

Date: February 28, 2017

Reference: C9826109-22022017-001

To: Sales Partners Barco Displays

From: [REDACTED]

## URGENT MEDICAL DEVICE CORRECTION NOTICE

Dear Sir or Madam,

We would like to inform you about a safety-related update of the Installation Instructions for the MDRC-1119 Protective Front Cover Kit. 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
MDRC-1119 Front Cover Kit	C9826109
	C9826096
	C9826097
	C9826108

### Problem Description

We have received information about an event where the metal strips for fixation of the protective front cover have been removed from a display and re-applied to another display. As a result the strips are deformed resulting in a smaller contact surface with the front cover magnet strips. If the magnets no longer firmly attach to the metal strips, there is a risk that the protective front cover comes loose and may fall down.

### Potential Risks

If the protective front cover detaches from the display there is a potential risk that a person may be harmed when standing or sitting nearby. The front cover weighs about 400 grams and has sharp edges.

### Interim Corrective Action

There are no interim corrective actions required.

### Final Corrective Action

Barco has updated the Installation Instructions with the following warning:

**Warning: The metal strips are designed for single use only and shall never be re-applied after sticking the protective cover to the front of the LCD monitor since this could cause the protective cover to fall off which might result in serious personal injury.**

Please also note that the MDRC-1119 display, on which the protective front cover is used, is not certified for near-patient applications (see MDRC-1119 User Manual “Intended Use” statement.)

### Next Steps

- Please send this notice to your customers or other organizations on which this action has impact
- Please send back to Barco the attached acknowledgment letter 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,



**Date:** February 28, 2017

**Reference:** C9826109-22022017-001\_Acknowledgement\_Letter

**To:** Sales Partners Barco Displays

**From:** [REDACTED]

Dear Sales Partner,

Please complete this document and send it back to our service department within 7 days of receiving the Urgent Medical Device Correction Notice using one of the following e-mail addresses

- For US and Canadian customers : <mailto:service.medical.usa@barco.com>
- For all others : <mailto:service.healthcare.emea@barco.com>

I, \_\_\_\_\_ [Please fill in your name and position/title] of \_\_\_\_\_ [Please fill in the company name], hereby confirm to have received, read and understood the Urgent Medical Device Correction Notice on the Barco surgical displays.

I further confirm that we have provided this notice to our customers and organizations on which this has an impact.

Signature:

Date:

# **Protective Cover Installation**

## **MDRC Series**



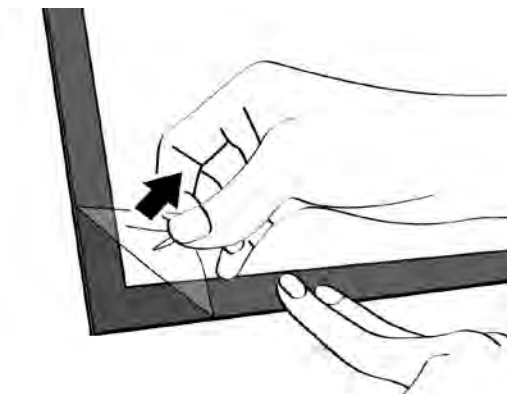
## Mounting procedure:

1. Take out the protective cover from the box and place it inner side up on a clean table.



2. Remove the film from the inner side of the protective cover.

**Note:** Remove the film fast and smoothly at one time.

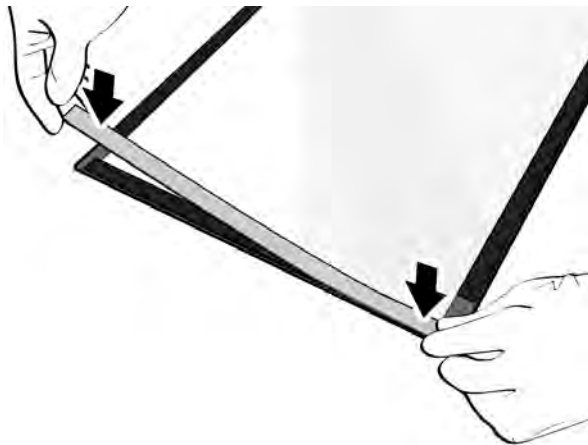


- Using gloves, align, and stick the 4 metal strips on the magnetic strips on each side of the protective cover.



**Warning:** The metal strips are designed for single use only and shall never be re-applied after sticking the protective cover to the front of the LCD monitor since this could cause the protective cover to fall off which might result in serious personal injury.

**Note:** Wear gloves to prevent fingerprint or dust on the protective cover.



4. The picture below shows the completed 4 metal strips.



5. Tear off the double tape on the metal strips.





6. The picture below shows the tear off tape of the 4 metal strips.



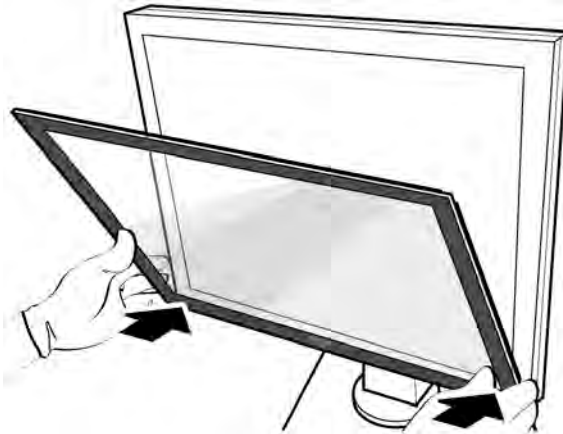
7. Well align and stick the protective cover on the front cover of the LCD monitor from bottom to top.



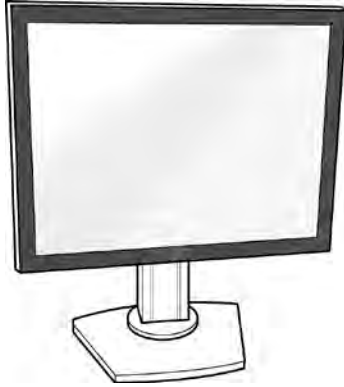
**Warning:** Make sure that protective cover is properly positioned on the LCD monitor.



**Warning:** The metal strips are designed for single use only and shall never be re-applied after sticking the protective cover to the front of the LCD monitor since this could cause the protective cover to fall off which might result in serious personal injury.

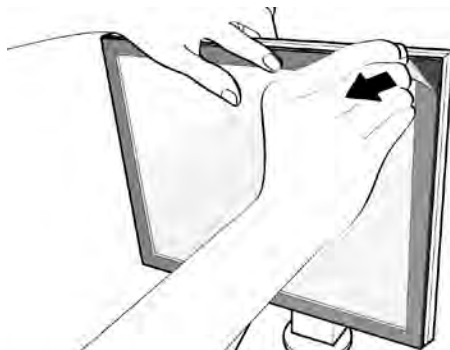


8. After mounting, press around the rim of the protective cover and leave it for at least 4 hours to allow the tape to adhere properly.



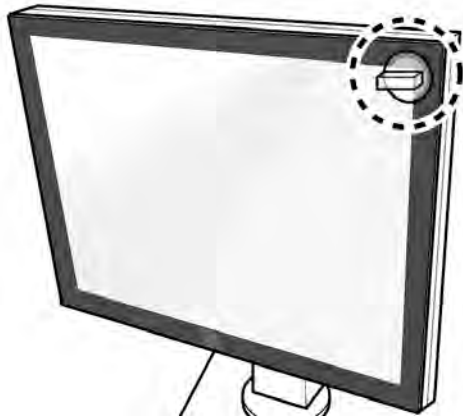
9. Remove the protective film from the outer side of the protective cover. The mounting procedure is then completed.

**Note:** Remove the film fast and smoothly at one time.



## **Dismounting procedure:**

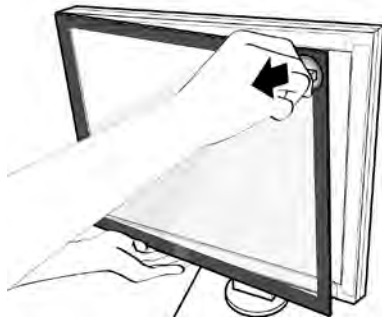
1. Take out the suction cup from the box and stick it on the upper-right corner of the protective cover.



2. Use the suction cup to remove the protective cover from the LCD monitor.



**Warning:** The metal strips are designed for single use only and shall never be re-applied after sticking the protective cover to the front of the LCD monitor since this could cause the protective cover to fall off which might result in serious personal injury.



3. After removing the protective cover from the LCD monitor, push the tab to remove the suction cup from the protective cover. The dismantling procedure is then completed.

