



World Federation for
Hospital Sterilization Sciences

DGSV

Deutsche Gesellschaft für
Sterilgutversorgung e.V.

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c/o PGR | IG4pro

**Evaluation of the efficacy of manual
versus
fully automated cleaning procedures
on surgical instruments**

Working Group

- Project Group Cleaning (PGR), joint group of instrument manufacturers
- Interest Group for Processing (IG4pro)
- Objective
 - Identification of worst case design characteristics
 - Comparison of test devices with real instruments allowing a simplified validation of cleaning those geometries
 - Education, publication, standardization

Working Group

- History

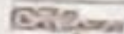
36 | ORIGINAL ARTICLE

Central Europe 15011

Investigations into reproducible cleaning of instruments based on a worst-case model

Project Group Cleaning PGR

Journal Article 2017, 9 (4): 425-437



Keywords

- surgical instruments
- sterilization
- process challenge device

Sterilisability of Reusable Surgical Instruments

Part 1: General Introduction – PCO Designing Process – Experimental Design

Working Group Reusable Instruments

DERBY
DOWN With IAHCSMM



From the Sterile Site to the Front Line • Keeping 100% Infection-Free

Journal Article 2017, 9 (4): 438-449

Keywords

- surgical instruments
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- process challenge device

Sterilisability of Reusable Surgical Instruments

Part 2: Study Results – Implications for Working Practices in the CSSD

Working Group Reusable Instruments

Agenda

- PCD (Process Challenging Device) – critical design
- Contamination and Acceptance Criteria
- Manual cleaning
- Automated cleaning
- Summary and Outlook

Critical Geometries in Standard Instruments

- instrument surfaces
- crevices
- luminae
- mated surfaces
- threads
- angled crevices

Is a narrow crevice more or less critical than a wide one?



Is a narrow crevice more or less critical than a wide?

- Instrument Box Locks come in various sizes
- crevices vary widely depending on manufacturer, design, lot and age
- not detachable
- no visual control possible
- effect of axis questionable



PCD – Process Challenging Device

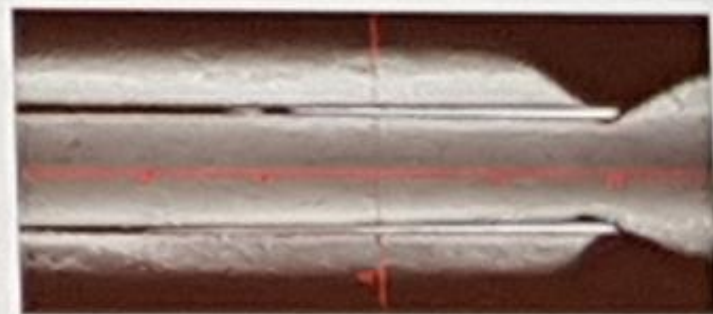
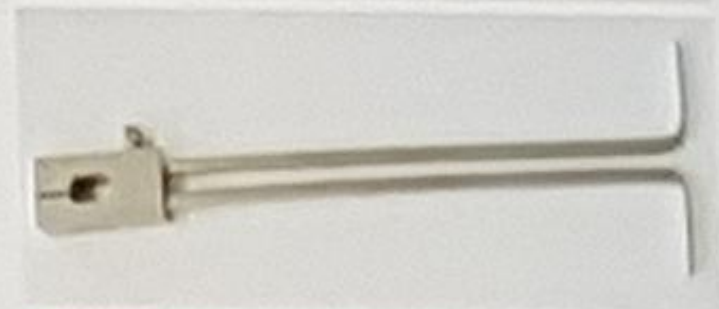
• Characteristics

- the geometry feature posing the greatest challenge to cleaning is the crevice
- PCD with different crevices widths corresponding to the range of instruments with box locks

• Cross Check

- To link the PCD results to „real instruments“ a typical box lock instrument was added (needle holder)
- crevice width varies between 0,04 mm - 0,11 mm
- Shows the transferability to PCD

Gap width (mm)	Surface Area (mm)
0,03 mm	10x10
0,11 mm	10x10
0,27 mm	10x10
0,42 mm	10x10



Contamination

- **Test soil characteristics**

- Heparinized sheep blood + sterile water 9:1
- Addition of 150 ml protamine sulfate to 10 ml test soil prior to contamination
- Coagulation time $3 \text{ min} < t_c < 6 \text{ min}$

- **Application of test soil**

- Cavities of PCD / needle holder completely filled with test soil
- Amount of test soil depending on cavities width
- Contaminated devices allowed to dry for 1h under laminar flow



Test Device	Applied Soil
PCD 0,03 mm	10 μl
PCD 0,11 mm	20 μl
PCD 0,27 mm	40 μl
PCD 0,42 mm	60 μl
Needle holder	50 μl

Acceptance Criteria

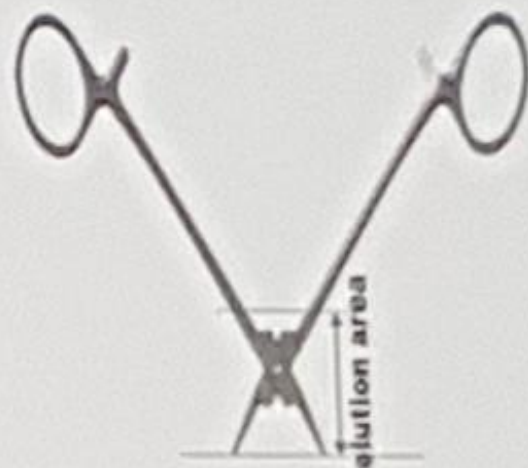
1. Visually Clean

2. Protein content (BCA)

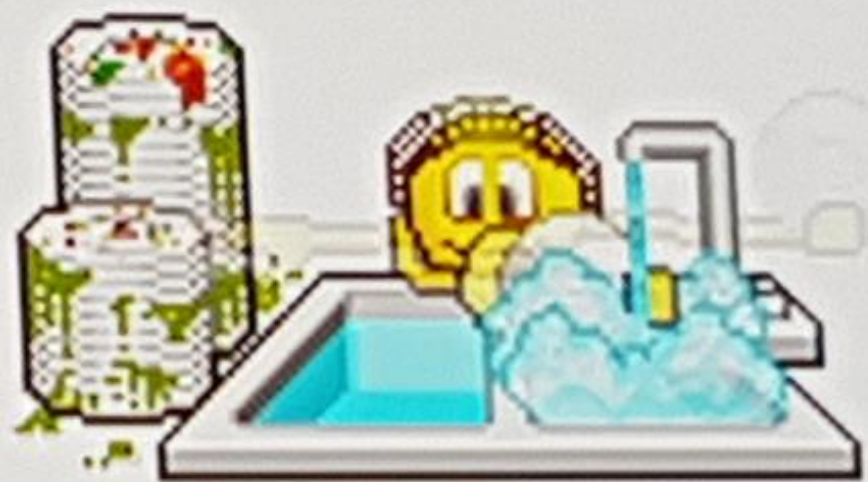
- Based on recommendation by DGKH, DGSV, AKI and VAH*
- Limit $< 3,0 \mu\text{g}/\text{cm}^2$
- Only contaminated area diluted by SDS



	PCD	Needle holder
surface area [cm ²] of elution area	5,8	20,4
limit [$\mu\text{g}/\text{item}$]	$<17,4$	$<61,2$



*Source: Leitlinie zur Validierung der manuellen Reinigung und manuellen chemischen Desinfektion von Medizinprodukten



MANUAL CLEANING

Manual Cleaning Process

- **Development of manual cleaning process**

Test Sample	Gap width (mm)
PCD 1	0,03
PCD 2	0,11
PCD 3	0,27
PCD 4	0,42
Needle holder	0,04-0,11

Process step	Screening 1	Screening 2	Screening 3
Rinsing	Unspecified	Unspecified	Specified
Ultra sonic	-	Yes	Yes
Brushing	Unspecified	Unspecified	Specified
Rinsing	Unspecified	Unspecified	Specified
RESULTS	fail	variance	passed

Manual Cleaning Process

- Development of manual cleaning process

Test Sample	Gap width (mm)
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RESULTS	fail	variance	passed



Example of failure

• Manual Cleaning Process

- Outer surface flushed and brushed under running cold tap water until visually clean (PCDs closed / NH 90° opened)

→ Video:



- Ultrasonic treatment for 5 minutes (0,7% Cidezyme).

→ PCDs closed / NH 90° opened



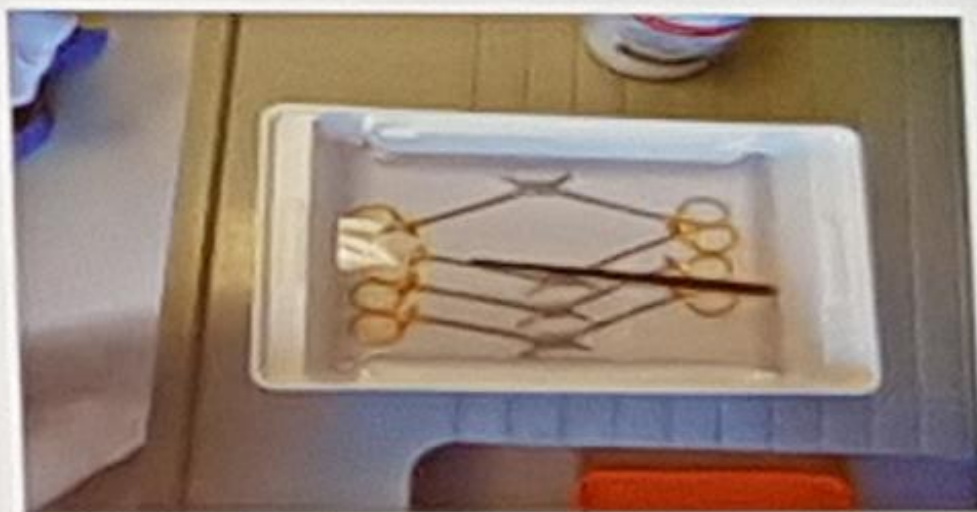
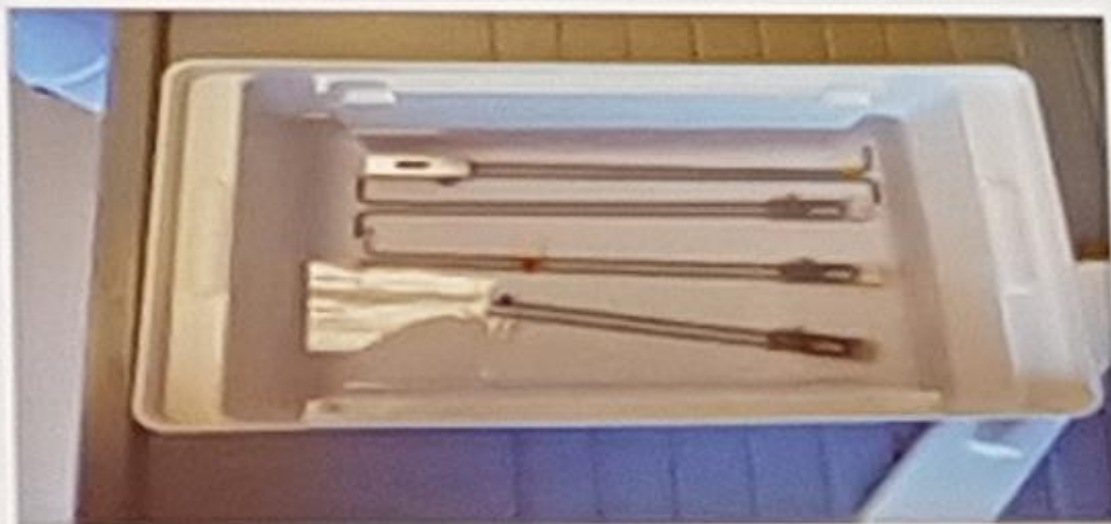
• Manual Cleaning Process

- Neutralization for 10 sec under running cold tap water (PCDs closed, orientation of the crevice towards water stream/ NH 90° opened)

→ Video:



- Soaking in cleaning detergent (0,7% Cidezyme at room temp.) for 5 minutes (PCDs closed / NH 90° opened. NH were closed and opened for 5 times at the beginning)



• Manual Cleaning Process

- After the 5 min exposure time underneath the water surface: brushing from each side of the crevice for 5 times (same for PCDs and NH)

→ Video:

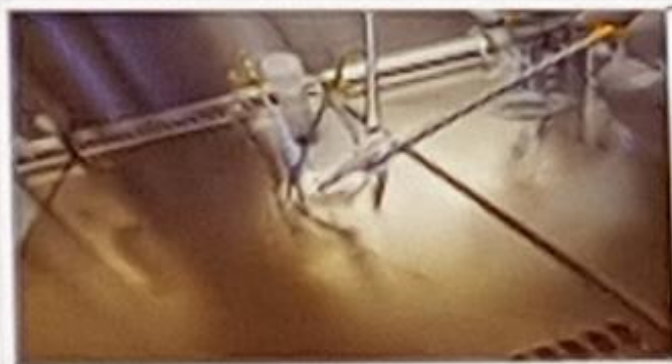
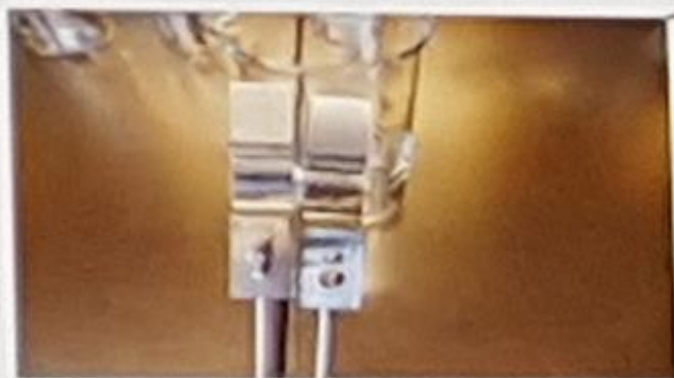


- Rinsing for 10 sec. under running cold tap water (orientation of the crevice towards water stream)

→ Video:



Visual Results

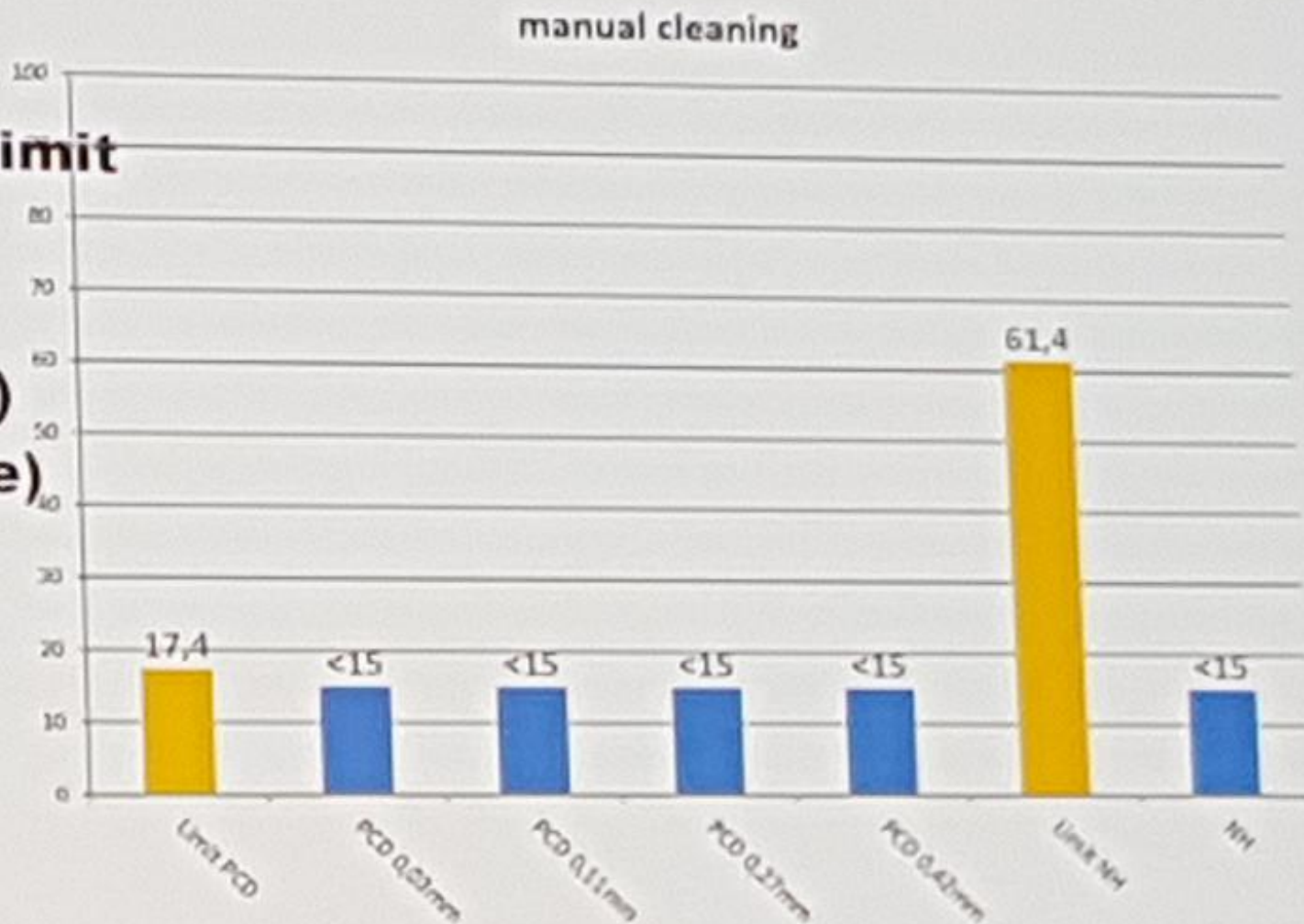
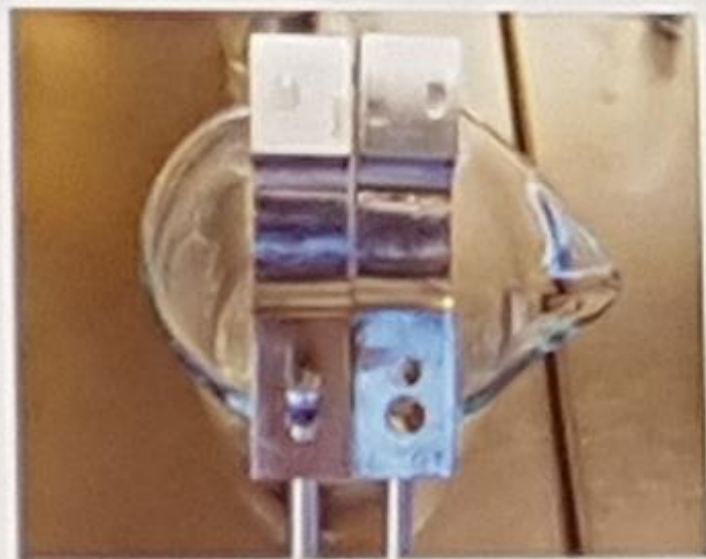


Results

<15 μ g = below detection limit

Good results:

- Needleholder (9 results)
- All PCDs (9 results / size)



Note: each result consists out of 9 single test results

Lessons learned

- **Effective / successful manual cleaning requires thoroughly following the described steps in the *IFU* = the validated cleaning procedure**
- **Even small deviation, e.g. influence of operator, could have a huge impact on the results**
- **SOP/Instructions must be as specific as necessary**
- **Significant labor efforts for each individual instrument**

Machine Cleaning Process

- Loading in standard mesh basket
- Machine Miele 7835CD
- Cleaning Process
 - European standard process

1

- Precleaning; 4 min

2

- Cleaning; alkaline, 5ml/l; 10 min, 55° C

3

- Neutralization; 1 min

4

- Rinse, 2 min

Test Sample	Gap width (mm)
PCD 1	0,03
PCD 4	0,42
Needle holder	0,04-0,11



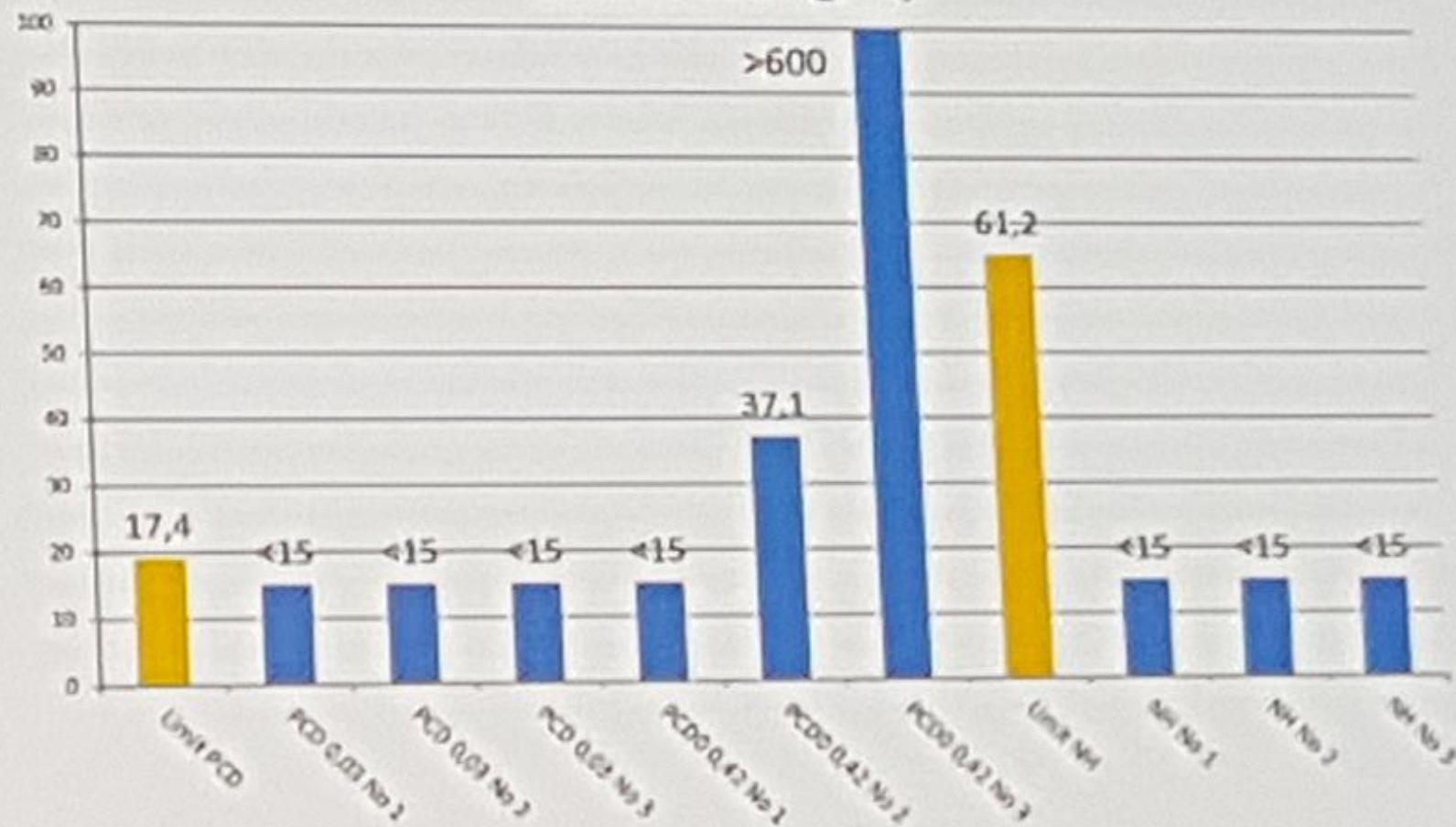
Crevice orientation of PCD

Results

<15µg= below
detection limit



Machine Cleaning only

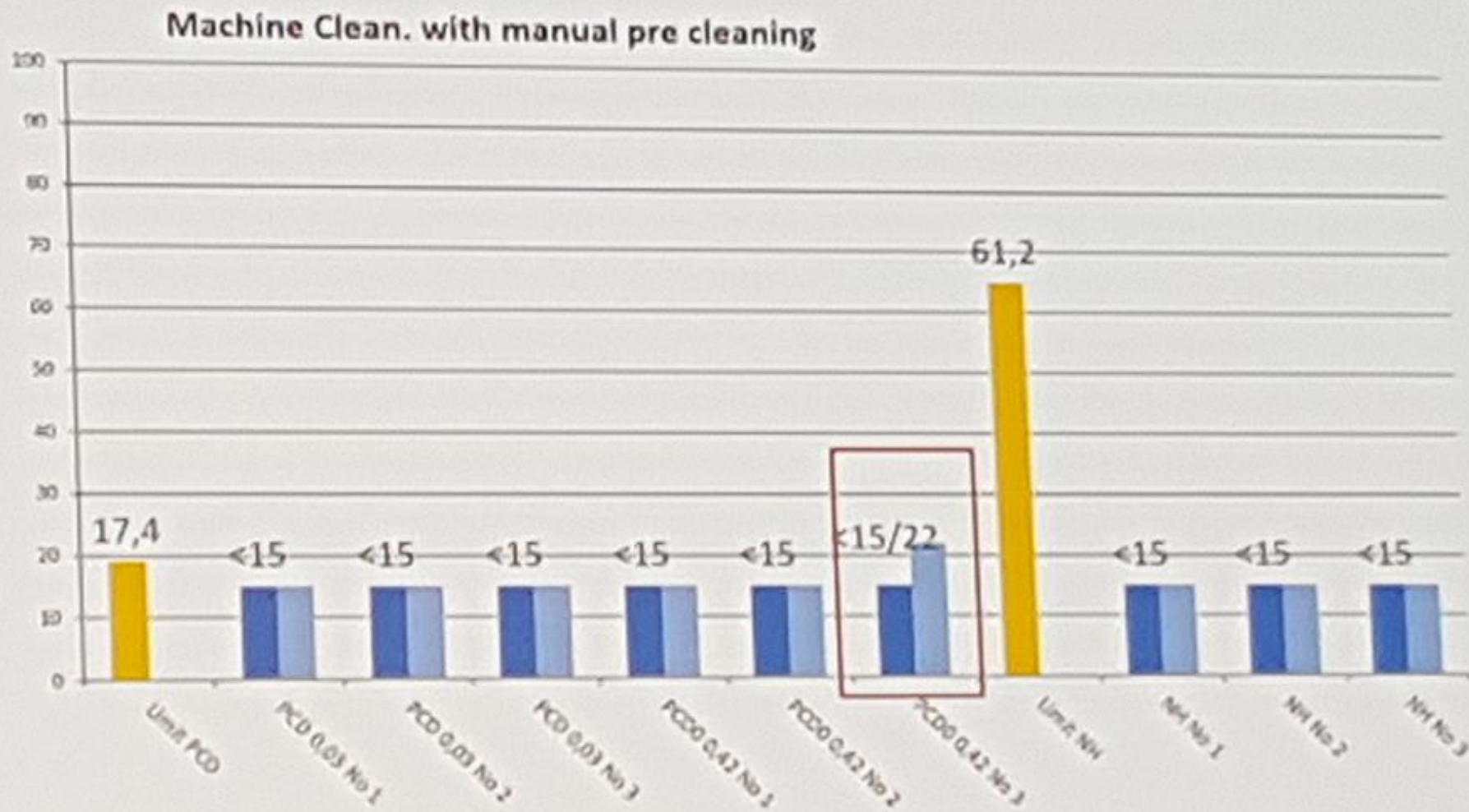


2nd Test

- **Additional manual Pre Cleaning due to strong deviation of results for widest crevice**
- **Manual flushing before machine cleaning process**
- **machine cleaning process as before**

Results

- Visually all clean
- One PCD 0,42 mm slightly above AC



Lessons learned

- **Machine cleaning can provide stable good results, but depends on**
 - geometry,
 - Process capability
- **manual pre cleaning may be required**
- **Less manual effort necessary**
- **Cleaning results / Performance needs to be verified in each specific process parameters**

SUMMARY AND OUTLOOK

Summary

- **PCDs are helpful tools to design and validate cleaning processes for user and manufacturer**
- **Automated and manual cleaning are equivalent if done right**
 - Manual cleaning requires more efforts
- **Efficacy of both processes depends on various parameters**
 - Geometry
 - Level of contamination
 - Specification of cleaning steps
 - Human factor

Outlook

- **Influence of various process parameters has to be further investigated**
- **Additional geometries represented by PCD will be investigated, e.g. MIC**





**Thank you
for your attention**