Relevance of the Bowie and Dick Test today ??

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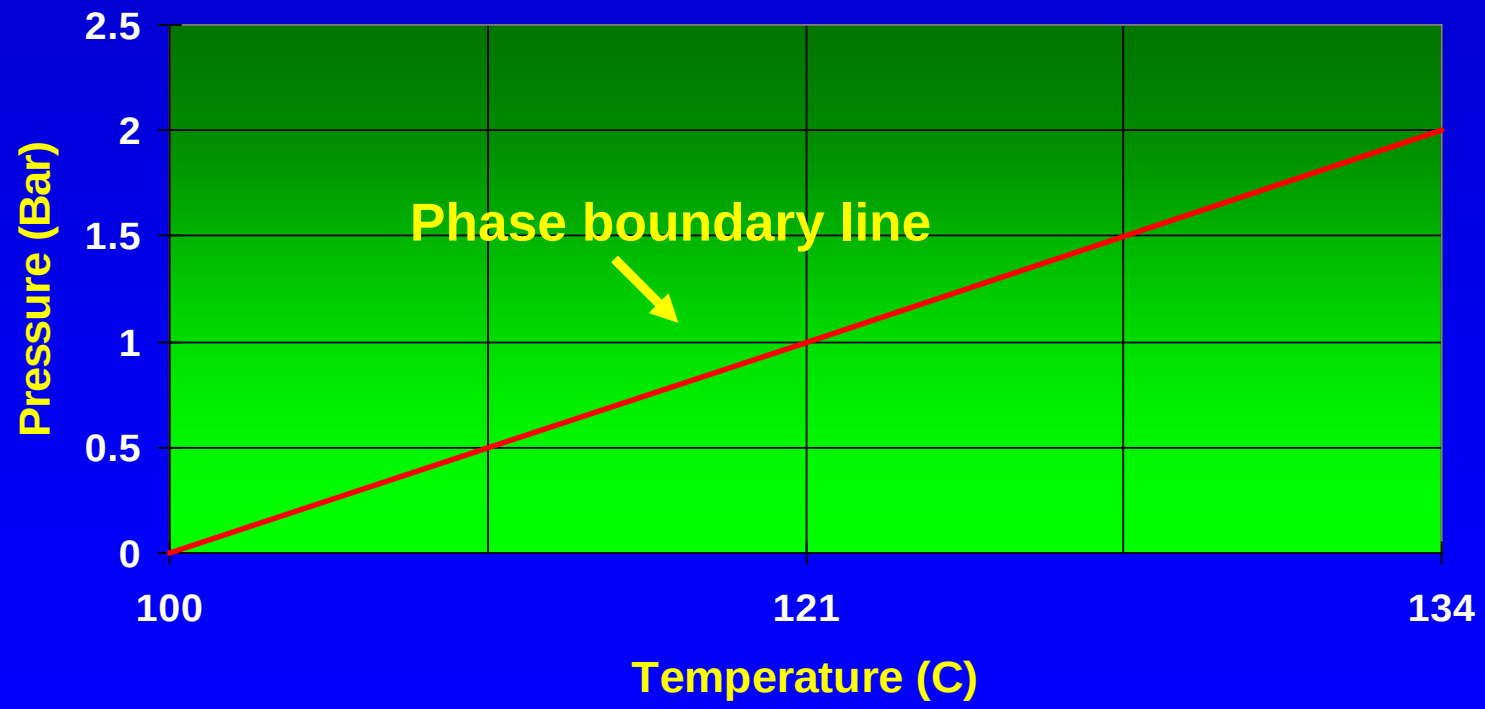
Objectives

- Daltons law and the Bowie and Dick test
- Practical experiments conducted in Sterilization Research Labs
- Independent Certification and Validation
- Conclusion

Dalton's Law

- In theory, it is possible to detect the presence of air in steam by measuring and comparing the pressure and temperature
- 1 bar of steam + 1 bar of steam = 2 bar
  - temperature = 134°C
- 1 bar of air + 1 bar of steam = 2 bar
  - temperature 13°C cooler

Steam



The Bowie Dick Test

50 Years On…

Origins of the Bowie Dick Test

- Published in 1963 in the Lancet by Bowie, Kelsey and Thompson
- Devised by Bowie and Dick
- Inspired by work by Scott, Henry and Savage, dated back to pre-1937

Bowie Dick Test Today

- Is the Bowie Dick test still relevant today?
- We don’t sterilize packs of towels like we used to!
- Does the Bowie Dick test accurately assess steam penetration?

Experimental Details

Experimental Details

- Inject air into a sterilizer
- Measure the effect in
  - 1 Empty chamber
  - 2 Chamber loaded with a tray of surgical instruments
  - 3 Chamber loaded with 4 trays of surgical instruments
  - 4 Chamber loaded with 7 kg towel pack
  - 5 Chamber loaded with Bowie Dick pack

Empty Chamber

- Research sterilizer
  - Chamber volume 400 litres
- Rather than **leak** air into the chamber, air was **injected** into the chamber at a defined point
- The quantity of air injected was gradually increased

Air Injection Point

Results - Empty Chamber

- No air injected
  - Temperature and pressure were as dictated by steam tables i.e. correct for saturated steam
- As the volume of air was increased, **no fault could be detected** by temperature vs. pressure comparisons

Single Tray

- Sterilizer loaded with **single tray of instruments** used commonly in hospitals
- Trays wrapped in
  - Non-woven paper (Westfield Medical)
  - Woven PTFE textile
  - Spun-bonded polypropylene (Kimberly Clark)
- Wrapping techniques used as recommended by wrap manufacturer

Results – Single Tray

- The paper tray wrap produced **2 or 3°C of superheat**, so it was difficult to compare temperature vs. pressure.
- With the other materials, locations within the tray near to the instruments after **1% air** injection showed temperature / pressure variations **slightly larger** than Dalton's Law would suggest

Conclusions - Single Tray

- The tray contents are **drawing steam**, and with it, air
- The **concentrated air** (rather than evenly distributed) would account for the **non-Dalton behaviour**
- It is not uncommon that hydrophilic materials such as cotton and paper produce small amounts of **exothermic superheat**

Multitray

- Thermocouples were placed throughout the chamber and trays
- Cycles were run firstly with no air, then with varying quantities of air injected

Results - Multitray

- Again the paper tray wraps produced 2 or 3°C of superheat, so it was difficult to compare temperature vs. pressure.
- No air injected
  - Temperature and pressure were as dictated by steam tables i.e. correct for saturated steam
- As the volume of air was increased, **no fault could be detected** by temperature vs. pressure comparisons

Conclusions - Multitray

- Air is being **shared**, or distributed, amongst the 4 trays
- No fault was evident

Results - 7kg Towel Pack

- With **no air injected**, pressure and temperature monitoring showed **no deviation** from normal
- When injecting air, volumes as small as **0.02%** (i.e. 50 times smaller than for a single tray) of the chamber volume created significant fault conditions

Conclusions – 7 kg Towel Pack

- The 7 kg towel pack is **highly efficient** at concentrating any available air
- This concentration easily shows discrepancies between temperature and pressure readings

Bowie Dick Test Pack

- Single Use Bowie Dick Test Pack, validated to EN867 – 4, was placed in the chamber as indicated by the manufacturer

Results - Bowie Dick Test Pack

- When no air was injected, the result was pass result
- When air injection of 0.02% of chamber volume was injected, a large fail result was obtained.

Conclusions - Bowie Dick Test Pack

- The disposable Bowie Dick Pack is calibrated against the 7kg towel pack, so it is not surprising that it performs similarly to it

Research Conclusions

- In an empty chamber, **air is very difficult to detect** as it is randomly distributed throughout the chamber
- A single tray of instruments will **attract a significant amount of air** towards the tray, suppressing the temperature by several °C

Research Conclusions

- Air will be distributed between **several trays**, and will be difficult to detect by temperature/pressure measurements
- A **7 kg towel pack** still remains one of the **most demanding challenges** for a porous load sterilizer
- The performance of a validated Bowie Dick Pack matches the towel pack

Research Conclusions

- It is **not possible to show presence of air** in a steam environment unless the pressure and temperature probes have identical (rapid) response times and can accurately measure less than **0.3 mbar**
- **Air will only be detected if there is a load or challenge to concentrate the air**

The Bowie Dick Test

- It can be seen that it is the **principle** of the Bowie Dick test which is important because the same principles for steam sterilization still apply today, just as they did in the 1930's

Standards

- In order to ensure that Alternative Bowie Dick tests and other chemical indicators comply to minimum requirements, we have standards.

Importance of Standards

- Standards define important minimum safety factors for products
- EN 867-4 specifies these requirements for disposable-type Bowie Dick tests
- EN 867-1 and ISO 11140 – 1 & 2
- But conformance to these standards are declared by the product manufacturers themselves

Limitations of standards

- Self certifying
- No overseeing body
- Opportunity for fraudulent claims

What is the solution for REAL peace of mind……

Independent Validation & Certification

New products

- The user or purchaser of a product may take one of 3 options:
  - assume that it could not be sold unless it was satisfactory
  - take the word of the manufacturer or supplier
  - seek independent verification

A Declaration

- A declaration about a product or service may be :
  - self certified
    - i.e a declaration made by the product manufacturer or service provider
  - independent
    - i.e the product or service has been assessed by a recognised test house and a certificate appropriately issued

Self Certification

- Relies on the manufacturer or service provider to give an accurate and honest claim
- There is potential for abuse
  - generally used for products that do not have a significant safety element

Independent Certification

- Cannot be abused as the manufacturer or service provider has no input
- Often required when the product or service has a strong safety element

Independent assessors

- Often called test houses, accreditation bodies or notified bodies
- They are regulated and controlled by competent authorities

EN 45011 - General requirements for bodies operating product certification systems

- Services available to all applicants
- Be impartial
- Have a documented structure
- Have a quality system
- Be free from any commercial or financial pressures
- Award a quality certificate and internationally recognised quality mark

Summary

- The Bowie Dick pack is **scientifically proven** as still being relevant and accurate for the demands of today's Sterile Services Managers.

Conclusion

- You all validate and document the processes in your department.
- Ensure that the products you are using are Validated.
- If you don’t ask the question no one else will !

Be a demanding customer