# Cleaning of robotic instruments: Can we reduce the work load in the CSSD and improve patient safety?

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wfhss
World Federation for Hospital Sterilisation Sciences

Involved in Robotic developments since 1991

The Artemis project together with the Nuclear Research Center Karlsruhe

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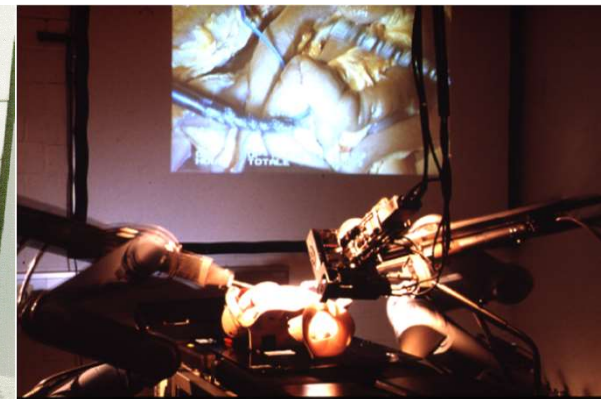
Asensus
Auris
Avatera
CMR
Ethicon
Globus Medical
Intuitive
Medicaroid
Medtronic
Stryker
Titan Medical
Transenterix

Since 2001 SMP is validating reprocessing processes on Robotic devices.

In the meanwhile we have performed or are still performing validation studies for 8 manufacturers of surgical robots.

At least one manufacturer is providing a single use solution.

Most of the devices used with the robots need manual pretreatment which can take up to 15 minutes manual time per device.

Recommendation for Performance Qualification on da Vinci instruments

IG WiG Working Group –Recommendation, Validation of da Vinci Instrument Reprocessing Process

IG WiG, Interessengemeinschaft Wiederaufbereitung im Gesundheitswesen

Translation into English language from Original German publication

Recommendation
## Validation of da Vinci Instrument Reprocessing Process

Different countries have different acceptance criteria's

No.	Criterion	Acceptance level	References
1	Amount of soil visible on the sample at the end of the cleaning process	No soil visible	DIN EN ISO 15883-5:2021-11 RKI guideline: 2012 AAMI TIR 30: 2011 Guideline DGKH, DGSV, AKI: 2017
2	The total amount of protein per sample shall be	<100 µg	RKI guideline: 2012
3	The total amount of protein per sample shall be	< 200 µg	EN ISO 15883-1:2014
4	The amount of protein/cm^2 shall be	< 3.0 µg/cm^2	Guideline DGKH, DGSV, AKI: 2017 DIN EN ISO 15883-5:2021-11
5	The amount of protein/cm^2 shall be	< 6.4 µg/cm^2	AAMI TIR 30: 2011 ANSI/AAMI ST98: 2022
6	The amount of hemoglobin/cm^2 shall be	< 1.0 µg/cm^2	DIN EN ISO 15883-5:2021-11
7	The amount of hemoglobin/cm^2 shall be	< 2.2 µg/cm^2	AAMI TIR 30: 2011 ANSI/AAMI ST98: 2022

Summary Statistics of Performance Qualification Testing at 28 Hospitals in Germany

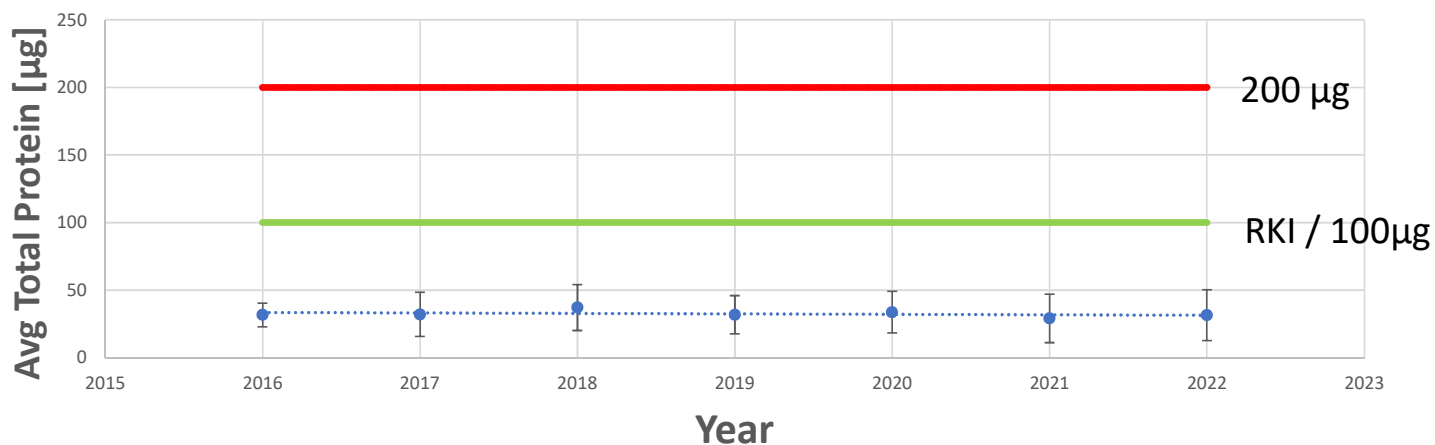| Year	N	Total Protein [µg]		Number		
		Ave	SD	<100µg	100-199µg	>=200µg
2012	61	176,3	115,4	19	21	21
2013	89	72,7	82,4	73	13	3
2014	73	35,1	34,5	70	2	1
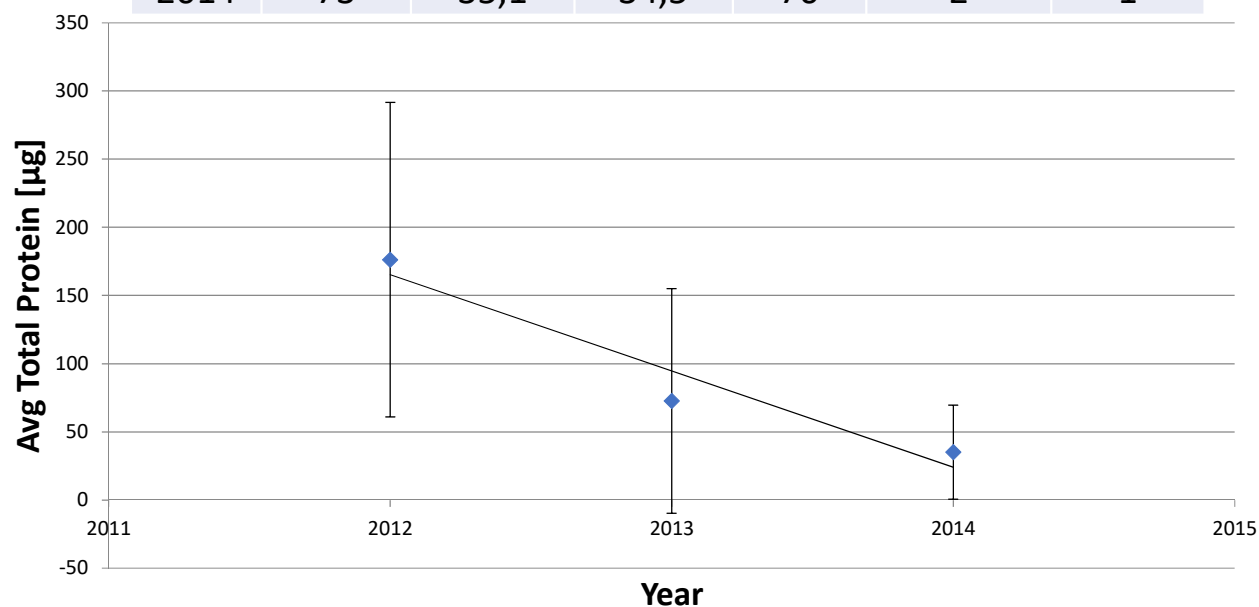
Wallace, Wille, Roth, Hubert; Central Service 2015; 23:182-87

Performance qualification data from SMP on hospital used devices

| Year | Tested Devices (all families) | Type I | | Type II | | Xi + Si 8mm | | | |
		Xi 8mm	Si 8mm	Xi 8mm	Si 8mm	results over 100 µg (excluded from AVG)	N	AVG [µg]	SD [µg]
2016	38	9	12	0	9	-	30	31,7	8,8
2017	57	13	5	21	13	440; 153	50	32,1	16,3
2018	80	33	6	16	21	114; 124	74	37,2	17,0
2019	140	55	6	49	25	137; 119; 407; 265; 121	130	31,9	14,1
2020	128	53	8	62	5	151; 138; 108; 101; 126; 122	122	33,8	15,3
2021	113	26	4	76	4	-	110	29,1	17,9
2022	124	56	4	51	11	110; 103; 136; 103	98	31,6	18,8
		245	45	275	88				
Total	680		653			~96%			

Dirty Side, Automated Cleaning

Dirty Side Preparation		Prepare for Automated Cleaning and Disinfection		Conduct Automated Cleaning and Disinfection	
Step 1	Remove Accessories	Step 4	Prime	Step 11	Automated Cleaning
Step 2	Check Indicator	Step 5	Soak	Step 12	Transfer
Step 3	Prepare Solution	Step 6	Flush		
		Step 7	Spray		
		Step 8	Brush		
		Step 9	Rinse		
		Step 10	Inspect		

Time for the pre-cleaning step: ~ 35 – 40 minutes including minimum of 5 minutes manual action

Tested WDs by SMP: Until today more then 20 different types

AT-OS	AWD655-10
Belimed	WD 290
BHT	WD M5 ISO
Getinge	56M / 8668 / 88T
KEN / (Matachana)	IQ5 / IQ6 (LD500/LD1000)
Medisafe	PCF / Niagara PCF
Steelco / Miele	PWD8626
Miura	WD RQ-50E
MMM	Uniclean PL2
SHINVA	PC-150L / Victor6000
SMEG	WD7015T / 6010
Steelco	DS1000 / DS600 / US300
Steris	AMSCO 7053HP / 5053

According ISO 17664 the manufacturer of a medical device has to provide at least on automated method.

For DaVinci instruments more than 20 types of washer has been successfully tested.

Tests have been performed with different chemistries.

The available data from the PQ-tests on da Vinci instruments are showing a high improvement over the years

Latest since 2013 the results were under the threshold of 100 µg of protein per device

The ongoing performance qualification data show, that good cleaning results can be repeatedly reached.
95% of the devices have been beneath 100 µg. The average was ~ 34 µg

This was reached by:

• Intensive training of the staff of the CSSD by the manufacturer

• Improvement of the IFU

• Development of specific cycles for DaVinci instruments

• Testing, testing, testing to reduce the low failure quote of the manual pre-cleaning from 4% to 0%

2005: Start with Medisafe SI PCF and daVinci:

Only manual pre-cleaning of the tip is needed,
but for thermal disinfection a WD is needed

- Pre-Wash –internal & external @ 40psi
- Detergent Dispense
- De-gas
- 15 minute Ultrasonic Main Wash – internal/external 40psi
- Pre-Rinse – internal & external @ 40psi
- Final Rinse
- Empty – each cycle

Cycle time around 30 minutes

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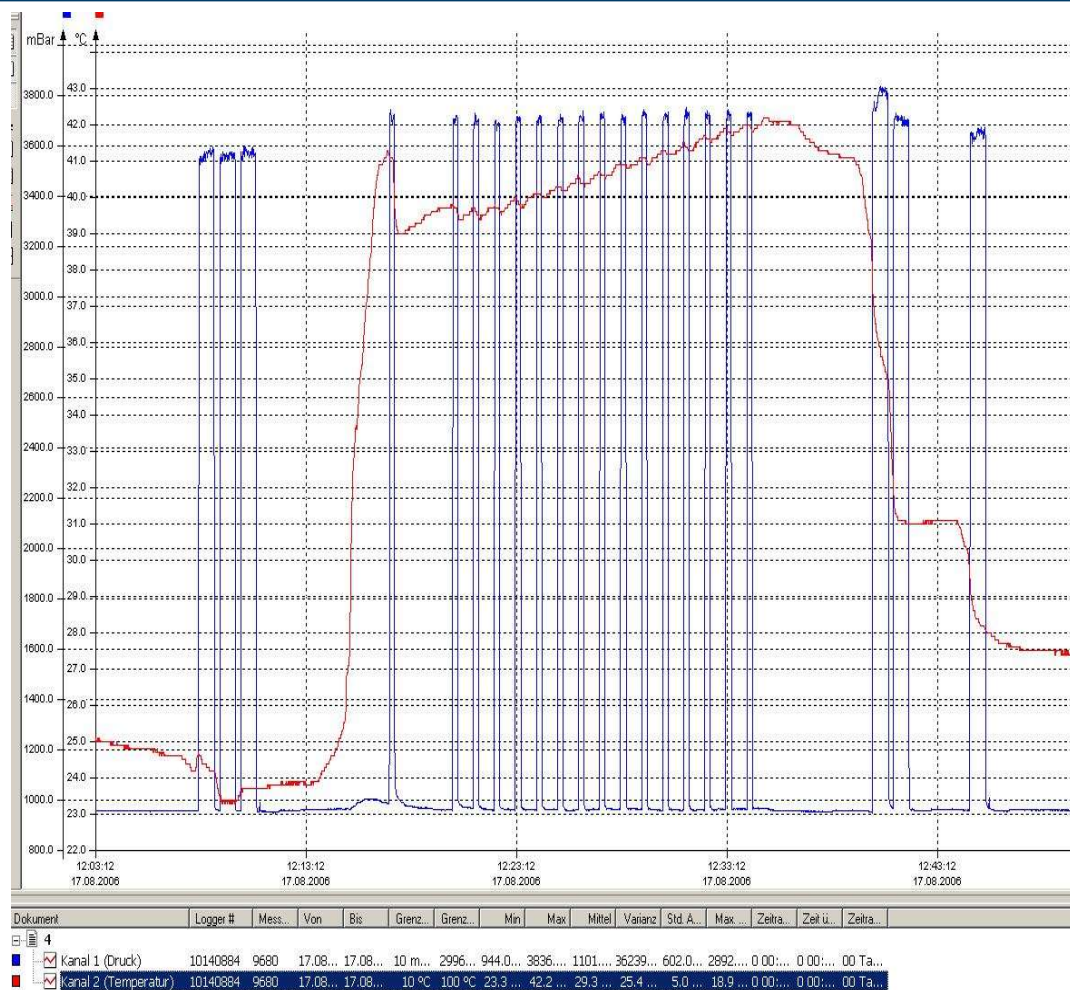
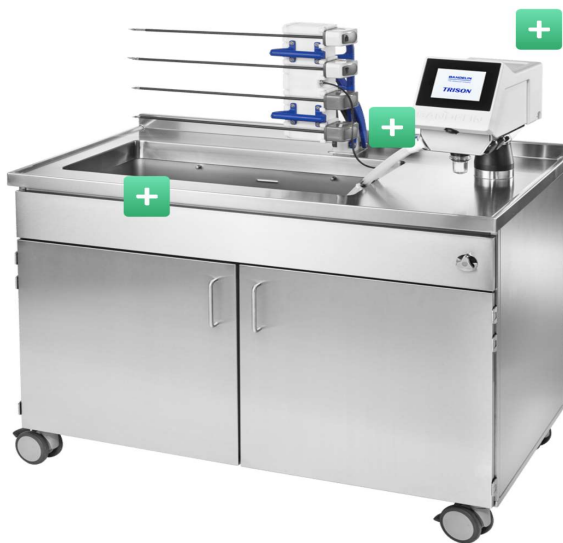High water pressure in combination
with ultrasonic irrigation delivered
good results

Reducing the work load

2015: Bandelin Trison

- No manual pre-cleaning of the tip is needed, as the Trison is articulating the tip of the device
- but a full cycle in a WD is needed afterwards

- Manual work is limited to load and unload the Trison
- Cycle time around 30 minutes

Comparison of the outcome of manual pre-cleaning and pre-cleaning with Trison

Sample	After contamination Zr [counts/s]	After manual pre-cleaning Zr [counts/s]	Reduction of radioactivity after manual pre-cleaning %
Maryland Bipolar Forceps (Sample Size n = 18)	Average = 241.8 SD = 22.5	Average = 113.0 SD = 25.0	Average = 53.1 SD = 10.3
Monopolar Curved Scissors (Sample Size n = 15)	Average = 232.5 SD = 26.9	Average = 112.0 SD = 62.1	Average = 52.3 SD = 25.1

Table 8: Statistical summary manual pre-cleaning

SD=Standard deviation

| Sample	After contamination Zr [counts/s]	After pre-cleaning in TRISON ultrasonic bath Zr [counts/s]	Reduction of radioactivity after pre-cleaning %
Maryland Bipolar Forceps (Sample Size n = 9)	Average = 266.4 SD = 19.0	Average = 16.9 SD = 15.1	Average = 93.8 SD = 5.2
Monopolar Curved Scissors (Sample Size n =9)	Average = 266.1 SD = 14.5	Average = 25.3 SD = 29.6	Average = 90.4 SD = 11.4

Table 9: Statistical summary pre-cleaning in TRISON ultrasonic bath

SD=Standard deviation

The standardized pre-cleaning step of Trison delivers more safety for the patient

Typical Da Vinci cycle: ~ 1 hour only for cleaning   Specific load carrier are needed
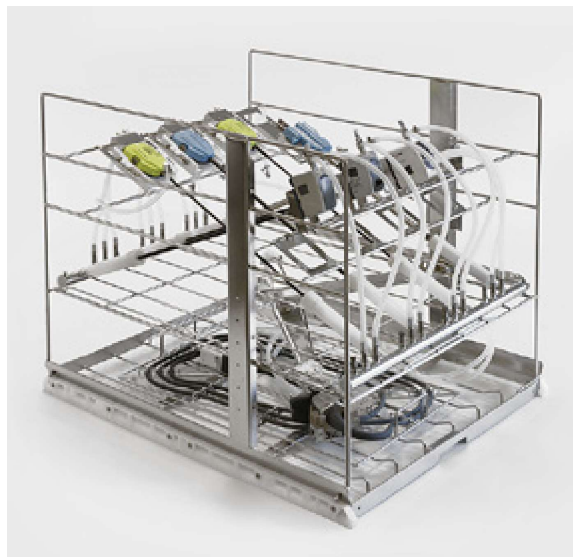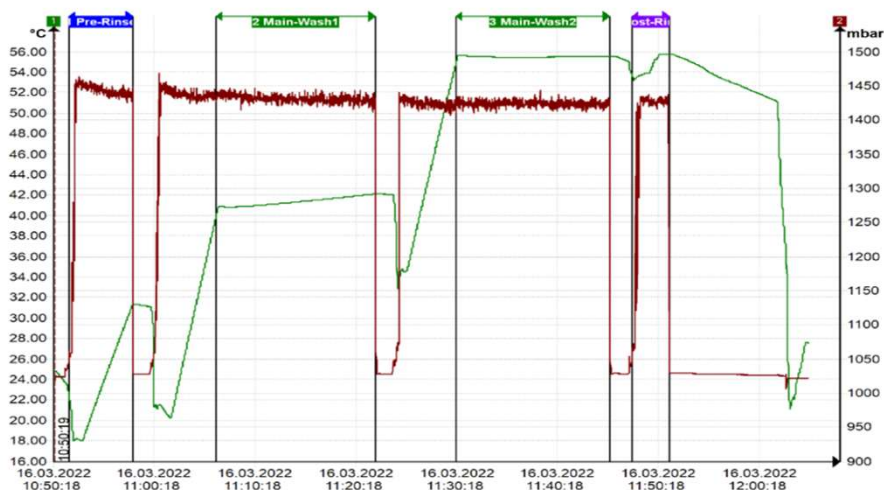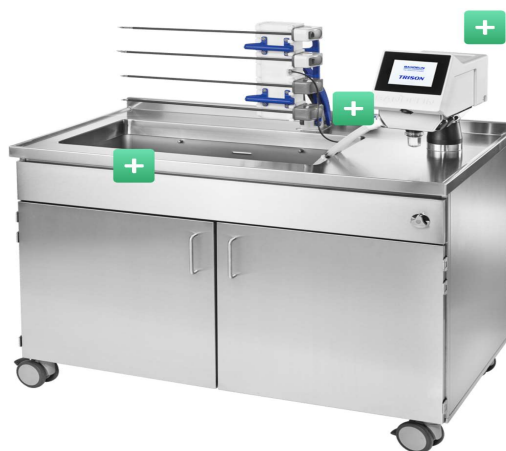

- Prewash
- 2 x 10 minutes main wash
- 1 or 2 times rinse
- Time without disinfection more than 1 hour

High consumption of water, electricity and chemistry as two main washes are performed

2019: Bandelin Trison in combination with WD

- No manual pre-cleaning of the tip is needed
- a full cycle in a WD is needed afterwards
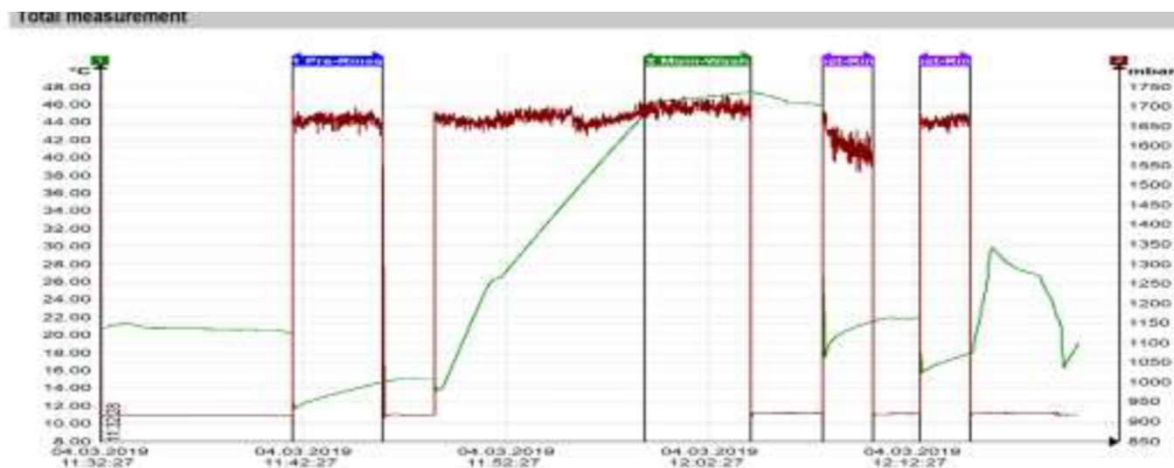- Specific tray for DaVinci instruments
- Space for other instruments

da Vinci.Surgery

Cycle time around 30 minutes   plus   cycle time of 45 minutes

2019: Bandelin Trison in combination with WD

Trison: 30 minutes

WD:
- Prewash
- 5 minutes main wash
- 2 times rinse
- Time without disinfection around 35 minutes

Lower consumption of water, electricity, chemistry and time as only one main wash is performed

Time for cleaning including precleaning but without thermal disinfection: 65 minutes

2022: Bandelin Trison **(modified process)** in combination with WD

The modified process is shorter and less stressing of the instruments.
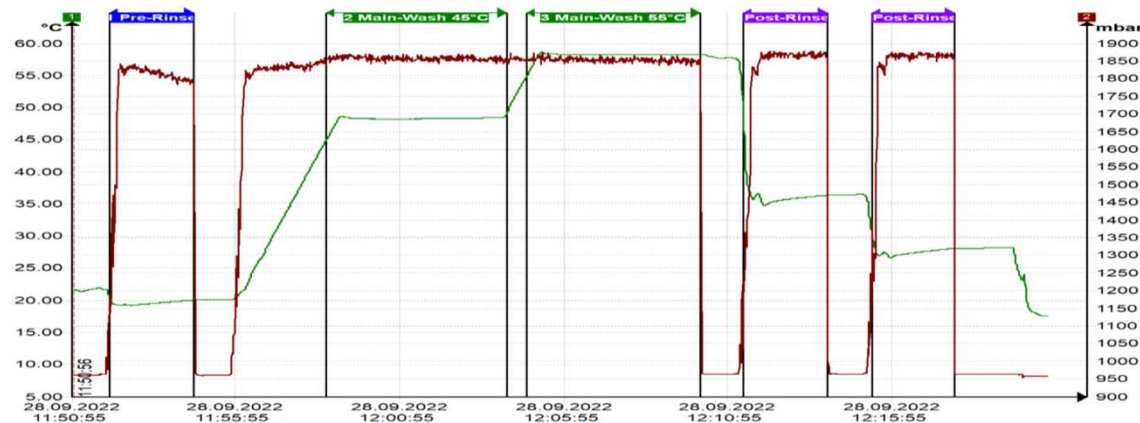
2022: Bandelin Trison **(modified process)** in combination with WD

Trison: 10 minutes (only 3 sequences)

- Ultrasonic cavitation during the complete the process.

- Movement of the instruments tip in all his axes.

  Every sequence includes alternate irrigation with flow check of the internal channels of 4 instruments
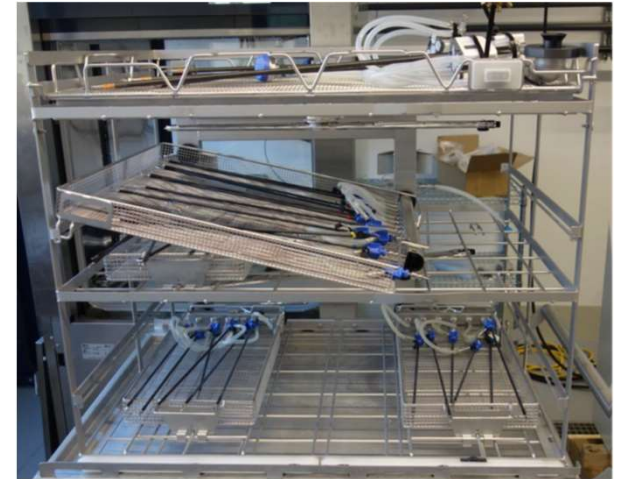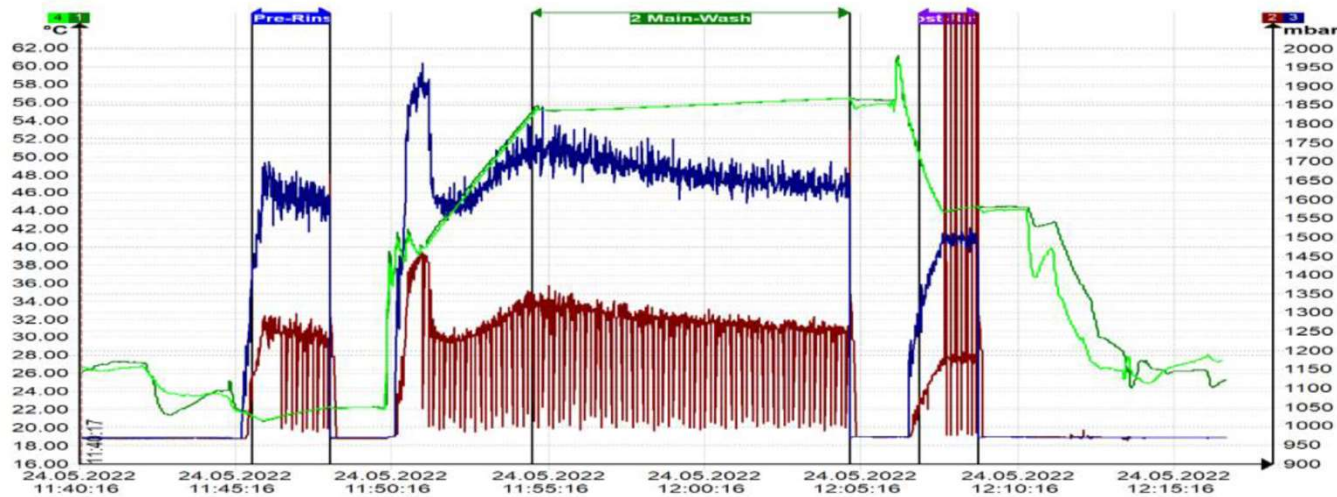
WD process

- Prewash
- 5 minutes main wash
- 2 times rinse
- Time without disinfection around 27 minutes

Lower consumption of water, electricity, chemistry and time as only one main wash is performed

Time for cleaning including precleaning but without thermal disinfection: 37 minutes

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Other solutions: High water pressure used during a full cycle

Time for cleaning without thermal disinfection: 25 minutes

Different ways

Manual pre-cleaning with full validated cycle as known until today

Standardized pre-cleaning with Trison followed by a standard MIS-cycle

Improved patients safety
Less work load

Specific WD with high pressure

Improved patients safety
Less work load

The future should be:

Devices which can be reprocessed like standard device and no need of specific accessories

Conclusion

It has been shown by clincal data, that a high level of safety for the patients has been reached in the last decade

Ongoing examinations are showing, that the high level could be hold over the years

For DaVinci devices a high number of cleaning cycles with different w/d and chemistry has been validated

New developments in the washing technology is reducing the manual pre-cleaning and are reducing the eviromental foot print.

The hurdle of validation has been set quite high for competitive robotic instruments manufacturer