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

Phase boundary line

Temperature (°C)

Pressure (Bar)
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

Air injection
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
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

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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