
Elma

Cleaning medical

Surgical instruments and implants

Difference between surgical instruments and implants

Surgical instruments:

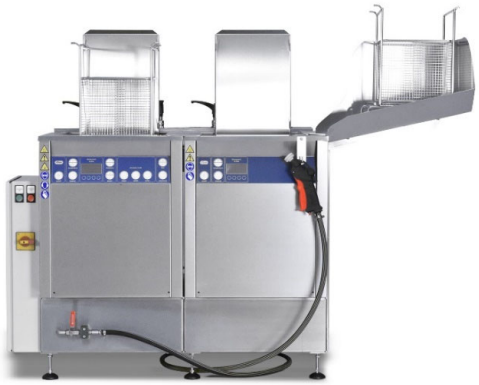
Knifes, Siccors, different tools, endoscopes etc. During surgery those instruments are used. They do not remain in the human body.
Most often they are getting cleaned, sterilized and packed for the next operation.

Medical implants:

Screws, dental implants, artificial bones, plates, different joints (hip, knee, fingers toes etc.), pacemaker, stents.
Those parts remain in the body. Depending on time in the body, additional specification on cleanliness.

Pre-Cleaning – Elma solutions

- Table top units in different types and sizes, e.g. Elmasonic Med, Elmasonic ST
- Flex 1 or Flex 2 based on our X-tra line program
- Usually the customers realizing the drying process through using of compressed air.
- Sometimes short X-tra lines are used if customer wants to dry with the line



Cleaning process – pre cleaning

Process Step	Cleaning	RO-Rinsing	Drying
Tank version	Pro	Pro	WLT or VTR
Ultrasonic	25/45 kHz	25/45 kHz	
Dosing with or without LF Measurement	X		
Filtration	X		
Oil separator	X		
Conti flow		X	
Lift-out		(X)	
Piping	Stainless Steel	Stainless Steel	

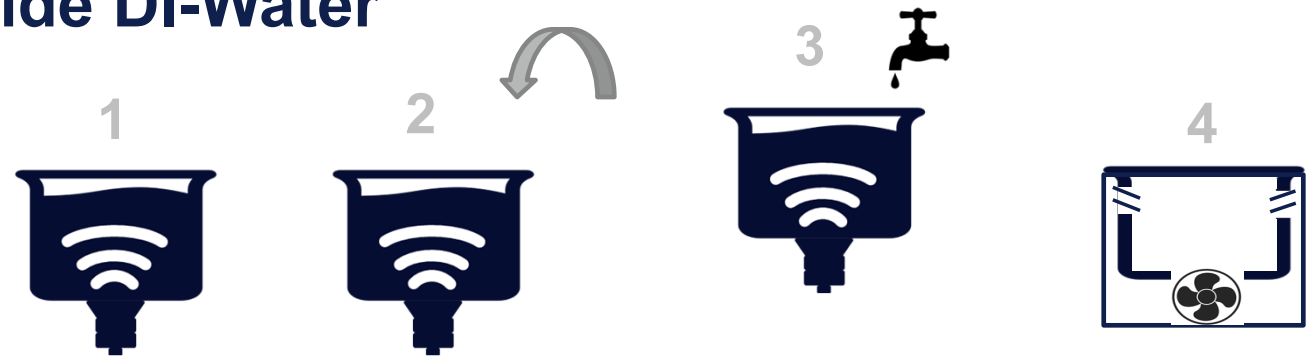
IPC (In-process cleaning) – Elma solutions

- Usually X-tra line pro/pre-4-WLT-M or R → R is more and more common
- Manual or automatic X-tra line, during the last year more and more automatic cleaning lines.
- Pure water system: Elmapur 85 is enough.

IPC (In-process cleaning) – Elma standard process

Process Step	Cleaning	Pre Rinsing (Softened Water)	DI-Rinsing 1	DI-Rinsing 2	Drying
Tank version	Pro	Pro	Pro or Pre	Pro or Pre	WLT or VTR
Ultrasonic	25/45 kHz	25/45 kHz	25/45 kHz	25/45 or 37/130 kHz	
Dosing with LF Measurement	X				
Filtration	X				
Oil seperator	X				
Conti flow		X		X	
cascade			X		
Lift-Out				X	
Piping	Stainless Steel	Stainless Steel	Stainless Steel or PP IR	Stainless Steel or PP IR	

IPC (In-process cleaning) – Elma standard process if customer provide DI-Water



Process Step	Cleaning	DI-Rinsing 1	DI-Rinsing 2	Drying
Tank version	Pro	Pro or Pre	Pro or Pre	WLT or VTR
Ultrasonic	25/45 kHz	25/45 kHz	25/45 or 37/130 kHz	
Dosing with LF Measurement	X			
Filtration	X			
Oil seperator	X			
Conti flow			X	
cascade		X		
Lift-Out			X	
Piping	Stainless Steel	Stainless Steel or PP IR	Stainless Steel or PP IR	

Final-Cleaning

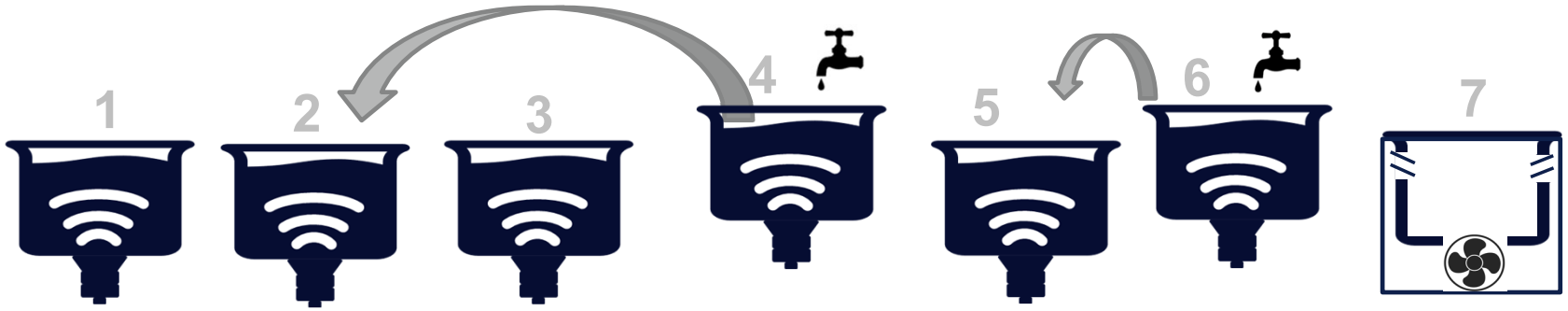
- Usually X-tra line pro/pre-4-WLT-R
- Pure water system: Elmapur 300 or 600 med is necessary
- Interlock to a clean room (typical class ISO 7 or 8) in which the customer do the packaging is common.

Final Cleaning – Elma standard process

Process Step	Cleaning	Pre Rinsing (Softened Water)	DI-Rinsing 1	DI-Rinsing 2	Drying
Tank version	Pre	Pre	Pre	Pre	WLT-F or VTR-F
Ultrasonic	25/45 kHz	25/45 kHz	25/45 kHz	25/45 or 37/130 kHz	
Dosing with LF Measurement	X				
Filtration	X				
Oil seperator	X				
Conti flow		X		X	
cascade			X		
Lift-Out				X	
Piping	Stainless Steel	PP IR	PP IR or PVDF WNF	PP IR or PVDF WNF	

Final Cleaning and Passivation of Surgical Instruments

Elma Standard Process for Citric Acid Passivation



Process Step	Cleaning	Pre Rinse 1 (softened Water)	Passivation	Pre rinse 2 (softened Water)	DI-rinse 1	DI-rinse 2	Drying
Tank version	Pre	Pre	Pre	Pre	Pre	Pre	WLT-F or VTR-F
Ultrasonic	25/45 kHz	25/45 kHz	25/45 kHz	25/45 kHz	37/130 kHz	37/130 kHz	
Dosing with LF Measurement	X		X				
Filtration	X						
Oil separator	X						
Conti flow				X		X	
cascade		X			X		
Lift-Out						X	
Piping	Stainless Steel	PP IR	Stainless Steel	PP IR	PP IR or PVDF WNF	PP IR or PVDF WNF	

Final Cleaning and Passivation of Medical Implants

Elma Standard Process for Nitric Acid Passivation

Process Step	Cleaning	Pre Rinse 1	Passivation	Pre rinse 2	Pre rinse 3	DI-rinse 1	Di-rinse 2	Drying
Tank version	Pre	Pre	Pre	Pre	Pre	Pre	Pre	WLT-F or VTR-F
Ultrasonic	25/45 kHz	25/45 kHz		25/45 kHz	37/130 kHz	37/130 kHz	37/130 kHz	
Dosing with LF Measurement	X		with special dosing included in a safety containment	two rinses needed to dilute H2NO3 drag out before DI rinsing				
Filtration	X							
Conti flow		X			X		X	
cascade				X		X		
Lift-Out							X	
Piping	Stainless Steel	PP IR	PFA	PFA	PP IR	PP IR or PVDF WNF	PP IR or PVDF WNF	

Cleaning processes – general rules

Ultrasonic Frequencies:

Ultrasonic Frequencies are selected to clean but not destroy the surface or structures of parts to be cleaned

US-Frequency	Material	Process Steps in the field of medical industry
25 kHz	Steel, Stainless Steel, Ceramics, Titanium	Cleaning or Pre Rinsing
37...**40**...45 **kHz**	**Aluminium**, Copper, Zinc, Standard Glass Substrates, delicate parts, Electronics, plastics	Cleaning or Pre Rinsing
80...**130 kHz**	**polished mirrors**, sensitive parts, delicate structures, coated surfaces In Medical: For the final rinsing Steps.	Final Rinsing

Cleaning processes – general Rules

Cleaning tanks:

If you have to clean **one part with one specific material and contamination**	**One** cleaning tank
If you have **heavy contamination**	One pre-cleaning tank followed by a final cleaning tank (**2 tanks**)
If you have **different materials or contaminations**	Maybe **different cleaning tanks** needed

Cleaning processes – general rules

Rinsing tanks:

Number of Rinsing Tanks	Application
No or **One** rinsing tank	Basic Cleaning, Pre cleaning
Two Rinsing tanks with DI-Water in cascade	In-process cleaning (IPC)
Three Rinsing tanks: Pre rinse with softened water followed by 2 DI-rinsing in cascade	In-process cleaning (IPC) or Final Cleaning
Four Rinsing tanks: 2 x Pre rinse with softened water followed by 2 DI-rinsing	Final Cleaning with citric acid passivation
Five Rinsing tanks: 3 x Pre rinse with softened water followed by 2 DI-rinsing	Final Cleaning with nitric acid passivation

Cleaning processes – general rules

Dryer:

Type of Dryer	Meaning	Application
WLT	Standard hot air dryer	Pre Cleaning, IPC
WLT-F	Hot air dryer with Hepa 14 Filter	Final Cleaning
VTR	Standard vacuum dryer	Pre Cleaning, IPC
VTR with Heater	Vacuum dryer intermediate ventilation with hot air (=alternating operation)	Pre Cleaning, IPC
VTR-F with Heater	Vacuum dryer with Filter and intermediate ventilation with hot air (=alternating operation)	Final Cleaning

Cleaning processes – general rules

Piping:

Type	Meaning	Application	Advantage	Disadvantage
PP standard	PP (Polypropylene) piping with socked welded connections, some connections with EPDM hose	Usually not used in medical industry. If there is very cost sensitive project, this piping can used instead of stainless steel	Cheapest possible piping	Many undercuts with room for high risk for growing of biologicals (Bacteria, etc.)
PP IR	PP piping with infrared welded connections	IPC, Final Cleaning	Very good welding quality, no undercuts	Maximal temperature is limited (60 °C)
Stainless Steel	Stainless Steel pipes with press fitting system, sealing available in EPDM of FKM (Viton)	Cleaning and passivation tanks (citric acid) in all process steps (pre-cleaning, IPC, final cleaning)	• The most robust material of piping • Can be used for very high temperatures, up to 80 °C.	Many undercuts with room for high risk for growing of biologicals (Bacteria, etc.). Don't critical if having highly alkaline cleaning agent or strongly acidic passivation agent.
PVDF WNF	PVDF (Polyvinylidene fluoride), WNF=bead and seamless welding	Final rinsing in final Cleaning lines	• Best available welding quality the WNF method • No undercuts, very smooth surface inside and outside of the piping in the welded area • Sanitisation with hot water is possible, very high temperatures possible	expensive
PFA WNF	PFA (Perfluoroalkoxy alkane), WNF = bead and seamless welding	Just needed for passivation tanks with nitric acid	Best resistance against HNO3.	very expensive

Cleaning processes – general rules

DI-Water System:

Type	Features and available options	Application
Elmapur 85	Quite simple, Pro Piping.	In-Process Cleaning
Elmapur 300 med	Customized system, many possible options: • usually piping made from PP IR • PVDF piping also available • TOC online sensor or Particle meter • Ultrafiltration module (to remove endotoxins) • TOC reduction with UV reactor • Conductivity sensors • Data logger • Own PLC control • …	Final Cleaning for smaller lines (size 300, 550, 800)
Elmapur 600 med		• Final Cleaning for bigger lines (size 800, 1600) **or** if the drag out is high **or** if the throughput is high (e.g. 10 baskets per hour) • Price is similar to 300 med

Cleaning processes – general rules

Last rinsing tank:

Extras	advantage
Lift Out	• Perfect for pre drying of simple surfaces • Reducing of drag-out less water → less possible stains • Ultrasonic must be switched off during lift-out process
Conductivity Sensor	to check the DI-water quality
Online TOC sensor	to monitor Total Organic Carbon (Photonics and Medical)
Online particle meter	to monitor micro particles in liquid (Photonics)

Chemicals for Medical provided by Elma

Elma Medtech Clean **A26**	Elma Medtech Clean **A25**	Elma Medtech Clean **N10**	Elma Medtech Clean **S15**	Elma Medtech Clean **S16**	Elma Medtech Clean **S20**
Highly alcaline	**alcaline**	**neutral**	**acidic**	**strongly acidic**	**strongly acidic**
pH: 13-14	pH: 12	pH: 7	pH: 3	pH: 2	pH: 1
			Use as passivation agent ASTM 967-05, Citric	Use as passivation agent ASTM 967-05, Citric	Use as passivation agent

All products in this table are class I medical devices according to (EU) 2017/745 - Medical Device Regulation (MDR). They therefore have a declaration of conformity and the batch traceability is given.

Medical key words

Key word	meaning	details
FDA	Food and Drug Administration	US institution to controll all products in USA on quality, very important for US import.
passivation	Chemical process with nitric or citric acid to remove iron oxidation	Processes are specified depending on medical use. Acid, concentration and time are specified depending on later use
DI-water	De-Ionized water in best quality	To reach best values we need for implants beside UV-lamps also UV-reactors to kill all bacteria and a ultra-filtration to remove the small „dead bodies“ (=endotoxines) for a low TOC value.
Sanitization	Cleaning DI water circulation loop with either chemicals or hot water (70-80°C) to remove biological growth	If hot temperature is specified we need expensive PVDF piping. Standard PP is ok <60°C
Data logger (according FDA 21 CFR part 11)	Transfer of process information to customers network or storage locally at the line	Sotware application to transfer data with XML or PDF-file
User Level Management (according FDA 21 CFR part 11)	Having different User levels in the cleaning lines software	Adjustable levels for operator, process engineer, maintenance stuff, etc.
Audit trail (according FDA 21 CFR part 11)	all changes in a process have to be protocolled	Whoever and whenever a process is being changed, will be protocolled and saved and cannot be easily manipulated (Software)

Medical Key words (Validation)

Key word	meaning	details
Validation	Absolutely common in the field of medical. More or less each line Elma sold in this business is validated by the customer.	The purpose of process validation is to establish documented evidence that the production equipment is correctly installed, operates according to requirements, and performs safely. It is also to demonstrate that the manufacturing process under normal operating conditions will consistently produce conforming products.
URS	User requirement specification	User Requirement Specification (URS) is a technical reference document specially prepared for purchase of capital equipment within the manufacturing sector. The specification is used to provide a list of requirements for new equipment and can also outline any associated commercial requirements within the scope of supply. The User Requirements Specification highlights the needs of the end user as well as any regulatory requirements that surround the particular environment or industry. URS shall provide a clear list and description of all applicable client requirement to be fulfilled by the manufacturer of a machine equipment. A comprehensive and well written URS is the base for the machine development process and will help clarifying the client need and as well save time and resources during the development by setting clear goals.
FAT	factory acceptance test at Elma	
SAT	site acceptance test at customer site	

Medical Key words (Validation)

Key word	meaning	details
FDS	Functional Design Specification	The FDS Functional Design Specification is written on the base of URS document in order to describe how the design of the newly developed machine is going to fulfill the requirement of the client. The FDS provides the basis of the design of the system and will be used as well to verify and validate the system during the testing, ensuring all the required functions are present and that they operate correctly. FDS should details all the functions, operator interactions control and sequencing associated with the system, thus allowing the user to confirm, before the system is developed that the proposed solution fully meets its requirements.
HDS	Hardware Design Specification	The HDS Hardware Design Specification is a document that provides an overall description of the hardware and implementation. It provides description of main components and interactions and as well requirement for proper connection to utilities and installation.
SDS	Software-Design Specification	The SDS Software Design Specification is a document that provides an overall description of the software, implementation, functions and interface with the users.

Medical Key words (Validation)

Key word	meaning	details
DQ	Design Qualification (comparison / verification of design of the machine and URS)	The first element of the validation of new facilities, systems or equipment could be design qualification (DQ).
IQ	Installation Qualification (comparison / verification of installed line and HDS / SDS)	IQ validates that equipment is correctly installed IQ is the first step in the validation process. In this phase, you verify that the manufacturing equipment meets the design specifications and has been correctly installed and configured according to requirements. You need to confirm that all necessary documents, drawings, and manuals are correctly executed and available. During IQ, equipment maintenance as well as calibration schedules and procedures should be established.
OQ	Operational Qualification (comparison / verification of cleaning line and FDS)	OQ validates that equipment operates as intended OQ is the second step in the validation process. In this phase, you verify that the manufacturing equipment operates according to requirements. You need to carry out tests for each component to confirm that every part of the manufacturing equipment operates as intended at pre-set thresholds. By challenging the manufacturing process using “worst-case” conditions, it is possible to determine your process window and to ensure a reproducible manufacturing process resulting in conforming products.
PQ	Performance Qualification	PQ validates process stability over time PQ is the third and last step of the validation process. In this phase, you verify process stability over time by running the equipment several times with a load under normal operating conditions to challenge its functionality and safety. This will demonstrate if the process will produce a product that conforms to its requirements.

Medical Key words – typical contaminations and acceptance criteria

Key word	meaning	details	unit	typical values surgical instruments	medical implants
Bioburden	Bioburden refers to the total microbial count of a surface. The aim of bioburden identification is to determine the population of viable microorganisms (bacteria and fungi) on or in a product or its packaging.	https://www.cleancontrolling.com/en/medical/infothek/testing-methods/determination-of-bioburden	English: CFU - colony forming unit German: KBE - Kolonie-bildende Einheit	< 100 CFU per part	< 5 CFU per part
In vitro cytotoxicity	The ability of a substance to damage cells or tissue is referred to as cytotoxicity.	https://www.cleancontrolling.com/en/medical/infothek/testing-methods/in-vitro-cytotoxicity-test	% growth inhibition	< 30 % growth inhibition	< 10 % growth inhibition
Endotoxin	Endotoxins are part of the outer cell membrane of gram-negative bacteria, which can lead to inflammation and other physiological reactions in the human body.	https://www.cleancontrolling.com/en/medical/infothek/testing-methods/endotoxin-test	EU/ml - endotoxin units per milliliter, or EU per test object	<20 EU per part	< 0,1 EU per part
TOC	TOC as a sum parameter for water-soluble organic residues (process auxiliaries, especially cleaning agents).	https://www.cleancontrolling.com/en/medical/infothek/testing-methods/toc-determination	µg/test object or for water samples µg/ml	< 500 µg per part	< 50 µg per part
THC	THC as a sum parameter for the solvent-soluble organic residues (process auxiliaries, especially oils, greases, lubricants, etc.).	https://www.cleancontrolling.com/en/medical/infothek/testing-methods/thc-determination	µg/test object	< 500 µg per part	< 50 µg per part

Passivation acc. ASTM 967-05 (immersion process)

Name	Concentration	time	temperature
Citric 1	4 – 10 mass %	Min. 4 min	60 - 71°C
Citric 2	4 – 10 mass %	Min. 10 min	49 - 60°C
Citric 3	4 – 10 mass %	Min. 20 min	21 - 49°C
Citric 4	Flexible, but the defined tests must be passed.		
Citric 5	Flexible, but the defined tests must be passed and the pH value must be between 1,8 and 2,2		

Name	concentration	time	temperature
Nitric 1	20 - 25 vol% + Natriumdichromat	Min. 20 min	49 - 54°C
Nitric 2	20 - 45 vol%	Min. 30 min	21 - 32°C
Nitric 3	20 - 25 vol%	Min. 20 min	49 - 60°C
Nitric 4	45 - 55 vol%	Min. 30 min	49 - 54°C
Nitric 5	Flexible, but the defined tests must be passed.		

Test procedure acc. ASTM A967-05

Practice	Type
Practice A	Water immersion test
Practice B	High Humidity Test
Practice C	Salt Spray Test

Practice	Type
Practice D	Copper Sulfate Test
Practice E	Potassium Ferricyanide – Nitric
Practice F	Free Iron Test

Thank you
for your attention.