

Urgent Medical Device Field Correction - Immediate Action Required

Sony LMD-1951MD Monitor used with SpyGlass

DATE

Dear Materials Manager / Field Action Contact:

Boston Scientific, on behalf of Sony Electronics Inc., is implementing this Medical Device Field Correction for specific Sony LMD-1951MD Monitors used with SpyGlass. In some situations, the Sony Monitor may either not turn on, or may lose image during use. 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 is used with the monitor. See Background Information (page 5) for Sony risk assessment of this issue.

Immediate Action to be taken by customer

- 1) If you possess an AC adapter for your affected monitors, only use the AC adapter when the monitors are in use.
- 2) If you do not possess an AC adapter for each of the affected monitors, stop using the monitor and take the monitor out of service.
- 3) For each of the affected monitors follow the Sony correction instructions document enclosed with this letter (*AC Adapter Setting Procedure and Completion Report*). Per the instructions (1) affix the warning sticker (warning that the AC inlet should not be used) to the rear of the monitor; and (2) place the adhesive seal over the AC inlet.

*If you no longer have an AC Adapter you may contact Sony to request a replacement at:

Phone: 1-866-789-7669

E-Mail: LMD1951MD.Support@am.sony.com

Permanent corrective action to be taken by Sony Electronics, Inc.

Sony Electronics Inc. will send a representative to your facility to replace the power board of any 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 in approximately February 2015. **You will be contacted beginning in February 2015 with respect to scheduling the replacement of the power board. Until the unit(s)' power board has been replaced, continue to follow the Immediate Action above.**

This issue only affects Spy Glass Video Monitors (SONY LMD-1951MD) in the table below. Affected products can be identified by confirming the serial numbers on the product label affixed at the rear of the monitor.

Affected Sony Monitors used with SpyGlass

Product Description	Material Number (UPN)	Serial Number
SONY LMD-1951MD MONITORS	M00546120	3000858, 3000971, 3000998, 3001001, 3001002, 3001003, 3001006, 3001007, 3001009, 3001011, 3001014, 3001017, 3001018, 3001019, 3001020, 3001022, 3001023, 3001024, 3001025, 3001026, 3001027, 3001222, 3001242, 3001259, 3001278, 3001358, 3001368, 3001371, 3001372, 3001373, 3001374, 3001376, 3002007, 3002008, 3002009, 3002011, 3002012, 3002013, 3002014, 3002016, 3002017, 3002031, 3002033, 3002036, 3002037, 3002038, 3002039, 3002040, 3002042, 3002043, 3002044, 3002116, 3002117, 3002118, 3002120, 3002121, 3002122, 3002124, 3002126, 3002127, 3002131, 3002168, 3002173, 3002174, 3002178, 3002180, 3002197, 3002358, 3002359, 3002398, 3002401, 3002402, 3002408, 3002411, 3002464, 3002472, 3002476, 3002478, 3002479, 3002480, 3002507, 3002525, 3002527, 3002528, 3002529, 3002530, 3002531, 3002532, 3002533, 3002535, 3002972, 3002978, 3002983, 3002987, 3002989, 3002990, 3002992, 3002999, 3003004, 3003027, 3003029, 3003037, 3003055, 3003057, 3003060, 3003061, 3003063, 3003072, 3003074, 3003075, 3003076, 3003077, 3003087, 3003095, 3003099, 3003100, 3003128, 3003129, 3003130, 3003131, 3003133, 3003134, 3003135, 3003136, 3003137, 3003168, 3003170, 3003171, 3003173, 3003174, 3003176, 3003178, 3003257, 3003258, 3003259, 3003261, 3003262, 3003267, 3003268, 3003274, 3003275, 3004233, 3004234, 3004236, 3004237, 3004238, 3004239, 3004250, 3004254, 3004355, 3004361, 3004376, 3004380, 3004630, 3004660, 3004792, 3004810, 3004819
	M0054612S0	3001841, 3001849
	M0054612Z0	3001355, 3002477, 3002986, 3003003

Please Note: The affected Sony Monitors used with SpyGlass are not being recalled and you are not required to return your Sony Monitor used with SpyGlass to Boston Scientific.

Please read carefully through the enclosed Field Correction Instructions. Your local Sales Representative can answer any questions that you may have regarding this Field Correction.

We appreciate your understanding as we take action to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

Name

Title

Phone

E-mail

Encl: Field Correction Instructions

Account Reply Verification Tracking Form

Sony Immediate Action kit (AC Adapter Setting Procedure and Completion Report and stickers)

Urgent Medical Device Field Correction - Immediate Action Required

Field Correction Instructions

The account Reply Verification Tracking Form and AC Adapter Setting Procedure and Completion Report enclosed with this Customer Field Correction Notice must be completed and returned.

1. **Immediately follow the enclosed AC Adapter Setting Procedure and Completion Report from Sony to seal the AC inlet and affix the warning label.**
2. **Complete and return the Account Reply Verification Tracking Form (RVTF), and AC Adapter Setting Procedure and Completion Report.**
 - Complete the enclosed Account Reply Verification Tracking Form following the directions on this page and the Account Reply Verification Tracking Form.
 - Fill out the bottom portion of the AC Adapter Setting Procedure and Completion Report.
 - Return both the Account Reply Verification Tracking Form and the AC Adapter Setting Procedure and Completion Report:

Email: E-mail

or

Fax to: Fax Number

Please email or fax your Account Reply Verification Tracking Form(s) and Sony AC Adapter Setting Procedure and Completion Report immediately upon completing the steps above. Please return both your reply form and AC Adapter Setting Procedure and Completion Report on or before Monday March 9, 2015.