REPUBLIC OF LEBANON MINISTRY OF PUBLIC HEALTH

The Director General



الجمهورية اللبناني وزارة الصحة العامة المدير العام

رقم المحفوظات: ٥> / ٧ > رقم اللصادر : ١٣/٧ < ٨٩٦٥ بيروت، في : ٢٩ آي ٣٠١٣

جانب نقيب المستشفيات الخاصة فى لبنان

الموضوع: إشعار بمتابعة جهاز طبي Imaging, patient support, powered table. Platinum X-ray system

الجهاز المعنى بالمتابعة:

- Imaging, patient support, powered table. Platinum X-ray system Trade Mark: APELEM Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود مشاكل في عمل الجهاز المذكور أعلاه مما يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ريطاً:

التوصية الصادرة عن الشركة المصنعة.



المحفو ظات



Museum Street - Hussein Mansour Blg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb



URGENT FIELD SAFETY NOTICE

PLATINUM

Field Safety Corrective Action n° A13060061AA Advice regarding the safe use of the foot rest

Date: 1st July 2013

Attention: Potential risk while using the PLATINUM foot rest

Details on affected devices: PLATINUM x-ray system, Trademark APELEM, with foot rest Ref. Z6F35081

Description of the problem and action to be taken: A use error while setting up the foot rest has been observed that may result in a patient injury.

To address this hazard a service bulletin has been issued. It describes the safe setting up of the foot rest.

Should you have any question, please contact the after sales service team.

Transmission of this Field Safety Notice:

This safety notice needs to be passed on to all those who need to be aware within your organization. Please transfer this notice to other organisations on which this action has an impact.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agencies.

Laure Landucci Quality and Regulatory Affairs Manager



Apelem - DMS Group 175 Allée Von Neumann - 30035 Nîmes Cedex 1 - France

service@apelem.com - +33 466 29 30 05