement enclosures
- Replacement supply and exhaust filters

**POWER SUPPLY**

- 240/110v 1ph
- 50/60Hz 13Amp

**TECHNICAL REQUIREMENTS**
ISOPHARM

Providing operator protection to <1 µg/m³, ISOPHARM is an innovative product forming part of our initiative to offer cost effective containment solutions while maintaining the high standards required within the pharmaceutical industry.

Available with 2, 3 or 4 gloveports and entry/exit airlock, IsoPharm is the ideal solution for small scale weighing and dispensing operations handling highly potent API’s.

Drawing on our extensive experience with Isolator projects the IsoPharm Isolator has been designed with operator ergonomics and ease of use at the centre of our design process. The control philosophy provides essential operations, all accessible through the easy to use HMI.

**Design Features**
- Noise circa 65dBa
- Single chamber design complete with interlocked entry / exit airlock
- 0.6 µm Ra / <22 µ inch Ra Internal finish
- Internal radius corners
- Hinge open front access door for equipment / process set up
- Closed loop control and glove breach protection

**ISOPHARM’S DIMENSIONS:**

<table>
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<tr>
<th></th>
<th>Overall Width</th>
<th>Overall Depth</th>
<th>Overall Height</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Glove</td>
<td>1,730 - 68 1/8’’</td>
<td>650 - 25 5/8’’</td>
<td>2,300 - 90 1/8’’</td>
</tr>
<tr>
<td>3 Glove</td>
<td>2,150 - 84 5/8’’</td>
<td>650 - 25 5/8’’</td>
<td>2,300 - 90 1/2’’</td>
</tr>
<tr>
<td>4 Glove</td>
<td>2,570 - 101 1/8’’</td>
<td>650 - 25 5/8’’</td>
<td>2,300 - 90 1/2’’</td>
</tr>
</tbody>
</table>

**Working Chamber Width** | **W.C. Height**
- 1,050 - 41 3/8’’ | 850 - 33 1/2’’
- 1,475 - 58’’ | 850 - 33 1/2’’
- 1,895 - 74 3/8’’ | 850 - 33 1/2’’

**Available Options**
- Waste bag out port
- Rapid transfer port
- Alternative gauntlet materials
- Adjustable height support frame
- Hazardous Area Compliance
- IQ/OQ Documentation
- Witnessed Factory Acceptance Testing
- Environmental control / measurement
- Glove test kit
- Cleaning system - Wash gun or Spray ball equipment

**Power Supply**
- 400V N + E
- 3ph 16Am

**Pneumatic Supply**
- 80 psig (5.5 bar) to 90 psig (6.0 bar), dry filtered air to 40 Microns, 50ltr/min flow rate

**Contamination Level**
- <1µg/m³
GLOVE TESTER

Constructed in 304 stainless steel, the Mobile Automated Glove Tester is a new addition to Extract’s Standard Product Range. The system is capable of testing 1 to 6 glove ports at one time with the full cycle taking under 5 minutes, increasing efficiency of production cycles.

DESIGN FEATURES

The unit creates a positive pressure inside each glove while monitoring the pressure via the PLC system. This happens simultaneously no matter how many glove ports are chosen for the test.

- Significant time saving
- Rapid Identification of leaks
- Full PDF report of system validation
- Pre-delivery Inspection Documentation
- Pre-loaded parameters for differing glove materials
- Programmable custom parameters to suit specific needs
- Standardised system with off the shelf replacement spare parts

POWER SUPPLY
1PH 50/60HZ SUPPLY

PNEUMATIC SUPPLY
80 psig (5.5 bar) to 90 psig (6.0 bar), dry filtered air to 0.22 Microns

EXTRACT TECHNOLOGY
also offers custom containment and aseptic systems as well as mobile cleanroom solutions:

- DOWNFLOW BOOTHS
- CUSTOM CONTAINMENT ISOLATORS
- SAMPLING FACILITIES
- MOBILE CLEANROOMS
- CUSTOM ASEPIC ISOLATORS
- PACK OFF AND PROCESS

USB DATA LOGGING
- Technical requirements

FOR MORE INFORMATION ON OUR PRODUCTS PLEASE VISIT OUR WEBSITE OR CONTACT US DIRECTLY:

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