Guidance for manufacturers on reporting adverse incidents involving Neurostimulators under the vigilance system

To be read in conjunction with the guidelines on a medical devices vigilance system MEDDEV 2.12/1

Report as individual events (in line with MEDDEV timescales)
Telemetry failure (during or after implantation)
Fracture of accessory / introducer items
Premature battery depletion
Inability of rechargeable battery to hold charge
Mechanical failure of pulse generator (including internal components)
Electrical failure of pulse generator
Unexplained loss of therapy
Neuropraxia
Tissue Damage

Report as periodic summary reports (PSR)*	
	Periodicity
Lead fracture	3 monthly
Lead shorts	3 monthly
Lead migration	3 monthly
High lead impedance	3 monthly
Electromagnetic interference	3 monthly

Report at time adverse trend is identified
A change in stimulation due to fibrosis around electrode

*** If you can't use PSR, then report these events individually.**