2019 HCU Hydrogen peroxide

Permission to print:	Yes
Region	ANZ
Description:	The IFU for the LivaNova 3T heater Cooler unit changed in October 2018 requiring daily monitoring of hydrogen peroxide levels and where the concentration falls below 100ppm the addition of 100ml 3% H2O2. The IFU states: LivaNova has observed that in a limited number of devices tested after a period of clinical use, the concentration of hydrogen peroxide decreased rapidly to zero within a day. In the devices where rapid hydrogen peroxide loss occurred, LivaNova observed the degradation of a nickel coating on cooling coils in the tanks, resulting in exposed copper. LivaNova believes the rapid hydrogen peroxide decrease may be caused by a reaction between the exposed copper and the hydrogen peroxide. In an audit of 10 3T HCUs, 8 of which are 18months old and 2 retrofitted 12 months ago, all 10 devices had H2O2 concentrations well below the 100 ppm threshold (range 0-30ppm) every day for 7 consecutive days despite following the H202 top up provisions in the IFU. The degradation of H2O2 appears immediate even in relatively new devices. NTM and bacterial monitoring have not revealed positive results, likely due to the disinfection process. The nickel coating on the cooling coils appears short lived and rigorous following of the 3T HCUs disinfection AND peroxide monitoring IFUs is required. Daily routine addition of 100ml H2O2 (that restored the H2O2 concentration to ~150ppm) may be considered.
GOOD CATCH - what went	Routine daily pre op testing program of all 3T HCUs that ensured rapid loss os H2O2 concentration was countered.
What could we do better	Use HCUs that do not aerosol water vapour
Preventive actions	Daily testing of H2O2 concentration of all 3T HCUs and result documentation
Catagory	Heater Cooler unit
Incident type	Near Miss
Commentary	This report is of interest as PIRS is aware of centres that are using this devcie and not routinely monitoring hydrogen peroxide levels daily as required by the IFU. The experience in this report is of note in that the drop in hydrogen peroxide concentration was immediate and severe and despite H2O2 supplemenation daily, all devices that are relatively new. PIRS ed