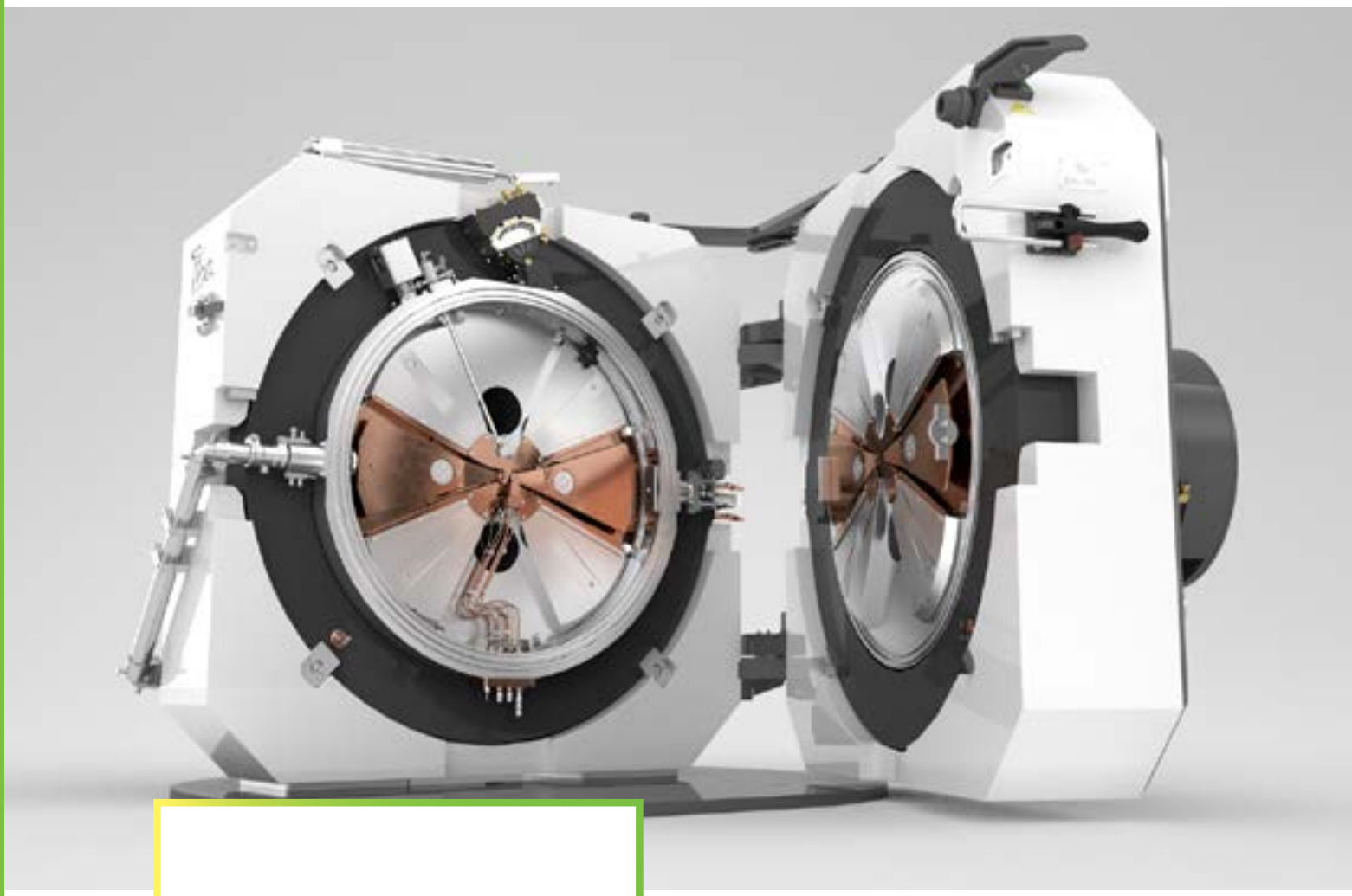
Life.
Science.



CYCLONE® KEY

^{18}F Access Granted

RADIO
PHARMA
SOLUTIONS

^{18}F Access Granted

PET imaging has been well established over the last decades for cancer diagnosis in many countries. But unfortunately, not everyone has been able to join this journey. For various reasons, there are still regions in the world with limited access to this technology.

Also, many hospitals are looking for their independence in terms of radiopharmaceuticals supply in limited spaces ensuring a reliable in-house production.

To answer these needs, IBA is opening the door to a new reality by making PET diagnosis accessible to everyone, everywhere through a new low-energy technology that is more compact, accessible, and user-friendly. And because smaller does not mean less performant, our new cyclotron retains all the characteristics of the Cyclone® family: performance, reliability, and profitability.

For more than 35 years, IBA has built a strong and recognized worldwide leadership in radiopharmaceuticals production solutions, Thanks to our continuous process of innovation and improvement, the Cyclone® family has become a benchmark for high efficiency cyclotrons.

So, go ahead and let us guide you to ACCESS this new reality with the smallest cyclotron of IBA range: the **Cyclone® KEY**.

The Cyclone® KEY

Cyclone® KEY's design originates from the well-established Cyclone® KIUBE, the highest market standards in term of radioisotopes production capacity and reliability. The **Cyclone® KEY** is a compact and fully automated proton acceleration cyclotron (up to 9,2 Mev) enabling a simple yet efficient multiple isotopes production.

It has one of the smallest footprints of all clinical cyclotrons to enable easy installation and operation. Thanks to **Cyclone® KEY** compact size, our experts have managed to minimize the size of the (c)GMP radiopharmacy down to 80 m^2. By reducing your initial investment and allowing you to go for optimized production tailored to your size, IBA makes PET technology affordable for everyone, everywhere.

A hassle-free journey.

High technology, smooth process.

At IBA, we firmly believe that every hospital facility should have unimpeded access to PET diagnosis.

To this end, the Cyclone® KEY has been developed to offer a smooth and simplified installation, operation and maintenance.

Simple Software:

- Extensively guided step by step production procedures
- Several pre-encoded recipes and automated process to reduce the number of human interventions during production.
- Automated self-check prior starting irradiation.
- Operating the cyclotron in automated mode limits the number of parameters to be configurated to the strict minimum

Simplified design to simplified maintenance:

- Single exit port
- A single source
- Simple access to major parts : Ion source, 6 strippers carousel, targets
- Autotuned target position
- Target changer : a single water cooling connection for up to 3 targets, no helium cooling is necessary
- No compressed air required

Safety first

- Cyclone® KEY has been designed to minimize radiation dose exposure to maintenance personnel.
- Components can be easily and quickly handled.
- Careful selection of material for a reduced activation.

Simplified design for simplified maintenance & operation.

The most compact Cyclone®

Small footprint, big possibilities.

At IBA, we don't compromise.

Our engineers have mobilized their extensive expertise to reduce the size of the **Cyclone® KEY** as much as possible, to help solving the congestion problems that users often face, all while maintaining the impressive performance levels of the technologies developed by IBA.
The **Cyclone® KEY offers the same** high standards as the Cyclone® range, ensuring stable and efficient production at all times.

Replace your obsolete Cyclotron

Cyclone® KEY fits any existing vault or even previous PET camera room.
The cyclotron replacement will require minimal building modifications such as no trenches and no civil work if suitable building supporting structure.

→ **L** : 1,5m / 4.9 ft
W : 1,4m / 4.6 ft
H : 1.35m / 4.4 ft

High performance

IBA makes Cyclone® technology affordable for everyone, everywhere.

Up to
3 Ci of ^{18}F
per run.

With the **Cyclone® KEY**, IBA has developed a viable alternative for all hospital facilities looking to become independent in their radioisotopes production.

By reducing installation costs and optimizing production capacity tailored to your needs, IBA opens the doors to a new reality.

Cyclone® KEY could generate up to 3 Ci of ^{18}F in 2 hours of irradiation. Combined with a Synthera®+ chemistry, the production capacity can reach up to 30 FDG doses per run.

The system is designed for **high reliability**, meeting clinical demands by providing tracers for 4 to 5 PET/CT cameras. Several productions may be run consecutively with high reliability.

The target changer can be configured in several different ways to meet your needs. A combination of up to 3 liquid targets [^{18}F or ^{13}N], or a combination of ^{11}C gas and liquid target can be installed for production of tracers beyond oncology such as neurology applications.

A fully integrated solution·

Beyond the technology, a complete solution

Acquiring and operating a cyclotron can sometimes seem like a complex process.

With **IntegraLab®**, IBA has developed a smooth integration process that can be tailored to your needs. From definition of the project to the day-to-day operation of your equipment, our teams of experts use their years of expertise to define and support the solution that best suits you.

01 BUILD

- → GMP layout
- → Detailed room data sheets and associated set of drawings
- → Definition and dimensioning of utilities (HVAC, gases, power supply...).

02 EQUIPEMENT & INTEGRATION

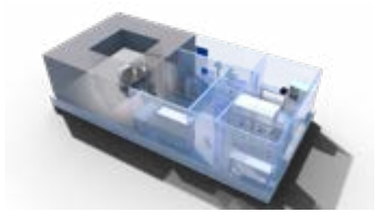
- → 1 Cyclone® KEY
- → 1 Nirta® Liquid ^{18}F
- → 1 Synthera®+ for FDG
- → 1 Synthera®+ for other ^{18}F compounds
- → 1 combined hotcell production and dispensing
- → Compact quality control
- → Radiation monitoring
- → Lab equipment

03 TRAIN AND VALIDATE

GMP

- → Start-up training on equipment
- → File for (C)GMP certification :
  - Validation master plan
  - Quality risk management
  - Site master file
  - Template documentation for pharmaceutical quality system including batch records & sops.

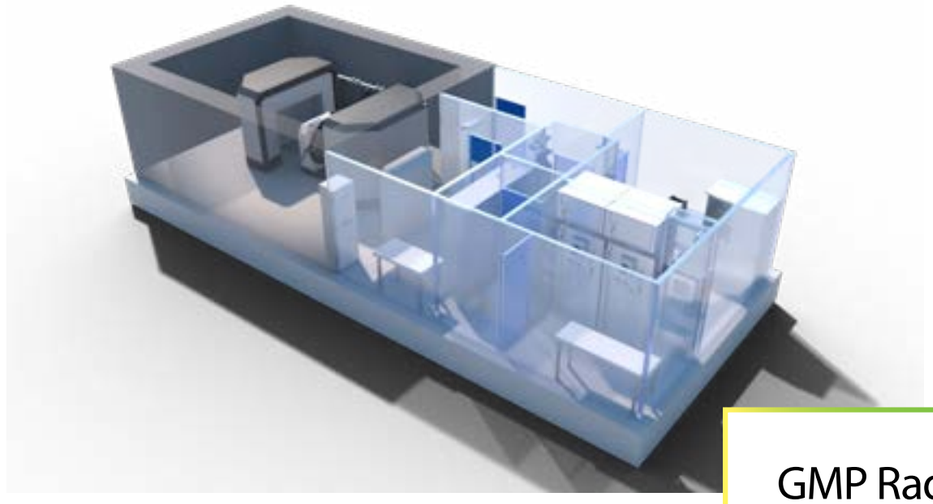
04 OPERATE

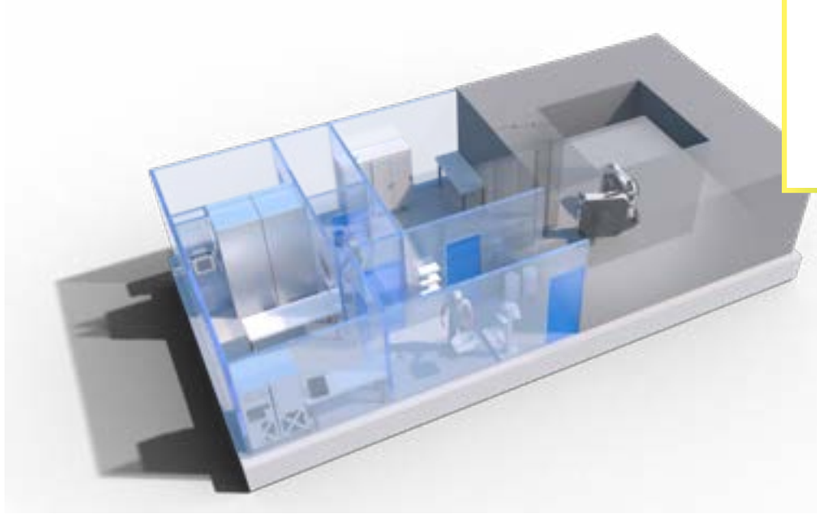


- → Detailed list of material provided :
  - Production & QC Consumables
  - Facility Operation/Cleaning Consumables
  - Recommended spare parts list
- → IBA equipment maintenance
- → Equipment warranty

A fully integrated solution·

Thanks to Cyclone® KEY compact size, the overall facility footprint is significantly compressed reducing your initial investment and allowing you to opt for optimized production tailored to your size.
IBA's team of experts in (c)GMP radiopharmacy setting-up have managed to minimize the size of it down to 80 m² for FDG production, making PET technology affordable and accessible.





GMP Radio-pharmacy
80 m² /
861 sqf

Technical features

HIGH CAPACITY PROTON BEAM	CYCLONE® KEY
Energy	9,2 MeV
Extracted beam current	> 100 µA
TARGET FLEXIBILITY	
Number of target ports	1
Simultaneous installed targets	Up to 3
LOW POWER CONSUMPTION	
Stand-by mode	< 3 kW
Beam-on mode	< 37 kW
COMPACT DESIGN	
Cyclotron weight	7,5 Tons
Self-shielding weight	46 Tons
Cyclotron overall dimensions [m]	1,5 x 1,4 x 1.35 [l x w x h]
Internal room dimensions [m]	3.15 x 3.15 x 2,2 [l x w x h]
Internal room dimensions with self-shielding [m]	6,05 x 4,3 x 2,7 [l x w x h]
Self-shielding overall dimensions (open/closed) [m]	5,8 x 3 x 2,2 / 3,6 x 3 x 2,2 [l x w x h]

Nirta® Target Technology

	^{18}F	^{13}N
Chemical form	F^-	NH_3
Target reaction	$^{18}O(p,n)^{18}F$	$^{16}O(p,\alpha)^{13}N$
Target material	$[^{18}O]$-H_2O	$[^{16}O]$-H_2O + 5mMol Ethanol
Window material	Havar	Havar
Insert material	Niobium	Niobium
Grid material	Pyrolytic Carbon	Pyrolytic Carbon
Beam energy	9 MeV	9 MeV
Max current on target (µA)	>80	>80
Target yield (mCi/µA sat)	90	5
Irradiation time (min)	120	10
Insert volume (ml)	1,84 / 1,5	1,84 / 1,5
Recovered activity EOB (mCi) / (GBq)	3000 / 111	200/7

www.iba-radiopharmasolutions.com

Life.
Science.

ABOUT IBA (Ion Beam Applications S.A.)

IBA 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 long-standing expertise, IBA RadioPharma Solutions supports hospitals and radiopharmaceutical distribution centers with their in-house radioisotope production by providing them with global solutions, from project design to the operation of the facility. In addition to high-quality technology production equipment, IBA has developed in-depth experience in setting up GMP radiopharmaceuticals production centers.

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