EDITORIAL

Electrical Safety Standards for Electrocardiographic Apparatus

AMERICAN HEART ASSOCIATION COMMITTEE ON ELECTROCARDIOGRAPHY:
DAVID B. GESELOWITZ, PH.D. (CHAIRMAN), ROBERT C. ARZBAECHER, PH.D.,
ROGER C. BARR, PH.D., STANLEY A. BRILLER, M.D., ANTHONY N. DAMATO, M.D.,
NANCY FLOWERS, M.D., KAY MILLAR, M.D., G. CHARLES OLIVER, M.D.,
ROBERT PLOONEY, PH.D., AND RALPH E. SMITH, M.D.

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.

Address for correspondence: David B. Geselowitz, Ph.D., Pennsylvania State University, 254 Hammond Building, University Park, Pennsylvania 16802.
Received June 6, 1979; revision accepted September 21, 1979. Circulation 61, No. 4, 1980.
It has become common practice to avoid a ground-
ing connection of any kind to a patient because a
second connection, inadvertent or not, may com-
plete a path for dangerous electrical current. For ex-
ample, 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 nor-
mal hospital use. In contrast to the AHA recom-
endations, 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.10-13 There may be more un-
reported 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 Apparatus4 not be
applied to ECG and VCG apparatus. The ANSI stan-
dard in its present form will encourage the develop-
ment of ECG apparatus distinctly less safe under nor-
mal 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.2

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Electrical safety standards for electrocardiographic apparatus.
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Circulation. 1980;61:669-670
doi: 10.1161/01.CIR.61.4.669

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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http://circ.ahajournals.org/content/61/4/669.citation