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Aktivni medicinski pripomočki za vsaditev – Posebne zahteve za aparate srce-pljuča (HLM)

Active implantable medical devices - Particular requirements for Heart-Lung Machines (HLM)

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Active implantable medical devices - Particular requirements for Heart-Lung Machines (HLM)

(to be completed)

Medizinische elektrische Geräte - Besondere Anforderungen für die Sicherheit von Herz-Lungen-Maschinen (HLM)

This draft European Standard is submitted to CENELEC members for CENELEC enquiry.
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It has been drawn up by Technical Committee CENELEC TC 62.

If this draft becomes a European Standard, CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Foreword

This draft European Standard was prepared by the Technical Committee CENELEC TC 62, Electrical equipment in medical practice . It is submitted to the CENELEC enquiry.

This draft European Standard is to be read in conjunction with EN 60601-1. Where the "General Standard" is quoted, this means a reference to the latest version of EN 60601-1.

Subclauses which are additional to those in EN 60601-1 are numbered starting from 101.

Section 1 - General

1 Scope and object

This clause of the General Standard applies except as follows:

***Addition*:**

This particular Standard applies to HEART-LUNG-MACHINES (HLM) as defined in 2.104, hereinafter referred as HLM.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Replacement:

2.1.5
applied part

the TUBING SET and or all parts permanently and conductivity connected to it and/or to the PATIENT

Addition:

2.101
arterial blood-pump

the pump for transportation of blood in an EXTRA-CORPOREAL CIRCUIT

2.102
pressure monitoring

device for monitoring pressure, consisting of a sensor, alarm and display

2.103
gas flow device

device for the setting/display of a constant volume gas flow

2.104
heart lung machine (HLM)

device which, partially or totally, takes over the pumping function of the heart and the gas exchange function of the lungs for a short time in order to maintain the vital functions of the body, hereinafter referred to as HLM

2.105
console

the base unit for the reception of the functional units and the ACCESSORIES of the HLM

2.106
air detector

means for the detection of air bubbles consisting of a sensor and an alarm

2.107
level monitoring

device for monitoring a specified liquid level, consisting of a sensor and alarm

2.108
oxygenator

device for the purpose of replacing the gas exchange function of the lungs

the content is in accordance with the definition shown in 3.1 of EN 12022

2.109
pump for cardioplegic solutions

means for the transportation of cardioplegic solutions

2.110
suction pump

pump which enables suction by creating low pressure

2.111
suction device

device for sucking of blood and other liquids

2.112
temperature device

device for monitoring the temperature in the cardiopulmonary bypass and/or to PATIENT, comprising of a sensor, an alarm and a display

2.113
heater/cooler device

device for maintaining, reducing or increasing the body core temperature by controlling the blood temperature in the EXTRA-CORPOREAL CIRCUIT

2.114
data interface

normative reference to CEN/TC 251

2.115
protective device

means which senses a specified parameter (or parameters) or a constructional feature specifically designed to protect the PATIENT against SAFETY HAZARDS which may arise

2.116
tubing set

means for connecting the functional parts of the HLM with each other and the PATIENT'S circulation by TEMPERATURE DEVICE, HEATER/COOLER DEVICE, PROTECTIVE DEVICE, to the HLM

2.117
venous return flow set

means to adjust the venous back flow from the PATIENT

2.118
extracorporal circuit

blood circuit between venous and arterial blood access points

2.119
arterial line blood filter

accessory device used as part of the cardiopulmonary bypass system in the atrerial blood return line for filtering particles such as blood clots, debris and gas emboli from the blood (see ISO 15675)

3 General requirements

This clause of the General Standard applies except as follows:

3.6 ***Addition :***

3.6 ja) Failure of a PROTECTIVE DEVICE (see 51.112)

3.7.101 Air in the TUBING SET

4 General requirements for tests

This clause of the General Standard applies in full.

5 Classification

This clause of the General Standard applies except as follows:

5.3 ***Addition:***

HLM shall have a minimum IPX4 degree of protection against ingress of water (see EN 60529).

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.8.2 ***Instruction for use***

Addition:

aa) The instructions for use shall additionally:

1) contain information that the HLM is a fail live system and its safe use cannot be ensured by technical means only. Therefore the knowledge and skills of the perfusionist are crucial (see Annex AA);
2) if applicable, contain a statement regarding the connection of the POTENTIAL EQUALISATION CONDUCTOR;
3) draw the attention of the OPERATOR to the potential SAFETY HAZARD arising from improper connection of the TUBING SET;
4) draw the attention of the OPERATOR to the potential SAFETY HAZARD arising from improper use of the HLM;

5) contain a statement that the mechanical stability of the HLM may be impaired if the limits of the stated SAFE WORKING LOAD are exceeded;

6) if applicable, describe at least one method of setting the occlusion;

7) draw attention to the safety hazards caused by setting the wrong occlusion;

8) describe safety hazards caused by incorrect connection to the gas supply unit;

9) describe the adjustment of the alarm limits for each PROTECTIVE DEVICE;

10) contain a description of the tests necessary to check the integrity of TUBING SET;

11) draw the attention of the OPERATOR to the precautions necessary to check the proper function of the HLM prior to use;

12) describe the safety hazards caused by incorrect selection of the TUBING SET diameter;

13) contain a statement that proper blood oxygenation has to be checked using an independent means (e.g. measurement of blood gases or oxygen saturation);

14) provide all data interface information;

15) explain the procedure to be used in the case of an ARTERIAL PUMP accidental stop;

16) explain at least one method of removing air from the arterial line;

17) if applicable, contain information regarding the flow rate accuracy for each recommended tubing set.

Compliance is checked by inspection.

6.8.3 *Technical description*

Addition:

The technical description shall additionally:

1) describe the particular measures to be taken or conditions to be complied with when installing the HLM or bringing it into service. This shall include guidance on the type and number of tests to be performed;

2) describe the range of sound pressure level of any adjustable audible alarm source;

3) describe the audible alarm silence period;

4) describe the override time(s) for any PROTECTIVE DEVICE;

5) recommend that the HLM is connected to an uninterruptible power source.

Compliance is checked by inspection.

Section 2 - Environmental conditions

The clauses and subclauses of this section of the General Standard apply.

Section 3 - Protection against electric shock hazards

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

19 Continuous LEAKAGE CURRENT and PATIENT AUXILIARY CURRENTS

19.4 Tests

Addition:

h) Measurement of the PATIENT LEAKAGE CURRENT

101) Measurement of the PATIENT LEAKAGE CURRENT shall be made from the APPLIED PART filled with saline solution.

The point of measurement shall be where the APPLIED PART lines are connected. For the duration of the test, a test solution with a conductivity of (13,5 ± 0,5) mS/cm at a temperature of 25 °C shall be flowing in the APPLIED PART circuit. The EQUIPMENT shall be fully equipped for the intended use as specified by the manufacturer.

Section 4 – Protection against mechanical hazards

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

22 Moving parts

22.4 *Amendment:*

Moving parts of the HLM which may cause physical injury to the OPERATOR/perfusionist shall be guarded by shielding which can only be removed by intentional operation.

Compliance is checked by inspection.

24 Stability in NORMAL USE

Requirements for additional loads under consideration.

Section 5 – Protection from unwanted or excessive radiation

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

36 Electromagnetic compatibility

Addition:

36.101 Immunity

If the HLM is exposed to a radiated radio frequency electromagnetic field, the HLM shall

a) continue to perform its intended function as specified by the manufacturer up to and including a radiated electromagnetic field level of 3 V/m; and

b) continue to perform its intended function as specified by the manufacturer or fail without creating runaway/change of pump direction at a radiated electromagnetic field level of up to 10 V/m.

Section 6 – Protection against hazards flammable anaesthetic mixture ignition

The clauses and subclauses of this section of the General Standard apply.

Section 7 – Protection against excessive temperatures and other SAFETY HAZARDS

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

46 Human errors

Addition:

NOTE The essential purpose of the HLM is to maintain blood circulation to the PATIENT and the competance of the perfusionist is paramount to the safe operation of the HLM.

49 Interruption of the power supply

This clause of the General Standard applies except as follows:

Addition:

49.101 *In the event of a POWER SUPPLY interruption of the to the HLM, the following safe conditions shall be achieved:*

a) an audible alarm shall be activated, for at least 1 min;

b) it shall be possible to operate the ARTERIAL PUMP using an alternative power supply source or by manual means.

Compliance is under consideration.

Section 8 – Accuracy of operating data and protection against hazardous output

This clause of the General Standard applies except as follows:

50 Operating data accuracy

50.2 *Control and instrument accuracy*

Addition:

The ARTERIAL PUMP shall produce the blood flow specified by the manufacturer over the specified operating range using the recommended TUBING SET AND OXYGENATOR.

Compliance is checked by volumetric measurement.

50.2.101 The accuracy of the blood TEMPERATURE DEVICE in the HLM shall be ± 0,5 °C or better.

Compliance is checked by taking a reference measurement in the fluid next temperature sensor.

50.2.102 If the device for measuring the patient core temperature is part of the HLM it shall be in accordance with EN 12470 [1)].

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1) At draft stage.