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Coleraine, Northern Ireland

Armstrong Medical

Product Advisory

Conserving Oxygen During COVID-19 Pandemic

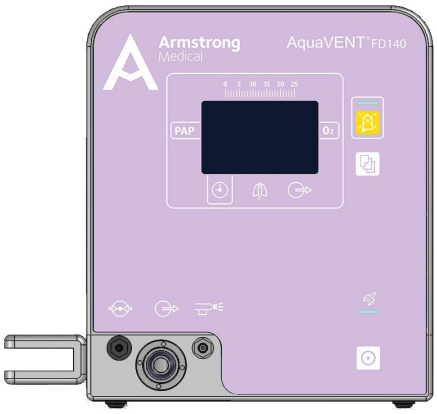
Where concerns exist regarding continuity of oxygen supply in hospitals, alterative use of FD140 *(Salvia GmbH, Kronberg, DE)* and FD140i *(Armstrong Medical Limited, Coleraine, NI)* in conjunction with Armstrong Medical CPAP breathing circuits and accessories should be considered as a temporary intervention to conserve oxygen supply.

This advisory relates to use of CPAP and CPAP Paed therapy modes on FD140 and FD140i. **It <u>does not</u> relate to Helmet CPAP mode on these devices.**

This advisory must be considered in combination with the User Manuals for FD140 and FD140i and the breathing circuit(s) IFU (Instructions For Use).

Indications for use of FD140 and FD140i:
Patients must be medically indicated by a healthcare professional for the respective therapy having already been assessed as conscious and breathing spontaneously and not at significant risk of conditions of exacerbation caused by the therapy or at risk of a prolonged apnoeic event. Additional patient observations are advised when assessment of Type 1 respiratory failure patients indicates that intubation and mechanical ventilation is the preferred modality, but a decision is taken to first try non-invasive high flow CPAP therapy as an interim measure to avoid intubation.

Within the ongoing pandemic, we advise judicious use of oxygen where concerns exist regarding oxygen supply <u>and</u> where Type 1 respiratory failure SARS-CoV-2 patients are being treated with high flow CPAP by face mask, tracheal tube or tracheostomy tube. We suggest consideration of actions 1 and/or 2 below, as compromise conditions for the delivery of therapy on CPAP and CPAP Paed modes on FD140 and FD140i:



1. **Reduce gas flow rate immediately following successful reversal of hypoxaemia**
2. **Reduce oxygen % immediately following successful reversal of hypoxaemia**

1. Reduce gas flow rate

It is possible, and even likely, that in many cases, the patient's peak inspiratory demand will not be met by a flow rate <30L/min. We caution reduction in flow rate below 30L/min. 30L/min should therefore be considered as a starting point for CPAP under this advisory.

Insufficient gas flow to meet peak inspiratory demand will prevent attainment of inspiratory positive airway pressure (iPAP). Peak inspiratory demand during CPAP varies in response to, for example, apnoea, pain, sighing, oscitation. The peak does not represent the underlaying baseline inspiratory demand, which will be much lower. Peak inspiratory demand is therefore an exceptional event whereas baseline inspiratory demand will be closer to 30L/min in adults.

Pressure exerted on the airway during the expiratory phase is not affected by reduced gas flow rate and will be applied at the value of the PEEP valve connected to the breathing circuit. If we refer to the resulting therapy as *ePAP* (expiratory positive airway pressure), the clinical effect is centred on avoiding alveolar collapse during inspiratory phase but maintaining and maximising the lung surface available for gas exchange during expiratory phase. Gas flow rate should never be reduced, such that the 'free breathing valve' within FD140 or FD140i is activated during inspiratory phase or that the anti-asphyxiation valve on the face mask is activated. Such a scenario would indicate such insufficient gas flow rate causing alveolar collapse during inspiratory phase; or pressure vacuum – both of which are undesirable in this patient cohort. When using reduced gas flow rate, the alarm setting for 'Pmin' may need to be adjusted downwards to avoid unnecessary alert to low pressure levels.

2. Reduce oxygen %

SARS-CoV-2 patients with corrected and stable SaO_2 resulting from high flow CPAP therapy remain at risk of deterioration due to underlying disease morbidities or medication strategy. Continuous SpO_2 and frequent blood gas analysis are advised when reducing oxygen % in gas flow. Once hypoxaemia has been reversed and is considered to be stable, one of two paths to reduce oxygen % in gas flow should be considered:

a. **Titration of oxygen % downwards from an elevated value, as a means to establish an underlying acceptable SaO_2 or SpO_2, or**
b. **Titration of oxygen % upwards from 25% to the attainment of an underlying acceptable SaO_2 or SpO_2**