

Medical Device Alert

Immediate action

Ref: MDA/2009/038 Issued: 10 June 2009 at 11:30

Device

Implantable pacemakers.
Medtronic Kappa[®] 600/700/900 series and
Sigma[®] 100/200/300 series IPGs.

Specific serial numbers may be entered
online to determine if they are affected
(<http://KappaSigmaSNList.medtronic.com>).



Problem

Certain Kappa[®] and Sigma[®] series pacemakers may suffer sudden unexpected failure giving rise to bradycardia symptoms (fainting or light headedness). Serious injury or death may occur in pacemaker dependent patients.

Action by

Cardiac physiologists, cardiologists, cardiothoracic surgeons who implant these pacemakers or who manage implanted patients.
Physiological measurement technicians.

CAS deadlines

Action underway: 29 June 2009
Action complete: 04 September 2009

Action

- Consider replacing all affected pacemakers in pacing dependent patients.
- Advise patients to seek medical treatment immediately if they experience a return of their bradycardia symptoms.
- Follow up all other patients implanted with affected pacemakers at intervals of no more than six months.
- Report any incidents involving Kappa[®] and Sigma[®] pacemaker failures to the MHRA and Medtronic.

Contact

Manufacturer

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Link to full Medical Device Alert

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON049142>