Monitoring the efficacy of surface steam sterilization processes with temperature and pressure alone

Is this a Valid Approach ?

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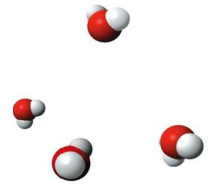
Contents

- Basic Requirements for moist heat sterilization.
  - Source of moisture, saturated steam, steam tables, consequences of residual air.
- Monitoring the surface steam sterilization process
- What the standards require.
  - During the holding time, temperature, pressure and theoretical temp. PCD results
- Use of T-P correlation alone.
  - Daltons Law of Partial Pressures.
- Evidence
- BIER vessel studies (reported in 2000 at WFHSS Zurich)
- Laboratory studies in which air causes thermometric failures in a textile pack
- Field studies comparing routine Pass and Fail daily test results using an electronic Bowie and Dick Test instrument.

Basic requirements for moist heat sterilization



Steam or Moist Heat sterilization is achieved by exposing surfaces which need to be sterilized (the medical device) to;

- **Adequate temperature** eg 121 °C or 134 °C
- **Adequate time** eg 15 mins or 3 mins
- **In the presence of moisture** ie water molecules which may be in vapour or liquid state (surface steam sterilization or contained product eg IV infusions).
- **These are the "Process Variables" for a moist heat sterilization process**
  - (ISO 17665)
  - **Note pressure does not contribute to microbial kill. It is a cycle variable used to control the process.**

3.40
process variable
chemical or physical attribute within a cleaning, disinfection, packaging, or sterilization process, changes in which can alter its effectiveness

Note 1 to entry: For the purposes of this document, process variables are conditions within a sterilization process, changes in which alter microbicidal effectiveness, i.e. exposure time and temperature in the presence of moist heat.

ISO 11139:2018 Sterilization of health care products - Vocabulary – Terms used in sterilization and related equipment and process standards (ISO11139:2018) modified with note from ISO 17665-CD2:2019

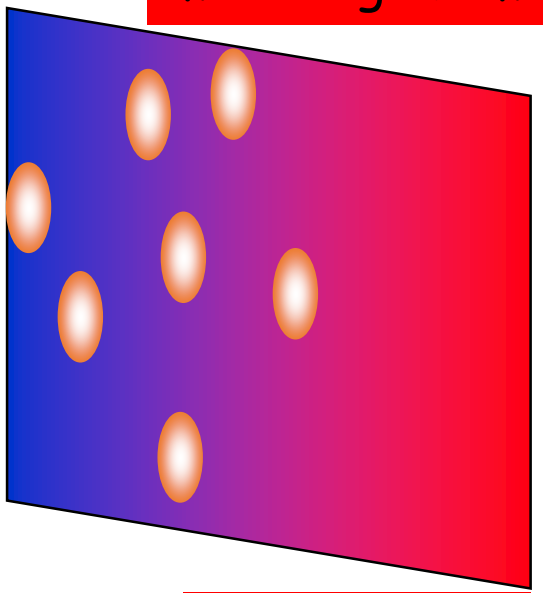
Commonly Used Time Temperature Relationships for moist heat sterilization

Temperature (° C)	Time (mins)
134	3*
132	4
126	10*
121	15*
115	30 *rarely used today*

***Medical Research Council ,Lancet. 1959 Feb 28;1(7070):425-35**

The source of moisture in Surface Steam Sterilisation; Saturated Steam

Time at Temperature in the presence of moisture kills the microorgansims

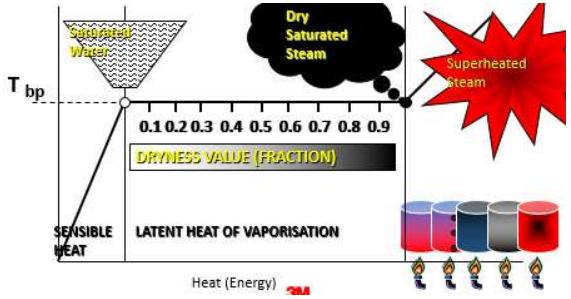


Surface Heats Up

Energy is released while condensate forms

Steam hits cold surface

"Latent Heat of Condensation"

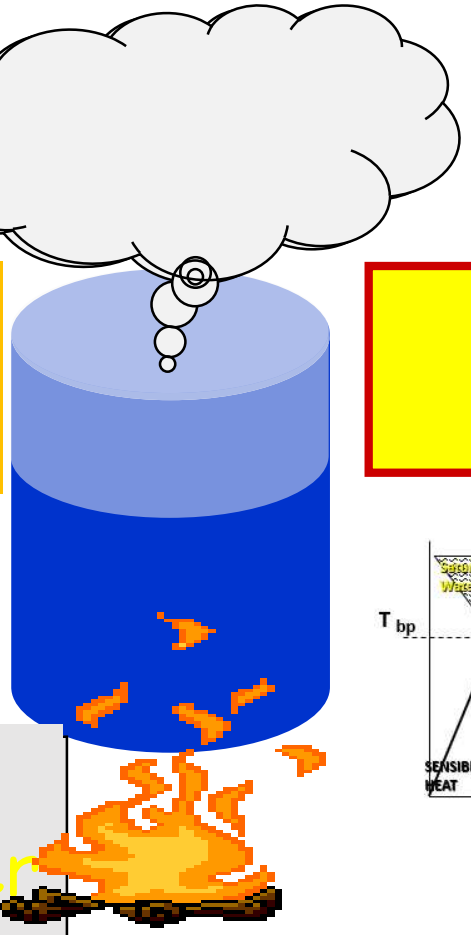


Process Variables

Temperature

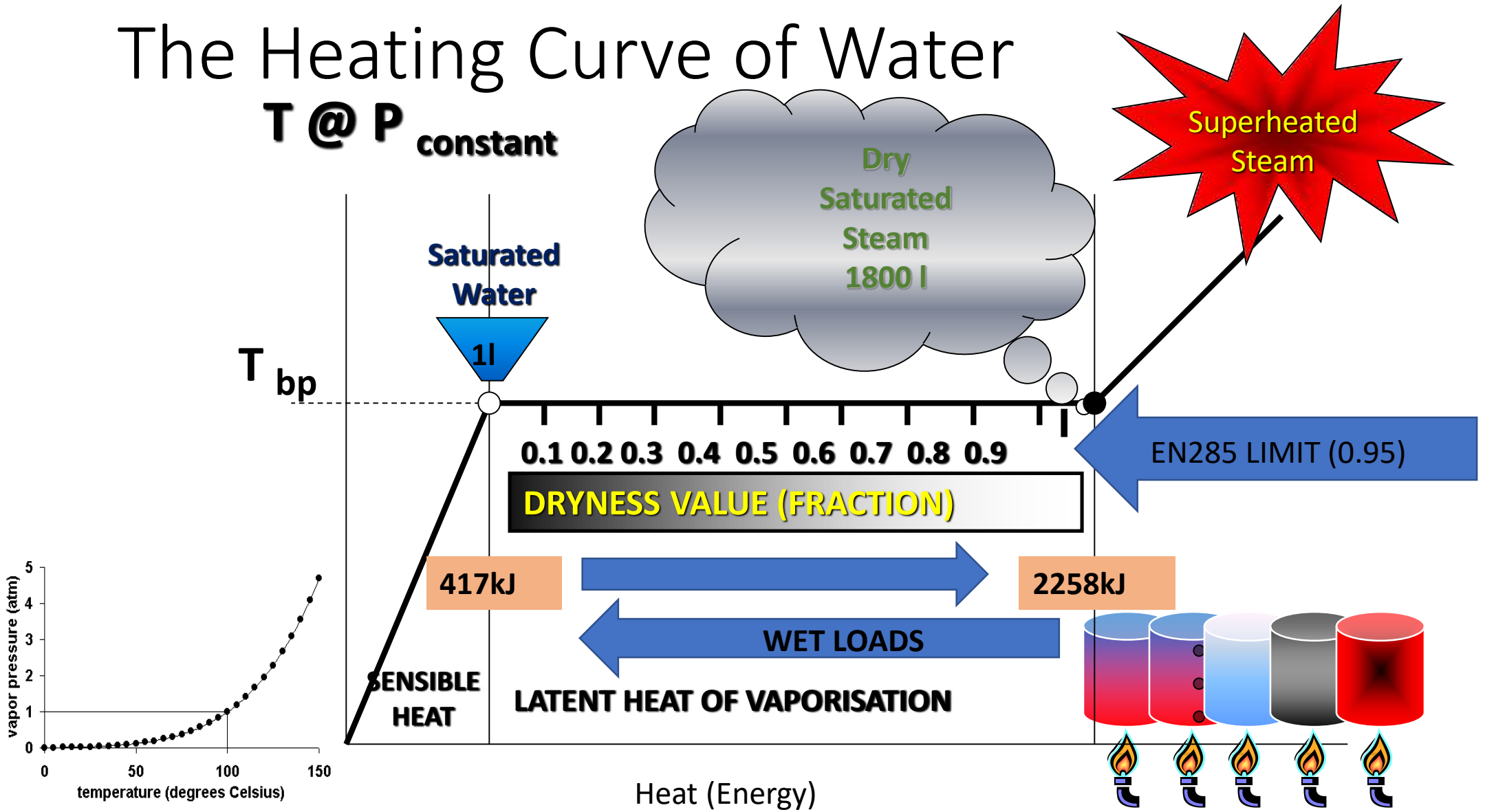
Time

Moisture



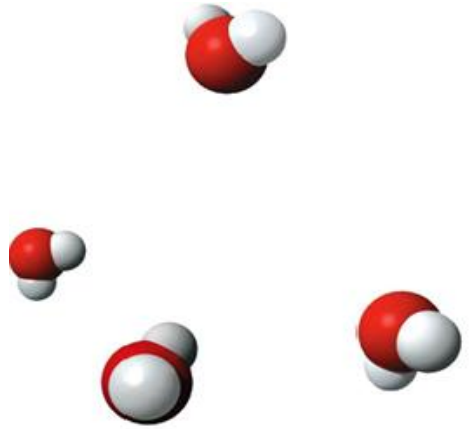
Energy turns water into steam

ENERGY DIAGRAM
The Heating Curve of Water



Thermodynamic properties of Water.

Saturated Steam Tables
For any given Pressure, Temperature can be predicted
In order to get high temperatures we need high pressures
At 134 °C we need *ca* 3 BarA steam pressure

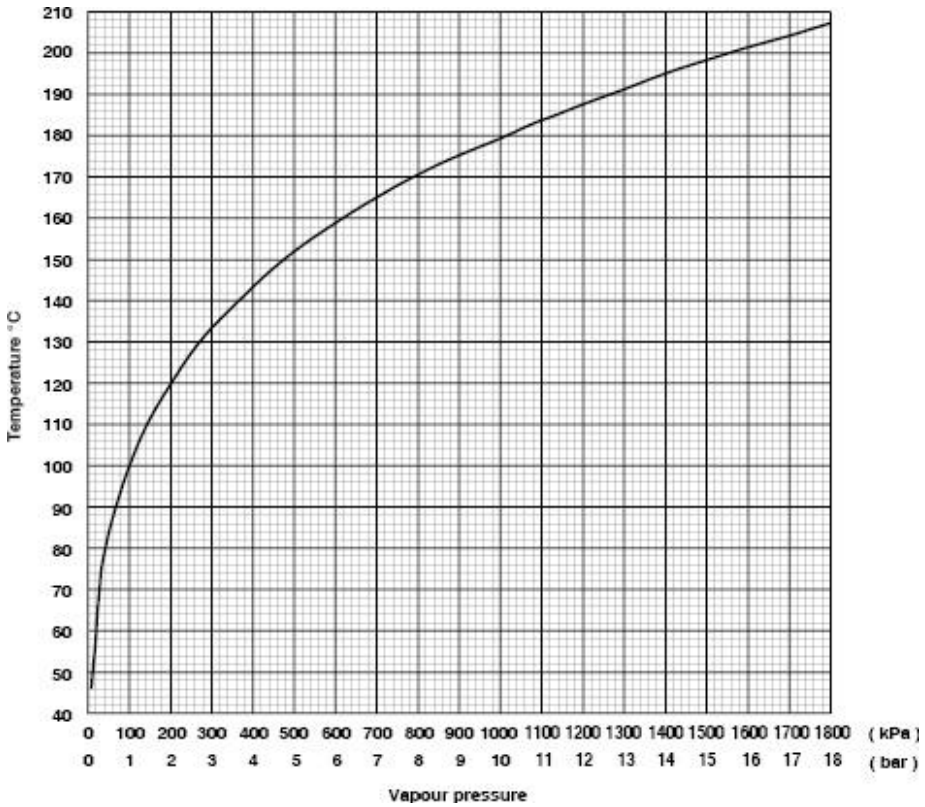


- International Association for the Properties of Water and Steam

STEAM TABLES

GAUGE PRESSURE bar	GAUGE PRESSURE kPa	ABSOLUTE PRESSURE bar	ABSOLUTE PRESSURE kPa	TEMPERATURE °C
0·65	65·0	1·663	166·3	114·51
0·70	70·0	1·713	171·3	115·40
0·75	75·0	1·763	176·3	116·28
0·80	80·0	1·813	181·3	117·14
0·85	85·0	1·863	186·3	117·96
0·90	90·0	1·913	191·3	118·80
0·95	95·0	1·963	196·3	119·63
1·00	100·0	2·013	201·3	120·42
1·05	105·0	2·063	206·3	121·21
1·10	110·0	2·113	211·3	121·96
1·15	115·0	2·163	216·3	122·73
1·20	120·0	2·213	221·3	123·46
1·25	125·0	2·263	226·3	124·18
1·30	130·0	2·313	231·3	124·90
1·35	135·0	2·363	236·3	125·59
1·40	140·0	2·413	241·3	126·28
1·45	145·0	2·463	246·3	126·96
1·50	150·0	2·513	251·3	127·62
1·55	155·0	2·563	256·3	128·26
1·60	160·0	2·613	261·3	128·89
1·65	165·0	2·663	266·3	129·51
1·70	170·0	2·713	271·3	130·13
1·75	175·0	2·763	276·3	130·75
1·80	180·0	2·813	281·3	131·37
1·85	185·0	2·863	286·3	131·96
1·90	190·0			132·54
1·95	195·0	2·963	296·3	133·13
2·00	200·0	3·013	301·3	133·69
2·05	205·0	3·063	306·3	134·25
2·10	210·0	3·113	311·3	134·80
2·15	215·0			135·36
2·20	220·0	3·213	321·3	135·88
2·25	225·0	3·263	326·3	136·43

76 SI



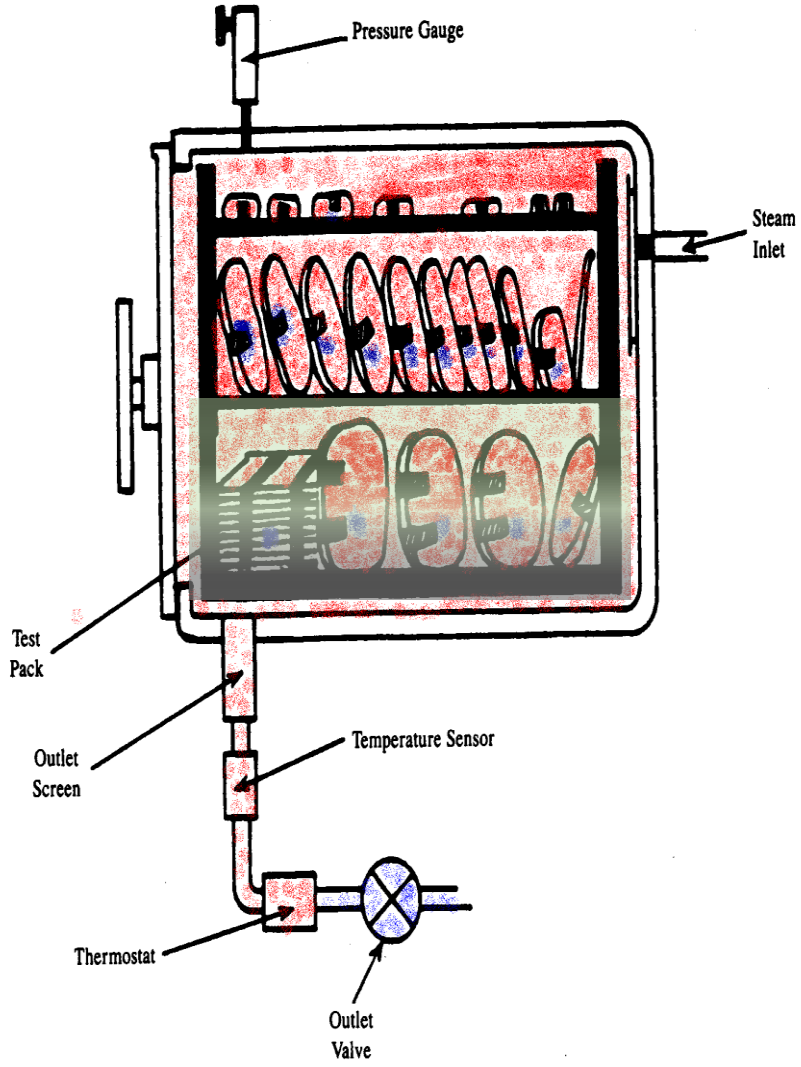
In Surface Steam Sterilization There is a Fundamental Problem

If you don't get the air out (*of the chamber and load*)……

……you can't get the steam in !

Porous Loads

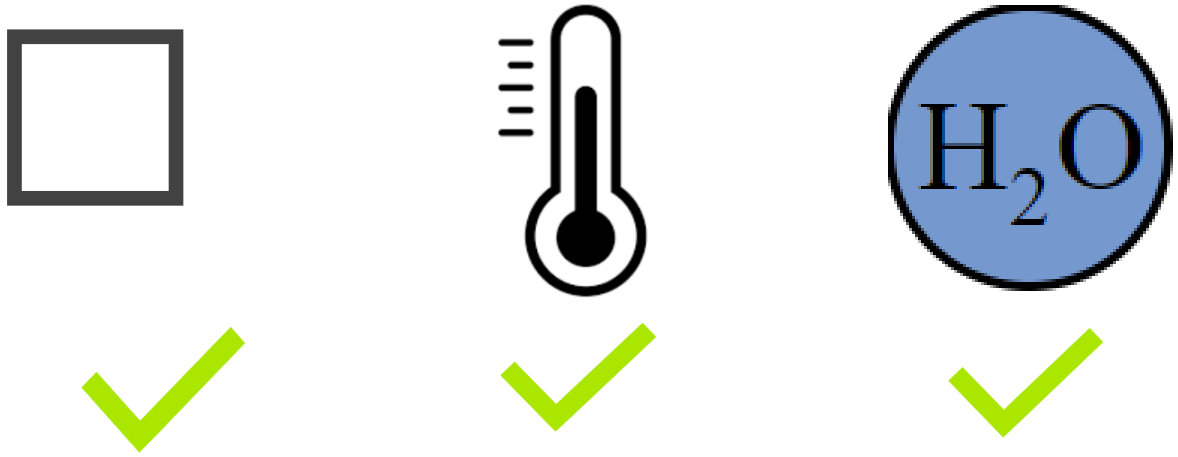
- Residual Air Locates in Packs.
- Preventing steam penetration.
- Resulting in incomplete sterilization.
- Same applies to lumened instruments.



What we need to monitor and how to ensure effective sterilization

Moist Heat Sterilization Process Variables

- Time
- Temperature
- Moisture



INSIDE A PCD

Monitoring Sensors

Physical Indicators

Respond to the absence of air or detect presence of moisture

Chemical Indicators

Respond to defined process parameters

Biological Indicators

Respond to all process variables and demonstrate kill

What Do The Standards Say?
ISO 17665
Sterilization of Health Care Products
Moist Heat

SM

Routine Monitoring
Every Load Monitoring

ISO 17665-1, 2

10.1 – Every production cycle must be monitored and process data recorded and evaluated

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Routine monitoring and control according to ISO 17665

10.5 For saturated steam processes, the data shall include (if applicable):

a) sterilization temperature, chamber pressure and theoretical steam temperature during the plateau period;

b) duration of the plateau period;

c) the chamber temperature and the chamber pressure for at least each stage of the operating cycle;

d) the results obtained from a process challenge device;

e) temperatures and/or pressures in a process monitoring system, if used as part of process control.

Achieving compliance;

10.5

a) examination of the temperature, pressure and the theoretical steam temperature show that they fall within the specified tolerances
   - eg within 2C of each other and within 134 to 137 C, 3050 to 3313 mB

b) Time of the plateau period
   - eg >3mins

c) The temperature and pressure at each pressure transition stage on the cycle printout.

d) results from a PCD show air removal and steam penetration
   - (and where possible time at temp.)

e) results from a built in air detector (see later)

It is becoming common to measure T and P (and t) alone to monitor steam sterilization processes and assume the presence of saturated steam if $T_{measured} = T_{theoretical}$ from pressure (according to saturated steam tables).

Is this a valid approach ?

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Theoretical Consideration

- In PURE saturated steam if you know the pressure it is possible to calculate the temperature of the steam.
- By Inference:
- If $T_{measured} = T_{theoretical}$ calculated from P then 100% steam is present.

- Similarly :
- If $T_{measured} < T_{theoretical}$ calculated from P then air must be present
  - (According to Daltons Law of Partial Pressures in Gas Mixtures).

What percentage of residual air in steam is required to allow $T_{measured} < T_{theoretical}$?
(Method Sensitivity)

- But note if $T_{measured} > T_{calculated\ from\ P}$ then superheated steam must be present

Detection of Failure using T-P correlation

Three bodies of evidence will now be presented.

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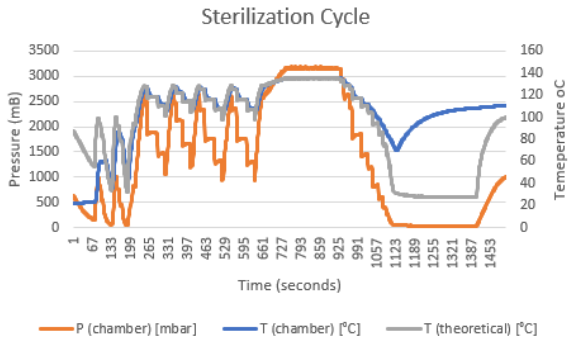
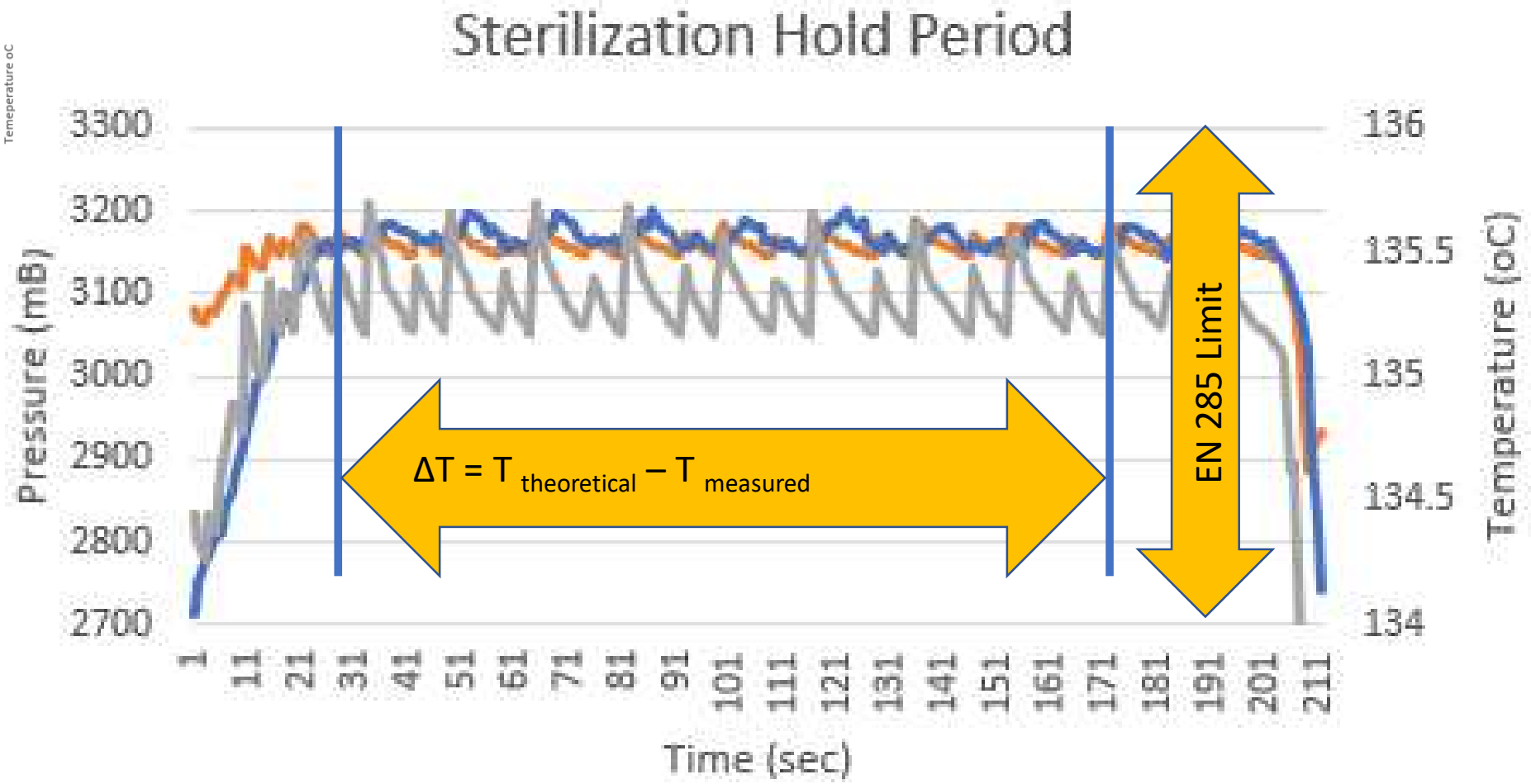
Calculation Method

Calculated T theoretical – T measured for Pass and Fail Cycles and compare statistically for differences





Detection of Failure using T-P correlation 1. in a 10l BIER vessel.

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BIER VESSEL STUDIES

Experiments carried out in a 10L BIER vessel.

Test 1.

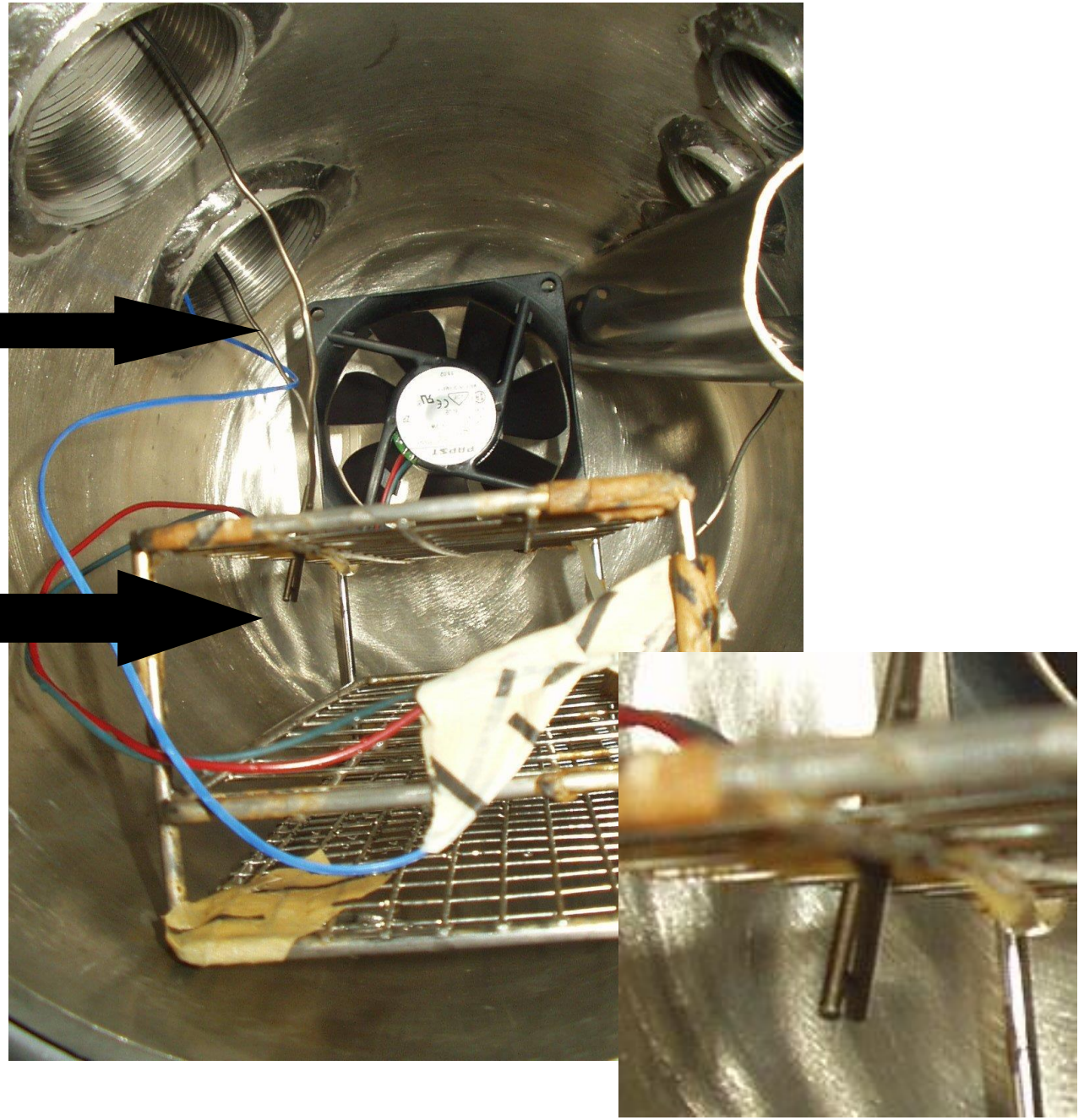
- **Chamber evac to *ca* 40 mB**
  - **434ml Residual Air**
- **Steam admitted to *ca* 3060 mB**
  - **1.25% air in steam at 3060mB**
- **Holding time 18 minutes.**
- **Chamber evac to 50 mB.**

Test 2.

- **Chamber evac to *ca* 160 mB**
  - **1579ml Residual Air**
- **Steam admitted to *ca* 3060 mB**
  - **5.22% air in steam at 3060mB**
- **Holding time 18 minutes**
- **Chamber evac to 50mB**

Sensor Positioning

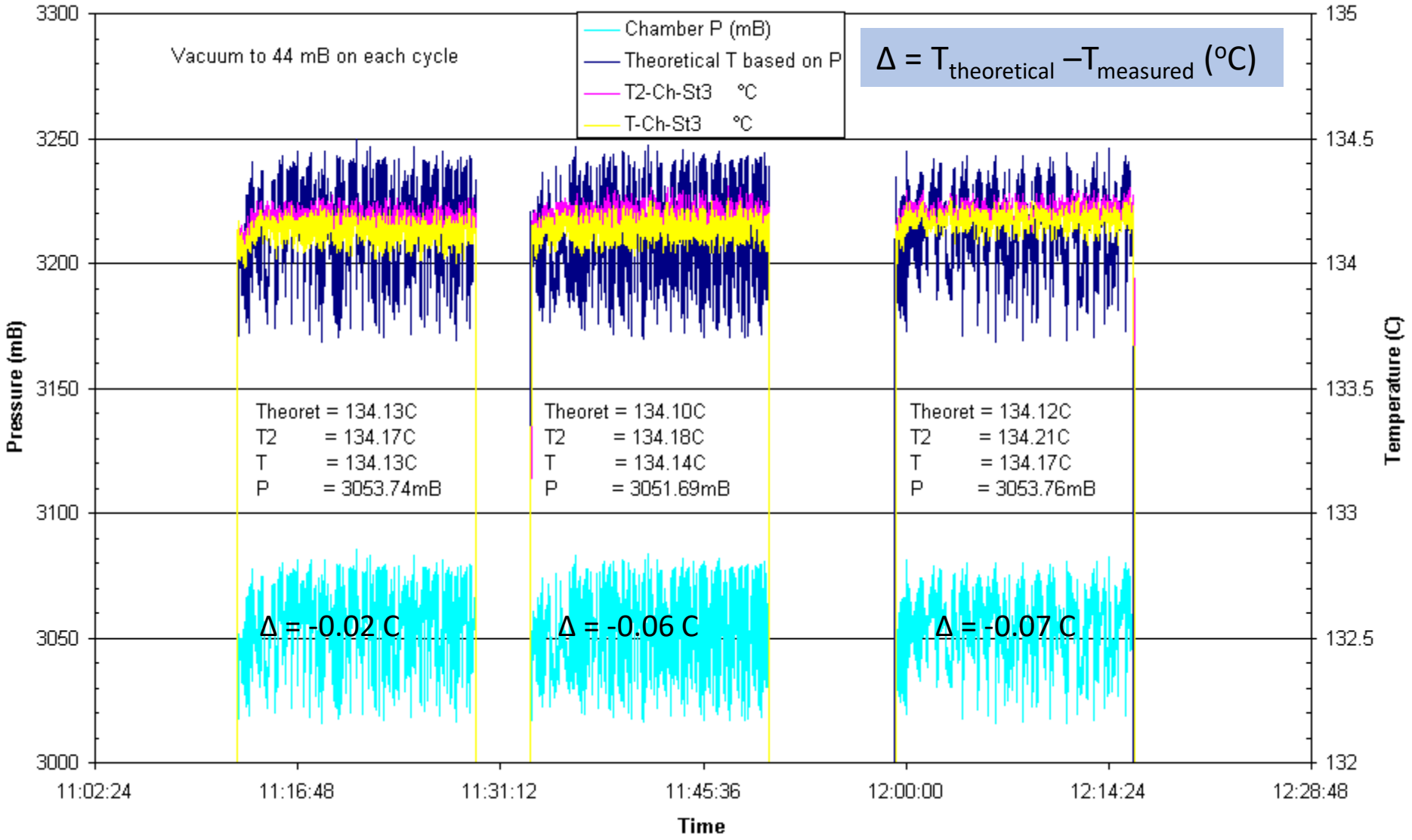
- Fan
- Probe 1 & 2



BIER VESSEL STUDIES

Residual Air Level = *ca* 1.4% at 3060mB

The measured and calculated temperature during BIER vessel cycles. Triplicate tests



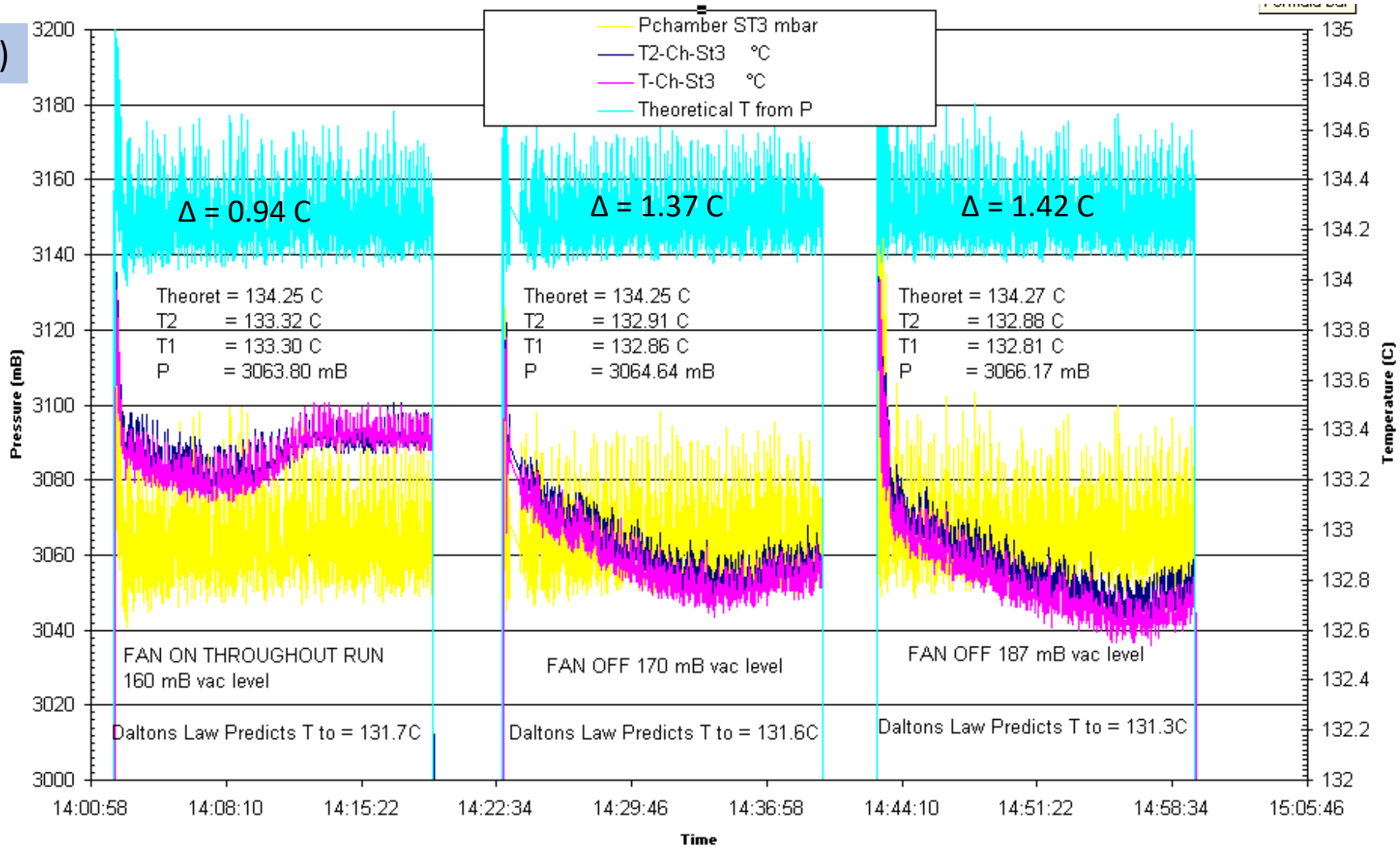
BIER VESSEL STUDIES –

Residual Air Level = *ca* 5.5% at 3060 mB

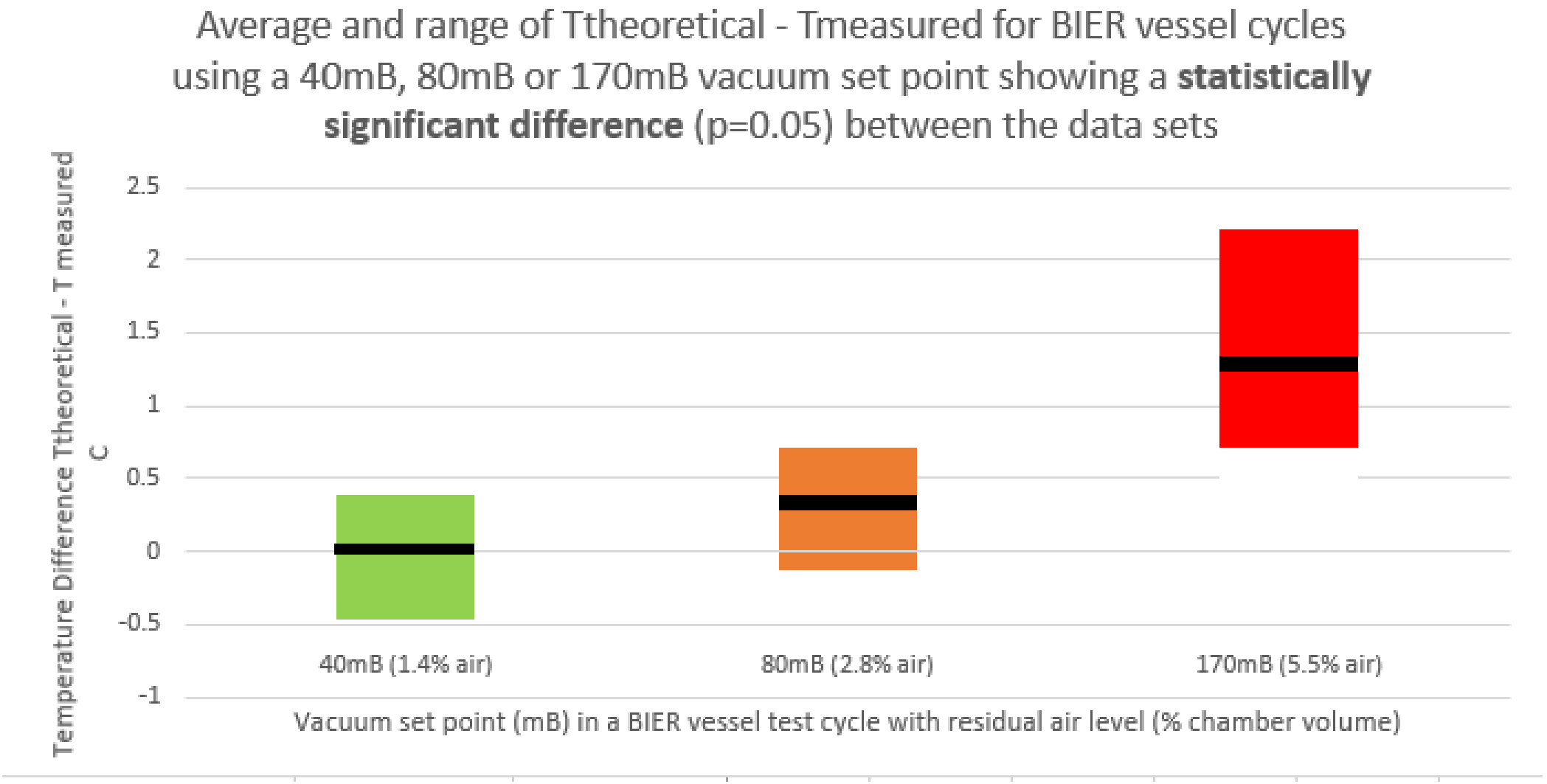
The measured and calculated temperature during BIER vessel cycles. Triplicate tests

$\Delta = T_{theoretical} - T_{measured}$ (°C)

Differences detected are significant at p=0.05
But passes EN285 requirement of Delta not more than 2°C



Statistical Analysis of the two BIER vessel cycles



Detection of Failure using T-P correlation 2. in a large test vessel.

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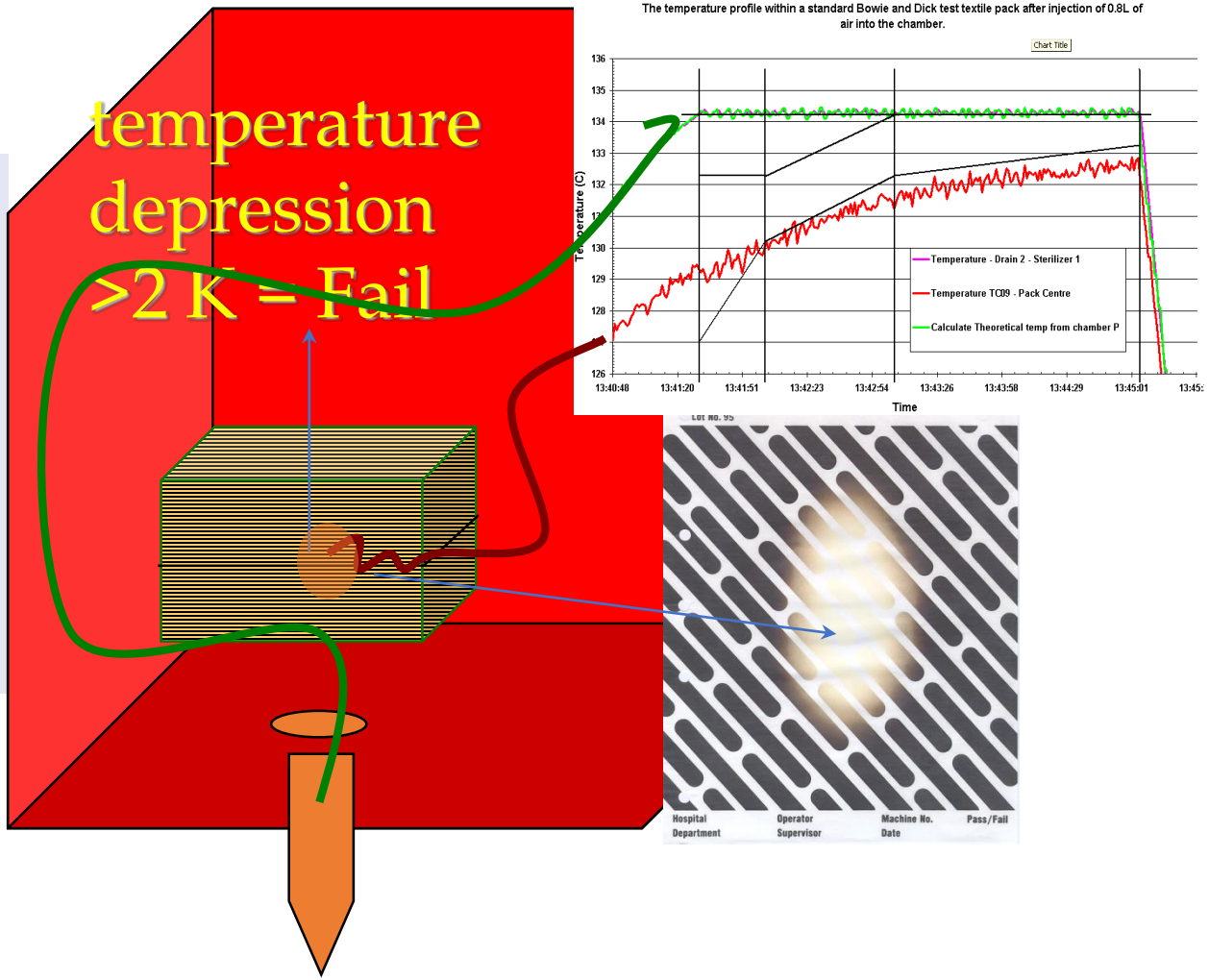
EXPERIMENTS
Materials and Methods

- Standard Textile pack as per EN 285.
- Thermocouple matrix of 7 TC's
  - positioned centrally then equidistant at a 2 to 3cm radius from the centre.
- programmable steam sterilizer.
- T and P sensors calibrated to National Standards.
- 5 Replicate tests using a sub atmospheric pulsing cycle with vacuum set points at 55, 175 and 200mB
- Data Analysis during stable holding period:
  - T theoretical calculated from pressure according to steam tables.
  - T measured taken from the chamber reference point ie Drain
  - T difference then calculated (T theoretical – T measured)
    - A negative number indicates measured temp is higher than calculated.
  - Maximum temperature depression from within the textile pack indicating an air pocket.
  - Statistical comparisons between data sets carried out

Small Load Thermometric Test

The temperature depression

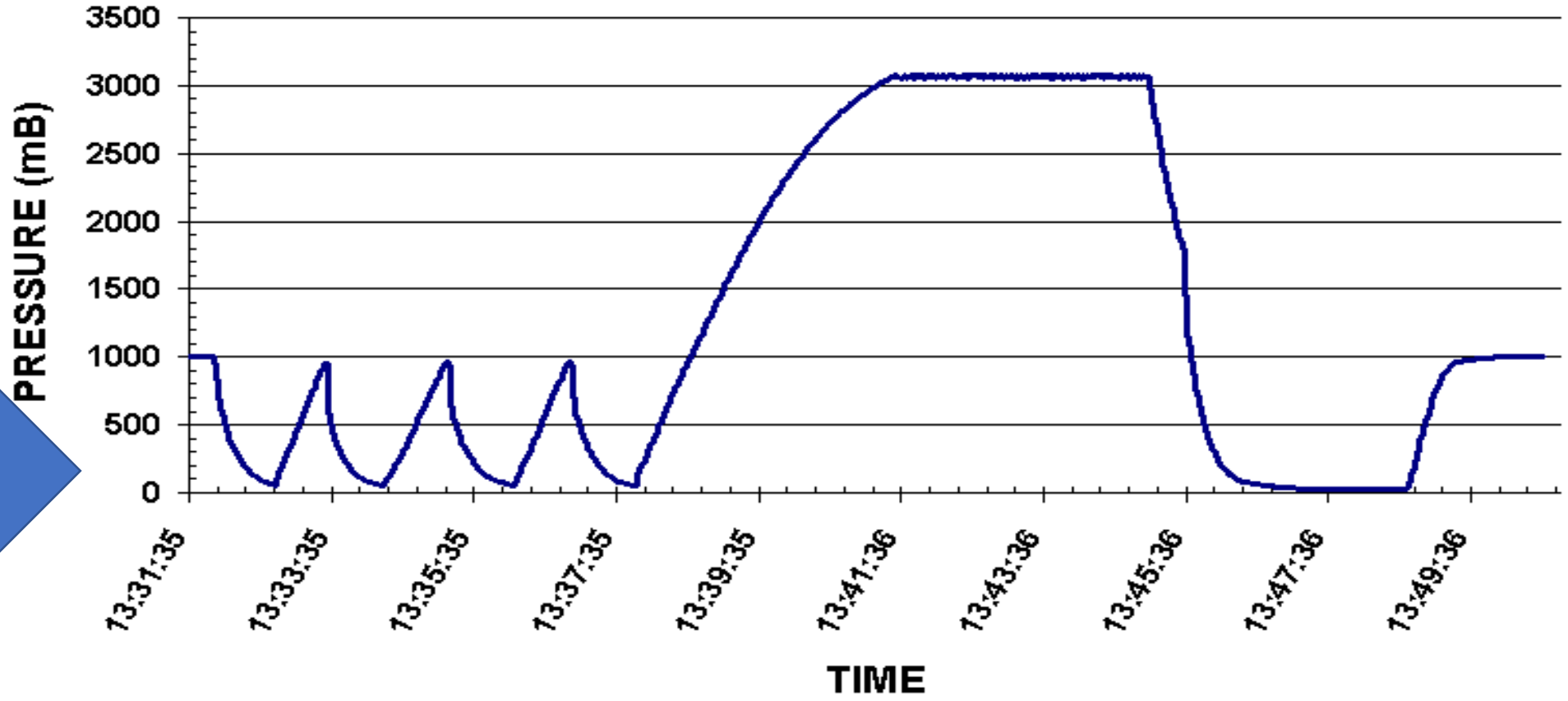
Note this is representative of the EN285 small load thermometric test used by engineers during validation



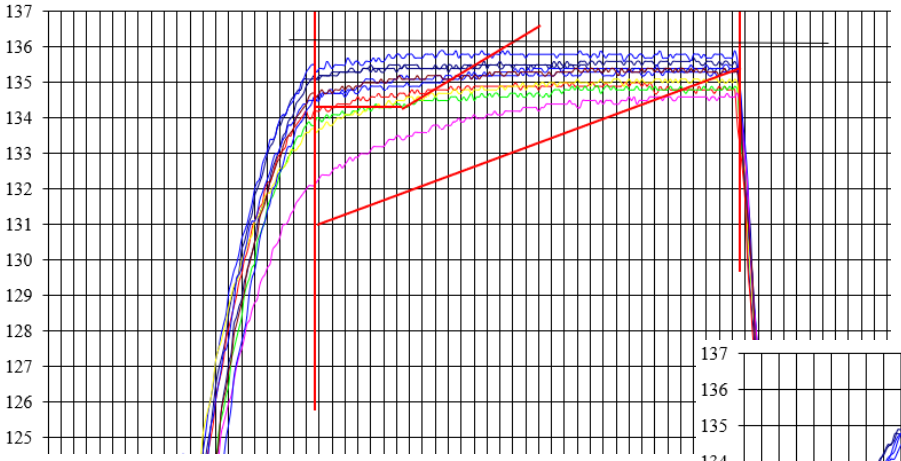
Test Cycle

Vac Set Point	Dilution factor	residual air (L)	% Ch Vol
55.0000	109282.1529	0.0031	0.0003
175.0000	1066.2224	0.3208	0.0329
200.0000	625.0000	0.5472	0.0561

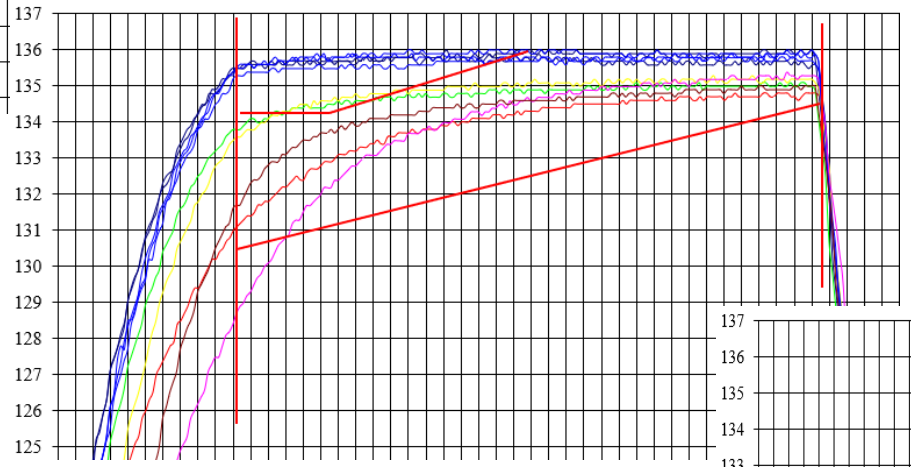
Vac set points at 55, 175 & 200mB



Temperature from drain and textile test packs

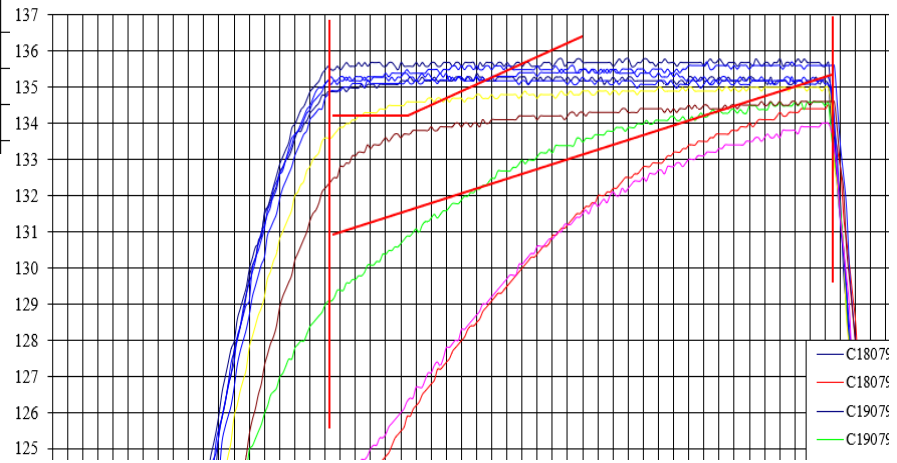


175mB
14ºC

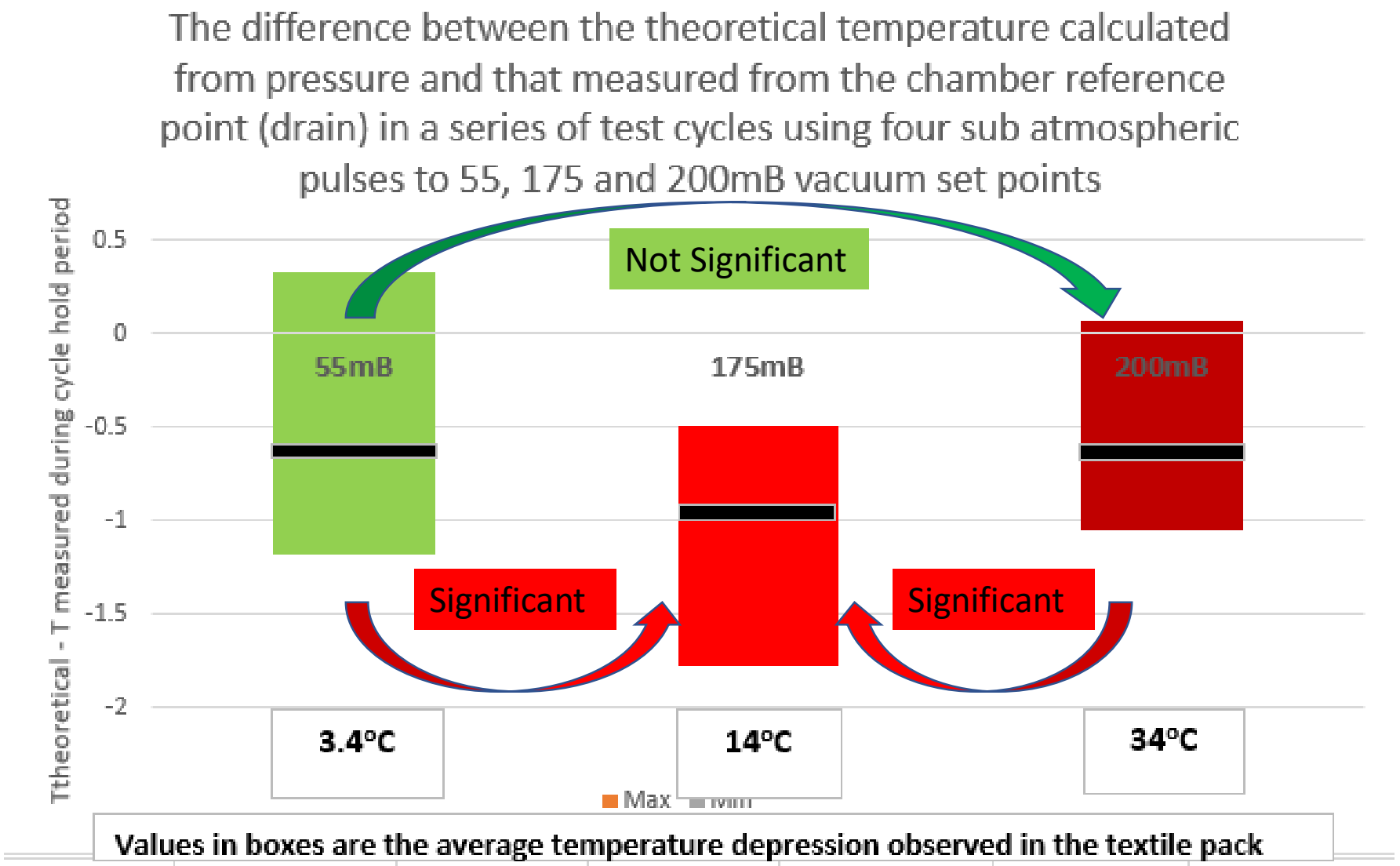


200mB
34oC

55mB
3.4ºC



Summary of Results from textile test pack tests



The difference between the 55 and 175mB data sets was significant at p=0.05 ie the measured temperature was higher than the theoretical temperature calculated from pressure (calibration differences or superheat?).
The difference between the 55 and 200 mB data sets was not significant at p=0.05.

Temperature and Pressure correlation could not detect the process failures.

Detection of Failure using T-P correlation

3. In hospital production sterilizers.

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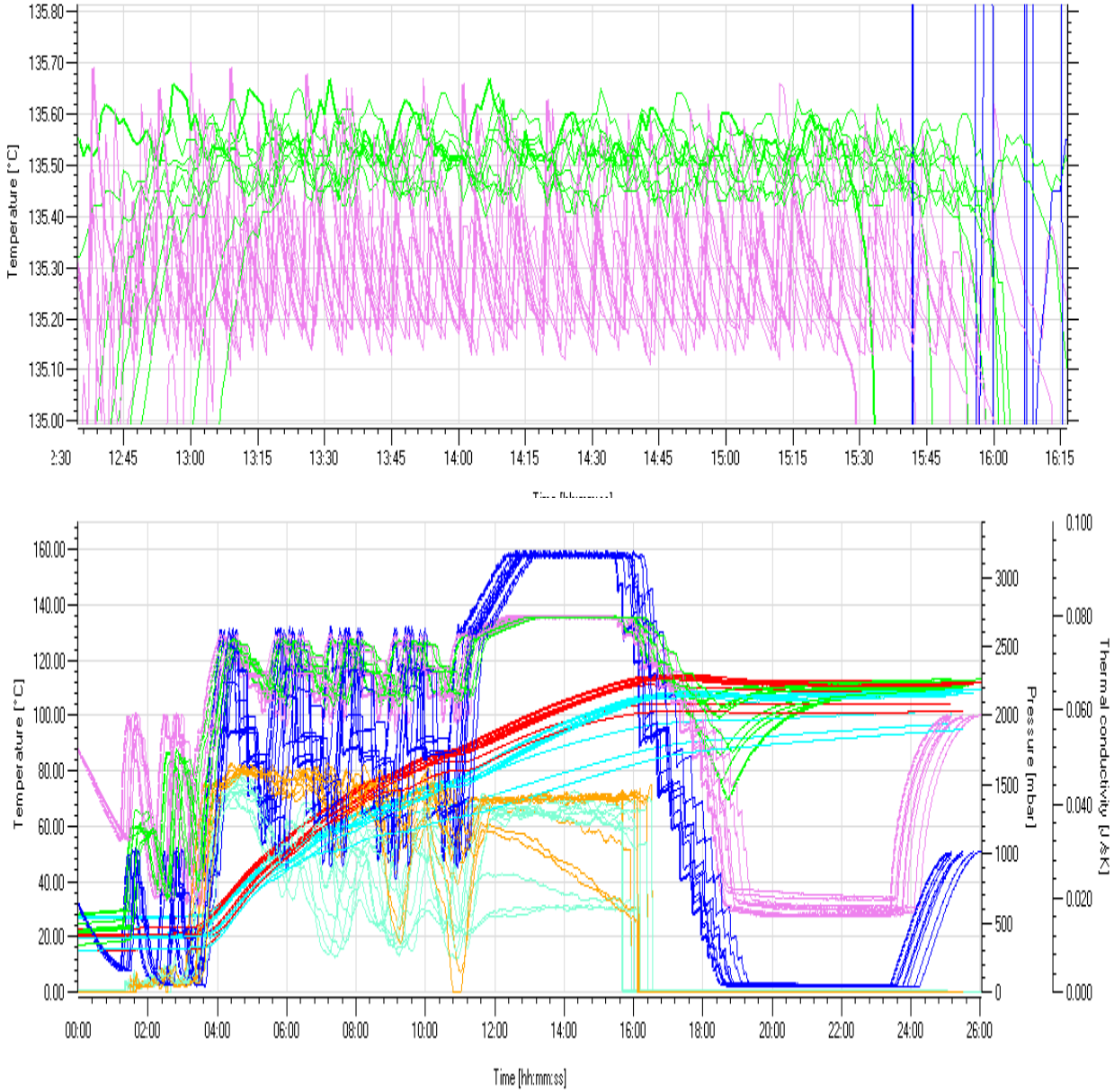
Method

- The data obtained from an electronic Bowie and Dick Test Instrument which was used to carry out the daily BDT in routine production sterilizers (700l) from a large District General Hospital in UK was analysed;
- BDT results examined between 11-1-2014 and 19-2-2015 (686 cycles). 9 BDT fails were observed(1.3%)
- When a fail cycle was observed either the previous or next Pass BDT test cycle was paired with the fail cycle for comparative purposes.
- The following data analysis was then carried out.
  - Once the sterilization process had reached equilibrium during the sterilization hold period->
  - $T_{difference} = T_{theroretical} - T_{measured}$ was determined for Pass and Fail pairs (9 pairs in total).
  - T test was then used to compare $T_{difference}$ for each dataset pair (Pass and Fail).

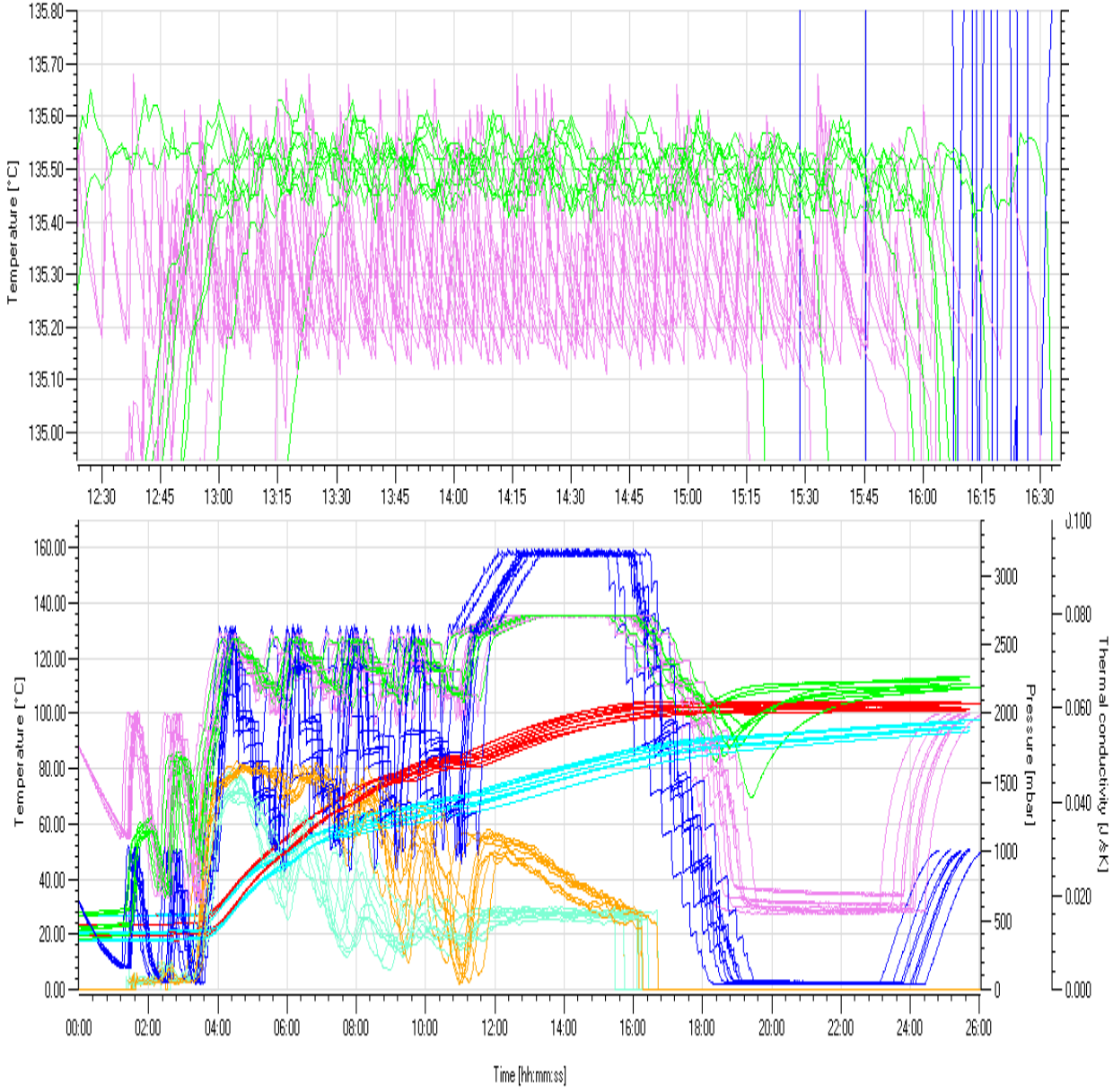
- Hypothesis : If $T_{difference}$ Fail is statistically significantly greater than $T_{difference}$ Pass then the correlation of T-P is a valid approach for detecting air removal and steam penetration. **The difference was not significantly greater.**

Bowie and Dick Pass and Fail Cycles

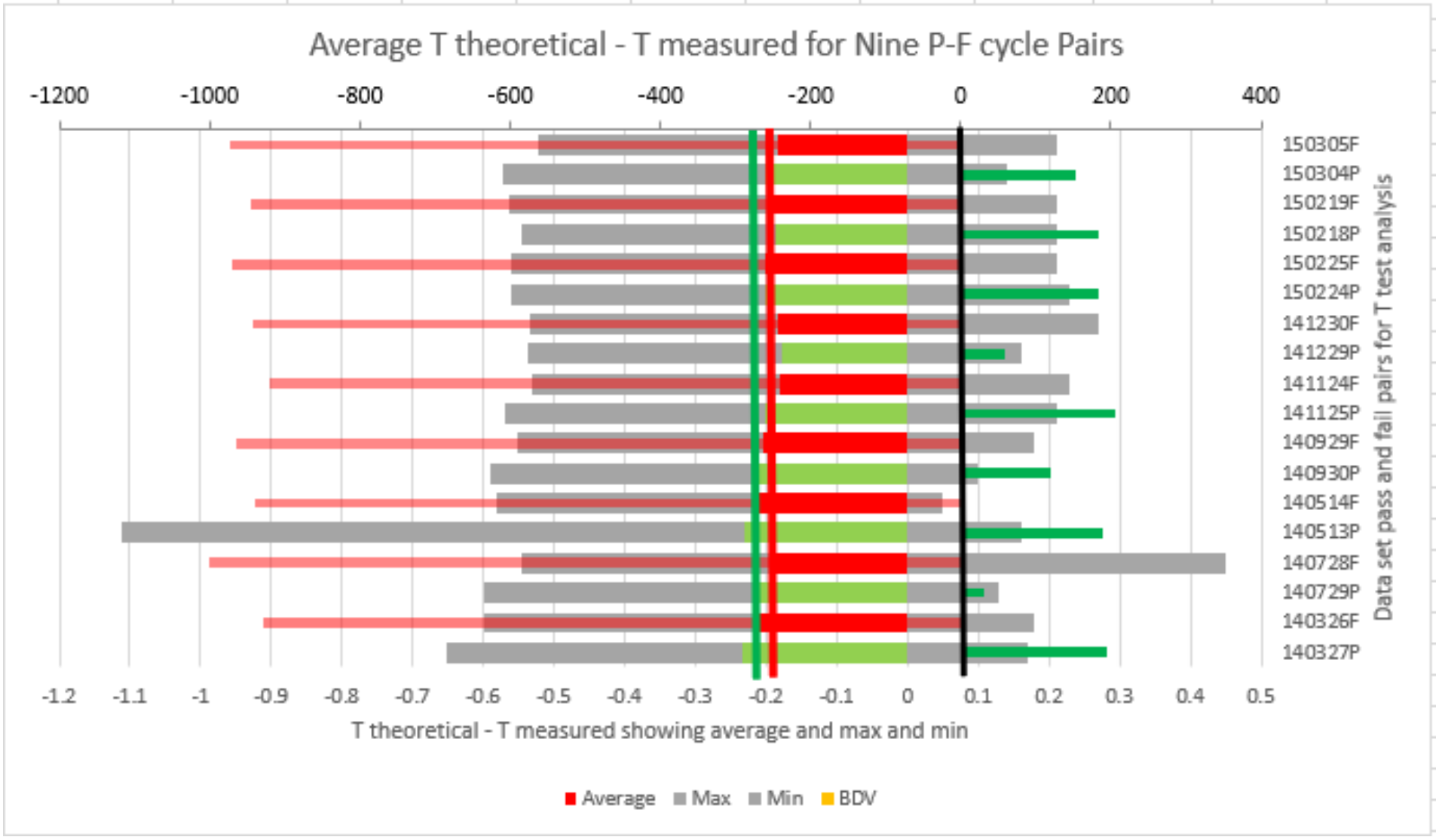
- Pass



- Fails



Results of Data Analysis



The difference between the theoretical temperature and the measured temperature was approximately -0.2 ^{o}C indicating measured temperature was higher indicating slight superheat or more likely a 0.2 ^{o}C calibration offset in the measurement equipment. Differences between Pass and Fail pairs were NOT SIGNIFICANT at p=0.05 when using T test.

Range T_{th}-T_m for data set

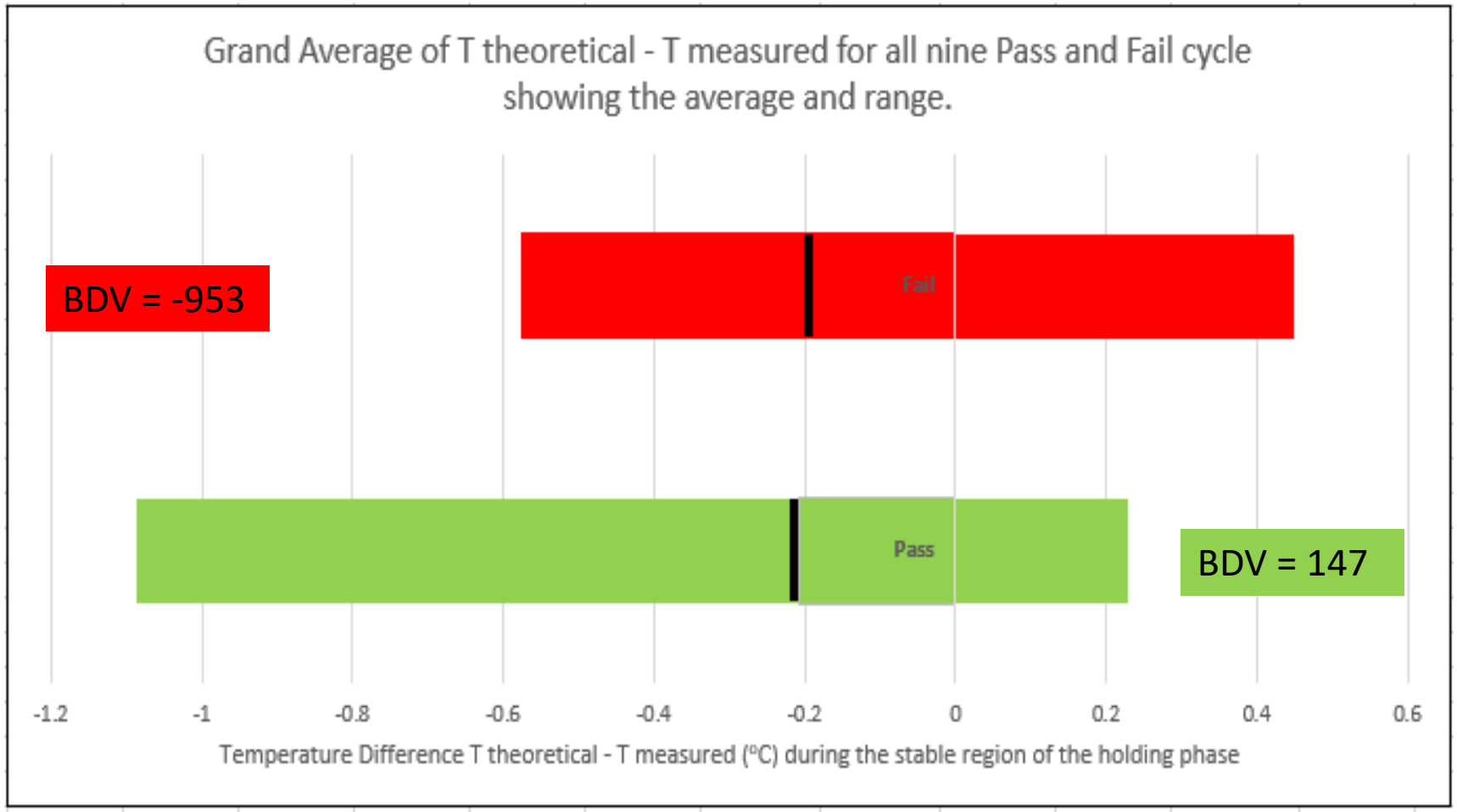
Av T_{th}-T_m for Fail data set

Av T_{th}-T_m for Pass data set

BDV for Pass cycles

BDV for Fail cycles

Grand Average of T theoretical – T measured during the stable period of the holding phase along with the range for nine Pass and Fail pairs of Bowie and Dick Test cycles (empty chamber) from a 700L hospital production sterilizer. Also shown the Bowie and Dick Test factor (BDV) indicating Pass or Fail (negative Fail, positive Pass)



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Monitoring the efficacy of surface steam sterilization processes with temperature and pressure alone
Is this a Valid Approach ?

No it is not

T-P correlation will NOT detect the levels of residual air which will cause a steam penetration test failure in a surface steam sterilization process

Correlating T-P does note demonstrate presence of moisture – hence use a PCD

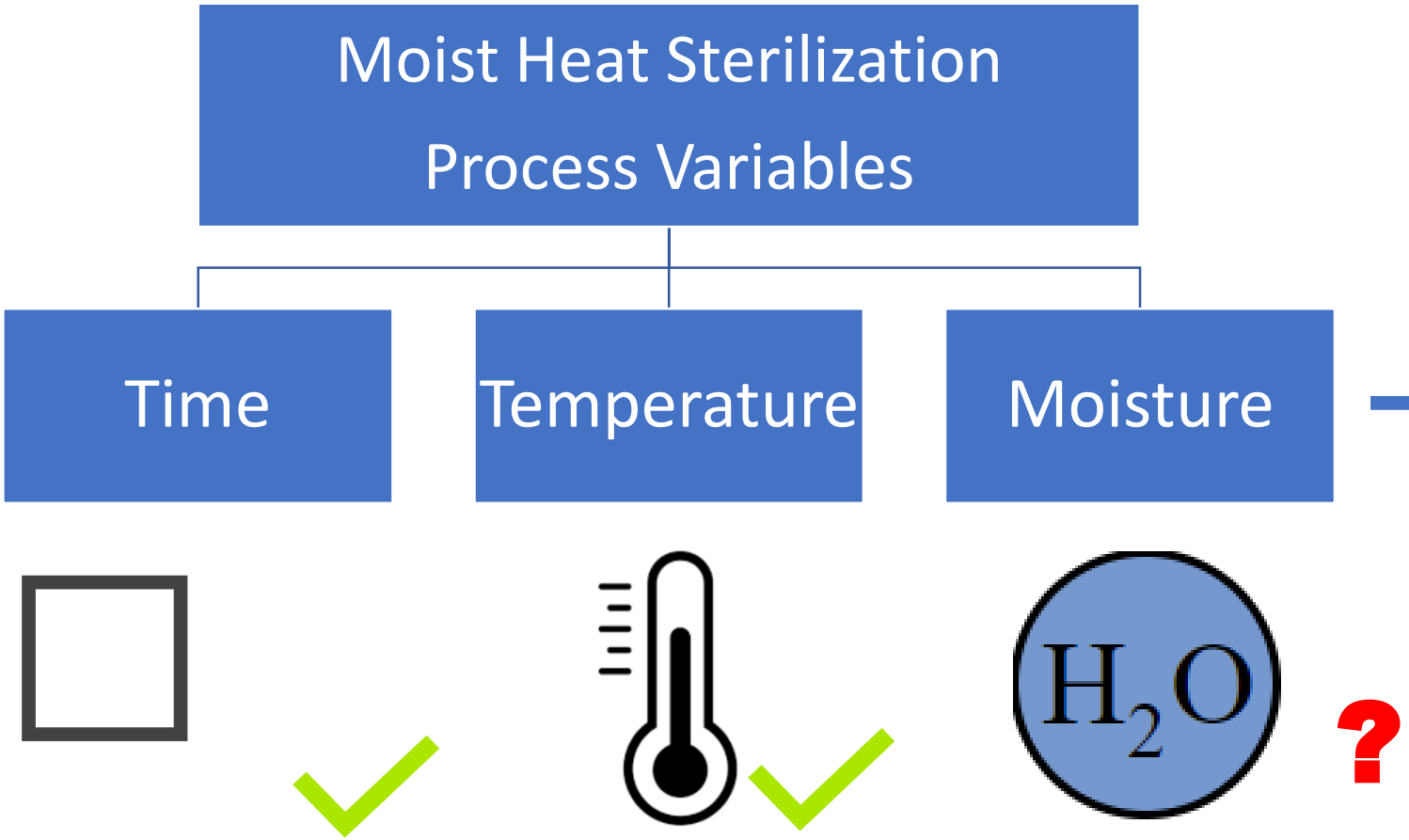
EN ISO 17665;

Clause 10.5 for saturated steam processes the data shall include

a) sterilization temperature, chamber pressure and theoretical steam temperature during the plateau period

d) The results obtained from a PCD device

e) Temperature and or pressure in a process monitoring system



How do we establish the presence of moisture ?

Steam Table T-P Correlation to demonstrate steam saturation

INSIDE A PCD

Absence of Air implies presence of moisture
Air Detectors

Indicators which respond to Moisture
Chemical and / or Biological

Instrumental Methods ?

THE END – Thank You

Theoretical calculation

- 0.8L air at 1013 mB required to create a BDT fail.
- At 3066mB 0.8L at atmosph is compressed to 0.264L
- 0.264L air in a 300L chamber is 0.0881%
- 0.0881% of 3066 mB = 2.7 mB
- Daltons Law , PT = Pair + P steam
- Therefore P steam = PT – P air = 3066 – 2.7 = 3063.3mB
- Using steam tables to convert
- T = (0.0116 x P) + 98.705
- T = (0.0116 x 3063.3) + 98.705 = 134.24 C
- So Steam at 3066 = 134.27, steam at 3063.3 = 134.24C
- We are trying to detect a 0.03C difference in T