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Optimisation of the process for manually operated jacket steam sterilisers

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Abstract
The aim of the research was to find an optimal process for a manually operated jacketed steam steriliser, which is mainly used in developing countries.
The experiments were focussed on the steam penetration into a textile test pack and the drying procedure. The performance of the various test cycles was evaluated against the requirements in the European standards for large steam sterilisers and the validation of steam sterilisers, by measuring the temperature and pressure in the steriliser and textile test packs.
The standard sterilisation process as recommended by the manufacturer of the steam steriliser did not fulfil the requirements by far and could not be considered as a proper sterilisation process. The optimum process for sterilisation of a worst case load (textile in top and bottom perforated sterilisation drums) was found to be: 20 minutes steam flushing at atmospheric pressure, three times a slow pressure build-up to 300 kPa followed by a drop to 100 kPa and finally a slow pressure build-up to the sterilisation pressure. This process has however not been proven suitable for the sterilisation of hollow medical devices. The optimum drying result was obtained by the use of an external condensation vessel.
The condensation vessel also contributed to cost effective operation by it's simple design and low water consumption.

Contents

Samenvatting

Het doel van dit onderzoek was om een optimaal proces te ontwikkelen voor een handbediende dubbelwandige stoomsterilisator, welke hoofdzakelijk in ontwikkelingslanden wordt toegepast. De experimenten richtten zich op de stoompenetratie in een textielpakket en de droging van het pakket. De evaluatie van de testcycli vond plaats aan de hand van temperatuur- en drukregistratie in de sterilisator en de lading. Er zijn geen testen met biologische indicatoren uitgevoerd.
De metingen zijn uitgevoerd volgens de Europese standaard voor grote stoomsterilisatoren. Ten behoeve van de interpretatie van de meetgegevens is een pakket van eisen samengesteld uit de Europese (concept) normen voor grote en kleine stoomsterilisatoren en de norm voor de validatie van stoomsterilisatieprocessen.

Het sterilisatieproces dat door de fabrikant wordt aanbevolen heeft een zeer lage effectiviteit en kan derhalve niet als sterilisatie worden aangemerkt. Het is gebleken dat in een standaard textielpakket nagenoeg geen stoompenetratie plaats vond.
Teneinde een sterilisatieproces te ontwikkelen waarmee drie textielpakketten verpakt in sterilisatiecontainers effectief gesteriliseerd kunnen worden is een groot aantal experimenten uitgevoerd. De standaard gemonteerde stoom-ejector is daarbij niet gebruikt. De effectiviteit van de ejector bleek namelijk bijzonder laag te zijn. Het diepste vacuüm dat met deze ejector was te bereiken was slechts 50 kPa. Dit is niet voldoende om een effectieve stoompenetratie mogelijk te maken. Het gebruik van een electrisch aangedreven water-ring vacuümpomp is evenmin onderzocht, vanwege de relatief hoge kosten en de kwetsbaarheid van een dergelijke pomp. Daarom is al snel overgestapt op de ontwikkeling van een sterilisatieproces waarbij de ontluchting middels andere methoden gerealiseerd wordt.
Uit eerder onderzoek[1] is gebleken dat middels het “gravity displacement principe” de lucht uit de sterilisatiekamer en textielpakketten is te verdrijven. In combinatie met boven atmosferische stoompulsen gaf dit effectieve sterilisatieprocessen. Deze principes zijn verder onderzocht. Er is een reeks processen uitgeprobeerd waarbij de parameters gevarieerd zijn die het “gravity displacement” principe beïnvloeden, te weten stoomdruk en de tijd gedurende de sterilisatorkamer wordt doorgestoomd. Daarnaast is geëxperimenteerd met stoompulsen, waarbij het aantal en de druk van de pulsen is gevarieerd.
Een proces met 20 minuten stoom doorblazen, gevolgd door driemaal een rustige drukstijging tot 300 kPa en drukafbouw tot 100 kPa, met vervolgens een langzame drukopbouw tot de sterilisatiedruk is voldoende effectief om textiel in een ronde stalen container met filters in het deksel en de bodem te steriliseren.
Op dit moment is echter nog niet aangetoond dat dit proces ook voldoet voor de sterilisatie van holle medische hulpmiddelen.

Een subdoel van het onderzoek was de ontwikkeling van een methode om de textielpakketten droog uit de sterilisator te krijgen. De meeste verpakkingsmaterialen die voor het verpakken van medische materialen worden gebruikt zijn alleen in droge toestand een goede bacteriebarrière. Het is daarom belangrijk dat de producten aan het eind van het sterilisatieproces droog zijn. De meest effectieve droging wordt bereikt door de sterilisatiekamer na de sterilisatiefase vacuüm te zuigen. Condensaat dat zich in de lading bevindt zal bij drukverlaging vlot verdampen. De diepte van het vacuüm dat met de standaard stoom-ejector was op te wekken bleek onvoldoende om de lading te drogen. Ook de

[1] Loenen E.S.P.J., The performance of basic steam sterilizers, Technische Universiteit Eindhoven / Wetenschapswinkel Eindhoven, (February 1995)

toepassing van de water-ring vacuümpomp bleek geen afdoende effect te geven. Het onderzoek is derhalve toegespitst op de ontwikkeling van een goedkoop en betrouwbaar vacuümsysteem ten behoeve van het drogen van de lading.
Bij het condenseren van stoom treedt een sterke volume vermindering op die in een gesloten systeem, zoals de sterilisatorkamer, een drukverlaging geeft. Dit principe werd gehanteerd door na de sterilisatiefase de stoom naar een extern vat te leiden en de stoom in dat vat met water te koelen en te condenseren. Het is gebleken dat hierdoor op eenvoudige wijze en tegen lage kosten een toereikende droging is te bereiken.

Dit rapport bevat slechts een deel van alle metingen die zijn uitgevoerd gedurende dit onderzoek. De uitwerking van alle uitgevoerde metingen kan verkregen worden bij J.F.M.M. Huys.

Summary

The aim of the research was to find an optimal process for a manually operated jacketed steam steriliser, of a type that is mainly used in developing countries. The experiments were focussed on the steam penetration into a textile test pack and the drying procedure. The performance of the test cycles was evaluated by temperature and pressure measurement in the steriliser and the test pack. Process testing using biological indicators has not been performed. The tests were performed according to the European standard for large steam sterilisers. For the interpretation of the test results a set of requirements was composed from the requirements in the European (draft) standards for large steam sterilisers, small steam sterilisers and the validation of steam sterilisation processes.

The standard sterilisation process as recommended by the manufacturer of the steam steriliser showed a very poor efficacy and could not be considered as sterilisation. Hardly any steam penetration was observed in a standard textile pack.
For the development of an effective sterilisation process for the sterilisation of three textile packs, packed in sterilisation containers, a large number of experiments were performed. The steam ejector that is fitted to the steriliser was not used to create a vacuum. The effectiveness of this steam ejector proved to be rather poor. A vacuum of only 50kPa could be created, which is insufficient to remove the air to the extend necessary for effective steam penetration into the load. The use of an electrically powered water ring vacuum pump has been considered, but rejected. These pumps are rather expensive and fragile. The research was focussed on the development of a sterilisation process in which the air removal is achieved by alternative means.
Earlier research has shown[1] that air can be removed adequately from the steriliser chamber and textile packs by gravity displacement. Combined with super atmospheric steam pulses effective sterilisation processes can be achieved. The application of both principles was further investigated in this research. A number of processes have been performed in which the parameters known to influence the gravity displacement, time and steam pressure, have been varied. Other experiments focussed on the effect of the super atmospheric steam pulses by variation of the number and the pressure of the pulses.
The optimum process for sterilisation of textile in top and bottom perforated sterilisation drums was found to be: 20 minutes steam flushing at atmospheric pressure, three times a slow pressure build-up to 300 kPa followed by a pressure reduction to 100 kPa and finally a slow pressure build-up to the sterilisation pressure.
The process has not yet been proven to be suitable for the sterilisation of hollow medical devices.

Part of the research was spent on the development of a method to obtain dry textile packs from the steriliser. Most packaging materials for medical devices are considered to be a microbial barrier only under dry conditions. It is therefor essential that the sterilised goods are dry at the end of the sterilisation cycle. The most effective drying is achieved by the creation of a vacuum in the steriliser chamber after the sterilisation phase. The condensate in the sterilised goods will rapidly evaporate at reduced pressures. The vacuum created with the steam ejector proved to be insufficient to dry the load. Also the use of the water ring vacuum pump was not effective. The research was focussed on the development of a low cost and reliable vacuum system for drying purposes.

[1] Loenen E.S.P.J., The performance of basic steam sterilizers, Technische Universiteit Eindhoven / Wetenschapswinkel Eindhoven, (February 1995)

When steam condenses the volume of the steam reduces. In a closed system, such as a sterilisation vessel, this will give a pressure reduction. This principle was put to use by passing the steam from the steriliser chamber into an external vessel and subsequently cooling the steam with water and condensing the steam in this vessel. This method proved to be a low cost means to create an effective drying vacuum.

This report only contains a part of all the measurements that were performed during this research. The data of all measurements can be obtained from mr. J.F.M.M. Huys.

1 Introduction

1.1 Sterilisation in developing countries

Steam sterilisation in the Western world has grown into an advanced technology over the last thirty years. Steam sterilisers in the European hospitals are nowadays computer controlled and apply fractionated vacuum processes. When vacuum is mentioned, this means a pressure well below atmospheric pressure. A fractionated vacuum is generally seen as a necessity for the sterilisation of hollow and porous loads, such as syringes, injection needles and textile. The high capacity vacuum systems on modern sterilisers also facilitate drying of the load. During the processes, several process variables are recorded in order to verify whether the process has met the requirements. In contrast with the Western world, many hospitals in developing countries have manually operated steam sterilisers. The most commonly used sterilisers lack the technical means to create a vacuum or can only create a partial vacuum, thus hindering both the steam penetration into the load and the drying of the load after sterilisation. The poor financial situation of the hospitals in developing countries prevents the use of modern technology. Other problems are the lack of knowledge about the advanced technology and the poor supply of spare parts. The infrastructure necessary for operating advanced technology is often not available. Experience has shown that the introduction of modern western equipment in developing countries is bound to fail.

The research described in this report focussed on a steam steriliser, which is commonly used in developing countries. The process, which is recommended by the manufacturer, formed the basis from which improvements were made.

1.2 Principle of steam sterilisation

Micro-organisms, such as bacteria and viruses cause many diseases. Surgical instruments should be free from any of such organism to prevent infections. Examples of different ways to kill the organisms are sterilisation by steam, hot air, toxic gasses and radiation. Steam is a safe, effective and readily available sterilising agent.
To achieve a sterile product in a steam steriliser, saturated steam conditions should be maintained for 3 minutes at a temperature of 134 °C or 15 minutes at a temperature of 121 °C on all parts of the load.
At the start of a sterilisation cycle there is air inside the chamber. In the case of hollow and porous loads, such as textile, there is also air inside the load. Air prevents the penetration of steam into hollow and porous items and hinders the achievement of the saturated steam conditions. Therefore, it is necessary to remove the air from the chamber and the load, before the actual sterilisation phase.
The air can effectively be removed using vacuum pulses. Another way to evacuate the air from the chamber is the so-called “gravity displacement” or “downward displacement”. This principle is based on the fact that cold air is heavier then steam. When steam enters the upper part of the chamber the air will be driven out through the exhaust in the bottom of the steriliser. A variety on the downward displacement process uses super atmospheric steam pulses.

1.3 The sterilisation process

The profile of a sterilisation process can be divided in three parts:
1. air removal/pre-conditioning
2. sterilisation
3. drying.

During the first part of a sterilisation process, the air should be removed from the chamber and the load for optimal sterilisation. After air removal, steam is supplied to the chamber. Due to the condensation of the steam, the load contains moisture. At the end of the process the load needs to be dry to reduce the chance of re-contamination when the load is taken out of the steriliser. Drying is ideally performed using a vacuum system. The vacuum facilitates fast evaporation of the condensate.

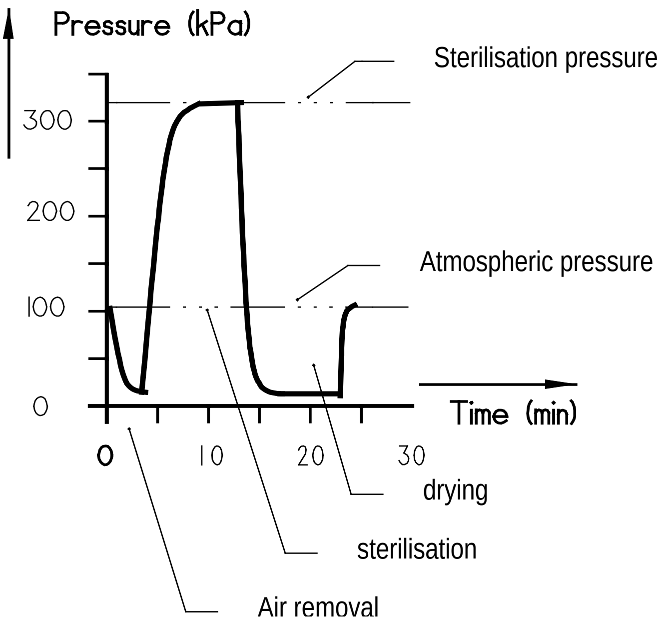


Figure 1.1: Schematic representation of a sterilisation process using a single vacuum pulse for air removal. Drying is also vacuum assisted.

1.4 The process requirements

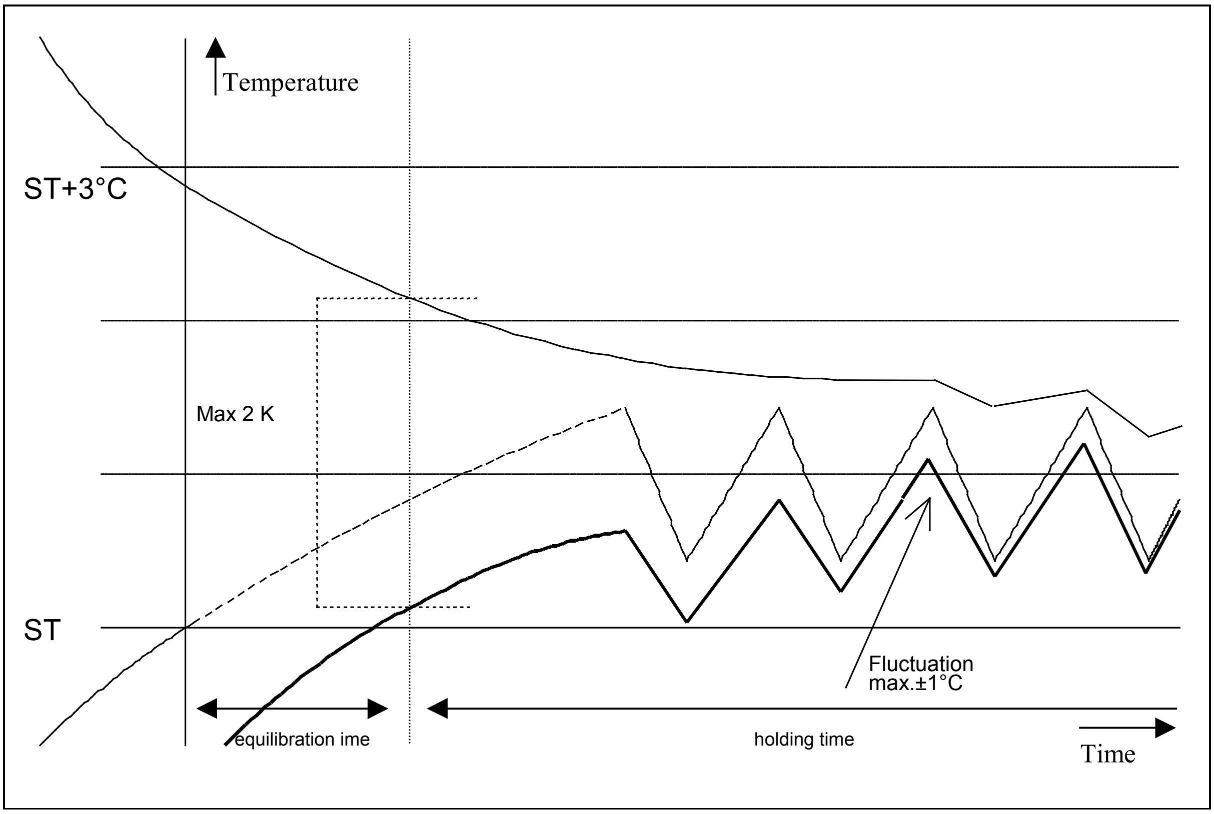
1.4.1 Sterilisation

The measurements described in the report were judged according to requirements for steam penetration in the EN285, EN554 paragraph 5.3.2. and prEN1306 (Aug. 1999).
These standards do not specify strict and uniform requirements for the temperature profile during the holding time (see fig 1.2.). The requirements for steam penetration from EN285 and prEN13060 as well as the example requirements given in EN554 are adopted to formulate the requirements in this report. For the purpose of this research the following requirements were applied:

a. the temperature and the pressure throughout the holding time should be kept constant or should follow a pre-determined profile;

b. the temperatures in the load and the theoretical steam temperature measured throughout the holding time:
   1. should be within the specified sterilisation temperature band with the upper limit equal to the sterilisation temperature plus 3 K;
   2. should not fluctuate by more than 1 K;
   3. should not differ from each other by more the 2 K.

c. the equilibration time should not exceed 15 s, provided that the energy input is sufficient to give an increase of the theoretical steam temperature of at least 8 K/minute otherwise the equilibration time should not exceed 30 s.



--------------	= temperature at the temperature control sensor of the steriliser
――――――	= Highest prevailing temperature
━━━━━━	= Lowest prevailing temperature
ST	= sterilisation temperature

Figure 1.2: Example of a graph of a sterilisation process

1.4.2 Load dryness

In the European standard for large steam sterilisers the requirement for dryness is specified as the maximal allowable increase in moisture content during sterilisation.
The acceptable increase in moisture content for a textile load is 1 % of it's weight when tested in accordance with the test procedure described in the standard (EN 285 paragraph 8.4.1).

1.5 Validation of sterilisers

The definition of validation according to EN 554 is: “Documented procedure for obtaining, recording and interpreting data required to show that a process will consistently comply with predetermined specifications”.
A steriliser can be validated by microbiological and/or physical means. Microbiological validation is performed by using a product with a predetermined contamination. According to the EN 554 paragraph 1.4 the use of biological indicators should be limited to special applications where physical means of validations alone are insufficient.
During the physical validation, the pressure in the chamber and the temperatures in the load are measured. The temperature profiles are checked to meet the performance requirements (see fig 1.2). The theoretical steam temperature, which is calculated from the measured pressure is taken into the data evaluation as a measured temperature.
The relationship between the theoretical steam temperature and the pressure of saturated steam is given by the following equation:

$$\Theta_{th} = \frac{4880}{(13.1 - \ln(p))} - 273{,}15$$ (p is the pressure in bar and Θ_{th} the theoretical steam temperature in °C)

For the purpose of this study, the physical means were considered to be appropriate.

1.6 Objectives of this research

The goal of this research is to find a process for a manually operated jacketed steriliser which fulfils the stated requirements for steam penetration and load dryness while keeping the power and water consumption as low as possible. Moreover, these requirements must also be fulfilled if metal containers are used as packaging.

2 The steriliser and the test equipment

2.1 Steriliser specs

The steriliser used for the experiments was a KSG 40/60-2, manufactured by KSG Sterilisers, Olching (Germany). The steriliser is fitted with a jacket that also functions as a electrically heated steam generator. The pipe work of the steriliser is schematically shown in figure 2.1. The steriliser is equipped with a steam ejector to create a vacuum.
Figure 2.1 shows the steriliser with the pipe work used for the measurements.

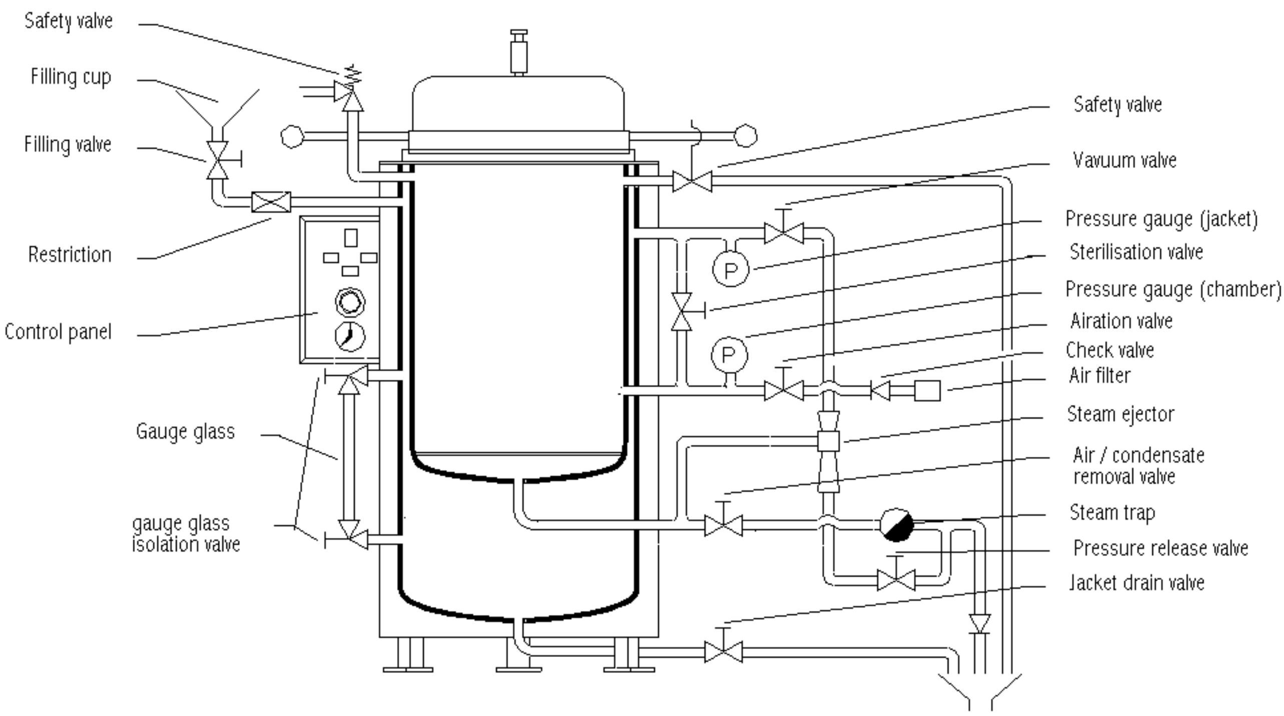


Figure 2.1: Drawing of the steriliser and the pipe work.

When the report refers to the 'standard configuration' the configuration show in figure 2.1 is meant.

The specifications of the steriliser are:

Dimensions of the steriliser:	outer diameter:	600 mm
	chamber diameter:	400 mm
	chamber height:	600 mm
	chamber volume:	0.075 m^3
Operating pressure:		2.5 bar
Operating temperature:		134°C
Water volume in jacket at 'low' level		31 litre
Water supply between 'high' and 'low' level:		14 litre
Current per phase:		14,4 A
Maximum power consumption:		9.5 kW
Power supply:		230/400 V
Current type:		three-phase current
Power frequency:		50/60 Hz

2.1.1 Elevated steam inlet

In the standard configuration of the steriliser, the steam enters the chamber at half height. It was suspected that this could give poor results for the downward displacement. Therefore a copper tube was placed into the original steam inlet to elevate the steam inlet to the upper part of the chamber (Figure. 2.2).

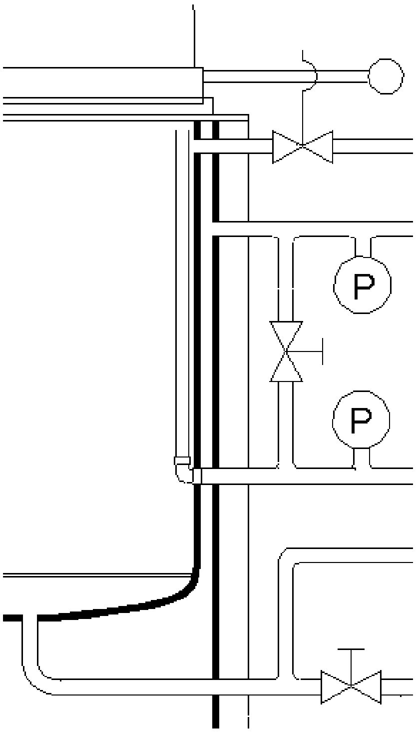


Figure 2.2: Elevated steam inlet

The copper tube has a length of 50 cm an inner diameter of 13 mm. The tube was placed into the standard steam inlet by means of a tight fitting knee joint.

2.1.2 Vacuum systems

2.1.2.1 The steam ejector

The steam ejector (figure 2.1) was factory mounted on the steriliser. No specifications of the steam ejector were given by the manufacturer.

2.1.2.2 The water ring pump

The water ring pump is powered by the three-phase motor.
The specifications of the motor:

Make:	Dietz-Motoren, Heroldstatt, Germany
Type:	DR 80B/2 0
Power consumption:	1 kW

The specification of the water ring pump:

Make:	Speck Pumpen, Roth, Germany
Type:	30-GR-50 / V 28217

2.1.2.3 The external condensation vessel

The external condensation vessel is a stainless steel jacketed vessel as shown in figure 2.3. The vessel is 30 cm high, the inner diameter and an outer diameter are respectively 8 cm and 13 cm. The inner cavity has a volume of 1 litre.

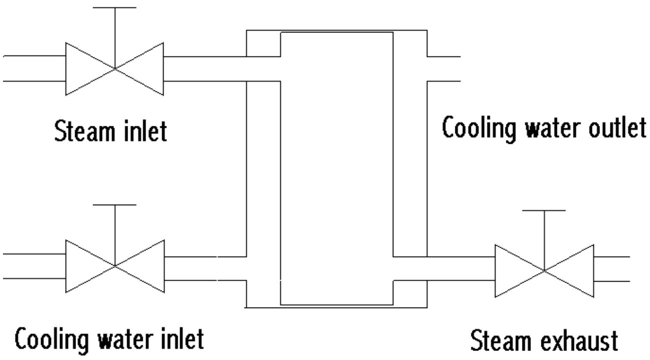


Figure 2.3: Drawing of the external condensation vessel.

The external condensation vessel was connected to the chamber of the steriliser and the water supply (figure 2.4).

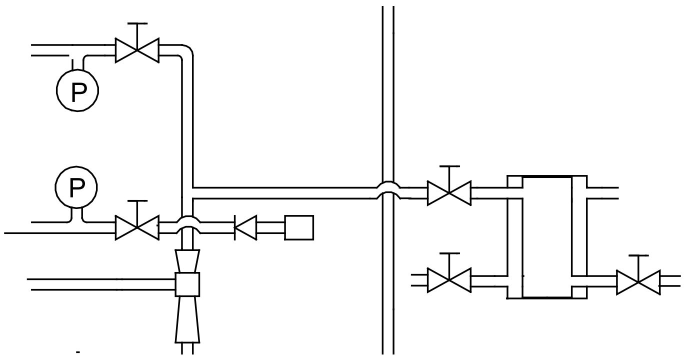


Figure 2.4: Connection of the external condensation vessel to the steriliser

The idea of the condensation vessel is based on the fact that steam decreases approximately 1600 times in volume when it condenses. The vessel is connected to the chamber of the steriliser allowing steam to enter the vessel. By means of the cooling water, which flows through the jacket of the condensation vessel, the steam condenses. Condensation lowers the pressure in the inner cavity, facilitating steam from the chamber to enter the vessel. This process causes the pressure to decrease to the pressure corresponding with the vapour pressure of water at the temperature of the cooling water.

2.2 Operating the steriliser

Each process consisted of a number of subsequent steps, which were performed by manually operating the valves of the steriliser. These steps were:

- steam flushing
- steam pulsing
- creating a vacuum for air removal and drying, using different vacuum systems
- sterilising
- drying.

Each of these steps is described below.

Steam flushing
Steam flushing was done to remove air from the chamber. All the valves were closed except the pressure release valve and the air-condensate removal valve. The sterilisation valve (steam inlet) was opened until the desired flushing pressure was reached. For steam flushing just above atmospheric pressure, the sterilisation valve was opened a little. During steam flushing at 120 kPa, the chamber was kept at this pressure by manually opening and closing the sterilisation valve.

Pressure build-up
To build up the chamber pressure all the valves were closed, except the air-condensate removal valve to the steam trap. This way, only the air and condensate could exit the chamber. By opening the sterilisation valve the pressure in the chamber increased.

Slow pressure build-up
To increase the pressure slowly the same procedure as for the above mentioned pressure build up was used, except for the fact that the sterilisation valve was only partially open. Therefore, the sterilisation valve was fitted with a stop limiting the maximum opening of the valve. When a slow pressure build-up before a sterilisation phase was performed, the sterilisation valve was opened completely when the pressure reaches 300 kPa.

Pressure reduction
At first all the valves were closed and thereafter the pressure release valve was opened allowing steam to exit the chamber.

Creating a vacuum by means of steam ejector
To create a vacuum all valves were closed. The pressure release valve and the vacuum valve were opened sequentially. When the desired pressure in the steriliser chamber was reached, first the vacuum valve was closed and then the sterilisation valve.

Creating a vacuum by means of the water ring pump
To create a vacuum with the water ring pump, all valves of the steriliser and the valve to the water ring pump were closed. The valve for water supply to the water ring pump was opened. Thereafter, the vacuum pump was switched on. Then the valve to the vacuum pump was opened. When the desired vacuum was reached, the valve to the water ring pump was closed, and the vacuum pump was turned off.

Creating a vacuum in an external condensation vessel for drying
At first, all valves of the steriliser and the condensation vessel were closed. For the proper functioning of the condensation vessel, all air had to be removed from the vessel by opening both the exhaust valve and the steam inlet valve of the condensation vessel sequentially. This caused the pressure in the steriliser chamber to decrease. When the chamber pressure reached 200 kPa, the exhaust valve of the external condensation vessel was closed. The residual steam in the chamber was removed by opening the pressure release valve of the steriliser. When the chamber reached atmospheric pressure, the pressure release valve of the steriliser was closed again.
The cooling water valve on the condensation vessel was opened and drying started. After the desired time of drying the cooling water of the condensation vessel was closed and the air inlet valve was opened. The lid of the steriliser could then be opened.

Sterilisation phase
Fifteen seconds after the pressure reached the 305 kPa (corresponding saturation temperature is 134 °C), the sterilisation time started. During the sterilisation phase the pressure was controlled by the steriliser's prestostat which controlled the heating of the water in the jacket. Since the steriliser chamber was in open contact with the jacket during the sterilisation phase, the pressure in the jacket equalled the pressure in the steriliser chamber. When the sterilisation time had elapsed, all valves were closed.

2.3 Measuring equipment

2.3.1 Data acquisition equipment

Recorder system:

Make:	Chessel / Eurotherm
Type:	4250 M
Accuracy:	0.5 °C

Computer:

Make:	Compaq prolinea 3/25zs
CPU:	386
Hard disk space:	40 Mb
Software:	Chessel ISP data acquisition software.

The recorder had 24 channels which could be configured as input channels. Channel 1-8 were used as thermocouples inputs. The recorder had internal cold junction compensation. Channel 17 and 18 were used to measure the output of the pressure sensor. The measured data were printed and sent to the computer each second.

2.3.2 Thermocouples

Twisted Teflon thermocouple wire of the type K was used for the thermocouples. The thermocouples were made by stripping, firmly twisting the stripped ends of the wires and welding wires using an electric current.
The temperature measurement system (recorder and thermocouples) was calibrated within three days before a measurement was performed. The thermocouples were calibrated by means of an internal two point calibration (at room temperature and at 144°C) on the recorder. The thermocouples and a reference thermometer (paragraph 2.3.6) were placed in an oil bath (paragraph 2.3.4) which was kept at constant temperature in a range of ±0.1°C.

2.3.3 Pressure sensor

Make:	Wika
Type:	897.10.515 (pressure sensor) / 907.15.510 (display)
Scale:	0 to 4 bar (absolute)
Resolution:	0.001 bar
Accuracy:	±0.002 bar

The pressure sensor was calibrated annually. The recorder was set to give identical pressure readings as the calibrated display connected to the sensor.

2.3.4 Oil bath

For calibration, the thermocouples were placed in a thermostatically controlled bath filled with silicon oil.

Make:	MGW Lauda
Type:	CS

The thermocouples and the reference thermometer were placed in a hollow metal cylinder, which operates as a temperature buffer. This ensures that the temperature change during the calibration time (less then 1minute) is negligible.

2.3.5 Reference thermometer

Make:	ASL
Type:	F25
Scale:	0°C to 200°C
Resolution:	0.001 °C
Accuracy:	0.05 °C
Identification nr.:	3388/VSL 86 T 007

2.3.6 Balance

Make:	Mettler Toledo
Type:	PG2000
Maximum capacity:	2100 g
Scale increment:	0.01 g
Linearity:	+/- 0.02 g
Repeatability:	0.005 g

Figure 2.5: View of the equipment

3 The performance tests

For the measurements during this research, the sterilisation temperature was 134°C. To prevent over-exposure of the chemical indicator sheet (B&D test indicator sheet) the holding time was limited to 4 minutes when the indicator sheet was used.

3.1 The load and packaging materials

Unless specified otherwise, a standard test pack was used. The influence of different kinds of packaging systems was also determined.

3.1.1 Standard test pack

The standard test pack consisted of a number of plain cotton sheets as described in EN 285, paragraph 26.1. Each individual sheet was folded to approximately 22 cm ×30 cm and stacked to a height of approximately 25 cm. The pack was wrapped with a cotton sheet and closed with a piece of autoclave tape. During the measurements the standard test pack was placed on a wired basket to position the test pack in the centre of the steriliser chamber.’

3.1.2 Drums with filters in the lid and bottom

Stainless steel drums with a diameter of 350 mm and a height of 190 mm were used. Both the lid and the bottom of the drum were perforated and fitted with filters. These drums are re-usable, durable and provide a microbial barrier. The drums were filled with 21 sheets folded to 220 mm × 300 mm. The sheets were placed crosswise on each other. A B&D-test sheet was placed in the middle. These drums will be referred to as “filtered drums” in this report.

3.1.3 Schimmelbusch drum

The Schimmelbusch drum is a drum with holes in the sides, which can be closed and opened by shifting a metal band. During sterilisation the holes are opened. After sterilisation the holes should be closed again. In the time between opening the steriliser and closing the holes, recontamination can however occur. Schimmelbusch drums are commonly used in hospitals of developing countries. The drums are re-usable and durable. The diameter of the Schimmelbush was 320 mm with a height of 240 mm.
During the measurements the drum was filled with 21 sheets folded to 200 mm ×300 mm. The sheets were placed crosswise on top of each other.

3.1.4 B&D indicator sheet

A B&D indicator sheet was a paper coated with a special ink. This ink changes colour if the sheet is exposed to steam of a pre-determined temperature during a pre-determined period. The B&D sheets used in the measurements should turn black completely if exposed to saturated steam of 134°C for 4 minutes. During the measurements with a standard test pack the B&D sheet was placed in the middle of the test pack or in the middle of the stack of sheets in the sterilisation drum. During thermometric measurements the indicator sheet and the thermocouple in the centre of the test pack were separated by one sheet of textile.

3.2 Test methods

3.2.1 Air removal

3.2.1.1 Empty chamber

For measurements in an empty chamber, the thermocouples were placed according to figure 3.1. Thermocouple 7 was placed 2 cm under the lid. Thermocouple 2 was placed in the drain. Thermocouple 8 was attached to the wall of the chamber using aluminium tape. Thermocouple 5, 6 and 3 were placed on a diagonal line through the chamber. These thermocouples were fixed on the wired baskets with a piece of autoclave tape. Except for thermocouple 8 all thermocouples were measuring in the free chamber space.

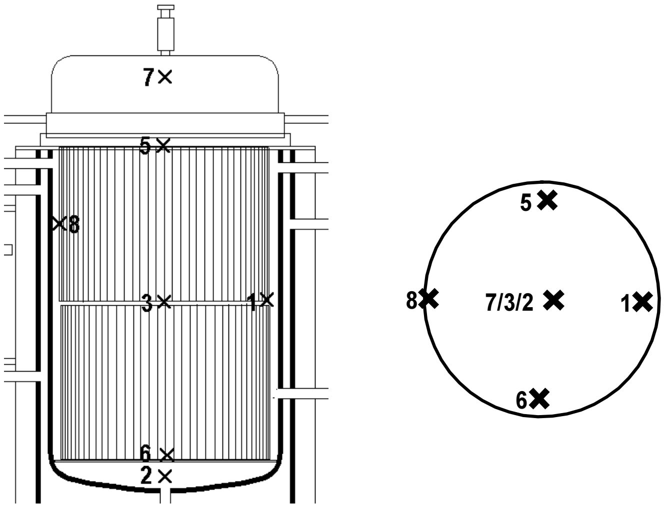


Figure 3.1: Placement of thermocouples (indicated by X) for an empty chamber measurement.

3.2.1.2. Standard test pack

For measurements using the standard test pack, the thermocouples were placed according to figure 3.2. Thermocouple 8 was placed in the nominal geometric centre of the pack. Thermocouple 1 was placed 7 sheets under thermocouple 8. Thermocouple 5 was placed under the first layer of textile on the top of the pack. Thermocouple 3 was placed under the first layer of textile at the bottom of the pack. The thermocouples were fixed with a piece of autoclave tape.

Three thermocouples were placed in the free chamber space. Thermocouple 6 was placed 5 cm above the test pack. Thermocouple 7 was placed 2 cm under the lid of the steriliser. Thermocouple 2 was placed in the drain of the chamber.

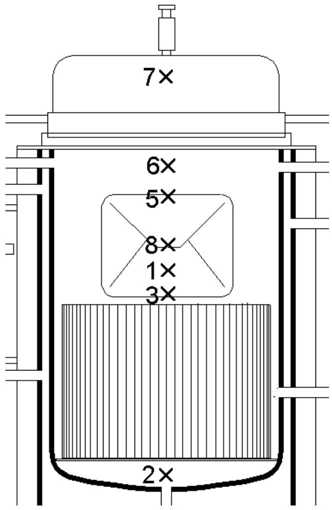


Figure 3.2: Placement of the thermocouples for the standard test pack.

3.2.1.3. Filtered drums and Schimmelbusch drums

For a filtered drum or a Schimmelbusch drum, the position of the thermocouples is given in figure 3.3. Thermocouple 7 was placed 2 cm under the lid. Thermocouple 2 was placed in the drain of the chamber. Thermocouple 8 was placed in the centre of the textile pack in the drum. Thermocouple 1 was placed at a quarter height measured from the bottom of the textile pack. Thermocouple 5 was placed on the top of the textile just under the first layer of textile. Thermocouple 3 was placed at the bottom of the textile just above the bottom layer. Thermocouple 6 was placed 5 cm above the drum.

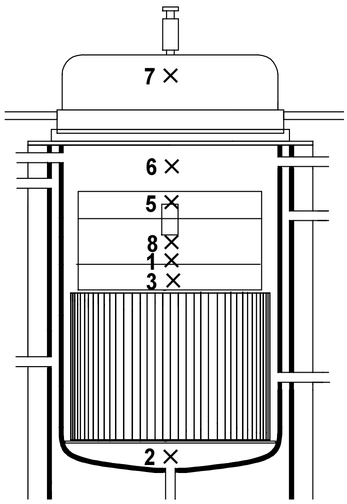


Figure 3.3: Placement of thermocouples for drums

3.2.2 Drying

Three plastic bags were labelled with the letters a, b and c. The sheets from the top, the centre and the bottom of the pack were numbered respectively with the letters a, b and c. The plastic bags and the sheets were weighed separately. The sheets were placed back in the standard pack and sterilised.
At the end of the sterilisation process, the test pack was taken from the chamber and the labelled sheets were placed into the corresponding bags as swift as possible. The plastic bags

were closed to prevent evaporation of moisture. The plastic bags with the sheets were weighed.
To calculate the change of moisture content (change in moisture content) the following equation was used:

$$cmc = \frac{m_3 - m_2 - m_1}{m_2} \times 100\%$$

m_1 is the mass of a plastic bag, in grams

m_2 is the mass of a sheet before sterilisation, in grams

m_3 is the mass of a sheet in its bag after sterilisation, in grams

3.2.3 Water consumption

The water consumption during cooling with the external condensation vessel was measured by collecting the water from the outlet of the condensation vessel in a measuring beaker during a known time period.

3.3 The test series

Finding the optimum process is a matter of experience and multiple experiments, where results are used as input for subsequent experiments. Annex 2 gives an account of all the measurements that were performed. Not all test results are discussed in this report. The measurements discussed and printed in this reported are limited to those measurements that:

- directly contributed towards defining the optimum process for the sterilisation of textile in containers;
- were performed using processes that gave satisfactory results without the installation of additional (electrical) equipment to the steriliser.

The numbers of these measurements are printed in bold in the text.

3.3.1 Air removal

If a vacuum pulse from 100- 50 kPa was created for air removal, the table in Annex 2 will mention the use of the steam ejector for air removal.

3.3.1.1 Empty chamber test

In the empty chamber, the following process was performed: one pre-vacuum to 50 kPa, a sterilisation period of 4 minutes and a drying vacuum to 50 kPa. **Measurement 40** was performed to give an indication of the air removal in an empty chamber. Measurement 39 was performed using an elevated steam inlet.

3.3.1.2 Standard process as recommended by the manufacturer

The standard process described by the manufacturer consists of a pre-vacuum of 50 kPa, a sterilisation period of 30 minutes and a drying vacuum of 50 kPa using the steam ejector. This process is further described in **measurement 17**. A B&D sheet was used as a visual indication of steam penetration into the test pack.
Measurements 18 and 19 were performed with the same process, but the sterilisation time was limited to 4 minutes (as described for the B&D-test sheet), using the standard and an

elevated steam inlet. For comparison purposes measurement 24 was similar to measurement 27, but omitting the pre-vacuum.

3.3.1.3 Pulses

Measurements were done to determine the influence of the actual value and the speed of the steam pressure-build up and reduction. During all these measurements, a standard test pack was used as the test load.

At first two processes with a single pulse from 300 to 100 kPa were performed. Measurement 10 was performed with the standard configuration. Measurement 25 was performed using the elevated steam inlet.
Two tests were performed with a pressure drop of only 100 kPa instead of 200 kPa to test the hypothesis that smaller pulses result in lower energy and water consumption. Measurement 11 was performed with a pulse from 200 to 100 kPa and in measurement 14 a pulse from 300 to 200 kPa was applied. Both measurements were performed with the standard steam inlet configuration.
Two processes were performed with a combination of a steam pulse and a vacuum pulse. During measurement 12 a pulse from 300 to 50 kPa was created. After a pressure rise to 300 kPa, the pressure is reduced to 100 kPa. Thereafter a vacuum to 50 kPa was created using the steam ejector. During measurement 13 a pulse from 300 to 50 kPa was also created. During this measurement the steam ejector was active during the whole pulse from 300 to 100 kPa to create a rapid pressure decrease. Theoretically a sharp edged pulse is more effective for air removal.
During **measurement 15** two pulses from 300 to 50 kPa were created sequentially. This was done because a single pulse was not enough to fulfil the requirements of the European standard. During **measurement 16** 3 pulses from 300 to 50 kPa were created sequentially.
In **measurements 15** and **16** the water consumption to create vacuum pulses was relatively high. Therefore, 4 tests were performed to see the effect of 2 and 3 pulses without a vacuum. Measurement 27 was performed with 2 pulses from 300 to 100 kPa with the standard configuration. **Measurement 26** was performed in the same way as measurement 27 but using an elevated steam inlet. Measurement 33 was performed with 3 sequential pulses from 300 to 100 kPa with the standard steam inlet configuration. **Measurement 44** was performed in the same way as measurement 33 using an elevated steam inlet.

3.3.1.4 Steam flushing at atmospheric pressure

The time of steam flushing and the pressure during the steam flushing were varied. The elevated steam inlet was also tested.
Measurement 28 was performed with the elevated steam inlet and steam flushing for 11 minutes at a pressure just above atmospheric pressure. The process continued with a slow pressure build-up, a sterilisation period of 4 minutes and a drying vacuum to 50 kPa by means of the steam ejector. The results of this procedure were not in line with the requirements.
Measurement 29 was performed with an steam flushing of 11 minutes (the same as in measurement 28), a slow steam build-up to 300 kPa, a pulse from 300 to 100 kPa a fast pressure build-up to the sterilisation pressure, a sterilisation period of 4 minutes and a drying vacuum to 50 kPa. This was done to give an indication of the effect of a pulse, from 300 to 100 kPa, after a slow pressure build-up
To improve the air removal, **measurement 30** was performed with an increase of the steam flushing time to 20 minutes. Measurement 31 was performed in the same way but using an elevated steam inlet.

To investigate the effect of a fast steam build-up after the steam flushing period measurements 35 and 45 were performed. During both measurements a fast pressure build-up was created after the steam flushing period. The difference between both measurements was that measurement 45 was performed using an elevated steam inlet and measurement 35 with the standard configuration.
Measurement 41 was performed to investigate the effect of a decrease of the steam flushing time to 15 minutes. Steam flushing at atmospheric pressure was followed by a slow steam build-up to 300 kPa, a pulse from 300 to 100 kPa, a fast pressure build-up, a sterilisation period of 4 minutes and a drying vacuum to 50 kPa. Measurement 36 was performed in the same way but using an elevated steam inlet.
During measurement 43, the steam flushing time was increased to 30 minutes compared to measurement 41. Measurement 47 was performed in the same way but using an elevated steam inlet.
To improve the results found in **measurement 30** measurement 46 was performed with a slow pressure build-up instead of a fast steam build-up after the pulse from 300 to 100 kPa Measurement 48 was performed in the same way as measurement 46, but using an elevated steam inlet.

3.3.2 Drying

3.3.2.1 Steam ejector

During measurement 1 up to measurement 53, a drying vacuum to 50 kPa was created by means of a steam ejector, except for measurements 32 and 50 to allow investigation of the effect of the vacuum by the steam ejector. The effect of a drying vacuum can only be tested properly when the sheets are completely penetrated by steam. Theoretically a poor steam penetration has the apparent advantage of a relative dry load at the end of the process.

3.3.2.2 External condensation vessel

Seven measurements were performed with a drying phase by means of the external condensation vessel. The configuration as described in paragraph 2.1.3.3 was used. The process performed before the drying is described in measurement 50 (steam flushing for 20 minutes, slow steam build-up, pulse from 300 to 100 kPa, slow steam build-up to the sterilisation pressure, sterilisation for 4 minutes). This process gave the most efficient steam penetration.
Measurement 55 was performed with an opened steam inlet valve of the external condensation vessel during the whole process. At the end of the sterilisation phase the steam in the steriliser chamber was not released prior to the cooling of the condensation vessel. The condensation vessel was maximally cooled. Because of relative poor drying during measurement 55, measurement 56 was performed. At the end of the sterilisation phase pressure in the steriliser chamber was released to the atmospheric pressure. After this pressure release, the condensation vessel was cooled maximally for 15 minutes.
At the end of the process during measurement 56 it seemed that the external condensation vessel was full of water. Measurement 57 was performed in the same way as measurement 56 but during the process the valve to the sterilisation vessel was closed. The inlet to the condensation vessel was opened after the pressure was reduced to atmospheric pressure.
Measurement 58 was performed as described in paragraph 2.2. using a drying time of 15 minutes and a flow of cooling water of 0.49 l/min. The condensation vessel during measurement 60 was cooled for 15 minutes with 1.1 litre of water per minute. **Measurement 61** was performed using a cooling time of 30 minutes at a cooling water flow of 0.8 l/min.

Measurement 66 was performed as measurement 50 but without a load. The test was performed as described in paragraph 2.2. to get an indication of the amount of condensate formed in the condensation vessel from the steam in an empty chamber. Measurement 50 was performed as a reference for the change in moisture content.

3.3.2.3 Water ring pump
Because the results of drying using a water ring pump were not significantly better than when using the steam ejector, the use of the water ring pump will not be discussed any further.

3.3.3 Packaging

3.3.3.1 Schimmelbusch drums
The first measurement performed with the Schimmelbusch was measurement 52. The holes in the walls of the Schimmelbusch were completely opened during these tests. The following process was used: 20 minutes steam flushing at atmospheric pressure, a slow pressure build-up to 300 kPa, a pulse to 100 kPa, a slow pressure build-up followed by sterilisation, drying vacuum to 50 kPa by means of the steam ejector.
The process for measurement 69 was: steam flushing at atmospheric pressure for 20 minutes, twice a slow pressure build-up to 300 kPa and a pulse to 100 kPa, a slow pressure build-up, followed by sterilisation, followed by drying using the external condensation vessel for 30 minutes and a cooling water supply of 0.51 litre/minute.

3.3.3.2 Filtered drums
During measurement 53 the load consisted of a filtered drum filled with 21 cotton sheets placed crosswise in the drum. The following process was used: 20 minutes steam flushing at atmospheric pressure, slow pressure build-up to 300 kPa, pulse to 100 kPa, slow pressure build-up, sterilisation, drying vacuum to 50 kPa by means of the steam ejector.
During measurement 68 the same process was used as in measurement 53 but using twice a slow pressure build-up to 300 kPa and a pulse to 100 kPa. The drying was performed by means of the external condensation vessel for 30 minutes and a cooling water supply of 0.58 litter/minute.
During **measurement 71**, three filtered drums were placed in the steriliser. The process used for this measurement was identical to the process used for measurement 68.
Measurement 72 was performed as **measurement 71** but with three times a slow pressure build-up to 300 kPa and a pulse to 100 kPa. The drying was performed with the external condensation vessel, for 30 minutes with a cooling water flow of 0.7 litre/minute.

4 Results and discussion

4.1 Tests for air removal

4.1.1 Empty chamber

There was still air in the chamber during the empty chamber measurements, because the temperatures in the chamber were still a few degrees Celsius under the theoretical temperature at the beginning of the sterilisation phase (**measurement** 39 and **40)**. The elevation of the steam inlet improved the process marginally. Both processes were not in accordance with the requirements described in paragraph 1.5.1.

4.1.2 Process recommended by the manufacturer

The steam did not penetrate the test pack when the standard process recommended by the manufacturer was used (**measurement 17**). Therefore, no sterilisation can be expected in the test pack. The B&D sheet of **measurement 17** kept its original colour expect for the edges and at the end of the sterilisation period the temperature in centre of the test pack reached only 40°C which was a large deviation form the required 134°C. Measurement18 showed that at the end of the limited sterilisation period, the temperature in the centre of the test pack had not changed. Moreover, at the end of the sterilisation period, the temperatures in the free chamber space were 1.5 degrees below the theoretical temperature, which indicate that residual air was left in the chamber. The temperatures measured at the top and the bottom of the test pack were respectively 13.6 and 6°C below the theoretical temperature. The elevated steam inlet improved the air removal in the upper part of the chamber slightly and no other improvements were noted (measurement 19)
Application of the pre-vacuum did not improve the efficacy considerably (measurement 18 vs. 24).

4.1.3 Pulses

The process performed with a pulse from 300 to 50 kPa during the air removal stage (measurement 12) improved the process compared with a pulse from 300 to 100 kPa (measurement 10). No residual air could be detected in the chamber. The temperatures, measured at the end of the sterilisation time in the centre and at 1/4 of the test pack, indicated that less air remained, but the process did not fulfil the requirements.
By increasing the number of pulses of 300 to 50 kPa, the process improved **(measurements** 12**, 15, 16).** When three pulses from 300 to 50 kPa were created **(measurement 16)**, all temperatures followed the theoretical temperature at the end of the 3rd pulse, which was in agreement with the requirements.
Using two pulses form 300 kPa to 50 kPa is more effective than using two pulses form 300 kPa to 100 kPa, but also uses more water (measurement 15 vs. 27). A process with three pulses from 300 to 100 kPa did not fulfilling the requirements (at the end of the sterilisation period the measured temperature in the centre and at 1/4 of the pack were respectively 72 and 54°C in measurement 33). **Measurement 44** (three pulses from 300 to 100 kPa using an elevated steam inlet) could not be compared with measurement 33 because the first pressure build-up took about 3 minutes longer than in **measurement 44**.

4.1.4 Steam flushing

Increasing the flushing time from 5 to 11 minutes improved the efficacy of the process (measurement 21 vs. measurement 28). After 11 minutes of steam flushing, the temperature in the drain did not increase significantly (measurement 28). When this steam flushing was followed by a slow pressure build-up the temperatures in the centre and at 1/4 of the test pack were respectively 54 and 100°C at the end of the sterilisation time (measurement 28).
When steam flushing for 11 minutes and a subsequent steam build-up were followed by a pulse from 300 to 100 kPa and a fast pressure build-up to the sterilisation pressure, the efficacy of the process improved considerably (measurement 28 vs. **29**). However, the requirements were not met; the temperatures in the centre and at 1/4 from the bottom of the pack were respectively 122 and 130°C at the end of the sterilisation period.
By extending the flushing time to 20 minutes, the process fulfilled the requirements (**measurement 29** vs. **measurement 30** and measurement 31).
The effect of a fast steam build-up proved to be less effective than a slow pressure build-up. When a fast, instead of a slow, steam build-up was used at the end of the flushing phase, the process did not fulfil the requirements (**measurement 30** vs. measurement 45). At the end of the sterilisation period of measurement 45, the measured temperatures in the centre and at 1/4 of the bottom of the pack were respectively 3.5 and 1.5°C below the theoretical temperature.
A steam flushing period of 15 minutes instead of 20 minutes proved to be insufficient (measurement 36 vs. **measurement 30**). The measured temperatures reached the 134°C at 0.5 minute before the end of the sterilisation period (measurement 36).

Extending the flushing time to 30 minutes improved the efficacy of the process (**measurement 30** vs. measurement 47 and measurement 43).
Using an elevated steam inlet and using a slow steam build up to the sterilisation pressure improved the efficacy of the process (measurement 48 vs. measurement 47 and **measurement 30**). Using the standard configuration also led to a process fulfilling the requirements (measurement 46 vs. measurement 48).
It was concluded that steam flushing for 20 minutes at a pressure slightly over atmospheric followed by a single steam pulse gave sufficient steam penetration in a standard test pack.

4.2 Tests for drying

4.2.1 Steam ejector

During most processes, the sheets at the top of the pack had a relative high steam penetration. These sheets - when the standard configuration was used - had a change in moisture content of about 3%. During some tests using an elevated steam inlet, the increase in moisture content was relatively high; 6.8% (measurement 19) and 5.6% (measurement 26). This was probably caused by the condensate, formed in the steam pipes on the outside of the steriliser, that was sprayed into the upper part of the chamber. Moreover, it is likely that it will “rain” from the lid onto the load, which might be more pronounced in the case of the elevated steam inlet.
The effect of the drying vacuum seemed to be insignificant. Measurement 18 (pre-vacuum to 50 kPa, sterilisation for 4 minutes, drying vacuum to 50 kPa) showed a change in moisture content of 3.2%, 1.7% and 3.5% for respectively the upper, middle and bottom sheet. Omitting the drying vacuum led to a larger change in moisture content for the upper sheet, but not for the other sheets (measurement 18 vs. measurement 32). The upper, middle and bottom sheet of the test pack had change in moisture content’s of respectively 3.5%, 1.8%,

3.5% (measurement 32). The change in moisture content during measurement 16 (three steam pulses of 300-50 kPa, 4 min. sterilisation) was for the upper, middle and bottom sheet respectively 3.1%, 2.9% and 4.3%.
The elevated steam inlet did not improve the dryness (measurement 46 vs. measurement 48). The increase in moisture content of the upper, middle and bottom sheet of the test pack (steam flushing for 20 minutes, slow steam build-up, pulse from 300 to 100 kPa, slow steam build-up to sterilisation pressure, sterilisation for 4 minutes and drying vacuum to 50 kPa) was respectively 2.6%, 2.7%, 0.2%. Measurement 48, performed like measurement 46 using an elevated steam inlet, the change in moisture content was respectively 2.6%, 2.5%, 0.4%. Remarkable was the low change in moisture content of the sheet in the bottom of the test pack.
Measurement 50 (steam flushing for 20 minutes, slow steam build-up, pulse from 300 to 100 kPa, slow steam build-up, sterilisation for 4 minutes) was performed in the same way as measurement 46 and 48 but without an drying vacuum. By means of this measurement the increase of moisture caused by the process, without the vacuum, could be determined. The moisture contents of the upper, middle and bottom sheet were respectively 3.4%, 3.5%, 1.9%. Comparing these moisture contents, this means that the drying pulse reduced the moisture content about 1%. This was much more when compared with measurement 18 and 32.
This indicates that the effectiveness of the vacuum pulse depends on the process performed before the drying vacuum even if steam penetrated the whole test pack.

4.2.2 External condensation vessel

Measurement 55 showed that the idea behind the condensation vessel worked; by cooling the vessel, the pressure in the chamber decreased.
The condensation vessel should only be used during the drying phase. When the condensation vessel was in contact with the chamber during the entire process (measurement 56), the condensation vessel contained 940 ml water at the end of the process, while the volume of the condensation vessel was 1000 ml. Only part of the 940 ml water condensed during the drying period.
When the valve to the condensation vessel was just opened, no condensation occurred in the condensation vessel. After opening the valve to the condensation vessel in measurement 57, and opening the tap for the cooling water, no vacuum was created. This was caused by air in the condensation vessel that does not condensate. This indicated that the residual air should be removed from the vessel before cooling.
When the air was removed from the condensation vessel, the drying improved compared to other methods. At the end of the sterilisation phase of measurement 58 (process like measurement 56), first the drain of the sterilisation vessel was opened and afterwards the valve between the chamber and the external condensation vessel was opened. The steam in the chamber was released through the condensation vessel. The drain of the condensation vessel was closed when the chamber pressure reached 200 kPa. The rest of the chamber pressure was relieved through the drain of the steriliser. At the end of the drying phase, by cooling the condensation vessel for 15 minutes with 0.49 l/min, the pressure was 17 kPa and the temperature of the cooling water was 26°C. The change in moisture content of the upper, middle and bottom sheet of the test pack were respectively 1.3%, 1.7% and - 1.7%. The average increase in moisture content during the process was 0.43%.
Increasing the flow of cooling water improved the drying capabilities of the condensation vessel (measurement 58 vs. measurement 60). Measurement 60 was performed like measurement 58, but using a cooling water flow of 1.1 l/min, the change in moisture content of the upper, middle and bottom sheet were respectively 1.2%, 1.2% and –3%. The average increase in moisture content was -0.2%. At the end of the drying phase the pressure in the

chamber was 16 kPa and the condensate collected in the condensation vessel was 280 ml. During **measurement 61** the condensation vessel was cooled with 0.8 litre/minute for 30 minutes. At the end of the drying process the pressure was approximately 16 kPa. The changes in moisture content of the sheets at the top, in the middle and at the bottom of the test pack were respectively -0.1%, 1.5%, -3.5%. This process gave the best result for drying.

4.3 Packaging systems

4.3.1 Schimmelbusch drum

The most efficacious process for the standard test pack did not work for a Schimmelbusch drum (measurement 52). At the end of the sterilisation phase of measurement 52, the temperature at 1/4 of the textile pack in the Schimmelbusch reaches a maximum of 82.5°C. The B&D sheet placed in the centre of the textile pack indicated that steam did not penetrate the centre of the pack.
Measurement 69 was performed with twice a slow pressure build-up to 300 kPa followed by a pulse down to 100 kPa. The steam penetration was improved compared to measurement 52 (one slow pressure build-up to 300 kPa with a pulse to 100 kPa). However, steam penetration was still not sufficient.

4.3.2 Drums with filter in lid and bottom

The steam penetration in measurement 53 (20 minutes steam flushing at atmospheric pressure, slow pressure build-up to 300 kPa, pulse to 100 kPa, slow pressure build-up, sterilisation, drying vacuum to 50 kPa by means of the steam ejector) was not in line with the requirements. At the end of the sterilisation phase the temperature at 1/4 from the bottom of the textile reached 128°C and the B&D sheet showed a white spot beside the centre.
The process for measurement 68 (20 minutes steam flushing at atmospheric pressure, two times a slow pressure build-up to 300 kPa with a pulse to 100 kPa, slow pressure build-up, sterilisation, drying vacuum by means of external condensation vessel for 30 minutes with a cooling water flow of 0.85 litre/minute) gave a better result than the process of measurement 53. At the start of the sterilisation phase all the measured temperatures were above the theoretical temperature. The process complied to the requirements (described in paragraph 1.4.1.). The dryness of the sheets differs slightly compared to **measurement 61** (20 minutes steam flushing at atmospheric pressure, slow pressure build-up to 300 kPa, pulse to 100 kPa, slow pressure build-up, sterilisation, drying vacuum by means of external condensation vessel for 30 minutes to with a cooling water flow of 0.75 litre/minute). The average change in moisture content of the upper, centre and bottom sheet were -0.7% (**measurement 61)** and -0.6% (measurement 68).
It was possible to sterilise three stacked drums. The process of **measurement 71** (twice a slow steam build-up to 300 kPa followed by a pulse to 100 kPa), did not meet the requirements. In the centre of the bottom drum the temperature was only 131.5°C at the start of the sterilisation phase. **Measurement 72** was similar to measurement 71, but three instead of two pressure build-ups to 300 kPa followed by a pulse to 100 kPa were used. During this measurement the steam penetration of the centre of the 21 textile sheets in the drums met the requirements. The drying was performed by means of the external condensation vessel. A drying period of 30 minutes with a cooling water flow of 0.7 litre/minute was performed. The average change in moisture content of the upper, centre and bottom sheets in each drum were respectively -0.27%, -0.23% and -0.50%.

4.4 General observations

The hysteresis of the pressure control was quite large, which gave rise to a considerable fluctuation in temperature and pressure. It was therefore difficult to keep the temperature and pressure inside the band as specified in the requirements.
The operation of the steriliser is rather complex; many valves are to be operated in the right sequence. This might lead to mistakes during operation.

5 Conclusions

5.1 Air removal

The process recommended by the manufacturer **(measurement 17)** did not remotely meet the requirements for steam penetration in a standard test pack. Even in the free chamber space a temperature depression, due to residual air, was measured.
The only process (**measurement 72)** that was capable of giving acceptable steam penetration into three loaded filtered drums consisted of steam flushing at atmospheric pressure for 20 minutes, 3 times a slow pressure build-up to 300 kPa followed by a pulse to 100 kPa, and a slow pressure build-up towards sterilisation pressure.

5.2 Elevated steam inlet

It was concluded that its effect was small. During processes with an empty chamber or a full load, the use of the elevated steam inlet gave a small increase in performance. When the steriliser is redesigned, elevation of the steam inlet is a small, but simple improvement of the steriliser.

5.3 Drying

It was concluded that the effect of the steam ejector with a vacuum to 50 kPa depends on the pre-process. The steam ejector showed a better result with a pre-process of steam flushing than a pre-process with pulsing.
The external condensation vessel proved to be the most effective way to create a drying vacuum in comparison to the steam ejector. In an empty chamber, a vacuum was created down to 12 kPa. During the experiments with the standard test pack the sheets at the top and bottom of the test pack were drier after sterilisation than before. To allow for proper functioning it appeared to be necessary to flush all the air from the external condensation vessel before cooling. This was readily established by using the condensation vessel as a steam exhaust at the end of the sterilisation phase. The water consumption for cooling during **measurement 61** was 24 l, a volume that will fit a jerrycan. Moreover, the water can be cooled down and used again.

5.4 Packaging systems

The drums increased the barrier for the steam to penetrate the textile. A process using three times a slow pressure build-up followed by a pulse down to 100 kPa and thereafter a slow pressure build-up to the sterilisation pressure was necessary for adequate steam penetration in three stacked filtered drums. The average moisture content during this process was in line with the requirements in EN285 **(measurement 72**).
Two measurements were performed with a single Schimmelbusch drum filled with textile. Even the process that gave a satisfactory result for a stack of three filtered drums, did not meet the requirements. This result and the fact that a Schimmelbusch drum does not provide a microbial barrier, led to the conclusion that the use of the Schimmelbusch drum can not be recommended.

6 Recommendations

6.1 Sterilisation procedure

The process illustrated in figure 6.1 resulted in an adequate steam penetration in three stacked filtered drums, containing textile (**measurement 72**). It also resulted in an acceptable change in moisture content.
The recommendation for drying is to use an external condensation vessel. For optimal function of the vessel at first the air in the inner cavity of the vessel needs to be flushed out by steam. The cooling water should be as cold as possible. The flow of cooling water should be at least 0.7 litre/minute, during the drying phase.

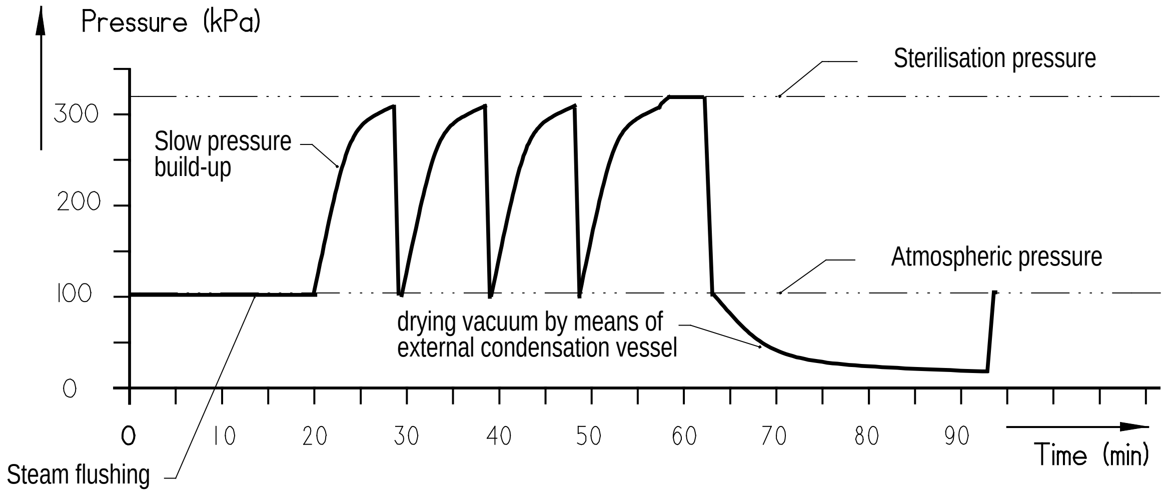


Figure 6.1: Recommended sterilisation procedure

6.2 Technical design of the steriliser

- The pipe work should be constructed in a way that the condensate in the pipe work can flow into the jacket of the steriliser to reduce the needless moisture increase of the load by spraying of moisture.
- The steam inlet should be elevated.
- The lid should be thermally isolated to prevent condensation in the chamber and to reduce the energy consumption.
- The hysteresis of automatic pressure control should be reduced to maintain the temperature band as described in the requirements.
- An improved control (mechanical) system to reduce the number of operator actions is considered essential.

6.3 Further research

6.3.1 Different loads

During the measurements in this report only measurements were performed with textile. The recommended procedure was not tested with a load of metal instruments, nor with hollow instruments. For a complete evaluation of a steriliser this should be done.

6.3.2 Other steps in the chain of supply of sterile goods

An optimal process for sterilisation is just one step in the whole process of sterile supply. Taking into account the circumstances and facilities in developing countries, further research is necessary on:

- Cleaning of used medical instruments
- Transport systems for dirty and sterilised goods
- Storage of sterilised goods

For the further development of the sterilisation process the following research is proposed:

- Development of a system for performance testing of sterilisers for users and technicians
- Packaging systems for developing countries
- The possibilities of dry heat sterilisation

Definitions

Equilibration time
Period which elapses between the attainment of the sterilisation temperature in the chamber and the attainment of the sterilisation temperature at all points within the load (EN 554).

Holding time
Period for which the temperature of all points within the steriliser is held within the sterilisation temperature band.
Note:
The holding time follows immediately after the equilibration time. The extent of the holding time is related to the sterilisation temperature (EN 285).

Plateau phase
Equilibration time plus holding time (EN 285).

Sterile
Condition of a medical device that is free from viable microorganisms (EN 556).

Sterilisation
Process undertaken to render a steriliser load sterile (EN 285).

Theoretical steam temperature
Temperature of steam calculated from the prevailing pressure.

Validation
Documented procedure for obtaining, recording and interpreting data required to show that a process will consistently comply with predetermined specifications.

References

Huys J., Sterilisation of medical supplies by steam, volume 1- General Theory, Heart Consultancy, Wageningen, The Netherlands (1996)

Loenen E.S.P.J., The performance of basic steam sterilzers, Technische Universiteit Eindhoven / wewi e, Eindhoven, (February 1995)

Standards for sterilisation, in search for an appropriate concept, J.F.M.M. Huys, Africa Health, (March 1999)

Drastic performance improvement of hand-operated sterilizers at hardly any cost, J.F.M.M. Huys, Memisa Medisch, (June 1998)

EN 285, Sterilisation - Steam sterilisers - Large sterilisers - Requirements and testing, CEN European Committee for Standardisation, Brussels (October 1996)

EN 554, Sterilisation of medical devices - validation and routine control of sterilisation by moist heat, CEN European Committee for Standardisation, Brussel (November 1994)

prEN 13060-1, Sterilisation - Steam sterilisers - Small sterilisers - Requirements and testing, CEN European Committee for Standardisation, Brussel (August 1999)

Appendix 1: Mailing list

1. Inspecteur Generaal voor de Gezondheidszorg
2. Hoofdinspecteur voor de Farmacie en de Medische Technologie
3. Mrs. dr. A. van Sliedregt, Inspectie voor de Gezondheidszorg
4. Coördinator Inspectie voor de Gezondheidszorg
5. H.P. van Dijk, Coordinator VWS
6. Directeur Genees-en Hulpmiddelenvoorziening (GMV)
7. Mr. A. de Vries, Directie Genees-en Hulpmiddelenvoorziening (GMV)
8. Bureau BAIS, VWS
9. Voorzitter Gezondheidsraad
10. Ir. J.H.A.M. Vink, Hogeschool Enschede
11. Ir. J.T.M. Laurense, Technische Universiteit Eindhoven
12. Dr. Ph. de Vries, Universitair Medisch Centrum Utrecht
13. Mrs. G.A. Sills, International Federation for Sterile Supply, Beeston Fields (UK)
14. Ir. J.P.C.M. van Doornmalen, KW2, Amersfoort
15. Mr. A. Fabrizius, Missionsärztliches Institut Armauer Hansen Institut, Würzburg (D)
16. Mr. W. Aeckersberg, Technologie Tranfer Marburg
17. Mr. H.W. Schmid, KSG Sterilisatoren GmbH, Olching (D)
18. Mr. H. Sauer, Webeco Hygiene in Medizin und Labor GmbH & Co KG, Lübeck (D).
19. Dr. A. Issakov, World Health Organization (WHO), Geneva (CH)
20. Depot Nederlandse Publicaties en Nederlandse Bibliografie
21. Directie RIVM
22. Directeur sector Risico's, Mileu en Gezondheid, RIVM
23. Hoofd Laboratorium voor Geneesmiddelen en Medische Hulpmiddelen, RIVM
24. Hoofd afdeling Medische Hulpmiddelen, RIVM

25-31. Auteurs

32. SBD/Voorlichting & Public Relations, RIVM
33. Bureau Rapportenregistratie, RIVM
34. Bibliotheek RIVM

35-44. Exemplaren voor verkoop

45-50. Reserve exemplaren

Appendix 2: Overview of test program

Nr	Steaminlet		Load	Air removal									Sterilisation	Drying				
	Stand	Elev		*Pulses*		*Steam Flushing (min)*				*Steam Ejector*	*Water ring pump*		time(min)	*Steam Ejector*	*Water ring pump*		*External condensation vessel*	
				depth (kPa-kPa)	nr	P(kPa)	time(min)	slow buid-up	fast build-up		depth (kPa-kPa)	nr			depth (kPa-kPa)	nr	time(min)	cooling(l/min)
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		
9																		
10	x		Test pack	300-100	1								4	x				
11	x		Test pack	200-100	1								4	x				
12	x		Test pack	300-50	1								4	x				
13	x		Test pack	300-50 fast	1								4	x				
14	x		Test pack	300-200	1								4	x				
15	**x**		**Test pack**	**300-50**	**2**								**4**	**x**				
16	**x**		**Test pack**	**300-50**	**3**								**4**	**x**				
17	**x**		**Test pack**							**x**			**30**	**x**				
18	x		Test pack							x			4	x				
19		X	Test pack							x			4	x				
20		X	Test pack			120	5		1				4	x				
21	x		Test pack			120	5		1				4	x				
22		X	Test pack			120	1		1				4	x				
23	x		Test pack			120	1		1				4	x				
24	x		Test pack										4	x				
25		X	Test pack	300-100	1								4	x				

	Steaminlet		**Load**	**Air removal**									**Sterilisation**	**Drying**				
	Stand	*Elev*		*Pulses*		*Steam Flushing (min)*				*Steam Ejector*	*Water ring pump*		time(min)	*Steam Ejector*	*Water ring pump*		*External condensation vessel*	
Nr				depth (kPa-kPa)	nr	P(kPa)	time(min)	slow build-up	fast build-up		depth (kPa-kPa)	nr			depth (kPa-kPa)	nr	time(min)	cooling(l.min)
26		**X**	**Test pack**	**300-100**	**2**								**4**	**x**				
27	x		Test pack	300-100	2								4	x				
28		X	Test pack			atm	11						4	x				
29		X	Test pack			atm	11	1					4	x				
30		**X**	**Test pack**			**atm**	**20**	**1**	**1**				**4**	**x**				
31	x		Test pack			atm	20		2				4	x				
32	x		Test pack							x			4					
33	x		Test pack	300-100	3								4	x				
34																		
35		X	Test pack			atm	20		2				4	x				
36		X	Test pack			atm	15	1	1				4	x				
37																		
38																		
39		X	none							x			4	x				
40	x		none							x			4	x				
41	x		Test pack			atm	15	1	1				4	x				
42																		
43		X	Test pack			atm	30	1	1				4	x				
44		**X**	**Test pack**	**300-100**	**3**								**4**	**x**				
45	x		Test pack			atm	20		2				4	x				
46	x		Test pack			atm	20	2					4	x				
47	x		Test pack			atm	30	1	1				4	x				
48		X	Test pack			atm	20	2					4	x				
49		X	Test pack			atm	20	1					4	x				
50		X	Test pack			atm	20	2					4					

Nr	Steaminlet		Load	Air removal									Sterilisation	Drying				
	Stand	Elev		Pulses		Steam Flushing (min)				Steam	Water ring pump		time(min)	Steam	Water ring pump		External condensation vessel	
				depth (kPa-kPa)	nr	P(kPa)	time(min)	slow build-up	fast build-up	Ejector	depth (kPa-kPa)	nr		Ejector	depth (kPa-kPa)	nr	time(min)	cooling(l.min)
51		X	Test pack			atm	20	2					4	x				
52		X	Schimmel			atm	20	2					4	x				
53		X	Drum			atm	20	2					4	x				
54		X	Test pack							x			4	x				
55		X	Test pack			atm	20	2					4				15	fully opened
56		X	Test pack			atm	20	2					4				15	fully opened
57		X	Test pack			atm	20	2					4				none	none
58		X	Test pack			atm	20	2					4				15	0,49
59		X	Schimmel			atm	20	2					4					
60		X	Test pack			atm	20	2					4				15	1,1
61		**X**	**Test pack**			**atm**	**20**	**2**					**4**				**30**	**0,8**
62		X	Test pack								8	1	30		20	1		
63																		
64		X	Test pack								100-8 & 150-8	2	4		20	1		
65		X	Test pack								100-8 & 150-20(2x)	3	4		20	1		
66		X	None			atm	20	2					4				15	1,4
67			Heating up															
68		X	Drum			atm	20	3					4				30	0,85
69		X	Schimmel			atm	20	3					4				30	0,51
70		X											4					
71		**X**	**3 drums**			**atm**	**20**	**3**					**4**				**30**	**0,5**
72		**X**	**3 drums**			**atm**	**30**	**4**					**4**				**30**	**0,7**

Measurement 15

Key process parameters:	2 pulses from 300 to 50 kPa

Load:	test pack

Steaminlet	**standard**	**elevated**
	x	

Change in moisture content	**(%)**
Sheet a	3
Sheet b	-1
Sheet c	6.3
Average of a, b and c	2.8

Water consumption	**(liter)**
	3.25

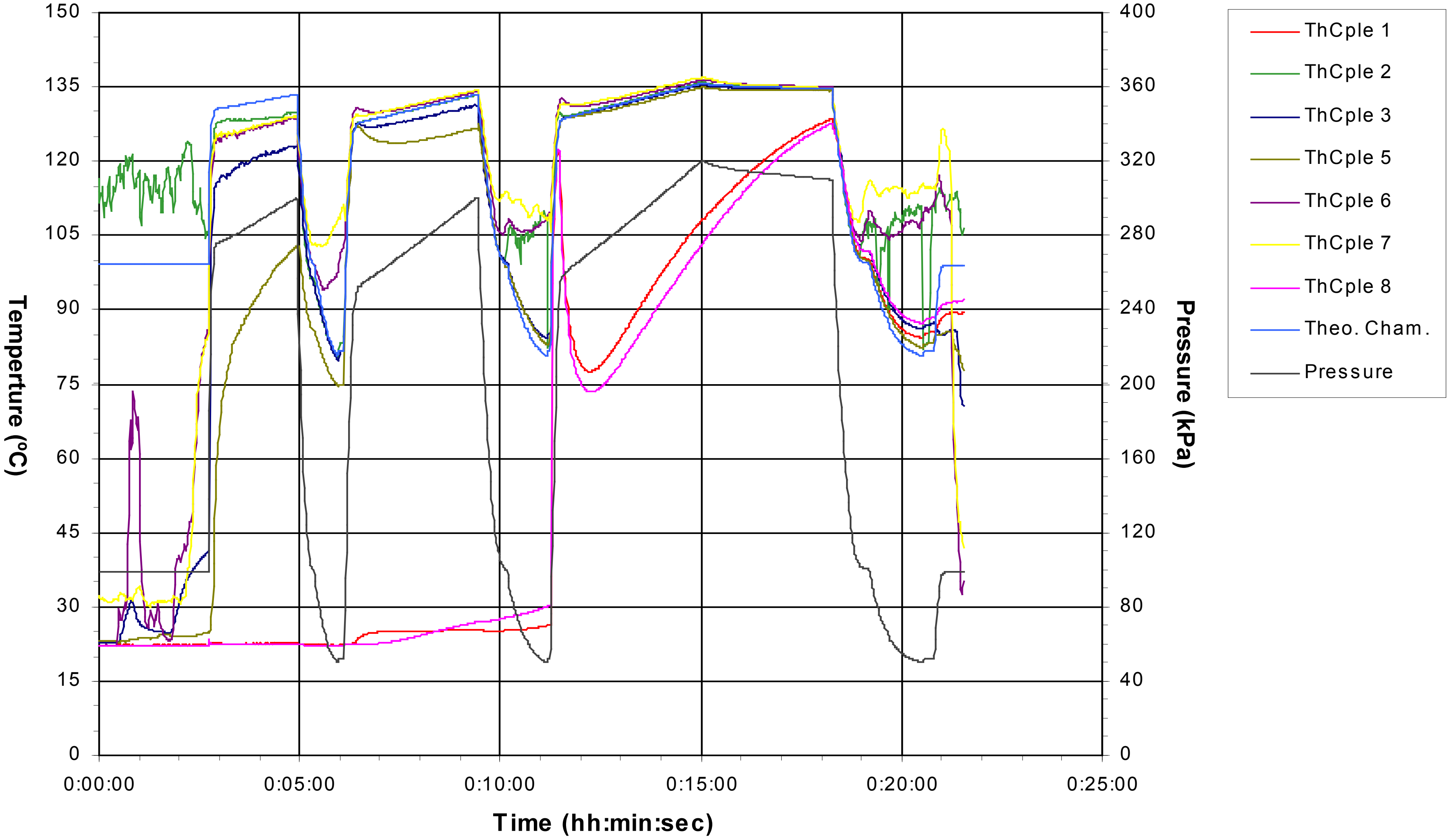
Power consumption	**(kWh)**
	?

Temperature during the sterilisation phase	**(°C)**
Min	92
Max	137
max band between min & max	43

B&D sheet	**(+/-)**
	-

Measurement 15, KSG 40-60, Standard test pack, B&D

two pulses from 300 to 50 kPa, sterilisation 4 min, drying vacuum to 50 kPa



Measurement 16

Key process parameters:	3 pulses from 300 to 50 kPa

Load:	test pack

Steaminlet	**standard**	**Elevated**
	x	

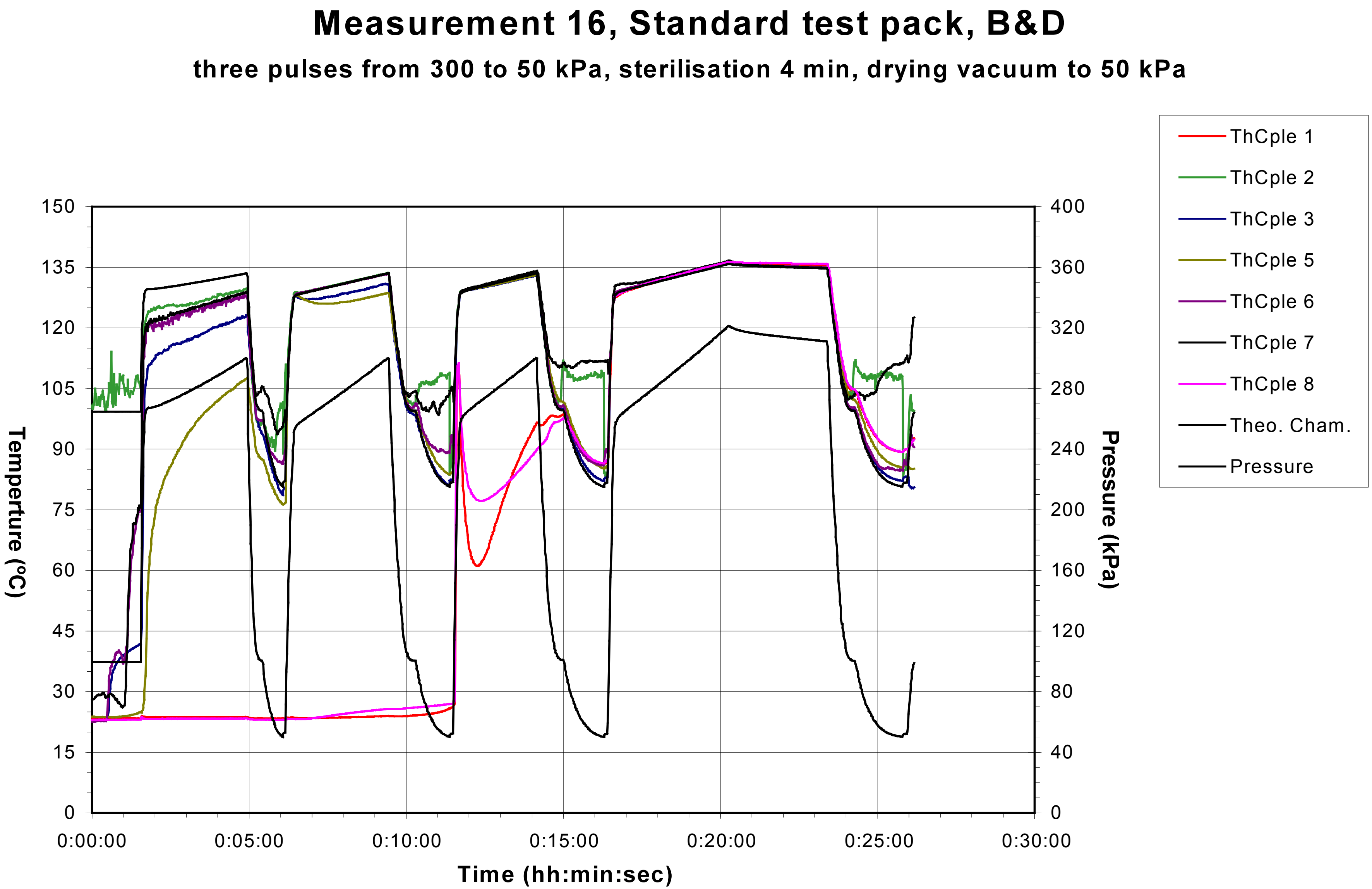
Change in moisture content	**(%)**
Sheet a	3.1
Sheet b	2.9
Sheet c	4.3
Average of a, b and c	3.4

Water consumption	**(liter)**
	4.75

Power consumption	**(kWh)**
	?

Temperature during the sterilisation phase	**(°C)**
Min	134
Max	136.5
max band between min & max	1

B&D sheet	**(+/-)**
	+



Measurement 16, Standard test pack, B&D
three pulses from 300 to 50 kPa, sterilisation 4 min, drying vacuum to 50 kPa
Temperture (°C)
Pressure (kPa)
Time (hh:min:sec)
150
135
120
105
90
75
60
45
30
15
0
400
360
320
280
240
200
160
120
80
40
0
0:00:00
0:05:00
0:10:00
0:15:00
0:20:00
0:25:00
0:30:00
ThCple 1
ThCple 2
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.
Pressure

Measurement 17

Key process parameters:	1 prevacuum to 50 kPa by means of steam jet pump, sterilisation 30 min, drying vacuum to 50 kPa

Load:	test pack

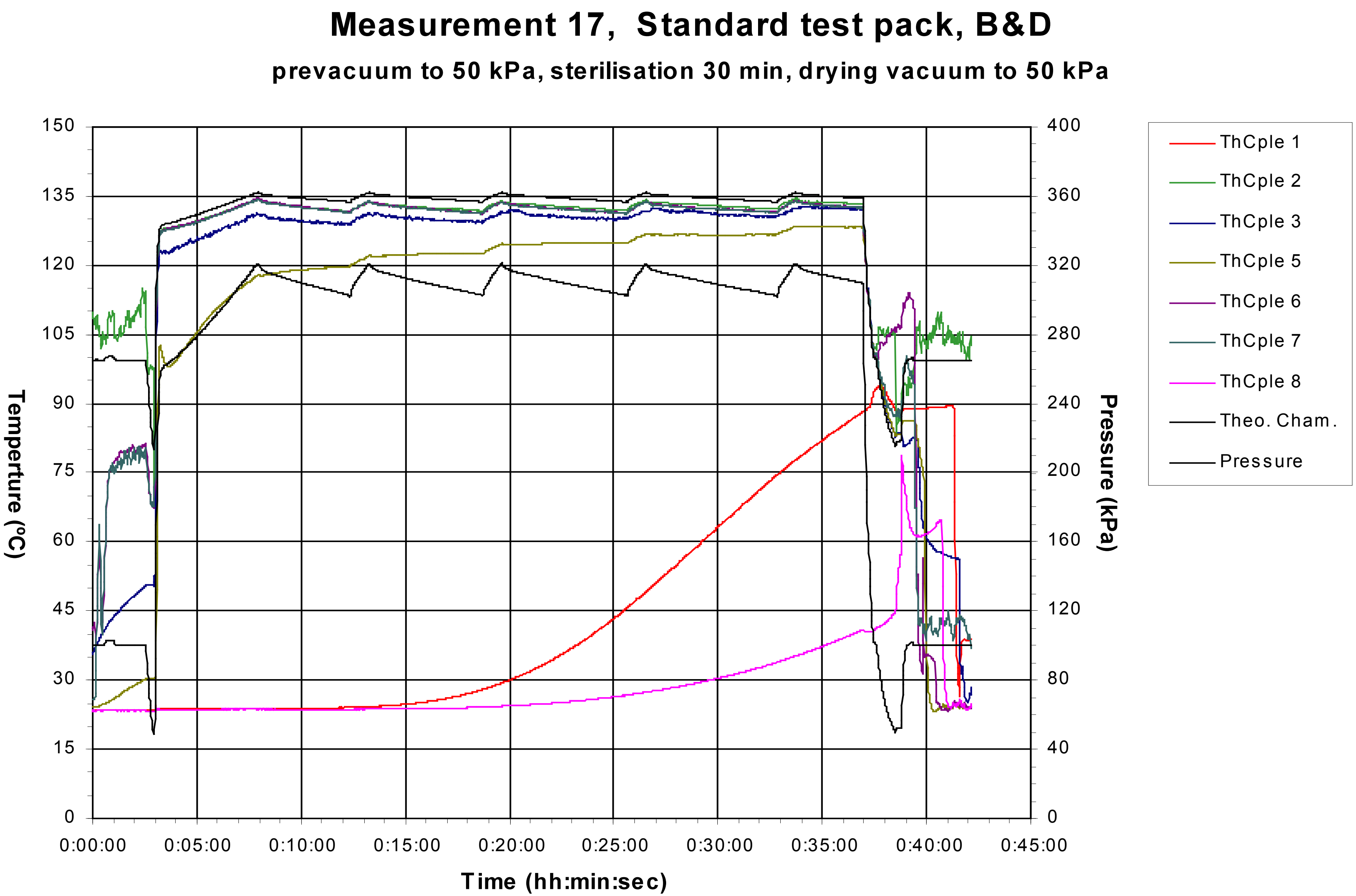
Steaminlet	**standard**	**elevated**
	x	

Change in moisture content	**(%)**
Sheet a	3.3
Sheet b	2.8
Sheet c	3.7
Average of a, b and c	3.3

Water consumption	**(liter)**
	2.3

Temperature during the sterilisation phase	**(°C)**
Min	22
Max	134
Max band between min & max	112

B&D sheet	**(+/-)**
	-



Measurement 17, Standard test pack, B&D
prevacuum to 50 kPa, sterilisation 30 min, drying vacuum to 50 kPa
Temperture (°C)
Pressure (kPa)
Time (hh:min:sec)
150
135
120
105
90
75
60
45
30
15
0
400
360
320
280
240
200
160
120
80
40
0
0:00:00
0:05:00
0:10:00
0:15:00
0:20:00
0:25:00
0:30:00
0:35:00
0:40:00
0:45:00
ThCple 1
ThCple 2
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.
Pressure

Measurement 26

Key process parameters:	2 pulses from 300 to 100 kPa

Load:	test pack

Steaminlet	**standard**	**elevated**
		x

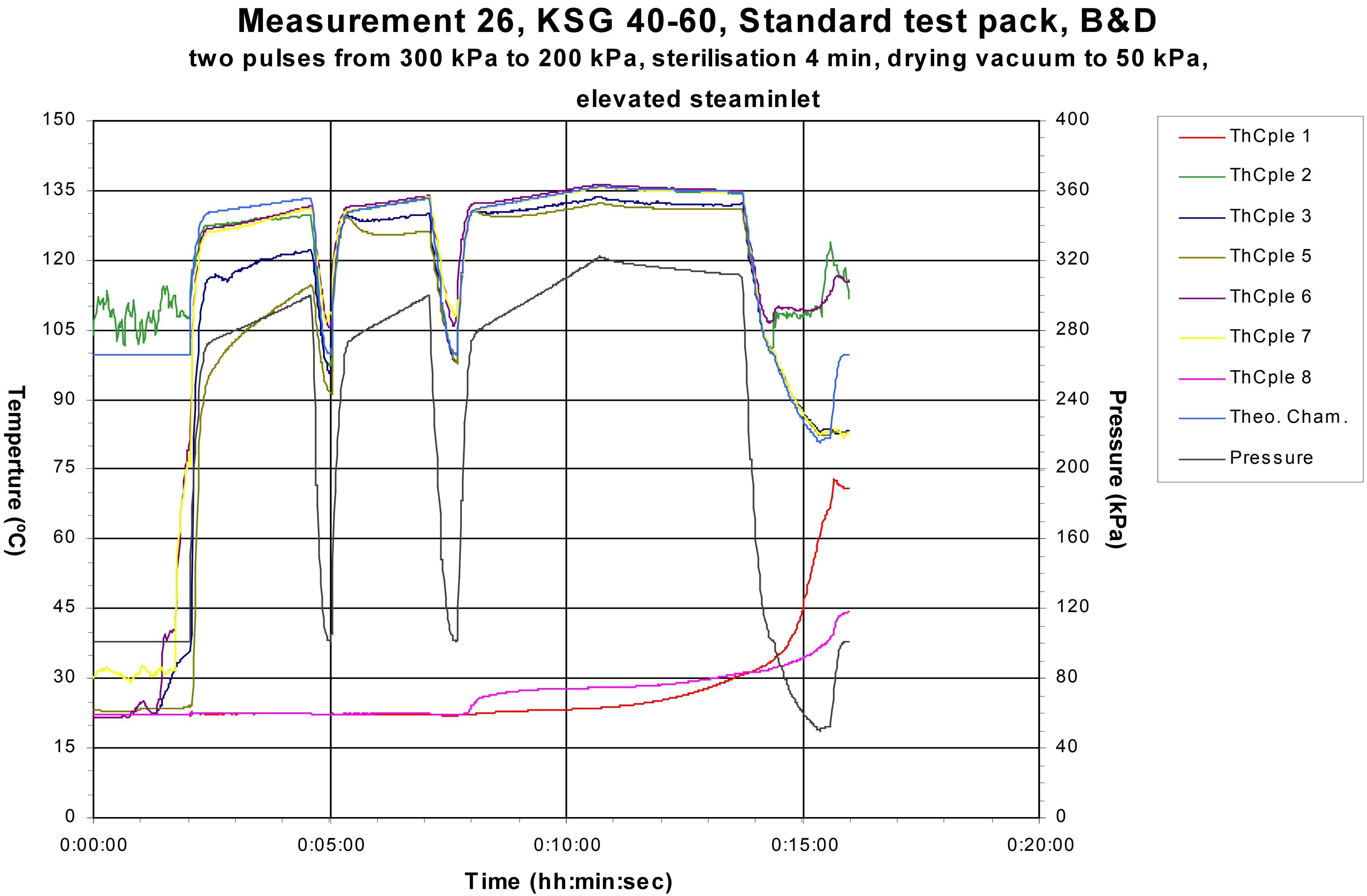
Change in moisture content	**(%)**
Sheet a	5.6
Sheet b	2.9
Sheet c	3
Average of a, b and c	3.8

Water consumption	**(liter)**
	2.3

Power consumption	**(kWh)**
	1.4 calc

Temperature during the sterilisation phase	**(°C)**
min	24
max	136
max band between min & max	112

B&D sheet	**(+/-)**
	-


Measurement 26, KSG 40-60, Standard test pack, B&D
two pulses from 300 kPa to 200 kPa, sterilisation 4 min, drying vacuum to 50 kPa,
elevated steaminlet
Temperture (°C)
Pressure (kPa)
Time (hh:min:sec)
150
135
120
105
90
75
60
45
30
15
0
400
360
320
280
240
200
160
120
80
40
0
0:00:00
0:05:00
0:10:00
0:15:00
0:20:00
ThCple 1
ThCple 2
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.
Pressure

Measurement 29

Key process parameters:	steam flushing at atmospheric pressure for 11 minutes, slow pressure build-up to 300 kPa, pulse to 100 kPa

Load:	test pack

Steaminlet	standard	elevated
		x

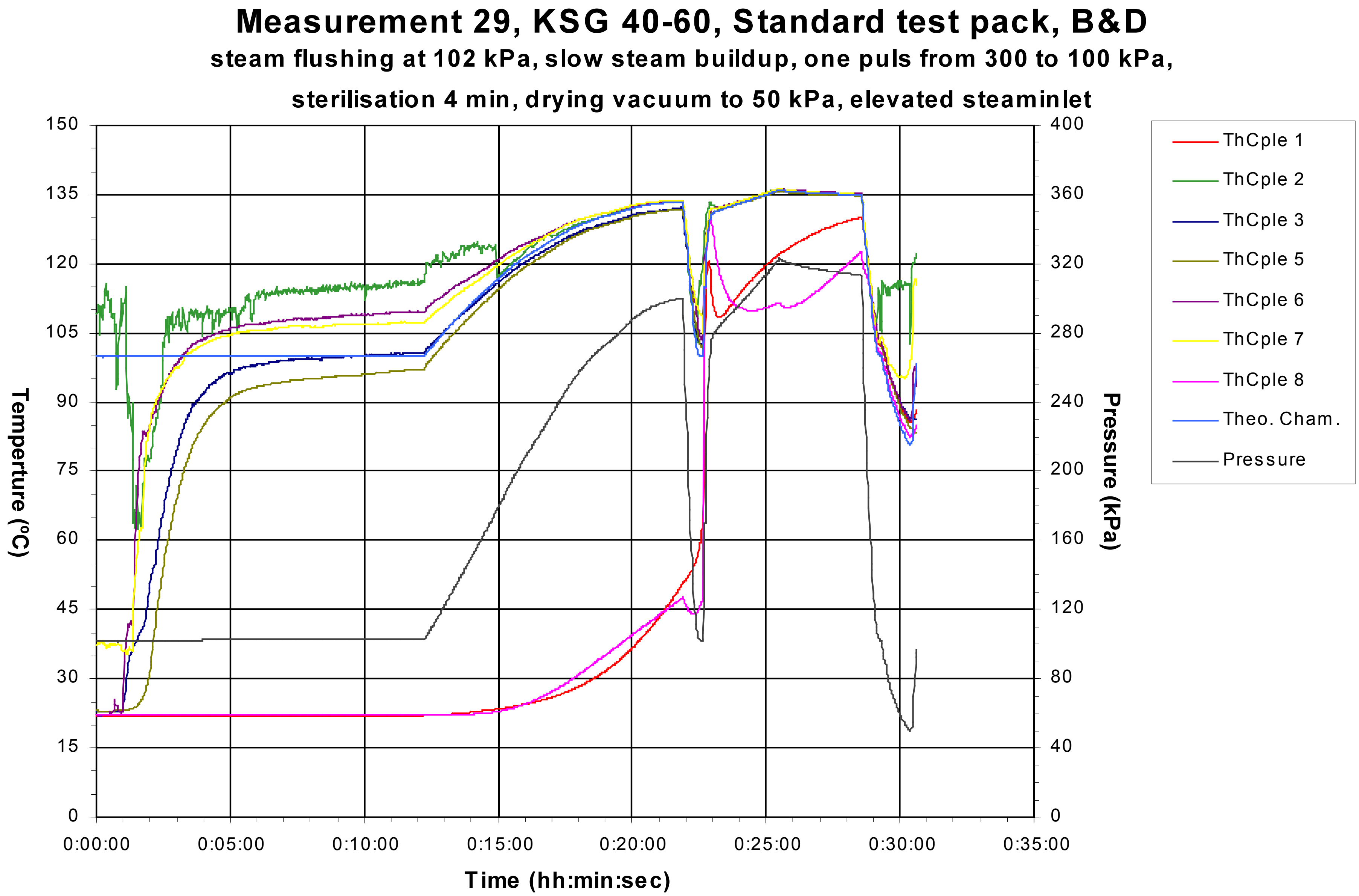
Change in moisture content	(%)
Sheet a	2.6
Sheet b	3.2
Sheet c	1.9
Average of a, b and c	2.6

Water consumption	(liter)
	2.7

Power consumption	(kWh)
	1.95 calc

Temperature during the sterilisation phase	(°C)
min	110
max	136
max band between min & max	25.5

B&D sheet	(+/-)
	-


Measurement 29, KSG 40-60, Standard test pack, B&D
steam flushing at 102 kPa, slow steam buildup, one puls from 300 to 100 kPa,
sterilisation 4 min, drying vacuum to 50 kPa, elevated steaminlet
Temperture (°C)
Pressure (kPa)
Time (hh:min:sec)
150
135
120
105
90
75
60
45
30
15
0
400
360
320
280
240
200
160
120
80
40
0
0:00:00
0:05:00
0:10:00
0:15:00
0:20:00
0:25:00
0:30:00
0:35:00
ThCple 1
ThCple 2
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.
Pressure

Measurement 30

Key process parameters:	steam flushing at atmospheric pressure for 20 minutes, slow pressure build-up to 300 kPa, pulse to 100 kPa

Load:	test pack

Steaminlet	**standard**	**elevated**
		x

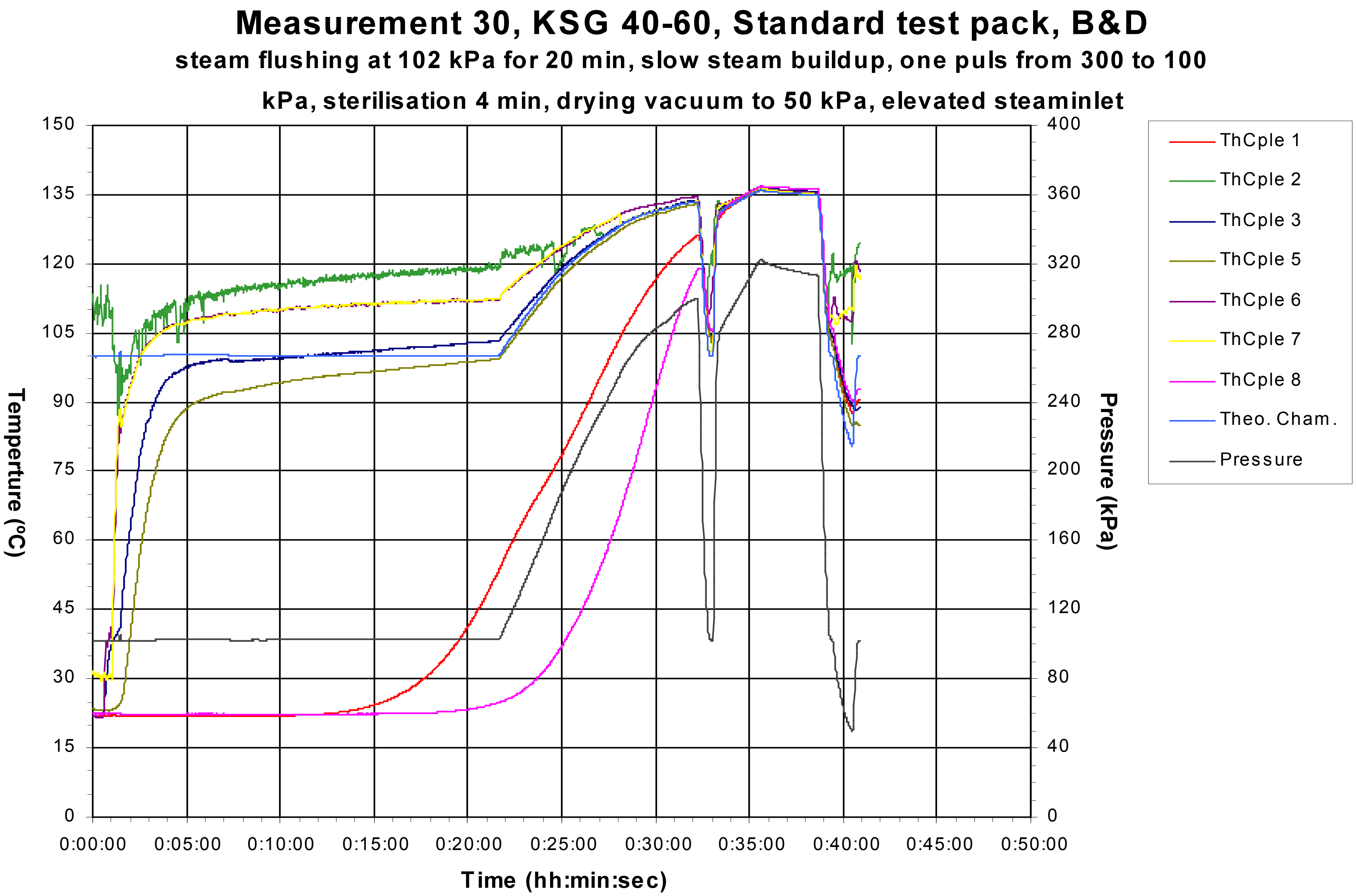
Change in moisture content	**(%)**
Sheet a	2.2
Sheet b	2.8
Sheet c	1
Average of a, b and c	2

Water consumption	**(liter)**
	4.3

Power consumption	**(kWh)**
	2.4 calc

Temperature during the sterilisation phase	**(°C)**
min	134
max	136.5
max band between min & max	1.5

B&D sheet	**(+/-)**
	+



Measurement 30, KSG 40-60, Standard test pack, B&D
steam flushing at 102 kPa for 20 min, slow steam buildup, one puls from 300 to 100 kPa, sterilisation 4 min, drying vacuum to 50 kPa, elevated steaminlet
Temperture (°C)
Pressure (kPa)
Time (hh:min:sec)
0
15
30
45
60
75
90
105
120
135
150
0
40
80
120
160
200
240
280
320
360
400
0:00:00
0:05:00
0:10:00
0:15:00
0:20:00
0:25:00
0:30:00
0:35:00
0:40:00
0:45:00
0:50:00
ThCple 1
ThCple 2
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.
Pressure

Measurement 40

Key process parameters:	prevacuum to 50 kPa by means of the steam ejector

Load:	none

Steam inlet	**standard**	**elevated**
	x	

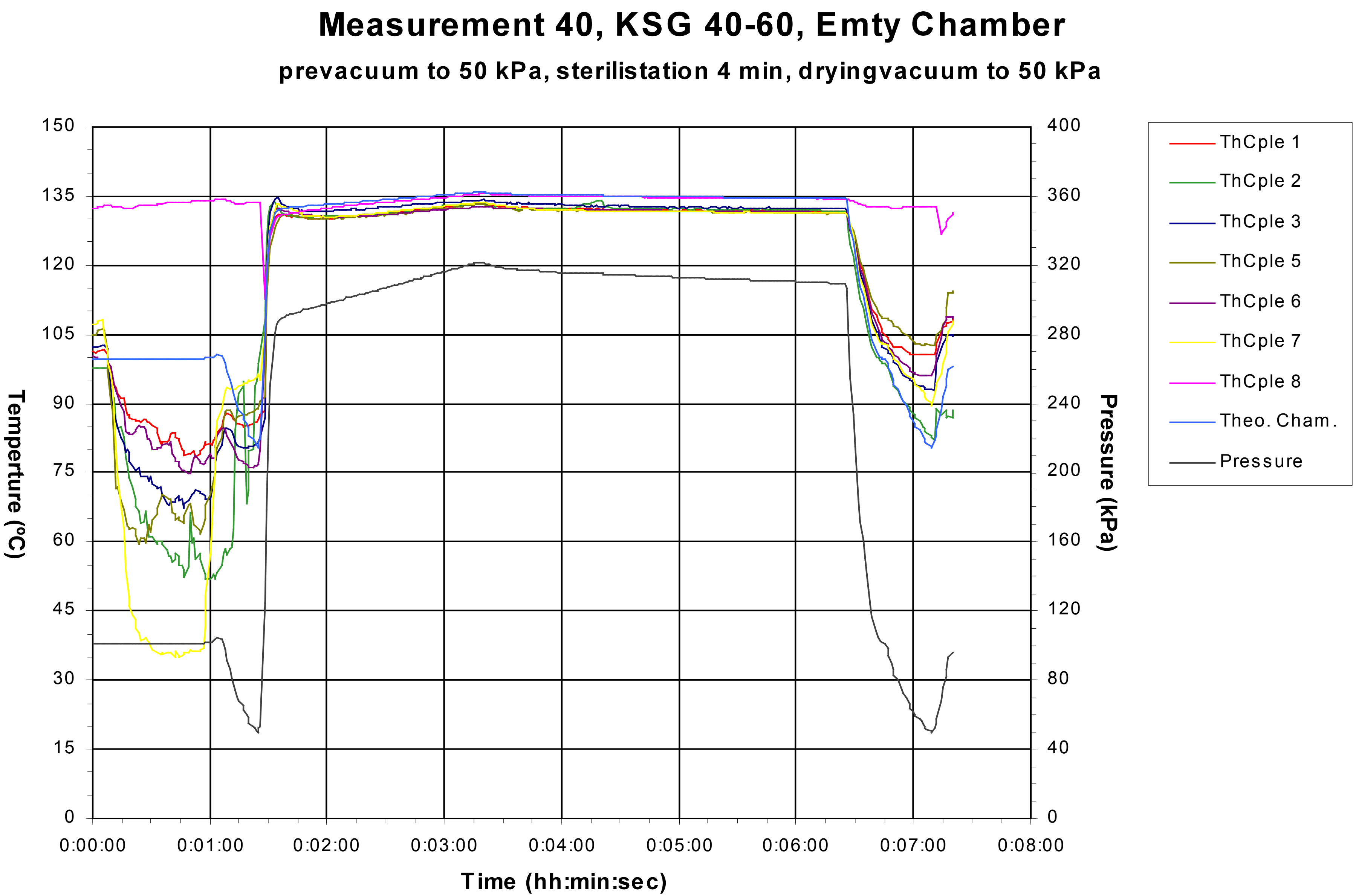
Change in moisture content	**(%)**
Sheet a	-
Sheet b	-
Sheet c	-
Average of a, b and c	-

Water consumption	**(liter)**
	?

Power consumption	**(kWh)**
	?

Temperature during the sterilisation phase	**(°C)**
min	131
max	134
max band between min & max	2

B&D sheet	**(+/-)**


Measurement 40, KSG 40-60, Emty Chamber
prevacuum to 50 kPa, sterilistation 4 min, dryingvacuum to 50 kPa
Temperture (°C)
Pressure (kPa)
Time (hh:min:sec)
150
135
120
105
90
75
60
45
30
15
0
400
360
320
280
240
200
160
120
80
40
0
0:00:00
0:01:00
0:02:00
0:03:00
0:04:00
0:05:00
0:06:00
0:07:00
0:08:00
ThCple 1
ThCple 2
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.
Pressure

Measurement 44

Key process parameters:	3 pulses from 300 to 100 kPa

Load:	test pack

Steam inlet	**standard**	**elevated**
		x

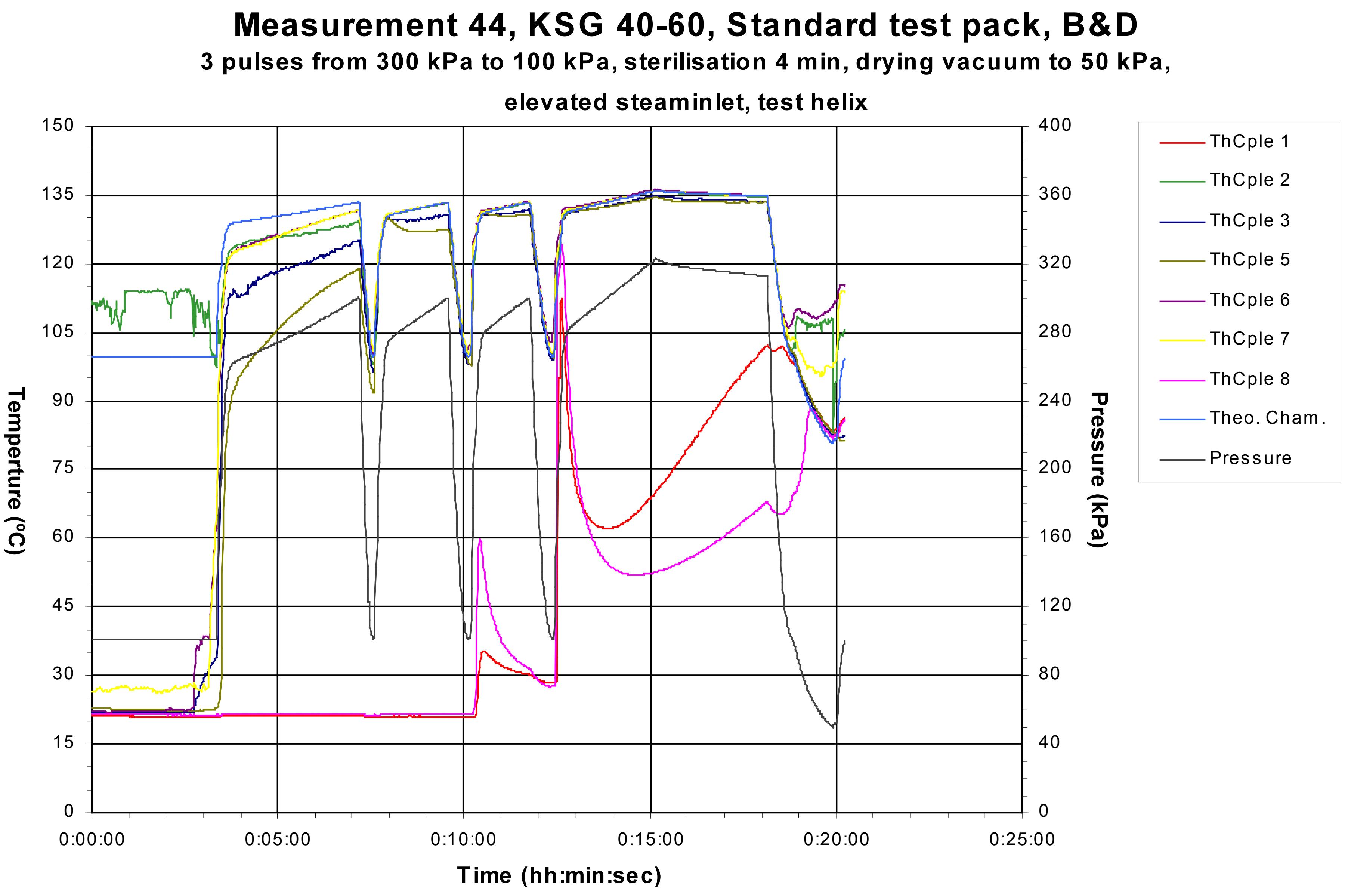
Change in moisture content	**(%)**
Sheet a	3.8
Sheet b	2.8
Sheet c	4.3
Average of a, b and c	3.6

Water consumption	**(liter)**
	2.95

Power consumption	**(kWh)**
	1.93

Temperature during the sterilisation phase	**(°C)**
min	51
max	136
max band between min & max	83

B&D sheet	**(+/-)**
	-


Measurement 44, KSG 40-60, Standard test pack, B&D
3 pulses from 300 kPa to 100 kPa, sterilisation 4 min, drying vacuum to 50 kPa, elevated steaminlet, test helix
Temperture (°C)
Pressure (kPa)
Time (hh:min:sec)
ThCple 1
ThCple 2
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.
Pressure

Measurement 61

Key process parameters:	- steam flushing at atmospheric pressure for 20 minutes, slow pressure build-up to 300 kPa, pulse to 100 kPa, slow pressure build-up - drying with condensation vessel for 30 minutes with 0.8 liter/minute

Load:	test pack

Steam inlet	**standard**	**elevated**
		x

Change in moisture content	**(%)**
Sheet a	-0.1
Sheet b	1.5
Sheet c	-3.5
Average of a, b and c	-0.7

Water consumption	**(liter)**
	3.5

Power consumption	**(kWh)**
	3.1

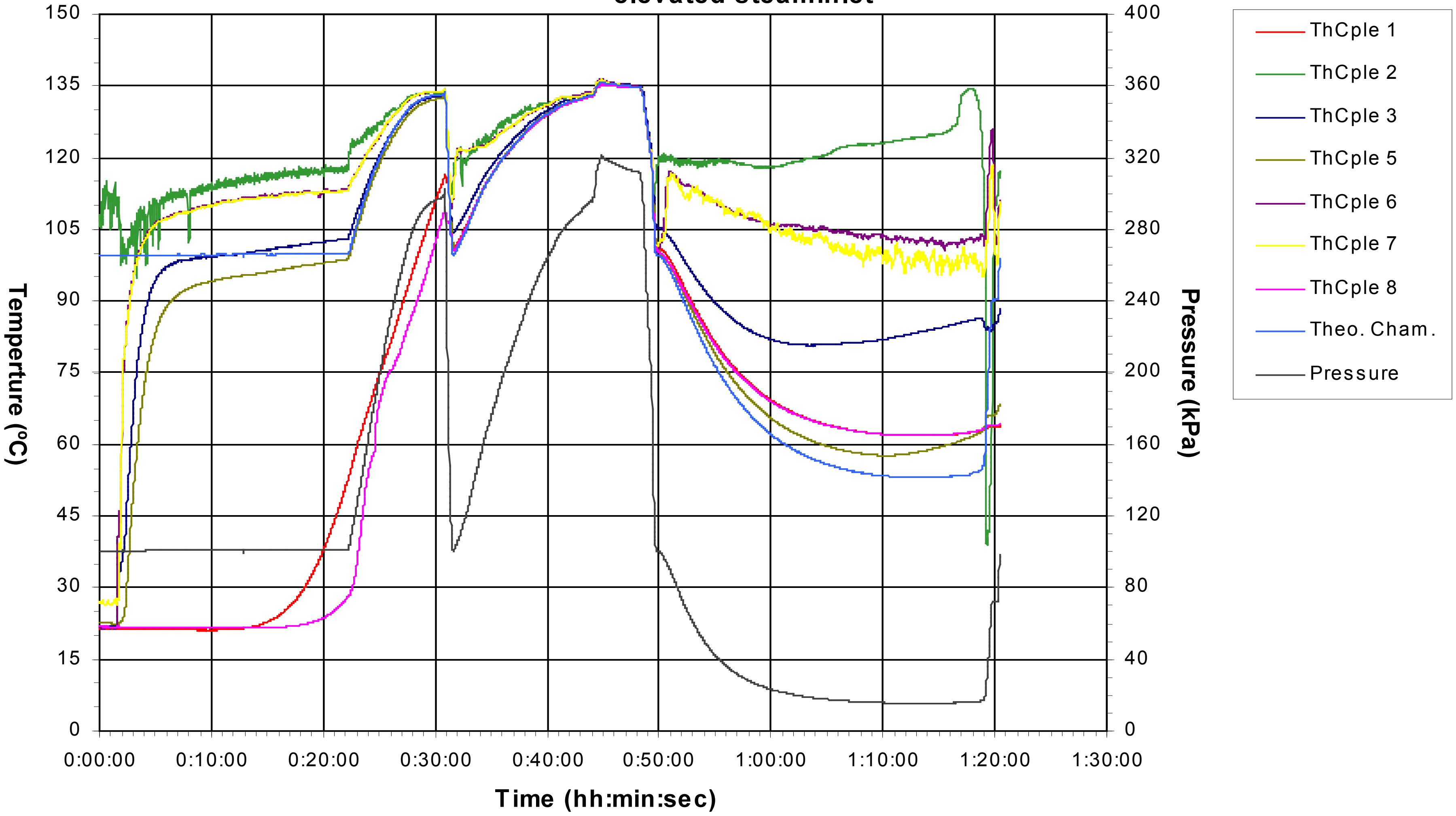
Temperature during the sterilisation phase	**(°C)**
Min	134
Max	136
Max band between min & max	1

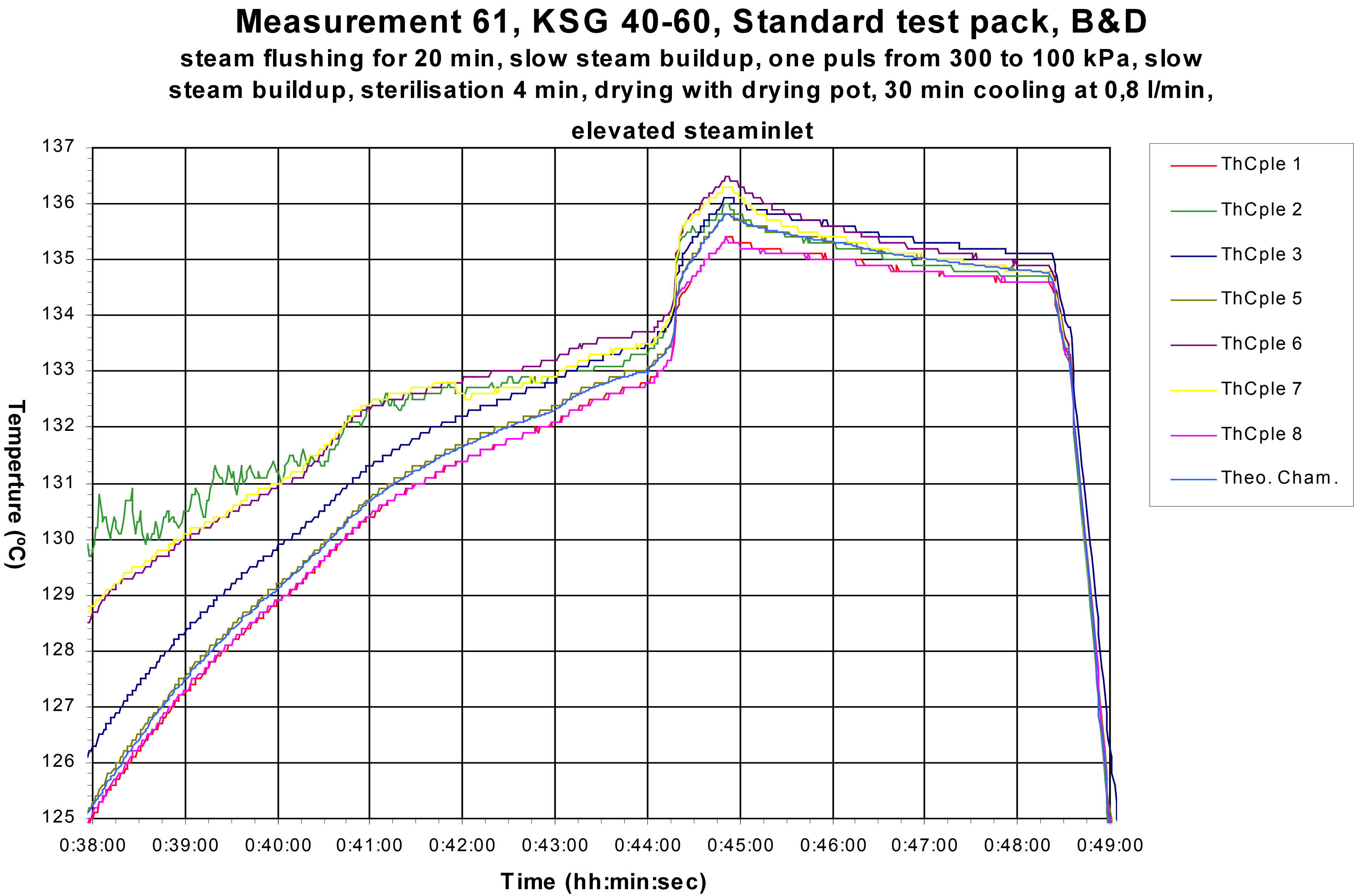
B&D sheet	**(+/-)**
	+

Temperature of cooling water after (min)	**(°C)**
0	70
2.5	61
5	48
7.5	35
10	31
15	25
20	22
25	21
30	21
Volume of condense in condensation vessel after drying	**(ml)**
	280

Measurement 61, KSG 40-60, Standard test pack, B&D

steam flushing for 20 min, slow steam buildup, one puls from 300 to 100 kPa, slow steam buildup, sterilisation 4 min, drying with drying pot, 30 min cooling at 0,8 l/min, elevated steaminlet




Measurement 61, KSG 40-60, Standard test pack, B&D
steam flushing for 20 min, slow steam buildup, one puls from 300 to 100 kPa, slow steam buildup, sterilisation 4 min, drying with drying pot, 30 min cooling at 0,8 l/min, elevated steaminlet
Temperture (°C)
137
136
135
134
133
132
131
130
129
128
127
126
125
0:38:00
0:39:00
0:40:00
0:41:00
0:42:00
0:43:00
0:44:00
0:45:00
0:46:00
0:47:00
0:48:00
0:49:00
Time (hh:min:sec)
ThCple 1
ThCple 2
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.

Measurement 71

Key process parameters:	- steam flushing at atmospheric pressure for 20 minutes, 2 slow pressure build-up to 300 kPa with a pulse to 100 kPa, a slow pressure build-up before sterilisation - drying with external condensation vessel for 30 minutes with 0.5 liter /minute

Load:	3 filtered drums, each filled with 21 sheets

Steam inlet	**standard**	**elevated**
		x

Change in moisture content	**upper drum (%)**	**middle drum (%)**	**lower drum (%)**
Sheet a	1.55	-0.12	2.20
Sheet b	1.71	2.74	1.65
Sheet c	-1.02	-0.78	-1.48
Average of a, b and c	0.74	0.61	0.79

Water consumption	**(liter)**
	?

Power consumption	**(kWh)**
	2.25

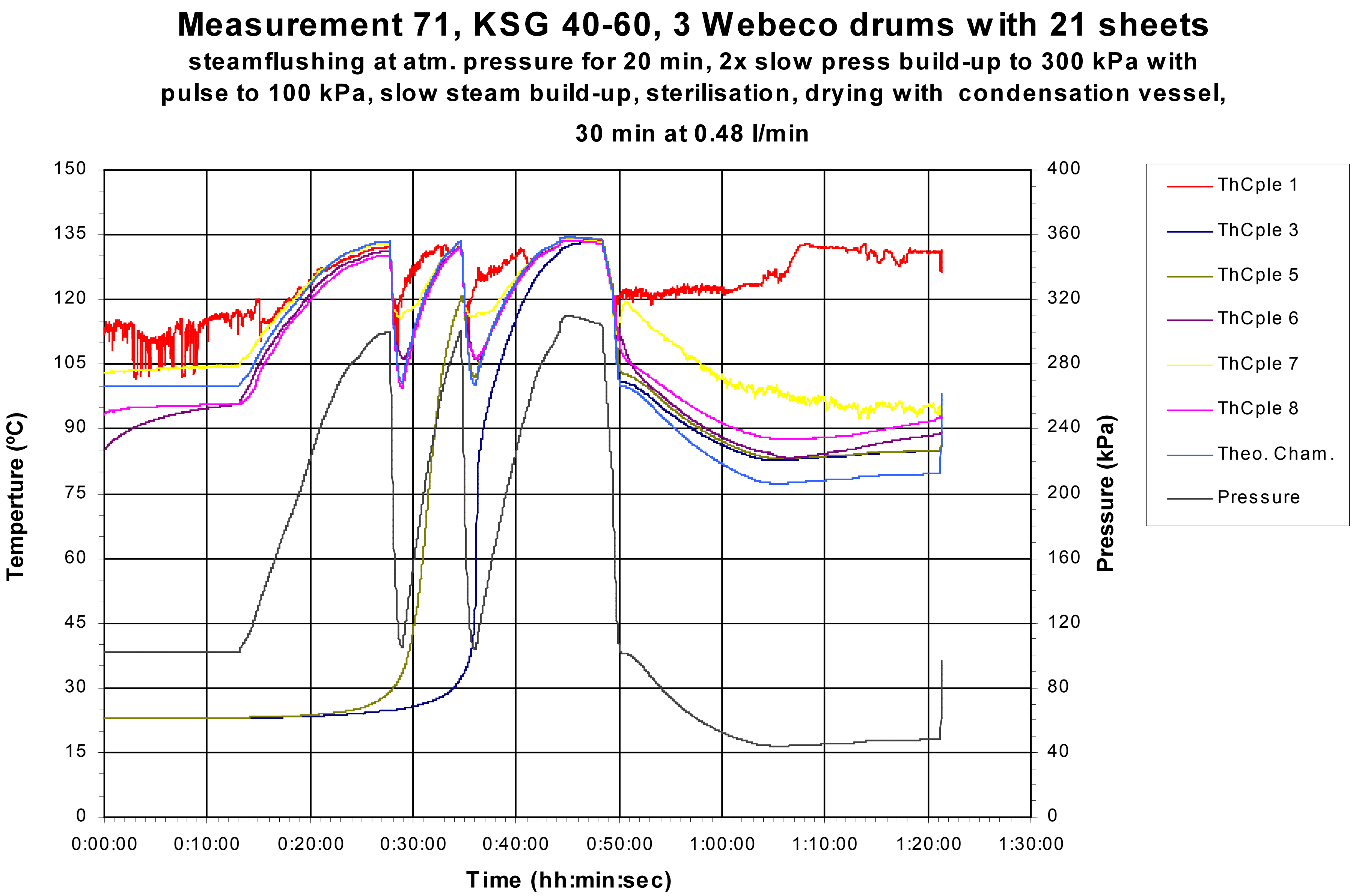
Temperature during the sterilisation phase	**(°C)**
Min	132
Max	134.5
max band between min & max	2.5

B&D sheet	**upper drum (+/-)**	**middle drum (+/-)**	**lower drum (+/-)**
	+	+	+

Temperature of cooling water after (min)	**(°C)**
0	73
2.5	72
5	66

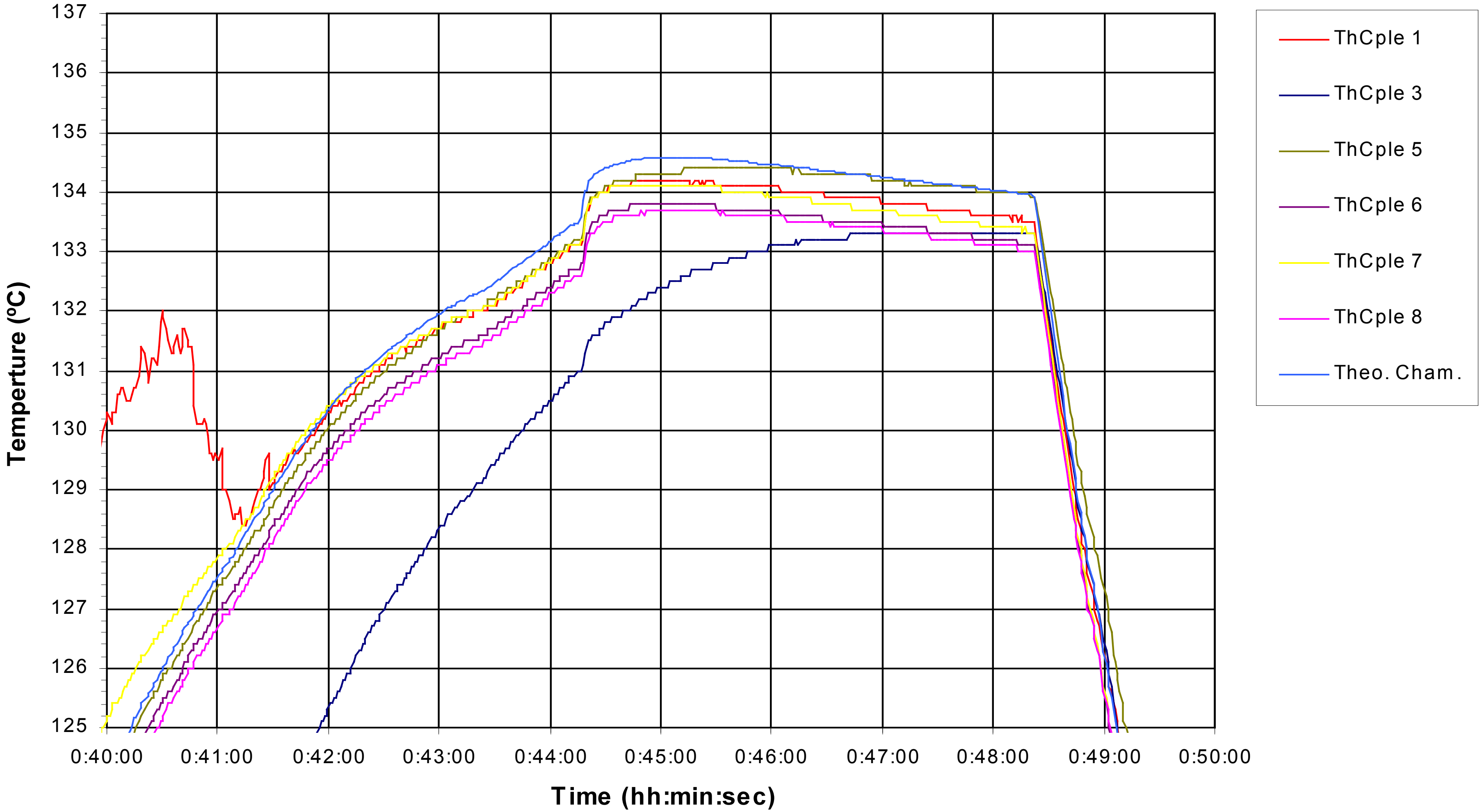
Volume of condense in condensation vessel after drying	**(ml)**
	315

The thermocouples were placed in different positions as described in paragraph 3.3.1.1. Thermocouple 7 was placed 2 cm under the lid. Thermocouple 1 is placed in the drain. Thermocouple 3 is placed in the centre of the textile in the lowest drum. Thermocouple 8 is placed in the centre of the textile in the drum in the middle of the steriliser. Thermocouple 5 is placed in the centre of the textile of the highest drum. In the same drum thermocouple 6 is


Measurement 71, KSG 40-60, 3 Webeco drums with 21 sheets
steamflushing at atm. pressure for 20 min, 2x slow press build-up to 300 kPa with pulse to 100 kPa, slow steam build-up, sterilisation, drying with condensation vessel, 30 min at 0.48 l/min
Temperture (ºC)
Pressure (kPa)
Time (hh:min:sec)
150
135
120
105
90
75
60
45
30
15
0
400
360
320
280
240
200
160
120
80
40
0
0:00:00
0:10:00
0:20:00
0:30:00
0:40:00
0:50:00
1:00:00
1:10:00
1:20:00
1:30:00
ThCple 1
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.
Pressure

Measurement 71, KSG 40-60, 3 Webeco drums with 21 sheets

steamflushing at atm. pressure for 20 min, 2x slow press build-up to 300 kPa with pulse to 100 kPa, slow steam build-up, sterilisation, drying with condensation vessel, 30 min at 0.48 l/min



Measurement 72

Key process parameters:	- steam flushing at atmospheric pressure for 20 minutes, 3 slow pressure build-ups to 300 kPa with a pulse to 100 kPa, a slow pressure build-up before sterilisation - drying with external condensation vessel for 30 minutes with 0.7 liter /minute

Load:	3 filtered drums each filled with 21 sheets

Steam inlet	**standard**	**elevated**
		x

Change in moisture content	**upper drum (%)**	**middle drum (%)**	**lower drum (%)**
Sheet a	-0.10	0.43	0.56
Sheet b	0.82	0.55	0.59
Sheet c	-1.74	-1.66	-2.66
Average of a, b and c	-0.34	-0.23	0.50

Water consumption	**(liter)**
	5.15

Power consumption	**(kWh)**
	4.08

Temperature during the sterilisation phase	**(°C)**
Min	133.5
Max	135
max band between min & max	1.25

B&D sheet	**upper Drum (+/-)**	**middle drum (+/-)**	**Lower drum (+/-)**
	+	+	+

Temperature of cooling water after (min)	**(°C)**
0	71
2.5	74
5	65
7.5	54
10	45
15	35
20	32
25	29
30	27

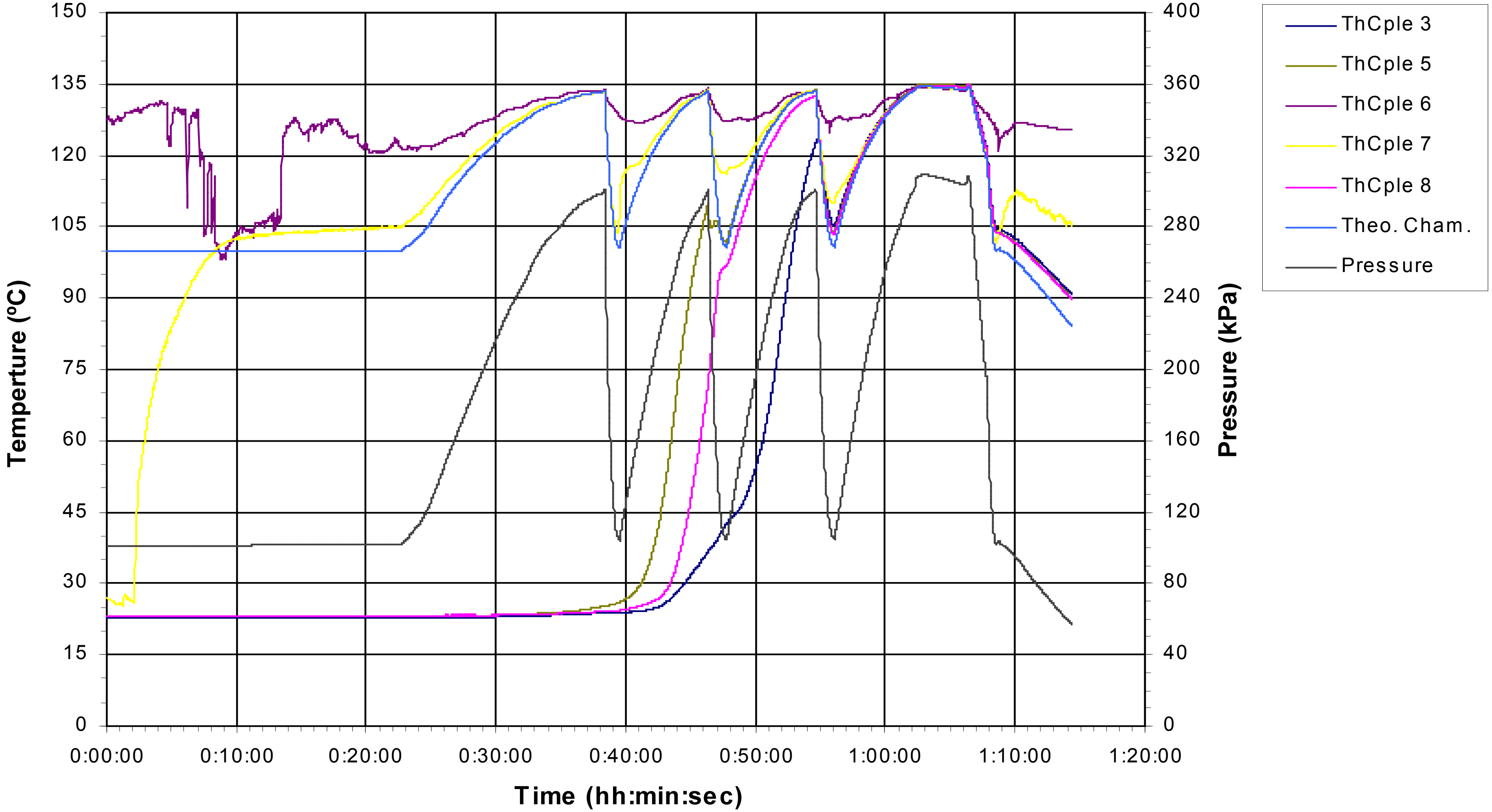
The thermocouples were placed in different positions as described in paragraph 3.3.1.1. Thermocouple 7 was placed 2 cm under the lid. Thermocouple 6 is placed in the drain. Thermocouple 3 is placed in the centre of the textile in the lowest drum. Thermocouple 8 is placed in the centre of the textile in the drum in the middle of the steriliser and thermocouple 5 is placed in the centre of the textile of the highest drum.

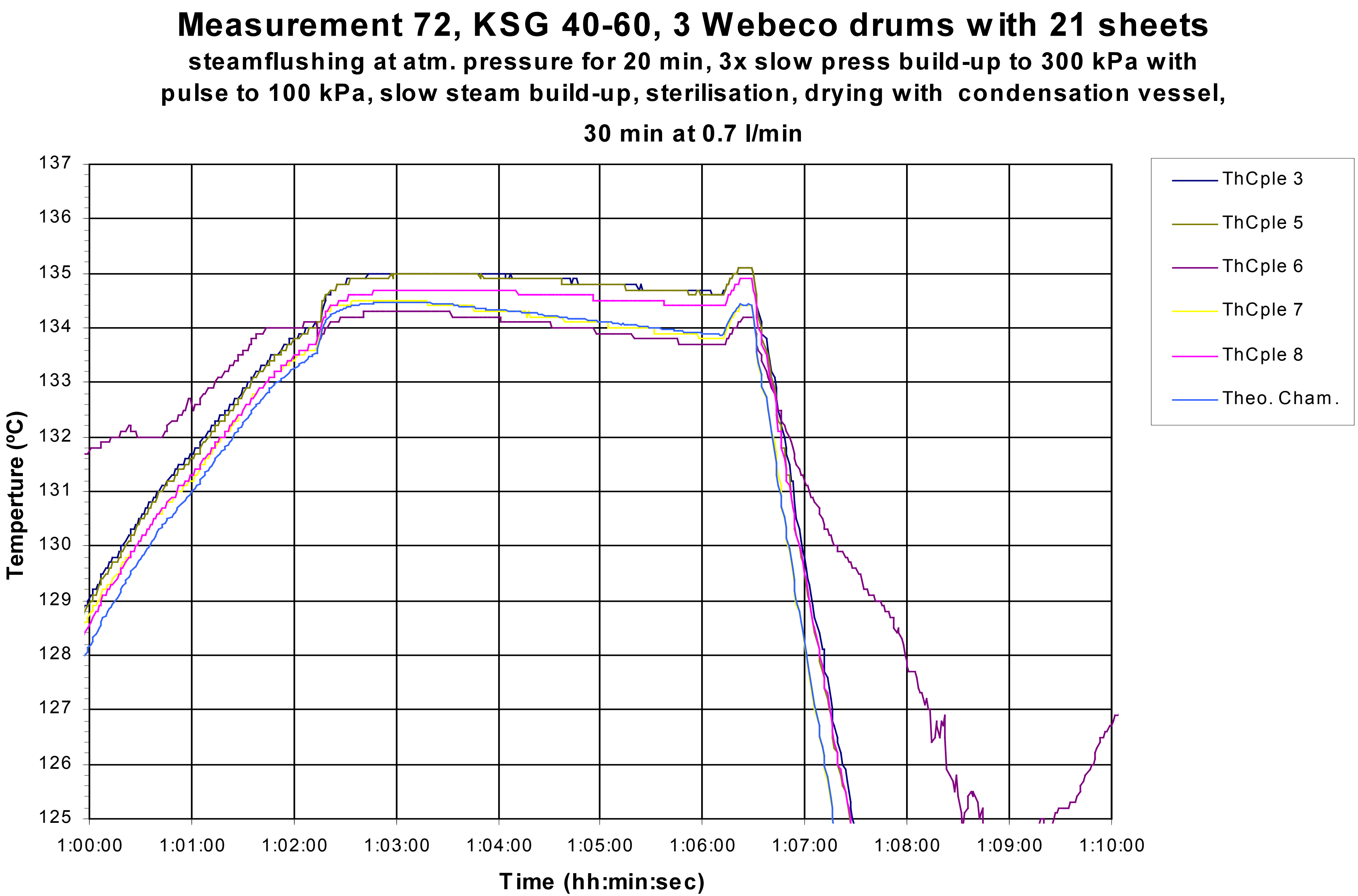
The pressure at the end of the drying phase is 18 kPa.

Measurement 72, KSG 40-60, 3 Webeco drums with 21 sheets

steamflushing at atm. pressure for 20 min, 3x slow press build-up to 300 kPa with pulse to 100 kPa, slow steam build-up, sterilisation, drying with condensation vessel,

30 min at 0.7 l/min





Measurement 72, KSG 40-60, 3 Webeco drums with 21 sheets
steamflushing at atm. pressure for 20 min, 3x slow press build-up to 300 kPa with
pulse to 100 kPa, slow steam build-up, sterilisation, drying with condensation vessel,
30 min at 0.7 l/min
Temperture (ºC)
137
136
135
134
133
132
131
130
129
128
127
126
125
1:00:00
1:01:00
1:02:00
1:03:00
1:04:00
1:05:00
1:06:00
1:07:00
1:08:00
1:09:00
1:10:00
Time (hh:min:sec)
ThCple 3
ThCple 5
ThCple 6
ThCple 7
ThCple 8
Theo. Cham.