

Best Cyclotron Systems, Inc.

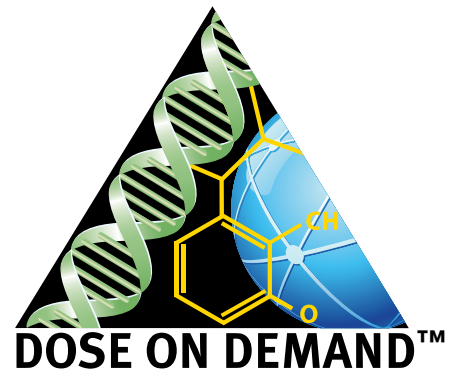


Dose On Demand™
B-100 BEST CYCLOTRON, INC.

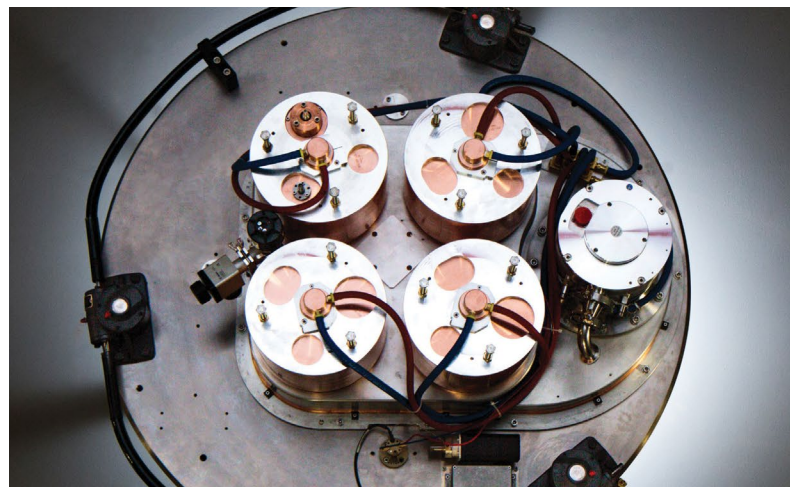


Best[®] Cyclotron Systems, Inc.

B-100 BIOMARKER GENERATOR



The B-100 Biomarker Generator is a revolutionary development in radiopharmaceutical 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

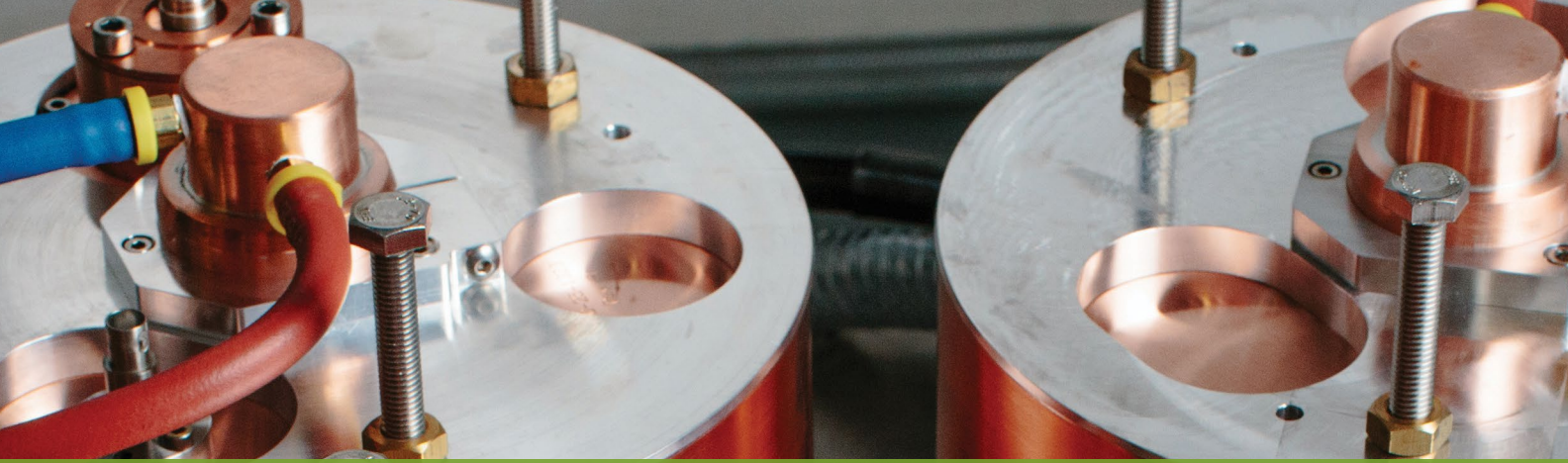
The B-100 Biomarker Generator integrates a compact mini-cyclotron, kit based micro-chemistry, and automated quality control, simplifying in-house production of [18F]FDG and advanced biomarkers.

- 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 and chemistry self-shielding
- Complete production lab in a 30²m area

Economical Solution

The B-100 Biomarker Generator provides a unique, affordable, and powerful alternative to conventional cyclotron solutions.

- 30²m area vs 300²m 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 B-100 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 B-100 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 B-100 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.

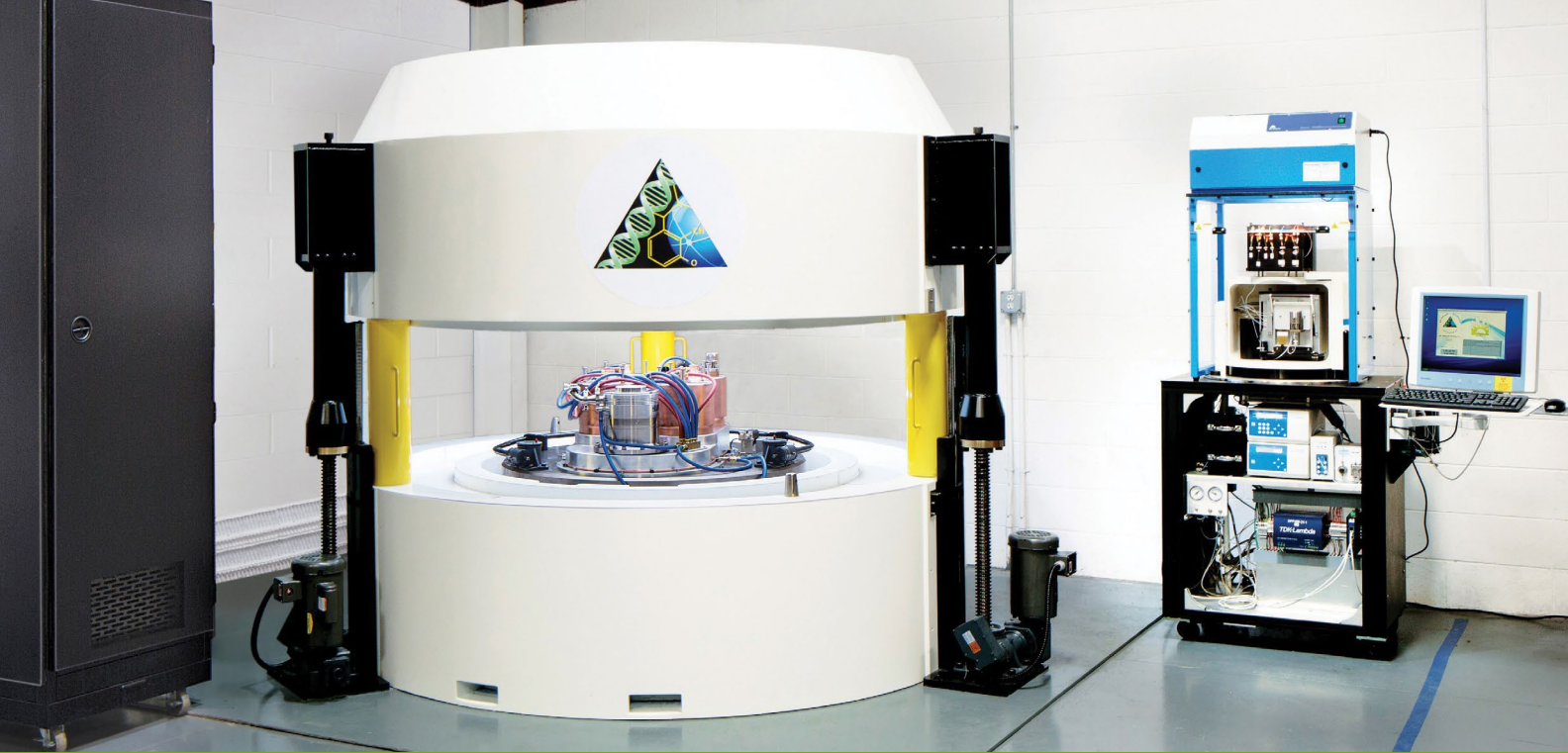
These features translate into significantly less capital investment initially, and lower ongoing operating costs compared to conventional PET biomarker laboratories.

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 B-100 Biomarker Generator is less than 1/4 that of conventional cyclotron solutions.

Automated Production

The B-100 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 Cyclotron Systems, Inc. (BCSI) is developing optional kits and modules for [¹⁸F]FMISO, [¹⁸F]FLT, and [¹⁸F]F-Choline. The B-100 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, BCSI seeks to fully support both prospective and committed customers throughout the entire lifecycle of the client relationship. Recognizing that many BCSI customers may be new to PET, and the unique logistical as well as regulatory considerations in evaluating and implementing technology that involves radioactive drugs, BCSI 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 “B-100 Operator” Training

Dose-cycle planning, clinical workflow, QC record keeping

Technical “B-100 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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