DEVICE

BULLETIN

MEDICAL DEVICES AGENCY

Emergency service radios and mobile data terminals: compatibility problems with medical devices.

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The Medical Devices Agency helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

Our primary responsibility is to ensure that medical devices achieve their fullest potential to help healthcare professionals give patients and other users the high standard of care they have a right to expect.

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CONTENTS

1. EXECUTIVE SUMMARY

This device bulletin covers the impact of radio communications on the safe use of medical devices (including pacemakers implanted in patients) both **inside ambulances** and **at the scene of an accident in the vicinity of emergency vehicles.** It extends the guidance in DB9702 "Electromagnetic compatibility of medical devices with mobile communications".

We also consider the possible risks to devices within healthcare facilities, both **when emergency vehicles are parked nearby** and **when mobile data terminals are in use**. The latter are transmitting devices which send and receive text messages, and are frequently used by servicing personnel.

We conclude that there is a significant risk of dangerous interference which should be minimised:

- The use of portable handsets and cellphones inside ambulances should be restricted.
- Special precautions are needed if a patient with an external pacemaker is being transported.
- Displaying warning notices, providing staff training, and relocating parking bays are possible actions if risks of interference prove unacceptable when emergency vehicles are parked immediately outside patient treatment areas.
- Caution should be exercised when treating patients with medical devices at the scene of an accident if an emergency vehicle is in the immediate vicinity.
- Mobile data terminals should be subjected to any restrictions which are locally applied to cellphones.

2. RECOMMENDATIONS

2.1 Ambulance vehicle radio interference

A risk assessment should be carried out before medical devices are used inside an ambulance. Any changes to the vehicle radio system (for example, introducing a vehicle location system) should trigger a new assessment.

2.2 Portable handsets in ambulances

Portable radio handsets (including cellphones) pose a significant risk of interference with medical devices when operated inside an ambulance. Where possible handsets should be used outside the ambulance or else communication should be via the vehicle radio.

2.3 Patients with external pacemakers

External pacemakers are especially susceptible to radio interference. We recommend positioning the device as far as possible from the vehicle's aerial(s). A warning notice inside the ambulance should indicate the position of the aerial(s).

2.4 Patients needing treatment at the roadside

Clinical staff should be aware that radio interference may cause devices to malfunction if they have to work closer than 5m to an emergency service vehicle. Emergency service vehicles include ambulances, police cars and motorcycles, fire appliances and breakdown trucks.

2.5 Staff training

Ambulance, paramedic, cardiac and accident and emergency staff should be trained so that they can recognise common interference events, and act appropriately.

2.6 Ambulance staff using portable handsets inside hospitals

We repeat here the guidance in DB9702 on the use of portable radio handsets on hospital premises.

Emergency Services radio handsets:

- Personnel carrying these phones should be made aware of the possible risks.
- Personnel should always make themselves known to hospital staff in charge of the area they are entering.
- Emergency service handsets should only be used in hospitals **in an emergency**: never for routine communication.
- Personnel should move well away from treatment areas before initiating or answering a call.
- Staff operating base stations should not try to contact an officer on routine matters while he or she is on hospital premises.

2.7 Interference from emergency service vehicles parked near treatment facilities

If parts of patient treatment areas fall within 5m of an emergency service vehicle parking bay, then a risk assessment should be performed:

- Have treatment facility staff experienced interference events?
- Is sensitive equipment (see DB 9702 “Electromagnetic compatibility of medical devices with mobile communications” for risk categories) located at points within the building close to the parked ambulances?
- Does interference have potentially serious consequences?

If risks are low, staff should be alerted to the possibility of interference and training provided in how to recognise and deal with interference events.

If risks are moderate, displaying warning notices requesting emergency service personnel not to use their radios should be considered.

If risks are high, then relocating parking bays further from the building should be considered.

2.8 Mobile data terminals

The use of these devices should be subject to any local restrictions which apply to cellphones. Mobile data terminals must **never** be placed on any medical device.

3. BACKGROUND

Many electrically-powered medical devices fail to function properly when exposed to strong electro-magnetic fields immediately surrounding a radio transmitter such as a cellphone, a portable communications handset, a two-way radio, or a vehicle radio. A recently reported adverse incident, for example, involves an incubator being transported in an ambulance switching itself off completely as a result of interference from an ambulance radio handset. The incubator needed to be turned off and on again to reset it.

The Medical Devices Agency (MDA) Device Bulletin DB9702 "Electromagnetic compatibility of medical devices with mobile communications" reports the results of a large-scale study. We subjected many different types of medical device to fields generated by a large range of portable communications equipment. Tests were conducted in hospital Biomedical Engineering and Medical Physics departments and Device Evaluation Centres. Emergency service radio handsets, including ambulance and fire-service radios, caused the most severe problems.

Emergency vehicles typically have:

- **a vehicle radio** – a two-way radio mounted on the dashboard, connected to a roof aerial;
- **a portable radio handset** which is stored in a holster in the cab, and carried by personnel who need to leave the vehicle.

These devices communicate using electromagnetic radiation – they are designed to be received at distant base stations, and will inevitably give rise to strong local electric fields.

An ambulance interior is a difficult environment for medical devices, with a strong risk of electrical interference:

- the antenna of the powerful vehicle radio is close to the cabin roof;
- radio handsets operated inside the vehicle cause reflections which are likely to increase the field strength within the vehicle.

We have extended our study to cover devices commonly used in ambulances, and have tested their susceptibility to interference inside a typical ambulance, using both the vehicle radio and an ambulance radio handset.

Measurements of electric field strengths inside and surrounding an ambulance while the vehicle radio is transmitting provide a basis for assessing the risk to devices operated inside and close to ambulances, and in facilities with ambulances parked immediately outside. Electric field strength is measured in volts per metre (Vm^{-1}), and current IEC standards specify that medical devices should be designed to resist electrical interference as follows:

- **Life support devices: $10Vm^{-1}$**
- **Other medical devices: $3Vm^{-1}$**

These values provide convenient benchmarks for assessing risks. Fields up to $3Vm^{-1}$ are often encountered as background levels in healthcare facilities, and are unlikely to cause many interference problems, and very unlikely to cause serious problems.

Fields between 3 and $10Vm^{-1}$ typical of most of the measurements we made inside ambulances represent moderate risk levels. **Staff working in these environments need training to recognise interference events and respond appropriately** (see recommendation 2.5).

Table 1 gives the distances from the transmitting aerials for the various types of radio covered here at which the benchmark field strength levels of 3 and $10Vm^{-1}$ are exceeded. Fields **closer** to the transmitting aerials than the distances listed in the table will exceed the benchmark values. The values in this table are derived from measured field strengths by linear interpolation on a reciprocal scale for distance.

Table 1. Critical distances from transmitting aerial for benchmark field strengths.

Source	distance for 3 Vm^{-1}	distance for 10 Vm^{-1}
Ambulance vehicle radio	6m	2m
Handset	2m	0.5m
Fire appliance vehicle radio	6m	2m
Motorcycle radio	6m	2m
Helicopter ambulance	7m	2m
Mobile data terminal	1.5m	0.5m

The likelihood that a field above 10 Vm^{-1} will cause impaired functioning of medical devices increases sharply with increasing field strength, and operating devices in the presence of such fields presents an unacceptable risk. Such fields occur:

- close to vehicles;
- in the immediate vicinity of radio handsets and mobile data terminals;
- up near the roof level inside an ambulance when the vehicle radio operates;
- as a consequence of operating radio handsets inside an ambulance.

4. SURVEY RESULTS

61 ambulance personnel in East Anglia responded to a survey asking about their experiences of problems with electromagnetic interference. Appendix 3 contains the questionnaire report. 41% of respondents had experienced problems. Critical medical devices affected included monitors and defibrillators.

5. RESULTS OF TESTS ON MEDICAL DEVICES

Table 2 lists the effects of the electric fields generated by both the vehicle radio and the radio handset on each of the devices tested. The "effects" column summarises any malfunctions which appeared when the source was turned on. In each case lower field strengths than the one cited in the table did not cause any problems. The distances next to the "handset" labels in the source column are the furthest at which the interference effects could be detected. Field strength measurements were taken as close as possible to the device under test. Appendix 1 has technical details of the radios, including power ratings and operating frequencies, and Appendix 2 details of test methods.

Table 2. Effects on medical devices.

Type	**Model**	**Source of interference** (distance away)	**Field** (Vm^{-1})	**Effects**
Infusion pump	Baxter DCR Flo-gard	Vehicle	26	A1 Service Alarm - pump cannot be reset
Infusion pump	IVAC P3000	Handset (14cms)	45	Syringe alarm
Infusion pump	IVAC P6000	Handset (14cms)	45	Occlusion alarm
Infusion pump	Baxter Flo-gard 6201	Handset (0cms)	420	NO EFFECT
Infusion pump	IVAC IPX4	Handset (0cms)	420	Occlusion error
Infusion pump	IVAC 560	Handset (70cms)	18	PUMP DISABLED fix me, flow sensor error. Must be switched off to reset.
Infusion pump	IVAC 597	Handset (7cms)	60	Error 1
Infusion pump	MEDIS	Handset (0cms)	420	NO EFFECT
Infusion pump	Danby Baxter DCR	Handset (30cms)	26	Service alarm
Defibrillator	Codemaster XL	Handset (0cms)	420	Wobble on display
Defibrillator	Codemaster 100	Handset (1.6m)	4	Downward spike on ECG trace
Defibrillator	Marquette 900	Handset (0cms)	420	ECG spike. Loss of display. Interference on display
Defibrillator	Lifepak 10	Handset (0cms)	420	Tiny baseline shift
External pacemaker	Pacesetter 446	Vehicle	9	Sense light responds to radio on/off
External pacemaker	Pacesetter 446	Handset (1m)	6	Continuous sense
External pacemaker	APC EV4543	Handset (5cms)	125	Sense light responds to radio on/off
Patient monitor	Kontron 7840	Handset (20cms)	31	Central display illuminates, rate becomes unreliable

As expected, most of the problems were caused when the radio handset was brought close to devices. This observation supports recommendation 2.1, which proposes that **handsets should not be used inside the vehicle.**

The vehicle radio only affected:
- external pacemakers;
- devices operated high up in the space near the forward cabin skylight (Figure 1).

Most of the devices tested showed only minor interference phenomena, and then only at the very high field levels experienced in the immediate neighbourhood of the radio handset. In all cases but one (the Baxter DCR Flo-gard pump) the effects ceased as soon as the radio was turned off. The DCR Flo-gard pump alarmed and displayed an A1 alarm error message. It was impossible to reset the pump (or stop the alarm sounding) without breaking seals to remove the internal battery. This problem was replicated with two further samples of the same pump.

Interference effects from the vehicle radio on devices placed close to the patient couch were rare, limited to the Pacesetter 446 external pacemaker, and the Hewlett Packard Codemaster 100 defibrillator. The defibrillator had an interference spike on its ECG trace when the radio was switched on. This sort of artefact is easily recognised, and recommendation 2.5 proposes suitable training.

The external pacemaker went into continuous sense mode throughout the time the radio was transmitting, which is potentially dangerous for a patient. Section 6.4 gives details of device tests with a fire appliance radio, and sections 8 and 9 cover implanted pacemakers and tests with mobile data terminals respectively. In vehicles with front-mounted aerials problems are least likely if the pacemaker is positioned towards the rear end of the patient couch.

6. FIELD STRENGTH MEASUREMENTS

6.1 Measurements inside an ambulance

Figure 1 shows the positions inside the working space of an ambulance where we made spot readings of field strengths when the vehicle transmitter was operating. High readings were obtained close to the skylight, which allows signals from the roof-mounted aerial to penetrate into the cabin. Moderate readings were obtained in a region above the patient couch towards the front of the vehicle, including areas around the drip pole, grab rail, and storage shelves.

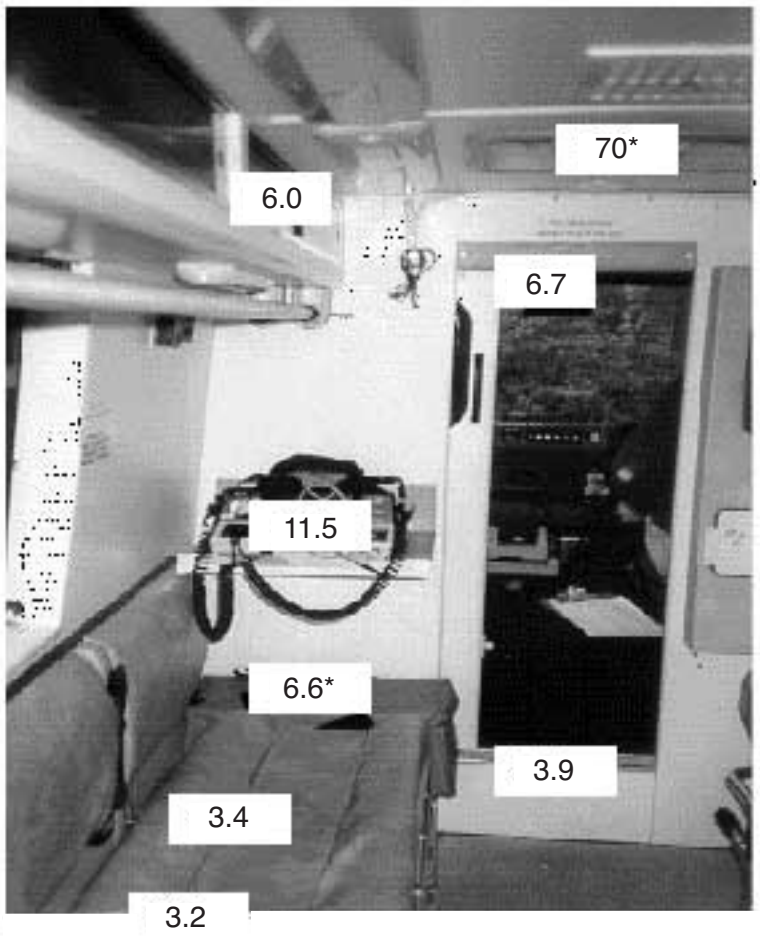


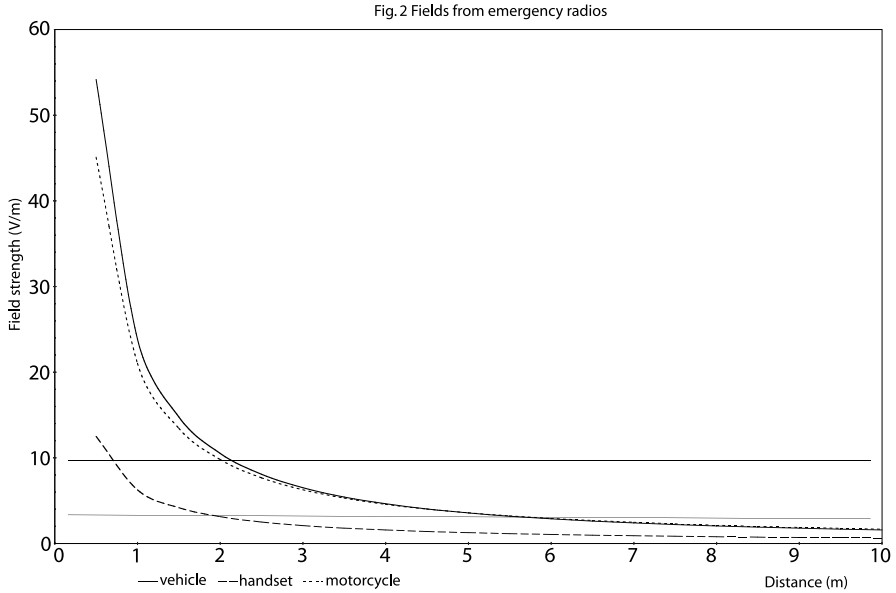
Fig. 1 Spot measurements of Field Strength (Vm^{-1}) when vehicle radio operates. *average values

6.2 Outside the vehicle - distance from the interference source

Figure 2 shows how the measured field strength in volts per metre falls off with distance from the transmitting aerials of an ambulance vehicle-mounted radio, a radio handset and a paramedic's motorcycle radio. Horizontal lines mark the 3 and 10Vm^{-1} benchmark field strengths.

Situations in which devices are used in a building close to a parked ambulance need a risk assessment before considering expensive remedial action such as moving parking bays.

Fig. 2 Fields from emergency radios



6.3 Variation between vehicles with similar transmitters

Table 3 shows values of electric fields for seven ambulances of the same general design, all measured under strictly comparable conditions. Field strength measurements inside the ambulances show considerable variability, possibly due to small changes in the relative positions of the skylight, the transmitting aerial, and the radio installation.

Table 3. Measurements on 7 ambulances.

Ambulance	At roof aerial	Near skylight (inside)	Bunk (head end)
1	501	65.4	8.7
2	646	84.0	5.6
3	553	71.0	5.2
4	542	92.6	11.6
5	446	64.2	4.5
6	449	75.2	5.7
7		40.5	5.0
Mean ± SE	**523±28**	**70±6**	**6.6±0.9**

6.4 Spatial distribution of fields around vehicles

Figure 3 shows field strength measurements moving away from an ambulance along forward, backward and sideways tracks. Measurements were taken on the ground, 1m above the ground, and 2.4m above the ground (level with the roof-mounted aerial). The 2.4m data show little dependence on the track direction, and are summarised in Figure 2. Close to the ambulance the field distribution near the ground is dominated by the screening effects of the metal in the vehicle body.

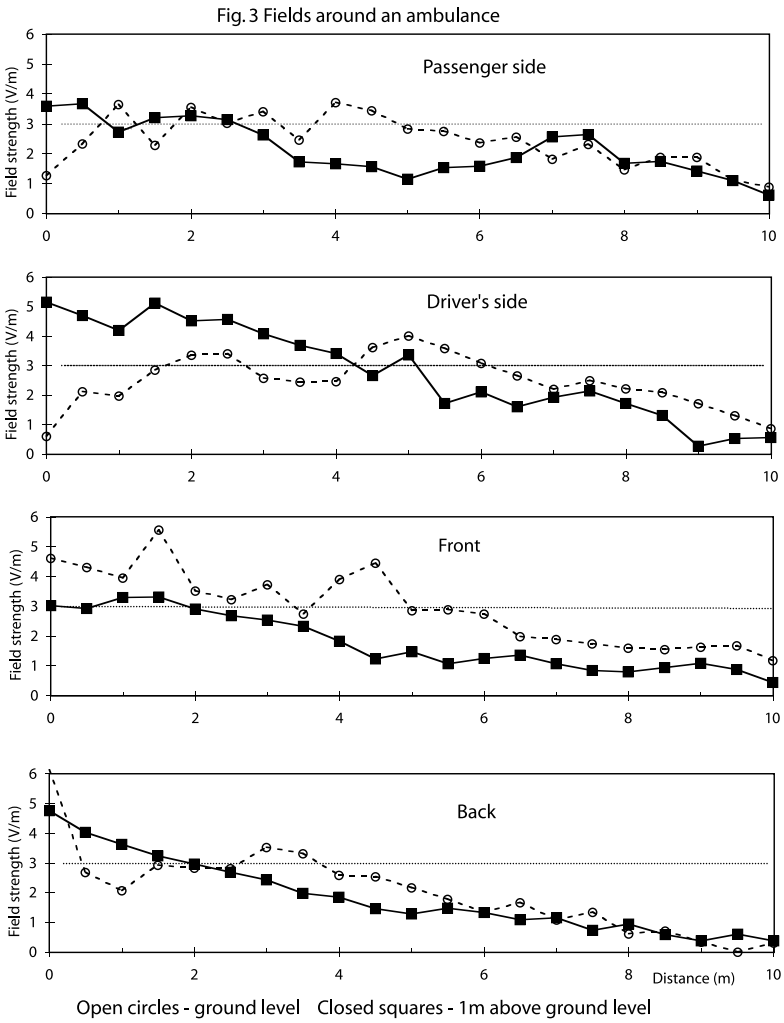


Fig. 3 Fields around an ambulance

Figure 4 averages the data for 0 and 1m heights for all four directions, to produce an indication of likely fields if a patient has to be treated in the road close to an ambulance. The horizontal distances on this graph are distances from the vehicle body, not from the transmitting aerial as in Figure 3. The bars on the data points show standard errors for the averages, and indicate the likely range of uncertainty around each data point. You have to move 5m from the ambulance to be confident that fields will be less than 3Vm^{-1} (upper error bar no longer crosses the 3Vm^{-1} line).

Figure 5 gives the field distribution along a track moving away from a paramedic's motorcycle. In this case, with a small vehicle and a low-mounted transmitting aerial, readings are not markedly affected by height above the ground or track direction.

Figure 6 shows the distribution of the electric fields caused by the vehicle radio on a fire appliance parked on open ground. No field strengths exceed 10 Vm^{-1}, and fields fell below 3 Vm^{-1} at a distance of 5 m from the appliance in any direction. Figure 7 contrasts the measurements along a track moving away from the front of the appliance when parked on open ground and when parked close to buildings. Reflections from surrounding buildings cause marked standing waves, with localised regions experiencing field strengths up to 22 Vm^{-1}.

Fig. 4 Fields close to an ambulance

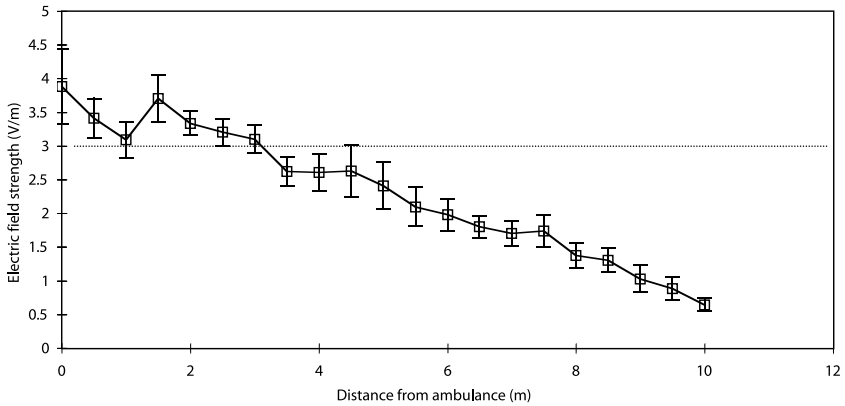


Fig. 5 Fields around a paramedic's motorcycle

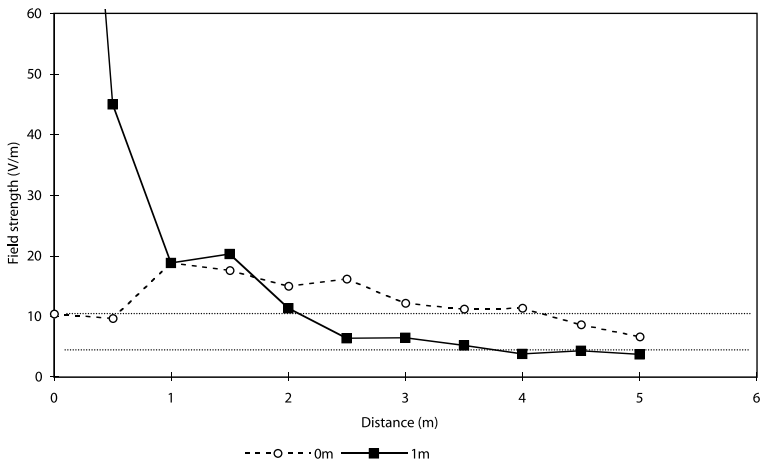
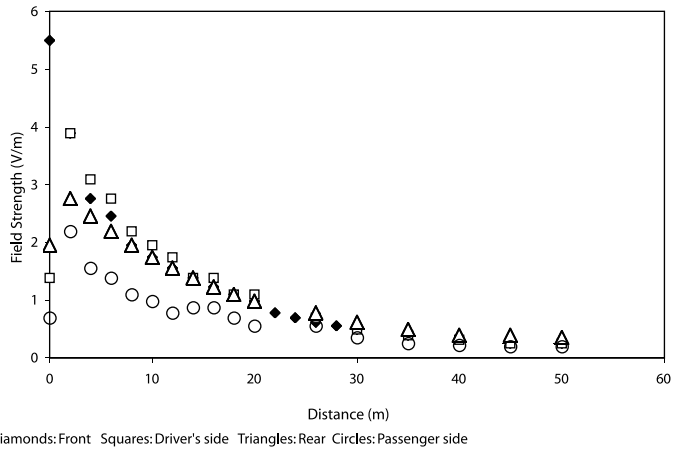
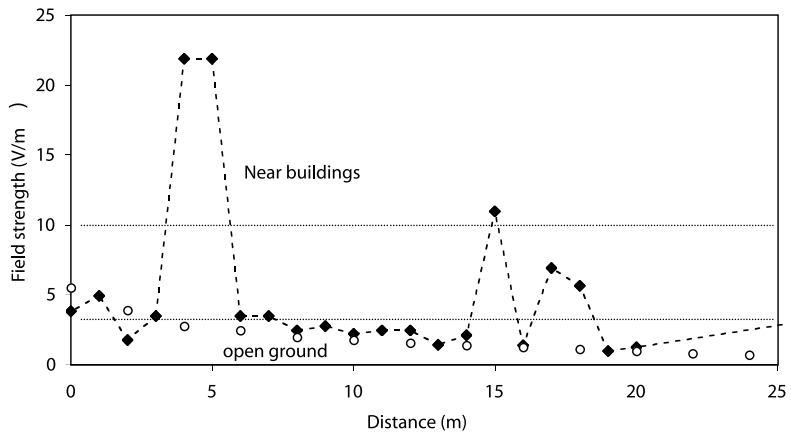


Fig. 6 Fields around a fire appliance - open ground



Diamonds: Front Squares: Driver's side Triangles: Rear Circles: Passenger side

Fig. 7 Fire appliance fields near buildings



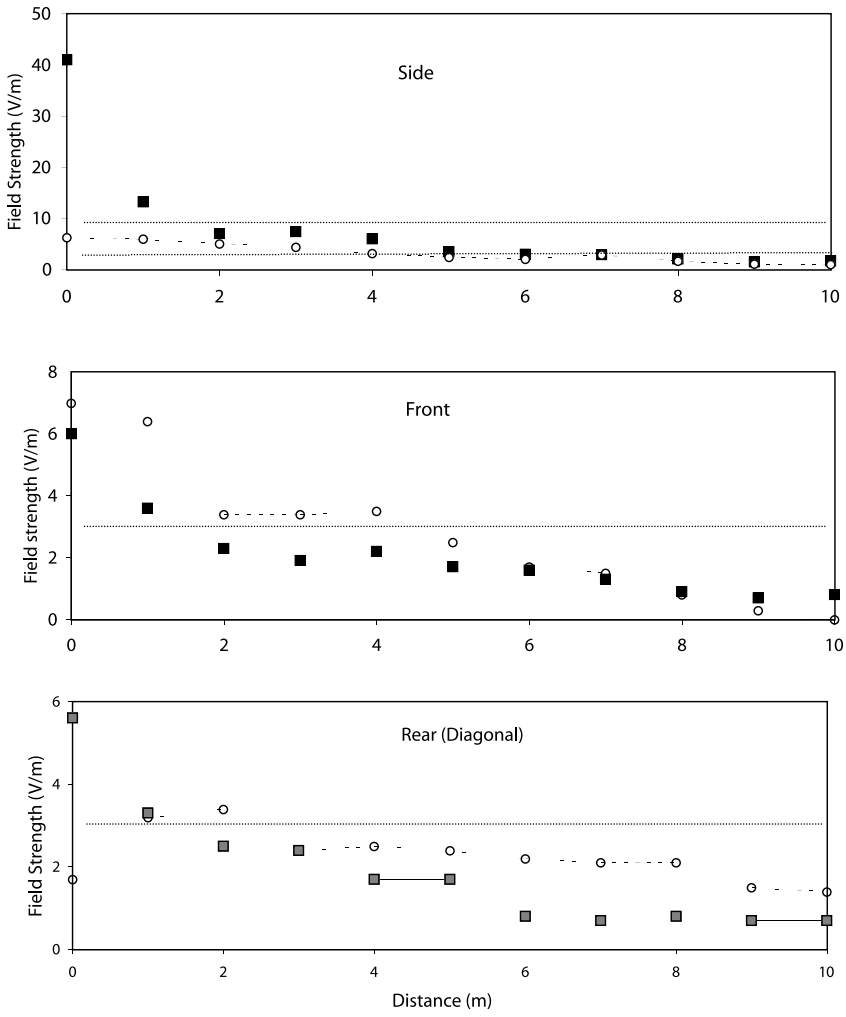
6.5 Fire appliance

The field strength inside the front cab when the radio was operating was 3.8 Vm^{-1}, and in the rear cab it was 2.5 Vm^{-1}. Tests with Physio Control 500 and Heartstream Forerunner defibrillators showed that neither the fire engine radio nor that mounted on a fire car affected the device at any distance. If a fireman's portable radio handset was operated touching the underside of the Heartstream Forerunner defibrillator, voice messages were suppressed. This is unlikely to happen in normal use.

6.6 Emergency Helicopter Air Ambulance

Helicopters use several radio and radar systems, ranging in power from 100W to 6W, and in frequency from 118 MHz to 2.37 GHz. The air traffic control radio is the one most likely to be in operation when the aircraft is on the ground during patient transfers. Figure 8 shows the distribution of the field due to this radio. Field strength falls below 3 Vm^{-1} at a distance of 5m from the helicopter. The maximum measured field inside the helicopter was 7.8 Vm^{-1} and the field at the patient's head was 4.6 Vm^{-1}. Interference problems are unlikely, but if any electro-medical devices are in use the crew should monitor the patient closely during the transfer.

Fig. 8 Fields around a helicopter



Circles: Ground level Squares 2.4 m high

7. RISK ASSESSMENT

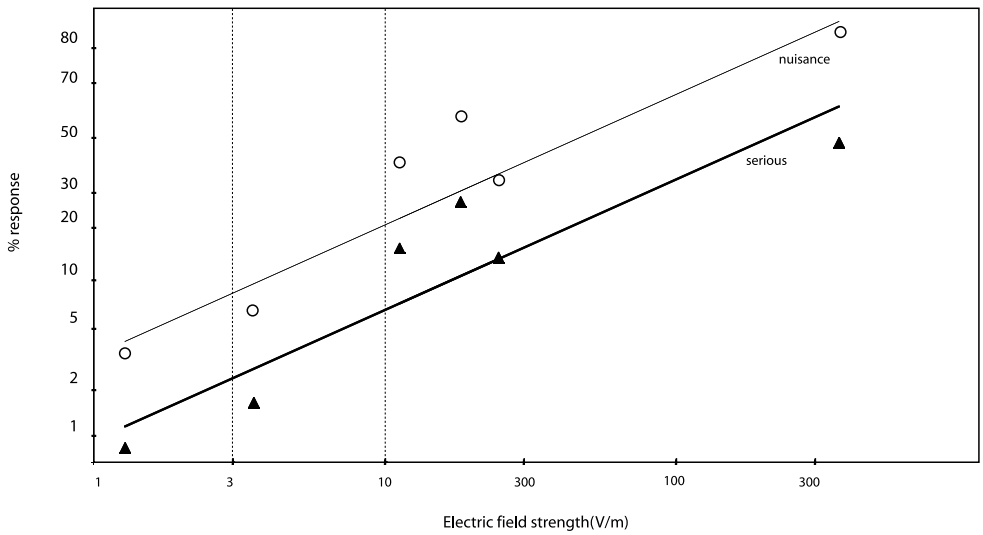
Figure 9 shows the impact of electric fields on medical devices. Electric field strength is plotted against the likelihood of interference on non-linear scales chosen to produce a linear relationship (see figure caption for details). The data derive from our earlier large-scale study (DB 9702) in which the whole range of medical devices were tested with fields generated by mobile phones and radios. Responses divide into two classes – serious responses which would have had a direct effect on a patient's treatment, and nuisance responses – transitory malfunctions plainly due to interference, and unlikely to cause harm. Figure 9 shows separate lines for each class of response. Serious responses occur typically at approximately four times the field strength needed to produce nuisance responses.

The graph can be used to estimate the likelihood of interference given a particular field strength. Possible interpretation problems include:

- not all classes of medical device are equally susceptible – there is clear evidence that physiological and cardiac monitors, defibrillators and external pacemakers are much more susceptible than other devices;
- the frequency of the transmission affects the probability of interference for any particular field strength.

In general, radios transmitting at frequencies below 500MHz (e.g. emergency radios and two-way radios) are more prone to cause interference than those transmitting above 1GHz (mobile phones).

Fig. 9 Field strength/response curves for emc



X-axis: logarithmic scale
Y-axis: where p=%response/100, scale is ln(p/(1-p)) [logit]

8. IMPLANTED PACEMAKERS

Pacemakers are designed to withstand the most common forms of electromagnetic interference which patients are likely to encounter in daily life. Current pacemaker standards require that devices perform safely and predictably in the presence of electric fields due to radio signals representative of normal daily living exposure. In the ambulance environment, however, field strengths and therefore subsequent pacemaker exposure can be high due to close proximity with either the ambulance roof aerial, or the personal handset used by ambulance personnel. The pacemaker testing program was devised to observe if any interference effects were likely to take place in the presence increased RF exposure.

Tests were performed using the ambulance vehicle radio with patients seated both inside and outside the vehicle, where field strengths were at a maximum. A further test was performed using a radio handset unit inside and outside the ambulance at distances down to a minimum of 15cm from the site of implant.

Appendix 4 includes details of testing techniques. The most likely effect of interference on the pacemaker involved reversion to safety backup mode, which would increase the patient's heart rate to the known default rate. No safety backup mode pacing was observed in any of the tests, and neither was there any evidence of high rate pacing artefacts caused by the pacemaker tracking the high frequency radio signal.

Under the conditions of our test, in no case were we able to detect any effect of the electric field on the pacemaker.

Our conclusion is that neither vehicle radios nor portable handsets present a significant hazard for people with implanted pacemakers.

9. MOBILE DATA TERMINALS

Data terminals consist of a keyboard and display screen, and provide a text equivalent of a mobile phone – text messages can be sent and received between terminals on the same data network. We investigated this equipment following verbal reports of interference problems from users, and an adverse incident report involving a mobile data terminal interfering with an image on a monitor.

These devices are frequently used by maintenance personnel on hospital premises, and we have tested a range of medical devices for susceptibility at two centres using a typical mobile data terminal (Table 4). Tests followed the protocol used for device tests in DB9702, "Electromagnetic compatibility of medical devices with mobile communications".

Table 4. Test results for mobile data terminal.

Type	Model	Distance		
		0m	0.5m	1m
Pump	Graseby 3300	Fault code 10 – intermittent	none	none
Pump	Baxter flogard 6201	None	none	none
Pulse oximeter	Datex Satlite trans OSP200	Slight trace distortion when close to finger probe	none	none
Haemodialyser	Hospal-Cobe renal Centrysystem 3	None	none	none
Haemodialyser	Althin Medical system 1000	None	none	none
Humidifier	Fisher Payke; MR700	Machine reset	none	none
Cardiac monitor/defib.	Physio Control	Trace distorted. Heart rate reading erratic. No effect on shock delivery	Trace only distorted	none
Cardiac monitor	Graseby 304	1 x double QRS wave. Heart rate reading increased by 10 bpm	none	none
Haematocrit monitor	In-Line Diagnostics Crit-Line IIr	None	none	none
Mobile X-ray	IGE Senograph 600	None	none	none
Ultrasound scanner	Acoustic imaging	VDU display jumps. 3-4 jumps per transmission	display jumps	display jumps
Mobile X-ray	IGE AMX4	Not applicable (screening)	none	none
Mobile X-ray	Philips Practix 2000	None	none	none

Table 5 summarises these findings, giving the percentage of medical devices responding at three distances from the device, with comparative data from a cellphone and emergency services radio handset.

Table 5. Impact of mobile data terminals on medical devices.

Device	Distance		
	0 m	**0.5 m**	**1.0 m**
Mobile data terminal	50%	10%	0%
Cellphone	34%	6.5%	3.5%
Emergency radio	84%	58%	40%

Table 6 shows measured field strengths (volts/metre) for the same three classes of communication equipment.

Table 6. Fields from mobile data terminals, with comparison data.

Device	Distance		
	0m	**0.5m**	**1.0m**
Mobile data terminal	17.8	11.4	6.0
Cellphone	24.5	3.5	1.3
Emergency radio	363	18	11

In summary:

- The interference potential of the mobile data terminal system is between that of a emergency services radio handset and a mobile cellphone.
- **We would recommend that mobile data terminals should never be operated while they are standing on any kind of medical device, and that the healthcare organisation's policy for cellphones be applied to these devices (see DB9702).**

APPENDIX 1. RADIO DETAILS/ FREQUENCIES/POWERS

Application	Radio type	Frequency	Power
Fire appliance	Marconi RC690 (AM)	80.0125 MHz	20 W
Handheld (fire)	Philips PFX LVU	457.0375 MHz	2 W
Ambulance	Pye Telecom M294E	171.2375 MHz	25 W

APPENDIX 2. METHODOLOGY – FIELD STRENGTH MEASUREMENT DEVICES/ TEST PROTOCOLS

All the field strength measurements in this device bulletin are calibrated against a Holaday Industries electric field probe, type HI-4422, with an operating range of 1 - 300 Vm^{-1}, used with a HI-4416 numeric readout, which was the most linear and sensitive device available. Readings were in some cases taken with a Holaday Industries HI-4433-MSE probe, and with a Chase Receiver (GPR 40.2), but readings from both these sources were converted using calibration curves against the HI-4422 probe. Except where stated, field measurements around vehicles were made on open field sites at least 100m from the nearest building.

APPENDIX 3. SURVEY RESULTS

1.) **Have you experienced or suspected medical equipment suffering from interference problems?**

often	14
once or twice	16
never	36

2.) **Were these problems caused by:**

radio handsets	1
vehicle radio	14
mobile phone	4
don't know	11

3.) **Was the medical equipment:**

in the ambulance	24
attached to a patient being moved	5
in a ward	0
at the roadside	2

4.) **Type of equipment:**

infusion pump	1
defibrillator	5
monitor	20
incubator	1
pulse oximeter	18

5.) **What kind of problem:**

alarm sounded	6
unusual equipment behaviour	16
stopped working	3
wouldn't start	2
interference mode	8
error message	1
settings went wrong	1
display trace unreadable	14
impossible readings	12
unexpected patient symptoms	3

APPENDIX 4. TABLE OF PACEMAKERS EVALUATED

Manufacturer/Model	Mode	Polarity	Number
Medtronic			
Minuet	DDD	uni + bipolar	5
Premier	VVI	unipolar	1
Elite 7076	DDDR	unipolar	1
Thera 7964i	DDD	uni + bipolar	2
Minix 8340	VVI	bipolar	1
Prodigy 7864	DDD	uni + bipolar	3
Prevail 8084	VVI	unipolar	1
Siemens			
Multilog	VVI	uni + bipolar	2
Sensilog	VVIR	unipolar	1
Pacesetter			
Trilogy	DDDR	bipolar	1
Paragon	DDD	uni + bipolar	4
Synchrony II	DDDR	unipolar	1
2314L	DDD	bipolar	1
Sorin			
Miniswing	VVIR	uni + bipolar	4
Biotronik			
Logos	DDD	unipolar	1
Dromos	DDDR	bipolar	1
Vitatron			
Diamond 800	DDDR	bipolar	2
CPI			
460	VVI	unipolar	1
1230	DDDR	bipolar	2
950	DDD	bipolar	1
ELA			
Chorus	DDD	uni + bipolar	2
Opus	VVI	unipolar	1
6244	DDD	unipolar	1
Telectronics			
Simplex 8232	VVI	unipolar	3
Meta 1206	VVIR	bipolar	1
158C	VVI	unipolar	1

45 volunteers with implanted pacemakers, but without pacemaker dependency, were involved in the study. All basic pacing rates were decreased to 40ppm to expose the underlying rhythm. It was assumed that any pacing artefacts seen during exposure to the electric fields, were as a result of the pacemaker operating in noise reversion mode. During testing

patients were monitored using a three-lead ECG. Heart rhythm was visually monitored with an ECG display for any evidence that the pacemaker had reverted to safety backup mode. Following the tests, all patient pacemaker programs were returned to their previous settings.

Manufacturers were initially contacted to discuss the most likely form of interference which may arise from ambulance transmitter systems. It was determined that interference effects were unlikely but reversion to safety back-up mode pacing was the most probable. Tracking of the high frequency signal/modulation and inhibition from the same was not considered likely.

Patients were selected for possible participation in the testing programme from within a single pacing centre, and were randomly selected from as wide a base of pacemaker manufacturers and models as possible. Final patient selection, however, was made on a non-pacemaker dependency basis with each having underlying rhythm.

Patients were contacted by post to seek their participation and, prior to testing, were asked to sign a consent form after having been provided with detailed information and suitable explanation. On the day of testing, each patient's pacing rate was adjusted to reveal intrinsic underlying rhythm without pacing but no change was made to sensitivity or threshold settings.

DISTRIBUTION

This Device Bulletin should be brought to the attention of anyone responsible for the operation or use of Electromedical devices or mobile communication equipment in the hospital or community. Particularly doctors, nurses, biomedical technicians/engineers, risk and hospital managers.

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