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BG-75 BIOMARKER GENERATOR

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BG-75 BIOMARKER GENERATOR

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The BG-75 Biomarker Generator is a revolutionary development in radio-pharmaceutical production that delivers a single or batch dose of [18F]FDG, and additional advanced [18F] biomarkers, "on demand". The system provides integration of all components needed to produce and qualify PET biomarkers into a single, self-contained system that occupies a fraction of the space required by conventional solutions, simplifying the implementation of PET.

Simple Integration

The BG-75 Biomarker Generator integrates a compact mini-cyclotron, kit based micro-chemistry, and automated quality control, simplifying in-house production of [18F] FDG and advanced biomarkers.

- Push button graphic interface
- Kit based chemistry
- Single or batch dose production
- Final dose delivery to syringe or vial (option)
- Automated quality control testing
- Integrated cyclotron & chemistry self-shielding
- Complete production lab in a 30^2m area

Economical Solution

The BG-75 Biomarker Generator provides a unique, affordable, and powerful alternative to conventional cyclotron solutions.

- 30^2m area vs 300^2m reduces build-out costs
- QC automation reduces specialist support
- 1-2 FTE vs. 4-5 FTE reduces operational costs
- Lower radiation minimizes regulatory burden

Fully Integrated Design

The BG-75 Biomarker Generator system integrates a 7.5 MeV cyclotron, Chemistry Production Module (CPM), and Quality Control Module (QCM) for on-site production of [18F]FDG, providing automated production and quality control testing. Both the cyclotron and chemistry modules are self-shielded, reducing radiation to <1 mR/hr at the minimum 5.5m x 5.5m room boundary.

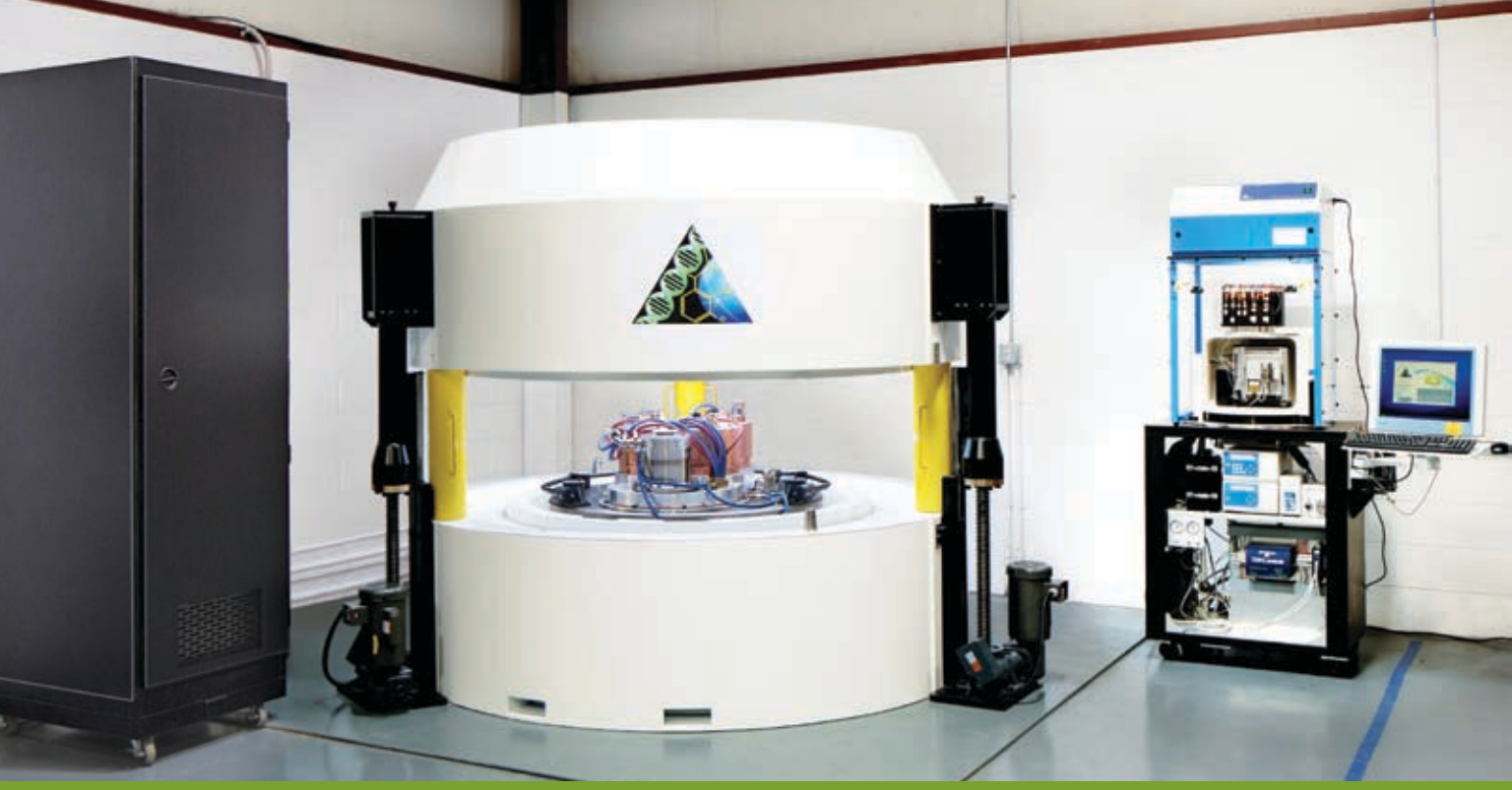
Due to the system's small footprint and self-shielding, the BG-75 Biomarker Generator can be easily incorporated into an existing clinical or research setting, adjacent to PET imaging equipment if needed. By contrast, standard PET biomarker laboratories produce batches of positron-emitting isotopes in a conventional medical cyclotron, which poses a far greater radiation burden requiring significant physical containment of both the cyclotron and all downstream processing steps. Typically, a concrete-reinforced bunker is specially built to contain the cyclotron, with separate "hot" labs dedicated to radiochemistry and QC, and several highly specialized staff to operate the cyclotron and perform the complex functions. In comparison, the BG-75 Biomarker Generator is scaled for a single engineer/operator, occupies 1/10 the space, requires little infrastructure modification, and has embedded chemistry and QC processes that greatly simplify the entire radiopharmaceutical production cycle.

These features translate into significantly less capital investment initially, and lower ongoing operating costs compared to conventional PET biomarker laboratories. Additionally, due to its self-contained design and lower energy, decommissioning the system at the end of its useful life is much simpler and far less costly. Overall, the total cost of ownership for the Best ABT BG-75 Biomarker Generator is less than 1/4 that of conventional cyclotron solutions.

Automated Production

The BG-75 Chemistry Module greatly simplifies the workflow associated with radiopharmaceutical production by miniaturizing and automating the processes for biomarker radiolabeling and quality control. The system is provided with the necessary consumables for daily operation including Dose Synthesis Cards and Reagent Kits for biomarker synthesis, and maintenance, cleaning, and SST cards for quality control calibration.

The [18F]FDG production kit contains two different size daily Reagent Kits to meet your site's needs, and support scalability. The standard [18F]FDG Chemistry Module supports clinical [18F] NaF dose production, and Best ABT is developing optional kits and modules for [18F]FMISO, [18F]FLT, and [18F]F-Choline. The BG-75 Biomarker Generator can also be interfaced to several OEM PET synthesis modules to produce a comprehensive list of [18F] biomarkers for research applications.



True to its vision of expanding the use and usefulness of PET around the globe, Best ABT seeks to fully support both prospective and committed customers throughout the entire lifecycle of the client relationship. Recognizing that many Best ABT customers may be new to PET, and the unique logistical as well as regulatory considerations in evaluating and implementing technology that involves radioactive drugs, Best ABT offers a comprehensive suite of services that enables customers to maximize value from their investment.

FACILITY REQUIREMENTS

Minimum Room Size
5.5m x 5.5m

Electrical Supply
220 – 250 VAC, 100A

Chilled Water Supply
7°C ± 3°C

Early Stage Project Support
Financial and business plan development

Drug Regulatory Consultation
Support for documenting Pharmacopeia compliance

Device Regulatory Consultation
Product registration for importation

Site Readiness Planning
Architectural and utility requirements, construction planning and inspections

Logistics Planning & Export Control
Partnerships available for export/import logistics

Supply Channel Development & Execution
Tools for forecasting and managing consumables inventory

Applications "BG-75 Operator" Training
Dose-cycle planning, clinical workflow, QC record keeping

Technical "BG-75 Engineering" Training
System maintenance, troubleshooting and process monitoring

Technical Support & Service
Ongoing technical support and service, both in the warranty period and afterward

Best ABT Molecular Imaging 3024 Topside Business Park Drive, Louisville, TN 37777 USA
tel: 865 982 0098 800 336 4970 www.bestabt.com www.teambest.com

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Best™ Cyclotron Systems

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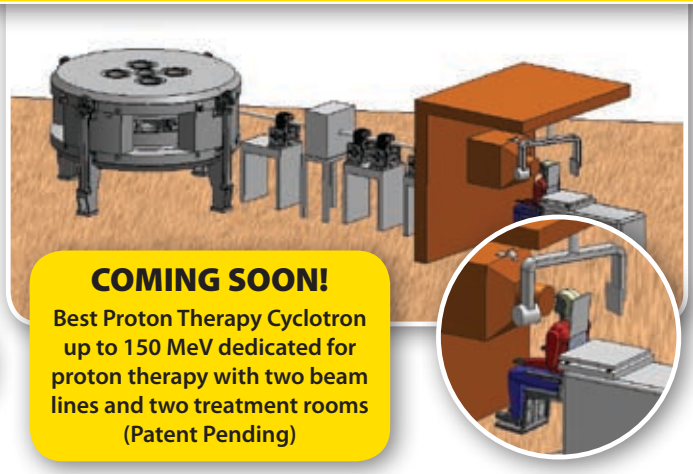
Best Cyclotron Systems provides 1–3 MeV Deuteron Cyclotrons (NEW Patent Pending), 70–150 MeV Proton Therapy Cyclotrons (NEW Patent Pending), 3–90 MeV High Current Neutron Production Cyclotrons (NEW Patent Pending) as well as 15/20u/25/30u/35/70 MeV Proton Cyclotrons & 35/70 MeV Multi-Particle Alpha/Deuteron/Proton Cyclotrons

- Currents from 100uA to 1000uA (or higher) depending on the particle beam are available on all Best Cyclotron Systems
- Best 20u to 25 MeV and 30u to 35 MeV are fully upgradeable on site

NEW Best Cyclotrons	1–3 MeV	Deuterons for materials analysis (Patent Pending)
	70–150 MeV	For Proton Therapy (Patent Pending)
	3–90 MeV	High current proton beams for neutron production and delivery (Patent Pending)
Best 15p Cyclotron	15 MeV	Proton only, capable of high current up to 1000 Micro Amps, for medical radioisotopes
Best 20u/25p Cyclotrons	20, 25–15 MeV	Proton only, capable of high current up to 1000 Micro Amps, for medical radioisotopes
Best 30u/35p Cyclotrons	30, 35–15 MeV	Proton only, capable of high current up to 1000 Micro Amps, for medical radioisotopes
Best 70p Cyclotron	70–35 MeV	Proton only, capable of high current up to 1000 Micro Amps, for medical radioisotopes
Best 150p Cyclotron	From 70 MeV up to 150 MeV (non-variable)	For all Medical Treatments including Benign and Malignant Tumors for Neurological, Eye, Head/Neck, Pediatric, Lung Cancers, Vascular/Cardiac/Stenosis /Ablation, etc. (Patent Pending)

Installation of Best 70 MeV Cyclotron at INFN, Legnaro, Italy



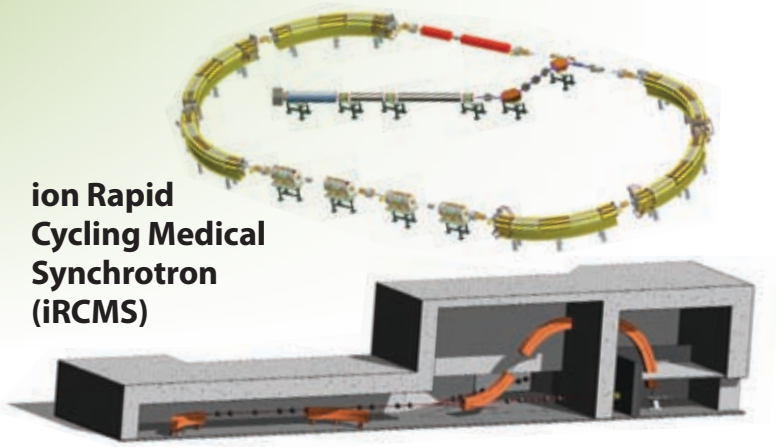
COMING SOON!

Best Proton Therapy Cyclotron up to 150 MeV dedicated for proton therapy with two beam lines and two treatment rooms (Patent Pending)

Best™ Particle Therapy

400 MeV Rapid Cycling Medical Synchrotron for Proton-to-Carbon Heavy Ion Therapy:

- Intrinsically small beams facilitating beam delivery with precision
- Small beam sizes – small magnets, light gantries – smaller footprint
- Highly efficient single turn extraction
- Efficient extraction – less shielding
- Flexibility – heavy ion beam therapy (protons and/or carbon), beam delivery modalities



ion Rapid Cycling Medical Synchrotron (iRCMS)

* Best iRCMS is under development and not available for sale currently.

www.bestcyclotron.com • www.bestproton.com • www.teambest.com

USA tel: 703 451 2378 800 336 4970 • CANADA tel: 604 681 3327 866 909 4647

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