

SYNTHERA[®] + BETTER, SMARTER, STRONGER.



**RADIO
PHARMA
SOLUTIONS**

**BETTER, SMARTER,
STRONGER.**

With more than 500 units installed worldwide, the Synthera® family has proven to be highly efficient and trustworthy. Now, through its program of continuous innovation, IBA has redesigned Synthera® to meet and exceed the ever-growing customer expectations. The result is the new Synthera®+, giving radiopharma producers more capacity, more potential and more reliability.

Synthera®+ is the most compact radiosynthesis module on the market. For increased flexibility, different combinations of Synthera®+ modules and accessories can be installed in the same hot cell.

500+

Units installed worldwide, the Synthera®+ family has proven to be highly efficient and trustworthy.

After using Synthera® for many years with high reliability and yield for routine production, I was really impressed by the new Synthera®+ generation with enhanced capabilities, especially for the IFP™ Loader which will drastically increase our production capacity.

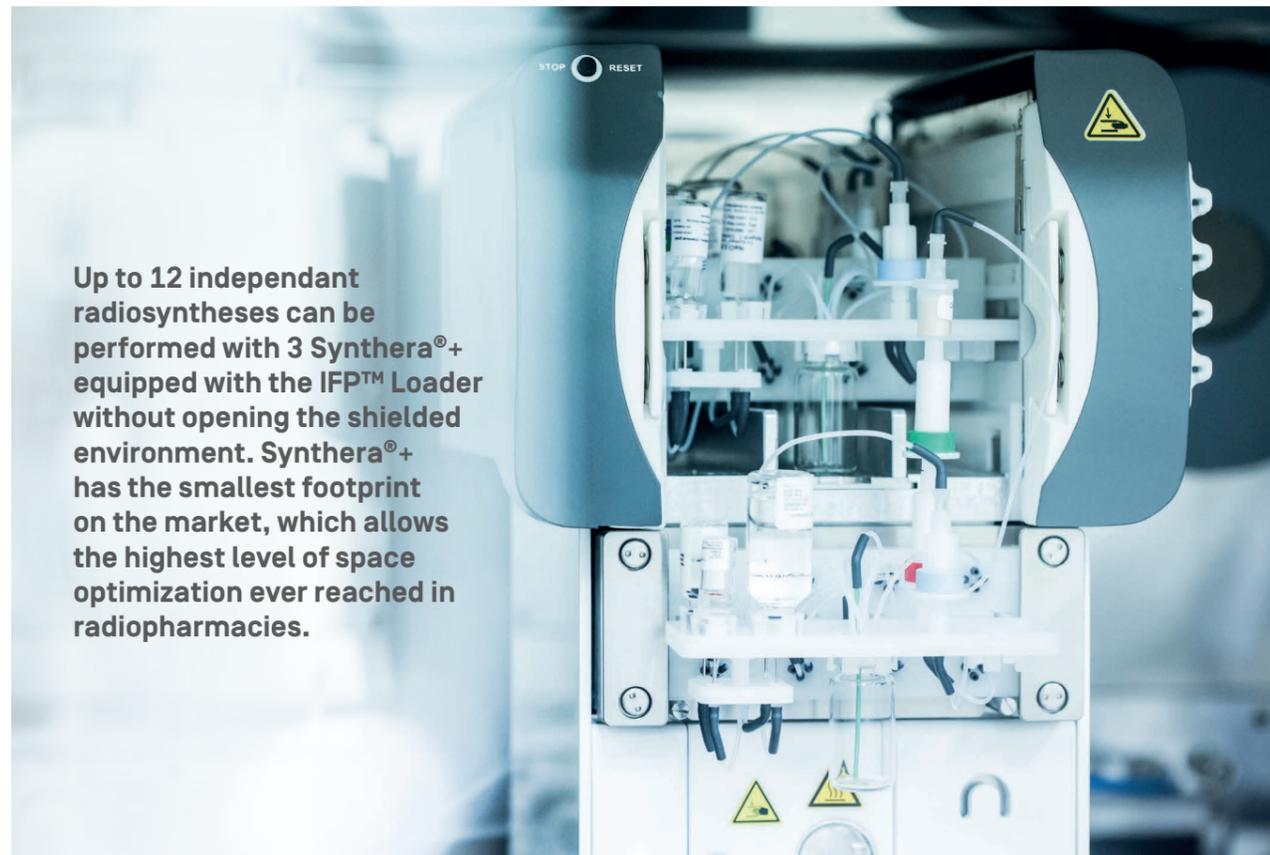
Kevin ROLAND
Senior Director PET/cyclotrons Operations at Isologic
Innovative Radiopharmaceuticals (ISOLOGIC), Canada

BETTER

MULTIPLE RUNS WITH AUTOMATED IFP™ LOADER

Up to 12 runs

of multiple tracers
in the same hotcell



Up to 12 independant radiosyntheses can be performed with 3 Synthera®+ equipped with the IFP™ Loader without opening the shielded environment. Synthera®+ has the smallest footprint on the market, which allows the highest level of space optimization ever reached in radiopharmacies.



The disposable, Single-use IFP™ prevents cross-contamination which is aligned with [c]GMP requirements.

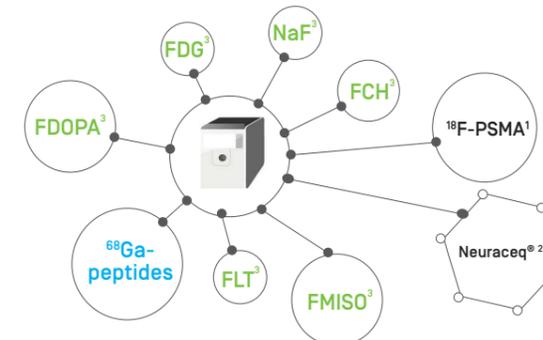
The Integrated Fluidic Processor (IFP™) is the heart of the Synthera®+ operation. All synthesis steps take place entirely within the IFP™ system. Combined with specific reagents and recipes. The IFP™ can accommodate a multitude of syntheses.

MULTIPLE TRACERS PRODUCTION

Ready-to-go
Radiopharmaceuticals

All Molecules in one hot cell

COMMERCIALY AVAILABLE RADIOPHARMACEUTICALS



New tracers in the pipeline in development

¹ [¹⁸F]-PSMA available soon
² Piramal Imaging proprietary molecule
³ ¹⁸F-labelled compounds : [¹⁸F]FDOPA, [¹⁸F]FDG, [¹⁸F]NaF, [¹⁸F]FLT, [¹⁸F]FMISO, [¹⁸F]FCHOLINE

ONE SOFTWARE PLATFORM

The software integrates multiple-module control. Several units controlled by one PC only.

INTEGRATED SYNTERA®+ HPLC

On-line liquid chromatography purification ("semi-preparative" HPLC) is fully integrated.

TODAY AND TOMORROW

Customized applications are supported by open software with graphical tools. By accessing the quick-start menu, the user is only one click away from synthesizing a wide range of tracers.

LIBRARY OF COMPOUNDS ONLINE

Free access to Production Scripts

The Library of Compounds allows the User's Community to share and exchange radiochemistry application-protocols on Synthera® family of products.

Synthera® users can simply download the scripts (recipes) from other research laboratories and manufacturers

worldwide. There is no reason to start from scratch when others have already done it!

Create your account right now on : synthera-libraryofcompounds.com



Several in-house radiotracers have already been developed by Synthera® users:

- [¹⁸F]-FTT
- [¹⁸F]-FTP
- [¹⁸F] PRO4.MZ
- [¹⁸F]FET
- [¹⁸F]FES
- [¹⁸F]fallypride
- [¹⁸F]FT-DTBZ
- [¹⁸F] cisFPro
- [¹⁸F]-MHMZ
- And many others...

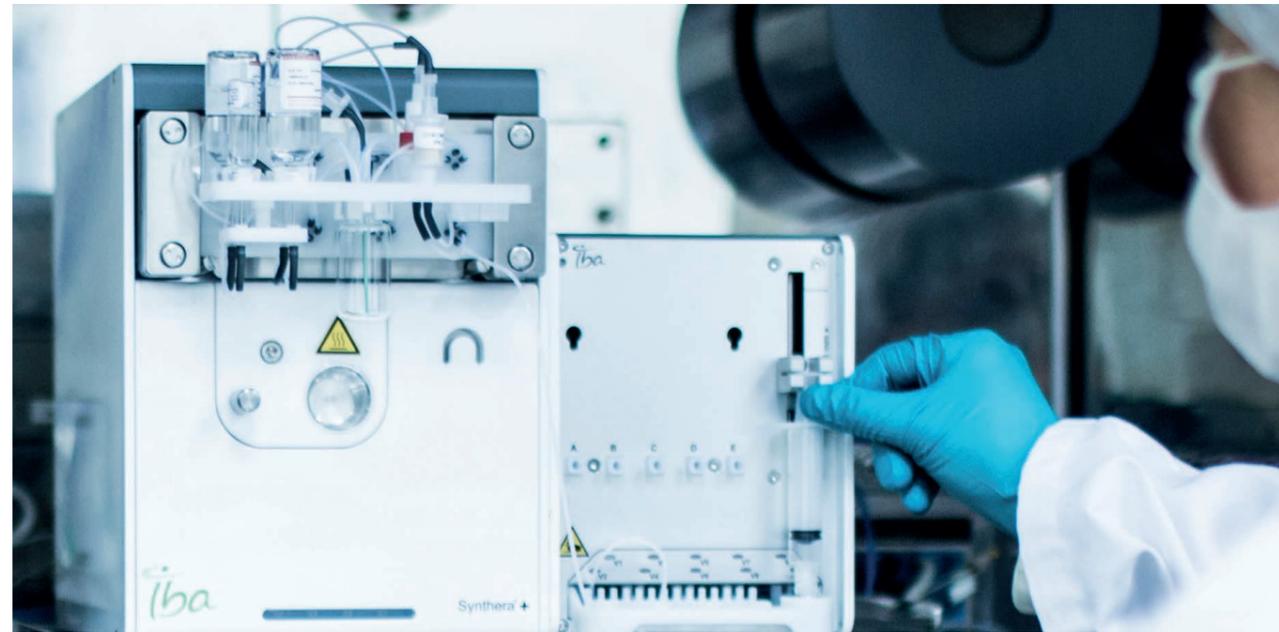


SMARTER

ACCESSORY-BASED PLATFORM

Synthera®+ is the most cost and space-efficient solution due to its multi-run capability, increased performance with high yield, minimal hot cell investment and optimized maintenance.

Synthera®+ is an accessory-based platform allowing you to start from a basic setup then add functionalities over time, ensuring that you continuously meet your demands in the future.



SYNTHERA® EXTENSION

FOR EXTRA FUNCTIONALITIES

Synthera® Extension complements the functionality of the Synthera® family platform with its additional valves and a syringe driver for more complex processes such as ⁶⁸Ga-peptides* labelling (for both generator and cyclotron liquid target solutions).

Additionally, diverse research applications have been developed on the Synthera® Extension as a standalone module, such as : [¹⁸F]NaF**; separation/purification of ⁸⁹Zr, ⁶⁴Cu, ^{99m}Tc to obtain ⁸⁹Zr-oxalate, ⁶⁴Cu-chloride, ^{99m}Tc-pertechnetate, respectively.

The module employs a re-usable support cassette where disposable tubing can be placed, which eliminates the need to use an additional IFP™ for complex syntheses.

*Patent pending on the complete liquid target process: EP15170854
**Coming soon



We have a range of five Synthera® platforms in our labs and the most recent one is the Synthera® Extension. With the Synthera® Extension, we are producing ⁶⁸Ga-PSMA and ⁶⁸Ga-DOTATATE on routine with high yields and in a reliable way to meet the high demands of our clinicians.



Andrés Amaral
Project Manager at PositronPharma, Chile



IFP™ AUTOMATED LOADER

MULTIPLY YOUR PRODUCTION CAPABILITY BY 4

The IFP™ Loader enables you to carry out independent multiple runs of multiple molecules or of a single tracer.

Four consecutive runs can be performed without opening the hot cell with ZERO radiation exposure to the operator and ZERO downtime between runs.

You can add up to 3 Synthera®+ with the IFP™ Loader within the same selected hot cell: up to 12 runs of multiple tracers without opening the hot cell!

More capacity with the benefit of not having to invest in more hot cells.



SYNTHERA®+ HPLC

FOR MORE COMPLEX PURIFICATION

IBA's new HPLC is highly resistant to radiation exposure with all electronic components outside the hot cell and is fully integrated to the new Synthera®+ software generation.

It is more robust, it has extra valves adding more functionalities to the system (e.g. reformulation). The new Synthera®+ HPLC radiation detector is more accurate allowing a precise peak detection and collection.



FIXED IFP™

NEW DEVELOPMENTS SIMPLER AND MORE COST-EFFECTIVE

The Fixed IFP™* is also an optional accessory. Synthera®+ is the only synthesizer compatible with both disposable and non-disposable cassette systems (the Fixed IFP™ cassette). Users can easily convert the Synthera®+ from a non-cassette-based to a cassette-based platform, which facilitates the translation from development to routine applications.

*Coming soon.

STRONGER

INCREASED UPTIME, REDUCED MAINTENANCE

All Synthera®+ electronic components are placed outside of the hot cell to ensure higher resistance to radiation damage, leading to longer hardware life time, reduced maintenance and increased uptime.

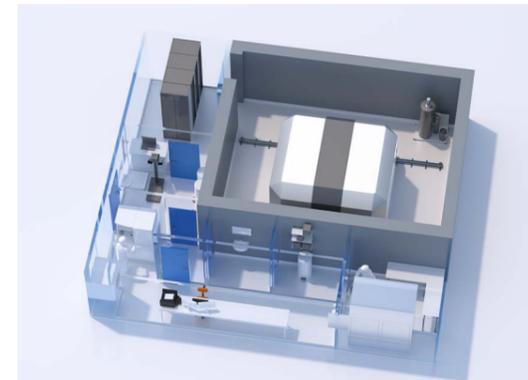


We have selected the Synthera®+ for its high production capacity, increased with the IFP™ Loader system. We expect to reach maximized uptime with reduced maintenance costs as a result of the Synthera®+ high activity resistance.

Tamer Yagan
General Manager
Nukleon, Turkey



YOUR FULLY INTEGRATED RADIOPHARMACY



➤ INTEGRALAB® SOLUTION

FROM PROJECT TO REALITY

IBA IntegraLab® is a fully integrated solution combining equipment and services for the establishment of your (c)GMP radiopharmaceutical production centers.

The synthesizer is the heart of your (c)GMP radiopharmaceutical process. The IntegraLab® team of experts will help you implement the Synthera® platform process into your production site.



➤ CYCLONE® KIUBE

MAX POTENTIAL, MAX CAPACITY

Synthera®+ perfectly complements the Cyclone® KIUBE with its capability to efficiently process 2 x 15 Curies of ¹⁸F leading to the highest production ever reached at a single cyclotron facility.

2 x 15 Ci

of ¹⁸F capability.
for the highest
production capability

TECHNICAL FEATURES

SYNTHERA® CONSUMABLES

IFP™	<ul style="list-style-type: none"> - Single-use system - Double wrapping pack - Plastic frame - Up to 6 vials, 2 cartridge holders - 1 reactor vial - Integrated interconnecting tubes
Reagent Sets	Set with certificate of analysis for each of the commercially available tracer
Synthesis steps IFP™ available	IFP™ Nucleophilic IFP™ Alkylation IFP™ Distillation IFP™ Chromatography Other IFPs™ are available
Ancillary Supplies Set	Purification, cartridges and filters Syringes and needles
Worldwide suppliers	<ul style="list-style-type: none"> - ABX Advanced Chemical Compounds - Huayi Isotopes - Rotem Industries

Patented : EP1343533, EP1877175, US8287819, US7235216, CA2428274, CN1310680, JP4293304

SOFTWARE

Integrated software	Up to several Synthera®+ units & accessories
Graphical interface	Microsoft® Windows-based
Remote access	Diagnosis and maintenance
(c)GMP compliance	<ul style="list-style-type: none"> - Password protected three-level access software - Protected electronic records, print integrity and full audit trail - Built-in material batch number tracking system
Open software	<ul style="list-style-type: none"> - Adjustable parameters - Automatic data-logging

UTILITIES

Compressed air	6-7 bar
Power supply	100-240 VAC (50-60Hz)

CONTROL BOX & COMPUTER

Control box	PLC-based & Ethernet communication
Dimensions (wxdxh)	17.5 x 22 x 12.7 cm (located outside of the hot cell)
Router	Local area network
Personal computer	Single PC for up to 5 units
Laptop dimensions	35.5 cm x 26 cm x 4.0 cm 14 in x 10.3 in x 1.6 in

SYNTHERA®+ SYNTHESIZER

Synthera®+	<ul style="list-style-type: none"> - Fully automated synthesizer with auto-ejectable system - Radiation, temperature, gas & compressed air sensors - Heating system up to 180°
Dimensions (wxdxh)	17.8 cm x 27.1 cm x 24.7 cm 7 in x 10.7 in x 9.7 in
Hot cell internal minimum size for 1 module (wxdxh)	25 cm x 50 cm x 50 cm 9.8 in x 19.7 in x 19.7 in

International patents : EP1343533 et EP1877175
US8287819 & US7235216

SYNTHERA®+ IFP™ LOADER

Synthera®+ IFP™ Loader	Synthera®+ can be optionally connected to an automatic IFP™ Loader system. This accessory enables the module to perform up to 4 consecutive runs of multiple tracers without opening the hot cell
Dimensions Synthera®+ synthesizer Processing base module with Loader (wxdxh)	23 cm x 29.2 cm x 38.7 cm 9 in x 11.5 in x 15.2 in
Hot cell internal minimum size for 1 base module with Loader (wxdxh)	30 cm x 50 cm x 50 cm 11.8 in x 19.7 in x 19.7 in

Patent pending : EP16193281

SYNTHERA®+ HPLC

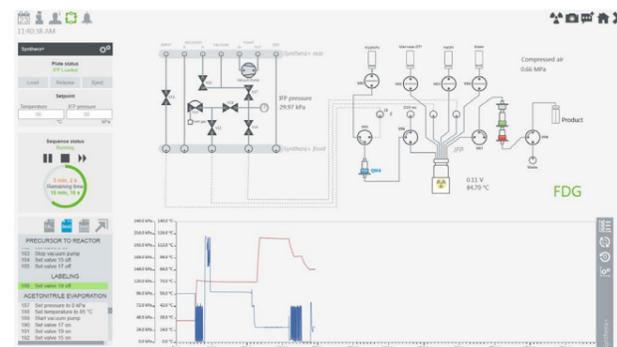
Synthera®+ HPLC	<ul style="list-style-type: none"> - High Performance Liquid Chromatography system - Isocratic high pressure pump (10ml/min-300 bar) - High pressure 6-port switching valve - Injector loop (5 ml) - UV detector (optional) - Radiodetector - 2 extra analogical auxiliary input ports
Dimensions (wxdxh)	9.3 cm x 24 cm x 24.7 cm 3.7 in x 9.5 in x 9.7 in
Hot cell internal minimum size for 1 unit (wxdxh)	25 cm x 45 cm x 45 cm 9.8 in x 17.7 in x 17.7 in

SYNTHERA® EXTENSION

Synthera® Extension	<ul style="list-style-type: none"> - 10 independent pinch valves - 1 syringe driver with standard volume of 6 mL (but can be adapted to other volumes) - 1 inert gas line with pressure regulator, pressure sensor & solenoid valve. - 5 fixed versatile internal Tefzel® lines [allowing to connect elements such as waste bottle, vent-line, recovery bottle, rinsing liquid feed] - Hold points for customization.
Dimensions (wxdxh)	13.2 cm x 17 cm x 17 cm 5.2 in x 6.7 in x 6.7 in
Hot cell internal minimum size for 1 unit (wxdxh)	20 x 25 x 25 cm 7.9 in x 9.8 in x 9.8 in



Synthera®+ software : home page



Synthera®+ software : synthesis page



Synthera®+ Platform

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 GMP radiopharmaceuticals production centers.

ABOUT INTEGRALAB® AND SYNThERA®+

IntegraLab® is a fully integrated solution combining equipment and services for the development of Radiopharmaceutical Production Centers. IntegraLab® includes the building designed with full regulatory compliance and the selection, integration, supply and installation of suitable high-technology equipment to match your radioisotope production goals.

Synthera®+ is a multi-purpose automated synthesizer for the production of ¹⁸F₂FDG, other compounds [¹⁸FCH, ¹⁸FLT, Na¹⁸F, ⁶⁸Ga peptides ...]. This smallest available module on the market is designed to accommodate a wide range of radiochemistry processes.

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PROTECT +
ENHANCE +
SAVE LIVES