VARIAN
medical systems

Wireless Compliance Statements

Visual Coaching Device

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Document ID	P1015323-001-A
Document Title	*Wireless Compliance Statements–Visual Coaching Device*
Abstract	This document provides wireless compliance statements for the Visual Coaching Device (VCD) as used for the following product: ■ Respiratory Gating for Scanners 1.1 (or higher) This publication is the English-language original.
Manufacturer	Varian Medical Systems, Inc. 3100 Hansen Way Palo Alto, CA 94304-1038 United States of America
European Authorized Representative	Varian Medical Systems UK Ltd. Oncology House Gatwick Road, Crawley West Sussex RH10 9RG United Kingdom

FDA 21 CFR 820 Quality System Regulations (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.
EU REACH SVHC Disclosure	The link to the current EU REACH SVHC disclosure statement can be found at 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 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.

In compliance with EU Commission Directive No 207/2012, Varian will send EU customers 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.

CAUTION: US Federal law restricts this device to sale by or on the order of a physician.

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Chapter 1 USA

FCC

FCC 15.105

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC 15.19

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference; and
2. This device must accept any interference received, including interference that may cause undesired operation of the device.

FCC 15.21

NOTICE: Changes or modifications made to this equipment not expressly approved by Varian Medical Systems may void the FCC authorization to operate this equipment.

FCC 2.1091, FCC 2.1093, FCC OET Bulletin 65

For body worn operation, this device has been tested and meets FCC RF exposure guidelines when used in close proximity to the human body.

Chapter 2 Canada

RSS-Gen / CNR-Gen

RSS-Gen 8.4

This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:

1. This device may not cause harmful interference; and
2. This device must accept any interference received, including interference that may cause undesired operation of the device.

CNR-Gen 8.4

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. l'appareil ne doit pas produire de brouillage;
2. l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Chapter 3 Japan

Japanese Radio Law and Japanese Telecommunications Business Law Compliance

This device is granted pursuant to the Japanese Radio Law (電波法) and the Japanese Telecommunications Business Law (電気通信事業法). This device should not be modified (otherwise the granted designation number will become invalid).

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