

X-VENT Disclosures



The X-VENT is a continuous use, emergency ventilator intended to provide invasive and non-invasive ventilatory support for adult patients > 35 kg of weight with respiratory insufficiency or failure. The X-VENT is to be used under prescription only and is intended to be used in hospitals, hospital-type facilities, or other institutional health care environments. X-VENT provides patients with emergency ventilatory support when no alternative standard ventilators are available. The X-VENT is intended for use by qualified physicians and respiratory therapists who have undergone training on the use of the X-VENT ventilator.



The Breathe Strong X-VENT Emergency Ventilator has not been FDA cleared or approved. Enexor Health Systems, LLC has filed for this ventilator to be authorized by the FDA in accordance with the Ventilator EUA dated March 24, 2020. The X-VENT has since received FDA approval under the aforementioned EUA. The X-VENT Emergency Ventilator will be authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of ventilators under section 564(b)(1) of the Action 21 U.S.C 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



This ventilator has not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.



This ventilator relies on the integrity of the protective earth ground to reduce the risk of electrical shock. Check the integrity and verify the function of the protective earth ground of the supply mains receptacle prior to use.



Due to the rapid development cycle for this emergency use device, all efforts were made to verify the software, but defects may still exist. The consequences of these defects are unknown.



This ventilator has been protected with a 128-bit encrypted password to prevent software tampering and system intrusions. The external communication port(s) on this device have been restricted to the functions described in the user manual and will not permit access to the software on this unit. Do not connect this unit to a LAN, WAN or other networked communications system.



The software for this ventilator was not developed using a controlled life cycle development process as outline in IEC 62304[4].



Unit Over 40 lbs (> 18 kg).



Do Not Obstruct Air Vents.