Matrix E

Conformity Technical Dossier

inspired memorable objects IMO

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II Prior Notice

This "Conformity Technical Dossier" is issued to comply de UE Directive 2077/47/EE.

It follows the following standards precepts:

- IEC/EN 60601-2-38
- IEC/EN 60601-2-52:2010
- IEC/EN 60601-1
- IEC/EN 60601-4
- IEC/EN 60601-1-1
- IEC/EN 60601-1-2
- MDD 93/42/EEC
- NP EN ISO 9001:2008 (Certificado EIC E-1318 de 2009-02-27 e suas actualizações)

Belongs to this documents the following product's documentation, considered by practical purposes as already reproduced:

- User Manual;
- Service Manual;
- Risks Analysis Dossier;
- Clinical Evaluation Dossier;
- Tests and Trials Reports;
- Product Data Sheet;
- Commercial Brochures.

1 Product description

1.1 Product identification

Hospital beds Matrix E range and their accessories.

Product Range:

Matrix E hospital beds can be made into several variants by optionals that can be mounted from a common basic structure. These variants are identified by numeric value that follows the abbreviation. E.g. Matrix E20, E30, E40, E60, etc.

It can also, depending on variant design of its side guards or head/feet boards, the symbol T being replaced by another letter, without affecting or changing the characteristics of the product and its specifications.

This products, under the Medical Devices Class I notification, were registered at INFARMED with No. CLI/119/09 dd 2009-12-03.

1.2 Therapeutic purposes

Regarding the legislation above mentioned, the current product is a medical device with therapeutic purposes, which may be used alone or together with other medical devices, to sustain, modify or recover biologic functions or structures, on behalf an illness treatment or relieve, injury or disability.

Is main function is an external support for bedridden patients allowing is rest while lying down, or to support several therapeutic positions, such as height adjustment, back-rest, leg-rest, feet vascular position, Trendelenburg, Anti-Trendelenburg.

Additionally, grants some functions beyond the bedridden positions, namely some patient protection to falls, lateral, posterior and anterior sides, supports to patient position changes, and support to several medical devices, such as blood/serum containers, x-ray examinations, orthopaedic traction, etc.

1.3 Product general description

* See respective “Data Sheet”.

* See “Service Manual” (SM-944), § 2.

1.4 Models Range

* See “User Manual” (MI-944), § 7.3.

1.5 Accessories

* See “User Manual” (MI-944), § 4.

2 Product conception aims

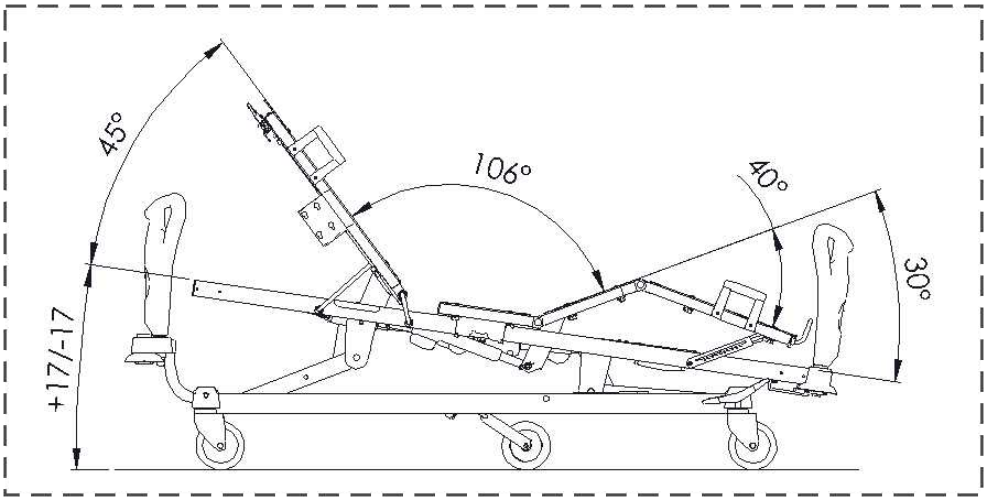
2.1 General conditions

This product was designed considering the following requirements:

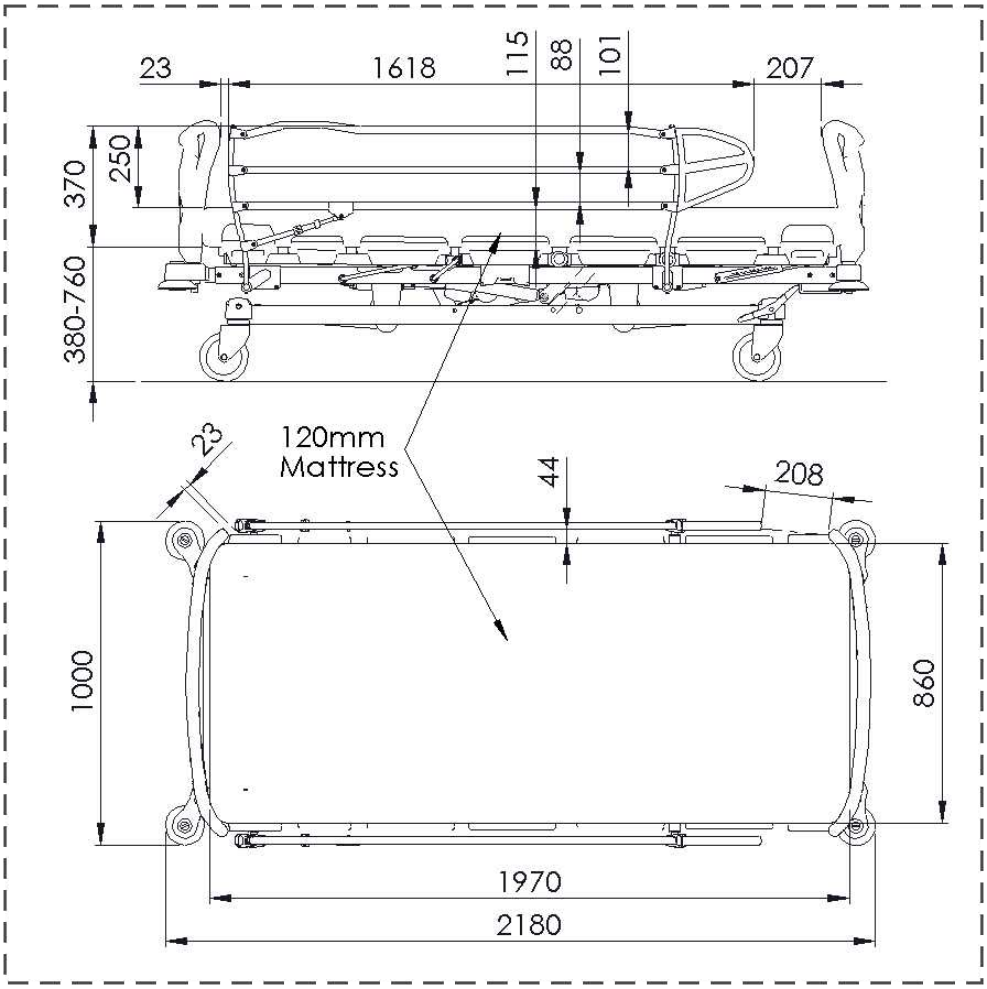
- Patient safety, comfort and ergonomics;
- Caregivers safety and operationally;
- State of the art technical features incorporation;
- Ownership costs optimisation throughout life time increase and maintenance costs minimisation;
- Design trends incorporation looking for modern and pleasant interior decorations;
- Environmental policies on using recyclable materials.

2.2 Product diagrams

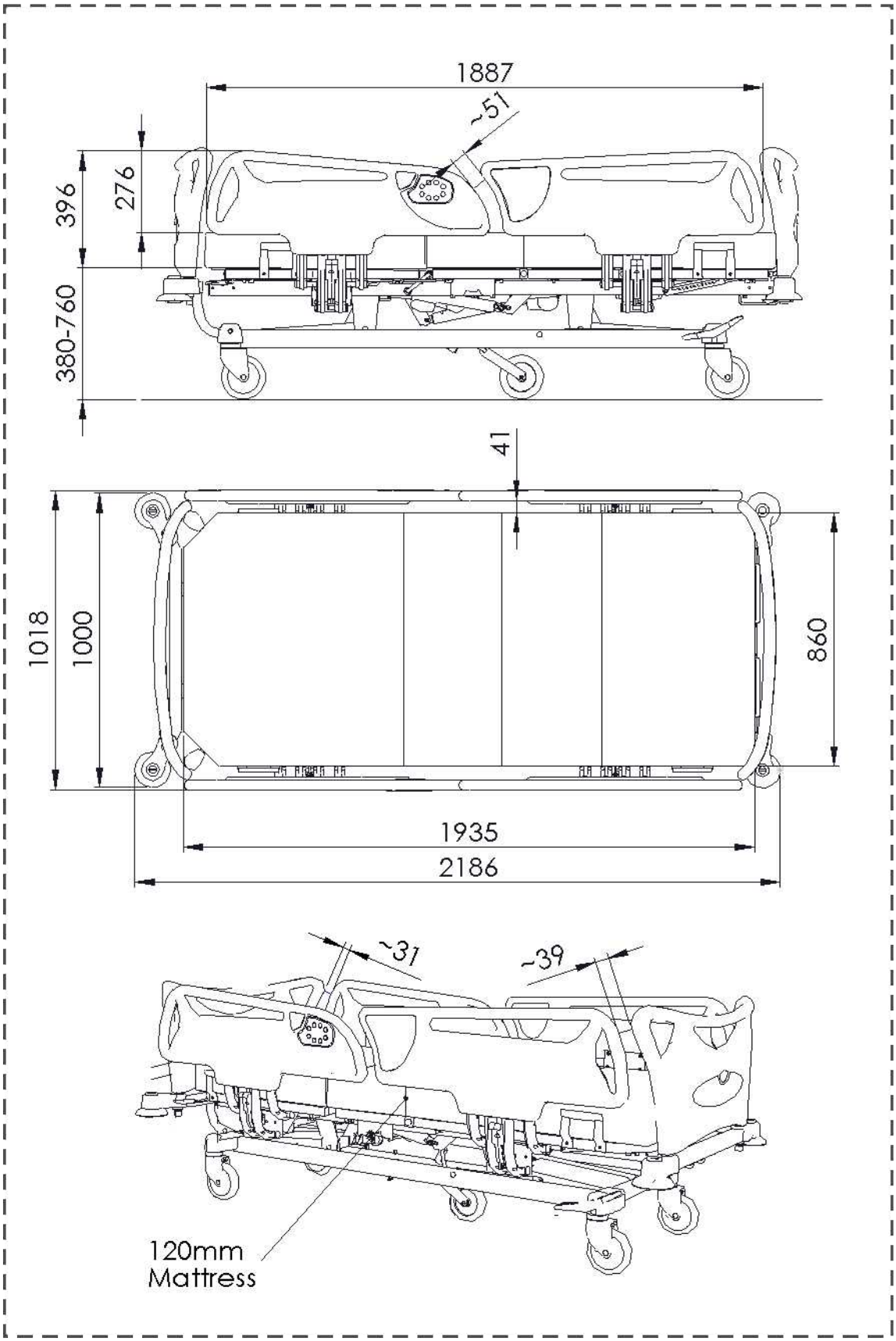
* See “User Manual” (MI-944), § 7.1.



Pic. 1 – Hospital bed Matrix E40 – Folding sections (max. angles)



Pic. 2 – Hospital bed Matrix E20 with accordion siderails 120 mm mattress



Pic. 3 – Hospital bed Matrix E40 with split siderails HPDE and 120 mm mattress

2.3 Dimensions and Capacities

* See “User Manual” (MI-944), § 7.2.

2.4 Components

* See “User Manual” (MI-944), § 7.1.

* See “Service Manual” (SM-944), § 2.

2.5 Constructive Methods

Components made in mild steel tube and profiles: conformation by CNC mandrel bending machine. Welding by automatic MIG welding robot system. Drilling by mechanical stamping press or column drilling machine. Threading by cutting taps into electromechanical taping.

Components made in mild steel sheet: Cutting and puncturing on CNC automatic machines. Bending on CNC automatic bending machines or in mechanical stamping machines. Welding by semi-automatic electro-arc MIG machines and clamping or plates resistance welding machines.

Mechanical Components: made by lathes and millings CNC tool-machines.

Plastic components: by thermo-plastic injection, several polymers, such ABS, Polypropylene, Polyethylene, Nylon and PVC.

Boards: made in HPL phenolic resin by CNC mechanical cutters, milling and drilling CNC automatic pantographs. Edges polishing on linear automatic machines.

Aluminium components: by injecting or casting. Mechanical polishing with sandpaper and brushes belts to get gloss finishes.

Metals paint: Chain system, epoxy resin electrostatic coating, followed by drying on 200ºC polymerization continuous oven. Surfaces anti-rusting pre-preparation by chemical treatment, amorphous phosphate, passivation and washing in continuous tunnel.

Quality control: All manufacturing stages are submitted to a quality control inspection, under the scope of the ISO 9001 standard established on plant management.

2.6 Diagrama sequencial de fabrico

Stages	Components	Manufacturing Operation	Equipment and Means
1	Profiles and tubes components	Profiles sectioning Edges grinding	Tape hacksaw Mechanical stamper Sandpaper polisher
	Steel sheet components	Formats sectioning	Plate shear machine Mechanical stamper
	Mechanical components	Profiles cutting	Tape hacksaw Disk hacksaw
	Plastic components	Injection	Injection machine
	Boards and plates	Formats sectioning	CNC squaring machine
	Aluminium components	Injection Casting	Alu injection machine Casting machine
2	Tubes and profiles components	Bending	CNC mandrel bender
	Steel sheet components	Punctoring Stamping	CNC punctoring machine Hydraulic stamper
	Boards and plates	Milling and Drilling	CNC pantograph
3	Tubes and profiles components	Drilling Threading	Mechanical stamper Column drilling machine Electromechanical threader
	Steel sheet components	Bending	Hydraulic Bender
	Mechanical components	Lathing Milling	Pararel automatic lathe Revolver automatic lathe Universal milling machine
	Boards and plates	Edging Edging polish	Continuous edger Continuous polishing
	Aluminium components	Polishing	Brush polisher
4	Tubes and profiles components Steel sheet components	Clamps Resistance welder Electro-arc welder	Clamp welder machine MIG semi-automatic welder MIG welder robot
5	Tubes and profiles components Steel sheet components	Metal painting	Constinuous automatic coating line with previous chemical treatment
	Boards and plates	Finish	Manual
6	All	Components assemblage	Manual
7	All	Packing	Manual Plastic film machine

3 Actuation and control electric components

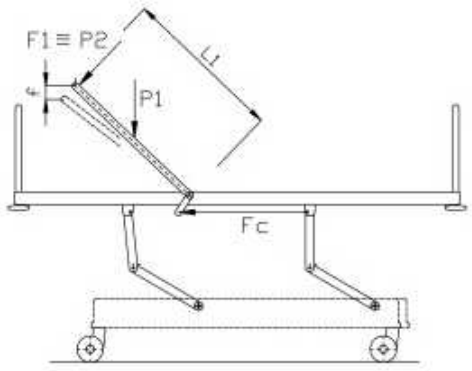
* See “Service Manual” (SM-944), § 2.3.

* See “User Manual” (MI-944), § 2.

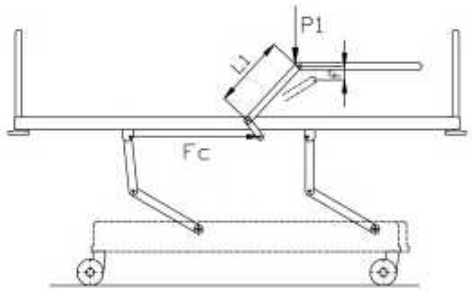
4 Operation

* See “User Manual” (MI-944), § 2.

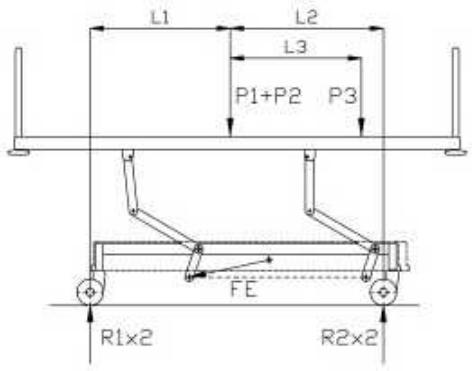
5 Studies



Pic. 4 – Loads and stress - Backrest section



Pic. 5 – Loads and stress - Leg rest section



Pic. 6 – Loads and stress - Main frame elevation

5.1 Loads

Concerning standard EN 60601-1 and EN 60601-2-38 and IEC 60601-2-52:

Load referring patient weight:	1350	N
Load referring mattress weight:	200	N
Load referring accessories weight:	150	N
Safe working load (SWL):	1850	N
SWL distribution over section 1-backrest:	45	%
SWL distribution over section 2-pelvis:	25	%
SWL distribution over section 3/4-leg rest:	30	%

5.2 Backrest section

See picture 4, drawing from § 5.

Caption:

P1 – Backrest section SWL load = 1850x45%=815N

kc – Stress overloading factor = 1.4

Fc – Sustaining element's rod load (n)

L1 = 76.8 cm

L2 – Sustaining crowbar length = 9.5 cm

Fc=(765N*(76.8/2)*cos45º)*(9.5*sen70º)^-1 = 2480N

Electric actuator-nominal power = 4000 N

Safety coefficient = 4000/2480 = 1.6

Hardness:

Vector to P2=800N = 3.4mm

Maximum load without plastic deformation = 6370 N

5.3 Leg rest section

See picture 5, drawing from § 5.

Caption:

P1 - Leg rest section SWL load = 1850Nx30%=555N

kc - Stress overloading factor = 1.3

Fp - Sustaining element's rod load (N)

L1 = 34.2 cm

L2 - Sustaining crowbar length = 8.5 cm

Fp=(555*(34.2/2)*cos 30º)*(8.5*sen88º)^-1 = 967N

Electric actuator-nominal power = 2500 N

Safety coefficient = 2500/967 = 2.58

Hardness:

Vector to P2=1000N = 1.5mm

Maximum load without plastic deformation = 6060 N

5.4 Main frame and horizontal elevation

See picture 6, drawing from § 5.

Caption:

P1 – Patient weight = 135 kg

P2 – Platform and accessories own weight = 35 kg

P3 – Random use weight = 60 kg

kc – Stress overweight factor = 1.3

kd – Stress horizontal dynamic overweight factor = 1.5

fe – Sustaining element's rod load (N)

R1 – Anterior caster load (N)

R2 – Posterior caster load (N)

Vb – Motor stroke gear ration = 350/150

L1 - 61.2 cm

L2 = 78.3 cm

L3 = 60.0 cm

Confirmation: P1+P2+P3=2400N > 1700 (SWL)

Caster static load:

R2=1/2*(1.3*170*9.8*61.2+1.3*60*9.8*(61.2+60))*(61.2+78.3)^-1 = 807N

R1=1/2*(1.3*170*9.8 - 2*835= 587N

Caster nominal static load = 1200N

Safety coefficient = 1200/807 = 1.49

Casters dynamic load:

R2=1.5*1/2*(170*9.8*61.2)*(61.2+78.3)^-1 = 548N

Caster nominal overall load = 1000N

Safety coefficient = 1000/548 = 1.82

Elevation stress:

Fe=170*9.8*(350/150)/cos 20º=4135N

Elevation device nominal load=6000N

Safety coefficient = 2*6000/4135=2,9

Hardness:

Maximum p1+p2+p3 without frame deformation = 8240N

Vector to P3=200kg, edge measurement = 3.2mm

5.5 Operation noise level

Referring to Matrix E hospital beds, models E20, E30, E40 e E60.

Operation requirements:

Normal operation, equipped with its standard accessories, including side-rails and mattress, and charged with an overload corresponding to the PWL 185 kg, regarding the trial conditions of standards EN 60601-2-52 and EN 60601-2-38.

Measurement method: DS/EN iso 3746

Operation maximal noise level: 40 db(A)

Motorised components based on LINAK LA27.

6 Trials tests release and release frequency

6.1 Materials trial tests

Trial	Standard	Frequency
Paint specular gloss measurement	ISO 2813	1
Paint shock resistance measurement	ISO 6272	1
Paint film hardness	ASTM D 3363	1
Paint washing resistance	DIN 5378	1
High Pressure Laminate coating hardness	ASTM D 3363	1
High Pressure Laminate washing resistance	DIN 5378	1
Varnishing layer hardness	ASTM D 3363	1
Varnishing washing resistance	DIN 5378	1
Polymer identification	Espec. LNEC	1
Resistance to liquids	NP 2376	1
Resistance to water	Espec. CTIMM	1
Dry film thickness	NP 1884 Met.4	1
Abrasion measurement. Grid cell method	ISO 2409	2

6.2 Products trial tests

Trial	Standard	Frequency
Impact test	EN 60601-2-38	3
Drop down masses	EN 60601-2-38	3
Shields mechanical resistance	EN 60601-1	3
Sloping plane stability	EN 60601-2-38	3
Longitudinal stability	EN 60601-2-38	3
Lateral stability	EN 60601-2-38	3
Rebound test	EN 60601-2-38	4
Head/foot boards loading test	EN 60601-2-38	3
Siderails resistance and closing latch reliability	EN 60601-2-52	3
Siderails trapping safety	EN 60601-2-38	3
Siderails opening safety	EN 60601-2-38	3
Operation noise level	EN 60601-2-38	4
cont.		

Electric devices hazard protection	EN 60601-2-52	4
Electric overheat protection	EN 60601-1	3
Mobile parts trapping protection	EN 60601-2-52	3
Static loads regarding patient weight	EN 60601-2-52	3
Dynamic loads regarding patient weight	EN 60601-2-52	3
Dynamic trial to lifting system	EN 60601-2-52	3
Patient lifting trapeze trial	EN 60601-2-52	3
Headboard extraction test	EN 60601-2-52	3

6.3 Trial tests frequency

§ 6.2 table caption:

1 - Quarterly tests to materials over the quality control scope.

2 - Quarterly laboratory testing, with daily local control.

3 - Tests on product homologation, or when there are changes in specifications, components or manufacturing methods.

4 - Samples testing in each manufacturing lot.

7 Risks analysis

According to “Risks Analysis and Management” dossier, document belonging to product documentation.

8 Adopted solutions

The solutions adopted in these hospital beds conception and manufacture followed the patient and caregivers safety principles over the standards scope, public technical and scientific knowledge, as well as the company own know-how as a developer of this kind of products along more than 5 decades.

The adopted solutions identification and justification contents are expressed on the “Risks Analysis and Management” dossier at § 5 - Risk management and adopted solutions.

In the mentioned chapter is identified each solution adopted to prevent the several risks evaluated.

The “Risks Analysis and Management” dossier belongs to product documentation.

9 Clinic Evaluation

Matrix E hospital beds were designed and are manufactured in order their use does not compromise the patient's, caregivers and occasional visitors clinical condition or the physical safety.

Adopted solutions in the design and manufacturing, described and explained throughout this document, and others that belongs to product's documentation, are subject to clinical evaluation, demonstrating compliance with the essential requirements.

The clinical evaluation procedure was based on public scientific literature available and relevant for safety and functional performance. Several studies and reports issued by hospitals, masters and doctoral theses, focuses in hospital beds ergonomic and safety use and specially the conclusions of the FDA - "Hospital Bed Safety Workgroup" (HBSW) were used.

Regarding the Directive No. 2007/47/EC issued by European Union and based on the "Risks Analysis and Management Dossier" it is demonstrated there are no risks or pernicious influences over patient's health condition, considering a product current and normal use, and excluding anomalous hazards or safety issues which are not predictable by the manufacturer, such as the ones caused by patient mental disorders, neurological involuntary and random movements that may cause falls and light collisions with body parts and some minor injuries in contact with bed components.

From the above, this clinic evaluation report was settled and checked in hospital environment, the risks have been identified globally and the solutions adopted has an effective result.

Regarding the item § 10 of the above mentioned directive is inferred that the "Clinic Evaluation Dossier" should be:

- Mentioned and released on product's technical documentation;
- Performed regularly as part of after-selling surveillance plan;
- And the analysis reports being monitored and updated.

A clinic evaluation plan was made, based on everything stated and justified above, with the following procedures:

Analysis: Checking in a hospital environment, that the products do not contain other risks beyond those identified in "Risks Analysis and Management" dossier and managing that the adopted solutions are effective.

Query Documentation: "Risks Analysis and Management" dossier.

Periodicity: Bianual, considering the most relevant supplies.

Inquired staff: Caregivers, namely nurses and maintenance engineers.

Monitoring: The reports should be analysed in order to check if product needs any revision.

Filing: Reports should be filed on confidential mode for five years according to stipulated in the directive mentioned above.

10 User Manual

“User Manual”, freely available, is an independent document, while beingpart of the product documentation pack.

11 Identification label

Is described in § 7.4 of the “User Manual” the individual bed serial number and corresponding badge plate.

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