imtmedical	**FORM Field Safety Notice (FSN)**

URGENT FIELD SAFETY NOTICE
bellavista™ Ventilators
Ceasing of Ventilation with Technical Failure Alarm 305
for Field Safety Corrective Action FSCA-2021-001

17 December 2021 FSN Ref: FSCA-2021-001-FSN-1

Attention: Distributors and users of bellavista™ ventilators (1000, 1000 US, 1000e, 1000e US, 1000 neo and 1000 Set).

Dear Customer,

The purpose of this communication is to inform you of a product Field Safety Corrective Action (FSCA) initiated by imtmedical ag, as part of Vyaire Medical, involving bellavista™ ventilators that can cease ventilation and generate a Technical Failure Alarm 305 – "Communication to CFB disconnected."

Affected Devices

The devices affected by this FSCA are stated in the following table:

bellavista™ Model	REF No.	Description	Software Version(s)	Conditions for Device to be Potentially Affected	Indentifying Affected Devices
BV 1000	301.100.000	bellavista™ ventilator	6.0.1600.0 or higher	Software option "Data Communication" installed *AND* data communication port configured to "HL7"	Refer to the separate, attached document, *Appendix to Urgent Field Safety Notice FSCA-2021-001-FSN-1: Units Affected List for FSCA-2021-001*
BV 1000 US	301.100.030				
BV 1000e	301.100.100				
BV 1000e US	301.100.130				
BV 1000 neo	301.100.060				
BV 1000 Set	301.100.200				

Problem Description

Cease in ventilation: Technical Failure Alarm 305 – "Communication to CFB disconnected" triggered
imtmedical ag has received reports that on bellavista™ ventilators with generation 6 (G6) hardware (see affected devices above), ventilation is ceased during clinical use, and ventilation monitoring waveforms and parameters frozen (not updated). The ventilator generates a continuous audible and visual high priority alarm for technical failure 305. Ventilation is suspended until the unit is rebooted or replaced.

For the failure condition to occur, the following conditions must exist:

1. Software version 6.0.1600.0 (released 12 February 2021) or higher installed *AND*
2. software option "Data Communication" installed *AND*
3. data communication port configured to "HL7" (only possible when condition 2 is fulfilled)

Potential health risk: Hypoxia, hypercapnia

Root Cause: Investigation by imtmedical ag determined that the device logs show that the communication between the user interface controller (EPC) and the ventilation controller (CFB) is interrupted and only after a restart of the machine the communication is re-established. Conflict in memory resource allocation between software tasks causes the ventilation controller software to stop, resulting in the generation of the technical failure alarm 305. The failure condition involves a combination of software version 6.0.1600.0 or higher and active HL7 data transmission.

Note that technical failure alarm 305 – "Communication to CFB disconnected" can be generated due to other causes with no interruption of ventilation.

Actions to be taken by the manufacturer

- imtmedical ag will send the FSCA package which will include: FSN in English and in national language, *FORM Field Safety Corrective Action (FSCA) Distributor Response*, and *FORM Field Safety Corrective Action (FSCA) End-User Response* to all affected distributors.
- imtmedical ag has determined a list of affected devices. Refer to the separate, attached document, *Appendix to Urgent Field Safety Notice FSCA-2021-001-FSN-1: Units Affected List for FSCA-2021-001* for a list of affected serial numbers.
- imtmedical ag will provide a software update to remedy the issue.
- imtmedical ag has deactivated/removed affected software versions from the iVista platform.
- imtmedical ag has implemented a sales hold for the "Data Communication" software option until the software fix is released.
- imtmedical ag will collect and follow up on all response forms and the execution and completion of this corrective action.

Actions to be taken by the distributors

- Notify immediately all affected end-users by providing them with the FSCA package containing this *FSN* and *FORM Field Safety Corrective Action (FSCA) End-User Response*.
- Return the completed and signed *FORM Field Safety Corrective Action (FSCA) Distributor Response* to imtmedical ag using the email address as indicated on the form.
- If any user facilities have distributed any affected products to other persons or facilities, promptly forward a copy of this *FSN* and *FORM Field Safety Corrective Action (FSCA) End-User Response* to those recipients. Include contact information of those parties in the *FORM Field Safety Corrective Action (FSCA) Distributor Response* for device tracking purposes and further support.
- For all customers with ventilators containing the software option "Data Communication" and the software version 6.0.1600.0 or higher, please install the software patch to fix the issue as soon as available. imtmedical ag will inform you of the availability of the software patch in a separate communication.
- Identify any affected devices by serial number using the Units Affected List in the separate, attached document, *Appendix to Urgent Field Safety Notice FSCA-2021-001-FSN-1: Units Affected List for FSCA-2021-001*.

Actions to be taken by the users

- Check receipt and contents of the FSCA package (this *FSN* and the *FORM Field Safety Corrective Action (FSCA) End-User Response*.

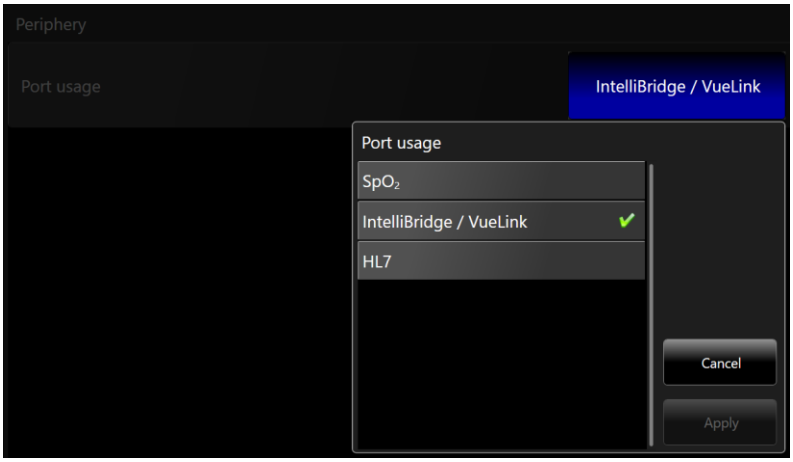
- If affected devices are transferred to another location or organization, make sure to forward the complete FSCA package to the respective users accordingly.
- All users of the affected products shall read and take into consideration all instructions and information provided in this *FSN*.
- Identify any affected devices by serial number using the Units Affected List in the separate, attached document, *Appendix to Urgent Field Safety Notice FSCA-2021-001-FSN-1: Units Affected List for FSCA-2021-001*.
- It is mandatory to disable the HL7 protocol where enabled.
- Perform the following steps on each affected bellavista™ ventilator until the software patch to fix the issue is available:

1. Open **Configuration Assist**.

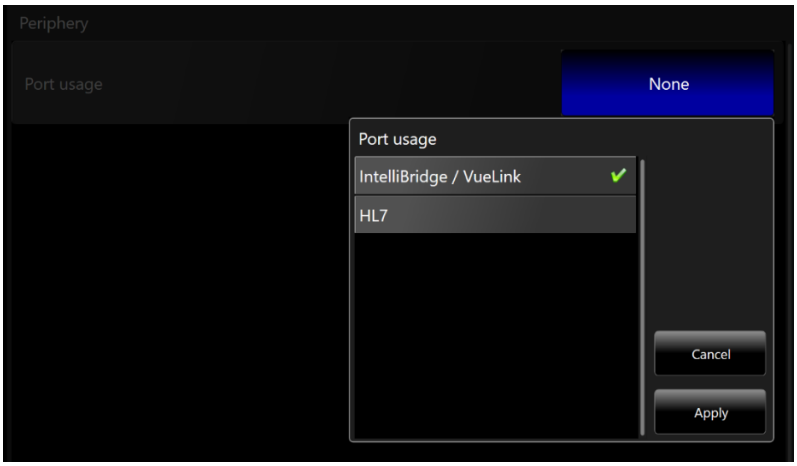
2. Select the **Periphery** settings.

3. Ensure that **Port usage** is **NOT** configured to “HL7”.

   For 13.3” devices, select “IntelliBridge / VueLink” or “SpO_2”.



For 17.3” devices, select “IntelliBridge / VueLink”.



4. Check if patient profiles have been stored inside the ventilator with the HL7 protocol activated. If that’s the case, you have to renew and store (overwrite) the profiles with the IntelliBridge/VueLink or SpO_2 setting. Otherwise, the HL7 protocol would be activated again when choosing a patient profile with HL7 protocol setting.

- Fully complete and return the signed FORM Field Safety Corrective Action (FSCA) End-User Response to imtmedical ag directly as per the instructions on the form.
- If the failure condition described above occurs, take the device out of use and contact your imtmedical / Vyaire service partner.

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 FSN has been notified to the appropriate Regulatory Agencies.

imtmedical | Field Safety Corrective Action (FSCA) End User Response Form

FSCA-2021-001

bellavista™ Ventilators
Ceasing of Ventilation with Technical Failure Alarm 305
for Field Safety Corrective Action FSCA-2021-001

Details of affected parts and products:

Affected Products according to Field Safety Notice (FSN) FSCA-2021-001-FSN-1

bellavista™ Model	REF No.	Description	Software Version(s)	Conditions for Device to be Potentially Affected	Indentifying Affected Devices
BV 1000	301.100.000	bellavista™ ventilator	6.0.1600.0 or higher	Software option "Data Communication" installed *AND* data communication port configured to "HL7"	Refer to the separate, attached document, *Appendix to Urgent Field Safety Notice FSCA-2021-001-FSN-1: Units Affected List for FSCA-2021-001*
BV 1000 US	301.100.030				
BV 1000e	301.100.100				
BV 1000e US	301.100.130				
BV 1000 neo	301.100.060				
BV 1000 Set	301.100.200				

Refer to the Field Safety Notice FSCA-2021-001-FSN-1 for instructions to determine whether you have any affected devices, and follow all instructions contained in the FSN.

User Declaration

Number of affected devices (total)	
FOR EACH AFFECTED DEVICE PLEASE PROVIDE (if necessary, attach extra page)	
Device Serial Number	Software Version

imtmedical

Field Safety Corrective Action (FSCA) End User Response Form

Please verify the following by checking the box below.

☐ I have received the FSCA package, comprising *the Field Safety Notice (FSCA-2021-001-FSN-1)* and *FSCA End User Response Form*, and understood the content and will follow and implement the instructions accordingly.

☐ I confirm that all users of the affected devices were and will be informed about the FSCA immediately and the FSCA package provided.

☐ I have identified all affected devices and have entered them on or attached them to this response form.

☐ I confirm that the HL7 data communication protocol will not be used until the software fix is available.

☐ I confirm that affected devices were transferred to another location/organization and the complete FSCA package was forwarded to the respective users accordingly.

- List contact details of recipients_____

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End User Details			
Contact person (name)			
Hospital (address)			
Country			
Email address			
Date		Signature	

PLEASE SEND THIS RESPONSE FORM TO THE FOLLOWING EMAIL ADDRESS:
GMB-AMS-FSCAresponsecentre@vyaire.com

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.**