Ultra-high performance heat insulation transportation box

BioBox PLUS

Transportation Package System for Temperature Sensitive Medical Substances

SUGIYAMA-GEN Co.,Ltd.

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- **Establishment** : 1932
- **Scope of business** :

  Medical devices and ancillaries for healthcare market
- **Main product line**
  - Micro lab. related
  - Animal lab. related
  - Environmental analysis related
  - Glassware for physical/chemical analysis
  - Stainless steel container

Recent Business Focus

- Packing solution for safe and temperature controlled transportation of pharmaceuticals and specimen
  - **BioBox Plus (patent applied)**: transportation system for temperature sensitive medical substances.

    examples are as follows;
    - Vaccines
    - General temperature/Freezing sensitive pharmaceuticals
    - Pharmaceuticals/Specimen for clinical trial
    - Specimen for microbiological analysis
    - Others which require strict temperature control
  - **BARRIAPOUCH (with patent)**: pouch for safe transportation of bio-hazard substances

BioBox Plus Presentation

- **Contents**:
  - Requirements about transportation of temperature sensitive medical substances
  - Product configuration
    - Illustration of BioBox Plus
  - Product specifications and features
  - Heat insulation technology
    - Illustration of outer box panel
  - Temperature control technology
  - Temperature control System & Procedure
  - Case study
  - Summary
  - Validation reports on temperature control

Requirements for Transportation of Temperature Sensitive Medical Substances

- **Safe and effective transportation**
- **Stable and homogeneous temperature control, temperature ranging from**

  2℃ - 8 ℃

  15℃ - 25℃

  (This presentation covers mostly 2-8℃)
- **Durable packaging/storage for long term use**
- **Environmentally friendly system, materials**

Product Configuration

High performance insulation outer box to contain

-(**heat sensitive substance)**

-**phase change materials (PCM)**

cooling agent (coolant/PCM)

heating agent (PCM)

-**inner box**

with pocket for invoice, documents, etc. on surface of lid and front of box

Options:

-**Temperature monitoring instrument**

-**Battery driven heater**

-**Anti-freezing agent**

- Note: Outer box itself is widely used in Japan due to superlative heat insulation.

Illustration of BioBox PLUS Appearance

BioBox PLUS Components

Inner box
PLUS Inner Box

PCM A : Phase change material
Coolant

PCM B : Phase change material
ThermoPack PLUS 4

Product Specifications

- **Name**: BioBox Plus
- **Made of Aluminum with high thermal conductivity**
- **Patent applied**
- **Product code**: SBE-P45
- **Dimensions:** STD size
  (customization is available based on customer requirements)
  -Outside box
  External (mm): 512(+-10)*388(+-10)*454(+-10)height
  Internal (mm): 418(+-10)*294(+-10)*364(+-10)height
  (Storage volume (without Inside box): 44.7L
  -Inside box
  Internal (mm): 372(+-2)*272(+-2)*184(+-2)height
- **Storage volume** (with inside box and PCM): 18.6L
- **Net weight** (Kg): about 5.5Kg plus weight of PCM
  (depending on selection)
- **Materials**: refer to "Illustration of Outer Box Panel Cross Section"

Product Features

Outer box: (Heat insulation)

-Five faces and lid are made of superlative vacuum insulation panel and Styrene form layers.

-All corners are covered by the same insulation.

-Lid fits into box with captive labyrinth for air tightness and strength

-Relatively thin thickness of panels

Phase change materials(PCM) : (Temperature control)

– 2 kinds of PCM are employed for cooling and heating

(In case of temperature ranges of 2 ℃ -8℃)

(Other kind of PCM is for temperature ranges of 15 ℃ -25℃)

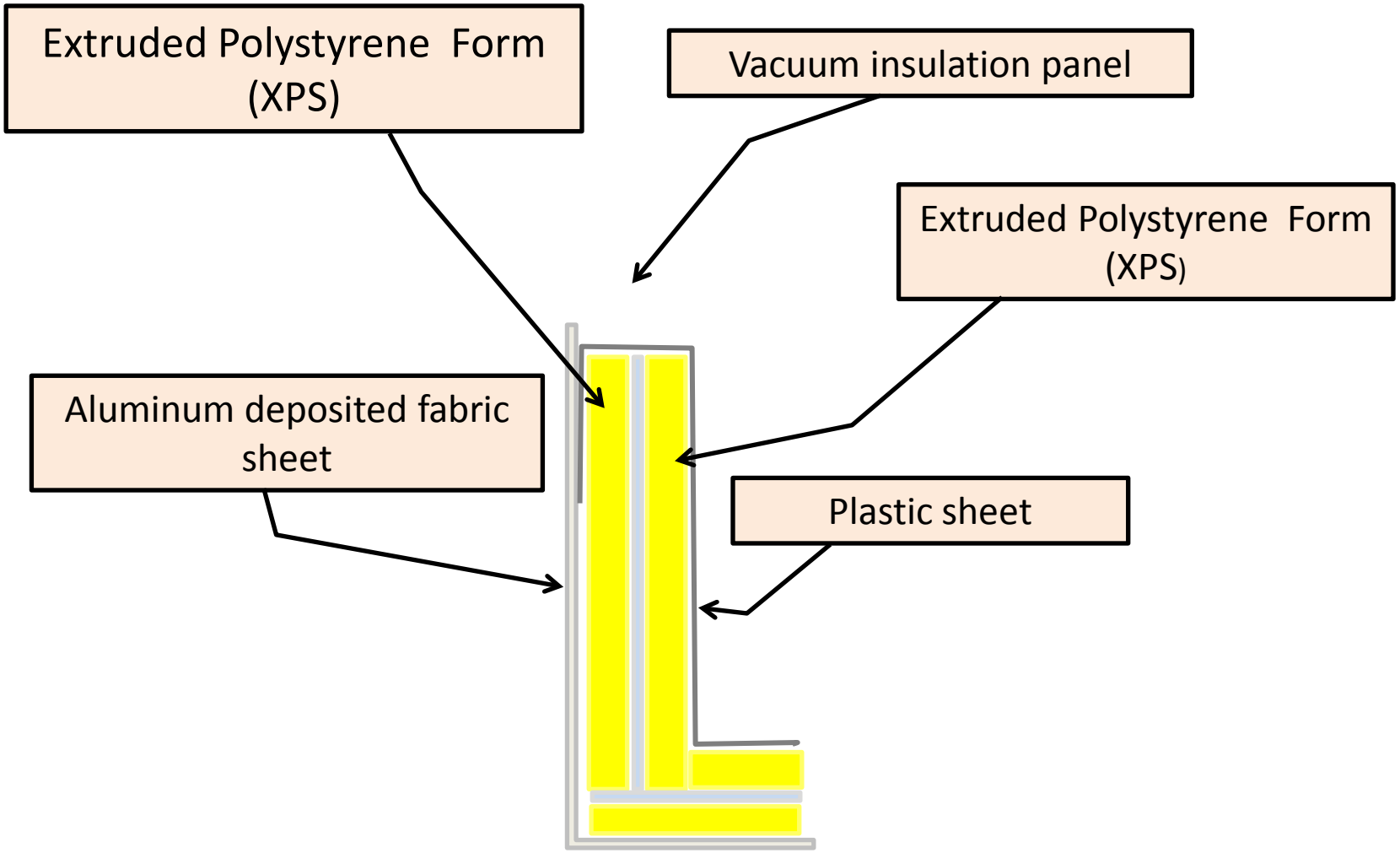
Inner box: (Heat distribution)

-Inner Box is made of Aluminum plates which bring homogeneity of temperature distribution within inner box

Heat Insulation Technology
Outer Box Panel

- **Heat insulation panel of the outer box**
  - **Panel is made of 3 layers.**
    - **Outer layer: Extruded Polystyrene form**
    - **Middle layer: Vacuum insulation panel**
    - **Inner layer: Extruded Polystyrene form**

Illustration of Outer Box Panel Cross Section



Temperature Control Technology

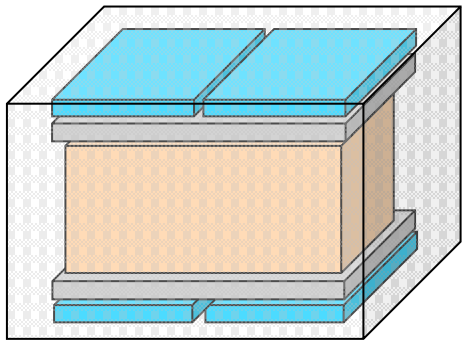
- Between the inside of the outer box and the outside of the inner box, 2 kinds of cooling and heating agents(PCM) are put to minimize effect of ambient temperature and effect of cooling agent from heat up and freezing respectively. Both utilize latent heat.
- Appropriate PCMs and their volumes must be selected and associated pre-conditioning is necessary to utilize the phase change from solid to liquid and vice versa.
- Inner box is made of the Aluminum plates.

  It can bring even temperature distribution due to good heat energy transmission of Aluminum.

Illustration of BioBox Plus and Components & Procedure Controlled temperature range (2-8℃)

＜Preconditioning＞

PCM A ：Stabilize PCM in refrigerator at temperature not higher than -15℃ over 10 hours
PCM B ：Stabilize PCM in a refrigerator at temperature not lower than 4℃over 6 hours



＜Procedure＞

① Install PCM A

② Install PCM B

③ Put inner box and store heat sensitive substances

④ Install PCM B

⑤ Install PCM A

One Case Study

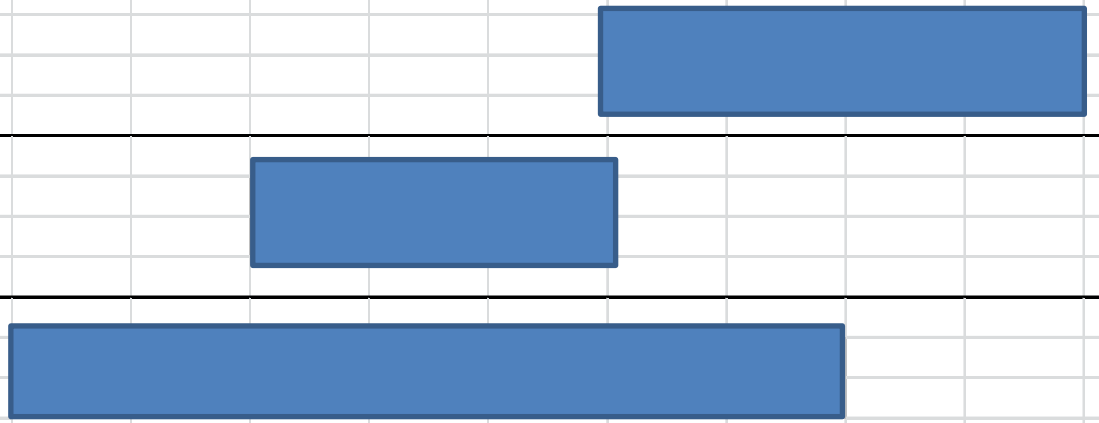
- **Assumptions**
  - **Ambient temperature**: 35℃
  - **Targeted control temperature**: 2 ℃ - 8℃
- **Heat energy transmission**
  - **Heat energy is transferred from the ambient air to the inside of the box through the insulation panel.**
  - **Incoming heat energy of PCM A becomes latent energy resulting in melting at 0℃.**
  - **PCM A takes heat energy of PCM B resulting in solidifying of PCM B at 3.5℃.**

Application Matrix(2-8℃ 24Hr)
PCM & Volume vs. Ambient Temp.

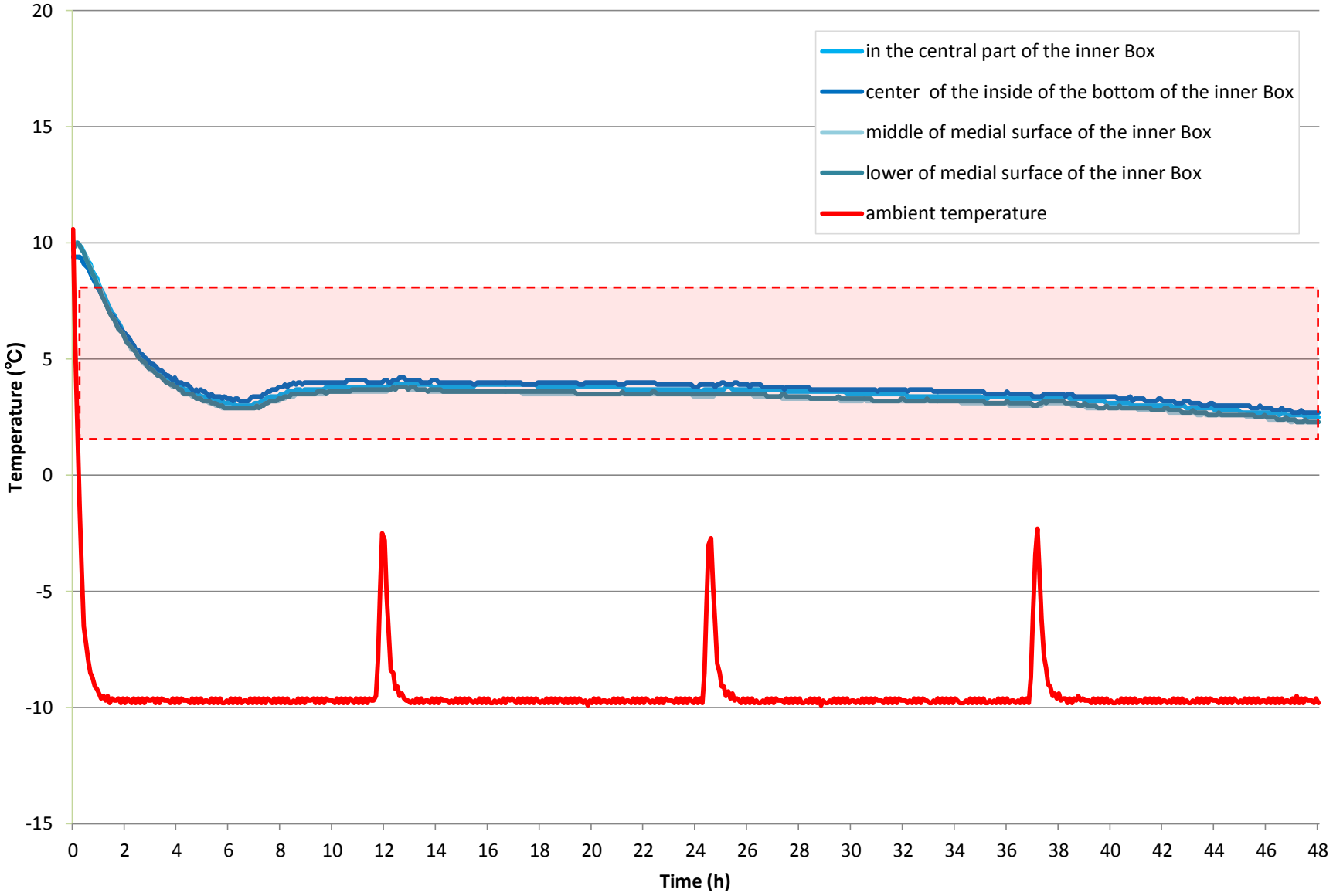
Cnotrol Target Temp. 2-8℃ Storage Span 24Hr			Ambient temp.(℃)									
Heat control agent			-10	-5	0	5	10	15	20	25	30	35
Name	Position	Weight (Kg)										
Thermopack Plus4	Top	2										
	Bottom	2										
Cooling agent	Top	2										
	Bottom	2										
Thermopack Plus4	Top	2										
	Bottom	2										
Cooling agent	Top	1										
	Bottom	1										
Thermopack Plus4	Top	2										
	Bottom	2										
Cooling agent	Top	0.5										
	Bottom	0.5										
Thermopack Plus4	Top	2										
	Bottom	4										
Cooling agent	Top	2										
	Bottom	2										
Thermopack Plus4	Top	2										
	Bottom	4										
Cooling agent	Top	1										
	Bottom	1										
Thermopack Plus4	Top	4										
	Bottom	4										
Cooling agent	Top	2										
	Bottom	2										

Application Matrix (2-8℃ 48Hr)
PCM & Volume VS Ambient Temp.

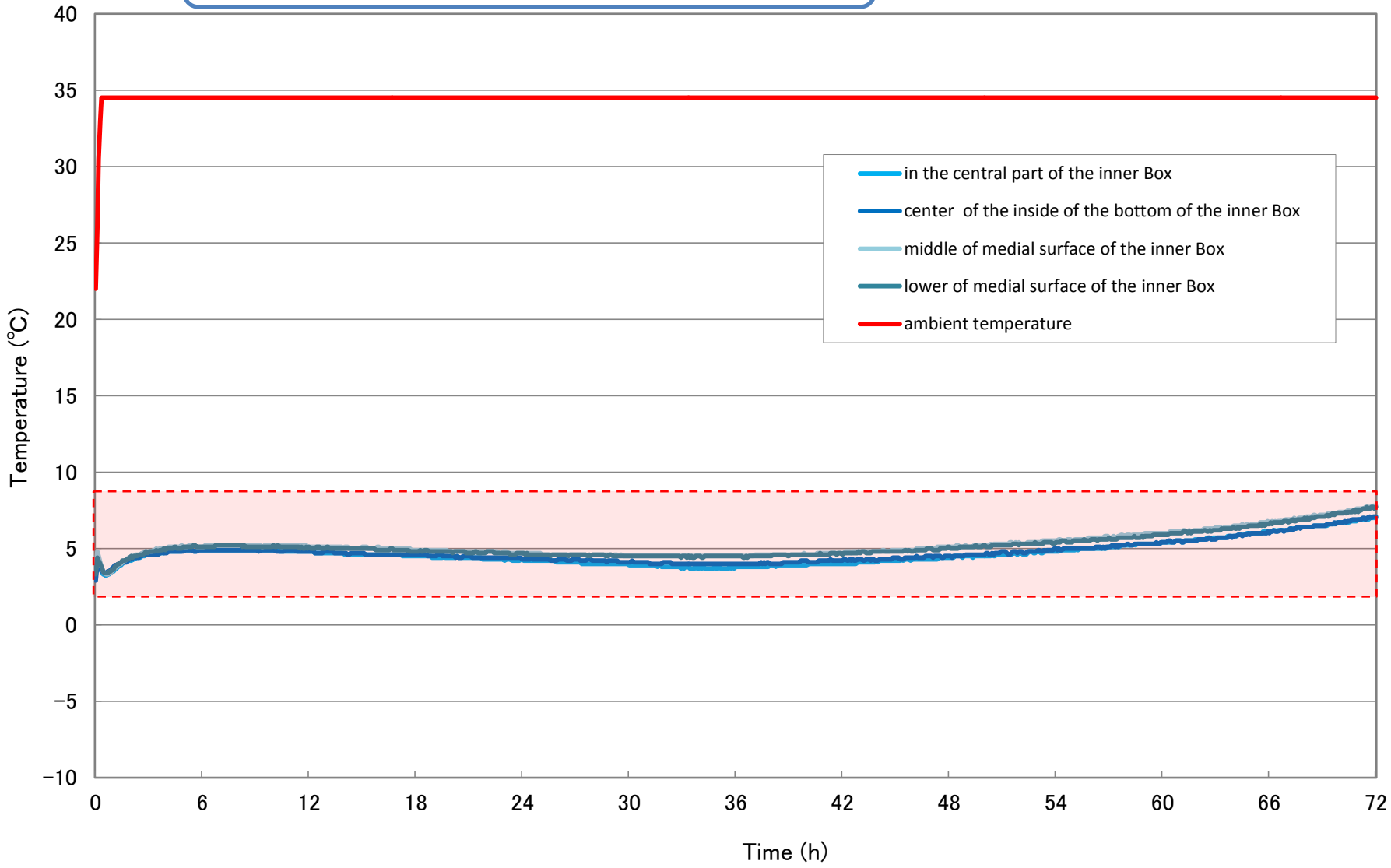
Cnotrol Target Temp. 2-8℃ Storage Span 48Hr			Ambient temp.(℃)									
Heat control agent			-10	-5	0	5	10	15	20	25	30	35
Name	Position	Weight (Kg)										
Thermopack Plus4	Top	2										
	Bottom	2										
Cooling agent	Top	2										
	Bottom	2										
Thermopack Plus4	Top	2										
	Bottom	2										
Cooling agent	Top	0.5										
	Bottom	0.5										
Thermopack Plus4	Top	4										
	Bottom	4										
Cooling agent	Top	1										
	Bottom	1										



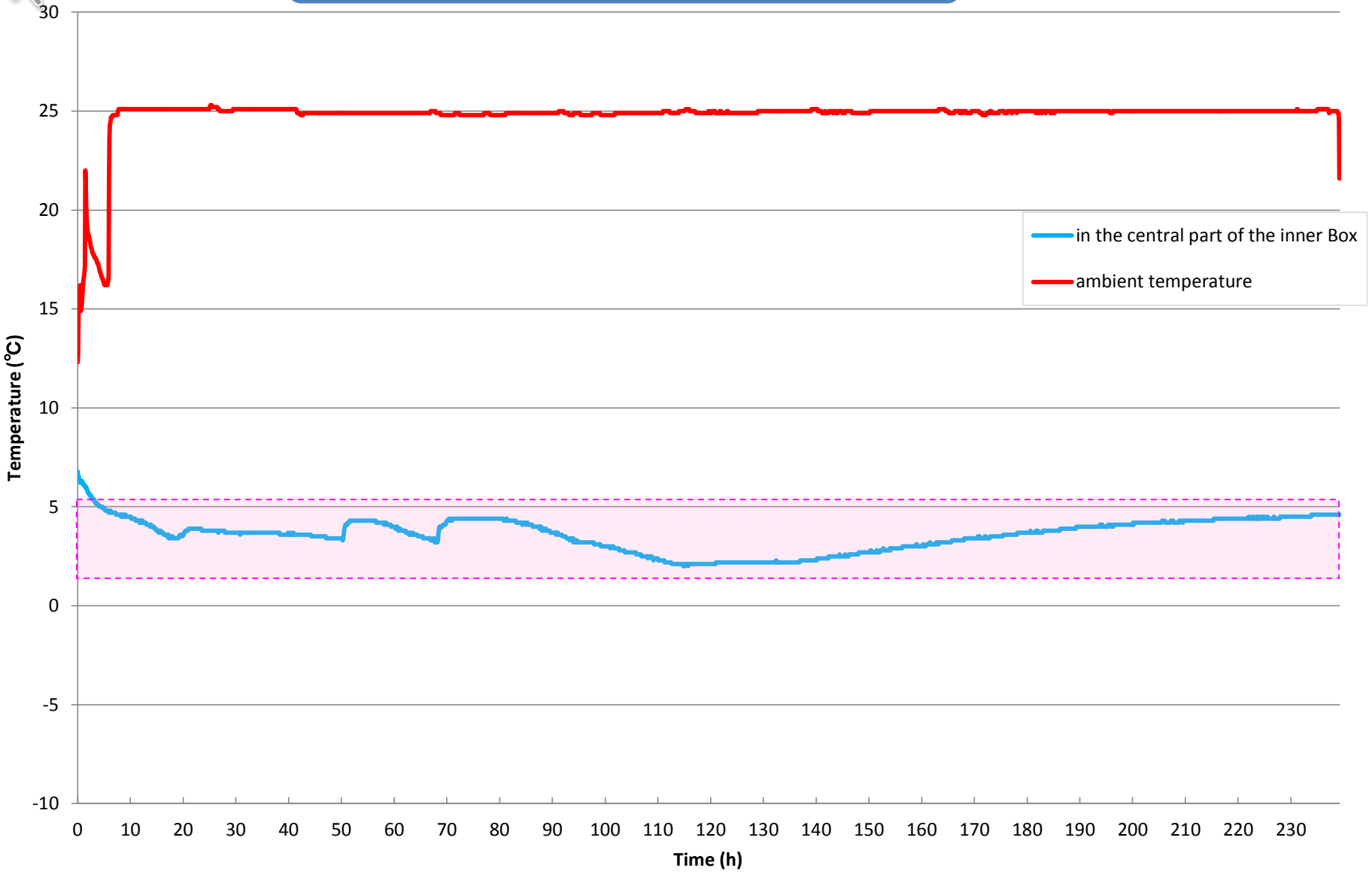
2-8℃ 48Hr Ambient -10℃



2-8℃ 72Hr Ambient 35℃

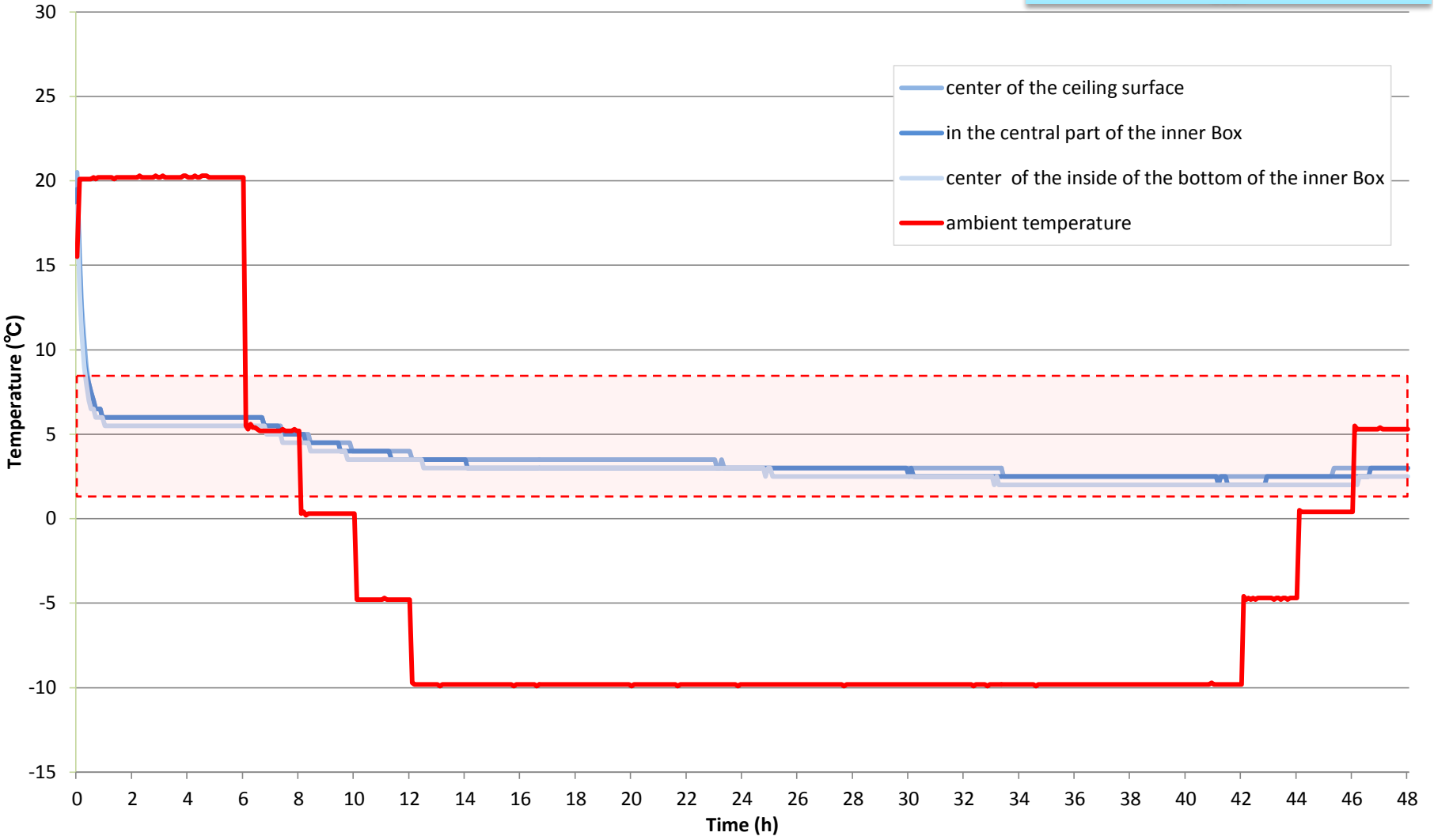


2-6℃ 240Hr Ambient 25℃



2－8℃ 48 Hr Temp fluctuation (－10℃--＋20℃)

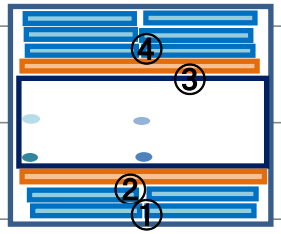
2011.01.29～01.31
Testing Agency : SUGIYAMA-GEN Co., Ltd.



BioBox PLUS 2-8℃ 72Hr Ambient

2012.12.21～12.25
Testing Agency：SUGIYAMA-GEN Co.,

＜Test Condition＞
Cold Box ： BioBox PLUS
coolant ：Grade 0 ℃ 500 g × 8 sheets ・・・①
inject condition ： freezer→in a moment inject BioBox PLUS
phase change material (Thermo Pack 4)：Grade 4 ℃ 1500 g × 1 sheet・・・②
inject condition ： keeping refrigerator (over 5 ℃)→in a moment inject BioBox PLUS
phase change material (Thermo Pack 4)：Grade 4 ℃ 2000 g × 1 sheet・・・③
inject condition ： keeping refrigerator (over 5 ℃)→in a moment inject BioBox PLUS
coolant ：Grade 0 ℃ 500 g × 12 sheets ・・・④
inject condition ： freezer→in a moment inject BioBox PLUS



APEX INTERNATIONAL AICB-444L 2-8℃ 96Hr Ambient

2012.12.21～12.25
Testing Agency：SUGIYAMA-GEN Co.,

＜Test Condition＞
Cold Box ： APEX INTERNATIONAL 444-L
Coolant ： Cool Pack × 44 sheets（Desinated position of the maker）
inject Condition ： keeping refrigerator (Around 3～5℃）→in a moment inject Cold

Summary of BioBox PLUS

- **Superlative heat insulation outer box** brought by about 100% box coverage of vacuum insulation panel with durability. This box itself is widely used in Japan due to superlative heat insulation.
- **Effective use of phase change materials** for good temperature control. Preconditioning requires only a normal refrigerator.
- **Aluminum inner box** brings good, homogeneous temperature distribution.