Lessons Learned from Cardiac Pacemakers and ICDs

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In the beginning -

Courtesy of Medtronic, Inc.
Medtronic 5mm bipolar

Cordis 6mm unipolar

Courtesy of Medtronic, Inc.
1.0

INTRODUCTION

This standard, designated VS-1, was developed by a group of pacemaker manufacturers in order to eliminate the need for adapters in connecting the lead of one manufacturer to the pulse generator of a different manufacturer. Adherence to this standard will benefit both the user and the manufacturer. The physician and patient will benefit, since such interconnections will not require the use of any extra components (i.e., the adapter), the cost is reduced, and the reliability and safety of the system is higher without the addition of an adapter. Confusion, mistakes and delays will be eliminated during replacement procedures especially on emergency bases. The manufacturer also benefits, because the expense of designing, manufacturing, and distributing this extra bit of hardware is avoided.
INTRODUCTION

The development of this standard was prompted by the concern of clinicians over the variety of apparently similar but incompatible pacing leads of the low-profile in-line type (frequently referred to as 3.2 mm leads, based on the major diameter of the lead connector area). The purpose of this document is to define a standard connector, IS-1, to provide interchangeability between lead and pulse generators from different manufacturers. The reliability and function of a particular connector part are solely the responsibility of the manufacturers.
**Benefits**

- Few adapters
- Less hardware
- Simplifies change-outs

- Greater patient safety
- Increased confidence

**IS-1 Lead Connector**

*(Unipolar/Bipolar)*

- Connector terminal pin (cathode)
- Lead sealing ring zone
- Optional sealing ring zone in p.g. header cavity
- Lead sealing ring zone
- Lead connector body
- IS-1 markings *("IS-1UNI" or "IS-1 BI")*

*(Nominal dimensions shown in mm)*
ISO 11318

Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements

Introduction

The purpose of this International Standard is to specify a standard connector assembly, DF-1, to provide interchangeability between implantable defibrillator leads and defibrillator pulse generators from different manufacturers. The safety, reliability and function of a particular connector part are the responsibility of the manufacturer.
ISO 27186

Active implantable medical devices —
Four-pole connector system for implantable cardiac rhythm management devices — Dimensional and test requirements

Introduction

The purpose of this International Standard is to specify a four-pin connector assembly to provide interchangeability between implantable leads and pulse generators for cardiac rhythm management from different manufacturers. The safety, reliability, biocompatibility, biostability and function of any particular part are the responsibility of the manufacturer.

The four-pin connector was created to allow for a reduction in the number of individual lead connectors, reduce pocket bulk associated with existing bifurcated or trifurcated leads, reduce interaction of the lead bodies in the pocket and reduce set screw connections.

This International Standard establishes two types of connector assembly: a “high voltage connector” and a “low voltage only connector”, each of which has several configurations. The high voltage connectors either have two low voltage contacts combined with one or two high voltage contacts, or they have only two high voltage contacts. The low voltage only connectors have either three or four low voltage contacts.
When things are going well, is it time to sit back and chill?
Opportunity yet unrealized
Opportunity yet unrealized………..

Case for a universal programmer.
Questions?
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