

# Unitron Group

## Product

## Synthera®

To accommodate a wide range of radiochemistries

## IBA



### IBA about UNITRON

*Synthera® and Synthera® HPLC are the most recurrent products sold by IBA RadioPharma Solution for the synthesis of radioactive tracers used for diagnostics of cancers. IBA started a selection process in order to find the best partner who could do the production of those products with the flexibility required by this market, and also with a very high and reliable quality level (ISO13485 certification was mandatory), at the best cost in order to remain competitive. After a qualification process where Unitron had to learn a lot on the very compact product that Synthera® is, and had to acquire new mechanical skills, we started the serial production end of 2013.*

*Unitron convinces and demonstrates us a high level of quality and flexibility in the management of the production of the Synthera®. It is really a reliable partner with which we wish to continue a long and fruitful cooperation.*



**Following the decision to move production of the compact and fully automatic Synthera® to Western Europe, IBA (Ion Beam Applications SA) sought a producer who could meet the high quality standards (ISO13485 certification). The choice fell on Unitron due to the flexible organisation, production in work cells and the extensive knowledge of production tools such as FMEA, DMAIC and Lean manufacturing. Moreover, Unitron proved capable of building a strong network of industry contacts in the field of mechatronics.**

IBA is a cancer diagnostics and treatment company and the worldwide technology leader in the field of proton therapy and radiopharmaceuticals. 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.

### More value for money

Integralab is fully integrated solution combining equipment and services for the establishment of radiopharmaceuticals production centers. A key component is the Synthera®. Synthera® is a multi-purpose automated synthesizer for the production of <sup>18</sup>F-FDG, other <sup>18</sup>F labelled compounds (<sup>18</sup>FCH, <sup>18</sup>FLT, NA<sup>18</sup>F) as well as radiopharmaceuticals. Synthera® is designed to accommodate a wide range of radiochemistries. The main characteristics of the Synthera® are: most compact, multi-tracers and multi-run. This means a cost effective choice and more value for money.

Synthera® can be used together with Synthera® HPLC (High Performance Liquid chromatography) which is able to perform the purification of the radiopharmaceuticals produced with Synthera®.

Complex mechatronics - Highest quality level

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## IBA

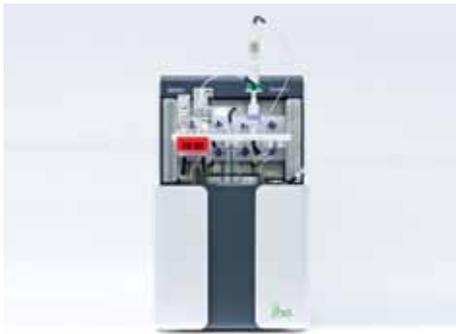
### Technical specifications

- Synthera®  
Fully automated synthesizer with auto-ejectable system. Radiation, temperature and gas compressed air sensors. Heating system up to 180° (with built-in air cooling). Dimensions (wxdxh) 17x29x28.5 cm
- Control box  
PLC-based & Ethernet communication
- Router  
Local area network
- Personal computer  
Single PC for up to 5 units

### IBA

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### Unitron about IBA

*IBA expected an exceptionally high standard from Unitron. By correctly implementing and applying our processes and related methods, such as FMEA and audits, we were able to achieve this and significant mechanical knowledge in the process. We built a strong network of contacts in the field of mechatronics within a relatively short period of time. Knowledge sharing and transfer of knowledge are a natural by-product of our interaction within the network. This network also affords us the ability to provide added value in this area, now and in the future.*



The Synthera® is CE marked and has the quality level of a medical device. This places high demands on the people and practices of Unitron.

### Production in work cell

The production of Synthera® is a complex process. Because of the large number of different components, Unitron opts for the Kanban logistics system, which is fast and efficient. Moreover, Unitron developed a special work cell, integrating the principles of a flexible work cell with a product-related work cell. The different sub-assemblies are assembled in the same work cell and then stored in special sealed containers. This ensures a stable, quiet process which, despite the complexity, is rather simple and transparent.

### Learning organisation

As a learning organisation, Unitron is always open to more knowledge. Thus, the access control of the mechanics has been set up efficiently together with IBA and Unitron's network. The drawings are optimised and numerous hardware improvements have been implemented. Synthera® comes in a specially designed case with a control box for the control, a laptop for the recipe and process monitoring and a router as network device.

### Unitron Group

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Unitron develops and manufactures complete products such as medical equipment and specific industrial electronic products. This ranges from the realisation of a totally new concept to modification and optimisation of existing products. When combined with our experience and operational capabilities, the result is a complete business concept. Unitron operates in a variety of markets throughout the world.