11 January 2022, Coleraine, Northern Ireland
FSN Ref: SI21-68
FSCA Ref: 2021/012/020/701/018

Urgent Field Safety Notice – risk of device unexpected shutdown

AquaVENT® FD140i Gas Flow Driver for CPAP and HFOT

Product codes AMFD140i-UK, AMFD140i-EU, AMFD140i-UK2, AMFD140i-EU2

Please pass this Field Safety Notice (FSN) to all persons in your organisation who need to be aware of it.

Type of Action:	To communicate an identified issue which may result in unexpected shutdown of device during clinical use
Device:	AquaVENT® FD140i Gas Flow Driver
Manufacturer:	Armstrong Medical Limited (Coleraine, Northern Ireland)
Date of Issue:	11 January 2022
For Attention of:	Nursing and medical staff (caregivers) working in critical care, emergency care and high-dependency areas of hospitals and all others to whom potentially affected devices have been transferred, including distributors.
Scope of Action:	Manufacturing serial number specific corrective action
Keywords:	Breathing System, Flow Driver, HFOT, CPAP

Summary
AquaVENT® FD140i Gas Flow Driver is a respiratory therapy device. It assists respiration using continuous positive airway pressure (CPAP) and high flow oxygen therapy (HFOT) in patients in a hospital setting.

We have been made aware of a number of incidents during clinical use of the AquaVENT® FD140i Gas Flow Driver. Investigation of the reported incidents suggests that the devices involved were in use on battery power, rather than on mains power.

During the reported incidents, the devices underwent unexpected power shutdown, without appropriate alarms. This required intervention by caregivers to avert patient harm. The device defect has been traced to a characteristic of software version 1.01, which runs on all devices in the field at this time.

The unwanted behaviour relates to a loss of communication between the FLASH memory stored on the main printed circuit board and the back-up battery when the device is powered OFF when receiving a mains power charging current.

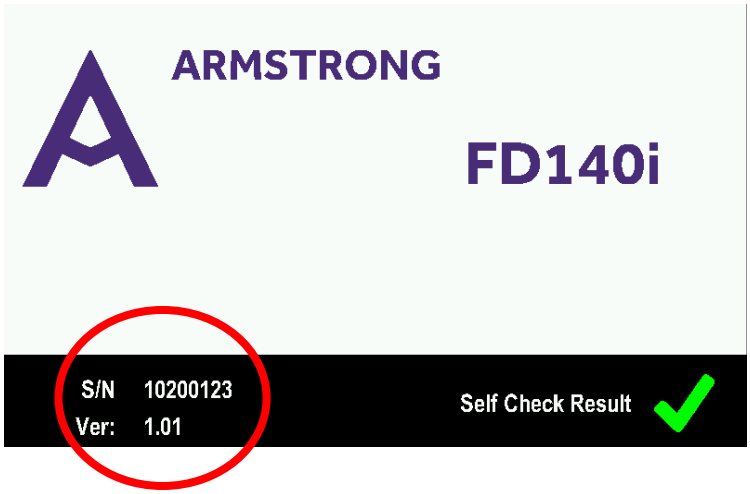
In software version 1.01, the device requires connection to mains power when the device is powered ON as a means to update the FLASH memory with the accurate remaining % capacity within the battery.

The loss of communication potentially allows storage, within the FLASH memory, of an erroneous battery % charge level that could be higher or lower than the actual remaining % capacity within the battery. If a device, in that condition, were to be powered ON without mains power supply, the device – which is then running on battery power – may shutdown (power OFF) unexpectedly during clinical therapy, without warning and without the expected audible and visual alarms associated with battery capacity depletion.

Affected devices:
See appendices A and B. AquaVENT® FD140i Gas Flow Drivers sold under product codes AMFD140i-UK, AMFD140i-UK2, AMFD140i-EU and AMFD140i-EU2 and in the serial number ranges 10200006 to 10200284, 1021109 to 1021140 and 20200187 to 20210046.

Action in the field:

All devices having software version 1.01 will be updated with new software release version 1.02. Our representatives will make contact with you soon to arrange for the new release software to be installed. The current software running on your device is displayed during device switch ON at conclusion of the Self Check. Please see graphic, *right*.



Advice for continued safe use (until replacement software has been installed):

The device should be used on mains power. The device can be used on battery power ONLY where mains power supply is not available or convenient to use, such as during a short time-period during patient transportation. If use on battery power is required, the device must first have been powered ON whilst receiving mains charging. Prior to clinical use on battery power, the device should be fully charged (that is, displaying 100% remaining battery charge accompanied by a solid green battery indicator LED) before disconnecting from mains power supply and running the device on battery power. **Failure to follow this advice for continued safe use could result in patient injury secondary to oxygen desaturation and / or alveolar collapse.**

Other actions:

The device user manual will be revised and re-issued as version 06. On page 08, the following text will be added:

> *Clinical use of FD140i should be on mains power. Use on battery power should be restricted to short periods where mains power is not available or convenient to use, such as during patient transportation. In the event that FD140i is to be used on battery power, ensure that it is charged prior to use - preferably showing 100% remaining battery capacity on the display. Full battery charge level is associated with a solid green indicator LED. This LED is located on the bottom right of the front panel, above the 'ON/OFF' button.*

Appendix A

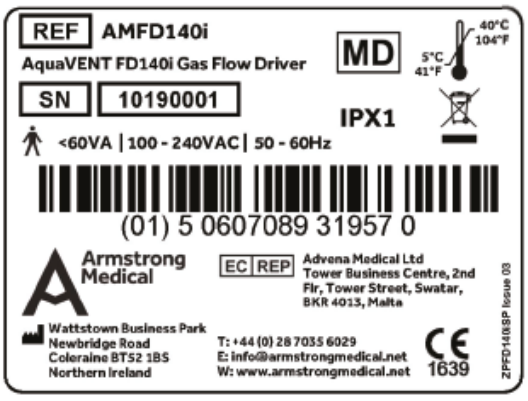
Serial number format

Example 1: 10190001

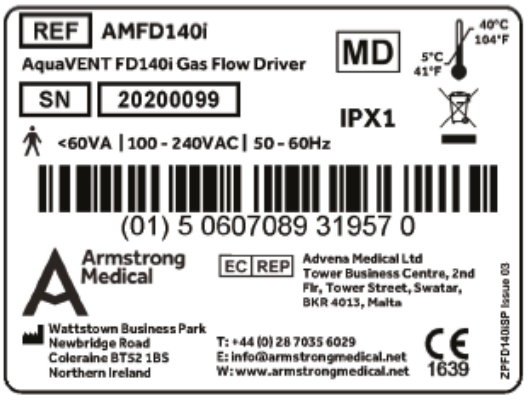
10190001 First "10" represents device with paramagnetic oxygen sensor option
10190001 "19" represents 2019 (year of manufacture)
10190001 Last "1" represents the 1st device manufactured

Example 2: 20200099

20200099 First "20" represents device with oxygen fuel cell option
20200099 "20" represents 2020 (year of manufacture)
20200099 Represents the 99th device manufactured



Example 1



Example 2

Appendix B

List of affected serial numbers by product code

Product Code: AMFD140i-UK			
10200006	10200047	10200091	10200148
10200007	10200048	10200092	10200149
10200008	10200049	10200093	10200150
10200009	10200050	10200094	10200152
10200010	10200053	10200095	10200153
10200011	10200054	10200096	10200197
10200012	10200055	10200097	10200198
10200013	10200056	10200098	10200199
10200014	10200057	10200099	10200200
10200015	10200058	10200100	10200201
10200016	10200059	10200101	10200202
10200017	10200060	10200102	10200204
10200018	10200061	10200103	10200205
10200019	10200062	10200104	10200206
10200020	10200063	10200105	10200207
10200021	10200064	10200106	10200208
10200022	10200065	10200107	10200209
10200023	10200066	10200110	10200227
10200024	10200067	10200111	10200228
10200025	10200068	10200113	10200234
10200026	10200069	10200114	10200235
10200027	10200070	10200115	10200236
10200028	10200071	10200116	10200239
10200029	10200072	10200118	10200241
10200030	10200073	10200119	10200242
10200031	10200074	10200120	10200243
10200032	10200075	10200122	10200244
10200033	10200076	10200123	10200245
10200034	10200077	10200124	10200246
10200035	10200078	10200125	10200248
10200036	10200079	10200127	10200250
10200037	10200080	10200128	10200253
10200038	10200081	10200129	10200254
10200039	10200082	10200132	10200261
10200040	10200083	10200134	10200280
10200041	10200084	10200136	10200281
10200042	10200085	10200142	10200283
10200043	10200086	10200143	10200284
10200044	10200087	10200145	10210139
10200045	10200089	10200146	10210140
10200046	10200090	10200147	

Product Code: AMFD140i-UK2			
20200187	20200192	20200216	20200226
20200188	20200211	20200217	20210044
20200189	20200212	20200218	20210045
20200190	20200214	20200222	20210046
20200191	20200215	20200224	

Product Code: AMFD140i-EU			
10200157	10200171	10200258	10200271
10200158	10200172	10200259	10200272
10200159	10200173	10200260	10200273
10200161	10200175	10200262	10200274
10200162	10200176	10200263	10200275
10200163	10200177	10200264	10200276
10200165	10200178	10200265	10200277
10200166	10200179	10200266	10200278
10200167	10200180	10200267	10200279
10200168	10200255	10200268	10210109
10200169	10200256	10200269	
10200170	10200257	10200270	

Product Code: AMFD140i-EU2			
10200186	20200225	20200299	20200306
20200213	20200231	20200300	20200307
20200219	20200232	20200301	20200308
20200220	20200233	20200302	20200309
20200221	20200238	20200304	
20200223	20200252	20200305	

Armstrong Medical Limited confirms that this Field Safety Notice has been notified to the UK Competent Authority - Medicines and Healthcare Products Regulatory Agency (MHRA).

Armstrong Medical Limited confirms that this Field Safety Notice has been notified to all Competent Authorities, in jurisdictions where the device is made available on the market.

Field Safety Notice Response Form

FSN Reference: SI21-68 Date: 11 January 2022

Please complete the information below and return to quality@armstrongmedical.net. Alternatively, please telephone Armstrong Medical on 00 44 (0)28 70356029 and ask for the Sales Department.

Hospital or Delivery Location Name: _____

Hospital or Delivery Location Address: _____

_____

_____

_____

☐ We confirm that we have received this FSN and have distributed it to relevant individuals or departments within our organisation.

☐ **Armstrong Medical Distributors Only:** We confirm that we have received this FSN and have distributed it to all customers that have been supplied with the products listed above.

Form Completed by:

Name: _____

Department or Position: _____

e-mail Address: _____

Contact telephone number: _____

Date: _____