



MT AND RCB BLOOD TRANSPORT BOX



Blood transport boxes are Class IIa medical devices according to the European Medical Device Regulation (EU) 2017/745 and bear a CE0123 marking.



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TABLE OF CONTENTS

	page
1 Model Overview _____	5
2 Important Information _____	6
2.1 Warnings and Cautions _____	6
2.1.1 Warnings _____	7
2.1.2 Cautions _____	7
2.2 Labels and Symbols on the Packaging _____	8
2.3 Unpacking and Inspection _____	8
2.4 Intended Use _____	9
2.5 Indications and contraindications _____	9
3 Installation Procedure _____	10
3.1 Cooling elements: Waterpacks _____	10
3.1.1 Preparation of waterpacks _____	10
3.1.2 Using waterpacks with blood components _____	11
3.2 Cooling elements: PCM Packs _____	12
3.2.1 Types of PCM Packs _____	12
3.2.2 Preconditioning of the PCM packs _____	12
3.3 Fixing and adjusting straps _____	14
3.3.1 Clip-on strap _____	14
3.3.2 Velcro strap _____	14
4 Cleaning and Maintenance _____	15
5 Disposal _____	15

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1 Model Overview

Group

Model name

MT

Blood transport boxes

**MT2
MT4
MT8
MT12
MT25**

RCB

Blood transport boxes

**RCB4
RCB8
RCB12E
RCB12U
RCB25E
RCB25U**

MT Eutectics

Blood transport boxes

**MT4-ET+4, MT4-ET+22, MT4-ET+37, MT4-ET-32,
MT8-ET+4, MT8-ET+22, MT8-ET+37, MT8-ET-32
MT12-ET+4, MT12-ET-32
MT25-ET+4, MT25-ET+22, MT25-ET-32**

2 Important Information

- Before using the transport box, read these operating instructions carefully, including all the information on operation, safety, use and maintenance.
- B Medical Systems does not guarantee any safety, if the appliance is used for any purposes other than the intended use or if any procedures other than those mentioned in this operating manual are used.
- Keep these operating instructions ready at hand and leave them with the unit, so that all users can find out about the functions and safety regulations.
- Contact our sales representative or agent for any problems related to these operating instructions.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- These operating instructions may not be reproduced in any form without the written permission of our company.
- Our company guarantees the product under certain warranty conditions. We shall in no way be responsible for any loss or damage of content.

2.1 Warnings and Cautions

- It is of utmost importance that any user complies with these operating instructions as they contain important safety advice.
- Items and procedures are described so that this unit can be used correctly and safely. Following the advised precautions will prevent possible injury to the user and any other person.
- Precautions are illustrated in the following way:



WARNING

A **WARNING** is a statement that alerts to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.



CAUTION

A **CAUTION** is a statement that alerts to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.

2.1.1 Warnings









- Before cleaning, always take out the cooling elements and load.
- These devices must only be used by adults. Do not allow children to play with it or touch the controls.
- When transporting or moving the device, be aware of its weight.
- Do not store flammable or explosive substances inside these appliances (e.g. aerosols with flammable propellant). These may cause explosion or fire.
- Do not insert metal objects such as a pin or a wire into any vent, gap or any outlet.
- All servicing and repairs must be carried out by a qualified customer service engineer. Work performed by persons with insufficient technical knowledge may adversely affect the performance or cause physical injury or damage to the equipment.
- Only genuine spare parts may be used. Use of any other parts may affect the performance or cause physical injury or damage to the equipment.
- The loading must never exceed the maximum load

2.1.2 Cautions



- Check whether the appliance has been delivered undamaged. If you find that damage has occurred in transit, immediately contact the delivery service or relevant sales outlet, submitting the delivery note or proof of purchase. Do not operate a unit that has been damaged in transit! If you are unsure, contact your sales outlet and ask them.
- Follow the instructions for transport and storage of the product marked on the packaging.

2.2 Labels and Symbols on the Packaging

SKU <h1>9106704171</h1>	UDI-DI  5450104434044
Prod.Nr. <h1>991.7705.xx</h1> 	Date of manufacture :  JJJJMMTT
Product type / Model Blood Transport Box <h1>MT12</h1> BLUE	Order Nr. ORDER - LNE 
CE 0123	Ser.Nr. 0000000 Qty 1 
	manufactured by :  medical systems B Medical Systems S.à.r.l. Op der Hei, 17 L - 9809 Hosingen <i>country of origin :</i> LUXEMBOURG

2.3 Unpacking and Inspection



CAUTION

- Check whether the unit has been delivered undamaged. If you find that damage has occurred in transit, immediately contact the delivery service or relevant sales outlet, submitting the delivery note or proof of purchase.
- Do not operate a unit that has been damaged in transit! If you are unsure, contact your sales outlet and ask them.

- Make your contribution to saving the environment. Bear in mind that orderly and proper disposal of packing materials is required. Packaging materials and devices are always recyclable and should be taken for recycling.

2.4 Intended Use

Blood transport boxes are thermal insulated containers intended for the safe transport of pre-conditioned whole blood or other blood components by use of frozen water packs or PCMs as cooling elements.

It should only be used by pharmacists, doctors, laboratory staff or other staff that's trained and/or experienced in dealing with whole blood and blood components.

The blood transport boxes must be operated by organizations that have the knowledge of the relevant FDA, AABB, EU or any other applicable regulations on blood and blood products and have implemented procedures according to these regulations. The necessary transport temperature and the suitable transport period have to be defined by the organization with the above described knowledge only.

The containers are designed to operate at an ambient temperature between -10°C and +43°C. Operation outside these conditions is not validated.

The blood transport boxes are nonstationary type devices and are intended to be used for the transport of blood in- and outdoors.

The devices are not intended to be used for cooling of blood or blood components.

2.5 Indications and contraindications

- As the transport of blood or blood components is considered as a temporary storage condition, the blood transport boxes are classified as a Medical Devices Class IIa according to MDR (EU) 2017/745. They are not medical devices according to FDA CDRH. These appliances must be operated by pharmacists, doctors, laboratory staff or other staff that is trained and/or experienced in dealing with those products.
- Transport boxes are not intended to be used for cooling of blood or blood components. These appliances must be operated by personnel who have the knowledge of the relevant regulations and have implemented procedures according to these regulations.
- The suitable storage period have to be defined by authorized personnel with the above described knowledge.
- All devices are designed to operate under the conditions documented in this manual. Operation outside these conditions are not validated and have to be validated according to the organisations procedures.
- All devices are transportation equipment and must only be used for temporary storage. They are not intended to be used for cooling of foodstuffs.

3 Installation Procedure



WARNING

- Preparation of the cooling elements should be done by authorized personnel.
- Ensure that the transport boxes are adequately loaded with the correct amount of preconditioned cooling elements and maximum allowed storage load.
- The devices must only be used by adults. Do not allow children to play with it or touch the controls.
- Do not store flammable or explosive substances inside these appliances (e.g. aerosols with flammable propellant). These may cause explosion or fire.
- Make sure that no sharp or pointed objects come into contact with the cooling elements.
- Do not insert metal objects such as a pin or a wire into any vent, gap or any outlet.
- Avoid long door openings to prevent that the inner temperature rises to high.
- Make sure that the lid closes correctly and that the door gasket seals correctly against the container.
- Prior to using a transport box for the first time, the user should carry out his own tests and define a validation process under relevant conditions with the available equipment. We recommend employing worst case scenario testing conditions. The cooling elements provide a highly stable and well-designed system component, which, however, must be adapted to the specific requirements of the user.
- For the assessment and documentation of the product temperature over the transport period, the use of a temperature logging device is highly recommended. B Medical Systems will not be liable for products stored out of specification, which are further processed or administered after the transport.



CAUTION

- Use the correct cooling element for the type of transport box you have purchased. Only MT-ET transport boxes are intended to be used with PCM packs.
- Load the cooling elements and blood bags in accordance with the specific packing instruction of the box.

3.1 Cooling elements: Waterpacks

3.1.1 Preparation of waterpacks

- Fill the waterpacks with cold, clean water according to the figure 1. The waterpacks must be filled in an upright position. The fill level must not exceed the indication level. The remaining air space allows the expansion of the filled water that occurs during crystallisation, when liquid transforms into a solid state.
- Prior to freezing, the tightness of the waterpack must be verified by applying strong pressure simultaneously to both sides. Neither water nor air should be released. If a waterpack has a leak, it must not be used and must be replaced with a new original one. Do not use waterpacks with a different construction or provided by a different manufacturer.
- Standard freezers (household appliances) can be used to freeze the icepacks. The freezing temperature must be at least -20°C. B Medical System recommends the use of a waterpack freezer, which has been specifically designed for this purpose.

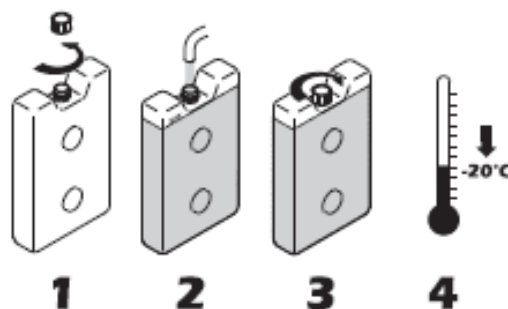


Figure 1 - preparing waterpacks

3.1.2 Using waterpacks with blood components

- For transport of temperature sensitive blood components, do not use the deep frozen waterpacks. Take the frozen waterpacks out of the freezer and allow them to thaw prior to use. The ready-to-use waterpack must have a temperature of about 0° C. The easiest way to check this, is the "finger-pressure-test": after having been kept at room temperature (25 °) for about 30 minutes, the ice starts melting and bubbles occur below the top surface, when pressing the waterpack with a finger. At lower ambient temperatures, the amount of time until the water pack is ready-to-use may be longer.
- Load the waterpacks and blood bags in accordance with the specific packing instruction of the box.
- Always store the blood bags in the provided containers in such a way to avoid direct contact with the waterpacks.
- When packing or unpacking the box, do not leave the lid open for an unnecessarily long time.

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3.2 Cooling elements: PCM Packs



WARNING

- PCM Packs must be carefully preconditioned for the specified temperature prior to each use.
- PCM Packs must never be opened.
- The elements must not come into contact with any pointed or sharp objects.
- PCM Packs must be disposed of immediately if any coolant leaks, due to improper handling or a defect. Any products that have come into contact with leaked coolant must also be disposed of immediately.
- Damaged PCM packs should be disposed of in accordance with local regulatory requirements.
- The product has been designed specifically to minimise risks for personnel and equipment during use. None of the materials used, pose any health or security hazards for personnel.
- We have taken every precaution to prevent any potential hazards and to eliminate any danger of injury to the user.
- No hazardous materials were used in the manufacture of the PCM Pack. The liquid content is a paraffin mixture or a solution of inorganic salts. Never heat the pack above 80°C or cool below - 80°C.
- PCM Packs must be stored out of reach of children.
- Do not touch, inhale or ingest any escaping fluids.
- Safety data sheets can be provided by the manufacturer on request.

- PCM Packs are heat accumulation elements, containing a so-called phase change material (PCM). The PCM stores latent heat at the required temperature at phase change (liquid/solid). The stored product will therefore remain at a near constant temperature for a specific period of time, without requiring active temperature control.
- Load the PCM packs and blood bags in accordance with the specific packing instruction of the box.

3.2.1 Types of PCM Packs

- PCM Packs are available in 2 sizes: 0.3 L and 0.6 L.
- The packs are designed for the following 4 specific temperature ranges:

Storage element	Colour	Storage Temperature
PCM+4	blue	+2°C to +8°C
PCM+22	green	+15°C to +25°C
PCM+37	yellow	over +35°
PCM-32	orange	under -30°C

3.2.2 Preconditioning of the PCM packs

- To ensure that the PCM packs are fully charged, they should be heated or cooled, as shown in the table below, to a specific temperature for a specific time, depending on the ambient temperature. The contents of a charged heat storage battery is completely liquid. The contents of a charged cold storage battery is completely solid.
- The values in the following table can be used as a guideline for preconditioning the PCM packs:

Ambient Temp.	Preconditioning
> 4° C	≤ -3° C
> 22° C	≤ 15° C
> 37° C	≤ 30° C
< -32° C	≤ - 40° C

Ambient Temp.	Preconditioning
< 4° C	≥ 11° C
< 22° C	≥ 29° C
< 37 C	≥ 44° C
NA	NA

The PCM packs should be preconditioned for a minimum of **72 hours!**

Important Guidance:

- If the ambient temperature lies above the required storage temperature, the PCM Pack should be solid before use.
- If the ambient temperature lies below the required storage temperature, the PCM Pack should be liquid before use.
- If you are unable to precondition the PCM to the approximate preconditioning temperature, you can precondition to a higher or lower temperature, however make sure prior to loading your product, that the PCM packs / internal temperature of the transport box does not greatly exceed the necessary transport storage temperature range.

NOTE: The duration of the hold-over varies with the ambient temperature, transport box used and the product to be transported. This user manual may therefore only be used as a guide. The risk of temperature deviation during use is greatly increased, if the packs have not been properly preconditioned. It is important to maintain a distance of at least 1.5 cm between packs during the preconditioning phase to ensure optimised air circulation around the packs.

3.3 Fixing and adjusting straps



CAUTION

- Before using the straps of the transport boxes, make sure that they are adequately fastened.
- Loosening of the straps can cause the transport boxes to fall, leading to damaging of the box and / or the stored product.

3.3.1 Clip-on strap

- The clip-on straps are easily fastened to the transport box.
- Use the clips to attached the strap to the designated fixation rings on either side of the transport box.
- Before every use, ensure that the strap is tightly secured to the transport box.
- For comfortable use, adjust the straps to the appropriate height of the user, by sliding the strap along the buckle.

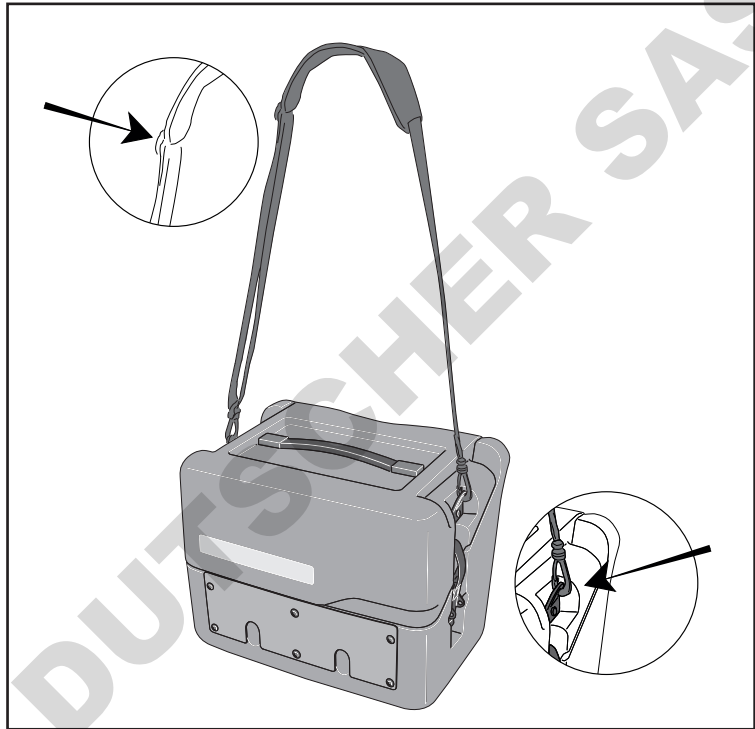


Figure 2 - Clip-on strap

3.3.2 Velcro strap

- The velcro straps are easily fastened to the transport box.
- Slide the strap through the designated fixation rings on either side of the transport box.
- Once the lid is closed, attach the velcro on either side of the transport box.
- Before every use, ensure that the strap is tightly secured to the transport box.
- It is important that the velcro is attached either side of the box after every lid opening. The velcro attachment maintains the lid securely in place.
- For comfortable use, adjust the straps to the appropriate height of the user, by sliding the strap along the buckle.

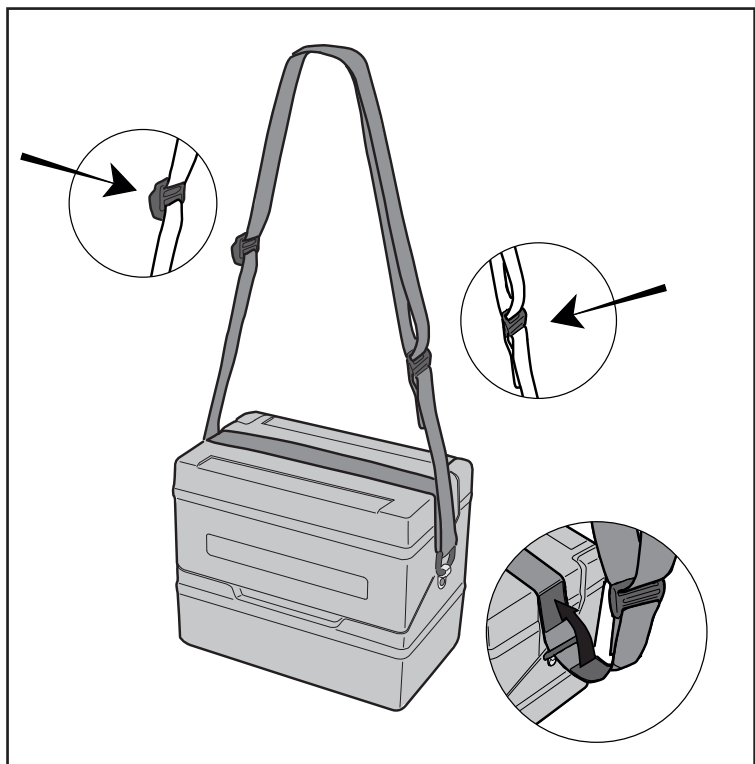


Figure 3- Velcro Strap

4 Cleaning and Maintenance



CAUTION

- Before using the transport box, it should be cleaned inside and outside.
- For cleaning, use only gentle cleaning agents. Never use aggressive or caustic cleaning agents, scouring powder, steel wool, abrasive sponges or chemical solvents.
- Before cleaning, make sure the load stored has been transferred to a permanent storage device.
- If there is damage or any type of issue to your device, call the B Medical System service team for further information.
- Only genuine spare parts must be used. Use of any other parts may affect the performance of the unit or cause physical injury or damage to the equipment.

- For disinfecting, we recommend all the surface disinfecting agents commonly used by the customer, provided they are recommended by the national organizations. For disinfecting small areas, we recommend using a concentrated alcoholic agent.
- Other than the cleaning procedures described in this manual, follow the internal policy and procedures on cleaning, disinfection and maintenance established by your facility.
- A visual inspection of the transport container should be done after every use or after every shift.
- Open the container and remove the icepacks. All parts of the transport box must be completely dried.
- Check the icepacks for deformations and tightness. Refreeze the icepacks as described above.

The following points of the transport containers are now inspected, according to the following criteria :
(different equipment depending on model)

- 1 Check the lid and the body for damages in the form of buckling, dents, tears and missing or broken parts.
- 2 Check the hinges of the lid and the related screws with regard to condition and function.
- 3 Check the catches of the lid and the related screws with regard to condition, function and secure position.
- 4 Check the Silicon seal between the lid and the body for damage, elasticity and secure position.
- 5 Following the visual inspection, the surface of entire box, including all replacement parts, should be cleaned with a standard disinfectant in accordance with the operating instructions of the manufacturer of the disinfectant or the company's own hygiene

5 Disposal



WARNING

- Before scrapping an old unit, remove the lid so that nothing essential is forgotten inside the device.
- Follow the local prescriptions on disposal of hazardous equipment.

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