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

26July2023 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-

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,

Abraham Agboli
Senior Manager, Quality Assurance
Fabrik im Schiffli
CH-8816 Hirzel
Switzerland
Email: abraham.agboli@vyaire.com

Distributor's Field Safety Corrective Action Response Form
FSCA-23-003
Acutronic Medical Systems AG TV1 Ventilator (REMOVAL)

Affected Products (according to FSN *FSCA-23-003-FSN-1*)

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

Distributor Self-declaration

Device Model Reference	7050.IB	7250.IB	122011
Number of affected devices distributed to the market			
Number of distributed devices remaining on market			
Number of affected devices in distributor inventory			
FOR EACH AFFECTED DEVICE PLEASE PROVIDE DETAILS IN TABLE 1 AT THE END OF THIS DOCUMENT. (*add extra page as needed*)			

Mark applicable check boxes below.

☐ I have received the FSCA package, comprising the Field Safety Notice (FSCA-23-003-FSN-1), the FSCA Distributor Response Form, the FSCA End-User Response Form and List of Affected Devices.

☐ I confirm that I understand all the instructions noted within the Field Safety Notice (FSCA-23-003-FSN-1).

☐ I confirm that all affected devices and users have been identified at the end of this document.

☐ The FSCA package has been distributed to all identified affected users.

☐ The FSCA package has **NOT** been distributed to all identified affected users. Please identify end-users not notified and rationale below. *(add table rows as needed)*

End User not Notified	Rationale

☐ I was not able to fulfil the requirements specified in the FSN (FSCA-23-003-FSN-1). Please specify requirements not met and rationale below.

- Rationale_____

Target Response Rate set by Acutronic Medical Systems AG: **100%**

By signing this form, I certify the following (mark applicable check boxes)

Distributor (company name)			
Address of Distributor			
Email address			
Telephone number			
Name of person completing form (please print)			
Function of person completing form			
Signature of person completing form		Date	

PLEASE SEND THIS RESPONSE FORM FOR THIS MANDATORY FIELD SAFETY CORRECTIVE ACTION TO THE FOLLOWING ADDRESS:
GMB-AMS-FSCAresponsecentre@vyaire.com

Contact Information
For responses, feedback, 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

Abraham Agboli
Senior Manager, Quality Assurance
Fabrik im Schiffli
CH-8816 Hirzel
Switzerland

Table 1: Affected Devices

Device Serial Number	Country	User facility name and address

End-User's Field Safety Corrective Action Response Form
FSCA-23-003
Acutronic Medical Systems AG TV1 Ventilator (REMOVAL)

Affected Products (according to FSN *FSCA-23-003-FSN-1*)

Affected Products (according to FSN *FSCA-23-003-FSN-1*) Device Group Name	**Model Reference Number**	**Description**	**Affected Devices**
TV1 Ventilator	7050.IB 7250.IB 122011	Neonatal and paediatric ventilator	See List of Affected Devices.

End-User Declaration

Please answer all the questions by checking the appropriate boxes

1. Have you received the FSCA package, comprising the Field Safety Notice (FSCA-23-003-FSN-1), the FSCA End-User Response Form, and List of Affected Devices? If NO, please elaborate:	YES ☐	NO ☐
2. Have you read and understand the content of the Field Safety Notice (FSCA-23-003-FSN-1), and will you follow the instructions accordingly? If NO, please elaborate:	YES ☐	NO ☐
3. Have you confirmed that all affected devices, TV1 Ventilators provided with International Biomedical AG transport incubators, have been identified? If NO, please elaborate:	YES ☐	NO ☐
4. Have the TV1 Ventilators been transferred to another location/organization? If YES, please specify in Table 1 at the end of this document.	YES ☐	NO ☐
5. If devices were transferred to another location/organization, has the FSCA package been forwarded to the respective users accordingly? If NO, please elaborate:	YES ☐	NO ☐

If you answered NO to questions 1 or 2 please contact your International Biomedical AG or the Contact Information below urgently for clarification.

User Details			
Contact person (name)			
Hospital / Health Care Facility (address)			
Country			
email address			
Date		Signature	

PLEASE SEND THIS RESPONSE FORM FOR THIS MANDATORY FIELD SAFETY CORRECTIVE ACTION TO THE FOLLOWING ADDRESS:
GMB-AMS-FSCAresponsecentre@vyaire.com

Contact Information
For responses, feedback, 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

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Table 1: Transferred Devices

Device Serial Number	Country	User facility name and address