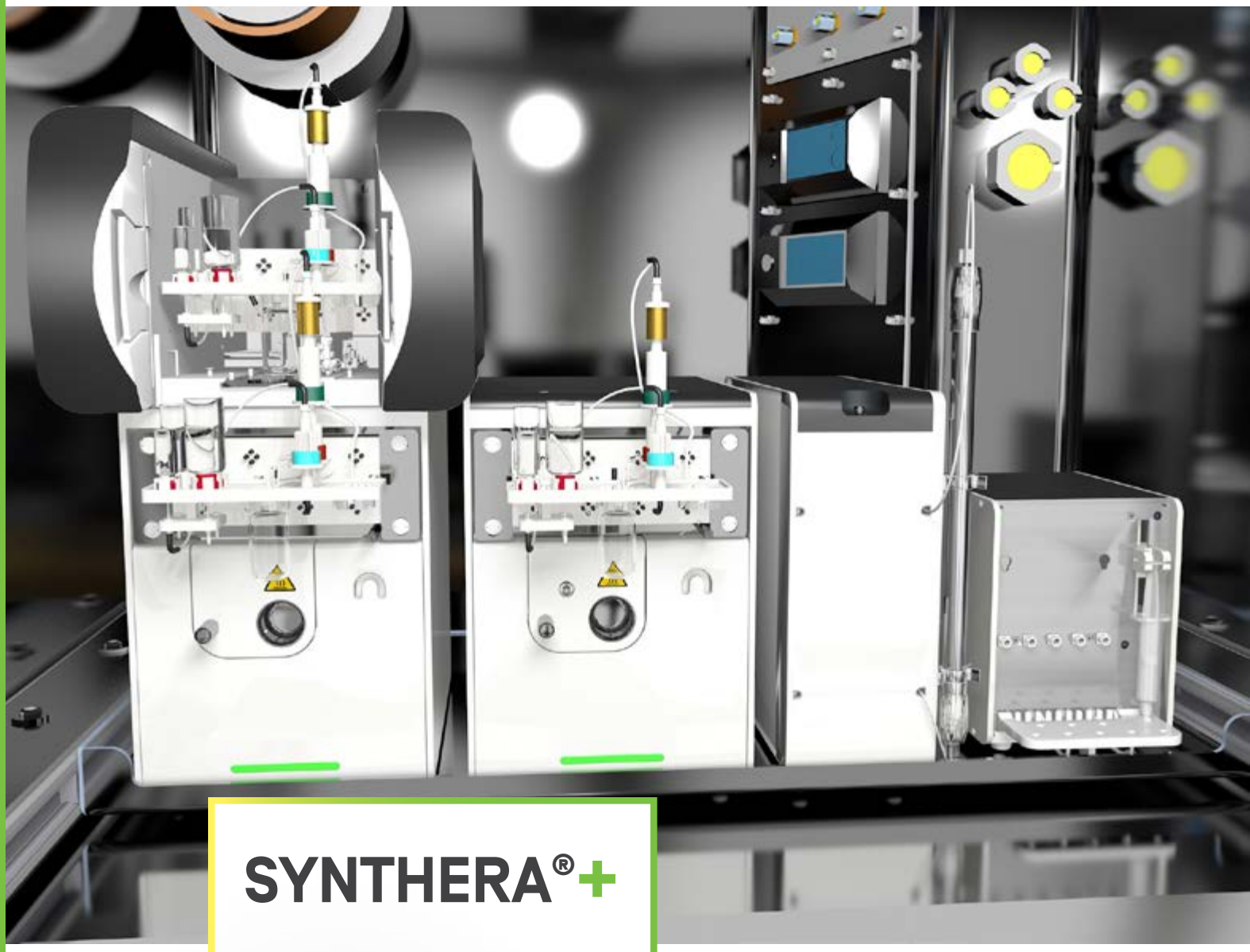
Life.
Science.



SYNTHERA®+

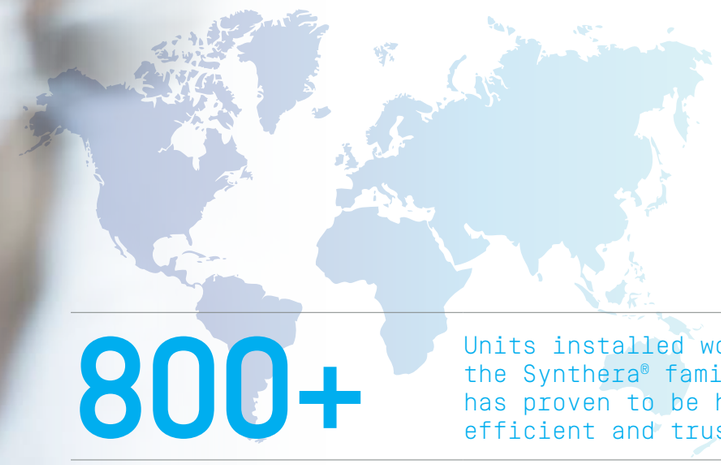
BETTER,
SMARTER,
STRONGER.

RADIO
PHARMA
SOLUTIONS

BETTER, SMARTER, STRONGER.

With more than 800 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.



800+

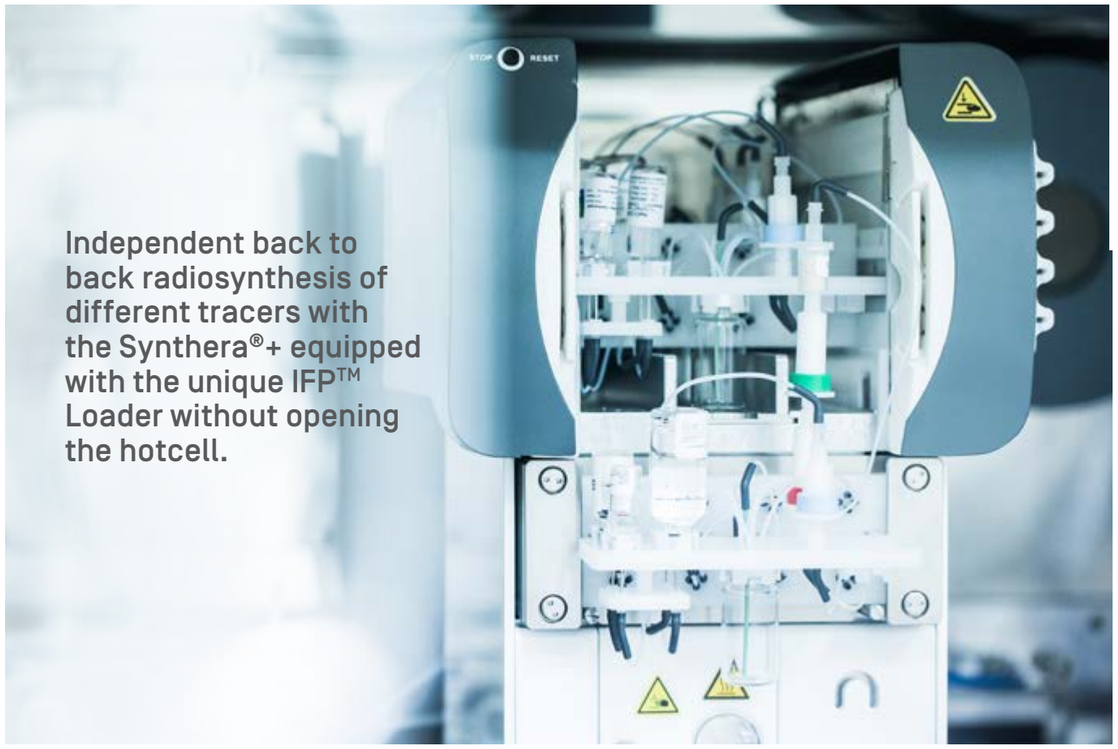
Units installed worldwide, the Synthera® family has proven to be highly efficient and trustworthy.

«In 2021, we have transferred our daily FDG production to Synthera®+. The production has been reliable and robust. It was very easy to train our staff to operate the synthesizer through its very user-friendly software platform. The IFP™-loader permitted us to produce other radiopharmaceuticals in sequence with [^{18}F]FDG (such as [^{18}F]FPSMA-1007) without manual intervention.»

Jan Courtyn
Production Manager
Radio-pharmacy UZ Gent, Belgium

BETTER.

MULTIPLE RUNS OF DIFFERENT TRACERS



Independent back to back radiosynthesis of different tracers with the Synthera®+ equipped with the unique IFP™ Loader without opening the hotcell.

4 runs of different tracers with one Synthera® and the automated IFP™ Loader wihtout opening the hot cell

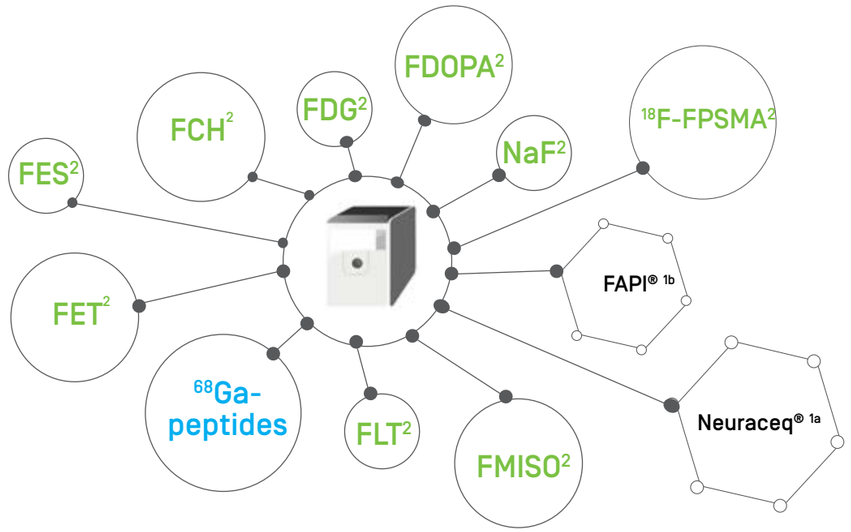
The disposable, Single-use IFP™, prevents cross-contamination which is aligned with [c]GMP requirements.

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 processes.

MULTIPLE TRACERS PRODUCTION

Ready-to-go radiopharmaceuticals

COMMERCIALLY AVAILABLE RADIOPHARMACEUTICALS



New tracers in the pipeline in development

[1] Proprietary molecules: a. Life Molecular Imaging, b. [18F]FAPI-74 is currently not an approved radiopharmaceutical in any jurisdiction including the United States and European Union.This compound is licensed to Sofie Biosciences. End-User may contact Sofie Biosciences to access the compound.
[2] 18F-labelled compounds :[18F]FDG, [18F]FPSMA-1007, [18F]NaF, [18F]FLT,[18F]FMISO, [18F]FCHOLINE, [18F]FET, [18F]FES, [18F]FDOPA

«The compact and fully automated Synthera®+ Synthesizer perfectly matched our needs for a space and cost efficient solution. With 2 Synthera®+ and associated IFP™ loaders, we can easily accommodate our routine FDG production with multiple runs consecutively. The setup is simple and the new software is user-friendly. We are confident to match our production needs for today and the near future.»

Tri Hien Viet Huynh
Head of Cyclotron and Radiochemistry
Herlev University Hospital, Denmark

HIGHEST COMPLIANCE AND MAX EASE OF USE

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 new developments.

MULTI-PLATFORM

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

OPEN SOFTWARE

Gives you maximum flexibility to develop new radiotracers and 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.

SYNTHERA® + REMOTE ACCESS SERVICE

The remote access allows supervision of the Synthera® + or diagnostic from any location. The 24/7 helpdesk provides you with peace of mind, with IBA experts analyzing your Synthera® + data in order to diagnose and solve your problems remotely.

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 (Sequence, Visual pathway and radiopharmaceuticals description) 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

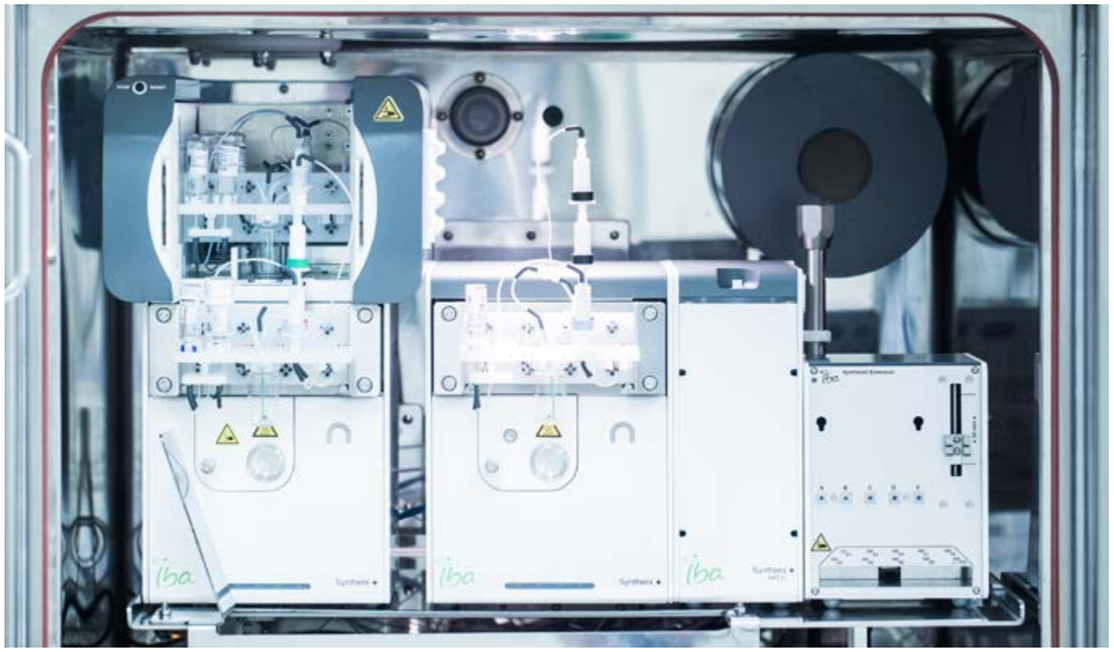
For almost 35 years, the most prestigious diagnosis and research centers trusted IBA's high technology equipment for their radiopharmaceuticals production.

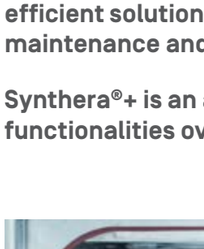
SMARTER.

ACCESSORY-BASED PLATFORM

Synthera®+ has the smallest footprint on the market, which allows the highest level of space optimization ever reached in radiopharmacies. Synthera®+ is the most cost and space-efficient solution due to its multi-run capability, minimal hot cell investment, optimized maintenance and increased performance.

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





«Thanks to the Synthera® platform we have the flexibility to produce a variety of PET tracers for clinical applications. At Positronpharma, we produce [18F]FDG on a daily basis, [18F]FPSMA-1007 (2x weekly),18F-PR04.MZ, 18F-Neuraceq, 18F-PI-2620, [18F]F-AlF-FAPi-74, [18F]F-AlF-Nota-Octreotide (2x monthly), [18F]FET and research tracers such as [18F]F-tryptophan and [18F]F-tretazines using the Synthera®+.»

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

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.

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

* Patents: EP3308852, JP6953243, US10919019

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

SYNTHERA® EXTENSION

FOR EXTRA FUNCTIONNALITIES

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 ^{68}Ga liquid target productions* and elution of Ge/Ga generator when necessary.**
[^{18}F]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 : [^{18}F]NaF; separation/purification of Zirconium-89, Copper-64, Technecium-99m to obtain ^{89}Zr-oxalate, ^{64}Cu-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.

**Patents on the complete liquid target process: EP3101660, JP6632472, US10600528*
***It depends on the type of generator.*

STRONGER.

INCREASED UPTIME, REDUCED MAINTENANCE

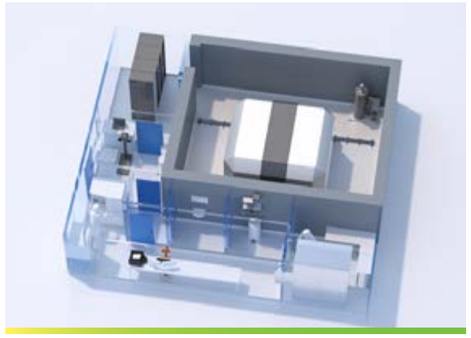
All Synthera®+ sensitive electronic components are placed outside of the hot cell to ensure higher resistance to radiation damage, leading to longer hardware life time, increased uptime and reduced maintenance.

*«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, Protugal

*Over a period of 18 months, no major failure has occured on the Synthera +, providing a proven track-record for the robustness of the system.

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®+ platform perfectly complements the Cyclone® KIUBE with its capability to efficiently process 2 x 15 Curies of Fluorine-18(^{18}F) leading to a high radiopharmaceutical production.

2 x 15 Ci

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

TECHNICAL FEATURES.

SYNTHERA® CONSUMABLES

IFP™	- Single-use system - Double wrapping pack - Plastic frame - Up to 5 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	- ABX GmbH, Germany - HIC (Huayi Isotopes Company), China - Rotem Industries, Israel - Fluidomica, Portugal

Patented : EP1877175, US8287819, US7235216

SOFTWARE

Integrated software	Up to several Synthera®+ units & accessories
Graphical interface	Microsoft® Windows-based
Remote access	Diagnosis and maintenance
(c)GMP compliance (follows 21 CFR part 11)	- Password protected three-level access software - Automatic data-logging
Open software	- Adjustable parameters - Creation of new recipes (sequences) or adaptation from existing ones
Full audit trail	Protected electronic records, print integrity and full traceability

UTILITIES

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

CONTROL UNIT & COMPUTER

Control units (control box & CPU	PLC-based & Ethernet communication
Dimensions (wxdxh)	28 x 19,7 x 11,6 cm (located outside of the hot cell)
Personal computer	Single PC for up to 14 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®+	- Fully automated synthesizer with auto-ejectable system - Radiation, temperature,gas & compressed air sensors - Heating system up to 180° - 1 extra analogical auxiliary input ports
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

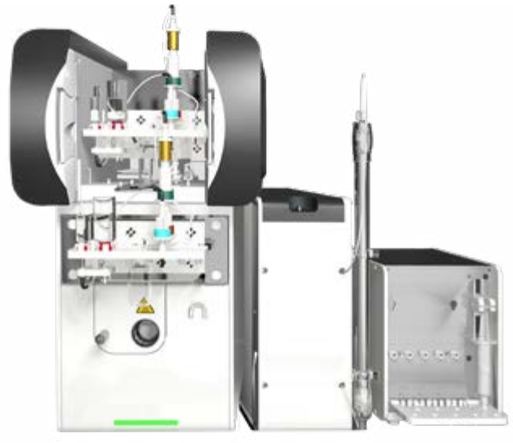
Patents: EP3308852, JP6953243, US10919019

SYNTHERA®+ HPLC

Synthera®+ HPLC	- High Performance Liquid Chromatography system - Isocratic high pressure pump (10ml/min-300 bar). Possibility to have a 50ml/min pump head. - 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	- 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



HOW TO COMBINE YOUR EQUIPMENT?

Synthera® +

- FDG
- FPSMA-1007
- NaF
- FET
- FES
- FAPI-74

- FCH
- Ga-DOTA-NOC [1]
- Ga-PSMA-11 [2]

Synthera® +
Synthera® Extension

- FLT
- FMISO
- Neuraceq®

Synthera® +
Synthera® + HPLC

- FDOPA

Synthera® +
Synthera® + HPLC
Synthera® Extension

Up to 4 consecutives runs[3], e.g. :

- 1 run of FPSMA, 2 runs of FDG, 1 run of NaF
- 1 run of FLT, 2 runs of FDG, 1 run of NaF
- 1 run of Ga-DOTANOC, 2 runs of FDG, 1 run of NaF

1. [68Ga]Ga-DOTA-noc
2. [68Ga]Ga-PSMA-11
3. The combinations of Synthera®+ with Synthera®+ HPLC and/or Synthera® Extension can only be used for one run per Synthera®+ and its IFP™ Loader set up. For a second run with the same set up, a second Synthera®+ HPLC and/or Synthera® Extension has to be employed.

READY-TO-GO RADIOPHARMACEUTICALS

Radiopharmaceutical	IFP™	Synthera®+	Synthera®+ HPLC	Synthera® extension
[18F]FDG	Nucleophilic	✓		
[18F]NaF	Chromatography	✓		or ✓
[18F]PSMA	IFP™ for synthesis of FPSMA-1007	✓		
[18F]FET	IFP™ for synthesis of FET	✓		
[18F]FES[1]	IFP™ for synthesis of FES	✓		
[18F]FLT	Nucleophilic	✓	✓	
[18F]FMISO	Nucleophilic	✓	✓	
[18F]FCH	Distillation & Alkylation	✓		✓
[18F]FDOPA[1]	IFP™ for synthesis of FDOPA	✓	✓	✓
68Ga-peptides[2]	Theranostics	✓		✓
Neuraceq® [3a]	Nucleophilic	✓	✓	
[18F]FAPI[1],[3b]	IFP™ for synthesis of FAPI-74	✓		

All radiotracers comply (where applicable) with the current European Pharmacopeia
1. Ready-to-use consumables are under development at the preferred suppliers
2. Peptites: [68Ga]Ga-DOTANOC, [68Ga]Ga-DOTATATE, [68Ga]Ga-PSMA-11
3. Proprietary molecules: a. Life Molecular Imaging, b. [18F]-FAPI-74 is currently not an approved radiopharmaceutical in any jurisdiction including the United States and European Union.This compound is licensed to Sofie Biosciences. End-User may contact Sofie Biosciences to access the compound.

iba-synthera.com

Life.
Science.

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 ^{18}FDG, other compounds (^{18}FCH, ^{18}FLT, Na^{18}F, ^{68}Ga peptides ...). This smallest available module on the market is designed to accommodate a wide range of radiochemistry processes.

CONTACT US:

Chemin du Cyclotron, 3 | 1348 Louvain-la-Neuve, Belgium
Tel.: + 32 10 201 275 | Fax: + 32 10 47 59 58 | Radiopharmasolutions@iba-group.com

Certified
B
Corporation

iba