Validation and routine monitoring of steam sterilisers in Dutch hospitals

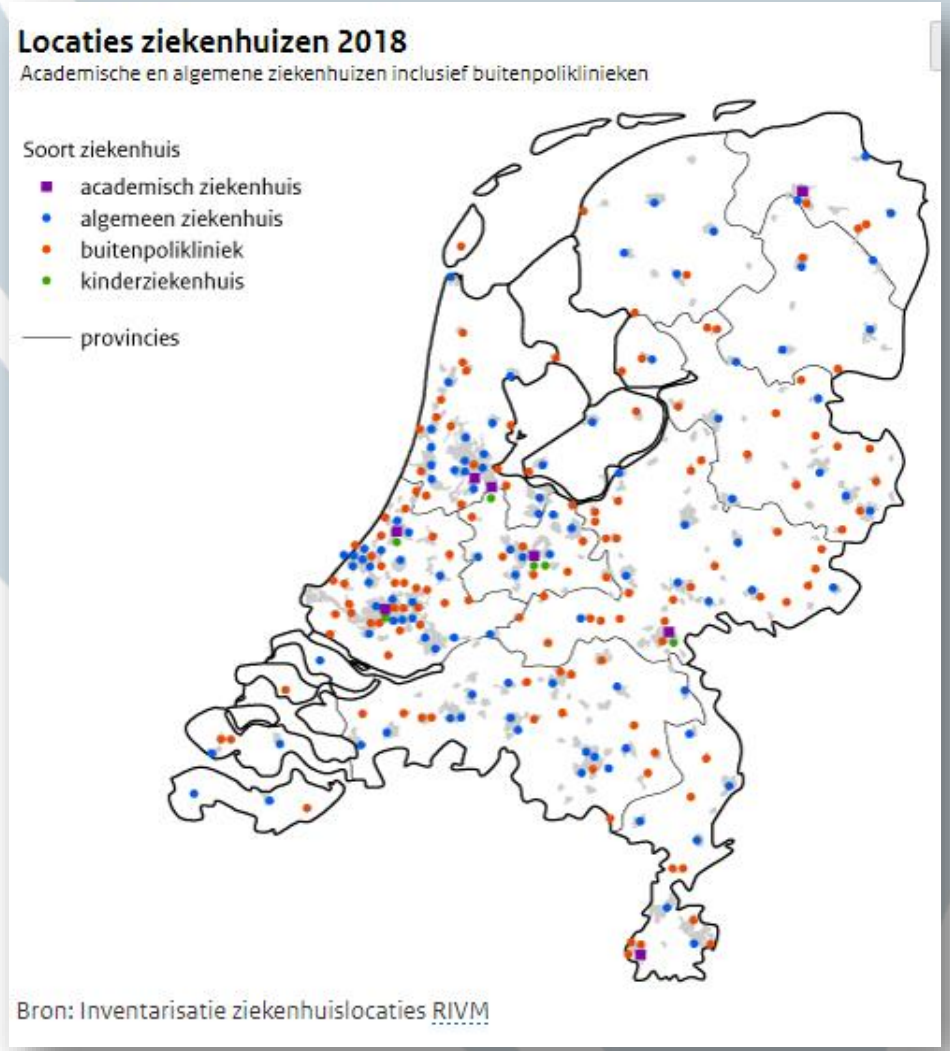
By working party of the association of experts sterile medical devices in Dutch hospitals

Mr. ir. R.C. (Remon) van der Aa, boardmember vDSMH

Introduction working group

R.C. van der Aa (presenter), M. Bartels, C. te Beest, J. Binnendijk, S. Dekker, J.P.C.M. van Doornmalen, M. van Hoof, S. Krooshof, H. Leeuw, J. Middelhoven, M.J. Meertens, S. Oostveen, P. Steegh, F. van de Vondervoort, J. Vermeer

No conflict of interest !



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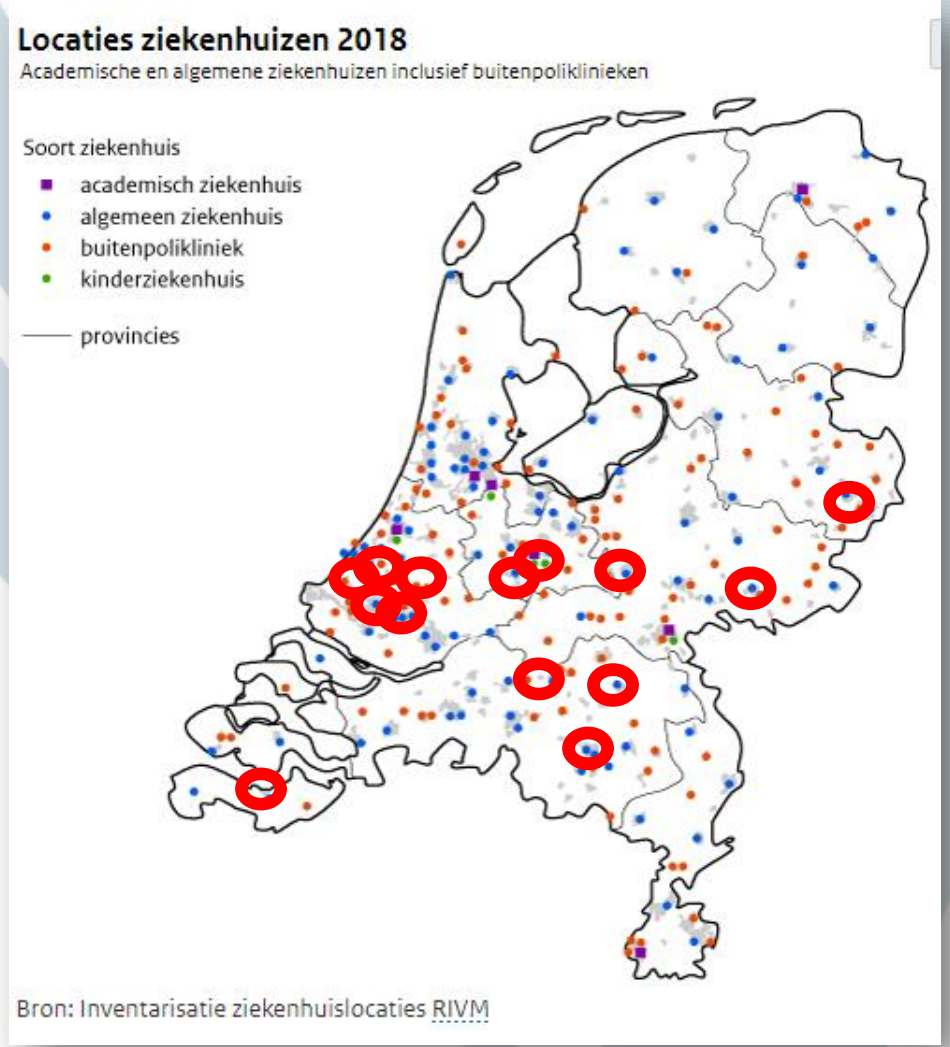

Contents

- Problem definition
- Background
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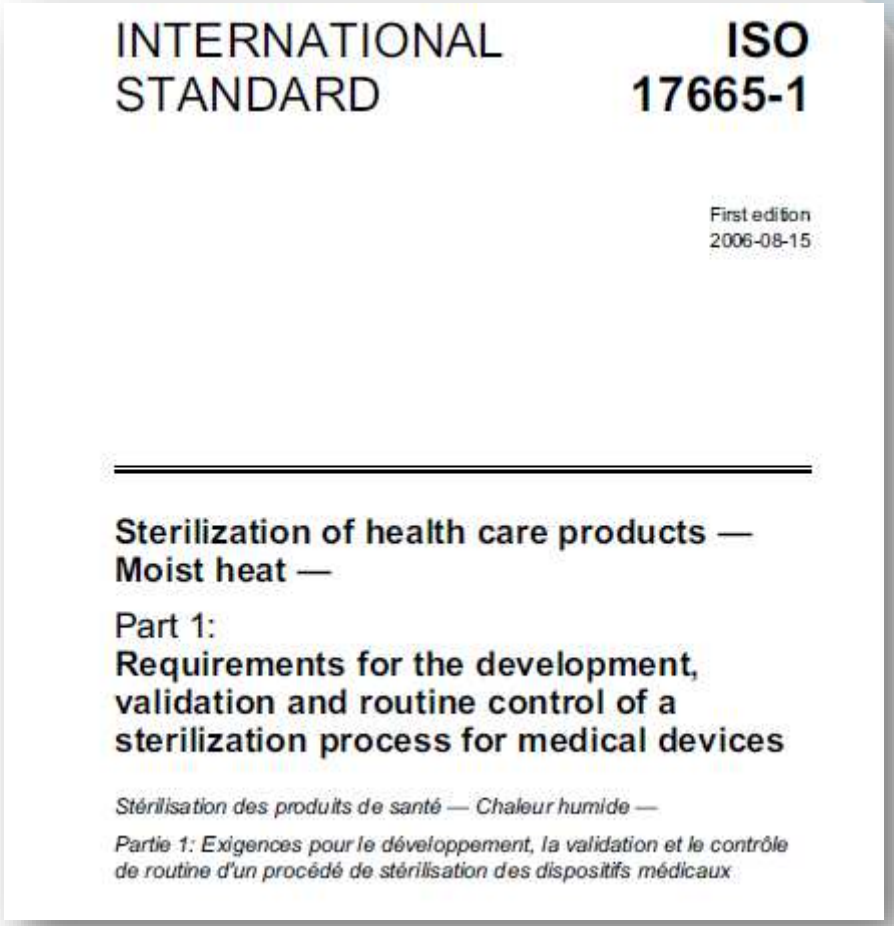
- Method
- Results
- Discussion and conclusion

Problem definition

- Standards recommend a **periodic** validation for surface steam sterilisers
- Dutch hospitals → Yearly validation
- Not literature based rational or added value

Background
Steam Sterilisation standards



INTERNATIONAL STANDARD

ISO 17665-1

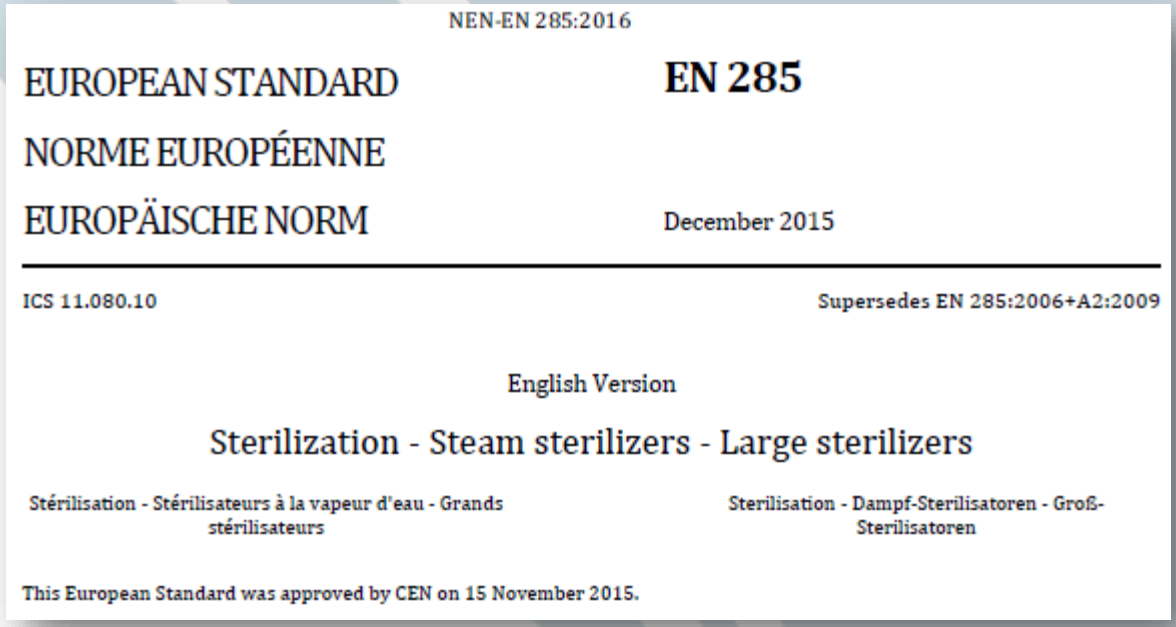
First edition
2006-08-15

Sterilization of health care products — Moist heat —

Part 1:
Requirements for the development, validation and routine control of a sterilization process for medical devices

Stérilisation des produits de santé — Chaleur humide —

Partie 1: Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux



NEN-EN 285:2016

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 285

December 2015

ICS 11.080.10

Supersedes EN 285:2006+A2:2009

English Version

Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This European Standard was approved by CEN on 15 November 2015.

Background
Types of validation

1) Performance qualification (PQ) – ‘initial validation’
2) Performance re-qualification (PrQ) – ‘yearly re-validation’

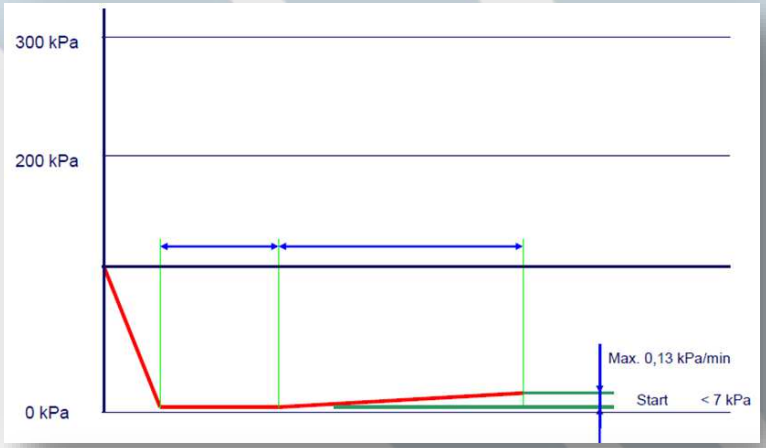
This presentation: validation = PrQ

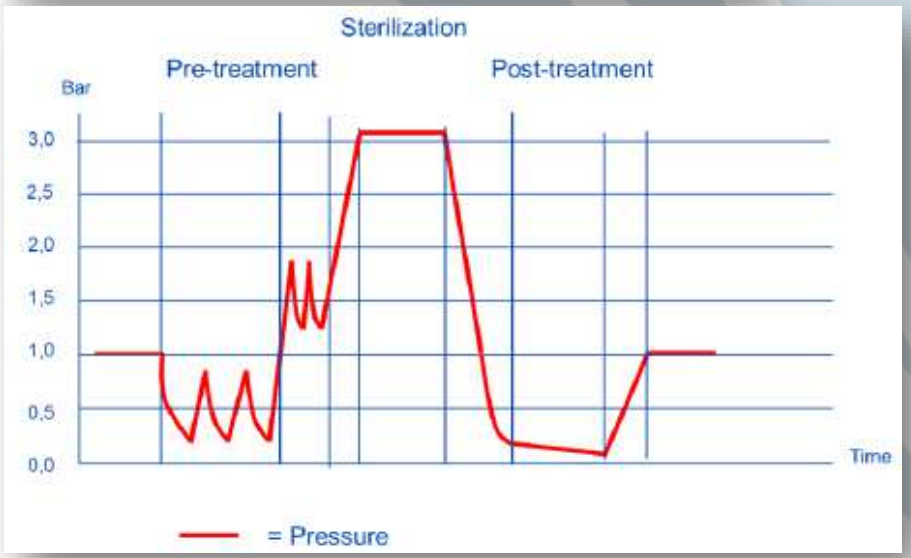
Background
Steam Sterilisation validation measurements

performed measurement	criteria
air leakage test	EN 285
steam penetration test	EN 285
134 °C standard process empty	ISO 17665
134 °C standard process 100 % load	ISO 17665
121 °C standard process empty	ISO 17665
121 °C standard process 100 % load	ISO 17665

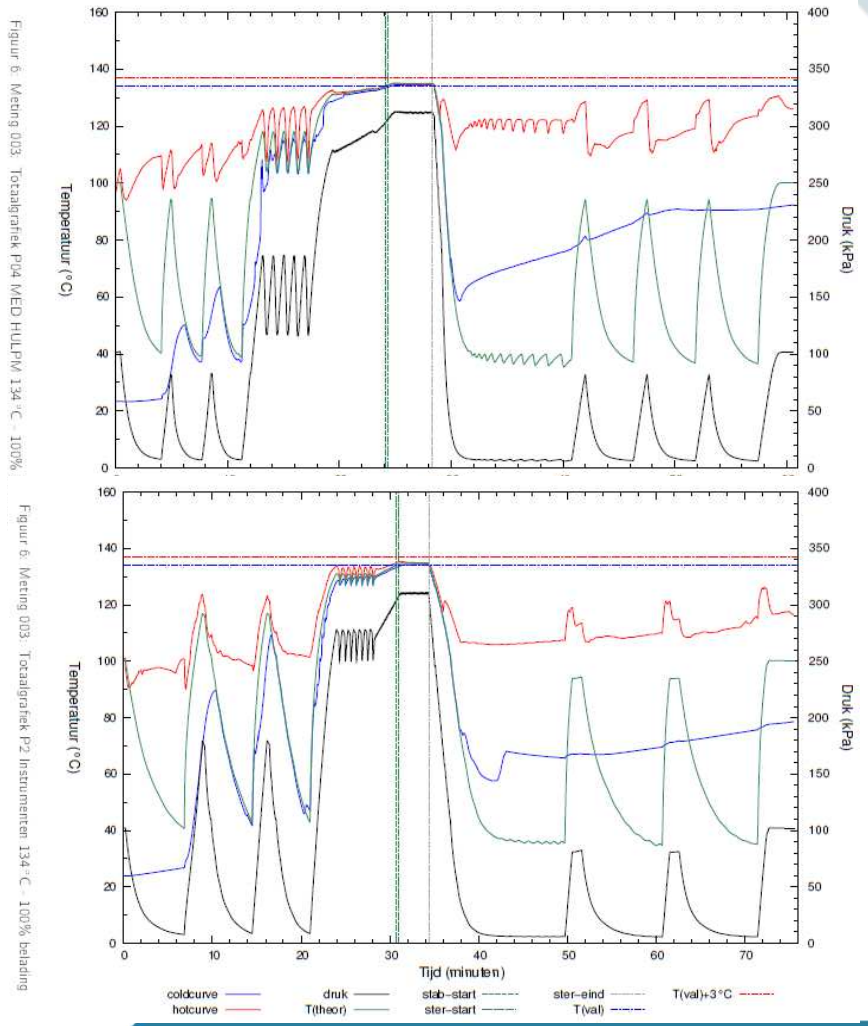
reproducibility	-

technical state of the steriliser	criteria
recorder/registration printer	EN285
temperature registration	EN285
pressure registration	EN285
temperature display	EN285
pressure display	EN285
indicating pressure gauge	EN285





Background
Validation data in report



Figuur 6: Meting 003: Totaalgrafiek P04 MED HULPM 134 °C - 100%

Figuur 6: Meting 003: Totaalgrafiek P2 Instrumenten 134 °C - 100% beladi

6.1 Conclusies

Gemeten processen

Meting	Beschrijving	Criteria	Conform
001	P01 LEKTEST	EN285	ja
005	P03 MED. HULPM. 134 °C - ETS	EN285	ja
003	P03 MED. HULPM. 134 °C - leeg	ISO17665	ja
004	P03 MED. HULPM. 134 °C - 100% belading	ISO17665	ja

Reproduceerbaarheid processen

Programma	Reproduceerbaar
P03 MED. HULPM. 134 °C	ja

6.2 Technische controles

Technische staat

Er werden geen primaire gebreken geconstateerd.

Instrumentatie

Instrument	Criteria	Conform
recorder/registratieprinter	EN285	ja
temperatuurregistratie	EN285	ja
drukregistratie	EN285	ja
temperatuurdisplay	EN285	ja
drukdisplay	EN285	ja
aanwijzende manometer(s)	EN285	ja

Background
Routine monitoring Steam Sterilisers

- Technical maintenance
  - routine procedure 2 times a year
  - corrective
- Loading pattern
  - heavy instruments below
  - Loading orientation
  - every process: wet load
- Wrapping
  - standard type wrapping material
  - every process: pinholes or defects
- Process
  - daily time-out with Electronic Test System (ETS) *
  - every process by steam steriliser IMS: temperature, pressure and time *
  - every process manual: indication tape colour change and check of graphs
- Load
  - no new Process Challenge Devices (PCD): long lumen, plastics, heavy products

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  - daily time-out with Electronic Test System (ETS) *
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  - every process manual: indication tape colour change and check of graphs
- Load
  - no new Process Challenge Devices (PCD): long lumen, plastics, heavy products

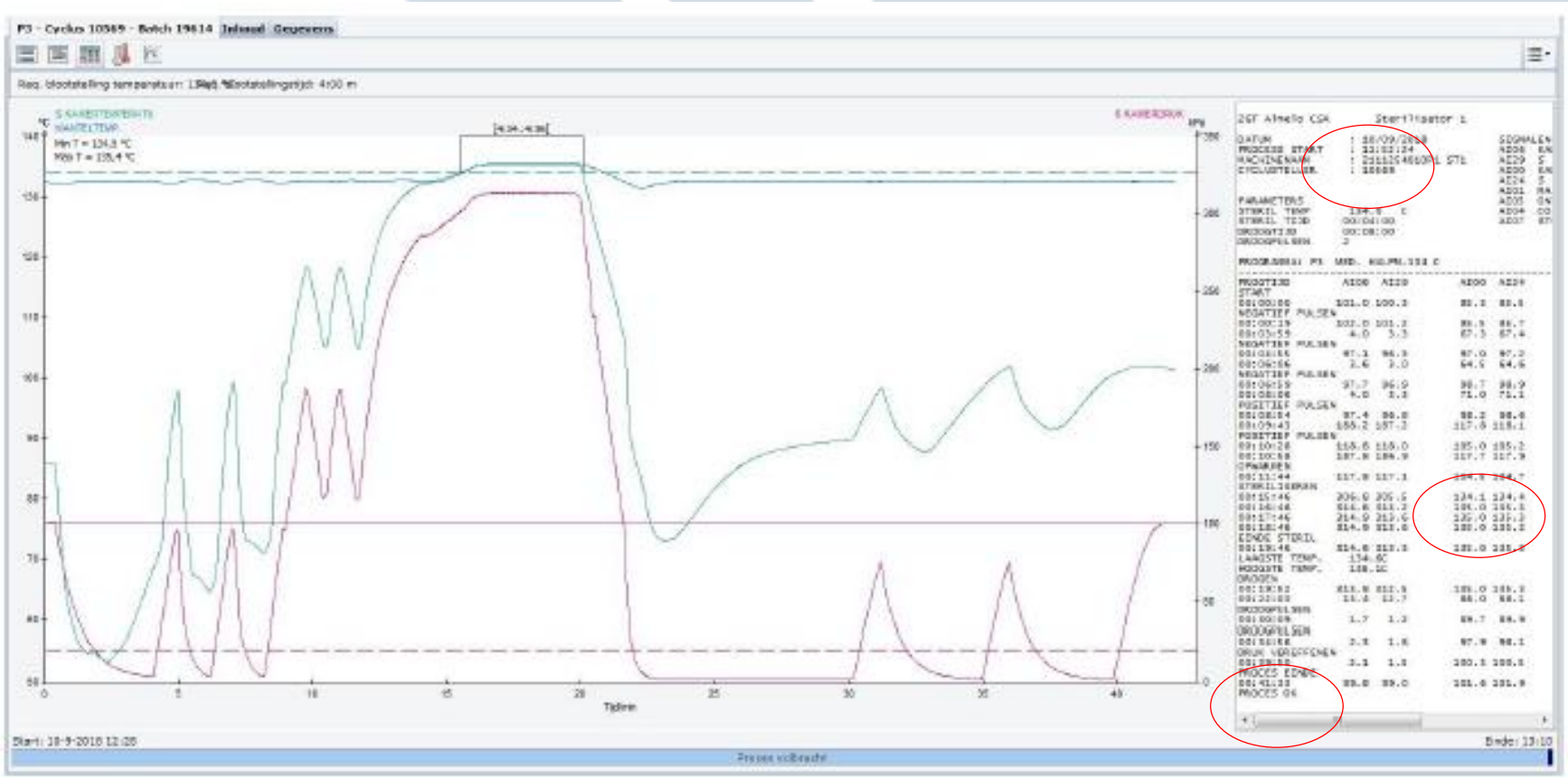
* = more detail

Background
Process monitoring every cycle

- Control steriliser = pressure
- IMS steriliser =
  - Temperature
  - Pressure
  - Time
  - *NCG's*

  (or daily ETS?)

Process aborted



Background
Facilities steam steriliser

- Quality of facilities influence success of steam sterilisation cycle
  - Steam supply
  - Vacuum system
  - Compressed air
  - Water

Facilities are part of the validation activities

Background
Process monitoring daily reproducibility

- Electronic Test System (ETS)
  - Air leakage
  - Steam penetration
  - Non Condensable Gases (NCG)
  - Process reproducibility

Research Question

Is **parametric** routine monitoring instead of **periodic** validation for surface steam sterilisers feasible?

Method

- Last 5 validation report of 1 steriliser located in CSSD
- Only tests from standards
- Similar on all included 13 sterilisers
- Including reproducibility, technical state and deviations

performed measurement	criteria
air leakage test	EN 285
steam penetration test	EN 285
134 °C standard process empty	ISO 17665
134 °C standard process 100 % load	ISO 17665
121 °C standard process empty	ISO 17665
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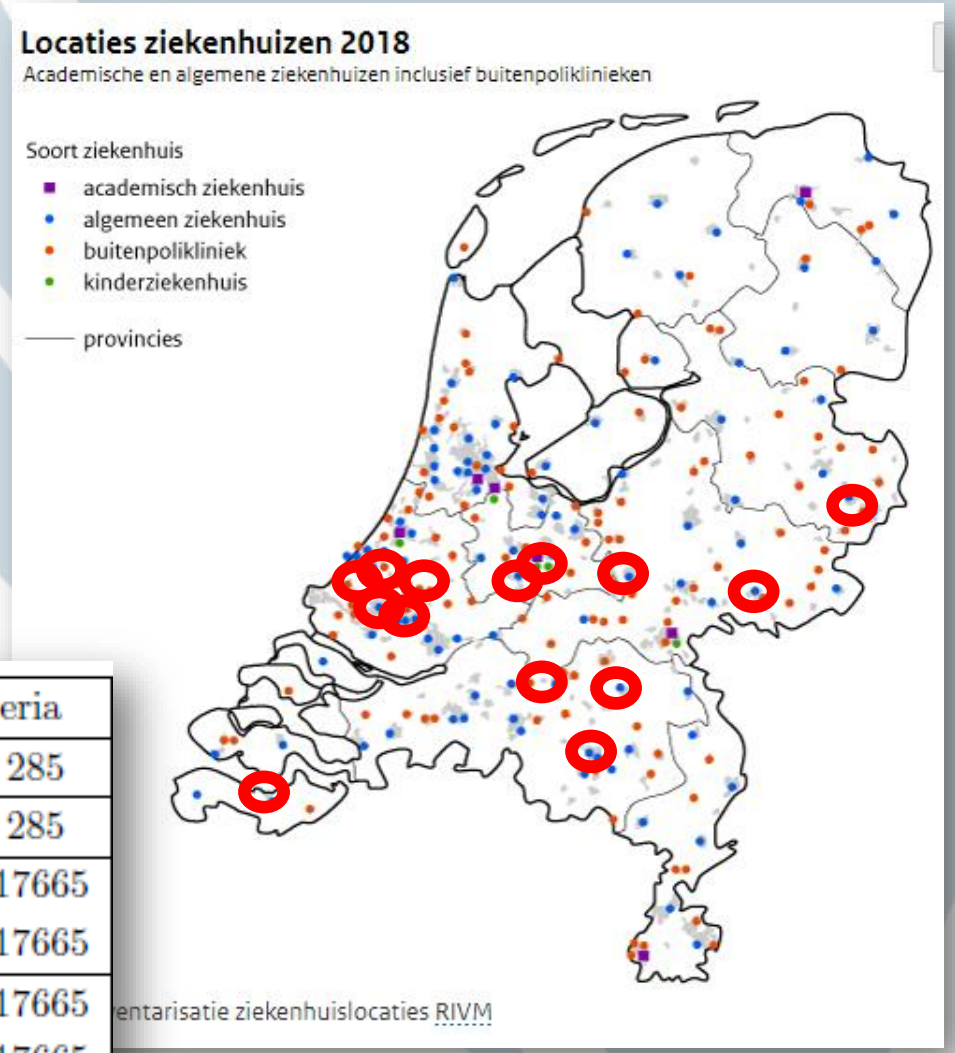

Results

- 1 steriliser in production in 2014
- 1 steriliser no air leakage test
- No restriction in steam penetration
  - ETS or standard Bowie and Dick
- Standard processes 121°C / 134°C
- Reproducibility (no exact method)

- Reported deviations
  - Cause of deviation is known:

  Phaco handpiece / polymer material

year of validation		2017	2016	2015	2014	2013
number of sterilisers		13	13	13	13	12
performed measurement	criteria					
air leakage test	EN 285	12/12	11/12	12/12	12/12	12/12
Steam penetration test	EN 285	13/13	13/13	13/13	13/13	13/13
134 °C standard process empty	ISO 17665	11/12	11/12	11/12	12/12	9/10
134 °C standard process 100 % load	ISO 17665	10/13	12/13	9/13	12/13	12/12
121 °C standard process empty	ISO 17665	6/6	7/7	6/7	8/8	8/8
121 °C standard process 100 % load	ISO 17665	5/5	6/6	4/6	7/7	7/7
reproducibility	-	9/9	9/9	7/7	7/7	7/7
technical state of the steriliser	criteria					
recorder/registration printer	EN285	13/13	13/13	13/13	13/13	12/12
temperature registration	EN285	13/13	13/13	11/13	13/13	12/12
pressure registration	EN285	13/13	13/13	12/13	13/13	12/12
temperature display	EN285	13/13	13/13	13/13	13/13	12/12
pressure display	EN285	13/13	13/13	13/13	13/13	12/12
indicating pressure gauge	EN285	12/13	12/13	11/12	11/12	10/11
reports reporting deviation		10	10	10	10	10
reported deviations in summary		9	13	9	15	1
proposed reported actions		2	1	4	3	1

Results – compliance

- 64 reports
- Air leakage (100%)
- Steam penetration (100%)
- 134°C empty load (93%)
- 134°C full load 55/64 (86%)
  - 8/64 (13%) phaco hand-piece
  - 1/64 (1%) slower warming polymer
- Technical state (98%)

year of validation		2017	2016	2015	2014	2013
number of sterilisers		13	13	13	13	12
performed measurement	criteria					
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pressure display	EN285	13/13	13/13	13/13	13/13	12/12
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Results – closer inspection

Not a changed combination of:

- Steriliser (and facilities)
- Process
- Load
- Loading pattern
- Wrapping
- Maintenance

The results of the validation did not change either

year of validation		2017	2016	2015	2014	2013
number of sterilisers		13	13	13	13	12
performed measurement	criteria					
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pressure registration	EN285	13/13	13/13	12/13	13/13	12/12
temperature display	EN285	13/13	13/13	13/13	13/13	12/12
pressure display	EN285	13/13	13/13	13/13	13/13	12/12
indicating pressure gauge	EN285	12/13	12/13	11/12	11/12	10/11
reports reporting deviation		10	10	10	10	10
reported deviations in summary		9	13	9	15	1
proposed reported actions		2	1	4	3	1

Discussion

- Results of validation are predictable when:
  - Combination of steriliser (and facilities), process, load, loading pattern, wrapping, maintenance is not changed
- Only then:
  - Time interval between validations can be increased
- Otherwise (one or more components change):
  - Temperature mapping in load have added value, i.e. validation

Conclusion

Research Question:

Is **parametric** routine monitoring instead of **periodic** validation for surface steam sterilisers feasible?

Conclusion:

Yes, if the essential parameters (actual steam sterilisation conditions), measured in every process, are similar to those before maintenance, complete validation (PrQ) has no added value and it should not be considered necessary.

Advise:

Measure actual steam sterilisation conditions in every process

(including NCG's)

References

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More information in white paper (in English)

https://www.vdsmh.nl/publicaties/valideren/publicatie-white-paper-validatie-monitoring