

# // THE INTERNATIONAL VALID STANDARD IEC 60601

## Which directives are valid for medical control devices in Europe?

The EC directive for medical devices (MDD) or in Germany the law for medical devices, appendix I, name basic requirements for medical devices: »The products must be designed and produced, that their use ... does not endanger ... the safety of the patients«. So the solutions for the design and development of the products chosen by the manufacturer must meet the basic principles of integrated safety, under consideration of the general approved state-of-the-art. »Selecting the appropriate solutions the manufacturer must apply the following basic principles in the given sequence: 1. Elimination or minimization of hazards (integration of the safety concept into the development and manufacturing of the product). 2. If necessary, appropriate safety measurements including alarm appliances against hazards that cannot be eliminated. 3. Instruction of the operator about remaining hazards that cannot be secured by protective measures«.

The standard IEC 60601 determines the safety concepts for electrical medical devices worldwide. In the IEC 60601-1 (medical electrical devices) it is stated: 1. section 3.1: »The devices may not cause under normal conditions and at a first fault ... any endangerings ... «. 2. section 2.10.11 defines the conditions of the first fault: »State, where a single protective measurement inside the device has become defective ...«. 3. section 52.1 »The devices must be designed and produced in such a way that even at a first fault no endangering occurs«.

The complementing standards of series IEC 60601 describe the requirements that are assigned to each device class (example: IEC 60601-2-22 for laser devices and IEC 60601-2-24 for infusion pumps).

Furthermore the EN 1441 (risk analysis) must be observed. More details of risk analysis and risk management can be found on the following pages.

## IEC 60601-1, third edition: What is the benefit of the revised standards ?

For the safety concepts of electrical medical devices the internationally valid standard IEC 60601 is of great importance. This standard is being revised at the moment; the third edition will be published prospectively in 2005.

The past experiences had with this standard were used to integrate a number of improvements into the draft of the third edition. Because medical devices are increasingly applied in systems, the application field of the standard refers now to basic safety and the functional safety of devices and systems. Therefore the claims of the complementing standard IEC 60601-1-1 are implemented in the basic standard. The integration of functional safety is a new idea.

The basic idea of the revised standard takes up two further very important topics: safety during operation (usability), as well as risk management.