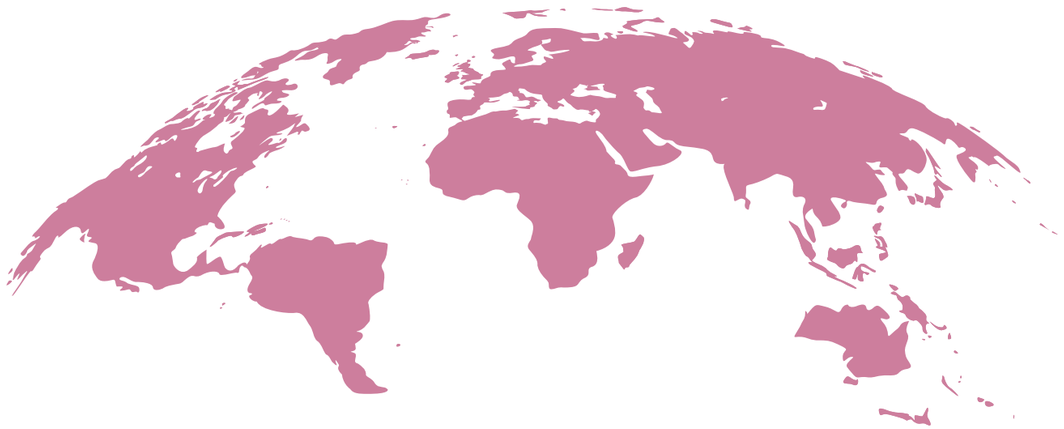
Specifications are subject to change without prior notice. Please refer to the actual product for final parameters.



APEX Medical Solutions

102 Unit, 70 Fulton Way, Richmond Hill, Ontario, L4B 1J5 Canada

+1 416-298-3366

info@apex-med.ca

VER. APN2601



HOT CELL

SYNTHESIS MODULE DISPENSING SYSTEM

APEX Medical Solutions

Synthesis Module
OnePlatform Automatic Synthesizer



OnePlatform Automatic Synthesizer

OnePlatform 3.1s is a general-purpose radiochemical automated synthesizer, which is mainly used for the preparation of ^{18}F and ^{11}C complex nuclide drugs and also includes the labeling of nuclear medicine metal nuclides such as ^{68}Ga, ^{64}Cu, ^{90}Y, ^{89}Zr, ^{177}Lu. It can realize the synthesis scheme of the current mainstream PET tracer.

Main Technical Specifications:

High-Efficiency Heating & Cooling
Powerful 100W+ metal conduction (up to 200°C) with gentle water-cooling for speed and safety.

Versatile & Flexible Configuration
20 valves and 5 syringes design, fully compatible with diverse PET tracer syntheses.

Integrated HPLC Chromatography
Built-in gradient HPLC with radiation/UV detection for seamless, on-platform purification.

GMP-Compliant Disposable Kits
Supports single-use reagent kits and cassettes to eliminate cross-contamination and simplify operation.

Technical Parameter
Dimensions (WxHxD): 510mm× 510mm×500mm
Weight: 45kg

Control system
Software interface type: TCP/IP
Communication cables: network cables, USB
Local Control: Yes
Remote Control: Yes
Computer: Desktop PC or laptop Windows operating system
Configure synthesis module + chromatography module

Power
Standby status: 60W
Working status: 330W
Peak status: 460W

Dispensing Unit
Automated Dispensing System



APDS002

The Automatic Dispensing System is a high-precision, automated solution engineered to meet the most stringent GMP standards for radiopharmaceutical processing. Designed for seamless integration within a hot cell, the system allows operators to manage the entire workflow remotely via an external laptop, ensuring maximum safety and operational efficiency.
This all-in-one platform combines radionuclide handling, precision filling, and automated capping into a single, synchronized process. By automating the transition from bulk radionuclides to diluted, sealed, and measured vials, the system significantly minimizes radiation exposure to personnel while maintaining exceptional dosage accuracy. From automated cap retrieval and crimping to real-time activity monitoring, every feature is built to ensure a sterile, reliable, and safe production environment.

Technical Specifications

Integrated Workflow	One-step completion of dispensing, dilution, and activity measurement.
Dispensing Modes	Dual modes: Activity-based or Volume-based dispensing.
Target Container	Sterile vials.
Automation Features	Automatic half-life correction, real-time activity measurement, and cap crimping.
Dilution System	Automated concentration adjustment using Water for Injection (WFI).
Dispensing Precision	Linearity: ± 5%
Volume Range	0.1 mL — 10 mL (Resolution: 0.1 mL).
Operational Speed	High throughput: ≤ 60 seconds per cycle.
Measurement Method	Dynamic weighing and real-time activity monitoring.
System Diagnostics	Continuous full-system self-testing for fail-safe operation.
Device Interoperability	Seamless communication with dose calibrators (Fully compatible with Capintec CRC series).
Data Management	Comprehensive database for entry, storage, query, and report printing.
Connectivity	Standard RS-232, USB, and Ethernet (LAN) interfaces.

Dispensing Unit
Automated Dispensing System



APDS001

Our Dispensing Unit is engineered for high-precision liquid handling, integrating dilution, mixing, and automated filling into a single, compact system. Designed for seamless upstream integration, it ensures sterile and accurate processing for sensitive medical solutions.

Core Functionalities

1. Dilution & Homogenization

•Automated Intake:
The mixing vessel receives upstream stock solution and introduces diluents via a high-precision peristaltic pump based on pre-set formulations.

•Bubble Mixing:
Utilizing advanced bubbling technology, the system ensures a perfectly homogenous mixture of stock and diluents before proceeding to the filling stage.

2. Advanced Quantitative Filling

Powered by cutting-edge dosage control technology, the module automates the entire packaging workflow:

•De-capping & De-stoppering
•Precision Filling
•In-line Weight Verification
(Real-time accuracy checks)
•Re-stoppering, Re-capping, & Crimping

Technical Specifications

Feature	Specification
External Dimensions	300 * 350 * 400 mm
Weight	Approx. 30 KG
Throughput (Capacity)	Approx. 100s / pcs
Options	Customizable single-use dispensing kits

Hot Cell
Synthesis Hot Cell



Model: APHC-75C

The hot cell features a fully isolated protective design with a clean, arc-shaped stainless steel interior, which is perfectly suited for the synthesis of positron radioactive drugs. It meets high standards of lead shielding and biological cleanliness, ensuring compliance with radiation safety environmental standards and guaranteeing a cGMP clean pharmaceutical environment during the synthesis of positron radioactive drugs.

The hot cell is composed of three structural parts:

★The control area, located at the top of the hot cell, is equipped with an independent ventilation system, hot cell control unit, gas valves, and a radiation dose monitoring and interlock unit inside the hot cell.

★The working area, situated in the middle of the hot cell, where the operator gains access by opening the front shielding door. The spacious internal dimensions are designed to accommodate the installation of all synthesizers available on the market.

★The auxiliary area, located at the bottom of the hot cell, provides auxiliary functional requirements for the hot cell.

Main Technical Specifications:

Compliant with cGMP biological cleanliness level for the working area

Independent synthesis lead cell constructed from seamless welded stainless steel
Cleanliness level: Class C
Negative pressure: -50 Pa to -200 Pa
Airflow: 300 m^3/h
Sealing: Secondary sealing
Supply air: High-efficiency filter
Exhaust air: Activated carbon filter

Ergonomically designed operational control panel

Hot cell control: Centralized integrated control with a full touch human-machine interface
Visual observation: Independent high-definition display for real-time observation
Negative pressure indicator: Analogue negative pressure gauge

Lead shielding compliant with ICRP radiation environmental safety standards (lead equivalence customizable)

Front shielding: 75 mm Pb
Side shielding: 60 mm Pb
Target Line Shielding: 50 mm Pb equivalent shielding
Radiation dose at the surface of the hot cell: Target Line Shielding: 50 mm Pb equivalent shielding
Radiation dose at the surface of the hot cell: <5μSv/h @ 3 Ci-F18
Radiation dose at 30 cm from the hot cell: <1μSv/h @ 3 Ci-F18

Dimensions:

Internal dimensions: W850 * D619 * H700 mm
External dimensions: W1185 * D1117 * H2400 mm
Additional accessories: Lighting, UV light, ozone sterilization unit, target line sealing flange, Airtight power outlets,etc.

Hot Cell
Dual Lead-lined Synthesis Hot Cell



Model: APHC-75C2

The hot cell employs a fully isolated protective design with a clean, arc-shaped stainless steel interior, which is fully compliant with the requirements for the synthesis of positron-emitting radioactive drugs. It features high-standard lead shielding and biological cleanliness safety requirements, meeting both radiation safety environmental standards and ensuring a cGMP clean pharmaceutical environment during the synthesis of positron-emitting radioactive drugs.

The hot cell is composed of three structural parts:

★The control area, located at the top of the hot cell, is equipped with an independent ventilation system, hot cell control unit, gas valves, and an internal radiation dose monitoring and interlock unit.

★The working area, situated in the middle of the hot cell, allows operators to enter through the front shielded door. The spacious internal dimensions are designed to accommodate the installation of all synthesizers available on the market.

★The auxiliary area, located at the bottom of the hot cell, provides the auxiliary functional requirements for the hot cell.

Main Technical Specifications:

The working area complies with cGMP biological cleanliness standards.

The double-chamber synthesis lead cell is constructed from seamless welded stainless steel.
Cleanliness level: Class C
Negative pressure: -50 Pa to -200 Pa
Airflow: 300 m^3/h
Sealing: Secondary sealing
Supply air: High-efficiency filter
Exhaust air: Activated carbon filter

Ergonomically designed operational control panel

Hot cell control: Centralized integrated control with a full-touch human-machine interface
Visual observation: Independent high-definition display for real-time monitoring
Negative pressure indicator: Analogue negative pressure gauge

Lead shielding complies with ICRP radiation environmental safety standards (lead equivalence customizable)

Front shielding: 75 mm Pb
Side shielding: 60 mm Pb
Target Line Shielding: 50 mm Pb equivalent shielding
Radiation dose at the surface of the hot cell: <5 μSv/h @ 3 Ci-F18
Radiation dose at 30 cm from the hot cell: <1 μSv/h @ 3 Ci-F18

Dimensions:

nternal dimensions: W850 * D619 * H700 mm
External dimensions: W1185 * D1117 * H2400 mm
Additional accessories: Lighting, UV light, ozone sterilization unit, target line sealing flange, airtight power outlets, etc.

Hot Cell
Dispensing Hot Cell



Model:APFZ-65C

The APFZ-65C Fractional Hot Cell provides radiation shielding for radiopharmaceutical dispensing via three zones: a top control area with HEPA filtration, a middle working area with lead glass and ports, and a bottom auxiliary area featuring an ionization chamber and transport system.

Main Technical Specifications:

Compliant with cGMP biological cleanliness level for the working area

An integrated stainless steel work area equipped with a vertical laminar flow negative pressure ventilation system.
Cleanliness level: Class A (ISO 100)
Air supply method: Vertical laminar flow
Laminar flow velocity: 0.35-0.56 m/sec
Exhaust air volume: 500 m^3/h
Sealing method: Inflatable air seal
Air supply filtration: Complete high-efficiency HEPA 99.995%@0.5μm (H14)
Exhaust air filtration: Radioactive gas filter adsorption
Front shielding: 65mm Pb
Side shielding: 60 mm Pb
Target line shielding: 50 mm Pb equivalent

Ergonomically designed operational control panel

Control: Human-machine interface for control and feedback of all information
Visible lead glass window: 320 mm (w) *220 mm (h)
Dose monitoring display: Integrated into the human-machine interface

Dimensions:

Internal dimensions:
850 mm (w) * 590 mm (d) * 680 mm (h)
External dimensions:
1125 mm (w) * 1078 mm (d) * 2400 mm (h)
Accessories:
Lighting, UV light, ozone sterilization unit, power outlets, etc.

Radioactive material shielding transfer device

Shielding tray:
Made of stainless steel 304,¢ 115 mm,5mm pb
Transfer method: Pneumatic/linear drive

Activity meter ionization chamber shielding

Measurement well shielding: 60 mm Pb

Real-time dose monitoring and radiation safety interlock device

Energy range: 50 KeV — 1.5 MeV
Dose range: 0 μSv/h — 9999 μSv/h
Threshold setting:
Arbitrary setting of interlock thresholds

Protective Glove Box
(Protective Fume Hood)



Cat. No.: APFH-40A
Material: Lead;Stainless steel
External Dimension: 1172mm (L)*763mm (W)*2200 mm (H)
Internal Dimension: 856mm (L)x 527mm (W)x 568 mm (H)
Shield: 40mm Pb
Weight: 7800KG
Power supply: Single-phase 220V/50Hz,3kW

Product Introduction

The protective glove box features a fully isolated protective design and an independent air supply and exhaust system, designed to meet the requirements for the rinsing, filling, and labeling of radioactive pharmaceuticals. This glove box provides high-standard radiation protection, ensuring safety. Ensures that operators comply with radiation safety environmental standards during the rinsing, filling, and labeling of radioactive pharmaceuticals.

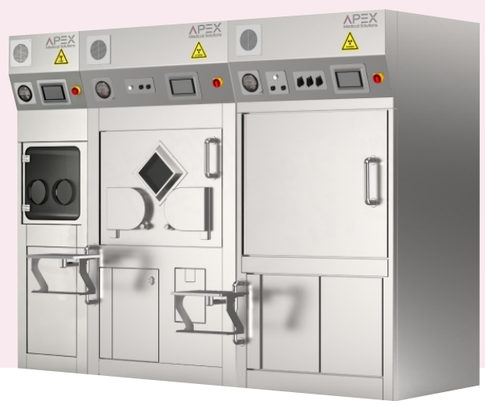
Main Technical Description

The protective glove box consists of three distinct sections: thecontrol area, located at the top, is equipped with an independent exhaust unit; the downward-sloping 15° operating control panel facilitates easy daily use and observation by the operator; the work area, situated in the middle, features a leaded glass viewing window on the front and two access handholes for entering the work area; the auxiliary area, located at the bottom, is fitted with a radioactivity meter ionization chamber shielding well and a shielded conveying system, fully meeting the operational requirements for the handling of radioactive pharmaceuticals during the rinsing, filling, and labeling processes.

Cleaniness Class: Class D
Airflow mode: Top supply with bottom return
Laminar wind speed: 0.35-0.56 m/sec
Exhaust airvolume: 800 m2/h
Air supplyfiltration: completely efficient HEPA99.995% @ 0.5um (H14)
Ventilationfiltration: Radioactive gas filter adsorption

Other accessories: lighting lamp, UV lamp, ozone sterilization unit, power socket, etc.

Automated Radiopharmaceutical Production Line



Cat. No.: APPL-40，APPL-65，APPL-75
Material: Lead;Stainless steel
External Dimension: 3090mm (L)*1083mm (W)*2400 mm (H)
Shield: 40/65/75mm Pb
Weight: 12600KG
Power supply: Single-phase 220V / 50Hz, 3kW

Product Introduction

This fully automated synthesis and dispensing production line consists of three core modules: the antechamber (pre-room), the synthesis hot cell, and the dispensing hot cell, forming a highly integrated automated solution for radiopharmaceutical production. The line adopts a fully enclosed shielded design and fully automated process control, meeting the complete workflow requirements from synthesis to dispensing of positron-emitting radiopharmaceuticals such as F-18.





Fully Automatic Radionuclide Dosage Dispenser

Cat. No.: APDD-01
Material: Tungsten alloy
External Dimension: 353mm(L)*221mm(W)*523mm(H)
Filling method: Activity-based flling, Volume-based filling
Syringe protection: 18 mmPb



Activity Meter

Cat. No.: APAM-01
Capacity: Up to 250 GBQ (6 CI)
Resolution: Maximum 0.1 u CI (0.01 MBQ)
Filling gas: ultra-pure argon at 12 atm pressure
lonization chambert ype: Thin-walled deep-well type





HOT CELL SYNTHESIS MODULE DISPENSING SYSTEM

