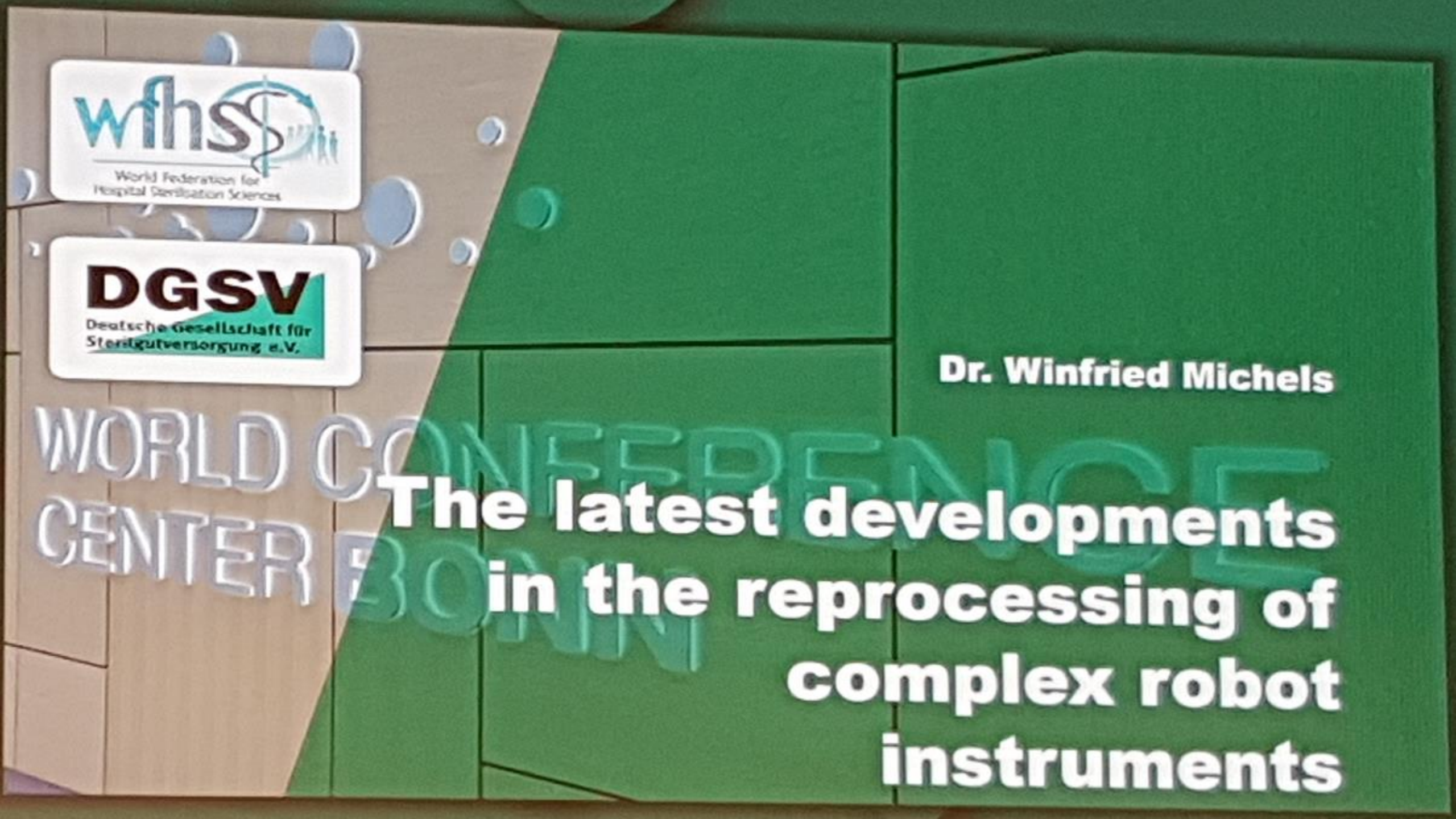
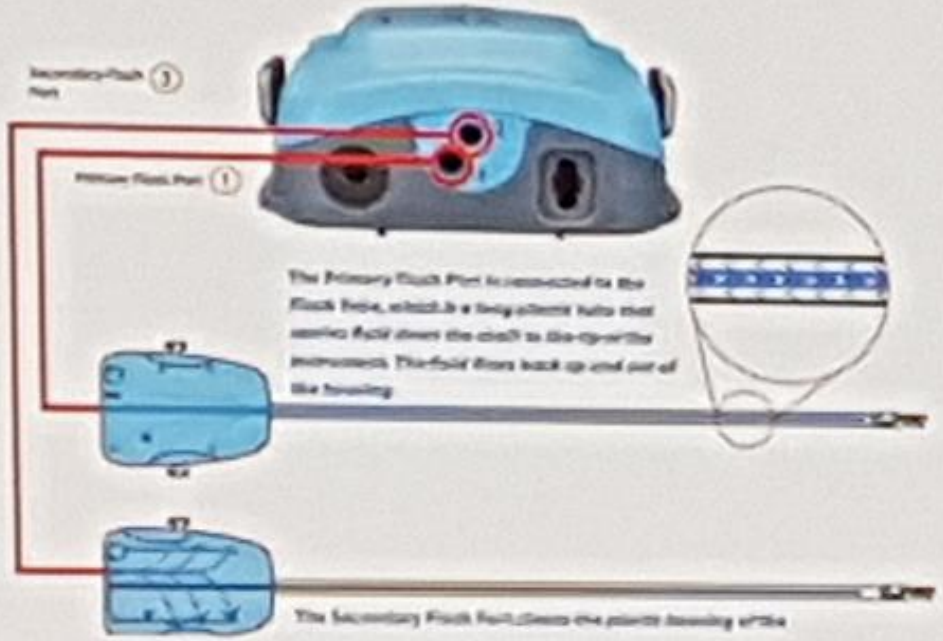


Dr. Winfried Michels

The latest developments in the reprocessing of complex robot instruments

EndoWrist Shaft instruments - Complex Instruments critical B



Generation SI

Generation XI

Manufacturer's instructions for automatic reprocessing

Pre-cleaning before the automatic process for a load of 3-4 instruments takes about an hour to complete.

Automated Cleaning Summary Cleaning process in the SPD or CSSD must begin within 60 minutes after procedure.	
Preparation in OR	
Prime/Soak in water or cleaner	
Transport to SPD or CSSD	
Preparation for Automated Cleaning in the SPD or CSSD	
Cleaner Prime and Soak	30 min
Flush	20 sec
Spray Tip	30 sec
Brush	60 sec
Rinse	60 sec
Inspect	
Automated Cleaning	
Automated Cleaning & Thermal Disinfection with a Washer Disinfector	
Post-Automated Cleaning	
Dry	
Inspect	
Lubricate	
Package and Sterilize	

Excerpt from the operation manual

Reprocessing Instructions Appendices

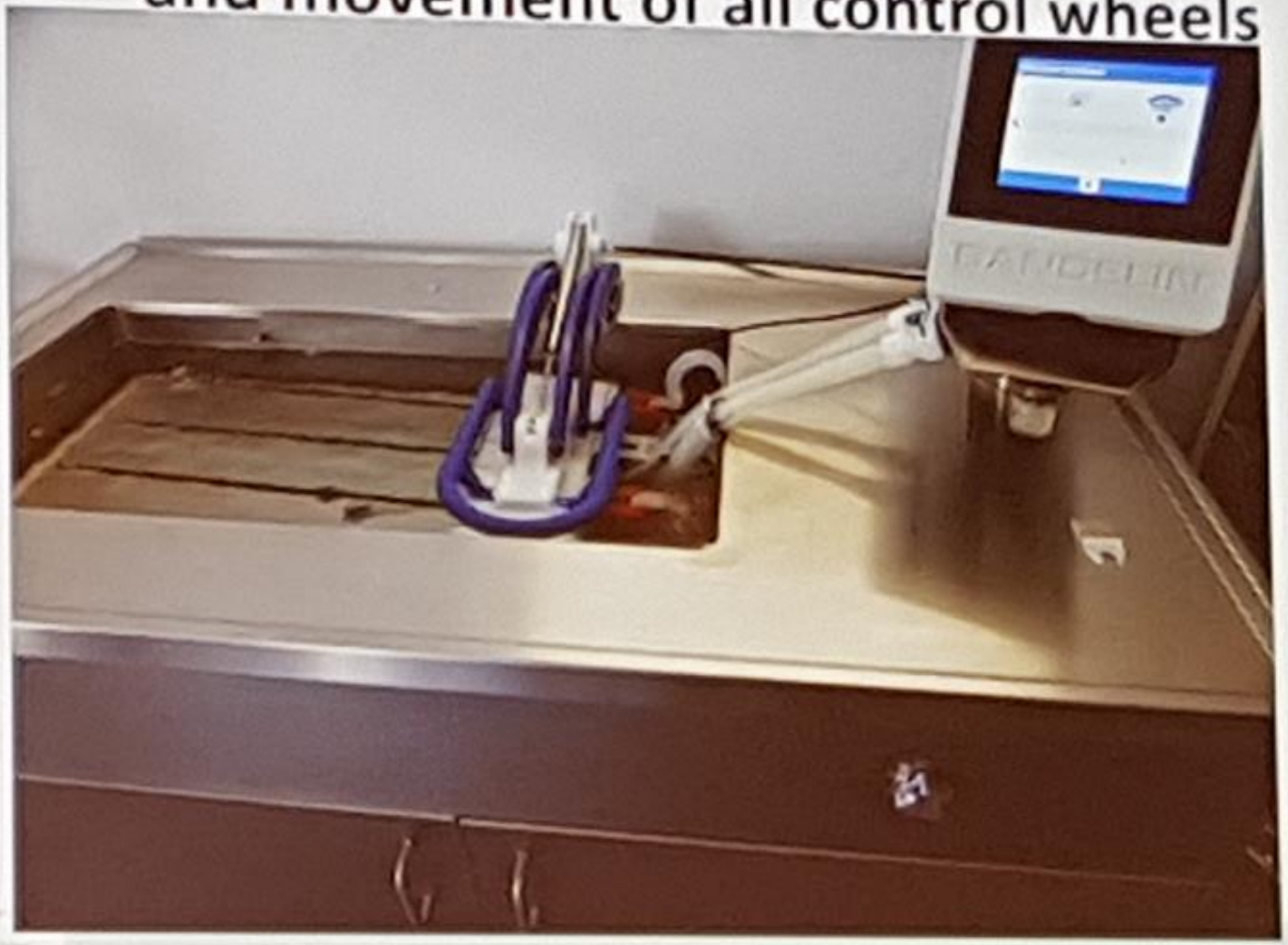
Cleaning, disinfection, and sterilization information for reusable instruments and accessories used with *da Vinci Xi* System.

Appendix B: Supplementary information for automated cleaning

The WDs specified in the Appendix have considerably longer cleaning phases for Robot instruments compared with those in normal programmes for surgical instruments.
Ususally only 3-4 instruments are reprocessed per load, so that the chamber of the WD can be said to be almost empty.
Filling up the load with other instruments is not feasible as very few if any are available to be reprocessed at the same time.

Summary: disproportionate water, chemical and energy consumption!

Pre-cleaning in an ultrasound bath with flushing and movement of all control wheels

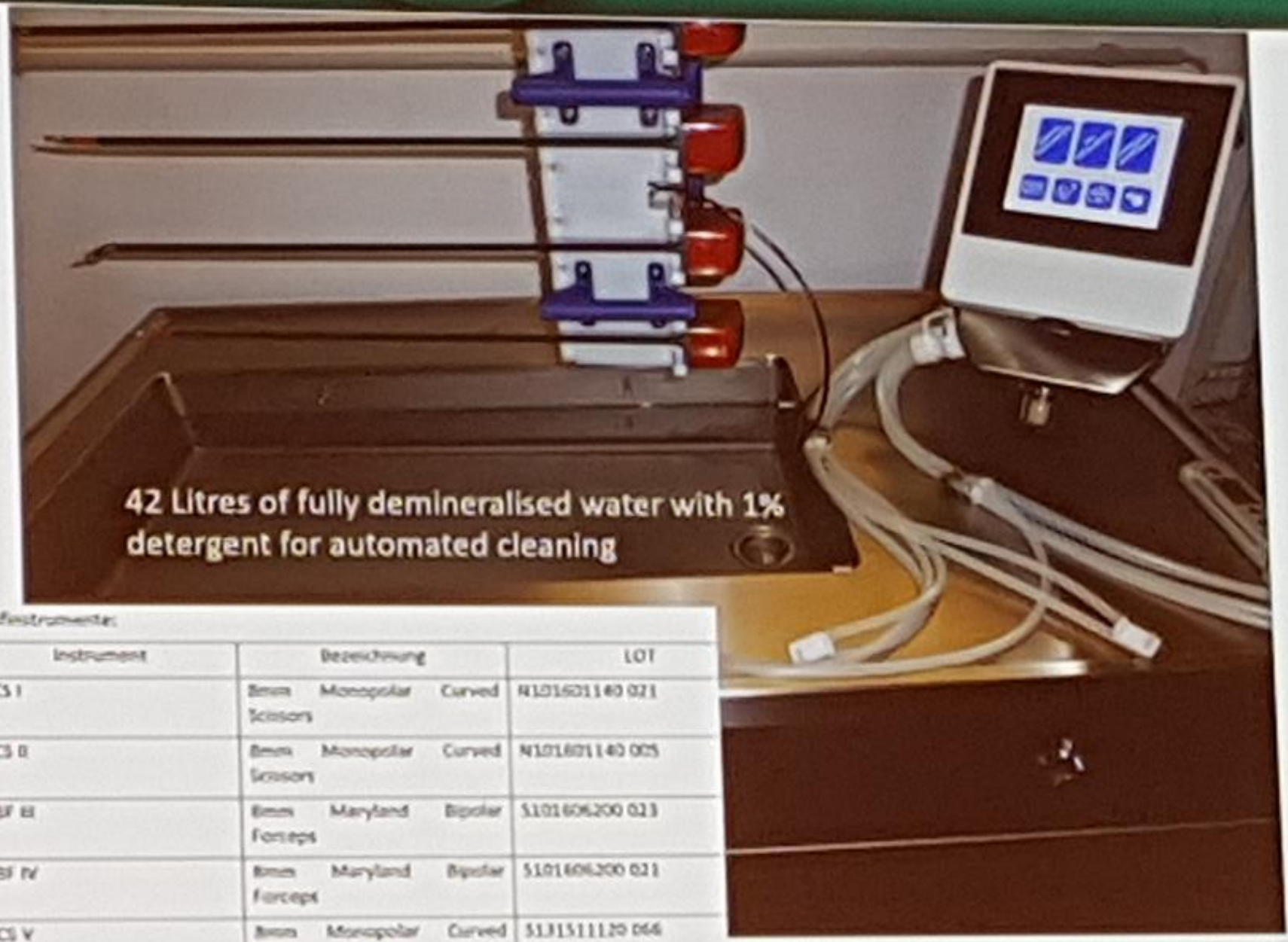


What can the ultrasound bath achieve?

- Tests show that according to the ISI test protocol, pre-treatment in the ultrasound bath followed by WD reprocessing (which is also tested according to the same protocol), achieves very good results for robot instruments (<100 µg/instrument).
- In some CSSDs the ultrasound bath successfully replaces manual pre-treatment.
- But what does the ultrasound bath itself achieve and what level of cleaning remains for the WD to accomplish?

Testing the cleaning performance of the ultrasound bath – Contamination -

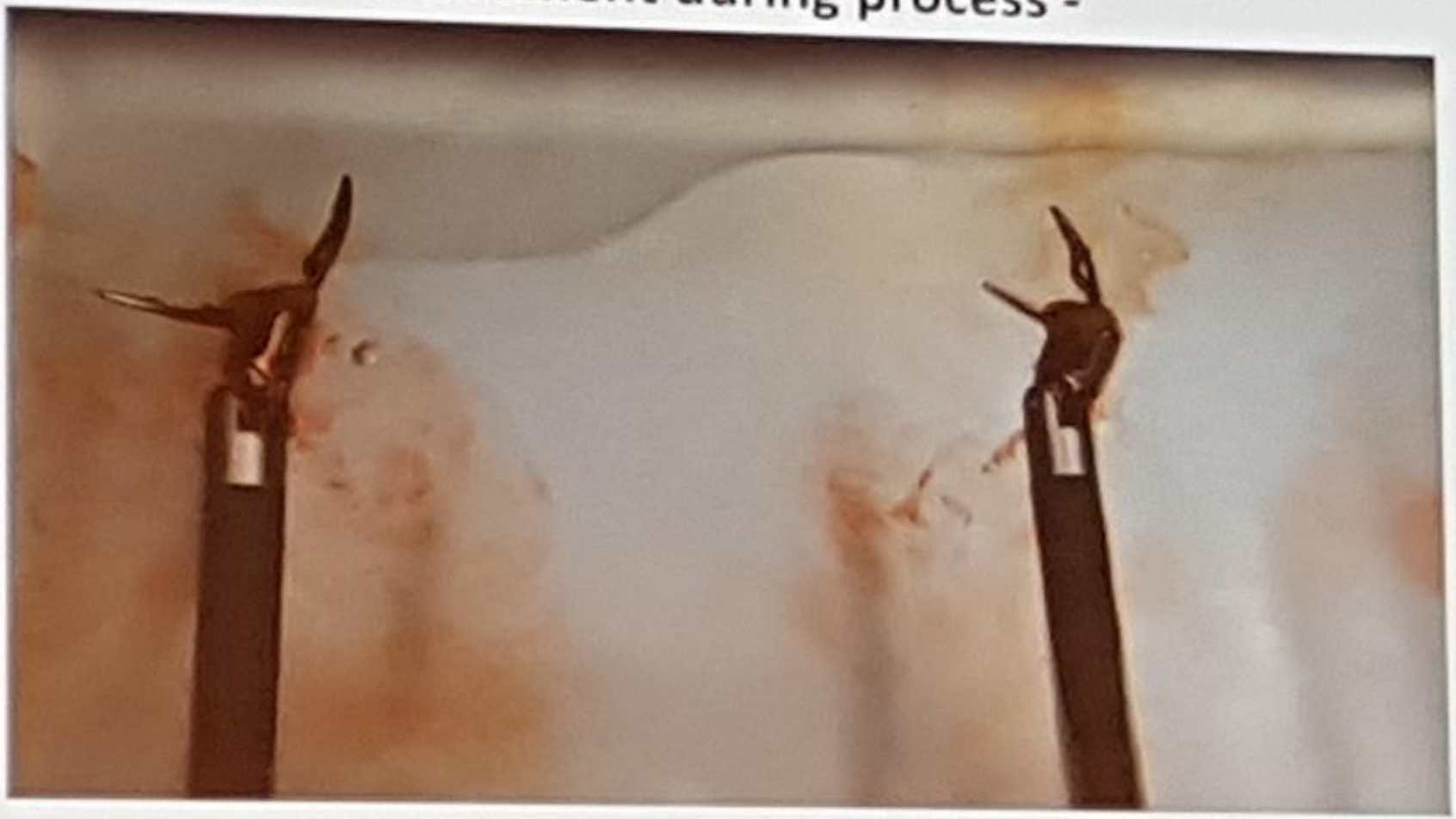
Contamination in the shaft in front of the distal seal using 600 µl coagulable sheep's blood and movement of the Bowden cables as well as contamination of the working end via immersion in 5 ml sheep's blood also with movement of the Bowden cables. Afterwards they are kept in ambient conditions for an hour.



Prüfinstrumente:

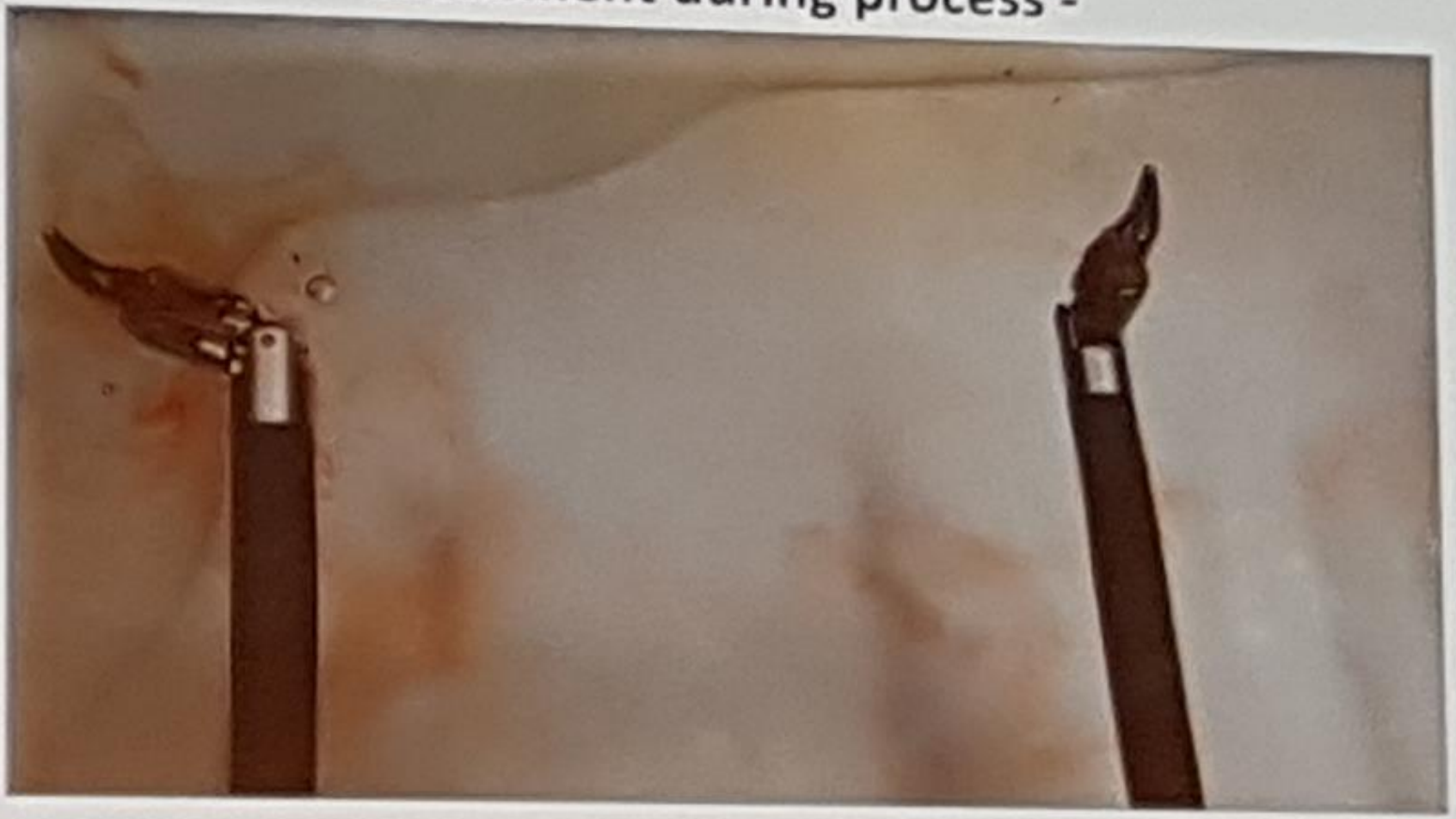
Instrument	Bezeichnung	LOT
MCS I	8mm Monopolar Curved Scissors	N1016021140 021
MCS II	8mm Monopolar Curved Scissors	N1016021140 005
MBF III	8mm Maryland Bipolar Forceps	51016062O0 023
MBF IV	8mm Maryland Bipolar Forceps	51016062O0 021
MCS V	8mm Monopolar Curved Scissors	51315111O0 066

Testing the cleaning performance of the ultrasound bath
- Movement during process -



Testing the cleaning performance of the ultrasound bath
- Movement during process -

Testing the cleaning performance of the ultrasound bath
- Movement during process -



Post-treatment of the instruments

- After being processed in the ultrasound bath, the instruments were taken out singly and were flushed via Port 1 using a syringe of 3 x 10ml fully demineralised water, to rinse away detergent solution and solutes. The exterior of the shaft and the tip were briefly rinsed using a laboratory spray bottle.
- The Bowden cables were not moved. On the one hand a small amount of detergent solution and solutes remains in the contact areas of the cables, on the other hand there is no additional cleaning effect.
- Pressurised air was used to blow through and over the instrument and sample taking was conducted for the determination of haemoglobin and residual protein.

Sampling/Extraction

Extraction followed, using 1% sodium dodecylsulfate solution at pH11, exactly according to the published method of the Da Vinci working group:

A method for testing the cleaning of MIS robotic instruments. Zentr Steril 2013; 21: 195 – 207

Protein analysis

A modified Biuret/BCA method (Roti®-Quant universal (Artikel 0120.1, Carl Roth, Karlsruhe) was used because detergent traces are certainly present and the detergents used themselves have a more or less strong OPA sensitivity.

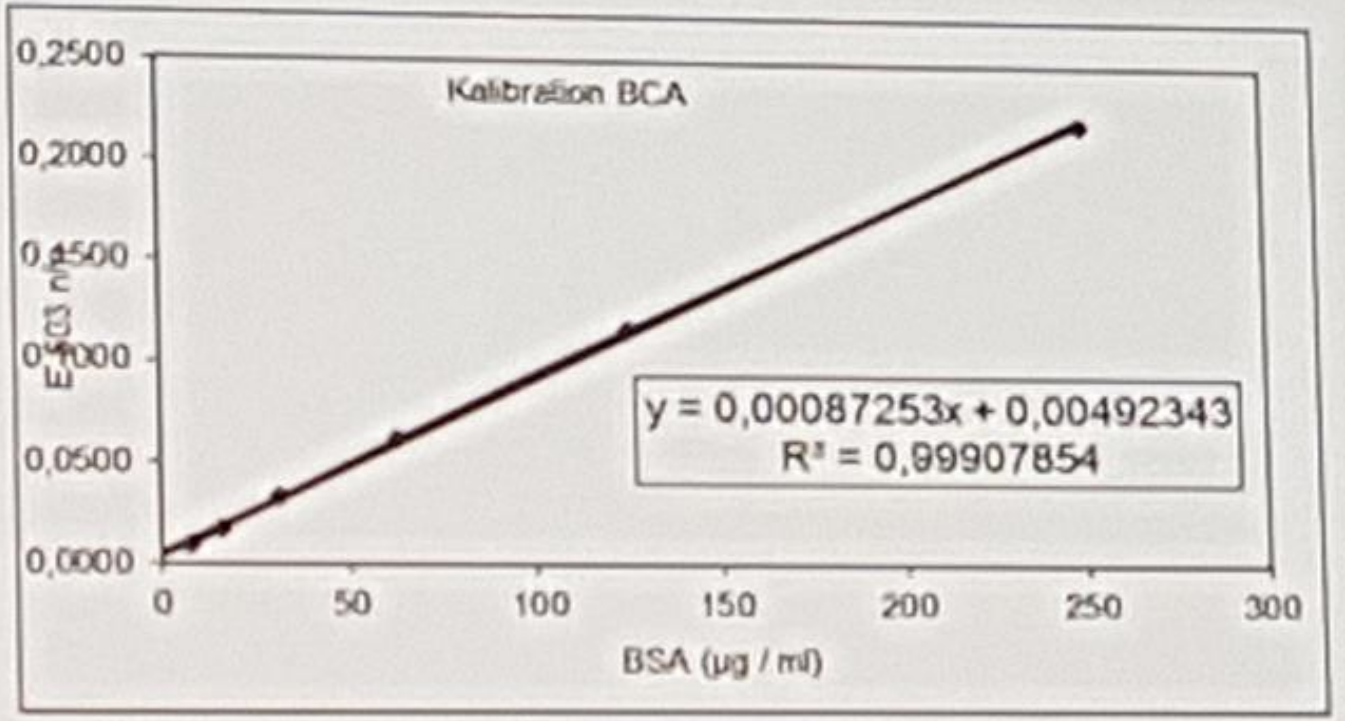


Abb.: Kalibrierung der BCA-Methode mit Rinderserumalbumin (BSA)

Quantification limit: 3,5 µg/ml bzw. 21 µg/instrument

Haemoglobin analysis

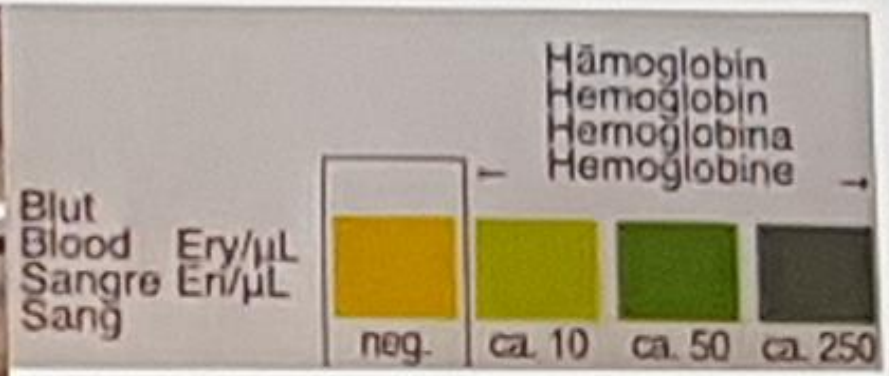
Semi-quantitative testing for haemoglobin followed, using test sticks for detecting microhaematuria: Medi-Test Combi V (Macherey & Nagel, Düren).
For blood contamination the rapid test delivers an additional important result about the effectivity of cleaning. Further information in

Central Service 1/2017

Haemoglobin as analyte for evaluation of cleaning

Winfried Michels

Color change by detergent solution after processing in the TRISON.



Results

Process 1:

Instrument	optical	µg protein per instrument	Haemoglobin per µl extract
MCS I	negative	55.5	0
MCS II	negative	<LOQ	0
MBF III	negative	41.8	10
MBF IV	negative	34.9	0
MCS V as negative control	negative	34.9	0

<LOQ = less than limit of quantification

Process 2:

Instrument	optical	µg protein per instrument	Haemoglobin per µl extract
MCS II	negative	90.3	0
MCS V	negative	76.5	0
MBF III	reddish residue in interspace of the tip	296.6	50
MBF IV	reddish residue in interspace of the tip	344.6	50
MCS I as negative control	negative	42.1	0

Results

When contaminating the MBF for these tests by immersion, a large drop of blood remains in the wide hollow space between the pulleys and cables. This does not dry out completely and is not broken up by the ultrasound, but remains as a reddish fibrin ‚sponge', which absorbs ultrasound like a rubber ball. But in the practical situation this scenario is quite unlikely to occur and so for subsequent tests we prevent a large drop of blood from remaining in this area.

Results

Process 3:

Instrument	optical	µg protein per instrument	Haemoglobin per µl extract
MCS II	negative	48.6	0
MCS V	negative	76.2	0
MBF III	negative	96.8	10
MBF IV	negative	131.2	10
MCS I as negative control	negative	55.5	0

Process 4:

Instrument	optical	µg protein pro instrument	Haemoglobin per µl extract
MCS II	negative	<LOQ	0
MCS V	negative	124.3	50
MBF III	negative	<LOQ	10
MBF IV	negative	138.1	50
MCS I as negative control	negative	21.2	0

<LOQ = less than limit of quantification

Results

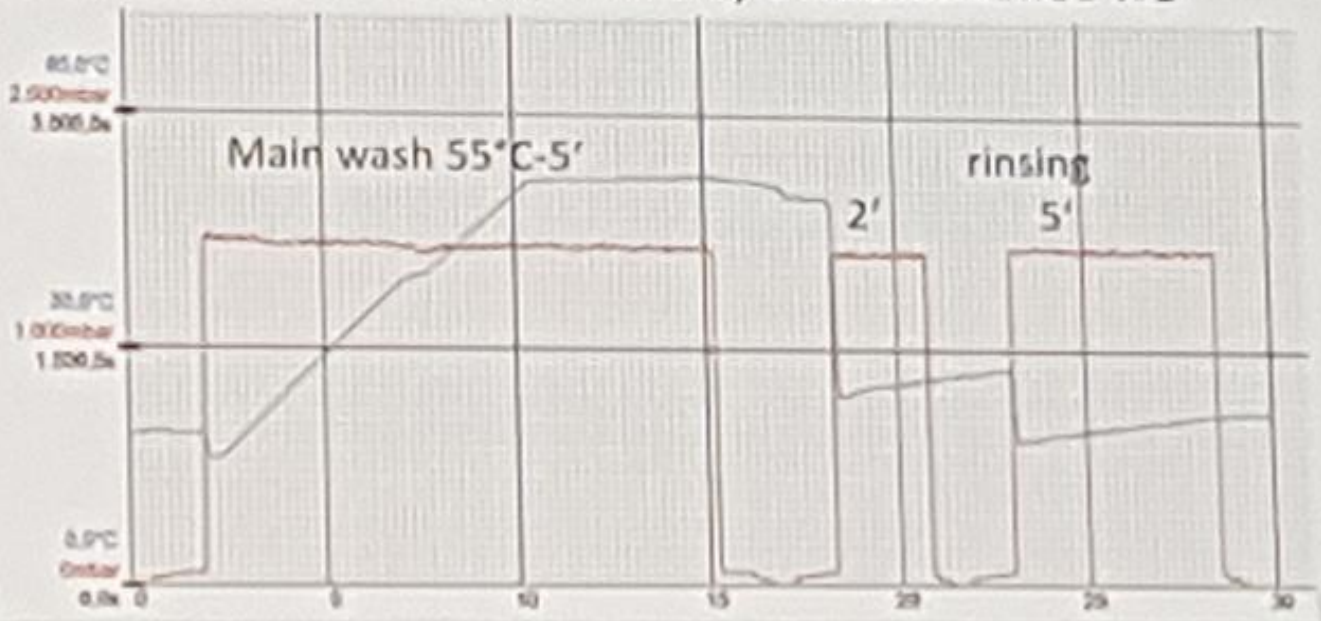
Process 5:

Instrument	optical	µg protein per instrument	Haemoglobin per µl extract
MCS II	negative	55.5	0
MCS V	negative	117.4	50
MBF III	negative	41.8	0
MBF IV	negative	165.0	10
MCS I as negative control	negative	28.0	0

For the values for the test instruments, the values for the negative control can be certainly be substracted.
An MBF was not used as a negative control. As the MCS are always much more intensively flushed, it can be presumed that the MBF as a negative control could have rather higher protein values.

Implications

- The TRISON ultrasound bath not only replaces manual pre-treatment, it achieves almost complete cleaning.
- Because the WD is tested for the same cleaning performance and the processes are suitably designed, savings in consumption of resources and time taken should be possible.
- In this combination, and using the same method, we tested cleaning after use of the ultrasound bath, followed by a foreshortened WD process.



Combination ultrasound bath and WD

Four loads each holding two MCS and two MBF were treated in the TRISON, then put through a foreshortened process in the UNICLEAN PL II (MMM).

Also during these tests, after treatment of the MBF in the ultrasound bath, there were single instances where reddish fibrin ‚sponge' was seen between the distal pulleys.

Results for the combination of ultrasound bath and foreshortened WD process

	Instrument	optical	µg protein per instrument	Haemoglobin per µl extract
Load 1	MCS I	negative	<LOQ	0
	MCS II	negative	<LOQ	0
	MBF III	negative	<LOQ	0
	MBF IV	negative	<LOQ	0
Load 2	MCS V	negative	<LOQ	0
	MCS VI	negative	28.04	0
	MBF VII	negative **	<LOQ	0
	MBF VIII	negative	<LOQ	0
Load 3	MCS I	negative	<LOQ	0
	MCS II	negative	<LOQ	0
	MBF III	negative	<LOQ	0
	MBF IV	negative	<LOQ	0
Load 4	MCS II	negative	<LOQ	0
	MCS V	negative	21.2	0
	MBF III	negative	41.8	0
	MBF IV	negative	21.2	0

<LOQ = less than limit of quantification

Verification using instruments soild by actual use in the Caritas Hospital St. Josef, Regensburg

Load	Instrument	Haemoglobin µg/µl	Protein µg/0 ml
1	1	~10	98.1 *
1	2	<LOD	<LOQ
1	3	<LOD	<LOQ
2	1	<LOD	<LOQ
2	2	<10	<LOQ
2	3	10-50	144.2 **
3	1	<LOD	23.4
3	2	<LOD	<LOQ
3	3	<LOD	23.5
4	1	<LOD	<LOQ
4	2	<LOD	<LOQ
4	3	<LOD	<LOQ
5	1	<LOD	23.4
5	2	<LOD	23.4
5	3	~10	75.0

* Curved Bipolar Dissector with severe encrusting without brushing before ultrasound treatment, but intensively cleaned with a brush before being processed in the WD (UNICLEAN PL II)

** Curved Bipolar Dissector with severe encrustring only quickly brushed before the ultrasound treatment

For loads 3 - 5 only the CBD was cleaned with a brush until optically clean before being treated in the TRISON.

Post-checks as part of the routine at the Caritas Hospital St. Josef, Regensburg

Load	Instrument	Haemoglobin µg/µl	Protein µg/6 ml
1	Curved Bipolar Dissector	~10	77.2
1	Large Needle Driver	<LOD	<LOQ
1	Monopolar Curved Scissors	<NG	47.9
2	Curved Bipolar Dissector	50	113,8*
2	Large Needle Driver	<LOD	<LOQ
2	Monopolar Curved Scissors	<LOD	25.9

On account of the personnel dependence is brushing no adequate solution!

Curved Bipolar Dissector after an operation

Hydrogen peroxide treatment of cauterisation residues

- For EndoWrist instruments, due to material incompatibilities, this treatment is prohibited by the manufacturer.
- The usually recommended 3% hydrogen peroxide solution is even with lower soiling not or hardly efficient.

Elektrodes after cauterisation

Elektrodes after 60 minutes in 3% hydrogen peroxide

Steam cleaning leads to denaturation of soiling in distal interior and cannot be applied.
Only the development of a standardised mechanical treatment can be aim-leading.

Summary

- The ultrasound bath TRISON is very efficient at cleaning and in combination with a suitable wash-disinfection process it is very safe to conclude that low residual protein values in the area of the quantification limit of the BCA method can be attained.
- Manual pre-treatments are replaced for robot instruments, except for cauterising instruments.
- For the WD, the cleaning process can be significantly shortened, consumption of resources is reduced and considerable time is saved.
- To facilitate and improve cleaning of cauterising instruments research and development is urgently required.

Thank you for your attention!