



F2172-02 (Reapproved 2011)

**Standard Specification for
Blood/Intravenous Fluid/Irrigation Fluid Warmers**



CONTENTS

INTRODUCTION	Page 3
SECTION ONE - GENERAL	
Clause	
1 Scope and object	4
2 Terminology and definitions	5
3 General requirements	6
6 Identification, marking and documents	6
SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	8
SECTION SEVEN - PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	8
45 Pressure vessels and parts subject to PRESSURE	9
SECTION EIGHT - ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT	
50 Accuracy of operating data	9
51 Protection against hazardous output	10
SECTION NINE - ABNORMAL OPERATION AND FAULT CONDITIONS: ENVIRONMENTAL TESTS	
52 Abnormal operation and fault conditions	12
SECTION TEN - CONSTRUCTIONAL REQUIREMENT	
56 Components and general assembly	14
Appendix/Annexes	
L References - Publications mentioned in this standard	15
AA Rationale to particular sub-clauses	16
BB Test method for hemolysis	19



In this Specification Standard, the following print types are used:

requirements, compliance with which can be tested, and definitions: in roman type.
 explanations, advice, introductions, general statements, exceptions and references: in smaller type.
test specifications: in italic type.
 TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN
 CLAUSE 2 AND IN IEC 601-1: SMALL CAPITALS.

INTRODUCTION

This Standard Specification amends and supplements IEC 601-1 (second edition, 1988): *Medical electrical equipment - Part 1: General requirements for safety*. as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the General Standard (see 1.3).

This Standard Specification is necessary because of the special attention which has to be given to FLUID WARMERS, which are frequently used for PATIENTS in operating theaters, intensive care units, and other situations.

Additional requirements for safety, beyond those stated in the General Standard, are specified.

While *K* (degree Kelvin) is the recognized unit and symbol for absolute temperature and temperature difference, nevertheless the ° C has been used throughout this Specification Standard because all measurements will commonly be made using equipment marked with the Celsius temperature scale.

An asterisk (*) by a clause or sub-clause number indicates that some explanatory notes are given in annex AA at the end of this Specification Standard.



MEDICAL ELECTRICAL EQUIPMENT -

Part 2: Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers

SECTION ONE - GENERAL

The clauses and sub-clauses of this section of the General Standard apply, except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Standard Specification specifies requirements for FLUID WARMERS as defined in 2.2.101.

1.2 Object

Addition:

The object of this Standard Specification is to establish requirements for FLUID WARMERS which minimize hazards to PATIENT and OPERATOR and to specify tests by which compliance can be verified.

1.3 Particular Standards

Addition:

This Standard Specification refers to IEC 601-1 (1988): *Medical electrical equipment - Part 1: General requirements for safety, as amended by its amendments 1(1991) and 2 (1995).*

For brevity Part 1 is referred to in this Standard Specification either as the General Standard or as the General requirement(s).

The numbering of sections, clauses and sub-clauses of this Standard Specification corresponds to that of the General Standard.

The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or sub-clause of the General Standard is replaced completely by the text of this Standard Specification.

“Addition” means that the text of this Standard Specification is additional to the requirements of the General Standard.

“Amendment” means that the clause or sub-clause of the General Standard is amended as indicated by the text of this Standard Specification.



Sub-clauses or figures which are additional to those of the General Standard are numbered starting from 101. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

The term "this Standard" is used to make a reference to the General Standard and this Standard Specification taken together.

Where there is no corresponding section, clause or sub-clause in this Standard Specification, the section, clause or sub-clause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Standard Specification.

1.101 *Equipment excluded*

This Standard Specification does not apply to:

- Non-inline fluid warmers, e.g. warming cabinets, fresh frozen plasma/frozen red cell thawing devices, electric bowl heaters
- Extracorporeal / open-heart bypass warming circuits
- Fluid warmers integral to dialysis units

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1 *EQUIPMENT Parts, Auxiliaries and ACCESSORIES*

Additional definition:

2.1.101 *FLUID PATH*

The channel through which the product intended for PATIENT infusion or irrigation flows in-line (through a closed pathway) from its source (e.g., blood bag, intravenous solution bag, or irrigation fluid bag) to the PATIENT. The fluid path is an APPLIED PART.

2.2 *EQUIPMENT types (classification)*

Additional definitions:

2.2.101 *FLUID WARMER*

EQUIPMENT intended to warm fluid as it passes in-line (through a closed pathway) from its source (e.g., blood bag, intravenous solution bag, or irrigation fluid bag) to the PATIENT. This includes:

- In-line blood warmers
- In-line intravenous fluid warmers
- In-line irrigation fluid warmers

2.10 *Operation of EQUIPMENT*

Additional definitions:

*2.10.101 *SET POINT TEMPERATURE*

The temperature, which may be OPERATOR adjustable, used by the FLUID WARMER as the desired temperature



of the blood, Intravenous solution or irrigation fluid.

2.10.102 ACTIVE CONTROLLED TEMPERATURE

The temperature displayed by the FLUID WARMER and derived from a sensor in the FLUID WARMER.

2.10.103 OUTPUT FLUID TEMPERATURE

The temperature of the fluid at the exit of the FLUID PATH.

2.12 Miscellaneous

Additional definition:

2.12.101 HEMOLYSIS

Alteration, dissolution, or destruction of red blood cells in such a manner that hemoglobin is released into the medium in which the cells are suspended.

2.12.102 RISK ASSESSMENT

Overall process of risk analysis and risk evaluation (ISO/IEC Guide 51: 1999, definition 3.12)

2.12.103 HEAT TRANSFER FLUID

A liquid or gas used to indirectly transfer heat to the blood, intravenous solution or irrigation fluid.

3 General requirements

This clause of the General Standard applies except as follows:

- 3.6 The following SINGLE FAULT CONDITIONS are the subject of specific requirements and tests in this Standard.

Additional item:

- aa) contact between a PATIENT and the HEAT TRANSFER FLUID caused by a leak from the device (see Section Three).

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Additional items:

- aa) FLUID WARMERS

EQUIPMENT or EQUIPMENT parts shall be marked as follows:

- 1) Where appropriate: to warn against possible SAFETY HAZARDS from penetration by sharp objects.
- 2) To specify, in the case of EQUIPMENT parts supplied or controlled by an external sensing device, that