

URGENT – NOTIFICATION DE SÉCURITÉ

Objet :	Clinac® C-Series haute énergie : boulons de contrepoids desserrés
Appellation commerciale du produit concerné :	Clinac C-Series haute énergie
Identifiant FSCA :	CP-00480
Date de notification :	2010-12-29
Type d'action :	Notification
Détails sur les dispositifs concernés :	Voir liste en annexe.

Description du problème :

Varian a identifié une anomalie d'installation selon laquelle il arrive dans certains cas que les boulons qui serrent le contrepoids du bras ne soient pas serrés au couple requis. Dans le pire des scénarios (ce cas ne s'est jamais produit), le contrepoids risque de se détacher du bras. Le bras se trouve déséquilibré et devient libre de basculer, ce qui présente un danger de collision avec le patient, le radiothérapeute ou un technicien de maintenance. Les problèmes constatés et les mesures à prendre pour les éviter ou les atténuer, ainsi que les mesures prises par Varian pour y répondre, sont décrits dans ce document.

Contexte :

Pour les accélérateurs Clinac non couverts par le contrat PMI de Varian, il est possible que les boulons de serrage du contrepoids n'aient pas été serrés selon les dernières caractéristiques de couple indiquées par Varian en 2009. Ces boulons de contrepoids risquent de se desserrer et de finir par céder sous l'effet de l'usure.

Pour le matériel faisant l'objet d'un contrat PMI auprès de Varian, une inspection annuelle de ces boulons a été effectuée pour en vérifier le serrage.

Définitions :

Définition du contrepoids :

Pour les Clinac haute énergie sans bouclier rétractable, le contrepoids est un poids relié à la partie inférieure du bras (Figure 1) afin de l'équilibrer. Le contrepoids pèse environ 2 700 kg.

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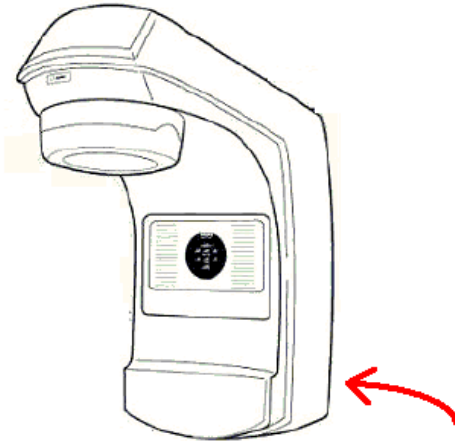


Figure 1 – Emplacement du contrepoids

Définition de la PMI :

Inspection de maintenance périodique - programme d'inspections de maintenance du Clinac à intervalles réguliers effectuée par Varian Service.

Détails :

Pour les accélérateurs Clinac haute énergie sans bouclier rétractable, Varian installe un contrepoids dans la partie inférieure du bras du Clinac (Figure 1) afin de l'équilibrer. Le contrepoids se situe sous le couvercle en fibre de verre et il est fixé au bras par deux goupilles d'alignement et quatre gros boulons. Varian s'est rendu compte que, dans plusieurs installations clients, un ou plusieurs boulons n'avaient pas été correctement serrés par l'équipe d'installation selon les caractéristiques de couple préconisées par Varian et avaient fini par se desserrer. Dans tous les cas, les boulons desserrés ont été détectés durant la PMI ou suite à des bruits inhabituels remarqués par le client lors de la rotation du bras.

Varian n'est pas au courant de cas où le contrepoids s'est détaché du bras. Toutefois, si les boulons desserrés ne sont pas resserrés, ils seront sujets à une fatigue par tension. Selon l'emplacement des boulons desserrés et la gravité de la défaillance, on a estimé que les boulons ne rempliraient plus correctement leur fonction au bout d'une période de 2 à 2,5 ans. Une défaillance des boulons entraînerait une chute du contrepoids de la machine.

Étant donné la position du contrepoids au dos du bras, la chute du contrepoids ne présente pas un danger pour les patients ; toutefois, elle peut poser un danger aux radiothérapeutes ou au personnel technique. Le bras se trouve déséquilibré et risque de basculer librement, posant un danger à quiconque se trouve sur sa trajectoire, y compris patient, radiothérapeute et personnel technique.

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Procédure corrective recommandée :

- Recherchez immédiatement la cause de TOUT bruit inhabituel provenant du Clinac. Signalez tout bruit inhabituel aux responsables de la maintenance de votre Clinac (par ex. Varian Service, maintenance par une tierce partie, maintenance interne).
- Si vous n'avez pas de contrat de service Varian :
 - Veillez à effectuer une inspection annuelle des boulons du contrepoids, comme décrit à l'annexe A.

Mesures correctives prises par Varian :

- Les clients sont informés au moyen de la présente notification urgente de sécurité.
- Pour les clients sous contrat de service Varian, le service de maintenance Varian effectuera l'inspection des boulons du contrepoids dans le cadre de la procédure d'inspection de maintenance périodique (PMI).

Veillez informer du contenu de ce courrier les personnels concernés de votre service de radiothérapie.

Nous vous prions de bien vouloir nous excuser pour toute gêne éventuelle occasionnée par ce problème et vous remercions d'avance pour votre coopération. Pour toute précision complémentaire, n'hésitez pas à contacter le support technique de Varian dont vous dépendez localement.

Le signataire confirme par la présente que cet avis a été communiqué aux agences réglementaires compétentes.

Michael Pignataro, directeur des rapports et corrections

__2010-12-29__
Date

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Pour contacter le Centre d'assistance technique Varian pour l'oncologie (Oncology Helpdesk) :

Téléphone : États-Unis et Canada : 1 888 VARIAN5 (888 827 4265)
Europe : +41 41 749 8844

E-mail : Amérique du Nord : support-americas@varian.com
Australie/Nouvelle-Zélande : support-anz@varian.com
Europe : support-emea@varian.com
Asie du Sud-Est : seasia.apps.helpdesk@varian.com
Chine/Asie : china.apps.helpdesk@varian.com
Japon : japan.apps.helpdesk@varian.com
Amérique latine : soporte.al@varian.com

Internet : Site pour les clients Oncology Systems : www.myvarian.com
Site public de Varian Medical Systems : www.varian.com

ANNEXE A : INSPECTION ANNUELLE DES BOULONS DE MONTAGE DU CONTREPOIDS

1. Retirez les deux capots arrière du contrepoids.
2. Vérifiez le serrage de chacun des quatre boulons de montage. Inspectez les quatre paires de rondelles pour vous assurer qu'elles ne sont pas fissurées (cf. Figure 2).
3. Faites pivoter le bras vers les deux limites de fin de course tout en écoutant le bruit provenant de la zone du contrepoids.
4. En cas de problème, il peut s'avérer nécessaire de remplacer les rondelles ou de resserrer les boulons. Contactez Varian Medical Systems pour obtenir les numéros de référence et les instructions appropriées.



Figure 2 : Inspection des rondelles/boulons du contrepoids

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ANNEXE B LISTE DES NUMÉROS DE SÉRIE

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H272288	H272361	H272470	H272887	H273020	H273187	H290176	H290268	H290360	H290536	H291075
H272290	H272363	H272482	H272891	H273021	H273191	H290177	H290269	H290363	H290539	H291078
H272291	H272364	H272483	H272892	H273029	H273200	H290180	H290272	H290369	H290540	H291080
H272292	H272366	H272484	H272894	H273031	H273202	H290182	H290273	H290372	H290542	H291085
H272293	H272373	H272485	H272895	H273033	H273203	H290186	H290274	H290373	H290543	H291086
H272296	H272377	H272491	H272900	H273045	H273206	H290187	H290276	H290375	H290544	H291091
H272298	H272381	H272492	H272907	H273048	H273208	H290189	H290277	H290376	H290547	H291092
H272299	H272383	H272496	H272909	H273049	H273209	H290191	H290278	H290379	H290550	H291093
H272300	H272387	H272498	H272910	H273051	H290003	H290195	H290283	H290380	H290551	H291099
H272301	H272389	H272801	H272912	H273052	H290012	H290196	H290286	H290381	H290553	H291108
H272302	H272390	H272804	H272914	H273056	H290016	H290198	H290288	H290386	H290558	H291111
H272304	H272392	H272808	H272917	H273061	H290017	H290199	H290292	H290387	H290559	H291114
H272306	H272398	H272809	H272920	H273062	H290026	H290203	H290296	H290388	H290560	H291115
H272307	H272399	H272813	H272921	H273067	H290030	H290204	H290299	H290394	H290561	H291127
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H272311	H272405	H272820	H272934	H273072	H290033	H290208	H290306	H290400	H291002	H291130
H272312	H272406	H272821	H272936	H273078	H290100	H290209	H290309	H290401	H291004	H291132
H272313	H272408	H272822	H272937	H273093	H290103	H290210	H290310	H290402	H291006	H291137
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H272318	H272421	H272831	H272954	H273102	H290111	H290216	H290316	H290413	H291015	H291144

URGENT - NOTIFICATION DE SÉCURITÉ

Clinac® C-Series haute énergie : boulons de contrepoids desserrés

H291148	H293308	H293406	H293556	H293678	H293791	H293910	H294073	H294235	H294393
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H291154	H293316	H293421	H293562	H293682	H293796	H293935	H294095	H294256	H294397
H291157	H293320	H293423	H293567	H293684	H293802	H293938	H294098	H294265	H294399
H291158	H293321	H293424	H293568	H293687	H293803	H293942	H294100	H294284	H294403
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H291163	H293326	H293429	H293585	H293702	H293810	H293950	H294105	H294294	H294427
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