



Statistical evaluation of protein levels of test objects and real instruments after cleaning in washer-disinfectors: Results from the years 2015 - 2022

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Agenda

Motivation: Checking the effectiveness of cleaning processes of washer-disinfectors using quality-assured test devices (Crile clamps) per national guidelines and international standards with **quantitative evaluation of residual protein levels**

- of Crile clamps and real instruments after cleaning in a washer-disinfector both in clinics and in practices of resident doctors
- of dental test devices and real instruments after cleaning in a DAC Universal (Dentsply Sirona)
- of handpieces after automated (DAC Universal D) or manual cleaning

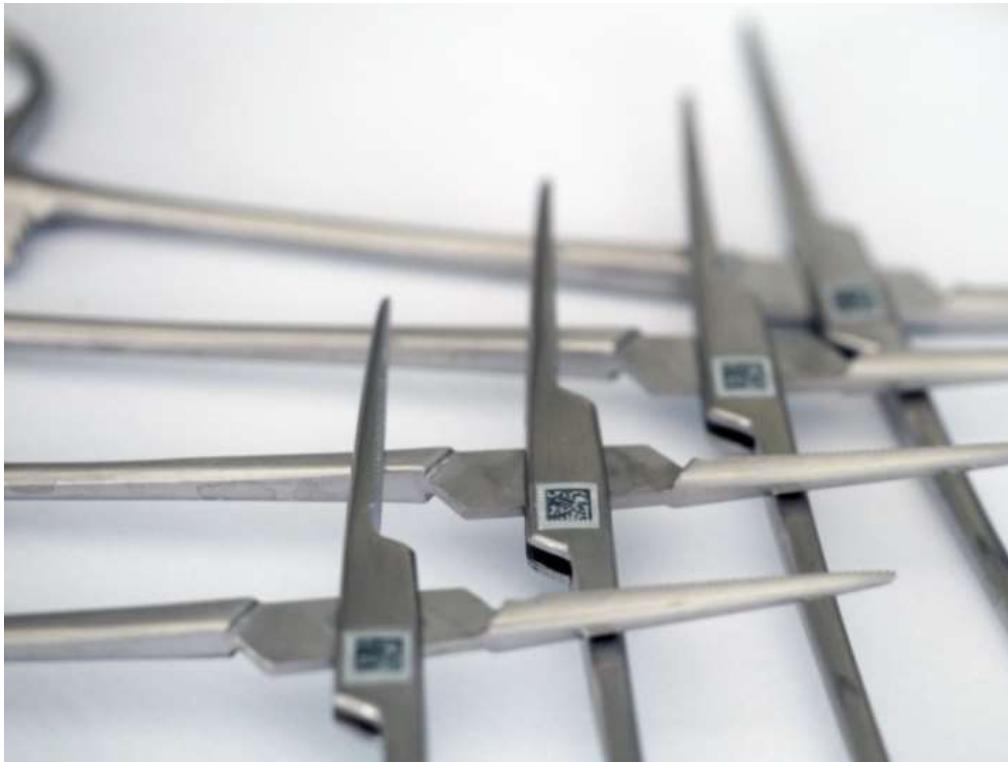
Motivation

- Successful cleaning is a mandatory prerequisite for subsequent disinfection and sterilization
- Evaluation and constant improvement of the effectiveness of cleaning processes
- Testing of the performance of washer-disinfectors and the installed cleaning processes with standardized equipment (test devices)
- Testing/Evaluation of the complete process of cleaning (pre-cleaning.....) using real contaminated instruments



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Test device: **Crile clamp**



Crile clamp

- standardized prepared and contaminated (guideline)
- dried
- vacuum packed
- stored
- sent out
- utilized by the validator
- returned to SMP
- evaluated in the laboratory of SMP



Quality assurance of test devices

Miele G7735 CD upper level and lower level

**3 min cold pre-rinse
5 min cleaning (55°C)
0,3 % alkaline detergent
1 min rinse**

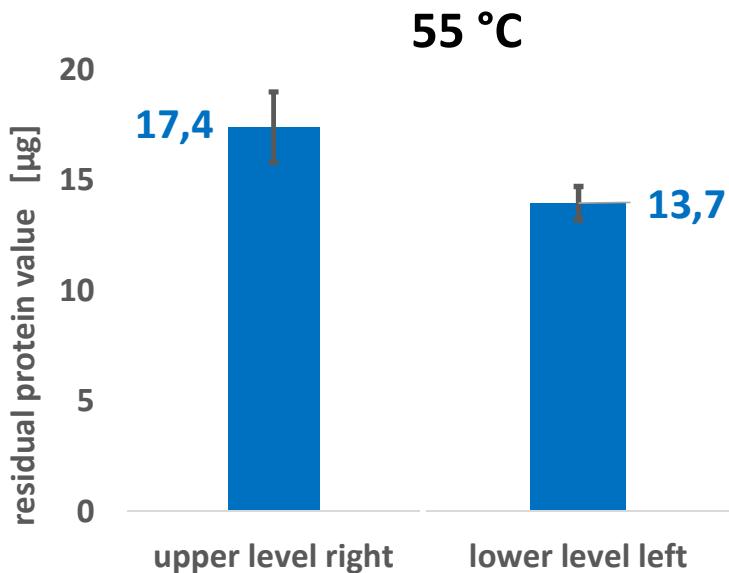
**3 min cold pre-rinse
10 min cleaning (70°C)
0,5 % alkaline detergent
1 min rinse**



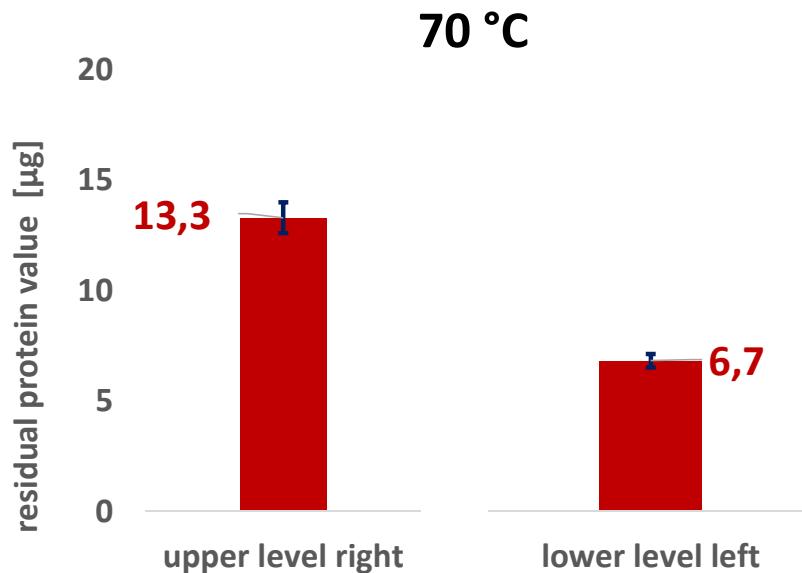
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Quality assurance of test devices (crile clamps) from 2016-2022

cleaned in an WD: Miele G7735 CD upper level and lower level



3 min cold pre-rinse
5 min cleaning (55 °C) 0,3 % alkaline detergent
1 min rinse

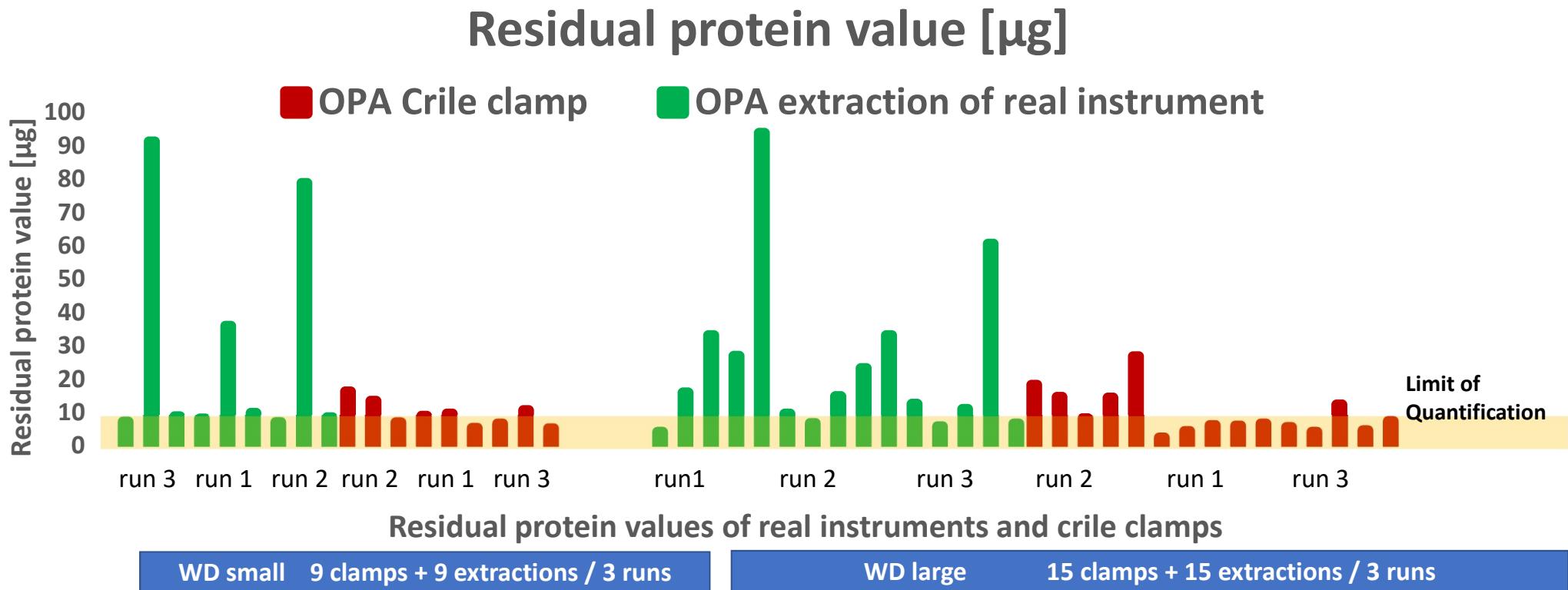


3 min cold pre-rinse
10 min cleaning (70 °C) 0,5 % alkaline detergent
1 min rinse

Every week (new batch of blood) 20 clamps are used for quality assurance: 7000 protein values for the SOP clamps

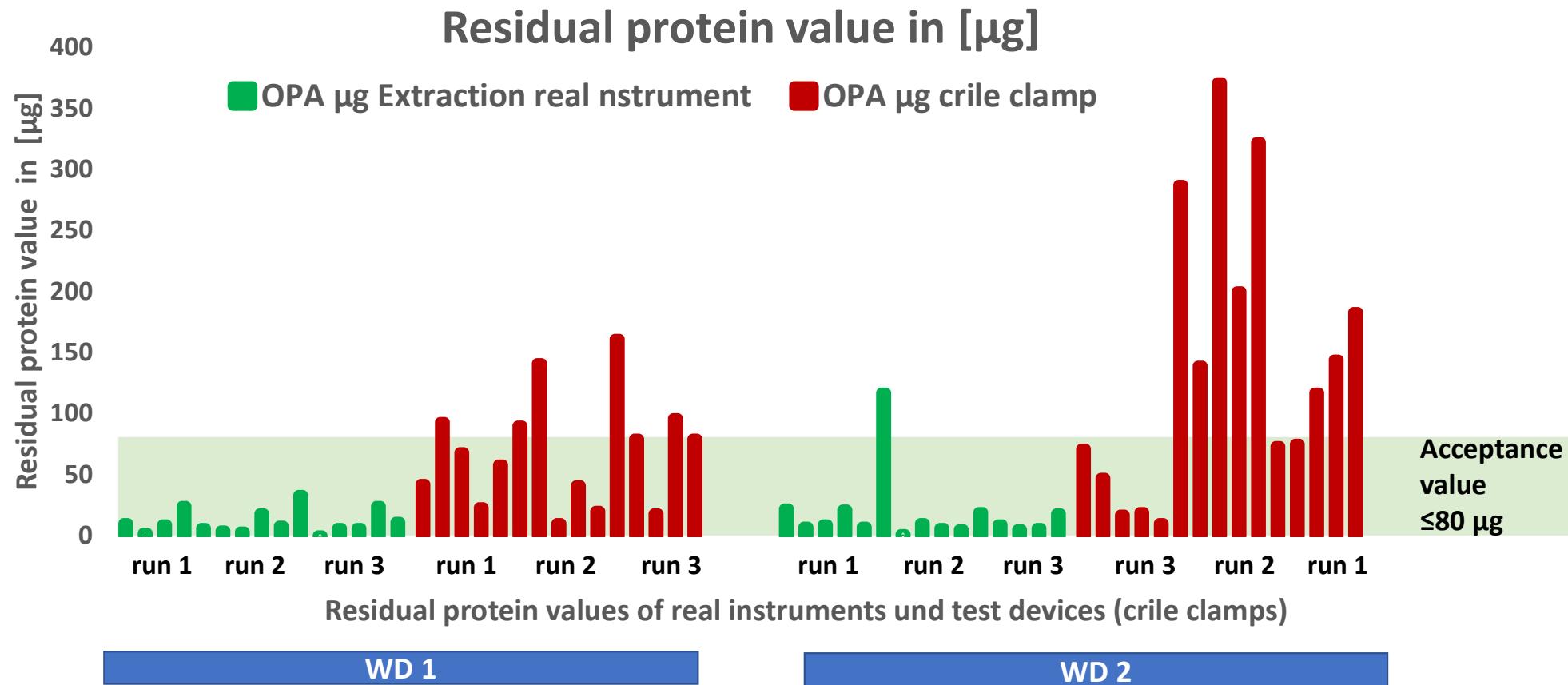
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Examples of initial validations in Washer Disinfectors (WD)



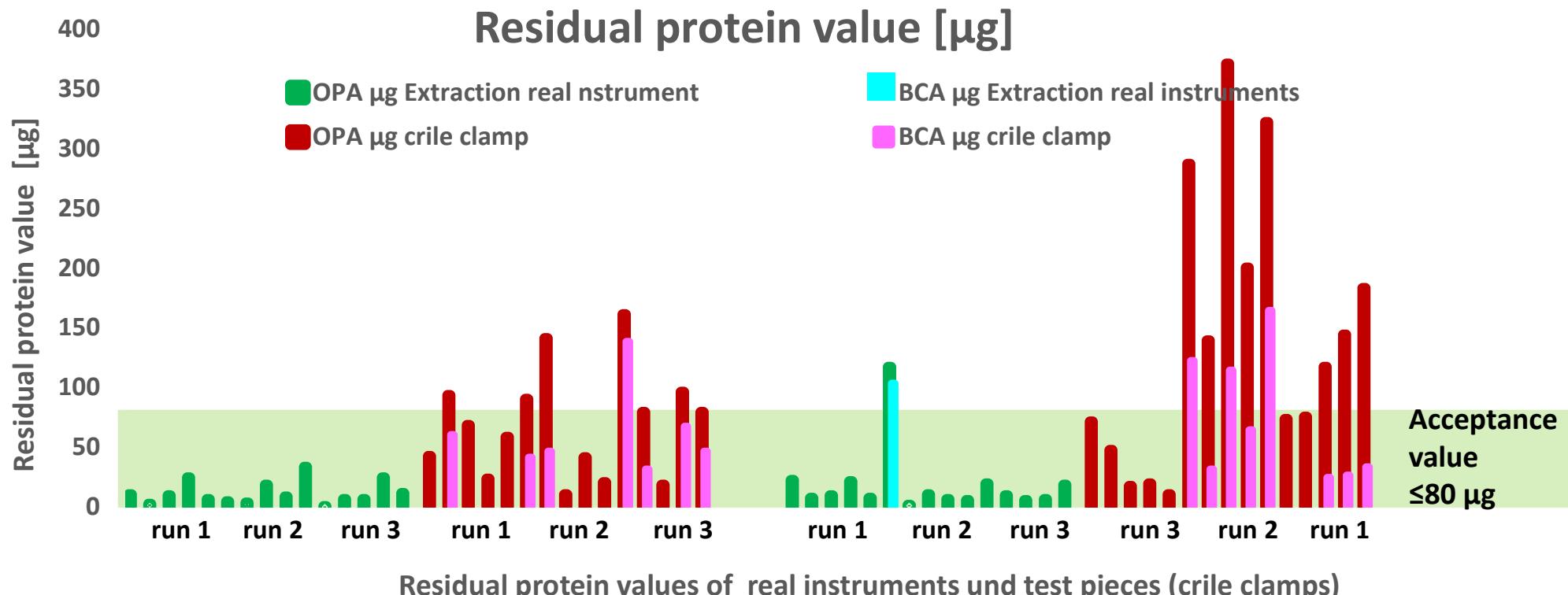
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Examples of initial validations in Washer Disinfectors (WD)



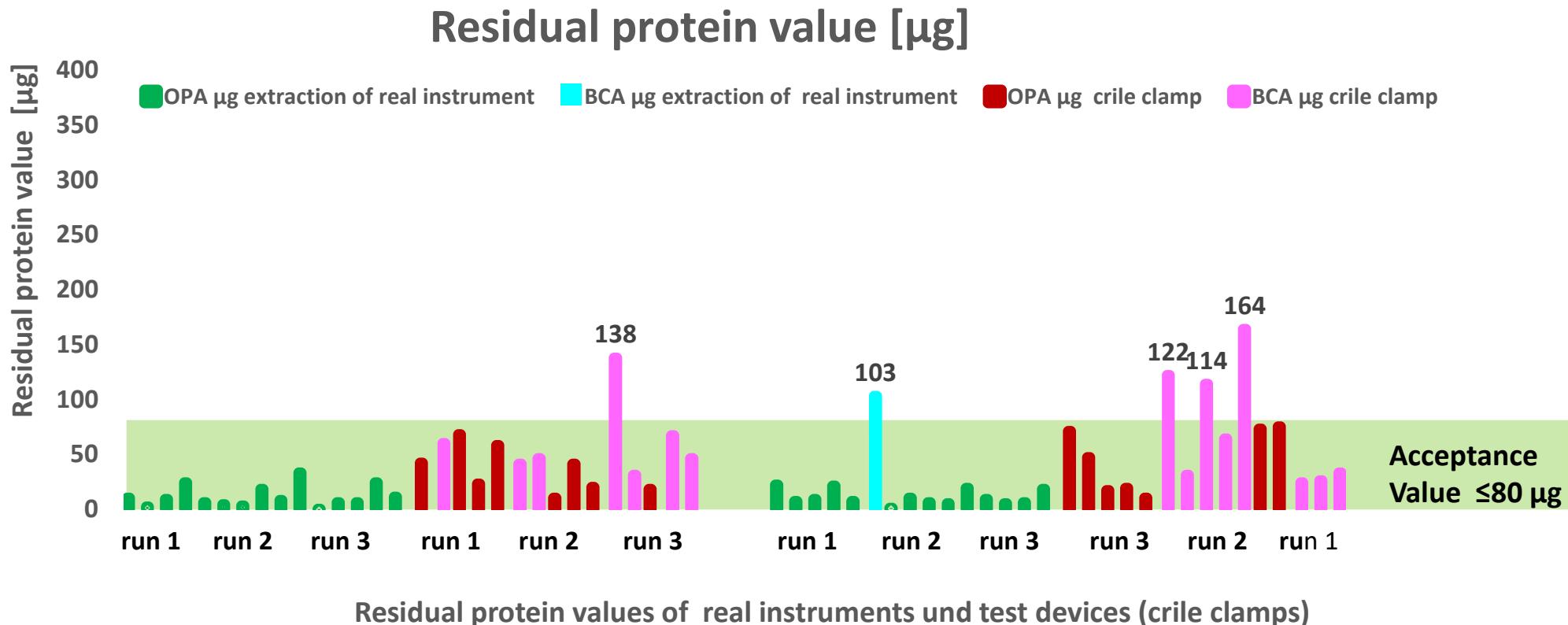
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Examples of initial validations in Washer Disinfectors (WD)



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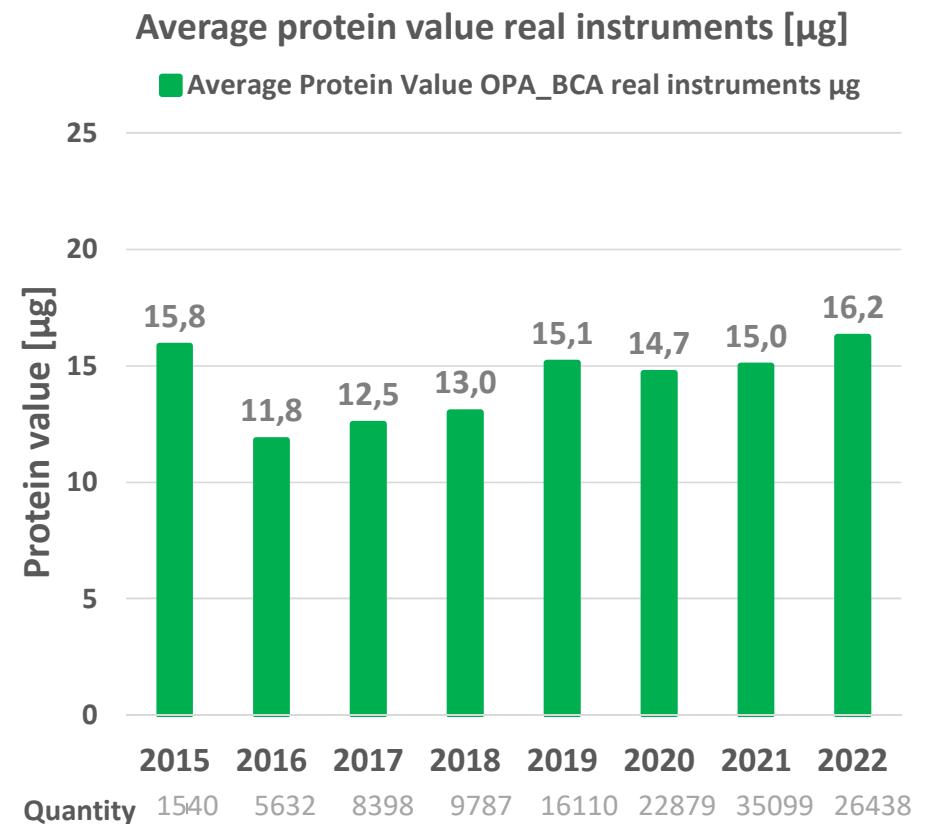
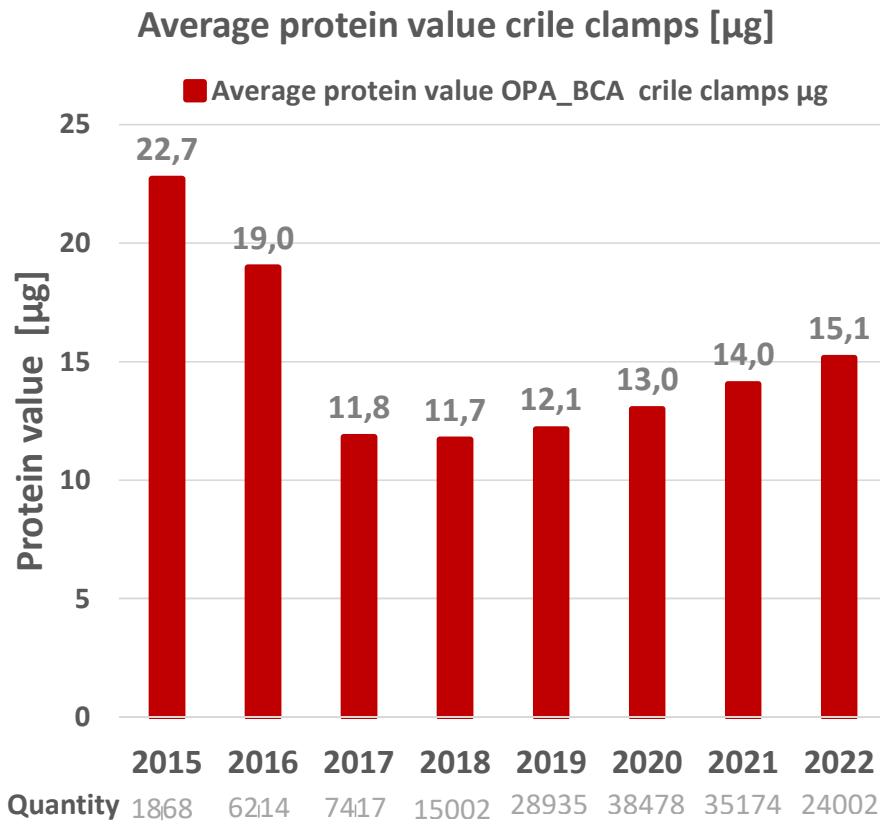
Examples of initial validations in Washer Disinfectors (WD)



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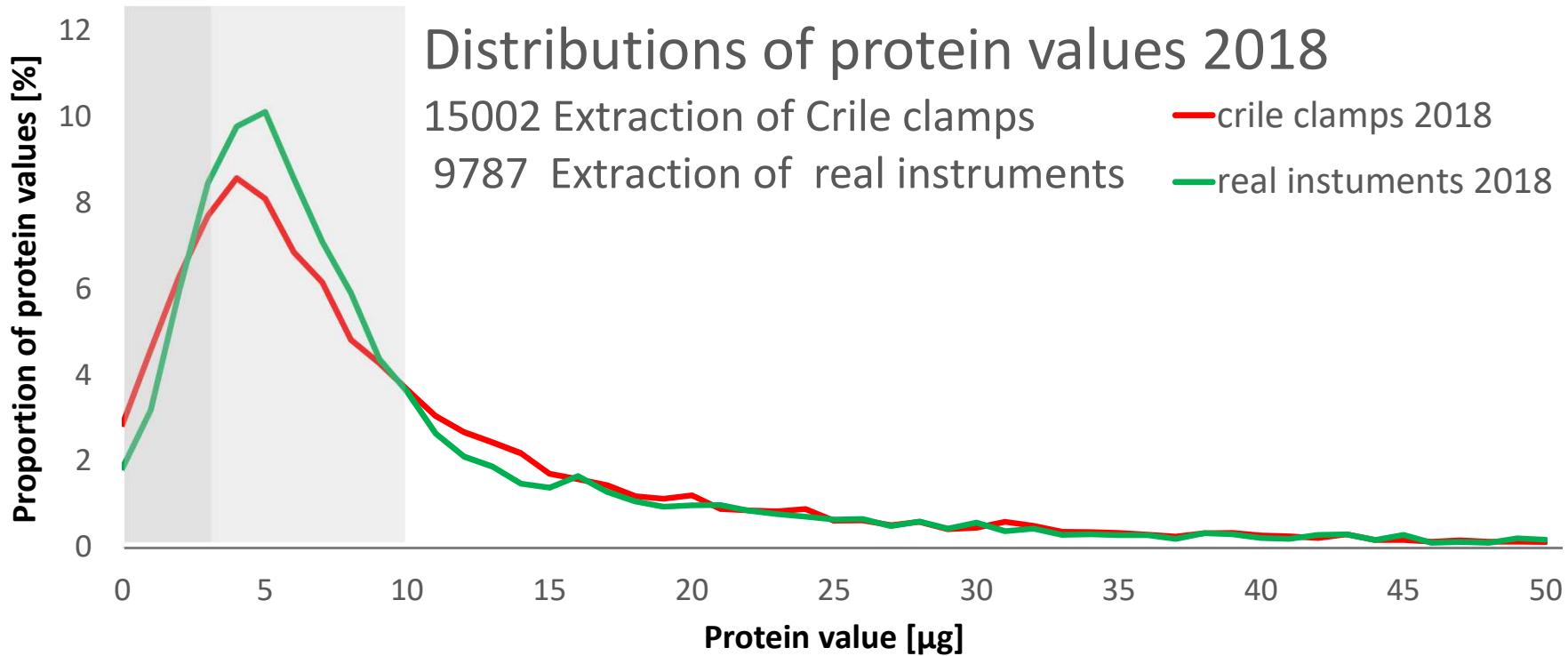
Average protein values from validations 2015 bis 2022

quantity: 159.500 crile clamps and quantity: 121.333 real instruments



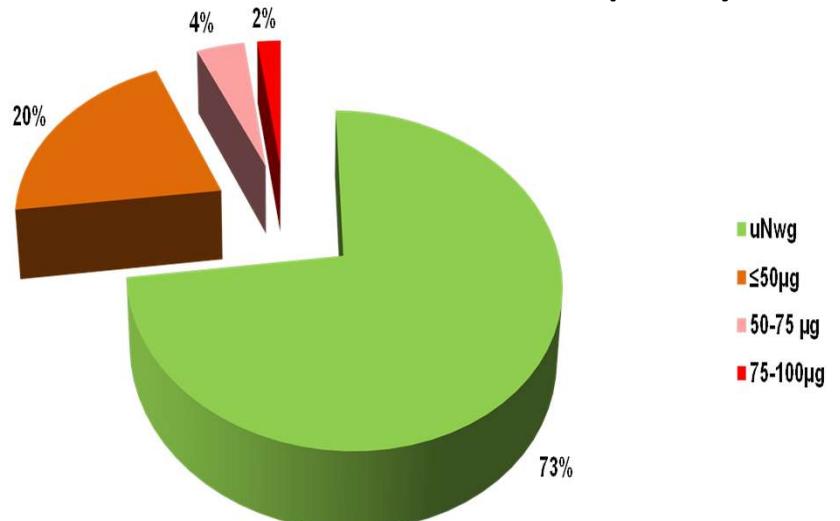
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Distributions of protein values (results in intervals of 1 µg)

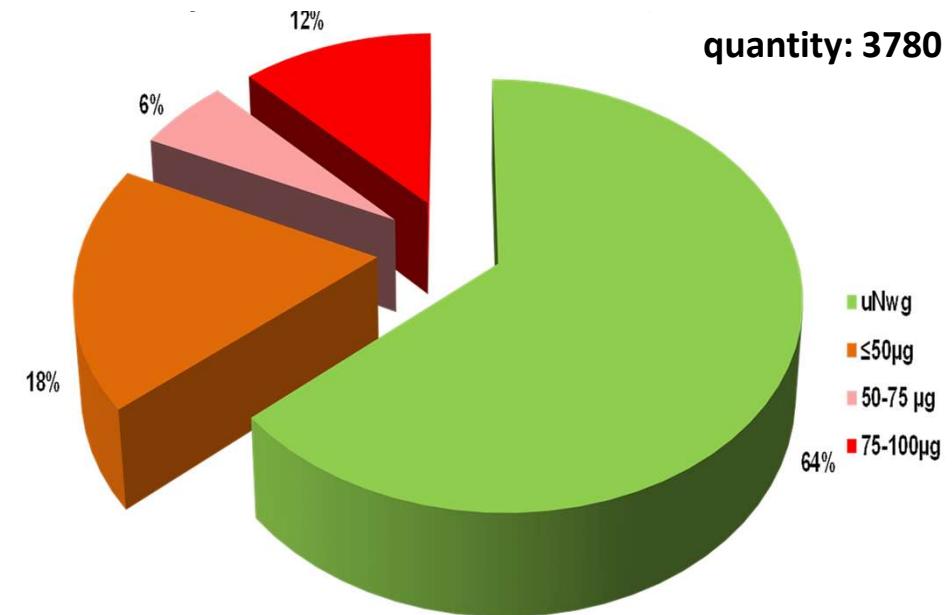


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Results of residual protein on testpieces Crile clamp



Results of residual protein on real instruments

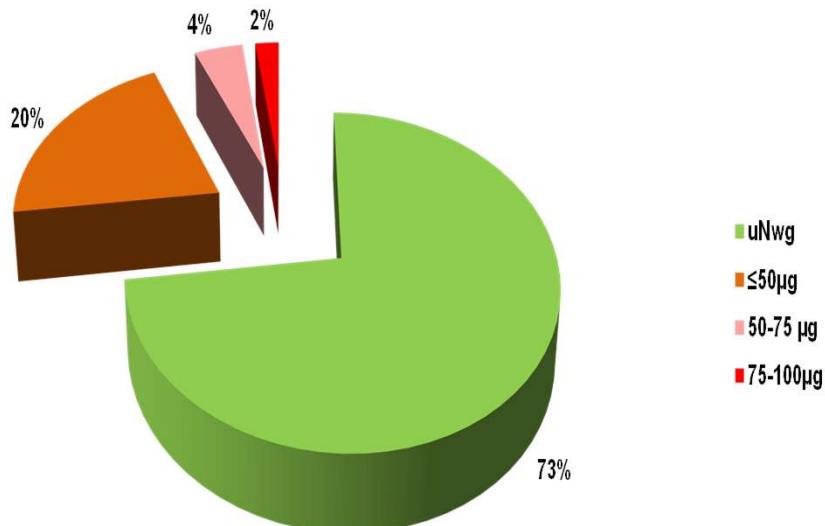


Validation reports from the years 2011 and 2012

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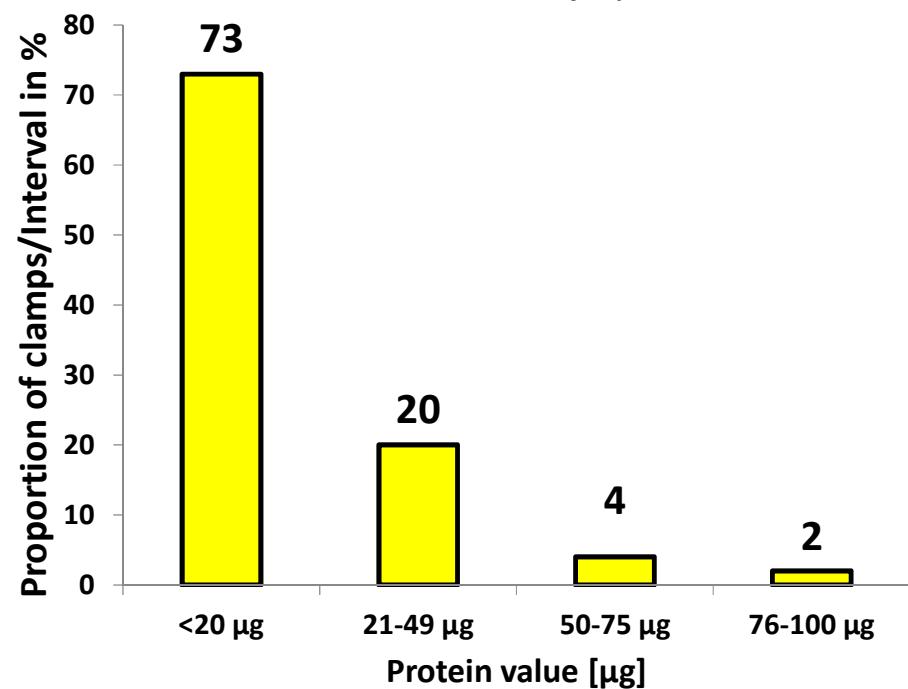
Results of residual protein on test devices - Crile clamp

quantity: 4122



Validation reports from the years 2011 and 2012

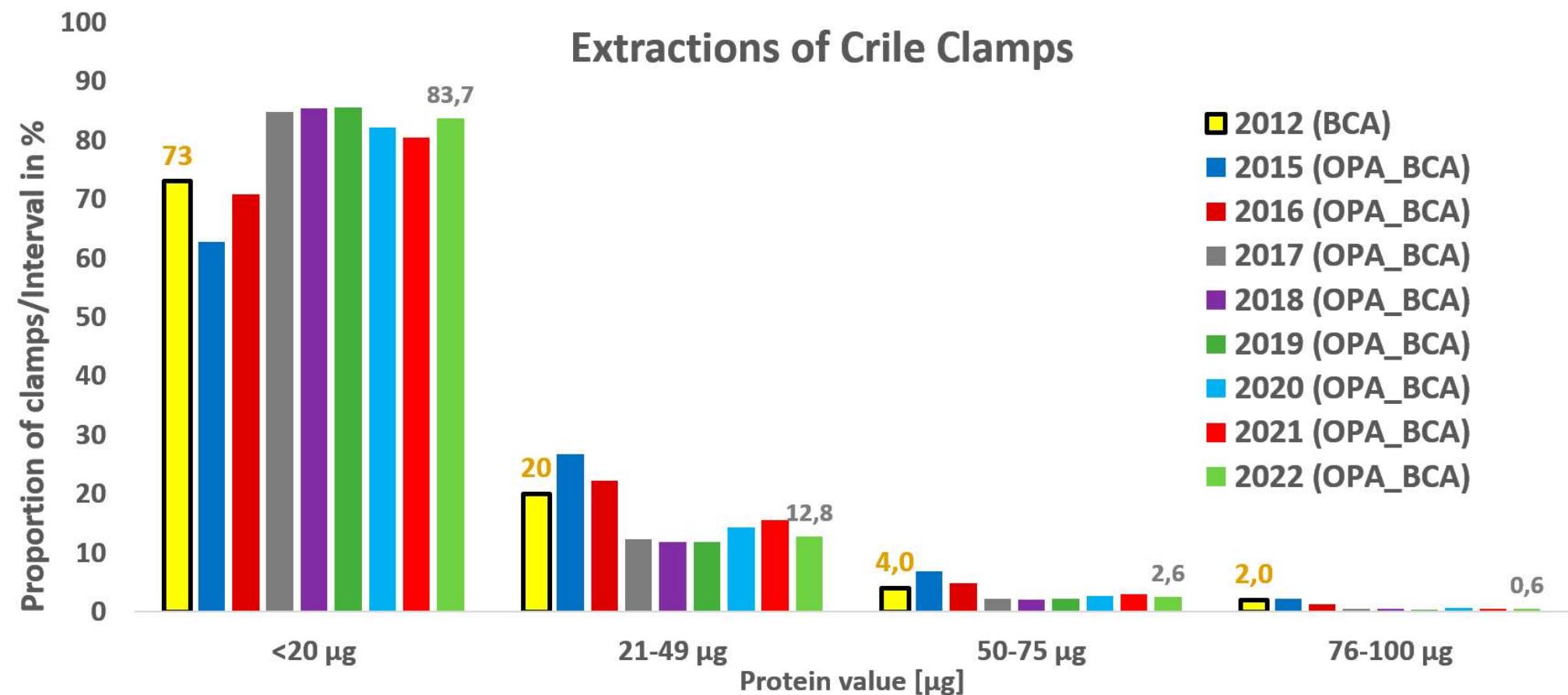
**Crile clamps 2011/12 (BCA data)
Zentralsterilisation 2013/ 3, in %**



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Proportion of Crile-clamps in % per interval

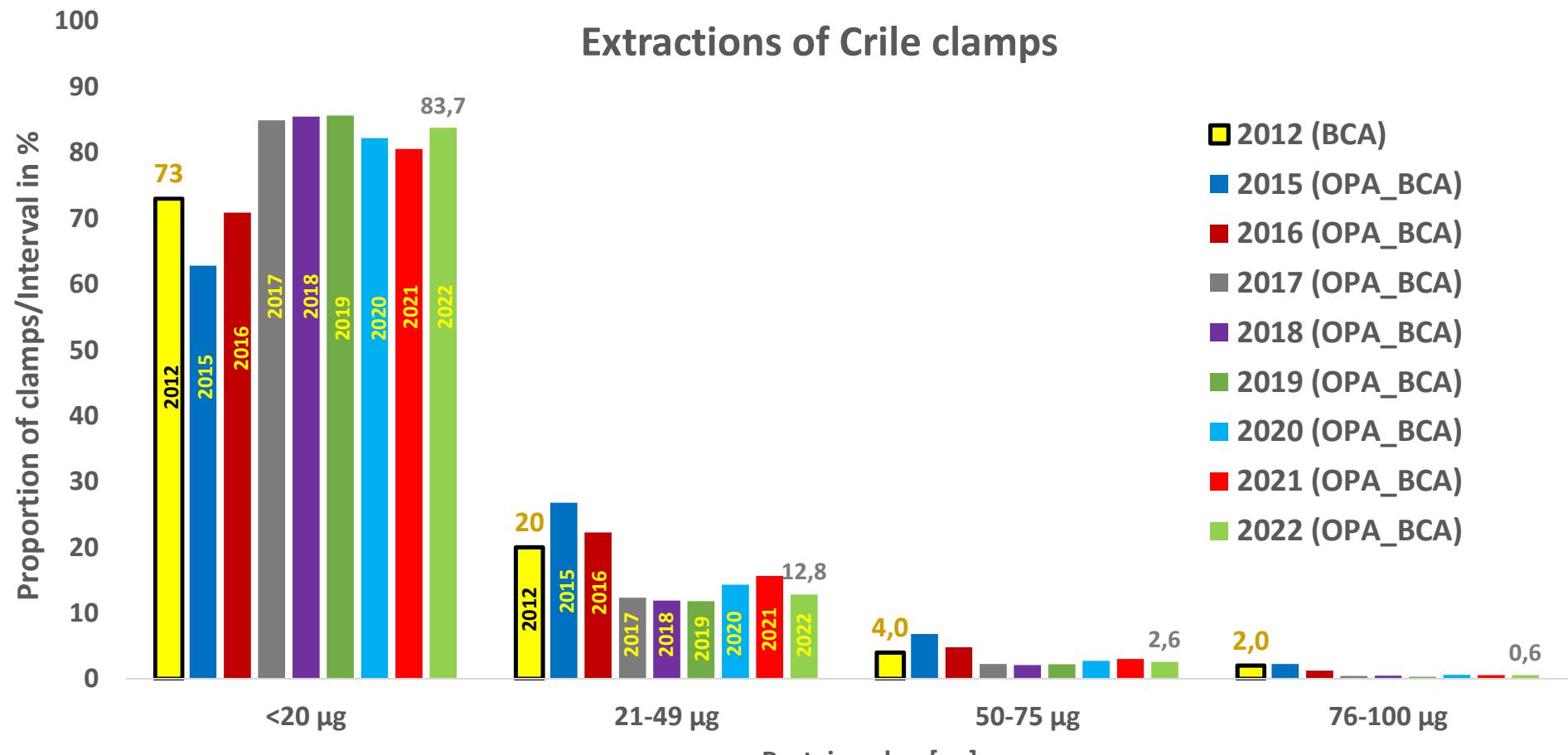
results of 4.122 clamps (2011/12) Results of 157.090 clamps(2015-2022)



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Proportion of Crile clamps in % per interval

Results of 4.122 clamps (2011/12) Results of 157.090 clamps (2015-2022)

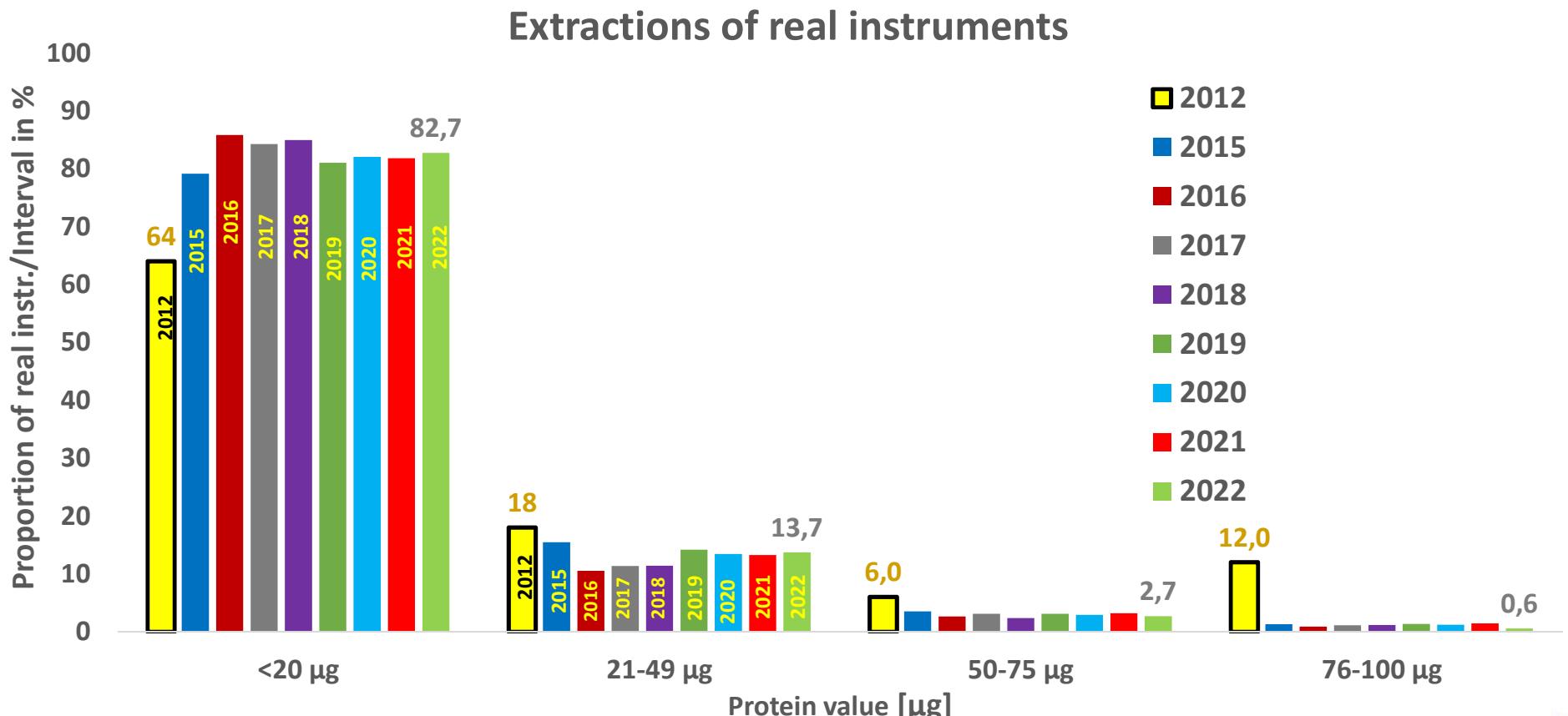


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Proportion of extraction of real instruments in % per interval

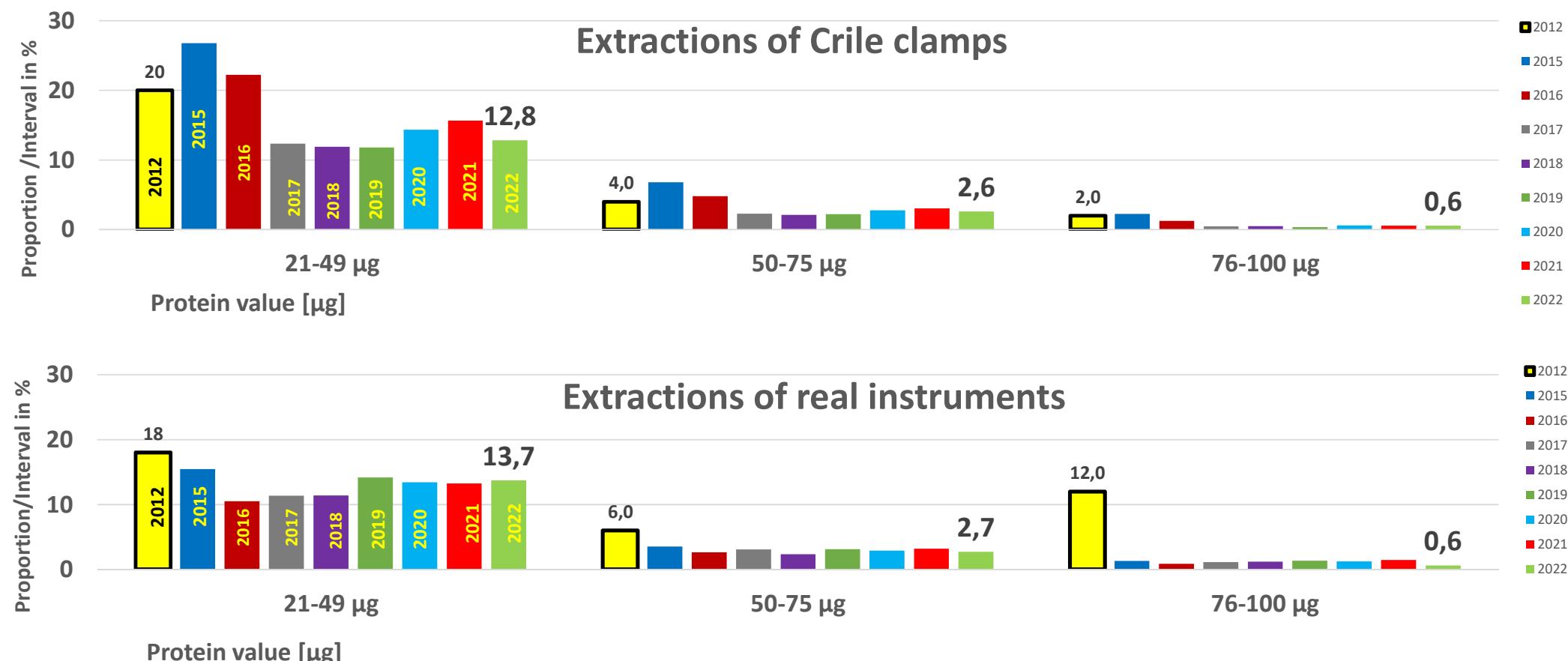
Results of 3.780 real instr. (2011/12)

Results of 125.883 real instr. (2015-2022)



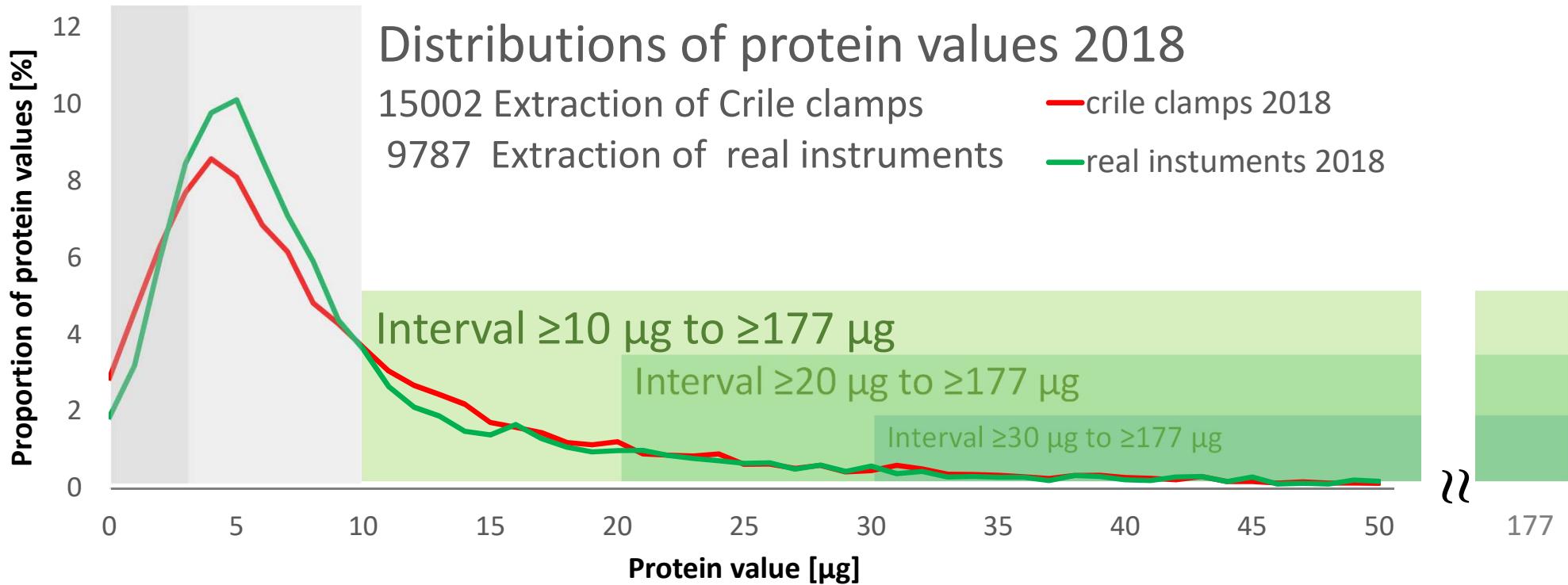
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Comparison of results: Crile clamps and real instruments



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Distributions of protein values (results in intervals of 1 µg)

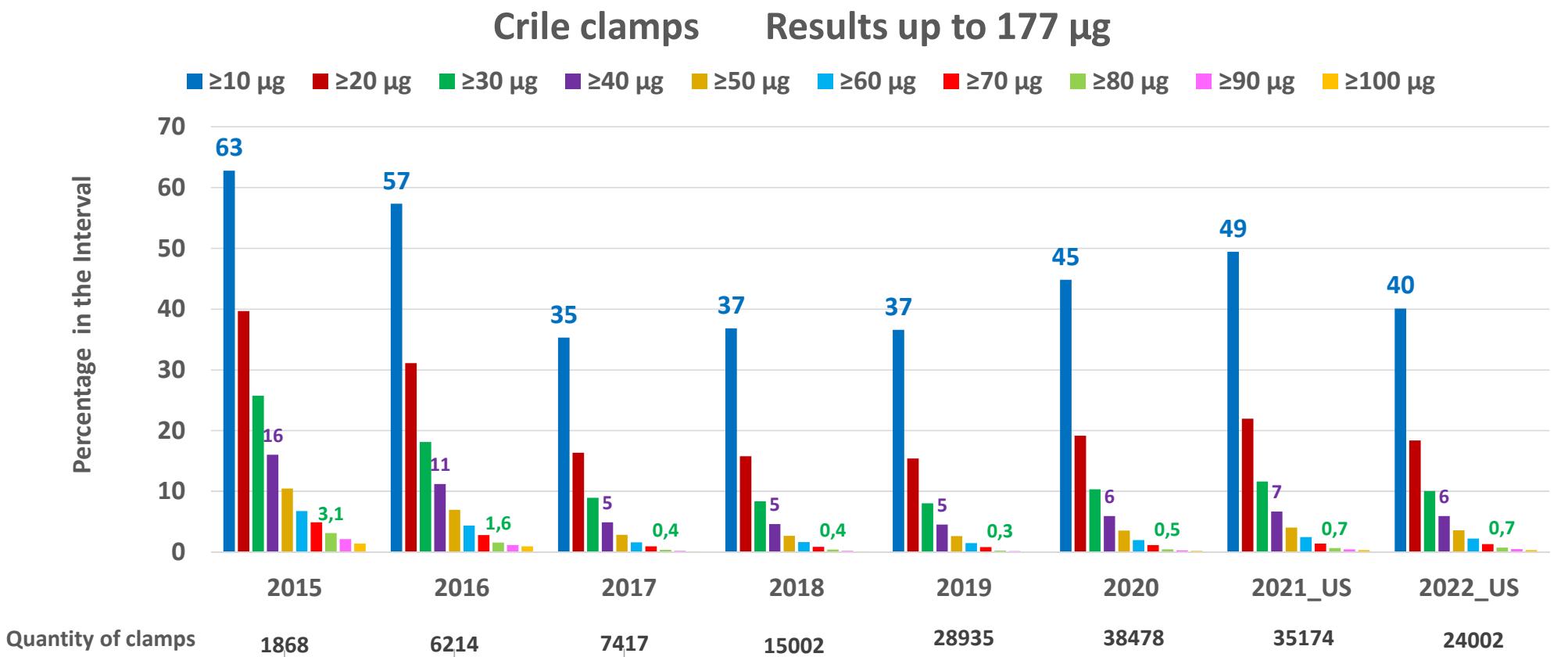


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Development over time 2015-2022

Results for crile clamps in intervals $\geq 10 \mu\text{g}$ to $\geq 100 \mu\text{g}$

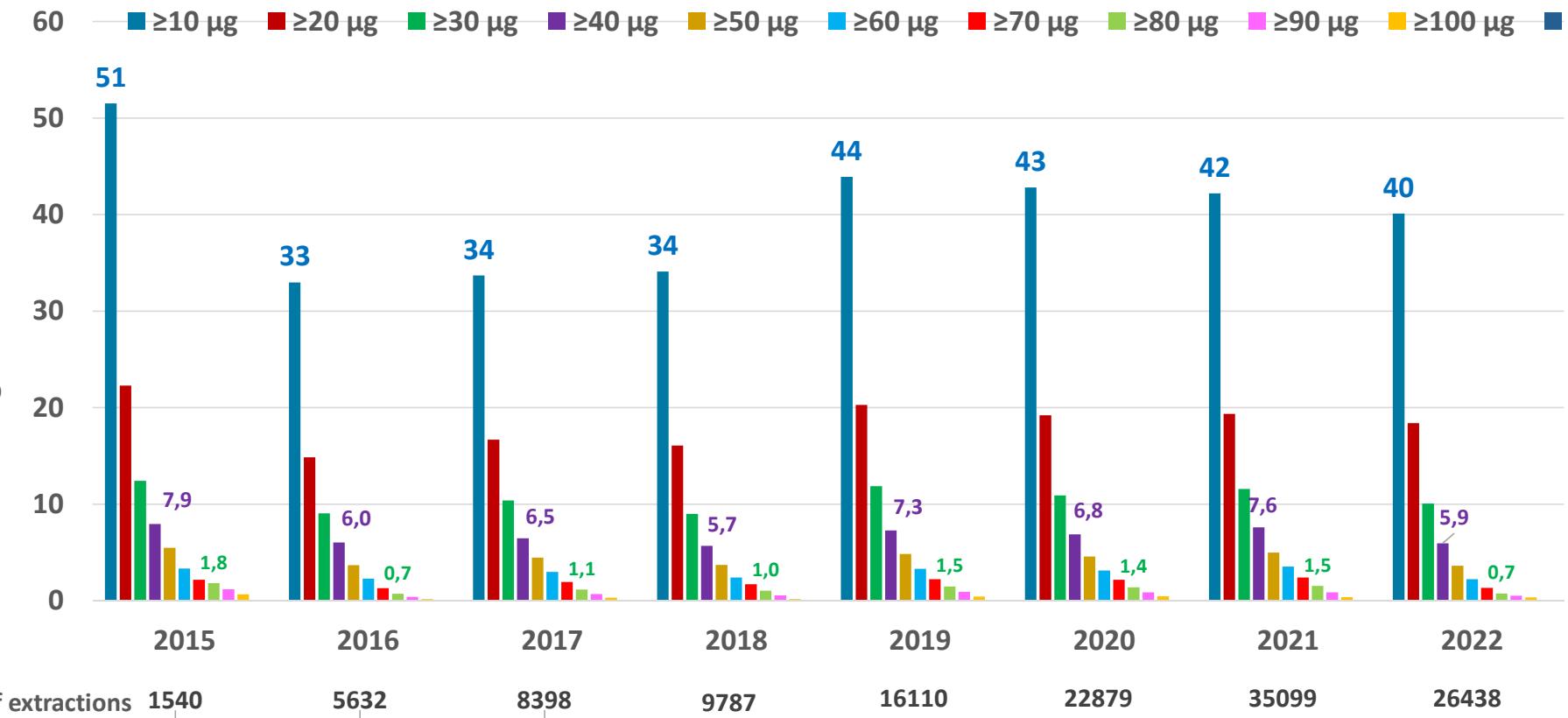


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Development over time - 2015-2022

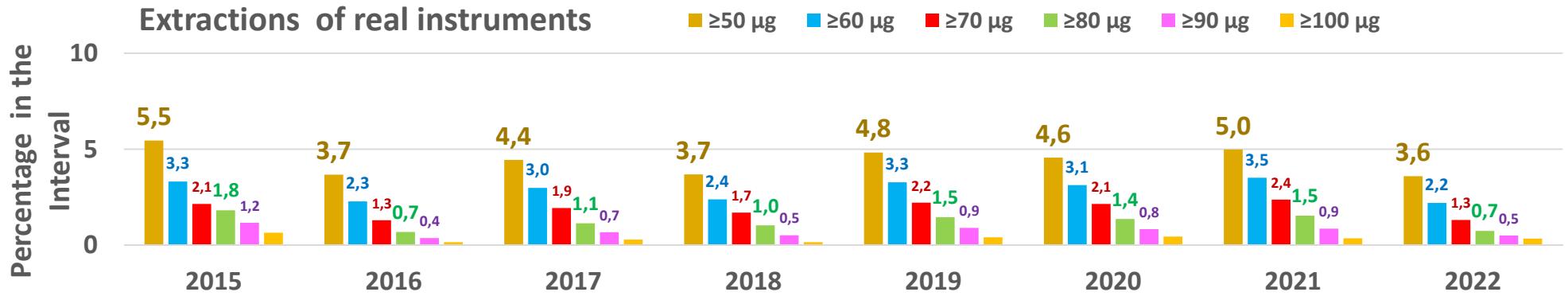
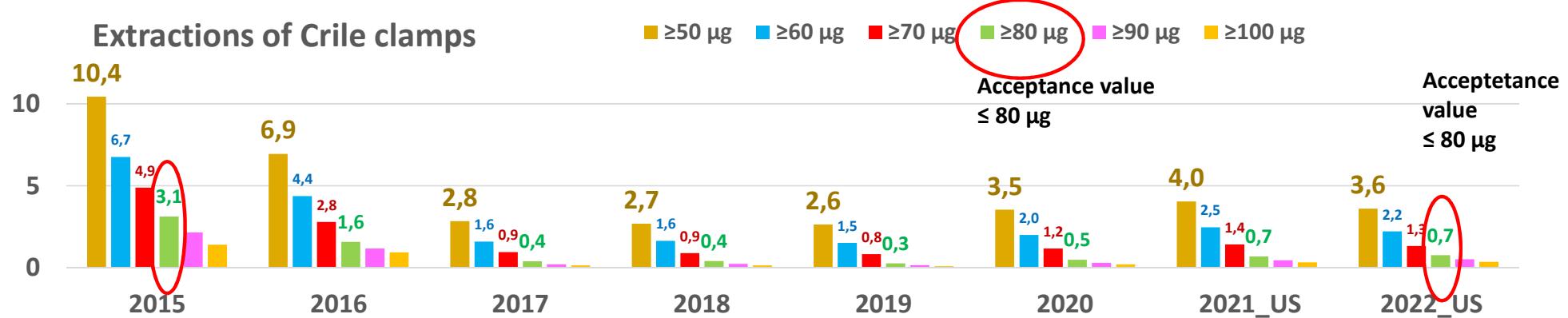
Results for real instruments in intervals $\geq 10 \mu\text{g}$ until $\geq 100 \mu\text{g}$

Extraction of real instruments



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Comparison for the intervals $\geq 50 \mu\text{g}$ to $\geq 100 \mu\text{g}$



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Development of dental test devices

DAC Universal - Dentsply Sirona

- Testing the cleaning performance of the spray channel in handpieces → **Cannula**.
- Testing the external cleaning of handpieces → **Hull**

suitable material (stainless steel)
inner diameter of the cannula (diameter 0.7 mm inside)
flow rate (comparable to that of an handpiece)
surface of the outer side (diameter 16 mm outer)
they should be universally applicable (Luer-Lock connector)



- **The reproducibility determines the quality of the test devices**

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DAC Universal MK3

Dentsply Sirona



Test device



DAC Universal is a medical device intended for hygienic reprocessing of dental instruments. The device is available with different load carriers (lids). With the standard lid / blue lid and therefore with the standard lid/blue lid program the device is intended to reprocess dental handpieces. The program contains cleaning, lubrication, and thermal disinfection of the instruments. "Dental handpieces are defined as rotating instruments split up into the categories straight handpieces, contra angles and turbines." Both electrics and air-driven instruments are included. All instruments are directly adapted to the load carrier – the adapter is individual and depending on the connection of the instrument.

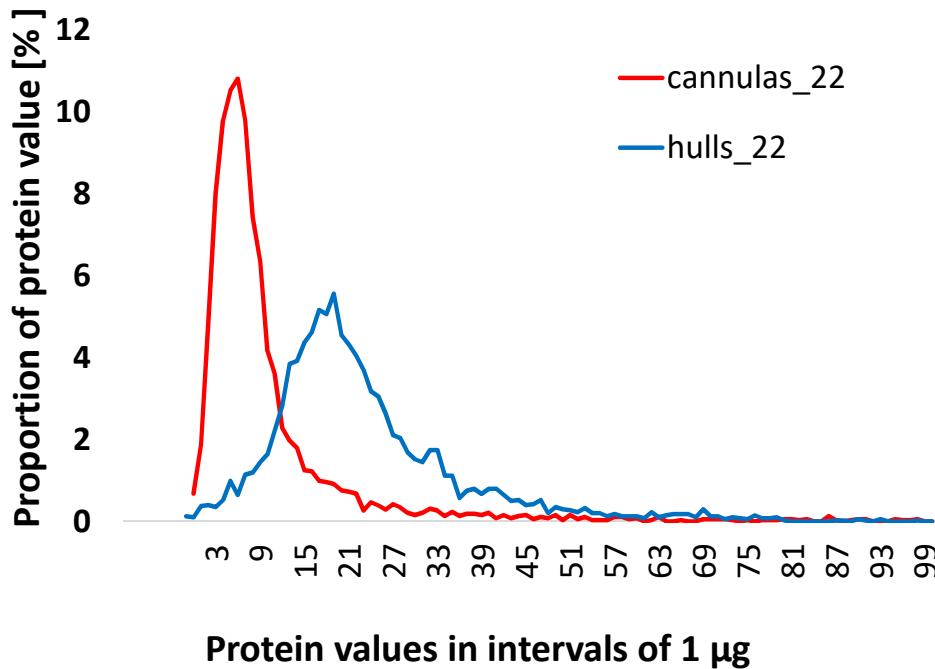
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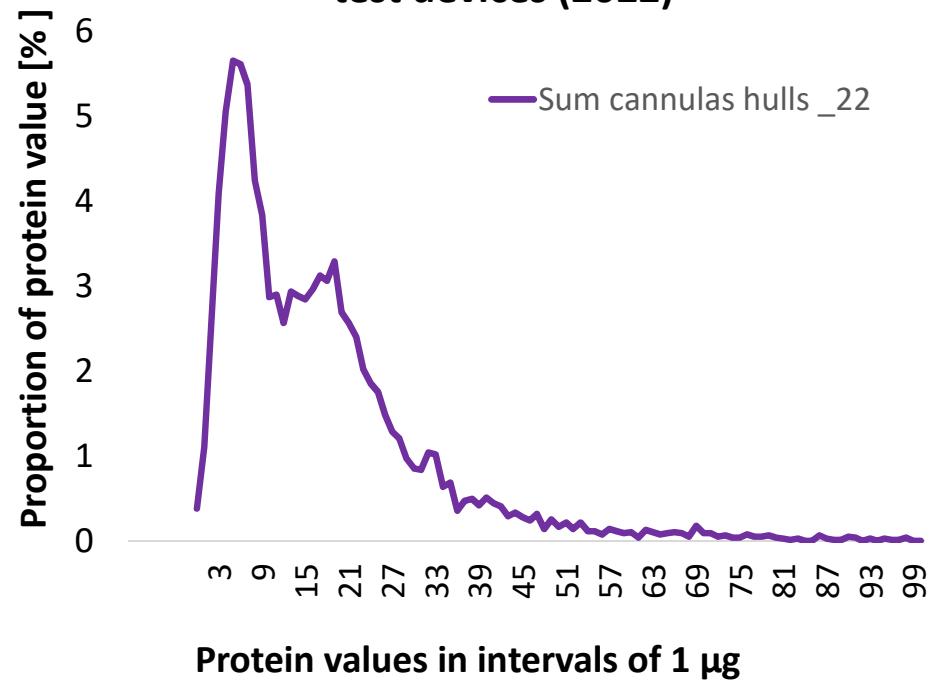
Distribution of protein values of dental test devices

(Data of 4000 hulls and cannulas each - 2022)

Distribution of the protein values of dental test devices (2022)

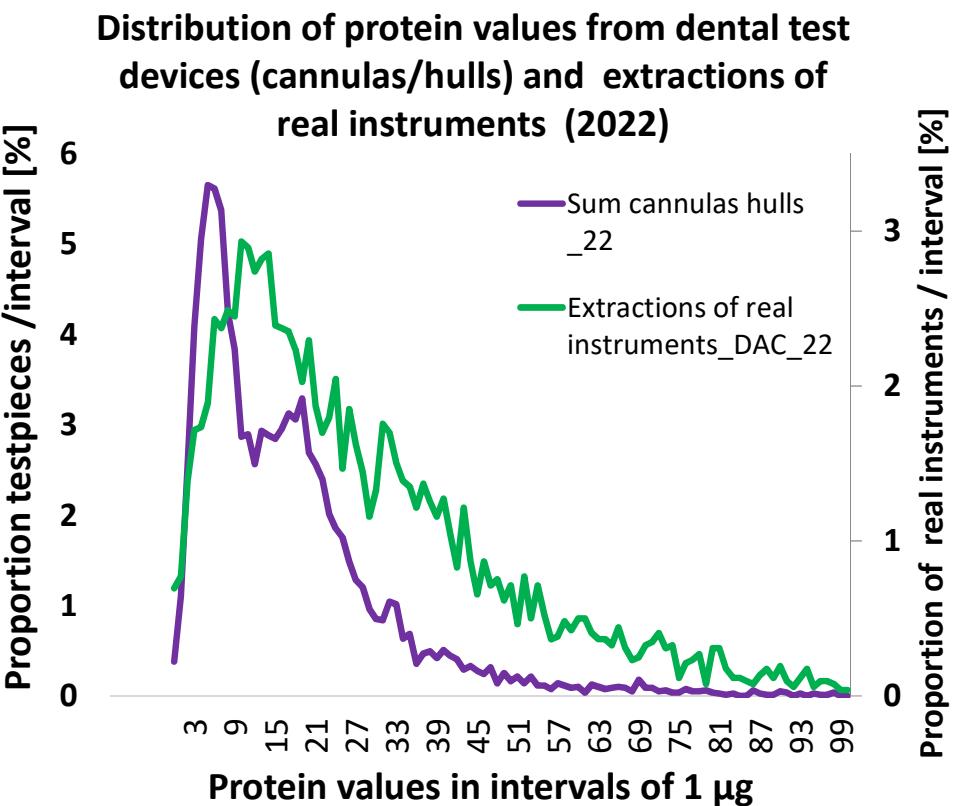
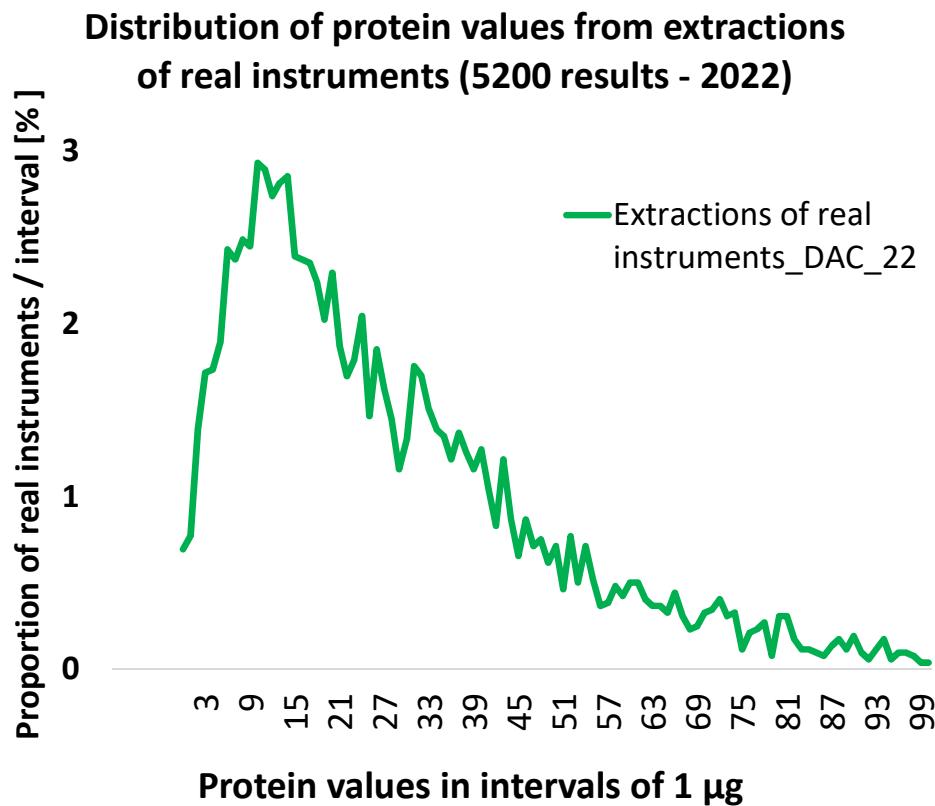


Distribution of the protein values of dental test devices (2022)



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Distribution of protein values extractions of real instruments compared to test devices (5200 results - 2022)

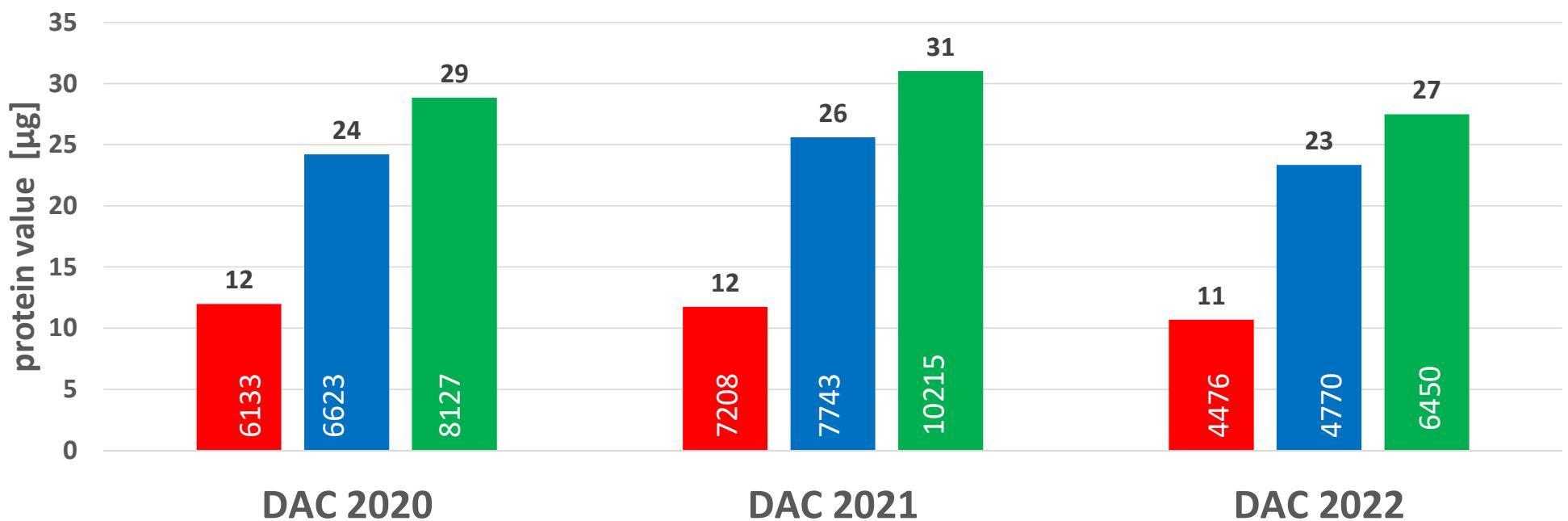


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Mean values in the years 2020-2022

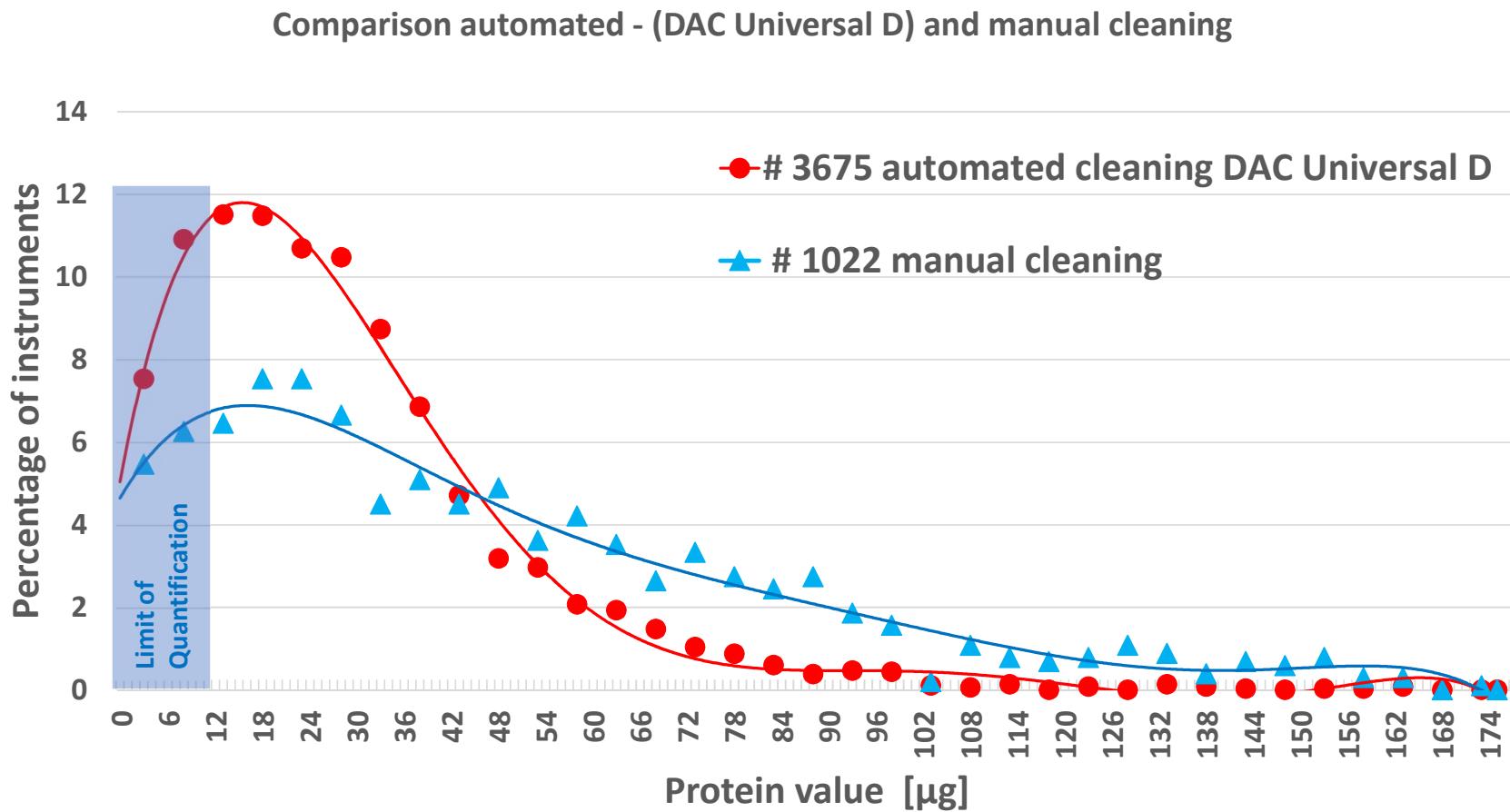
quantity: cannulas 18.235 / hulls 19.244 / real instruments 24.894

■ average value cannulas ■ average value hulls ■ average value real instruments



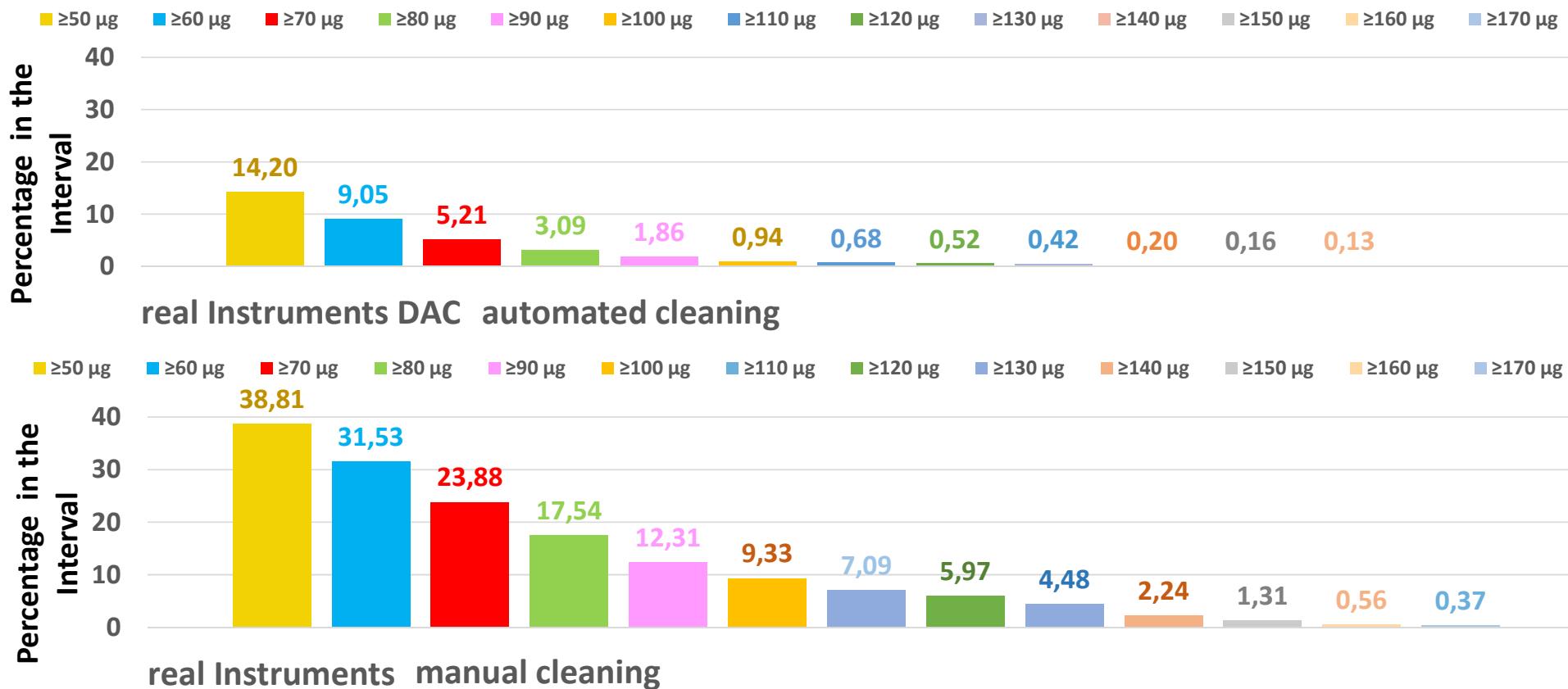
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Comparison automated- (DAC Universal D) and manual cleaning



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Comparison of automated and manual cleaning



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Conclusion / Take away

- The performance of automated cleaning processes in Germany between 2015 and 2022 was statistically evaluated using residual protein values from test devices and real instruments.
- It was shown that the systematic review of the cleaning performance of automatic processes initiated and described by the *German Guideline compiled by DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices* led to a measurable improvement in the results.
- The detailed analysis of the data provides a basis for the (re)definition of acceptance criteria.
- The development and implementation of test devices and validation strategies for washer-disinfectors for dental tools allows continuous monitoring of cleaning performance.
- It was shown that automated cleaning processes may lead to improved results as compared to manual cleaning