



QUALIFICATION REPORT

DHL FROZEN SOLUTION LARGE (-20°C)

Dry Ice Plates

SBS Summer & Static +30°C Ambient Test Profiles

Abstract

The following Qualification Report demonstrates how the system is conditioned, packed and performs when tested against the SBS Summer & Static +30°C ambient test profiles.

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Packaging Engineer

Signature:

Date: 20NOV2018

REPORT APPROVER

Gavin Hill
Senior Project Engineer

Signature:

Date: 20NOV2018

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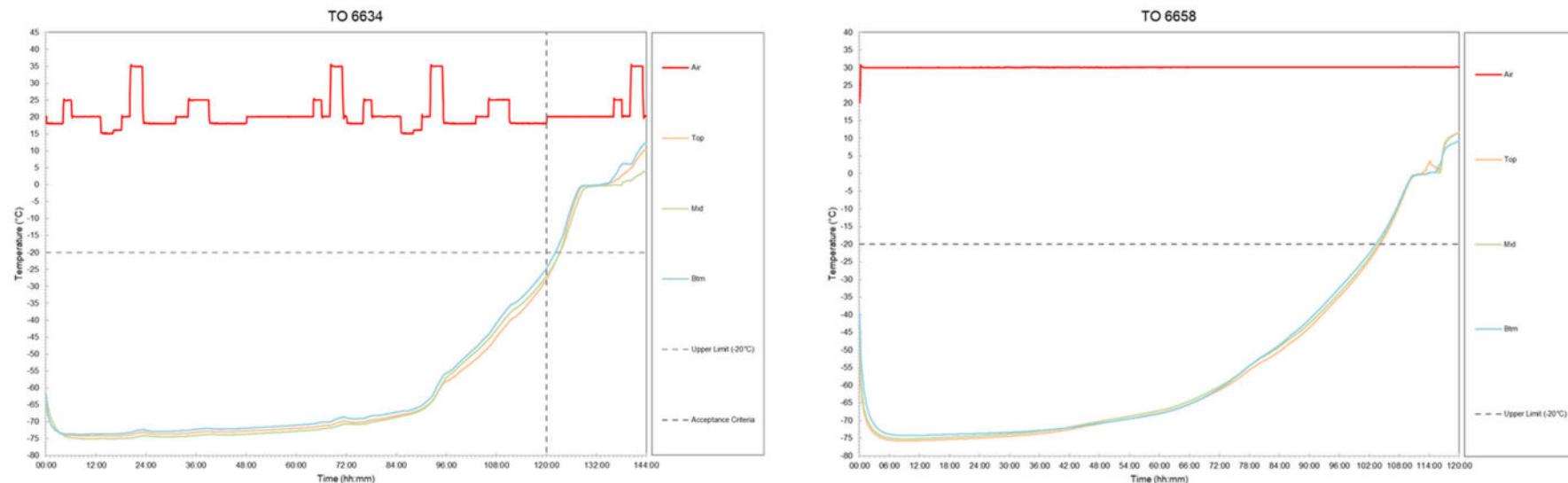
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Performance Disclaimer

Test results shown in this document illustrate the performance of a Softbox Temperature Control Packaging System under precisely controlled packing and testing conditions in an environmental chamber. The temperature profiles used for testing are designed to simulate fluctuations in ambient temperature experienced during live shipping. However, as Softbox has no control for what may happen during a live shipment, it cannot be held responsible for any temperature excursions, resulting loss of product or compensation claim that may result from the failure of its systems to perform.

Summary

Testing of the DHL FROZEN SOLUTION LARGE proves that each shipper tested has met the acceptance criteria set out in this qualification document. It also confirms the solutions ability to operate in extreme ambient conditions and to provide qualified temperature control in excess of 120:00 hh:mm.



Test Profile	Product Load	Duration Achieved	Minimum Temperature : °C Maximum Temperature : °C
SBS Summer TO 6634	Full Load	122:10 hh:mm	Minimum Temperature : -75.1°C Maximum Temperature : +12.1°C
Static +30°C TO 6658	Full Load	103:20 hh:mm	Minimum Temperature : -75.8°C Maximum Temperature : +11.7°C

1. Introduction

The range of single use DHL FROZEN SOLUTIONS have been developed to reliably transport temperature sensitive product below -20°C for a minimum of 72:00 hh:mm.

2. Test Objective

To qualify the DHL FROZEN SOLUTION LARGE Single use Temperature Control Packaging System against the SBS Summer test profile when packed with a maximum product load. The additional static +30°C test was performed to establish the sublimation rates of the dry ice within the shipper.

3. Test Scope

2 x DHL FROZEN SOLUTION LARGE Single use Temperature Control Packaging Systems packed with a maximum product load were prepared in ambient conditions.

All testing was carried out using new shippers and calibrated temperature logging equipment and environmental chambers.

Once packed the DHL FROZEN SOLUTION LARGE Single use Temperature Control Packaging System was placed into a calibrated temperature controlled environmental chamber which was preprogrammed with the stated test profiles.

Test product temperatures were recorded during the test with readings being taken at 5 minute intervals. The tests were run for a minimum of 120:00 hh:mm.

4. Test Acceptance Criteria

Maximum product load temperatures within the DHL FROZEN SOLUTION LARGE Single use Temperature Control Packaging System are to be maintained below -20°C for a minimum of 120:00 hh:mm when exposed to the SBS Summer test profile. There is no acceptance criteria for the static +30°C Profile test.

5. Test Method

5.1. Test Equipment

Equipment Description	Equipment Serial Numbers
Environmental Chamber	16956 (6)
Eurotherm 6180A Datalogger	PL1231000032-3112-PL3

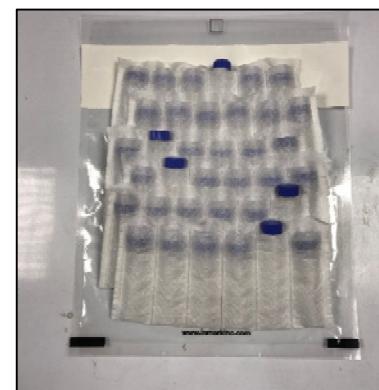
5.2. Test Materials

The shipper when tested contained the following Product Load.

Product	Product Name	Water Filled Vials
	Temperature Range	<-20°C
	Primary Packaging	Plastic Vials
	Primary Packaging Weight	14g
	Dose	10ml
	Vial Dimensions (mm)	13 x 13 x 93
	Product Orientation	Horizontal
Product Load	Full Load Quantity	36 Water Filled Vials
	Full Load Dimensions (mm)	180 x 145 x 150

5.3. Product Load Images

5.3.1. Image of Maximum Product Load



5.4. Temperature Probe Locations

The product load was probed using calibrated Eurotherm data logger PT100 probes as below.

5.4.1 Maximum Load

3 probes were placed within the water filled vials as per fig 1.

1 probe was placed within the Environmental Chamber to measure the ambient temperature for the duration of the test.

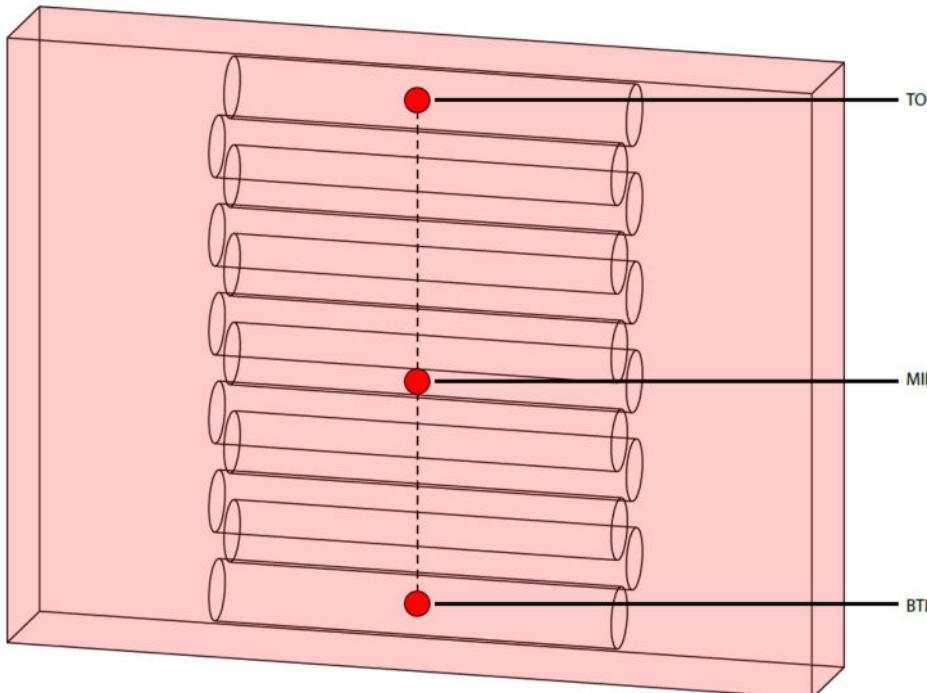


Fig 1

5.4.2 Data Logger / Probe Tracking

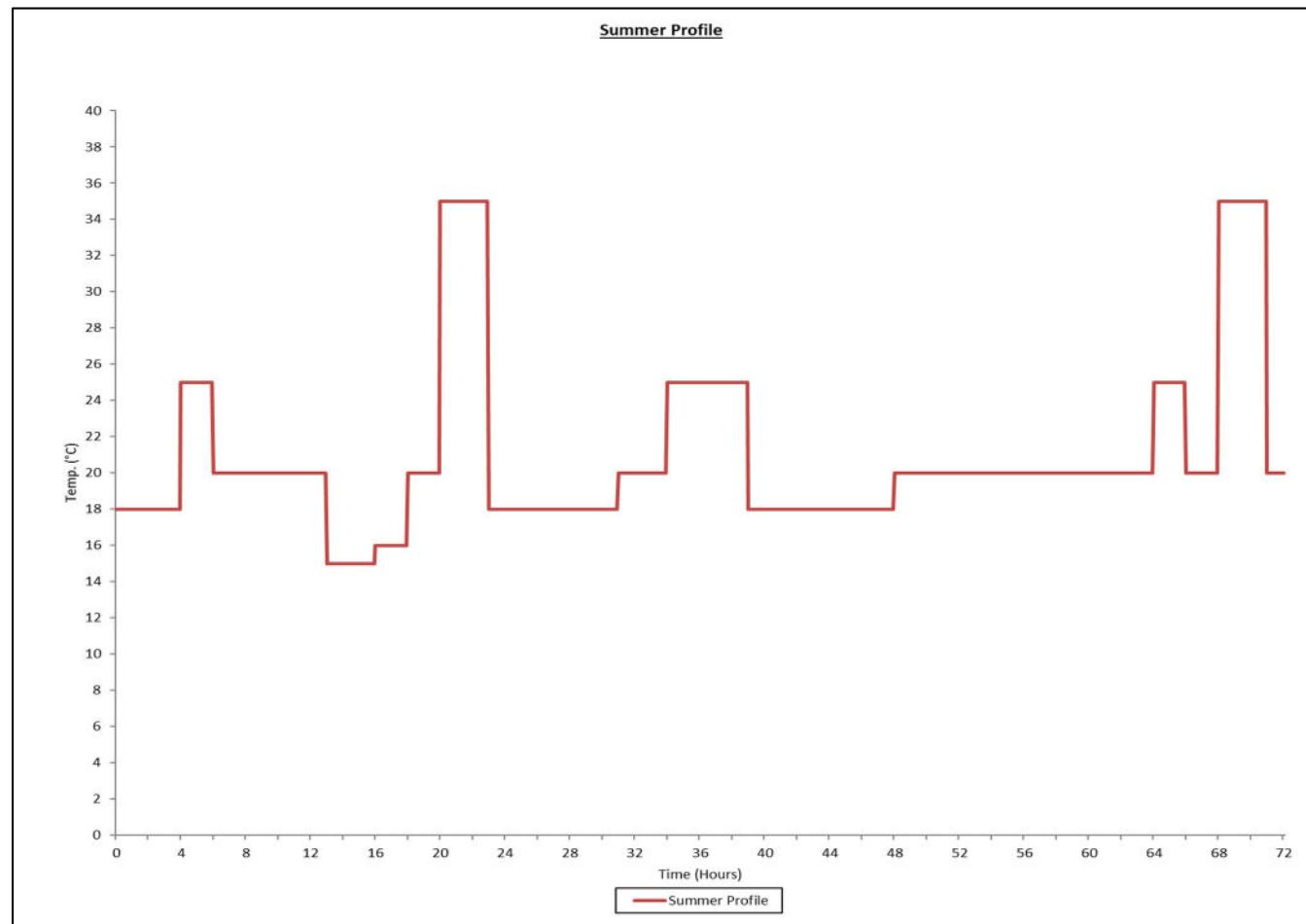
Probe Position	Datalogger Probe No.
Ambient	6180A probe 12

Full Load	Datalogger Probe No.
Top	6180A probe 7
Mid	6180A probe 9
Btm	6180A probe 10

5.5. Ambient Test Profiles

5.5.1. SBS Summer

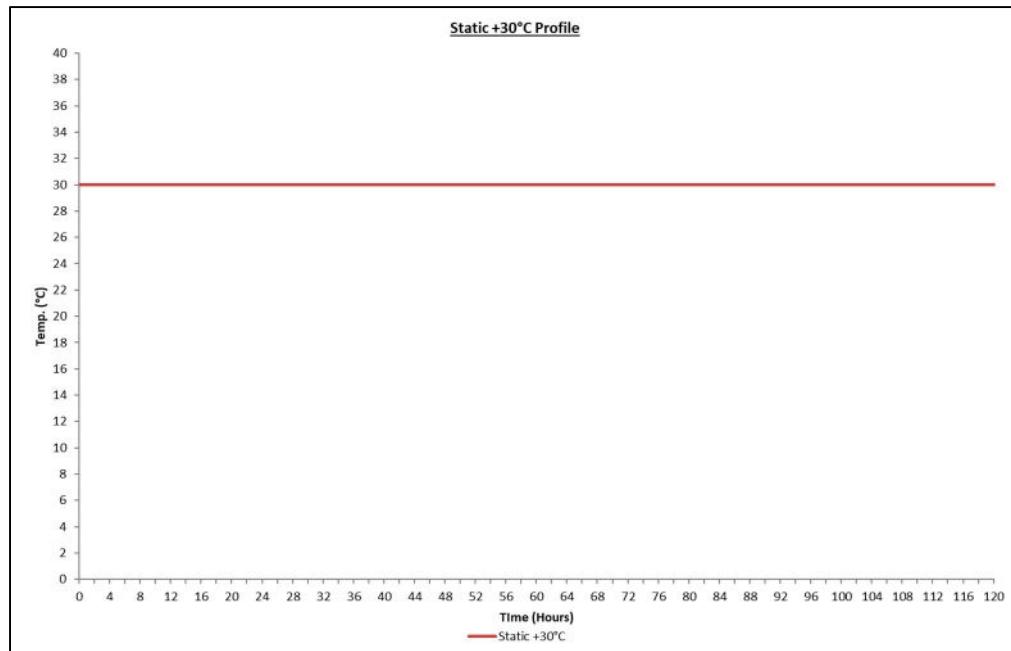
Elapsed Time	Segment Duration	Segment Temperature (°C)
4	4	18
6	2	25
13	7	20
16	3	15
18	2	16
20	2	20
23	3	35
31	8	18
34	3	20
37	3	25
39	2	25
48	9	18
64	16	20
66	2	25
68	2	20
71	3	35
72	1	20



Note : For systems with expected durations beyond 72 Hours, the above 72 Hour Profile is repeated in cycle. The justification for this cycling is based upon the fact that the levels and durations of temperatures experienced on such a transit network will continue to be similar regardless of the length of the transit period.

5.5.2. Static +30°C

Elapsed Time	Segment Duration	Segment Temperature (°C)
120	120	+30°C



6. Test Procedure

6.1. Dry Ice Quantity

9.560kg of dry ice (16 plates). Approximate plate weight – 750g.

6.2. Test Product Conditioning

The maximum product load was placed into dry ice prior to the test starting to allow it to stabilise.

6.3. Test Initiation

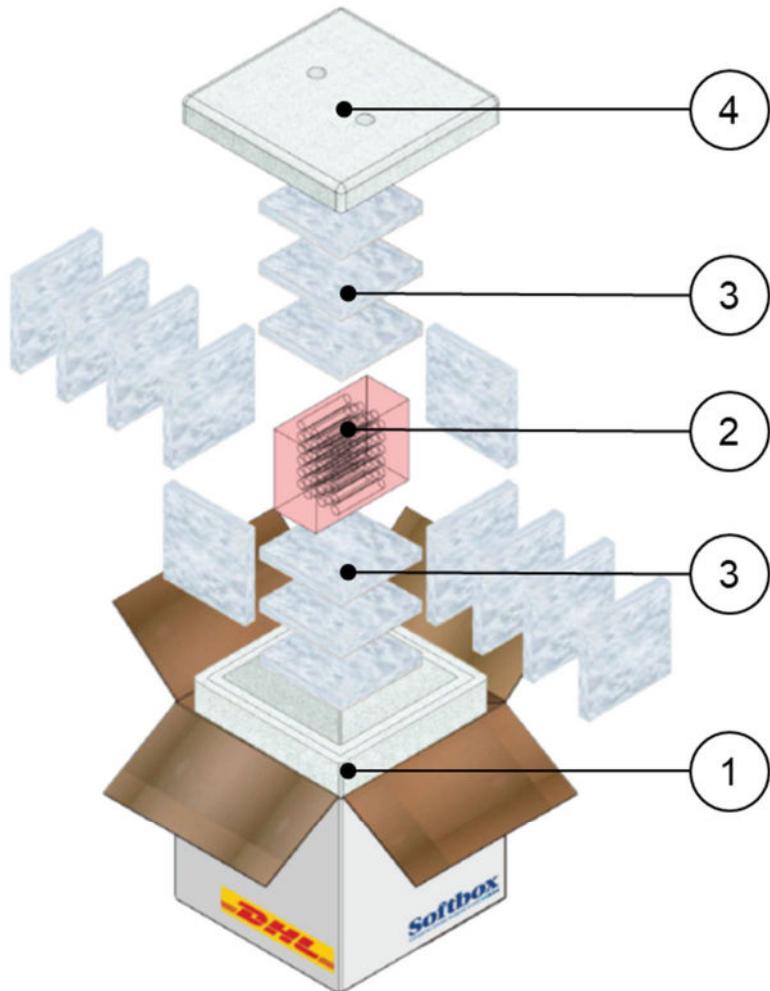
The Environmental Chamber was set to the start temperature of the ambient test profile as described in section 5.5.

Each DHL FROZEN SOLUTION LARGE Single use Temperature Control Packaging System was packed within an ambient environment with a set point of +20°C ($\pm 2^\circ\text{C}$) according to the System Diagram (Section 6.4) and Packing Instructions (Section 6.5).

Each packed DHL FROZEN SOLUTION LARGE Single use Temperature Control Packaging System was then placed into the Environmental Chamber. The test profile was then set to run.

6.4. Packing Diagram / System Specification

SYSTEM DIAGRAM



SYSTEM SPECIFICATION

Item	Components	Quantity	Weights and Dimensions
1	DHL Frozen Solution Large Base	1	Tare Weight 12.0kg
2	Test Product Load	1	Volumetric Weight 14kg
3	16 x Dry Ice Plates	9.560kg	Product Dimensions L x W x H 180x145x150mm
4	DHL Frozen Solution Large Lid	1	Shipper Dimensions L x W x H 395x395x448mm

Freezing Media

9.560kg of dry ice (16 plates). Approximate plate weight - 750g.

6.5. Packing Instruction

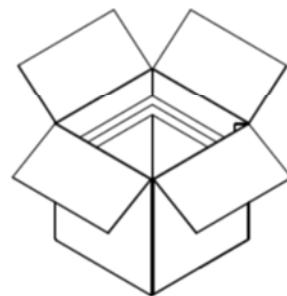


Fig.1
Remove the Frozen Solution lid and prepare to pack.

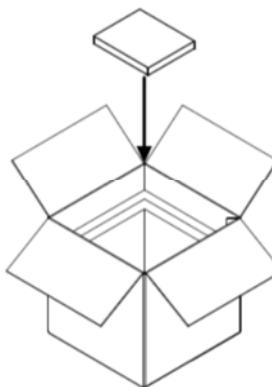


Fig.2
Place 3 x dry ice plates in the base of the Frozen Solution.

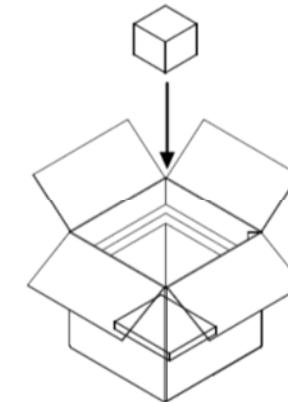


Fig.3
Place product load on the dry ice plates.

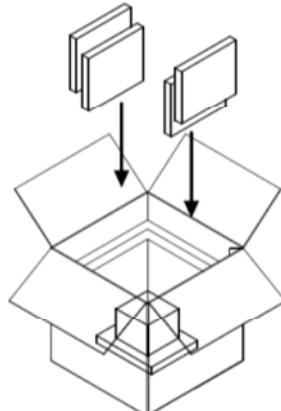


Fig.4
Place 10 x dry ice plates around the product load.

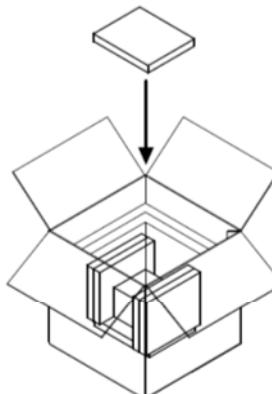


Fig.5
Place 3 x dry ice plates on the product load.

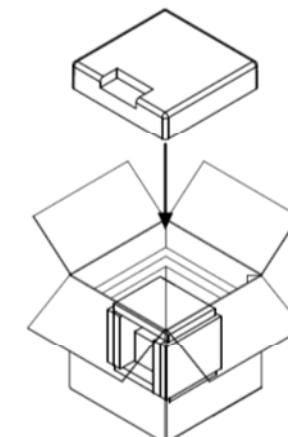
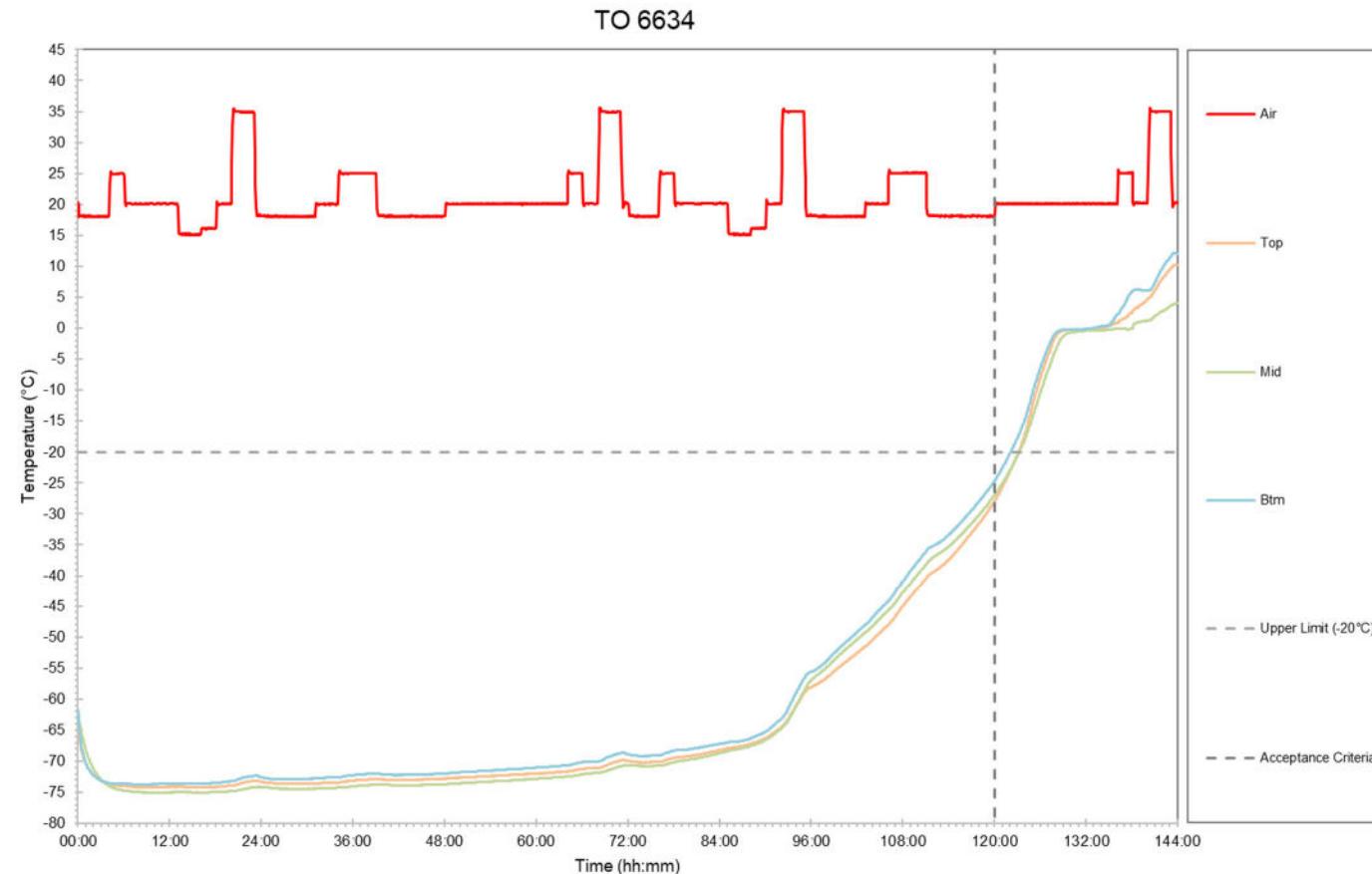


Fig.6
Place the lid on the Frozen Solution and secure outer carton with tape.

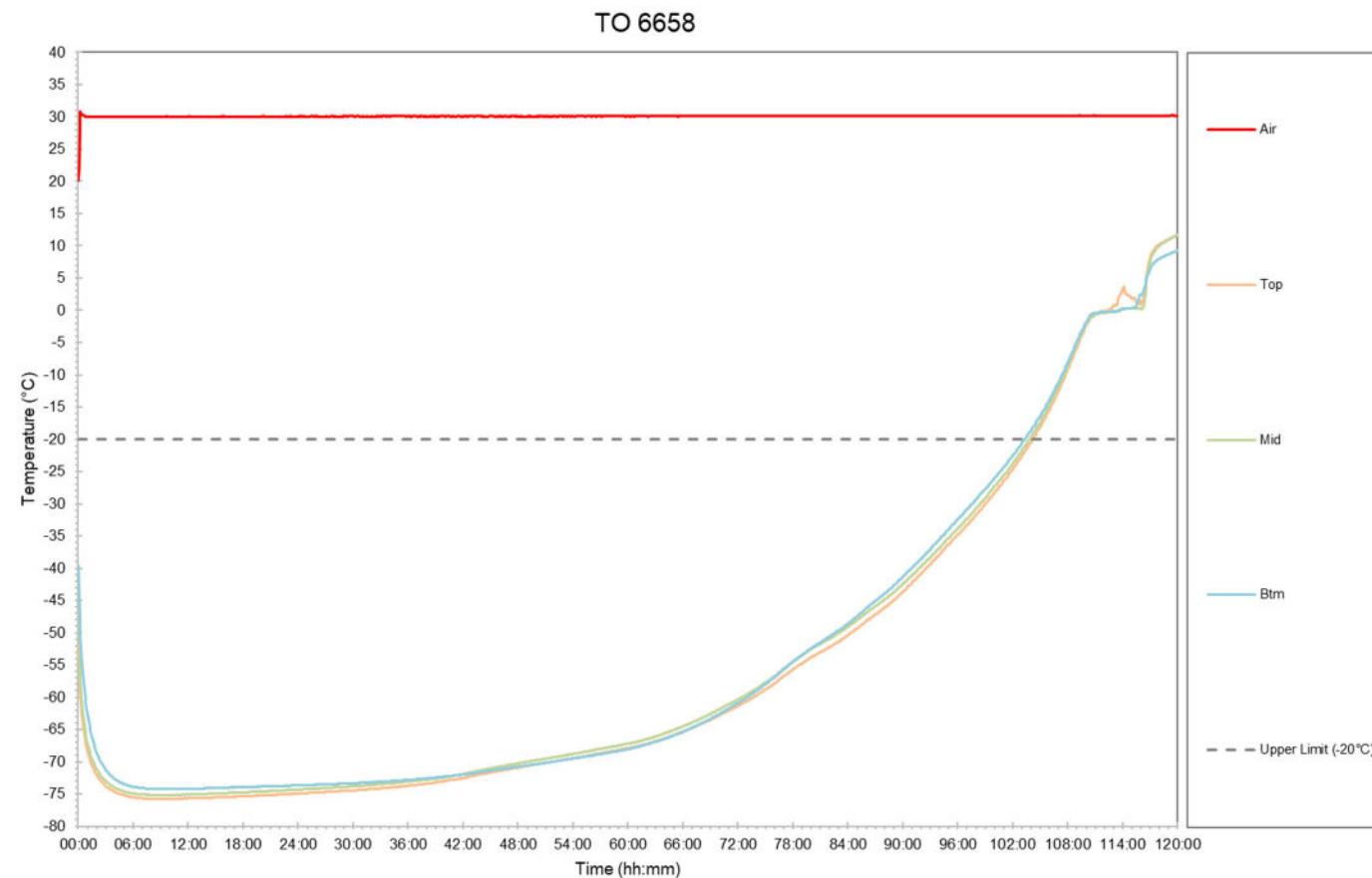
7. Test Results

7.1. TO 6634 – SBS Summer



	Temperature / Time	Probe Location
Product Load Temp $<-20^{\circ}\text{C}$	-19.9°C / 122:10 hh:mm	Btm
Maximum Temperature / Elapsed Test Time	+12.1°C / 143:25 hh:mm	Btm
Minimum Temperature / Elapsed Test Time	-75.1°C / 09:45 hh:mm	Mid

7.2. TO 6658 – Static +30°C



	Temperature / Time	Probe Location
Product Load Temp <-20°C	-19.9°C / 103:20	Btm
Maximum Temperature / Elapsed Test Time	+11.7°C / 119:55 hh:mm	Top
Minimum Temperature / Elapsed Test Time	-75.8°C / 07:35 hh:mm	Top
Sublimation Rate	0.0928kg/Hr	

8. Deviations and observations

8.1. Deviations

No deviations were recorded during this testing.

8.2. Observations

The DHL FROZEN SOLUTION LARGE exceeded the 120:00 hh:mm acceptance criteria when tested against the SBS Summer Profile. When tested against the Static +30°C profile the temperature of the maximum product load remained below -20°C for 103:20 hh:mm. This demonstrates a dry ice sublimation rate of 0.0928kg/Hr at +30°C.

9. Conclusion

Testing of DHL FROZEN SOLUTION LARGE Single use Temperature Control Packaging System proves that each shipper tested with a maximum product load has met the acceptance criteria set out in this Qualification Report.

10. Change History

Version	Date	Changes
V1	20NOV2018	Original Version

11. Appendix A - Calibration Certificates

11.1. Test Chamber Calibration Certificate

CLIMATEC

Unit 23, The Empire Centre, Imperial Way, Watford WD24 4YH
Tel: 01923 237178 Fax: 01923 237403 www.climatec.ltd.uk

CALIBRATION CERTIFICATE No. 3781

Date of Calibration :	12 th January 2018
Customer :	Softbox Systems - Thame
Climatec Job Number :	15322
Chamber Make/Model/Serial N°.:	Vindon / No. 6 / 16956
Cal Device Make/Model/Serial N°.:	TME / 2020 / 55454
Equipment Used Expiry Date :	17 October 2018
Traceable to UKAS Certificate N°.:	CN259065
Instrument Calibrated :	Eurotherm 2704

SETPOINT	READING	ACTUAL VALUE
-20°C	-20°C	-20.1°C
+5°C	+5°C	+4.8°C
+50°C	+50°C	+49.6°C

The uncertainty of measurement for these readings is ±0.8°C

[Signature]
14 FEB 2018

Calibration Engineer: Jason Wren

11.2. Data Logging Equipment Calibration Certificates

CERTIFICATE OF CALIBRATION

Certificate No.: T13120
Date of Issue: 19th December 2017
Customer: Softbox Systems Ltd
Customer Order No.: UK01-REQ-000208
Tempcon Works Order No.: 83731

ITEM NO	DESCRIPTION	SERIAL NO
A	6180A Chart Recorder	PL1231000032-3112-PL3 U15
B x 48	PT100 Probes	Ch 1 - 48

ITEM NO	APPLIED INPUT	EQUIPMENT TEST RESULTS
A+B1	-25.0°C	-24.8°C
A+B1	5.0°C	5.2°C
A+B1	39.9°C	39.8°C
A+B2	-25.0°C	-24.8°C
A+B2	5.0°C	5.2°C
A+B2	39.9°C	39.7°C
A+B3	-25.0°C	-24.8°C
A+B3	5.0°C	5.1°C
A+B3	39.9°C	39.7°C
A+B4	-25.0°C	-24.8°C
A+B4	5.0°C	5.2°C
A+B4	39.9°C	39.7°C
A+B5	-25.0°C	-24.9°C
A+B5	5.0°C	5.2°C
A+B5	39.9°C	39.9°C

[Signature]
21 DEC 2017

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CERTIFICATE OF CALIBRATION **Page 2**

A+B6	-25.0°C	-24.8°C
A+B6	5.0°C	5.0°C
A+B6	39.9°C	39.7°C
A+B7	-25.0°C	-25.0°C
A+B7	5.0°C	4.9°C
A+B7	39.9°C	39.7°C
A+B8	-25.0°C	-25.2°C
A+B8	5.0°C	4.8°C
A+B8	39.9°C	39.7°C
A+B9	-25.0°C	-25.2°C
A+B9	5.0°C	4.9°C
A+B9	39.9°C	39.7°C
A+B10	-25.0°C	-25.0°C
A+B10	5.0°C	4.9°C
A+B10	39.9°C	39.7°C
A+B11	-25.0°C	-24.9°C
A+B11	5.0°C	5.0°C
A+B11	39.9°C	39.7°C
A+B12	-25.0°C	-25.1°C
A+B12	5.0°C	5.0°C
A+B12	39.9°C	39.7°C
A+B13	-25.0°C	-25.1°C
A+B13	5.0°C	5.0°C
A+B13	39.9°C	39.7°C
A+B14	-25.0°C	-25.0°C
A+B14	5.0°C	5.1°C
A+B14	39.9°C	39.7°C

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CERTIFICATE OF CALIBRATION **Page 3**

A+B15	-25.0°C	-24.8°C
A+B15	5.0°C	5.2°C
A+B15	39.9°C	39.7°C
A+B16	-25.0°C	-25.0°C
A+B16	5.0°C	5.1°C
A+B16	39.9°C	39.8°C
A+B17	-25.0°C	-24.8°C
A+B17	5.0°C	5.1°C
A+B17	39.9°C	39.9°C
A+B18	-24.9°C	-24.7°C
A+B18	5.0°C	5.1°C
A+B18	39.9°C	39.7°C
A+B19	-24.9°C	-24.7°C
A+B19	5.0°C	5.2°C
A+B19	39.9°C	40.1°C
A+B20	-24.9°C	-24.9°C
A+B20	5.0°C	5.0°C
A+B20	39.9°C	39.8°C
A+B21	-24.9°C	-24.9°C
A+B21	5.0°C	5.0°C
A+B21	39.9°C	39.8°C
A+B22	-24.9°C	-24.9°C
A+B22	5.0°C	5.0°C
A+B22	39.9°C	39.8°C
A+B23	-25.0°C	-25.0°C
A+B23	5.0°C	5.1°C
A+B23	39.9°C	39.8°C

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CERTIFICATE OF CALIBRATION **Page 4**

A+B24	-25.0°C	-24.8°C
A+B24	5.0°C	5.2°C
A+B24	39.9°C	39.8°C
A+B25	-25.0°C	-25.0°C
A+B25	5.0°C	5.0°C
A+B25	39.9°C	39.8°C
A+B26	-25.0°C	-24.9°C
A+B26	5.0°C	5.1°C
A+B26	39.9°C	39.8°C
A+B27	-25.0°C	-25.2°C
A+B27	5.0°C	4.9°C
A+B27	39.9°C	39.8°C
A+B28	-25.0°C	-24.9°C
A+B28	5.0°C	5.1°C
A+B28	39.9°C	40.0°C
A+B29	-25.0°C	-24.9°C
A+B29	5.0°C	5.0°C
A+B29	39.9°C	39.8°C
A+B30	-25.0°C	-25.1°C
A+B30	5.0°C	5.0°C
A+B30	39.9°C	39.8°C
A+B31	-25.0°C	-25.0°C
A+B31	5.0°C	4.9°C
A+B31	39.9°C	39.8°C
A+B32	-25.0°C	-25.2°C
A+B32	5.0°C	4.9°C
A+B32	39.9°C	39.7°C

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CERTIFICATE OF CALIBRATION **Page 5**

A+B33	-25.0°C	-25.2°C
A+B33	5.0°C	5.0°C
A+B33	39.9°C	39.8°C
A+B34	-25.0°C	-25.2°C
A+B34	5.0°C	4.9°C
A+B34	39.9°C	39.7°C
A+B35	-25.0°C	-25.1°C
A+B35	5.0°C	5.1°C
A+B35	39.9°C	39.9°C
A+B36	-25.0°C	-25.0°C
A+B36	5.0°C	5.2°C
A+B36	39.9°C	40.0°C
A+B37	-25.0°C	-25.1°C
A+B37	5.0°C	4.9°C
A+B37	39.9°C	39.7°C
A+B38	-25.0°C	-25.2°C
A+B38	5.0°C	4.9°C
A+B38	39.9°C	39.7°C
A+B39	-25.0°C	-25.0°C
A+B39	5.0°C	4.9°C
A+B39	39.9°C	39.7°C
A+B40	-25.0°C	-25.0°C
A+B40	5.0°C	5.2°C
A+B40	39.9°C	39.8°C
A+B41	-25.0°C	-25.2°C
A+B41	5.0°C	4.9°C
A+B41	39.9°C	39.7°C
A+B42	-25.0°C	-25.2°C
A+B42	5.0°C	4.9°C
A+B42	39.9°C	39.8°C

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12. Appendix B - Table of Readings

CERTIFICATE OF CALIBRATION		
	MEASURED	STANDARD
A+B43	-25.0°C	-25.1°C
A+B43	5.0°C	4.9°C
A+B43	39.9°C	39.8°C
A+B44	-25.0°C	-25.0°C
A+B44	5.0°C	5.1°C
A+B44	39.9°C	39.8°C
A+B45	-25.0°C	-25.2°C
A+B45	5.0°C	4.8°C
A+B45	39.9°C	39.7°C
A+B46	-25.0°C	-25.2°C
A+B46	5.0°C	4.9°C
A+B46	39.9°C	39.7°C
A+B47	-25.0°C	-25.2°C
A+B47	5.0°C	4.9°C
A+B47	39.9°C	39.7°C
A+B48	-25.0°C	-25.2°C
A+B48	5.0°C	4.9°C
A+B48	39.9°C	39.7°C

This is to certify that the whole of the supplies detailed hereon have been inspected, calibrated and tested using test equipment which has been calibrated by a UKAS accredited laboratory.
Tempcon test equipment: **T1085**

- Copies of the test instrumentation UKAS certificates are available upon request.
- The above measured values apply to the measurement and are not intended to indicate the specification, or repeatability of the instrument.
- The International Temperature Scale of 1990, is used for temperature measurement.
- Uncertainties are for a confidence probability of not less than 95%.
- Laboratory parameters at time of calibration: 20.1°C, 58%RH

Signed..... *[Signature]*

Quality Assurance

Tempcon Instrumentation Limited is registered in the United Kingdom at the address stated on this Certificate. Registration Number: 1535366

F102.L

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