



## 1. DEVICE/EQUIPMENT:

FocalSim radiotherapy treatment planning software manufactured by Computerized Medical Systems Inc.  
FocalSim software versions 4.3.1 to 4.34.02 inclusive.

## 2. PROBLEM:

Computerized Medical Systems (CMS) Inc. has identified an error in the FocalSim software which can result in an incorrect radiotherapy dose being given to a patient. FocalSim software is an accessory to the CMS XiO radiotherapy treatment planning system software. FocalSim runs on a desktop PC.

This event can occur when a plan is imported into FocalSim via DICOM and then transferred into the XiO treatment planning software for dose calculation.

Any radiotherapy beams added in FocalSim or copied (in FocalSim or XiO) from beams contained in the FocalSim plan will also have the potential for incorrect dose calculations.

The problem is detectable by reviewing the weight of the beam in the source index or weight page, as compared to the displayed dose for that beam at the weight point.

CMS Inc. has provided guidance to users to ensure that this error does not occur prior to the intended software upgrade. The manufacturer has confirmed that beams imported into FocalSim via DICOM cannot be used for dose calculations or to create templates. If a plan is imported into FocalSim via DICOM, a marker point should be added to indicate the isocentre and a new plan created in FocalSim with the isocentre aligned to this marker.

Alternatively, a treatment plan can be imported directly into XiO.

CMS Inc. has developed a software update (FocalSim version 4.4.0) which will rectify this issue. This software is currently available to users.

## 3. ACTION BY:

All involved in the use of the FocalSim planning software, including medical physicists, planning radiographers and dosimetrists.

## 4. ACTION:

- Contact the manufacturer's representative to arrange for the software upgrade.
- In the interim, follow the manufacturer's guidance given in their customer advisory notice. See Problem above.

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- EBME departments
- Health and safety managers
- Medical directors
- Medical physics departments
- Radiation oncology departments
- Radiation oncologists
- Radiographer superintendents
- Radiographers
- Risk managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Paul Shane Bennetts  
Medical Devices Group  
Marlborough House  
Riding Street  
Southport PR8 1EW

Tel: 01704 544 944

Fax: 01704 544 050

E-mail: [Paul.Bennetts@ecmedica.com](mailto:Paul.Bennetts@ecmedica.com)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/046 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

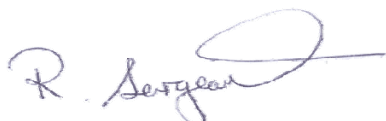
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

**Acknowledge Receipt of Alert:**  
20<sup>th</sup> June 2008

**Action Under Way:**  
30<sup>th</sup> June 2008

**Action Complete:**  
9<sup>th</sup> July 2008



Robert Sergeant  
NIAIC Operational Manager

#### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*