

Antony, October 13, 2018

Important safety notice about our BM Medical TERMINAL UNIT range

This letter is addressed to AIR LIQUIDE MEDICAL SYSTEMS customers in charge of the installations and to the end users of the products concerned by this information

File reference: R1816156 / FRC 18-0589

Dear customers, Air Liquide Medical Systems is voluntarily issuing a safety notice concerning the parts in the BM standard NF Medical Terminal Unit range, namely:

- BM 000100 - MEDICAL TERMINAL UNIT BM O2 NF
- BM 000200 - MEDICAL TERMINAL UNIT BM VACUUM NF
- BM 000300 - MEDICAL TERMINAL UNIT BM AIR NF
- BM 000400 - MEDICAL TERMINAL UNIT BM N2O NF
- BM 000500 - MEDICAL TERMINAL UNIT BM N2 NF
- BM 000800 - MEDICAL TERMINAL UNIT BM CO2 NF
- BM 005000 - MEDICAL TERMINAL UNIT BM AIR-800 NF

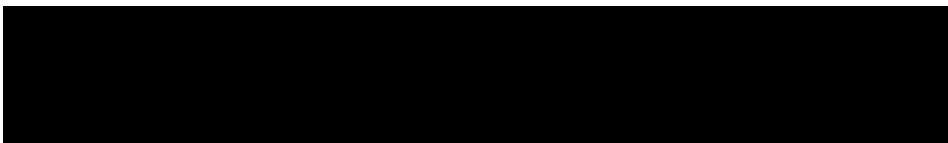


As part of its post-market monitoring, one case of inability to connect a Medical Device (namely a flow meter) to a BM Oxygen Medical Terminal Unit from batch 18-04 was reported to AIR LIQUIDE MEDICAL SYSTEMS.

AIR LIQUIDE MEDICAL SYSTEMS has detected a manufacturing quality defect in BM MEDICAL TERMINAL UNITS during the chrome-plating phase.

We request that you distribute this safety notice to all your installer customers and to healthcare facilities' end users.

We apologize in advance for the inconvenience caused by this safety measure. Yours sincerely,



Air Liquide Medical Systems

PARC DE HAUTE TECHNOLOGIE

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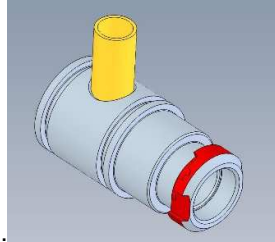
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www.device.airliquidehealthcare.com

Important safety notice

R18 16156

Problem description



Exceedance of the normative diameter D tolerance
(25 +/-0.1)

Red area in the drawing.

Products affected

BM MEDICAL TERMINAL UNIT range

Part numbers: BM000100, BM000200, BM000300, BM000400, BM00500, BM000800 et BM005000

Batches 17-10 to 18-07.

Potential risk

Difficulties in assembling the BM medical terminal unit during the installation phase may occur.

In very rare cases, when the BM medical terminal unit has been installed using a tightening nut **not manufactured by AIR LIQUIDE MEDICAL SYSTEMS**, it **may not be possible** to connect a medical device that uses the NF S90-116 standard.

For the attention of installers before implementation

Potential Risk Assembly difficulties during the installation phase of the BM medical terminal unit may occur.

We request that our installer customers carry out a check of their stock before installing the device in a healthcare facility.

Case of installation of the device with the lock nut manufactured by AIR LIQUIDE MEDICAL SYSTEMS

If the device is intended to be installed using the lock nut supplied by Air Liquide Medical Systems with the following part numbers

- BM001200, BM00100, BM001100 - BM Connector Housing Range
- BL050100 - Nickel-plated lock nut sold as spare part

If this nut does not fit on the D25, this means that the BM Medical Terminal Unit is not in compliance and should not be installed.

We would also like to remind you that the assembly of this nut must be carried out properly, i.e. without forcing and without using an operating tool.

We also remind you that this nut must not be modified to facilitate assembly.

Case of installation of the device without the lock nut manufactured by AIR LIQUIDE MEDICAL SYSTEMS

If the device is intended to be installed using a nut that is not supplied by Air Liquide Medical Systems. It is essential to check the external diameter of the BM medical terminal unit in terms of its diameter (D25 +/- 0.1) to ensure that it complies with the NF S90-116 standard.

Should any non-compliance be detected during this inspection, please return the defective item through the usual channels used to deal with your non-compliances.

For attention of users

Potential Risk **In very rare cases**, when the BM medical terminal unit has been installed using a tightening nut **not manufactured by AIR LIQUIDE MEDICAL SYSTEMS**, it **may not be possible** to connect a medical device that uses the NF S90-116 standard.

To date, only one site has reported this case of connection incompatibility to AIR LIQUIDE MEDICAL SYSTEM.

It is only in very rare cases that it is impossible to connect a medical device to the BM medical terminal unit.

Nevertheless, Air Liquide Medical Systems, in consultation with its regulatory authority (ANSM), requests that you be alert to any inability to connect a medical device that may occur:

- When a new nursing station is being opened,
- When replacing equipment intended to be plugged into existing BM medical terminal units.

If this connection incompatibility does eventually arise, please contact your usual contact person.
