THERMO KING

User Guide

SP Truck Multi-Temperature

PharmaSolutions
GDP compliant

GDP qualification of equipment with temperature controlled units for the transport of pharmaceutical products
This document is only valid in conjunction with the GDP validated equipment certificate and on completion of the qualification process

Revision A

April 2022

TK 61296–1–MS-EN

TRANE TECHNOLOGIES

Introduction

This manual is published for informational purposes only. Thermo King® makes no representations warranties express or implied, with respect to the information recommendations and descriptions contained herein. Information provided should not be regarded as all-inclusive or covering all contingencies. If further information is required, Thermo King Service Department should be consulted.

Thermo King's warranty shall not apply to any equipment which has been "so installed, maintained, repaired or altered as, in the manufacturer's judgment, to affect its integrity."

Manufacturer shall have no liability to any person or entity for any personal injury, property damage or any other direct, indirect, special, or consequential damages whatsoever, arising out of the use of this manual or any information, recommendations or descriptions contained herein. The procedures described herein should only be undertaken by suitably qualified personnel. Failure to implement these procedures correctly may cause damage to the Thermo King unit or other property or personal injury.

Emergency Assistance

Thermo Assistance is a multi-lingual communication tool designed to put you in direct contact with an authorized Thermo King dealer.

Thermo Assistance should only be contacted for breakdown and repair assistance.

To use this system, you need the following information before you call: (phone charges will apply)

- Contact Phone Number
- Type of TK Unit
- Thermostat Temperature Setting
- Ambient temperature
- Present Load Temperature
- Probable Cause of Fault
- Warranty Details of the Unit
- Payment Details for the Repair

Leave your name and contact number and a Thermo Assistance Operator will call you back. At this point you can give details of the service required and the repair will be organized.

No payment at point of repair for customers with a ThermoKare service contract or with a guaranty of payment from their Thermo King home-dealer

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ThermoAssistance
00800 80 85 85 85

Belgium	+32 270 01 735
Denmark	+45 38 48 76 94
France	+33 171 23 05 03
Germany	+49 695 00 70 740
Italy	+39 02 69 63 32 13
Spain	+34 914 53 34 65
The Netherlands	+31 202 01 51 09
United Kingdom	+44 845 85 01 101
Kazakhstan	+7 7273458096
Russia	+7 4992718539
Others	+32 270 01 735

BEA261

Revision History

Revision A (04/22) New format

General Information

The maintenance information in this manual covers unit models:	
Multi-temperature Thermo King units for truck	
T-1000R Spectrum	
T-1200R Spectrum	
UT-1200 Spectrum	
Kit Pharma Solutions SP Truck MT	706828
For further information, refer to:	
T-series Operator Manual	TK 60483-1-OP
Truck T-series Spectrum Installation Manual	TK 61409-1-IM
UT series Operators Manual	TK 60652-1-OP
UT Spectrum Installation Manual	TK 61415-1-IM
The information in this manual is provided to assist owners, operators and service people in the proper upkeep and maintenance of Thermo King units.	

- The term “unit” is referring to temperature controlled units listed above.
- The term “body” refers to an “insulated equipment” as defined in ATP Annex 1
- The term “IN” refers to a “Normally insulated equipment” as defined in ATP Annex 1
- The term “IR” refers to a “Heavily insulated equipment” as defined in ATP Annex 1

Recover Refrigerant

Note: *In the USA, EPA Section 608 Certification is required to work on refrigeration systems. In the EU, local F-gas Regulations must be observed when working on refrigeration systems.*

At Thermo King®, we recognize the need to preserve the environment and limit the potential harm to the ozone layer that can result from allowing refrigerant to escape into the atmosphere.

We strictly adhere to a policy that promotes the recovery and limits the loss of refrigerant into the atmosphere.

When working on transport temperature control systems, a recovery process that prevents or minimizes refrigerant loss to the atmosphere is required by law. In addition, service personnel must be aware of the applicable European Union, National, Federal, State, and/or Local regulations governing the use of refrigerants and certification of technicians. For additional information on regulations and technician programs, contact your local THERMO KING dealer.

Service Tools - Use the proper service tools. Gauge manifold sets should include appropriate shutoff valves or disconnects near the end of each service line.

Recovery Equipment - Recovery equipment must be used. Proper recovering, storing and recycling of refrigerants is an important part of all service work.

Service Procedures - Recommended procedures must be used to minimize refrigerant loss.

Components may be isolated by closing service valves and performing system pump-downs.

Components unable to be isolated for service must be repaired only after refrigerant is properly recovered.

About This Manual

Purpose

The information in this manual is provided to assist owners, operators and service people for GDP qualification of equipment with temperature controlled unit for the transport of pharmaceutical products.

This GDP Qualification Documentation is in line with the EU guideline of Good Distribution Practices of medical products for human usage (GDP) and annex 15 "Qualification and Validation" of the Good Manufacturing Practice for Medicinal products for Human and Veterinary Use (GMP).

Units covered in this manual are Thermo King Truck Multi-Temperature Units: T-1000R Spectrum, T-1200R Spectrum and UT-1200 Spectrum.

Note: *This document is only valid in conjunction with the GDP qualified equipment certificate and is qualified on completion of the qualification process. This Certificate should be stored in the supplied pouch at the front of this manual along with the GDP Approval letters by Independent pharmaceutical company.*

Contents

GDP Qualification Documentation

This manual is organized into the following chapters:

Chapter	Purpose
Certificate of the equipment qualified GDP compliant	Validation of the Installation Qualification for specific equipment. ***Note:*** *(To be inserted in pouch provided at the front of this Manual.)*
GDP Approval letter by Independent pharmaceutical company	• Validation of Thermo King GDP Protocol. • Qualification and Validation of standard equipment ***Note:*** *(To be inserted in pouch provided at the front of this Manual.)*
Qualification Plan	Summarizes the minimum information that is included in this qualification report, Purpose, User Requirements Specifications, stages of qualification, qualification method, and responsibilities.
Risk Assessment	Identifies sensible measures to control the risks during the transport of pharmaceutical products with temperature controlled equipment.
Design Qualification	Lists equipment specifications and provides a documented verification that the proposed design of the equipment is suitable for the intended purpose.
Installation Qualification	Confirms that the equipment is installed and conforms to the approved design qualification and the manufacturer's recommendations.
Operational Qualification	Confirms that the equipment performs as intended throughout the anticipated operating ranges and provides operating guidance.
Performance Qualification	Provides temperature mapping test results that prove that the equipment can perform effectively and reproducibly, based on the approved process method and product specification.
Certification	Certificate of Approval of Trane Technologies Quality Management system.

Contacting Thermo King Service

Before you call Thermo King Service, have the following information on hand (for exact data see serial plate on your unit):

- Unit Type (commonly typed on serial plate after code DESC)
- System or Model number (commonly coded on serial plate after code ITEM)
  - System number has usually six digits format (example 901902)
  - Model number is the same as System number but with M letter at the end (example 901902M)
- Serial Number

Who to call: Your Thermo King Dealer Representative or Thermo King Service Center.

Blank Pages

This manual may contain blank pages at the end of chapters. This is normal. There is no information missing from the manual.

Roadside/Curbside Terminology

Roadside/Curbside terminology: These terms can be confusing because of differences between North America and Europe. Please note:

Curbside:	The side of the truck to the driver's right when the driver is in his seat and facing forward.
Roadside:	The side of the truck to the driver's left when the driver is in his seat and facing forward.

Customer Satisfaction Survey

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THERMO KING

Table of Contents

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Safety Precautions

Danger, Warning, Caution, and Notice

Thermo King® recommends that all service be performed by a Thermo King dealer and to be aware of several general safety practices.

Safety advisories appear throughout this manual as required. Your personal safety and the proper operation of this unit depend upon the strict observance of these precautions. The four types of advisories are defined as follows:

⚠ Danger

Hazard!

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ Warning

Hazard!

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ Caution

Hazard!

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury and unsafe practices.

Notice

Hazard!

Indicates a situation that could result in equipment or property-damage only accidents.

Battery Installation and Cable Routing

⚠ Warning

Hazard of Explosion!

An improperly installed battery could result in a fire, explosion, or injury. A Thermo King approved battery must be installed and properly secured to the battery tray.

⚠ Warning

Hazard of Explosion!

Improperly installed battery cables could result in a fire, explosion, or injury. Battery cables must be installed, routed, and secured properly to prevent them from rubbing, chaffing, or making contact with hot, sharp, or rotating components.

⚠ Warning

Fire Hazard!

Do not attach fuel lines to battery cables or electrical harnesses. This has the potential to cause a fire and could cause serious injury or death.

⚠ Warning

Personal Protective Equipment (PPE) Required!

A battery can be dangerous. A battery contains a flammable gas that can ignite or explode. A battery stores enough electricity to burn you if it discharges quickly. A battery contains battery acid that can burn you. Always wear goggles or safety glasses and personal protective equipment when working with a battery. If you get battery acid on you, immediately flush it with water and get medical attention.

⚠ Warning

Hazard of Explosion!

Always cover battery terminals to prevent them from making contact with metal components during battery installation. Battery terminals grounding against metal could cause the battery to explode.

⚠ Caution

Hazardous Service Procedures!

Set all unit electrical controls to the OFF position before connecting battery cables to the battery to prevent the unit from starting unexpectedly and causing personal injury.

Notice

Equipment Damage!

Do not connect other manufacturers equipment or accessories to the unit or to the Thermo King Batteries unless approved by Thermo King. Failure to do so can result in severe damage to equipment and void the warranty.

TK Lithium Ion Battery Safety

This product is safe with normal use. Exposure to the ingredients contained within and/or their combustion products could be harmful. Risk of exposure occurs only if the battery is mechanically, thermally, or electrically abused to the point of compromising the enclosure. If this occurs, exposure to the electrolyte solution contained within can occur by inhalation, ingestion, eye contact, and skin contact. The battery should not be opened or burned.

⚠ Warning

Risk of Injury!

Vapors or mists from a compromised battery/cell may cause respiratory irritation.

⚠ Warning

Risk of Injury!

Swallowing the contents of a compromised cell may cause serious chemical burns of the mouth, oesophagus, and gastrointestinal tract.

⚠ Warning

Risk of Injury!

Contact with the contents of a compromised cell/battery can cause severe irritation or burns to the skin.

⚠ Warning

Risk of Injury!

Contact with the contents of a compromised cell/battery can cause severe irritation or burns to the eye.

Refrigerant Hazards

⚠ Danger

Hazardous Pressures!

Always store refrigerant in proper containers, out of direct sunlight and away from intense heat. Heat increases pressure inside storage containers, which can cause them to burst and could result in severe personal injury.

⚠ Danger

Combustible Hazard!

Do not use oxygen (O_2) or compressed air for leak testing. Oxygen mixed with refrigerant is combustible.

⚠ Warning

Hazardous Gases!

Do not use a Halide torch. When a flame comes in contact with refrigerant, toxic gases are produced. These gases can cause suffocation, even death.

⚠ Warning

Personal Protective Equipment (PPE) Required!

Refrigerant in a liquid state evaporates rapidly when exposed to the atmosphere, freezing anything it contacts. Wear butyl lined gloves and other clothing and eye wear when handling refrigerant to help prevent frostbite. When working with or around hazardous chemicals, ALWAYS refer to the applicable Material Data Safety Sheets (MSDS) and OSHA/GHS (Global Harmonized System of Classification and Labelling of Chemicals) guidelines for information on allowable personal exposure levels, proper respiratory protection, and handling instructions.

Notice

Equipment Damage!

When being transferred, refrigerant must be in liquid state to avoid possible equipment damage.

Refrigerant Oil Hazards

⚠ Warning

Personal Protective Equipment (PPE) Required!

Protect your eyes from contact with refrigerant oil. The oil can cause serious eye injuries. Protect skin and clothing from prolonged or repeated contact with refrigerant oil. To prevent irritation, wash your hands and clothing thoroughly after handling the oil. Rubber gloves are recommended. When working with or around hazardous chemicals, ALWAYS refer to the applicable Material Data Safety Sheets (MSDS) and OSHA/GHS (Global Harmonized System of Classification and Labelling of Chemicals) guidelines for information on allowable personal exposure levels, proper respiratory protection, and handling instructions.

Notice

Equipment Damage!

Use the correct oil in Thermo King systems to avoid damaging equipment and nullifying its warranty.

Notice

Equipment Damage!

Do not mix refrigerant oils. Mixing incompatible oils will damage the system.

Notice

Equipment Damage!

Use dedicated refrigeration equipment to prevent contaminating refrigeration systems with the wrong type of oil or refrigerant.

Notice

System Contamination!

Do not expose the refrigerant oil to the air any longer than necessary. Store refrigerant oil in an approved sealed container to avoid moisture contamination. The oil will absorb moisture, which results in much longer evacuation times and possible system contamination.

Notice

Material Damage!

Wipe up spills immediately. Refrigerant oil can damage paints and rubber materials.

Electrical Hazards

High Voltage

Important: *Do not move the vehicle if the power cable or the electric standby icon is illuminated.*

⚠ Danger

Hazardous Voltage!

Lethal amounts of voltage are present in some electrical circuits. Use extreme care when working on an operating refrigeration unit. If there is a risk of energized electrical contact, arc, or flash, technicians MUST put on all PPE in accordance with OSHA, NFPA 70E, or other local, state, or country-specific requirements for arc flash protection PRIOR to servicing the unit. NEVER PERFORM ANY SWITCHING, DISCONNECTING, OR VOLTAGE TESTING WITHOUT PROPER ELECTRICAL PPE AND ARC FLASHING CLOTHING. ELECTRICAL METERS AND EQUIPMENT MUST BE PROPERLY RATED FOR INTENDED VOLTAGE.

⚠ Warning

Hazardous Voltage!

Treat all wires and connections as if they were high voltage until a meter and wiring diagram indicate otherwise. Only use tools with insulated handles. Never hold uninsulated metal tools near exposed, energized conductors. If there is a risk of energized electrical contact, arc, or flash, technicians MUST put on all PPE in accordance with OSHA, NFPA 70E, or other local, state, or country-specific requirements for arc flash protection PRIOR to servicing the unit. NEVER PERFORM ANY SWITCHING, DISCONNECTING, OR VOLTAGE TESTING WITHOUT PROPER ELECTRICAL PPE AND ARC FLASHING CLOTHING. ELECTRICAL METERS AND EQUIPMENT MUST BE PROPERLY RATED FOR INTENDED VOLTAGE.

⚠ Warning

Hazardous Voltage!

Never work alone on high voltage circuits in the refrigeration unit. Another person should be nearby to shut off the unit and provide aid in the event of an accident. If there is a risk of energized electrical contact, arc, or flash, technicians MUST put on all PPE in accordance with OSHA, NFPA 70E, or other local, state, or country-specific requirements for arc flash protection PRIOR to servicing the unit. NEVER PERFORM ANY SWITCHING, DISCONNECTING, OR VOLTAGE TESTING WITHOUT PROPER ELECTRICAL PPE AND ARC FLASHING CLOTHING. ELECTRICAL METERS AND EQUIPMENT MUST BE PROPERLY RATED FOR INTENDED VOLTAGE.

⚠ Warning

Personal Protective Equipment (PPE) Required!

In the event of an electrical accident, all required PPE should be near the work area in accordance with OSHA, NFPE 70E, or other local, state, or country-specific requirements for a Category 3 risk.

⚠ Warning

Risk of Injury!

Do not make rapid moves when working on high voltage circuits in refrigeration units. Do not grab for falling tools because you might accidentally touch a high voltage source.

⚠ Warning

Hazardous Voltage w/Capacitors!

Be careful when working with electrical circuits that contain capacitors. Some capacitors hold a significant electrical charge that might cause burns or shocks if accidentally discharged. Capacitors must be discharged before working on electrical circuits. If there is a risk of energized electrical contact, arc, or flash, technicians MUST put on all PPE in accordance with OSHA, NFPA 70E, or other local, state, or country-specific requirements for arc flash protection PRIOR to servicing the unit. NEVER PERFORM ANY SWITCHING, DISCONNECTING, OR VOLTAGE TESTING WITHOUT PROPER ELECTRICAL PPE AND ARC FLASHING CLOTHING. ELECTRICAL METERS AND EQUIPMENT MUST BE PROPERLY RATED FOR INTENDED VOLTAGE.

Low Voltage

⚠ Warning

Live Electrical Components!

Control circuits used in refrigeration units are low voltage (12 to 48 Vdc). However, the large amount of amperage available can cause severe burns if accidentally shorted to ground with metal objects, such as tools. Do not wear jewelry, watches, or rings because they increase the risk of shorting out electrical circuits and damaging equipment or causing severe burns. If there is a risk of energized electrical contact, arc, or flash, technicians MUST put on all PPE in accordance with OSHA, NFPA 70E, or other local, state, or country-specific requirements for arc flash protection PRIOR to servicing the unit. NEVER PERFORM ANY SWITCHING, DISCONNECTING, OR VOLTAGE TESTING WITHOUT PROPER ELECTRICAL PPE AND ARC FLASHING CLOTHING. ELECTRICAL METERS AND EQUIPMENT MUST BE PROPERLY RATED FOR INTENDED VOLTAGE.

Controller/Microprocessor Service Precautions

Take precautions to prevent electrostatic discharge when servicing the controller or microprocessor and its related components. Even tiny amounts of current can severely damage or destroy electronic components.

Observe the following precautions when servicing a controller or microprocessor control system to avoid damaging electronic components. Refer to the applicable unit, controller, or microprocessor diagnostic manual for more information.

- If the unit has a service or microprocessor ON/OFF switch, turn it OFF before connecting or disconnecting the battery.

- Disconnect power to the unit.
- Avoid wearing clothing that generates static electricity (wool, nylon, polyester, etc.).
- Wear a wrist strap (P/N 204-622 or equivalent) with the lead end connected to the microprocessor or unit ground terminal (if equipped). These straps are available from most electronic equipment distributors. DO NOT wear these straps with power applied to the unit.
- Avoid unnecessary contact with the electronic components.
- Store and ship electronic components in antistatic bags and protective packaging.
- Leave electronic components in their antistatic packing materials until you're ready to use them.
- After servicing any electronic components, check the wiring for possible errors before restoring power to the unit.
- Never use a battery and a light bulb to test circuits on any controller or microprocessor-based equipment.

Welding Precautions

Take precautions before electrically welding any portion of the unit or the vehicle to which it is attached. Verify that welding currents are not allowed to flow through the unit's electronic circuits.

Observe the following precautions when welding to avoid damaging electronic components.

- If the unit has a service switch, or microprocessor ON/OFF, turn it OFF before connecting or disconnecting the battery.
- Disconnect power to the unit.
- Disconnect all wire harnesses from the microprocessor. Disconnect the ECU and the battery charger if so equipped.
- If there are any electrical circuit breakers in the control box, switch them OFF.
- Close the control box.
- Components that could be damaged by welding sparks should be removed from the unit.
- Use normal welding procedures, but keep the ground return electrode as close to the area being welded as practical. This will reduce the likelihood of stray welding currents passing through any electronic circuits.

First Aid

REFRIGERANT

- **Eyes:** For contact with liquid, immediately flush eyes with large amounts of water and get prompt medical attention.
- **Skin:** Flush area with large amounts of warm water. Do not apply heat. Remove contaminated clothing and shoes. Wrap burns with dry, sterile, bulky dressing to protect from infection. Get prompt medical attention. Wash contaminated clothing before reuse.
- **Inhalation:** Move victim to fresh air and use Cardio Pulmonary Resuscitation (CPR) or mouth-to-mouth resuscitation to restore breathing, if necessary. Stay with victim until emergency personnel arrive.
- **Frost Bite:** In the event of frost bite , the objectives of First Aid are to protect the frozen area from further injury, warm the affected area rapidly, and to maintain respiration.

REFRIGERANT OIL

- **Eyes:** Immediately flush with large amounts of water for at least 15 minutes. Get prompt medical attention.
- **Skin:** Remove contaminated clothing. Wash thoroughly with soap and water. Get medical attention if irritation persists.
- **Inhalation:** Move victim to fresh air and use Cardio Pulmonary Resuscitation (CPR) or mouth-to-mouth resuscitation to restore breathing, if necessary. Stay with victim until emergency personnel arrive.
- **Ingestion:** Do not induce vomiting. Immediately contact local poison control center or physician.

ENGINE COOLANT

- **Eyes:** Immediately flush with large amounts of water for at least 15 minutes. Get prompt medical attention.
- **Skin:** Remove contaminated clothing. Wash thoroughly with soap and water. Get medical attention if irritation persists.
- **Ingestion:** Do not induce vomiting. Immediately contact local poison control center or physician.

BATTERY ACID

- **Eyes:** Immediately flush with large amounts of water for at least 15 minutes. Get prompt medical attention. Wash skin with soap and water.
- **Skin:** Immediately remove contaminated clothing. Wash skin with large volumes of water, for at least 15 minutes. Wash skin with soap and water. Do not apply fatty compounds. Seek immediate medical assistance.
- **Inhalation:** Provide fresh air. Rinse mouth and nose with water. Seek immediate medical assistance.
- **Ingestion:** If the injured person is fully conscious: make the person drink extensive amounts of milk. Do not induce vomiting. Take the injured person immediately to a hospital.

ELECTRICAL SHOCK

Take IMMEDIATE action after a person has received an electrical shock. Get quick medical assistance, if possible.

The source of the shock must be quickly stopped, by either shutting off the power or removing the victim. If the power cannot be shut off, the wire should be cut with an non-conductive tool, such as a wood-handle axe or thickly insulated cable cutters. Rescuers should wear insulated gloves and safety glasses, and avoid looking at wires being cut. The ensuing flash can cause burns and blindness.

If the victim must be removed from a live circuit, pull the victim away with a non-conductive material. Use wood, rope, a belt or coat to pull or push the victim away from the current. DO NOT TOUCH the victim. You will receive a shock from current flowing through the victim's body. After separating the victim from power source, immediately check for signs of a pulse and respiration. If no pulse is present, start Cardio Pulmonary Resuscitation (CPR). If a pulse is present, respiration might be restored by using mouth-to-mouth resuscitation. Call for emergency medical assistance.

ASPHYXIATION

Move victim to fresh air and use Cardio Pulmonary Resuscitation (CPR) or mouth-to-mouth resuscitation to restore breathing, if necessary. Stay with victim until emergency personnel arrive.

THERMO KING

Qualification Plan

Prepared for Thermo King, for validation of temperature controlled equipment Multi-Temperatures units for truck:

T-1000R Spectrum, T-1200R Spectrum and UT-1200 Spectrum

Thermo King designs and builds temperature controlled transport equipment.

These types of equipment can be validated for a specific desired temperature range for the transport of pharmaceutical products.

- Temperature below -20°C
- Temperature between +2°C and +8°C
- Temperature between +15°C and +25 °C

Note: *To ensure total flexibility the validation is to be performed at all stated ranges from above.*

Purpose

This qualification plan describes the procedure for qualifying:

- a refrigeration truck type ATP-FRC certified consisting of an IR body (0.4 W/m^2.K or better insulation) and a refrigerated unit type Thermo King multi-temperatures T-1000R Spectrum or T-1200R Spectrum.
- a refrigeration truck type ATP-FNA certified consisting of an IN body (0.7 W/m^2.K or better insulation) and a refrigerated unit type Thermo King multi-temperatures UT-1200 Spectrum.

The qualification provides the documented proof of the fact that the respective refrigerated equipment (ATP certified body + Thermo King refrigerated unit) fulfils the user requirements (URS), GDP and GMP requirements for the transport of medicines. This document specifies the responsibilities and activities that are to be carried out for the qualification. The specific activities and criteria are described and documented in the various test cases.

User Requirements Specifications (URS)

The equipment is designed to ensure that pre-temperature-controlled goods maintain an adjustable set temperature both for low and high ambient temperatures (winter -30°C and summer +50°C).

It must be possible to operate the equipment within the following temperature ranges:

- Temperature below -20°C
- Temperature between +2°C and +8°C
- Temperature between +15°C and +25°C

Design Qualification (DQ)

Those equipment-types:

- A **2 zones I_R body of 9.12m x 2.47m x 2.54m (L x W x H) internal dimensions** equipped of a **Thermo King** refrigerated unit **T-1000R Spectrum S3+S3 or T-1200R Spectrum S3+S3.**
- A **2 zones I_N body** of **8.93m x 2.47m x 2.44m (L x W x H) internal dimensions** equipped of a **Thermo King** refrigerated unit **UT-1200 Spectrum S3+S3.**

The above have been designed and qualified to meet the specific desired temperature ranges for the transport of pharmaceutical products..

Note: *Please refer to the document* ***GDP-TK-DQ-SP-ST****.*

Installation Qualification (IQ)

The specific equipment has been installed successfully and was proved to comply with the design qualification and installation qualification of the sample-type equipment.

Note: *Please refer to the document* ***GDP-TK-DQ-SP-MT****.*

Operational Qualification (OQ)

The specific equipment has been proven to perform according to the sample-type equipment. Operating guidance and planned maintenance schedule has been provided to ensure a correct use of the equipment during its lifetime.

The conditions of the performance test of the sample-type were defined.

Note: *Please refer to the document* ***GDP-TK-IQ-SP-MT****.*

Performance Qualification (PQ)

A basic Performance qualification was performed on the sample-type equipment. The tests were performed according to the test cases defined in the Operational Qualification in order to simulate most common real life conditions. Tests were performed in accordance with ATP standards and test method FDX 15-140. The tests were successfully completed.

As a result of the test, some recommendations have been provided to ensure an optimal use of the equipment in the different operational modes.

Note: *Please refer to the document* ***GDP-TK-IQ-SP-MT****.*

Qualification with a Sample–Type Approach

Thermo King did use a sample-type approach for the qualification of transport equipment. The sample-type approach consists of performing an initial full qualification on one equipment using the worst case scenario (including thermal mapping in extreme ambient conditions) and all new or existing equipment of the same design specifications are also qualified once IQ and OQ is completed successfully.

- A basic PQ for one member of each sample-type, selected as the most critical or challenging application in the family. Basic PQs are empty load temperature mapping performed in temperature-controlled chamber to better simulate worst case conditions.
- For each new and existing unit, an IQ and OQ have to be completed successfully at a Thermo King authorized workshop location. The verification is conducted by a Thermo King trained technician. The verification includes, above all, the equipment's design specifications and set point verification, sensor calibration and equipment performance check.

Responsibility

The qualification activities will be organized by the qualification team:

Organisation	**Activity**
Thermo King Pharma Team	• Define GDP Protocol for transport equipment. • Define GDP qualification per sample-type. • Create and update GDP qualification documentation. • Create GDP certificate for each new or existing equipment proven GDP qualified
Trane Technologies Engineering Center	• Conduct thermal mapping tests of selected transport Equipment in line with GDP. • Provide results of thermal mapping tests performed.
External pharmaceutical consultant company	• Provide the approval of the sample-type GDP qualification. • Sign GDP certificate for each new or existing equipment proven GDP qualified.
Thermo King authorized dealers	• For each new or existing equipment, perform IQ and OQ check.

Qualification Facility

The qualification tests will be performed at the Trane Technologies Equipment Manufacturing Engineering and Technology Centre, Prague, Czech Republic. This organization is an accredited ATP-test-station and has the IATF 16949 and ISO 17025 certifications.

Risk Analysis Thermo King

The transport process is defined as a closed temperature controlled storage box in transit. This box can be used in a single temperature mode and set at four different temperature ranges (Deep Frozen, Frozen, Chilled and Ambient).

The risk analysis based on the Failure Mode and Effects Analysis (FMEA) methodology has been conducted in order to ensure that potential problems during the process of distributing pharmaceutical products have been considered and addressed before the first use of the transport temperature controlled equipment.

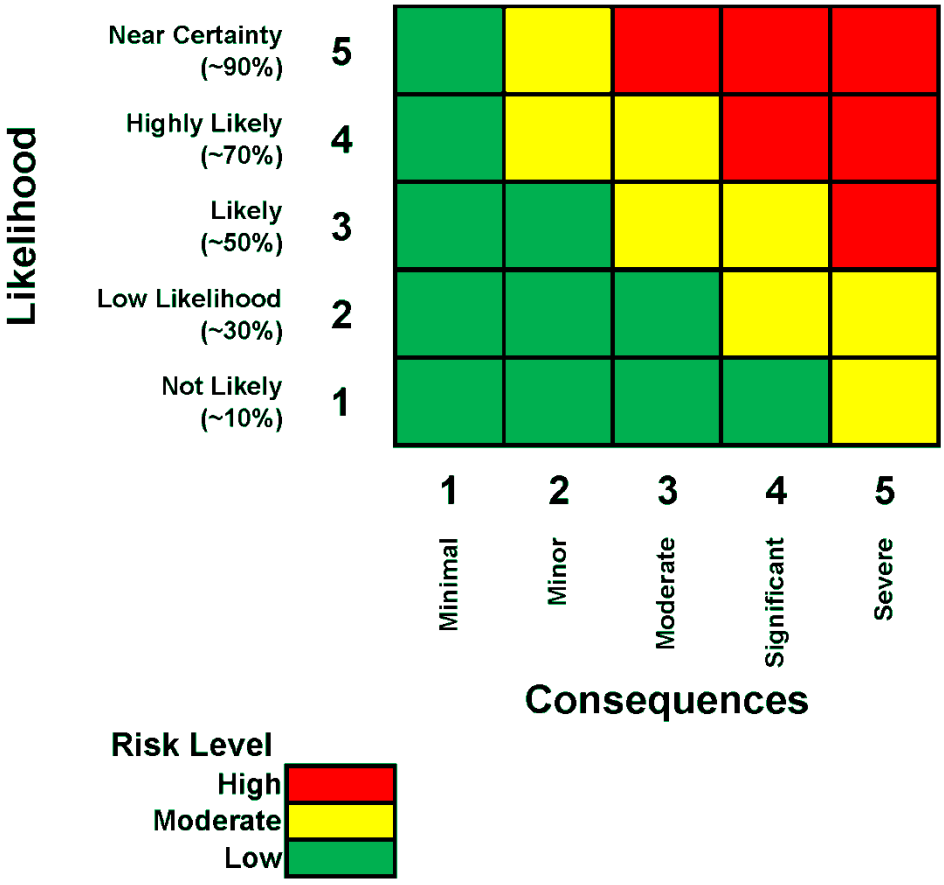
Risk Reporting Matrix

Thermo King used the risk reporting matrix (see below figure) to identify and classify potential problems while using the specific transport equipment:

- A 2 zones IR body (0.4 W/m^2.K or better insulation) equipped of a Thermo King refrigerated unit T-1000R Spectrum S3+S3 or T-1200R Spectrum S3+S3 for the transport of medicinal products.
- A 2 zones IN body (0.7 W/m^2.K or better insulation) equipped of a Thermo King refrigerated unit UT-1200 Spectrum S3+S3.

for the transport of medicinal products.

Figure 1. Risk Reporting Matrix



Identified Risks and Preventative Actions

Table 1. Closed Box

Process	Defining the Possible Process Problem	Likelihood	Consequence	Risk	Preventative Action
Poor design of the transport equipment	Equipment not equivalent to sample-type equipment fully GDP qualified Poor quality finishes (example: bad insulation)	2	4	8 (Moderate)	1. At IQ, check that the equipment design specifications are similar to sample-type equipment fully GDP qualified. 2. At IQ, check that the refrigeration body is sufficiently and tightly insulated and body specifications correspond to ATP standards. 3. At IQ, check that the refrigeration machine only uses approved refrigerant and is labelled according to Refrigerant: R404A, and R452A.
	The refrigerated unit has been installed incorrectly on the body				Installation Qualification to be conducted and checked by Thermo King authorized and trained technician.
Temperature excursions	Unexplained temperature excursions	3	4	12 (Moderate)	Datalogger and/or a monitoring system should be installed on the transport equipment.
	Installations obstructing the discharge air flow				Correctly check design specifications of the equipment at point of sales.
	Transport equipment not pre-cooled before loading goods				Pre-cool the transport equipment to the set -temperature before loading the products.
	Products not loaded at correct temperature.				Implement correct loading/unloading practices.
	Inadequate split of the compartments of the transport equipment.				When operating the equipment in multi-temperatures mode, the splitting of the compartment zones should be up to $^1/_2$ of the total body length.
Settings of the refrigerated unit	Incorrect settings of set points for the temperature range to be maintained	3	4	12 (Moderate)	To maintain the best temperature management within the load-space in winter and summer time, Thermo King recommends operation with the following set point temperatures: • +20°C Setpoint for temperature range +15°C to +25°C • +5°C Set-point for temperature range +2°C to +8°C • -25°C Set-point for temperature below -20°C
	Incorrect settings of the refrigerated unit then the vehicle is being used in multi-temperatures mode.				At IQ, a specific configuration file is loaded to the controller. When operating the equipment in multi-temperatures mode, ZONE PRIORITY function must be DISABLED.
	Incorrect settings of the refrigerated unit when the vehicle is being used in single temperature mode.				At IQ, a specific configuration file is loaded to the controller. In case of single-temperature operation the unit must run in SINGLE ZONE CONTROL (SZC) mode and the dividing wall must be stowed in such a way that it does not interrupt the airflow from each remote evaporator. For ease of use, SZC mode should be added to the Main (driver) menu.

Table 2. Environment

Process	Defining the Possible Process Problem	Likelihood	Consequence	Risk	Preventative Action
Temperature Europe	Expected ambient temperature in the regions can go up to extremes.	3	3	9 (Moderate)	Full Qualification of sample-type equipment (temperature mapping) has been successfully performed at extreme temperatures from -30°C to +40°C.
	Risk of temperature excursion due to high delta difference with inside temperature.				Refrigeration capacity reserve: Thermo King equipment are designed as standard to overcome temperature met in Middle East Africa regions, with temperatures up to 55°C.
Solar radiation	In summer time, the effect of solar radiation can have a negative impact on the surface temperature of the equipment. The darker the body colour, the higher temperature increase.	2	3	6 (Moderate)	In DQ, recommended body to be white in colour with a max. 20% decal coverage. Refrigeration capacity reserve: Thermo King equipment are designed as standard with reserve capacity of 75% based on ATP standards.
Door opening at non temperature controlled storage location	Depending on: • duration of the opening • temperature in the carrier and outside temperature • switch on/off of the cooling unit during opening doors	3	4	12 (Moderate)	Minimize door opening time. Load and unload the transport equipment at temperature controlled loading docks of storage location. Driver training on best loading/unloading practices should be conducted. Door opening tests have been performed to enable better risk management.

Table 3. Process / Operational Qualification

Process	Defining the Possible Process Problem	Likelihood	Consequence	Risk	Preventative Action
Temperature sensor accuracy check	Invalid temperature registration	2	4	8 (Moderate)	At IQ check Process, all sensors that are used for temperature control and monitoring are to be checked. A proof of calibration check of each sensor as part of IQ Process. Yearly calibration check of all sensors that are used for temperature control and monitoring. Minimum sensor requirements and location should be in accordance with equipment manufacturer's recommendations. The calibration process should be in line with the EN13486.
Breakdown / Damage of the equipment	No regular maintenance of the transport equipment Maintenance not done correctly No use of genuine parts	2	4	8 (Moderate)	A maintenance contract with Thermo King or authorized Thermo King dealer should be in place. If no maintenance contract, the user of the equipment should prove that he has the right schedule maintenance, repair procedures, genuine parts, breakdown risk assessment, and training in place.The user should be open to regular audits. All replacement parts are to be from genuine manufacturer's parts.

Table 3. Process / Operational Qualification (continued)

Process	Defining the Possible Process Problem	Likelihood	Consequence	Risk	Preventative Action
Lack of hygiene	Risk of contamination of pharmaceutical products	3	3	9 (Moderate)	A Cleaning Procedure should be in place. The internal space is easily accessible for cleaning. The internal surfaces of the refrigeration body are corrosion-resistant and comply with hygiene regulations. Pharmaceutical products should not be transported in a mixed load with food products.
Incorrect operating mode	Transport equipment not used appropriately Lack of knowledge on how to use the refrigerated unit	3	4	12 (Moderate)	Thermo King provides an Operational manual to use efficiently the transport equipment. Conduct Training of drivers on GDP and how to use the refrigerated unit.

THERMO KING

Design Qualification

Prepared for Thermo King, for validation of temperature controlled equipment Multi-Temperatures units for truck:

T-1000R Spectrum, T-1200R Spectrum and UT-1200 Spectrum

Thermo King designs and builds temperature controlled transport equipment.

These types of equipment can be validated for a specific desired temperature range for the transport of pharmaceutical products.

- Temperature below -20°C
- Temperature between +2°C and +8°C
- Temperature between +15°C and +25 °C

To ensure total flexibility the validation is to be performed at all stated ranges from above.

Scope

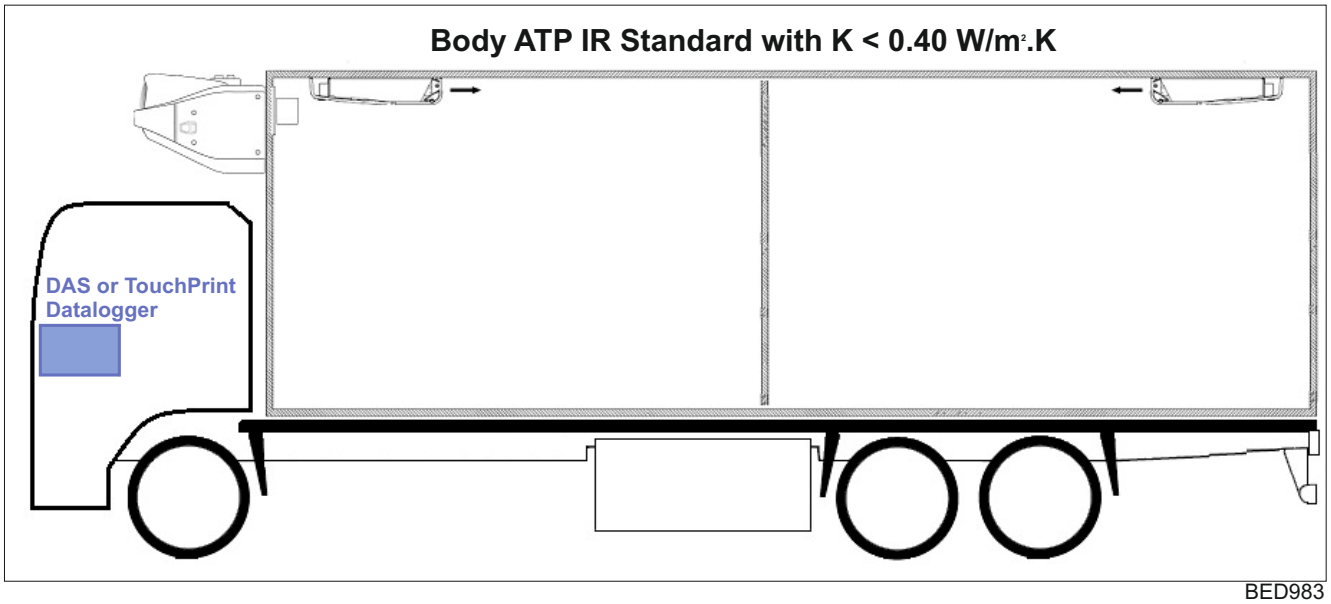
The scope of the qualification work will be done to the equipment (a refrigerated unit designed and built by Thermo King with an ATP certified body) for the transportation, under temperature restrictions, of medicines.
A standard configuration is defined for each group.

Equipment Specifications

Truck body with Thermo King T-1000R Spectrum or T-1200R Spectrum unit

- A 2 zones multi-temperatures truck body **ATP IR** standards with internal dimensions (L x W x H) of 9.12m x 2.47m x 2.54m resulting with an internal surface of 103.73 m^2. Owing to the many configurations the bodies' sizes are to be calculated in cubic metres therefore it results with a body with maximum total internal volume of **57 m^3**. An internal volume that is smaller is permissible as long as the internal surface is not smaller by more than 20%.
- A K factor of 0.40 $W/m^2.K$. A better K factor is also permissible.
- Body white in colour. A maximum 20% of the external surface decal coverage is recommended.
- Body with **double rear doors** with **door switches**. A door arrangement that is better than this is also permissible. Unit is to be configured to force ZONE NULL when opening the doors. Thermal curtains are recommended.
- A transversal movable dividing wall with a K factor as required and laid out in ATP (see table 1 in section “Detail specifications”). A K factor that is better than those from table 1 is also permissible.
- Thermo King **S3** remote evaporators installed in each of the 2 zones. Evaporator fans are to be configured to run in NULL mode. ZONE PRIORITY function must be DISABLED.
- A **specific configuration file** for pharmaceutical application used for tighter temperature management.
- A temperature datalogger which complies with EN12830 standard with at least one sensor in each zone. Thermo King **DAS** or **TouchPrint Datalogger** are recommended.

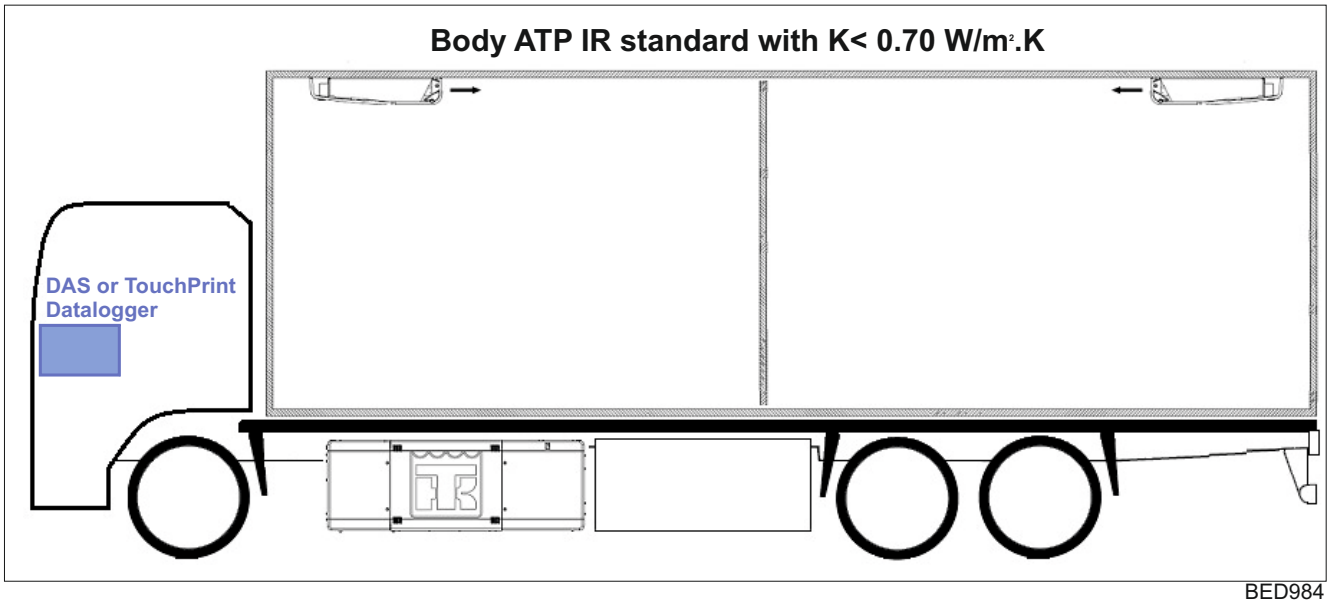
Figure 2. Truck with T-1000R/1200R Spectrum S3+S3



Truck body with Thermo King UT-1200 Spectrum unit

- A 2 zones multi-temperatures truck body ATP IN standards with internal dimensions (L x W x H) of 8.93m x 2.47m x 2.44m resulting with an internal surface of 99.71 m^2. Owing to the many configurations the bodies' sizes are to be calculated in cubic metres therefore it results with a body with maximum total internal volume of 54 m^3. An internal volume that is smaller is permissible as long as the internal surface is not smaller by more than 20%.
- A K factor of 0.70 $W/m^2.K$. A better K factor is also permissible.
- Body white in colour. A maximum 20% of the external surface decal coverage is recommended.
- Body with double rear doors and single side door with door switches. A door arrangement that is better than this is also permissible. Unit is to be configured to force ZONE NULL when opening the doors. Thermal curtains are recommended.
- A transversal movable dividing wall with a K factor as required and laid out in ATP (see table 1 in section “Detail specifications”). A K factor that is better than those from table 1 is also permissible.
- Thermo King S3 remote evaporators installed in each of the 2 zones. Evaporator fans are to be configured to run in NULL mode. ZONE PRIORITY function must be DISABLED.
- A specific configuration file for pharmaceutical application used for tighter temperature management.
- A temperature datalogger which complies with EN12830 standard with at least one sensor in each zone. Thermo King DAS or TouchPrint Datalogger are recommended.

Figure 3. Truck with UT-1200 Spectrum S3+S3



Temperature Range Table

Table 4. Truck body with Thermo King T-1200R Spectrum unit

Temperature Range	Extreme Ambient Temperature	Recommended Setpoint	Max Average Deviation from Setpoint
Temperature below -20°C	+40°C / -30°C	-25°C	+5/-6°C of setpoint
Temperature between 2°C and 8°C	+40°C / -30°C	+6°C	+2/-4°C of setpoint
Temperature between 15°C and 25°C	+40°C / -30°C	+20°C	+3/-5 °C of setpoint

Table 5. Truck body with Thermo King T-1000R Spectrum unit

Temperature Range	Extreme Ambient Temperature	Recommended Setpoint	Max Average Deviation from Setpoint
Temperature between 2°C and 8°C	+40°C / -30°C	+6°C	+2/-3°C of setpoint
Temperature between 15°C and 25°C	+40°C / -30°C	+20°C	+2/-4°C of setpoint

Table 6. Truck body with Thermo King UT-1200 Spectrum unit

Temperature Range	Extreme Ambient Temperature	Recommended Setpoint	Max Average Deviation from Setpoint
Temperature between 2°C and 8°C	+40°C / -30°C	+5°C	+/-3°C of setpoint
Temperature between 15°C and 25°C	+40°C / -30°C	+20°C	+2/-3°C of setpoint

Note: *To ensure total flexibility the qualification is to be performed at all stated ranges from above.*

Additional Validations and Variations

Addition of truck body ATP IR standards with UT-1200 Spectrum S3+S3

2 zones multi-temperatures truck body ATP IR standard with a 0.40 W/m2 K insulation or better with UT-1200 Spectrum S3+S3 is approved in parallel because it offers better insulation and ensure equivalent temperature management.

Addition of Whisper Option for T-1000R Spectrum and T-1200R Spectrum

T-1000R Spectrum S3+S3 Whisper and T-1200R Spectrum S3+S3 Whisper are approved in parallel.

Addition of rear rolling doors in lieu et place of double rear doors

Assuming that K factor coefficient remains below 0.40 W/m2 K and therefore the vehicle is FRC declared, body equipped with rear rolling doors instead of double rear doors are approved in parallel.

Variations on body sizes

Smaller body sizes appropriate to the unit design are also included because the performance will be improved as body size reduces:

- T-1000R Spectrum S3+S3 and T-1200R Spectrum S3+S3 should not be used on a body volume that is less than 45m3 and not more than 57m3; this would require a different specification unit.
- UT-1200 Spectrum S3+S3 should not be used on a body volume that is less than 43m3 and not more than 54m3; this would require a different specification unit.

Detailed Specifications

Diving Wall ATP Specification

Table 7. Diving wall ATP Specification

	K factor coefficient		Minimum thickness of diving wall
	Removable	Fixed	
GRP floor Longitudinal	2.0 W/m^2.K	1.5 W/m^2.K	25 mm
GRP floor Transversal	2.6 W/m^2.K	1.5 W/m^2.K	40 mm
Aluminium floor Longitudinal	3.0 W/m^2.K	2.0 W/m^2.K	25 mm
Aluminium floor Transversal	3.2 W/m^2.K	2.0 W/m^2.K	40 mm

Diving wall coefficients include a safety margin to allow for degradation and thermal leakages.

Refrigerated Unit capacity:

	Refrigeration capacities [1]
Refrigerant	R-404A/R-452A

Unit Model	**T-1200R Spectrum S3+S3**		
		Total Nominal	Remote Evaporator S3
Capacity on engine power	0 °C	12 080 W	8 120 W
	-20 °C	7 620 W	4 640 W
Capacity on electric standby	0 °C	7 560 W	7 163 W
	-20 °C	4 720 W	4 010 W

Unit Model	**T-1000R Spectrum S3+S3**	
	Total Nominal	Remote Evaporator S3

Capacity on engine power	0 °C	9 990 W	7 540 W
	-20 °C	5 790 W	4 230 W
Capacity on electric standby	0 °C	6 280 W	6 190 W
	-20 °C	3 860 W	3 490 W

Unit Model	**T-1200R Spectrum S3+S3**		
		Total Nominal	Remote Evaporator S3
Capacity on engine power	0 °C	10 560 W	7 720 W
	-20 °C	6 030 W	4 410 W
Capacity on electric standby	0 °C	7 560 W	6 840 W
	-20 °C	4 720 W	3 820 W
Airflow volume at 0 Pa static pressure			2 000 m3/hr
Discharge velocity (Air throw)			9.50 m/sec

Maximum zone length [2]	5.50 m

[1] At +30°C ambient temperature under ATP conditions

[2] Maximum recommended dimensions: these are guidelines based on airflow and air velocity requirements based upon the following assumptions: K factor = 0.4W/m2.K, internal height up to 2.5 m, width up to 2.5 m, zero heat load from produce carried. For each application, a heat load calculation must be performed.

Truck Multi-temperatures and GDP Qualified Configurations

Units and Evaporator Dimensions - T1000R Spectrum and T-1200R Spectrum

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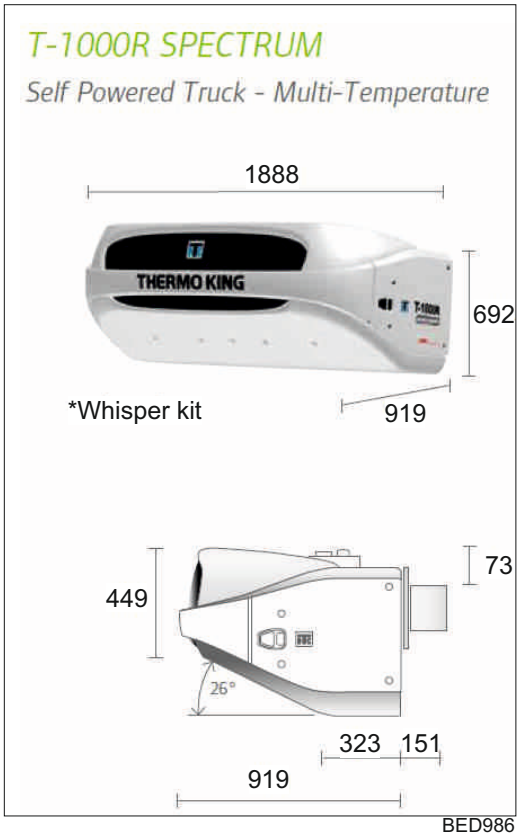

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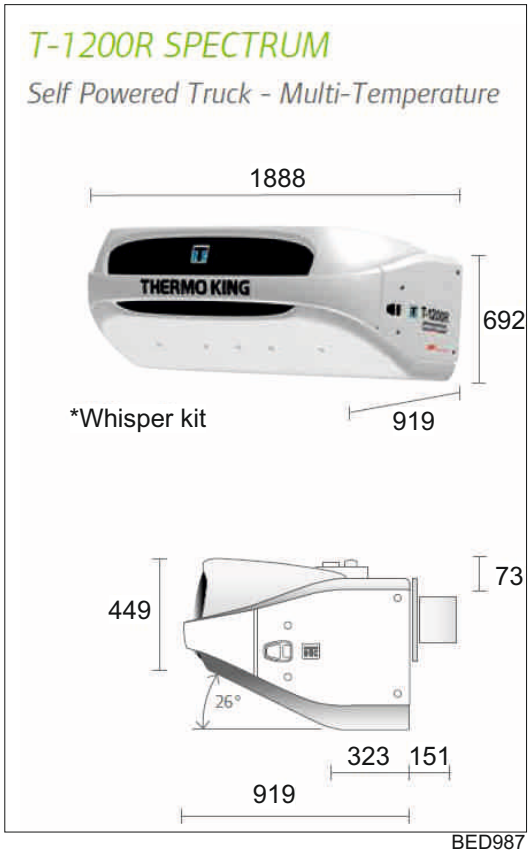

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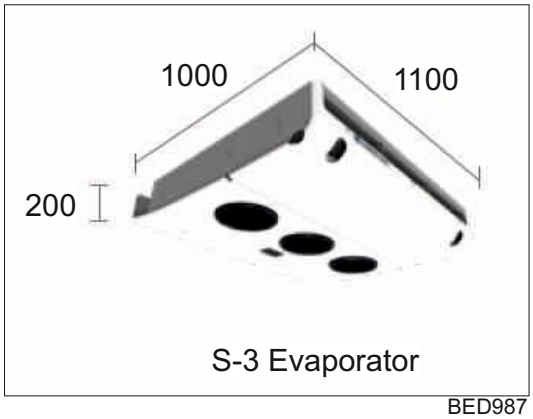

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Units and Evaporator Dimensions - UT Spectrum

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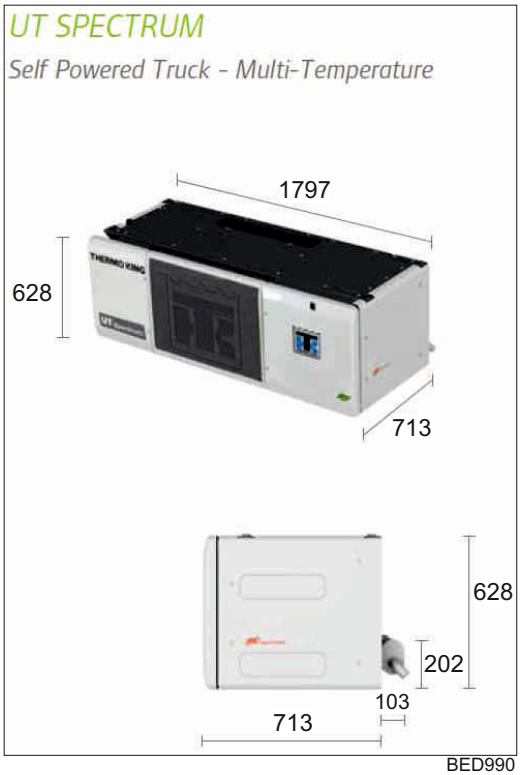

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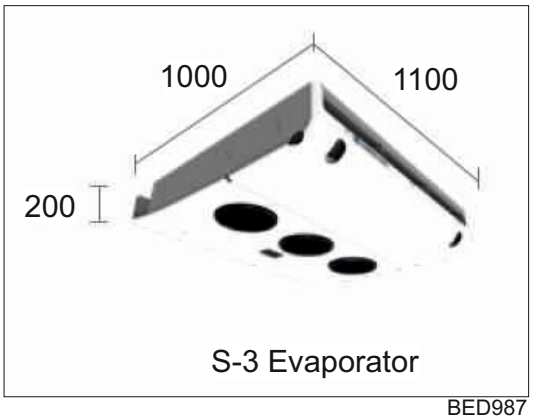

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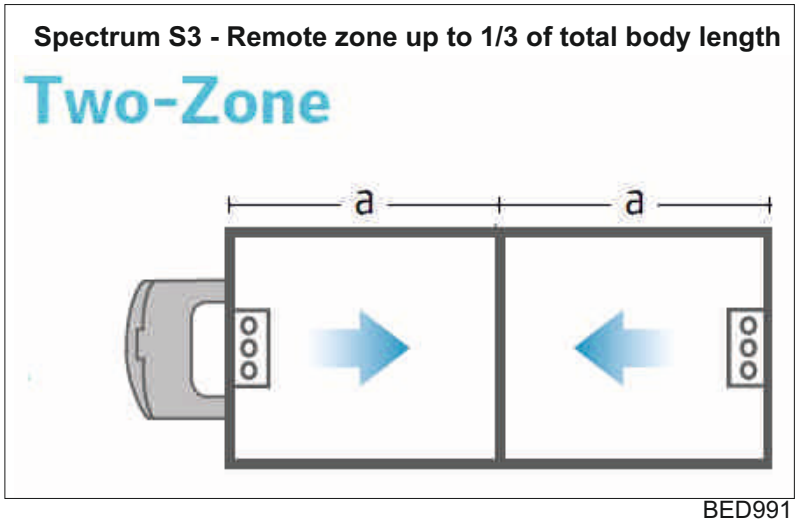
Figure 4. Truck GDP qualified multi-temperatures zone plans



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Installation Qualification

Prepared for Thermo King, for validation of temperature controlled equipment Multi-Temperatures units for truck:

T-1000R Spectrum, T-1200R Spectrum and UT-1200 Spectrum

For each individual equipment (truck + body + refrigerated unit) a specific TK PharmaSolutions - IQOQ Check-MUL document has to be completed by the Thermo King official dealer to confirm that Installation Qualification conforms to the requirements of the Design Qualification: GDP-TK-DQ-SP-MT. The latest valid revision of this document has to be used and is available from Thermo King EMEA InfoCentral intranet.

The vehicle has been inspected and conforms to the design qualification document GDP-TK-DQ-SP-MT. Photographic evidence is available on request.

- **Door switches** are installed and unit is configured to force ZONE NULL when opening the doors. Thermal curtains are recommended as described in **GDP-TK-DQ-SP-MT**.
- The transversal movable dividing wall as defined in **GDP-TK-DQ-SP-MT** is installed and displacement is in accordance of Load Space Considerations described in **GDP-TK-OQ-SP-MT.**
- Thermo King **S3** remote evaporators are installed in each of the 2 zones. Evaporator fans are to be configured to run in NULL mode as described in **GDP-TK-DQ-SP-MT**.
- The specific configuration file as described in **GDP-TK-DQ-SP-MT** is loaded to the unit controller.
- A temperature datalogger as described in **GDP-TK-DQ-SP-MT** with at least one sensor in each zone is installed and configured as per customer settings. Thermo King **DAS** or **TouchPrint Datalogger** are recommended.

THERMO KING

Operational Qualification

Prepared for Thermo King, for validation of temperature controlled equipment Multi-Temperatures units for truck:

T-1000R Spectrum, T-1200R Spectrum and UT-1200 Spectrum

Description of the Qualified Operation

The truck shall be used:

- For transport of pharmaceuticals (in combination with Medical devices)
- To maintain and control air temperature at a set temperature.
- In multi-temperature operation (< -20°C, +2°C to +8 °C or +15°C to +25°C) in two compartments.
- At ambient temperature between -30°C and +40°C.
- The vehicle will be used for transportation between temperature controlled loading docks of storage locations.
- According to the drivers instructions supplied by Thermo King on use of Thermo King equipment.

The objective of this qualification is to successfully qualify the designed use of this equipment.

The Operational Qualification conforms to the requirements of the Design Qualification: **GDP-TK-DQ-SP-MT**.

Support of the Defined Aspects of Use

- For transport of pharmaceuticals (in combination with Medical devices).
  - Combination of pharmaceuticals and medical devices in one load is approved. Mixing loads of food and chemical substances is not permitted even when the compartments are separated as a multi-temperatures load.
- The load space should be kept clean at all times and only cleaning agents that will not affect the products should be used.
- To maintain and control air temperature at a set temperature.
  - The products (pharmaceuticals) will be loaded at the correct temperature because they are leaving a temperature controlled storage location. It is stated that the refrigeration unit and box is used to maintain and not change the temperature of the products. The trailer is not designed for cooling down or warming up pharmaceuticals, and therefore it should not be used for this purpose. However there is reserve capacity to overcome unscheduled temperature changes within the air pocket surrounding the load.
- This trailer is qualified in multi-temperatures and single-temperature modes based on the details below:
  - **In multi-temperature mode:**

    In case of multi-temperatures operation, the dividing wall must be locked in vertical position and setpoint must be set according to the requested range in each zone. **ZONE PRIORITY** function must be **DISABLED**.
- **For T-1200R Spectrum S3+S3:**
  - Ranges < -20°C, +2°C to +8 °C or +15°C to +25°C can be operated in any of the 2 zones.
- **For T-1000R Spectrum S3+S3 and UT-1200 S3+S3:**
  - Ranges +2°C to +8 °C or +15°C to +25°C can be operated in any of the 2 zones.
  - The range < -20°C cannot be operated.
  - **In single-temperature mode:**

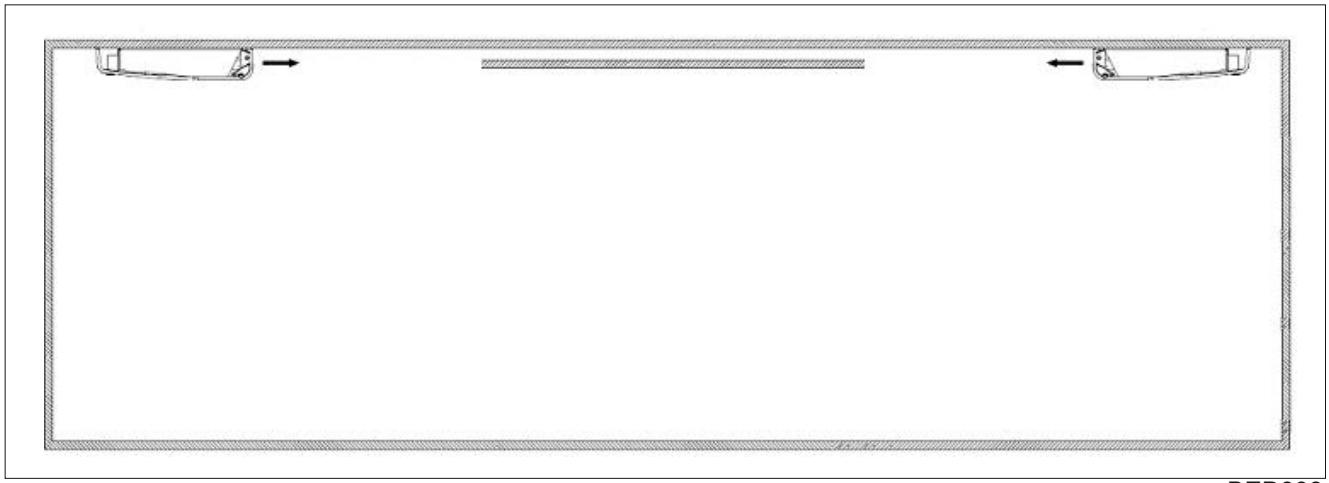
    In case of single-temperature operation the unit must run in **SINGLE ZONE CONTROL (SZC)**mode and the dividing wall must be stowed in such a way that it does not interrupt the airflow from each remote evaporator. For ease of use, SZC mode should be added to the Main (driver) menu.
- **For T-1200R Spectrum S3+S3:**
  - Ranges < -20°C, +2°C to +8 °C or +15°C to +25°C can be operated.
- **For T-1000R Spectrum S3+S3 and UT-1200 S3+S3:**
  - Ranges +2°C to +8 °C or +15°C to +25°C can be operated.
  - The range < -20°C cannot be operated:

- When operating the equipment in multi-temperatures mode, the splitting of the compartment zones should be up to 1/2 of the total body length:
- At ambient temperature between -30°C and +40 °C.
  - This GDP qualification is performed for use in the ambient temperatures as tested. To provide qualification for the expected ambient temperatures in these regions the qualification test temperatures will be performed in the following manner, minimum to be set at -30°C (to simulate average winter temperatures in Northern Europe) and maximum +40 °C (to simulate average high summer temperatures in the South of Europe).
- The vehicle will be used for transportation between temperature controlled loading docks of storage locations.
  - Door openings can have a major effect on the temperature inside the body, depending on the difference in ambient temperature and temperature inside the box. To minimise this effect, this is recommended to open doors of the truck only at loading and unloading at temperature controlled warehouse. In these warehouses the product and the environment is temperature controlled.
  - If the vehicle is to be used with multiple door openings in a non-controlled environment, based on the results of a risk analysis a complementary Performance Qualification may have to be performed by the customer.
- The equipment has to be used according to the driver's instructions supplied by Thermo King on use of Thermo King Equipment. These driver instructions are to be found in the specific Operator Manual.
- The equipment must be run and checked to ensure that all elements are functioning correctly.
- The load space considerations indicated here after must also be taken into account.

Load Space Consideration

- The load space should be kept clean at all times and only cleaning agents that will not affect the products should be used.
- A compartment moveable dividing wall is used in multi-temperatures applications to separate the compartments to allow them to operate at different temperatures. This dividing wall must not be positioned any less than 1300mm from the air outlet of the remote zone evaporator.
- A minimum of 100 mm clearance must be provided between the top of the load and the air intake of the zone remote evaporator.
- An air gap between the load and the walls should be maintained at all times:
  - If the dividing wall is positioned tightly against the load, satisfactory air circulation and temperature management will not be achieved.
  - If the load is positioned tightly against the body internal walls, satisfactory air circulation and temperature management will not be achieved.
- If the unit is to be used as a single-temperature mode, the dividing wall should be stowed in such a way that it does not interrupt the airflow from each remote evaporator.

Figure 5. Recommended position of dividing wall in single temperature operation



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Layout of Sample-type Truck Qualification

The objective of this GDP qualification is to successfully qualify the designed configuration of the equipment mentioned in the Design Qualification: **GDP-TK-DQ-SP-MT**.

For this qualification three issues are important:

- The flow of temperature controlled air in the load space has to reach all parts of the load space. Therefore, a fixed return air system is essential.
- The capacity of the unit that is used to manage the temperature within the load space has to be sufficient to maintain the products at the set temperature range recommended by the manufacturer of the product (pharmaceutical company). Therefore, the base colour white plus allowable 20% decal coverage is set to the DQ. Other darker colours would decrease the cooling capacity of the truck.
- The temperature logging equipment used for the calibration process must in itself be calibrated to each temperature range. This will be checked and confirmed during the OQ (Operational Qualification) process.

The equipment must comply with the three requirements as laid out above and should be measured with calibrated temperature dataloggers and must be registered as such. This will be checked and confirmed during the OQ (Operational Qualification) process.

Technical and User Data

Risk Management for Transport Equipment

Assumptions that are made:

- The temperature qualification is performed in an empty body, as this is considered as the worst case scenario to higher temperatures variation.
- The products (pharmaceuticals) will be loaded at the correct temperature, because they are leaving a temperature controlled storage. It is stated that the refrigeration unit and box is used to maintain the temperature of the products not change the temperature, though this is possible over time.
- The of the physical state (dry, liquid), pharmaceutical forms (tablets, capsules, crèmes) of the medicines, the primary package material (plastic, glass) used to pack these are enormous. The secondary package materials will probably be boxes made from cardboard.
- The capacity of a transport refrigeration unit as well as the minimum insulation of a body is regulated by ATP testing standards. Because this guideline is the current standard for temperature testing, this test protocol is used as the basis for GDP qualification.
- At ambient temperature between -30°C and +40 °C
  - **Worst-case scenario for multi-temperatures trucks:**

    The greatest difference in the set-temperatures between zone 1 and zone 2 and in two extreme ambient temperatures.

Table 8. Worst-case scenario of tests for Multi temperature Trucks

	Ambient temperature	Zone 1	Zone 2
1	+40 °C	-25°C	+20 °C
2	-30 °C	-25°C	+20 °C

Acceptance Criteria

Regarding the acceptance criteria considered in Thermo King Protocol, the air temperature should remain within the required temperature range. For example, if the requirement is for temperature range +2.0°C to +8.0°C, the minimum air temperature recorded should not be below +2.0°C, and the maximum should not exceed +8.0°C.

Qualification Test for Multi-temperature Vehicles

- Deviation of registered data of thermocouples 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 should not exceed maximum deviation as mentioned in section “Acceptance Criteria”.
- The average temperature of all thermocouples should not exceed maximum deviation as mentioned in section “Acceptance Criteria”.

- Ambient temperature is to be logged. The logged temperature should not exceed +/-2 °C of required temperature.
- Return air and discharge air temperature of the unit evaporators is to be logged: Temperatures should not exceed the requirement for the specific temperature being tested.
- Test time is 2.5 hours in steady state.

Table 9. Multi-temperatures operation for T-1200R Spectrum S3+S3

Zones	Zone 1	Zone 2
Length	1/2	1/2
Zone 2 Evaporators	S3	S3
Setpoints	+20°C	-25°C
	+20°C	+6°C
	-25°C	+6°C
Ambient Temperature 1	+40°C	+40°C
Ambient Temperature 2	-30°C	-30°C

Table 10. Multi-temperatures operation for T-1000R Spectrum S3+S3 and UT-1200 S3+S3

Zones	Zone 1	Zone 2
Length	1/2	1/2
Zone 2 Evaporators	S3	S3
Setpoints	+20°C	+6°C
Ambient Temperature 1	+40°C	+40°C
Ambient Temperature 2	-30°C	-30°C

Table 11. Single temperature operation for T-1200R Spectrum S3+S3

Zones	Unique Zone	
Length	Total length	
Evaporator	S3	S3
Setpoints	+20°C	
	+6°C	
	-25°C	
Ambient Temperature 1	+40°C	
Ambient Temperature 2	-30°C	

Table 12. Single temperature operation for T-1000R Spectrum S3+S3 and UT-1200 S3+S3

Zones	Unique Zone	
Length	Total length	
Evaporator	S3	S3

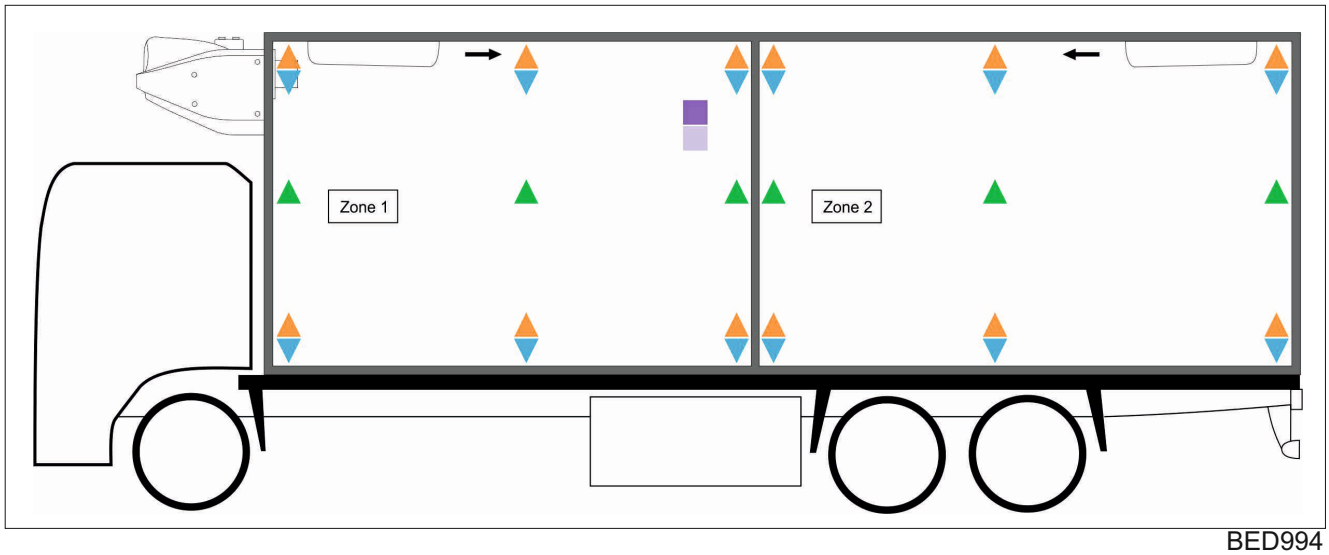
Table 12. Single temperature operation for T-1000R Spectrum S3+S3 and UT-1200 S3+S3 (continued)

Setpoints	+20°C
	+6°C
Ambient Temperature 1	+40°C
Ambient Temperature 2	-30°C

Thermocouple Locations

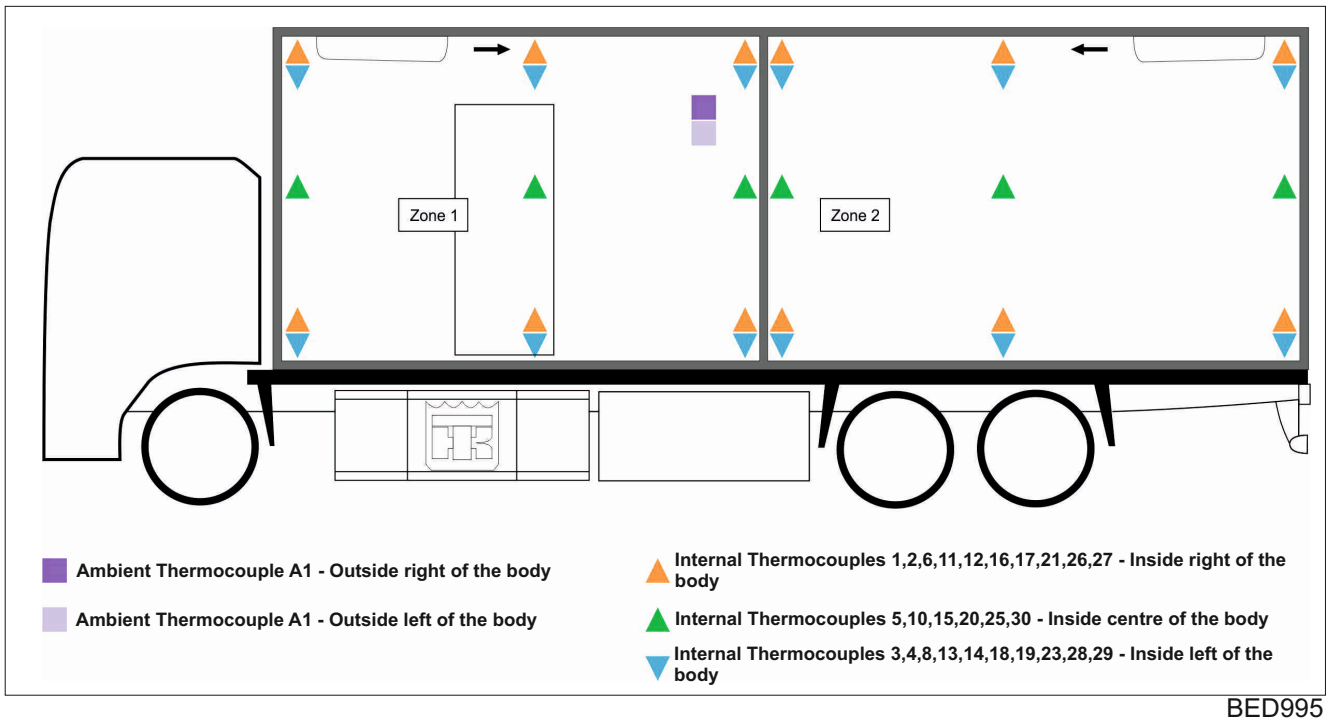
There is no information in GDP guideline as to location of or how many thermo couplings for temperature measurement should be inserted into the load space during the qualification test. Therefore, the locations of the thermo couplings are referred to as in the ATP guideline. ATP is using standard NFX 15-140. This means 15 thermocouples per zone are utilised in the box during the multi-temperatures qualification test and 25 thermocouples for the single temperature qualification test. These loggers are calibrated and the calibration documents are available under request.

Figure 6. T-1200R S3+S3 and T-1000R S3+S3 thermocouple locations multi-temperatures operation Z1 length = 1/2 / Z2 length = 1/2 of total length



BED994

Figure 7. UT-1200 S3+S3 thermocouple locations multi-temperatures operation Z1 length = 1/2/ Z2 length = 1/2 of total length.



BED995

Figure 8. Thermocouple locations for multi-temperatures operation

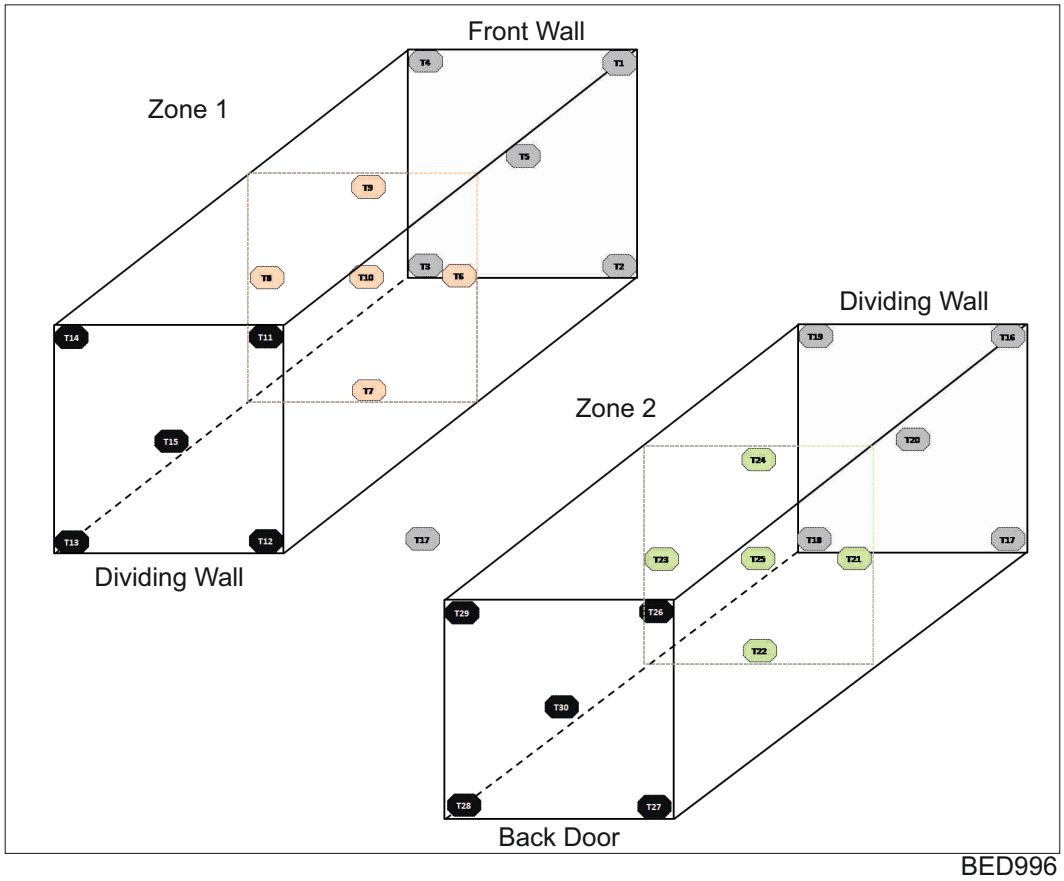


Figure 9. T-1200R S3+S3 and T-1000R Spectrum S3+S3 thermocouple locations, single temperature operation

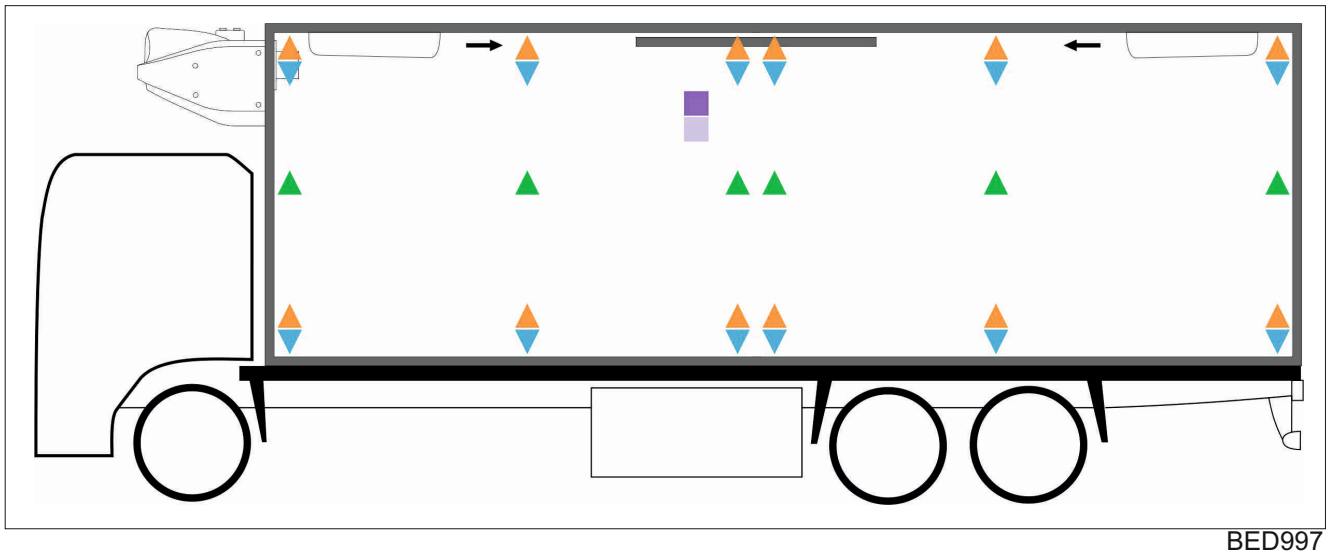
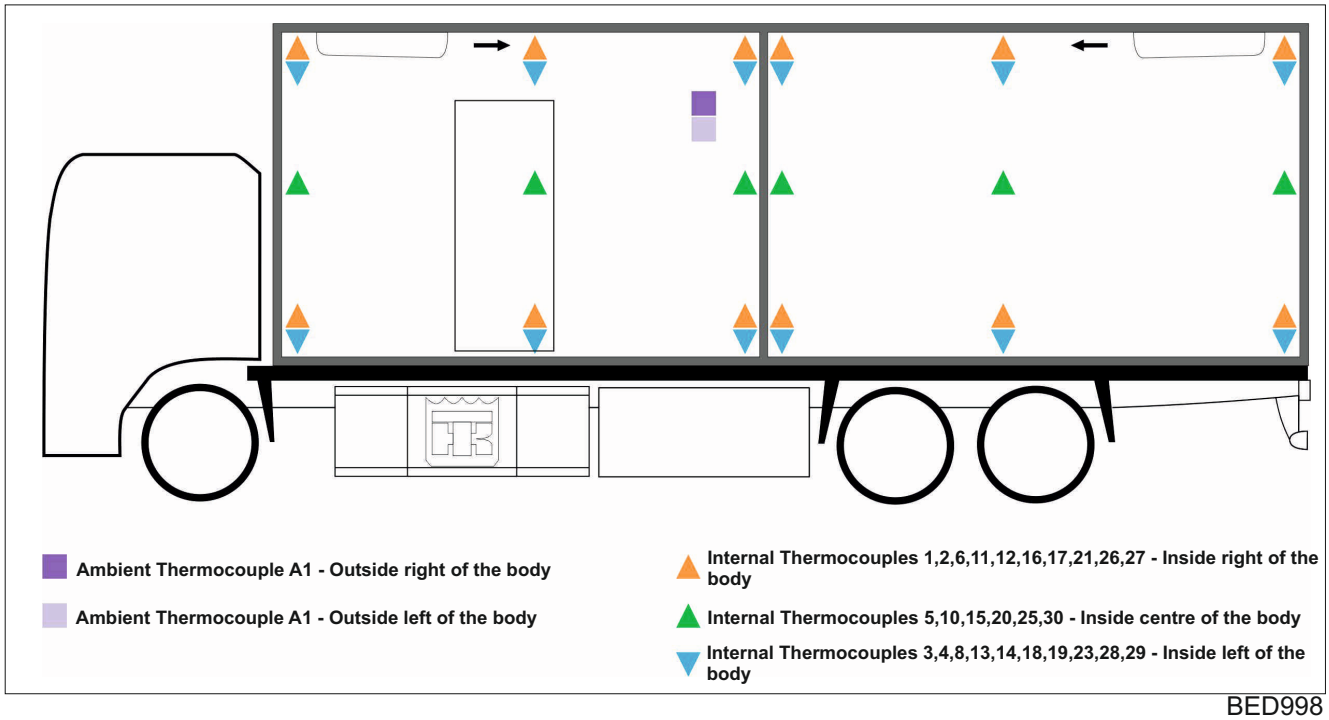
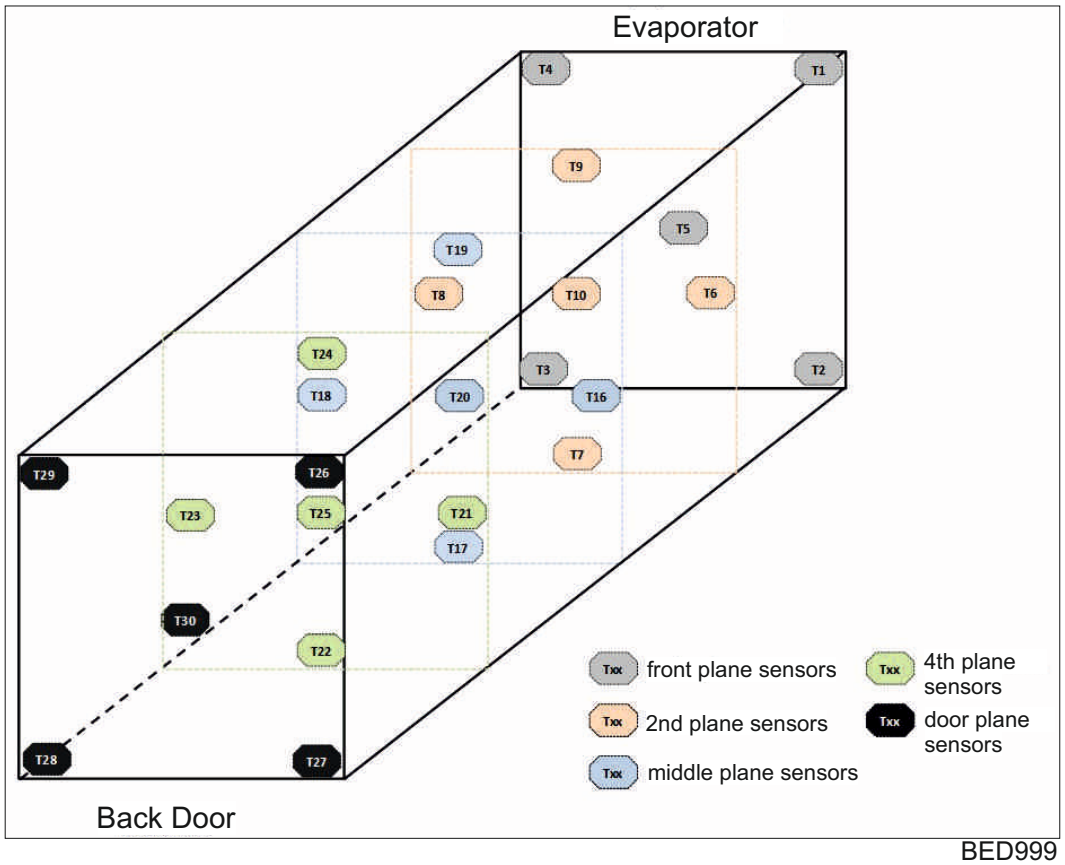


Figure 10. UT-1200 S3+S3 thermocouple locations, single temperature operation



BED998

Figure 11. Thermocouple locations for single-temperature operation



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Operational Qualification on the Field

For each individual equipment (vehicle + refrigerated unit) a specific **TK PharmaSolutions - IQOQ Check-MUL** document has to be completed by the Thermo King official dealer. The latest valid revision of this document has to be used and is available from Thermo King EMEA InfoCentral intranet.

This document confirms that:

- Installation is conducted as per **GDP-TK-IQ-SP-MT.**
- A calibration check has been performed in an empty body for each qualified range. This calibration check is performed for the controlling sensors and the datalogger sensors and the results are attached to this document. The results are available on request in electronic format.
- All required risk management and due diligence protocols are in place and comply with the GDP requirements. This protocol's minimum requirements should be:
  - Scheduled maintenance
  - Breakdown repairs
  - Annual 3-temperatures calibration check
  - Availability of service history
  - Asset management

THERMO KING

Performance Qualification

Prepared for Thermo King, for validation of temperature controlled equipment Multi-Temperatures units for truck:

T-1000R Spectrum, T-1200R Spectrum and UT-1200 Spectrum

Introduction

Thermo King designs and builds temperature controlled transport equipment.

These types of equipment can be validated for a specific desired temperature range for the transport of pharmaceutical products.

Due to the fact that several test were performed on the different units in time, not all the tests are performed under the same circumstances.

Table 13. Truck body with T-1000R Spectrum S3+S3

Temperature Range	Extreme Ambient Temperature	Recommended Setpoint	Max Average Deviation from Setpoint
Temperature between 2°C and 8°C	+40°C / -30°C	+6°C	+2/-3°C of setpoint
Temperature between 15°C and 25°C	+40°C / -30°C	+20°C	+2/-3°C of setpoint

Table 14. Truck body with T-1200R Spectrum S3+S3

Temperature Range	Extreme Ambient Temperature	Recommended Setpoint	Max Average Deviation from Setpoint
Temperature below -20°C	+40°C / -30°C	-25°C	+5/-5°C of setpoint
Temperature between 2°C and 8°C	+40°C / -30°C	+6°C	+2/-4°C of setpoint
Temperature between 15°C and 25°C	+40°C / -30°C	+20°C	+3/-5°C of setpoint

Table 15. Truck body with UT-1200 Spectrum S3+S3

Temperature Range	Extreme Ambient Temperature	Recommended Setpoint	Max Average Deviation from Setpoint
Temperature between 2°C and 8°C	+40°C / -30°C	+6°C	+3/-3°C of setpoint
Temperature between 15°C and 25°C	+40°C / -30°C	+20°C	+3/-5°C of setpoint

Note: *To ensure total flexibility the qualification is to be performed at all stated ranges from above.*

Purpose

This protocol defines the qualification of the equipment (a refrigerated unit designed and built by Thermo King with an ATP certified body) for the transportation, under temperature restrictions, of medicines.

The qualification is based on the following documents: **GDP-TK-VMP**, **GDP-TK-DQ-SP-MT**, **GDP-TK-IQ-SP-MT** and **GDP-TK-OQ-SP-MT**.

Scope

The scope of the qualification work will be done to the equipment: a refrigerated unit designed and built by Thermo King with an ATP certified body.

A standard configuration is defined for each group.

For multi-temperatures truck the specifications are as per the Design Qualification **GDP-TK-DQ-SP-MT**.

Evaluation of the Qualification Test

T-1200R Spectrum S3+S3 - Multi-temperatures Tests

Table 16. Multi-Temperatures Operation - Configuration as in GDP-TK-OQ-SP-MT figure 6, dividing wall in middle position of total length (Zone 1)

Ambient	Setpoint	Min/Max sensor temperature	Average temperature	Average temperature deviation
+40°C	+20°C	+17/+22 °C	+19 °C	-2 /+1°C of setpoint
	+20°C	+17/+22 °C	+20 °C	-2 /+1°C of setpoint
	+6°C	+2/+8 °C	+6 °C	-2 /+1°C of setpoint
-30°C	+20°C	+15/+21 °C	+18 °C	-2 /+1°C of setpoint
	+20°C	+15/+23 °C	+17 °C	-5 /+0°C of setpoint
	+6°C	+2/+8 °C	+5 °C	-3 /+2°C of setpoint

Table 17. Multi-Temperatures Operation - Configuration as in GDP-TK-OQ-SP-MT figure 6, dividing wall in middle position of total length (Zone 2)

Ambient	Setpoint	Min/Max sensor temperature	Average temperature	Average temperature deviation
+40°C	+6°C	+3/+8 °C	+6°C	- /+1°C of setpoint
	-25°C	-27/-21 °C	-25°C	-1 /+2°C of setpoint
	-25°C	-27/-20 °C	-24°C	0 /+3°C of setpoint
-30°C	+6°C	+4/+7 °C	+6°C	-1/+2°C of setpoint
	-25°C	-28/-24 °C	-26°C	-2 /+0°C of setpoint
	-25°C	-29/-21 °C	-26°C	-2 /+1°C of setpoint

Table 18. Door opening - Configuration as in GDP-TK-OQ-SP-MT figure 6, dividing wall in middle position of total length

Ambient	Setpoint		5 minutes rear door opening		10 minutes rear doors opening	
	Zone 1	Zone 2	Air temperature peak (Z2)	Recovery time after closing doors	Air temperature peak (Z2)	Recovery time after closing doors
+40°C	+20°C	+6°C	+33.9 °C	11 minutes	+37.3 °C	22 minutes
	+20°C	-25°C	+29.7 °C	87 minutes	-	-
	+6°C	+20°C	+36 °C	5 minutes	+37.7 °C	6 minutes
	-25°C	+6°C	+32.9 °C	17 minutes	+35.8 °C	18 minutes
	-25°C	+20°C	+35.3 °C	4 minutes	+38.4 °C	4 minutes
-30°C	+20°C	+6°C	-24.4 °C	16 minutes	-27.3 °C	23 minutes
	+20°C	+20°C	-20.9 °C	25 minutes	-25.8 °C	39 minutes
	+6°C	+20°C	-21.1 °C	19 minutes	-26.9 °C	27 minutes
	+6°C	+6°C	-23.6 °C	9 minutes	-26.8 °C	14 minutes

Table 19. Failure Test - Configuration as in GDP-TK-OQ-SP-MT figure 6, dividing wall in middle position of total length

Ambient	Zone 1			Zone 2		
	Setpoint	Time to move out of the range	Rules to apply	Setpoint	Time to move out of the range	Rules to apply
+40°C	+6°C	10minutes	Above +8°C or max 2hrs.	+20°C	2 hours	Above +25°C or max 2hrs.
	+6°C	8 minutes	Above +8°C or max 2hrs.	-25°C	15 minutes	Above -20°C or max 2hrs.
	-25°C	11 minutes	Above -20°C or max 2hrs.	+20°C	2 hours	Above +25°C or max 2hrs.
-30°C	-25°C	N.A.	Non Applicable	+6°C	7 minutes	Below +2°C or max 2hrs.
	-25°C	N.A.	Non Applicable	+20°C	4 minutes	Below +15°C or max 2hrs.
	+20°C	20 minutes	Below +15°C or max 2hrs.	+6°C	35 minutes	Below +2°C or max 2hrs.

T-1200R Spectrum S3+S3 - Single-temperature Tests

Table 20. Single Temperature Operation - Configuration as in GDP-TK-OQ-SP-MT figure 9, Single Zone Control and dividing wall stowed

Ambient	Setpoint	Min/Max sensor temperature	Average temperature	Average temperature deviation
+40°C	+20°C	+16/+21 °C	+19 °C	-2 / 0°C of setpoint
	+6°C	+2/+8 °C	+5 °C	-2 / 0°C of setpoint
	-25°C	-27/-20°C	-24 °C	0 /+2°C of setpoint
-30°C	+20°C	+16/+22 °C	+19 °C	-3 / 0°C of setpoint
	+6°C	+2/+8 °C	+5 °C	-2 / 0°C of setpoint
	-25°C	-31/-25 °C	-28 °C	-4 /-1°C of setpoint

Table 21. Door opening - Configuration as in GDP-TK-OQ-SP-MT figure 9, Single Zone Control and dividing wall stowed

Ambient	Setpoint	5 minutes rear door opening		10 minutes rear doors opening	
		Air temperature peak (Z2)	Recovery time after closing doors	Air temperature peak (Z2)	Recovery time after closing doors
+40°C	+20°C	+36.5 °C	6 minutes	+38 °C	8 minutes
	+6°C	+34.2 °C	30 minutes	+36.5 °C	41 minutes
	-25°C	+31.7 °C	117 minutes	-	-
-30°C	+20°C	-24.5 °C	34 minutes	-26 °C	55 minutes
	+6°C	-26 °C	24 minutes	-28.2 °C	34 minutes

Table 22. Failure Test - Configuration as in GDP-TK-OQ-SP-MT figure 9, Single Zone Control and dividing wall stowed

Ambient	Setpoint	Time to move out of the range	Rules to apply
+40°C	+6°C	20 minutes	Above +8°C or max 2hrs.
	-25°C	15 minutes	Above -20°C or max 2hrs.

Table 22. Failure Test - Configuration as in GDP-TK-OQ-SP-MT figure 9, Single Zone Control and dividing wall stowed (continued)

-30°C	+20°C	11 minutes	Below +15°C or max 2hrs.
	+6°C	20 minutes	Below +2°C or max 2hrs.

T-1000R Spectrum S3+S3 - Multi-temperatures tests

Table 23. Multi-Temperatures Operation - Configuration as in GDP-TK-OQ-SP-MT figure 6, dividing wall in middle position of total length (Zone 1)

Ambient	Setpoint	Min/Max sensor temperature	Average temperature	Average temperature deviation
+40°C	+20°C	+17/+22 °C	+20 °C	-2 / 0°C of setpoint
-30°C	+20°C	+16/+21 °C	+18 °C	-3 / 0°C of setpoint

Table 24. Multi-Temperatures Operation - Configuration as in GDP-TK-OQ-SP-MT figure 6, dividing wall in middle position of total length (Zone 2)

Ambient	Setpoint	Min/Max sensor temperature	Average temperature	Average temperature deviation
+40°C	+6°C	+3/+8 °C	+6 °C	- / +1°C of setpoint
-30°C	+6°C	+4/+7 °C	+5 °C	-2 / 0°C of setpoint

Table 25. Door Opening - Configuration as in GDP-TK-OQ-SP-MT figure 6, dividing wall in middle position of total length

Ambient	Setpoint		5 minutes rear door opening		10 minutes rear doors opening	
	Zone 1	Zone 2	Air temperature peak (Z2)	Recovery time after closing doors	Air temperature peak (Z2)	Recovery time after closing doors
+40°C	+20°C	+6°C	+34.2 °C	19 minutes	+36.7 °C	24 minutes
	+6°C	+20°C	+36.7 °C	4 minutes	+37.9 °C	5 minutes
-30°C	+6°C	+20°C	-20.7 °C	34 minutes	-25.5 °C	59 minutes
	+20°C	+6°C	-24.4 °C	15 minutes	-27.9 °C	24 minutes

Table 26. Failure test - Configuration as in GDP-TK-OQ-SP-MT figure 6, dividing wall in middle position of total length

Ambient	Zone 1			Zone 2		
	Setpoint	Time to move out of the range	Rules to apply	Setpoint	Time to move out of the range	Rules to apply
+40°C	+6°C	8 minutes	Above +8°C or max 2hrs.	+20°C	2 hours	Above +25°C or max 2hrs.
	+20°C	2 hours	Above +25°C or max 2hrs.	+6°C	10 minutes	Above +8°C or max 2hrs.
-30°C	+6°C	86 minutes	Below +2°C or max 2hrs.	+20°C	36 minutes	Below +15°C or max 2hrs.
	+20°C	35 minutes	Below +15°C or max 2hrs.	+6°C	65 minutes	Below +2°C or max 2hrs.

T-1000R Spectrum S3+S3 - Single-temperature Tests

Table 27. Single Temperature Operation - Configuration as in GDP-TK-OQ-SP-MT figure 9, Single Zone Control and dividing wall stowed

Ambient	Setpoint	Min/Max sensor temperature	Average temperature	Average temperature deviation
+40°C	+20°C	+16/+21 °C	+19 °C	-2 / 0°C of setpoint
	+6°C	+2/+8 °C	+5 °C	-2 / 0°C of setpoint
-30°C	+20°C	+16/+22 °C	+19 °C	-3 / 0°C of setpoint
	+6°C	+2/+8 °C	+5°C	-2 / 0°C of setpoint

Table 28. Door opening - Configuration as in GDP-TK-OQ-SP-MT figure 9, Single Zone Control and dividing wall stowed

Ambient	Setpoint	5 minutes rear door opening		10 minutes rear doors opening	
		Air temperature peak (Z2)	Recovery time after closing doors	Air temperature peak (Z2)	Recovery time after closing doors
+40°C	+20°C	+36.5 °C	6 minutes	+38 °C	8 minutes
	+6°C	+34.2 °C	30 minutes	+36.5 °C	41 minutes
-30°C	+20°C	-24.5 °C	34 minutes	-26 °C	55 minutes
	+6°C	-26 °C	24 minutes	-28.2 °C	34 minutes

Table 29. Failure Test - Configuration as in GDP-TK-OQ-SP-MT figure 9, Single Zone Control and dividing wall stowed

Ambient	Setpoint	Time to move out of the range	Rules to apply
+40°C	+6°C	20 minutes	Above +8°C or max 2hrs.
-30°C	+20°C	11 minutes	Below +15°C or max 2hrs.
	+6°C	20 minutes	Below +2°C or max 2hrs.

UT-1200 Spectrum S3+S3 - Multi-Temperatures Tests

Table 30. Multi-Temperatures Operation - Configuration as in GDP-TK-OQ-SP-MT figure 7, dividing wall in middle position of total length (Zone 1)

Ambient	Setpoint	Min/Max sensor temperature	Average temperature	Average temperature deviation
+40°C	+20°C	+17/+22 °C	+20 °C	- / +1°C of setpoint
-30°C	+20°C	+15/+22 °C	+18°C	-3 / 0°C of setpoint

Table 31. Multi-Temperatures Operation - Configuration as in GDP-TK-OQ-SP-MT figure 7, dividing wall in middle position of total length (Zone 2)

Ambient	Setpoint	Min/Max sensor temperature	Average temperature	Average temperature deviation
+40°C	+5°C	+2/+8 °C	+6 °C	-1 / +2°C of setpoint
-30°C	+5°C	+3/+7 °C	+4°C	-4 / 0°C of setpoint

Table 32. Door opening 5 minutes - Configuration as in GDP-TK-OQ-SP-MT figure 7, dividing wall in middle position of total length

Ambient	Zone 1 (side door)			Zone 2 (rear doors)		
	Setpoint	Air temperature peak	Recovery time after closing doors	Setpoint	Air temperature peak	Recovery time after closing doors
+40°C	+5°C	+31.8°C	9 minutes	+20°C	+30.9°C	4 minutes
	+20°C	+35.6°C	4 minutes	+5°C	+25.7°C	20 minutes
-30°C	+5°C	-27.5°C	18 minutes	+20°C	-13.8°C	29 minutes
	+20°C	-25.3°C	25 minutes	+5°C	-17.3°C	37 minutes

Table 33. Door opening 10 minutes - Configuration as in GDP-TK-OQ-SP-MT figure 7, dividing wall in middle position of total length

Ambient	Zone 1 (side door)			Zone 2 (rear doors)		
	Setpoint	Air temperature peak	Recovery time after closing doors	Setpoint	Air temperature peak	Recovery time after closing doors
+40°C	+5°C	+37.8°C	13 minutes	+20°C	+35.3°C	8 minutes
	+20°C	+38.5°C	6 minutes	+5°C	+34°C	25 minutes
-30°C	+5°C	-29.6°C	35 minutes	+20°C	-20.1°C	55 minutes
	+20°C	-29.8°C	45 minutes	+5°C	-25°C	55 minutes

Table 34. Failure test - Configuration as in GDP-TK-OQ-SP-MT figure 7, dividing wall in middle position of total length

Ambient	Zone 1			Zone 2		
	Set-point	Time to move out of the range	Rules to apply	Setpoint	Time to move out of the range	Rules to apply
+40°C	+5°C	18 minutes	Above +8°C or max 2hrs.	+20°C	2 hours	Above +25°C or max 2hrs.
	+20°C	102 minutes	Above +25°C or max 2hrs.	+5°C	15 minutes	Above +8°C or max 2hrs.
-30°C	+5°C	13 minutes	Below +2°C or max 2hrs.	+20°C	15 minutes	Below +15°C or max 2hrs.
	+20°C	15 minutes	Below +15°C or max 2hrs.	+5°C	7 minutes	Below +2°C or max 2hrs.

UT-1200 Spectrum S3+S3 - Single-temperature Tests

Table 35. Single Temperature Operation - Configuration as in GDP-TK-OQ-SP-MT figure 10, Single Zone Control and dividing wall stowed

Ambient	Setpoint	Min/Max sensor temperature	Average temperature	Average temperature deviation
+40°C	+20°C	+17/+23 °C	+20 °C	-1 / 0°C of setpoint
	+5°C	+2/+7 °C	+5°C	- / +1°C of setpoint
-30°C	+20°C	+15/+21 °C	+19 °C	-1°C of setpoint
	+5°C	+2/+6 °C	+4°C	-3 / 0°C of setpoint

Table 36. Door open - Configuration as in GDP-TK-OQ-SP-MT figure 10, Single Zone Control and dividing wall stowed

Ambient	Setpoint	5 minutes rear door opening		10 minutes rear doors opening	
		Air temperature peak	Recovery time after closing doors	Air temperature peak	Recovery time after closing doors
+40°C	+20°C	+30.4 °C	3 minutes	+35.7 °C	7 minutes
	+5°C	+25.9 °C	17 minutes	+33.2 °C	25 minutes
-30°C	+20°C	-9.4 °C	16 minutes	-21.9 °C	46 minutes
	+5°C	-15.3 °C	16 minutes	-25.6 °C	28 minutes

Table 37. Failure test - Configuration as in GDP-TK-OQ-SP-MT figure 10, Single Zone Control and wall stowed

Ambient	Setpoint	Time to move out of the range	Rules to apply
+40°C	+5°C	19 minutes	Above +8°C or max 2hrs.
	+20°C	8 minutes	Above -20°C or max 2hrs.
-30°C	+20°C	16 minutes	Below +15°C or max 2hrs.
	+5°C	8 minutes	Below +2°C or max 2hrs.

Hotspot / Coldspot Identification

As an indicator to support Risk Analysis of the customer the following Hot and Cold spots have been identified in an empty body.

Refer to **figures 8** and **11** for thermocouples locations.

During COOLING Cycle - Multi-temperature Operation

Table 38. T-1000R Spectrum S3+S3 and T-1200R Spectrum S3+S3

	Unit model	Zone 1	Zone 2
Hotspot	T-1000R Spectrum S3+S3	T4	T29
	T-1200R Spectrum S3+S3		
Coldspot	T-1000R Spectrum S3+S3	T9	T20
	T-1200R Spectrum S3+S3	T14	T17

Table 39. UT-1200 Spectrum S3+S3

	Unit model	Zone 1	Zone 2
Hotspot	UT-12000 Spectrum S3+S3	T1	T16
Coldspot		T11	T19

During COOLING Cycle - Single-temperature Operation

Table 40. T-1000R Spectrum S3+S3 and T-1200R Spectrum S3+S3

	Unit model	Unique zone
Hotspot	T-1000R Spectrum S3+S3	T4
	T-1200R Spectrum S3+S3	

Table 40. T-1000R Spectrum S3+S3 and T-1200R Spectrum S3+S3 (continued)

Coldspot	T-1000R Spectrum S3+S3	T9
	T-1200R Spectrum S3+S3	

Table 41. For UT-1200 Spectrum S3+S3

	Unit model	Unique zone
Hotspot	UT-12000 Spectrum S3+S3	T1
Coldspot		T10

During HEATING Cycle - Multi-temperature Operation

Table 42. T-1000R Spectrum S3+S3 and T-1200R Spectrum S3+S3

	Unit model	Zone 1	Zone 2
Hotspot	T-1000R Spectrum S3+S3	T9	T19
	T-1200R Spectrum S3+S3		T20
Coldspot	T-1000R Spectrum S3+S3	T9	T26
	T-1200R Spectrum S3+S3	T2	T17

Table 43. UT-1200 Spectrum S3+S3

	Unit model	Zone 1	Zone 2
Hotspot	UT-12000 Spectrum S3+S3	T11	T19
Coldspot		T14	T16

During HEATING Cycle - Single-temperature Operation

Table 44. T-1000R Spectrum S3+S3 and T-1200R Spectrum S3+S3

	Unit model	Unique zone
Hotspot	T-1000R Spectrum S3+S3	T9
	T-1200R Spectrum S3+S3	
Coldspot	T-1000R Spectrum S3+S3	T29
	T-1200R Spectrum S3+S3	

Table 45. For UT-1200 Spectrum S3+S3

	Unit model	Unique zone
Hotspot	UT-12000 Spectrum S3+S3	T10
Coldspot		T28

Recommendations

To maintain the best temperature management within the load-space it is recommended to operate with the following set-point temperatures in the following ranges:

For T-1200R Spectrum S3+S3

- +20 °C for temperature range +15 °C to +25 °C
- +6 °C for temperature range +2 °C to +8 °C
- -25 °C for temperature below -20 °C

For T-1000R Spectrum S3+S3

- +20 °C for temperature range +15 °C to +25 °C
- +6 °C for temperature range +2 °C to +8 °C

For UT-1200 Spectrum S3+S3

- +20 °C for temperature range +15 °C to +25 °C
- +5 °C for temperature range +2 °C to +8 °C

Note: *The splitting of the zones for the trailer multi-temperature should be as stated in the qualification test:* ***dividing wall in middle position of the total length.***

Important: *When operating in multi-temperatures mode ZONE PRIORITY function must be* ***DISABLED****.*

Important: *For customers who want to use the mentioned equipment as a single temperature load, the dividing wall should be stowed in such a way that it does not interrupt the airflow from each evaporator and the unit must run in* ***SINGLE ZONE CONTROL****.*

Appendix

Certificate of Prague Accreditation - ISO 17025
Certificate of Prague Accreditation - IATF 16949

EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Olšanská 54/3, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

CERTIFICATE OF ACCREDITATION

No. 121/2023

Trane Technologies s.r.o.
with registered office č.p. 292, 280 02 Ovčáry, Company Registration No. 63989069

to the Testing Laboratory No. **1680**
ETC Prague

Scope of accreditation:

Performance of functional dynamic, seismic, climatic and thermal tests for the resistance of components and products; testing of electromagnetic compatibility and electrostatic discharge immunity to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of Accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO/IEC 17025:2018

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 573/2021 of 5. 11. 2021, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **14. 3. 2028**

Prague: 14. 3. 2023

Český institut pro akreditaci, o.p.s.
NÁRODNÍ AKREDITAČNÍ ORGÁN
-3-

Jan Velíšek
Director of the Department
of Testing and Calibration Laboratories
Czech Accreditation Institute
Public Service Company

Certification date:	30 August 2022
Expiry date:	29 August 2025
Certificate number:	10465770
IATF Certificate number:	0456850

Certificate of Approval

This is to certify that the Management System of:

Thermo King Manufacturing s.r.o.

No. 292 Kolín District, 280 02 Ovčáry, Czech Republic

has been approved by LRQA to the following standards:

IATF 16949:2016

Approval number(s): IATF 16949 – 00021327-001

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:
Design and Manufacture of Refrigeration and Air Conditioning Equipment.

Cliff Muckleroy

Area Operations Manager Americas

Issued by: LRQA Limited

Approval number(s): 00021327-001
Certificate number: 10465770
IATF Certificate number: 0456850

Certificate Schedule

Location	Activities
Trane Technologies s.r.o., ETC Prague Florianova 2460, 253 01 Hostivice, Czech Republic	**IATF 16949:2016** Testing, Laboratory, R&D.
Trane Technologies International Limited No. 292 Kolín District, 280 02 Ovčáry, Czech Republic	**IATF 16949:2016** Product Design.
Trane Technologies International Limited Lenneke Marelaan 6, 1932 Sint-Stevens-Woluwe, Belgium	**IATF 16949:2016** Sales.
Trane Technologies International Limited Monivea Road, Co Galway Mervue, Ireland	**IATF 16949:2016** Warranty Management, Customer Service, Supplier Management, Purchasing, Continual Improvement, IT.

Thermo King – by Trane Technologies (NYSE: TT), a global climate innovator – is a worldwide leader in sustainable transport temperature control solutions. Thermo King has been providing transport temperature control solutions for a variety of applications, including trailers, truck bodies, buses, air, shipboard containers and railway cars since 1938. For more information, visit www.thermoking.com or www.tranetechnologies.com.

TK 61296–1–MS-EN 04 Apr 2022
Supersedes TK 61296–1–MS-EN ((no date found))