

# Defibrillator design and development—a review

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*This article discusses what is currently known about ventricular fibrillation (VF) and follows the historical development of efforts to deal with it. The modern damped sinusoidal defibrillator is examined in detail and associated hazards and safety standards are considered. Advice is given concerning the choice of defibrillators.*

## Review of basic cardiac electrophysiology

Normal cardiac muscle cells exhibit a property called automaticity, whereby in the absence of any other stimuli they will automatically depolarize at fixed time intervals. Typical values of relevant parameters are given in table 1.

The time between depolarization and the completion of repolarization is referred to as the refractory period, and during this time a cell will not respond to normal stimuli. During the latter part of this interval, however, a cell will respond to a larger than normal stimulus and may then be considered to be only relatively refractory.

As a group of cells depolarize, and thereby stimulate adjacent cells, a depolarization 'wave' is propagated through the tissue but it is prevented from oscillating due to the rating of the refractory period. This same principle assures that the group of cells with the fastest automaticity, normally the sino-atrial (SA) node, becomes the pacemaker for the initiation of systole, and hence the cardiac cycle.

In systole, the SA node (see figures 1 and 2) depolarizes sending a wave across the atria causing them to contract and pump blood into the ventricles. The stimulus travels slowly through the atrio-ventricular (AV) node, over the highly conductive pathways of the Bundle of His and the Purkinje network, and depolarizes the ventricles which contract, causing blood to flow through the arteries. The ventricles finally enter a refractory phase and repolarize.

Table 1. Automaticity of depolarization.

Cell type	Rate per minute [1]
SA node	70-75
AV node	60
Bundle of His	50-55
Purkinje network	40-45
Myocardium	30-35

## Ventricular fibrillation

Many deaths from ischaemic heart disease are sudden and result from ventricular fibrillation (VF) [2]. The capacity for treating the arrhythmia with electric shocks has relieved much of its former reputation as an invariably terminal condition ('Sekunden Hertz Tod' [3]), it still is, however, more threatening to life than other arrhythmias.

A surface recording of ventricular fibrillation displays complete electrical asynchrony (figure 3). This erratic activity

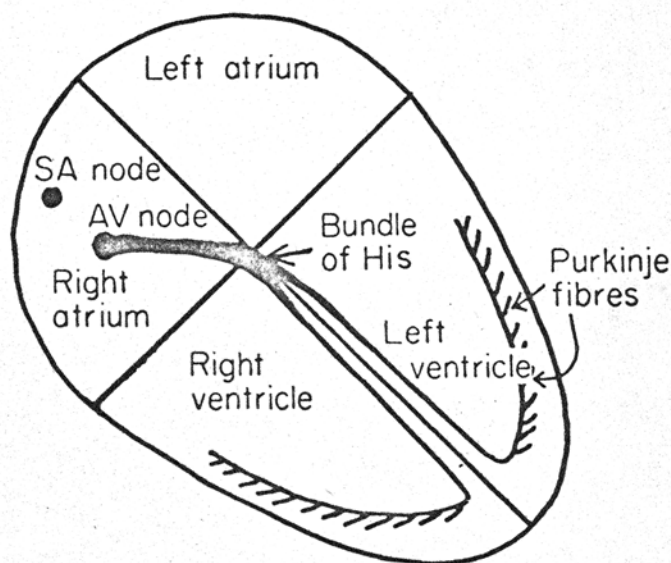


Figure 1. Electrical representation of the human heart.

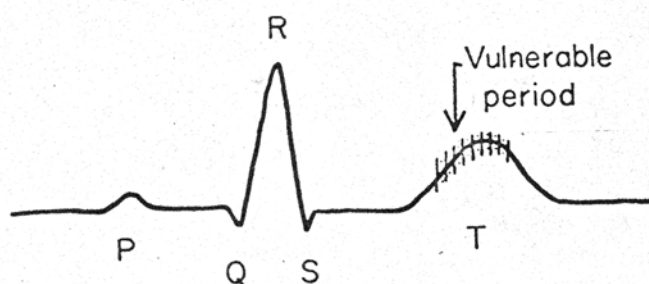


Figure 2. Surface electrocardiogram: 'P' corresponds to atrial depolarization, 'QRS' results from ventricular depolarization, 'T' shows where the ventricles repolarize. Note the vulnerable period for VF (see text).

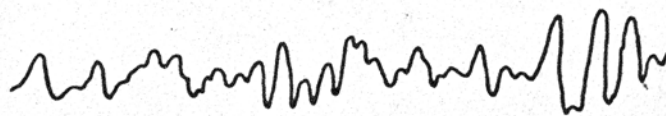


Figure 3. ECG of the heart in ventricular fibrillation (VF).

prevents the muscle cells of the ventricles from producing a coordinated contraction, so their pumping action is disabled as in cardiac standstill.

Wiggers and Wegria, in their classic investigation [4] of ventricular fibrillation, concluded that heart muscle is inherently capable of fibrillation and that it is not necessary to postulate any abnormal properties. They gave a detailed account of the 'vulnerable period' for ventricular fibrillation. Electrical stimuli applied during diastole never produce fibrillation but the ventricles are particularly vulnerable to fibrillation for a period of 20 to 40 ms, commencing approximately 30 ms before the apex of the T-wave (figure 2). This period can actually be much longer in certain clinical circumstances [5].

Fibrillation often arises through ectopic beats falling within the vulnerable period of the preceding beat [3], however, external stimuli (for example electric shock) will have the same effect. It may also arise due to large areas of the ventricles becoming asynchronous for pathological reasons, and Ewy [6] reports that ventricular fibrillation has been observed in patients with acute myocardial infarction in the absence of precipitating ectopics. There has been much discussion concerning what actually happens, electrically speaking, during ventricular fibrillation and Scherf and Schott have produced an excellent historical review [3]. Zipes [5] gives the following account which reflects current theories. The normal orderly spread of excitation in the ventricles is disrupted due to ectopic or premature beats, or to conduction disturbances which can lead to blocks in the presence of increased rates (i.e. ventricular tachycardia). A grossly irregular wavefront results and becomes even more disorganized as it propagates, finding different local areas with variations in conduction velocity and refractory phase. The resulting asynchronous activation rapidly spreads to encompass the entire ventricle.

Lewis established that there is no evidence for a single wavefront in circus movement as is seen in other arrhythmias [7], but whether the final state (ventricular fibrillation) is due to multiple centres of impulse formation being created, or to localized re-entrant circuits, is not clear [3]. There is a strong possibility that both mechanisms can be involved either separately or jointly in different cases [3 and 5]. Microelectrode studies have done little to resolve this question—the size of the cultures involved would lead one to relate the fibrillation to either a single cell or to a cell group [5].

Zipes concludes that, in order to make a fibrillation-proof ventricle, an anti-arrhythmic agent is required which promotes electrical uniformity by lengthening refractoriness without impairing conduction. In the absence of such an agency, however, it is necessary to concentrate on the conversion of ventricular fibrillation into normal sinus rhythm.

In small animals, ventricular fibrillation terminates spontaneously and cannot be sustained [5], but Wiggers and Wegria have observed this phenomenon only once in 400 episodes of ventricular fibrillation in dogs [4]. This seems to indicate that a certain 'critical mass' is necessary to sustain ventricular fibrillation, and work by Zipes and others [5, 6 and 8] adds support to this theory. On this basis there is little hope of being able to achieve spontaneous defibrillation in man in clinical practice. In theory, defibrillation could be accomplished by depolarization of a critical mass of ventricular tissue such that there would be insufficient excitable tissue to sustain the arrhythmia. Clinically this technique is effective irrespective of where the discharge is delivered in the cardiac cycle, but it does not explain why some arrhythmias require greater energies for reversion than others [9]. The critical mass concept may, however, account for the success with intracavitary defibrillation noted by several groups [5, 10 and 11]. De Silva *et al.* [9] and Crampton [8] point out that the discharge used to alleviate an arrhythmia may in fact

create a symptom, such as prolonged block or asystole, which favours the re-emergence of ventricular arrhythmias, including ventricular fibrillation, hence a critical approach to the use of high energies is required [9].

## Historical background to defibrillator development

Ventricular fibrillation had been produced and subsequently terminated in animal experiments by Abildgaard in 1775 [12], but it was not described until the works of Erichsen [13] in 1842 and Hoffa and Ludwig [14] in 1850. McWilliam [15], writing in the *British Medical Journal* (1889), felt that there was evidence to link ventricular fibrillation with sudden death, based on his investigations of cardiac physiology. Ventricular fibrillation was usually fatal if it lasted more than a few tens of seconds (this was the situation until 1960) and as such there was not much impetus to the development of a 'defibrillator'.

By the 1930s the growing electric-power industry, faced with the fact that its workers were at risk from VF due to the danger of high-voltage shocks, had financed a good deal of research into defibrillation [16]. One outcome of this work was the investigation by Hooker *et al.* [17]; they examined various alternating current (a.c.) and capacitor discharge circuits and concluded that the a.c. circuits were the best choice. This is the type of device which was used by Beck and coworkers [18] for the first defibrillation of an exposed human heart in 1947, and by Zoll and coworkers [19] who achieved the first closed-chest defibrillation in a human in 1956. Both of these results were achieved during surgery—speed of application was still a limiting factor to widespread use. The development of closed-chest cardiac massage by Kouwenhoven's group [20] in 1960 extended this period to several minutes, giving the impetus for further development of defibrillators [6].

A group led by Lown, following earlier work by Gurvich and Yuniev [21 and 22] and McKay and Leeds [23] developed the modern defibrillator by discharging the capacitor through an inductor, producing a damped half-sinusoidal waveform. Lown was able to demonstrate the superiority of this type of defibrillator in a comparative study [24]; it was not only more effective, but produced fewer post-defibrillation arrhythmias and less myocardial damage [6]. Lown was involved in the first synchronized a.c. discharge in 1961 [25] and soon adapted the new defibrillator to the same task with marked success, producing a series of papers throughout the 1960s and coining the term 'cardioversion'.

Several other types of defibrillator [10, 26, 27 and 28] have since been produced either commercially or experimentally, but the vast majority of those currently available today are of the half-sinusoidal type (see figure 4), either damped (Lown), or critically damped (Edmark, or Pantridge which is somewhat wider). The reasons for the dominance of this type of unit probably lie in its simple design which gives rise to fewer reliability problems, and in its improved success rates in humans. Comparative studies with other waveforms are lacking, but due to the high success rates that now seem attainable with the half-sinusoidal waveform [8, 9 and 29] there does not seem to be much merit in performing any now, with one exception. Kouwenhoven produced a portable defibrillator in 1962 which yielded a full sinewave output and which was used successfully on a variety of arrhythmias. Jude [6] expresses the opinion that this waveform probably merits more attention due to the lower energy required. Negovsky *et al.* [27] report a comparative study using a similar device which is produced commercially in the Soviet Union. They claim an 80–100% success rate, in-

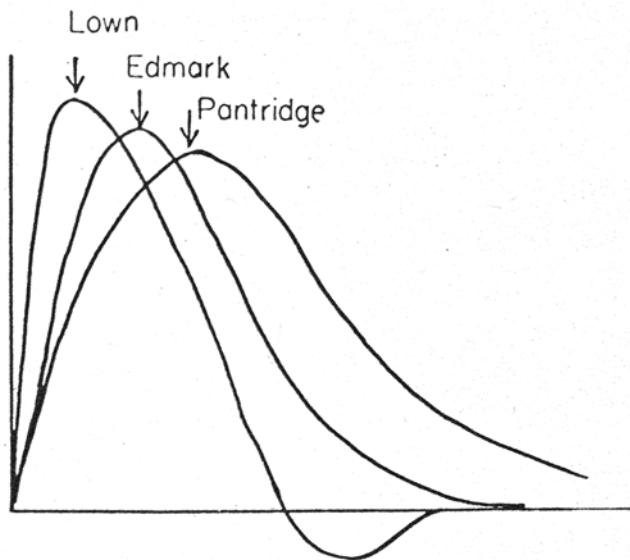


Figure 4. Typical defibrillator output voltage waveforms for capacitor-inductor discharge. The Lown waveform is damped, the Edmark and Pantridge waveforms are critically damped with the Pantridge being slightly broader.

dependent of weight, and note that the device has a maximum delivered output of 200 J. The significant claim is that (referring to earlier work by Gurvich [30]) the defibrillation is achieved by the peak-to-peak current, while myocardial damage is related to the peak current in one direction. If such results can be verified [31], this would be the most significant development in defibrillators since the advent of the Lown waveform. To concur with Tacker [32], most of the developments in defibrillators since 1962 have been of an engineering nature.

## The damped sinusoidal defibrillator

### Basic circuit design and components

The different variations in output waveform available from damped sinusoidal defibrillators are due to the specific values of the storage capacitor and to the pulse-shaping inductor through which it is discharged. In all other respects they share the same basic design requirements. Figure 5 shows a typical design and makes a convenient reference for the discussion which follows.

When the defibrillator is discharged across a patient's chest a circuit is formed, which can be analysed as a damped electrical oscillator consisting of the capacitor ( $C$ ), the inductor ( $L$ ) and a resistance ( $R$ ). The resistance equals the series combination of the effective series resistance of the inductor and the patient's trans-thoracic resistance (TTR) of which more will be said later. This yields an equation of the standard form:

$$L\ddot{q} + R\dot{q} + \frac{1}{C}q = 0$$

with  $L$ ,  $C$  and  $R$  being the above parameters and  $q$  being the charge. This yields a critically damped waveform when:

$$R^2 = 4L/C$$

or an overdamped waveform when:

$$R^2 > 4L/C.$$

There has recently been a trend for various manufacturers to specify the load impedance into which a defibrillator must be

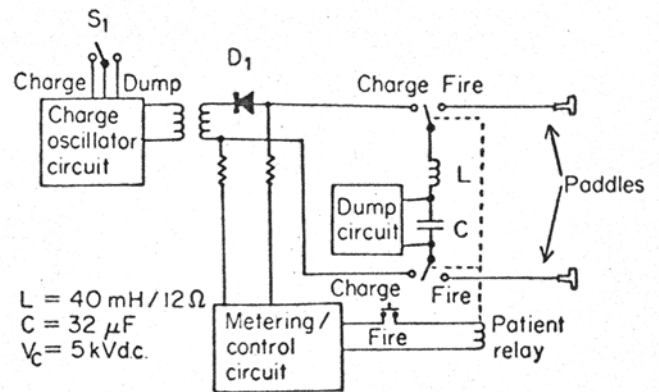


Figure 5. A typical damped sinusoidal defibrillator.

discharged to yield a critically damped waveform, with a range from 45 to 65  $\Omega$  in most models. Such a description of the waveform is to be preferred to using the terms 'Lown', 'Edmark' or 'Pantridge' waveform as the damping of the waveform is dependent upon the TTR which can vary significantly. Component selection begins with the capacitor and typical values are in the range from 30 to 45  $\mu\text{F}$ . Currently available models use a single capacitor, as opposed to the banks of capacitors found in some earlier ones. Suitable capacitors are made of either mylar or polyvinylidene fluoride (K-Film).

The K-Film capacitor [33 and 34] deserves special mention because it has found widespread application in the design of smaller, lightweight defibrillators. These capacitors represent a reduction in size and weight of about 50% relative to mylar capacitors. The lifetime of this type of capacitor will be drastically reduced if it is operated at higher than its rated voltage, or if voltage reversal (for example the undershoot of a Lown waveform) exceeds 10%. This explains why most designs using such capacitors are either critically damped or slightly underdamped with a 50  $\Omega$  load. One further characteristic of importance to the designer is the absorption of the capacitor's stored energy by its own dielectric. This causes the available stored energy to decay [35] at a rate which may exceed that specified by the relevant standards [36 and 37]. This can be overcome within the design of the charge control circuitry. Mylar capacitors are by comparison much more tolerant to abuse, their dielectric absorption is minimal and, while twice the size and weight of the equivalent K-Film capacitors, they cost only half as much.

The series inductor (or output choke) is the next consideration. This is very flexible once the electrical specifications have been worked out for the desired damping. The inductor may either be purchased from a standard selection or can be custom-built to fit a given space within the overall physical design of the defibrillator. The location of the inductor relative to the patient relay in the circuit is arbitrary. As shown in our typical circuit, it has a role in limiting the initial surge of current into the capacitor but this is limited by the remaining circuitry in any event. While this is the most common configuration, the inductor is often connected in the paddle circuit, with one model (Philips BD500 [38]) curiously placing half of the inductance in line with each paddle.

A relay is required to connect the above components to the patient via the paddles. This relay is also the point at which the patient circuit is isolated from the remaining circuitry in most models (as in figure 5). Several models leave the storage capacitor connected to the charging circuitry and achieve



isolation via the output transformer of the charge oscillator. In such cases the patient relay switches the paddles from the monitor circuitry to the capacitor and inductor.

A patient relay should be bounce-free and capable of providing the required contact isolation to withstand one-and-a-half times the peak voltage of the capacitor, as well as the required creepage and clearance distances [37 and 39], in line with the operating voltage. Kilovac high voltage/medical relays [40], such as the model KM-14, have often been employed for this purpose. They are highly reliable and compact vacuum relays and the only problems encountered with them are due to the way in which they have been implemented by a few manufacturers. Their coil terminals are not as robust as their contact terminals and can easily be damaged when attempting to remove heavy wiring or diodes from them. In addition, meeting creepage and clearance distances for the contact terminals can be difficult due to the compact size of the relays, particularly for the models that are not potted. Efforts to meet such requirements have in some cases been rather crude and not up to the engineering standards of the remainder of the units concerned. This emphasizes the need to consult the relay manufacturer in the design stage, if the finished product is to look professional in all respects. Many manufacturers have produced their own open-frame relays either for economy or to provide additional low-voltage contacts in addition to switching the capacitor. This is a simple approach to a failsafe system for switching several functions at once, such as discharge and monitor isolation.

Before any of the above components can serve their intended purpose, it is necessary to charge the storage capacitor to a selected level. In defibrillators delivering 360 J into 50  $\Omega$ , the voltage on a fully charged capacitor is normally in the region of 5 kV. A d.c. to d.c. convertor is the only practical method of achieving this. Two basic types of circuit have been employed here [41 and 42]. The first type consists of an oscillator with step-up transformer and voltage-multiplier chain. The oscillator usually saturates and consists of a pair of power transistors with transformer feedback or driven by a rectangular waveform. The secondary of the transformer is normally connected to a Cockcroft-Walton type multiplier having the capability of an output voltage roughly 10% higher than that actually required for a fully charged capacitor. The multiplier should also be potted in a suitable compound: this reduces problems of corona discharge and dust build-up due to static electricity, while at the same time allowing for a more compact assembly.

The second type of circuit commonly employed is the flyback oscillator. This has several minor theoretical advantages but the fact that the circuit parameters are less critical allows an efficient circuit to be designed around a single power device. Standard flyback transformers with C-I cores (such as television line output transformers) run cooler than ordinary inverter transformers and are therefore more reliable. Their use requires more space than a similar pot-cored transformer due to their larger size and in consideration of clearance distances, but this has not been a major drawback and at least one lightweight compact defibrillator (Physio-Control Lifepak 5 [43 and 44]) incorporates a flyback transformer with a C-I core. Flyback oscillators can be used in conjunction with a voltage multiplier as with the preceding type of inverter or may be utilized as a current pump. The flyback oscillator as a generic type is the most common circuit for new designs but the variations are numerous and there is as yet no 'standard' circuit.

Charging the storage capacitor to a given energy level requires a mechanism for turning the charge circuitry on and off and a means of monitoring the stored energy level. There are several methods of achieving these functions either jointly or

independently. In addition there are several variations of the control circuitry, most of which affect the 'FIRE' controls.

The operator must be able to select a desired energy level and there are two basic methods of allowing for this: manually and automatically. In the manual method a single button is depressed until the desired level has been reached as indicated on a voltmeter.

The automatic method allows the desired level to be selected manually via a control and then the unit automatically charges to the pre-selected level after momentarily activating the 'charge' control. This method uses a comparator circuit which disables the charge circuitry when the voltage or the storage capacitor attains the pre-selected level. The initial selection can either be continuous, as with a rotary control, or from a fixed set of values as provided by a switch or pushbuttons in which case the Association for the Advancement of Medical Instrumentation's (AAMI) standard [36] specifies the choice and number of values to be used. With this method the charge level may be indicated by a meter or, more simply, by a lamp which shows that the selected level has been attained. Metering circuits should not place an effective load of less than 5 M $\Omega$  across the capacitor [36 and 45], but any load will cause some decay in stored energy, so further circuitry must be employed to overcome this problem unless the operator has some quantitative indication of the state of charge of the capacitor.

Such circuitry is also beneficial in other cases (for example, with K-Film capacitors), even when a meter is employed as it helps to ensure that the patient receives the desired energy. One such circuit gives the comparator a degree of hysteresis, so that when the stored energy falls by approximately 5% the charge circuitry is reactivated. Such circuits should be deactivated by firing the defibrillator. Another circuit commonly used, often in conjunction with the above, is the priming circuit.

The Cambridge 73618 defibrillator [35] (no longer manufactured) utilized a circuit whereby it would charge up immediately the energy level was selected, but in order to fire the unit it was first necessary to 'prime' it by pressing a 'prime' button. This then yielded a 'prime period' of approximately 10 s during which the unit could be fired. This design has several features which would not be incorporated into contemporary designs, but the concept of a prime period in a modified form is widely used. In contemporary designs, charging the storage capacitor switches on a monostable which enables the firing controls. After a prime period of 30-90 s the monostable resets and the firing controls are disabled. It is good practice with such a circuit to discharge the capacitor into an internal dummy load when the prime period has expired.

Circuits for discharging the storage capacitor via an internal load (dumping) are used in a variety of other ways. Cardiac Recorders [46] use this method to reduce the stored energy to a lower value by holding in a button. Physio-Control [43] dump the entire stored charge whenever a new energy level is selected. In both cases the user has a clear indication of the state of the charge of the storage capacitor, but some other designs do not reset when lower energy is selected and hence may be charged to 300 J when the operator has reselected a much lower value. Although there will normally be a meter to indicate the higher stored charge, good design must preclude any possibility of confusion due to the near battlefield conditions under which a defibrillator is likely to be used. As with all aspects of medical equipment, dump circuitry should be designed to fail safe. On this basis, the commonest technique is to use a relay to connect the internal load across the storage capacitor. The relay contacts are normally closed to ensure that the capacitor is discharged automatically on switching the unit off. When the charge oscillator is activated, the relay is energized and the load is

disconnected from the capacitor. Firing the defibrillator will simultaneously de-energize the relay causing the internal load to be connected across the capacitor once again. The standards [36 and 37] specify a maximum time constant of 10 s for the discharge circuit, while for most currently available units the figure is roughly 3 s or 10 k $\Omega$  across a 32  $\mu$ F capacitor. This will obviously allow for smaller relay contacts than are required for the patient relay but the same high-voltage considerations must be applied. It is also good practice to use a snubber network across the relay contacts to prolong their useful life.

Where meters are used to indicate defibrillator energy they adopt the convention of displaying the energy which can be delivered into a 50  $\Omega$  load. With the damped sinusoidal defibrillator this is achieved using a voltmeter to measure the voltage on the charged capacitor. Analogue meters have been used successfully for many years and there are only a few problems that arise. Their covers are sometimes not strong enough to withstand the standard impact test [35 and 39]. Since the deliverable energy increases as the square of the voltage, a non-linear scale results and when edgewise panelmeters are used there can be parallax errors (particularly with smaller meters) and this limits the practical accuracy of the meter. In the past few years, several manufacturers have utilized digital displays for this purpose, either via on-screen alphanumerics or directly with digital panel meters. While several firms have used this technology, only one manually charged defibrillator has been produced with such a meter. If the storage capacitor is to be manually charged, the operator must be able to read the meter continuously, which for a digital display requires the charge rate to be slowed considerably. In the one case where this was attempted by a manufacturer, the last digit of the display was always displayed as a zero and the time necessary to charge up to maximum energy was 16 s (two to three times the norm). In automatic-charging systems only the final value matters and so there is no limit upon the charging time nor on the display resolution caused by human factors. With the trend towards annotating recorders [47], it would seem that most new models will follow this latter design since the necessary information is being processed digitally in any event.

### The energy controversy

In the mid 1970s Tacker *et al.* [48] questioned the efficacy of conventional defibrillators (i.e. those storing less than 400 J). On the basis of animal studies and on retrospective studies in man they concluded that such devices would not successfully defibrillate 33% of patients weighing over 50 kg and 50% of those weighing over 80 kg. They argued that defibrillators capable of delivering a 'dose' of up to 6.6 J/kg of a patient's body weight were needed and this was adopted by the American Heart Association (AHA) and included in its standard course for advanced cardiac life support [8]. In response to this, 10 American manufacturers began to offer high-output defibrillators [29].

In 1975 a group led by Pantridge, reporting on a lightweight defibrillator that they had developed, cited clinical results that were in sharp contrast to the high-energy claims [2]. Eighty-two episodes were recorded with 73 defibrillating on the first shock and seven more on the second shock, all at a low energy of 200 J stored (165 J delivered into 50  $\Omega$ ). Many researchers were sceptical of the case for higher energies and several prospective surveys in man were initiated using conventional defibrillators.

The literature documenting the debate over the energy necessary for defibrillation is quite extensive; the high-energy

advocates have lost ground steadily and their arguments seem to have been refuted successfully on all fronts [16 and 49]. This is reflected in revised AHA guidelines, current draft safety standards (both AAMI [36] and the International Electrotechnical Committee [IEC] [37]) and by the American Food and Drug Association's (FDA) classification system wherein devices capable of delivering over 400 J will require pre-market approval. The shortcomings of the high-energy argument have been discussed by Crampton in great detail [8]. The vigour with which the debate has been conducted exposes the need for an active scientific approach to clinical studies in general.

Cherwek [29] points out that although the high-energy requirements had been proposed, they remained clinically untested. Investigations by Patton and Pantridge [50] revealed that successful defibrillation occurred at a mean current of 0.35 A/kg, which is approximately one third of the predicted value based upon animal experiments. They also found no statistical correlation between the current required for defibrillation and a patient's body weight, undermining a basic assumption of the high-energy advocates. Other researchers [8 and 51] have also been critical of this assumption, as there is no fundamental reason to assume that a physical current should behave like a pharmacological agent where the specified 'dose' is dependent upon body weight. The general conclusion now seems to be that the vast majority of viable patients will successfully defibrillate at an energy of approximately 200 J (i.e. half the output of a conventional device), irrespective of body weight [2, 8, 9, 29, 50, 51 and 52].

### Defibrillator paddles

The majority of applications require a defibrillator to have paddles suitable for external application to adults. These are usually shaped like a steam-iron with the handle parallel to the electrode, although several European manufacturers still use the older 'plunger' design with handles perpendicular to the electrodes. In either design the ergonomics of any incorporated controls should be considered for users with widely varying hand sizes [44]. As with all hand-held devices, paddles should be robust and able to withstand being dropped. The point at which the cable enters into the paddles also requires special attention—it can be subject to a good deal of stress [54]. In order to preclude any danger to the operator from the high-voltage discharge, air-clearance distances should be high and creepage distances to any part liable to be touched by the operator should be even higher [37] to compensate for the possibility of conductive gel spreading over the edges of the paddles. External paddles should also be easily cleanable with soap and water to avoid the build-up of dried conductive gel. The choice of metal for the electrodes is not very critical unless the paddles are also used for monitoring purposes, in which case polarization effects [53] must be taken into account. The IEC defibrillator standard furnishes a suitable test for measuring the recovery time of defibrillator/monitors [37].

When defibrillation is required during open-chest surgery it is necessary to apply the shock (5–10 J normally [9]) directly to the heart. Internal paddles are usually slightly concave discs on long handles with insulated grips. The main requirement of such paddles is that they must be capable of being sterilized, which for most hospitals means steam 'autoclaving'. Controls such as fire buttons are not very tolerant of cleaning procedures and so internal paddles often have a very short life. Some manufacturers have used a front-panel control for firing the internal paddles, but many operators prefer to be in full control and insist on at least one switch on the paddles. The author knows of at

least one instance where internal paddles have been modified and fitted with a removable switch for this reason. One obvious consequence of the need for sterilization is that internal paddles must be detachable by the operator. Due to the recent availability of a much wider range of suitable connectors made of insulating materials, most manufacturers are no longer faced with the isolation problems which connectors with conductive bodies can present.

Paediatric usage is another area calling for special attention to the choice of paddles. Adult paddles are often too large for use on a child and will not locate firmly in place, leading to unnecessary burns at the edges. Also, due to the necessarily close proximity of the paddles (see figure 6), little of the current would flow through the chest or heart. The solution for paediatric use is to provide a smaller electrode area, however, the use of such electrodes on adults is not advisable [9], as shall be explained in the next section. The most practical solution to providing suitable external paddles is used by Philips and also by Hewlett-Packard in their latest model [47]. The paddles have user-detachable adult electrodes beneath which are mounted the smaller paediatric electrodes. Many other manufacturers can supply 'paediatric adaptors' that clip on over their standard adult paddles, unfortunately there is seldom any provision for the storage of such adaptors. The third solution is a selection of paddle assemblies of different sizes; this may, however, only be practical in operating theatres. Neonates present special problems for defibrillation, as they do with monitoring systems, and in such cases it has been known [1] for paediatric internal paddles to be used for external defibrillation.

One additional method of defibrillation uses anterior-posterior paddles. The anterior paddle is a conventional external paddle, while the posterior electrode is a large disc which is placed on the patient's back, directly beneath the heart. This method is significantly more efficient [8 and 9], requiring less energy and therefore reducing the risks of complications. This method has not found widespread clinical acceptance, however, due to the difficulty in placing the posterior electrode.

### Transthoracic resistance

It was shown earlier that the resistance which a patient presents to a defibrillator affects the waveform which is produced. This also determines the energy which is delivered to the patient, due to the resistive element of the output choke forming a voltage divider with the resistance of the patient circuit. In order to reduce the practical consequences of this effect, both the IEC and AAMI standards specify that the delivered energy should be within  $\pm 4$  J or  $\pm 15\%$  (whichever is greater) with a 50  $\Omega$  load. The broader range of 25 to 100  $\Omega$  is then given a wider tolerance, with the IEC standard being more stringent at higher energies, while the AAMI standard imposes a closer tolerance on lower delivered energies.

The term 'transthoracic resistance' or TTR is used to describe the above resistance although it is a function of the paddles and interface material (gel, saline pads, etc.) as well as the chest impedance. Several authors [6, 8, 26, 32, 55 and 56] have noted the significance of TTR and the lack of available data concerning defibrillation attempts in human subjects. Tacker [32] points out that this is due to the fact that meticulous data-gathering is difficult in an emergency. The advent of defibrillators with annotating recorders such as the Hewlett-Packard 78660 [47 and 57] should ease this task.

The conventional value of 50  $\Omega$  for TTR is based on 3.5 in diameter (62 cm<sup>2</sup>) paddles [10], but the Russian literature often quotes much lower values—Soviet paddles are generally 10–12 cm in diameter [80–115 cm<sup>2</sup>] [6 and 27]. Kugelberg [26]

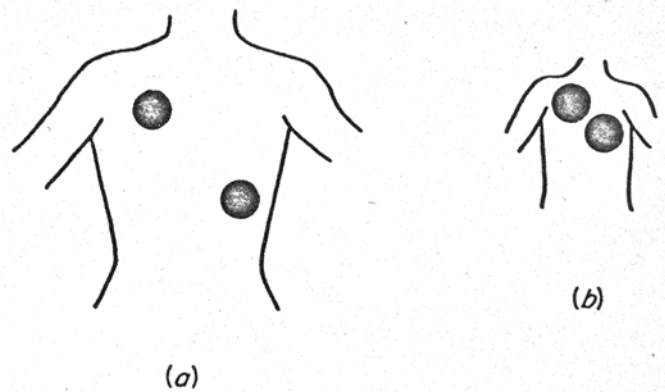


Figure 6. Adult-size defibrillator paddles placed on (a) an adult, and (b) a child.

reported a mean value of 131  $\Omega$  (range 94–210  $\Omega$ ) using 33 cm<sup>2</sup> paddles and noted that this value decreased as paddle size increased. His argument was that paddle size did not matter, it was only the current that counted. Considerations of other factors, such as current density and voltage gradients, have led to the adoption of minimum sizes for defibrillator electrodes (for example, 50 cm<sup>2</sup> for external adult paddles) in both IEC and AAMI standards. More recently Kerber *et al.* [55], in an investigation of various factors contributing to TTR, called for larger paddles noting that a substantial portion of the resistance occurs at the paddle/skin interface (most paddles in Europe and America are 50–60 cm<sup>2</sup> in area).

Ewy [6] again stressed the need for a low impedance interface and, together with Taren [58], has developed a method of classifying the relative suitability of various gels and pastes for use in defibrillation. Unfortunately, the method is not suitable for impregnated pads. Results from this method correlate with earlier observations *in vivo*, but one surprising result was that several products marketed for use in defibrillation appear to be ill-suited to the purpose. One caution is that this method does not take account of the effect of how well the gel works into the skin and leads to the false result that bare metal electrodes would yield the lowest values of TTR. Other workers have tried to devise methods for estimating transthoracic resistance before defibrillation in order that the desired current might be delivered to the patient. In 1950, Vanremmoortere [56] modified an a.c. defibrillator so that the unknown TTR could be measured via a Wheatstone bridge and, more recently, Geddes [10 and 59] has been looking into the possibilities of using medium frequency currents in the range 20 to 60 kHz.

There are many other factors unrelated to the engineering aspects of defibrillators which affect the value of transthoracic resistance [6, 8 and 55]. Kerber *et al.* [55] noted that repeated shocks at the same energy level reduced TTR by 8% (peak current reduced by 4% which is clinically insignificant) in seven out of a group of 10 patients, the remaining three showing no change. They also cite the need for firm pressure (approximately 50 N force) to be applied to the paddles. Crampton [8] suggests that pathological changes in tissue resistivity such as, with ischaemia, may contribute significantly to TTR and that this may relate to the differences observed between coronary and non-coronary patients.

### Monitors and cardioversion

In Britain, as in Europe [60], it is not considered advisable to defibrillate without visual confirmation of the ECG waveform.



This stems from the fact that it is not clinically possible otherwise to distinguish VF from a heart that is contracting weakly or not contracting at all. The Emergency Care Research Institute (ECRI) [61] in the United States has recently expressed similar thoughts and concluded that either an ECG monitor or cardiograph should be used, even in emergencies. This does not imply that defibrillators without monitors should be banned, but that they should only be considered for use in areas where monitoring facilities are already provided.

A monitor suitable for emergency diagnosis of VF does not require a very elaborate specification, in fact some models with small screens and rather limited bandwidths have been found to be clinically acceptable [35 and 44]. In an emergency, the ability to monitor via the paddles is of paramount importance and a limited bandwidth can serve to reduce the effects of artefacts and noise pick-up due to the size of the electrodes. In such cases a standard three-electrode patient cable may also be provided for prolonged monitoring where there is the possibility of the recurrence of the arrhythmia, such as in the post-operative recovery room or during transport. In the latter case the rejection of artefacts requires the same sort of response as that necessary for paddle monitoring.

A defibrillator can be used therapeutically to convert various other arrhythmias and has proven to be both more expedient and less hazardous than chemotherapy [3, 9, 16 and 62]. In such cases there is roughly a 5% possibility of a random discharge falling within the vulnerable period of the ventricles. The discharge can be timed to fall outside of this period by triggering on any part of the cardiac cycle. This technique is called 'cardioversion' or 'synchronized defibrillation'. The R-wave is normally used for synchronization because a strong distinct complex can be provided using optimal lead placement (for example Lead II). In order to maintain a reasonable base-line, and to avoid reducing the R-wave height, the frequency response should be no less than 1 to 20 Hz [49], while 0.5 to 25 Hz would be considered reasonable [44 and 63].

Early synchronizers were adjustable, rather like the trigger level controls on oscilloscopes, but such controls are rarely seen now due to the development of better R-wave detection circuitry. They also required the R-wave to be of positive polarity or that a manual switch be provided to reverse polarity. The most common form of detector now in use is a filter/rectifier combination, which will detect R-waves of either polarity and time the discharge accordingly. This overcomes a common source of operator error. Automatic detection circuits, however, are not infallible and it is still necessary for the operator to check that the device is synchronizing properly. With ventricular tachycardia, for instance, it may be difficult to differentiate between a broad QRS and a prominent T-wave. Synchronization on both would afford a 50% chance of hitting the vulnerable period, and in such cases the only recourse is to fire the defibrillator in the emergency mode where this risk is considerably less [9].

It is now quite common for defibrillators to revert to the emergency mode on turn-on, as the mode select switch has in the past been a common source of reported defibrillator failures due to operator error [49]. Owing to the situation prevailing during cardioversion and emergency defibrillation this would appear to be the best approach and personal experience bears this out. Related to this is the choice as to which mode the defibrillator should be in immediately following a synchronized discharge. Here the issue is open to firm arguments for both possibilities and the only viable solution is that adopted in the current draft of the IEC defibrillator standard [37]. This stipulates that whenever a defibrillator is in the synchronized mode it shall be clearly indicated to the user via an indicator lamp or audible tone. The marking of the mode switch position will not suffice, as

it does not stand out, and a 'sync marker' on the ECG is likewise inadequate as it will not appear in the absence of a QRS complex as in VF.

Sync markers are used to indicate where the defibrillator discharge will occur during the cardiac cycle. A marker is added to the ECG trace as a pulse, as a high-frequency burst, or by flashing, blanking or modulating the intensity of a portion of the trace. On some units the only indication is that the QRS or sync indicator lamps will flash and while it is easy to detect T-wave synchronization at normal sinus rhythm this may not be the case with tachycardias. Lown *et al.* [64] provided a simple method of testing the performance of such systems, this was when they reported on their initial clinical experiences with cardioversion using a d.c. defibrillator in 1964. A modified version of this follows. One wire (LA or RA) of the monitoring cable should be wrapped once around one of the paddle leads and the cable then connected to an ECG simulator. The defibrillator should then be charged up to approximately 200 J (more or less as required) and the synchronized mode selected. The defibrillator should then be discharged into a dummy load and this should cause a small transient to be coupled to the ECG trace showing where the discharge occurred, which should be on the R-wave.

One final aspect of defibrillators for cardioversion is the selection of energy levels. Some arrhythmias will require energy levels similar to those used for the treatment of ventricular fibrillation, while others will revert at energies as low as 5 J. There is, therefore, a need to be able to select a range of low energies accurately and so models with minimal meter indications (or selection buttons) of 40 and 80 J must be considered inadequate.

## Hazards

In the standby mode, or while monitoring the patient, a defibrillator/monitor is subject to the same hazards that an ECG monitor might present [39 and 65]. When actually being used as a defibrillator, however, several aspects of the design and use of the equipment are potentially hazardous. All of these hazards can be overcome through good design by the manufacturer and good practice by the user.

When charging the defibrillator there are elevated a.c. voltages present and, obviously, the high d.c. voltage which is accumulating in the storage capacitor. These can lead to greatly increased leakage currents through stray capacitance and across dielectrics. The metal casing of the storage capacitor will also contribute a high leakage current unless it is adequately insulated.

Discharging a defibrillator generates a pulse of several thousand volts and up to 100 A, hence it would be impossible not to generate a few transients within the unit itself at the same time. It would seem highly likely that such transients may account for the high incidence of component failures in defibrillators [35, 44 and 61] when compared with other types of equipment of equivalent technical complexity. Transients may also interfere with the operation of the defibrillator's circuitry, especially solid-state latches and flip-flops, and in one model could even cause the unit to switch-off its power. The author has found that charging a defibrillator to maximum energy and then discharging it into a 25  $\Omega$  load provides a reasonable test for potential operational problems with transients.

Subclause 17 of the IEC defibrillator standard [37 and 45] specifies a maximum capacitance of 2 nF between the defibrillator electrodes and anything likely to be touched by the operator, including the patient cable and signal connections

such as ECG output sockets. In addition, the requirement is established that any energies transmitted via such contact shall be limited to a charge of  $100\text{ }\mu\text{C}$ , which is unpleasant but not dangerous. The same requirement limits the possibility of shocks from other equipment connected to the defibrillator, due to voltage surges on signal lines.

The use of conductive interfaces, such as gels, between the paddles and the patient can cause serious problems unless care is taken at all times. During cardiac massage, gel may get onto the user's hands and then be spread over the paddle handles, leaving the user at risk; or it can smear across the patient's chest causing most of the delivered energy to arc across the surface instead of depolarizing the heart. Paddles should never be returned to their storage position (even temporarily) until they have been cleaned and any residual gel has been removed. Incidents have occurred where the build-up of dried gel in the defibrillator case has led to operators being shocked inadvertently.

One important consideration is that the defibrillator should not damage the myocardium—this would only weaken it further. Ewy [6] gives a good account of work by himself and others on this topic, but points out that there is no agreed indication of myocardial damage and each group of researchers (see Negovsky *et al.* [27] and De Silva *et al.* [9]) provide their own definition. It is generally agreed, however, that adverse effects tend to increase (perhaps due to stimulation of the autonomic nervous system [32 and 66]) with increasing energy or current, and a maximum permitted peak output voltage of 5 kV into  $100\text{ }\Omega$  has also been established [37].

A defibrillator discharge is quite capable of damaging other equipment, such as patient monitoring systems, and it has not been possible to avoid this in the past without detaching all other patient connections prior to defibrillation. The IEC has developed a rather severe test, compliance with which means that a piece of equipment is proof against defibrillators. Such 'defibrillation-protected' equipment may be left connected to the patient at all times. Details of the test may be found in the IEC draft defibrillator-monitor standard [37 and 45] where it has been applied to the monitoring sections of defibrillators.

## Standards

The advent of an international standard for the safety of electro-medical equipment (IEC 601-1 [67]) and its adoption as a British standard (BS5724: Part I [39]) has served to raise the general quality of the design and construction of equipment marketed in the UK. BS5724: Part I is, however, only a general standard and does not cover the specific dangers associated with defibrillators as mentioned in the preceding section.

There are presently two major standards which address the particular safety requirements of defibrillator/monitors and many test organizations have additional provisions which must be complied with. The TUV in Germany, for instance, places specific requirements on the function of control buttons on the paddles.

The IEC has produced a draft safety standard for defibrillator/monitors [37 and 45], which is meant to be used in conjunction with the general standard. This is an international standard and is expected to be adopted by the UK after the final version is published by the IEC. The current draft is being used as a provisional standard for the evaluation of defibrillators in Sheffield on behalf of the DHSS [44].

A second standard has been produced by AAMI and has been proposed for adoption as the American national standard. This is essentially a stand-alone document, only referring elsewhere for leakage current requirements.

A major distinction between the two standards is that AAMI's standard has formulated performance requirements, which are directly related to defibrillators used in recent clinical trials with very high success rates. Since these trials demonstrated [8 and 29] that diagnosis, technique etc. were the key factors contributing to a high success rate it is hardly justifiable to draw waveform specifications from such results. In addition, it is likely that the low success rates previously evident would be based on a similar range of waveforms. In reading the 'Rationale' of the AAMI standard one is impressed with the fact that the pressure of the FDA's medical devices classification system may be to blame.

The scope of the two standards is otherwise similar, with the AAMI standard generally tending to be more restrictive to design, although not unreasonably so, and the IEC standard more rigorous in its testing. Recently proposed amendments to the IEC standard [45] have further enhanced its coverage and of the two standards it should best retain its relevance as the design of defibrillator/monitors changes.

## Choice of units

Published evaluations of defibrillators [44, 49 and 60] give detailed advice on points to consider when purchasing a defibrillator, and the following topics are worthy of mention here.

### Energy selection

The range of energy levels which can be accurately selected by the user should provide sufficient choice compatible with the defibrillator's intended use. In this respect most units are fully suited to emergency use on adult patients but use for cardioversion, internal defibrillation or use with small children and neonates is limited in some cases.

### Cardioversion facilities

Energies from 5 to 400 J may be necessary, so a good spread of values is mandatory. A lead selector switch and variable gain control are useful in adjusting for correct triggering. The QRS detector should not respond to pacemaker pulses and should display a marker on the monitor trace to show where the discharge will occur. It should be clearly indicated whenever the sync mode has been selected. Although good practice calls for the synchronizing signal to be derived from the patient lead, the ability to derive it from the paddles is still quite common and as such should not unduly influence selection of a defibrillator.

### Paddles

If special paddles or adaptors are to be used will they store away or will they have to be removed after each application? Internal paddles must be removed for sterilization but paediatric paddles can be troublesome and are worth looking into ahead of time.

### Monitors

The trace should be easily viewable from a distance at which the paddles can be used comfortably. Good contrast will to some extent compensate for small size, so size alone is not the key. Display bandwidth should always be noted; this was discussed earlier. Several models feature removable monitors. Some of these are standard bedside monitors and can be exchanged if they go faulty, others because of their size and weight can be transported with a patient. In all such cases the situation might arise when the defibrillator will be without a monitor and this may therefore render the unit unsuitable for use. Such units are seldom recommended by our department for this reason.



### Recorders

Defibrillator/monitors generally offer a built-in recorder, which may be anything from a single-lead 1–20 Hz unit to a full 12-lead system with diagnostic bandwidth. Some also switch on to record the event immediately the defibrillator is activated. A recent development is the printing of additional data along the edge of the recording, as with the annotating recorder in the Hewlett-Packard 78660A [47].

A recorder is not a necessary feature in a defibrillator but may be the simplest option where documentation of defibrillation events is required under local rules, particularly in the USA. Since the ECG trace can be derived from the paddles, most recorders have only a monitoring bandwidth in the interest of providing a reasonable recording. Stein *et al.* [63] have expressed the view that this may be a potential source of falsely abnormal recordings. They point out that when the recordings are placed in a patient's notes there is no indication that they were not taken on a recorder with a diagnostic bandwidth and hence S-T segment depression (see figure 7) may be attributed to the patient rather than the recorder. The use of the so-called 'diagnostic' recorders which some units offer is also limited. ECRI [49] have pointed out typical shortcomings as lack of lead markers, calibrated gain settings and an expanded trace (50 mm/s) facility. It is better to purchase a separate ECG recorder if diagnostic tracings are required since the additional cost may only amount to a few hundred pounds [68].

### Conditions of use

The key to choosing the right defibrillator lies in defining its intended area of application. Where the unit is only required to be present during clinical investigations (for example in drug trials), one of the less glamorous mains-only models may be both more economical and more reliable in that a lack of batteries eliminates all of their associated problems. All other applications, except perhaps in ambulances, should have battery and mains-power capabilities. This eliminates having to find an unused socket in high-technology areas, like operating theatres or intensive care units, while at the same time offering a back-up system for batteries which have been inadvertently exhausted. Units which will be used on a trolley offer very few problems given that they will fit onto it in a usable position. Defibrillators that will generally need to be carried to the scene of the emergency, because their area of application precludes the use of a trolley (upstairs, over thresholds, across courtyards etc.), have two major requirements. First, they should be light enough for one person to carry and at the same time the carrying handle(s) should be located so that this can be accomplished without undue discomfort: some units will hang straight while others can leave one with bruised shins. The second, and equally important point, is that there must be provision for ensuring that any necessary accessories are transported with the unit if it is to be of any use at the scene of the emergency. This can take the form of a storage compartment built into the defibrillator casing or some form of pouch attached to the unit. In many cases neither option is offered by the manufacturer.

### The future

The trend towards smaller, lightweight defibrillators seems to have been abandoned for the moment by most of the major manufacturers; there should be, however, considerable size and weight reductions evident in models designed over the next five years. This is mainly due to recent developments in display technology, such as the flat-screen oscilloscope [69] and the television watch [70], which should make defibrillators weighing less than 20 lb commonplace. While Pantridge and co-

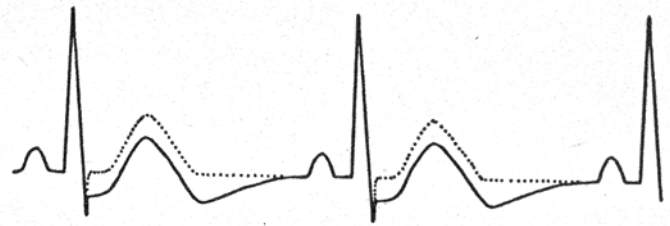


Figure 7. S-T segment depression due to the frequency response of the recorder being 3db down at 0.5 Hz. The dotted line shows the effect of extending the frequency response down to 0.05 Hz.

workers at the Royal Victoria Hospital in Belfast continue in their pursuit of the ultimate portable defibrillator, some manufacturers are evolving their designs into cardiac-care systems. The Siemens Theracard PM [71] is one such example, which, in addition to being a defibrillator/monitor/recorder, incorporates a pacemaker capable of stimulation via the defibrillation electrodes or via a separate oesophageal probe.

Batteries used in defibrillators have until recently been almost exclusively of the nickel-cadmium variety. There are many long-term problems with this type of battery, which make it difficult to maintain a guaranteed capacity when used in a defibrillator unless it is exercised regularly. Improvements in sealed lead-acid batteries have made them increasingly more suitable for defibrillator use and at least one British manufacturer (Albury Instruments [72]) is using them. Lithium batteries are also being explored. The Datascope M/D3 [73] offered a single-use lithium battery as an emergency back-up measure and now Cardiac Recorders [46] have produced a lithium battery-pack for their Model 280/4, which has a capacity for 180 400-J shocks and a shelf-life of 10 years. While this latter battery is approximately five times more expensive than its nickel-cadmium equivalent, it eliminates the need for a mains-powered charger. Additionally, being a primary battery, it will require high reliability in the defibrillator design as it cannot be tested every day, as is often done with rechargeable batteries.

The needs of the American market, combined with the decreasing cost of ready-built recorder modules, will cause the recorder to become a standard component rather than an optional accessory. The trend has already begun as the option now is not to have the recorder—five years ago having the recorder was the option. From the point of view of research, the Hewlett-Packard 78660A [57] provides a unique form of data-logging. It records the event and lists relevant parameters: TTR, peak current, energy selected and delivered etc.; while it is a boon to researchers, the mass appeal of this information is likely to be limited and it will be interesting to see how many other manufacturers produce a similar recorder.

While the conventional defibrillator has been responsible for saving many lives, logistically it has never been able to address the problem of patients at long-term risk of sudden death who will not respond to chemotherapy. This has been the motivation behind efforts to develop an automatic defibrillator [10]. Such a device should ideally detect life-threatening arrhythmias and deliver a defibrillating shock. A team in Brighton have recently reported clinical results with an automatic defibrillator/pacemaker manufactured by the Cardiac Resuscitator Corporation [74 and 75]. Although the concept of an automatic implantable defibrillator remains controversial in many respects [9 and 76], recent clinical results from human subjects reported by Watkins

*et al.* [11] show great promise. Jude [11] feels that such devices will one day be applied as widely as pacemakers are now.

Preliminary studies on the possibility of using ultrasound for defibrillation have been reported by a group at the Kaunas Medical Institute, Lithuanian SSR, USSR [77]. They used a frequency of 500 kHz at intensities of up to  $10 \text{ W cm}^{-2}$  applied directly to the exposed hearts of dogs. Examining the effect upon the refractory period of myocardial cells they found that intensities of  $4 \text{ W cm}^{-2}$  produced an increase of 37%, while  $8 \text{ W cm}^{-2}$  shortened the refractory period by a similar amount. Further increased intensity inhibited electrical activity in the myocardial cells. They feel that this may find a use in the prevention, rather than the treatment, of arrhythmias.

There have been several papers on designing digital meters for measuring the output of defibrillators to within 0.5% [78, 79 and 80]. In view of the accuracy with which clinical data can be gathered and with which energy levels are selected for treatment, there would seem to be no merit in such devices, unless they could be produced at a price which is competitive with available analogue models. The Simonsen & Weel EM-1 [81], for example, has an accuracy of 3% and is sufficient for the needs of most maintenance departments. Digital techniques, however, may lead to a more portable battery-operated unit.

Improvements to defibrillators themselves await further clinical information [32]. The discussion on the energy controversy shows that limitations to attainable efficacy may be more to do with human (operator) factors than with the defibrillators themselves. Having devices capable of achieving defibrillation, the task is now to minimize the risks to the patient. This requires investigation into (1) how to define cardiac damage [82]; (2) a definition of effective defibrillation; and (3) resolution of the question as to whether it is current or energy that is responsible for successful defibrillation.

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