

Conformity Certification

Report Identification	Report No.	192133	
	Test description	Conformity test of a Bowie-Dick-Simulation test according to DIN EN ISO 11140-4 for processes at 121 °C.	
	International standards	DIN EN ISO 11140-4:2007 DIN EN 285:2016	
	Operation procedure No	AA 6.2-10-01 AA 6.2-10-02 PA 6.2-10-03	
	Date of receipt	2019-07-05	(YYYY-MM-DD)
	Date of issue	2019-09-17	(YYYY-MM-DD)
	Processing time	2019-05-08 - 2019-09-13	(YYYY-MM-DD)
	Order no.	202093	
Test laboratory	Address of record	SAL-GmbH Auf der Lind 10 65529 Waldems Esch	
Customer	Address	Ellab A/S Trollesmindealle 25 3400 Hillerød Denmark	
Conformity assessment	Process	Result	
	DIN EN ISO 11140-4, Annex B; Process B1 at 121 °C	CONFORM	
	DIN EN ISO 11140-4, Annex B; Process B2 at 121 °C	CONFORM	
	DIN EN ISO 11140-4, Annex B; Process B3 at 121 °C	CONFORM	


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The results are valid exclusively for the tested sample and are reproducible only under the exact conditions under which they were determined. For further information, do not hesitate to contact us.
Thank you for your order.

Waldems, 2019-09-17 (YYYY-MM-DD)



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Introduction

Laboratory report of SAL-GmbH, test laboratory accredited by the German accreditation body (Deutsche Akkreditierungsstelle GmbH) according to DIN EN ISO/IEC 17025 and Council 93/42/EWG and 90/385/EWG.

The accreditation is only valid for the scope specified by the annex to the accreditation certificate [D-PL-18398-02-01]. The German accreditation body is signatory to the multilateral agreements of the EA (European Co-operation for Accreditation), ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum) for the mutual recognition of laboratory reports.

Sample Identification

Description Ellab Electronic BD-Tester
 Manufacturer Ellab A/S; Denmark
 Serial-No. Data logging unit: 401180, 401193, 401174, 401186, 401168
 PCD: 66304970
 Picture



Test equipment

330-035 P	Type of equipment Manufacturer Type Serial-No.	Test sterilizer Lautenschläger, Germany ZentraCERT 1144
330-024 P	Type of equipment Manufacturer Type Serial-No.	Data logging unit Ahlborn, Germany A5690-2C KL A08110217/00
330-024 P	Type of equipment Manufacturer Type Serial-No.	Thermocouples Ephymess, Germany 925105832942000 (NA)---
310-014 P	Type of equipment Manufacturer Type Serial-No.	Pressure sensor JUMO, Germany 4364-242/091 109638
310-029 P	Type of equipment Manufacturer Type Serial-No.	Balance KERN, Germany 572-57 85176200
330-032 P	Type of equipment Manufacturer Type Serial-No.	Humidity and temperature measurement Wiesmann & Thies, Germany 57613 85176200

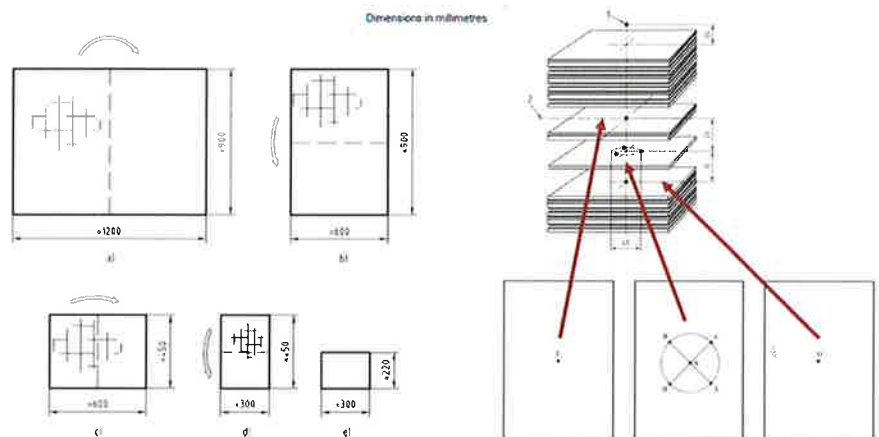
330-010 P	Type of equipment	Temperature calibration oven
	Manufacturer	ISOTECH, USA
	Type	Drago Basic
	Serial-No.	38007/1

Test approach Reference Test pack The equivalence test is carried out with the standard cotton test package according to DIN EN 285 and DIN EN ISO 11140-4.

The test package is composed of plain cotton sheets, each bleached to white and having approximate dimensions of 900 mm x 1200 mm. The number of threads per centimeter in the warp is 30 ± 6 and the number of threads in the weft is 27 ± 5 . The areic mass is $185 \pm 5 \text{ g/cm}^2$. The edges which are not selvages are not hemmed.

The sheets were not subjected to any fabric conditioning agent during laundering and have a relative humidity of 40 % to 60 % and a temperature between 20 °C to 30 °C. They are folded and equilibrated for at least 2 h under the above mentioned conditions prior to testing.

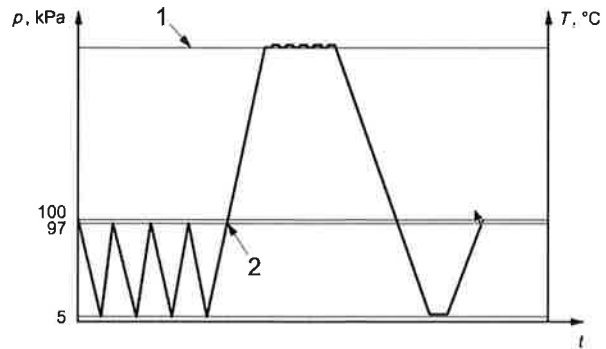
After equilibration the sheets are folded to approximately 220 mm x 300 mm and stacked to a height of 200 - 250 mm after compression by hand. The pack is wrapped in a similar fabric and secured with tape not exceeding 25 mm in width. Afterwards the package is weighted. The total mass of the pack is $7,0 \text{ kg} \pm 2 \%$.



After processing, the pack is aired. After airing and prior to use, the inner conditions of the pack have to be within 20 °C to 30 °C and 40 % to 60 % relative humidity.

Test cycles Detailed description of the test cycles can be found in DIN EN ISO 11140-4, Annex B:

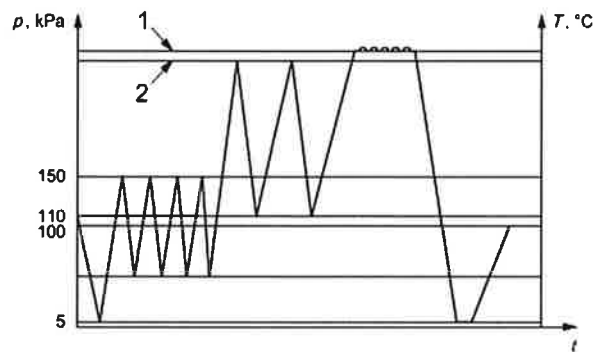
Cycle B1:



Key

- 1 set operating pressure (kPa)
- 2 air injection

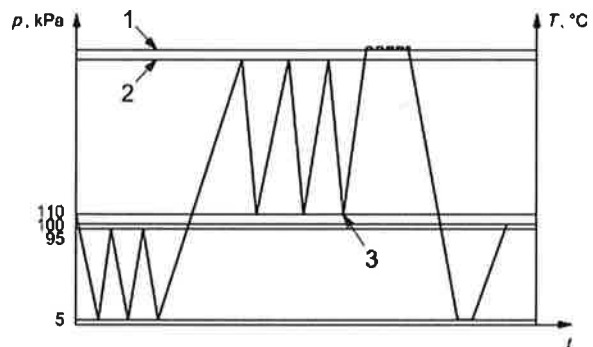
Cycle B2:



Key

- 1 set operating pressure
- 2 set operating pressure minus 10 kPa

Cycle B3:



Key

- 1 set operating pressure (kPa)
- 2 set operating pressure minus 20 kPa
- 3 air injection

All test cycles are carried out with the following specification:

Pressure change rate: 100 kPa/min

Sterilization temperature: 121 °C -0K/+1,5K¹

Exposure period: 15:00 min ± 5 s

According to DIN EN ISO 11140-4, the following processes have to be carried out:

Test conditions	Cycles according to DIN EN ISO 11140-4, Annex B		
	B1	B2	B3
PASS	✓	✓	✓
FAIL modified air removal	✓	✓	✗
FAIL induced leakage	✓	✗	✗
FAIL air injection	✓	✗	✓

PASS-Cycles Three consecutive runs of both BD-test-pack and *Ellab BD-Test* are carried out according to the description of processes B1, B2 and B3 in DIN EN ISO 11140-4. Both the BD-test-pack and the *Ellab BD-Test* require to show a PASS result in order to achieve conformity.

FAIL-Cycles The reference fault condition for each fault scenario is created as follows:

Modified air removal:

The pressure setpoint of each subatmospheric evacuation step is raised in 2,5 kPa-steps, until the standard BD-pack shows a FAIL result.

Induced leak:

During a PASS cycle a defined leak is induced. The amount of air which flows into the chamber is increased by 10 L/h-steps until the BD-pack shows a FAIL-result.

Air injection:

Air is injected during the come-up period of the test process. The point in time of injection can be seen in the graph above. The amount of injected air is increased until the BD-pack shows a FAIL-result.

¹ Sterilizer temperature sensor output may be delayed in comparison to thermocouple measurement.

The reference fault conditions have to meet the following criteria according to ISO 11140-4:

- The elapsed time between the chamber attaining the set operating pressure and the chamber reference temperature attaining the set temperature shall not exceed 5s.
- At the time the chamber reference temperature attains the set temperature, the temperature measured in the standard test pack shall show a temperature depression of 2 K or greater.
- The temperature depression shall remain at 2 K or greater throughout the reference fault period.
- The test equilibration time shall be 90 s.
- The temperature depression at the beginning of the reference fault period shall be not greater than 7 K.
- The temperature depression at the end of the reference fault period shall be not greater than 4 K.
- The temperature depression at the end of the minimum permitted equilibration time shall be not greater than 2 K.
- The temperature depression at the end of exposure time, or 10 min, whichever is shorter, shall not be greater than 1 K.

To increase the safety level of the measurement, the fault conditions can be defined closer to the PASS result, which makes it harder for the test item to fulfill the requirements.

After successful iteration to a suitable FAIL condition, the BD-test pack has to show three FAIL results in three consecutive runs of the named process. Hence, the test item *Ellab BD-Test* also needs to show a FAIL in three consecutive runs.

Test result Results for process B1 according to DIN EN ISO 11140-4, Annex B:

Process	run	Result BD-test pack	run	Result Ellab BD-Test	Conform?
B1 PASS 1/3	2792	PASS	2817	PASS	CONFORM
B1 PASS 2/3	2793	PASS	2818	PASS	CONFORM
B1 PASS 3/3	2794	PASS	2819	PASS	CONFORM
B1 FAIL 1/3 Modified air removal 4 x 20,0 kPa – 97 kPa	2806	FAIL	2820	FAIL	CONFORM
B1 FAIL 2/3 Modified air removal 4 x 20,0 kPa – 97 kPa	2807	FAIL	2821	FAIL	CONFORM
B1 FAIL 3/3 Modified air removal 4 x 20,0 kPa – 97 kPa	2808	FAIL	2822	FAIL	CONFORM
B1 FAIL 1/3 Leakage, 20 L/h	2913	FAIL	2918	FAIL	CONFORM
B1 FAIL 2/3 Leakage, 20 L/h	2914	FAIL	2919	FAIL	CONFORM
B1 FAIL 3/3 Leakage, 20 L/h	2915	FAIL	2920	FAIL	CONFORM
B1 FAIL 1/3 Injection, 1L@1bar	2895	FAIL	2900	FAIL	CONFORM
B1 FAIL 2/3 Injection, 1L@1bar	2896	FAIL	2901	FAIL	CONFORM
B1 FAIL 3/3 Injection, 1L@1bar	2897	FAIL	2902	FAIL	CONFORM

Results for process B2 according to DIN EN ISO 11140-4, Annex B:

Process	run	Result BD-test pack	run	Result Ellab BD-Test	Conform?
B2 PASS 1/3	2823	PASS	2838	PASS	CONFORM
B2 PASS 2/3	2824	PASS	2839	PASS	CONFORM
B2 PASS 3/3	2825	PASS	2840	PASS	CONFORM
B2 FAIL 1/3 Modified air removal 5 x 50,0 kPa	2852	FAIL	2857	FAIL	CONFORM
B2 FAIL 2/3 Modified air removal 5 x 50,0 kPa	2853	FAIL	2858	FAIL	CONFORM
B2 FAIL 3/3 Modified air removal 5 x 50,0 kPa	2854	FAIL	2859	FAIL	CONFORM

Results for process B3 according to DIN EN ISO 11140-4, Annex B:

Process	run	Result BD-test pack	run	Result Ellab BD-Test	Conform?
B3 PASS 1/3	2828	PASS	2831*	PASS	CONFORM
B3 PASS 2/3	2829	PASS	2833	PASS	CONFORM
B3 PASS 3/3	2830	PASS	2834	PASS	CONFORM
B3 FAIL 1/3 Injection, 1L@1bar	2861	FAIL	2903	FAIL	CONFORM
B3 FAIL 2/3 Injection, 1L@1bar	2862	FAIL	2904	FAIL	CONFORM
B3 FAIL 3/3 Injection, 1L@1bar	2863	FAIL	2905	FAIL	CONFORM

*: run 2832 was a process with a malfunction of the sterilizer. See annex B3 PASS, sterilizer documentation. So, the processes 2831, 2833 and 2834 can be considered as consecutively.

Annex

- 1 Accreditation Certificate SAL GmbH
- 2 Results Process DIN EN ISO 11140-1; B1 at 121 °C
- 3 Results Process DIN EN ISO 11140-1; B2 at 121 °C
- 4 Results Process DIN EN ISO 11140-1; B3 at 121 °C
- 5 Calibration Certificates