



Issue Date: 22nd June 2020

SAFETY ALERT NOTICE.

Drug / Product / Device : Lifepak 15 Trunk Cable with 4-wire limb leads & Medi 9 Spray.

Identified Issue / Concern / Problem/ Evidence of harm.

An engineering inspection and testing was undertaken following a reported fault in several Lifepak 15 devices. The LP15's appeared to display a VF like rhythm on the Lead II view on the display screen and at times a relatively Organised rhythm appeared though no patient was connected.

It transpires that when the cables are repeatedly exposed to Medi 9 spray which is sprayed and allowed to air dry rather than wiping dry that after approx. 5 cycles the residue builds to a conductive layer and the cables function in the manner of an antenna leading to capture of background signals such as Wi-Fi, tetra radio and external radio waves.

The cables also become sufficiently conductive to pick up a practitioners ECG when the cables are held but without touching the connectors.

In all cases the application of ECG dots and connection of an actual or simulated patient overcomes the phantom signal and the devices operate correctly.

Cleaning the residue off the cables with Clinell wipes either Alcohol, antimicrobial or universal resolved the issue



Actions Required / Risk Treatment strategy

Do not use Medi 9 Spray to disinfect the cables from the Lifepak 15.

Only use Clinell wipes – Alcohol, Antimicrobial or Universal to wipe the leads.

Issued by: Quality, Safety & Risk.