THERMO KING

User Guide

Multi-Temperature
Trailer with S3A Remote Evaporator

A-500 Spectrum

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 B

September 2023

TK 62125–2–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
- 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

THERMO KING
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	(07/23) Initial Release
Revision B	(09/23) General Updates

General Information

Temperature controlled units covered:

Multi-Temperature Trailer units

A-500 Spectrum with S3A remote Evaporator

Kit Pharma Solutions TR-MT_A	905231

For further information, refer to:

A-series Spectrum Operator Manual	TK 61738-2-OP
A-series Spectrum Installation Manual	TK 62044-2-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.

Note: *When used in this manual, the term "unit" is referring to temperature- controlled unit A-500 Spectrum equipped with S3A remote evaporator in ZONE 2.*

Recover Refrigerant

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 Trailer Multi-Temperature Units: A-500 Spectrum and S3A remote evaporator in ZONE 2.

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 Barcode)
  - All advancer models are covered under model/system number TKTRLA + 8 digits)
- 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

Let your voice be heard!

Your feedback will help improve our manuals. The survey is accessible through any internet-connected device with a web browser.

Scan the Quick Response (QR) code or click Technical Publications EMEA Feedback

THERMO KING

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

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.

⚠ Caution

Risk of Injury OR Equipment Damage!!

The host unit is shipped with the refrigerant on the high side and the remote evaporators with the nitrogen on the low side.

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 trailer: A-500 Spectrum and S3A remote evaporator in ZONE 2.

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.

Purpose

This qualification plan describes the procedure for qualifying a refrigeration trailer body type with similar or better insulation than ATP-FRC standards (0.4W/m^2.K), and equipped with a refrigerated unit type Thermo King multi-temperatures A-500 Spectrum and S3A remote evaporator..

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 -25°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

Overall Qualification Results

Unit Specifications		**Box Specifications**				**Pharmaceutical Temperature Ranges**				**Test Ambient**	
Unit Model	Refrigerant	Doors Front/ Back/ Side	Insula-tion Class (ATP mark)	Internal Volume/Length		+15/ +25°C Ambient	+2/ +8°C Chilled	-20°C Frozen	<-20°C Deep frozen	Ex-treme HIGH	Ex-treme LOW
				Min.	Max.						
Multi-temperatures Advancer Trailer units (refer to TK 62125-2-MS)											
A-500 Spectrum 2 S3A	R-452A	2 Back	IR (FRC)	13.60 m		Qualified			N.A	+45°C	-30°C

Design Qualification (DQ)

Equipment, a trailer body of 13.6 m x 2.5 m x 2.7 m (L x W x H) and K-factor of 0.4 W/m^2. K or better equipped with a Thermo King refrigerated unit A-500 Spectrum and S3A remote evaporator has 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-TR-MT_A****.*

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-IQ-TR-MT_A****.*

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-OQ-TR-MT_A****.*

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 NFX 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-PQ-TR-MT_A****.*

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.

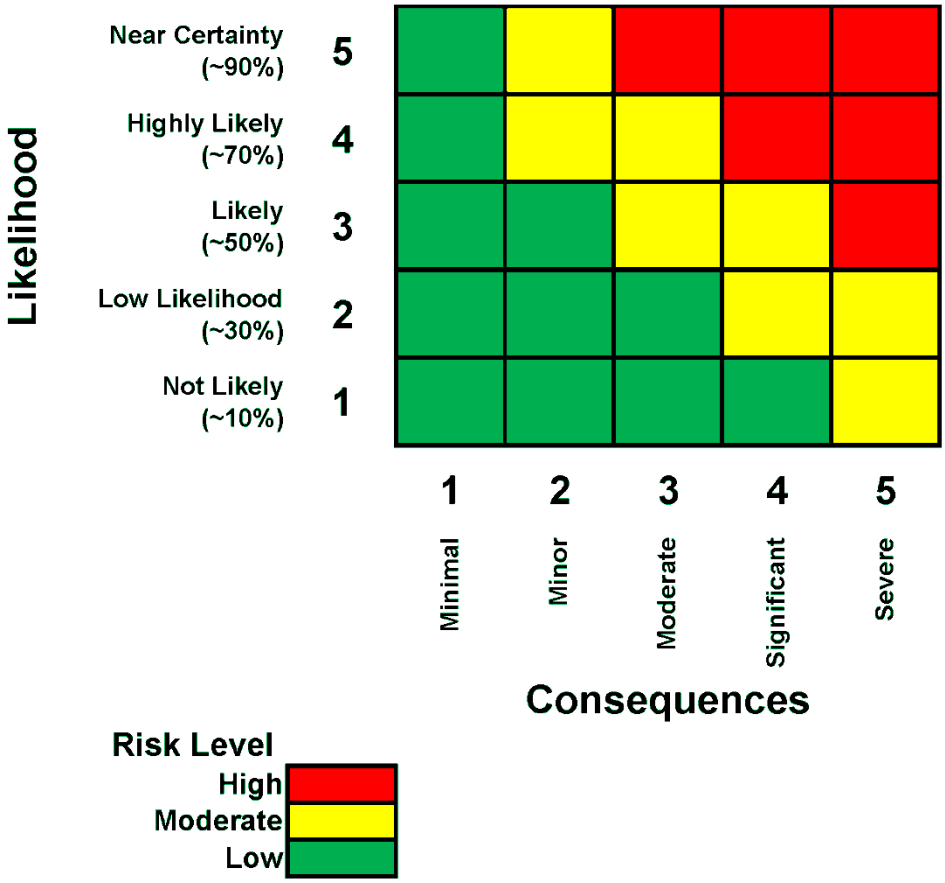
Risk Reporting Matrix

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

- a refrigeration trailer body type with similar or better insulation than ATP-FRC standards (0.4W/m^2.K), and equipped with a refrigerated unit type Thermo King multi-temperatures unit A-500 Spectrum with S3A remote evaporator

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 unit only uses approved refrigerant and is labelled according to refrigerant R-452A.
	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.				For the configuration trailer spectrum S3A, Zone 2 maximum split should be 1/3.
	Blower speed not set correctly for diesel and electric operation resulting in poor airflow.				At IQ, Check that the equipment design specifications are like the sample-type equipment. Ensure the blower speed for DIESEL operation pull down and steady state is HIGH and for ELECTRIC operation pull down and steady state is MAXIMUM.
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 Set-point for temperature range +15°C to +25°C • +5°C Set-point for temperature range +2°C to +8°C • -23°C Set-point for temperature below -20°C
	Incorrect settings of the refrigerated unit then the vehicle is being used in multi-temperatures mode.				For A-500 Spectrum and S3A remote evaporator, ensure software revision 3.0.2. or later is installed. FRESH + FROZEN RANGE CONTROLLING SENSOR is set to RETURN AIR.
	Incorrect settings of the refrigerated unit when the vehicle is being used in single temperature mode.				To use the trailer as single temperature mode, Zone 2 should be switched off and the dividing door should be stowed in such a way that it does not interrupt the airflow from the main unit evaporator.

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 +45°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.
Driver's 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.

Design Qualification

Prepared for Thermo King, for validation of temperature controlled equipment Trailer A-500 Spectrum and S3A remote evaporator.

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

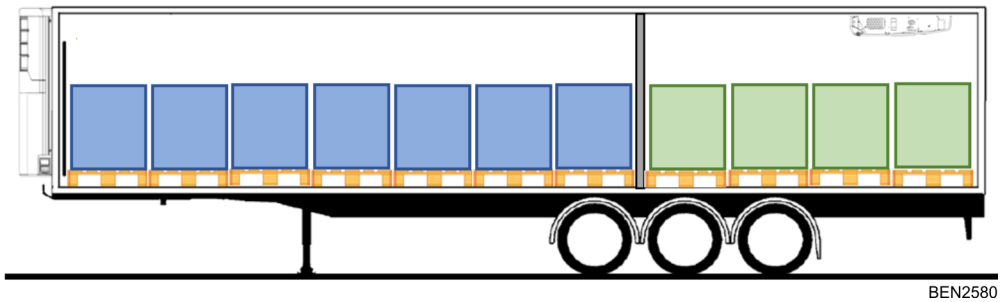
The scope of the qualification work will be done to the equipment (a refrigerated unit designed and built by Thermo King with an ATP certified body) for the transportation, under temperature restrictions, of medicines.
A standard configuration is defined for each group.

Equipment Specifications

Trailer body with A-500 Spectrum unit with S3A remote evaporator

- Trailer body multi-temperature Industry standard, ATP IR (13.6 m x 2.5 m x 2.7 m (L x W x H)). An interior volume that is smaller is also permissible.
- A K factor of 0.40 W/m2.K. A better K factor is also permissible.
- Body white in colour. A maximum 20% of the external surface decal coverage is recommended.
- A fixed and solid type return air bulkhead system is installed in accordance with Thermo King recommended standards. Refer to Figure "Recommended minimal distances".
- Thermo King A-500 Spectrum for Zone 1.
- Spectrum S3A evaporator for temperature management in Zone 2.
- Host and Remote Zones are set to control the temperature on the RETURN air sensor for both fresh and frozen application.
- Blower speed for diesel pull-down and steady state HIGH and electric pull-down and steady state MAXIMUM, adjusted in programmable features.
- Movable wall with a K factor as required and laid out in ATP certification agreement, see table in section "Detail specifications". A K factor that is better than this is also permissible.

Figure 2. Trailer with A-500 Spectrum and S3A remote evaporator



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.

Temperature Range Table

Thermo King recommends to run the unit with the recommended Setpoints below:

Table 4. Test Results - Trailer body with A-500 Spectrum and S3A remote evaporator

Temperature Range	Extreme Ambient Temperature	Recommended Setpoint	Max Average Deviation from Setpoint
Temperature between -20°C	+43°C / -30°C	–23°C	+3/-4°C of setpoint
Temperature between 2°C and 8°C	+45°C / -30°C	+4°C	+2/-3°C of setpoint
Temperature between 15°C and 25°C	+45°C / -30°C	+20°C	+3/-4°C of setpoint

Efficient loading practices and operating procedures have to be followed to ensure optimum air circulation and temperature management.

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

Detailed Specifications

Dividing Wall ATP Specifications

Table 5. Dividing wall ATP specifications

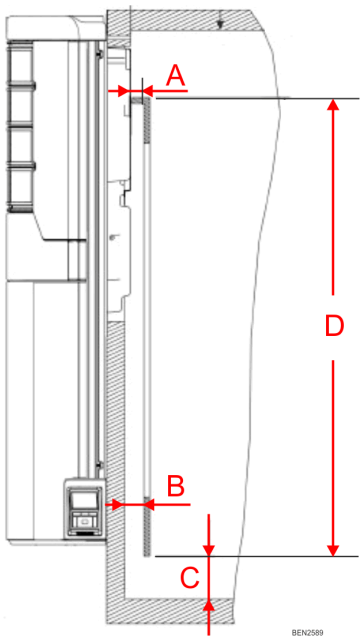
	K factor coefficient		Minimum thickness of dividing wall
	Removable	Fixed	
GRP floor Longitudinal	2.0 W/m². K	1.5 W/m². K	25 mm
GRP floor Transversal	2.6 W/m². K	1.5 W/m². K	40 mm
Aluminium floor Longitudinal	3.0 W/m². K	2.0 W/m². K	25 mm
Aluminium floor Transversal	3.2 W/m². K	2.0 W/m². K	40 mm

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

Return air Bulkhead

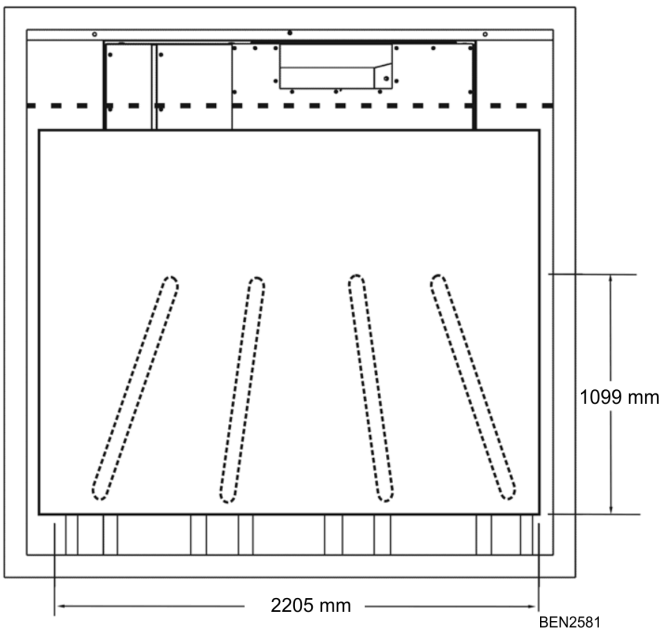
Important: *Return air bulkhead panel to be of solid fixed type allowing a minimum return air gap of 52 mm from the evaporator panels and the top should be closed to conform to Thermo King recommended minimum standards.*

Figure 3. Recommended minimal distances



A	Minimum 52 mm	B	Minimum 82 mm
C	Minimum 200 mm	D	Minimum 1927 mm

Figure 4. Thermo King recommended return air bulkhead specification



Note: *Dimension B MUST be maintained, no matter what the thickness of the trailer wall. With thicker trailer wall where the refrigerated unit is not protruding into the box; maintaining dimension A could reduce dimension B to less than 82 mm. If this is the case, dimension B must be maintained to 82 mm and as a result of this, dimension A may be more than 52 mm.*

A-500 Spectrum Software

The A-500 Spectrum unit must be loaded with software revision equal to or later than the following:

- Rev.3.0.2

Unit Capacity

Table 6. Unit Specifications - Trailer multi-temperatures

		A-500 Spectrum	
		Zone 1 Host Unit	**Zone 2 Remote Evaporator (S3A)**
	at ambient Temperature (1)	**Refrigeration capacity**	
Refrigerant	R-452A		
Capacity on engine power	0 °C	18555 W(NOMINAL)	8901 W(INDIVIDUAL)
	–20 °C	9981 W(NOMINAL)	5358 W(INDIVIDUAL)
Capacity on electric standby	0 °C	15359 W(NOMINAL)	8200 W(INDIVIDUAL)
	–20 °C	7612 W(NOMINAL)	3949 W(INDIVIDUAL)
Heating capacity	–10 °C	—	—
	–20 °C	—	—
Airflow volume @ 0 Pa static pressure	5 000 m^3/hr		2000 m^3/hr
Discharge velocity (Air throw)	15 m/sec		9.5 m/sec
Maximum dimensions (2)			5.3 m

(1) at +30°C ambient temperature under ATP conditions
(2) Maximum recommended dimensions: these are guidelines based on airflow and air velocity requirements. For each application, a heat load calculation must be performed. All calculations are based upon the following assumptions: Trailer wall k value = 0.4W/m^2K, internal trailer length up to 13.5 m, height up to 2.5 m, width up to 2.5 m, zero heat load from produce carried.

GDP Qualified Configurations

Figure 5. Tested Trailer Dimensions

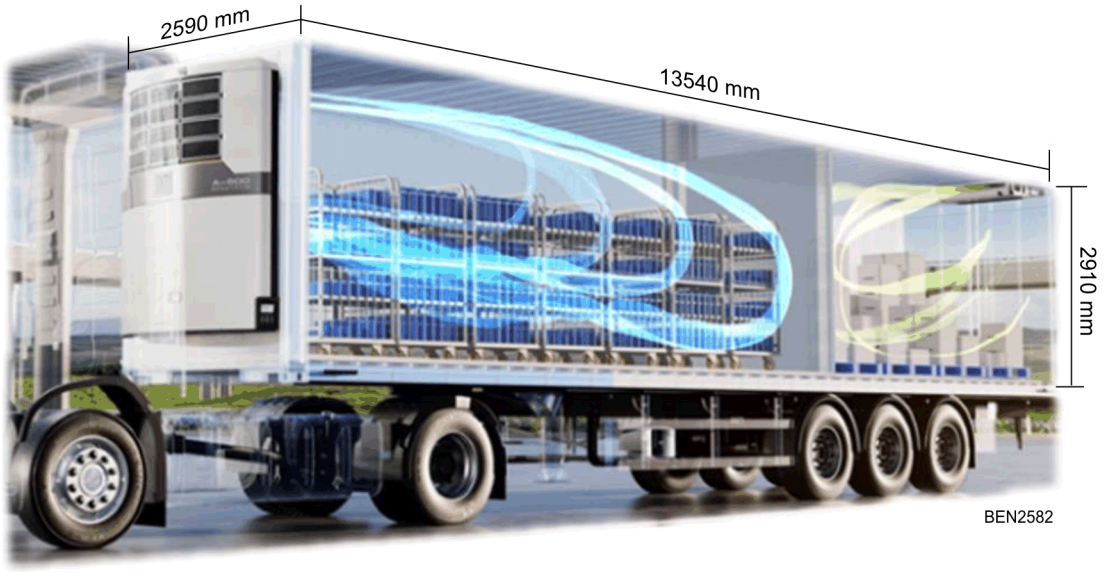
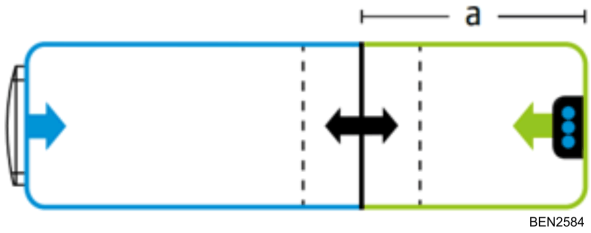


Figure 6. Tested Evaporator Dimensions

Spectrum S3A - Remote zone up to 1/3 of total body length

Figure 7. Trailer GDP Qualified multi-temperature zone plans



THERMO KING

Installation Qualification

Prepared for Thermo King, for validation of temperature controlled equipment Trailer Multi-Temperature units for trailer : A-500 Spectrum with S3A remote evaporator.

The installation Qualification is completed and conforms to the requirements of the Design Qualification **GDP-TK-DQ-TR-MT_A.**

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

- FRESH and FROZEN RANGE CONTROLLING SENSOR has been set as described in **GDP-TK-DQ-TR-MT_A.**
- A solid return air bulkhead has been installed as described in **GDP-TK-DQ-TR-MT_A.**
- ZONE 1 blower speeds have been set as described in **GDP-TK-DQ-TR-MT_A.**

THERMO KING

Operational Qualification

Prepared for Thermo King, for validation of temperature controlled equipment Trailer Multi-Temperatures units : A-500 Spectrum with S3A Remote Evaporator.

Description of the Qualified Operation

The trailer shall be used:

- For transport of pharmaceuticals (in combination with Medical devices)
- To maintain and control air temperature at a set temperature.
- In single-temperature operation (< -20°C, between +2°C and +8 °C or between +15°C and +25°C) in ZONE 1 compartment.
- In multi-temperature operation (< -20°C, between +2°C and +8 °C or between +15°C and +25°C) in two compartments with the dividing wall in place.
- At ambient temperatures between -25 °C and +40 °C
- At ambient temperatures between -30 °C and +45 °C
- The vehicle will be used for transportation between temperature controlled loading docks of storage locations.
- According to the driver's instructions supplied by Thermo King on use of Thermo King equipment.
- For transport of pharmaceuticals (in combination with medical devices)
- To maintain and control air temperature at a set temperature.

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-TR-MT_A.**

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-temperature and single-temperature modes based on the details below:

  When operating the equipment in multi-temperatures mode, the splitting of the compartment zones should be as stated below:

  – For the A-500 Spectrum unit with a S3A remote evaporator, ZONE 2 maximum split should be 1/3 of the total load space. If a larger ZONE 2 compartment is required, consult with your Thermo King Dealer.

  – For customers who want to use the mentioned equipment as a single-temperature load, the dividing door must be stowed in such a way that it does not interrupt the airflow from the main ZONE 1 host unit evaporator.

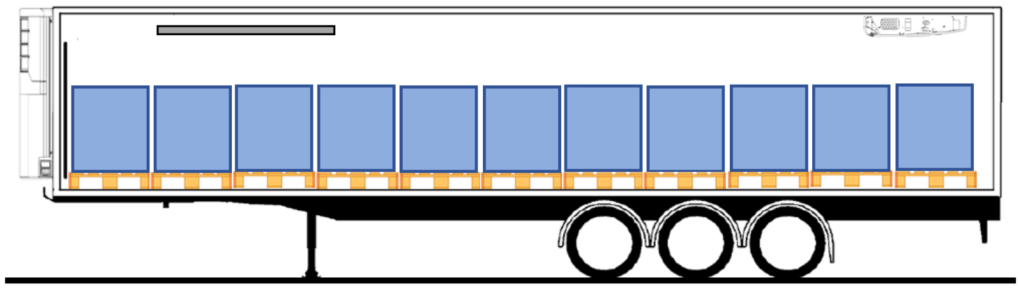
    - Zone 2 must be switched off.
- Unit can operate at ambient temperature between -30°C and +45 °C.
- This GDP qualification is performed for use in the ambient temperatures as tested. To provide qualification for the expected ambient temperatures in these regions the qualification test temperatures will be performed in the following manner, minimum to be set at -30°C (to simulate average winter temperatures in Northern Europe) and maximum +45 °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 trailer, depending on the difference in ambient temperature and temperature inside the trailer. To minimize this effect, this is recommended to open doors of the trailer 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 drivers instructions supplied by Thermo King on use of Thermo King refrigerated Equipment. These driver instructions can be found in multiple languages via a QR code decal located at the unit's controller.
- The equipment must be run and checked to ensure that all elements are functioning correctly.
- The load space considerations indicated below must also be considered.

Load Space Considerations

- The load space must be always kept clean and only cleaning agents that will not affect the products should be used.
- If an air chute is installed and extends the full length of the box provision should be made to allow for the dividing door to be closed. Therefore, a system is required that facilitates the air chute to open to allow correct air distribution from the chute.
- A compartment moveable dividing wall is used in multi-temperatures applications to separate the compartments to allow them to operate at different temperatures. The dividing door must not be positioned any less than 1300 mm from the air outlet of the remote ZONE 2 S3A evaporator and any less than 2500 mm from the air outlet of the host ZONE 1 evaporator.
- If a small load is carried at one temperature, ZONE 1 should be utilised, and the dividing wall should be used to reduce the compartment size. The dividing wall must not be positioned any less than 2500 mm from the air outlet of the host ZONE 1 evaporator. This will provide better air/temperature management and help reduce fuel consumption.
- A minimum of 100 mm clearance must be provided between the top of the load and the air intake of a remote ZONE 2 S3A evaporator.
- An air gap of minimum 50 mm should be always maintained between the load and the walls.
- 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 door should be stowed in such a way that it does not interrupt the airflow from the main host ZONE 1 unit evaporator. The recommended position of the stowed bulkhead is shown below; this will aid airflow when operating in single temperature mode.

Figure 8. Recommended position of dividing wall in single temperature operation



BEN2585

Layout of Sample-type Advancer Trailer 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-TR-MT_A.**

For this qualification three issues are important:

- The flow of temperature-controlled air in the load space must reach all parts of the load space. Therefore, a fixed return air system is essential.
  - Return air bulkhead panel to be of solid fixed type allowing a minimum return air gap of 52 mm from the evaporator panels and the top should be closed to conform to Thermo King recommended minimum standards.
- 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 Advancer trailer.
- 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 data-loggers and must be registered as such. This will be checked and confirmed during the OQ process.

Technical and User Data

Risk Management for Transport Equipment

Assumptions that are made:

- The temperature qualification is performed on an empty body, as this is considered as the worst-case scenario to higher temperature variation.
- The products (pharmaceuticals) will be loaded at the correct temperature, because they are leaving a temperature-controlled storage. It is stated that the box is used to maintain the temperature of the products do not change the temperature, though this is possible over time.
- The spectrum 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 are understood to 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 +45 °C
  - Worst-case scenario for trailer equipped with a A-500 Spectrum with S3A remote evaporator:

    The greatest difference in the set-temperatures between ZONE 1 and ZONE 2 operating in two extreme ambient temperatures

Table 7. Worst-case scenario of tests for multi temperature trailers

	Ambient Temperature	**Zone 1**	**Zone 2**
1	+45°C	-25°C	+20 °C
2	+40°C	+5°C	-25°C
3	-30°C	+20°C	+5°C
4	-30°C	+5°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 the registered data loggers Ti1-01 to Ti1-15 to Ti2-01 to Ti02-15 (seen in figure 7) must not exceed maximum deviation as mentioned in section “Acceptance Criteria”.
- The average temperature of all loggers should not exceed maximum deviation as mentioned in section “Acceptance Criteria”.
- Ambient temperature logged. Te01 toTe12 (seen in figure 9) for both Single and Multi-Temperature operation. The logged temperature must not exceed +/-2 °C of required temperature.
- Return air and discharge air temperature of the unit evaporators is logged. The data loggers are named EAIT-1, EAOT-1 (ZONE 1 / seen in figure 7 and 8) and EAIT-2, EAOT-2 (ZONE2 seen in figure 7). Temperatures must not exceed the requirement for the specific temperature being tested.
- Test time is 2.5 hours once steady state is achieved.

Table 8. Multi-Temperatures operation with S3A remote evaporator

Type	**A-500 Spectrum with S3A remote evaporator (2-ZONE configuration)**		
Zones		**Zone 1**	**Zone 2**
Setpoints		**2/3**	**1/3**
Zone 2 Evaporator		**S3A**	
Setpoints	**Ambient**	**Setpoint**	**Setpoint**
	+45°C	-23°C	+5°C
	+45°C	-23°C	+20°C
	+45°C	+5°C	+20°C
	+40°C	+5°C	-25°C
	+45°C	+20°C	+5°C
	-30°C	+20°C	+5°C
	-30°C	+5°C	+20°C
	-30°C	-23°C	+5°C
	-30°C	-23°C	+20°C

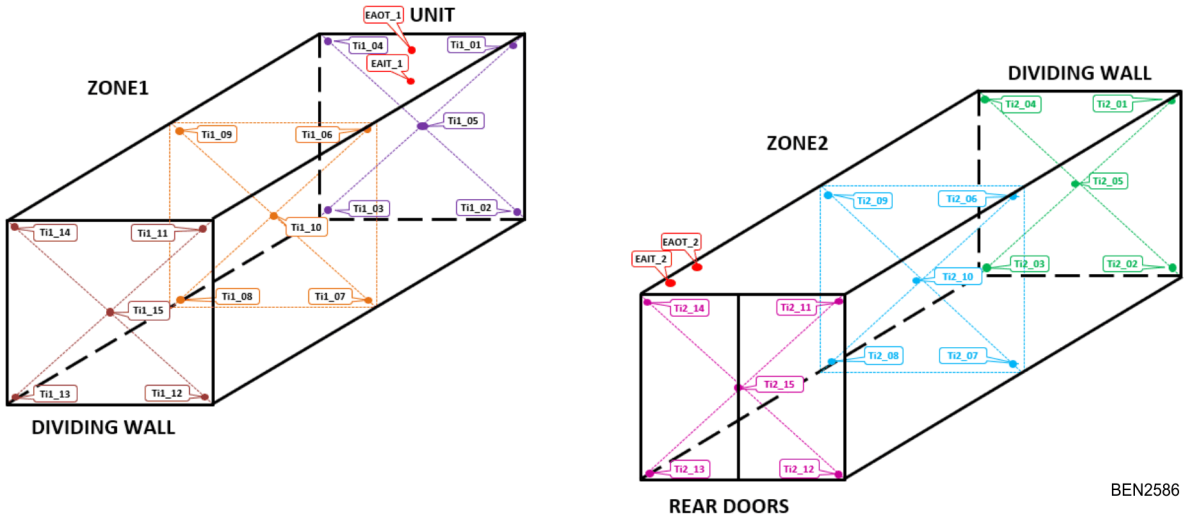
Table 9. Single-Temperature operation with S3A evaporator

Type	**A-500 Spectrum with S3A remote evaporator (One zone operation-ZONE 1)**		
Zones		**Zone 1**	**Zone 2**
Length		**Full**	**Off**
Zone 2 Evaporator		**S3A**	
Setpoints	**Ambient**	**Setpoint**	**Setpoint**
	+43°C	-25°C	off
	+45°C	+4°C	off
	+45°C	+20°C	off
	-30°C	-23°C	off
	-30°C	+5°C	off
	-30°C	+20°C	off

Thermocouple Locations

There is no information in the GDP guideline as to the 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 thermocouples are referred to as in standard NFX 15-140. This means 20- 25 thermocouples locations are utilised in the box during the qualification test. These thermocouples are calibrated, and the calibration documents are available under request.

Figure 9. Multi-temperature thermocouple locations, Zone split, Zone 1 ⅔ and Zone 2 ⅓



- EAIT_1 Return air sensor Zone 1
- EAOT_1 Supply air sensor Zone 1
- EAIT_2 Return air sensor Zone 2
- EAOT_2 Supply air sensor Zone 2

Thermocouples Ti1_01, Ti1_06, Ti1_11, Ti2_01, Ti2_06 and Ti2_11 are located at Top right corner 150 mm away from any wall/door.

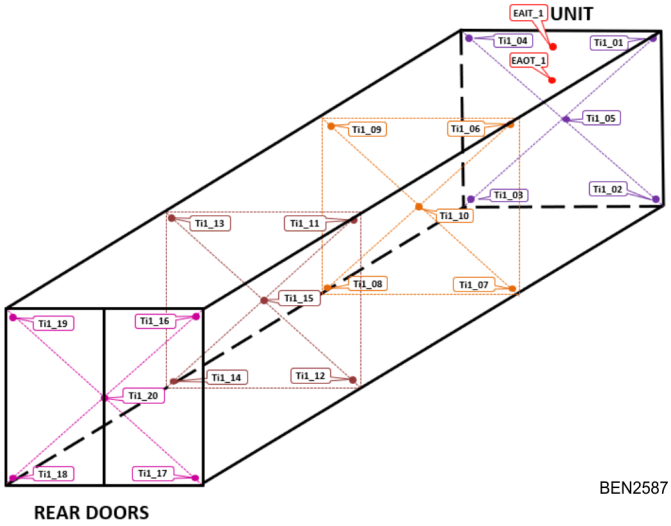
Thermocouples Ti1_02, Ti1_07, Ti1_12, Ti2_02, Ti2_07 and Ti2_12 are located at Right bottom corner between boxes and wall.

Thermocouples Ti1_03, Ti1_08, Ti1_13, Ti2_03, Ti2_08 and Ti2_13 are located at Left bottom corner between boxes and wall.

Thermocouples Ti1_04, Ti1_09, Ti1_14, Ti2_04, Ti2_09 and Ti2_14 are located at Top left corner 150 mm away from any wall/door.

Thermocouples Ti1_05, Ti1_10, Ti1_15, Ti2_05, Ti2_10 and Ti2_15 are located in the centre.

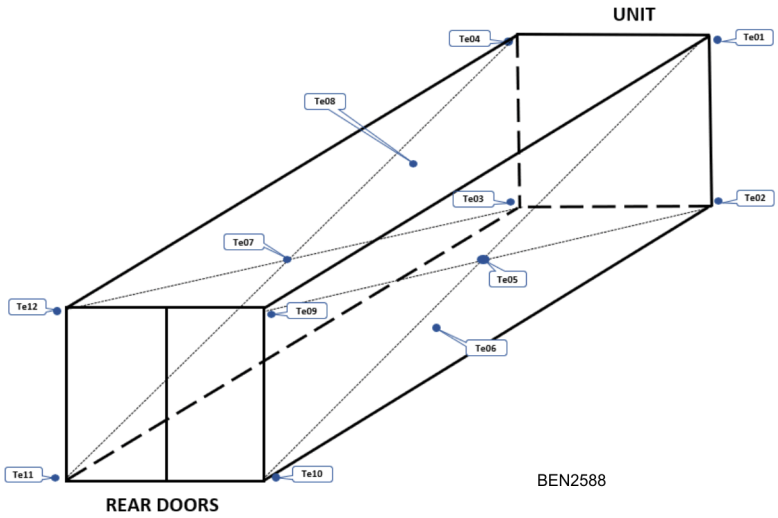
Figure 10. Single temperature operation thermocouple locations, Zone 2 switched off and dividing door stowed.



- EAIT_1 Return air sensor
- EAOT_1 Supply air sensor

Thermocouples Ti1_01, Ti1_06, Ti1_11, and Ti1_16 are located at Top right corner 150 mm away from any wall/door.
Thermocouples Ti1_02, Ti1_07, Ti1_12, and Ti1_17 are located at Right bottom corner 150 mm away from any wall/door.
Thermocouples Ti1_03, Ti1_08, Ti1_13 and Ti1_18 are located at Left bottom corner 150 mm away from any wall/door.
Thermocouples Ti1_04, Ti1_09, Ti1_14 and Ti1_19 are located at Top left corner 150 mm away from any wall/door.
Thermocouples Ti1_05, Ti1_10, Ti1_15 and Ti1_20 are located in the centre.

Figure 11. Multi-Temperature and Single-Temperature ambient thermocouple location



Ambient Sensors Te01 and Te09 are located at Top right corner 150 mm away from any wall/door.
Ambient Sensors Te02 and Te10 are located at Right bottom corner 150 mm away from any wall/door.
Ambient Sensors Te03 and Te11 are located at Left bottom corner 150 mm away from any wall/door.
Ambient Sensors Te04 and Te12 are located at Left bottom corner 150 mm away from any wall/door.
Ambient Sensors Te05 is located at Center of the left wall 150 mm away from any wall/door.
Ambient Sensors Te06 is located at Center of the floor 150 mm away from any wall/door.

Ambient Sensors Te07 is located at Center of the right wall 150 mm away from any wall/door.

Ambient Sensors Te08 is located at Center of the ceiling 150 mm away from any wall/door.

Operational Qualification Checklist

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-DQ-TR-MT_A**.
- A 3-temperature calibration check has been performed and the results attached to this document. The results are also 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 Trailer Multi-Temperature with unit A-500 Spectrum with S3A remote evaporator in ZONE 2.

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 10. Overview tests performed

Temperature Range	Extreme Ambient Temperature	ZONE 1 setpoint	Max Setpoint deviation ZONE 1	ZONE 2 setpoint	Max Setpoint deviation ZONE 2
Temperature below -20°C	+43°C	-23°C	+3°C /-3°C of setpoint	off	-
	-30°C	-23°C	+1°C /-1°C of setpoint	off	-
Temperature between +2°C and +8°C	+45°C	+5°C	+2°C /-2.5°C of setpoint	off	-
	-30°C	+5°C	+1°C /-2.5°C of setpoint	off	-
Temperature between +15°C and +25 °C	+45°C	+20°C	+1°C /-1 °C of setpoint	off	-
	-30°C	+20°C	+1°C /-3 °C of setpoint	off	-
Temperature below -20°C	-30°C	-23 °C	+2°C /-2 °C of setpoint	+5°C	+2°C /-2°C of setpoint
				+20°C	+3°C /-3°C of setpoint
	+45°C	-23 °C	+3°C /-1 °C of setpoint	+5°C	+3°C /-3°C of setpoint
				+20°C	+3°C /-2°C of setpoint
Temperature between +2°C and +8°C	+45°C	+5°C	+2°C /-1 °C of setpoint	+20°C	+1°C /-2°C of setpoint
	+40°C	+5°C	+2°C /-1.5 °C of setpoint	-25°C	+1°C /-3°C of setpoint
	-30°C	+5°C	+2°C /-2 °C of setpoint	+20°C	+4°C /-4°C of setpoint
Temperature between +15°C and +25 °C	+45°C	+20°C	+1°C /-1 °C of setpoint	+5°C	+2°C /-2°C of setpoint
	-30°C	+20°C	+1°C /-2 °C of setpoint	+5°C	+2°C /-2°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-TR-MT_A, GDP-TK-IQ-TR-MT_A and DP-TK-OQ-TR-MT_A.**

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 the multi-temperature trailer the specifications are as per the Design Qualification **GDP-TK-DQ-TR-MT_A.**

Evaluation of the Qualification Test

Test results - A-500 Spectrum with S3A remote evaporator in ZONE 2

Figure 12. Test results – Multi -Temperatures operation with S3A remote evaporator

Climate Controlled Room (CCR) temperature	Zone 1 Setpoint	Min / Max sensor temperature	Min / Max Avg. temperature	Average temperature deviation	Zone 2 Setpoint	Min / Max sensor temperature	Min / Max Avg. temperature	Average temperature deviation	Test Type	Test
+45°C	-23°C	-23.9°C / -20.2°C	-22.9°C / -21.8°C	0.8°C	5°C	3.2°C / 7.2°C	4.5°C / 6.0°C	0.2°C	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E01
'+45°C	-23°C	-23.8°C / -14.7°C	-22.9°C / -16.3°C	3.6°C	5°C	3.2°C / 41.7°C	4.6°C / 33.7°C	15.8°C	Doors Opening 7-min (30.5-min recovery)	E02
'+45°C	-23°C	-14.8°C / -9.4°C	-22.9°C / -11.5°C	8.4°C	5°C	3.4°C / 12.0°C	4.6°C / 10.0°C	2.5°C	Failure Mode (out of range in 6.5-min)	E03
'+45°C	-23°C	-23.9°C / -21.0°C	-22.9°C / -22.2°C	0.5°C	20°C	17.7°C / 21.9°C	19.3°C / 21.0°C	0.0°C	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E04
'+45°C	-23°C	-23.9°C / -21.2°C	-22.9°C / -22.3°C	0.4°C	20°C	17.9°C / 22.7°C	19.7°C / 21.8°C	0.5°C	Stability Test (2.5hours) Cycle Sentry	E05
'+45°C	5°C	4.6°C / 6.4°C	5.1°C / 5.3°C	0.4°C	20°C	18.6°C / 20.9°C	19.5°C / 19.6°C	-0.4°C	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E06
'+45°C	5°C	4.4°C / 7.2°C	5.0°C / 6.0°C	0.7°C	20°C	18.5°C / 44.6°C	19.6°C / 35.3°C	9.5°C	Doors Opening 7-min (9-min recovery)	E07
'+45°C	5°C	4.8°C / 14.6°C	5.3°C / 13.0°C	4.4°C	20°C	18.6°C / 25.2°C	19.5°C / 24.0°C	1.8°C	Failure Mode (out of range in 11.5-min)	E08
'+40°C	5°C	3.5°C / 7.0°C	4.3°C / 6.2°C	0.3°C	-25°C	-27.3°C / -22.9°C	-25.6°C / -25.0°C	-0.2°C	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E09
'+45°C	20°C	19.2°C / 20.8°C	19.5°C / 20.3°C	-0.1°C	5°C	3.4°C / 6.5°C	4.6°C / 5.1°C	-0.1°C	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E11
-30°C	20°C	18.8°C / 20.6°C	19.4°C / 20.0°C	-0.3°C	5°C	3.2°C / 6.2°C	4.2°C / 5.0°C	-0.4°C	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E13
-30°C	20°C	18.1°C / 20.1°C	18.8°C / 19.6°C	-0.9°C	5°C	3.1°C / 6.3°C	4.1°C / 5.0°C	-0.4°C	Stability Test (2.5hours) (ELECTRIC)	E14
-30°C	5°C	3.4°C / 6.7°C	3.8°C / 6.2°C	0.0°C	20°C	15.9°C / 24.0°C	17.9°C / 20.9°C	-0.3°C	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E15
-30°C	5°C	3.9°C / 6.6°C	4.5°C / 6.1°C	0.3°C	20°C	-27.2°C / 22.7°C	-18.6°C / 19.7°C	-20.9°C	Doors Opening 7-min (38.5-min recovery)	E16
-30°C	5°C	1.7°C / 6.0°C	2.6°C / 5.5°C	-1.1°C	20°C	9.4°C / 21.8°C	11.2°C / 19.6°C	-4.5°C	Failure Mode (out of range in 7-min)	E17
-30°C	-23°C	-24.1°C / -20.8°C	-23.6°C / -21.6°C	0.5°C	5°C	2.2°C / 7.3°C	3.0°C / 5.1°C	-0.6°C	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E18
-30°C	-23°C	-25.1°C / -19.7°C	-24.2°C / -20.8°C	0.6°C	5°C	-27.0°C / 7.2°C	-21.2°C / 4.9°C	-14.0°C	Doors Opening 7-min (57.5-min recovery)	E19
-30°C	-23°C	-23.6°C / -21.9°C	-23.3°C / -22.5°C	0.2°C	5°C	3.4°C / 7.4°C	4.5°C / 5.6°C	0.2°C	Stability Test (2.5hours) (ELECTRIC)	E21
-30°C	-23°C	-23.7°C / -21.3°C	-23.1°C / -22.2°C	0.4°C	20°C	17.2°C / 22.9°C	19.1°C / 20.4°C	-0.1°C	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E22

Note: *Configuration as in Figure 9: Multi-Temperature thermocouple locations.*

Figure 13. Test results – Multi -Temperatures operation with S3A remote evaporator

Climate Controlled Room (CCR) temperature	Zone 1 Setpoint	Min / Max sensor temperature	Min / Max Avg. temperature	Average temperature deviation	Zone 2 Setpoint	Min / Max sensor temperature	Min / Max Avg. temperature	Average temperature deviation	Test Type	Test
-30°C	5°C	2.5°C / 5.1°C	4.1°C / 4.3°C	-1.0°C	Off	-		-	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E23
-30°C	5°C	-27.9°C / 5.8°C	-18.2°C / 4.3°C	-14.0°C	Off	-		-	Doors Opening 7-min (59.5-min recovery)	E24
-30°C	5°C	0.9°C / 5.9°C	2.4°C / 4.8°C	-1.5°C	Off	-		-	Failure Mode (out of range in 8-min)	E25
-30°C	5°C	3.0°C / 5.6°C	4.6°C / 4.7°C	-0.5°C	Off	-		-	Stability Test (2.5hours) (ELECTRIC)	E26
-30°C	20°C	16.9°C / 21.1°C	19.1°C / 19.6°C	-0.8°C	Off	-		-	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E27
-30°C	20°C	-26.8°C / 21.1°C	-13.6°C / 19.5°C	-20.0°C	Off	-		-	Doors Opening 7-min (35-min recovery)	E28
-30°C	20°C	12.9°C / 21.1°C	15.4°C / 19.4°C	-2.8°C	Off	-		-	Failure Mode (out of range in 7-min)	E29
-30°C	-23°C	-23.5°C / -22.6°C	-23.3°C / -23.0°C	-0.1°C	Off	-		-	Stability Test (2.5hours)	E30
-30°C	-23°C	-25.1°C / -12.7°C	-24.6°C / -21.0°C	2.2°C	Off	-		-	Stability Test (2.5hours) (DIESEL / CYCLE SENTRY)	E31
+43°C	-23°C	-26.1°C / -21.1°C	-24.3°C / -23.7°C	-0.8°C	Off	-		-	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E32
+43°C	-23°C	-25.6°C / 33.2°C	-24.2°C / 8.0°C	20.9°C	Off	-		-	Doors Opening 3-min (>60-min recovery)	E33
+43°C	-23°C	-25.6°C / -19.1°C	-24.1°C / -21.2°C	0.5°C	Off	-		-	Failure Mode (out of range in 8-min)	E34
+45°C	5°C	3.5°C / 7.5°C	4.7°C / 5.2°C	0.2°C	Off	-		-	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E35
+45°C	5°C	3.5°C / 39.0°C	4.8°C / 22.7°C	12.5°C	Off	-		-	Doors Opening 3-min (50-min recovery)	E36
+45°C	5°C	3.8°C / 10.1°C	5.1°C / 8.5°C	1.9°C	Off	-		-	Failure Mode (out of range in 6-min)	E37
+45°C	5°C	3.3°C / 7.0°C	4.4°C / 4.6°C	-0.2°C	Off	-		-	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E38
+45°C	20°C	19.7°C / 22.5°C	20.6°C / 20.7°C	0.9°C	Off	-		-	Stability Test (2.5hours) (DIESEL / CONTINUOIS)	E39
+45°C	20°C	19.3°C / 22.2°C	20.3°C / 20.4°C	0.5°C	Off	-		-	Stability Test (2.5hours) (DIESEL / CYCLE SENTRY)	E40

Note: *Configuration as in Figure 10: Single temperature operation thermocouple locations.*

Temperature mapping results of the validation are presented in a separate PQ report and are available on request following the signing of an NDA (Non-Disclosure Agreement).

The report number is **ZZ-1771-23_Pharma_Advancer A500 with S3A.**

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.

Table 11. Recommended setpoint temperatures.

Temperature Range	Extreme Ambient Temperature	ZONE 1 setpoint	ZONE 2 setpoint
Temperature below -20°C	+43°C	-23°C	off
	-30°C	-23°C	off
Temperature between +2°C and +8°C	+45°C	+5°C	off
	-30°C	+5°C	off
Temperature between +15°C and +25 °C	+45°C	+20°C	off
	-30°C	+20°C	off
Temperature below -20°C	-30°C	-23 °C	+5°C
			+20°C
	+45°C	-23 °C	+5°C
			+20°C
Temperature between +2°C and +8°C	+45°C	+5°C	+20°C
	+40°C	+5°C	-25°C
	-30°C	+5°C	+20°C
Temperature between +15°C and +25 °C	+45°C	+20°C	+5°C
	-30°C	+20°C	+5°C

- The splitting of the zones for multi-temperature operation must be as stated in the qualification test: 2/3 and 1/3.
- For the configuration trailer with S3A, Zone 2 maximum split must be 1/3. If a larger Zone 2 compartment is required, please consult with your Thermo King Dealer.

When operating in multi-temperatures mode:

- For A-500 Spectrum with S3A remote evaporator software version must be equal to or higher than v.3.0.2.
- CONTROLLING SENSOR for both FRESH and FROZEN range is set RETURN AIR for Zone 1.
- Blower speed for DIESEL operation pull down and steady state is set HIGH.
- Blower speed for ELECTRIC operation pull down and steady state is MAXIMUM.
- Customers who will use the mentioned equipment as a single-temperature unit, the dividing door must be stowed in such a way that it does not interrupt the airflow from the main host unit evaporator and, Zone 2 must be switched off.

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 62125–2–MS-EN 15 Sep 2023
Supersedes (New)