



رقم المحفوظات: ٤٤٨
رقم الصادر: ١٣/٧/٢٥٩٤٢
بيروت، في: ٠ - آب - ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Therapy, Lasers Laser. STAR Excimer Laser System Models S3,
S4 and S4 IR.

الجهاز المعنى بالمتابعة:

- Therapy, Lasers Laser. STAR Excimer Laser System Models S3, S4 and S4 IR.
- Trade Mark: Abbott Medical Optic
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

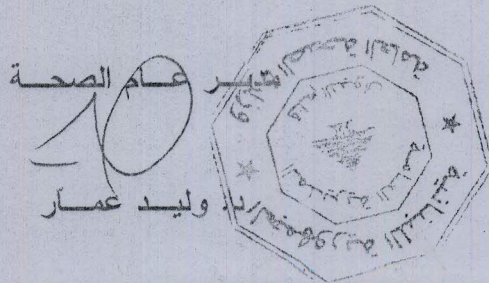
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد
أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات
المعنية.

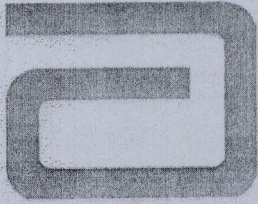
مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات





AMO Ireland
Block B
Liffey Valley Office Campus
Quarryvale, Co. Dublin
Ireland

ADVISORY NOTICE

Abbott Medical Optics (AMO) STAR Excimer Laser System Models S3, S4 and S4 IR

June 4, 2013

Dear STAR Excimer Laser Customer:

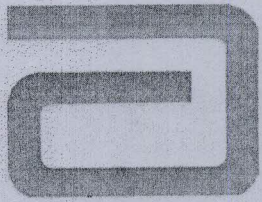
Abbott Medical Optics (AMO) is providing this advisory notice to all customers who use the AMO STAR S3, S4 and S4 IR Excimer Laser Systems to make you aware of an issue that has an unlikely potential to result in inadvertent laser firing. This issue was identified through an in-house training exercise under specific conditions unlikely to occur in a clinical setting. To date there have been no reports of inadvertent laser firing or any injuries associated with this issue.

In AMO's ongoing commitment to safety, we will be replacing a circuit board component in your laser at your next service visit at no additional cost to you. You may continue to treat patients with your laser. AMO has not identified any records of an inadvertent firing of the laser associated with this issue. In the unlikely event that you believe the laser system is initiating a treatment without your direct input, immediately press the Laser Stop button located on the doctor's panel per the instructions contained within the Star Operators manual located in sections titled "General Precautions" and "Turn System Off in Emergency".

For each surgeon at your site, complete and return the attached form to AMO via fax at [insert regional fax number] within the next 3 business days as an acknowledgement of:

- Receipt of this advisory notice
- Understanding of the information contained within this letter

Please share the information in this advisory notice with all personnel who operate your STAR Excimer Laser System(s). AMO appreciates your attention to this issue and we apologize for any inconvenience this action may cause. AMO is committed to providing you with state-of-the-art technology that allows you to perform the safest and most effective laser vision correction treatments possible and as such, we are constantly improving our technology and ensuring it always meets our mutual high quality standards. We appreciate your cooperation in these efforts.



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Quarryvale, Co. Dublin
Ireland

If you have any questions related to the operation of STAR Excimer Laser System or the documentation requirements associated with this letter, please call [insert regional telephone number] and you will be directed to a representative who will be pleased to assist you.

Thank you,

Michelle Hall
Vigilance Specialist
Abbott Medical Optics Inc.