



Instructions for use
PAX Stretcher Mattress – TMS





Instructions for use

PAX Stretcher Mattress – TMS

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For the safe use of this product, please read and follow this instruction manual before first use.

These instructions for use apply to the following products:

Item name:	PAX Stretcher Mattress - TMS - universal
Item number:	292595201
Item name:	PAX Stretcher Mattress - TMS - Stollenwerk
Item number:	290777203
Item name:	PAX Stretcher Mattress - TMS - Stollenwerk CPS
Item number:	290787203
Item name:	PAX Stretcher Mattress - TMS - Stryker M1
Item number:	290797203
Item name:	PAX Stretcher Mattress - TMS - Stryker Power Pro
Item number:	290807203
Item name:	PAX Stretcher Mattress - TMS - Stryker Power Pro XT
Item number:	290817203
Item name:	PAX Stretcher Mattress - TMS - Ferno IN-X
Item number:	290827203
Item name:	PAX Stretcher Mattress - TMS - Ferno Mondial
Item number:	290837203
Item name:	PAX Stretcher Mattress - TMS - Ferno Viper
Item number:	290847203
Item name:	PAX Stretcher Mattress - TMS - Kartsana BRAVA SILVER JUPITER
Item number:	290857203
Item name:	PAX Stretcher Mattress - TMS - Kartsana SUPERBRAVA
Item number:	290867203
Item name:	PAX Stretcher Mattress - TMS - Frestems
Item number:	291443503
Item name:	PAX Stretcher Mattress - TMS - Spencer QMX 777+
Item number:	291707203
Item name:	PAX Stretcher Mattress - TMS - Spencer QMX 779
Item number:	291717203



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PAX Stretcher Mattress – TMS



NOTE:

For better readability and clarity in these instructions for use, the simplified designation **PAX Stretcher Mattress - TMS** is used.

All information regarding handling applies equally to the products listed in the table.

Intended use

The PAX Stretcher Mattress – TMS is designed to support the patient during treatment and transport on a standard stretcher.

It is equipped with an integrated temperature management system to enhance patient comfort.

The PAX Stretcher Mattress – TMS is attached to the stretcher or secured by the patient restraint system.

The PAX Stretcher Mattress – TMS – universal can also be mounted on a vacuum mattress or another transport and positioning system as an alternative to a standard stretcher. The heating system can be switched prior to arrival at the emergency site.

When the patient is placed on the pre-warmed stretcher, they can immediately feel the soothing warmth. This heating function offers a pleasant added benefit, and not just during the colder months.



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Illustration



Example image:
PAX Stretcher Mattress - TMS - Stryker M1

- 1 Headrest
- 2 Belt guide
- 3 Battery compartment with control panel
- 4 Heating zones
- 5 Footrest



Example image:
PAX Stretcher Mattress - TMS - universal

- 1 Headrest
- 2 Optional mounting eyelets
- 3 Battery compartment with control panel
- 4 Heating zones



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MD User group

The PAX Stretcher Mattress – TMS is a medical device which may only be used by trained personnel who have received regular training on the product. The operator and the user of the medical device are responsible for providing instruction. The type and indication of application is based on the current, generally recognized medical guidelines and recommendations of the relevant professional associations.

If the product is classified by the operator as a self-explanatory product for the group of intended users, this must be documented by the operator in a suitable form (e.g. risk analysis).
A general classification of the product as self-explanatory by the manufacturer is not possible, as this always depends on the intended user group.



Observe the occupational health and safety guidelines applicable to you when using the PAX Stretcher Mattress – TMS



When using the PAX Stretcher Mattress – TMS, the following general instructions must be observed:

- Only rechargeable batteries approved by the manufacturer for this medical device may be used.
- To maintain performance and extend the battery's service life, it is recommended that you charge it at least once a week.
- The instructions for use supplied with the battery and the charging system must be read and followed before use.
- Batteries must only be charged using the charging system that is intended and approved for this purpose.
- The heating system must only be activated if the user has sufficient knowledge of the patient's clinical condition and is professionally qualified to carry out the procedure.
- The use of unauthorised accessories may adversely affect the system's electromagnetic compatibility.



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General safety instructions for using the PAX Stretcher Mattress – TMS:

- The battery must only be inserted into the housing using the designated battery compartment.
- The battery housing must always be closed properly, ensuring that the battery compartment clicks fully into position, regardless of whether a battery is inserted.
- Neither the battery nor the battery compartment must be cleaned with high-pressure washers.
- Moisture on the electrical contacts of the battery, the housing and the charging station must be avoided at all times.
- If there is visible or suspected damage to the system, the product must not be used any further.
- Repairs and maintenance work must be carried out exclusively by the manufacturer or a service center authorized by the manufacturer. In this case, the product must be returned to the seller.
- Damage caused by pointed or sharp-edged objects must be avoided.
- After use, the product must be reprocessed in accordance with the cleaning and disinfection instructions and checked for any externally visible damage.
- The emission characteristics of this device allow it to be used in industrial settings as well as in hospitals.
- If the system switches itself off, it can be restarted by switching it on again, provided there is no fault or damage.
- The product must not be stacked with other equipment or operated in the immediate presence of other equipment, unless this is explicitly intended.
- Portable or mobile high-frequency and radio devices (HF/Rf devices) with antennas may interfere with the operation of medical electrical equipment. A minimum distance of 30 cm must be maintained.

Intended patient group

- Adults and adolescents
- Children and schoolchildren
- Product is not gender-specific



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Use for children, pregnant or breastfeeding women

The use of the PAX Stretcher Mattress – TMS in these patient groups does not require any special precautions. For the specific treatment the therapy recommendations of the relevant expert associations must be observed.

Restriction on use / contraindications

The PAX Stretcher Mattress – TMS must only be activated if there is a medical indication and the conditions for its use are met. The decision on its use must be made by a qualified user, taking into account the patient's clinical condition.

**SAFETY NOTE:**

The heating system must not be activated in patients with the following conditions:

- Hyperthermic disorders, excluding burns, in particular:
 - Heatstroke
 - Heat exhaustionResuscitation situations where the patient's core body temperature is in the range from $\geq 32^{\circ}\text{C}$ to febrile.
- Pyrexia / fever.
- Systemic inflammatory response syndrome (SIRS) in the presence of a febrile body temperature.
- Malignant hyperthermia, particularly when occurring during induction of anaesthesia.
- Localised or extensive inflammation in the area of application.
- Infectious skin conditions or parasitic infestation in the area of contact with the product.

The PAX Stretcher Mattress – TMS is designed to regulate the patient's body temperature and can be used in various positioning scenarios.

Unwanted side effects when using the medical device

No undesirable side effects are to be expected, if the product is used as intended.

**SAFETY NOTE**

The product has no life-sustaining or life-supporting effects.
The product may only be used in a proper and undamaged condition.

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PAX Stretcher Mattress – TMS

Product overview / Instructions for use

①.

The system will only operate if a sufficiently charged battery is inserted. To do this, open the safety flap.



②.

Remove the battery tray and insert the charged battery into it.

Guide the battery from the handle of the battery tray under the seal so that the battery's electrical contacts are facing upwards and towards the rear.

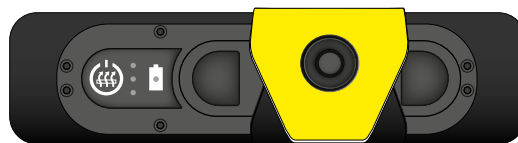
Then press the battery fully into the battery tray until it clicks audibly into place.

Insert the battery tray into the battery compartment – the tray will click into place automatically.



③.

Close the safety flap to secure the battery by pressing the push button.



④.

Perform a system check by briefly pressing the ON/OFF button.

The current battery charge level will be displayed for approximately 5 seconds.

⑤.

Activate the heating system by pressing the ON/OFF button for approximately 2 seconds. The system starts at the highest heat setting (level 3) by default; this is indicated by three white LEDs lighting up.

Instructions for use

PAX Stretcher Mattress – TMS

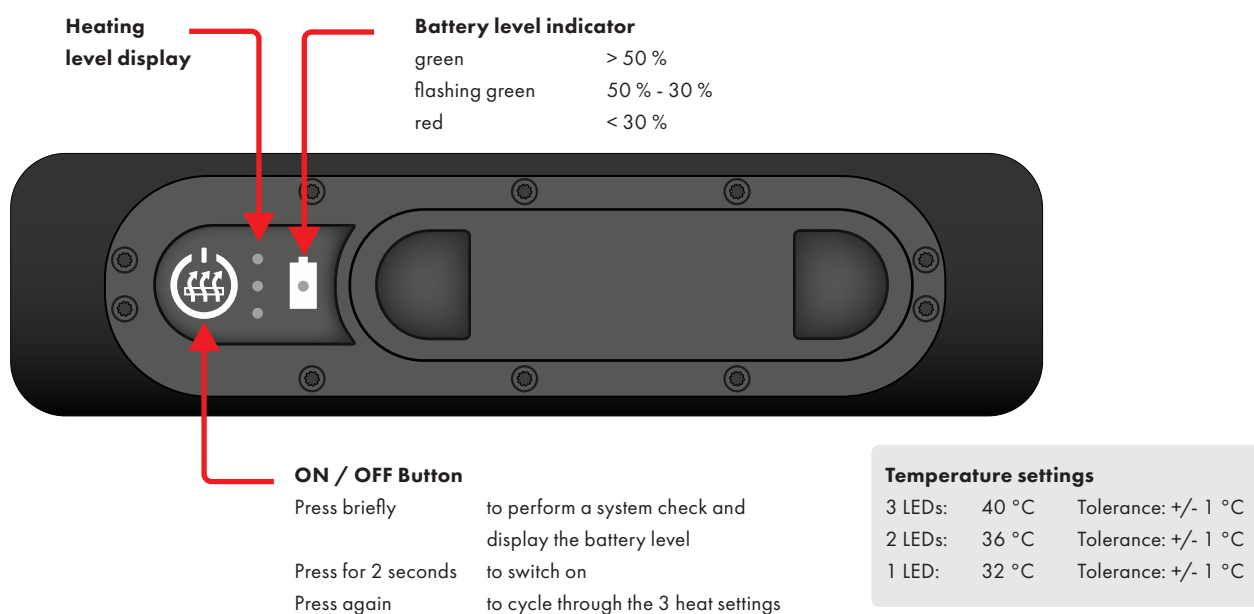
The system will only operate if a sufficiently charged battery is fitted.
To do this, open the safety tab.

⑥

Press the ON / OFF button briefly again to switch between the heating levels:

- Level 3: Heats up to approx. 40 °C
- Level 2: Heats up to approx. 36 °C
- Level 1: Heats up to approx. 32 °C

The system then switches back to Level 3.



⑦

Press and hold the ON / OFF button (for approx. 2 seconds) whilst the heating system is active to switch the system off.
Always switch the system off before changing the battery.

If the discharged battery is not immediately replaced with a fully charged spare battery, the battery compartment must still be closed by ensuring the empty battery tray is fully locked into place.
This ensures the battery compartment remains clean and dry.

The battery charge level is indicated as follows:

- Green LED: Battery charge level $\geq 50\%$
- Flashing green LED: Battery charge level 30% – 50%
- Red LED: Battery charge level < 30%

The heating system switches off automatically after 45 minutes of operation.
If required, the system can then be switched on again immediately.



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Actions in the event of product malfunction or changes in performance

In the event of any noticeable malfunctions, changes in performance or visible damage to the product, use must be discontinued immediately. In such cases, the product must not be used any further.

The user must carefully inspect the system for any externally visible damage or malfunctions.

If any damage, malfunctions or uncertainties regarding safe use are detected, the manufacturer or an authorised dealer must be contacted. Unauthorised repairs or modifications to the product are not permitted.

Spare parts and accessories, in particular batteries and chargers, must be obtained exclusively from the manufacturer or via the ordering options specified on the manufacturer's website.

Only components approved by the manufacturer may be used.

Accessories that can be used together with the PAX Stretcher Mattress – TMS

PAX Item number: **290000000**

Description of accessory: **Lithium-ion battery**

Manufacturer / Type: **RRC-2040-2-RRC**

PAX Item number: **290010000**

Description of accessory: **Single-unit charger**

Manufacturer / Type: **RRC-SMB-MBC-RRC**

PAX Item number: **290020000**

Description of accessory: **CAR charger** (without charging cradle)

Manufacturer / Type: **RRC-SMB-CAR-RRC**

PAX Item number: **70759-004**

Description of accessory: **Connection cable**

Manufacturer / Type: **IEC320-C5(EU)**



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Medical devices that can be used in combination with the PAX Stretcher Mattress – TMS

The PAX Stretcher Mattress – TMS can be combined with all medical devices approved for patient transport or patient positioning when used as intended. Examples are given below: Stretcher, scoop stretcher, rescue sheet, spine board, helicopter stretcher, hospital bed, X-ray table, A&E stretcher, etc. (List is not exhaustive – in case of questionable combination possibilities, please contact the manufacturer).

Only components approved by the manufacturer may be used.

Notes on restrictions when combining medical devices and accessories for medical devices with the PAX Stretcher Mattress – TMS

If the product is used as intended, no restrictions are to be expected when combining it with medical devices and accessories for medical devices.

**NOTE:**

The battery used is not a medical device itself within the meaning of Regulation (EU) 2017/745 (MDR). It is intended as an accessory in accordance with Article 2(2) of the MDR and serves to enable the medical device to function.

The safe and intended use of the medical device requires the use of a suitable and specified battery.

Instructions for the correct installation of the medical device prior to first use

Before using the medical device for the first time, remove it from its packaging and completely remove all packaging and protective materials. After unpacking, check the product immediately to ensure it is complete, undamaged and free from external damage. If any components are missing or there is visible damage, the product must not be put into service.

In this case, contact the manufacturer or an authorised dealer.

Notes on special treatment / preparation of the medical device before use

The PAX Stretcher Mattress – TMS must be reprocessed according to the instructions under Reprocessing – Cleaning and care / disinfection before the first and all subsequent uses on the patient.



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Checking the safe and operational condition of the medical device

Immediately before using the PAX Stretcher Mattress – TMS, it must be visually inspected to ensure that it is in perfect technical and hygienic condition. Damaged products must be replaced immediately.

This applies in particular to properly reconditioned devices.



NOTE:

As an immediate action in the event of suspected or obvious damage to the PAX Stretcher Mattress – TMS, this medical device must not be used and must be replaced immediately with a functional Stretcher Mattress.

Information on possible mutual interference during examinations and treatments



Magnetic Resonance Imaging (MRI)

The PAX Stretcher Mattress – TMS is not suitable for use in magnetic resonance imaging! Due to the electronic components and heating elements it contains, the product must not be used in an MRI environment or left with the patient.



X-ray and Computer Tomography (CT)

The PAX Stretcher Mattress – TMS is, in principle, radiolucent and can remain on the patient whilst X-ray examinations and CT scans are being carried out. However, due to the heating elements and electronic components integrated into the stretcher pad, artefacts may occur which could impair the image quality and the diagnostic value of the examination. The decision as to whether the PAX Stretcher Mattress – TMS should remain in place during the examination rests with the responsible medical staff.



Further diagnostic procedures

When used as intended, no significant mutual interference is generally to be expected during EEG, ECG or ultrasound examinations. However, due to the design of the PAX Stretcher Mattress – TMS and its integrated components, artefacts or minor impairments to measurement or image quality may occur in isolated cases. The clinical evaluation of the examination results is the responsibility of the relevant medical staff.



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Maintenance actions

Maintenance actions include, in particular, inspections and servicing that are necessary to ensure the continued safe and proper operation of the medical devices.

Inspection and maintenance

The PAX Stretcher Mattress – TMS must be checked regularly for damage and function.

Damaged components and accessories must be replaced with original spare parts in accordance with the manufacturer's instructions.

Further maintenance and servicing actions by the operator or user are not intended by the manufacturer.

Repair and maintenance

The repair of medical devices includes, in particular, the repair to restore functionality.

For reasons of product liability and safety, more extensive repair and maintenance work may only be carried out by authorized specialist companies using original spare parts.

Please contact our customer service department if repairs or maintenance work needs to be carried out.

Reusability

The PAX Stretcher Mattress – TMS can be reused as long as it remains in working order and the material is undamaged. Before reusing the product, the user must ensure that it is in good condition.

Only products in technically and hygienically sound condition may be reused.

The product must not be reused if there are any signs of material wear or fatigue.

In addition, before each reuse, the condition of the battery and the electronic components controlling the heating elements must be checked.

The battery must be sufficiently charged and must not show any signs of damage, overheating, deformation or leakage.

The electronic components, controls, displays and connection points must function correctly and must not show any visible damage or corrosion.

The shoulder pad must not be reused if malfunctions in the heating control, uneven heating, electronic failures or signs of moisture ingress are detected.

Repairs or the replacement of battery or electronic components must only be carried out by authorised specialist personnel.

Once the battery has reached the maximum number of charge or usage cycles specified by the manufacturer, the product must be taken out of service or disposed of in accordance with the manufacturer's instructions.



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Reprocessing – cleaning and care / disinfection

The PAX Stretcher Mattress – TMS should be cleaned using a wipe-down disinfection method. To do this, use a slightly damp cloth in combination with a suitable disinfectant.

To clean the battery compartment, the interior can also be wiped down with a slightly damp cloth and a suitable disinfectant. The battery compartment must then be left open until it is completely dry. The battery tray must not be reinserted until it is completely dry.



NOTE:

Make sure to avoid touching or getting the electrical contacts on the rear inner wall of the battery compartment wet, as this may lead to corrosion and impair functionality.

Reprocessing - disinfection

Disinfection of the PAX Stretcher Mattress – TMS, by means of a surface wipe disinfection is possible with commercially available disinfectants of the substance classes alcohols, aldehydes and amines.

The use of other classes of substances may result in irreversible damage to the surface and material, and therefore may affect the performance and safety of the product. Do not use solvents!

For questions regarding the applicability of special disinfectants, please contact the manufacturer. The product is not intended for sterilization.



NOTE:

Disinfection using hydrogen peroxide or halogen-based disinfectants (e.g. chlorine or iodine compounds) is not permitted, as these substances may damage materials and electronic components.



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PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - universal

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - universal
Item number:	292595201
Length:	136 cm
Width:	43 cm
Height:	6 cm
Weight:	1,26 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/00212383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 05
GMDN:	37329
UDI-DI:	4260745484244



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Stollenwerk

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Stollenwerk
Item number:	290777203
Length:	185 cm
Width:	50 cm
Height:	10 cm
Weight:	ca. 6 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484077



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Stollenwerk CPS

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Stollenwerk CPS
Item number:	290787203
Length:	130 cm
Width:	48 cm
Height:	10 cm
Weight:	ca. 4 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484084



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Stryker M1

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Stryker M1
Item number:	290797203
Length:	183,5 cm
Width:	45 cm
Height:	10 cm
Weight:	ca. 5 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484091



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Stryker Power Pro

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Stryker Power Pro
Item number:	290807203
Length:	189,5 cm
Width:	49 cm
Height:	10 cm
Weight:	ca. 5 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484107



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Power Pro XT

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Power Pro XT
Item number:	290817203
Length:	189,5 cm
Width:	55 cm
Height:	10 cm
Weight:	ca. 6 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484114



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Ferno IN-X

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS – Ferno IN-X
Item number:	290827203
Length:	185 cm
Width:	42 cm
Height:	10 cm
Weight:	ca. 6 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484121



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Ferno Mondial

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS – Ferno Mondial
Item number:	290837203
Length:	191 cm
Width:	45 cm
Height:	10 cm
Weight:	ca. 5 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484138



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Ferno Viper

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Ferno Viper
Item number:	290847203
Length:	191 cm
Width:	45 cm
Height:	10 cm
Weight:	ca. 5 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484145



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Kartsana BRAVA SILVER JUPITER

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Kartsana BRAVA SILVER JUPITER
Item number:	290857203
Length:	188 cm
Width:	45 cm
Height:	10 cm
Weight:	ca. 5 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484152



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Kartsana SUPERBRAVA

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Kartsana SUPERBRAVA
Item number:	290867203
Length:	196 cm
Width:	54,5 cm
Height:	10 cm
Weight:	ca. 6 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484169



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Frestems

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Frestems
Item number:	291443503
Length:	189 cm
Width:	46 cm
Height:	1 cm
Weight:	ca. 3,5 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484176



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Spencer QMX 777+

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Spencer QMX 777+
Item number:	291707203
Length:	182 cm
Width:	45 cm
Height:	9 cm
Weight:	ca. 6,5 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484183



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery:

- PAX Stretcher Mattress - TMS - Spencer QMX 779

Technical data / Performance characteristics of the product:

Item name:	PAX Stretcher Mattress - TMS - Spencer QMX 779
Item number:	291717203
Length:	183 cm
Width:	47 cm
Height:	9 cm
Weight:	ca. 6,5 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Plan Comfort black MP Bottom side: PAX Plan black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/0021 2383
Registration EUDAMED	
Registration UK – MHRA:	
UMDNS:	17-547
EMDN:	V 08 05 0199
GMDN:	37329
UDI-DI:	4260745484190



Instructions for use

PAX Stretcher Mattress – TMS

Scope of delivery (optional):

- Lithium-ion battery RRC-2040-2-RRC
- Single-unit charger RRC-SMB-MBC-RRC
- Car adapter RRC-SMB-CAR-RRC

Technical specifications / features of the optional products:

Item name: Lithium-ion battery RRC-2040-2-RRC
Item number: 290000000



Information:

This battery is a stand-alone product and is intended solely to supply power to the medical device referred to in these instructions for use. It is not a medical device in its own right, but is intended as an accessory in accordance with Article 2(2) of Regulation (EU) 2017/745 (MDR).

The battery is intended solely for use as intended with the PAX Stretcher Mattress – TMS medical device.

Technical specifications / features of the optional products:

Item name: Single-unit charger RRC-SMB-MBC-M
Item number: 290010000



Information:

Technical specifications / features of the optional products:

Item name: Car adapter DC/DC RRC-SMB-CAR
Item number: 290020000



Information:



Instructions for use

PAX Stretcher Mattress – TMS

Storage

The PAX Stretcher Mattress – TMS can be stored in the rescue vehicle within a temperature range of -30°C - +70°C. For long-term storage, room temperature is recommended to protect the material.



The following information on storage temperatures and conditions applies exclusively to the battery of the PAX Stretcher Mattress – TMS:

Battery storage temperatures (depending on the duration of storage):

- Up to < 1 year: -20 °C to +20 °C
- Up to < 3 months: -20 °C to +45 °C
- Up to < 1 month: -20 °C to +60 °C

Additional notes on battery storage:

- Ideally, store the battery at temperatures below 20 °C and in low-humidity conditions.
- Avoid exposure to dust and corrosive gas atmospheres.
- For optimum service life, the battery should be stored with a charge level of 40-60%

Shelf life

The product is designed to serve for a period of 5 years from the date of first commissioning by the operator. Once this service life has expired, the manufacturer must carry out a comprehensive functional test and, if necessary, carry out repairs.

Use of the product after the end of its service life is considered improper use.

Please contact the manufacturer to arrange the safety inspection.

Information on proper disposal of the medical device and its accessories

- This product contains electrical and electronic components and is subject to the regulations of the German Electrical and Electronic Equipment Act (ElektroG).
- The device must not be disposed of with household waste.
- Please take the device to a separate collection point for electrical and electronic waste or hand it in at an appropriate collection point.
- Alternatively, the device may be returned to the manufacturer following prior consultation.
- Before disposal or return, the device must be cleaned and disinfected in accordance with the applicable hygiene regulations.
- The removable battery must be removed from the device before return and either disposed of separately in accordance with the applicable battery regulations or sent back with the device.



Instructions for use

PAX Stretcher Mattress – TMS

Information on proper disposal of the battery

- The device contains a removable Li-ion battery, which must be removed before the device is disposed or returned.
- The symbol of the crossed-out dustbin indicates that batteries and devices containing built-in batteries must be disposed of separately from household waste.
- You can return the battery free of charge to local collection points or anywhere where batteries are sold.



- Further information on disposal:

Information on proper disposal of the packaging

- The product packaging can be recycled.
- The metal parts can be recycled as scrap metal.
- Plastic parts can be sent for plastic recycling.
- Disposal must be carried out in accordance with the respective national legal regulations.
- Please ask the city/municipal administration about local waste disposal companies.

Warranty

The manufacturer provides a warranty for this product in accordance with legal provisions. This covers material and manufacturing defects. Excluded from this are wearing parts and components/assemblies that are subject to normal wear and tear as well as damage resulting from excessive strain, improper use, damage caused by force or unauthorized modification/repair. In the event of a warranty claim, please contact the manufacturer.



SAFETY NOTE

Any serious incident that has occurred in relation to the device must be reported immediately to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.



NOTE

Only batteries approved by the manufacturer may be used to operate this medical device. The use of unauthorised batteries or batteries of equivalent design from other manufacturers is not permitted and may lead to malfunctions or hazards.

The manufacturer accepts no liability for damage resulting from improper use, the use of unauthorised batteries or incorrect replacement.



MANUFACTURER:
X-CEN-TEK GmbH & Co. KG

**Westerburger Weg 30
26203 Wardenburg
Germany**

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Email: info@pax-bags.de
Web: www.pax-bags.com



This product is compliant with the Essential Requirements of Annex I of EC Regulation 2017/745 for medical devices / MDR.

The symbol of a crossed-out dustbin on batteries or rechargeable batteries indicates that these must not be disposed of with household waste at the end of their service life.

Batteries and rechargeable batteries may contain harmful substances which, if disposed of incorrectly, can damage the environment and harm health. If batteries or rechargeable batteries contain mercury, cadmium or lead, the relevant chemical symbol (Hg, Cd or Pb) is shown below the crossed-out wheeled bin symbol.

End users are legally obliged to return used batteries and accumulators. These can be returned free of charge at places selling batteries or accumulators, as well as at designated public collection points. You can obtain information on suitable collection points from your local council or municipal authority.

CH REP

**MK-Med Medizintechnik AG
Industriezone Basper 33
CH-3942 Raron
CHRN-AR-200003155**

UK REP

**PAX – bags UK Ltd.
Merlin House, No.1 Langstone Business Park,
Priory Drive
NP18 2HJ Newport - UK**

Subject to technical changes

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