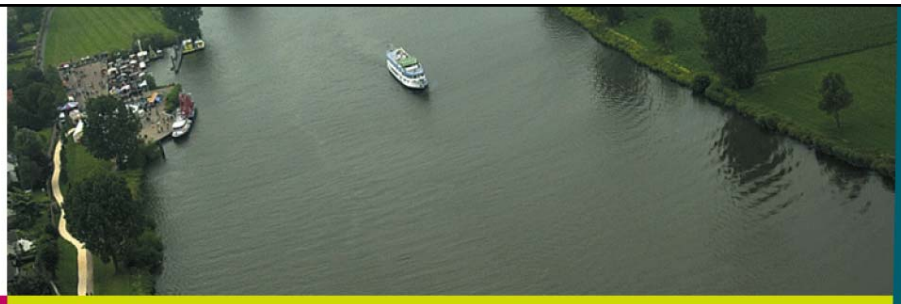

Instructions for the reprocessing of reusable medical devices

Does ISO 17664 make a difference?

Adrie de Bruijn

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Introduction

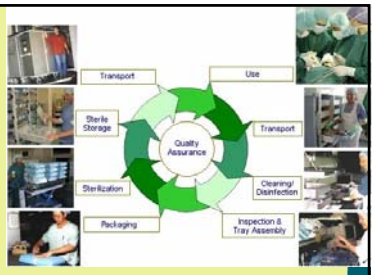
National Institute for Public Health and the Environment (www.rivm.nl)

- Our mission is to benefit people, society and the environment, matching our expertise, knowledge and research with that of colleagues from around the world
  - 1400 employees
  - Annual turnover >100 M€
- Medical Technology Section (http://www.rivm.nl/preventie/hulpmiddelen/)
- Research based advise to the policy makers of the Ministry and to the Health Care Inspectorate
- Prevention of disease transmission; cleaning, disinfection, sterilisation

What will I talk about?

- Medical Device Directive and ISO 17664
- Impression about quality of instructions for reprocessing
- Conclusion, does ISO 17664 make a difference?
- What can you do?

Instructions for reprocessing



- Medical Device Directive demands that instructions for reuse must be provided for all resterilizable medical devices
- §13.6(h): if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.
- However, the MDD does not give detailed specifications for the content of these instructions.
- Fortunately, we have the standard ISO17664 (?)

EN/ISO 17664

"Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices"

(2004)


INTERNATIONAL STANDARD **ISO 17664**

First edition 2004-03-01

Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices

Stérilisation des dispositifs médicaux — Informations devant être fournies par le fabricant pour le processus de restérilisation des dispositifs médicaux

Reference number ISO 17664:2004(E)

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General requirements, ISO 17664

- The manufacturer has to provide specifications for every detail of every step in the reprocessing procedure
- The recommended processes must be validated
- The manufacturer has to take into account:
  - The training and knowledge of the personnel
  - The available cleaning, disinfection and sterilisation processes
- The limitations on the reprocessing must be stated
  - Number of reprocessing cycles, or
  - A method to determine the lifespan of the medical device.
  - Limits in process parameters

Sounds very well,

But, will the manufacturer really do all these things?

First impressions

- The “grape vine” does not sound too positive
- 2005; Expert panel using a 96 items checklist based on ISO 17664
- In total 26 checklists were completed
- Non of the instructions for reuse fulfilled all ‘ISO-requirements’
- 61% of the instructions for reuse was judged as inadequate

First impressions

- Most instructions available in Dutch, but poor translations, disregarding Dutch jargon; “thermal sterilised” instead of autoclaved, “Health and Safety laws” instead of ARBO.
- References to foreign national standards instead of NEN (EN and ISO) standards; e.g. AAMI, DIN.
- References to foreign national advisory committees “UK working party for TSE” instead of the Dutch counterpart “WIP”.
- These foreign regulations may not be (are not) applicable in the Netherlands and may not be available or accessible.
- Non SI-units are used; °F instead of °C, Psi for steam pressure instead of kPa, inHG for vacuumpressure instead of kPa.

First impressions

- The prescribed processes are not available in the Dutch CSSDs (although this is required by ISO 17664).
  - Sterilisation at 132°C (USA) or 135°C (D) instead of 134°C.
  - Gravity displacement cycle instead of multiple vacuum.
  - Flash sterilisation cycle; abandoned in NL.
  - Validated sterilisation process according to AAMI standards; instead of specific process parameters.
  - Disinfection after cleaning is rarely mentioned, where this is standard procedure in Dutch CSSD.
  - One (D) manufacturer mentions disinfection at 93°C for 10 minutes, where 90°C for 5 minutes is standard.

First impressions

- Some manufacturers do not provide any information on the processes, but leave it up to the user or refer to the manufacturer of equipment or materials.
  - … in a suitable process
  - A process validated by the hospital
  - … using a suitable detergent
  - A process optimized for the cleaning
  - … wrap in suitable packaging material
  - Hospital has to ensure that the process is suitable for the cleaning of the instruments.
  - According to the instructions of the WD manufacturer
  - According to the instructions of the detergent manufacturer

First impressions

- "I am not really interested whether the instructions for reuse meet the requirements in the standard."
- "I want to known if I can reprocess the devices with the equipment and materials I have."
- "We do not judge the reprocessing possibilities only from paper. We also examine the device itself."
- "I wish that the supplier of the instruments would contact the CSSD before the instruments are delivered, so we can prepare and where necessary adapt the existing procedures."

Validated process….

- Test soil; rabbit blood / oil mixture
- Test organisms *B. subtilus* spores 10^6
- Applied to internal parts of instrument in the area where the shaft attaches

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Validated process….

- Laboratory performed manual cleaning
- Detailed instructions
  - Immersed in detergent solution, scrubbed 2 times, rinse with 1 liter of water
  - Shaft flushed with 30 ml detergent, emptied, repeated, filled with 30 ml, soaking for 2 minutes and again flushing
  - Procedure is different from the instruction for reprocessing!
- Result: < 3 log reduction, for both the shaft and the handle
- Not accepted.

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Validated process?

- So…… the manufacturer requested a modification of protocol
- Test soil applied on the exterior of the handle and the shaft…

Validated process?

- Result: > 3 log reduction
- Acceptable!

- This is only one case,
  so not necessarily representative,
  but it makes one wonder….

Current Study

- TEE probes; IGZ report 2004
- “Fabrikanten van TEE-scopen dienen duidelijker aan te geven hoe scopen gereinigd en gedesinfecteerd moeten worden en daarbij aan te sluiten bij de gebruikelijke werkwijzen; machinale reiniging en desinfectie van alle endoscopen.”
- 8 fabrikanten, 7 handleidingen
- Geen enkele machinale reiniging en desinfectie!

Summary

- The manufacturer has to provide specifications for every detail of every step in the reprocessing procedure
- The recommended processes must be validated
- The manufacturer has to take into account:
  - The training and knowledge of the personnel
  - The available cleaning, disinfection and sterilisation processes

- Limitations on the reprocessing must be stated
  - Number of reprocessing cycles, or
  - A method to determine the lifespan of the medical device.

Conclusions

- ISO 17664 is a reference document intended for the manufacturers to write better instructions for reprocessing.
- Does ISO 17664 make a difference?
- My impression: No, it does not!

  You do not get instructions for reprocessing that take into account the SOPs of the Dutch (European) CSSDs.
- Similar experience in Germany (Hairson-Klein, Held; Aseptica nr. 4, Nov. 2007)
- But still, ISO 17664 may be a helpful guide in discussions with your supplier

What can you do? (personal opinion, open for debate)

- Check the instructions and the device before buying
- Make sure that you are a key decision maker in the purchase procedure
- Use your expert judgment
  - Can the medical device be cleaned in an automated WD?
  - Is an acceptable alternative method for manual cleaning and disinfection given? (method and necessary time)
  - Are you convinced that the medical device can be adequately cleaned and disinfected?
  - Can you check the proper functioning of the device after cleaning?
  - Can you package and sterilise the medical device?
- Use a checklist; vDSMH or RIVM

What can you do?

- Ultimate question: Can you reprocess the medical device in your CSSD?
  - Be flexible and creative, think about the needs of the medical staff
  - When necessary use special trolleys in WD (MIC instruments), even when time consuming
  - Convert to manual cleaning; sometimes it is necessary, but time consuming, thus expensive
  - Convert to disposable instruments
- Can you "modify" the instructions?
  - Expert judgment, on your own responsibility (sterilisation 132°C ⇒134°C)
  - With the consent of the manufacturer (not the supplier)

What can you do?

- When you do not get any cooperation of the manufacturer, team-up with vDSMH (or are you the only one having problems?).
- When there is a structural problem, notify IGZ Website www.igz.nl; Melding maken.