



AirCurve™ 10

ENGLISH

Information – AirCurve 10 ST

R_x Only

Indications for use

The ResMed AirCurve 10 ST devices are indicated to provide CPAP and bi-level therapy for patients weighing more than 66 lbs (30 kg), with respiratory insufficiency or OSA. They are intended for home and hospital use.

The ResMed AirCurve 10 ST devices can be used with an attachable humidifier that is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

Note: The indications for use for respiratory insufficiency have not been cleared by the FDA. The expanded indications shown are permissible per FDA Guidance, "Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency." The original indications for use state:

The AirCurve 10 ST device is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lbs (30 kg). It is intended for use in the hospital and home.

Additional precautions when in contact with COVID-19 patients on non-invasive ventilation (NIV)

- Due to risk of dispersion of aerosolized virus during NIV, healthcare workers should use airborne protection by wearing respirators N95 or FFP2 standard or equivalent, eye protection, gloves and gowns; aprons should also be used if gowns are not fluid resistant.
- To prevent cross-contamination, combination antibacterial/antiviral filters should be used on circuits.
- Circuits and accessories are to be replaced or decontaminated and disinfected (refer to associated user/clinical guides or service manual for reprocessing method).
- Clean all surfaces with approved surface disinfectants.

Notes about the device

- This is NOT a life support ventilator.
- This device is not designed to provide invasive ventilation.
- iVAPS or VAuto (self-adjusting) modes are not available in this device.
- This device does not have an internal battery – transport of patient using this device would require an external battery.
- This device does not have alarms, sophisticated monitoring or modes, and the pressure generation is not sufficient to care for those with significant lung injury.



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