



SYNTHERA[®] + BETTER, SMARTER, STRONGER.

PROTECT +
ENHANCE +
SAVE LIVES

RADIO
PHARMA
SOLUTIONS

**BETTER, SMARTER,
STRONGER.**

With more than 650 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.

650+

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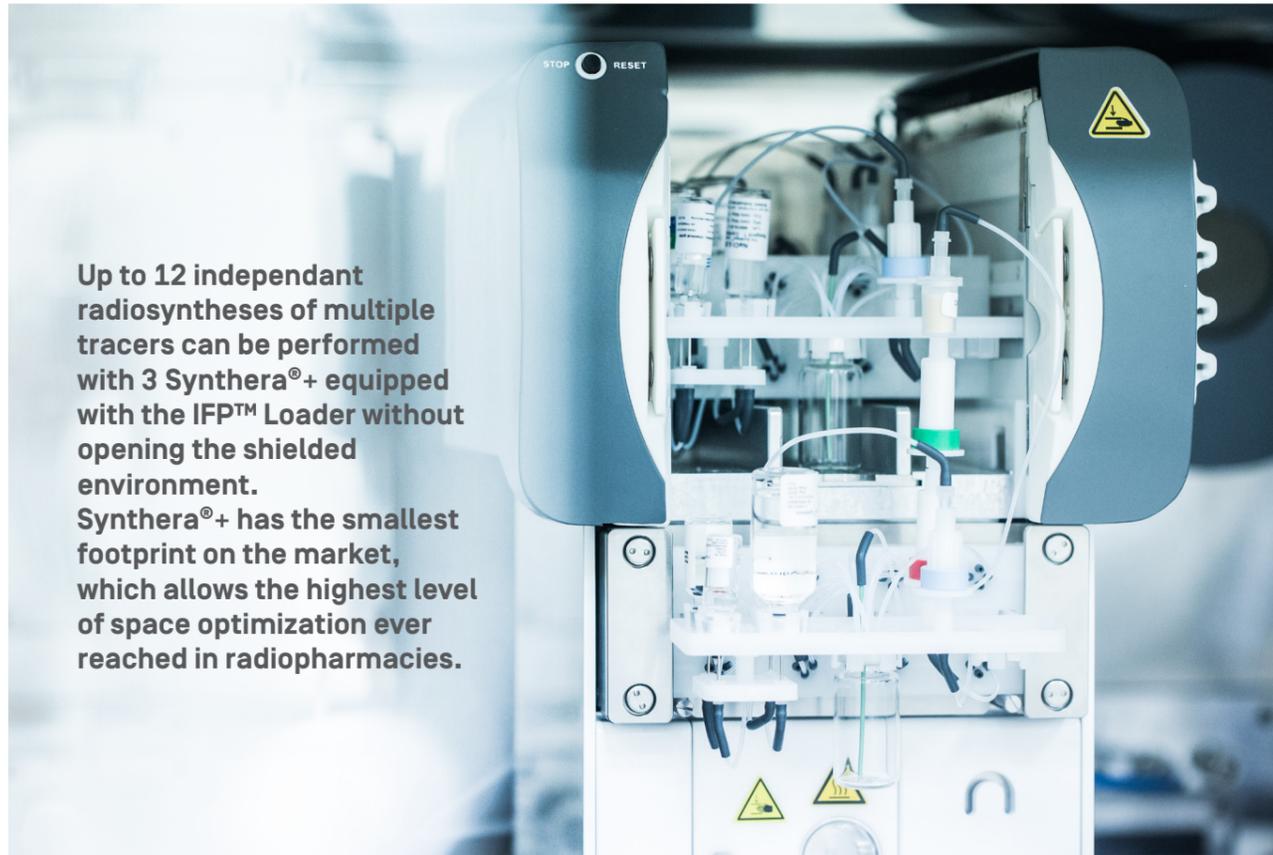


We have 5 Synthera®+, which have been used starting our first patient FDG production in January 2019. We are currently producing F-18 FDG and F-18 PSMA routinely, and other tracers such as Cyclone® KIUBE produced Ga-68 Dotanoc are approaching. So far our experience of Synthera®+ is good, the synthesizer is compact and reliable.

Kim Bergström
Head of Cyclotron Unit
HUS Medical Imaging Center, Helsinki, Finland

BETTER

MULTIPLE RUNS OF MULTIPLE TRACERS



Up to 12 independent radiosyntheses of multiple tracers 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.

Up to 12 runs

 in the same hotcell with the automated ifp™ Loader

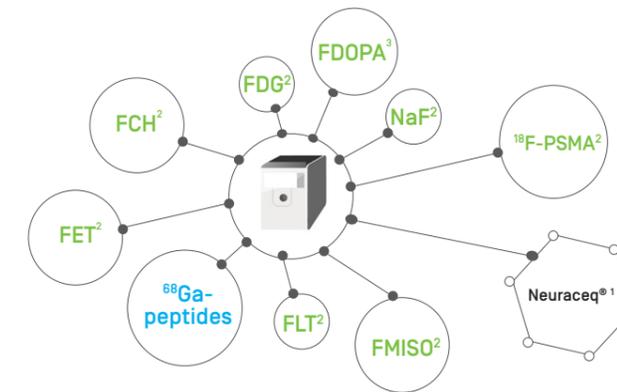
The disposable, single-use IFP™ prevents cross-contamination which is aligned with [c]GMP requirements.

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

COMMERCIALY AVAILABLE RADIOPHARMACEUTICALS



New tracers in the pipeline in development

¹ Life Molecular Imaging proprietary molecule
² ¹⁸F-labelled compounds : [¹⁸F]FDG, [¹⁸F]PSMA, [¹⁸F]NaF, [¹⁸F]FLT, [¹⁸F]FMISO, [¹⁸F]FCHOLINE, [¹⁸F]FET
³ [¹⁸F]FDOPA under development

All molecules in one hot cell

ONE SOFTWARE PLATFORM

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

INTEGRATED SYNThERA[®]+ 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.

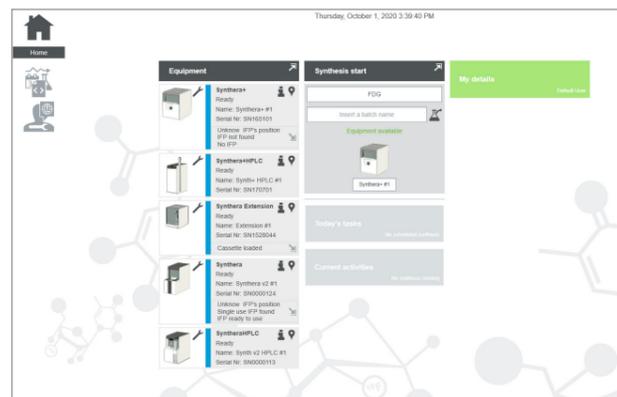


I'm satisfied with the Synthera[®]+ with loader; it's great to run a number of batches on the same module especially for those who have only one hotcell. It is more reliable with all the electronic components outside. I would definitely recommend the Synthera[®]+ for FDG multirun.

Vladislav Bronfenmakher
Head of production,
European Medical Center, Moscow, Russia

MAX EASE OF USE AND THE HIGHEST COMPLIANCE

Synthera® Software



Synthera+ software : home page



Synthera+ software : synthesis page

Because software is a key component in a product, Synthera®+ software was designed to enhance users experience in routine production as well as research.

MULTI-PLATFORM

You can control all your Synthera®* platforms with one computer; Synthera®+, Synthera®+ HPLC, Synthera® V2, Synthera® Extension, Synthera® HPLC.

OPEN SOURCE SOFTWARE

Gives you maximum flexibility to create new recipes for free.

HIGHEST REGULATORY COMPLIANCE

As the software follows 21 CFR part 11 (Full audit trail, Electronic signatures, Archives and backups), you have a complete traceability.

USER-FRIENDLY

An intuitive interface for ease of operation of the system.

FREE ACCESS TO PRODUCTION RECIPES



Library of Compounds Online

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-PR04.MZ
- [¹⁸F]FES
- ¹⁸F-Fallypride
- [¹⁸F]FP-DTBZ
- 4-cis-[¹⁸F]Fluoro-l-proline
- ¹⁸F-MHMZ
- 2[¹⁸F]FA
- 3[¹⁸F]Fluoro-4-aminopyridine

And many others...

WORLDWIDE COLLABORATIONS

For almost 35 years, the most prestigious diagnosis and research centers trusted IBA's high technology equipment for their radiopharmaceuticals production.



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.



UNIQUE 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.

* Patent application EP3308852A1



SYNTERA®+ 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. The new Synthera®+ HPLC radiation detector is more accurate allowing a precise peak detection and collection.



SYNTERA® 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 post-process purification in ⁶⁸Ga liquid target productions* and elution of Ge/Ga generator when necessary.** [¹⁸F]NaF can also be produced on Synthera® Extension on routine basis.

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.



Thanks to the Synthera® platform we have the flexibility to produce a variety of PET tracers for clinical applications. At Positronpharma, we produce FDG and Ga-peptides on a daily basis as well as ¹⁸F-PSMA-1007 (2x weekly), ¹⁸F-PR04MZ, Neuraceq, ¹⁸F-PI-2620, ¹⁸F-AIF-FAPi-74 (2x monthly), and ¹⁸F-FET (on order).

Vasko Kramer, PhD,
Head of R&D,
Positronpharma SA, Chile

*Patent pending on the complete liquid target process: EP15170854

**It depends on the type of generator.

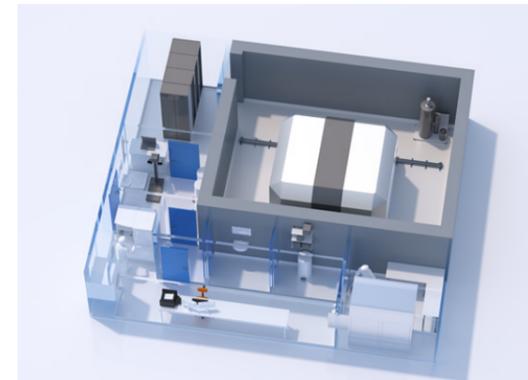
STRONGER

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.



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

capability to process high amount of ¹⁸F activities on a daily basis with the highest uptime



Combining reliability and friendliness of use, the Synthera + has quickly become the workhorse of our production routine with **an integrated incoming activity of over 4000 Ci without any major failure.**

Prof. Antero Abrunhosa, Ph.D.
Director at ICNAS
Coimbra, Portugal



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 GmbH, Germany - HIC (Huayi Isotopes Company), China - Rotem Industries, Israel

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)	28 x 20 x 12 cm (located outside of the hot cell)
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

*May depend on laptop model evolution

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 application EP3308852A1, EP3308852A1

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 - 1 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





ABOUT IBA

IBA (Ion Beam Applications) is a global medical technology company focused on bringing integrated and innovative solutions for the diagnosis and treatment of cancer. 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 ¹⁸F, 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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While all care has been taken to ensure that the information contained in this publication is correct, we accept no responsibility for any inaccuracy and reserve the right to modify this information. Technical specifications are based on standard operating conditions and may be subject to variations.

