

PASSIVE SHIPPING SOLUTION THERMOCARE

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1. Overview

This document is intended for Swiss Post business customers wishing to use the ThermoCare passive shipping solution for the transport of medicines in accordance with EU GDP 2013/C 343/01.

The core component of the ThermoCare service is the ThermoCare Box, which guarantees a required temperature range during a set period of time inside the box without active energy supply during transport. In addition to Swiss Post's established and certified internal processes and the associated qualification procedure, two specific requirements must be met for ThermoCare services to comply with the provisions of the Guidelines on Good Distribution Practice (EU GDP 2013/C 343/01):

- Transport time of the consignment less than 25 hours during the week
- Compliance with storage conditions and times at the shipping customer

This was confirmed by the external review by the DQS/SQS in autumn 2017. The corresponding certificate is published in the same place as this document.

2. Technical solution

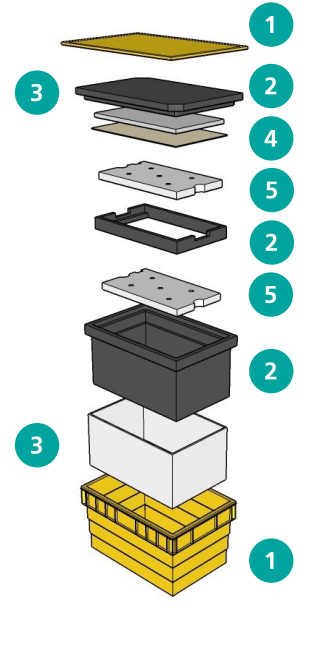
The ThermoCare Box, in particular the interior with the insulation components, was developed by va-Q-tec AG in Würzburg, Germany. The company also manufactures and successfully markets and uses them as standard in the life sciences sector domestically and internationally.

To ensure the internal temperature of the box is maintained within a defined temperature range (e.g. "Cold": 2° to 8° C) for the entire duration of the transport, additional thermal mass through latent heat/cool storage elements (PCMs) is required in addition to the thermal insulation of the inner box.

2.1 ThermoCare Box

The structure and dimensions of the ThermoCare Box used by Swiss Post are identical for both of the temperature ranges offered. The filling volume varies however, because the number and size of the PCM elements used for "Cold" are different to the ones for "Ambient"

2.1.1 Structure of the ThermoCare Box



Element	Description	Impact
-1- Outer box	Plastic box made of recyclable polypropylene	Protects against mechanical stress and environmental influences
-2- Inner box	Inner box made of expanded polypropylene (EPP).	Has an additional, insulating effect; protects the vacuum panels from mechanical damage.
-3- Vacuum panels	A panel for the box body and one for the lid	Thermal insulation on all six inner sides
-4- Protective lid	Internal cover of the box made of polypropylene.	Protects the vacuum panels in the lid; has an additional insulating effect.
-5- PCM elements	Latent cool/heat storage elements consisting of a paraffin mixture.	Storage of thermal energy

Schematic representation of the Thermocare Box (ThermoCare Ambient configuration)

2.1.2 Dimensions and weight

Number of PCMs	2 x 2.3 kg	2 x 2.3 kg and 2 x 0.8 kg
Empty weight without PCMs in kg	5.4	5.4*
Empty weight incl. PCMs in kg	10.0 (outer box: 2.7 kg)	11.6* (outer box: 2.7 kg)
External dimensions in mm	598 x 398 x 341	598 x 398 x 341
Internal dimensions in mm (top)	442 x 252 (396 x 252 in the fixation strip area)	382 x 252*
Internal dimensions in mm (bottom)	442 x 252	382 x 252
Effective depth in mm	182 (162 below the fixation strip)	182*
Effective volume in litres	20.0	17.5*
Number of PCMs return solution	3 x 2.3 kg	2 x 2.3 kg and 4 x 0.8 kg

*without cardboard inlay

2.1.3 Performance

The service life of the vacuum panels has been well researched scientifically. The panels used in the ThermoCare passive shipping solution are designed for a service life of 20 years.

Extensive studies have been conducted on the energy performance of the PCM elements. The cycle stability of the filling of the PCM elements has been thoroughly tested by the manufacturer. The filling material does not undergo ageing, which means that capacity loss only occurs as a result of damage to the casing.

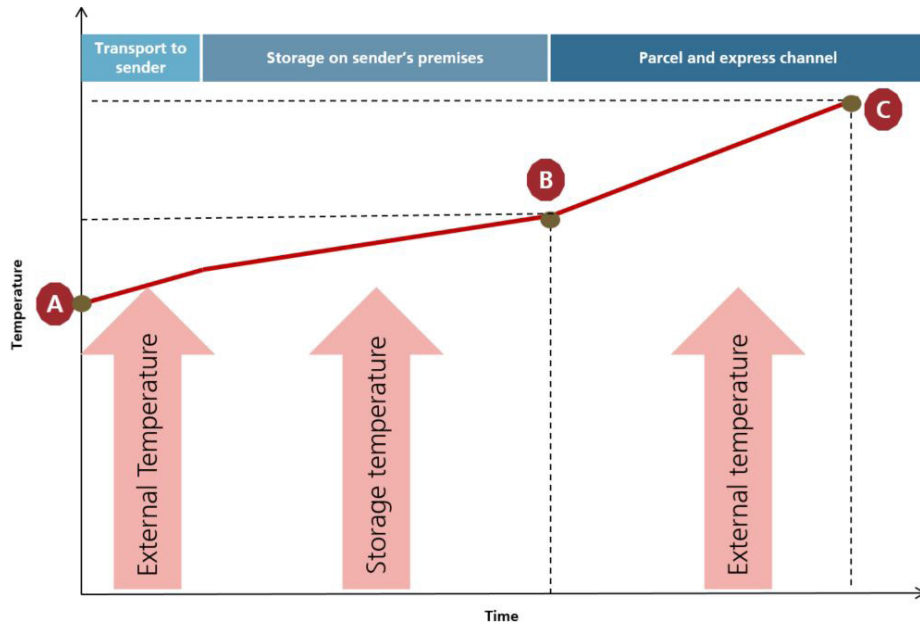
2.2 Energy model

In the energy model, the air temperature in the interior of the ThermoCare Box is considered.

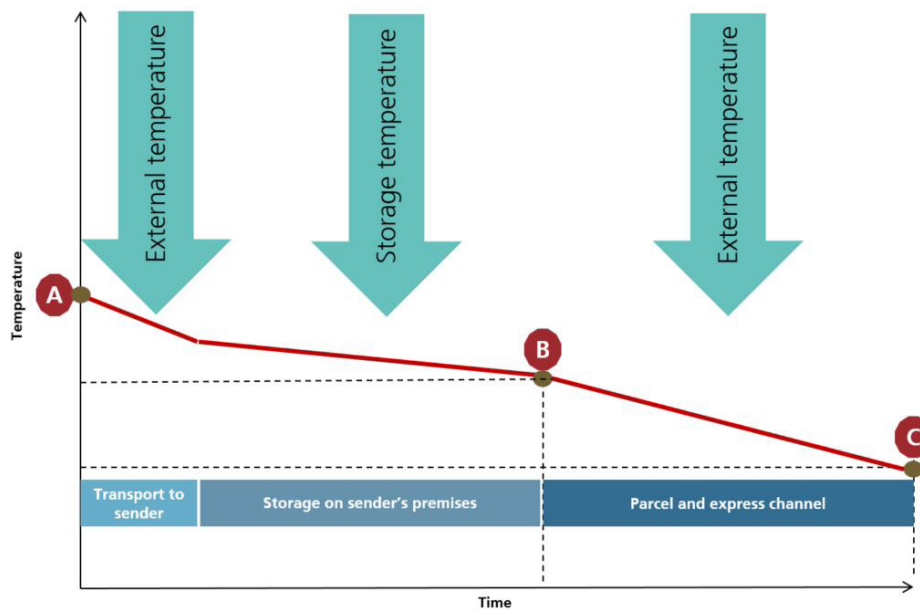
The PCM elements are charged by Swiss Post with the required thermal energy (point A) to keep the ThermoCare Box within a defined temperature range over the entire transport route.

During the summer, the ThermoCare Box potentially absorbs energy from both the warm outside temperature and the storage temperature at the sender. During transport from B to C, the maximum permissible temperature must never be exceeded.

In winter, the ThermoCare Box potentially loses energy during transport, both from the outside temperature and from the storage temperature at the sender. During transport from B to C, the temperature must never fall below the minimum permissible temperature.



Summer model: warm conditions



Winter model: cold conditions

3. Process

The ThermoCare Box is delivered via the ordinary parcel and express channel – and if necessary also via the SameDay channel – and is regarded as a standard consignment during distribution. The basic process is always the same when using the ThermoCare Box at Post CH Ltd:



3.1 Preconditioning and preparation

The PCM elements are charged with thermal energy during the preconditioning process. Then the controlled and cleaned boxes are equipped with the necessary number of PCM elements and sealed. The preconditioning and preparation is standardized according to qualified specifications.

3.2 Transport to sender

The ThermoCare Boxes are transported to the sender as individually agreed with Swiss Post. The qualified service includes a maximum transport time of 5 hours in this process step.

3.3 Picking at the sender

For each temperature range, it has been determined in a standardized procedure under what combination of storage time and average storage temperature at the sender customer the performance promise for the shipping can be maintained. These basic values are specified to the sender customer as framework conditions in a quality agreement that must be signed by both parties.

3.4 Distribution to the consignment recipient

The processing and delivery either takes place as part of standard parcel shipping with the basic "PostPac Priority" service within 25 hours from collection at the sender or with the basic Swiss-Express "Moon" service with delivery by 9 a.m. the following day at the latest. With the SameDay afternoon service which is available for certain delivery areas, urgent consignments can even reach their recipients on the same day (by 5 p.m. at the latest). When posting on a Friday, ThermoCare boxes are temporarily stored until Sunday in qualified, actively temperature-controlled vehicles and are delivered on Monday.

3.5 Return of empty boxes

Similar to the process with Dispoboxes, the empty ThermoCare Boxes are collected by mail carriers, or taken back immediately at the time of delivery after being emptied by the recipient. The ThermoCare Boxes are then returned to Swiss Post for inspection, cleaning and reprocessing.

4. Qualification

The requirements of the ThermoCare Box in terms of insulation properties have been verified by Swiss Post based on a dedicated climate profile for the transport routes in Switzerland. For this purpose, measurements were taken from over 300 consignments with sensors on the outside both in winter and in summer. The development of this internal Swiss Post national climate profile is based on worst case scenarios with regards to transport routes, duration and outside temperatures and is stricter than the ISTA 7E climate profile established on the market for Europe.

Appropriate measurements must first be carried out as part of development and qualification tests in climate chambers to assess whether the ThermoCare Box can meet a performance promise in the parcel/express channel in Switzerland. The following benchmark figures are defined for these measurements:

- Air temperature inside the box
- An empty box is measured – i.e. the insulation performance of the box is based on the minimum usable volume and contains no thermal mass from the shipment item which enhances insulation performance.
- The sensor value with the critical temperature is always taken (no average values)
- No tolerance is accepted for compliance with a temperature range

Illustrative test reports for ThermoCare Ambient and ThermoCare Cold, with the curves for the summer and winter scenarios, can be found in the same place as this document.

The yellow ThermoCare Box which is being supplied from mid-2018 instead of the previous blue ThermoCare-Box has no impact on the effectiveness of the box's insulation. The change affects only the colour of the polypropylene outer shell.

Following the tests in climate chambers at neutral, external locations, standardized field tests with test consignments to all regions of Switzerland are carried out before the introduction of a ThermoCare service.

4.1 ThermoCare Ambient

The initial qualification of ThermoCare Ambient was completed in mid-April 2017 and approved by the Executive Board of the PostLogistics Group unit for ongoing operations; in September 2017, after summer field tests which were also successful, it was successfully tested and certified for GDP compatibility by SQS/DQS.

The qualification included tests which are not required for other ThermoCare services. These include, in particular, mechanical tests (e.g. damage during transport and interim storage), as well as checks for contamination risks and compliance with hygiene standards. The checks for contamination risks and compliance with hygiene standards are monitored in regular internal audits, among other measures. The qualification of ThermoCare Ambient resulted in the following special requirements for compliance with the 15°C to 25°C temperature range.

	Winter scenario	Summer scenario
Sender storage temperature	21°C to 25°C	20°C to 22°C
Period	20 August to 8 July	9 July to 19 August

4.2 ThermoCare Cold

The initial qualification of ThermoCare Cold was successfully completed at the beginning of April 2018 and approved by the Executive Board of the PostLogistics Group unit for ongoing operations. The acceptance criteria of the subsequent summer field tests have also been met and approved.

	Cold storage	Storage at room temperature
Sender storage temperature	3°C to 4°C	5°C to 22°C
Permissible storage duration	7 days	1 day (24 hrs)

5. Certification

In September 2017, the ThermoCare solution was tested for GDP compatibility by the company SQS/DQS for the first time. The solution was certified for the entire service – from qualification, to the reprocessing of the boxes, to delivery logistics. The ongoing quality of the ThermoCare solution is ensured by means of regular recertification audits by SQS/DQS.

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