# PILNA KOREKTA DOTYCZĄCA URZĄDZENIA MEDYCZNEGO
# PILNE ZAWIADOMIENIE DOTYCZĄCE BEZPIECZEŃSTWA

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| ***Temat:*** | Nieprawidłowe wartości odczytu położenia spowodowane nadmierną rezystancją złącza |
| ***Nazwa handlowa produktu, którego dotyczy zawiadomienie:*** | C-Series Clinac lub Trilogy, wersje 7.x i 8.x |
| ***Nr referencyjny/identyfikator FSCA:*** | **CP-06611** |
| ***Data zawiadomienia:*** | |
| ***Rodzaje działań:*** | Wyłącznie zawiadomienie |
| ***Szczegółowe informacje na temat produktów, których dotyczy zawiadomienie:*** | Patrz załącznik |

**Opis usterki:**

Celem niniejszego listu jest powiadomienie o zgłoszeniu otrzymanym przez firmę Varian odnośnie do nieprawidłowości związanych z przyspieszaczem C-Series Clinac®. Nieprawidłowość ta wynika z nadmiernej rezystancji złącza, która spowodowała zmianę rzeczywistego położenia szczęki w stosunku do jej żądanego położenia, o czym nie został powiadomiony operator. Niezgodność została wykryta podczas codziennej kontroli porannej oraz weryfikacji pola oświetlonego. Do firmy Varian nie dotarły żadne informacje o zastosowaniu niewłaściwej dawki w wyniku wspomnianej rozbieżności. Badania wykazały, iż podobny problem może wystąpić w osi gantry lub stołu. Nie ma to wpływu na kolimator wielolistkowy. W niniejszym zawiadomieniu podano szczegółowe informacje dotyczące sprawy oraz opisano kroki, jakie należy podjąć, aby uniknąć wystąpienia problemu lub złagodzić jego skutki.

**Informacje szczegółowe:**

Nadmierna rezystancja złącza w liniach doprowadzających napięcie referencyjne do potencjometrów może powodować rozbieżność pomiędzy rzeczywistym położeniem a położeniem wynikającym z odczytu. To z kolei może prowadzić do nieprawidłowych ustawień, np. wielkości pola terapeutycznego. Wartość napięcia jest monitorowana w chwili wyjścia ze źródła zasilania, ale nie w potencjometrach. Mierzalny spadek napięcia może prowadzić do sytuacji, w której rzeczywista pozycja może różnić się w dowolnym kierunku od pozycji zamierzonej.

Przewody drutowe, przez które przepływa dodatnie i ujemne napięcie referencyjne, są używane zarówno w przypadku głównych, jak i dodatkowych wskaźników odczytu położenia. Stąd też zmiana rezystancji złącza spowodowałaby takie samo przesunięcie w obydwu odczytach. Zmiana rezystancji, która wystąpiłaby w czasie, gdy urządzenie znajduje się w trybie gotowości lub emisji wiązki, uruchomiłaby blokadę, przerywając leczenie.

Mimo iż prawdopodobieństwo niezauważenia tego rodzaju rozbieżności podczas rutynowej kontroli jakości jest bardzo niskie, zakładając użycie zalecanego pola oświetlonego, to gdyby np. błąd położenia szczęki nie został wykryty, rzeczywisty rozmiar pola byłby większy lub mniejszy od zamierzonego. Leczenie z zastosowaniem pola całkowicie ukształtowanego przez kolimator

trzeciorzędowy ograniczyłoby wpływ niewielkich błędów dotyczących położenia szczęki. Dotyczy to również pól ukształtowanych przez kolimator wielolistkowy (w tym pól Dynamic MLC i RapidArc) na potrzeby leczenia SRS przy użyciu kolimatora stożkowego oraz leczenia polem elektronowym przy użyciu stożka elektronów. Niewykrycie znacznych błędów dotyczących położenia szczęki może jednak prowadzić do poważnych urazów, nawet mimo zastosowania metody kolimacji trzeciorzędowej.

Środki kontroli jakości oraz standardowe wykorzystanie pola oświetlonego mogą przyczynić się do wykrycia problemu. Bardzo istotne jest rutynowe wykonywanie obydwu czynności. Codzienna kontrola zgodności z wykorzystaniem pola oświetlonego oraz skali mechanicznej umożliwia stwierdzenie wszelkich rozbieżności pomiędzy żądanym a rzeczywistym rozmiarem pola, obrotem gantry, kolimatora czy stołu lub położeniem stołu. Pole oświetlone pozwala również na skontrolowanie rozmiaru pola, jego kształtu oraz linii dopasowania i należy z niego korzystać w przypadku wszystkich pól. Poranna kontrola powinna obejmować sprawdzenie wskaźnika rozmiaru kolimatora zgodnie z procedurami codziennej kontroli jakości zalecanymi przez AAPM. Kontrole pola oświetlonego oraz skali mechanicznej wystarczą do identyfikacji wszelkich odchyleń odczytu.

**Zalecane działania użytkownika**

We wszystkich działach w swojej placówce należy przygotować kompleksowy program zapewnienia jakości. Do pomocy można użyć następujących materiałów:

1. *„AAPM code of practice for radiotherapy accelerators: Report of AAPM Radiation Therapy Committee Task Group”,* Medical Physics, rocznik 21, nr 7, lipiec 1994 r.
2. *„Comprehensive Quality Assurance for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group”,* Medical Physics, rocznik 21, nr 4, kwiecień 1994 r.

Przed przystąpieniem do leczenia pacjentów danego dnia należy przeprowadzić kontrolę jakości. W dokumentach grupy AAPM Task Group 142 zaleca się przeprowadzanie kontroli wskaźnika rozmiaru kolimatora codziennie bez względu na typ leczenia.[1]

Dodatkowo wszelkie rozbieżności pomiędzy rzeczywistym a planowanym rozmiarem pola należy zgłaszać fizykowi medycznemu i dopiero po zbadaniu przez niego problemu można kontynuować leczenie.

**Działania podjęte przez firmę Varian:**

Firma Varian prześle niniejsze zawiadomienie do wszystkich klientów, którzy mogli otrzymać wadliwe produkty.

Firma Varian podejmuje wysiłki w kierunku opracowania rozwiązań technicznych, które pozwolą usunąć opisywany problem.

**Prosimy o przekazanie treści niniejszego zawiadomienia odpowiednim pracownikom oddziału radioterapii. Niniejszy dokument zostanie zamieszczony do wglądu na stronie internetowej działu obsługi klienta firmy Varian: http://www.MyVarian.com.**

[1] Klein *i in.*: *„QA of Medical Accelerator*: *Report of Task Group”*, Medical Physics, rocznik 36, nr 9, wrzesień 2009

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# PILNE ZAWIADOMIENIE DOTYCZĄCE BEZPIECZEŃSTWA

**Specjalne instrukcje dla klientów spoza Stanów Zjednoczonych i Kanady:** W celu spełnienia wymogów prawnych po przeczytaniu niniejszego dokumentu należy wypełnić i przesłać do firmy Varian Medical Systems jeden z załączonych dokumentów: dowód powiadomienia (Proof of Notification) lub kartę potwierdzenia odbioru (Receipt Verification Card).

Przepraszamy za wszelkie niedogodności i z góry dziękujemy za współpracę. Dodatkowe informacje można uzyskać w lokalnym dziale obsługi klienta firmy Varian lub u kierownika regionalnego.

Niżej podpisany potwierdza przekazanie niniejszego zawiadomienia odpowiedniemu organowi nadzorującemu.

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Mika Miettinen, Data
Director, Global Quality Assurance and Product Reliability

**Informacje kontaktowe biura obsługi Varian dot. systemów onkologicznych:**

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| **Tel.:** | USA i Kanada: 1 888 VARIAN5 (888 827 4265)<br>Europa: +41 41 749 8844 |
| **E-mail:** | Ameryka Północna: support-americas@varian.com<br>Australia/Nowa Zelandia: support-anz@varian.com<br>Europa: support-emea@varian.com<br>Azja Południowo-Wschodnia: support-sea@varian.com<br>Chiny / Azja: support-china@varian.com<br>Japonia: support-japan@varian.com<br>Ameryka Łacińska: soporte.al@varian.com |
| **Internet:** | Strona internetowa dla użytkowników systemów onkologicznych – www.myvarian.com<br>Strona internetowa firmy Varian Medical Systems – www.varian.com |

# PILNA KOREKTA DOTYCZĄCA URZĄDZENIA MEDYCZNEGO
# PILNE ZAWIADOMIENIE DOTYCZĄCE BEZPIECZEŃSTWA

ZAŁĄCZNIK
LISTA NUMERÓW SERYJNYCH

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