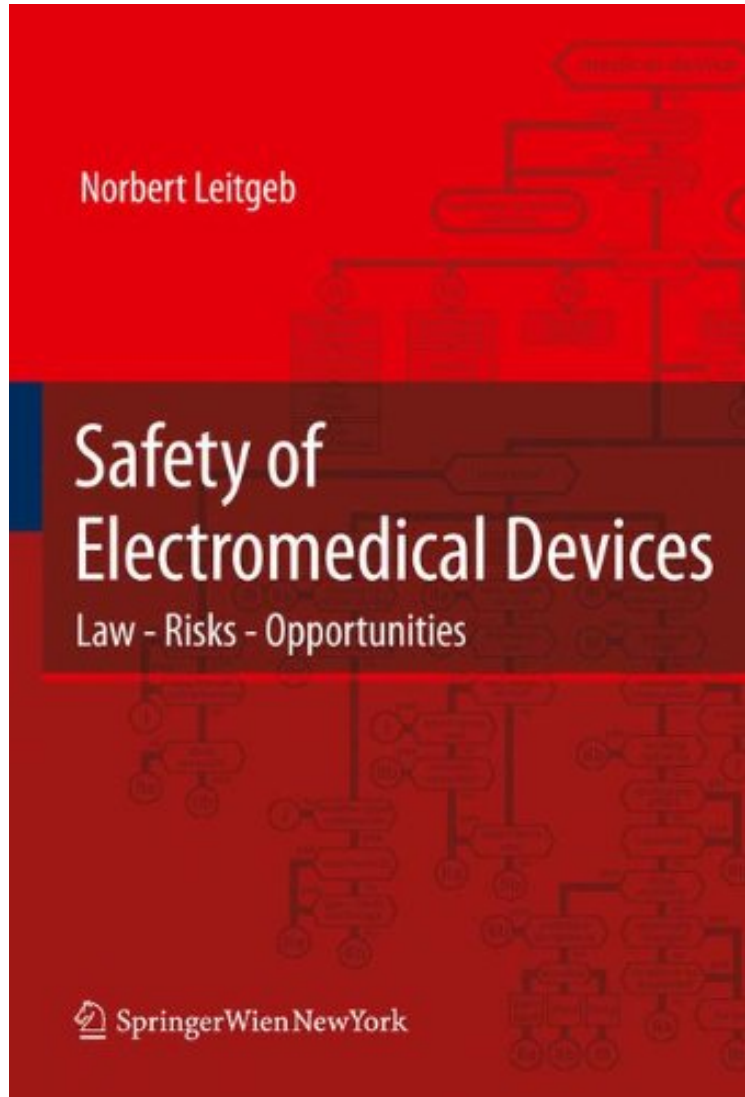


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Safety of Electromedical Devices: Law - Risks - Opportunities

Norbert Leitgeb

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Preface Development in the field of medical technology has resulted in a manifold of medical devices enabling us to diagnose illnesses more reliably, treat them more efficiently and compensate for handicaps more effectively. However,

these improvements are also associated with safety risks. Today, patients are in contact with an increasing number of medical devices longer and more intensively than before. Applied parts are put into contact with the body, probes may be introduced into the body via natural or surgical orifices, and even whole devices may be implanted for many years. The application of devices is no longer restricted to medical locations only. Home use by lay people is increasing and involves even critical devices such as for dialysis, nerve and muscle stimulation and ventilation. In contrast to users patients are in a special situation. Their life could depend on the performance of a device, they might be unconscious, may have impaired reactions, or have been made insensitive to pain by medication, and hence they may be exposed to hazards without their awareness and protection by their own reaction. Therefore, medical devices must meet particularly stringent safety requirements. However, the question arises how safe is safe enough? The readiness to accept risks depends on a variety of accompanying circumstances. In fact, subjective risk perception varies among individuals and differs from country to country, and frequently only in rare cases it is in agreement with assessments of objective scientific analyses.