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ANALYSIS OF THE EFFECT OF AUXILIARY CURRENT FREQUENCY ON PATIENT'S SAFETY IN BIOIMPEDANCE SPECTROSCOPY MEASUREMENTS

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Medical devices, like any electrical equipment, produce leakage currents. A leakage current is an electric current that flows in an unwanted conductive path from the current source to the chassis, or to the ground. The flow path of such current may pass through the patient, posing a risk of shock or even death. The levels of permissible leakage currents are specified in EN 60601-1. The aims of our research are analysis of the effect of patient auxiliary current and patient leakage current on patient's safety during bioimpedance spectroscopy measurements, and to evaluate the effectiveness of the applied protection means from the low-frequency (<5 kHz) current by simulating a single fault condition in the device which can by unintentional set frequency below normal used range. The tests were carried out on a measurement system consists of a measurement circuit, oscilloscope and wave generator. Test scenarios were prepared in which the test measurement system was subjected to different loads: in idle mode, with a 20Ω Ohm resistor, and with simulated patient load according to the standard EN 60601-1. For each load, gain and phase of the output voltage of the circuit were measured. The obtained results were then compared with the graph of current attenuation of the measuring system as a function of frequency, available in the standard EN 60601-1. The results obtained confirmed the effectiveness of the applied protection means against patient leakage current and patient auxiliary current for low-frequency currents (<5 kHz). Medical devices must be efficient and reliable. Safety testing is one of the key components to ensuring their proper operation. Fulfilling the relevant requirements for basic safety and operation of medical devices is a guarantee for the safety of patients and medical personnel.