

Safety Communication

رسالة سلامة

Restart of the monitor when working with the graphical user interface

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| Device/ Product Description: | Intensive care ventilation devices | |
| Affected product: | Models | elisa 300, elisa 500, elisa 600, elisa 800, elisa 800VIT |
| | Software Versions | 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: | <ol style="list-style-type: none"> 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. <p>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</p> | |

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