

Kingdom of Saudi Arabia عند المملكة الصربية السعودية عند المحادث المملكة الصامة للضفاء والدواء المعلقة المامة المعلقة المعلقة العامة المعلقة العامة المعلقة العامة العامة

Medical Device Sector Surveillance & Biometrics Executive Department قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Restart of the monitor when working with the graphical user interface

| Device/ Product Description: | Intensive care ventilation devices | | |
|------------------------------|--|---|--|
| Affected product: | Models Software Versions | elisa 300, elisa 500, elisa 600, elisa 800, elisa 800VIT SW 2.02.x, 2.04.0, 2.04.1, 2.04.2, 2.05.x | |
| Manufacturer: | Löwenstein Medical Innovation GmbH & Co. KG | | |
| Problem: | A problem with crashes when working with the graphical user interface, which leads to a restart of the control unit (monitor). Under certain circumstances, the screen can be restarted. Ventilation is continued and maintained with the previous settings. | | |
| Recommendation /Actions: | 1- Review this notice and ensure that all affected personnel within your organization are aware of the contents. 2- Follow the instructions provided in Here. 3- Contact the Authorized Representative for required assistance. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center | | |

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| Devices/Products photo: | | | |
|------------------------------|--------------------------|------------------------|--|
| Authorized Representative | AR name: | Bio Standards | |
| Details | Assigned Contact Person: | Ahmed Al Shareef | |
| | Mobile/Phone: | 0545459900 | |
| | Email: | info@bio-standards.com | |

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