STERILIZATION PROGRAMS, AIR REMOVAL AND STEAM PENETRATION

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Sterilization Programs, Air Removal and Steam Penetration

Agenda:

How steam sterilization works

Why air is a problem

How is air removed

What are the effects of poor air removal

Different cycle types

Monitoring air removal

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Steam sterilization works by:

Using steam to transfer energy from the boiler/generator to the load in the sterilizer

The steam contains two packets of energy

1. that to raise its temperature from cold to boiling point
2. that to turn boiling water into steam at the same temperature

For each kilogram of steam energy 2 is approximately 4-5 times that of energy 1

When steam condenses energy 2 is given to the surface it condenses on – this condensation is vital

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Why is air a problem?

It inhibits the access of steam (and hence energy transfer) to ALL surfaces – *ie inhibits steam penetration*

It acts as an insulator to inhibit energy transfer

It mixes with the steam to destroy the fixed pressure/temperature relationship used to control the sterilizer

It is non-condensible and contains little energy to transfer

Thus AIR MUST BE REMOVED FROM THE ENTIRE CHAMBER

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A steam sterilizer cycle consists of:

Air removal – *the stage without which sterilization will not occur*

Heat-up

Sterilization – *the central 3 minutes of a 45-minute cycle*

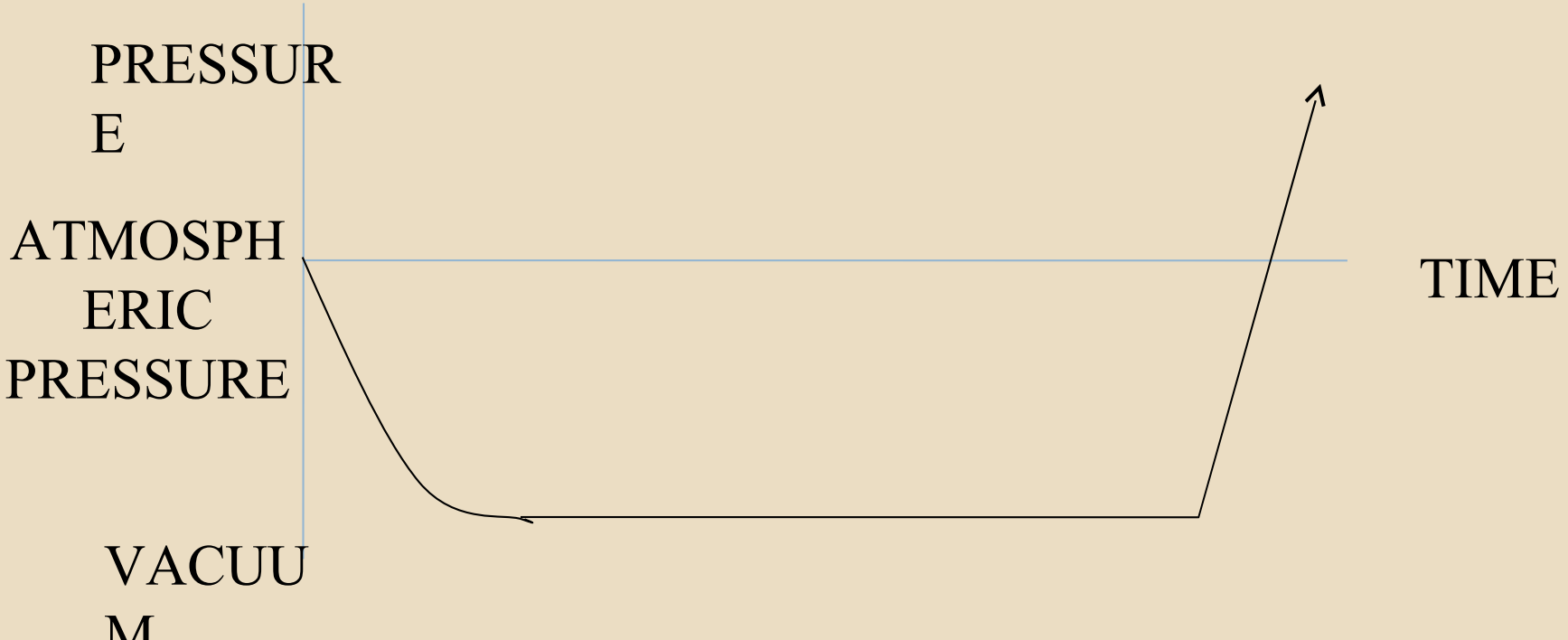
Steam removal

Drying

Air inlet

How is air removed?

1. A long, deep vacuum at the start of the cycle?



How is air removed?

2. Pulsing

Conclusion:

Pulsing is the most efficient method

The efficiency depends upon:

1. The number of pulses
2. The depth of each pulse

So which is the best pulsing system design?

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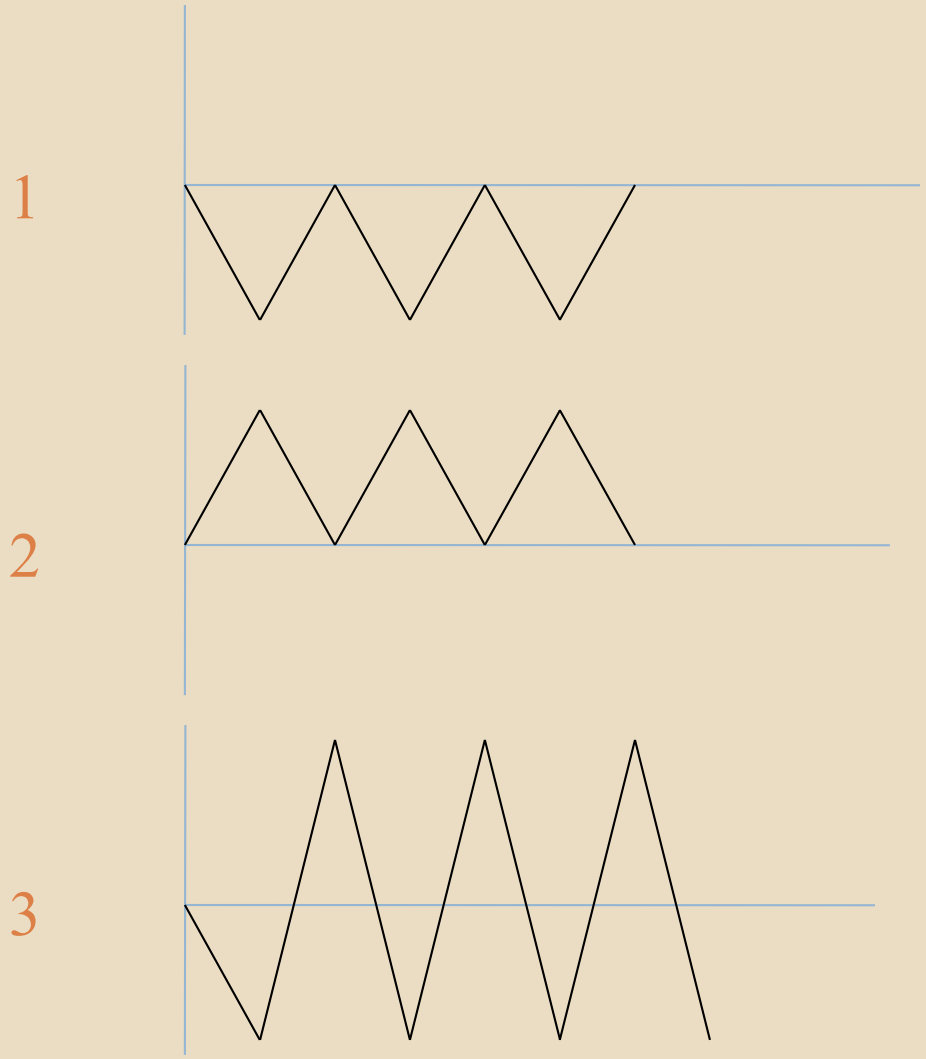

Advantages & disadvantages:

Negative pulses

Can induce air through leaks

Positive pulses

Less efficient but no air ingress

Trans-atmospheric pulses

Most efficient but has negative sections

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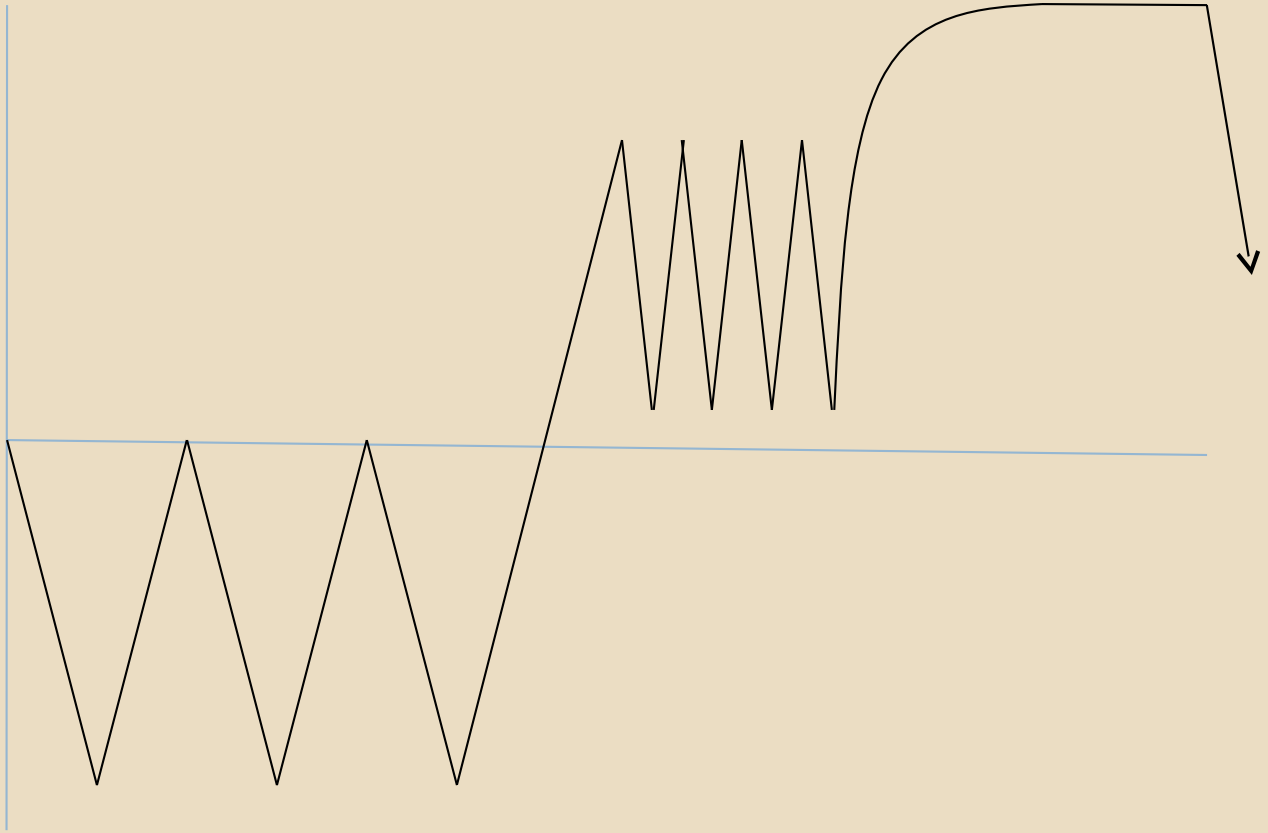
A possible final cycle – a compromise:



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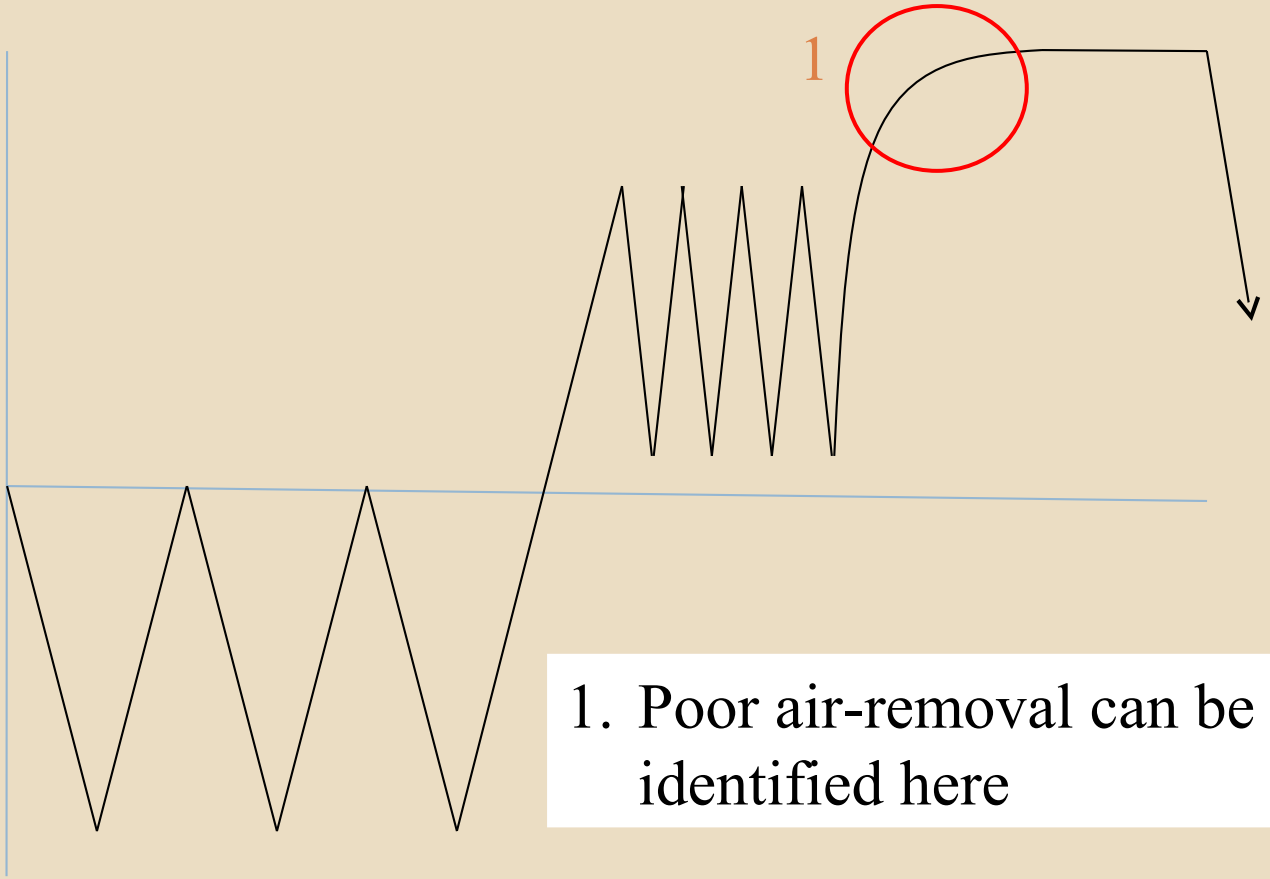
Important points for air removal:



1. Poor air-removal can be identified here

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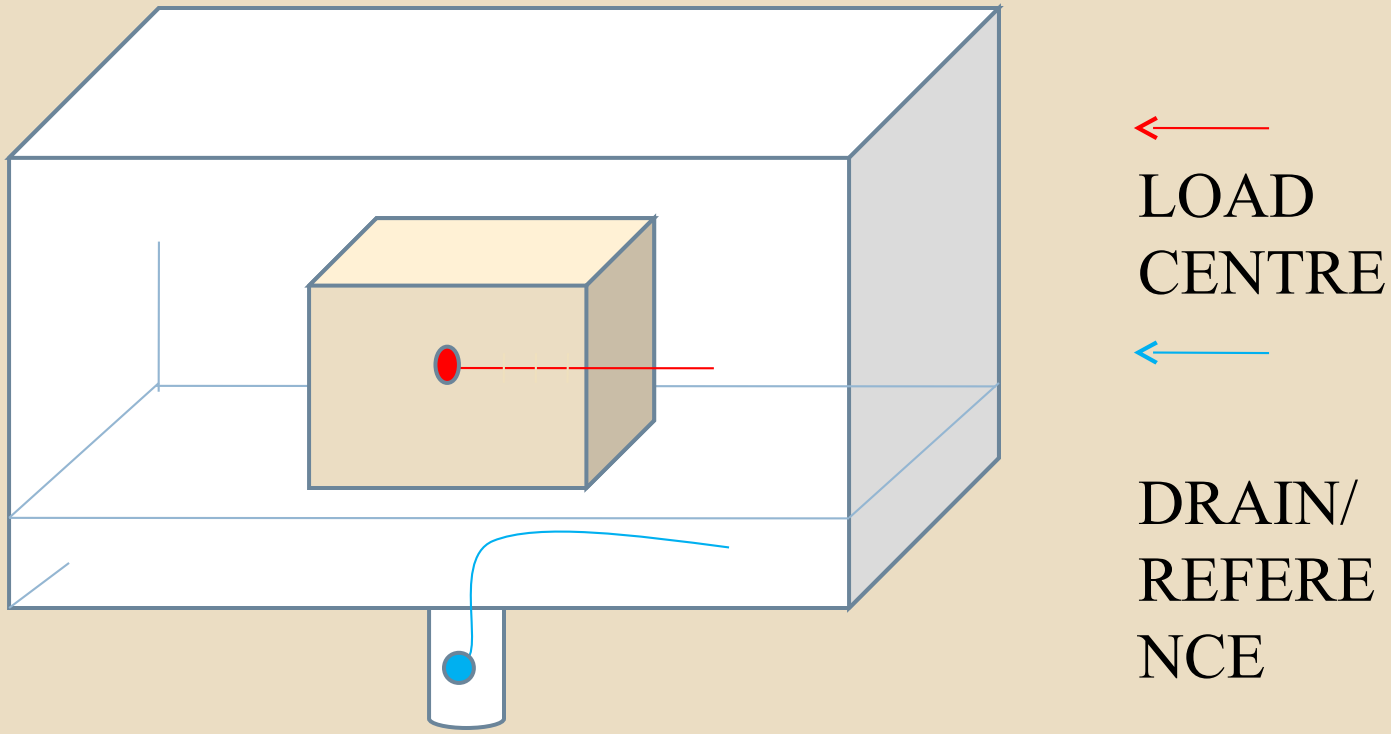
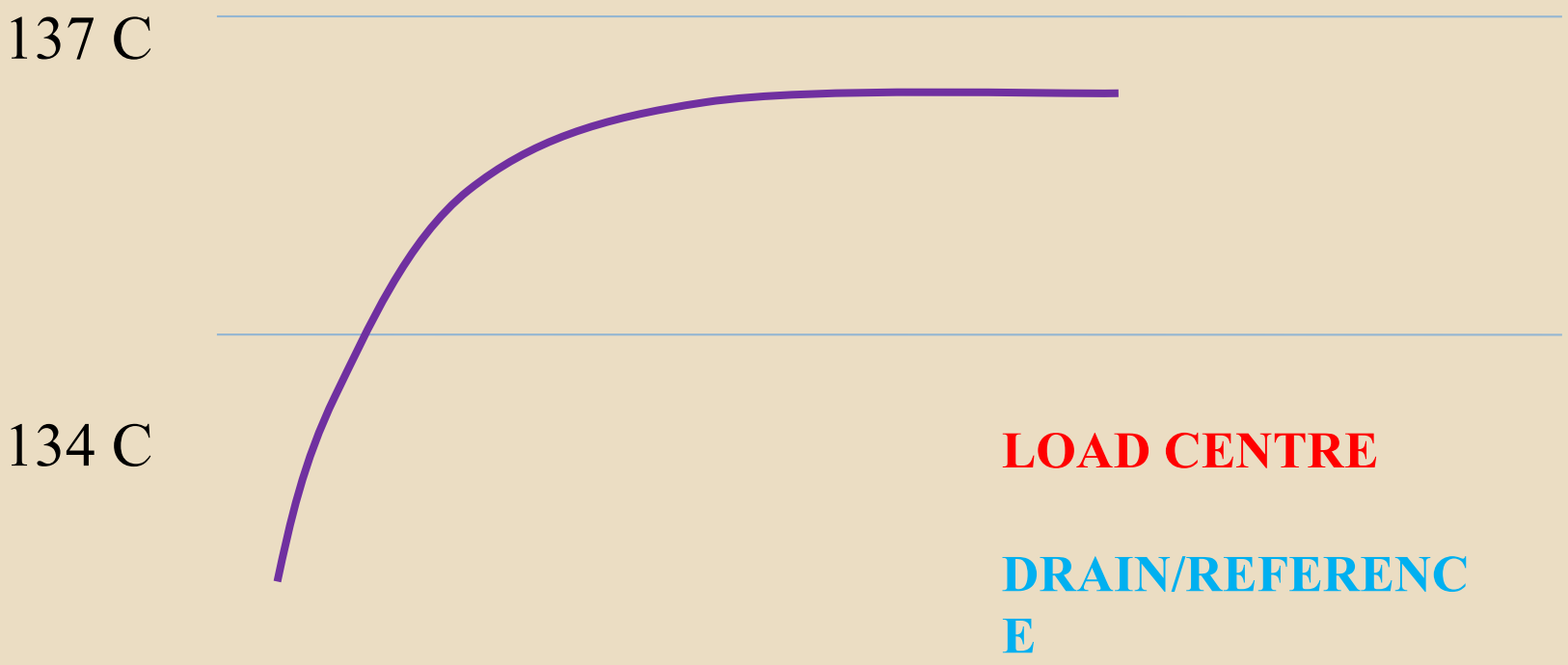
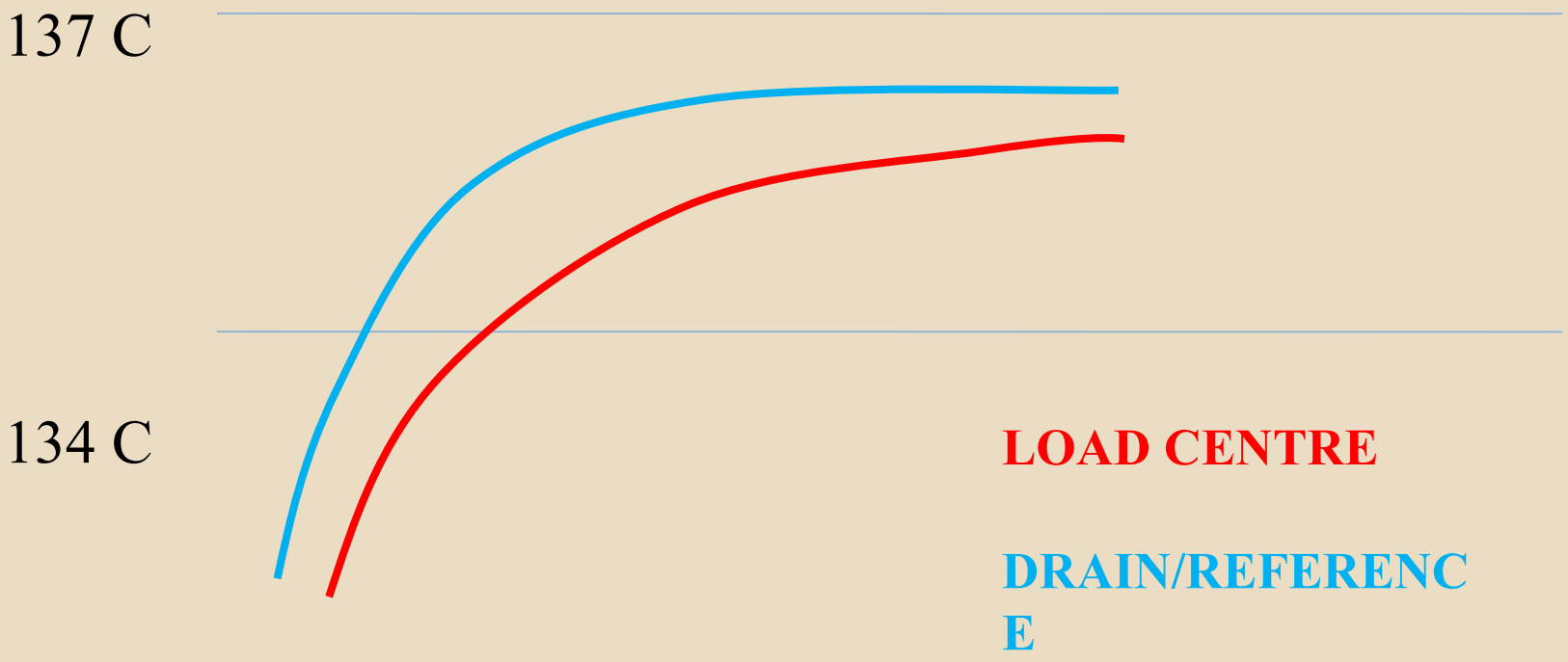
Measuring air-removal:



Thermocouple traces: perfection



Thermocouple traces: reality



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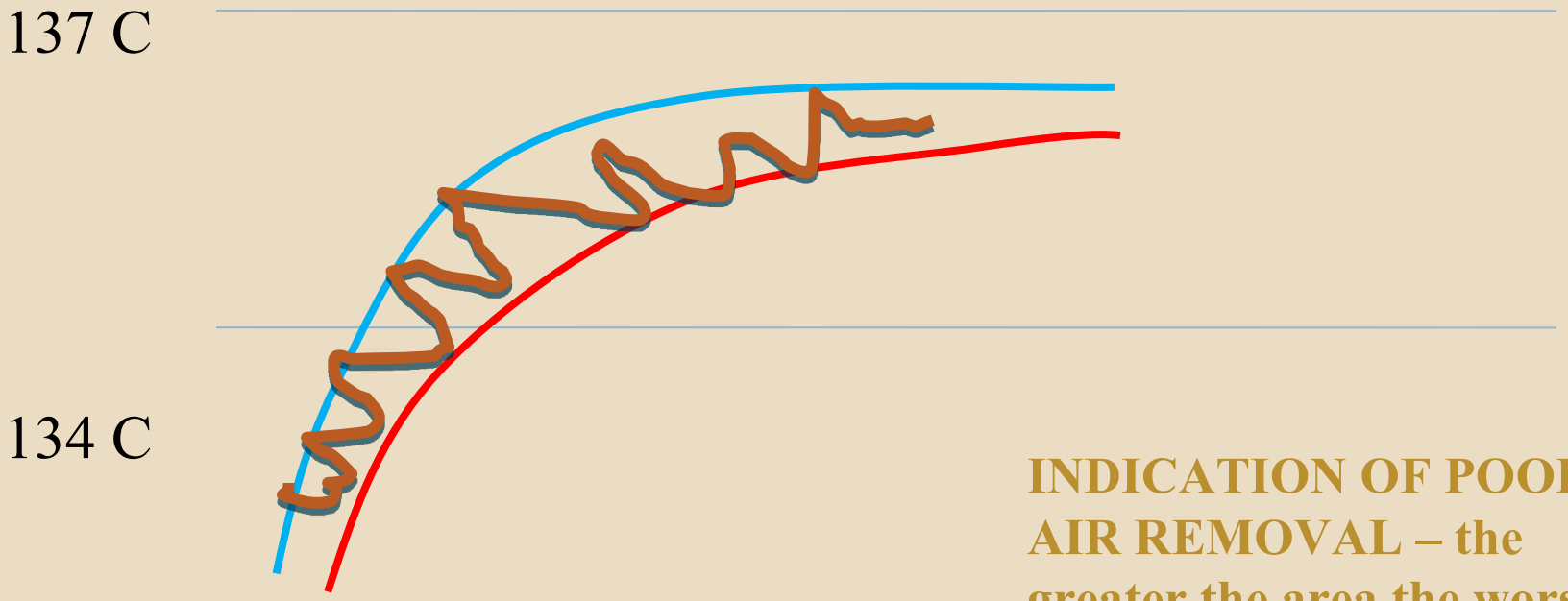
Thermocouple traces:



INDICATION OF POOR AIR REMOVAL – the greater the area the worse the air removal

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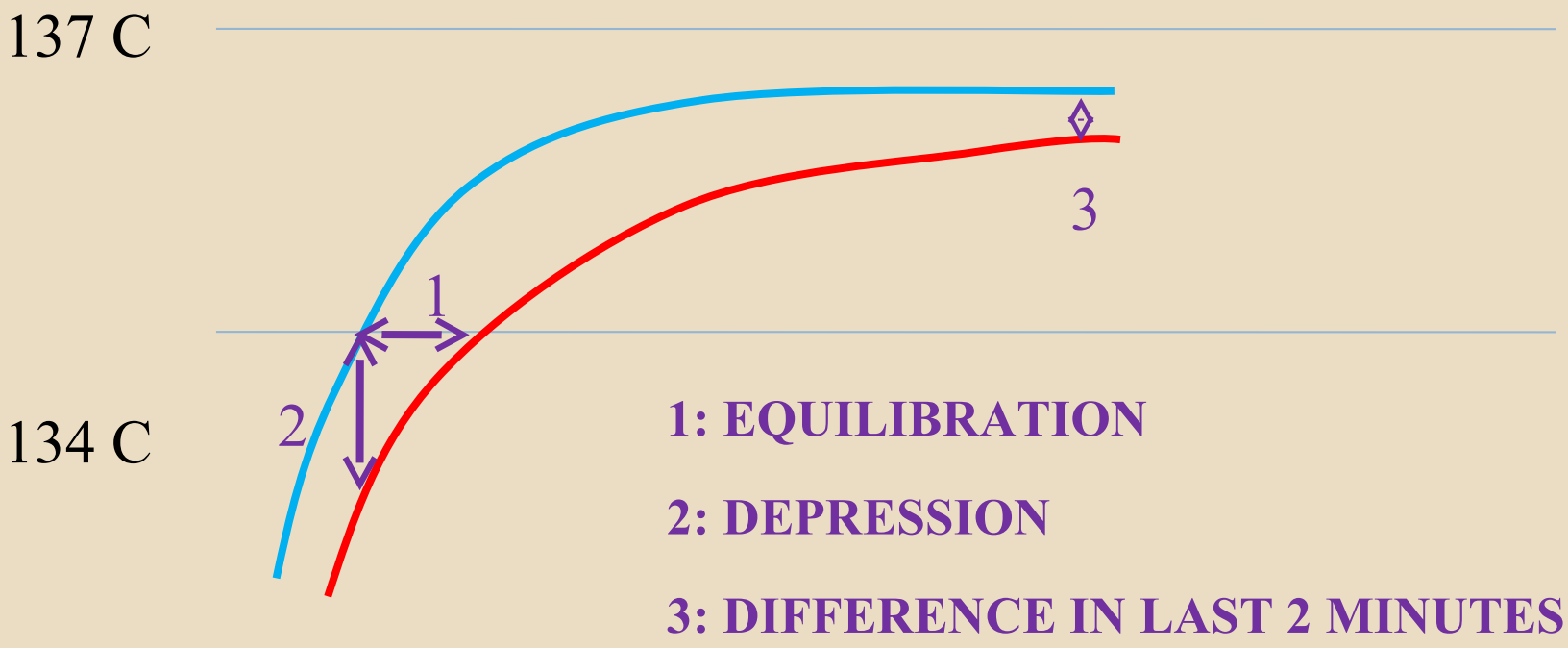
Thermocouple traces:

* = points at which measurement can be done

Quantification of thermocouple traces:



Quantification of thermocouple traces:

AIR REMOVAL CAN NOW BE QUANTIFIED BY PUTTING VALUES TO THESE THREE PARAMETERS

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Comparison of parameter values in the UK:

DOCUMENT	YEAR	1 equilibration	2 depression	3 difference
HTM 10	1968	-	-	-
HTM 10	1980	-	-	0
HTM 2010	1994	15	2*	2
EN 285 >>	1994 >>	15	2*	2

* = for air detectors

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Air removal monitoring:

- Internal sensors and timers (control)
- Bowie & Dick test (daily test
- Process Challenge devices (in-chamber in-cycle when used)
- Air detector (external in-cycle every cycle)

Bowie & Dick test:

Initially defined with Standard Test Pack (textile)

Later quantified via Standards

Parameter definitions used to define failure chemistry

NOTE: parameter values and test pack details may differ in different parts of the World

Air detector:

- A device to automatically monitor the efficacy of the air-removal process – it can automatically fail the cycle if it measures unacceptable air removal
- It can function each cycle
- It is part of the control system, not an accessory
- It can abort cycles at an early stage of air-removal
  - ie it can be predictive
- It must be validated and periodically tested with care and skill
- It is extremely accurate and precise

Air detector:

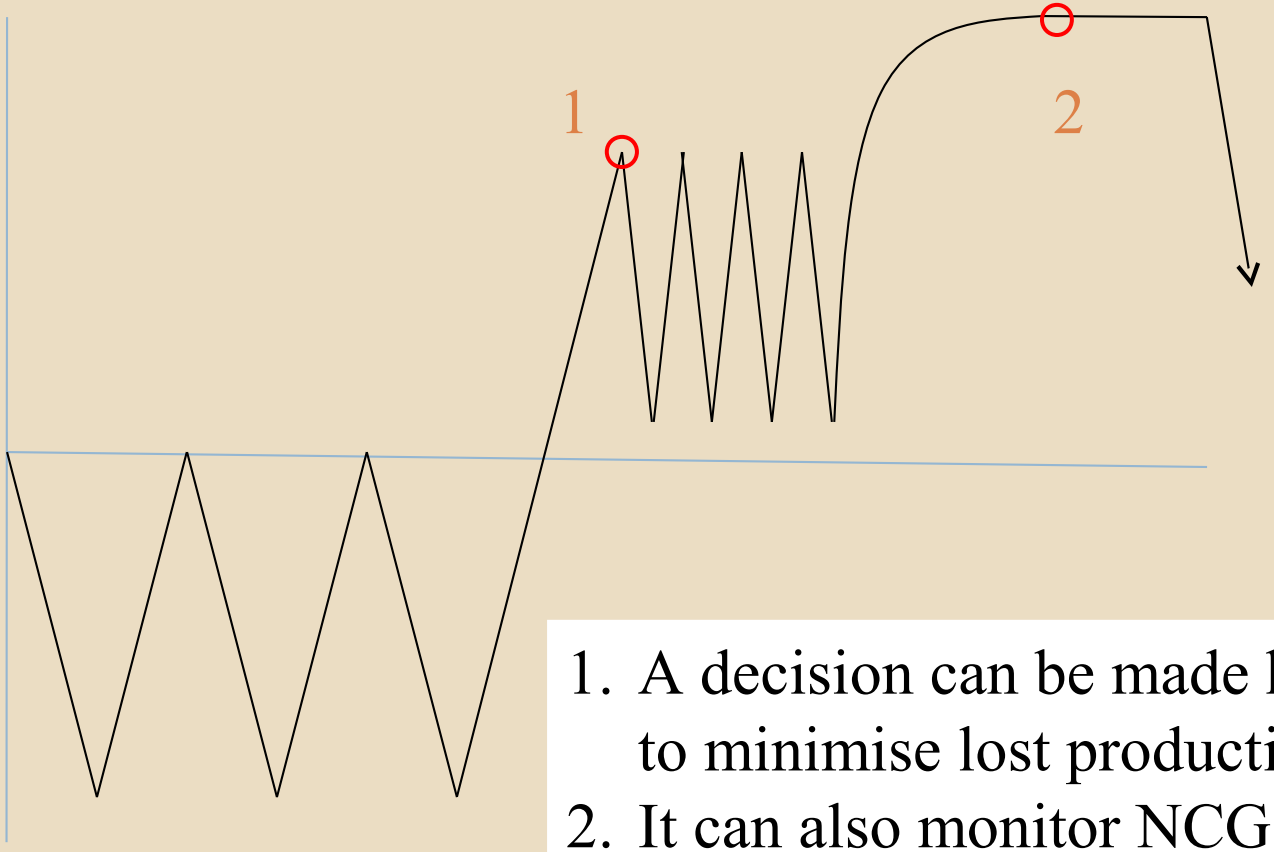
It works by sealing a sample of chamber contents and, by condensation caused by heat loss, separates residual air

The amount of air can be measured by either its partial pressure or temperature depression

It is part of the chamber but external to it to enable the heat loss to occur

A temperature-operated air detector can be predictive and can be used to monitor hold-time conditions

Important points for air detector:



1. A decision can be made here to minimise lost productivity
2. It can also monitor NCG levels

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Summary:

- Complete air-removal is essential to good sterilization
- Pulsing is the most efficient method of air removal
- A variety of pulsing systems may be used – they each have benefits and disadvantages
- Poor air-removal can be shown by thermometric testing
- Thermometric data can be used to quantify air-removal and thus define performance of air-removal monitors
- Bowie & Dick test parameters can be thus defined but may differ from place to place
- An air-detector is an accurate and repeatable method of monitoring every process cycle

Thank you

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