Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 103 **dated** 27/05/20 **Regarding GHC Safety Alert of Ventilators Bellavista (Mfr: Vyaire Medical, Inc- Imtmedical ag).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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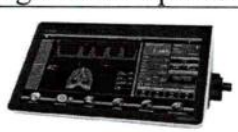
Circular No. 103 / 2020

04 - Shwal -1441 H

27 -May-2020

Safety Alert of Ventilators (Bellavista) from Vyaire Medical, Inc- Imtmedical ag

Source	(NCMDR) National Center for Medical Devices Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15135
Product	Ventilators (Bellavista)
Manufacturer	Vyaire Medical, Inc- Imtmedical ag
The affected products	All affected Models (see attachments) Serial Number range: 1000100 and higher.
Reason	Mentioned devices can experience the following intermittent failures in the filed 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 Louis and 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.
Action	• Review this notice and ensure that affected personnel are aware of the contents. • All users of the mentioned devices shall read and take into consideration the immediate mitigated measures provided in attachment A in the attached file below. • Inspect the inventory to identify the affected devices of the above-mentioned serial number range. • Contact the local agent for required correction.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail Med-device@moh.gov.om

VAP

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

The affected products:

Commercial Name	Catalogue number	Hardware Generation	Serial Number (SN) Prefix
bellavista 1000 ventillator	301.100.000	G2/3/4/5/6	MB 1000100 and higher
bellavista 1000 US ventillator	301.100.030		
bellavista 1000 NEO ventillator	301.100.060		
bellavista 1000e 17.3" ventillator	301.100.100		
bellavista 1000 set ventillator	301.100.200		
bellavista 950 ventillator	950.100.000		

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