

Observation sheet

Patient number

Pacemaker brand

Pacemaker model

Polarity adjustment:

Programmed sensitivity:

| Position | Activation PM |
|------------------------------|---------------|
| 1 cm magnet | |
| 1.5 cm magnet | |
| 2 cm magnet | |
| Garment: side with pacemaker | |
| Garment: opposite side | |

Comments

Research Report

Effect of magnets inserted into a garment upon the operation of cardiac pacemakers

**Dr. Robert Frank
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Summary of Protocol

Effect of magnets inserted into a garment upon the operation of cardiac pacemakers.

Investigators

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Type of study

Study of the operation of implanted cardiac pacemakers in the presence of a magnetic field by magnets intended to hold parts of clothes together.

Form of administration

Short-term exposure to an approaching garment with inserted magnets

Subjects:

Implanted adults at less than 85 years of age without uncompensated cardiopathy

Number: 80 patients during a period of 3 months, at the consultation of consistent pacemakers, allowing a sampling of 8 brands of pacemakers implanted in France.

Development of the study and criterion of supervision

Exposure in two circumstances:

The approaching of a magnet at a measured distance, 2, 1,5, and 1 cm, to evaluate the maximum distance of activation and of the magnetic switch of the pacemaker.

Stimulation of a real case: taking up a stuffed toy wearing pants and suspenders that are held up by a system of magnets.

Inclusion of subjects after a cardiologic exam, ECG, and testing of the cardiac pacemaker, and regular testing with the control magnet.

Supervision with the ECG recording by continuous telemétrie, by a doctor qualified in cardiac stimulation.

Results

77 patients agreed to participate in the trial, corresponding to 8 brands of pacemakers. No device was activated by the magnet beyond 2 cm. In 22 cases of the taking up of a stuffed toy wearing a garment held up by a system of magnets going along the magnetic route of the pacemaker, there were no undesirable effects for the patient.

Effect of magnets situated in a garment upon the functioning of cardiac pacemakers.

I – Introduction

The cardiac pacemakers are sensitive to continuous, powerful magnetic fields, exceeding 1mT (10 gauss) because they contain a magnetic switch that made them pass an asynchronous mode when one affixes a magnet directly on the case (1,2). This plan of action serves to verify the integrity of the functioning of the pacemaker at the time of the consultations of control, and the battery charge of the device (3). Outside of particular situations, industrial environments, installations of nuclear magnetic resonance, no magnetic field in regular life is strong enough to reproduce this effect. Certain circumstances can however place a magnet directly upon the case. This is the case with certain cellular phones that one avoids transporting in a breast pocket on the side of the pacemaker (5). This is also the case with a new technique to hold together the assembly of clothing parts by small magnets (6). The goal of the study is to verify the potential effect of this type of garment on a patient equipped with a cardiac pacemaker, that this garment is worn by the subject himself, or by a person in a close environment, such as a small child.

II – Objectives and justification of the study

The direct effect of a magnet on the pacemakers is well known, since its is a everyday practiced manoeuvre at each consultation of a cardiac pacemaker wearer, that takes place in a center of stimulation or in the office of the cardiologist. The insertion of an active magnet of a magnetic switch that places the pacemaker into an asynchronous mode. In such a mode, the pacemaker sends impulses to the heart without being inhibited by the spontaneous contractions, as this is normally the case of all pacemakers that function in a “sentinel” mode. The frequency of the stimulation is characteristic of the brand of pacemaker, close to 100 per

minute, and slows down with the exhaustion of the battery. This plan of action serves to verify the integrity of the functioning of the pacemaker at the time of consultations of control, and the charge of the battery of the device. It only can lead to the patient having the minor inconveniences of perceiving a modification of his cardiac rhythm, of temporary acceleration less than or equal to 100/mn, or of simple irregularity, according to effect of the magnet on the stimulator model that he is wearing. This manouvre does not lead to any particular grave risk. Tests have shown, when there is more than 20 years, cases of transitory inhibitions at the time of the magnet displacement facing the case of certain models of pacemakers, essentially linked to a unipolar electrode. These very old models are no longer currently seen, as their expected life does not surpass ten years. Otherwise, a VENTRICULAIRE asynchronous stimulation falling in the zone considered vulnerable of repolarization, that is to say on the top of the T wave of the electrocardiogram, can make one fear the release of a trouble of a grave VENTRICULAIRE rhythm. This risk does not in fact exist for intensities of more than 100 times bigger than that of the cardiac pacemaker, and one does not come across this in regular practice. This in particular was never produced during the consultations in the Jean Rostand center where several thousand magnet tests are done per year. This is equally the case of centers of telesurveillance of American cardiac pacemakers where patients were asked to carry out this manouvre at home. This takes place only in exceptional circumstances that this threshold can be pulled down to dangerous values, in particular, at the acute phase of a infarctus of the myocardium, that represents a theoretic counter indication to the magnet test of a patient that is not dependent on the stimulation.

On the other hand, the effect of magnets on a pacemaker through clothes is not known. The magnetic field can maybe be alleviated; all the more that it is a matter of two magnets next to one another. It is important, before the diffusion of such closing systems, to know what advice one must give to patients who can where such devices or in regular life to be

close to people wearing clothes containing these magnetized closures particularly intended for small children and for the handicapped.

III - Selection of subjects

Types of pacemakers: 8 makers exist in France: Biotronic, CPI-Guidant, Ela médical, Medico, Medtronic, St Jude-Pacesetter, Sorin, and Vitatron. Some are the type of pacemaker, single chamber or double chamber; they involve a similar magnetic switch in their case.

Number of patients: During a period of 3 months, 80 patients will be recruited for the consultation of cardiac stimulation, with devices implanted in PREPECTORAL position, to the right or to the left.

Criterion of inclusion: adult subject, of less than 85 years of age, clinically in good health, with no sign of cardiac insufficiency or coronary insufficiency, followed in the services of the cardiology department of the Jean Rostand hospital, done voluntarily and having signed a clear consent.

Criterion of exclusion: Subject of more than 85 years of age, or in a precarious cardiovascular state. Taking of medications is not a criterion of exclusion.

IV – Material and method of exposure

Magnets: Employment of small magnets of magnetic, rectangular ceramic at the size of 15 mm x 10 mm x 2 mm. Their strength, such that the description of their fabrication describes, is of 1900 gauss at 0 mm, 320 at 10 mm, 5 at 50 mm, 0 to 500 mm, the magnetic field decreasing with the square distance.

Pacemakers: They are left in their way of normal functioning with the sensibility and the habitual programmed polarity of the patient to remain in the circumstances of regular life.

Experimental plan of action:

1 - Patients are bare-chested.

2 – The magnets are glued at the bottom of three boxes at a known depth, respectively, 1, 1,5, and 2 cm, that are placed facing the pacemaker, at the place where the magnet of the habitual test is placed against the skin produced this effect.

3 – They are on the other hand placed in the suspenders of children's pants worn by a stuffed bear of the size of a small child that the patient, standing, takes into his arms, of the side of the pacemaker; and of the opposite side.



Surveillance and recordings

The surveillance of the ECG is fulfilled continuously by telemétrie with recording on paper for each sequence. At a total of 6 sequences recorded, 4 with the magnets alone (the habitual test of the consultation, and those with the magnets tested at 3 distances of the device) and two with the garment.

The surveillance is done by an expert cardiologist in cardiac stimulation, permanently present during the consultation, assisted by a nurse who is competent in this field.

Criterion of judgment

The influence of the magnet on the cardiac pacemaker is visible on the ECG. If the pacemaker is inhibited by the spontaneous, more rapid rhythm of the patient, the stimulation interferes in the asynchronous mode with the spontaneous rhythm. If it is permanently pulled electrically, one remarks an acceleration of the stimulation frequency. One estimates the largest distance between the case and the magnet that leads this phenomenon, allowing to estimate a security distance. One notes finally the depth of implantation of the pacemaker; that can be superficial, under the skin, its visible and perceivable contours at the PALPATION, profound, non visible, and almost not perceptible, or in an average position.

V – Development of the study

This study occurs in the consultation room of the cardiological services of Jean Rostand, 39-41 rue Jean Le Galleau at Ivry sur Seine, on the 5th floor, where there the tests are routinely carried out with the magnet at the time of the control of the implanted pacemakers, consultations one after another for volunteer patients. That prolongs a habitual consultation by 15 minutes. The duration of the study is 3 months.

VI – Team of investigators

Medical team

Dr. Robert Frank, Hospital Doctor, Chief of cardiology services of the Jean Rostand Hospital, and Dr. Aimé Bonny, Cardiologist

Coordination and research

The protocol was elaborated by Dr. Frank. The recruitment of volunteers and the information concerning the protocol were provided by Dr. Aimé Bonny, the analysis of plans were provided by Dr. Bonny and Dr. Frank.

VII – Results

Included population: 77 patients could be recruited during the period of study of 3 months. The number of pacemakers varies according to the brands in function of the present patients at the consultation of their agreement for the testing.

| Brand | Number |
|--------------------|--------|
| Biotronik | 8 |
| Guidant-CPI | 9 |
| Ela | 12 |
| Intermedics | 3 |
| Medico | 2 |
| Medtronic | 13 |
| Sorin | 1 |
| St Jude-Pacesetter | 19 |
| Teletronics | 6 |
| Vitatron | 4 |

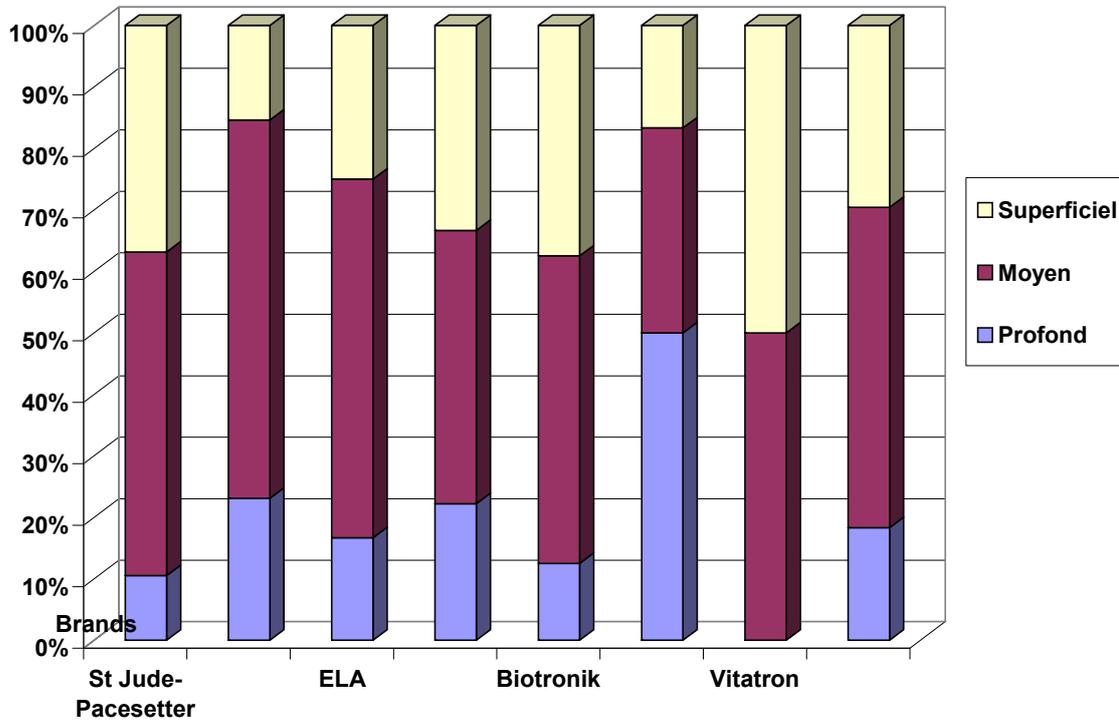
The weak number of devices of the brand Médico, Sorin and Intermedics, dismissed their use in the final analysis. For 4 years, the pacemakers of Intermedics are no longer implanted due to the fact that the business died out, those of Medico and Sorin are not frequently implanted in our center.

The synthesis of the results and the list of observations are presented under the numeric form in tables 1 and 2, situated in the appendice.

The situation of the case was classed as “profound” in 15 cases, since it was RETROPECTORAL, or it was difficultly palpable through the skin, “superficial” in 22 cases

when the details of contour were directly perceptible under the skin, and “average” in 40 others.

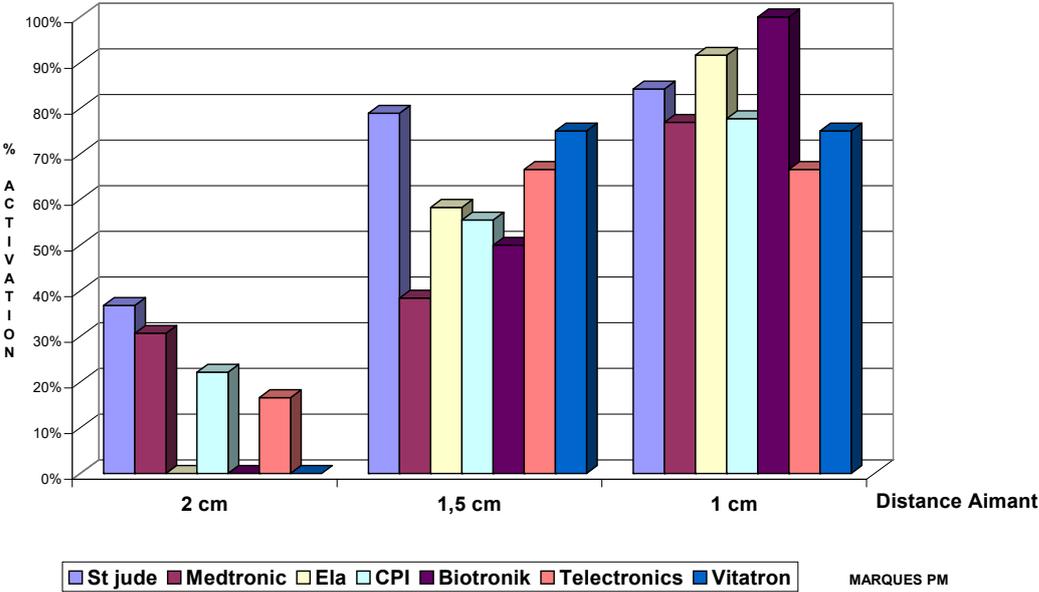
Graph: Pacemakers’ depth



1 – Sensibility of pacemakers on isolated magnets:

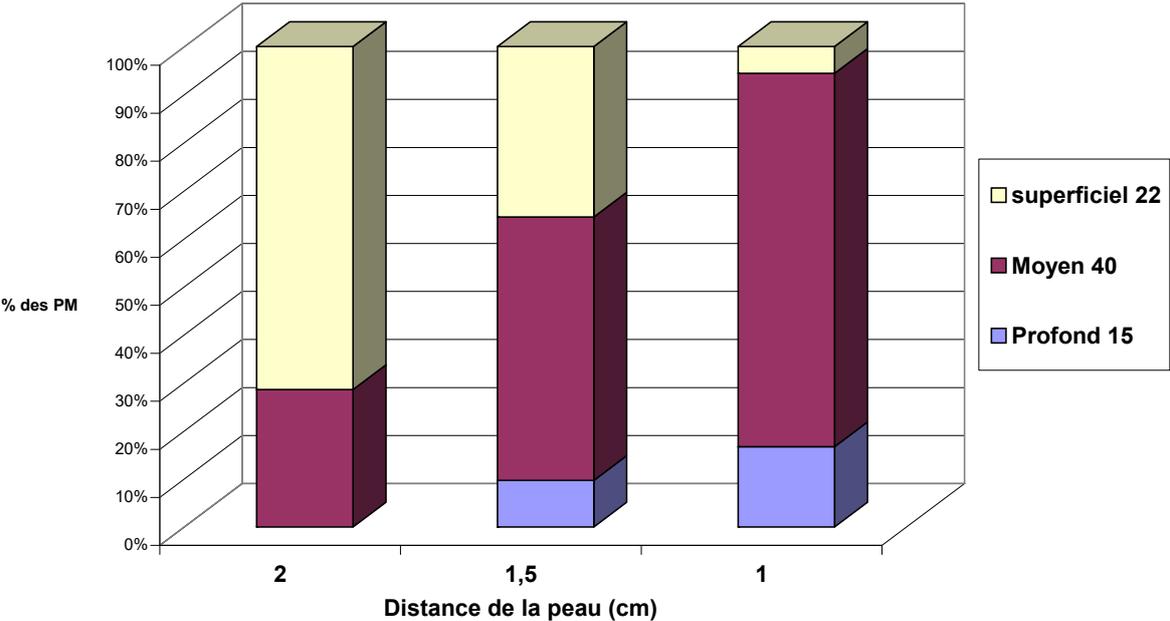
Beyond 2 cm, no magnetic switch reacts to the magnet. At 2 cm, 14 pacemakers react, that is to say 35 to 78 percent of the brands. Lastly, at 1 cm, 65 to 95 percent are activated according to the brand. Finally, even placed on the skin facing the case, all the pacemakers pass the magnetic field under the effect of the magnet.

Graph: activation PM / magnet / distance of the magnet



This distance of activation depends on the depth of implantation of the case:

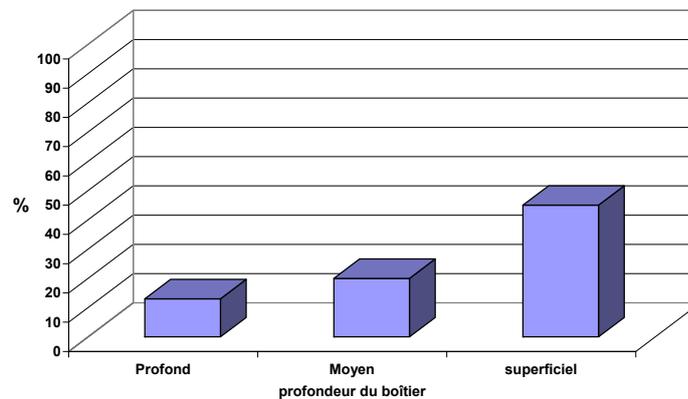
Graph: maximum distance of the magnetic effect according to the depth of the PM



2 – The approach of a garment with magnetized closures

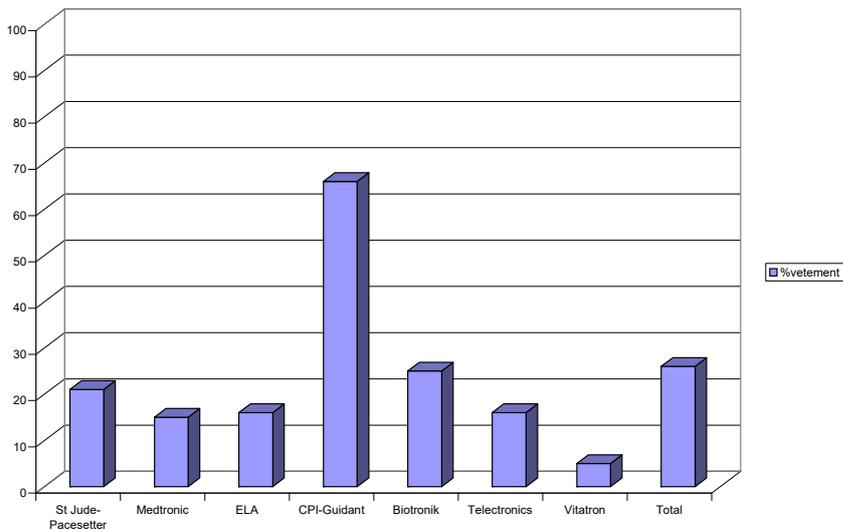
From the opposite side of the pacemaker, no effect is noticed. In contrast, the support of the garment against the shoulder where the active pacemaker is implanted the magnetic switch in 20 of 77 cases (26 percent). This diversity of responses depends again upon the depth of the implantation:

Graph: activation by the garment

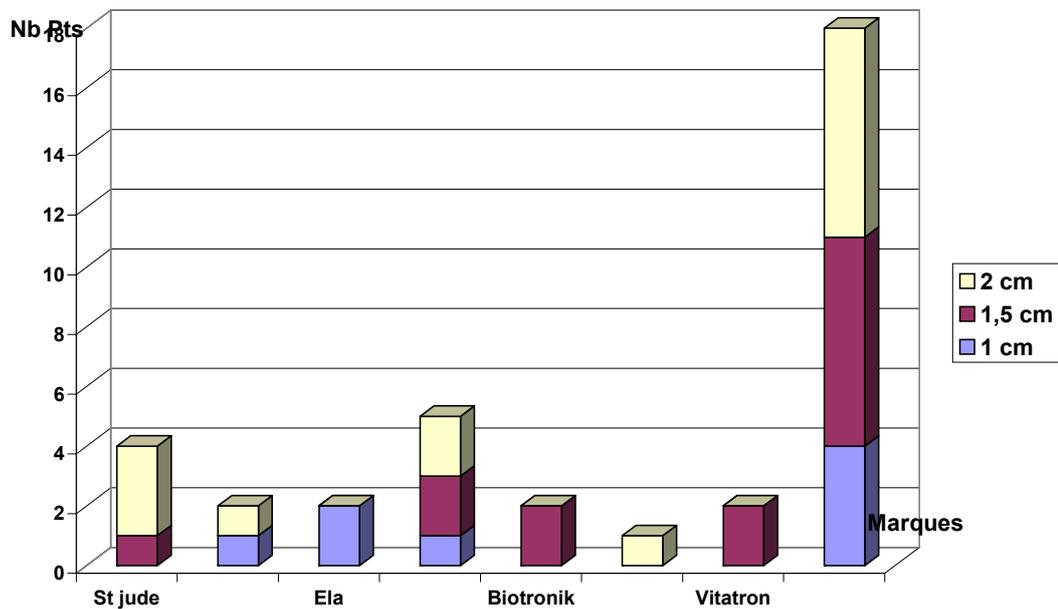


Those that are implanted the most profoundly are the least influenced (13 percent), and this probability of activating the magnetic switch increases all the more than when the case is superficial. This activation is noticed in all of the brands except for one, in between 10 and 20 percent of models. The pacemakers of CPI-Guidant appear to be more sensitive, when their proportion of superficial devices is not different than the others, since the two levels of devices are activated by the magnets of the garment.

Graph : Percentage of activation of the pacemaker by the garment



Graph : Maximum distance of magnetic effect on the PM activated by the garment



It is evident that these are the most sensitive pacemakers to the test magnet which there are for the magnets of the garment.

No undesirable effect has been noticed during the study.

VIII Conclusions:

The magnets inserted into clothes, of an intensity comparable to those used in the study, do not activate the magnetic switch beyond 2 cm of the case of the pacemaker. Closures situated on the opposite side of the device or in the back do not have any effect. In contrast, a HOMOLATERALE closure at the pacemaker must be more than two cm away to not activate the switch. Even the fact of taking up a subject wearing such a type of garment can lead to a reaction of the pacemaker if the magnetized closure is at 2 cm from the case. The risk of such an asynchronous stimulation remains in every way insignificant, a palpitation sensation at most. It is comparable to that of patients where the pacemaker is controlled in the center of the implantation.

Tableau 1 : Résultats en fonction des marques de stimulateurs et de la profondeur du boîtier(profond, moyen et superficiel), à l'approche du vêtement , et des aimants calibrés à 2, 1,5 et 1 cm

| Distance PM | | Profond | | | | | Moyen | | | | | Superficiel | | | | |
|--------------|-----------|-----------|----------|----------|-----------|----------|-----------|------------|----------|-----------|-----------|-------------|-----------|-----------|-----------|----------|
| Marque | total | N | Vêtmnt | 2 | 1,5 cm | 1 | N | Vêtmnt | 2 | 1,5 | 1 | N | Vêtmnt | 2 | 1,5 | 1 |
| St jude | 19 | 2 | 0 | 0 | 1 | 0 | 10 | 1 (1,5cm) | 0 | 7 | 1 | 7 | 3 (2 cm) | 7 | 0 | 0 |
| Medtronic | 13 | 3 | 1 (1cm) | 0 | 0 | 2 | 8 | 1 (2 cm) | 2 | 1 | 3 | 2 | 0 | 2 | 0 | 0 |
| ELA | 12 | 2 | 0 | 0 | 0 | 1 | 7 | 1 (1 cm) | 0 | 5 | 2 | 3 | 1 (1 cm) | 0 | 2 | 1 |
| CPI | 9 | 2 | 1 (0cm) | 0 | 0 | 0 | 4 | 3(1;1,5;2) | 1 | 1 | 2 | 3 | 2(1,5;2) | 1 | 2 | 0 |
| Biotronik | 8 | 1 | 0 | 0 | 1 | 0 | 4 | 0 | 0 | 0 | 4 | 3 | 2(1,5cm) | 0 | 3 | 0 |
| telectronic | 6 | 3 | 0 | 0 | 1 | 0 | 2 | 1 (2 cm) | 1 | 1 | 0 | 1 | 0 | 0 | 1 | 0 |
| Vitatron | 4 | 0 | 0 | 0 | 0 | 0 | 2 | 1 (1,5 cm) | 0 | 1 | 1 | 2 | 1 (1,5cm) | 0 | 2 | 0 |
| intermed. | 3 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| Medico | 2 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 1 | 0 |
| Sorin | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TOTAL | 77 | 15 | 2 | 0 | 3 | 3 | 40 | 8 | 4 | 17 | 14 | 22 | 10 | 10 | 11 | 1 |

Tableau 2 : Liste des stimulateurs testés, marque, modèle et distance de l'aimant activant l'interrupteur magnétique (en cm), et effet des aimants du vêtement porté par l'ours en peluche serré contre l'épaule du patient

| Numero | Marque | Modèle | Aimant(cm) | Profondeur | Vêtement |
|--------|-------------|--------------|-------------|------------|----------|
| 25 | biotronik | keros | 1 | moyen | non |
| 29 | biotronik | keros | 1,5 | superf, | non |
| 39 | biotronik | actros sr | 1,5 | profond | non |
| 47 | biotronik | actros sr | 1 | moyen | non |
| 49 | biotronik | actros sr | 1 | moyen | non |
| 57 | biotronik | physios tc | 1 | moyen | non |
| 72 | biotronik | physios | 1,5 | superf, | oui |
| 77 | biotronik | actros dr | 1,5 | superf, | oui |
| 1 | cpi-guidant | méridian sr | 1,5 | superf, | non |
| 6 | cpi-guidant | pulsar | 1 | moyen | non |
| 17 | cpi-guidant | 1230 ddr | 0 | profond | non |
| 23 | cpi-guidant | vigor | 0 | profond | oui |
| 48 | cpi-guidant | pulsar | 2 | moyen | oui |
| 58 | cpi-guidant | delta | 1,5 | superf, | oui |
| 63 | cpi-guidant | 976 | 2 | superf, | oui |
| 68 | cpi-guidant | 976 | 1,5 | moyen | oui |
| 76 | cpi-guidant | discovery dr | 1 | moyen | oui |
| 2 | ela | chorus | 1,5 | moyen | non |
| 3 | ela | talent dr | 1,5 | moyen | non |
| 14 | ela | talent 213 | 1 | moyen | non |
| 18 | ela | bs 45 d | 1,5 | moyen | non |
| 26 | ela | sr 113 | 1 | profond | non |
| 33 | ela | talent | 1,5 | superf, | non |
| 37 | ela | chorus | 1,5 | superf, | non |
| 46 | ela | opus rm | 1,5 | moyen | non |
| 52 | ela | talent sr | 1 | superf, | oui |
| 60 | ela | chorus | 1,5 | moyen | non |
| 64 | ela | chorus rm | 1 | moyen | oui |
| 70 | ela | talent 213 | 0 | profond | non |
| 19 | intermedics | marathon | 0 | profond | non |
| 28 | intermedics | marathon dr | 1,5 | moyen | non |
| 41 | intermedics | marathon dr | 0 | moyen | non |
| 15 | medico | kerfos | 1 | moyen | non |
| 61 | medico | physios adv | 1,5 | superf, | oui |
| 8 | medtronic | thera dr | 1 | profond | oui |
| 11 | medtronic | 5024 | 0 | moyen | non |
| 16 | medtronic | ssr 303 | 0 | profond | non |
| 22 | medtronic | thera dr | 1,5 | moyen | non |
| 27 | medtronic | elite 7075 | 1 | moyen | non |
| 30 | medtronic | sigma s103 | 2 | superf, | non |
| 31 | medtronic | thera | 1 | profond | non |
| 32 | medtronic | thera | 1 | moyen | non |
| 43 | medtronic | elite 7075 | 0 | moyen | non |
| 45 | medtronic | thera dr | 1 | moyen | non |
| 50 | medtronic | thera | 2 | moyen | non |
| 59 | medtronic | prodigy? | 2 | superf, | non |

| | | | | | |
|----|--------------|-------------|-----|---------|-----|
| 67 | medtronic | kappa kdr | 2 | moyen | oui |
| 5 | sorin | living 1 | 0 | profond | non |
| 7 | st jude | 2040s | 1,5 | moyen | non |
| 9 | st jude | 2425 T | 2 | superf, | non |
| 13 | st jude | 1450 T | 1,5 | moyen | non |
| 42 | st jude | sensolog | 0 | profond | non |
| 53 | st jude | entity | 2 | superf, | oui |
| 62 | st jude | trilogy dr+ | 0 | moyen | non |
| 73 | st jude | sensorithm | 1 | moyen | non |
| 74 | st jude | afinity | 2 | superf, | oui |
| 75 | st jude | trilogy | 2,5 | superf, | oui |
| 4 | st jude | afinity | 1,5 | moyen | non |
| 20 | st jude | trilogy | 1,5 | profond | non |
| 24 | st jude | paragon | 2 | superf, | non |
| 34 | st jude | paragon | 2 | superf, | non |
| 35 | st jude | regency | 1,5 | moyen | non |
| 36 | st jude | synchrony | 2 | superf, | non |
| 51 | st jude | entity | 1,5 | moyen | non |
| 54 | st jude | regency | 1,5 | moyen | non |
| 66 | st jude | afinity | 1,5 | moyen | oui |
| 69 | st jude | afinity | 1,5 | moyen | non |
| 10 | telectronics | meta 3 | 1,5 | superf, | non |
| 12 | telectronics | 8224 | 1,5 | profond | non |
| 21 | telectronics | reflex ddd | 0 | profond | non |
| 40 | telectronics | 1206 | 1,5 | moyen | non |
| 56 | telectronics | meta ddr | 2 | moyen | oui |
| 71 | telectronics | Aurora | 0 | profond | non |
| 38 | vitatron | vita 2 | 1,5 | superf, | non |
| 44 | vitatron | vita 2 | 1 | moyen | non |
| 55 | vitatron | Clarity | 1,5 | superf, | oui |
| 65 | vitatron | Diamond | 1,5 | moyen | oui |

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Clothes containing magnetic zips/buttons influence the functioning of pacemakers

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03-07 September 2005
Stockholm-Sweden**



ESC Stockholm 07/09/05

Clothes containing magnetic zips/buttons influence the functioning of pacemakers

Background

- ✓ **Pacemaker have a magnetic switch used for temporary testing of the device**
- ✓ **It puts the pacemaker in an asynchronous mode**
- ✓ **This reed switch is sensitive to magnetic fields above 10 gauss (1millitesla)**



Clothes containing magnetic zips/buttons influence the functioning of pacemakers

Background

- ✓ **The risks of magnetic activation, done thousand hundred of times every day worldwide in pacemaker clinics, is some mild discomfort to the patient.**
- ✓ **However a risk of induction of ventricular arrhythmias has been observed in few patients with acute coronary ischemia or advanced stage of heart failure, due to a low threshold of ventricular vulnerability**



Clothes containing magnetic zips/buttons influence the functioning of pacemakers

Background

- ✓ **Outside the pacemaker clinic, inadvertent magnetic activation can mostly be encountered in industrial environment (high power stations), or Nuclear Magnetic Resonance unit**
- ✓ **However in daily life mobile phone and magnetic buttons on clothes may reach such level of magnetic field if close to the device**



Clothes containing magnetic zips/buttons influence the functioning of pacemakers

Background

- ✓ **The purpose of this study is to investigate in people implanted with a pacemaker in pectoral position the effect of wearing clothes with magnetic zips/buttons, or approached by persons wearing such clothes, as small children**



Clothes containing magnetic zips/buttons influence the functioning of pacemakers

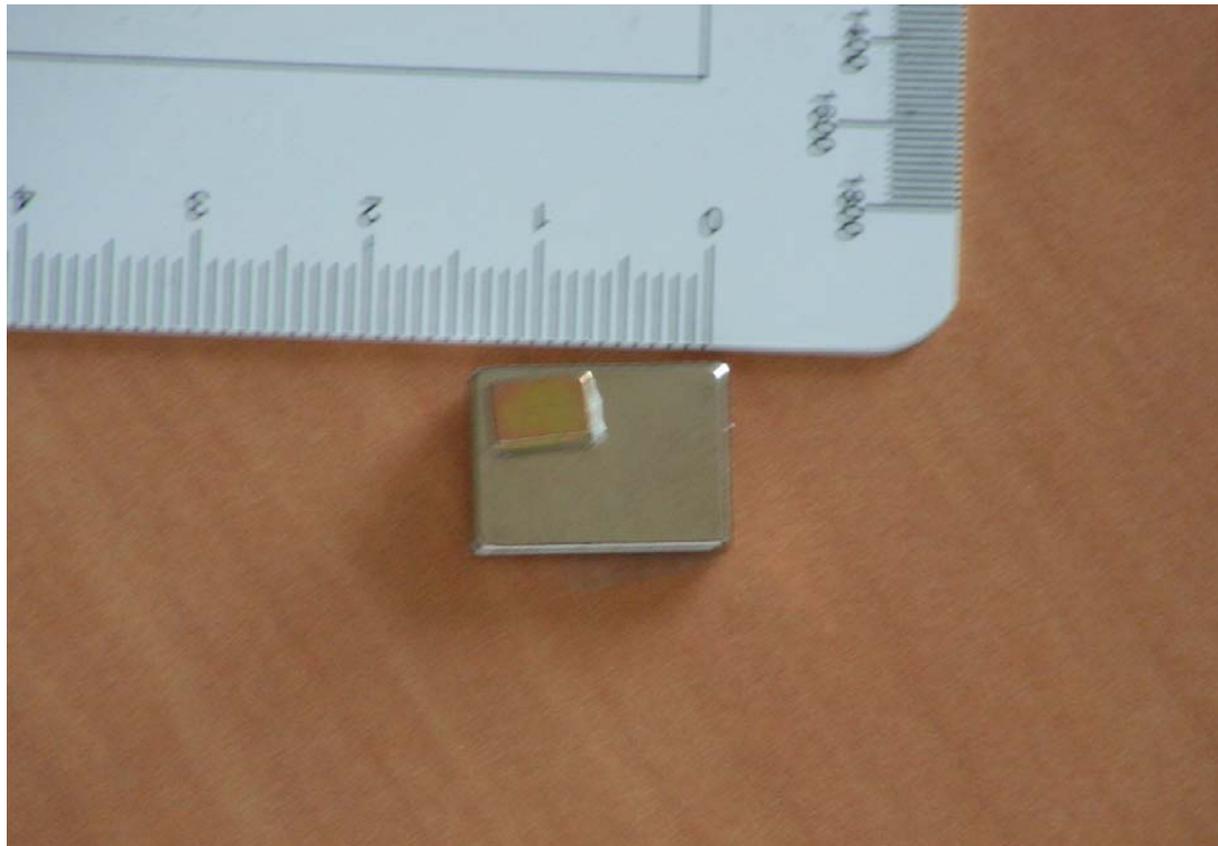
Aims

- ✓ **Evaluate the largest distance where a magnetic button can activate the reed switch**
- ✓ **test the effect of holding a child wearing such a cloth**



Material & Method

- ✓ **Rectangular, ceramic magnet, sizes 15 mm x 10 mm x 2 mm were used. Their power is 1900 Gauss measured at 0 mm, 320 Gauss at 10 mm, 5 Gauss at 50 mm.**



Material & Method

- ✓ Magnets were put at the bottom of boxes with the following depths: 10 mm, 15 mm & 20 mm.



- ✓ Each box was placed on the skin in front of the pacemaker

Material & Method

- ✓ **Teddy bear of a child size wearing a dress with magnetic braces**



- ✓ **Patients carried the teddy bear, holding it in front of the pacemaker, and on the opposite side**

Material & Method

- ✓ **Continuous ECG** recording by telemetry and paper recording have performed
- ✓ **Inclusion criteria**
 - Adult subjects below 85 with pacemaker
 - Without HF or active CAD
 - Who signed agreement for study
- ✓ **Exclusion criteria**
 - Adult subject above 85
 - Precarious cardiovascular state
- ✓ **End point:** to induce
 - pacing in asynchronous magnetic mode

Results

- ✓ Over a three-months period.
- ✓ 77 subjects were included.
- ✓ 10 brands of PM were represented
- ✓ 3 groups of patients according to the depth of implantation

The depth of pacemaker's implantation

- ✓ Deep (non perceptible): 15 cases.
- ✓ Medium: 40 cases.
- ✓ Superficial (visible contours under the skin): 22 cases.



Clothes containing magnetic zips/buttons influence the functioning of pacemakers

Results

| manufacturer | Nber |
|---------------------------|-------------|
| St Jude Pacesetter | 19 |
| Medtronic | 13 |
| Ela medical | 12 |
| Guidant-CPI | 9 |
| Biotronik | 8 |
| Telectronics | 6 |
| Vitatron | 4 |
| Intermedics | 3 |
| Medico | 2 |
| Sorin | 1 |



Clothes containing magnetic zips/buttons influence the functioning of pacemakers

Results

Sensitivity of PM with the magnet distance

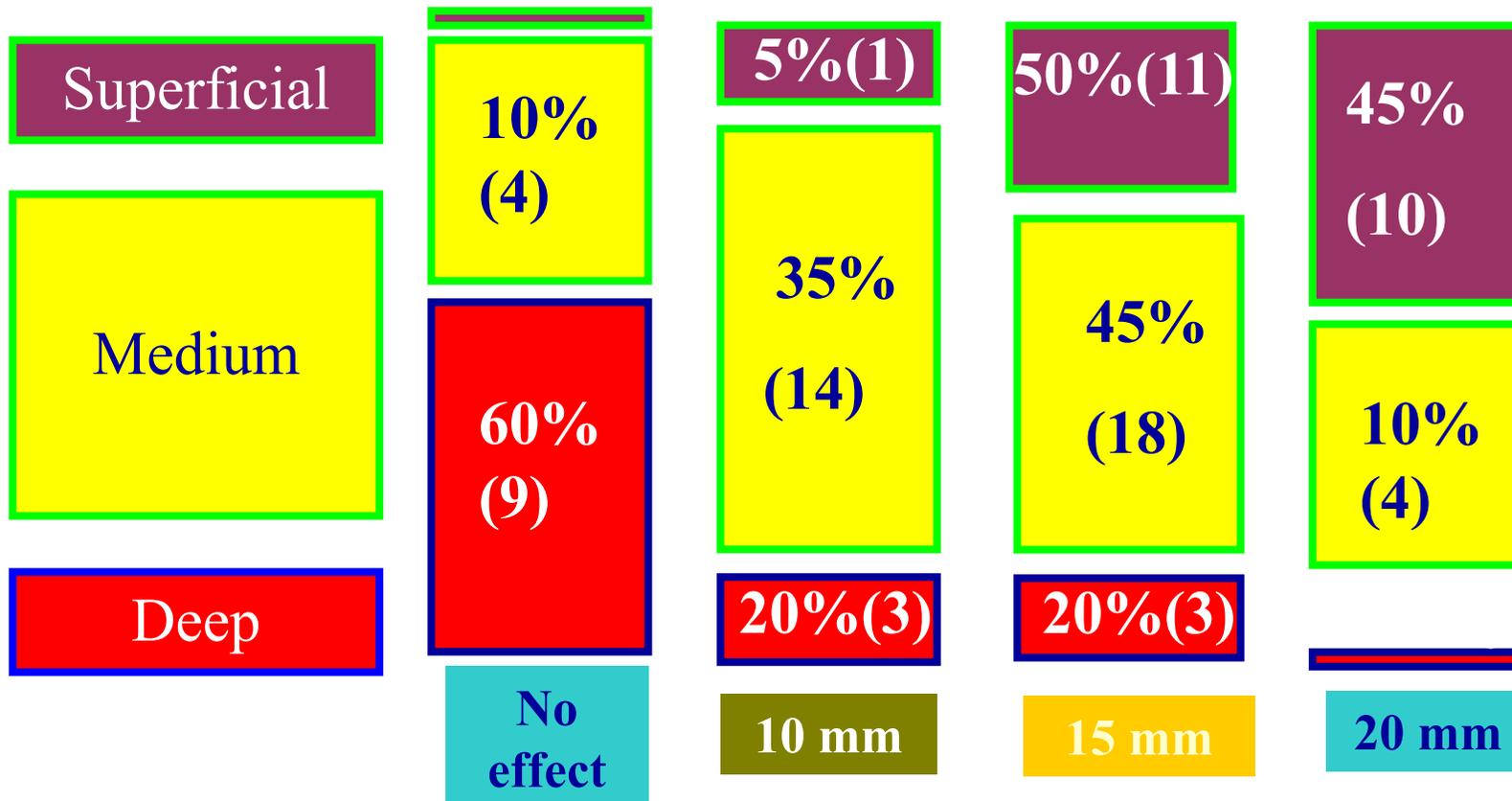
- ✓ > 20 mm from the skin: no response.**
- ✓ 20 mm: 14 PM were activated**
- ✓ 15 mm: 35 PM were activated**
- ✓ 10 mm: 65 PM were activated**



Clothes containing magnetic zips/buttons influence the functioning of pacemakers

Results

Sensibility of PM to isolated magnet



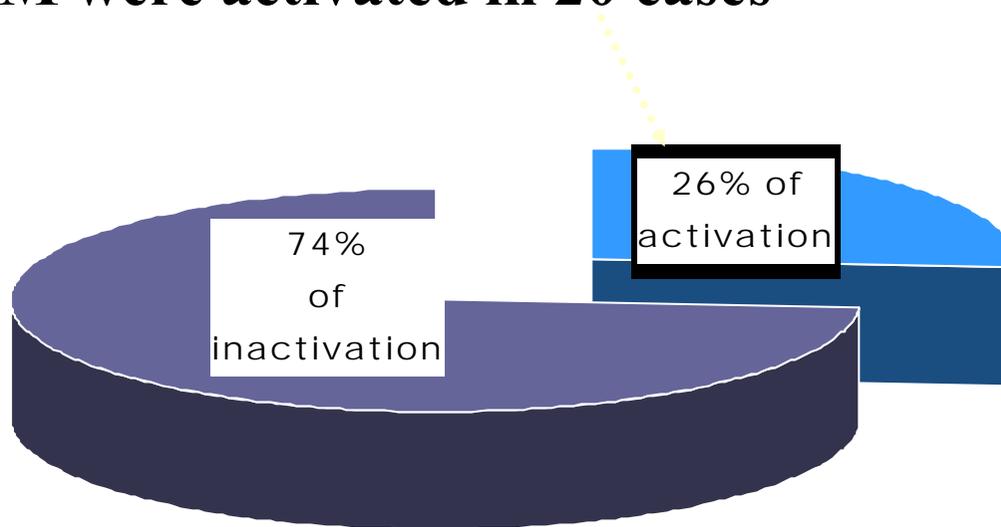
Clothes containing magnetic zips/buttons influence the functioning of pacemakers

Results

Sensitivity of PM

to magnetic zips/button on the cloth

PM were activated in 20 cases



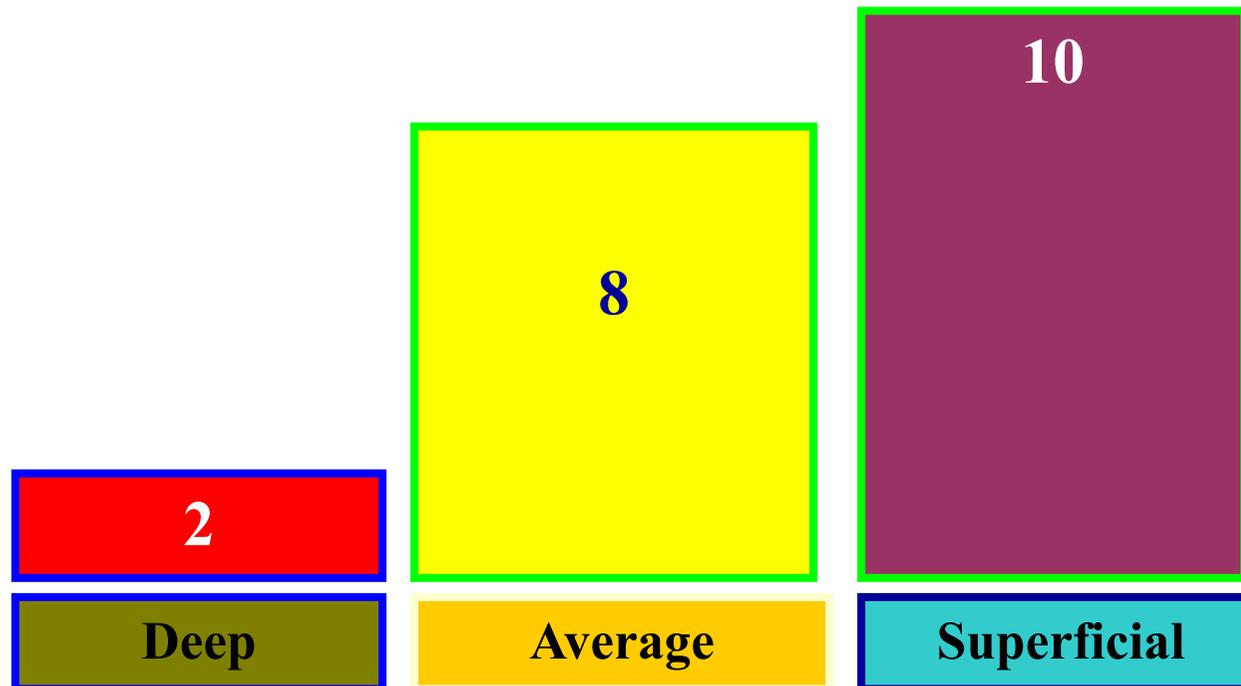
Chi2 Sig : p <0.01



Results

Sensibility of PM to magnetic zips/buttons

PM were activated in 20 cases ...



Results

Sensibility of PM to magnetic zips/buttons

✓ **Out of 22 superficially placed PM :**

□ **45% were sensitive to the teddy bear wearing magnetic zips.**



Clothes containing magnetic zips/buttons influence the functioning of pacemakers

Conclusion

- ✓ Magnetic buttons of the size used for the study are safe if weared at more than 2 cm from the pacemaker
- ✓ Would they be nearer, the only effect could be a discomfort due to the asynchronous mode in stable cardiovascular patients , which has not be observed in the experimental conditions of our population
- ✓ new buttons with an shorter range of magnetic field are now available, therefore limiting more the risks of interference

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Thank you!

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Clothes containing magnetic zips/buttons influence the functioning of pacemakers

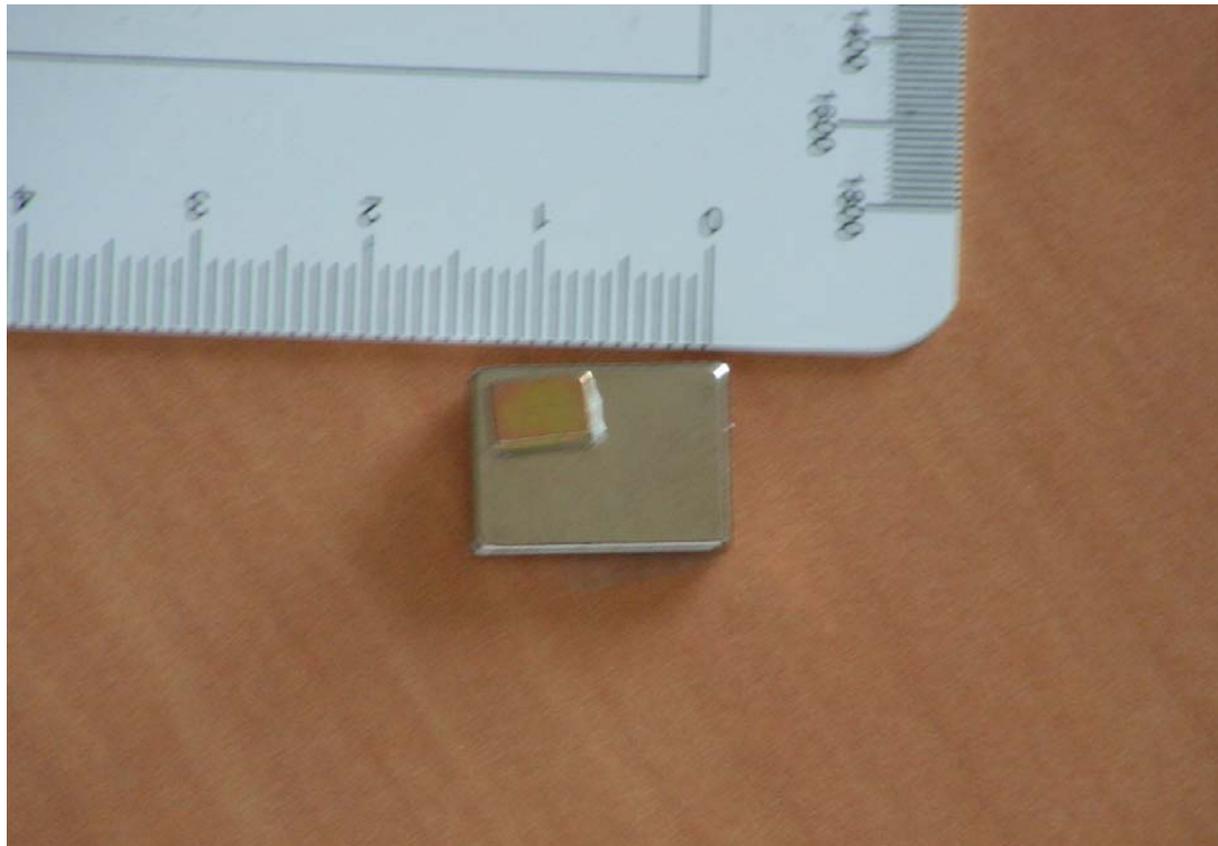
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- ✓ **Evaluate the largest distance where a magnetic button can activate the reed switch**
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- ✓ **Rectangular, ceramic magnet, sizes 15 mm x 10 mm x 2 mm were used. Their power is 1900 Gauss measured at 0 mm, 320 Gauss at 10 mm, 5 Gauss at 50 mm.**



Material & Method

- ✓ Magnets were put at the bottom of boxes with the following depths: 10 mm, 15 mm & 20 mm.



- ✓ Each box was placed on the skin in front of the pacemaker

Material & Method

- ✓ **Teddy bear of a child size wearing a dress with magnetic braces**



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- ✓ **Continuous ECG** recording by telemetry and paper recording have performed
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- ✓ **End point:** to induce
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Results

- ✓ Over a three-months period.
- ✓ 77 subjects were included.
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- ✓ 3 groups of patients according to the depth of implantation

The depth of pacemaker's implantation

- ✓ Deep (non perceptible): 15 cases.
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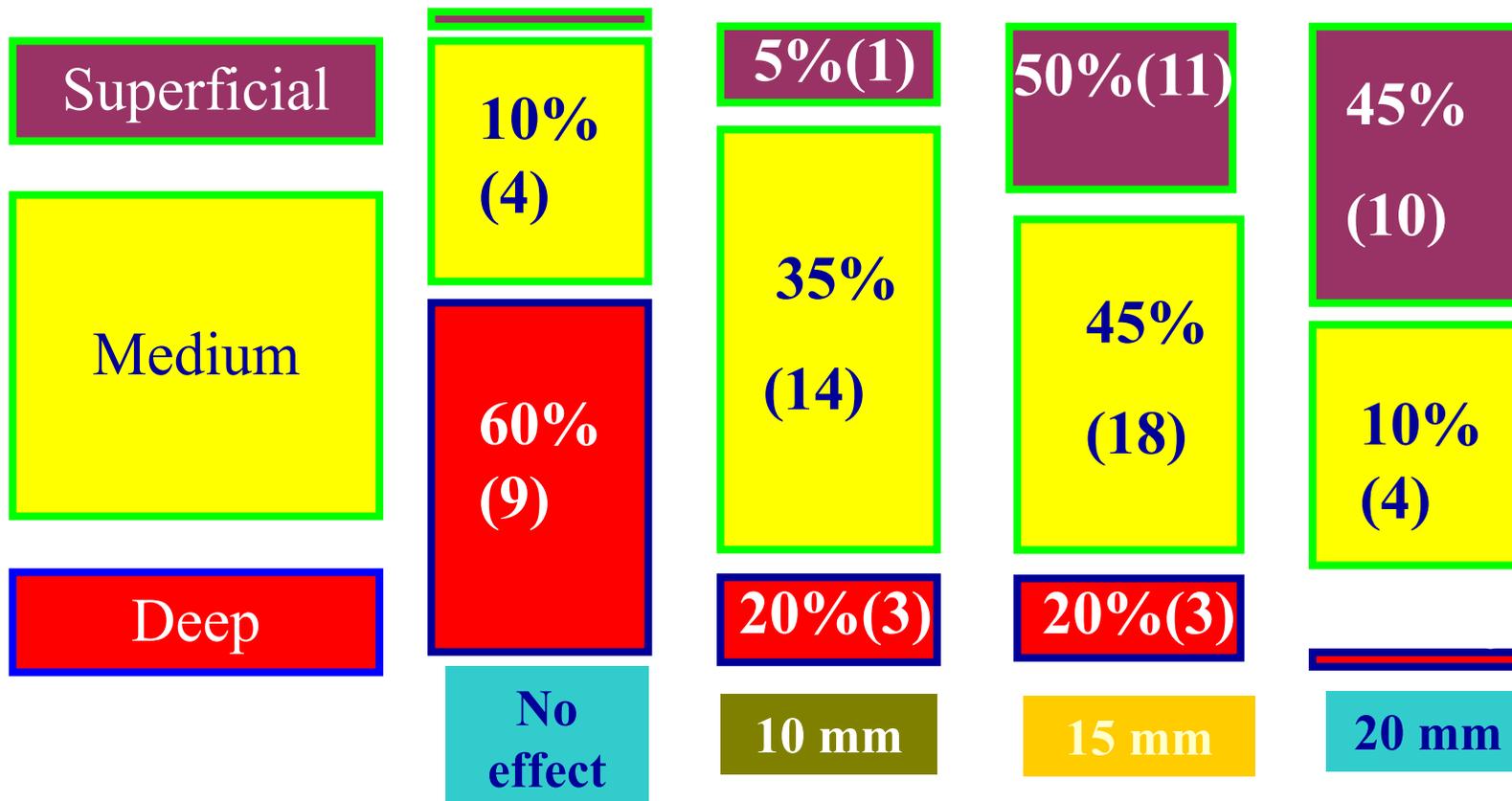
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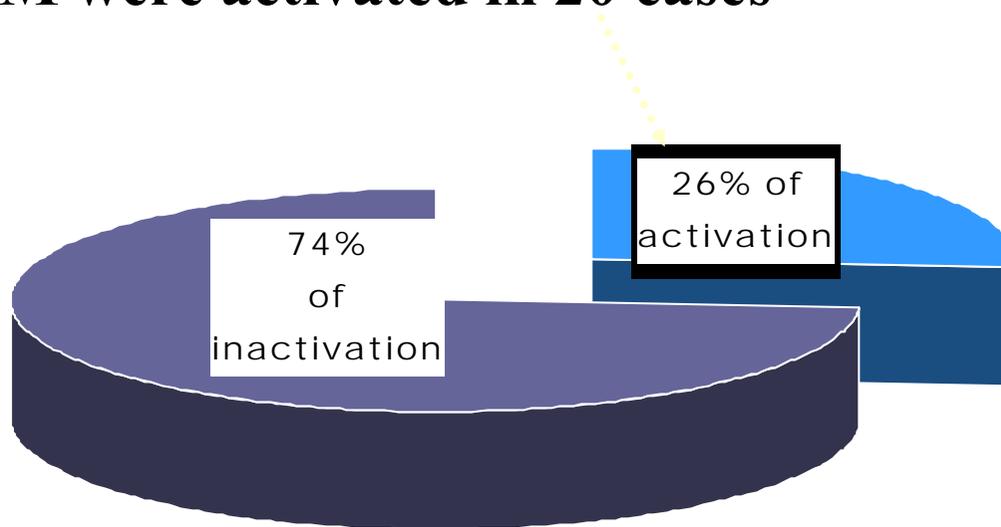
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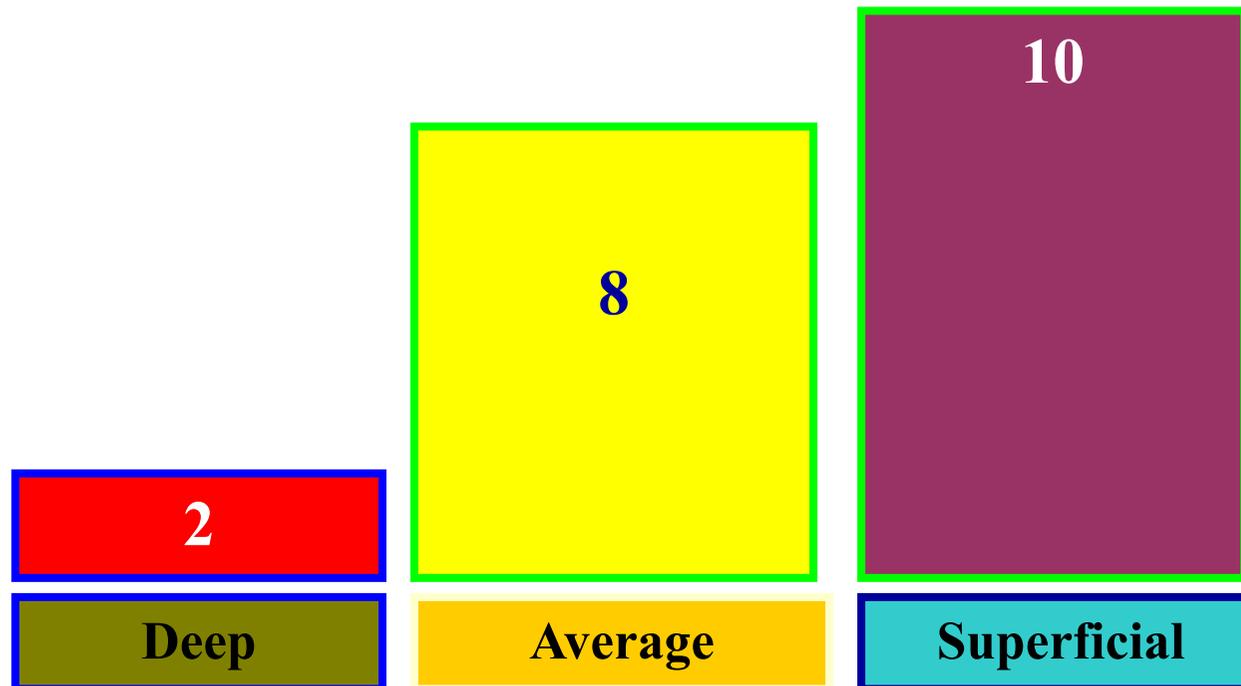
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□ **45% were sensitive to the teddy bear wearing magnetic zips.**



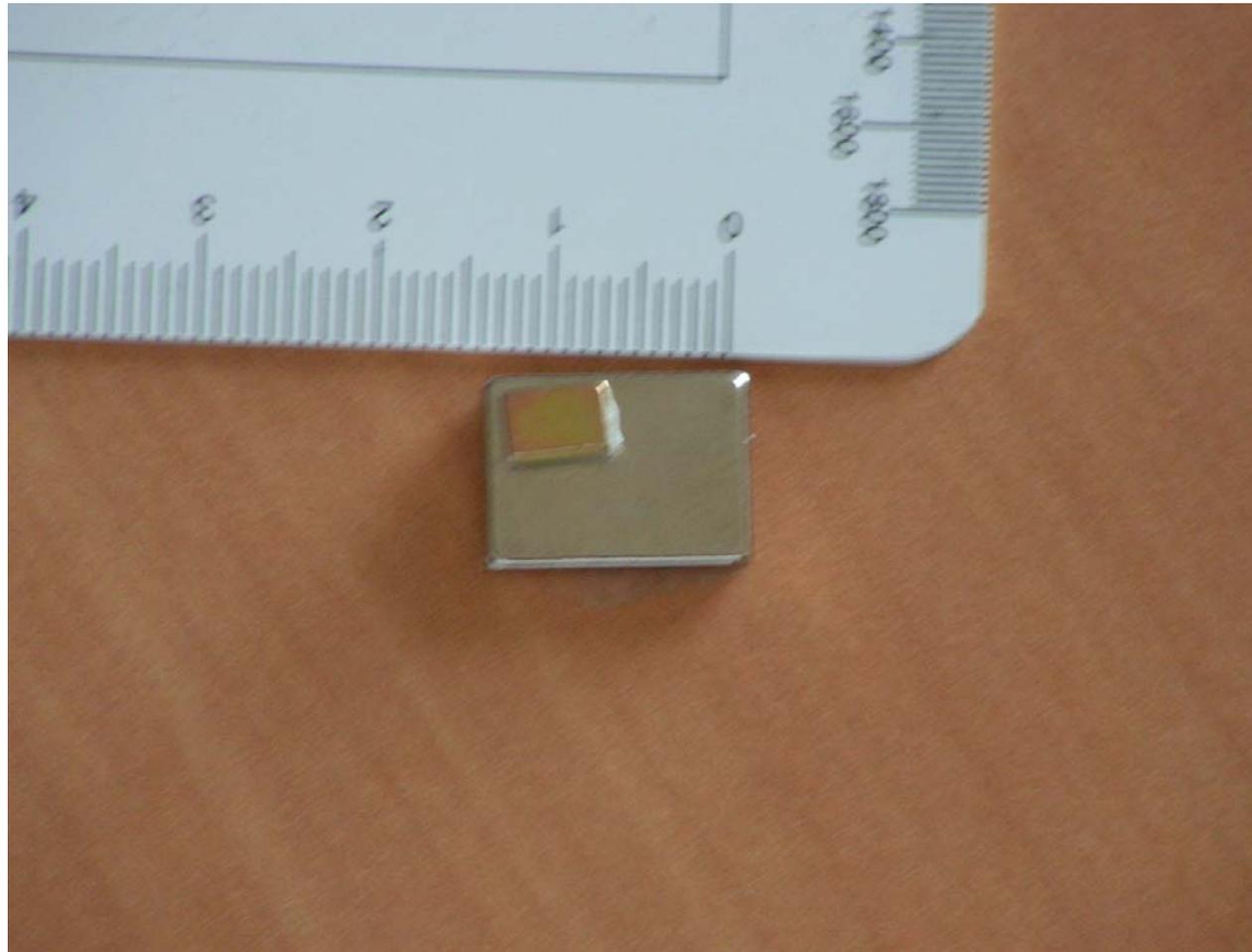
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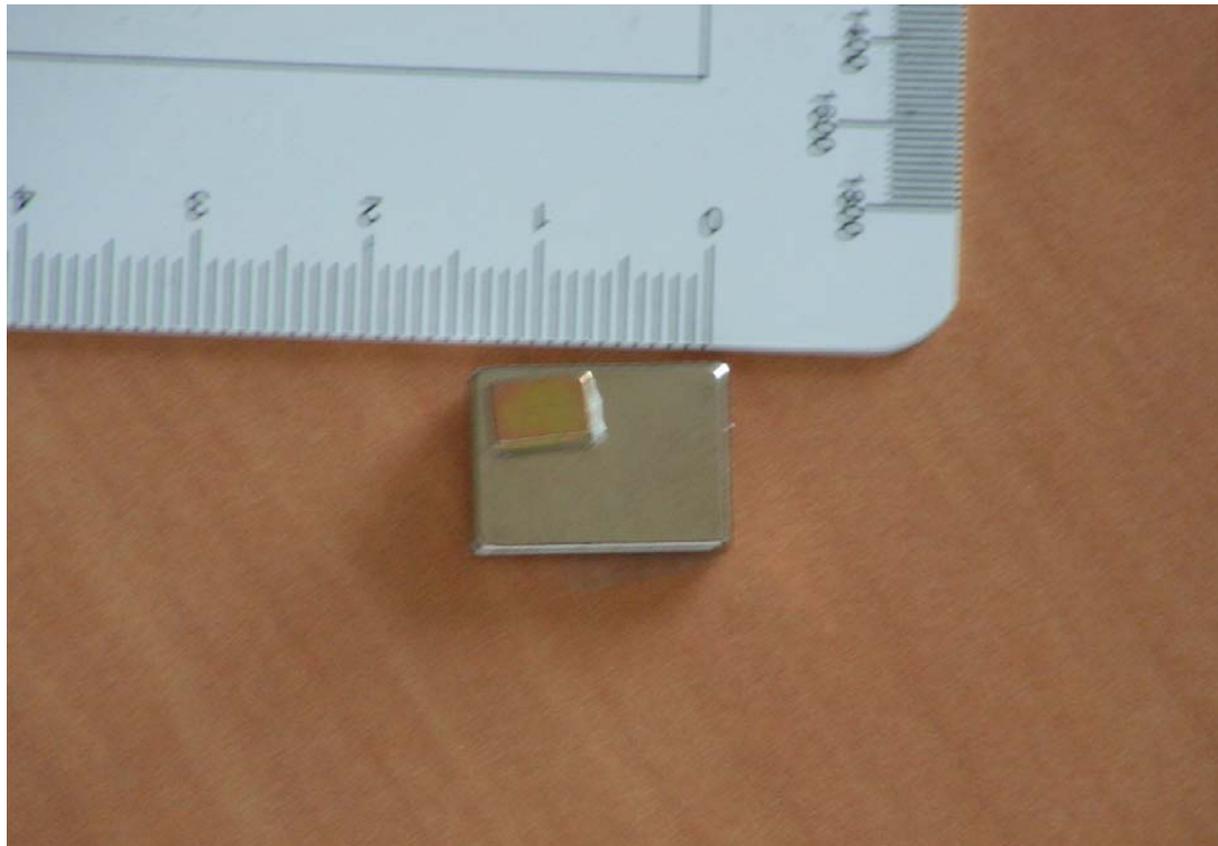
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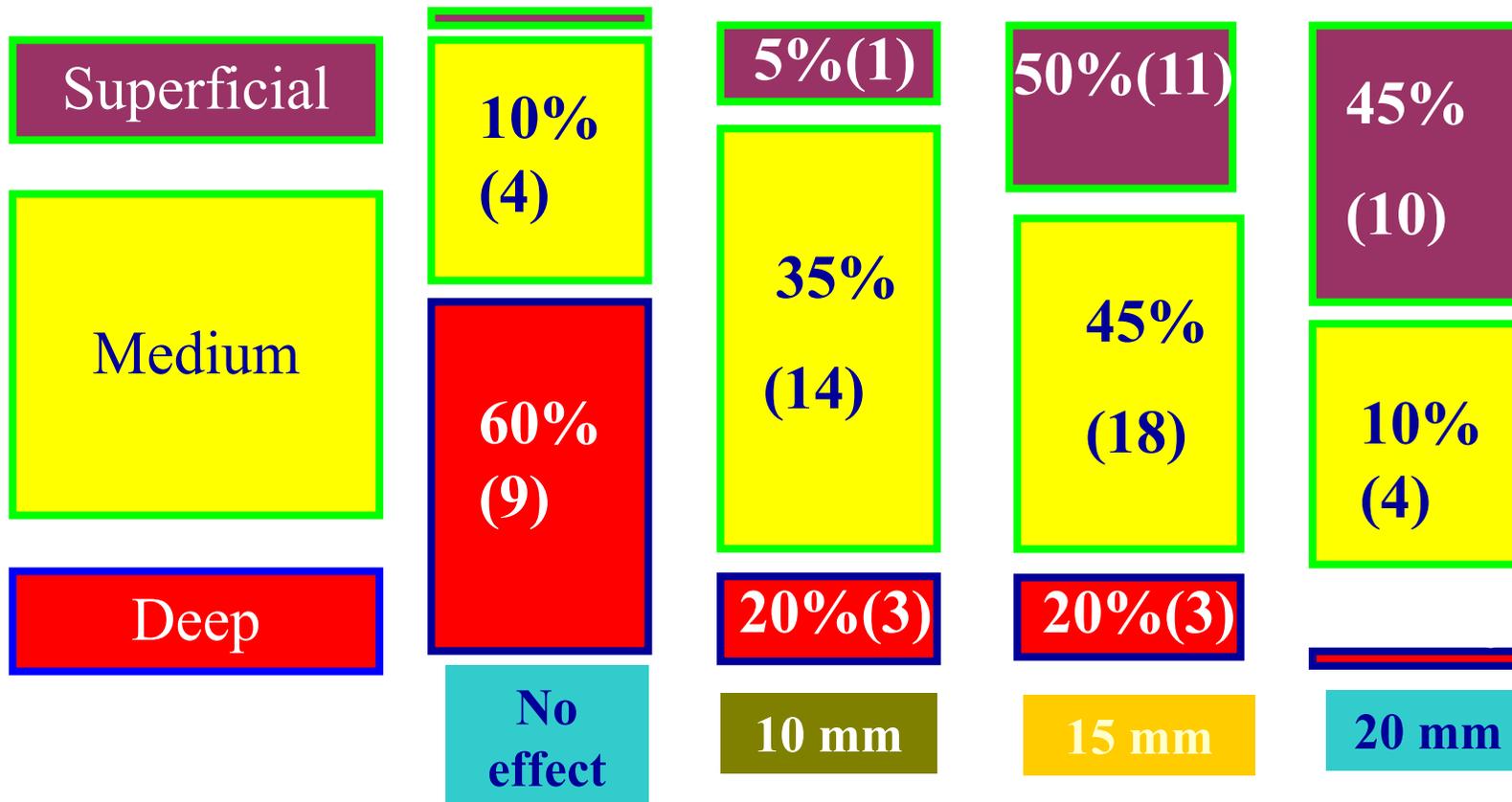
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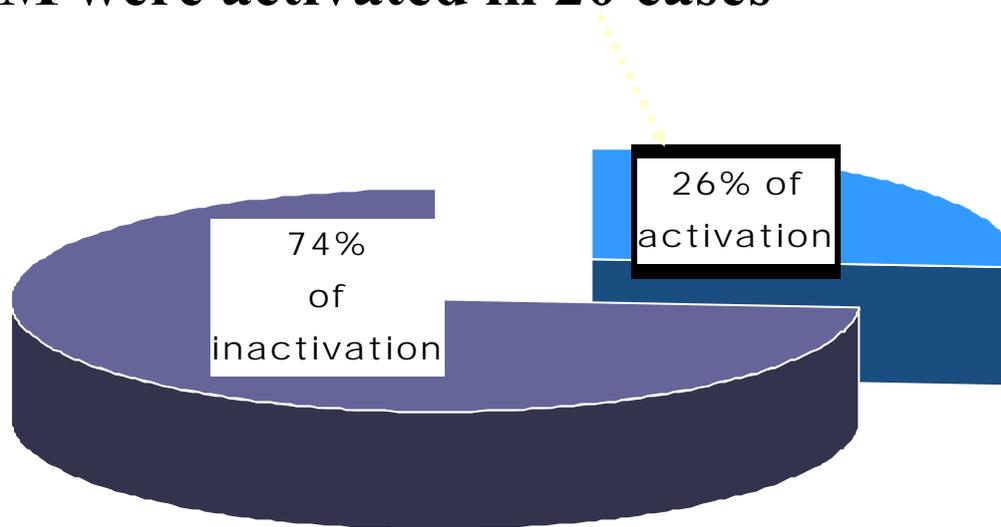
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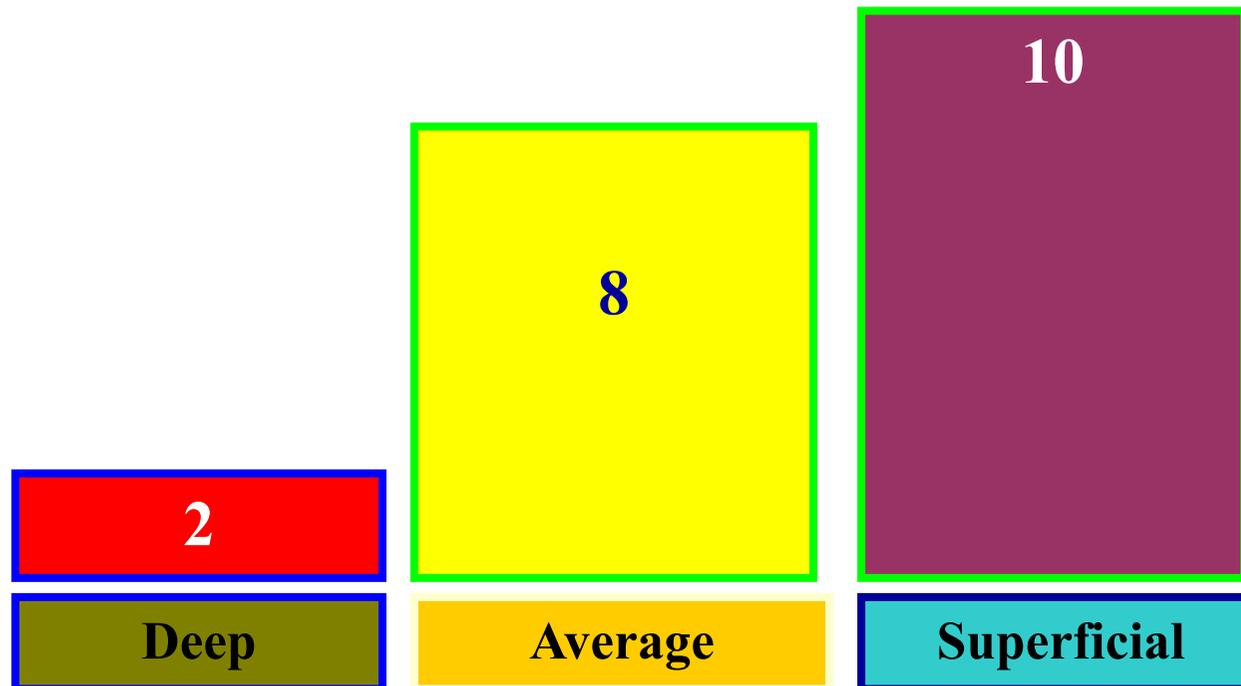
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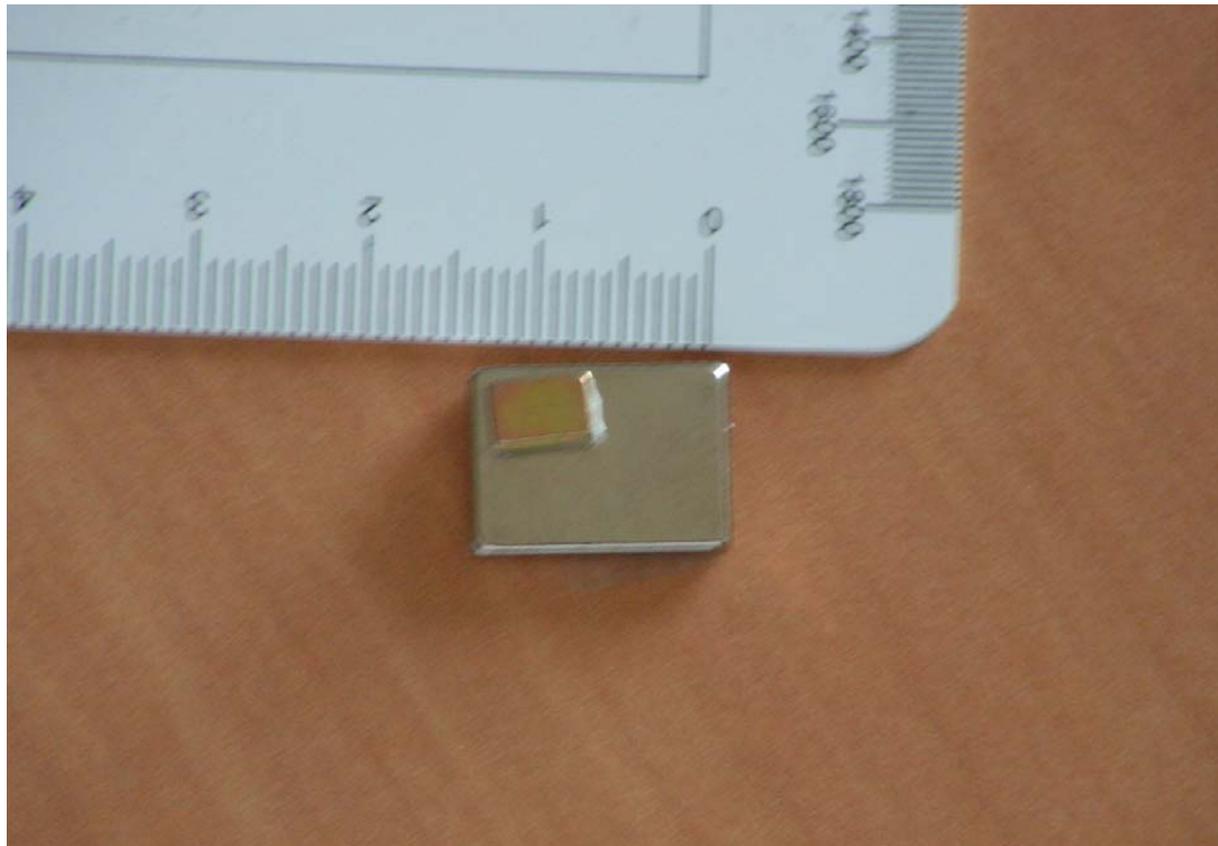
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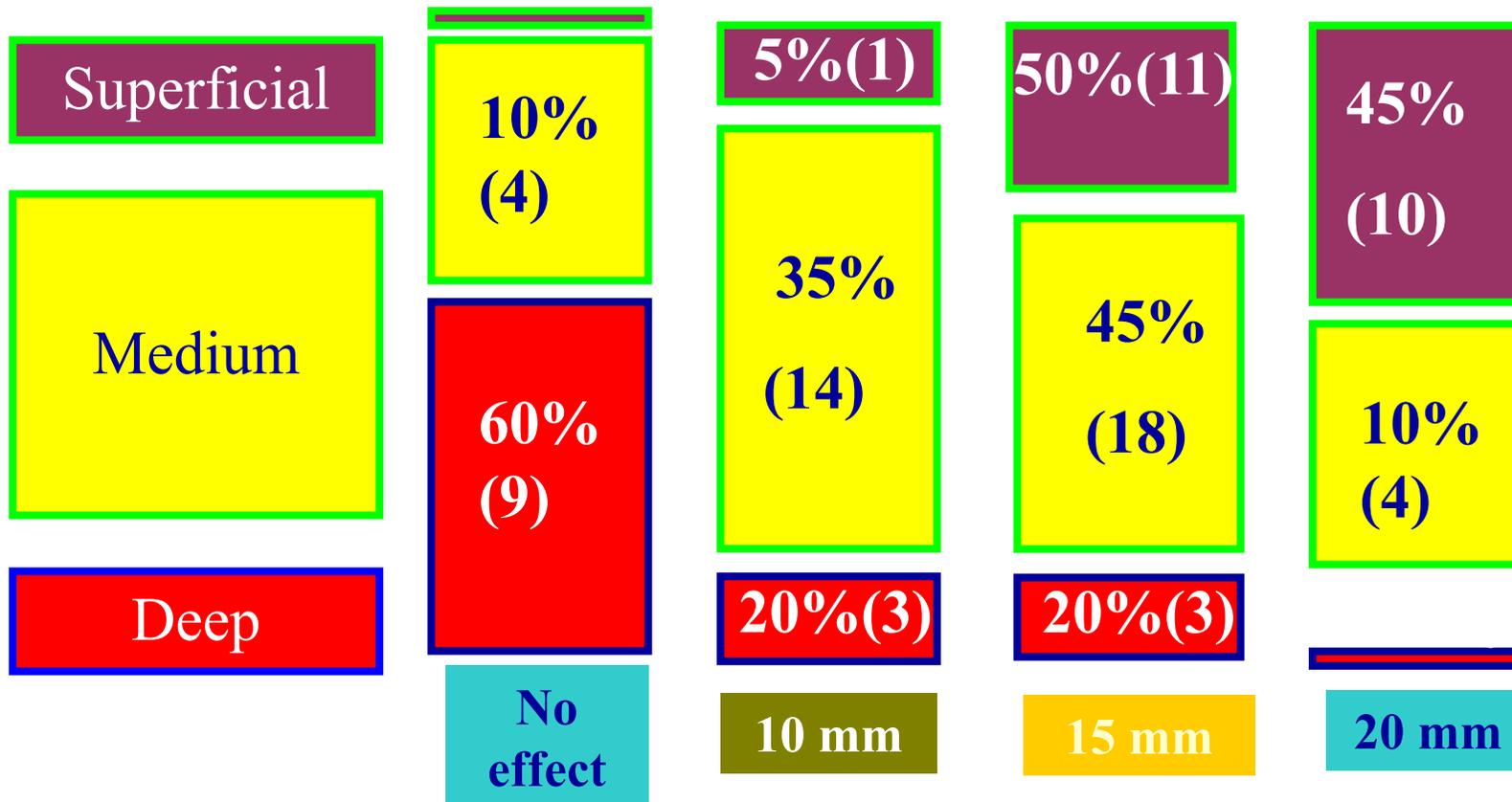
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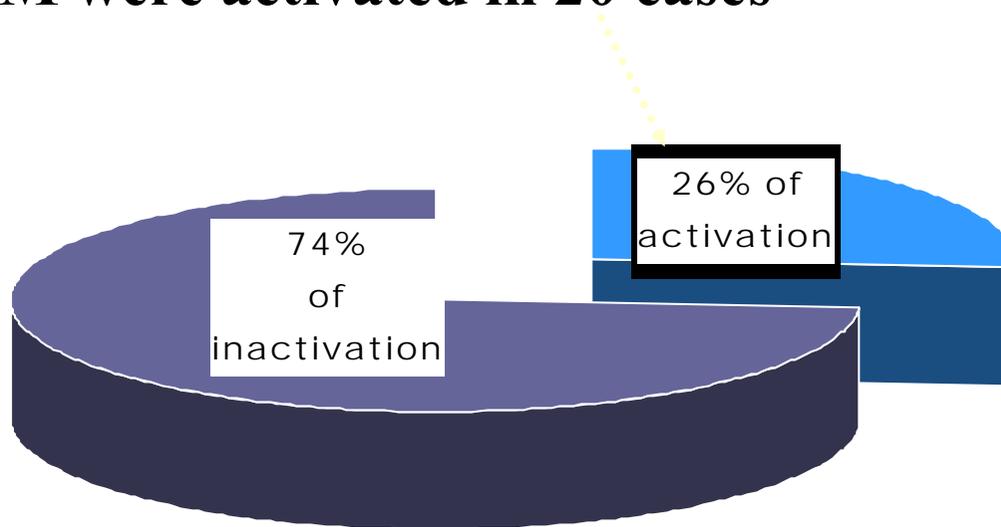
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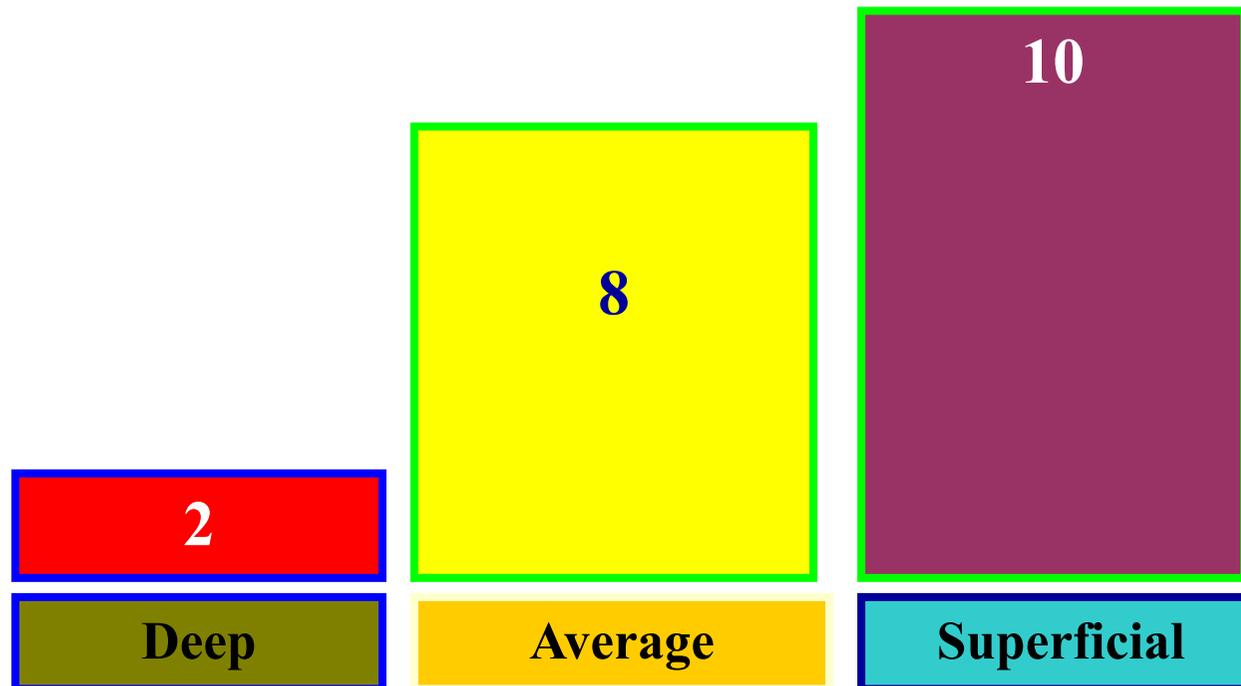
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Thank you!

Letter of Doctor Robert FRANK to Eric SITBON dated 2003-10-08

(Free translation into English)

Dear Sir,

I have received your letter safely giving the data of the magnets that can be used in clothing articles.

These magnets do not give rise to particular risks for pacemaker users. Indeed, the cardiac stimulative is responsive to magnetic fields superior to $100\mu\text{T}$ (1 Gauss), that is to say 1 Gauss. The effect of this magnetic field is to activate a switch located in the circuit of the stimulative which induces it to send impulses with a constant frequency for driving the heart. This type of operating has no inconvenience whatsoever and it is repeated hundreds of thousands times in grafting centres of stimulatives at every control of the stimulative. The stimulatives are implanted in the upper part of the thorax, at the level of the left or of the right shoulder. The tests we carried out have not shown an activation of the magnetic switch when we are placed at more than 2cm from the case for some models, and from 1cm for the most of models, depending on the localization more or less depth of the apparatus. This corresponds with the characteristics of the magnetic field of the concerned magnets.

Therefore, there is no risk at all for a patient using a pacemaker to dress a cloth containing this type of magnet, provided it is placed more than 2cm from the case, which happens with shoes and bras.

(...conventional ending of the letter...)



**GROUPE HOSPITALIER
PITIÉ-SALPÊTRIÈRE**

47-83, boulevard de l'Hôpital
75651 PARIS Cedex 13
Standard : 01 42 16 00 00
: 01 42 17 60 60

de l'étranger, composer le :
33 1 et les 8 derniers chiffres

Monsieur Eric SITBON
9, Rue du Croissant
75002 PARIS

Paris, le 8 Octobre 2003

Réf : RF/JS

INSTITUT DE CARDIOLOGIE

DEPARTEMENT
DE
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Unité de Rythmologie

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Dr J.-C. PETITOT
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Dr T. ZERAH

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01 42 16 30 63
Consultation :
01 42 16 28 91 / 92 / 93
Secrétariat :
01 42 16 30 52 / 54 / 81
Télécopie :
01 42 16 30 56 / 57

Cher Monsieur,

J'ai bien reçu votre lettre donnant les caractéristiques des aimants qu'on peut utiliser à usage vestimentaire.

Ces aimants n'entraînent pas de risque particulier pour les porteurs de pacemaker. En effet, le stimulateur cardiaque est sensible à des champs magnétiques supérieurs à 100µTesla, soit 1 Gauss. L'effet de ce champ magnétique, est d'activer un interrupteur placé dans le circuit du stimulateur qui l'amène à envoyer à fréquence constante des impulsions pour entraîner le cœur. Ce type de fonctionnement n'a aucun inconvénient et répété des centaines de milliers de fois dans un centre d'implantation de stimulateurs cardiaques à chaque contrôle du stimulateur. Les stimulateurs sont implantés à la partie haute du thorax, au niveau de l'épaule gauche ou de l'épaule droite. Les tests que nous avons pratiqués n'ont pas montré d'activation de l'interrupteur magnétique lorsqu'on est à plus de 2cm du boîtier sur quelques modèles, et chez la plupart de 1cm, selon la localisation plus ou moins profonde de l'appareil. Cela correspond aux caractéristiques du champ magnétique de ces aimants.

Il n'y a donc aucun risque à ce qu'un patient porteur d'un pacemaker puisse porter un vêtement contenant ce type d'aimant, du moment que celui-ci est placé à plus de 2cm du boîtier, ce qui est le cas des chaussures et des soutiens gorges.

Je vous prie de croire, Cher Monsieur, à l'expression de mes sentiments les meilleurs.

Docteur Robert FRANK
Médecin des Hôpitaux