

Information Disclaimer

Abstract Information disclaimer for Eclipse Beam data.

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Notice

This information provides information concerning the use of Eclipse Beam data. For complete information concerning components, safety instructions, installation, maintenance, troubleshooting, etc., refer to the applicable Varian product Instructions For Use and Reference Guides.

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

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FDA 21 CFR 820 Quality System Regulation

(cGMPs)

Varian Medical Systems, Oncology Systems products are designed and manufactured in accordance with the requirements specified within this federal regulation.

ISO 13485

Varian Medical Systems, Oncology Systems products are designed and manufactured in accordance with the requirements specified within the ISO 13485 quality standard.

CE

Varian Medical Systems, Oncology Systems products meet the requirements of Council Directive MDD 93/42/EEC.

IEC62083

Eclipse™ Treatment Planning System is IEC62083:2009 compliant.

EU REACH SVHC Disclosure

The link to the current EU REACH SVHC disclosure statement is:

http://www.varian.com/us/corporate/legal/reach.html

HIPAA

Varian's products and services are specifically designed to include features that help our customers comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The software application uses a secure login process, requiring a user name and password that supports role-based access. Users are assigned to groups, each with certain access rights, which may include the ability to edit and add data or may limit access to data. When a user adds or modifies data within the database, a record is made that includes which data were changed, the user ID, and the date and time the changes were made. This establishes an audit trail that can be examined by authorized system administrators.

WHO

ICD-O codes and terms used by permission of WHO, from:

 International Classification of Diseases and for Oncology (ICD-O), 3rd edition, Geneva, World Health Organization, 2000.

ICD-10 codes and terms used by permission of WHO, from:

 International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10). Vols 1–3, Geneva, World Health Organization, 1992.





Electronic labeling

This symbol on the label indicates that the Instructions for Use for the corresponding product are available at www.MyVarian.com. Access the Instructions for Use in electronic form by logging in with your assigned MyVarian user credentials.

On request, Varian will send you a free printed copy of the Instructions for Use within 7 days. Use the "Paper Document Request" form provided on the Varian webpage to order your copy.

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