



Test Report: Patient Handling Equipment used in Road Ambulances Part 1: General Stretcher Systems and Patient Handling Equipment

Legislation

BS EN 1865-1:2010+A1:2015

Test Details

Location of Test: Manufacturer Area / Ankara / Turkey
Date of Test: 03 January 2018
VCA Representative(s): İsmail Sertesen , Burak Yüksel
Manufacturer's Representative(s): Göksel Kaçar
Reason for Test Report: Test report only

Manufacturer Details

Name and Address: EMS MOBİL SİSTEMLER A.Ş.
1. Organize Sanayi Bölgesi Kırımhanlığı Cad. No:9
Sincan-Ankara / TURKEY
Type: EMS-001
Commercial Description: Target Transferli Sedye (ES-126) , Target Ana Sedye (ES-125)
Category: Component

Conclusion

The above mentioned component was tested in accordance with the above mentioned legislation and was found to comply in all respects.

Signature:

Name: İsmail Sertesen
Position: Type Approval Engineer
Date: 03 January 2018

List of Annexes

| Annex | No of Pages | Subject |
|-------|-------------|-------------------------------|
| I | 2 | General drawings of stretcher |
| II | 77 | User guide of stretcher |



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| | | |
|-----|----|--|
| III | 6 | Test report of stretcher according to EN 597-1:1994 (Document Nr.: MT20160423 , date: 12.05.2016) |
| IV | 10 | Test report of stretcher according to EN ISO 14971:2012 (Document Nr.: FR.7.04.02.01 , date: 01.12.2014) |
| V | 28 | Test report of stretcher according to EN 1789:2007 + A2:2014 (Document Nr.: 10R07065 , date: 10.07.2015) |

Worst Case Rationale

There is two stretcher model. Both types were tested separately according to BS EN 1865-1:2010+A1:2015. Progressive smouldering or flaming ignition, risk management and dynamic tests reports were added in annexes.

Note: Include information on variants and versions this report covers, as applicable

Tests Required

Yes, NA, See Report ... / Approval ... / Annex ...

| | |
|--|-----|
| General: | Yes |
| Main Stretcher: | Yes |
| Chair Stretcher: | NA |
| Transfer Mattress: | NA |
| Carrying Sheet: | NA |
| Pick-up Stretcher: | NA |
| Vacuum Mattress: | NA |
| Long Spinal Board: | NA |
| Foldable Carrying Chair: | NA |
| Non-foldable Carrying Chair (Sedan Chair): | NA |
| Marking: | NA |

Component Specification

Part Number(s):

Manufacturer's Documentation

Manufacturer's documentation is complete and reflects the agreed specification for the component tested, and covers all variants and versions agreed in the worst case rationale.

Yes

Facility and Equipment Checks

Calibration certificates checked and valid, recorded in the following table:

Yes

| Equipment | Serial / Certificate No. | Calibration due* |
|--------------|--------------------------|------------------|
| Tape Measure | GCS-TM29 / 17-25272 | 05.2018 |
| Inclinometer | 992000394 / 7.111842 | 05.2018 |
| Caliper | GCS-VC17 / 17-25276 | 05.2018 |
| Weighbridge | 5311 / 5198 | 05.2018 |

*Specify calibrated date + (interval) or calibration due date.



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| Test Requirements | | Complies Yes / NA |
|--------------------------|---|------------------------------|
| General | | |
| 4.1. | When lifting and carrying devices are operated and maintained in accordance with manufacturer instructions, they do not present any high level of risk. Any identified risk is reduced to an acceptable level by using risk management principles, in accordance with EN ISO 14971:2012, taking account of normal and single fault condition. | Yes |
| 4.1. | Carrying handles on devices for handling of patients permits fixation in extended positions. | Yes |
| 4.1. | All equipment for the handling of patients is free of any sharp edges. The minimum radius is 0.5 mm. | Yes |
| 4.1. | All patient restraint systems have a quick release system. | Yes |
| 4.1. | Lying-sitting part is made of a strong material, which is bacterial-resistant, fungal-resistant, stain-resistant, putrid-resistant, easy to clean and disinfect, washable, waterproof and petrol-oil resistant. | Yes |



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Main Stretcher

General

4.2.1. Main stretcher consists of a stretcher part that can be used either alone or in combination with an integrated or detachable undercarriage. Yes

4.2.1. It is designed so that the full weight of the patient and the carried stretcher part will only be lifted/carried by the personnel for the minimum period of time. Yes

Dimensions

4.2.2. Dimensions are measured from the outermost edges. Yes

4.2.2. Length (1,950⁺²⁰/₋₅₀) mm: 1960 mm Yes

4.2.2. Width (550 ± 20) mm: 551 mm Yes

4.2.2. Height is a maximum of 300 mm from loading assembly to unloaded lying part: 280 mm Yes

Note: This height dimension does not apply to stretchers with mono-block undercarriages. If a mono-block is not available, the stretcher shall be constructed such that it is detachable from the undercarriage. Where a stretcher support is used, the measurement shall be taken from the top surface of the stretcher support to the lying part of the stretcher.

4.2.2. Length and width of the frame of the undercarriage, when located in the ambulance, does not exceed length and width of the stretcher part. Yes
(For ES-126)

Length: 1960 mm
Width: 550 mm

Mass

4.2.3. Mass, excluding mattress and patient restraints, is not more than: Yes

- Stretcher part – 23 kg: 18,55 kg
(For ES-126)
- Undercarriage, including stretcher – 51 kg (combined weight): 50,2 kg
(For ES-126)
- Stretcher part with integrated undercarriage – mono-block 45 kg: 44,3 kg
(For ES-125)

Note: In all cases, the mass should be as low as possible.

4.2.4. Loading capacity is a minimum of 150 kg: 200 kg Yes



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Frame

| | | | | | | |
|-------------|--|---------------------|----|-----|----|-----|
| 4.2.5.1. | Frame is a sturdy, lightweight, non-twisting construction, enabling use of cardiopulmonary resuscitation. All corners of the frame have been radiused for greater safety. | Yes | | | | |
| 4.2.5.1. | It is possible to lock and secure the stretcher and undercarriage against lateral, longitudinal and vertical movements. | Yes | | | | |
| 4.2.5.1. | All mechanisms are constructed to prevent damage to the user and the patient. | Yes | | | | |
| 4.2.5.2.(a) | If swing-down side rails are mounted, they have a minimum length of 500 mm and a minimum height between 150 mm and 200 mm, measured from the top of the stretcher frame to the top of the side rail. Length: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td>505</td><td>mm</td></tr></table> Height: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td>195</td><td>mm</td></tr></table> | 505 | mm | 195 | mm | Yes |
| 505 | mm | | | | | |
| 195 | mm | | | | | |
| 4.2.5.2.(b) | If longitudinal handles are incorporated, they are fitted to the ends of the longitudinal frame such that they lock and do not twist when they are stowed or in use. They are designed to minimise the risk of injuries to hands and wrists when being operated or when the stretcher is carried in a non-horizontal position. The stretcher allows the fixation and use of a carrying harness. | Yes | | | | |
| 4.2.5.2.(c) | Stretcher has both a water and scratch resistant paint finish, or is manufactured of corrosion-resistant material. Both are unaffected by disinfectants. | Yes | | | | |
| 4.2.5.2.(d) | If intended to be used without undercarriage, there are four wheels with a minimum diameter of 100 mm suitably placed to ensure stability. | Yes (For ES-125) | | | | |
| 4.2.5.2.(e) | If intended to be used with undercarriage, the stretcher is able to be fixed to the undercarriage without using supplementary means. A safe handling and lowering of the undercarriage is ensured. | Yes (For ES-126) | | | | |
| 4.2.5.2.(f) | Fixed stretcher is easy to release from the stretcher fastener. | Yes (For ES-126) | | | | |
| Note | There is a facility to attach a support for infusion. | Yes | | | | |
| 4.2.5.3.(a) | Undercarriage is fitted with four wheels, with a diameter of at least 100 mm. At the foot end, there is a minimum of two wheels that swivel 360° and at least two wheels are fitted with a brake. | Yes | | | | |



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| | | | |
|------------------------------------|--|--------|---------------------|
| 4.2.5.3.(b) | Undercarriage is suitable for a road ambulance loading and unloading, with a maximum height of 750 mm: | 810 mm | Yes |
| 4.2.5.3.(c) | Undercarriage has a simple mechanism for height adjustment and has a minimum of two levels (car position and fully unfolded). | | Yes |
| 4.2.5.3.(d) | Supporting mechanism automatically stays in place when fully unfolded. | | Yes |
| 4.2.5.3.(e) | Operating controls are ergonomically designed to take into consideration human body dimensions and physical strength, and anatomical and physiological requirements of human beings. The operating controls are clearly and permanently labelled, preferably with graphical symbols, indicating their positions and settings. If the controls can initiate movements that could be dangerous to persons, they are secured against unintentional operation. | | Yes |
| 4.2.5.3.(f) | All functions of the stretcher remain completely unimpaired when connected to the undercarriage. | | Yes (For ES-126) |
| 4.2.5.3.(g) | Undercarriage has both a water and scratch-resistant paint finish, or is manufactured of corrosion-resistant material. Both are unaffected by disinfectants. | | Yes (For ES-126) |
| 4.2.5.3.(h) | If the undercarriage is used with a detachable stretcher, it is possible to connect or disconnect them easily. The stretcher is secured in such a manner that unintentional separation of undercarriage and stretcher cannot occur. It is possible to load and unload the undercarriage and stretcher to ensure the safety and comfort of the patient and the operators. | | Yes (For ES-126) |
| Lying Part of the Stretcher | | | |
| 4.2.6.(a) | Lying area is flat over the complete surface and is made of sturdy, lightweight construction. The thorax area is manufactured of sturdy, lightweight material, which allows cardiopulmonary resuscitation without acting as a spring or giving way. The materials are unaffected by disinfectants. | | Yes |
| 4.2.6.(b) | Lying area is non-slip and covered with a transfer mattress, or a mattress that provides patient comfort. It is firm enough to enable cardiopulmonary resuscitation to be undertaken. The mattress is able to conform to the various treatment configurations provided by the stretcher. The mattress has welded seams to prevent the ingress of patient fluids and facilitate infectious control cleaning; in addition, the materials are unaffected by disinfectants. The mattress is fixed securely to the lying part of the stretcher. | | Yes |



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4.2.6.(c) Lying area has an adjustable head-end/backrest with a minimum length of 600 mm. It is possible to raise the backrest at least 75° and there are at least five fixing positions within this range. It is possible to maintain the angle of adjustment under all normal conditions of loading and unloading. Yes

| | | |
|---------|-----|----|
| Length: | 710 | mm |
| Angle: | 77 | ° |

4.2.6.(d) Lying area has an adjustable footrest with a minimum length of 900 mm. It is possible to raise the leg section (shock position) by at least 15°. It is possible to maintain the angle of adjustment under all normal conditions of loading and unloading. Yes

| | | |
|---------|-----|----|
| Length: | 900 | mm |
| Angle: | 35 | ° |

Note: It is desirable to have a system to minimise the lifting effort of the operator.

Restraint System

4.2.7. Stretcher has a minimum of two quick-release patient restraints capable of accepting a device for restraining children. Yes

Flammability – Toxicity Burning Gases

4.2.8. There is no progressive smouldering or flaming ignition when tested in accordance with EN 597-1:1994. Yes

Reference: See Document (Annex III)

Deformation of the Frame

4.2.9. Frame does not bend or break when tested in accordance with 5.1.1. Yes

| | Any Failure or Deformation |
|--|-------------------------------|
| 5.1.1.1. Stretcher frame | No any failure or deformation |
| 5.1.1.2. Undercarriage frame (100 m push test) | No any failure or deformation |
| Undercarriage frame (obstacle test) | No any failure or deformation |

Fixation

4.2.10. Fixation is in accordance with 4.5.9 of EN 1789:2007+A2:2014. There is no deformation of the fixation when tested in accordance with 5.1.2 in this document. Yes

Reference: See Document (Annex V)



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Issue: 0

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Deformation of the Lying Area

4.2.11. There is no deformation of the lying area when tested in accordance with 5.1.3.

Resistance to Torsion

4.2.12. There is no remaining deformation due to torsion when tested in accordance with 5.1.4.
Deflection measured: mm

Splaying of the Wheels

4.2.13. Wheels do not splay more than 2 mm in total during the test specified in 5.1.5 and there is no permanent deformation.