

Summary of technological characteristics of Device and Predicate Device:Carbon dioxide analyzer.

The CO2 functionality uses the Servo-i screen for presentation of mainstream CO2 measurements. The airway adapter is placed at the Y-piece and the sensor is snapped on to the airway adapter. The CO2 Analyser module receives signals from the sensor that reflects the variations of CO2 in expiratory gas. This allows for continuously monitoring shown in a waveform indicating the CO2 concentration and numerical presentations of EtCO2 and V̇CO2.

The CO2 functionality for the Servo-i CO2 module is equivalent to the CO2 analyzer in Siemens Infinity CO2 pod (file number K003550), an accessory item employed with the Siemens ServoVentilator 300A, which also is technologically based and componentry sourced as Sensor and input electronics card from Novamatrix. (file number K963380)

Bi-Vent mode

Bi-Vent is a Biphasic positive airway pressure (BIPAP™) which is equivalent to airway pressure release ventilation (APRV) which has been designed to provide ventilatory support with unrestricted, spontaneous breathing. These modalities operate by periodic switching between two levels of continuous positive airway pressure while allowing spontaneous breathing in any phase of the ventilatory cycle. However, in the absence of spontaneous breathing, airway pressure release ventilation/biphasic positive airway pressure is identical to conventional pressure-limited, time-cycled, mechanical ventilation, eg Pressure Control.

Bi-Vent ventilator mode is used on many ventilators for both critical care and home care. The Bi-Vent mode is substantially equivalent to Puritan Bennet 840 ventilator with NeoMode option (K001646), Dräger Evita 4 – (K980642) for adult and with Neo flow for neonates , Savina (Dräger – K003068), Galileo (Hamilton - K001686), and Harmony S/T Respirationics - K984407 and KnightStar 330 (Nellcor – K003075)

The technology used is assessed, verification and design validation on animals show that the ServoVentilator System has the equivalent clinical performance with the above options.