imtmedical

30.OCT.2019

Urgent Field Safety Notice – FSN 2019-001

Attention: Distributors and end-users of bellavista1000 and 950 series ventilators.

Details on affected bellavista1000 and 950 ventilators:

Commercial Name	Catalogue number	Hardware Generation	Serial number (SN) prefix
bellavista 1000 ventilator	301.100.000	G2/3/4/5/6	MB100100 and higher
bellavista 1000 US ventilator	301.100.030		
bellavista 1000 NEO ventilator	301.100.060		
bellavista 1000e 17,3" ventilator	301.100.100		
bellavista 1000 Set ventilator	301.100.200		
bellavista 950 ventilator	950.100.000		

Dear Valued Customer:

The purpose of this letter is to advise users that imtmedical ag is issuing a Field Safety Corrective Action (FSCA) for its bellavista ventilators, referenced above.

imtmedical ag takes seriously all product complaints and consistent with its quality management system and processes, reviews all customer complaints and initiates investigations as warranted. Issues with bellavista ventilators have been identified through those investigations as well as post-market surveillance data.

Description of the problem:

The bellavista 1000 and 950 ventilators hardware generations G2/3/4/5/6 can experience the following intermittent failures in the field during ventilation:

- **Lack of acoustic high priority alarm** (continuous alarm tone) under specific conditions which may cause a delay in immediate action required to avert a life-threating situation.
- **Presence of a 'no alarm' condition** during a disconnect under specific use conditions which may cause a system leakage and potential for loss in ventilation therapy without activation of a disconnection alarm.
- **Presence of a 'failsafe state'** under specific use conditions which may cause a device (ventilator) response by suspending ventilation to the patient.

Detailed information on the discovered issues, as well as the corrective actions or corrective action plan, can be found in the **Attachment A** included as part of this notification.

There are no reports of patient or user injury related to these intermittent failures, *to-date*. imtmedical has developed a software update to correct these issues. This software update will be available by **no later than December 31st, 2019.** In order to ensure that adverse health consequences during use of the bellavista 1000 and 950 ventilators hardware generations G2/3/4/5/6 remain as low as possible, clinicians are encouraged to follow the User Manual and consider the immediate mitigative measures (per **Attachment A**).

Actions to be taken by the distributors:

- Immediately forward this notification to all customers further distributed the bellavista 1000 and 950 ventilators (hardware generations G2/3/4/5/6) of the above-mentioned serial number range.
- Inspect inventory to identify the affected bellavista ventilators of the above-mentioned serial number range.
- Execute the software update in a timely manner, as available and make the updated user manual available to the users.

- Return the completed and signed Response Form to imtmedical ag as per the provided instructions.

Actions to be taken by the end-users:

- Make sure that the content of this FSN is forwarded to any potential user of the bellavista ventilators.
- All users of the bellavista ventilators shall read and take into considerations the immediate mitigative measures provided in **Attachment A** of this FSN.
- Inspect inventory to identify the affected bellavista ventilators of the above-mentioned serial number range.
- Work with your distributor to ensure the software update is executed in a timely manner, as available.

Actions being taken by the manufacturer:

- imtmedical ag has determined the root cause of these software anomalies and has developed a software update.
- imtmedical ag will send the FSN letter and Response Form for distributors and/or end users in scope of this action.
- imtmedical ag will determine recall effectiveness by collecting all response forms to verify the FSN was received, confirm the product involved has been corrected (software update via iVista), and if the product was further distributed that those additional consignees were notified.
- Imtmedical ag will provide an update of the user manual that will include the description of the software changes.

Contact Information:

For questions, concerns or any events that reasonably suggest being related to the subject of this FSCA OR to return the Distributor Response form, please email imtmedical at GMB-AMS-FSCAresponsecentre@vyaire.com or your local distributor.

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

Attachment A: Issue Details and Corrective Action or Action Plan
Attachment B: Response Form

Robert Arnott
SVP, QRA Vyaire Medical

imtmedical

30.OCT.2019

Attachment A - Issue Details and Corrective Action or Action Plan

Issue	Circumstances which must activate / be present for Issue to occur	Outcome	Potential Risk	Corrective Action - Software update via iVista	Immediate Mitigative Measures to be considered	User Manuals Changes
Lack of acoustic high priority alarm	Active **Medium Priority** alarm is muted by clinician. During the 11 second **Medium Priority** alarm duration, a **High Priority** alarm activates.	Activation of **High Priority** alarm activates visually (red alarm lights) and alarm message on the screen without acoustics (missing audible alarm).	Hypoxia, Life-threatening	bellavista 1000 and 950 ventilators hardware generations G6 (identified by serial number) available via iVista software. bellavista 1000 and 950 ventilators hardware generations G2/3/4/5 (identified by serial number) available by **no later than 31DEC2019**. *To understand availability of this software correction please work closely with your distributor, authorized tech service engineer or your sales representative.	External sensors (SpO2 and CO2) in combination with other vital signs monitoring methods shall be used when monitoring the vital functions of a patient during bellavista ventilator use.	Change of alarm behaviour and "Alarms muted" feature described in **Chapter 8.3** of the updated bellavista user manual Additional alarm described in the List of alarms under Alarm ID 216 "Alarms muted"
Presence of a 'no alarm' Condition	All of the following sequential actions taken by the user: -Ventilator must be in PSV mode and the patient is synchronous with the vent (flow and rate) -A high circuit resistance (over 5.5mbar/L/S @990L/min) is reached -A disconnection condition occurs between the iFlow sensor and the patient circuit	System leakage without activation of disconnection alarm	Hypoxia	bellavista 1000 and 950 ventilators hardware generations G6 (identified by serial number) available via iVista software.) bellavista 1000 and 950 ventilators hardware generations G2/3/4/5 (identified by serial number) available by **no later than 31DEC2019**. *To understand availability of this software correction please work closely with your distributor, authorized tech service engineer or your sales representative.	External sensors (SpO2 and CO2) in combination with other vital signs monitoring methods shall be used when monitoring the vital functions of a patient during bellavista ventilator use.	Not applicable to the User Manual
Presence of a 'failsafe state'	Issue may be triggered on neonatal software during a closed suctioning procedure when the following sequential actions are taken by the user: -an inappropriately high suction setting is set (outside of clinical best practices) -selection of an inappropriately large catheter (>50% of the endotracheal tube inner diameter, outside of clinical best practices)	The device (ventilator) may respond by suspending ventilation to the patient.	Hypoxia, Life-threatening	bellavista 1000 and 950 ventilators hardware generations G6 (identified by serial number) available via iVista software. bellavista 1000 and 950 ventilators hardware generations G2/3/4/5 (identified by serial number) available by **no later than 31DEC2019**. *To understand availability of this software correction please work closely with your distributor, authorized tech service engineer or your sales representative.	Practice guidelines suggest that suction pressure should be set as low as possible and yet effectively clear secretions. Diameter of the suction catheter should not exceed one half the inner diameter of the artificial airway in adults, providing an internal-to-external diameter ratio of 0.5 in adults, and 0.5-0.66 in infants and small children.	Detailed information about the Technical failure alarm ID 300 in **Chapter 13.3.1** of the updated user manual