Urgent Field Safety Notice

SONY LMD-1951MD MONITORS
Possibility of monitor switching off or not displaying image
Medical Device Recall

Date: 14th January 2015

Attention: All relevant personnel

Dear Customers and Users of the SONY LMD-1951MD monitors,

The purpose of this letter is to advise you that Sony Corporation and its European Authorised Representative Sony Deutschland GmbH (hereafter "Sony") are executing a voluntary Field Safety Corrective Action in relation to its LMD-1951MD 19 inch medical grade liquid crystal display (LCD) monitors with light-emitting diode (LED) backlight technology.

The corrective action is intended to address a potential issue that could affect the performance of the LMD-1951MD monitors.

Sony has discovered through reports from the market that, in some situations, a LMD-1951MD monitor has either not turned on or has lost image during clinical use. Sony has not received any injury reports relating, either directly or indirectly, to this potential issue. As a precautionary measure and in order to ensure compliance with applicable requirements, Sony has decided to take the measures identified in the table below in relation to the LMD-1951MD monitor.

No other Sony monitors are affected by this voluntary Field Safety Corrective Action.

Our records indicate that you have purchased one or more LMD-1951MD monitors.

AFFECTED PRODUCTS	SONY LMD-1951MD Monitors with the following serial numbers: 3000038-3004884, 3100035-3100058, 3100065-3100145.
PROBLEM DESCRIPTION	The LMD-1951MD monitor either does not switch on or is losing the image during clinical use. Sony's investigation indicates that the issue is the result of a potential disconnection of the internal power supply caused by a failure of a power board integrated circuit. The failure mode does not occur when an AC adapter (AC-110MD) is used with the monitor. To date, Sony has not received any reports of adverse events occurring due to this failure mode. Moreover, all reports from the field regarding this failure mode have been received from non-European countries such as China, Japan and Taiwan. We have concluded from our investigation that this failure mode is not likely to result in adverse health consequences. • If the failure mode occurs during the pre-operative period, the procedure may need to be postponed causing patient and user inconvenience. In this scenario, the patient has not yet been anesthetized. • If the failure mode occurs during the perioperative

	period, it would be reasonably expected that the patient would experience no injury or limited injury (transient, minor impairment) because the patient would be, at most, subjected to a prolonged procedure (and potentially exposed to additional anaesthesia) while a backup system or alternative technique is being used to complete the operation. • In order for the reasonable worst-case injury (i.e. tearing or laceration of a structure, loss of haemostasis causing a haemorrhagic complication) to occur, all of the following events would need to be present: (1) prolonged loss of visualization due to alternative visualization not becoming available in a reasonable time frame; (2) loss of visualization at the precise moment of a critical juncture of the procedure which could not be interrupted (these moments are of very limited duration compared to the overall duration of the procedure); and (3) the surgeon is unable to temporarily hold the structure in place until visualization is restored. The likelihood of these events all happening at the exact moment of loss of visualization is improbable. There could be certain complications if a patient needs to be converted to open surgery. Sony is taking this action to reduce the risk of this failure mode from occurring. As a precautionary measure, Sony asks all customers/users to take the actions identified below.
ACTIONS TO BE TAKEN BY CUSTOMER / USER	1.) Identify existing stocks of the LMD-1951MD monitors. 2.) If you possess an AC adapter (AC-110MD) for each of the affected monitors, use only the AC adaptor when the monitors are in use. 3.) Complete and return to the following email address LMD-1951MDrecall@eu.sony.com the reply form provided on the last page of this Field Safety Notice. 4.) Customers/users who do not possess an AC adapter (AC-110MD) for each of the affected monitors should stop using the monitor and take the monitor out of service until the permanent corrective action described below is implemented.
ACTIONS PLANNED BY SONY	For users who already possess an AC adaptor (AC-110MD) and for each of their affected monitors, Sony plans to modify the monitors as a temporary measure. Once the reply form is received from the customer by Sony, modification kits will be sent to customers as soon as possible with detailed instructions on how to conduct the modification. These modification kits will consist of: (1) a sticker (warning that the AC inlet should not be used) to be affixed to the rear of the monitor; and (2) an adhesive seal to be placed over the AC inlet. As a permanent corrective action, Sony will replace the power board of all affected units with a redesigned power board that does not exhibit this failure mode. The new power boards will be installed during future field service visits beginning around February 2015. You will be contacted immediately by Sony

	once the reply form is received by the company. Sony anticipates that these actions can be implemented in the field within 6 months.
HOW TO IDENTIFY AFFECTED UNITS	The LMD-1951MD monitors with the following serial numbers are affected by this field action: 3000038-3004884, 3100035-3100058, 3100065-3100145. Affected units can be identified by: • Confirming the serial number (7 digits) printed in the warranty certificate; or • Confirming the serial number on the product label affixed at the rear of the product: Rear of the product  Serial number 
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this problem, please contact LMD-1951MDrecall@eu.sony.com.

Transmission of this Field Safety Notice:

Please pass this Field Safety Notice on to all those who need to be aware of this action within your organisation.

Please also ensure that the Field Safety Notice is passed to any organisation to which the Image Display Monitor LMD-1951MD has been transferred or is being used.

Please maintain awareness on this Field Safety Notice both within your organisation and among interested third parties to ensure effectiveness of the corrective action.

In accordance with applicable rules, the competent authorities in your country have been notified of this corrective action.

Sony Corporation apologises for any inconvenience this action may cause you. If you have any questions or concerns, please contact us.

Thank you for your continued support.

Name: Maschke, Henrike
Title: Safety Officer for Medical Device in accordance with Section 30 of the German Act on Medical Devices
Signature

Manufacturer of the SONY LMD-1951MD monitors

Sony Corporation
1-7-1 Konan, Minato-ku
108-0075 Tokyo,
Japan

European Authorised Representative
Sony Deutschland GmbH
Stuttgart Technology Centre
Hedelfinger Str. 61
70327 Stuttgart, Germany

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Reply Form

Sony is committed to providing the highest quality products to its customers. We would be grateful if you could acknowledge receipt of this Field Safety Notice by communicating with us at the following email address LMD-1951MDrecall@eu.sony.com within 10 calendar days of receipt of this Notice.

Company Name:	
Contact Name:	
Phone number:	
Email address:	
Address:	

Please complete as appropriate:

☐ I have no inventory of LMD-1951MD monitors.

☐ I have inventory of LMD-1951MD monitors with the following serial numbers:

☐ Number of LMD-1951MD monitors: [ ].

☐ Number of LMD-1951MD monitors for which I possess an AC adapter (AC-110MD).

☐ Our LMD-1951MD monitor(s) is/are no longer in service and was/were discarded.

☐ I have transferred the purchased LMD-1951MD(s) to:

Customer / Facility Name:	
Customer / Facility Address:	
Details of installation (e.g. examination or operating room; AC adaptor used; AC inlet used):	
Serial numbers:	
Comments:	

Name Date
Signature