



URGENT – ACTION CORRECTIVE DE SECURITE

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188
États-Unis

Référence GE Healthcare: FMI 34093

7 août 2018

Destinataires: Correspondant Local de Matériorigilance
Chef de l'anesthésie
Directeur des services de génie biomédical / clinique
Administrateur des soins de santé / gestionnaire de risques

Objet: **Risque de perte de débit de gaz frais - Systèmes d'anesthésie Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 et 9100c NXT**

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 Sur les systèmes équipés de l'option Sortie auxiliaire de gaz frais (ACGO), il est possible que le commutateur de la sortie auxiliaire de gaz frais repasse soudainement de la position ACGO à la position circuit fermé. Sur les systèmes équipés de la fonction Aux O2 + Air, le commutateur risque de repasser soudainement de la position Aux O2 + Air à la position circuit fermé. Ces situations peuvent conduire à une hypoxie. Il serait toujours possible de ventiler le patient en utilisant le circuit respiratoire fermé soit en ventilation manuelle soit en ventilation mécanique. Aucune blessure n'a été signalée pour ce problème.

Instructions de sécurité Vous pouvez continuer d'utiliser les systèmes d'anesthésie répertoriés dans la liste des produits concernés ci-dessous. Si vous remarquez que le commutateur repasse de la position ACGO/Aux à la position circuit fermé alors que vous utilisez la fonction ACGO ou Aux O2+Air, servez-vous du circuit respiratoire fermé pour ventiler le patient. Une indication à l'écran signale si les fonctions ACGO ou Aux O2+Air sont actives. Si le commutateur repasse à la position circuit fermé, vous remarquez que l'indication à l'écran disparaît, le commutateur tourne sur la position circuit fermé et le débit du gaz émanant de la sortie ACGO ou Aux O2+Air s'interrompt. Si vous constatez l'un de ces signes, merci d'utiliser le circuit respiratoire fermé pour ventiler le patient. À tout moment, le clinicien peut utiliser un ballon auto-gonflant pour ventiler le patient et/ou passer sur un autre appareil d'anesthésie.

Produits concernés Pour les systèmes d'anesthésie Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 et 9100c NXT, reportez-vous à l'annexe présentant une liste des numéros de série concernés :

Carestation 620 A1 (GTIN : 00840682103985)
Carestation 650 A1 (GTIN : 00840682103947)
Carestation 650c A1 (GTIN : 00840682103954)

Correction du produit GE Healthcare corrigera gratuitement tous les produits concernés. Un représentant GE Healthcare vous contactera afin de convenir d'un rendez-vous pour 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 de service.

Vous pouvez aussi contacter le support technique au numéro suivant : 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 W. Dennison
Vice President - Quality & Regulatory
GE Healthcare



Jeff Hersh, PhD M.D.
Chief Medical Officer – Medical Safety
GE Healthcare

Annexe

Liste des numéros de série concernés

Systèmes Carestation 620/650/650c A1&A2 ACGO concernés

SM617220006WA	SM618040003WA	SM618040004WA	SM618050009WA	SM618050010WA	SM618060002WA
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Systèmes Carestation 620/650/650c A1 Aux O2+Air concernés

SM718060103WA	SM718220057MA	SM718250007WA	SM718250008WA	SM718250012MA	
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Systèmes Carestation 30 ACGO concernés

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Systèmes 9100c NXT ACGO concernés

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