REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧/٢٥
رقم الصادر: ١٢/١/٢٢٥٩
بيروت، في: ٣ تشرين الأول ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Vision One Laser System

الجهاز المعني بالمتابعة:

- Vision One Laser System
- Trade Mark: Lumenis Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA
والذي يشير الى وجود خلل في عمل الصنف المذكور أعلاه مما قد يؤثر على سلامة المريض،
نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
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Medical & Radiation Emitting Device Recalls

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Class 2 Recall
Vision One Laser System Model

See Related Information[21]

Date Posted	September 11, 2013
Recall Number	Z-2191-2013
Product	Vision One Laser System Model GA-0025020, Serial No: 10050, 10051, 10053. Intended for use in the treatment of ocular pathology.
Code Information	Model: GA-0025020
Recalling Firm/ Manufacturer	Lumenis, Inc. 3959 W 1820 S Salt Lake City, Utah 84104
For Additional Information Contact	Mr. Rick Gaykowski 801-656-2690
Reason for Recall	Lumenis has initiated a recall on certain models of Vision One System due to a potential for unintended laser exposure to the user.
Action	Customer's were notified via letter on 8/19/13. Service visits to consignees were scheduled with anticipated completion on 8/26/13 to replace the control board. Consignee monitoring was performed by use of return reply verification tracking cards returned by the Lumenis service engineer after completion of CPU board replacement.
Quantity in Commerce	3 units
Distribution	Distributed in the states of NJ, PA, and IL.

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