EN 50637 - Medical beds for children

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January 2020

In 2009, from the joint work between IEC and ISO, the IEC 60601-2-52 standard "Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds" was published.
IEC 60601-2-52, which has also been published as an EN standard and has had several amendments over the years, applies to medical beds intended for adults.
The document has been included in the list of harmonized standards and can therefore be used, in combination with other applicable standards, to presume compliance with the directive on medical devices.
The purpose of the standard is to define the particular requirements relating to the basic safety and essential performance of medical beds intended for adults.
When we speak of a medical bed, we refer to a "device, for which the intended use is sleep/rest, consisting of a mattress support platform having the function of assistance during diagnosis, monitoring, prevention, treatment, alleviation of suffering or compensation for an injury or physical handicap ".

Being a standard created to regulate the safety aspects of adult beds, over the years there has been the problem of regulating the safety aspects related to medical beds for children.
From an analysis conducted by the competent authorities of the European standardization commission, it has been realized that the current set of standards is not suitable for the needs of children or adults with an atypical anatomy.
Part of the safety issue is due to the fact that adult medical beds are not properly labeled as "designed only for adults with a normal anatomy". Therefore, users are not always aware of the risk that adult medical beds used by young patients or adults with atypical anatomy can present.

In order to prevent the entrapment of these subjects in medical beds and the entrapment of children in medical cots, EN 50637 was published in 2017 "Medical electrical equipment - special requirements for the basic safety and essential performance of medical beds for children".
The standard covered the request to specify technical requirements, in particular as regards the distance between the bars of the side rail, so that the beds can be safely used by children and adults with atypical anatomy.
The latter are those patients who do not fall within the "adult patient" parameters defined by the standard: "patient with a physical size equal to or greater than 146 cm (height), mass equal to or greater than 40 kg and body mass index (BMI) equal to or greater than 17".
On the other side, for the purposes of the standard, a child is defined as a "patient with a physical size equal to or less than 155 cm (height) and a mass equal to or less than 70 kg.

In a normative annex of EN 50637 the working group that developed the standard recognizes that the defi-

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nitions of the terms “adult” and “child” are based on physical characteristics which vary from one country to another. In order to achieve high levels of safety for patients and operators, we need to rely on the “caregivers” (a English term that has now has become international and which describes the persons who cares for one or more people requiring assistance - as sick, disabled, elderly and children) to use their professional judgment to differentiate the needs of children from those of adults in relation to medical equipment, taking into account not only the individual physical, psychological and medical needs, but also the patient preferences.

The dimensional requirements of this particular standard are based on anthropometric data.
The average length of about 145 cm correspond to the age of 12 in different countries such as Japan, China and Hungary. In the Netherlands, the height of 12 year-old boys and girls correspond to 156 cm (CHILDATA The Handbook of Child Measurements and Capabilities, Department of Trade and Industry, Consumer Safety Unit). The 97th percentile weight of a 12 year old girl in the Netherlands is 62 kg.

The use of EN 50637 is not simple since it is a very specific standard and therefore the interpretation and application of the requirements must always be considered in combination with the general standard IEC 60601-1 “Medical electrical equipment - Part 1: General requirements relating to fundamental safety and essential performance “.
The standard applies to medical beds with an internal length up to 180 cm, suitable for a body length up to 155 cm. The 180 cm limit is set to minimize the misuse of a parent who divides the bed with a child or when the bed is used by an adult. If a manufacturer wishes to produce a bed that can be used by a child and by an adult at the same time, i.e. with a length of 180 cm or more. In conclusion the product will have to comply with both EN 60601-2-52 and this particular standard (EN 50637).

In any case it must be also reported that EN 50637 does not apply to:
- incubators, covered by EN 60601-2-19;
- children’s beds, covered by EN 716-1 and EN 716-2;
- cots, covered by EN 1130 (all parts);
- bunk beds and high beds, covered by EN 747-1 and EN 747-2.

The fields of application provided by EN 50637 are therefore the following:

Application environment 1: INTENSIVE CARE managed in hospitals where 24 h medical supervision is provided with constant support to maintain or improve the patient’s vital functions, such as by the use of intensive care beds.

Application Environment 2: ACUTE CARE managed in hospitals or other healthcare facilities where medical supervision is required and procedures and equipment are often used to improve the patient condition.

Application environment 3: LONG TERM CARE managed in a medical structure where medical supervision may be required and monitoring and procedures may be used to maintain or improve the patient’s condition.
This includes the use of beds for inpatient nursing homes and rehabilitation.

Application environment 4: CARE PROVIDED AT HOME, for example a bed used in home care to alleviate or compensate for disabilities, injuries, illness.

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In a note of the standard, it is specified that when the medical device is designed exclusively for an area of application 4, all other areas of use are excluded.

Application environment 5: AMBULATORY ASSISTANCE in hospitals or other healthcare facilities, under medical supervision, where the device is used for the treatment, diagnosis or monitoring of diseases, injuries or disabilities.

Also in this standard, as in IEC 60601-2-5, great importance has been given to the patient safety, in particular to the potential risks of entrapment and strangulation.
The term "entrapment" identifies an event in which a patient is captured, trapped or stuck in spaces inside or around the side rails, mattress or bed frame.
The document contains a series of dimensions with purpose of narrowing the openings inside and around the bed system so that the parts of the human body cannot easily pass through it.
All prescriptions related to potential traps have been elaborated on the basis of available anthropometric data referring to the neck diameter, chest width, head diameter, head width, jaw width, face, feet width, etc., trying to cover all the different percentiles.

Another fundamental prescription considered, to ensure the safety of the patient, is the height and minimum length of the side rails to ensure protection against involuntary falls (involuntary sliding or rolling outside the mattress).
In any case, the side rails are considered very critical and compliance with the established dimensional requirements is not considered sufficient to avoid the different dangers for the patient. In fact, the same minimum height requirement could increase the risk of injury if a patient climbs and falls.
For this reason, the requirement to evaluate all potential related problems has been added
by means of the Risk Analysis.
The definition of minimum dimensions, both in terms of height and length of the side rails, is an attempt to define the best compromise between the different risks.
Moreover, the standard contains a series of tests: static load, durability and impact, to verify the resistance of the side rails and the reliability of the locking mechanism of the side rails and the lifting bracket.
In addition to the requirements and checks relating to the electrical, mechanical, radiation, electromagnetic compatibility, water ingress, cleaning, disinfection, etc., the manufacturer must also perform and comply with a series of tests to ascertain the safety and mechanical strength of the bed with static resistance and durability tests, impacts on the mattress support platform, load on the edge of the mattress support platform, durability of the mobile sections of the platform, etc.

Tests are also required to verify bed instability in various situations and the standard defines requirements referring to the minimum and maximum angles between the mobile section of the backrest and the section of the legs / upper part of the legs.

Marking, warnings and safety notices to be provided are dealt with in detail in the standard.
Currently, by decision of IEC TC 62, the joint working group (JWG) between IEC and ISO is working to implement the European standard as an IEC (International Electrotechnical Commission) standard.

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