

# Medical Market Laboratory EMEA




## Biological and chemical indicators

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Croatia, March 28, 2009)



# Outline

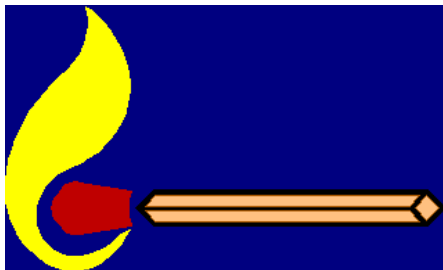
- 
- Sterilization definitions
  - Purpose of monitoring
  - Norms
  - Testing
  - CI class 5 and 6
  - Conclusions

# Definition Sterile

- Definition


Free of all viable organisms

[ISO 11139:2006, clause 2.43]



YES --- it burns!

# Definition Sterile, statically

- 
- 4.1 For a terminally-sterilized medical device to be designated "STERILE", the theoretical probability of there being a viable micro-organism present on/in the device shall be equal to or less than  $1 \times 10^{-6}$ .

NOTE Permission for acceptance of a probability greater than that specified in 4.1 may be sought through the appropriate regulatory bodies. Such permission requires consideration of the individual situation, including consideration of the risk analysis (see, for example, EN 1441) undertaken by the manufacturer of the medical device.

- EN 556-1:2001 (E), clause 4.1

# Medical Research Council (1959, MRC)



| Perkins       |              | MRC           |              |
|---------------|--------------|---------------|--------------|
| Time<br>[min] | Temp<br>[°C] | Time<br>[min] | Temp<br>[°C] |
| 2             | 132          | 3             | 134          |
| 8             | 125          | 10            | 127          |
| 12            | 121          | 15            | 121          |


## Rational MRC: Steam quality

# Purpose

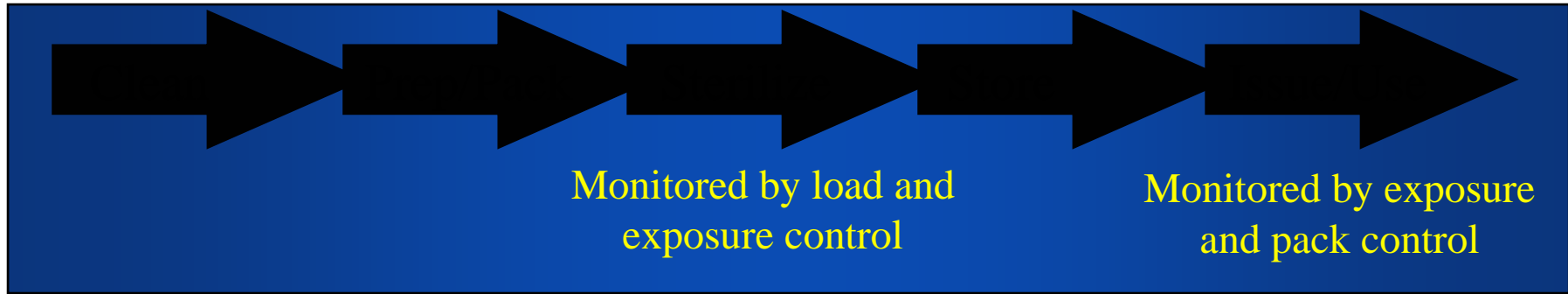
- To come to sterile Medical Device after a sterilization run
  - *Reproducible*
  - *Effective*
  - *Prove*
  - *Documented prove*



# Combination of factors

- 
- Sterilizer
  - Process
  - Load
  - Wrapping
  - Loading pattern

# Monitoring



| Process Monitoring | How Often?   | With What?                |
|--------------------|--------------|---------------------------|
| Equipment Control  | Every day    | Bowie Dick Test           |
| Exposure Control   | Every pack   | Ind. Tape, Strips, Labels |
| Load Control       | Every load   | BI / CI Test Packs        |
| Pack Control       | Every pack   | Chemical Indicators       |
| Record Keeping     | Every action | Labels, Record books      |



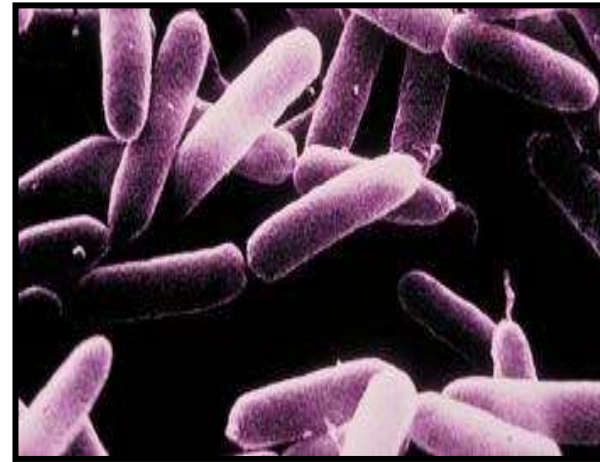


# Indicators



- Biological
- Chemical
- Physical

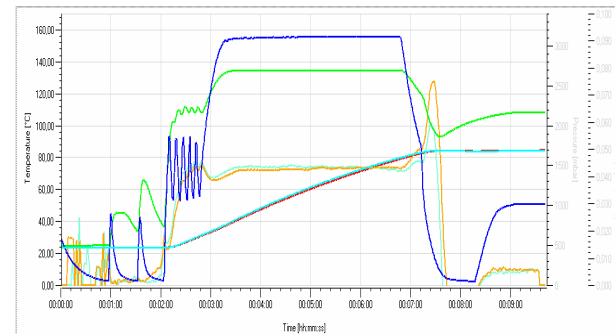
The real stuff



Easy to use



Much information



# Biological indicator norm ISO 11138

- Biological indicators ISO 11138
  - *Part 1: General requirements*
  - *Part 2: Biological indicators for ethylene oxide sterilization processes*
  - *Part 3: Biological indicators for moist heat sterilization processes*
  - *Part 4: Biological indicators for dry heat sterilization processes*
  - *Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*



# Use biological indicators

- Before process:
  - *Put indicator(s) in the load*
- After process
  - *Take indicator out*
  - *Incubate*
  - *Read results*




# Disadvantage biological indicator

- Incubation time
  - *BUT:*
  - *Rapid read out Biological Indicators within 3 to 4 hours*
  - *Possibly even faster (Research ongoing)*
- Contamination brought into sterilizer
  - *BUT:*
  - *Biological indicators in closed vials*




# Chemical indicators norm ISO 11140

- 
- *Part 1: General requirements*
  - *Part 2: Test equipment and methods*
  - *Part 3: Class 2 indicators for steam penetration test sheets*
  - *Part 4: Class 2 indicators for steam penetration test packs*
  - *Part 5: Class 2 indicators for air removal test sheets and packs*
  - *Part 6: possibly Process Challenge Devices for steam sterilization (New work item ISO/TC 198/WG 6)*

## *ISO 11140 Part 1: General requirements*

### *Clause 4 Classification*


- 
- *4.2 Class 1: process indicators*
  - *4.3 Class 2: indicators for use in specific tests*
  - *4.4 Class 3: single variable indicators*
  - *4.5 Class 4: multi-variable indicators*
  - *4.6 Class 5: integrating indicators*
  - *4.7 Class 6: emulating indicators*

## Class 2 indicators

- *Part 3: Class 2 indicators for steam penetration test sheets*
  - 'Original' Bowie and Dick test
- *Part 4: Class 2 indicators for steam penetration test packs*
  - Steam penetration test 'Europe'
  - Alternatives for the 'original' Bowie and Dick test for Europe
- *Part 5: Class 2 indicators for air removal test sheets and pack*
  - Air removal test 'USA'
  - Alternatives for the 'original' Bowie and Dick test for USA



# Testing Indicators

- 
- Why do your customers want to “test” indicators?
  - Because they want to know if they “work”!
  - What does “work” mean?
  - Show a “Pass” in a good cycle.
  - Show a “Fail” in a bad cycle.
  - The “Fail” situation is the one, which should concern them most!




# Differences in test pack

## Alternative Europe


| f                          | ISO 11140-3:2000   | ISO 11140-4:2001  | ISO 11140-5:2000   |
|----------------------------|--|---|--|
| Test Pack Density          | 0,42 kg/dm <sup>3</sup>  | 0,42 kg/dm <sup>3</sup>   | 0,20 kg/dm <sup>3</sup>  |
| Test Pack Size             | 220 x 300 x 250 mm   | 220 x 300 x 250 mm  | 220 x 300 x<br>250 – 280 mm  |
| Criteria for pass decision | Temp in pack not more than 0,5 °C lower than drain throughout plateau.                       | Temp in pack not more than 1 °C lower than set operating temperature measured in drain.   | Temp in pack not more than 0,5 °C lower than drain throughout plateau.                           |
| Criteria for fail decision | Temperature in pack between 2-3 °C lower than drain temperature at the beginning of Plateau. | Temperature in pack between 2-7 °C lower than the drain at the start of the holding stage and between 2-4°C at the start of, and not more than 1 °C at the end of, the plateau stage. | 2 °C difference between drain and centre of pack 1 minute before end of 3,5 minute 134 °C cycle. |



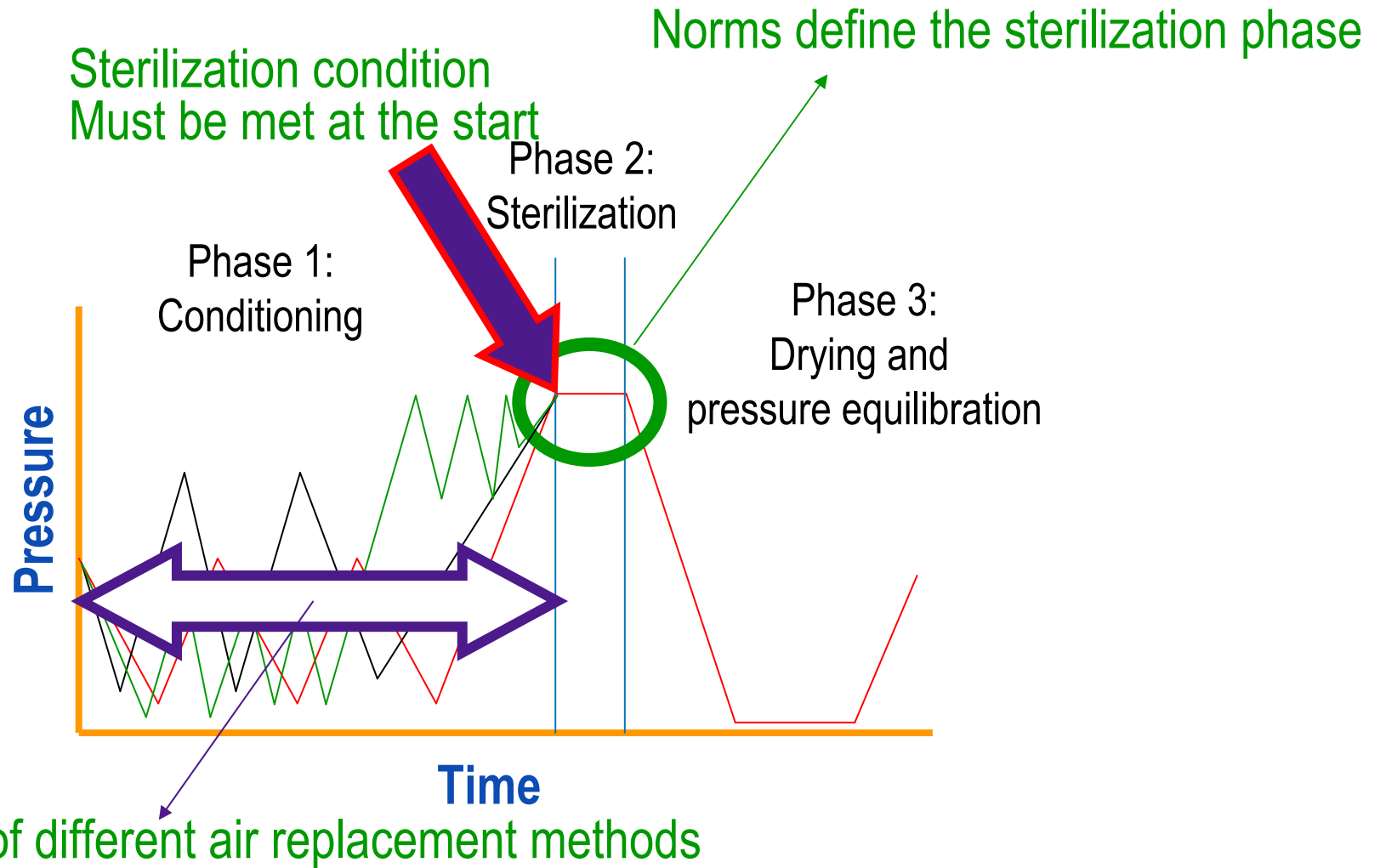
# Testing indicators

- 
- Customers want to “test” indicators?
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  - Show a “Pass” in a good cycle.
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## ISO 11140 Part 2: Test equipment and methods

- 
- The following criteria test cycle conditions must be met:
    - *reproducible*
    - *stable*
    - *controlled*
    - *predictable*
  - This is especially important for the “Fail” condition.
  - Testing is a specialism


# Processes



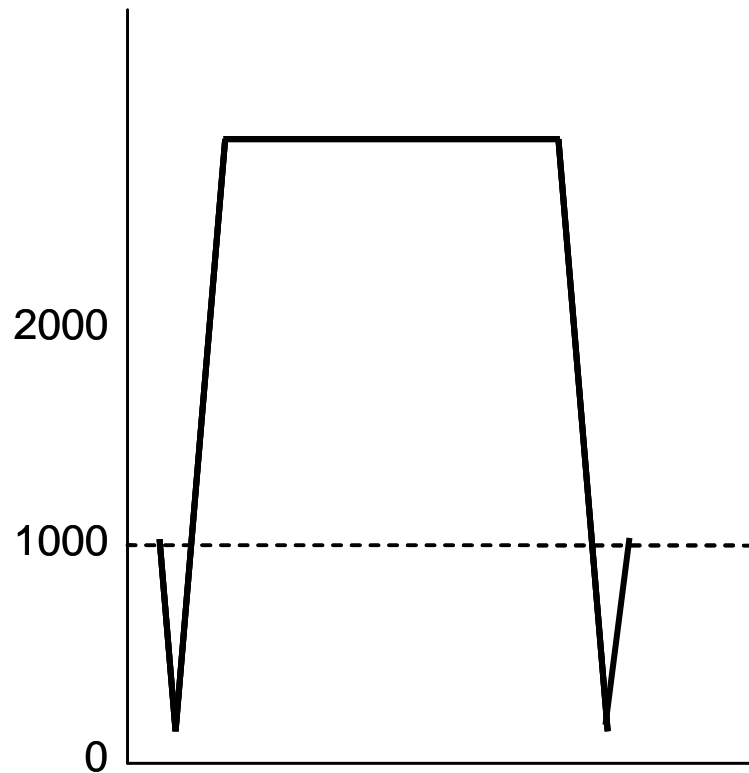
**No standards method**



# Testing Indicators

- 
- Those requirements can only be achieved with dedicated, highly specialized test equipment.
  - ISO and CEN have defined requirements for test equipment in various standards.
    - *EN ISO 18472 describes BIER/CIER (Biological Indicator Evaluation Resistometer/Chemical ...)*
    - *EN ISO 11140-3/4 describes test sterilizer for Bowie Dick Test products*

# Consensus in norm committee: standard process

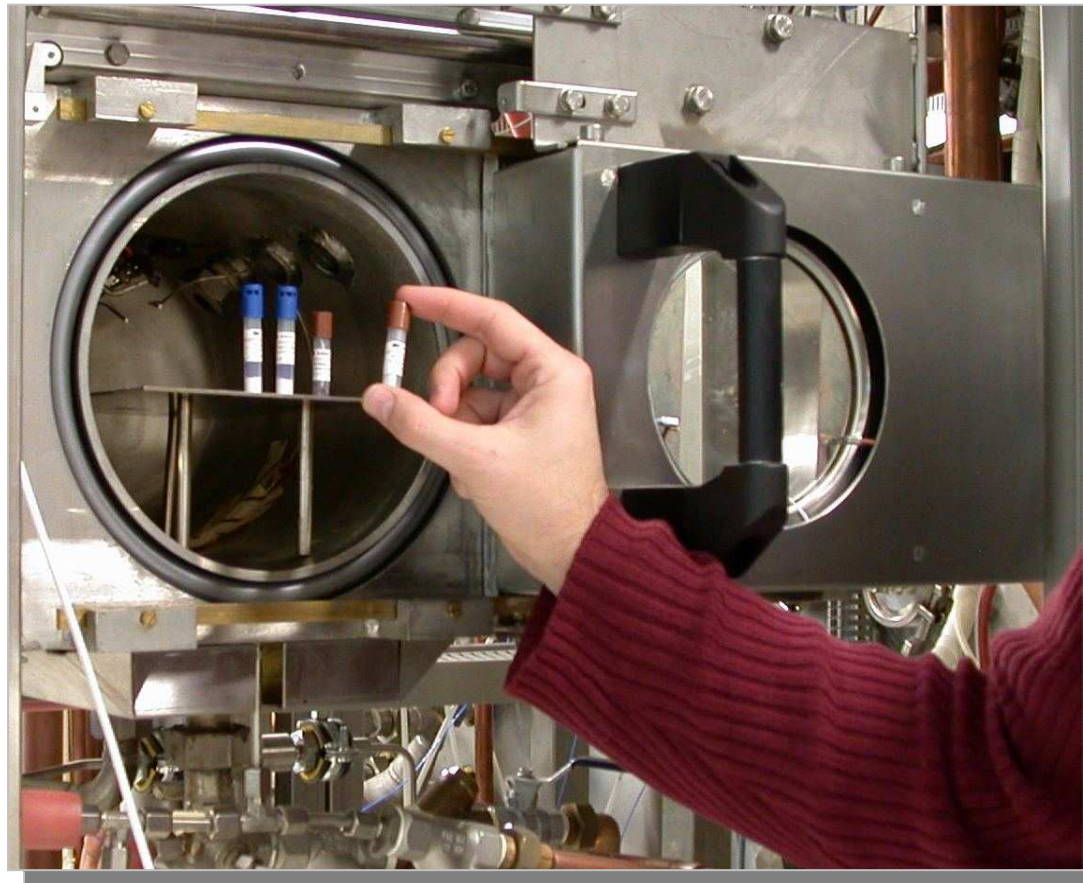


“Square wave” means:

- fast deep vacuum
- fast pressure increase
- Test period
- fast deep vacuum
- fast equilibration

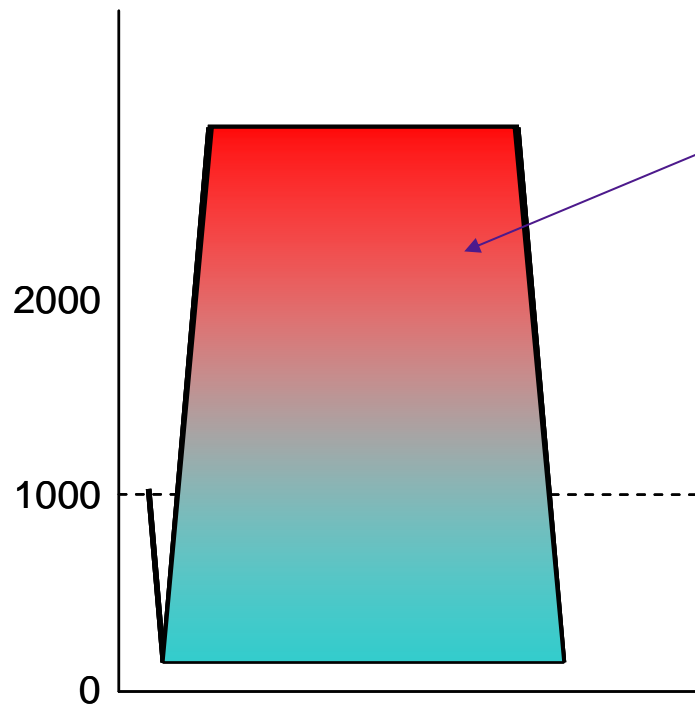
# Resistometer

- For testing biological and chemical indicators



# Reaction

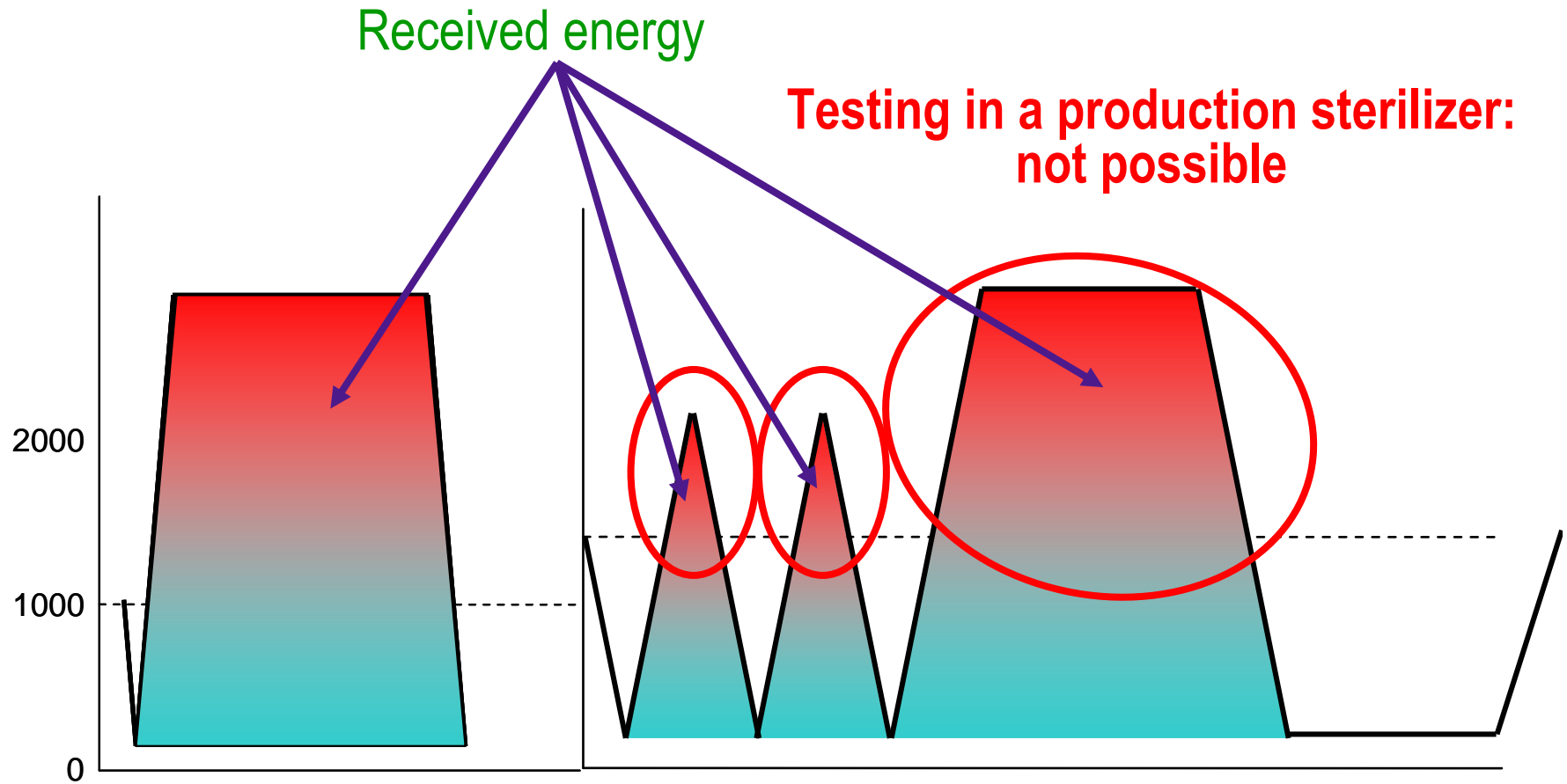
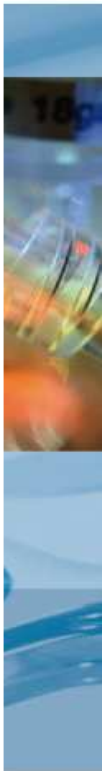
- Indicators react on their conditions.
- For steam: moist and temperature



Surface is a measure for the Energy received by the indicator



# Received energy



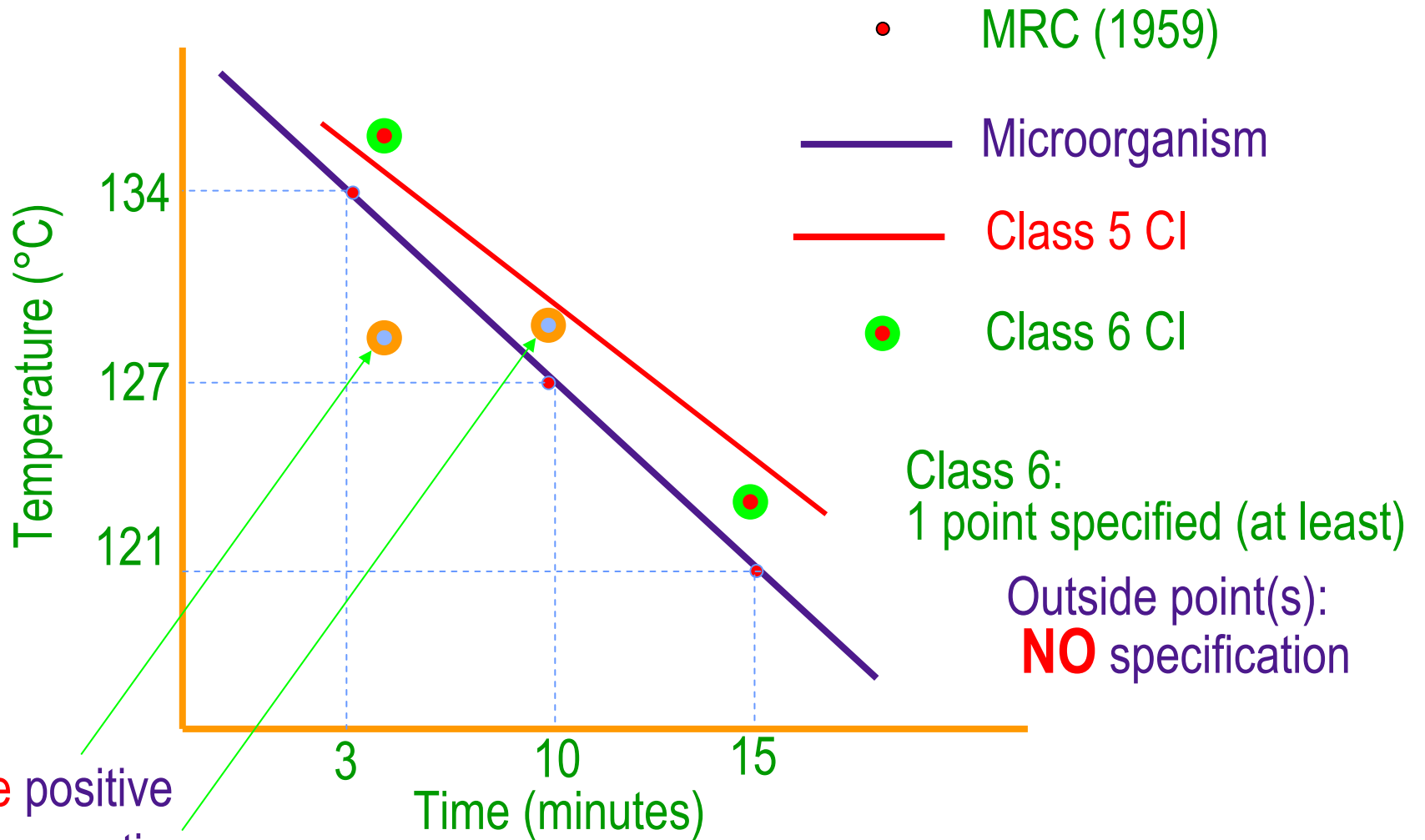
## Testing Bowie and Dick test packs

- Test sterilizer is specified
- 3 defined processes in the standard
- Fail and pass conditions are define
- If compliance with standards is claimed:

Documented prove must be available

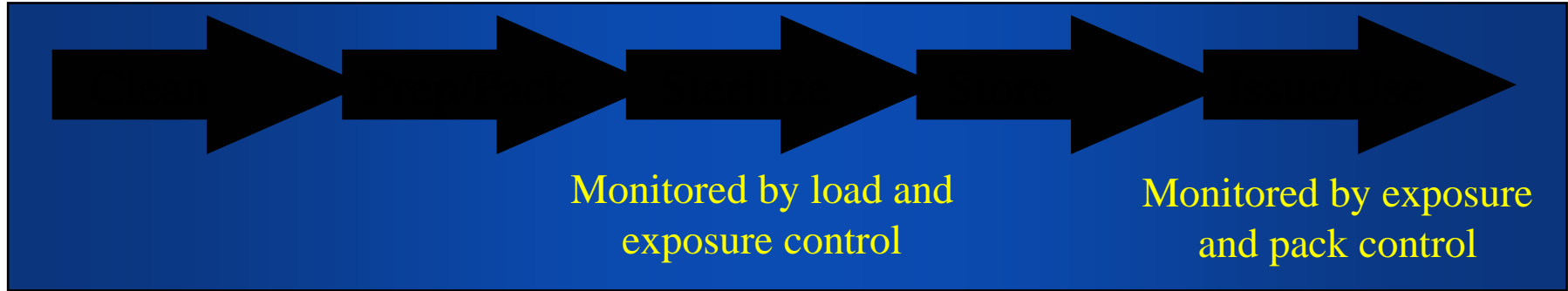


# Class 5 and class 6 indicators



False positive  
False negative


# 5 steps of monitoring




| Process Monitoring | How Often?   | With What?                |
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| Record Keeping     | Every action | Labels, Record books      |



# Monitoring

- 
- Every sterilization process must monitored
  - Depending on:
    - *Law*
    - *Norms and standards*
    - *Quality system*
    - *Working procedures of the institute*
  - A monitoring system can be chosen

# Conclusion

- 
- Different methods for monitoring
  - Type of monitoring depends on the situation
  - With wrong use: A false sense of safety will be introduced