

THE REUSE OF PERMANENT CARDIAC PACEMAKERS

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"The harvesting of cadaver organs such as kidneys, livers, hearts, etc. is widely applauded. We now live in the era of mechanical organs. Does not a similar obligation and opportunity apply to precious artificial organs such as long-lived pacemakers?" [Harken, 1984].

= INTRODUCTION =

Over the past 25 years more and more "disposable" items of medical equipment have come into use. When the cost of such items has been significant and the process of reconditioning them has appeared to be safe, consideration has been given to their reuse. Thus in spite of the fact that they may be labelled and officially approved "for single use only" it has now become common practice to wash and sterilize such items of equipment after use and to reuse them, either for the same patient, or for different patients,

Such practices, though they may realize financial savings, raise important ethical and legal issues which have not yet been satisfactorily resolved. Though reuse is common, it is by no means universally practiced and the frequency with which it is carried out varies greatly from one country to another, from hospital to hospital within the same country and even between one health professional and another in the same institution.

The *Conseil d'évaluation des technologies de la santé du Québec* considers that this state of affairs is undesirable. Such practices should, above all, be overt and the question of whether to reuse such equipment or not should be formally decided by the relevant health authority after due consideration. In an attempt to promote this process and to assist the relevant decision-makers, the Conseil is reviewing the question of the reuse of some of these items of equipment. The Conseil does not intend to recommend whether such practices should be undertaken or not. It aims rather to offer to decision-makers a synthesis of the relevant information concerning in particular: the safety of such practices, the ethical and legal issues which they raise, and the extent of any possible financial savings which may result from them. The reuse of cardiac pacemakers is the subject of the present review.

Permanent cardiac pacemakers are electronic devices which are implanted under the patient's skin and attached to the heart with insulated wire leads. They are mostly used for patients whose hearts beat too slowly or would stop beating completely if they were not stimulated electrically and sometimes for patients whose hearts beat too fast. These devices can prolong life and often improve its quality.

Due to changes in the patients cardiac status or to infection, these instruments are sometimes removed

while they still are capable of functioning normally for many years. More often they are removed after death after only a brief period of use. Since 1975, many such instruments have been cleaned, sterilized and reused, a procedure referred to as "refurbishing" [Mond, 1980]. In addition, it can happen that a new pacemaker may become "unsterile" due to damage to, or removal from, its container. Such instruments may be used after resterilization alone.

The object of this review is to consider the safety and the legal and ethical issues which should influence the decision to reuse such instruments and to estimate the potential savings which a policy of reuse might engender.

= PRESENT STATUS OF PACEMAKER REUSE =

Since 1978, there have been reports of the safe installation of reused pacemakers, deriving from Australia, Brazil, Canada, Finland, France, Hungary, Italy, Israel, India, Sweden and the U.S.A. [Mond, 1980; Costa, 1983; Rosengarten, Chiu, 1989; Havia, 1978; Schüller, 1985; Mugica, 1986; Kovacs, 1981; Feruglio, 1979; Amikam, 1979; Boal, 1985; Balachander, 1989; Arén, 1979; Mansour, 1985]. However, the history of pacemaker reuse is longer than this. For example, in 1985, Kruse could report 16 years experience of reuse involving 369 instruments, 61 of which were reused twice, 23 three times, 1 four times and 2 five times [Kruse, 1985].

Official attitudes to the reuse of pacemakers in these countries vary. In most, the practice is officially ignored. In the U.S.A., the Food and Drug Administration determined in 1980 "that pacemaker reuse is an objectionable practice" [FDA, 1980]. The same body has, however, authorised the export of certain models for reuse in Sweden and Switzerland [MDDI, 1988]. In France, since 1984, pacemakers can only be reused under the responsibility of the manufacturer who reconditions the instrument [Mugica, 1991].

The longevity of modern new pacemakers varies from 5 to 15 years. It depends on many factors including the design, the duration and power of each pulse the pacemaker is set to deliver and the proportion of the time its pacing function is called into action. Most models can be expected to function normally for at least 10 years. Newly designed or more expensive pacemakers do not necessarily have a longer functioning life [Song, 1990].

Pacemakers are normally only considered for reuse when there is a reliable clinical record indicating that the instrument has had no malfunction, and has an adequate remaining life often arbitrarily set at a minimum of 5 years. In spite of a 5 year or more life-expectancy, instruments which have been in use

for over 2 years, are usually not reused. Estimates of future functioning battery life are based both on electrical testing and on the expected longevity of the pacemaker model in question as modified by the record of function during the first use. Furthermore, pacemakers are not considered for reuse if they have been exposed to mechanical shock after removal from the patient, or when they have been recovered from a patient who has died suddenly, when pacemaker malfunction cannot be excluded.

Patients are usually considered as potential recipients of used pacemakers when the duration of their expected need may be short lived such as during recovery from certain heart operations, or when, for any cause, their life-expectancy is estimated to be less than that of the instrument to be implanted. Many pacemaker patients tend to be older, to have coexisting diseases and to have a relatively short life-expectancy [Otterstad, 1981; Simon, 1979; Simon, 1982; Hanson, 1984; Alpert, 1982]. Of all patients who had pacemakers implanted in Quebec in 1990, approximately 50% were 75 years of age or older according to the data of the Régie de l'assurance-maladie du Québec.

= SAFETY OF PACEMAKER REUSE =

Even new pacemakers carry the risk of electrical malfunction or of becoming infected. Clearly the same risks pertain to reused pacemakers. The question at issue is whether the risks associated with use of a used pacemaker are any greater.

Malfunction. Unexpected malfunction must be distinguished from predictable battery depletion. Battery life will be shortened in proportion to the first use but there is no reason to anticipate that reuse of a pacemaker which has only functioned for a short while should be associated with a higher failure rate due to malfunction than during first use. Indeed, it has been suggested that electrical failure may be less frequent in a used instrument than in a new one [Tyers, 1985]. The principles of electrical evaluation are presented by Bernstein [Bernstein, 1985] but the exact testing protocol must be defined for each model and type (see Annex 2).

Infection. New cardiac pacemakers not infrequently become infected and have to be removed for this reason. The same can obviously happen in the case of re-used instruments. Reuse could only be the cause of infection in the event of failure of cleaning and sterilization procedures to achieve sterility. Extensive experience has accumulated in many countries since 1978 without reported increase in the risk of infection or malfunction [Mansour, 1985]. For example, in a recent report 23 pacemakers which were removed because of gross infection of the implant site, were sterilized with ethylene oxide and reimplanted without any evidence of subsequent infections [Byrd, 1991]. Protocols for safe reconditioning are described in Annex 2.

Data of nearly 2,000 reused pacemakers collected at the policy conference of the North American Society of Pacing and Electrophysiology in 1984, confirmed the absence of increased mortality and morbidity due to infection, rejection or hepatitis which might be attributable to pacemaker reutilization [Boal, 1985]. There was one instance of premature pulse generator failure, an incidence which was considered to compare favourably with that of new pacemaker use. It was concluded that: "The world experience thus indicates that the reuse of cardiac pulse generators is medically efficacious and safe if they are properly cleansed, sterilized, reliably tested for function and battery life and the use of the particular pulse generator is individualized to a patient's needs as is the current practice with the variety of new pacemakers that are available" [Boal, 1985].

The risk of reuse is therefore the risk that an instrument might be improperly selected due to an inaccurate history of use, or improperly cleaned, tested or sterilized. Thus the maintenance of a precise record of the instrument's shelf life and history of use after installation, must be maintained with meticulous care and instruments cannot be safely reused in the absence of such a record.

Ideally, pacemaker manufacturers should refurbish their own instruments and one presently does so at a charge of \$300¹ each in Canada. Instruments made by other manufacturers must, however, still be refurbished by the institution which contemplates their reuse. Refurbishing of used instruments or resterilization of new instruments which have become unsterile, should then only be undertaken by properly trained professionals using approved protocols (see Annex 1 and 2). The maintaining of high standards of testing and sterilization might best be assured by the creation of an appropriate private or public agency to carry out this function on behalf of all hospitals.

Although there is a considerable accumulated experience of the installation of used pacemakers, this has not been systematically collected and further documentation of this practice would be highly desirable. Thus, creation of a publicly funded registry to record pacemaker reuse for at least the next few years should be considered.

= PROJECTED COST SAVINGS =

Although some authors have expressed skepticism [Kahan, 1985; Myers, 1986], it is evident that pacemaker reuse could generate modest financial savings. In Quebec in 1990, 2,349 pacemakers were

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Telectronics, Thornhill, Ontario.

installed [RAMQ]. Their price is unknown but the average price of 384 pacemakers installed at the Montreal Heart Institute was \$2,720 [Roy, 1991]. Assuming an average price for new instruments of \$2,700, the cost of new pacemakers was approximately \$6.3 million dollars in 1990.

The number of pacemakers which might be recovered and become available for reuse is uncertain. In the U.S.A., in 1986, one study found that 19% of patients died within 6 months of a new pacemaker implant, 38% within one year and 58% within two years [Pringle, 1986]. In Quebec, in 1991, the proportion of new instruments which were of the type referred to as Class 1 or 2 in Annex 2 and which might thus have been reused is confidential to the manufacturers. One author estimates that approximately 45% might be Class 1 or 2, and that approximately 25% of these (or 11% of all pacemakers installed) were potentially available for reuse [Rosengarten, 1991]. If one uses these estimates, approximately 244 instruments per year might be reimplanted. This figure is obviously unstable and might increase or diminish as the market changes. A study to establish this information would be highly desirable.

The costs of refurbishing a pacemaker in hospital have been estimated to be "insignificant" [Mond, 1980] or less than \$50 [Rosengarten, 1989]. The only company which refurbishes pacemakers, charges \$300 for this service. If the latter figure is used, the net saving through reimplanting this number of used instruments, would be of the order of \$660,000 per year in Quebec.

= ETHICAL and LEGAL IMPLICATIONS =

In any system in which some patient may be denied some benefit due to lack of resources, any wastage, is clearly ethically unjustifiable. To throw away pacemakers while they retain the greater part of their functional life is thus an act which should not be done without good reason. Sometimes cited as justification, are the potential legal and ethical problems connected with this practice [McIntosh, 1985]. However, the principal issues raised by the reuse of implantable devices, in particular the issues of safety and consent, can be satisfactorily resolved. The ethical issues are reviewed by Jennings [Jennings, 1985].

Permission to remove an implanted pacemaker after death may or may not be a legal necessity, according to circumstances. In Sweden, the removal of pacemakers from deceased patients is required by the health authorities. The explantation is not regarded as an autopsy and thus cannot be refused by the relatives [Schüller, 1985].

In Quebec, a pacemaker can be removed after death when the user has given specific prior written

permission. Even in the absence of such permission, an instrument may be removed after death with the consent of the next of kin, unless the deceased has previously expressed opposition to removal. (Civil Code of Lower Canada. Articles 21, 22).

Before the removal of an instrument intended for reuse, death must be certified by two physicians who are not involved in the removal or reutilisation process.

The liability of the manufacturer. Normally the sales contract includes a clause indicating that the guarantee does not apply in the event of reuse. In the absence of such a clause, the responsibility of the manufacturer is less clear.

Legal liability of the doctors and the hospital. Negligence is the failure to exercise ordinary care under the circumstance. When the nature of the act is complex, such as the refurbishing of a pacemaker, reasonable prudence will require that it be undertaken by those possessing the special skills or talents. In the case of infection or malfunction of a reused pacemaker, negligence would then turn not only on whether safe protocols had been properly established and were being followed, but on the skills and training of the individuals responsible for each stage of the refurbishing process. As regards the USA the issue is reviewed in depth by Brown whose article should be consulted [Brown, 1985]. The report on the "Reuse of Disposables" published by Health and Welfare, Canada should also be consulted by any institution considering a policy of reutilization [Health and Welfare, Canada, 1985].

Permission to implant. There is no reason to exempt implantation of refurbished devices from the general ethical and legal requirements of informed and voluntary consent. Therefore, all patients must normally be fully informed of the reasons for the installation of a pacemaker, new or reconditioned, of the risks involved and of the make and characteristics of the instrument about to be installed. The fact that an instrument is refurbished, should be part of this information.

Food and Drugs Act. The sale of a cardiac pacemaker by the manufacturer is subject to the new device requirements of the medical devices regulations of the Canadian Federal Food and Drugs Act and the Medical Devices Regulations, in particular Part V [HPB, 1987]. Manufacturers are required to submit evidence of the safety and effectiveness of the device and receive a notice of compliance before selling it. Similarly, in the opinion of the Canadian Department of Health and Welfare, if a pacemaker is refurbished and implanted in a patient, then the pacemaker is distributed (i.e. "sold" as defined in the Food and Drugs Act), and the hospital which implants it would be considered as a manufacturer and would be subject to the Food and Drugs Act and the Medical Devices Regulations. The hospital would have, furthermore, to submit all of the documentation usually required to obtain a notice of compliance (see Annex 3) [Liston, 1991].

As Liston points out, since the hospital does not possess all the documentation usually required to

obtain a notice of compliance, it will be necessary to approach the various pacemaker manufacturers for this documentation. If this is not supplied, "it will be difficult for the hospital to be in compliance with the Medical Devices Regulations" [Liston, 1991].

This question may prove to be a major obstacle to widespread reuse of pacemakers other than the instruments refurbished by Teletronics. This company, the only one which at present refurbishes its instruments, has obtained the relevant notice of compliance for this procedure. How great a problem it will be for other bodies, such as hospitals, to obtain the documentation necessary to refurbish other brands of pacemaker, will not be known for certain until the notice of compliance is applied for. Should the procedure be more difficult than any one hospital will wish to undertake, this would be an additional reason to consider the creation of a centralised refurbishing agency.

= CONCLUSION =

Implantable pacemakers are, at present, being reused to a limited extent in Quebec. The *Conseil d'évaluation des technologies de la santé du Québec*, after review of the evidence, believes that this procedure can be safely carried out, subject to the definition and observance of precise norms.

The potential number of pacemakers which might be available for reuse in Quebec is not known and a study to establish this number would be most desirable. However, there is no convincing justification for not realizing whatever savings are eventually shown to be available and preliminary estimates indicate that reuse of these instruments could generate some modest financial savings to the Health Care System (approximately \$600,000 in 1990).

The refurbishing of pacemakers should optimally be carried out by the manufacturer. Since at present, only one company undertakes this procedure, the refurbishing of other makes must be carried out by the hospitals which intend to reuse, or by an agency created to carry out this function on their behalf.

These instruments should only be refurbished by trained personnel using approved protocols (see Annex I) in approved institutions (see Annex 2). The creation of a registry to monitor this practice for the next few years to ascertain whether reuse of these instruments is being carried out safely in practice, would be most desirable. It should receive public funding.

Institutions which intend to undertake reutilization will have to conform to the requirements of the medical devices regulations of the Canadian Food and Drugs Act and obtain a notice of compliance.

The decision to reuse, and how to reuse these instruments, is a clinical matter for the relevant physicians. However, the motive for reuse is primarily one of cost saving. Accordingly, when refurbishing and reuse are contemplated by a hospital, the decision should be considered and *formally* taken by that institution in consultation with its medical advisers.

The reuse of these instruments is relatively new and, at present, there are seldom formal protocols defining the procedures. At the time an institution decides to authorise reutilization of these instruments, the principles guiding reuse and the precise protocols to be followed, should be defined and officially approved.

As long as the agreed guidelines and protocols are adhered to, an institution which authorizes such instrument reuse should take full responsibility for any jurisprudence which might arise therefrom.

We furnish in Annex 1 and 2, examples of the *types* of guidelines which should be adopted by institutions considering undertaking reutilization of pacemakers. These are not presented as the *only* guidelines to be considered. However, reimplantation of these instruments cannot be guaranteed to be a safe procedure in the absence of guidelines.

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ANNEX 1

SUGGESTED GUIDELINES for the REUSE of PERMANENT PACEMAKERS

The *Conseil d'évaluation des technologies de la santé du Québec* does not intend to make recommendations concerning pacemaker reuse. However, the safety of this practice cannot be evaluated in the absence of clear indications of precisely how they may be used.

The following guidelines are furnished as an example of the issues which should be addressed. When an institution considers approval of this practice, regulations such as the following, should be agreed on.

- 1 - Pacemakers will not be reused in the absence of a reliable instrument history from which the length of the probable future functioning life of the instrument can be predicted.
- 2 - Pacemakers which have been in use for over 2 years, **or** which have an expected future life of less than 5 years, will not be reused except when short-term pacing is envisaged.
- 3 - Pacemakers will not be used where malfunction cannot be excluded as a possible cause of the death of the previous patient in whom the instrument was installed.
- 4 - No implantable pacemaker will be reused which has, or could have been, subjected to mechanical shocks, at the time of removal and subsequently.
- 5 - Permission to remove a pacemaker after death will be obtained at the time the instrument is implanted. No instrument will be removed in the absence of such permission or the permission of the next of kin.
- 6 - The patient (the "recipient") will be informed that the instrument to be installed has been used.
- 7 - Refurbishing, (cleaning, sterilizing and testing) of used pacemakers, or resterilizing of new pacemakers, will only be carried out by trained personnel in accordance with strict and defined protocols such as those

included in Annex 2. The protocols used will be defined and subsequently adhered to in every detail.

- 8 - A record will be kept of each stage of each refurbishment and will be signed by the technicians, microbiologists and cardiologists involved.
- 9 - Only appropriately trained personnel will undertake refurbishing. (No suitable training has yet been defined for the personnel responsible for this process. If refurbishing becomes an accepted practice in Quebec, standards should be defined by organizations such as the Association des cardiologues du Québec and the Association des microbiologistes du Québec. Until that is done, refurbishing should be closely supervised by the responsible cardiologist and microbiologist who should record the protocols used and the educational background and specific experience of each individual involved in the process).

These guidelines are offered as a focus for discussion, to be modified or added to by the institution and the physician in charge wherever necessary. But whether modified or not, a set of such guidelines addressing each of these issues, should always exist and should be observed in any institution which practices reuse of these instruments.

ANNEX 2

PROTOCOLS for REFURBISHING PERMANENT PACEMAKERS

The contents of Annex 2 were initially prepared by Dr. M. Rosengarten, Dr. G. Richards and the Infections Disease Committee of the Montreal General Hospital. They have been revised in the light of comments received from Dr. M. Brazeau, directeur scientifique, Mr. N.G. Lambert, ingénieur-chimiste and Mrs. Louise Jetté, responsable des marqueurs épidémiologiques, Laboratoire de santé publique du Québec and Maureen Best, Head Biosafety Division, Laboratory Centre for Disease Control, Health and Welfare, Canada.

= REFURBISHING CHARACTERISTICS =

Implanted electronic devices have different mechanical characteristics that make them more or less suitable for manufacturer or hospital refurbishing. These characteristics determine the feasibility of cleaning and resterilizing the devices, and include: Header materials, the method with which the header is attached to the pacemaker body or can, the transparency of the header material, and the dead spaces in the header. For purposes of refurbishing, pacemakers can be grouped in three distinct refurbishing classes.

CLASS I: (Silicone rubber header)

- | | | |
|----|-----------------------------------|--|
| 1. | <u>Manufacturer refurbishing:</u> | simple, highly recommended.
available for one make. |
| 2. | <u>Hospital refurbishing:</u> | not recommended. |

These pacemakers are constructed with a metal can and a soft silicone header. Manufacturer refurbishing is simple as the soft silicone rubber header is easy to remove. Hospital refurbishing is not recommended, as only the manufacturer has the techniques to replace the header. Furthermore, this is difficult to clean as the rubber is not clear and can hide blood products.

Class I devices are the easiest to reuse as the manufacturer refurbishes, tests, sterilizes and repacks the device. This refurbishing service is accepted by the Bureau of Medical Devices (Health Protection Branch, Ottawa) and is currently used by many Canadian hospitals. The current charge for this service is \$300.

CLASS 2: (Epoxy resin header bonded to pacemaker can)

1. Manufacturer refurbishing: not available.
2. Hospital refurbishing: simple, recommended.

These devices have a header that is bonded or poured directly onto the pacemaker can. All such devices allow easy removal of the set screws (the set screws secure the leads to the pacemaker) and all have clear epoxy headers that allow visualization of the interior of the header to assure complete cleaning. Standard silicone boots are available from most manufacturers to assure that insulating coatings remain intact and replacement parts such as set screws, O rings and caps are available as standard supplies from the manufacturers. Pacemakers with silicone set screw grommet covers can have the cover removed for removal of the set screw. A new set screw is used at the time of implant and the set screw well sealed with standard silicone pacemaker repair glue. Some of the newer pacemakers with VS-I connectors require no parts to be replaced.

Class 2 devices are simple to clean and reuse in the hospital setting.

CLASS 3: (Combination epoxy and silicone header, glued to pacemaker can)

1. Manufacturer refurbishing: possible, not available.
2. Hospital refurbishing: difficult.

These devices are constructed with an epoxy head which is glued with silicone glue to the pacemaker can. Many of these devices have a silicone sleeve as well as silicone grommets and plugs. The epoxy header is clear but the devices are difficult to refurbish in the hospital as the silicone sleeve is often damaged on recovery of the pacemaker and the header contains dead spaces which can fill with biological fluids which are impossible to remove by cleaning. Hospital reuse requires removal of the set screw grommet and set screw and thorough inspection for biological products after device cleaning. At implant, the set screw is replaced with a new set screw and the set screw well, filled with silicone glue. The lead is sealed with silicone glue if the sleeve is damaged. These devices are potentially manufacturer refurbishable with relative ease as the header can be removed from the device.

HOSPITAL REFURBISHING PROTOCOL

= GENERAL DESCRIPTION =

Stage 1: The removal, decontamination-cleaning of the device for safe handling at the electronic test stage (particularly with reference to HIV and Hepatitis B). A second brief cleaning-decontamination of the device prior to final sterilization.

Stage 2: Ethylene oxide gas sterilization with monitoring.

Stage 3: Aeration, storage, labelling and quarantine until the monitoring procedures are completed.

STAGE I: REMOVAL, DECONTAMINATION-CLEANING, TESTING

Appropriate protective clothing to be worn, particularly gloves. Disposable brushes, disposable syringes and needles and freshly disinfected rinsing trays are used.

Removal: The device is removed from the patient or cadaver, rinsed with tap water and placed in a sealed plastic bag.

a) Decontamination:

Approved agents to disinfect for HIV and HV viruses include proprietary demand-release chlorine dioxide generators, ethylene Oxide gas, and glutaraldehyde. Of the liquid solutions glutaraldehyde is preferred by at least one manufacturer. At this time, 2% activated glutaraldehyde is the preferred method of decontamination.

Chlorine active agent:

Agent: An agent such as Presept Disinfectant Tablets (sodium dichloroisocyanurate, Surgicos Kirkton Campus, Livingston, West Lothian U.K. EH54 7AT).

Dilution: 140ppm (one five gram tablet in 20 litres of water, recommended for plastics).

Temperature: Room.

Soak Time: One hour.

Tray: Surgikos model CX10 (Surgikos, Arlington Texas, U.S.A. 76010).

NOTE: A syringe and needle is used to irrigate the lead connection hole (with the chlorine solution) and to remove air before the device is placed in the solution.

Rinsing: The device is rinsed in the sterilization tray by agitation of the basket with three changes of water at room temperature.

Ethylene Oxide (ETO):

Packaging: The pacemaker is packaged in an approved paper wrapper, and then in double polythene pouches (paper on one side and plastic on the other) in accordance with AORN (Association of Operating Room Nurses, USA) and AAMI (Association for the Advancement of Medical Instrumentation) recommendations. An integrator is included in the first paper wrapper, and the outer wrapper is labelled indicating the expiry date and the load number.

Sterilization: Sterilization in accordance with the manufacturer's specifications and accepted guide lines of (AAMI). ETO sterilization takes place for two hours at 55°C and 60% humidity.

Monitoring is carried on in accordance with AORN specifications for a standard biological test pack. This consists essentially of a biological indicator. Integrators are placed in each package sterilized.

Aeration, Storage Quarantine: Aeration is 30 hours at 55.C in an aerating device or in the sterilizer. Storage placement and environment are as specified for sterile wrap supplies for standard CSR procedures according to the APIC (Association for Practitioners in Infection Control) manual. The device is placed in a protective container. Labelling includes date of processing, process batch reference number, device history.

The device is released for testing upon expiration of aeration phase after negative biological, chemical and process monitor tests.

Glutaraldehyde 2%: (recommended)

Dilution: Undiluted, freshly activated.

Temperature: Room.

Soak Time: In accordance with manufacturers' instructions, but not less than 1 hour.

Tray: Surgikos model CX10 (Surgikos Arlington, Texas, U.S.A. 76010).

NOTE: A syringe and needle is used to irrigate the lead connection hole (with the chlorine solution) to remove air before the device is placed

in the solution.

Rinsing: The device is rinsed in the sterilization tray by agitation of the basket with three changes of water at room temperature.

b) Cleaning:

Agent: Agent such as Haemo-sol E.A. (Haemo-Sol Inc, 7301 York Road, Baltimore, MD, U.S.A. 21204).

Dilution: 1/2 oz per gallon of tap water.

Temperature: 50 ° C.

Soak time: One hour.

Tray: Tray such as Surgikos model CX10 (Surgikos, Arlington Texas, U.S.A. 76010).

NOTE: A syringe and needle is used to irrigate the lead connection holes with the Haemo-sol solution and remove air from the device before it is placed in the solution. This is repeated at 30 minutes to help the removal of material. At this time the device can be scrubbed with a disposable brush and the lead connection hole cleaned with a disposable pipe cleaner.

Rinsing: (Cleaning cycle). The device is rinsed in the sterilization tray by agitation of the basket with three changes of tap water at room temperature (to remove potentially antigenic material). The device is then dried with paper towels and the lead passage blown out with compressed air. The device is wrapped in several layers of paper towel and protected from mechanical shock.

c) Electronic Testing:

These tests are *device specific*. The procedure that follows is *only* for the three Intermedics pacemakers listed below when measured with an Intermedics Compupace pacemaker analyser. It is given only as an example. *Appropriate test procedures must be identified for each make and type of instrument.*

TEST/PACER	UNITS	PRIMA	SUPRIMA II	QUANTUM
pulse amplitude	volts	5,2 or greater	5,4 or greater	5,4 or greater

pulse rate with rate set at	beats/min	>70 NA	>71 72	72±0,1 72
Magnet pulse rate	beats/min	>70	87±3	87±3
Refractory period	msec	325±15	332±15	330±20
sensitivity set at	mv number	2,4±0,3	2,4±0,3 # 4	2,4±0,3 # 4

d) Cleaning-disinfection: (after test procedure)

Agent: 70%-90% ethylene alcohol.

Soak Duration: 10 minutes.

Drying: Air drying.

Tray: Surgikos model CX10 (Surgikos, Arlington, Texas, 76010).

STAGE 2: ETHYLENE OXIDE STERILIZATION

Packaging:

The pacemaker is packaged in an approved paper wrapper, and then in double polythene pouches (paper on one side and plastic on the other) in accordance with AORN and AAMI recommendations. An integrator is included in the first paper wrapper, and the outer wrapper is labelled indicating the expiry date and the load number.

Sterilization:

Sterilization is carried out in accordance with the manufacturer's specifications and accepted guide lines of (AAMI). ETO sterilization takes place for two hours at 55°C and 60% humidity.

Monitoring is carried on in accordance with AORN specifications for a standard biological test pack. This consists essentially of a biological indicator. (Eg. A spore-exposure device designed specifically for ethylene oxide sterilizer testing). Integrators are placed in each package sterilized.

STAGE 3: AERATION, STORAGE QUARANTINE

Aeration lasts 48 hours at 55°C in an aerating device or in the appropriate sterilizer. Storage placement and environment are as specified for sterile wrap supplies for standard CSR procedures (APIC manual). The device is placed in a protective container. Labelling includes date of processing, process batch reference number, and device history. The device is released for implantation upon expiration of aeration phase after negative biological, chemical and process monitor tests.

QUALITY CONTROL

- 1) A "check sheet" should accompany each pacemaker from the time of removal until the time of reimplantation, and then be stored permanently as documentation of the process. The check sheet should contain, as a minimum.
 - a) The pacemaker type, manufacturer, specifications, serial number and other technical data;
 - b) Installation date;
 - c) Removal date. Circumstances of removal;
 - d) A list of the procedures done, and the signature of individual having done each of the procedures (Eg. transport, cleaning, sterilisation, testing, etc.);
 - e) Results of the sterility indicators.
- 2) A general quality control programme should be established which should include random pyrogen testing, random sterility testing, central storage of all "check sheets", and the name of the individual responsible for monitoring all of these items.
- 3) Through the cooperation of bodies such as the Association des cardiologistes du Québec, the Association des microbiologistes du Québec and the Laboratoire de santé publique du Québec, a procedure of inspection and certification of each institution which undertakes refurbishing and resterilization of pacemakers, should be instituted.

ANNEX 3

INFORMATION LETTER

Health Protection Branch