Annual EFHSS and NfS Conference 2006

Jack van Asten memorial Lecture

Standards and norms under continuous development

Research leads to clear norms

Ir. Joost P.C.M van Doornmalen
Manager Validation & Monitoring, Bureau Veritas

Jack A.A.M. van Asten

1956 - 2002

Jack

- Motivating and enthusiastic colleague in the field of decontamination
- Broad interests and new ideas
- Innovation
- Norm contribution
- Source for inspiration
- Pragmatic
- Critical
- Thinking in solutions

Contents

- Introduction
- History
- Steam sterilization
- Decontamination
- Conclusion

Brief history sterilization

- Fundamental research about 1850 to 1960

  [Pasteur; Bigolow, 1921; Arrhenius, 1922; Rahn, 1943; Precht, 1955]
- In the period 1958 to 1963

  [MRC, NASA]
- Development of the F-value theory and the L-value theory

  [Asten van J.A.A.M. and Dorpema J.W., 1983]
- New sterilization methods

New sterilization methods

- Most of the sterilization methods applied are more or less known, but improved:
  - High pressure
  - Ultra sound
  - Pulsed light treatment
  - Oscillating magnetic fields

[David Hurrell, DSc-EFHSS conference, London 2005]

- Comply with IS014937

ISO 14937

- Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937: 2000)

- About 50 pages

Examples unclear norms

Cleaning disinfection (ISO15883):

Why do we have over 10 test to prove clean?

Steam sterilization (EN554 - ISO17665)

Why are there differences in criteria for steam sterilizers ?

New sterilizing methods (ISO14937)

Does not every claim made by the manufacturer be proved?

Standards and norms under continuous development

Research leads to clear norms and standards

Steam sterilization

- World wide most applied sterilization method
- Norms (national, international)
- Discrepancies
- Literature and research

Steam sterilization conditions

- Principle mechanism is coagulation: Water and energy is needed

  [Savage, 1937; Rahn, 1945; Precht, 1955; Sykes, 1965; …]

- Experimental data, death rate: natural logaritm

  [Biolow, 1921; Rahn, 1943; Perkins, 1956, …]

Perkins [1955]

Time [min]	Temp [°C]
2	132
8	125
12	121

100% saturated steam

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

Medical Research Council
(1959, MRC)

Perkins		MRC		difference	
Time [min]	Temp [°C]	Time [min]	Temp [°C]	Time [min]	Temp [°C]
2	132	3	134	+1 (50 %)	+2 (1.5 %)
8	125	10	127	+2 (25 %)	+2 (1.6 %)
12	121	15	121	+4 (30%)	+0

Rational MRC: Steam quality

F- value definition

- The *F*- value is the time in minutes required to kill all the spores in suspension when at a temperature of 121 °C or 250 °F.

[Block, 1983]

Often used: $F=F_{ref}10^{(T_{ref}-T)/z}$

F-value

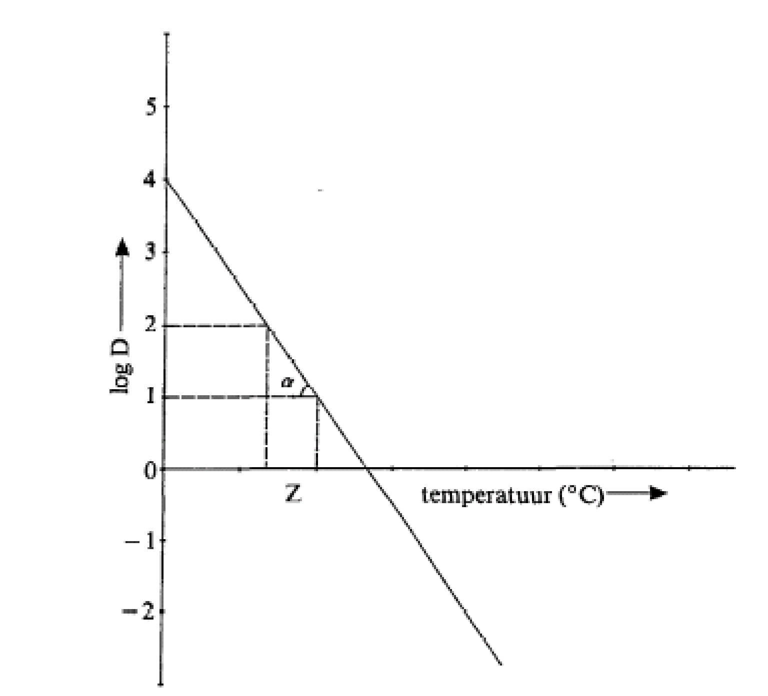
Perkins		MRC		*F*-value	
Time [min]	Temp [°C]	Time [min]	Temp [°C]	Time [min]	Temp [°C]
2	132	3	134	3	134
8	125	10	127	8.9	127
12	121	15	121	17.5	121

Differences

Perkins		MRC		*F*-value	
Time [min]	Temp [°C]	Time [min]	Temp [°C]	Time [min]	Temp [°C]
+1	+ 1	-	0	3	134
+2	+0.9	-	-1.1	8.9	127
0	+5.5	-	+2.5	17.5	121

Time discrepancies MRC - *F*-value

- *D*-value In literature approached as linear logarithm (straight line on log axis).

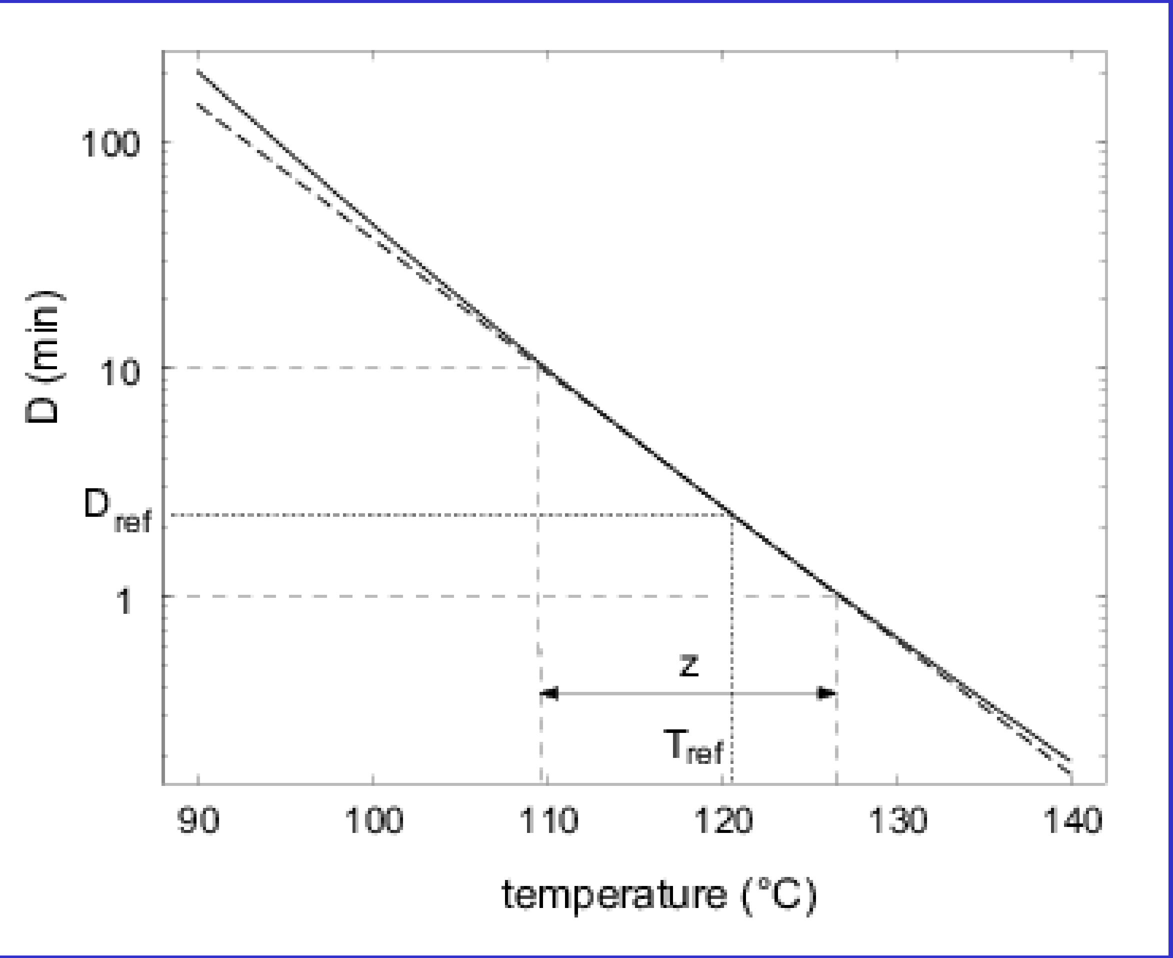


[source NEN steriliseren steriliteit]

Mathematical approach

- More exact calculation show that the z-value is not logarithm dependent on the temperature or the *D*- value.

z value



Suggestion

- Stick to the values of the MRC:
  - At least until new prove is giving
  - Technically it is possible
  - Proven to be safe

MRC	
Temp [°C]	Time [°C]
3	134
10	127
15	121

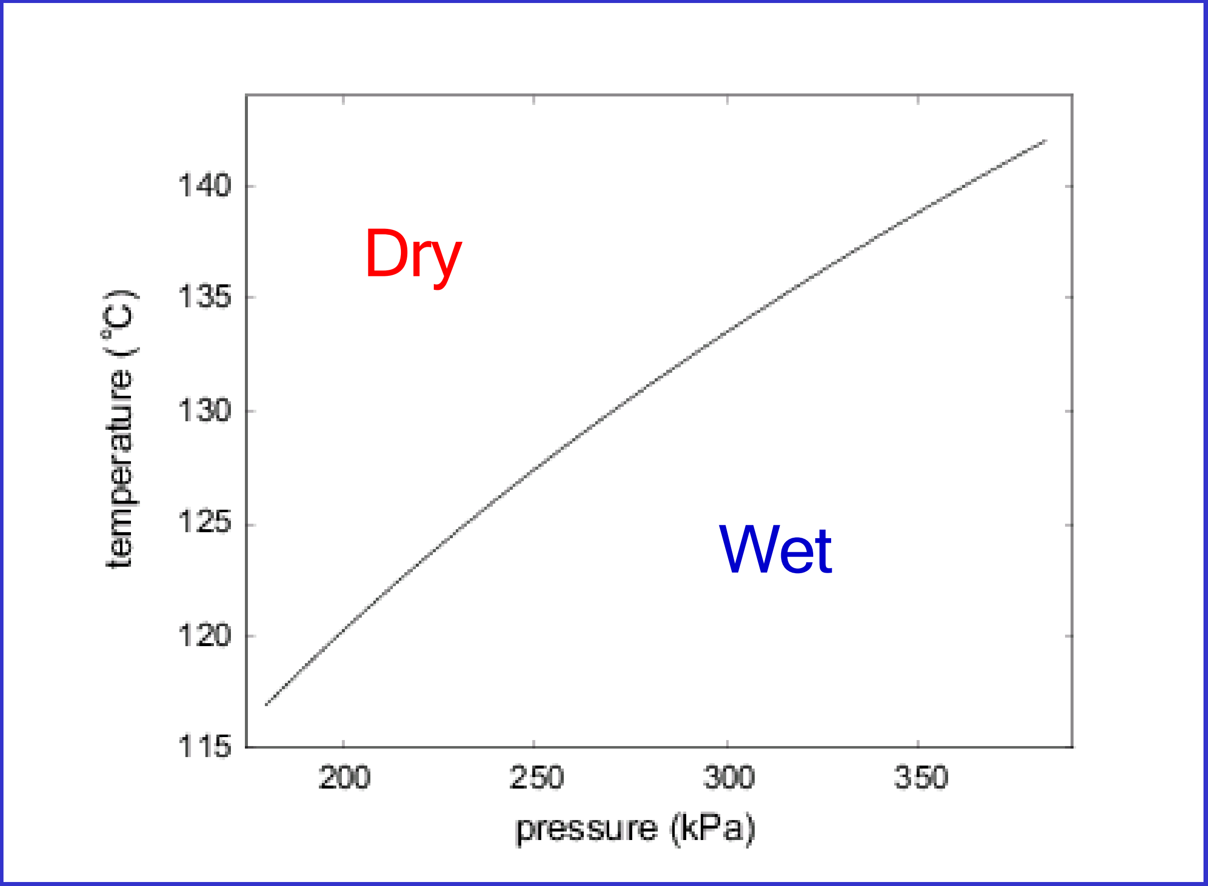
Accuracy

- Available information based on water like liquid sterilization
  - Savage (1937) at 105 °C, maximum 1 °C overheated
  - MRC definition
- Steam sterilisation 100% saturated steam is necessary for ‘Perkins’ times

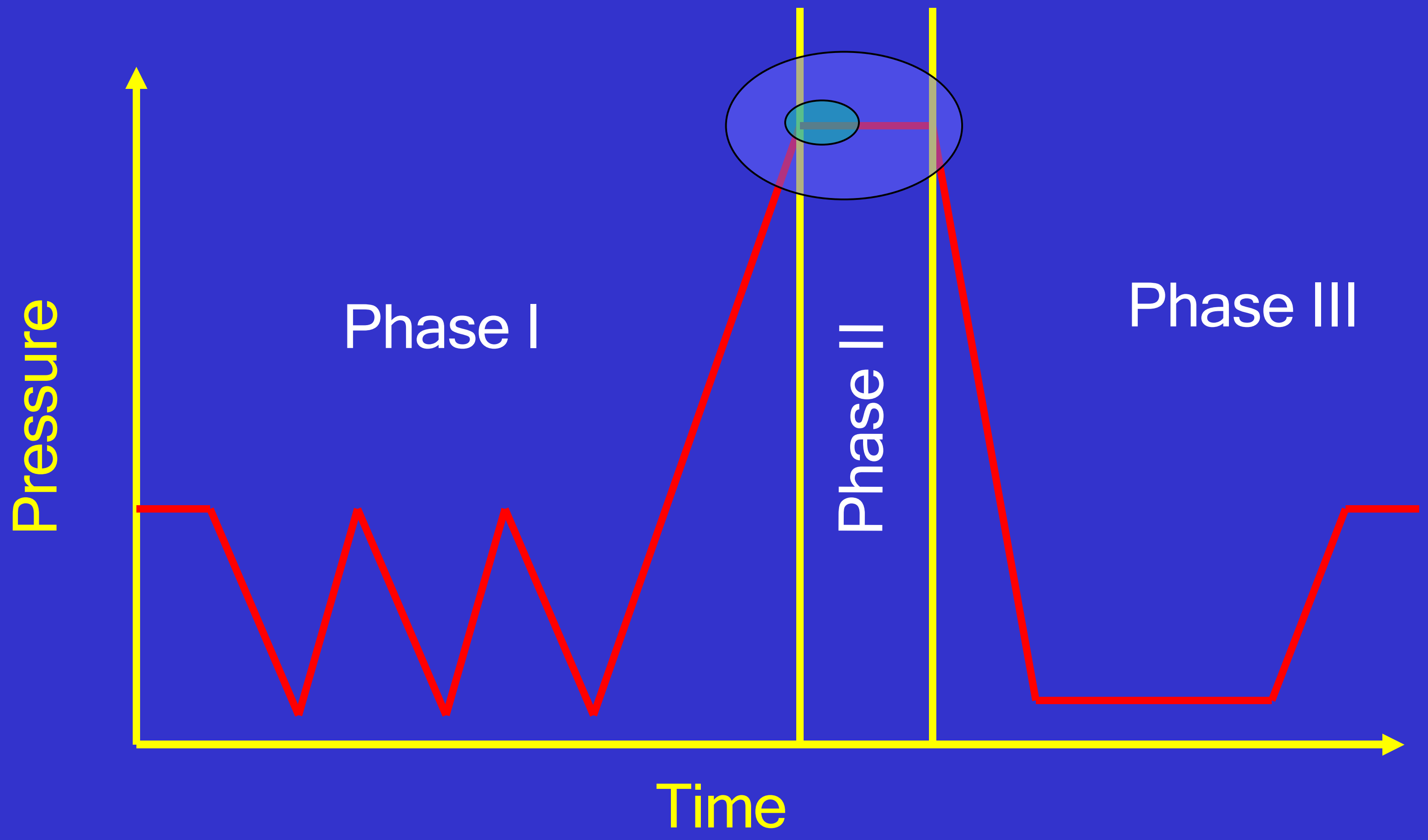
Saturated steam

- Saturation not direct measured
  - Accuracy
  - Responds time sensor
  - (Costs)
- p-T relation, calculation of the theoretical temperature: $T_{th} = f\ (p)$
- Relation only for 100 % saturated steam

p-T relation in graph



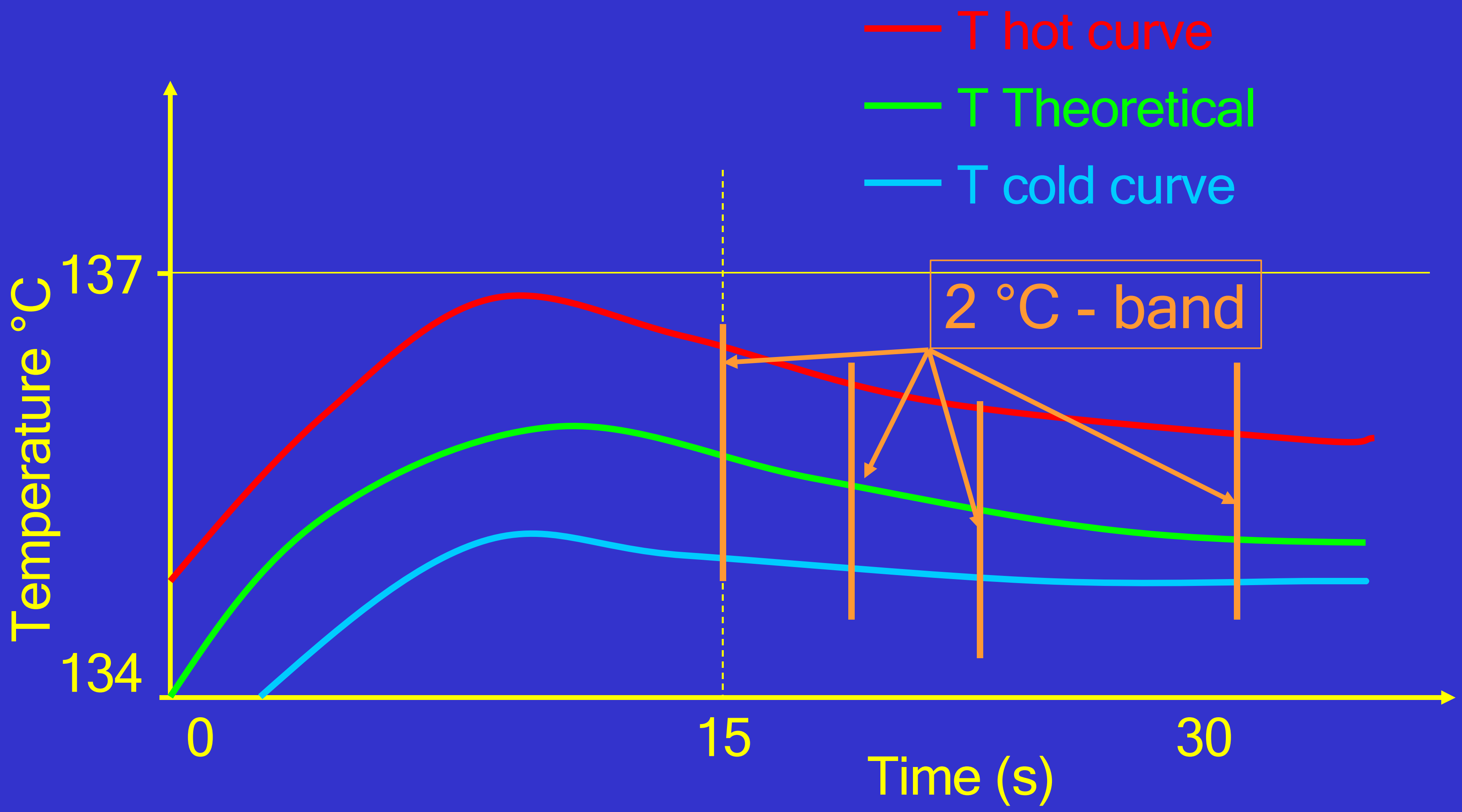
Steam sterilization process



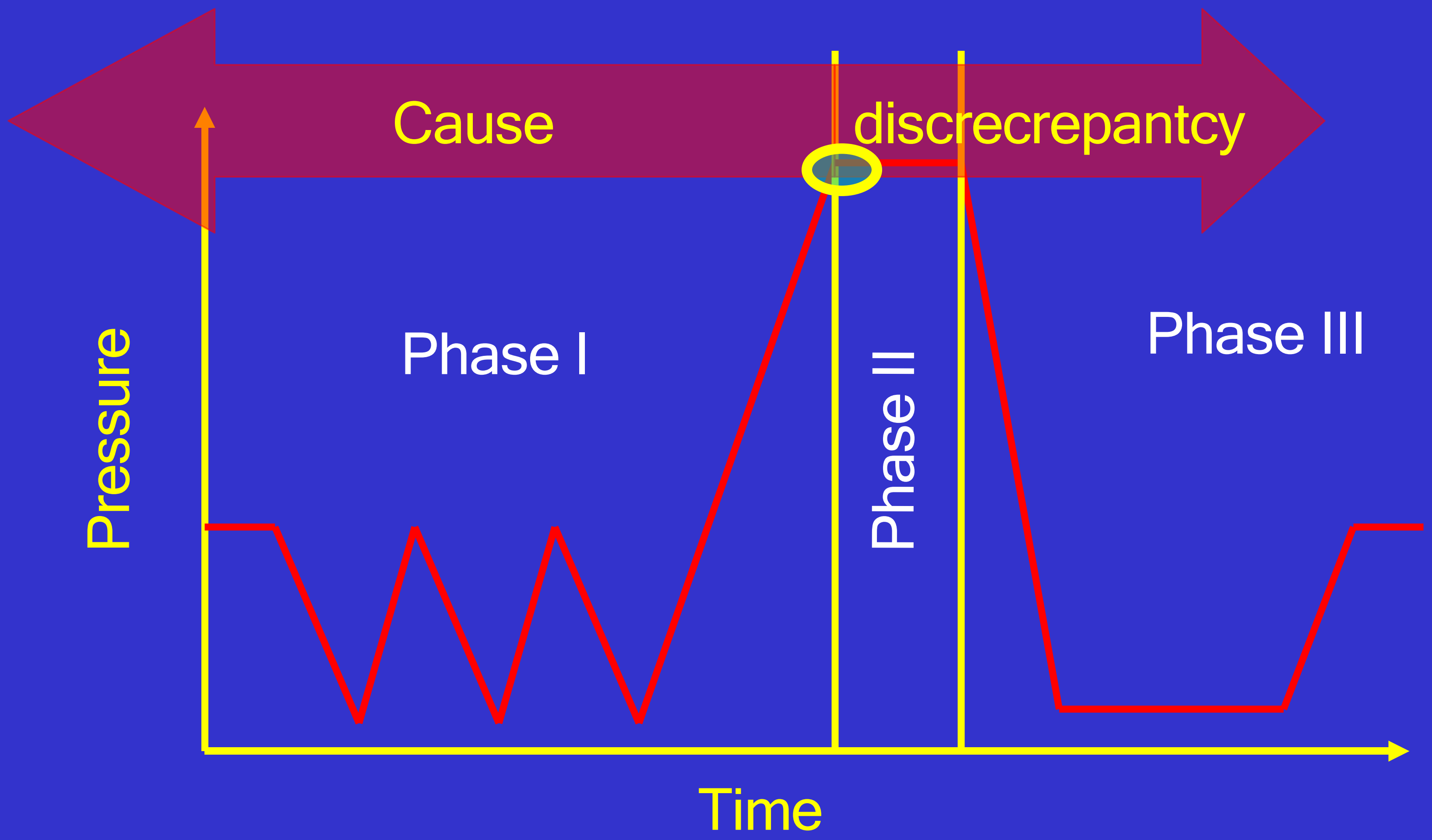
Temperature bands

- 3 °C - band
  - Protection
- 2 °C - band
  - Overheated steam
    - 100% saturated steam: 134 °C for 3 min
    - Dry heat: 134 °C over 12 hours

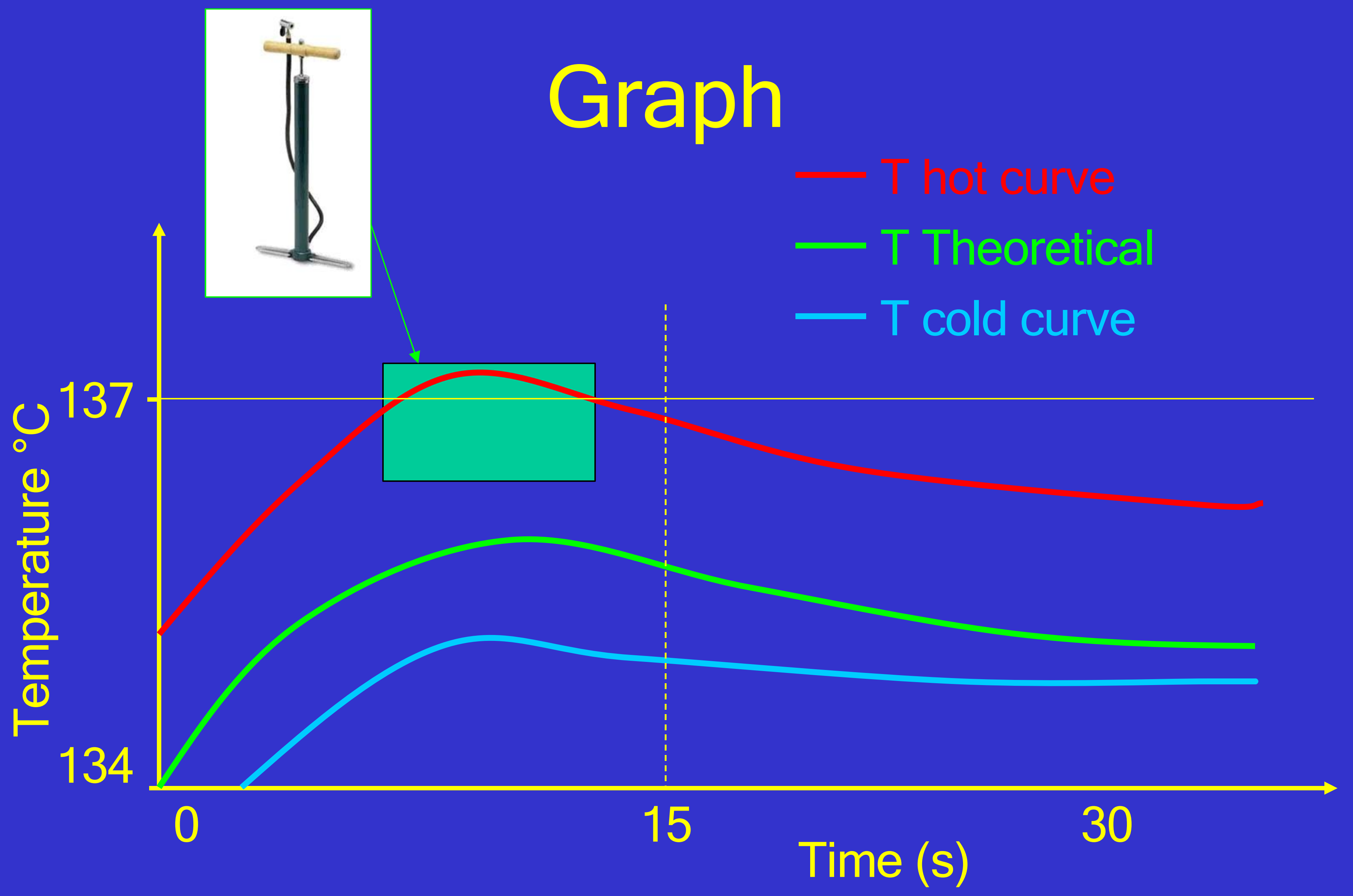
Graph


T hot curve
T Theoretical
T cold curve
137
134
Temperature °C
2 °C - band
0
15
30
Time (s)

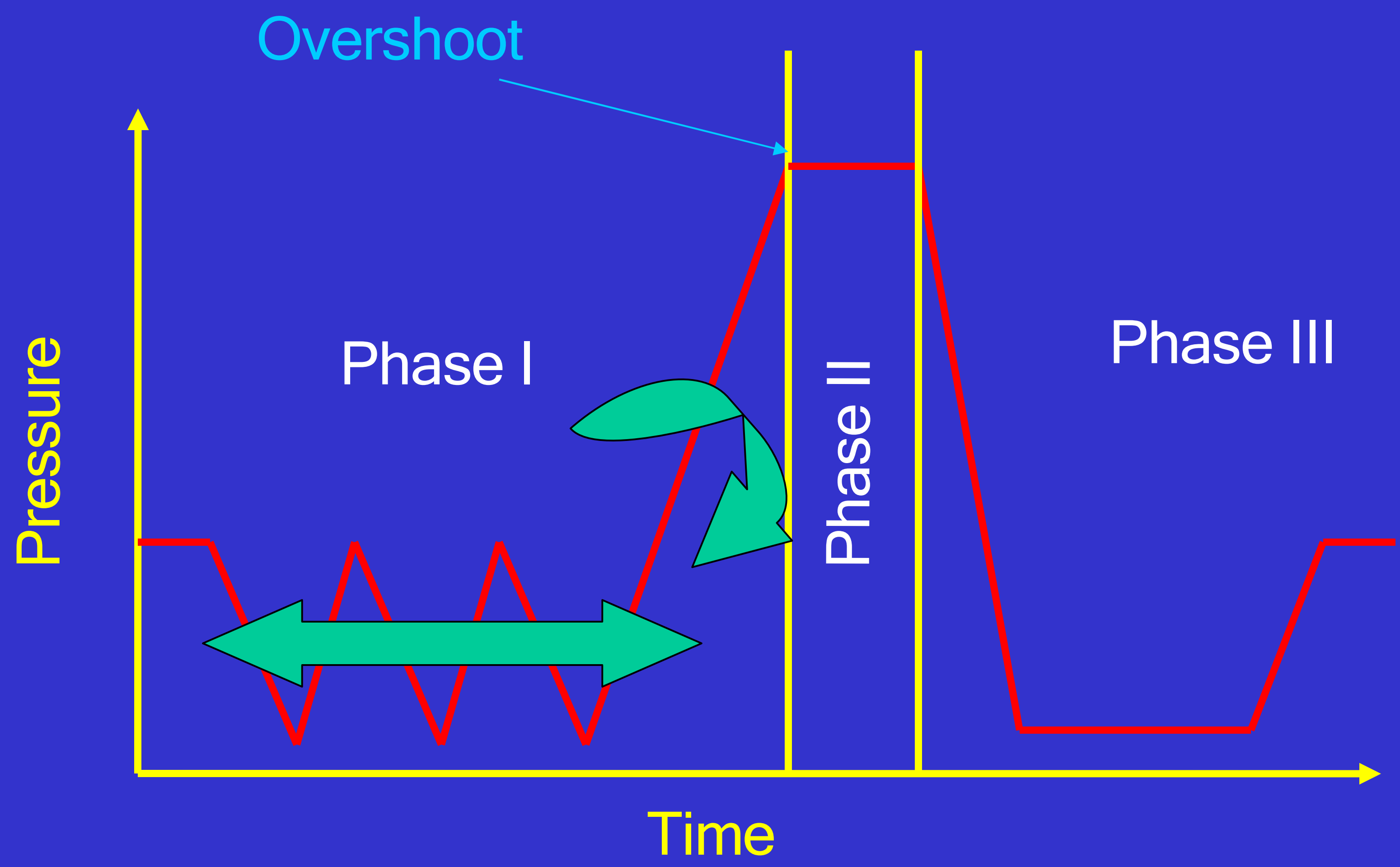
Discrepanties to norms



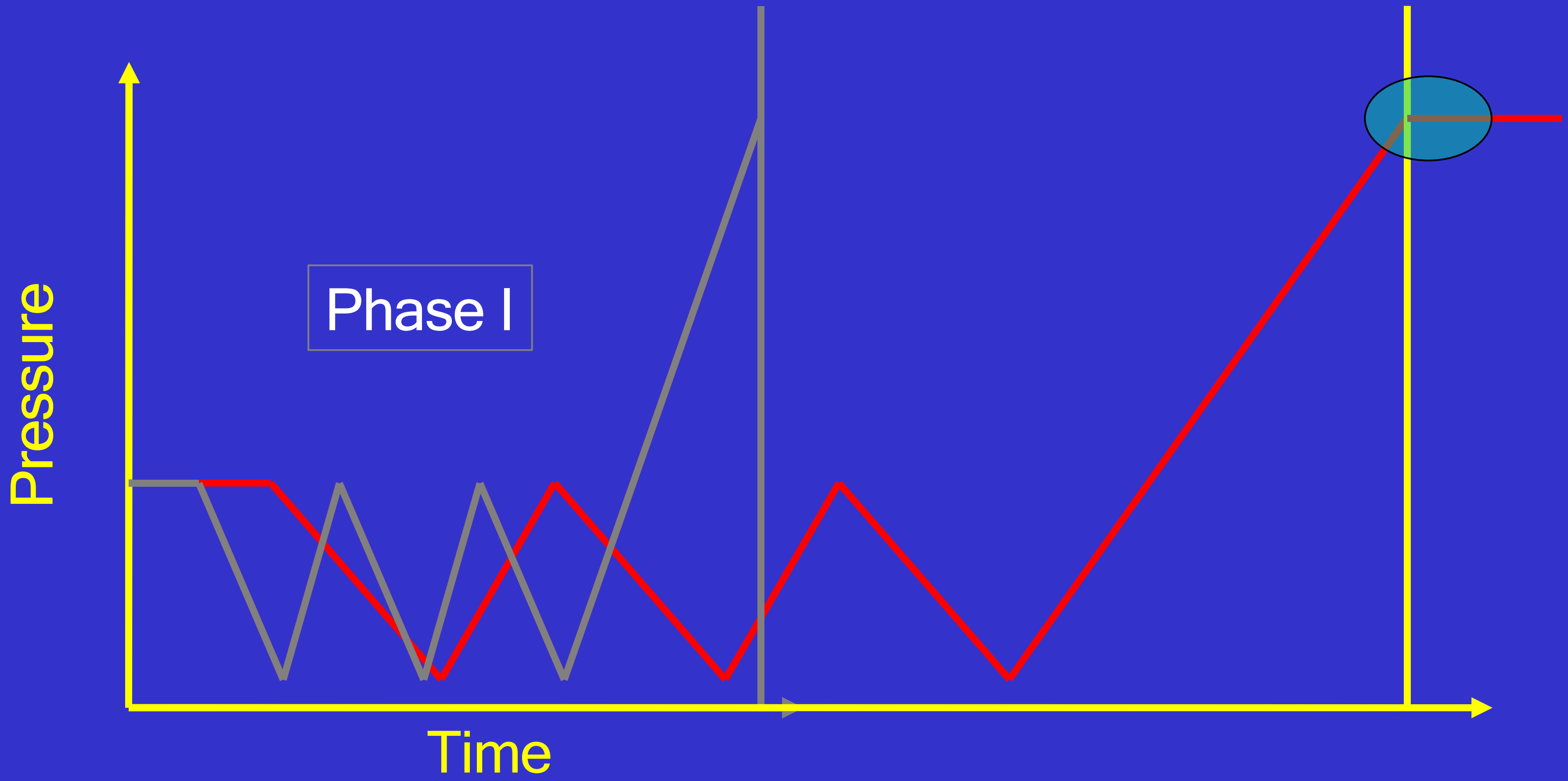
Graph


T hot curve
T Theoretical
T cold curve
137
134
Temperature °C
0
15
30
Time (s)

Possible solution



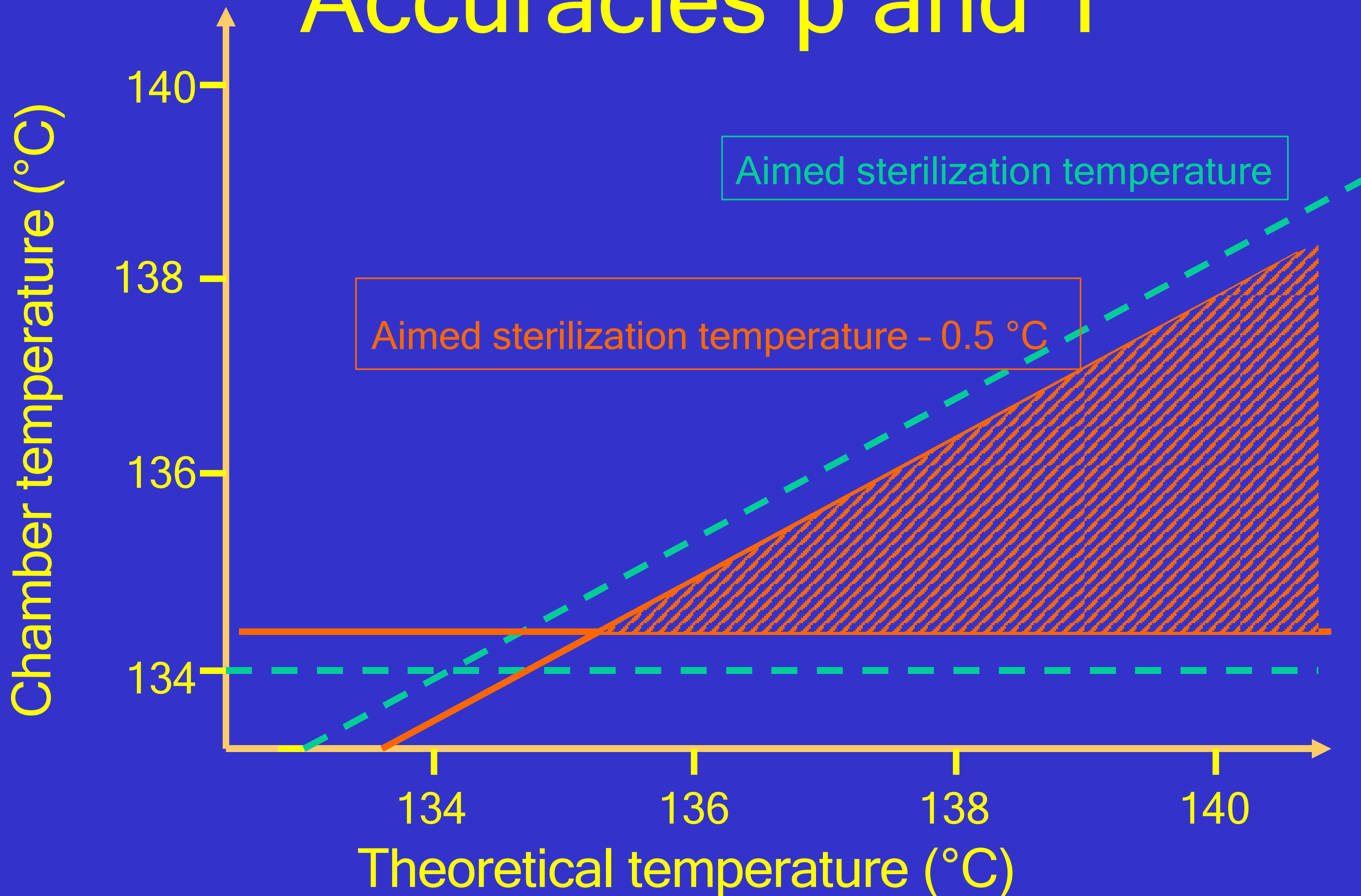
Possible solution



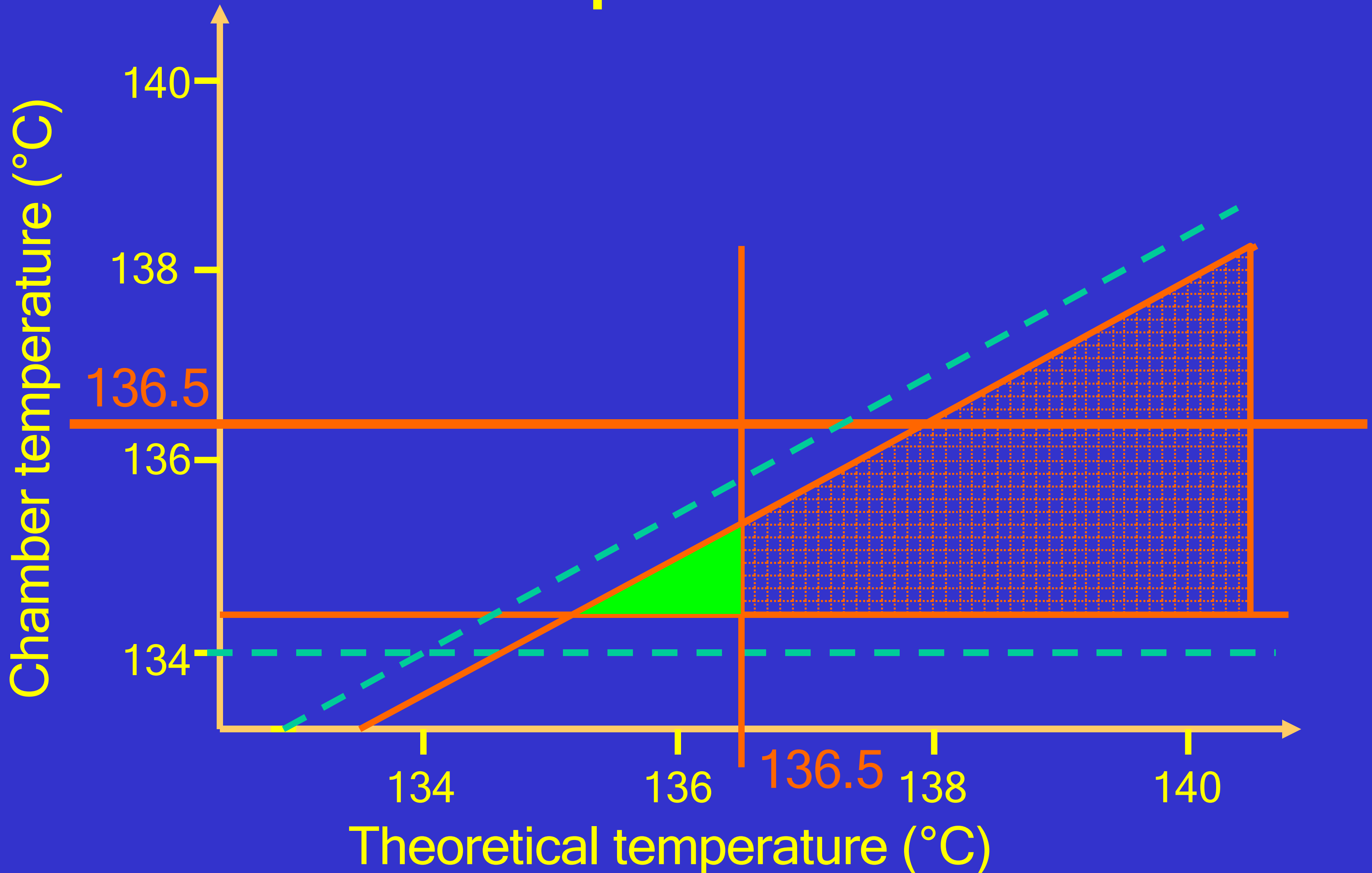
Contradiction

- Duration steam sterilizing process
- Process time versus on production
  - Temperature overshoot
  - Steam penetration of narrow lumen

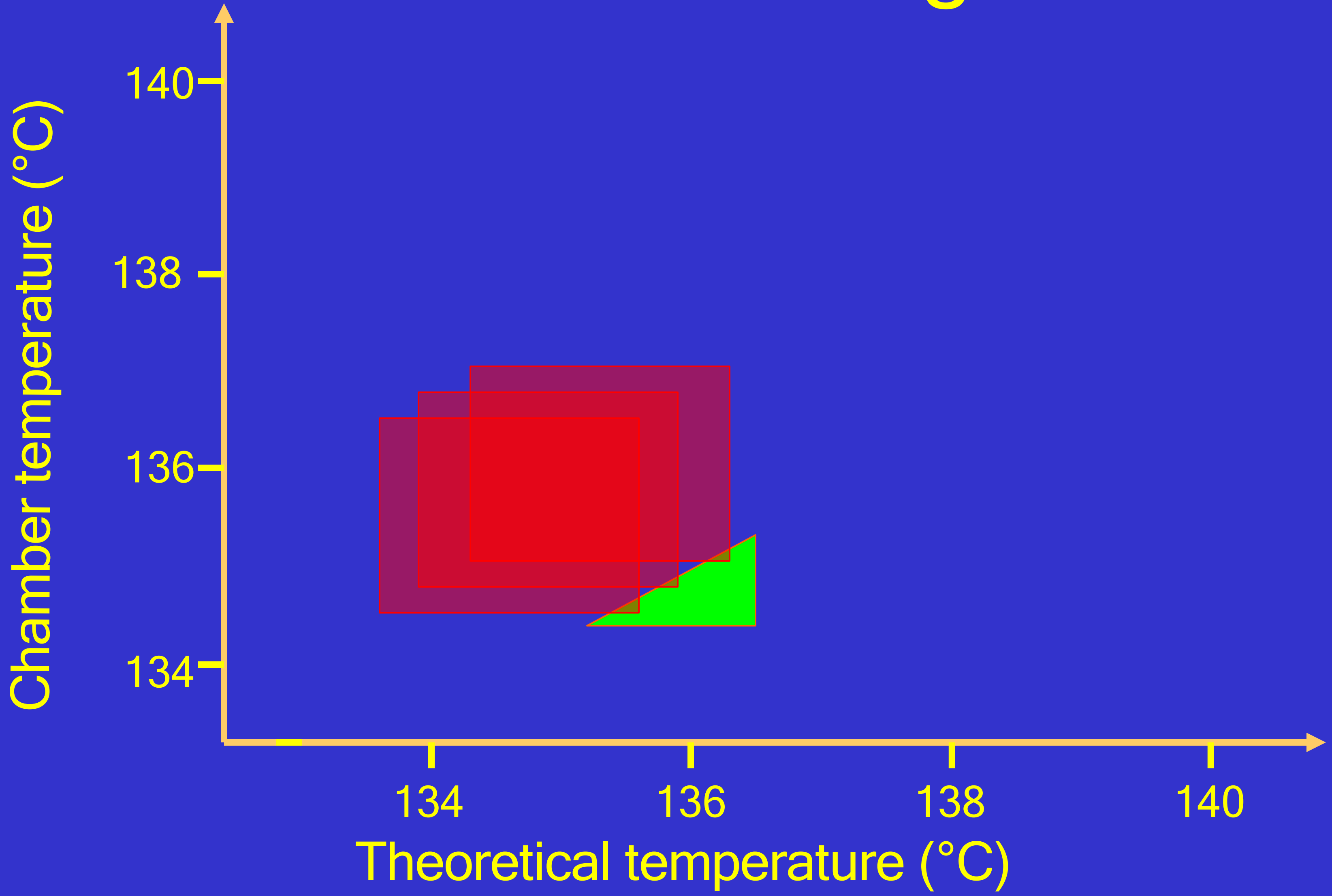
Accuracies p and T



Temperatures



Overheated / NC gasses



Result specification

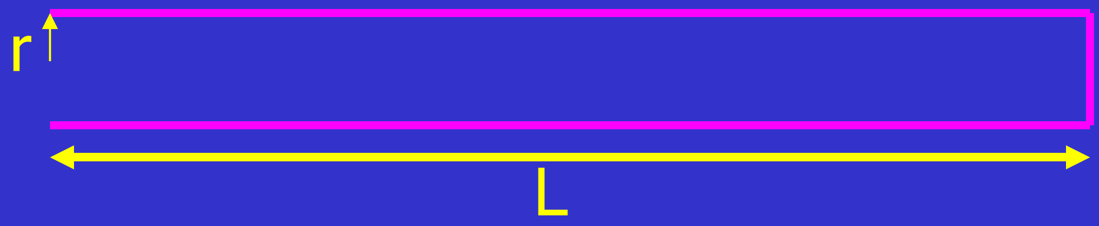
- Research show that p and T criteria are realistic

[IGZ, 1996 and 2000: van Doornmalen Dankert, 2005]

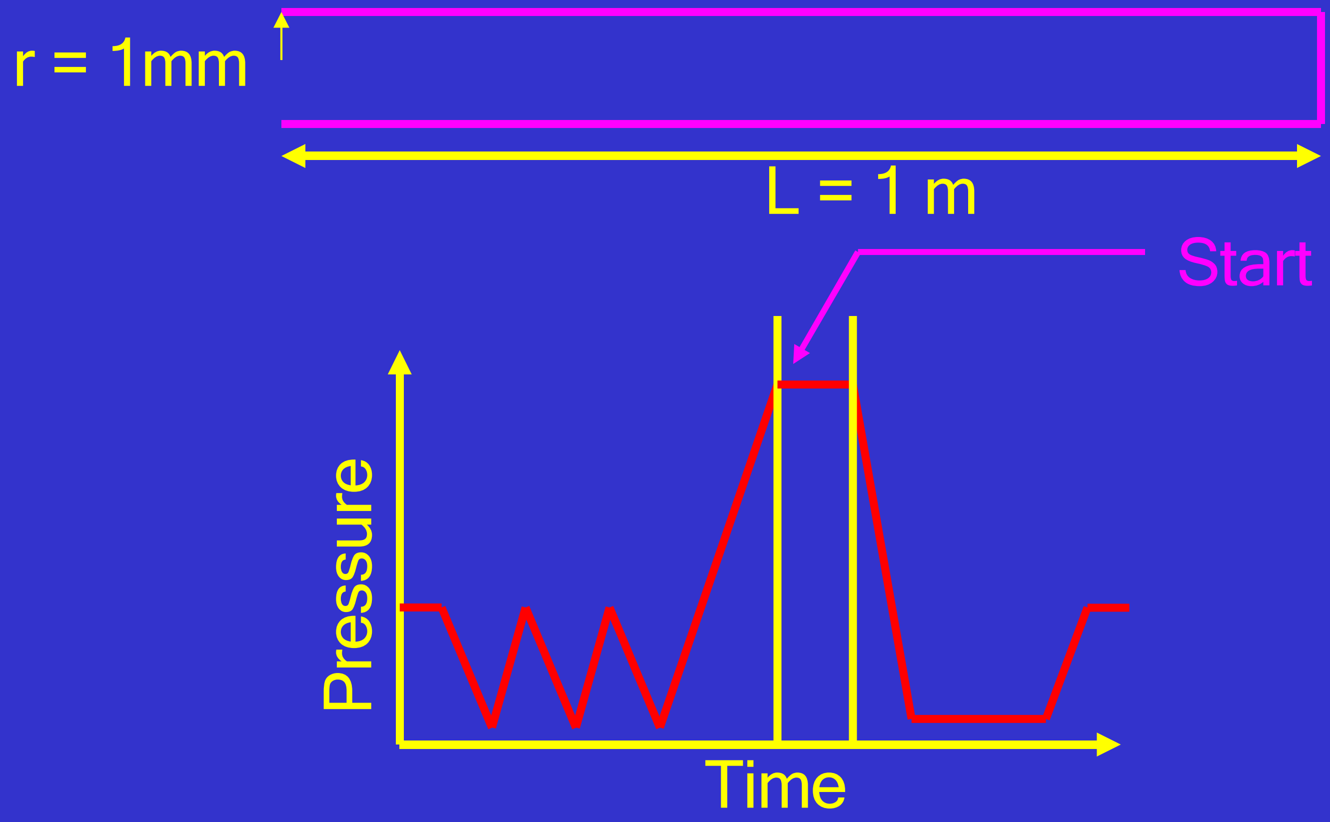
- Narrow lumen

Narrow lumen, worst case

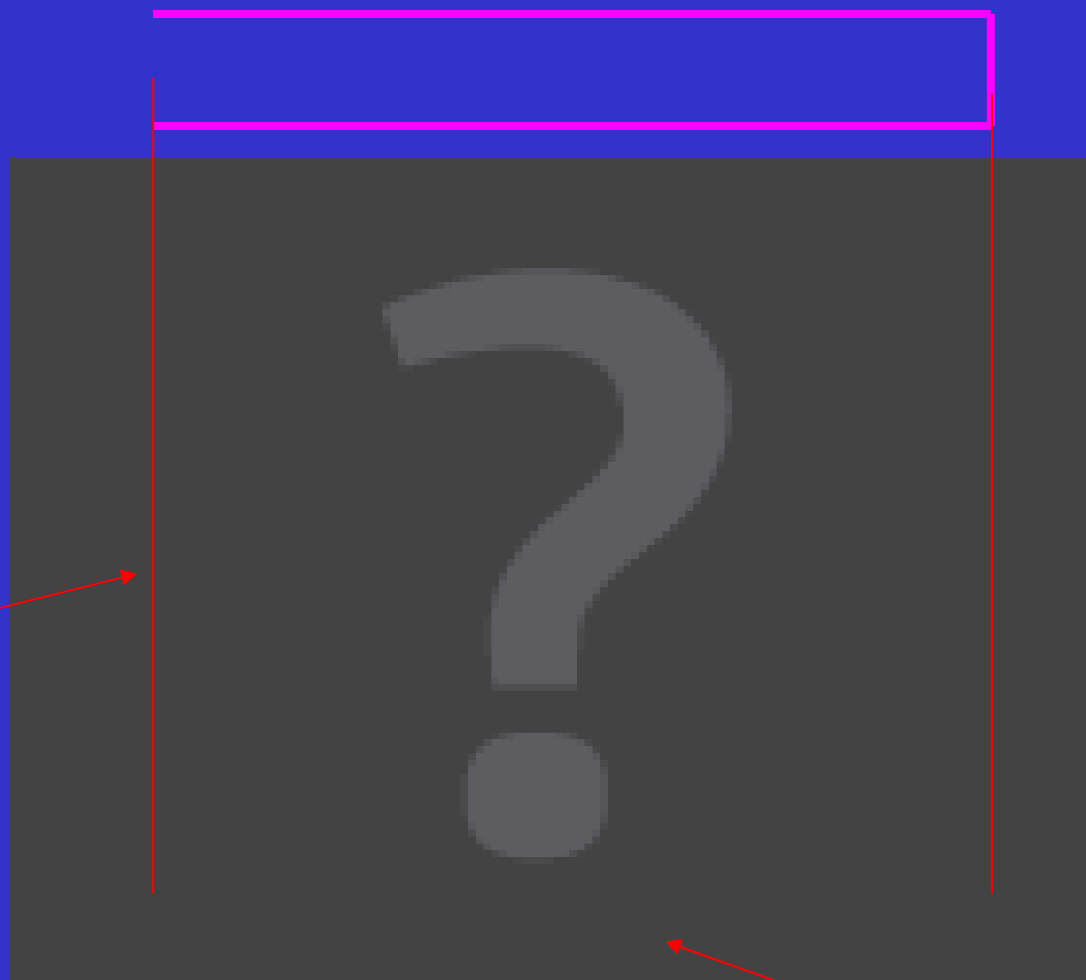
- First approach:
  - Infinitely thin wall
  - No condensation
- At start 100 % saturated steam at L(0)
- Calculation gas composition c(x)



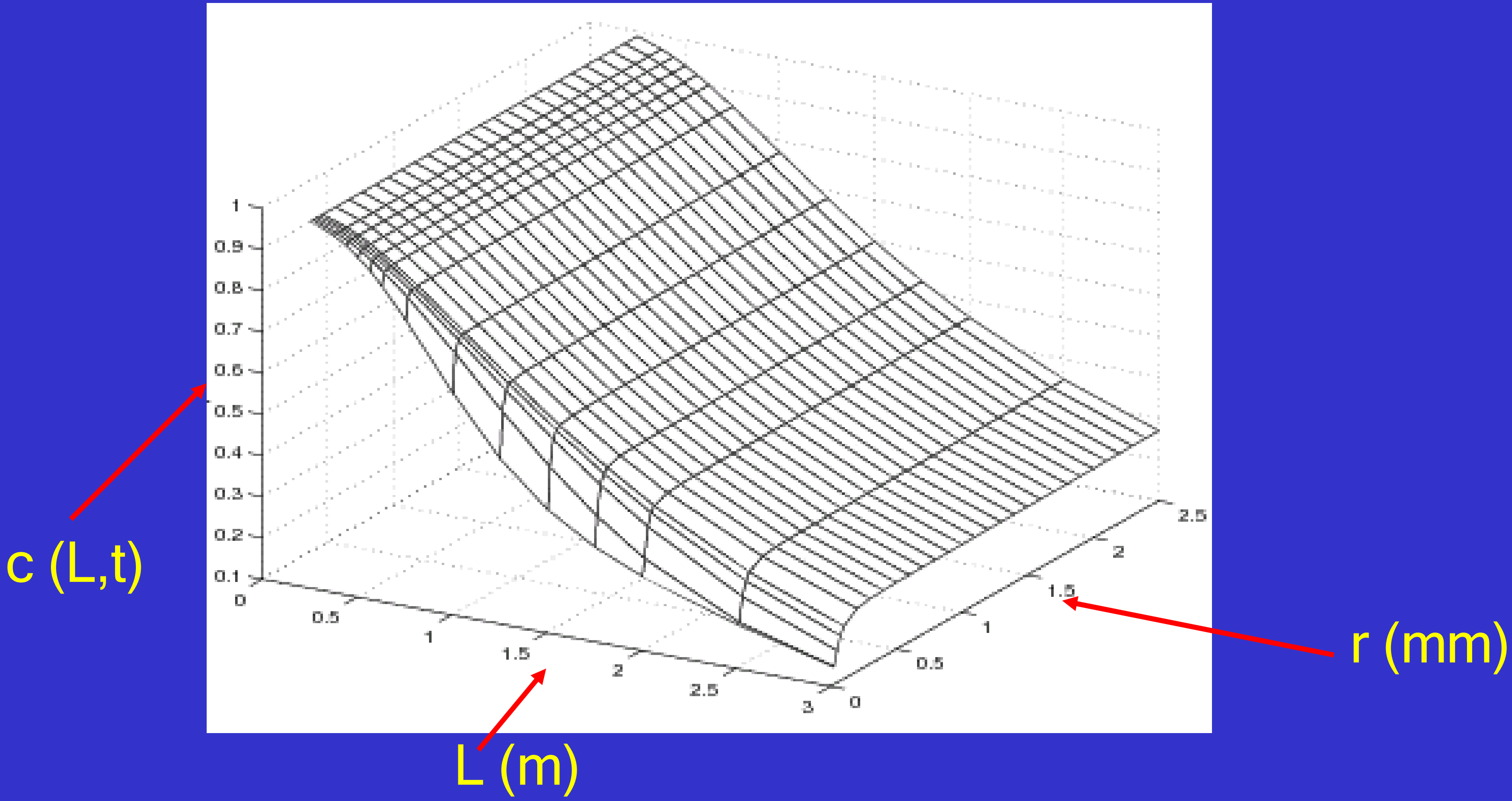
No condensation



Animation (dry)



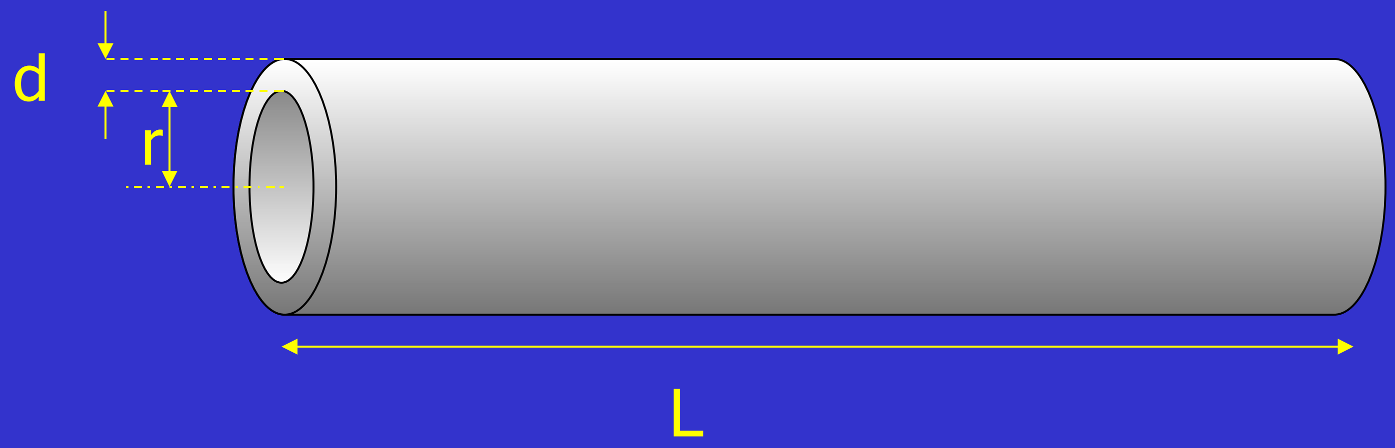
Variations in L and r



Lumen

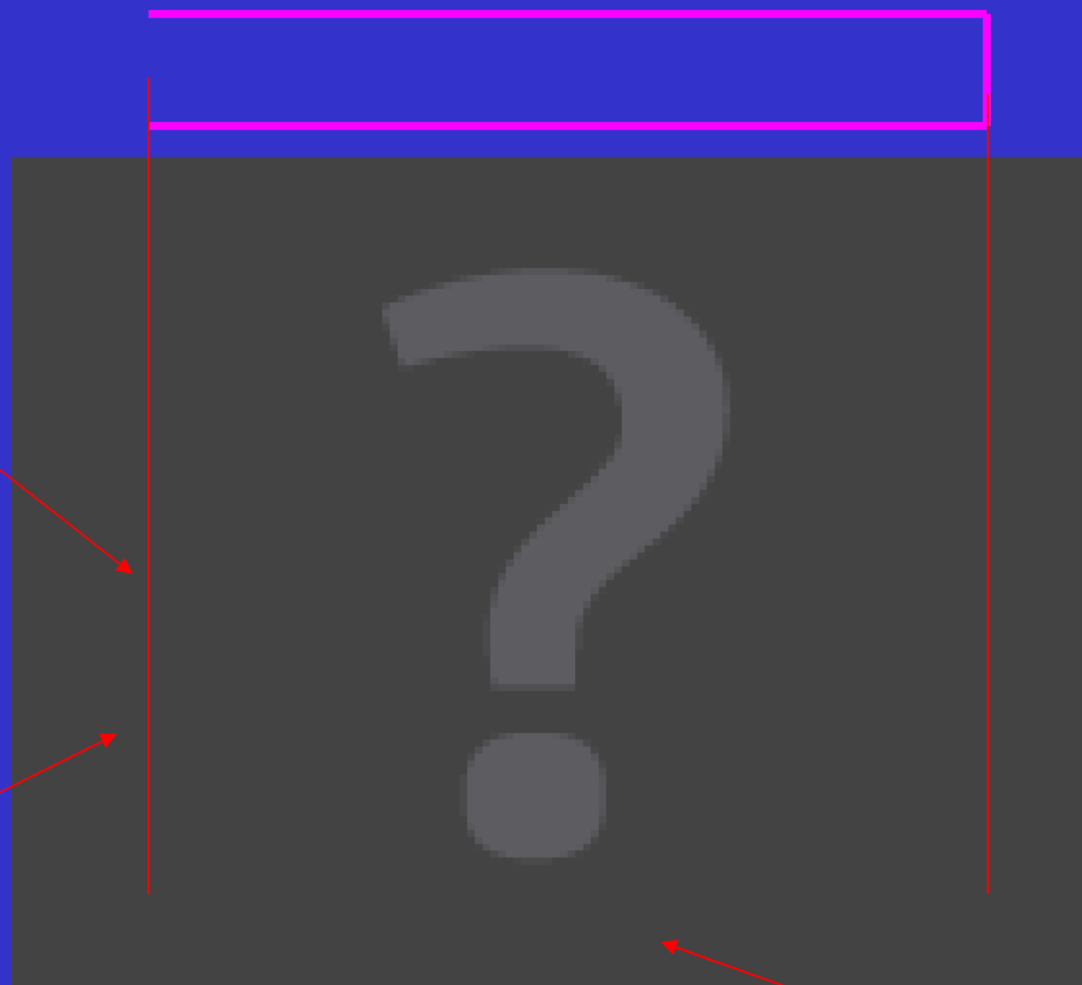
- So far, no condensation
- What about condensation
- System more complex

Tube configuration



- Configuration d = 1 mm, r = 1 mm, L = 1 m
- tube material:
  teflon (ρ = 2.2 103 kg/m3, c = 10 10^2 J/kg^{-1} K^{-1})
- Heat transfer
- Mass transfer
- Condensation form (film, droplets)

First approach with condensation



Comparison

Although, theory not complete

- Because of:
  - Heat transfer model
  - Mass transfer model
  - Condensation form
  - Configuration of device
  - Experimental data not available
  - But general applicable
  - Further research is necessary

Criteria for steam sterilization of lumen

- With 100 % saturated at the entrance of the lumen
- Criteria for steam sterilisation appear not to be too strict for strict

Weakest link

- Without cleaning no disinfection no sterilization

Evaluation of disinfection and sterilization of reusable angioscopes with the duck hepatitis B model

X. Chaufour, MD; K. Vickery, PhD; Sydney, Australia; J Vasc Surg 1999; 30: 277-282.

Research plan

Anglio scope

Contaminate

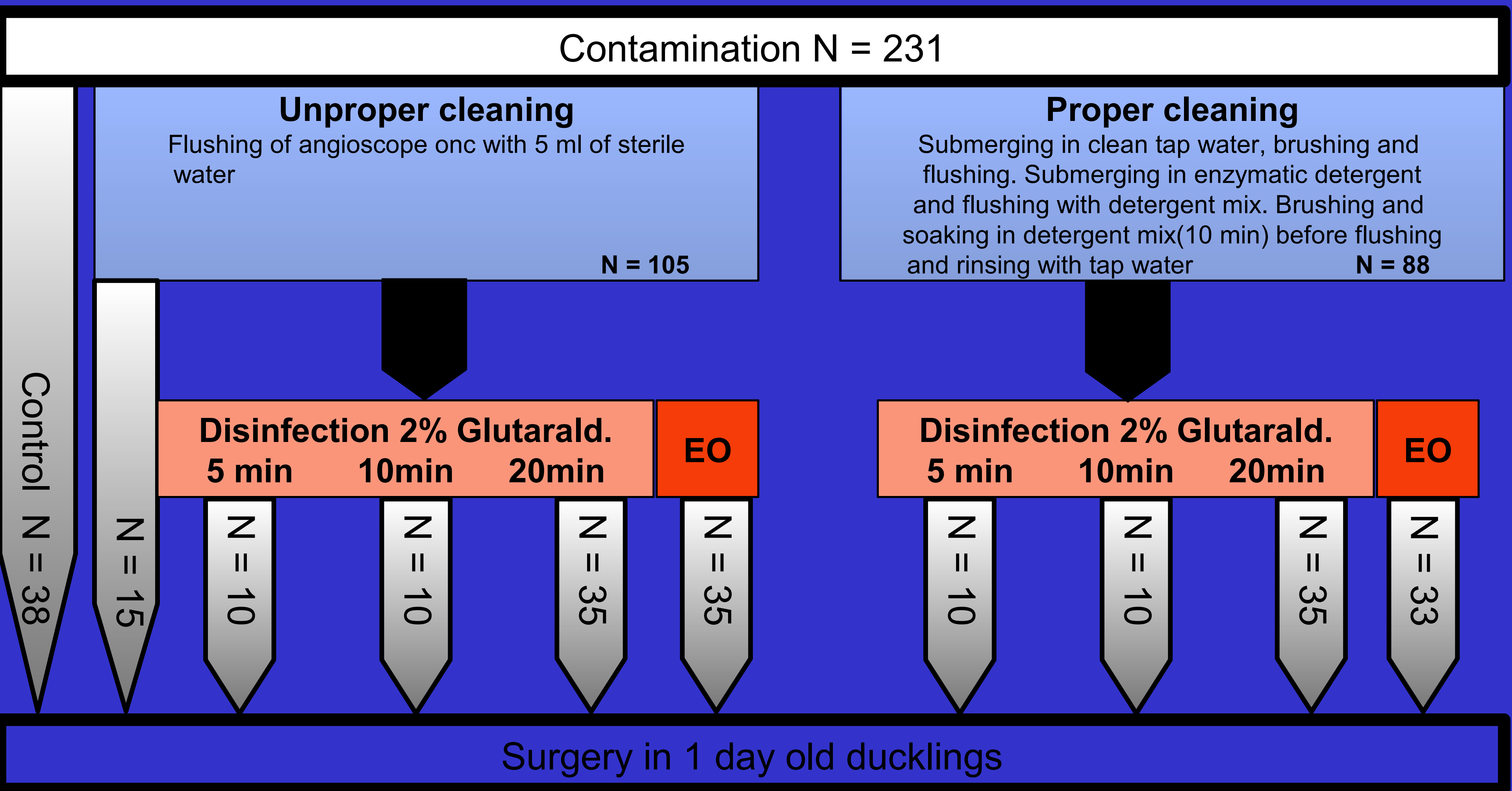
Cut into pieces

Process pieces in different way

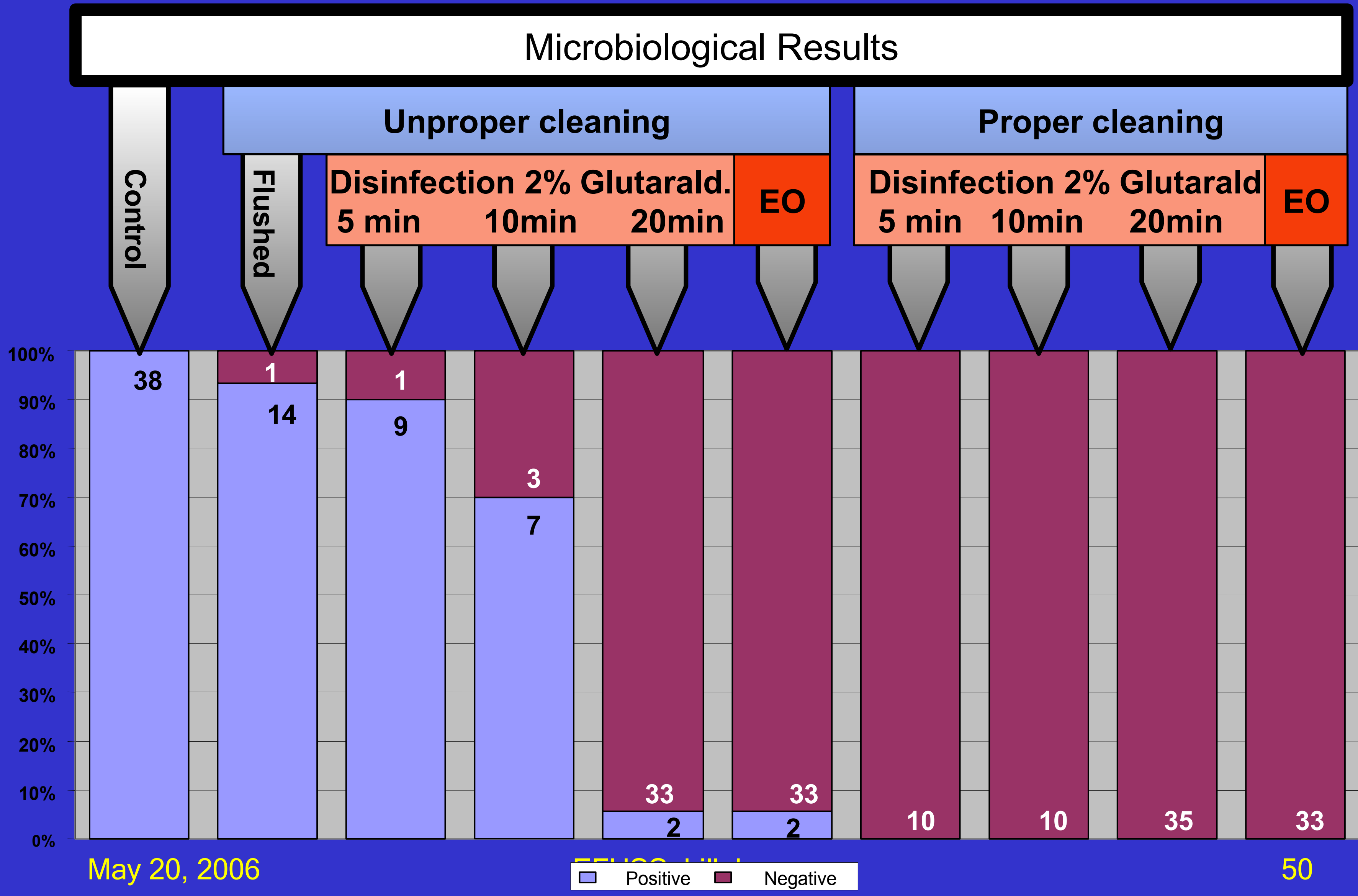
Use (/ contaminate) 231 duck

Results

Methods of decontamination



Result



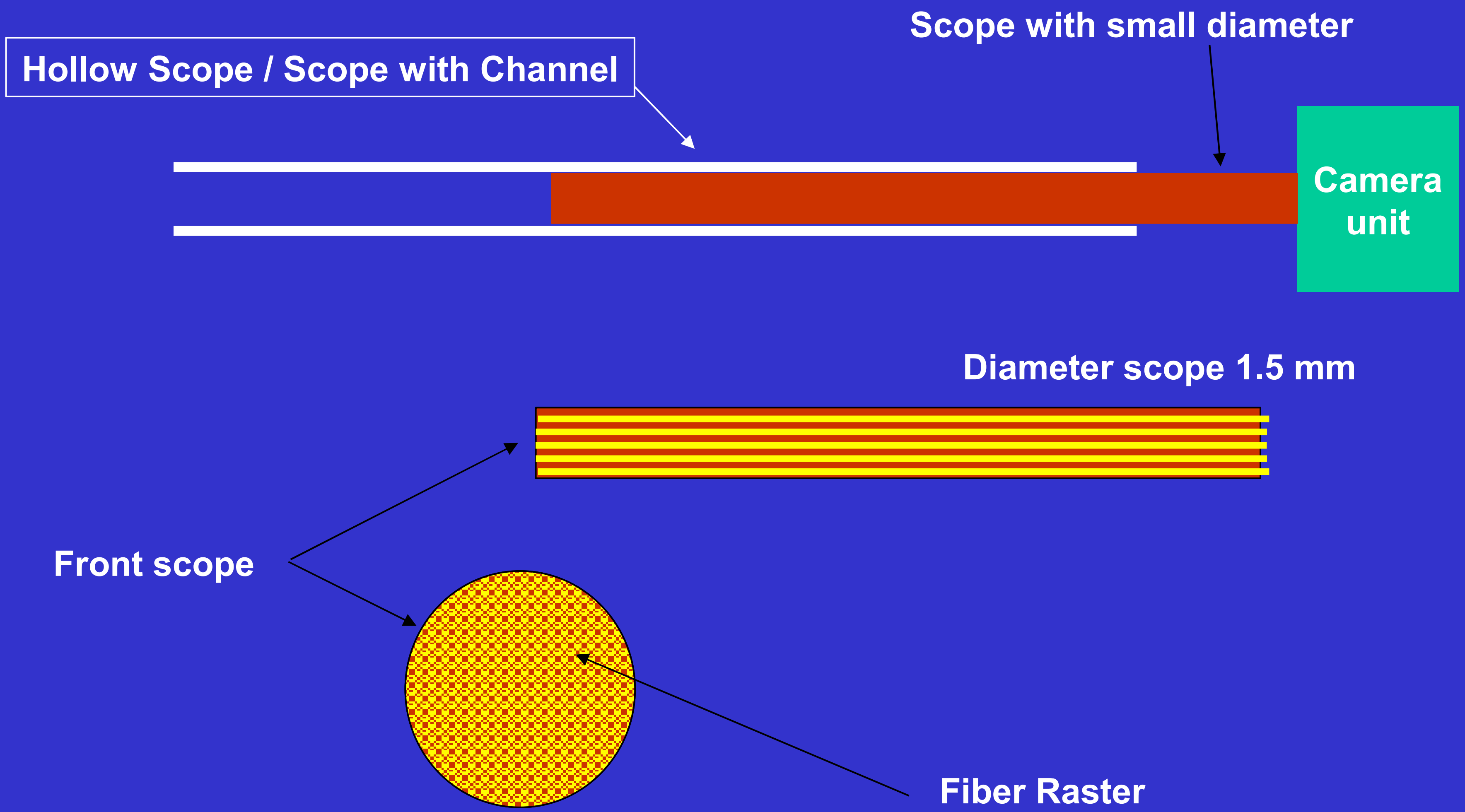
Microbiological Results
Control
Flushed
Unproper cleaning
Disinfection 2% Glutarald.
5 min 10min 20min
EO
Proper cleaning
Disinfection 2% Glutarald
5 min 10min 20min
EO
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
38
1
14
1
9
3
7
33
2
33
2
10
10
35
33
Positive
Negative

Cleaning / disinfection

- Conclusion (Chaufour et al.)
  Cleaning/disinfection before sterilisation is necessary

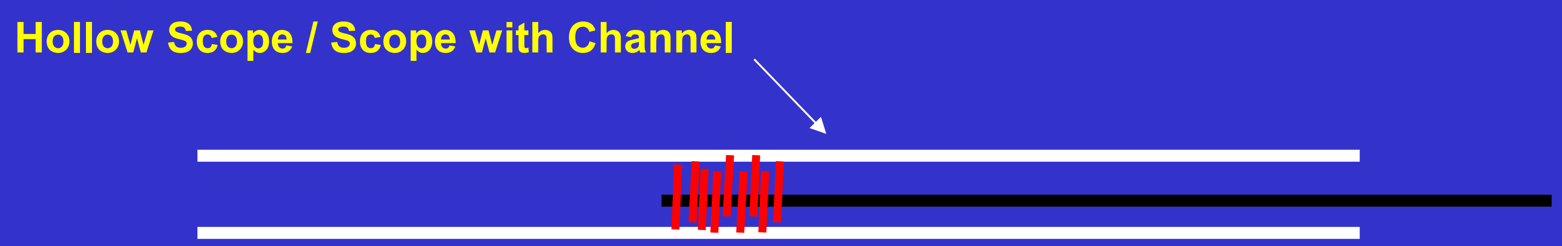
- Cleaning/disinfection challenges
  - Scopes

Example scopes



Dirty scope

Cleaning a scope



Inside the scope

Summarized scopes

- Scopes can be dirty
- Definitions for cleaning and disinfection should be defined (perhaps depending on use)
- Cleaning method could be a point of attention

In general

- (Steam) sterilization and cleaning/disinfection procedures and processes need
  - (more) scientific prove
  - research (to optimise processes)

Challenges

- Not proven methods may lead to a false sense of safety
- Education
- Scientific prove, ends discussions/interpretations
- Norms and standards should be scientifically based
- *Commercial interest*

Conclusion

Due to ongoing science, norms and standards will, and should be changing continuously

Annual EFHSS and NfS Conference 2006

Jack van Asten Memorial Lecture

Standards and norms under continuous development

Takker De for Deres oppmerksomhet

Thank you, for your attention