Technical Information Report

AAMI TIR26:2000

Ventricular assist and heart replacement systems

AAMI Association for the Advancement of Medical Instrumentation

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Approved 16 October 2000
Association for the Advancement of Medical Instrumentation

Abstract: Provides guidance for gathering data and information to demonstrate the safety and effectiveness of ventricular assist and heart replacement systems for patients with heart dysfunction.

Keywords: electromedical device, ventricular assist device, artificial heart, implants

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Dept., 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

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Printed in the United States of America

ISBN 1–57020–147–1

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Committee representation

Association for the Advancement of Medical Instrumentation

Mechanical Circulatory Support Systems Committee

This technical information report (TIR) was developed by the Mechanical Circulatory Support Systems Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Mechanical Circulatory Support Systems Committee** had the following members:

Cochairs:	Robert T.V. Kung
	John T. Watson
Members:	Edwin F. Bjoro, Quality Assurance/Reliability Consulting Specialist, Fairfax, VA
	O.H. Frazier, MD, Texas Heart Institute
	Leonard A.R. Golding, MD, Cleveland Clinic Foundation
	Robert T.V. Kung, PhD, Abiomed Inc.
	James Lee, World Heart Corporation
	William T. Maloney, MD, American Association for Thoracic Surgery
	Jean E. Rinaldi, U.S. Food and Drug Administration
	Gerson Rosenberg, PhD, M.S. Hershey Medical Center
	Rhona B. Shanker, Medical Device Auditing & Consulting
	Richard G. Smith, Cardiowest Technologies Inc.
	James J. Thompson, Arrow International Inc.
	John T. Watson, PhD, NIH, National Heart, Lung, and Blood Institute
Alternates:	Francisco Arabia, MD, Cardiowest Technologies Inc.
	Alan S. Berson, PhD, NIH, National Heart, Lung, and Blood Institute
	Jal S. Jassawalla, World Heart Corporation
	Jeffrey P. Lewis, Arrow International Inc.

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

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Foreword

This technical information report (TIR) was developed by the Mechanical Circulatory Support Systems Committee of the Association for the Advancement of Medical Instrumentation (AAMI) in cooperation with the American Society for Artificial Internal Organs and the Society of Thoracic Surgeons. In addition, representatives of many other medical and technical organizations, as well as representatives of government agencies, contributed to this effort.

This TIR reflects the conscientious efforts of concerned physicians and clinical engineers, in consultation with device manufacturers, to develop a guidance document for those performance levels that could be reasonably achieved as of this writing.

Ventricular assist devices and total artificial hearts require extensive validation information. This document covers the documentation required to evaluate both the pump and the console for these devices. Manufacturers are encouraged to apply this document according to the unique characteristics of their system or component. For example, recommendations may be modified or omitted for appropriate application to a particular system or component if appropriate scientific justification is provided. Although this document was developed to meet the needs of an expanding body of knowledge and is based on current technology, the committee will periodically revise the criteria to keep them current.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

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Introduction

Heart failure is a major public health problem. According to recent statistics from the American Heart Association, 4.8 million Americans have heart failure, and, in 1996, more than 43,000 Americans died of this disease. The number of new cases is around 400,000 per year (Schocken 1992). Further, heart failure is implicated as a contributing factor in more than 250,000 deaths each year (Yusuf 1992). Overall, hospital admissions for heart failure have increased 10-fold since 1970 (Lorell 1994). Particularly at risk for heart failure are the elderly (≥ 60 years), who account for 70 % of heart failure patients (Haldeman *et al* 1998), and for whom congestive heart failure is the leading cause of hospitalization. Heart failure is the largest diagnosis-related group (DRG) for Medicare payments. However, although the prevalence of heart failure increases with age, almost one-third of patients—1.6 million Americans—contract the disease before the age of 60. The economic costs are enormous; $21 billion is the estimated U.S. cost for treating this condition (American Heart Association 1999). There is a poor prognosis for the Medicare population; about 17 % of men and 24 % of women survive 6 years after their first hospitalization for heart failure (Croft 1999).

Despite recent developments of pharmacologic agents developed specifically to treat advancing heart failure, the prognosis for 1-year survival for patients with class IV heart failure is between 40 % and 50 % (AHA 2000) and about 25 % at 2 years. For the vast majority of these patients, cardiac replacement therapy in the form of cardiac transplantation is the only viable treatment option. According to recent statistics provided by the United Network for Organ Sharing (UNOS), cardiac transplant patients have an in-hospital mortality of less than 5 %, a 1-year actuarial survival rate approaching 85 %, and 5-year survival rates of greater than 70 %. Yet the success of cardiac transplantation remains limited by the complications of chronic immunosuppressive therapy, by the development of accelerated allograft atherosclerosis, and, most important, by the continuing serious shortage of donor organs. An enormous difference remains between the number of Americans annually who might benefit from cardiac transplantation (~15,000–70,000) versus those who actually receive transplants (2,427 in 1997; UNOS). And, because the number of cardiac transplants is not expected to increase appreciably in the foreseeable future, there is considerable interest in developing new therapies for patients suffering from end-stage heart failure.

The Institute of Medicine evaluated the Artificial Heart Program of the National Heart, Lung, and Blood Institute in 1991 (Hogness 1991). The panel concluded that by the year 2010, there could be an annual pool of 35,000 to 70,000 candidates for mechanical circulatory support or some other form of treatment. Surgical procedures such as left ventriculectomy and myoplasty have not led to clinical benefit in most patients. Xenotransplantation using nonhuman hearts is under active investigation. Areas of concern include immunologic response of the host, inadequate performance of the non-human heart, and the possibility of transferring infectious organisms to the host. These agents sometimes have long incubation periods (10–20 years) as seen with human immunodeficiency virus and acquired immune deficiency syndrome (HIV–AIDS). An additional patient group with acutely failing hearts numbering in the tens to 100,000 annually may benefit from artificial heart therapy.

For the foreseeable future, the need for mechanical circulatory support is well defined and growing. This guidance document is intended to assist research teams and manufacturers in producing highly reliable ventricular assist devices and artificial hearts—at a reasonable cost to society—that will provide a good quality of life for patients with heart failure during their remaining lifetimes.

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1 Scope

This document is intended to be a guideline for gathering data and information to demonstrate the safety and effectiveness of ventricular assist and heart replacement systems for patients with heart dysfunction. Manufacturers are encouraged to apply this document according to the unique characteristics of their system or component. For example, some of the evaluations may be modified or omitted if appropriate scientific justification is provided.

This document identifies the preclinical *in vitro*, *in vivo*, and clinical evaluations that should be performed to meet the requirements of the scope of this document.

NOTE—This technical report is considered "informative," and use of the terms "shall," "should," and so forth should be considered within the context of this technical report only. That is, if the decision is made to use these guidelines, then the guidelines should be followed in adherence with the requirements ("shall") and recommendations ("should") as set forth in this technical report.

2 References

The following documents contain provisions that, through reference in this text, constitute provisions of this technical information report (TIR). At the time of publication, the editions indicated were valid. All documents are subject to revision, and parties to agreements based on this Association for the Advancement of Medical Instrumentation (AAMI) TIR are encouraged to investigate the possibility of applying the *most recent editions* of the documents listed below. The Association for the Advancement of Medical Instrumentation maintains a register of currently valid AAMI/American National Standards.

2.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI). *Cardiovascular implants—Vascular graft prostheses*. ANSI/AAMI VP20:1994. Arlington (Vir.): AAMI, 1994. American National Standard.

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI). *Biological evaluation of medical devices—Part 1: Evaluation and testing*. ANSI/AAMI/ISO 10993-1:1997. Arlington (Vir.): AAMI, 1997. American National Standard.

2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI). *Quality systems—Medical devices—Particular requirements for the application of ISO 9001*. ANSI/AAMI/ISO 13485:1996. Arlington (Vir.): AAMI, 1996. American National Standard.

2.4 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI). *Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied*. ANSI/AAMI/ISO 15223:2000. Arlington (Vir.): AAMI, 2000. American National Standard.

2.5 AMERICAN SOCIETY FOR ARTIFICIAL INTERNAL ORGANS (ASAIO). *Long term mechanical circulatory support system reliability recommendation*. *ASAIO J.* 1998. 44:108–14.

2.6 CODE OF FEDERAL REGULATIONS. *Investigational device exemptions*. 21 CFR Part 812. And *Pre-market approval of medical devices*. 21 CFR Part 814.

2.7 CODE OF FEDERAL REGULATIONS. *Federal Food, Drug, and Cosmetic Act*, as amended in February 1998, and related regulations. 21 CFR Parts 800–899.

2.8 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment. Part 1: General requirements for safety, second edition*. IEC 60601-1:1988. Geneva: IEC, 1988.

2.9 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment, Part 1: General requirements for safety—2. Collateral standard: Electromagnetic compatibility—Requirements and texts*. IEC 60601-1-2:1993. Geneva: IEC, 1993.

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