

Customer Product Bulletin

Guidance on compatibility of Tunstall products

Pacemakers, Implantable Cardioverter Defibrillators (ICDs) and Heart Failure Devices

The following provides guidance on the compatibility of Tunstall's telecare products with medical devices such as pacemakers. The approach to compatibility here is that one product should not emit more than a defined level of electromagnetic radiation, whilst a compatible second device should not be susceptible to radiation below specified levels.

Pacemakers and other medical devices should be manufactured such that they can withstand Electromagnetic Interferences (EMI) in accordance with their associated mandatory European regulations. These standards vary by product type, and users need to check details with the respective suppliers.

It is mandatory that social/community alarm and telecare products conform with the European Electromagnetic Compatibility directive (2004/108/EC) or R&TTE Directive (1999/5/EC), which requires compliance with the following standards:

- a) Emissions (EN 55022: 2010)
Defines limits and methods of measurement of radio disturbance characteristics of information technology equipment
- b) Mains Harmonics (EN 61000-3-2: 2006 + Amendments)
EMC Limits for harmonic current emissions
- c) Immunity (EN 50130-4: 2011)
Immunity requirements for Fire, Intruder and Social Alarm Systems.
- d) Radio EMC
EN 300 220-2: 2009 'Electromagnetic Compatibility and Radio Spectrum Matters for Short-Range Devices': This standard defines the EMC requirements for the low-power radio systems used in social alarms.

EN 301 489-3: 2002 EMC standard for Short Range Devices (SRD) operating on frequencies between 9KHz and 40GHz.

It is confirmed that **Tunstall products fully conform to these mandatory standards. If you employ social/community alarm or telecare equipment from another supplier then you should request confirmation and certification of compliance to these standards.**

Users should also request confirmation from medical device suppliers that their product is manufactured to the appropriate Electromagnetic Compatibility standards.

Further information on compatibility of pacemakers can be found on various websites, for example <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Technicalinformation/Electromagneticinterference/> .

<http://www.bostonscientific.com/templatedata/imports/HTML/CRM/patient/>

The information on these websites indicates to users those devices and the level of formally agreed risk that pacemakers can contend with.