Technical Information Report

AAMI TIR60: 2014/(R)2019

Common mode rejection in ECG monitoring

AAMI
Advancing Safety in Health Technology

Common mode rejection in ECG monitoring

Approved 24 October 2014 and reaffirmed 11 October 2019 by
AAMI

Abstract: This technical information report (TIR) provides the details of how to correctly build, calibrate, and use the CMR test circuit specified in ECG performance standards. It also preserves the history, rationale, and performance requirements of the test method, as included in ANSI/AAMI EC13:2002, *Cardiac monitors, heart rate meters, and alarms*, which was revised by the adoption and finalization of ANSI/AAMI/IEC 60601-2-27:2011, *Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*.

Keywords: line frequency, CMR, channel noise, cardiac monitor

AAMI Technical Information Report

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

Printed in the United States of America

ISBN 1-57020-567-1

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Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph (ECG) Committee

This technical information report was developed by the ECG Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Electrocardiograph Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Acknowledgments

The AAMI ECG Committee would like to thank Mr. Carl Pantiskas, formerly of Draeger, for providing the guidance and leadership and for insisting that the “Common mode rejection” section from the old ANSI/AAMI EC13:2002, *Cardiac monitors, heart rate meters, and alarms,* be preserved when this standard is replaced by ANSI/AAMI/IEC 60601-2-27:2011, *Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*.

Foreword

The AAMI ECG Committee recently adopted and finalized ANSI/AAMI/IEC 60601-2-27:2011, *Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment,* which replaced ANSI/AAMI EC13:2002, *Cardiac monitors, heart rate meters, and alarms*. In so doing, the ECG Committee members discovered that there are some sections in the EC13 standard which are not present in ANSI/AAMI/IEC 60601-2-27:2011. After much discussion, the committee members decided to preserve the "Common mode rejection" section from the EC13 standard as an AAMI technical information report (TIR). It is hoped that this TIR will be sent to IEC so that this section may be included in the future 60601-2-27 or stand alone as an IEC technical report (TR).

The AAMI ECG Committee develops the U.S. position and votes on ECG-related standards under the purview of the the U.S. technical advisory group (TAG) for IEC/SC 62D, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). The United States made considerable contributions to the ECG-related standards.

AAMI TIR60:2014, *Common mode rejection for ECG monitoring,* is intended to provide guidance on a particular subject matter relating to the ECG monitors.

Common mode rejection for ECG monitoring

1 Scope

This technical information report (TIR) provides the details of how to correctly build, calibrate, and use the CMR test circuit specified in ECG performance standards. It also preserves the history, rationale, and performance requirements of the test method.

2 Background

This TIR was created principally to preserve what was formerly Annex C of ANSI/AAMI EC13:2002 before this standard was replaced and harmonized into ANSI/AAMI/ IEC 60601-2-27:2011 without this information included. It has also been created to preserve the rationale and historical background for minimum CMR performance requirements, to offer references on the range of CMR observed in the past, and to discuss why this fixture appropriately models the conditions encountered in clinical practice – none of which are preserved in the newer international ECG performance standards.

Many U.S. and international ECG performance standards specify the use of a CMR fixture of this design and include the same minimum device CMR performance, but offer little guidance for properly building, calibrating, and using this CMR fixture. This TIR fills that gap.

3 Applicability and use

This TIR can be used with ANSI/AAMI/IEC 60601-2-25, ANSI/AAMI/IEC 60601-2-27, ANSI/AAMI/IEC 60601-2-47, and any other ECG standards that require performing a CMR test.

4 Common mode rejection requirement

The cardiac monitor shall have the capability of rejecting line frequency signal mode interfering voltages as encountered on the surface of the body. A line frequency signal, with 10 V rms source and a 200 picofarad (pF) source capacitance, applied from power ground to all patient electrode connections connected to a common node and with a parallel combination of a 51 kilohm resistor and 47 nF capacitor imbalance impedance in series with each patient lead, including the RL or green lead, if supplied, shall not produce an output signal exceeding 1 mV peak-to-valley (p-v) referred-to-input (RTI) over a 60 second period. The test shall be done while any line frequency notch filter (if provided) is turned off, even if it requires special software or a special method of accessing the control over that filter. This requirement shall be met with sequential shorting of the series-impedance-simulating lead imbalance in each active lead and with a +/- 300 mV dc offset potential placed in series with any patient electrode connection. The manufacturer's recommended patient cable shall be used for verification testing.

NOTE—IEC ECG standards differ from their former ANSI/AAMI ECG counterparts by defining this testing to be done with the 51 kilohm/47 nF series-impedance-simulating lead imbalance in all but one of the active leads being shorted while one of switches S1 – Sn at a time is sequentially opened. Although this different test method gives different performance during individual CMR tests, the worst case performance of the group of all CMR tests is virtually the same with either test method.

NOTE—In conducting a test to verify this capability, undesirable stray and leakage capacitance may result from shielding components and from patient cable capacitances when the cable is connected to the voltage source. The test method takes these capacitances into consideration.