

Elaborating of a Reprocessing Instruction According to ISO 17664

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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:

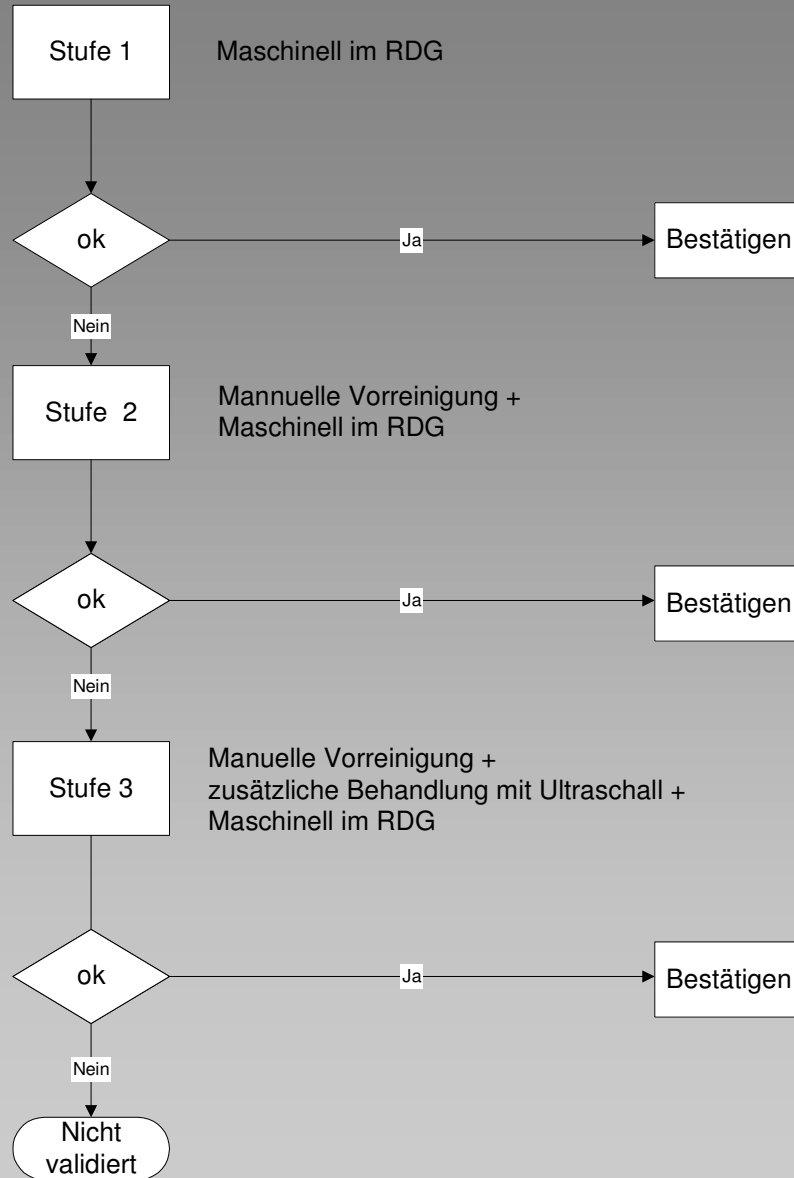
- identification and concentration of chemicals required for cleaning;
- identification of water quality,
- accessories required for cleaning process;
- techniques to be used including rinsing;
- ..process temperature(s);
- ...limits on temperature, concentration of solution(s), exposure time,
- ...limits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

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 equipment 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.

Exempel 1: Automated alkaline process with manuellt pre-cleaning



Alkaline process: Step 1

Automated cleaning in the WD

The cleaning is performed only in a washer disinfector 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.

Automated cleaning in the w/d

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- 2 min intermediate rinsing with warm water (>40°C)

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Alkaline process: Step 3

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.

Additional pre-cleaning with ultrasonic:

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

Automated cleaning in the w/d

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After dismantling the instruments are placed on the specific tray and the cleaning and disinfection program Vario TD is started:

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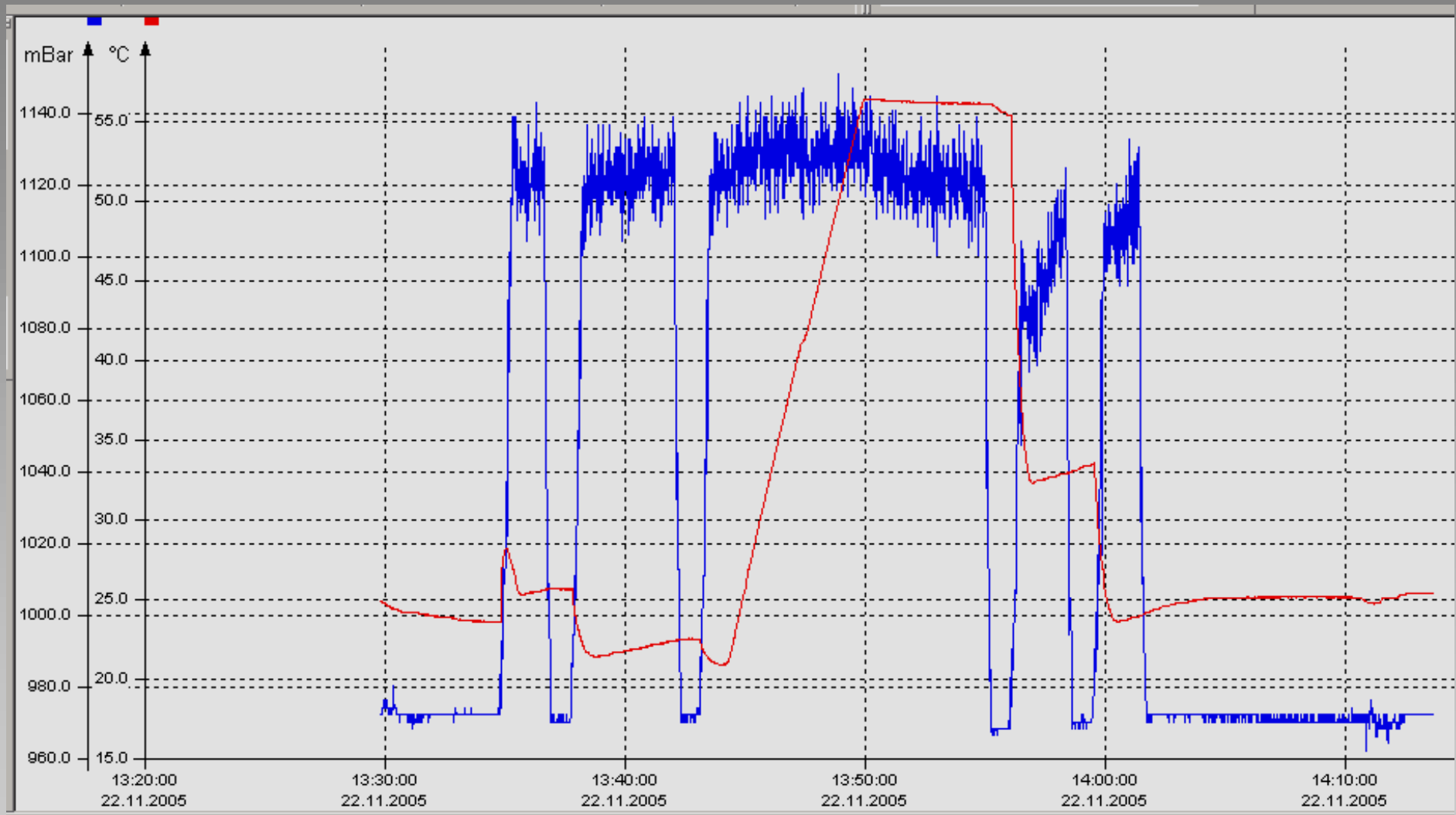
- 3 min neutralizing with warm water (>40 °C)

- emptying

- 2 min intermediate rinsing with warm water (>40 °C)

- emptying

Stabile Water Pressure



Automated Cleaning Process ?



Specification of the groups

- Group 1:** **Critical A Instruments,**
like hooks; don't need validation
- Group 2:** **Critical B Instrumentse**
Scissors, Clamps
- Group 3:** **Shift shaft instruments**
need validation, as the result of the cleaning can not be inspected
- 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**
have 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 A Instruments,**
like hooks, don't need validation

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: **Critical B Instruments**
scissors and clamps are already covered by the
requirements for the WD

Sub-classification:

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

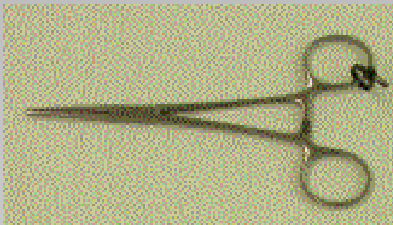
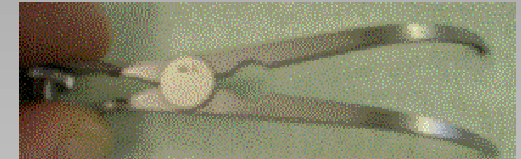
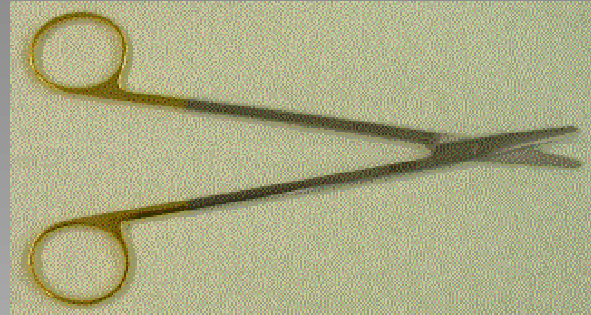
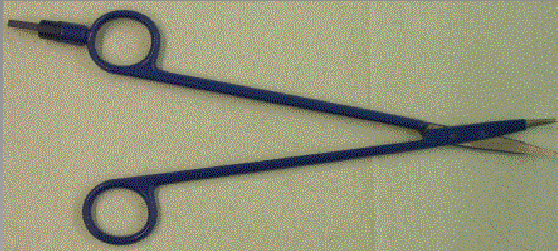
B: Box lock approx. 12 x 20 mm

C: Box lock approx. 16 x 25 mm

D: Instruments with pivot joint

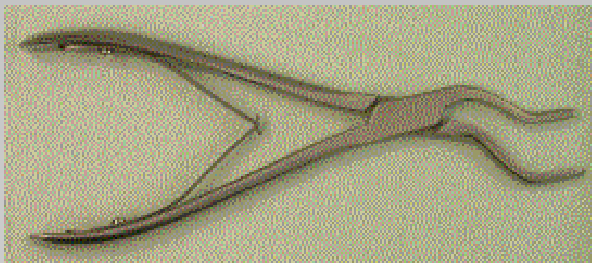
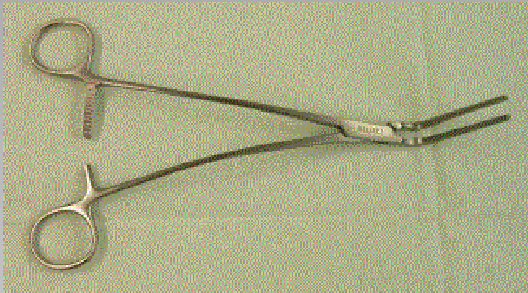
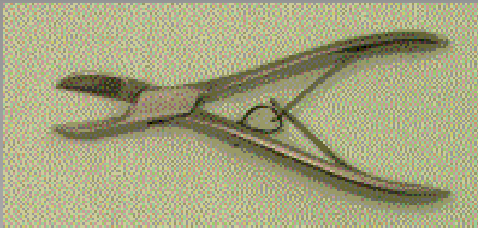
Group 2 (Instruments with hidden surfaces): Crile Clamp, etc.

Category A



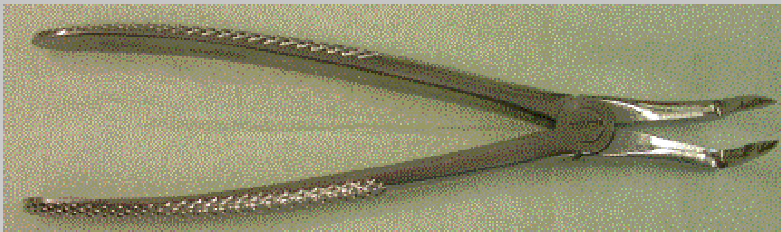
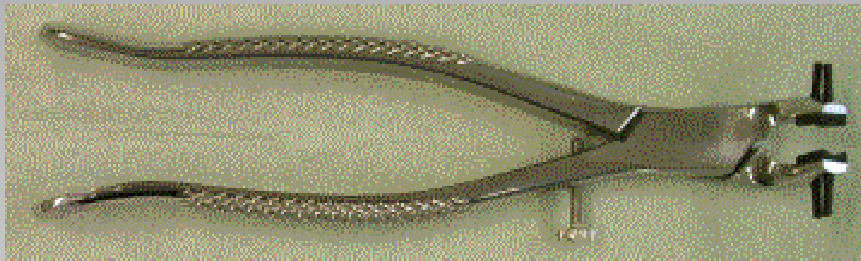
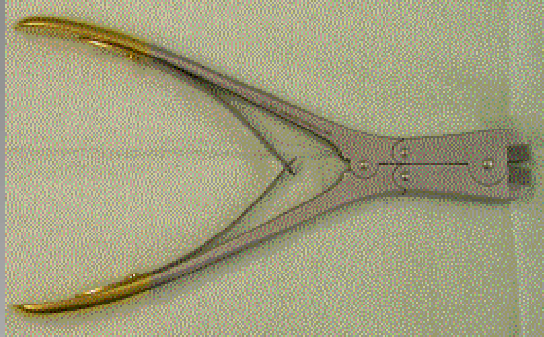
**Group 2 (Instruments with hidden surfaces):
Side cutter etc.**

Category B



**Group 2 (Instruments with hidden surfaces):
Side cutter etc.**

Category C

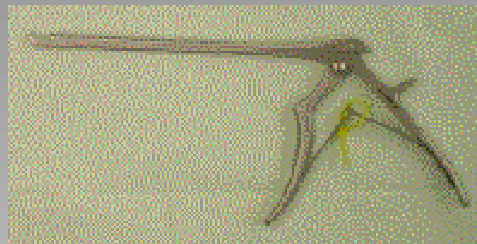
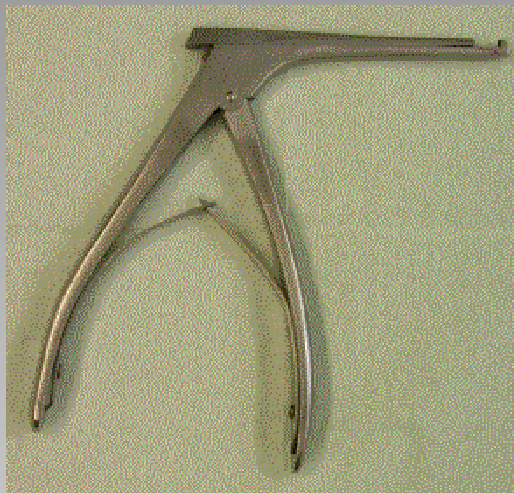


Group 3 (Shift shaft instruments):
Rongeur, Arthroskopiezangen etc.

Category A up to 3 mm diameter

Category B 3 to 5 mm

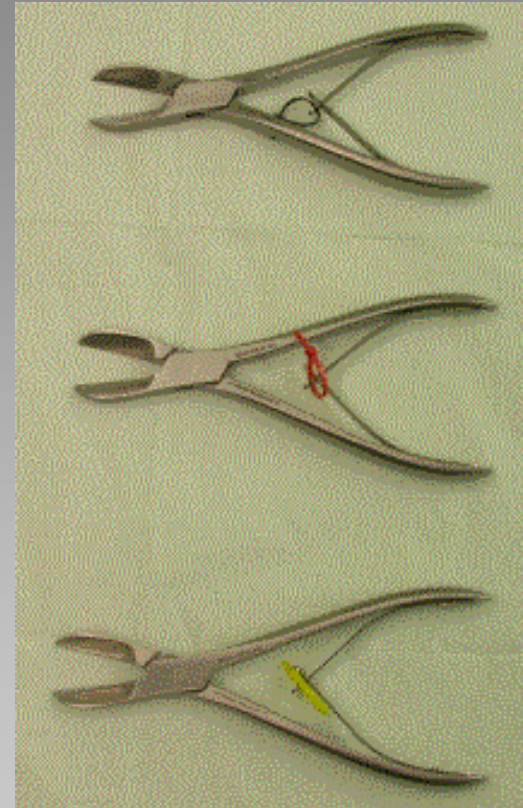
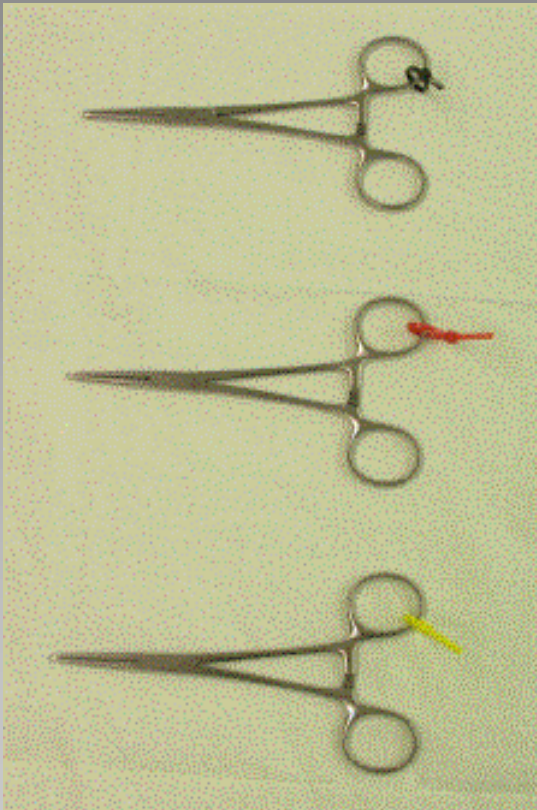
Category C bigger than 5 mm



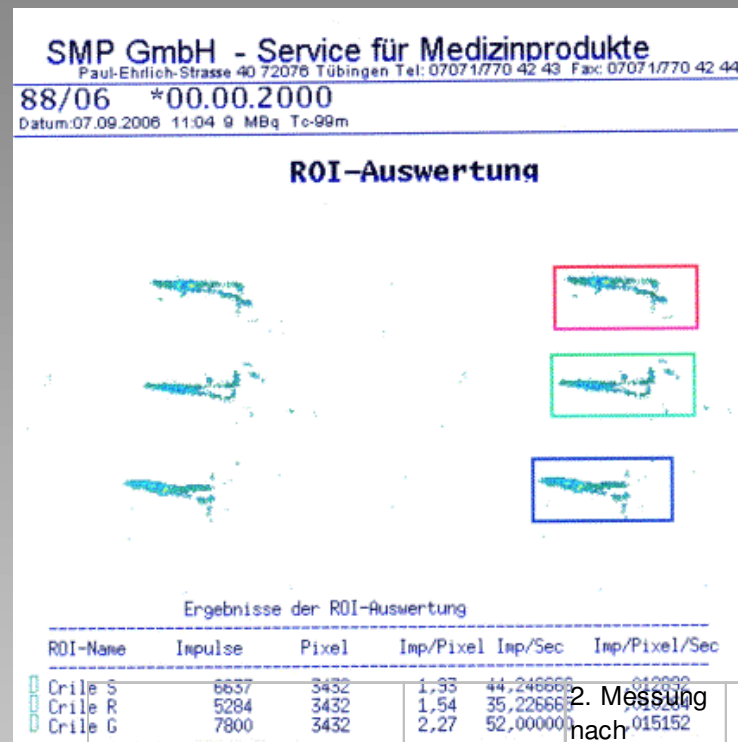
Definitions for the minimum requirements for the Instrument design

- Gap length and depth
- Dismantling of Instruments
- Rinsing of Lumen
- Definition of Diameters

**Group 2 (Instruments with hidden surfaces):
Crile Clamp, Side cutter etc.**



Group 2 (Instruments with hidden surfaces): Crile Clamp,

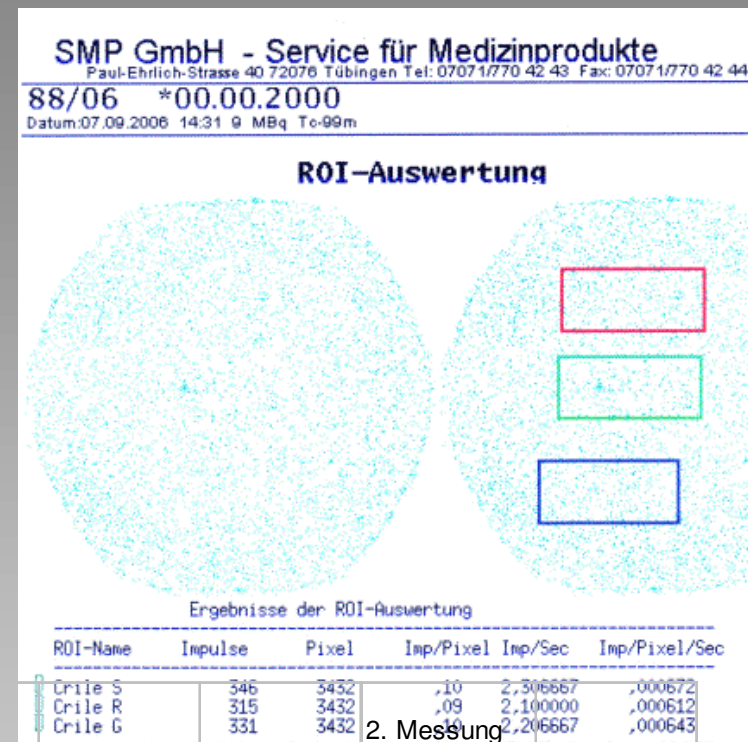


2. Messung
nach

1. Messung
nach
Kontaminati
on

Vorreinigung
+ 10 min
40°C
Einweichen

4. Messung
nach
Reinigung



2. Messung

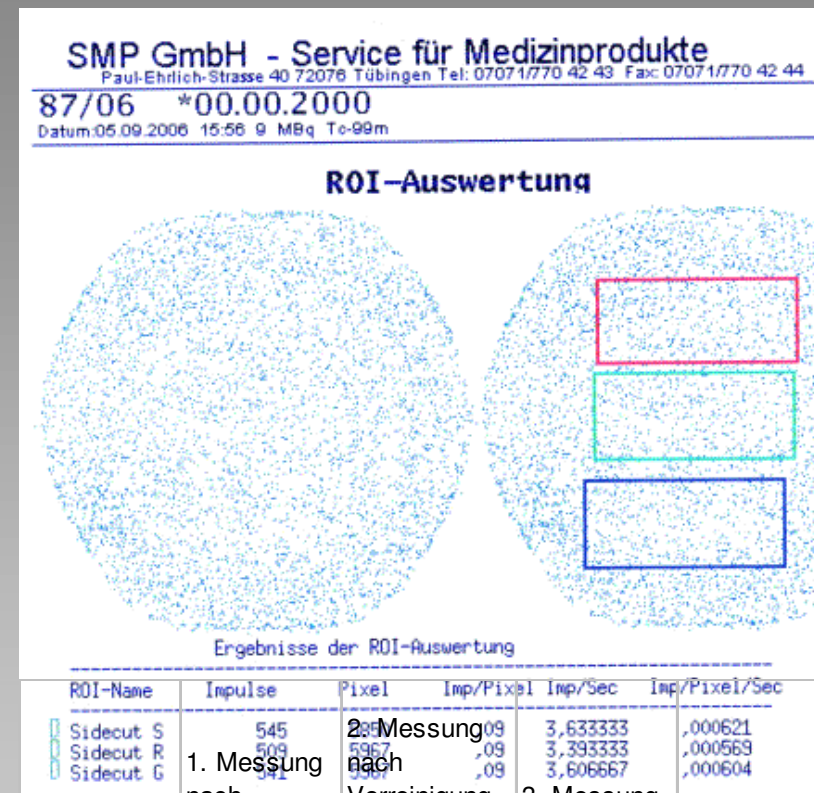
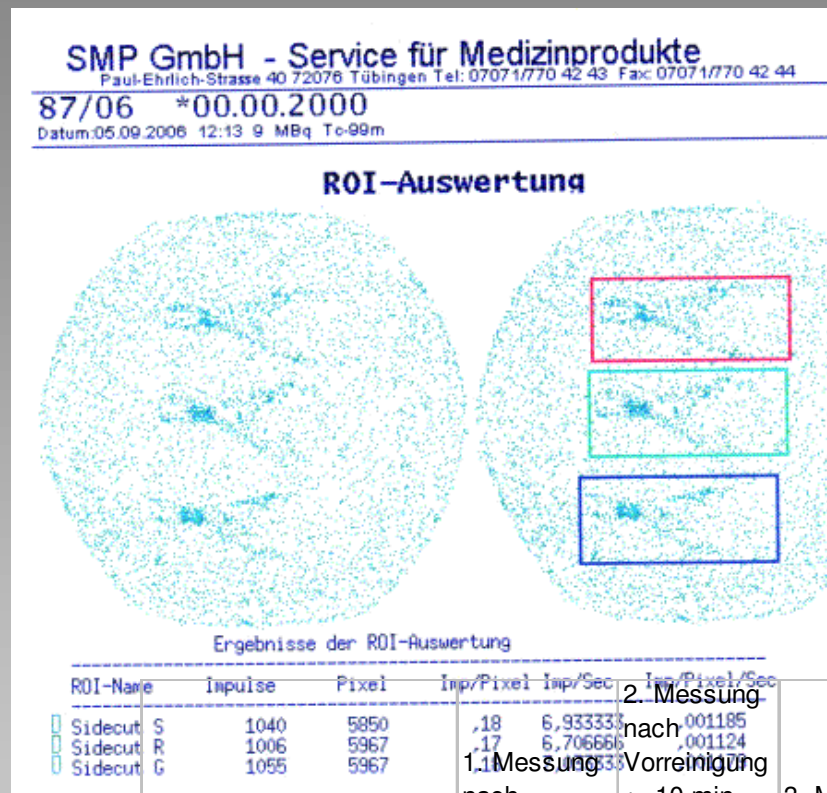
1. Messung
nach
Kontaminati
on

nach
Vorreinigung
+ Ultraschall
10 min 40°C

3. Messung
nach
Reinigung

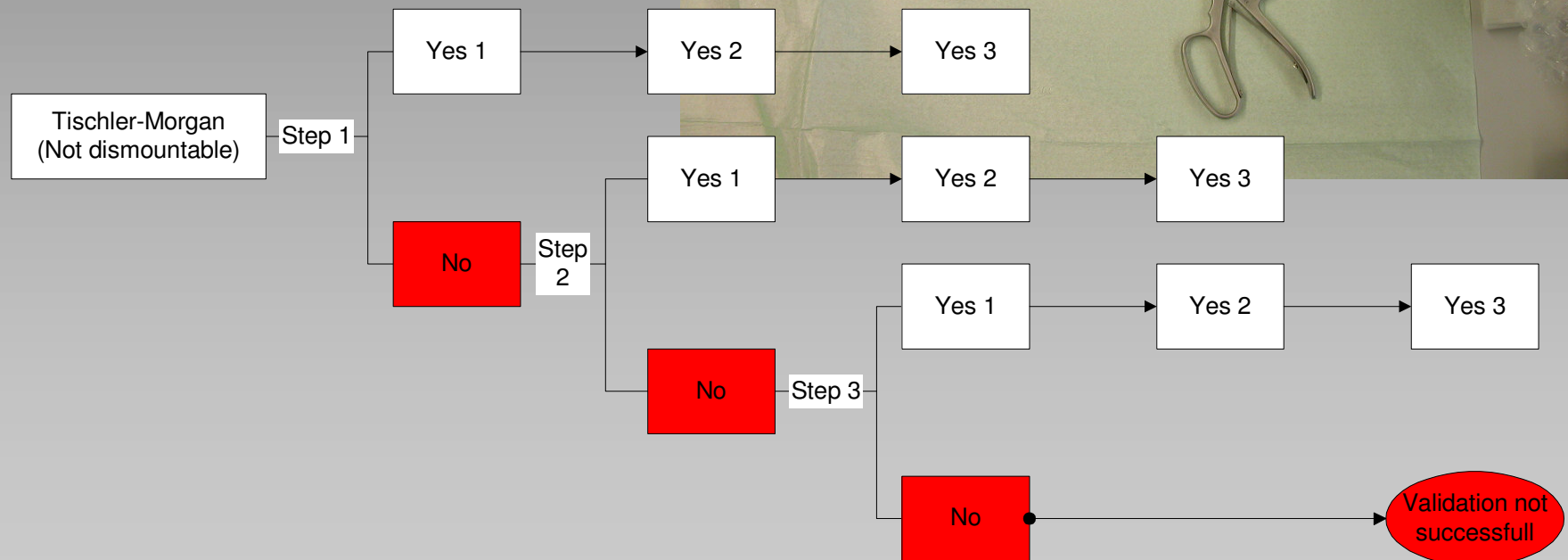
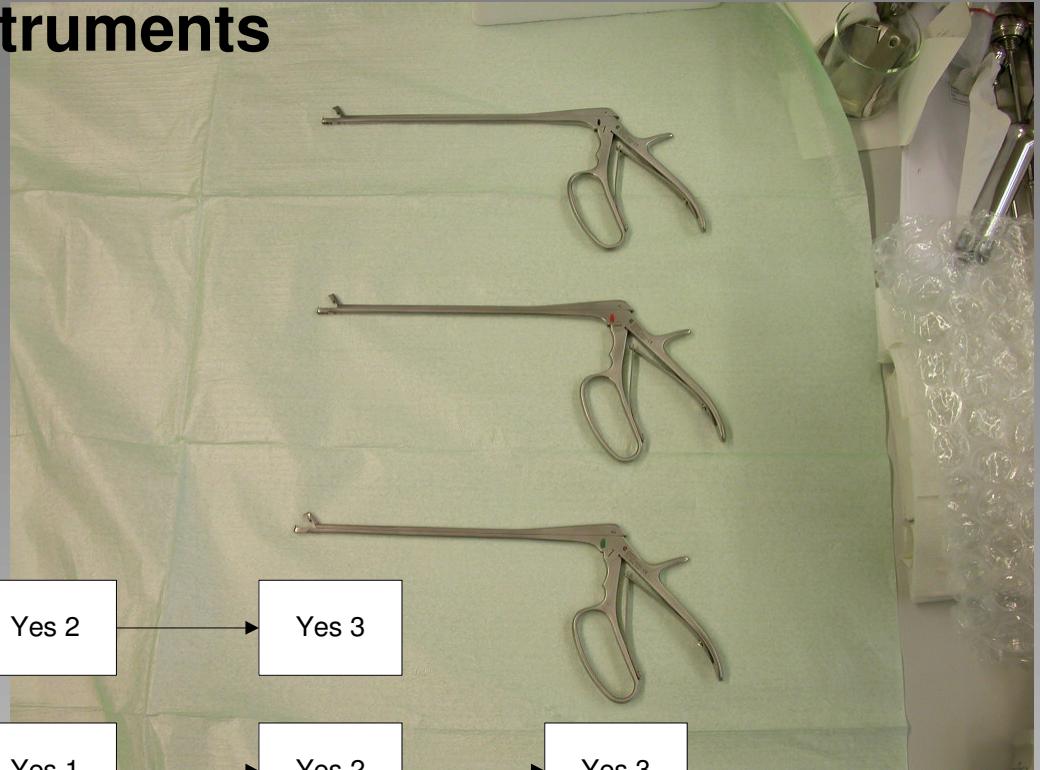
Nr.87/26	Zr	Zr	Zr		Zr	Zr	Zr
Crile clamp 1	98	4	4		122	3	3
Crile clamp 2	66	3	3		97	3	3
Crile clamp 3	121	2	2		145	3	3

Group 2 (Instruments with hidden surfaces): Side cutter

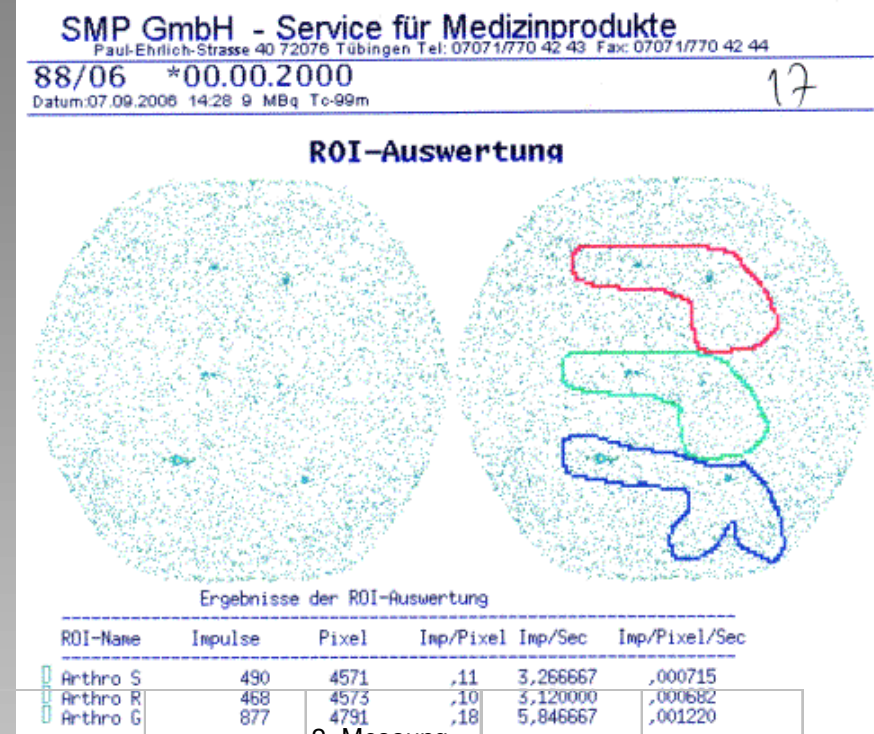
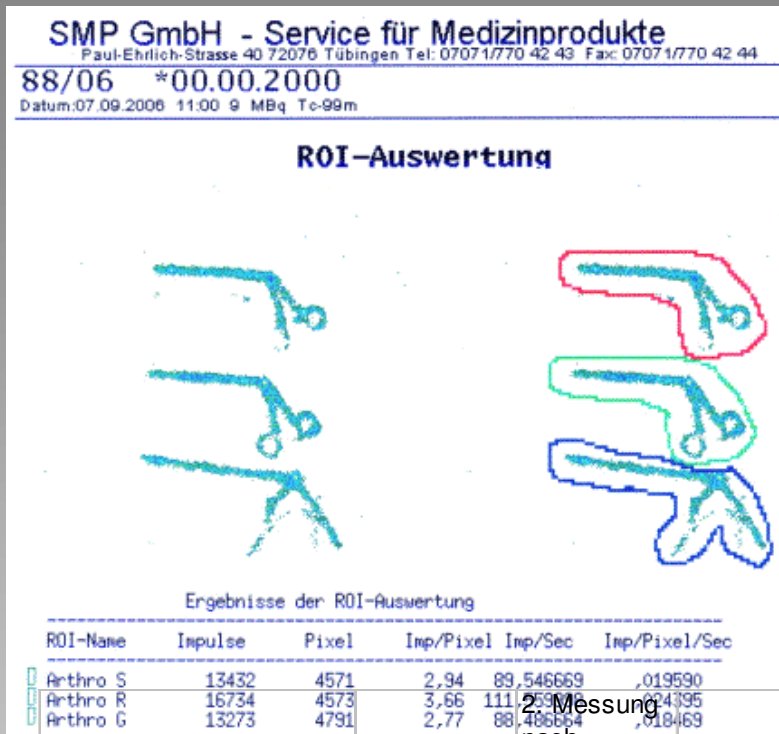


	2. Messung							
	nach							
	1. Messung	Vorreinigung						
	nach	+ 10 min	3. Messung					
	Kontaminati	40°C	nach					
	on	Einweichen	Reinigung					
Nr.87/26	Zr	Zr	Zr		Zr	Zr	Zr	
Wire cutter 1	69	10	10		95	4	4	
Wire cutter 2	79	9	7		57	4	4	
Wire cutter 3	59	9	8		65	3	4	

Group 3: Shift shaft instruments



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



1. Messung
nach
Kontaminati
on

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

4. Messung
nach
Reinigung

1. Messung
nach
Kontaminati
on

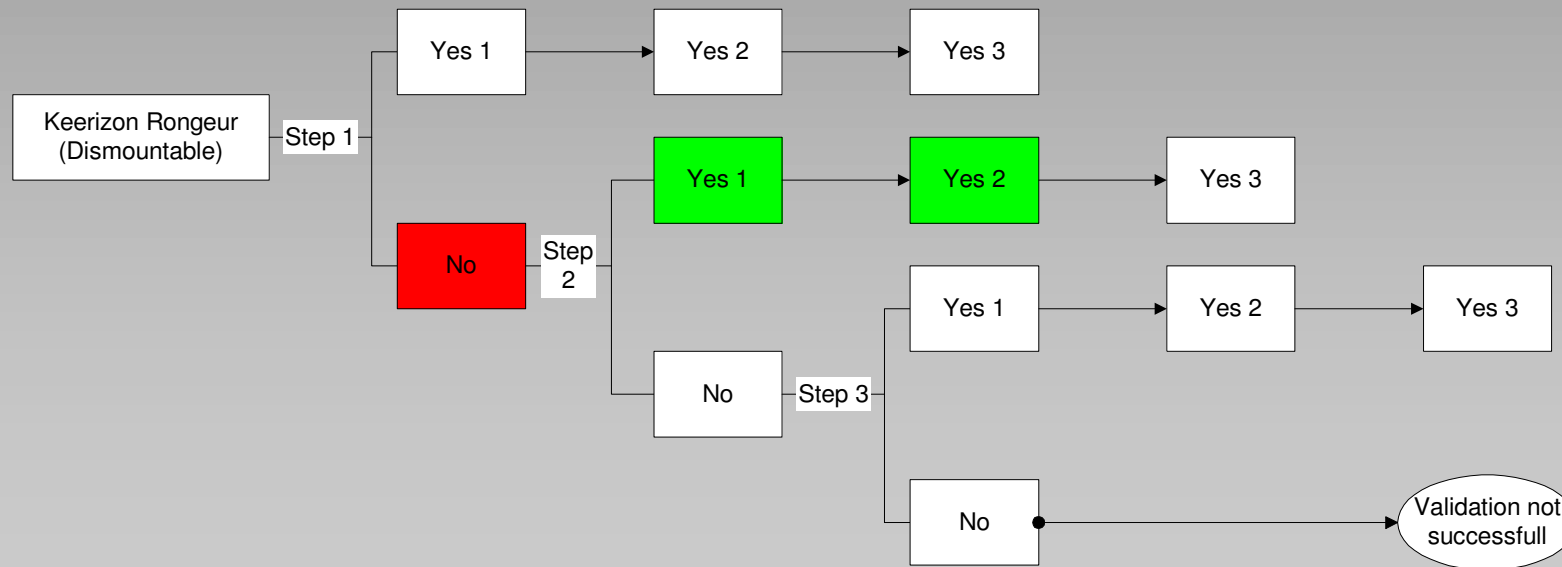
2. Messung
nach
Vorreinigung
+ Ultraschall
10 min 40°C

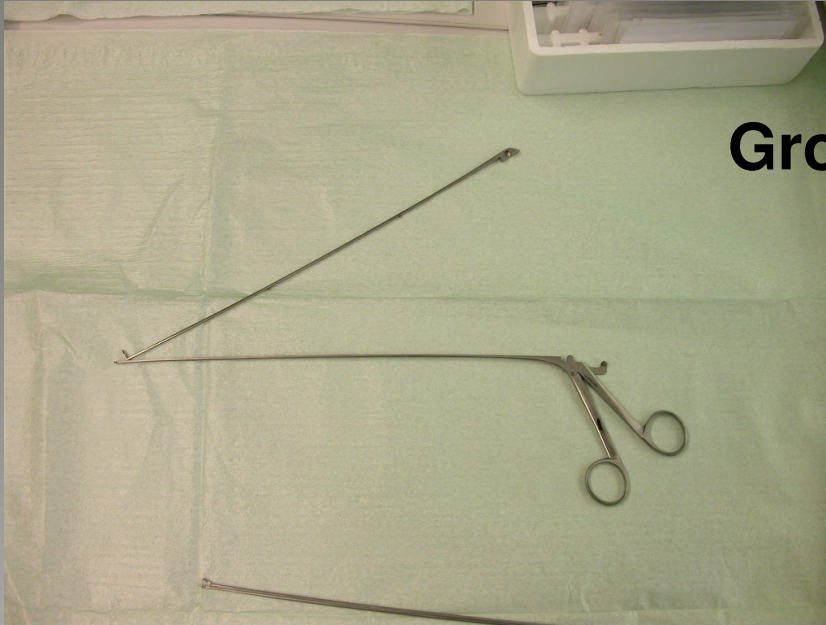
3. Messung
nach
Reinigung

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	

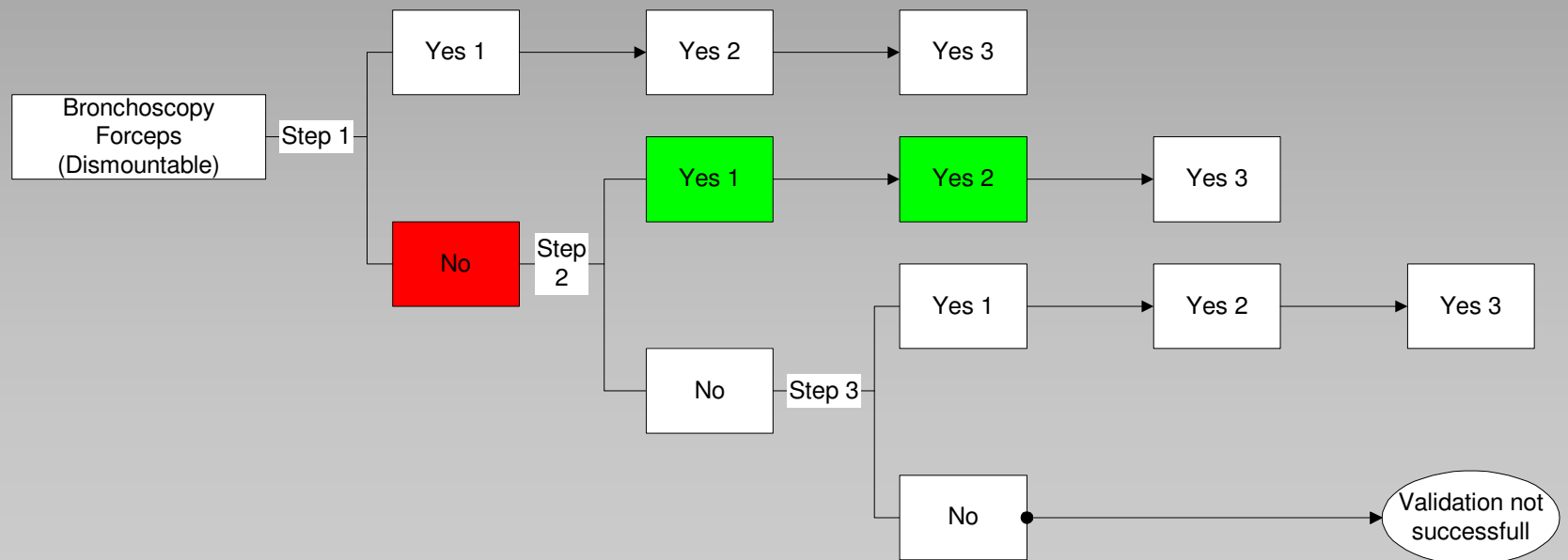


Group 3: Shift shaft instruments





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Conclusion

- 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.

View to a bright future

