

Beyond Shielding, Toward Intelligence

Mortenson H1: GMP-Compliant Hot Cell for Radiopharmaceuticals

A smart, flexible, and fully GMP-compliant hot cell solution for safe handling of radiopharmaceutical



Key Features & Benefits

Mortenson H1, designed and validated in accordance with the GMP guidelines for handling radiopharmaceuticals. A smart, self-contained shielding designed for the safe, precise, and compliant dispensing of radiopharmaceuticals. It integrates radiation shielding, Grade A aseptic environment, and automated features to meet the stringent demands of hospitals, nuclear medicine departments, and radiopharmaceutical manufacturers worldwide.

- **Smart Environmental Control System**
It achieves intelligent dynamic adjustments of internal pressure and airflow speed to adapt to different operational requirements, while maintaining a Class A clean environment (ISO 14644-1) internally.
- **Smart Human-Machine Interface (HMI)**
It features a graphical interface design with modular scheduling for various operational modes (e.g., work, standby, sterilization, etc.), and includes voice alerts for threshold exceedances, ensuring comfortable, intuitive, and error-resistant interaction.
- **Stable Sealing Performance**
It meets the leak-tightness requirements of ISO 10648-2 class 2, and has been validated for reproducible sealing performance over more than 200 operational cycles.
- **Automated Product Transfer in a closed system**
It utilizes pass-through drawers and automated lifting mechanisms to reduce operator burden and eliminate cross-contamination with the external environment during the product transfer, while complying with GMP requirements.

• Expendable Functional Interfaces

VHP Sterilization Interface: it is compatible with vaporized hydrogen peroxide (VHP) dry-mist sterilization systems, while achieving a ≥ 6 -log reduction of spores. It operates at an ambient temperature, and can offer energy-saving, eco-friendly, and residue-free decontamination.

Online Particle Monitoring Interface: it can be connected particle counters.

In -Situ Filter Leak Test Interface: it is fitted with self-sealing valves.

Process Gas Interface: it is fitted with on-off valves.

• End-to-End GMP Validation Services

It provides a complete suite of validation services—from requirement design and engineering installation to operational use—based on radiopharmaceutical GMP principles.

• Remote Monitoring and AI Interfaces

It enables real-time monitoring of equipment's operating parameters, runtime, maintenance records, etc., through a remote supervision platform. It can be integrated with AI models for more efficient and rational lifecycle management.

• Energy-Efficient and Eco-Friendly Design

Optimized through CFD analysis to reduce operating temperature and energy consumption and combined with intelligent control programs and a proprietary VHP system, it can achieve a 30% reduction in energy use and a 50% reduction in VHP consumption, compared to conventional equipment.

• Future-Ready Flexibility

The modular design supports easy upgrades and integration with additional functional modules, allowing seamless adaptation to regulatory updates and evolving requirements.

Technical Specifications

Category	Parameter
DIMENSIONS AND WEIGHT	- External dimensions: 1200(w) x 1220(d) x 2600(h) mm
	- Internal dimensions: 900(w) x 750(d) x 650(h) mm
	- Weight: approx. 6500 Kg
Shielding	60 mm Pb (Frontal 75 mm Pb)
Containment	ISO 10648-2, Class 2
Cleanliness	ISO 14644-1 Class 4 (Grade A)
Laminar Flow	0.45 m/s $\pm 20\%$ (at 150 mm below filter face)
Pressure Control	Adjustable negative pressure, -20 to -150 Pa
Decontamination	Validated Vaporized Hydrogen Peroxide (VHP) cycle
Material Transfer	Pass-through drawers with automated lift system
Standards & Validation	Designed to meet global radiopharmaceutical GMP requirements. Supports full validation protocols (IQ/OQ/PQ), electronic data recording, and audit trails.