

Risk Analysis Report

This product has been in continual use since 1985 without complaint or adverse effects.

Warnings are given in the instructions for use, that it should not be used with needle electrodes, and that it should be used with care with pacemakers.

The change of processor, change in software coding & change in discrete components does not change the functionality of the product or the risk posed to the patient or user.

Some change in suppliers recently, but as the same parts have been sourced from alternatives, the functionality of the product remains the same, as does the risk posed to the patient or user.

The Mk3 is changed to the original in looks and certain component parts, but is inherently the same instrument. The functionality of the unit has not changed.