



F 2196-02

**Standard Specification for
Circulating Liquid and Forced Air Patient
Temperature Management Devices**



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*INTRODUCTION

This Particular Standard is necessary because attention needs to be given to features of PATIENT TEMPERATURE MANAGEMENT DEVICES for FORCED AIR DEVICES and CIRCULATING LIQUID DEVICES which are used to warm PATIENTS in operating rooms, intensive care units and other areas of health care facilities, often when the PATIENT may be unable to react if excessive temperatures were to be produced.

It has been estimated that CIRCULATING LIQUID DEVICES and FORCED AIR DEVICES are used at least 7 million times a year in the USA alone. Although these devices have an extraordinarily safe history, their ever-increasing utilization (as well as their relative ease of application) in preventing or treating hypothermia indicates the need for a standard dealing with their essential requirements.

This particular specification amends and supplements IEC (International Electrotechnical Committee) 60601-1 and its amendments, henceforth known as the "General Standard," Additional requirements, beyond those stated in the General Standard, are specified.

This particular standard addresses the limitations of IEC 60601-2-35: "Particular requirements for the safety of blankets, pads, and mattresses, intended for heating in medical use," specifically in the area of FORCED AIR DEVICES and the test procedures for CIRCULATING LIQUID DEVICES. These sections have been updated to reflect current safety requirements for these devices.

This particular standard also addresses the limitations of ASTM C1055-99, "Standard Guide for Heated System Surface Conditions that Produce Burn Injuries", specifically in the area of FORCED AIR DEVICES, which has been updated to reflect the current safety requirements for these devices in health care institutions.

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

A rationale for the most important requirements is given in Annex AA. An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in Annex AA. Annex AA is for information only.

Annexes BB, CC, DD, EE, FF, GG, and HH form an integral part of this Particular Standard.

In this Particular 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 60601-1: SMALL CAPITALS.
- This Particular Standard is intended to address the specifications for two similar, but distinct, technologies: FORCED AIR DEVICES, and CIRCULATING LIQUID DEVICES. For clauses of this Particular Standard that apply to both technologies, the clause will not be specifically entitled. For clauses that are related to FORCED AIR DEVICES, the clause will be entitled as such. For clauses that relate to CIRCULATING LIQUID DEVICES, the clause will be entitled as such.



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MEDICAL ELECTRICAL EQUIPMENT

Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices

SECTION ONE - GENERAL

The clauses and subclauses 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 particular Standard is limited to the use of the specified devices for warming only.

1.2 Object

Addition:

The object of this Particular Standard is to establish requirements for PATIENT TEMPERATURE MANAGEMENT DEVICES, which minimize hazards to PATIENT and OPERATOR and to specify tests by which compliance can be verified.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1: *Medical electrical equipment - Part 1: General requirements for safety*.

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

The numbering of sections, clauses and subclauses of this Particular Standard 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 subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses 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 Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause 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 Particular Standard.

***1.101 Equipment excluded**

This Particular Standard does not apply to:

- CONTROLLERS or BLANKETS intended for physiotherapy,
- radiant warmers,
- incubators,
- electric BLANKETS
- cooling devices

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.2 Equipment types (classification)

2.2.101 CONTROLLER

Device, which includes the HOSE, intended to supply, regulate, and transfer thermal energy to a BLANKET.

2.2.102 BLANKET

APPLIED PART intended to be used with a CONTROLLER to transfer thermal energy to all or part of the body of a PATIENT.

2.2.103 LOW PRIORITY ALARM

A visual signal, or a combination of audible and visual signals indicating that operator awareness is required. (Reference: ASTM F 1463 – 93 (Reapproved 1999) Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care)

2.12 Miscellaneous

Additional subclause:

2.12.101 CONTACT SURFACE TEMPERATURE

The temperature resulting from the heat transferred to a target surface by the APPLIED PART.

Note: The CONTACT SURFACE TEMPERATURE is measured by the test methods described in Annexes BB, CC, DD, EE, FF, and GG .



2.12.102 FORCED AIR DEVICE

PATIENT TEMPERATURE MANAGEMENT DEVICE that uses air as the heat transfer medium to warm a patient and is comprised of a CONTROLLER and a BLANKET.

2.12.103 CIRCULATING LIQUID DEVICE

PATIENT TEMPERATURE MANAGEMENT DEVICE that uses circulating liquid as the heat transfer medium to warm a patient and is comprised of a CONTROLLER and a BLANKET.

2.12.104 FREE-HOSING

Hazardous practice or condition of using the CONTROLLER without a BLANKET

2.12.105 PATIENT TEMPERATURE MANAGEMENT DEVICE

Heat-transfer system using EQUIPMENT intended to raise and maintain patient temperature

2.12.106 HOSE

Component of the CONTROLLER that is the conduit for the heat transfer medium to and/or from the BLANKET.

2.12.107 NOZZLE

The end of the HOSE that connects to the BLANKET

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) FORCED AIR DEVICE used for warming*

A. A BLANKET shall be marked to indicate how it is intended to be oriented in NORMAL USE.

B. The HOSE shall be marked within 15 cm of the BLANKET end of the HOSE to caution that the HOSE NOZZLE must be connected to a BLANKET. The marking shall include the symbol shown in Annex HH.

bb) CIRCULATING LIQUID DEVICES

A. A BLANKET shall be marked to indicate how it is intended to be oriented in NORMAL USE.

6.3 Marking of controls and instruments

Addition to 6.3 b):

- Each heated temperature control position shall be LEGIBLY marked in degrees C.



6.8 ACCOMPANYING DOCUMENTS

6.8.1 General

Addition:

The following shall be included in full in the ACCOMPANYING DOCUMENTS (see also 6.1 d) of the General Standard):

- all markings specified in 6.1

aa) CONTROLLERS

For FORCED AIR DEVICES:

- markings to caution that the HOSE NOZZLE must be connected to a BLANKET. The following statement shall accompany the “NO FREE HOSING” symbol shown in ANNEX HH:

“CAUTION! Hose Nozzle MUST be connected to a compatible Forced Air Blanket or thermal injury may occur.”

6.8.2 Instructions for use

Additional item:

* 6.8.2 aa) CONTROLLERS

The instructions for use shall additionally contain the following:

- a description of system operating modes and patient conditions where the system can be safely used;
- a statement that the OPERATOR should monitor the temperature of the PATIENT at regular intervals;
- if appropriate, a caution that the HOSE, if allowed to contact the patient, may lead to thermal injury.
- for FORCED AIR DEVICES
 - a caution that the HOSE NOZZLE must be connected to a BLANKET and that non-observance may lead to thermal injury;
 - a warning against using the device during aortic cross clamping and that non-observance may lead to thermal injury;
 - a warning describing the possible SAFETY HAZARDS of using the device with ischemic limbs and that non-observance may lead to thermal injury.
 - a warning describing the possible thermal injury hazards of patient contact with the HOSE, if applicable



* 6.8.2 bb) BLANKETS

The instructions for use shall contain the following:

- a description of system operating modes and patient conditions where the system can be safely used;
- a statement that the OPERATOR should monitor the temperature of the PATIENT at regular intervals;
- An indication of how the BLANKET is to be positioned during normal use, e.g.:
 - over the PATIENT;
 - under the PATIENT;
 - directly in contact with the PATIENT;
 - separated from the PATIENT by an intermediate layer, or layers, of material ;
 - whether it has to be used flat (without creases),
 - whether it can be wrapped around the PATIENT.
- a statement identifying which CONTROLLER(S) can be used safely with the BLANKET. The description shall include, as applicable, the CONTROLLER model number, revision level, product version, options or any other element that could affect the safety of the combination.

for FORCED AIR DEVICES:

- a warning against using the device during aortic cross clamping;
- a warning describing the possible SAFETY HAZARDS of using the device with ischemic limbs;

for CIRCULATING LIQUID DEVICES:

- a warning that the use of materials of good thermal conductivity, such as water, gel and similar substances on the BLANKET, with the CONTROLLER not switched on may decrease the temperature of a PATIENT;
- a warning against folding or methods of storage, other than those specified by the manufacturer, if a SAFETY HAZARD could result or if this could affect the useful life of the BLANKET.

*6.8.2 cc) Temperature sensors

- Temperature sensors required for temperature control which are designed to be attached to or inserted into a PATIENT shall have their intended use identified.



SECTION THREE - PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

*19.2 SINGLE FAULT CONDITIONS

Addition to 19.2 a):

For CIRCULATING LIQUID DEVICES:

- perforation of a BLANKET heated by circulation of liquid from a CONTROLLER. The liquid is replaced by isotonic water (0,9 g sodium chloride per litre of water). The PATIENT LEAKAGE CURRENT is measured using an electrode 5 mm x 5 mm positioned in the saline in contact with the surface which provides heat to the liquid.

19.4 Tests

h) Measurement of the PATIENT LEAKAGE CURRENT

9) *Replacement:*

An APPLIED PART consisting of a surface of insulating material is tested using metal foil as mentioned in 19.4 g) 5).

- *for a BLANKET large enough for a PATIENT not to be in contact with the whole surface, a foil of area 100 cm x 30 cm is used;*
- *for a BLANKET whose area is less than 100 cm x 30 cm, the whole BLANKET is covered by foil.*

SECTION FOUR - PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of the General Standard apply, except as follows:

* 21 Mechanical strength

This clause of the General Standard applies except as follows:

* 21.102 Circulating liquid BLANKETS using bonded constructions, shall demonstrate no separation of layers after being submitted to a pressure of 110 % of the maximum operating pressure for 2 hours.

NOTE - Bonded means welded or glued

Compliance is checked by

1. *Determine maximum operating pressure of system by connecting BLANKET to be tested to CONTROLLER. Monitor pressure on the inlet of BLANKET. Occlude return line and note maximum pressure reading.*
2. *Connect BLANKET to separate temperature controlled water supply capable of delivering sufficient flow to produce a pressure at the inlet to the BLANKET equal to 110% of maximum operating pressure as determined in previous step.*
3. *Adjust water temperature to maximum allowable from CONTROLLER.*
4. *Maintain pressure and temperature for a period of 2 hours.*
5. *BLANKET must not leak during this time.*