REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧١/٢٥
رقم الصادر : ١٢/١/٢٨٦٠٢
بيروت، في : ٢٠ آب ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Anesthesia Unit Vaporizers, Tec 6 and Tec 6 Plus Vaporizers

الجهاز المعني بالمتابعة:

- Anesthesia Unit Vaporizers, Tec 6 and Tec 6 Plus Vaporizers
- Trade Mark: GE Healthcare
- Local Representative:

بناء على التقرير الصادر عن الوكالة الأوسترالية TGA والذي يشير الى وجود خلل في عمل الصنف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن الوكالة الأوسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

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Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2013-RN-00237-1
Product Name/Description[iii]	Avance CS2 Anesthesia Carestation All devices are affected ARTG Number: 93955
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Commencement Date[vi]	15/03/2013
Responsible Entity[vii]	GE Healthcare Australia Pty Ltd
Reason / Issue[viii]	The Avance CS2 may experience an intermittent display unit failure while in use, which could result in unexpected system performance and may include the loss of mechanical ventilation and balance gas delivery (Medical AIR or N20)
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	GE Healthcare is advising end users of work around instructions to mitigate safety issues. A correction is planned to be implemented for all affected systems.
Contact Information[xi]	1300 722 229 - GE National Service and Support Centre

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] ***Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the***