

Temperature Mapping Study Report

Rev. 1.3 - 19-MAY-2026

LOWENCO.2026.MAPPING.REPORT

Approval

Original Author : Steffen Føns Nielsen, COO , Eupry ApS

Initials / Date :

Signature :

Reviewed by : Jakob Konradsen, Head of Quality , Eupry ApS

Initials / Date :

Signature :

Approved by : Patrick Bjerregaard, Refrigeration Manager, Lowenco

Initials / Date :

Signature :

Table of contents

Approval.....	1
Table of contents.....	2
Executive Summary.....	4
Acronyms and glossary.....	5
References.....	7
Appendix list.....	8
Test Plan list.....	9
1. Purpose.....	10
2. Scope.....	10
3. Roles and responsibilities.....	11
4. Description of equipment.....	12
4.1. Equipment information.....	12
4.2. Unit layout.....	13
4.3. Influences.....	13
4.3.1. Internal influences.....	13
4.3.2. External influences.....	14
4.4. Normal use and Loading.....	14
4.6. Door use description.....	14
4.7. Temperature control.....	14
4.8. Mapping history.....	14
5. Methodology.....	15
5.1. Test Equipment.....	15
5.2. Identification of test equipment.....	15
5.3. Software.....	15
5.4. Objectives.....	16
6. Acceptance Criteria.....	17
6.1. Accepted excursions.....	17
7. Risk assessment.....	18
8. Datalogger placement.....	18
8.1. Rationales.....	19
R Risk point.....	20
8.2. Placement of data loggers.....	20
9. Test Procedure.....	22
9.1. Mapping exercise order.....	22
9.2. Placement of data loggers.....	22
9.2.1. Placement of loggers during empty studies.....	23
9.2.2. Placement of loggers during loaded studies.....	26

9.3. Conditions during study.....	28
9.4. Stabilization.....	28
9.5. Mapping studies.....	28
9.6. Test documentation.....	28
9.7. Non-conformities.....	28
9.8. Data review.....	29
9.9. Mapping data and conclusions.....	29
Raw data.....	29
10. Mapping data results.....	30
10.1. TP3 - Empty Stability Study (OQ).....	30
Temperature data.....	30
Hot and cold spots.....	31
Conclusion.....	32
10.2. TP4 - Empty Door Opening Study - (OQ).....	33
Temperature data.....	33
Door opening impact.....	35
Conclusion.....	37
10.5. TP5 - Empty Power Failure Study - (OQ).....	38
Temperature data.....	38
Power failure details.....	39
10.6. TP6 - Loaded Stability Study (PQ).....	41
Temperature data.....	41
Conclusion.....	43
10.7. TP9 - Loaded Power Failure Study - (PQ).....	44
Temperature data.....	44
Power failure details.....	45
Conclusion.....	46
11. Overall conclusions and recommendations.....	47
11.1. Monitoring recommendations.....	47
12. Change history.....	48

Executive Summary

A temperature mapping study was conducted on the Lowenco large-scale ultra-low temperature (ULT) storage unit to verify compliance with the required operating range of -85 °C to -75 °C under both empty and loaded conditions. The study included Operational Qualification (OQ) and Performance Qualification (PQ) testing consisting of:

- Empty Stability Study
- Empty Door Opening Study
- Empty Power Failure Study
- Loaded Stability Study
- Loaded Power Failure Study

The stability studies confirmed that the unit maintained compliant and stable temperatures throughout both empty and loaded operation with minimal variation from the -80 °C setpoint. No non-conformities were observed during the qualification activities.

The door opening study demonstrated that all positions recovered to compliant temperatures within a maximum of 18 minutes following door openings.

Power failure testing identified the upper storage positions as the most critical risk areas. During the empty power failure study, the first excursion occurred after 47 minutes. During the loaded power failure study, top positions exceeded limits within the first hour, while lower positions remained compliant for significantly longer periods, with the last excursion occurring after more than 25 hours.

Final Conclusion and Recommendation

The mapping study demonstrates that the Lowenco ULT storage unit is suitable for long-term storage at -80 °C and is capable of maintaining compliant temperature conditions during normal operation. The unit showed excellent stability and acceptable recovery after door openings.

It is recommended to:

- Maintain a minimum interval of 18 minutes between door openings.
 - Focus continuous temperature monitoring on identified hot spots and upper storage positions
-

Acronyms and glossary

Acronym	Meaning
Ambient Temperature	Temperature ranges between 15 °C to 25 °C.
ULT	Temperature ranges between -85 °C to -75 °C.
EDLM	Electronic Data Logging Monitor
Datalogging interval	Also known as the logging interval or sampling rate, refers to the frequency at which a datalogger records data.
Deviation	Any observed temperature excursions or deviations from the acceptance criteria defined in the mapping protocol and test plans.
Excursions	Any temperature measurements outside the acceptable ranges described in the mapping protocol and URS documentation.
HVAC-system	Heating, ventilation and air conditioning system
MPE	Maximum Permissible Error
Non-conformity or NC	A nonconformity is defined as a deviation from the approved mapping protocol, test plan, or any requirements outlined in the User Requirement Specification (URS). It refers to failures in the execution or documentation of the study that do not comply with the specified procedures or instructions. It does not include temperature excursions or other measurement results that fall outside the defined temperature range, as these are classified separately as temperature excursion or deviation, not nonconformities.
TP	Test plan
OQ	Operational qualification
PQ	Performance qualification
Rev.	Document revision number

Acronym	Meaning
URS	User requirement specification
Upload interval	The frequency at which data is transmitted to Eupry's data cloud system.

References

The following documents were taken into account for the creation of this report.

Document ID	Title and Revision
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, Second edition, 2021
P OS-01B	Good Documentation Practice for Mappings
LOWENCO.2026.MAPPING.PROTOCOL	Temperature Mapping Protocol, rev. 1.2
LOWENCO.2026.MAPPING.TP1	Documentation of Training - Sign in sheet - Test Plan, rev. 1.0
LOWENCO.2026.MAPPING.TP2	Data logger Placement and Identification - Test Plan, rev. 1.0
LOWENCO.2026.MAPPING.TP3	Empty Stability Study (OQ) - Test Plan, rev. 1.0
LOWENCO.2026.MAPPING.TP4	Empty Door Opening Study (OQ) - Test Plan, rev. 1.0
LOWENCO.2026.MAPPING.TP5	Empty Power Failure Study (OQ) - Test Plan, rev. 1.0
LOWENCO.2026.MAPPING.TP6	Loaded Stability Study - Test Plan (PQ) - Test Plan, rev. 1.0
LOWENCO.2026.MAPPING.TP7	Door opening scheme / Warning letter
LOWENCO.2026.MAPPING.TP8	Mapping warning letter.
LOWENCO.2026.MAPPING.TP9	Empty Power Failure Study (OQ) - Test Plan, rev. 1.0

Appendix list

The following documents are attached as appendices to this report.

Document ID	Title and Revision
Appendix 1:	Data sheet for MadgeTech CryoTemp
Appendix 2:	Calibration certificates
Appendix 3:	Raw data files
Appendix 4:	Protocol and Test Plans

Test Plan list

The following test plan documentation was followed for the execution of this mapping study. The documented information was used for the data analysis and the final conclusions.

No.	Document ID	Title and Revision
TP1	LOWENCO.2026.MAPPING.TP1	Documentation of Training - Sign in sheet - Test Plan, rev. 1.0
TP2	LOWENCO.2026.MAPPING.TP2	Data logger Placement and Identification - Test Plan, rev. 1.0
TP3	LOWENCO.2026.MAPPING.TP3	Empty Stability Study (OQ) - Test Plan, rev. 1.0
TP4	LOWENCO.2026.MAPPING.TP4	Empty Door Opening Study (OQ) - Test Plan, rev. 1.0
TP5	LOWENCO.2026.MAPPING.TP5	Empty Power Failure Study (OQ) - Test Plan, rev. 1.0
TP6	LOWENCO.2026.MAPPING.TP6	Loaded Stability Study - Test Plan (PQ) - Test Plan, rev. 1.0
TP7	LOWENCO.2026.MAPPING.TP7	Door opening scheme / Warning letter
TP8	LOWENCO.2026.MAPPING.TP8	Mapping warning letter.
TP0	LOWENCO.2026.MAPPING.TP9	Empty Power Failure Study (OQ) - Test Plan, rev. 1.0

1. Purpose

A mapping study has been performed to provide information on the temperature performance of the unit. The aim of the study was to evaluate the compliance of the mapped area to acceptable levels and to external governmental regulations.

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

2. Scope

The scope of the mapping exercises described in this document was to map the mentioned unit to ensure that it is able to maintain temperature within the compliant range.

The purpose of this was to document whether or not the unit is compliant with the internal and the regulatory requirements.

This mapping report has been created based on “Temperature Mapping Study Protocol rev. 1.2”, 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.

3. Roles and responsibilities

3.1. Original report author

The report has been authored by Steffen Føns Nielsen, COO, Eupry ApS

3.1.1. Revision author

Report rev. 1.0 has been revised by Jakob Konradsen, Head of Quality, Eupry ApS

3.2. Report Reviewer

Jakob Konradsen, Head of Quality, Eupry ApS has reviewed this report and associated test plans.

3.3. Report Approval

Patrick Bjerregaard, Refrigeration Manager, Lowenco, was appointed as responsible for approving the mapping exercise results and report.

4. Description of equipment

4.1. Equipment information

Owner	Lowenco A/S
Address	Bavnevej 10, 6580 Vamdrup
Test Freezer Room the unit is located in	Warehouse at Lowenco
Unit ID #	Test Freezer
Unit serial number	N/A
Model	-80°C Large-scale storage unit (LSSU)
Manufacturer	Lowenco A/S
Usage	Long term storage of temperature sensitive assets at -80C.
Temperature range	-20°C to -80°C
Dimensions	Volume 19.82 m ³ 5,850 mm (W) × 1,600 mm (D) × 2,200 mm (H) (<i>Length x Width x Height</i>)
Storage capacity	8 storage trollies.
Setpoint Temperature	-80.0 °C

4.2. Unit layout

The layout of the unit can be seen on Figure 1.

The unit is designed with 4 access doors to access 8 trollies for storage of assets or products.

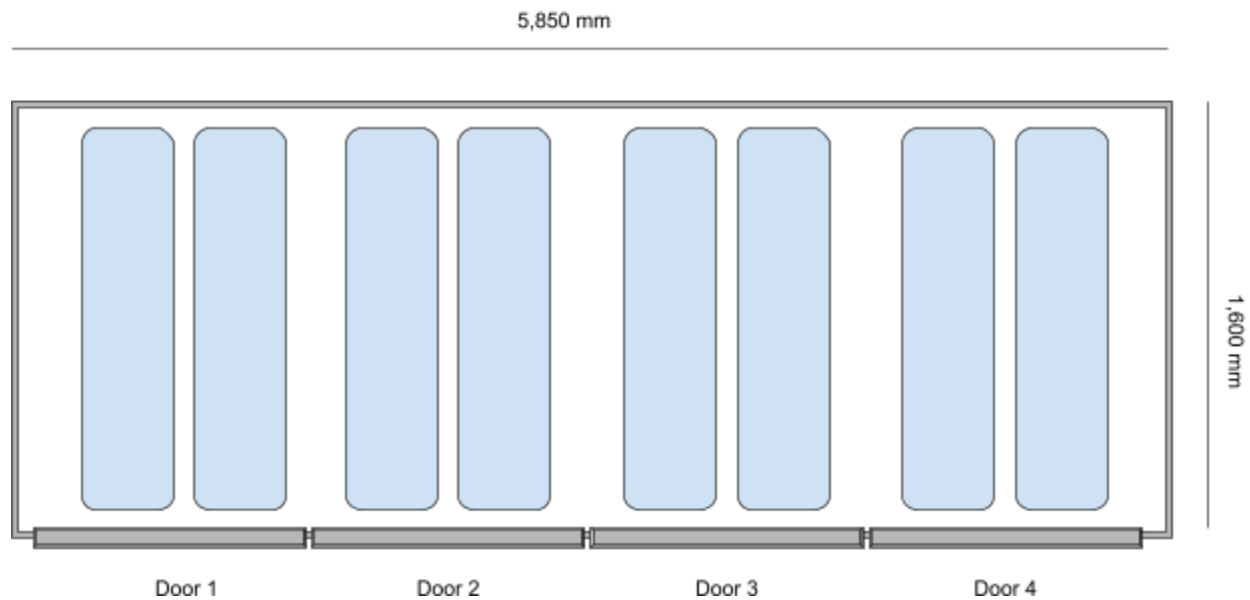


Figure 1: Image representation of the actual unit.

4.3. Influences

4.3.1. Internal influences

The internal influences consist of:

1. Internal blowout fans from evaporators supplying cooled air to the internal volume of the unit.
2. Doors that experience a lower level of thermal insulation than the rest of the unit.

4.3.2. External influences

The equipment is placed in an ambient temperature room, and as such no major influences are to be expected from daily or seasonal changes. The room's temperature is expected to be 15 °C to 25 °C. The front of the unit is kept at -20 °C, however it was observed that this area was at up to +1°C for a short period of time.

1. The environment in front of the doors is kept at -20C under normal conditions.
2. The environment at the remaining 3 sides are expected to be at ambient temperature (15C to 25C).
3. The unit is standing on concrete floor, deemed to have minimal impact on thermal performance

4.4. Normal use and Loading

The unit will be used for long term storage of sensitive products at temperatures between -80 °C.

When the unit will be in operation, it is expected that the loading will vary from 10 % to 100 %, meaning that all trolleys will be filled with product.

4.6. Door use description

During normal operation the unit's door will be opened approximately 20 times per day, for approximately 30 seconds. The openings are expected to be performed at a minimum interval of 20 minutes.

4.7. Temperature control

The temperature control is handled via an internal temperature control sensor in the unit.

4.8. Mapping history

The unit does not have a previous mapping history, and this is the initial FAT mapping of the unit.

5. Methodology

5.1. Test Equipment

The data sheet for the equipment used is attached to the mapping study documentation, see Appendix 1.

The information for the equipment that will be used in the mapping is listed below:

Specifications for dataloggers to be used for mapping study	
MPE	$\pm 0.5\text{ }^{\circ}\text{C}$
Calibration points	-80 °C Traceable Calibration
Calibration date limit	≤ 90 days prior to use
Datalogging interval	30 seconds
Operating range	-86 °C* to +35 °C

Table 1: Requirements for the temperature mapping equipment.

EDLMS to be used for the mapping study must be calibrated prior and after the mapping study to confirm validity of results.

5.2. Identification of test equipment

The equipment is identified using the unique serial number placed on the side of each data logger.

5.3. Software

All data has been extracted from the application software to be used for data analysis.

The software is a data viewing and export tool designed for use in mapping exercises and other applications where data exploration and viewing is required.

5.4. Objectives

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

1. Measure temperature variations at each location within the specified area to determine temperature stability.
2. Document high and low temperatures in the described area, to determine hot and cold zones.
3. Gain information on the unit's ability to handle door openings.
4. Gain information on the unit's ability to handle power failures, and derived power failure to non-compliance period.
5. Gain information on the unit's ability to maintain the temperature within range during loading.
6. Gain information on the duration the equipment needs to reach the setpoint temperature after the first connection to power.
7. Gain data on suitable placement of temperature monitoring for subsequent use, and make recommendations based on the gathered data.

6. Acceptance Criteria

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

	Low Limit	High Limit
Temperature measurements (all measurement points)	-85.0 °C	-75.0 °C
Temperature when accounting for MPE ($\pm$ ADD MPE °C)	-85.5°C	-74.5 °C

Table 2: Temperature measurements and criteria. The criteria are in °C.

6.1. Accepted excursions

It is allowed for all positions to measure up to 5 °C above and below the accepted temperature range for 15 minutes during the mapping period.

7. Risk assessment

The following risks have been identified:

- A. The dataloggers will be placed in a grid in accordance with *WHO Technical Report Series, No. 961, 2011*, taking into account risk areas such as corners, locations adjacent to the ventilation/temperature control system. Based on the identified internal and external influences, dataloggers will be placed to mitigate the possibility of non-conformant temperatures near these locations.
- B. The loggers will be placed in accordance with *WHO Technical Report Series, No. 961, 2011* and *ISPE, Good Practice Guide: Controlled Temperature Chamber Mapping and Monitoring, Second edition, 2021* taking into account the areas where goods will be stored.
- C. The door opening test simulates normal operation / the worst case scenario. The test is included to gain information on positions at risk of being out of the accepted range when being influenced by this scenario.
- D. The power failure test simulates the worst case scenario during no loading, as this has the smallest amount of thermal mass to maintain temperatures in the acceptable range. The test is included to gain information on positions at risk of being out of the accepted range when being influenced by this scenario.
- E. Due to the equipment being situated inside a temperature-controlled environment, a single mapping exercise was performed, as it has not been deemed necessary to perform summer and winter mapping.

8. Datalogger placement

Placements are numbered and described as Bottom Height, Middle Height and Top Height. The distribution of the loggers inside the equipment is as shown in the figure below which follows the following principles:

- I. All four corners, both at the top and the bottom of the area
- II. The lowest point at which goods shall be placed
- III. The highest point at which goods shall be placed

- IV. At potential risk points, such as in close proximity to evaporator units or any other feature that may affect the flow of air around the unit. Where evaporator units are central, points both in front and behind the units shall be mapped as the rear can create a hotspot.
- V. At each storage level from the bottom to the top of the unit.

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

8.1. Rationales

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

List of rationales:

D	Door
G	Grid logger
V	Ventilation

R Risk point

8.2. Placement of data loggers

The datalogger placements for the unit will be listed below.

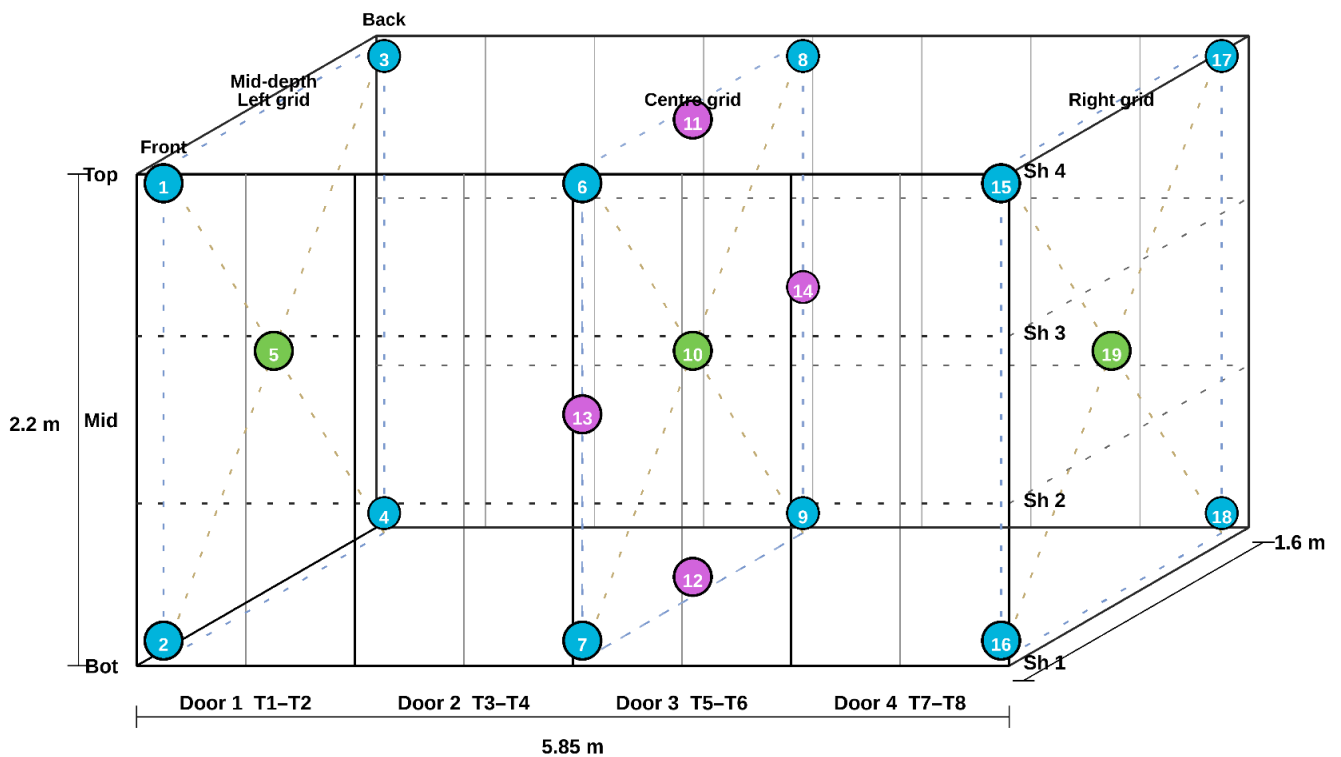


Figure 2: Datalogger placement

The placements of the dataloggers and their rationales are listed below:

Placement	Rationale	Placement	Rationale
1	G,D	11	G,R
2	G,D	12	G
3	G	13	G,D
4	G	14	G
5	G	15	G,D
6	G,D	16	G,D
7	G,D	17	G
8	G	18	G
9	G	19	G
10	G		

Table 3: Placement of temperature dataloggers during the mapping and their rationales.

According to “TP2 Datalogger Identification” 3 extra data loggers were placed:

1. Extra 1: Door 4 - Above placement 19 at 1.90 m
2. Extra 2: Door 3 - Right Trolley in the middle at 0.90 m
3. Extra 3: Door 2 - Left Trolley at 1.00m

9. Test Procedure

9.1. Mapping exercise order

The mapping exercise was conducted in the following order as depicted in tables below.

	Study timeline						
Duration:	24 hours	48 hours	4 hours (approx.)	2 hours (approx.)	12 hours (or until stable conditions)	48 hours (approx.)	72 hours (approx.)
Objective:	Stabilization	Stability Study Empty (OQ)	Door opening study Empty (PQ)	Power failure study Empty (PQ)	Stabilization after loading	Stability Study Loaded (PQ)	Power failure study Empty (PQ)
Test Plan:	TP3	TP3	TP4	TP5	TP6	TP6	TP9

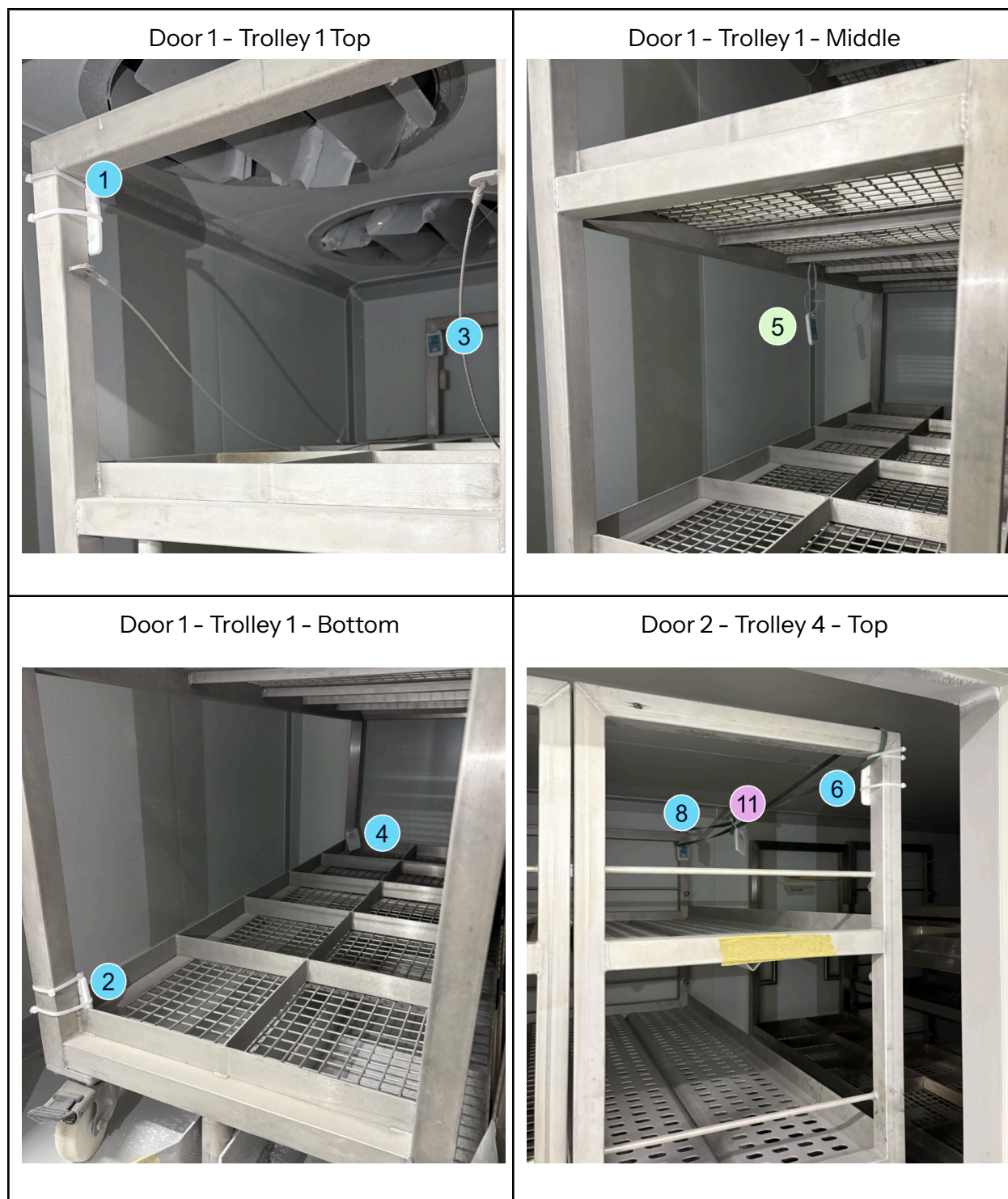
Table 4: Mapping procedure for empty and loaded unit.

9.2. Placement of data loggers

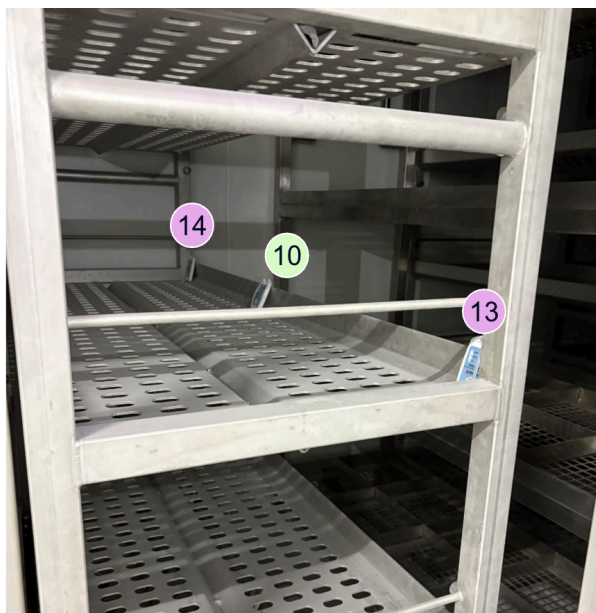
All dataloggers were placed on designated positions before all mapping exercises, and this is documented in test plan “*TP2 - Datalogger placement and identification*”.

The test was filled out during the datalogger installation along with the test plan “*TP1 - Documentation of Training*”.

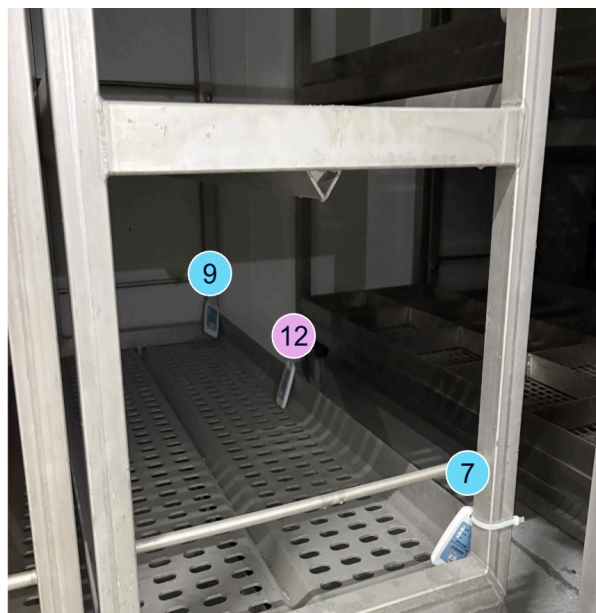
9.2.1. Placement of loggers during empty studies



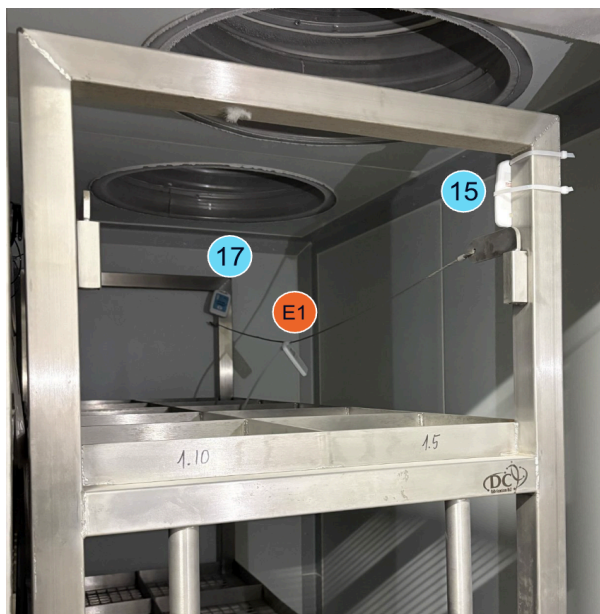
Door 2 - Trolley 4 - Middle



Door 2 - Trolley 4 - Bottom



Door 4 - Trolley 8 - Top



Door 4 - Trolley 8 - Middle



Door 4 - Trolley 8 - Bottom



9.2.2. Placement of loggers during loaded studies



Door 4 - Trolley 8



9.3. Conditions during study

No activity inside the unit unless part of the test plan was detected during the studies.

Empty

No goods were present in the unit except for trolleys and the data loggers.

Loaded

The unit was filled with frozen dummy goods on all trolleys consisting of bottles of material simulating worst case loading during expected operational conditions. The loading is documented in the above pictures.

The loading capacity was a full load as noted in the test plan *TP6 - Loaded Stability Study*

9.4. Stabilization

Prior to some of the tests the temperature was stabilized. Therefore, a stabilization period took place before conducting some of the tests as specified in the table representing the timeline for the mapping study.

9.5. Mapping studies

The mapping study was performed as described in the associated test plans listed in the “*Test Plan list*” section.

9.6. Test documentation

All filled-in test plans are 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

9.7. Non-conformities

No observed non-conformities have been identified.

9.8. Data review

All data has been reviewed prior to the making of this report and deemed fulfilled.

9.9. 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 is included in this report.

The following sections analyze data gathered during the mapping. Every test scenario has 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
- 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
- The test plans can be found in the associated appendix

Raw data

The raw data collected during the study is found in Appendix 2 for all tests.

10. Mapping data results

10.1. TP3 - Empty Stability Study (OQ)

Temperature data

Summary 2026-04-07 18:00:00 (CET) to 2026-04-09 18:00:00 (CET)

Placement	Min	Mean	Max	Delta	Std dev (stability)	Homogeneity
Position 1	-81.90 °C	-80.63 °C	-79.80 °C	2.10 °C	0.40 °C	—
Position 2	-82.40 °C	-81.15 °C	-80.40 °C	2.00 °C	0.37 °C	—
Position 3	-82.40 °C	-81.21 °C	-80.40 °C	2.00 °C	0.36 °C	—
Position 4	-82.40 °C	-81.19 °C	-80.40 °C	2.00 °C	0.36 °C	—
Position 5	-82.30 °C	-81.11 °C	-80.40 °C	1.90 °C	0.37 °C	—
Position 6	-81.20 °C	-80.08 °C	-79.40 °C	1.80 °C	0.37 °C	—
Position 7	-81.90 °C	-80.75 °C	-80.00 °C	1.90 °C	0.36 °C	—
Position 8	-80.70 °C	-79.58 °C	-78.90 °C	1.80 °C	0.38 °C	—
Position 9	-81.70 °C	-80.62 °C	-80.00 °C	1.70 °C	0.35 °C	—
Position 10	-82.10 °C	-80.92 °C	-80.20 °C	1.90 °C	0.36 °C	—
Position 11	-80.90 °C	-79.63 °C	-78.90 °C	2.00 °C	0.42 °C	—
Position 12	-82.00 °C	-80.85 °C	-80.10 °C	1.90 °C	0.36 °C	—
Position 13	-82.10 °C	-80.92 °C	-80.20 °C	1.90 °C	0.37 °C	—
Position 14	-81.70 °C	-80.60 °C	-80.00 °C	1.70 °C	0.36 °C	—
Position 15	-80.90 °C	-79.71 °C	-79.00 °C	1.90 °C	0.37 °C	—
Position 16	-80.30 °C	-79.24 °C	-78.60 °C	1.70 °C	0.34 °C	—
Position 17	-81.80 °C	-80.63 °C	-80.00 °C	1.80 °C	0.35 °C	—
Position 18	-81.00 °C	-79.92 °C	-79.30 °C	1.70 °C	0.33 °C	—
Position 19	-81.90 °C	-80.70 °C	-80.00 °C	1.90 °C	0.36 °C	—
Extra 1	-82.00 °C	-80.82 °C	-80.10 °C	1.90 °C	0.37 °C	—
Extra 2	-82.00 °C	-80.85 °C	-80.20 °C	1.80 °C	0.37 °C	—
Extra 3	-82.20 °C	-81.07 °C	-80.40 °C	1.80 °C	0.36 °C	—
Overall	-82.40 °C	-80.55 °C	-78.60 °C	3.80 °C	0.68 °C	0.57 °C

Table 5: Temperature data obtained during the empty stability study, where the bold indications are the coldest and the hottest areas respectively.

Graphical representation of temperature data

TEMPERATURE PROFILES — ALL SENSORS

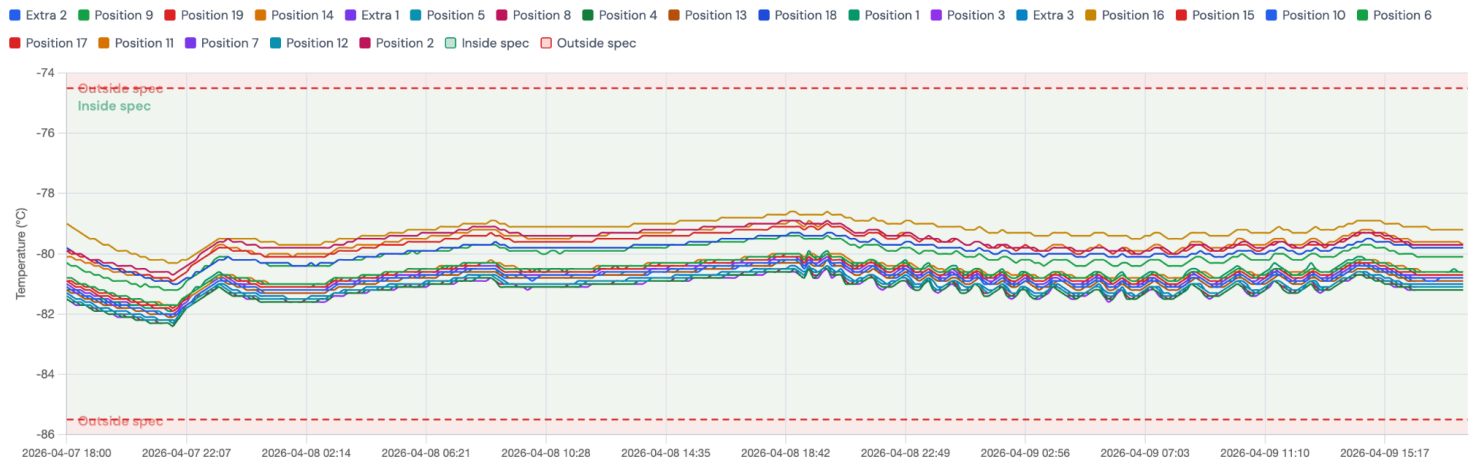


Figure 3: Graphical representation of the temperature measurements for all positions.

Hot and cold spots

Hot/Cold Spot	Placement	Min	Mean	Max
Hot Spot (Peak)	Position 16	-80.30 °C	-79.24 °C	-78.60 °C
Hot Spot (Mean)	Position 16	-80.30 °C	-79.24 °C	-78.60 °C
Cold Spot (Peak)	Position 4	-82.40 °C	-81.19 °C	-80.40 °C
Cold Spot (Mean)	Position 3	-82.40 °C	-81.21 °C	-80.40 °C

Table 6: Hot and cold spots measured during the study, where the bold indications are the coldest and the hottest areas respectively.

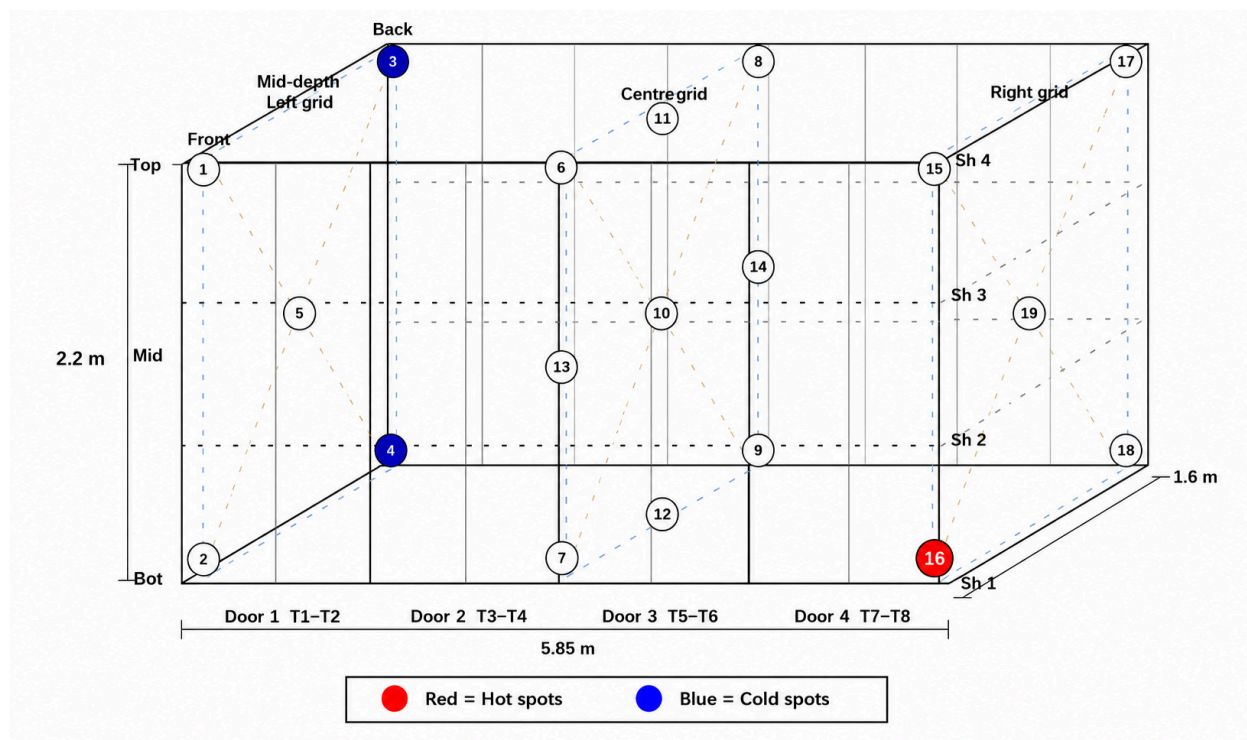


Figure 4: Hot and cold spots for Empty Stability Study (OQ)

Conclusion

The unit consistently maintained temperatures within the defined range for the duration of the empty stability study. With a recorded homogeneity of 0.57°C and a standard deviation of 0.68°C, the unit demonstrated exceptional stability, ensuring that the internal storage volume remained consistently near the -80°C set point.

No non-conformities were observed during the empty stability study.

10.2. TP4 - Empty Door Opening Study - (OQ)

Temperature data

Temperature data from within measurement area

Placement	Min	Mean	Max	Delta	Std dev (stability)	Homogeneity
Position 1	-81.10 °C	-78.25 °C	-75.80 °C	5.30 °C	1.47 °C	—
Position 2	-81.30 °C	-78.78 °C	-75.50 °C	5.80 °C	1.55 °C	—
Position 3	-81.40 °C	-78.88 °C	-76.70 °C	4.70 °C	1.31 °C	—
Position 4	-81.40 °C	-78.97 °C	-76.80 °C	4.60 °C	1.34 °C	—
Position 5	-81.30 °C	-78.74 °C	-76.50 °C	4.80 °C	1.34 °C	—
Position 6	-80.50 °C	-76.38 °C	-72.40 °C	8.10 °C	1.77 °C	—
Position 7	-81.00 °C	-78.76 °C	-76.70 °C	4.30 °C	1.10 °C	—
Position 8	-80.10 °C	-75.15 °C	-71.80 °C	8.30 °C	1.80 °C	—
Position 9	-80.80 °C	-78.97 °C	-77.40 °C	3.40 °C	0.94 °C	—
Position 10	-81.20 °C	-78.94 °C	-77.20 °C	4.00 °C	0.99 °C	—
Position 11	-80.00 °C	-75.93 °C	-69.90 °C	10.10 °C	2.25 °C	—
Position 12	-81.10 °C	-78.98 °C	-77.10 °C	4.00 °C	1.04 °C	—
Position 13	-81.20 °C	-78.85 °C	-77.10 °C	4.10 °C	1.04 °C	—
Position 14	-80.90 °C	-78.90 °C	-77.60 °C	3.30 °C	0.83 °C	—
Position 15	-80.00 °C	-77.04 °C	-70.30 °C	9.70 °C	1.87 °C	—
Position 16	-79.40 °C	-77.92 °C	-77.10 °C	2.30 °C	0.68 °C	—
Position 17	-80.90 °C	-77.52 °C	-73.40 °C	7.50 °C	1.70 °C	—
Position 18	-80.10 °C	-78.69 °C	-77.90 °C	2.20 °C	0.64 °C	—
Position 19	-81.00 °C	-78.62 °C	-76.80 °C	4.20 °C	1.01 °C	—
Extra 1	-81.10 °C	-78.43 °C	-76.10 °C	5.00 °C	1.25 °C	—
Extra 2	-81.20 °C	-78.85 °C	-77.40 °C	3.80 °C	0.93 °C	—
Extra 3	-81.30 °C	-79.08 °C	-77.40 °C	3.90 °C	0.97 °C	—
Overall	-81.40 °C	-78.21 °C	-69.90 °C	11.50 °C	1.72 °C	1.09 °C

Table 7: Temperature data obtained during the empty door opening 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

TEMPERATURE PROFILES — ALL SENSORS

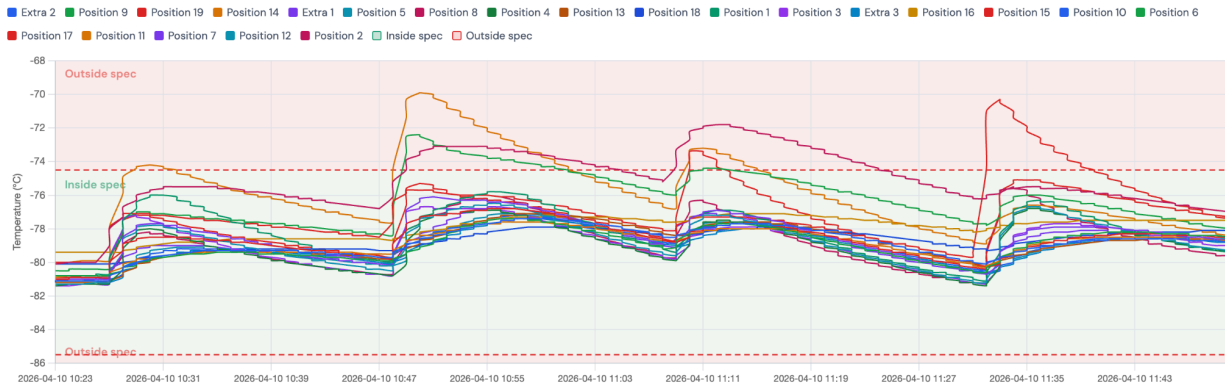


Figure 5: Graphical representation of the temperature measurements for all positions.

Hot and cold spots

Hot/Cold Spot	Placement	Min	Mean	Max
Hot Spot (Peak)	Position 11	-80.00 °C	-75.93 °C	-69.90 °C
Hot Spot (Mean)	Position 8	-80.10 °C	-75.15 °C	-71.80 °C
Cold Spot (Peak)	Position 4	-81.40 °C	-78.97 °C	-76.80 °C
Cold Spot (Mean)	Extra 3	-81.30 °C	-79.08 °C	-77.40 °C

Table 8: Hot and cold spots measured during the study, where the bold indication is the coldest and hottest area respectively. The values highlighted with red indicate high excursions.

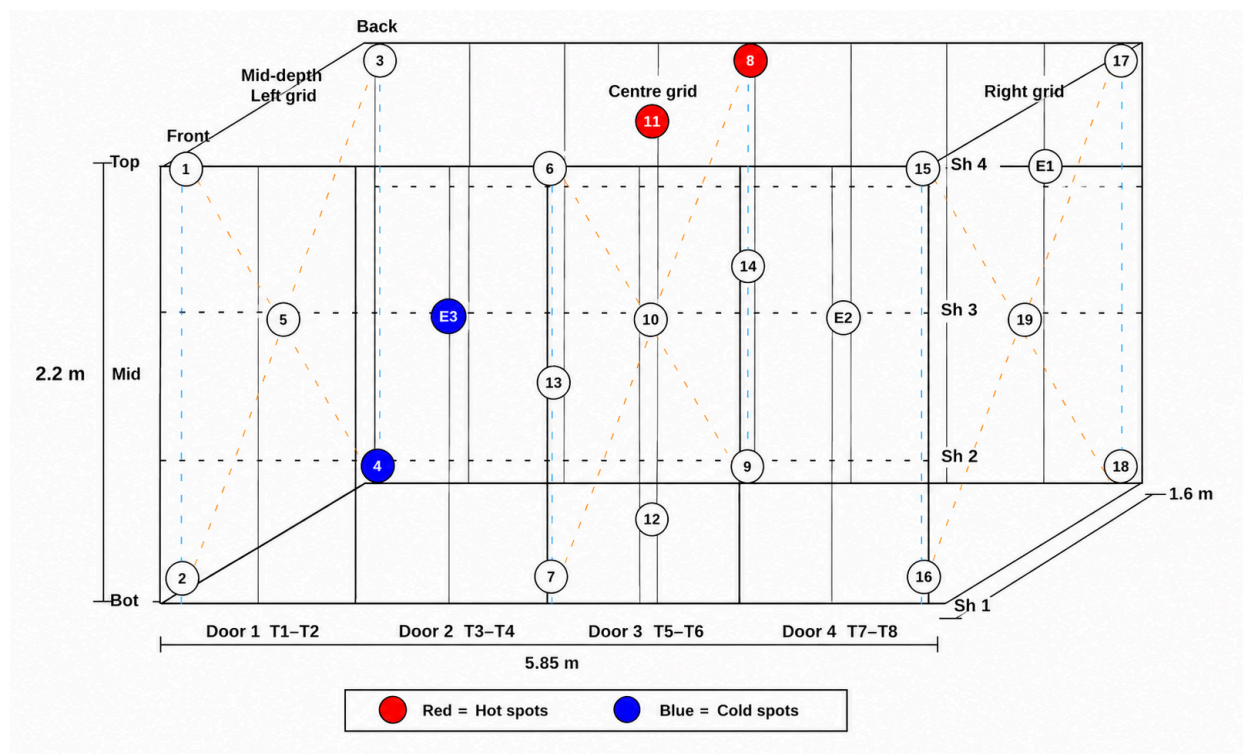


Figure 6: Hot and cold spots for Empty Door Opening Study (OQ)

Door opening impact

In the following section, the details on the door openings have been listed along with the observed excursion details..

Door openings Scheme

No.	Duration of door opening	10-APR-2026		Comment
		Start time	End time	
1	30 sec.	10:26.00	10:26.30	Position 11 went out of upper limit after door 1 was open, but came back within spec after 6 minutes
2	30 sec.	10:47.00	10:47.30	Position 6, 8 and 11 went out of upper limit after door 2 was open, but all were back within spec after 18 minutes
3	30 sec.	11:08.00	11:08.30	Position 6, 8, 11, 17 went out of upper limit after door 3 was open, but all were back within spec after 16 minutes
4	30 sec.	11:31.00	11:31.30	Position 15 went out of upper limit after door 4 was open, but went back within spec after 8 minutes

Table 9: Door opening scheme information of door opening test.

Observed excursions

No.	Positions to measure excursions	Positions to measure excursions after doors closed				Positions to measure compliance after doors closed			
		First	Time	Last	Time	First	Time	Last	Time
1	11	11	10:29			11	10:32		
2	6, 8 and 11	11	10:48	8	10:49	6	11:00	8	11:05
3	6,8 11 and 17	8	11:09	6	11:11	17	11:12	8	11:24
4	15	15	11:32			15	11:40		

Table 10: Excursion table list of door openings impact on the unit. The “No.” in this table are correlated with the number of the executed door openings listed in the “Door openings Scheme” table above.

Conclusion

The door opening studies confirmed that all positions returned to the required temperature range within no more than 18 minutes following a door opening. Consequently, to ensure the unit remains consistently within the specifications, a minimum interval of 18 minutes is recommended between successive door openings.

No non-conformities were observed during the empty door opening studies.

Positions to measure excursions after power was cut

Position	Excursion	Time	Duration
Position 11	Above limit	12:50:00	0:47:30
Position 17	Above limit	12:56:00	0:53:30
Position 6	Above limit	12:58:00	0:55:30
Position 1	Above limit	12:59:00	0:56:30
Position 15	Above limit	12:59:00	0:56:30
Position 3	Above limit	13:00:00	0:57:30
Extra 1	Above limit	13:01:00	0:58:30
Position 8	Above limit	13:03:00	1:00:30
Position 19	Above limit	13:34:00	1:31:30
Position 5	Above limit	13:35:00	1:32:30
Position 10	Above limit	13:47:00	1:44:30
Extra 2	Above limit	13:50:00	1:47:30
Position 14	Above limit	13:51:00	1:48:30
Position 13	Above limit	13:52:00	1:49:30
Extra 3	Above limit	13:53:00	1:50:30
Position 16	Above limit	14:00:00	1:57:30
Position 18	Above limit	14:07:00	2:04:30
Position 4	Above limit	14:10:00	2:07:30
Position 7	Above limit	14:12:00	2:09:30
Position 9	Above limit	14:14:00	2:11:30
Position 12	Above limit	14:15:00	2:12:30
Position 2	Above limit	14:20:00	2:17:30

Table 13: Excursion table list of the power failure impact on the unit.

Conclusion

Upon cutting the power, position 11 was the first to record a temperature excursion, occurring after a duration of 47 minutes and 30 seconds. The last excursion was detected at position 2, which happened 2 hours, 17 minutes and 30 seconds following the power cut.

10.6. TP6 - Loaded Stability Study (PQ)

Temperature data

Temperature data from within measurement area

Position	Min	Mean	Max	Delta	Std dev (stability)	Homogeneity
Position 1	-81.80 °C	-79.80 °C	-78.60 °C	3.20 °C	0.98 °C	—
Position 2	-82.00 °C	-80.86 °C	-79.50 °C	2.50 °C	0.49 °C	—
Position 3	-82.50 °C	-81.13 °C	-79.20 °C	3.30 °C	0.60 °C	—
Position 4	-82.40 °C	-81.10 °C	-79.40 °C	3.00 °C	0.55 °C	—
Position 5	-82.30 °C	-80.89 °C	-79.70 °C	2.60 °C	0.59 °C	—
Position 6	-81.50 °C	-80.10 °C	-78.40 °C	3.10 °C	0.62 °C	—
Position 7	-81.50 °C	-80.04 °C	-79.00 °C	2.50 °C	0.60 °C	—
Position 8	-82.00 °C	-80.55 °C	-79.50 °C	2.50 °C	0.59 °C	—
Position 9	-81.50 °C	-80.30 °C	-79.50 °C	2.00 °C	0.48 °C	—
Position 10	-82.00 °C	-80.96 °C	-80.40 °C	1.60 °C	0.39 °C	—
Position 11	-81.90 °C	-80.07 °C	-79.00 °C	2.90 °C	0.82 °C	—
Position 12	-81.60 °C	-80.66 °C	-79.80 °C	1.80 °C	0.37 °C	—
Position 13	-82.00 °C	-80.77 °C	-79.70 °C	2.30 °C	0.52 °C	—
Position 14	-82.00 °C	-80.78 °C	-79.70 °C	2.30 °C	0.50 °C	—
Position 15	-81.00 °C	-79.22 °C	-78.30 °C	2.70 °C	0.82 °C	—
Position 16	-80.90 °C	-79.59 °C	-78.90 °C	2.00 °C	0.51 °C	—
Position 17	-81.70 °C	-80.33 °C	-78.90 °C	2.80 °C	0.57 °C	—
Position 18	-80.90 °C	-79.83 °C	-79.20 °C	1.70 °C	0.40 °C	—
Position 19	-81.90 °C	-80.75 °C	-80.00 °C	1.90 °C	0.45 °C	—
Extra 1	-81.90 °C	-80.01 °C	-79.00 °C	2.90 °C	0.82 °C	—
Extra 2	-82.10 °C	-81.01 °C	-80.30 °C	1.80 °C	0.41 °C	—
Extra 3	-82.40 °C	-80.96 °C	-79.60 °C	2.80 °C	0.62 °C	—
Overall	-82.50 °C	-80.44 °C	-78.30 °C	4.20 °C	0.80 °C	0.53 °C

Table 14: Temperature data obtained during the loaded study, where the bold indication is the coldest and hottest area respectively.

Graphical representation of temperature data

TEMPERATURE PROFILES — ALL SENSORS

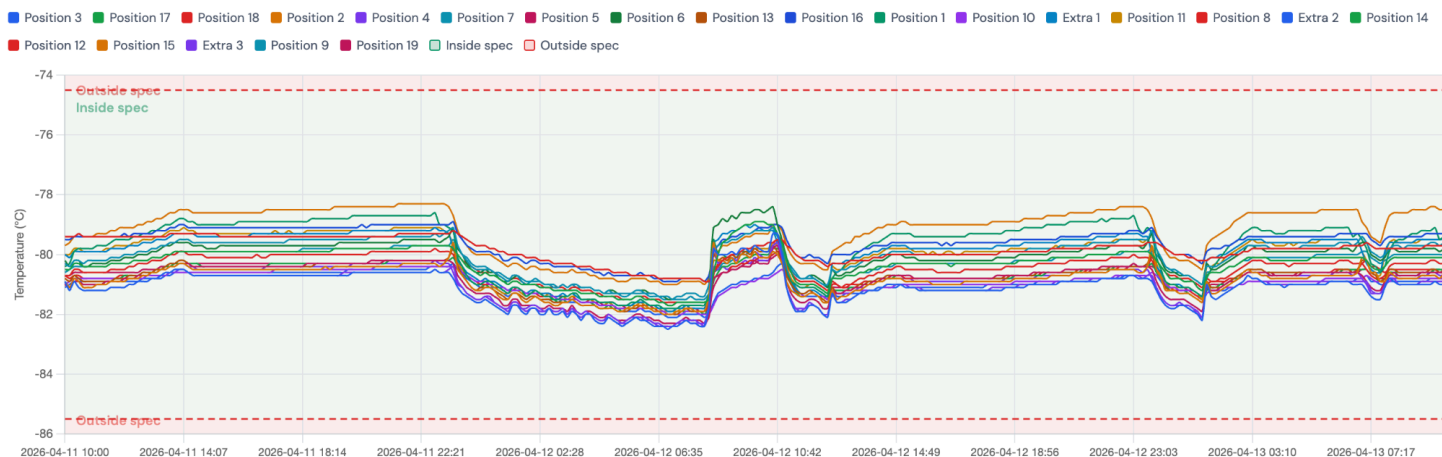


Figure 9: Graphical representation of the temperature measurements for all positions.

Hot and cold spots

Hot/Cold Spot	Placement	Min	Mean	Max
Hot Spot (Peak)	Position 15	-81.00 °C	-79.22 °C	-78.30 °C
Hot Spot (Mean)	Position 15	-81.00 °C	-79.22 °C	-78.30 °C
Cold Spot (Peak)	Position 3	-82.50 °C	-81.13 °C	-79.20 °C
Cold Spot (Mean)	Position 3	-82.50 °C	-81.13 °C	-79.20 °C

Table 15: Hot and cold spots measured during the study, where the bold indication is the coldest and hottest area respectively.

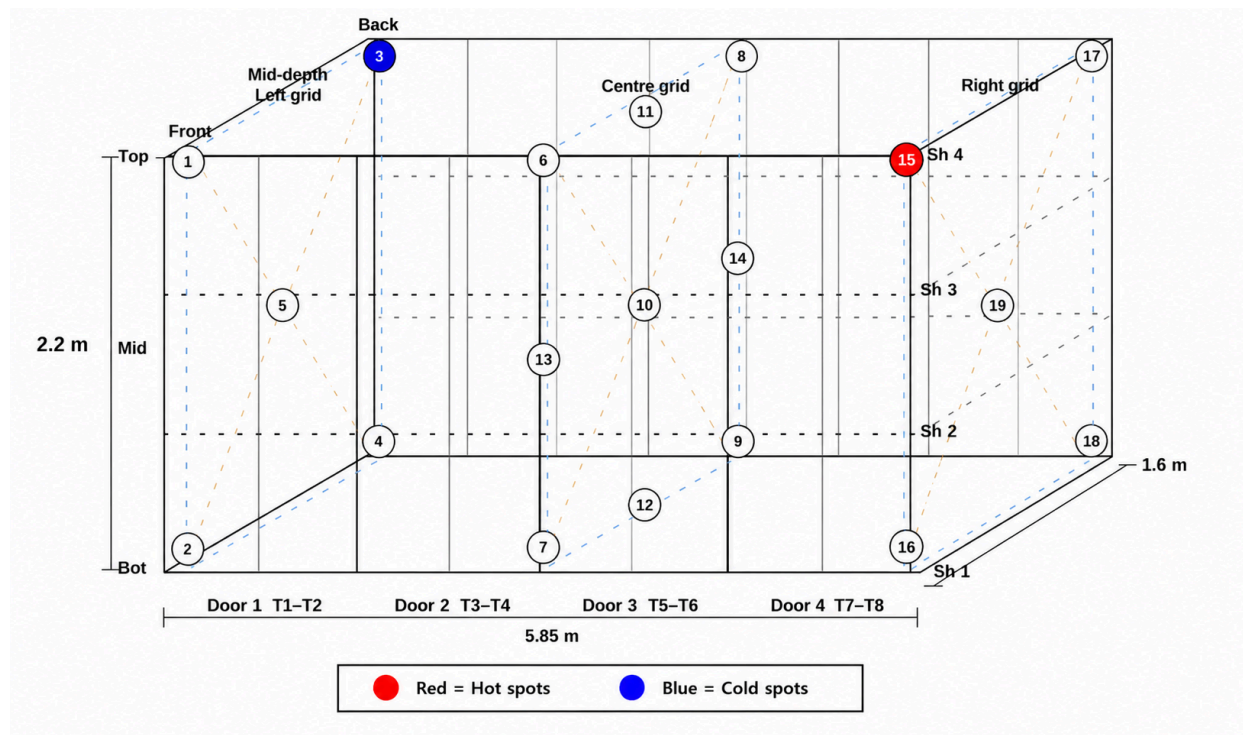


Figure 10: Hot and cold spots for Loaded Stability Study (PQ)

Conclusion

The unit consistently maintained temperatures within the defined range for the duration of the loaded stability study. With a recorded homogeneity of 0.53°C and a standard deviation of 0.80°C , the unit demonstrated exceptional stability, ensuring that the internal storage volume remained consistently near the -80°C set point.

No non-conformities were observed during the loaded stability study.

visible on the graph. These top positions reach the excursion more than 12 hours before the other positions.

11. Overall conclusions and recommendations

- Stability studies proved the unit maintains required temperatures with minimal deviation from the set point.
- The door openings studies showed all positions recovered within max 18 minutes. Therefore, a minimum 18-minute interval between openings is recommended.
- The empty power failure study demonstrated it takes 47 minutes to first excursion
- The loaded power failure studied showed the top position was fast to reach excursion, already within first hour, but the remaining positions took more than 12 hours longer
- Therefore, the risk spots are clearly the top positions during a power failure

11.1. Monitoring recommendations

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 above, in the sections summarizing 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:

Monitoring recommendations		Explanation
Cold spots	Position 1, 2, 3, 4 and 12	Recommended positions when the peak values are taken into consideration.
Hot spots	Position 8, 11, 15, 16 and Extra 1	Recommended positions when the peak values are taken into consideration.
Risk spots	Position 6 and 17	Part of the top positions to reach an excursion must faster during a power failure

Table 19: Monitoring recommendation list table.

12. Change history

Revision #	Initials	Date	Comment
1.0	SFN	30-APR-2026	First draft
1.1	SFN	01-MAY-2026	Minor edits
1.2	SFN	18-MAY-2026	Updates based on feedback from Patrick
1.3	SFN	19-MAY-2026	Corrected the figures to include the extra data logger position when being hot and cold spots.