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YOUR MESSAGE OF:

YOUR REF:

OUR REF:

Clinical trial of the home mechanical ventilation device CUBE 30 ATV with serial number 001030007917 and 001010005217

Question:

Useability of the Cube 30 ATV for non-invasive artificial ventilation in a clinical setting was to be tested. The Cube 30 ATV is a device to be used in spontaneously breathing patients who are fully conscious, have a body weight of at least 13 kg and are suffering from respiratory insufficiency.

Following diseases are included:

- Chronic obstructive pulmonary disease (COPD)
- Neurological, muscular and neuromuscular disorders such as diaphragmatic paresis
- Restrictive respiratory tract disorders, such as scoliosis, thorax deformities or cystic fibrosis
- Central respiratory tract regulation disorders
- Obstructive sleep apnoea syndrome (OSA)

The device is suitable for both home usage and in the clinical setting (hospitals, sleep laboratories etc.).

The Cube 30 ATV device has a solid housing and an intuitive design. Various assisted and controlled ventilation modes for mask ventilation can be set.

The device has been tested on five patients at the Clemens Hospital in Münster, on different pneumological wards. These patients had obesity hypoventilation syndrome with respiratory failure, various stages of COPD or lung emphysema. BiLevel APCV mode was used as a general rule. A good and adequate breathing pattern could be achieved using this on clinical stable patients. The device was subjectively regarded as comfortable. Various parameters such as inhalation triggers were adjusted by the company during the device trail. The device can now be used like other devices on the market, with advantages in the area of operation.

Conclusion:

In summary, the Cube 30 ATV was tested on patients in a medical evaluation. The device was praised for its user friendliness, and its effectiveness for the above indications, and ensured success in hospital treatment. The device has enough reserve capacity for the identified area of application with sufficient inspiratory pressure, inhalation flow and triggering. The device is in a position to take over at least some of the work of breathing for patients with neurological conditions, with insufficient alveolar respiration and chronic lung conditions which overload the respiratory muscles. No particular risks or complications resulting from the intended use of the device have been identified. The device can be operated by the patient safety, and access to the medical menu is encrypted. This guarantees that the device will be used properly.

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