Clinical Bulletin

Supplemental Oxygen and Low Dispersion Circuit with CPAP and Bi-level Devices for COVID-19

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This clinical bulletin provides clinicians treating COVID-19 patients with factors to consider when seeking methods to reduce the dispersion of aerosolized virus, and increase FiO_2 in the healthcare setting.

This low dispersion circuit is not the intended use for these devices, but emerging clinical practice in treating COVID-19 shows that it is a likely need given the ventilator shortage and the concern of infection risk to healthcare workers during the COVID-19 pandemic.

This circuit configuration applies to continuous positive airway pressure (CPAP), spontaneous (S), spontaneous timed (ST), pressure assist control (PAC), and timed (T) modes in Lumis, AirCurve, AirSense and S9 platforms. These devices are identified differently throughout global regions. **Section 6 describes the appropriate device name per region.**

Patient and device instructions for these devices should continue to be followed in addition to the information provided within this bulletin. **A summary of warnings and cautions are in section 5 of this bulletin.**

1. Circuit Setup

The low dispersion circuit is depicted below:

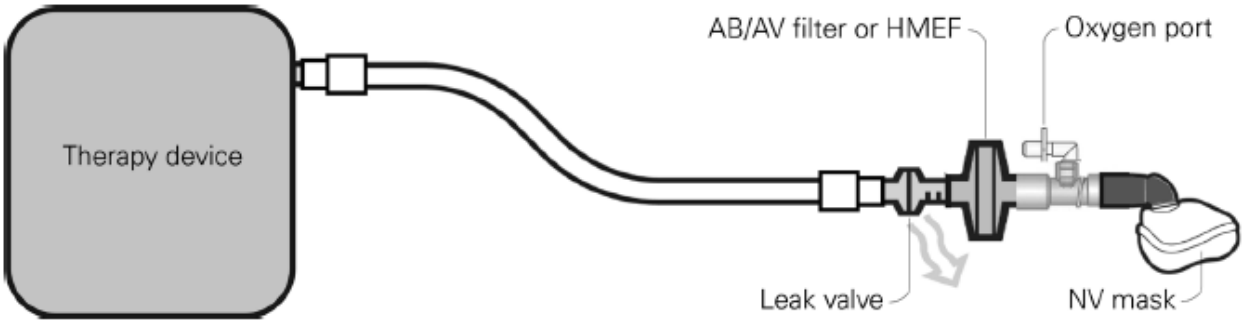

Figure 1: Low dispersion circuit setup

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The low dispersion circuit features, in succession: a Non Vented mask, an oxygen sideport connector, an Antibacterial/antiviral filter or Heat Moisture Exchange Filter, a ResMed Leak Valve and standard tubing.

Circuit component	Part description	Part number
Anti-bacterial (AB) / Anti-viral (AV) filter	Antibacterial filter – Adult, 50 pk	24966
Heat moisture exchanger filter (HMEF)	HME filter – Adult, 50 pk	24967
Oxygen port	Sideport oxygen connector	14915
Leak valve	ResMed leak valve ROW	24988

ResMed Leak Valve

14915 Oxygen Sideport Connector

26960 Oxygen Connector Port*

Quattro FX NV

Quattro Air NV

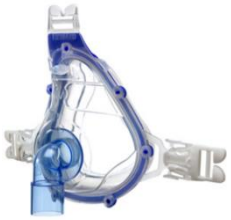

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Figure 2. ResMed Circuit Ancillary Materials

***The 26960 oxygen connector port is also compatible with this circuit configuration

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2. Use of Low Dispersion Circuit and Supplemental Oxygen with CPAP and Bi-level Devices

ResMed has reviewed the risks associated with the use of this circuit configuration (with and without supplemental oxygen), and considers these risks to be clinically acceptable with the warnings and cautions listed in Section 5.

The assessment was performed on CPAP, S, ST, PAC and T modes in the following devices: S9 VPAP ST/ST-A, Lumis ST/ST-A, AirCurve 10 ST, S9 Elite (CPAP mode only), S9 AutoSet (CPAP mode only) and AirSense 10 Elite (CPAP mode only) and AirSense 10 AutoSet (CPAP mode only).

The Intelligent Volume-Assured Pressure Support (iVAPS) therapy mode was not assessed and is not recommended for this circuit configuration.

All mentioned devices do not comply to essential performance specifications required for a life support ventilator. The key differences between these devices and an invasive ventilator are:

- Lack of therapy alarms
- No internal battery
- No oxygen blender.

2.1 CO_2 retention

Circuit accessories (eg, AB/AV filter, oxygen port, non-vented mask) placed between the leak port and the patient, contribute to increased dead-space which may lead to some rebreathing.

In order to minimize this, clinicians may consider switching to bi-level mode instead of CPAP, and/or increasing pressure support if patient CO_2 levels increase. See warnings and cautions in section 5.

2.2 Mask Setting

When using this circuit configuration, it is recommended that the user select either the “nasal” or “full face” mask setting.

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3. Ventilator Performance Impact

Testing and clinical assessment by ResMed showed the ventilator performance was acceptable, but there may be a few impacts when Lumis, AirCurve, AirSense and S9 devices are used with a low dispersion circuit and with an oxygen flowrate of higher than 15L/min. **Also see warnings and cautions in section 5 of this bulletin**.

				
Device	**Lumis ST and AirCurve ST**	**Lumis ST-A, AirCurve ST-A, S9 VPAP ST-A**	**AirSense 10 Elite and AirSense 10 AutoSet**	**S9 Elite, 29 AutoSet, S9 VPAP ST**
Location	Hospital use only			
Oxygen	• Indicated for up to 15L/min • May affect device performance with increasing O_2 levels • Mitigate risk through external monitoring			
Supervision	Monitoring with alarms strongly recommended			
Power	• Loss of power will stop ventilation • No internal battery			
Humidification or heated tubes	• Do not use integrated humidifier or heated tubes • Heat-moisture exchanger (HME) may be used			
Alarms	No integrated alarms, no alarm if ventilation stops. Notification on the screen will alert on high leak and blocked tube.	• Total power failure • Blocked tube • Disconnection • Low pressure • Low minute ventilation	No integrated alarms, no alarm if ventilation stops. Notification on the screen will alert on high leak and blocked tube.	No integrated alarms, no alarm if ventilation stops. Notification on the screen will alert on high leak and blocked tube.
Dead space	AB filter, oxygen port, NV mask contribute to dead space, adjust pressure support to compensate.			
iVAPS	Do not use iVAPS mode as target volume accuracy will be degraded		iVAPS mode not available	iVAPS mode not available

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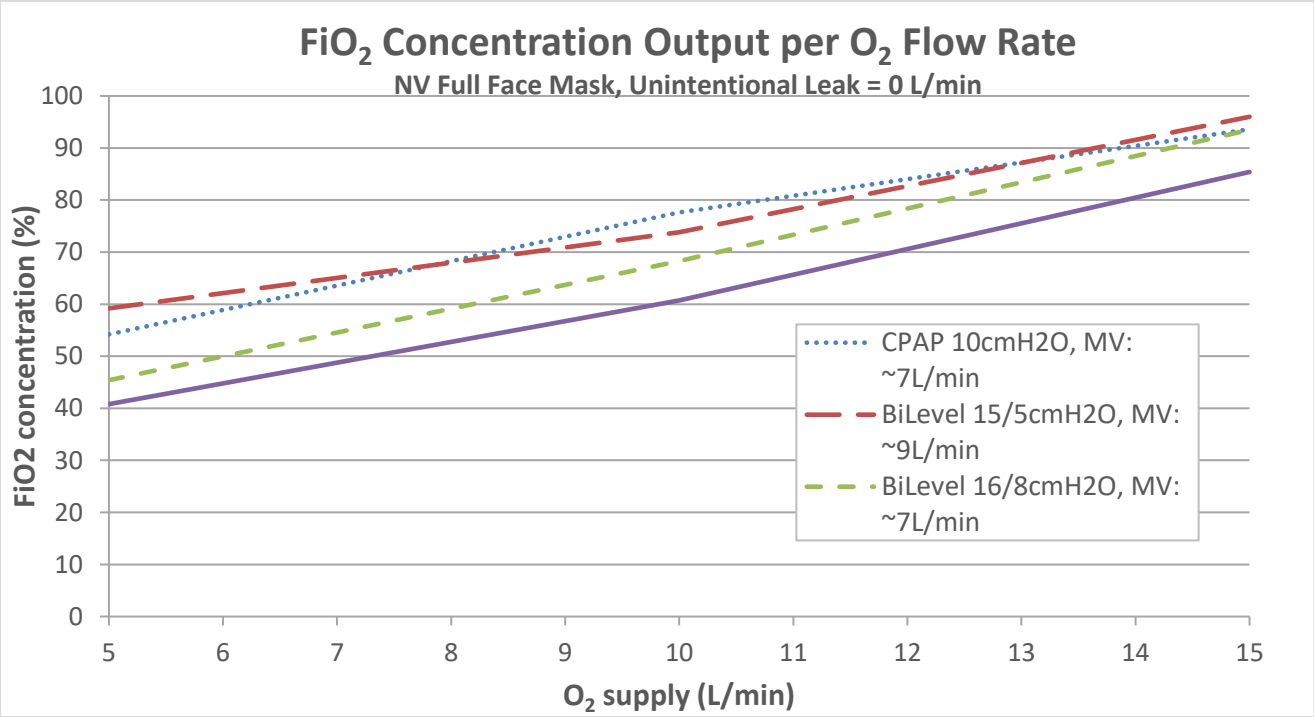
4. Supplemental oxygen

With increasing O_2 flow levels, triggering may be less sensitive to patient efforts and trigger delay may be increased. This may lead to asynchrony for very low patient flows, but can be improved by increasing the trigger sensitivity.

Pressure delivery and device reported values may be impacted by increasing O_2 flow levels, but not to the extent to impact patient safety or significantly reduce accuracy.

4.1 FiO_2

ResMed performed bench testing to provide users with guidance on the expected FiO_2 when using the recommended circuit. A compliant lung model (Resistance = 5 cmH2O, Compliance = 50 ml/cmH2O[1]) is used to achieve pressure waveforms and minute ventilations representative of COVID-19 patients. The breath rate is 20 bpm. CPAP: active patient model with 20 bpm. Bi-level: passive patient model with device backup rate set to 20 bpm.



[1] COVID-19 Does Not Lead to a "Typical" Acute Respiratory Distress Syndrome. Am J Respir Crit Care Med. 2020 Mar 30

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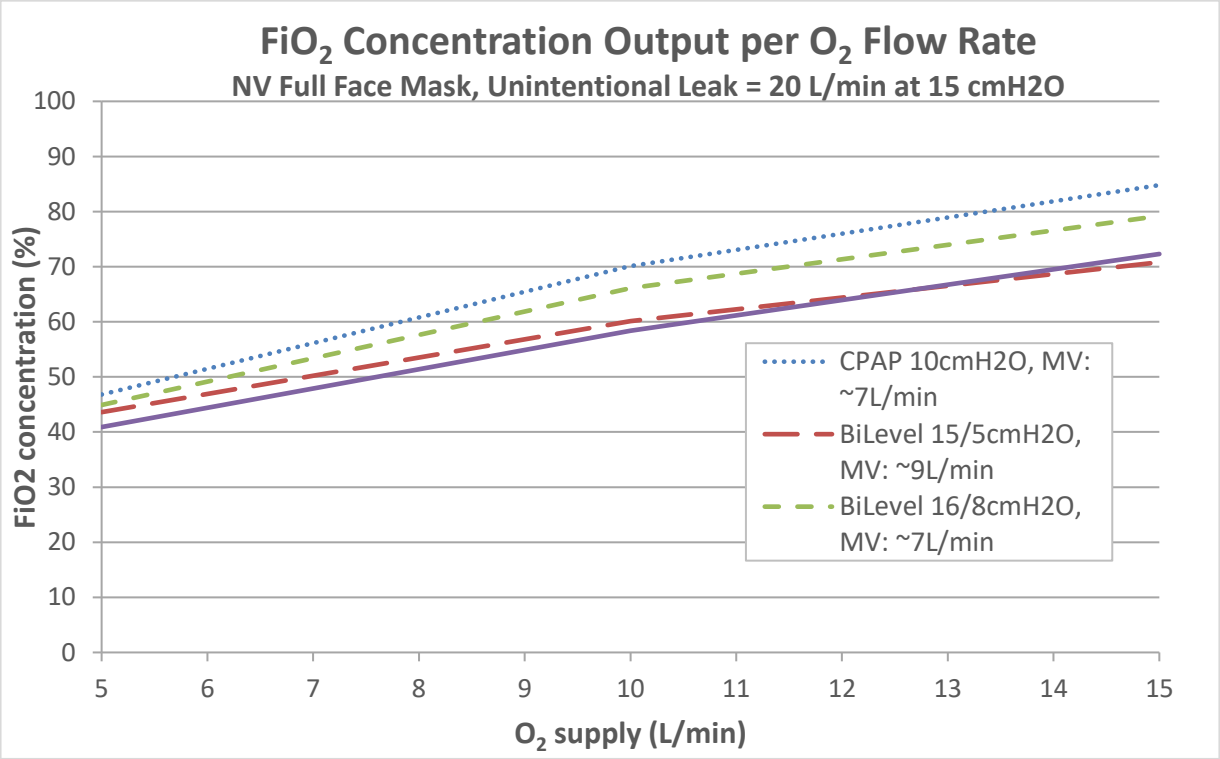
FiO_2 Concentration Output per O_2 Flow Rate, NV Full Face Mask, Unintentional Leak = 0 L/min

Mode	CPAP	Bilevel	Bilevel	Bilevel
Pressure	10 cmH_2O	15/5 cmH_2O	16/8 cmH_2O	20/10 cmH_2O
Minute Ventilation	~7 L/min	~9 L/min	~7 L/min	~9 L/min
O_2 Flow Rate	FiO_2			
5 L/min	54%	59%	45%	41%
10 L/min	78%	74%	68%	61%
15 L/min	94%	96%	94%	85%



FiO_2 Concentration Output per O2 Flow Rate, NV Full Face Mask, Unintentional Leak = 20 L/min

Mode	CPAP	Bilevel	Bilevel	Bilevel
Pressure	10 cmH_2O	15/5 cmH_2O	16/8 cmH_2O	20/10 cmH_2O
Minute Ventilation	~7 L/min	~9 L/min	~7 L/min	~9 L/min
O_2 Flow Rate	FiO_2			
5 L/min	47%	45%	45%	41%
10 L/min	70%	60%	66%	58%
15 L/min	85%	71%	79%	72%

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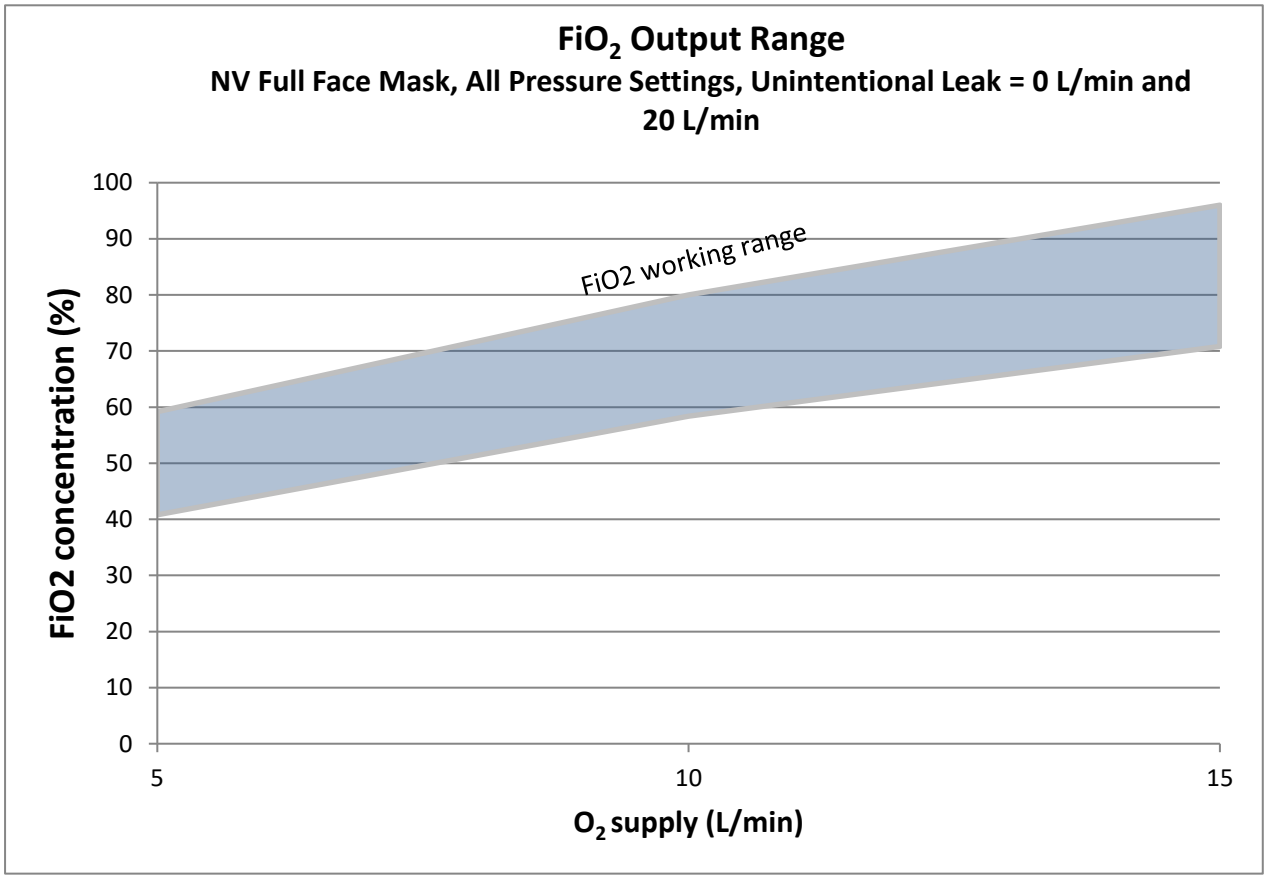
When interpreting FiO_2 values, it is important to keep in mind that various factors can influence the end results, both in bench testing and in the clinical application.
As can be seen in the graphs, both the **pressure settings and the resulting minute ventilation** create variation of at least 20% FiO_2. Additional variation may be caused by other confounding factors including but are not limited to: patient breath rate, inspiratory peak flows, unintentional[2] leak, and intentional leak of the ResMed leak valve.



Generally, FiO_2 values will range between 50% and 80% at 10 L/min of O_2 supply, and between 70% and 95% at 15 L/min of O_2 supply, accounting for up to 20 L/min of unintentional mask leak.

[2] Unintentional leak refers to the air leak at the mask face interface, as opposed to intentional leak through the leak valve.

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4.2 Blocked tube alert

All devices contain a blocked tube alert/mitigation that may be falsely triggered with >15 L/min of supplemental O_2. Devices will stop therapy if this mitigation occurs. If supplemental oxygen is added to the circuit at higher than 15 L/min, this might lead to false activation of 'blocked tube' alert, which leads to ventilation stop. Only Lumis ST-A, AirCurve ST-A and S9 VPAP ST-A will signal this alert with an audible alarm. The remaining listed devices do not contain audible alarms however, a notification on the screen will signal the blocked tube alert and lead to ventilation stop.

If using high flow levels of oxygen, external monitoring and supervision is recommended. If blocked tube alert occurs and ventilation stops, clinician may opt to increase pressure support, or decrease level of supplemental oxygen flow. Observe at least five minutes of the device operation during patient breath triggering when adding high flow rate of oxygen. See warnings and cautions on section 5.

4.3 Non-Vented mask alarm

An increased level of oxygen increases the likelihood of false triggering of the Non-Vented Mask alarm in Lumis ST-A, AirCurve ST-A and S9 VPAP ST-A. Clinicians should assess if opting to turn off the alarm in this circuit configuration would be appropriate and suit patient needs.

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5. Warnings and Cautions

When using the low dispersion circuit configuration, it is subject to the addition of the following:

Warning: This circuit, or the use of supplemental oxygen at the mask, may impact device performance and the effectiveness of alarms. When using this configuration with patients whose condition may deteriorate without adequate ventilation, use of independent patient monitoring equipment with alarms is strongly recommended.

Warning: Use of the device with this circuit configuration shall be limited to emergency use due to resource limitation in a hospital only.

Warning: The use of supplemental oxygen in excess of 15 L/min with a vented circuit with a ResMed Leak Valve may result in false triggering of the 'blocked tube' mitigation leading to ventilation stop[3]. The audible alarm is only present in Lumis ST-A, S9 VPAP ST-A and AirCurve 10 ST-A (US only) devices. 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.

Caution: Circuit accessories (eg, AB/AV filter, oxygen port, non-vented mask) placed between the leak port and the patient contribute to increased dead-space which may lead to some rebreathing. Clinicians should consider minimizing that dead-space and adjusting device settings (eg, increasing pressure support/ventilation) to compensate for the increased dead-space if increase in patient CO_2 level is detected.

Caution: iVAPS mode is not recommended with this circuit configuration, especially when used with levels of entrained oxygen greater than 4 L/min. While the therapy continues 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, potentially affecting the efficacy of the treatment.

[3] Higher levels of supplemental oxygen and resistance circuits result in lower 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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Note: As currently stated in Lumis ST-A, AirCurve ST-A and S9 VPAP ST-A Clinical guides, the use of supplemental oxygen with a vented circuit may result in false triggering of the Non-Vented mask alarm – with increased level of oxygen up to 20 L/min, it 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.

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6. Device Regional Identification

The described circuit configuration applies to Lumis, AirCurve, AirSense and S9 platforms. The table below describes the appropriate device commercial name and function differentiated per region. Please note this does not apply to adaptive servo-ventilation (ASV), Autoset (APAP), iVAPS modes.

	Regional Availability			Available Modes					
Product Name	**AMR**	**EMEA**	**AGM**	**CPAP**	**S**	**T**	**ST**	**PAC**	**Pressure Range* (cmH_2O)**
S9 Elite		•	•	•					4-20
S9 Autoset		•	•	•					4-20
S9 VPAP ST	•	•	•	•	•	•	•	•	ROW 2-25 AMR 3-25
S9 VPAP ST-A	•	•	•	•	•	•	•	•	ROW 2-30 AMR 3-30
AirSense 10 Autoset	•	•	•	•					4-20
AirSense 10 Elite	•	•	•	•					4-20
AirCurve 10 ST	•	•		•	•	•	•		ROW 2-25 AMR 3-25
AirCurve 10 ST-A	•			•	•	•	•	•	3-30
Lumis 100/150 ST		•	•	•	•	•	•	•	2-25
Lumis 100/150 ST-A		•	•	•	•	•	•	•	2-30

Legend:

AMR: Americas

EMEA: Europe, Middle East, Africa

AGM: Asia Growth Markets

ROW: Rest of World

*CPAP is always 4-20

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7. Multipatient use

See the relevant device Clinical guide for Multipatient use details.

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

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Clinical Bulletin CB#010

Title of Clinical Bulletin: Supplemental Oxygen and Low Dispersion Circuit in CPAP and Bi-level devices for COVID-19.

1. Details

Brief Details: Clinical Bulletin describes the use of a low dispersion circuit with CPAP and bi-level devices (Lumis, AirCurve, AirSense and S9) in the context of addressing a shortage of dedicated ICU ventilators during the COVID-19 pandemic crisis.

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