imtmedical

30.OCT.2019

Urgent Field Safety Notice – FSN 2019-002

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

Details on affected bellavista1000 ventilators:

Commercial Name	Catalogue number	Hardware Generation	Serial number (SN) prefix
bellavista 1000 ventilator	301.100.000	G6	See attachment B
bellavista 1000 NEO ventilator	301.100.060		
bellavista 1000e 17,3" ventilator	301.100.100		
Bellavista 1000 Set ventilator	301.100.200		

Dear Valued Customer:

The purpose of this Field Safety Notification (FSN) is to inform customers of an intermittent failure as it relates to a non-responsive touch screen of the 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. An issue with bellavista ventilators has been identified through those investigations as well as post-market surveillance data.

Description of the problem:

The bellavista 1000 ventilators hardware generation G6 of the above-mentioned serial number range can experience the following intermittent failure in the field during ventilation:

- **Presence of non-responsive touch screen** resulting in the touch screen being non-responsive to user inputs.

Detailed information on the discovered issue, as well as, potential mitigations can be found in **Table 1**, included as part of this notification.

There are no reports of patient or user injury related to this intermittent failure, *to-date*. Imtmedical has developed a Software update to correct this intermittent failure. This Software update will be available to by **no later than January 31, 2020.** In order to ensure that adverse health consequences during use of the bellavista 1000 ventilators hardware generation G6 remain as low as possible, clinicians are encouraged to follow Instructions for Use (IFU) and consider the immediate mitigative measures (per **Table 1**) as provided in this notification.

Actions to be taken by distributors:

- Immediately forward this notification to all customers further distributed the bellavista 1000 ventilators hardware generation G6 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.
- Return the completed and signed Response Form to imtmedial ag as per the provided instructions.

Actions to be taken by 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 consideration the immediate mitigative measures provided in **Table 1** 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.

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Actions being taken by the manufacturer:

- Imtmedical has developed a software update that will be available by **no later than 2020-01-31.**
- 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.

Table 1 - Issue Details and Mitigative Measures

Issue	Circumstance for Issue to Occur	Outcome	Potential Risk	Immediate Mitigative Measures to be considered
Presence of non-responsive touch screen	Spontaneous intermittent failure potential that results in non-responsive touch screen to user inputs	Ventilation at the previously inputted settings, as well as alarm functionalities, will continue without disruption. At worst case, changes cannot be made to current ventilation settings if required in response to change in patient condition.	Not clinically significant procedural delay requiring exchange with back-up means of ventilation.	• Standard of care of ventilated patients is to have resuscitative devices available at bedside as well as backup means of ventilation for emergent situations or when it is suspected that a ventilator is not functioning as intended. • The devices are shipped with a screen protector over the glass User Interface Monitor (UIM) for shipment. Remove this shipment protector from the UIM prior to use. • Ensure that the UIM is free from contact with other objects (cables, leads) or materials (condensation, other). • Do not clean the UIM while in use.

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: Response Form
Attachment B: Serial Numbers affected

[redacted]

Robert Arnott
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