ResMed

Clinical Bulletin

Use of Bi-level Devices with Endotracheal Tube

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This bulletin is intended to provide transparency, clarity, and specificity on the risk of invasive ventilation with endotracheal tube using a bi-level device, in the context of ventilator shortage during the COVID-19 pandemic. **Warnings and cautions are in section 4 of this bulletin**.

Reportedly non-invasive ventilators are being used for invasive ventilation during the COVID-19 public health emergency. ResMed is neither agreeing nor objecting to this use case, but emerging clinical practice in treating COVID-19 patients shows that these devices are being used invasively with an endotracheal tube. The American Association for Respiratory Care has released resources for clinicians on Bi-level Devices Converted to Ventilators (https://www.aarc.org/resources/clinical-resources/bilevel-devices-converted-to-ventilators/)

This clinical bulletin provides clinicians treating dependent patients in the COVID-19 public health emergency, with warnings and risks associated with the use of a ResMed bi-level device (Lumis ST, AirCurve 10 ST, Lumis ST-A, and AirCurve 10 ST-A) with an endotracheal tube.

Patient and device instructions in the Lumis ST, AirCurve 10 ST, Lumis ST-A, and AirCurve 10 ST-A should continue to be followed in addition to the information provided within this bulletin. These devices are not intended for life support. ResMed's user guides are not being modified for these devices. Moreover, indications for use have not been modified, with the exception of AirCurve 10 ST which has received Emergency Use Authorization (EUA) from the FDA to include indications for use in the treatment of patients with respiratory insufficiency.

1. Use of Bi-level devices with Endotracheal Tube

ResMed has reviewed the risks associated with the use of an endotracheal tube with a Lumis ST, AirCurve 10 ST, Lumis ST-A, and AirCurve 10 ST-A device. This use case should not be considered lightly, and should only be resorted to if there is a dire need to support the patient's condition.

The intended use of the Lumis ST, AirCurve 10 ST, Lumis ST-A, and AirCurve 10 ST-A devices is to treat non-dependent patients with obstructive or restrictive respiratory conditions. The key differences between these devices and an invasive ventilator are:

- Lack of therapy alarms (ST devices) or a limited set of alarms (ST-A devices)
- No internal battery
- No oxygen blender
- Does not comply to essential performance specifications required for a life support ventilator.

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1.1. Circuit setup

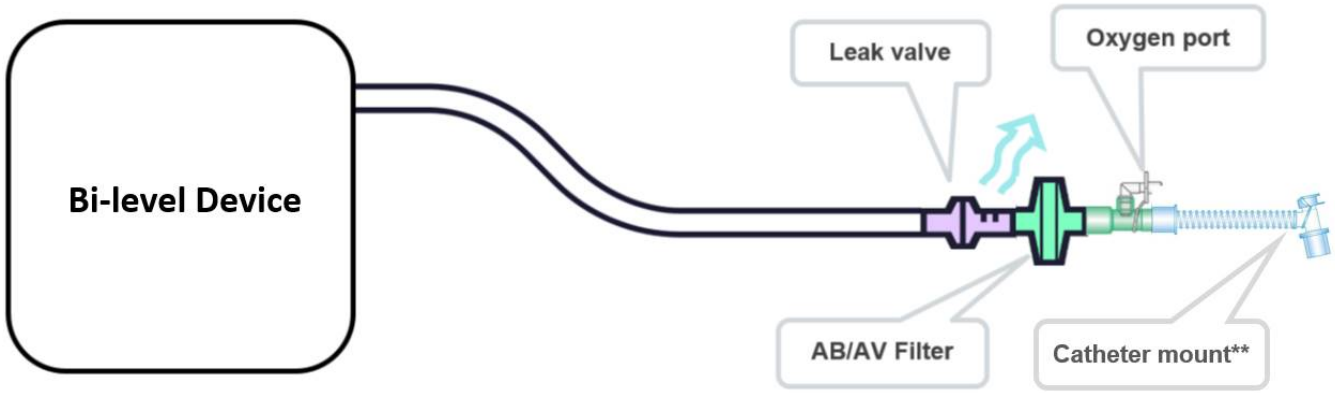

Figure 1: Bi-level Device Circuit Setup
**The catheter mount is not a ResMed component.

1.2. Adding supplemental oxygen

Supplemental oxygen should be added into the breathing system via a ResMed side port O2 connector or an integrated leur port on a heat moisture exchanger filter. It is important to note that an increasing level of added O2 has potential to impair triggering and accuracy of therapy/monitoring and alarms (e.g. Lumis/AirCurve 10 ST-A high leak alarm, non-vented mask alarm). Therapy and alarm operation must be verified each time oxygen flow is adjusted. See the Clinical guide for full details.

2. Ventilator Performance Impact

Bench testing by ResMed has highlighted the following performance impacts when Lumis ST, AirCurve 10 ST, Lumis ST-A, and AirCurve 10 ST-A are used with an endotracheal tube and with an oxygen flowrate of 20L/min. **Also see warnings and cautions in section 4 of this bulletin**.

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Device	**Lumis ST and AirCurve 10 ST**	**Lumis ST-A and AirCurve 10 ST-A**
Location	Hospital use only	Hospital use only
Oxygen	• Can use up to 20L/min depending on circuit configuration • May affect performance • Mitigate risk through external monitoring.	• Can use up to 20L/min depending on circuit configuration • May affect performance • Mitigate risk through external monitoring.
Supervision	Monitoring with independent physiological alarms strongly recommended.	Monitoring with independent physiological alarms strongly recommended.
Power	Loss of power will stop ventilation • No internal battery Monitoring with alarms strongly recommended.	Loss of power will stop ventilation • No internal battery Monitoring with alarms strongly recommended.
Humidification or heated tubes	Do not use integrated humidifier or heated tubes. Heat-moisture exchanger (HME) may be used.	Do not use integrated humidifier or heated tubes. Heat-moisture exchanger (HME) may be used.
Alarms	• No integrated alarms, no alarm if ventilation stops. • Buzzer will alert on high leak and blocked tube if enabled.	• Total power failure • Blocked tube • Disconnection • Low pressure • Low minute ventilation • High Leak • Non-vented mask • Low SpO2 • Apnea Alarm
Dead space	AB filter, oxygen port, catheter mount contribute to dead space volume, adjust therapy settings to compensate based on independent patient monitoring.	AB filter, oxygen port, catheter mount contribute to dead space volume, adjust therapy settings to compensate based on independent patient monitoring
iVAPS	Do not use iVAPS mode as target volume accuracy will be affected by this use case.	Do not use iVAPS mode as target volume accuracy will be affected by this use case.

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3. Multipatient use

See the Lumis ST, Lumis ST-A, AirCurve 10 ST and AirCurve 10 ST-A Clinical guides for Multipatient use details.

4. Warnings and Cautions

Warning: *use of a Lumis ST, Lumis ST-A, AirCurve 10 ST and AirCurve 10 ST-A ventilator, with an endotracheal tube, for invasive ventilation, shall be limited to emergency use due to resource limitation in a hospital use only.*

Warning: *Lumis ST, Lumis ST-A, AirCurve 10 ST and AirCurve 10 ST-A are not life support ventilators. Use on patients with no spontaneous breathing, or whose condition may deteriorate without adequate ventilation, requires close supervision. Use of independent monitoring equipment with alarms is strongly recommended.*

Warning: *This product does not contain an internal battery. Loss of power will result in ventilation stopping. Use of independent monitoring equipment with alarms and an external battery or uninterruptable power supply is strongly recommended.*

Warning: *Do not use the integrated humidifier or heated tubes with invasive interfaces. Use of the humidifier may lead to insufficient humidification or aspiration of water. If humidification is required, a heat-moisture exchanger (HME) may be used.*

Warning*: This circuit, or the use of supplemental oxygen proximal to the patient, may impact ventilator performance and the effectiveness of alarms. When using this configuration with patients whose condition may deteriorate without adequate ventilation, independent external monitoring of the patient shall be used.*

Warning: *the use of supplemental oxygen in excess of 15L/min with a vented circuit may result in false triggering of the 'blocked tube' mitigation leading to ventilation stop[1]. It is annunciated by an alarm* **only** *for Lumis/AirCurve 10 ST-A. Large supplemental oxygen levels should be verified as compatible by observing the patient for at least five minutes initially to check that a 'blocked tube' event is not triggered.*
If the 'blocked tube' mitigation occurs and ventilation stops:

- *ensure the patient is cared for*
- *check the air tubing, remove any blockages and/or decrease the level of supplemental oxygen and/or increase the overall pressure setting*
- *Press the dial to clear the message and then press Start/Stop to restart the device.*
- *Continue to monitor the patient*
- *if the problem persists, stop using the device and contact your local ResMed dealer or ResMed office.*

[1] Large levels of supplemental oxygen and higher resistance circuits result in less average output flow being measured by the device. If this level is low enough for approximately two consecutive minutes, the device may falsely record a blocked tube event.

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Caution: *Circuit accessories placed between the leak port and the patient (AB filter, oxygen port, catheter mount), all contribute to increased dead-space which may lead to some rebreathing – clinicians should consider minimizing that dead-space and should consider adjusting ventilator settings (e.g. increasing pressure support/ventilation) to compensate for the increased dead-space, should they detect increase in patient CO2 level.*

Caution: *iVAPS is not recommended with this circuit configuration, especially when used with level of entrained oxygen greater than 4 LPM because, while the therapy will continue to provide pressures within the clinician's set boundaries (PSmin and PSmax) the accuracy of control of volume (target Va for iVAPS) might be degraded hence potentially affecting the efficacy of the treatment.*

Note: *As currently stated in Lumis/AirCurve 10 ST-A Clinical guide, the use of supplemental oxygen with a vented circuit may result in false triggering on the Non-Vented mask alarm – an increased level of oxygen increases the likelihood of false triggering of the Non-Vented mask alarm therefore the clinician should assess if it is best to keep the alarm ON or to turn it OFF.*

For further information, please contact your nearest ResMed office. See ResMed.com for details.

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Title of Clinical Bulletin: Use of Bi-level Devices with Endotracheal Tubes

1. Details

Brief Details: Clinical Bulletin describes the use of a low dispersion circuit with bi-level devices (Lumis ST, Lumis ST-A, AirCurve 10 10 ST) in the context of addressing a shortage of dedicated ICU ventilators during the COVID-19 pandemic crisis.

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2. Distribution

By Medical Affairs to:

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(iii) Clinicians