

Notification urgente de sécurité

Objet : **Le mode manuel (freins desserrés) du plateau de la table de traitement n'est pas inactivé par le commutateur de désactivation des mouvements en mode radiochirurgie stéréotaxique (SRS).**

Produit concerné : Accélérateurs Clinac en version 7.x dotés de l'option « SRS Motion Disable » [Désactivation des mouvements en modeSRS]

Appareils concernés : **Voir l'annexe**

Identifiant FSCA : **CP-00283**

Date de notification : 2009/05/29

Service à contacter : Centre d'assistance technique Varian pour l'oncologie (*Oncology Helpdesk*) - 888-VARIAN5 (888-827-4265)
E-mail : tps.support@us.varian.com ou onc.helpdesk@varian.com

Le présent courrier a pour but de vous avertir d'une anomalie identifiée sur les accélérateurs Clinacs hautes énergies en version 7.X ; l'anomalie concerne la fonction du commutateur de désactivation des mouvements en mode stéréotaxique.

Cette alerte de matériovigilance décrit l'anomalie, explique les mesures correctives que doivent mettre en œuvre les utilisateurs et vous informe des mesures actuellement mises en place par Varian pour résoudre ce problème.

Anomalie :

Sur les Clinacs en Version 7.x, il est possible de déplacer la table de traitement en mode manuel (freins desserrés) alors que la fonction d'interdiction des mouvements en mode stéréotaxique est active. Cette situation peut présenter un danger pour un patient dont le traitement nécessite l'immobilisation de la tête dans un cadre stéréotaxique monté sur un support au sol ou sur un socle.

Détails :

Lorsque le commutateur de désactivation des mouvements en mode stéréotaxique (Stereotactic Motion Disable Switch), situé dans le statif du bras, est positionné de manière à couper l'alimentation électrique des moteurs et des freins, les moteurs sont désactivés, les freins sont serrés et le voyant (DEL) du tableau de commutation (Switch Panel Assembly) est allumé, signalant qu'aucun courant électrique ne peut être transmis aux moteurs et aux freins. Même si ce commutateur empêche les mouvements motorisés, l'utilisateur a toujours la possibilité de mettre le plateau de la table en mode manuel (freins desserrés) en appuyant sur les boutons **LAT** ou **LNG** de l'un ou l'autre des tableaux de commande latéraux de la table, boutons encadrés en rouge sur la Figure 1 ci-dessous. Lorsque le plateau de la table est ainsi libéré, le manipulateur peut

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déplacer le patient manuellement. Dans le cas d'un patient traité par SRS et appareillé d'un cadre de stéréotaxie crânienne monté sur un support au sol ou sur un socle, le fait de déplacer le patient peut entraîner des lésions cervicales lorsque le plateau de la table est libre.

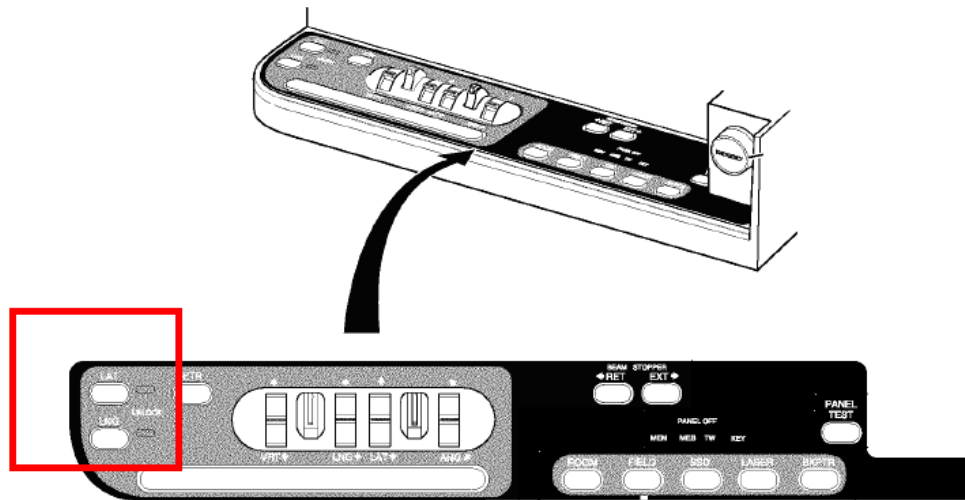


Figure 1 : Les boutons LAT et LNG d'un des tableaux de commande latéraux de la table de traitement sont indiqués par le rectangle rouge.

Bien qu'en retrait (voir Figure 2), ces boutons peuvent être activés accidentellement si l'utilisateur se sert des commandes de déplacement de la table accessibles sur les côtés. Lorsque ces commutateurs de libération du plateau (mode manuel) sont activés, le voyant lumineux en regard du bouton utilisé s'allume et on entend un déclic. Dans le cas d'un patient traité par SRS et appareillé d'un cadre de stéréotaxie crânienne monté sur un support au sol ou sur un socle autre que la table de traitement, l'utilisateur doit impérativement s'abstenir d'activer le mode manuel (freins desserrés) de la table afin de limiter le risque de déplacement accidentel du patient.

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Mesure recommandée à l'utilisateur:

Veillez tout particulièrement à ne pas déclencher le mode « free float » de la table (freins desserrés) lors du traitement SRS d'un patient dont la tête est immobilisée par un cadre stéréotaxique monté sur un support au sol ou sur un socle.

Mesures correctives prises par Varian :

Varian notifie tous les clients concernés par le présent avis. Varian va corriger ce problème de fonctionnement et transmettra le correctif technique à tous ses clients équipés d'un support au sol fourni par Varian. Le personnel technique vous contactera dès que possible concernant l'installation du correctif sur votre système. Si vous utilisez un support au sol ou socle non fourni par Varian, contactez le support technique de Varian dont vous dépendez localement pour être ajouté à la liste des clients dont le système doit être corrigé.

Veillez communiquer le contenu de cette lettre aux personnes concernées de votre service de radiothérapie.

Nous vous prions de bien vouloir nous excuser pour tout désagrément causé et vous remercions d'avance pour votre coopération. Pour toute clarification complémentaire, n'hésitez pas à contacter le support technique de Varian dont vous dépendez localement.

Nous confirmons par la présente que cet avis a été fourni aux agences réglementaires concernées.

2009/05/29

Dave Hall, Directeur des rapports et corrections

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ANNEXE A

LISTE DES NUMÉROS DE SÉRIE DES APPAREILS CONCERNÉS

Les numéros de série des systèmes concernés apparaissent ci-dessous. Les quatre derniers chiffres représentent le numéro de série de l'appareil.

| | | | | | | | | | |
|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| H140001 | H140136 | H140221 | H140719 | H140759 | H140798 | H271041 | H271626 | H271951 | H272197 |
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| H140025 | H140140 | H140225 | H140723 | H140763 | H140802 | H271167 | H271693 | H271973 | H272220 |
| H140026 | H140141 | H140226 | H140724 | H140764 | H140804 | H271169 | H271711 | H271974 | H272223 |
| H140027 | H140142 | H140227 | H140725 | H140765 | H140805 | H271190 | H271720 | H271975 | H272231 |
| H140031 | H140143 | H140228 | H140726 | H140766 | H140806 | H271194 | H271724 | H271976 | H272236 |
| H140043 | H140144 | H140229 | H140727 | H140767 | H140807 | H271242 | H271762 | H271993 | H272237 |
| H140045 | H140145 | H140230 | H140728 | H140768 | H140808 | H271258 | H271780 | H271994 | H272238 |
| H140046 | H140146 | H140231 | H140729 | H140769 | H140809 | H271265 | H271783 | H272000 | H272259 |
| H140047 | H140147 | H140232 | H140730 | H140770 | H140810 | H271308 | H271785 | H272009 | H272271 |
| H140058 | H140148 | H140233 | H140731 | H140771 | H140811 | H271334 | H271797 | H272023 | H272277 |
| H140062 | H140149 | H140234 | H140732 | H140772 | H140812 | H271362 | H271802 | H272029 | H272283 |
| H140067 | H140150 | H140235 | H140733 | H140773 | H140813 | H271370 | H271825 | H272033 | H272291 |
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| H140071 | H140152 | H140237 | H140735 | H140775 | H140815 | H271393 | H271833 | H272043 | H272301 |
| H140073 | H140153 | H140238 | H140736 | H140776 | H140817 | H271400 | H271835 | H272045 | H272302 |
| H140076 | H140154 | H140239 | H140737 | H140777 | H140819 | H271407 | H271838 | H272049 | H272306 |
| H140077 | H140201 | H140240 | H140739 | H140778 | H140820 | H271413 | H271856 | H272052 | H272307 |
| H140088 | H140202 | H140700 | H140740 | H140779 | H140821 | H271425 | H271858 | H272062 | H272309 |
| H140090 | H140203 | H140701 | H140741 | H140780 | H140822 | H271438 | H271860 | H272069 | H272310 |
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| H140096 | H140205 | H140703 | H140743 | H140782 | H140825 | H271452 | H271870 | H272086 | H272325 |
| H140097 | H140206 | H140704 | H140744 | H140783 | H140826 | H271497 | H271872 | H272089 | H272326 |
| H140098 | H140207 | H140705 | H140745 | H140784 | H140827 | H271502 | H271879 | H272111 | H272327 |
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| H140133 | H140218 | H140716 | H140756 | H140795 | H270788 | H271594 | H271935 | H272187 | H272370 |
| H140134 | H140219 | H140717 | H140757 | H140796 | H270794 | H271607 | H271941 | H272188 | H272372 |
| H140135 | H140220 | H140718 | H140758 | H140797 | H270862 | H271624 | H271942 | H272195 | H272388 |

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| H291210 | H291255 | H293322 | H293368 | H293414 | H293459 | H293504 | H293552 | H293599 | H293644 |
| H291211 | H291256 | H293323 | H293369 | H293415 | H293460 | H293505 | H293553 | H293600 | H293645 |
| H291212 | H291257 | H293324 | H293370 | H293416 | H293461 | H293506 | H293554 | H293601 | H293646 |
| H291213 | H291258 | H293325 | H293371 | H293417 | H293462 | H293507 | H293555 | H293602 | H293647 |
| H291214 | H291259 | H293326 | H293372 | H293418 | H293463 | H293508 | H293556 | H293603 | H293648 |
| H291215 | H291260 | H293327 | H293373 | H293419 | H293464 | H293509 | H293557 | H293604 | H293649 |
| H291216 | H291261 | H293328 | H293374 | H293420 | H293465 | H293510 | H293558 | H293605 | H293650 |
| H291217 | H291262 | H293329 | H293375 | H293421 | H293466 | H293511 | H293559 | H293606 | H293651 |
| H291218 | H291263 | H293330 | H293376 | H293422 | H293467 | H293512 | H293560 | H293607 | H293652 |
| H291219 | H291264 | H293331 | H293377 | H293423 | H293468 | H293513 | H293561 | H293608 | H293653 |
| H291220 | H291265 | H293332 | H293378 | H293424 | H293469 | H293514 | H293562 | H293609 | H293654 |

Notification urgente de sécurité

Le mode manuel (freins desserrés) du plateau de la table de traitement n'est pas inactivé par le commutateur de désactivation des mouvements en mode radiochirurgie stéréotaxique (SRS)

| | | | | | | | | | |
|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| H293655 | H293702 | H293750 | H293798 | H293846 | H293891 | H293941 | H293989 | H294037 | H294085 |
| H293656 | H293703 | H293751 | H293799 | H293847 | H293892 | H293942 | H293990 | H294038 | H294086 |
| H293657 | H293704 | H293752 | H293800 | H293848 | H293893 | H293943 | H293991 | H294039 | H294088 |
| H293658 | H293705 | H293753 | H293801 | H293849 | H293894 | H293944 | H293992 | H294040 | H294089 |
| H293659 | H293706 | H293754 | H293802 | H293850 | H293895 | H293946 | H293993 | H294041 | H294090 |
| H293660 | H293707 | H293755 | H293803 | H293851 | H293896 | H293947 | H293994 | H294042 | H294091 |
| H293661 | H293708 | H293756 | H293804 | H293852 | H293897 | H293948 | H293995 | H294043 | H294092 |
| H293662 | H293709 | H293758 | H293805 | H293853 | H293898 | H293949 | H293996 | H294044 | H294093 |
| H293663 | H293710 | H293759 | H293806 | H293854 | H293899 | H293950 | H293997 | H294045 | H294095 |
| H293664 | H293712 | H293760 | H293807 | H293855 | H293900 | H293951 | H293998 | H294046 | H294097 |
| H293665 | H293713 | H293761 | H293808 | H293856 | H293901 | H293952 | H293999 | H294047 | H294098 |
| H293666 | H293714 | H293762 | H293809 | H293857 | H293902 | H293953 | H294000 | H294048 | H294099 |
| H293667 | H293715 | H293763 | H293812 | H293858 | H293903 | H293954 | H294001 | H294049 | H294100 |
| H293668 | H293716 | H293764 | H293813 | H293859 | H293904 | H293955 | H294002 | H294050 | H294101 |
| H293669 | H293717 | H293765 | H293814 | H293860 | H293905 | H293956 | H294003 | H294051 | H294102 |
| H293670 | H293718 | H293767 | H293815 | H293861 | H293907 | H293957 | H294004 | H294052 | H294103 |
| H293671 | H293719 | H293769 | H293816 | H293862 | H293908 | H293958 | H294005 | H294053 | H294104 |
| H293672 | H293720 | H293770 | H293817 | H293863 | H293909 | H293959 | H294006 | H294054 | H294105 |
| H293673 | H293721 | H293771 | H293818 | H293864 | H293910 | H293960 | H294007 | H294055 | H294106 |
| H293674 | H293723 | H293772 | H293819 | H293865 | H293911 | H293962 | H294008 | H294056 | H294107 |
| H293675 | H293724 | H293773 | H293820 | H293866 | H293912 | H293963 | H294009 | H294058 | H294108 |
| H293676 | H293725 | H293774 | H293821 | H293867 | H293913 | H293964 | H294010 | H294059 | H294109 |
| H293678 | H293726 | H293775 | H293822 | H293868 | H293914 | H293965 | H294011 | H294060 | H294110 |
| H293679 | H293727 | H293776 | H293823 | H293869 | H293915 | H293966 | H294012 | H294061 | H294111 |
| H293681 | H293728 | H293777 | H293824 | H293870 | H293916 | H293967 | H294013 | H294062 | H294112 |
| H293682 | H293729 | H293778 | H293825 | H293871 | H293917 | H293968 | H294016 | H294063 | H294113 |
| H293683 | H293730 | H293779 | H293826 | H293872 | H293918 | H293969 | H294017 | H294064 | H294114 |
| H293684 | H293732 | H293780 | H293827 | H293873 | H293919 | H293970 | H294018 | H294065 | H294116 |
| H293685 | H293733 | H293781 | H293828 | H293874 | H293920 | H293971 | H294020 | H294067 | H294117 |
| H293686 | H293734 | H293782 | H293829 | H293875 | H293921 | H293972 | H294021 | H294068 | H294118 |
| H293687 | H293735 | H293783 | H293830 | H293876 | H293922 | H293974 | H294022 | H294069 | H294119 |
| H293688 | H293736 | H293784 | H293831 | H293877 | H293923 | H293975 | H294023 | H294070 | H294120 |
| H293689 | H293737 | H293785 | H293832 | H293878 | H293924 | H293976 | H294024 | H294071 | H294121 |
| H293690 | H293738 | H293786 | H293834 | H293879 | H293925 | H293977 | H294025 | H294072 | H294122 |
| H293691 | H293739 | H293787 | H293835 | H293880 | H293926 | H293978 | H294026 | H294073 | H294123 |
| H293692 | H293740 | H293788 | H293836 | H293881 | H293928 | H293979 | H294027 | H294074 | H294124 |
| H293693 | H293741 | H293789 | H293837 | H293882 | H293929 | H293980 | H294028 | H294075 | H294125 |
| H293694 | H293742 | H293790 | H293838 | H293883 | H293930 | H293981 | H294029 | H294076 | H294126 |
| H293695 | H293743 | H293791 | H293839 | H293884 | H293931 | H293982 | H294030 | H294077 | H294127 |
| H293696 | H293744 | H293792 | H293840 | H293885 | H293932 | H293983 | H294031 | H294078 | H294128 |
| H293697 | H293745 | H293793 | H293841 | H293886 | H293933 | H293984 | H294032 | H294079 | H294129 |
| H293698 | H293746 | H293794 | H293842 | H293887 | H293934 | H293985 | H294033 | H294080 | H294130 |
| H293699 | H293747 | H293795 | H293843 | H293888 | H293935 | H293986 | H294034 | H294081 | H294131 |
| H293700 | H293748 | H293796 | H293844 | H293889 | H293936 | H293987 | H294035 | H294082 | H294132 |
| H293701 | H293749 | H293797 | H293845 | H293890 | H293938 | H293988 | H294036 | H294083 | H294133 |

Notification urgente de sécurité

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| | | | | |
|---------|---------|---------|---------|---------|
| H294134 | H294186 | H294240 | H294299 | H294366 |
| H294135 | H294187 | H294241 | H294301 | H294372 |
| H294136 | H294188 | H294242 | H294302 | H294373 |
| H294137 | H294189 | H294243 | H294303 | H294376 |
| H294138 | H294190 | H294244 | H294304 | H294377 |
| H294140 | H294191 | H294245 | H294306 | H294378 |
| H294142 | H294192 | H294246 | H294307 | H294380 |
| H294143 | H294193 | H294247 | H294308 | H294381 |
| H294144 | H294194 | H294252 | H294309 | H294382 |
| H294145 | H294195 | H294254 | H294312 | H294384 |
| H294146 | H294196 | H294256 | H294314 | H294386 |
| H294148 | H294197 | H294257 | H294316 | H294389 |
| H294149 | H294198 | H294258 | H294317 | H294392 |
| H294150 | H294199 | H294261 | H294318 | |
| H294151 | H294200 | H294262 | H294320 | |
| H294152 | H294201 | H294263 | H294321 | |
| H294154 | H294202 | H294264 | H294322 | |
| H294155 | H294203 | H294266 | H294323 | |
| H294156 | H294204 | H294267 | H294324 | |
| H294157 | H294205 | H294269 | H294325 | |
| H294158 | H294207 | H294270 | H294326 | |
| H294159 | H294208 | H294271 | H294327 | |
| H294161 | H294209 | H294272 | H294328 | |
| H294162 | H294210 | H294273 | H294330 | |
| H294163 | H294214 | H294275 | H294331 | |
| H294164 | H294216 | H294276 | H294332 | |
| H294165 | H294217 | H294277 | H294333 | |
| H294166 | H294218 | H294278 | H294334 | |
| H294167 | H294219 | H294279 | H294336 | |
| H294168 | H294220 | H294280 | H294337 | |
| H294169 | H294221 | H294281 | H294338 | |
| H294170 | H294222 | H294282 | H294340 | |
| H294172 | H294223 | H294283 | H294341 | |
| H294173 | H294224 | H294285 | H294342 | |
| H294174 | H294225 | H294286 | H294343 | |
| H294175 | H294226 | H294287 | H294348 | |
| H294176 | H294227 | H294288 | H294350 | |
| H294177 | H294228 | H294289 | H294353 | |
| H294178 | H294230 | H294290 | H294354 | |
| H294179 | H294232 | H294293 | H294355 | |
| H294180 | H294234 | H294294 | H294358 | |
| H294181 | H294235 | H294295 | H294360 | |
| H294182 | H294236 | H294296 | H294361 | |
| H294184 | H294237 | H294297 | H294363 | |
| H294185 | H294239 | H294298 | H294364 | |