Field Safety Notice

Affected Device
medin-NC3 (REF 3000)
Medin Reference ID: MEDIN-FSN-2026-001
BfArM Nr: 30339/26
FIMEA Reference ID: P3732

Olching, 2026-07-20

1. Sender

Manufacturer	medin Medical Innovations GmbH Adam-Geisler-Str. 1 82140 Olching Germany

2. Addressee

This Field Safety Notice is intended for the following recipients when the affected configuration described in Section 3 applies:

- Healthcare professionals, users and operators of affected medin-NC3 devices.
- Local distribution partners and authorized service partners responsible for identifying affected devices, informing affected customers and arranging the required software update.

3. Identification of the affected medical devices

Product category	NEONATAL/PEDIATRIC VENTILATORS (EMDN Z1203010503)
Affected device	medin-NC3, REF 3000, UDI-DI 0406013900101
Affected configuration	All medin-NC3 devices are equipped with the HY-LINE H2B665 battery and running software versions earlier than CPU V1.2, Display V111, and Pneumatic A14.00.
Required corrected configuration	Devices equipped with the HY-LINE H2B665 battery shall be operated with CPU software version V1.2 or later, Display software version V111 or later, and Pneumatic software version A14.00 or later.
Not affected	Devices equipped with the HY-LINE H2B665 battery and running CPU software version V1.2 or later, Display software version V111 or later, and Pneumatic software version A14.00 or later.

4. Description of the Problem, Including the Identified Root Cause

medin has identified that medin-NC3 devices equipped with HY-LINE H2B665 battery operated with software below CPU V1.2, Display V111 and Pneumatic A14.00 may issue a medium-priority temperature alarm. The exact alarm name / device alarm text is: **“Temperature”**.

The alarm condition may occur during operation when the new internal battery type HY-LINE H2B665 is installed without the corresponding software update. Based on medin’s technical assessment to date, the alarm is a false / nuisance temperature alarm and does not indicate confirmed overheating of the device.

Identified root cause: the affected battery type requires the corrected software configuration to monitor and interpret the relevant battery parameters correctly. Older software versions do not fully support this battery configuration and may therefore trigger the temperature alarm although the device is not actually overheating.

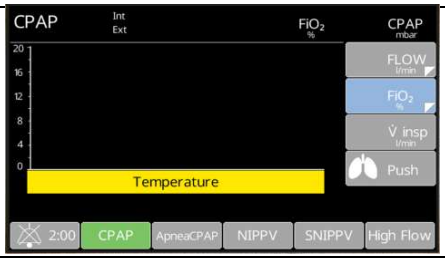

Fig. 1 – Device alarm message placeholder

4.1 Background

For the medin-NC3 devices, a new internal battery type, HY-LINE H2B665, has been introduced. This battery type requires the software configuration specified in Section 3. Accordingly, this FSCA involves identifying all affected devices running software versions earlier than those specified in Section 3 and updating them to the required software configuration.

4.2 Risk to patients, users or third parties when using the product

A direct technical risk resulting from overheating is not anticipated, as no actual overheating has been observed to date. The relevant indirect risk is the potential for user uncertainty or an unnecessary replacement of the device. Depending on the clinical situation, this may result in a temporary interruption of therapy or require additional interventions on the patient.

Alarm behavior after acknowledgment: The alarm cannot be cleared by acknowledgment and will remain active until the required software update has been performed.

Until the software update has been completed, the alarm should be treated as a relevant device alarm. Users should follow their local clinical procedures, ensure appropriate patient monitoring, and contact the distributor / authorized service partner responsible.

4.3 Patients already treated with affected devices

No specific follow-up action is required for patients previously treated with an affected medin-NC3 device if the alarm did not occur and no clinical issue was observed.

5. Measures to be taken by the addressee

For medin-NC3 devices meeting the affected configuration described in Section 3, the following actions are required.

5.1 Actions for healthcare professionals, users and operators

- Affected devices shall be made available to the distributor responsible or authorized service partner for implementation of the required software update.
- If the temperature alarm occurs, follow the device instructions and applicable local clinical procedures. Ensure appropriate patient monitoring, assess whether it is safe to continue therapy, and contact the distributor responsible or authorized service partner without delay.
- Following the occurrence of the alarm, the device should not be returned to routine clinical use until the required software update has been completed, unless continued use is clinically necessary.

5.2 Actions for distribution partners and authorized service partners

- Identify all medin-NC3 devices in your installed base that meet the affected configuration in Section 3.
- Inform only customers with affected devices and arrange the required software update.
- Update affected devices to CPU V1.2 or higher, Display V111 or higher and Pneumatic A14.00 or higher in accordance with the applicable Service Manual and medin instructions.
- Ensure that any battery replacement using the affected battery type HY-LINE H2B665 is performed together with the required software update, and document completion of the action.

6. Sharing of this Field Safety Notice

Please ensure that this Field Safety Notice is shared with all people within your organization who need to be aware of the affected device configuration and the required actions. Distribution partners and authorized service partners shall forward this information only to customers with affected medin-NC3 devices as defined in Section 3.

7. Contact Person

Should you have any questions, please contact your local distribution partner or medin Medical Innovations GmbH.

Email: jmetzner@medin-medical.com
Phone: +49 81 424 484 647

Confirmation of receipt of urgent safety information

Medin Reference ID: **MEDIN-FSN-2026-001**

By signing below, I confirm that I have received and read the current Field Safety Notice.

By signing below, I confirm that I will follow the instructions regarding the affected device configuration and the required corrective action.

For distribution partners / authorized service partners: by signing below, I confirm that affected customers will be informed and that the required software update will be arranged for affected medin-NC3 devices.

Name:	
Company:	
Country:	
Date:	
Signature:	

Please sign this confirmation and send it by email to your product supplier or to medin Medical Innovations GmbH.

Note: Your contact person in this matter is your local distribution partner.