

DATE 15-Jul-2022

Urgent Field Safety Notice

MNA-240 ENC – Update of Installation Instructions

For Attention of: Barco Valued Customer

Dear Madam or Sir,

We would like to inform you about a safety-related update of the installation instructions in the Instructions for Use of MNA-240. The updated instructions are sent along with this Notice.

This action will be reported to the appropriate regulatory Authorities.

Attached to this Notice are 2 response forms. Please complete and return response form 1 after receiving this Notice, and response form 2 after completion of the instructions in this Notice.

Affected products and how to identify them:

Part number	Model Name
K9303078A	MNA-240 ENC DP
K9303097A	MNA-240 ENC DP MQ
K9303099A	MNA-240 ENC DP OL

Part number and revision can be found on the product label:

The product label contains the following information:

- BARCO** logo and address: Barco NV, President Kennedypark 35 8500 Kortrijk - Belgium
- FC** (FCC) compliance notice: This device complies with part 15 of the FCC rules. Operation is subject to following two conditions: (1) This device may not cause harmful interference (2) This device must accept any interference received including interference that may cause undesired operation.
- CAN ICES-001 (B)/NMB-001 (B)** and **MADE IN BELGIUM** / 比利时制造 合格证
- Model - 显示器 - 产品型号: MNA-240**
- Type 类型: ENC DP**
- I-MAX: 4 A**
- U-NOM: 12V DC** and date **2021-10-05**
- Regulatory symbols: CE, IS 13252 (Part 1)/IEC 60950-1, UL CERTIFIED, MD, R-41008141, www.bis.gov.in, BARCO-BEL/MD/001161
- REF K9303078A** (Part Number)
- REVISION: 版本 X16** (Revision)
- UDI** (01)05415334000056 (11)211005 (21)2530617367
- SN** 2530617367



Reason for this action:

Barco has become aware of several installations in operating rooms where the way of installing the MNA encoders caused the internal temperature in the encoder to exceed the maximum specification, which increased the risk of malfunction.

After internal investigation Barco decided to update the Instructions for Use with more detailed instructions how to install the encoders to allow an optimal airflow and to avoid overheating.

Potential risks:

If the installation does not allow an optimal airflow inside and around the MNA encoder, there is an increased risk of malfunction, potentially leading to image loss during a surgical procedure.

Actions to be taken by the customer:

1. Fill out and send back Response Form 1 to your Barco Key Account Manager after receipt of this Notice.
2. Read the updated installation instructions, including the potential risk of wrong installation.
3. Inform your relevant partners and ask them to evaluate if their installations must be adapted.
4. Fill out and send back Response Form 2 to your Barco Key Account Manager after completion of the actions.

If you need any further information or support concerning this issue, please contact your Barco Key Account Manager.

We truly regret any inconvenience this may cause on your end and appreciate your understanding and co-operation.

Sincerely yours,

XXX

Barco NV

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ENABLING BRIGHT OUTCOMES



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Response form 1 (after receiving the FSN)

To: Barco Key Account Manager

From: (Name, position and company)

I hereby confirm to have received, read and understood the Urgent Field Safety Notice regarding the Barco MNA-240 ENC DP devices.

Estimated time of completion of the actions:

Signature:

Date:



Response form 2 (after completion of the actions)

To: Barco Key Account Manager

From: (Name, position and company)

I hereby confirm to have completely executed the actions described in this notice. I declare that 100% of our relevant partners have been informed about the updated installation instructions and the risk of not complying to them.

Signature:

Date:

