

Date: Thursday, May 28th, 2015

Reference: 9313188-05282015-001-C_Medical_Device_Correction_Notice

To: Sales Partners Barco Surgical Displays

From: Dries Geldof, Director Quality Barco
Erik De Kuyffer, Customer Service Manager Barco

URGENT MEDICAL DEVICE CORRECTION NOTICE

Dear,

We would like to inform you about a field corrective action that Barco proposes to implement on the Barco surgical displays listed below. Please ensure that your customers and users are made aware of this notification and the recommended actions and that you are the primary contact for them concerning this issue. Please provide each of your customers or users with a copy of this notice.

Products involved

Display	Part Number	Additional Part Number
Surgical Display MDSC-2224 (24 inch)	K9307916	991932387121
	K9307917	991932387131
	K9307912	991932387071
	K9307913	991932387081
Surgical Display MDSC-2226 (26 inch)	K9307907	991932387031
	K9307906	991932387011
	K9307908	991932387021
		991932387041
		991932387111
		991932389071
		991932389081
	991932389091	
	991932387061	
	991932387141	
Surgical Display MDSC-2242 (42 inch)	K9307914	991932387091
	K9307915	991932387101

Problem Description

The surgical display types listed above could lose the user- defined settings, including failover, under the following condition

After being in stand-by mode or being in autosearch mode for at least an accumulative time of 4,152 hours (173 calendar days) and the unit is powered off and back on or went in stand-by mode and back on .

The accumulative time does not need to be continuous. One of the lost settings is the user setting for automatic failover switching.

Barco has investigated this behavior and confirms that both the failover mode and user (defined) profile settings will indeed be lost on the products involved. However, the factory settings are never lost.

The behavior is caused by a firmware issue on the Barco surgical displays listed above.

Potential Risks

There is a potential risk in applications where the user settings for automatic failover are used during surgical procedures. In the above described conditions, if the failover mode has been set by the user and the active image source drops, there is potential risk not to get the automatic source switch to the failover channel (although manual switching is still possible). As a consequence, the image on the display will go black during the surgical procedure.

If you use the default factory setting, this failover issue does not occur.

Interim Corrective Action

In case the installation has been pre-cabled, and activated for automatic failover, and the end-user relies on this behavior and the device has been installed and used for longer than 173 calendar days, as a short term solution we recommend to either

- Verify the correctness of the failover mode setting in the user settings before each use; or
- Disable the failover mode in the user settings of the OSD and if needed switch manually to the backup source.

With this intermediate fix, the display can continue its normal operation, until the final corrective action will be implemented.

Users which do not use failover user settings are not affected by this issue.

For the displays that are currently still in the warehouse, please do not to ship them to end customers.

Final Corrective Action

Barco has identified the root cause. The new firmware version to fix this issue still needs to be validated and tested. The new firmware will be released within 2 to 5 weeks.

When the firmware is available, implement this corrective action especially in case the end-user relies on the failover mechanism.

Implementing the solution can be carried out through a local firmware upgrade by either you (i.e. display reseller) or Barco.

Barco will provide an upgrade kit consisting of the tools, instructions, labels and new firmware. If additional assistance or information is required, please contact Barco.

While all relevant units in your or your customers' possession should be upgraded, those originally shipped to you prior to December 2014 should be the first priority for upgrading.

Next Steps

- Please send this notice to your customers or other organizations on which this action has impact
- For the displays that are currently still in the warehouse, do not ship them to end customers.
- Contact Barco within 2 weeks of receipt of this notice, to coordinate the receipt and quantity of the upgrade kits needed. Barco will contact you, once the upgrade kit becomes available.
- Please send back to Barco the attached acknowledgment letter and questionnaire by e-mail within 7 days of receipt of this notice.

Contact reference person

In case of questions about this corrective action, please contact our service team at

For US and Canadian customers: <mailto:service.medical.usa@barco.com>

For all others: <mailto:service.healthcare.emea@barco.com>

Barco confirms that this corrective action has been reported to the appropriate Regulatory Agencies.

We sincerely apologize for the inconvenience,

Geldof Dries,
Quality Director

Erik De Kuyffer
Customer Service Manager