New standard for medical beds - EN 60601-2-52
What will be covered in this presentation?

1. What is IEC
2. History of medical bed standards
3. Areas of use
4. When the new standard will come into place
5. The 7 key elements of the standard
6. Overview
7. FAQ’s
What is IEC?

IEC stands for International Electrotechnical Committee

The world’s leading organisation for the preparation and publication of International Standards for all electrical, electronic and related technologies
History of medical bed standards

1996 – IEC 60601-2-38
First international bed standard published for electrically operated hospital beds

2000 - EN 1970
The additional European standard was published which focused on adjustable beds for disabled people

Over the last decade, a number of incidents have occurred with patients becoming entrapped in the side rails of medical beds
New standard for medical beds - IEC 60601-2-52

2010 – IEC 60601-2-52

• Approved by IEC and ISO members

• Covers homecare, nursing home and hospital beds

• Put in place to ensure patient safety

• Also ensures essential performance of all medical beds
Areas of use

Application environment 1 (Hospital intensive 24h supervision)
Intensive/critical care provided in a hospital where 24 h medical supervision and constant monitoring is required and provision of life support system/equipment used in medical procedures is essential to maintain or improve the vital functions of the patient.

Application environment 2 (Hospital/medical facility, acute and medical supervision)
Acute care provided in a hospital or other medical facility where medical supervision and monitoring is required and me equipment used in medical procedures is often provided to help maintain or improve the condition of the patient.

Application environment 3 (Medical area, Long Term Care)
Long term care in a medical area where medical supervision is required and monitoring is provided if necessary and me equipment used in medical procedures may be provided to help maintain or improve the condition of the patient.
NOTE: This includes use in nursing homes, rehabilitation and geriatric facilities.

Application environment 4 (Domestic Care: Ergonomic req. are normative))
Care provided in a domestic area and me equipment is used to alleviate or compensate for an injury, disability or disease.
NOTE: This excludes use in all other application environments (e.g. nursing homes, rehabilitation and geriatric facilities) when a medical bed is purely designed for application environment 4.

Application environment 5 (Ambulatory)
Outpatient (ambulatory) care, which is provided in a hospital or other medical facility, under medical supervision and me equipment, is provided for the need of persons with illness, injury or disability for treatment, diagnosis or monitoring.
When is the new standard going to be enforced?

• Approved 1st April 2010
• Enforced 1st April 2013

Responsible
• Manufacturers of medical beds must comply to the requirements of the new standard
The 7 key elements of the new bed standard
Element 1

Changes in the gaps and clearances of side rails

- Calculated looking at a percentile of an adult male and female head, neck and chest dimensions

- Minimum 22cm distance between top of mattress and top of side rails
- Less that 6cm or more than 31.8cm gap between side rails and bed ends
- Less than 12cm gap between side rail bars and mattress platform and bottom rail
• A **wedge tool** is used for testing
• Tests the 60mm distance and V-shaped openings
Element 1 cont.

Wedge tool examples

FAIL

PASS

FAIL
Element 2

- Side-rails must with-hold a force of **250N/ 25.5kg** between all the bars
- Includes the lower bar and the bed frame

<table>
<thead>
<tr>
<th>Standard</th>
<th>Force</th>
<th>Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>En 1970</td>
<td>30N</td>
<td>Home care beds</td>
</tr>
<tr>
<td>IEC 60601-2-38</td>
<td>50N</td>
<td>Hospital beds</td>
</tr>
<tr>
<td>IEC 60601-2-52</td>
<td>250N</td>
<td>New standards for beds</td>
</tr>
</tbody>
</table>
• Test is done using a Cone tool
Element 3

- Bed user manuals must specify the mattress size
- Reduces the risk of a patient becoming entrapped between the mattress and side rail

Please note: the bed manufacturer must specify technical dimensions of the mattress only. This is not a specification of a mattress brand
The safety of a mattress and medical bed combination is tested by placing the cone tool as showed below.
Element 3 cont.

Test of compliance

<table>
<thead>
<tr>
<th>Key</th>
<th>Passed</th>
<th>Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Side rail</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Mattress</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Cone tool</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Mattress platform</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IEC 2145/00

IEC 2147/00
Element 4

Locking mechanism on the side rails must be more robust

• Must withstand a 30,000 cycle test (up and down)
  • Followed by a static load to evaluate robustness and stability of side rails
• Must withstand a 3,000 cycles with 10kg applied to load
  • Longitudinal and transverse direction
  • Simulates shaking and bouncing of side tails by a patient
Safe working load (SWL) **and** Maximum patient weight must be visible on the bed frame.
Element 6

Stability of the bed

• 220kg weight used
  • Equivalent of two adults on an empty bed
• Two tests carried out:
  1. 110kg weight on edge of the bed and 110kg on the opposite edge
  2. 220kg on the same edge at the same time
Element 7

- All motor systems subjected to an EMC & EMV test
  - EMC = Electromagnetic Compliance
  - EMV = Electromagnetic Emission

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR. 11 (partly)</td>
<td>Group 1</td>
<td>The medical bed uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR. 11 (partly)</td>
<td>Class B</td>
<td>The medical bed is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td>Complies</td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td>Complies</td>
</tr>
<tr>
<td>Immunity test</td>
<td>IEC 60601 test level</td>
<td>Compliance level</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>----------------------------------------------------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact</td>
<td>± 6 kV contact</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>± 8 kV air</td>
<td>± 8 kV air</td>
</tr>
<tr>
<td>Electrostatic transient / burst</td>
<td>± 2 kV for power supply lines</td>
<td>± 2 kV for power supply lines</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>± 1 kV for input/output lines</td>
<td>± 1 kV for input/output lines</td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV differential mode</td>
<td>± 1 kV differential mode</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>± 2 kV common mode</td>
<td>± 2 kV common mode</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt; 5% ( U_T ) (&gt;95% dip in ( U_T )) for 0.5 cycle</td>
<td>&lt; 5% ( U_T ) (&gt;95% dip in ( U_T )) for 0.5 cycle</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40% ( U_T ) (60% dip in ( U_T )) for 5 cycles</td>
<td>40% ( U_T ) (60% dip in ( U_T )) for 5 cycles</td>
</tr>
<tr>
<td></td>
<td>70% ( U_T ) (30% dip in ( U_T )) for 25 cycles</td>
<td>70% ( U_T ) (30% dip in ( U_T )) for 25 cycles</td>
</tr>
<tr>
<td></td>
<td>&lt; 5% ( U_T ) (&gt;95% dip in ( U_T )) for 5 sec</td>
<td>&lt; 5% ( U_T ) (&gt;95% dip in ( U_T )) for 5 sec</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
</tr>
</tbody>
</table>
Overview

• Enforced 1st April 2013
• Put in place to ensure patient safety and essential performance of beds
• Applies to all medical beds
• Replaced IEC 60601-2-38 and EN 1970 bed standards

• Key elements of the new standard are:
  1. The clarification of areas of use
  2. Changes to the gaps and clearances on safety sides
  3. The fit of the mattress to the bed
  4. Specification of safe working load and patient weight
  5. Ensuring stability and electrical safety

By purchasing a bed that conforms to the new IEC/ EN 60601-2-52 bed standard, you can ensure your bed stocks provide essential safety for your service users
FAQ’s

Q  Can I use beds in my fleet that comply with EN 1970?
A  Yes, it is the manufacturers who will not be able to supply beds from April 2013 that do not meet IEC 60601-2-52.