Cleaning
How to do it?
What is good enough?

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You can clean without disinfecting, but you cannot disinfect without cleaning !

If it is not clean, you cannot sterilize it !

Earle Spaulding

Digital public library of America
Dr. Earle Spaulding | DPLA

Goal

Hygienic Safety

Value Preservation

Reliability

Efficiency

Everywhere in the world?

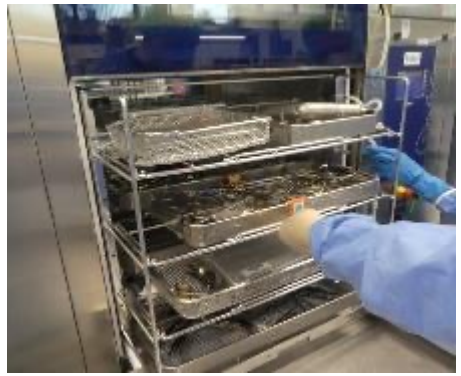
Why is cleaning so difficult?

- Multiple Process Steps
- Multiple manual Factors
  - Including Machine Cleaning (Loading,...)

Kontamination
Point-of-Use-Cleaning

Transportation Time/
Condition

Pre Cleaning

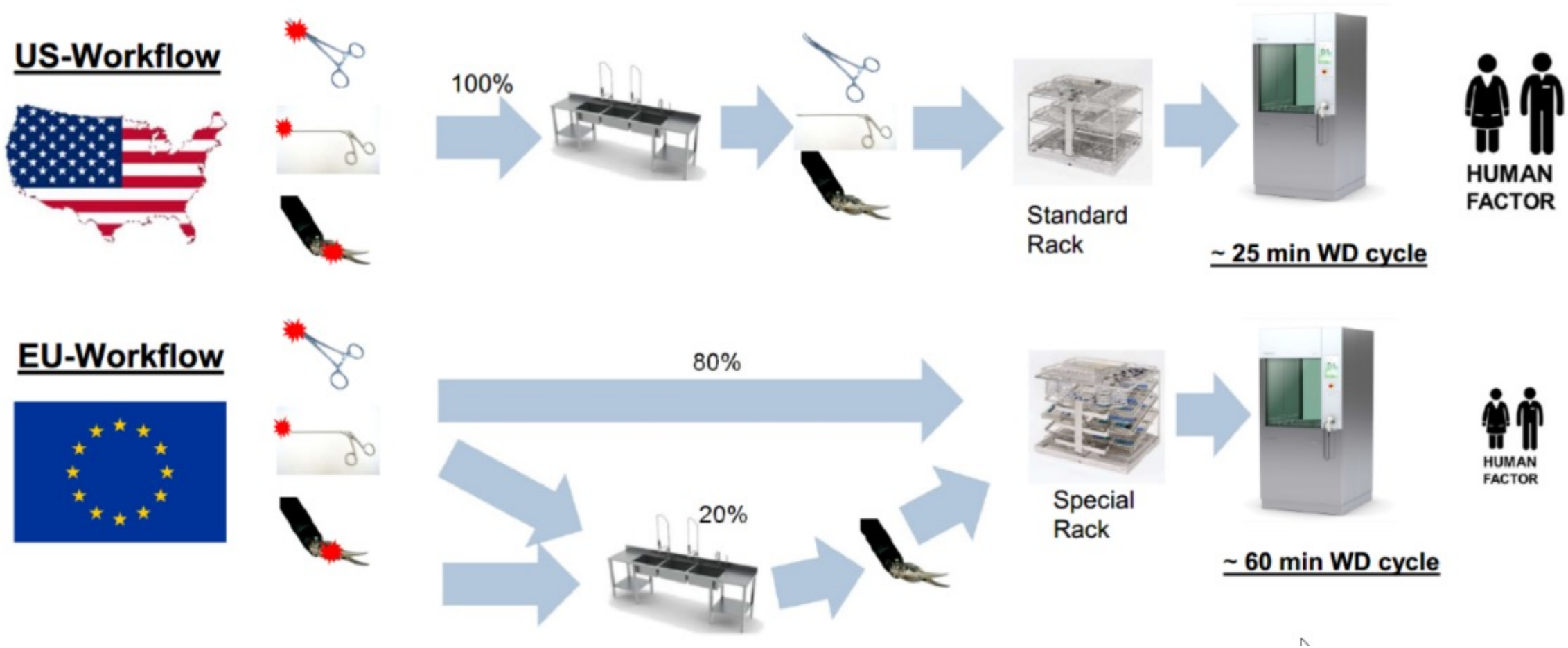


Machine Cleaning

Visual Inspection

2nd Cleaning

Different Philosophies – Different Ways to Rome



Graphics by Markus Auly, CH

What is clean ? - Where is Rome?

- Biocompatibility ISO10993 :2021: complex laboratory test
  - Pyrogens, Senzitation, Cytotoxicity, Haemocompatibility, ...
  - Used by Medical Device Manufacturers

- ISO 15883 Part 1 Washer-Disinfector General Requirements (2020)
  Part 2 Requirements and Test Methods 2009
  Part 5 Test Soils and Test Methods 2021

Different Analytes
- Visually clean
- 3/ 6,4µg /cm² Protein (Warning Level / Action Level)
- 1/ 2,2µg / cm² Hemoglobin
- 6 /12µg /cm² TOC
- 10 / 22fmol ATP
- ....

Risk Based Approach: no harm below this limit
Feasibility Based Approach : achievable with **reasonable** effort

Table 1

ISO 10993 BIOCOMPATIBILITY TESTS

DEVICE CATEGORY			BIOLOGICAL EFFECTS											
Device Type	Body Contact	Contact Duration: Limited ☐ Less than 24 hours; Prolonged ☐ 24 hours to 30 days; Permanent ☐ Over 30 days	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Systemic Toxicity (acute)	Pyrogenicity	Sub-acute and Sub-chronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity
Surface	Skin	Limited	•	•	•								
		Prolonged	•	•	•								
		Permanent	•	•	•								
	Mucosal Membrane	Limited	•	•	•								
		Prolonged	•	•	•								
		Permanent	•	•	•			•	•				
	Breached or compromised surfaces	Limited	•	•	•								
		Prolonged	•	•	•								
		Permanent	•	•	•			•	•				
External Communicating	Blood Path, Indirect	Limited	•	•	•	•	•				•		
		Prolonged	•	•	•	•	•				•		
		Permanent	•	•		•	•	•	•		•	•	•
	Tissue/Bone/ Dentin	Limited	•	•	•								
		Prolonged	•	•	•	•	•	•	•	•			
		Permanent	•	•	•	•	•	•	•	•		•	•
	Circulating Blood	Limited	•	•	•	•	•				•		
		Prolonged	•	•	•	•	•	•	•	•	•		
		Permanent	•	•	•	•	•	•	•	•	•	•	•
Implant	Tissue/Bone	Limited	•	•	•								
		Prolonged	•	•	•	•	•	•	•	•			
		Permanent	•	•	•	•	•	•	•	•		•	•
	Blood	Limited	•	•	•	•	•	•		•	•		
		Prolonged	•	•	•	•	•	•	•	•	•		
		Permanent	•	•	•	•	•	•	•	•	•	•	•

*Additional tests may be required to satisfy FDA requirements

Table 1: Acceptance criteria for real-use instruments

Group	Examples of the instrument type	Method	Acceptance Level	Warning Level
1	Instruments without hinges or cavities (not hollowware) *Sharp spoons, retractors*	Visual inspection	≤ 3 µg/cm²	> 3 to ≤ 6µg/cm²
2	Hinged Instruments *Scissors, Clamps*	At least a semi-quantitative protein measurement after elution in a polypropylene bag	< 75 µg per Instrument (up to a length of 15 cm)	> 75 to ≤ 150 µg per Instrument
			< 100 µg per Instrument (with a length of > 15 cm)	> 100 to ≤ 200 µg per Instrument
		Elution analogous to Crile Clamps as test objects for the functional part with a hinge	< 50 µg per Instrument	> 50 to ≤ 100 µg per Instrument
3	Shift-shaft instruments*** *Punches, Rongeurs*	Quantitative protein measurement after elution of the entire instrument in a polyproylene bag	< 100 µg per Instrument	> 100 to ≤ 200 µg per Instrument
		Partial elution on the functional end in a reagent glass with ultrasonication	< 50 µg per Instrument	> 50 to ≤ 100 µg per Instrument
4	Hollowware/lumen instruments	Quantitative protein measurement, e.g., the shaft of a dismantlable instrument is sampled from the inside only (flushing of the tube)	< 75 µg per Instrument (up to 4 mm inner diameter)	> 75 to ≤ 150 µg per Instrument
			< 100 µg per Instrument shaft tube (greater than 4 mm inner diameter)	> 100 to ≤ 200 µg per Instrument
		– Working element isolated for elution, in a closed tube for example.	< 50 µg per functional portion of the instrument	> 50 to ≤ 100 µg per functional portion of the instrument
		– The jaw and its hinge is eluted in a reagent glass with ultrasonication	< 40 µg per jaw with hinge	> 40 to ≤ 80 µg per jaw with hingei
5	MIcrosurgical instruments	Quantitative protein measurement after elution of the entire instrument	< 50 µg per Instrument < 20 µg per Instrument (Ophthalmic Instruments)	> 50 to ≤ 100 µg per Instrument > 20 to ≤ 40 µg per Instrument

*

Guidance for Validation, Germany - [MHP_ZS-Supplement-ENG-2017_E-Paper.pdf (dgsv-ev.de)]

< 100µg before Cleaning

< 100µg hardly achievable

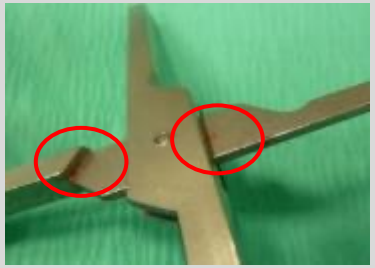
Visual Inspection is important, but not a sufficient Criteria

Visible contamination is just the tip of the Iceberg !!!

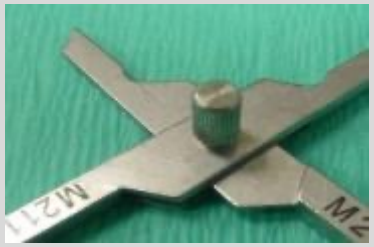
⇒ Other Test Methods

⇒ Process is Crucial !

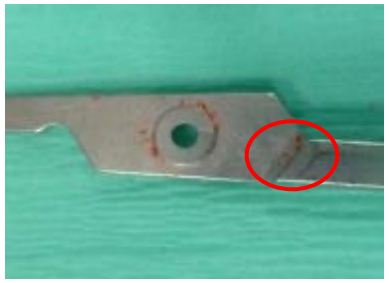
Cleaning



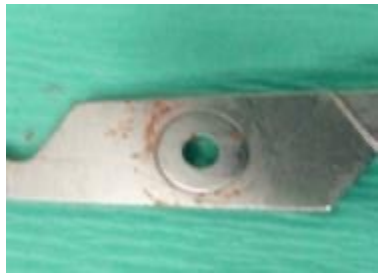
Residue !
=> post cleaning



Visually o.k.
=> sterilization



Inside



Inside

Outside surfaces are relatively easy to clean !

How to Test?

Systematics

- Test Soil
- Test Geometry
- (Recovery)
- Test Method

Example
German Guideline

Minimum
detectable Limit
(Concetration)

Protein
Biuret -
BCA -
OPA -Test

Clinically used
Instrument

reactivated
sheep blood
100µl

Crile Clamp

Cleaning
Processs

Elution SDS 1%

- Recovery Rate

Protein Test by Elution

Group 1

Group 2
(& Crile-clamp PCD)

Group 3

Group 4

- ISO 15883
- German Guideline

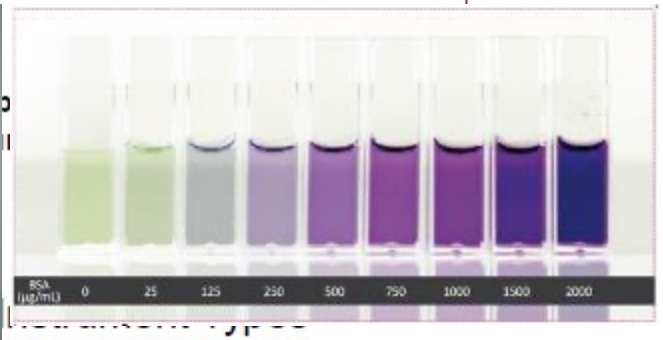
(on site or laboratory)

⇒ Joints

⇒ Lumen

⇒ Crevices

⇒ Swab (only surface)



- Incubation (Temperature)
- Photometer

Other methods

Hemoglobin

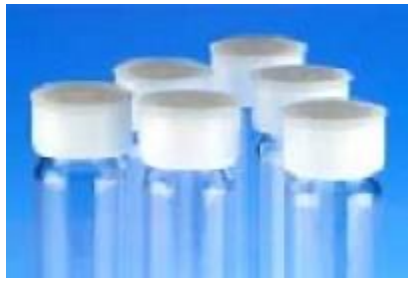
- Swab
- water soluble
- Semi -quantitative

ATP

- Swab
- Measuring RLU
- Surfaces !

- Before thermal disinfection !
- Devices can not be used for surgery afterwards

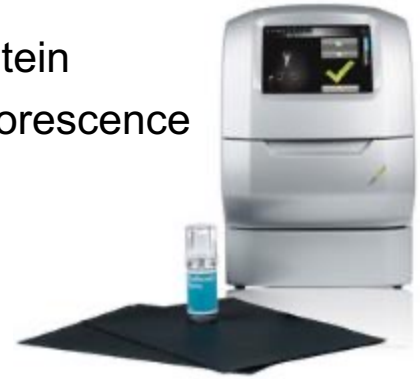
TOC

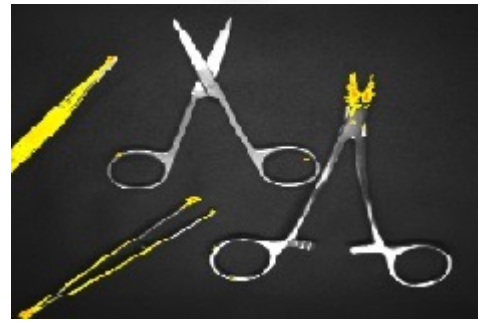


- Elution by water or phosphoric acid
- Very sensitive
- All carbon (oil,…)

Pro Reveal

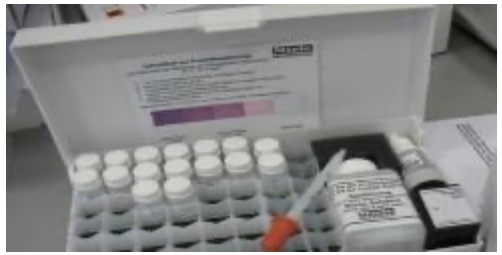
- Protein
- Fluorescence





Simplified Tests

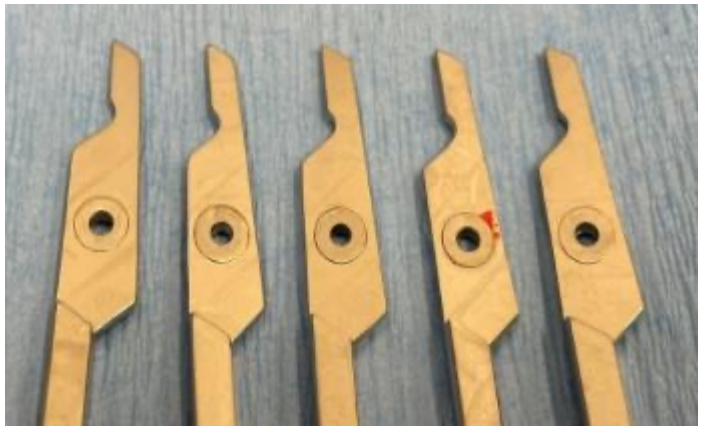
Biuret Protein Test (Room Temperature)

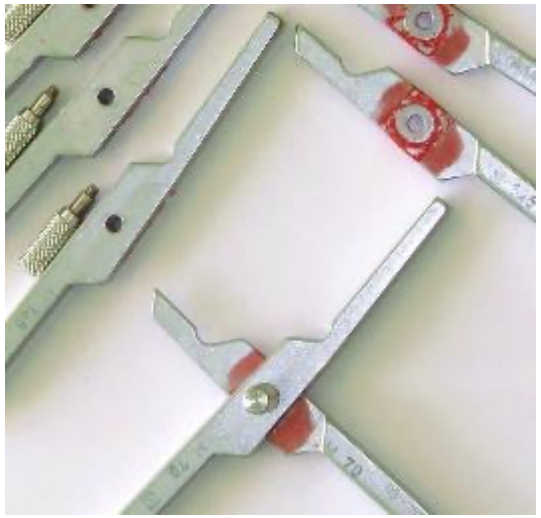


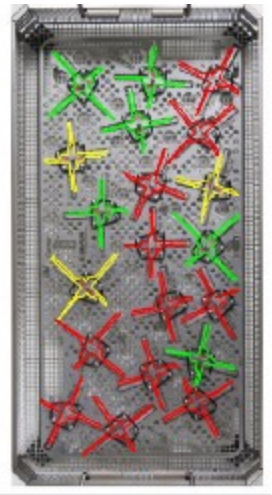
- Semi Quantitative
- Similar manual Work

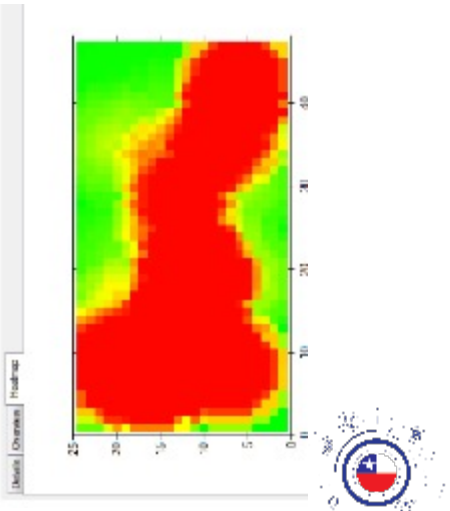
(no longer available)

Process Challenge Device (PCD) - Visual or Camera



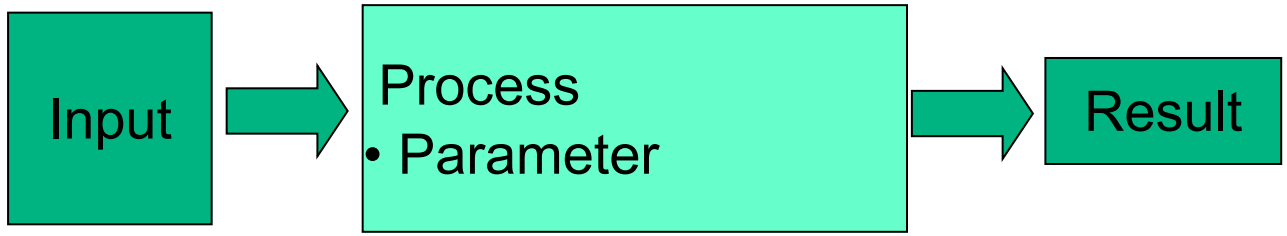






How to get a good Process…

Idea of Process Validation

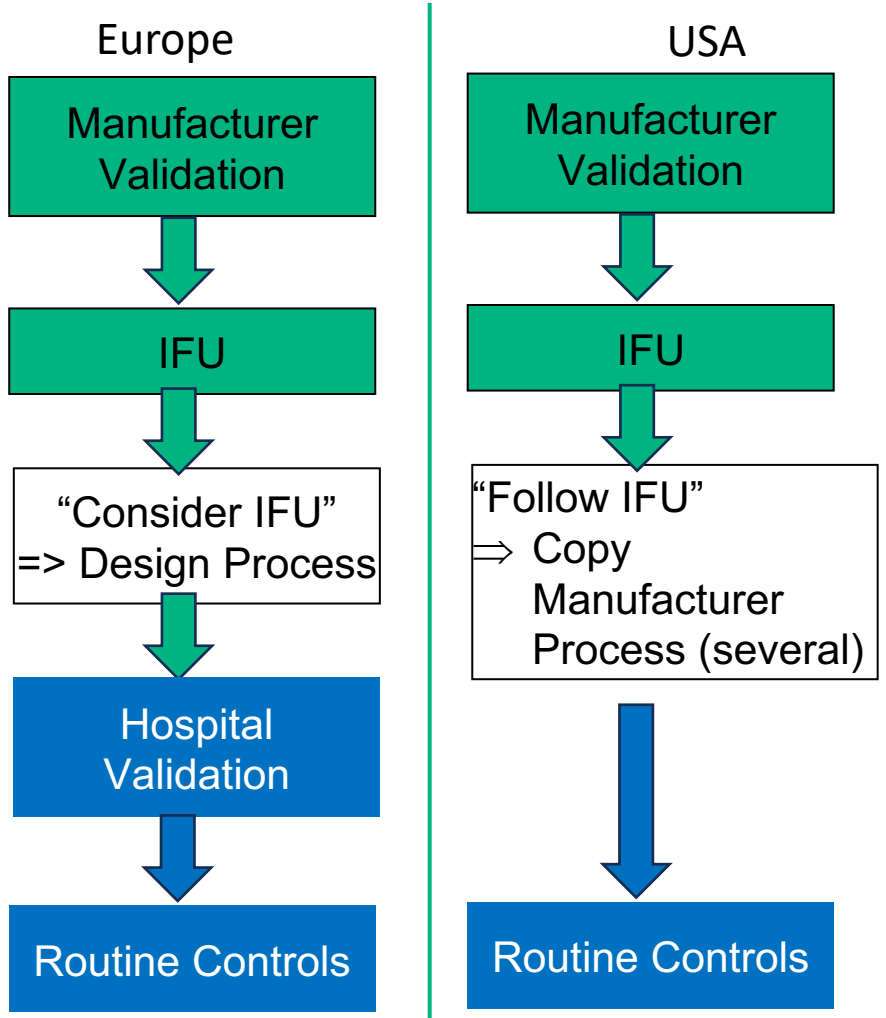


A validation gives proofs that:

- a Process
- which is completely described by Parameters
- with fixed Input
- will always give the same Results

Validations are used if a process result is important but can not be measured continuously with reasonable effort

- Multiple Instruments
- Several runs



What do we get? - Challenge of Variation

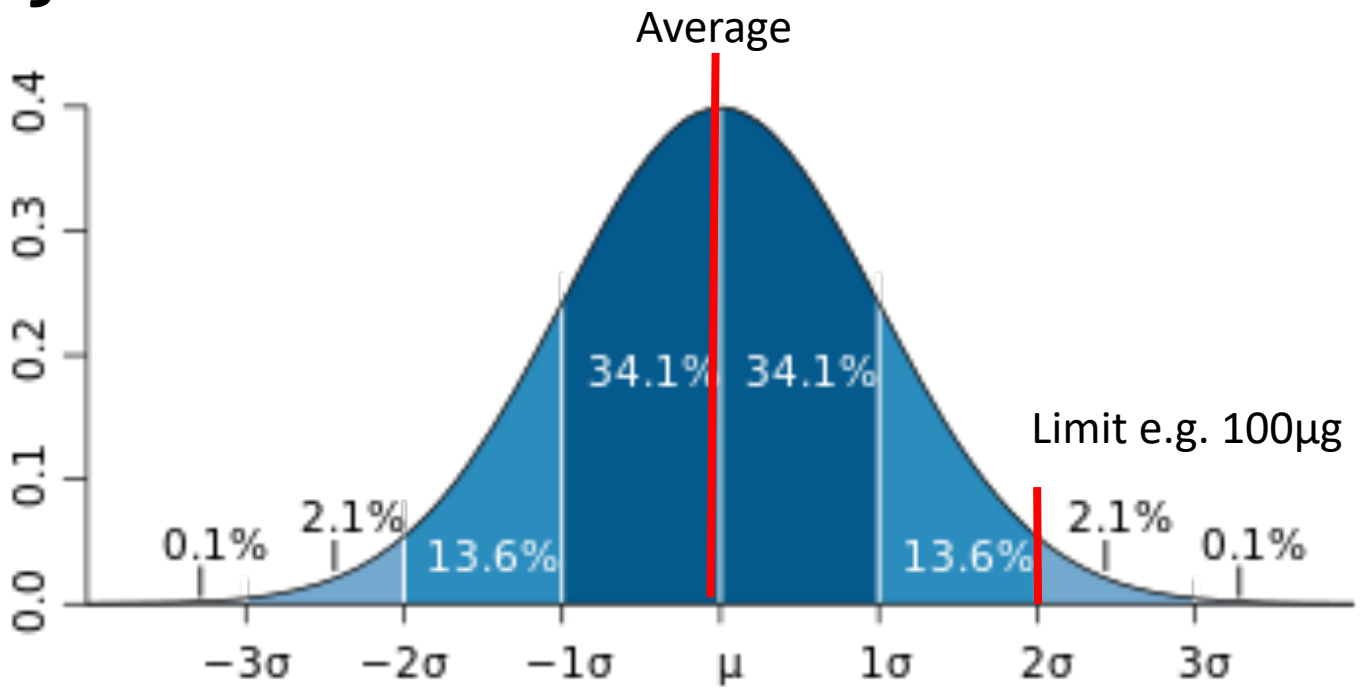
Clinical Instruments Variation

- Soil (Blood, Bone, Salvia, Disinfectants….)
- Geometry
- Waiting Time

Process Variation

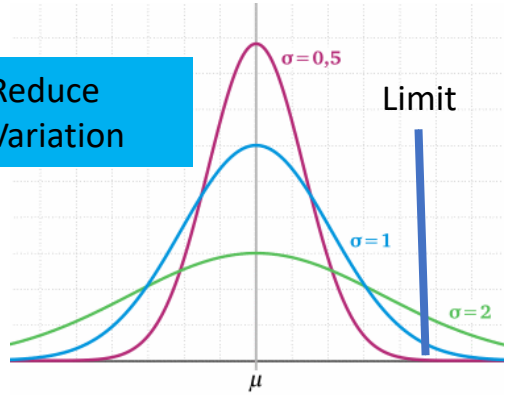
- Position
- Loading
- Random…..

=> How standardized? Worst?

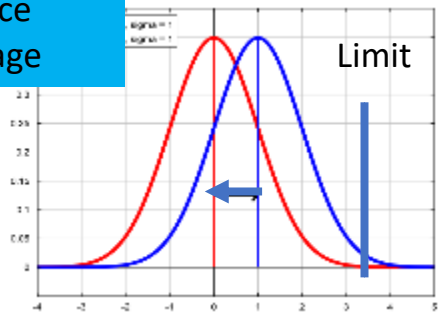


- High Standard Deviations (10-25µg)
- Outliers
- Difficult to achieve 1 log safety (10µg versus 100µg)

Reduce Variation



Reduce Average



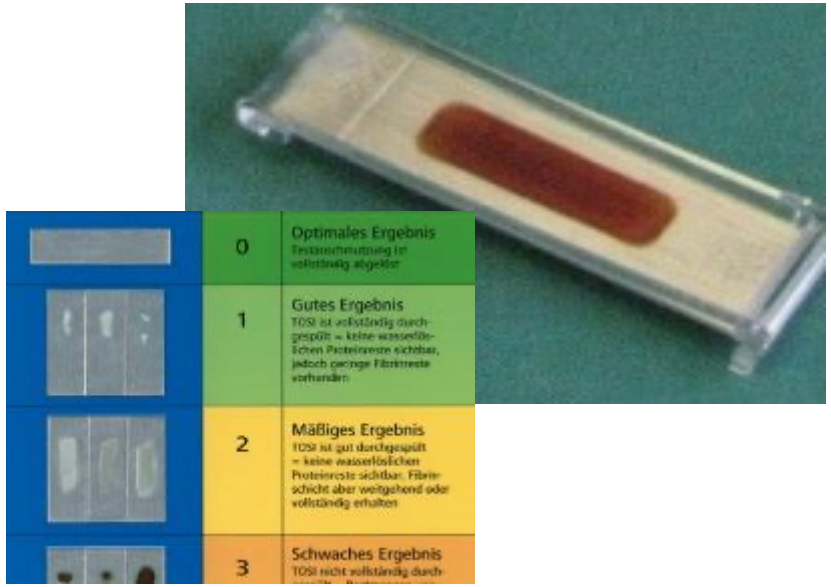
What may go wrong?

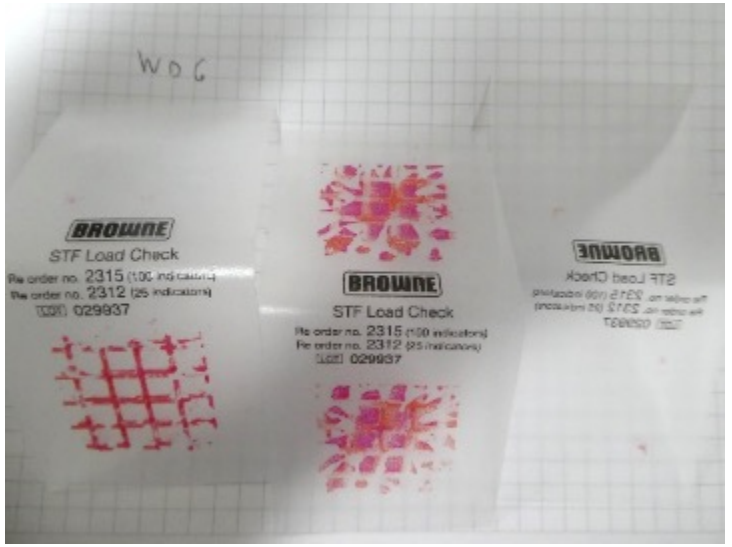
- Temperature / Time (Machine ?)
- Wrong Dosage (Machine ?)
- Poor Pressure
- Blocked Spray Arm
- Wrong Cleaner
- Bad Water Quality
- .....

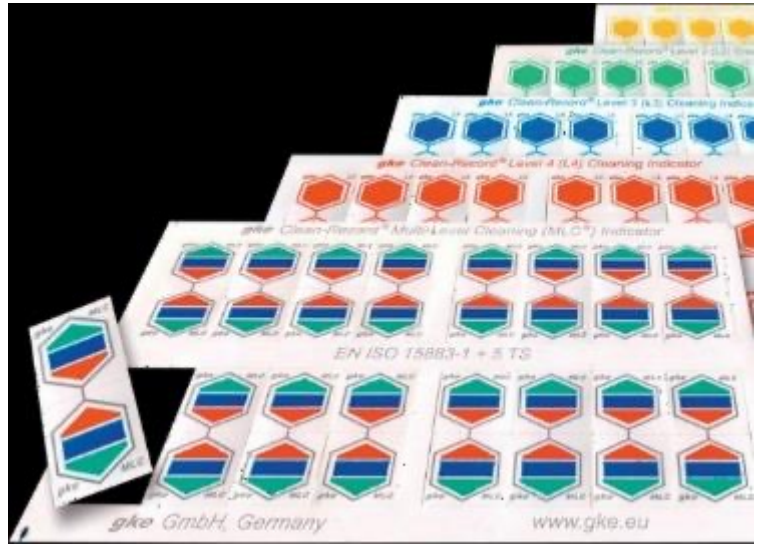
What does a routine Control do?

- Test Soil (Behavior ?)
- Geometry (As Instruments ?)
- Location / Loading (Always the same?)
- Visual Inspection (Criteria ?)

- Safety Margin?





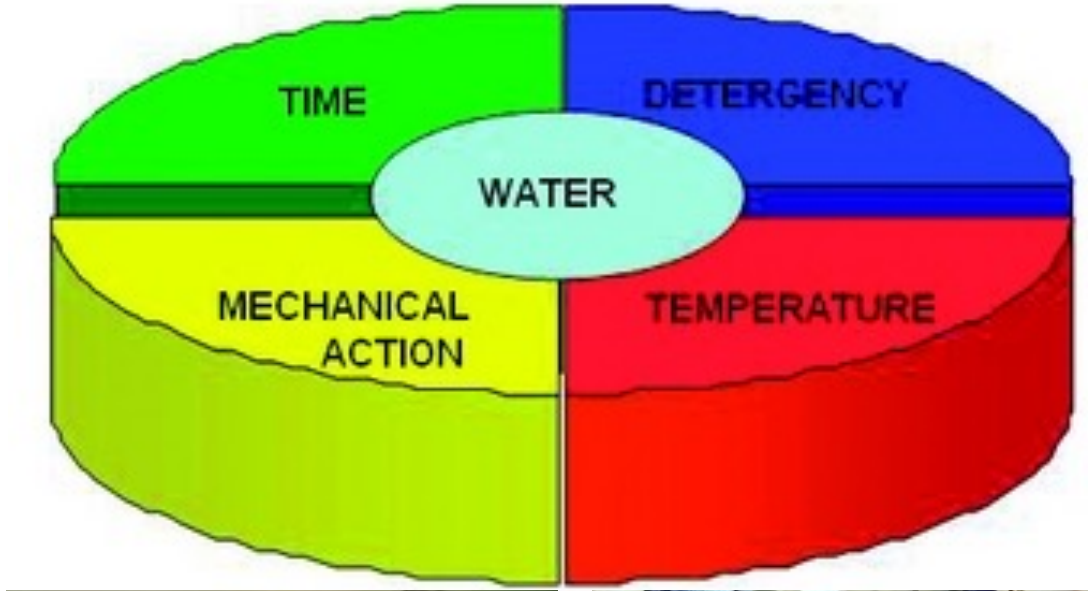


Influence Factors

OR Factors
- Instrument Design
- Contamination

Manual Preparation
- Pre-Cleaning in OR
- Time of Transportation
- Mode of Transportation (Dry, moist,....)

Manual Cleaning
- 20°C (-40°C)
- Neutral or mild alcaline detergent
- Time ?
- **Mechanical Action !**



Mechanical (Machine) Cleaning
- Loading Cart
- Loading

- Spray (Machine Design)
- Pressure

- Pre-Cleaning
- 45°C – 75°C
- Cleaning Time
  - Heating Time
- Detergent (Dosage, Dosage Temp)
- Water Quality

Examples from IFU – Manual Process

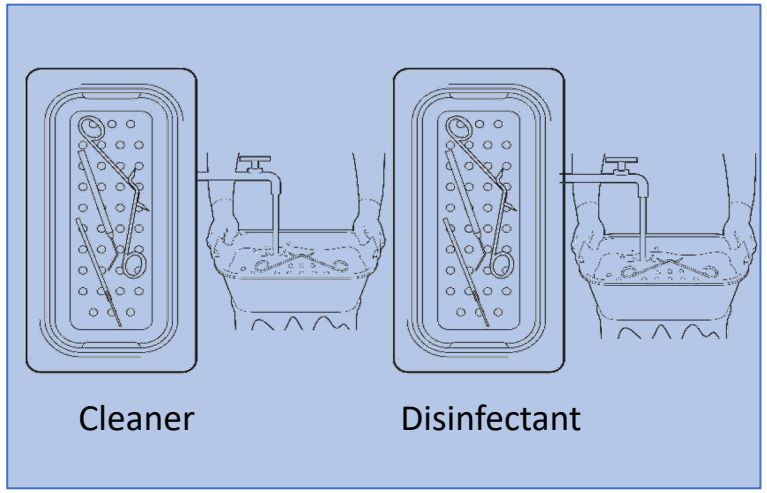
Europe

- Cleaning
  - Shower
  - Ultrasound (5-15min)
  - Brush

  (Neutral Enzymatic, Alkylamine, Mild Alkaline)
- Rinse
- Disinfect (Alkylamine, Aldehyde)
- Rinse (demineralized Water)
- Dry (Drying Cabinet, compressed Air)

- Packing
- Steam Sterilization

« Protection of People in packing Area »



USA

- Cleaning
  - Soaking (10min)
  - Brush
  - (Ultrasound 5min)

  (Neutral Enzymatic)
- Rinse (demineralized Water)
- Dry (Drying Cabinet, Cloth)

- Packing
- Steam Sterilization

« Either Disinfection or Sterilization»

Examples from IFU – Machine Cleaning

Europe

Time	Program Step	Temp. / Water	Chemistry
(ca 5 min)	pre clean	20°C, soft water 3min	none
(ca 15 min)	Cleaning	55°C, 10min Demi Water	Mild Alcaline Cleaner
(ca 4 min)	intermediate rinse	Demi Water	none
(ca 12 min)	final rinse, thermal disinfection	93°C 3 min A°3000 Demi Water	None Evtl. Rinse aid
(ca. 15 min)	Drying	-130°C, circulating	
Total Time 55-60 min			

USA (with pre cleaning)

Time	Program Step	Temp. / Water	Chemistry
(ca 3 min)	pre clean	20°C, soft water cold 1min	none
(ca 7 min)	Cleaning	60°C, 5 min soft water, hot	Neutral / Enzymatic Cleaner
(ca 2 min)	intermediate rinse	soft water, hot	none
(ca 9 min)	final rinse, thermal disinfection	90°C 1 min A°600 Demi Water	Lubricant/ Rinse aid
(ca. 12 min)	Drying	-130°C, circulating	
Total Time 35-45min			

Manual Cleaning

- Blood and Test Soil
- Elution and BCA-Protein Test

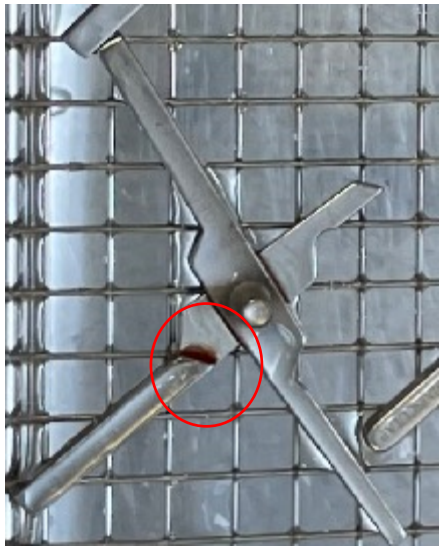
- Little effect of soaking
- Limited removal by Ultrasound only

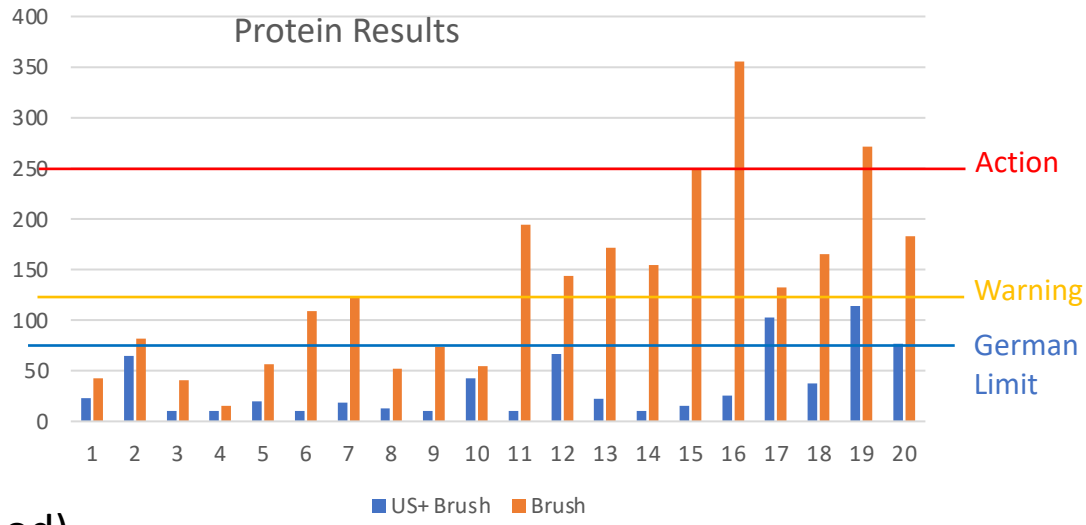
- Brushing more effective on Test Soil (brittle)

Protein Test
- OK with brushing (until Visibly clean)
  - Ca 45s per instrument
- Good effect with Ultrasound and Brush

- Acceptable ???
- High Variation !

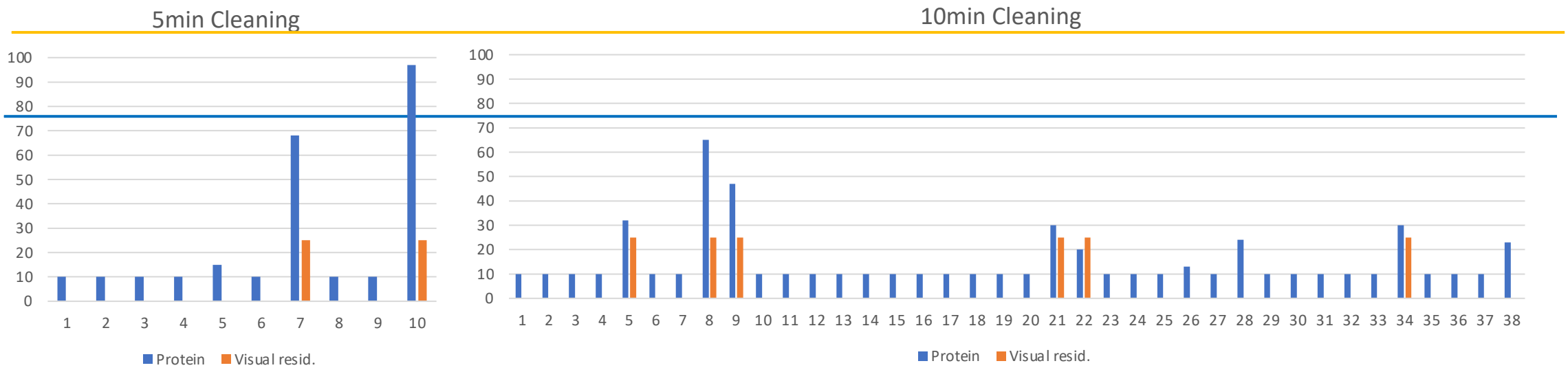
PCDs after Soaking only (Blood and Test Soil)





PCDs after US only (Blood)

Cleaning Time (Protein)

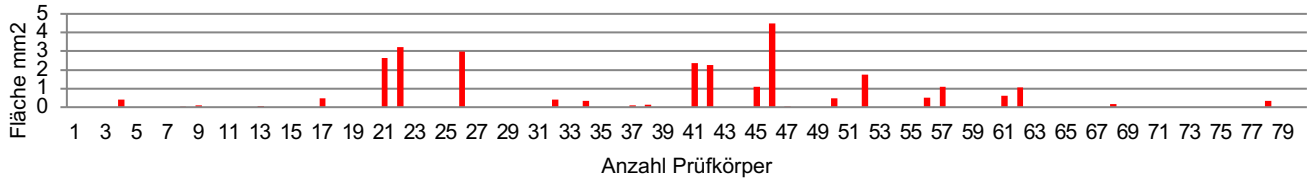


- 5min: 20% visual residue, 20% 70-95µg Protein
- 10min: 15% visual residue, 5% 45-65µg, 15% 15-30µg Protein

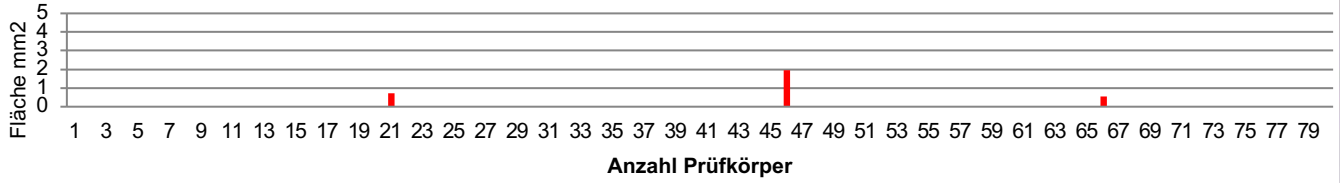
Based on PCDs

Effect of Time

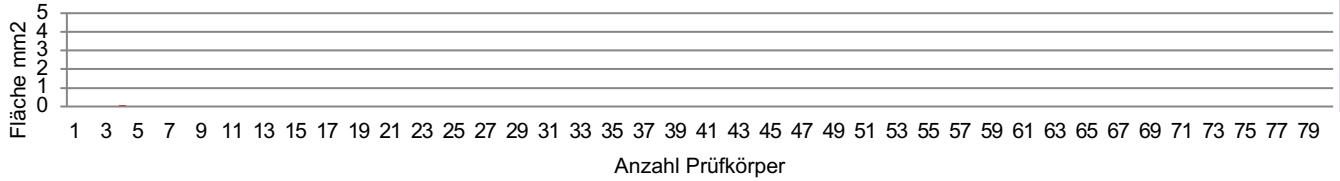
Holding 5 Min. - Ø0.34mm2



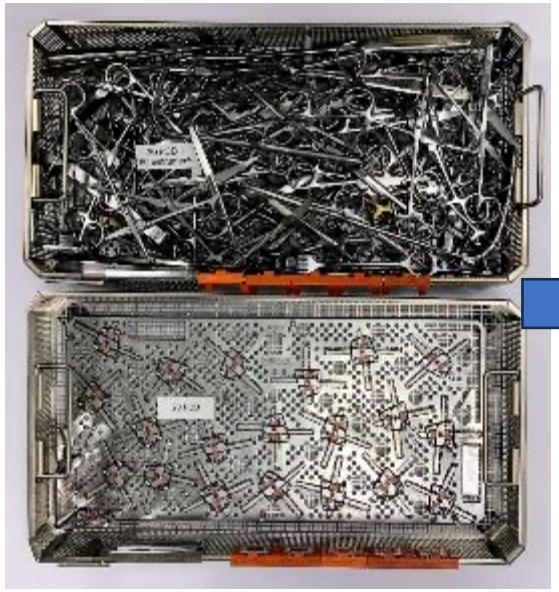
Holding 10 Min. - Ø0.041mm2

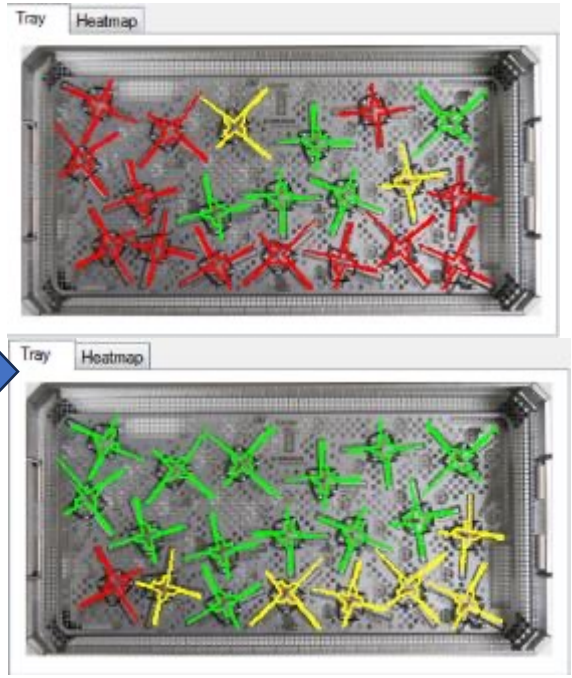


Holding 20 Min. - Ø0.001mm2



Effect of Loading



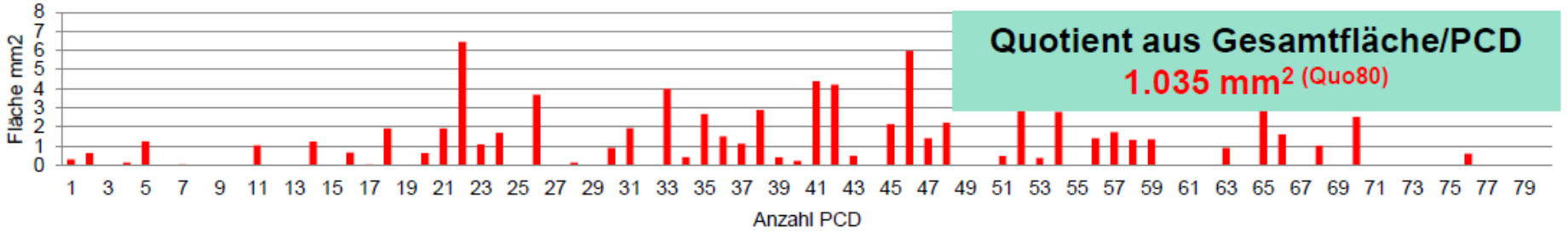


Test Results

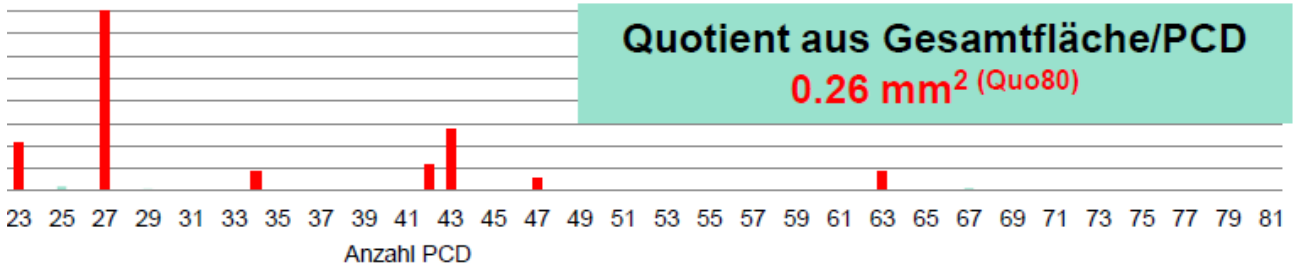
Machine Cleaning

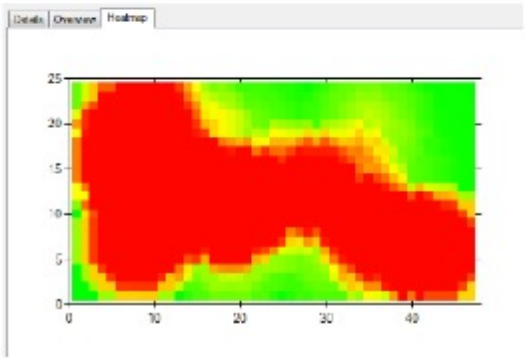
- Pressure (Mechanics)
- Cleaning Time
- Cleaner
  - Tenside
  - Alcalinity
  - Enzymes
- Cleaner adapted temperature
- Water quality
- (Machine pre cleaning)

Low water / pressure

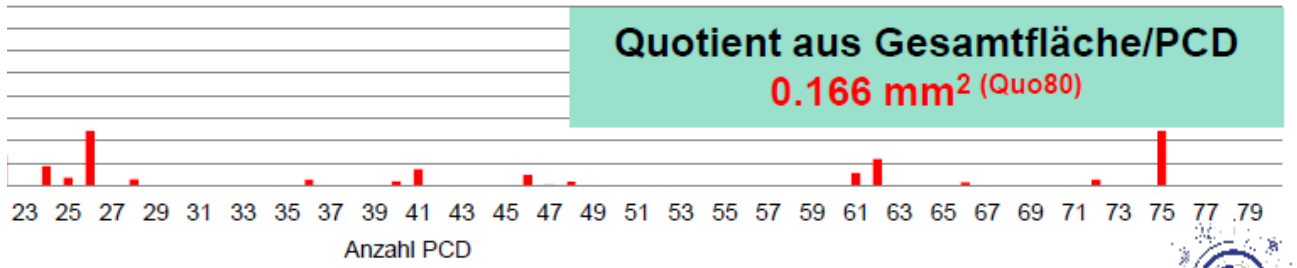


Standard water / pressure





Elevated water / pressure



RECOMMENDATIONS

Part 1 – Pay more Attention to proper Cleaning

- Use washer-disinfectors whereever possible !
- Test / validate Results !
- Define Relation Manual / Machine-Cleaning
- Optimize Cleaning Processes
  - Higher Performance creates Saftety Margin
- Do efficent routine Controls
- Have a Quality Control Strategy

Remember:

- « If it is not clean, you can not sterilize it ! »
- « Science is valid worldwide »

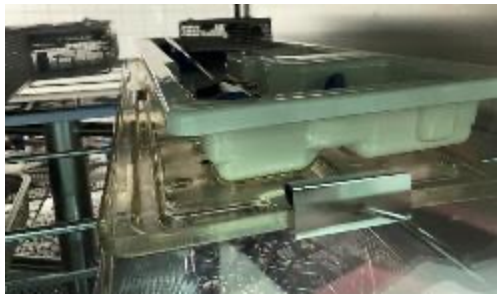
This is so much work....

Safety => 1 log

Steam Sterilization => 6 log

- Bowie-Dick Test
- Vacuum Test
- Biological Indicator
- Chemical Indicator
- .....

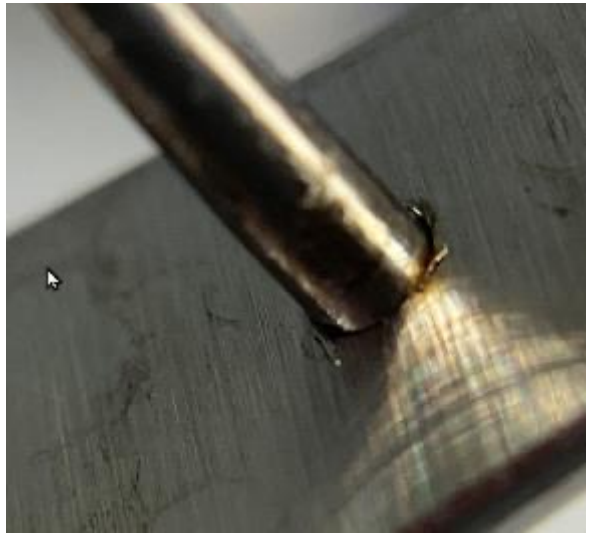
Loading



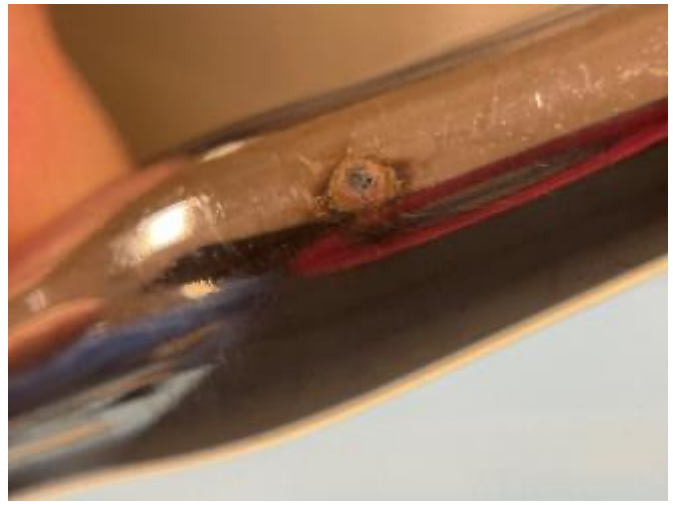
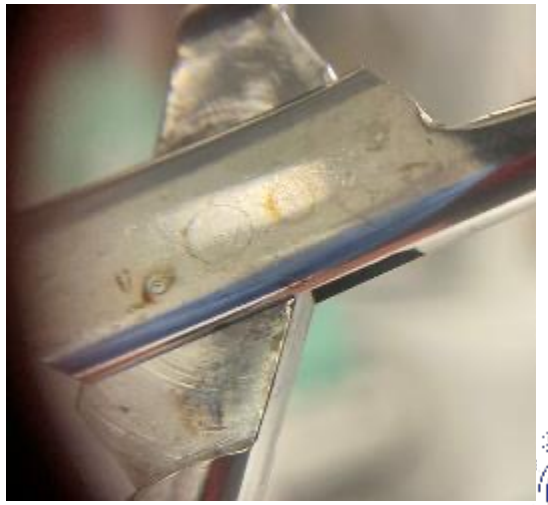
- Split bigger Trays or use wide Stringers
- Wash System Trays separately
- Place minimal invasive Instruments in special Racks
    - Lumen Connection (inner cleaning)

Watch your Instruments !





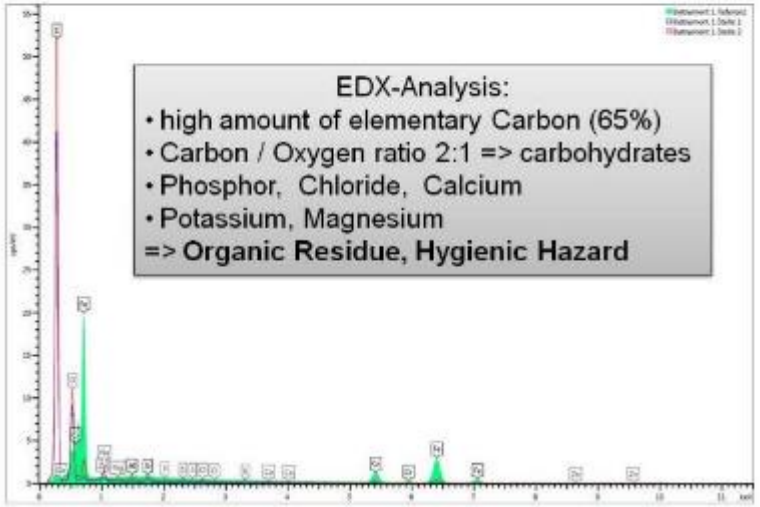

Visible Residue on Instruments indicates Process Errors !

Side Note: Brown Stains on Instruments – Corrosion or Residue?

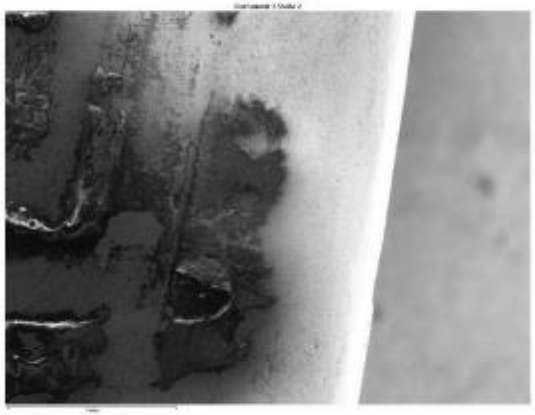
- REM-Picture: Structure / Dimension
- EDX Analysis

Instruments picked from working Sets
primary Asessment: Corrosion



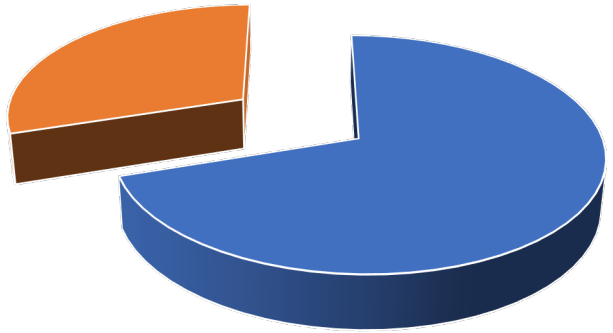
EDX-Analysis:
- high amount of elementary Carbon (65%)
- Carbon / Oxygen ratio 2:1 => carbohydrates
- Phosphor, Chloride, Calcium
- Potassium, Magnesium

=> **Organic Residue, Hygienic Hazard**



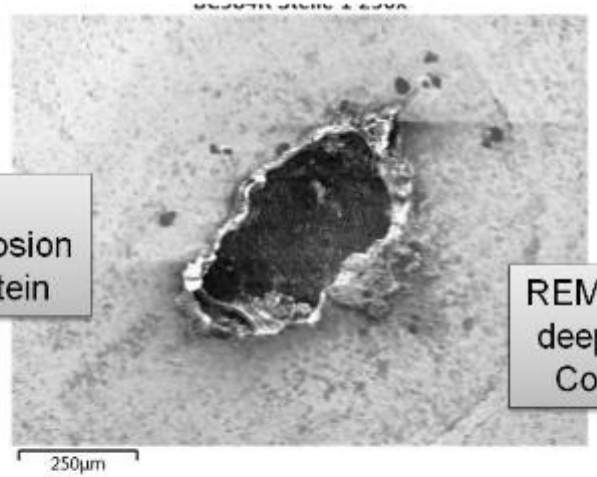
REM Picture => Structure, Volume
here: about 90µg of Protein

Condition of Instruments



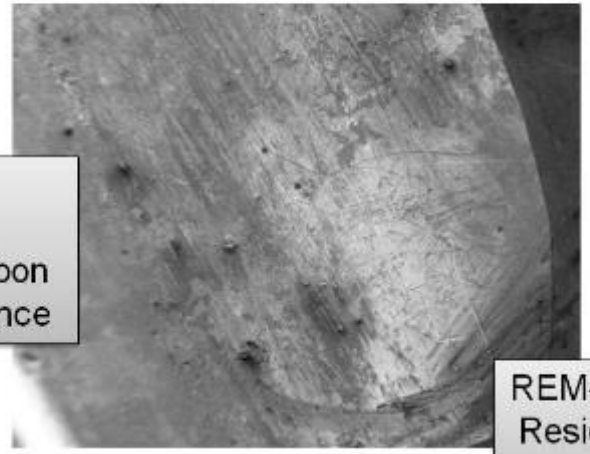
In average 30% have Surface Changes or functional Damages

Example:
Old Pitting Corrosion
here 63µg Protein



REM-Picture:
deep Pitting
Corrosion

Example:
12% Carbon
no link between carbon
and visual appearance



REM-Picture:
Residue on
Surface

Results:

- In 24 of 34 analyzed instruments, the elementary carbon content of residue was more than 10%
- Co-Elements like Nitrogen, Sulfur, Potassium frequently point **towards organic / patient residue**

Wfhss 2017

Part 2 – Quality Control Strategy .....

- Education / Standards
- Equipment (Magnification)
- Time

What to do, if…..

- Easily accessible back up stock
- Procedure for 2nd cleaning
- Fast and thorough repair / replace process (out of CSSD)

Backup

Remove

"2nd Cleaning"

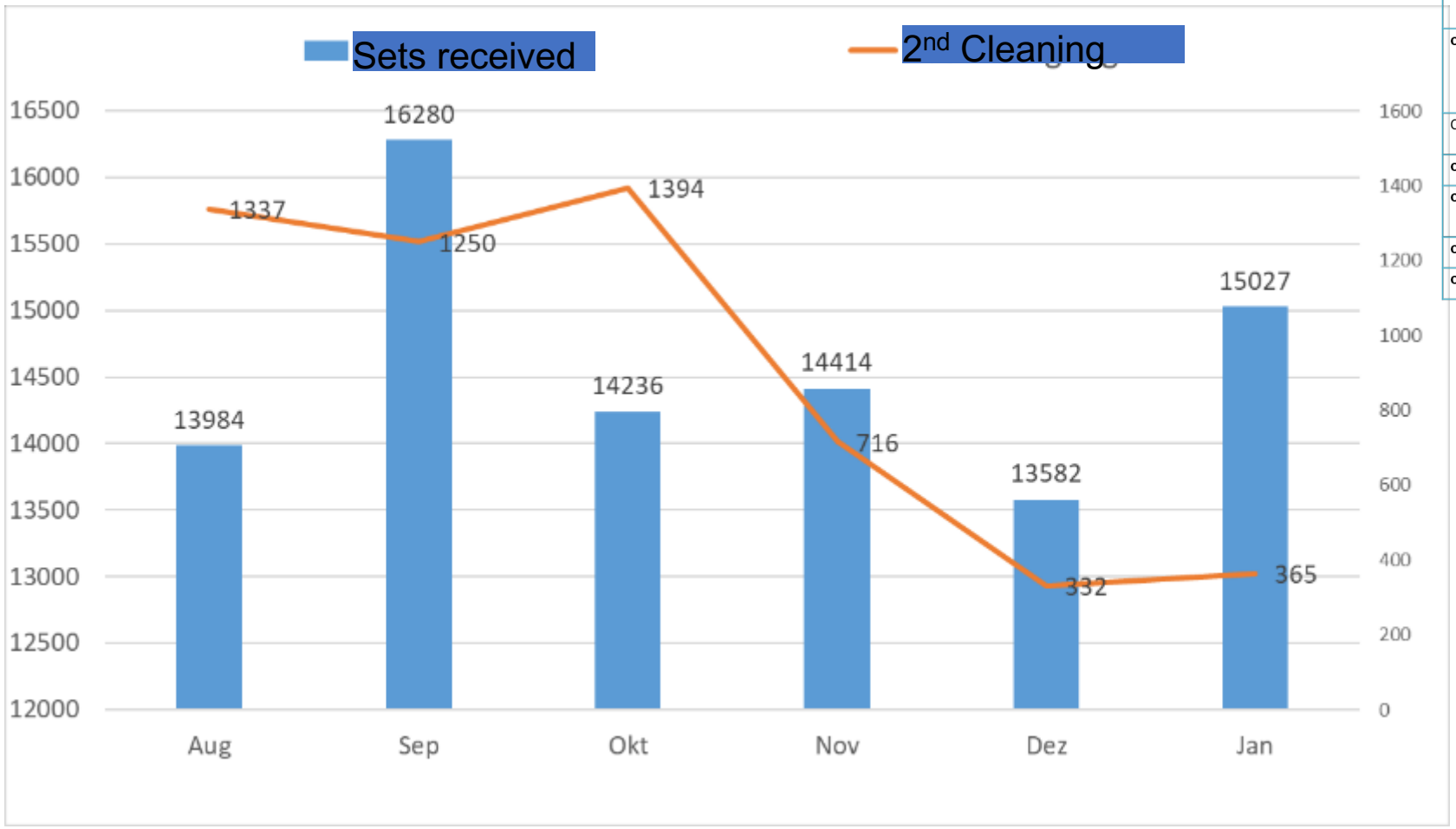
Repair

Quality Management

- 2nd Inspection
- Record of findings

Inspection Result			Date / Name		
Set	Item Code	Description	Age / repair / Machine	Issue	Action

It works.....



Zeit	Schritt	Wasser / Temp.	Chemie
ca. 4 min	Vorreinigung	Weich- Wasser ca. 25°C	-
ca. 20 min	Reinigen	VE-Wasser Dosierung bei 35°C 5min 45°C 10min Haltezeit bei 58°C	**Thermosept Xtra 6ml**
Ca 6min	Neutralisation	VE-Wasser 3min /50°C	Thermsoept NKZ 2ml/l
ca. 1 min	Zwischenspülung	VE-Wasser	**keine**
ca. 10 min	Schlussspülung, thermische Desinfektion	VE-Wasser , vorgeheizt 4min, 93°C	**keine**
ca. 14 min	Trocknung	75°C	
ca. 65 min			

- Pre cleaning with detergent 1ml/l
- Additional 5 min cleaning 45°C / 55°C
- Neutralization

Let us go for better cleaning !

Thank you very much for your kind attention !

Dr. Gerhard Kirmse

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