



Early Detection
Saves Lives

What is Nuclear Medicine?

Nuclear Medicine is a medical specialty that uses small amounts of radioactive tracers -called radiopharmaceuticals- to create images of organs and lesions helping to treat diseases such as various cancers, cardiovascular and neurological disorders.

The imaging technics used in nuclear medicine work by injecting into the patient's body targeted radiopharmaceuticals that accumulate within organs or lesions to reveal specific biochemical processes which help visualize how far the disease has spread or to see how well the treatment is working.

As the incidence of diseases such as cancer has increased worldwide so has the use of Nuclear Medicine facilitated by advancements in imaging equipment (SPECT and PET) which has become a mandatory part of the protocols for the treatment of cancer patients.

Yet such techniques are still fundamentally dependent on the availability of the necessary radiopharmaceuticals. The production of such radiopharmaceuticals has proven to be complex and costly up to now.

BEST ABT's minicyclotron fully automatic technology, offers the possibility to produce radiopharmaceuticals, "on demand", safely, well established and economically within the hospital in a < 60m² surface



OUR MISSION

To Increase Global Access to PET Imaging



The world's first "Dose on Demand" Solution





Dose On Demand

BG-75 BIOMAKER GENERATOR





ABT MOLECULAR IMAGING

BG-75 "DOSE ON DEMAND™" BIOMARKER GENERATOR

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.

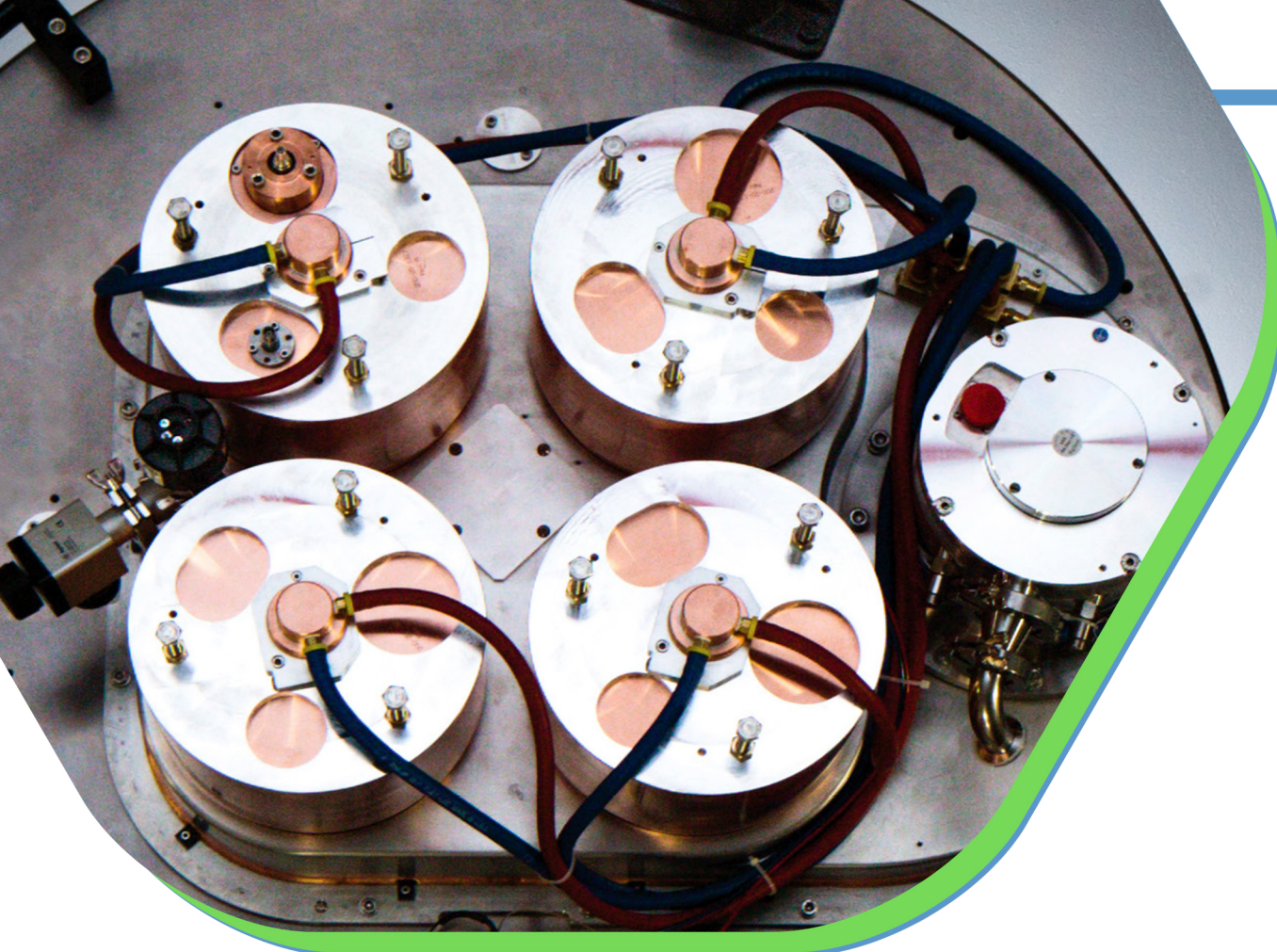
- Push button graphic interface
- Kit based chemistry
- Single or batch dose production
- Final dose delivery to syringe or vial (option)
- Automated quality control testing
- Integrated cyclotron & chemistry self-shielding
- Complete production lab in a 302m area

Economical Solution

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

- 30 m² area vs 300 m² 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 <math><1\text{ mR/hr}</math> 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 one-tenth 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 ABT BG-75 Biomarker Generator is less than one fourth that of conventional cyclotron solutions.

AUTOMATED PRODUCTION

The BG-75 Chemistry Module greatly simplifies the work-flow 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 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.

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

FACILITY REQUIREMENTS

Minimum Room Size

5.5m x 5.5m

Electrical Supply

220 - 250 VAC, 100A

Chilled Water Supply

7°C ± 3°C





ABT MOLECULAR IMAGING

BG-75 “DOSE-ON-DEMAND™” BIOMARKER GENERATOR

TECHNICAL SPECIFICATIONS

CYCLOTRON:

Low energy, positive ion radioisotope generator offers simplicity

Beam Characteristics:

Particle	Proton
Internal Beam Energy	7.5 [MeV]
Internal Beam Current	≤ 6 μA for [¹⁸ F] production (typical)

Physical Design:

Pole Diameter	748 [mm]
Beam Radius	350 [mm]
Dee System	4
Dee Operating Voltage	16 [kV] maximum
Frequency	71.6 [MHz]
Magnetic Field	1.2 Tesla average ; 1.8 Tesla hill sector

Physical Dimensions:

Cyclotron Mass	3.18 metric tons
Cyclotron Height	1.01 [m]
Cyclotron Diameter	1.25 [m]

SITE AND INSTALLATION REQUIREMENTS:

Self-shield integrated design reduces facility modification

Generator Shields:

Casing	4.7mm Carbon Steel
Gamma and Neutron Shielding	Dense Concrete and Boronated Polyethylene
Diameter	2.39 [m]
Height	1.63 [m]
Mass	19.05 metric tons

Chemistry Platform:

Dimensions	813 mm X 686 mm X 1016 mm
Mass	0.45 metric tons

Facility Requirements:

Room vertical height	2.74 m finished room height 3.05 m during rigging
Room size	5.5 m x 5.5 m minimum
Ambient air temperature & humidity	21°C ± 3°C; < 55% rel humidity
Radiation Field (at room boundary)	< 1 [mrem/hr]
(Based upon typical facility layout, typical use and stainless steel target)	

Utility Requirements:

Electrical Requirements

BG Control Cabinet:	220 – 250 VAC, 4-wire, 100A
CPM/QCM Cart:	110 – 120 VAC, 10A capacity
BG Water - Water Heat Exchanger:	220 – 240 VAC, 10A capacity

Chilled Water Requirments

Chilled Water System temperature:	7°C ± 3°C (45°F ± 5°F)
Chilled Water Supply Pressure:	275.790 KPa (40 psig)
Chilled Water Flow Rate Capability:	38 liter/min (10 gal/min)

F-18 AND FDG:

Multiple target ports and simple [¹⁸F] target design

F-18 Production:

Internal Target Ports	2 nd (2nd target port option)
Target volume	< 250 ul
Target current	≤ 6 μA (typical)
Stainless Target, [¹⁸ F] Production	> 32 [mCi] in 35 [min]
Tantalum Target, [¹⁸ F] Production	> 32 [mCi] in 25 [min] (Option)

FDG Production:

FDG PET Radiopharmaceutical dose production on-demand; Sequential cycle time specifications after first dose production

Performance Specification	Standard Config.	HiPro* Config.
Single FDG Dose Production (10-12 mCi)	<45 min	<30 min
Typical Batch FDG Dose Production (16-18 mCi)	<60 min	<45 min
Product Volume (ml)	2.0 – 3.6	2.0 – 3.6
Reagent Kit Size (# doses)	8 or 16	8 or 16

Standard configuration includes high flow Stainless Steel target, and base CPM configuration.

*HiPro Performance Options includes Tantalum target, reduced CPM cycle time, and HiPro CPM production scripts.

Batch FDG Cards are available in both the Standard and HiPro Configurations [F-18]FDG Quality Control Tests calibrated for USP or EUPh Standards

BG-75 QCM INTEGRATED TESTS:

Auto Quality Control Tests:

	USP	EUPh
Radiochemical Identity (retention time)	± 15 sec	± 15 sec
Radiochemical Purity	≥ 90%	≥ 95%
Chemical Purity (Kryptofix)	N/A	≤ 600 μg/ml
pH	4.5 – 7.5	4.5 – 8.5
Residual Solvent (MeCN)	≤ 400 ppm	≤ 400 ppm
Residual Solvent (EtOH)	≤ 5 000 ppm	≤ 5 000 ppm
Sterile Filter Integrity Test	≤ 10 psi loss	≤ 10 psi loss

Non-Automatically Conducted Quality Control Tests*:

	USP	EUPh
Radionuclidic Purity (MCA)	≥ 99.5%	≥ 99.9% (Test A) ≥ 99.9% (Test B)
Chemical Purity (Kryptofix spot test)	≤ 50 μg/ml	N/A
BET (Charles River Endosafe unit)	175 EU/dose	175 EU/dose
Radionuclidic Identity (Dose calibrator)	105 – 115 min	105 – 115 min
Sterility (Local testing lab)	Negative	Negative

* Requires conventional QC equipment and techniques

DISCLAIMER: The ABT Biomarker Generator and its component systems including targets and automated chemistry and quality control systems are delivered as laboratory equipment for the production and testing of PET radioisotopes and biomarkers. It is the exclusive responsibility of the user to comply with local and federal regulations for the production of PET radioisotopes and biomarkers and for the administration of the products made with the Biomarker Generator for human use. ABT disclaims all responsibility in this respect.

ALL SPECIFICATIONS ARE SUBJECT TO CHANGE

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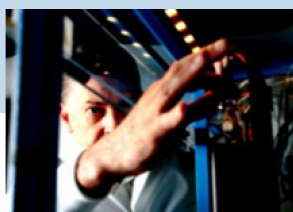




The new HiPro Performance Option includes Tantalum target, reduced CPM cycle time, and HiPro CPM production scripts, for batch FDG production.



Higher F-18 Output
New Tantalum target increases cyclotron F-18 production efficiency.



Higher [18F]FDG Output
FDG Chemistry Production Module hardware upgrade and production scripts reduce FDG synthesis time.



Batch Production
New DSC-Vial provides shielded vial delivery, facilitating batch production for multi-dose [18F]FDG dispensing.

[18F]FDG Production with HiPro Upgrade

Single dose (10-12 mCi) [18F]FDG production every 30 minutes, and batch dose (16-18 mCi) production every 45 minutes

Single dose production workflow		7:00	8:00	9:00					
Startup/Prime/Clean/SST									
Dose 1	Bombardment								
	Synthesis/QC								
Dose 2	Bombardment								
	Synthesis/QC								
Dose 3	Bombardment								
	Synthesis/QC								

Dose #	Time	Dose #	Time
1	9:00	9	13:00
2	9:30	10	13:30
3	10:00	11	14:00
4	10:30	12	14:30
5	11:00	13	15:00
6	11:30	14	16:00
7	12:00	15	16:30
8	12:30	16	17:00





ABT MOLECULAR IMAGING

BEST- ABT Molecular Imaging (“ABT”) designs, manufactures and distributes affordable, smallfootprint biomarker generators for Positron Emission Tomography (“PET”) imaging agents

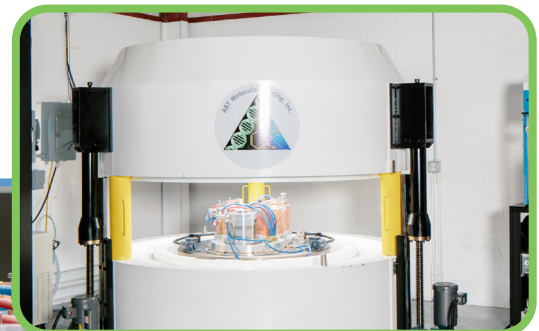
BEST - ABT MOLECULAR IMAGING OVERVIEW

- BEST - ABT is a leading privately owned company that designs, manufactures, and distributes small-footprint biomarker generator systems and related accessories for PET imaging agents.
- The Company’s BG-75 Biomarker Generator produces individual or batch doses of sterile, quality-controlled contrast material on-demand, in a prepared syringe or vial, for injection directly into a patient.
 - The BG-75 includes a self-shielded mini-cyclotron for producing the positron emitting isotope and microchemistry system for labeling specific molecules with the positron emitting isotopes with touch screen interface, and it also includes an integrated quality control system for performing common QC tests on the finished product prior to injection.
 - The BG-75 functions as a self-contained PET biomarker lab that fits in a single 35 m2 space and can be easily integrated into an existing clinical or research setting without the need for highly specialized staff.
 - The size, cost, and complexity differences between ABT’s solution and competitors’ products provide easier access to radioisotopes and enable the expansion of advanced radiochemistry research in molecular imaging.
- The Company has four major patents covering its mini-cyclotron, chemistry module, and dose synthesis card.
- BEST-ABT has sold 50 Biomarker Generators globally, including in the USA, South America, Africa, Europa and Asia.
- The Company was founded by Dr. Ron Nutt in 2006 in Knoxville, TN with the vision of universal access to PET, the gold standard of cancer imaging.



Micro-Chemistry with Automated Quality Control

Mini-Cyclotron



compact Self-shielding



Large Unmet Medical Need for PET Technology



Source: International Agency for Research on Cancer, "International Journal of Cancer"



Strictly Private & Confidential

BEST-ABT 's Advantages

- ✓ Point of Care : FDG dose available to inject in patient within 1 hour, not dispensed hours after production with conventional cyclotron bulk production
- ✓ Requires much less space than conventional cyclotron solutions, and requires no quality control lab.
- ✓ Only system to integrate automated QC, while conventional solutions require a full QC Lab and the radiochemist expertise to conduct testing.
- ✓ No additional shielding required. Even self-shielded conventional cyclotrons require additional concrete due to high radiation bulk production vs. the BG-75 “on-demand” production.
- ✓ Lower repair costs and less breakage / down time due to lower radiation, internal targets, and on-demand vs. bulk production.
- ✓ Less operating cost, and does not require advanced technical personnel to operate.

**Faster, easier,
and more cost effective
FDG Production**



Production of FDG : Conventional Cyclotron vs. BG-75 Biomarker Generator

BULK FDG PRODUCTION PROCESS

12:30AM
to 3:30AM
(3 Hours)

3:30AM
to 4:30AM
(1 Hours)

4:30AM to
5AM
(30 Minutes)

5AM to 7AM
(1-2 Hours)

**Total
6 Hours**

- Typically 2 cyclotrons are engaged to create multiple batches of FDG biomarker / tracer
- Nuclear reaction takes place in each cyclotron:
 - After 2-3 hours of irradiation, the radioactive fluorine-18 is ready to be attached to glucose
- The fluorine-18 is then fed into a reactor where the isotope is attached to a glucose (sugar) molecule to create FDG
- FDG is diluted to match specifications requested by client
- First copy of each FDG production batch is sent to quality control for conformity and analyzed by radio-chemist
- FDG is packaged automatically, or remotely with Articulated Arms (Pliers)
- FDG is prepared for shipment to client
- FDG is received by client and ready for injection (times vary based on delivery, receiving, and stocking)

REMAINING LIFE OF FDG UPON DELIVERY: 2.0 HOURS

ABT “DOSE-ON-DEMAND” PROCESS

Sur demande
(3 Doses par
heure)

- Simple one-button operation engages mini-cyclotron to create single or dual-dose of FDG.
- Nuclear reaction takes place in the cyclotron whereby fluorine-18 isotopes are created rapidly on an as-needed basis.
- Via the Company's Dose Synthesis Cards, the fluorine-18 is attached to a glucose (sugar) molecule to create FDG.
- Built-in micro-chemistry automatically completes quality control checks of the FDG.
- Automated process packages FDG into final product vial without the need of environmentally controlled rooms.
- FDG is ready on-site for injection.

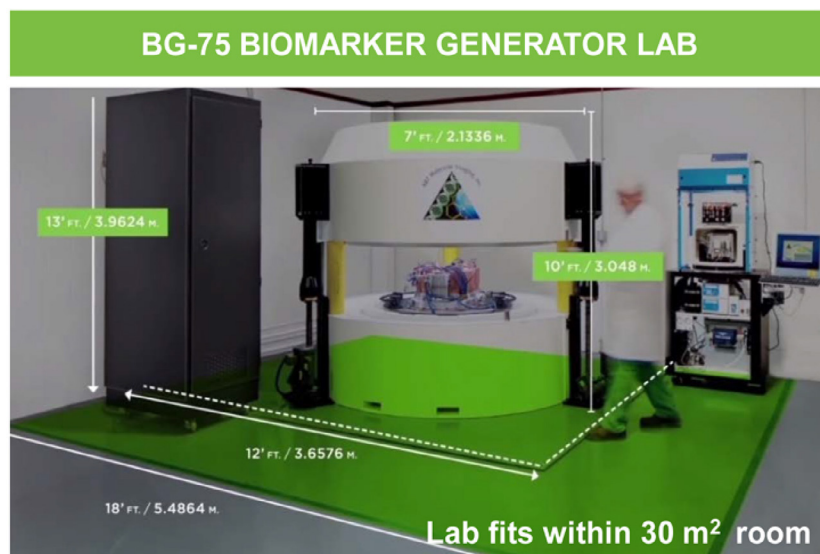
REMAINING LIFE OF FDG UPON DELIVERY: 2.0 HOURS

Note: Assumes FDG useful life is 7 hours based on data from BV Cyclotron VU. Times shown are estimates 14



ABT's Integrated Solution: "Dose-on-Demand" BG-75 Biomarker Generator

- ABT's BG-75 Biomarker Generator integrates a **radioisotope generator with kit-based micro-radiochemistry and automated quality control** to provide PET biomarkers at a user's fingertip.
 - Simple graphic user interface navigates the user through the production process while embedded production and quality control processes minimize the need for specialized staff
- The BG-75's self-shielding, small size and low power requirements allow for a simple installation with minimal facility modifications
 - A complete PET biomarker lab can fit within a 35 m² space
 - Self-shielded accelerator and chemistry produces a low radiation burden
 - Minimal modifications to a facility are needed to implement, resulting in a quick and low cost installation
- The BG-75 is scaled for a single user and is a cost effective solution to either introduce or expand the use of PET within a facility
 - Consumable reagent kits and dose synthesis cards make it well suited for dose-on-demand
 - Low infrastructure requirements dramatically reduce operating costs
- ABT's BG-75 produces the critical PET biomarker, FDG, for today's clinical needs and is easily adaptable for future radioisotopes and PET biomarkers of tomorrow
 - Single and dual-dose production of an FDG dose as fast as every 30 minutes or small batch production every hour.
 - Advanced F-18 biomarker capability including FMISO, FLT



BG-75 BIOMARKER GENERATOR COMPONENTS



BG-75 Mini-Cyclotron

• Beam Characteristics :

- **Particle:** Proton
- **Internal Beam Energy:** 7,5 MeV
- **Internal Beam Current:** <math>< 5 \mu\text{A}</math> pour la production de F-18
- **Internal Target Ports:** 3 (non-simultaneous)

• Physical Design :

- **Pole Diameter:** 74,8 mm
- **Extraction Radius:** 35 cm
- **Dee System:** 4
- **Dee Operating Voltage:** 16 kV max
- **Frequency:** 72 MHz
- **Magnetic Field:** 1,2 Tesla moy. / 1,8 Tesla max

• Physical Dimensions :

- **Magnet Mass:** 3,5 tons
- **Cyclotron Height:** 0,37 m
- **Cyclotron Diameter:** 1,25 m

• Other Key Features :

- Low power
- Simple one button operation and fast production
- Access to target and ion source for simple replacement
- Turbo pump versus oil-based diffusion pump
- Lower regulatory burden due to less radiation exposure

BG-75 BIOMARKER GENERATOR COMPONENTS



BG-75 Micro-Chemistry Unit

• Key Features :

- **Final Radioactivity Yield:** 10-13 mCi's single dose, 26-28 mCi's batch dose
- **Final Product Volume:** 2,0 ml
- **Control System:** HMI with embedded control
- **Consumables:**
 - Reagent kits, containing chemicals for radiolabeling reaction
 - Sterile, disposable, single-use Dose Synthesis Cards containing production components
- Programmable and capable of producing any one- or two-step F-18 radiochemistry process.
- Self-shielded, installed adjacent to the accelerator shield

• Quality Control

- Embedded quality control process minimizes the need for highly specialized staff
- System uses embedded methods, micro-sensors, and small-scale analytics (HPLC, radiation detector, pH meter) to perform multiple tests as required by pharmacopeia standards to qualify radiopharmaceutical for human injection
 - pH
 - Filter integrity
 - Residual volatile organics
 - Radiochemical purity
 - Radiochemical identity
 - Chemical Purity

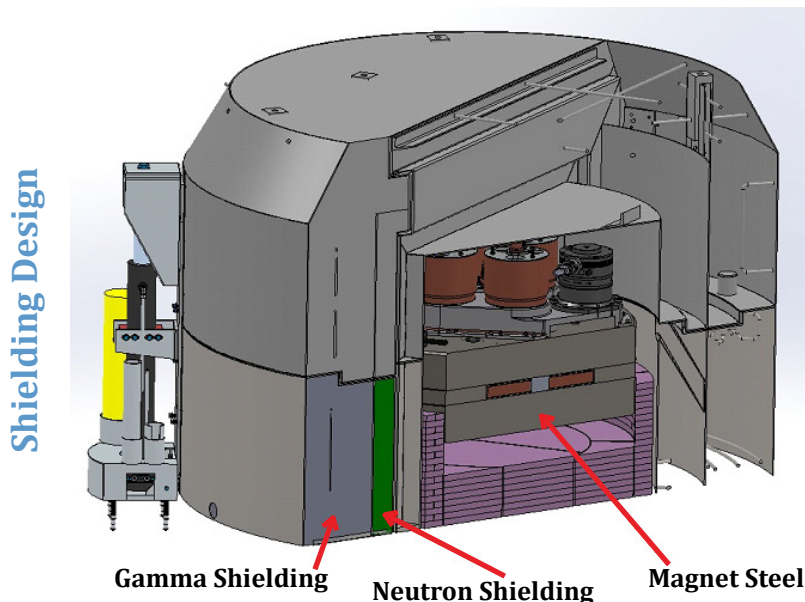
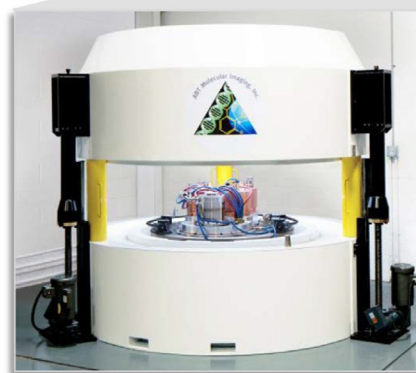
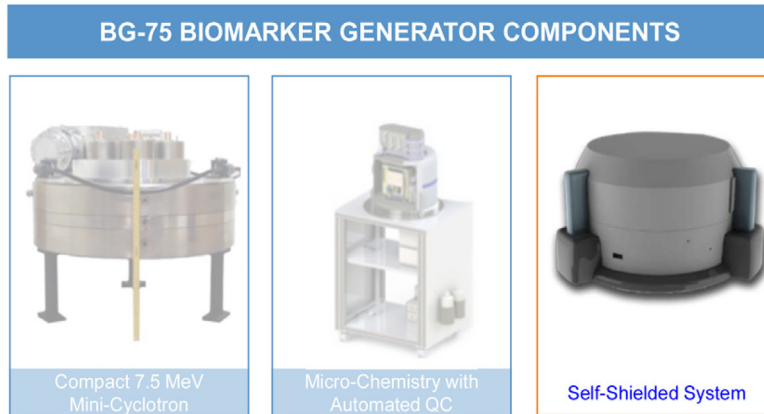
BG-75 BIOMARKER GENERATOR COMPONENTS











BG-75 Shielding

• **Key Features :**

- **Material Casing :** ¼" steel
- **Shielding Material :** Dense concrete and boronated polyethylene
- **Diameter :** 2,39 m
- **Height :** 1,63 m
- **Weight :** 21 tons
- **Radiation Field Room Boundary:** <1 mR / hour
- Self-shielding for generator and chemistry minimizes exposure, eliminates the need for additional lead enclosures, and reduces facility modifications
- Opens vertically for servicing



Conventional Cyclotron Systems vs ABT BG-75 Biomarker Generator

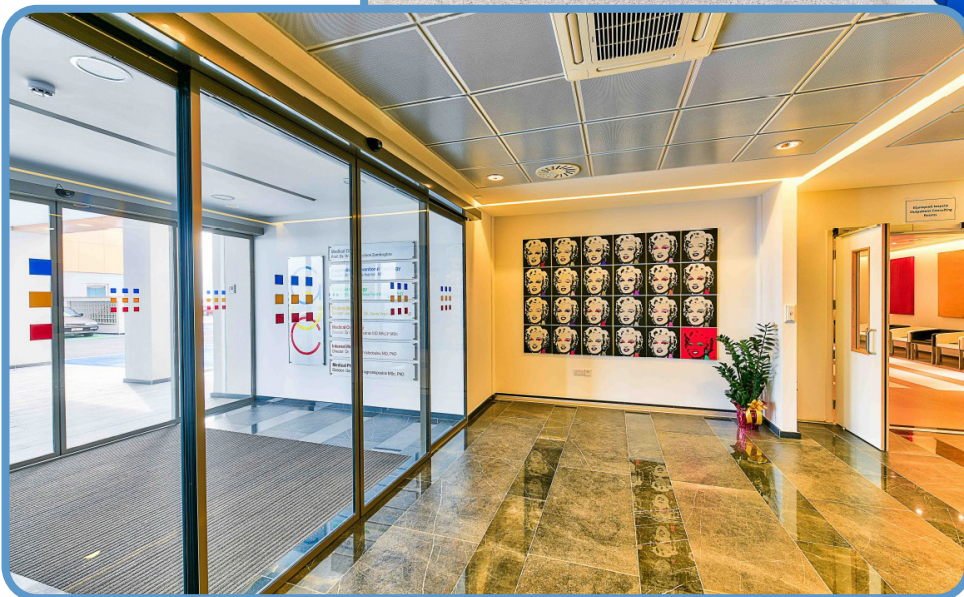
	Conventional Systems	ABT BG-75 Biomarker Generator
SPACE REQUIREMENT	<div style="border: 1px dashed black; width: 60px; height: 60px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> 200 M² </div>	<div style="border: 1px dashed black; width: 60px; height: 60px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> 30 M² </div>
PERSONNEL NEEDED	 5-7 Full-Time Employees	 1 Full-Time Employees
CAPITAL EXPENDITURE REQUIRED		
ONGOING OPERATING EXPENSE PER YEAR		
PRODUCTION CYCLE TIME		



Global Sales and Installations: Cyprus Oncology Center



Global Sales and Installations: Cyprus Oncology Center



OUR SCIENTIFIC COMMITTEE

THE MEDI-LUXTRADING/PHARMANUCLEAR SERVICES (MLT/PNS) [www.pharmanuclearservices.com] partnership and its Scientific Committee will assist in the establishment and the proper functioning of the new PET Center in your country.

The use of Nuclear Medicine, facilitated by the significant advancements of imaging equipment like PET, has become a mandatory and a crucial part of diagnostic, treatment protocols and the evaluation of their efficacy. These therapeutic decisions imply the highest quality of the examinations. Participation in clinical trials will be possible if the PET center complies with international standards.

The scientific committee consists of 7 experts, led by Professor Denis Guilloteau (Head of in vitro Nuclear Medicine Department and Director of Inserm U1253 "Imaging and Brain" (iBrain) of Tours University Hospital Bretonneau (France)) will bring their support to the following phases:

- PET center set-up: installation, compliance with radioprotection regulations and pharmaceutical standards; equipment and human resources.
- Training in the production of radiopharmaceuticals (synthesis, control, dispensing) Although ABT system is automated, the PET center personnel must be familiar with the fundamental principles such as isotopes production in a cyclotron, the synthesis, the specific biomarkers, the quality assurance and quality control system amongst others.
- Conduct of medical examinations in line with protocols
- Interpretation of images
- Relationships with requesting departments and the organisation of internal meetings



THE PACK EQUIPMENT

We offer a “blue print” project for a complete Nuclear Medicine facilities project in order to validate the technical installation and identify the team of technicians who will be involved in the department. Our team will bring the required support and provide specific training programs.

The Pack Equipment includes :

- The PET/SCAN: an absolute requirement
- The Mini cyclotron: the essential complement to the PET/SCAN
- Additional Laboratory Equipment for routine operation and maintenance of the BG-75 System and PET/SCAN
- Additional Planning Equipment for PET/SCAN and BG-75 System

Space required :

- For the diagnostic part: +-100m2 for the PET/SCAN and 60 m2 the mini cyclotron
- For the radiotherapy part (in option): 204 m2 (in a bunker) The PET center will be the center of excellence for a national and international visibility offering to patients the best diagnostic and therapeutic protocols.



THE MAINTENANCE

You access a new generation of customized services bundle

- Specially designed to attend your needs
- Managed through our own network

A MAINTENANCE TECHNICIAN ON SITE

We will build close relationships and help you to achieve your performance objectives:

- On-site dedicated maintenance technician
- Quick remote access to our MLT/PNS experts
- Fast responses associated with an on-site intervention plan
- Proactive maintenance and getting an optimal performance level
- Enjoying privileged assistance and guaranteed upgrades
- Online clinical training

A TOTAL AVAILABILITY TO HELP MANAGE YOUR EQUIPMENT

The objective is to maximize your productivity and return on your investment through :

- Optimal warranty for you equipment
- Fast responses associated with an on-site intervention plan
- Proactive monitoring and maintenance program
- Priority services

FULL COVERAGE

We respect you budget with high quality assistance and cost-effectiveness with:

- A reliable assistance and short response time
- A guaranteed on-site fast intervention time
- A timely intervention planning notification
- A privileged access to MLT/PNS experts



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W W W . P N S M L T . C O M

