Can Temperature And Pressure Datalogging Replace The Bowie and Dick Test ?

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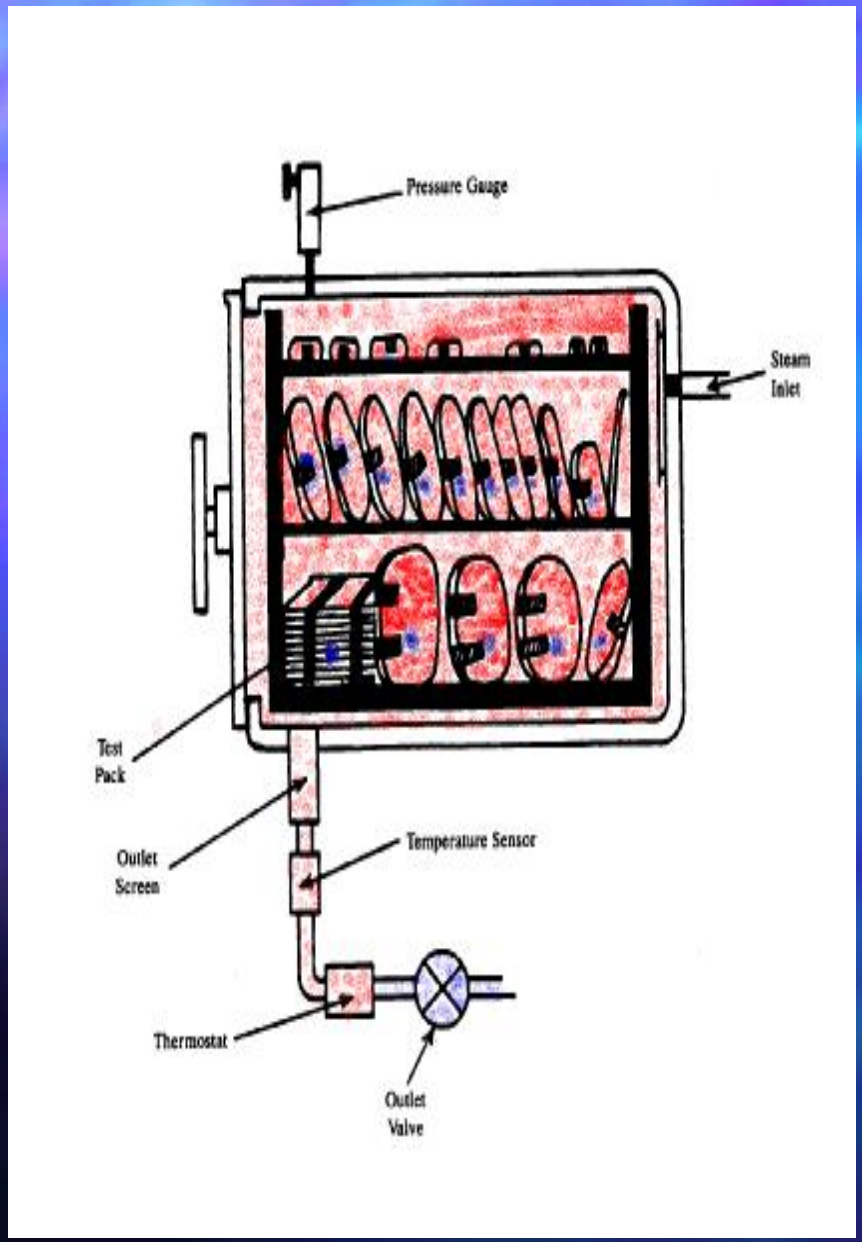
If You Don’t Get the Air Out….

….You Can’t Get the Steam in



- Residual Air Locates in Packs….
- ….Preventing steam penetration…
- ….resulting in incomplete sterilization.

- …Similarly for lumened instruments…
- A bolus of air is trapped within the centre of an open ended or end of a blind, tube…
- …Preventing steam penetration…
- …Leading to incomplete sterilization.

- **With the advent of vacuum assisted porous load sterilizers in the 1940's and '50's the problem of residual air was recognised leading to the development in 1963 of "The Bowie and Dick Test"**

- *Bowie, JH, Kelsey, JC and Thompson, GR, Lancet I, 586 (1963)*

- Subsequently adopted in various formats by numerous regulatory authorities throughout the world.
- Later given the more generic title of

  “The air removal & steam penetration test.”
- Enshrined in standards:

EN 554 -6.3.4

- *"If the sterilization process includes air removal from the product, a steam penetration test shall be carried out at the commencement of each day the sterilizer is to be used."*

ISO/CDV 17665 *10.3.4* (currently in draft form).

- ***"If the sterilization process relies on the removal of air from the sterilizer chamber in order to achieve rapid and even penetration of steam into the sterilizer load a steam penetration test shall be carried out at specified intervals."***

EN 285: 7.1.12

- *"Means shall be provided to ensure that the requirement for steam penetration throughout the sterilizer chamber and sterilizer load is achieved during each sterilization cycle ..."*

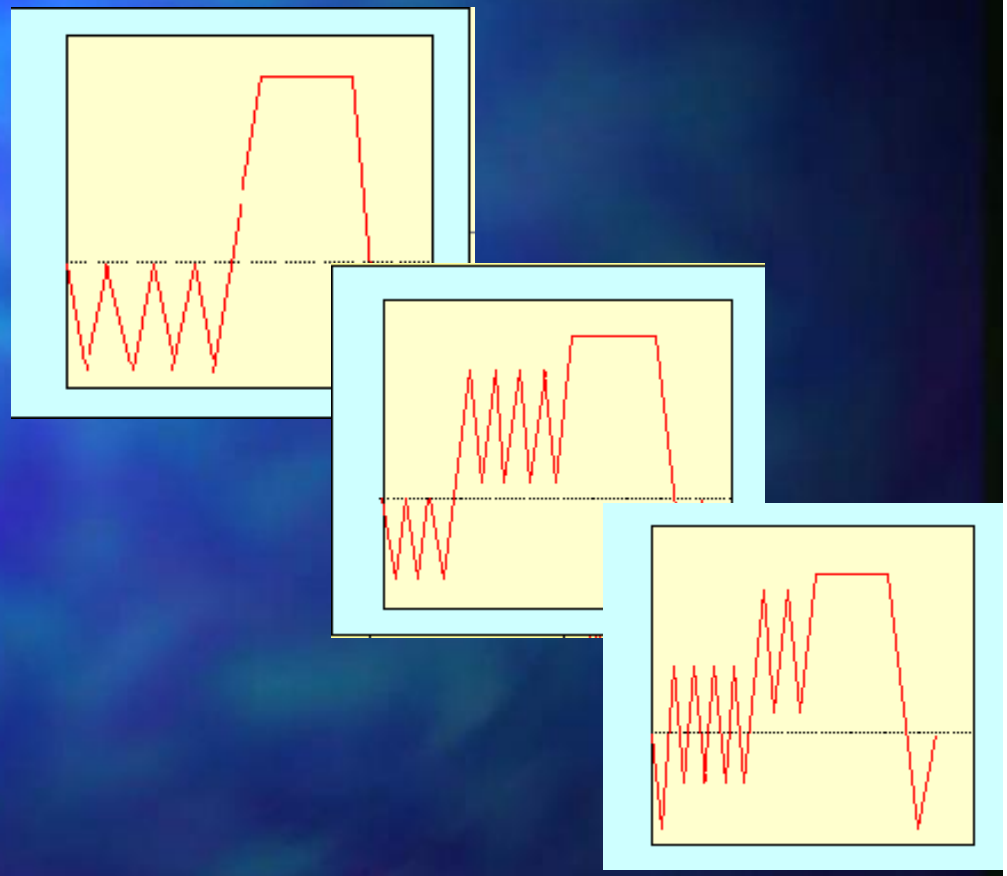
In Practice

- The daily steam penetration test is described in EN 285 (textile pack) and EN 867-3 (test sheet for use in textile pack).
- OR more commonly used:
- Alternative commercially produced products complying with EN 867-4

Validation of Alternatives cf EN 867-4

- Test for Pass response
- Test for Fail response in:
- Inadequate Vacuum
- Chamber Leaks
- Air Injection

- Using three test cycles



- The conventional means of assessing the adequacy of air removal and steam penetration is to use:
- A steam penetration test daily
- plus
- Air detectors fitted to the steri
- Process Challenge Devices for monitoring every load.

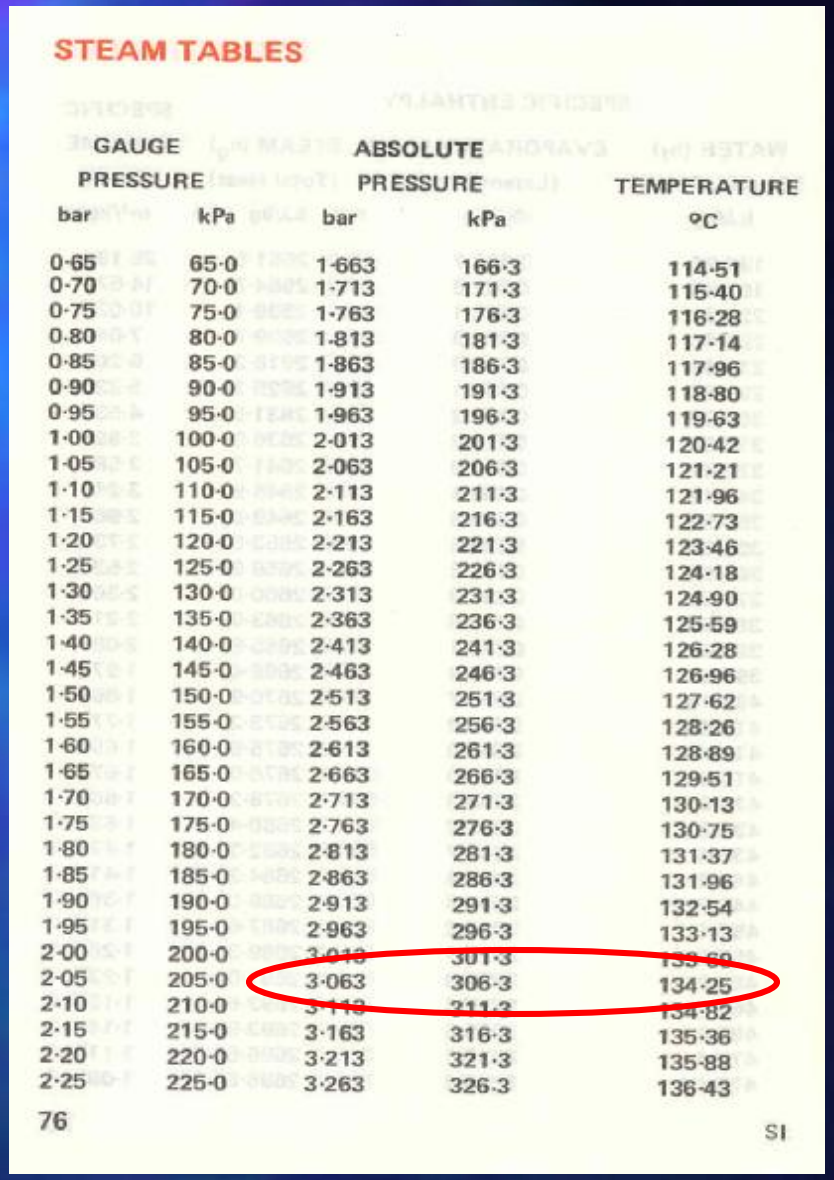
T and P measurement.

- In recent times the accuracy and resolution of measuring instruments has improved significantly. Thus
- Pressure = +/- 1mB
- Temperature = +/- 0.01C
- Such measurement capabilities have also been claimed for stand alone dataloggers.

- As a consequence of improvements in datalogging accuracy it has been suggested that measurements of T and P alone can replace the conventional steam penetration or Bowie and Dick Test.

On What Basis is this claim made?

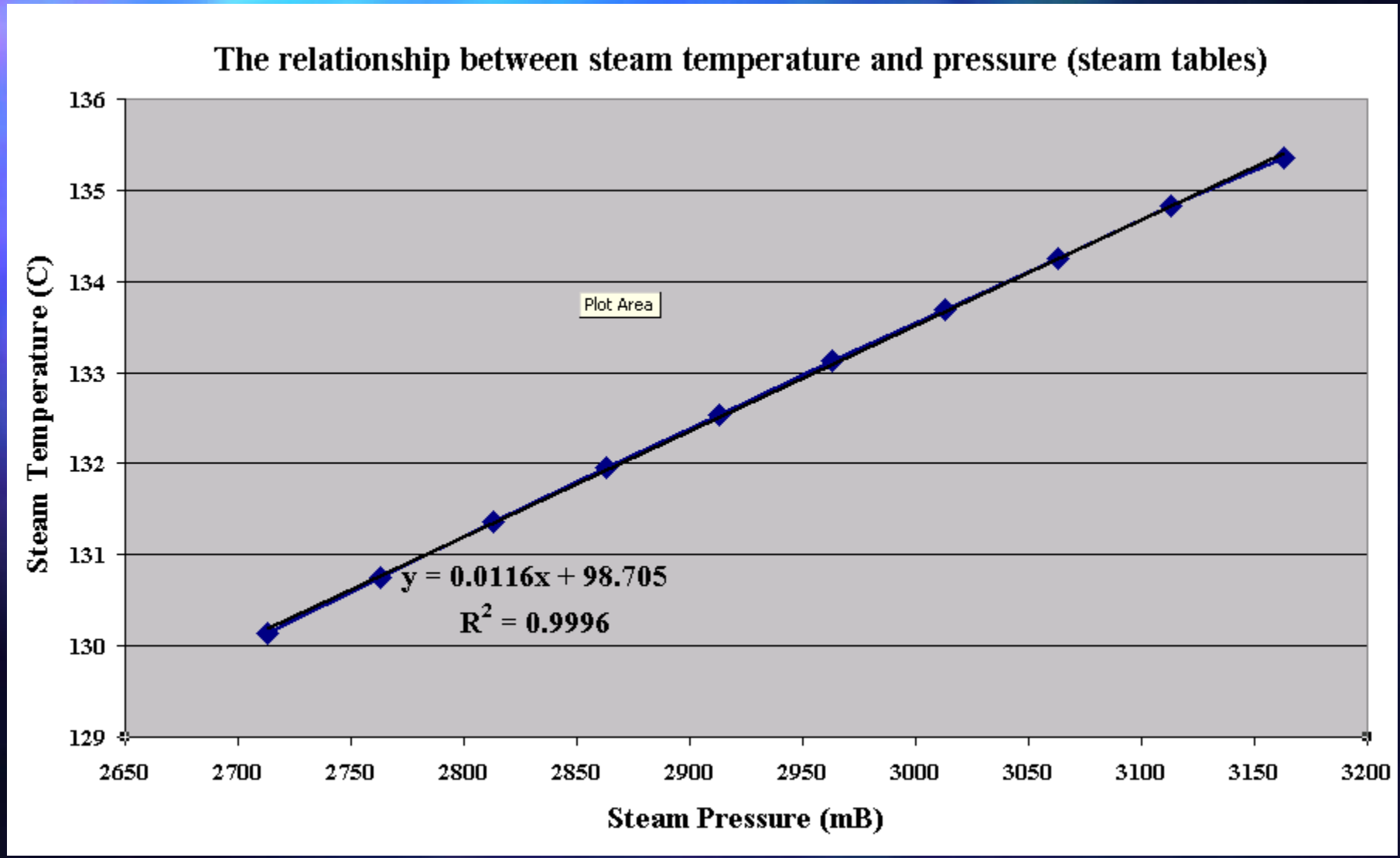
- This assertion is based on the fact that in a dry saturated steam environment temperature is directly related to pressure as described in steam tables.



STEAM TABLES

GAUGE PRESSURE		ABSOLUTE PRESSURE		TEMPERATURE
bar	kPa	bar	kPa	°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	2·913	291·3	132·54
1·95	195·0	2·963	296·3	133·13
2·00	200·0	[illegible]	[illegible]	[illegible]
2·05	205·0	3·063	306·3	134·25
2·10	210·0	[illegible]	[illegible]	[illegible]
2·15	215·0	3·163	316·3	135·36
2·20	220·0	3·213	321·3	135·88
2·25	225·0	3·263	326·3	136·43

Over a limited range of values steam tables are approximately linear.



- Thus:
- In PURE saturated steam if you know the pressure it is possible to calculate the temperature of the steam.
- By Inference:
- If the measured Temperature is equal to the calculated temperature then 100% pure steam is present.
- Therefore :
- In a porous load cycle If $T_m = T_{calc}$ during sterilization stage then adequate air removal has taken place.
- Similarly :
- If $T_m \neq T_{calc}$ then air must be present (Daltons Law of Partial Pressures).

Daltons Law of Partial Pressures

(1766-1844)

- In a mixture of gases the total pressure exerted by the mixture will equal the sum of the partial pressures of the individual components of the mix.
- $P_T = P_{g1} + P_{g2} + \ldots P_{gn.}$
- In an air steam mixture:
- $P_{Total} = P_{steam} + P_{air.}$

BUT

- In an air steam mixture the only contributor to temperature is steam but the temperature of the steam depends on its partial pressure.

- Thus in an air steam mixture the measured temperature will inevitably be lower than the calculated temperature based on the measured pressure.

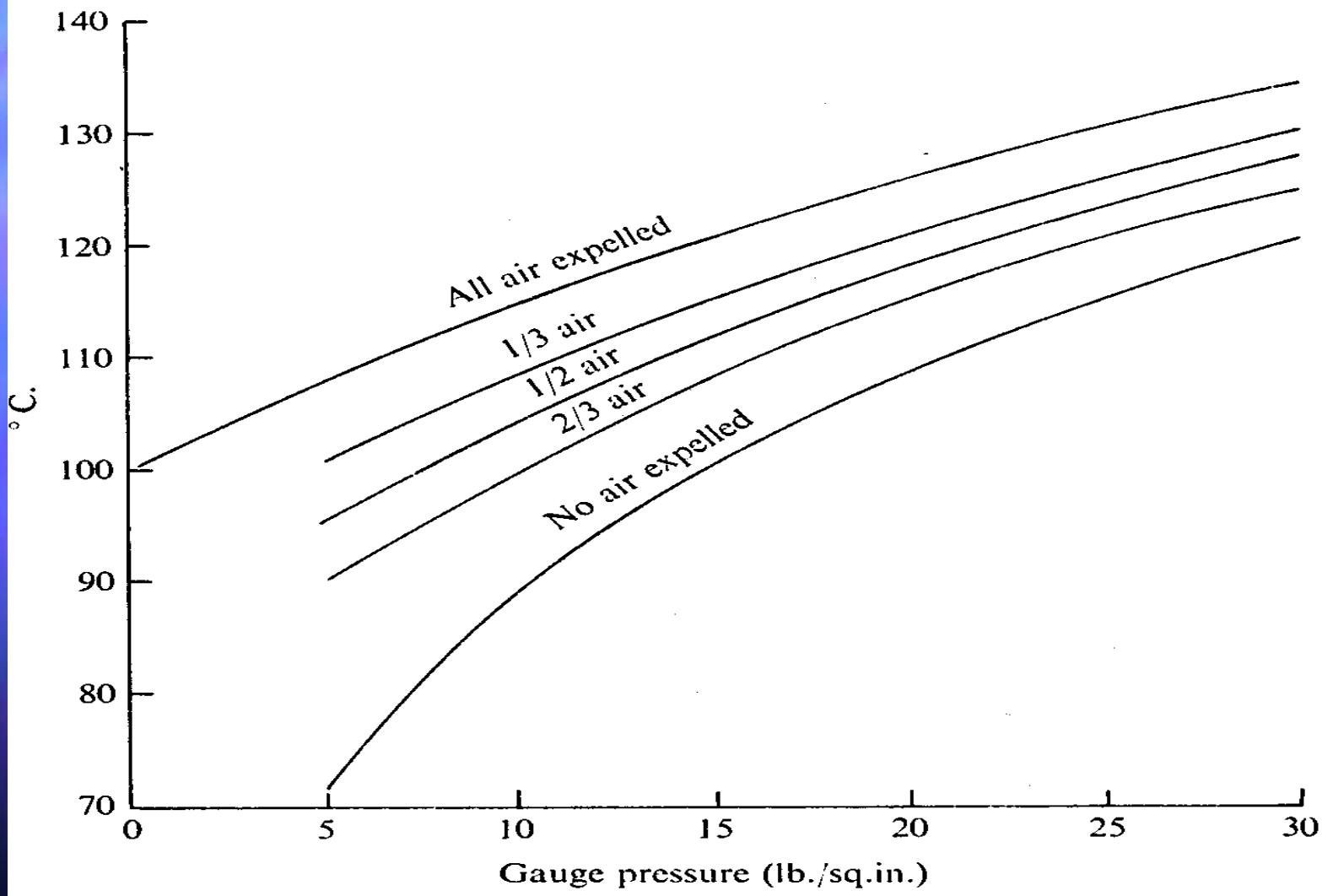


Fig. 4.6. Temperatures of mixtures of air and saturated steam at various pressures. Ordinate: temperature. Abscissa: gauge pressure.

From: Meynell & Meynell, Theory and Practice of Experimental Bacteriology, 2nd edn, 1970, Cambridge University Press.

Hypothesis

- If measured T is equal to calculated T then there is no residual air present.

- If measured T is not equal to calculated T then air is present.

Does This Work In Practice?

QUESTION

- How much residual air is required to cause a Steam Penetration Test failure ?

QUESTION

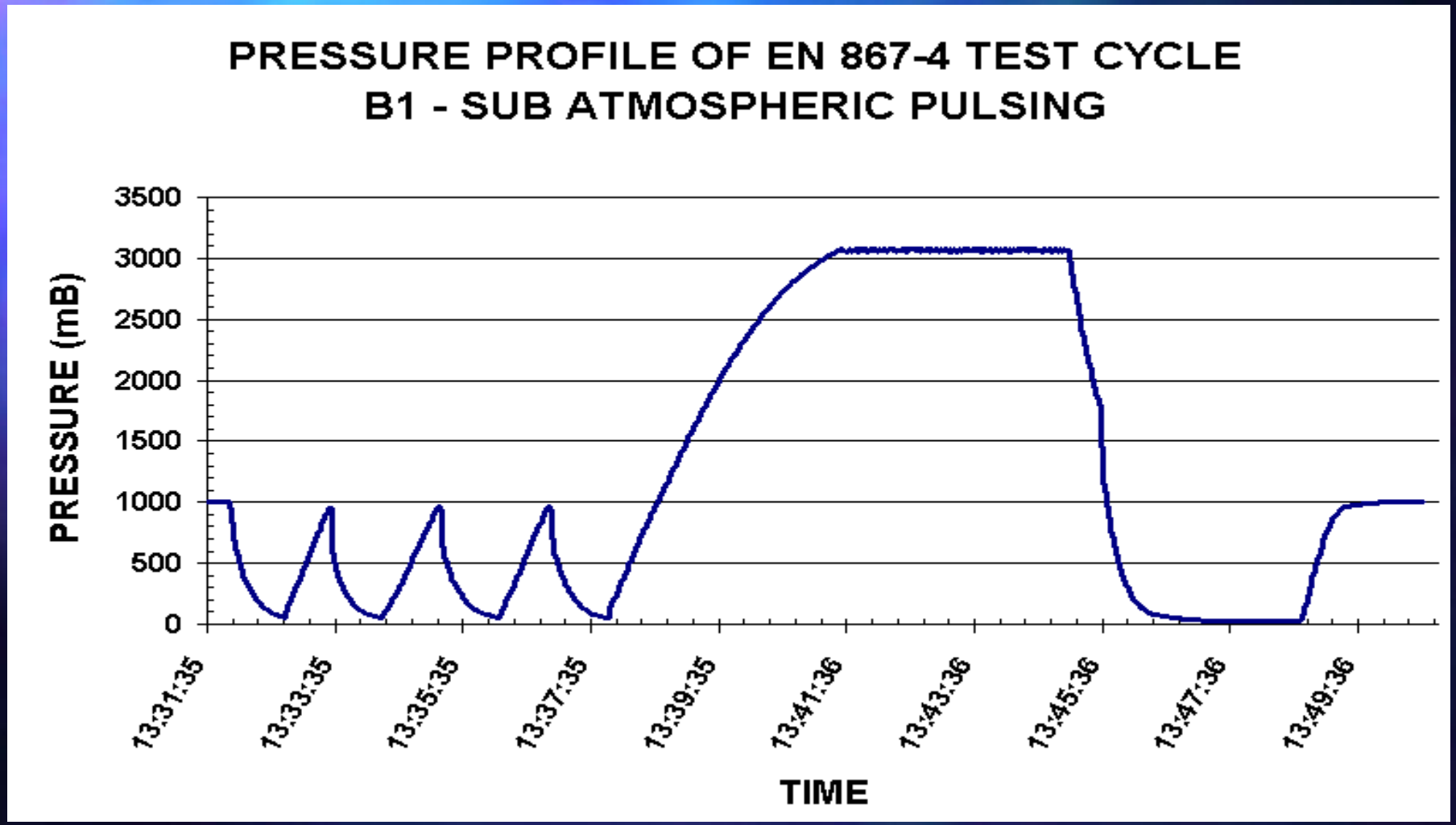
- Does the volume of air create a significant difference between the calculated and measured temperature ?

- If the answer to the final question is NO then measurement of T and P and calculation of T from P cannot replace the BDT.

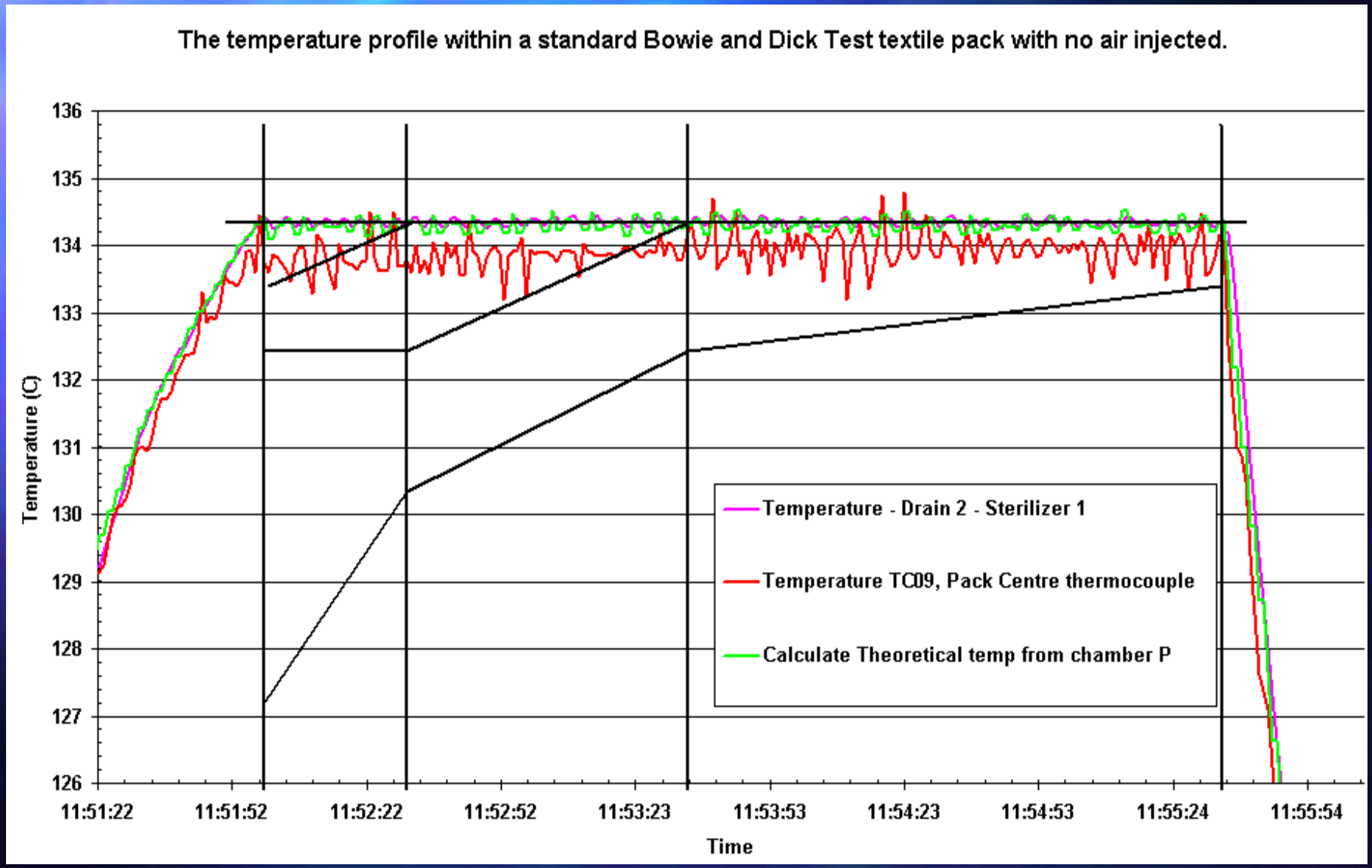
EXPERIMENT
Materials

- 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.
- 300L programmable steam sterilizer.
- High Accuracy T and P sensors calibrated to National Standards.
- Air Injection Apparatus (as per EN 867-4)

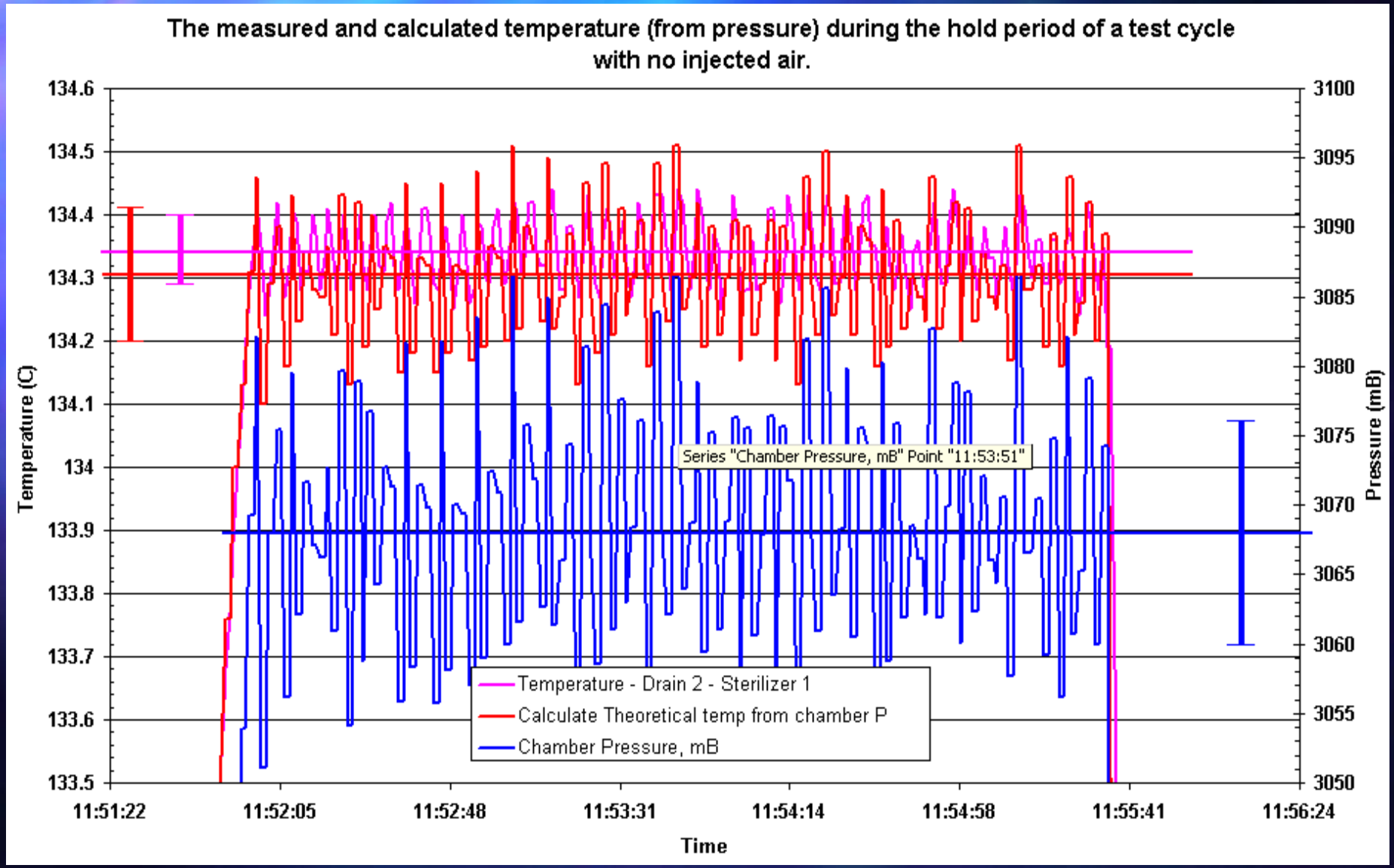
Pass Cycle


PRESSURE PROFILE OF EN 867-4 TEST CYCLE
B1 - SUB ATMOSPHERIC PULSING
PRESSURE (mB)
3500
3000
2500
2000
1500
1000
500
0
13:31:35
13:33:35
13:35:35
13:37:35
13:39:35
13:41:36
13:43:36
13:45:36
13:47:36
13:49:36
TIME

EXPERIMENT – PASS CYCLE



EXPERIMENT – Pass Cycle

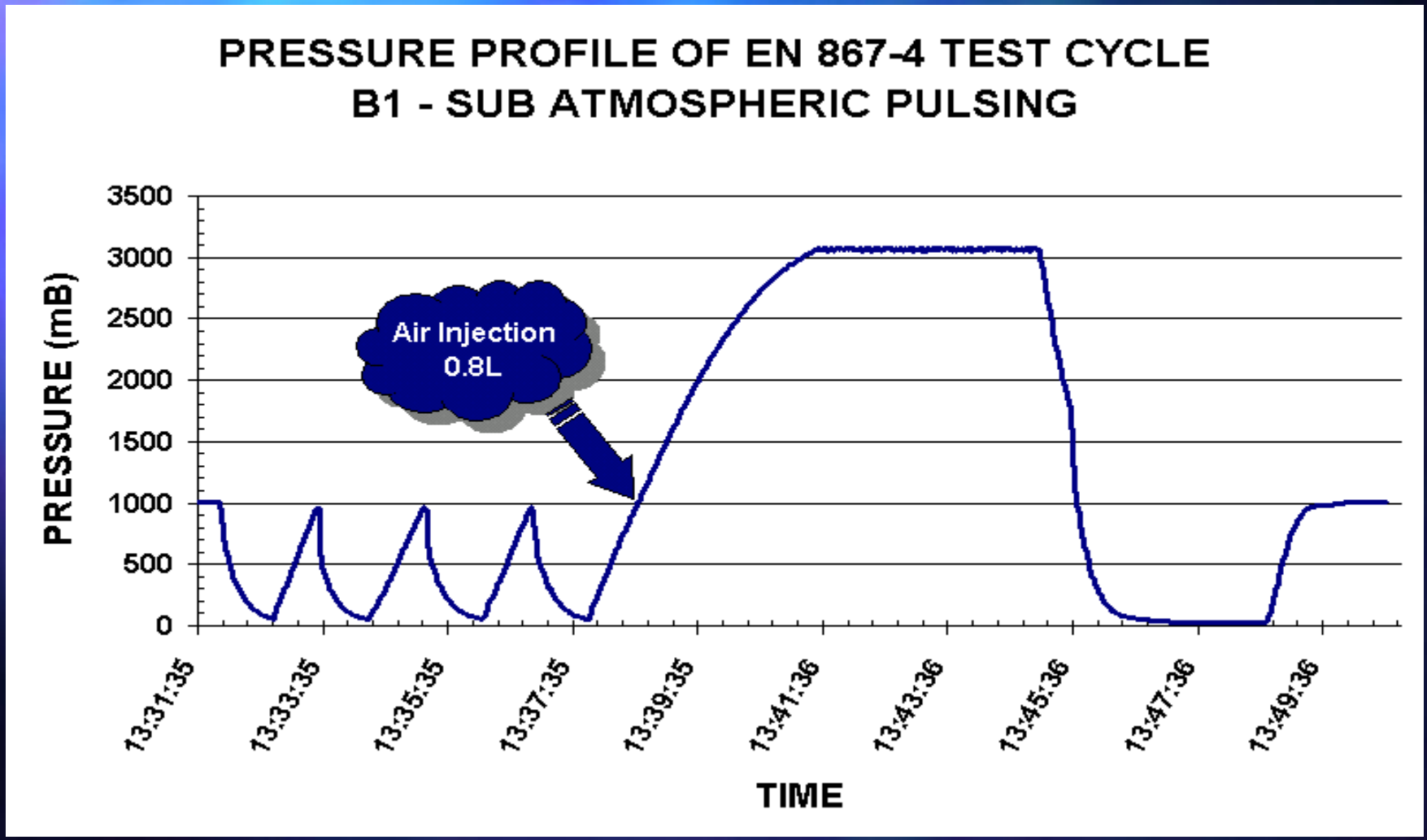


EXPERIMENT

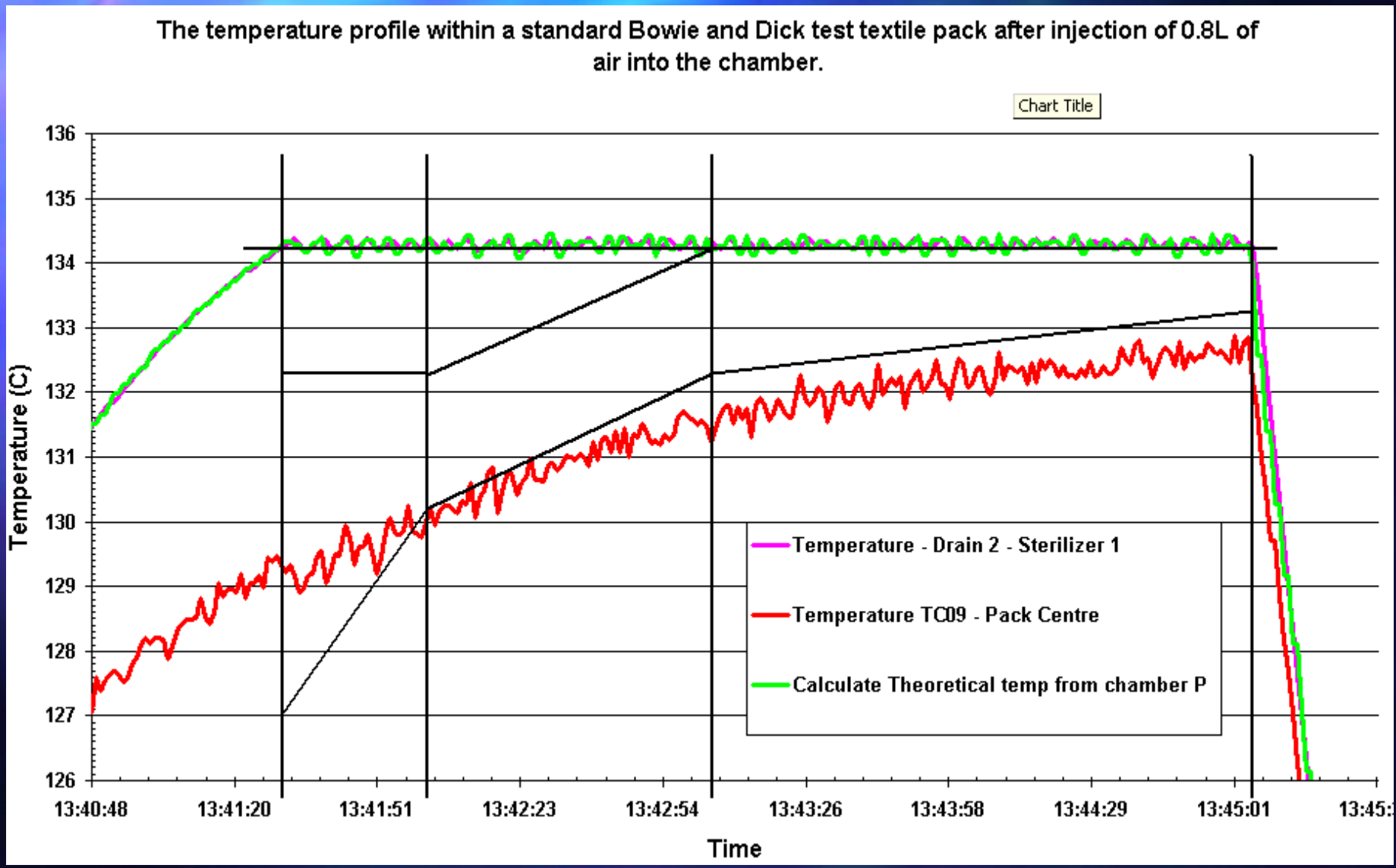
Statistical Analysis of Results during hold phase – No air injected

	Drain T C	Calc. T C	Pressure mB
Mean	134.34	134.30	3068
Std Dev	0.053	0.103	8.85
Max	134.44	134.51	3086
Min	134.19	134.10	3051

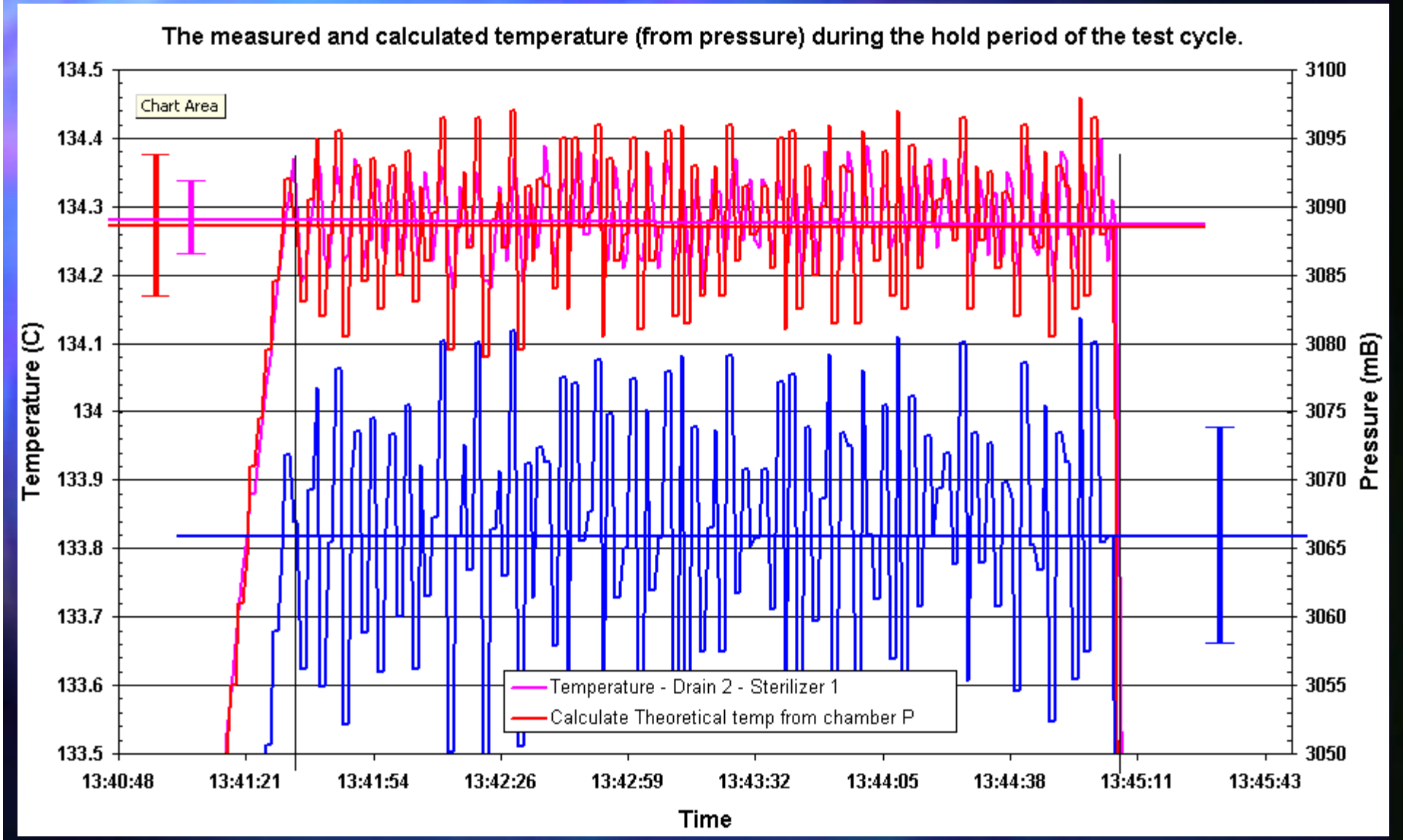
EXPERIMENT – Fail Cycle Method



EXPERIMENT – FAIL CYCLE



EXPERIMENT-FAIL CYCLE



EXPERIMENT

Summary of Results during hold phase
Air Injected

	Drain T C	Calc. T C	Pressure mB
Mean	134.29	134.28	3066
Std Dev	0.056	0.102	8.83
Max	134.39	134.46	3082
Min	134.18	134.08	3050

CONCLUSIONS

- A VOLUME OF AIR (0.8L) SUFFICIENT TO CAUSE A STEAM PENETRATION TEST (BOWIE AND DICK TEST) FAILURE COULD NOT BE DETECTED BY SIMPLE INSPECTION OF TEMPERATURE AND PRESSURE MEASUREMENT ALONE.

- DATALOGGING ALONE CANNOT REPLACE THE BOWIE AND DICK TEST !