

DATE 15-Jul-2022

Urgent Field Safety Notice

MNA-240 ENC DP KS – Update of Installation Instructions

For Attention of: KARL STORZ SE & Co. KG

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
K9303098A	MNA-240 ENC DP KS
K9303078A	MNA-240 ENC DP

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

BARCO Barco NV
 President Kennedypark 35 8500 Kortrijk - Belgium

FCC
 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)
 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 KS
I-MAX: 4 A
U-NOM: 12V DC 2020-11-12

R-41008141
 www.bis.gov.in

REF: K9303098A Part Number
REVISION: 版次 X08 091011 Revision
UDI (01)05415334001664
 (11)201112
 (21)2530472321
SN 2530472321



Reason for this action:

Barco has become aware of an incident, reported by a hospital to the Authorities, where the affected device has malfunctioned, resulting in loss of video output. Barco has determined that the root cause is related to the way of installing the MNA encoders, causing the internal temperature in the encoder to exceed the maximum specification.

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. Inform your end customers about the updated installation instructions and notify them about the potential risk of wrong installation.
3. Ask your customers to inspect all installations. Where the installation is not conform the new installation instructions, adapt the installation and take the necessary measures to reduce the risk of temperature increase.
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,



EVP Surgical & Modality

Barco NV



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 KS 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. 100% of the installations have been inspected and have been adapted according to the updated installation instructions, or have otherwise been found to comply with the updated installation instructions.

Signature:

Date:

