

SCHERING



Diagnostics and
Radiopharmaceuticals



Blood irradiation

IBL 437 C

**Irradiator for blood products
and biological samples**

SCHERING
CIS bio international



INTRODUCTION

The IBL 437 C is a self-shielded irradiator containing up to 189 TBq (5100 curies) of cesium 137.

Radiation levels at surface are below 2.5 $\mu\text{Sv/h}$ (2.5mR/h), in compliance with the relevant international Regulations.

The samples are loaded into a 3.8 liters (one american Gallon) canister and installed into the unit.

Proximity sensors check the closing of the door and the positioning of the canister.

The irradiation time is set in seconds through a digital timer. The time sequence begins when the sample reaches the irradiation position.

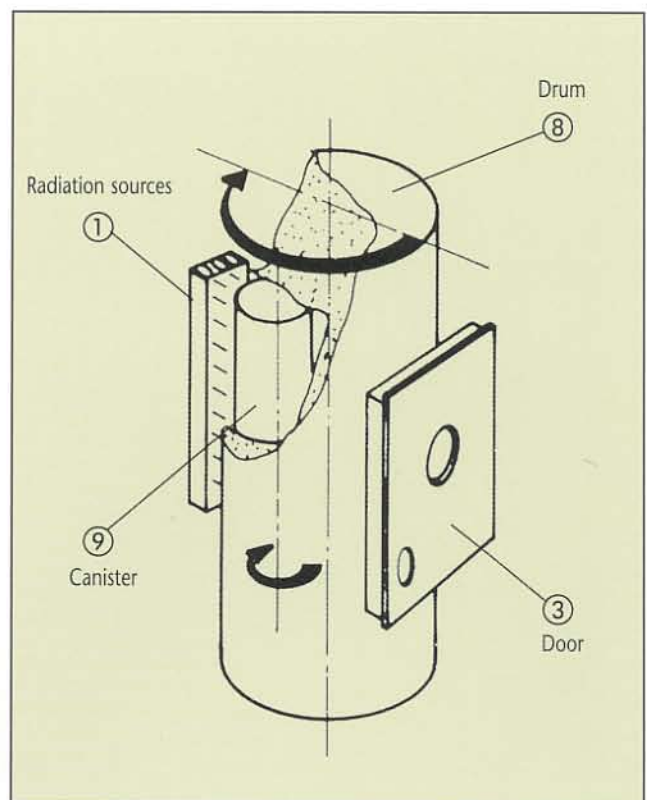
When the IBL 437 C is activated from the control panel, the drum rotates on 180° for exposure to radiation sources. Simultaneously the sample canister begins its rotation at 18 rpm to provide a homogeneous dose to the samples.



1. Radiation sources - 2. Manufacturer's label - 3. Door of the irradiation chamber - 4. Window - 5. Removable panels - 6. Control panel - 7. Emergency switch - 8. Drum - 9. Canister.

STANDARD CONFIGURATION

As a standard, the IBL 437 C is loaded with one Cesium source (63 TBq/1700 Ci).



APPLICATIONS

IRRADIATION OF BLOOD PRODUCTS

The large capacity canister handles any combination of whole blood, packed red cells, platelets, pooled cells, satellite packs or pediatric bags in the following packaging (frozen or not):

- Standard single donor platelet bags.
- Standard packed cells bags.
- Whole blood bags.
- Preloaded syringes.

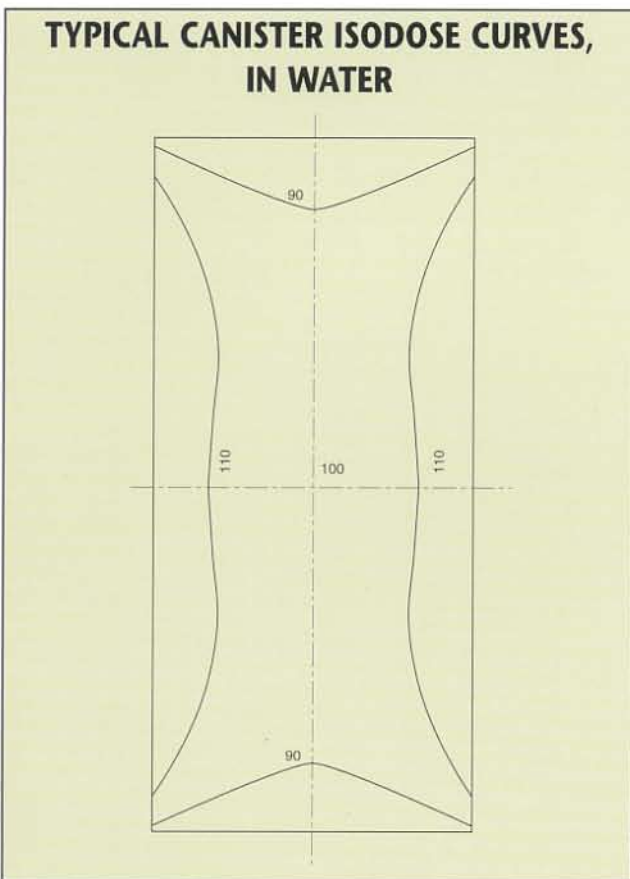
The irradiation of blood products is an easy and safe method to inhibit lymphocyte division and eliminate the risk of post transfusion Graft Versus Host Disease.

OTHER IRRADIATIONS

- Malignant cells.
- Small laboratory animals.
- Transplant organs (skin tissues, bone fragments,...)
- Viruses

RADIATION UNIFORMITY

The canister rotation ensures a dose homogeneity to the sample. The approximate dose rate distribution in the irradiation canister rotating at 18 rpm is shown on the isodose curve.



FEATURES

SPECIFICATIONS

• Dimensions:

Width	670 mm (26.4 in)
Length	650 mm (25.6 in)
Height	1500 mm (59.1 in)

Unit weight 2150 kg (4700 lbs)

• Electrical specifications:

100-240 V
50-60 Hz
Max power : 180 VA

• Radiation:

Source: Cesium-137 sources
Double encapsulated stainless steel
ANSI/ISO 2919/E 63446 ic
(corrosion and fire tested)

IBL 437 can be delivered with 1, 2 or 3 sources for a maximal nominal central dose rate of 9 Gy (900 RAD) \pm 10% per minute in water.

• Revolving drum:

The time required to place the sample or samples in irradiation position is 6 seconds. The rotation is provided by a 24 volts DC motor (power: 55 watt).

• Irradiation chamber:

The dimensions of the sample canister are:
Diameter 130 mm (5.1 in)
Height 290 mm (11.4 in)
Volume 3.8 liters

• Rotation speed of the canister: 18 rpm.

IBL 437 C is Class II B medical device,
CE marked according to 93/42/CEE
directive : CE 0459

FEATURES

OPERATION AND SAFETY CONTROLS

A door interlock security switch.

A back-up battery driving back the sample canister to loading position in the event of main power supply failure.

Proximity sensors verifying that the door is closed.

An emergency shut-off switch.

A crank is provided for emergency operation.

- The IBL 437 C is monitored by an electronic controller.
- Count down time begins when the canister has reached the irradiation position and it cannot be changed during irradiation. Maximum irradiation time is 999999 seconds.
- The IBL cannot be activated without canister into the irradiation chamber (Sensor control).
- The rotating speed and canister position are permanently monitored.

RADIATION SHIELDING

The radiation levels are less than $25 \mu\text{ Sv/h}$ (2.5 mR/h) at the surface of the unit loaded with 189 TBq (5100 curies).

A report of Radioprotection and a calibration certificate are provided with each unit.

QUALITY ASSURANCE REQUIREMENTS

A dedicated software, named DoseWriter[®] can be supplied as a Computerized Data Management System.

Its specifications are:

Security (access restricted by personal ID and password).

Barcode Data Entry (Blood unit number, Product code, Blood type, ...).

Storage of data.

Report Forms (individual report per blood bag, per operator, ...).

Automatic Calculation (Cs137 decay, cycle time, canister rotation, ...).

SCHERING

CIS bio international



B.P.32 - 91192 GIF-SUR-YVETTE CEDEX / FRANCE

Tel.: +33 1 69 85 73 67 (network)

Tel.: +33 1 69 85 70 15 (marketing)

Fax: +33 1 69 85 75 16

http: //www.cisbiointernational.fr

Subsidiaries:

SCHERING Wien Ges.m.b.H.
Scheringgasse 2
A-1147 Wien - AUSTRIA
Tel. +43 1 97 307 320 - Fax +43 1 97 307 161

N.V. SCHERING S.A.
J.E. Mommaertsloan 14
B-1831 Diegem (Machelen) - BELGIUM
Tel. (2) 712 85 00 - Fax (2) 712 85 10

SCHERING Nederland B.V.
Van Houten Industriepark 1
Postbus 116
1380 AC Weesp - THE NETHERLANDS
Tel. (294) 462424 - Fax (294) 462451

SCHERING S.p.A.
Via E. Schering, 21
20090 Segrate (MI) - ITALY
Tel. 39 (0) 22165-252 - Fax 39 (0) 221 65 806

SCHERING Health Care Ltd
The Brow, Burgess Hill
West Sussex RH15 9NE - GREAT BRITAIN
Tel. (1) 444 23 23 23
Fax (1) 444 24 66 13

INSTALLATION

SHIPMENT

The irradiator is shipped in B (U) type returnable container (U.S. DOT licensed).

INSTALLATION REQUIREMENTS

The installation is performed by an authorized (and licensed) CIS bio international engineer.

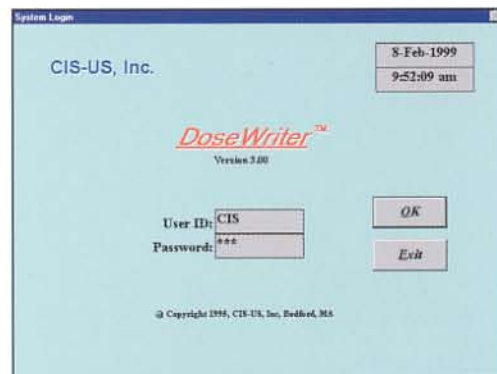
Recommended area 2.5 meters x 2.5 meters.

Loading plan: 5.2 T/m².

Repartition plates can be supplied as an option.

CUSTOMER SERVICES

Preventive maintenance, as well as control of irradiation dosimetry (Mapping) can be provided by our customer service.



Some examples of some DoseWriter[®] screens.

SCHERING Deutschland GmbH
GE Diagnostika und Radiopharmaka
Max-Dohm Strasse 10
D-10589 Berlin - GERMANY
Tel. (30) 349 89 239 - Fax (30) 349 89 429

SCHERING España SA
Division Medicina Nuclear
C/Méndez Alvaro, 55
Madrid 28045 - SPAIN
Tel. (91) 506 93 50 - Fax (91) 467 95 25

SCHERING Lusitana, Lda
Apartado 16
2726 901 Mem Martins - PORTUGAL
Tel. (21) 926 99 00 - Fax (21) 921 84 71

SCHERING OY
Eerikinkatu 24
FIN - 00100 Helsinki - FINLAND
Tel. 96 850 440 - Fax 96 852 822

CIS DIAGNOSTIKI S.A.
9, Constantin Paleologou Str.
152 32 Halandri - Athens - GREECE
Tel. (1) 68 45 903 - Fax (1) 68 34 323

CIS US Inc
10, De Angelo Drive
Bedford, 01730 Massachusetts, USA
Tel. (781) 275 7120 - Fax (781) 275 5191

NIHON SCHERING K.K.
6-64, Nishimiyahara 2 - Chome
Yodogawaku, Osaka - JAPAN
Tel. +81 6 6396 2593 - Fax +81 6 6398 2040

SCHERING (Schweiz) AG
Blegistrasse 5 - Postfach
6341 Baar - SWITZERLAND
Tel. (041) 766 60 60 - Fax (041) 766 60 19