Temperature Mapping Study Report

Rev. 1.0 - 22-JUL-2025

SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T

Approval

Original author	Zinonas Christou, Validation Assistant, Eupry ApS
Date/sign	22-JUL-2025 
Reviewed by	Athina Magklara, Sr. Validation Specialist , Eupry ApS
Date/sign	22-JUL-2025 
Approved by	Michael Hoff - Fleet , Facilities & Safety Manager
Date/sign	

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Introduction

This mapping report has been created based on the mapping protocol of **SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T, rev. 1.0** and all tests have been performed in accordance with said mapping protocol.

All tests are described in detail in the attached mapping protocol and the associated test plans.

This report contains the required documentation based on the mapping protocol, as well as conclusions and recommendations based on the data gathered during the mapping exercise.

Purpose

During the validation of the mentioned unit, a mapping study has been performed to provide information on the temperature performance of the equipment, and to evaluate its compliance to internal requirements as well as external governmental regulations.

A summary of the results of the mapping exercises is presented in this report, along with conclusions and recommendations based on these results.

Acronyms and glossary

Acronym	Meaning
Ambient Temperature	Room temperatures between 15℃ - 25℃
ca.	Circa (=approximately)
Cold Temperature	Room temperatures between 2℃ - 8℃
EDLM	Electronic Data Logging Monitor
HVAC-system	Heating, ventilation and air conditioning system
MPE	Maximum Permissible Error
OQ	Operational qualification
Rev.	Document revision number
TP	Test Plan

References

Document #	Title and revision
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
N/A	Temperature mapping of storage areas Technical supplement to WHO Technical Report Series, No. 961, 2011
N/A	ISPE, Good Practice Guide: Controlled Temperature Chamber Mapping and Monitoring, 2016
SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T	Temperature Mapping Protocol, rev. 1.0
SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T.TP1	Documentation of Training - Test Plan, rev. 1.0
SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T.TP2	Datalogger Placement and Identification - Test Plan, rev. 1.0
SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T.TP3	Empty Stability Study - Test Plan, rev. 1.0
SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T.TP4	Door opening scheme/Warning letter - Test Plan, rev. 1.0
Appendix 1	Calibration certificates
Appendix 2	Raw data files
Appendix 3	Mapping data report files
Appendix 4	Picture documentation of datalogger placement
Appendix 5	Scanned TPs

Roles and responsibilities

Original author
The mapping report has been authored by Eupry ApS, Zinonas Christou.

Review
Athina Magklara from Eupry ApS will review this mapping report and associated test plans.

Approval
Michael Hoff is appointed as responsible for approving the mapping report and associated test plans.

Qualified third party
Sir Lancellot has commissioned Eupry ApS as a qualified third party to write the final report.

Tester
Tester is responsible for performing the mapping exercises and filling in test plans during mapping exercises. Employees from Sir Lancellot were chosen as responsible testers according to the training test plan SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T.TP1.

Description of Equipment

Equipment data

Owner	Sir Lancellot Delivery & Courier Service
Address	1019 4th Ave, Lester, PA 19029, US
Model/Brand	2024 Freightliner M2 106 Plus
Vehicle license plate number	ZKC5278
Vehicle Number	3326T
No. of footer truck family	8 pallets
Usage	Transportation of pharmaceuticals and specimens
Dimensions	18 ft x 7.5 ft x 12ft 6 inches (5.5 m x 2.27 m x 3.84 m) *(Length x Width x Height)*
Temperature range	• Ambient: 15 °C to 25 °C • Cold: 2 °C to 8 °C
Temperature set-point	• Ambient: 20 °C • Cold: 5 °C

Equipment layout

The maximum height of the stored goods is up to 6 ft (1.83 m).

The layout of the unit can be seen on **figure 1**.

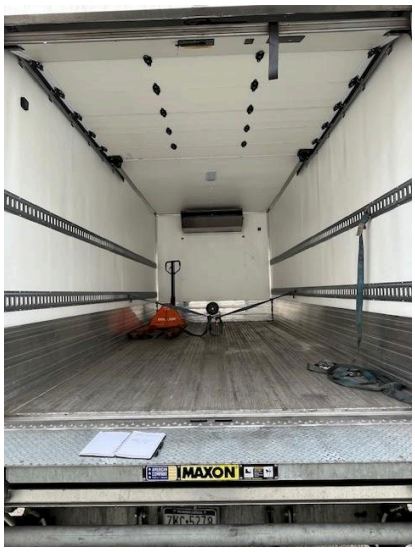

***Figure 1**: Image representation of the actual unit or layout of the unit that was mapped.*

During the mapping exercise, the equipment was mapped in 2 different temperature setpoints at 2 °C - 8 °C and 15 °C - 25 °C.

External influences

The external influences consisted of:

1. Non conformant temperatures entering from the door facing the external environment.
2. Non conformant temperatures were acquired from the evaporators placed on one side of the trailer.

Internal influences

The internal influences consisted 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 transportation of pharmaceuticals and specimens at temperatures of 2 °C - 8 °C and 15 °C - 25 °C.
The unit will be used for trips of approximately 4-6 hours with 2 stops in between.

Loading

When the unit will be in operation, it is expected that the loading will be 25% of the capacity.

Door openings

A door is placed in the back end of the trailer, which is used for loading and unloading goods. During normal operation the door is being opened for a duration of ca. 20 minutes per day for loading and unloading of goods.

Temperature control

The temperature is controlled by a HVAC system and the placement can be seen in **Figure 1**.

Scope

The scope of the described mapping exercises was to map the mentioned equipment during the summer season to ensure that the unit is able to maintain the temperature within the compliant range.
The purpose of this was to document whether or not the equipment is compliant with the URS and regulatory requirements. Additionally, the mapping was performed to identify the hot and cold spots during the mapping activities.
Subsequently, a winter mapping is to be performed.

History

The unit has no prior history of temperature mapping.

Objectives

The mapping exercise aimed 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.

Acceptance criteria

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

Cold conditions

	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 1: *Temperature measurements and criteria for cold conditions.*

Ambient conditions

	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 2: *Temperature measurements and criteria for ambient conditions.*

Deviations

Any observed non-conformities were assessed with a deviation process.

Risk assessment

The following risks have been identified:

- Based on the identified external influences, loggers were placed to mitigate the possibility of non-conformant temperatures near these locations.
- The loggers were 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 gate/door.
- The number of loggers was less than recommended in the *WHO Technical Report Series, No. 961, 2011 Annex 9* but is justified with the assumption that the unit is symmetrical and the air flow is evenly distributed.
- Based on the identified internal influences, loggers were placed to mitigate the possibility of non-conformant temperatures near the ventilation system and door.
- The mapping was conducted without loading of goods in order to validate that it operates as required.
- The mapping was done during summer time. A subsequent loaded mapping will be carried out during a winter mapping at a later date.
- The placements considered the thermoisolution properties of the datalogger devices which enabled them to not affect the external probes temperature measurements. It was crucial for the external sensors to not touch any surfaces of the room. When attached to the datalogger devices, the sensors were surrounded by free air and the dataloggers were fixed in place with non-temperature conductive material. External probes which measure the temperatures, were surrounded by thermal isolation that ensured the probes were only measuring the temperature within the free air.

Methodology

Test equipment

EDLMs used for measuring the temperature in the designated positions were of the type DW2ST with external sensor type P1T from Eupry Aps.
Datasheet for the sensors will be attached to the mapping study documentation in the attached appendices.

EDLM requirements for P1T (Temperature sensors):

MPE	± 0.50 °C
Calibration points	-20 °C, 0 °C, 50 °C (Traceable calibration)
Calibration date limit	≦ 360 days prior to use
Data logging interval	3 minutes
Operating range	-30 °C to 50 °C

Table 3: *Requirements for the temperature mapping equipment.*

Identification of test equipment

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

Placement of dataloggers

Following the risk assessment above, the number of temperature loggers was decided to be 9 temperature data loggers.

Placements were named as B = bottom, M=middle and T = top.

- B = 0.66 ft (0.20 m) above floor (Bottom of goods placed on pallets)
- M= 3.28 ft (1 m) above floor (Middle of goods placed on pallets)
- T = 6 ft (1.83 m) above floor (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
G	Grid logger
C	Compressor

Overview of placements

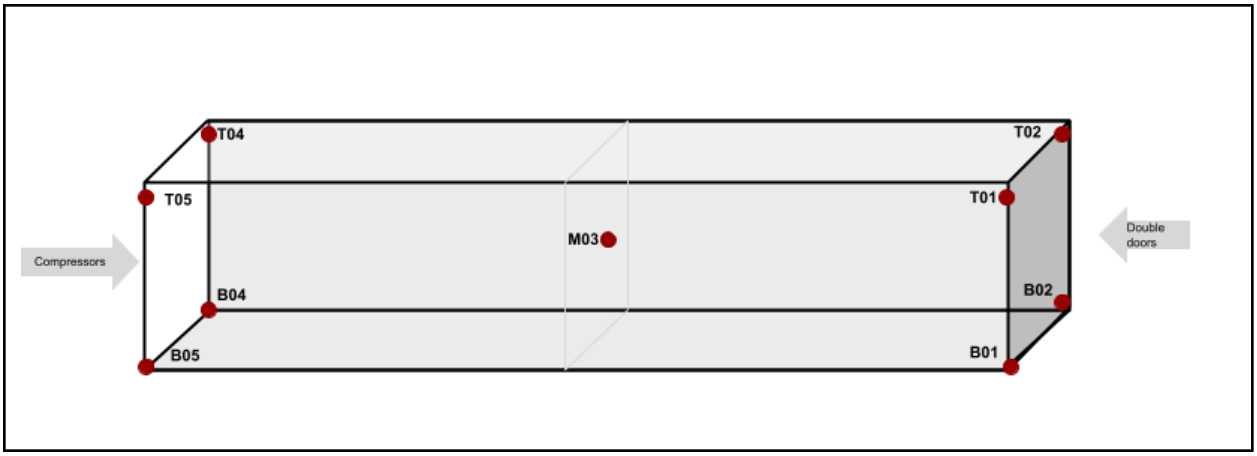

***Figure 2**: Placement of temperature loggers during mapping exercises.*

Placement	EDLM identifier	Probe ID	Height	Rationale	Comments
B01	31196	25279	0.2 m	G, D	N/A
T01	33269	35290	1.83 m	G, D	N/A
B02	32633	28746	0.2 m	G, D	N/A
T02	27117	25105	1.83 m	G, D	N/A
M03	33256	25889	1 m	G, D, V	N/A
B04	32637	13866	0.2 m	G, V	N/A
T04	33267	22158	1.83 m	G, V	N/A

Placement	EDLM identifier	Probe ID	Height	Rationale	Comments
B05	32309	29240	0.2 m	G, V	N/A
T05	33208	24369	1.83 m	G, V	N/A

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

Performed tests

During the mapping exercise the following tests were performed in timezone GMT - 4 and in the following order:

	Empty - OQ			
Duration:	3 hours	12 hours	3 hours	12 hours
Start Time & Date:	12:00 11-JUN-2025	15:00 11-JUN-2025	09:45 12-JUN-2025	12:45 12-JUN-2025
End Time & Date:	15:00 11-JUN-2025	03:00 12-JUN-2025	12:45 12-JUN-2025	00:45 13-JUN-2025
Timezone:	GMT - 4	GMT - 4	GMT - 4	GMT - 4
Objective:	Stabilization (Cold)	Stability study (Cold)	Stabilization (Ambient)	Stability study (Ambient)
Test Plan	TP3.A	TP3.A	TP3.B	TP3.B

Table 5: *Mapping procedure for empty unit.*

Test procedures

Placement of dataloggers

All dataloggers were placed on designated positions before all mapping exercises, and this was documented in test plan SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T.TP2. A picture documentation was taken and has been attached in **appendix 4**.

Conditions during test

Any activity during the mapping tests was logged in test plan SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T.TP4 throughout all the mapping exercises performed in said unit.

Empty
No goods were present in the unit.

Stabilization

Prior to each test all the temperature loggers were within the acceptable temperature range unless otherwise stated in the non-conformity section.

The unit was allowed to stabilize before any mapping exercises. During stabilization, **no door openings** were performed, and **no loading** of the unit took place. A stabilization of 3 hours took place prior to the start of testing, as specified in **table 5** representing the timeline for all mapping scenarios.

Temperature data during the mapping period (Outside air)

All mapping activities took place from the 11-JUN-2025 until the 13-JUN-2025, and the outside temperature during that period has been collected from *www.visualcrossing.com* :

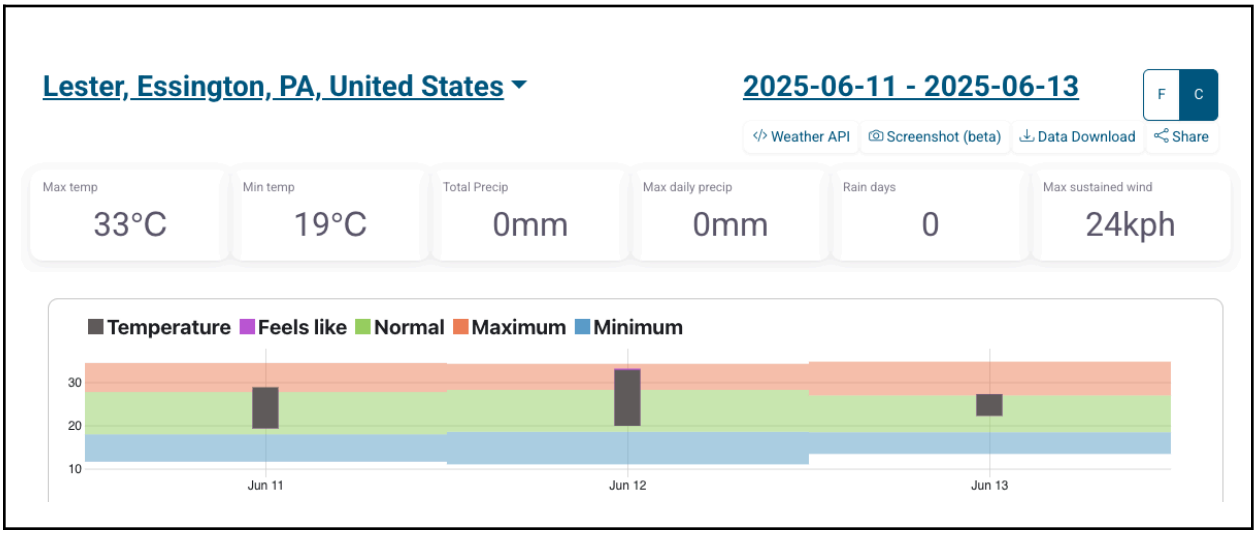

***Figure 3**: Graphical representation of the outdoors temperature during the mapping activities. Graph has been exported from www.visualcrossing.com .*

Mapping Study Execution

Stability test - Empty

The mapping was performed as described in SIR.LANCELLOT.SUMMER.2025.TRAILER.3326T.TP3 Empty Stability Study.

Test documentation

The performance of each test has been documented on the associated test plan.

- TP1 – Documentation of Training
- TP2 – Datalogger Placement and Identification
- TP3 - Empty Stability Study Test
- TP4 - Door opening scheme/Warning letter

All filled-in test plans will be appended to this report in digital format.
All documentation has been reviewed and approved and has been deemed acceptable.
Furthermore, all measurements from the mapping exercise are appended to this report.

Non-conformities

All observed non-conformities have been described in the non-conformities sections and have been assessed accordingly.

Data review

All data has been reviewed prior to the making of this report and deemed fulfilled completely.
All non-conformities have been processed with associated comments as shown in the non-conformities section.

Mapping data and conclusions

First each scenario was discussed and concluded, and thereafter an overall conclusion was included.
Graphical representation of temperatures for every scenario will be attached to this report.

The following sections analyze data gathered during the mapping. Every test scenario have its own sections with subsections as follows:

- Table with temperature data from within measurement area containing minimum, mean, and maximum values for all dataloggers
- Graphical representation of the temperature data
- Cold spots and hot spots (both peaks and mean values) are indicated in the data tables as blue and red boxes respectively with bold typography
- Excursions below the accepted range marked with blue boxes
- Excursions above the accepted range marked with red boxes

- Sub-conclusions on every test-scenario
- List of non-conformities if any non-conformities have occurred during the study
- The raw data collected during the study is found in the associated appendix
- The mapping data report files can be found in the associated appendix

TP3.A - Empty Stability test (OQ) - Cold Temperature

Raw data

The raw data collected during the study is found in the associated folder.

Minimum, maximum and average

The following thermal characteristics were observed during the study.

Temperature data from within measurement area

Placement (Datalogger)	Min	Mean	Max
B01 (31196)	4.86 °C	5.94 °C	7.16 °C
B02 (32633)	5.01 °C	6.10 °C	7.29 °C
B04 (32637)	5.33 °C	6.18 °C	6.99 °C
B05 (32309)	5.38 °C	6.26 °C	7.05 °C
M03 (33256)	4.60 °C	5.51 °C	7.41 °C
T01 (33269)	**3.89 °C**	5.24 °C	7.13 °C
T02 (27117)	3.99 °C	5.50 °C	7.38 °C
T04 (33267)	5.73 °C	6.52 °C	**9.54 °C**
T05 (33208)	5.46 °C	6.39 °C	8.19 °C
Overall	*3.89 °C*	*5.96 °C*	*9.54 °C*

Table 6: *Temperature data obtained during the empty stability study, where the bold indication is the coldest and hottest area respectively. The values highlighted with red indicate high excursions.*

Graphical representation of temperature data

All temperatures

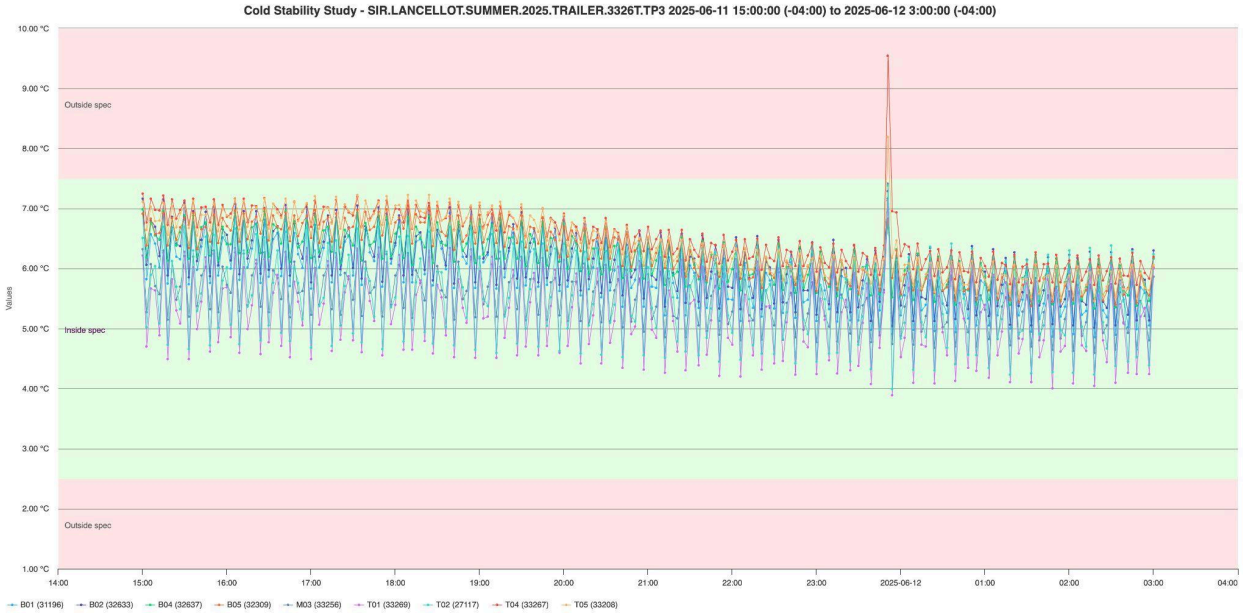

***Figure 4**: Graphical representation of the temperature measurements for all positions.*

Hot and cold spots

Hot/Cold Spot	Placement (Datalogger)	Min	Mean	Max
Hot Spot (Peak)	T04 (33267)	5.73 °C	6.52 °C	**9.54 °C**
Hot Spot (Mean)	T04 (33267)	5.73 °C	**6.52 °C**	9.54 °C
Cold Spot (Peak)	T01 (33269)	**3.89 °C**	5.24 °C	7.13 °C
Cold Spot (Mean)	T01 (33269)	3.89 °C	**5.24 °C**	7.13 °C

***Table 7:** Hot and cold spots measured during the study, where the bold indication is the coldest and hottest area respectively.*

Observed excursions

The detailed excursion list can be found in **appendix 3**.
Positions T04 and T05 measured high excursions at 23:45 11-JUN-2025 lasting between 6 minutes.

Tendencies of interest

The highest temperature peak and mean were both at position T04 at 9.54 ℃ and 6.52 ℃, respectively.
The lowest temperature peak and mean were both at position T01 at 3.89 ℃ and 5.24 ℃, respectively.

Conclusion

The unit was able to maintain the temperature within the acceptable range except for positions T04 and T05. when specified in **appendix 3**.
In addition, all the positions experienced a peak in temperature at the time of excursions.

The table that follows lists the peak and mean hot and cold spots for when the MPE is taken into consideration. These placements will be considered as candidates for monitoring in the overall conclusions.

Hot spots		Cold spots	
Highest - Peak	**Highest - Mean**	**Lowest - Peak**	**Lowest - Mean**
T04 (33267)	T04 (33267) T05 (33208) B05 (32309) B04 (32637) B02 (32633)	T01 (33269) T02 (27117)	T01 (33269) T02 (27117) M03 (33256)

***Table 8**: Hot and cold spots list table where MPE is taken into consideration.*

Non-conformities

No non-conformities were observed during the study.

TP3.B - Empty Stability test (OQ) - Ambient Temperature

Raw data

The raw data collected during the study is found in the associated folder.

Minimum, maximum and average

The following thermal characteristics were observed during the study.

Temperature data from within measurement area

Placement (Datalogger)	Min	Mean	Max
B01 (31196)	19.61 °C	20.58 °C	21.38 °C
B02 (32633)	19.82 °C	20.80 °C	**21.74 °C**
B04 (32637)	20.04 °C	20.80 °C	21.43 °C
B05 (32309)	20.12 °C	20.82 °C	21.45 °C
M03 (33256)	19.64 °C	20.36 °C	21.05 °C
T01 (33269)	**19.12 °C**	20.10 °C	21.04 °C
T02 (27117)	19.39 °C	20.45 °C	21.52 °C
T04 (33267)	20.30 °C	21.05 °C	21.55 °C
T05 (33208)	20.13 °C	20.96 °C	21.66 °C
Overall	*19.12 °C*	*20.66 °C*	*21.74 °C*

Table 9: *Temperature data obtained during the empty door opening study, where the bold indication is the coldest and hottest area respectively.*

Graphical representation of temperature data

All temperatures

***Figure 5**: Graphical representation of the temperature measurements for all positions.*

Hot and cold spots

Hot/Cold Spot	Placement (Datalogger)	Min	Mean	Max
Hot Spot (Peak)	B02 (32633)	19.82 °C	20.80 °C	**21.74 °C**
Hot Spot (Mean)	T04 (33267)	20.30 °C	**21.05 °C**	21.55 °C
Cold Spot (Peak)	T01 (33269)	**19.12 °C**	20.10 °C	21.04 °C
Cold Spot (Mean)	T01 (33269)	19.12 °C	**20.10 °C**	21.04 °C

***Table 10:** Hot and cold spots measured during the study, where the bold indication is the coldest and hottest area respectively.*

Tendencies of interest

The highest temperature peak and mean were at position B02 at 21.74 ℃ and T04 at 21.05℃, respectively.
The lowest temperature peak and mean were both at position T01 at 19.12℃ and at 20.10 ℃, respectively.

Conclusion

The unit was able to maintain the temperature within the acceptable range throughout the period of this test.

The table that follows lists the peak and mean hot and cold spots for when the MPE is taken into consideration. These placements will be considered as candidates for monitoring in the overall conclusions.

Hot spots		Cold spots	
Highest - Peak	**Highest - Mean**	**Lowest - Peak**	**Lowest - Mean**
B02 (32633) T05 (33208) T04 (33267) T02 (27117) B05 (32309) B04 (32637) B01 (31196)	T04 (33267) T05 (33208) B05 (32309) B02 (32633) B04 (32637) B01 (31196)	T01 (33269) T02 (27117) B01 (31196)	T01 (33269) M03 (33256) T02 (27117) B01 (31196)

***Table 11**: Hot and cold spots list table where MPE is taken into consideration.*

Non-conformities

No non-conformities were observed during the study.

Overall conclusion and recommendations

The unit was able to maintain the temperature within the acceptable range for ambient testing conditions.
During the cold temperature study, the unit was able to maintain the temperature within the acceptable range for all positions except for positions T04 and T05 as when specified in **appendix 3**.

It is recommended that mitigation actions are taken such as the placement of monitoring to these locations.

Overview of the mapping results for hot and cold spots

Test ID:	Hot spots:		Cold spot:	
	Peak	Mean	Peak	Mean
Empty Stability Study - Cold	T04 (33267)	T04 (33267) T05 (33208) B05 (32309) B04 (32637) B02 (32633)	T01 (33269) T02 (27117)	T01 (33269) T02 (27117) M03 (33256)
Empty Stability Study - Ambient	B02 (32633) T05 (33208) T04 (33267) T02 (27117) B05 (32309) B04 (32637) B01 (31196)	T04 (33267) T05 (33208) B05 (32309) B02 (32633) B04 (32637) B01 (31196)	T01 (33269) T02 (27117) B01 (31196)	T01 (33269) M03 (33256) T02 (27117) B01 (31196)

The recommendation for placement of temperature monitoring dataloggers is based on the analysis of hot and cold spots and the risks enlisted previously in the risk assessment section. As seen in the table above summarizing all the hot and cold spots found during the mapping period, it can be concluded that many positions are statistically candidates for the cold/hot positions.

Recommendations for the placement of constant temperature monitoring are as follows, with placement of fixed monitoring in some/all of the listed positions:
The placement should consist of at least 1 fixed monitor for the hot and cold spots respectively.

Cold spots:

- T01, T02 and B01

Hot spots:

- All positions except T01 and M03

Lastly, the fixed monitoring should take consideration into areas at risk of measuring temperatures outside of the accepted range such as, close to the doors, near the ventilation and temperature control system and so forth.

Risk spots:

- T04 and T05

Change history

Revision #	Initials	Date	Comment
1.0	ZCH	22-JUL-2025	First Revision.

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