

**REPORT ON THE MICROBIOLOGICAL AND
TEMPERATURE DISTRIBUTION TESTS IN THE
SINTION MICROWAVE DISINFECTOR/STERILIZER**

November 20th to 23rd 2006

($\frac{1}{4}$)

Contents

1 EXECUTIVE SUMMARY	4
1.1 NON SPECIFIED MEDICAL WASTES	4
1.2 RIGID GEL CONTAINERS	4
2 INTRODUCTION	4
3 AIM OF THE TEST RUNS	4
4 PRINCIPLE OF FUNCTION	5
5 METHODS AND MATERIALS	5
5.1 MICROBIOLOGICAL EFFICACY TESTING	5
5.2 TEMPERATURE RECORDING	5
5.3 TEST LOADS	6
5.3.1 Test Load A	6
5.3.2 Test Load B	7
5.3.3 Test Load C	8
6 TEST RUNS	9
6.1 TEST RUN SERIAL 1	9
6.1.1 Test Run 1.1	9
6.1.2 Test Run 1.2	10
6.2 TEST RUN SERIAL 2	11
6.2.1 Test Run 2.1	11
6.2.2 Test Run 2.2	11
6.2.3 Test Run 2.3	11
6.2.4 Test Run 2.4	12
6.2.5 Test Run 2.5	12
6.2.6 Test Run 2.6	12
6.2.7 Test Run 2.7	13
6.2.8 Test Run 2.8	13
7 RESULTS	14
7.1 CHARTS	14
7.1.1 Test Run Serial 1	14
7.1.2 Test Run Serial 2	14
7.2 MICROBIOLOGICAL TESTS	19

Images

<i>Figure 5-1: Drawing Load A</i>	6
<i>Figure 5-2: Load A</i>	6
<i>Figure 5-3: Draft Load B</i>	7
<i>Figure 6-1: Printout 6.1</i>	9
<i>Figure 6-2: Printout 6.2</i>	10
<i>Figure 7-1: TEST RUN NO. 2.1</i>	14
<i>Figure 7-2: TEST RUN NO. 2.2</i>	15
<i>Figure 7-3: TEST RUN NO. 2.3</i>	15
<i>Figure 7-4: TEST RUN NO. 2.4</i>	16
<i>Figure 7-5: TEST RUN NO. 2.5</i>	16
<i>Figure 7-6: Label 2.5</i>	16
<i>Figure 7-7: TEST RUN NO. 2.6</i>	17
<i>Figure 7-8: TEST RUN NO. 2.7</i>	17
<i>Figure 7-9: Label 2.7</i>	17

Figure 7-10: TEST RUN NO.2.8

18

Figure 7-11: Label 2.8

18

1 EXECUTIVE SUMMARY

1.1 NON SPECIFIED MEDICAL WASTES

The test runs applying SINTION programmes 3 and 4 achieved STAATT Level IV on all test strip positions

1.2 RIGID GEL CONTAINERS

The test runs 2.7 and 2.8, applying a not validated program version, partially achieved STAATT Level IV. The microbiological analysis method was only qualitative (growth or non-growth) and does not afford a quantification of the \log_{10} reduction when 6 \log_{10} was not reached.

The microbiological results were obtained in test runs which in subsequent comparison turn out as not having been the optimal choice.

As one important aim was to find the shortest effective cycle, the tests were to indicate the borderline of effectiveness. For loads of 4 pcs. of 500 ml containers this borderline looks to be at about 45 minutes applying the programme parameters of test run 2.4, which regrettably is not documented by spore strips.

For loads up to 3 pcs. of 2000 ml containers the borderline for meeting STAATT Level IV has to be expected at about 65 minutes, maybe even shorter, if a cycle variant as tested in test runs 2.4 and 2.5 could be applied with prolonged holding time.

2 INTRODUCTION

The tests were performed at the CMB factory and guided and microbiologically analyzed by the *INSTITUT FÜR KRANKENHAUSHYGIENE UND MIKROBIOLOGIE Graz*.

Treating rigid containers filled with gel or loose clusters of gel comes out to be a problem of physical restriction. The temperature chards in this test report visualise the fact that the core suffers from a heavy temperature delay as long as the energy only penetrates from the surface. This certainty was to expect out of theoretical cognitions. Therefore mere autoclaving has got no chance to meet STAATT Level III in an acceptable time frame, when a gel body's diameter exceeds a few centimetres.

The SINTION's performance on gel bodies up to 120 mm in diameter and 230 mm in height shows results close to STAATT Level IV, and Level IV can obviously be afforded by a programme adaptation and a slight extention of the holding time if needed at all, as real terms hardly would bring as massive gel bodies as worst case tested.

As a result of the tests it can be said in accordance with the theories of warming, that the diameter of gel bodies increases the time constant of temperature equalization over proportional with increasing diameter. Destroying rigid bodies could aggravate the problem, as the free gel tends to form clusters.

3 AIM OF THE TEST RUNS

The aim was to prove the SINTION's capability to disinfect gel in rigid containers as well as in non specified medical wastes according to STAATT Level III. This requires a *G stearothermophilus* or *B subtilis* reduction rate of 4 \log_{10} .

4 PRINCIPLE OF FUNCTION

The SINTION combines the technique of sterilization by saturated steam with that by microwave-generated heat.

In the first case, the thermal energy is supplied by condensing steam to the surface of the wastes. From there it diffuses into the depth, influenced by thermal conductivity, convection, situation e.g.

In case of heating with microwaves, microwave absorbing materials convert the electromagnetic energy into thermal energy. The electromagnetic field is influenced by geometry, situation of absorbers, dielectric constants e.g. Heating occurs into the wastes themselves and heat spreads by thermal conductivity from favoured areas to such in sections of weaker field or shielded ones.

The main absorbing material in the SINTION is water molecules.

5 METHODS AND MATERIALS

5.1 MICROBIOLOGICAL EFFICACY TESTING

Spore probes containing *B atrophaeus* and *G stearothermophilus* (population $1,0 \times 10^6$, Lot 54 2501 Exp 07/07) were used throughout this test.

They were used in form of strips and single edged hollow bodies.

5.2 TEMPERATURE RECORDING

The used tempearture recording equipment was:

- 3 pcs.Thermocouples type K
- Extension wires to datalogger
- Datalogger Fluke HYDRA Serie 2-2645 A
- Laptop with recorder software

The datalogger in common with the thermocouples was calibrated on 2006-04-19 by

Sensotech Mess- und Regeltechnik
Kalsdorfer Straße 48
A-8073 Feldkirchen

and the results journalized in *TESTO Kalibrierschein Calibration No. 038116*

5.3 TEST LOADS

5.3.1 Test Load A

Test load A was used to approve the SINTION's competency to disinfect non specific clinical waste according to STAATT Level III.

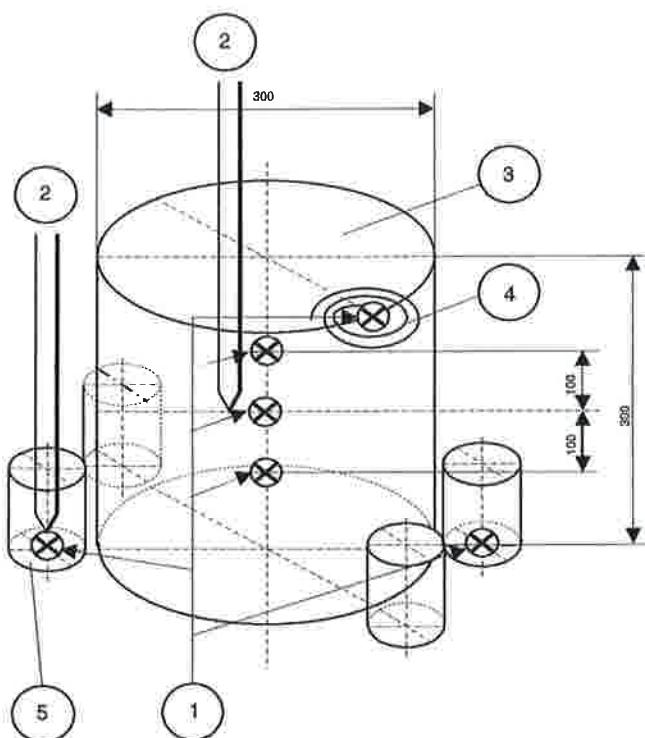


Figure 5-1: Drawing Load A

1. Spore Strip
2. Thermocouple in center of cellulose packing
3. Thermocouple in glass bottle
4. Cellulose packing
5. Hollow body
6. 500 ml glass bottles, Ø 120 mm x 230 mm



Figure 5-2: Load A

5.3.2 Test Load B

Test load B was used to approve the SINTION's competency to disinfect gel in smaller rigid containers according to STAATT Level III.

Vernagel absorbent powder was used as the solidifying agent (Vernacare, Folds Road, Bolton BL 2 2TX). Each sachet solidifies 350 ml, therefore 1,5 sachets were used in a full 500 ml container.

The containers were placed on the bottom of the treatment chamber. Three of them had been filled with jelly. Into the empty fourth one the thermocouples and spore strips fixed on delicate pillars of 1-mm-NiCr-wire were placed and then the container doped with 1,5 sachets of Vernagel and filled with water.

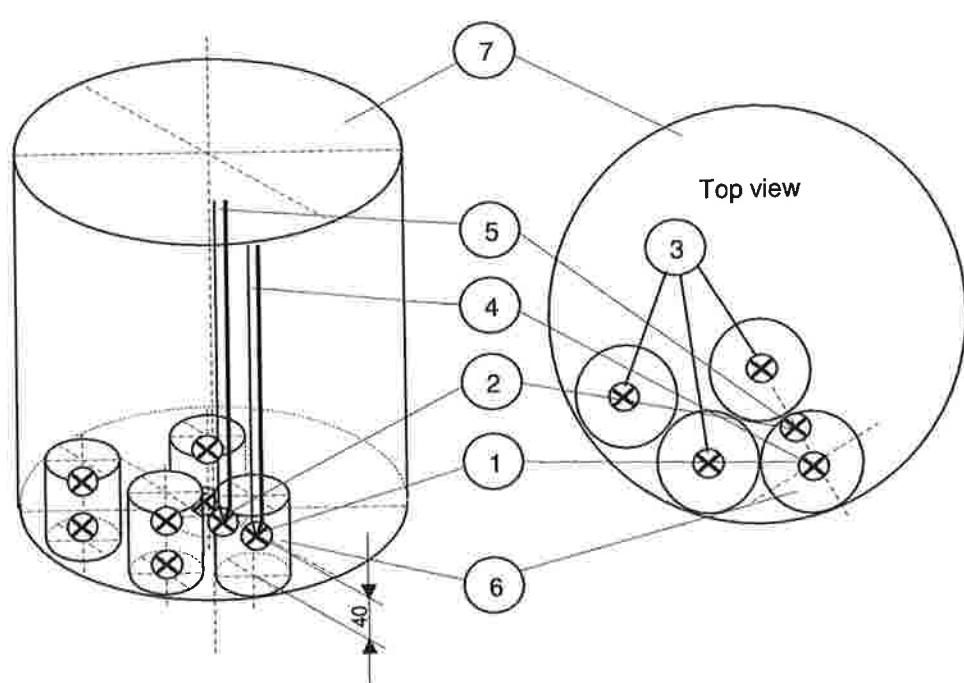


Figure 5-3: Draft Load B

1. Spore strip in centreline
2. Spore strip in near-mantle layer
3. Two spore strips, one 40mm and the second 80 mm above bottom
4. Thermocouple in centreline
5. Thermocouple in near-mantle layer
6. 500 ml polypropylene container, Ø 70 mm x 140 mm
7. Treatment chamber

5.3.3 Test Load C

Test Load C was used to approve the SINTION's competency to disinfect gel in large rigid containers according to STAATT Level III.

Vernagel absorbent powder was used as the solidifying agent (Vernacare, Folds Road, Bolton BL 2 2TX). Each sachet solidifies 350 ml, therefore 5 sachets were used in a full 2000 ml container.

The containers were placed on the bottom of the treatment chamber. Two of them had been filled with jelly. Into the empty third one the thermocouples and spore strips fixed on delicate pillars of 1-mm-NiCr-wire were placed and then the container doped with 5 sachets of Vernagel and filled with water.

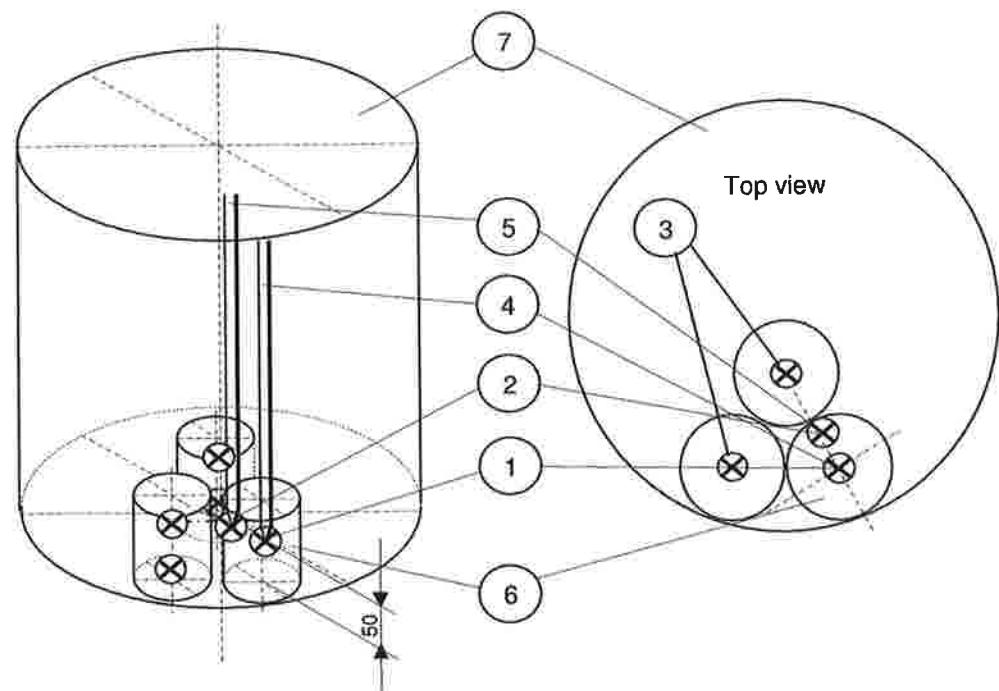


Figure 5-4: Draft Load C

1. Spore strip in centreline
2. Spore strip in near-mantle layer
3. Two spore strips 60 resp. 150mm high
4. Thermocouple in centreline
5. Thermocouple in near-mantle layer
6. 2000 ml glass container
7. Treatment chamber

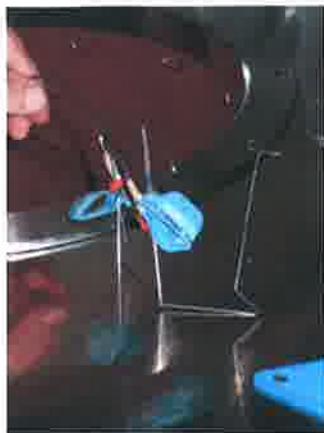


Figure 5-5: Fixation

6 TEST RUNS

6.1 TEST RUN SERIAL 1

6.1.1 Test Run 1.1

Test run parameters:

Test Load A
SINTION programme 3 (validated for disinfection)

```
***** SINTION 1.1 ** CMB-Austria ****
Ser.Nr.: 06/09/001      Charge: 000023

Betriebsparameter:
VD=2    BD= 2.10 bar (121°C)  Hz=0360 sec
p(V1)=0.15 bar           p(O1)=1.20 bar
p(V2)=0.30 bar           p(O2)=2.10 bar

Datum: 06-11-20
Start: 11:52  Ende: 12:20  Dauer: 27:51
effektive Hz: 0683 sec
----- DESINFEKTION OK -----
```

Figure 6-1: Printout 6.1

6.1.2 Test Run 1.2

Test run parameters:

Test Load A
SINTION programme 4 (validated for sterilization))

***** SINTION 1.1 ** CMB-Austria *****
Ser. No. 06/09/001 Load: 000027

operation parameter
VS=2 OP= 2.90 bar (132'C) HT=0360 sec
p(V1)=0.15 bar p(S1)=1.20 bar
p(V2)=0.30 bar p(S2)=2.90 bar

date: 06-11-20
start: 14:33 end: 15:11 dura.: 37:27
holding time: 1404 sec
----- STERILIZATION OK -----

Figure 6-2: Printout 6.2

6.2 TEST RUN SERIAL 2

6.2.1 Test Run 2.1

Test run parameters:

Test Load C without spore strips
SINTION programme 5

- VD 2
- p(V1) 0,15 bar_{abs}
- p(S1) 1,25 bar_{abs}
- p(V2) 0,30 bar_{abs}
- p(S2) 2,70 bar_{abs}
- OP 2,70 bar_{abs}
- Temp 130 °C
- HT 1800 sec

6.2.2 Test Run 2.2

Test run parameters:

Test Load C without spore strips
SINTION programme 5

- VD 1
- p(V1) 0,15 bar_{abs}
- p(S1) 1,25 bar_{abs}
- OP 2,70 bar_{abs}
- Temp 130 °C
- HT 1200 sec

6.2.3 Test Run 2.3

Test run parameters:

Test Load B without spore strips
SINTION programme 5

- VD 2
- p(V1) 0,15 bar_{abs}
- p(S1) 1,25 bar_{abs}
- p(V2) 0,30 bar_{abs}
- p(S2) 2,70 bar_{abs}
- OP 2,70 bar_{abs}
- Temp 130 °C
- HT 1200 sec

6.2.4 Test Run 2.4

Test run parameters:

Test Load B without spore strips

SINTION programme 5

- VD 2
- p(V1) 0,15 bar_{abs}
- p(S1) 1,25 bar_{abs}
- p(V2) 0,30 bar_{abs}
- p(S2) 2,70 bar_{abs}
- OP 2,70 bar_{abs}
- Temp 130 °C
- HT 1200 sec
- Pressure hysteresis 0,1 bar_{abs}

6.2.5 Test Run 2.5

Test run parameters:

Test Load C without spore strips

SINTION programme 5

- VD 2
- p(V1) 0,15 bar_{abs}
- p(S1) 1,25 bar_{abs}
- p(V2) 0,30 bar_{abs}
- p(S2) 2,70 bar_{abs}
- OP 2,70 bar_{abs}
- Temp 130 °C
- HT 1200 sec
- Pressure hysteresis 0,1 bar_{abs}

6.2.6 Test Run 2.6

Test run parameters:

Test Load C without spore strips

SINTION programme 5

- VD 1
- p(V1) 0,15 bar_{abs}
- p(S1) 1,25 bar_{abs}
- OP 2,70 bar_{abs}
- Temp 130 °C
- HT 1800 sec; stopped after all temperatures were equalizing at 130 °C for 16 min.

6.2.7 Test Run 2.7

Test run parameters:

- Test Load C
SINTION programme 5
- VD 1
 - p(V1) 0,15 bar_{abs}
 - p(S1) 1,25 bar_{abs}
 - OP 2,70 bar_{abs}
 - Temp 130 °C
 - HT 1800 sec

6.2.8 Test Run 2.8

Test run parameters:

- Test Load B
SINTION programme 5
- VD 1
 - p(V1) 0,15 bar_{abs}
 - p(S1) 1,25 bar_{abs}
 - OP 2,70 bar_{abs}
 - Temp 130 °C
 - HT 1200 sec

7 RESULTS

7.1 CHARTS

7.1.1 Test Run Serial 1

No chart available

7.1.2 Test Run Serial 2

- | | | |
|----------------------------------|--------------------|------------|
| 1. Treatment chamber temperature | °C | light blue |
| 2. Outer layer temperature | °C | dark blue |
| 3. Core temperature | °C | light blue |
| 4. Reference | 121 °C | green |
| 5. Treatment chamber pressure | bar _{abs} | red |

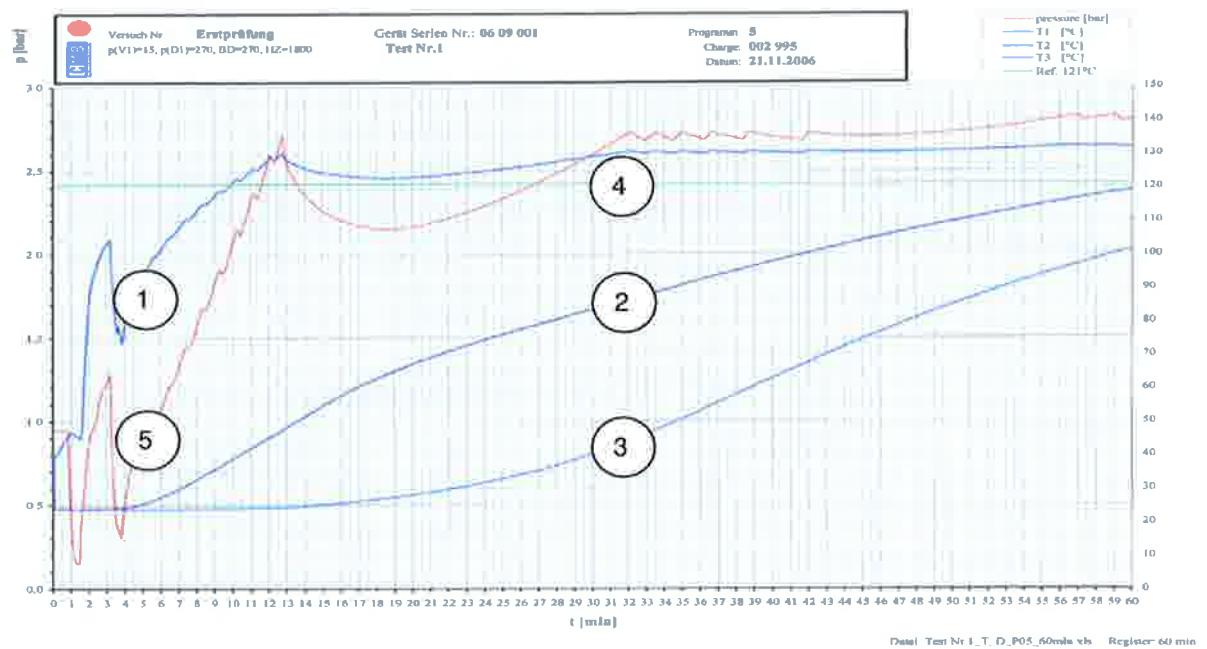


Figure 7-1: TEST RUN NO. 2.1

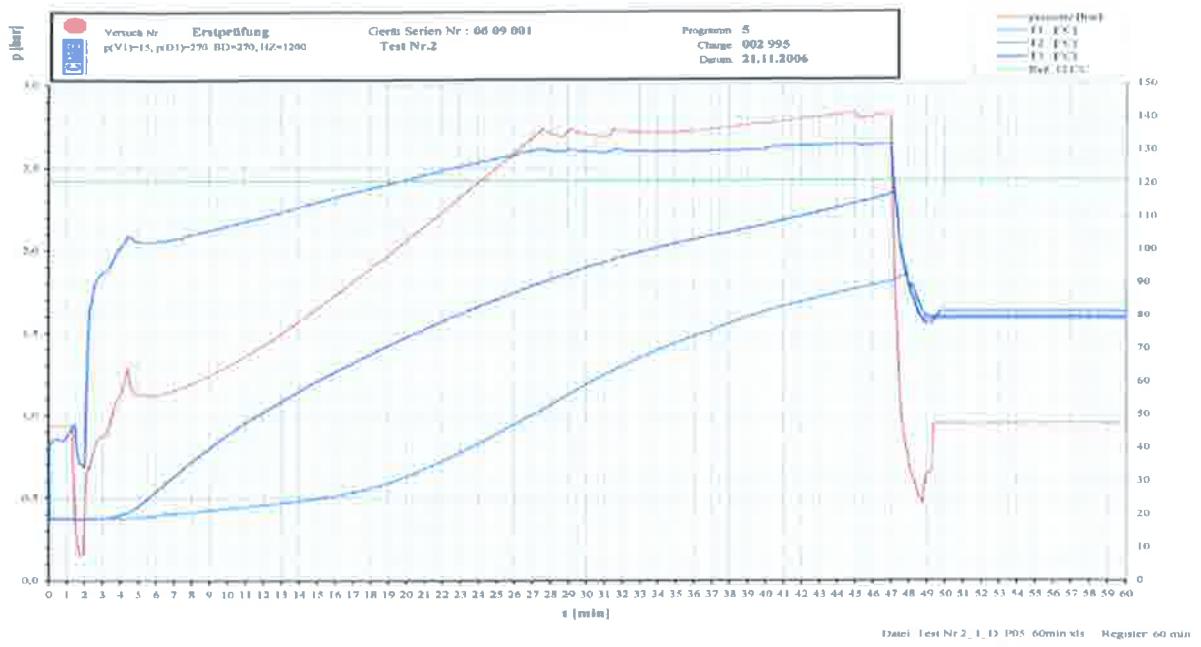


Figure 7-2: TEST RUN NO. 2.2

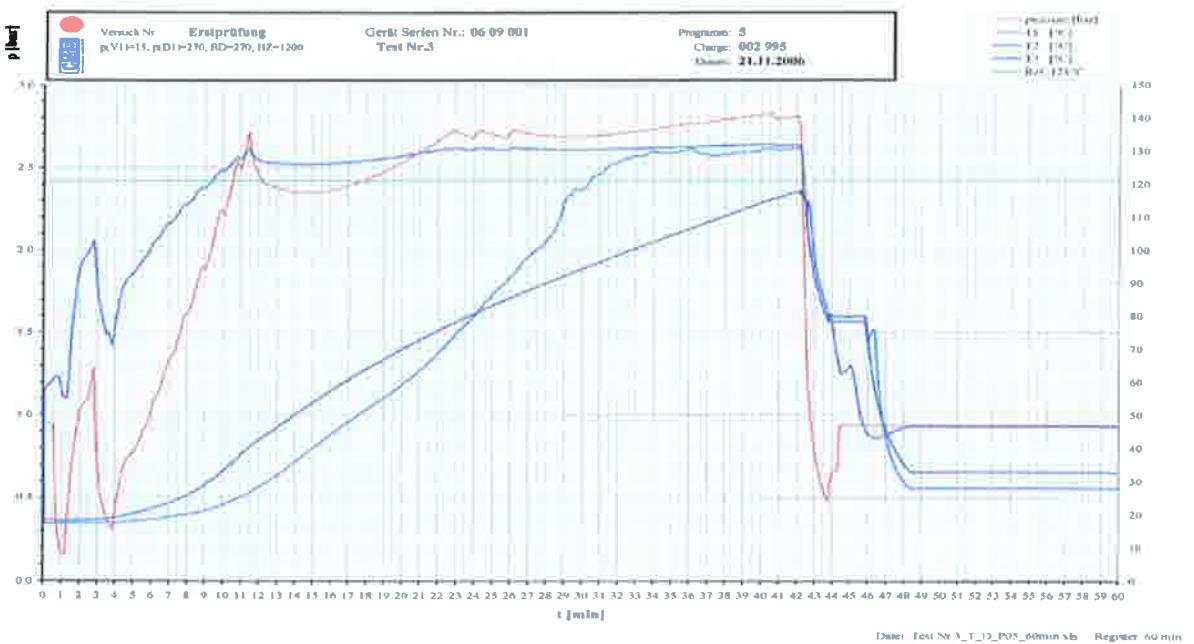


Figure 7-3: TEST RUN NO. 2.3

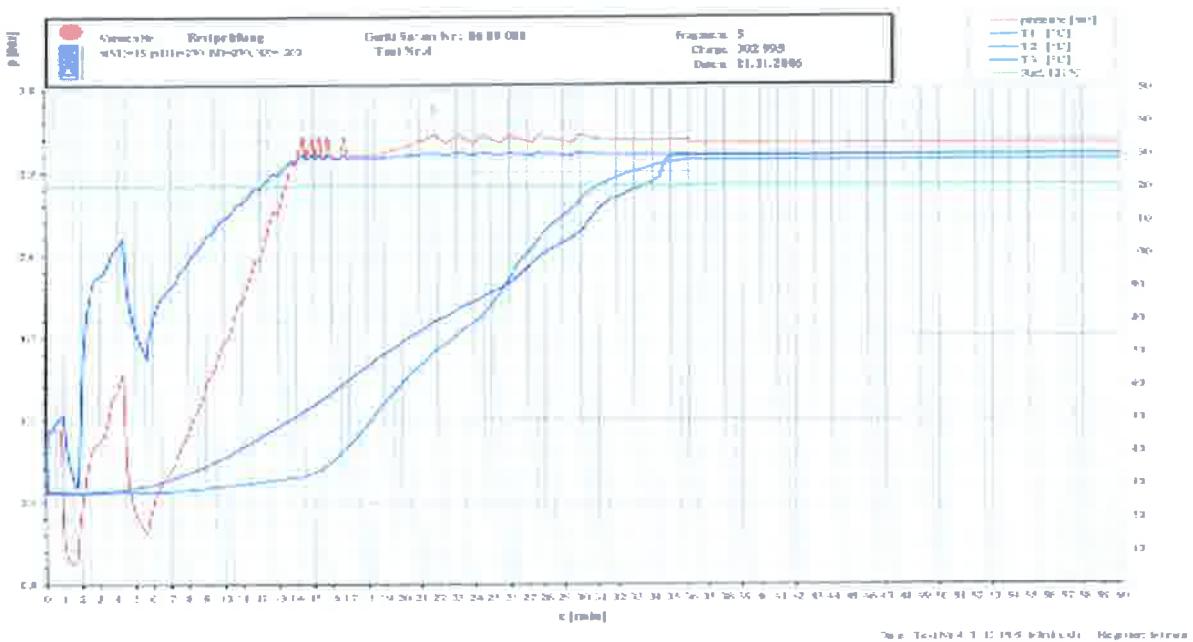


Figure 7-4: TEST RUN NO. 2.4

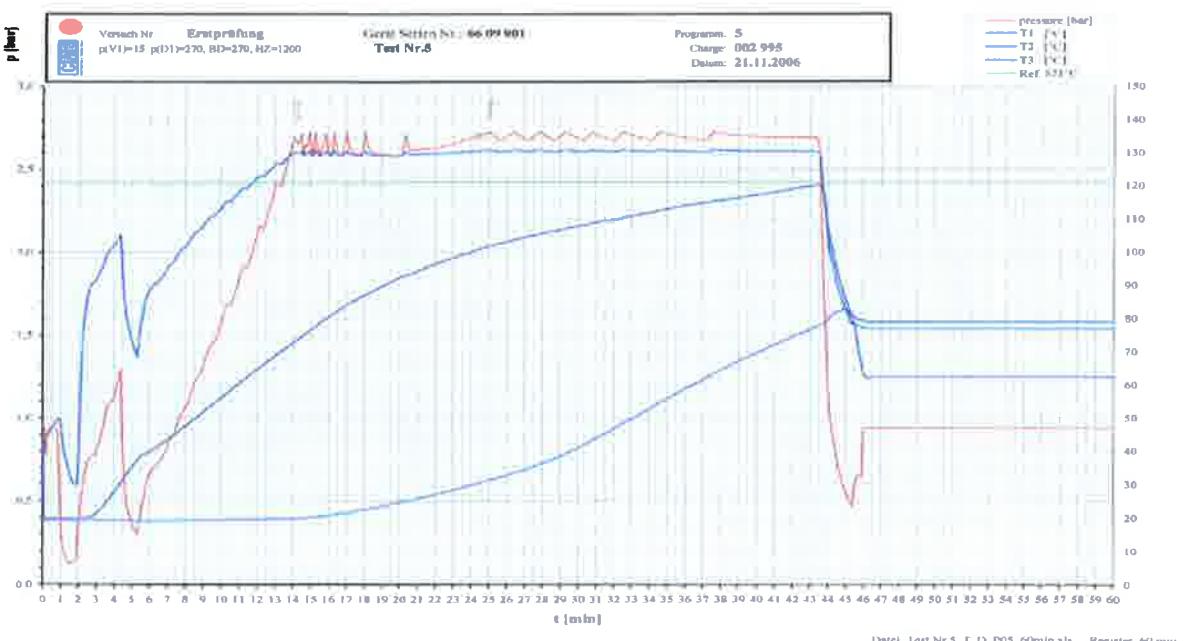


Figure 7-5: TEST RUN NO. 2.5

```

***** Sintion 1.1 *****
CMB   Ser. #: 06-09-051      Batch: 000000000035
US-2   Ops: 2-70bar(129 °C) holding time: 000120sec
       p(S1)=16bar             p(V2)=0-30bar
       p(S2)=2-70bar            p(V3)=0-30bar
PROGRAMME RUNS OK
Date: 06-11-21          Printed 06-11-21 18:55:48
start: 08:17    end: 10:00 duration: 01:43
HT: 000130sec
Weight: 3.70kg

```

Figure 7-6: Label 2.5

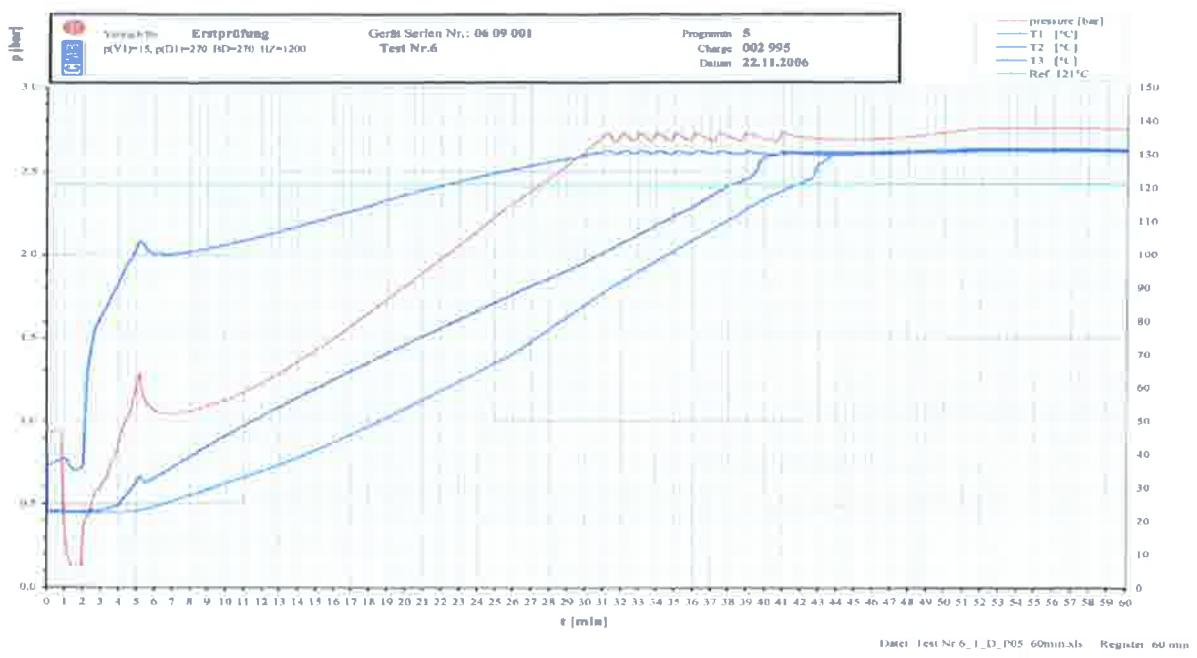


Figure 7-7: TEST RUN NO. 2.6

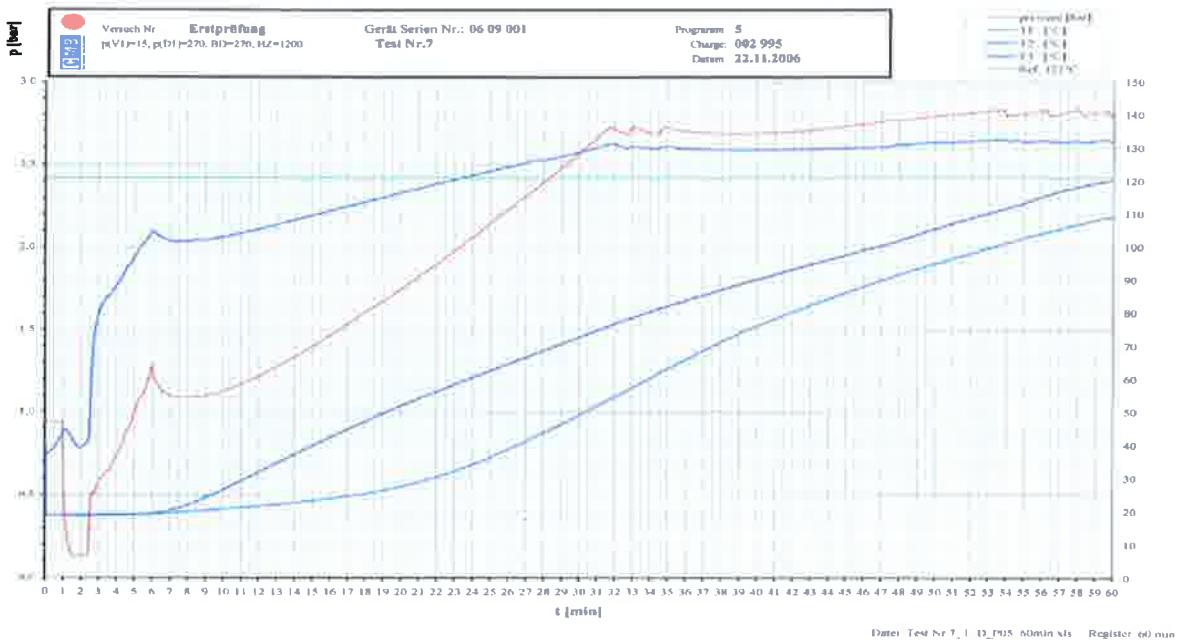


Figure 7-8: TEST RUN NO. 2.7



Figure 7-9: Label 2.7

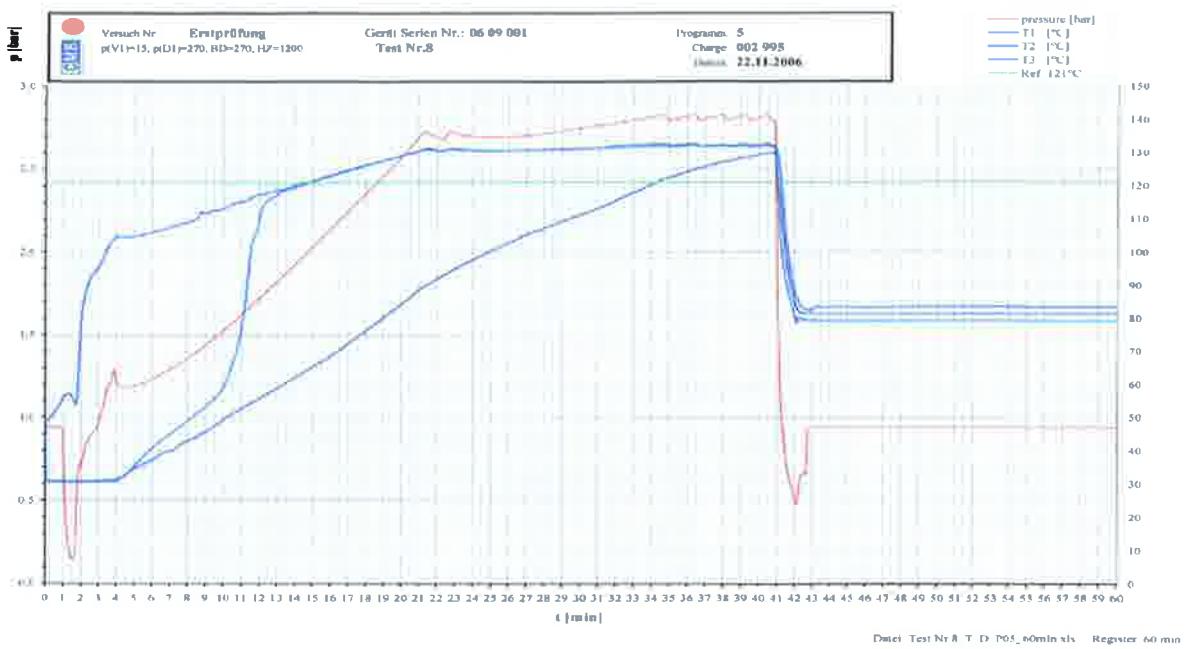


Figure 7-10: TEST RUN NO.2.8

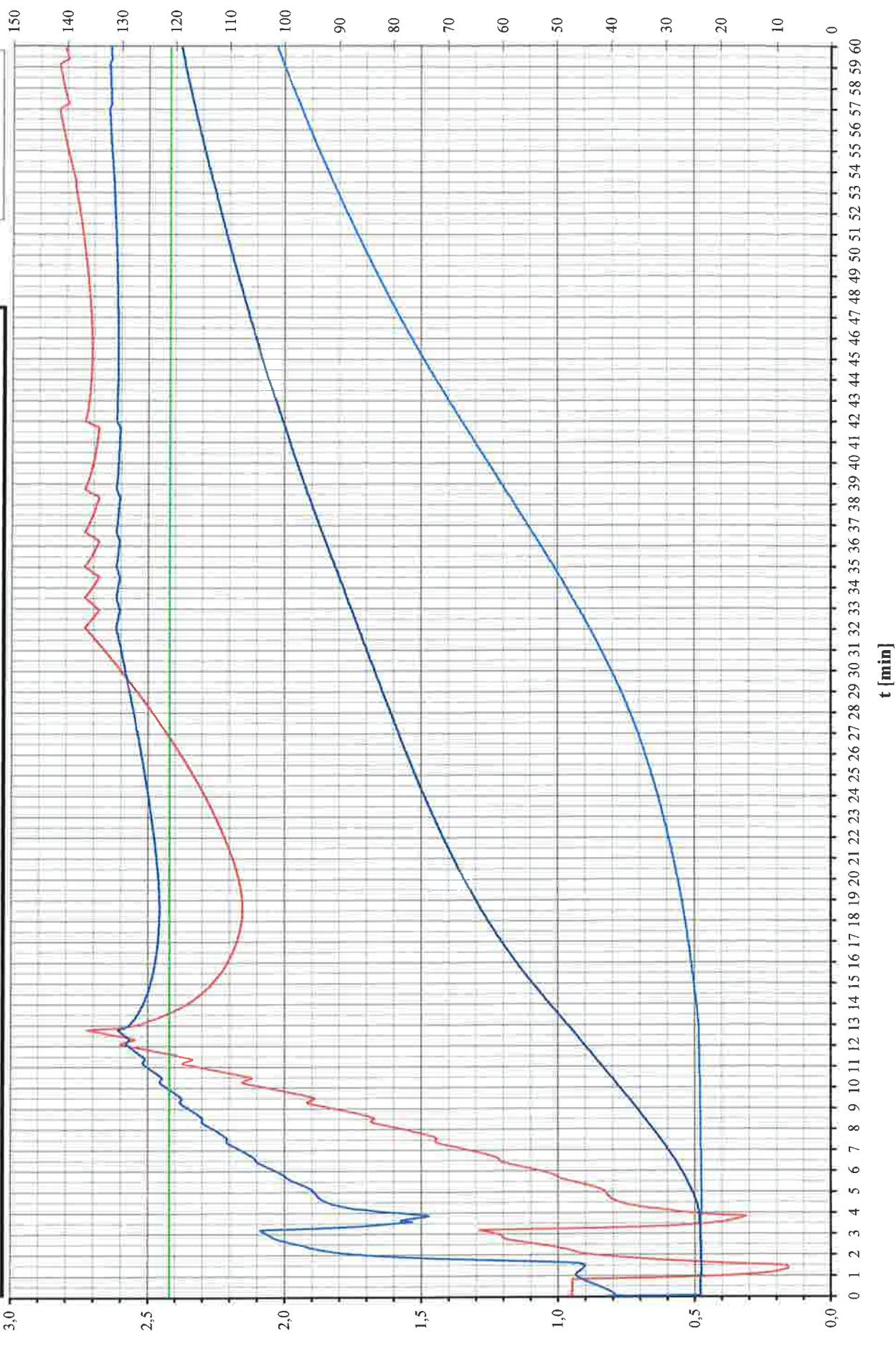
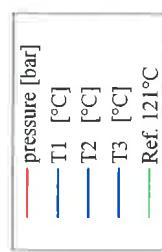
```

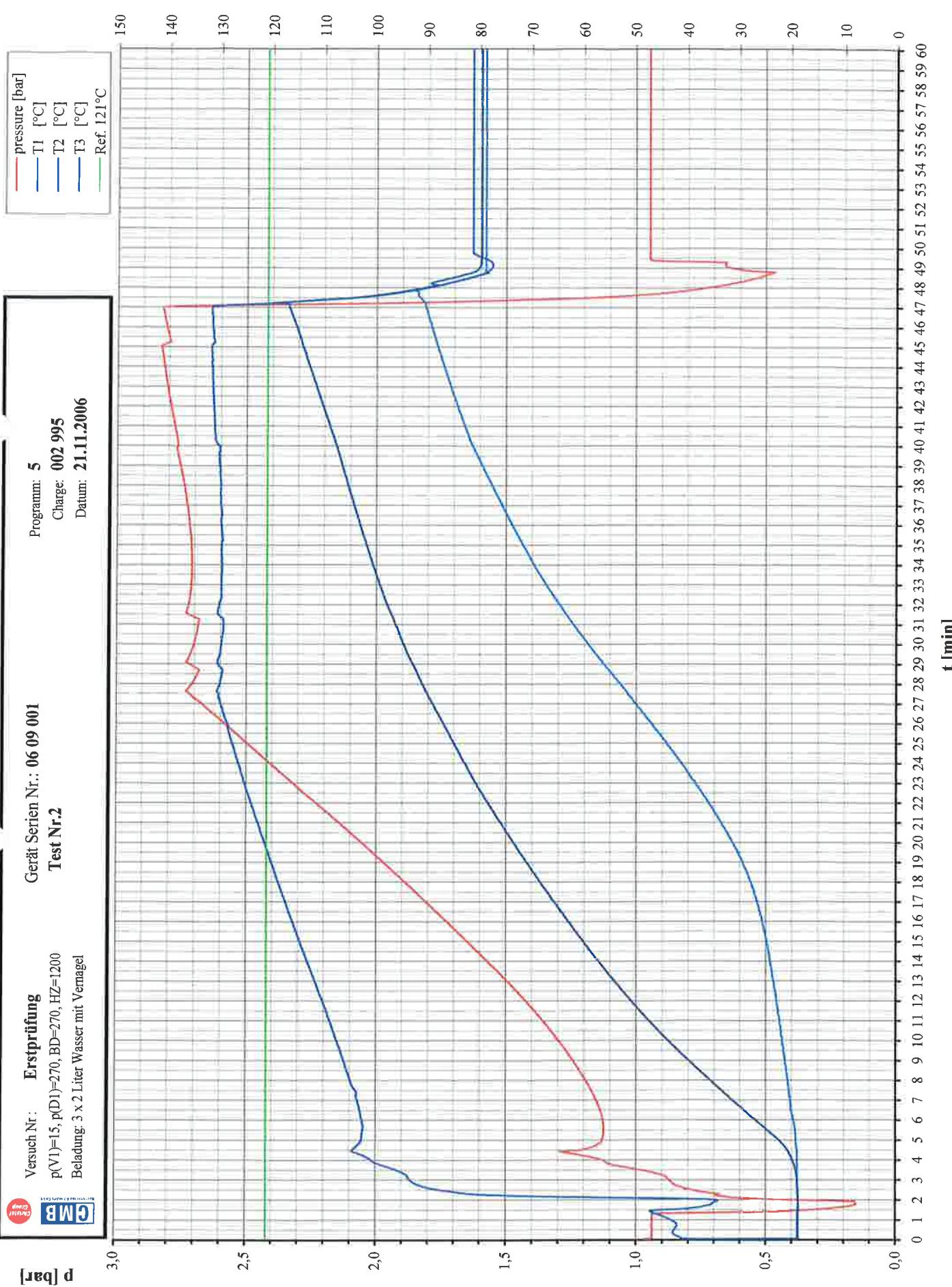
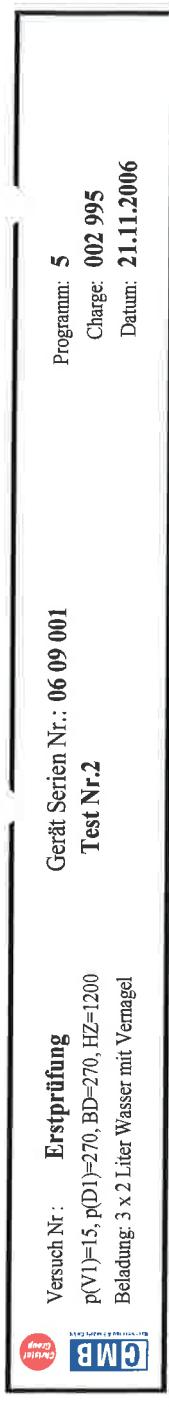
Sintion 1.1
CNB Sat. 06 24/11/2006 Load: 000000000038
05-1 06-2 08-1 29-0 Holding Time: 0001200sec
07-21,-0 15min pr(81)-1 Zoor
PROGRAMME RUNS OK
date: 06-11-22
07-21, 12-4 Am 12:56 duration: 40 sec
11-1 0001200sec
weight: 2.82kg printed: 06-11-22 12:49:24
CMD - Australia

```

Figure 7-11: Label 2.8

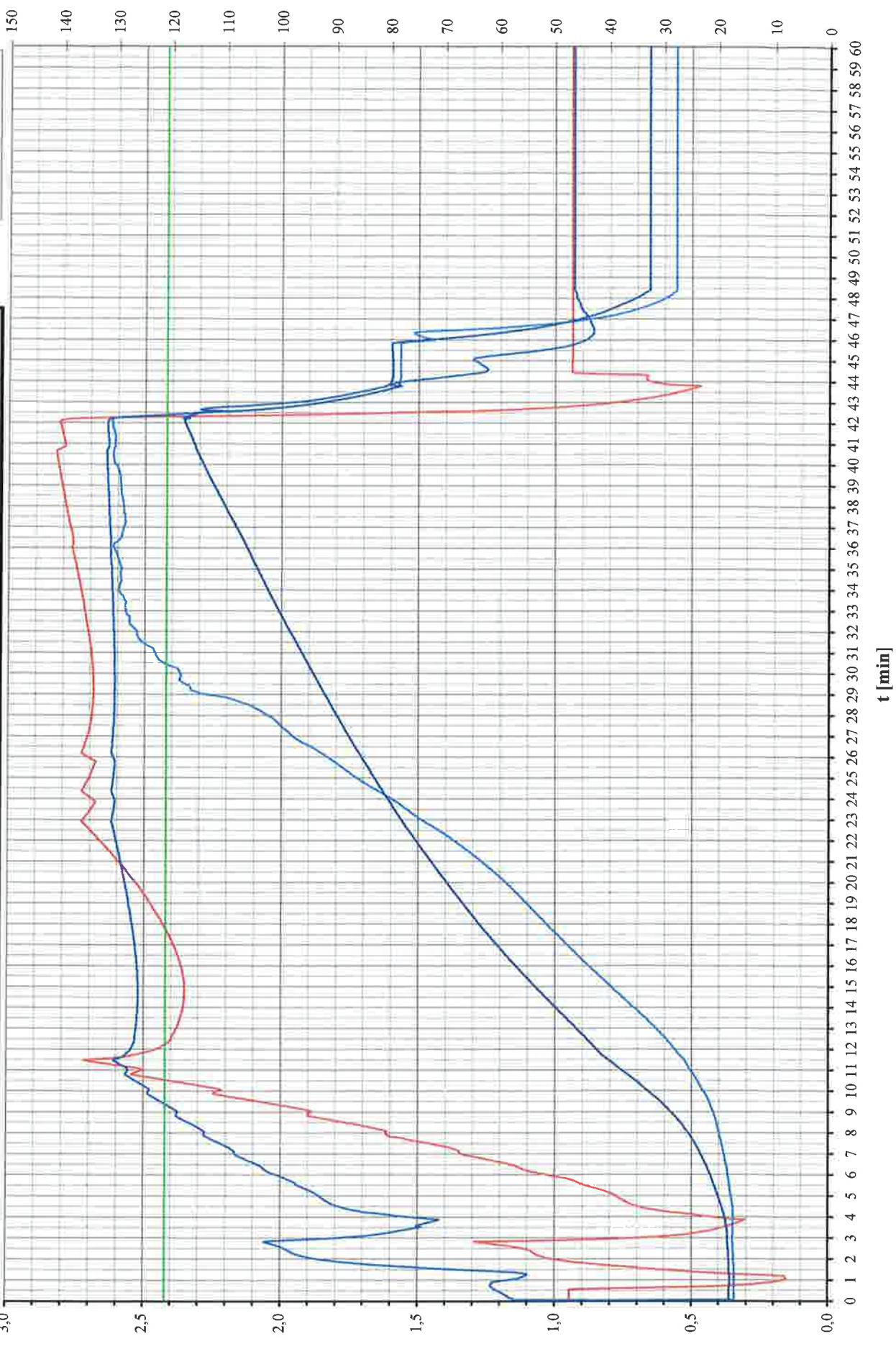
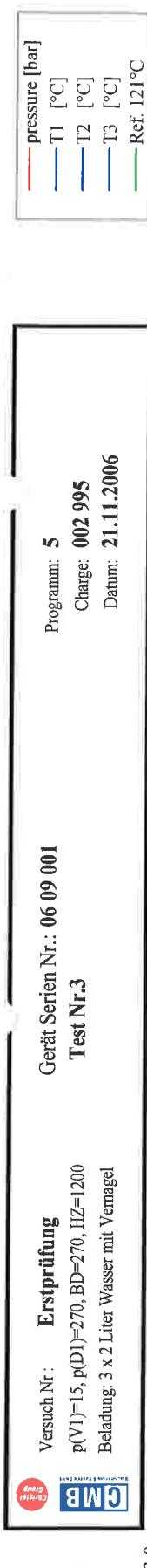
7.2 MICROBIOLOGICAL TESTS

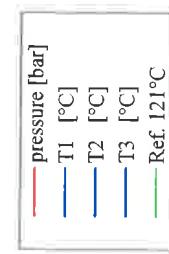




Datei: TestNr.2_T_D_P05_60min.xls Register: 60 min

t [min]



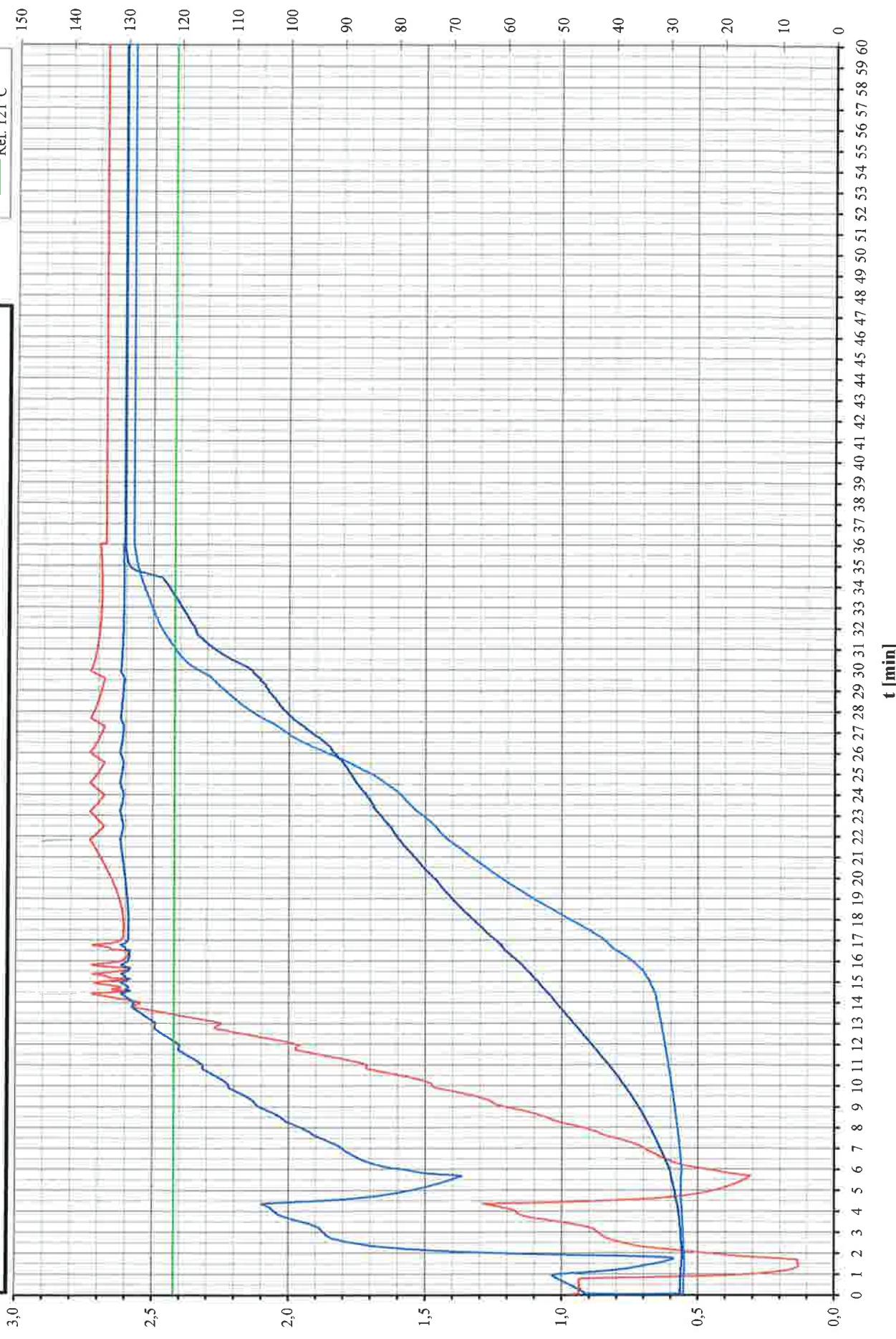


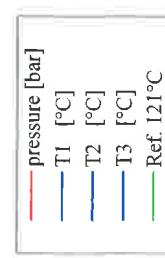
Programm: 5
 Charge: 002 995
 Datum: 21.11.2006

Versuch Nr.: 06 09 001
Erstprüfung
 $p(V1)=15, p(D1)=270, BD=270, HZ=1200$
 Beladung: 3 x 2 Liter Wasser mit Vernagel



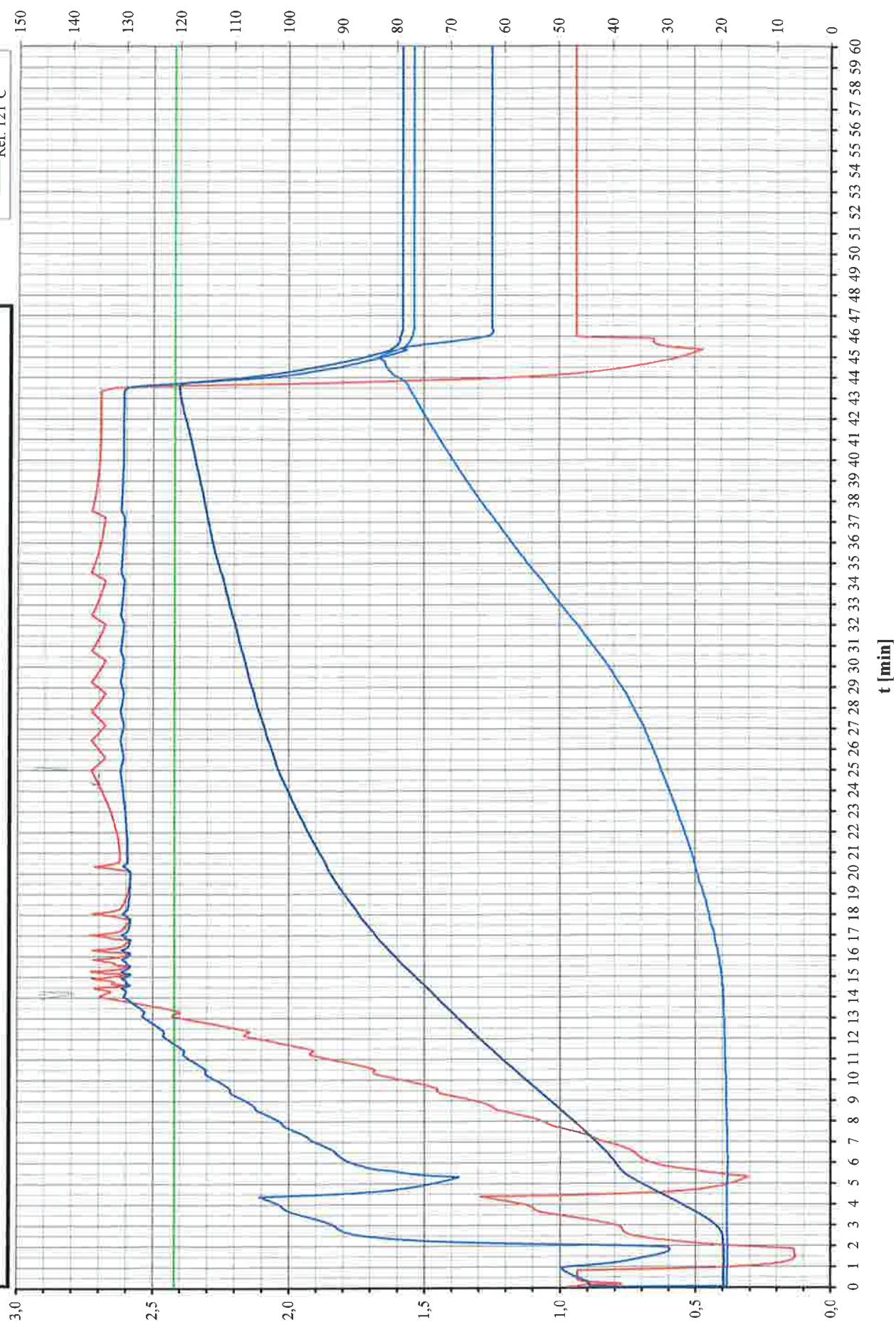
P [bar]

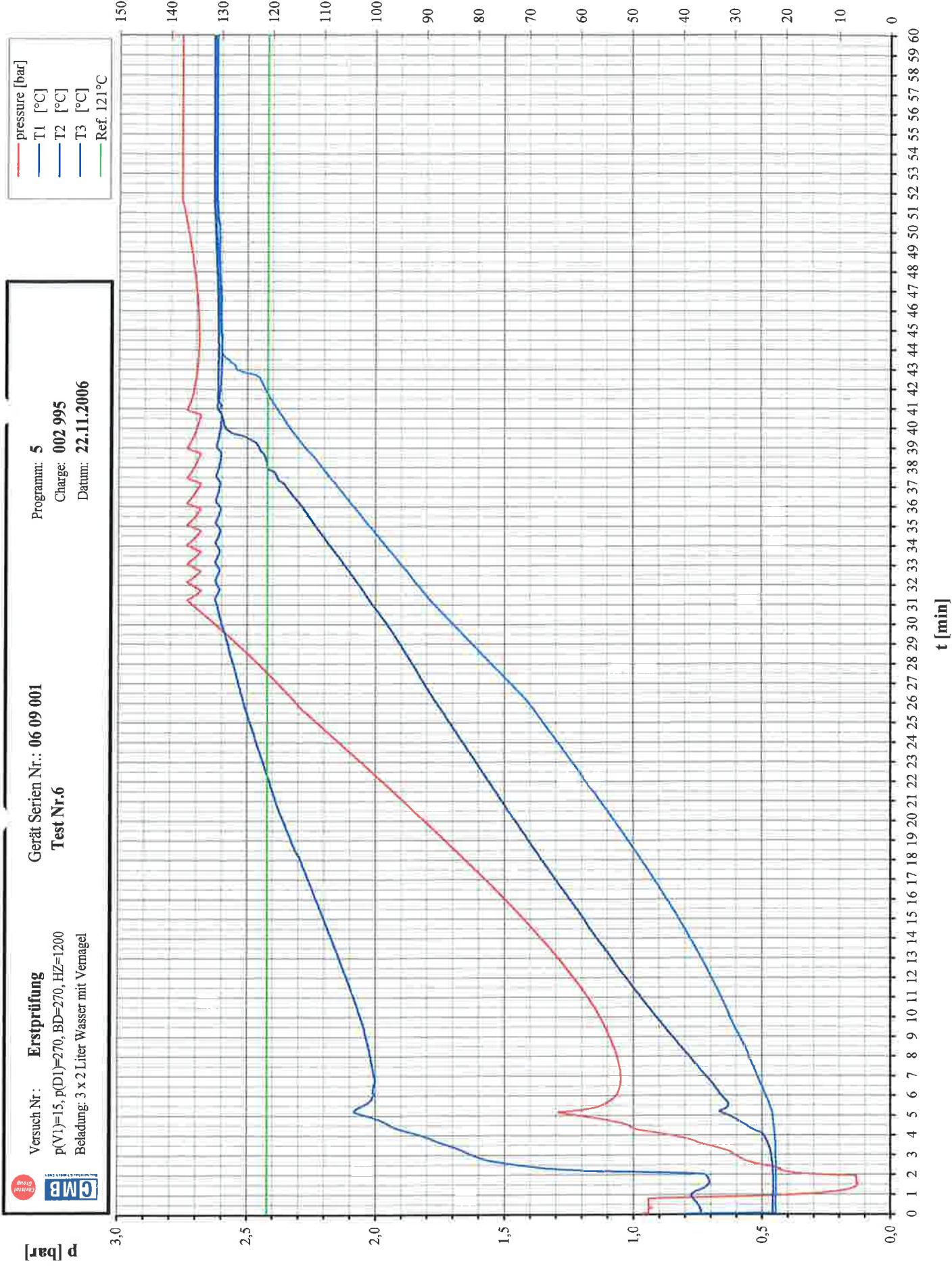


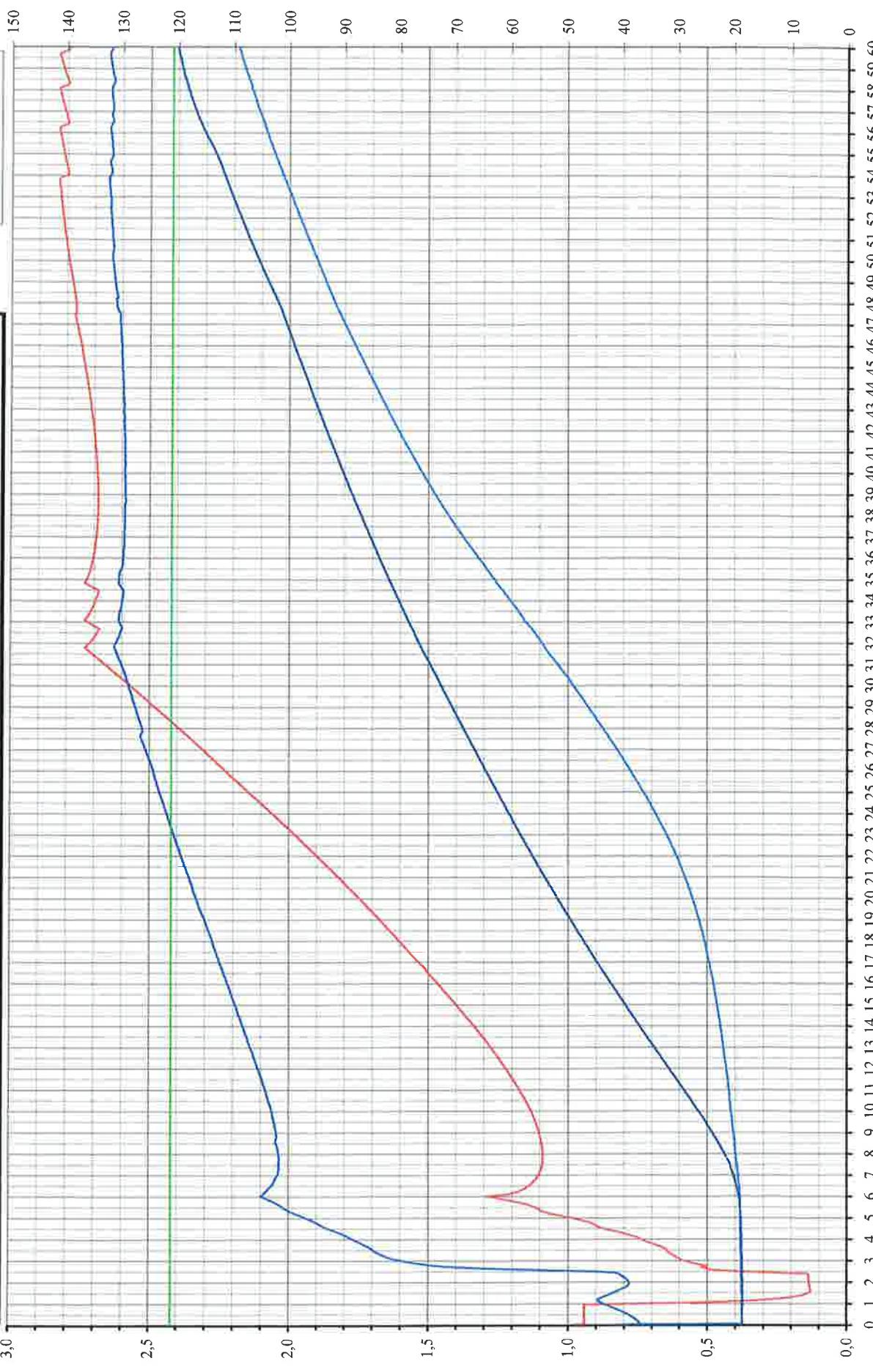
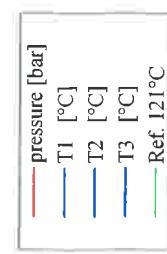


Programm: 5
 Charge: 002 995
 Datum: 21.11.2006

Versuch Nr.: Erstprüfung
 Test Nr.5
 $p(V1)=1,5, p(D1)=270, BD=1200$
 Beladung: 3 x 2 Liter Wasser mit Vernagel







Datei: Test Nr.7_T_D_P05_60min.xls Register: 60 min



Datei: TestNr.8_T_D_P05_60min.xls Register: 60 min

t [min]