

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.

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
<p>Presence of non-responsive touch screen</p>	<p>Spontaneous intermittent failure potential that results in non-responsive touch screen to user inputs</p>	<p>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.</p>	<p>Not clinically significant procedural delay requiring exchange with back-up means of ventilation.</p>	<ul style="list-style-type: none"> • 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



Robert Arnott
SVP, QRA Vyaire Medical

Affected Serial Number for the FSCA 2019-002

MB160000	MB160041	MB160084	MB160125
MB160001	MB160042	MB160085	MB160126
MB160002	MB160043	MB160086	MB160127
MB160003	MB160044	MB160087	MB160128
MB160004	MB160045	MB160088	MB160129
MB160005	MB160046	MB160089	MB160130
MB160006	MB160047	MB160090	MB160131
MB160007	MB160048	MB160091	MB160132
MB160008	MB160049	MB160092	MB160133
MB160009	MB160050	MB160093	MB160134
MB160010	MB160051	MB160094	MB160135
MB160011	MB160052	MB160095	MB160136
MB160012	MB160054	MB160096	MB160137
MB160013	MB160056	MB160097	MB160138
MB160014	MB160057	MB160098	MB160139
MB160015	MB160058	MB160099	MB160140
MB160016	MB160059	MB160100	MB160141
MB160017	MB160060	MB160101	MB160142
MB160018	MB160061	MB160102	MB160143
MB160019	MB160062	MB160103	MB160144
MB160020	MB160063	MB160104	MB160145
MB160021	MB160064	MB160105	MB160146
MB160022	MB160065	MB160106	MB160147
MB160023	MB160066	MB160107	MB160148
MB160024	MB160067	MB160108	MB160149
MB160025	MB160068	MB160109	MB160150
MB160026	MB160069	MB160110	MB160151
MB160027	MB160070	MB160111	MB160152
MB160028	MB160071	MB160112	MB160153
MB160029	MB160072	MB160113	MB160154
MB160030	MB160073	MB160114	MB160155
MB160031	MB160074	MB160115	MB160156
MB160032	MB160075	MB160116	MB160157
MB160033	MB160076	MB160117	MB160158
MB160034	MB160077	MB160118	MB160159
MB160035	MB160078	MB160119	MB160160
MB160036	MB160079	MB160120	MB160161
MB160037	MB160080	MB160121	MB160162
MB160038	MB160081	MB160122	MB160163
MB160039	MB160082	MB160123	MB160164
MB160040	MB160083	MB160124	MB160165

MB160166	MB170372	MB170077	MB170098
MB160167	MB170375	MB170076	MB170078
MB160168	MB170042	MB170091	MB170134
MB160169	MB170038	MB170095	MB170075
MB160170	MB170039	MB170100	MB170129
MB160171	MB170022	MB170102	MB170207
MB160172	MB170082	MB170127	MB170163
MB160173	MB170030	MB170126	MB170212
MB160174	MB170031	MB170118	MB170203
MB160175	MB170027	MB170117	MB170199
MB160176	MB170037	MB170099	MB170198
MB160177	MB170033	MB170109	MB170115
MB160178	MB170034	MB170071	MB170150
MB160179	MB170035	MB170106	MB170135
MB160180	MB170036	MB170089	MB170114
MB160181	MB170043	MB170069	MB170116
MB160182	MB170051	MB170070	MB170193
MB160183	MB170050	MB170068	MB170191
MB160184	MB170046	MB170112	MB170192
MB160185	MB170045	MB170086	MB170194
MB160186	MB170049	MB170085	MB170204
MB160187	MB170052	MB170084	MB170195
MB160188	MB170054	MB170079	MB170232
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MB160190	MB170044	MB170108	MB170197
MB160191	MB170055	MB170110	MB170205
MB160192	MB170040	MB170101	MB200030
MB160193	MB170041	MB170111	MB200065
MB160194	MB170059	MB170083	MB200042
MB160195	MB170061	MB170088	MB200035
MB160196	MB170029	MB170090	MB200029
MB160197	MB170021	MB170104	MB200036
MB160198	MB170047	MB170113	MB200031
MB160199	MB170058	MB170067	MB200028
MB160200	MB170056	MB170081	MB200050
MB160201	MB170057	MB170131	MB200018
MB160219	MB170060	MB170073	MB200017
MB160231	MB170065	MB170124	MB200019
MB160234	MB170023	MB170122	MB200015
MB160238	MB170063	MB170123	MB200020
MB170376	MB170062	MB170103	MB200023
MB170364	MB170107	MB170121	MB200016
MB170354	MB170087	MB170119	MB200022
MB170358	MB170066	MB170130	MB200007
MB170351	MB170105	MB170074	MB200021
MB170369	MB170125	MB170094	MB200010

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MB200056	MB170209	MB170231	MB170305
MB200060	MB170208	MB170188	MB170244
MB200057	MB170182	MB170179	MB170282
MB200055	MB170158	MB170185	MB170267
MB200047	MB170147	MB170233	MB170281
MB200049	MB170146	MB170228	MB190009
MB200046	MB170154	MB170230	MB190019
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MB200033	MB170202	MB170274	MB170310
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MB200012	MB170155	MB170259	MB170315
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MB200005	MB170317	MB170275	MB170319
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