

Unsuitable for COVID-19 patients: The inability to easily adjust oxygen concentrations, the inability to set tidal volumes directly and the poor performance of pre-use checks and calibrations make the Shangrila 510s unsuitable as a substitute for a critical care ventilator in all but extreme circumstances. The description under Indications for Use in the Service Manual: “Shangrila510S ventilator is mainly used in the emergency rooms of hospitals, transfer after operations, field and occasions where first-aid or transfer is needed”, supports this view.

The lack of readily available IFUs, re-processing instructions and calibration instructions contravene the requirements of CE marking and should be rectified.

Poor usability is, in part, a result of the Shangrila 510s being of an outdated design and it is not truly a Volume Controlled Ventilator. For short transport use in patients with relatively normal lungs, it will function adequately. It is not suitable as an ICU ventilator and performs less well than other basic transport ventilators (ParaPac, Oxylog) in use in the NHS.

The extraordinary circumstances facing the NHS and many other healthcare systems in March 2020 made the usual process of device procurement (selection, medical engineering training and assessment, clinical training and assessment, detailed procurement instructions) difficult if not impossible to follow. As a result, hose incompatibility, oxygen sensors, casing and breathing system choices were not properly identified.

Even in pandemic times rapid external review of new technology procured for the NHS should be undertaken to identify suitability and training needs.