THE ASSESSMENT AND PERFORMANCE OF IMPLANTED CARDIAC PACEMAKERS

by

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Royal Infirmary
Stobhill General Hospital
Southern General Hospital
Western Infirmary
Knightswood Hospital
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Declaration

Although, as explained above, pacemaker work is essentially of a collaborative nature, the results of assessment procedures, the arguments developed from those procedures; and the concepts and data on performance, are all exclusively the work of the author of this thesis.

The pacemaker frontal plane vector technique was outlined, by invitation, in an editorial in the American Heart Journal[67] and in somewhat more detail[113] after it had been presented at the 9th International Conference on Medical and Biological Engineering in Melbourne, Australia in August 1971. It was subsequently summarised, by invitation, at the 4th International Symposium on Cardiac Pacing which was held in Groningen, The Netherlands in April, 1973.

Some of the performance concepts and earlier performance data have been presented in earlier papers[88, 8, 113].

1. General

The first implantation in a patient of a cardiac pacemaker having its own power source took place in 1959[1]. This pacemaker had to be recharged inductively, but by 1960[2, 3], pacemakers using mercury cells as the power source were being implanted. Since then tens of thousands of pacemakers have been implanted and there is now little doubt that the implantation of a cardiac pacemaker has become the preferred method of treatment for patients in chronic heart block who experience symptoms of the disease. The symptoms arise from ventricular standstill before a ventricular pacemaker has become established and subsequently from low cardiac output. The former sudden transient loss of consciousness from interruption of cerebral blood flow is referred to as a Stokes-Adams attack. This is sometimes accompanied with convulsions. The subsequent low ventricular rhythm causes tiredness, faintness, breathlessness with effort, and sometimes congestive cardiac failure. The implantation of a pacemaker is also recommended in patients with sinus bradycardia or sinus arrest, both of which can produce similar symptoms. In addition, since the first Stokes-Adams attack may be fatal, there are some clinicians in the U.S.A. and Europe who believe in prophylactic implantation of a pacemaker in certain circumstances[4].

The total number of pacemakers which has been implanted throughout the world is not known but some facts are available for certain countries. For instance, it was estimated in 1970[5], that there was a total of 46,000 patients alive in the United States and Canada who had an implanted pacemaker. The annual rate of implantations is not known but rates are known for some European countries. In Sweden, in 1969, initial implantations were taking place at the rate of 96 per year per million of the population; for Norway and Denmark the corresponding figure was 45, and for Finland, 21[6]. In the London area the incidence of initial implantations in 1969 was approximately 35 per year per million of the population[7].

The first pacemaker implantation in Glasgow took place on 11th June, 1962. Figure 1 shows the numbers of initial implantations which have taken place each year since then. The 1972 figure of 76 initial implantations represents about 26 initial implantations per

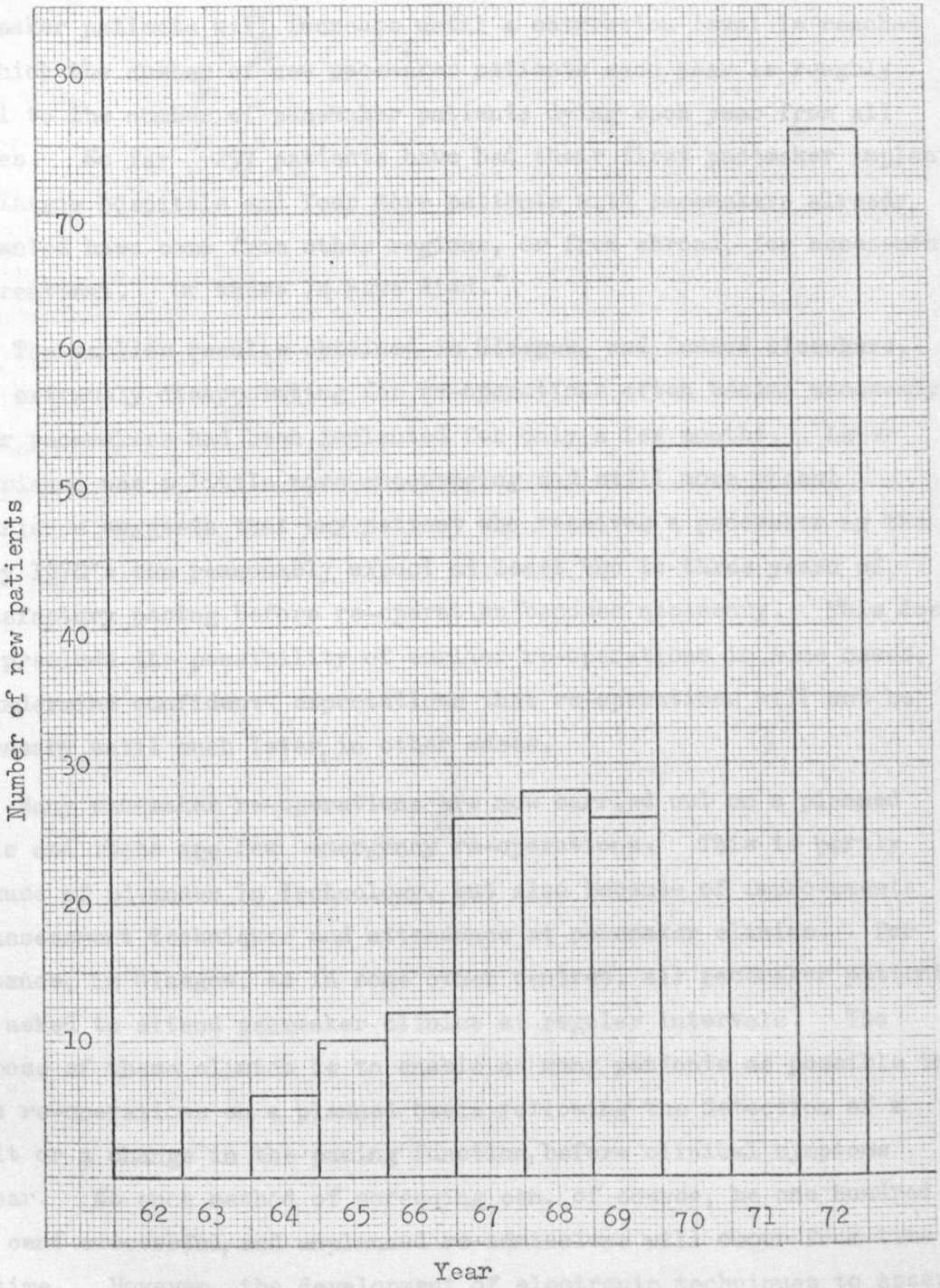

Figure 1. Annual increases in number of primary pacemaker implants in Glasgow.

year per million of the population in the Western Region of Scotland.* This is well below the 1969 figures quoted above for Sweden, Norway and Denmark. In addition to the six initial implantations taking place each month on average during 1972, there were about three re-operations each month on existing pacemaker patients. As the rate of initial implantations increases each year, the total number of living pacemaker patients will increase until a saturation level is reached at which the number of new pacemaker patients each year is roughly equal to the number of pacemaker patients dying each year from all causes. So far 297 patients have had their first pacemaker implanted in Glasgow hospitals and four more patients with pacemakers already implanted have come from other regions, or from abroad, for assessment or treatment. Of these 74 have died.+

The earlier results obtained in Glasgow, and indeed elsewhere, were extremely disappointing for re-operations often became necessary after pacemakers had been implanted for only a few months. Later experience was a little more encouraging and still more recent experience suggests that any patient who receives a pacemaker in the early 1970's can reasonably expect at least two to three years of satisfactory pacing before re-operation becomes necessary. This does not preclude the possibility of earlier re-operations in some cases, or undermine confident expectations that re-operations will not be necessary until much later, in other cases.

Many pacemaker re-operations are now carried out on a planned basis and there are few emergency re-operations. This is partly because of advances in technology, but also because of improvements in assessment techniques and attendance at pacemaker clinics. For instance, in Glasgow, as in some other centres, all pacemaker patients are asked to attend pacemaker clinics at regular intervals. The purpose of these clinics is to enable as many patients as possible to have re-operations on a planned basis following the detection of a fault or a change in the pacing function, before clinical symptoms appear. No such method of screening can, of course, be one hundred per cent successful, and unplanned re-admissions will occur from time to time. However, the development of electronic techniques to assess the implanted pacemaker and a careful study of the associated pacing function over many years has resulted in fewer unplanned admissions to hospitals. The same techniques and experience have also reduced the

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* Population of the Region, 2,955,566 (Annual Report of the Western Regional Hospital Board, 1971)

\+ 31st December, 1972

number of emergency re-operations which have been necessary from amongst any unplanned admissions.

The assessment techniques are discussed in detail in Part II. If they are systematically followed and understood, rapid assessment of a pacemaker and its pacing function ought to be possible whatever type or make of pacemaker has been implanted.

A difficult problem which faces any physician or surgeon contemplating using a pacemaker is that of deciding which type and make of pacemaker to use. The former is a somewhat easier decision in that there are few types from which to choose but there is a number of manufacturers of each type from which to choose. In this connection, performance following implantation ought to be the most important single factor which should decide the make of pacemaker which is to be used. Unfortunately manufacturers' reliability data is sparse and there is little meaningful data published in the professional journals, so that comparisons on performance are extremely difficult to make. Glasgow's data on performance, however, is presented in Part III in an explicit manner, which if adopted by other users, would enable performance comparisons to be made between different makes and types of pacemakers.

2. Terminology

In any serious study on implanted cardiac pacemakers it is important to be extremely careful about the terminology which is used. After many years of implantable cardiac pacemaking, many authors use terms which they have not clearly defined and some authors apparently use the same terms in different ways. In many cases such omissions and errors are inexcusable, though it must be borne in mind that some changes are inevitable from time to time as a new field is developed. In addition, completely new terms may have to be introduced to explain new phenomena or to clarify existing knowledge and concepts.

Appendix I gives, for convenience, an explanation of some of the terms used in this thesis. The terms marked with an asterisk have been introduced by the author[8, 9] in an attempt to clarify existing terminology which was either incorrect, or inexplicit and misleading, or because there was a need to introduce new terms, as for instance, when discussing the performance of implanted cardiac pacemakers.

3. Types of Pacemakers

There are two distinct kinds of pacemakers: bipolar ones and unipolar ones. Each kind consists of two principal parts, the electrode-lead system and the generator.

In the case of a bipolar electrode-lead system both electrodes are either inside the heart (endocardial), in the wall of the heart (myocardial or intramural), or on the surface of the heart (epicardial). Unipolar electrode-lead systems have only one electrode in one of these positions, the second electrode is at or near the generator.

The endocardial electrode-lead system is often referred to as a "pacing catheter" or merely "catheter" when used in a pacing context.

The unipolar catheter has an apparent advantage in that the catheter is of smaller diameter than the bipolar one; but experience with over 300 bipolar catheters has shown that it has been necessary to seek a second vein for insertion of the catheter because the lumen has been too small, on only a small number of occasions. A more important advantage is that the pacemaker stimuli, obtained by placing electrodes on the surface of the body, are much greater in a unipolar case compared with a bipolar one. On the other hand, unipolar pacemakers are believed to be ten times more susceptible to interference from external electromagnetic radiation than bipolar ones[10] and they have the advantage of built-in redundancy in the event of failure of one of the conducting leads.

Generators may be classified as asynchronous, demand (that is, QRS blocking), or synchronous (that is, ventricular triggered or atrial triggered). All types produce essentially a "square-wave" pulse of electricity whose duration or width is usually less than one millisecond and whose pulse repetition rate is about 70 per minute. The maximum amplitude of the pulse is typically in the range four to seven volts (delivering five to 15 milliamps) but the actual shape of the pulse is determined by the output circuit of the generators.

The asynchronous generator is the simplest form of generator, in which electrical pulses are produced at a fixed repetition rate. With some earlier models it was possible to adjust the rate at operation using a Keith needle, or even after operation by introducing a Keith needle transcutaneously into a rate control socket. Amplitude

control was similarly possible on some earlier models but both controls have been omitted in more recent models in the interests of increased reliability.

The asynchronous generator may be implanted in those patients having a slow ventricular rhythm from constant atrioventricular block, provided there is no tendency for interference rhythms to occur. The implanted pacemaker then takes over complete control of ventricular contractions. It has the advantage of being relatively simple and cheap. Hitherto, its reliability could be associated with simple circuitry when discrete components were used, but this is probably less true today with the advent of integrated circuits.

One main disadvantage of the asynchronous generator is that it continues to produce stimulating pulses if the patient's heart returns to sinus rhythm. There is evidence that some patients formerly in constant atrioventricular block return to sinus rhythm after a period of artificial pacing. Certainly this has been the case with a number of pacemaker patients in Glasgow. Sowton[11] claims that about twenty-five per cent of paced patients return to sinus rhythm, at least intermittently and Thalen[12] claims that between twenty and forty per cent of patients in atrioventricular block return to atrioventricular conduction within two years of receiving their first asynchronous pacemaker. In these circumstances the natural pacemaker and the implanted pacemaker compete for the control of the ventricles and it is then possible for a pacemaker pulse to occur during the so called vulnerable part of the "T" wave. (The resulting arrhythmia may be a dual rhythm in which two pacemakers contribute to the action of the heart, i.e. parasystole). This competition, which may also occur when idioventricular foci arise and cause spontaneous contractions, can cause repetitive arrhythmias leading to ventricular fibrillation.

Wiggers and Wégria[13] are usually credited with having established in 1940 that there is such a vulnerable period susceptible to electrical stimuli which can result in repetitive arrhythmias and ventricular fibrillation. Dittmar[14] et al. in 1962, and Elmqvist[15] et al. in 1963, reported having seen the phenomenon occur in pacemaker patients, but Linenthal and Zoll[16] in 1962 reported that repetitive arrhythmias had <u>not</u> occurred in these circumstances. Competitive pacing has been observed in a number of patients in Glasgow, though as far as can be ascertained, with possibly one exception, it has not resulted in ventricular fibrillation. Nevertheless other workers[17,18,19,20,21,22]

have reported seeing repetitive arrhythmias leading to ventricular fibrillation. It is now thought that this is unlikely to happen with present designs of pacemakers in most circumstances but under certain conditions (hypoxia, electrolyte imbalance, cardiotoxic drugs, surgery) [23,24,25] the threshold for fibrillation is reduced so that the hazard becomes a real one.

One other apparent disadvantage of the asynchronous generator is that its rate is fixed and it cannot increase cardiac output as and when required. In practice, however, this has not proved to be a serious limitation, probably because many pacemaker patients are elderly, and even middle aged patients presumably do not require significant changes in cardiac output.

The concept of "demand" pacing first arose in 1962. Zacouto[26] invented a device which enabled the electrical stimulation to be " ... automatically stopped when there was no need for it to operate". In this way continuous run-down of the battery was avoided and it reduced electrolysis of cardiac tissues in the neighbourhood of the electrodes. Later the same year, Berkovits[27] in describing a "defibrillator" which enabled a heart to be stimulated outside the vulnerable period, also stated that the associated pacemaker automatically switched itself on if "... abnormal heartbeat frequency" is detected. Both Zacouto and Berkovits can therefore claim to be part originators of the concept of demand pacing.

Within a few years, reports were being published on the successful clinical use of external demand generators[28,29] and thereafter reports on the clinical use of totally implantable demand pacemakers began to appear[25,30,31,32,33,34,35].

A demand generator is essentially an asynchronous generator to which has been added additional circuitry to inhibit the pacemaker output under certain conditions. Whenever there is a ventricular contraction the associated electrophysiological signal is picked up by the electrode-lead system, be it endocardial, myocardial, etc. and this re-sets the timing circuit in the generator, thereby preventing the emission of a pulse from the generator until a certain pre-set interval of time has elapsed. If during this pre-set interval a further ventricular contraction occurs the timing circuit is re-set again and the emission of a pulse is further delayed by the pre-set time interval. In this way repeated ventricular contractions which occur at time intervals smaller than the pre-set time interval of the timing circuit,

will result in continuous inhibition of the generator pulse. If, however, a ventricular contraction does not occur before the latest pre-set time interval has elapsed, the generator will then emit a pulse, produce a paced ventricular contraction and re-set its timing circuit. This process is repeated if further natural ventricular contractions do not occur during the successive pre-set time intervals. Thus this type of pacemaker only provides a stimulating pulse when it is needed, that is, on demand; hence its name.

The pre-set interval of time is determined by the rate chosen at operation. Thus a basic generator rate of 70 p.p.m. gives a pre-set time interval of 0.857 second .

The timing circuit is specifically designed for optimum sensitivity to ventricular contractions. The QRS complexes may be of either sign provided the amplitude exceeds about one millivolt and provided the rate of change of the signal is sufficiently great. Thus although repolarisation of the ventricles (the "T" wave) will produce a signal at the generator which is sufficiently large, its slow rise-time prevents it from re-setting the timing circuit.

Any ventricular contraction will cause the timing circuit in the generator to be re-set. Thus if a patient is in sinus rhythm and the period between conducted ventricular contractions is less than the pre-set time interval for emission of pulses from the generator then the output from the generator will be inhibited. If for any reason A-V conduction ceases and as is usually the case, an ectopic focus (that is, a focus outside the sinus node) takes over, ventricular contractions will still occur but the time interval between these contractions will be so great that the timing circuit will not be re-set in time to prevent emission of pacing pulses from the generator. But an ectopic focus which becomes active during sinus rhythm will re-set the timing circuit provided it falls outside the short refractory period (150-250 milliseconds) immediately following emission of a pulse. Competitive pacing is therefore unlikely with a demand pacemaker which is functioning properly.

Demand generators should therefore be used in patients who are normally in sinus rhythm and occasionally have A-V blockage, that is, in cases of intermittent heart block. They should also be used in patients who are normally in complete heart block who have, or are known to have had interfering rhythms, whether of sinus or ectopic origin. Any complete heart block patient who reverts to sinus rhythm

after a period of fixed rate pacing should also ideally have the asynchronous generator replaced by a demand generator.

Demand generators should last longer in the presence of sinus rhythm because the current drain is only a fraction of the normal current drain when pulses are being emitted regularly. On the other hand demand generators are more sophisticated with possibly a higher probability of failure though the design of more recent models is such that in the event of a failure occurring in the timing circuit they revert to an asynchronous function. Demand generators are also more expensive than asynchronous generators. However, possibly the greatest disadvantage is the hazard from external sources of electromagnetic radiation. Many authors[36-52] have reported on this hazard from various sources of electromagnetic radiation which include: microwave ovens, radar transmitters, ignition systems, X-ray equipment, diathermy apparatus, etc. More recent models are less susceptible to such sources of electromagnetic radiation.

The ventricular synchronous pacemaker was designed so as to avoid inhibition from electromagnetic radiation outside the body. This pacemaker was first referred to as a demand pacemaker[53], and still is by some, but this is a misnomer in that it delivers pulses continuously to the heart.

When the heart is functioning normally each spontaneous QRS complex of whatever origin triggers the pulse generator and this in turn emits a pulse to the ventricle via the same electrodes after a delay of about 10 milliseconds (that is, during the QRS complex). The pulse therefore stimulates the ventricles during the absolute refractory period of ventricular activity and so cannot cause a competing rhythm, neither can it stimulate during the vulnerable part of the "T" wave. Safeguards are built in the generator so that if the inherent ventricular rate falls below 60 b.p.m. the generator rate remains at 60 p.p.m. and if it exceeds 120 b.p.m. then the generator itself develops 2:1 block, 3:1 block, etc. depending on the ventricular rate. After emission of a pulse, the generator itself has a refractory period, or "dead-time" of about 400 milliseconds during which time it is insensitive to "T" waves, other physiological signals, or electromagnetic radiation external to the body. Thereafter, an "active period" returns when the generator triggering circuit may be re-set by a ventricular contraction. If, however, ventricular contraction does not occur after a certain time (corresponding to a rate of, say,

70 p.p.m.) the generator will emit a pulse.

Ventricular synchronous generators can be used in the same circumstances as demand generators[54, 55, 56].

The ventricular synchronous generator consumes more energy than either the asynchronous generator or demand generator and this may prove to be a serious disadvantage.

Another kind of synchronous pacemaker is the atrial synchronous pacemaker which enables the atrial activity to control the ventricular activity via an implanted pacemaker. This concept is credited to Stephenson[57] et al.

The atrial synchronous pacemaker requires an additional electrode-lead system to the atrium to pick-up the atrial signals. These signals trigger the timing circuit in the generator which subsequently emits, about 120 milliseconds later, a pacing pulse to the ventricles. This artificial P-R interval ensures that the pacing pulse occurs during the refractory period of any naturally conducted pulses. As the atrial rate varies the generator output to the ventricle varies in synchronism with it. In the absence of an atrial signal, the pacemaker emits a pacing pulse after a certain pre-set time interval. Safeguards are built into the design of the generator to ensure that the ventricular rate can vary only within pre-set limits. If the atrial rate exceeds about 120 contractions per minute, then the generator itself develops 2:1 block, 3:1 block, etc. as is the case with the ventricular synchronous pacemaker. Similarly if sinus bradycardia or sinus arrest develops and the atrial rate falls below the lower pre-set limit, then the patient is paced at the lower set rate. If chronic heart block or intermittent heart block occurs, the ventricular rate is always determined by the atrial rate, within the limits specified but in these circumstances paced ventricular contractions occur.

A completely implantable atrial synchronous pacemaker was first implanted in a patient in 1962[58]. In the earlier implants thoracotomies were carried out to place a pick-up electrode on the atrial appendage[58, 59, 60, 61]. Later, Rodewald[62] et al. used an electrode sited inside the atrium and later still[63, 64] the sensing electrode was placed on the atrium by means of media-stinoscopy.

The atrial synchronous pacemaker is useful for patients with conduction defects who also have heart failure in that any kind of artificial pacing which also improves the hemodynamic characteristics of the heart has an additional attraction. This type of pacemaker would also appear to have an advantage for younger patients whose hearts are perhaps normal apart from a conduction defect, who would benefit from atrial control of the ventricles during periods when excessive demands are being made on the heart. However, nothing would be gained by its use in cases of sinus bradycardia, atrial fibrillation or atrial flutter.

Atrial synchronous pacing is evidently successful[65, 66] but is not widely used. This is probably because of the need for an atrial sensing electrode-lead system. In addition, its probable poorer reliability, extra cost, and earlier depletion of cells make it relatively unattractive compared with other generators.

4. Material on which Assessment Procedures have been Developed and Performance Determined

Part II of this thesis is based on personal experience gained with 296 of the 297 patients who received their first pacemaker implant in Glasgow hospitals between 11th June, 1962 and 31st December, 1972: four other patients have also been referred to Glasgow pacemaker clinics after having a pacemaker implanted elsewhere.

The performance data given in Part III is deduced over a shorter period of time, namely 1st July, 1966 to 30th June, 1972. It is necessary to choose a specific period of time when obtaining performance data because some of the basic facts from which the overall picture is derived change from month to month.

During the six-year period 237 patients underwent over 400 pacemaker operations. Four of these patients received their first pacemaker implant elsewhere; one patient came from the U.S.A., had an electrode-lead system replaced and returned home shortly afterwards (Patient No. 260); one other patient, from the U.S.A., has remained in the region and has since had a generator replaced (Patient No. 166); two other patients (Nos. 62 and 98) came to Glasgow from elsewhere in the United Kingdom with pacemakers implanted and subsequently underwent re-operations. (Another patient (No. 230) came from elsewhere in the United Kingdom with a Devices pacemaker implanted but no re-operation was undertaken in the review period). Thus, 233 patients received their first implant in Glasgow hospitals during the six-year period. Two of these patients received Cordis atrial synchronous pacemakers. One (Patient No. 28) has received only Cordis pacemakers, but the other (Patient No. 102) received a Medtronic pacemaker at re-operation. Four patients who received their primary pacemaker implant in Glasgow were lost to follow-up before 30th June, 1972 because they moved elsewhere. The performance data in Part III has therefore been provided by 231 pacemaker patients who received their first Medtronic pacemaker in Glasgow hospitals (but excluding the most recent implants in the four patients lost to follow-up) and by the other patients mentioned earlier who subsequently received Medtronic generators or electrode-lead systems at re-operations. The data has in some cases, however, been confined to 227 patients, when the four patients lost to follow-up have been excluded (Sections 8 and 9 of Part III).

Table 1 gives the numbers of different types of generators which were implanted during the six-year period. None of the Cordis generators is included in the performance data in Part III. Table 2 shows how the percentage of Medtronic demand generators used each year has increased since the first was implanted on 19th September, 1967. Table 3 gives the numbers of different types of electrode-lead systems which were implanted during the six-year period. None of the Cordis electrode-lead systems is included in the performance data in Part III. Exceptional reference is made in Part III to two Medtronic electrode-lead systems implanted before 1st July, 1966 which have very long "incomplete implant lifetimes". On five occasions Medtronic electrode-lead systems were converted at re-operations to unipolar systems by introducing an "indifferent lead" (Medtronic type 5814/7), thus making one faulty lead of a bipolar system redundant. These five indifferent leads have not been listed in Table 3 since they can be used with either endocardial or myocardial systems.

TYPES OF GENERATORS		
Asynchronous	Demand	Atrial Synchronous
Medtronic - bipolar	Medtronic - bipolar	Cordis - unipolar
type 5870C 117	type 5841 50	Atricor 7
type 5870 3	type 5842 44	
type 5862C 120	type 5942 56	
Cordis - unipolar		
Ventricor 1		

Table 1. Numbers of different types of generators implanted between 1st July, 1966 and 30th June, 1972

Year	Asynchronous	Demand	% Demand
1967	30	2	6.3
1968	47	10	17.6
1969	32	13	29.0
1970	61	42	41.0
1971	51	49	49.0
1972	37	78	68.0

Table 2. Changes in percentages of demand generators used in the period 1967 to 1972.

TYPES OF ELECTRODE-LEAD SYSTEMS	
Endocardial	Myocardial
Medtronic - bipolar	Medtronic - bipolar
type 5816 47	type 5814 15
type 5818 232	
Cordis - unipolar	Cordis - unipolar
Ventricor 1	Atricor 2

Table 3. Numbers of different types of electrode-lead systems implanted between 1st July, 1966 and 30th June, 1972.

Part II - Assessment

1. Important Factors in Assessment: Pacemaker Faults and Problems

In any scientific investigation, whether it be in the realm of an exact science such as physics, or in a less exact branch of the natural sciences such as clinical medicine in which precise measurements are often impossible, the conclusions reached in any particular situation should always be made in the light of the maximum amount of knowledge available. In practice, very often one single piece of information may point immediately to the source of the trouble but if a systematic method of assessment is always adopted it is more likely that a correct diagnosis will be made in more obscure cases.

Any clinician, with responsibility for a pacemaker patient, not only needs confirmation from time to time that the pacemaker is still technically sound and that the pacing function is satisfactory, but when some change occurs, perhaps without clinical symptoms in the first instance, it is also desirable to know of the change, or changes, so that appropriate arrangements can be made on a planned basis for whatever future action is necessary. There is a number of factors which have to be considered in following up pacemaker patients. These important factors are listed below:

(a) Post-operative surgical difficulties and patient's general condition
(b) Patient's pulse
(c) Patient's electrocardiograms
(d) The pacemaker frontal plane vectors
(e) The pacemaker pulse parameters
(f) Radiological information

In the case of endocardial electrode-lead systems, more particularly bipolar ones, the usefulness of factors (c), (d) and (e) in any assessments depend on the angle formed by a line drawn through the centre of the electrodes and the frontal plane of the body, remaining more or less constant. The dependence on the constancy of this angle is perhaps less important so far as electrocardiograms are concerned, because, as explained in section 4, not too much significance should be attached to the magnitude of the pacemaker pulses, as seen on an electrocardiogram: the "sign" or "sense" of the pacemaker pulses is much more significant and, in general, very big changes in this angle are necessary before the signs of any pacemaker pulses are changed

on an electrocardiogram. Fortunately, there is some indirect evidence that in many cases electrodes do acquire stable positions, otherwise the reproducibility of pacemaker frontal plane vectors would be impossible. There is also some direct necrotic evidence from Glasgow[8, 67] and from elsewhere[68, 69] that the distal end of the catheter usually becomes completely enveloped by new fibrous tissue which anchors the electrodes to the endocardium. Additional indirect evidence is afforded by the inability on a number of occasions to withdraw a catheter from the ventricle.

All the factors listed above should be considered when assessment is taking place, whatever type or make of pacemaker has been implanted. In many cases the arguments used are common to all makes and types of pacemaker but when results do depend on the type (and perhaps make) of pacemaker implanted, these differences are emphasised in the detailed discussions in the relevant sections.

There are also many faults or difficulties which arise in pacing which are common to all makes and types of pacemakers. Perhaps the most common fault in all pacemakers is a reduction in output from premature failure of one or more of the mercury cells forming the battery. In the case of many of the Medtronic generators used in Glasgow the new lower output has remained steady and pacing has continued satisfactorily though often at a changed rate. However, one of the earlier types of Medtronic demand generators used, often displayed substantial falls in output (often with big changes in rate), sufficient in fact to cause loss of pacing (i.e. generator-block). Faults in the electronic circuitry can also cause generator-block, though this is expected to become even more rare with the increasing use of integrated circuits and canning techniques. Generator-block from simultaneous natural depletion of all cells is, of course, another possibility. With the more sophisticated generators, electronic circuitry faults can also occur in the "sensing circuit" which receives small signals from either the ventricle or the atrium.

Changes in generator rate from the premature failure of one or more cells are in fact as common as reductions in output from the same cause. With certain generators there is an increase in rate with fall in output whereas with other makes (or types) of generators there is a decrease in rate with fall in output. Most Medtronic generators used in Glasgow have shown a small step change in rate (associated with a step reduction in output) and pacing has remained satisfactory. Fortunately, where there

has been a big step increase in rate this has usually been accompanied with a big reduction in output sufficient to cause generator-block. Large step decreases in rate are less dangerous, but they too are sometimes accompanied with generator-block.

Not all models of generators exhibit a rate change when the output falls. One generator used in Glasgow shows no change in rate when one of its five cells fails prematurely and another generator with a more sophisticated arrangement of its cells also shows no change in rate when as many as three cells in one "bank of three" fail and one cell, in the second bank of three, fails. Rate changes are, of course, possible from other causes in these and in other generators, just as are changes in pulse width and pulse shape.

Small changes in output and rate do not require immediate attention and provided pacing is continuing at a stable and safe rate re-operation can be arranged to take place in the near future on a planned basis.

The failure of an electrode-lead system however can be more serious, though fortunately this is less common. If, for instance, a conducting lead fails, the insulation remaining intact, a large and perhaps variable resistance is introduced into the output circuit of the generator and if the latter is a low impedance source, i.e. a constant voltage generator, it will result in a big reduction in current output. If the two broken ends occasionally touch each other, as a result of body movements, then the resistance is reduced and the current increases. Thus the current output may vary considerably between being fairly normal and being very small or virtually zero. Intermittent pacing is certain: complete loss of pacing is possible from pacemaker-block.

A temporary pacing catheter connected to an external generator may be required if during non-paced periods the patient's idioventricular rate is so low that it would place the patient at unnecessary risk while awaiting re-operation.

On the other hand, the failure of the insulation on one lead of a bipolar electrode-lead system, the conductor itself remaining intact, is less serious in that pacing continues satisfactorily. This is because the bipolar system has become a unibip pacing system: current still flows between the two electrodes inside the ventricle or in the myocardium, etc. but it also flows between the lead exposed at the broken insulation and the electrode at the heart which is associated with the other conductor. When the insulation on the lead of a

unipolar system fails it is conceivable that if the break occurs at a point some distance from the heart then the greater part of the current might take the alternative path so that the current through the heart muscle is small and pacing may become intermittent or cease altogether.

Re-operations have certainly not been essential in the case of failures of insulation on one lead of bipolar systems but the increased current drain on the battery because of the reduced resultant impedance, is, of course, a disadvantage, just as it would be with a similar faulty unipolar electrode-lead system which has been allowed to remain implanted because pacing has continued to be satisfactory.

The most common iatrogenic problem with endocardial pacemakers is displacement of the distal end of the catheter to another part of the ventricle, especially during the few months immediately following first emplacement. Displacement has even occurred into the inferior vena-cava. Included in this same category are: extrusion of a generator or a catheter near the neck wound; infection, either primary infection or secondary to extrusion; migration of a generator; exit-block in which the threshold for pacing has increased above the output of the pacemaker and entrance-block in which a demand generator is not being inhibited by ventricular contractions because the ventricular signals are too small and/or have the wrong shape.

All these iatrogenic problems demand re-operations. Total loss of pacing from displacement or exit-block would require immediate attention if symptoms have re-appeared. Temporary loss of pacing without symptoms can be considered less urgently along with the other iatrogenic problems referred to above.

Leaking insulating screws in the generator, or "boots" of the generator which leak electrically because insulating lubricant has escaped, are not regarded as technical failures, but might also be more appropriately classified as iatrogenic problems. In the case of bipolar electrode-lead systems such leaks associated with <u>one</u> of the conductors can be tolerated in that pacing will still continue just as it continues when the insulation on one lead of a bipolar system fails. If leaks occur at both screws, both boots, or a screw and a boot associated with different conductors, then the leak may be sufficient to cause loss of pacing. Similarly, if with a unipolar pacemaker the leakage at the generator/electrode-lead system interface is sufficiently big, it is conceivable that pacing will cease.

If pacing remains satisfactory, electrical leaks can be accepted until one of the other faults or complications necessitates re-operation. But failure to re-operate when electrical leakage occurs will cause earlier battery depletion from the increased current drain as is the case when insulation failures occur. A second disadvantages is that when body fluids are able to enter screw sockets, it has been established that corrosion of the stainless steel Allan setscrews occurs. The removal of these screws becomes more difficult if the hexagonal socket is allowed, through corrosion, to become cylindrical; apart from any possible tissue reaction which might develop if the process is allowed to continue long enough. These disadvantages and risks must be weighed against the risks which obtain in any particular case from re-operation to stop electrical leaks.

2. Post-operative Surgical Difficulties and Patient's General Condition

When a pacemaker patient attends a pacemaker clinic, the clinician responsible must satisfy himself on several counts:

(1) that the pacemaker itself is technically sound

(2) that the pacing function is normal, or is at least satisfactory

(The factors which enable items (1) and (2) to be assessed are discussed in detail in the remainder of Part II).

(3) that surgical recovery has been satisfactory and that complications have not arisen from the implant

(4) that the patient's general condition is satisfactory.

The latter aspects (3) and (4), are very important. Some are readily discernible to the clinician. For instance, wounds need to be examined particularly in the immediate post-operative period for primary infection and sinuses. Later, generator migration might occur, though impending extrusion of a generator, or impending extrusion of a catheter at the neck wound, is more likely. Ideally, these potential extrusions should be detected before the surface of the skin is broken so that secondary infection is less likely.

Whilst it is possible for a patient to have a conduction defect and yet have an otherwise perfectly healthy heart, some patients do have related problems. Many, for instance, have had a myocardial infarct. Left ventricular failure and congestive cardiac failure are also sometimes in evidence. Fortunately, modern drugs usually offer some relief in these respects which a normally functioning pacemaker is unable to do.

Comments made by the patients themselves relating to a recent incident should not be automatically associated with a pacemaker failure or loss of pacing. Indeed, a patient who complains of having had a period of dizziness, or even complete loss of consciousness, might have a pacemaker implanted which is functioning perfectly. For instance, one patient who complained in this manner had had a minor cerebral vascular accident. In another case, it was discovered that excessive pressure on a carotid artery, caused by the sudden backwards movement of the head, had resulted in temporary loss of consciousness on several occasions. In yet another case, in which the patient lay unconscious at the bottom of his staircase for some considerable time, the cause has remained obscure, but his pacemaker has not yet been shown to be failing in any way.

3. Patient's Pulse

3.1 Counting of pulse

A simple diagnostic investigation which can be made on any pacemaker patient is that of counting the patient's pulse. If, however, this counting is to be of any value in pacemaker assessment, it must be carried out most carefully. In other clinical examinations, accurate counting of the patient's pulse is unimportant, and in any case the rate often varies; but in the case of a pacemaker patient accuracy is essential since a change in the patient's pulse can be highly significant. The patient's pulse should therefore be counted over a full minute and ideally a stopwatch should be used to synchronise the "zero" of time with the "zero" pulse. The practice of counting pulses over a quarter of a minute is not satisfactory since an error of one, which is extremely common because counting has begun with "one" instead of "zero" could given an error in pulse measurement of four over a full minute.

Figure 2 is a copy of a patient's pulse recorded by nurses immediately following implantation of an asynchronous pacemaker. The pacemaker rate increased from 69 to 70 pulses per minute with the temperature change following implantation but the patient's pulse according to observations made by nurses, who incidentally were unaware of the special interest being taken in their observations, varied between 57 and 86 beats per minute. A pulse greater than 70 b.p.m. was, if anything, to be expected in the immediate post-operative period because of the likelihood of ectopic beats, but oddly enough at no time during this period was a pulse greater than 70 b.p.m. recorded. In the absence of ectopic beats the patient's pulse was steady at 70 b.p.m. but on many occasions a significantly different pulse was recorded. This example is typical of the inaccurate observations which are repeatedly made on pacemaker patients. However, in sub-sections 3.2 to 3.5 it is assumed that the patient's pulse has been counted accurately.

3.2 Possible causes of changes in pulse of patient having an implanted asynchronous pacemaker

The electrical pulses from an asynchronous pacemaker should be causing the ventricles to contract at a regular rate so that the patient's pulse should also be regular and at a fixed rate.

An increase in the patient's pulse when an asynchronous pacemaker

Patient 81

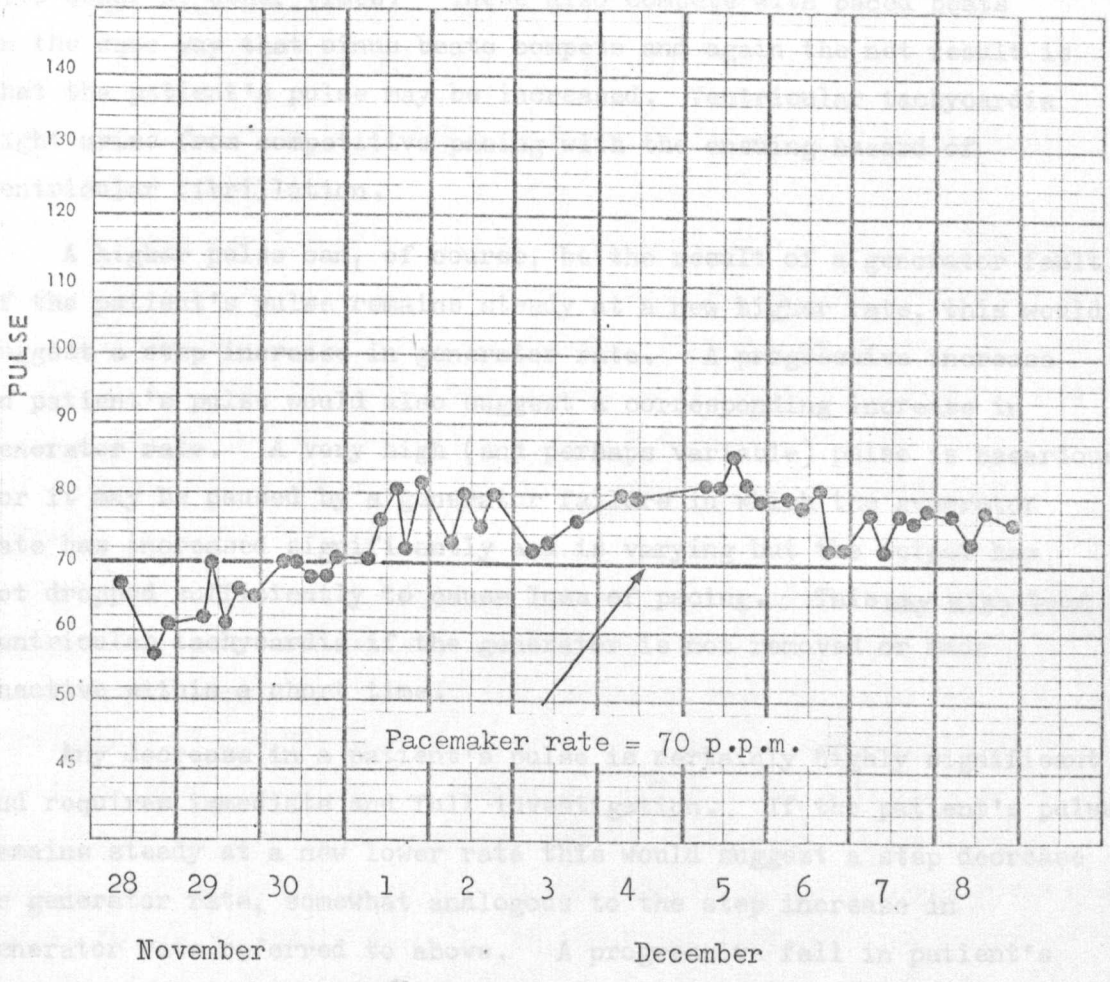


Figure 2. Observations made by nurses of patient's pulse following implantation of asynchronous pacemaker on 28th November, 1970.

has been implanted does not necessarily mean that the generator rate has increased. For instance, as mentioned previously[11, 12] (Part I, section 3) it is known that sometimes a patient in complete heart block may return to sinus rhythm after being artificially paced for a time, so that the natural rhythm competes with the paced rhythm with the net effect that the patient's pulse may be increased above the rate of the asynchronous generator. The possibility of ectopic beats during the first 48 hours or so after an operation has already been mentioned in the previous sub-section, but ectopic beats can also occur at other times. These also compete with paced beats in the same way that sinus beats compete and again the net result is that the patient's pulse may be increased. Ventricular tachycardia might arise from competitive pacing with the ensuing hazard of ventricular fibrillation.

A higher pulse can, of course, be the result of a generator fault. If the patient's pulse remains steady at a new higher rate, this would suggest a step increase in generator rate. A progressive increase in patient's pulse would also suggest a corresponding increase in generator rate. A very high (and perhaps variable) pulse is hazardous for it may be caused by a generator failure in which the generator rate has increased significantly and is varying but the output has not dropped sufficiently to cause loss of pacing. This may also lead to ventricular tachycardia if the generator is not removed or made inactive within a short time.

Any decrease in a patient's pulse is certainly highly significant and requires immediate and full investigation. If the patient's pulse remains steady at a new lower rate this would suggest a step decrease in generator rate, somewhat analogous to the step increase in generator rate referred to above. A progressive fall in patient's pulse would also suggest a corresponding falling generator rate.

The patient's pulse may, however, be lower and variable because of partial loss of pacing although the generator rate is unchanged. Loss of pacing may have occurred because the catheter has been displaced or, because in the case of a myocardial/epicardial system, an electrode may have become loose. Alternatively, a conducting lead may have fractured the insulating remaining intact, or the impedance may have increased sufficiently to limit the pacemaker output significantly especially with constant voltage generators (intermittent pacemaker-block). Intermittent generator-block or intermittent exit-

block are other possibilities. Intermittent loss of pacing from any of these causes might, nevertheless, be combined with a fall in generator rate.

If the patient's pulse has reverted to its former idioventricular rate then there is complete loss of pacing from one (or more) of the causes mentioned in the previous paragraph. If either pacemaker-block, generator-block, or exit-block is responsible it must have become constant. Any change in generator rate is irrelevant when complete loss of pacing occurs. Indeed, in a number of cases very large increases in generator rate were fortunately accompanied with big reductions in generator output (i.e. constant battery-block).

3.3 Possible causes of changes in pulse of patient having an implanted demand pacemaker

Somewhat similar arguments to those used in sub-section 3.2 can be applied to patients who have received demand pacemakers, but there is one important point to be noted. Thus, whereas when an asynchronous pacemaker has been implanted any change in the patient's pulse requires further investigation, any patient with a demand pacemaker implanted may have a varying pulse and yet the pacemaker may be functioning normally in every respect.

As stated in Part I, section 3, demand pacemakers are usually implanted in patients who are normally in sinus rhythm but have intermittent heart block. If the generator rate has been set sufficiently below the normal sinus rate, then the generator will be inhibited when conduction is occurring, so that the patient's pulse will exceed the generator rate, and may be variable. If conduction ceases, the patient's pulse should not fall below the generator rate and it should be constant. If, on the other hand, the generator rate has been set at operation just below the normal sinus rate, then parasystole rhythm will occur, in which there is a period of natural ventricular contractions during which the demand pacemaker is inhibited and this is followed by a period of paced ventricular contractions, and so on. In these circumstances the patient's pulse will not fall below the generator rate but it may be slightly greater than the generator rate, and be variable. Alternatively, if the generator rate has been wrongly set, at operation, at a value well above the natural sinus rate, the generator will not be inhibited and the patient's pulse should be constant at the generator rate.

Demand generators are also used in patients in complete heart block who have, or have had, interfering rhythms, whether of sinus or ectopic origin. In the absence of such rhythms the idioventricular rate is usually well below the generator rate and the generator is not inhibited so that the patient's pulse should be constant at the generator rate. If there is a spontaneous ventricular contraction, either of sinus or ectopic origin, this will inhibit the demand generator, assuming it has not occurred within the last refractory period of the generator. If there is a number of such spontaneous ventricular contractions there will be recurrent inhibition of the demand generator but the overall effect will probably be that the patient's pulse will be increased above the generator rate. An increased pulse cannot be certain in these circumstances, because "runs" of ectopic ventricular contractions may inhibit the demand generator but they may not always produce corresponding satisfactory peripheral pulses and may cause ventricular tachycardia.

Finally, there is an additional possibility with demand generators in that entrance-block might occur. In these circumstances inhibition of the pacemaker ceases, either temporarily or permanently. With temporary entrance-block some paced contractions might occur, thus giving a variable pulse; with permanent entrance-block, the pacemaker has in effect become an asynchronous one and the pulse will again be variable from competitive pacing.

3.4 Possible causes of changes in pulse of patient having an implanted ventricular synchronous pacemaker

Again similar arguments to those used in sub-section 3.2 can be applied to patients who have received ventricular synchronous pacemakers. However, as was the case for demand pacemakers, it should be noted that the patient's pulse may be varying and yet the pacemaker may be functioning normally in every respect.

Ventricular synchronous pacemakers are used in the same circumstances as demand pacemakers. During periods of sinus or ectopic rhythms the pacemaker will have no effect and the patient's pulse will follow the ventricular rate within the lower and upper limits of the generator. During periods of heart block, however, when an idioventricular rhythm would otherwise supervene, an untriggered pacemaker pulse stimulates the ventricles at the lower pre-set generator rate of, say, 60 p.p.m. During periods of heart block, therefore, the patient's pulse should not fall below the lower pre-set generator rate.

Alternatively, if a ventricular synchronous pacemaker is implanted in a patient who is normally in heart block, but interference rhythms arise, then the patient's pulse will increase from the lower pre-set generator rate during the times that interference rhythms are present. This assumes that the natural activity (whether of sinus or ectopic origin) has occurred about 400 milliseconds after emission of a pacing pulse; otherwise, the sensing circuit in the generator is inoperative.

If the sensing part of the pacemaker fails, and in some cases when premature battery depletion occurs, the pacemaker becomes in effect an asynchronous one. Thus, there will be a variable pulse from competitive pacing when conduction is occurring or a constant pulse at the lower pre-set generator rate in the presence of heart-block.

3.5 Possible causes of changes in pulse of patient having an implanted atrial synchronous pacemaker

Once again similar arguments to those used in sub-section 3.2 can be applied to patients who have received atrial synchronous pacemakers. In this case, however, a constant patient pulse may be indicative that the pacemaker is not functioning normally.

As explained in Part I, section 3, atrial synchronous pacemakers can be used in almost all the conditions in which the other pacemakers can be used. During sinus rhythm the atrial synchronised pacemaker pulses have no effect so that the patient's pulse varies naturally, except that the pacemaker imposes a lower limit of about 60 b.p.m. and an upper one of about 120 b.p.m. During periods of heart block the atrial synchronised pacemaker pulses become effective and artificially maintain atrial control over the ventricles. Thus, a variable pulse is maintained within the above limits.

Interference rhythms in patients, who are in heart block, will certainly affect the patient's pulse if they originate in the atria because the ventricles are controlled by the atrial rate, via the pacemaker. Idioventricular foci will result in competitive pacing and will therefore cause the pulse to vary.

If the atrial electrode-lead system fails in any way so that triggering pulses are not received by the generator, then the generator reverts to an asynchronous one, which produces pulses at a basic rate of about 60 per minute. This is also the case when one of the

cells in the battery fails. The pulse therefore becomes constant, or variable in the presence of competing rhythms.

4. Electrocardiography

4.1 Electrocardiograms and "unpaced" patients

Electrocardiography is the observation, recording and measurement of changes in potential between a number of pairs of points on the surface of the body and their correlation with the action and physical state of the heart.

In practice, small electrodes are placed on the surface of the body at the chosen "points" and these acquire the same varying potential as the skin immediately underneath. Good electrical contact between skin and the electrode is ensured by means of "electrode jelly" which is rubbed into the surface of the skin and has excellent conducting properties. Although many sites may be chosen for these electrodes, it has become common practice to use "limb" and "chest" electrodes. Limb electrodes were first suggested by Einthoven in 1907[70]. Later, at a meeting of the Chelsea Clinical Society on 19th March, 1912[71] he stressed, "The galvanometer must be connected to the human body in such a way that the image of the string is deflected upwards when the base or the right half of the heart is negative in respect to the apex or the left half". The word "must" was probably not intended, for reversal of the connections merely reverses the deflections. Nevertheless, to achieve this end, Einthoven had in effect in 1907[70] defined limb leads as follows. (See Appendix II for details):

$$\text{Lead I} = V_{LA} - V_{RA}$$

$$\text{Lead II} = V_{LL} - V_{RA}$$

$$\text{Lead III} = V_{LL} - V_{LA}$$

The custom of having "upwards" or "positive" deflections on Leads I and II was subsequently widely adopted so that these arbitrary definitions became established as the Einthoven "Limb Leads". He is also generally credited with the relationship between these limb leads, namely,

$$\text{Lead II} - \text{Lead I} = \text{Lead III}$$

or more simply

$$\text{II} - \text{I} = \text{III}$$

though, as is shown in Appendix II, this is merely an expression of a more fundamental concept.

Figure 3 shows typical variations in potential obtained from Leads I, II and III in a normal healthy adult. Whichever of these leads is considered, the variations in potential shown on the recording (i.e. on the electrocardiogram or E.C.G.), all follow essentially the same form. This form is shown diagrammatically in figure 4 in which the symbols used are those introduced by Einthoven. Typical time intervals are shown over various parts of the cycle. The "P" wave is associated with the propagation through the atria of the natural electrical pulse which originates in the sino-atrial node. It takes between 0.120 and 0.200 second (120 to 200 milliseconds) for this pulse to pass from the sino-atrial node, through the atria and the atrio-ventricular node to the upper part of the ventricles depending on the heart rate. This period of time is referred to as the P-R interval. The QRS complex represents the depolarisation of the ventricular muscles (corresponding to contraction of the ventricles) and indicates the time necessary for the pulse to pass from the atrio-ventricular node along the bundle of His, and along the left and right bundles to the Perkinje fibres. This typically occurs over a period of about 80 milliseconds, though in a normal person it should not take longer than about 120 milliseconds. After completion of ventricular contraction (systole or depolarisation), there is a pause indicated by the S-T segment before the atria and ventricles begin to refill and repolarisation takes place during the "T" wave in preparation for the next cycle.

A careful study of an electrocardiogram will enable many characteristics of the patient's heart to be determined so that appropriate treatment can be prescribed. For instance, from an electrocardiogram it is possible to observe, amongst other things:

(1) the atrial rate and the ventricular rate
(2) the time relationships between the different parts of the electrocardiogram, e.g. P-R and Q-T intervals
(3) the duration or width of complexes e.g. the width of the QRS complexes
(4) rhythm disturbances (e.g. ectopics, tachycardias, fibrillations, bradycardias, etc.)
(5) the sequential action (or otherwise) of the atria and ventricles (e.g. diagnosis of atrio-ventricular dissociation with block, more commonly referred to as heart block).

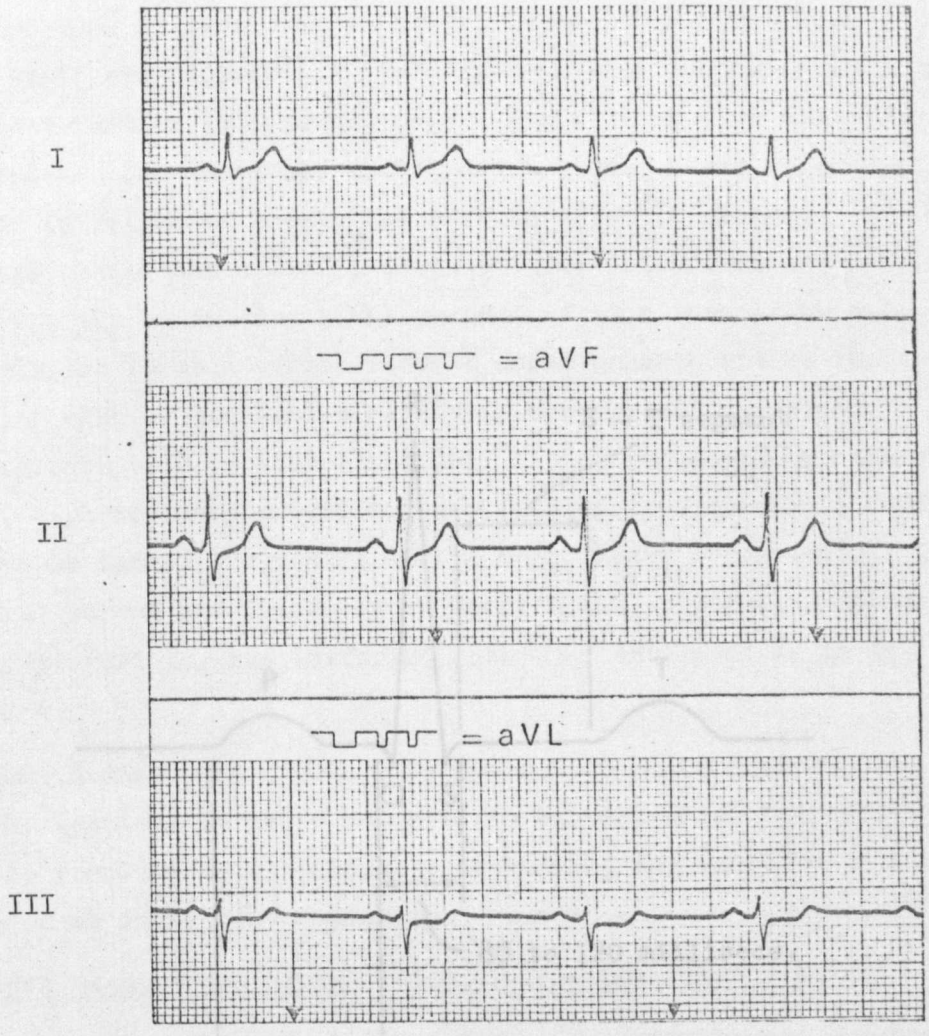


Figure 3. Electrocardiogram of normal healthy adult (Leads I, II and III)

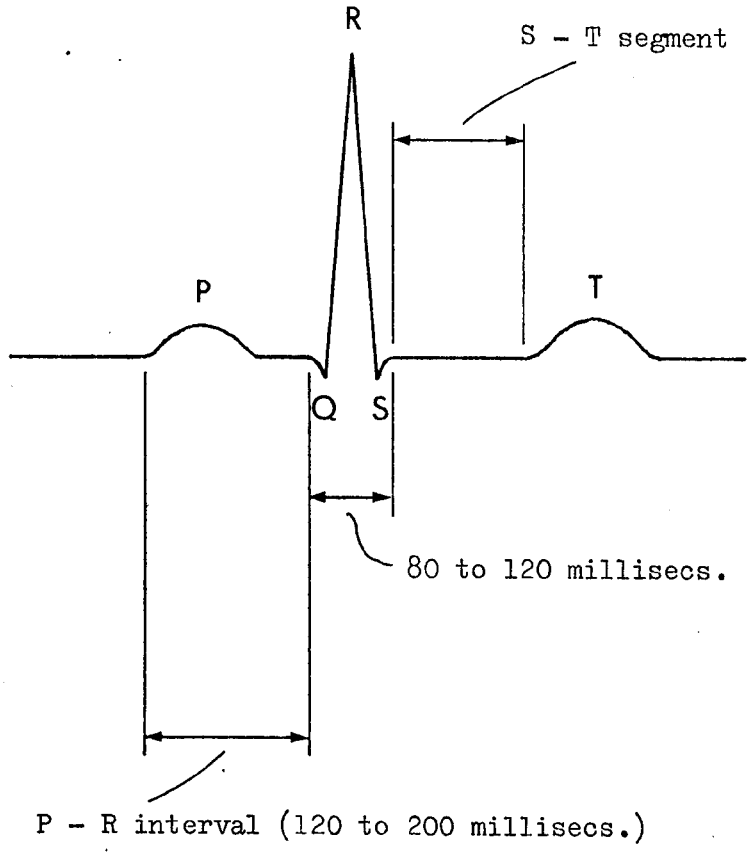


Figure 4. Diagrammatic version of one cycle of a typical E.C.G.

Figures 5, 6 and 7 show the E.C.G.'s obtained from three patients having different kinds of heart block; namely, first degree, second degree and third degree, respectively. In first degree heart block the P-R interval is prolonged to greater than 200 milliseconds, but no heart beats are "missed". The danger is that the deterioration will proceed further into second degree heart block when missed beats are apparent. For instance, in 2:1 heart-block, every other beat is absent and in 3:1 heart block, one beat in three is absent. In third degree heart block the atrial and ventricular activities are completely dissociated, the ventricles being controlled at a much lower rate by an idioventricular focus. These defects arise because either the atrio-ventricular node or the bundle of His is electrically impaired. The defect may have been present at birth; it can be caused by numerous diseases, e.g. coronary artery disease leading to a myocardial infarct; and it can be caused surgically during major heart operations. If, in cases of second and third degree heart block, clinical symptoms develop (see Part I), the preferred method of treatment is to implant a pacemaker.

Figure 8 shows the E.C.G. of a patient in sinus bradycardia. If similar symptoms to those referred to earlier occur they can usually be resolved by artificially increasing the ventricular rate by means of an implanted pacemaker.

4.2 Normal electrocardiograms obtained from pacemaker patients

The electrocardiogram obtained from a patient who has a pacemaker implanted is different from that of a normal healthy person, and different from that obtained from the patient prior to its implantation. Thus the change in ventricular rate is also accompanied with a change in the paced physiological complexes because the artificial electrical stimulation produced by the pacemaker originates at the sites of the electrodes instead of in the sino-atrial node, or in an ectopic focus.

The two pacemaker electrodes, at least one of which is on or in the heart, form an "electric-dipole". The pulses of current flowing between these electrodes through the volume of the body, or part of the volume of the body, cause potential differences to be set-up between different points on the surface of the body just as potential differences arise between different points on the surface of the body as a result of the natural electrical activity of the heart. These time-dependent pacemaker potential differences can be observed and recorded in a somewhat similar manner as time dependent naturally produced potential differences.

Patient 317

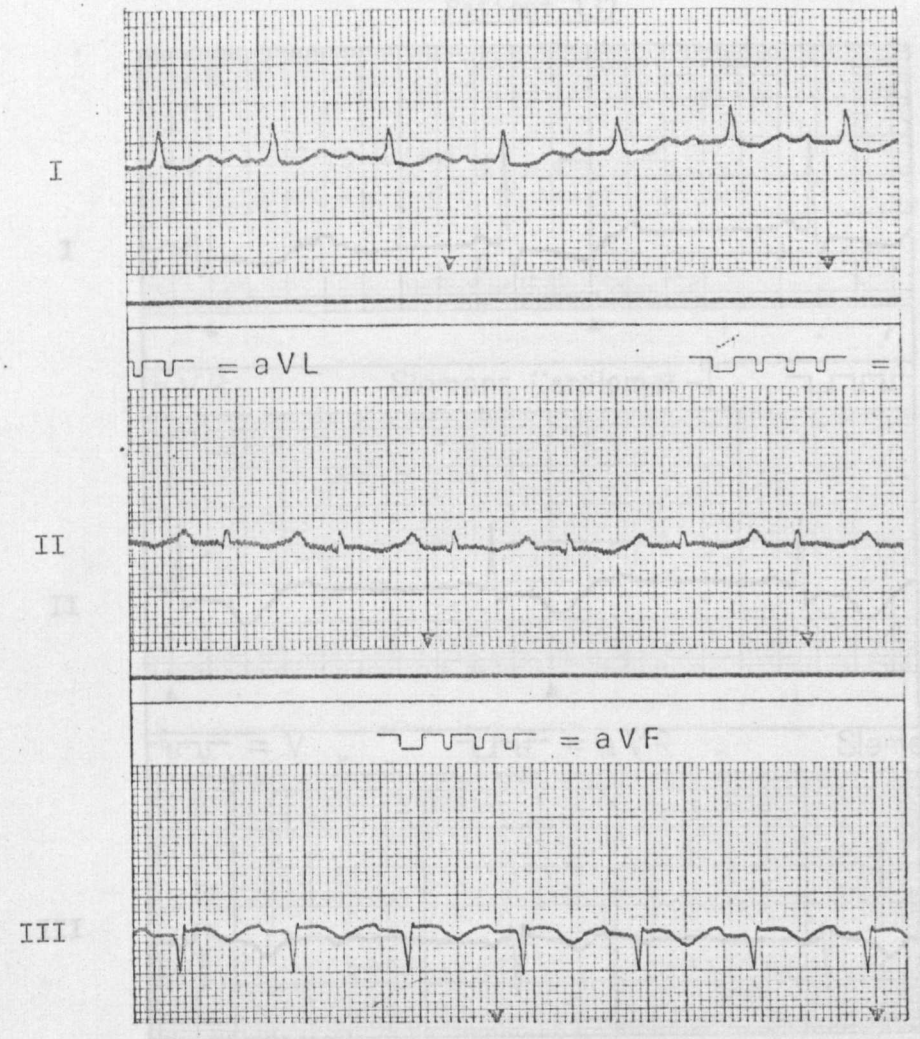


Figure 5. E.C.G. of patient with first degree heart block

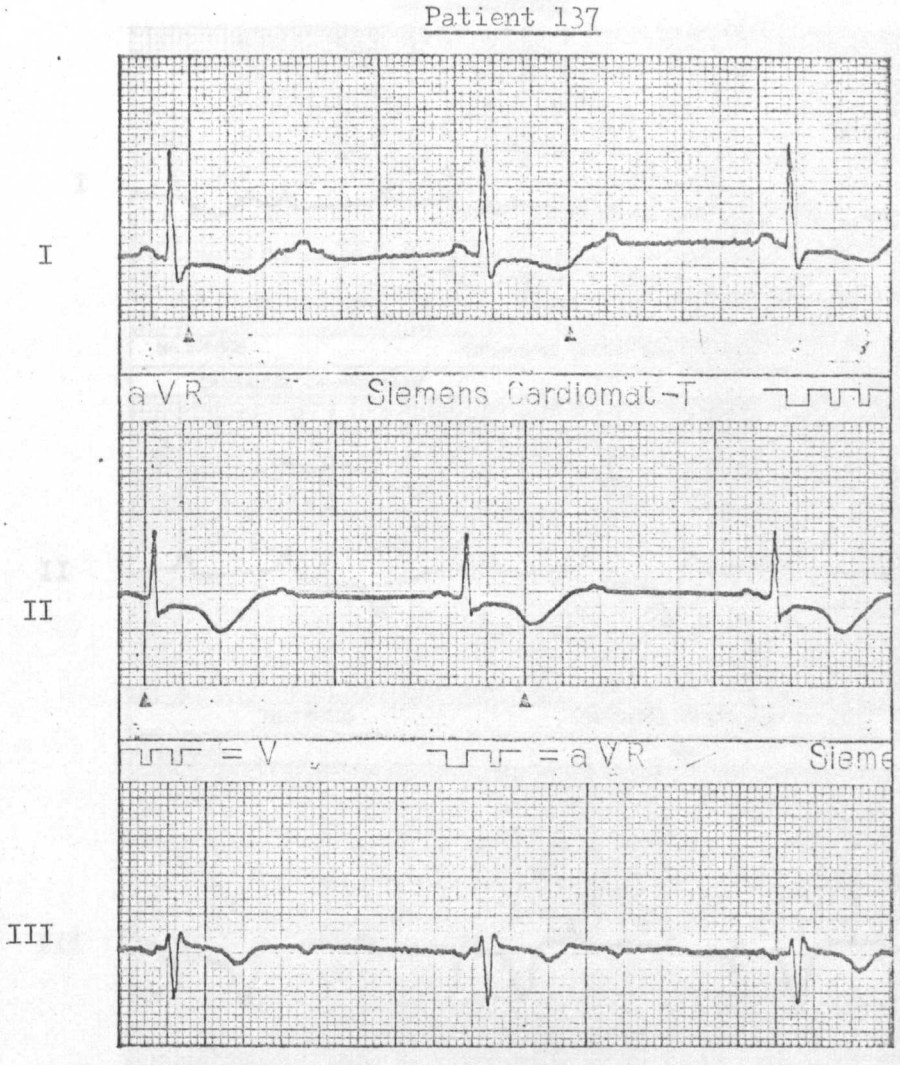


Figure 6. E.C.G. of patient with second degree heart block (2:1 block)

Patient 321

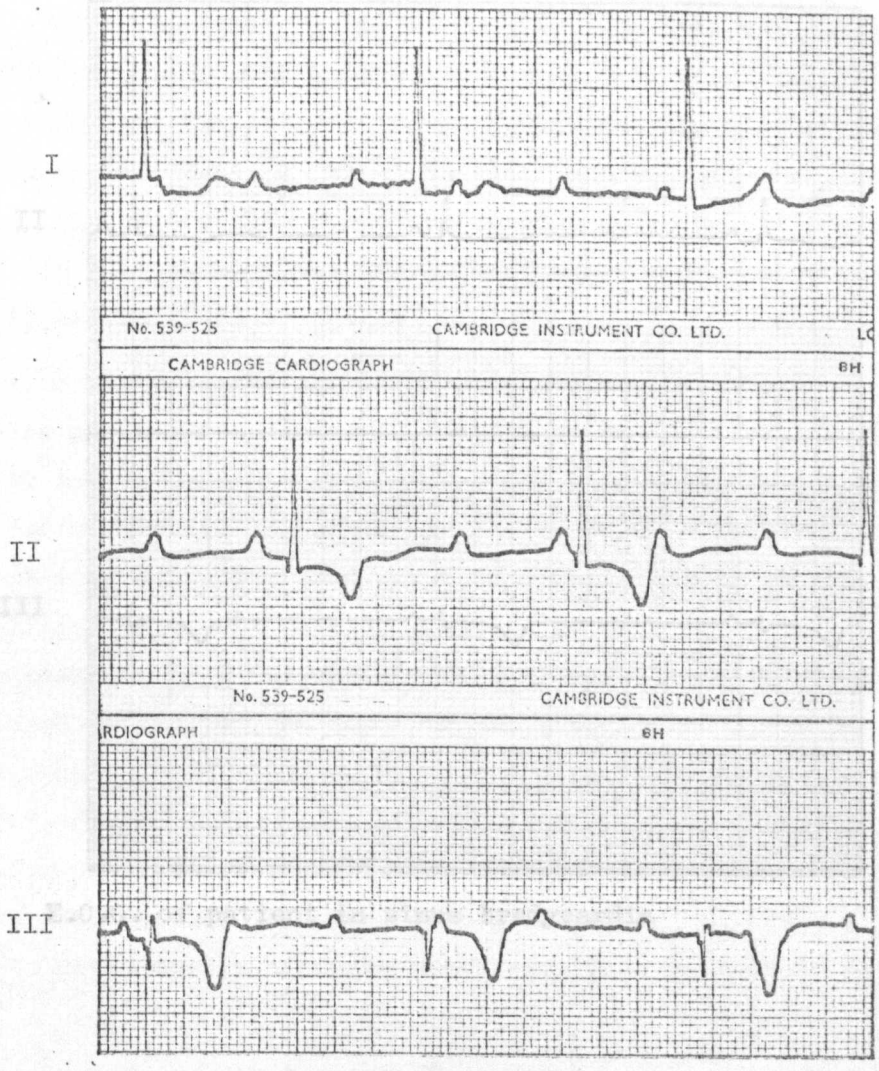


Figure 7. E.C.G. of patient with third degree heart block

Patient 115

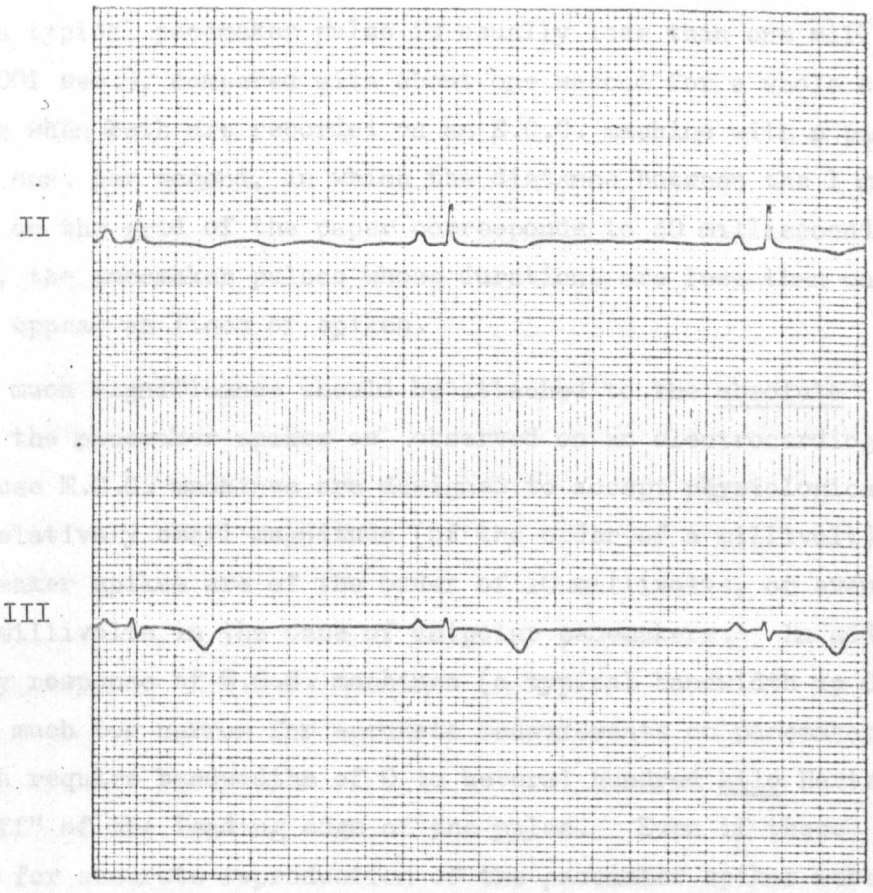


Figure 8. E.C.G. of patient in sinus bradycardia

Pacemaker pulses can be observed on a normal electrocardiogram, integrated with the natural physiological electrical activity, and they appear as straight lines or pacemaker "spikes". This is because the duration of a typical pacemaker pulse is usually less than one millisecond (< 0.001 sec.), compared with about one second for a whole cardiac cycle. Thus when both are recorded on an E.C.G. machine with a paper speed of 2.5 cms. per second, in which the distance between the 1 mm spaced lines on the grid of the paper corresponds to 40 milliseconds (0.040 sec.), the pacemaker pulses whose durations are less than one millisecond, appear as lines or spikes.

Not too much significance should be attached to the absolute magnitude of the pacemaker spikes as observed on an electrocardiogram. This is because E.C.G. machines are designed to accept physiological signals of relatively small magnitude (of the order of a millivolt) whereas pacemaker spikes are of the order of 10 millivolts, or even hundreds of millivolts in the case of unipolar pacemakers. In addition the frequency response of E.C.G. machines (a typical bandwidth is 0 to 50 Hertz) is much too narrow for accurate measurements on pacemaker pulses, which require bandwidths of 0 to several hundred kilo Hertz to avoid "cut-off" of the leading edge of the pulse. Even if these requirements for accurate reproduction of the pacemaker spikes were met, it is doubtful whether the usual arrangements for calibrating E.C.G. machines would enable accurate measurements to be made of the spikes.

Thus, the absolute magnitude of the pacemaker spikes on an E.C.G. should not be used for serious measurements. However, if the spikes were reproduced perfectly, their absolute magnitudes would depend on a number of factors. These are: the type of pacemaker (unipolar or bipolar); whether an endocardial system or myocardial/epicardial system is being used (with the latter kinds, lower output generators are sometimes used); the output characteristics of the generator and the patient load presented to the generator; the physiological characteristics of the patient; and finally, at any instant, for a given set of circumstances as specified above, on the respiration phase (i.e. relaxed breathing, full inspiration or expiration).

Useful information can often be deduced, however, from the "sense" or "sign" of the pacemaker spike. In the case of an endocardial bipolar pacemaker the pacemaker spikes should appear negative on Leads I and II, assuming the distal electrode has been made negative.

This is because having adopted a convention for the physiological signal so that "P" waves and "QRS" complexes are positive when depolarisation emanates from the sino-atrial node, then when artificial depolarisation takes place in the opposite direction, the pacemaker spikes will be negative on Leads I and II.

Figure 9 will help to explain this in which the vector (a) represents the natural resultant electric dipole of the ventricles at any instant and (b) represents the artificial electric dipole, i.e. the pacemaker dipole. It is assumed that the catheter is sited in the apex of the right ventricle and the distal end has been made negative. Two components of this latter dipole (or vector), when resolved as shown on to the same triangle used for resolving the components of the natural dipole, can only be negative. The resolved component on to the third side of the triangle can be negative or positive depending on the precise orientation of the electrodes within the heart.

Figure 10 gives a typical paced E.C.G. for Leads I, II and III in which the pacemaker spikes are negative on all three Leads. The magnitudes of the spikes vary with respiration, especially on Lead III. Lead III spikes are also very sensitive to the relative positions of the electrodes in the right ventricle with reference to a particular torso. Thus Lead III pacemaker spikes are often positive as shown in figure 11.

Although it is customary to make the distal electrode negative, a better threshold is occasionally obtained with the connections reversed, that is, with the proximal electrode made negative. Figures 12(a) and 12(b) show such a case in which at first operation the distal electrode was made negative, but at re-operation for change of a faulty generator the distal electrode was made positive. In such circumstances the directions of the pacemaker spikes are reversed as shown.

In the case of a bipolar myocardial or epicardial pacemaker, the pacemaker spikes as seen on a particular Lead of an E.C.G. can be either positive, negative or even zero depending on the polarities of the electrodes on the heart and their relative positions. If a lower output generator is used, as is sometimes the case, the pacemaker spikes will certainly be smaller than is the case with endocardial pacemakers. Indeed, the pacemaker spikes may be so small on <u>all</u> Leads that it may be difficult to see them on an E.C.G. obtained using a machine operating at the usual sensitivity of 1 mV ≡ 1 cm. Figures 13, 14, and 15 have been chosen to demonstrate positive, negative and zero pacemaker spikes on different Leads.

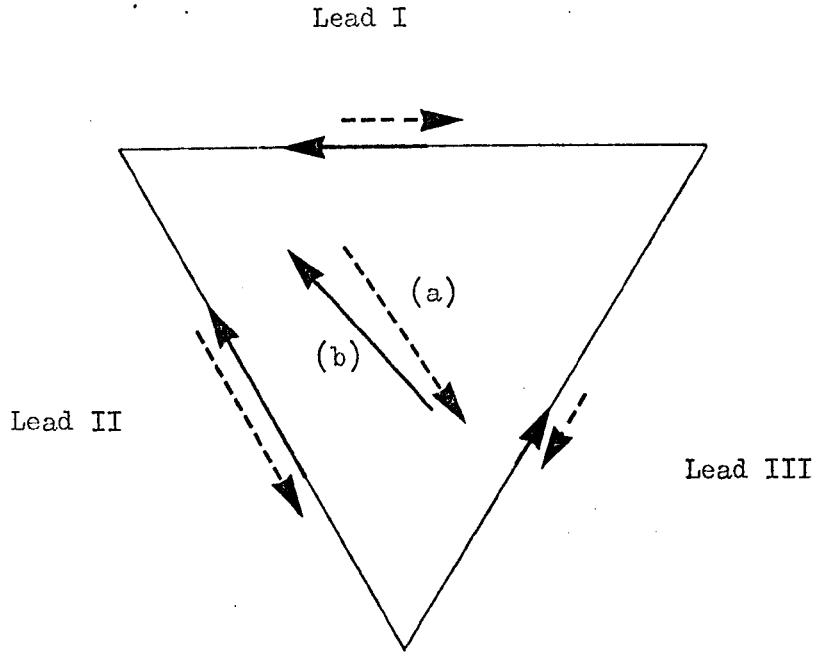


Figure 9. The "sense" of pacemaker spikes from an endocardial pacemaker.

(a) natural resultant electric dipole

(b) pacemaker electric dipole (distal electrode negative)

Patient 79

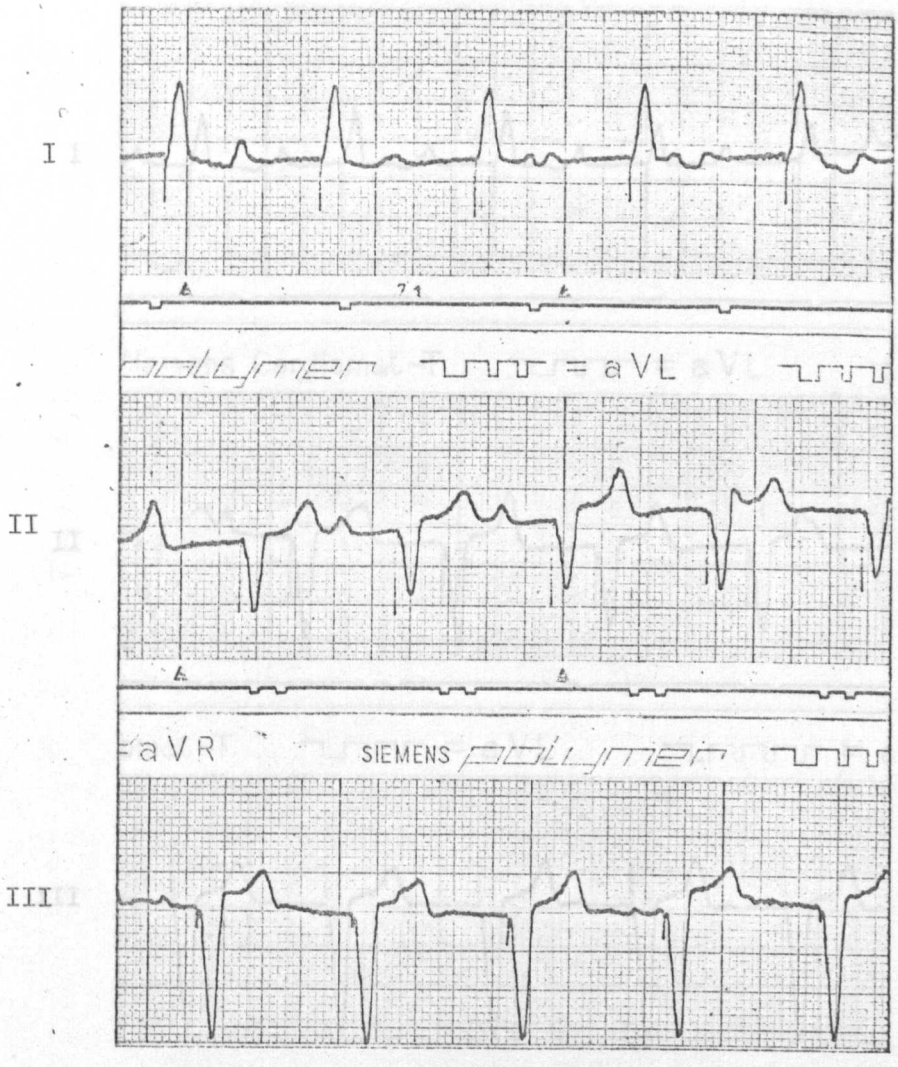


Figure 10. E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted (distal electrode, negative).

Patient 134

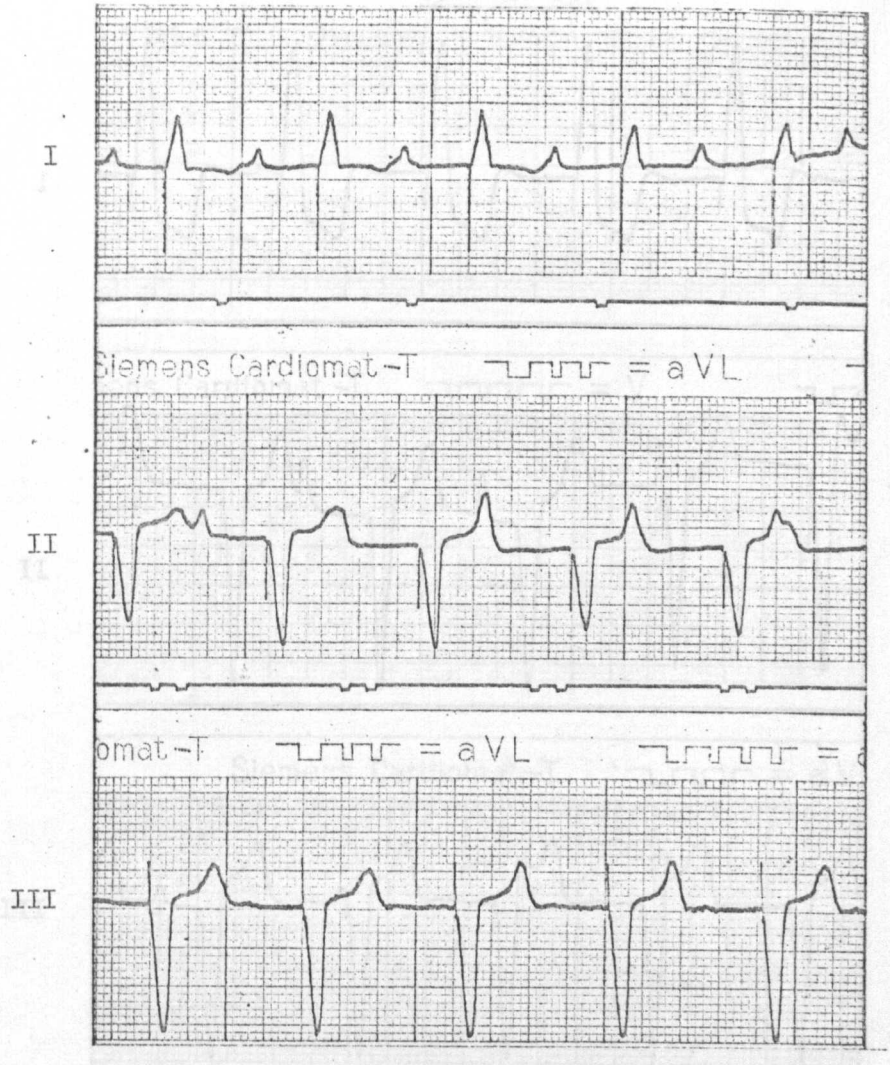


Figure 11. E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted (distal electrode negative).

Patient 157

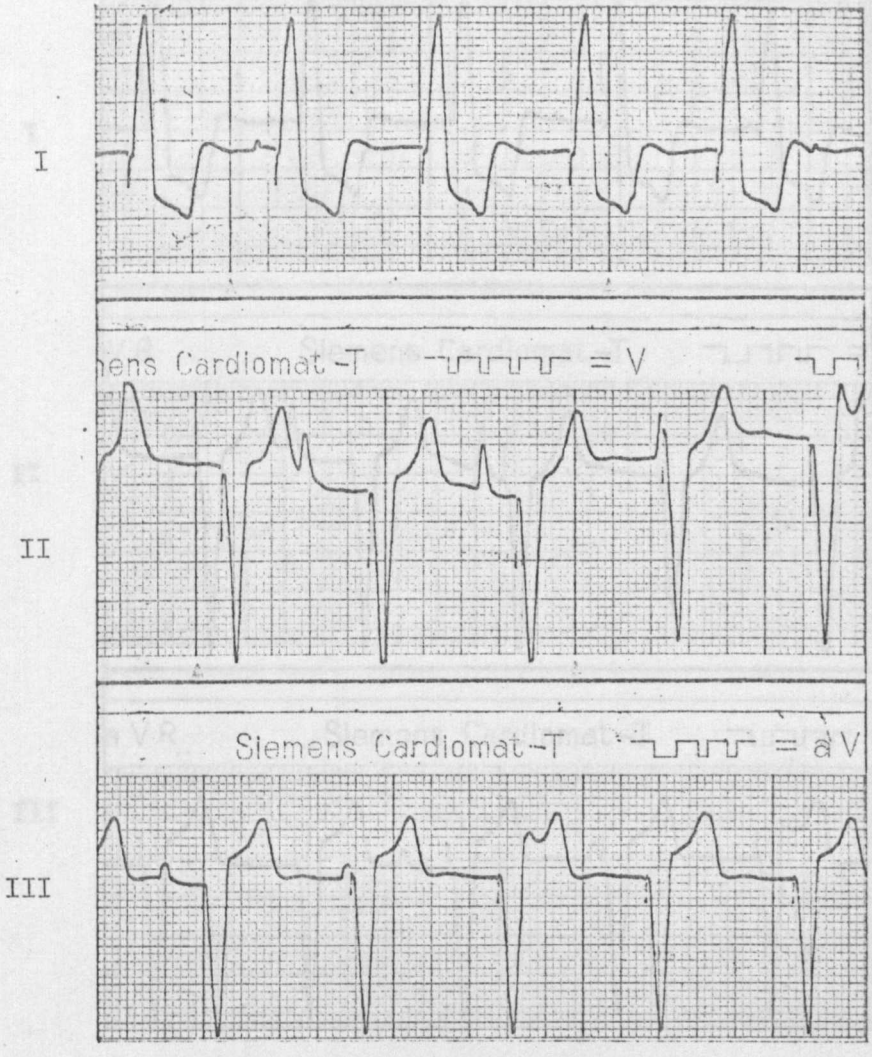


Figure 12(a). E.C.G. of patient having bipolar endocardial demand pacemaker implanted (distal electrode negative). (Pacemaker was not being inhibited).

Patient 157

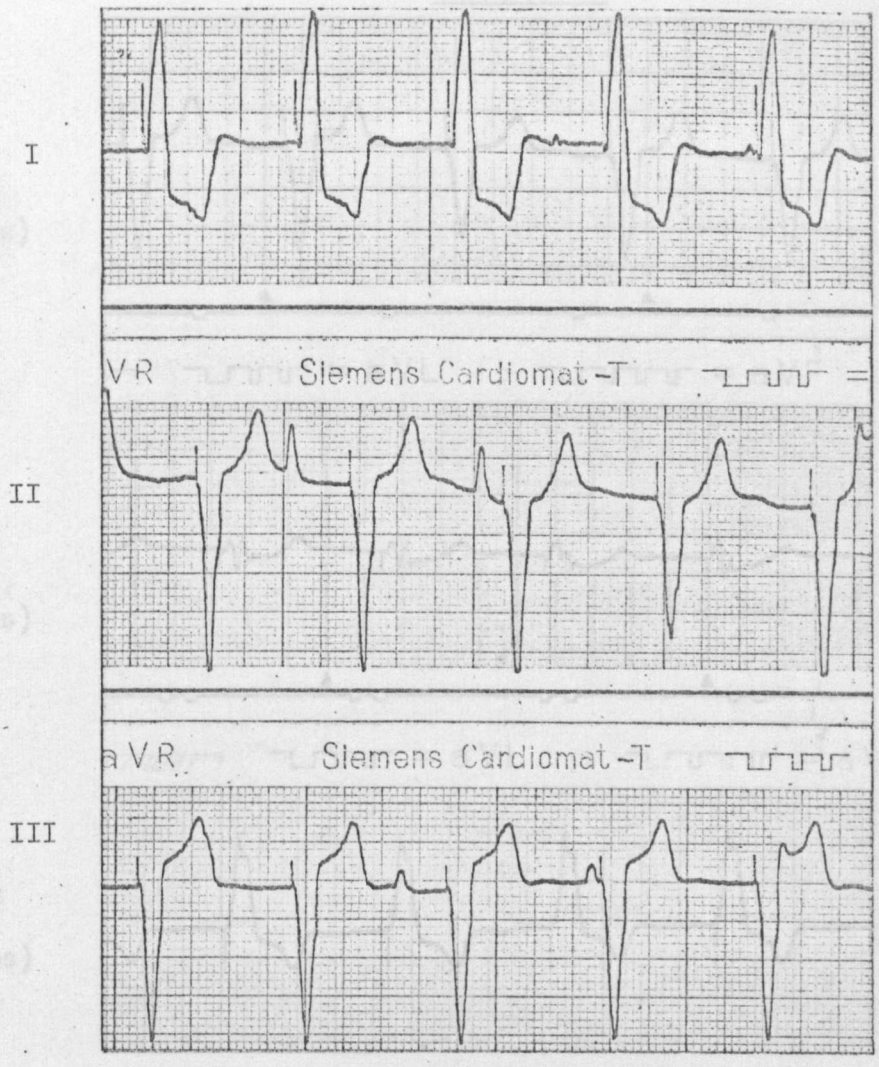


Figure 12(b). E.C.G. of patient having bipolar endocardial demand pacemaker implanted (distal electrode positive, i.e. connections to 12(a) reversed). (Pacemaker was not being inhibited).

Patient 126

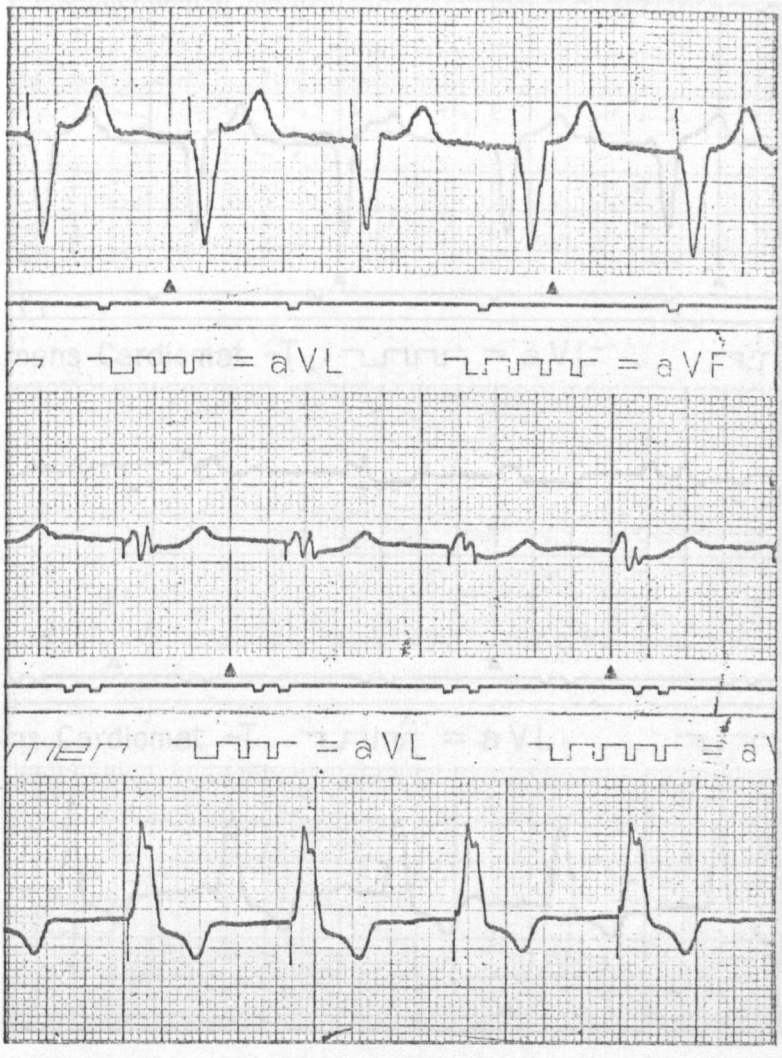


Figure 13. E.C.G. of patient having bipolar myocardial asynchronous pacemaker implanted.

Patient 130

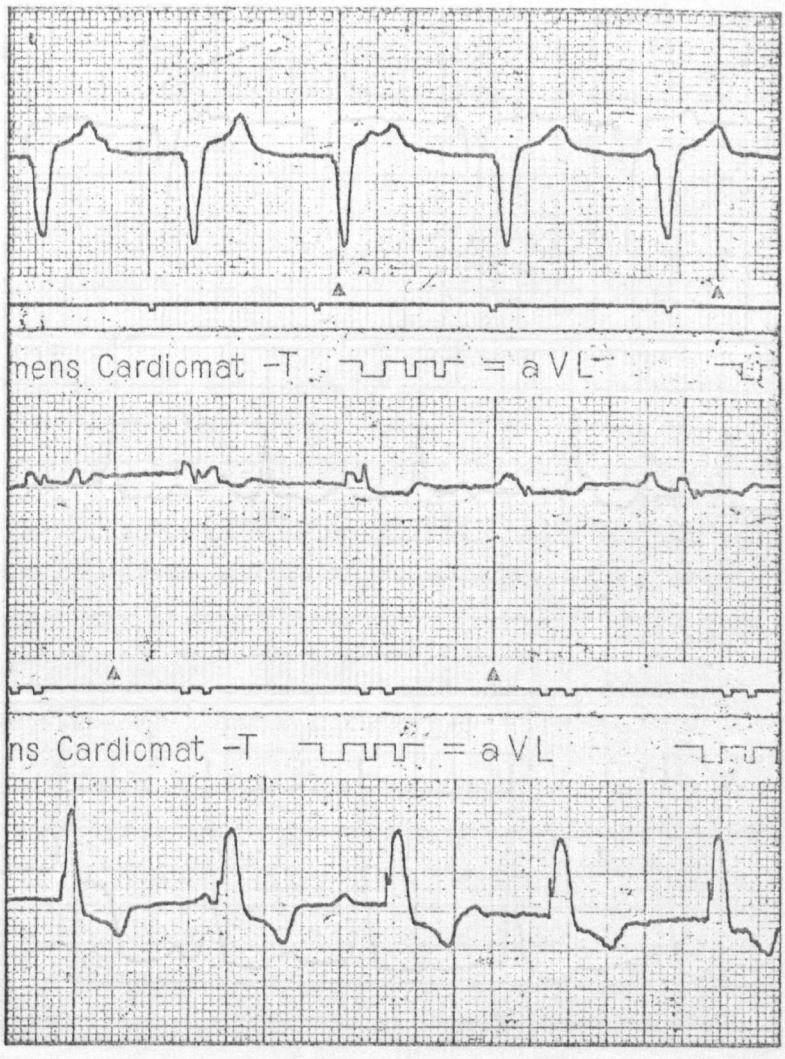


Figure 14. E.C.G. of patient having bipolar myocardial asynchronous pacemaker implanted.

Patient 17

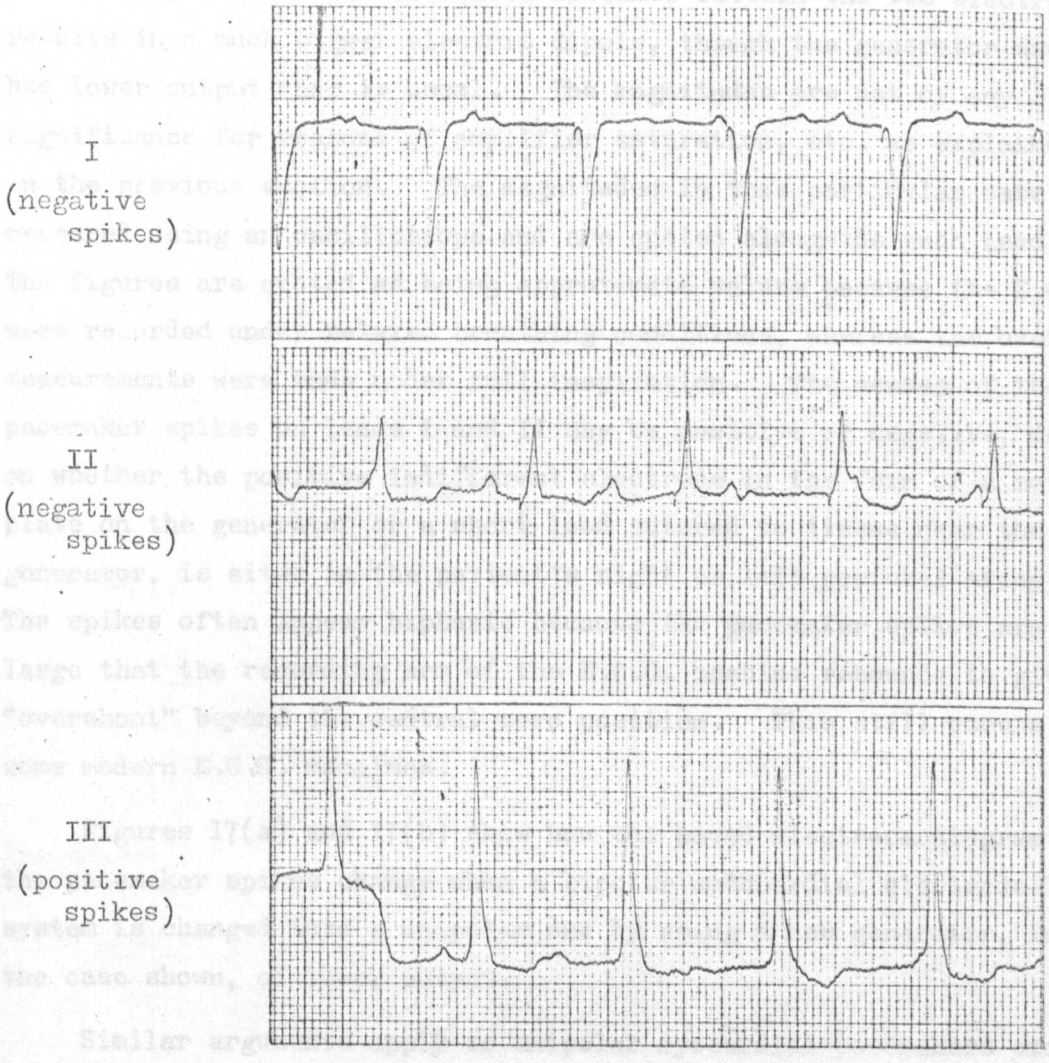


Figure 15. E.C.G. of patient having bipolar myocardial asynchronous pacemaker implanted.

Figure 16 shows pacemaker spikes produced by a unipolar endocardial pacemaker. The spikes are much bigger than is the case with bipolar pacemakers, because the increased distance between the two electrodes results in a much bigger electric dipole, though the generator used had lower output than is usual. The magnitudes are not of any significance for reasons of amplifier saturation, etc. as explained in the previous section. The magnitudes in this particular case were measured using an oscilloscope and are quoted alongside each Lead. The figures are quoted as being approximate values because the E.C.G.'s were recorded under relaxed breathing conditions, whereas the oscilloscope measurements were made under full inspiration. The senses of the pacemaker spikes on Leads I and II may be positive or negative, depending on whether the positive indifferent electrode in the form of a metal plate on the generator or a short lead sutured to tissue near the generator, is sited in the patient's right or left pectoral areas. The spikes often appear biphasic because the pacemaker spikes are so large that the recording arm of the E.C.G. machine rebounds to give "overshoot" beyond the central zero position. This still occurs with some modern E.C.G. machines.

Figures 17(a) and 17(b) show how the paced electrocardiogram and the pacemaker spikes change when a bipolar endocardial electrode-lead system is changed into a unipolar one by using a new generator, in the case shown, of lower output.

Similar arguments apply to unipolar myocardial pacemakers except that in such cases the generator is usually implanted in the abdominal region, for instance behind the rectus muscle. Leads II and III should therefore show positive pacemaker spikes assuming the electrode on the heart has been made negative, whereas Lead I pacemaker spikes may be positive or negative. Figures 18 and 19 show two cases. Once again the magnitudes of the pacemaker spikes bear little relationship to the actual magnitudes of the pacemaker pulses.

The observations regarding the sense of the pacemaker spikes apply to all types (and makes) of pacemakers whether they be asynchronous, demand or synchronous pacemakers. However, with the more sophisticated pacemakers, further deductions can be made from examination of an E.C.G.

Patient 18

I
(negative spikes)
139 mV

II
(negative spikes)
182 mV

III
(negative spikes)
37.5 mV

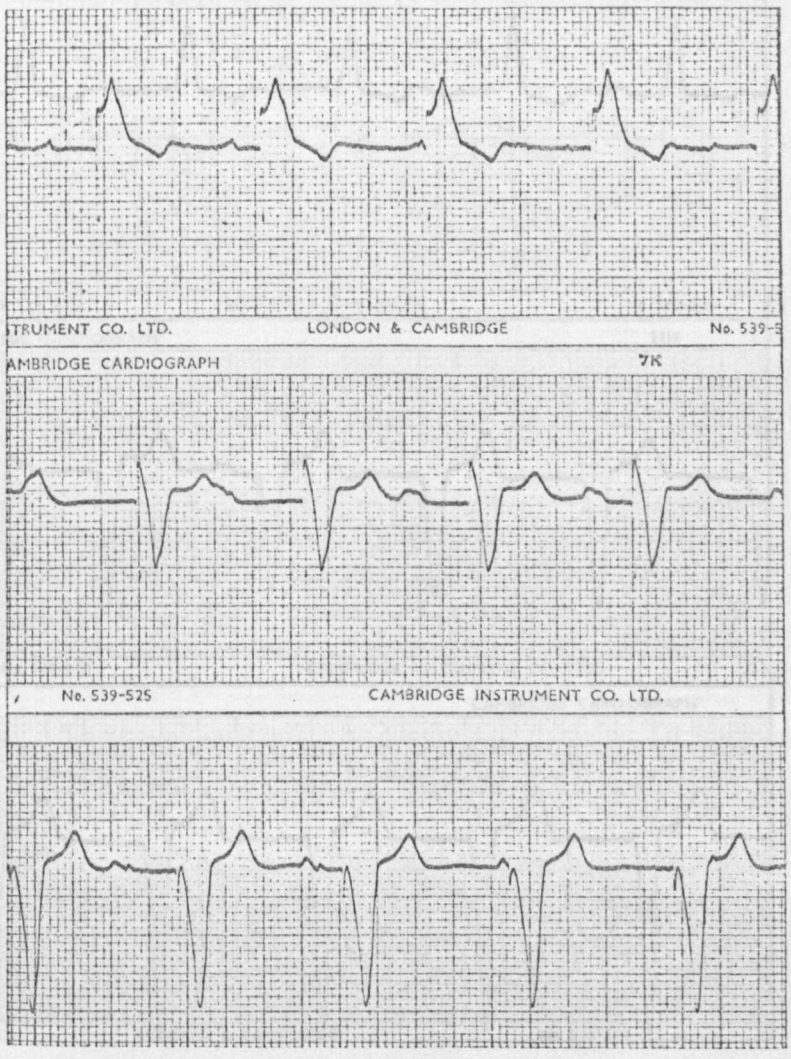


Figure 16. E.C.G. of patient having unipolar endocardial asynchronous pacemaker implanted. Low output generator implanted behind right pectoralis major.

Patient 17

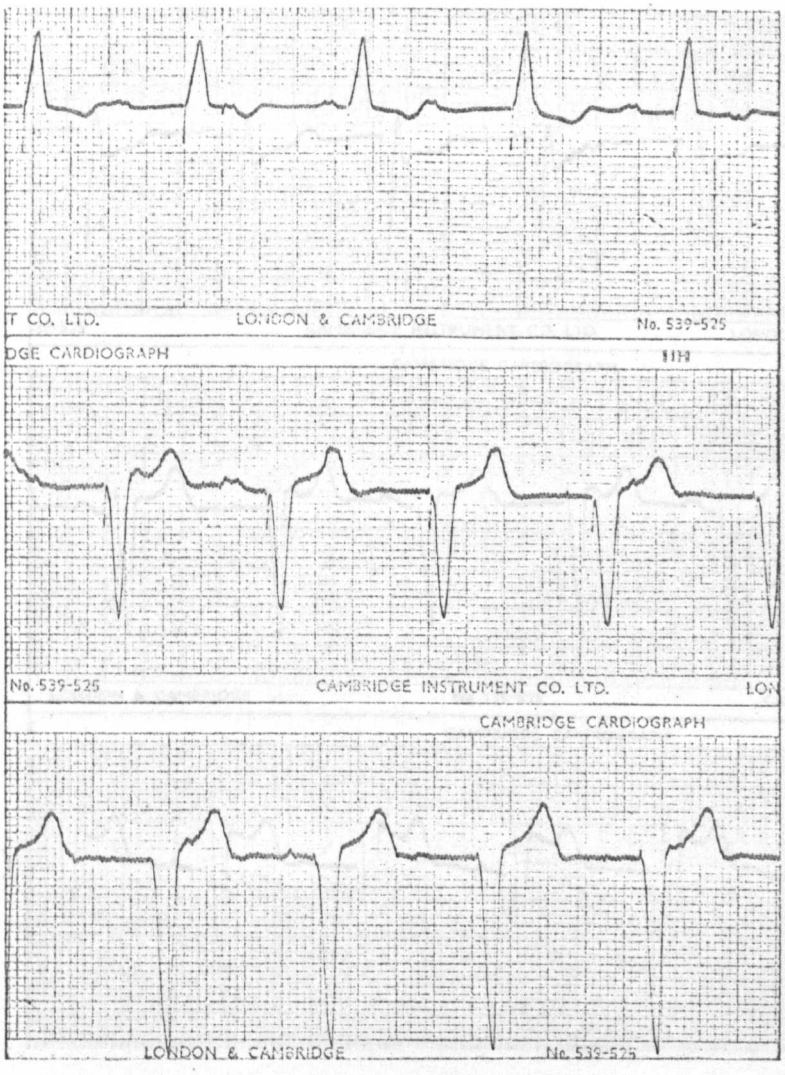


Figure 17(a). E.C.G. of patient having bipolar endocardial demand pacemaker implanted (no inhibitions taking place).

Patient 17

I
(positive spikes)
212 mV

II
(negative spikes)
87 mV

III
(negative spikes)
312 mV

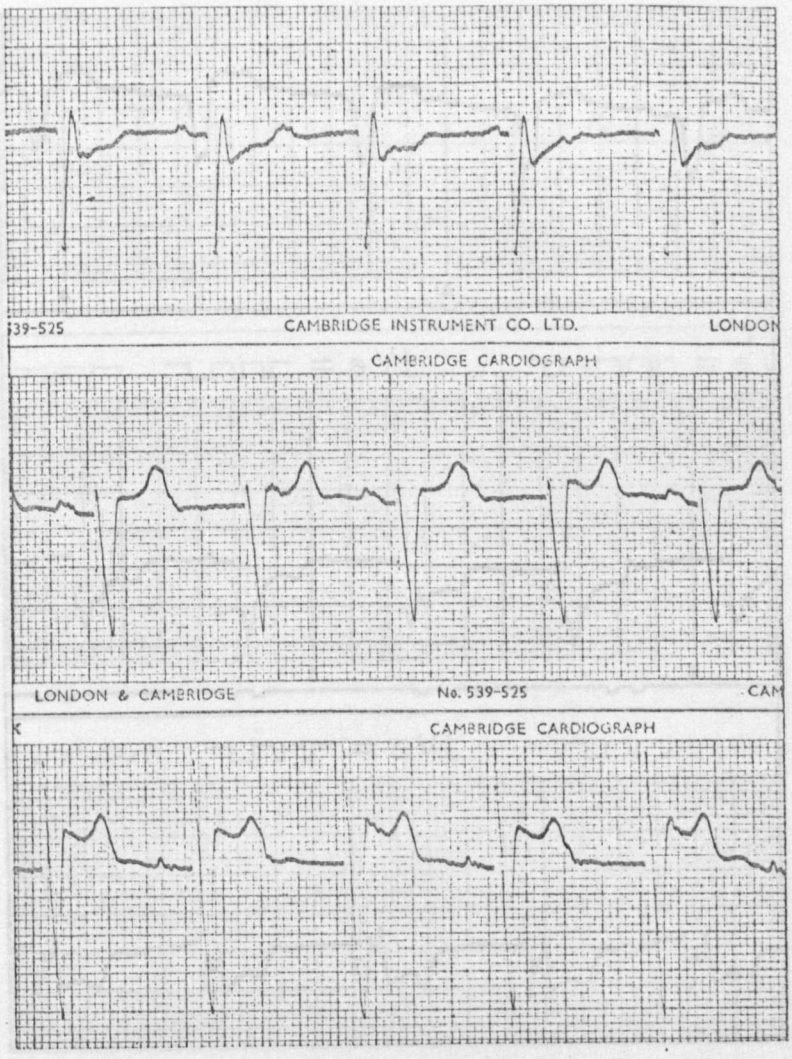


Figure 17(b). E.C.G. of patient in 17(a) after conversion to unipolar system. New unipolar demand generator of lower output implanted behind left pectoralis major. (No inhibitions taking place).

Patient 138

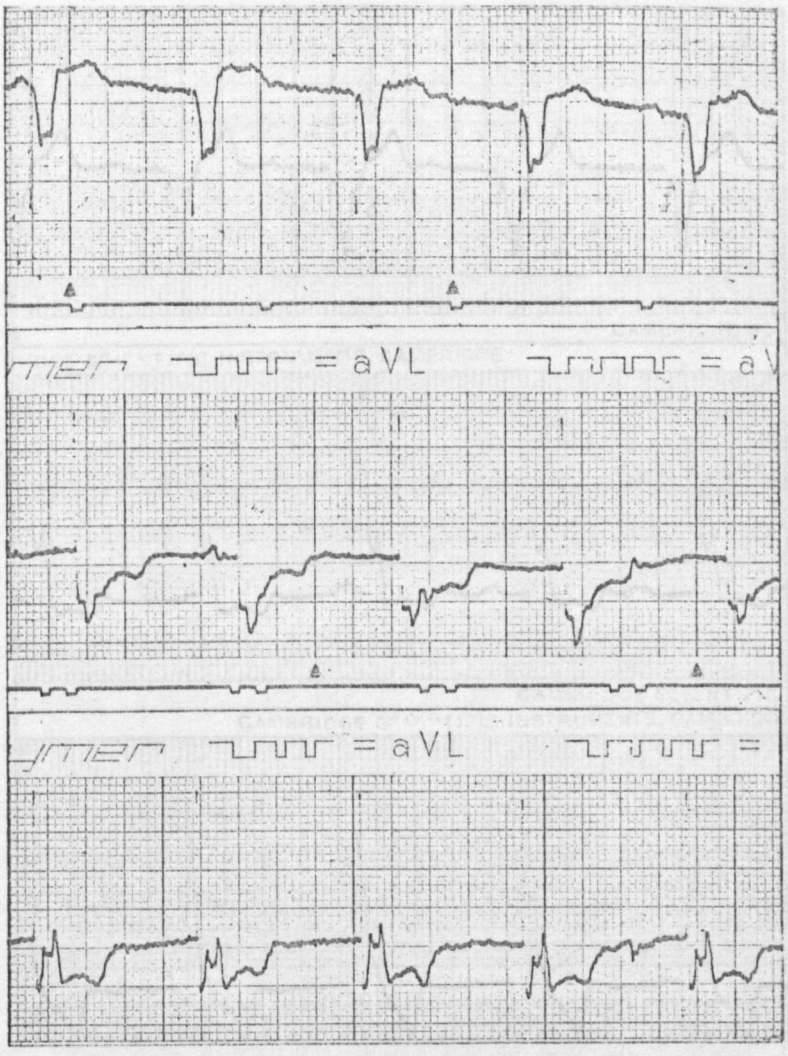


Figure 18. E.C.G. of patient having unipolar myocardial asynchronous pacemaker implanted (electrode in myocardium, negative).

Patient 91

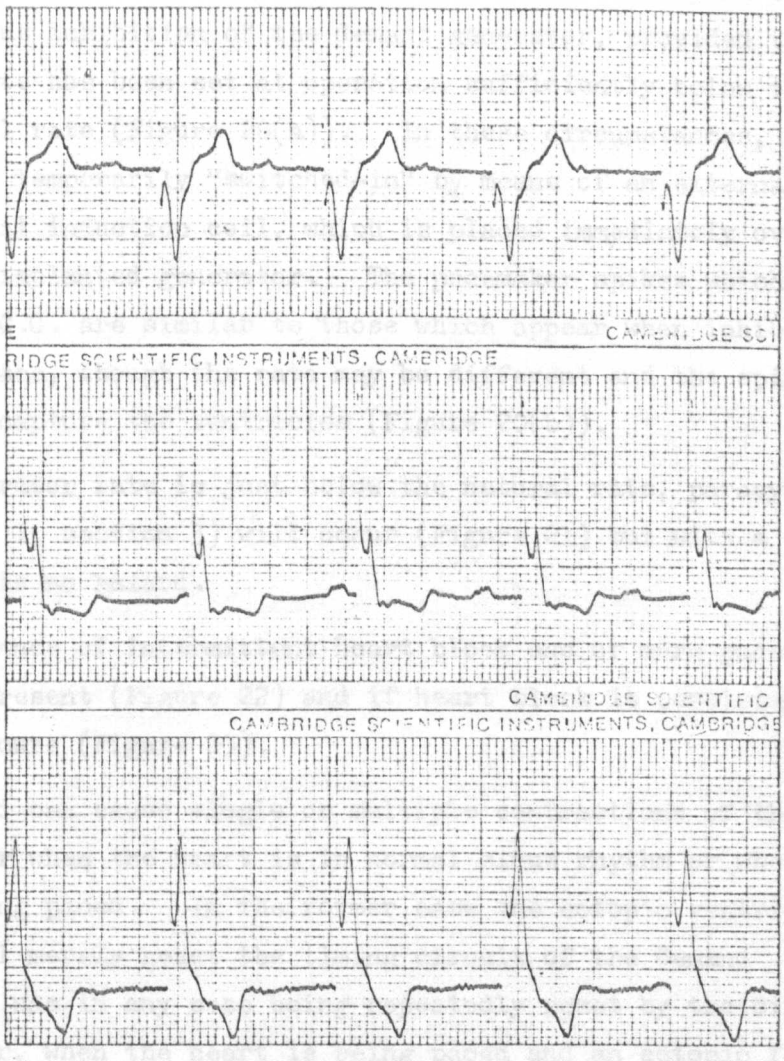


Figure 19. E.C.G. of patient having unipolar myocardial asynchronous pacemaker implanted. (Electrode in myocardium, positive).

In the case of a demand pacemaker, pacemaker spikes may be absent from the E.C.G. and yet the pacemaker may be functioning perfectly normally. Thus, whilst a patient is in sinus rhythm there will be continuous inhibition of the demand generator, provided that the generator rate has been set at operation sufficiently below the patient's natural rate (Figure 20(a)). In these circumstances, the generator can be temporarily "switched-in" by means of an external magnet or external induction coil, which is placed immediately over the site of the implanted generator. The pacemaker spikes which then appear on the E.C.G. are similar to those which appear when inhibition is not taking place, though the rate may be different and the spikes will not always capture the ventricles (Figure 20(b)).

If the generator rate is just below the natural rate, parasystole rhythm (see Part I, section 3) will occur (Figure 21) but with a demand generator there is no hazard.

In the presence of intermittent heart block one or more pacemaker spikes will be present (Figure 22) and if heart block is persistent no inhibition occurs (Figure 23).

Ectopic foci can cause single or multiple contractions of the ventricles either when the heart is in normal sinus rhythm or when the heart is being paced. In the former case the ectopic ventricular contractions will merely reset the timing circuit of the demand generator, which was in any case being repeatedly reset by the sinus rhythm. However, when the heart is being paced and an ectopic foci produces a ventricular contraction, this will reset the timing circuit of the demand generator, assuming it has not occurred during the generator refractory period following emission of a pulse, so that pacemaker spikes are delayed, rather than suppressed (Figure 24).

If a demand pacemaker is implanted in a patient having sinus bradycardia, there will be similar delays in the emission of the pacemaker pulse, when a naturally conducted contraction occurs outside the refractory period of the implanted generator (Figure 25).

With the ventricular synchronous pacemaker, pacemaker spikes should never be absent from the E.C.G. None of this type has been implanted in Glasgow so it is impossible to include an E.C.G. obtained directly from one of the Glasgow patients.

Patient 285

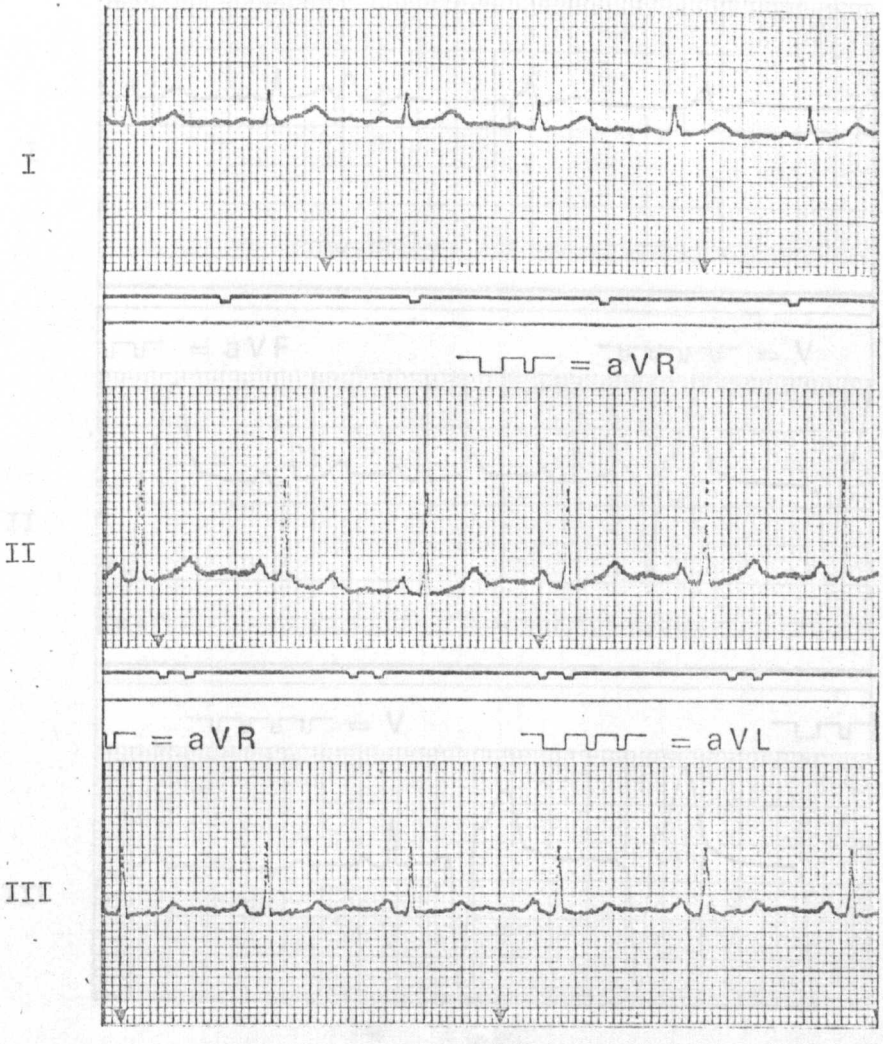


Figure 20(a). E.C.G. of patient having bipolar endocardial demand pacemaker implanted - showing continuous inhibition.

Patient 285

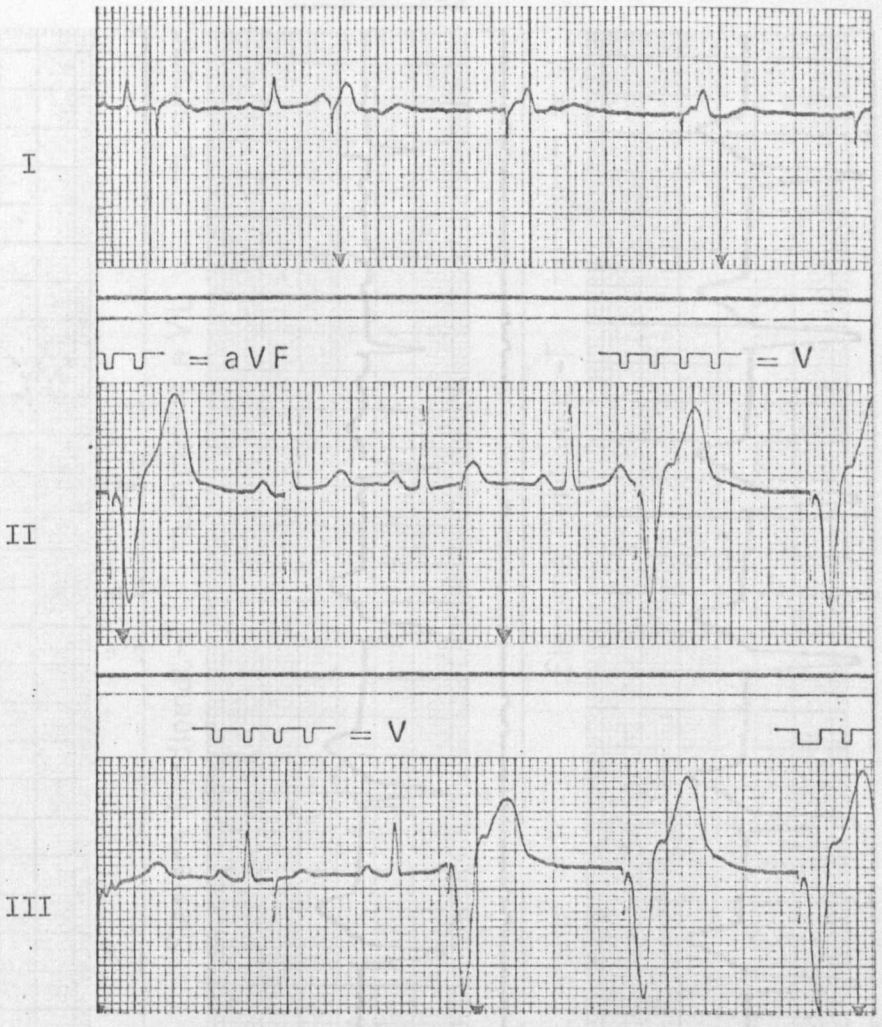


Figure 20(b). E.C.G. of patient having bipolar endocardial demand pacemaker implanted - normally inhibited pacemaker in patient referred to in Figure 20(a), "switched-in" by external magnet.

Patient 185

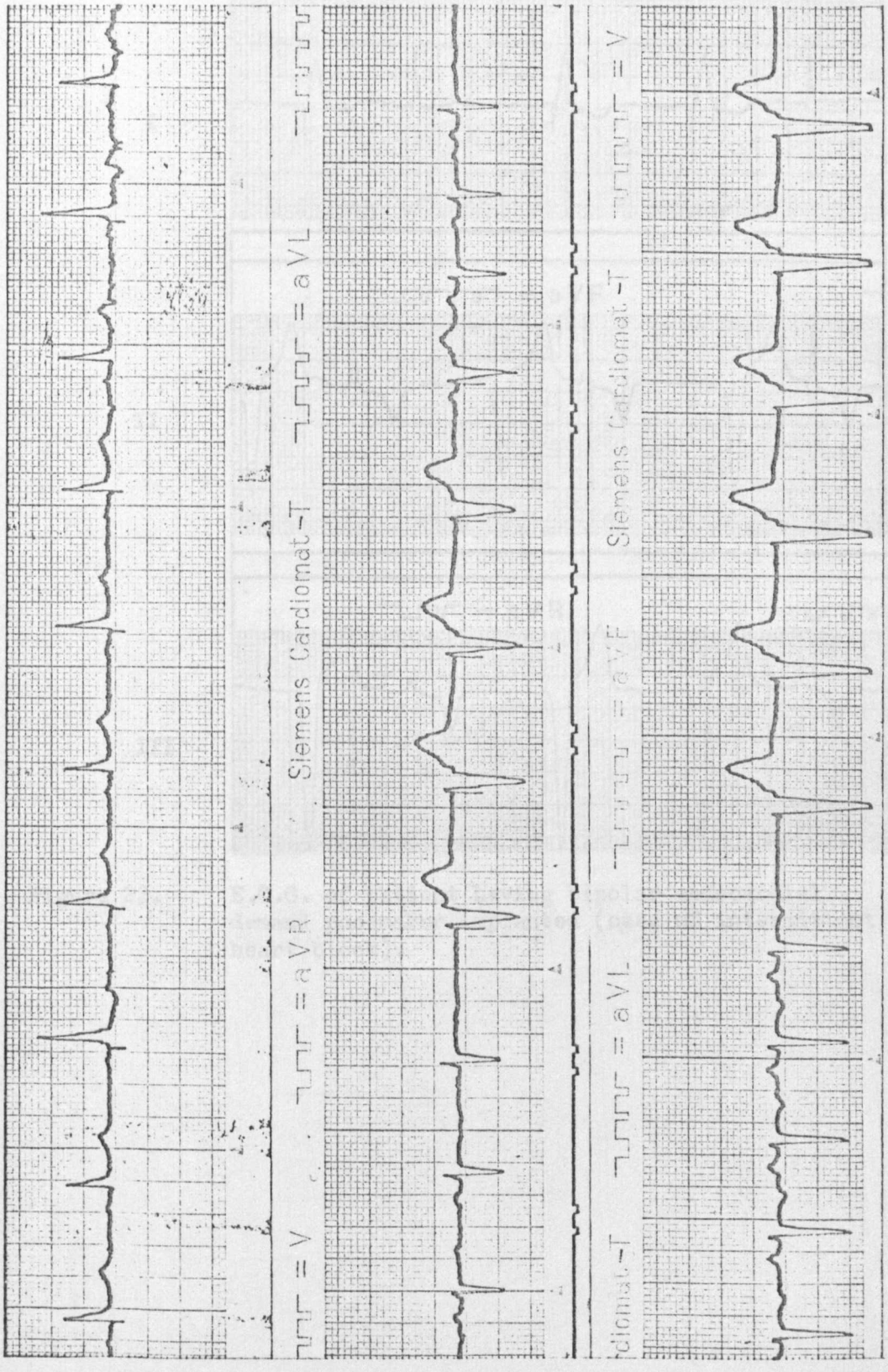


Figure 21. E.C.G. of patient having bipolar endocardial demand pacemaker implanted showing parasystole rhythm.

Patient 228

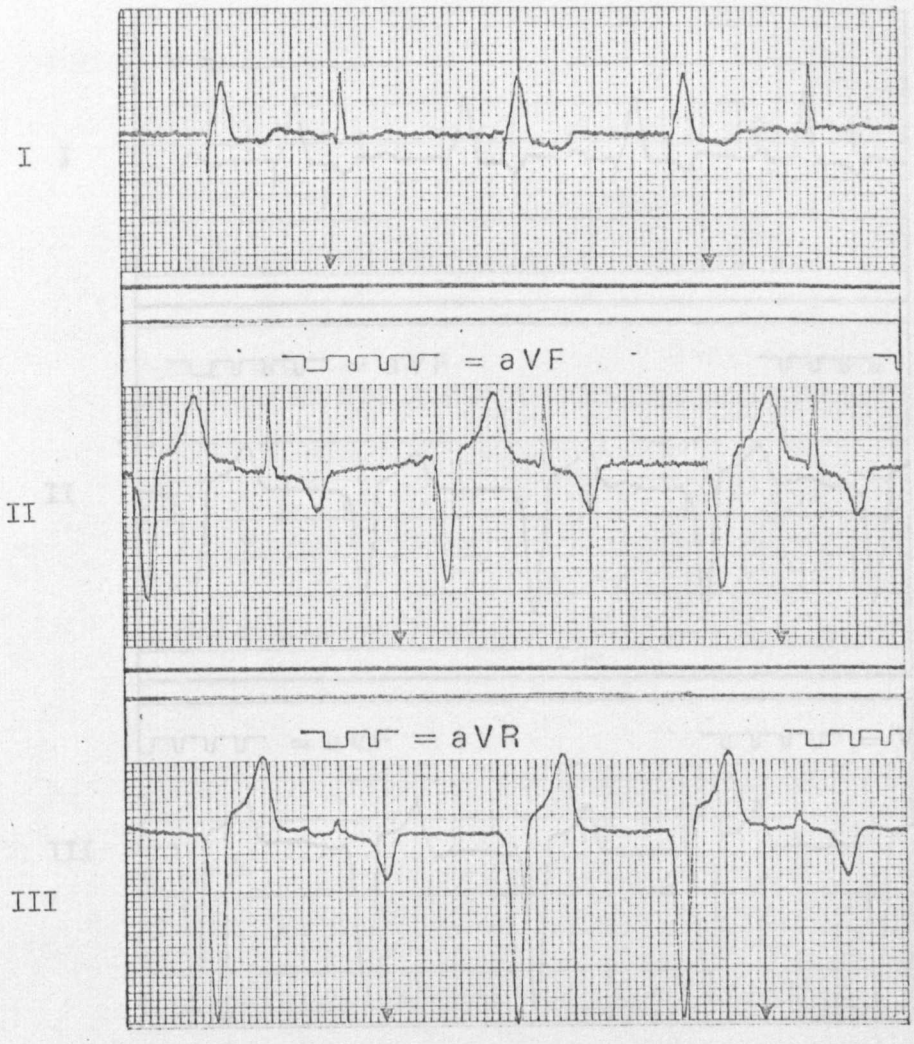


Figure 22. E.C.G. of patient having bipolar endocardial demand pacemaker implanted (case of intermittent heart block).

Patient 180

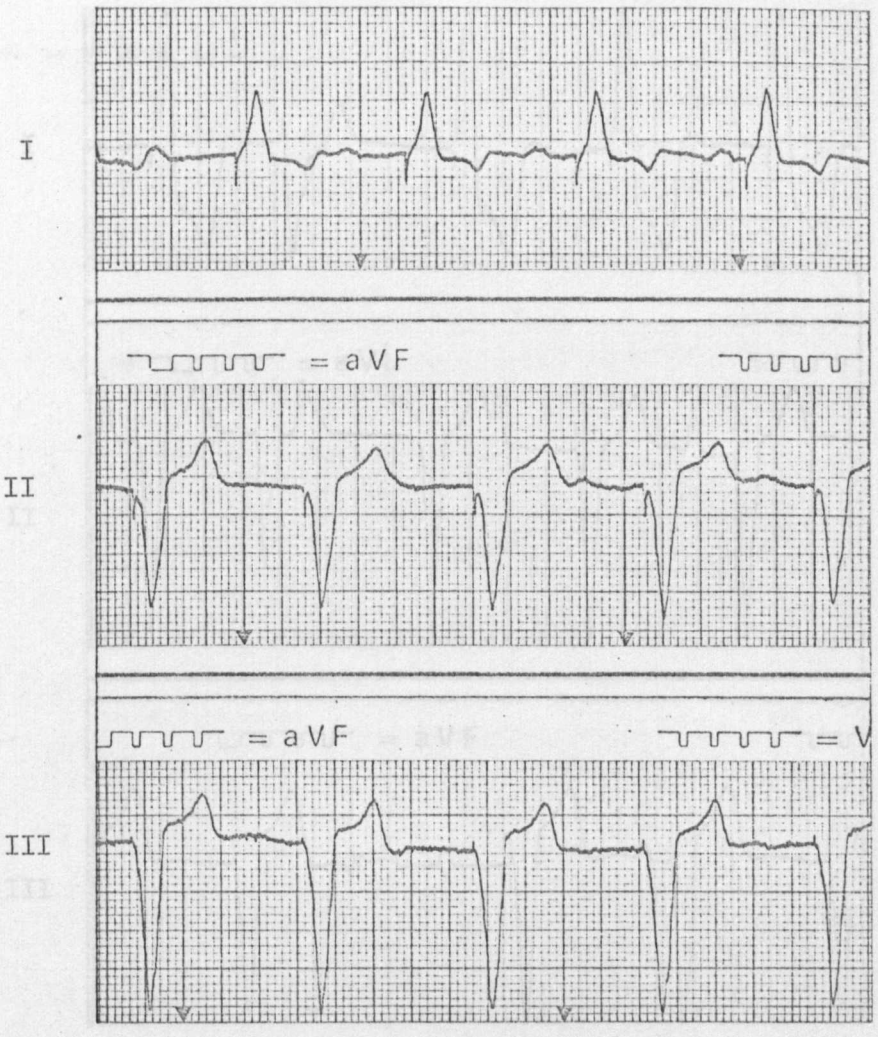


Figure 23. E.C.G. of patient having bipolar endocardial demand pacemaker implanted (Case of complete heart block)

Patient 157

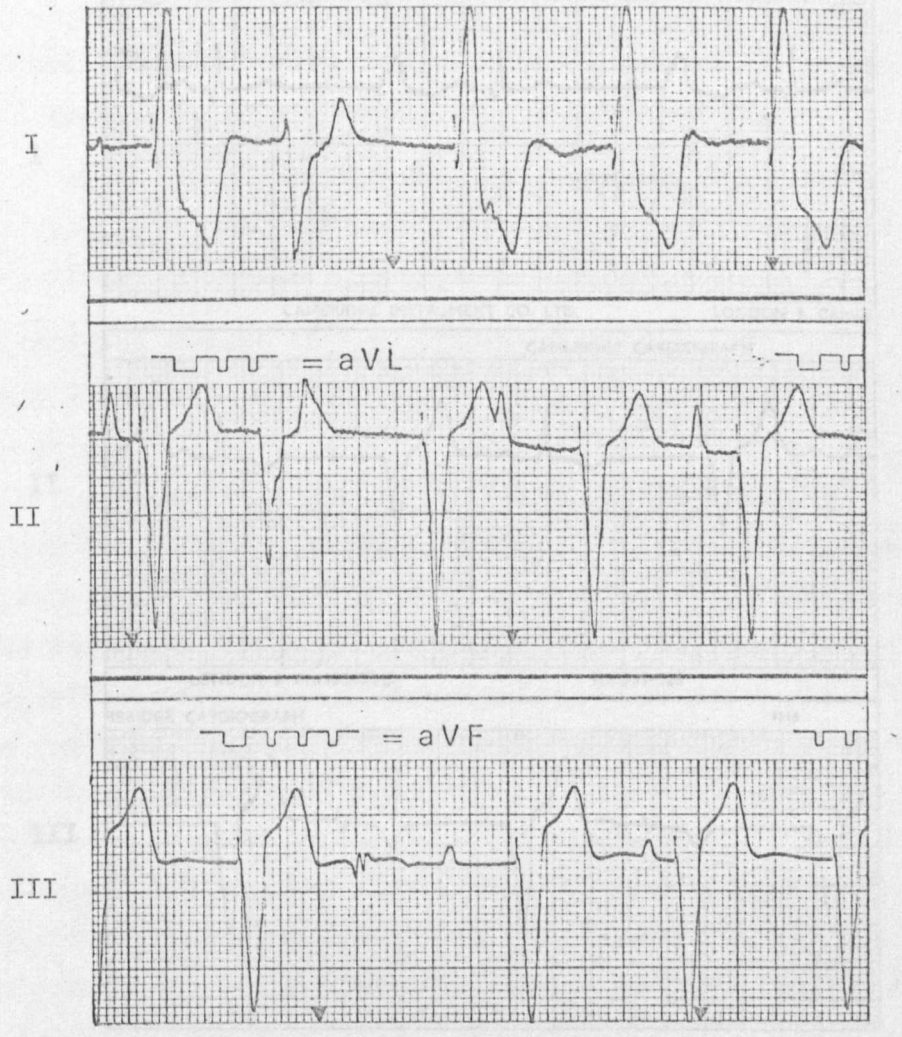
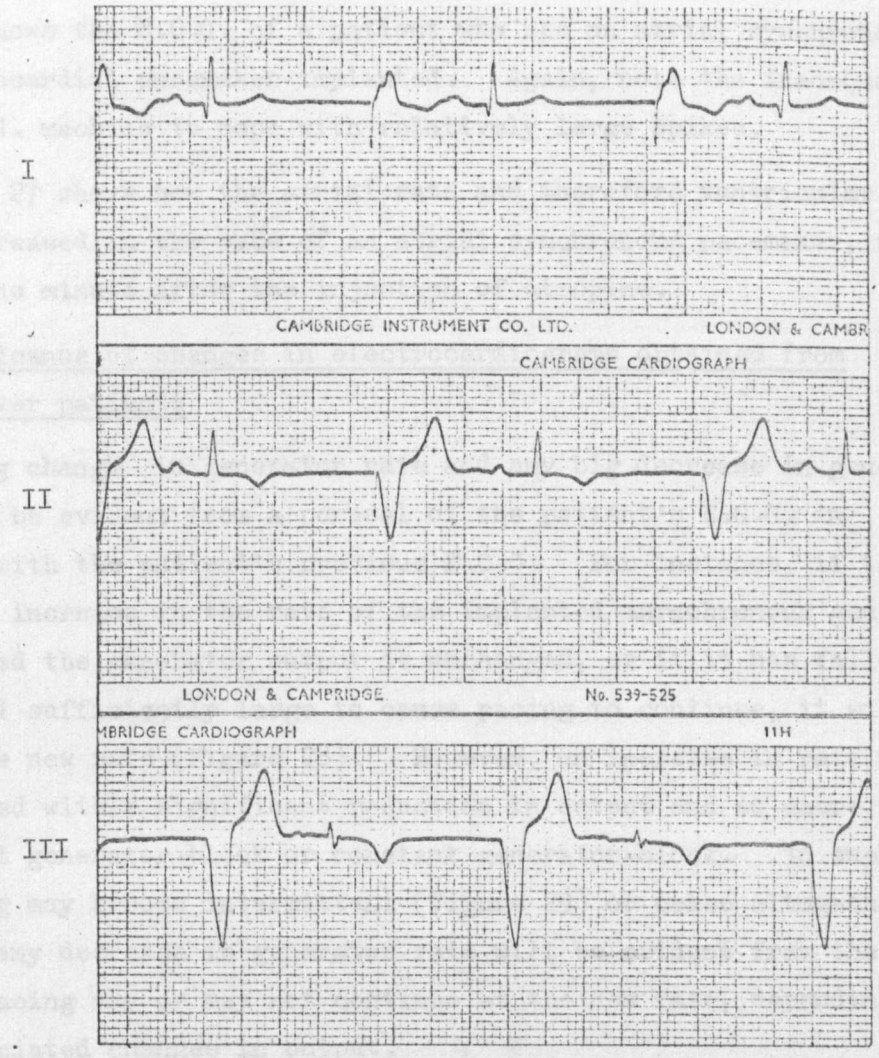


Figure 24. E.C.G. of patient having bipolar endocardial demand pacemaker implanted - showing delays in emission of pacemaker spikes from an ectopic focus (distal electrode positive).

Patient 115



Patient 25. E.C.G. of patient having bipolar endocardial demand pacemaker implanted showing delays in emission of pacemaker spikes (from sinus bradycardia).

With an atrial synchronous pacemaker, the pacemaker spike is synchronised with the atrial activity so that a pacemaker spike should follow each "P" wave after a delay of about 120 to 160 milliseconds. Figure 26 shows the E.C.G. of a patient who has an atrial synchronous unipolar myocardial pacemaker implanted. Again, note the inadequacy of the E.C.G. machine to cope with relatively large spikes.

Figure 27 shows how the atrial rate and therefore ventricular rate is increased in the case of an atrial synchronous pacemaker, in less than one minute after the injection of atropine.

4.3 Significance of changes in electrocardiograms obtained from pacemaker patients

Any big change in generator rate and any big decrease in generator output will be evident from a perusal of the patient's E.C.G. in comparison with the patient's previous E.C.G. For instance, if there has been an increase in the rate of the implanted asynchronous generator, then provided the generator output is unchanged, or if it has fallen but is still sufficiently large to cause pacing to continue, it will do so at the new rate (Figure 28). However, an increase in rate might be associated with a significant reduction in output and so cause intermittent generator-block or constant generator-block. In such cases pacing may become intermittent (Figure 29) or cease altogether. Similarly, any decrease in generator rate will be evident from the E.C.G. and again pacing may or may not continue at the new rate, depending on the associated changes in output.

Other changes in the E.C.G. are possible with rate changes in the case of demand generators. If the rate of a demand generator, which was hitherto being continuously inhibited by sinus rhythm, increases to a value above the sinus rate, then inhibition will no longer occur, and provided the generator output has not simultaneously decreased too much, pacing will occur at the new rate. The converse is also true, namely that a demand generator which was not being inhibited because its rate was greater than sinus rate suddenly becomes inhibited when its rate falls below the latter rate. Sinus rhythm supervenes and a paced rhythm will only occur when heart-block develops assuming the generator output has not fallen sufficiently to produce generator-block .

Patient 26

I
(negative spikes)
12 mV

II
(positive spikes)
58 mV

III
(positive spikes)
68 mV

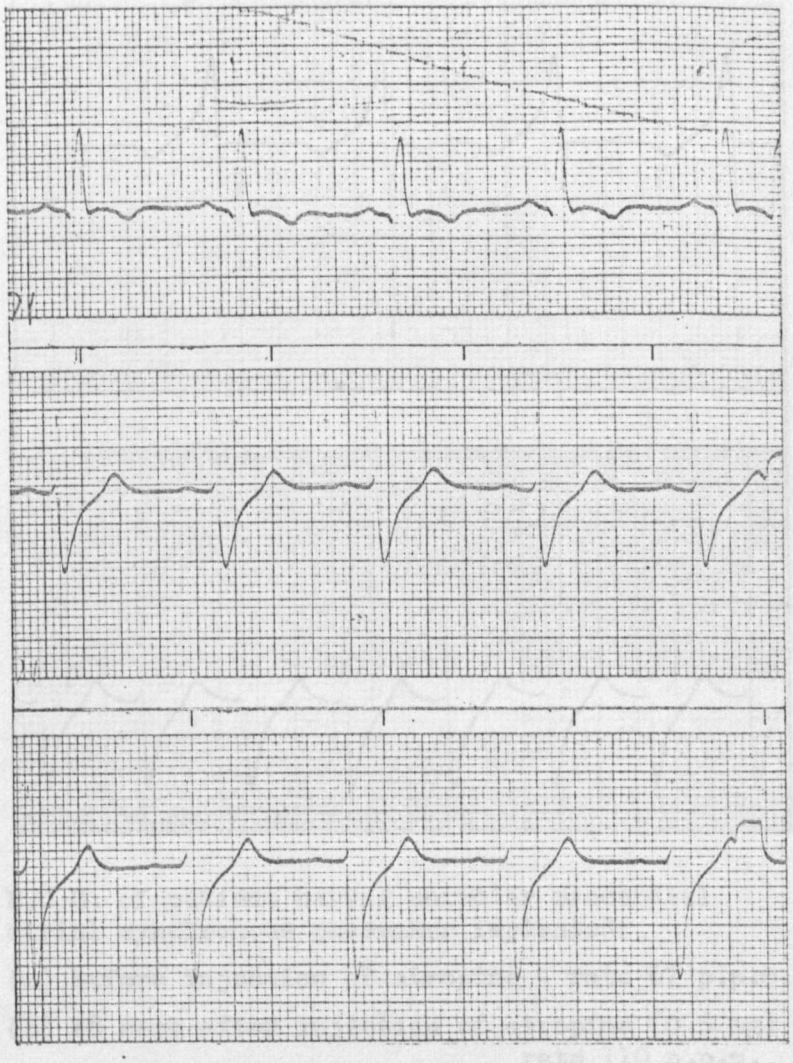


Figure 26. E.C.G. of patient having unipolar myocardial atrial synchronous pacemaker implanted.

Patient 26

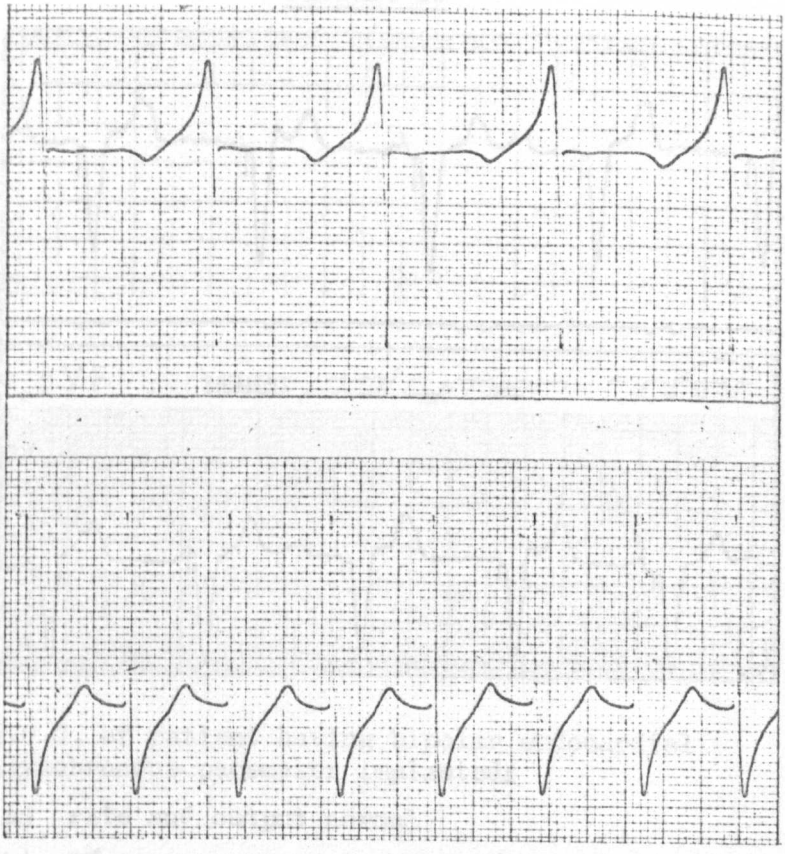


Figure 27. E.C.G. of patient having unipolar myocardial atrial synchronous pacemaker implanted:

(a) before injection of atropine - rate 67 p.p.m.

(b) 48 secs after injection of atropine (0.6 mg) - rate 110 p.p.m.

Patient 86

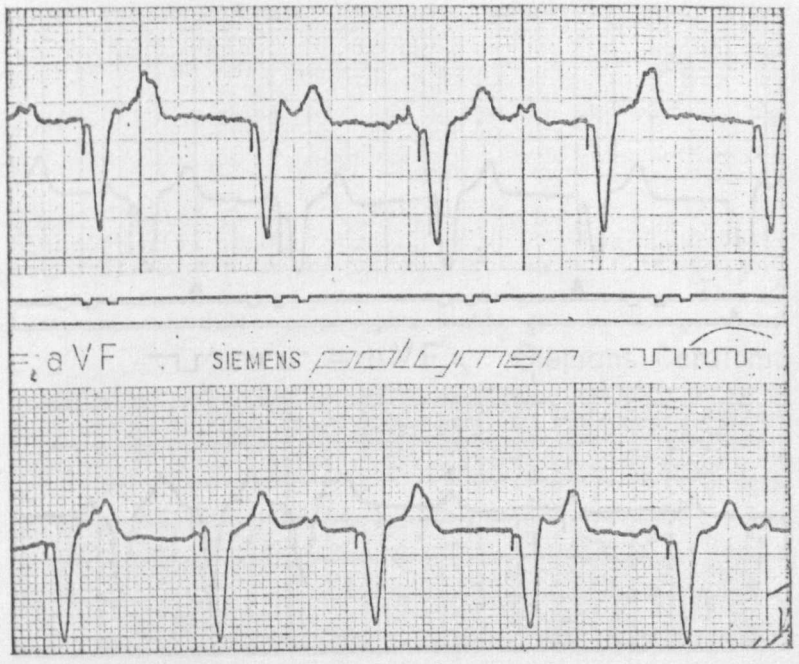


Figure 28. E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted:

(a) rate and output normal

(b) 9% increase in rate and 26% fall in output

Patient 81

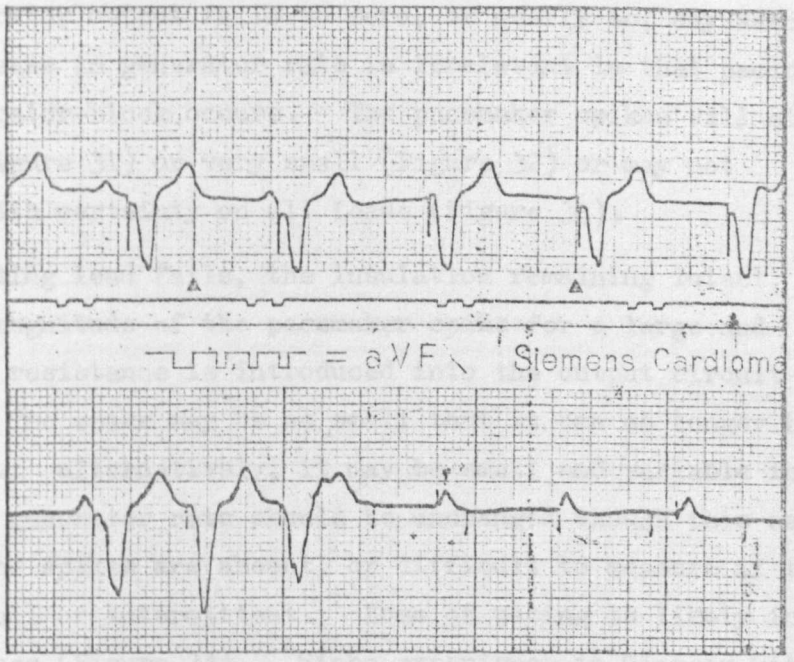


Figure 29. E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted:

(a) rate and output normal

(b) 71% increase in rate and 57% fall in output

A very big increase in generator rate, without a sufficiently big reduction in output to cause loss of pacing, will induce hazardous tachycardias (Figure 30).

If the generator output falls to zero, or nearly so, any associated increase or decrease in generator rate is irrelevant in that pacing ceases when generator-block occurs. The pacemaker spikes will at best be small (Figure 31) or very small (Figure 32) or may not be discernible with certainty on all Leads (Figure 33).

If a conducting lead fails, the insulation remaining intact, this will effect the magnitude of the pacemaker spike for a large and perhaps variable resistance is introduced into the output circuit of the generator. The spike may be so small that it can no longer be seen on an E.C.G.; alternatively, it may be small and variable in magnitude. The generator rate should be unchanged though this cannot be measured if the spikes are absent, or difficult to measure if they are extremely small or intermittent. Loss of pacing is likely in these circumstances (Figure 34). Since experience in Glasgow with several hundred Medtronic generators has shown that intermittent generator faults are rare, any lack of regularity in the pacemaker spikes with this make of generator would suggest that a conductor has broken rather than a generator has failed (assuming that inhibition is not taking place in the case of a demand generator).

It was shown in sub-section 4.2 that the pacemaker spike can be of either sign, depending on the conditions obtaining in a particular patient. However, any change in the sign of a pacemaker spike will be of some significance. If measurements are being made, for the first time, after a pacemaker operation and the results obtained are different from those expected, then the connections to the patient's limbs must be checked to ensure that they have not been inadvertently reversed. For instance, a common mistake, by even the most experienced personnel, is to connect the right arm lead to the left arm, and vice-versa. This is excusable because any experienced person immediately checks the connections to the limb electrodes whenever unusual results are obtained. Further, if the E.C.G. is being taken for the first time after a bipolar pacemaker has been implanted, it could indicate that the distal electrode has been made positive, though this may have been done intentionally.

Patient 43

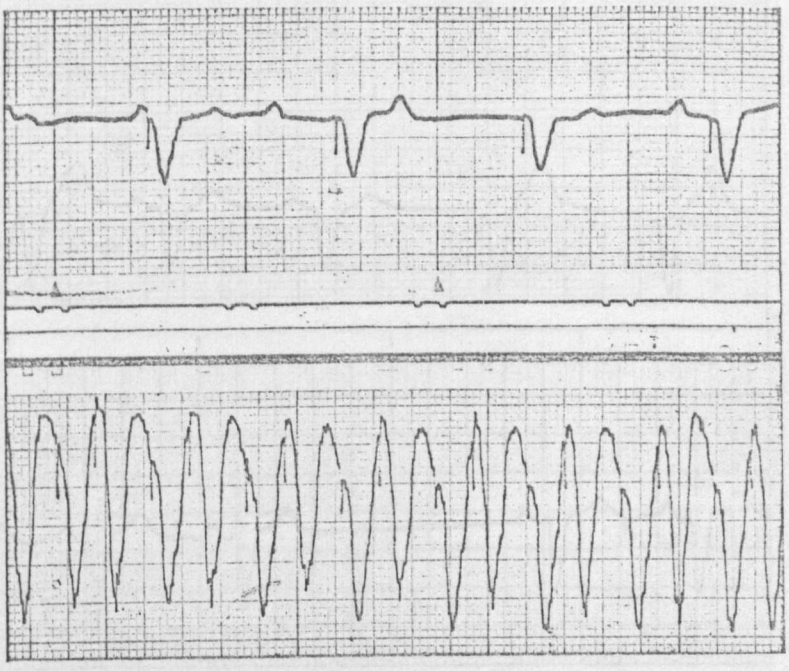


Figure 30. E.C.G. of patient having bipolar endocardial demand pacemaker implanted:

(a) rate and output normal

(b) enormous increase in rate and small decrease in output

Patient 144

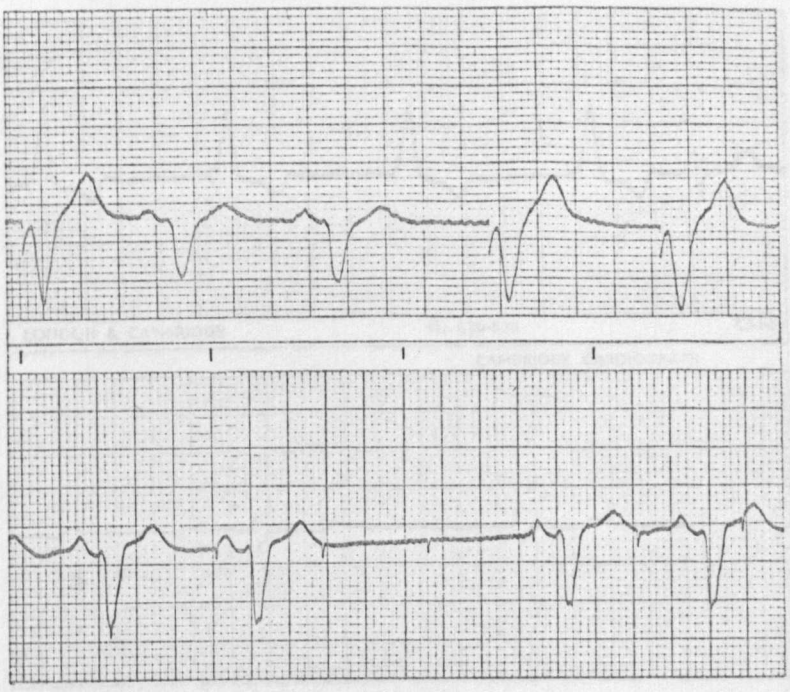


Figure 31. E.C.G. of patient having bipolar endocardial demand pacemaker implanted

(a) rate and output normal (with some inhibitions)

(b) 63% increase in rate and almost 100% fall in output

Patient 53

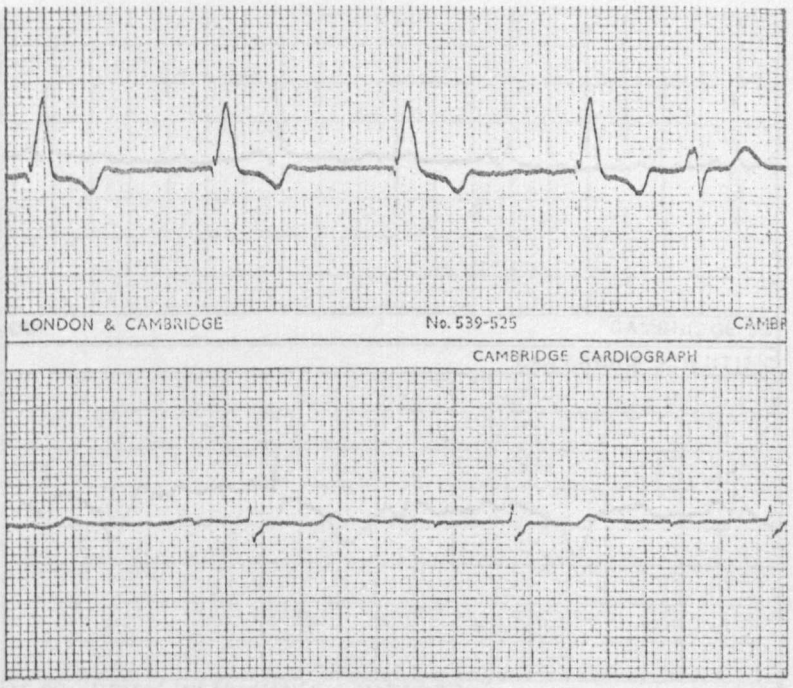


Figure 32. E.C.G. of patient having bipolar endocardial demand pacemaker implanted.

(a) rate and output normal

(b) 19% decrease in rate and approximately 100% fall in output

Patient 96

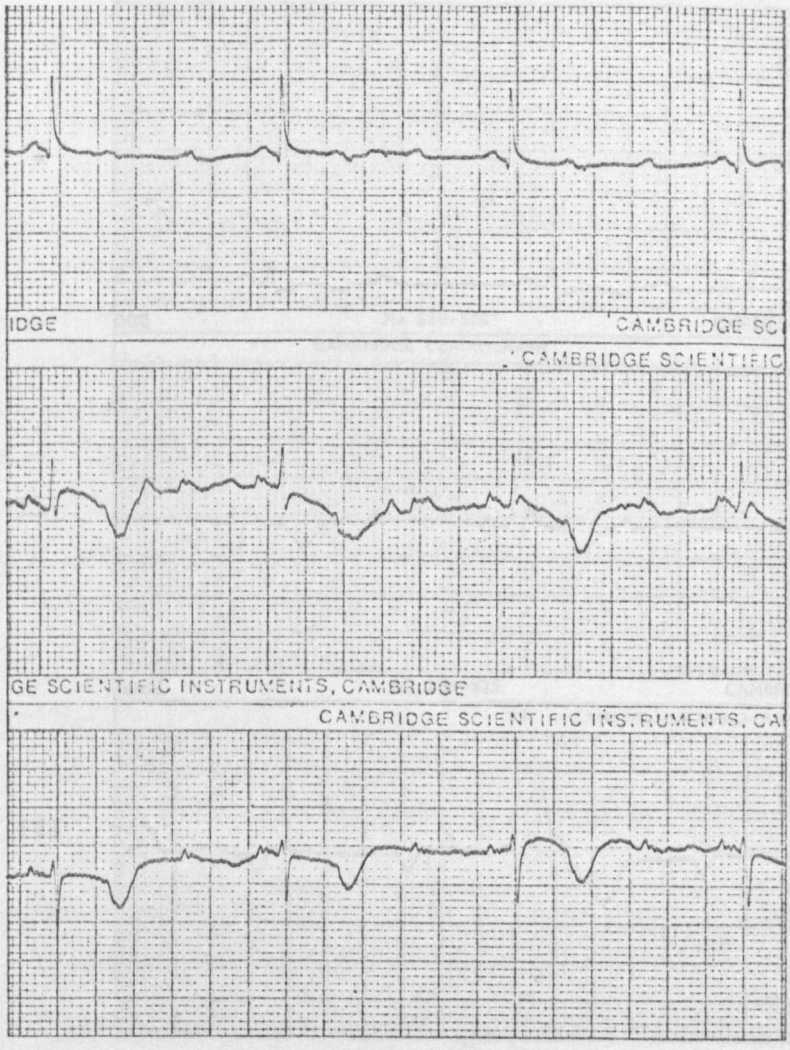


Figure 33. E.C.G. of patient having bipolar endocardial demand pacemaker implanted. Rate had decreased by 32% and approximately 100% fall in output.

Patient 48

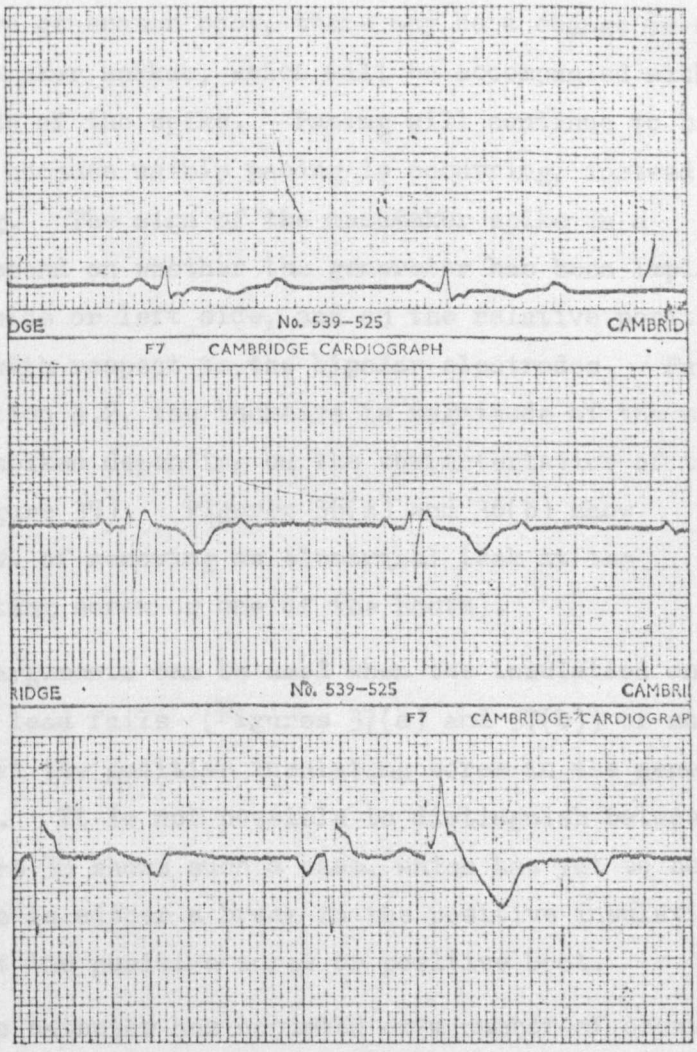


Figure 34. E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted. Conducting lead broken. Single pacemaker spike visible on Lead III.

If the insulation on the negative conducting lead of a bipolar electrode-lead system fails, or an electrical leak occurs at the negative insulating screw in the generator, or insulating lubricant seeps out of the negative generator boot, there may be a change in some of the signs of the pacemaker spikes, which will be accompanied with an increase in the magnitude of the spike. Pacing will continue to be satisfactory. This is because unibip pacing is occurring, instead of merely bipolar pacing. The sign of the pacemaker spike in a particular Lead, will depend on whether the generator has been implanted in the patient's right side or left side, and on the relative positions of the break (or leak) with respect to the bipolar electrodes. Further, as explained in sub-section 4.2, the increase in magnitude of the spike may result in biphasic spikes depending on the characteristics of the E.C.G. machine used (Figure 35). Figures 36(a) and 36(b) show the effects on the E.C.G. of removing an electrical leak at the generator (at an insulating screw or one of the boots).

Precisely similar arguments can be used when the insulation on the positive conducting lead fails (Figures 37(a) and 37(b)) or an electrical leak occurs at the positive insulating screw in the generator or at the positive boot. It is not possible to distinguish between a break and a leak. Figure 38 shows such a case, which has yet to be resolved, in which there is either a break in the positive insulation or an electrical leak at the positive screw or positive boot.

Displacement of the catheter has occurred on a number of occasions (see Part III). Displacement into another part of the ventricle will give a different paced physiological signal (assuming pacing is still continuing) and possibly pacing spikes of different signs (Figures 39(a) and 39(b)). In cases of very bad displacement, e.g. to the region of the tricuspid valve, pacing spikes may be absent and pacing may have ceased. Figure 40 shows such a case in which some of the absent spikes are evidently not the result of inhibitions. Figure 41 shows a less severe case of displacement in which the catheter was withdrawn "over the spine": pacing became intermittent though sinus controlled contractions were still able on occasions to inhibit the demand pacemaker.

If a patient returns, either intermittently or continuously, to sinus rhythm after a period of pacing (or if an asynchronous generator has been implanted when a demand one should have been used) there will be competitive pacing (Figure 42). The E.C.G. might also be complex during the period immediately after implantation, when ectopic foci

Patient 53

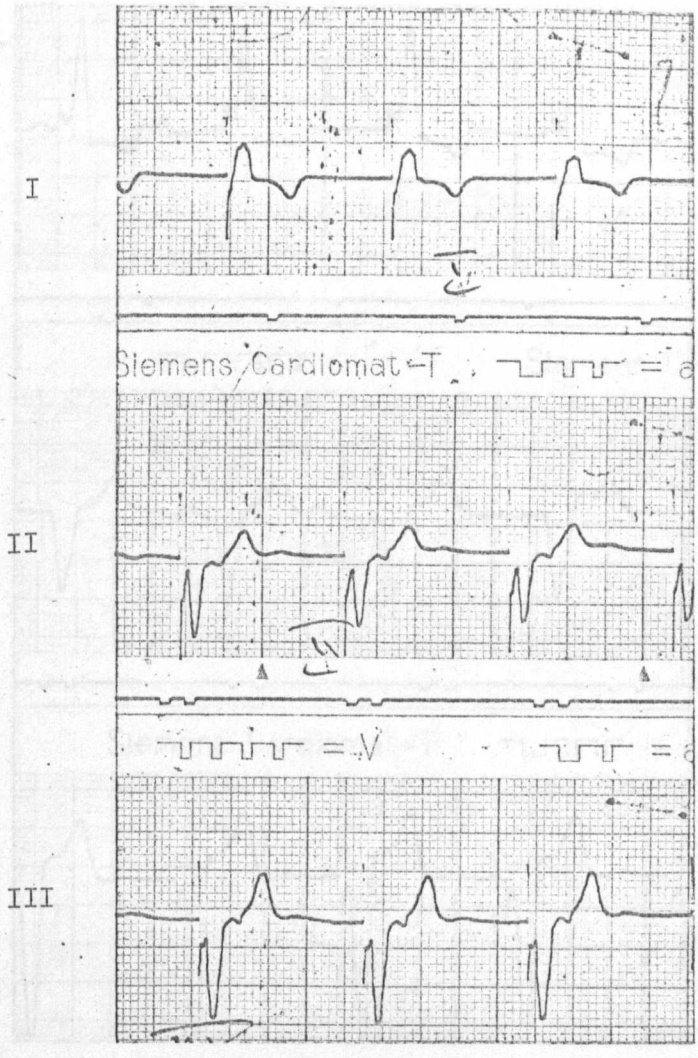


Figure 35. E.C.G. of patient having bipolar endocardial pacemaker implanted in which insulation on negative conductor has failed.

Patient 64

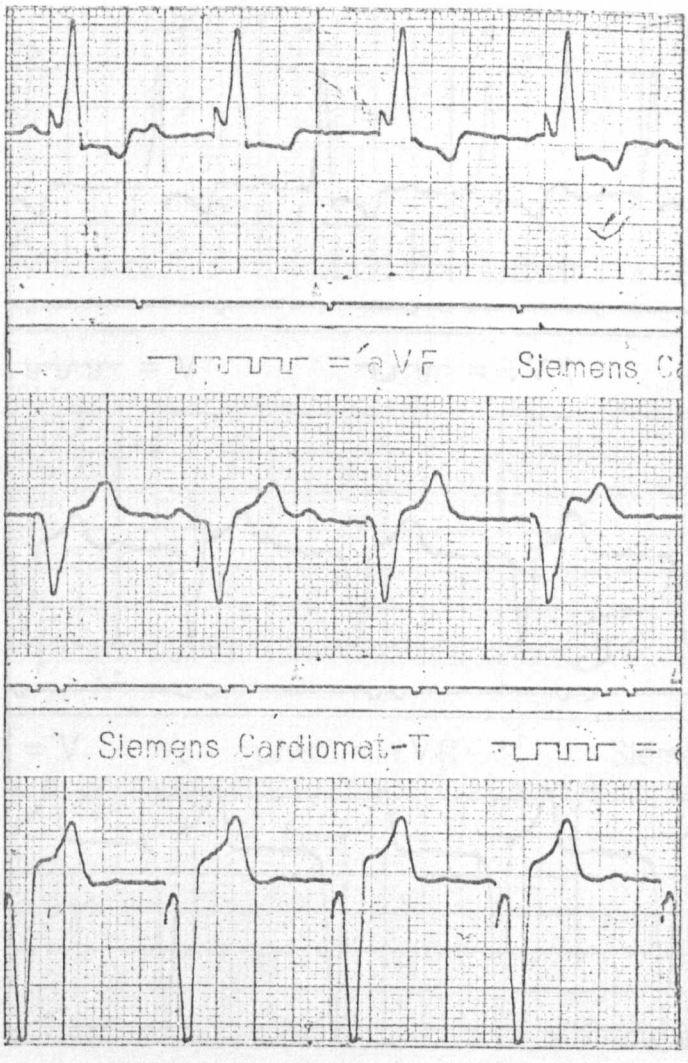


Figure 36(a). E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted in which negative insulating screw at generator was leaking electrically.

Patient 64

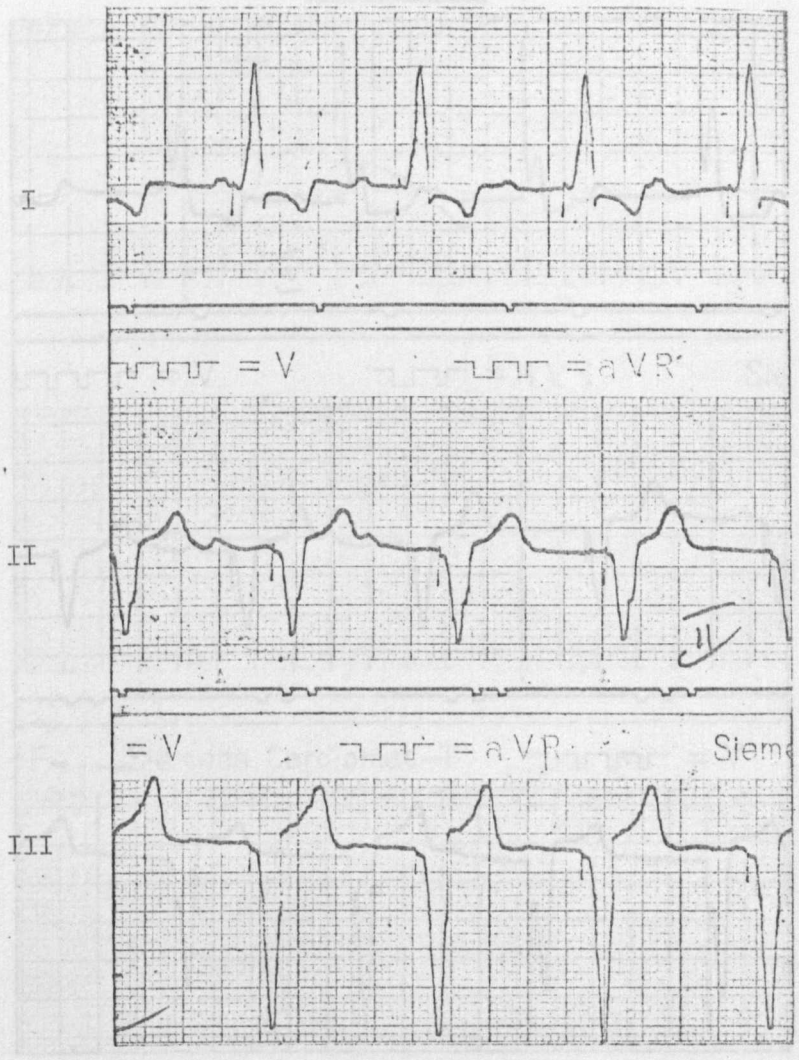


Figure 36(b). E.C.G. of patient in Figure 36(a) after fault had been corrected.

Patient 49

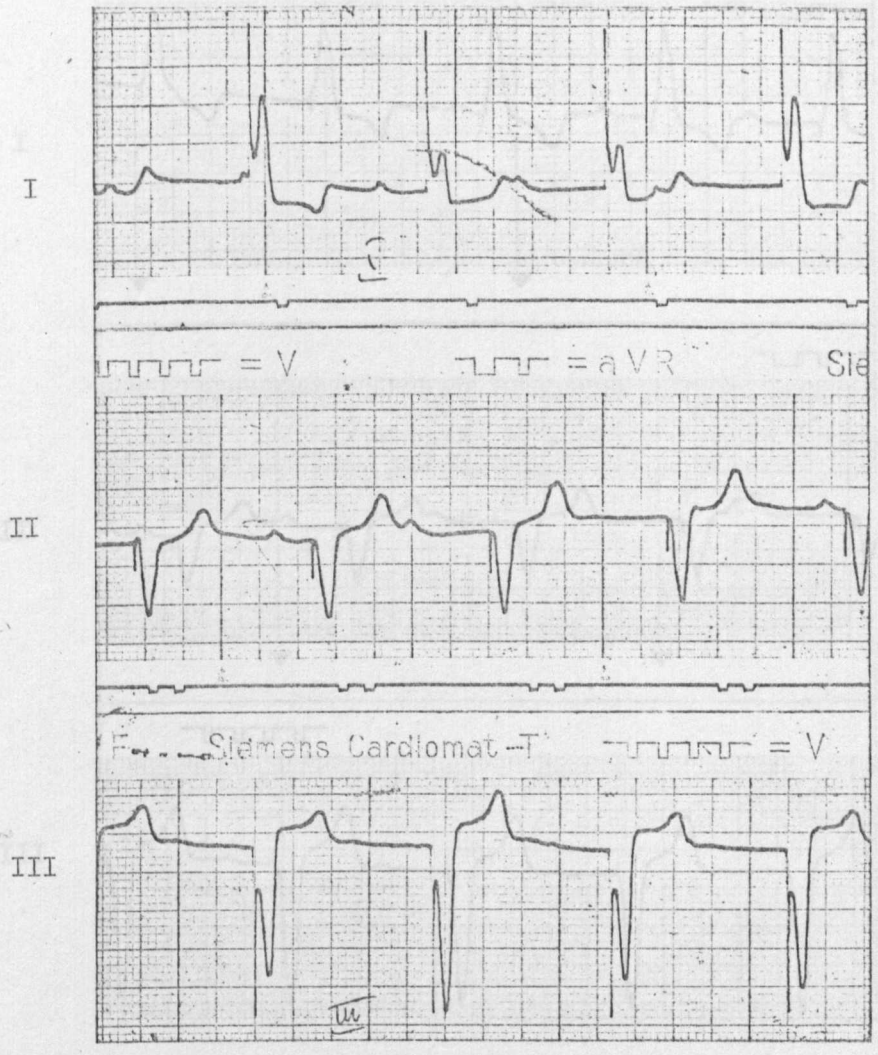


Figure 37(a). E.C.G. of patient having bipolar endocardial demand pacemaker implanted with break in the insulation on the positive lead near the generator.

Patient 49

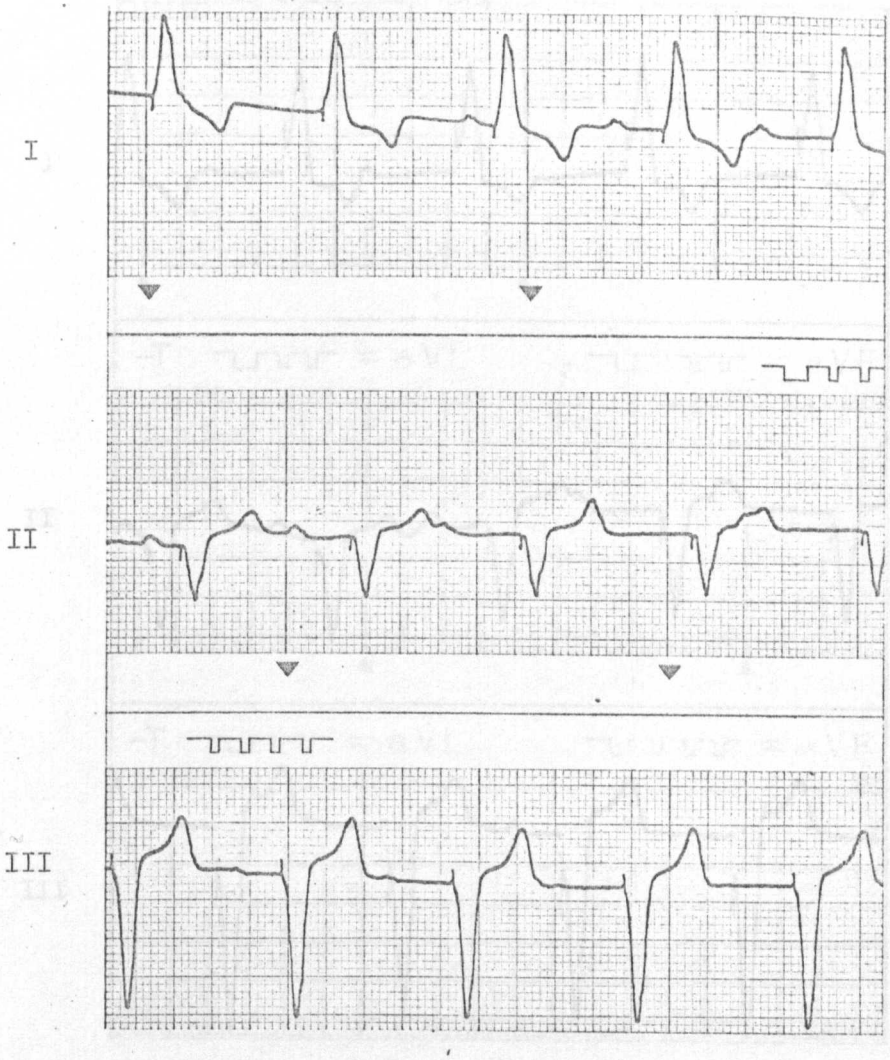


Figure 37(b). E.C.G. of patient in Figure 37(a) after break had been repaired at re-operation for change of generator.

Patient 118

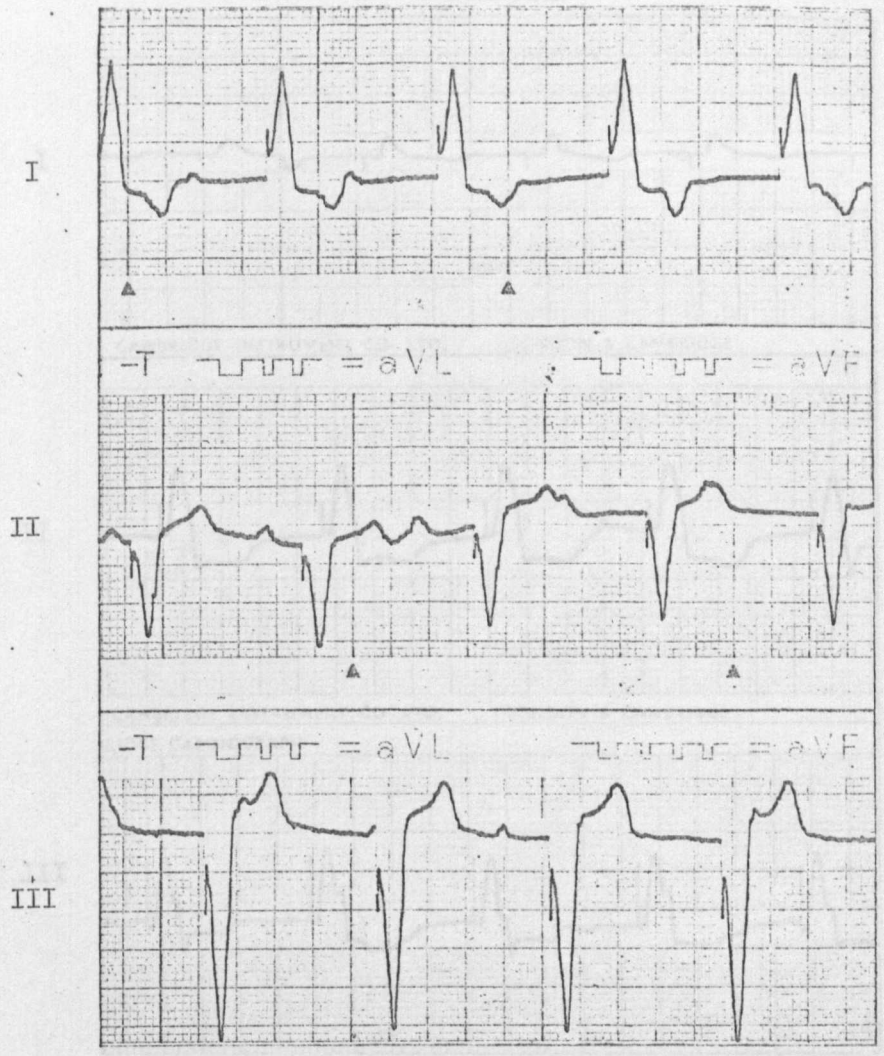


Figure 38. E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted with either a break in the insulation on the positive lead or a leaking positive insulating screw, or "boot", at the generator.

Patient 5

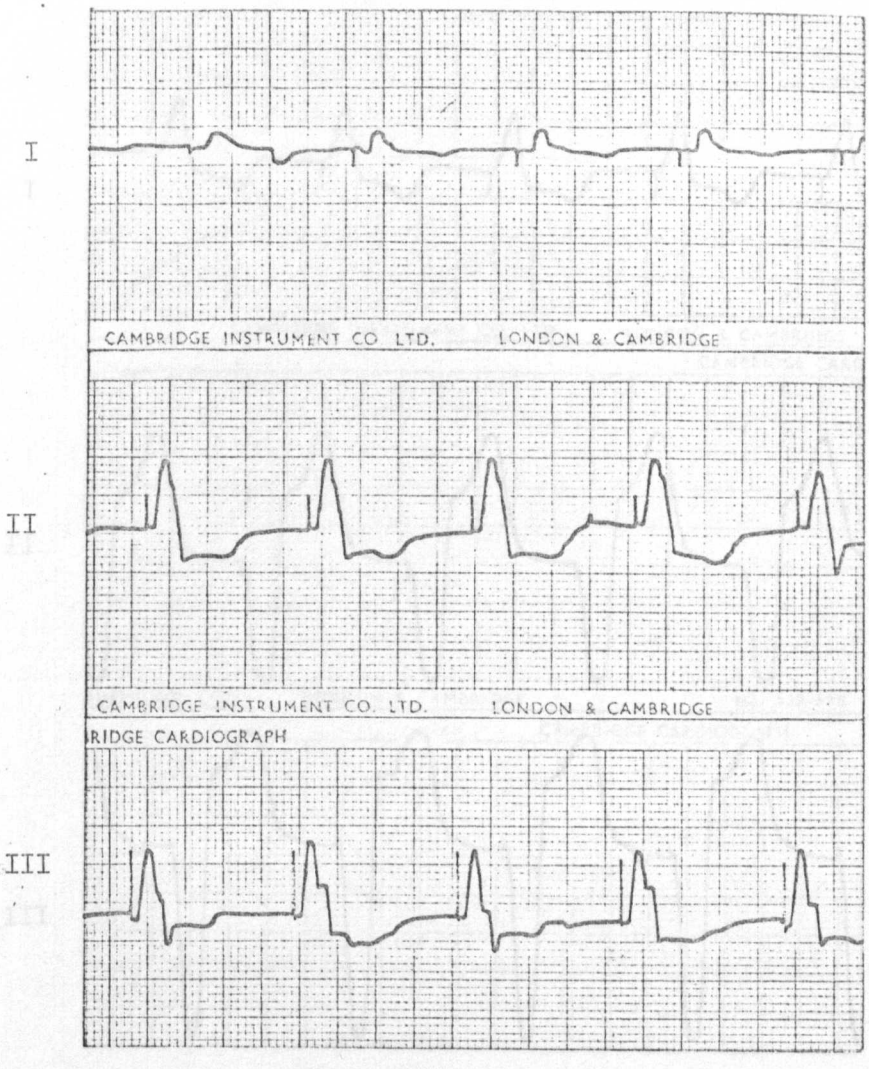


Figure 39(a). E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted. Catheter tip pointing "upwards" to outflow tract in right ventricle.

Patient 5

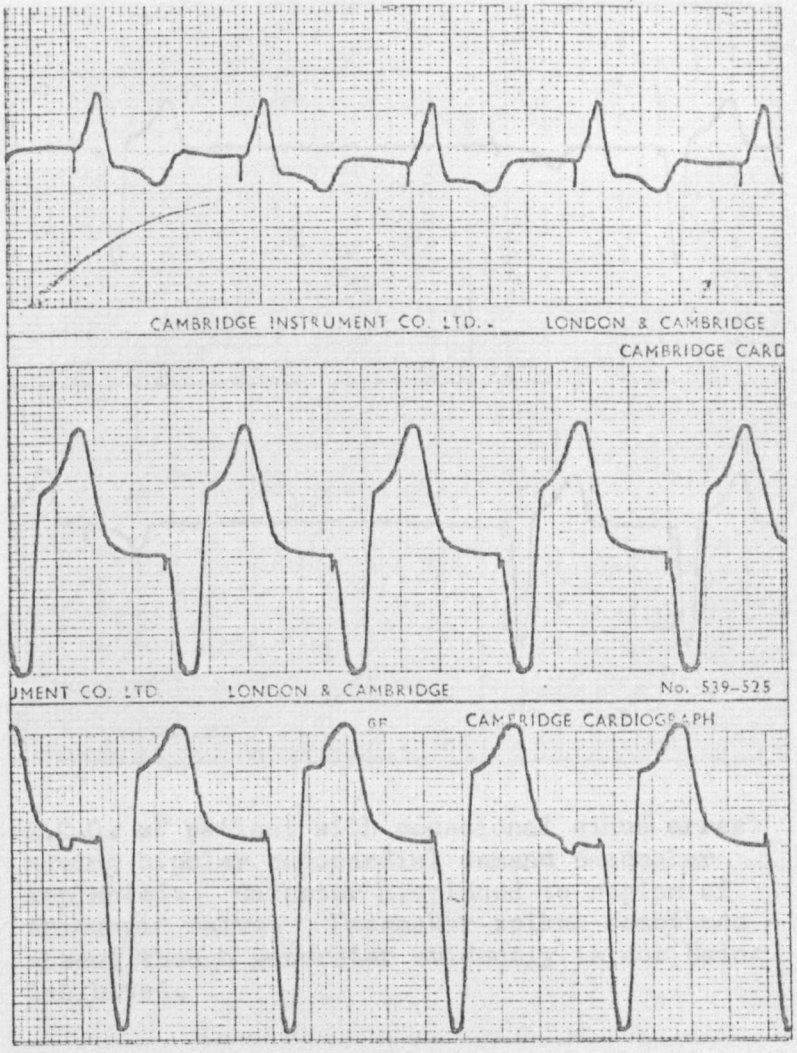


Figure 39(b). E.C.G. of patient in Figure 39(a) after new catheter (and generator) had been sited in normal position.

Patient 115

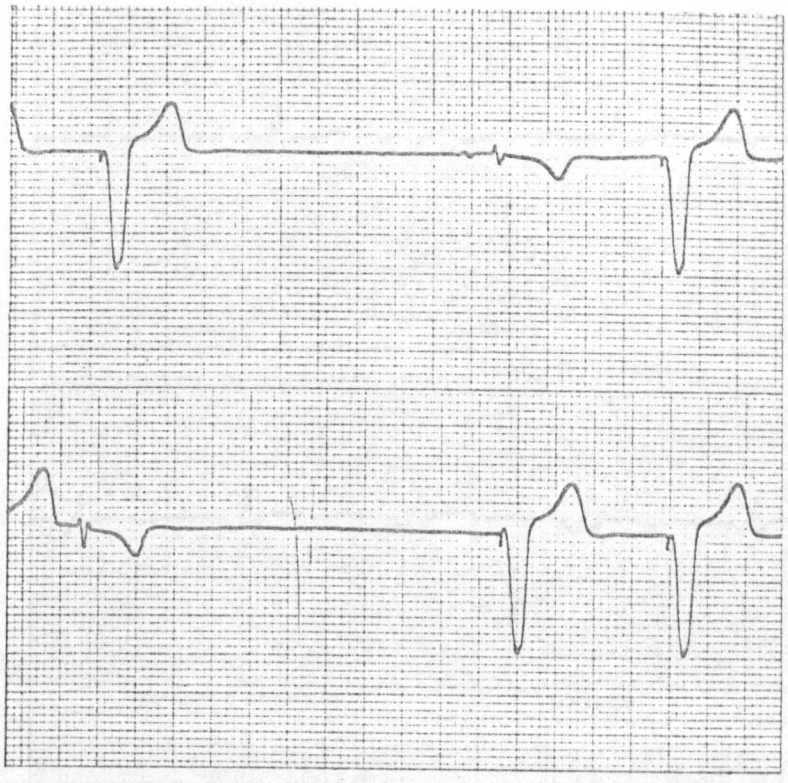


Figure 40. E.C.G. of patient with occasional sinus arrest having bipolar endocardial demand pacemaker implanted. Catheter displaced to region of tricuspid valve. Pacemaker spikes sometimes absent though generator evidently is not being inhibited.

Patient 207

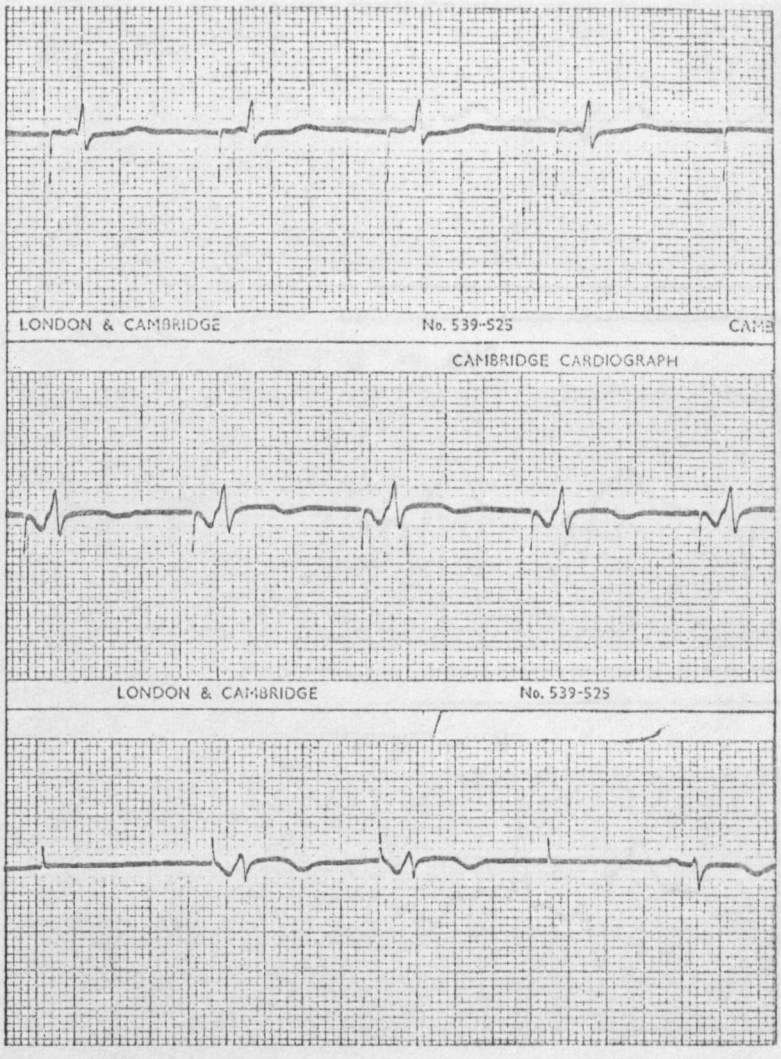


Figure 41. E.C.G. of patient with "lazy sinus" having bipolar endocardial demand pacemaker implanted. Catheter slightly displaced "over spine".

(a) pacemaker spikes always present except once when inhibited (Lead III)

(b) pacing intermittent when spikes are present.

Patient 106

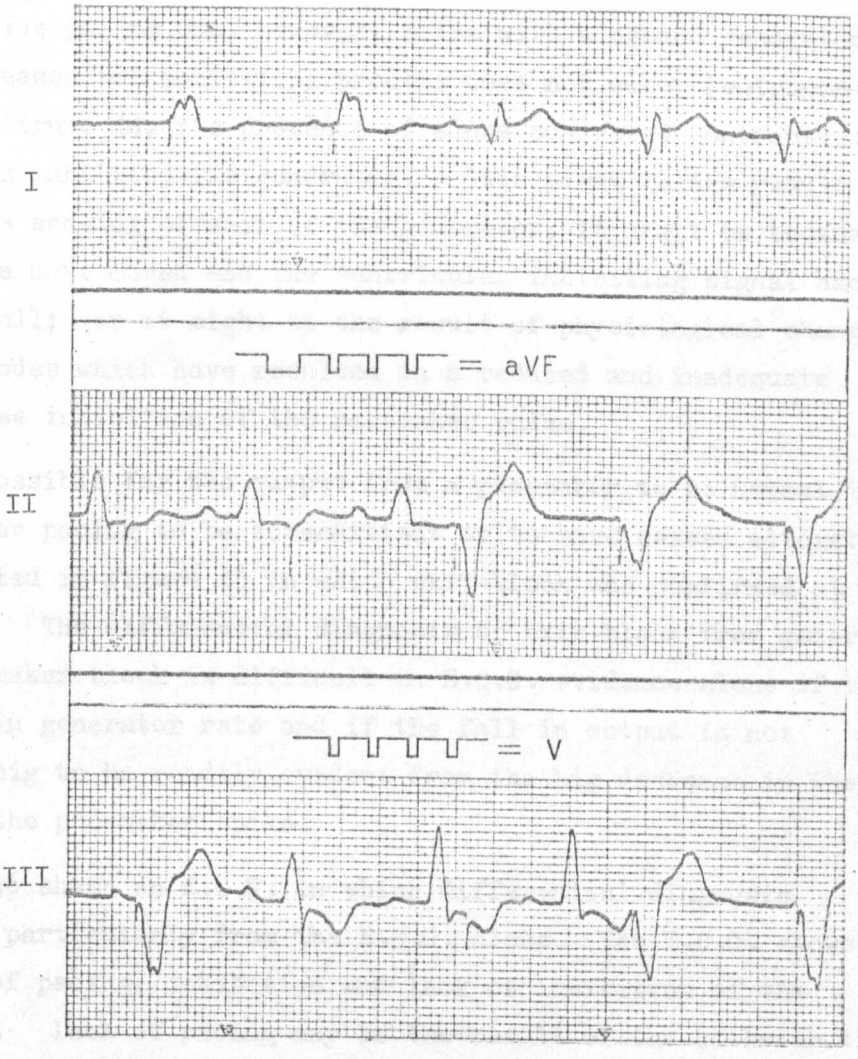


Figure 42. E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted, showing competitive pacing from sinus rhythm.

are active outside the heart's refractory period and sometimes ectopic foci become active several months after implantation of a pacemaker (Figure 43).

Competitive pacing can, however, arise with a demand generator if for some reason the inhibiting process does not occur (entrance-block). In figure 44, the presence of sinus conducted contractions has not always inhibited the generator. This might be the result of a fault in the sensing circuit of the generator, it might be because the electrodes have moved and the ventricular inhibiting signal has become too small; or it might be the result of physiological changes at the electrodes which have resulted in a reduced and inadequate signal to cause inhibition of the pacemaker pulse.

It is possible for the output from a pacemaker to be normal in every respect and for pacing to be intermittent or to have ceased altogether. This is depicted in figure 45 in which exit-block was confirmed at re-operation. The differential diagnosis of exit-block from generator-block or pacemaker block is difficult on E.C.G. evidence alone if there is no change in generator rate and if the fall in output is not sufficiently big to be readily evident from the big decrease in the magnitude of the pacemaker spike.

Figure 46 shows an E.C.G. in which differential diagnosis is difficult, particularly from the E.C.G. alone. The E.C.G. shows pacing, lack of pacing, inhibition and lack of inhibition of the pacing pulses. Lack of pacing may be the result of the catheter tip being displaced slightly or simply exit-block. Occasional lack of inhibition may also be the result of a small displacement or a smaller sensing signal from physiological changes at the electrodes. A faulty generator is another possibility which could explain both difficulties.

It has already been explained that the pacemaker spikes from unipolar pacemakers are large. The same arguments regarding rate changes can be applied to unipolar pacemakers as were applied to bipolar ones. Figure 47 shows a case of a unipolar synchronous pacemaker in which the generator rate became constant, i.e. "P" wave synchrony was lost, when the generator output fell.

All the other arguments presented above for bipolar pacemakers apply equally well to unipolar ones though the following points ought to be emphasised:

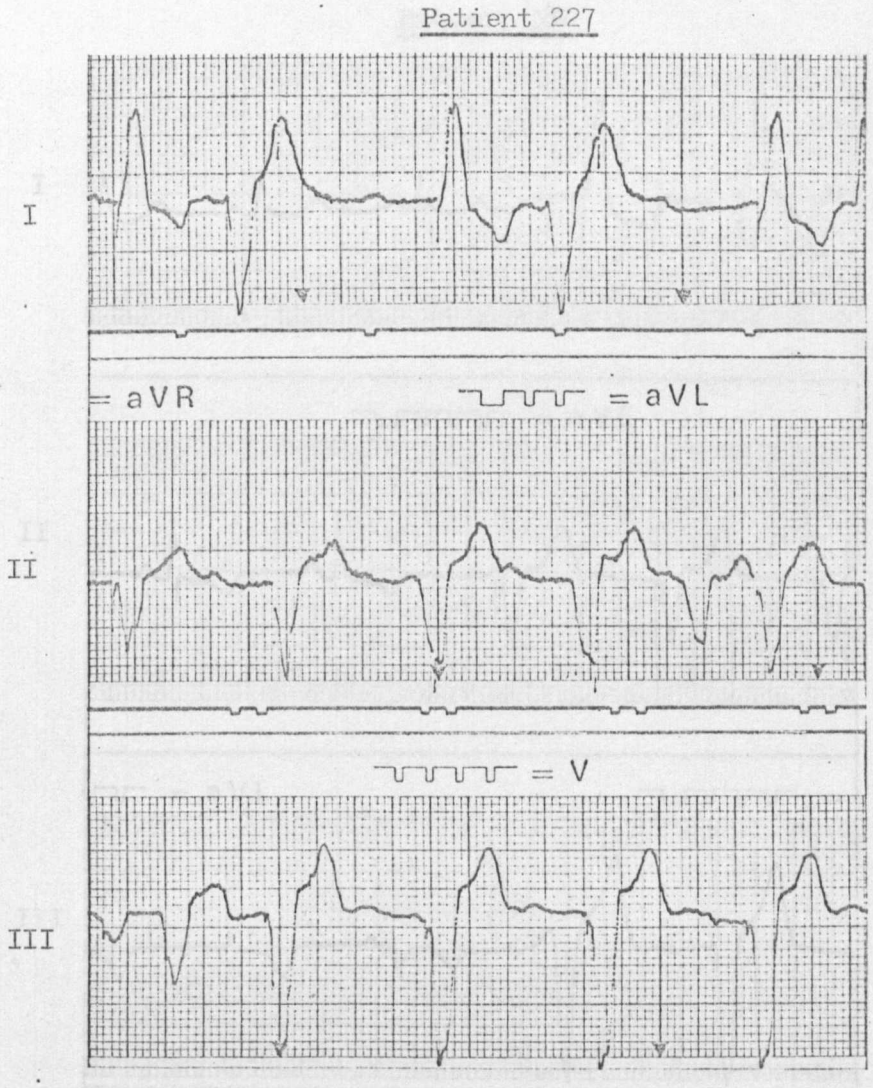


Figure 43. E.C.G. of patient having bipolar endocardial asynchronous pacemaker implanted, showing competitive pacing from ectopic foci some months after implantation of a pacemaker.

Patient 287

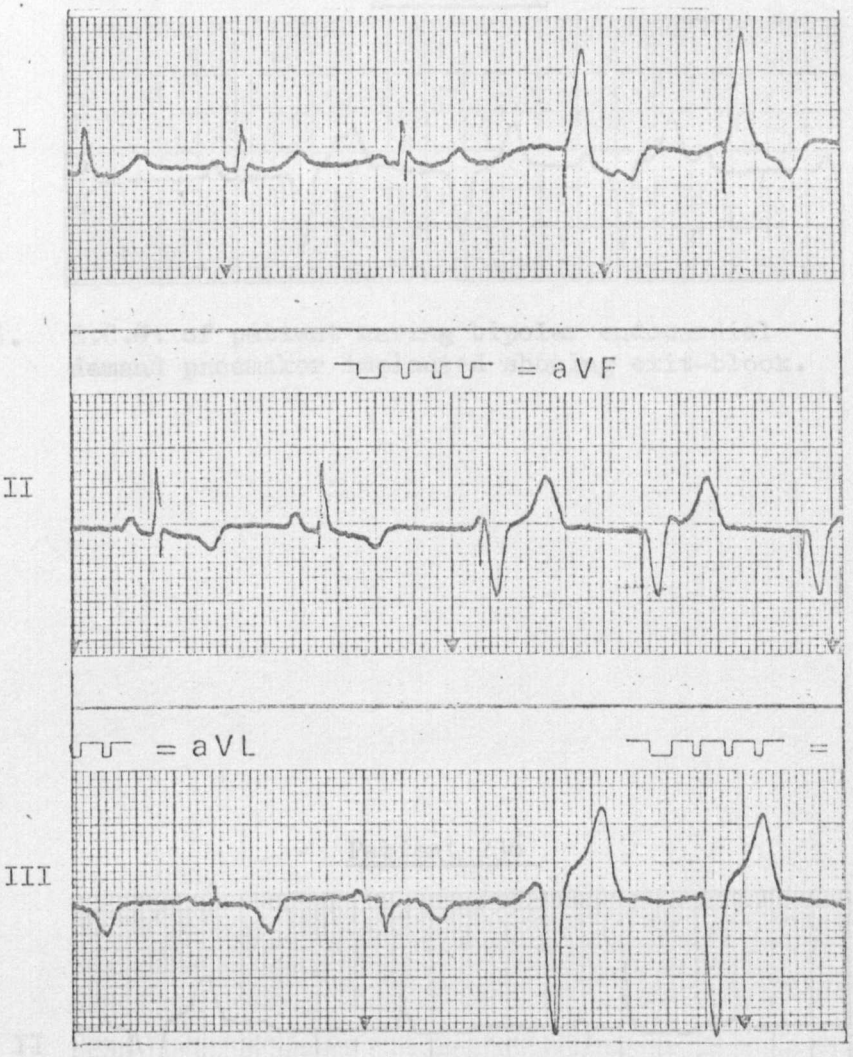


Figure 44. E.C.G. of patient having bipolar endocardial demand pacemaker implanted showing entrance-block.

Patient 288

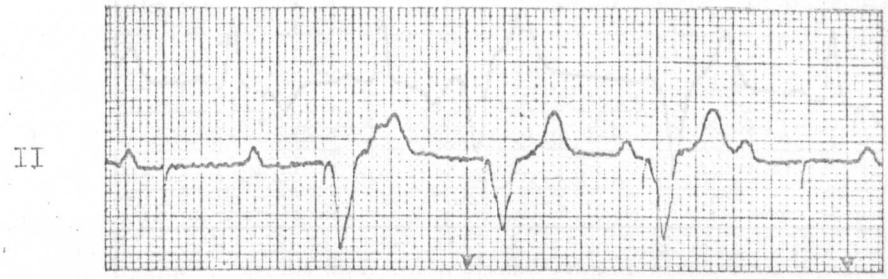


Figure 45. E.C.G. of patient having bipolar endocardial demand pacemaker implanted showing exit-block.

Patient 236

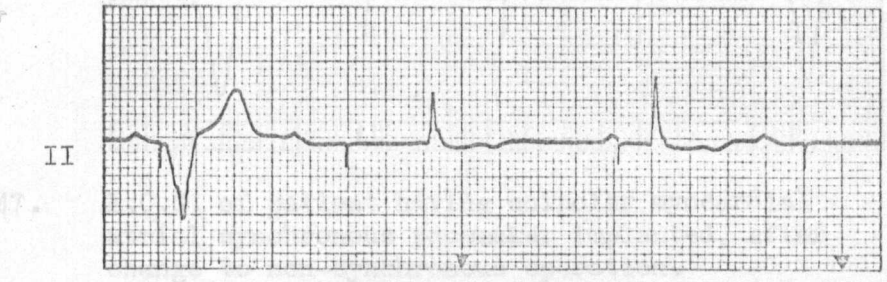


Figure 46. E.C.G. of patient having bipolar demand pacemaker implanted showing occasional lack of pacing and occasional entrance-block.

Patient 26

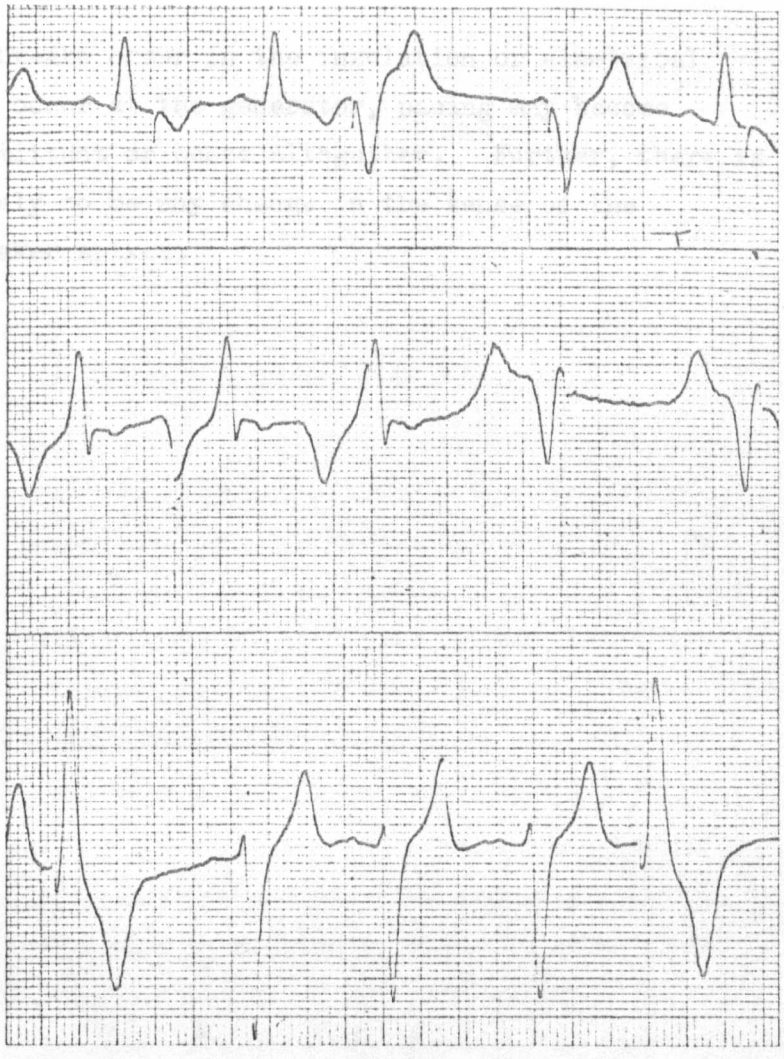


Figure 47. E.C.G. of patient having unipolar myocardial atrial synchronous pacemaker implanted, after change to non-synchronous operation.

(1) Because the pacemaker spikes are so large, they may appear to be biphasic when obtained from certain E.C.G. machines.

(2) When breaks occur in the insulation or electrical leaks occur at the generator, pacing may become intermittent or cease altogether. Further, there is unlikely to be any change in the sense of the pacemaker spikes.

5. Pacemaker Frontal Plane Vectors

5.1 General concepts

Whilst Einthoven[71] was studying the natural electrical activity of the heart in 1912, he introduced the concept of the heart being at the centre of an equilateral triangle in the frontal plane of the body, the apexes of the triangle being the junctions of the left arm, right arm and left leg to the torso. Although this was evidently not true physically, the concept enabled him to achieve useful clinical results on the "Direction and manifest size of the resulting potential difference"[72], which today is referred to as the "Heart vector" or "Effective resultant electric dipole".

The same concept has been applied to implanted pacemakers for the current flowing between the two pacemaker electrodes lying in the apex of the right ventricle, or between the two electrodes sutured into the myocardium, form an electric dipole. This is a vector quantity whose direction is given by a line joining the electrodes and whose magnitude depends on the distance apart of the electrodes and the current flowing between them.

The orientation of the electrodes in the body, the flow of current between them and consequently the electric dipole and pacemaker vector, are all essentially three dimensional phenomena. However, as explained above in section 1, there is some direct evidence and a considerable amount of indirect evidence that the positions of the electrodes are stabilised by fibrous tissue after a time and therefore their orientation with respect to each other becomes fixed so that the component vector in the frontal plane of the body becomes representative in direction and magnitude of the "three dimensional" pacemaker vector. Any changes in the magnitude of the pacemaker vector will be reflected in a change in the magnitude of the pacemaker frontal plane vector. Any change in orientation of the pacemaker vector, for example, from displacement of a catheter will be reflected in a change in direction (and probably magnitude) of the pacemaker frontal plane vector.

If the pacemaker frontal plane vector is referred to an equilateral triangle it can be split into components as shown in figure 48(a). The converse is also true, namely, that if the components on Leads I, II and III of the pacemaker frontal plane vector can be measured, then the magnitude and direction of the vector can be synthesised from any two of these components as shown in figure 48(b).

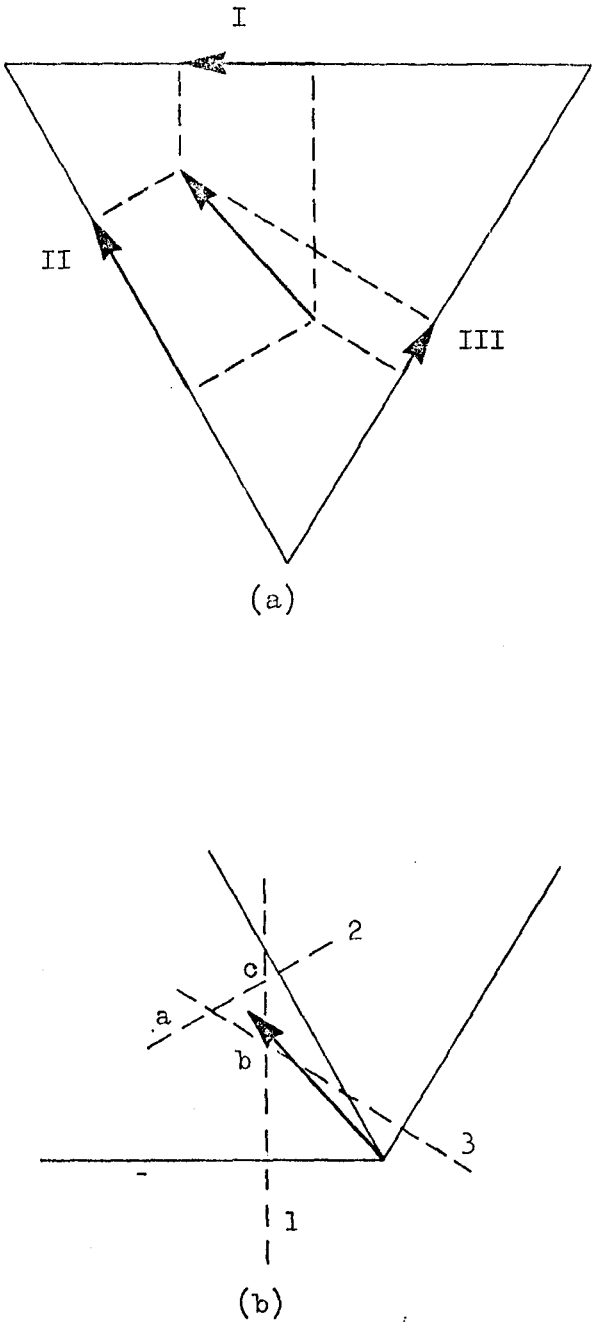


Figure 48. Pacemaker frontal plane vector referred to an equilateral triangle.

(a) component parts of pacemaker frontal plane vector

(b) synthesis of pacemaker frontal plane vector.

If all three possible combinations of pairs are used a mean vector is obtained.

The appropriate values of the pacemaker spikes on the different Leads are obtained in the manner explained in the next section. Ideally, of course, the three measurements on the different Leads should be taken simultaneously. This is not feasible without at least duplicating expensive equipment and in practice consecutive measurements are made on different Leads. This may result in the spikes being chosen which correspond to different parts of the breathing cycle. Thus the three different combinations of pairs of readings on the three Leads might give vectors which differ considerably in magnitude. An "error triangle" a b c (Figure 48(b)) can be formed by joining together the "arrowheads" of the three vectors obtained. If the side of this triangle is large (for example, greater than a few millimetres for bipolar systems) the pairs of results are not compatible and the three readings should be repeated.

Some improvements in the methods of assessment came about with the introduction of more sophisticated electronic equipment[73]. This has provided digital display of pulse parameters such as width, period (or rate) (Section 6), and pulse amplitude in terms of the leading edge of the pulse. However, for selection of the appropriate value of the leading edge, digital display alone proved unsatisfactory.

The acquisition of a new storage oscilloscope with X-Y facilities has provided a solution, which with a further modification to the equipment has enabled not only direct display of pacemaker frontal plane vectors based on X-Y co-ordinates but also X-t and Y-t displays simultaneously[74]. The original intention was to record on film successive vectors for comparison but experience has shown that the best procedure with existing equipment is to observe the variations in magnitude and orientation of the pacemaker frontal plane vectors with breathing and choose the corresponding value of X, or Y, or both, (for example, maximum X (say), minimum Y (say), or both), which correspond to say, full inspiration. The X-t and Y-t plots are then observed under, say, full inspiration and the appropriate values of X and Y measured. These values are then used to give a plot of the pacemaker frontal plane vector. The consistency of results has been improved in this way. Pulse width and period are still recorded digitally.

The pacemaker frontal plane vector technique depends on measurement of the leading edges of the pacemaker pulses and can be used with constant voltage generators, constant current generators, and constant voltage but current limited generators.

5.2 Measurement of leading edge of pacemaker pulses

In section 4 it was stated that the magnitude of the pacemaker spike, as observed on an E.C.G., is not a true indication of the absolute magnitude of the spike, primarily because the E.C.G. machine is designed for recording much smaller physiological signals, but to a lesser extent, because its frequency response is inadequate. Even the true sense of the spike is sometimes difficult to determine because, with some E.C.G. machines, even modern machines, a biphasic spike is produced when the much larger unipolar and unibip pulses are being considered. (Pacemaker pulses are usually biphasic but the second phase is extremely small and occurs over a relatively long period of time so that for most practical purposes they are considered as having only one phase).

The abovementioned difficulties can be overcome by replacing the E.C.G. machine with a differential oscilloscope. In this way the pacemaker spikes obtained for instance from Leads I, II and III, can be displayed as "square wave" pulses provided a suitable fast and triggered time base has been chosen (Figure 49). The "senses" of the pacemaker pulses should be the same as the corresponding pacemaker "spikes" on the E.C.G. if the same sign conventions are to be used for physiological phenomena and pacemaker pulses. If they differ the connections to the differential oscilloscope should be reversed. This needs to be done only once preferably with a bipolar pacemaker so as to avoid the biphasic spikes referred to above, if the connections to the oscilloscope are suitably marked for future use. The general shape of the pulses obtained will depend on the output characteristics of the implanted generator. The pulses shown in figure 49 for example are typical of those obtained from a constant voltage capacitive output generator. The relative magnitudes of the leading edge and the trailing edge in each lead will depend on the load impedance arising from the electrode-lead system and the body (Appendix III). However, the actual magnitude (and sense) of the leading edge (and therefore the trailing edge too) will depend on a number of factors.

Patient 134

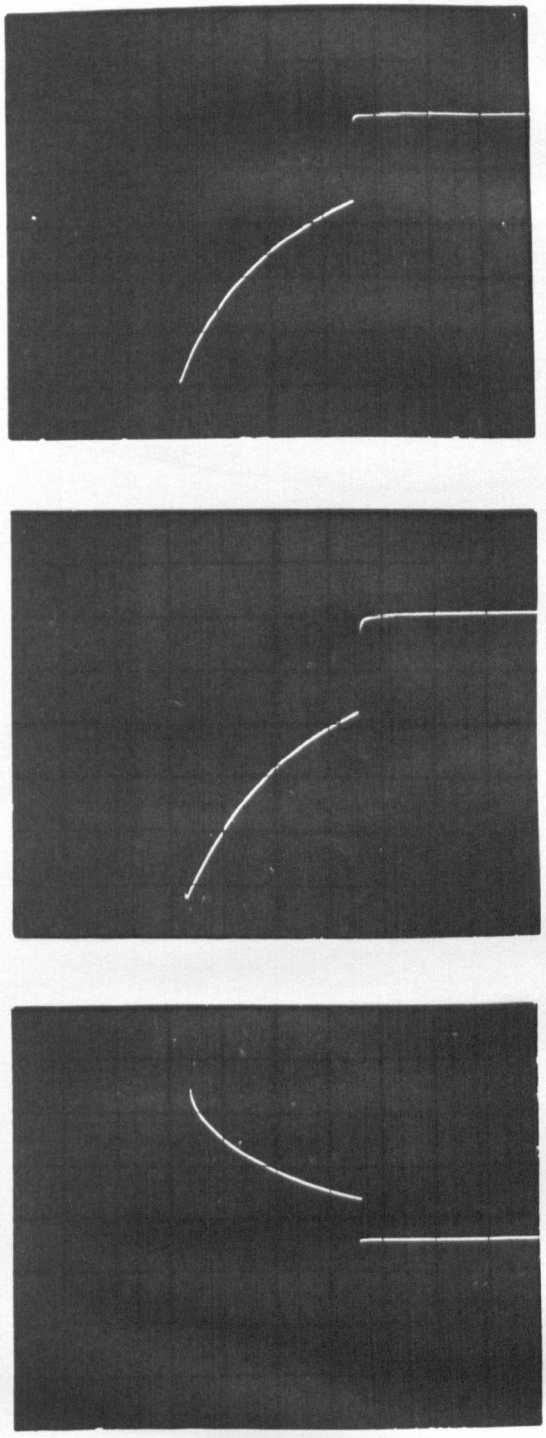


Figure 49. Typical pacemaker pulses from bipolar endocardial asynchronous pacemaker obtained via skin electrodes (Leads I, II and III).

These are:-

(1) the positions and polarities of the electrodes
(2) configuration size, and motion of the patient's internal organs with breathing
(3) the Lead being considered (e.g. Lead I, II, III etc.)
(4) the patient's position (e.g. supine, sitting)
(5) the output characteristics of the pacemaker. (with a "constant voltage" pacemaker, this will depend on the resultant load impedance formed by the resistance of the electrode-lead system and the impedance of the patient's body).

Fortunately the effects of some of these factors can be eliminated, or minimised, when consecutive measurements on the same patient, with a specific pacemaker implanted, are being compared. Thus item (1) may be wholly determined at first emplacement and when the generator is connected to the electrode-lead system. In the case of endocardial electrode-lead systems there may be subsequent movement of the electrodes with respect to each other, or together with respect to the heart, but eventually fibrous tissue usually stabilises the positions of the electrodes, though, this may take some months. Likewise the effects of item (4) can be eliminated by asking the patient to be, for instance, supine, whenever measurements are made. The effect of item (3) is eliminated provided only the same Leads are compared, or alternatively as is done in practice, a resultant measurement is obtained based on the individual Lead measurements.

Item (5) cannot be completely eliminated in the first few months following first emplacement of the electrodes. It was assumed when these investigations began that the load impedance was constant but it is now believed that is only the case after the electrodes have become enveloped with fibrous tissue and this, as already indicated, may take some months.

The effects of breathing in item (2) can be considerable so that reproducibility of results from the same patient can be difficult particularly when the signals from the surface of the body are small, as they are with bipolar pacemakers. For instance, typical signals on all leads are of the order of a few millivolts, or at best of the order of ten millivolts. With unipolar pacemakers the signals are

much bigger, of the order of hundreds of millivolts; reproducibility is easier because the effects of breathing are smaller.

The effects of breathing are,, however, limited to some extent by trying to observe the magnitude of the pulse under conditions of "full inspiration". Unfortunately, some patients particularly very elderly ones and those suffering from bronchitis or asthma have difficulty in breathing "fully-in", let alone "holding" their breath for a few seconds.

The availability of a differential storage oscilloscope brought about a slightly different but very important approach to this problem. Hitherto measurements had been made after recording the oscilloscope trace on polaroid film. However with the acquisition of a storage oscilloscope it was soon realised that by changing the time-base of the oscilloscope and reverting to a pacemaker spike, or rather a series of spikes, it was much easier to choose the required pacemaker spike corresponding to full inspiration from a sequence or "train" of stored pacemaker spikes.

Variations in the pacemaker spikes with breathing differ in different patients. In some cases the minimum value corresponds to full inspiration, in another, the maximum value; and in some an intermediate value corresponds to full inspiration. With Lead III measurements in which the distal end of a bipolar catheter has been placed in the apex of the right ventricle, there is sometimes a reversal of the sense of the spike with full inspiration. Extra care is therefore sometimes necessary to select the correct spike for measurement on Lead III, which corresponds to full inspiration. Figure 50 shows typical spikes obtained on Leads I, II and III, the spikes marked corresponding to full inspiration. The storage oscilloscope has enabled a mean value to be obtained for pacemaker spikes stored under relaxed breathing conditions in the case of those patients who have difficulty in breathing "fully in". On the death of the patient, these variations in the pacemaker spikes disappear (Figure 51).

It is the magnitude and sense of the leading edge of the pacemaker pulse which determines the magnitude and sense of the pacemaker spike: these carefully measured pacemaker spikes are the cornerstone of pacemaker frontal plane vector-cardiography.

Patient 244

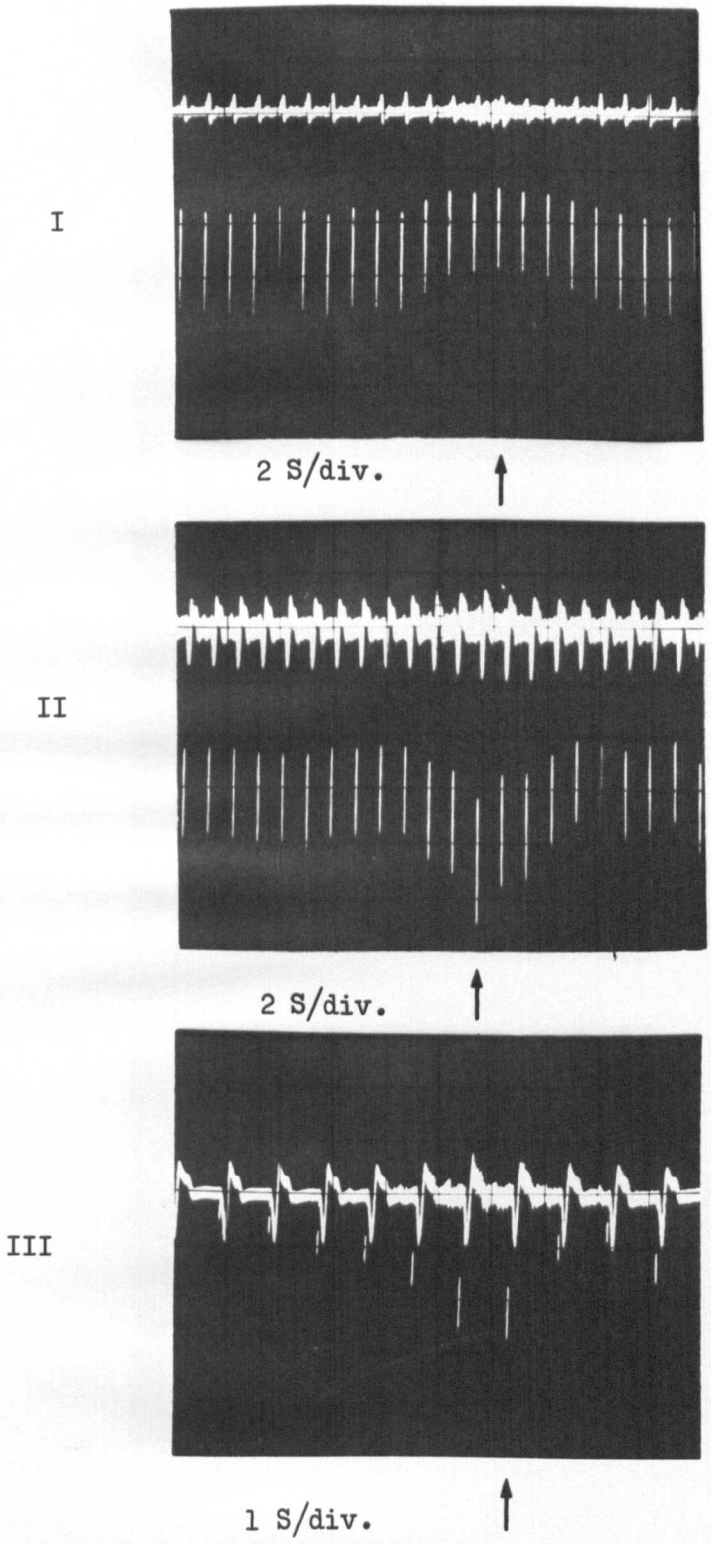


Figure 50. Variations of pacemaker spikes with breathing in Leads I, II and III. (The arrows indicate the instants of full inspiration).

Patient 317

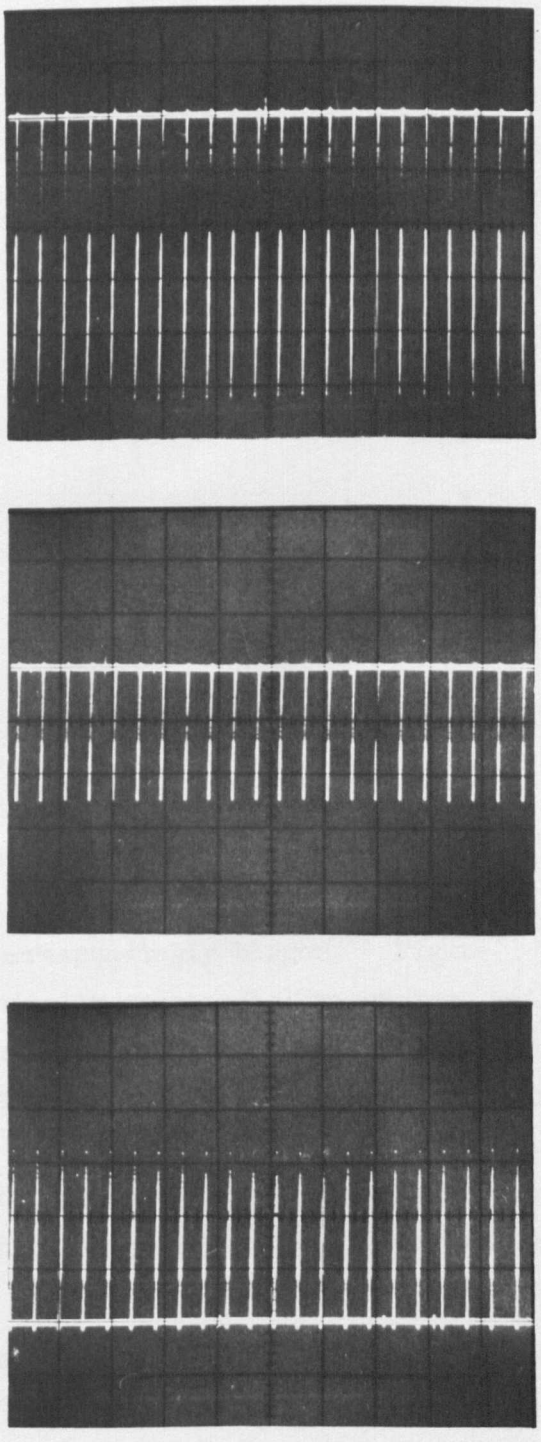


Figure 51. Pacemaker spikes of constant magnitude recorded from deceased patient (Leads I, II and III)

5.3 Normal pacemaker frontal plane vectors

Typical pacemaker frontal plane vectors are shown in figure 52 which were obtained from a patient having a bipolar endocardial electrode-lead system implanted. Consecutive vectors are not identical and the cluster of arrowheads is in part a measure of the difficulties which obtain in trying to take consecutive measurements under identical physiological conditions, apart from calibration and observational errors on the oscilloscope. There is some loose correlation between the pacemaker frontal plane vector and the orientation of the electrodes in the body as shown by X-ray examination (Figure 53). Precise correlation is unimportant because only changes in magnitude and direction of successive vectors are being sought.

When myocardial/epicardial or intramural bipolar electrode-lead systems are used, the two electrodes on or in the myocardium can have any positions and polarity with respect to each other so that the pacemaker frontal plane vectors can be in any direction (Figure 54).

In the case of unipolar pacemakers the direction of the vectors will depend on the relative positions and polarities of the electrode at the heart and the indifferent electrode at or near the generator. As explained earlier the magnitude of the pacemaker spikes are much bigger with unipolar pacemakers than with bipolar ones so that the vectors are correspondingly bigger. Figure 55 shows vectors obtained from a unipolar endocardial pacemaker, with the generator implanted in the axilla and figure 56 shows vectors obtained from a unipolar myocardial pacemaker, the generator having been implanted behind the rectus sheath.. An indication of the differences in magnitude of the bipolar and unipolar pacemaker vectors is shown in figure 57 in which a myocardial bipolar system was converted into a unipolar one.

As already mentioned it has recently become possible to display pacemaker frontal plane vectors directly on an oscilloscope screen (Figures 58, 59 , 60 and 61). This has the great advantage as already mentioned that any changes with breathing can be observed on the screen and this enables a better choice of vector to be made for consecutive observations. Bipolar pacemaker frontal plane vectors can vary considerably in direction and magnitude with breathing whereas unipolar ones are less sensitive as regards direction and relatively smaller magnitude changes occur.

Patient 77

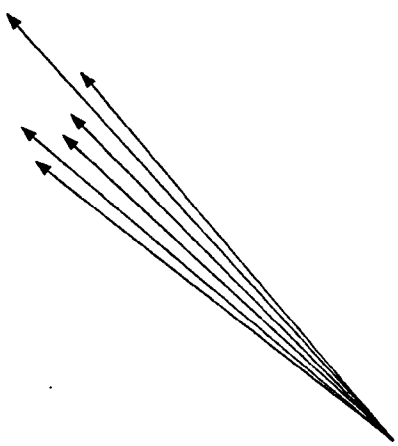


Figure 52. Pacemaker frontal plane vectors: bipolar endocardial pacemaker (1 mV/cm)

Patient 77

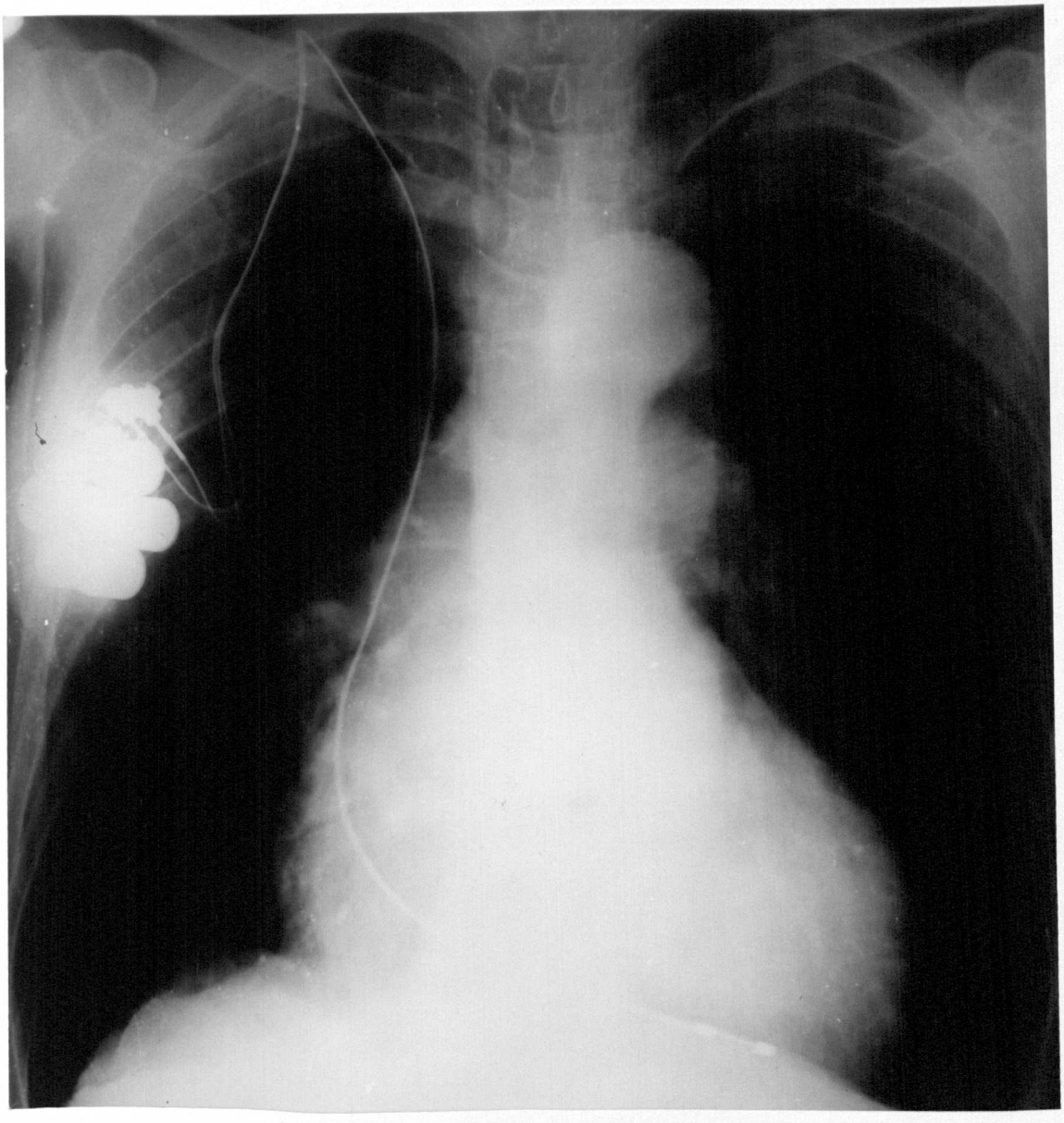


Figure 53. Radiograph showing the orientation of the electrodes in patient referred to in figure 52.

Patients 265, 126, 13, 130 and 17

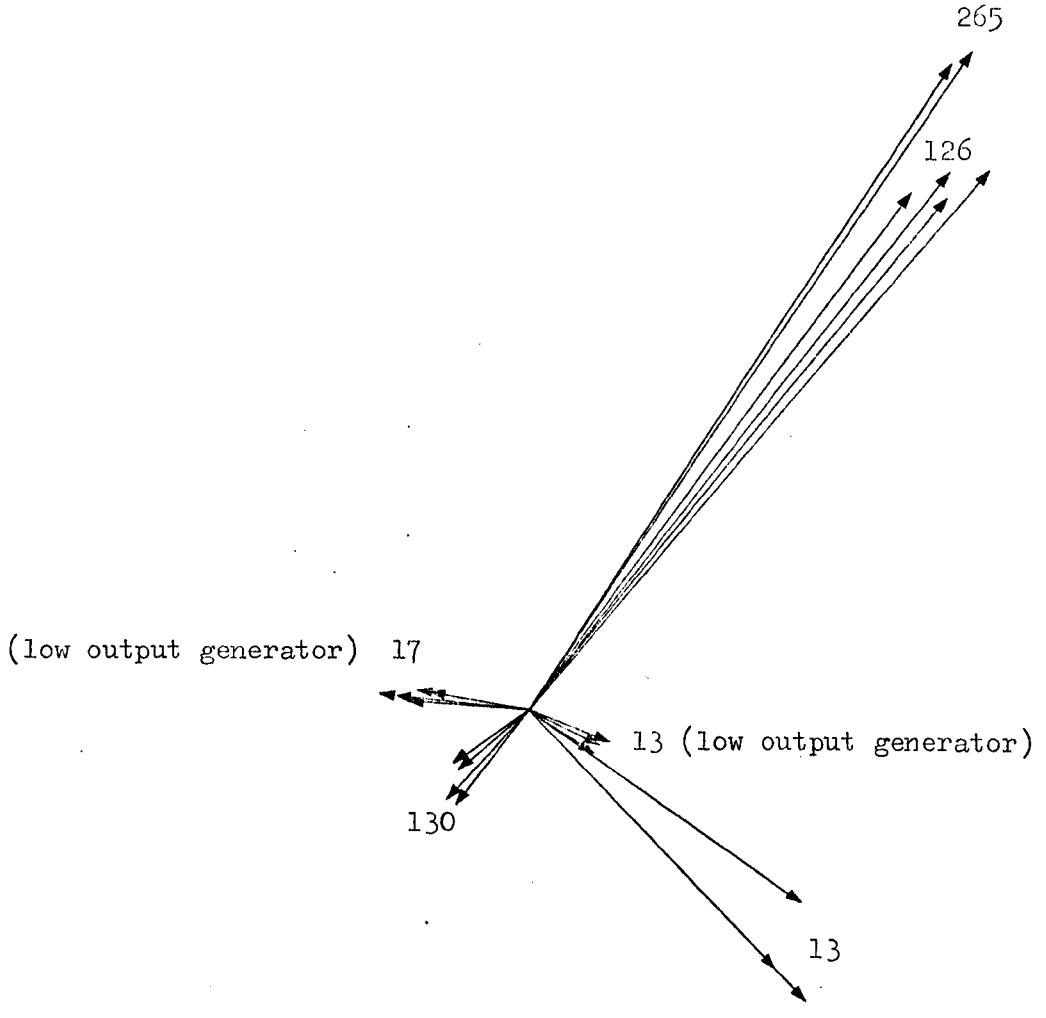


Figure 54. Different orientations of pacemaker frontal plane vectors: five patients with bipolar myocardial pacemakers (1 mV/cm)

Patient 230

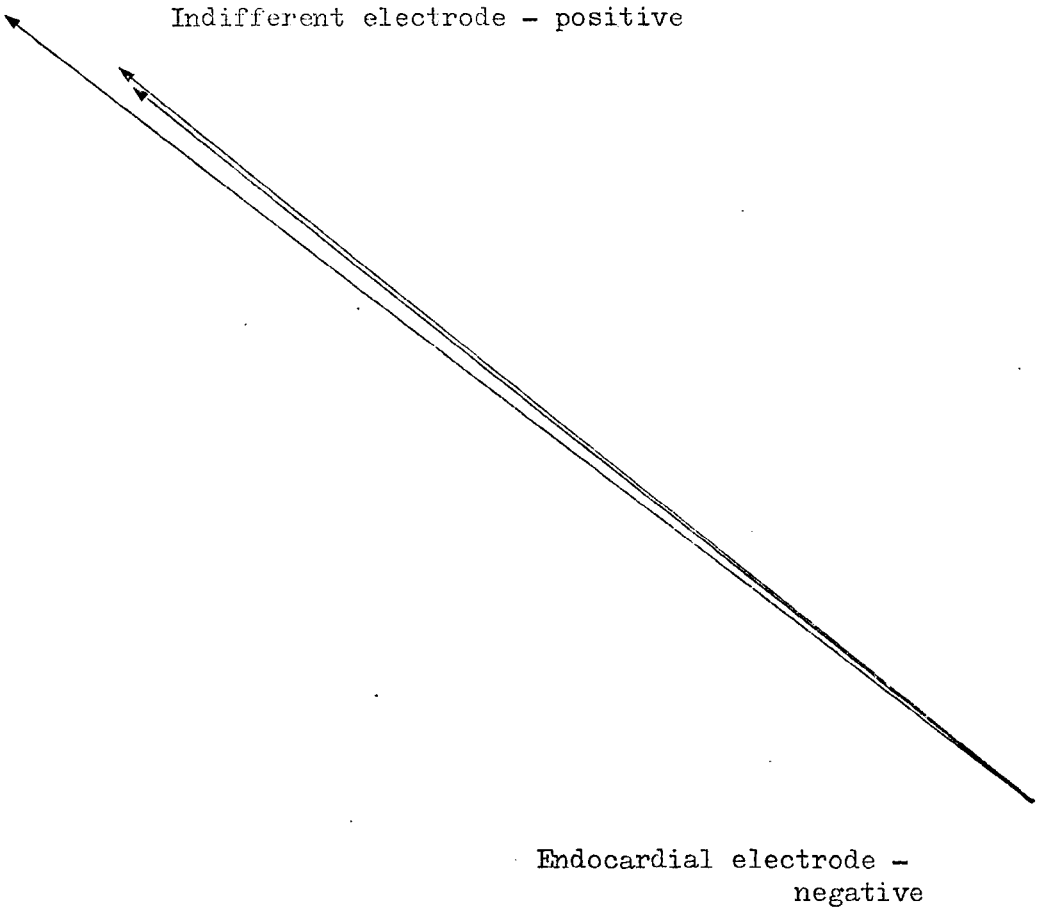


Figure 55. Pacemaker frontal plane vectors: unipolar endocardial pacemaker (10 mV/cm)

Patient 107

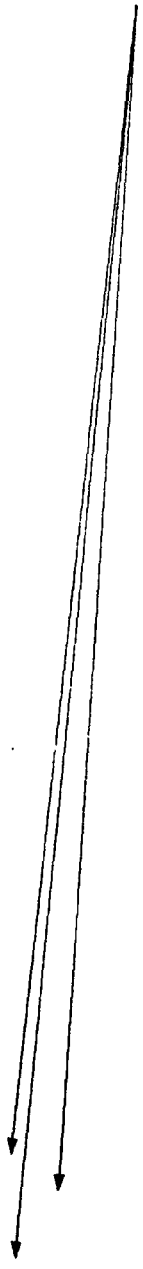


Figure 56. Pacemaker frontal plane vectors: unipolar myocardial pacemaker (20 mV/cm.)

Patient 138

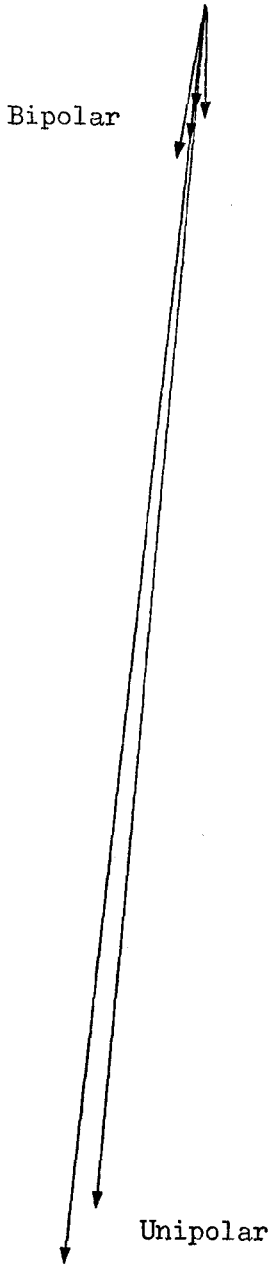


Figure 57. Pacemaker frontal plane vectors: change from bipolar to unipolar myocardial pacemaker (0.05 mV/cm)

Patient 286 2.5 mV/div.

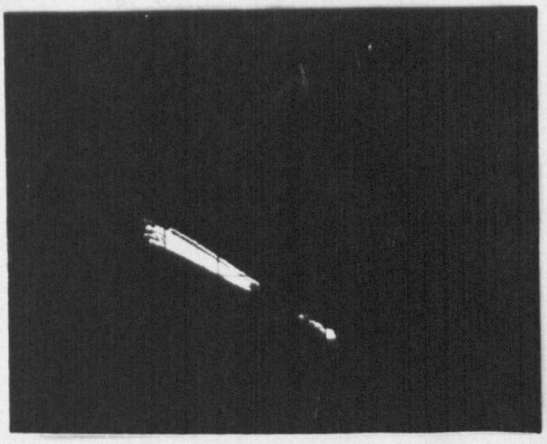


Figure 58. Direct display of pacemaker frontal plane vectors - bipolar endocardial pacemaker.

Patient 88 5 mV/div.

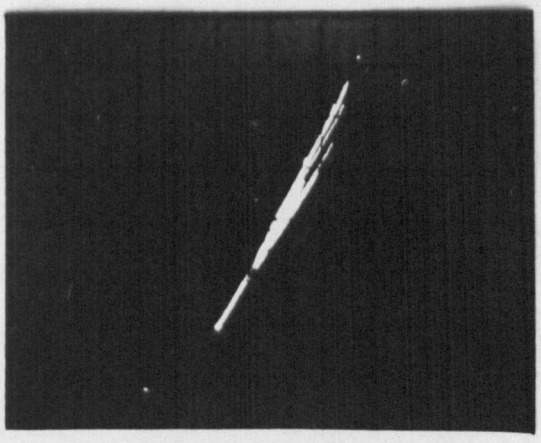
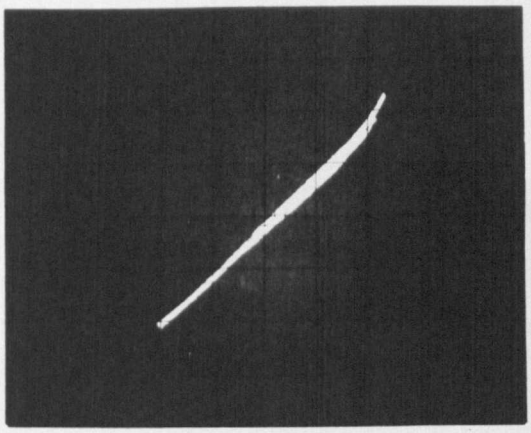


Figure 59. Direct display of pacemaker frontal plane vectors - bipolar myocardial pacemaker.

Patient 145 50 mV/div.

Indifferent electrode positive

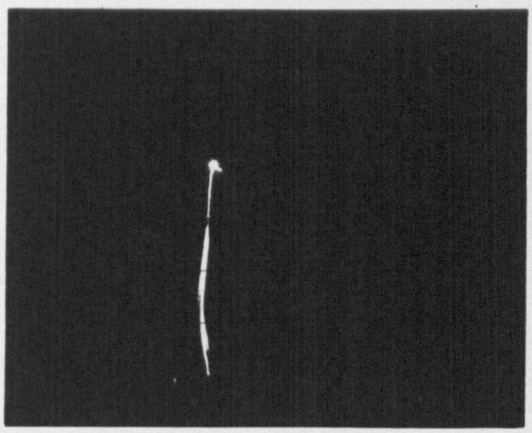


Endocardial electrode negative

Figure 60. Direct display of pacemaker frontal plane vectors - unipolar endocardial pacemaker.

Patient 107 100 mV/div.

Myocardial electrode negative



Indifferent electrode positive

Figure 61. Direct display of pacemaker frontal plane vectors - unipolar myocardial pacemaker.

Although, as already mentioned, the pacemaker frontal plane vector technique can be applied to any make and type of pacemaker, it should be noted that in the case of constant current generators the direct display of the vector will be different in that the maximum value of the vector will be represented by a dot. This is because there is no relatively slow "droop" on the trailing edge of the pulse.

The changes in the directions and magnitudes of pacemaker frontal plane vectors with respect to earlier vectors are exemplified in the next sub-section and the reasons for the changes are given.

5.4 Significance of changes in pacemaker frontal plane vectors

It has been mentioned earlier that the most common technical fault which now occurs with implanted pacemakers, is premature failure of one or more of the mercury cells. The reduction in voltage output which follows causes a corresponding reduction in current output so that the pacemaker electric dipole is also reduced in magnitude and this is reflected in a reduction in the magnitude of the pacemaker frontal plane vector. In fact the premature failure of a cell in any make or type of pacemaker will result in a reduction in the magnitude of the pacemaker frontal plane vector.

Figure 62 shows a reduction in magnitude of pacemaker frontal plane vectors following premature failure of mercury cells in a bipolar endocardial pacemaker. In figure 63 , a bipolar myocardial pacemaker showed a similar reduction in the vector when its output decreased. Few unipolar endocardial pacemakers have been used, and none has failed in this manner but figure 64 shows the changes which occurred in the pacemaker frontal plane vectors when the output of a unipolar myocardial pacemaker decreased.

There is usually a big margin between the pacing threshold and the normal output of a generator so that a significant reduction in output must normally occur before pacing ceases. Certainly in cases similar to those referred to above pacing has remained satisfactory until the generator could be changed, usually at re-operation on a planned basis the following week.

The detection of a decrease in the magnitude of pacemaker frontal plane vectors, and therefore a decrease in output of the generator is of special value with generators which are designed not to show a change in pulse rate when premature depletion of a cell occurs. The Medtronic asynchronous generator, type 5862C and the Medtronic demand generator, type 58 is another. Its successor, type 5942, was similarly designed though

Patient 20

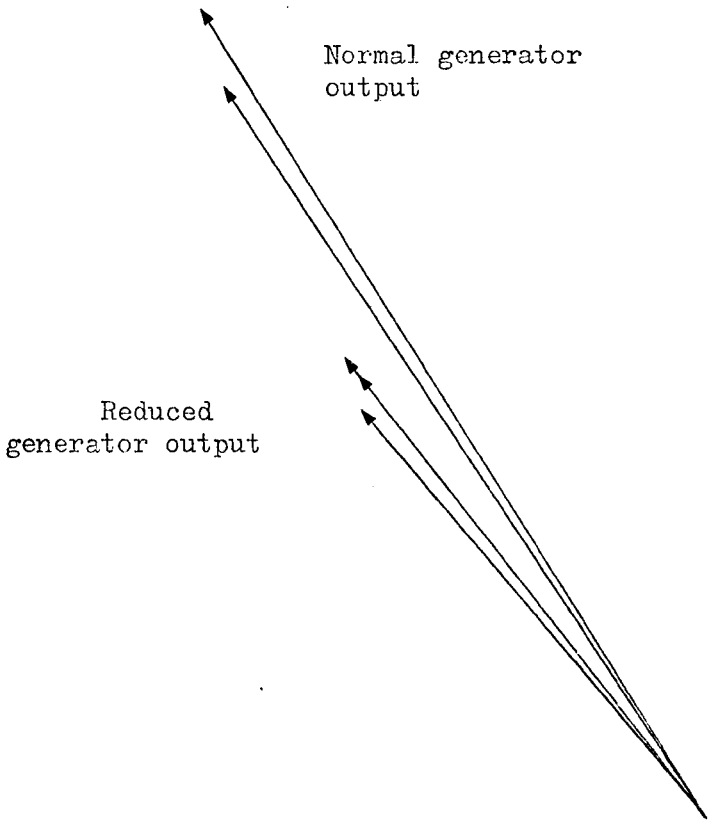


Figure 62. Reduction in magnitude of pacemaker frontal plane vectors with fall in output of bipolar endocardial pacemaker (1 mV/cm.)

Patient 88

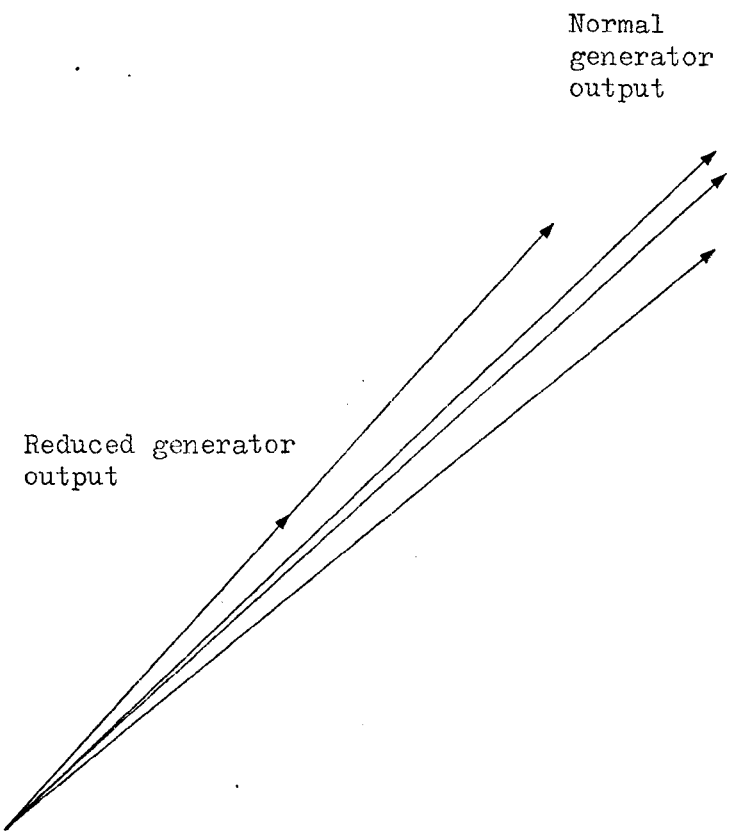


Figure 63. Reduction in magnitude of pacemaker frontal plane vector with fall in output of bipolar myocardial pacemaker (2 mV/cm.)

Patient 28

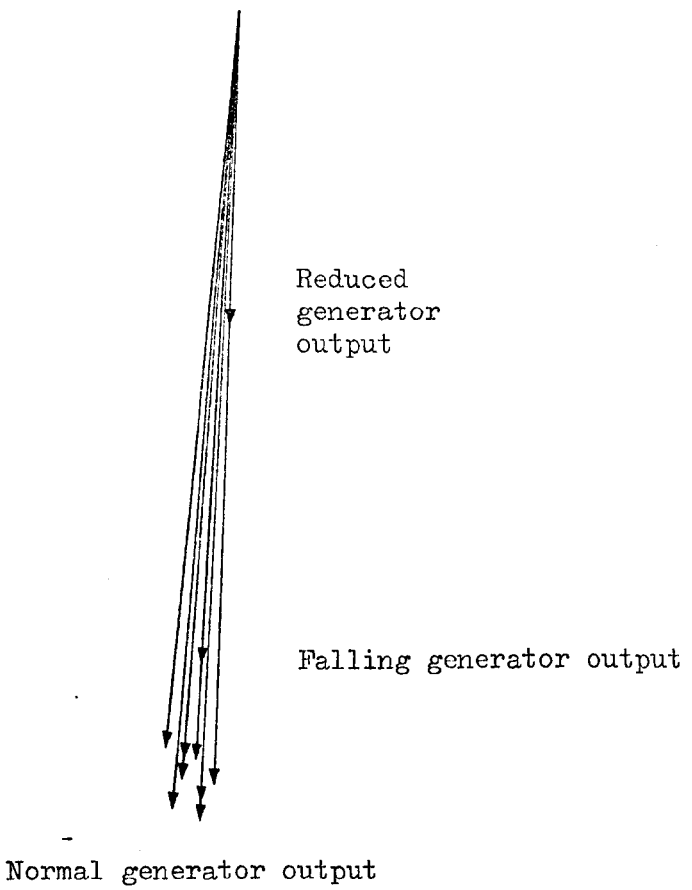


Figure 64. Reduction in magnitude of pacemaker frontal plane vectors with fall in output of unipolar myocardial pacemaker (20 mV/cm.)

a modification was made to this model in April 1972 which will result in a step decrease in generator rate when a cell fails prematurely.

A big reduction in generator output, from whatever cause, will give a corresponding reduction in the pacemaker frontal plane vector (Figure 65). Fortunately such big reductions have not occurred except with one particular generator (Medtronic, type 5841). These big reductions in output often have been accompanied with large decreases, or increases, in generator rate (Figure 90), though this has been of little consequence because generator-block has occurred.

A break in a conducting lead, the insulation remaining intact, will also cause a big reduction in the magnitude of the pacemaker frontal plane vector. This is, as explained before, because the high and perhaps variable resistance introduced into the output of the generator will cause a corresponding reduction in flow of current. (The reduction may be so great that it may be impossible to obtain a vector). Figure 66 shows one such case. Differential diagnosis between almost zero output because of a fault in the generator and almost zero output because of a break in a conducting lead is difficult if the output is very small. A stable generator rate would however suggest that there is <u>not</u> a break in the conducting lead.

If the insulation on one lead of a bipolar electrode-lead system fails this will cause changes in the magnitude and direction of the pacemaker frontal plane vector, as explained in sub-section 4.3 when changes in the pacemaker spikes were discussed. Thus a break in the insulation on the "negative" conductor will often result in an increase in the magnitude of the pacemaker frontal plane vector and a change in its direction. The change in direction will depend on the relative positions of the positive electrode at the heart and the point at which the broken insulation occurs and the resultant electric dipole which is formed from these unibip conditions. In general the changes in direction will be readily evident (Figure 67) but it is possible to envisage a case in which the extrapolated line drawn through myocardial electrodes is co-linear, or nearly so, with a line drawn through one of these electrodes and the point at which the break in the insulation has occurred. In these circumstances there will be virtually no change in direction but the magnitude will change.

Patient 53

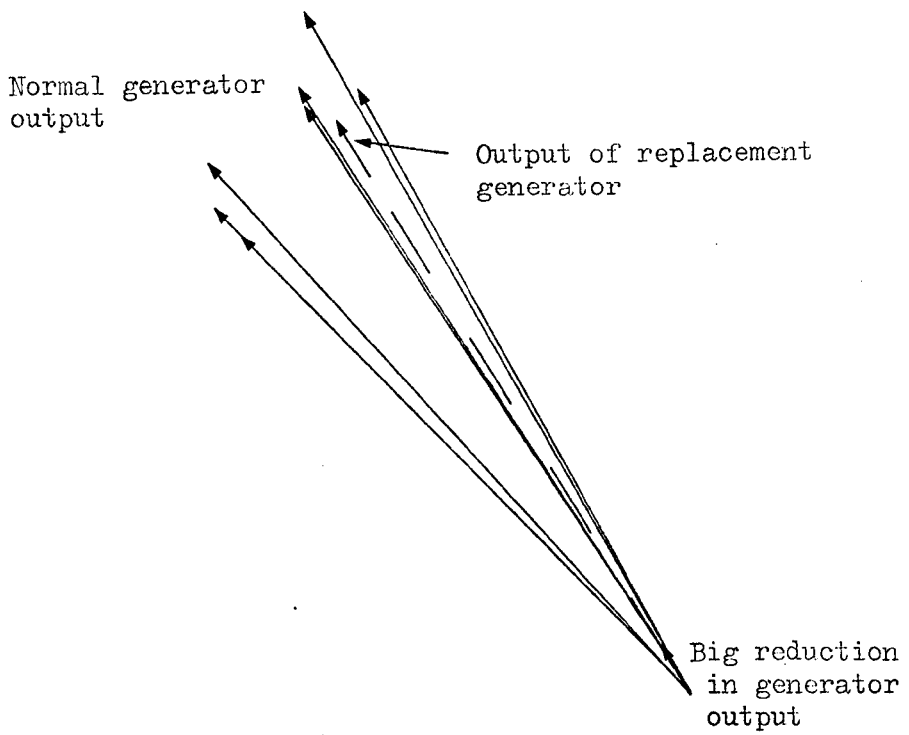


Figure 65. Big reduction in magnitude of pacemaker frontal plane vector with big reduction in generator output (1 mV/cm.)

Patient 43

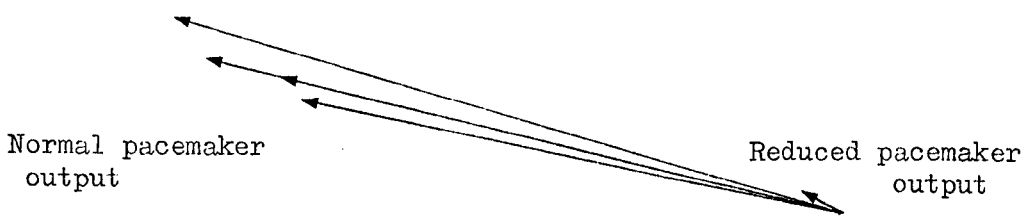


Figure 66. Conspicuous reduction in the magnitude of pacemaker frontal plane vector following a break in a conducting lead (1 mV/cm.)

Patient 51

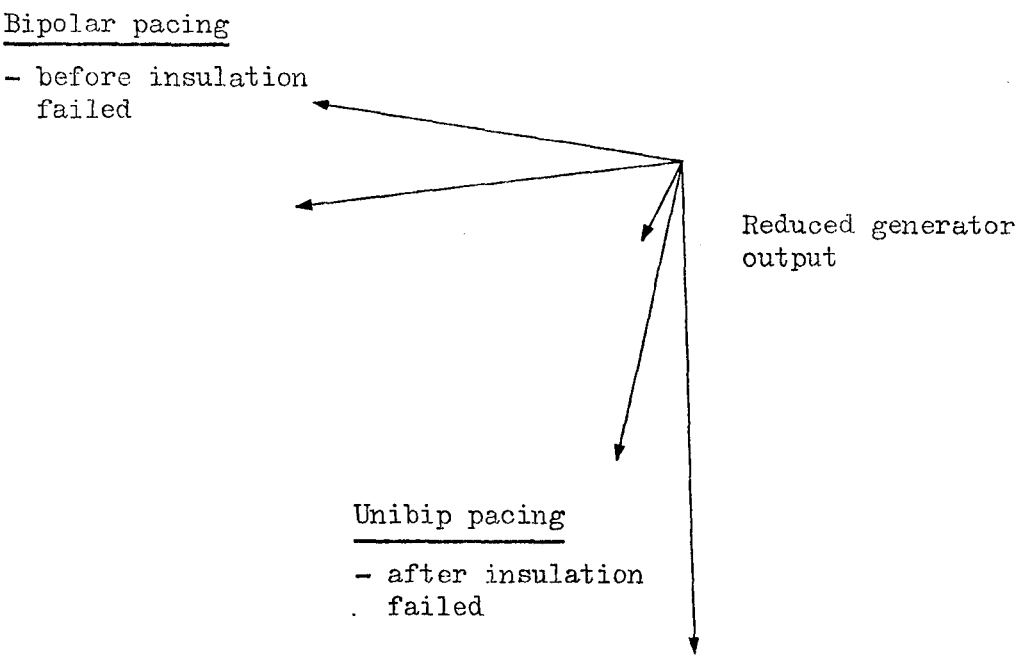


Figure 67. Rotation of pacemaker frontal plane vectors following break in insulation on "negative" conducting lead, accompanied with fall in output of generator. Generator implanted in right axilla (1 mV/cm.)

Similar results will be obtained when an electrical leak occurs at a negative insulating screw in the generator or when the insulating lubricant seeps out of the negative generator boot. Figure 68 shows an example of the former, which was confirmed at re-operation, after which the vector returned to normal.

It is not possible to distinguish with certainty whether there has been a break in the insulation or whether an electrical leak is occurring. Possibly the exception is that if the leak is small and variable it will give varying pacemaker frontal plane vectors. This is presumably the explanation of the varying pacemaker vectors seen in Figure 68 .

Similar arguments can be advanced when a break occurs in the insulation on the "positive" lead of a bipolar electrode-lead system. In these circumstances if the generator has been implanted in the patient's right side and a break occurs in the insulation near the generator, or near the point of entry to the jugular vein, the resultant electric dipole may well have a direction which is not so very different from the direction of the original electric dipole. If, however, the generator has been implanted in the patient's left side, in similar circumstances there is not only a change in magnitude but a significant change in direction which is readily discernible (Figure 69). It is for this reason that in Glasgow it has now been the practice, other things being equal, such as the availability of a suitable external jugular vein, to use the left external jugular vein for entry into the right ventricle and to implant the generator behind the patient's left pectoralis major.

Similar results will likewise be obtained when an electrical leak occurs at a positive insulating screw or when the insulating lubricant seeps out of the positive generator boot.

Figure 70 shows a case in which there was a rotation of the pacemaker frontal plane vectors following replacement of a failing generator. Either the insulation on the "positive" lead has failed or there is an electrical leak at the positive socket of the generator. One of these has yet to be confirmed.

Gross displacements of catheters can be detected by means of the pacemaker frontal plane vector technique. Figure 71 shows a case of an abnormal vector obtained when the catheter tip was found to be pointing towards the pulmonary outflow tract. Figure 72

Patient 64

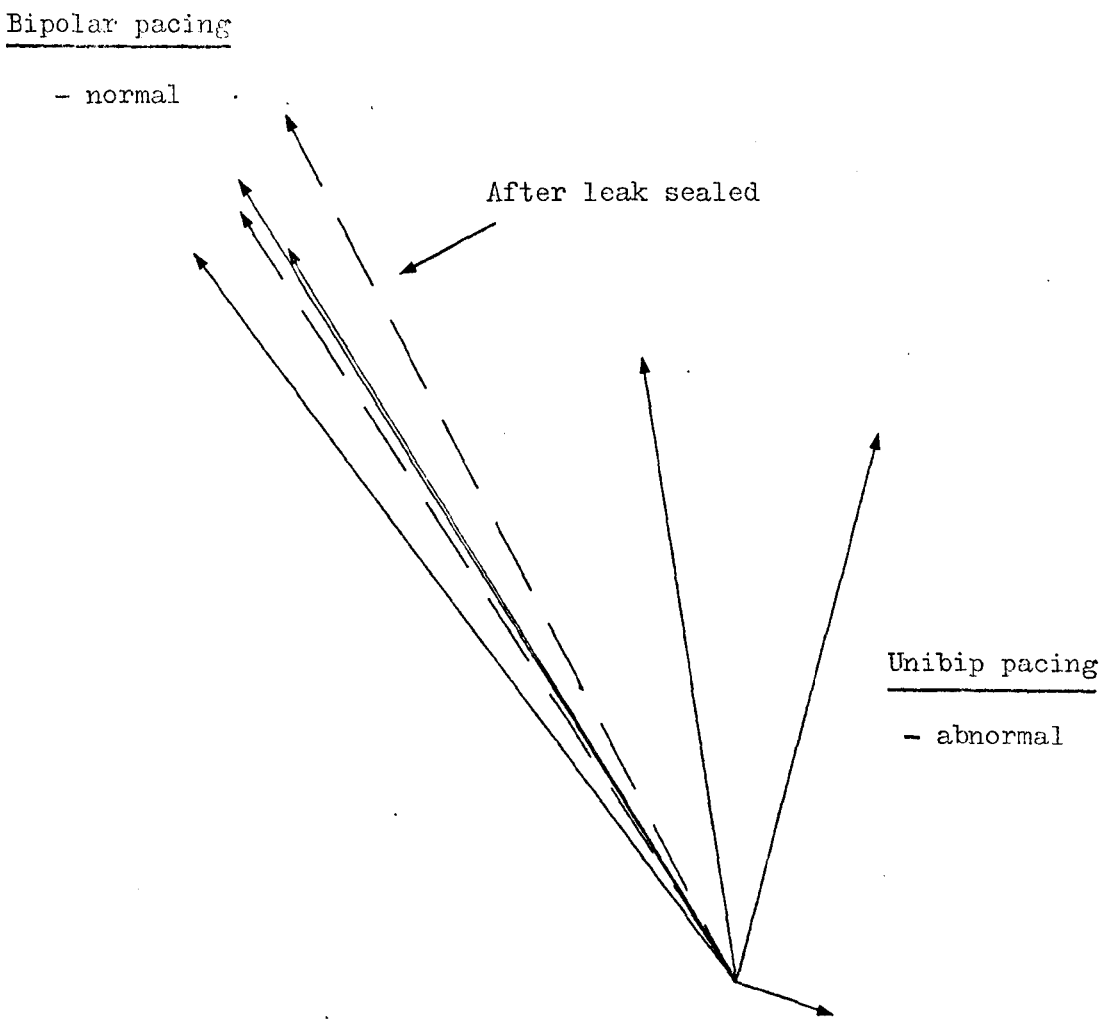


Figure 68. Changes in pacemaker frontal plane vectors caused by leaking negative insulating screw. Generator implanted behind right pectoralis major (1 mV/cm.)

Patient 49

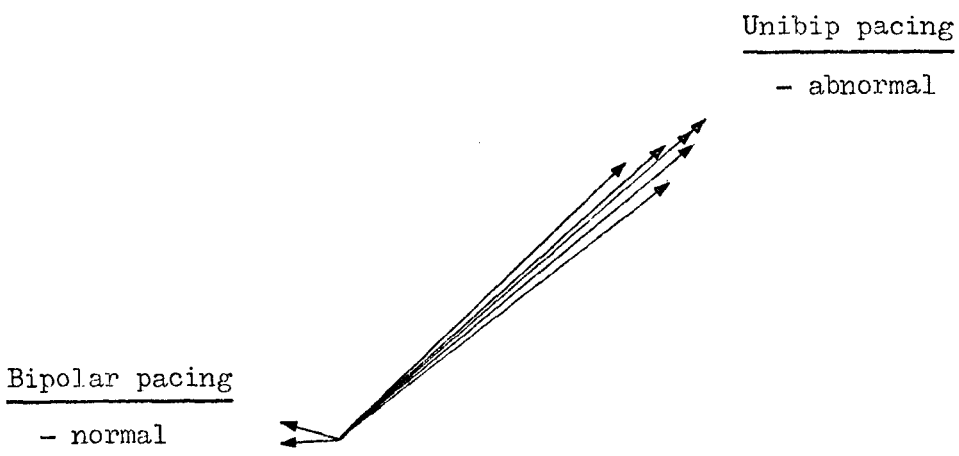


Figure 69. Changes in pacemaker frontal plane vectors caused by break in insulation on "positive" conducting lead. Generator implanted behind left pectoralis major (0.05 mV/cm.)

Patient 118

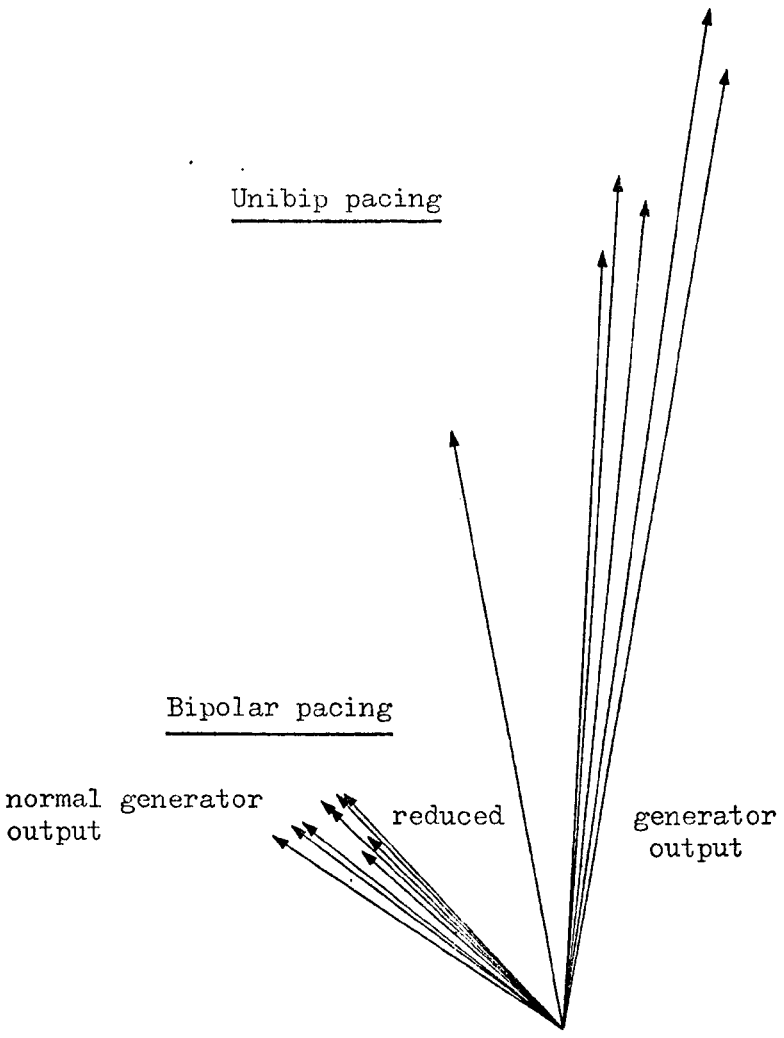


Figure 70. Rotation of pacemaker frontal plane vectors following replacement of failing generator. Break in insulation on "positive" lead, or "positive" electrical leak at generator, yet to be confirmed. Generator implanted behind left pectoralis major (2 mV/cm.)

Patient 5

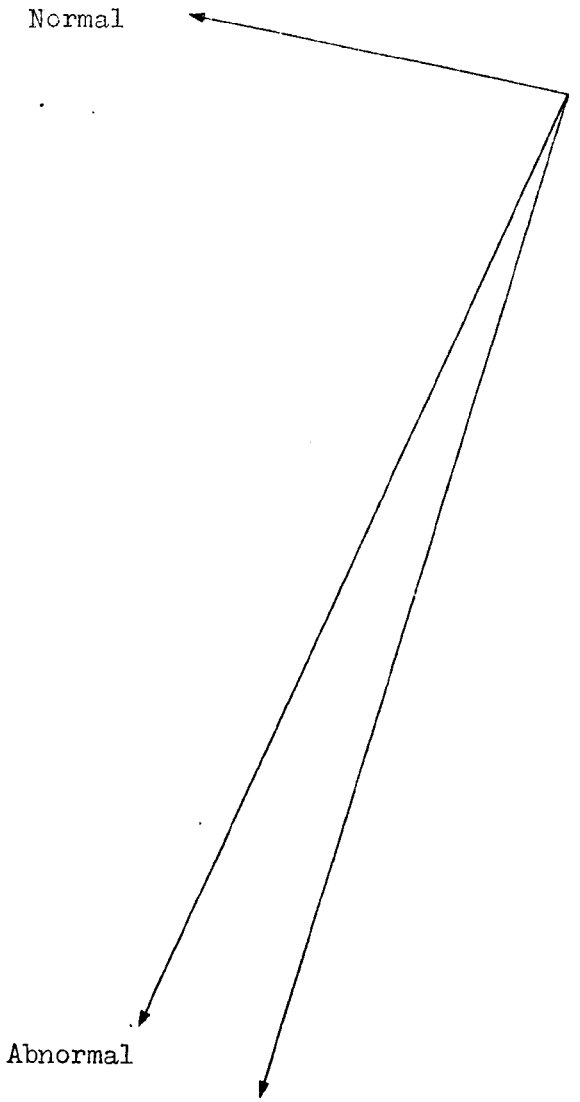


Figure 71. Changes in pacemaker frontal plane vectors caused by displacement of catheter. Catheter tip pointing to outflow tract (1 mV/cm.)

Patient 119

Figure 72. Abnormal pacemaker frontal plane vectors for bipolar endocardial pacemaker. Catheter displaced and in the right atrium with the tip pointing "downwards" (1 mV/cm.)

is another example in which an abnormal vector was obtained when the catheter was found to be "floating" inside the right atrium with the tip pointing "downwards".

The occurrence of exit-block can readily be confirmed by means of the pacemaker frontal plane vector technique. Thus consistent pacemaker frontal plane vectors confirm that the output of the pacemaker is unchanged, that the electrodes have not moved, so that threshold difficulties in the form of exit-block obtain. Figure 73 is a rare example in our experience of exit-block in which the problem was resolved by turning a bipolar myocardial pacemaker into a unipolar one since one unipolar threshold was found at re-operation not to be excessive. Unfortunately the active unipolar conductor, but not the insulation, failed at a later stage.

In principle the same arguments presented above apply in a similar manner to unipolar pacemakers. Certainly reductions in generator output, from whatever cause, and breaks in the conducting lead will produce corresponding changes in the magnitude of the pacemaker frontal vectors. However, if there is gross displacement of a catheter this may be reflected in a change in the direction of the pacemaker frontal plane vector. Exit-block will certainly be confirmed by neither a change in the magnitude nor a change in the direction of the pacemaker frontal plane vector.

Although no experience is available as yet in Glasgow with breaks in the insulation, or electrical leaks with unipolar pacemakers, the changes which occur in the pacemaker frontal plane vectors will be smaller both in magnitude and direction if the breaks or leaks occur at or near the generator.

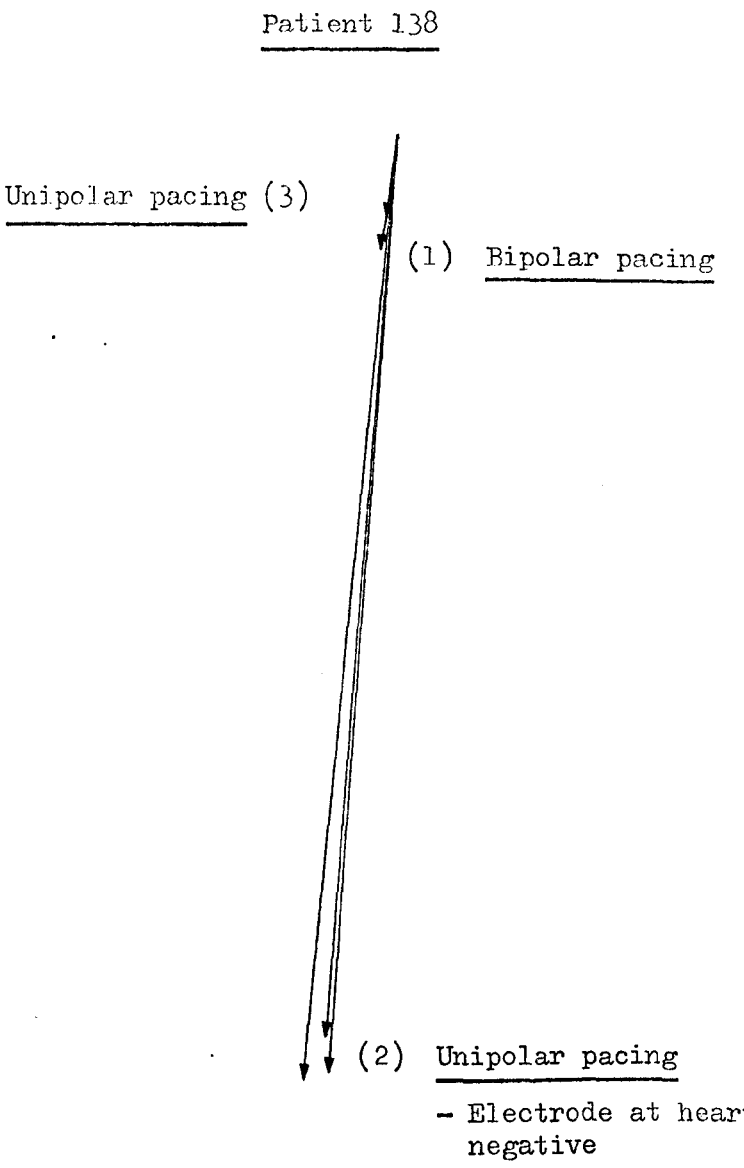


Figure 73. Pacemaker frontal plane vectors for myocardial pacemakers (20 mV/cm.):

(1) typical of cluster of vectors for particular bipolar myocardial pacemaker
(2) vectors from unipolar system, following exit-block at positive electrode
(3) reduction in unipolar vector following break in conducting lead (insulation intact).

6. Pacemaker Pulses

6.1 Characteristic pulse shapes

As already mentioned in sub-section 5.2, the choice of a suitable fast and triggered time-base on a differential oscilloscope, will enable the pacemaker spikes obtained from patient limb electrodes to be viewed as "square-wave" pulses. These pulses have a characteristic shape which depend on the output circuit of the implanted generator.

The basic characteristic pulse shapes are of three kinds:

(a) constant voltage
(b) constant current
(c) constant voltage, but current limited

The constant voltage generator has a small internal resistance in a capacitive output circuit. The leading edge voltage at the output terminals therefore remains constant for all values of resistance above a certain minimum. In the case of Medtronic asynchronous generators, type 5862C, this value is typically about 500 ohm. Since the resistance of the bipolar catheter used with this generator is 150 ohm, the patient load need be only 350 ohm to achieve constant voltage conditions. At values less than 500 ohm, the leading edge voltage begins to fall slightly. As the resistance increases the time-constant (CR) of the output circuit increases so that the trailing edges become more nearly equal to the leading edges. Patient loads are not purely resistive but are complex and it has been observed that in the case of emplaced Medtronic bipolar catheters typical impedances are in the region of 500 ohm to 1000 ohm, including the resistance of the electrode-lead system (150 ohm). The current flowing is dependent on the load resistance (impedance) and even over the limited range just quoted the current variations are considerable. Figure 74 shows the output curves of voltage and current for different values of resistance for a Medtronic asynchronous generator (type 5862C) and these are characteristic of the output curves for constant voltage generators. Figures 75 and 76 show how the voltage and current pulse shapes vary with different resistive loads. These are characteristic of a constant voltage capacitive output generator.

The constant current generator has a very high internal resistance so that there is little variation in current over a certain range of resistance. The smaller the current, the greater the resistance range over which this is true (Figure 77). For bigger currents the

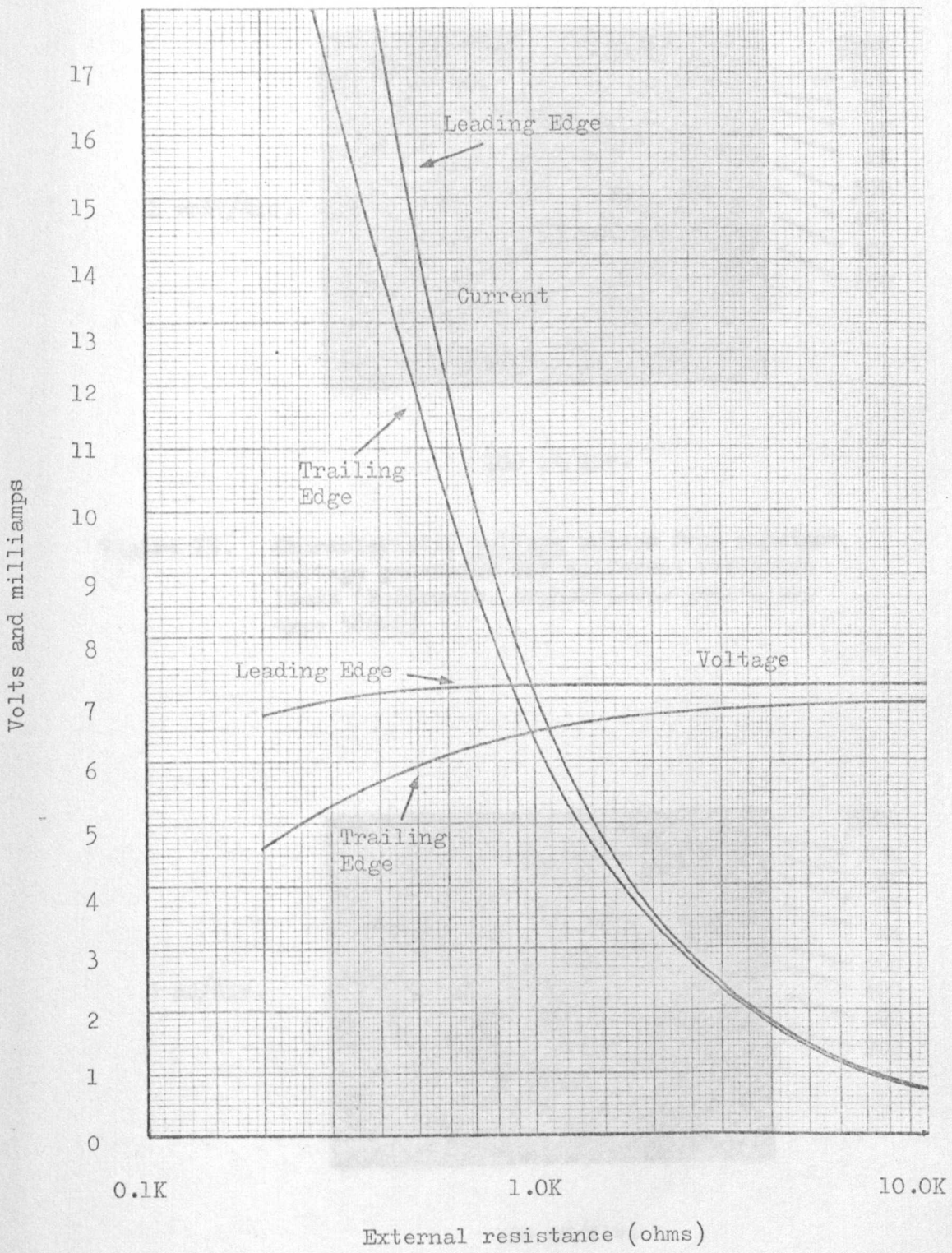
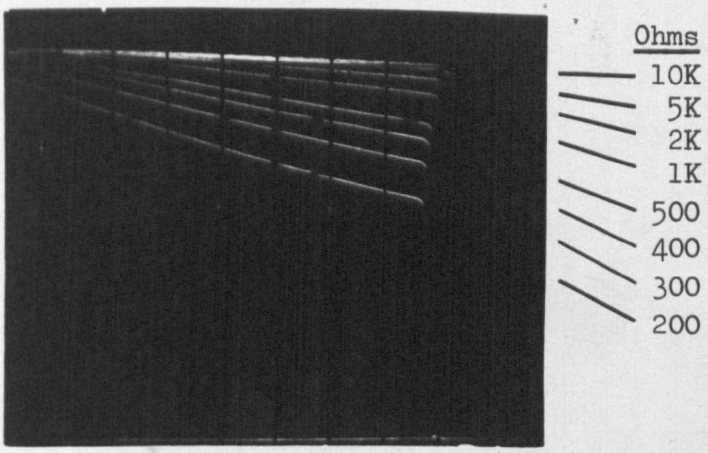


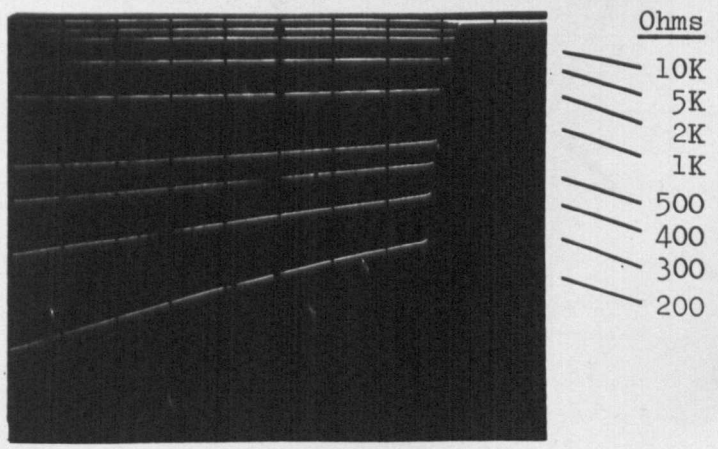
Figure 74. Characteristic output curves for constant voltage generator (Medtronic asynchronous generator, type 5862C)



1 volt/div.

100 μS/div.

Figure 75. Characteristic voltage pulses from constant voltage generator for different resistive loads (Medtronic, asynchronous generator, type 5862C)



5 mA/div.

100 μS/div.

Figure 76. Characteristic current pulses from constant voltage generator for different resistive loads (Medtronic, asynchronous generator, type 5862C)

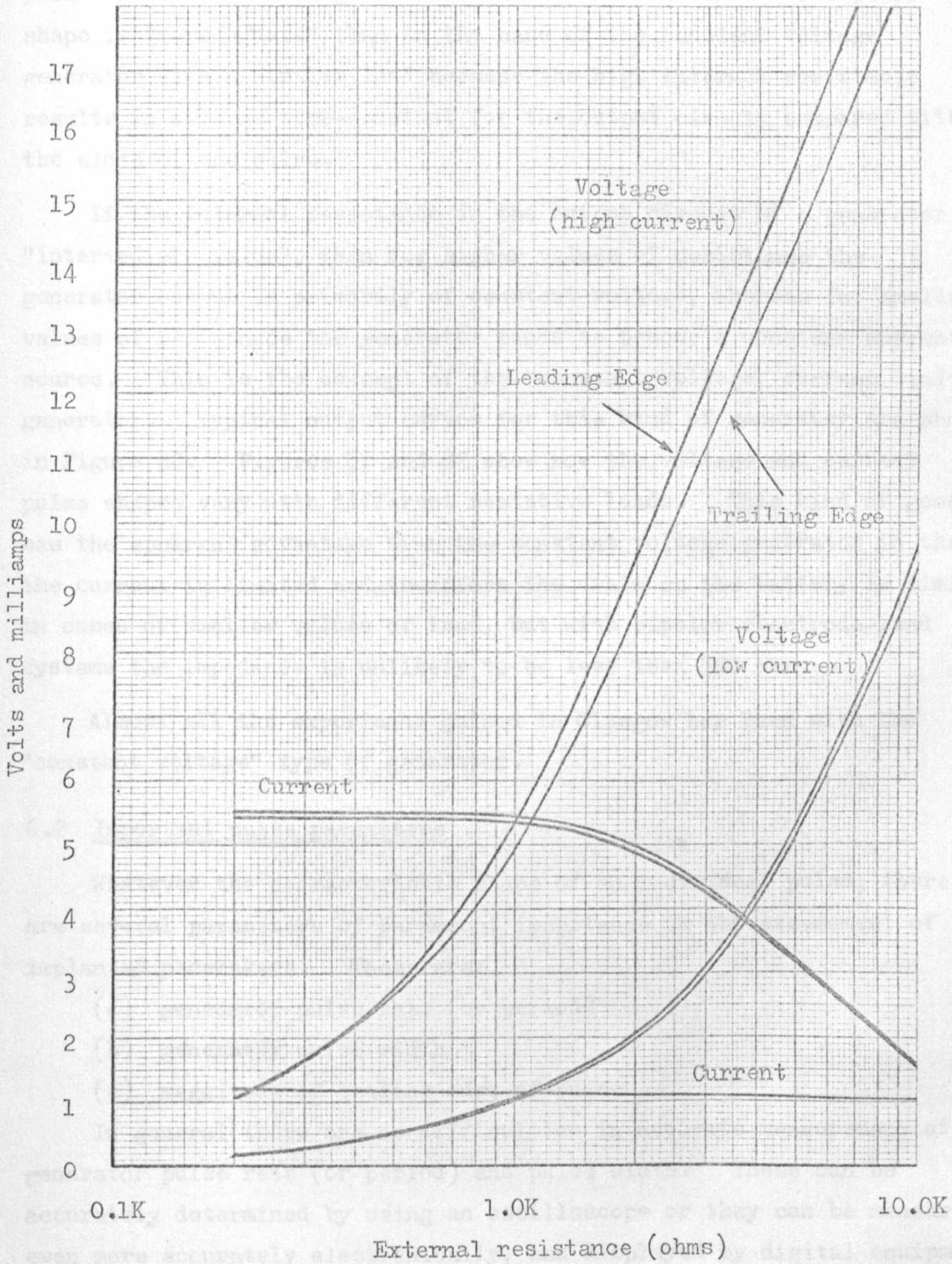


Figure 77. Characteristic output curves for constant current generator (Medtronic external demand generator, type 5880)

design is such that the current is more or less constant over the range of impedances which are typical with patient loads, e.g. up to 1000 ohm. Figures 78 and 79 show that the voltage, and current, pulse shapes over a range of resistances are constant. The pulse shape is "more square" than in the case of the constant voltage generator with a similar load because the high internal resistance results in a large time-constant for the output circuit compared with the width of the pulse.

If the internal resistance in the output circuit of a generator is of "intermediate value", then for higher values of resistance the generator output is primarily of constant voltage, whereas for smaller values of resistance the generator tends to become a constant current source. This is the concept of the "constant voltage, current limited" generator. Typical output curves for this kind of generator are shown in Figure 80. Figures 81 and 82 show how the voltage and current pulse shapes vary with different resistive loads. This kind of generator has the apparent advantage over the constant voltage generator in that the current is limited and therefore the drain on the battery is limited in cases of smaller values of load, but with bipolar electrode-lead systems the impedance is unlikely to be less than 500 ohm.

Almost all the experience gained in Glasgow has been with the "constant voltage" type of generator.

6.2 Important pulse parameters

Whatever the characteristic shape of an individual pulse, there are several parameters of paramount importance in the assessment of implanted pacemakers. These are:

(a) generator pulse rate (or period)

(b) generator pulse width

(c) magnitude of leading edge of pulse

In general there are no difficulties in accurate measurement of generator pulse rate (or period) and pulse width. These can be accurately determined by using an oscilloscope or they can be measured even more accurately electronically, and displayed by digital equipment described in the literature[73, 75] and by equipment recently marketed by Vitatron Ltd. Even simple measurement of generator rate from pulses on the oscilloscope, using a stopwatch (provided the pitfalls referred to in sub-section 3.1 are avoided) will be more accurate than measurements made from the pacemaker spikes on an E.C.G., because variations in paper speed make this method less reliable.

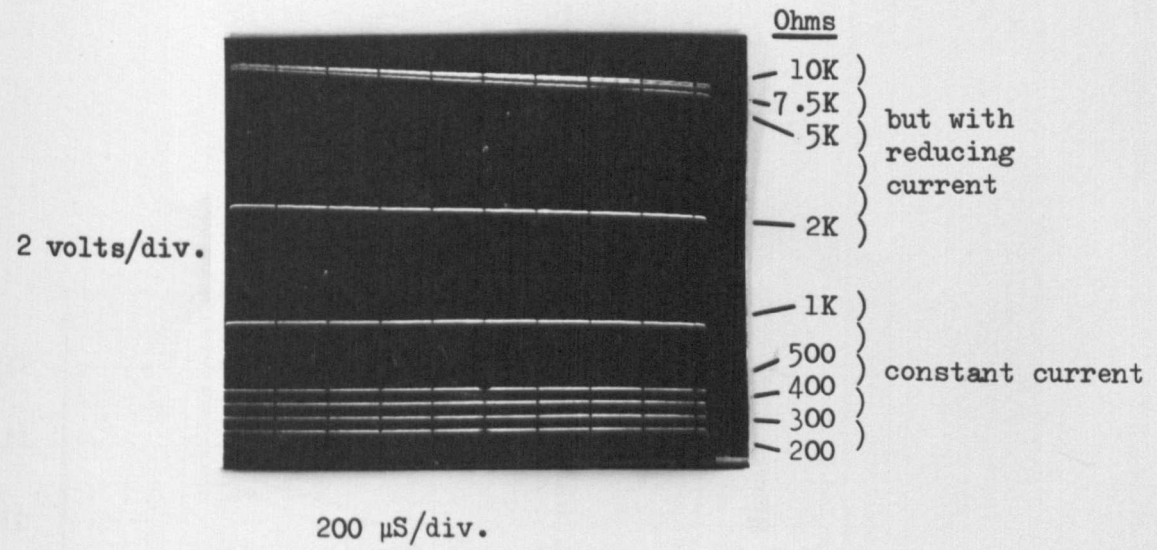


Figure 78. Characteristic voltage pulses from constant current generator for different resistive loads. (Medtronic external demand generator, type 5880)

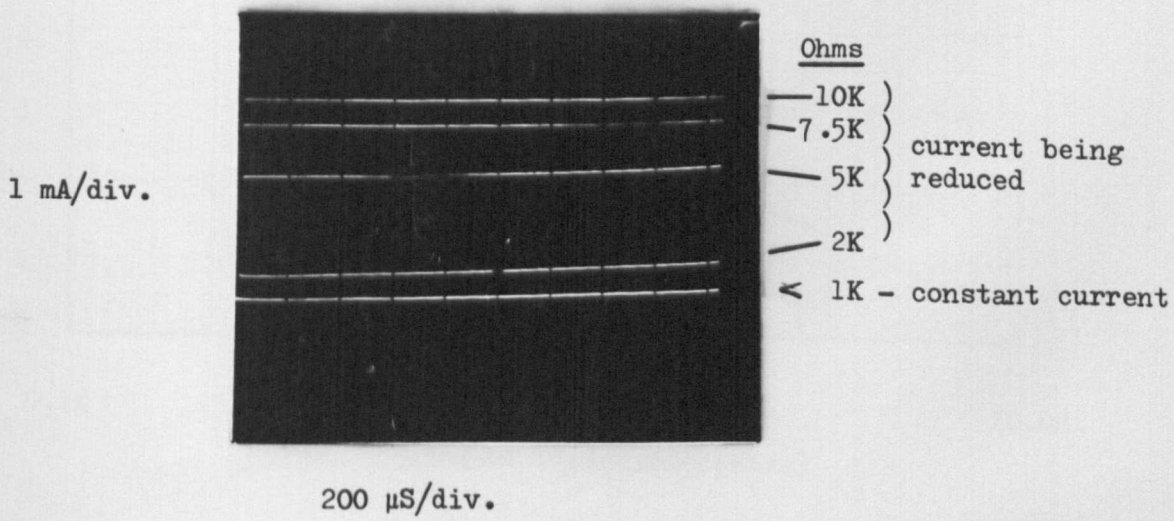


Figure 79. Characteristic current pulses from constant current generator for different resistive loads (Medtronic external demand generator, type 5880)

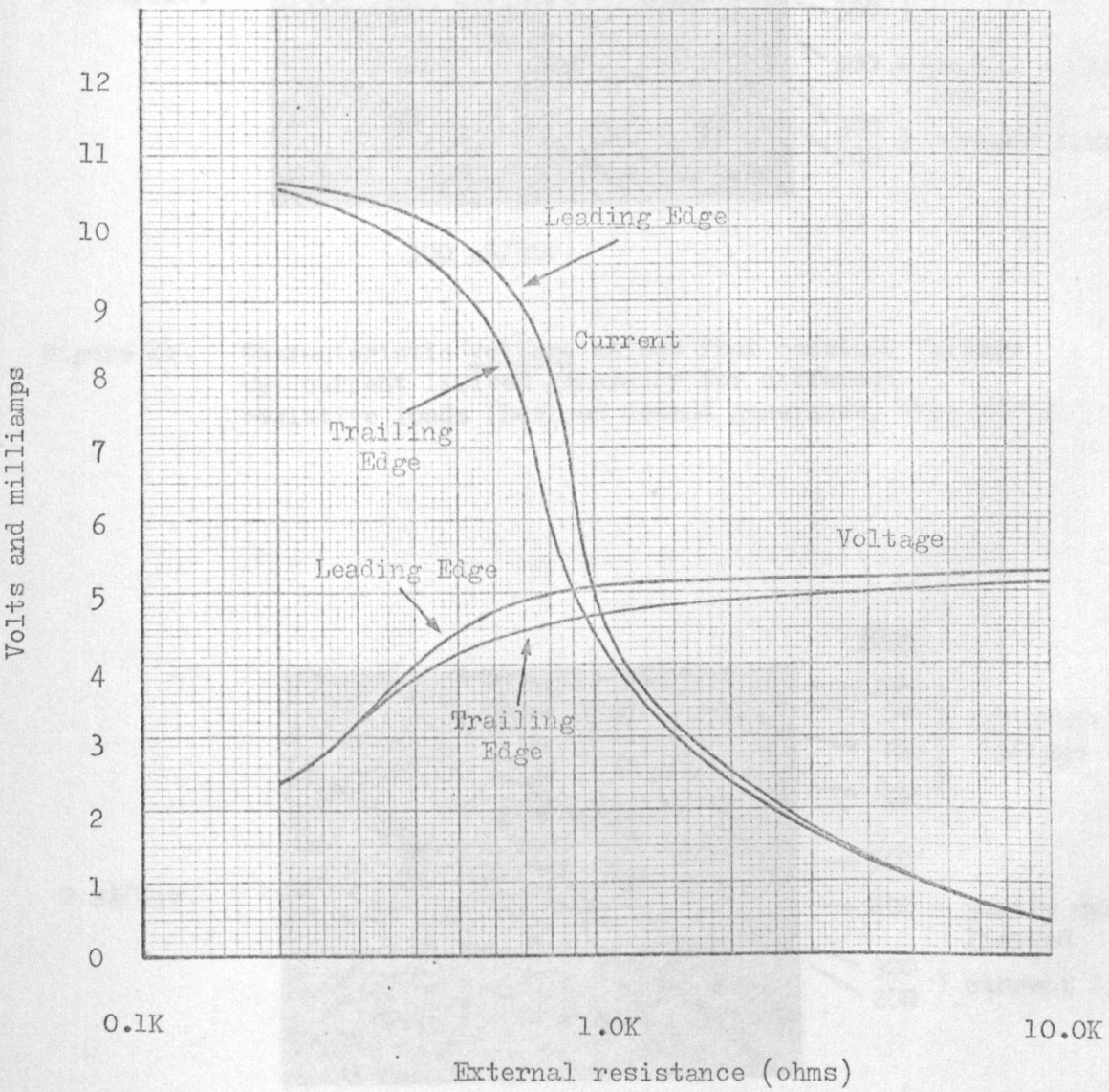


Figure 80. Characteristic output curves for constant voltage, current limit generator. (Devices demand generator, type BD85)

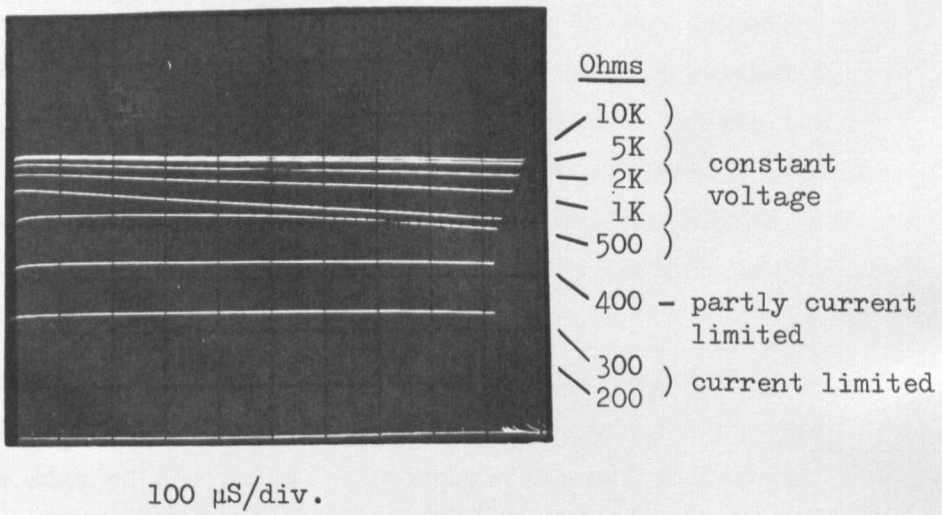


Figure 81. Characteristic voltage pulses from constant voltage but current limited generator for different resistive loads (Devices demand generator, type BD85)

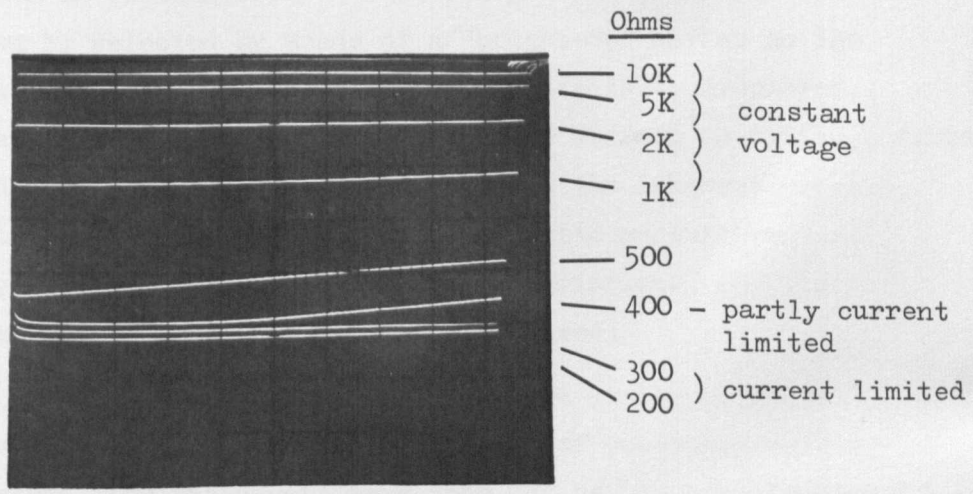
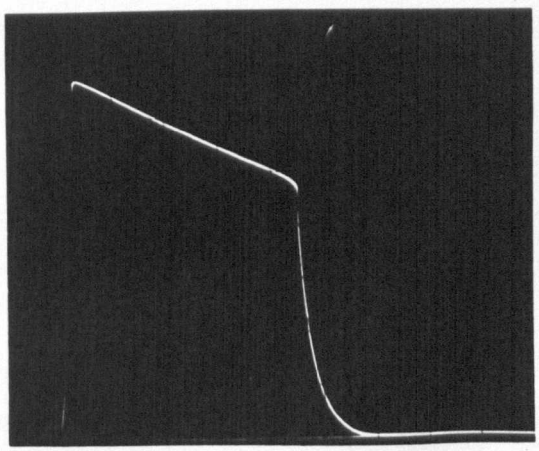


Figure 82. Characteristic current pulses from constant voltage but current limited generator for different resistive loads (Devices demand generator, type BD85)

Another method of counting generator rate is that of "radio-auscultation"[76]. Certain makes of generators emit sufficient electromagnetic radiation to produce "clicks" on a radio receiver which is placed on the skin directly over the site of implantation of the generator. The receiver should be tuned and orientated to give the loudest click: each click corresponds to the emission of a pulse from the implanted generator. A more recent development, namely the canning of demand generators in titanium to reduce the effects of external electromagnetic radiation, has naturally been effective in attenuating electromagnetic radiation from within the generator, so that with these canned generators the radio-auscultation technique is ineffective.

In measuring pulse width from an oscilloscope care should be taken to ensure that the pulse is triggered at the lowest possible level on the leading edge of the pulse. Discrepancies can also arise because of the difficulties in choosing the correct end-point of the trailing edge of a pulse which has a relatively long fall-time. Figure 83 is an example of such a pulse obtained directly from a Medtronic demand generator, type 5942, having a 500 ohm load. If during direct measurement on an oscilloscope, the same point is selected in the fall-time, then consistent results should be obtained. This is still possible when sophisticated electronic timers are used in conjunction with an oscilloscope: thus the precise point for measurement can be selected by means of a "bright-up" marker on the displayed pulse, and the selected width is then digitally displayed. However, any automatic electronic analysis, which depends on differentiation of the trailing edge of the pulse, cannot resolve the inherent problem resulting from the slow fall-time. Such automatic measurements will result in pulse widths which show some slight variations, and the oscilloscope methods referred to above must be used.

The importance of measuring the leading edge of the pulse accurately has already been dealt with in terms of pacemaker spikes. It can be measured from the square wave form but, as has already been explained, there is some difficulty in picking out the leading edge amplitude which corresponds to full inspiration, or whatever reference state has been chosen. This is particularly true of bipolar pacemakers in which the amplitudes of pulses are only of the order of a few millivolts.



1 volt/div.

200 μS/div.

Figure 83. Pulse from Medtronic demand generator, type 5942, showing curved portion of last part of trailing edge. (Resistive load of 500 ohms)

6.3 Time-constant of slow-part of constant voltage pulses

The mathematical analysis of the output pulse from a constant voltage source, having a capacitive output and purely resistive external load, is given in Appendix III, Parts 1 and 2. As explained in Part 3 of this Appendix, the time constant is too long for its direct measurement from a pulse. If, however, the time required for the amplitude to fall to 90.5% of its initial value is measured directly from the pulse, this corresponds to one-tenth of the time-constant for a particular generator and a given resistive load, so that the time constant can be quickly estimated. The task is made easier if, in storing the pulse on the screen of the oscilloscope, maximum use is made of the screen available. The vertical amplifier can be in the "uncalibrated" mode and the sensitivity adjusted accordingly since time-constants are independent of absolute magnitudes. If the measurements are repeated with a different external resistance, a different time constant will be obtained, and from a knowledge of the two time constants and two known resistances the effective capacitance and internal resistance of the output stage of the generator can be calculated.

An alternative indirect method is to plot the logarithm of the relative magnitudes of the pulse, over the time period of the pulse, for two values of resistance as explained in the previous paragraph, and from the slopes of the straight line curves obtained, the effective capacitance, internal resistance and time constant (for a given external resistance) can be determined.

The time-constant will remain constant if the external load remains constant and if the electrical characteristics of the output stage of the generator remain constant. However, another method of checking whether any such changes have occurred, is to measure the amplitude of the pulse at some arbitrary time such as 500 microseconds from the leading edge of the pulse, and express it as a fraction of the leading edge value (decay ratio).

The replacement of the purely resistive load by an electrically complex patient load gives a complex pulse, the latter part of which (after 500 microseconds from the leading edge) follows an exponential decay which can be defined by a single time constant. Nevertheless, for the sake of simplicity and, since only changes in electrical characteristics are being sought, rather than absolute values, the decay ratio referred to above is often used to ascertain the constancy

(or otherwise) of electrical output circuit parameters, rather than the true electrical time constant.

The pulse shapes obtained with bipolar pacemakers are different from those obtained with unipolar pacemakers (Appendix III, Part 4). because the patient loads are different. However, with both types it is just as easy to calculate the true time constant of the latter part of the pulse or to calculate the decay-ratio with reference to the earlier part of the pulse. It is important when carrying out these investigations to ensure that the pulse is as large as possible. As already mentioned the vertical amplifier should be switched to the uncalibrated mode and adjusted accordingly, but the time-base must remain in the calibrated mode if true time constants and decay-ratios over specific periods of time are to be calculated. These measurements are simplified further if the peak of the pulse is aligned with a major screen grid line by adjustment of the "X" shift control (i.e. the rise time of the pulse which may be 40 to 80 microseconds can be ignored) and if the Y shift control is adjusted so that the zero of the pulse coincides with a major screen grid line. The pulses can be recorded at any part of the breathing cycle. Although respiration does effect the magnitude of the pacemaker pulses it does not appear to alter the time-constant or the decay ratio for a particular patient.

6.4 Significance of changes in pulse parameters

Whatever the characteristic pulse shape (i.e. constant voltage, constant current, etc.) the pulse width should remain virtually unchanged. In the case of the Medtronic generators used in Glasgow large changes in pulse width have never occurred. When they have occurred, they have always been so small that they have not resulted in the generator being replaced. These small changes have probably been caused by changes in the load impedance. Even when there has been a reduction in output of the generator it has not been accompanied with a significant change in pulse width. Other workers, for instance Smith[77] et al. who have reported on their experiences with Elema-Schonander pacemakers, have found that changes in pulse width have been of great value in giving early warning of impending generator failure. Accurate measurement of pulse width is therefore not only of importance, in that it confirms that this parameter is unchanged, but it seems that with at least one generator it is a useful indication of impending generator failure.

Similarly generator pulse rate (period) should remain unchanged. Experience in Glasgow with Medtronic generators has shown that this parameter has changed on many occasions, usually from premature failure of one or more cells, and a change in rate has therefore been accompanied with a reduction in output. (Part II, section 1, Part III, sub-section 2.1). In only a few cases has the rate change been sufficient to warrant emergency re-operations. As already mentioned (Part II, section 1) some of the Medtronic generators (types 5862C, 5842 and 5942) which have been implanted in patients in Glasgow are of such a design that there is no change in rate with first fall in output. Other workers, however, using different makes of pacemakers, have reported on their dependence on rate changes for early warning of generator failure and, in these circumstances, generator rate is a very important factor and evidently needs to be measured accurately.

A reduction in generator output, from failure of one or more cells, will give a reduction in the magnitude of the leading edge of the pulse, on all Leads, whatever the characteristic nature of the generator pulse. (If the angle between an imaginary line drawn through the electrodes and the frontal plane increases posteriorly, there will be a reduction in the leading edge of the pulse on all Leads though as explained in Part II, section 1, this is a rare occurrence after the first few months following first emplacement of a catheter).

Changes in resistance (impedance) in the output circuit of the generator can effect the current flowing between the electrodes and therefore the size and shape of the pulse detected via skin electrodes. In the case of a constant voltage generator any increase in the resistance in the output circuit, from whatever cause, will not only reduce the amplitude of the leading edge of the pulse but the time constant and the decay-ratio are both increased. Conversely any effective decrease in resistance (e.g. as a result of unibip pacing) will increase the magnitude of the leading edge of the pulse, decrease the time constant and decrease the decay ratio. A very large increase in resistance, however, may reduce the magnitude of the pulse so much that it becomes impossible to record a pulse for measurements. This has occurred on a number of occasions when electrode-lead systems have fractured, the insulation remaining intact.

With constant current generators a small increase in resistance in the range 200 ohm to 1000 ohm in the output circuit, from whatever cause, will have a small effect on the magnitude of the leading edge of the current pulse, and it will have little effect on the time-constant in the output circuit so that the wave-shape will be unchanged provided the increase in resistance is small compared with the internal resistance of the generator. A larger increase in resistance (> 2 K ohm, < 10 K ohm) will, however, reduce the current but cause little change in the pulse shape. Enormous increases in resistance will cause further significant reductions in current and cause changes in the pulse shape.

In the case of a constant voltage but current limited generator, an increase in the resistance from, say, 500 ohm, will cause a reduction in the magnitude of the leading-edge of the pulse and an increase in the time constant, just as was the case for a constant voltage generator. As explained previously, an enormous increase in resistance resulting from a break in an electrode-lead, the insulation remaining intact, will result in a small pulse which may be so small that it is difficult to observe and impossible to record. Any decreases in resistance below about 500 ohm will result in proportionately smaller and smaller current increases so that the generator becomes current-limited.

6.5 Review of earlier published work on pacemaker pulses

Analysis of the pacemaker pulses obtained from electrodes placed on the skin overlying the bipolar myocardial electrodes (or in the case of unipolar pacemakers one electrode is placed over the site of the indifferent electrode) which is connected to an oscilloscope, was first described by Nickel[78] in 1964. A measure of the time-constant of the slow part of the pulse was obtained in terms of the ratio of the magnitude of the pulse 0.5 millisecond after the leading edge to the magnitude of the leading edge itself. He suggested that this quotient can be used as an indicator of impedance or changes in impedance in the output stage of the pacemaker circuit.

Knuckey[79] et al. published their experiences on the usefulness of pulse width, pulse rate and leading edge measurements using limb electrodes based on 10 patients in 1965. Although they obtained satisfactory and meaningful results with unipolar pacemakers, they added, "the small pulses from a bipolar system do not give a good indication of stimulating potential". This was because with bipolar

systems "the pulse amplitude was, at the most, twice as large as the deviation due to respiration and week-by-week changes".

Schaldack[80] et al. in 1966, in a paper applied to unipolar pacemakers, show the changes in pulse shape resulting from a "fractured electrode", and a change in tissue resistance, both of which result in an increased resistive load (increased time-constant), as well as the result of a decrease in resistive load (decreased time-constant) resulting from an "electrode shunt" (break in the insulation). These possible changes in pulse shape are depicted.

No mention is made of bipolar pacemakers.

Van den Berg[81] et al., in a comprehensive analytical treatment in 1967, examined pacemaker pulses in more detail than others had done previously. Their technique has become known as the "photo-analysis" technique, because the pacemaker pulses from Leads I, II and III are observed (via skin electrodes) on the oscilloscope screen and recorded on polaroid film for further analysis.

In their analysis the output circuits of the three types of pacemakers (constant current, constant voltage, constant voltage but current limited) are discussed in terms of possible changes in "maximal pulse amplitude, plateau duration, slope, impulse duration and frequency". Many simulated faults are shown and the authors claim that in their hands with "about 1000 measurements on 200 patients during one and a half years" the method of photo-analysis has been very useful.

They made an observation not made by other authors that a complex situation can arise when an electrode-lead system fractures, the insulation remaining intact. They demonstrated that if a lead breaks, the resistance increases, but if fluid is present between the two broken ends of the conductor, then when the two metallic end surfaces are in contact, any current which still flows can cause polarisation at the two end surfaces and this produces a pulse shape with a much smaller time constant and a smaller decay-ratio.

They too came to the conclusion that unipolar voltage pacemakers and voltage but current limited pacemakers are preferable for the method of photo-analysis.

Sowton[82] in 1967 reported he had found changes in generator rate of plus or minus five pulses per minute to be a most useful indicator of the need to replace a generator. Additional useful information could also be provided by "waveform analysis" of constant voltage pacemakers. In waveform analysis, Sowton extended the tests conducted by Knuckey and colleagues to include time constant measurements, first suggested by Nickel and measured in terms of a decay-ratio at 0.5 millisecond from the leading edge of the pulse. Waveform analysis thus included measurement of pulse width, leading edge amplitude and decay-ratio at 0.5 millisecond from the leading edge of the pulse. Unipolar pacemakers were being used routinely because of the relative ease with which these measurements can be made when compared with bipolar pacemakers.

Ryden[83] in 1968 also reported his use of the same waveform analysis technique. However, another arbitrary time of 0.4 millisecond was used in determining the decay-ratio.

Davies and Siddons[84] in 1969 used the same technique and the same time of 0.4 millisecond. They too, for the same reasons, expressed by Sowton, preferred to use unipolar pacemakers.

Ryden[75] et al. described in 1970 electronic digital equipment specially designed for use with unipolar constant voltage pacemakers. Although somewhat similar equipment has been in use in Glasgow for some time (Thomas[73] et al.) Ryden's equipment provided digital display of the actual time constant of the slow part of the pacemaker pulse.

Sowton and Gray[85] in a more recent paper (1971) reported further on the usefulness of the waveform analysis technique in "the diagnosis of exit-block, electrode failure and premature battery exhaustion and in determining the optimum time for pacemaker replacements". Later in the paper they state, " . . . we do not feel that satisfactory amplitude measurements can be obtained with this method for bipolar pacing".

7. Radiological Information

Pacemaker patients attending pacemaker clinics do not normally undergo routine radiological screening, neither do they normally have a chest X-ray taken. If, however, any of the previous investigations has raised doubts about certain aspects of the pacemaker, or the pacing function, an X-ray is taken and sometimes, in addition, X-ray screening is carried out. For instance, as has already been mentioned, a change in the direction of the pacemaker frontal plane vector might be the result of a displaced catheter: an X-ray film of the chest readily confirms or rejects this as a possible cause of the change in direction of the vector. If a break in a conducting lead is suspected, an X-ray might reveal the location of the break, though this is not certain, particularly if the insulation is intact so that the two broken ends remain essentially in the same line. However, any sharp discontinuities or gaps in the line of the conductor will be clearly discernible (Figures 84 and 85). Insulation failures will not, of course, be evident from X-ray examinations.

Radiological examination of the generator in-vivo is not very helpful, except perhaps in helping to distinguish the type and make of generator in a patient who has arrived from another hospital, or from abroad, when perhaps in an emergency there is little time to obtain information on the generator through normal channels.

Greatbatch[86] et al. in 1965 first showed that useful information on the state of mercury cells could be deduced by means of X-rays. Later in 1965, Lillehei[87] et al. applied the technique to in-vivo studies. X-ray examination gives a useful indication of the chemical state of the cells, i.e. the reserve of chemical energy remaining in the cells. This is based on the fact that as the cells release electrical energy, mercuric oxide is converted to free radio-opaque metallic mercury which can be quantitatively estimated by radiological examination. Unfortunately, it is difficult to obtain good X-ray films of the mercury cells in-vivo and because of this the technique has not been widely adopted. The technique has, however, proved to be more useful in assessing the state of the cells after removal. Figure 86 shows examples of (a) cells prior to implantation and (b) after depletion of one cell has occurred.

Patient 166

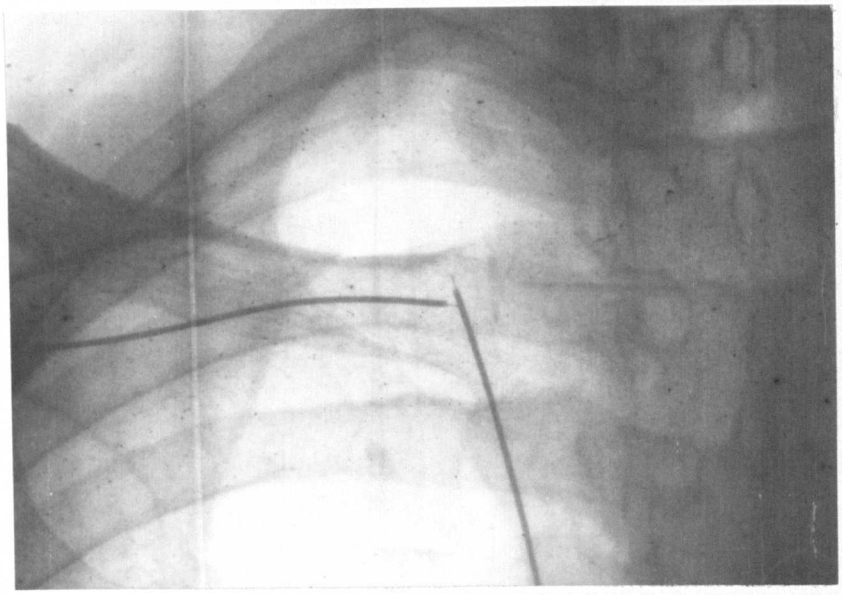


Figure 84. Radiograph showing broken unipolar endocardial electrode-lead system.

Patient 91

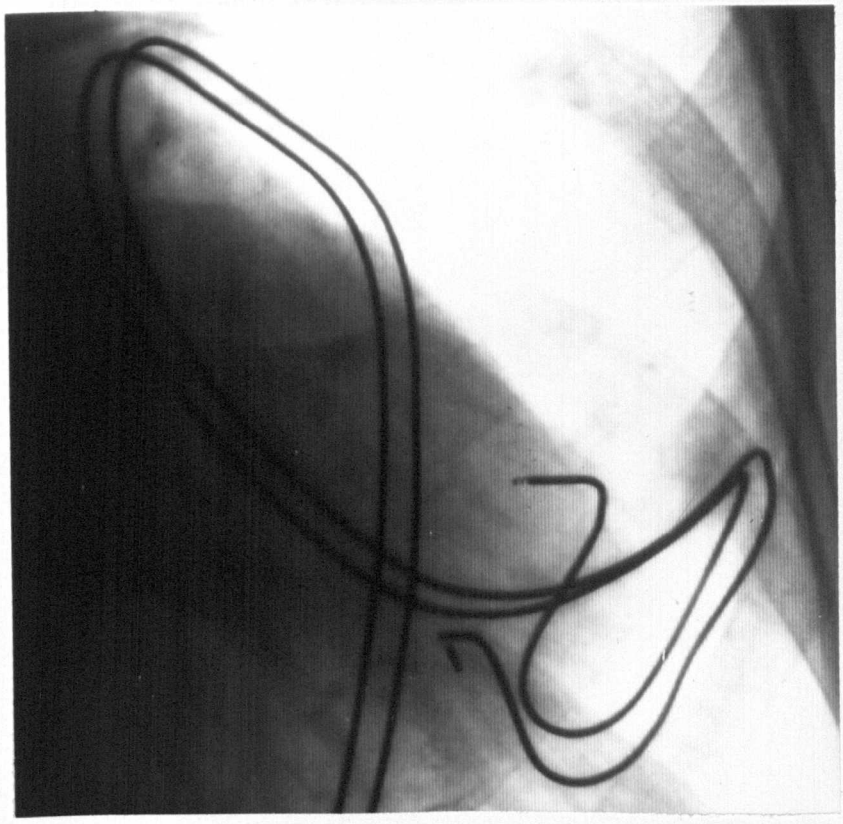
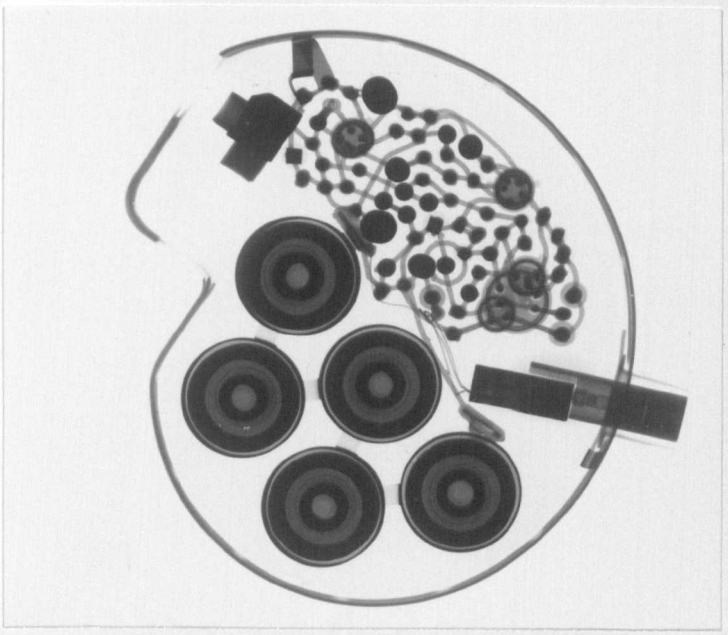


Figure 85. Radiograph showing break in one lead of bipolar myocardial electrode-lead system.

(a)



(b)

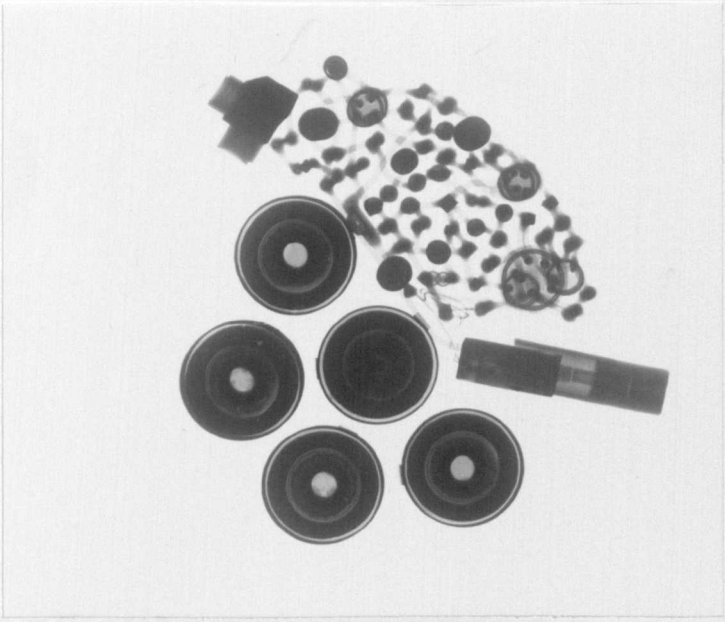


Figure 86. Radiographs of Medtronic generators showing mercury cells:

(a) in "new" condition before implantation of generator, type 5942, and

(b) after premature failure of one cell and removal from patient, type 5842

Part III - Performance

1. General

Once a systematic method has been established for assessing implanted cardiac pacemakers it then becomes possible to analyse their performance. By performance is meant a comprehensive assembly and analysis of data relating to the faults and problems discussed in Part II. Deaths of pacemaker patients also affect some performance data, and care is taken to distinguish between those deaths which are related, or may be related, to the pacemaker implant as discussed in section 10, and the total number of deaths which affect the data presented in section 4.

In assembling data and making any analyses it becomes necessary to choose a particular period of time. This is necessary because the basic data is changing each month: new patients are receiving their first implants; other patients are undergoing re-operations for replacement generators or other complication; and deaths occur from time to time. The period chosen for this study, as indicated in Part I, is 1st July, 1966 to 30th June, 1972. The former date was chosen some time after the first implant in Glasgow took place, so as to exclude some of the data associated with the earlier generators and the "teething troubles" associated with the first implants. The latter date was chosen so as to allow sufficient time for the data to be assembled and compiled in a meaningful form for this thesis.

It soon became evident that there was a need to introduce new terms, carefully defined, which could be used to describe the performance of implanted pacemakers in terms of various "implant lifetimes". These terms are introduced in the succeeding sections. They have also been introduced in the hope that if they become widely adopted, it will become possible for the first time to make comparisons between the performance of generators and electrode-lead systems of different types and makes which are used in different pacing Centres.

One of the difficulties inherent in assembling pacemaker data is that a number of years must elapse following implantation to build-up actual data on "failed implant lifetimes" (Section 2) as opposed to manufacturers' predictions, extrapolations, etc. By the time enough data has been compiled on a particular generator, the manufacturer in the light of experience, technological developments, etc. may

have changed the design and perhaps the processes of manufacture . Nevertheless, the assembling of performance data on generators and electrode-lead systems which are no longer in production will show, in retrospect, what progress has been made and may highlight characteristics which can be relevant to current products.

A suitable unit of time for measuring implant lifetimes is "month" rather than "year". For the purpose of the implant lifetimes presented in this study a month refers to a calendar month (e.g. from 2nd January to 2nd February is equal to one month; from 2nd January to 2nd April is three months). Any period in excess of 15 days is counted as a month. Thus the period 2nd January to 19th April would be counted as four months. Calendar months may of course be of 28, 29, 30 or 31 days duration so that the term "month" is a slightly variable amount but it is much more convenient to use calendar months in calculating implant lifetimes and any lack of precision in this respect is of no significance.

2. Failed Implant Lifetimes

2.1 Generators

One of the performance definitions introduced earlier[8] is "Failed implant lifetime". Although the meaning remains unchanged, perhaps a better wording is "the time between implantation of a generator and the occurrence of a technical fault". In the case of generators, by a "fault" is meant a reduction in electrical output from the generator itself, or a change in generator rate, or both, whether it is caused by premature failure of mercury cells or a fault in the "circuitry". This latter term is intended to include discrete electronic components as well as integrated circuits produced by thin film and thick film techniques. Detection of such a generator fault may take place at a pacemaker clinic, or confirmation of an apparent fault in an implanted generator can occur following emergency admission to hospital. In the former case the actual date of its occurrence is unknown, but the date of detection is used for compiling implant lifetime data.

Figure 87 shows the failed implant lifetimes of Medtronic asynchronous generators (Type 5870C) implanted during the period 1st July, 1966 to 30th June, 1972, which subsequently failed in the same period. The longest failed implant lifetime achieved by this generator was 46 months.

The failure characteristics of Medtronic generators (Type 5870C), referred to above are given in figure 88. In all the cases shown, except two, one in which there was a very small decrease in rate associated with a decrease in output, and another in which the rate did not change when the output decreased, the increase in rate was accompanied with a decrease in output. In a few cases, the rate increased to more than 100 p.p.m. and these changes were associated with large decreases in output of more than 50%, with one exception.

The Medtronic asynchronous generator (Type 5870C), was superseded in February 1970 by a new model (Type 5862C) which uses integrated circuits instead of discrete components. Not one of these had failed by 30th June, 1972. Reference will be made again to these generators when "incomplete implant lifetimes" are discussed in the next section.

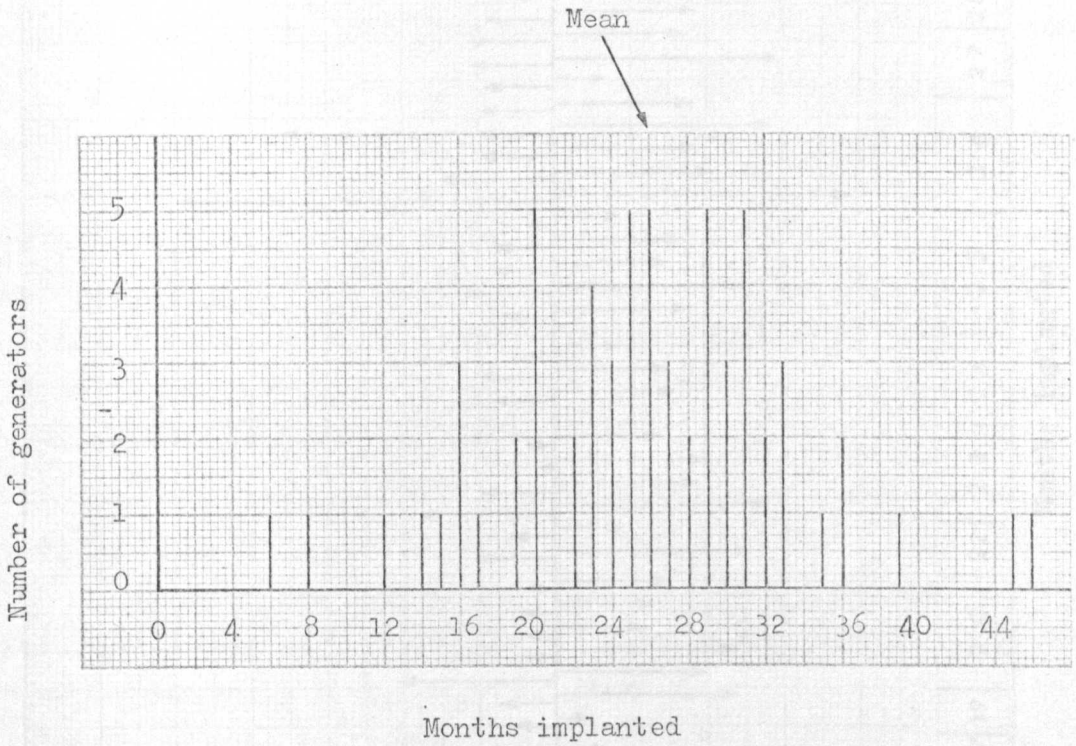


Figure 87. Failed implant lifetimes of Medtronic asynchronous generators (type 5870C)

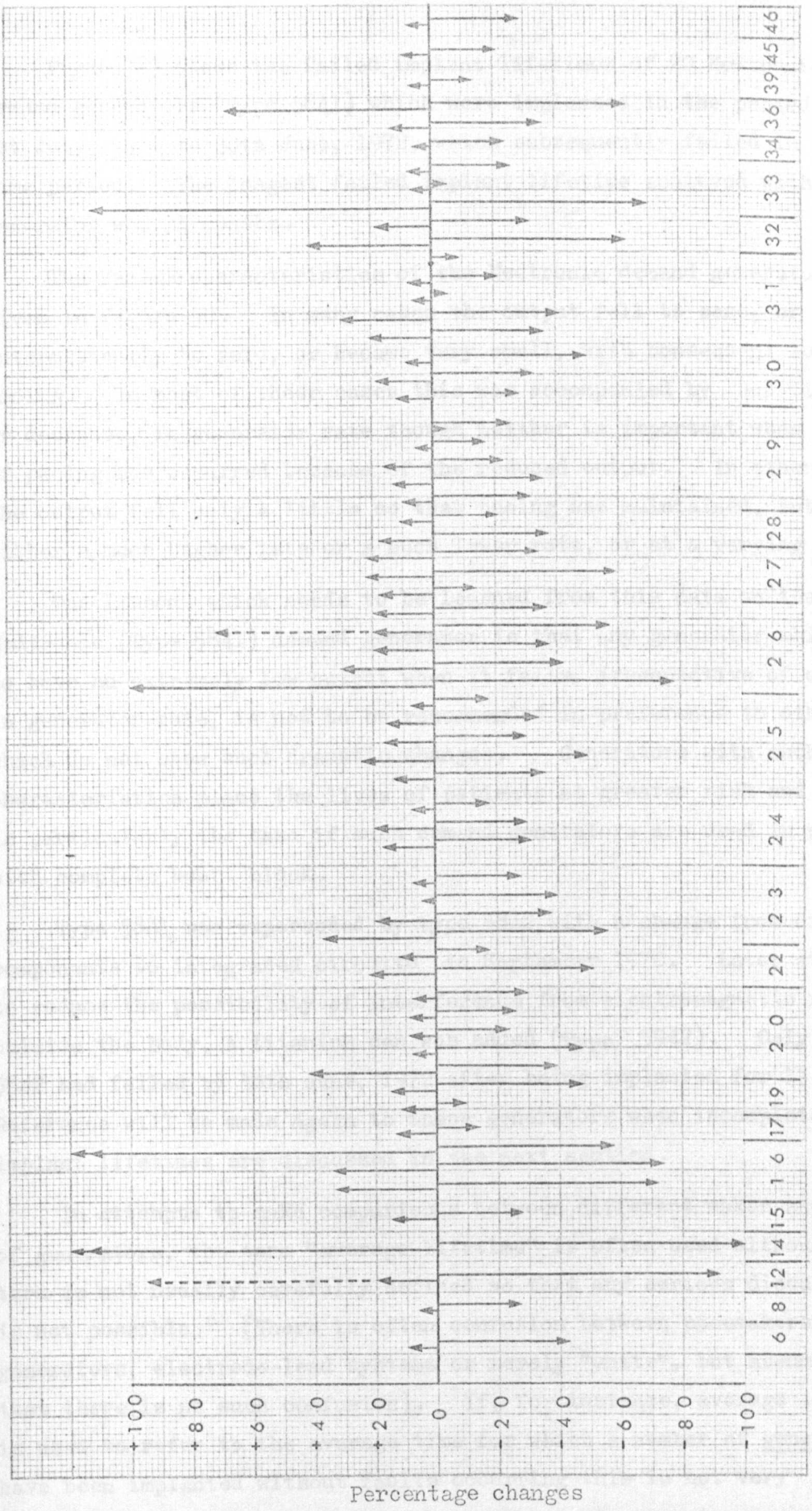


Figure 88. Failure characteristics of Medtronic asynchronous generators (type 5870C). (The first of each pair is rate change before removal: the second, is the change in output measured after removal).

Figure 89 shows the failed implant lifetimes of 20 Medtronic demand generators (Type 5841) which were implanted in the period 1st July, 1966 to 30th June, 1972, which subsequently failed in the same period. The longest failed implant lifetime achieved with this generator was 34 months.

The failure characteristics of the Medtronic demand generators are given in figure 90. In many cases the output fell to zero, or intermittently to zero, or became very small, with consequent loss of pacing. In most of these cases this was accompanied by an increase, or decrease, in generator rate though neither is important when loss of pacing has occurred because of the reduced output. In other cases the output fell only a little so that pacing was maintained, but at either a much higher rate or a much lower rate, or at a varying rate.

The lesson which needs to be learned from this data on the Medtronic (Type 5841) demand generator is that any generator which tends to have an extremely low output when it fails, irrespective of changes in generator rate, is not to be recommended in preference to others which do not show such dramatic changes. Generators with such characteristics place the lives of patients at greater risk and this is particularly the case if such demand generators are used in patients with complete heart block.

Type 5841 was superseded by type 5842 with a change from discrete components to integrated circuits in September 1970. Later still, to reduce the possibility of interference from electromagnetic radiation outside the body, a titanium can was added (Type 5942). Only one 5842 had failed by 30th June, 1972 after being implanted for 17 months. Reference will be made again to these generators when incomplete implant lifetimes are discussed in the next section.

In attempts to make comparisons between different makes and types of generators, the term "average lifetime" is often used although the term is not usually carefully defined so that any serious discussion is not possible. (There is often confusion between pacemakers, generators, electrode-lead systems or merely "units", but assume here that there is no such confusion). If, for instance, average lifetime is used to refer to the average time for which a number of <u>generators</u> have been implanted without faults occurring this is not very explicit or meaningful, because the more recent generator implants will always weight the average adversely. On the other hand, if

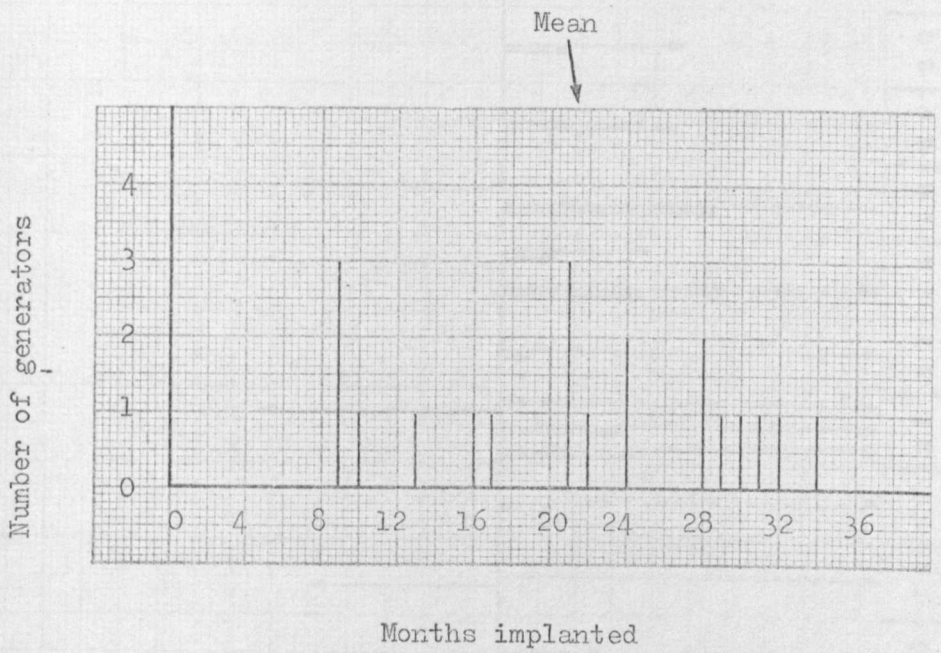


Figure 89. Failed implant lifetimes of Medtronic demand generators (type 5841)

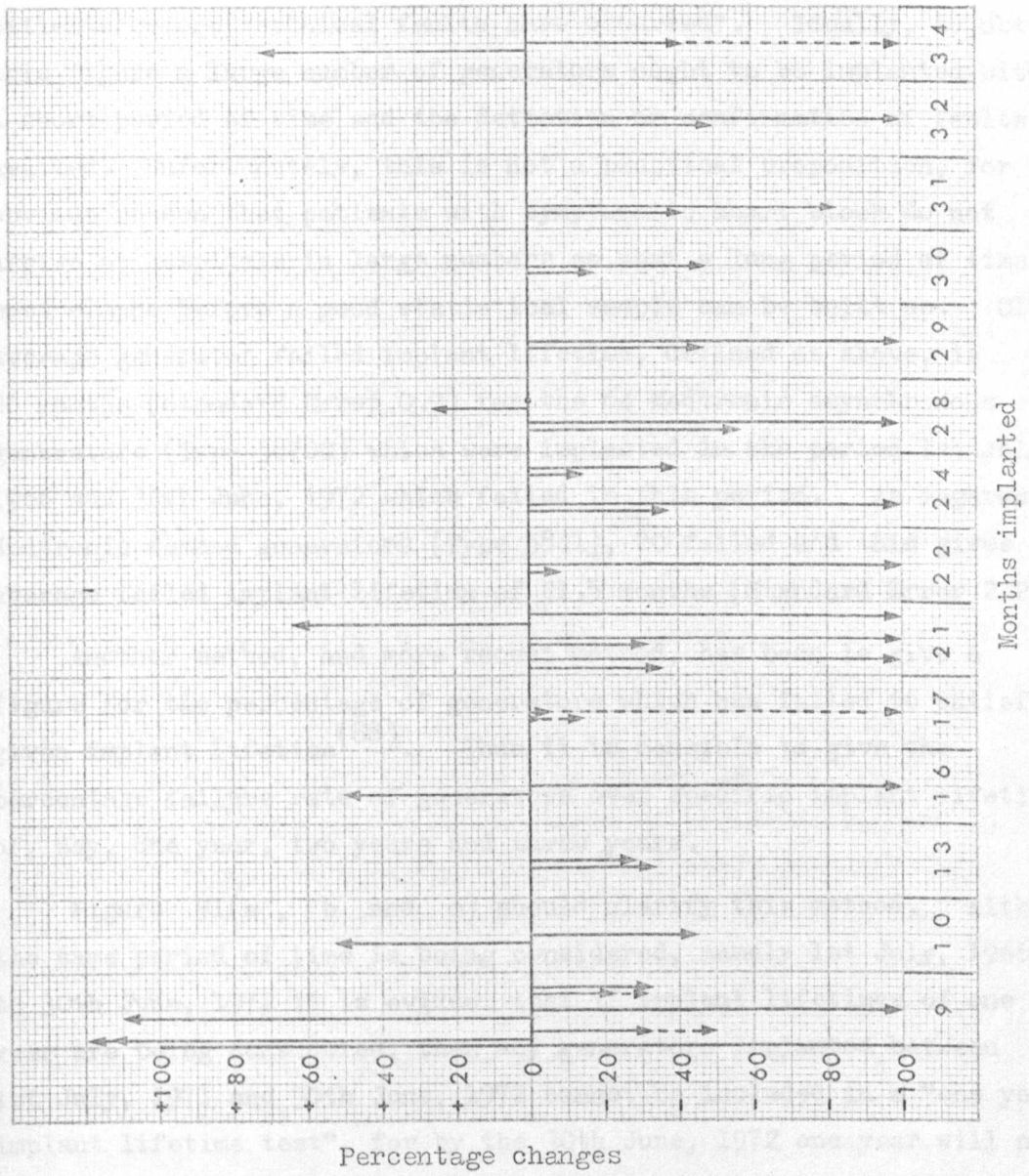


Figure 90. Failure characteristics of Medtronic demand generators (type 5841). (The first of each pair is rate change before removal: the second, is the change in output measured after removal).

electrode-lead systems are being considered, it should be borne in mind that a break in the insulation on one lead of a bipolar catheter will not cause loss of pacing; so that in the absence of comprehensive detection techniques such an unobserved failure would increase the average lifetime of implanted electrode-lead systems.

In an attempt to clarify this vaguely used term "average lifetime" generator average lifetime was formerly defined[88] as "the arithmetic average of the periods of time that generators have successfully paced patients before technical faults have occurred". Ideally, to obtain this figure a large number of generators ought to be implanted within a short period of time and the detection or confirmation of faults awaited. Unfortunately, this is not a practical proposition, for the obvious reason that patients with symptomatic heart block do not arrive at hospitals in large numbers so that a long period of time must elapse before a good statistical sample can be built up. Glasgow's average generator failed implant lifetime, defined as above, is 26 months (Standard Error 0.9) for the 64 Medtronic asynchronous generators (Type 5870C) which were implanted in the period 1st July, 1966 and 30th June, 1972 which failed in this period. As regards Medtronic demand generators (Type 5841), 20 failed and this gives an average failed implant lifetime of 21.5 months (Standard Error 2.2).

Another method, and more recent method, has been to give a figure for the percentage of generators which has failed to satisfy a given implant lifetime[88]. Thus it is possible to give the percentage failure rate of generators over specific implant lifetimes of, say, one year, two years and three years.

Figure 91(a , b and c) should clarify this method. Although the same period of time is being considered, namely 1st July, 1966 to 30th June, 1972 it is evident that if implant lifetimes of one year are being considered, then any generators implanted between 1st July, 1971 and 30th June, 1972 cannot be included in a "one year implant lifetime test", for by the 30th June, 1972 one year will not have elapsed. Thus only generators implanted in the period 1st July, 1966 to 30th June, 1971 can be subjected to the "one year implant lifetime' test. There is yet a further restriction to be imposed on this latter group of implanted generators. If any of them have implant lifetimes of less than one year, for any reason other than technical failure of the generator, then these too must be excluded from the "one year implant lifetime test". Thus, bearing these factors in

mind, analysis of the Glasgow data shows that of the generators implanted in the period 1st July, 1966 to 30th June, 1971, 93 qualified for the one year implant lifetime test but two failed in the period 1st July, 1966 to 30th June, 1972 because of technical faults in the generator. The one year implant failure rate for this group of generators is therefore 2.2% (Standard Error 1.5%).

Figure 91(b) gives the corresponding figures when a two years' implant lifetime is being considered. Thus 81 generators were implanted in the period 1st July, 1966 and 30th June, 1970 and 22 of these failed within two years during the specified six years' period. Thus the two years' implant failure rate for this group of generators is 27.2% (Standard Error 4.9%).

Figure 91(c) shows that the three years' implant failure rate for the asynchronous generator is 87.7% (Standard Error 4.3%).

Figure 92(a , b and c) give the corresponding data for Medtronic demand generators (Type 5841), of 7.5% (S.E. 4.2%), 37.1% (S.E. 9.3%) and 92.3% (S.E. 7.4%) for one, two and three years' implant failure rates respectively.

The above data may be presented graphically as in figure 93. The numbers alongside the curves give the numbers of generators which, in retrospect, qualified for the chosen implant lifetime test in that they had been implanted soon enough, yet did not have their implant lifetimes curtailed for non-technical reasons. These numbers decrease as the "number of months implanted" increases because, as explained earlier, the more recent implants cannot be included when the longer implant lifetimes are being considered, whilst others which might have been able to satisfy the implant lifetime criteria, were removed for non-technical reasons before the specified implant lifetime being considered had elapsed. The two curves suggest that the Medtronic demand generator (Type 5841), was less reliable than the Medtronic asynchronous generator (Type 5870C). This poorer reliability coupled with poor failure characteristics makes it in retrospect very much less attractive than the asynchronous generator (Type 5870C).

Figure 94 gives the percentage of generators which satisfactorily completed given implant lifetimes when subjected to the same criteria as were applied in figure 93.

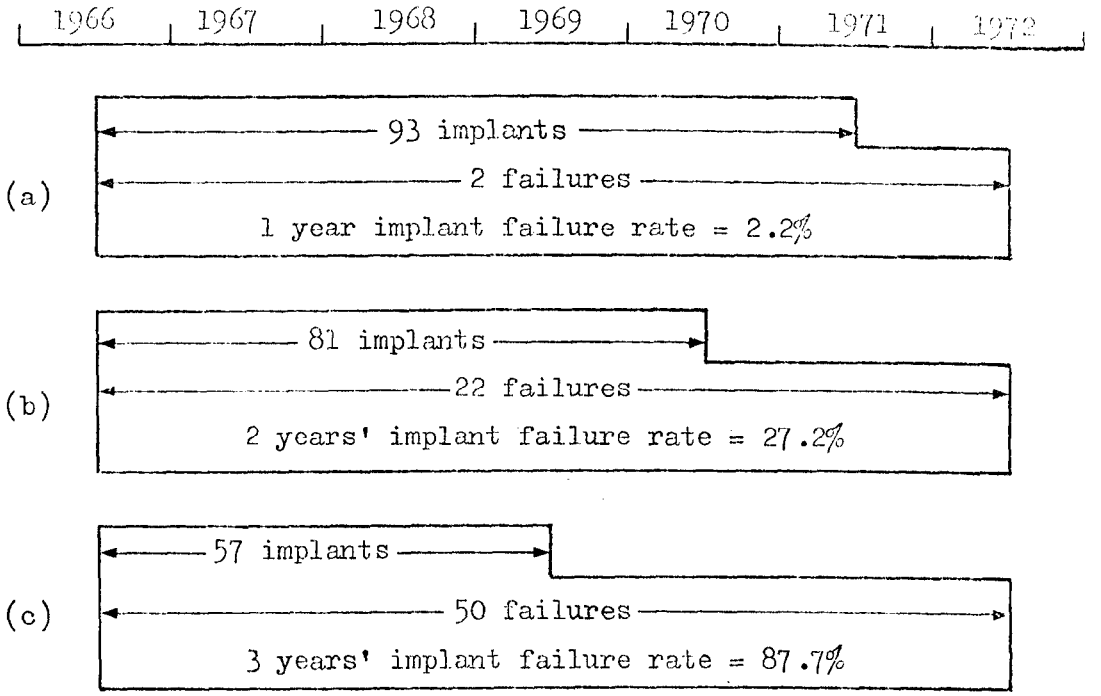


Figure 91. One, two and three years' implant failure rates for Medtronic asynchronous generators (type 5870C)

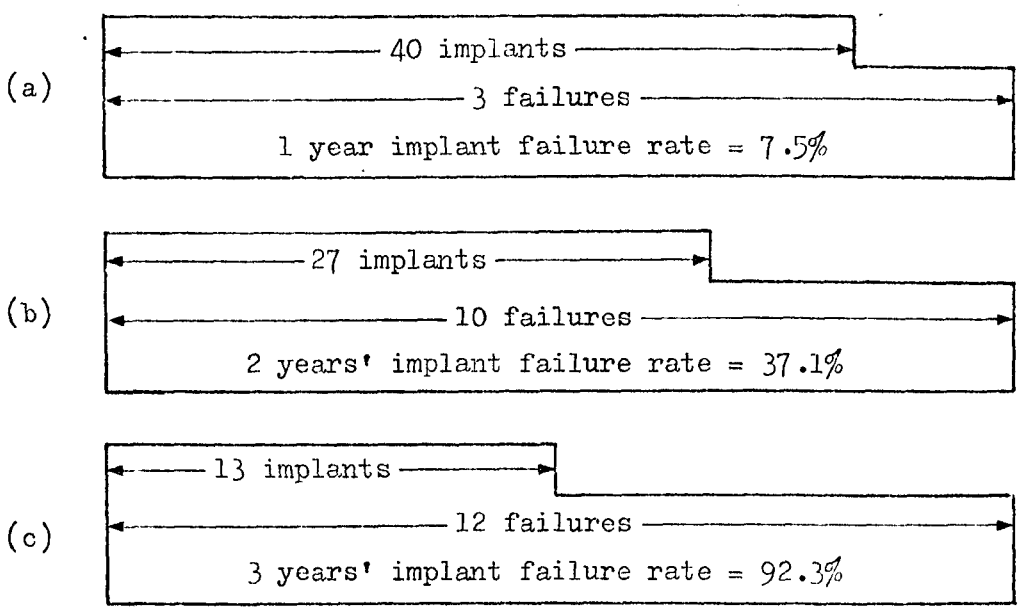


Figure 92. One, two and three years' implant failure rates for Medtronic demand generators (type 5841)

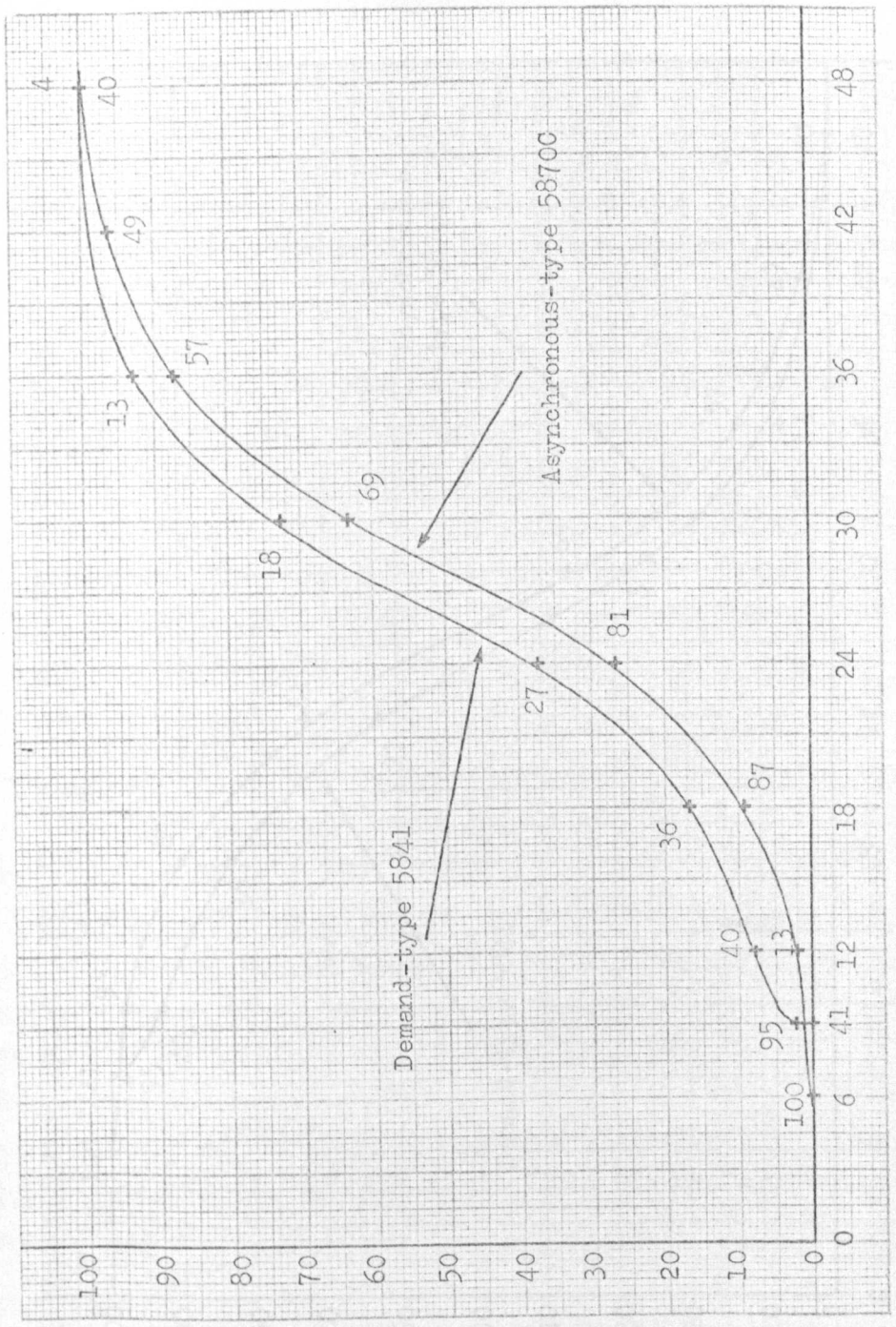
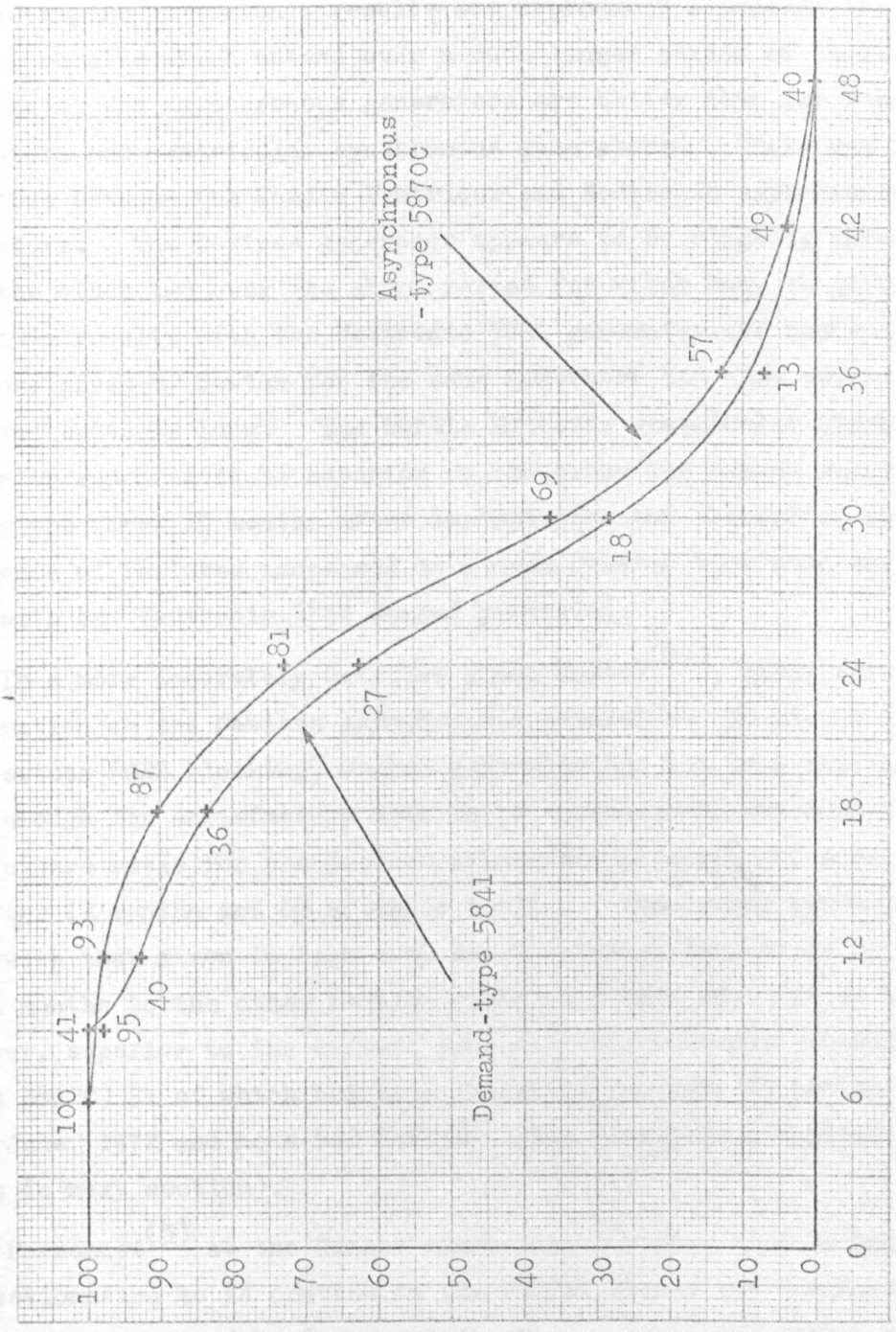


Figure 93. Failure rates for implanted Medtronic generators.



Percentage of generators which have not failed over given implant lifetimes

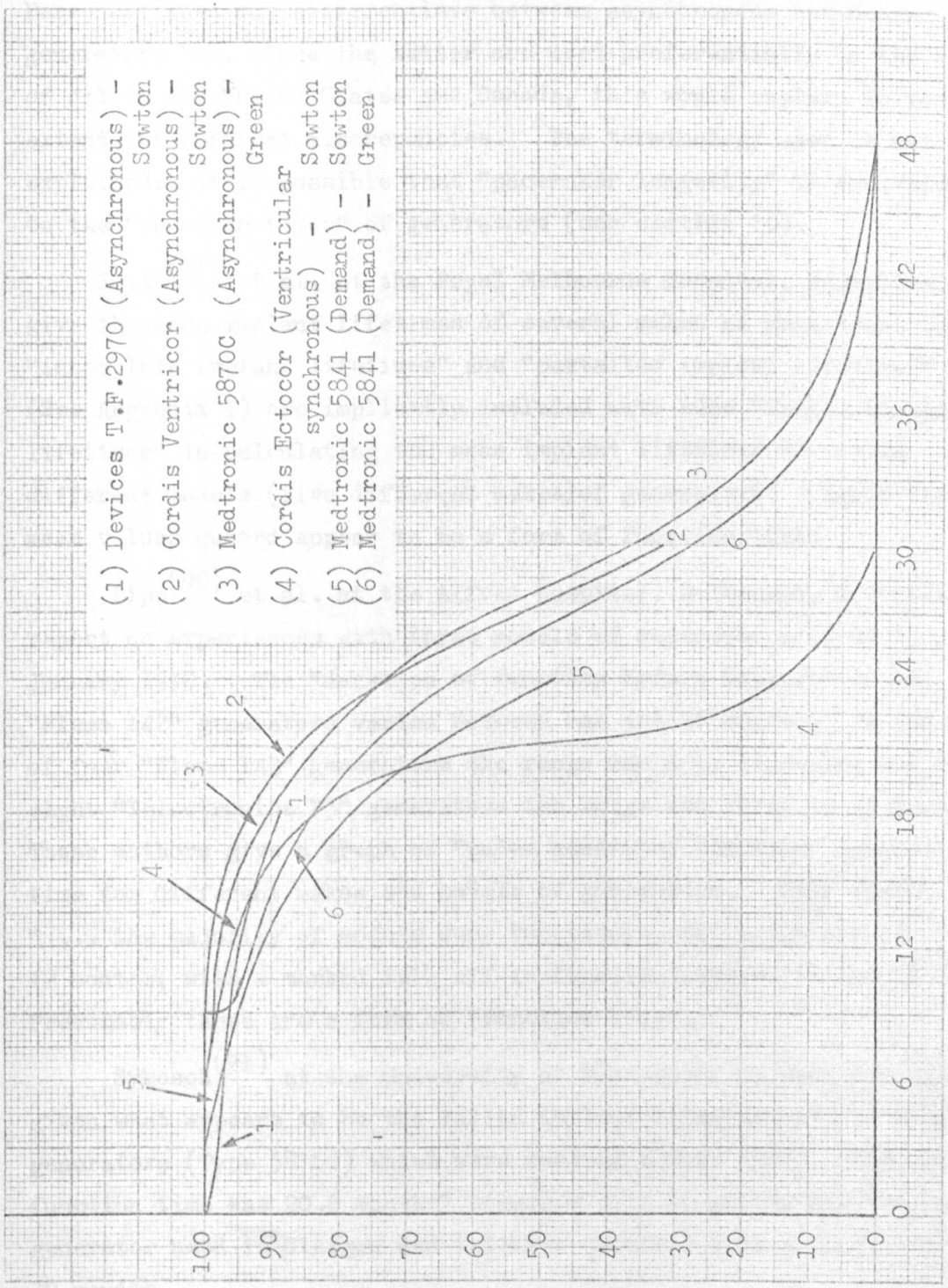
Figure 94. Non-failure rates for implanted Medtronic generators.

Sowton[7] in a paper presented at the "Symposium on Pacemakers" in Monaco in September 1970 gives some results for "longevity of different models of implanted pacemakers at the National Heart Hospital" in London. Data was restricted to that obtained over the three years prior to 1st September, 1970.

In figure 95 Sowton's results are reproduced alongside the Glasgow results which extend over a much longer period of time. The results for asynchronous generators are better than for demand generators and ventricular synchronous generators. There was little to choose between the Cordis Ventricor and Medtronic asynchronous generators. The Devices generator appears to be slightly inferior than the other two over the short period for which data is given. Glasgow's results with the Medtronic 5841 generator are superior to those given by Sowton for the same generator and they extend over a period twice as long. The Cordis Ectocor, ventricular synchronous generator appeared to be superior to the other two demand generators during the first 18 months after implantation but thereafter the incidence of failures increased at a much greater rate than was the case with the Medtronic 5841 demand generator.

In a more accurately entitled paper Sowton[89], gives more information on the Devices asynchronous generator. He states that the Devices (QRS blocking) demand generator has not been available long enough for satisfactory data to be established, but adds that the failure rates for the Devices asynchronous generator, model 2970, were 4% after 12 months and 8% after 21 months. The former percentage agrees well with that given in figure 95 but the latter percentage is superior at 21 months to the other results given in figure 95. It is not, however, superior to the current Medtronic asynchronous generator (Type 5862C) 21 of which had been implanted for over 21 months by 30th June, 1972 and none had failed (See "Incomplete implant life-times in next section).

Parsonnet[5] at the Monaco conference reported that he had submitted a questionnaire to 74 centres in the United States and Canada and from the replies received he deduced that, "..... there was almost uniform opinion with regard to pacemaker longevity" (His emphasis). "All respondents stated that 50% of their units failed by approximately the 23rd month of use, a far cry from the early optimistic projections of five years". It is assumed that by "units" is meant "generators" though earlier in the paper the term "unit" is used for "pacemaker".



Percentage of generators which have not failed over given implant lifetimes.

Figure 95. Comparisons of non-failed implant lifetimes of generators.

By comparison with figure 93 it is readily seen that Glasgow's equivalent figure for asynchronous generators over a six years' period was approximately 28 months and for demand generators 26 months. Parsonnet does not differentiate between asynchronous and demand generators but, since the latter are used preferentially in the ratio of 4:1 in the United States and Canada, this would explain to some extent the apparent discrepancies. The terminology used is not explained: it is possible that "pacemaker longevity" is equivalent to the "function-times" of generators (see section 10).

Smith[77] et al. at the Royal Melbourne Hospital, Australia, give the mean implant lifetimes of several makes of generators but some "incomplete implant lifetimes" and "curtailed implant lifetimes" (See Appendix I) are implicitly included with some "failed implant lifetimes" in calculating the mean implant lifetimes of eleven different models (five different makes) of generators. Again the mean values quoted appear to be a form of function-time.

Lipp[90] et al. at the Alfred Hospital, Melbourne, Australia report on experiences with three models of generator used up to January 1970. The "duration of function before failure" of 16 "Elema 142" generators varied between one and 18 months. In the case of four "Elema 143" generators the range was 4 to 17 months and for eight "Telectronics P5" generators the range was three to 15 months. These authors give a graph of "pulse generator function" against time for different makes and models of generators. They state, " ... the majority of models were functioning until the end of 12 months, with a marked fall off in function between 12 and 18 months". Presumably these are a form of "function-time".

Sykosch[91] at the University of Düsseldorf in West Germany has given what appears to be the failed implant lifetimes of 218 Medtronic generators (Type 5870C) which were removed before 1969. The "mean function time was 20.6 months" compared with 26 months for the same generator used in Glasgow and failures occurred over a range six to 39 months.

Witte[92] et al. at the Humboldt University, West Berlin, in a report referring to the period 1963 to 1968, state, "An average service life of 15.7 months with a minimum of 9 and a maximum of 27 months has been calculated for the Devices (asynchronous) pacemaker. The Cordis pacemaker functioned an average for 18.3 months, the average results for the atrium controlled pacemaker (Atricor) being poorer and for the fixed-frequency system (Ventricor) being better". No

attempt is made to define "average service life".

2.2 Electrode-lead systems

The definition of "failed implant lifetimes" for generators applies equally well to electrode-lead systems. In this case, however, by a "fault" is meant a break in the insulation on a conducting lead, a break in the conducting lead alone, or both. Detection of a break in the insulation usually takes place at a pacemaker clinic whereas a break in a conducting lead alone will result in emergency admission to hospital. In the former case the actual date of its occurrence is unknown, but the date of detection is used for compiling implant lifetime data.

During the period 1st July, 1966 to 30th June, 1972, 15 myocardial bipolar electrode-lead systems (Medtronic, type 5814) were implanted and three of them failed during this period. In one case a conducting lead only broke, in or near the myocardium with a failed implant lifetime of 22 months (Patient 138). In another case, both the conducting lead and insulation broke in or near the myocardium with a failed implant lifetime of 17 months (Patient 91). In yet a third case the insulation only broke near the generator, again giving a failed implant lifetime of 17 months (Patient 107). There was also an electrical leak at the generator socket of the same lead in this latter case.

During the same period 47 endocardial bipolar electrode-lead systems (Medtronic, type 5816) were implanted. In four cases a conducting lead only broke with failed implant lifetimes of 4, 10, 12 and 14 months. In four more cases the insulation on the "negative" conductor fractured with failed implant lifetimes of 3, 4, 6 and 10 months. The "positive" insulation fractured in two other cases, with failed implant lifetimes of 15 and 33 months.

On 1st April, 1968, the first endocardial bipolar electrode-lead system of modified design (Type 5818) was implanted. In the remainder of the period under review, 232 were implanted. In this series no conducting lead failed, though the "positive" insulation ruptured in one case giving a failed implant lifetime of 8 months.

In one other case after re-operation, to re-implant an extruded generator, it was noticed the next day from vector studies that a break had developed in the "negative" insulation. At a further re-operation this break was confirmed. It had occurred near the generator presumably as a result of handling. It was repaired but before the operation was completed the repair was evidently leaking. It thus remains in the patient as a unibip electrode lead system. This break is not included with the other statistics on failed implant lifetimes, since it can reasonably be assumed to be the result of handling at the re-operation.

A broken conductor alone, with intact insulation, as already explained, is a most serious hazard and in each of the above-mentioned cases emergency admission to hospital was necessary. In those cases in which the patient's own rhythm became very low or inadequate, a temporary pacing catheter had to be introduced as quickly as possible so that the pulse could be restored to normal by means of an external generator.

It was also explained earlier that when the insulation ruptures on one conducting lead (with or without a broken conductor at the same point), pacing continues and emergency admissions are not necessary. In practice this proved to be the case in all the cases referred to above.

With the type 5816 electrode-lead system, three of the breaks in the conducting lead occurred between the electrodes. In the other case the electrode-lead system remains in the patient and confirmation has not yet been possible. The breaks in the conducting leads of two myocardial electrode-lead systems have been confirmed by X-rays.

All the cases of ruptured insulation referred to above were subsequently confirmed at re-operations, save in one case, a myocardial one, in which the myocardial electrode-lead remains in the patient. A break in the conductor was confirmed by X-ray, but the relatively low threshold obtained with this conductor and an indifferent lead, implies that the insulation was broken at this point. An impedance measurement would certainly have confirmed this but the appropriate equipment was not available when re-operation took place. However, there is also further strong indirect evidence of broken insulation, in that the broken conducting lead in this case did not result in an emergency admission to hospital.

A knowledge of the reliability of electrode-lead systems is important, not only because without such knowledge there can be no real incentive to produce more reliable systems, but because isotope-powered generators are now being produced with design implant lifetimes of 10 years. If re-operations become necessary within 10 years, because of broken conducting leads, then the value of isotope-powered generators will be mitigated and the enormous expense involved in their development will be challenged.

There is very little data published on the reliability of electrode-lead systems. Sowton[7, 89], Parsonnet[5] and Smith[77] et al. do not mention the failed implant lifetimes of electrode-lead systems.

Lipp[90] et al. state that of the 32 "epicardial electrodes" (presumably epicardial electrode-lead systems) used, with one exception, between 1962 and November 1966, 14 "fractured electrodes" developed. This represents a high failure rate of 43%. Thereafter, but before 1st January, 1970, "transvenous pacing" was used on 49 occasions. No failures are reported. Five different generators are listed in the paper, namely: Devices, Electrodyne, Elema, Medtronic and Electronics, but it is not stated which of the associated epicardial electrode-lead systems failed.

Sykosch[91] has reported on electrode-lead failures over the period 1961 to October 1968. Of the 415 transvenous electrode-lead systems used, eight had "fractured electrodes" and three had "defects in insulation". One hundred and twenty-one myocardial electrode-lead systems were used: there were 25 "fractured electrodes" and one "defect of insulation". Eight epicardial electrode-lead systems were used: in two cases there were "fractured electrodes" but no "defects of insulation". There is no explicit reference to the makes of electrode-lead systems used, but since during the same period 218 Medtronic generators were replaced, it must be assumed that many of the electrode-lead systems referred to were made by Medtronic.

Witte[92] et al. state that "electrode fractures" have not occurred at any time during the period 1963 to 1968 with endocardial electrode-lead systems. However, a total of 36 "electrode fractures" are listed for myocardial/epicardial electrode-lead systems. The 19 Devices fractures always occurred with the indifferent electrode-lead system.

Siggers and Deuchar[93] report two Devices endocardial "fractured electrode wires" during the period May 1967 and January 1970 "in the 56 patient years of pacing".

Bernstein[94] et al. state that "breakage of wires" occurred on three occasions between 1965 and 1969 during which 92 endocardial electrode-lead systems were used (Medtronic, type 5816 - 90 used; Cordis - 2 used).

3. Incomplete Implant Lifetimes

3.1 Generators

It has already been suggested that, when discussing the implant lifetimes of those generators which have failed, it is also important to consider the implant lifetimes of those other generators which have not failed and are still implanted. In other words, sufficient time may not have elapsed since implantation of the generator for a generator fault to have developed, or for replacement to have occurred for any other reason.

The term "incomplete implant lifetime" was first introduced in the autumn of 1970[8] as "the current time for which a generator has been implanted without technical failure or removal for any reason". Further experience shows that a slight amendment should be made to this definition so that it is more precise. Thus the incomplete implant lifetime is redefined as, "the current time for which a generator has been implanted without technical failure, without replacement for any other reason, and without the death of the patient having occurred". An incomplete implant lifetime has a unique value at a specific point in time, whereas "failed implant lifetimes" are independent of time.

Figure 96 shows how any incomplete implant lifetime may change at any time into one of the other categories. Those categories, which have not yet been defined, will be defined later in this thesis.

It should be emphasised that the incomplete implant lifetimes given below are with reference to 30th June, 1972.

On the 30th June, 1972 only five Medtronic asynchronous generators, type 5870C, remained implanted. These incomplete implant lifetimes are given in Table 4.

In February 1970 the first Medtronic asynchronous generator, type 5862C, was implanted. Figure 97 gives the incomplete implant lifetimes of all the generators of this type which were subsequently implanted up to 30th June, 1972. (As stated in sub-section 2.1, not one of these had failed by that date).

The incomplete implant lifetimes of the 11 remaining Medtronic demand generators, type 5841, on the 30th June, 1972 are given in Table 5.

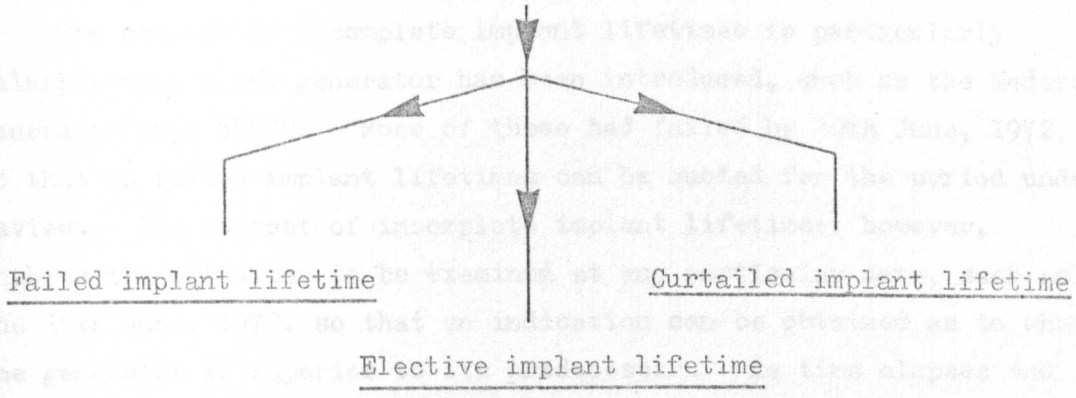


Figure 96. Relationships between various implant lifetimes.

Months implanted	26	28	29	34	36
No. of generators	1	1	1	1	1

Table 4. Incomplete implant lifetimes of Medtronic asynchronous generators, type 5870C, on 30th June, 1972.

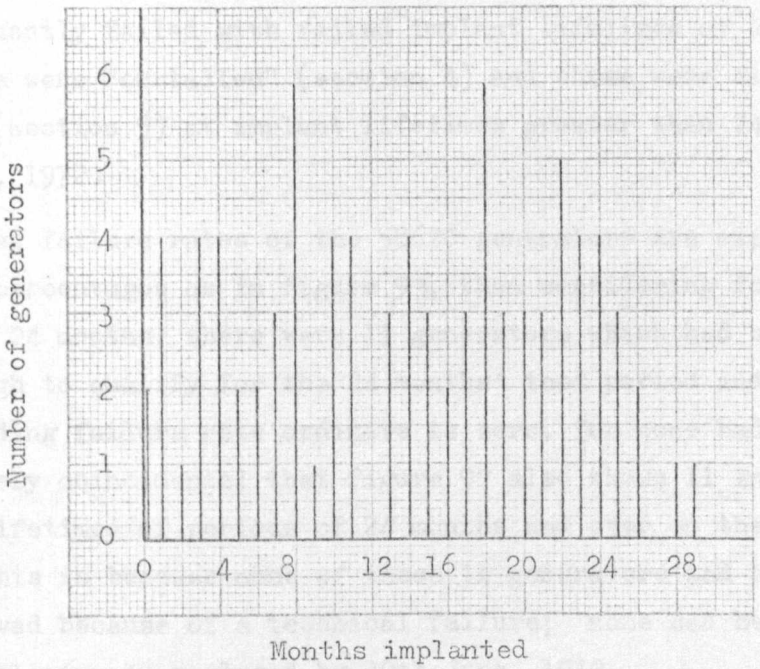


Figure 97. Incomplete implant lifetimes of Medtronic asynchronous generators, type 5862C, on 30th June, 1972.

Type 5841, was superseded by type 5842, which was subsequently modified with the addition of a titanium casing to become type 5942. Figure 98 gives the incomplete implant lifetimes of these later models (Only one of these had failed, type 5842, by 30th June 1972, with a failed implant lifetime of 17 months).

The concept of incomplete implant lifetimes is particularly valuable when a new generator has been introduced, such as the Medtronic generator type 5862C. None of these had failed by 30th June, 1972, so that no failed implant lifetimes can be quoted for the period under review. The concept of incomplete implant lifetimes, however, enables the situation to be examined at any particular date, such as the 30th June, 1972, so that an indication can be obtained as to whether the generator is superior to its predecessor. As time elapses and generators begin to fail, such failures can be shown in terms of failed implant lifetimes or its counterpart "non-failed implant lifetimes" expressed in terms of percentages.

Figure 91 shows that 81 asynchronous generators, type 5870C, were implanted in the period 1st July, 1966 to 30th June, 1970. Twenty-two of these failed over the period 1st July, 1966 to 30th June, 1972. What happened to the remaining 59? Ought these to show as 59 incomplete implant lifetimes on 30th June 1972? In fact, only five remained implanted on the 30th June, 1972 with incomplete implant lifetimes which have already been quoted in Table 4. Of the 54 other generators, 42 subsequently failed with failed implant lifetimes of 24 months or more, nine were "curtailed" (section 4) and three were electively replaced (section 5) at implant lifetimes greater than 24 months by 30th June, 1972.

If the failure rates of the 5862C generators are expressed in terms of percentages as in figure 93, then considering for example a period of 24 months, there were 11 generators which had been implanted long enough to qualify for the 24 months' test period and the corresponding failure rate ordinate is zero, for none had failed. It is purely coincidental that figure 97 also shows 11 incomplete implant lifetimes of periods of 24 months and over on the 30th June, 1972. This is because none of these 11 generators had subsequently been removed because of a technical failure; none had been "curtailed"; and none electively replaced by 30th June, 1972.

Months implanted	22	23	24	25	26	27	29	47
No. of generators	4	1	1	1	1	1	1	1

Table 5. Incomplete implant lifetimes of Medtronic demand generators, type 5841, on 30th June, 1972

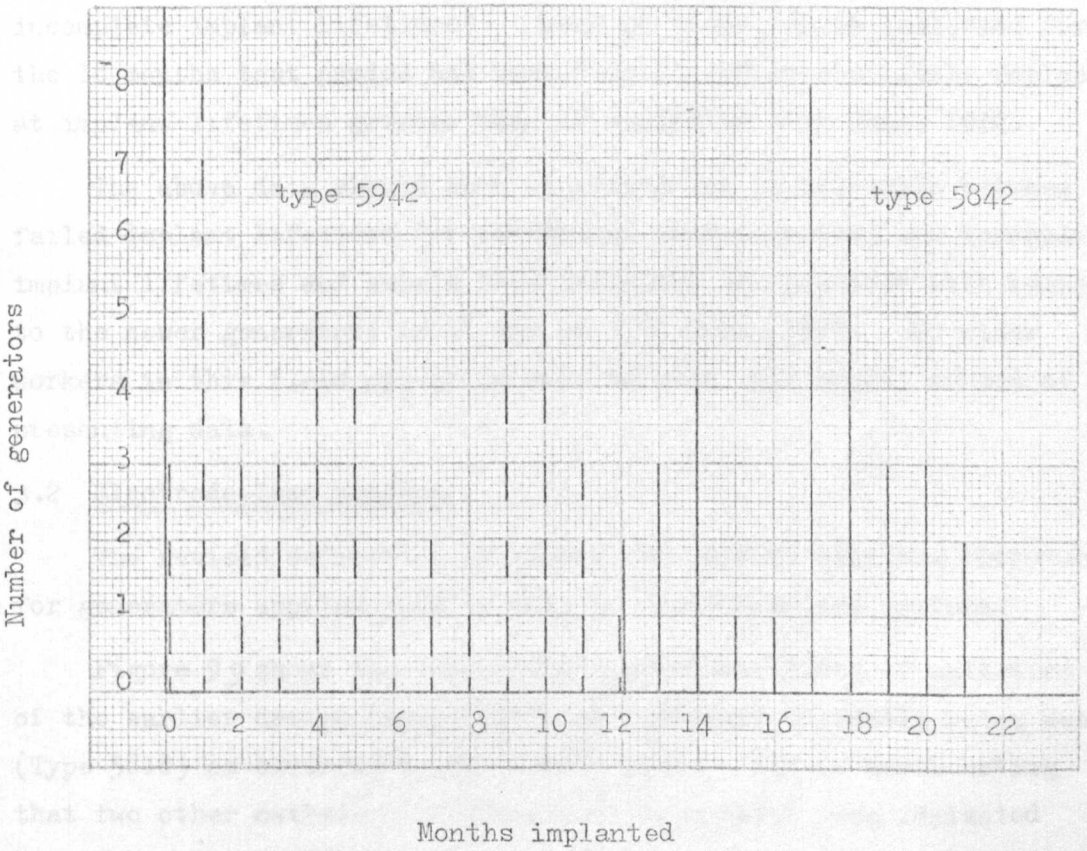


Figure 98. Incomplete implant lifetimes of Medtronic demand generators, types 5842 and 5942 on 30th June, 1972

Similar arguments can be applied to Medtronic demand generators. Consider figure 92 which shows that 27 demand generators, type 5841, qualified for the two years' implant test in the period 1st July, 1966 to 30th June, 1970, and that 10 failed in the six years' period. What happened to the remaining 17 generators? Subsequently six were still found to be implanted on the 30th June, 1972 at implant lifetimes of 24 months and upwards (See Table 5 for incomplete implant lifetimes). Nine others failed at 24 months or more (see figure 89 for failed implant lifetimes) and two were subsequently electively replaced.

The history of the later types of demand generators (Types 5842 and 5942) can be considered in a similar manner. Thus during the period 1st July, 1966 to (say) 31st December, 1970, if 18 months' test periods are being considered, 16 demand generators of the 5842 type had been implanted sufficiently long ago to qualify for the 18 months implant test period. (Many others of these two types had been implanted later and did not qualify time-wise). In the period 1st July, 1966 to 30th June, 1972, one failed after being implanted for 17 months, thus giving a failure rate of 6.25%. All the others were still implanted on the 30th June, 1972 (see figure 98 for incomplete implant lifetimes). None of those, which qualified for the 18 months test period had been "curtailed" or electively replaced at implant lifetimes greater than 18 months by 30th June, 1972.

The above data should have clarified the relationship between failed implant lifetimes (or percentage failure rates) and incomplete implant lifetimes and should have indicated the position with respect to the newer generators as it was on 30th June, 1972. No other workers in this field appear to have adopted this useful method of presenting data.

3.2 Electrode-lead systems

The revised definition of incomplete implant lifetime introduced for generators applies equally well to electrode-lead systems.

Figure 99 shows the incomplete implant lifetimes of catheters of the earlier design (Type 5816) and catheters currently being used (Type 5818) as observed on 30th June, 1972. (It is worth noting that two other catheters of the former type which were implanted before 1st July, 1966 and are therefore not shown on the above figure, had incomplete lifetimes of 80 and 81 months respectively on 30th June, 1972).

The incomplete implant lifetimes of six Medtronic bipolar myocardial electrode-lead systems are given in Table 6. (In addition one myocardial electrode-lead system which was implanted before 1st July, 1966 had an incomplete implant lifetime of 82 months on 30th June, 1972).

An extensive search of the literature has not revealed any data on incomplete implant lifetimes of electrode-lead systems. Such data will become of paramount importance in relation to isotope-powered generators as explained in sub-section 2.2, when failed implant lifetimes of electrode-lead systems were discussed.

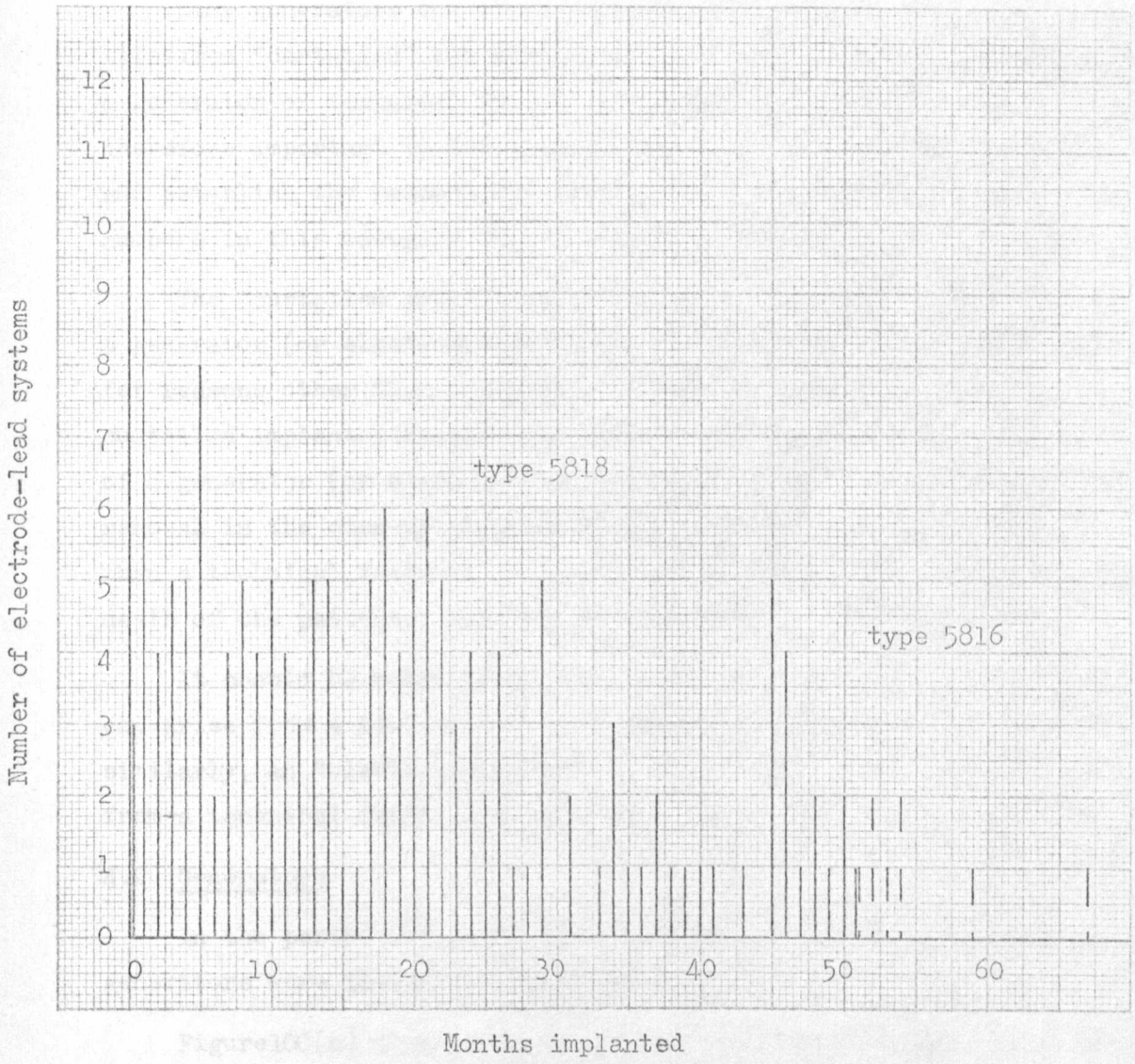


Figure 99. Incomplete implant lifetimes of Medtronic bipolar endocardial electrode-lead systems, types 5816 and 5818 on 30th June, 1972.

Months implanted	13	14	15	17	26
No. of myocardial electrode-lead systems	1	2	1	1	1

Table 6. Incomplete implant lifetimes of Medtronic bipolar myocardial electrode-lead systems, type 5814 on 30th June, 1972.

Displacement of the catheter shortly after first emplacement is the greatest single hazard with the endocardial pacemaker. This hazard is discussed in more detail in section 6, when all displacements are considered. In theory, displacement of a catheter and its subsequent remanipulation should not necessitate generator replacement, whether the catheter has been successfully remanipulated or not. In practice, such displacements often lead to replacements of generators which were still working perfectly well at re-operation. With the earlier implants medical adhesive was used at the generator/catheter interface and on a few occasions it proved difficult to separate the two successfully, so that a whole pacemaker had to be replaced following the displacement of a catheter. On another occasion, separation was successful but the "boots" of the generator were damaged during the separation. The use of "silicone lubricant", in place of medical adhesive, subsequently eliminated this problem.

Although displacement is more likely to occur shortly after first emplacement it can occur later. When it did occur later, and after a time which was of the same order of magnitude as the earlier "failed implant lifetimes", there was a tendency to replace the generator after successfully remanipulating the catheter. Again, because of the much longer "failed implant lifetimes" which are now being obtained, coupled with the probability that displacement is more likely to occur within a short time after first emplacement, this reason for curtailing the implant lifetimes of generators is likely to disappear.

There will, however, always be a number of miscellaneous reasons, for example, accidentally making a generator non-sterile, which will result in the lifetime of a generator being curtailed as a result of the remanipulation of a catheter.

Nine of the remaining 56 generator curtailments, referred to above, arose directly from the catheter being displaced. Figure 100(c) shows the distribution of the remaining 47 generator curtailments.

The remaining generator curtailments arose from a number of reasons. In one case complete loss of pacemaker output was later attributed to loose Allen set screws in the generator sockets. Although in another case the Allen set screws were tight it was discovered that a thin film of silicone lubricant over the terminal plugs of the catheter reduced the pacemaker output to nil. Generators were changed on a number of occasions when conducting leads fractured.

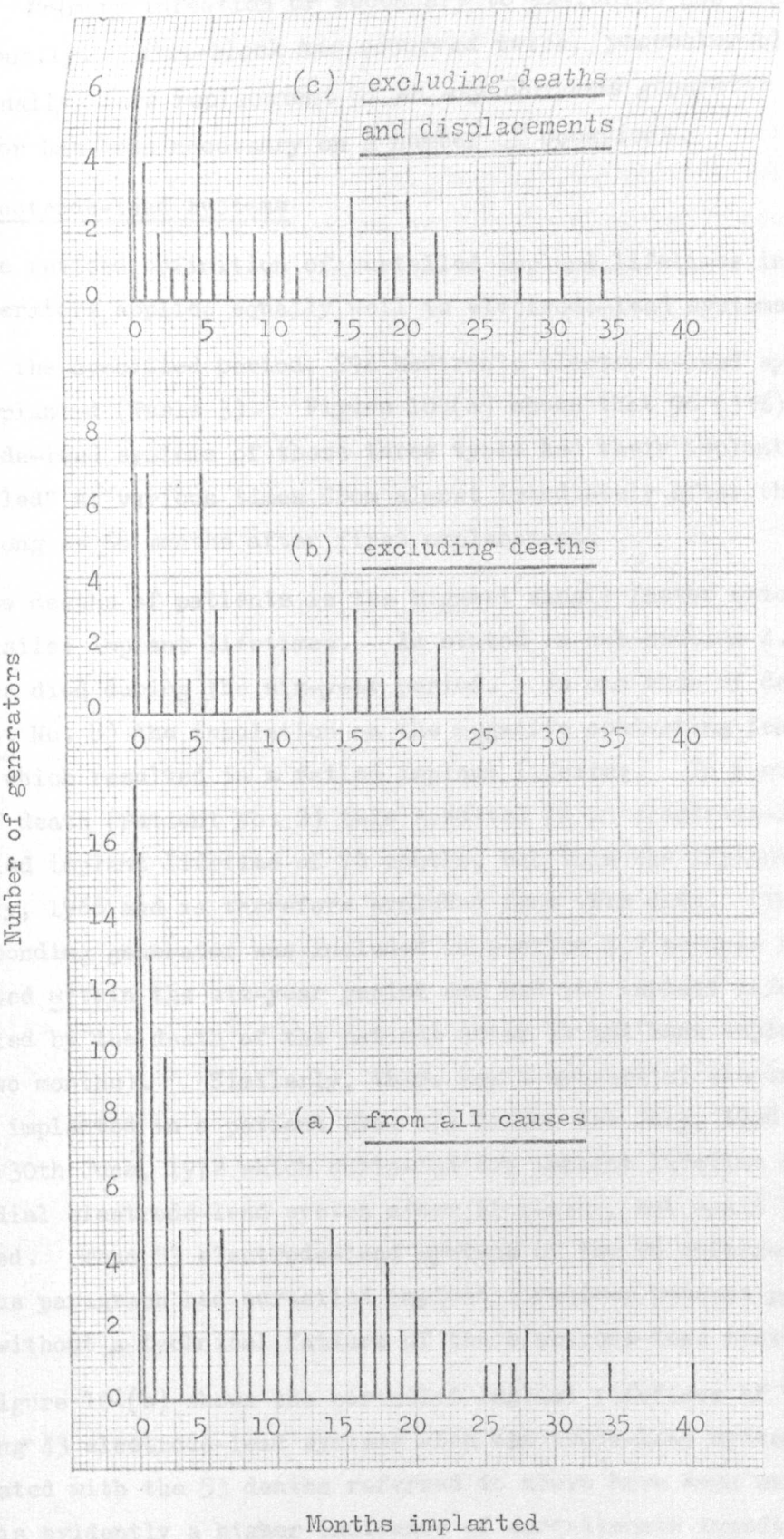


Figure 100. Curtailed implant lifetimes of Medtronic generators, types 5870C, 5862C, 5841, 5842 and 5942.

Migration of the generator posteriorily from the axilla was another cause. Primary infection or secondary to extrusion has occurred occasionally. Exit-block has occurred twice, pacemaker-block once and, finally, mere replacement of an asynchronous generator for a demand generator has been necessary on a number of occasions.

4.3 Electrode-lead systems

The revised definition of curtailed implant lifetimes introduced for generators applies equally well to electrode-lead systems.

In the specified period, 294 Medtronic electrode-lead systems were implanted (Table 3). Figure 101(a) shows that 96 (33%) of these electrode-lead systems of these three types had their implant lifetimes "curtailed" at various times from almost immediately after the operation to as long as 68 months after first emplacement.

The deaths of patients is the biggest single factor which contributes to curtailed implant lifetimes. As stated in sub-section 4.2, 56 patients died during the six-year period. In one case of death (Patient No. 8) the insulation on the negative conducting lead had failed which resulted in a failed implant lifetime. In another case of death (Patient No. 2) this resulted in an electrode-lead system curtailed implant lifetime of 73 months, but this was implanted before 1st July, 1966 and is therefore excluded from this data. (The corresponding generator was included in section 4.2 because it was implanted within the six-year period and had its implant lifetime curtailed by the death of the patient after it had been implanted for only two months). Similarly, there was a myocardial electrode-lead system implanted in a patient (No. 17) before 1st July, 1966 who died before 30th June, 1972 which curtailed the implant lifetime of the myocardial electrode-lead system after 71 months, but again it has been excluded. Thus 53 electrode-lead systems of the 96 referred to in the previous paragraph had curtailed implant lifetimes because patients died, without a technical failure of the electrode-lead systems.

Figure 101(b) shows the curtailed implant lifetimes of the remaining 43 electrode-lead systems when electrode-lead systems associated with the 53 deaths referred to above have been excluded. There is evidently a higher incidence of curtailments immediately after first emplacement of electrode-lead systems.

As already mentioned (sub-section 4.2), displacement of a catheter is a serious hazard in the period immediately following first emplacement. This should not, in theory, necessitate its replacement, but in practice this is sometimes necessary. For instance, in the early days of pacemaking it was more difficult to separate the generator from the catheter, so that complete replacement was sometimes necessary. There were, and still are, however, miscellaneous reasons which necessitate replacement of catheters: contamination of a catheter during remanipulation; or merely the emplacement of a second catheter via the other side of the patient following displacement of the first catheter. This latter procedure is desirable in those patients who are known to be at great risk following the displacement of the first catheter. In fact 18 catheters were displaced (apart from the one already mentioned which resulted in the death of the patient) which caused new catheters to be used. Many of these displacements occurred soon after first emplacement. Figure 101(c) shows the frequency of curtailed implant lifetimes when those resulting from deaths and displacements are excluded. The remaining distribution is random and caused by several factors.

No attempt is made to quantify the various factors, which caused curtailed implant lifetimes with these 25 remaining electrode-lead systems. Suffice it to say that they were associated with generator failures, generator migration from the axilla posteriorily, generator infection and/or rejection, catheter rejection at the neck, high thresholds which were found when failing generators came to be replaced or exit-block. In one of the cases in this latter category, exit-block had occurred on only one lead of the bipolar myocardial electrode-lead system. This was effectively removed (and therefore "curtailed") by making it redundant and using an "indifferent lead", thus converting to a unipolar myocardial electrode-lead system.

The two curtailments at 68 months were for different reasons. In one case, a high threshold was found when a generator came to be replaced and, in the other case, the generator looked as though it was about to extrude, and thus a new pacemaker was implanted on the other side

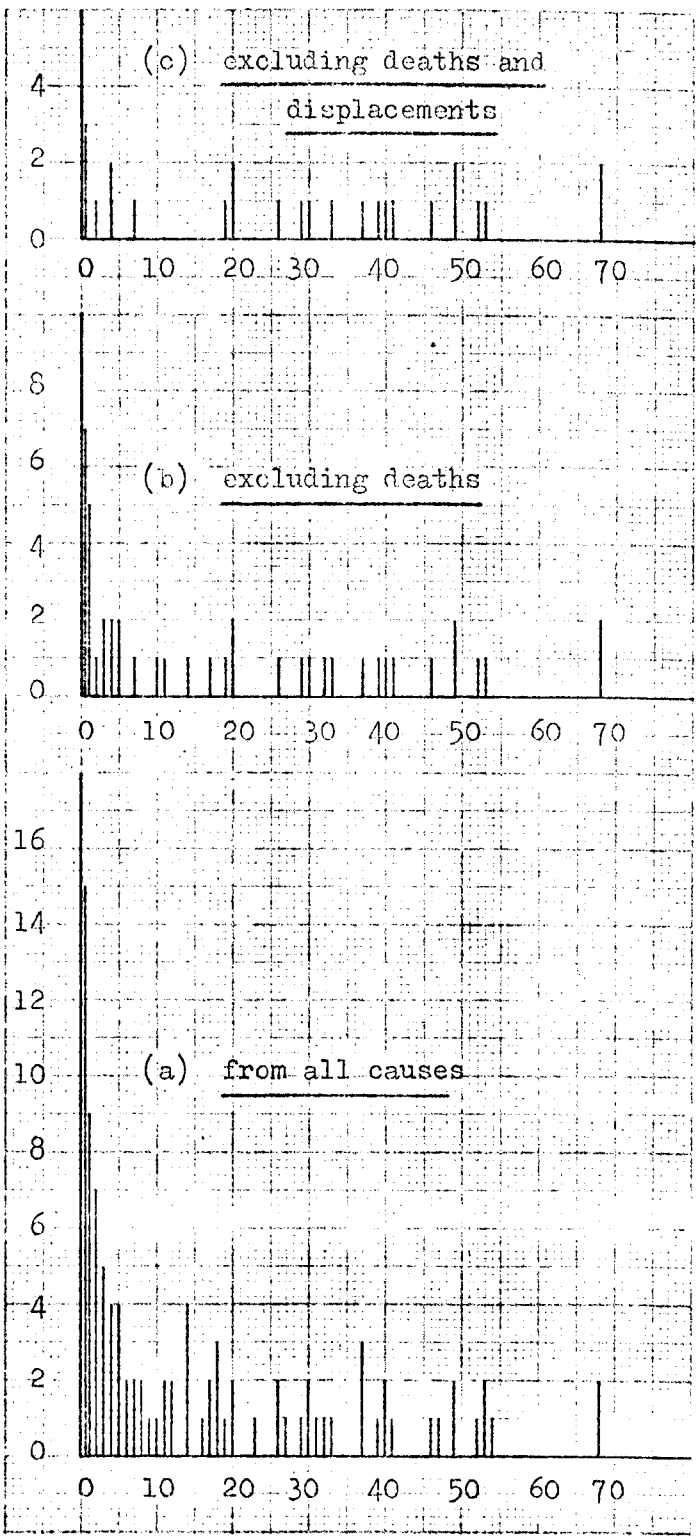


Figure 101 Curtailed implant lifetimes of Medtronic electrode-lead systems, types 5816, 5818 and 5814.

5. Elective Implant Lifetimes - Generators Only

The term "elective implant lifetime" was defined earlier[8]. It is redefined as "the time between implantation of a generator and its removal, although there was no technical failure, no loss of pacing and no complications such as infection, extrusion or migration, etc". The term is not applicable to electrode-lead systems.

There is, in fact, at present no case to be made for replacement of generators on a rational elective basis, provided arrangements have been made for systematic assessment at pacemaker clinics. Examination of the data (Figure 87) for asynchronous Medtronic generators shows that the most probable failed implant lifetime is not immediately obvious. However, the arithmetic mean was calculated as 26 months and this, in retrospect, might suggest that elective replacement ought to have been carried out at 25 months. However, such elective replacement would have done nothing for the 25 generators which failed before being implanted for 25 months; and 34 others would have been replaced sooner than was essential, in those cases in which failure occurred at various implant lifetimes after 25 months. Moreover, there were five others which were still performing satisfactorily at times considerably greater than 25 months (Table 4). Four of the later models had also been implanted for a period greater than 25 months (Figure 97) and were still functioning satisfactorily on 30th June, 1972. If similar considerations are made of the Medtronic demand generator (Type 5841) then figure 89 shows that it would be impossible to choose an elective implant lifetime on any rational basis, for "the spread" about the mean is so large.

However, if arrangements have not been made for systematic assessment of pacemakers at pacemaker clinics, then there might well be a case for elective replacement of generators, rather than await the return of symptoms following the development of a fault, or depletion of batteries, though any decision as to when a generator should be electively replaced, must be an irrational one.

Whilst it will always be necessary for one or two better equipped and more experienced pacemaker centres to provide failure data on which future policy can be recommended for smaller hospitals, the time might come when elective replacement can be recommended on a rational basis. If, for instance, one of the major centres could provide an actual failed implant lifetime curve for a particular make and type of generator as is depicted in the theoretical curve (Figure 102) then it would be possible to choose an elective implant lifetime on a

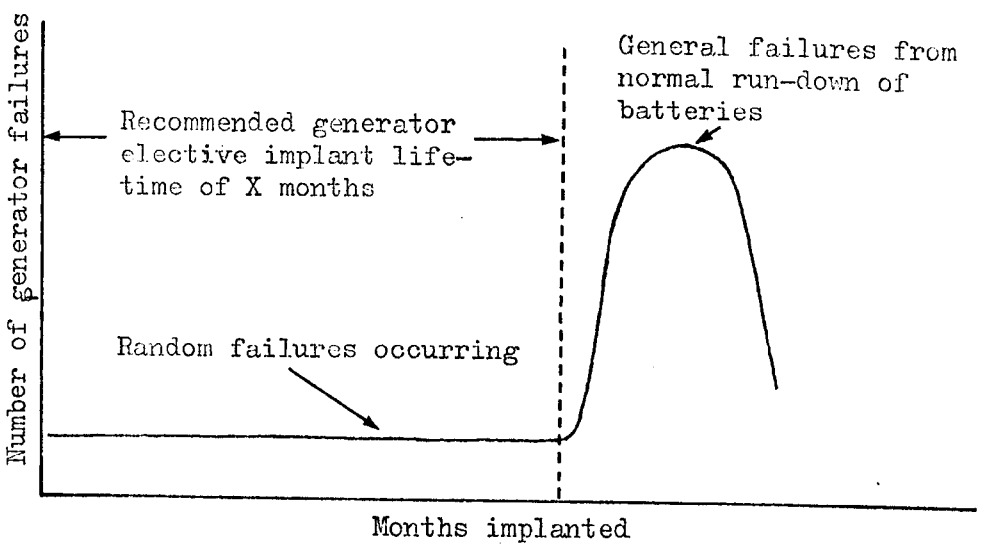


Figure 102. Theoretical "generator failed implant lifetime" characteristic curve which would justify elective replacement of generators.

rational basis.

This is not to say that elective replacement must never take place: on the contrary, it has occurred in a small number of cases in Glasgow. In one case (Patient No. 13), the patient was going abroad for several months and since his generator had been implanted for 34 months, it was replaced on humanitarian grounds. A second case (Patient No. 1), may be similarly classified. The patient feared that failure would occur while she was on holiday in Britain, though her generator had been implanted for only 28 months. This fear was not entirely groundless, since the failed implant lifetimes of her four previous generators were: $3\frac{1}{2}$ months, 17 months, 19 months and 27 months. In another case (Patient No. 107), a generator was changed after only six months, following detection of a suspected fault and subsequent warning from the manufacturer of a possible early fault developing in that particular generator. However, the suspected fault was not confirmed after removal, and it became evident, that in this particular case, the warning had undermined objective assessment. What had been assumed to be a failed implant lifetime had become retrospectively an elective implant lifetime. Similarly, in three other cases (Patient Nos. 30 , 48 , 85), in which generators were replaced after 23 months, 26 months and 29 months respectively, they were classified retrospectively as having been electively replaced, since no technical faults were subsequently found and there were no other complications prior to the re-operations. In one other case (Patient No. 133), the external magnetic linkage coil used for switching-in the earlier Medtronic demand generator (Type 5841) showed a varying pulse width. The suspected varying pulse width was later discovered to have been caused by movements of the external coil. The generator pulse width was, in fact, normal so that this generator was retrospectively classed as having been electively replaced.

Examination of the literature shows that in some centres routine elective replacement of generators is apparently taking place. Shepard[95] et al. state, "Fifty-seven . . . replacements of normally functioning pulse generators were done at scheduled, elective times. The earliest of these was 15 months and the latest 41 months after the previous operation". No explanation is given why some generators were electively replaced sooner than others.

Two less recent publications have referred to policies with regard to elective replacement of generators. Williams and Campbell[96] stated in 1969, "Our current policy is to replace units at two and a half years, recognising that some units will fail before this time". Harrington[97] et al. state without giving adequate reasons, "we now feel that all units should be electively replaced at thirty months".

Sowton[98] in 1968 stated " . . . a date should be set for elective replacement before the patient leaves hospital after pacemaker implantation, the time of replacement being chosen so that there is at least a 90% chance of continuing normal function". Although this policy recommendation may be admirable, no specific times are recommended for elective replacement. A more recent paper by Sowton[89] suggests that elective replacement has been abandoned with the establishment of pacemaker clinics and the introduction of assessment techniques.

Do manufacturers encourage elective replacement of generators? Chardack[99] has shown that elective replacement at 18 months will limit the incidence of generator failures to about 10% and for those hospitals which consider this to be preferable, the Medtronic Company has removed any financial inhibitions to elective replacement at or after 18 months. Thus, for those generators electively replaced at 18 months full credit is allowed pro-rata, based on a theoretical implant lifetime of 36 months. Any generator electively replaced after a longer period of time would qualify at the same rate, but elective replacement at less than 18 months would qualify for only half this rate. Medtronic does not recommend elective replacement at 18 months.

Devices[100] " . . . still have difficulty in giving a meaningful answer" regarding elective replacement of generators but "St. George's Hospital is at present electively changing our fixed-rate 2970 unit at 30 months and the 2980 demand unit at 24 months".

Biotronik[101] do not recommend elective replacement of generators. Should a generator fail within 24 months of leaving the factory it is replaced free of charge and the replacement is similarly guaranteed.

Vitatron[102] and Cordis[103] do not recommend elective replacement of generators.

6. Displacement of Catheters

It was mentioned earlier that displacement of the catheter is a real hazard with endocardial pacemakers particularly in the period immediately following first emplacement. It was also emphasised that all displacements do not lead to "curtailed implant lifetimes" but, since displacement of the catheter has been reported from many centres as being a frequent occurrence, it warrants a special consideration in any assessment of performance.

The displacement of a catheter may not always be a very serious occurrence. Thus displacement may be small, such as when the catheter is slightly withdrawn from the apex of the right ventricle but the tip of the catheter continues to point towards the apex of the ventricle. Then pacing will probably become intermittent. Pacing will also probably become intermittent if there is a much bigger displacement which results in the tip pointing towards, for instance, the pulmonary outflow tract. An even more serious displacement with loss of pacing is when the catheter tip is displaced into the atrium or into the vena-cava. All the above mentioned kinds of displacements were observed and recorded in the Glasgow group of pacemaker patients. It is believed that other minor movements of catheter tips took place but these did not produce "missed pacing beats" and they have not therefore been recorded as displacements. In addition, those displacements, which occurred before the patient left the operating theatre, have not been recorded in the data given below.

Whenever "missed beats" were observed re-operation took place. Remanipulation of the catheter, occasionally without disconnecting the generator, was sometimes successful. In some cases in which remanipulation was unsuccessful a new catheter was used and emplaced via a different vein. Occasionally new catheters and generators were used and this resulted in curtailed implant lifetimes of the former pacemaker, but this is less likely to occur now because of the ease with which the generator can now be separated from the catheter.

The majority of the catheters (225) were emplaced via an external jugular or similar vein. In 37 cases an internal jugular vein was used and in 17 cases a cephalic vein was used.

Analysis of the data shows that of the 225 Medtronic catheters (Types 5816 and 5818) which were implanted via an external jugular vein, during the six years' period, 20 were displaced, though only 16 of these displacements occurred with different catheters. Thus, in one case, the same catheter was displaced three times and in two other cases the same catheter was displaced twice. The times of displacement are normally measured from the time of first emplacement, but in those cases in which a second or third displacement occurred, the times listed are those measured from the second or third emplacement respectively, and not from the times of first emplacement. Thus on seven occasions displacement took place within 15 days or less; four occasions at one month; two at 2 months; one at 4 months; one at 5 months. In a further case of displacement at 8 months a sinus near the entrance to the jugular vein may have "released" the sutures in this vicinity and enhanced displacement. Thus:

$$\text{Displacement probability factor} = \frac{16}{225} = 7.1\% \quad (\text{S.E. } 1.7\%)$$

It should be noted that in three cases of displacement a second displacement occurred within a further 15 days and in one of these three cases yet a third displacement occurred within a further 15 days. Evidently with these three patients it was difficult to lodge the tip of the catheter within the trebiculae and possibly the heart movements were abnormally great.

In one other case a displacement of the catheter was observed at 10 months, shortly after a generator had been replaced, though this "post-operative accident" cannot be placed in the same category as the other 20 cases.

Experience concerning displacement of catheters, emplaced via an internal jugular vein, suggested a greater incident of displacements than appeared to be the case when external jugular veins were used. Only 37 Medtronic catheters have been emplaced via an internal jugular vein but one was displaced at one month, one at two months, three at three months, and one at 10 months. Thus:

$$\text{Displacement probability factor} = \frac{6}{37} = 16.2\% \quad (\text{S.E. } 6.1\%)$$

Although experience using an internal jugular vein is limited the vein is not now used by choice. One other catheter emplaced via an internal jugular vein was found to be displaced at 26 months, shortly after a generator had been replaced.

Early experience of catheters emplaced via cephalic veins was also disappointing and this vein is not now used by choice. Seventeen Medtronic catheters were emplaced via this vein and six were subsequently displaced. Two were displaced within 15 days, another after one month, one after two months, another after three months and yet another after four months. Thus:

$$\text{Displacement probability factor} = \frac{6}{17} = 35.3\% \quad (\text{S.E. } 11.6\%)$$

One other catheter emplaced via a cephalic vein was found to be displaced at 30 months, again shortly after a generator had been replaced.

The longest time between first emplacement of a catheter and its displacement was 10 months, if three cases are excluded in which displacement occurred following replacement of a generator at 10 months, 26 months and 30 months respectively. Most of the displacements took place much sooner than 10 months after first emplacement. It is reasonable to assume that displacement becomes less of a hazard as fibrous tissue builds-up around the electrodes, thus stabilising the distal end of the catheter (Part II, section 1).

The data in the literature is sparse and often inexplicit. Lipp[90] et al. state that 9 out of 51 catheters (18%) were displaced but give no details about the types of catheter though only four out of 162 generators used were of the Medtronic type. All except two of the displacements occurred within one month of first emplacement and remanipulation of the catheter was successful in all cases. The longest time between emplacement and displacement was six months. Mainly the external jugular vein route was used, though in some cases the internal jugular vein was used.

Sykosch[91] prefers the cephalic vein route instead of a jugular vein or alternatively direct implantation through a subclavian vein. In 22 cases out of 415 (5.3%) "with pervenously implanted electrodes displacement of the tips of the electrodes was observed, requiring repositioning". The types of catheters are not specified.

Witte[92] et al. implanted endocardial pacemakers of different makes (Biotronik, Cordis, Devices, Elema, Vitratron) in 100 patients. In 27 patients the catheter become displaced up to a maximum of 14 months after first emplacement. No indication is given of thevein used for introducing the catheter into the apex.

Siggers and Deuchar[93] state that in the period between May 1967 and January 1970 when 28 catheters were implanted, mainly of Devices manufacture, only one was displaced (4%). It is not stated whether this was emplaced via an external or internal jugular vein.

Bernstein[94] et al. used 92 catheters (90 Medtronic, type 5816) and two Cordis catheters over an eight years' period. "Whenever possible the cephalic vein was used; if insertion of the catheter proved impossible, however, the external or at times, the internal jugular vein was used". ". . . 20 catheters required repositioning, usually within the first week after implantation", i.e. 22%.

Shepard[95] et al. state that the transvenous route was used on 103 patients and that in six cases catheters were displaced within 30 days of first emplacement. In one other case there was "reverse migration of the catheter in the ventricle after 2.5 years pacing". An internal jugular vein was used on 65 occasions; an external jugular vein on 35 occasions and a cephalic, on three occasions. The types and makes of catheters used are not given: indeed, this also applies to the generators used.

Schaudig[104] et al. refer to 309 "intracardial electrodes", of the flexible Elema type emplaced mainly via "a right jugular vein" but it is not stated what proportion, if any, of internal jugular veins was used. A "dislocation rate" of 19% is given with more than 70% of the dislocations occurring within the first month after implantation.

Since displacements are a real hazard to patients and can cause a big increase in workload, often at inopportune times, there is evidently a real need for better documentation on the number of displacements, the veins used, the types of catheters used, and recurrent displacements, so that this hazard and workload can be minimised in the future.

7. Exit-Block, Pacemaker-Block (impedance changes), Generator-Block and Threshold Changes

Any study on the performance of implanted pacemakers must include further reference to several phenomena which led to curtailed implant lifetimes.

"Exit-block" was first defined as the "inability of an impulse to leave its point of origin, the mechanism for which is conceived as an encircling zone of refractory tissue denying passage to the emerging pulse"[105]. Mowry[106] et al. first applied it to the pacemaker situation in which the myocardium becomes unresponsive to a normally functioning pacemaker, because of an increase in the myocardial threshold to a level greater than the output of the pacemaker. It is not, of course, peculiar to myocardial electrodes. In this work the term exit-block is therefore limited to those cases in which the generator output has remained normal, the electrode-lead system has remained intact and in a stable position, but the threshold for satisfactory stimulation has increased above the output of the pacemaker. Since thresholds are believed to vary somewhat over a twenty-four hour period, the condition of exit-block may first be intermittent before a further general increase in threshold makes the condition "permanent".

When temporary or permanent exit-block occurs the pacing stimulus is seen at regular intervals on the E.C.G. (except possibly in the case of demand pacemakers); the pacemaker frontal plane vectors are normal in direction and magnitude; the generator pulse width, period (rate) and shape are normal. During experience in Glasgow over a six years' period when 294 electrode-lead systems were implanted only two cases of exit-block were observed.

In one such case (Patient No. 46) pacing became intermittent and exit-block was predicted. At re-operation high thresholds were confirmed: the catheter had been implanted for 49 months. A new catheter (and generator) were implanted when very low thresholds were obtained.

In another case (Patient No. 204) in which pacing had ceased because of exit-block, this was resolved by converting a bipolar myocardial electrode-lead system into a unipolar one by introducing an indifferent lead. This occurred within four months of first implantation of the myocardial electrode-lead system.

Exit-block will always result in a curtailed implant lifetime of an electrode-lead system but the generator may continue to be used after re-operation.

There was another case (Patient No. 18) which cannot be described as exit-block: although the threshold had increased significantly this was accompanied by a big reduction in pacemaker output. The reduction occurred not because of natural battery depletion, premature failure of cells, or because of a generator fault, but because the load impedance presented to the generator had increased significantly, perhaps as a result of physiological changes or because of changes in the resistance of the electrode-lead system. In this case, pacing first became intermittent with a Medtronic bipolar catheter after it had been implanted for 52 months. At re-operation, it was discovered that the energy being delivered by the generator per pulse was about the same as the threshold energy required to produce heart muscle contractions. This was partly because the load impedance had increased from about 1.0 k ohm to 1.8 k ohm and partly because the threshold had increased. This was eventually resolved by making one electrode-lead, the distal one in this case, redundant. Both the unipolar threshold and unipolar impedance were much lower and pacing became satisfactory with the increased current which flowed. This is an example of pacemaker-block.

In pacemaker-block there is a reduction in generator output because of natural battery depletion or because of premature failure of cells or because of a fault in the generator; or simply a reduction in pacemaker output, because of an increase in load impedance (either the electrode-lead system itself or in the patient load), to a value below the threshold obtaining at that particular time. The threshold need not necessarily have increased so that the definition of pacemaker-block is independent of changes in thresholds. A generator fault would, of course, lead to a generator failed implant lifetime and possibly an electrode-lead system curtailed implant lifetime. An increase in electrode-lead system resistance would result in an electrode-lead system failed implant lifetime and possibly a generator curtailed implant lifetime. On the other hand, an increase in patient load impedance would result in an electrode-lead system curtailed implant lifetime and possibly a generator curtailed implant lifetime. Thus pacemaker-block can result in both failed and curtailed implant lifetimes, depending on the circumstances.

Another case of pacemaker-block probably occurred in 1968 (Patient No. 7) when a new generator was connected to a catheter with a relatively high threshold (about 3.5 mA). More recent examination of this case suggests that the reduced pacemaker frontal plane vectors probably arose from an increase in patient impedance. This produced a lower generator output, probably sufficient to cause pacemaker-block. After re-operation, the removed generator was found to be working normally but unfortunately threshold and impedance measurements were not made at re-operation. The catheter appeared to be in a normal position and it may have been displaced "backwards" but the fact that it had been implanted for 49 months makes this less likely.

If there is a loss of pacing because of a fall in output from the generator, whatever the cause, this was defined as battery-block[9]. Perhaps a better term would be "generator-block", since loss of pacing can, as indicated, be caused by circuitry failures not associated with batteries.

In one case of generator-block (Patient No. 42) this was coupled with a significant increase in threshold. The patient became dizzy because of lack of pacing and a reduction in generator output was detected. This was confirmed at re-operation as being the result of a failing generator. It was discovered that the threshold had increased to a value which was comparable with the reduced generator output.

Generator-block arising from generator failure has been a rare occurrence, because in nearly all cases of failing generators (with the exception of a number of 5841 generator failures) re-operation has always taken place shortly after a fall in output has been detected, but with the output still above the threshold.
The cases of pacemaker block and generator block, referred to above, have been singled out because the reduction in output was accompanied with abnormally high thresholds and clinical symptoms.

It is, of course, possible to have a fall in generator output and an increase in the threshold without any clinical symptoms, provided that the former does not decrease too much and the latter does not increase too much. In fact, in nearly all cases in which a failing generator has been replaced an increase in threshold has been observed. This is usually small, however, and over a period of two to three years the threshold may become twice its initial value but

this does not warrant replacement of an electrode-lead system. Such cases are not examples of exit-block for pacing is continuing and there is a reduction in generator output; neither can they be regarded as examples of generator-block because the generator output has not fallen below the threshold obtaining at that time. However, if thresholds on generator replacement are a little higher than is normally expected, it is sometimes difficult to decide whether to replace an electrode-lead system.

The cause of the increase in threshold is believed to be due to the fibrous tissue which grows around the electrodes and completely envelopes them (Part II, section 1). The new fibrous tissue increases the distance between the electrodes and the heart muscle fibres and, in effect, the current density at the nearest muscle fibres is decreased so that the current flowing from the pacemaker must be increased to restore the current density in the nearest muscle fibres to a level which is necessary for depolarisation to occur.

Any big patient-load impedance changes can be of some significance when a constant voltage generator has been implanted for, as explained above, pacemaker-block may follow. In the majority of cases the total load impedance (patient-load plus electrode-lead system) on first emplacement of a catheter is about 800 ohm, though it has been much lower, and much larger. The physiological factors which determine patient-load impedance, with a given electrode-lead system, are not yet understood and more time is required for further measurements to be made as and when the opportunity arises, particularly at re-operations for replacement of generators. By this time, electrodes have usually become stabilised and it will be interesting to see whether at successive re-operations the same impedance values are obtained in the same patient.

Exit-block is discussed in the literature. Chardack[107] et al. claimed in 1965 that exit-block is unlikely when, as is the case with Medtronic pacemakers, platinum electrodes and biphasic pulses are used. Kahn[108] et al., Williams and Campbell[96] claim that they have had no cases of exit-block when using the Medtronic pacemaker whilst Gerst[109] et al. claim, that in a series of 71 patients, exit-block occurred with five myocardial electrode-lead systems, with a maximum period for development of exit-block of 13 months. Preston[110] et al., using myocardial pacemakers manufactured by the General Electric Company found that "exit-block" was "the second most common cause of

failure (14%) in a series of 128 pacemaker implantations". All occurred within a period of three months following implantation.

Many other workers report difficulties in this connection, but most give inexplicit data on the incidence of exit-block, on the types of pacemakers used and on the times at which it occurred (Sowton[82], Sowton and Gray[85], Sykosch[91], Lipp[90] et al. and Shepard[95] et al.).

Preston[110] et al. attempt to correlate impedance with threshold values but finally conclude that there is no simple association. Measurements made in Glasgow show that the two are unrelated, but more data is required before scientifically based deductions can be made from the measurements made so far.

8. Migration, Extrusion, Infection

In a number of cases in which pacemakers were implanted during the six-year review period, re-operation became necessary because the generator had moved from its original site of implantation or because the generator was being extruded. Sometimes catheters began to extrude from the neck. Primary infection sometimes developed in a wound but infection secondary to extrusion has also occurred. In many of these cases it became necessary to replace the generator, or catheter, or both at first re-operation; in other cases one or both were eventually replaced after a further re-operation when the first attempt to solve a difficulty failed. Migration, extrusion and infection have therefore resulted in a number of generators and catheters having curtailed implant lifetimes.

Of the 227 patients (Part I, section 4) who received their first Medtronic pacemaker implant in Glasgow hospitals during the six-year period, none of whom was lost to follow-up, 27 of them (12%) underwent re-operations because of one or more of the above difficulties. Indeed three of them underwent more than one re-operation before these difficulties were eventually resolved.

Generator migration has been a rare occurrence during this six-year review period. Five of the earlier endocardial pacemakers which were implanted in the axillary area demanded further surgical intervention, because they had been displaced from their original sites. Four had migrated posteriorily with consequent discomfort and risk of damage to, or displacement of, the catheter; the fifth had moved into the substance of the breast and was causing discomfort. Migration has not occurred since generators have been implanted in the pectoralis major region.

Implantation of the-generator in the area of the pectoralis major has, however, led to the extrusion of a number of generators. This has occurred with 12 patients. In two of these patients extrusion occurred with replacement generators and, in another of these cases in which re-operation took place to resite a generator because of a sinus, extrusion occurred 11 days later, only to be followed by a further extrusion of the same generator and catheter one year later. Fortunately, since generators have been implanted at the first operation routinely behind the pectoralis major, migration and extrusion have not occurred.

If the catheter near the point of entry to the external jugular vein is too near the surface of the skin it may cause pressure necrosis, which leads to the development of a sore, eventual extrusion of the "loop" in the catheter with the consequent hazards of infection and possible displacement of the distal end of the catheter. Re-operations have been necessary on eight occasions because of catheter extrusions in the neck. Extrusion has not occurred with any catheter which has been implanted under the clavicle. This procedure is gradually becoming more acceptable, but there are surgical difficulties with consequent hazards.

In 11 patients infection and sinuses developed after surgery for implantation of a pacemaker.

It seems that the problems of migration and extrusion will decrease and result in fewer curtailed implant lifetimes now that generators are routinely placed behind the pectoralis major and more and more catheters are being passed under the clavicle. It is inevitable, however, as with any surgical procedure, that infection will occur from time to time.

Examination of the literature shows that other workers have problems with migration, extrusion and infection, though the details are not sufficiently explicit to enable useful observations to be made on their experiences.

9. Deaths of Pacemakers Patients

No study on the performance of implanted pacemakers would be complete without a reference to the patients themselves. It is important to emphasise that the prime purpose in implanting a cardiac pacemaker is to improve the quality of life: if patient lifetimes are extended as a result of implanting a pacemaker (and this has yet to be proved) this is merely a complementary bonus.

In any study relating to the deaths of patients, age on presentation for treatment, is likely to be of some relevance to prognosis. Figure 103 shows the age distribution of the 227 patients (Part I, section 4) at the time they received their first Medtronic pacemakers (the four lost to follow-up have been excluded). The most frequently occurring age group, the mode, is 70 to 75 years: the youngest patient was a boy of 13 and the oldest, was a man of 88.

Forty-nine* (22%) of the 227 patients had died by 30th June, 1972. The causes of death, as far as could be ascertained, are given in Appendix IV. It is pertinent to ask how many died, directly or indirectly, as a result of pacemaker failures or pacemaker complications at operations or thereafter.

One patient (No. 32) died directly as a result of a generator failure.

Eight deaths can be attributed directly or indirectly to the implantation of a pacemaker. In one case (No. 33) the catheter penetrated the myocardium and the patient died suddenly at home after a thoracotomy to reposition it. This incidentally is the only confirmed case of penetration of the myocardium in the Glasgow group of patients. In another case (No. 38) the patient was re-admitted to hospital on an unplanned basis, since pacing had become intermittent from a failing generator. A temporary pacing catheter was introduced and connected to an external pacemaker. Unfortunately competitive pacing from the two pacemakers resulted in ventricular fibrillation and death of the patient. One patient (No. 127) became asystolic whilst an endocardial pacemaker was being implanted; this caused cerebral damage and the patient died four days later.

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* The apparent discrepancy with 56 given in section 4.2 arises because in this section only those patients are considered who received their first pacemaker between 1st July, 1966 and 30th June, 1972 in Glasgow hospitals.

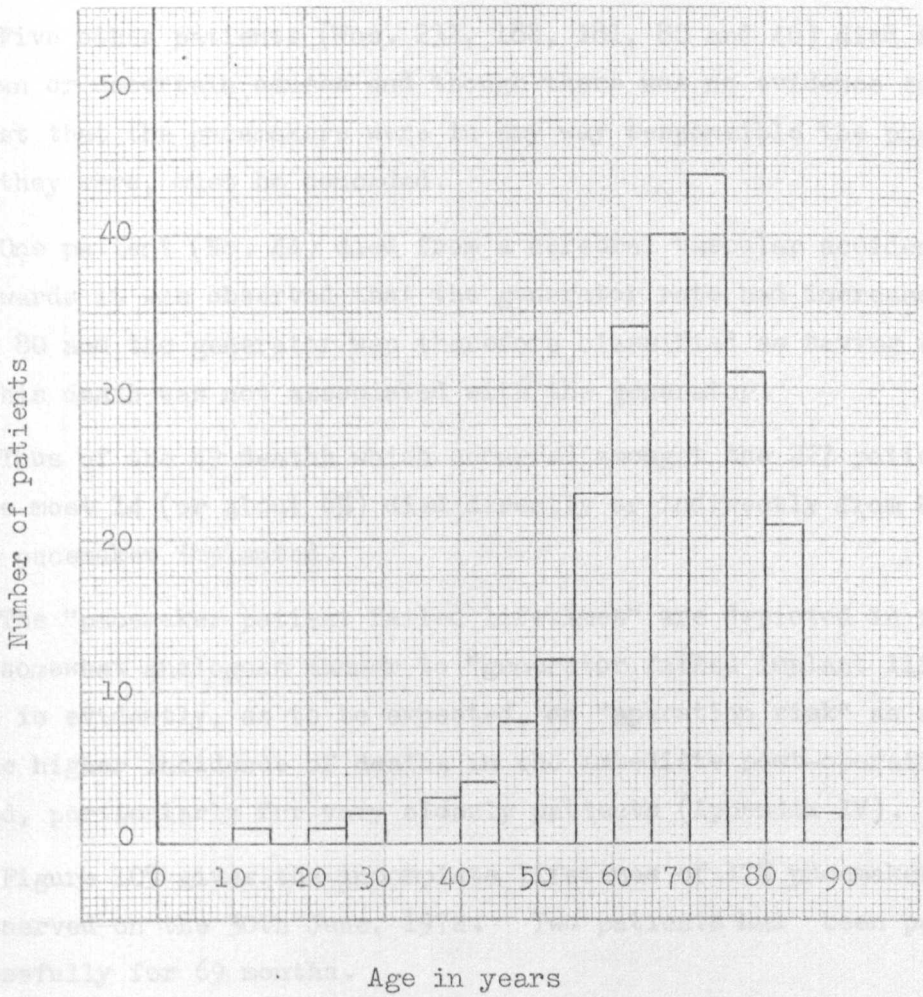

Figure 103. Age distribution of 227 pacemaker patients on receiving first implant.

A displaced catheter caused the death of one patient (No. 171) who was found in a street. The post-mortem showed that the catheter had been displaced into the right atrium with consequential loss of pacing and no doubt asystole. Ventricular fibrillation from competitive pacing may have resulted in the death of one patient (No. 178). The death of another patient (No. 212) was probably caused by the break-up of a mural thrombus at the pacemaker electrodes in the right ventricle which caused multiple pulmonary infarcts and consequential infection. Pulmonary embolism perhaps arising from the pacemaker electrodes certainly caused the death of another patient (No. 97) and may likewise have been responsible for the death of another (No. 59).

Five other patients (Nos. 232, 188, 181, 80 and 46) died from unknown or uncertain causes and though there was no evidence to suggest that the pacemakers were in any way responsible the possibility that they were, must be conceded.

One patient (No. 44) died from a cerebral vascular accident: afterwards it was observed that the generator rate had increased to about 80 and the generator was therefore classified as having failed, but this death was not associated with the generator.

Thus of the 49 deaths which occurred amongst the 227 patients, at the most 14 (or about 6%) died directly or indirectly from having had a pacemaker implanted.

The "pacemaker patient failed lifetimes" are depicted in figure 104 in a somewhat analogous manner to "generator failed implant lifetimes". There is evidently, as to be expected, an "operation risk" as shown by the higher incidence of deaths in the immediate post-operative period, particularly for very elderly patients (Appendix IV).

Figure 105 gives the incomplete lifetimes of 178 pacemaker patients as observed on the 30th June, 1972. Two patients had been paced successfully for 69 months.

(It ought to be mentioned in passing that 10 of the patients who received pacemakers prior to 1st July, 1966 were also alive on 30th June, 1972. This included the first patient in Glasgow who received her pacemaker in June 1962 at the age of 60).

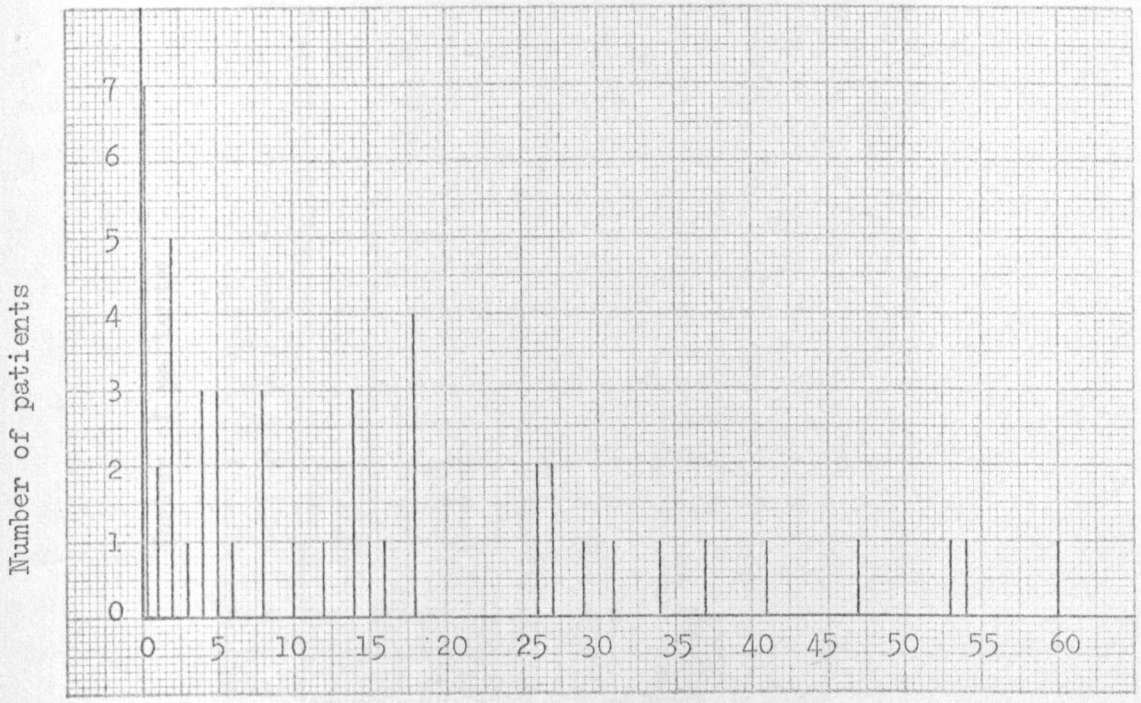

Figure 104. Pacemaker patient failed lifetimes.

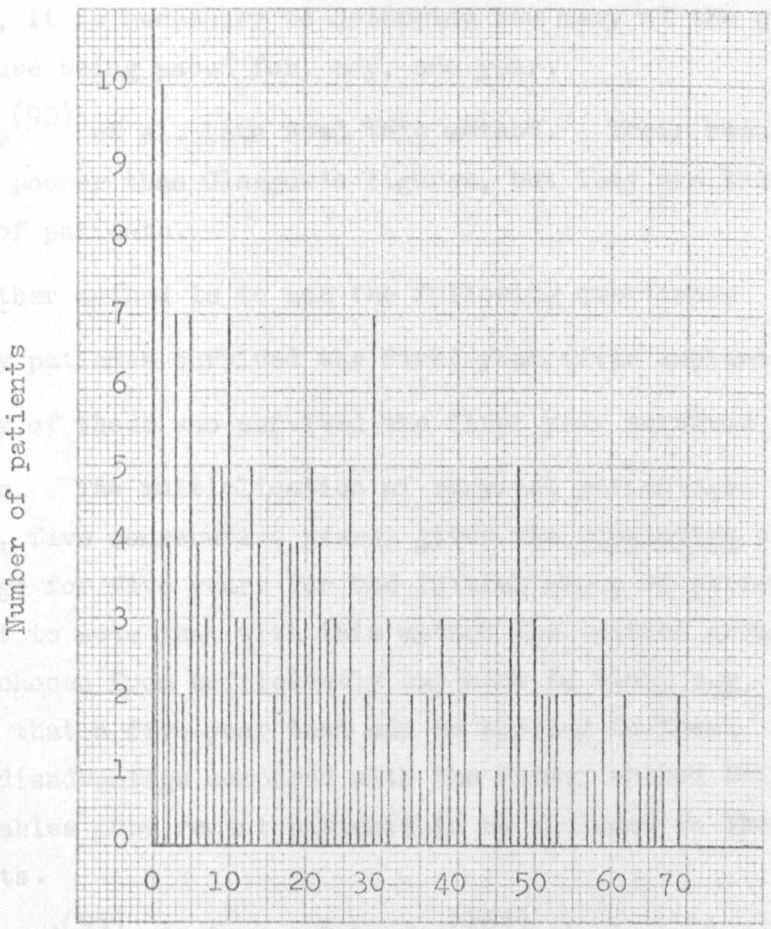

Figure 105. Incomplete lifetimes of 178 pacemaker patients on 30th June, 1972.

Another method of depicting patient deaths, or survivals, is shown in figure 106. In calculating the percentages of patients who have survived various periods of pacing, the same technique is used as was used when generator failure rates were being calculated (Part III, sub-section 2.1, figure 93). In this method all patients are considered who received their first pacemaker within a given period of time, in this case between 1st July, 1966 and 30th June, 1972, and all deaths in this period are considered. In order to obtain the percentage of patients surviving after, say, one year of pacing, it is necessary first to ask how many patients in the six-year period might have survived for at least one year (159 in figure 106). This "qualifying number" obviously decreases as the period of time increases. Secondly, it is necessary to determine how many of the given number died before being paced for, say, one year.

Lipp[90] et al. have used this method. Their results are somewhat poorer than Glasgow's figures, but they are based on smaller numbers of patients.

Another method is to ask the following questions:

"How many patients survived the first year after implantation?";

"How many of those who survived the first year survived a second year?";

and so on. The multiplication of survival percentages for each year for, say, five consecutive years, gives the cumulative survival percentage for five years for the initial group of patients. It is important to note that with this method the initial group of patients must be chosen from sufficiently far back in time, e.g. 5 years, in order that a five-year test can be applied to them. This appears to be a disadvantage compared with the former method (Figure 106) which enables more recent patients to be included in the shorter life-time tests.

Shepard[95] et al. and Schaudig[104] et al. have nevertheless used this method of calculating survival rates.

It has been shown that the patient failures arising directly or indirectly from a pacemaker implant was about 6%, over a six-year period. With this in mind, the survival graph suggests that the curve is probably more characteristic of the age group of the pacemaker patients, perhaps more especially those with heart disease, rather than being related to the pacemaker itself or with the effects of the implanted pacemaker.

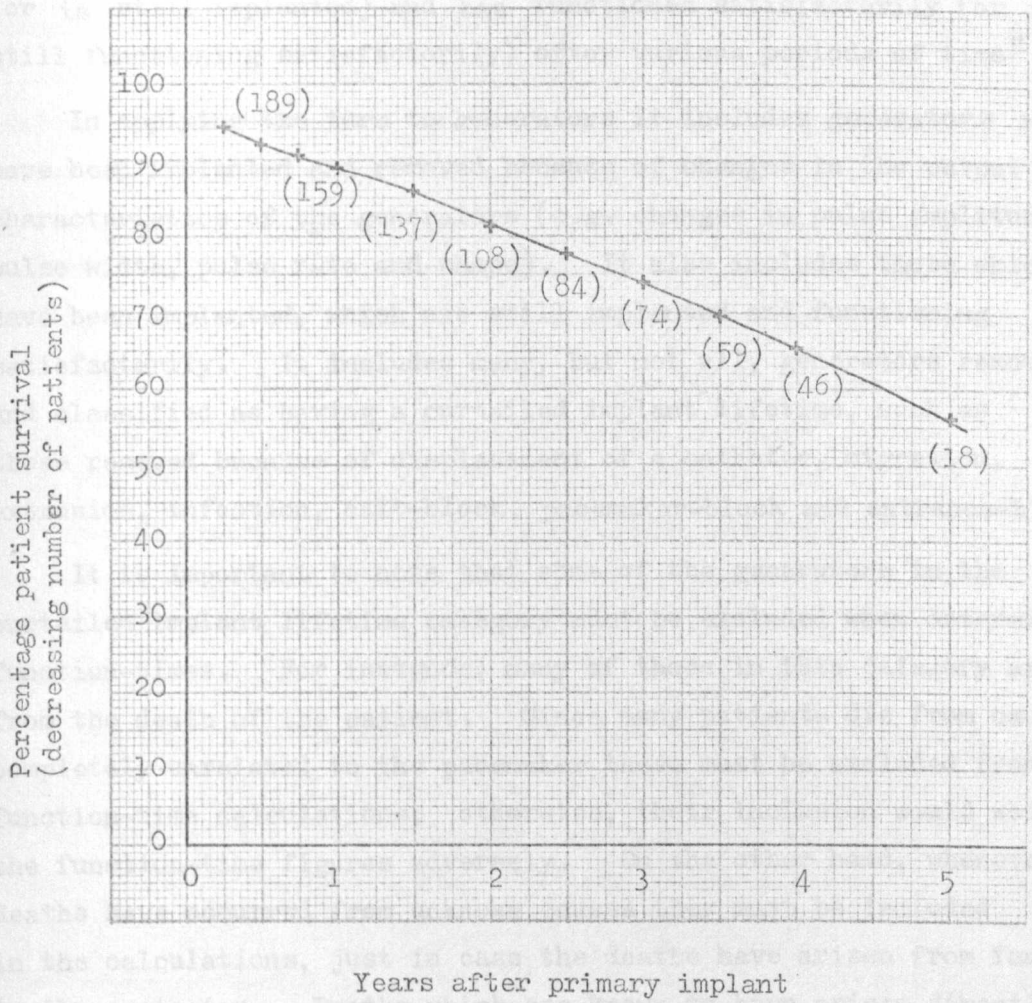

Figure 106. Patient survival expressed as percentage of the total number who could have been followed for specific periods of time. (The figures in parentheses are the numbers of patients at the beginning of the chosen period).

10. Function-times

10.1 Definition and important exclusions

It is now possible in the light of earlier definitions and the data presented so far, to introduce a term "function-time" as an indicative figure of merit for a given type and make of generator (or electrode-lead system). A term "cumulative function-time" has been used by Schaudig[104] et al., without a clear explanation as to its meaning, but in this thesis, "function-time" is defined as "the percentage of generators (or electrode-lead systems) which has been implanted (or is still implanted) and has functioned satisfactorily (or is still functioning satisfactorily) after various periods of time".

In applying the term to generators it includes generators which have been implanted and removed because of changes in the output characteristics of the generators (e.g. changes in pulse amplitude, pulse width, pulse rate and shape). It also includes those which have been implanted, which are still implanted and functioning satisfactorily. It includes many, but not all, generators removed and classified as having a curtailed implant lifetime, such as those removed because of displacement of a catheter, migration, extrusion, infection, exit-block, pacemaker-block and entrance-block.

It is important to note that some of the generators in the curtailed implant lifetime category must be excluded when determining function-times. For instance, many of those in this category arise from the death of the patient. Since many patients die from causes completely unrelated to the pacemaker these must be excluded from function-time calculations; otherwise, their inclusion would weight the function-time figures adversely. On the other hand, whenever deaths have occurred from unknown causes they must be included in the calculations, just in case the deaths have arisen from faults in the generator. Deaths which are known to have arisen directly, or indirectly, from the implantation of a pacemaker must, of course, be included.

The elective replacement of a generator, as explained in Part III, section 5, is an arbitrary decision as regards the performance of the generator, but has occasionally been carried out in special circumstances. Any generator which has been electively replaced must not be included in the function-time calculations.

Since function-times include those generators which are still implanted (i.e. incomplete implant lifetimes) it should be borne in mind that if, say, a six-year period is being studied, many of the generators implanted towards the end of the six-year period cannot be included. Thus, if the one-year function-time is being calculated, only those generators implanted during the first five years of the period can be included (By analogy with figures 91(a) and 92(a)).

10.2 Generators

Figure 107 shows the function-times and non-failed implant lifetimes of Medtronic asynchronous generators, type 5870C. The function-times are much worse than the non-failed implant lifetimes especially during the earlier months after implantation for it is during these earlier months that factors other than the failure of the generator are predominant. Much later these factors are less important and the failure rate of the generator itself becomes the over-riding factor. At 24 months the function-time was 50% (S.E. 5.0%).

With the asynchronous generator type 5862C, no failures had occurred by 30th June, 1972 over a period of 27 months from the time that the first generator of this type was implanted, so that the non-failed implant lifetime curve for these generators will be superior to the corresponding 5870C curve. The function-time at 18 months for the 5862C generator is 79% (S.E. 5.9%) compared with a corresponding figure of 69% (S.E. 4.6%) for the 5870C generator.

Figure 108 shows similar curves for the Medtronic demand generator, type 5841. At 21 months the function-time was 50% (S.E. 7.8%) whereas the corresponding figure of 50% (S.E. 5.0%) occurred at 24 months for the 5870C asynchronous generator. This is to be expected since the non-failed implant lifetime curve for the demand generator is generally worse than the corresponding curve for the asynchronous generator.

Only one of the later models (types 5842 and 5942) had failed at 17 months by 30th June, 1972 so that the non-failed implant lifetime curve for these generators will be superior to the 5841 curve. The function-time for the 5842/5942 generators at 18 months is 88% (S.E. 8.3%) compared with a corresponding figure of 60% (S.E. 7.7%) for their predecessor, type 5841.

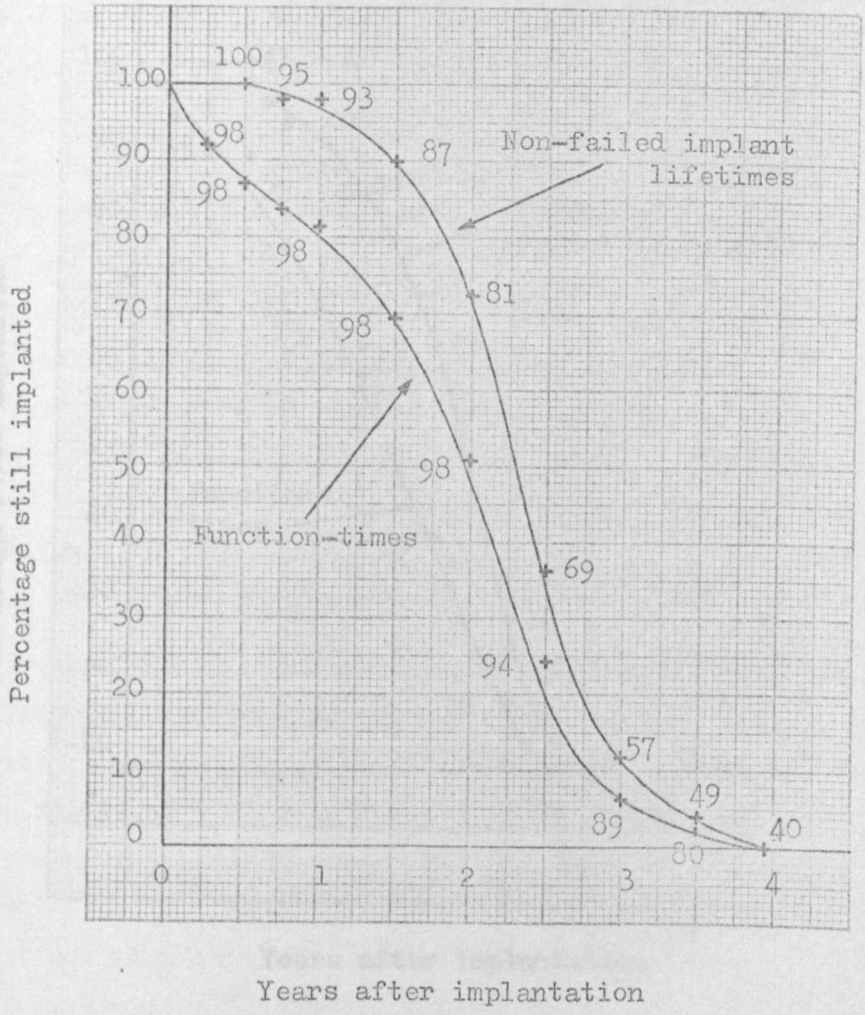

Figure 107. Function-times and non-failed implant lifetimes of Medtronic asynchronous generators, type 5870C.

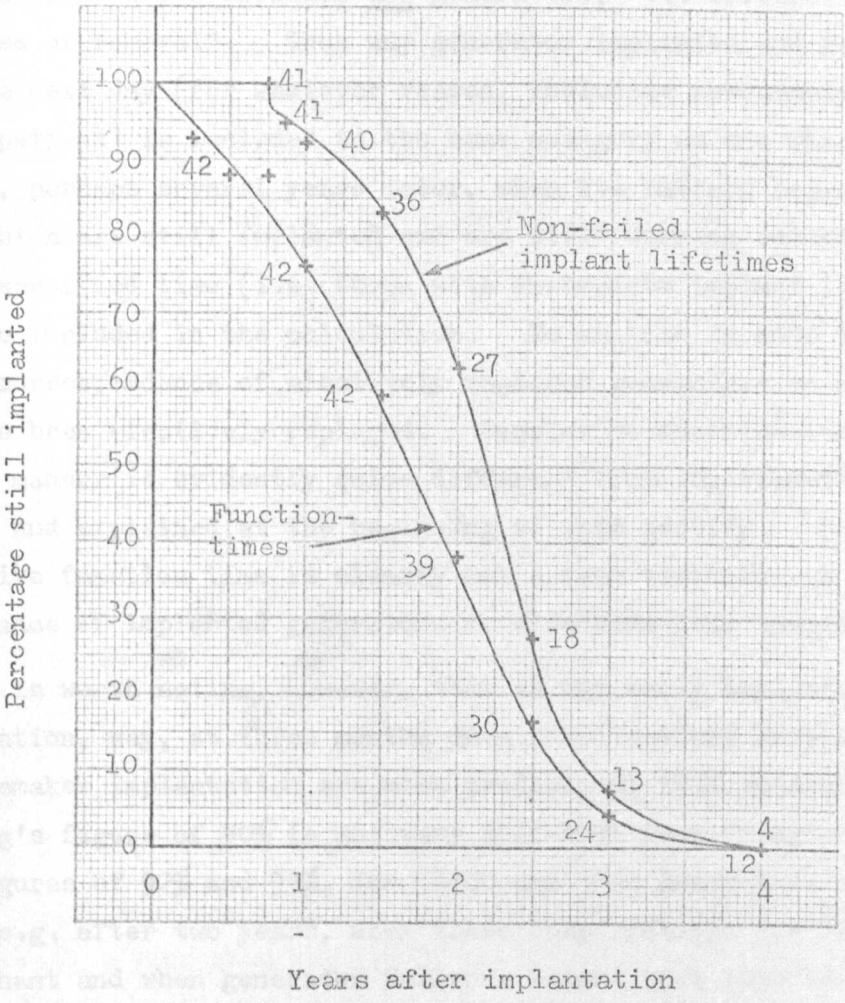

Figure 108. Function-times and non-failed implant lifetimes of Medtronic demand generators, type 5841.

More time is evidently required to enable better comparisons to be made with these later generators but preliminary indications of performance based on these function-times are encouraging.

Schaudig[104] et al. give the "cumulative function times" of "impulse generators" and "pacemaker electrodes" implanted during the period 1962 to 1969. Cumulative function times are not defined in the paper.

Correspondence with Professor Schaudig has revealed that cumulative function time is in effect a "cumulative (clinical) function-time" which includes all generators, "... irrespective of the cause of removal". Thus any generator implanted and removed even the next day (for whatever reason, including presumably death of the patient) is included in the same category as one which is removed, perhaps several years later, when its battery begins to fail. Those which are still implanted and are still working satisfactorily at the specified time (i.e. those with incomplete implant lifetimes) are also included in the calculation. No mention is made in the paper or in the correspondence of electively replaced generators so presumably none has been electively replaced. Cumulative function-time compiled in this manner is evidently quite different from function-time as defined and explained at the beginning of this section. Schaudig's cumulative function time is clearly not a true indicator of the performance of implanted generators or electrode-lead systems.

It is worth noting, however, that in the early days after implantation, say, at three months when complications arising from the pacemaker implantation are more predominant than generator failures, Schaudig's figure of 90% is not very different from Glasgow's function-time figures of 92% and 93%, for 5870C and 5841 generators respectively. Later, e.g. after two years, when these complications are less predominant and when generator failures become more important, Schaudig's figure is 28% compared with Glasgow's figures of 51% (S.E. 5.0%) and 39% (S.E. 7.8%) respectively. Presumably this is because the deaths of all patients have been included apart from any elective replacements which may have occurred and may have been included in the calculations.

The paper[104] referred to above, by Schaudig and colleagues, though published in 1971 was probably written earlier in 1970. However, in September 1970, Schaudig and Zimmerman[111] presented a paper at the Monaco Conference which is much more meaningful. It is evident from this paper that in calculating cumulative function-times of generators and electrode-lead systems certain of these items have been excluded. For instance, generators are excluded in all cases in which the patient has died. They are also excluded in those cases in which follow-up of the patient has lapsed or the generator has been "routinely exchanged", (i.e. presumably, electively replaced). It is believed that all other generators which gave rise to failed implant lifetimes, incomplete implant lifetimes and all other cases in the curtailed implant lifetime category have been (correctly) used in the calculation of this cumulative function-time.

Schaudig and colleagues used a computer programme OIS[112] to calculate cumulative function times. Their later paper[111] gives, amongst others, the cumulative function-times of Medtronic asynchronous generators though the type number is not stated. The cumulative function-times after one and two years are 91% and 61% respectively, compared with Glasgow's figures of 82% (S.E. 3.9%) and 51% (S.E. 5.0%) for the asynchronous generator, type 5870C. Similarly results are given for a Medtronic demand generator though again no type number is specified. Schaudig's figure after one year is 85% compared with Glasgow's figure of 76% (S.E. 6.6%) for Medtronic demand generator , type 5841. Glasgow's figures may be different from Schaudig's, because different generators have been compared. They would, however, in any case be expected to be different and indeed better because generators associated with all the deaths have been excluded.

Although Schaudig's second attempt to calculate cumulative function-time is much better than the first, it is still different from that presented in this thesis. It is the author's view that whenever deaths from unknown causes have occurred they should be included in calculations on function-times just as in other cases in which deaths which are known to have arisen directly or indirectly from the implantation of a pacemaker should be included.

The computer programme OIS evidently calculates the cumulative function-times so that presumably this means that a specific group of generators (or electrode-lead systems) is studied in a similar manner to the way in which patient survival was considered in section 9.

Thus the graphs presented by Schaudig have been normalised with respect to a fixed number of patients with the disadvantage referred to in section 9.

It should be the aim of each pacemaker centre to have a generator function-time curve which is as close as possible to the corresponding generator non-failed implant lifetime curve.

10.3 Electrode-lead systems

Similar calculations on "function-times" can be made for electrode-lead systems as was done for generators. Precisely the same conditions were imposed as explained in sub-section 10.1. The calculations have in fact only been carried out for endocardial electrode-lead systems since so few myocardial ones have been used.

The function-times of endocardial electrode-lead systems are given in figure 109. These are much worse than non-failed implant lifetimes because, as was the case with generators, many factors other than technical failures of electrode-lead systems are included.

Schaudig and Zimmerman[111] calculate the "function-time of pacemaker electrodes" and give results for Cordis and Elema-Schonander endocardial electrode-lead systems. Again their results are superior to Glasgow's presumably because of the same differences in the method of compilation referred to when generator function-times were discussed.

It should be the aim of each pacemaker centre to have an electrode-lead system function-time curve which is as close as possible to the corresponding electrode-lead non-failed implant lifetime curve.

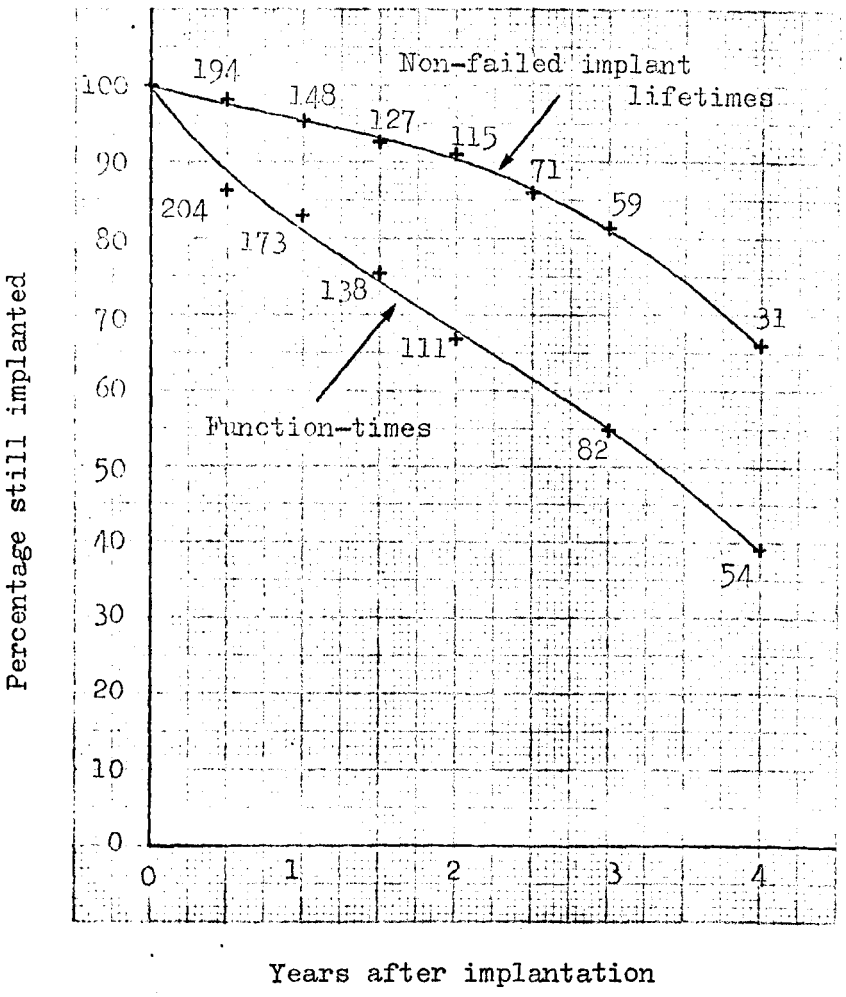

Figure 109. Function-times and non-failed implant lifetimes of Medtronic endocardial electrode-lead systems, types 5816 and 5818.

Part IV - Conclusions

1. Assessment

The number of new patients who have required pacemakers in Glasgow hospitals since 1962 has grown almost exponentially, though the 1972 rate of implantation in new patients was still well below that for many other countries. It appears therefore that the total number of living pacemaker patients in the Western Region of Scotland will continue to increase for some time yet.

If the maximum benefits are to accrue to these pacemaker patients it is desirable to introduce systematic assessment techniques rather than await loss of pacing, return of symptoms and emergency re-admission to hospital. Regular attendance at pacemaker clinics is therefore advocated. Attendance at a clinic not only reveals the general well being of the patient, and discloses any post-surgical problems, but it also enables the pacing function to be checked and any adverse changes in the pacemaker itself to be detected. No single investigation is completely satisfactory, but ideally a combination of several simple investigations can quickly check, in a comprehensive way, both the pacing function and the pacemaker itself.

Patients are often asked to check their own pulse each day and measurement of the patient's pulse is the simplest of the observations made at a pacemaker clinic. Pulse measurement can certainly be a good indicator of satisfactory pacemaker function, and an indirect guide to the state of the pacemaker itself. However, if any deductions are to be made from this simple measurement, it is imperative that the patient's pulse is measured accurately; and that the type of pacemaker which has been implanted is known and its mode of operation is fully understood.

If an asynchronous pacemaker has been implanted and the patient is in complete heart block the pulse should be constant at the fixed generator rate. Any increase in pulse will be the result of competitive pacing or a generator fault; whilst a decrease in pulse will signify either a reduction in generator rate, pacemaker block (including generator block), exit-block, a displaced catheter or a loose electrode.

A varying pulse should normally be a good omen when a demand pacemaker has been implanted but it should not fall below a lower specified rate. However, the pulse will also be variable in the presence of entrance-block, if competitive pacing is occurring; otherwise, it will be constant at the basic generator rate. On the other hand, a constant pulse is perfectly normal if the basic generator rate is above the patient's rate which obtains when conduction is occurring. Any specific increase in pulse above the basic generator rate, or any gradually increasing pulse, will be the result of a generator fault; whilst a decrease below the lower specified rate could be caused by the faults suggested at the end of the previous paragraph; or additionally, by external electromagnetic radiation. (This latter possibility is less likely to occur with the latest designs of demand generators especially with bipolar electrode-lead systems)

A varying pulse is also a good omen with ventricular synchronised pacemakers, within upper and lower limits imposed by the generator. However, whilst a steady pulse at the lower pre-set generator rate is to be expected during periods of heart-block, this is also the case if the pacemaker sensing circuit fails and if one cell fails. Any increase in pulse above the normal upper limit of the generator; or a persistently steady pulse (especially when the patient is being exercised) above the lower limit of the generator; or a progressive increase in pulse; will be the result of a generator fault. Any decrease below the lower limit could be caused by the faults referred to when asynchronous pacemakers were discussed in this context.

A varying pulse, within upper and lower limits imposed by the generator is also to be expected at all times, including periods of heart block, when an atrial synchronous pacemaker has been implanted. Only when the sensing electrode-lead, or sensing circuit itself fails; or when premature failure of a cell occurs, should the pulse become steady at the lower fixed rate. Any increase in pulse above the normal upper limit of the generator; or a persistently steady pulse (especially when the patient is being exercised) above the lower limit of the generator; or a progressive increase in pulse; will be the result of a generator fault. As with the other types of pacemakers any decrease in pulse below the lower limit could be caused by the faults referred to when asynchronous pacemakers were discussed in this context.

The electrocardiogram of a pacemaker patient is of considerable value in direct assessment of pacemaker function and of the state of the pacemaker itself, though it has some limitations in the latter respect. Thus the effectiveness of pacemaker spikes will immediately be evident from an E.C.G. as will any large changes in generator rate. Very small apparent changes in generator rate should be regarded with caution because of possible variations in paper speed.

The magnitudes of the pacemaker spikes on the different Leads of an E.C.G. are not the true magnitudes and should therefore only be considered with caution: but changes in the magnitudes of the spikes on <u>all</u> Leads are significant. A large increase in the magnitude of the spikes on all Leads would suggest that a bipolar system has become a unibip system. Conversely, a large reduction in the magnitudes of the pacemaker spikes on <u>all</u> Leads would mean pacemaker-block (including generator-block).

The senses of the pacemaker spikes are readily seen with bipolar systems but with unipolar systems this is sometimes less obvious. In some cases, the biphasic spike makes it impossible to decide on the true sense of the pacemaker spike. Changes in the sense of bipolar pacemaker spikes are, however, very important for they may be the result of a displaced catheter or a change from bipolar pacing to unibip pacing.

Pacemaker spikes should always be present on the E.C.G. with all types of pacemakers on at least some of the Leads, except when, of course, a demand generator has been implanted and continuous inhibition is taking place. The spikes are ineffective in producing QRS complexes with ventricular synchronous pacemakers and atrial synchronous pacemakers in certain circumstances but otherwise the failure of pacemaker spikes to produce QRS complexes may be the result of pacemaker-block (including generator-block) or exit-block. Pacemaker-block (including generator-block) may in fact result in the absence of pacemaker spikes on all Leads.

An E.C.G. will readily reveal competitive pacing, from whatever cause; interference from external electromagnetic radiation and entrance-block.

The pacemaker frontal plane vector technique supplements the observations referred to above, particularly as regards any changes in pacemaker output or in the direction of the resultant pacemaker electric dipole. It is, for instance, useful for detecting step changes in output from the premature failure of one cell. Such changes do not produce clinical symptoms and cannot be detected with such certainty from a reduction in the pacemaker spike on an E.C.G., especially in the case of unipolar pacemakers. This detection of a reduction in output is especially useful with any generator which does not show any change in rate with first fall in output from premature failure of cells.

This vector technique readily detects any gross changes in the direction of the resultant pacemaker electric dipole, as for instance, when a bipolar system becomes a unibip system. With endocardial electrode-lead systems certain changes in the direction of the vector are accentuated when the generator is implanted in the patient's left side. In addition gross movements of a catheter are readily detected by the vector technique.

When exit-block occurs the magnitude and direction of the pacemaker frontal plane vector are unchanged.

It is not always possible to distinguish with certainty between a very large reduction in generator output and a broken conducting lead (with intact insulation) because both might give a very small vector. However, in the former case the output, though much smaller will probably be regular, and perhaps be at a new rate; whereas in the latter case, the pulses may be intermittent. It is, of course, possible to have a generator with a low output and intermittent rate.

Some variations in the vectors can be expected in the first few months following first emplacement of a catheter, when electrodes are "settling-in". Later, however, in the majority of cases, the results become more consistent.

There is rarely precise correlation between the direction of the pacemaker frontal plane vector and the line drawn through the implanted pacemaker electrodes, as recorded in a chest X-ray film. This is presumably because, for convenience, an equilateral triangle is used as a basis for synthesising the vector. The different is of little clinical importance though it is of future academic interest.

Examination at a pacemaker clinic should include examination of the pacemaker pulse parameters: pulse shape, width, and rate (or period). Observation of the pacemaker pulse shape on an oscilloscope, via skin electrodes, is certainly desirable. Although in the majority of cases the shape will readily be judged to be normal, a polaroid film record should be retained for later reference and possible scrutiny.

When analysis of a pulse is required because of a suspected change in pulse shape, or a suspected change in impedance in the output circuit, a comparison of the "decay-ratio" with a previous value in the same patient gives a measure of the consistency of the output circuit of the pacemaker, including patient load. It is not more difficult to calculate decay-ratios for bipolar pacemakers, save in exceptional circumstances, as has been suggested by a number of authors. An alternative to calculating decay-ratio is to determine the true electrical time constant of the output circuit of the pacemaker. This is determined from the latter part of the pulse. The calculation is, however, somewhat tedious and is not to be undertaken routinely.

The leading-edge values can always be measured very easily in spike form using a storage oscilloscope, Thus the claim, which has also been made by the authors referred to above, that it is much more difficult to measure the leading edge values when bipolar systems are used, is also a fallacy. (It is, in fact, the leading-edge values which are used to form the pacemaker frontal plane vectors).

In the exceptional circumstance of a broken conductor, with intact insulation, the pulse amplitude on all Leads may be very small indeed and waveform analysis is then impossible.

Pacemaker pulse width can be measured directly and accurately via skin electrodes from an oscilloscope display. In addition, digital equipment is now commercially available for direct display of pulse width, but it should be borne in mind that digital information in isolation from an analogue presentation is generally unsatisfactory.

Digital equipment will give spurious results when the pulse shape changes and the leading-edge rise-time and/or the trailing-edge fall-time increase significantly. Slightly variable results are also obtained with generators such as the Medtronic generators, types 5842 and 5942, which produce a pulse with a rather slow fall-time over the last part of the trailing edge of the pulse. With such pulse shapes digital equipment is at an inherent disadvantage and the advantage

of increased accuracy normally afforded by this form of equipment, is lost.

Experience with Medtronic generators has revealed few changes in pulse width and in no case (except one, in which a generator was replaced in error) has a generator been removed because of changes in pulse width. Nevertheless, other makes of generators do show changes in pulse width (e.g. with premature depletion of a cell) and for this reason it should be measured routinely at clinics.

Generator rate (or period) can also be measured accurately via skin electrodes using either an oscilloscope, or even more accurately, using digital equipment.

When an asynchronous generator has been implanted the rate should remain unchanged. Small changes may, however, occur following implantation, but if pacing is still satisfactory and stable at the new rate there is no need for concern. However, any subsequent changes of several pulses per minute ought to be regarded with caution. For instance, many manufacturers have designed generators so that there is a definite step change in rate of about 5 pulses per minute when there is a fall in output from premature failure of a mercury cell. In these circumstances, (the reduction in output will also be shown by a reduction in the magnitude of the pacemaker frontal plane vector) re-operation should be arranged for the near future. If there is a progressive change in rate, a very high rate, or a very low one, this suggests a generator fault which has to be rectified by re-operation without delay.

In the case of implanted demand generators extra care must be exercised when determining rate since ventricular activity may be delaying emission of pacemaker pulses. However, all manufacturers provide external control of the rate of the implanted generator and successive measurements by this means should give consistent results. If the basic generator rate, or the externally controlled rate, changes by more than a few pulses per minute a generator fault has developed. A basic step change in rate could also be indicative of a premature cell failure.

A ventricular synchronous pacemaker will also exhibit a varying generator rate within lower and upper limits. However for testing purposes external control of rate is possible and this should be consistent. Any generator which is consistently at the lower rate limit irrespective of spontaneous ventricular activity and any which

shows rates outside the specified range should be regarded as being faulty.

A varying generator rate is also to be expected within upper and lower limits in the case of atrial synchronous pacemakers. If the rate is consistently at the lower limit, or, at any time, outside the specified limits, then a lead fault or generator fault has developed.

It should be borne in mind that whilst very often a change in rate is indicative of the premature failure of one or more cells, the converse is not always true. Thus at least one major manufacturer produces generators which do not exhibit a change in generator rate with first fall in output from cell failures.

Small changes in rate are not in themselves hazardous and do not require immediate re-operation provided the changes are not progressive, pacing is continuing and is stable; and provided there has not been a very large reduction in output with the consequent hazard of generator-block and asystole.

Radiological chest examinations need not be routinely carried out at pacemaker clinics. However, whenever there is any doubt about the integrity of the electrode-lead system, or the position of the distal end of the catheter in the case of endocardial pacemakers, an X-ray examination is desirable. Such examination will not necessarily reveal a break in a conducting lead, except perhaps when the insulation has also fractured and there is a sharp discontinuity and separation of the ends of the conducting lead. Sometimes radiological screening may reveal a break under dynamic conditions which is not visible on an X-ray film. Gross displacements of catheters are readily observed on an X-ray film but very minor movements are naturally more difficult to diagnose with certainty. Radiological examination of the mercury cells in-vivo is not widely practised but gives confirmatory evidence of premature cell failures after the generator has been removed.

2. Performance

The techniques referred to above in assessing the pacing function and the pacemaker itself are limited in value if the patient is not receiving the best pacemaker, or at least one of the best pacemakers, which modern science and technology can provide. In this respect, performance after implantation is probably the most important single factor in the choice of pacemaker.

The concept of failed implant lifetimes introduced in this thesis gives a simple visual picture of the basic performance data of generators. It is not particularly meaningful to quote average failed implant lifetimes especially when failures have occurred over such a broad spectrum of time. A better method is to give the percentage of generators which has failed to satisfy given implant lifetimes, though great care must be exercised in determining these percentages.

Generator failures are defined as a change in rate, or output, irrespective of the cause. Generator failures should, however, ideally show only small changes in rate or output. The patient is not therefore placed at unnecessary risk, and assuming a new stable condition has been obtained, re-operation can then take place on a planned basis. Generators which more often than not exhibit large reductions in output, with consequent loss of pacing (generator-block), should not continue to be implanted. Similarly, the use of any generator which, more often than not, exhibits large increases or decreases in rate should also be discontinued.

Many generators and electrode-lead systems are removed, or effectively removed, for reasons other than a technical failure or either. These curtailed implant lifetimes are no reflection on the technical performance of the pacemaker.

Elective replacement of generators should not take place if arrangements have been made for periodic assessment at pacemaker clinics. In the absence of such arrangements the time of elective replacement cannot be made on a rational basis because of the wide spectrum of failed implant lifetimes. Theoretical calculations of the time of failure are of no avail since the majority of failures arise from premature failures of cells. However, if more recent designs of generators show a narrower spectrum of failed implant lifetimes it may be possible to recommend an elective replacement time on a rational basis. It will, nevertheless, always be necessary for a few of the larger and better equipped pacemaker centres to provide basic data from

which such recommendations can be made. Elective replacement will, of course, always be necessary in a small number of cases, in special circumstances, on humanitarian grounds. It may also become desirable, after some arbitrary time, if it becomes known that a particular model of generator has an unacceptable and hazardous failure characteristic.

Displacement of the catheter continues to be a hazard during the first few months following first emplacement. In Glasgow, the catheter is now by choice emplaced via an external jugular vein. Other centres, however, have other preferences and there is evidently a need for more carefully compiled data on displacements to be collected from a number of centres, so that any tentative findings from any one centre can be substantiated, or refuted. It is conceivable, however, that there is a subjective factor to be considered, namely, the relative skills of physicians, or surgeons, which might override the relative merits of the different access routes.

Exit-block on the other hand has been a rare occurrence. It is not understood why some other centres have had a high incidence of exit-block. Long-term threshold increases have been observed when generators have been replaced, but it remains to be seen whether further increases will be observed when third and fourth generators come to be replaced.

More investigations are required to determine absolute values of the complex impedance which a particular patient and configuration of electrodes present to the implanted pacemaker. It appears that changes in impedance sometimes occur and this can result in pacemaker-block. Impedances and thresholds are independent of each other.

Migration, extrusion and pressure necrosis of the skin have all resulted in re-operations on pacemaker patients. However migration and extrusion of generators have become relatively rare occurrences since generators have been placed routinely behind the pectoralis major. Pressure necrosis of the skin in the neck near the entrance to the jugular vein is also less common since there is now a tendency to place the catheter as far below the surface of the skin as is practical. In some cases the catheter is passed under the clavicle but this is not yet routine practice because of the attendant surgical hazards.

Infection and sinuses have also resulted in re-operations. Only constant vigilence to maintain standards will keep the numbers involved in this regard to a minimum.

Most of the deaths which occur are unrelated to the pacemaker and the survival rate of pacemaker patients is probably related to their age group rather than the pacemaker.

Function-times of generators (and electrode-lead systems) can be used as an indicative figure of merit for a given generator implanted in a given centre. It is a figure of merit which takes into account all factors relating to the implant lifetimes (some of which may be peculiar to a given centre) but it should exclude all cases in which the death of the patient is unrelated to the pacemaker, as well as any cases in which generators have been electively replaced. It should be the aim of each centre to produce function-time curves as close as possible to the corresponding failed implant lifetime curves.

The concept of failed implant lifetimes can also be applied to electrode-lead systems though the number of failures is usually much smaller.

In the case of electrode-lead systems, by failure is meant a break in a conducting lead, with or without intact insulation, or a break in the insulation alone. A broken conducting lead, with intact insulation is hazardous in that pacing ceases (pacemaker-block) or at best becomes intermittent, so that the patient requires immediate hospitalisation. Thus any electrode-lead system which exhibits a high incidence of broken conductors, with intact insulation, should no longer be used. In the case of bipolar electrode-lead systems the failure of the insulation on one lead is not hazardous for pacing continues. This may not be the case with unipolar electrode-lead systems if the break in the insulation occurs at some distance from the heart.

Failed implant lifetimes are retrospective and are unchanged with time. Incomplete implant lifetimes are, however, time-dependent. They are particularly useful for assessing the progress which is being made with a later model of generator when none, or few of which, have failed. It is also useful when applied to electrode-lead systems since relatively few failures occur; a knowledge of these incomplete implant lifetimes is also of interest in relation to isotope-powered generators.

In terms of reliability statistics, there has been some further improvements compared with earlier results. For instance, by 30th June, 1972 not one of the asynchronous generators, type 5862C, had failed and only one of the demand generators, type 5842 had failed after being implanted for 17 months; the former type had a maximum incomplete implant lifetime of 29 months, whilst it was 22 months in the latter case. Not one conducting lead in a catheter, type 5818, had failed, but the insulation failed in one case after the catheter had been implanted for 8 months. The maximum incomplete implant lifetime of this type of catheter was 51 months on 30th June, 1972.

It is not possible to compare these current results with results from other centres since published data is not available. However, it is hoped that this thesis will result in better assessment procedures being adopted in other centres and that it will encourage more careful assembly of meaningful data. It will then be possible to make better comparisons between results obtained in different centres. From this point of view, the assessment procedures and the methods of assembling performance data, which are given in this thesis, are more important than the actual data itself.

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Pacemaker Terminology

The terms marked with an asterisk have been introduced by the author. Although "function-time" has been used by other workers, as far as can be ascertained, it has never before been carefully defined.

Pacemaker: This is the "pulse generator" and the "electrode-lead system".

Pulse generator or generator: This is the "electronic circuitry" and "battery" with its encapsulation or container.

Asynchronous (fixed-rate) generator: Electrical pulses are produced at fixed intervals of time. With certain types of generator the amplitude and repetition frequency (rate) of the pulses can be decided within limits on implantation and for this reason the former name is preferred.

Demand (QRS blocking) generator: Electrical pulses are produced at fixed intervals of time but sinus and ectopic foci produce electrical activity which suppresses the electrical output from the generator for a specified time. Suppression continues as long as sinus or ectopic foci produce electrical activity within specified times. The uninhibited generator rate can be decided within limits on implantation.

Ventricular synchronous generator: In this case the generator pulses are not suppressed but are always in synchronism with sinus or ectopic beats if these occur.

Atrial synchronous generator: The generator rate is always in synchronism with the atrial rate. In other words if the atrial rate increases the generator rate increases so that the ventricular paced rate is increased.

*Electrode-lead system: This system may be "endocardial" in which electrodes are placed inside the right ventricle; "myocardial" (or intramural) in which electrodes are sutured into the left ventricle; or "epicardial" in which electrodes are sewn onto the outer surface of the myocardium.

Unipolar (or monopolar) electrode-lead system: Only one electrode is sited at the heart (the "active" electrode) and the other electrode is sited at or near the generator.

Bipolar electrode-lead system: Two electrodes are sited at the heart.

Unipolar pacing catheter (or unipolar catheter): This refers to a single electrode-lead system which includes the insulated conducting lead and the single electrode at its distal end.

Bipolar pacing catheter (or bipolar catheter): This refers to an electrode-lead system which includes two insulated conducting leads one of which is connected to a distal electrode and the other is connected to a proximal electrode.

Unipolar myocardial/intramural/epicardial electrode-lead system: This refers to a single electrode-lead system which includes an insulated conducting lead and distal electrode, together with an indifferent electrode lead system or simply an indifferent electrode plate on the surface of the generator itself.

Bipolar myocardial/intramural/epicardial electrode-lead system: In this sytem two electrodes are sited at the heart which are connected to the generator via two separately insulated conducting leads.

*Unibip pacing system: When the insulation on one conducting lead of a bipolar system fails, a second conducting path appears so that both unipolar and bipolar (unibip) currents stimulate the heart.

Pacemaker spike: This is the pacemaker pulse which appears as a line on an E.C.G. because the duration of the pulse is very small compared with duration of the heart cycle; or if an oscilloscope is being used because a relatively slow time-base has been selected.

*Failed implant lifetime: This is the time between implantation of a generator (or electrode-lead system) and the occurrence of a technical fault.

*Incomplete implant lifetime: This is the current time for which a generator (or electrode-lead system) has been implanted without technical failure, without replacement for any other reason, and without the death of the patient having occurred. (It has a unique value only at a specific point in time).

*Curtailed implant lifetime: This is the time between implantation of a generator (or electrode-lead system) and its removal (or effective removal in the case of electrode-lead systems) for reasons other than a technical failure; or the time between implantation, and the death of the patient, for reasons other than a technical failure. (It should

also be noted that a "generator curtailed implant lifetime" can arise from a technical failure of an electrode-lead system and likewise an "electrode-lead system curtailed implant lifetime" can arise from a technical fault in a generator).

*Elective implant lifetime: This is the time between implantation of a generator and its removal, although there was no technical failure, no loss of pacing and no complications such as infection, migration, extrusion, etc.

Exit-block: The output of the generator has remained normal, the electrode-lead system has remained intact and in a stable position, but the threshold for satisfactory stimulation has increased above the output of the pacemaker.

Entrance-block (demand, QRS blocking generator): This is the failure of ventricular activity to suppress the output from the demand generator.

*Generator-block (formerly battery-block): Loss of pacing (from whatever cause) because of a fall in generator output below the threshold obtaining at a particular time.

*Pacemaker-block: Loss of pacing from whatever cause because of a fall in pacemaker output below the threshold obtaining at a particular time.

*Function-time: This is the percentage of generators (or electrode-lead systems) which has been implanted (or is still implanted) and has functioned satisfactorily (or is still functioning satisfactorily) after various periods of time.

The Relationships between Potential Differences Measured between Different Points on the Surface of the Body

Consider three points, figure 110 on the surface of the body corresponding to the junction of the right arm (RA), left arm (LA) and left leg (LL) with the torso.

Assume that the LA is at the highest positive potential (+++ve)
Assume that the RA is at the next highest potential (++ve) (or -ve)
Assume that the LL is at the least highest potential (+ve) (or --ve)

The potential difference between LA and LL is the work done in moving unit negative charge from LA to LL which is equal to the work done in moving unit negative charge from LA to LL via RA.

$$\text{i.e. Work done}_{(LA-LL)} = \text{Work done}_{(LA-RA)} + \text{Work done}_{(RA\ LL)} \qquad (1)$$

This is a fundamental concept applicable to any three points at different potentials.

It is Einthoven, however, a Dutch physiologist, who is credited with the application of this general law to the human body. First it should be noted that it was he who introduced the concept of "Leads". "Lead I" was introduced as the difference in potential between the right and left hands; "Lead II", the difference in potential between the right hand and left foot, and "Lead III" as the difference in potential between the left hand and left foot. Analytically, this can only be stated as:

$$\text{Lead I} = V_{RA} \sim V_{LA}$$
$$\text{Lead II} = V_{RA} \sim V_{LL}$$
$$\text{Lead III} = V_{LA} \sim V_{LL}$$

However, in applying the above concept to the human body, Einthoven stated that the relationship between the leads was as follows:

$$\text{Lead II} - \text{Lead I} = \text{Lead III}$$

In doing this he defined, perhaps unwittingly, the Leads more explicitly as:

$$\text{Lead I} = V_{LA} - V_{RA}$$
$$\text{Lead II} = V_{LL} - V_{RA}$$
$$\text{Lead III} = V_{LL} - V_{LA}$$

for applying these Lead definitions to formula (1) above gives:

$$-\text{Lead III} = \text{Lead I} - \text{Lead II}$$

$$\text{or} \quad \underline{\text{Lead II} - \text{Lead I} = \text{Lead III}}$$

His implied definition of Leads gave "upwards" or "positive" deflections on Leads I and II, which presumably is what he wanted.

As far as can be ascertained Einthoven first introduced this relationship between Leads in 1907, when giving an inaugural dissertation at Leiden[70].

> "It is self-evident that between the three different mentioned Leads taken from the same person, there must exist a close relationship of such a kind that as soon as two values are known, the third can be calculated.
>
> There must therefore be a difference in potential between Lead II (from the right hand and the left foot) and Lead I (from the right and left hands) equal to the potential from Lead III (from the left hand and the left foot) which gives us the simple relationship:
>
> Lead II - Lead I = Lead III ".

Today, electrodes are placed on the left arm, right arm and left leg. Since the limbs are regarded as equipotential surfaces the potential differences measured correspond with "points" on the torso to which the limbs are attached.

If LA, RA and LL were at <u>steady</u> potentials the above relationship between the Leads would remain for as long as the potentials remained steady. Thus consecutive measurements could be made of I, II and III and the above relationship would hold.

If LA, RA and LL are at potentials which vary with time then for the above relationship to hold measurements I, II and III should be made simultaneously. If, however, the points LA, RA and LL are undergoing cyclic variations and consecutive measurements are made of I, II and III at the same part of the cycle and under identical physiological conditions (e.g. full inspiration, supine, etc.) then again the same relationship will hold. But any deviations from a truly cyclic phenomenon (in magnitude, time, or both) or in physiological conditions will mean that the relationship will not

hold when consecutive measurements are made.

The definitions given above for "Leads" and the relationship between them are not dependent on the points LA, RA and LL forming an equilateral triangle. Further, although specific polarities and relative magnitudes have been given to these points in figure 110 for explanatory purposes, similar arguments apply to other possible polarities and relative magnitudes.

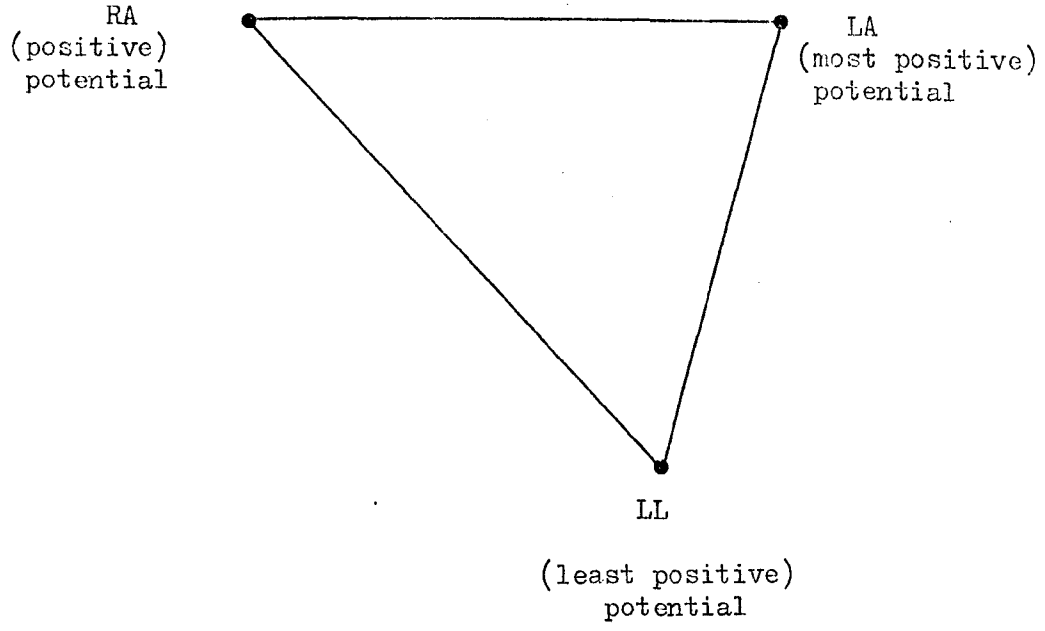
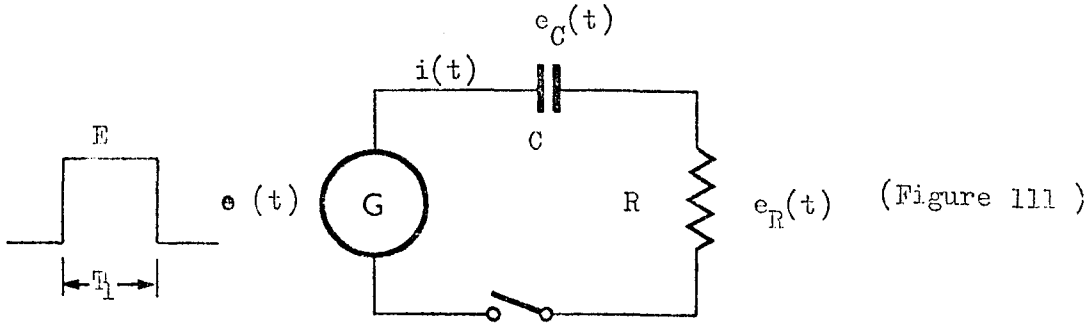


Figure 110. Diagrammatic representation of three points on human torso (junctions of three limbs with torso) at different potentials.

ANALYTICAL TREATMENT OF "SQUARE-WAVE" PULSES *

Part 1. Response of R-C circuit to single "square-wave" pulse



(Figure 111)

In the equivalent circuit (Figure 111) assume that G is the equivalent pulse forming generator. Let C be the effective output capacitance and let R be the effective resistance in the output circuit.

At any instant in the circuit Kirchhoff's voltage law applies. Thus:

$$e(t) = i(t) \cdot R + \frac{q}{C}$$

$$= i(t) \cdot R + \frac{1}{C}\int i\,dt$$

Using the Laplace operator on both sides

$$\mathcal{L}\, e(t) = R\,\mathcal{L}\, i(t) + \frac{1}{C}\,\mathcal{L}\int i\,dt$$

Suppose $e(t) = E$

Then $\mathcal{L}\, e(t) = \mathcal{L}\, E = \frac{E}{p}$

$$\mathcal{L}\, i(t) = i(p)$$

$$\mathcal{L}\int i\,dt = \frac{1}{p}\,\mathcal{L}\, i(t) + \frac{I(0+)}{p}$$

and $$\frac{E}{p} = R\, i(p) + \frac{i(p)}{Cp} + \frac{1}{C\,p} \cdot I(0+)$$

Now I (0 +) is the value of I(t) evaluated infinitesimally close to, and to the right of t = 0; this term represents the initial condition and is used instead of I (0) to avoid confusion which may arise when f(t) has a discontinuity at t = 0. Thus

*(Parts I and II are based on a method outlined in "Pulse Circuits" by Houpis and Lubelfeld).

$$\int_{0+} i(t)dt = \int_{0+} dq = C \int_{0+} dv = \left[CV \right]_{0+}$$

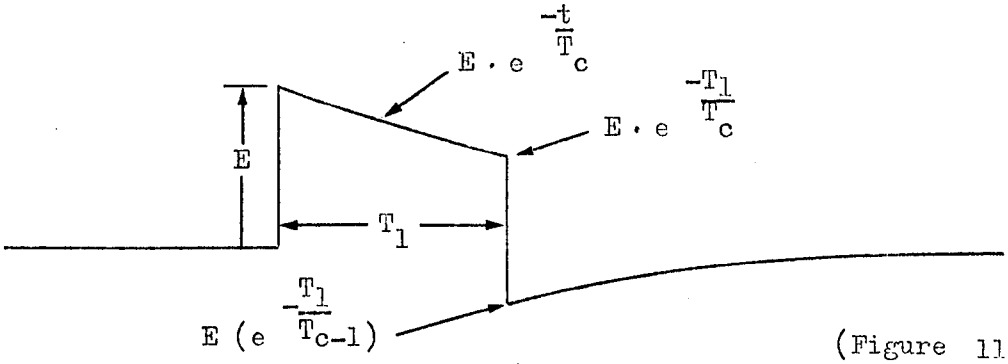
Since V = 0 when t = 0+ then I(0+) = 0

$$\text{then } i(p) = \frac{\frac{E}{R}}{(p + \frac{1}{RC})}$$

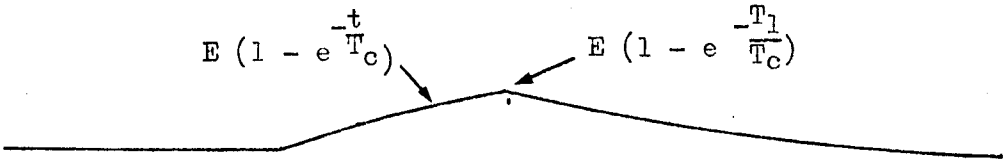
Since $\mathcal{L}^{-1} \left(\frac{A}{(p + \alpha)}\right)$ is $A \cdot e^{-\alpha t}$

$$\text{then } \underline{i(t) = \frac{E}{R} \cdot e^{-\frac{t}{RC}}} \quad \text{for } 0 < t < T_1$$

$$\left.\begin{array}{l} \text{and } \underline{e_R(t) = E \cdot e^{\frac{-t}{T_c}}} \\ \text{and } \underline{e_C(t) = E\,(1 - e^{\frac{-t}{T_c}})} \end{array}\right\} \quad 0 < t < T_1$$



(Figure 112)



At t = T_1

$$\frac{e_R(t) = E \cdot e^{\frac{-T_1}{T_c}}}{e_C(t) = E\,(1 - e^{\frac{-T_1}{T_c}})}$$

Also at $t = T_1$ voltage across R is suddenly reduced by E to

$$(E \cdot e^{\frac{-T1}{Tc}} - E) = E\left(e^{\frac{-T1}{Tc}} - 1\right).$$

The voltage across the condenser cannot change instantaneously since its voltage drop depends on the charge on its plates so that time is required for any changes to occur. Thus at $t = T_1$ the voltage

$$e_c(T_1) = E\left(1 - e^{\frac{-T_1}{Tc}}\right)$$

It is now necessary to develop expressions for the remaining two curves.

Consider I(0+) with respect to the new time ($t = 0$). I(0+) is the value of the function $-\int_{0+} i\,(t)\,dt$ evaluated close to and to the right of $t = 0$.

The negative sign is necessary because the charge on the condenser is now decreasing.

$$\text{i.e.} \quad I(0+) = -\int_{0+} i\,(t)\,dt = -\int_{0+} dq = -\left[Q\right]_{0+} = -C\left[V\right]_{0+}$$

$$= \frac{-C\,E\,e^{\frac{-T1}{Tc}}}{}$$

$$\therefore \frac{I\,(0+)}{p} = \frac{-C\,E\,e^{\frac{-T1}{Tc}}}{p}$$

The Laplacian of Kirchhoff's voltage law when applied to the circuit at the new time $t = 0$ is:

$$\mathcal{L}(-E) = R\,\mathcal{L}\,i(t) + \frac{1}{C}\int i\,dt$$

$$\frac{-E}{p} = R\,i(p) + \frac{i(p)}{Cp} - \frac{E}{p} \cdot e^{\frac{-T1}{Tc}}$$

from which

$$i(p) = \frac{-E\left(1 - e^{\frac{-T1}{Tc}}\right)}{R\,(p + \alpha)}$$

This is of the form: $\frac{A}{(p + \alpha)}$ where $A = \frac{-E\left(1 - e^{\frac{-T1}{Tc}}\right)}{R}$

and $\alpha = \frac{1}{CR}$

Hence $i(t) = \frac{-E}{R}\left(1 - e^{\frac{-T1}{Tc}}\right) \cdot e^{\frac{-t}{RC}}$

and $e_R(t) = -E\left(1 - e^{\frac{-T1}{Tc}}\right) \cdot e^{\frac{-t}{RC}}$

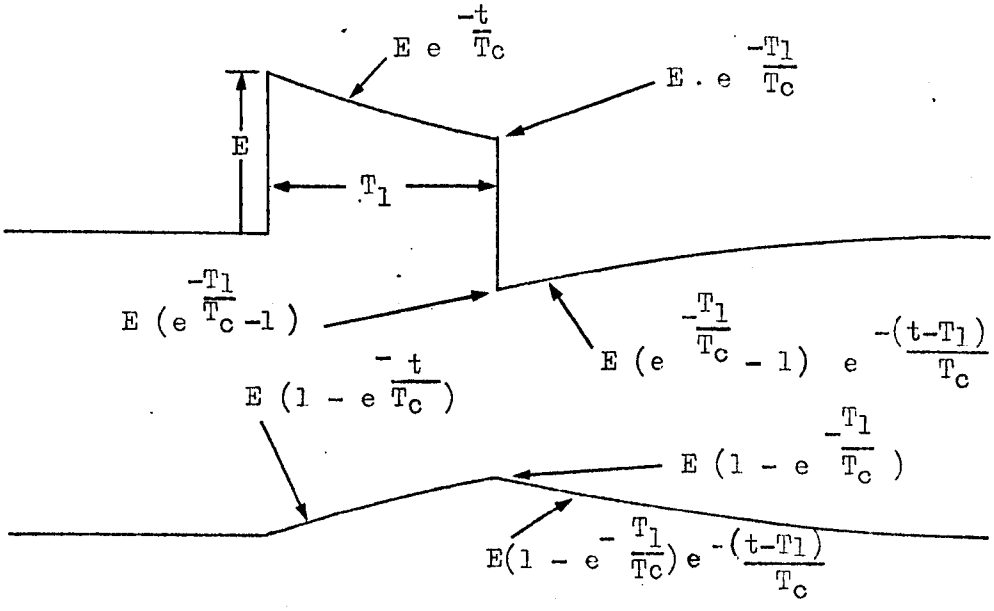
If this equation is referred back to the original zero of time, then:

$$e_R(t) = E\left(e^{\frac{-T1}{Tc}} - 1\right) \cdot e^{\frac{-(t-T_1)}{Tc}} \quad \text{for } t > T_1$$

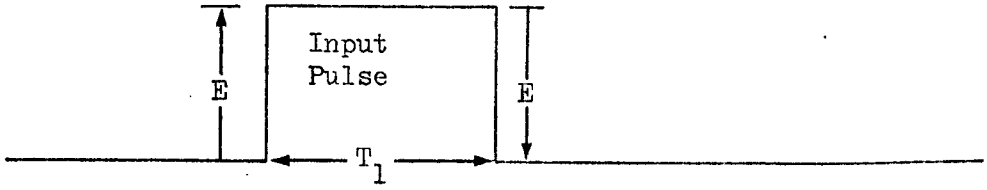
Now $e_i(t) = 0$ for $t > T_1$

$$\therefore e_C(t) = E\left(1 - e^{\frac{-T1}{Tc}}\right) \cdot e^{\frac{-(t-T1)}{Tc}} \quad \text{for } t > T_1$$

It is now possible to give the equations for all parts of this single cycle (Figure 113 below).

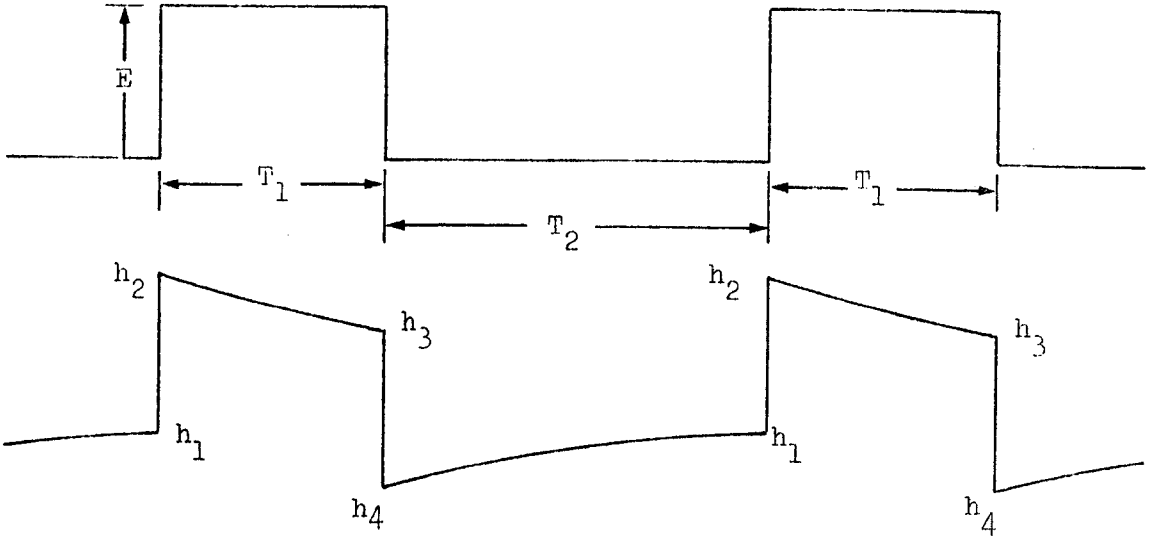


(Figure 113)



Part 2. Response of R-C circuit to recurrent "square-wave" pulses

From a knowledge of the response to a single pulse it is possible to deduce the steady-state response to recurrent pulses.



(Figure 114)

h_1, h_2, h_3 and h_4 are unknown points.

But

$$h_2 = h_1 + E$$

$$h_3 = h_2 \cdot e^{\frac{-T1}{Tc}}$$

$$h_4 = h_3 - E$$

$$h_1 = h_4 \cdot e^{\frac{-(t-T_1)}{Tc}} = h_4 \cdot e^{\frac{-T2}{Tc}}$$

from which:

$$h_1 = E\left[\frac{\left(e^{\frac{-T1}{Tc}} - 1\right)}{\left(1 - e^{\frac{-(T1+T2)}{Tc}}\right)}\right] \cdot e^{\frac{-T2}{Tc}}$$

$$h_2 = \frac{E\ (1 - e^{-\frac{T_2}{T_c}})}{(1 - e^{-\frac{(T_1 + T_2)}{T_c}})}$$

$$h_3 = E\left[\frac{(1 - e^{\frac{-T_2}{T_c}})}{(1 - e^{-\frac{(T_1 + T_2)}{T_c}})}\right] \cdot e^{\frac{-T_1}{T_c}}$$

$$h_4 = E\ \frac{(e^{\frac{-T_1}{T_c}} - 1)}{(1 - e^{-\frac{(T_1 + T_2)}{T_c}})}$$

If Re = 750 ohm and Ce = 5 μF and repetition frequency (rate) = 70 pulses per minute, then:

Period = $T_1 + T_2$ = 0.86

Width = T_1 = 0.0008 sec. (say) $T_2 \simeq 0.86$ sec.

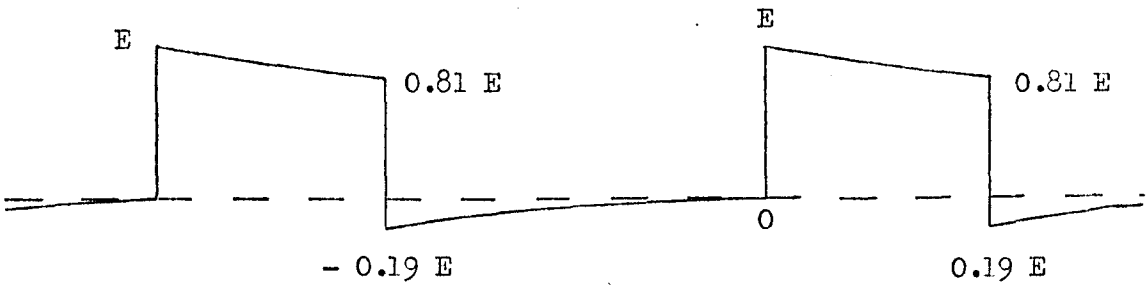
Time-constant, CR = 3.750 millisec.

and h_1 = 0

h_2 = E

h_3 = 0.81E

h_4 = − 0.19E



(Figure 115)

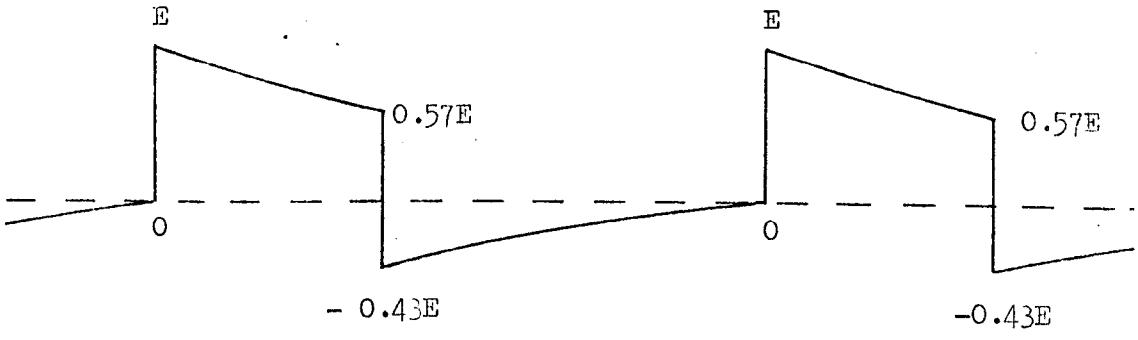
If Re is smaller, say 300 ohm, and if Ce = 5 μF then the "droop" becomes more pronounced and the undershoot becomes bigger.

Thus $h_1 = 0$

$h_2 = E$

$h_3 = 0.57E$

$h_4 = 0.43E$



(Figure 116)

Part 3. Determination of time-constant (Tc), effective capacitance (C), internal resistance (R_{int}) and "decay-ratio" in R-C circuits

Time-constant is defined as the time required for the output to fall to $^1/_{e}$th of its initial value. Thus in general

$$e_R(t) = E \cdot e^{\frac{-t}{Tc}} \qquad (1)$$

and at time $t = T_c$, for given external R.

$$e_R(T_c) = \frac{E}{e^1} = \underline{0.368\ E}$$

Unfortunately the time-constant is long compared with the duration of the pacemaker pulse so that it cannot be measured directly.

If however the time chosen is $^1/_{10}$th of the time-constant, then at this time

$$e_R\left(\frac{T_c}{10}\right) = \frac{E}{e^{1/10}} = \frac{E}{1.105} = \underline{0.905E} \qquad (2)$$

In practice there is no need to measure E absolutely. Oscilloscope sensitivity can be adjusted to make maximum use of screen size (Figures 117(a), (b) and (c)) and the time (t_1) corresponding to a value of 90.5% E is then measured. Thus

$$T_{c1} = 10 \times t_1 = C.\ R = C\ (R_1 + R_{internal})$$

where C is effective capacitance in Farads and $R_{}$ is effective resistance in ohms when t_1 is in seconds. R_1 is the value at the arbitrary external resistance (1000 ohm). In order to determine the values of C and $R_{(internal)}$, the process can be repeated using a different value of external resistance R_2 (500 ohm). Hence,

$$T_{c2} = 10 \times t_2 = C.\ (R_2 + R_{internal})$$

From these two simultaneous equations $R_{int.}$ and C can be determined. For Medtronic asynchronous generator type 5862C (Serial No. IE1703N) the values calculated by this method were

$$R_{int} = \underline{300\ ohm} \quad C = \underline{5.0\ \mu F}$$

with T_{c1} = 6.5 millisec. and T_{c2} = 4.0 millisec.

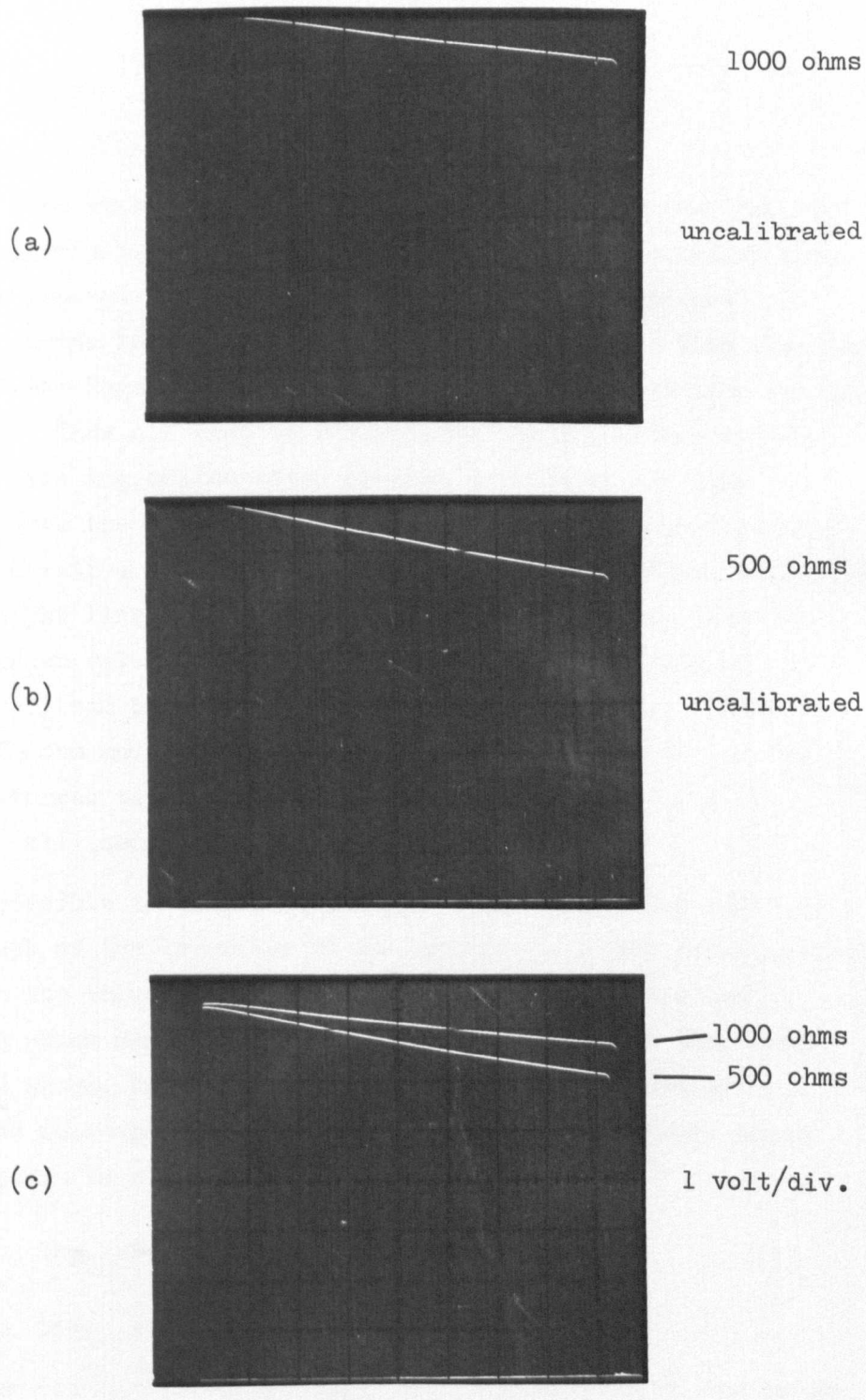


Figure 117. Pulses from Medtronic asynchronous generator, type 5862C, with different external loads, as shown in (a) and (b). In (c), (a) and (b) are compared.

Alternatively, if the logarithm of both sides of equation (1) above are taken then the graph of $\log_{10} e_R(t)$ against t is a straight line whose slope is given by

$$\frac{0.4343}{(R_{int} + R)C} = \frac{\log_{10} E - \log_{10} e_R(t)}{t}$$

Thus if the slow part of a pulse is measured carefully and $\log_{10} e_R(t)$ is plotted against t, (Figure 118) a straight line is obtained whose slope can be determined. In calculating the slope the same calibration factor is applicable to both E and $e_R(t)$ so that when the difference of the logarithms is being obtained the calibration factor cancels out. Thus all that is required is the difference between E and $e_R(t)$ on the log. scales which is then divided by the time (in seconds) to give the slope of the straight line. A second logarithmic plot obtained with a different value of external resistance will give another straight line of different slope. From the two measured slopes and known values of external resistance, the values of R_{int}, C and T_c can be determined for a given generator. Comparable values of 313 ohm and 5.1 μF were obtained by this method for the generator referred to above, with T_{c1} = 6.7 millisec. and T_{c2} = 4.1 millisec.

It is possible to obtain a value of T_c quite quickly and simply from the graph of the logarithm of the amplitude of the pulse against time, though the value is likely to be less accurate than the method above which depends on the slope of the graph. Thus from equation (2) above, during a time corresponding to one-tenth T_c, the amplitude decreases from E to $\frac{E}{1.105}$. On a logarithmic scale this corresponds to a change from

$$\log_{10} E \quad \text{to} \quad (\log_{10} E - \log_{10} 1.05)$$

$$\text{or} \quad \log_{10} E \quad \text{to} \quad (\log_{10} E - 0.043)$$

Thus whatever the actual magnitude of the leading edge of the pulse a reduction of 0.043 on the logarithmic scale corresponds to a time of $(1/10\ T_c)$. Hence from graph

$$T_{c1} = 6.7 \text{ millisec.}$$

$$\text{and } T_{c2} = 4.2 \text{ millisec.}$$

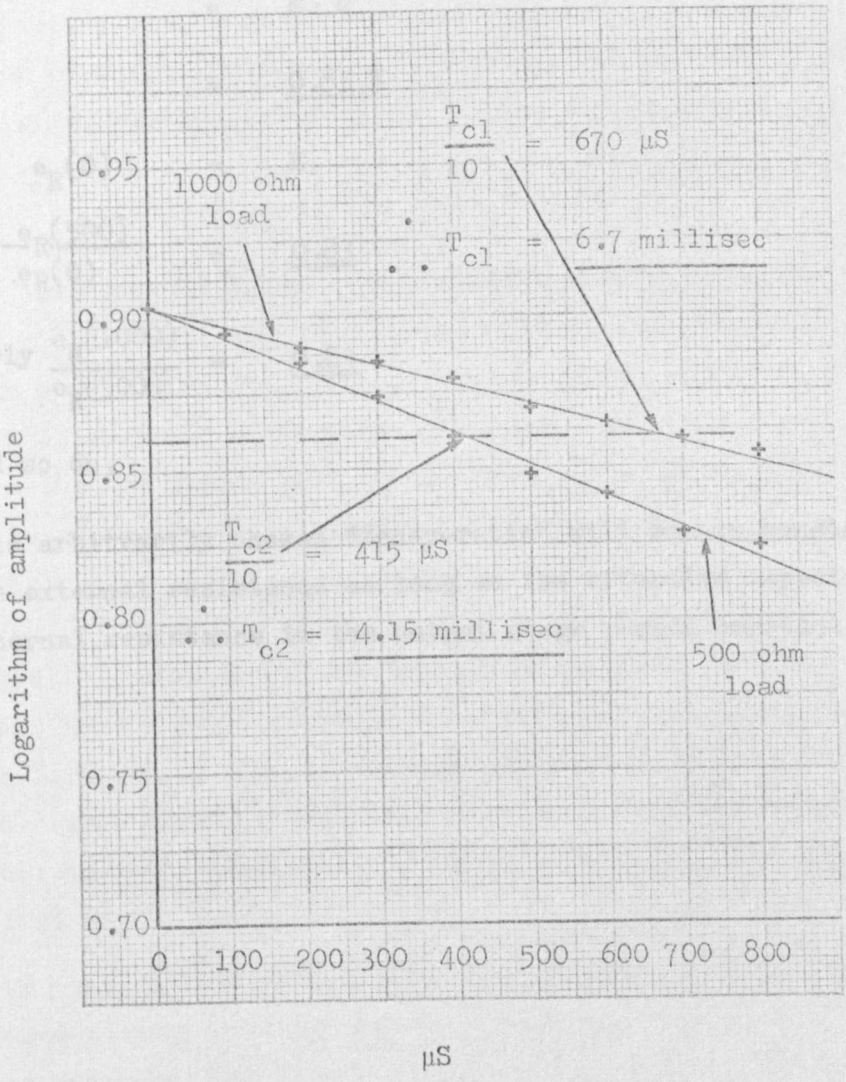


Figure 118. Variations in logarithm of pulse amplitude with time for different external loads. (Medtronic generator, type 5862C, serial no. IE.1703N).

The greater the slope of the slow part of the pulse, the smaller is the time-constant of the output circuit of the pacemaker.

In general $e_R(t) = E \cdot e^{\frac{-t}{Tc}}$

If t is arbitrarily chosen as 500 μsec. (say) and if T_c is 4.0 millisec., then

$$e_R(500) = E \cdot e^{\frac{-500}{4000}}$$

$$= E \cdot e^{-0.125}$$

$$= \underline{0.83\ E}$$

Now $e_R(0) = E$

$$\therefore \frac{e_R(500)}{e_R(0)} = \underline{0.83}$$

Similarly $\frac{e_R(1000)}{e_R(500)} = \underline{0.83}$

and so on.

This arbitrarily chosen "decay-ratio" will remain constant for a given external resistance as long as the effective capacitance and internal resistance in the output stage remain constant.

Part 4. Examination of "square-wave" pulses applied to complex patient loads

When the purely resistive load referred to in the previous Part is replaced by an electrode-lead system and electrically complex patient load, the resulting pulse shape is also complex. Figure 119 shows the pulse shape of a current pulse flowing via a bipolar catheter into a patient load. The semi-logarithmic plot of current pulse amplitude with time (Figure 120) suggests a transient phenomenon over the first part of the pulse but the latter part of the pulse is of an exponential form and can be represented by an equation of the form:

$$i(t) = A \cdot e^{\frac{-t}{Tc1}}$$

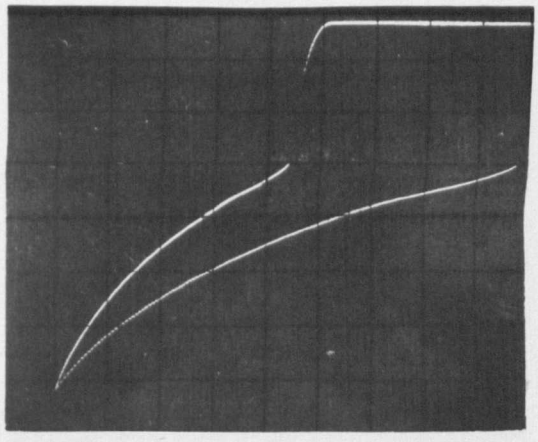
When this current pulse is observed as a voltage pulse (Figure 121) via skin electrodes, the pulse shape is essentially the same. Thus again the semi-logarithmic plot of voltage pulse amplitude with time (Figure 122) suggests a transient phenomenon over the first part of the pulse but the latter part of the pulse is of an exponential form and can be represented by an equation of the form:

$$e(t) = B \cdot e^{\frac{-t}{Tc2}}$$

Figure 123 shows a typical voltage pulse shape obtained via skin electrodes from a patient having a unipolar pacemaker implanted. The semi-logarithmic plot of voltage pulse amplitude with time is shown in figure 124. A transient phenomenon is also evident in these cases, but again an exponential form becomes predominant over the latter part of the pulse.

It is evident that with electrically complex patient loads no single time-constant can be used to define the slow part of the pacemaker pulse but the transient phenomenon appears to disappear about 600 microseconds after the leading edge of the pulse. Further long-term investigations are necessary to learn more about this transient phenomenon, but a constant "decay-ratio" first suggested by Nickel (sub-section 6.5) does at least confirm that those factors which affect it, are unchanged. There is no difficulty in obtaining the ratio from two measurements made directly from the oscilloscope or from a polaroid photograph of the pulse.

Patient 323



Uncalibrated
(mA/div.)

200 and 100 μS/div.

Figure 119. Shape of current pulse flowing into patient via bipolar endocardial electrode-lead system.

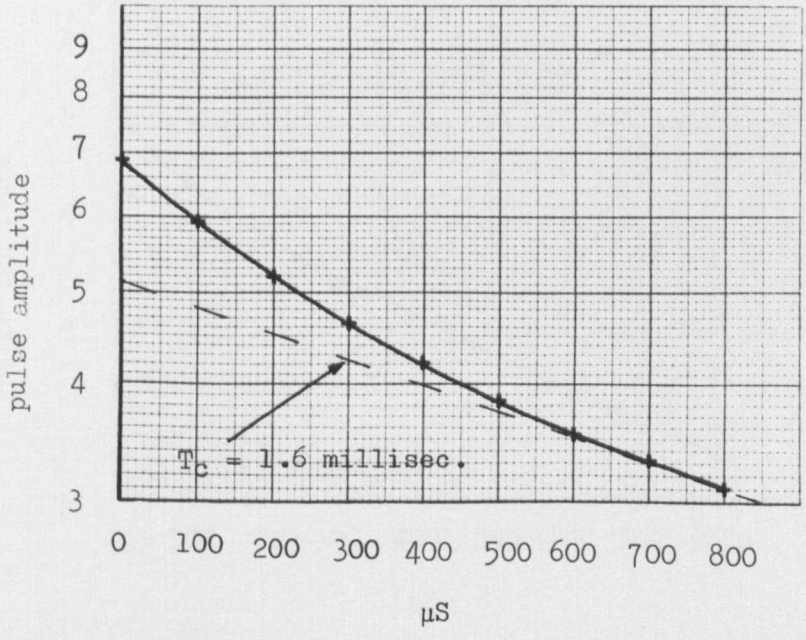
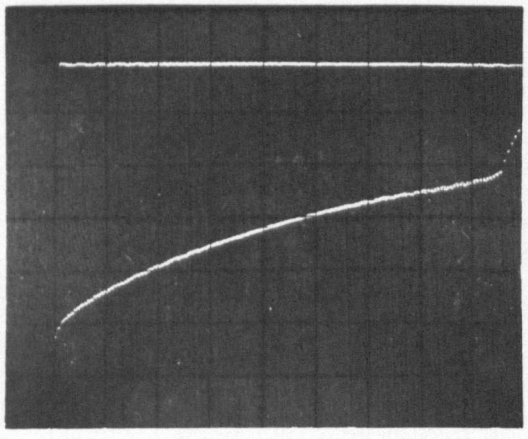


Figure 120. Semilogarithmic plot of current pulse amplitude (figure 119) with time.

Patient 323



Uncalibrated
(mV/div.)

100 μS/div.

Figure 121. Voltage pulse via skin electrodes produced by current pulse in figure 119.

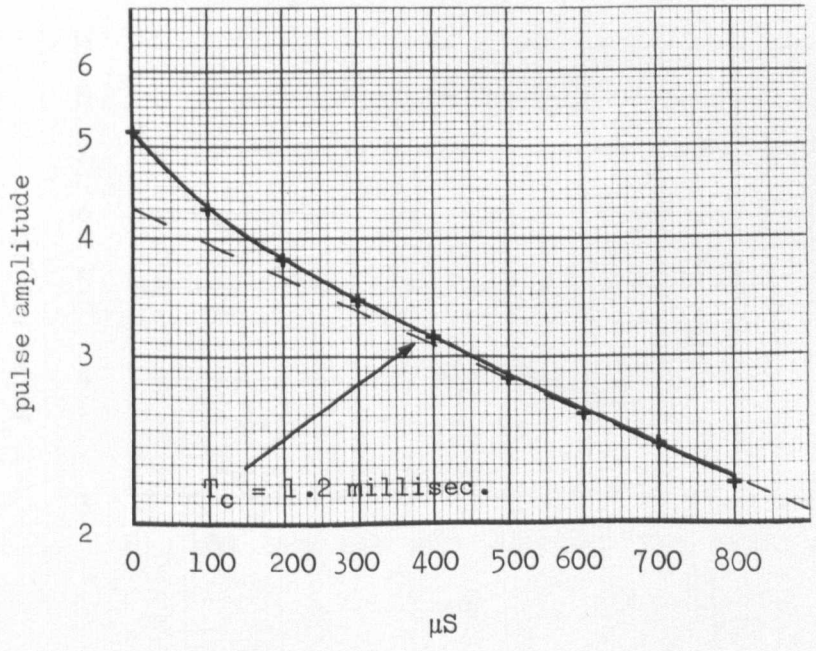


Figure 122. Semilogarithmic plot of voltage pulse amplitude (figure 121) with time.

5 mV/div.

100 μS/div.

Figure 123. Voltage pulse via skin electrodes from current flowing through unipolar myocardial electrode-lead system.

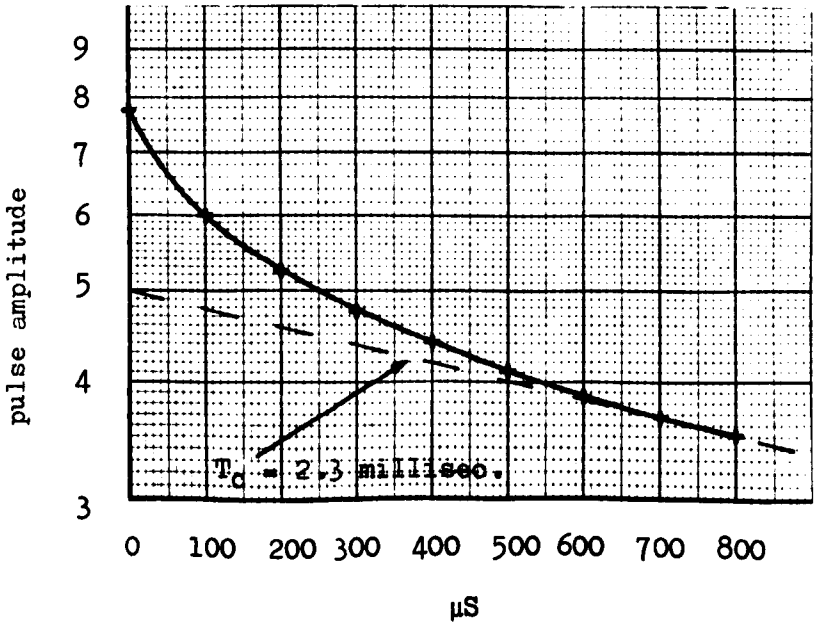


Figure 124. Semilogarithmic plot of voltage pulse amplitude (figure 123) with time.

In those cases in which a change has been observed in the "decay-ratio", the electrical time constant of the pacemaker output circuit should also be checked from a semilogarithmic plot of voltage pulse amplitude with time (e.g. Figures 122 and 124). If the effective capacitance and resistance in the output circuit of the implanted generator are unchanged, then any change in time-constant can be attributed to changes in the remainder of the pacemaker output circuit. The values of the effective capacitance and resistance in the output circuit of the generator itself can be checked immediately after the generator has been removed from the patient.

Causes of Deaths of Pacemaker Patients

(There were 49 deaths amongst 227 pacemaker patients during the period between 1st July 1966 and 30th June 1972).

Patient No.*	Time after last operation	Age at first implant	Cause
135/01	1 day	80	Cardiac failure
255/01	1 day	76	Cardiac failure
127/01	4 days	79	Cerebral damage during operation
178/02	4 days	76	Myocardial infarction/ventricular fibrillation
232/01	5 days	83	Unknown
140/01	6 days	69	Cardiac failure following thoracotomy for myocardial pacemaker
59/01	+2 weeks	73	Cardiac failure or pulmonary embolism
188/01	4 weeks	74	Unknown
176/01	6 weeks	71	Aortic incompetence and congestive cardiac failure
136/02	7 weeks	55	Myocardial infarction
212/01	7 weeks	77	Mural thrombus associated with pacemaker: multiple pulmonary infarcts, with infection
247/01	8 weeks	75	Cardiac failure
93/01	8 weeks	66	Myocardial infarction
237/01	8 weeks	77	Bronchial pneumonia
171/01	11 weeks	72	Found dead in street: catheter had been displaced into right atrium
47/01	18 weeks	50	Awaiting mitral valve operation and myocardial pacemaker.
219/01	18 weeks	71	Diabetic ketoacidosis
215/01	19 weeks	48	After triple valve replacement
55/01	20 weeks	73	Myocarditis and congestive cardiac failure
231/01	20 weeks	75	Myocardial infarction
56/01	22 weeks	68	Myocardial infarction

* The number after the oblique stroke refers to the latest operation to replace the generator, electrode-lead system, or both, after which death occurred.

+ "one week" > 3 days

Patient No.	Time after last operation	Age at first implant	Cause
41/01	27 weeks	60	Cardiac failure, acute bronchitis, carcinoma
152/01	33 weeks	55	Staphylococcal septicemia
104/01	34 weeks	69	Congestive cardiac failure, severe aortic valve disease and pulmonary fibrosis
181/02	35 weeks	56	Cause uncertain but probably congestive cardiac failure
113/02	41 weeks	82	Renal failure
80/01	51 weeks	61	Unknown
72/01	1yr. 8 wks.	82	Cerebral thrombosis and terminal bronchial pneumonia
172/01	1yr. 8 wks.	42	Chronic viral myocarditis
165/01	1yr. 8 wks.	51	Congestive cardiac failure
51/02	1yr.15 wks.	77	Myocardial infarction
32/01	1yr.19 wks.	68	Generator failure
75/01	1yr.24 wks.	81	Myocardial infarction
33/01	1yr.25 wks.	72	Catheter penetrated myocardium: suddenly at home following thoracotomy
111/01	1yr.26 wks.	64	Cerebral and coronary sclerosis and bronchial pneumonia
125/01	1yr.27 wks.	68	Carcinoma of the pancreas
74/01	2yrs.10wks.	78	Cerebral vascular accident
40/03	2yrs.11wks.	62	Myocardial infarction
130/01	2yrs.12wks.	72	Myocardial infarction
60/02	2yrs.17wks.	64	Congestive cardiac failure and bronchial pneumonia
52/02	2yrs.23wks.	67	Myocardial infarction and congestive cardiac failure
97/02	2yrs.32wks.	57	Pulmonary embolism
61/01	2yrs.46wks.	68	Carcinoma of right breast
87/03	3yrs. 6wks.	70	Carcinoma of lung
86/03	3yrs.21wks.	73	Broncho-pneumonia following fractured femoral neck
38/02	3yrs.48wks.	64	Emergency admission for loss of pacing: ventricular fibrillation caused by temporary pacemaker
44/02	4yrs.21wks.	79	Cerebral vascular accident
39/02	4yrs.28wks.	50	Myocardial infarction
46/04	5 yrs.	62	Unknown

THE ASSESSMENT AND PERFORMANCE

OF

IMPLANTED CARDIAC PACEMAKERS

SUMMARY

of

Ph.D. Thesis

by

G. D. GREEN

Glasgow University

June 1973

Between 11th June 1962, when the first cardiac pacemaker was implanted in a Glasgow hospital, and the 31st December 1972, 297 patients in Glasgow hospitals received their first pacemaker. During this period there was an exponential increase in the number of new pacemaker patients. Some form of "follow-up" of these patients became desirable and the increasing number of patients warranted the establishment of regular pacemaker clinics. The purpose of this thesis is to identify the guidelines and establish facts as a basis for good aftercare techniques; and to develop concepts and collect data on performance, which will enable better comparisons to be made between the different makes, and types, of pacemakers.

At a pacemaker clinic, both the pacing function and the pacemaker itself, are checked. These investigations are particularly useful in those cases in which adverse changes have occurred, some of which may be potentially hazardous, and yet no clinical symptoms have appeared. The investigations which are made to assess the pacemaker include: a measurement of the patient's pulse; examination of the patient's E.C.G. and pacemaker frontal plane vector. (This latter technique has been specially developed in Glasgow for pacemaker assessment); and examination of the pacemaker pulse parameters (generator rate or period, width and shape). In addition, in exceptional circumstances, radiological examination is also carried out. Each of these aspects is discussed in detail and numerous results are presented.

The performance of pacemakers, implanted during a six-year period ending 30th June, 1972 is discussed in great detail using carefully defined terms. Both generators and electrode-lead systems are considered. (There is a dearth of such information from manufacturers, but perhaps less understandable, is the paucity of meaningful data in the literature).

It is concluded that measurement of a patient's pulse has limited value as an indicator of satisfactory pacing function, particularly when demand or synchronous pacemakers have been implanted. An abnormal pulse measurement does not necessarily mean that the pacemaker itself is faulty and conversely a normal pulse measurement is not proof that adverse changes have not occurred in the pacemaker. An electrocardiogram is of considerable value for seeing the response to the pacemaker pulse, for revealing pacemaker complications (competing rhythms, entrance-block, pacemaker-block or exit-block) and for showing changes in the pacemaker "spike". The pacemaker frontal plane vector

technique shows changes in pacemaker output, changes in the direction of the resultant electric-dipole (arising from electrical leaks at the generator, or breaks in the insulation) and confirms the occurrence of exit-block. Careful recording of the pacemaker pulse parameters (generator rate or period, width and shape) provides further evidence of the state of the pacemaker itself. Radiological examinations will not necessarily reveal any breaks in the conducting leads themselves and routine radiological examinations at pacemaker clinics are not necessary.

Great care is necessary in assembling performance data. The performance of generators can best be expressed in terms of "failed implant lifetimes" (% failure rates, or % non-failure rates). However, "incomplete implant lifetimes" are more useful for electrode-lead systems, and for more recent designs of implanted generators, since in both cases relatively few failures have probably occurred. Non-technical pacemaker difficulties can be reflected by "curtailed implant lifetimes" and the pacemakers of dec eased patients can be included in this category. The term "function-time" can be used to reflect the overall position with reference to a particular generator or electrode-lead system, but it should exclude those pacemakers "removed" from patients whose deaths are known to have been unrelated to the pacemaker. Similarly, any generators which were electively replaced must be excluded from function-time calculations and be listed separately.

It should be the aim of each pacing centre to produce a "function-time "curve which is as close as possible to the corresponding "non-failed implant lifetime" curve. On the other hand, comparisons of the technical reliabilities of generators used in different hospitals, or pacemaker centres, should be made in terms of "failed implant lifetimes" (% failure rates or % non-failure rates).

In general, there is no case to be made, at present, for elective replacement of generators on any rational basis. It is, however, necessary at arbitrary times on humanitarian grounds; and may likewise become advisable at an arbitrary time, if a particular generator begins to reveal that it has certain hazardous and therefore unacceptable failure characteristics. The attendance at pacemaker clinics of patients who have such generators implanted is of much less value compared with those patients who are fortunate enough to have generators implanted which do not show such characteristics.