



AK MedTec

SMART TEXTILES

Heated stretcher padding

Manual



www.akmedtec.com

CE



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01 General safety instructions

- Do not try to insert the battery into the housing without the battery insert!
- Always close the battery housing by snapping the insert into place (with and without battery)!
- Do not use high pressure cleaners to clean the battery or plug-in module!
- Avoid moisture on the electrical contacts of the battery, the housing and the charging station under all circumstances!
- The heating system works best when the outside temperature does not drop below -20 ° C and does not rise above 40 ° C.
- If the system is visibly damaged, it must not be used any longer. It then must be repaired before further use. For proper repair, contact the seller.
- None of the components should be damaged by pointed or sharp edged objects.
- The product is suitable for reuse. After use, the product must be maintained (see section on cleaning and disinfection instructions) and checked for any externally visible damage. If the system is undamaged, it is ready for use again.

02 General instructions

- Only use batteries that have been approved by AK MedTec GmbH! The battery should be charged once a week to extend its lifetime.
- Please also read the instructions supplied with the battery and charger.
- Only charge the batteries with the appropriate charging system!
- Only switch on the heating system if you are familiar with the condition of the patient and if you can take responsibility for it.

03 Usage

This product was developed to make transporting the patient as comfortable as possible. This stretcher support is attached to the stretcher or held by the patient belt system. The heating system can be switched on long before it arrives at the place of use. If the patient is placed on the already warmed up stretcher, he can immediately feel the soothing warmth. This heating function offers pleasant added value not only during the cold season.

04 Indication / contraindication

The body temperature is one of the most fundamental vital parameters of our organism. The original goal of the heated stretcher is the supply of warmth to the patient through active preheating or immediate heating of the stretcher. An efficient supply of heat helps to maintain the patient's personal well-being.

Not applicable to:

1. Hyperthermic disorders (except burns)
 - Heat stroke
 - Exhaustion of heat
 - Insolation
2. Resuscitation (if body temperature is in the range of 32° C to fever)
3. Pyrexia / fever
4. SIRS (if body temperature is febrile)
5. In the complication of malignant hyperthermia during induction of anesthesia (mutation at the ryanodin - 1 receptor)
6. Local / extensive inflammation
7. Skin infections / parasite infection

Switch on the heating system when the patient needs it and when the requirements are met. All patients will be happy that the surface of the stretcher corresponds to their body temperature and feels comfortable. The stretcher pad is not only optimally usable in the supine position.

05 Declaration of conformity



CE Konformitätserklärung Declaration of Conformity

Hersteller/Manufacturer:

AK MedTec GmbH, Grüne Aue 3 a, 04769 Naundorf, Germany

Das Medizinprodukt mit den unter Produktbezeichnung genannten Bezeichnungen erfüllt die grundlegenden Anforderungen nach der Richtlinie 93/42 EWG, Anhang 1. Das durch die Richtlinie vorgesehene Konformitätsbewertungsverfahren wurde durchgeführt. Es findet der Anhang VII der vorgenannten Richtlinie Anwendung.

The medical device with the designations mentioned under product designation fulfills the essential requirements according to Directive 93/42 EEC, Annex 1. The conformity assessment procedure provided for by the Directive has been carried out. Annex VII to Directive 93/42/EEC shall apply.

Produktbezeichnung / Designation of equipment:

Beheizbare Tragenauflage
Heatable wear pad

Zum Nachweis entsprechend / For verification in accordance with:

RICHTLINIE 93/42/EWG DES RATES vom 14. Juni 1993 über Medizinprodukte
COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

Klasse / Class

Klasse 1 / Class 1

wurden folgende harmonisierte Normen herangezogen / The following standards were applied:

EN ISO 13485:2016 Medizinprodukte — Qualitätsmanagementsysteme — Anforderungen für regulatorische Zwecke (ISO 13485:2016),
EN ISO 14971:2012 Medizinprodukte — Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2007, korrigierte Fassung 2007-10-01)

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

EN ISO 14971 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

Der oben genannte Hersteller hält folgende Dokumentation zur Einsicht bereit:

- Medizinprodukteakte / Technische Dokumentation

The manufacturer mentioned above keeps the following documentation available for inspection:

- Medical device file / Technical documentation

Diese Erklärung wird verantwortlich für den Hersteller abgegeben durch:

This declaration is issued for manufacturer by:

Name, Vorname (name, first name)

Körner, Andreas

Position / position

Geschäftsführer / Managing Director

AK MedTec GmbH

Andreas Körner
Grüne Aue 3a
04769 Naundorf
Tel. 0353/7358116
info@ak-medtec.de

Naundorf, den 30.11.2019

Ort, Datum / Place, Date)


Unterschrift / Signature

06 Lifetime

Four years are given for the life of the heated stretcher pad.

07 Product and packaging information

Every product is carefully tested and packaged by AK MedTec GmbH.

Scope of delivery: The product including all components is supplied in a box. The batteries as well as the charging station and their cables have their own packaging, so that they can be safely stored within the large packaging box and are protected during transport.

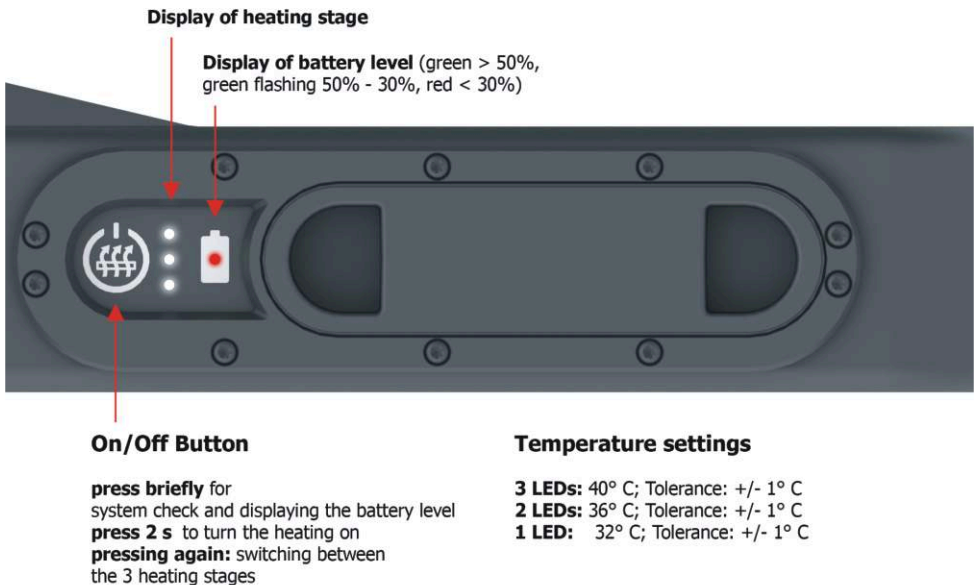
Depending on the order, the package includes a stretcher pad, two batteries, a charging station and a charging cable. The instructions for usage are included in each product or can be downloaded from www.akmedtec.com.

Please read them carefully. Please also check the content for completeness and integrity immediately after unpacking

08 Product overview

a) Operation

1. The system only works if a charged battery has been inserted: To do this, open the magnetic lock on the safety flap, remove the battery insert and insert the charged battery so that the contacts of the battery are at the top of the rear. Put the battery insert into the battery housing. The slot automatically engages.
2. Close the tab to secure the battery with a magnetic lock.
3. Run a system check by briefly pressing the On / Off button → the current battery status is displayed for 5 s.
4. Press the On / Off button (approx. 2 s) to activate the heating → system starts at the highest heating level, 3 white LEDs light up.
5. Press again briefly → Switch through the heating levels starting from level 3 (heats up to 40 ° C) to level 2 (up to 36 ° C) to level 1 (up to 32 ° C) and again to level 3.



6. When pressing the On / Off button longer (about 2 seconds) when the heating is already on → system shuts down.

Before changing the battery, please switch off the system. If you do not immediately replace the battery with the fully charged second battery, close the battery housing by snapping the empty battery insert into place. This way, a clean and dry battery case can be maintained.

The battery level indicator shows a green LED up to a battery charge level of 50%. A battery charge level of 30 - 50% is indicated by a flashing green LED. If the charge level drops below 30%, the LED lights up red.

The heating switches off automatically after 45 minutes. It can then be switched on again immediately if necessary.

b) Opening the safety flap



The fastener of the safety flap is opened by pulling the flap to the right. Thus the magnet can be released. Since the fastener integrated in the stretcher carrier only provides an exit for the magnet in one direction, it can only be opened in this specific way. Any pull in other directions (e.g. upwards) is therefore not expedient.

Please note the functionality of the magnetic fastener, otherwise you can tear the fastener out of the mat.



c) Technical data

The stretcher supports dimensions: 1850 x 500 x 80 mm. Two heating surfaces of the respective size of 290 x 290 mm are integrated. The product has three heating levels and heats up to a maximum of 40° C. The heating system works at outside temperatures from -20° C to 40° C. The battery is a lithium-ion battery (manufacturer RRC, RRC2040-2 6 x 18650 cells (3S2P) with 11.25V / 6400mAh / 72.0Wh).

Type charger: Manufacturer RRC, RRC-SMB-MBC

Type charger cable: Manufacturer Sunny, IEC320-C5 (EU)

The control panel is a foil display integrated in the battery case.

09 Precautions

The heating switches off automatically before the stretcher overheats or if one of the sensors attached to the heating surfaces is broken. The stretcher supports the foam core and its cushion cover is flame retardant. The battery insert and the safety flap ensure that the battery remains securely and firmly in the housing at all times. The special fastener of this flap is one of the most compact and versatile models from the Fidlock portfolio. Its functionality is based on the Fidlock principle, which combines the convenience of a magnetic lock with a stable mechanical snap lock.

10 Cleaning and disinfection instructions

The stretcher support is best cleaned with a damp cloth and disinfectant spray or wiping disinfectant. Please use suitable disinfectants for this. To clean the interior of the battery case, wipe with a damp cloth and disinfectant spray. But please make absolutely sure not to touch the electronic contacts on the rear wall in the battery housing, as these can corrode otherwise. The cleaned battery housing must remain open to dry completely. Only then the battery insert can be reinserted.

11 Storage and shipping information

Please note that the battery, although it basically meets all the requirements for air traffic, may only be sent by plane if the responsible airline has given its permission. Once you have obtained this, switch on the shipping mode of the battery before the flight. Make sure that the battery is not more than 30% charged. If you want to send or store the product, do not leave the battery plugged in, but keep it separately:

Ideally in the original packaging in which it is also protected.

If you want to keep the heated stretcher support unused for a long time, it is best to do so in the original packaging. You still need to charge the batteries from time to time. If you don't, their life cycle will shorten significantly. Include all instructions in the storage box so that the information is accessible if required. Store the heated stretcher support together with all associated components.

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12 Professional disposal

If the stretcher bed has had its day and is to be disposed of, please take care of a suitable and environmentally friendly recycling option. Never dispose of them in household waste.

13 Warranty

If handled properly, we offer a 24-month guarantee. For this period of 24 months, AK MedTec GmbH guarantees that the heated stretcher support functions properly. The battery must be considered separately. The warranty for the battery alone is 12 months. The product has been carefully designed and manufactured. It maintains high technical standards regarding quality and manufacture. Nevertheless should anything not function properly in the first 24 months (or 12 months regarding the battery) after purchase, please contact your specialist dealer. In this case, keep your invoice. You can only assert your claims if all provisions of these instructions for use have been complied with and the product has been used properly and as intended.



Contact

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