Final Report - An Evaluation of Potential GPRS 900/1800 MHz and WCDMA 1900 MHz Interference to Medical Devices

Steve Iskra and Barry Thomas

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EXECUTIVE SUMMARY

Since the widespread introduction of mobile telephone services in the late 1980s, numerous studies have been conducted to assess the potential for radio frequency (RF) interference from mobile telephone handsets to consumer and business electronic equipment. Of particular interest has been the proliferation of handsets into environments with potentially sensitive electronic devices such as health centres and hospitals, which utilise life and non-life supporting medical equipment, and the influence of RF fields from handsets on body worn devices such as hearing aids.

The main aim of this study was to compare the potential for interference to medical devices from RF fields radiated by GPRS 900/1800 MHz and WCDMA 1900 MHz handsets (at their nominal in-band transmission frequencies). GPRS is a packet-based radio service that overlays additional control signalling on an existing GSM network and uses the same air interface as a GSM handset. It uses additional timeslots to obtain increased data rates which are necessary to support new mobile data and multimedia applications. In this study, a two-timeslot GPRS signal was used to simulate uplink transmission. Most GPRS and WCDMA (frequency division duplex (FDD) mode) handsets will have nominal peak output power levels of 2 W and 125 mW respectively.

This work was conducted at Telstra’s Research Laboratories and sponsored by the GSM Association Environment Working Group Chaired by Brent Gerstle (SingTel Optus) and coordinated by Dr Jack Rowley, Director Environmental Affairs, GSM Association.

The study was conducted by using balanced half wave dipole antennas as substitutes for actual handsets. The procedure involved energising the dipoles with either a GPRS or WCDMA signal at the standard power level, and physically bringing the dipole towards the medical device whilst noting the distance at which interference became apparent. Additional testing was performed with signals that were characteristic of radio transmissions from GSM 900/1800 MHz handsets, and with 900/1800 MHz signals that comply with the requirements of the international immunity standard to RF fields, IEC 61000-4-3. This additional test data gives a sense of the overall interference impact that GPRS and WCDMA (FDD) handsets may have relative to current handset technologies and to the internationally recognised standard for radiated RF immunity.

Five medical devices were tested: two combined pulse oximeter/ECG monitors, a combined pulse oximeter and blood pressure monitor, a cardiac defibrillator and a humidifier. For the humidifier, signals at 900 MHz were more prone to causing interference than those at the higher frequencies of 1800/1900 MHz. A 900 MHz GSM/GPRS and 80% AM 1kHz signal caused a sudden drop in temperature (of the treated air) when the dipole was placed 6 and 9 cm respectively from the front fact of the humidifier. A similar effect was seen only for WCDMA 6x960ksps with power control when the dipole was touching the face of the humidifier (0 cm). No effect was observed with 1800 MHz signals.

Two pulse oximeters experienced no interference for any of the test signals. This type of result is not unexpected when compared to other studies that report that up to 53% of devices tested exhibited no incidents of interference, even when the mobile was brought to the surface of the device. A third pulse oximeter produced audible interference when subjected to 900 and 1800 MHz signals but not to WCDMA. The distance from the device at which audible interference was first observed was 24 cm for 1800 MHz GSM/GPRS and 5 cm for 900 MHz GSM/GPRS signals. This result is interesting since it runs counter to the statistical trend reported in our previous study [15] and observed in other studies ([17], [20]) which found that 1800 MHz GSM was less likely to cause interference than 900 MHz GSM. However, and by definition, there is a statistical chance that devices will exhibit an increased
sensitivity to RF at higher frequencies. The overall immunity characteristics of a device will depend on the type of internal electronics, layout of circuitry, wiring and cabling, filtering and case construction. The departure from the statistical trend may have resulted from a particular design approach incorporated in the Agilent A1 patient monitor, or it may point to a more general trend that will become evident as more medical devices are tested.

Cardiac defibrillators appear in studies as the device most frequently affected by interference, no doubt because of the long leads carrying small voltages from a human torso. The study found that audible interference from the defibrillator was most notable for GSM/GPRS 900 MHz signals and least notable for WCDMA. Functionally, the defibrillator was found to be an extremely robust device in the presence of interference – it did not malfunction except under a most contrived condition which would not be encountered in practice. This would appear to show that interference could be minimised in the most sensitive of medical devices by a combination of careful design and waveform analysis algorithms.

A conclusion that can be drawn from the study, and supported by results from our previous study for the GSMA (An Evaluation of Potential GPRS 900 MHz and WCDMA 1900 MHz Interference to Consumer Electronics), is that WCDMA handsets are unlikely to be a significant interference threat when compared to 900/1800 MHz GSM/GPRS. It is generally a non-existent threat in comparison to GSM and GPRS (two timeslots) at either 900 or 1800 MHz.
Final report - An Evaluation of potential GPRS 900/1800 MHz and WCDMA 1900 MHz Interference to Medical Devices

1. Introduction

Since the widespread introduction of mobile telephone services in the 1980s, numerous studies have been conducted to assess the potential for radio frequency (RF) interference from mobile telephone handsets to consumer and business electronic equipment. Of particular interest has been the proliferation of handsets into environments such as health centres and hospitals, which utilise life and non-life supporting medical equipment, and the influence of RF fields from handsets on body worn devices such as hearing aids. To control and minimise the likelihood of interference, protocols on the use of mobile technologies have been introduced in hospitals [1], and immunity standards have been developed for medical equipment [2] and devices such as hearing aids [3].

To date, a significant body of data has been collected which establishes the RF interference potential of existing analogue and digital mobile technologies to a range of electrical and electronic devices. However, new mobile technologies are constantly emerging, and it is the aim of this report to assess the potential for interference from GPRS (General Packet Radio Service) 900/1800 MHz and wideband CDMA (WCDMA) 1900 MHz handsets to consumer electronic equipment. GPRS is a packet based radio service that overlays additional control signalling on an existing GSM network and uses the same air interface as a GSM handset. It uses additional timeslots to obtain increased data rates, which are necessary to support new mobile data and multimedia applications.

This report is in a series examining the interference potential of GPRS and WCDMA to a range of consumer electronics and medical devices. This work was conducted at Telstra’s Research Laboratories and is sponsored by the GSM Association Environment Working Group Chaired by Brent Gerstle (SingTel Optus) and co-ordinated by Dr Jack Rowley, Director Environmental Affairs, GSM Association.

2. Overview

An evaluation of the potential for RF interference to medical devices has been conducted by selecting a small range of equipment and subjecting them to electromagnetic fields that are characteristic of radio transmissions from GPRS or WCDMA (frequency division duplex (FDD) mode) compliant handsets. The medical devices used in the interim study were a pulse oximeter, blood pressure monitor and a humidifier, followed by a defibrillator and patient monitor in this final report.

The study has been enhanced by additional testing with fields that are characteristic of radio transmissions from GSM 900 and 1800 MHz handsets, and 900/1800 MHz fields that comply with the requirements of the international immunity standard to radio frequency fields, IEC 61000-4-3 [5]. This additional test data gives a sense of the overall interference impact that GPRS and WCDMA handsets may have relative to current handset technologies and to the internationally recognised standard for radiated RF immunity.

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The actual frequencies used for testing were 905.2 MHz (GSM/GPRS and 80% amplitude modulated (AM) with a 1kHz sinewave), 1810.4 MHz (GSM and 80% AM 1kHz sinewave) and 1920 MHz (WCDMA). In this report, these test frequencies are referred to as 900, 1800 or 1900 MHz respectively. The nominal transmit power for mobile handsets is:

- **GPRS 900 MHz**: 2 W peak, average dependent on number of uplink timeslots
- **GSM 900 MHz**: 2 W peak, 250 mW average
- **GSM 1800 MHz**: 1 W peak, 125 mW average
- **WCDMA (FDD) 1900 MHz**: 125 mW peak

The medical devices in the interim report were subjected to vertically and horizontally polarised fields. The devices were rotated in azimuth so that each of the four vertical faces was exposed to the field and the worst case interference result was recorded. The functioning of the medical device was noted and changes in performance were recorded along with field polarisation.

### 3. Test Conditions

#### 3.1 The radiated test fields

The intention of interference testing is to subject medical devices to RF fields which are representative in strength and frequency/time characteristics to that generated by actual mobile handsets for either GPRS or WCDMA (FDD) technology. As has been noted, additional testing has been performed simulating time division multiple access (TDMA) GSM signals and with the amplitude modulated signal specified in the IEC 61000-4-3.

The first device tested was the pulse oximeter. The electromagnetic test field conditions were created in an semi-anechoic chamber using the method described in IEC 61000-4-3 [5], which establishes a ‘uniform’ plane wave environment in which the equipment is placed. Field strength levels up to 30 volts per metre (V/m) were possible with the available test equipment.

In tests on subsequent devices, it became apparent that the immunity of equipment was generally greater than the field strengths that could be generated with the available test equipment. Specifically, it was not possible to generate plane wave conditions at field strengths greater than 30 V/m. To overcome this difficulty, tests were performed using the dipole method described in 3.2.

#### 3.2 Dipole Method

The method used in this report for establishing a field at the medical device uses the procedure outlined in the ANSI standard C63.18-1997 [6]. A balanced, Roberts [7] half-wave dipole was used as a substitute for an actual handset.
At distances greater than one-sixth of a wavelength from the dipole, the free-space, far-field can be determined by use of the dipole equation (1).

$$E = 7\frac{\sqrt{P}}{d}$$ -- (1)

where

- $E$ electric field in volts per metre
- $P$ transmitted power in watts
- $d$ distance from the dipole antenna in metres

Figure 1 shows the peak field strength as a function of distance from a half-wave dipole transmitting at the nominal peak transmit power of 2 W at 900 MHz, 1 W at 1800 MHz and 0.125 W at 1900 MHz. Due to antenna mismatch, in free-space the actual power delivered to the dipole was 1.96 W at 900 MHz, 0.95 W at 1800 MHz and 0.107 W at 1900 MHz.

Figure 1: Variation with distance of the free-space, far-fields from handsets for different peak transmit power levels calculated using Equation (1)

At distances within one-sixth of a wavelength from the dipole, approximately 5 cm at 900 MHz and 2.5 cm at 1800 MHz, the simple inverse distance relationship of Equation (1) does not hold. A more comprehensive analysis of the fields near a dipole is provided by Jordan and Balmain [8]. The equations are shown in Appendix A along with example calculations and plots of the free-space field near the dipole. Note also that at very close distances to an object, mutual coupling between the dipole and object may result in a change in the dipole current (see Appendix B for further discussion).

4. The test signals

A Rohde & Schwarz (R&S) signal generator (model SMIQ 03B) was used to produce the following test signals: GPRS (2 timeslots), GSM, WCDMA and 80% amplitude modulated carrier with a 1 kHz sinewave. Sinewave amplitude modulation is specified in IEC 61000-4-3 and is the basis of EMC immunity product standards such as CISPR 24 (IEC immunity standard for information technology equipment) [9].
4.1 GSM/GPRS

In a GSM network, users are allocated carrier frequencies that are then divided in time using a time division multiple access (TDMA) scheme. The basic unit of time in this TDMA scheme is called a *burst period* (timeslot) which lasts for 0.577 ms. GPRS is a packet based radio service that overlays additional control signalling on an existing GSM network and uses the same air interface as a GSM handset. The essential difference between GPRS and GSM that is of relevance to these tests is the use of additional timeslots by GPRS to obtain increased data rates and therefore support new mobile data and multimedia applications. Figure 2 below illustrates the differences.

![Timeslot (TS) diagram](Figure 2: TDMA characteristics of GSM and GPRS (2 timeslots, 0 & 4). The pulse repetition rate for GSM is 217 Hz and 434 Hz for GPRS TS 0 & 4.)

The use of additional timeslots by GPRS changes the time-varying characteristics of the modulated signal and increases the time-averaged transmit power in direct proportion to the number of timeslots. These, as well as the peak signal level, may influence the type and amount of interference produced in medical devices.
Figure 3 shows the basic TDMA characteristics of a GSM signal produced by the signal generator. The plot was obtained with a HP 8546A spectrum analyser in ZERO SPAN mode with 300 kHz resolution bandwidth and 100 kHz video bandwidth (carrier frequency 905.2 MHz). The pulse-like nature of transmission is evident with the carrier turned on for 0.577 ms and the pulses repeated every 4.615 ms (4.613 ms measured).

Figure 3: TDMA characteristics of GSM signal. The carrier was modulated with random data using the GMSK (Gaussian Minimum Shift Keying) scheme.
GPRS test signals were based on a network supporting handsets capable of transmitting two timeslots. Time slot (TS) combinations of TS 0 & 1, TS 0 & 2, TS 0 & 3 and TS 0 & 4 were used to simulate GPRS handset uplink transmission. Figure 4 shows the envelope of the signal carrier for timeslot combination of 0 and 4 (GPRS TS 0 & 4). The signal generator produced a pulse of width 0.577 ms with a period of 2.29 ms.

Initial testing revealed that the differences in interference outcomes obtained from the four TS combinations were slight, mainly exhibiting as shifts in demodulated audio tones and changes to images on the LCD screen. The majority of GPRS testing was performed with the timeslot combinations of TS 0 & 2 and TS 0 & 4.

Figure 4: TDMA characteristics of GPRS (timeslots 0 and 4). The carrier was modulated with random data using the GMSK (Gaussian Minimum Shift Keying) scheme.

\[\text{Figure 4: TDMA characteristics of GPRS (timeslots 0 and 4). The carrier was modulated with random data using the GMSK (Gaussian Minimum Shift Keying) scheme.}\]

\[\text{\textsuperscript{1} This is consistent with the majority of commercially available products. See }\]

4.2 WCDMA

The ITU first initiated the process of defining the standard for 3rd generation (3G) mobile systems\(^2\) and in 1998 the Third Generation Partnership Project (3GPP) was formed to continue with the work. WCDMA is a 3G mobile technology designed by 3GPP to provide global mobile access to real-time and non real-time applications including voice, high speed data and multimedia applications. It is CDMA based but its spectral bandwidth has been increased to 5 MHz and it operates in the 1900-2000 MHz frequency band. Figure 5 shows a WCDMA (FDD) signal produced by the signal generator. Network dimensioning and planning can support data rates of up to or more than 2 Mbps from handsets.

![WCDMA (FDD) spectral bandwidth](image)

**Figure 5: WCDMA (FDD) spectral bandwidth (curve shown for 15 ksps, uplink)**

Two modes of operation for WCDMA have been specified – frequency division duplex (FDD) and time division duplex (TDD). FDD allocates frequency bands (uplink/downlink pairs) to users whilst in TDD the user is allocated timeslots. The signal generator can produce FDD physical channel layer signals to simulate either downlink (base station) or uplink (handset) operation based on version 3.4.1 (Release ‘99) of the WCDMA standard. The signal generator was not equipped for TDD operation.

The WCDMA uplink direction uses QPSK-like in-phase (I) and quadrature phase (Q) multiplexing for user data and physical layer control information\(^10\). The control information is carried by the Dedicated Physical Control Channel (DPCCH) and the user data (along with higher layer information) is carried on one or more Dedicated Physical Data Channels (DPDCH). Each channel (DPDCH) has a maximum data rate of 960 kilo symbols per second (ksps), which is equivalent to 480 kbps if the channel coding rate is half. Up to six channels can be used by a handset resulting in a maximum uplink user data rate of 2 Mbps or more.

\(^2\) In the ITU, 3rd generation systems are known as International Mobile Telephony 2000 (IMT-2000). Within IMT-2000, several different air interfaces are defined based on either CDMA (eg., WCDMA) or TDMA (eg., EDGE) technology.
To evaluate the impact of different data rates on the interference potential of WCDMA (FDD), the signal generator was configured in its handset (mobile station) mode to produce three signals: 1 channel of 15 ksps; 6 channels of 960 ksps; and 6 channels of 960 ksps with carrier amplitude power control in 1 dB steps.

The plots in Figure 6 show the time-instantaneous level of the carrier for 15 ksps and 6x960 ksps WCDMA transmission. When higher data rates are required, multiple channels are used which have the effect of increasing the peak-to-average level of the signal.

![Figure 6: Example time domain plot of WCDMA (FDD) 15 ksps and 6x960 ksps signals, and the unmodulated carrier. Note that the resolution bandwidth of the analyser (3 MHz) is less than the WCDMA signal (5 MHz) so that relative levels are indicative rather than absolute.](image)

The handset power is controlled by the base station in a closed-loop power control, ensuring that the received power is at the correct and constant level. The power control is in 1, 2 or 3 dB steps, and the rate of variation is 1500 Hz [11]. Power control is implemented in handsets to compensate for signal variations due to relative movement between the handset and the environment. The actual power variations will depend on the velocity of the user and the environment. The signal generator implements a simple form of power control as shown in Figure 7 (saw-tooth carrier amplitude). A 1 dB power step was chosen as representative of typical situations.

Note that power control imposes amplitude modulation on the carrier, which in turn can be another source of interference to electronic equipment. The components of modulation will be 1500 Hz in the spectrum of the power variations (eg., 1 dB steps), and a wider continuous spectrum at lower frequencies which represent the time varying channel power (eg., saw-tooth function in Figure 7).
Figure 7: 6 x 960 kbps with power control applied (carrier level reducing in steps of 1 dB at rate of 1500 Hz). Plot also shows the level of the unmodulated carrier. The signal generator power control function is shown operating over the period of one radio frame (10 ms). In practice, handset power control can accommodate deeper fades (by choosing larger power control steps) that span over multiple radio frames.

4.3 Sinewave amplitude modulation (sinewave AM)

Additional testing was performed with a signal that was 80% amplitude modulated with a 1kHz sinewave – see Figure 8. This allowed comparison of results obtained with GPRS and GSM test signals with the recommended test signal defined in the international immunity standard IEC 61000-4-3.

Note that the peak amplitude of the AM signal is 80% higher than the carrier level. This contrasts with GPRS/GSM signals where the peak level is equal to the carrier level (see Table 1).
4.4 Measured average and peak power of test signals

The peak and average power of test signals was either measured with an Agilent E4416A power meter and E9326A power sensor, or for WCDMA the values were obtained from the information displayed by the signal generator. Table 1 below shows these values.

<table>
<thead>
<tr>
<th>Power</th>
<th>Unmodulated carrier (reference level)</th>
<th>Test signal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>80% AM (2 slots)</td>
<td>GPRS</td>
</tr>
<tr>
<td>Average</td>
<td>0 dB</td>
<td>+1.2 dB</td>
</tr>
<tr>
<td>Peak</td>
<td>0 dB</td>
<td>+5.1 dB</td>
</tr>
</tbody>
</table>

1 Single channel: data rate between 15 and 960 kbps
2 Six channels of 960 kbps

Table 1: Measured average and peak power of test signals referenced to the unmodulated carrier. (+PC = with power control)

For any test signal, the power to the dipole was adjusted to ensure that the instantaneous peak power level did not exceed the nominal peak transmit power level for that particular radio technology (see also Section 2).
4.5 Equipment tested

Tables 2(a) and 2(b) below summarise the range of medical devices tested for the earlier interim report and additional medical devices tested for this final report.

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>Function Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse oximeter (Nellcor)</td>
<td>Measurement of heart rate and the percentage saturated oxygen level in haemoglobin (SaO₂).</td>
</tr>
<tr>
<td>Blood pressure monitor (Critikon Dinamap)</td>
<td>Measurement of blood pressure (systolic and diastolic levels) (mm/Hg) and heart rate.</td>
</tr>
<tr>
<td>Humidifier (Fisher and Paykel)</td>
<td>Supplies of air to a patient at a controlled temperature and humidity.</td>
</tr>
</tbody>
</table>

Table 2a: Medical devices tested for Interim Report

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>Function Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AED (Automatic External Defibrillator) (Philips Medical Systems)</td>
<td>Analysis of heart waveform to detect ventricular fibrillation (VF) occurrence and to advise via voice announcements whether or not a shock should be administered to a patient.</td>
</tr>
<tr>
<td>Patient monitor (Agilent A1)</td>
<td>Measures blood pressure and the percentage saturated oxygen level in haemoglobin (SaO₂).</td>
</tr>
</tbody>
</table>

Table 2b: Additional medical devices tested for Final Report

5. Results

5.1 Introduction

Testing of medical devices is more complex and intricate than testing consumer devices, the subject of the first TRL report on electromagnetic interference for the GSM Association [12]. The effects of interference on medical devices are not always audible (as for broadcast receivers) and not always immediately visible (as for a television set). Further, there are two classes of medical devices for which interference effects are more important for one class of device than the other, viz., therapeutic devices and physiological devices.

Therapeutic devices have a direct effect on patient well being. Incorrect operation of infusion pumps, incubators, humidifiers and defibrillators due to interference can endanger a patient’s life. An infusion pump, for example, could infuse a fatal dose of an intravenously administered drug.

Physiological devices display information for patient monitoring purposes. This information, if in error, could lead medical staff to take corrective action based on wrong information induced by interference into a monitor display, thereby indirectly endangering a patient’s well being. Such devices include Pulse Oximeters and Blood Pressure (BP) monitors.

Valid data for both classes of devices can be only gained by taking time series of measurements to observe, firstly, the normal "baseline" operation of a therapeutic device such as a humidifier, which can have a warm-up time of 15 minutes or more, and secondly to observe the perturbation of normal “baseline” performance in the presence of interference.

For a diagnostic device such as a BP monitor the situation is even more difficult as variance of patient physiological parameters may subtly mask the effect of interference. Therefore, an important adjunct in evaluating medical devices for interference effects is to use patient simulators wherever possible in place of human subjects to reduce the variance of data in devices subjected to interference.

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Interference effects on such devices may only be evident using a statistical test of significance on a large number of samples, eg., 16 or 32 consecutive parameter observations recorded and the mean and 95% confidence interval computed as a test of significance.

A different difficulty was encountered with the Philips FR2 AED (Automatic External Defibrillator) responding to amplitude modulation (AM) effects. The defibrillator did not demonstrate any response to high field strengths from a stationary dipole even 1 cm from the face of the device. However, relative movement of the source dipole with respect to the defibrillator resulted in a changing interference field causing an AM interference type affect in the device as evidenced in both the LCD display and the data stored on the removable compact flash card. Faster and more pronounced movements (at a given distance) caused greater excursions in the data.

The test methodology issue was to decide what constituted a reasonable simulation of a mobile phone handset. The methodology employed was to move the dipole slowly over the face of the defibrillator at given distances, simulating a person using a mobile phone with slow movement. This is referred to in the report as the “test methodology” to distinguish it from different motions of the dipole that gave rise to different AM effects in the defibrillator response to interference.

Another issue with the defibrillator was whether the AM could give rise to a diagnostic error in the defibrillator analysis algorithms. It was found that an error could be induced and this finding is presented.

A summary of results for all devices tested is given in Table 3. The Table has been extended with additional tests for the devices tested in the interim report as well as the range of tests for the additional devices in this final report. More detailed explanation of results for the medical devices under test is given further below.
<table>
<thead>
<tr>
<th>MEDICAL DEVICE TYPE</th>
<th>GSM</th>
<th>GPRS TS0, TS2</th>
<th>GPRS TS0, TS4</th>
<th>GSM</th>
<th>GPRS TS0, TS2</th>
<th>GPRS TS0, TS4</th>
<th>15 kbps</th>
<th>960 kbps (6 channels)</th>
<th>960 kbps (6 channels + 1 dB power control)</th>
<th>900 MHz</th>
<th>1800 MHz</th>
<th>1900 MHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT MONITOR (N200/N50E)</td>
<td>-4</td>
<td>-4</td>
<td>-4</td>
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<td>-4</td>
<td>-4</td>
<td>-4</td>
<td>-4</td>
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<td>-4</td>
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<td>-4</td>
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<tr>
<td>Pulse oximeter (measures arterial oxyhaemoglobin saturation - SaO₂) and ECG monitor</td>
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<tr>
<td>PATIENT MONITOR (NPB-290)</td>
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<td>-4</td>
<td>-4</td>
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<tr>
<td>Pulse oximeter (measures arterial oxyhaemoglobin saturation - SaO₂) and Blood Pressure monitor</td>
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<tr>
<td>HUMIDIFIER</td>
<td>+6a</td>
<td>+6a</td>
<td>+6a</td>
<td>-4</td>
<td>-4</td>
<td>-4</td>
<td>-4</td>
<td>+5</td>
<td>+6b</td>
<td>-4</td>
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<td>-4</td>
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<tr>
<td>Delivers humidified air at body temperature to critical care patients</td>
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<tr>
<td>CARDIAC DEFIBRILLATOR</td>
<td>180⁷</td>
<td>180⁷</td>
<td>180⁷</td>
<td>70⁷</td>
<td>70⁷</td>
<td>70⁷</td>
<td>-</td>
<td>3⁷</td>
<td>155⁷</td>
<td>30⁷</td>
<td>16⁷</td>
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<tr>
<td>AED (Automatic External Defibrillator) for reviving victims of sudden cardiac arrest (heart in ventricular fibrillation)</td>
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<td>(see also Table 4)</td>
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</tr>
<tr>
<td>PATIENT MONITOR (A1)</td>
<td>5⁸</td>
<td>4⁸</td>
<td>5⁸</td>
<td>21⁸</td>
<td>23⁸</td>
<td>24⁸</td>
<td>-</td>
<td>-</td>
<td>2⁸</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Pulse oximeter (measures arterial oxyhaemoglobin saturation - SaO₂) and ECG monitor</td>
<td></td>
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</tbody>
</table>

Table 3: First effect on medical device (cm)

“—” indicates no effect found. “+4” indicates an effect was found

[S] indicates patient simulator used [H] indicates human subject used

Notes:
1. 2 W peak power.
2. 1 W peak power.
3. 125 mW peak power.
4. no effect at 1 cm from face of device.
5. Effect only observed for 6x90 ksps with 1 dB Power Control with dipole touching front face of device.
   Single channel data rates between 15 and 690 ksps did not result in an observed interference effect.
6. (a) Effect observed 6 cm from front face of device; (b) Effect observed 9 cm from front face of device.
7. Distance of the first interference to the defibrillator. This was an audio interference that affected the Recorded Voice Announcements (RVAs) from the device.
   Other effects caused AM disturbance to the LCD screen image, which was a real effect as confirmed by printout from the data stored in the defibrillator’s 8 MB flash card. See Tables 4(c) and 4(d) for a complete listing of all effects on the defibrillator.
8. Distance of the first interference to the patient monitor.

Report prepared by: 19 30 June 2004
Telstra Research Laboratories
GPRS/WCDMA Medical devices RF interference report
5.2 Pulse oximeter

5.2.1 Interim Report results – radiated test field

Two models of Nellcor Pulse Oximeters were used. These were the Nellcor N200/N50E (Figure 9) and the Nellcor NPB-290 (Figure 10). Both models measure heart rate and the arterial oxyhaemoglobin saturation level in blood (SaO₂) using a transmission photoplethysmogram, more commonly called a “finger probe” (Figure 11).

Additionally, an ECG simulator (Figure 12) could also be used with the model N200/N50E pulse oximeter. The bottom unit in this latter device (Figure 9) is a display and chart printout module. The chart printout proved invaluable in determining whether interference effects observed in the N200/N50E pulse oximeter were genuine.

Both devices were exposed to GSM, GPRS, WCDMA and 80% AM 1 kHz modulated test signals for both vertical and horizontal dipole polarisations. The radiated test fields were launched from a yagi in the case of 900MHz and a pyramidal horn in the case of 1800/1900 MHz. The field strength was measured with a Wandel & Golterman EMR-300 EM Radiation Meter in 9 positions in a 500mm x 500mm vertical
plane containing one of the vertical faces of the device under test (test setup as outlined in IEC61000-4-3)

No effects were observed for any of the measurement parameters of heart rate, \( \text{SaO}_2 \), or ECG and only a few illustrative examples are presented.

Figure 13 shows a waveform printout for ECG with the interference off. Figure 14 shows a printout with the N200/N50E exposed to 900 MHz GSM at 30 volts/metre.

![Figure 13: N200/N50E pulse oximeter ECG printout with RF interference OFF](image)

![Figure 14: N200/N50E pulse oximeter ECG printout with RF interference ON – 900 MHz GSM at 30 volts/metre](image)

It is clear that there is no effect on the pulse oximeter as shown by comparative printouts from the N200/N50E display unit. The result was the same for the plethysmogram "finger probe" printouts (graphs not shown).

An effect was at first, however, noticed in the N200/N50E display for an ECG waveform when exposed to 80% AM 1 kHz modulation at 30 volts/metre. When the displayed result was printed on the display unit printer the effect was not evident. Therefore, the only effect observed was an artefact of interference into the display itself and not an effect on the functionality of the device proper. Figure 15 shows the N200/N50E display with the trace doubling effect due to interference, while Figure 16 shows a printout of the same waveform.

5.2.2 Final Report results - re-visit using Dipole Method

No effects were seen in the Nellcor N200/N50E pulse oximeter on a subsequent re-visit using the Dipole Method with peak power level correction as detailed in Section 4.4, Table 1.
Figure 15: N200/N50E pulse oximeter display with RF interference ON – 900 MHz 80% AM 1 kHz at 30 volts/metre

Figure 16: N200/N50E pulse oximeter ECG printout with RF interference ON – 900 MHz 80% AM 1 kHz at 30 volts/metre

5.3 Blood pressure monitor

This device was a Critikon Dinamap “Vital Sign” 8100 Blood Pressure (BP) monitor. Early attempts at assessing normal “baseline” performance with no field using a human subject were frustrated by excessive variations in performance. Physiological variations in the human subjects were too great for measurement consistency. A BP simulator was located which in use gave much more consistent, though still variable measurement results. The simulator was a student project named “KANUDKA 2000 LIMITED CHROME MILLENIUM EDITION”.

Figure 17 shows the measurement setup for exposing interference via a Roberts Dipole – early measurements were made using a yagi and horn as for the Pulse Oximeter. The BP simulator is out of the picture as it was placed behind the BP monitor to minimise interference effects on the measurement setup. Figure 18 shows a closeup of the BP monitor display panel and Roberts Dipole. The four parameters measured are:
- MAP (Mean Arterial Pressure) (mmHg)
- Heart rate (beats/minute)
- Systolic blood pressure (mmHg)
- Diastolic blood pressure (mmHg)

Clearly, the MAP is a computed result within the BP monitor itself.

Figure 17: BP monitor and Roberts Dipole measurement setup

Figure 18: Display panel and Roberts Dipole

Figure 19 shows the BP simulator, while Figures 20 and 21 show the BP cuff married to the simulator. Due to the variations in measured BP mentioned above, it was necessary to tape the cuff to prevent movement on the simulator.

Figure 19: BP simulator front view without cuff

The measurement variations at first appearance gave statistically significant differences in baseline performance, leading to a conclusion that the interference was producing genuine effects on the BP monitor. It was found that re-positioning and re-tensioning of the BP cuff on the simulator could give rise to variable results. This necessitated taking data sets close together in time to minimise this effect, as well as to begin and end a measurement series with a "no field" data set to avoid any wrong conclusions.
A measurement methodology was adopted where the BP simulator was set to take a measurement at its minimum sample time of 60 seconds. This fitted nicely as a sample set took about 40 seconds to complete, more or less depending on whether one or two cuff inflation cycles were initiated by the BP monitor. 32 samples of the display panel readings were taken for each measurement condition of interference field on and field off. The mean and 95% confidence intervals were computed for each data set and the results graphed.

Two measurement setups were employed in the work with the BP monitor:

(a) The interference waveforms were launched from a yagi in the case of 900MHz and a pyramidal horn in the case of 1800/1900 MHz. The field strength was measured with a Wandel & Golterman EMR-300 EM Radiation Meter in 9 positions in a 500mm x 500mm vertical plane containing one of the vertical faces of the device under test (test setup as outlined in IEC61000-4-3).

(b) As the setup in (a) did not produce any effects in the BP monitor, a re-visit series of measurements was made using a Roberts Dipole to produce a greater field strength close to the BP monitor.

During both measurement setups the BP monitor was exposed to 900 and 1800 MHz GSM and GPRS, 1900 MHz WCDMA and 80% AM 1 kHz modulated test signals for all frequencies in both vertical and horizontal dipole polarisations (see Table 3).
As indicated above, no significant effect could be induced into the BP monitor by any interference that altered the functionality of the device, whether with the yagi/horn in the first setup, or the Roberts Dipole in the second “re-visit” setup. The only effect achievable was with the dipole very close to the front panel display, which was to make the “decimal point” LEDs flicker slightly. Otherwise, there is “no result”. Consequently, no figures are presented.

5.4 Humidifier

Initially, a Fisher & Paykel MR850AEA Humidifier was exposed to 900 MHz and 1800 MHz GSM and GPRS test signals in both vertical and horizontal polarisations using the Dipole Method. Vertical polarisation had no observable or measurable effect beyond causing the decimal point LED in the humidifier display to flicker slightly, but all horizontally polarised waveforms caused the humidifier to lose temperature control, with onset of the effect dependent on distance from the device. The humidifier was also exposed to 1900 MHz WCDMA at three symbol rates of 15 kbps, 6 x 960 kbps and 6 x 960 kbps with 1 dB power control.

To discover the extent of the changes due to the test signals, it was first necessary to determine the normal “baseline” operation of the MR850 humidifier. Unlike earlier Fisher & Paykel models that had a manually set temperature control, the MR850 humidifier has two inbuilt, switch-selectable modes of operation – “invasive” and “bypass”. The “invasive” mode operates at 37°C ± 0.5°C and the “bypass” mode at 31°C ± 0.5°C.

To ensure that the temperature changes seen on the MR850 display were not artefacts of the display panel due only to interference exposure, a Luxtron 790 Fluoroptic Thermometer with temperature probes (unaffected by RF fields) were placed at three points to monitor actual temperature changes. The effects induced in the device were found to be real; that is, temperature changes displayed or alarms being triggered in the presence of interference were found to be genuine. Figure 22 and Figure 23 show the measurement setup in TRL’s semi-anechoic room.

As the humidifier cannot be operated without an airflow, two computer fans were improvised with suitable funnelling to blow air into the humidifier. Figure 22 shows these fans mounted on a tripod in the foreground. The left foreground of Figure 22 shows the power supply to run the fans with the fluoroptic thermometer display unit immediately behind. Just to the right is a stand holding the blue airway hose from the humidifier to the patient – one fluoroptic temperature probe was placed on the humidifier probe at this point. At the rear right hand side sitting on the white polystyrene box is the MR850 humidifier. Two more fluoroptic temperature probes were placed here – one on the chamber air outlet and the other on the humidifier chamber hotplate. At the far right of the picture is the Roberts Dipole mounted on a wooden pole. The humidifier features and dipole are shown closeup in Figure 23.
Figure 22: Setup for Fisher & Paykel MR850AEA humidifier interference measurements

Figure 23: Fisher & Paykel MR850AEA humidifier and 900 MHz Roberts Dipole
A series of measurements were made to observe the normal “baseline” behaviour of the MR859 humidifier in its two modes of “invasive” and “bypass” operation without any interference applied. Figure 24 shows a 112-minute cycle of operation with no interference applied. The time from turn-on to reach a stable 37°C for the “invasive” mode is 15 minutes; from “invasive” mode to “bypass” mode of 31°C takes 7 minutes; and to return to the 37°C “invasive” mode takes 13 minutes.

Another series of measurements was then made in the presence of fields representative of modulation and power levels consistent with various mobile phone technologies. See Table 3 for a brief summary of interference outcomes.

The humidifier showed two distinct modes of failure. The first occurred when the right-hand side of the front panel was exposed to the dipole field. The device showed a sudden loss of temperature control with the displayed and actual temperature falling. Figure 25 is a measurement of the Fisher & Paykel MR850 humidifier showing a sudden loss of temperature control upon momentary (~5 seconds) exposure to GSM 900 MHz generated by the dipole at 6cm from the front face of the device. Shortly after, the device showed a sharp recovery which then tapered off to a slower recovery to specification 14 minutes after the humidifier regained temperature control. This effect also occurred for GPRS 900 MHz (for any combination of two timeslots) when the dipole was approximately 6 cm from the front face. The distance at which the effect became evident increased to 9 cm for 80% AM 1kHz at 900 MHz. This effect was not evident for GSM or GPRS 1800 MHz. For WCDMA 1900 MHz, this effect was evident only for 6 channel transmission at 960 ksp/s per channel and with power control (6 x 960 ksp/s + PC).

The second effect occurred when the left-hand side of the front panel was exposed to the dipole field. This caused the red alarm LED and 6 white alarm LEDs to light up, the “E11” error code to be displayed, and a “beep” to occur. This was a “lockup” condition and to reset the humidifier the power had to be turned off and on. Signals at 900 MHz (GSM/GPRS/80% AM 1kHz) caused this condition to occur at similar distances to those for the first effect. This effect was evident for WCDMA but only for 6 channel transmission at 960 ksp/s per channel and with power control (6 x 960 ksp/s + PC) and only at 0 cm from the front panel.
Figure 24: Fisher & Paykel MR850AEA humidifier - NO RF FIELD applied. 
"Mixed mode" to illustrate normal "baseline" operation of humidifier
Figure 25: Fisher & Paykel MR850AEA. Example of interference to humidifier - "invasive mode" and GSM 900MHz.
5.5 Philips Medical Systems FR2 AED (Automatic External Defibrillator)

5.5.1 Features of the defibrillator and test setup

This medical device is an ideal candidate for studying the interference effects of mobile phone technologies because it can be used by non-medical personnel with minimal training. It is found widely in the public domain, being used for example at sporting events, in ambulances, in hospitals, in workplaces, in aircraft and so on.

The simulator used in the defibrillator tests is capable of generating 20 different cardiac rhythms, of which only three were used in the interference tests. These are listed here and shown in Figure 26 [Appendix C [1]]

(a) VF (Ventricular Fibrillation)  
(b) NSR (Natural Sinus Rhythm – the normal cardiac rhythm)  
(c) ASYS (Asystole – no heartbeat at all)

Figure 26: Three cardiac waveforms used in testing the FR2 Philips defibrillator
As the VF waveform is chaotic and aperiodic it was felt that the periodic NSR waveform would be better to use to be able to note any interference effects on the device. The asystole waveform was used in tests to more clearly show the effects of interference. It was also used to determine if the device algorithm could be “tricked” into advising a shock where “no shock advised” should be the appropriate response.

A most valuable feature of this device is that the LCD display data is written to a Compact Flash card of 8 Mbytes capacity, which is then read into a PC. A software package then allows the data to be displayed and printed. Selected printed waveforms were then scanned into a file for editing and insertion in this report. The device has many important and innovative features that are too detailed to cover in this report, but the interested reader is referred to the technical reference manual, which is available as a pdf document on the internet [13].

A significant feature of the FR2 defibrillator is the use of Recorded Voice Announcements (RVAs) to guide an operator in assessment of a patient’s condition. From the moment of switching on the defibrillator, RVAs guide the operator through every phase of operation – from placement and connection of the chest pads to a patient’s torso, through analysis of the patient’s cardiac rhythm, to finally advising whether a shock is or is not advised. No shock is administered automatically. The person operating the defibrillator must push a button to deliver a shock to a patient, and the “shock button” is not armed until the defibrillator decides a shock is necessary and has announced this to the operator [Appendix C [1]].

The defibrillator can only be used in an interference test setup by using a cardiac waveform simulator, in this case a Symbio Corporation Model CS1201 Code Simulator, connected to the defibrillator in parallel with the chest adhesive pads. It was also necessary to connect a 45 ohm resistor across the chest pad leads to simulate the chest impedance of a human torso – the defibrillator will not otherwise work. As the simulator was not directly plug/signal compatible with the defibrillator, the output was amplified to drive the defibrillator display to full-screen.

As work progressed on the defibrillator a variety of effects became clear. However, as mentioned in the Introduction (5.1) the finding of no interference effects from a 2W stationary dipole at 1 cm from the defibrillator brought into sharp focus what constituted a reasonable simulation of a mobile phone handset.

The test methodology employed was to move the dipole slowly over the face of the defibrillator at given distances, simulating a person using a mobile phone with slow movement – the “test methodology”. The simulator was set to deliver a Normal Sinus Rhythm to the defibrillator. The dipole-to-defibrillator distance was closely maintained by using a scaled wooden pole as a measuring stick held tightly with the pole-mounted dipole. The results are presented in section 5.5.2 and 5.5.3 below. Other effects encountered during the work are discussed in section 5.5.4 (Appendix C [2], [3]).

5.5.2 Results – preliminary discussion

Before discussing the effects observed using the “test methodology”, it is necessary to again emphasise that the major response of the defibrillator to interference depends on relative motion of the dipole with respect to the defibrillator. With no relative motion of the dipole to the defibrillator no induced interference effects occur to affect the device. The audio effects that occur are proximity effects and not motion dependent.
It is a valid measurement methodology to place stationary dipoles at spatially separated points around a device and note interference effects. However, Figure 27 below clearly shows that for this defibrillator at 1 cm distance from the face of the device a stationary Roberts dipole transmitting 2 watts at 900 MHz with 80% AM 1 kHz modulation has no effect whatsoever.

Figure 27 shows at the top an ASYSTOLE (no heart beat) rhythm with no interference presented to the defibrillator, then Positions #1 to #9 show the response to 2W 900 MHz 80% AM at 1 cm from the device face in 9 stationary positions – 3 across the top, 3 across the middle and 3 across the bottom of the device. No significant interference effect could be seen. Horizontal polarisation is shown but the effect was the same for vertical polarisation.

Asystole waveform with RF OFF

The 9 waveforms below are with RF ON at 1 cm distance from defibrillator face.

Position #1  Position #2  Position #3
Position #4  Position #5  Position #6
Position #7  Position #8  Position #9

Figure 27: Philips FR2 Defibrillator showing ASYSTOLE cardiac rhythm response to 2 watts 900 MHz 80% AM 1 kHz at 1 cm distance in 9 STATIONARY positions across the face of the device
5.5.3 Results – using the “test methodology”

The Philips Medical Systems FR2 AED was exposed to 900 and 1800 MHz GSM and GPRS waveforms. The defibrillator was also exposed to 1900 MHz WCDMA waveforms at symbol rates of 15 ksps in 1 channel, 960 ksps in 6 channels and 960 ksps in 6 channels with the 1 dB-step power control feature of the R&S SMIQ 03B signal generator. As an exposure comparison, for each of the three frequency bands of 900, 1800 and 1900 MHz an additional exposure was made with 80% audio modulation (AM) at 1 kHz, which is the IEC 61000-4-3 immunity test signals [5]. All tests were performed for both horizontal and vertical polarisation.

The defibrillator was first exposed to a test field to determine the distance at which audio interference first appeared from the device and then exposed again to determine the distance at which other interference effects became apparent. The audio effects consisted of interference to the Recorded Voice Announcements (RVAs) of the defibrillator. No audio interference occurred when the RVAs were not active [Appendix C [3]].

Results for the “test methodology” are presented in Table 4(a) to (d). For the test conditions in the Table, four clear results are evident:

(a) No measurable interference from 1900 MHz WCDMA or 1900 MHz 80% AM 1 kHz modulation.
(b) The single worst interferer is 900 MHz with 80% AM 1 kHz modulation.
(c) 900 MHz GSM/GPRS is worse for interference than 1800 MHz GSM/GPRS
(d) Interference from 900 MHz horizontal polarisation is markedly worse than vertical polarisation.

In Table 4 the results for audio interference are just as clear as for visual interference, but are in effect “just observations” as they have no affect at all on the functionality of the defibrillator apart from making unintelligible the RVAs at the worst interference levels. When the audio interference is very severe the RVAs to guide operators cannot be heard at all. The audio interference could be regarded as an “early warning” to cease operating whatever device is causing the audio interference, or to at least move away from the defibrillator so the RVAs can be heard. Table 4 also clearly shows that interference into the audio circuits becomes very obvious long before any visual interference affects become apparent on the LCD screen. It should be remembered that the audio interference is only heard when the FR2 processor initiates a Recorded Voice Announcement for user guidance.

Figure 28 shows the test setup with the simulator and amplifier to the left away from the test field, with the chest pads and torso impedance terminating resistor in front of the amplifier. The FR2 defibrillator is mounted on a test stand to the right. Figure 29 shows a closeup view of the defibrillator [Appendix C [2]].
Figure 28: Philips FR2 Defibrillator test setup

Figure 29: Closeup view of the Philips FR2 defibrillator
Table 4(a): Distance of first effect on FR2 defibrillator LCD screen (cm) – H-POL

<table>
<thead>
<tr>
<th>900 MHz GSM/GPRS</th>
<th>1800 MHz GSM/GPRS</th>
<th>1900 MHz WCDMA</th>
</tr>
</thead>
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<td>GSM TS0</td>
<td>GPRS TS0, TS2</td>
<td>15 ksps</td>
</tr>
<tr>
<td>GPRS TS0, TS4</td>
<td>80% AM 1 kHz</td>
<td>6 x 960 ksps</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 x 960 ksps + PC</td>
</tr>
<tr>
<td>3&lt;sup&gt;i&lt;/sup&gt;</td>
<td>7&lt;sup&gt;i&lt;/sup&gt;</td>
<td>–</td>
</tr>
<tr>
<td>9&lt;sup&gt;i&lt;/sup&gt;</td>
<td>20&lt;sup&gt;i&lt;/sup&gt;</td>
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<tr>
<td>1&lt;sup&gt;i&lt;/sup&gt;</td>
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Table 4(b): Distance of first effect on FR2 defibrillator LCD screen (cm) – V-POL

<table>
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<th>1800 MHz GSM/GPRS</th>
<th>1900 MHz WCDMA</th>
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<td>GSM TS0</td>
<td>GPRS TS0, TS2</td>
<td>15 ksps</td>
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<tr>
<td>GPRS TS0, TS4</td>
<td>80% AM 1 kHz</td>
<td>6 x 960 ksps</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 x 960 ksps + PC</td>
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<tr>
<td>–</td>
<td>–</td>
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</tr>
<tr>
<td>3&lt;sup&gt;i&lt;/sup&gt;</td>
<td>6&lt;sup&gt;i&lt;/sup&gt;</td>
<td>–</td>
</tr>
<tr>
<td>2&lt;sup&gt;i&lt;/sup&gt;</td>
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Table 4(c): Distance of first effect of audible interference from FR2 defibrillator (cm) – H-POL

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<th>1900 MHz WCDMA</th>
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<td>GSM TS0</td>
<td>GPRS TS0, TS2</td>
<td>15 ksps</td>
</tr>
<tr>
<td>GPRS TS0, TS4</td>
<td>80% AM 1 kHz</td>
<td>6 x 960 ksps</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 x 960 ksps + PC</td>
</tr>
<tr>
<td>85&lt;sup&gt;2&lt;/sup&gt;</td>
<td>125&lt;sup&gt;2&lt;/sup&gt;</td>
<td>–</td>
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<td>–</td>
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<td>–</td>
<td>3&lt;sup&gt;2&lt;/sup&gt; (slight)</td>
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<tr>
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<td>–</td>
<td>23&lt;sup&gt;2&lt;/sup&gt;</td>
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Table 4(d): Distance of first effect of audible interference from FR2 defibrillator (cm) – V-POL

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<th>1900 MHz WCDMA</th>
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<td>GPRS TS0, TS2</td>
<td>15 ksps</td>
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<td>80% AM 1 kHz</td>
<td>6 x 960 ksps</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 x 960 ksps + PC</td>
</tr>
<tr>
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<td>70&lt;sup&gt;2&lt;/sup&gt;</td>
<td>70&lt;sup&gt;2&lt;/sup&gt;</td>
<td>70&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>30&lt;sup&gt;2&lt;/sup&gt;</td>
<td>–</td>
<td>3&lt;sup&gt;2&lt;/sup&gt; (slight)</td>
</tr>
<tr>
<td>–</td>
<td>–</td>
<td>16&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

GENERAL NOTE: “–” in the Table represents no effect observable at 1 cm distance from the front face of the defibrillator

OTHER NOTES:
(1). Distance (cm) for “first effect” visual interference on LCD screen with a given “test methodology”.
(2). Distance (cm) for “first effect” of audio interference into Recorded Voice Announcement (RVA) circuits.
5.5.4 FR2 defibrillator – other results

In the course of working with the Philips FR2 defibrillator other interference effects became apparent. The first point to be noted in these “other” test results is that 900 MHz CW caused distortion to the image on the defibrillator LCD screen and audio interference to the RVAs. This and other effects are discussed below in Sections (i) to (iv).

(i) The first interference test using the “test methodology” was to see if CW would affect the defibrillator. Figure 30 shows recorded defibrillator waveforms on exposure to 900 MHz CW. The first waveform shown is Normal Sinus Rhythm (NSR), the normal heart beat waveform. Note that this is far from regular in fine structure and the variations that the waveform exhibits make interpretation of interference effects more difficult. The subsequent waveforms were recorded at the noted distances from the front of the defibrillator.

In Figure 30, interference effects on the defibrillator caused positive and negative excursions of the response from 1 to 2 minor divisions around the grid line situated 1 minor division below the grid centre line. A similar result was found by Morrissey et al [11, pp 50, Fig. 3(c)] in a defibrillator exposed to a 900 MHz GSM cellphone.
Normal Sinus Rhythm (NSR)

No CW RF exposure

5 cm CW RF exposure

10 cm CW RF exposure

20 cm CW RF exposure

60 cm CW RF exposure

Figure 30: 900 MHz CW H-POL exposure to FR2 defibrillator
(ii) With the “test methodology” the worst condition for interference was found to be 900 MHz with 80% AM at 1 kHz with first effect occurring at 20 cm from the face of the defibrillator. However, as noted earlier, if the dipole was placed in a stationary position 1 cm from the defibrillator no interference effects occurred, clearly supporting the notion of an AM effect due to movement of the dipole rather than a proximity effect due to the interference field. To that extent the results reported here are somewhat arbitrary, particularly considering that the functional integrity of the FR2 defibrillator is not compromised by any tests with the “test methodology”.

Using the “test methodology” and the NSR (normal heart beat) simulator waveform, Figure 31 shows the interference effect of 900 MHz H-POL with 80% AM at 1 kHz at 5 cm, 10 cm, 20 cm and 60 cm distance from the FR2 defibrillator face.
AM type effects were quite pronounced when the source dipole was moved rapidly around the face of the device without, however, having any effect on the functionality of the defibrillator analysis algorithms. That is, the defibrillator was very robust to relatively fast, random motion of the source dipole.

A completely different result occurred when the dipole was rapidly moved up-and-down in the same position with an approximately 3 Hz regular motion. In this case, it was possible to modulate the defibrillator LCD waveform to simulate ventricular fibrillation, a fatal heart condition that can only be reversed (i.e., “defibrillated”) with an electric shock. In this condition, the defibrillator analysis algorithm announces “shock advised” and arms the device for manual delivery of a shock when in fact, it should have responded “no shock advised” [Appendix C [3], [4]].

It has to be said that this is a highly artificial test that simply would never occur in practice, but points out the difficulty of choosing a test methodology when a stationary dipole 1 cm from the defibrillator face does not produce any effect due to interference. It is also an important test in so far as it verifies that the observed effects are genuinely affecting the defibrillator, rather than being artefacts of the display as was the case with the Nellcor Pulse Oximeter as reported in Section 5.2.1.

Figure 32 shows the cardiac simulator asystole waveform in the top image. The next two images underneath are the asystole waveform with the VF (ventricular fibrillation) waveform induced by manually moving the H-POL dipole (with 900 MHz 80% AM 1 kHz modulation) up and down at about 3 Hz close to the face of the defibrillator.

![Figure 32: Defibrillator “shock advised” error response to induced interference simulating ventricular fibrillation waveform with 900 MHz 80% AM 1 kHz modulation](image-url)
(iv) Switching the modulation on-and-off to gauge the relative levels of audio interference to the RVAs produced an artefact that was not realised until the particular file was viewed after loading into a computer. The “keying” effect of modulation being switched on-and-off is clearly evident in Figure 33 below. This figure is presented uncritically for information only. The interference was 1900 MHz 80% AM 1 kHz. Apart from the 1 kHz tone evident as audio interference, no malfunction of the defibrillator occurred.

Figure 33: Effect from keying modulation on-and-off
5.6 Agilent A1 Patient Monitor

5.6.1 Features of the patient monitor and test setup

The Agilent A1 Patient Monitor is a compact, portable, battery powered device that measures blood pressure (BP - systolic, diastolic and MAP - Mean Arterial Pressure) and heart rate, as well as the arterial oxyhaemoglobin saturation level in blood (\(\text{SaO}_2\)). Figure 34 shows the device and an 900 MHz Roberts Dipole.

![Figure 34: Agilent A1 Patient Monitor](image)

A simulator is very desirable to use when testing this device to eliminate the physiological variability of a human subject, as found with the first patient monitor. However, as no simulator was available a human subject was used in this instance.

A test run showed some variability in the human subject over time, so the methodology adopted to minimise the variability was to make series of measurements as close together as possible. Each series began with two “baseline” measurements with interference off, then interference exposures made for a sequence of test conditions, with a final “baseline” measurement with interference again switched off. The “bracketing” of real measurements with “baseline” interference off measurements allows a realistic interpretation of statistical significance compromised by human subject physiological variability.

Each measurement used the “STAT” feature of the patient monitor that allowed as many automatic measurements as possible to be taken in a 5-minute time interval. This was important as it enabled minimal movement of the human subject whilst measurements were being made.
16 valid measurements were taken using the STAT feature for each test condition. This usually took three five-minute intervals. For each test condition the 16 measurements were entered into a spreadsheet and the mean and 95% confidence interval computed and graphed.

Figure 35 shows the setup for the human subject. The subject sits far enough away from the patient monitor to minimise perturbation of the dipole field, yet be able to see and read the LCD figures clearly. The signal generator is close by so that interference can be switched on and off with ease as required. Figure 36 shows the subject wearing the BP cuff, with the SaO2 sensor clipped to a toe. Figure 37 shows a closeup of the blood pressure cuff and the SaO2 sensor.

Figure 35: Human subject as source for BP and SaO2 A1 Patient Monitor tests
Figure 36: Human subject in measurement position

Figure 37(a) BP cuff

Figure 37(b) Transmission photoplethysmogram – measures the percentage saturated oxygen level in haemoglobin (SaO₂)

Figure 37: Closeup view of the measurement sensors
5.6.2 Measurement technique and interference results for Agilent A1 Patient Monitor functionality

Previous measurements clearly showed the 900 MHz 80% AM 1 kHz waveform to be a severe test condition. So, to determine a measurement methodology the patient monitor was first exposed to this waveform by moving the dipole slowly over the device surfaces as BP and SaO2 measurements were in progress. No outstanding "hot spot" that perturbed figures displayed on the LCD could be detected. A number of fixed positions at the front, rear and side of the Agilent A1 Patient Monitor were then exposed to this field at 1 cm. A series of 16 successive BP and SaO2 parameters were recorded for each position for both horizontal and vertical polarisation and the mean and 95% confidence interval computed and graphed.

The results (not presented) clearly showed the variability of the data over time pointing up the physiological variation of the human subject. Yet, the stability within a series of measurements made close together in time was equally clear. Taking into account the human subject’s physiological variation, the initial result showed that for the Agilent A1 Patient Monitor there is no statistically significant response to 900 MHz 80% AM 1 kHz interference (the IEC 61000-4-3 80% AM 1 kHz interference immunity test waveform).

As no "hot spot" was found to affect the Agilent A1 patient Monitor a single point in the centre of the front panel was chosen for measurements using the full range of test signals at a distance of 1 cm for both horizontal and vertical polarisation.

Figures 38 and 39 show the results for the Agilent A1 Patient Monitor in this single position. The data point markers are open to indicate data noted with RF OFF, while closed markers indicate data noted with RF ON. Each data point represents 16 successive valid samples for which the mean and 95% confidence interval has been computed. Of the four parameters plotted, the top three are, in order top to bottom, systolic, MAP (Mean Arterial Pressure) and diastolic blood pressure in mm/Hg. The round, green data points at the bottom of the graph are heart rate in beats/minute.

The data is grouped by the continuous time interval over which each data set was recorded, with a notation at the top of the graph recording the time interval. The length of breaks in recording are noted in vertical text between measurement series.

Figure 38 shows the results for 900 MHz GSM, GPRS and 80% AM 1 kHz tests. Figure 39 shows the results for 1900 MHz WCDMA for the three symbol rates indicated and for 80% AM 1 kHz waveform. It is clear that the data in Figures 38 and 39 do not show any statistical significance. The 1800 MHz measurements are not presented as they also had no statistical significance.

The results for SaO2 (arterial oxyhaemoglobin saturation - a completely separate measurement within the patient monitor) are not presented, as there was clearly no affect on this parameter.

5.6.3 Results of audible and visual interference for Agilent A1 Patient Monitor

In addition to the measurements described in the above section, other interference effects were observed that affected the patient monitor’s audio and LCD screen display circuits. These effects were separately observable and the results are shown in Table 5.
The first result is that 1900 MHz WCDMA does not induce any audio interference into the A1 Patient Monitor. Neither does 1900 MHz 80% AM 1 kHz modulation, yet 1800 MHz 80% AM 1 kHz modulation causes interference. Also, the audio interference was highly localised, with the worst interference for H-POL occurring at an angle 30° above the top edge of the monitor. For V-POL the worst interference occurred directly in front of the speaker/function wheel divide. The effects on the LCD screen occurred around the function wheel/LCD screen divide.

The effects on the LCD screen occurred around the function wheel/LCD screen divide. These effects were analogous to turning the function wheel to select an area representing a function of the device. A “bold” black border rotates around the LCD screen function block areas as the function wheel is turned. The interference induces this effect exactly [Appendix C [5], [6], [7], [8]]).

The most significant finding was that unlike all devices tested for this report, the Agilent A1 Patient Monitor showed worse interference for GSM/GPRS 1800 MHz than for GSM/GPRS 900 MHz test signals as far as observable interference effects were concerned. However, as presented in the previous section, in terms of the functionality of the Patient Monitor no statistically significant impairment was found.
Figure 38: Agilent A1 Patient Monitor - 900MHz GSM, GPRS & 80% AM 1 kHz

Figure 39: Agilent A1 Patient Monitor 1900MHz WCDMA and 80% AM 1 kHz
<table>
<thead>
<tr>
<th>GSM/GPRS 900 MHz</th>
<th>GSM/GPRS 1800 MHz</th>
<th>WCDMA 1900 MHz</th>
<th>80% AM 1 kHz (IEC 61000-4-3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>15 kcps</td>
</tr>
<tr>
<td>GSM TS0</td>
<td>GPRS TS0, TS2</td>
<td>GPRS TS0, TS4</td>
<td>21^2</td>
</tr>
<tr>
<td>3^1</td>
<td>3^1</td>
<td>3^1</td>
<td>5^3</td>
</tr>
</tbody>
</table>

**Table 5(a): Distance of first effect on Agilent A1 Patient Monitor (cm) – H-POL**

<table>
<thead>
<tr>
<th>GSM/GPRS 900 MHz</th>
<th>GSM/GPRS 1800 MHz</th>
<th>WCDMA 1900 MHz</th>
<th>80% AM 1 kHz (IEC 61000-4-3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>15 kcps</td>
</tr>
<tr>
<td>GSM TS0</td>
<td>GPRS TS0, TS2</td>
<td>GPRS TS0, TS4</td>
<td>21^7</td>
</tr>
<tr>
<td>5^5</td>
<td>4^5</td>
<td>5^5</td>
<td>21^8</td>
</tr>
</tbody>
</table>

**Table 5(b): Distance of first effect on Agilent A1 Patient Monitor (cm) – V-POL**

**NOTE:** “–” in the Table represents no effect observable with dipole contacting front face of the A1 Patient Monitor

**ADDITIONAL NOTES:**

(1). For 900 MHz H-POL audio interference is directly in front of Patient Monitor speaker/function wheel/LCD screen general area.

(2). For 1800 MHz H-POL audio interference is highly localised and at maximum at an angle 30º above top edge of monitor.

(3). For 1800 MHz H-POL a proximity effect causes a “function wheel search” effect in front of and analogous to turning the A1 Patient Monitor Function Wheel.

(4). No clear-cut effect could be established for a given distance but the effect was intermittently observable.

(5). For 900 MHz V-POL audio interference is directly in front of Patient Monitor speaker/function wheel/LCD screen general area.

(6). For 900 MHz V-POL a proximity effect causes a “function wheel search” effect in front of and analogous to turning the A1 Patient Monitor Function Wheel.

(7). For 1800 MHz V-POL audio interference is highly localised and at maximum level in front of the Patient Monitor function wheel.

(8). For 1800 MHz V-POL a proximity effect causes a “function wheel search” effect in front of and analogous to turning the A1 Patient Monitor Function Wheel.
6. Conclusions

The following observations can be made for the interference tests conducted on the three medical devices in the interim report of December 2003 and the two additional devices presented in this final report.

Devices can be immune to electric field strengths levels that are significantly higher than 10 V/m – measurements were conducted in the range 27 to 30 V/m. The pulse oximeter and blood pressure monitor were completely immune to all test signals. This is consistent with the observations of other studies [14][15][16] that found a significant proportion of devices were unaffected by mobile phones, even when the phone was transmitting at maximum power and in close proximity to the devices.

For the humidifier, signals at 900 MHz were more prone to causing interference than those at the higher frequencies of 1800/1900 MHz. A 900 MHz GSM/GPRS and 80% AM 1kHz signal caused a sudden drop in temperature (of the treated air) when the dipole was placed 6 and 9 cm respectively from the front fact of the humidifier. A similar effect was seen only for WCDMA 6x960ksps with power control when the dipole was touching the face of the humidifier (0 cm). No effect was observed with 1800 MHz signals.

The pulse oximeters N200/N50E and NPB-290 experienced no interference for any of the test signals. This type of result is consistent with other studies such as [15] which report that up to 53% of devices tested exhibited no incidents of interference, even when the mobile was brought to the surface of the device. Pulse oximeter A1 produced audible interference when subjected to 900 and 1800 MHz signals but not to WCDMA. The distance from the device at which audible interference was first observed was 24 cm for 1800 MHz GSM/GPRS and 5 cm for 900 MHz GSM/GPRS signals. This result was interesting since it runs counter to the statistical trend reported in our previous study [15] and observed in other studies ([17], [20]), which found that 1800 MHz GSM was less likely to cause interference than 900 MHz GSM. However, and by definition, there is a statistical chance that devices will exhibit an increased sensitivity to RF at higher frequencies. The overall immunity characteristics of a device will depend on the type of internal electronics, layout of circuitry, wiring and cabling, filtering and case construction. The departure from the statistical trend may have resulted from a particular design approach incorporated in the Agilent A1 patient monitor, or it may point to a more general trend that will become evident as more medical devices are tested.

Defibrillators appear in studies as the device most frequently affected by interference, no doubt because of the long leads carrying small voltages from a human torso. The study found that audible interference from the defibrillator was most notable for GSM/GPRS 900 MHz signals and least notable for WCDMA. Functionally, the Philips FR2 defibrillator was found to be an extremely robust device in the presence of interference – it did not malfunction except under a most contrived condition which would not be encountered in practice. This would appear to show that interference could be minimised in the most sensitive of medical devices by a combination of careful design and waveform analysis algorithms.

A conclusion that can be drawn from the study, and supported by results from our previous study [12], is that WCDMA handsets are unlikely to be a significant interference threat when compared to 900/1800 MHz GSM/GPRS. It is generally a non-existent threat in comparison to GSM and GPRS (two timeslots) at either 900 or 1800 MHz. Recently there have been calls [18] [19] to review hospital policies on
mobile phone use and this report provides data relevant for newer mobile phone technologies.

7. Acknowledgements

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Appendix A

Fields Near a Dipole Antenna

Consider the half-wave dipole below with half height $H$ and drive current $I_m$.

The components of the field at $P$ are $E_z$, $E_y$ and $H_\phi$ and the equations describing them are given by [8]:

$$E_z = \frac{-j\beta I_m}{4\pi\omega\epsilon y} \left( \frac{e^{-j\beta R_1}}{R_1} + \frac{e^{-j\beta R_2}}{R_2} - 2 \cos \beta H \frac{e^{-j\beta R}}{R} \right)$$

$$E_y = j30 I_m \left( \frac{z - H}{y} \frac{e^{-j\beta R_1}}{R_1} + \frac{z + H}{y} \frac{e^{-j\beta R_2}}{R_2} - \frac{2z \cos \beta H}{y} \frac{e^{-j\beta R}}{R} \right)$$

$$H_\phi = \frac{j30 I_m}{\eta y} (e^{-j\beta R_1} + e^{-j\beta R_2} - 2 \cos \beta H \cdot e^{-j\beta R})$$

The total electric field $E_t$ is the vector sum of its components $E_z$ and $E_y$.

Figures A.1, A.2 and A.3 show plots of the magnitude of the total electric field $E_t$ and the magnetic field $H_\phi$ along the z-axis at $y=0.025$ mm for 900 MHz, 1800 MHz and 1900 MHz.
Figure A.1: Electric and magnetic fields as a function of $z$ at $y=0.025m$. Calculated at 900 MHz for an antenna with height $H=0.0898m$, and a drive current $I_m=0.165 A$. The antenna current is based on a nominal 2 W radiated power and an impedance of 73 $\Omega$.

Figure A.2: Electric and magnetic fields as a function of $z$ at $y=0.025m$. Calculated at 1800 MHz for an antenna with height $H=0.0449m$, and a drive current $I_m=0.117 A$. The antenna current is based on a nominal 1 W radiated power and an impedance of 73 $\Omega$. 
Figure A.3: Electric and magnetic fields as a function of z at y=0.025m. Calculated at 1900 MHz for an antenna with height H=0.0449 m, and a drive current Im=0.041 A. The antenna current is based on a nominal 0.125 W radiated power and an impedance of 73 Ω.
Appendix B

Influence of device under test on dipole current

A series of measurements were performed to determine the change in dipole current for different separation distances between the dipole and device under test.

The measurements were performed at 900 MHz and 1900 MHz with half-wave dipoles. The dipole impedance was measured in free-space and then at different distances from a number of devices (Fig B.1). The devices included a metal box of dimensions 25 cm x 21 cm x 13 cm, the pulse oximeter, and three different humidifiers (including the Fisher & Paykel MR850AEA).

![Figure B.1: Measurement setup for determining change in dipole impedance as a function of electrical distance d from a device](image)

For the constant source generator (Vs) with impedance 73 Ω, the magnitude of the ratio in decibels of the dipole current |I(d)| at distance d to the free-space dipole current (Ifs) is given by the equation:

\[
\frac{|I(d)|}{|Ifs|} \text{dB} = 20 \times \log_{10} \left( \frac{73 + Zfs}{73 + Z(d)} \right)
\]

where:

Zfs: dipole impedance in free-space \((d=\infty)\)
Z(d): dipole impedance at electrical distance d (in wavelengths) from device

A plot of Equation (1) for frequencies 900 MHz and 1900 MHz is shown in Figure B.2 below.
The results show that the dipole current changes by between 2 to 3 dB from its free-space value at 0.1λ from a device. This implies that the simple field calculations of Appendix A become inaccurate when the device under test is in the near field of the dipole (less than d=λ/6).

It is clear from the calculations in Appendix A and B that for small dipole separations, the level of the field incident on the device under test is a complex function of the frequency, separation, device size and materials. However, incident field strengths significantly in excess of those shown in Figure 1 will occur for some separations.

Figure B.2: Plots of Equation (1) for 1900 MHz and 900 MHz
Appendix C

MPEG videos of testing Philips Medical Systems FR2 defibrillator and Agilent A1 Patient Monitor

To give a better appreciation of the issues involved with testing the Philips FR2 defibrillator and the Agilent A1 Patient Monitor, during the course of the work presented in this final report eight “rough copy” mpeg video files were shot with a 4 megapixel digital camera. These are available on CD from the authors or the GSMA by request. The mpeg file titles, sizes and running times are:

[1] Introducing defib & VF, NSR, ASYSTOLE waveforms [3m 09s].mpg
   67.2 Mbytes  3m 09secs

[2] Test setup for FR2 defibrillator [1m 15s].mpg
   26.9 Mbytes  1m 15secs

[3] Asystole mode & defib tricked into advising shock [1m 30s].mpg
   32.1 Mbytes  1m 30secs

[4] Long 'play around' tricking defib into advising shock [13m 53secs].mpg
   74.0 Mbytes  13m 53secs

[5] A1 Patient Monitor function wheel interference_a [3m 00secs].mpg
   16.1 Mbytes  3m 00secs

[6] A1 Patient Monitor function wheel interference_b [1m 03secs].mpg
   22.6 Mbytes  1m 03secs

[7] A1 Patient Monitor function wheel interference_b [0m 15secs].mpg
   5.3 Mbytes  0m 15secs

[8] A1 Patient Monitor function wheel interference_b [0m 15secs].mpg
   1.3 Mbytes  0m 15secs

The last four files for the Agilent A1 Patient Monitor are essentially of the same effect on the LCD screen. A number were shot because of the poor resolution of the mpeg function on the digital camera used, hoping that the effect would be clearer with repetition.