

Gammacell[®] 1000 Elite / 3000 Elan
Superior Performance and Unparalleled Dose Uniformity

T-A Graft-Versus-Host Disease

Transfusion-Associated GVHD has become a major concern in current transfusion practices for immuno-deficient and immuno-suppressed patients because of the associated high mortality rate. Immuno-suppressive therapies have not proven effective for TA-GVHD. Virtually all cellular blood components have been implicated in reported cases of the disease. The syndrome develops after transfusion of whole blood, red blood cells, platelets, non-frozen plasma and leukocytes, harvested from both normal donors and donors with chronic myelocytic leukemia.

Since patient treatment of TA-GVHD is almost always ineffective, management must focus on prevention by minimizing the risk of developing the condition. Prevention has centered on reducing or inactivating transfused donor lymphocytes. The methods presently available in blood banks to physically remove T lymphocytes through washing or filtration do not provide effective prophylaxis against TA-GVHD. Inactivation of transfused lymphocytes with the use of gamma irradiation of blood components remains the most effective method for inhibiting lymphocyte blast transformation and mitotic activity. Current medical practice and the AABB recommend using irradiated blood for immuno-incompetent or immuno-compromised patients.

Adapted from Transfusion Medicine Topic Update, August 1996, Yale University School of Medicine, University of Connecticut School of Medicine

Gammacell® 1000 Elite/3000 Elan Features

Safety & Security

- Safe to use in any conventional hospital, clinic or laboratory environment (check local requirements)
- Built-in security restricts access to the programming function with passwords and key lock
- Barcode reader can scan ISBT-128, ABC Codabar and other blood labelling to record the unit number, product code, blood type, collection, expiry dates, and irradiation verification indicators
- Bypass mode allows for operation of the unit without the main control system
- In the event of a power failure, the battery back-up ensures the cycle underway is completed, and then can power approximately 20 additional cycles

Quality & Design

- Quality is assured through the advanced monitoring and control system, which tracks the irradiation process, thereby confirming the canister rotation, irradiation time and product position
- Modular design of control system allows for easy maintenance and future upgrades
- Four-line, vacuum-fluorescent, menu-driven display screen with step-by-step instructions makes it easy to operate
- Ergonomically designed to easily load and unload the blood bags
- Optional components for research are available (test tube & rodent holders)

Record Keeping

- A complete record of the irradiation cycle is generated when connected to a printer or computer
- Ethernet (web browser) access and LIMS interface provide digital traceability options for irradiated product data

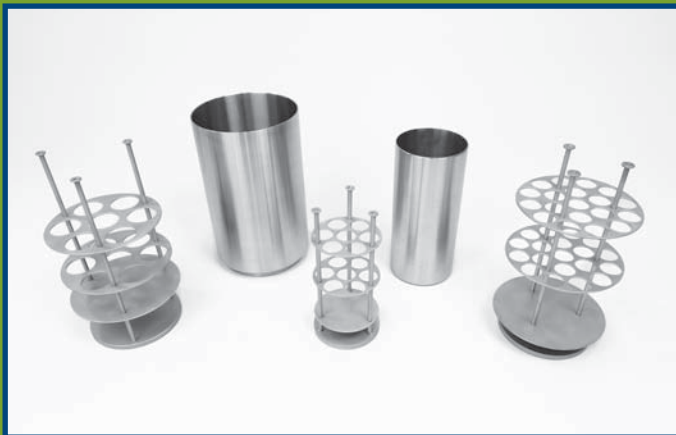
Technical Specifications

	Gammacell® 1000 Elite	Gammacell® 3000 Elan
Source Details		
Type (special form)	Caesium¹³⁷	Caesium¹³⁷
Position	Fixed Source(s)/Turning Canister	Fixed Source(s)/Turning Canister
Model & Typical Source Activity*	Model A = 575 Ci (21.3 TBq) Model I = 1300 Ci (48.1 TBq) Model II = 2600 Ci (96.2 TBq)	n/a Model I = 1300 Ci (48.1 TBq) Model II = 2600 Ci (96.2 TBq)
External Dose Rate	≤ 10 µSv/h (1 mrem/h) at 5 cm (1.94 in) from front	≤ 5 µSv/h (0.5 mrem/h) at 5 cm (1.94 in) from front
Dosimetry Measurements		
Canister Volume	0.824 L (0.22 US gal)	2.34 L (0.62 US gal)
Bags (300 ml) Per Canister Volume	1	4
Dose Uniformity (min/CEN/max)	21-25-29 Gy (1.4 : 1)	19-25-33 Gy (1.7 : 1)
Central Dose Rate (by model)	3.5, 7.6 or 14.3 Gy/min (± 20%)	4.5 or 8.7 Gy/min (± 20%)
Time for 25 Gy Central	7.1, 3.3 or 1.7 min	5.6 or 2.9 min
Dose Uniformity (MIN/cen/max)	25-30-35 Gy (1.4 : 1)	25-33-43.5 Gy (1.7 : 1)
Time for 25 Gy Minimum	8.6, 3.9 or 2.1 min	7.4 or 3.8 min
Unit Measurements		
Height	1550 mm (61 in)	1550 mm (61 in)
Width	800 mm (31.5 in)	800 mm (31.5 in)
Depth (with shelf)	980 mm (38.5 in)	980 mm (38.5 in)
Weight	1150 kg (2535 lbs)	1479 kg (3260 lbs)
Floor Loading	1467 kg/m ² (301 lbs/sq ft)	1886 kg/m ² (388 lbs/sq ft)
Floor Loading Area	0.78 m ² (8.4 sq ft)	0.78 m ² (8.4 sq ft)
Canister Diameter (internal)	80 mm (3.1 in)	124 mm (4.9 in)
Canister Height (internal)	164 mm (6.5 in)	194 mm (7.7 in)
Other Requirements		
Single-phase Power (outlet)	100 V, 50 or 60 Hz , 300 VA (with ground) 115 V, 60 Hz, 300 VA (with ground) 230 V, 50 Hz, 300 VA (with ground)	100 V, 50 or 60 Hz , 300 VA (with ground) 115 V, 60 Hz, 300 VA (with ground) 230 V, 50 Hz, 300 VA (with ground)
Room Dimensions	2.13 m (w) x 1.83 m (d) x 2.44 m (h) 7 ft (w) x 6 ft (d) x 8 ft (h)	2.13 m (w) x 1.83 m (d) x 2.44 m (h) 7 ft (w) x 6 ft (d) x 8 ft (h)

*Source activity may be +/-20% of typical activity. Other source activities are available upon request.

Accessories & Requirements

Research Accessories



Test Tube Holders GC 1000/3000



Rodent Holders GC 1000/3000

Quality & Safety Standards

All units are manufactured in accordance with US FDA Good Manufacturing Practices. Best® Theratronics is certified to ISO 9001, ISO 13485 & the European Medical Device Directive (CE Mark).

Certification & Documentation

Each Caesium-137 source meets the IAEA requirements for Special Form Radioactive material and is certified to be leak tight. A complete documentation package, including a unit specific dose map and a measurement certificate of activity with central dose rate, accompanies every Gammacell® 1000 & 3000.

Customer Requirements

Customers need to obtain a radioactive materials possession license (or equivalent) and an import

license (if needed) before the Gammacell® 1000 & 3000 can be shipped. Best® Theratronics helps prepare license submission documents required for radioactive materials possession. When applying for a license, customers should quote the maximum activity of 708 Ci.

Shipping

The Gammacell® 1000 & 3000 are shipped in two parts:

- The radiation shield and radiation sources are sent together as a Radioactive Materials (RAM) transport package, which meets international transportation and safety regulations
- The second package contains the cabinet, control system and related parts

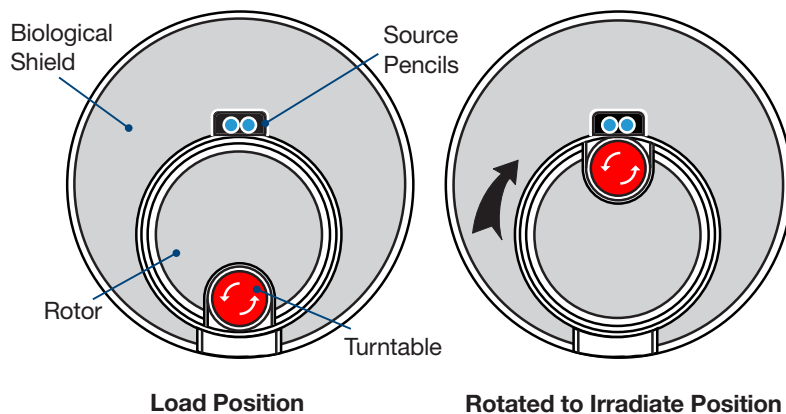
Blood Irradiation Guidelines

US FDA (2000)	EDQM Council of Europe (2010)	UK BCSH (2010)
15 Gy minimum	25 Gy minimum	25 Gy minimum
25 Gy central	50 Gy maximum	50 Gy maximum
50 Gy maximum		

Superior Performance and Unparalleled Dose Uniformity

Overhead view of Gammacell® 1000/3000

Fully shielded in either the load or irradiate position.



Typical Dose Uniformity

Exceptional dose uniformity is critical to ensuring a tight dose delivery to the product. These diagrams illustrate the high dose uniformity delivered by the Gammacell® 1000 Elite when 25 Gy and 30 Gy are targeted to the centre of the canister. The Gammacell® 3000 Elan delivers similarly exceptional dose uniformity.

Side view of Gammacell® 3000 Elan

Overlapping source configuration improves dose uniformity.

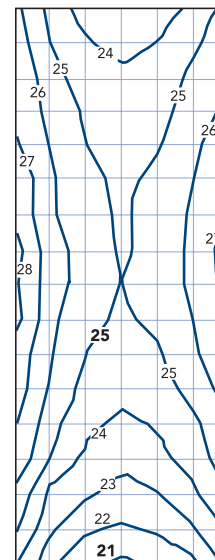
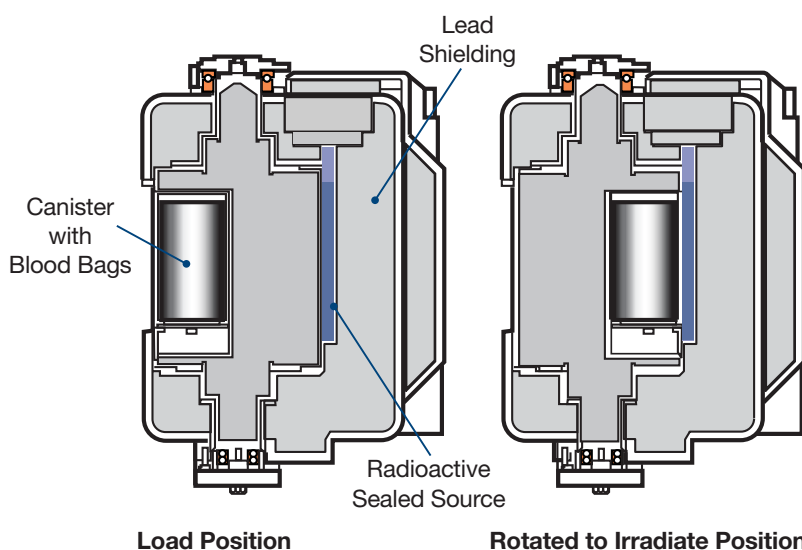


Figure 1: GC 1000 25 Gy targeted to centre of canister

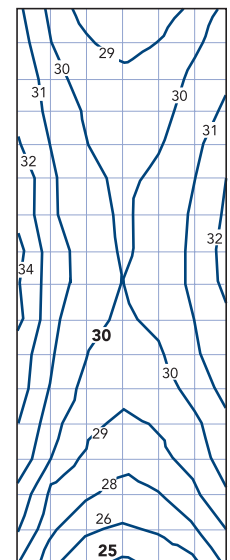


Figure 2: GC 1000 30 Gy targeted to centre of canister

Healthcare For Everyone

Best® Theratronics' products and services are used throughout the world to prevent, diagnose and treat disease. Our applied research and innovation play an integral part in improving global healthcare.

"Our TeamBest® companies are committed to making quality healthcare affordable and accessible globally."

Krishnan Suthanthiran
President, Best Medical International

Best® Theratronics Ltd. is a member of TeamBest®
– a family of Best® Medical companies.

From brachytherapy seeds and equipment, dosimetry kits, phantoms, treatment planning systems, an array of medical/health physics equipment, and product remanufacturing/servicing, to radioactive sources, gamma teletherapy machines, cyclotron systems, and particle therapy treatment, TeamBest® has it all!

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