



Instructions for use

# PAX Warming Blanket - THX





## Instructions for use

### PAX Warming Blanket - THX



**Product:** PAX Warming Blanket - THX

**Accessory:** PAX Power Pack – 60/1

**Status:** 27.07.2022; Version 1.0  
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For safe use of this product, please read and follow these Instructions for use before first use. These Instructions for use apply to the following products:

**Trade name:** PAX Warming Blanket - THX      **Item No:** 278165201

**Trade name:** PAX Power Pack – 60/1      **Item No:** 278170000

## Intended purpose of the product

The PAX Warming Blanket - THX is intended to maintain warmth and increase the comfort of the patient during care and transport. The warming blanket may only be operated under the supervision of trained personnel.

## **MD** Intended use / user group

The PAX Warming Blanket - THX is intended to be placed on the chest (thorax - THX) of the patient. Do not place the patient on the PAX Warming Blanket - THX. This can lead to an unintentional build-up of heat and injuries to the patient. Place the warming blanket with the side close to the patient (without logo & labelling) on the patient's chest.



PAX Warming Blanket - THX Patient averted side



PAX Warming Blanket - THX Patient near side



## Instructions for use PAX Warming Blanket - THX

The PAX Warming Blanket - THX is a medical device that may only be used by trained personnel who have been regularly trained on the product. The operator of the medical device is responsible for carrying out the Instructions.

The type and indication of use is based on the current, generally recognised medical guidelines and recommendations of the relevant professional associations.

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



**When using the PAX Warming Blanket - THX, the following handling conditions must be particularly observed:**

- ▲ Place the PAX Warming Blanket - THX with the side close to the patient only on the patient's chest. Do not place the patient on the warming blanket - danger of heat accumulation!
- ▲ Before applying the PAX Warming Blanket - THX, open wounds or non-intact skin areas must be treated according to the current recommendations for aseptic wound treatment and covered sterilely.
- ▲ During the use of the PAX Warming Blanket - THX, the patient's body temperature must be closely monitored.
- ▲ Checking the correct connection of the PAX Warming Blanket - THX to the PAX Power Pack - 60/1
- ▲ Please observe the occupational health and safety regulations and other applicable guidelines when using the PAX Warming Blanket - THX and the PAX Power Pack - 60/1, especially in special ambient conditions.

Do not use in potentially explosive atmospheres.

The product is intended for multiple use, after proper reprocessing.



## Instructions for use PAX Warming Blanket - THX

### Intended patient target groups:

- ▲ Children, teenagers and adults

### Use on children, pregnant or nursing women

The PAX Warming Blanket - THX may not be used in case of increased body temperature / hyperthermia.  
The PAX Warming Blanket - THX and the PAX Power Pack - 60/1 are splash-proof, but not completely waterproof.  
It is essential to avoid immersing the products in water.

### Restrictions of use / Contraindications

The PAX Warming Blanket - THX may not be used in case of increased body temperature / hyperthermia.  
The PAX Warming Blanket - THX and the PAX Power Pack - 60/1 are splash-proof, but not completely waterproof.  
It is essential to avoid immersing the products in water.



The product is not intended for use in potentially explosive atmospheres.

### Any undesirable side effects associated with the use of the product

Undesirable side effects are not to be expected if the product is used as intended, due to the safety devices provided.  
The product may only be used in proper and undamaged condition.

## Instructions for use PAX Warming Blanket - THX



### Safety Instructions - warning & operating signals

The PAX Warming Blanket - THX and the PAX Power Pack - 60/1 have both a visual and an acoustic warning and signalling system.

#### Control elements PAX Power Pack - 60/1

- |   |                      |   |  |
|---|----------------------|---|--|
| ① | Main & safety switch | ③ | Charge level - display                           |
| ② | PAX Function Switch  | ④ | Connection socket plug PAX Warming Blanket - THX |
|   |                      | ⑤ | Charging socket for charger                      |



- |   |   |   |   |
|---|---|---|---|
| ② | <b>Displays PAX Function Switch</b>   | ③ | <b>Charge level - display</b>   |
| ▲ | flashing green - warming blanket is heating up and has not yet reached target temperature   | ▲ | four triangles light up - full charge 100%                            |
| ▲ | green steady light - heating blanket has reached target temperature & everything OK   | ▲ | three triangles light up - Charge 75 %                                |
| ▲ | yellow flashing & 1 short signal tone at start - 1 heating circuit is defective - heating blanket continues heating with one heating circuit - target temperature not reached | ▲ | two triangles light up - Charge 50%                                   |
| ▲ | yellow permanently on - 1 heating circuit is defective - heating blanket has reached target temperature   | ▲ | one triangle lights up - Charge 25%                                   |
| ▲ | flashing red & short signal tone at start - malfunction - heating blanket switched off & not heating  | ▲ | last triangle flashes - at charge < 10% & Signal tone regular beeping |



## Instructions for use PAX Warming Blanket - THX

### Measures in the event of malfunctions or changes in the performance of the product

In the case of a malfunction of the PAX Warming Blanket - THX indicated by the warning and operating signals, the user must react and decide according to the situation. In cases of limited functionality of the PAX Warming Blanket - THX (yellow light), it can still be used until the end of the application.

Immediately after the use, the allegedly defective PAX Warming Blanket - THX on the rescue vehicle must be exchanged for a fully functional warming blanket. If there is any doubt about the proper functioning of the PAX Warming Blanket - THX, stop the use immediately and disconnect the power supply by pressing the main & safety switch ❶, on the side of the PAX Power Pack - 60/1.

The PAX Warming Blanket - THX or the PAX Power Pack - 60/1 must be subjected to a technical inspection.

For further information on how to proceed, please contact the manufacturer.

### Combination of medical devices

The PAX Warming Blanket - THX is intended for use in combination with the PAX Power Pack - 60/1.

The PAX Warming Blanket - THX can be used in combination with rescue and transport bags that are approved for transporting patients.

The PAX Warming Blanket - THX can be combined with all medical devices approved for patient transport or patient positioning when used as intended. Examples of these are: Stretcher, vacuum mattress, scoop stretcher, sling, spineboard / long spine board or helicopter stretcher, hospital bed, ambulance stretcher, etc. (List is not exhaustive - if there is any question about possible combinations, please contact the manufacturer).



**Warming blankets must not be used in combination with other heat sources. The simultaneous use of e.g. warm air systems, heat lamps, incubators or warming mats can lead to overheating and injury to the patient.**

### Notes on the proper installation of the medical device before use

Before using the PAX Warming Blanket - THX, the plug must be connected to the connection socket ❷ of the PAX Power Pack - 60/1.



**ATTENTION: The PAX Warming Blanket - THX may only be operated with the PAX Power Pack - 60/1 as power source.**

**Connection to other power sources or supply voltages may cause irreparable damage to the product and endanger the patient, users or third parties.**



## Instructions for use PAX Warming Blanket - THX

### Notes on special preparation of the medical device before use

The PAX Power Pack - 60/1 is delivered in a medium state of charge.  
Before using the PAX Power Pack - 60/1, it must be charged with the supplied charger to a charge level of 100%.

### Checking the safe and operational condition of the medical device

Immediately before using the PAX Warming Blanket - THX and the PAX Power Pack - 60/1, they must be visually inspected to ensure that they are in perfect condition. Damaged products must not be used and must be replaced immediately. This applies in particular to properly reprocessed products.

After activating the PAX Power Pack - 60/1 by pressing the main & safety switch ①, on the right side of the PAX Power Pack - 60/1, the PAX Warming Blanket - THX is in an operational state.

The heating of the PAX Warming Blanket - THX is activated by pressing the PAX Function Switch ②, on the front side of the PAX Power Pack - 60/1.

A green flashing switch signals the proper function of the system in the warming phase.

As soon as the target temperature is reached on the side of the PAX Warming Blanket - THX close to the patient, the PAX function switch ② switches to a green, permanent light.

A possibly beginning reheating is signalled by a renewed green flashing of the PAX function switch ② on the front side.



**As an immediate measure in the event of suspected or obvious damage to the PAX Warming Blanket - THX or the PAX Power Pack - 60/1, the medical products must not be used and should be replaced immediately with functional products.**

### Notes on possible mutual interferences during examinations and treatments

The PAX Warming Blanket - THX is not permeable to X-rays and can lead to restrictions in the validity of radiological examinations.

When performing magnetic resonance imaging, EEG, ECG or ultrasound examinations, the PAX Warming Blanket - THX may cause artefacts due to magnetic interaction and/or electromagnetic interference.

Therefore, it is imperative that the PAX Warming Blanket - THX is removed from the patient before carrying out X-ray examinations / computer tomographies / magnetic resonance tomographies / EEG / ECG or ultrasound examinations and all other examinations and treatments in which interactions can potentially occur.



## Instructions for use PAX Warming Blanket - THX

### Maintenance & servicing

The PAX Warming Blanket - THX and the PAX Power Pack - 60/1 must be checked regularly for damage and proper functioning. Regular calibration is not necessary if the product is used as intended. Further maintenance and servicing measures by the operator or user are not planned.

### Repairs

For reasons of product liability and safety, repair, maintenance and servicing work may only be carried out by authorised specialist companies using original spare parts. Please contact the manufacturer if repairs or maintenance are required.

### Reusability

The PAX Warming Blanket - THX can be reused if the function is maintained and the material is undamaged. Before using the product again, the user must be satisfied that it is in proper condition. Only products in perfect technical and hygienic condition may be used again. If there are signs of material wear or material fatigue, the product must not be reused.

### Reprocessing - cleaning and care / Disinfection

The PAX Warming Blanket - THX can be roughly cleaned with water and a soap mixture. Extreme mechanical cleaning, which can lead to deterioration of the surface material, should be avoided.

### Disinfection

Disinfection of the PAX Warming Blanket - THX and the PAX Power Pack - 60/1, in the form of surface wipe disinfection, is only possible with alcohol-based (ethanol / propanol) disinfectants.

The use of other classes of substances may cause irreversible damage to the surfaces, cables and material, which in turn may affect the performance and safety of the product. Do not use solvents!

If you have any questions about the applicability of special disinfectants, please contact the manufacturer.



**The PAX Warming Blanket - THX is not intended to be processed in a washing machine.**

### Reprocessing - Sterilisation

The PAX Warming Blanket - THX is not intended for sterilisation or autoclave processing.





## Instructions for use PAX Warming Blanket - THX

### Scope of delivery

- ▲ 1 PAX Warming Blanket - THX Item No: 278165201
- ▲ 1 PAX Power Pack – 60/1 Item No: 278170000
- ▲ 1 Charger for PAX Power Pack - 60/1 Item No: 280920000

### Technical specifications / Performance features of the product:

#### PAX Warming Blanket - THX

- Length:** 48 cm
- Width:** 48 cm
- Rated voltage:** 12 Volt
- Max. power consumption:** 60 Watt
- Temperature range for application:** -20°C - +50°C



### Storage

The PAX Warming Blanket - THX and the PAX Power Pack - 60/1 do not require exceptional storage conditions for long-term storage (material storage).

Storage of the product at room temperature prolongs the performance of the system.

Short-term extreme storage temperatures in the rescue equipment or in use do not lead to a reduction in function.

### Limitation of the useful life

The product is intended for a service life of 5 years from the date of first commissioning by the operator. After expiry of the service life, an extended test of the functionality and, if necessary, repair must be carried out by the manufacturer.

Use of the product after the useful life has expired is equivalent to improper use. Please contact the manufacturer for the coordination of the safety check.



## Instructions for use PAX Warming Blanket - THX

### Information on the proper disposal of the medical device

According to §2 (2) sentence 10 German Electrical and Electronic Equipment Act (ElektroG), this active medical device is not subject to the German Electrical and Electronic Equipment Act (Elektro- und Elektronikgesetz) for disposal.

The product must be returned to the manufacturer for proper disposal at the end of its service life, as it is an active medical device that is expected to become infectious before the end of its service life and therefore requires special disposal.

Before returning the device to the manufacturer, please carry out a professional surface disinfection according to the Instructions in the section „Reprocessing - Cleaning and Care / Disinfection“ in order to avoid possible contamination during the return transport to the manufacturer.

### Information on the proper disposal of the packaging

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

### Warranty

The manufacturer provides a warranty for this product in accordance with the statutory provisions. This covers material and processing defects.

Excluded from this are wearing parts and parts/assemblies that are subject to normal wear and tear as well as damage resulting from excessive stress, improper use, violent damage or unauthorised modification/repair. damage or unauthorised modification/repair.

In the event of a warranty claim, please contact the manufacturer.



**Safety advice:**

All serious incidents occurring in connection with the product must be reported immediately to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.



## Instructions for use PAX Warming Blanket - THX



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

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