



DELIVERING
INNOVATION
TO PROTECT

extract-technology.com

STANDARD SOLUTIONS

UDAF STERIPHARM

UNIDIRECTIONAL AIRFLOW STANDARD ASEPTIC ISOLATOR

RECIRCULATED UNI-DIRECTION
AIRFLOW ACHIEVING
A GRADE A
ENVIRONMENT



STANDARD CONTAINMENT ISOLATOR

ACHIEVABLE
OPERATOR
PROTECTION
TO <math><1 \mu\text{G}/\text{M}^3</math>

ISOPHARM

FLEXIPHARM

FLEXIPHARM

IDEAL FOR R&D OR SINGLE
USE APPLICATIONS



TURBULENT FLOW STANDARD ASEPTIC ISOLATOR

POSITIVE PRESSURE
ENVIRONMENT
COMPLETE WITH
INTEGRATED HYDROGEN
PEROXIDE GENERATOR

STERIPHARM

MOBILE AUTOMATED GLOVE TESTER

TESTING UP TO 6 GLOVES AT
ONE TIME
FULL CYCLE IN
UNDER 5 MINUTES!



GLOVE TESTER





6 Log
Reduction in spore population

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 ASEPTIC 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.



TURBULENT AIRFLOW STERIPHARM

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

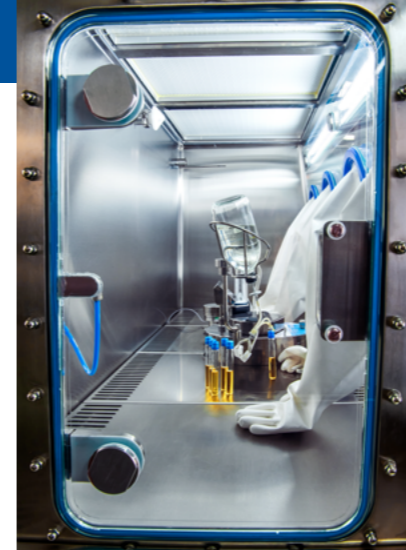
POWER SUPPLY
3PH 50/60HZ
400v N+E



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.



STERIPHARMS' DIMENSIONS :

SteriPharm Isolator	Overall Height
4 Glove with Airlock (TURB)	2,320 - 91 3/8"
4 Glove single chamber (TURB)	2,320 - 91 3/8"
4 Glove with Airlock (UDAF)	2,475 - 97 1/2"

Overall Width	Overall Depth	Chamber Width
3,180 - 125 1/5"	880 - 34 5/8"	1,840 - 72 1/2"
2,170 - 85 3/8"	880 - 34 5/8"	1,840 - 72 1/2"
3,180 - 125 1/5"	1,219 - 48"	1,840 - 72 1/2"

Chamber Depth	Chamber Height
600 - 23 5/8"	850 - 33 1/2"
600 - 23 5/8"	850 - 33 1/2"
740 - 29 1/8"	850 - 33 1/2"



UNIDIRECTIONAL AIRFLOW STERIPHARM

DESIGN FEATURES

- < 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

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

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



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

PROVIDING OPERATOR PROTECTION TO <1µG/M³, **FLEXIPHARM** IS A NEW INNOVATIVE PRODUCT FORMING PART OF OUR INITIATIVE TO OFFER A COST EFFECTIVE FLEXIBLE CONTAINMENT SOLUTION WHILE MAINTAINING THE HIGH STANDARDS REQUIRED WITHIN THE PHARMACEUTICAL INDUSTRY.

Available with 2, 3 or 4 gloveports, FlexiPharm is the ideal solution for small and single use applications

The control philosophy consists of a simple fan speed controller with green and red zoned visual indicators showing pressure within the enclosure.

FLEXIPHARM'S DIMENSIONS :

FlexiPharm	Overall Width	Overall Depth
2 Glove	1,380 - 54 3/8"	670 - 26 3/8"
3 Glove	1,880 - 74"	670 - 26 3/8"
4 Glove	2,380 - 93 3/4"	670 - 26 3/8"

Overall Height	Working Chamber Width
2,300 - 90 1/2"	1,000 - 39 3/8"
2,300 - 90 1/2"	1,500 - 59"
2,300 - 90 1/2"	2,000 - 78 3/4"

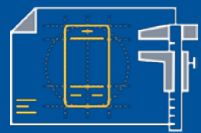
AVAILABLE OPTIONS

- > 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





IsoPharm technical requirements

POWER SUPPLY
400V N + E
3ph 16Am

PNEUMATIC SUPPLY
80psig (5.5 bar) to 90 psig
(6.0 bar), dry filtered air to
40 Microns, 50ltr/min flow
rate

ISOPHARM

PROVIDING OPERATOR PROTECTION TO $<1\mu\text{G}/\text{M}^3$, **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
- > Internal radius corners
- > Single chamber design complete with interlocked entry / exit airlock
- > Hinge open front access door for equipment / process set up
- > 0.6 μm Ra / $<22\mu$ inch Ra Internal finish
- > Closed loop control and glove breach protection

ISOPHARM'S DIMENSIONS :

IsoPharm Isolator	Overall Width	Overall Depth	Overall Height
2 Glove	1,730 - 68 1/8"	650 - 25 5/8"	2,300 - 90 1/2"
3 Glove	2,150 - 84 5/8"	650 - 25 5/8"	2,300 - 90 1/2"
4 Glove	2,570 - 101 1/5"	650 - 25 5/8"	2,300 - 90 1/2"

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 5/8"	850 - 33 1/2"



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



USB DATA LOGGING



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 ASEPTIC ISOLATORS



PACK OFF AND PROCESS

PLC CONTROLLED



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