# APPLICATION TECHNIQUE STERILIZATION

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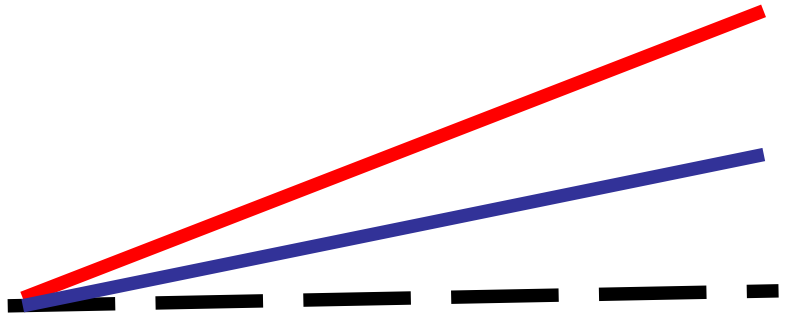
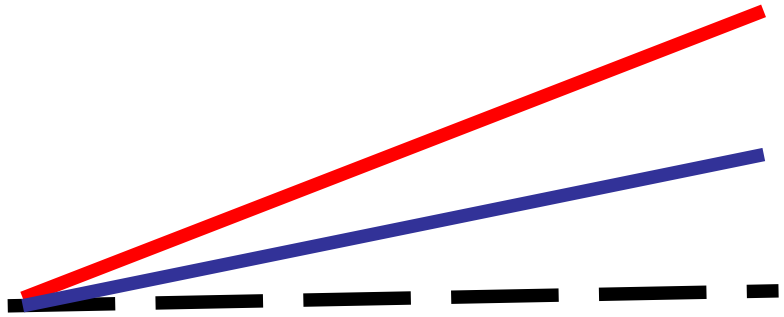
# Demands on the Sterilization process “ PAST“

- Technical construction according EN 285 (1996) „Type proof”
- Demands of the customer for the sterilization process
- Reached limits of the sterilizer



# Demands on the Sterilization process “NOW“

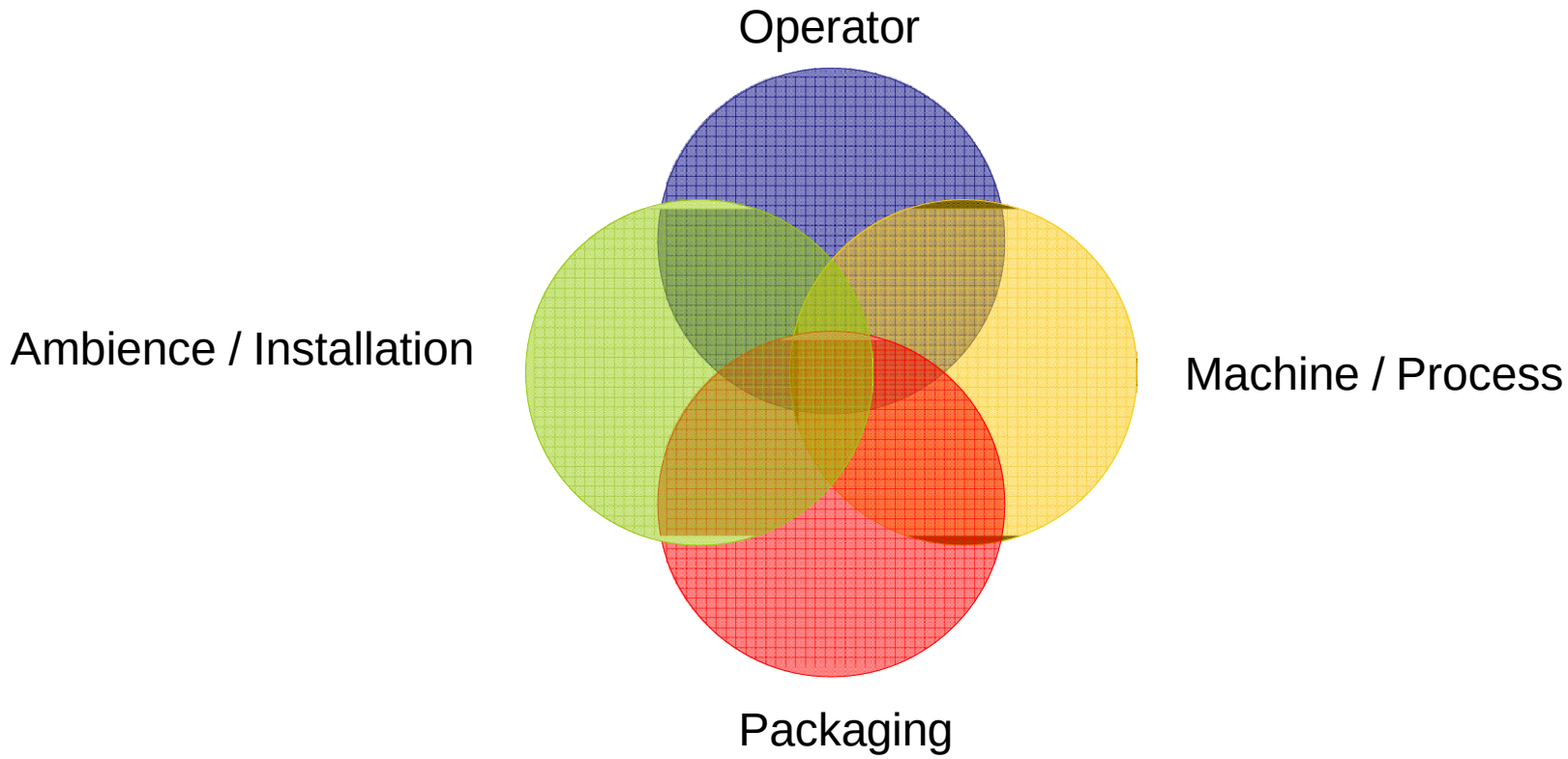
- Technical construction according EN 285 (2006) „Type proof”
- Reached limits of the sterilizer
- Demands of the customer for the sterilization process „*all-in-one device suitable for every purpose* and this for no costs“



# Customer requirements

- Sterile medical products
- Short batch times
- Maximum load
- No residual moisture
- All container and packaging possibilities are unlimited usable
- Everything has to be possible

# Factors for a good Sterilization process



# Packaging

# Rigid Packaging

- Container built according to EN 868 Part 8
- Test load 10 kg per StU

Drying performance according to EN 868 Part 6

- Residual moisture < 0.2% (Metal load)
- Residual moisture < 1.0% (Textile load)

# Material properties

- Container and cover made of stainless steel
- Container and cover made of Aluminium / Metal trays
- Aluminium container with stainless steel cover / Metal trays
- Aluminium container with stainless steel cover / Metal trays /  Condensate drain
- Aluminium container with plastic cover / Metal trays
- Container and cover made of Aluminium / Plastic trays
- Aluminium container with plastic cover / Plastic trays

# Calculation Amount of condensate (Stainless steel)

Heat requirement ($Q = m \times c \times \Delta t$)

$= 12kg \times 0.5kj/kg / K \times 114K = 686\ kj$

$\Delta t$ Temperature difference ($20°C - 134°C$)  c Specific heat capacity (1kg for $1°C$)

Energy capacity of steam  1 kg Steam $\cong$ 2000kj (r)

Steam quantity (md) = Quantity of condensate  $Q = md \times r$

$md = Q/r = 686kj / 2000kj = 0.342\ kg = 343g$ Steam

# Calculation Amount of condensate (Plastic)

Heat requirement ($Q = m \times c \times \Delta t$)

$= 12kg \times 2.5kj/kg / K \times 114K = 3420kj$

$\Delta t$ Temperature difference ($20°C - 134°C$)

Energy capacity of steam 1 kg Steam $\cong$ 2000kj (r)

Steam quantity (md) = Quantity of condensate $Q = md \times r$

$md = Q/r = 3420kj / 2000kj = 1.71kg = 1710g$ Steam

# Reminder

**Plastic needs**

**approx. 5 x more energy to heat up!**

**More Energy**

**= More condensate**

**= Longer drying time**

**= Longer process time**

# Flexible Packaging

- Papers (plain, crepe, semi crepe, fleece)
- Foils / pouches (Gas, Steam, Gamma-rays)
- No textiles (Textile alternative)
- Textiles

# Materials  Characters

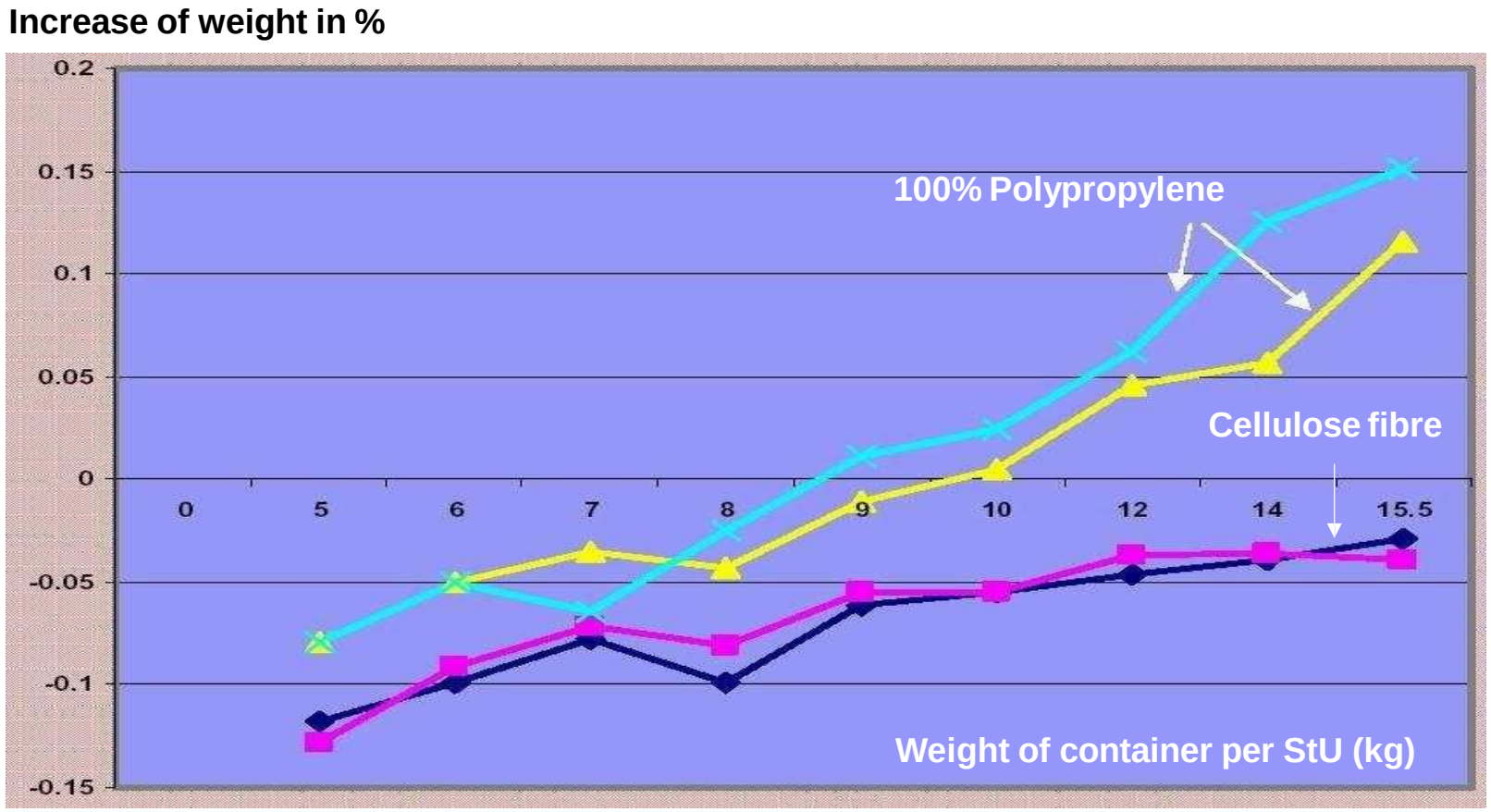
- Cotton
- Cellulose 100%
- Cellulose with binding material
- 100% Polypropylene
- Polypropylene with absorber coating

# Norm: EN 285 (Residual moisture)

- Sterilization process 3.5min at 134°C
- Drying capacity according to EN 285 (8.4.2)
- Test container 1 StU (14.1 kg ± 0.4 kg)

  (Container (4,2 kg) + Screws (8,6 kg)+ Tray (1,3 kg) + Cotton wrapping)
- Residual moisture < 0.2% (28.2 g with metal load)

# Condensate within the wrapping




If the weight of the container increases, also the amount of the condensate increases!

# Reminder

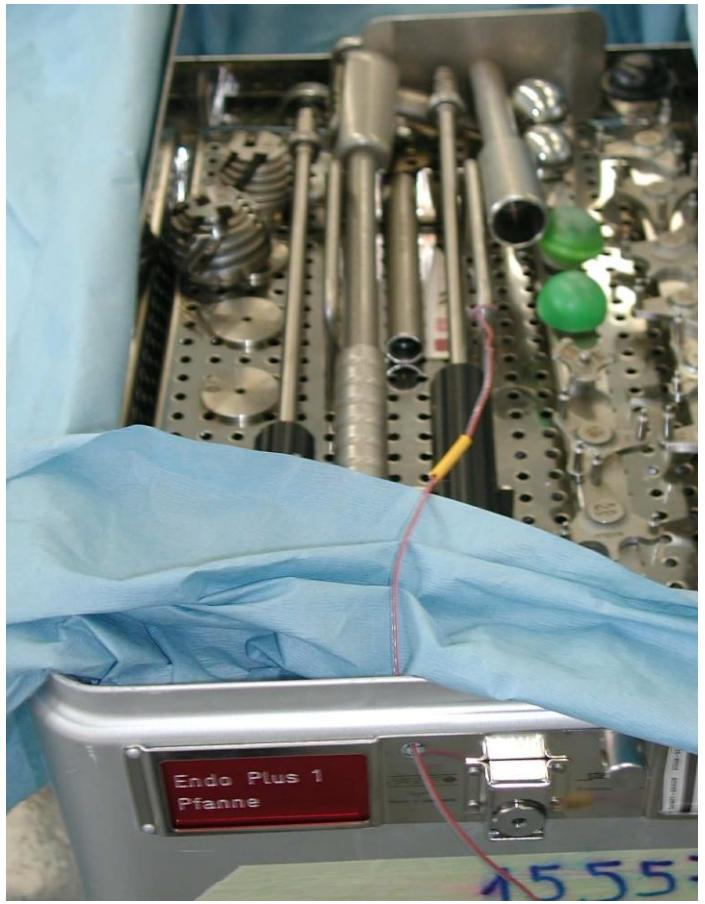
With increase of the container weight the condensate amount increases!

**More container weight**

**= More condensate**

**= Longer drying time**

**= Longer process time**



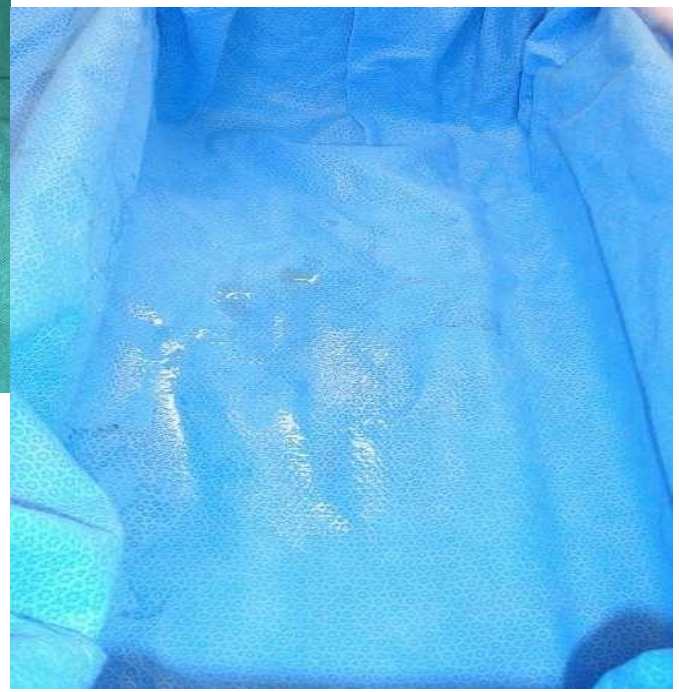
# Condensate residue (after drying)

Visible

- Drops
- Water accumulation

Non visible

- Integrated in sterilisation fleece



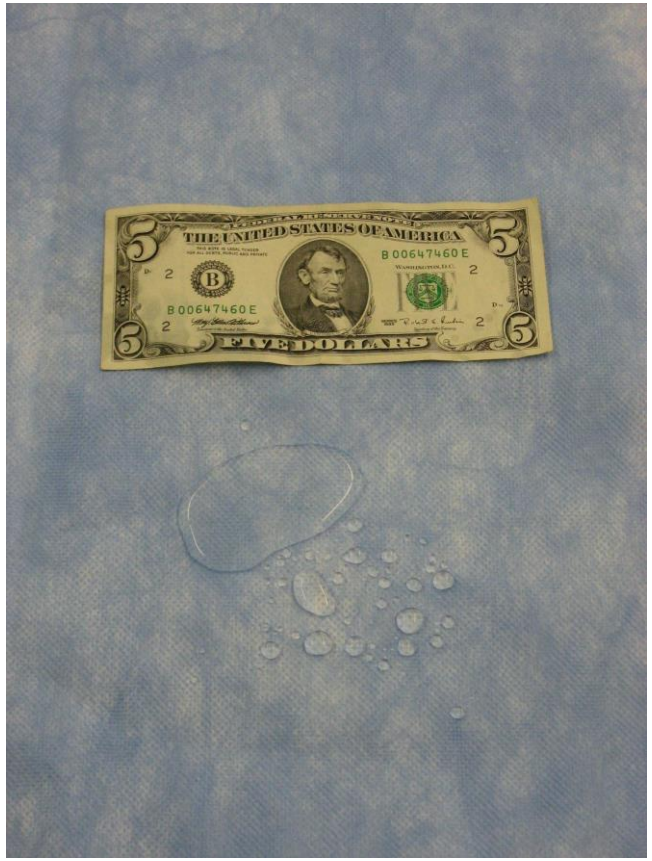
# Example with 10 ml water

- 100% Cellulose with chemical binding material


- Textile

# Example with 10 ml water

- Polypropylene with absorber

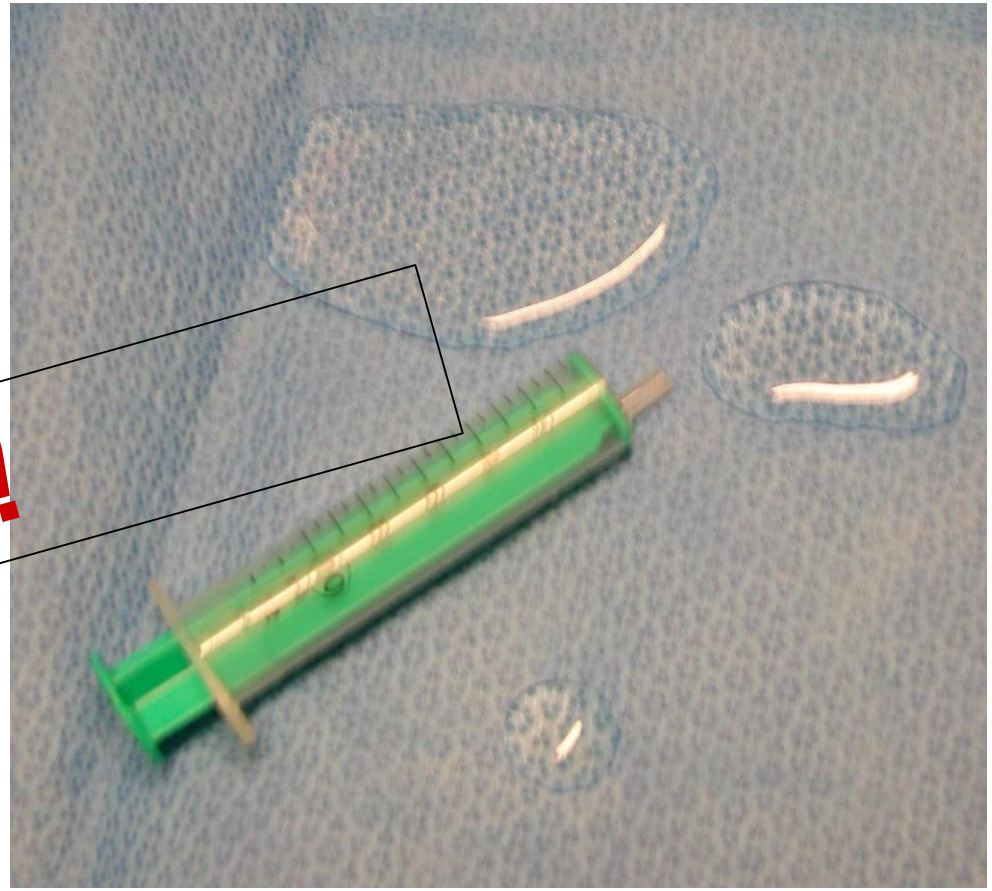



- 100% Polypropylene  Cellulose

# Visual check (Dryness)

- Drop < 1ml
- Big drop < 5ml
- Accumulation approx.10ml
- Allowed remaining quantity according to Norm: **28g**

**28g = WET !!**



# Picture source of error

# Picture Container full

- No maximum load indication from container producer

# Picture Container condensate

- After a load of 24kg instruments
- Marking from filter lid

# How to do it right:  Correct loading

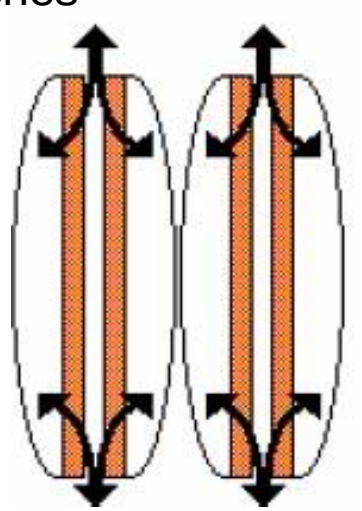
- Light sterile goods in flexible packs should be loaded on the top.
- Heavy containers should be placed at the bottom of the chamber.

Reasons:

- The heavier the items are, the higher is the amount of condensing water
- Lighter packs must be “protected” against drops of condensing water

# How to do it right:  Correct loading

- Pouches



- Unhindered in – and out of air  and steam

# Bad examples

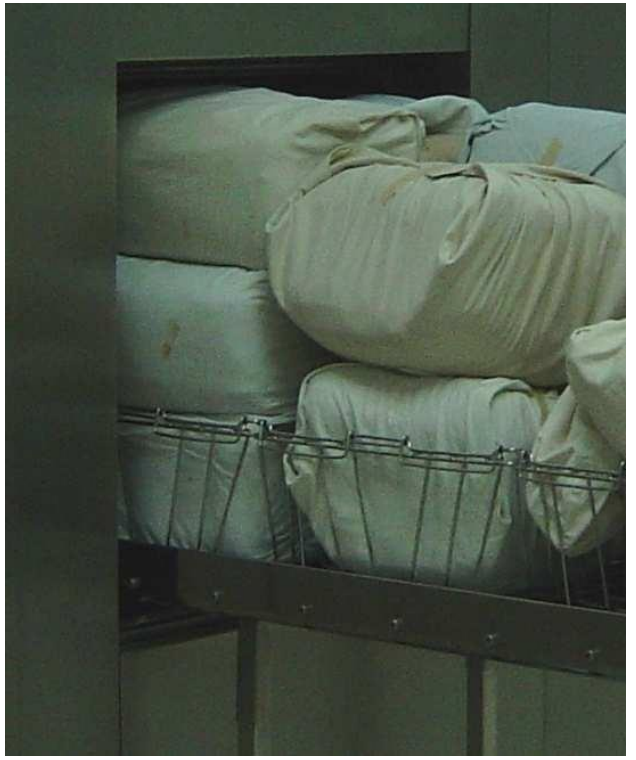
- Overloaded, packaging can not breath

- Foils down side

# Bad examples

- Textiles in contact with sterilizer chamber

  (Loading index = width of batch cart )



# Influence of packing materials to drying result

| Packing material | Drying result | Type |
|---|---|---|
| Cotton | ++ | 1- layer |
| Cellulose | ++ | 1- layer |
| Cellulose | + | 2- layer |
| Polypropylene + mixed fibres | ++ | 1- layer |
| Polypropylene + mixed fibres | + | 2- layer |
| 100% Polypropylene | O | 1- layer |
| 100% Polypropylene | - | 2- layer |

| -- | - | O | + | ++ |
|---|---|---|---|---|
| very bad | bad | average | good | Very good |

# Different containers led to different drying results

| Container | Drying result |
|---|---|
| Container and cover made of Aluminium / Metal trays | ++ |
| Aluminium container and cover made of stainless steel / Metal trays | + |
| Aluminium container with plastic cover / Metal trays | O |
| Container and cover made of Aluminium / Plastic trays | - |
| Aluminium container with plastic cover / Plastic trays | -- |

| -- | - | O | + | ++ |
|---|---|---|---|---|
| very bad | bad | average | good | Very good |

# Residual moisture MATRIX Container-10kg

- Based on Sterilization process 3.5min. 134°C, 25 Min drying

| Packaging / Container | Cotton cloth | 100 % Cellulose | Polypropylene and mixed fibres | 100% Polyproplene |
|---|---|---|---|---|
| Sainless steel with cond. drain | ☺ | ☺ | ☺ | ☺ |
| Sainless steel w/o cond. drain | ☺ | ☺ | ☺ | ☺ |
| Aluminium with Aluminium cover | ☺ | ☺ | ☺ | ☺ |
| Aluminium with plastic cover | ☺ | ☺ | | |

| bad | average | good | Very good |
|---|---|---|---|
| | | ☺ | ☺ |

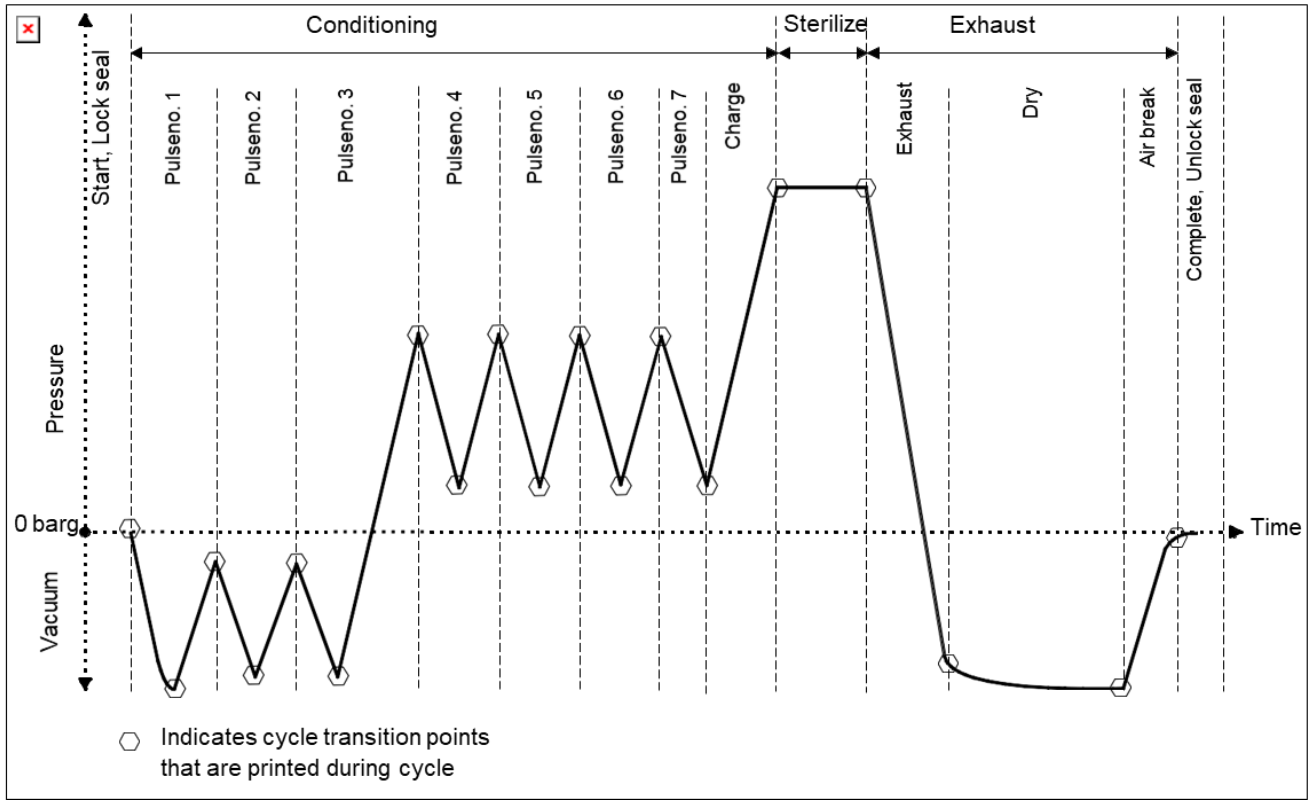
# Residual moisture MATRIX Container 12kg - 14kg

| Packaging / Container | Cotton cloth | 100 % Cellulose | Polypropylene and mixed fibres | 100% Polyproplene |
|---|---|---|---|---|
| Sainless steel with cond. drain | ☺ | ☺ | ☺ | |
| Sainless steel w/o cond. drain | ☺ | ☺ | | |
| Aluminium with Aluminium cover | ☺ | ☺ | | |
| Aluminium with plastic cover | ☺ | ☺ | | |

| bad | average | good | Very good |
|---|---|---|---|
| | | ☺ | ☺ |

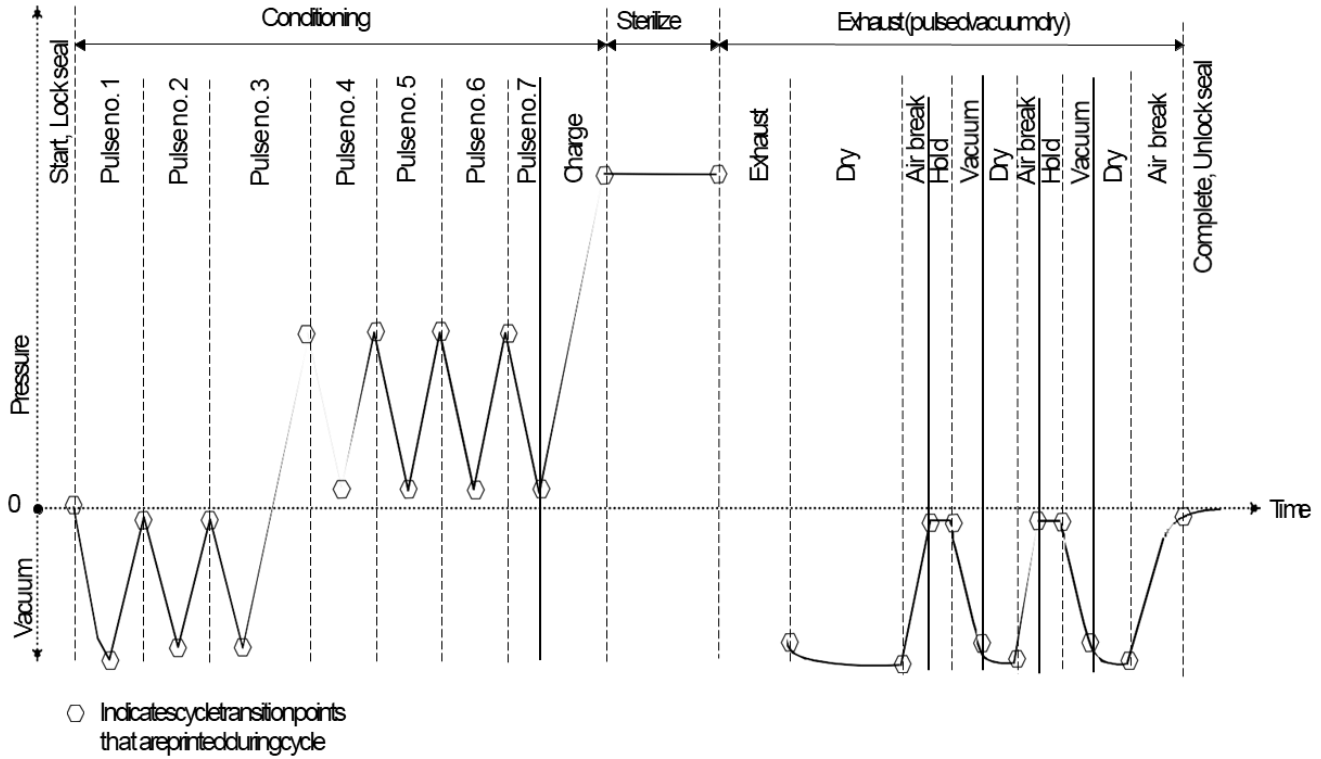
# Process

| No. | CYCLE | STERILIZE TEMP | STERILIZE TIME | DRY TIME | RECOMMENDEDLOAD |
|---|---|---|---|---|---|
| 1 | Instruments 134°C | 134°C | 4 minutes | 25 minutes | Instrument intraysor containers max. 7-8kg / trayor container |



# Process

| No. | CYCLE | STERILIZE TEMP | STERILIZE TIME | DRY TIME | RECOMMENDED LOAD |
|---|---|---|---|---|---|
| 7 | Heavy Instruments 134°C | 134°C | 4 minutes | 20 min. + 3*1,5 min | Heavy instruments in stainless steel containers, max. 14kg / container (gross weight) |

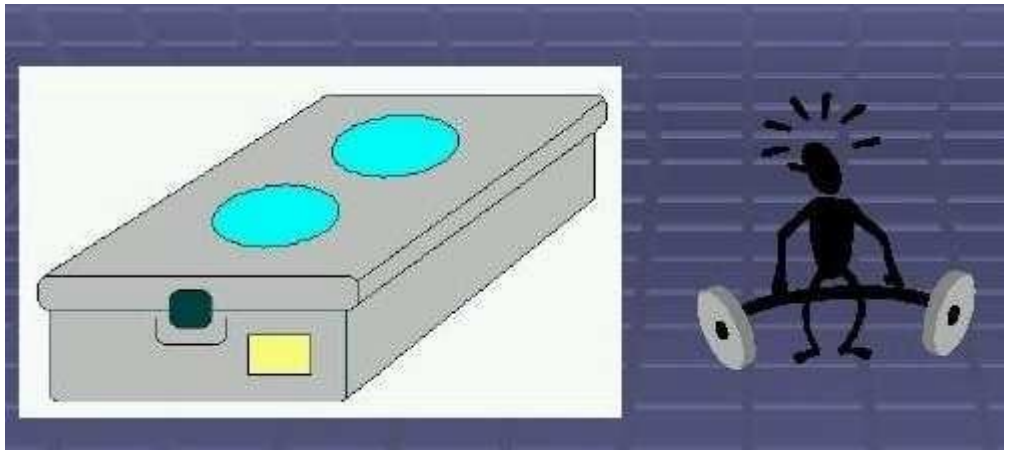


# Optimizing Residual moisture

- Total weight of container shall not exceed. 14 kg per StU
- Filling level of container max. 3cm below upper edge
- Minimize the use of plastic trays
- Use well absorbing wrapping material
- Pulsed-vacuum-dry is more effective vacuum dry

# Source of errors: Loading

- Container is to small
- Filling level of container is exceeded
- Size of packaging paper is to big
- Stacked containers
- Horizontal positioning of flexible pouches



# Source of errors: Installation

Steam to wet

- Steam supply without condensate trap
- Power of steam generator not sufficient
- Condensate trap (mechanical better than thermal)

# Xin cảm ơn

Mr. Edmond

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