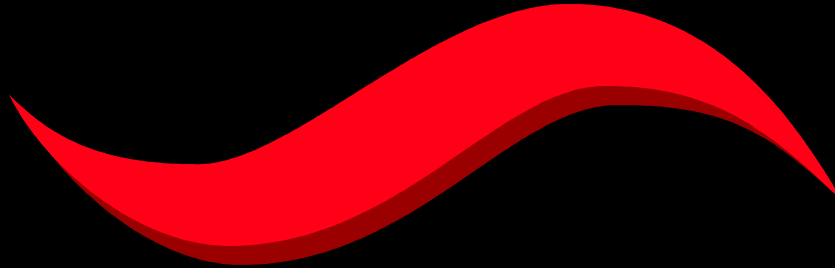


# IEE Seminar on EMC and Functional Safety

Healthcare Sector  
V C Clements *BSc, MSc, CEng MIEE*

22nd March 2001



RF Investigation Ltd  
Ewhurst Park, Ramsdell, Basingstoke, Hampshire, RG26 5RQ  
Tel: +44 (0) 1256 855400  
E-mail: sales@rfi-wireless.com

www.rfi-wireless.com

## Introduction



- ~ Safety is a major concern in Healthcare
- ~ EMC an increasingly important issue
- ~ Many safety related EMC problems reported by FDA
- ~ Need for EMC design and thorough testing essential
- ~ EMC design measures can lead to less safe equipment



2

FDA Examples of Interference Effects on Electro-Medical Equipment



- ~ Apnea monitor failed to register cessation of respiration
- ~ Anaesthesia gas monitor disrupted by surgical diathermy equipment
- ~ External Heart pacemaker failed during ambulance ride due to use of two-way radio
- ~ Powered Wheelchair moved involuntarily at high speed due to nearby transmitter
- ~ Pulse oximeter rebooted and lost parameters when in close proximity to transmitter



3

Interference from a 0.6W Analog Cell Phone (FDA)



Device	Effect	Proximity
Infusion Pump	Flow sensor triggered – causes pump to stop	0.2m of flow sensor
Incubator	Temperature settings fluctuate, causing the heating element to turn on	0.1m of the LED display
ECG/Apnea	False alarm	0.1m of monitor
Ventilator	Change in delivered gas volume	0.3m of right side
Oxygen Monitor	Oxygen saturation reading increases	0.13m of monitor



4

## The EM Environment for Medical Devices



- ~ Proliferation of sources of interference
- ~ Traditionally severe environments e.g theatre equipment
- ~ Medical devices used in wide range of environments
- ~ Patient-coupled devices
- ~ EN61000-2-5 Guide to EM environment classification and threat levels



5

## European Legislation on medical devices



The Medical Devices directive (MDD)  
93/42/EEC

The Active Implantable Medical Devices  
Directive 90/385/EEC

The In Vitro Diagnostic devices directive  
98/79/EC



6



## Scope of the MDD

Any instrument, apparatus, appliance, material or other article including software, whether used alone or in combination, intended to be used solely or principally for the purpose of:

- ” diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap;
- ” investigation, replacement or modification of the anatomy or of a physiological process;
- ” control of conception;

which does not achieve its principal intended action by pharmacological, immunological or metabolic means



## EMC Requirements of the MDD

General requirement that device should be safe and remain safe during use in its intended operating environment

Requirements for EMC are stated in Annex 1 as follows;

Clause 9.2

Devices must be designed and manufactured in such a way as to minimise as far as possible

- ” risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration
- ” risks of interference with other devices normally required for the investigations or for the treatment given

## EMC Requirements of the MDD



### Clause 12.5

- ” The devices must be designed and manufactured in such a way as to minimise the risk of creating electromagnetic fields which could impair the operation of other devices or equipment in the vicinity



9

## EMC Standards for Medical Devices



### EN60601-1-2

- ” Medical Electrical Equipment Part 1. General requirements for safety
- ” Section 1.2 Collateral standard: Electromagnetic compatibility - Requirements and tests

Emissions to CISPR 11

Immunity to EN61000-4 Series



10

## Suitability of Standard



- ~ Issues with Immunity -not severe enough?
  - ” 3V/m 80MHz to 3GHz test
- ~ Failure criteria -
  - ” “continues to perform intended function or fails without causing safety hazard”  
what about its unavailability?
- ~ No test methods or levels for radiated immunity of patient coupled devices



11

## Amendments in draft 2nd Edition



- ~ Failure criteria - “Clinical Utility must be maintained”
  - ” improvement
- ~ Immunity levels not mandated - user responsibility
  - ” risky



12

## EMC and Intrinsic Safety Design Issues



Mains Power Filters

Transient Suppression devices

Shielding

Grounding



13

## Summary



- ~ EMC is recognised as a major safety risk issue in medical devices
- ~ There are legal obligations to provide devices which are safe to use and which remain safe and able to deliver their function when operating in their intended environment
- ~ Beware of weaknesses in the immunity provisions of standards
- ~ Be aware of impacts of EMC design measures on intrinsic safety



14