SYNTHERA®
SMALL DIMENSIONS
HUGE POTENTIAL

www.iba-radiopharmasolutions.com
“With the 12 installed Synthera® in our premises, we successfully make more than 3000 FDG production runs a year. Soon, we are expecting to have 4 more installations. After 6 years of experience, we recommend the Synthera® for its high yield, consistency, and user friendliness.”

Harun Kucukmidil
Manager engineering department
Eczacıbaşı-Monrol Nukleer Ürünler Sanayi ve Ticaret A.S., Turkey

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THE WORLD WIDE REFERENCE FOR YOUR RADIO PHARMACEUTICAL PRODUCTION

350 MODULES INSTALLED WORLDWIDE
Synthera®, the new world reference for your radiopharmaceutical production.
SYNTHERA®, IDEAL FOR ROUTINE RADIOPHARMACEUTICALS PRODUCTION

A COST EFFECTIVE CHOICE
All molecules in one hot cell
The most compact module proven up-to-date (more than hundreds units running worldwide for many years).

Unlimited multi-runs
Multi-run is supported by the automated ejection of the IFP™.

Leasing and pack options
Limited cash-out at start.

MULTI-TRACERS PRODUCTION
Do-all-in-one platform
The software integrates multiple-module control.

Five units controlled by one PC only.

Integrated Synthera® HPLC
On-line liquid chromatography purification ("preparative" HPLC) is fully integrated.

Today and tomorrow
Customized applications are supported by open software with graphical tools.

By accessing quick-start menu, user is only one click away to synthesize a wide range of tracers.

EASY TO OPERATE
Guaranteed uptime
The Synthera® is built from commercial standard items, ensuring equipment robustness.
Diagnosis and maintenance are sped up by remote access feature.

(c)GMP & Regulatory compliance
• US DMF
• IQ OQ documentation
• PQ support for your application
• CMC support for Marketing authorisation, ANDA’s, NDA, IND

Safe for multi-runs
IFP™, into which all radioactive materials are confined is automatically ejected after synthesis and dropped into an integrated waste drawer minimizing personnel exposure.
The Integrated Fluidic Processor (IFP™) is the heart of the Synthera® operation. All synthesis steps take place entirely within the IFP™ system. Combined with specific reagents and recipes, IFP™ models can accommodate a multitude of synthesis.

A PALETTE OF COMMERCIAL IFP™ GIVES ACCESS TO MOST OF SYNTHESIS STEPS:
- IFP™ Nucleophilic
- IFP™ Alkylation
- IFP™ Distillation
- IFP™ Chromatography

MAIN BENEFITS:
- Single-use disposable system
- Mini-fluidic technology
- Automatic ejection
- Most compact.

UNLIMITED R&D ON SYNTHERA®

EXPAND YOUR POSSIBILITIES WITH IFP™ R&D

Optimize your research cost with the new IFP™ for R&D that offers the same IFP™ technology with an open tag for multi-use.

Customize your synthesis yourself. Several in-house radiotracers have already been developed by Synthera® users:
- FET
- FAZA
- Fluorodopamine
- MPPF
- Fallypride
- DMF (desmethoxyfallypride)
- PRO4.MZ
- FHBG
- FP-DTPZ
- F-AB5380
- Fluoroethylazide
- F-cis-4-fluoro-L-proline
- PPF

READY-TO-GO RADIOPHARMACEUTICALS

<table>
<thead>
<tr>
<th>RADIOPHARMACEUTICAL</th>
<th>YIELD</th>
<th>RADIOCHEMICAL PURITY</th>
<th>IFP™ NUCLEOPHILIC</th>
<th>SYNTHERA® NUCLEOPHILIC</th>
<th>SYNTHERA® ALKYLLATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDG</td>
<td>60 %</td>
<td>&gt;95 %</td>
<td>Nucleophilic</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>NaF</td>
<td>90 %</td>
<td>&gt;98 %</td>
<td>Chromatography</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>FLT</td>
<td>20 %</td>
<td>&gt;95 %</td>
<td>Nucleophilic</td>
<td>✓ ✓</td>
<td>✓ ✓</td>
</tr>
<tr>
<td>FCH</td>
<td>20 %</td>
<td>&gt;95 %</td>
<td>Distillation &amp; Alkylation</td>
<td>✓ ✓</td>
<td>✓ ✓</td>
</tr>
<tr>
<td>FMISO</td>
<td>30 %</td>
<td>&gt;95 %</td>
<td>Nucleophilic</td>
<td>✓ ✓</td>
<td>✓ ✓</td>
</tr>
<tr>
<td>PIRAMAL IMAGING PROPRIETARY MOLECULES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBB</td>
<td>-</td>
<td>&gt;98 %</td>
<td>Nucleophilic</td>
<td>✓ ✓</td>
<td>✓ ✓</td>
</tr>
<tr>
<td>FDOPA</td>
<td>-</td>
<td>&gt;98 %</td>
<td>-</td>
<td>✓ ✓</td>
<td>✓ ✓</td>
</tr>
</tbody>
</table>

1. The re-use of the IFP™ is the sole and exclusive end-user responsibility.
2. IBA has not validated the recipes developed by its customers on Synthera® platform. The sequences are not included in the delivery scope of the system.
3. The radiotracers cited or listed herein are not recognized by the US FDA currently. Therefore, the production and/or use of any of these radiopharmaceuticals is done under the sole and exclusive responsibility of the end-user. IBA cannot be held liable in any way for any adverse effect that might occur during or after production or usage.

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“Compared with other synthesis modules which we have been working for seventeen years, we can state that Synthera® module provides much greater reliability of production and higher synthesis yields.”

Ruth Catalan Goñi
University Clinic of Navarra
Pamplona, Spain
PACK OPTIONS
CHOOSE THE CONFIGURATION THAT MEETS YOUR NEEDS

INCREASE YOUR PRODUCTION CAPACITY FOR A REDUCED INVESTMENT

- Up to 30% saving on your investment
- More than double your production capacity thanks to IBA exclusive waste drawer

STANDARD FDG PRODUCTION
2 RUNS FDG A DAY

FDG PRODUCTION +NaF +FCH
2 RUNS FDG
+ 2 RUNS NaF OR FCH

MAXI FDG PRODUCTION +NaF +FCH
2x4 RUNS FDG OR 7 RUNS FDG
+ 1 RUN NaF OR FCH

ALL IN ONE HOTCELL

1 Synthera®
- Waste drawer
- 1 day training

2 Synthera®
- Waste drawers
- 1 day training

2 Synthera®
- HPLC
- Waste drawers
- 2 days training

4 Synthera®
- Waste drawers
- 2 days training

IBA IS THE ONLY COMPANY TO PROVIDE A LEASING OPTION FOR CHEMISTRY MODULES FOR ANY SYNATHERA CONFIGURATION YOU NEED.

Your benefits:
- Limited cash-out at start - Investment spread over 4 years
- Short repayment period
- Better matching of revenues versus costs over time
- On-balance sheet - you own Synthera® at end of financing.

*compared to investments for other synthesizers in hotcells.
### TECHNICAL SPECIFICATIONS

#### DISPOSABLE IFP™ SYSTEM

**THREE COMPONENTS**

<table>
<thead>
<tr>
<th>IFP™¹</th>
<th>Single-use system</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Double wrapping pack</td>
</tr>
<tr>
<td></td>
<td>Plastic frame</td>
</tr>
<tr>
<td></td>
<td>6 vial, 2 cartridge holders</td>
</tr>
<tr>
<td></td>
<td>1 reactor vial</td>
</tr>
<tr>
<td></td>
<td>Integrated interconnecting tubes</td>
</tr>
</tbody>
</table>

**Reagent Sets**²
- Set with certificate of analysis for each of the commercially available tracer

**Ancillary Supplies Set**
- Purification, GMA cartridges and filters
- Syringes and needles

**Worldwide suppliers**
- ABX Advanced chemical compounds
- Huayi Isotopes
- Rotem Industries

¹ Patented: EP1343533, AU2002337926, CN100478035, US7018614, IN209975, pending for USA and CA
² Patented: AU2002337926, CN100478035, US7018614, IN209975 pending for EU, JP, BR

#### SYNTHERA® PLATFORM

**HARDWARE**

- **Synthera**³
  - Fully automated synthesizer with auto-ejectable system
  - Radiation, temperature, gas & compressed air sensors
  - Heating system up to 180°(with built-in air cooling)

- **Synthera® HPLC**
  - High Performance Liquid Chromatography system
  - Isocratic high pressure pump (10ml/min- 300 bar)
  - High pressure 6-port switching valve
  - Injector loop (5 ml)
  - UV detector (optional)
  - Radiodetector
  - 2 extra analogical auxiliary input ports

**Control box**
- PLC-based & Ethernet communication

**Router**
- Local area network

**Personal computer**
- Single PC for up to 5 units

**SOFTWARE**

- **Integrated software**
  - Up to 3 Synthera® & 2 Synthera® HPLC

- **Graphical interface**
  - Microsoft® Windows based

- **Remote access**
  - Diagnosis and maintenance

- **(c)GMP compliance**
  - Password protected three-level access software
  - Protected electronic records, print integrity and audit trail
  - Built-in material batch number tracking system

- **Open software**
  - Adjustable parameters
  - Automatic datalogging

**SYNTHERA® PLATFORM DIMENSIONS (WXDXH)**

- Synthera®
  - 17 x 29 x 28.5 cm

- Synthera® HPLC
  - 17 x 29 x 28.5 cm

- Control box
  - 17.5 x 22 x 12.7 cm
  - (located outside of the hot cell)

**INSTALLATION REQUIREMENTS (WXDXH)**

- **One Synthera®**
  - 20 x 45 x 45 cm

- **Two Synthera®**
  - 40 x 45 x 45 cm

- **Three Synthera®**
  - 60 x 45 x 45 cm

- **For one Synthera® HPLC and one Synthera®**
  - 45 x 45 x 45 cm
  - (including processing unit; pre-column and column; radiodetector; waste and loop overflow and backflushing containers)

**UTILITIES**

- Compressed air
  - 6-7 bar

- Dual input ports for inert gases
  - 125-2 bar

³ Patented: US7235216, Europe patent pending
ABOUT IBA
IBA (Ion Beam Applications S.A.), is a cancer diagnostics and treatment company and the worldwide technology leader in the field of proton therapy. The company’s expertise lies in the development of next-generation proton therapy technologies and radiopharmaceuticals that provide oncology care providers with premium quality services and equipment, including IBA’s leading fully-integrated IntegraLab® system.

ABOUT IBA RADIOPHARMA SOLUTIONS
Based on longstanding expertise, IBA RadioPharma Solutions supports hospitals and radiopharmaceutical distribution centers with their in-house radioisotopes production by providing them global solutions, from project design to the operation of their facility. In addition to high-quality technology production equipment, IBA has developed in-depth experience in setting up (c)GMP radiopharmaceuticals production centers.

ABOUT INTEGRALAB® AND SYNHERA®
IntegraLab® is a fully integrated solution combining equipment and services for the establishment of radiopharmaceuticals production centers. IntegraLab® includes, among other services, the building design achieving full regulatory compliance and the selection, integration, supply and installation of suitable high-technology equipment to match the customer’s radioisotopes production goals.

Synthera® is a multi-purpose automated synthesizer for the production of 18F-FDG, other 18F-labeled compounds (18FCH, 18FLT, Na18F) as well as radiopharmaceuticals. Synthera® is designed to accommodate a wide range of radiochemistries.

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