

Translation of Validation Summary Report

DOMETIC MT4B

Original report in German established by



Table of Contents

Description of the Validation Method	3
Test Readings MT4B at +10°C Outside Temperature over 24 Hours	5
Performance Report	6
Chart	7
Test Readings MT4B at +32°C Outside Temperature over 24 Hours	8
Performance Report	9
Chart	10
Test Readings MT4B "Maximum Cold Life" at +32°C Outside Temperature	11
Performance Report	12
Chart	13
Test Readings MT4B "Maximum Cold Life" at +43°C Outside Temperature	14
Performance Report	15
Chart	16
Validation Results	17
Validation Report MT4B	18

Validation of the Dometic MT4B Containment for the Transport of Blood Preparations

1 Introduction

Object of the validation is the transport of erythrocyte concentrates (EC) in the Dometic MT4B transport container whilst maintaining the cold chain required for these preparations. The relevant German and European laws and directives require a storage temperature of $4^{\circ}\text{C} \pm 2\text{K}$ or a transport temperature between 1°C and 10°C .

The question of this validation is under what environmental conditions can erythrocyte concentrates be transported legally safely (and therefore without quality loss) over what period using the Dometic MT4B.

2 Basic Conditions

2.1 Description of System

The transport containers of the Dometic Series MT4B are cooled passively by means of ice packs. The casings are manufactured by rotation process and receive an insulation of polyurethane foam. The complete functional unit always consists of an outer and an inner container.

Summary of Individual Features

Description	MT4B
Outer dimensions (HxWxD in mm)	301 x 287 x 363
Weight	3,1 kg
Gross interior volume	8,1 l
Storage capacity (ECs at 270 ml each)	4 blood bags
Number of ice packs at 2°C to $+10^{\circ}\text{C}$ outside temperature	à 300 ml à 600 ml None
at $+10^{\circ}\text{C}$ to $+20^{\circ}\text{C}$ outside temperature	/ 1
at outside temperature of above $+20^{\circ}\text{C}$	3 2

In order to compensate for statistical deviations and series variations, three different test patterns are used for this validation.

2.2 Ambient Temperatures

Three ambient temperature ranges have been chosen for this validation: $+10^{\circ}\text{C}$, $+32^{\circ}\text{C}$, and $+43^{\circ}\text{C}$. As minimum or maximum limits, these temperature ranges cover more than 90% of the transport scenarios imaginable for Central Europe, including safety margins.

2.3 Charge

For the 24 hours tests at $+32^{\circ}\text{C}$ and $+43^{\circ}\text{C}$ the typical lower charge limit of blood bags is chosen as charge. These low charge levels are more unstable, and the resulting test readings are very telling in respect to critical temperature ranges. With increasing charges the preparations' temperatures in the secondary container become increasingly stable. In fact this means a charge of 1 blood bag at 270 ml.

In order to determine the Maximum Cold Life at $+32^{\circ}\text{C}$ and $+43^{\circ}\text{C}$, the maximum charge (i.e. 4 blood bags at 270 ml each) is used to determine the absolute performance limits.

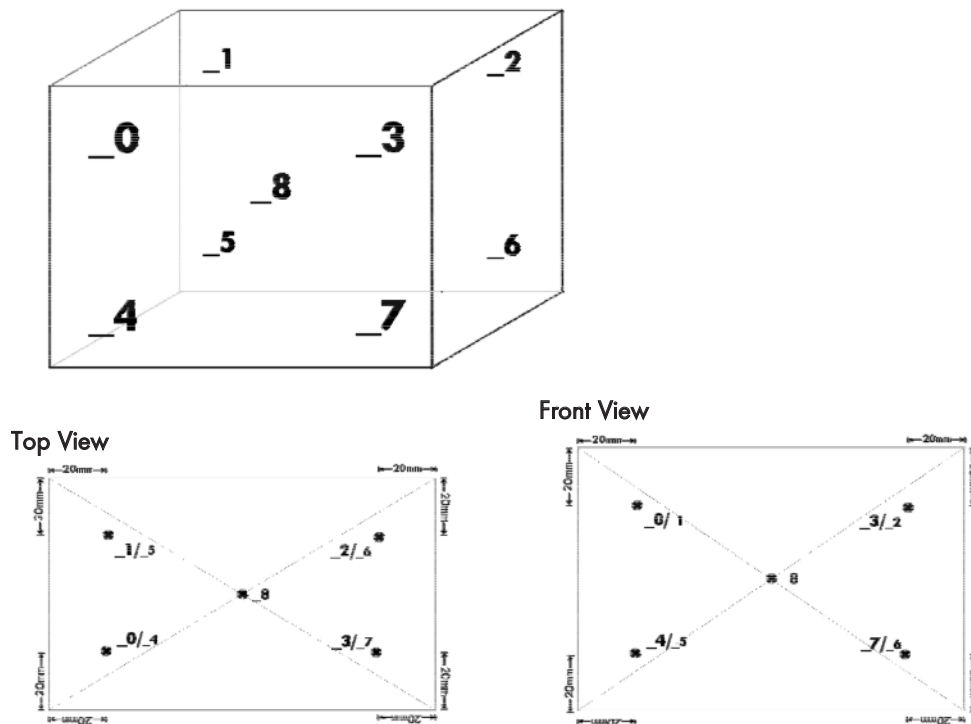
2.4 Time Frame

The validation is carried out for a transport time of 24 hours. This period covers almost 100% of the genuine range of usage times for Central Europe.

In addition, the time value "Maximum Cold Life" is determined for the ambient temperature ranges +32°C and +43°C. This value indicates the maximum amount of time the blood products can be held in the defined transport temperature ranges.

2.5 Check Points

The recording of test readings is carried out at ten points in the interior container of the transport container: eight check points in the corners of the container, always at a distance of two centimeters from all three nearest side walls, one check point at the intersection of the diagonals, and another one inside a blood bag. If more than one blood bag is used, the bag containing the sensor is placed in the centre.



The erythrocyte concentrate is substituted by a mixture consisting of 110 ml PAGGS-M and 160 ml HAES-Sterile 6% infusion solution. This mixture has very similar characteristics with respect to density and viscosity. Composelect by Fresenius HemoCare is used as blood bags.

2.6 Other

The ice packs are frozen to a core temperature of between -18°C and -22°C by storing them for at least 24 hours at the corresponding temperature. Before the boxes are equipped with the cooling elements, the elements are allowed to defrost at room temperature for 15-30 minutes.

Before starting a series of readings, the open (both interior and outer container are open) transport containers are exposed to the ambient temperature for at least six hours.

Test Readings

MT4B

At an outside temperature of +10°C over 24 hours

Performance Report for Dometic MT4B at +10°C over 24 h

Ambient temperature: +10°C
 Number of measuring runs: 3
 Duration of validation: 24 hours

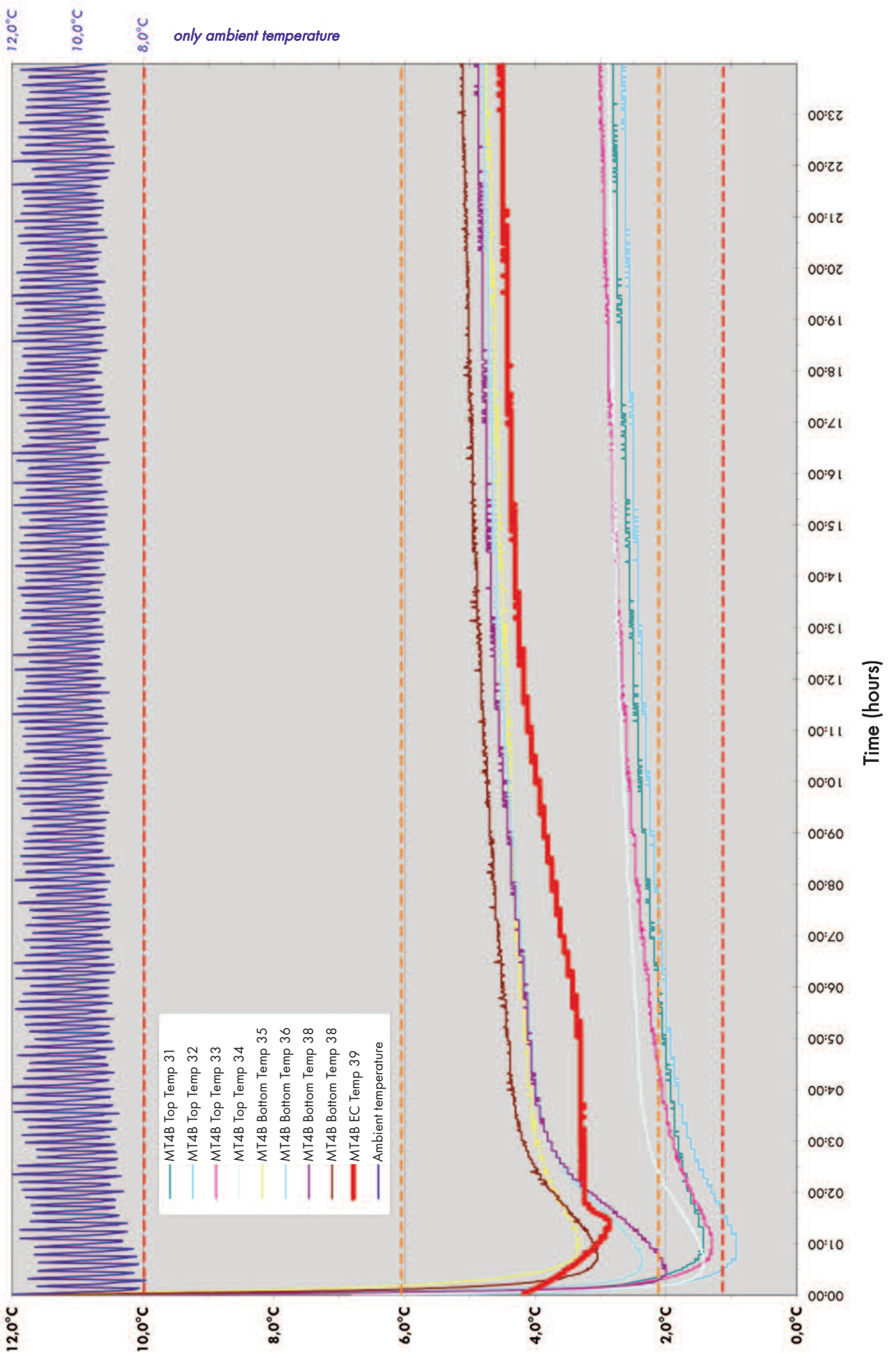
Ambient temperature	Measuring run 1	Measuring run 2	Measuring run 3	Accumulated	Absolute
Average temperature	10.70°C	10.46°C	10.51°C	10.21°C	10.21°C
Minimum value	8,20 °C	8,27 °C	8,28 °C	8,25 °C	8,20 °C
Maximum value	12,98 °C	12,72 °C	12,84 °C	12,85 °C	12,98 °C

Test readings MT4B	Charge: 1 EC at 270 ml; one cooling elements at 600 ml				
Temp 31 (air at top)					
Average temperature	2.65°C	1.98°C	2.24°C	2.39°C	2.39°C
Minimum value	1.51°C	1.35°C	1.09°C	1.43°C	1.09°C
Maximum value	6.19°C	6.29°C	6.50°C	6.50°C	6.50°C
Temp 32 (air at top)					
Average temperature	2.58°C	2.27°C	2.66°C	2.23°C	2.23°C
Minimum value	0.80°C	1.24°C	0.73°C	0.93°C	0.73°C
Maximum value	5.78°C	5.15°C	6.08°C	5.62°C	6.08°C
Temp 33 (air at top)					
Average temperature	3.00°C	2.27°C	2.63°C	2.54°C	2.54°C
Minimum value	1.63°C	1.21°C	1.32°C	1.30°C	1.21°C
Maximum value	6.30°C	6.81°C	6.39°C	6.67°C	6.81°C
Temp 34 (air at top)					
Average temperature	2.18°C	3.06°C	2.60°C	2.60°C	2.60°C
Minimum value	1.62°C	1.71°C	1.69°C	1.42°C	1.62°C
Maximum value	7.05°C	7.10°C	6.85°C	6.80°C	7.10°C
Temp 35 (air at bottom)					
Average temperature	4.82°C	4.43°C	3.95°C	4.41°C	4.41°C
Minimum value	3.08°C	2.97°C	3.47°C	3.31°C	2.97°C
Maximum value	12.52°C	12.86°C	12.33°C	12.71°C	12.86°C
Temp 36 (air at bottom)					
Average temperature	4.59°C	4.57°C	4.34°C	4.33°C	4.33°C
Minimum value	2.84°C	1.90°C	1.99°C	2.36°C	1.90°C
Maximum value	11.52°C	11.70°C	11.23°C	11.33°C	11.70°C
Temp 37 (air at bottom)					
Average temperature	4.15°C	3.99°C	3.97°C	4.37°C	4.37°C
Minimum value	1.95°C	2.27°C	1.79°C	2.00°C	1.79°C
Maximum value	11.03°C	11.32°C	10.84°C	10.93°C	11.32°C
Temp 38 (air at bottom)					
Average temperature	4.65°C	4.47 °C	4.70°C	4.70°C	4.70°C
Minimum value	2.90°C	2.63°C	3.49°C	3.05°C	2.63°C
Maximum value	12.40°C	11.76°C	12.55°C	12.12°C	12.55°C
Temp 39 (EC)					
Initial temperature	4.11°C	4.32°C	3.98°C	4.18°C	
Average temperature	3.89°C	3.83°C	4.06°C	3.99°C	3.99°C
Minimum value	1.89°C	3.28°C	2.17°C	2.87°C	1.89°C
Maximum value	4.45°C	4.44°C	4.60°C	4.56°C	4.60°C
Final temperature	4.47°C	4.86°C	4.40°C	4.50°C	

Storage temperatures for ECs (2°C - 6°C) were maintained for:
 Transport temperatures for ECs (1°C - 10°C) were maintained for:

> 24:00:00
 > 24:00:00

Temperature chart for Dometic MT4B over 24 hours at an ambient temperature of 10°C (accumulated results)



Test Readings

MT4B

At an outside temperature of +32°C over 24 hours

Performance Report for Dometic MT4B at +32°C over 24 h

Ambient temperature: +32°C
 Number of measuring runs: 3
 Duration of validation: 24 hours

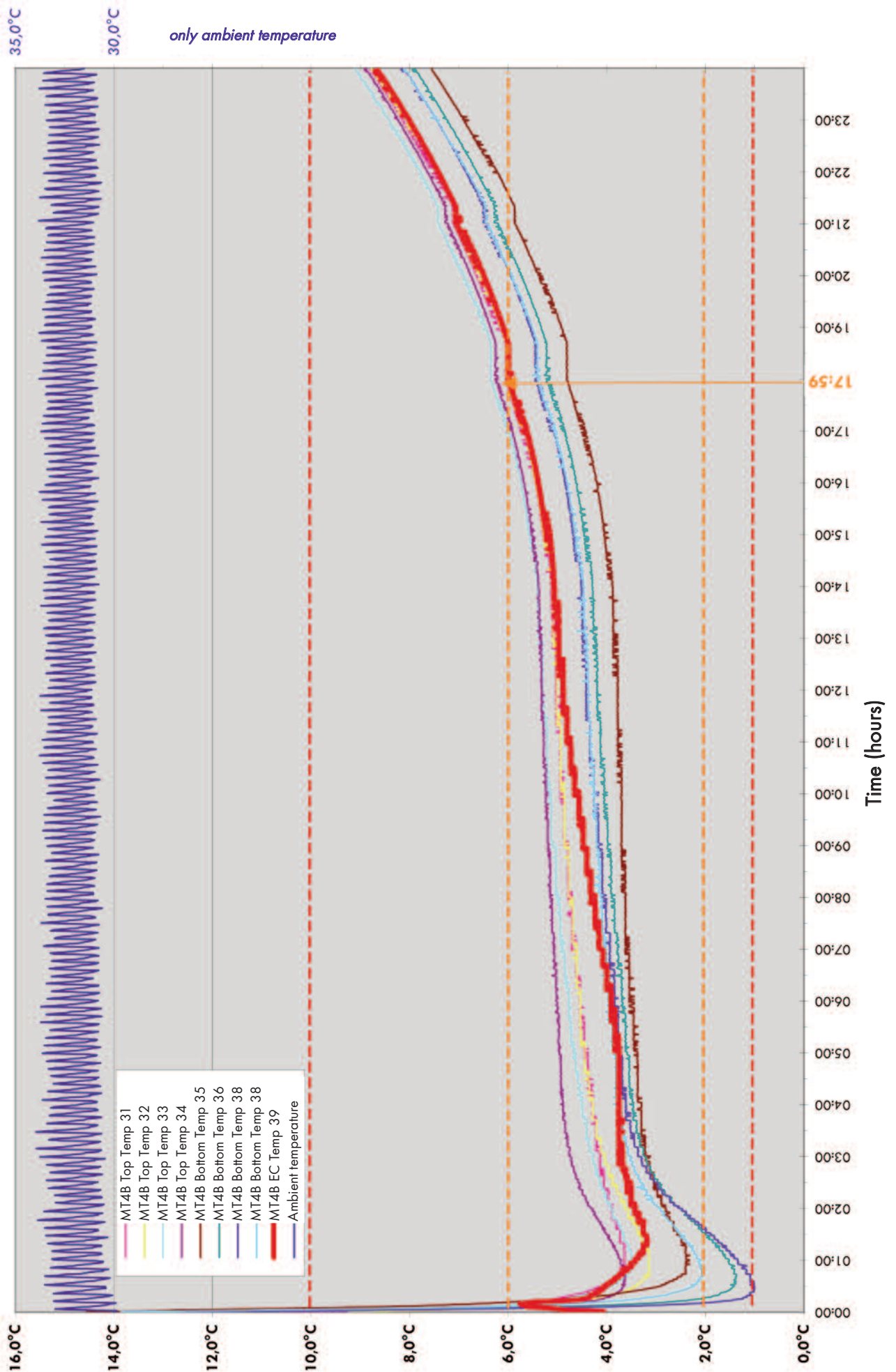
Ambient temperature	Measuring run 1	Measuring run 2	Measuring run 3	Accumulated	Absolute
Average temperature	32,36 °C	31,87 °C	31,75 °C	31,97 °C	31,97 °C
Minimum value	30,14 °C	30,33 °C	29,99 °C	30,15 °C	29,99 °C
Maximum value	34,38 °C	34,13 °C	34,02 °C	34,18 °C	34,38 °C

Test readings MT4B	Charge: 1 EC at 270 ml; three cooling elements à 300 ml and two à 600 ml				
Temp 31 (air at top)					
Average temperature	5.86°C	4.96°C	5.82°C	5.39°C	5.39°C
Minimum value	3.70°C	4.10°C	3.62°C	3.63°C	3.62°C
Maximum value	10.63°C	10.63°C	10.15°C	10.22°C	10.63°C
Temp 32 (air at top)					
Average temperature	4.96°C	5.34°C	5.04°C	5.32°C	5.32°C
Minimum value	2.97°C	3.45°C	3.39°C	3.13°C	2.97°C
Maximum value	9.64°C	8.93°C	8.90°C	9.24°C	9.64°C
Temp 33 (air at top)					
Average temperature	5.35°C	5.17°C	5.87°C	5.62	5.62°C
Minimum value	3.91°C	3.40°C	3.02°C	3.50°C	3.02°C
Maximum value	10.98°C	10.35°C	10.64°C	10.49°C	10.98°C
Temp 34 (air at top)					
Average temperature	5.18°C	5.61°C	5.92°C	5.66°C	5.66°C
Minimum value	3.70°C	3.61°C	3.91°C	3.62°C	3.61°C
Maximum value	10.73°C	10.94°C	11.12°C	10.63°C	11.12°C
Temp 35 (air at bottom)					
Average temperature	3.98°C	4.21°C	4.73°C	4.25°C	4.25°C
Minimum value	2.19°C	2.56°C	2.31°C	2.32°C	2.19°C
Maximum value	14.72°C	14.79°C	14.76°C	14.55°C	14.79°C
Temp 36 (air at bottom)					
Average temperature	4.83°C	4.57°C	4.64°C	4.43°C	4.43°C
Minimum value	1.59°C	1.49°C	0.93°C	1.36°C	0.93°C
Maximum value	13.44°C	13.19°C	13.19°C	13.03°C	13.44°C
Temp 37 (air at bottom)					
Average temperature	4.79°C	4.66°C	4.88°C	4.59°C	4.59°C
Minimum value	0.71°C	1.22°C	1.26°C	1.00°C	0.71°C
Maximum value	12.68°C	12.60°C	12.39°C	12.61°C	12.68°C
Temp 38 (air at bottom)					
Average temperature	4.68°C	5.11°C	4.26°C	4.70°C	4.70°C
Minimum value	1.68°C	1.68°C	1.57°C	2.06°C	1.57°C
Maximum value	13.98°C	13.75°C	13.63°C	13.86°C	13.98°C
Temp 39 (EC)					
Initial temperature	4.11°C	3.81°C	3.98°C	4.06°C	
Average temperature	4.90°C	5.12°C	5.05°C	5.12°C	5.12°C
Minimum value	1.89°C	2.72°C	2.17°C	3.17°C	1.89°C
Maximum value	8.26°C	8.64°C	9.02°C	8.70°C	9.02°C
Final temperature	9.06°C	8.71°C	8.27°C	8.66°C	

Storage temperatures for ECs (2°C - 6°C) were maintained for:
 Transport temperatures for ECs (1°C - 10°C) were maintained for:

17:59:00
 > 24:00:00

Temperature chart for Dometic MT4B over 24 hours at an ambient temperature of 32 °C (accumulated results)



Test Readings "Maximum Cold Life"

MT4B

At an outside temperature of +32°C

Performance Report for Dometic MT4B "Maximum Cold Life" at +32°C

Ambient temperature: +32°C
 Number of measuring runs: 3

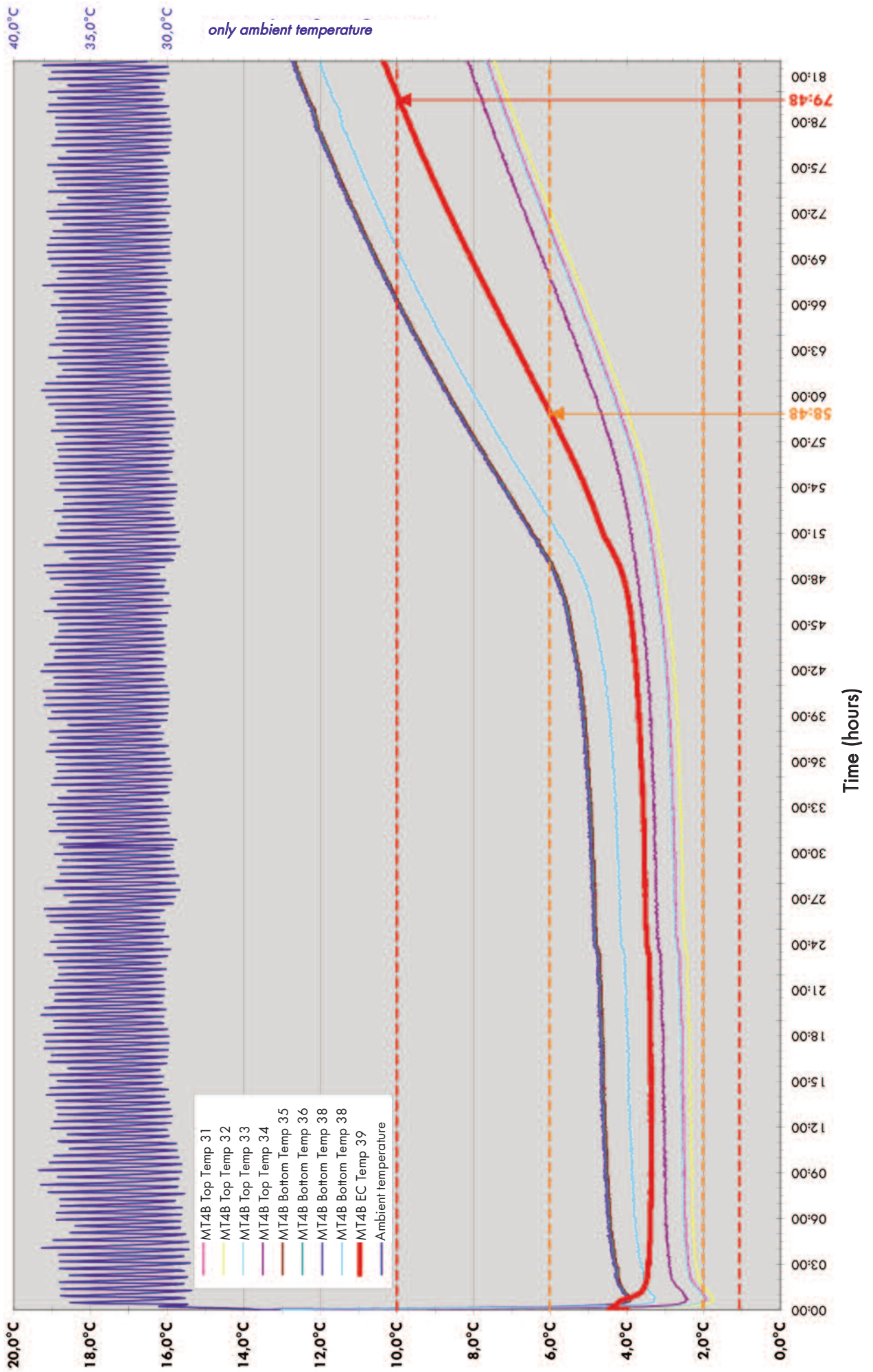
Ambient temperature	Measuring run 1	Measuring run 2	Measuring run 3	Accumulated	Absolute
Average temperature	33,21 °C	33,01 °C	33,00 °C	33,05 °C	33,05 °C
Minimum value	24,24 °C	24,18 °C	24,08 °C	24,17 °C	24,08 °C
Maximum value	38,74 °C	38,62 °C	38,74 °C	38,70 °C	38,74 °C

Test readings MT4B	Charge: 4 ECs at 270 ml each; 3 cooling elements à 300 ml and 2 à 600 ml				
Temp 31 (air at top)					
Average temperature	355°C	3.23°C	3.88°C	3.63°C	3.63°C
Minimum value	2.37°C	1.59°C	1.51°C	1.93°C	1.51°C
Maximum value	12.60°C	13.07°C	12.34°C	12.62°C	13.07°C
Temp 32 (air at top)					
Average temperature	3.87°C	3.05°C	3.31°C	3.44°C	3.44°C
Minimum value	2.31°C	2.71°C	2.38°C	1.73°C	1.70°C
Maximum value	12.81°C	12.04°C	12.89°C	12.40°C	12.89°C
Temp 33 (air at top)					
Average temperature	4.05°C	3.39°C	3.24°C	3.68°C	3.68°C
Minimum value	2.33°C	1.59°C	1.90°C	1.96°C	1.59°C
Maximum value	12.37°C	13.11°C	13.09°C	12.66°C	13.11°C
Temp 34 (air at top)					
Average temperature	3.89°C	4.12°C	4.38°C	4.13°C	4.13°C
Minimum value	2.11°C	2.68°C	2.10°C	2.42°C	2.10°C
Maximum value	13.36°C	13.38°C	13.12°C	13.13°C	13.38°C
Temp 35 (air at bottom)					
Average temperature	6.63°C	7.08°C	6.98°C	6.61°C	6.61°C
Minimum value	3.79°C	4.28°C	3.92°C	3.91°C	3.79°C
Maximum value	13.85°C	13.68°C	13.50°C	13.63°C	13.85°C
Temp 36 (air at bottom)					
Average temperature	6.85°C	6.18°C	6.84°C	6.66°C	6.66°C
Minimum value	4.40°C	3.86°C	4.07°C	3.94°C	3.86°C
Maximum value	13.44°C	13.41°C	13.17°C	13.67°C	13.44°C
Temp 37 (air at bottom)					
Average temperature	6.84°C	6.47°C	7.09°C	6.69°C	6.69°C
Minimum value	3.52°C	4.45°C	3.75°C	3.97°C	3.52°C
Maximum value	13.42°C	13.66°C	13.70°C	13.69°C	13.70°C
Temp 38 (air at bottom)					
Average temperature	6.07°C	6.26°C	6.26°C	5.98°C	5.98°C
Minimum value	2.92°C	3.73°C	3.29°C	3.25°C	2.92°C
Maximum value	13.34°C	12.89°C	12.63°C	13.02°C	13.34°C
Temp 39 (EC)					
Initial temperature	4.11°C	3.91°C	3.98°C	3.99°C	
Average temperature	4.46°C	5.38°C	4.65°C	4.94°C	4.94°C
Minimum value	1.89°C	3.35°C	2.17°C	3.36°C	1.89°C
Maximum value	9.99°C	9.99°C	9.99°C	9.99°C	9.99°C

Storage temperatures for ECs (2°C - 6°C) were maintained for:
 Transport temperatures for ECs (1°C - 10°C) were maintained for:

58:48
 79:48

Validation for Dometic MT4B Transport Container Maximum Cold Life at +32°C (accumulated results)



Test Readings "Maximum Cold Life"

MT4B

At an outside temperature of +43°C

Performance Report for Dometic MT4B "Maximum Cold Life" at +43°C

Ambient temperature: +43°C
 Number of measuring runs: 3

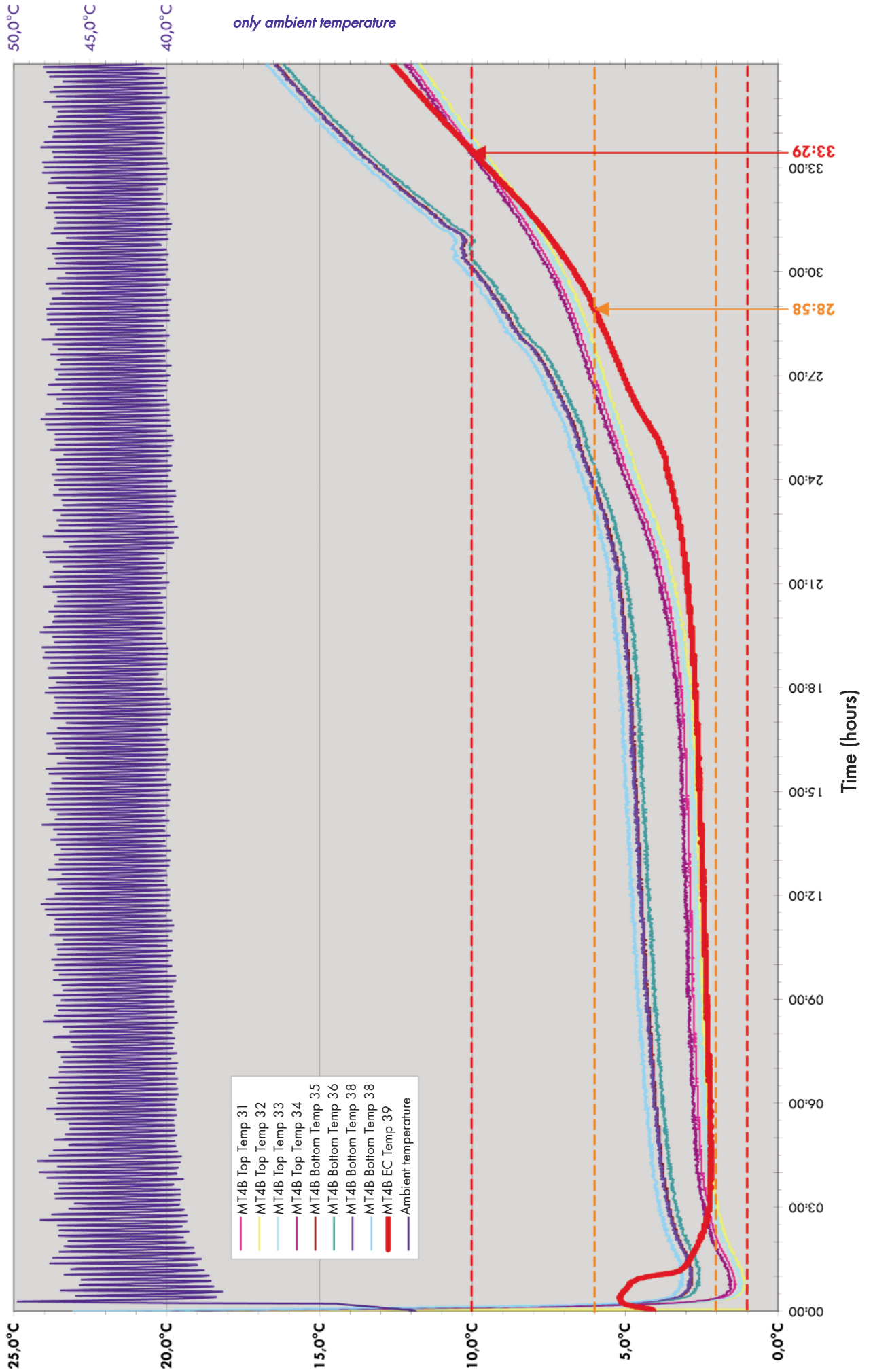
Ambient temperature	Measuring run 1	Measuring run 2	Measuring run 3	Accumulated	Absolute
Average temperature	43,88 °C	42,46 °C	42,98 °C	42,89 °C	42,89 °C
Minimum value	29,40 °C	29,25 °C	29,73 °C	29,60 °C	29,25 °C
Maximum value	46,05 °C	47,02 °C	45,88 °C	43,75 °C	47,02 °C

Test readings MT4B	Charge: 4 ECs at 270 ml each; 3 cooling elements à 300 ml and 2 à 600 ml				
Temp 31 (air at top)					
Average temperature	4.04°C	3.90°C	3.69°C	4.13°C	4.13°C
Minimum value	1.32°C	1.42°C	0.95°C	1.37°C	0.95°C
Maximum value	22.46°C	22.12°C	22.17°C	22.03°C	22.46°C
Temp 32 (air at top)					
Average temperature	3.67°C	3.84°C	3.96°C	3.82°C	3.82°C
Minimum value	1.29°C	0.79°C	0.57°C	1.00°C	0.57°C
Maximum value	21.47°C	21.96°C	21.30°C	21.71°C	21.96°C
Temp 33 (air at top)					
Average temperature	3.55°C	4.28°C	4.40°C	3.93°C	3.93°C
Minimum value	1.01°C	1.20°C	0.76°C	1.15°C	0.76°C
Maximum value	21.41 °C	22.13°C	21.95°C	21.86°C	22.13°C
Temp 34 (air at top)					
Average temperature	4.59°C	3.94°C	4.05°C	4.28°C	4.28°C
Minimum value	1.98°C	1.94°C	1.29°C	1.52°C	1.29°C
Maximum value	21.69°C	21.84°C	22.08°C	22.16°C	22.08°C
Temp 35 (air at bottom)					
Average temperature	5.90°C	5.47°C	5.82°C	5.79°C	5.79°C
Minimum value	2.33°C	3.31°C	2.64°C	2.81°C	2.33°C
Maximum value	22.30°C	22.64°C	22.89°C	22.75°C	22.89°C
Temp 36 (air at bottom)					
Average temperature	5.92°C	5.22°C	5.13°C	5.57°C	5.57°C
Minimum value	2.12°C	2.52°C	3.02°C	2.55°C	2.12°C
Maximum value	22.26°C	22.32°C	22.45°C	22.49°C	22.45°C
Temp 37 (air at bottom)					
Average temperature	5.87°C	5.59°C	5.68°C	5.84°C	5.84°C
Minimum value	2.35°C	2.96°C	3.07°C	2.81°C	2.35°C
Maximum value	22.28°C	22.55 °C	22.48°C	22.76°C	22.55°C
Temp 38 (air at bottom)					
Average temperature	5.67°C	6.06°C	6.38°C	6.12°C	6.12°C
Minimum value	2.86°C	3.00°C	2.87°C	3.09°C	2.86°C
Maximum value	23.21°C	23.16°C	22.79°C	23.06°C	23.21°C
Temp 39 (EC)					
Initial temperature	4.11°C	4.30°C	3.98°C	4.06°C	
Average temperature	3.60°C	3.64°C	3.20°C	3.68°C	3.68°C
Minimum value	1.89°C	2.39°C	2.17°C	2.17°C	1.89°C
Maximum value	9.97°C	9.99°C	9.99°C	9.98°C	9.99°C

Storage temperatures for ECs (2°C - 6°C) were maintained for:
 Transport temperatures for ECs (1°C - 10°C) were maintained for:

28:58
 33:29

Validation for Dometic MT4B Transport Container Maximum Cold Life at +43 °C (accumulated results)



Validation Results

Validation Report

DOMETIC MT4B

Object: Dometic MT4B
Special transport container for the transport of blood preparations
PROD-ID 991.5921.01; S/N 4470526, 4470520, 4470527

Range of application: Transport of erythrocyte concentrates
under Central European average climatic conditions

Results: Temp. +10°C over 24 h; 1 blood bag at 270 ml; 1 icepack at 600 ml

Ambient temperature	Average:	10.21°C
	Absolute minimum:	7.94°C
	Absolute maximum:	12.58°C
Blood bag core temperature	Initial temperature:	4.18°C
	Final temperature:	4.50°C
	Maximum temperature:	4.56°C
	Minimum temperature:	2.87°C

Temp. +32°C over 24 h; 1 blood bag at 270 ml; 3 icepacks at 300 ml + 2 à 600 ml

Ambient temperature	Average:	31.97°C
	Absolute minimum:	29.49°C
	Absolute maximum:	33.89°C
Blood bag core temperature	Initial temperature:	4.06°C
	Final temperature:	8.66°C
	Maximum temperature:	8.70°C
	Minimum temperature:	3.17°C

Temp. +32°C "Max. Cold Life"; 4 blood bags at 270ml; 3 icepacks at 300 ml + 2 à 600 ml

Ambient temperature	Average:	33.05°C
	Absolute minimum:	29.25°C
	Absolute maximum:	37.02°C
Blood bag core temperature	Initial temperature:	3.99°C
	Minimum temperature:	3.36°C
	Time until 6°C:	58h:48min
	Time until 10°C:	79h:48min

Temp. +43°C "Max. Cold Life"; 4 blood bags at 270ml; 3 icepacks at 300 ml + 2 à 600 ml

Ambient temperature	Average:	42.89°C
	Absolute minimum:	29.60°C
	Absolute maximum:	47.02°C
Blood bag core temperature	Initial temperature:	4.06°C
	Minimum temperature:	2.17°C
	Time until 6°C:	28h:58min
	Time until 10°C:	33h:29min

Evaluation:

The effect of the ambient temperature on one erythrocyte concentrate stored in a transport container of the type Dometic MT4B over a period of 24 hours, is small.

At an ambient temperature of +10°C, the preparations' core temperature within a MT4B charged with 1 blood bag at 270 ml over more than 24 hours remains within the legally required storage temperature range.

With the same charge and at an ambient temperature of +32°C, the storage temperature range of 2°C to 6°C is maintained for 17:59 hours and the transport temperature range (of 1°C to 10°C) is maintained for more than 24 hours.

With a full charge of 4 blood bags at 270 ml each and at an ambient temperature of +32°C, the storage temperature range is maintained for 58:48 hours and the transport temperature range for 79:48 hours, i.e. notably more than three days.

Under extreme conditions, at an ambient temperature of +43°C and with a full charge of 4 blood bags at 270 ml each, the storage temperatures are still maintained for more than 28:58 hours and the transport temperature range for over 33:29 hours.

The passive design of the transport container makes the container entirely impervious to operating errors or power cuts under any environmental conditions if it is correctly configured.

The casing of the transport container is extremely sturdy and almost entirely impervious against exterior forces, e.g. bumps and falls.

Furthermore, it can be cleaned and disinfected easily and thoroughly. The interior does not feature any inaccessible corners and areas.

Münster, 25th October 2005