

# Configuration of Surgical Instruments:

## Influence and Validation of the Cleaning Process according to ISO 17664

Klaus Roth

## Operation, which have been cancelled due to not sufficient reprocessed instruments

Year	2002	2003	2004	2005
Data of 57 hospitals**	1252	1661	1926	1765
Estimated for England and Wales	7500	9900	11500	10500

\*\* 57/340 Datensätze

\* mit freundl. Genehmigung G.Shapp MP

# Requirements of EN/ISO 17664

- Preparation at the point of use
- Transport
- Cleaning
- Disinfection
- Functionality testing
- Packaging
- Sterilisation
- Storage

# EN/ISO 17664

## 3.5 Cleaning

A validated method of cleaning shall be specified. At least one validated automated method using a washer-disinfector shall also be specified unless the medical device cannot withstand any such process, in which case a warning should be issued.

Where appropriate, at least the following information shall be included:

- .accessories required for cleaning process;
- .identification and concentration of chemicals required for cleaning;
- .identification of water quality,
- .limits and monitoring of chemical residues
- .limits on temperature, concentration of solution(s), exposure time,
- .process temperature(s);
- .techniques to be used including rinsing;

# **Project with 30 instrument manufacturer:**

## **Aim of the project**

**It is the aim of the research project to use the same reprocessing cycle for all kind of instruments.**

**Enhanced requirements for the cleaning process has to be fulfil by special manual pre-cleaning or special equipement for the pre-cleaning or the w/d.**

**To many different reprocessing cycles may lead to difficulties in the daily routine and following the specifications.**

## **Alkaline process: Step 1**

### **Automated cleaning in the w/d**

The cleaning are performed only in a washer disinfecter G 7735 CD (Miele) Directly after contamination without manually precleaning (Program abortion before disinfection step). After dismantling the instruments are placed on the specific tray and the cleaning and disinfection program Vario TD is started:

- 1 min pre-washing with cold water
- emptying
- 3 min pre-washing with cold water
- emptying
- 5 min washing with 0,5 % alkaline cleaner by 55°C (Dr. Weigert, Neodisher FA)
- emptying
- 3 min neutralizing with warm water (>40°C)
- emptying
- 2 min intermediate rinsing with warm water (>40°C)
- emptying

## **Alkaline process: Step 2**

### **Manually pre-cleaning**

- The instruments are immersed into cold tap water for 5 minutes.
- The instruments are brushed under cold tap water until all visible residues are removed.
- The instruments are dismantled and brushed again until all visible residues are removed.
- Inner lumens, threads and holes are flushed each with a water jet pistol for 5 seconds and brushed again.

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- Inner lumens, threads and holes are flushed each with a water jet pistol for 5 seconds and brushed again.

#### **Additional pre-cleanig with ultrasonic:**

- The instruments are immersed into an ultrasonic bath with alkaline detergent (Dr. Weigert neodisher FA 0,5%) and treatet with ultrasonic for 15 minutes at 40°C

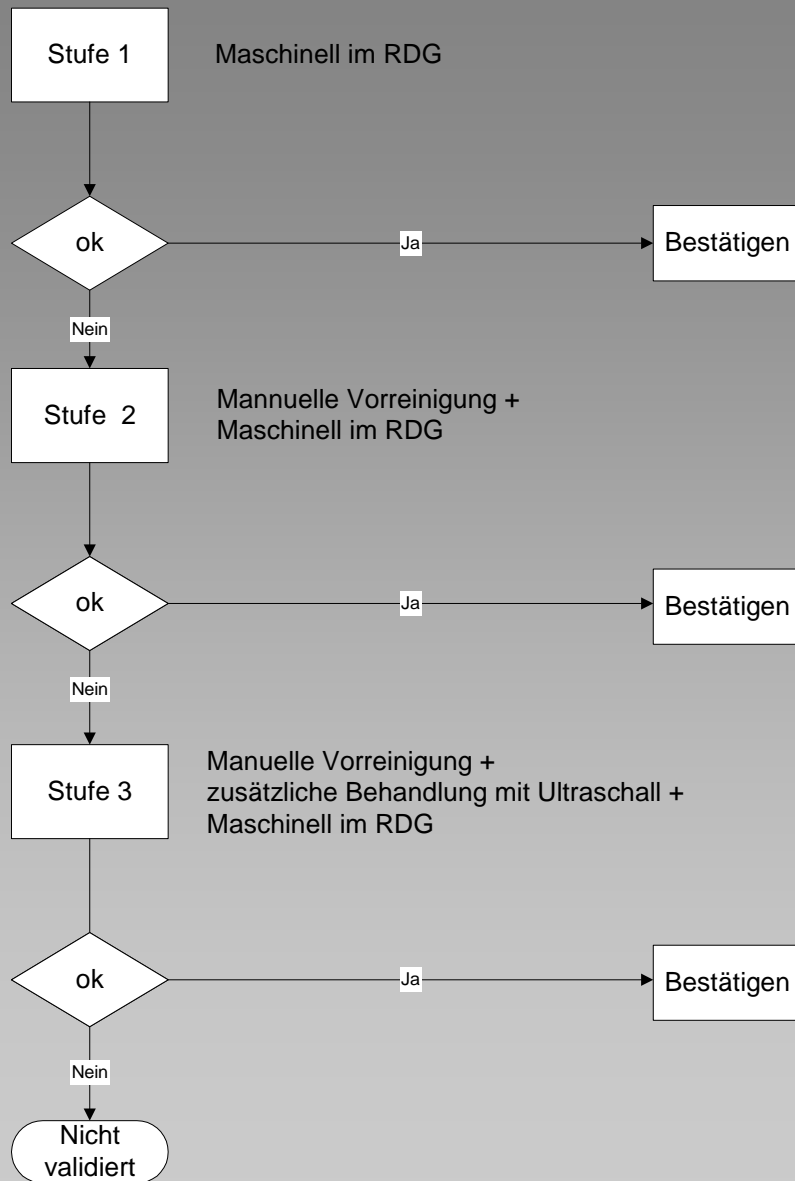
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## Exempel 1: Automated alkaline process with manuellt pre-cleaning



**Step 1: Automated cleaning in a W/D**

**Confirm**

**Step 2: Manual pre-cleaning  
Followed by automated cleaning**

**Confirm**

**Step 3: Manual pre-cleaning plus  
ultrasonic cleaning  
Followed by automated cleaning**

**Confirm**

**Not validated**

# Which Test Method should be selected?

Swab Test on  
the instruments?



Cleaning  
indicators?



# Radionuclide Method

**A non destructive test procedure for the validation of the cleaning process of surgical devices with lumens and hidden surfaces;**

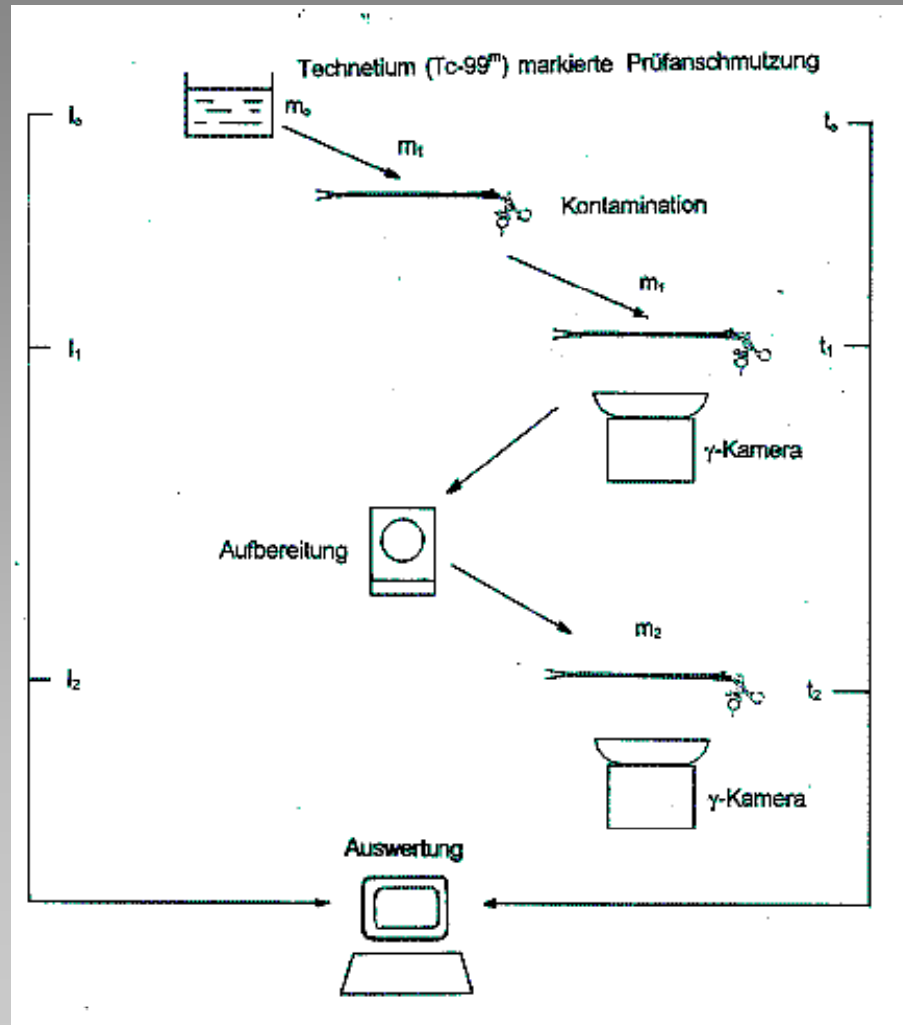
**e.g.**

- **forceps and scissors for open surgery**
- **devices for minimally invasive surgery**
- **devices for flexible endoscopy**

# Radionuclide Method

- Standardized in vitro contamination
- Quantification of remaining dirt
- Detection of problematic spots in instruments without destruction
- Validation method for cleaning processes
- Applied for ASTM – Standard
- Mentioned in AAMI TIR 30

# Radionuclide Method



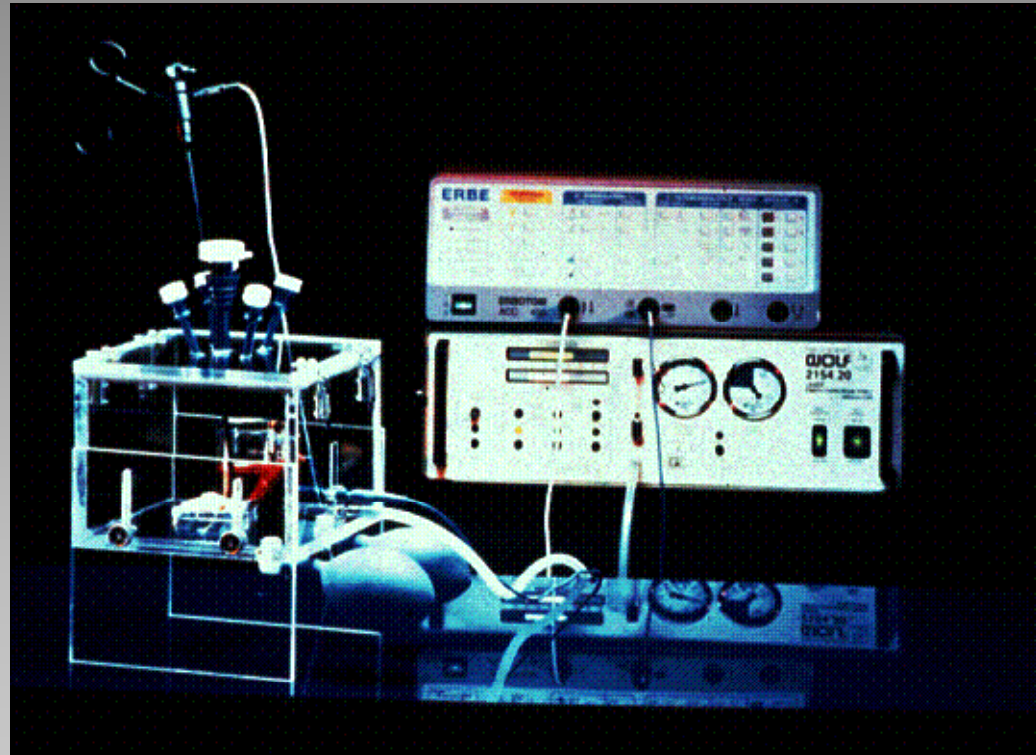
- Radioactive labelling of the blood with Tc 99m
- Contamination of the devices
- Measuring of the devices with the gammacamera
- Reprocessing of the devices
- Measuring of the devices after reprocessing
- Analysation

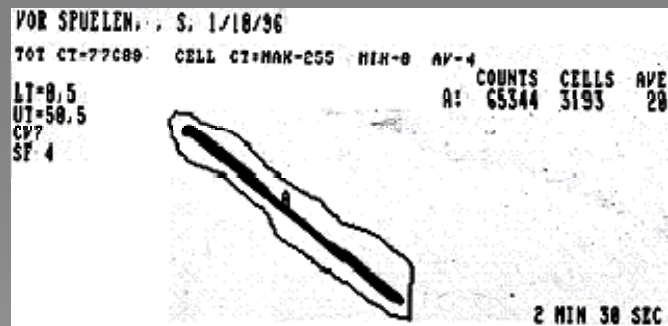
# Radionuclide Method

- **In vitro contamination of devices:**

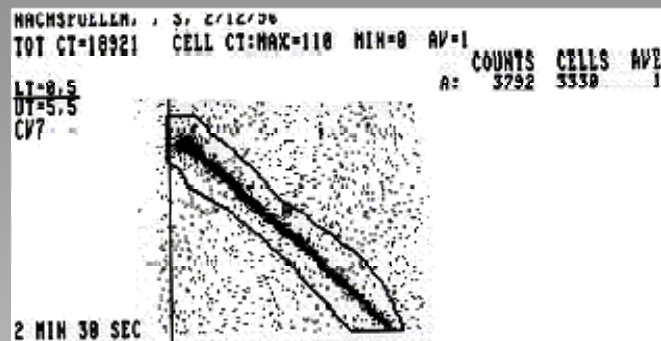
The devices are introduced into the simulation model, the tip of the device is submerged into radioactively labelled blood. The model is insufflated with 15 mm Hg. During the contamination time (10 min) the jaws of the device will be moved.

Insufflation pressure, capillary forces and pump effects lead to inside contamination of the device.

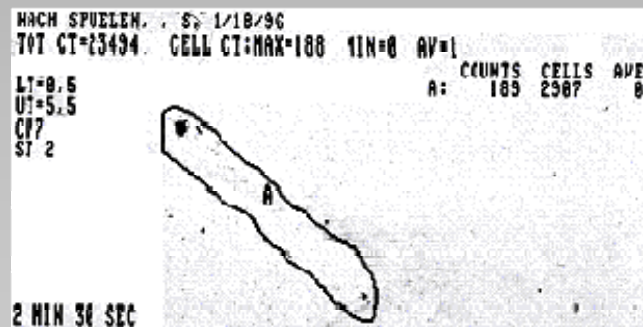




Picture 1 shows an MIS device before cleaning



Picture 2 shows the same device after cleaning. The inner lumen could not be cleaned due to an insufficient design of the device



Picture 3 shows the same device after redesign. Two spots in the area of the joints and the region of the rinsing port show remaining contamination. But the level of remaining contamination is beneath the acceptance criteria

# Classification of the instruments the groups

- Group 1:** **Critical A Instruments,**  
like hooks
- Group 2:** **Critical B Instrumentse**  
Scissors, Clamps
- Group 3:** **Shift shaft instruments**  
Rongeur etc.
- Group 4:** **Shaft instruments for MIS**  
need validation, as the result of the cleaning can not be inspected
- Group 5:** **Micro surgical Instruments**  
need validation, as the result of the cleaning can not be inspected
- Group 6:** **Complex Devices**  
has to be tested, as no analogical conclusions can be made
- Group 7:** **Flexible Instruments**  
need validation, as the result of the cleaning can not be inspected



# Classification in Groups

**Group 1:            Critical Instruments,**

## **Requirements:**

No drill hole with a relation smaller than 1 to 1

No dead end holes

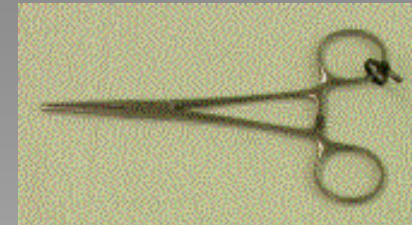
No hinges and joints

# Classification in Groups

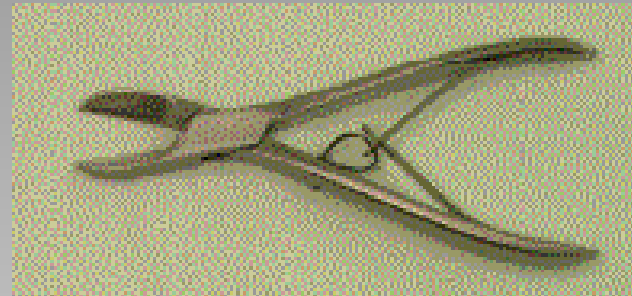
**Group 2: Forceps and Scissors**

**Sub-classification:**

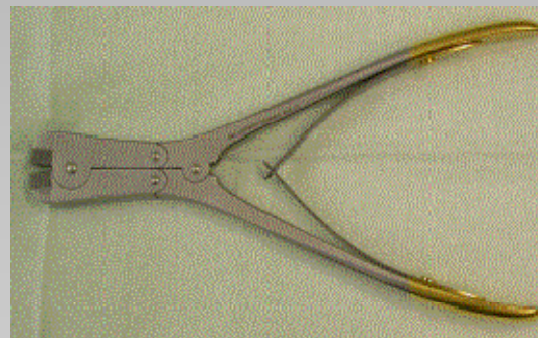
A: Crile-Clamp and similar hinge size, Box lock circa 7 x 14 mm



B: Box lock circa 12 x 20 mm



C: Box lock circa 16 x 25 mm



## Group 3 (Shift shaft instruments):

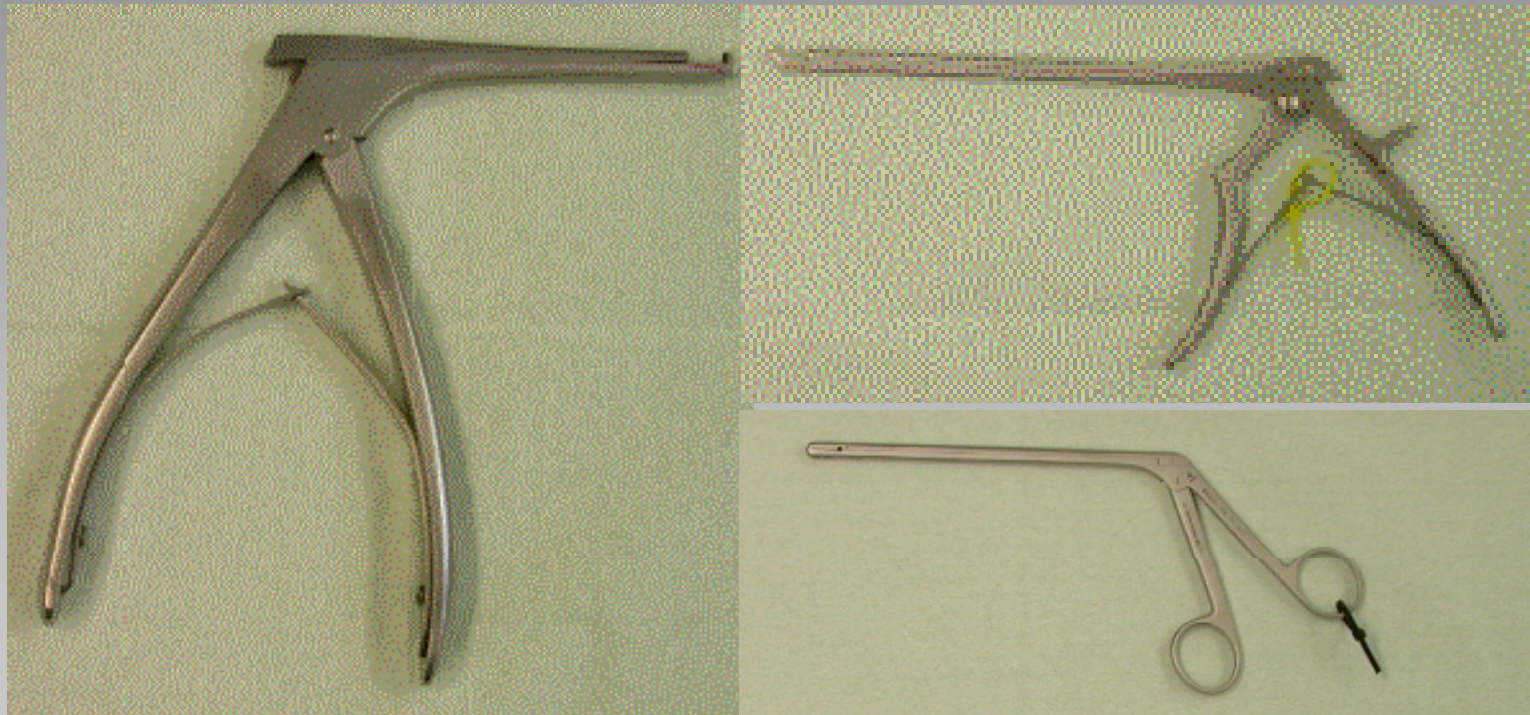
Rongeur, Arthroskopiezangen etc.

### Subclassification:

Category A up to 3 mm diameter

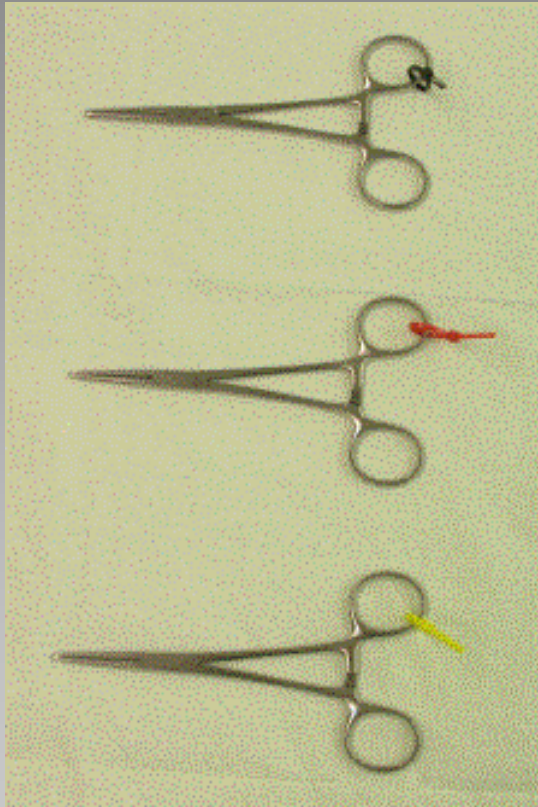
Category B 3 to 5 mm

Category C bigger than 5 mm



# Comparison of Group 2 Instruments

Crile Clamp,

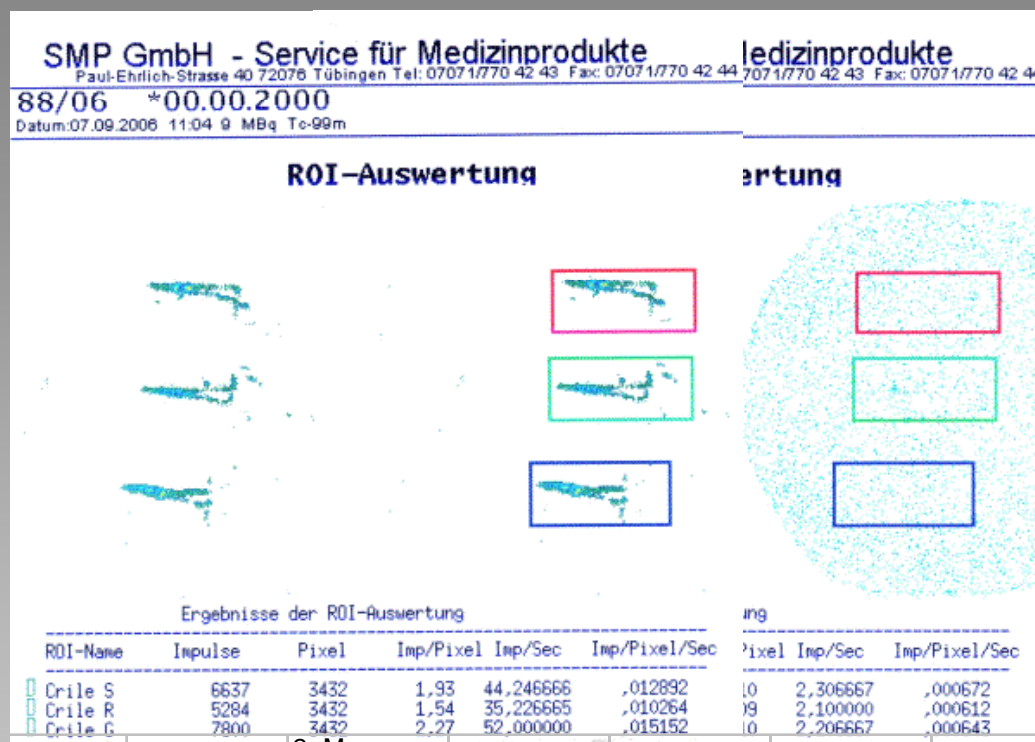


Side cutter



# Comparison of Group 2 Instruments

## Crile Clamp,



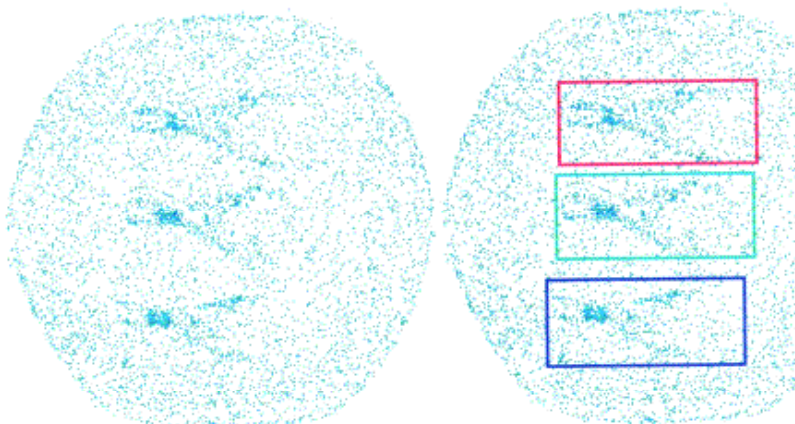
Nr.87/26	Zr	2. Messung nach Vorreinigung + 10 min 40°C Einweichen			Zr	2. Messung nach Vorreinigung + Ultraschall 10 min 40°C		Zr
		1. Messung nach Kontamination	4. Messung nach Reinigung			1. Messung nach Kontamination	3. Messung nach Reinigung	
Crile clamp 1	98	4	4		122	3	3	
Crile clamp 2	66	3	3		97	3	3	
Crile clamp 3	121	2	2		145	3	3	



## Group 2 (Instruments with hidden surfaces): Side cutter

**SMP GmbH - Service für Medizinprodukte**  
Paul-Ehrlich-Strasse 40 72076 Tübingen Tel: 07071/770 42 43 Fax: 07071/770 42 44  
**87/06 \*00.00.2000**  
Datum: 05.09.2006 12:13 9 MBq To-99m

### ROI-Auswertung



Ergebnisse der ROI-Auswertung

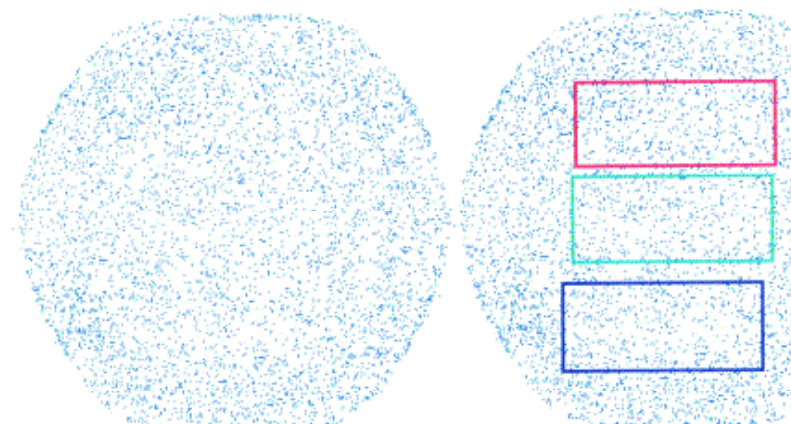
ROI-Name	Impulse	Pixel	Imp/Pixel	Imp/Sec	Imp/Pixel/Sec
Sidecut S	1040	5850	,18	6,933333	,001185
Sidecut R	1006	5967	,17	6,706667	,001124
Sidecut G	1055	5967	,18	6,933333	,001185

1. Messung  
nach  
Vorreinigung  
+ 10 min  
40°C  
Einweichen  
2. Messung  
nach  
Reinigung  
3. Messung  
nach  
Reinigung

Nr. 87/26	Zr	Zr	Zr		Zr	Zr	Zr	
Wire cutter 1	69	10	10		95	4	4	
Wire cutter 2	79	9	7		57	4	4	
Wire cutter 3	59	9	8		65	3	4	

**SMP GmbH - Service für Medizinprodukte**  
Paul-Ehrlich-Strasse 40 72076 Tübingen Tel: 07071/770 42 43 Fax: 07071/770 42 44  
**87/06 \*00.00.2000**  
Datum: 05.09.2006 15:58 9 MBq To-99m

### ROI-Auswertung

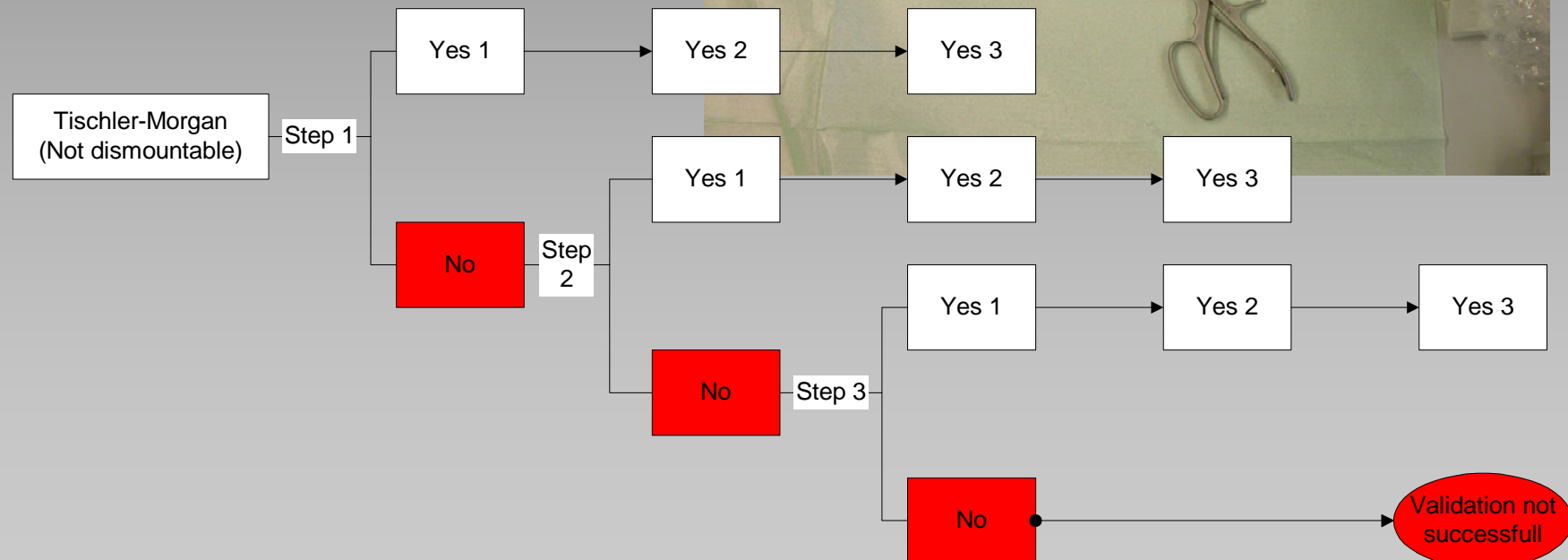


Ergebnisse der ROI-Auswertung

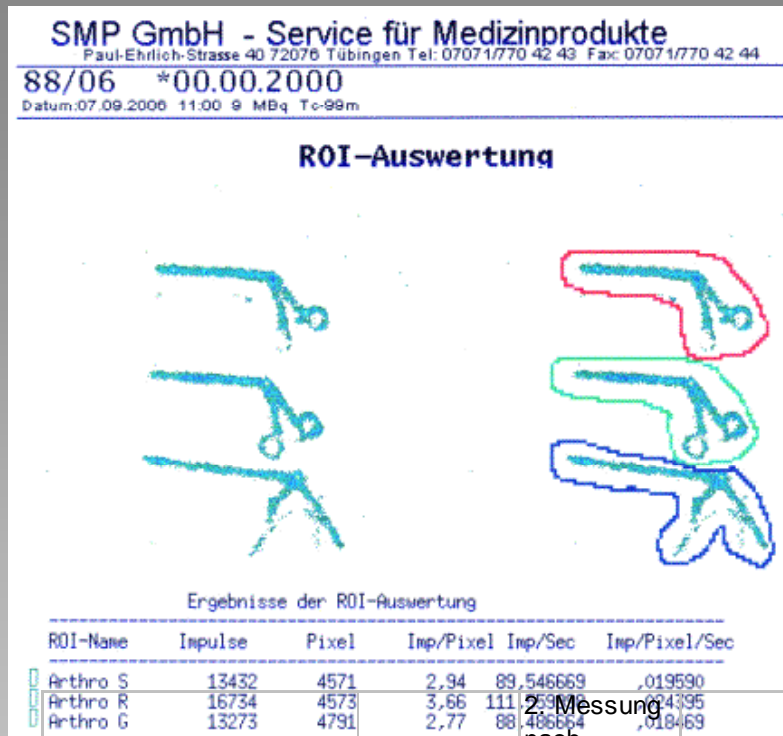
ROI-Name	Impulse	Pixel	Imp/Pixel	Imp/Sec	Imp/Pixel/Sec
Sidecut S	545	5967	,09	3,633333	,000621
Sidecut R	509	5967	,09	3,393333	,000569
Sidecut G	541	5967	,09	3,606667	,000604

1. Messung  
nach  
Vorreinigung  
+ 10 min  
40°C  
Reinigung  
2. Messung  
nach  
Reinigung  
3. Messung  
nach  
Reinigung

## Group 3: Shift shaft instruments



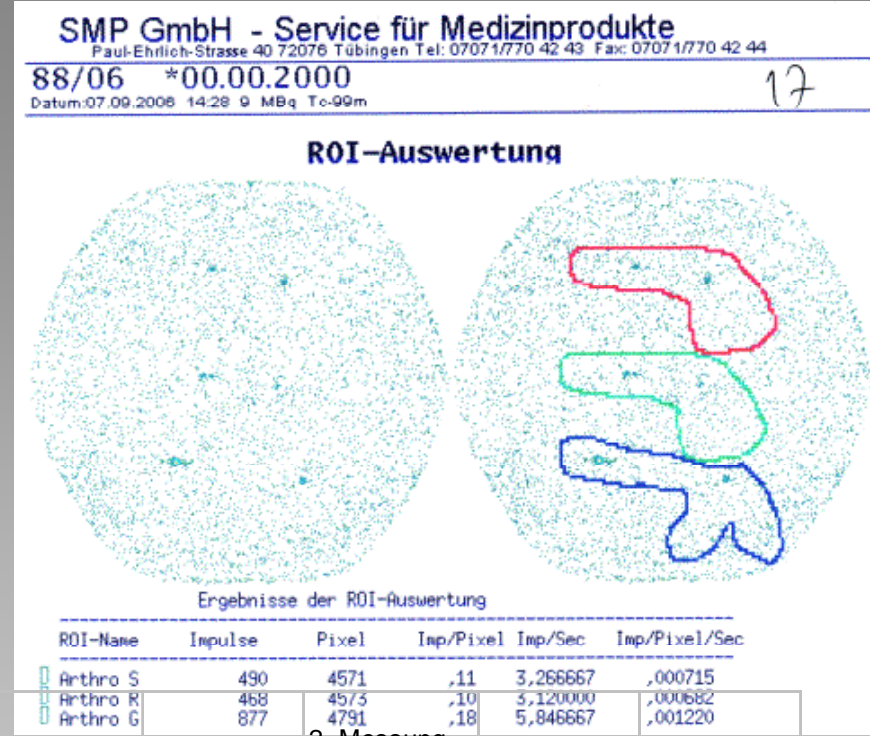
## Group 3 (Shift shaft instruments): Rongeur, Arthroskopiezangen etc.



1. Messung  
nach  
Kontaminati  
on

Vorreinigung  
+ 10 min  
40°C  
Einweichen

4. Messung  
nach  
Reinigung



1. Messung  
nach  
Kontaminati  
on

Vorreinigung  
+ Ultraschall  
10 min 40°C

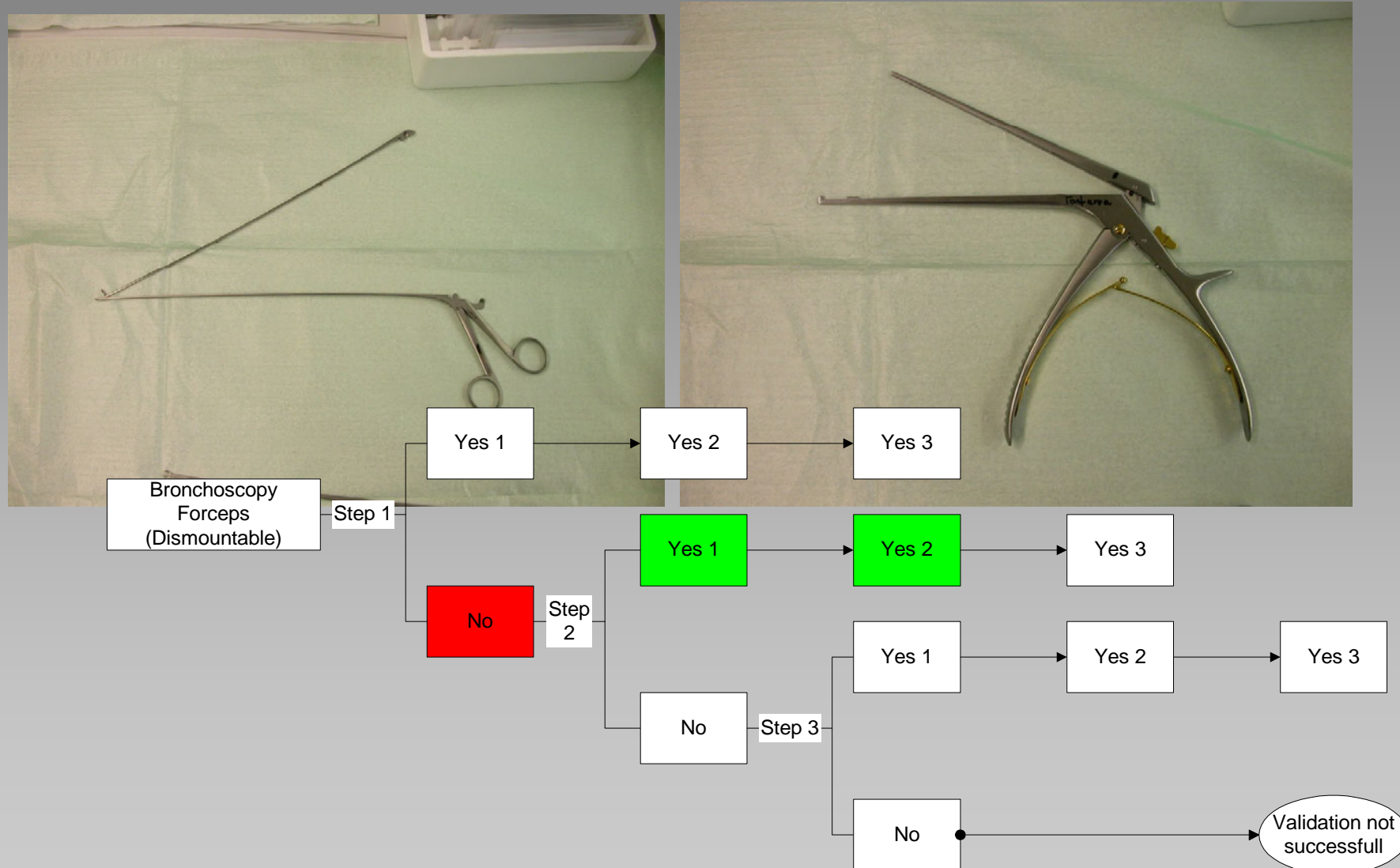
3. Messung  
nach  
Reinigung

Nr.87/26	Zr	Zr	Zr		Zr	Zr	Zr	
Rongeur 1	85	14	16		249	13	7	
Rongeur 2	121	11	10		311	12	7	
Rongeur 3	88	17	17		245	30	17	





## Group 3: Shift shaft instruments

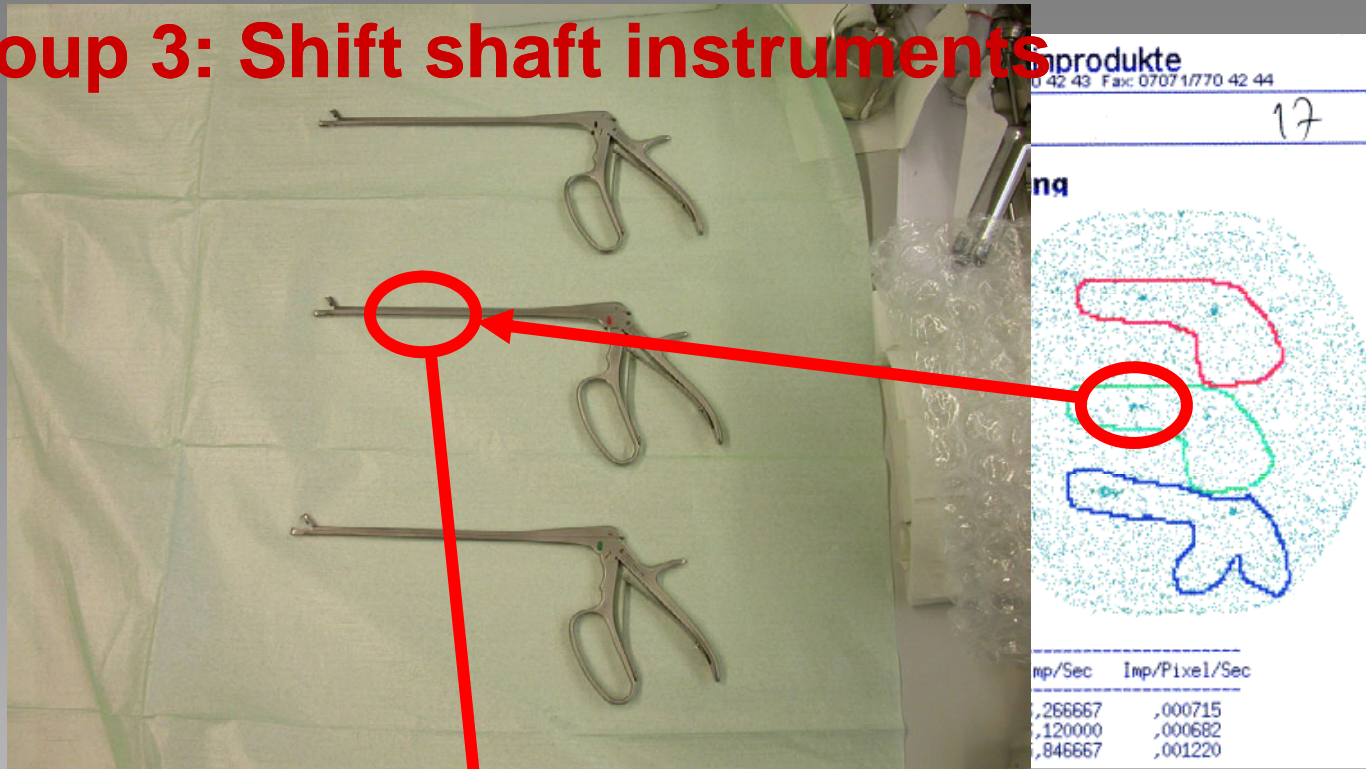




## Group 3: Shift shaft instruments



## Group 3: Shift shaft instruments



Group 2: Alkaline								
Effort for cleaning	Step 3							
	Step 2							
	Step 1							
		2 A Titan	2 A Ceramic	2 B	2 C	2 D	2 E	2 F
		Instruments sorted by category						

Tab. 58: Zusammengefasste Ergebnisse Gruppe 2 „Alkalisch maschinell und ggf. manuellen Vorreinigung“

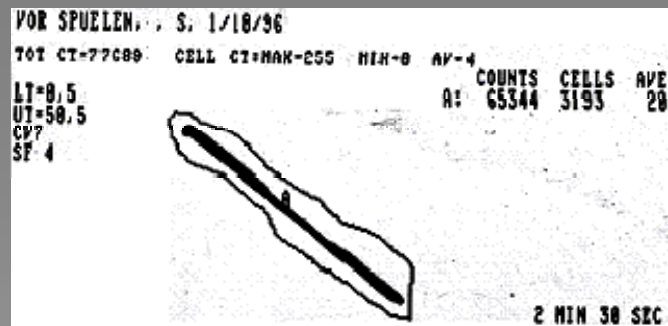
Group 2: Enzymatic automated and manual if necessary								
Effort for cleaning	Step 3				Validation not successfull			Validation not successfull
	Step 2							
	Step 1							
		2 A Titan	2 A Ceramic	2 B	2 C	2 D	2 E	2 F
		Instruments sorted by category						

Tab. 59: Zusammengefasste Ergebnisse Gruppe 2 „Enzymatisch maschinell und ggf. manuelle Vorreinigung“

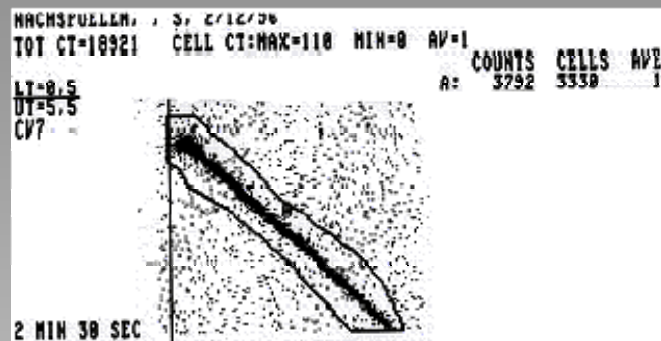
# Instruments for Minimally invasive surgery



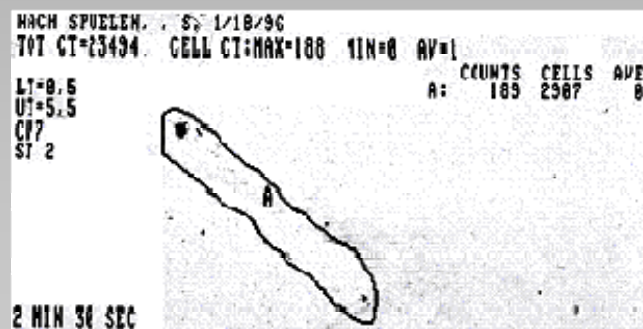




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Picture 2 shows the same device after cleaning. The inner lumen could not be cleaned due to an insufficient design of the device



Picture 3 shows the same device after redesign. Two spots in the area of the joints and the region of the rinsing port show remaining contamination. But the level of remaining contamination is beneath the acceptance criteria

Products:	Endoscopic Take-Apart Instrument / Company:.....	
ADVICE:	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device.  In case of damage the device should be reprocessed before sending back to the manufacturer for repair.	
Reprocessing Instructions		
Preparation at the Point of Use:	Remove gross soiling by submerge the instrument into cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.	
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.	
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state.	
Pre-Cleaning:	<b>Warning: Do not allow the instruments to rest on the bottom of an ultrasonic cleaner unit during cleaning, as damage or incomplete cleaning could result.</b> 10 minutes at 40°C in an ultrasonic bath with 0,5% detergent. Brushing the instrument under running tap water until all visible residues are removed Flushing the inner lumens of all parts with a water jet pistol (pressure min. 3 bar) with cold tap water for at least 10 seconds.	
Cleaning:	Manual Cleaning Process: 1. Rinsing under running tap water (<40°C) until all visible soil has been removed. If needed a soft bristle brush should be used to remove visible soil; 2. Submerge instruments in an detergent (if ultrasonic bath is used, ultrasonic process of 3 minutes and ultrasonic frequency of 35 kHz have been shown to be effective). Follow the instructions of the manufacturer of the detergent; 3. Rinse the instrument under running tap water to remove the detergent.	Automated Cleaning: Connect the instrument to a rack for MIS-instruments and start the program <ul style="list-style-type: none"><li>• 4 min pre-washing with cold water (&lt;40°C);</li><li>• 6 min washing with 0,5% detergent at 55°C;</li><li>• 3 min neutralising with warm water (&gt;40°C);</li><li>• 2 min intermediate rinsing with warm water (&gt;40°C).</li></ul> Special instructions of the manufacturer of the automated washing machine have to be followed.





<b>Disinfection:</b>	Manual Disinfection: 1. Submerge instruments in an disinfection detergent according to the instructions of the manufacturer of the detergent; 2. Rinse the instrument with sterile water to remove the detergent.	Automated Disinfection: Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A <sub>0</sub> -Value (see EN 15883)
<b>Drying:</b>	Manual Drying: Dry the instrument with a lint free towel. The instrument may never be heated up >140°C. To avoid water residues we recommend using sterile compressed air to insufflate cavities.	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
<b>Functional Testing, Maintenance:</b>	Functional testing, if available according to instructions of use and visual inspection for cleanliness. If necessary perform reprocessing process again until instrument is visibly clean.	
<b>Packaging:</b>	Appropriate packaging for sterilization.	
<b>Sterilization:</b>	<p>Sterilization of instruments by applying a fractionated pre-vacuum process (according DIN EN 554 / ISO 11134) under consideration of the respective country requirements.</p> <p><b>Parameters for the pre-vacuum cycle:</b>  3 prevacuum phases with at least 60 milli bar  Heat up to a minimum sterilization temperature of 132°-134°C  Minimum Holding time: 3,5 min  Drying time: minimum 10 min  <b>Flash sterilization is not allowed on lumen instruments!</b></p>	
<b>Storage:</b>	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.	
<b>Reprocessing validation study information</b>	<p>The following testing test devices, materials &amp; machines have been used in this validation study;</p> <p>Detergent: deconnex 28 Alka One, (Borer, Zuchwil, Switzerland)  deconnex 23 Neutrazym, (Borer, Zuchwil, Switzerland)</p> <p>Washer / Disinfector: Miele 7735 CD</p> <p>Instrument Rack: Miele E450-1</p> <p>Details: See report SMP 05506011407-1</p>	

# **Soluções H. Strübel para limpeza e esterilização de ciclo rápido**

**Otimização e economia para o seu centro cirúrgico**

Limpeza:



**DETERGENTE ENZIMÁTICO H-ZYME**  
3 enzimas, não espumante,  
maior aproveitamento  
da solução

**SONIC IRRIGATOR**

Lavadora Ultra-sônica, com sistema de bombeamento  
para limpeza de materiais de difícil acesso

**ENDO PURGE**

Equipamento para limpeza de endoscópios flexíveis.  
Eficácia na limpeza e secagem do interior dos lúmens

Esterilização:

Revisão 8/2008 - 52.000 exemplares distribuídos



# STRATTNER



## MANUTENÇÃO E CUIDADOS COM O INSTRUMENTAL CIRÚRGICO ENDOSCÓPICO

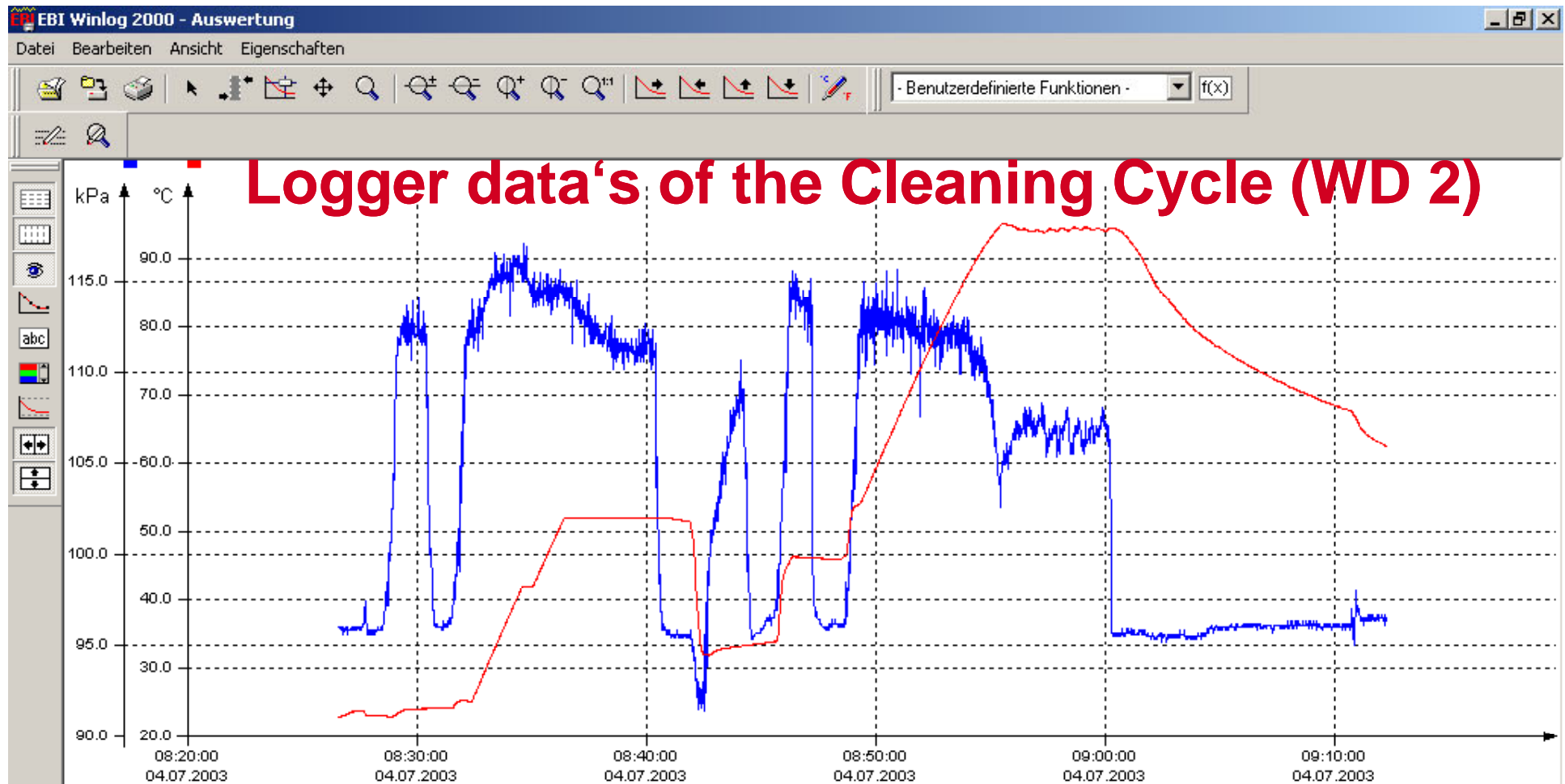
Guia de Recomendações

**SMP** GmbH  
Prüfen Validieren Forschen



# Complex Surgical Devices for Robotic Surgery





Die aktuellen Sicherheitseinstellungen sind nicht konform zu 21 CFR Part 11.

Dokument	Logger #	Mess...	Von	Bis	Grenz...	Grenz...	Min	Max	Mittel	Varianz	Std. A...	Max. ...	Zeitra...	Zeit...	Zeitraur
<b>vario td Skalpelle Acritec</b>															
<input checked="" type="checkbox"/> Kanal 1 (Kilopascal)	10140884	2747	04.07....	04.07....	1 kPa	300 kPa	91.4 kPa	117.1 kPa	103.9 k...	59.8 k...	7.7 kPa	25.7 k...	0 00:0...	0 00:...	00 Tage,
<input checked="" type="checkbox"/> Kanal 2 (Grad Celsius)	10140884	2747	04.07....	04.07....	10 °C	90 °C	22.8 °C	95.1 °C	59.4 °C	554.6 ...	23.5 °C	72.3 °C	0 00:2...	0 00:...	00 Tage,

Kurvenübersicht Messwerte

Bereit (\* Kurve ist geglättet \*\* Kurve ist berechnet)

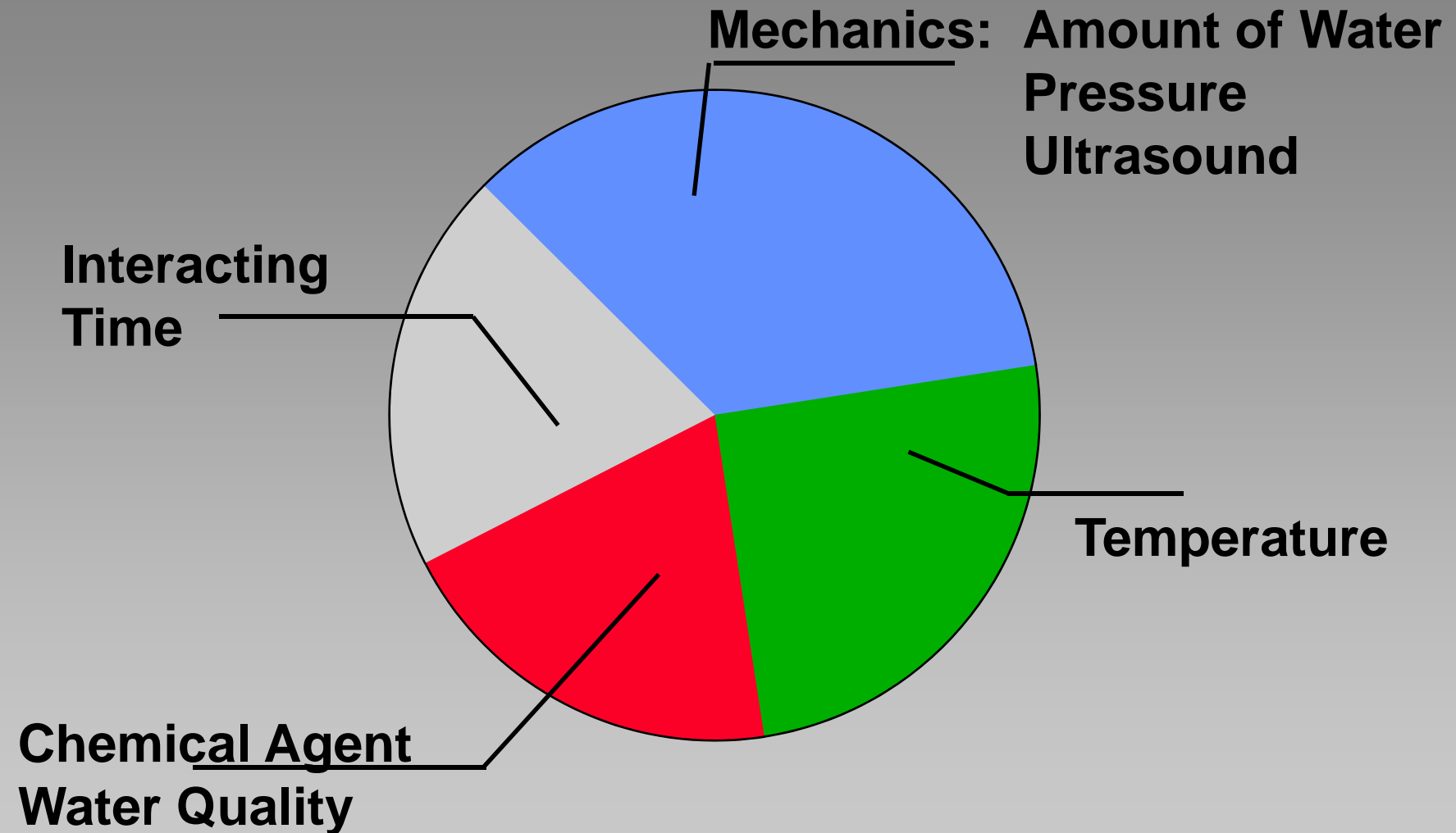
**SMP GmbH**  
Prüfen Validieren Forschen

Start Post... SFA... Vers... G:\G... 2004... Micr... EBI EBI ... 13:46

## Automated Cleaning Process ?

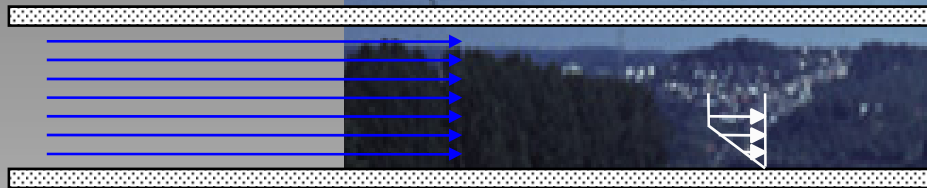


# Parameters of the Cleaning Cycle



# Influence of Velocity of Flow

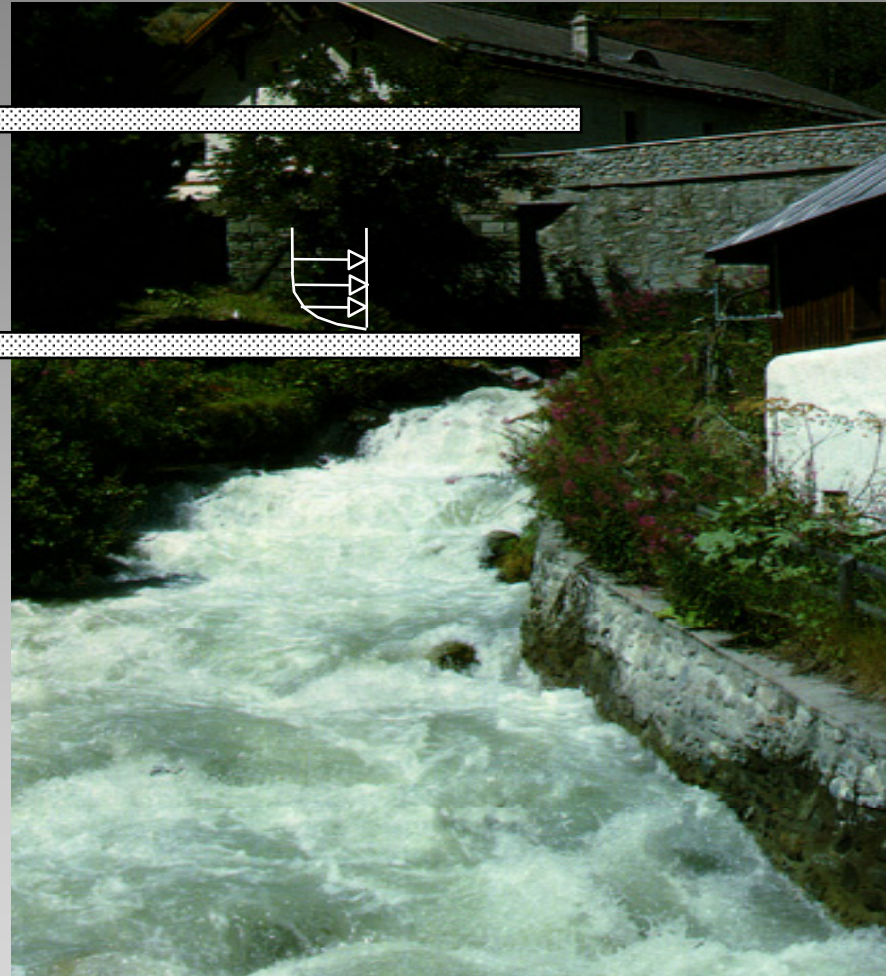
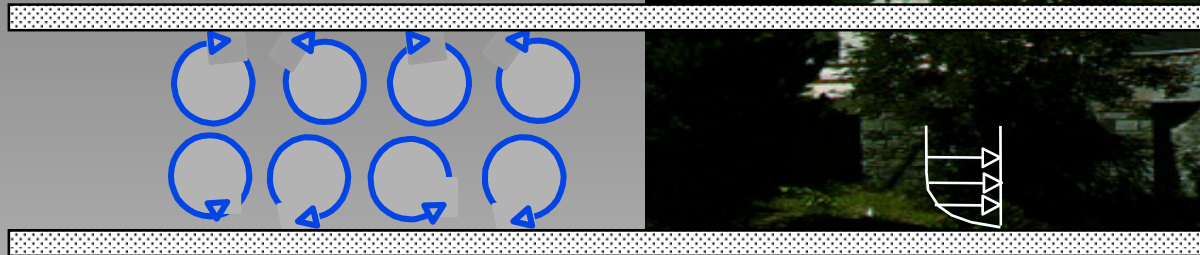
## Laminar Flow





# Influence of Velocity of Flow

## Turbulent Flow



$R_e$	Reynolds number
$\rho$	Density
$v$	Velocity
$l$	Length
$\mu$	Viscosity
$\nu$	kin. Viscosity

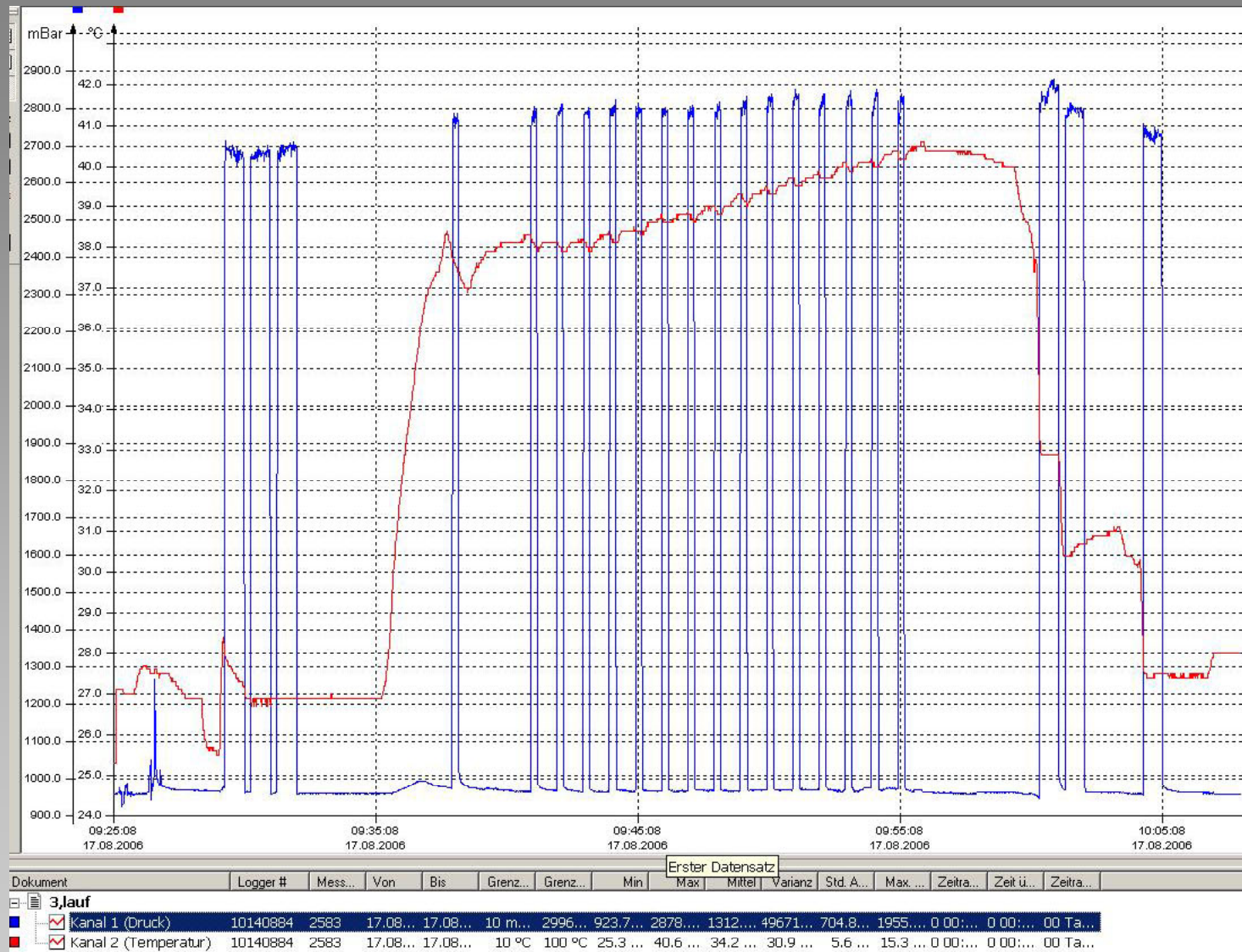
$$R_e = \frac{l \cdot \rho \cdot v}{\mu}$$

# Medisafe SI PCF

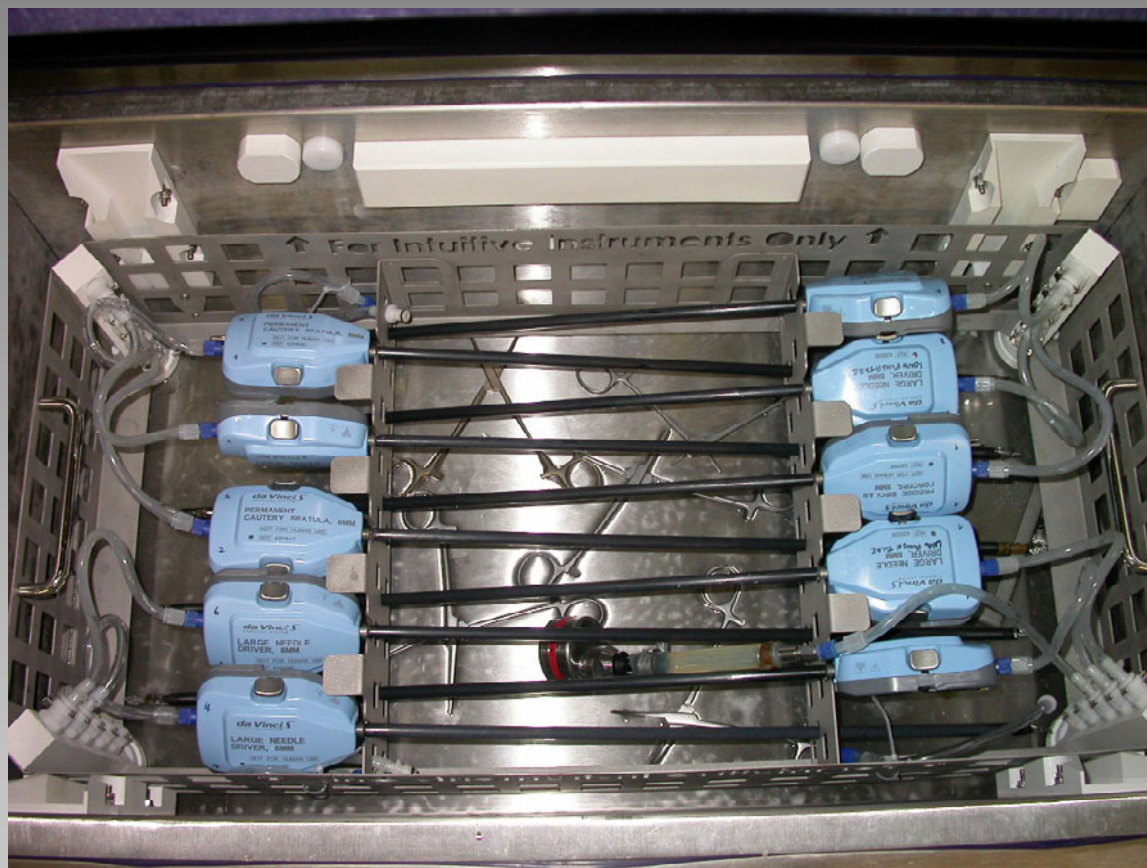


- Pre-Wash –internal & external @ 2 bar
- Detergent Dispense
- De-gas
- 15 minute Ultrasonic Main Wash – internal/external 2 bar
- Pre-Rinse – internal & external @ 2 bar
- Final Rinse
- Empty – each cycle

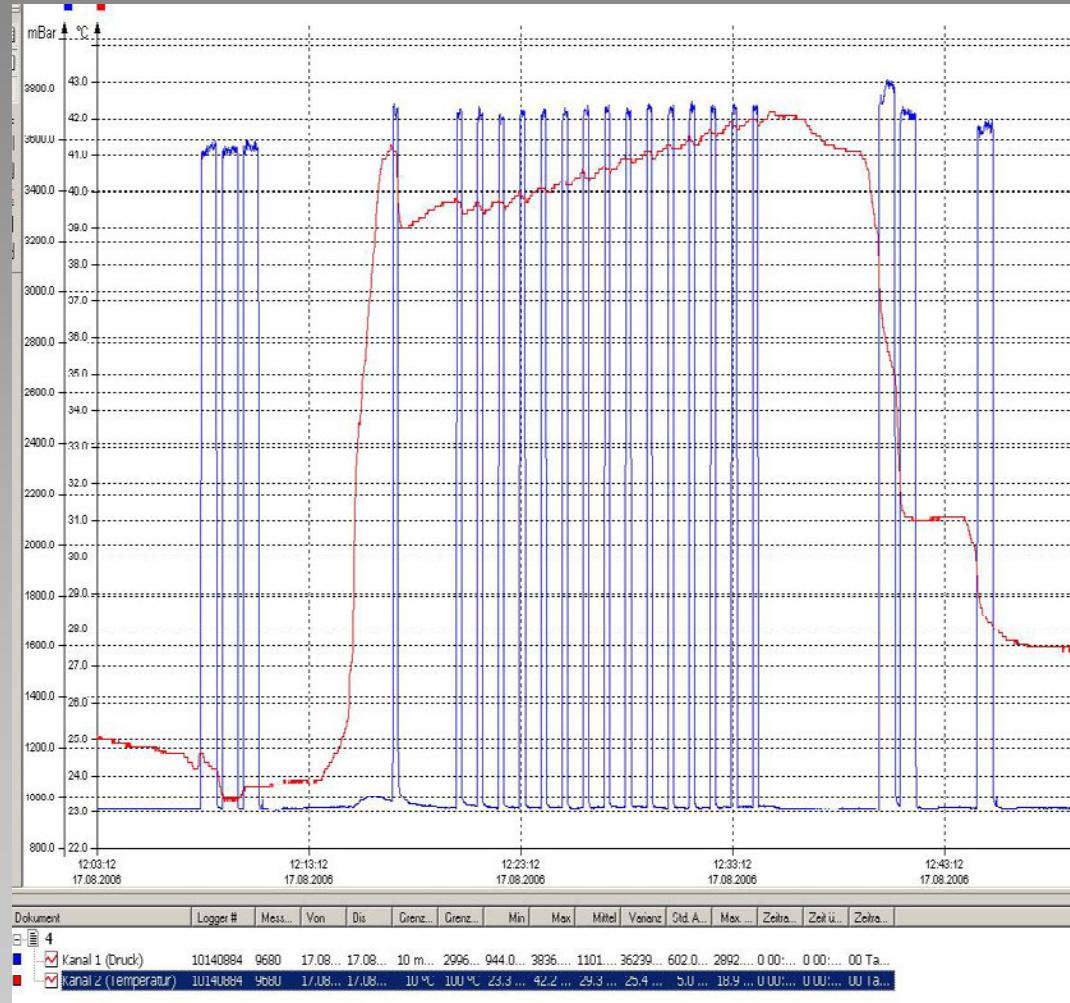
# Cycle in the Medisafe PCF







# Test procedure: OPA-Testing according to ISO 15883 Improved Cycle of the Medisafe PCF with High Pressure Ultrasonic Irrigation



- Pre-Wash –internal & external @ 3 bar
- Detergent Dispense
- De-gas
- 15 minute Ultrasonic Main Wash – internal/external 3 bar
- Pre-Rinse – internal & external @ 3 bar
- Final Rinse
- Empty – each cycle

## More Test with the PCF

**Investigation of MIS Instruments to avoid manual pre-cleaning:**

**Finished:**

**Conmed  
Boss  
Stryker**

**In preparation:**

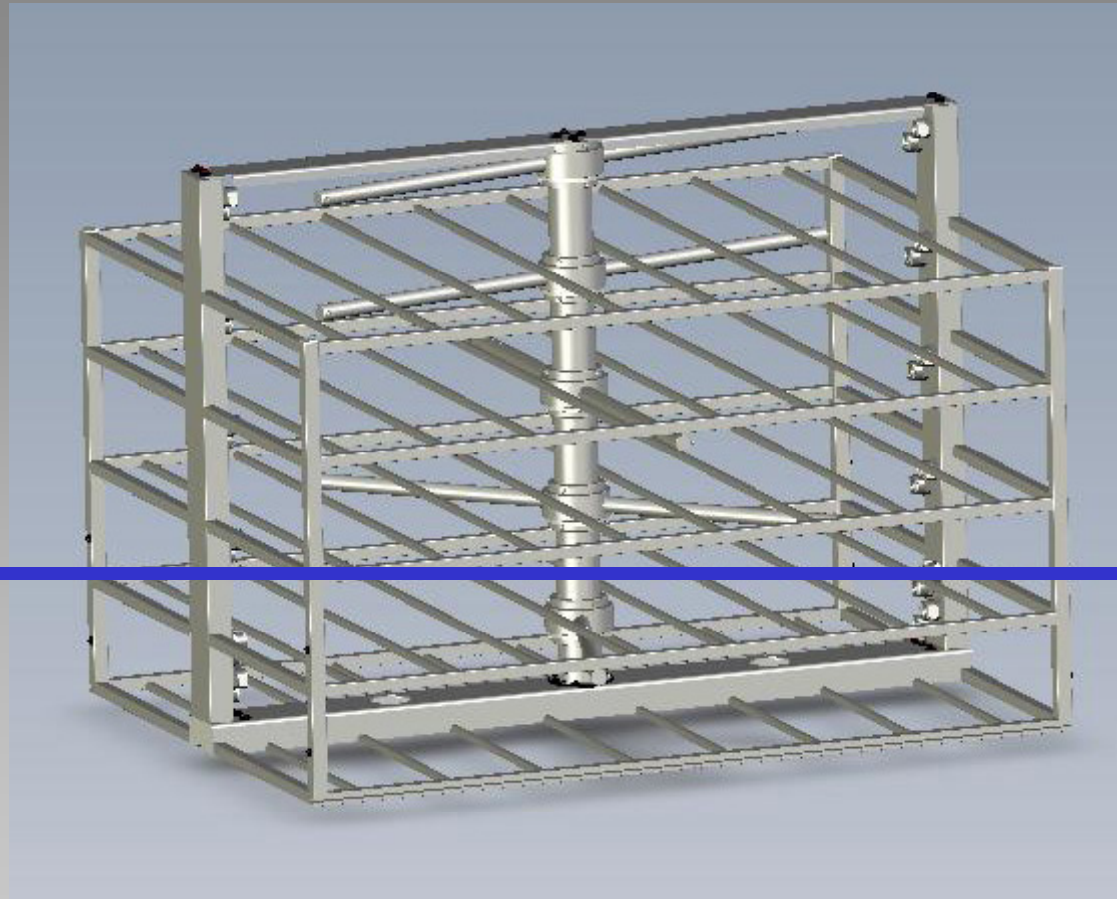
**Storz  
Wolf**



# New Washer / Disinfector: Niagara by Medisafe



# New Washer / Disinfector: Niagara by Medisafe



# Conclusion

**Tubular instruments need specific care for reprocessing**

**The cycle has to be validated by the manufacturer, as the lumen can not be visually inspected**

**High water pressure (3 bar or more) is needed to guarantee good cleaning results**

**Meanwhile specific trays and washer disinfectors incorporating ultrasonic irrigation are on the market, which provide good cleaning results of tubular instruments**

**It is important to analyze the reprocessing behavior before purchasing new instruments**

**Check what kind of information are available from the manufacturer**

**If instruments are substituted due to repair, make sure that the same instrument is not available in an easy to clean version.**

**Thank you for your attention**

**Further informations**

**[www.smpgmbh.com](http://www.smpgmbh.com)**