JFR Medical Instruments GmbH · Wasserwaage 8 · 24226 Heikendorf

pulmedix
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Vorgangsnummer: FSN-2025-09-eva
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Datum: 11.09.2025

**Field Safety Notice (FSN) – Eva exchange Activities (Update)**

**Subject**: Product Correction – eva Non-Invasive Ventilator – Modification of Power Supply

**Reference: KI-00001** dated 20.05.2025, **PKM-2025-06-eva** dated 18.06.2025 and **FSN-2025-07-eva** date 28.07.2025

(*This notice is a follow-up with updates to the Eva exchange activities.* ***No new incident*** *– only update of previous communication.*)

**Product Name**: eva – Non-Invasive Ventilator
UDI: 426049681CubeNIVDY
**Recipients**: Distributors, specialist dealers, medical professionals, users

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**Background**:

This notice is an update to previously published information (KI-00001, PKM-2025-06-eva and FSN-2025-07-eva), where ongoing market surveillance had identified inconsistent operating behavior in a limited number of Eva devices. The cause was traced to fluctuations in the internal control voltage supply.

Specifically, this communication provides an update to section 2 (the Manufacturer's Corrective Actions) to include further information regarding the measures to be taken, the device replacement program and the next steps in the exchange and upgrade of Eva devices.

The information provided in other sections of this notice are duplicate with information already provided in FSN-2025-07-eva (no updates) but are included here to consolidate relevant information in one place, for your convenience.

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**Reason for Correction:**

Market observation (January–June 2025) identified the following trends (≥ 3 similar reports), as previously reported in KI-00001 and PKM-2025-06-eva, now with an updated risk assessment:

a) Faulty control of the air humidifier, resulting in air not being heated or humidified; in some cases, this triggered error messages.

b) Device failed to start or therapy could not be initiated.

c) Device shut down in standby mode (no patient connected) despite power supply, and could only be restarted by disconnecting and reconnecting.

d) Therapy ended without user input and without triggering an acoustic or visual alarm.

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**1. Affected Products**

Product Name: eva – Non-Invasive Ventilator
Serial Numbers: ≤ 01 04 00582 2025

Intended Use (per IFU Section 1.1):
The device is intended for non-invasive, non-life-supporting ventilation of spontaneously breathing adults and children (≥ 13 kg) with respiratory insufficiency, including:

- COPD
- Neurological, muscular, or neuromuscular diseases (e.g., diaphragmatic paralysis)
- Restrictive ventilation disorders (e.g., scoliosis, thoracic deformities)
- Central respiratory regulation disorders
- Obstructive sleep apnea (OSA)
- Obesity hypoventilation syndrome (OHS)

The device is intended for use at home and in medical facilities.
Note: Only suitable ventilation masks according to ISO 17510 may be used.

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**2. Manufacturer's Corrective Actions (Update)**

- Modification of the 3.3 V control voltage supply to stabilize internal electronics.
- Software optimization for better control of power consumption in standby mode.
- All new devices from serial number 101 xx 1000 xxxx are factory-equipped with these modifications.
- The exchange activities are scheduled to be completed by the end of 2025.
- Distributors will plan and carry out the following steps:

a) Appointment Scheduling:

Eva distributor Nova:Med GmbH & Co. KG will contact medical professionals or users directly to schedule an exchange of Eva devices (all devices with serial number ≤ 01 04 00582 2025).

b) Device Exchange:

At the scheduled appointment, Nova:Med staff will provide a fully functional replacement device (already upgraded) and collect the previously used Eva device to be upgraded.

c) Upgrade Coordination:

Upgrade implementation will be coordinated between Nova:Med, Pulmedix GmbH, and JFR Medical Instruments GmbH.

*No further action is required by medical professionals or users.*



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## 3. Risk Assessment

The described issues were reassessed under ISO 14971 risk management, considering previous communications (KI-00001, PKM-2025-06-eva and FSN-2025-07-eva):

- For trends a–c, patients may inhale dry (unheated, unhumidified) air or experience delays in therapy initiation. These do not pose an immediate risk to patients.
- For trend d – observed in less than 1% of devices – the lack of alarm during unexpected therapy termination may pose increased risk for patients with worsening respiratory conditions.

**Recommended Action:**

Patients with worsening respiratory conditions should be closely monitored if using an eva device with serial number ≤ 01 04 00582 2025.

**Guidance: Stable patients vs. Patients with worsening respiratory conditions**

*(as a supplement to the initial risk assessment, to facilitate clinical monitoring)*

**Patients with worsening respiratory conditions:**

- New or increasing shortness of breath (even at rest)
- Decreasing oxygen saturation (e.g., < 90–92%, depending on baseline)
- Increased need for oxygen or ventilation support
- Clinical signs such as tachypnea, cyanosis, confusion, exhaustion
- Recent exacerbation, infection, or hospitalization due to respiratory issues

**Stable patients:**

- No new or increasing respiratory complaints
- Vital signs (including $SpO_2$) within individual normal range
- No increased need for respiratory support
- No recent acute events
- Patient feels consistently stable

## 4. Actions for Users and Operators

- Known errors or unusual behavior should still be reported immediately to the manufacturer or distributor.
- Only approved accessories (masks per ISO 17510) should be used.
- In case of technical irregularities, check power supply and restart if necessary (unplug and reconnect).

**For stable patients:**

- Continued use of affected devices is permitted; no immediate danger is posed.

**For patients with worsening respiratory conditions (see guidance in Section 3):**

- This group requires special attention while using an Eva device with serial number ≤ 01 04 00582 2025 that has not yet been modified.



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- Note for home use: Since many devices are used outside clinical settings, continuous medical monitoring is generally not possible. Therefore, increased vigilance by patients, relatives, or caregivers is essential.

Recommended monitoring actions:

- Daily self-monitoring or observation by relatives, especially for new or increasing shortness of breath, morning fatigue, or discomfort after ventilation.
- Regular checks to ensure the device operated continuously overnight. If possible, verify that ventilation ran as planned throughout sleep.
- Monitor oxygen saturation ($SpO_2$) with a pulse oximeter – either continuously or periodically, especially in the morning.
- Watch for signs of device malfunction, e.g., device off in the morning, unexpected therapy interruption, absence of sounds or warning signals.

Important note on assessing deterioration:

- If health worsens, assess whether this change may be related to known device trends (e.g., therapy interruption without alarm) or the natural progression of the underlying condition.
- In case of uncertainty, technical issues, or signs of clinical deterioration, seek medical advice immediately.

**5. Contact**

John Franco – Responsible Person under Article 15 MDR (PRRC)
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**6. Confirmation**

Please confirm receipt of this notice in writing and report affected devices.
This updated notice has been forwarded to the competent authority in accordance with applicable regulatory requirements. It replaces and supplements previous notices KI-00001, PKM-2025-06-eva and FSN-2025-07-eva.

Thank you for your cooperation and trust.
Sincerely,

11.09.2025

John Franco
JFR Medical Instruments GmbH



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