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3.1.4. Active medical devices

Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand alone software is considered to be an active medical device.

The concept "act by converting energy" includes conversion of energy in the device and/or conversion at the interface between the device and the tissues or in the tissues.

10The concept of "significant changes" includes changes in the nature, level and density of energy (see Rule 9). This means that for instance an electrode is not an active device under this classification system as long as the energy input is intended to be the same as the energy output. For instance, resistance in a wire that causes minor changes between input and output cannot be considered to constitute "significant change".

However, electrodes used in electrosurgery for cutting tissues or cauterisation are active devices because their operation depends on energy provided by a generator and their action is achieved by conversion of energy at the interface between the device and the tissue or in the tissue.

Electrodes intended for E.C.G. or E.E.G are normally not active devices because they do not normally act by conversion of energy.

However, it should be understood that an electrode, which is an accessory of an active implant, is covered under the relevant Directive for active implants. Further information on this issue can be found in "Guidelines relating to the application of the Council Directive 90/385/EEC on active implantable medical devices

The application of energy from the human body does not make a device "active" unless that energy is stored within the device for subsequent release. For instance, energy generated by human muscle and applied to the plunger of a syringe (thus causing a substance to be delivered to a patient) does not make this syringe an "active device". However, if a drug delivery system depends upon manual winding to preload a spring which is subsequently released to deliver a substance, then the device incorporating the spring is an "active device".

Medical devices using prestored gases and/or vacuum as a power source are regarded as active devices, e.g. gas mixers with anaesthesia machines and gas powered suction pumps.

Heating/cooling pads intended only to release stored thermal energy are not active devices because they do not act by conversion of energy. However, heating/cooling pads which act by chemical action (e.g. endothermic or exothermic reaction) are active devices as they are converting chemical energy into heat energy and or vice versa.

Radioactive sources that are intended to deliver ionising radiation are regarded as active medical devices, unless they are radiopharmaceuticals as defined in article 1 of Directive 2001/83/EC or radioactive implants as defined in article 1 of Directive 90/385/EEC.