

Medical Market Laboratory EMEA




Biological and chemical indicators

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Outline

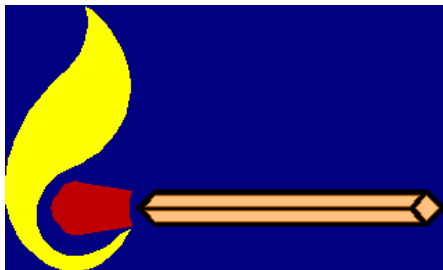
- 
- Sterilization definitions
 - Purpose of monitoring
 - Norms
 - Testing
 - CI class 5 and 6
 - Conclusions

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 1×10^{-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 [min]	Temp [°C]	Time [min]	Temp [°C]
2	132	3	134
8	125	10	127
12	121	15	121


Rational MRC: Steam quality

Purpose

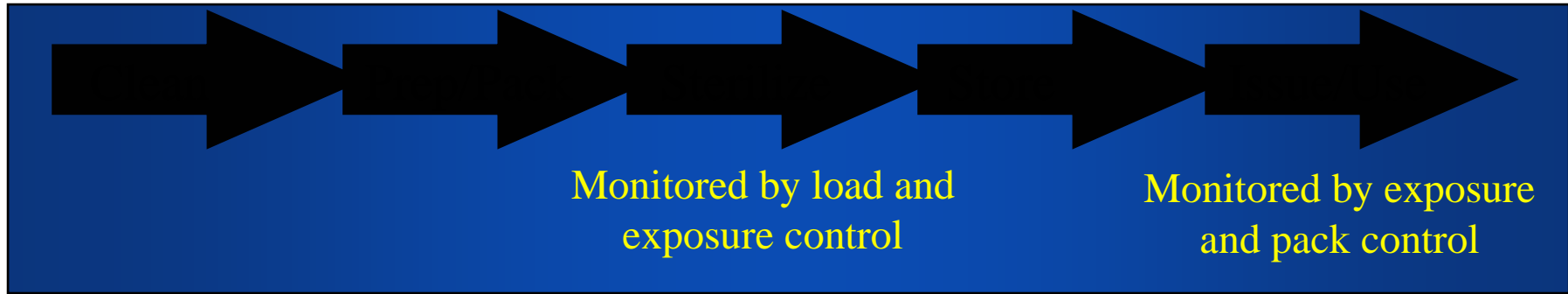
- To come to sterile Medical Device after a sterilization run
 - *Reproducible*
 - *Effective*
 - *Prove*
 - *Documented prove*



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

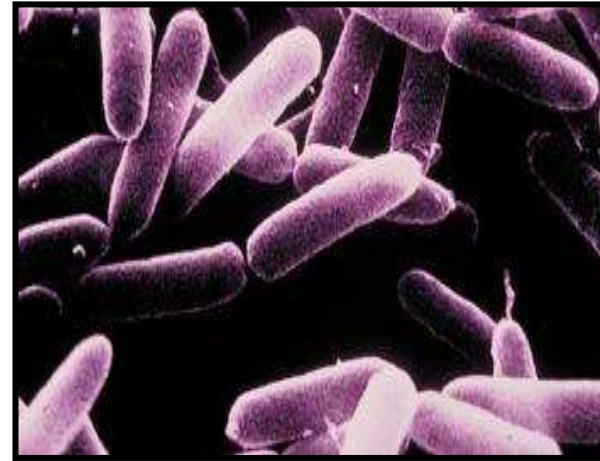


Indicators



- Biological
- Chemical
- Physical

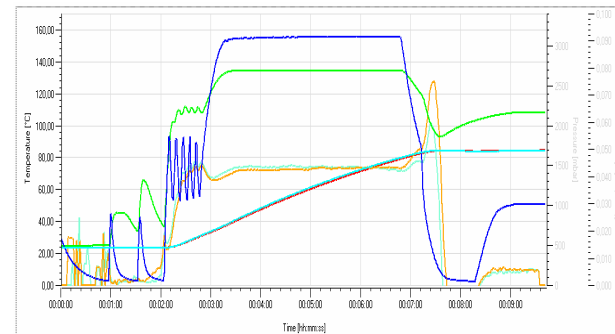
The real stuff



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 ³	0,42 kg/dm ³	0,20 kg/dm ³
Test Pack Size	220 x 300 x 250 mm	220 x 300 x 250 mm	220 x 300 x 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.



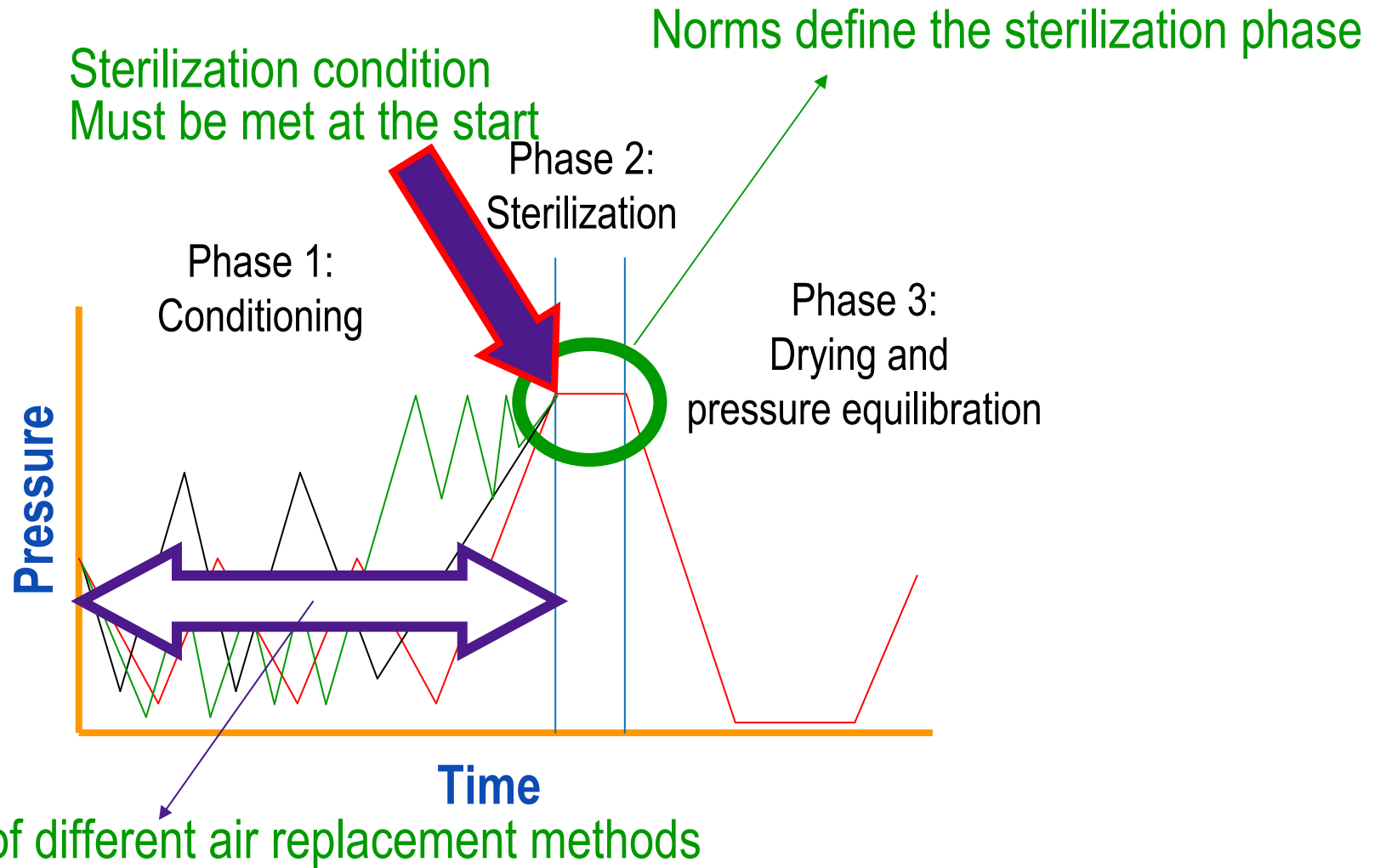
Testing indicators

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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



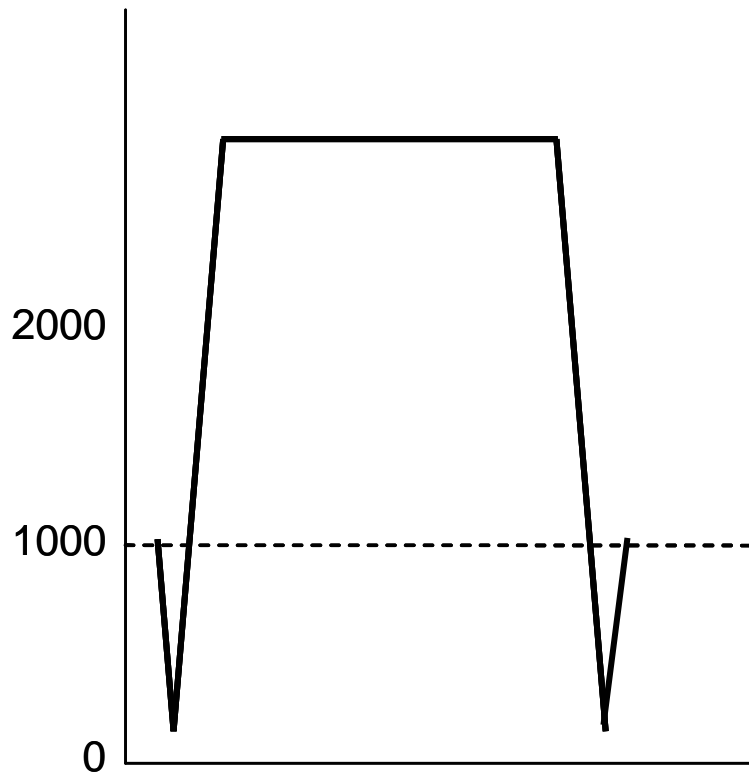
No standards method



Testing Indicators

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- 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

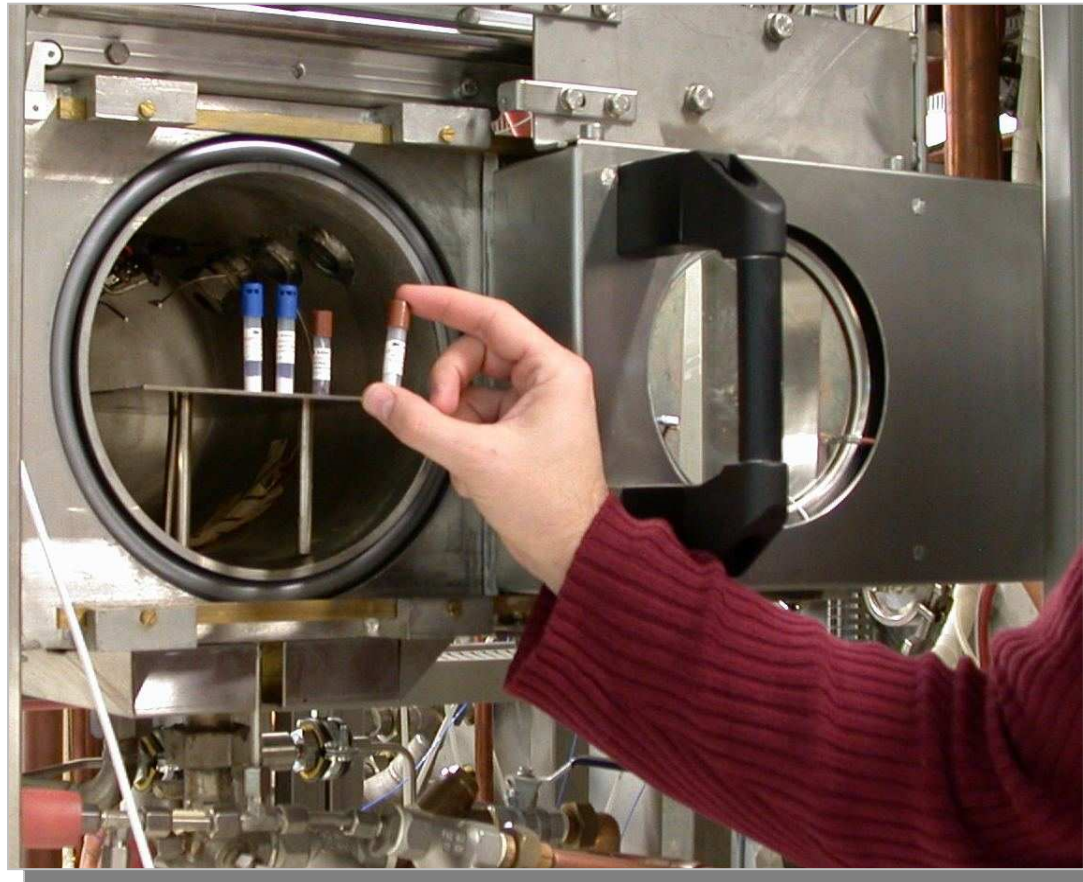


“Square wave” means:

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

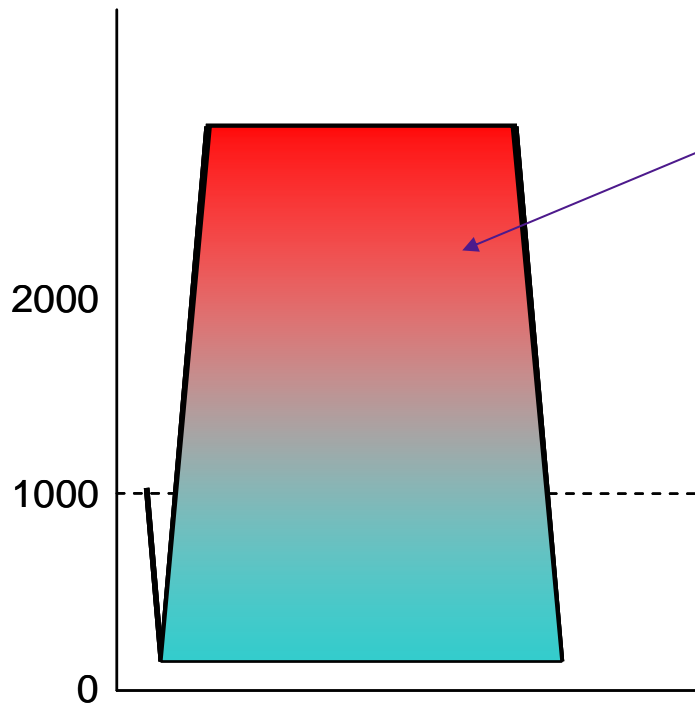
Resistometer

- For testing biological and chemical indicators



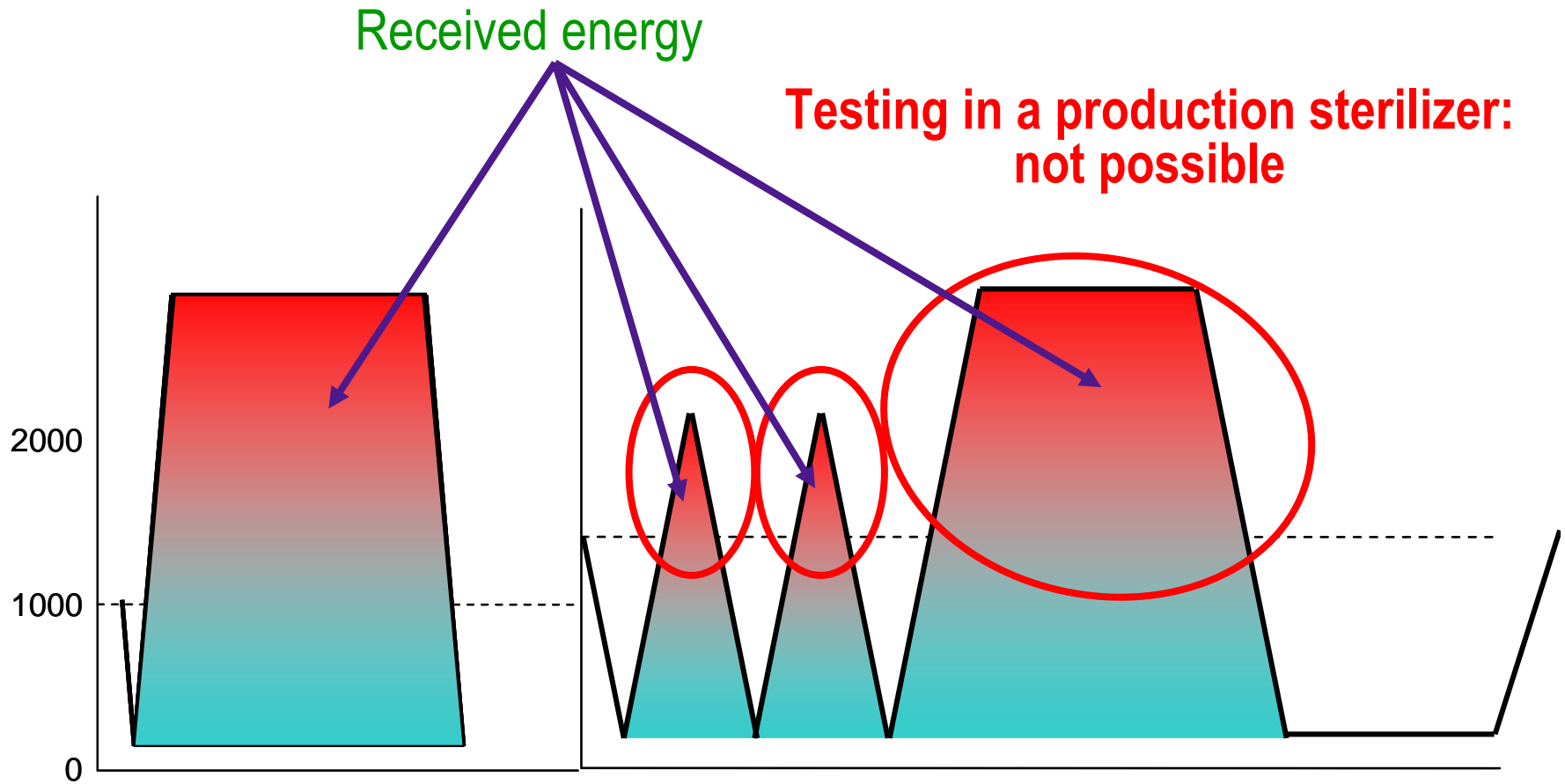
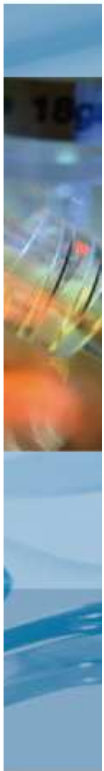
Reaction

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



Surface is a measure for the Energy received by the indicator

Received energy



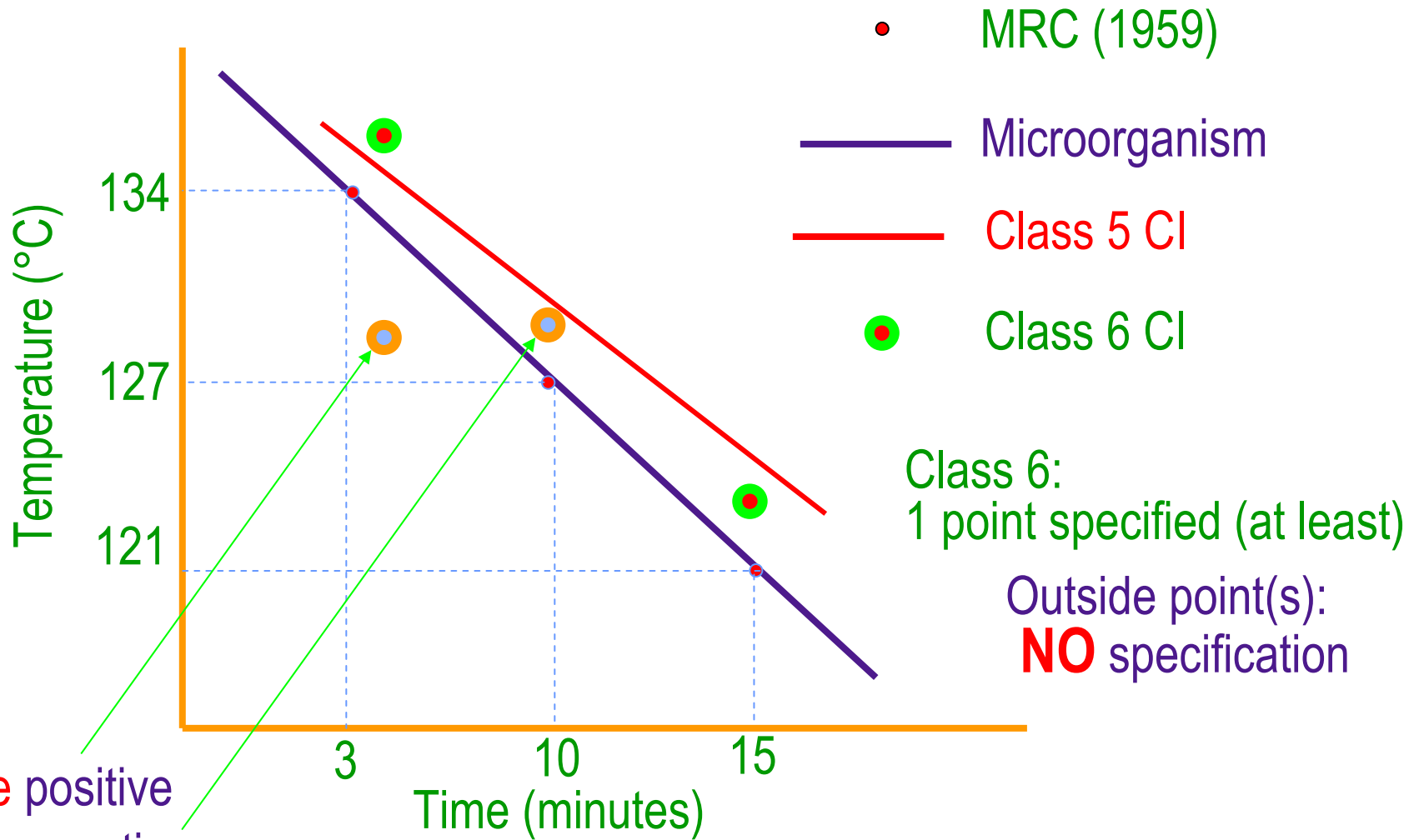
Testing Bowie and Dick test packs

- 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

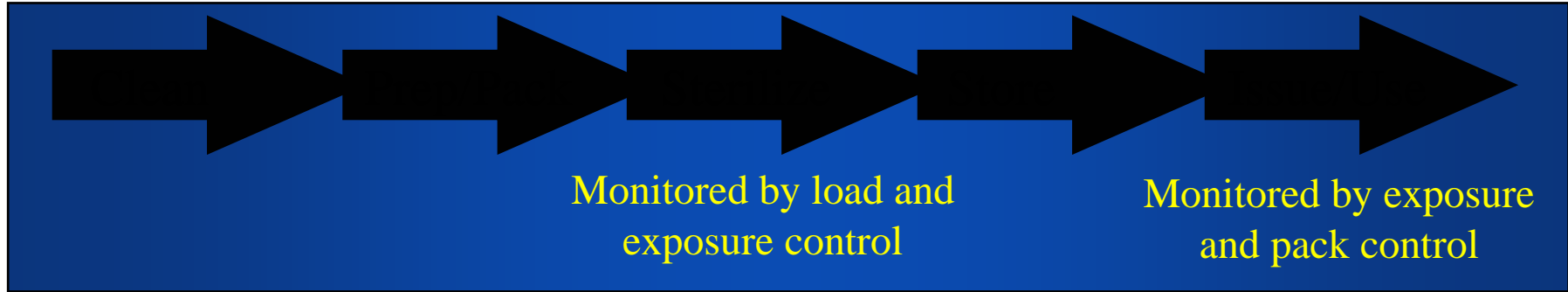


Class 5 and class 6 indicators



False positive
False negative


5 steps of monitoring




Process Monitoring	How Often?	With What?
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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



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

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