

It used by individuals with various skill levels from various cultural backgrounds?	The equipment should only be used by experienced trained personnel Symbols are used
There is Contact with enclosure, controls & Leads by the patient or user whilst using the product. ECG pads not supplied with product – customers use their own.	The contact is transient
Energy delivered to and/or extracted from the patient?	The equipment should only be used by experienced trained personnel It ca effect pacemakers ;Warning is given in the maual. Trained Anesthetists will be aware of this
Conclusion: The main risk is an non harmful but painful electric shock if the user inadvertently used a high setting or the leads had an intermittent fault. Since 1986 there have been no problems and one occurrence with a pacemaker. This product is not unique and it has a range of competitors.	

Signed: J.S.Lamb Date 01/11/11