

MB Thermo-Insulation-Set



1. Where can I find the qualification documents?

With the revision of the cooling elements, a new qualification became necessary. You can find these documents attached or download them from www.bito.com. Additionally, at a customer's request, we conducted a qualification at an ambient temperature of 20°C using only two cooling packs. The documentation is also attached. (The temperature range is maintained by the MBD64271 for 9 hours and by the MBD43271 for over 12 hours.)

2. How should the cooling elements be oriented?

The cooling elements can be positioned with either side facing the contents.

3. What should be considered for storing and cooling the packs?

The cooling elements should be stored or frozen lying flat.

IceCatch:

To avoid straining the film, ensure the elements are not preconditioned in a wet state when stacked. The elements can freeze together, and attempting to separate them may damage the film. The correct orientation of the elements when placing them in the boxes is no longer mandatory.

4. Can the cooling elements be reordered?

Yes. The item number for the cooling elements for the MBD43271 is 31361, and for the MBD64271, it is 31362. The item number for the hard-shell packs is 51295.

5. How long do the cooling elements need to be pre-cooled?

The cooling elements should be stored for at least 72 hours at -16°C to -20°C. To ensure even distribution of the liquid, they should be stored lying flat. It is crucial that the cooling elements are completely frozen (including the core) to use their full energy. The 72-hour freezing time is a general recommendation. This time may be shorter in some cases, but no binding statement can be made as cooling performance varies depending on the device and the freezing method.

Freezing time is significantly influenced by factors such as the amount of room temperature products placed in a freezer.

Customers can conduct their own tests to qualify/validate this process.

Possible procedure: Place a probe thermometer in the unfrozen state between the middle cooling elements (in the box or on a pallet), record the temperature, and determine the freezing time.

6. “Our freezer’s temperature is below -18°C.” Is it allowed to use the cooling elements at lower temperatures?

The cooling element can be stored or frozen below -18°C. However, it is not recommended to use the cooling element with a temperature significantly below -18°C in the container, as this would significantly alter the conditions.

The insulation layer is designed to buffer the introduced energy at a maximum of -18°C under the appropriate outside temperature.

We chose this temperature because most commercial freezers are typically set to -18°C.

7. Can the cooling elements be reused?

Absolutely. With normal use, they can be reused repeatedly. The cooling performance of the elements will not change significantly.

The cooling elements should not be bent, compressed, or thrown. They should also not be handled with sharp or pointed objects.

To ensure even distribution of the liquid when freezing and to avoid bulges, they must be frozen lying flat. Defective cooling elements can be disposed of in household waste (according to the EU Safety Data Sheet) as they are non-toxic.

8. What else should be considered when handling the cooling elements?

Both IceCatch and hard-shell cooling elements should not be bent, compressed, or thrown, as this could damage the support foam inside the IceCatch cooling elements. They should also not be handled with sharp or pointed objects.

9. The protective film of the IceCatch packs is damaged.

If the protective film of the IceCatch packs is damaged, they can no longer be used. This can happen due to improper handling or a production error.

10. What is the medium inside the cooling elements?

IceCatch:

Mostly normal water with preservatives. Color: Light green.

Additionally, a foamed structure acts as a shape-forming carrier. All components are non-toxic. They are safe for use in the pharmaceutical or food sectors due to the approved PA/PE film.

Hard-shell pack:

Eutectic gel, which offers 33% more cooling than water, produced through a unique manufacturing process.

11. The cooling element bulges slightly in the middle. Is this normal?

Yes, this is normal. All water-based packs freeze from the outside in. At the center—the last point to solidify—a slight bulge forms due to the volume increase from dissolved elements, dust, etc., which flow to the center during freezing. This effect can also be observed in hard-shell packs. This does not impair the functionality of the packs.

12. The cooling element/inside of the container becomes damp. Is this condensation?

Most likely, yes. Condensation occurs when air containing water vapor cools below the dew point upon contacting a cool surface. The white thermoformed insert forms two chambers on the sides where the packs stand. Some condensation can accumulate there without entering the interior. Condensation on the pack is not a reason for complaint.

The easiest way to check if the packs are leaking or if it is condensation is to weigh the packs. The small IceCatch pack weighs 350g and the large one 750g.

13. The cooling element does not stay in the lid.

A net can be hung in the lid to prevent the packs from falling out.

14. Can a “Neopor/EPP” lid be reordered separately?

Yes, that is possible.

All other parts—PS inner shell and cooling elements—can also be reordered individually.

15. Are there other sizes of MB thermal insulation inserts?

No, not currently.

The tools required to create a new size necessitate a minimum quantity of 2,000 units from our perspective. Please inquire—we would be happy to provide a quote.

Allit has developed an insert for the MB64321, which is also available through BITO.

16. Our use case differs from your qualified temperature profile. Does this have any impact?

Yes, any change in conditions also changes the outcome.

Our summer/winter profiles simulate a typical process for operators. After packing the goods, the containers usually wait for a while for the carrier. We assumed an average time of 4 hours. This is followed by transport in a heated or cooled vehicle. Then there is a phase of about 2 hours until the vehicle acclimates, albeit still above or below normal room temperature. Finally, delivery to the recipient takes place.

17. The temperature inside the container falls below 0°C. What are we doing wrong?

Important: Check if the cooling elements were placed in the insulated box with the unprinted, insulated side facing the product area according to the instructions.

Our temperature simulations have demonstrated that, under the specified parameters, the containers are qualified to transport temperature-sensitive products within the desired temperature range of +2°C to +8°C for the desired duration under simulated ambient conditions. However, changes in the tested parameters can significantly impact the system’s overall performance:

If the customer tested the boxes at a significantly different ambient temperature (e.g., +5°C instead of 22°C) in the initial phase, the internal temperature will also drop.

Testing the containers when empty also leads to lower internal temperatures. In our simulations, 2 PET bottles were placed in the MBD43271 and 4 PET bottles in the MBD64271 as product substitutes (filled with 200ml of water each, at approx. 5°C), and the temperature in the liquid was measured. Ultimately, the temperature in the liquid (product) is crucial, not the air temperature in the product area.

If the customer's process deviates from our simulation, it is advisable to conduct their own tests and possibly their own qualifications.

18. Where were the temperature loggers positioned during the qualification tests?

The temperature sensors were generally placed in the corresponding products during the tests. The products were centrally located in the container/thermal insulation set being tested.

19. Can we adjust the configuration to our typical individual application and temperature profile, and can it be qualified?

Yes, that is possible. If you send us the temperature profile, we can review, potentially develop, and qualify an alternative configuration. The cost of the tests, including the corresponding documentation, is approximately EUR 2,000.00 – 3,000.00 (maximum duration 48 hours).

20. How can the gray Neopor insulation boxes be cleaned?

To clean the Neopor boxes, we recommend using household soap solution with water, but the water temperature should not exceed 60°C.

Please do not use acidic or alkaline cleaners, such as bathroom or toilet cleaners. Wipe disinfection with low-alcohol wipes is not a problem. However, this should always be tested and approved by the user (hygiene specialist) beforehand.

21. How long do the insulation boxes and cooling elements last - When should they be replaced?

The material Styrofoam or Neopor is aging-resistant in a normal environment, and the manufactured parts and insulation containers are as well. If there are no mechanical or thermal damages to the box or lid, they retain their specified properties. This means that for use as reusable boxes, the boxes should be checked for reuse based on the following criteria: If the closure edges in the lid or the insulation box are visibly broken, so that a secure closure is no longer possible, the box or lid should no longer be reused.

If the lid, wall, or bottom are visibly damaged by breakages, so that the interior is no longer completely enclosed and thermally separated, the box or lid should not be reused. If the boxes or lids are dented from use, a small area dent less than 10% of the surface area and less than 20% of the depth is not impairing the box and it can continue to be used. Large-area dents should be sorted out for safety, as a break is expected due to the weakening. If there are large breakages at the holding elements of the cooling elements, so that the cooling elements can no longer be held securely, the boxes should no longer be reused.

All lids are fundamentally compatible with all boxes, meaning systems do not need to be completely discarded if only one part is defective. The remaining intact part can be kept as a spare part for continued use.

22. We recommend replacing the cooling elements if the following criteria are met:

- Obvious leakage in the film
- Actual weight:
 - < 675 g (IceCatch Solid Insulated 750g)
 - < 315 g (IceCatch Solid Insulated 350g)
- Damage/destruction of ≥10% of the support substrate area

23. What changes were made to the packs in May 2016?

In May 2016, the following changes were made to the IceCatch cooling elements:

The film was made slightly thicker to reduce the risk of damage. The packs were made slightly thinner to facilitate insertion into the container. The packs are now equipped with an internal insulation layer on both sides to increase mechanical strength. The foam carrier inside is thus protected on both sides. The packs were equipped with new printing, including instructions for use and the BITO logo. The qualification was repeated with the modified packs. See attachment. The system's performance remains well above the promised temperature maintenance duration of 12 hours.

Qualification and certification of the containers

We, as the manufacturer, qualify the containers for a specific temperature profile. However, customers must certify the containers themselves according to their specified standards.

24. The lid was revised in summer 2023:

The material of the lid was changed from Neopor to EPP. The color changed from gray to black. The revision made the lid more robust.



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