



## URGENT – ACTION CORRECTIVE DE SECURITE

GE Healthcare

Healthcare Systems  
9900 Innovation Drive  
Wauwatosa, WI 53226  
États-Unis

Référence GE Healthcare: FMI 36106

16 septembre 2014

Destinataires: Directeur de l'établissement / gestionnaire des risques  
Chef des infirmiers  
Directeur du service biomédical  
Correspondant local de Matéiovigilance

Objet: **Défaillance d'un élément du capteur d'O<sub>2</sub> sur les modules respiratoires CARESCAPE E-sCO, E-sCOV, E-sCAiO, E-sCAiOV, E-sCAiOE, E-sCAiOVE, les modules de gaz respiratoire N-CAiO en option et les unités d'échange de services respectives**

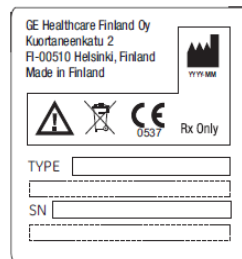
GE Healthcare a récemment pris connaissance d'un problème potentiel de sécurité dû à une défaillance d'un élément du capteur d'O<sub>2</sub> associé aux modules respiratoires CARESCAPE, aux modules de gaz respiratoire en option et à leurs unités d'échange de services respectives. **Assurez-vous que tous les utilisateurs potentiels de votre établissement ont pris connaissance de cet avis de sécurité et des actions recommandées.**

### Problème de sécurité

Les valeurs Et-/Fi O<sub>2</sub> affichées risquent d'être erronées. Un écart aléatoire des limites de tolérance autorisées d'un élément du capteur d'O<sub>2</sub> sur les modules respiratoires CARESCAPE, les modules de gaz respiratoire en option et leurs unités d'échange de services respectives peut entraîner une erreur lors du prélèvement des valeurs Et-/Fi O<sub>2</sub> (jusqu'à 50 % d'écart). Une valeur Et-/Fi O<sub>2</sub> erronée peut provoquer un événement hypoxique ou compromettre les prises de décisions cliniques.

### Instructions de sécurité

Vérifiez le numéro de série des modules respiratoires CARESCAPE et des modules de gaz respiratoire en option utilisés dans vos unités de soins. Le numéro de série (NS) du module se trouve sur la plaque signalétique de ce dernier, comme l'illustre l'image ci-dessous. La plaque signalétique de l'appareil se situe sur le côté du module.



Comparez le numéro de série de votre module à la liste des numéros de série des modules concernés qui se trouve en annexe du présent avis. Si le numéro de série de votre module se trouve dans la liste des modules concernés, **cessez immédiatement d'utiliser le module** et contactez le service d'assistance technique ou votre représentant local de maintenance.

### Produits concernés

Les numéros de série des modules respiratoires CARESCAPE concernés (E-sCO, E-sCOV, E-sCAiO, E-sCAiOV, E-sCAiOE, E-sCAiOVE), des modules de gaz respiratoire N-CAiO en option et de leurs unités d'échange de services respectives sont disponibles dans la liste fournie en annexe du présent avis.

Il est possible que les modules concernés soient actuellement utilisés avec les appareils hôtes GE suivants :

- Modules respiratoires CARESCAPE avec moniteurs CARESCAPE B850, B650 et B450, moniteurs modulaires S/5, dispositifs d'anesthésie Avance CS<sup>2</sup> et Aisys CS<sup>2</sup> et moniteur patient B40
- Modules de gaz respiratoire N-CAiO en option avec moniteur patient B40

**Correction  
du produit**

GE Healthcare procédera à une correction gratuite. Nous vous contacterons pour organiser cette correction.

**Contact**

Pour toutes questions relatives à cet avis de sécurité ou à l'identification des systèmes concernés, n'hésitez pas à prendre contact avec votre représentant local de vente ou le service d'assistance technique *au 04 78 66 62 38 choix 1*.

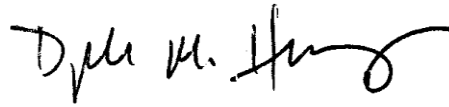
GE Healthcare confirme que les autorités réglementaires concernées ont été informées de cet avis de sécurité.

Soyez assurés que le maintien d'un niveau de sécurité et de qualité élevé est notre principale priorité. Pour toute question, n'hésitez pas à nous contacter immédiatement.

Cordialement,



James Dennison  
Vice-président QARA  
GE Healthcare Systems



Douglas M. Hansell, M.D., MPH  
Responsable médical en chef  
GE Healthcare

Annexe

Liste des numéros de série des appareils concernés : modules respiratoires CARESCAPE E-sCO, E-sCOV, E-sCAiO, E-sCAiOV, E-sCAiOE, E-sCAiOVE ; modules de gaz respiratoire N-CAiO en option et unités d'échange de services respectives

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SGV14149258HA	SGV14150078HA	SGV14159407HA	SGV14159967HA
SGV14150000HA	SGV14150079HA	SGV14159469HA	SGV14159971HA
SGV14150001HA	SGV14150165HA	SGV14159471HA	SGV14159974HA
SGV14150002HA	SGV14150167HA	SGV14159472HA	SGV14159975HA
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SGV14150006HA	SGV14150170HA	SGV14159484HA	SGV14159978HA
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SGV14150036HA	SGV14150172HA	SGV14159489HA	SGV14159980HA
SGV14150037HA	SGV14150173HA	SGV14159490HA	SGV14159981HA
SGV14150038HA	SGV14150174HA	SGV14159494HA	SGV14159982HA
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SGV14150067HA	SGV14150201HA	SGV14159709HA	SGV14160238HA
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SGV14150069HA	SGV14150203HA	SGV14159713HA	SGV14160241HA
SGV14150070HA	SGV14150204HA	SGV14159715HA	SGV14160242HA

## Annexe

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SGV14160243HA	SGV14160525HA	SGV14170930HA	SGV14181427HA
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SGV14160250HA	SGV14160532HA	SGV14171145HA	SGV14181433HA
SGV14160251HA	SGV14160534HA	SGV14171146HA	SGV14181434HA
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SGV14160255HA	SGV14160539HA	SGV14171151HA	SGV14181438HA
SGV14160256HA	SGV14160540HA	SGV14171152HA	SGV14181439HA
SGV14160257HA	SGV14160541HA	SGV14171153HA	SGV14181440HA
SGV14160258HA	SGV14160542HA	SGV14171154HA	SGV14181441HA
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SGV14160322HA	SGV14160547HA	SGV14171157HA	SGV14181446HA
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SGV14160524HA	SGV14170929HA	SGV14181426HA	SGV14181625HA

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SGV14181642HA	SGV14181997HA	SGV14192266HA	SGV14192644HA
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SGV14181895HA	SGV14192251HA	SGV14192629HA	SGV14192741HA

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