

Advanced Isolator Technology

STERILITY TEST

CONTAINMENT

CELL-GENE THERAPY

ASEPTIC FILLING LINE



ISOLATOR



STERILITY TEST ISOLATOR

무균실험용



- Easy access for maintenance area by one touch opening and closing system
- Built-in Vaporized Hydrogen peroxide (VHPS) generator for bio-decontamination which can reach 6-log Sterility Assurance Level
- The VHPS residual concentration is less than 1ppm after aeration
- Leakage rate is less than 0.5% / vol / hour
- Colored lighting for each mode

Features

- Pressure is adjustable within -80pa ~ +80pa
- Built-in Sterility Test Pump
- Comply with 21 CFR Part 11 electronic records and signature requirements
- GMP, USP, EP compliance
- Interlock, alarms record and audit trails
- Noise : $\leq 65\text{dB(A)}$ when in pressure hold stage

Items for choice

- Air Sampler, Particle Counter
- High / low Concentration H_2O_2 sensor
- Portable concentration H_2O_2 sensor for operator safe
- WiFi controlled glove integrity tester (GIT-WLAN)
- Wooden Mock-Up
- Pass through chamber

One Touch Cover open/close

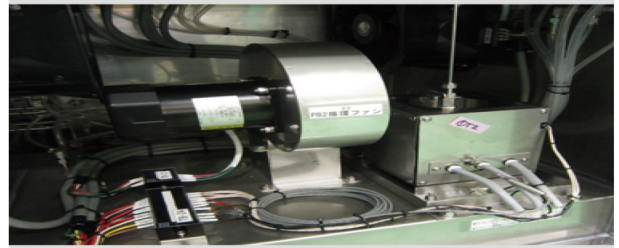


Calibration & Maintenance 시 신속하게 개폐 가능

VHP Generation System

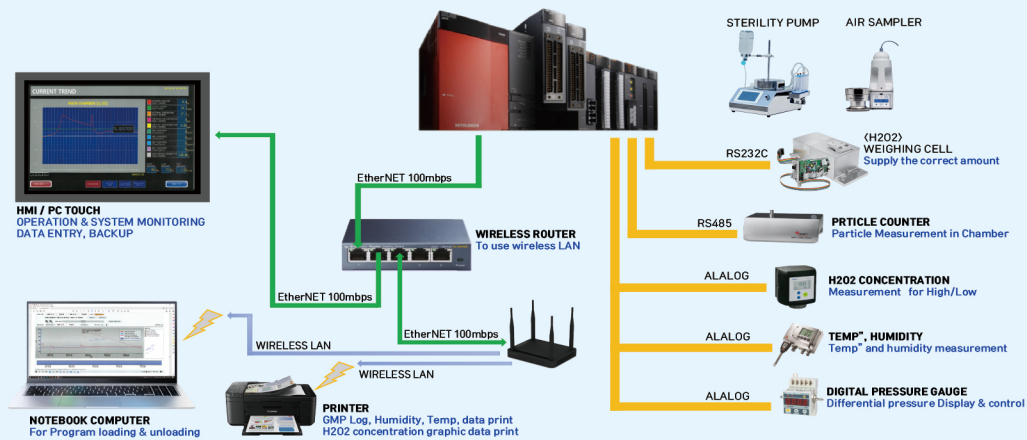


H₂O₂ Weighing

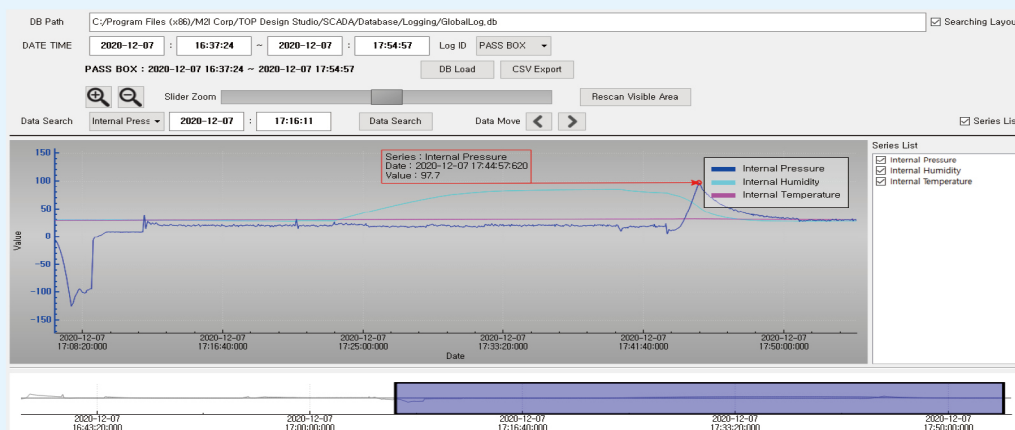


Heating plate for Vaporizing with safety sensor

» Isolator System Diagram



» Graphic on HMI



CONTAINMENT ISOLATOR

작업자 보호용



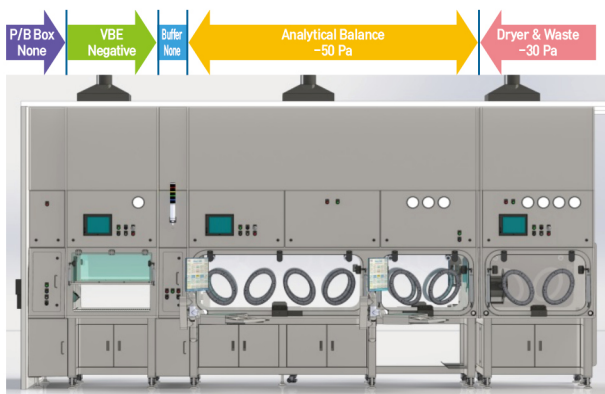
Containment Isolator

- Chamber pressure – 80pa to +80pa adjustable
- OEB 4 or OEB5
- H14 cylinder HEPA filters (PUSH-PUSH)
- Continuous liner bag system for material safety transfer
- PLC control with HMI for automatic control and operation
- Real time monitoring the differential pressure, humidity, temperature
- Critical process parameters can be stored

Options

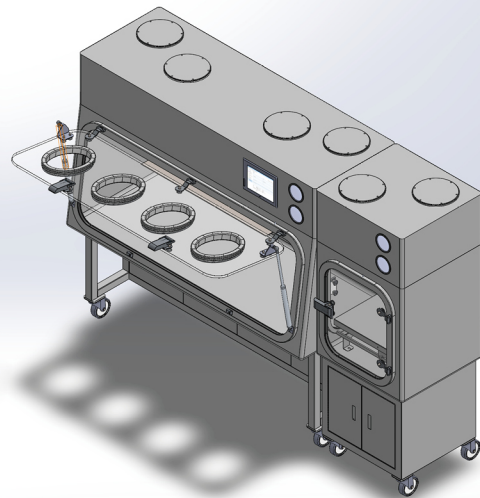
- Laminar flow with Bag-in-Bag-out H14 HEPA filters
- Explosion-proof
- Vibration-free platform for precision weighing
- WiFi controlled glove integrity tester (GIT-WLAN)
- Wooden Mock-Up
- SMEPAC TEST

Pressure Control Concep



Q.C, R&D, 생산시 독성물질로부터 작업자 보호를 위한
Pressure Zone Concept

Mixing & Weighing Isolator

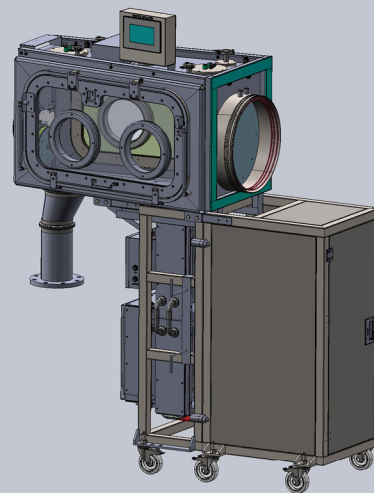


Mock up performance

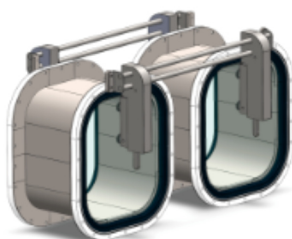


To identify glove positions for routine and non
routine interventions using a full scale Weighing
and Mixing

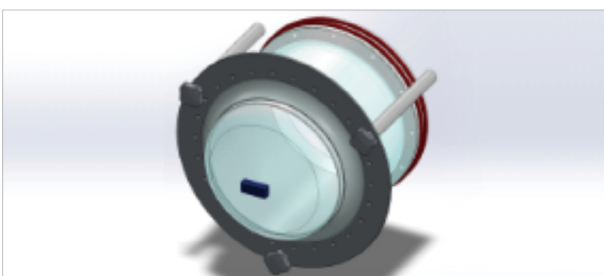
Raw Material feeding Isolator



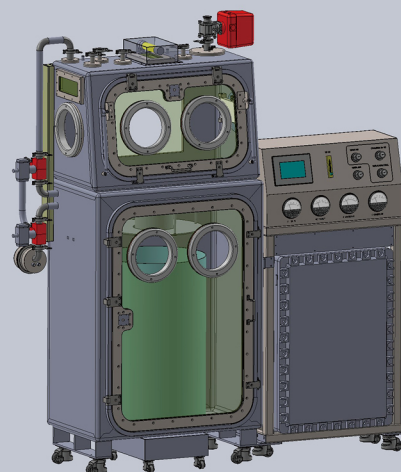
Pressure Buffer Port



Continuous Liner



Product packing Isolator



CELL AND GENE THERAPY ISOLATOR

세포 유전자용



Cell and Gene Therapy Isolator

- Customized technical solution
- Class A, ISO5, Aseptic environment
- Integrated VHPS® decontamination system
- Special liquid transfer technology for continuous and aseptic filling
- Real time monitoring the velocity, differential pressure, humidity, temperature

Advantages for cell & gene therapy process

- Increased sterility by reducing contamination risks
- Reduced human interventions
- Full process equipment integration within grade A / ISO 5 environment
- Smaller operational space
- Meet the GMP production requirements

Services

- Cell and Gene Therapy Isolator systems can be custom designed to suit individual customer requirements
- Complete validation protocols to comply with FDA, EMA, GMP, 21CFR Part 11 FAT, SAT, Training

Applications

- Designed for the users who require sterile conditions for R&D or pilot production of cell & gene products

AUTOMATIC ASEPTIC FILLING LINE ISOLATOR

무균생산용



Automatic Aseptic Filling Line Isolator

- Class A, ISO5, Aseptic environment
- Integrated VHPS® decontamination system
- Special liquid transfer technology for continuous and aseptic filling
- Real time monitoring the velocity, differential pressure, humidity, temperature

Features

- Class A, ISO5, Aseptic environment
- Integrated VHPS® decontamination system
- Special liquid transfer technology for continuous and aseptic filling
- Real time monitoring the velocity, differential pressure, humidity, temperature
- Temperature is adjustable to minimize the influence to products
- Critical process parameters can be stored and printed
- PLC control with HMI
- Leakage rate is less than 0.5% / vol / hour
- LED lamp, more than 300 Lux

WIRELESS GLOVE LEAK TESTER

무선 글로브 리크 테스터

- Wireless communication at GMP either Radio Frequency or WIFI
- Up to 100 μ m leakage detection by pressure decay
- One of the fastest testing time in reliable condition
- Batch report in PDF form generating and storage function
- Stable compatibility after simple program installation on exist PC
- 21 CFR PART 11 correspondence (Optional)
- 무선통신 방식의 완전 자동화로 GMP 현장에 적합(Radio Frequency, WIFI)
- Pressure decay 방식의 100 μ m 이상의 구멍 Size 판별가능
- 신뢰성 및 빠른 테스트 시간 (Study data 제공 및 측정시간 1분)
- 배치레포트 PDF출력 및 보관 가능
- 기존PC에 프로그램만 설치 후, 작동 가능한 뛰어난 호환성
- 21 CFR PART 11 대응(Optional)

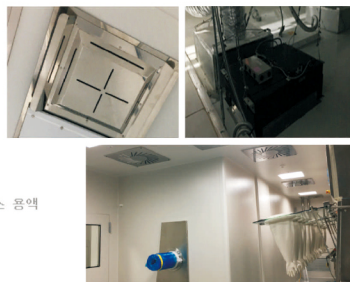
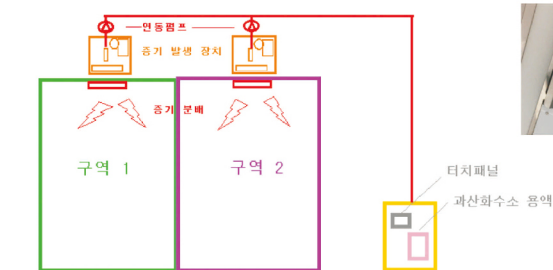


HPG ROOM DECONTAMINATION SYSTEM

과산화수소 실내 제염/멸균 장치

General

- 무균실(Grade B)의 제염/멸균을 위한 장치
- 이동식 및 천장 빌트인 타입의 다양한 모델을 보유 → 고객의 상황에 맞게 대응 가능
- 과산화수소 용액 (35%)의 사용량의 명확한 모니터링 및 가스 발생의 Loss가 없음
- 차별화된 가스 발생 기술
- 응축센서(SDM® / Airex 특허) 장착을 통한 응축 모니터링 기술
- 고객 상황에 최적화된 Cycle Development
- 일본 시장 점유율 80%의 다양한 경험과 기술력



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