

Design History

The Microstim was originally designed in MRI by a team of medical Physics Technicians headed by Mr Malcolm Purnell. At the time CE marking did not exist, ISO 9000 was not in operation and it was not until the mid 1990's that MRI and Viamed achieved ISO 9000 registration.

The current Microstim file therefore, can only be re-written as a product already designed and manufactured with a ten-year track record before the current legislation

We can only update the files as long as information not originally existing is not falsified.

1. We can update – essential requirements and changes to design.
2. We can complete the risk assessment assuming we were starting now but still with the current design.
3. EMC. The file produced was pre EMC legislation but was tested clinically in severe EMC conditions i.e. theatres. We have to ensure that the existing rationale still holds valid.
4. New information can be added to this file as long as it adds to its value and does not have the effect of reducing product credibility.