Multipulse Biowave®

Saves lives, protects hearts.

MULTIPULSE BIOWAVE

SCHILLER

The Art of Diagnostics

Multipulse Biowave® – gentle, safe defibrillation.

Sudden cardiac arrest – what exactly does it mean?

Sudden heart death is caused by cardiac arrhythmia, that is to say, a problem in the heart's stimulation mechanism. The heart no longer receives the regular electrical pulses it needs to contract the heart muscles, so it stops beating at its normal rhythm. The resulting ventricular fibrillation means that the heart muscle can no longer contract, the heart can no longer pump blood into the blood circulation system, and, as a result, circulation ceases within seconds. The patient becomes unconscious after just two minutes, and after three to five minutes, will suffer permanent harm, and after an average of ten minutes, brain death occurs.

Defibrillation – the only life-saving technique for sudden heart death!

To most people defibrillation means a strong electrical current or voltage pulse which re-stimulates the heart's electrical activity, enabling it to produce a regular heart beat. It is essential that the electrical characteristics of the defibrillation pulse are adapted to the physiological properties of the human heart, because only by doing so is it possible to ensure that defibrillation will be effective and not cause harm to the patient.

Criteria for successful defibrillation [1, 2]:

- **It must be applied quickly enough.** As every minute passes, the chances of survival for the cardiac arrest victim fall by 10%. Even after just five minutes irreversible brain damage is likely to occur, and another 10 minutes usually means that the patient will die.
- **The first phase must be long enough.** The first phase of the biphasic pulse must sustain the stimulation time required physiologically (4 – 5 ms) [3] in order to excite all the cells, halt the arrhythmia, and restore the heart rhythm.
- **It must be sufficiently efficient.** The pulse must be sufficiently effective, i.e. indicate a current peak exceeding the excitation threshold of the myocard cells.
- **The second phase must be appropriately sized.** This is in order to suppress the residual load from the first phase and avoid refibrillation (arrythmia restarting).
- **It must protect as much as possible.** Since the energy used in defibrillation has a harmful effect, it needs to be reduced to a minimum (lowest possible defibrillation threshold).

***Multipulse Biowave®* – gentle, safe defibrillation**

The ***Multipulse Biowave®***, the patented [4] defibrillation pulse wave implemented in SCHILLER equipment, is pulsed at high frequency. It consists of two fixed duration phases of current flowing in opposite directions (bi-phasic). The characteristics of ***Multipulse Biowave®*** ensure that it is extremely effective and safe while the energy is extremely low.

Multipulse Biowave® saves a life on Christmas Eve

13-year old Joan had collapsed suddenly while she was playing a game on her PC. Rapid deployment of a defibrillator saved her life.

There were no signs of any health problems and no warning. A viral infection caused Joan's heart to stop because of an undetected inflammation of her cardiac muscle. Without immediate resuscitation and the rapid deployment of a defibrillator the young patient would not have stood a chance.

Joan's vital functions were maintained after a neighbour carried out immediate heart massage and artificial respiration, and following the rapid arrival of a first aid team carrying a FRED® defibrillator from SCHILLER – implementing the protecting pulse technology of ***Multipulse Biowave®*** The emergency doctor who arrived later was able to send the youngster to the Children's hospital in Karlsruhe in a stable condition, thus completing a perfect rescue operation.

The defibrillator was a gift to the German Red Cross in Karlsruhe; the organisation has tirelessly been running a 'Battle against Cardiac Arrest' campaign to draw attention to the need for defibrillators.

Photo: DRK KV Karlsruhe e.V.

Current and Energy, what they mean for defibrillation.
"... it is the current that defibrillates. Not the energy."

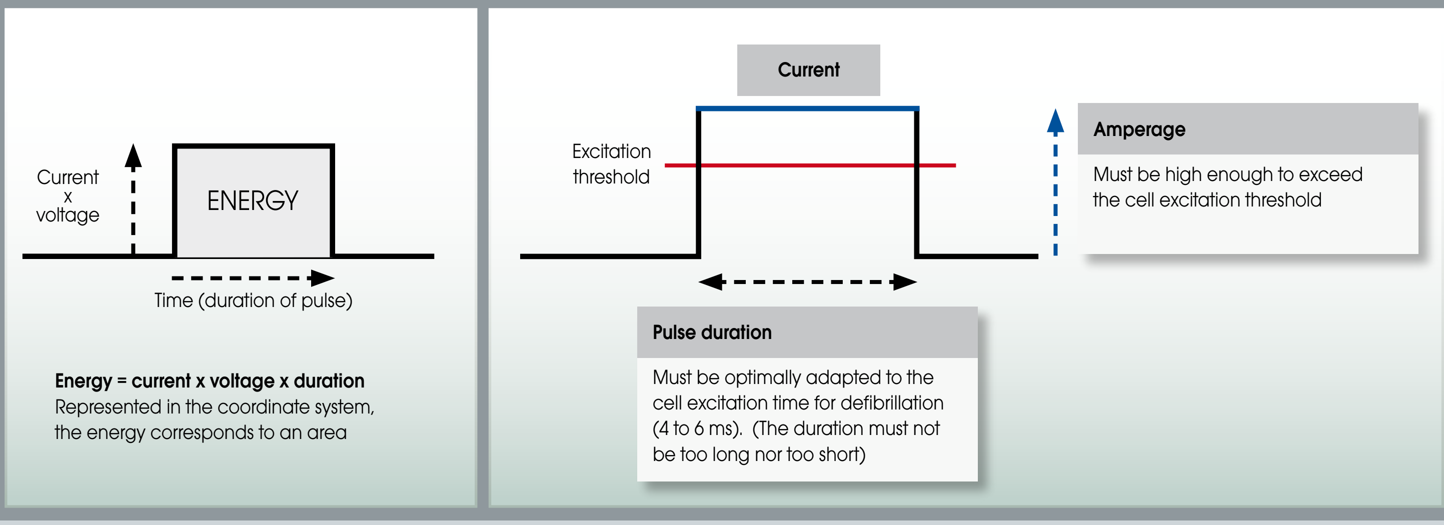
The effectiveness and thus the success of a defibrillation can be guaranteed only if, during the first phase, a current of a specified strength is applied for a specified period.
Although this elementary, electro-physiological principle has been known for over 100 years, repeatedly reasserted since then by many renowned scientists, and supported recently by some of the most important Organisations such as the AHA (American Heart Association) and the ERG (European Resuscitation Council), many circles still believe that it is the energy that is the crucial factor for effective defibrillation.

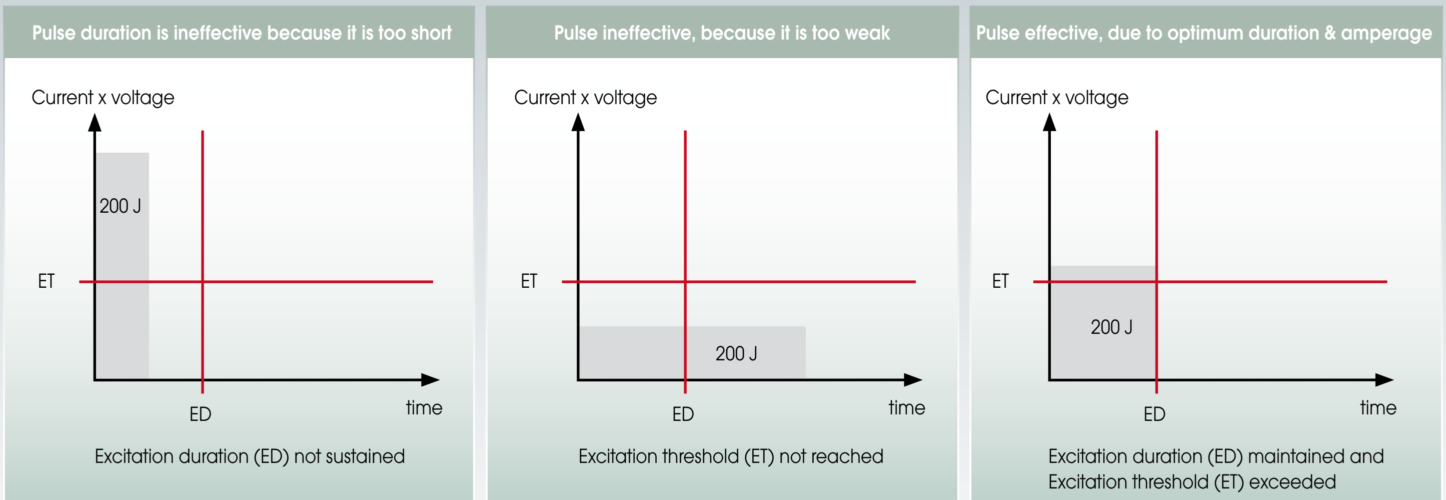
- The Energy in itself is not a factor for the effectiveness of a defibrillation pulse
- A high-energy pulse can be totally inefficient, i.e. not have a defibrillation effect if it does not reach the necessary amperage (excitation threshold) for a specified period (excitation time)

- Energy lacking sufficient efficiency, i.e. amperage, during the crucial phase (first phase), is unnecessary and can be considered to be a harmful factor
- Energy released beyond the cell excitation period is unnecessary and can be considered to be a harmful factor

The objective. A defibrillation pulse should as far as possible guarantee the greatest possible efficiency and safety!
- Since it has a harmful effect, the pulse energy must be kept as low as possible
- The pulse during the (first) phase - crucial for defibrillation - must be of sufficient duration and must reach sufficient amperage
- Existing pulses do not always meet the two basic conditions of a theoretical pulse. Often the pulses for the current are too weak, yet are applied for longer, thus releasing high levels of useless and harmful energy.

Duration and extent of shock – the determining factors for successful defibrillation





Energy is not a measurement of effectiveness:
Example of three pulses at the same energy value of 200 J, but only the third one (on the right) is capable of effective defibrillation.

Multipulse Biowave®:
The correct amperage – the best phase duration.

This biphasic pulse has a form that precisely meets the physiological requirements of a defibrillation procedure. The basic difference in this pulse – and its main advantage - is that it is released in pulse form.

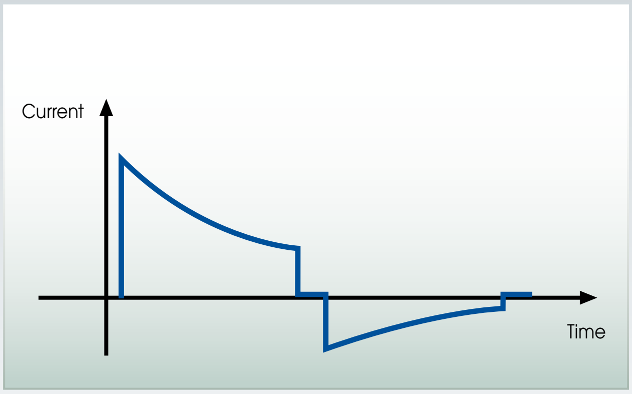
The principle of a pulsed shock

The principle of the pulsed curve type is that the current and the energy affect the heart for only some of the time – with the major advantage that less energy is released onto the heart than with a non-pulsed impulse.

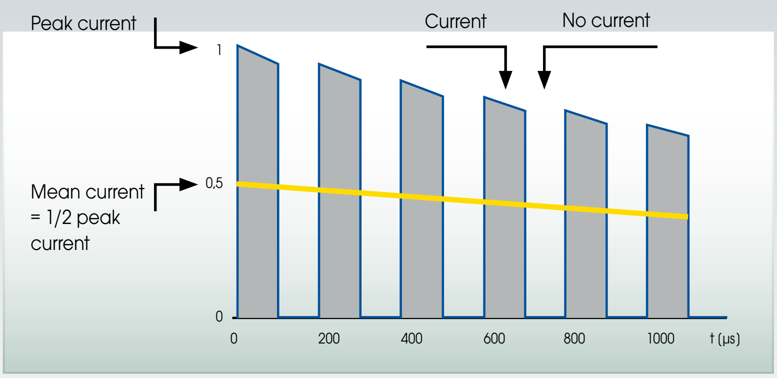
- The pulse signal consists of a series of single pulses separated from one another by pauses
- The duration of the single pulse and the subsequent pause is variable and is specified using what is known as the 'pulse duty factor'. For example the pulse duty factor is 50 % where the single pulse and the pause have the same duration (pulse duty factor = the ratio of pulse duration to the total duration of pulse + pause)

This pulse is therefore made up of a sufficiently high current **(= high efficiency) and with a particularly low – about half – energy requirement (= very low, or zero harm level).** This corresponds exactly to the principle of the best possible defibrillation.

Traditional, continuous biphase



The principle of the *Multipulse Biowave*® pulse



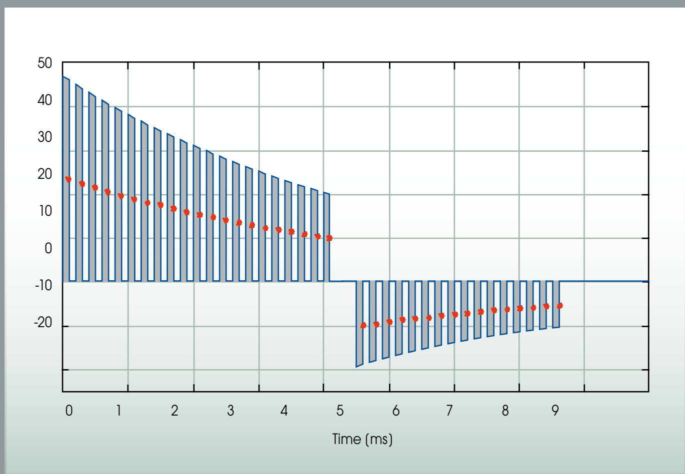
Half the energy released with strong and effective average current: In the interval between the pulses no current flows, and no energy is released.

Multipulse Biowave®:
Optimised to suit every patient.

Using the 'chopping' principle all the criteria can be applied successfully to every patient because the pulse duty factor can be selected to balance out the differing requirements and situations.

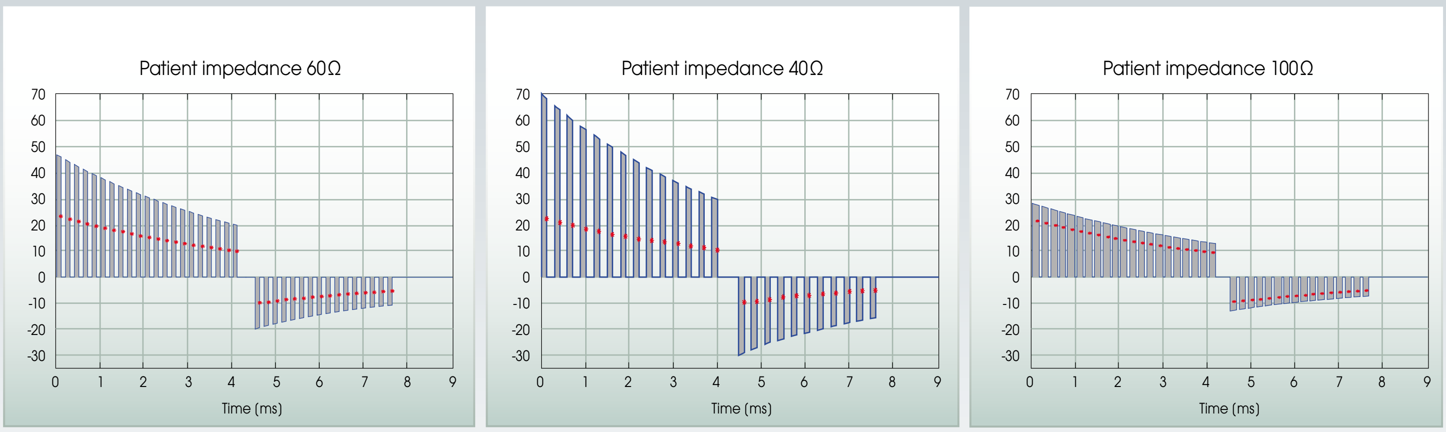
Adapting the pulse duty factor to differing patient impedances. Despite the fact that patients' impedance varies widely, a constant average current is maintained for all pulses.

Pulsed biphasic *Multipulse Biowave*®



Basic shape of the defibrillation pulse: Pulse duty cycle 50 %
Red marks indicate mean current.

Multipulse Biowave® – optimised to suit every patient



Example of how the ***Multipulse Biowave***® defibrillation pulse can be adapted to different patient impedances by selecting the pulse duty factor to maintain the mean current at constant [(5)].

Multipulse Biowave®:
Highly effective at very low energy – particularly gentle and protective.

Highly effective pulses require less energy – defibrillation is more successful, easier and less harmful. Fewer effective pulses (whether monophase or biphase) to compensate for the lack of effectiveness caused by the release of high energy (for example by increasing the period of the first phase to 10 ms where a patient indicates higher impedance, such as 100 W), which is particularly harmful where a heart has previously suffered ischaemic damage, and where several shocks are given.

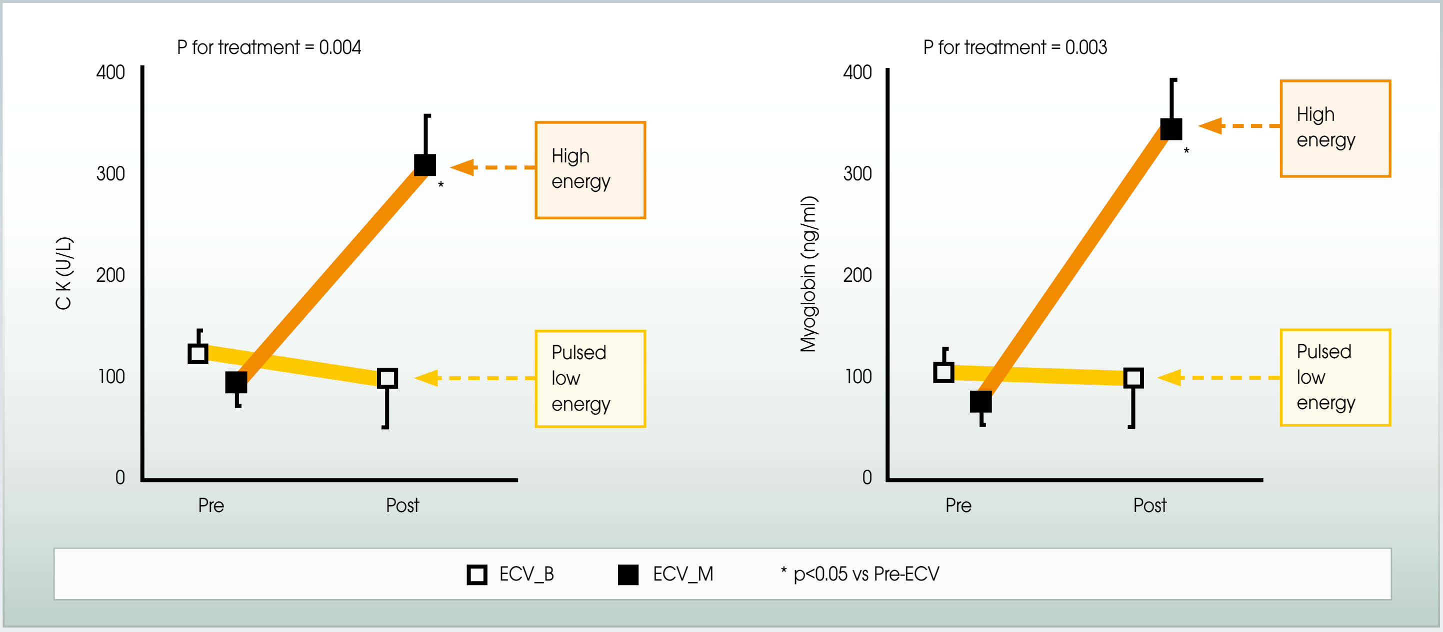
Clinical studies

These studies examined the effectiveness of ***Multipulse Biowave***® in the cardio version for atrial flutter and atrial fibrillation. The findings obtained are particularly suitable for assessing the effectiveness and safety of the pulse, because the ventricles are generally intact, i.e. that the effectiveness and safety of the shock are not hidden or falsified by the situational circumstances in the pre-clinical stage (ischaemia after lengthy cardiac arrest etc.) of the heart, which are present in the case of sudden heart death. The cardio version is in any case also more suitable as a source of findings than artificially induced ventricular fibrillation investigated in an electrophysiological laboratory where the parameters in no way relate to a real situation. The fibrillation is produced electrically, making defibrillation easier by a factor of 3, and the artificially provoked circulatory arrest lasts only 10 seconds.

Harm caused by energy is documented in the blood

A detailed study with cardio version patients at the University of Florence [6] examined the blood values of patients with regard to creatin, kinase and myoglobin values. These substances indicate damage to the muscle tissue caused by the shock. This damage can affect the success of resuscitation during preclinical defibrillation.

Harmfulness of the high energy shock



The creatin, kinase and myoglobin values in the blood, measured before (pre) and after (post) the cardio version, for high energy shocks (the orange line), and for shocks applied at lower, pulsed energy (yellow line). With the high energy shock there is a distinct rise in the blood values concerned [6].

Evidence of the effectiveness and safety of *Multipulse Biowave®*.
Documented in pre-clinical ECG: typical post shock effects on the ECG.

Preclinical studies

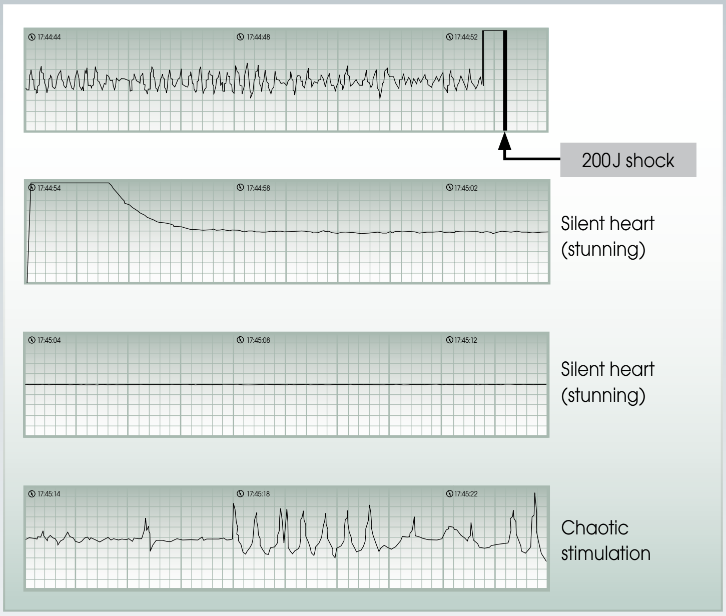
The quality (effectiveness and harmlessless) of a defibrillation pulse is to an extent indirectly shown in other ways – firstly in the post-shock effects of the patient signals immediately after the shock, and secondly in the successful resuscitation and survival rates of cardiac arrest patients.

Post-shock effects

After a high-energy defibrillation shock the ECG signal takes a long time to return.
However if the shock is made at low energy, and particularly with the ***Multipulse Biowave®***, this time is much shorter.

In addition, and regardless of this effect, after a successful defibrillation shock more or fewer physiological effects occur to the heart such as, for example, sustained asystolic or ventricular arrest (temporary paralysis of the heart muscle) and electrical instability. Firstly, these effects have a direct relationship with the condition of the heart muscle and the period of cardiac arrest prior to the shock, and secondly they are linked to the amount of energy applied. Where the shock energy is high the duration of such effects is basically longer (see examples 1 and 2) than with low energy shocks (and in particular with ***Multipulse Biowave®*** – examples 3 and 4.

Silent heart after high energy shock



Example 1

AV Block after high energy shock

Computer analysis of an original patient ECG with AV-block as the result of a high energy shock

Example 2

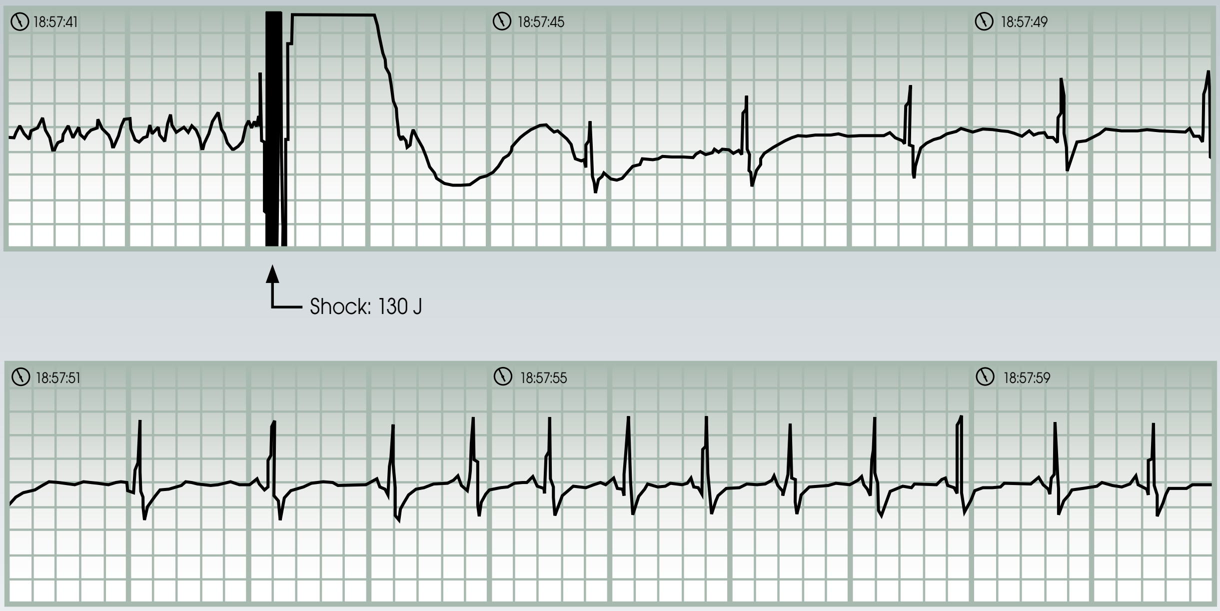
High energy shock (200 J single phase) with its characteristically relatively long return times for the signal, and the so-called 'silent heart' caused by stunning AV blocks and heart muscle instability which also occur frequently with high energy shocks.

Successful defibrillation with the low energy pulse *Multipulse Biowave®*

Example 3

Defibrillation with a 90 J ***Multipulse Biowave®***: shock. It is possible to see how the signal returns very quickly after the shock and how the sinus rhythm returns spontaneously immediately after the shock. Many users have given reports of lives saved with ***Multipulse Biowave®*** where the patients regain consciousness immediately after the shock and were able to speak – much to the surprise of the first emergency medical attendants.

Shock with 130 J *Multipulse Biowave®*



Original patient data: ventricular fibrillation sucessfully defibrillated with ***Multipulse Biowave®***.

Example 4

Resuscitation successes in cardiac arrest victims

	Valance [7] (biphase pulse)	A.P. Van Alem et al. [8] Biphase defibrillator using high energy
Defibrillated initial ventricular fibrillation	27	51
Ventricular fibrillation ends 5 s after shock		50 (98 %)
Effective shock (ventricular fibrillation ends 12 s after the first shock and return to organised rhythm within the first minute after the shock, with at least two complex rhythms occurring within an interval of less than 5 s)		35 (69 %)
Effective defibrillation including relapse into ventricular fibrillation that had been defibrillated more than once.	23 (85.2 %)	
Return to spontaneous circulation	12 (44.4 %)	31 (61 %)
Hospital admission rate	12 (44.4 %)	20 (40 %)
Hospital discharge rate	**6 (22.2 %)**	**7 (14 %)**
Surviving patients with no consequential damage	**5 (18.5 %)**	
Time from emergency call until semi automatic unit deployed	3 bis 12 min	3 bis 15 min
Proportion of CPR carried out by medical attendants	4.8 %	26 (51 %)

Comparison between two studies into effective defibrillation (according to several definitions). Circulation returns spontaneously, as does the survival rate – one with a biphase high energy pulse, and the other with the biphase pulsed impulse. Please note the major difference in the proportion of CPR carried out by medical attendants.

Standards and approvals that draw users and patients into a sense of false security:
Before a pulse may be used for defibrillation it must be subjected to an approvals procedure to check that it complies with certain standards.

European standards and approval:
These merely govern electrical safety and the accuracy of the values stated by the manufacturer, without taking into consideration the effectiveness or any harmfulness of the defibrillation pulse.

US standards and approval:
The American version adds a requirement to validate the pulse in an electrophysiological laboratory – where as we have already shown, the conditions are not at all relevant to defibrillation of pre-clinical ventricular fibrillation, and the results are therefore not representative.

Summary:
Based on the currently applicable terms of the approvals procedure for defibrillation pulses users and patients cannot be assured that an approved defibrillator is effective and clinically safe!

The maxim for defibrillation:
Sufficient CURRENT for effectiveness – minimum ENERGY to avoid harm to the patient!

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(3) Irnich W. (1990) The fundamental law of electrostimulation and its application to defibrillation. PACE, 13: 1433 – 1447 (p 1440)

(4) Cansell A. et al. (1999) Impulses or a series of impulses and device to generate them. US Patent 6.493.580. Priority date FR 1999 Jan. 27

(5) Irnich W, Cansell A. (2005) Principle and Advantage of Chopped Defibrillation Schocks. Biomedizinische Technik – Vol 50 – Suppl. vol. 1 – Part 1 : 727 – 728

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(7) Valance A. (2002) La défibrillation semi-automatique par les sapeurs-pompiers de Meurthe et Moselle – Thèse – Nancy – France

(8) A.P. van Alem et al. (2003) A prospective, randomized and blinded comparison of first shock success of monophasic and biphasic waveform in out-of-hospital cardiac arrest. Resuscitation 58: 17 – 24

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