isansys

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Urgent Field Safety Notice

Date of Deployment: 14th August 2017
Reference No. 14082017

To: All Healthcare professionals and users of Isansys Patient Gateway

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue: Isansys Lifecare has become aware of a potential safety issue that can occur on the Patient Gateway (Galaxy Samsung Tab S (SMT-800) and Tab S (SMT-805)). In certain circumstances, prolonged continuous charging of the Lithium Polymer batteries can lead to battery damage and expansion within the Samsung Tablet enclosure. Battery damage may lead to excess heat being generated, which could result in fire, charring, smoke, or sparking that could cause thermal injury. There have been no injuries reported as a result of this issue.

Safety Instructions: Turn off[1] the Samsung Galaxy Tab S Tablets, unplug from the mains and remove from the Patient Care environment.

Affected Product:

Serial No. SN	Model No.	Device Name
G0005	SM-T805	Patient Gateway
G0006	SM-T805	Patient Gateway
G0009	SM-T805	Patient Gateway
G0010	SM-T805	Patient Gateway
G0011	SM-T805	Patient Gateway
G0015	SM-T805	Patient Gateway
G0016	SM-T805	Patient Gateway
G0017	SM-T805	Patient Gateway
G0023	SM-T805	Patient Gateway
G0024	SM-T805	Patient Gateway
G0025	SM-T805	Patient Gateway
G0026	SM-T805	Patient Gateway
G0027	SM-T805	Patient Gateway
G0028	SM-T805	Patient Gateway
G0029	SM-T805	Patient Gateway

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[1] Turn the Patient Gateway off by removing the plug on the back of the bezel, and pressing and holding the start button. Reference PDE2 Quick start Guide.

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G0030	SM-T805	Patient Gateway
G0031	SM-T805	Patient Gateway
G0032	SM-T805	Patient Gateway
G0033	SM-T805	Patient Gateway
G0034	SM-T805	Patient Gateway
W0006	SM-T800	Patient Gateway
W0007	SM-T800	Patient Gateway
W0008	SM-T800	Patient Gateway
W0009	SM-T800	Patient Gateway
W0022	SM-T800	Patient Gateway
W0024	SM-T800	Patient Gateway
W0027	SM-T800	Patient Gateway
W0028	SM-T800	Patient Gateway
W0031	SM-T800	Patient Gateway
W0032	SM-T800	Patient Gateway
W0033	SM-T800	Patient Gateway
W0034	SM-T800	Patient Gateway
W0035	SM-T800	Patient Gateway
W0036	SM-T800	Patient Gateway
W0038	SM-T800	Patient Gateway
W0039	SM-T800	Patient Gateway
W0041	SM-T800	Patient Gateway
W0042	SM-T800	Patient Gateway
W0043	SM-T800	Patient Gateway
W0044	SM-T800	Patient Gateway
W0048	SM-T800	Patient Gateway
W0049	SM-T800	Patient Gateway
W0054	SM-T800	Patient Gateway
W0055	SM-T800	Patient Gateway
W0056	SM-T800	Patient Gateway
W0057	SM-T800	Patient Gateway
W0058	SM-T800	Patient Gateway

Product Correction: Isansys Lifecare Ltd will inspect and replace all affected products. An Isansys Lifecare representative will contact you to arrange for the inspection, collection and replacement of all affected items.

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Contact Information: If you have any questions or concerns regarding this notification, please contact Isansys Lifecare Ltd for an immediate response.

UK Technical Support Representative
Mat Key
01235 436225 or mat.key@isansys.com

UK Regulatory Affairs
Julian Jones
01235 436228 or julian.jones@isansys.com

Please be assured that maintaining the highest level of safety and quality is our highest priority. If you have any questions, please contact us immediately as per the contact information above.

Sincerely,

Julian Jones
Chief Compliance Officer
Isansys Lifecare Ltd.

Keith Errey
Chief Executive Officer
Isansys Lifecare Ltd.