

American  
National  
Standard



ANSI/AAMI  
EC12:2000/  
(R)2020  
Disposable ECG electrodes

# Disposable ECG electrodes

Developed by  
**Association for the Advancement of Medical Instrumentation**

Approved 13 May 2000 and reaffirmed 24 August 2010 and 30 December 2015 and 9 October 2020 by  
**American National Standards Institute, Inc.**

**Abstract:** This standard contains minimum labeling, safety, and performance requirements; test methods; and terminology for disposable electrocardiographic (ECG) electrodes.

**Keywords:** disposable electrodes, ECG monitoring, pregelled, nonpolarizing, electrode system

## AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

**CAUTION NOTICE:** This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

*Published by*

AAMI  
901 N. Glebe Road, Suite 300  
Arlington, VA 22203  
[www.aami.org](http://www.aami.org)

© 2000 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI at 901 N. Glebe Road, Suite 300, Arlington, VA 22203. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

**ISBN 1-57020-139-0**

# Contents

	Page
Committee representation.....	iv
Foreword.....	v
<b>1</b> Scope.....	<b>1</b>
<b>1.1</b> Inclusions.....	<b>1</b>
<b>1.2</b> Exclusions.....	<b>1</b>
<b>2</b> Normative references.....	<b>1</b>
<b>3</b> Definitions and abbreviations.....	<b>1</b>
<b>4</b> Requirements.....	<b>2</b>
<b>4.1</b> Labeling requirements.....	<b>2</b>
<b>4.2</b> Performance requirements.....	<b>2</b>
<b>4.2.1</b> Packaging and shelf life.....	<b>2</b>
<b>4.2.2</b> Electrical performance.....	<b>3</b>
<b>4.3</b> Safety requirements.....	<b>4</b>
<b>4.3.1</b> Biological response.....	<b>4</b>
<b>4.3.2</b> Pre-attached leadwire safety.....	<b>4</b>
<b>4.4</b> Adhesive performance (duration of use).....	<b>4</b>
<b>5</b> Tests.....	<b>4</b>
<b>5.1</b> Labeling.....	<b>4</b>
<b>5.2</b> Performance.....	<b>4</b>
<b>5.2.1</b> Packaging and shelf life.....	<b>4</b>
<b>5.2.2</b> Tests for electrical performance.....	<b>4</b>
<b>5.3</b> Safety.....	<b>6</b>
<b>5.3.1</b> Biological response evaluation.....	<b>6</b>
<b>5.3.2</b> Pre-attached leadwire safety.....	<b>6</b>
<b>5.4</b> Adhesive performance (duration of use).....	<b>7</b>
<b>Annexes</b>	
<b>A</b> Rationale for the development and provisions of this standard.....	<b>8</b>
<b>B</b> Cited references.....	<b>14</b>
<b>Tables</b>	
<b>1</b> Summary of labeling requirements.....	<b>2</b>
<b>2</b> Summary of performance requirements.....	<b>3</b>
<b>Figures</b>	
<b>1</b> Test circuit for offset instability/internal noise determination.....	<b>5</b>
<b>2</b> Defibrillation overload test circuit (all capacitor and resistor values have a tolerance of $\pm 10\%$ ).....	<b>5</b>