

Philips Healthcare
33, rue de Verdun
92156 Suresnes Cedex

A l'attention du Correspondant Local de Matéiovigilance

Suresnes, le 11 Février 2013

Objet : Notification de sécurité produit – Systèmes SureSigns VS2 +moniteur

Dossier suivi par : Nadjat Sekhri -(e-mail : nadjat.sekhri@philips.com-Tél: 01 47 28 66 02)
Ou (Pôle d'Assistance Clients au 0810.835.624. ou votre prestataire habituel si votre établissement est situé hors de la métropole)

N/Réf: LL/NS/13-0xxx- FSN 86201420A

Madame, Monsieur,

Philips Healthcare souhaite vous informer d'un problème de sécurité sur les systèmes SureSigns VS2 +moniteur

Un problème susceptible de présenter un risque pour les patients a été détecté sur les systèmes Philips SureSignsVS2+moniteur

Cette Notification de sécurité produit a pour objectif de vous informer sur :

- la nature du problème et les circonstances dans lesquelles il peut survenir ;
- les actions que le client/utilisateur doit prendre afin de prévenir tout risque pour les patients ou les utilisateurs ;
- les actions mises en œuvre par Philips pour remédier à ce problème.

Vous trouverez le détail de ce dysfonctionnement dans la notification de sécurité jointe à ce courrier.

Nous vous prions de bien vouloir diffuser cette notification auprès de toutes les personnes concernées par les informations qu'elle contient et d'en joindre un exemplaire dans le manuel utilisateur de votre système.

Si vous avez des questions relatives à cette notification nous vous suggérons de contacter notre pôle d'Assistance Clients au 0810.835.624.

Restant à votre disposition pour toute précision que vous jugeriez nécessaire, nous vous prions de croire, Madame, Monsieur, en l'assurance de notre meilleure considération.



Latifa Lakehal

Responsable Qualité et Affaires Réglementaires
Correspondant Matéiovigilance

PJ : Notification de sécurité produit – FSN 86201420A

URGENT – Notice corrective de matériel médical Moniteurs Patient SureSigns

- les actions prévues par Philips Healthcare pour remédier à ce problème.

Systèmes concernés	<p>Modèle : VS2+</p> <p>Produit : 863278, 863279</p> <p>Numéros de série :</p> <p>CN14800428, CN14800429, CN14800430, CN14800431, CN14800432, CN14800433, CN14800434, CN14800435, CN14800436, CN14800437, CN14800438, CN14800439, CN14800440, CN14800756, CN14800763, CN14800764, CN14800765, CN14800772, CN14800773, CN14800822, CN14800823, CN14800824, CN14800979, CN14801332, CN21201423, CN21201625, CN21202029, CN21202030, CN21202031, CN21202032, CN21202033, CN21202034, CN21202234, CN21202239, CN21202240, CN21202241, CN21202242, CN21202243, CN21202317, CN21202320, CN21202347, CN21202348, CN21202349, CN21202350, CN21202351, CN21202376, CN21202435, CN21202606, CN21202607, CN21202862, CN21202863, CN21202883, CN21203006, CN21203007, CN21203008, CN21203009, CN21203010, CN21203073, CN21203180, CN21203304, CN21203307, CN21203308, CN21203309, CN21203310, CN21203311, CN21203312, CN21203707, CN21203781, CN21203794, CN21203795, CN21203796, CN21203797, CN21203949, CN21203950, CN21203951, CN21203952, CN21203953, CN21204204, CN21204205, CN21204206, CN21204207, CN21204208, CN21204209, CN21204210, CN21204211, CN21203057, CN14800484, CN14800744, CN14800745, CN14800746, CN21203044, CN21203045, CN21203068, CN21203069, CN21203070, CN21203071, CN14800485, CN14800486, CN14800749, CN14800750, CN14800751, CN14800752, CN14800770, CN14800771, CN14800893, CN21201756, CN21201757, CN21201758, CN21201759, CN21201760, CN21202164, CN21202165, CN21202166, CN21202167, CN21202168, CN21202169, CN21202170, CN21202171, CN21202172, CN21202173, CN21202174, CN21202175, CN21202176, CN21202177, CN21202178, CN21202202, CN21202610, CN21202864, CN21203209, CN21203210, CN21203639, CN14801200, CN14801201, CN14801202, CN14801203, CN14801204, CN14801205, CN14801206, CN14801207, CN14801208, CN14801209, CN14801210, CN14801212, CN14801213, CN14801217, CN14801278, CN14801279, CN14801280, CN14801281, CN21201576, CN21201613, CN21202313, CN21202367, CN21202368, CN21202371, CN21202657, CN21203072, CN21203416, CN21203887, CN21203961, CN21203970, CN21204148, CN21204318, CN21202393, CN21202394,</p>
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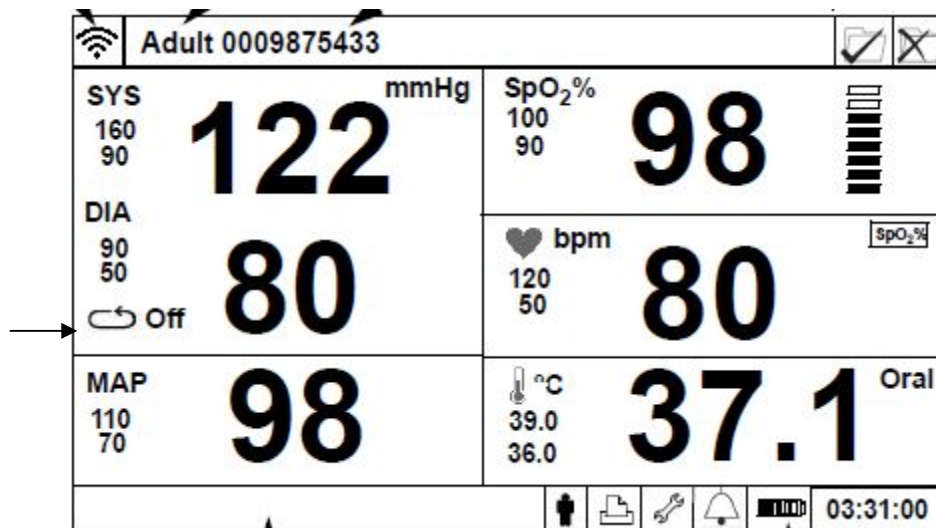
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Description du problème	<p>Philips Healthcare a mis en évidence qu'il est possible qu'un moniteur patient SureSigns VS2+ se verrouille, entraînant ainsi l'interruption du monitoring patient en cours d'utilisation.</p> <p>Ce cas de figure a été identifié par 5 clients sur un total de 10 appareils (0,3 % des appareils expédiés).</p>
Risques liés au problème	<p>Si l'appareil se verrouille alors qu'il se trouve en mode Intervalle PB et doit effectuer une surveillance continue de la SpO2 et de la PB d'un patient, ces paramètres ne sont plus mesurés et les alarmes de l'appareil ne fonctionnent plus. Dans pareil cas, le traitement du patient risque d'être retardé si le personnel soignant n'a pas conscience de l'interruption du monitoring de l'appareil.</p>
Identification des systèmes concernés	<p>La section "SYSTÈMES CONCERNÉS" de cette notification liste les modèles, références et numéros de série concernés par ce programme de correction. La référence (RÉF) et le numéro de série sont indiqués sur l'étiquette d'identification apposée à l'arrière de l'appareil.</p>
Action à mettre	<p>En attendant de recevoir le correctif de Philips, vous pouvez continuer d'utiliser les</p>

en œuvre par les utilisateurs

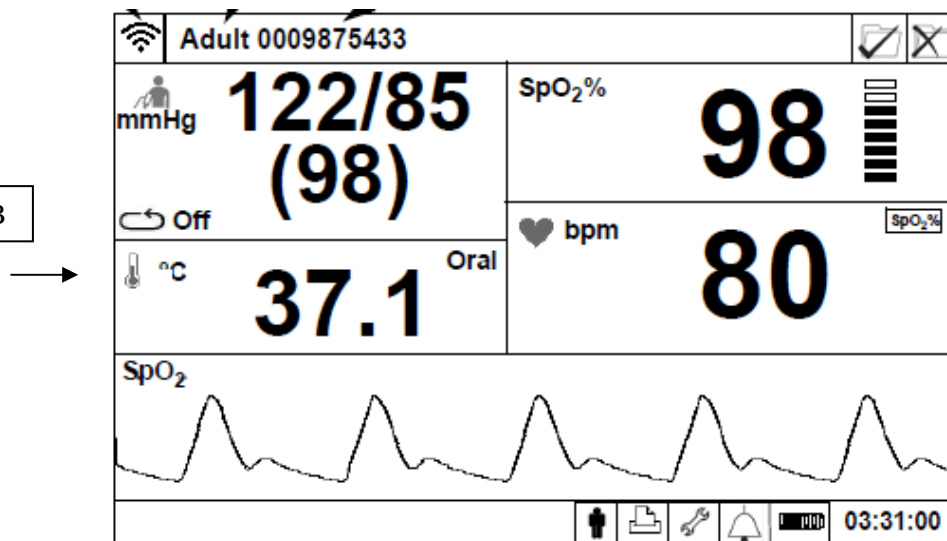
systèmes concernés, à condition que l'appareil ne soit pas en mode Intervalle PB.

Pour vérifier que l'appareil n'est pas en mode Intervalle PB, veuillez activer le mode d'affichage des paramètres vitaux ou des courbes. Assurez-vous que le mot "Désact" s'affiche à côté de l'icône Intervalle PB sur l'écran. Référez-vous à l'illustration ci-dessous :



Mode d'affichage des paramètres vitaux

Icône Intervalle PB



Mode d'affichage des courbes

Si l'appareil est en mode Intervalle PB, utilisez l'option Effacer programme pour supprimer le programme Intervalle PB. Lorsque vous sélectionnez le bouton Effacer programme, tous les réglages sont supprimés et les valeurs par défaut du programme sont rétablies.

Pour supprimer le programme Intervalle PB

- 1- Faites tourner le bouton de navigation jusqu'à ce que le panneau des valeurs

	<p>numériques de PB apparaisse en surbrillance.</p> <p>2- Appuyez sur le bouton de navigation. Le Menu Pression sanguine apparaît. Les réglages en cours sont affichés.</p> <p>3- Faites tourner le bouton de navigation jusqu'à ce que le bouton Intervalle PB apparaisse en surbrillance. Appuyez sur le bouton de navigation.</p> <p>4- Le Menu Intervalle PB apparaît.</p> <p>5- Faites tourner le bouton de navigation jusqu'à ce que le bouton Effacer programme apparaisse en surbrillance, puis appuyez sur le bouton de navigation. Une fenêtre de confirmation s'affiche.</p> <p>6- Sélectionnez Oui pour confirmer que vous souhaitez supprimer le programme Intervalle PB.</p> <p>Si le dispositif reste en mode Intervalle PB, n'utilisez plus l'appareil et contactez Philips.</p>
Remarque	Si le moniteur VS2+ se verrouille, déconnectez l'alimentation secteur et ôtez la batterie. Patientez pendant 60 secondes puis replacez la batterie et remettez l'appareil sous tension.
Actions correctives menées par Philips Healthcare	<p>Philips Healthcare travaille actuellement sur la conception de l'appareil afin de résoudre ce problème. Le correctif devrait être prêt d'ici 7 semaines. Le coût de mise en œuvre de ce correctif sera pris en charge gracieusement par Philips.</p> <p>Un représentant Philips Healthcare vous contactera afin d'organiser l'installation du correctif sur tous les appareils concernés.</p>
Informations Complémentaires et Assistance Technique	Si vous avez besoin d'informations supplémentaires ou d'assistance technique concernant cette notification, veuillez contacter notre Pôle d'Assistance Clients au 0810.835.624. ou votre prestataire habituel si votre établissement est situé hors de la métropole