VIGTIG KORREKTION AF MEDICINSK UDSTYR
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Emne:	Forkerte udlæsningsværdier for position som følge af kraftig konnektormodstand
Det berørte produkts handelsnavn:	C-Series Clinac eller Trilogy, version 7.x og 8.x
Reference / FSCA-identifikator:	**CP-06611**
Meddelelsesdato:	***2012-01-24***
Type af handling:	Kun meddelelse
Oplysninger om berørt udstyr:	Se bilag

Beskrivelse af problemet:

Dette brev har til formål at orientere dig om en hændelse, der er indberettet til Varian angående en C-Series Clinac®-accelerator. Hændelsen indebærer kraftig konnektormodstand, som bevirkede, at de faktiske kæbepositioner ikke svarede til de tilsigtede kæbepositioner, men operatøren fik ikke vist en advarsel om dette. Denne uoverensstemmelse blev konstateret under den daglige kvalitetssikringstest og lysfeltbekræftelse om morgenen. Varian har ikke fået indberetninger om fejladministration som følge af denne uoverensstemmelse. En undersøgelse afslørede, at et lignende problem kunne opstå på gantry- eller behandlingsbordsakserne. Dette påvirker ikke MLC. Denne meddelelse indeholder relevante oplysninger om, hvad du kan gøre for at undgå eller mindske dette problem.

Detaljer:

Kraftig konnektormodstand i de kabler, som leverer referencespændinger til potentiometrene, kan forårsage en uoverensstemmelse mellem de faktiske fysiske positioner i forhold til de tilsvarende positionsudlæsninger, hvilket fører til en forkert indstilling såsom behandlingsfeltstørrelse. Spændingen monitoreres ved strømforsyningen, men ikke ved potentiometrene. Et målbart spændingsdyk kan resultere i en situation, hvor den faktiske position muligvis er forskellig fra den tilsigtede position, i begge retninger.

Kablerne, som transporterer +/- spændingsreferencesignalerne, anvendes som både primære og sekundære positionsudlæsningsindikatorer. Derfor vil en modstandsændring i konnektoren resultere i samme offset i begge udlæsninger. En modstandsændring, som opstod, mens maskinen var i tilstanden Ready (Klar) eller Beam On (Stråle til), ville udløse en interlock-afbrydende behandling.

Selvom det er meget usandsynligt, at uoverensstemmelsen ikke ville blive opdaget ved rutinemæssige kvalitetssikringskontroller og anbefale brug af lysfeltet, hvis for eksempel en kæbepositionsfejl gik ubemærket hen, ville den effektive feltstørrelse være større eller mindre end beregnet. Behandlinger, hvor feltet er fuldt formet af en tertiær kollimator, ville begrænse effekten af små fejl i kæbepositioner. Dette omfatter felter, der er formet af en MLC, (herunder Dynamic MLC og RapidArc), SRS-behandlinger ved brug af en konisk kollimator og elektronbehandlinger ved brug af en elektronkegle. Ubemærkede væsentlige fejl i kæbepositioner ville dog resultere i alvorlige kvæstelser, uanset hvilken tertiær kollimationsmetode der blev anvendt.

Kvalitetssikringsforanstaltninger og standardbrug af lysfeltet kan identificere problemet. Det er bydende nødvendigt, at begge følges rutinemæssigt. En daglig konsistenskontrol af kvalitetskontrollen ved hjælp af lysfeltet og mekaniske skalaer kan bestemme eventuelle forskelle i den forventede og den faktiske feltstørrelse, kollimator, gantry eller lejerotation og lejeposition. Lysfeltet giver også kontrol af feltstørrelsen, feltformen og matchlinjen og bør bruges for hvert eneste felt. Kvalitetssikring om morgenen bør omfatte kontroller af kollimatorstørrelsesindikatoren i henhold til de af AAPM anbefalede daglige kvalitetssikringsprocedurer. En lysfeltkontrol og kontrol af mekanisk skala ville identificere eventuelle udlæsningsafvigelser.

Anbefalet brugerhandling
Alle afdelinger bør etablere et omfattende kvalitetssikringsprogram. Følgende er henvisninger til sådanne programmer:

1. *"AAPM code of practice for radiotherapy accelerators: Report of AAPM Radiation Therapy Committee Task Group."* Medical Physics, Vol. 21, No. 7, July 1994
2. *"Comprehensive Quality Assurance for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group,"* Medical Physics, Vol. 21, No. 4, April 1994

Før dagens behandlinger påbegyndes, skal der udføres kvalitetssikringstest. AAPM Task Group 142 anbefaler, at der udføres en kontrol af indikatoren for kollimatorstørrelse dagligt for alle behandlingstyper.[1]

Derudover bør alle uoverensstemmelser i billedfeltstørrelse i forhold til planlagt feltstørrelse indberettes til den medicinske fysiker med henblik på en undersøgelse, før behandling fortsættes.

Varian-handlinger:

Varian underretter alle eventuelt berørte kunder via dette brev.

Varian overvejer løbende mulige tekniske løsninger på dette problem.

Underret venligst det relevante personale, der arbejder på den pågældende stråleterapiafdeling, om dette brevs indhold. For fremtidig reference lægger vi dette dokument på Varians kundeservice-website: http://www.MyVarian.com.

Særlige instruktioner for kunder uden for USA og Canada: For at imødegå de lovmæssige krav beder vi dig venligst udfylde den vedhæftede meddelelsesattest eller det vedhæftede kvitteringsmodtagelseskort, så snart du har læst dette dokument, og returnere den/det til Varian Medical Systems.

Vi beklager ulejligheden og takker på forhånd for dit samarbejde. Hvis du har brug for yderligere oplysninger, er du velkommen til at kontakte den lokale Varian kundeserviceansvarlige.

[1] Klein *et al.*: *"QA of Medical Accelerator*: *Report of Task Group"*, Medical Physics, Vol.36, No. 9. september 2009,

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Undertegnede bekræfter hermed, at denne meddelelse er givet til den relevante kontrollerende myndighed.

24-Jan-2012

Peter J. Coronado,
Acting Director, Global Regulatory Affairs
on behalf of
Mika Miettinen,
Director, Global Quality Assurance and Product Reliability

Dato

Kontaktoplysninger for Varian Oncology Helpdesk

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Internet:	Oncology Systems kundewebsted - www.myvarian.com Varian Medical Systems offentligt websted - www.varian.com

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APPENDIKS
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VIGTIG KORREKTION AF MEDICINSK UDSTYR
VIGTIG SIKKERHEDSRELATERET MEDDELELSE

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H294457	H294519	H294588	H294651	H294714	H294779	H294843	H294908	H294977	H295041	H295110	H295182	H295299
H294458	H294520	H294589	H294652	H294715	H294780	H294844	H294910	H294978	H295042	H295111	H295183	H295300
H294459	H294521	H294590	H294653	H294716	H294781	H294845	H294911	H294979	H295043	H295112	H295184	H295301
H294460	H294522	H294591	H294654	H294717	H294782	H294846	H294912	H294980	H295044	H295114	H295185	
H294461	H294523	H294592	H294655	H294718	H294783	H294847	H294914	H294981	H295045	H295116	H295186	
H294462	H294524	H294593	H294656	H294719	H294784	H294848	H294915	H294982	H295046	H295117	H295188	
H294463	H294525	H294594	H294657	H294720	H294785	H294850	H294916	H294983	H295047	H295118	H295193	
H294464	H294526	H294595	H294658	H294723	H294786	H294851	H294917	H294984	H295048	H295119	H295195	
H294465	H294527	H294596	H294659	H294724	H294787	H294853	H294918	H294986	H295049	H295120	H295196	
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H294472	H294534	H294603	H294666	H294732	H294794	H294860	H294925	H294993	H295058	H295127	H295208	
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H294474	H294536	H294605	H294668	H294734	H294796	H294862	H294927	H294996	H295060	H295129	H295210	
H294475	H294537	H294606	H294669	H294735	H294797	H294863	H294928	H294997	H295061	H295130	H295211	
H294476	H294538	H294607	H294670	H294736	H294798	H294864	H294929	H294998	H295062	H295131	H295212	
H294477	H294539	H294608	H294671	H294737	H294799	H294865	H294930	H294999	H295063	H295132	H295213	
H294478	H294540	H294610	H294672	H294738	H294800	H294866	H294931	H295000	H295064	H295133	H295214	

Report Form Field Safety Corrective Action

Medical Devices Vigilance System (MEDDEV 2.12/1 rev 5)

1. Administrative information **Destination**	
Recipient Name of national competent authority The Danish Medicines Agency Address of national competent authority Axel Heides Gade 1 DK - 2300 – Kobenhavn Denmark	
Date of this report 2012-02-09	
Reference number assigned by the manufacturer CP-06611	
Incidence reference number and name of the coordinating National Competent Authority (if applicable)	
Identify to what other National Competent Authorities this report was **also** sent Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom	

2 Information on submitter of the report
Status of submitter ☒ Manufacturer ☐ Authorised representative within EEA ☐ Others (identify the role):

3 Manufacturer information	
Manufacturer name Varian Medical Systems, Inc.	
Manufacturer's contact person Peter J. Coronado	
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E-mail peter.coronado@varian.com	Country USA

4 Authorised representative information
Name of the authorised representative Varian Medical Systems UK, Ltd.
The authorised representative's contact person Per Persson
Address Gatwick Road

Postal code RH10 9RG	City Crawley
Phone +44 (0)1293 601200	Fax +44 (0)1293 533509
E-mail per.persson@varian.com	Country United Kingdom

5 National contact point information	
National contact point name	
Name of the contact person	
Address	
Postal code	City
Phone	Fax
E-mail	Country

6 Medical device information

Class

☐ AIMD Active implants

☐ MDD Class III

☒ MDD Class IIb

☐ MDD Class IIa

☐ MDD Class I

☐ IVD Annex II List A

☐ IVD Annex II List B

☐ IVD Devices for self-testing

☐ IVD General

Nomenclature system (preferable GMDN) GMDN
Nomenclature code 35159
Nomenclature text Accelerator system, linear
Commercial name/brand name/make C-Series Clinac or Trilogy
Model number H14, H18, H27, H29
Serial number(s) and/or lot/batch number(s) See list attached to Field Safety Notice
Software version number (if applicable) 2.x through 8.x
Manufacturing date/expiry date (if applicable) N/A
Accessories/associated device (if applicable) N/A
Notified body (NB) ID- number BSi / CE0086

7 Description of FSCA

Background information and reason for the FSCA

Product Indication :

The Varian High Energy Linear Accelerator is a computer controlled photon and electron beam producing, radiation therapy linear accelerator machine. The major components of the High Energy Linear Accelerator platform are: the Stand, the Gantry, the Couch, the Console with Electronics Cabinet, and the Modulator Cabinet. The Varian High Energy Linear Accelerator is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

Description of Issue:

An event has been reported to Varian involving a C-Series Clinac® accelerator. The event entails excessive connector resistance, which caused the actual jaw positions to differ from the intended jaw positions without warning the operator. Normal morning daily quality assurance testing and light field verification detected the discrepancy. Varian has not received any report of misadministration as a result of the discrepancy. Investigation found that a similar issue could arise on the gantry or couch axes. This does not affect the MLC.

Varian's investigation revealed excessive connector resistance in the lines providing reference voltages to the potentiometers. This can cause a discrepancy between the actual physical positions compared to the corresponding position readouts, leading to an incorrect setting such as treatment field size.

For versions 2.x – 6.x only: C-Series Clinac® version 3.x through 6.x only provide redundant C-Series Clinac® axis position feedback on the axes intended to move during irradiation, these are the upper jaws and the gantry (this redundancy is not included in version 2.x). On these versions, the axes not intended to move during irradiation are not equipped with secondary feedback of the positions. Thus these axes can be susceptible to failures that can affect the position accuracy of the single feedback source. These single feedback axes are the lower jaws, collimator rotation, and all couch axes.

Three reports has been received related to this issue (CP-00214 – Germany; CP-06495 - USA; CP-06611 - USA). In the reported cases, no misadministration or serious deterioration in the state of health was reported.

Note: There are 2 FSNs associated with this FSCA. The FSN labelled CP-06611 pertains to cusomers who have v7.x-8.x. The FSN labelled CP-06611v2-6 pertain to customers who have v2.x-6.x. Each FSN has a different consignee list and will therefore be distributed only to customers who are affected.

Root Cause:

Design deficiency: An unknown source of resistance was applied to the connection from the motor interface PCB to the potentiometers causing a discrepancy between the physical vs. readout positions of the gantry, collimator, jaw and couch. The wires carrying both +/- voltage reference are used for both primary and secondary position readout indicators, therefore a change in resistance to the connector would result in the same offset in both readouts.

Risk Analysis:

In this situation, when the reference voltage drops the actual jaw position may differ from the intended jaw position; the digital display will indicate only the intended jaw position and will not accurately show the actual jaw position. Any jaw could be affected and could result in unplanned dose to normal tissue and/or critical structures.

Additionally, the gantry position, collimator rotation and couch axes could be affected and the actual position may differ from the intended position.

The most serious probable scenario is a cranial-spinal treatment plan that would be using a

match line shift to 'feather' the hot and cold spots throughout the treatment course. This type of treatment does not always include additional collimation (MLC or a block) to the area that is being matched. If the physical jaw was not in the correct position, an under dose or over dose would occur. This error could gradually increase due to degradation and cause an increase in harm. It is reasonable to expect that a gradual error would be detected. However, if a sporadic error occurred, the discrepancy may be larger and may not be detected through normal QA processes.

Alternatively, if the light field was used to abut the fields and the field size was correct before performing a double exposure image, a subsequent auto go to the planned field size could result in an incorrect field size used for treatment.

Any organ at risk or critical structure that has reached the associated radiation tolerance limit could cause harm and/or late radiation effects. The degree of harm is based on the degree of error and the number of times the field size is incorrect during the course of treatment.

A risk hazard assessment of the consequences leading to the most probable scenario that could be expected if the anomaly occurred is Critical (Could result in permanent impairment or life-threatening injury). The Probability that harm will come to a patient as a result of this issue is Remote (Unlikely to occur but possible during the life of an individual item; unlikely but reasonably expected to occur in the installed base). The risk hazard concluded with an ALARP.

Description and justification of the action (corrective/preventive)

Varian had decided to further mitigate this issue as a Field Safety Corrective Action and will notify all affected Users with a Field Safety Notice. The FSN provides a description of the problem, and advises Users of the steps Varian is taking to address the issue.

For version 2.x – 6.x only: No technical solution is proposed for devices with v2.x to v6.x. The FSN communication serves as the corrective action mechanism for the installed base. These devices are manually driven and monitored by the user and only the y-jaws and the gantry rotation have secondary position readouts (SPROs).

For versions 7.x – 8.x only: Varian is continuing to evaluate possible technical solutions for this issue, but no technical solution is proposed at this time as mitigation. Varian's external corrective action consists of ensuring affected customer sites receive a copy of the FSN.

FSN distribution to affected users will begin immediately. In addition, the notices, including the customer distribution list will be forwarded to Varian Sales, Marketing, and Service organizations. Customer sites will be notified by appropriate methods, and will be requested to return proof of notification (via completed "Proof of Notification Form" or appropriate Postal system certified receipt of delivery) to Varian. The enclosed FSN will also be posted to the customer support site: http://www.MyVarian.com.

Advice on actions to be taken by the distributor and the user

Please refer to the FSN for further details

Attached please find

☒ Field Safety Notice (FSN) in English

☒ FSN in national language

☐ Others (please specify):

Time schedule for the implementation of the different actions

90 days to complete FSN distribution and collection of proofs (April 2012). The timeframe for a technical solution (for v7.x-8.x only) to be available has yet to be determined.

These countries within the EEA and Switzerland are affected by this FSCA

Within EEA and Switzerland:

☒ AT	☒ BE	☒ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK	☒ EE	☒ ES
☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE	☒ IS	☒ IT	☐ LI	☒ LT
☒ LU	☒ LV	☐ MT	☒ NL	☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒SI
☒SK									

Candidate Countries:

☐ HR ☒ TR

☐ All EEA, Candidate Countries and Switzerland

Others: French Polynesia, Guadeloupe, Martinique, Reunion

These countries outside the EEA and Switzerland are affected by this FSCA

Algeria, Angola, Argentina, Australia, Azerbaijan, Bahrain, Bangladesh, Belarus, Bolivia, Bosnia and Herzegovina, Brazil, Canada, Chile, China, Columbia, Costa Rica, Dominican Republic, Ecuador, Egypt, Georgia, Guatemala, Guam, Honduras, Hong Kong, India, Indonesia, Iran, Israel, Jamaica, Japan, Kazakhstan, Kenya, Kuwait, Lebanon, Macau, Macedonia, Malaysia, Mauritania, Mexico, Moldova, Morocco, Nepal, New Zealand, Oman, Pakistan, Panama, Paraguay, Peru, Philippines, Puerto Rico, Qatar, Russia, Saudi Arabia, Serbia, Singapore, South Africa, South Korea, Sri Lanka, Syria, Taiwan, Thailand, Trinidad and Tobago, Tunisia, Ukraine, United Arab Emirates, Uruguay, USA, Venezuela, Vietnam, Virgin Islands (American)

8 Comments

List of customer sites in EEA member states, candidate countries and territories.

V 2.x-6.x:

Austria	3	Ireland	1	Romania	5
Belgium	8	Italy	54	Slovakia	5
Czech Republic	6	Latvia	1	Slovenia	1
Denmark	2	Lithuania	2	Spain	37
Finland	9	Martinique	1	Sweden	10
France	61	Netherlands	5	Switzerland	9
Germany	53	Norway	3	Turkey	17
Greece	1	Poland	10	United Kingdom	34
Iceland	1	Portugal	9		

V 7.x-8.x:

Austria	4	Greece	3	Poland	11
Belgium	15	Guadeloupe	1	Portugal	10
Bulgaria	1	Hungary	1	Reunion	2
Cyprus	1	Ireland	6	Romania	2
Czech Republic	9	Italy	40	Slovakia	3
Denmark	6	Latvia	3	Slovenia	1
Estonia	1	Lithuania	3	Spain	31
Finland	11	Luxembourg	1	Sweden	9
France	88	Martinique	1	Switzerland	20
French Polynesia	1	Netherlands	8	Turkey	38
Germany	96	Norway	4	United Kingdom	39

I affirm that the information given above is correct to the best of my knowledge.

Signature

Peter J. Coronado	Palo Alto, California, USA	2012-02-09
Name	City	Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.