IEC TS 60479-1

Edition 4.0 2016-07

TECHNICAL SPECIFICATION

colour inside

BASIC SAFETY PUBLICATION

AMENDMENT 1

Effects of current on human beings and livestock –
Part 1: General aspects

IEC TS 60479-1:2005-07/AMD1:2016-07(en)

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FOREWORD

This amendment has been prepared by IEC technical committee 64: Electrical installations and protection against electric shock.

The text of this amendment is based on the following documents:

Enquiry draft	Report on voting
64/2095/DTS	64/2113/RVC

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

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FOREWORD

Add, after the sentence "The main changes with respect to the previous edition are listed below." and the existing dashed list items, the following new text:

– Extension of the applicability of the total body impedance to a frequency range up to 150 kHz;

– Clarification of the difference in anodic versus cathodic d.c. pulses;

– Extension of the ventricular fibrillation threshold of single pulses down to 1 µs pulse width;

– Addition of informative annexes:

Annex E: Theories of ventricular fibrillation;

Annex F: Quantities ULV and LLV;

Annex G: Circuit simulation methods in electric shock evaluation.

INTRODUCTION

Replace the existing introduction with the following new introduction:

INTRODUCTION

This basic safety publication is primarily intended for use by technical committees in the preparation of standards in accordance with the principles laid down in IEC Guide 104 and ISO/IEC Guide 51. It is not intended for use by manufacturers or certification bodies.

One of the responsibilities of a technical committee is, wherever applicable, to make use of basic safety publications in the preparation of its publications.

This technical specification provides basic guidance on the effects of shock current on human beings and livestock, for use in the establishment of electrical safety requirements.

In order to avoid errors in the interpretation of this technical specification, it should be emphasized that the data given herein is mainly based on experiments with animals as well as on information available from clinical observations. Only a few experiments with shock currents of short duration have been carried out on living human beings.

On the evidence available, mostly from animal research, the values are so conservative that this document applies to persons of normal physiological conditions including children, irrespective of age and weight.

There are, however, other aspects to be taken into account, such as probability of faults, probability of contact with live or faulty parts, ratio between touch voltage and fault voltage, experience gained, technical feasibilities, and economics. These parameters should be considered carefully when fixing safety requirements, for example, operating characteristics of protective devices for electrical installations.

The form of the document as has been adopted summarizes results so far achieved which are being used by technical committee 64 as a basis for fixing requirements for protection against shock. These results are considered important enough to justify an IEC publication which may serve as a guide to other IEC committees and countries having need of such information.

This technical specification applies to the threshold of ventricular fibrillation which is the main cause of deaths by electric current. The analysis of results of recent research work on cardiac physiology and on the fibrillation threshold, taken together, has made it possible to better appreciate the influence of the main physical parameters and, especially, of the duration of the current flow.

IEC TS 60479-1 contains information about body impedance and body current thresholds for various physiological effects. This information can be combined to derive estimates of a.c. and d.c. touch voltage thresholds for certain body current pathways, contact moisture conditions, and skin contact areas.

This technical specification refers specifically to the effects of electric current. When an assessment of the harmful effects of any event on human beings and livestock is being made, other non-electric phenomena, including falls, heat, fire, or others should be taken into account. These matters are beyond the scope of this technical specification, but may be extremely serious in their own right.

Further experimental data are under consideration, such as recent ongoing experimental work on "current induced heart fibrillation by excitation with discrete Fourier spectra" which is intended to contribute to frequency factor data.

4.5.3 Sinusoidal alternating current with frequencies up to 150 kHz

Replace the existing fourth paragraph with the following new text:

Figure 11 shows the frequency dependence of the total body impedance Z_T for a current path hand to hand and large surface areas of contact for a touch voltage of 25 V and frequencies from 25 Hz to 150 kHz. From the results, curves have been derived giving the dependence of the total body impedance Z_T of a population for the 50th percentile rank for touch voltages from 10 V to 1 000 V and a frequency range from 50 Hz to 150 kHz for a current path hand to hand or hand to foot for large surface areas of contact in dry condition. The curves are shown in Figure 12.

5 Effects of sinusoidal alternating current in the range of 15 Hz to 100 Hz

Replace the existing title with the following new title:

5 Effects of sinusoidal alternating current in the range of 15 Hz to 150 kHz

Replace the existing first paragraph with the following new text:

Clause 5 describes the effects of sinusoidal alternating current passing through the human body within the frequency range 15 Hz to 150 kHz.

6.6 Heart factor

Replace the existing Figure 12 with the following new Figure 12:

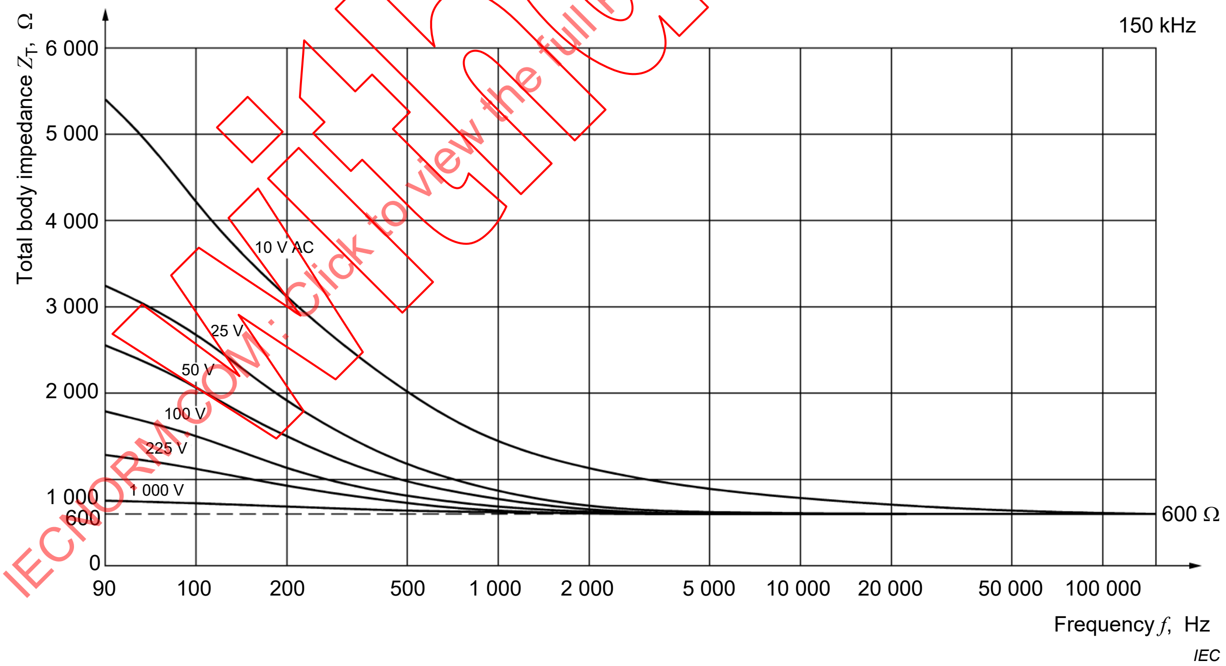

Figure 12 – Frequency dependence of the total body impedance Z_T of a population for a percentile rank of 50 % for touch voltages from 10 V to 1 000 V and a frequency range from 50 Hz to 150 kHz for a current path hand to hand or hand to foot, large surface areas of contact in dry conditions

Add, at the end of the existing Subclause 6.6 the following new Subclause 6.7:

6.7 Effects of anodic versus cathodic d.c. currents

An electrode is an interface to another medium where charged particles are interchanged.

NOTE Charged particles are to be differentiated, and an anion is a negatively charged particle and a cation is a positively charged particle.

An anode is an electrode which is at positive potential with respect to a lower potential reference, such as the positive terminal of a source. Anodic current is current that flows away from an anode.

A cathode is an electrode which is at negative potential with respect to a higher potential reference, such as the negative terminal of a source. Cathodic current is current that flows to a cathode.

To understand that current flow direction plays a role with d.c. pulses, first a simple explanatory model (Figure 24) is introduced.

The current in this context is conventional current as opposed to electron flow. Current is applied on a body part with an excitable structure (e.g. a nerve) inside via one small electrode 1 (called different electrode) and a large area electrode 2 (called indifferent electrode).

Current distribution is asymmetric with a large current density in area A and a low current density in area B. See Figure 24.

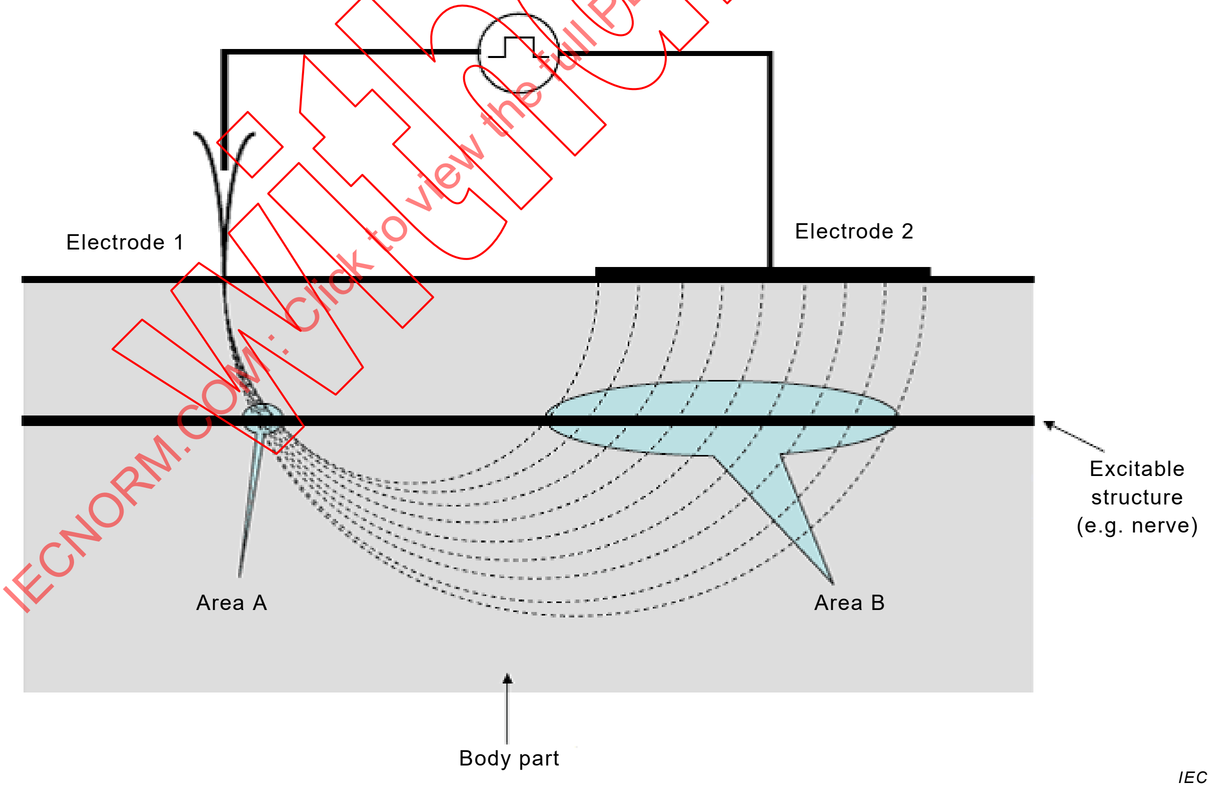

Figure 24 – Effects of anodic versus cathodic d.c. currents

Now various d.c. pulses show different behaviour: Responses of the excitable structure arises in the following order with respect to increasing excitation current depending on polarity and on either closing or opening the current flow of the circuit:

- cathodal make reaction (CMR);
- anodal make reaction (AMR);
- anodal break reaction (ABR);
- cathodal break reaction (CBR).

This is called the “Law of polar excitation”.

This behaviour can be explained as follows.

The outside of the membrane of the excitable structure becomes more negative in area A when electrode 1 is the cathode. This results in that the membrane is depolarized because the internal potential of the cell is also negative: The cell fires, is excited from area A at closing of the current circuit, a CMR results.

If the polarity is reversed (electrode 1 is now anode) then this same response is again arising from the cathode, but in this case it has its origin from area B with a lower current density, it is then called an AMR because the reference is always the small different electrode. The threshold is higher than for a CMR. This sequence can be reversed (so called anodal dip) for short pulses of about 180 ms due to a transient Ca^{2+} ion current.

If the current is flowing after the closure and then opened, an opening response can occur.

The lower threshold for that kind of response occurs again from area A in the anodal case, the reason for the opening reaction is that the channels responsible are depolarized again because they were "clamped" before, during the persisted current flow, resulting in an ABR.

The CBR with the highest threshold of all has then its origin from area B.

In principle this behaviour of excitable cells to d.c. pulses always occurs if the current distribution is asymmetric and the effect is more or less prominent depending on the difference in size and current flow between the different and indifferent electrode. At least for pulses delivered within 1 cm of the cardiac surface, cathodal d.c. pulse trains are slightly safer as they require 25 % more current to induce ventricular fibrillation than anodal pulse trains [32].

Also, in principle, this behaviour is present for different types of cells, not only for nerve cells but equally for heart cells. The effect of the polarity is valid as well as for perception and for fibrillation (see Figure 25).

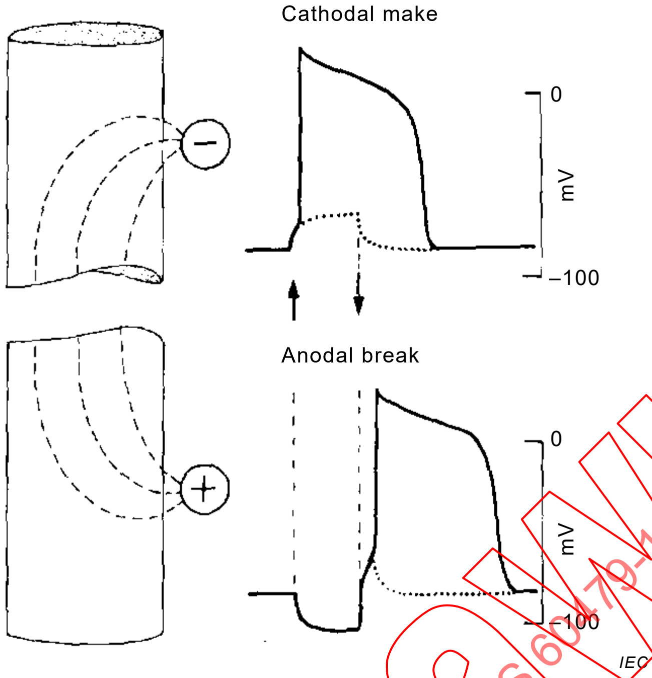

Figure 25 – Pulsed d.c. stimulation of single heart cells

The two types of pulsed d.c. stimulation appear due to changes in membrane potential during cathodic make and during cathodic break. Action potentials are elicited when the membrane potential attains the threshold.

Annex B

Add, after list item 3) the following new item 4) to the list:

4) Values for total body impedance above 2 000 Hz have been estimated by extrapolation from existing data and are shown in Figure 12.

Add, at the end of existing Annex D, the following new Annexes E, F and G:

Annex E
(informative)

Theories of ventricular fibrillation

Ventricular fibrillation (VF) is a phenomenon which has been better known since the detection of electrical activity of the heart (ECG) [35]. The main mechanism of this abnormal normally lethal activity of the heart ventricles was found when it was discovered that small volumed circulating exciting waves are responsible for minimal inefficient and only local blood pumping properties, in contrast to the straight strong and efficient normal excitation and pumping process.

The reason for the unexpected possibility for the transition from normal operation to the initiation of VF lies in the natural inherent inhomogeneity within the electrical repolarization phase of the ventricles. This phase is called the "vulnerable" phase because of the fact that an electrical impulse or d.c. or a.c. current from the outside can elicit VF during this period. VF can also be induced by rapid cardiac capture.

Experimental and theoretical research showed that the processes seem to be more complex than for circular excitation waves only. Also more sophisticated waveforms led to the conclusion that the initiation process of VF, as well as its persistence, has additional components compared to that of a simple re-entry of excitation [36]. These findings led to spiral waves breakup and to single and multiple wavelet hypothesis [37][38].

Moreover, the initiation of VF is increased by preceding ventricular extrasystole (VE) and the more frequently they arise the more dangerous they can be (see IEC TS 60479-2: 2007, 9.2). The reason for this phenomenon is that every additional VE increases the inhomogeneity during the ventricular repolarization [40][42]. The inner layers of the ventricular wall have per se a longer repolarization time than the outer layers and this difference is increased by more frequent VE which forms the substrate for fibrillation initiation. This is also true for direct current and explains why fibrillation due to direct current can take place [43].

Termination of VF is called ventricular defibrillation. Defibrillation is presently performed with a biphasic shock. There are three major theories of defibrillation:

- progressive depolarization [44];
- upper limit of vulnerability [45];
- virtual electrode induced re-excitation [46][47].

The role of the first phase is to charge the vast majority of the cardiac cell membranes with a large charge of 3 ms to 10 ms duration. The role of the second phase is to return the cell membrane voltage to zero [48].

Annex F
(informative)

Quantities ULV and LLV

The heart's threshold of fibrillation for a given waveform is the minimum value of current to which it should be subjected to precipitate ventricular fibrillation. The IEC 60479 series of standards devotes itself to determining this threshold for different waveforms.

It is noted however that "defibrillation" is a therapeutic modality used to treat a heart in fibrillation. This process involves passing a large impulsive current through the fibrillating heart with the intention of halting fibrillation.

The design of a defibrillator is beyond the present scope however the terms ULV and LLV are very commonly met in this context.

There is a band of currents which produce fibrillation in the myocardium if delivered in the vulnerable period (portions of the T-wave). Present literature suggests that strong short pulses delivered outside of the vulnerable period do not induce VF but only cause an extra cardiac contraction. Above this band of currents, the heart is reliably defibrillated by short (3 ms to10 ms) impulse shocks delivered in the same location in the cardiac cycle. This level is the upper limit of vulnerability (ULV) of the myocardium. It has been shown in multiple studies to be a good predictor of the defibrillation threshold for the myocardium, this parameter being important, for example, in determining the setting for an implantable cardiac defibrillator (ICD) [49].

The lower limit of vulnerability (LLV) is the fibrillation threshold as determined in the IEC 60479 series.

Annex G
(informative)

Circuit simulation methods in electric shock evaluation

The use of modelling in evaluation of any situation is valuable since the modelling is substituted for direct measurement of the application of forces which may be harmful or deleterious to the body [50]. Direct electric shock experimentation, whether on humans or animals, has been severely restricted over the last few decades forcing consideration of modelling as a substitute. Such modelling has been used for years, most recently in the evaluation of touch currents according to the frequency filtered effect as are evaluated in many product standards.

An important contribution to experimental data is ongoing in governmental funded experiments with animals.

Based on direct measurements on the heart (and necessary translation to the human) new simulation boundaries will provide input conditions to the whole body situation (e.g. touch models hand to hand, hand to foot). New simulation models based on control circuits levels up the voltage which contacts the human until the given current density (or other appropriate parameters) is reached. This ongoing and recent experimental work is under consideration.

The process of determination of a dangerous current involves determination of the current in the body, including at the myocardium. This is hard to perform experimentally, however it can be modelled using circuit analysis methods which require describing the body and its operation as an equivalent electrical circuit. This discussion is to inform readers of the existence of these models and to provide a reference to further discussions on, and usages of, them.

The body model which is commonly used is shown in IEC TS 60479-1, consisting of resistance and capacitance representing the combined impedances of the skin. In series with these is a simple resistance representing the body internal resistance.

A voltage is applied between the terminals of the model and the resulting current in the internal body resistance can be considered to approximate the myocardial current.

So, as a first approximation, measuring this current for an applied voltage will model the body current. Further analysis can be accommodated by adding a circuit that mimics the body response further. For instance, several filter networks have been developed that provides correction for the frequency filter effects noted in IEC TS 60479-2.

Hart [33] proposes the following modelling network as a useful one for modelling the startle-reaction frequency effect from the 'a' curve in Figure 20 (see Figure G.1).

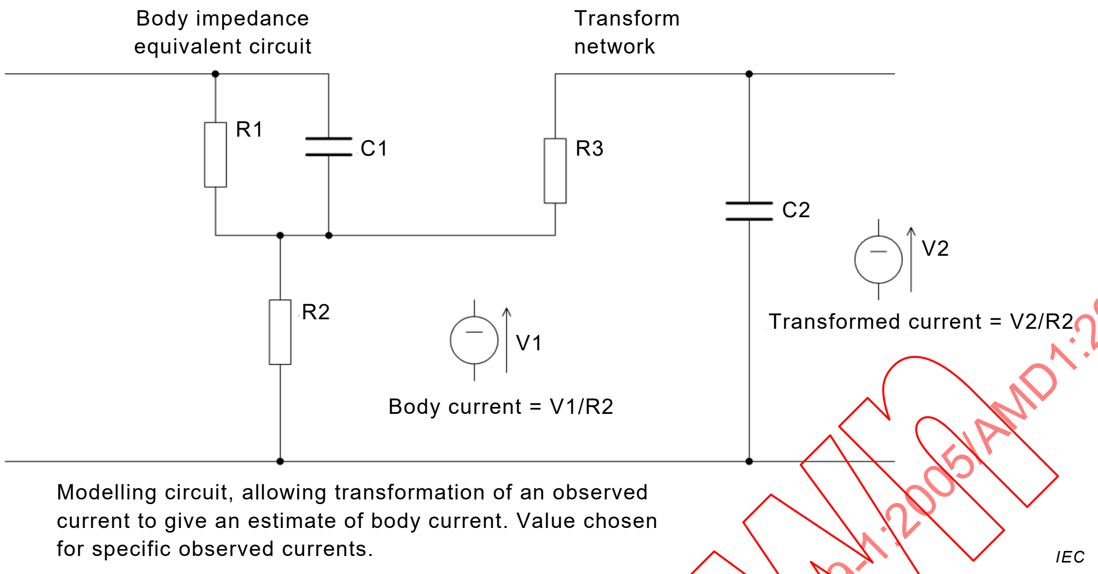

Figure G.1 – Electric shock in electrical model by Hart [33] including startle reaction effect

The parameters were determined empirically, with R1 and C1 representing the combined skin impedance and R2 being the internal body resistance. The voltage V1 is used to derive the actual body current (= V1/R2). A second network, R3 and C2 is added and is related to the startle-reaction frequency factor, whose input is the body current, and whose output is used to derive the body response corrected for frequency for this situation.

NOTE In some IEC standards R1 is also Rs and C1 is also Cs and R2 is also Rb.

Some values for the components that might be useful in other cases are tabulated as shown in Table G.1 (the values of R3 and C2 may be chosen to give a 3 ms time constant of a cardiac cell simulating the current at the heart, which may typically be taken as 5 % to10 % of the total internal current in magnitude).

Table G.1 – Body impedance examples (uncompensated)

Comments	Condition	R1 kΩ	C1 nF	R2 Ω
Large area contact (~10 000 mm^2)				
Hand to hand (or foot)	Worst case test value	1,5	220	500
Medium area contact (~1 000 mm^2)				
Hand to hand (or foot)	Flat hand – DRY	77	24	500
Hand to hand (or foot)	Gripping hand – DRY	25	50	400
Hand to opposite shoulder	Gripping hand – DRY	9,5	200	250
Hand to opposite shoulder	Gripping hand – WET	1,5	220	250
Hand to arm, high pressure grip	Gripping hand – WET	1,5	500	200
Small area contact (~ 100 mm^2)				
Finger to arm	Finger contact – DRY	60	7	800
Finger to arm, high pressure	Finger contact – WET	12	20	250
Near worse case small area	100 mm^2 probe contact	15	20	250
IEC 60601-1 medical standard	Standard test value	0	0	1 000

IEC 60990 provides two frequency factor correction circuits; the perception threshold 2 element frequency factor correction circuit shown above plus a 3 element letgo immobilization frequency factor correction circuit. These circuits have been extensively discussed by Perkins[34][35][51]. Note that these circuits mimic the inverse of the frequency factor curve, as explained in IEC 60990, which allows evaluation to the low frequency limit given in a product standard irrespective of the frequency of the current being measured.

Modelling of any electric shock condition, whether perception threshold, letgo threshold, or myocardial current leading to ventricular fibrillation, requires that the correct elements should be chosen for the model analysed. Assuming that the current is introduced through the skin, the correct skin model should be selected for the condition experienced. When suitable, nonlinear models of the skin should be used [52]. Product standards usually seek the worst case condition to maximize the current and minimize the risk of electric shock. The appropriate body resistance should be used and, finally, any correction for frequency or other important parameter should be added. Normal circuit analysis techniques can then be used to provide an estimate of the current in the body under those conditions.

Other modelling techniques can also be used: some researchers are using a whole body model which assigns properties, usually electrical properties for electric shock situations, to each granular body element as determined from a whole body CAT scan or MRI scan. Granularity to about 1 mm seems to be the current level available. This is adequate for some larger scale studies but not adequate to differentiate current differences in thin layers, such as nerve sheaths. This type of analysis deals with large sets of data and is best run on large, fast computer systems.

The explosive growth of computer modelling available on personal computers allows the development of electric shock modelling in significantly more detail than has been considered up till now.

Together with ongoing experimental work on animals in governmental funded projects and simulated transfer of the data to the human body, new insight is expected to be drawn which has the potential to justify knowledge about effects of higher frequency currents.