Source: CSELT (Italy)

Potential GSM Hazards on Cardiac Pacemakers

1 - Pacemaker Operation

Cardiac pacemakers are pulse generators implanted in subjects suffering from heart disease in order to stimulate artificially the beat of the heart.

Demand types sense when the heart beat is abnormal and make necessary corrections. Most pacemakers in use are of the demand type.

A simplified block diagram of a demand type pacemaker is shown in fig. 1. The circuit and the power supply (a solid state battery) are sealed in a titanium package to reduce the rejection phenomena as well as to improve the electromagnetic shielding.

The circuit is implanted in the abdomen of the patient while the pacing lead carries the pulses directly to the heart.

The pacing lead is a catheter introduced through veins and has the double function of exciting the cardiac activity and detecting the spontaneous signals. In fact when the detector reveals the natural heart beat (which is an electric pulse with a peak to peak amplitude near to 5 mV) turns off the pulse generator (which give out a peak to peak pulse of approximately 5 V). So acting the pacemaker reduces the power consumptions and avoids unnecessary stimulations. There are two different kinds of pacing leads: unipolar and bipolar, bipolar leads are less sensitive to the external interferences but they are less sensitive to the cardiac signal too.

Single channel and multichannel devices (i.e. with a stimulation ~~and detection in~~ more than a single heart point) are available according to the patient needs. In a large part of the pacemakers the physician can program the parameters of the implanted generator (e.g. amplitude, frequency, sensitivity) using a radio interface controlled by a computer. Moreover the radio interface allows the physician to get the operating parameters of the stimulator using some telemetry measurement functions built in into the device.

2 - GSM Interference to Pacemakers

Since the pacing lead acts as an antenna, exposure to an electromagnetic field may:

a) Introduce currents from the leads into the heart causing fibrillation or local heating;

b) Induce voltages in the lead that damage the pulse generator;

c) Induce voltages in the lead that the pacemaker confuses with the intrinsic heart signal and turn off the pulse generator.

Additionally implantable pulse generators incorporate reed switches which are used for controlling the battery charge and may be activated by strong magnetics fields.

The safety of implantable pacemakers and their protection against EMI (Electro Magnetic Interference) is the subject of the CENELEC European Standard 56001.

A draft amendment prepared by the Technical Committee 62 [1] suggests both the maximum ratings of interference and the measurement methods to which pacemakers should comply.

Surely clauses a) and b) do not concern the GSM system because the power of a direct radiation excited in the lead which can damage the heart or the pulse generator is very much higher than the power of the GSM fixed or mobile equipments. Moreover the transmission frequencies of the GSM system are so high that the by-pass capacitor which protects the pacemaker input filtrates enough the residual components. For instance it has been verified that AM radio broadcast transmissions using very high power (kilowatts or megawatts) can introduce a strong hazard.

Instead, clause c) has needed some investigations because an interfering signal with low frequency components approximating the heart beat could cause potential hazards even if their power is relatively low.

In case of GSM signals, while the normal burst transmission has a repetition rate of 216 Hz and risks cannot arise (consider that a 50 Hz component is already strongly filtered by the post-detector filter of the pacemaker detector input), the particular case of DTX (Discontinuous Transmission) mode had to be carefully investigated.

In fact DTX mode has signal components at frequencies much lower than in the case of normal GSM transmissions (see fig. 2): there is a sub-component with a repetition rate of 2.08 Hz, which corresponds to the transmission of the 8 timeslots of the SID (Silence Descriptor) message block frame and another low frequency component represented by the SACCH repetition rate (8.33 Hz). The amplitude and duty cycle (one timeslot out of 26) of this component are much lower than those of the previous one. Since electrical signals with a periodicity below 6-8 Hz inhibit the pulse generator while interfering signals with a periodicity above 6-8 Hz will revert the pacemaker operation into the so called asynchronous mode at the basic programmed rate, it was fundamental importance to identify possible danger thresholds.

In fact, if the power excited by these signals in an active pacemaker were high enough, the pulse generator could be turned off and the person could have a heart failure.

3 - Experimental Tests

Compatibility tests have been conducted both with unipolar and bipolar pacemakers manufactured by SORIN using the test set-up shown in fig. 3.

An arbitrary waveform generator jointly with an RF generator simulated the 900 MHz DTX transmission. The signal was amplified by a power amplifier.

Pacemakers were placed in a phantom, an imitation of the human body filled with a physiological solution (water and NaCl whose concentration corresponded to a specific conductivity of 0.5 S/m at 20°C room temperature) according to the standard values.

The phantom was a Plexiglas cylinder 1.7 m tall, with a diameter of 0.3 m. The pacing lead was placed in a loop similar to the one really done in the human chest and his distance from the plexiglas wall was not larger than 1 cm. An oscilloscope connected to two steel plates plunged into the solution was used to detect the regular operation of the generators.

Experiments were conducted in a controlled (anechoic) environment with the aim of measuring the field strength next to the phantom chest by an isotropic detector avoiding any unwanted component.

The measurement results show that no risk of hazards exists against pacemakers from GSM equipment.

In fact it has been verified that it is necessary an electric field of at least 40 V/m (corresponding to 8 W transmit peak power of a GSM equipment at 0.5 m distance) for inhibiting an unipolar pacemaker when the device is leaved in the air with the pacing lead loaded with a 500 ohm resistor simulating the tissue interface.

On the other hand, when the device was put into the physiological solution, it was not possible to inhibit his regular operation even with electric fields of 200 V/m (corresponding to 208 W transmit peak power at 0.5 m distance).

For bipolar pacemakers the results are even more reassuring: with the device in the open air the electrical field could inhibit the pulse generator only if it was above 75 V/m (corresponding to a transmit peak power of 28 W at 0.5 m distance). Obviously no inhibitions have been detected with the pacemaker plunged into the solution.

4 - Conclusions

DTX transmissions of a GSM equipment produce waveforms which could inhibit cardiac stimulators but formal experiments carried out with modern unipolar and bipolar pacemakers manufactured by SORIN have demonstrated that no real hazard exists.

References

[1] "Safety of implantable cardiac pacemakers", Draft CENELEC pr EN 50 061 (1989)

[2] "Immunity to disturbance of cardiac pacemakers in RF fields of powerful radio transmitters", Institut fur Runfunktechnik GMBH, Munchen, 1987.

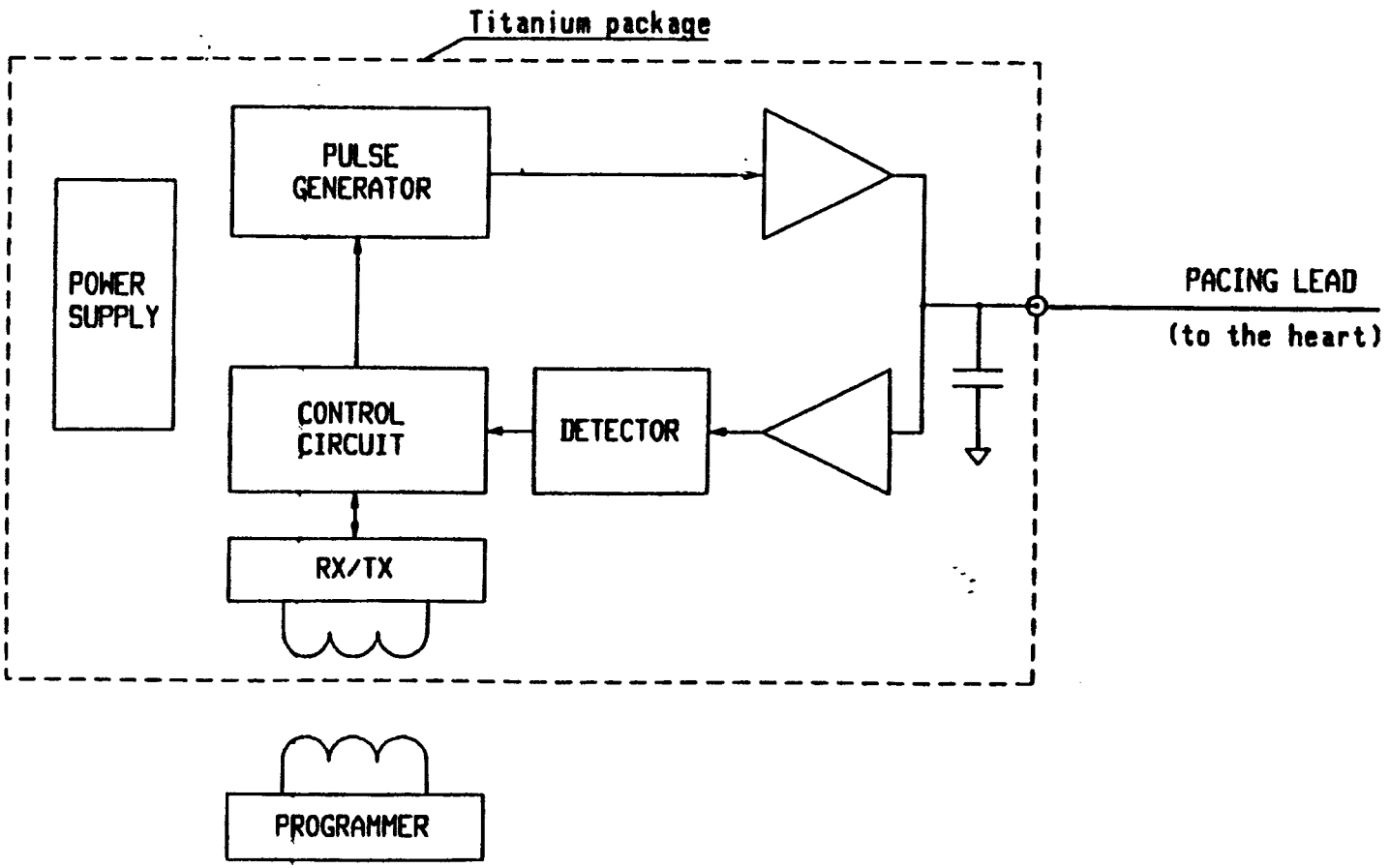

Fig. 1 Schematic diagram of a cardiac pacemaker

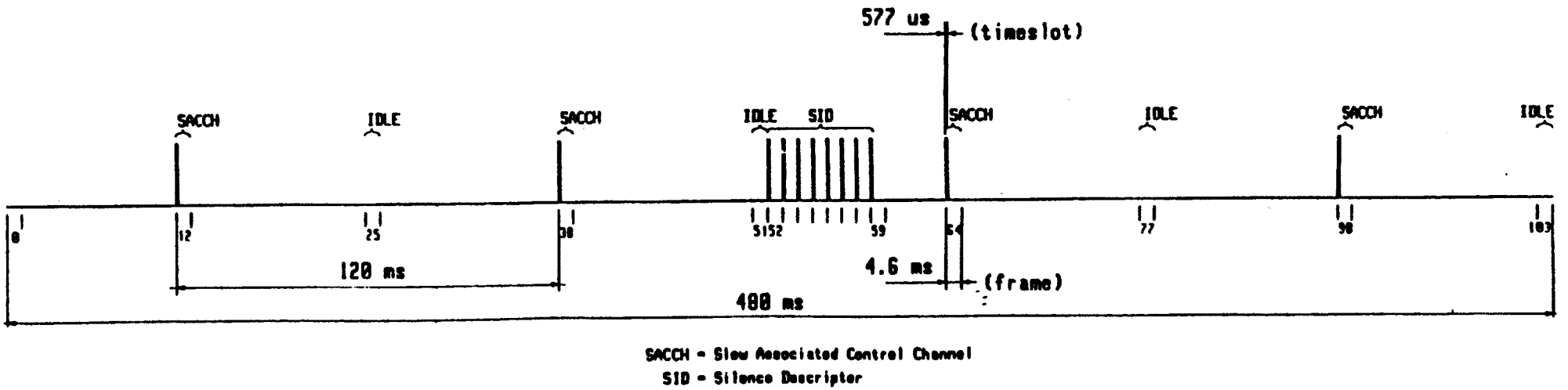

Fig. 2 GSM System Discontinuous Transmission (DTX)

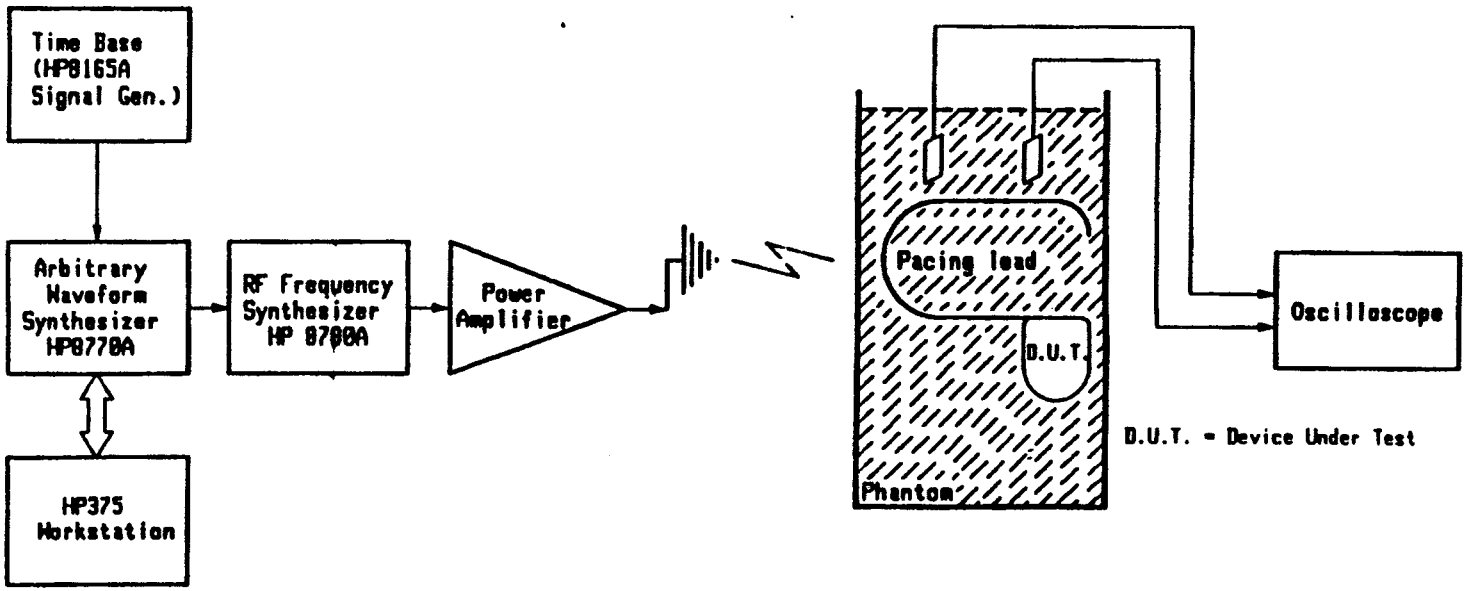

Fig. 3 Block Diagram of the experimental setup