



UNIVERSITA' CAMPUS BIO-MEDICO DI ROMA

Facoltà Dipartimentale di Ingegneria Biomedica

# The need for the revision of the IEC 60601 standards pertaining to electrocardiography

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**ABSTRACT:**

It is important to recognize that high fidelity in the reproduction of the ECG waveform requires a measurement system that preserves the ECG features and provides amplification selective to the physiological signal while rejecting external interference and noise. The most obvious implication is that the presence of a frequency-dependent skin-electrode interface introduces distortion to the signal in its propagation from its source to the input of the recording amplifier, which may lead to misdiagnosis of serious cardiac conditions unless the front-end stage is adapted to the source impedance. Therefore, attention is given to investigating the close relationship between the low-frequency response of the skin-electrode-amplifier network and the input impedance characteristics of electrocardiographs. The transient response of ECG amplifiers is investigated in the light of the IEC 60601 performance standard for ECG recording equipment. Recent test result on several electrode models suggests that the undershoot limit of 100  $\mu\text{V}$  and the recovery slope limit of 300  $\mu\text{V/s}$  in response to a 3 mV, 100 ms rectangular pulse are violated when the recommended 10 M $\Omega$  input impedance at the input of the recording amplifier is used. Signal distortions appear in the form of an exaggeration of an S wave and depression in the ST segment, which could be misinterpreted clinically as signs of myocardial ischemia or the onset of myocardial infarction when using a real recorded ECG signal with the recommended 10 M $\Omega$  input impedance at the amplifier input. Analysis and test result recommend that an amplifier input impedance exceeding 3G $\Omega$  and a cut off frequency no higher than 0.05 Hz are necessary to meet the IEC 60601 performance standard and avoid distortion in the ECG signal.



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