BS EN 1865-5:2012

BSI Standards Publication

Patient handling equipment used in road ambulances

Part 5: Stretcher support

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National foreword

This British Standard is the UK implementation of EN 1865-5:2012. Together with BS EN 1865-1:2010, BS EN 1865-2:2010, BS EN 1865-3:2012 and BS EN 1865-4:2012, it supersedes BS EN 1865:2000, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/239, Rescue systems.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

Patient handling equipment used in road ambulances - Part 5: Stretcher support

Spécifications d'équipements pour le transport de patient dans les ambulances routières - Partie 5: Table support brancard

Krankentransportmittel in Krankenkraftwagen - Teil 5: Festlegungen zur Krankentragenaufnahme

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Foreword

This document (EN 1865-5:2012) has been prepared by Technical Committee CEN/TC 239 “Rescue systems”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2012, and conflicting national standards shall be withdrawn at the latest by December 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document together with the EN 1865-1:2010, EN 1865-2:2010, EN 1865-3:2012 and EN 1865-4:2012 supersedes EN 1865:1999.

With respect to EN 1865:1999 the following changes were made:

a) the stretcher support was introduced as a new item;

b) the standard has been modified/integrated to meet the Medical Device Directive requirements;

c) the standard has been modified t/integrated to comply with the Machinery Directive 2006/42/EC and its Essential Health and Safety Requirements (EHSRs).

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

This European Standard is a part of EN 1865, *Patient handling equipment used in road ambulances*, which consists of the following parts:

— *Part 1: General stretcher systems and patient handling equipment*

— *Part 2: Power assisted stretcher*

— *Part 3: Heavy duty stretcher*

— *Part 4: Foldable patient transfer chair*

— *Part 5: Stretcher support*

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

1 Scope

This European Standard specifies the minimum requirements for the design and performance of stretcher supports that are installed in road ambulances to hold the main stretcher or incubator systems in accordance with EN 1865-1, EN 1865-2 and EN 13976-2 to ensure patient and operators safety and to minimise the physical effort required by staff operating the equipment.

In this European Standard reference is made to EN 1789.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1789:2007+A1:2010, *Medical vehicles and their equipment — Road ambulances*

EN 60601-1 (all subparts), *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1)*

ISO 6487, *Road vehicles — Measurement techniques in impact tests — Instrumentation*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
stretcher support
device that is fitted to the floor and/or sidewall of an ambulance, on which a stretcher or incubator is located

Note 1 to entry: Stretcher supports may be manually/power operated and may include a shock absorbing system.

Note 2 to entry: The stretcher support may be equipped with special devices to reduce the effect of acceleration forces of the vehicle to the stretcher or incubator during transportation.

Note 3 to entry: The stretcher support may be equipped with devices such as a tilting and extendable top tray, a fixed or folding ramp.

3.2
stretcher support with manual operation
support that can only be moved by using manual force of the operator

3.3
powered stretcher support
support that is completely or partially power-operated by means of actuators (electrical, hydraulic, pneumatic, etc.)

3.4
shock absorbing stretcher support
support with pneumatic, hydraulic, hydro-pneumatic or mechanical suspension(s)

Note 1 to entry: It is designed to cushion the effect of road surfaces, thus providing better comfort for the patient.

3.5
residual deflection
sum expressed in millimetres of permanent deformation and sliding displacement in test direction

4 Requirements

4.1 Edges

In order to reduce risk of injury to patients, staff and equipment, there shall be no exposed sharp edges.

4.2 Loading capacity

Stretcher supports shall be able to perform all their functions when loaded with a minimum mass of 220 kg. This load corresponds to the sum of the maximum weight allowed for the stretcher, undercarriage, minimum stretcher loading capacity (see EN 1865-1:2010, 4.2.3 and 4.2.4) and the fixation brackets.

Over this weight the stretcher support might not perform all functions, however, it shall be possible to load/ unload the stretcher with a load of 300 kg.

NOTE If the manufacturer declares a higher loading capacity, then tests described in Annex B should be performed using the manufacturer's advised maximum admissible loading.

4.3 Interface on ambulance floor or/and sidewall and stretcher support tray

The stretcher support manufacturer shall supply the installer with the following data:

a) mass and dimensions of the stretcher support;

b) position of the centre of gravity with regard to ambulance floor or/and sidewall and the top tray, at the maximum available height;

c) position of the fixing points with regard to the centre of gravity, including number of fixing points, type and mechanical characteristics of the connection devices to be used in order to allow the correct positioning of the floor/wall plate reinforcement;

d) to withstand a minimum load of 220 kg according to 4.2;

e) identification of the position on the tray where the connecting devices can be fitted (e.g. bolts) without adding any reinforcement.

4.4 Fixation on ambulance floor or/and sidewall and stretcher support tray

The fixation shall be in accordance with EN 1789:2007+A1:2010, 4.5.9. When tested in accordance with 4.8, there shall be no residual deflection exceeding the values given in Table 1.

Table 1 — Residual deflection

Test axis	Maximum deflection value (mm)
X+ / X-	**125**
Y+ / Y-	**125**
Z	**200**

After the test, the stretcher support shall conserve its integrity but not necessarily its functionality.

NOTE It is recognized that during the test some components may break.

4.5 Powered stretcher support

In the event of power failure, it shall be possible to operate the powered stretcher support manually.

If the powered system is fully automated, then an emergency stop button shall be provided in an accessible position.

4.6 Shock-absorbing stretcher support

Shock-absorbing supports shall have automatic self–adjusting and self-levelling suspension according to the loaded weight. The maximum time from the activation to completion of the readjustment shall be no greater than 20 s.

It shall be possible to lock the shock-absorbing function and set stretcher support in rigid and horizontal position to allow cardiopulmonary resuscitation.

In order to avoid sudden, uncontrolled dangerous movements in the event of an electrical power failure it shall be possible to unload the patient and therefore:

a) gas accumulators of the stretcher support shall not remain under-pressure;

b) the stretcher support shall smoothly discharge the suspension and set the stretcher support in the lowest available position.

4.7 EMC

Any electrical or electronic items shall conform to EN 60601-1.

NOTE If electrical and/or electronic items are used within the system, they should conform to the European Directive 2004/108/EC and any future updates.

4.8 Test method for fixation on ambulance floor or/and sidewall and stretcher support tray

4.8.1 General

Verification of conformity to 4.4 shall be made with centre of gravity of the dummy assembly adjusted at minimum 700 mm height, when possible, or at full height of the stretcher support when its height is lower.

Verification shall be carried out by dynamic testing.

NOTE The notified body which has to confirm the compliance with EN 1789:2007+A1:2010, 4.5.9, in accordance with EN 1789:2007+A1:2010, 5.3 should

a) be acknowledged by government authorities according to article 14 of the Directive 70/156/EEC and should be competent in the field of dynamic testing;

b) have an acknowledgement for the Directives 77/541/EEC and 74/408/EEC, and for Directive 96/79/EC.

The sample submitted for test shall be identical to or have the same characteristics and behaviour during the test as would the production item.

The stretcher support shall be loaded with a test mass of 126 kg (see Figure 1) which is then secured according to the manufacturer recommendation.

Fixation of the stretcher support on the test rig shall be done in accordance with the manufacturer's recommendation.

A test summary for completion by the test house is given in informative Annex A.

4.8.2 Dynamic testing

4.8.2.1 Measurement equipment and test conditions

The signal filtration for acceleration shall be CFC 60 according to ISO 6487.

The position of sensors and measurement chains for the acceleration on trolley shall be according to ISO 6487.

The deceleration measurement considered is the average deceleration of both right and left sensors at the centre of gravity equivalent to that of a trolley.

The test shall be made using a test mass of 126 kg (equivalent to 51 kg for the stretcher and 75 kg for the patient) as shown in Figure 1.

Dimensions in millimetres

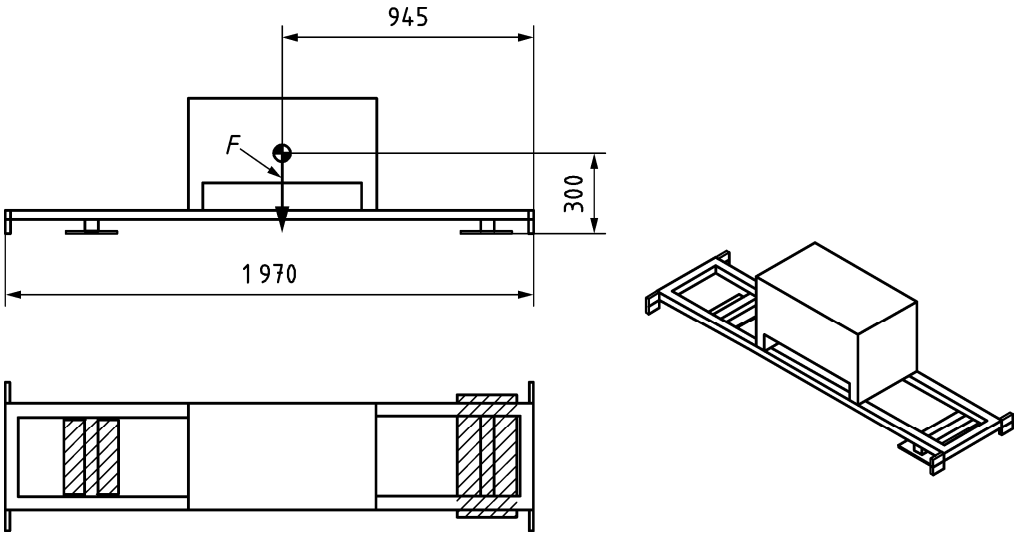
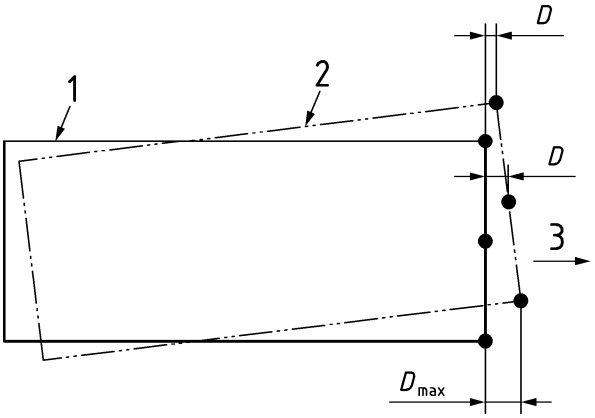
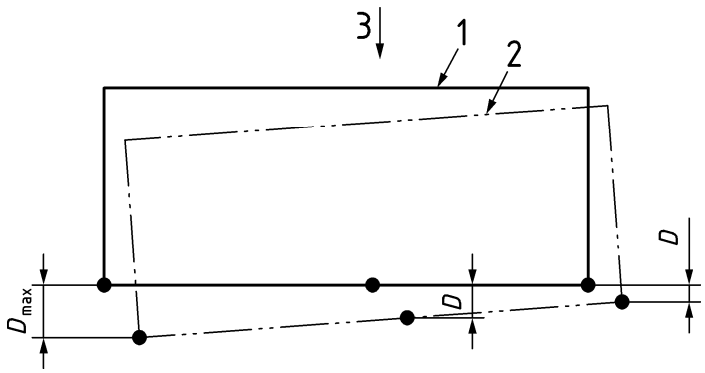


Figure 1 — Test mass

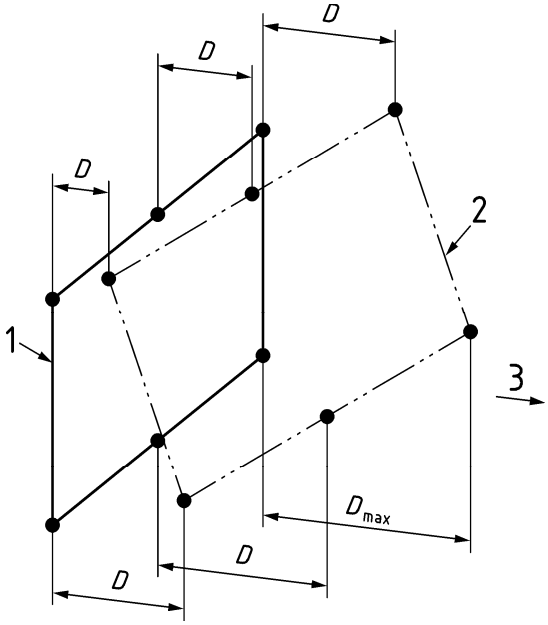
The measurement of the residual deflection shall be done by defining before the test three reference points for X and Y axes at both extremities and at the centre axis on the external part of the table top in the test direction and six reference points at both extremities and at the centre axis on the external part of the table top in the Z direction (see Figure 2). The deflection of these three/six points after the test shall be measured. None of the three measurements shall exceed the allowed deflection values (see Table 1).



a) Axis X+/X-



b) Axis Y+/Y-



c) Axis Z+/Z-

Key

1	before test
2	after test
3	test direction
D	deflection
D_{max}	maximum deflection < allowed deflection value

NOTE For the Z axis drawing, points are situated on the upper and lower part of the table top.

Figure 2 — Deflection of reference points

4.8.2.2 Procedure

The dynamic test shall be carried out using a test rig approved by the notified body and the following test method:

The test assembly shall be accelerated/decelerated in the longitudinal, transverse and vertical directions in accordance with Figure 3. The impact speed shall be between 30 km/h and 32 km/h, in accordance with EN 1789:2007+A1:2010, 4.5.9 and 5.3.

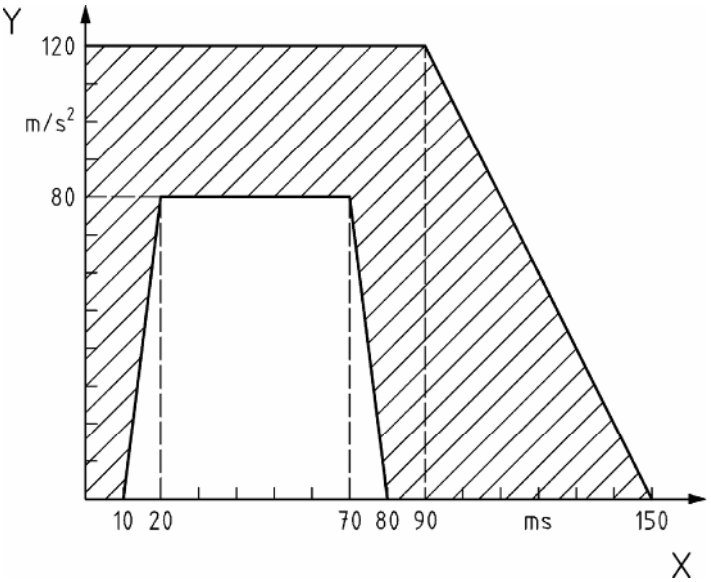


Figure 3 — Acceleration impulse

Annex A
(informative)

Test summary

This is to certify that table support produced

by .....

complies with EN 1865-5, dynamic tests have been carried out

from …….....

to ….……(dates)

Fixation of the table support on the test bench: as described below (add a figure).

Maximum fixation points allowed in each fixation area and type of fixation:

Test load fixation area on the support: as described below (add a figure).

Detailed data are to be found in test report number .....

Authorised designated official..... (name)

Signed.....

Date.....

Annex B
(informative)

Optional requirements

B.1 Sliding test

The test is performed with the stretcher support loaded with a mass of 220 kg.

NOTE If the manufacturer declares a higher loading capacity, then tests described in Annex B should be performed using the manufacturers advised maximum admissible loading.

B.2 Sideways movement

For stretcher supports that have a non-power assisted transverse movement.

Following release of the locking mechanism, it does not require a starting force of more than 200 N, (applied to the end of the stretcher support) to move the support in the intended direction.

B.3 Sliding tray (backwards and forward movement)

For stretcher supports that have a non-power assisted backwards and forwards movement.

Following release of the locking mechanism, it does not require a starting force of more than 100 N to move the support in the intended direction.

Where applicable, stretcher supports should be locked in the horizontal position for test purposes.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on Medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4 (all sub-clauses)	9.1	
4.4, 4.8	9.2	Covered for the risk of injury in connection with physical features and acceleration
4.5	12.1	**Second sentence only**
4.7	12.5	
4 (all sub-clauses)	12.7.1	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus do not provide presumption of conformity for the machinery directive.

Determination of whether a certain EHSR is “relevant” and thus applies to a particular device, pertains to the responsible parties (e.g. manufacturer, notified bodies, competent authorities) in accordance with the applicable procedures.

Table ZA.2 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.5	1.2.4.3	If a relevant hazard exists, the manufacturer has to cover this EHSR. Covered by clause 4.5 for fully automated systems.
4.5	1.2.6	If a relevant hazard exists, the manufacturer has to cover this EHSR. The requirement in clause 4.5 to provide a means to manually operate a powered stretcher support when power has failed partly covers this EHSR. Other parts are not covered.
-	1.3.7	If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard.
4.7	1.3.9	If a relevant hazard exists, the manufacturer has to cover this EHSR. Covered by reference to EN 60601-1.
-	1.6.2	If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard.
-	1.6.3	If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard.
-	3.6.2	To comply with this EHSR the manufacturer has to legibly and indelibly mark the machinery with the mass and nominal power. Not covered by this standard.

Bibliography

[1] EN 980, *Symbols for use in the labelling of medical devices*

[2] EN 1865-1:2010, *Patient handling equipment used in road ambulances — Part 1: General stretcher systems and patient handling equipment*

[3] EN 13976-2, *Rescue systems — Transportation of incubators — Part 2: System requirements*

[4] EN ISO 12100, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100)*

[5] *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*

[6] *Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC*

[7] *Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)*

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