EDITORIAL

Electrical Safety Standards for Electrocardiographic Apparatus

AMERICAN HEART ASSOCIATION COMMITTEE ON ELECTROCARDIOGRAPHY:

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IN 1972, the Committee on Electrocardiography of the American Heart Association (AHA) first published recommendations dealing with electrical safety in electrocardiographic (ECG) and vectorcardiographic (VCG) instruments. These specifications were restated in slightly altered form in 1975. To our knowledge, practically all manufacturers of ECG equipment sold in the United States now follow these recommendations.

In the fall of 1976, a panel of representatives from many national organizations, including the AHA, met to resolve differences between electrical safety specifications published by the AHA and by the Association for the Advancement of Medical Instrumentation (AAMI). The goal was to present to the American National Standards Institute (ANSI)* a united position on electrical safety. Despite many subsequent meetings involving members of the panel, only minor differences were resolved. Major disagreements have remained, and earlier this year, over the objection of the AHA, ANSI published an American National Standard Safe Current Limits for Electromedical Apparatus. The purpose of this editorial is to describe briefly the differences between the positions of the AHA and ANSI, to explain the significance of the differences, and to state the position of the AHA Committee on Electrocardiography on electrical safety.

The Committee believes that all ECG and VCG apparatus must be incapable of delivering more than 10 μA of leakage current to a patient. This magnitude of current is consistent with data from human and animal experiments. Studies on electrically induced fibrillation often deal with the average current required to produce fibrillation in groups of experimental subjects. However, the maximum leakage current allowable in ECG apparatus clearly must be lower than the minimal current needed to induce experimental fibrillation. Minimal current values experimentally resulting in fibrillation range down to about 20 μA; accordingly, a lower value, 10 μA, was selected as the maximum leakage current permissible. Currents of this magnitude or less are considered safe even when applied directly to the heart, as occurs when ECG measurements are made with an intracardiac catheter or postoperatively with a wire conductor attached to the myocardium during surgery.

In contrast, the ANSI standard permits another type of apparatus, the one "with nonisolated patient connection" in which up to 50 μA of leakage is permitted. The justification for this weaker standard is based upon the presumption that in certain clinical settings the requirement for lower value of leakage is unnecessary, and that apparatus with higher leakage is likely to be less expensive. Although the prospect of less expensive electrocardiographic apparatus appealed to members of the panel, no member from the electrocardiographic industry was able to provide any assurance that the cost would be less. Further, virtually all ECG and VCG apparatus produced after the announcement of the AHA recommendations in 1972 meet the 10-μA leakage recommendations of the AHA. In any event, the creation of "safe" and "less safe" categories of apparatus that might be confused by the user was clearly unacceptable to those representing the AHA's clinical interests.

*The American National Standards Institute, a private organization, is the nationally recognized coordinator of voluntary standards development and the clearinghouse for information on national and international standards.

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It has become common practice to avoid a grounding connection of any kind to a patient because a second connection, inadvertent or not, may complete a path for a dangerous electrical current. For example, a grounded or imperfectly grounded pressure sensor connected by a saline column in a catheter to the right ventricle might provide a path for a dangerous 100 μA of current if an ECG technician touched the paper transport mechanism of the ECG apparatus while touching the patient with the other hand. Therefore, the AHA recommends that no more than 10 μA shall flow from patient connections or from any other accessible metallic portion of the ECG or VCG apparatus. In contrast, a current leakage of up to 100 μA from exposed metal is permitted by the ANSI standard.

The AHA recommendations provide that the 10-μA limit on current leakage shall not be exceeded even if 1) single failures occur in the insulation of line-operated components such as the power cord, transformer or chart motor, 2) a single failure occurs in the electronic circuitry closest to the patient, 3) an incorrectly wired three-wire receptacle is used to energize the electrocardiograph, or 4) the power-line ground is disconnected. Further, no pathway between a power-line ground and an electrode may be less than 20-MΩ impedance measured at 60 Hz. It is further recommended that ECG and VCG apparatus be supplied with plugs durable enough to withstand normal hospital use. In contrast to the AHA recommendations, the ANSI standards do not cover the subject of electrical hazards that might accompany faults.

Before the 1972 AHA recommendations dealing with electrical safety, at least four publications noted the occurrence of ventricular fibrillation in humans due to ECG apparatus. There may be more unreported instances. Although no cause-and-effect relationship can be proved, we are unaware of similar incidents after major American manufacturers of ECG apparatus adopted the AHA recommendations.

The Electrocardiography Committee of the AHA urgently recommends that the ANSI standard on Safe Current Limits for Electromedical Apparatus not be applied to ECG and VCG apparatus. The ANSI standard in its present form will encourage the development of ECG apparatus distinctly less safe under normal and fault conditions than contemporary devices meeting AHA recommendations. We therefore urge that all ECG and VCG apparatus purchased for medical practice in this country meet the latest AHA recommendations.

References

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