Mehr Wert.
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Add value.
Inspire trust.

Technical Report No.
TR-713258709-01 (Revision 1)
dated
22.09.2022

Client:	Versapak Europe GmbH Dieselstraße 12 42781 Haan Germany
Manufacturer and / or location of manufacturing:	Versapak Romania SRL
Unit under test (UUT):	Thermal isolated medical bags PYTB1, PYTB2, PYTB3, BLTD1, BLTD2, PY-BHM, CCBX PHCY, VFT6999FRDG_T2
Test specification:	The relevant tests required were carried out according to the following listed standards: Temperature test to DIN EN 60068-2-1: 2008 Temperature test to DIN EN 60068-2-2: 2008
Test scope:	Stress of the UUT according to the detailed test specification in chapter 3 and check / logging of the temperatures of the loading inside the thermal isolated bags during the tests.
Test result:	The units under test were opened. The visual inspection showed no deficiencies or damages (see notes chapter 5 - test sequence). The measured data of the temperature tests were provided to the client for evaluation and validation. The validation was carried out by the client.

ilac-MRA DAkkS Deutsche Akkreditierungsstelle D-PL-11321-02-02

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1 Unit under test (UUT)

The units under test were Thermal insulated medical bags.

UUT No.	Type
1	PYTB1
2	PYTB2
3	PYTB3
4	BLTD2
5	BLTD1
6	PYBHM
7	CCBX PHCY
8	VFT6999FRDG_T2

The UUT were equipped with different loads, cool packs and thermal barriers during the tests.

The samples, cool packs and thermal barriers were preconditioned and combined according to specifications provided by the client.

The bags were assembled accordingly, the temperature sensors were positioned, and the bags were sealed.

Different test durations and temperatures were used to expose the bags during the tests. Details provided in chapter 3 of this test report.

The assembly with EUTECMA cool packs was specified by the client as follows:

BLD1: 2 x 500g, one below and one above.
BLD2: 3 x 500g above.
PYTB1: 2 x 500g, one below and one above.
PYTB2: 2 x 500g on the sides and 1 x 1100g on top.
PYTB3: 2 x 500g on the sides and 2 x 1100g on top.

The uninsulated sides of the EUTECMA cool packs had no contact with the samples.

The assembly with cool packs, 900g PCM and Tempack thermal barriers was specified by the client as follows:

The samples (plastic bottles) were loaded with the thermal barriers placed on top of the samples and the cool packs or 900g PCM at the top.

The plastic bottles filled with 0.5 l water were used simulating the load within the bags.

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Five designs from different manufacturers were used as cool packs:

1. <u>500g and 1100g from company EUTECMA</u>

500g

1100g

2. <u>Standard cool packs in the size of 400g and 750g</u>

400g

750g

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3. 900g PCM packs from company Tempack

900g

4. Thermal barriers 250g and 650g from company Tempack

250g

650g

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2 Order

2.1 Date of order, client

Company Versapak Europe GmbH orders from TÜV SÜD Product Service GmbH with order sheet dated 06.04.2022 order No. 70993 to test a.m. UUT.

2.2 Receipt of UUT

The samples were delivered by forwarding agent on 06.05.2022.

2.3 Reconsignment of UUT

The samples were sent back by forwarding agent on 21.07.2022.

3 Test specification

3.1 Temperature tests

3.1.1 Temperature storage Run 1 (Eutecma)

Ambient Temperature: 21°C
Duration: 48h

Configuration Load				Load	Preconditioning				Test conditions	
Bag	Load	Cool Pack	Thermal Barrier	Temperature Target Cool	Cool Packs	Dura-tion (h)	Thermal barrier	Dura-tion (h)	Ambient tempera-ture (h)	Dura-tion (h)
PYTB1	4 x 0,5l	2 x 500g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	21°C	48
PYTB2	12 x 0,5l	2 x 500g + 1x 1100g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	21°C	48
BLTD1	2 x 0,5l	2 x 500g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	21°C	48
BLTD2	6 x 0,5l	3 x 500g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	21°C	48

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3.1.2 Temperature storage Run 2 (Eutecma)

Ambient Temperature: 30°C
Duration: 48h

Configuration Load				Load	Preconditioning				Test conditions	
Bag	Load	Cool Pack	Thermal Barrier	Temperature Target Cool	Cool Packs	Dura-tion (h)	Thermal barrier	Dura-tion (h)	Ambient tempera-ture (h)	Dura-tion (h)
PYTB1	4 x 0,5l	2 x 500g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	30°C	48
PYTB2	12 x 0,5l	2 x 500g + 1x 1100g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	30°C	48
BLTD1	2 x 0,5l	2 x 500g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	30°C	48
BLTD2	6 x 0,5l	3 x 500g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	30°C	48

3.1.3 Temperature storage Run 3 (Eutecma)

Ambient Temperature: 40°C
Duration: 48h

Configuration Load				Load	Preconditioning				Test conditions	
Bag	Load	Cool Pack	Thermal Barrier	Temperature Target Cool	Cool Packs	Dura-tion (h)	Thermal barrier	Dura-tion (h)	Ambient tempera-ture (h)	Dura-tion (h)
PYTB2	12 x 0,5l	2 x 500g + 1x 1100g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	40°C	48

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3.1.4 Temperature storage Run 4

Ambient Temperature: 30°C
Duration: 24h

Configuration Load				Load	Preconditioning				Test conditions	
Bag	Load	Cool Pack	Thermal Barrier	Temperature Target Warm	Cool Packs	Dura-tion (h)	Thermal barrier	Dura-tion (h)	Ambient tempera-ture (h)	Dura-tion (h)
BLTD1	2 x 0,5l	1 x 900g PCM +20°C	N / A	+15°C to +25°C	+10°C	24	N / A	N / A	30°C	24
BLTD2	6 x 0,5l	1 x 900g PCM +20°C	N / A	+15°C to +25°C	+10°C	24	N / A	N / A	30°C	24

3.1.5 Temperature storage Run 5

Ambient Temperature: 30°C
Duration: 24h

Configuration Load				Load	Preconditioning				Test conditions	
Bag	Load	Cool Pack	Thermal Barrier	Temperature Target Cool	Cool Packs	Dura-tion (h)	Thermal barrier	Dura-tion (h)	Ambient tempera-ture (h)	Dura-tion (h)
PYTB1	4 x 0,5l	3 x 400g	1 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	30°C	24
PYTB2	12 x 0,5l	3 x 750g	1 x 650g Tempack	+2°C to +8°C	-18°C	24	4°C	24	30°C	24
PYTB3	16 x 0,5l	5 x 750g	2 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	30°C	24
BLTD1	2 x 0,5l	2 x 400g	1 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	30°C	24
BLTD2	6 x 0,5l	2 x 750g	2 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	30°C	24
PYBHM	8 x 0,5l	2 x 750g	1 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	30°C	24

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3.1.6 Temperature storage Run 6

Ambient Temperature: 21°C
Duration: 24h

Configuration Load				Load	Preconditioning				Test conditions	
Bag	Load	Cool Pack	Thermal Barrier	Temperature Target Cool	Cool Packs	Dura-tion (h)	Thermal barrier	Dura-tion (h)	Ambient tempera-ture (h)	Dura-tion (h)
PYTB1	4 x 0,5l	3 x 400g	1 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	21°C	24
PYTB2	12 x 0,5l	3 x 750g	1 x 650g Tempack	+2°C to +8°C	-18°C	24	4°C	24	21°C	24
PYTB3	16 x 0,5l	5 x 750g	2 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	21°C	24
BLTD1	2 x 0,5l	2 x 400g	1 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	21°C	24
BLTD2	6 x 0,5l	2 x 750g	2 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	21°C	24
PYBHM	8 x 0,5l	2 x 750g	1 x 250g Tempack	+2°C to +8°C	-18°C	24	4°C	24	21°C	24
CCBX PHCY	18 x 0,5l	3 x 750g	1 x 650g Tempack	+2°C to +8°C	-18°C	24	4°C	24	21°C	24
VFT699 9FRDG _T2	6 x 0,5l	N / A	N / A	+2°C to +8°C	N / A	N / A	N / A	N / A	21°C	24

3.1.7 Temperature storage Run 7

Ambient Temperature: 10°C
Duration: 24h

Configuration Load				Load	Preconditioning				Test conditions	
Bag	Load	Cool Pack	Thermal Barrier	Temperature Target Warm	Cool Packs	Dura-tion (h)	Thermal barrier	Dura-tion (h)	Ambient tempera-ture (h)	Dura-tion (h)
BLTD1	2 x 0,5l	1 x 900g PCM +20°C	N / A	+15°C to +25°C	+25°C	24	N / A	N / A	10°C	24
BLTD2	6 x 0,5l	1 x 900g PCM +20°C	N / A	+15°C to +25°C	+25°C	24	N / A	N / A	10°C	24

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3.1.8 Temperature storage Run 8 (Eutecma)

Ambient Temperature: 21°C
Duration: 48h

Configuration Load				Load	Preconditioning				Test conditions	
Bag	Load	Cool Pack	Thermal Barrier	Temperature Target Cool	Cool Packs	Dura-tion (h)	Thermal barrier	Dura-tion (h)	Ambient tempera-ture (h)	Dura-tion (h)
PYTB3	16 x 0,5l	2 x 500g + 1x 1100g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	21°C	48

3.1.9 Temperature storage Run 9 (Eutecma)

Ambient Temperature: 30°C
Duration: 48h

Configuration Load				Load	Preconditioning				Test conditions	
Bag	Load	Cool Pack	Thermal Barrier	Temperature Target Cool	Cool Packs	Dura-tion (h)	Thermal barrier	Dura-tion (h)	Ambient tempera-ture (h)	Dura-tion (h)
PYTB3	16 x 0,5l	2 x 500g + 1x 1100g EUTECMA	N / A	+2°C to +8°C	-18°C	24	N / A	N / A	30°C	48

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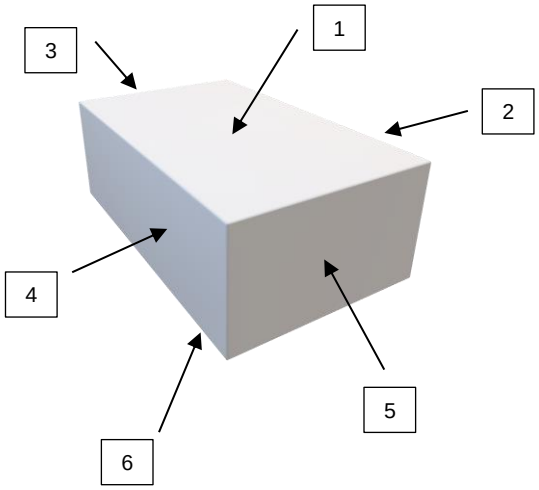
3.2 Drop test by free fall

The drop tests were carried out on each bag with the maximum weight (load) of the different packaging variants.

Height of fall:	1200 mm
1. drop	Surface 1
2. drop	Surface 2
3. drop	Surface 3
4. drop	Surface 4
5. drop	Surface 5
6. drop	Surface 6
7. drop	Surface 1
8. drop	Surface 2
9. drop	Surface 3
10. drop	Surface 4
11. drop	Surface 5
12. drop	Surface 6

Orientation of surfaces



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4 Test equipment

Equipment	Type	Ser. No.	Manufacturer	Cali-brated until
Climatic Chamber K9	PL-3J	15005229	Espec	10/2022
Climatic Chamber K12	HPP1060	W920.0067	Memmert	08/2022
Climatic Chamber K13	HPP1060	W920.0101	Memmert	08/2022
Temperature Chamber T1	VT4011	58566092610010	Vötsch	04/2023
Data Acquisition System	GL240	C91134257	Datatec	10/2022
Thermocouple element Product sensor 1	T	1 07-10/40-20-001	n.a	10/2022
Thermocouple element Product sensor 2	T	2 07-10/40-20-002	n.a.	10/2022
Thermocouple element Product sensor 1	T	1 07-10/40-20-003	n.a	10/2022
Thermocouple element Product sensor 2	T	2 07-10/40-20-004	n.a.	10/2022
Thermocouple element Product sensor 1	T	1 07-10/40-20-005	n.a	10/2022
Thermocouple element Product sensor 2	T	2 07-10/40-20-006	n.a.	10/2022
Thermocouple element Product sensor 1	T	1 07-10/40-20-007	n.a	10/2022
Thermocouple element Product sensor 2	T	2 07-10/40-20-008	n.a.	10/2022
Thermocouple element Product sensor 1	T	1 07-10/40-20-009	n.a	10/2022
Thermocouple element Product sensor 2	T	2 07-10/40-20-010	n.a.	10/2022
Thermocouple element Product sensor 1	T	1 07-10/40-20-011	n.a	10/2022
Thermocouple element Product sensor 2	T	2 07-10/40-20-012	n.a.	10/2022
Fall mechanism	PDT-56ED	M – 15761	Lansmont	n/a

All measuring equipment is calibrated regularly according to the calibration instructions of TÜV SÜD PRODUCT SERVICE GmbH. All calibrations are traced back to national standards.

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5 Test sequence

Test date: from 10.05.2022 to 14.07.2022

No.	Test specification	Period	Notes
1	Temperature storage test Run 1	10.05.2022 to 12.05.2022	

Type Coolant	Ambient Temp.	Duration	Limit Temperature	Time
PYTB1	21°C	48h	+8°C	17h 23min
PYTB2	21°C	48h	+8°C	29h 48min
BLTD1	21°C	48h	+8°C	21h 29min
BLTD2	21°C	48h	+8°C	28h 43min

No.	Test specification	Period	Notes
2	Temperature storage test Run 2	16.05.2022 to 18.05.2022	

Type Coolant	Ambient Temp.	Duration	Limit Temperature	Time
PYTB1	30°C	48h	+8°C	12h 47min
PYTB2	30°C	48h	+8°C	14h 52min
BLTD1	30°C	48h	+8°C	18h 12min
BLTD2	30°C	48h	+8°C	17h 20min

No.	Test specification	Period	Notes
3	Temperature storage test Run 3	23.05.2022 to 25.05.2022	

Type Coolant	Ambient Temp.	Duration	Limit Temperature	Time
PYTB2	40°C	48h	+8°C	8h 34min

No.	Test specification	Period	Notes
4	Temperature storage test Run 4	31.05.2022 to 01.06.2022	

Type Coolant	Ambient Temp.	Duration	Limit Temperature	Time
BLTD1	30°C	24h	+25°C	24h
BLTD2	30°C	24h	+25°C	24h

No.	Test specification	Period	Notes
5	Temperature storage test Run 5	02.06.2022 to 03.06.2022	

Type Coolant	Ambient Temp.	Duration	Limit Temperature	Time
PYTB1	30°C	24h	+8°C	4h 07min
PYTB2	30°C	24h	+8°C	9h 41min
PYTB3	30°C	24h	+8°C	12h 39min
BLTD1	30°C	24h	+8°C	6h 25min
BLTD2	30°C	24h	+8°C	5h 02min
PYBHM	30°C	24h	+8°C	7h 50min

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<table>
<tr><th>No.</th><th>Test specification</th><th>Period</th><th>Notes</th></tr>
<tr><td>6</td><td>Temperature storage test Run 6</td><td>04.07.2022 to 05.07.2022</td><td>
<table>
<tr><th>Type Coolant</th><th>Ambient Temp.</th><th>Duration</th><th>Limit Temperature</th><th>Time</th></tr>
<tr><td>PYTB1</td><td>21°C</td><td>24h</td><td>+8°C</td><td>6h 53min</td></tr>
<tr><td>PYTB2</td><td>21°C</td><td>24h</td><td>+8°C</td><td>22h 11min</td></tr>
<tr><td>PYTB3</td><td>21°C</td><td>24h</td><td>+8°C</td><td>24h</td></tr>
<tr><td>BLTD1</td><td>21°C</td><td>24h</td><td>+8°C</td><td>11h 59min</td></tr>
<tr><td>BLTD2</td><td>21°C</td><td>24h</td><td>+8°C</td><td>24h</td></tr>
<tr><td>PYBHM</td><td>21°C</td><td>24h</td><td>+8°C</td><td>24h</td></tr>
<tr><td>CCBX PHCY</td><td>21°C</td><td>24h</td><td>+8°C</td><td>24h</td></tr>
<tr><td>VFT6999 FRDG_T 2</td><td>21°C</td><td>24h</td><td>+8°C</td><td>2h 06min</td></tr>
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</td></tr>
<tr><td>7</td><td>Temperature storage test Run 7</td><td>14.06.2022 to 15.06.2022</td><td>
<table>
<tr><th>Type Coolant</th><th>Ambient Temp.</th><th>Duration</th><th>Limit Temperature</th><th>Time</th></tr>
<tr><td>BLTD1</td><td>10°C</td><td>24h</td><td>+15°C</td><td>24h</td></tr>
<tr><td>BLTD2</td><td>10°C</td><td>24h</td><td>+15°C</td><td>15h 29min</td></tr>
</table>
</td></tr>
<tr><td>8</td><td>Temperature storage test Run 8</td><td>20.06.2022 to 21.06.2022</td><td>
<table>
<tr><th>Type Coolant</th><th>Ambient Temp.</th><th>Duration</th><th>Limit Temperature</th><th>Time</th></tr>
<tr><td>PYTB3</td><td>21°C</td><td>48h</td><td>+8°C</td><td>31h 25min</td></tr>
</table>
</td></tr>
<tr><td>9</td><td>Temperature storage test Run 9</td><td>23.06.2022 to 25.06.2022</td><td>
<table>
<tr><th>Type Coolant</th><th>Ambient Temp.</th><th>Duration</th><th>Limit Temperature</th><th>Time</th></tr>
<tr><td>PYTB3</td><td>30°C</td><td>48h</td><td>+8°C</td><td>15h 55min</td></tr>
</table>
</td></tr>
<tr><td>10</td><td>Drop test</td><td>13.07.2022 to 14.07.2022</td><td>PYTB1, PYTB2, PYTB3, BLTD1, BLTD2, PYBHM, CCBX PHCY, VFT6999FRDG_T2
Height of fall: 1200mm
2 drops on each surface, totally 12 drops
No damage visible on the outside or inside of the thermal isolated medical bags.</td></tr>
</table>

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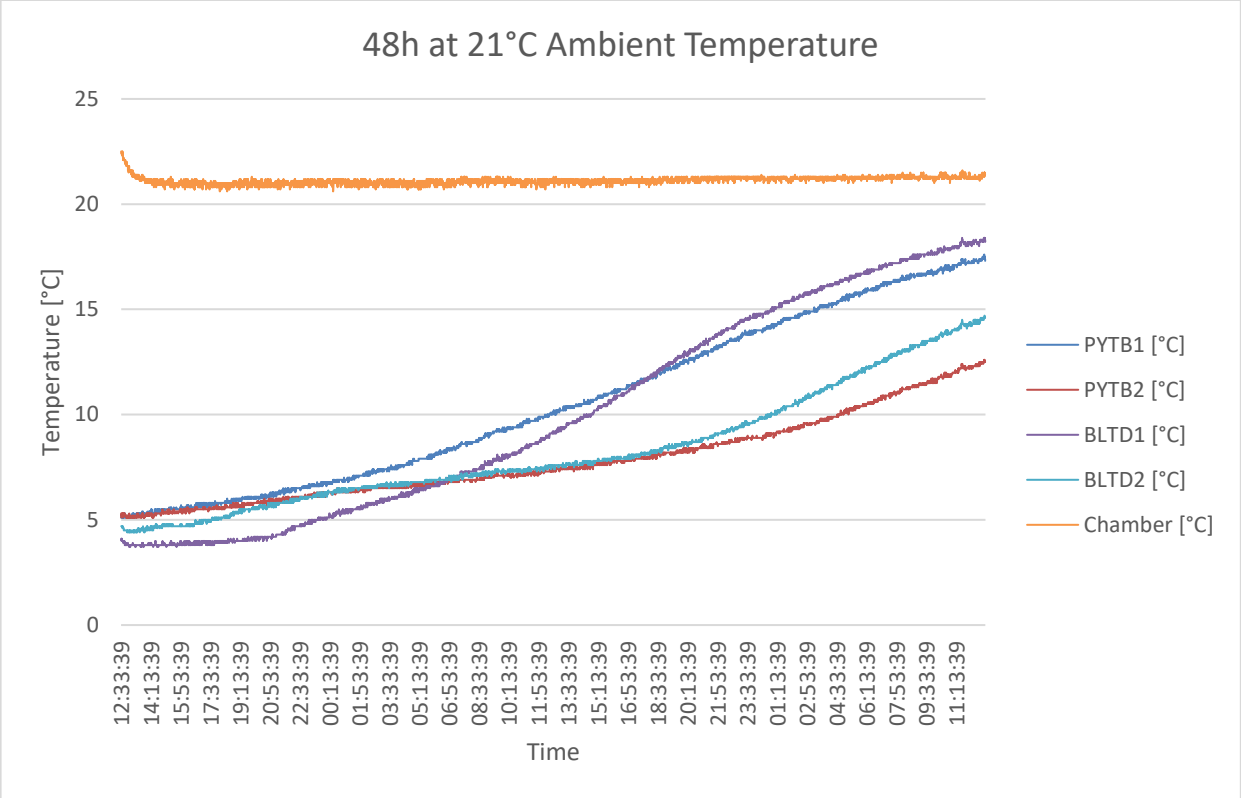
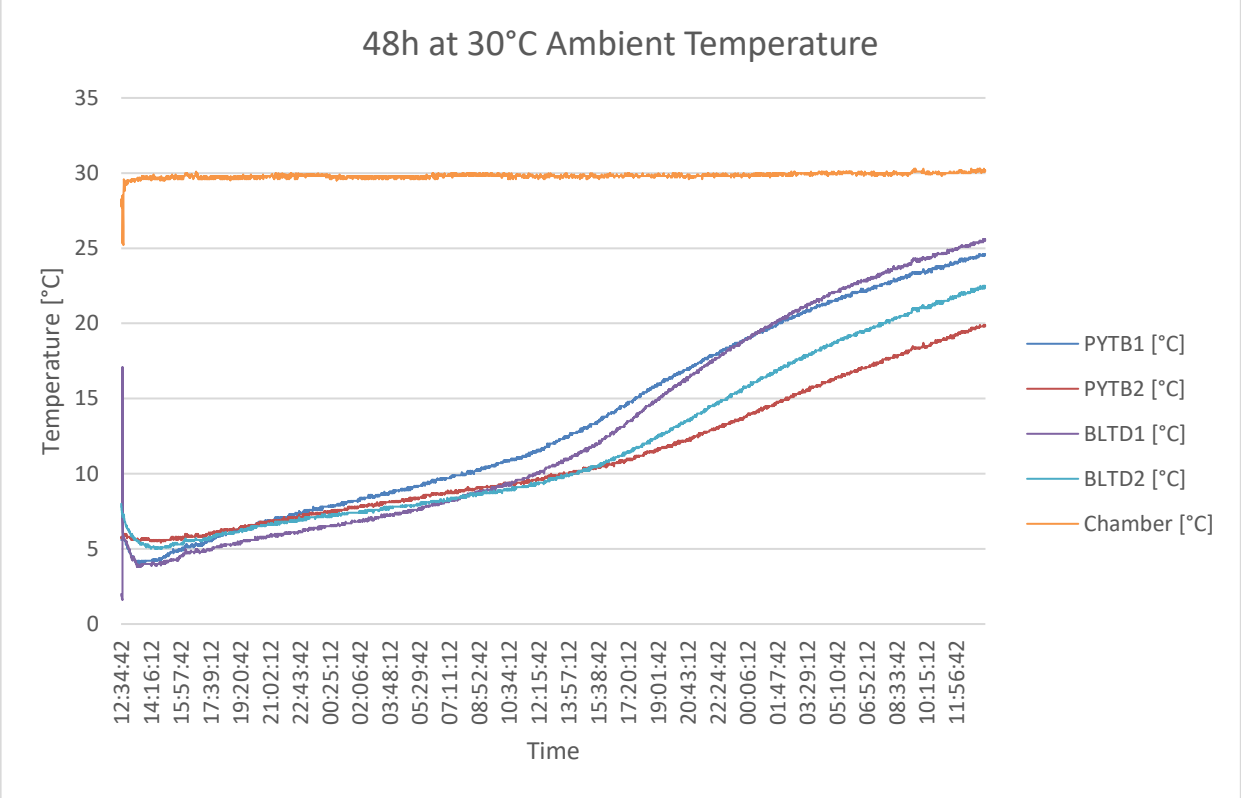
6 Test documentation

6.1 Measuring diagrams of the temperature storage test Run 1



6.2 Measuring diagrams of the temperature storage test Run 2



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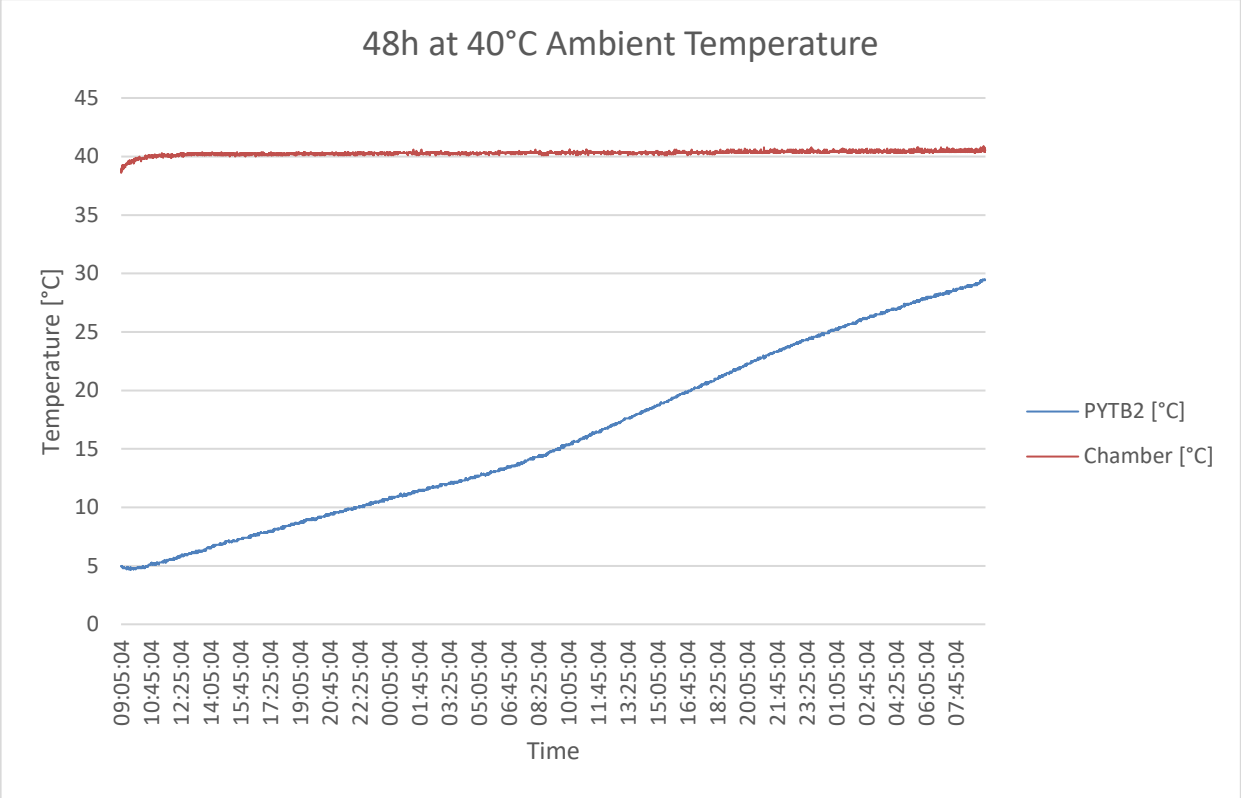
6.3 Measuring diagrams of the temperature storage test Run 3



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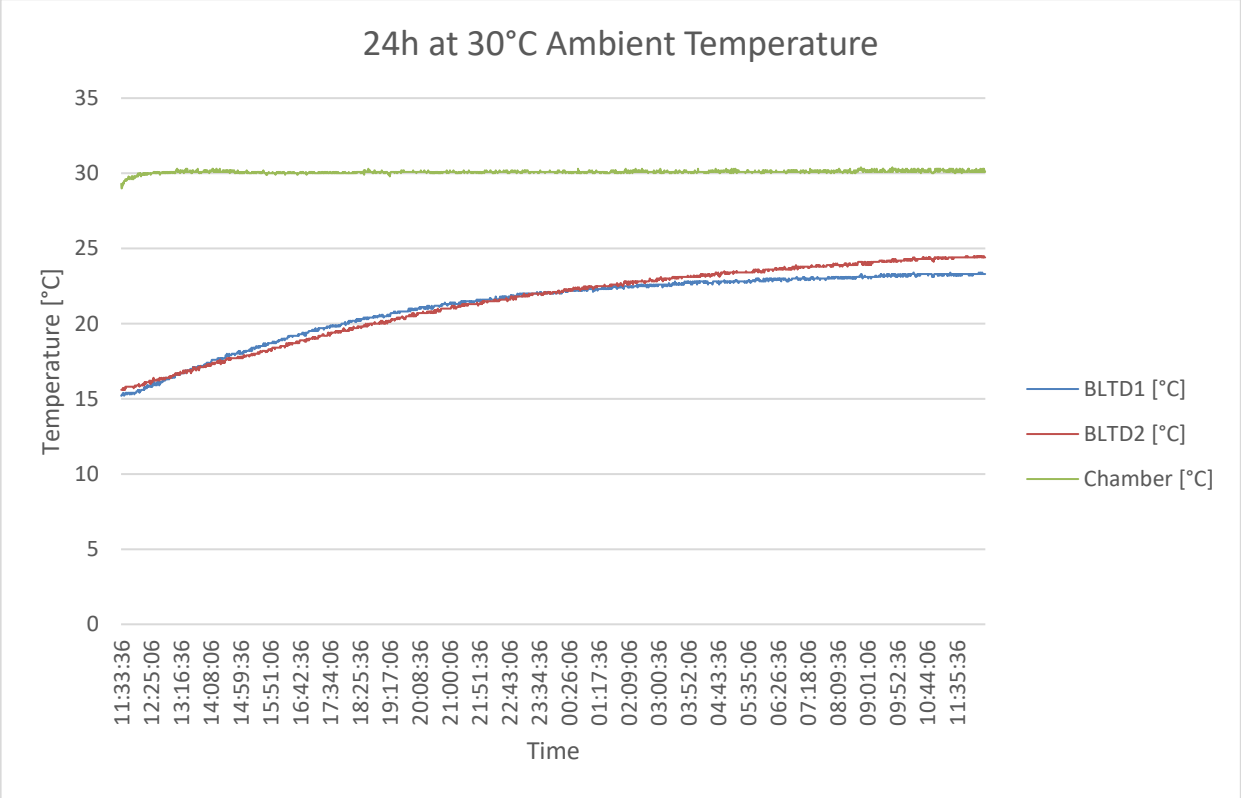
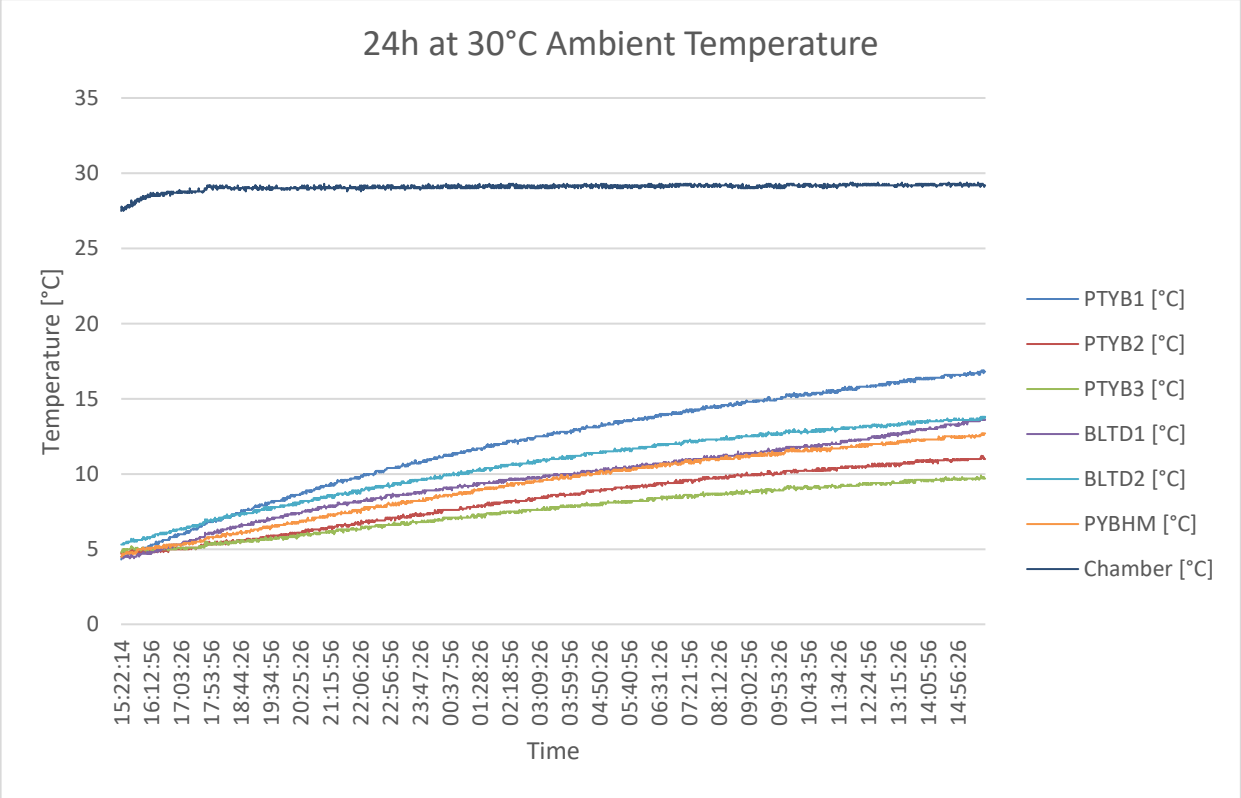
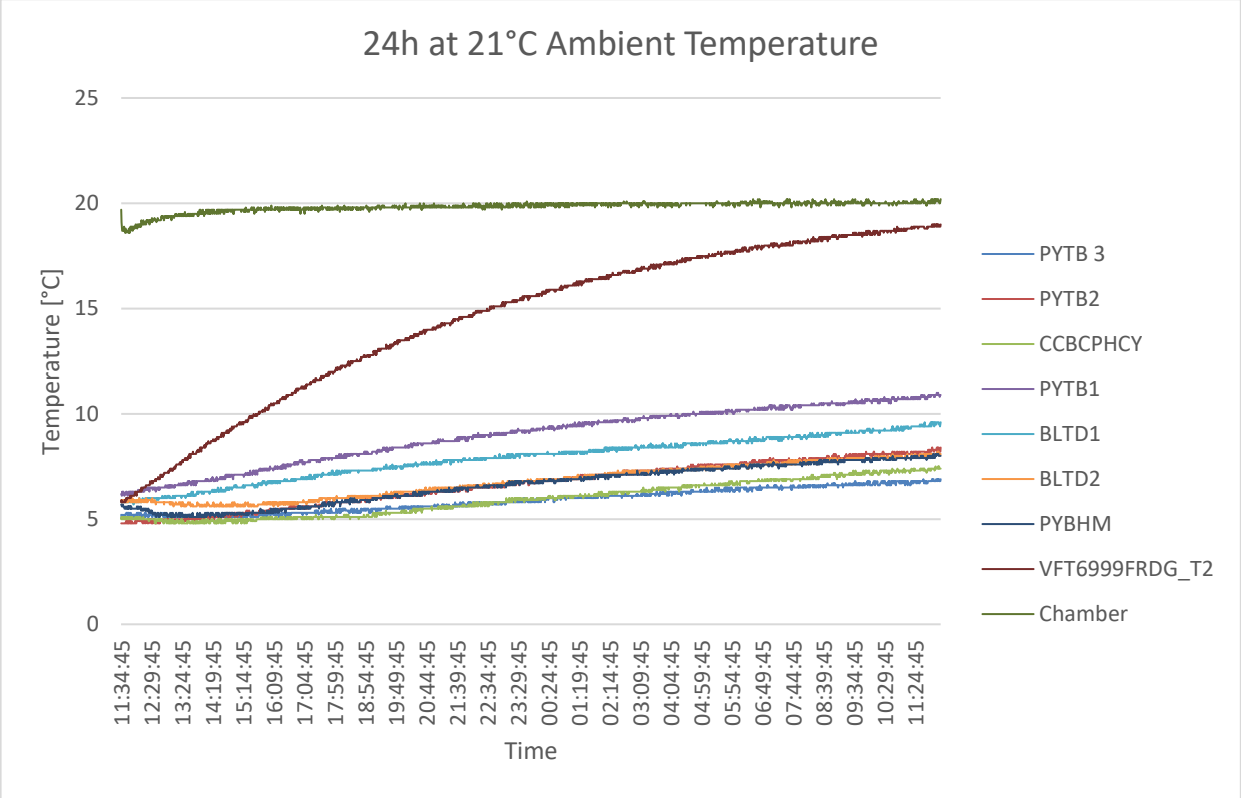
6.4 Measuring diagrams of the temperature storage test Run 4



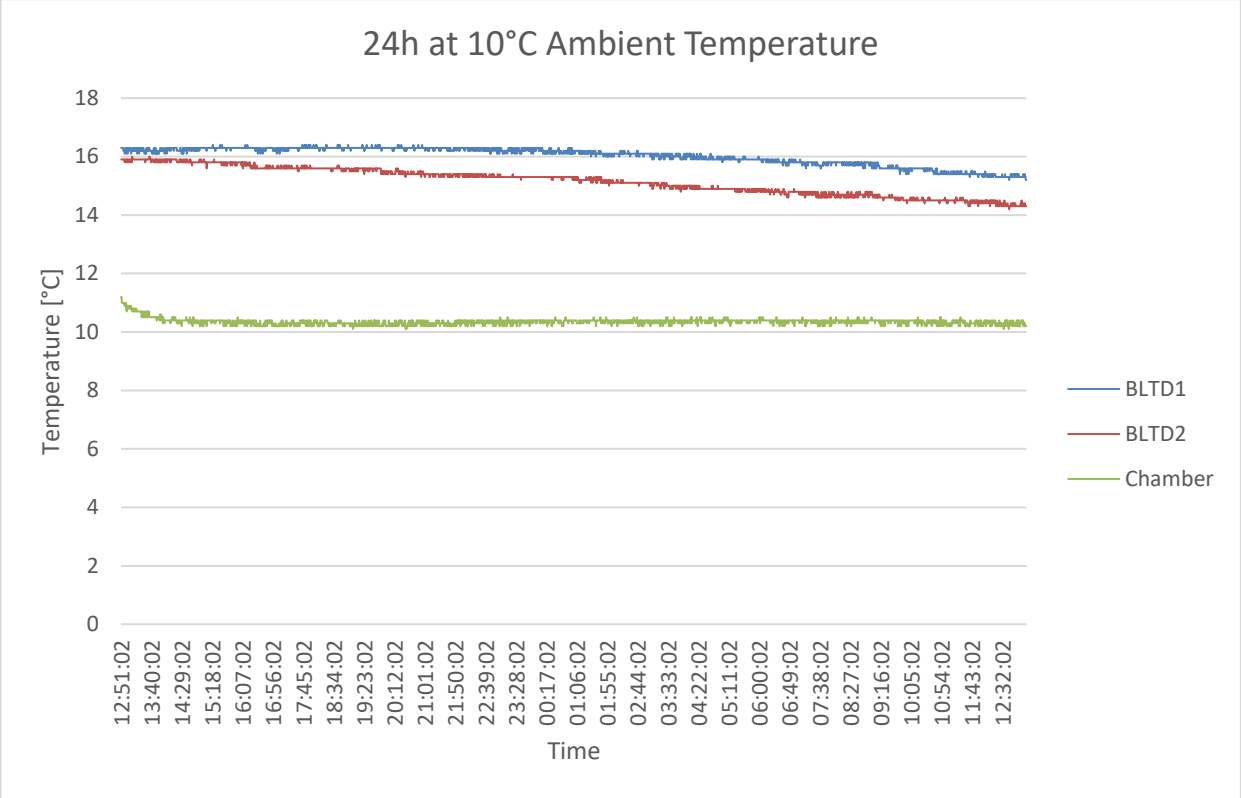
6.5 Measuring diagrams of the temperature storage test Run 5



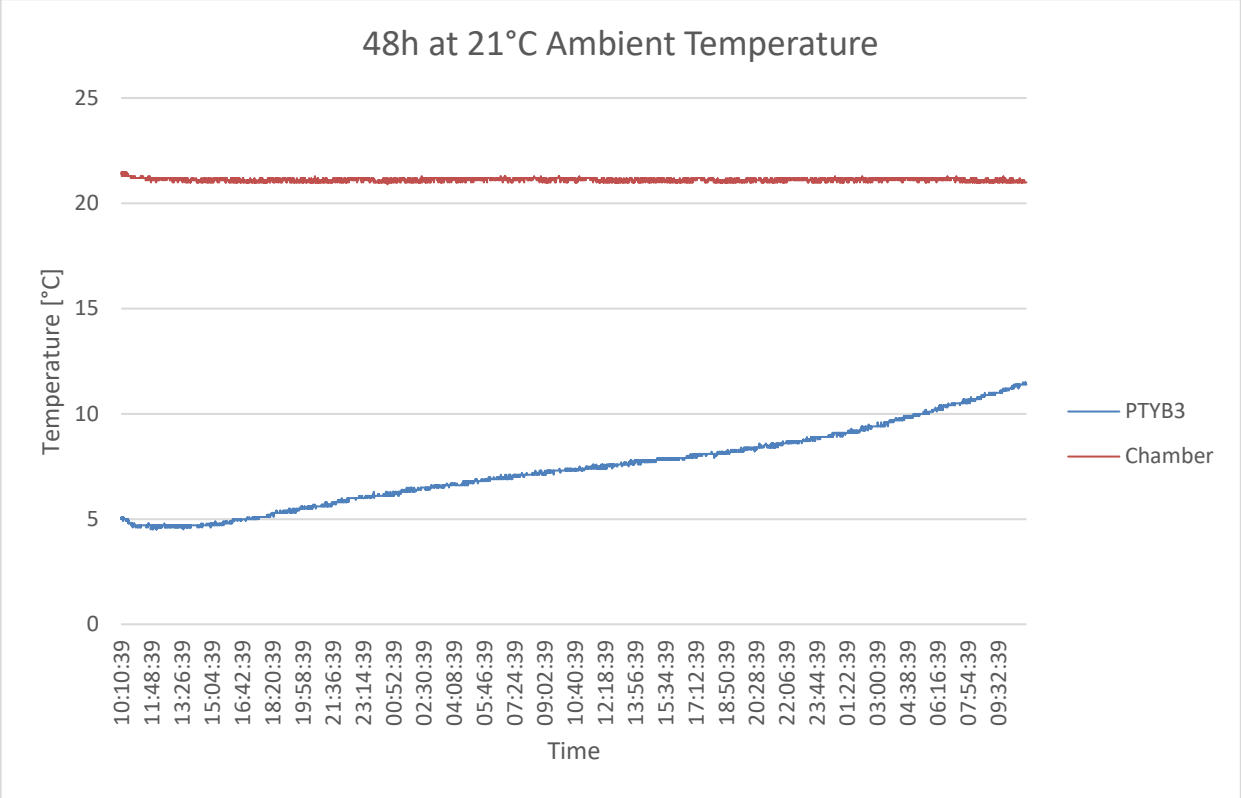
6.6 Measuring diagrams of the temperature storage test Run 6



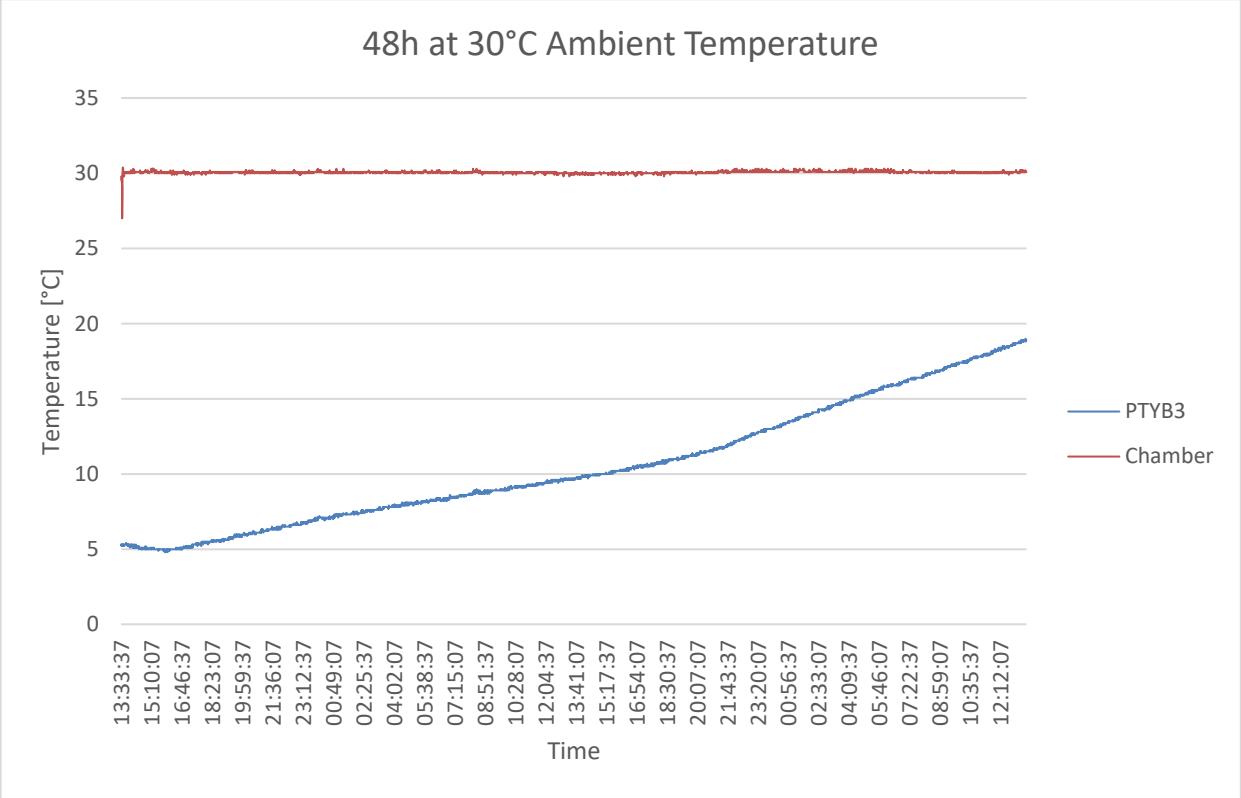
6.7 Measuring diagrams of the temperature storage test Run 7



6.8 Measuring diagrams of the temperature storage test Run 8



6.9 Measuring diagrams of the temperature storage test Run 9



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7 Photo documentation

1. Loading PYTB1

2. Loading PYTB1

3. Loaded PYTB1 in Temperature chamber

4. Loading PYTB2

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5. Loaded PYTB2 in Temperature chamber

6. Loading PYTB3

7. Loaded PYTB3 in Temperature chamber

8. Loaded BLTD1

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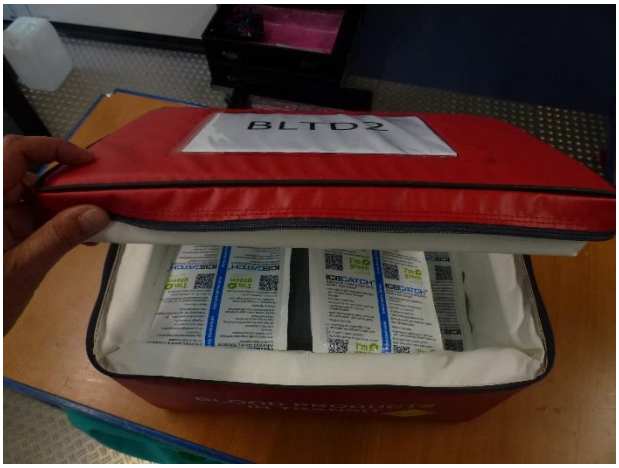
9. Loaded BLTD1 in Temperature chamber



10. Loading BLTD2

11. Loaded BLTD2 in Temperature chamber

12. Run 1 in Temperature chamber

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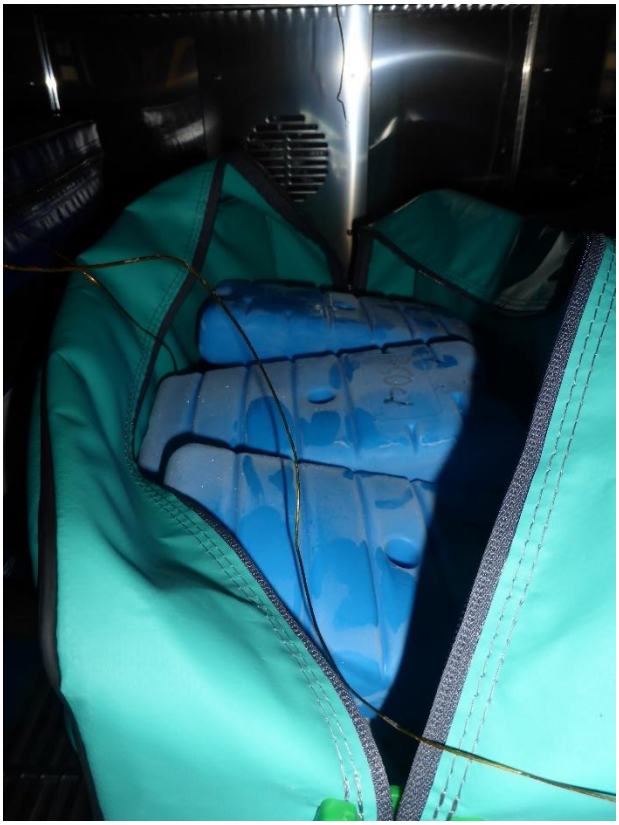
13. Loaded PYBHM



14. Loaded CCBX PHCY

15. Loaded VFT6999FRDG_T2

16. Run 6 in Temperature chamber

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17. PYTB1 before drop test

18. PYTB1 after drop test opened, no damages

19. PYTB2 before drop test

20. PYTB2 after drop test opened, no damages

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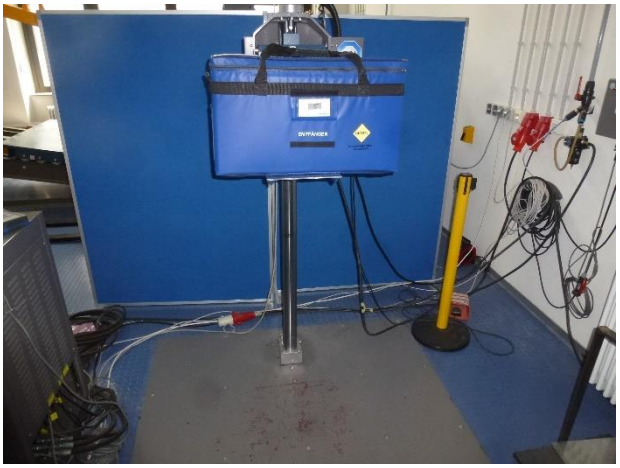
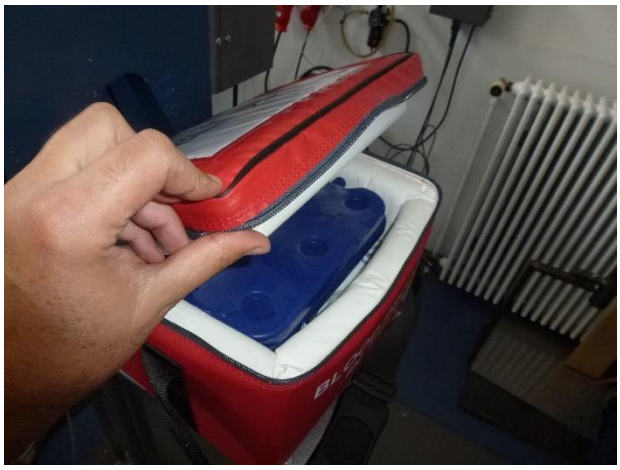


21. PYTB3 before drop test

22. PYTB3 after drop test opened, no damages

23. BLTD1 before drop test



24. BLTD1 after drop test opened, no damages

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25. BLTD2 before drop test

26. BLTD2 after drop test opened, no damages

27. PYBHM before drop test

28. PYBHM after drop test opened, no damages

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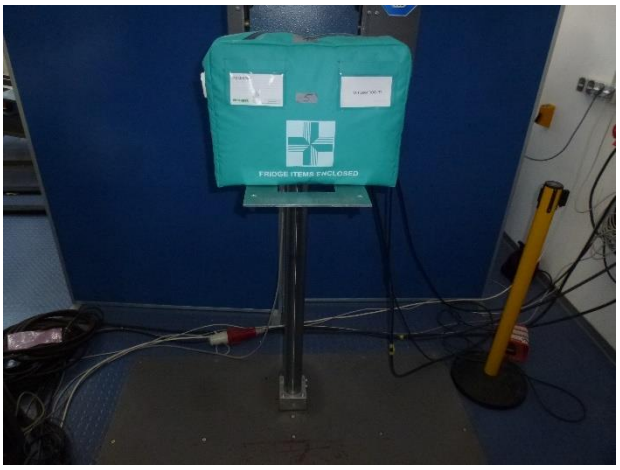
29. CCBX PHCY before drop test

30. CCBX PHCY after drop test opened, no damages



31. VFT6999FRDG_T2 before drop test

32. VFT6999FRDG_T2 after drop test opened, no damages

Verified	Edited
SIGN-ID 701797 22.09.2022 **Uwe Marlok**	***SIGN-ID 701592*** 22.09.2022 **Haridimos Mountogianakis**
Reviewer	Test Engineer

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