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

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 27/1/2022 Regarding GHC Safety Alert of Ventilators Bellavista (Mfr: Vyaire Medical, Inc- Intmedical 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
Circular No. 103 / 2020

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

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
<td>Ventilators (Bellavista)</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Vyaire Medical, Inc- Intmedical ag</td>
</tr>
</tbody>
</table>
| The affected products | All affected Models (see attachments)  
Serial Number range: 1000100 and higher. |

**Reason**

- 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-threatening 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**

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

Dr. Mohammed Hamdan Al Rubaie  
DIRECTOR GENERAL

Directorate General of Pharmaceutical Affairs & Drug Control  
Sultanate of Oman

dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358499 - E-mail: dg-padc@moh.gov.om
The affected products:

<table>
<thead>
<tr>
<th>Commercial Name</th>
<th>Catalogue number</th>
<th>Hardware Generation</th>
<th>Serial Number (SN) Prefix</th>
</tr>
</thead>
<tbody>
<tr>
<td>bellavista 1000 ventilator</td>
<td>301.100.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bellavista 1000 US ventilator</td>
<td>301.100.030</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bellavista 1000 NEO ventilator</td>
<td>301.100.060</td>
<td>G2/3/4/5/6</td>
<td>MB 1000100 and higher</td>
</tr>
<tr>
<td>bellavista 1000e 17.3&quot; ventilator</td>
<td>301.100.100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bellavista 1000 set ventilator</td>
<td>301.100.200</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bellavista 950 ventilator</td>
<td>950.100.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Issue</td>
<td>Circumstances which must activate / be present for Issue to occur</td>
<td>Outcome</td>
<td>Potential Risk</td>
</tr>
<tr>
<td>-------</td>
<td>---------------------------------------------------------------</td>
<td>---------</td>
<td>---------------</td>
</tr>
<tr>
<td>Lack of acoustic high priority alarm</td>
<td>Active Medium Priority alarm is muted by clinician. During the 11 second Medium Priority alarm duration, a High Priority alarm activates.</td>
<td>Activation of High Priority alarm activates visually (red alarm lights) and alarm message on the screen without acoustics (missing audible alarm).</td>
<td>Hypoxia, Life-threatening</td>
</tr>
<tr>
<td>Presence of a ‘no alarm’ condition</td>
<td>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</td>
<td>System leakage without activation of disconnection alarm</td>
<td>Hypoxia</td>
</tr>
<tr>
<td>Presence of a ‘failsafe state’</td>
<td>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 (&gt;50% of the endotracheal tube inner diameter, outside of clinical best practices)</td>
<td>The device (ventilator) may respond by suspending ventilation to the patient.</td>
<td>Hypoxia, Life-threatening</td>
</tr>
</tbody>
</table>