
URGENT FIELD SAFETY NOTICE
Acutronic Medical Systems AG TV1 Ventilator (REMOVAL)

26 July 2023

Field Safety Notice (FSN) Ref: FSCA-23-003-FSN-1

Attention: Users of the TV1 Ventilator

Dear Business Partners/End-Users,

The purpose of this communication is to inform you of a product Field Safety Corrective Action (FSCA) initiated by Acutronic Medical Systems AG (hereafter "Acutronic") involving the TV1 Ventilator. The TV1 Ventilators were sold by Acutronic Medical Systems AG from October 2010 through October 2018. Accordingly, the TV1 Ventilators have been on the market for 5 to 13 years. These ventilators will require maintenance to remain on the market. As the service life of 5 years has been reached and/or exceeded for the distributed TV1 ventilators, Acutronic Medical Systems AG has made a decision to remove the TV1 Ventilator from the market.

Affected Products

Device Name	Model Reference Number	Description	Affected Devices
TV1 Ventilator	7050.IB 7250.IB 122011	Neonatal and paediatric ventilator	See List of Affected Devices.

Problem Description & Potential Health Risk

The device life of 5 years has been reached and/or exceeded for the TV1 Ventilators. As Acutronic will no longer be supporting servicing of the TV1 Ventilators, risks related to device performance may exist if the devices remain on the market without maintenance. Risks related to the TV1 ventilator not operating as intended could result in potential health risk such as hypoxia and respiratory arrest.

Actions being taken by the manufacturer (Acutronic)

- Prepare and distribute the FSCA package to the Distributor.
- Collect and follow-up on all responses.



- Work with the Distributor (International Biomedical AG) to organize and facilitate the return of the TV1 Ventilators.
- Monitor the responses and status of the TV1 Ventilators.
- Dispose of the returned TV1 Ventilators.

Actions to be taken by the Distributor (International Biomedical AG)

- Acknowledge receipt of the FSCA package, containing this FSN, the FSCA Distributor Response Form, the FSCA End-User Response Form, and the List of Affected Units.
- Read the instructions provided in this FSN.
- Verify the serial number and location of the affected devices.
- Promptly forward the FSCA package, containing this FSN, the FSCA End-User Response Form, and the List of Affected Units to all identified affected users.
- Complete and return the signed FSCA Distributor Response Form as instructed on the form.
- Work with Acutronic to coordinate the return of the TV1 Ventilators.

Actions to be taken by the end-users

- Acknowledge receipt of the FSCA package, containing this FSN, the FSCA End-User Response Form, and the List of Affected Units.
- Read instructions provided in this FSN.
- Verify the serial number and location of the affected devices.
- Forward the FSCA package, including this FSN, to any potential users of the TV1 Ventilators.
- If devices were transferred to another location or organization, promptly forward the FSCA package, containing this FSN, the FSCA End-



Ventilation Beyond Limits

User Response Form, and the List of Affected Units to the respective user(s).

- Complete and return the signed FSCA End-User Response Form as instructed on the form.
- Return the affected devices to the Distributor site as instructed.

How to Identify Affected Devices

- Identify all transport incubators provided by International Biomedical AG.
- Visually inspect each transport incubator to determine if a TV1 Ventilator is installed.

How to Return Affected Devices

We will contact you upon receipt of the fully completed and signed **FSCA End-User Response Form** to arrange the product return.

Contact Information

For questions, concerns or any events that reasonably suggest being related to the subject of this FSCA or to related forms, please email GMB-AMS-FSCAresponsecentre@vyaire.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

Sincerely,

