Temperature Mapping Study Protocol

Rev. 1.1 - 24-JAN-2024

SIR.LANCELLOT.3148T.MAPPING

Approval

Original author	Marcella Tagliarini, QA Engineer, Eupry ApS
Date/sign	24-JAN-2024 
Reviewed by	Arsalan Bassir, Validation team lead, Eupry ApS
Date/sign	24-JAN-2024 
Approved by	Jeff Weingard, Fleet, Safety, and Facilities Manager, Sir Lancellot
Date/sign	24-JAN-2024 

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Acronyms and glossary

Definition	Meaning
EDLM	Electronic Data Logging Monitor
MPE	Maximum Permissible Error
TTSA	Time and Temperature Sensitive Assets
TP	Test Plan

References

Document #	Title
N/A	Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products, WHO Technical Report Series, No. 961, 2011 Annex 9
SIR.LANCELLOT.3148T.MAPPING .TP1	Documentation of Training - Test Plan, rev. 1.0
SIR.LANCELLOT.3148T.MAPPING .TP2	Datalogger Placement and Identification - Test Plan, rev. 1.0
SIR.LANCELLOT.3148T.MAPPING .TP3	Stability Study - Test Plan, rev. 1.0
SIR.LANCELLOT.3148T.MAPPING .TP4	Door opening scheme - Test Plan, rev. 1.0

Roles and responsibilities

Original author

The protocol has been authored by Marcella Tagliarini, Eupry ApS.

Review

Arsalan Bassir from Eupry ApS will review this protocol and associated test plans.

Approval

Jeff Weingard is appointed as responsible for approving the mapping exercise and protocol.

Qualified third party

Sir Lancellot Courier & Delivery Service has commissioned Eupry ApS as a qualified third party to create protocols and write the final report.

Tester

Tester is responsible for performing the mapping exercises and filling in test plans during mapping exercises. Arsalan Bassir from Eupry ApS has been chosen as the responsible tester according to the training test plan SIR.LANCELLOT.3148T.MAPPING.TP1.

Training

All personnel involved in performing mapping exercises, writing reports and filling in test plans must read and understand the mapping protocol and underlying procedures, which is documented in the SIR.LANCELLOT.3148T.MAPPING.TP1 Training test plan.

Purpose

The purpose of this document is to plan the mapping activities performed to said unit. The purpose of the mapping exercises is to ensure compliance with the internal and regulatory requirements and gain information on potential airflow issues, inhomogeneities or other thermal issues.

Description of equipment/facility

Unit data

Owner	SIR LANCELLOT DELIVERY & COURIER SERVICE
Address	1019 4th Ave Lester, PA 19029, US
Vehicle Number	3148T
Equipment ID	T890R50
Reefer Manufacturer	Thermoking
Vehicle	ISUZU FTR MT3 G2 54DK6S1F8PSA51829
Usage	Transportation of TTSAs
Temperature ranges	Cold: 2-8 °C
	Ambient: 15-25 °C
Set Temperatures	Cold : +5 °C
	Ambient : +20 °C

Unit layout

Table 1 shows the dimensions of the trailer to be mapped.

Body Length	211 inches
Body Width	95 inches
Body Height	92 inches

Table 1. *Unit's dimensions*

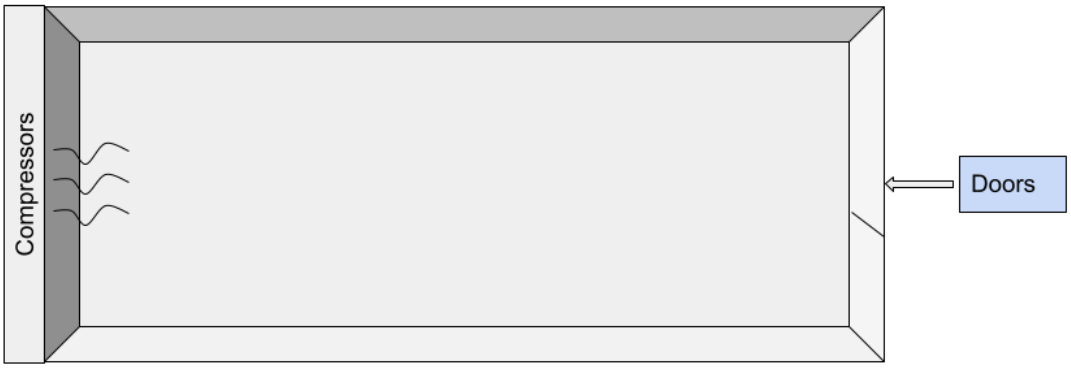

***Figure 1**. A graphical representation of the unit to be mapped seen from bird's-eye view.*

External influences

The external influences consists of:

1. Non-conformant temperatures entering from the doors facing the external environment.
2. Non-conformant temperatures acquired from the compressor.

Internal influences

The internal influences consist of:

1. Non-homogeneous distribution of temperatures inside the unit.
2. Unreasonable measurements by the control temperature sensor.

Normal use

The equipment is planned to be used for transport of TTSAs.

Loading

When the unit will be in operation, it is expected that the loading will vary from a few pallets to maximal loading of goods.

Door openings

A door is placed in the back end of the trailer, which is used for loading and unloading goods.

Temperature control

The temperature is controlled by a HVAC-system from ThermoKing.

Scope

The scope of the described mapping exercises is to map the mentioned unit to get a temperature distribution overview. The purpose of this is to document whether or not the facility is compliant with the internal and regulatory requirements.

History

No prior history of a temperature mapping has taken place.

Objectives

The mapping exercise will aim to gain information on the following subjects:

- Measure temperature variations at each location within the specified area to determine temperature stability.
- Document high and low temperatures in the described unit, to determine hot and cold zones.
- Gain data on suitable placement of temperature monitoring for subsequent use, and make recommendations based on the gathered data.

Mapping Report

After finalization of all tests, all required documentation from each testing protocol is placed in a single mapping report.
All gathered data must be shown in graphical format.

- Graphical representation of all temperatures in the given intervals.
- All relevant documentation for the completion of the mapping exercises.
- Any non-conformities experienced during the mapping exercise

Acceptance criteria

For the unit to be in compliance with internal requirements, the measured temperature characteristics must be within the following:

	Low Limit	High Limit
Temperature measurements (all measurement points)	2 °C	8 °C
Temperature when accounting for MPE (± 0.50°C)	2.50 °C	7.50 °C

Table 2a. *Temperature measurements and criteria -* ***Cold***

	Low Limit	High Limit
Temperature measurements (all measurement points)	15 °C	25 °C
Temperature when accounting for MPE (± 0.50°C)	15.50 °C	24.50 °C

Table 2b. *Temperature measurements and criteria -* ***Ambient***

Risk assessment

The following risks have been identified:

- Based on the identified external influences, loggers will be placed to mitigate the possibility of non-conformant temperatures near these locations.
- The loggers will be placed in a grid in accordance with *WHO Technical Report Series, No. 961, 2011 Annex 9* taking into account risk areas such as corners, locations adjacent to the ventilation system and the door.

- Based on the identified internal influences, loggers will be placed to mitigate the possibility of non-conformant temperatures near the cooling system and door.
- The mapping will be done without loading of goods in order to validate that it operates as required.

Methodology

Test equipment

EDLMs used for measuring the temperature in the designated positions are of the type DW1ST with external sensor type P1T from Eupry Aps.
Data sheet for the temperature sensor must be attached to the mapping study documentation.

EDLM requirements for P1T (Temperature sensors):

MPE	± 0.50 °C
Calibration points	-20 °C, 0 °C, and +50 °C (Traceable Calibration)
Calibration date limit	≦ 360 days prior to use
Datalogging interval	3 minutes
Operating range	-50 °C to +50 °C

Table 3. *EDLM requirements for P1T temperature sensors*

Identification of test equipment

Test equipment is identified using the unique Eupry serial number placed on the side of each data logger together with the serial number of each external sensor. In the mapping software, the identification of the data logger is used as the identifier.

Placement of data loggers

Following the risk assessment above, the number of temperature loggers are decided to be 13 dataloggers. The distribution of the loggers inside the unit is shown in **Figure 1**.

Placements are named as B = bottom, M= middle and T = top. The actual heights in meters will be documented in test plan SIR.LANCELLOT.3148T.MAPPING.TP2.

- B = Lowest height of goods to be stored on pallets
- M= Middle of goods placed on pallets
- T = Maximum height of goods stored on pallets

All loggers are placed according to the following rationales in order to mitigate risks identified in the risk assessment section.

Rationales

List of rationales:

D	Doors and gates
G	Grid logger
C	Compressor

Overview of placements

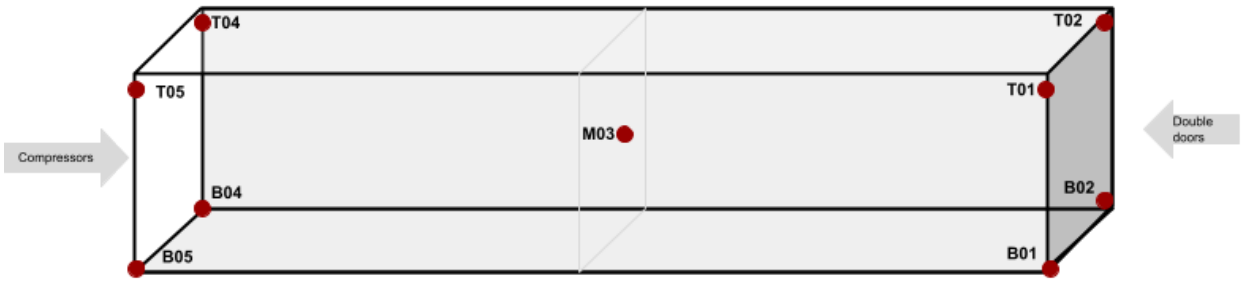

***Figure 2**. Placement of temperature loggers during mapping exercises.*

Placement	Rationale	Placement	Rationale
B01	G,D	B04	G, C
T01	G,D	T04	G
B02	G,D	B05	G, C
T02	G,D	T05	G
M03	G	N/A	N/A

Table 4. *Placement of temperature loggers during mapping exercises, with rationales.*

Performed tests

The mapping exercise shall be conducted in the following order as depicted in tables below:

	Stability study - Cold		Stability study - Ambient	
Duration:	3 hours (approx.)	12 hours (approx.)	3 hours (approx.)	12 hours (approx.)
Objective:	Stabilization	Empty Stability study	Stabilization	Empty Stability study
Test Plan:	TP3	TP3	TP3	TP3

Table 5. *Mapping procedure for empty unit.*

Test procedure

Placement of data loggers

All data loggers should be placed on designated positions before all mapping exercises, and this is documented in test plan SIR.LANCELLOT.3148T.MAPPING.TP2.

Conditions during tests

Any activity during the mapping tests will be logged in SIR.LANCELLOT.3148T.MAPPING.TP4 throughout all the mapping exercises performed in said unit.

Empty
The unit will be empty during the testing. Picture documentation will be addressed in the temperature mapping report.

Stabilization

Prior to the test the temperature must be stabilized. Therefore, a stabilization of approximately 3 hours must take place before conducting some of the tests as specified in **Table 5** representing the timeline for all mapping scenarios.

Stability test

The stability test is performed as described below, and documentation is performed in the test plan SIR.LANCELLOT.3148T.MAPPING.TP3.

Procedure for test
The mapping is started by noting the start time and date as specified in the test plan.

Qualified person - Report
The following must be included in the mapping report:

- Graph of all data
- Cold and hot spots
- Mean, min, max temperatures for all data loggers

Non-conformities

All non-conformities encountered during any mapping exercise are noted in the test plans during or after the mapping exercise. Any non-conformity must be handled for the mapping documentation to be considered as fulfilled.

All noted non-conformities should be noted with name and date, and be brought forward to the final mapping report together with an assessment of impact and conclusion.

Data review

The reviewer reviews all data produced by the tester prior to making the mapping report, and any non-conformance observed is noted with date and initials.

Procedure for documentation

The reviewer reviews all data produced by the tester prior to making the mapping report, and any non-conformance observed is noted with date and initials.

Change history

Revision #	Initials	Date	Comment
1.0	MMT	24-JAN-2024	First revision.
1.1	MMT	24-JAN-2024	Change on documents ID to match with the ones previously completed.

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