World Health Organization

Anexă

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Anexa 6

Achiziție sistem medical automat
Baie cu ultrasunet pentru instrumente chirurgicale generale 40 l-50l (Sonic Irrigator)

Lista cerințelor și specificațiilor

Sistem medical automat **Baie cu ultrasunet pentru instrumente chirurgicale generale**					
NUME, CATEGORIA ȘI CODIFICARE					
Parametrii			**Specificație minimă așteptată**	**Caietul de sarcini propus (de completat de ofertant)**	**Documentul de referință / broșura / pagina în care informațiile furnizate pot fi verificate de către comisia de evaluare**
1	Nume generic	Baie cu ultrasunet medicală pentru instrumente de chirurgie generală, instrumente canulate (cu lumen). Este conceput pentru a curăța temeinic (înlătura țesuturile, sângele și alți contaminanți) dintr-o varietate de instrumente chirurgicale reutilizabile.		**MODEL: US80** **Producător: Steelco S.p.a.** **Țara: Italia**	
CARACTERISTICI TEHNICE și CARACTERISTICI FIZICE					
2	CAPACITATE	40 l-50l	da	DA 43 l	pag. 1 din data sheet US 80
		Vasul echipametului fabricat din inox AISI 316L, carcasa din materiale necorozive ca AISI 304/316L sau alte materiale rezistente analogice	da	DA AISI 316L	pag. 2 din data sheet US 80
3	CADRU, CORP	versiune independentă sau de masă	opțional	DA	pag. 6 din brosură Ultrasonic
		Proces de operare: activitate cu ultrasunete, porturi de irigare și încălzire a apei.	da	DA	pag. 2 din data sheet US 80
		Încărcărcătură instrumente nu mai puțin de 5 kg.	da	DA maxim 20 kg	pag. 25 din Instructions manual Operating manual US 80
		minim 5 programe prestabilite din fabrică	≥ 5 programe	DA 20 programe standarte si 20 programe care pot create de utilizare	pag. 3 din data sheet US 80
		programe care pot fi programate de utilizator	da	DA 20 programe	pag. 3 din data sheet US 80

4	CICLU	Progresul ciclului sau numărul de cicluri ar trebui să fie vizibile pe ecran	da	DA	pag. 26 din Instructions manual Operating manual US 80 - *6.1 Control Panel*
		Tip de instrumente curățate: instrumente de chirurgie generală, instrumente canulate (cu lumen).	da	DA	
		Coșul pentru instrumente poate fi încărcat cu un amestec de instrumente generale și canulate în același timp.	da	DA	pag. 3 din data sheet US 80
		Informațiile minime de pe ecran în timpul unui ciclu de spălare: Etapa curentă a ciclului de spălare, Temperatura fluidelor, Afișează fie timpul scurs, fie timpul rămas pentru etapa curentă, Bara de progres și numele programului de spălare	da	DA	pag. 26 din Instructions manual Operating manual US 80 - *6.1 Control Panel*
		Coșul/Tava poate ține instrumente de minim 8 lumeni în același timp	da	DA 12 instrumnete care se conecteaza la fiecare la lumenul sau.	pag. 7 din brosură Ultrasonic
5	SIGURANȚĂ	Clasa 1 de protecție împotriva șocurilor electrice	da	DA	pag. 1 din data sheet US 80
		Sistem „deschis” pentru utilizarea detergenților și dezinfectanților, irigatorul sonic trebuie să fie deschis pentru a utiliza diferiți detergenți și substanțe chimice, nu numai de la producătorul de dispozitiv oferit.	da	DA	pag. 4 din data sheet US 80
		Loc special integrat pentru chimicale și detergenți	da	DA	pag. 21 din Instructions manual Operating manual US 80
		pompe de dozare integrate din oțel inoxidabil pentru produse chimice.	da	DA este mai avansat, sint pompă peristaltica astfel incit n are un contact direct cu dezinfectatul, find necesar schimbarea dor dubului care se foloseste la pompare	
6	Sistem de irigare, daul de apă, monitorizarea temperaturii	colectoare de spălare min.3 porturi în 2 colțuri ale coșului, producând până la 1,5 bar la un debit de 2,5 litri/min.	da	da in depedneta de tipului cosului care va fi instalat si dimetrul lumenlui prin care va fi pompata apa	
		Interval de măsurare: +2ºC până la +60ºC Afișare temperatură: +5ºC până la +60ºC Precizia măsurării: ±0,5ºC.	da	DA deperattura de lucru in cosul/tava in baia cu ultrasunet ajunge pena la valori de 95 grade	pag. 31 din Instructions manual Operating manual US 80
		Presiune: minim 2,0 bar până la maxim 10 bar	da	minima 1 bar maxima 8 bar	pag. 18 din Instructions manual Operating manual US 80
CARACTERISTICI ELECTRICE					
7		220V, 50 Hz, fază I, cu împământare, mufă Shucko	da	DA	pag. 4 din data sheet US 80
electronice					

8	electronice	*minim 4" multi* -color, ecran cu butoane sau opțiune de ecran tactil	da	DA 4,3 inch	pag. 3 din data sheet US 80
		Sistem cu ultrasunete : minim 10 traductoare piezoelectrice, care funcționează de la 38 kHz la 40 kHz, în funcție de sarcină. Putere minimă de 35 W per traductor.	da	DA 10 transductori, 38 kHz, puterea totala este de 1000 W cea ce inseamna 100 W per transductor.	pag. 2 din data sheet US 80
ACCESORII, CONSUMABILE, PIESE DE SCHIMB, ALTE COMPONENTE					
9	Accesorii/ piese de schimb	Coș pentru instrumente	1	DA inclus	
		Conexiuni Luer minime - nu mai puțin de 8	min. 8	DA inclus	
		Recipienți cu soluții chimice trebuie să fie prezenți	da	DA inclus	
INSTRUIRE, INSTALARE SI UTILIZARE					
10	Transport	Furnizorul trebuie să includă transportul până la unitatea medicală finală	da	DA	
11	Instalare	Irigatorul sonic trebuie să includă toate accesoriile pentru funcționarea normală, Furnizorul trebuie să efectueze verificările de instalare, siguranță și funcționare înainte de predare. Trebuie asigurată instruirea utilizatorilor și a tehnicienilor.	da	DA	
GARANȚIE ȘI ÎNTREȚINERE					
12	Garanție și deservire completă (inclusiv piese de schimb)	minim 24 luni	da	DA	
DOCUMENTAȚIE					
13	Cerințe de documentare	Toate documentele justificative, manualele de operare, de service trebuie prezentate în limba de stat sau în limba engleză. Manualul de utilizare/Instructiunile de utilizare trebuie prezentate în limba engleză și în limba de stat.	da	DA	
SIGURANȚĂ ȘI STANDARDE					
14	Standarde pentru producător	toate certificatele valabile enumerate mai jos: 1. Certificat de conofmritate CE conform directivei 93/42 EEC sau a Regulamentului 745 2. Declarația de conformitate CE conform directivei 93/42 EEC sau a Regulamentului 745 3. ISO 13485 și sau 9001 4. EN ISO 15883 5. Standard de siguranță IEC 61010 Cerințe de siguranță pentru mașinile de spălat și dezinfecția utilizate pentru tratarea materialelor medicale	toate certificatele trebuie prezentate în copii cu ștampila de confirmare	DA	pag. 8 din Instructions manual Operating manual US 80 si certificate atasate.

US 80

Ultrasonic washing device for hollow instruments

This benchtop automatic ultrasonic cleaning system is focused on the treatment of hollow reusable medical devices such as rigid endoscopes.

This unit is endowed with **Steelco Active Flushing** Technology that combines the action of ultrasonic with a powerful flushing, to reach the highest level of cleanliness even in the most intricate shapes.

Ultrasonic cleaning acts on immersed surfaces thousands times a second to ensure perfect cleanliness, it is safe for the most delicate and highly finished objects since there are no abrasives or harsh chemicals used and does not create scratches which would result in cleaning problems later.

High level results are achieved on each and every cycle performed resulting in a proven and traceable process to properly clean and decontaminate instruments for the following disinfection and sterilization phases.

Dimensions

External dimensions (WxDxH):
760x550x398h mm (29.9”x21.65”x15.7”)

Total height with open lid: 795 mm (31.30)”

Washing tank dimensions (WxDxH)
650x300x220h mm (25.9”x11.8”x8.66”)

Tank volume: 43 lt.

Washing basket dimensions (WxDxH)
600x250x100hmm (23.62”x9.84”x3.94”)

Water filling level
20 lt. (5.28 US gal.)

Washing basket capacity
up to 12 hollow instruments

Weight: 52kg

Operating weight: 82 kg

Standard compliances

It also fulfils the European EN 61010-1, EN 61010-2-040, EN 61326-1, EN ISO 14971 requirements.

Classified CE Medical Device EU Regulation 745/2017 (Medical Device Regulation). Class I medical device*.

*According to the legislation in force in Canada, the products covered by this documentation do not qualify as medical devices.

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Capitale sociale Euro 3.000.000,00 i.v. C.F., P.IVA e Numero Registro Imprese di Treviso: 04311220265 REA TV 339832

Operation

US 80 device is equipped as standard with a removable washing basket. The loading of the washing basket into the unit directly connects the hydraulic circuit of the device with the injection flushing system of the washing basket.

The washing basket can be removed from the ultrasonic device by easy lifting. This allows the surgical instruments loading and connection even with the basket removed, allowing load preparation even during other washing/flushing cycle operation.

Surgical hollow instruments are connected to the flushing injection system through different connectors: silicone pipes with female luer locks, silicone pipes with open end, silicone pipe equipped with plastic sleeves with silicone seals. All this to ensure water presence and circulation into instrument cavities.

By pushing the start cycle button, with closed tank cover, the tank is filled with cold water at minimum level to perform a prewashing phase followed by a drain phase.

Then the washing chamber is filled with a cold/warm mixed water and the detergent is dosed. Water/detergent solution level and temperature are control checked to allow phase execution.
The device performs an automatic degassing phase followed by the programmed ultrasonic/flushing sequence defined by the program in execution.

At the washing/flushing completion, the tank is completely drained.

A safety device checks that the cover remains closed during the whole washing cycle.

A visual alarm shows that the cycle has been successfully executed, the cover can be opened and net basket eventually removed.

Construction

- Washing tank made of stainless steel AISI 316 L (DIN 1.4404)
- Frame and external cabinet made of stainless steel AISI 304 (DIN 1.4301)
- Tank cover and washing basket made of stainless steel AISI 304 (DIN 1.4301)
- All the other components are made of stainless steel or material resistant to aggressive chemicals

Equipment included

Hinged top cover

- The lid opening and closing action is manual and assisted by gas springs.

Washing/flushing system

- Cold/warm water mixing system
- Automatic tank filling with water level control
- Water recirculation pump for powerful instrument flushing. Pump power 130W
- Pump max flowrate: 5,6 lt/min
- A water filtering system captures residue and prevents their re-circulation to grant excellent washing results.
- Heating element for washing water (temperature selectable). Power 900W (3x300W)
- Independently operated drain pump for efficiently pumping out wastewater
- Ultrasonic generator with radio frequency interference filter. Power 1000 W Ultrasonic frequency 38 kHz, automatic degassing procedure (time selectable)
- Nr. 10 ultrasonic transducers

Chemical dosing

- One (1) peristaltic pump provides precise addition of liquid chemical agents
- Automatic minimum level control of chemical with alarm

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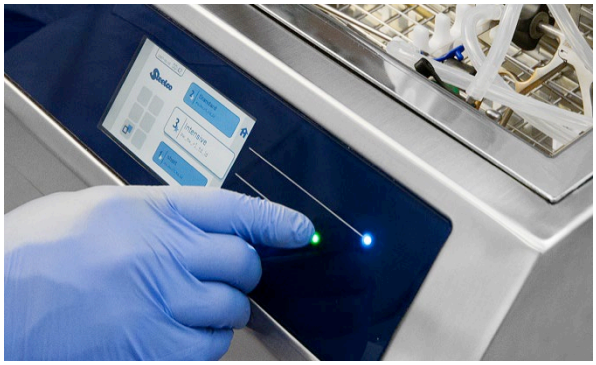
Control system

Microprocessor control system

- Microprocessor for total checking and displaying of single cycle phase with process residual time highlight.
- Possibility of up to 40 storable programs
- 20 standard programs, 20 user definable programs
- 3 levels password protected programming.

System control panel

- Soft touch control panel (touch function areas with status led) made of a single glass surface for perfect cleaning and disinfection to assure the operator a better protection against contamination when operating the machine and selecting the cycle type.



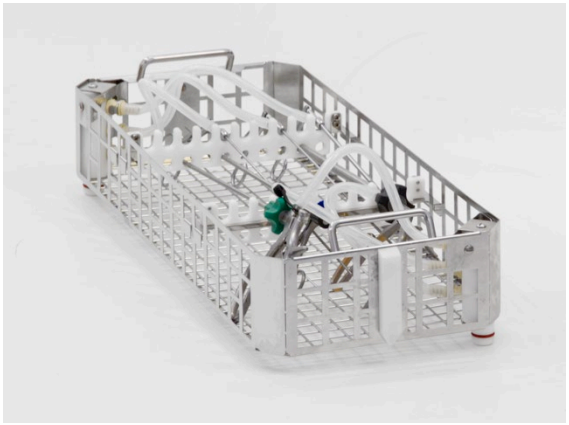
- TFT4,3" – QVGA (480x272px) graphic color display

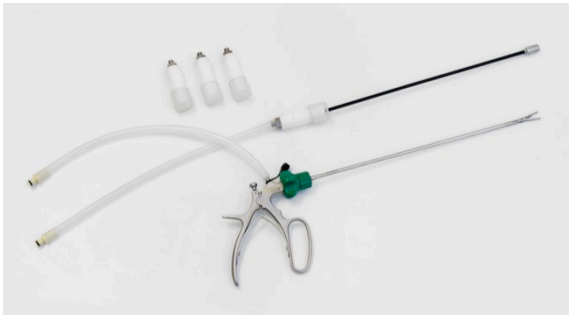
System monitoring

- Audible and visual alarms provide quality control for each wash cycle
- Water level sensors for minimum and working level
- Water overflow drain
- RS 232 Port for printer connection to monitor and validate washing cycle.
- USB port for historical cycle data up to 100 cycles, machine parameters and washing programs download.

Washing basket

- Removable washing basket with 2 instrument supports and 6 fast connections (CPC):
  - 3 connections with silicone pipes + injector sleeve with silicone seal
  - 3 connections with silicone pipes + female Luer Lock
- Instrument supports can be placed as desired or removed.





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Optional features

Accessories for instrumet connection

External printer

- For validating washing phases with detailed information

Cleaning chemicals

Dedicated cleaning chemicals are available.

Required utilities

For connection details please refer to installation drawing of the selected model/version.

Hot water

Cold Water

Drain Connection

Electrical requirements

  - **Total maximum power** 1.05 kW
- 230V/~/50Hz
- 208V/~/60Hz
- Other electrical connections are available to match electrical requirements of installation site.

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Ultrasonic

From delicate microsurgery instruments
to heavy duty sets

Miele Group Member

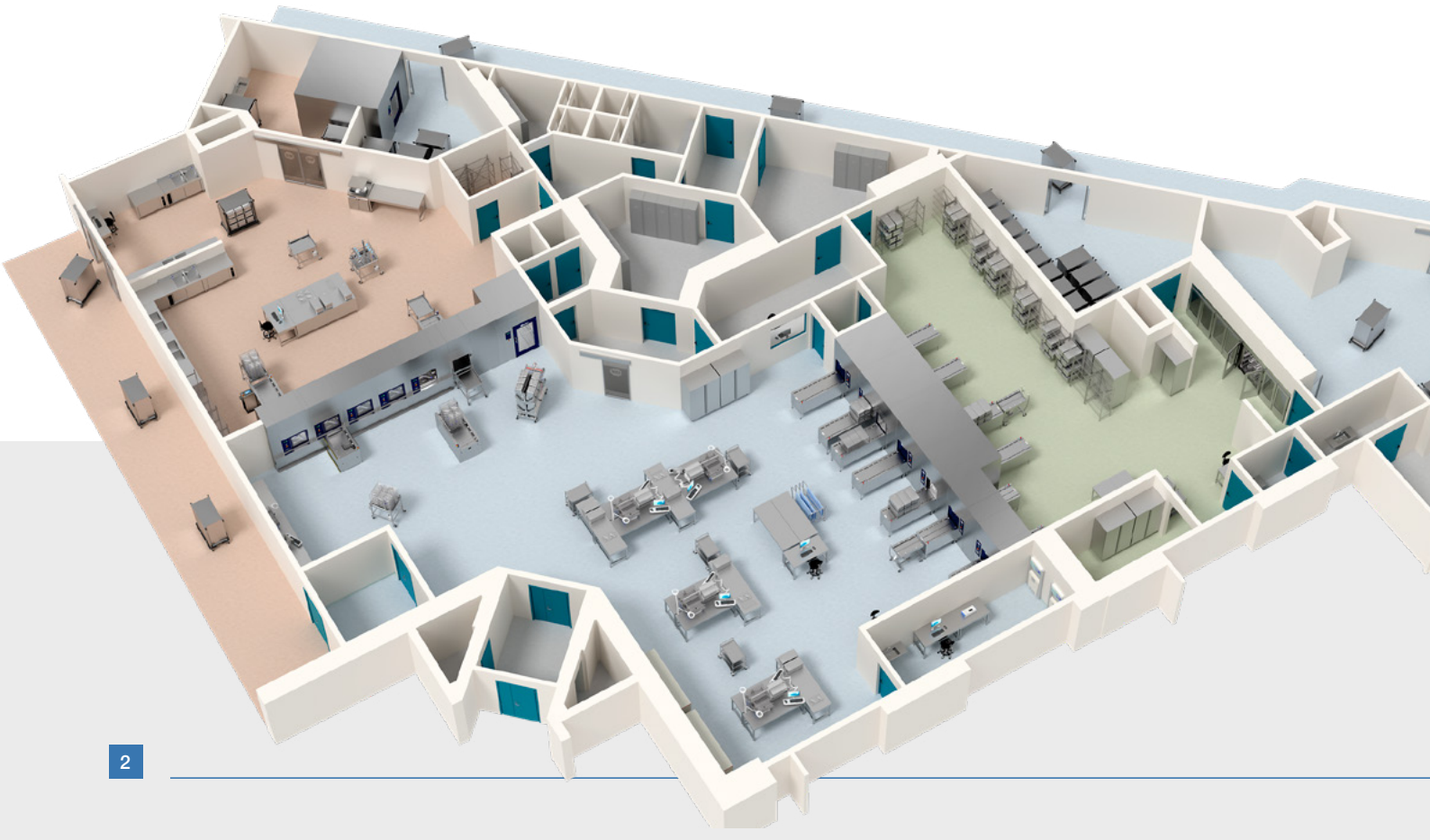
Driven by customer needs

Steelco is a leading infection control solution provider, supplying the healthcare, laboratory research and pharma sectors. Active in over 90 countries, Steelco has equipped numerous world renown hospitals and counts among its customers household names in the laboratory, pharmaceutical and industrial sectors.

Driven by customer feedback, Steelco develops, manufactures and supplies solutions that maximize infection control safety, optimize processes and minimize costs. Our focus on innovation has led us to become leaders in areas such as automation, improving the efficiency and working environment of those that use Steelco products.

With headquarters that overlook the Alps, a core value of Steelco is to minimize our carbon footprint by manufacturing in modern premises in as efficient a manner as possible. We are dedicated to reducing the energy and water consumption of our equipment whilst improving performance.

Whether you are just wishing to replace a single small machine or assistance in designing and equipping a large central CSSD, Steelco and it's factory trained dealers are here to help you make the best decision possible that works for you and then support you every step of the way.



Ultrasonic overview

Under ISO 17664 it is the instrument manufacturer's responsibility to provide instructions on how after use, instruments should be prepared, cleaned, disinfected, dried, inspected, maintained, tested, packaged, sterilized and stored.

Steelco has developed an innovative range of different ultrasonic units to meet different applications and capacities so that CSSD staff can reprocess instruments including complex microsurgery tools according to a manufacturer's instructions when these stipulate the use of an ultrasonic unit.

- ***Intuitive and automatic functions***
- ***Heasy to handle***
- ***Cannulated instrument connection***
- ***High capacity***
- ***Flexible configuration***

Standard compliant

Steelco Ultrasonic washers are designed and constructed to comply with the latest European guidelines on decontamination EN ISO 15883-1/2, CEN ISO/TS 15883-5 and classified CE Medical Device (Community rule 93/42/CEE) code nr. 0051.

Medical range Steelco products
Washer disinfectors and Sterilizer

CSSD range
Systems and Automations

Washer disinfectors
for transfer trolleys, sterile containers and bulky items

Steam Sterilzer
hospitals, CSSD and medical center

Steelco Ultrasonic range

Dedicated complex instruments

US 80 and 300 ultrasonic units have been developed for complex cannulated instruments combining ultrasonic power with Steelco's active flushing technology.

From 12 up to 40 cannulated instruments

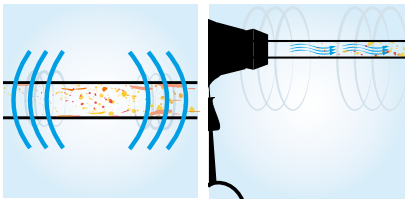
Dedicated general purposes

US 100 and US 200 meets the needs of busy CSSD departments that need large capacity ultrasonic cleaning units for the treatment of medical devices and rigid endoscopes.

3 x Din basket capacity per cycle.

US 1000 High Capacity Ultrasonic Cleaner

Steelco US 1000 has been designed to be integrated into high capacity automated washer systems, between a prewashing unit and automatically loaded washers to reduce total cycle time.
18 x Din basket capacity per cycle
Read more from Steelco CSSD range catalog



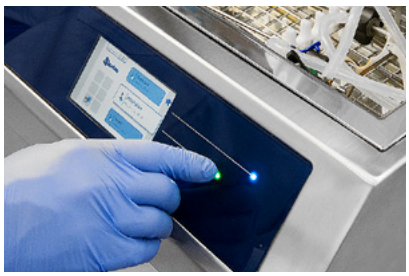
Steelco Active Flushing Technology

US 80 and US 300 feature Steelco Active Flushing Technology, sequentially pulsed and ultrasonic action to provide a powerful combined decontamination to clean even the most intricate of shapes and connections.

Safe and validated process

A soft touch glass control panel with graphic colour LCD display is intuitive to use and enables the selection of 20 preset programs or an additional 20 user defined programs.

The SteelcoTronic control system constantly monitors that all critical parameters such as temperature, detergent dosing, water level and equipment function are correct. Cycle information can be stored or printed. To protect users and avoid cross contamination risks, units will only operate with their lids closed.



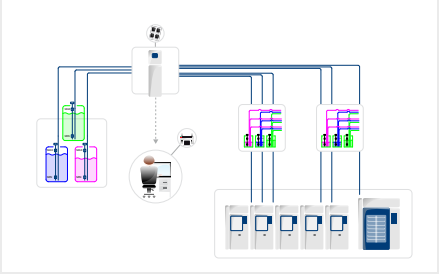
Chemistries to complement ultrasonic cleaning

For best results use Steelco chemistries that have been validated on ultrasonic units. Detergents are internally stored and together with water are automatically dosed to the correct level with a lowlevel detergent alarm fitted.

SteelcoChem

Centralized Chemical Dispensing System

- Cost reduction through the purchase of large volumes of detergents.
- No more need to replace small containers.
- Reduces the risk of incorrect product selection and operator exposure to spillages.
- The constant monitoring of consumption and of remaining volume of chemical minimizes the risk of downtime.



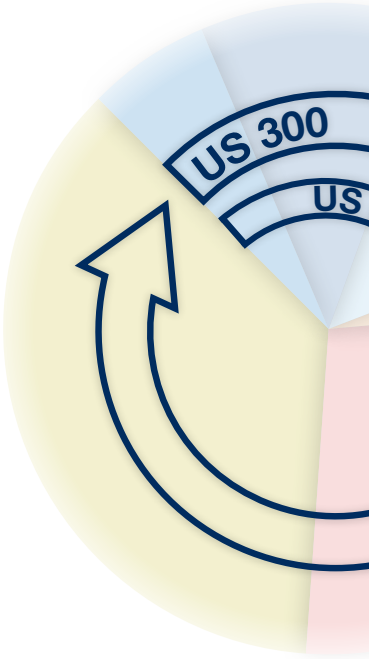
Installation example

US 80 and US 300

Ultrasonic system for cannulated instruments

US 300
ultrasonic unit

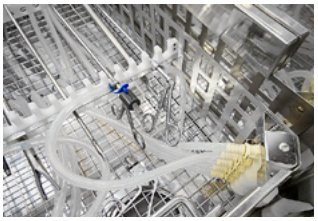
US 80
ultrasonic unit



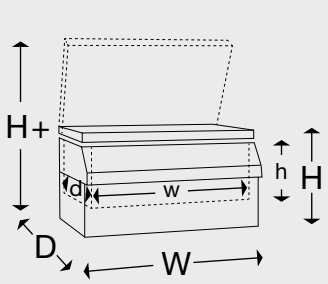
The increase in minimal invasive surgery and use of robots has driven the need for increasingly sophisticated instruments.

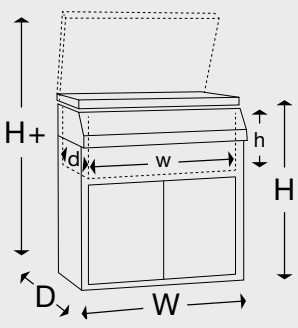
The smaller interior structures and connections within complex hollow lumen and microsurgical instruments pose added challenges for their reprocessing.

Responding to these challenges, Steelco has developed the US 80 and US 300 Ultrasonic units specifically for cannulated instruments.

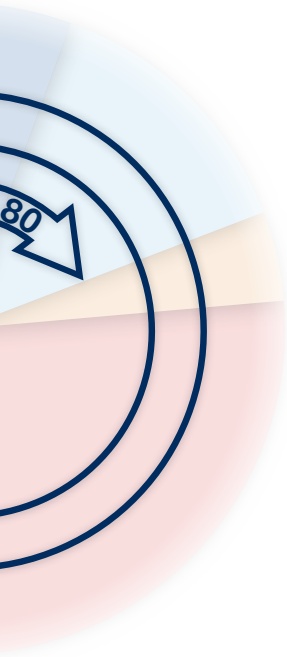


Washer dimensions





		W	D	H	H+	w	d	h
US 80	mm	760	560	398	795	650	300	220
	inches	29 7/8	22 1/16	15 11/16	31 5/16	25 9/16	11 13/16	8 11/16
US 300	mm	890	675	1045	1530	750	400	260
	inches	35	26 9/16	41 1/8	60 1/4	29 1/2	15 3/4	10 1/4



US 80 - Process cycle

Example of a standard cycle. Including automated drain phases. Custom cycles can be programmed.

1. Cold prewash
2. Water and detergent dosed with control of parameters
3. Steelco Active Flushing

→ Instruments ready for further processing

Capacity

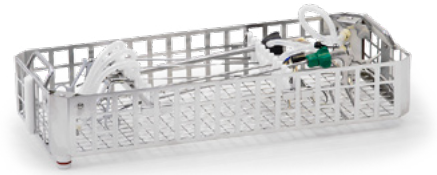
up to 12 hollow instruments in a single cycle

Features

US 80 is a small footprint benchtop size unit for the pretreatment of hollow instruments. Excellent cleaning results are obtained for **up to 12 hollow instruments** by the combined effects of Ultrasonic cleaning and Steelco's Active Flush technology.

All steps of the decontamination process are fully automated.

The injection-washing basket can be easily removed from the ultrasonic unit, allowing loading and connection of instruments on a separate workbench.



US 80 basket dimensions WxDxH
600x250x100mm / 23 5/8"x9 13/16"x3 15/16"

US 300 - Process cycle

Example of a standard cycle. Including automated drain phases. Custom cycles can be programmed.

1. Cold prewash
2. Water and detergent dosed with control of parameters
3. Steelco Active Flushing
4. Rinse with DI or RO water
5. Thermal disinfection
6. Forced hot air drying system

→ Instruments ready for sterilization

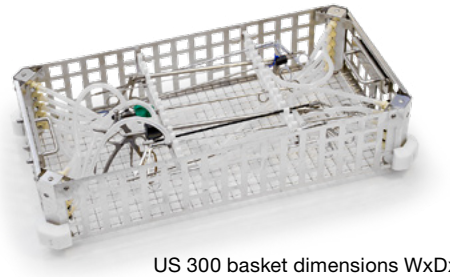
Capacity

Up to 40 hollow instruments in a single cycle

Features

The US 300 is a free standing unit that following the Steelco Active Flush cycle, will rinse instruments with DI or RO water prior to thermal disinfection, making instruments safe to handle and ready for sterilization.

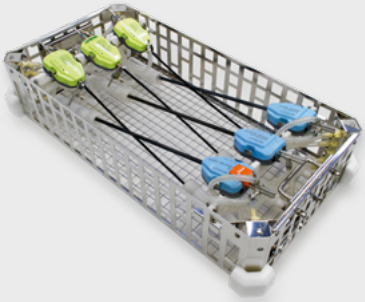
In addition to it's high capacity of reprocessing **up to 40 hollow instruments in a single cycle**, US 300 also has a number of additional features such as on board chemical storage of up to 2 chemistries and automatic lid opening option via IR sensor.

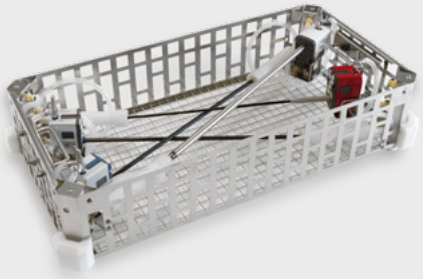


US 300 basket dimensions WxDxH
700x350x150mm / 27 9/16"x13 3/4"x5 15/16"

Connection kit for the validated reprocessing (washing and thermal disinfection) of "da Vinci®" robotic surgery instruments for US 300 model.

The connection kits allow the set up the standard loading basket with housings for the robotic surgical instruments and are available for the IS 3000 (Si) and IS 4000 (Xi) series.





US 100 and US 200

Ultrasonic cleaning systems

US 200
automatic module

US 100
automatic module

Steelco's ultrasonic cleaning systems are ideally suited to the needs of busy departments and can be easily installed in and pre-treatment areas.

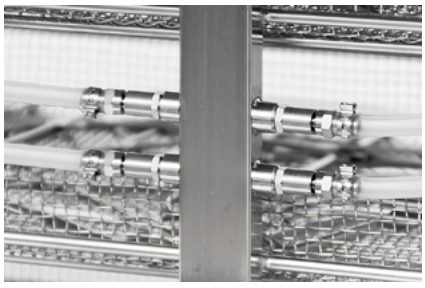
Both the US100 or US 200 model feature AISI 316L grade stainless steel wash tanks fitted with industrial style transducers and a powerful ultrasonic generator to provide high performance cleaning in a low maintenance durable unit.

Meeting international standards, critical process parameters such as temperature, ultrasonic power and time are monitored with user alarm systems fitted.

Powerful Cleaning Action

Outstanding cleaning results are achieved due to ultrasonic power of 3000W per tank with filter for radio frequency control and 0% to 100% power control. Frequency modulation technology ensures an even cavitation effect distribution.

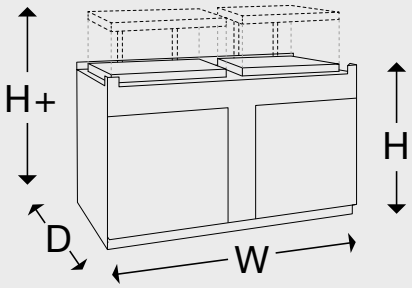
Supplied as standard with 38KHz ultrasonic frequency with other frequencies available on request. 4 Luer lock connections per tray level.



Washing chamber

Chamber dimension WxDxH
600 x 350 x 345mm
23 5/8" x 13 3/4" x 13 9/16"

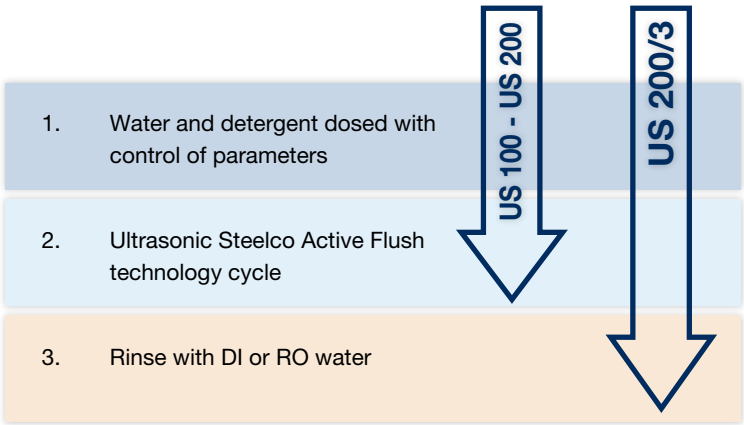
Wash cart dimension WxDxH
485 x 250 x 50mm
19 1/16" x 19 13/16" x 2"

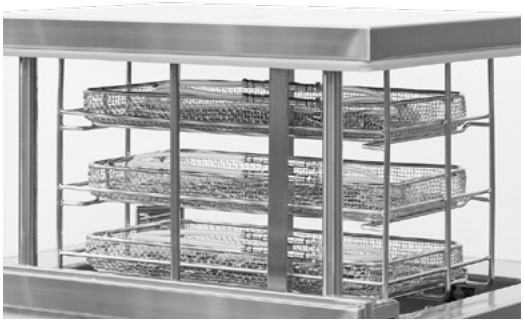


Washer dimensions

		W	D	H	H+
US 100	mm	800	700	950	1270
	inches	31 1/2	27 9/16	37 3/8	50
US 200	mm	1500	700	950	1270
	inches	59 1/8	27 9/16	37 3/8	50

Steps

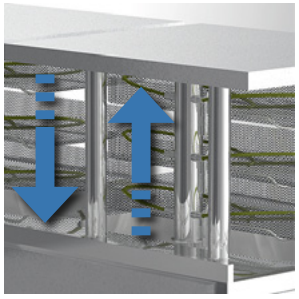




Frequency of automatic renewal of washing solution selected according to user requirements.

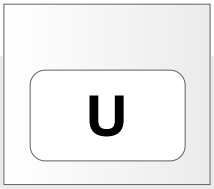
Features

- Automatic tank filling with water level control
- Automatic minimum level control of chemical with alarm
- Automatic degassing procedure (time selectable)
- Pump for automatic chemical dosing
- Intermittent functioning water recirculation pump
- Cold/warm water mixing system
- Baskets are automatically lowered and raised at the start and end of each cycle thereby reducing the risk of work related injuries manual lifting
- Pneumatic lift of the cover and baskets provided with security device



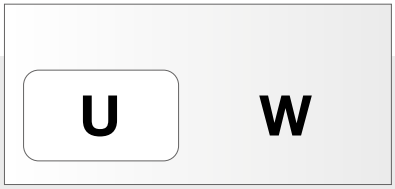
Tank configuration

US 100



1 ultrasonic tank
3 x Din 1/1 net baskets
12 Luer lock connections

US 200/1



1 ultrasonic tank
3 x Din 1/1 net baskets
12 Luer lock connections
+ integrated worksurface

US 200/2

2 ultrasonic tanks
6 x Din 1/1 net baskets in total
24 ultrasonic Luer lock connections

US 200/3

1 ultrasonic tank
3 x Din 1/1 net baskets and 12 luer lock connections
1 x Rinse tank with water spray nozzles

U ULTRASONIC UNIT **R** RINSE TANK **W** WORKSURFACE

Technical data

ultrasonic washers	US 80	US 300	US 100 US 200/1	US 200/2	US 200/3
CAPACITY					
number of ultrasonic tanks	1	1	1	2	1
total capacity of ultrasonic tanks - lt	43	78	72,5	2x72,5	72,5
water capacity at full fill level - lt	24	49	58	2x58	58
maximum number of cannulated instruments	12	40	12	2x12	12
number of connections	6	20	12	2x12	12
PROCESS					
"Active Flushing" technology	•	•	•	•	•
pressure control of washing circuits	○	○	-	-	-
drain water cooling system	-	○	-	-	-
forced hot air drying system	-	○	-	-	-
CONSTRUCTION					
external surfaces AISI 304	•	•	•	•	•
washing chamber AISI 316L	•	•	•	•	•
DOOR OPERATION					
manual	•	-	○	○	○
automatic - pneumatically actuated	-	-	•	•	•
automatic - electrically actuated	-	-	○	○	○
automatic - foot pedal operated	-	-	○	○	○
automatic - infrared sensor operated	-	•	○	○	○
automatic door locking	-	•	•	•	•
CONTROL PANEL					
soft touch, 4,3” graphic LCD display	•	•	○	○	○
touch button, LED display	-	-	•	•	•
standard programs	20	20	2	2	2
custom programs	20	20	1	1	1
USB port	•	•	-	-	-
RS232 serial port	•	•	○	○	○
integrated printer	○	○	○	○	○
ethernet port for paperless traceability	•	•	○	○	○
UTILITIES					
standard electrical connection others available on request	230V 50Hz	400V 3~+N 50Hz	230V 50Hz	230V 50Hz	230V 50Hz
total power W	1100	10000	3250	6350	3250
ultrasonic power W	1000	2000	3000	3000x2	3000
cold and warm water connections	•	•	•	•	•
DETERGENT DOSING SYSTEM					
standard dosing pump	1	1	1	2x1	1
additional dosing pump	○	○	○	○	○
internal detergent storage (5 l containers)	-	2	2	2	2
compatibility with central dosing system	•	•	•	•	•

• = Standard ○ = Optional - = Not available

Standard instrument connection accessories

	US 100 - US 200/1	US 200/2	US 200/3
US100501 Silicone tube with luer lock connection to machine, open end for instrument connection	12	2x12	12

	US 80	US 300
US300505 Silicone tube with easy connection to machine, female luer lock for connection to ported instruments	3	14
US300513 Silicone tube with easy connection to machine, sleeve with silicone seal for connection to unported instruments max instrument ø 10mm	3	6

Optional instrument connections and accessories

US300518
Connection kit for robotic instruments "da Vinci®" series IS 3000 (Si) - compatible only with US 300

US300530
Connection kit for robotic instruments "da Vinci®" series IS 4000 (Xi) - compatible only with US 300

US300512
Silicone tube with easy connection to machine, sleeve with silicone seal for connection to unported instruments - max ø 22mm

020651
Y adaptor for doubling flushing connections

9991362
Female luer lock connectors (2pcs.)

C095008
Cap for closing unused luer lock connections

C71
150Wx230Dx50H mm
5 15/16 W x 9 1/16 D x 2 H inches
mesh basket for small ware.

C87
Lid for C71 mesh basket.

C1190
110Wx150Dx50H mm
4 5/16 W x 5 15/16 D x 2 H inches
mesh basket for small ware.

C1191
Lid for C1190 mesh basket.

Miele Group Member

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STEELCO USA
West Palm Beach, USA
info-usa@steelcogroup.com

CE 0051*
* Only for products listed into the 909/MDD certificate

DC-PD-02-US EN Rev.05

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CERTIFICATO N.
CERTIFICATE N. **1050.2021**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA SALUTE E SICUREZZA SUL LAVORO
WE HEREBY CERTIFY THAT THE HEALTH AND SAFETY MANAGEMENT SYSTEM OPERATED BY

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 9/A - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 6-8 - 31039 RIESE PIO X (TV) Italy

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 45001:2018

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Vedere l'Allegato per l'attività (n°1 pagina)
View the Annex for the activity (n° 1 page)

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	23-08-2021	25-07-2023	22-08-2024

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 19, 18, 29

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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CISQ is a member of
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The International Certification Network
www.iqnet-certification.com

ALLEGATO CERTIFICATO N. **1050.2021**
ANNEX CERTIFICATE N.

Attività:
Activities:

Progettazione, produzione, installazione ed assistenza di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, sterilizzatori a vapore e/o a bassa temperatura, lavapadelle, lavastrumenti ad ultrasuoni ed apparecchi per il lavaggio, disinfezione e sterilizzazione chimica degli endoscopi termolabili. Progettazione, produzione, installazione ed assistenza di apparecchi per il lavaggio e disinfezione di vetreria, strumenti, carrelli, contenitori e parti di macchine speciali per il settore farmaceutico. Progettazione e commercializzazione di soluzioni disinfettanti per dispositivi medici invasivi e non invasivi. Commercializzazione di lavastrumenti per decontaminazione, sterilizzatori a vapore e relativi accessori. Commercializzazione di arredi e attrezzature/accessori a supporto dei processi di lavaggio, disinfezione, sterilizzazione e stoccaggio di attrezzature e strumenti. Processi: lavorazioni meccaniche, saldatura lamiere, assemblaggio, collaudo, imballaggio e spedizione di prodotti finiti.

Design, manufacturing, installation and service of washer disinfectors and trolley washers, washers for decontamination, steam and/or low temperature sterilizers, bedpan washers, ultrasonic washers and washers for the disinfection and the chemical sterilization of the thermolabile endoscopes. Design, manufacturing, installation and service of equipment for the washing and disinfection of glassware, instruments, trolleys, carboys and parts of special machines for the pharmaceutical industry. Commercialization of decontamination washers, steam sterilizers and their accessories. Commercialization of furniture/accessories to support washing, disinfection and sterilization processes as well as for the storage of instruments and tools. Processes: mechanical works, welding of metal sheets, assembly, testing, packaging and shipping of finished products.

Design, Produktion, Installation und Wartung von Reinigungsdesinfektionsautomaten und Wagenwaschanlagen zur Thermodesinfektion, Dekontaminationsgeraeten, Dampf- und / oder Niedertemperatur-Sterilisatoren, Steckbeckenspueler, Ultraschallreinigungsgeräten und Geräten zum Waschen, Desinfizieren und chemischen Sterilisieren von thermolabilen Endoskopen. Entwurf Herstellung Installation und Wartung von Anlagen zum Waschen und Desinfizieren von Glaswaren, Instrumenten, Wagen, Containern und Teilen von Spezialmaschinen für die pharmazeutische Industrie. Design und Marketing von Desinfektionslösungen für invasive und nicht-invasive Medizinprodukte. Vermarktung von Dekontaminationsgeräten, Dampfsterilisatoren und dazugehörigem Zubehör. Verkauf von Möbeln und Geräten / Zubehör zur Unterstützung der Reinigungsprozesse, Desinfektion, Sterilisation und Lagerung von Geräten und Werkzeugen.

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	23-08-2021	25-07-2023	22-08-2024

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
MS N° 0005MS
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 19, 18, 29

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The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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IQNET

Building trust together.

Certificate

CISQ/IMQ has issued an IQNET recognized certificate that the organization:

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 10/12/3/9A/6-8 - 31039 RIESE PIO X (TV) Italy

has implemented and maintains a

Occupational Health and Safety Management System

for the following scope: **Design, manufacturing, installation and service of washer disinfectors and trolley washers, washers for decontamination, steam and/or low temperature sterilizers, bedpan washers, ultrasonic washers and washers for the disinfection and the chemical sterilization of the thermolabile endoscopes. Design, manufacturing, installation and service of equipment for the washing and disinfection of glassware, instruments, trolleys, carboys and parts of special machines for the pharmaceutical industry. Commercialization of decontamination washers, steam sterilizers and their accessories. Commercialization of furniture/accessories to support washing, disinfection and sterilization processes as well as for the storage of instruments and tools. Processes: mechanical works, welding of metal sheets, assembly, testing, packaging and shipping of finished products.**

which fulfils the requirements of the following standard:

ISO 45001:2018

Issued on: **2023/07/25**
Expires on: **2024/08/22**

Registration Number: **IT – 134569-1050.2021**

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

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www.imq.it

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The International Certification Network

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CERTIFICATO N. **9191.SEE3**
CERTIFICATE N.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE AMBIENTALE DI
WE HEREBY CERTIFY THAT THE ENVIRONMENTAL MANAGEMENT SYSTEM OPERATED BY

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy
SITI/SITES

Vedere gli Allegati per gli altri Siti (n° 3 allegati)
Vedere gli Allegati per gli altri Siti (n° 3 annexes)

E' CONFORME ALLA NORMA /*IS IN COMPLIANCE WITH THE STANDARD*

ISO 14001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, installazione e assistenza di sistemi di lavaggio, disinfezione e sterilizzazione in ambito medico sanitario, farmaceutico e per i laboratori di ricerca mediate i processi di lavorazioni meccaniche, saldatura lamiere, assemblaggio, collaudo, imballaggio e spedizione di prodotti finiti. Commercializzazione di apparecchiature, strumenti ed accessori per i processi di lavaggio, disinfezione e sterilizzazione

Design, production, installation and service of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories through the processes of machining, sheet metal welding, assembly, testing, packaging and shipping of the finished products.. Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes.

Certificazione rilasciata in conformità al Regolamento Tecnico ACCREDIA RT-09

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	11/10/2017	21/07/2023	10/10/2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

IAF: 19,18,29

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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ALLEGATO n. **9191.SEE3-1**
ANNEX No.

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy

Attività:
Activities:

Progettazione, produzione, installazione e assistenza di sistemi di lavaggio, disinfezione e sterilizzazione in ambito medico sanitario, farmaceutico e per i laboratori di ricerca mediate i processi di lavorazioni meccaniche, saldatura lamiere, assemblaggio, collaudo, imballaggio e spedizione di prodotti finiti. Commercializzazione di apparecchiature, strumenti ed accessori per i processi di lavaggio, disinfezione e sterilizzazione Commercializzazione di apparecchiature, strumenti ed accessori per i processi di lavaggio, disinfezione e sterilizzazione. Commercializzazione di apparecchiature, strumenti ed accessori per i processi di lavaggio, disinfezione e sterilizzazione.

Design, production, installation and service of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories through the processes of machining, sheet metal welding, assembly, testing, packaging and shipping of the finished products. Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A: STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO: STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9191.SEE3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9191.SEE3

DATE	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	11/10/2017	21/07/2023	10/10/2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9191.SEE3
This document is part of certificate n. 9191.SEE3

IAF: 18,19,29

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
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ALLEGATO n. **9191.SEE3-2**
ANNEX No.

STEELCO SPA

VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 9A - 31039 RIESE PIO X (TV) Italy

Attività:
Activities:

Produzione di sistemi di lavaggio, disinfezione e sterilizzazione in ambito medico sanitario, farmaceutico e per i laboratori di ricerca

Production of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A: STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO: STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9191.SEE3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9191.SEE3

DATE	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	11/10/2017	21/07/2023	10/10/2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9191.SEE3
This document is part of certificate n. 9191.SEE3

IAF: 18,19

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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ALLEGATO n. **9191.SEE3-3**
ANNEX No.

STEELCO SPA

VIA DEL LAVORO 6-8 - 31039 RIESE PIO X (TV) Italy

Attività:
Activities:

Produzione di sistemi di lavaggio, disinfezione e sterilizzazione in ambito medico sanitario, farmaceutico e per i laboratori di ricerca. Magazzino prodotto finito

Production of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories. Warehouse for finished products

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A: STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO: STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9191.SEE3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9191.SEE3

DATE	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	11/10/2017	21/07/2023	10/10/2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
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Il presente documento integra il certificato n. 9191.SEE3
This document is part of certificate n. 9191.SEE3

IAF: 19

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IQNET

Building trust together.

Certificate

CISQ/IMQ has issued an IQNET recognized certificate that the organization:

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 9A - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 6-8 - 31039 RIESE PIO X (TV) Italy

has implemented and maintains a
Environmental Management System

for the following scope:
Design, production, installation and service of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories through the processes of machining, sheet metal welding, assembly, testing, packaging and shipping of the finished products.. Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes.

which fulfils the requirements of the following standard:

ISO 14001:2015

Issued on: **2023/07/21**
Expires on: **2026/10/10**

Registration Number: **IT – 112291-9191.SEE3**

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

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* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION DE CONFORMITÉ UE

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:

Name/Type: *Nome/Modello:* Nom/Modèle:	**US 80**	**LOT**	**---**
REF	**999XXXXX**	**SN**	**XXXXXXXXXXXX**
Basic UDI-DI: *UDI-DI di base:* IUD-ID de base:	**8051520USXX5Z**	**GMDN**	**36749**

[EN] Referring to Regulation (EU) 2017/745 (hereinafter the "MDR"), is classified on **I** class, according to rule 13 of the annex VIII, designed and manufactured in conformity with the general requirements of safety and performance of annex I, applying the provisions of the harmonized standards.
This declaration is of conformity is issued under the sole responsibility of the manufacturer.
The juridical person authorized to compile the technical documentation is Steelco S.p.A.
.

[IT] In riferimento al Regolamento (UE) 2017/745 (di seguito come “MDR”), è classificato in classe **I**, in accordo alla regola 13 dell’allegato VIII, è stato progettato e costruito in conformità ai requisiti generali di sicurezza e prestazione dell’allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante.
La persona giuridica autorizzata a costituire la documentazione tecnica è Steelco S.p.A.
.

[FR] En référence au Règlement (UE) 2017/745 (ci-après le “MDR”), est classifiée en classe **I**, en accord à la règle 13 annexe VIII, a été projetée et construit en conformité aux les exigences générales en matière de sécurité et de performances de l'annexe I, appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.
La personne juridique autorisée à constituer la documentation technique est Steelco S.p.A.
.

Applied regulations:
Regolamenti applicati:
Règlements appliqués:

- **2017/745/EU (Medical Devices Regulation)**
- **2011/65/EU (RoHS 2 Directive)**

Refers to the Annex for the applied standards.
Le norme applicate sono indicate in allegato.
Les normes appliquées sont indiquées en annexe.

RIESE PIO X, 20 / 09 / 2021

Chairman of the BOD & Chief Executive Officer
Presidente del CDA e Amministratore Delegato
Président du CDA et Director Général

Fabio Zardini
Steelco S.p.A.

ANNEX
ALLEGATO
ANNEXE

Name/Type:
Nome/Modello:
Nom/Modèle: **US 80**

LOT **---**

REF **999XXXXX**

SN **XXXXXXXXXXXX**

Applied standards:
Norme applicate:
Normes appliqués:

- **EN 61010-1:2010 + A1:2019**
- **EN ISO 14971:2019**
- **EN 61326-1:2013**

STEELCO S.p.A. Via Balegante, 27 – 31039 Riese Pio X (TV) ITALY Tel. +39 0423 7561 Fax +39 0423 755528
EUDAMED **SRN: ---** info@steelcogroup.com www.steelcogroup.com

www.imq.it

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CERTIFICATO N.
CERTIFICATE N. 9124.IST2

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n° 5 pagine)
View the Annexes for the Operative Units (n° 5 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, immissione in commercio, installazione, assistenza e commercializzazione di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, sterilizzatori a bassa temperatura, lavapadelle, lavastrumenti ad ultrasuoni per dispositivi medici ed apparecchi per il lavaggio, disinfezione e sterilizzazione chimica degli endoscopi termolabili e relativi accessori. Gestione della progettazione e della produzione, immissione in commercio di sterilizzatrici a vapore, autoclavi a vapore per disinfezione di dispositivi medici quali materassi e cuscini ospedalieri e relativi accessori. Gestione della progettazione e della produzione, immissione in commercio e commercializzazione di soluzioni disinfettanti per dispositivi medici invasivi e non invasivi

Design, manufacture, installation, placing on the market, service and trading of washer disinfectors for instruments and trolleys, instruments decontamination units, low temperature sterilizers, bedpan washers, instruments washers by ultrasounds for medical devices and equipment for the chemical washing, disinfection and sterilization of thermolable endoscopes and related accessories. Design and manufacture management, placing on the market of steam sterilizers units, steam disinfectors of medical devices, such as hospital mattresses and pillows and related accessories. Design and manufacture management, placing on the market and trading of disinfectant solutions for invasive and noninvasive medical devices

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-08-30	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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ERTIFICATO N.
CERTIFICATE N. 9120.IST1

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n° 5 pagine)
View the Annexes for the Operative Units (n° 5 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, installazione e assistenza di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, sterilizzatori a vapore e/o a bassa temperatura, lavastrumenti ad ultrasuoni, passacarrelli e relativi accessori per i settori laboratorio e stabulario. Progettazione, produzione, installazione ed assistenza di apparecchi e relativi accessori di apparecchi per il lavaggio e disinfezione di vetreria, strumenti, carrelli, contenitori e parti di macchine speciali per il settore farmaceutico. Commercializzazione di lavastrumenti per decontaminazione, sterilizzatori a vapore e relativi accessori. Commercializzazione di arredi ed attrezzature/accessori a supporto dei processi di lavaggio, disinfezione, sterilizzazione e stoccaggio di attrezzature e strumenti

Design, manufacture, installation and service of washer disinfectors for instruments and trolleys, instruments decontamination units, steam sterilizers units and/or low temperature sterilizers, instruments washers by ultrasounds, passthrough cabinets and related accessories for laboratory and life science industries. Design, manufacture, installation and service of washing and disinfecting equipment as washer disinfectors for instruments and trolleys, containers and special machine parts for pharmaceutical industry. Sale of instruments decontamination units, steam sterilizers units and related accessories. Sale of furniture and equipment/accessories for washing, disinfection, sterilization and storage processes for tools and instruments

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-03-25	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

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IAF: 19, 18, 29

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ALLEGATO N. **9120.IST1-1**
ANNEX N.

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV)

Attività:
Activities:

Progettazione, produzione, installazione, assistenza e commercializzazione di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, sterilizzatori a bassa temperatura, lavastrumenti ad ultrasuoni e relativi accessori per i settori laboratorio e stabulario. Progettazione, produzione di sterilizzatrici a vapore (secondo procedura di OBL con fornitore esterno)
Design, manufacture, installation, service and trading of washer disinfectors for instruments and trolleys, instruments decontamination units, low temperature sterilizers, instruments washers by ultrasounds and related accessories for laboratory and life science industries. Design, manufacture of steam sterilizers units (according to procedure of OBL with external supplier)

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9120.IST1

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-03-25	2024-04-22

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Management Systems Division - Flavio Ornago

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L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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This document is a part of certificate n. 9120.IST1

IAF: 19, 18, 29

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ALLEGATO N. **9120.IST1-2**
ANNEX N.

STEELCO SPA

VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV)

Attività:
Activities:

Produzione (lavorazioni meccaniche e conservazione materie prime)
Manufacture (mechanical processing and storing raw materials)

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9120.IST1

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-03-25	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
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This document is a part of certificate n. 9120.IST1

IAF: 18

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ALLEGATO N. **9120.IST1-3**
ANNEX N.

STEELCO SPA

VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV)

Attività:
Activities:

Progettazione, produzione, installazione ed assistenza di apparecchi e relativi accessori per il lavaggio e disinfezione di vetreria, strumenti, carrelli, contenitori e parti di macchine speciali per il settore farmaceutico
Design, manufacture, installation and service of equipment and related accessories for washing and disinfecting instruments and trolleys, containers and special machine parts for pharmaceutical industry

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
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	2006-05-05	2021-03-25	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
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This document is a part of certificate n. 9120.IST1

IAF: 19, 18

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ALLEGATO N. **9120.IST1-4**
ANNEX N.

STEELCO SPA

VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV)

Attività:
Activities:

Progettazione, produzione, installazione ed assistenza di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, apparecchi per il lavaggio/disinfezione e relativi accessori
Design, manufacture, installation and service of washer disinfectors for instruments and trolleys, instruments decontamination units, washing/disinfection devices and related accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9120.IST1

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION* 2006-05-05	EMISSIONE CORRENTE *CURRENT ISSUE* 2021-03-25	SCADENZA *EXPIRY* 2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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Il presente documento integra il certificato n. 9120.IST1
This document is a part of certificate n. 9120.IST1

IAF: 19

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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ALLEGATO N. **9120.IST1-5**
ANNEX N.

STEELCO SPA

VIA DEL LAVORO 9/A - 31039 RIESE PIO X (TV)

Attività:
Activities:

Progettazione e produzione di passacarrelli, accessori e componenti delle lavastrumenti o sterilizzatrici quali i sistemi di trasporto automatici
Design and manufacture of passthrough cabinets, accessories and components of instrument washers or sterilizers as the automatic transport systems

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9120.IST1

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-03-25	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9120.IST1
This document is a part of certificate n. 9120.IST1

IAF: 19, 18

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV)
VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV)
VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV)
VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV)
VIA DEL LAVORO 9/A - 31039 RIESE PIO X (TV)

has implemented and maintains a
Quality Management System
for the following scope:

Design, manufacture, installation and service of washer disinfectors for instruments and trolleys, instruments decontamination units, steam sterilizers units and/or low temperature sterilizers, instruments washers by ultrasounds, passthrough cabinets and related accessories for laboratory and life science industries. Design, manufacture, installation and service of washing and disinfecting equipment as washer disinfectors for instruments and trolleys, containers and special machine parts for pharmaceutical industry. Sale of instruments decontamination units, steam sterilizers units and related accessories. Sale of furniture and equipment/accessories for washing, disinfection, sterilization and storage processes for tools and instruments

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: **2021 - 03 - 25**
Expires on: ***2024 - 04 - 22***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 52077

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

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Steelco

Miele Group Member

Instructions manual
Operating manual

ULTRASONIC DECONTAMINATION BENCH

US 80

Serial N°:

CE

Steelco Miele Group Member

Via Balegante, 27
31039 Riese Pio X (TV)
ITALY

Manufacturer:

STEELCO S.p.A.
Via Balegante, 27
31039 Riese Pio X (TV)
ITALY

CONTENTS

Thank you for purchasing this appliance.

The installation, maintenance and operating instructions given in the following pages have been prepared to ensure the long life and good performance of the appliance.

Following the instructions carefully.

The appliance was designed and constructed using the latest technological innovations available.
Please take good care of it.

Your satisfaction is our best reward.

ATTENTION:
NON OBSERVANCE, EVEN IN PART, OF THE RULES INDICATED IN THIS MANUAL WILL CAUSE THE PRODUCT GUARANTEE TO BECOME INVALID AND RELIEVES THE MANUFACTURER OF ANY RESPONSIBILITY.

1. GENERAL RULES

1.1 Limits of manufacturer’s liability

The manufacturer shall not be held liable for failures or problems which arise due to tampering and/or incorrect applications and/or improper use of the machine.
The purchaser must comply with all instructions set forth in the user's manual, and he must in particular:

- Always work within the allowable limits for the use of the machine;
- Always carry out constant and diligent maintenance;
- Allow use of the machine by persons with proper skills and abilities for their role and purpose who have been properly trained and instructed;
- Use only manufacturer original spare parts.

Any modifications, adaptation or the like which may be made to machines which are subsequently placed on the market do not oblige the manufacturer to intervene on previously supplied machines, nor to consider the machine and the related user's manual lacking and inadequate.

The installation, maintenance and operating instructions given in the following pages have been prepared to ensure the long life and outstanding performance of the appliance.

For some especially demanding programming or maintenance operations, this manual serves as a memorandum of the main operations to be carried out.
Education on these topics can be obtained by attending training course held by the manufacturer

The instructions in this manual do not replace but rather are in addition to employer requirements to adhere to current legislation on standards of prevention and safety.

The machine is guaranteed for 15 months as from the time of shipment.

In case of serious accident that has occurred in relation to the device, it must be reported by the user and/or patient to the manufacturer and the competent authority of the Member State, in which the user and/or patient is established.

1.2 Manual validity, contents and conservation

This manual reflects the state of the art at the moment of manufacture and delivery of the appliance and is valid for its entire life cycle.
The manufacturer is at clients' disposal for further information or to receive suggestions for making the manual more compliant with the needs for which it was prepared.
The translation of the contents into the client's language has been carefully prepared.
In order to prevent possible accidents to persons or property due to in correct translation of the instructions, the client must:

- Not perform operations or manoeuvres with the machine if there are any doubts or uncertainties about the operation to be performed;
- Ask technical service for clarification of the instruction.
- If lost, ask for a new copy from the manufacturer.

It is important to keep this instruction manual with the machine for future reference.
If the machine is sold or transferred, the manual must be handed over to the new owners or user in order for them to become acquainted with its functioning and the relative warnings.

Read the warnings carefully before installing and using the machine.

This is a translation of the Italian text, which prevails in case of doubts.

1.3 Regulations

The purpose of the warnings is to safeguard the user in compliance with following Regulations and “Technical Product Standards”:

EUROPE:

- Regulation (EU) 2017/745 (Medical Devices);
- 2014/35/EC (Low Voltage Directive);
- 2014/30/EU (EMC - Electromagnetic compatibility directive);
- 2014/68/EU (PED Directive);
- EN 61010-1 (Safety);
- EN 61010-2-040 (Safety);
- 2011/65/EC (RoHS II);
- 2012/19/EC (WEEE);
- 2006/42/EC (Machine Directive).

and recognized international standards:

- IEC 61000 (Electromagnetic compatibility);
- ISO 14971 (Medical devices risk analysis);
- IEC 61326-1 (Electromagnetic compatibility);
- ISO 15883-1 (Cleaning efficacy);
- ISO/TS 15883-5 (Cleaning efficacy);
- IEC 60529 (IP Grade).

Steelco declares that this product, when it is equipped with a water steam version, is in accordance with PED 2014/68/UE directive art. 4 par. 3 and it has been designed and built in accordance with the correct building procedure.

2. SAFETY INFORMATION

Compliance with safety standards allow the operator to work productively and calmly, without the danger of harming himself or others.

Before starting work, the worker must be completely familiar with the functions and proper operation of the machine. He must know the precise function of all command and control devices of the machine.

2.1 Intended purpose, improper use

INTENDED PURPOSE:

The use of this device is intended for the pre-treatment, with or without ultrasounds, of surgical instruments, equipment and objects normally used in medical cabinets and hospital wards.

IMPROPER USE:

Improper use of this unit may be hazardous to the operator and may seriously damage the machine itself.

WARNING:
If the appliance is used in a manner not specified by the manufacturer, protection of the appliance may be compromised.

Any use other than that for which the machine was intended is forbidden.

The machine is indeed for indoor use only.

Advisory note: under ISO 17664:2004, it is the instrument manufacturer's responsibility to provide instructions for the processing of their instruments including how instruments should be prepared prior to use, cleaned, disinfected, dried, inspected, maintained, tested packaged, sterilized and stored. If medical devices have been used in any way such as being exposed to blood or compromised tissues, such devices must be terminally processed in accordance with the instrument manufacturer's guidelines, observing international and local standards as well as good hospital practices before each use with human patients. Washer disinfectors are part of the process for reprocessing reusable medical devices.
This washer disinfector device is not intended to be used for terminal disinfection or sterilization.

2.1.1 Application fields

- surgical instruments (cable or simple)
- dental instruments

2.2 Important warnings and suggestions

For proper use of the machine, and in order to safeguard employed staff, carefully comply with the following general and specific standards.

THE OPERATOR MUST:

- **Carefully adhere to the provisions and instructions** provided by the employer, managers and supervisors for individual and group safety.
- **Use safety devices appropriately and with care**, as well as group and individual safety gear provided by the employer.
- **Immediately inform the employer,** the manager and the supervisor of deficiencies in the aforementioned devices and means, as well as any hazardous conditions which he may become aware of, taking action directly in urgent cases within their scope of responsibilities and abilities to eliminate or reduce the deficiencies or hazards.

THE OPERATOR MUST NEVER:

- **Remove or modify, without authorization, the safety devices**, nor those for signalling and measuring, nor the individual and group safety gear.
- **Undertake on his own initiative operations or manoeuvres which are not his responsibility which** may compromise safety.
- **Insert foreign objects into the electrical parts.**
  Do not insert foreign bodies into the covers of the electrical motors or into the moving parts of the machine.
- **Provide power to the machine by tampering with the main switch and the safety devices.**

2.3 Safety recommendations

- If the new machine appears to be damaged, contact the retailer before starting it.
- Any modification of electrical and hydraulic systems necessary to install the machine must be carried out by qualified, authorised persons only.
- This machine must be operated by trained persons only.
- The machine was designed for washing (with or without ultrasounds) and decontamination (low level disinfection) of surgical instruments, equipment and objects normally used in hospital wards and medical studios.
- Any use other than that for which the machine was intended is forbidden.
- Keep cleaning unit and cleaning agents away from children, and also away from people not instructed for correct use by means of these instructions.
- **Do not soak into the tank full of liquid, parts of the body not protected by appropriated PPE.**
- **Do not soak into the tank full of liquid, animals, plants or any object that is not compatible with the chemicals used.**
- **It is not allowed to start the treatment with the door not completely closed.**
- It is forbidden for the user to carry out any work or repairs on the machine.
- Technical Assistance for this machine should be carried out by qualified and authorised operators only.
- The equipment should be installed by authorised persons only.
- Do not install the equipment in rooms where there is the risk of explosion.
- Do not expose the equipment to intense cold.
- The electrical safety of this machine is only guaranteed if it is connected to an efficient earth system.
- Take great care when handling detergents and additives: avoid contact, wear gloves and act in compliance with the safety recommendations indicated by the manufacturer of the chemical products.
- Do not inhale the fumes produced by chemical products.

WARNING:
The chemical products are an irritant for the eyes, in case of contact rinse thoroughly with plenty of water and consult a doctor.
If these products come into contact with the skin, rinse with plenty of water.

- The water in the tank is not drinking water.
- Do not wash the machine using high-pressure jets of water.
- Disconnect the machine from the electrical supply before carrying out maintenance work.
- The operator always has to verify before starting of the cycle the presence of the filters water in the sump and their correct positioning.
- **The acoustic pressure of the machine is below 70 dB(A).**
- **During ultrasonic treatment, the user must not touch with the device causes vibrations of the device.**

2.4 Recommendations to ensure high quality performance

- **The user must oversee the machine during the cycle.**
- **When the machine is running do not interrupt the cycle since this jeopardises the treatment.**
- **Use recommended detergents and chemical additives only.**
  The use of other products may damage the machine.
- **During the manipulation of treated objects, it is required the use of appropriated PPE to prevent contact with infected material and the risk of contamination.**
- **Recommending chemical additives does not make the manufacturer responsible for any damage to the materials and objects treated.**
- **Follow the manufacturer's indications when using chemical products and use them for the foreseen use only.**
- **Check that type of chemical product is suitable for the specific washing program used.**
- **The machine was designed for use with water and chemical additives.**
- **Do not use organic or other types of solvent as this may result in the risk of explosion or the rapid deterioration of certain machine parts.**
- **Residues of solvents or acids, particularly “hydrochloric acid”, can damage steel.**
- **Contact should be avoided.**
- **Use original accessories only.**
- **Do never use soap powder.**
- **Do never use foaming detergent.**
- **The machine is to be used only with the baskets and or accessories included by the manufacturer.**
- **Accessories which are not approved by the manufacturer may compromise the results achieved as well as user safety.**
  - **Wet location.**
  - **Mains supply voltage fluctuations: +/- 10%.**
  - **Overvoltage category: II.**
  - **Pollution degree: 2.**
  - **IP: 00.**
- **Do never use chemical products based on chlorides (bleaches, sodium hypochlorite, hydrochloric acid and so on).**
- **These kinds of chemical detergents irreparably damage the machine and jeopardise the integrity of materials and objects treated.**

The taps of the water feeding must be always turned off, as the safety and diagnosis system will be deactivated, in the following situations:

- **If the machine is left unused**
- **if the machine is disconnected from the electrical connection**

The manufacturer declines all responsibility for personal injury or material damage resulting from the non-observance of the above rules.

The non-observance of these rules produces the total and prompt cancellation of the guarantee.

2.5 Residual risks

The appliance includes a series of fixed guards to prevent access to hazardous internal parts or zones.

It is however considered that the **US 80** includes some residual risks.
Hereunder for each phase or significant work intervention are useful measures to be taken:

PHASE	BASKET LOADING
RISK	**Contusions and cuts to the upper limbs,** due to accidental contact with due to falling or striking against tools, objects and instruments, mainly while loading and handling the basket.
MEASURE	Assign staff that is instructed and equipped with work equipment (e.g. basket with protections, transport carts) and appropriate clothing and individual protection gear (e.g. shirts and protective gloves).

PHASE	OBTAINING DETERGENTS/CHEMICAL ADDITIVES
RISK	**Contact with body parts with chemical treatment products.**
MEASURE	Assign staff that is instructed and equipped with appropriate clothing and individual protection gear. Wear clothing, gloves and goggles and act in compliance with the safety recommendations indicated by the manufacturer of the chemical products.
FIRST AID MEASURE	• Immediately take off/remove clothing which has been contaminated or soaked by the product. • If the substances come into contact with the skin, wash off affected skin areas immediately and rinse with water.
RISK	**Inhalation of vapours of chemical treatment products.**
MEASURE	Assign staff that is instructed and equipped with appropriate clothing and individual protection gear. Comply with the safety instructions provided by the manufacturer of the chemical products and if there are none, wear a mask for the protection of the respiratory airways.
RISK	**Accidental release of chemical treatment product.**
MEASURE	Do not flush concentrate into drains, surface or ground waters. Collect spillage with adsorbent material (e.g. sand, earth, vermiculite, diatomaceous earth). Flush away minor amounts with plenty of water.
	**IN CASE OF CONTACT WITH BODY OR RELEASE OF CHEMICAL PRODUCT LOOK ALWAYS AT THE SAFETY MEASURES INDICATED IN THE CHEMICAL TECHNICAL DATASHEET.**

PHASE	MAINTENANCE OF INTERNAL EQUIPMENT
RISK	**Burns of body parts** by hot parts of the appliance.
MEASURE	Allow maintenance to be performed only by trained personnel, equipped with appropriate clothing and individual protection gear. Wear suitable clothing and protective gloves.

PHASE	EMISSION OF HAZARDOUS GAS
RISK	**Inhalation of vapours of hazardous gas.**
MEASURE	With a correct installation, concurring with the manufacturer prescription, using the authorized chemical product and concurring with the rules in force in your country, the machine don't generate hazardous gas.

2.6 Safety signals used

To inform personnel operating on the machines of obligations of behaviour and residual risks, adequate safety signals (as set forth by 92/58 EEC) are applied to the machine and near the work place.

GENERIC SAFETY SIGNALS:
In particular, labels with signals of obligation, prohibition and danger contained in this manual and pertinent to this machine and most commonly used are:

Electrical risk

Hand crushing risk

Caution hot surface

INDIVIDUAL SAFETY WEAR:
The evaluation of risks for the health and safety of workers carried out in the workplace and on any equipment used, as well as the evaluation of residual risks as indicated, allow the employer to evaluate the need to adopt the individual protection gear which is most suitable and appropriate to be provided to workers.
Considering the type of machine, it is felt that the individual protection gear should be provided to staff.

2.7 Training

Instructions for use of the machine will be provided by the STEELCO INSTALLATION TECHNICIAN during the start-up phase to MACHINE OPERATORS and MAINTENANCE TECHNICIANS for their areas of responsibility, who will be thus instructed and trained.
It will be the duty of the EMPLOYER to check that the degree of staff training is suitable for assigned duties.

2.7.1 Staff qualification

Depending on the difficulty of certain installation operations, and of the operation and maintenance of the system, professional profiles are identified as follows:

IS ***INSTALLATION and REPAIR TECHNICIAN:***
Specialized installation and maintenance staff capable of carrying out all machine positioning and installation operations, connection of various systems and machine start-up at the client's place of business, as well as all routine and special maintenance operations.
This operator is responsible for training staff for machine operation and for testing the machine.

AS ***RESPONSIBLE AUTHORITY FOR THE MACHINE IN THE WORKPLACE:***
Specialized staff assigned to the verification of safety devices and procedures for proper use of the machine incomplete absence or hazards.

The *responsible authority* is personally responsible for training courses for staff assigned to machine operation and maintenance.
He must ensure that staff assigned to operation has acquired all information required for use and routine maintenance of the machine, registering attendance and documenting comprehension tests.

The *responsible authority must* have a perfect understanding of all command, control and safety devices of the machine.
He must inform all personnel assigned to machine operation and maintenance of the instructions concerning *safety standards*, the *actions to be avoided* and the *first aid interventions* connected with use of the machine and the chemical treatment agents it contains.

The *responsible authority* must be aware of all correct procedures for carrying out in absolute absence of danger all operation and maintenance of the machine, as well as all procedures for disposal of any residual pollutants and manufacturing wastes.
He must always be present during extraordinary or routine maintenance and give his *approval to proceed* to staff assigned to operation or to personnel assigned to routine or special maintenance.

The *responsible authority* will be responsible for operation of all command, control and safety devices in the machines of the system.
He shall carry out scheduled verification of those devices in order to ensure their continued operation over time.

Ac MACHINE OPERATOR:

Skilled personnel assigned to machine operation.
The *machine operator must* be perfectly aware of all of the machine's command and control devices.

Only after approval by the *safety supervisor, the machine operator* must be capable of using the assigned commands to do the following:

- Commissioning and start-up of the machine;
- Loading and unloading of material to be treated in the baskets;
- Operation of the machine in the various possible working modes, such as the start of various programmed treatment cycles.
- Programming and setting data from the operator panel, adjustment of single control devices during working phases, starting or resetting of work functions.
- In addition, the *machine operator* must, by making use of all required individual protection gear and following adequate safety measures, be capable of performing some routine maintenance such as cleaning inside the machine, cleaning clogged filters, and disposing of pollutant waste materials produced during working.

2.8 Indication of sound level

The value shown refers to the measurement obtained on a machine of the same type as that covered herein and measured with an instrument at a height of 1.5 m at a distance of 1 m from the machine.

AVERAGE SOUND PRESSURE LEVEL: < 70 dB (A)

2.9 Transport and storage

Environment conditions:

- Temperature range -5 ... +50 °C;
- Relative Humidity range Max 80% (5 ÷ 31°C); 80…50% (31…40°C);
- Ventilation: Air exchange not required (required only if chemical tanks are installed).

2.10 Table of symbols

Symbols installed on the machine:

	Electrical risk
	Warning - hot surface
	Manufacturer
	Manufacturing date
	Attention! See the enclosed documentation for important warnings, such as warnings and precautions.
	See instruction for use
	Protective conductor terminal
	CE mark. It is reported on the serial number label.
	WEEE waste disposal
MD	Medical device indication
COD	It indicates the final product code of the medical device. It is reported in the serial number label. The “COD” corresponds to the article code in the system (AS 400) and in the sales invoice. This code can be variable depending on the model/specifications required by the customers. The machine model requested by the customer is in line with the model reported inside the technical documentation “DT-8051520DSXX2A” and in the DD-8051520DSXX2A medical device description document.
#	It indicates the model number of the product. It is reported on the serial number label.
UDI	It indicates the unique device identifier of the product. It is reported on the serial number label.

Medical device indication:

*According to the regulations in force in Canada, the products covered by this documentation do not qualify as medical devices.

3. INSTALLATION (FOR THE INSTALLER ONLY)

3.1 Activity prior to installation

PREPARATION OF INSTALLATION SITE:
Arrangements for connections to the electrical and plumbing systems must be provided by the client prior to machine installation.
Connections must be compliant with current directives in the country of installation.
They must comply with the instructions contained in the documentation (provided on request) prior to machine installation.

Environment conditions:

- Temperature range +5…+40°C;
- Relative Humidity range Max 80% (5 ÷ 31°C); 80…50% (31…40°C);
- Maximum altitude: 2.000 m MSL (for higher altitudes are available special versions of the device).

3.2 Positioning

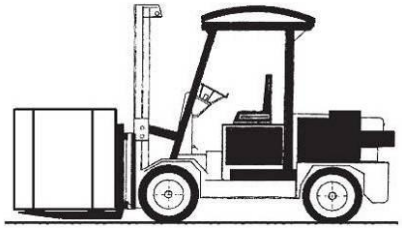
3.2.1 Movement, unpacking and placing

The machine is delivered to the client fully packed, resting on a wood base and completely protected by cardboard covering.

LIFTING AND MOVEMENT:
Movement of the machine is provided using transport and lifting equipment and must be observed the following indications:

- The lifting capability of the forklift must be greater than the total weight of the machine to be moved;
- The machine must be kept as close as possible to the ground during movement;
- Stack up: not allowed.
- Rotation: do not turn upside down.

The forklift operator must perform movement only when there are no persons or objects in the movement area.



UNPACKING AND PLACING:
Near the place of installation, unpack the machine.
Carefully follow these steps:
All the packaging materials can be recycled.

- Open the packaging carefully.
- Do not overturn the machine as this may cause irreparable damage.
- Cut the strap or open the box and remove the expanded polystyrene corner guards.
- Remove the box followed by the nylon bag.
- Caution: the bag represents a serious hazard for children and should be disposed of immediately.
- Place the machine on the work surface and level it by adjusting the feet.
  The machine must be placed horizontally with a maximum inclination of 1÷2°.
- Do not position the machine on surface which could cause a fire or fume hazard.

3.2.2 Maximum floor load

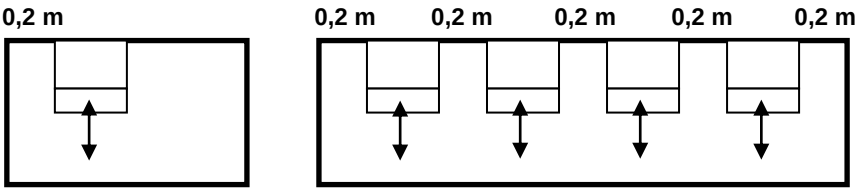
For the installation of the machine, the floor must be able to sustain a minimum load of:

- **150 kg/m^2**

3.2.3 Positioning of the machine

In normal conditions, the minimum dimensions are suggested for the use of the machine in a single installation or with the coil nearby.
For different installation ask for the distributors.

Minimum room ceiling height: 1,5 m



3.3 Water connection

To perform proper installation, account of following regulations:

- The machine has been connected to the water distribution network following the in force rules;
- Use only the tubes supplied with the machine;
- Don't cut short the rubber tubes supplied with the machine;
- Make sure that mains water pressure is between 100 kPa and 800 kPa;
  If it is below 100 kPa (1 bar g) dynamic pressure, you will need to install a pressure increase pump.
  If the pressure is higher than 800 kPa (8 bar g) a pressure reducer must be installed.
- If the average hardness of the water is higher than 7 °f, decalcified water must be used;
- For connection use cocks with an attachment of ¾", located in an easily accessible location as near as possible to the machine;
- Make sure that the general feeding tube is sufficient for the flow rate required from the machine and equipped with a general closing valve.

ATTENTION

For the specifications for water connections, refer to the plant installation.

During the machine installation, the installer must take the following step:

1. Identify the tubes supplied with the machine and make sure they are free from damages;
2. Identify the correspondence of the connection of flexible tubes to the water supply taps arranged in site, according to the references of the following chart.

CONNECTION	COLOUR
HOT WATER	RED
COLD WATER	BLUE

3. Screw and tighten up the pipe sleeve to the connection arranged in site.
4. Remove any debris in the pipes or in the taps. To perform this operation, open the tap and let the water flow in a pail.
5. Check the water temperature according to the specifications of the installation diagram.
6. Identify the correspondence of the connection of flexible tubes to the solenoid valve water supply of the machine.
7. Screw and tighten up the pipe sleeve to the connection arranged in site.
8. Open gradually the water supply taps and check the connections seal.
9. Terminated the connection, in case of water leaks repeat the procedure.

ATTENTION

The threaded connections can be easily damaged, therefore before to apply the maximum clamping, screw manually the locking sleeve for some threads.

Information:

- The back syphonage prevention system is already installed inside the machine concurring with IEC 61770;
- If it is not available the double connection to hot and cold water, the two supply pipes must be connected together;
- **The manufacturer declines all responsibility for damage or injury caused by noncompliance of the rules relating the supply installations.**
- **If you don't comply with the conditions above, the deriving damages will not warranty.**

ATTENTION

When the machine is not in operation, always close the supply cocks.

After the execution of the water connections, set the inlet water temperature on the relative parameters (7.43 – 7.44). Refer to section "Parameter list".

3.4 Electrical connection

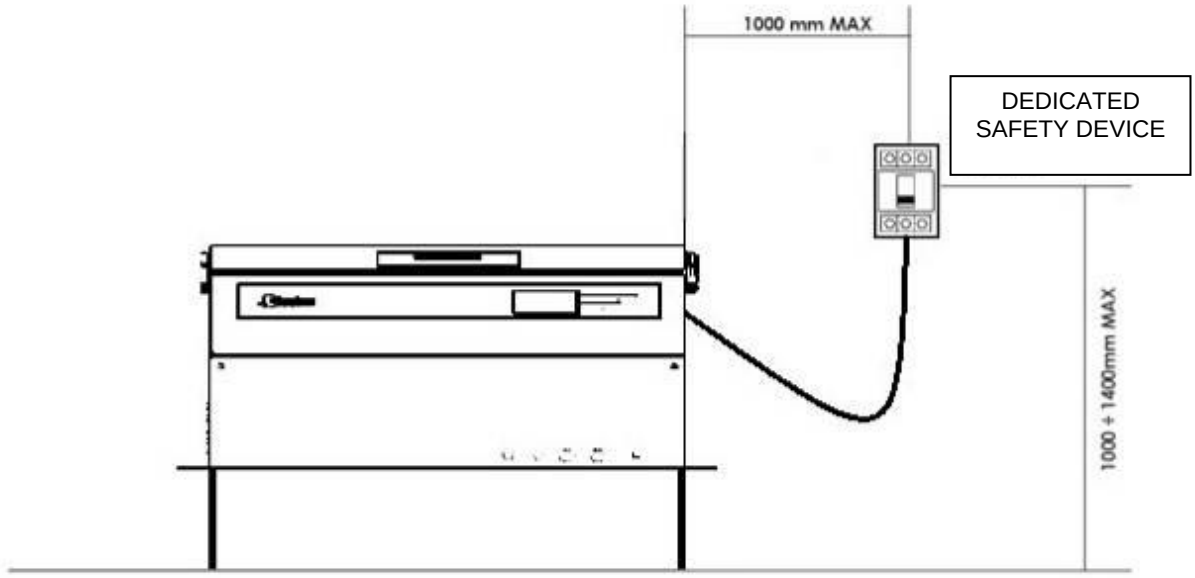
- Connection of the machine to the electrical mains must be made by qualified, skilled personnel.
- Power supply cable: It is compulsory for the retailer-installer to adapt the insulation class of the power supply cable to suit the working environment in compliance with Current Technical Regulations.
- Check that the electric specifications match those shown in the label.
- The electrical connection must be carried out in compliance with current technical regulations.
- Make sure that the mains voltage reading corresponds to the voltage indicated on the machine plate.
- Check that the power supply voltage does not differ by more than 10% from its nominal value.
- The frequency of the power supply voltage must not differ by more than 1% of its value.
- Connection of the machine to the mains must be provided with an earth connection and an equipotential circuit as set forth by current standards.
- Make sure that the electrical systems are efficiently earthed.

- The earth conductor is to be connected to the earth terminal identified by the standard symbol.

- The machine is equipped with a terminal identified by the relative symbol for equipotential connections between appliances (see rules for electrical plants).

- Connect the machine and the relative dedicated safety device (not supplied) by using a power cable compatible with the electrical characteristics of the machine.
- A dedicated safety device sized to suit the absorption and with a contact opening of at least 3mm must be installed.
- **The dedicated safety device must be positioned in an accessible place, free and not covered from other machine or anything that could obstruct the switch control;**
- The electrical connection from the mains to the machine is to be made on the terminals of the dedicated safety device (not provided).
- In case of prolonged unused of the machine is recommended that you execute the disconnection procedure of the electrical connection by placing the dedicated safety device in **"OFF"** state.
- The dedicated safety device must be provided with quality markings and must be indicated as an electrical shut-off device for the machine;
- The upstream electrical power line must be dimensioned and protected in accordance with current local regulations.
- Near the dedicated safety device, a sign must be placed which reads:

DEDICATED SAFETY DEVICE FOR MACHINE



3.5 Fuses

The fuses are used to protect the electrical circuits of machine from possible failure as overload or short circuits.
If the fuse takes action, the downstream connections and their function are no longer available.
The fuses must respect the characteristics (size, dimensions and tripping characteristic) indicated in the wiring diagram.

3.5.1 Replacement of fuse

ATTENTION

The replacement of fuse must be done from authorized operators only.
Before making the replacement procedure of fuse, establish and remove the cause of the fault.
If necessary, contact our technical assistance service.

Replacement procedure of fuse:

- Log off the machine in safety condition by dedicated safety device.
- Access at the electrical panel.
- Identify the fuse subjects to replacement, based on the wiring diagram.
- Remove the related fuse from electrical panel.
- Replace failure fuse with another fuse with same characteristics. The correct value of fuses are in the wiring diagram.

If at the reactivation of electrical devices the new fuse intervenes, repeat the diagnosis and replacement procedure as described previously.

ATTENTION

Use only fuses with the amperage and characteristics indicated in the wiring diagram.
The use of fuses other than those specified in the wiring diagram, void the warranty and can cause the risk of damage the machine.

3.6 Chemical products connections

The dosing system of chemical products is composed of:

- Dosing pump for chemical products.
- Presence sensor chemical product.
- The system can be equipped with meter quantity of dispensed product.

On the table below is shown the type of chemical that can be used:

PRODUCT	NOTE
ALKALINE / NEUTRAL	

ATTENTION

In order to guarantee the right treatment of the objects, we suggest the use of specific products.
In the case of necessity, ask for advises to the seller or the producer.

3.6.1 Presence sensor of chemical product

Each dosing pump is combined with a sensor that confirm the presence of chemical product inside the container. If the product is scarce, the electronic control system of the machine sends a message on video of lack of product.

3.6.2 Meter quantity of chemical product

Each dosing pump can be combined with a volumetric sensor for the quantity measurement of dispensed product. The electronic control system manages the value of required minimum quantity and, if necessary, stops the cycle.

3.6.3 Replacement of chemical product container

To replace the chemical product container, perform the following procedure:

- Take the new product container.
- Switch off the machine.
- Replace the chemical product container removing the level sensor from the empty tank and put into the new one.
- Close the topper of the chemical product container and place it in the area for the storage of chemical substances.
- Switch on the machine.

ATTENTION

The used chemical product can be dangerous if touched or inhaled. Before the use, read carefully the safety information supplied by the manufacturer of the chemical product and the label on the package.

During the operations of replacement of chemical product container, use the appropriate tools for individual protection (chemical protective gloves, face masks for breathing, etc.).

3.6.4 Warning

- For the maximum amount of product which can be used for washing cycle, follow the instructions for the product you are using.
- The quantity of supplied can be adjusted by following the directions given in “Chemical calibration” chapter.
- To ensure the efficiency of the chemical dosing system it is recommended to perform the calibration procedure every 6 months.
- To ensure the efficiency of the dispenser pumps for chemical products it is important to service them regularly as described in “Maintenance” chapter.
- Use liquid chemical products only machine cannot function with powder detergent.
- For the dispose of the chemical detergent and his tank follow the instruction indicated on the technical and safety data sheet provided by the manufacturer.
- Check that type of chemical product is suitable for the specific washing program used.
- Don’t place the chemical tank on the machine.

ATTENTION

Before undertaking any sort of special maintenance or movement of machine, empty tanks and chemical dosing circuit from the chemical. It is advised to execute a treatment cycle without chemical.

This procedure must be carried out in order to prevent contact of the chemical product with body parts and machine components that can be damage.

3.6.5 Information

- The machine has been validated in accordance with the provisions of Standard UNI EN ISO 15883.
- The type test was carried out using the most widely known chemical products on the market, concerning the type of chemical products, the concentrations and the cycle parameters used you can ask the Manufacturer for details.

3.7 Connecting the discharge

- The discharge pipe connection should be checked carefully.
- Use a discharge pipe suitable for organic and chemical materials and hot liquids.
- These models are equipped with one pipe connected to drain with diameter indicated on the installation plant.
- The drain pipe must be suitable to carry liquids at a temperature of 93 °C.

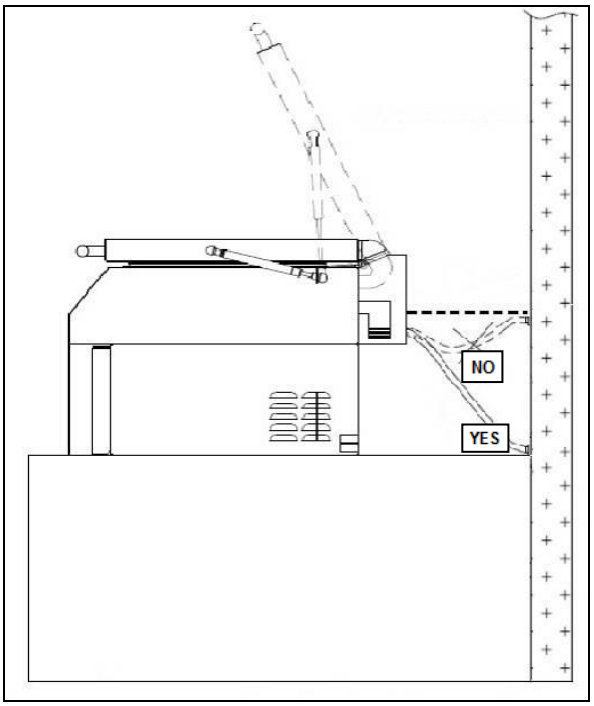
CONNECTING DRAIN PIPE:

The drain pipe is connected to the sewer network in the following manner:

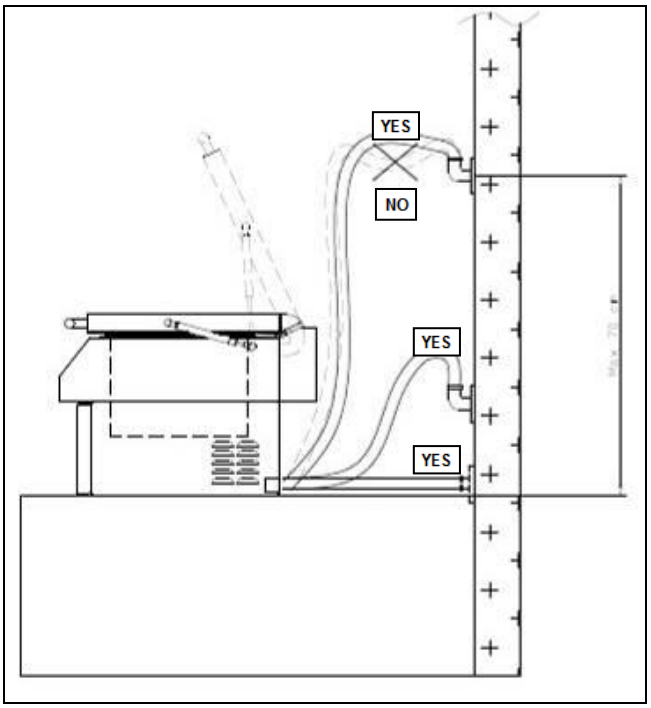
- Identify the drain pipe and relative fittings and assemble them.
- On the back of the machine, identify the drain manifold and connect the hose via the union and ring nut. Tighten the ring nut firmly.
- Insert the drain hose and clamp it in place.
- Insert the other end of the hose into the drain unit, fitting it properly and locking it in position.

IT IS NECESSARY TO FOLLOW THESE INSTRUCTIONS FOR DRAIN CONNECTION:

- Drain pipe must be connected by using a clamp.
- Drain pipe must not present angles or irregular curving in its course.
- Drain point must be placed at the same height of the machine drain point or on the floor.
- Flexible drain hose must not have siphons or water retention zones (see following pictures).



Overflow connection



Main drain connection

<u>Follow carefully these instructions as a wrong drain connection can cause the block of machine.</u>

- Diameter of drain main indicated on the installation plant.
- Avoid drain pipe extension.

	ATTENTION
	Drain must be done following International rules. **The manufacturer cannot be held responsible if an inaccurate use of machine causes pollution.**
	If the discharge pipe is clogged take great care when processing the water and avoid contact with hands, eyes, etc. In the case of contact, rinse the parts concerned with plenty of water.
	When the machine is connected to an exhaust ventilation system, the drain pipe should be positioned externally of the building, protected from any animal access, and make sure that it not causes any hazard.

3.8 Ambient ventilation requirements

During the normal operation, the machine warms up itself dispersing heat and hot air increasing the humidity value. Therefore, in order to guarantee a comfortable environment with good temperature and humidity for the operator, it is necessary to prepare an air conditioning or air circulation system capable to balance the emissions reported in the installation plan.

	**A detail of the machine connections is shown on the installation plant and electrical wiring.**

4. CHECKS PRIOR TO START-UP

4.1 Introduction

The preliminary adjustments and controls are performed by a skilled technician, who has been specifically trained for this purpose.

4.2 Checks of safety systems

Indicative list of adjustments and checks of safety systems and devices to be carried out:

- Check the mains supply voltage;
- Check the efficiency of the emergency and machine shutdown devices (circuit breaker);
- Check the efficiency of the door opening safety micro switch;
- Check the operation of machine controls, especially the **START** and **STOP** commands.

4.3 General controls

Indicative list of general adjustments and checks to be made:

- Check proper execution of general supplies of the machine (electrical and plumbing);
- Ensure that the MACHINE OPERATOR is trained for its use.

5. USING THE MACHINE (FOR THE USER)

5.1 Checks

Check the quantity of chemical additives present and top-up if necessary as described below:

- Check the machine status on the display and check that there are not any alarm messages.
- Check the quantity of chemical additives present and top-up if necessary, as described on section 3.6:

5.2 Opening and closing door

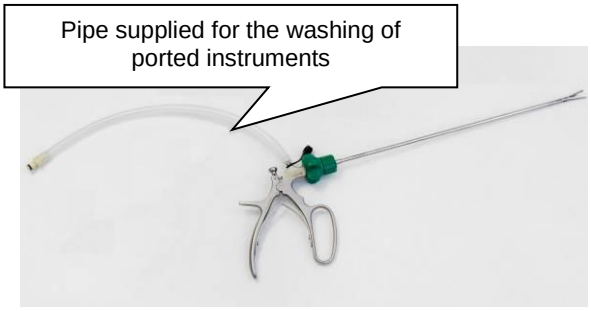
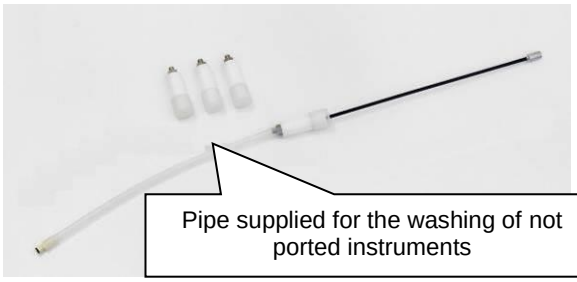
The opening and closing of door occur manually by means of handle.

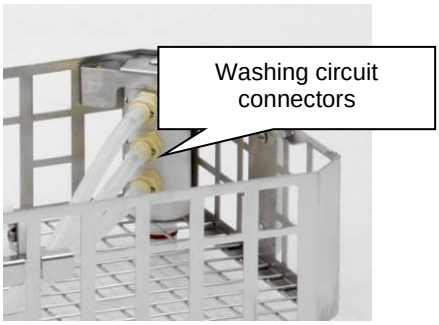
To open the door during a cycle, interrupt the cycle and remember that:

- The items inside the machine may be hot.
- The objects inside the machine could be contaminated.
- It is necessary to repeat the complete treatment cycle.

	ATTENTION
	Pay attention during door opening and closing operation, in order to eliminate the risk of crushing.
	When the machine is running, the cover must be kept free from obstacles that can condition the door opening/closing operation.
	It is forbidden to place objects above the machine, in order to operate safely during the door opening/closing operation.

5.3 Preparation

Connection procedure of ported instruments: Connect the instrument to be washed to the dedicated pipe end supplied.	
Connection procedure of not ported instruments: Insert the instruments into the quiver.	
Insert the instruments to be treated into the basket placing them carefully in the appropriate supports (movable and removable). Connect CPC connection of the pipe supplied to the washing circuit connector. **ATTENTION : Do not connect the unused pipes, in order to avoid leakage.**	



Insert the basket (with the items to be treated) into the tank.

ATTENTION : Push the basket toward the bottom of the tank in order to guarantee proper hydraulic connection.

WARNING
It is supposed to remove the support of the basket for the treatment of instrument different from ported and not ported instruments.
It is foreseen under request the possibility to double the connection (see catalog for accessory about particular instrument connection).

	ATTENTION
	The maximum load for each cycle is 20 kg (basket include).
	Do never emptying any solid waste into the machine. This will block the outlet system and destroy the machine.
	Never use the machine without basket.
	Check the patency of the hollow instruments before subjecting them to treatment in the machine.
	Check that the instrument connection channels are not blocked and that they allow the free passage of treatment water.

To disconnect the pipe from the washing circuit connector, press the tongue on top of the connector.	 

6. CONTROL PANEL AND SYMBOLS USED

This panel makes the machine easy to use as it indicates the stage of the cycle in progress and fault messages. For every page it is possible to have different combinations of command that can be activated or deactivated by using buttons related. The buttons have different colors and their functions will be shown in the display.	

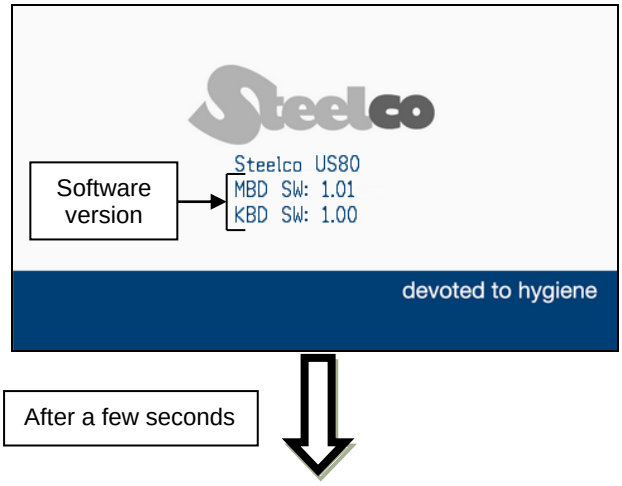
	**ATTENTION** **EVERY FIELD IS ACTIVE ONLY IF THE LED IS LIT.**

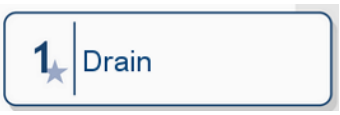
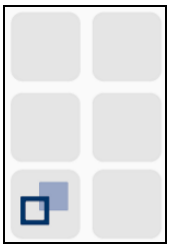
BUZZER

The buzzer sounds each time a key is pressed and intermittently in the case of a machine Shutdown.

6.1 Control panel

After the machine starting → LOADING PAGE

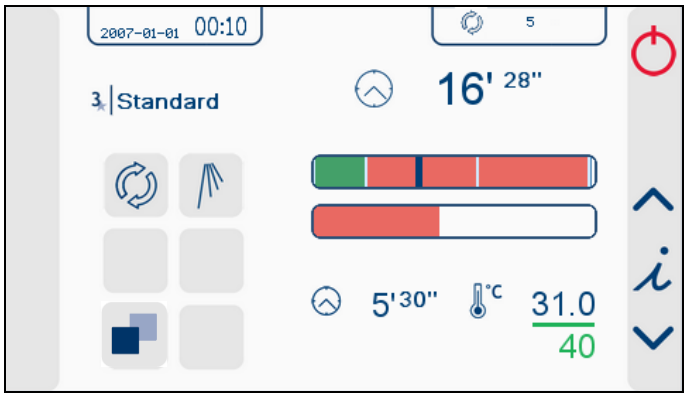


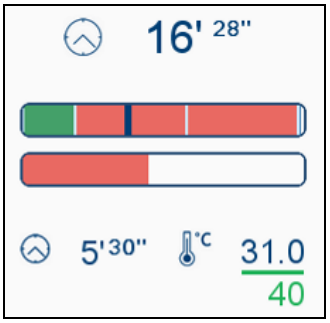
MAIN PAGE (STAND-BY)	
	
FIELD	**DESCRIPTION**
	Keep pressing the button for 5 seconds to display enter in the MENU.
	Press the button to scroll through the list of programs and select the program desired.
	Press the button to start the selected program.
	Program number with basic cycle identification symbol (factory data).**(*)**
	Program number with customer cycle identification symbol (saved by user).**(*)**
	 Program name with phases description.
	Graphic window of machine status.
	 Warning: low level of chemical product.
	 Door's condition: open / closed door. Warning: start cycle with open door.
	Number of saved reports.

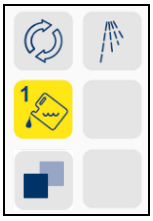
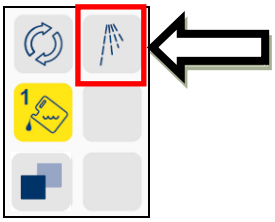
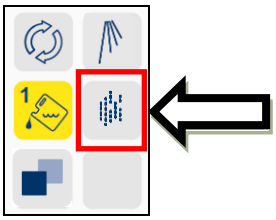
(*) If the user recognition is enabled (P1.02=1) but no user password has been stored (Ref. chapter "Recognition password of operator to start programs"), the following pop-up will appear.

Under this condition, it will not be possible to start the cycle selected.

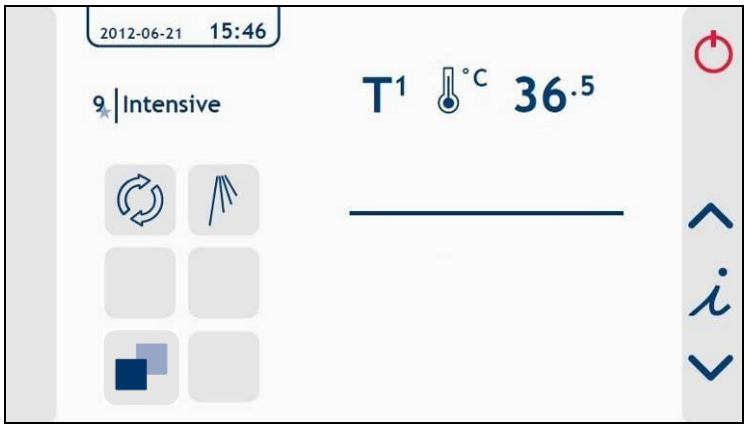
CYCLE IN PROGRESS PAGE



FIELD	DESCRIPTION	
	Pressing *STOP* button, the cycle in progress will be interrupted. In this condition, on the sidebar, appear the following buttons:	
		Pressing again *STOP* button, the cycle will be stopped definitively (For more information see par. *Interruption of a cycle*).
		Pressing *START* button, the cycle will be started again from the point at which it was interrupted.
	Press on the arrows to scroll the list of pages that contain data of cycle: • Temperature page; • Dosing chemical page; • Transducer page (Optional).	
	Cycle in progress.	
		Program's number with symbol that identify the basic cycle (factory data).
		Program's number with symbol that identify the customer cycle (saved by user).
		Remaining time to the end of cycle.
		Graphic representation of cycle's composition divided in different phases. Every phase is associated with a different color. The time indicator indicates the point of work reached during the cycle. *Colour* – *Phase* Blue – Drain Green – Prewash Red – Treatment
		Point reached during the phase.

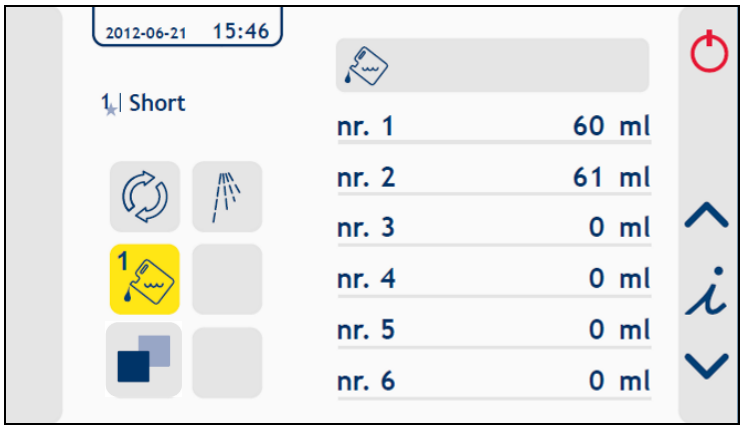
<table>
<tr><td></td><td>  </td><td>The values indicate:
- remaining time for the end phase;
- control temperature of chamber;
- setpoint value.</td></tr>
<tr><td rowspan="8">  </td><td colspan="2">Graphic representation of machine’s status.</td></tr>
<tr><td>  </td><td>Machine in cycle.</td></tr>
<tr><td rowspan="4">  </td><td>Phase in progress:</td></tr>
<tr><td>  </td><td>Prewash.</td></tr>
<tr><td>  </td><td>Treatment.</td></tr>
<tr><td>  </td><td>Drain.</td></tr>
<tr><td>  </td><td>Type of treatment: Degassing - Ultrasonic.</td></tr>
<tr><td>  </td><td>Warning: low level of chemical product.</td></tr>
<tr><td>  </td><td>Door’s condition: open / closed door.
Warning: start cycle with open door.</td></tr>
<tr><td>  </td><td colspan="2">Number of saved reports.</td></tr>
</table>

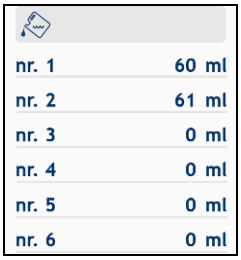
TEMPERATURE PAGE



FIELD	DESCRIPTION
	Control temperature into the tank.

DOSING CHEMICAL PAGE

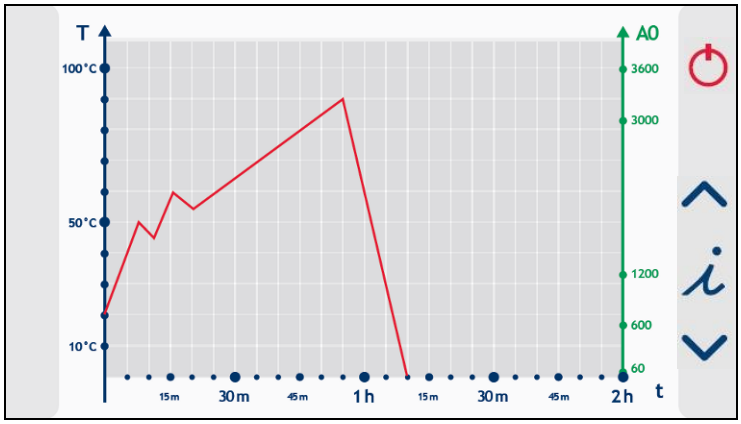


FIELD	DESCRIPTION
	Display the chemical quantity dosed in tank.

TRANSDUCER PAGE (OPTIONAL)

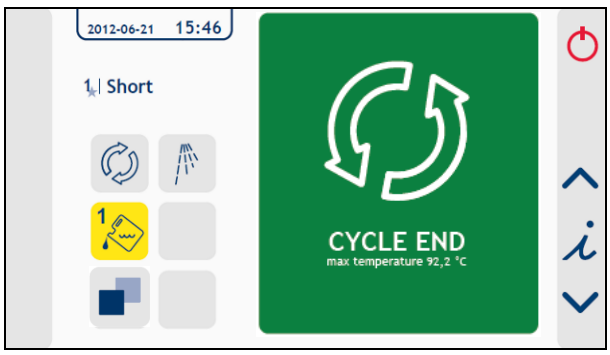
FIELD	DESCRIPTION
	It is possible to display the pressure value.

GRAPH



DESCRIPTION
The graph displays the cycle in progress. The red line indicates the tank temperature.

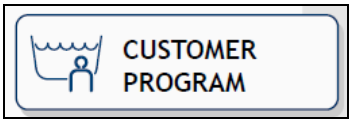
END CYCLE



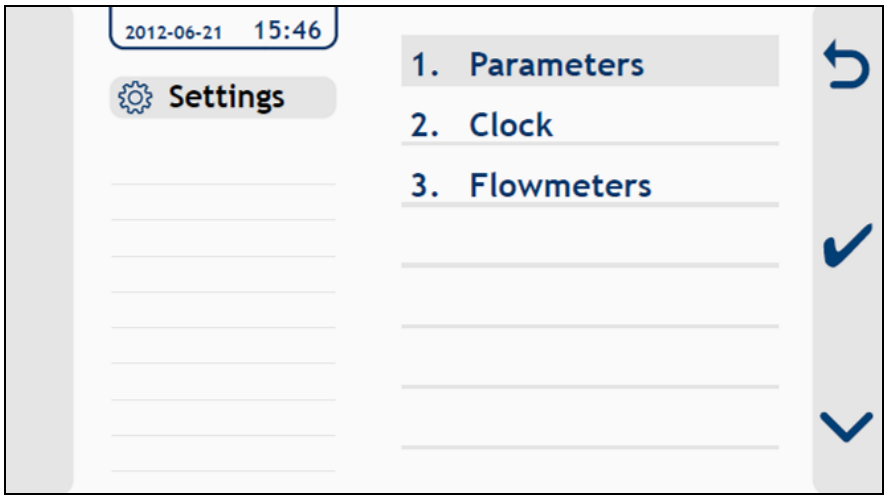
If the cycle is executed correctly, at the end of the cycle, a special window appears as shown in the picture.

6.2 Control panel - Menù -

MAIN PAGE (MENU)

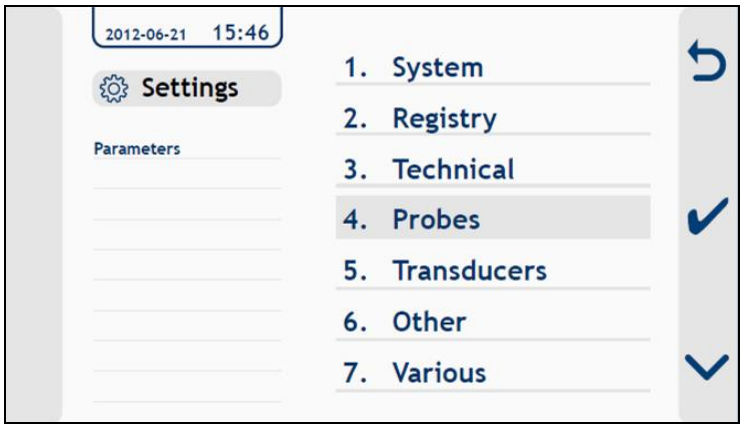
FIELD	DESCRIPTION
	Keep pressing the button for 5 seconds to exit from menu.
	Press on the arrow to scroll the list of submenu and select the one desired between: • Basic programs; • Customer programs; • Program selection; • Historical report; • USB; • Utility; • Settings.
	Press the button to enter in submenu.

EXAMPLE OF SUBMENU → SETTINGS PAGE



FIELD	DESCRIPTION
	Press this button to return at previously menu.
	Press on the arrow to scroll the list of fields: • Parameters; • Clock; • Flowmeters (Optional). • Operator; • Password. The selected field will be highlighted in grey. Press the button in the center to confirm and access at selected field.
	Visualization of path.

EXAMPLE OF SUBMENU → PARAMETERS PAGE

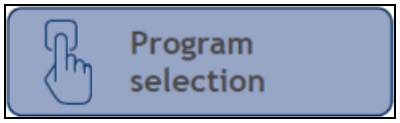


FIELD	DESCRIPTION
See screen described previously.	

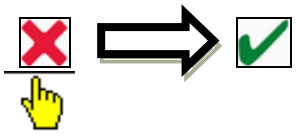
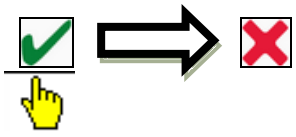
EXAMPLE OF SUBMENU → TRANSDUCER PAGE

FIELD	DESCRIPTION
NUM	Category (Ex. CHAR_STR, CHAR_NUM, NUM ecc.).
BAR	Unit of measurement.
2	Decimal numbers.
-1.00 1.00	Range.
-0.25 	Set the desired value as described: Press confirm button, the settable value will be highlighted in grey. With arrow set the characters and confirm with related button.

6.3 How to visualize and modify program status

	On the MAIN PAGE – MENU, press on the arrow to scroll the list of submenu and select “Program selection”; Press the button to enter in submenu “SELECTION”.

SELECTION PAGE

FIELD	DESCRIPTION
HOW TO VISUALIZE PROGRAM STATUS	
	Press the button to scroll through the list of programs and visualize the status of program desired.
	Disabled program.
	Enabled program.
HOW TO MODIFY PROGRAM STATUS	
	Press the button to scroll through the list of programs and select the program desired to modify its status.
	To enable the program into the MAIN PAGE, press the corresponding button. 
	To disable the program into the MAIN PAGE, press the corresponding button. 

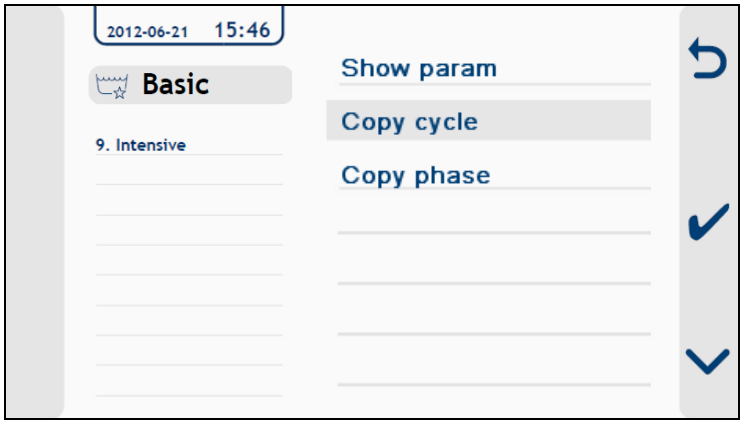
6.4 How to visualize and copy basic programs

	On the MAIN PAGE – MENU, press on the arrow to scroll the list of submenu and select “Basic programs”; Press the button to enter in submenu “BASIC”.

BASIC PROGRAMS - PAGE

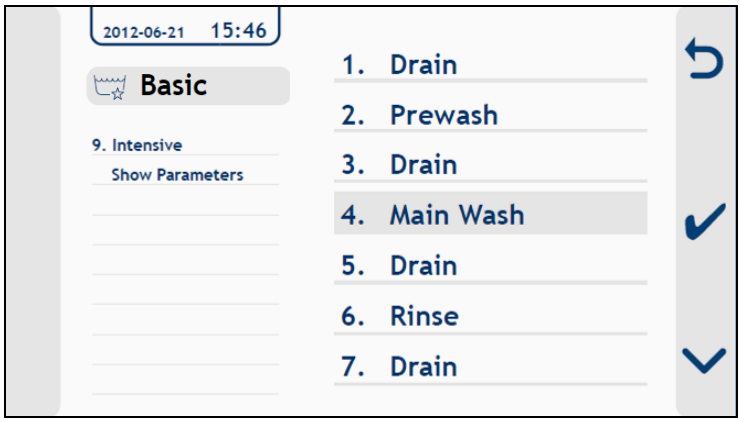
Scroll through the list of programs and select the program desired.
Enter into the program.

BASIC PROGRAM - PAGE



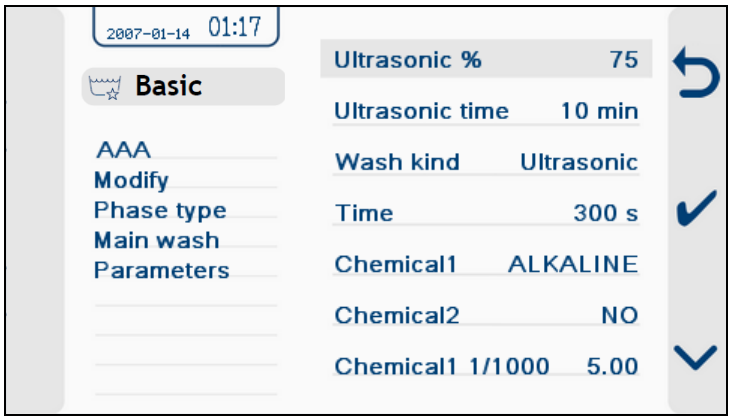
FIELD	DESCRIPTION
	Press on the arrow to scroll the list of fields: • Show parameters; • Copy cycle; • Copy phase. The selected field will be highlighted in grey. Press the button in the center to confirm and access at selected field.
	Press the button to visualize the desired parameters.
	Press the button to copy the cycle selected.
	Press the button to copy the selected phase.

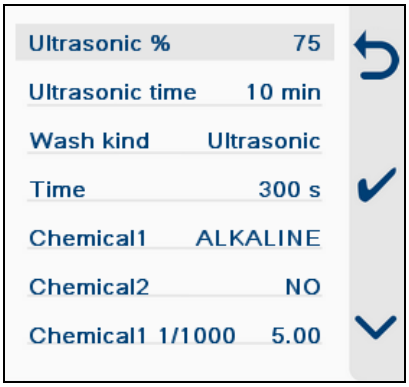
PROGRAM PHASES - PAGE



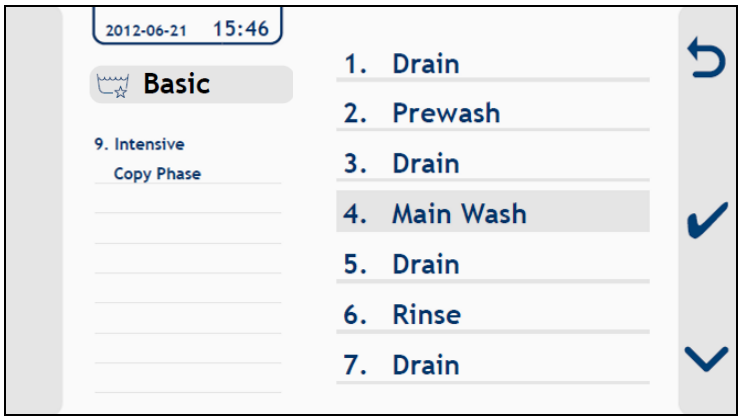
FIELD	DESCRIPTION
	List of the phases that compose the selected program. Press on the arrow to scroll the list. The phase selected will be highlighted in grey. Press the button in the center to confirm and access at selected field.

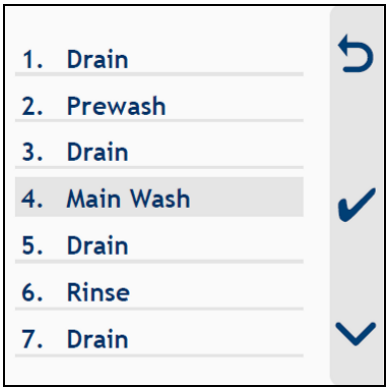
PHASE PARAMETERS - PAGE



FIELD	DESCRIPTION
	Access to the parameters of selected phase. Press on the arrow to scroll the list and visualize the value of each parameter.

PROGRAM PHASES - PAGE

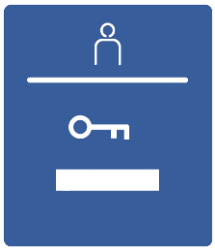


FIELD	DESCRIPTION
	List of the phases that compose the selected program. Press on the arrow to scroll the list. The phase selected will be highlighted in grey. Press the button in the center to copy the phase. To paste the phase, is necessary to access to the custom program: a password will be requested. Insert the password, select the desired cycle and then execute “Paste phase” command.

6.5 Customer programs modification

	On the MAIN PAGE – MENU, press on the arrow to scroll the list of submenu and select “Customer programs”; Press the button to enter in submenu “CUSTOM”.

A password will be requested. To insert the password, follow the procedure:



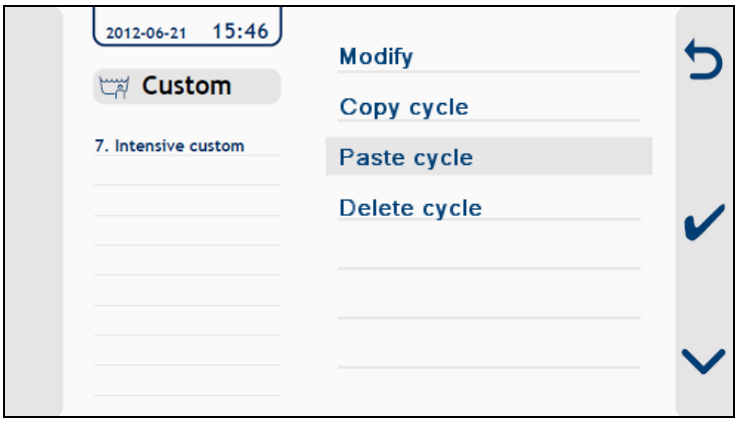
Press the arrow to set the first number of password and confirm by button related.
In automatic, after confirmation button, the arrow will move to the next number.
Continue with remaining numbers of password.

If an incorrect password is entered, the menu is closed immediately.

CUSTOMER PROGRAMS - PAGE

Scroll through the list of programs and select the program desired.
Enter into the program.

CUSTOMER PROGRAM - PAGE

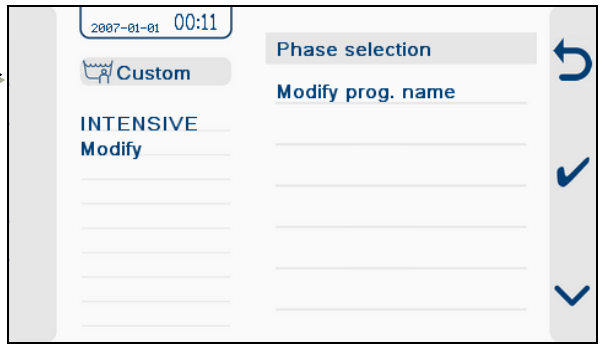


FIELD	DESCRIPTION
	Press on the arrow to scroll the list of fields: • Modify; • Copy cycle; • Paste cycle; • Delete cycle. The selected field will be highlighted in grey. Press the button in the center to confirm and access at selected field.
	Press the button to modify the desired phase, parameters and/or program name.
	Press the button to copy the selected program.
	Press the button to paste the selected program.
	Press the button to delete the selected program.

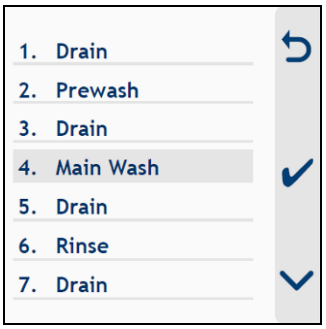
WARNING

To create or modify a customer program, it is necessary to copy a cycle from basic program.

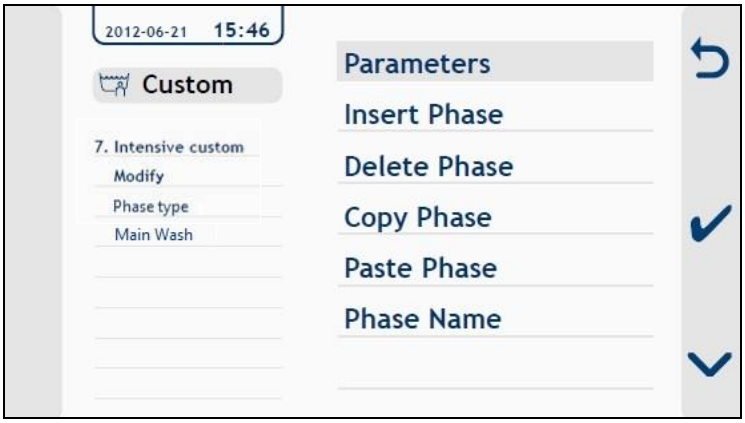
EXAMPLE:

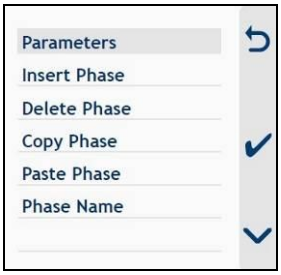


PROGRAM PHASES - PAGE

FIELD	DESCRIPTION
	List of the phases that compose the selected program. Press on the arrow to scroll the list. The selected phase will be highlighted in grey. Press the button in the center to confirm and access at selected field.

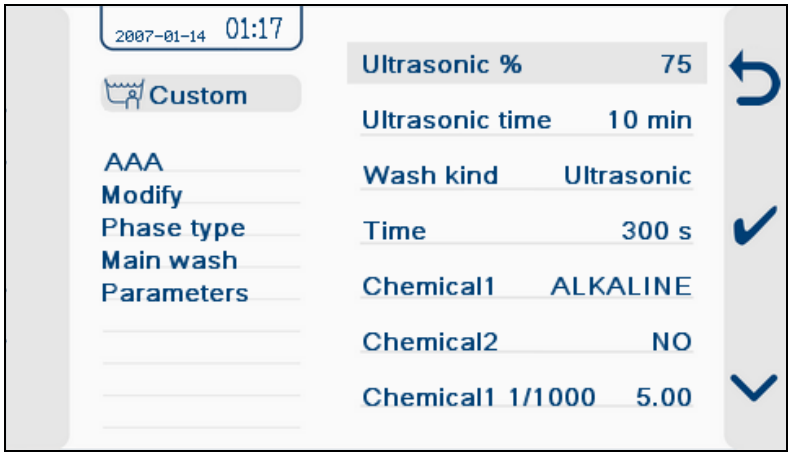
PARAMETERS MODIFICATION / PHASES MODIFICATION / PHASE NAME MODIFICATION

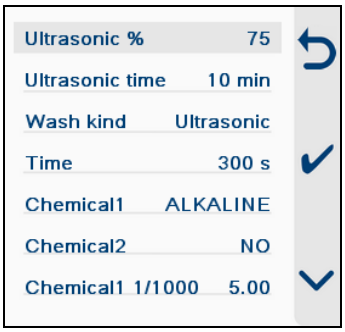


FIELD	DESCRIPTION
	List of possible modifications. Press on the arrow to scroll the list. The selected modification will be highlighted in grey. Press the button in the center to confirm and access at selected modification.

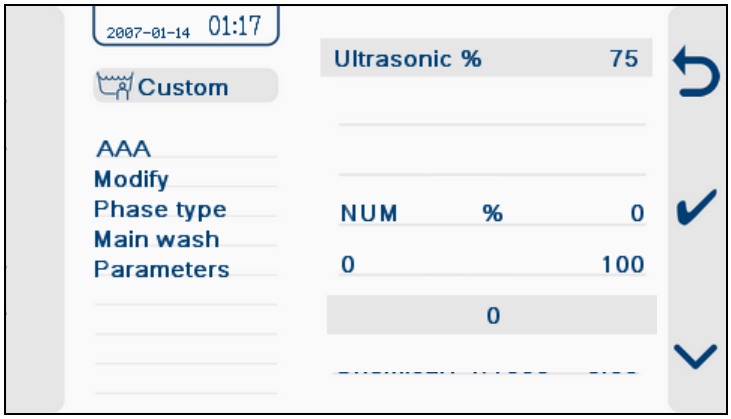
Example of procedure to modify a parameter value:

	Select “PARAMETERS” and press the button to enter in PHASE PARAMETERS - PAGE.

PHASE PARAMETERS - PAGE


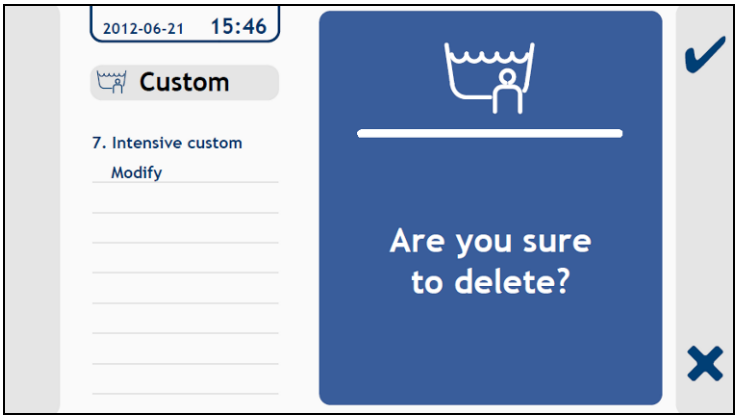
FIELD	DESCRIPTION
	Press on the arrow to scroll the list of parameters. The selected field will be highlighted in grey. Press the button in the center to confirm and access at parameter.

PARAMETER MODIFICATION - PAGE



FIELD	DESCRIPTION
NUM	Category (Ex. CHAR_STR, CHAR_NUM, NUM ecc.).
0	Decimal numbers.
0 99	Range.
18	Set the desired value as described: Press confirm button, the settable value will be highlighted in grey. With the arrow set the characters and confirm with related button.

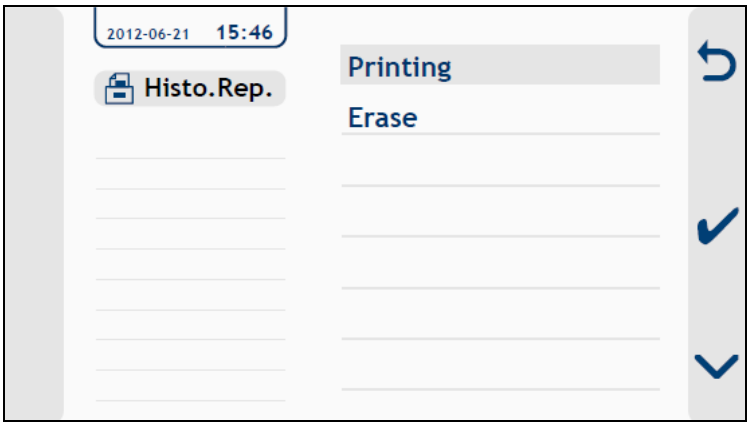
DELETE - PAGE



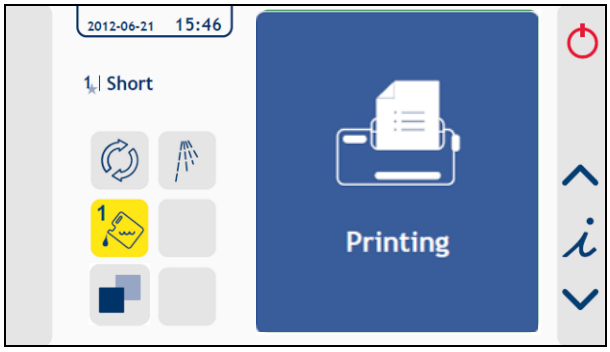
FIELD	DESCRIPTION
For delete operations (ex. delete phase, delete program), a confirmation will be request.	
✔	Press the button to confirm the cancellation.
✘	Press the button to cancel the cancellation.

6.6 Historical report

	On the MAIN PAGE – MENU, press on the arrow to scroll the list of submenu and select “Historical report”; Press the button to enter in submenu “Histo.Rep.”.

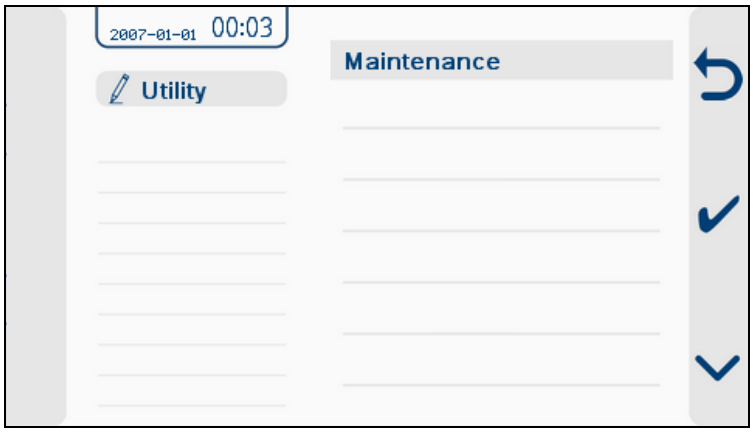
HISTORICAL REPORT - PAGE


FIELD	DESCRIPTION
	Press on the arrow to scroll the list of fields: • Printing; • Erase. The selected field will be highlighted in grey. Press the button in the center to confirm and access at selected field.
	Select “PRINTING” to activate printing of data.
	Select “ERASE” to activate deleting of data.

PRINTING	
	During printing, a special window appears as shown in the picture. In this phase, the display commands are deactivated.

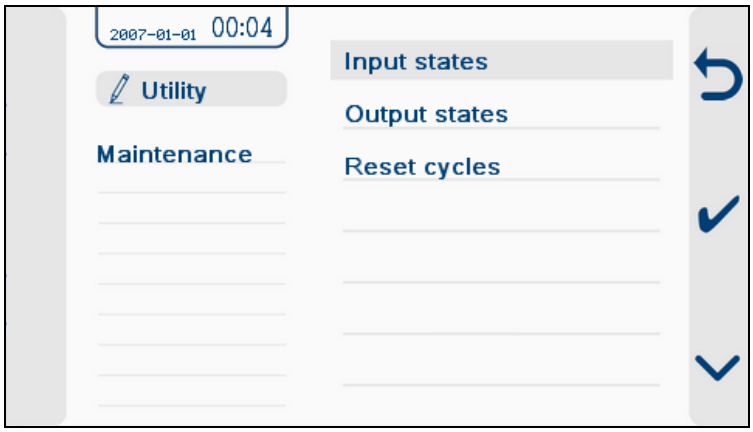
6.7 Utility

	On the MAIN PAGE – MENU, press on the arrow to scroll the list of submenu and select “Utility”; Press the button to enter in submenu “Utility.”.

UTILITY - PAGE


FIELD	DESCRIPTION
	Press on the arrow to scroll the list of fields: • Maintenance. The selected field will be highlighted in grey. Press the button in the center to confirm and access at selected field.

MAINTENANCE - PAGE



FIELD	DESCRIPTION
	Press on the arrow to scroll the list of fields: • Input states; • Output states; • Reset cycles; The selected field will be highlighted in grey. Press the button in the center to confirm and access at selected field.
	Select “INPUT STATES” in order to view the status of the desired component.
	Select “OUTPUT STATES” in order to view and/or modify the status of the desired component.
	Select “RESET CYCLES” in order to reset the number of the saved reports (The message “OK” indicates that the operation was executed correctly).

7. TREATMENT PROGRAM

Treatment programmes are built by assembling functional blocks called **"PHASES"** in a proper sequence, checking the handling of input parameters (water, chemicals, time and temperatures) in order to ensure the respect for the desired quality of treatment.

7.1 Description of phases

7.1.1 Pre-wash phase

In this phase the machine executes the cold water filling into the tank. Then washing pumps are activated for a time set by a parameter.

7.1.2 Drain phase

In this phase the machine executes the tank emptying through the activation of the drain valve.

7.1.3 Treatment phase

Hot, cold or "mixed" water is alternately loaded (depending on the parameters set in the relative stage). This allows to mix the water to reach the temperature set in the corresponding parameter. When the water filling stops, the pumps are activated to mix the water and to uniform the temperature.

If the temperature is lower than the set value, the pumps remain active and at the same time is activated the heating element; once is reached the temperature minimum required, chemical loading is activated.

7.1.4 Degassing phase

The excess air into the water is eliminated through activation of ultrasounds for a time set by parameter.

7.1.5 Ultrasonic phase

The phase is executed for a set time (set in minutes).
During this phase it is alternatively activated the ultrasonic generator and the flushing through pumps.

7.2 Details of the electronic card

The electronic card was designed following the indications given in the standards below:

EN 60335	Low voltage
EN 61000-6-3	Emissions
EN 61000-6-1	Immunity

8. MACHINE STATUS

8.1 Preparation

Perform the preparation phase like described at the paragraph 5.3.

8.2 Wait

The machine is ready to start a cycle.
The diagnostics are active.
If necessary, the display gives alarm or warning messages.

8.3 Cycle

Cycle mode is only accepted if the machine is in wait mode and the door is closed.
The cycle carries out the foreseen stages.
The diagnostic is active.
The user interface gives information concerning the stage in progress.

8.4 Alarms management

In case of lock with machine in stand-by, solve the cause of the alarm occurred and perform the unlocking procedure.
Once reset the alarm, the machine will return at the previous state.

In case of lock during the cycle, solve the cause of the alarm occurred and perform the unlocking procedure.
Once the alarm is reset:
-If parameter P3.53 is set to 0, the interrupted cycle will be managed according the parameter 3.5.
-If parameter P3.53 is set to 1, the machine executes a drain phase and then the interrupted cycle will be managed according the parameter 3.5.
-If parameter P3.53 is set to 2 and the machine during the phases has already dosed the chemical product, the machine executes a drain phase, then a water filling into the tank is executed and the washing pumps are activated for a time set by parameter P6.61. At the end of this operation the interrupted cycle will be managed according the parameter 3.5.

In the presence of anomaly which causes a block, a window appears that indicates the alarm. It is necessary to act correctly in order to restore it.

ATTENTION

In the presence of an alarm the machine stops itself, in this way the risk of causing breakages and/or malfunctions that may compromise the operation of the system is prevented or reduced.

Below you can find a list of all available machine alarms.

N° AL	MESSAGE DISPLAYED	DESCRIPTION
1	**Power fail**	It signals power failure during cycle.
2	**Load.door open**	Door open during cycle.
17	**No chemical 1**	Lack of chemical 1 (if enabled with alarm on **P3.6**). Diagnostic (with dispenser pump ordered active): • Status of pressure switch, if present. • No new impulse in excess of time **P6.12** if controlled by flowmeter.
18	**No chemical 2**	Lack of chemical 2 (if enabled with alarm on **P3.6**). Diagnostic (with dispenser pump ordered active): • Status of pressure switch, if present. • No new impulse in excess of time **P6.12** if controlled by flowmeter.
23	**Drain problem**	Overtime minimum tank level during the drain.
26	**Max°C prewash**	Tank temperature over maximum setup during prewashing.
27	**Lim°C cham.probe**	The chamber temperature exceeds the value of 102°C. (= max. set point limit 95°C + emergency 7°C) (tank heating element remote switch stuck or defective tank probe).
30	**Failure probe 1**	Chamber temperature 1st probe failure.
31	**Failure probe 2**	Chamber temperature 2nd probe failure.
34	**Temp. control**	It appears when: • Tank temperature over value ref. **P7.12**. • The temperature between the two probes has a difference higher than 1°C ref. **P7.11**.
35	**Com keyboards**	No serial connection between master board to the keyboard.
36	**Com display**	No serial connection between master board to the display.
39	**No chamb.heat.**	During tank heating phase, the temperature does not increase of 1°C into the prefixed time given by parameter **P6.1**.
42	**Thermal interv.**	The magnetothermic or inverter is tripped.
46	**Pump**	Washing pump switch on with pressure switch closed. The washing pump is uncorrect turning.
47	**Flowm.chemical 1**	The flowmeter product 1 had counted an impulses number superior to the threshold value set by parameter **P7.21** with pump switched off.
48	**Flowm.chemical 2**	The flowmeter product 2 had counted an impulses number superior to the threshold value set by parameter **P7.21** with pump switched off.
60	**TIME**	In the treatment phase, the thermal control time limit has expired (30 minutes), with counting started the first time that the tank temperature reaches +0,5 °C.
61	**Filling failure**	The water filling time exceeds the value set on parameter P6.8.
62	**Low pressure**	The pressure read by the analog transducer is lower than the minimum pressure value set on parameter 7.49.
63	**High pressure**	The pressure read by the analog transducer is greater than the maximum pressure value set on parameter 7.50.
64	**Conductivity**	During the rinsing phase, after the attemps number set on parameter P7.51, the conductivity value is greater than the recipe value.
65	**Ch1 temperature**	The set temperature of the chemical 1 is greater than the setpoint to be reached during the washing.
66	**Ch2 temperature**	The set temperature of the chemical 2 is greater than the setpoint to be reached during the washing.
67	**Water discrepancy**	During the filling of the tank, the low level sensor is not activated, while the high level sensor is.
80	**Door discrepancy**	Door micro switch disparity: one open and one closed at the same time.
81	**Door failure**	During a door movement command, the door result neither open nor closed.
82	**Door open.fail.**	After the door opening command, it does not open within the time set in parameter P6.15.
83	**Utrason.failure**	Ultrasounds are activated but the input is not received or the input is received but the ultrasounds are deactivated.

8.5 Warnings management

Warnings indicate to the user the occurred change of a specific operating condition.
Unlike alarms, the warnings don't prejudice the operation of the machine, that will continue its cycle.
In cases of warnings appearance, the user is obliged to intervene as fast as possible, in order don't prejudice the operation of the machine.

	In case of failure which does not lead to a block, a window appears which indicates the warning.
	In case of: - Lack of chemical - Door open during the cycle The icons that describe machine's status will be displayed in yellow.

Below you can find a list of all available machine warnings.

DISPLAY MESSAGE	DESCRIPTION
MAINTENANCE	See par. 19.1.1.
HOT MATERIAL	Very high temperature inside the chamber.
NO DISINFECTION	The cycle has been interrupted before the disinfection process end. Restart a cycle from the beginning.
	Inform that the door is open.
	The chemical product associated to dosing pump 1 is used-up (if it is set as a warning by **P3.6**) Diagnostics with dosing pump enabled: • Pressure switch state with pressure switch presence; • Lack of a new impulse after the time set by **P6.12** if a flowmeter is used.
	The chemical product associated to dosing pump 2 is used-up (if it is set as a warning by **P3.6**) Diagnostics with dosing pump enabled: • Pressure switch state with pressure switch presence; • Lack of a new impulse after the time set by **P6.12** if a flowmeter is used.
FULL MEMORY (N.a.)	The internal memory is full. Is not possible to save other historical data in the machine.
PASSW. LIMIT (N.a.)	The maximum number of password attempts has been reached.

9. PROCEDURE OF RESET

In case of LOCK, reactivate the cause of the alarm occurred and perform a procedure on the keyboard which consists of the sequence below, to reset the alarm:

1. Keep pressed the button “ALARM RESET” for five seconds.

2. Press the confirm sequence button signaled by green LED.

10. SPECIAL FEATURES

10.1 Power failure

In case of dropout in stand-by condition, the board will recur in the previous stand-by condition, at the voltage reactivation.

In case of dropout during the performance of a cycle at the voltage reactivation, the interrupted cycle will be managed according to the parameters setting 3.53 - 3.4.

10.2 Opening the door during a voltage drop

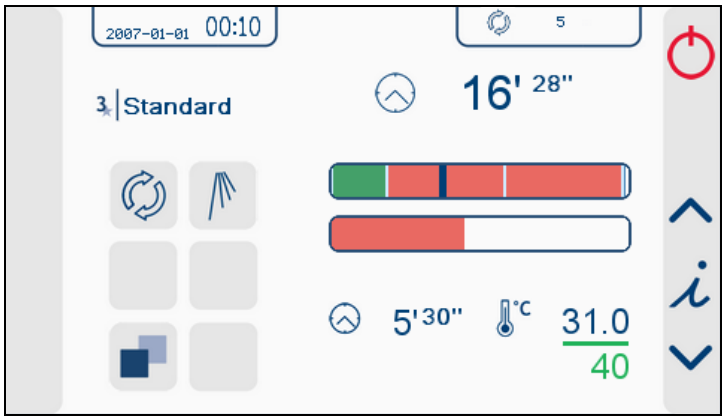
During a voltage drop, it is possible to open the door using the handle, bearing in mind that:

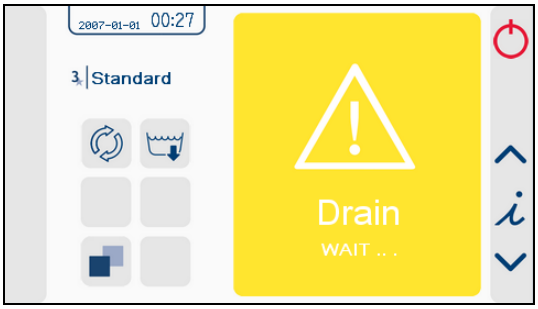
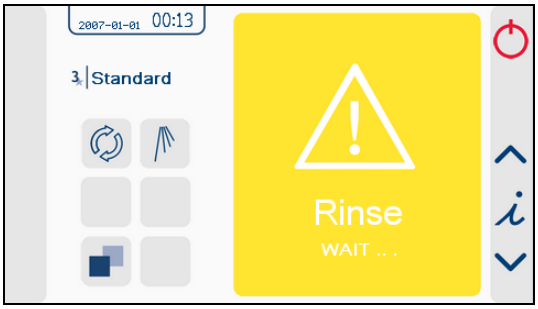
- The material in the machine could be very hot.
- The objects inside the machine could be contaminated.
- If the door is closed again, when the power returns, the interrupted cycle shall be managed according to the setting of parameters in 3.53 and 3.4.
- If the door remains open, when the power returns, the interrupted cycle shall be interrupted once again by alarm 2; the interrupted cycle shall be managed according to the setting of parameters 3.53 and 3.5.

	**ATTENTION**
	In order to handle the objects in the tank during a voltage drop, the use of opportune PPE is compulsory, so as to avoid both coming into contact with infected material and the risk of contamination.
	Do not immerse body parts that are not protected by opportune PPE into the tank liquid.

10.3 Interruption of a cycle

Is possible to interrupt a cycle as describe below:



FIELD	DESCRIPTION	
	**Pressing *STOP* button,** the cycle in progress is interrupted. In this condition, on the sidebar, appear the following buttons:	
		**Pressing again *STOP* button:** **-If parameter P3.53 is set to 0, the cycle is stopped definitively.** **-If parameter P3.53 is set to 1:** • the cycle is stopped definitively; • the machine executes a drain phase.  POP – UP → WAIT (DRAIN) Is necessary to wait before executes new operations. **-If parameter P3.53 is set to 2** and the machine during the phases has already dosed the chemical product: • the cycle is stopped definitively; • the machine executes a drain phase, then a rinse phase is performed for a time set by parameter P6.61.  POP – UP → WAIT (DRAIN + RINSE) Is necessary to wait before executes new operations.
		Pressing *START* button, the cycle is started again from the point at which it was interrupted.

11. WORK PROCEDURES

11.1 Introduction

The intended use of the machine is the washing (with or without ultrasounds) and decontamination (low level disinfection) of surgical instruments, equipment and objects normally used in hospital wards and medical studios.
It is therefore subject to constant contact with aggressive detergents and with contaminated instruments.
For this reason, it is necessary to provide some useful instructions for the operators who will be using it.

11.2 Instructions to personnel

The machine operator, in normal operating conditions, is not subject to risks if he works safely using suitable means of protection.
In order to work safely the operator must:

- Carefully comply with the instructions set forth in this manual.
- Use safety devices appropriately and with care, as well as group and individual safety gear provided in the workplace.
- Personally, take action, or inform appropriate people in the event of deficiencies in the aforementioned devices and means, as well as any hazardous conditions which he may become aware of, taking action directly in urgent cases within their scope of responsibilities and abilities to eliminate or reduce the deficiencies or hazards.

The maintenance technicians, in normal operating conditions, are not subject to risks if they work safely using suitable means of protection.
In order to work safely the maintenance technician must:

- Carefully comply with the instructions set forth in this manual.
- Use safety devices appropriately and with care, as well as group and individual safety gear provided in the workplace.
- Use special care in making repairs or replacing mechanical parts (e.g. drain pump, etc.) on malfunctioning machines which have not completed the treatment cycle.

11.3 Decontamination procedures

When making repairs or replacing mechanical parts on malfunctioning machines that have not completed the treatment, before undertaking any sort of maintenance on the internal parts of the machine, the disinfection procedure must be carried out in order to eliminate any pathogenic residues and protect operators who come into contact with the machine from the risk of infection.

The decontamination procedure must be performed by the system operator, who must be equipped with all provided individual protection gear.

MACHINE STATUS:
The machine must not be powered electrically and the dedicated safety device must be in the OFF position.
The person performing the task must ensure that there is no-one around the machine during this operation.

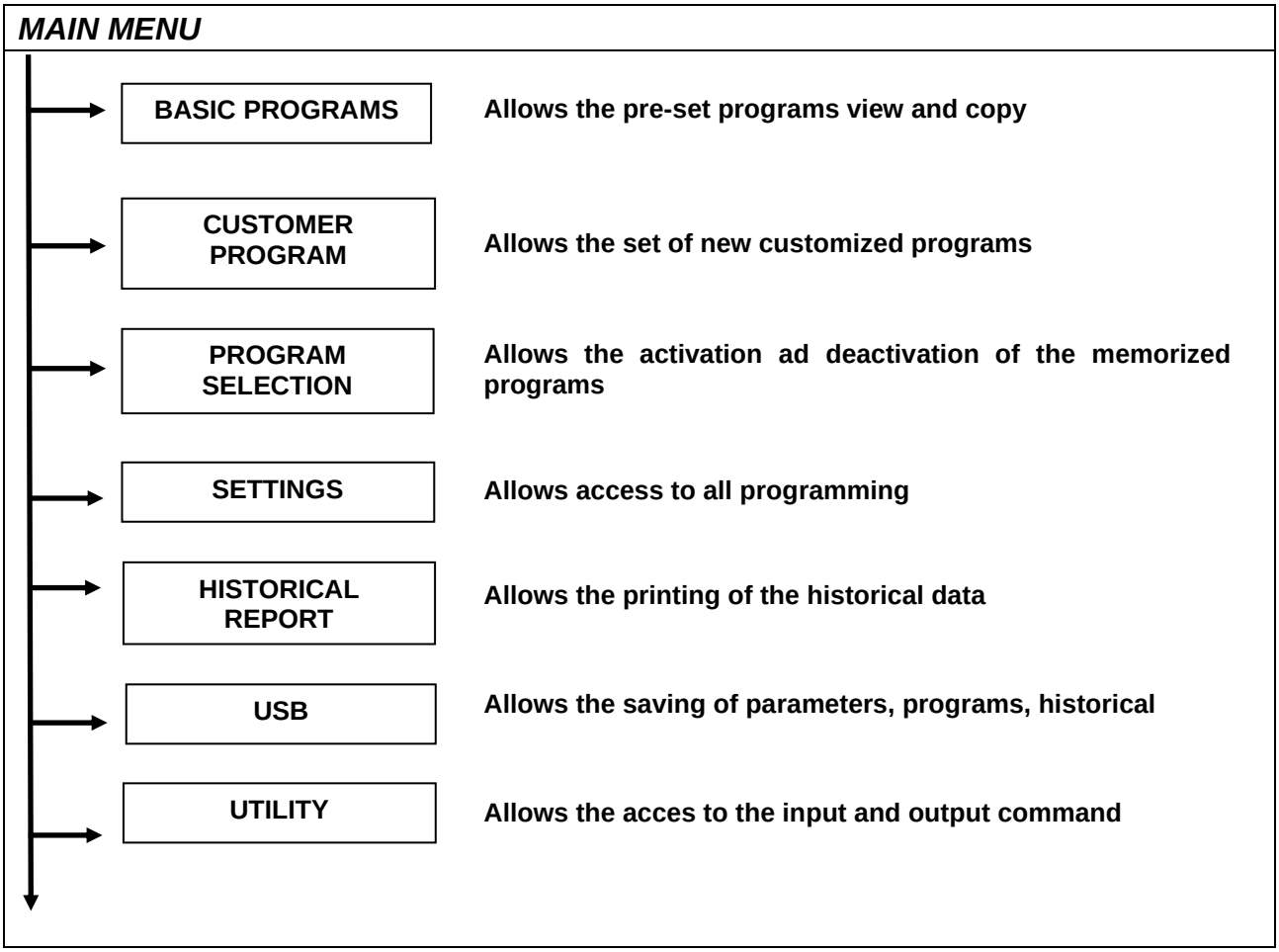
SAFETY SYSTEMS TO BE ADOPTED:
The operation must be carried out in compliance with standards
governing the use of disinfectant substances used (see technical information for the product being used, provided by the manufacturer), in compliance with standards concerning contact with parts of the machine which may be contaminated by pathogenic materials and with use of individual protection gear.

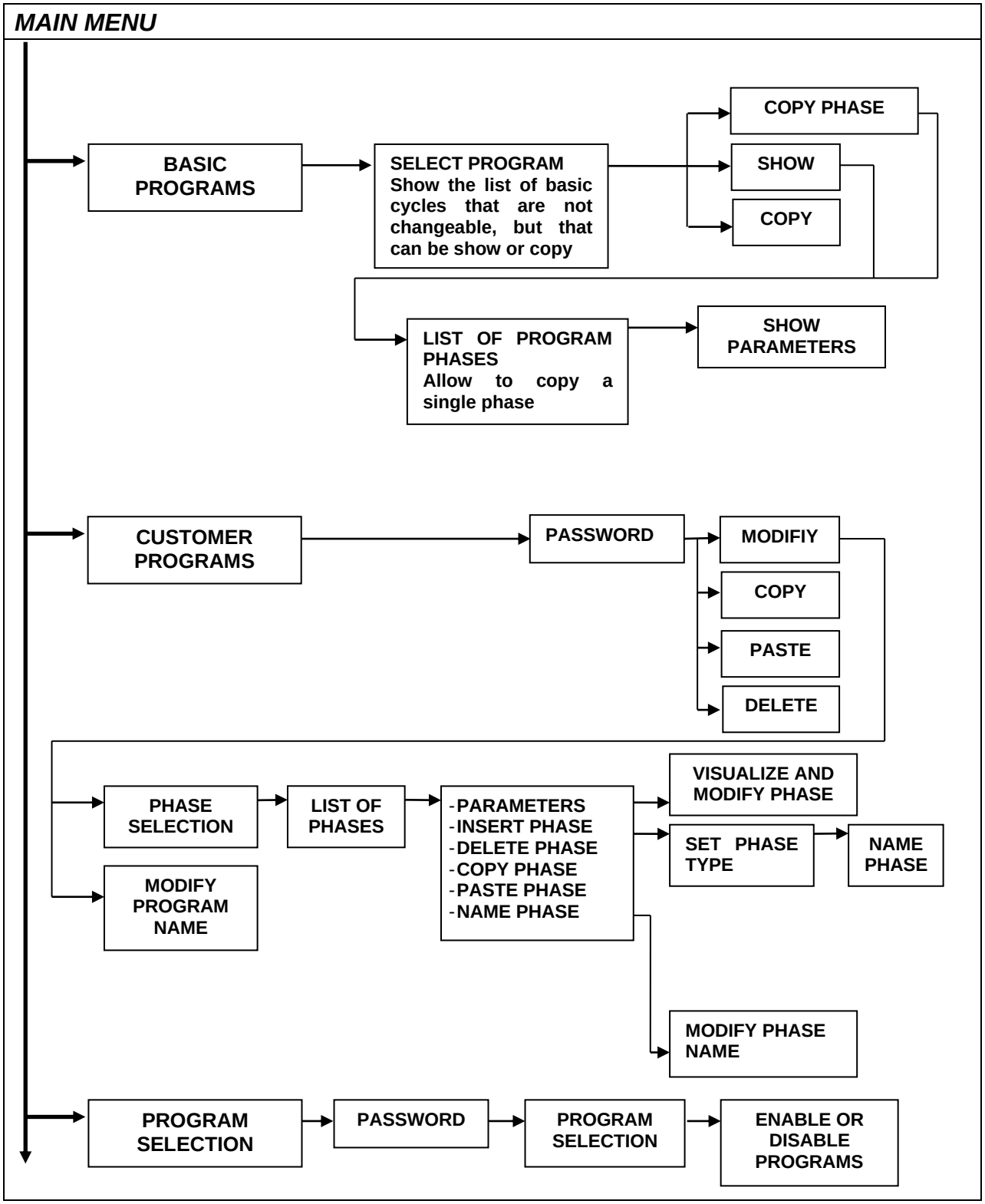
MODE OF INTERVENTION:
It is advisable to proceed with the disinfection of the machine as described in the chapter relating to maintenance.

When performing maintenance on parts of the machine which have not been reached by the disinfectant, take appropriate precautions and use suitable safety gear.

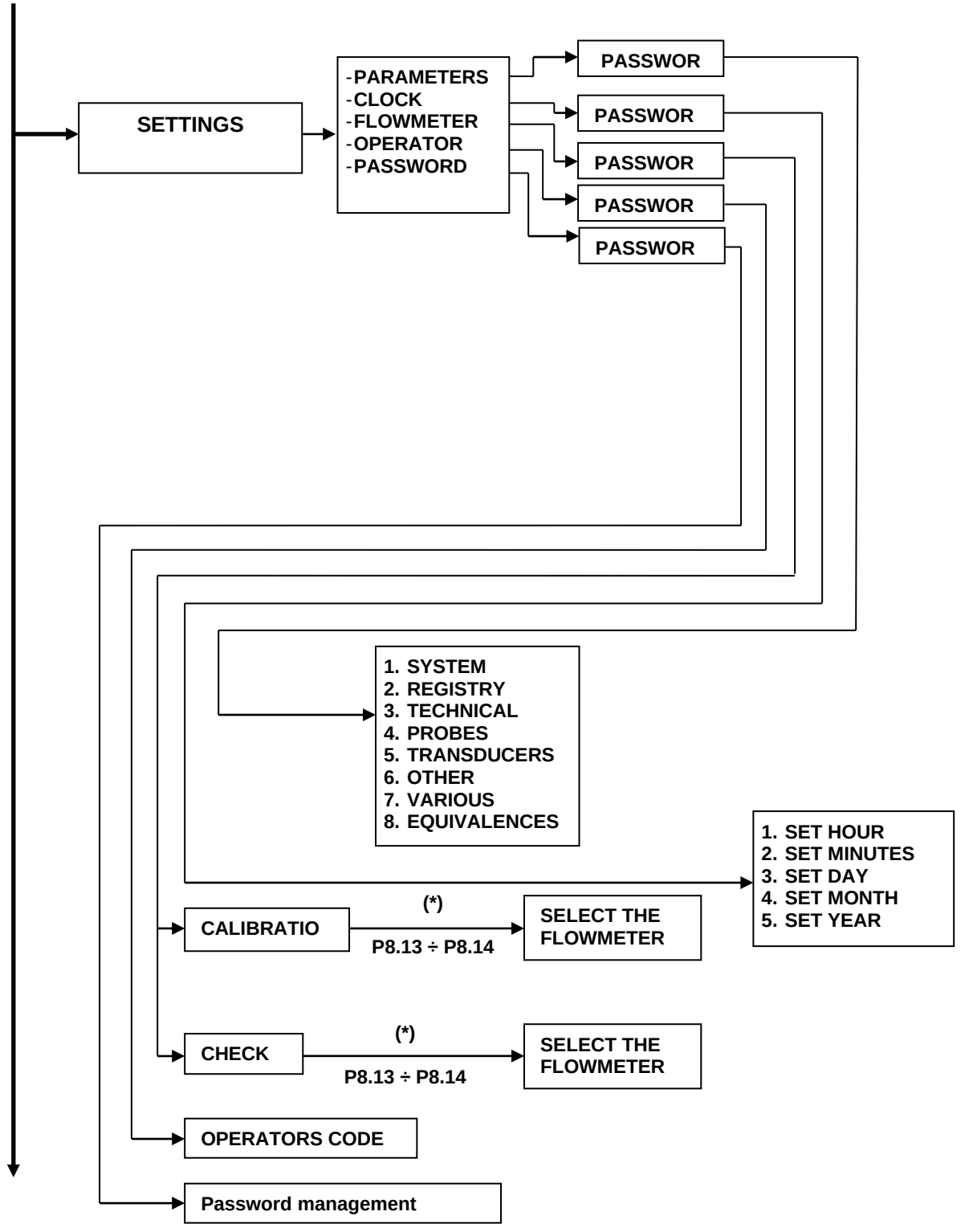
12. MENU

12.1 Menu plan



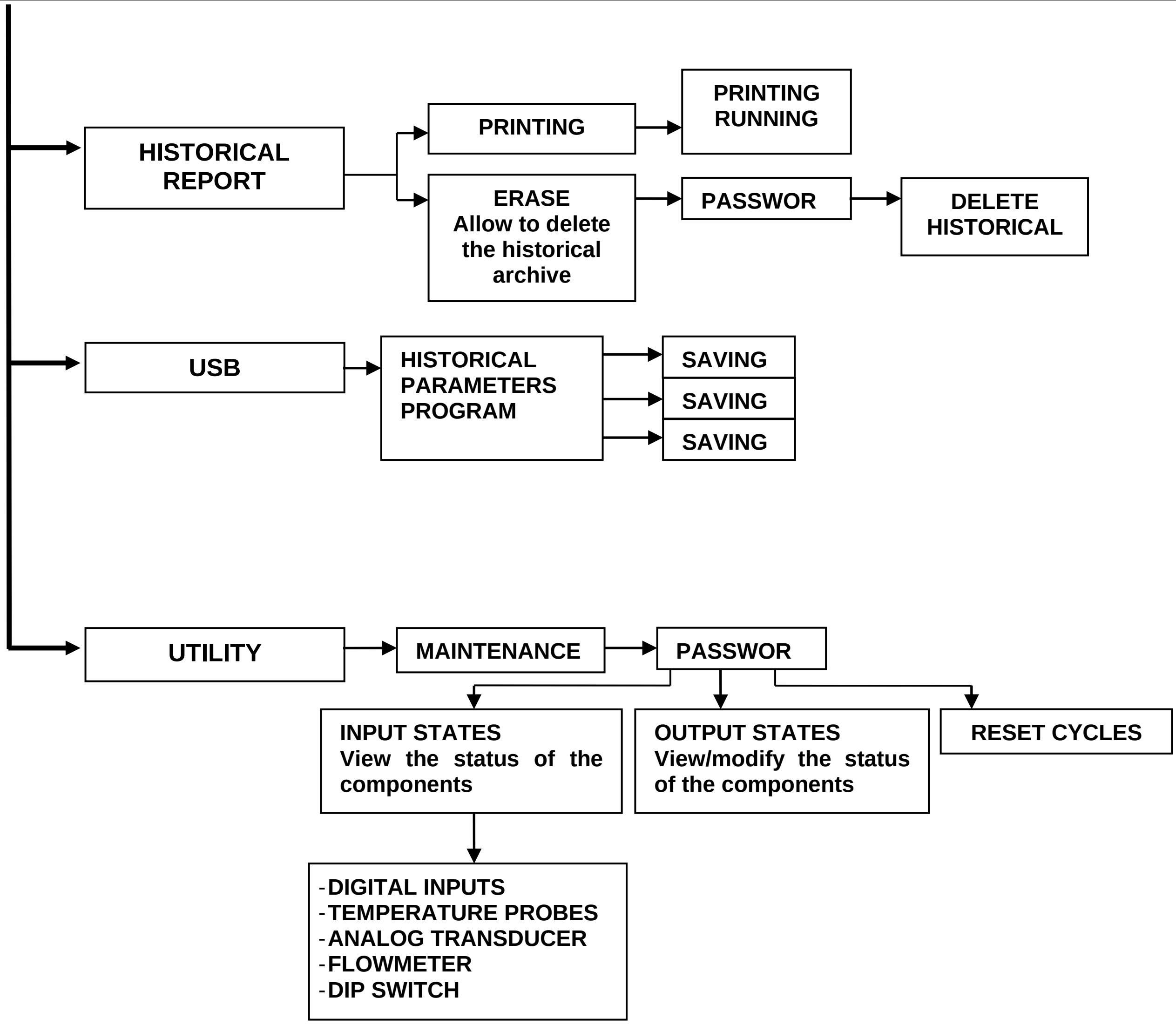

MAIN MENU
BASIC PROGRAMS
SELECT PROGRAM
Show the list of basic cycles that are not changeable, but that can be show or copy
COPY PHASE
SHOW
COPY
LIST OF PROGRAM PHASES
Allow to copy a single phase
SHOW PARAMETERS
CUSTOMER PROGRAMS
PASSWORD
MODIFIY
COPY
PASTE
DELETE
PHASE SELECTION
LIST OF PHASES
-PARAMETERS
-INSERT PHASE
-DELETE PHASE
-COPY PHASE
-PASTE PHASE
-NAME PHASE
VISUALIZE AND MODIFY PHASE
SET PHASE TYPE
NAME PHASE
MODIFY PROGRAM NAME
MODIFY PHASE NAME
PROGRAM SELECTION
PASSWORD
PROGRAM SELECTION
ENABLE OR DISABLE PROGRAMS

MAIN MENU



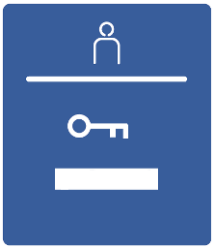
(*): active only if selected by the parameter relative.

MAIN MENU


HISTORICAL REPORT
PRINTING
PRINTING RUNNING
ERASE Allow to delete the historical archive
PASSWOR
DELETE HISTORICAL
USB
HISTORICAL PARAMETERS PROGRAM
SAVING
SAVING
SAVING
UTILITY
MAINTENANCE
PASSWOR
INPUT STATES View the status of the components
OUTPUT STATES View/modify the status of the components
RESET CYCLES
-DIGITAL INPUTS
-TEMPERATURE PROBES
-ANALOG TRANSDUCER
-FLOWMETER
-DIP SWITCH

13. PARAMETERS SETTINGS

To set parameters, a password will be requested. To insert the password, follow the procedure:



Press the arrow to set the first number of password and confirm by button related.
In automatic, after confirmation button, the arrow will move to the next number.
Continue with remaining numbers of password.
If an incorrect password is entered, the menu is closed immediately.

To modify the parameters, follow instructions described on section “EXAMPLE OF SUBMENU → TRANSDUCER PAGE”.

WARNING:
IT IS ALLOWED TO ENTER INTO PLANNING MENU WITH PASSWORD ONLY.

THE PASSWORD MUST BE REQUESTED FROM THE MANUFACTURER.

13.1 Parameters list

CATEGORY	SECTION	PARAMETER	DESCRIPTION	MIN	MAX	UDM	PASSWORD LEVEL
MACHINE	**1**	**1**	User name (0 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (1 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (2 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (3 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (4 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (5 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (6 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (7 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (8 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (9 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (10 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (11 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (12 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (13 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (14 characters)	,	~	CHAR_STR	PASSW.LEV.1
MACHINE	**1**	**1**	User name (15 characters)	,	~	CHAR_STR	PASSW.LEV.1
CYCLE	**1**	**2**	User recognition (0=disabled, 1=enabled)	0	1	SEL	PASSW.LEV.1
PRINTER	**1**	**4**	Graphic print out at the end of the cycle; 0 = no print out. 1 = print graph. 2 = table print out. 3 = print only on USB.	0	3	SEL	PASSW.LEV.2
DOOR	**1**	**15**	Automatic door opening at end of cycle(automatic door)	0	1	SEL	PASSW.LEV.2

CATEGORY	SECTION	PARAMETER	DESCRIPTION	MIN	MAX	UDM	PASSWORD LEVEL
CYCLE	1	16	Enable warning for full historical cycle; 0 = no warning 1 = warning without cycle start block. 2 = warning and block the cycle start. The warning will be reset if the historical cycle will be printed or on USB	0	2	SEL	PASSW.LEV.2
KEYBOARD	1	18	Maximum mistakes number on password input into the protected menu (0: function disabled)	0	100	NUM	PASSW.LEV.2
MACHINE	2	1	Machine model (0 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	1	Machine model (1 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	1	Machine model (2 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	1	Machine model (3 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	1	Machine model (4 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	1	Machine model (5 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	1	Machine model (6 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	1	Machine model (7 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	2	Machine serial number (0 characters)	0	9	CHAR_NUM	PASSW.LEV.2
MACHINE	2	2	Machine serial number (1 characters)	0	9	CHAR_NUM	PASSW.LEV.2
MACHINE	2	2	Machine serial number (2 characters)	0	9	CHAR_NUM	PASSW.LEV.2
MACHINE	2	2	Machine serial number (3 characters)	0	9	CHAR_NUM	PASSW.LEV.2
MACHINE	2	2	Machine serial number (4 characters)	0	9	CHAR_NUM	PASSW.LEV.2
MACHINE	2	3	Test day → dd	1	31	NUM	PASSW.LEV.2
MACHINE	2	3	Test month → mm	1	12	NUM	PASSW.LEV.2
MACHINE	2	3	Test year → yy	10	99	NUM	PASSW.LEV.2
KEYBOARD	2	4	Select language	0	7	SEL	PASSW.LEV.1
MACHINE	2	5	Station number	0	99	NUM	PASSW.LEV.2
MACHINE	2	6	Client/distributor (0 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	6	Client/distributor (1 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	6	Client/distributor (2 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	6	Client/distributor (3 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	6	Client/distributor (4 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	6	Client/distributor (5 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	6	Client/distributor (6 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	6	Client/distributor (7 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	2	6	Client/distributor (8 characters)	,	~	CHAR_STR	PASSW.LEV.2

CATEGORY	SECTION	PARAMETER	DESCRIPTION	MIN	MAX	UDM	PASSWORD LEVEL
MACHINE	**2**	**6**	Client/distributor (9 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	**2**	**6**	Client/distributor (10 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	**2**	**6**	Client/distributor (11 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	**2**	**6**	Client/distributor (12 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	**2**	**6**	Client/distributor (13 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	**2**	**6**	Client/distributor (14 characters)	,	~	CHAR_STR	PASSW.LEV.2
MACHINE	**2**	**6**	Client/distributor (15 characters)	,	~	CHAR_STR	PASSW.LEV.2
KEYBOARD	**2**	**8**	American Unit of measurement: (0=International, 1=American)	0	1	SEL	PASSW.LEV.2
MACHINE	**2**	**13**	Maintenance day	1	31	LINK_NUM	PASSW.LEV.2
MACHINE	**2**	**13**	Maintenance month	1	12	LINK_NUM	PASSW.LEV.2
MACHINE	**2**	**13**	Maintenance year	10	99	LINK_NUM	PASSW.LEV.2
PT 1000	**3**	**2**	Activate regulation probe (0=no, 1=yes)	0	1	SEL	PASSW.LEV.2
PRINT OUT	**3**	**3**	Printer on board	0	1	SEL	PASSW.LEV.2
CYCLE	**3**	**4**	Activate after cycle has been interrupted due to energy failure; 0 = when phase restarts. 1 = from the beginning of the cycle. 2 = from when cycle ends.	0	2	SEL	PASSW.LEV.2
CYCLE	**3**	**5**	Activate after cycle has been interrupted due to alarm 0 = when phase restarts. 1 = from the beginning of the cycle. 2 = from when cycle ends.	0	2	SEL	PASSW.LEV.2
CHEMICALS	**3**	**6**	Set in case of lack of chemical additives (0=warning, 1=alarm)	0	1	SEL	PASSW.LEV.2
PUMPS	**3**	**13**	Washing arms pump pressure switch presence	0	1	SEL	PASSW.LEV.2
PUMPS	**3**	**23**	Transducer (4-20 mA) to control impeller pump pressure	0	1	SEL	PASSW.LEV.2
WATER	**3**	**25**	Analogue probe (4-20 mA) for conductivity	0	1	SEL	PASSW.LEV.2
WATER	**3**	**38**	Absence of hot water; (1 = load cold water in its place).	0	1	SEL	PASSW.LEV.2
DOOR	**3**	**42**	Type door (0=manual, 1=automatic)	0	1	SEL	PASSW.LEV.2
CYCLE	**3**	**53**	Forced emptying of chamber after cycle interruption: 0=no, 1=only emptying, 2=emptying with rinse.	0	2	SEL	PASSW.LEV.2
PT 1000	**4**	**1**	Offset calibration chamber probe 1 at a 0°C.	-9,9	9,9	°C	PASSW.LEV.2
PT 1000	**4**	**2**	Offset calibration chamber probe 1 at a 100°C.	-9,9	9,9	°C	PASSW.LEV.2
PT 1000	**4**	**3**	Offset calibration chamber probe 2 at a 0°C.	-9,9	9,9	°C	PASSW.LEV.2

CATEGORY	SECTION	PARAMETER	DESCRIPTION	MIN	MAX	UDM	PASSWORD LEVEL
PT 1000	**4**	**4**	Offset calibration chamber probe 2 at a 100°C.	-9,9	9,9	°C	PASSW.LEV.2
PUMPS	**5**	**1**	Pressure scale lower limit.	-1	6	BAR	PASSW.LEV.2
PUMPS	**5**	**2**	Pressure scale upper limit.	0	10	BAR	PASSW.LEV.2
WATER	**5**	**3**	Conductibility scale lower limit.	0	500	uS_cm	PASSW.LEV.2
WATER	**5**	**4**	Conductibility scale upper limit.	0	20000	uS_cm	PASSW.LEV.2
CHAMBER	**6**	**1**	Max time per 1°C increase in the chamber.	0	999	SEC	PASSW.LEV.2
DRAINING	**6**	**3**	Maximum drainage time.	0	999	SEC	PASSW.LEV.2
WATER	**6**	**8**	Maximum waiting time for cold + warm water filling.	0	999	SEC	PASSW.LEV.2
CHEMICALS	**6**	**12**	Maximum waiting time for chemical products flowmeter impulse.	0	99,9	SEC	PASSW.LEV.2
DOOR	**6**	**15**	Max time for open/close door (only for automatic version)	0	99,9	SEC	PASSW.LEV.2
PUMPS	**6**	**17**	Delay in reading pump pressure switch.	0	99,9	SEC	PASSW.LEV.2
SYSTEM	**6**	**18**	Delay in reading thermal safety or resistance return input; 0 = diagnostics deactivated.	0	99,9	SEC	PASSW.LEV.2
CHEMICALS	**6**	**20**	Filling time for chemical product 1 dosing system.	0	999,9	SEC	PASSW.LEV.2
CHEMICALS	**6**	**21**	Filling time for chemical product 2 dosing system.	0	999,9	SEC	PASSW.LEV.2
DRAINING	**6**	**25**	Time taken for activating cooling drainage electrovalve.	0	99,9	SEC	PASSW.LEV.2
PRINT OUT	**6**	**47**	Sampling time for chamber temperature and pressure trends.	5	99	SEC	PASSW.LEV.2
CYCLE	**6**	**48**	Time in months to warn about forthcoming maintenance service since the last one carried out.	0	99	NUM	PASSW.LEV.2
CYCLE	**6**	**49**	Increase in machine hours to warn about the next maintenance service since the last one carried out.	0	9999	h	PASSW.LEV.2
DRAINING	**6**	**54**	Extra drain time after low level is reached.	0	99	SEC	PASSW.LEV.2
FILLING	**6**	**55**	Extra filling time after the high level reaching.	2	99	SEC	PASSW.LEV.2
PUMPS	**6**	**58**	Pumps activation time during the washing phase for mixing water.	2	99	SEC	PASSW.LEV.2
CONDUCTIVITY	**6**	**59**	Time to measure the conductivity in the tank.	0	99	SEC	PASSW.LEV.2
FILLING	**6**	**60**	Extra filling time after the low level reaching.	0	99	SEC	PASSW.LEV.2
RINSING	**6**	**61**	Rinsing time during forced draining.	0	999	SEC	PASSW.LEV.2
CHAMBER	**7**	**11**	Max. chamber probe temperature difference.	0	99	°C	PASSW.LEV.2

CATEGORY	SECTION	PARAMETER	DESCRIPTION	MIN	MAX	UDM	PASSWORD LEVEL
CHAMBER	**7**	**12**	Min. temperature for max. chamber temperature probes difference control.	0	95	°C	PASSW.LEV.2
PRE-WASH	**7**	**14**	Max. permitted temperature in pre-wash phase.	0	95	°C	PASSW.LEV.2
DRAINING	**7**	**15**	Min. temperature for drain cooling activation.	0	100	°C	PASSW.LEV.2
CHEMICALS	**7**	**21**	Max. chemical flowmeter impulse excess after switching off dosing pump.	0	99	N_IMPULSES	PASSW.LEV.2
CHAMBER	**7**	**22**	A0 temperature interval.	0	99	°C	PASSW.LEV.2
CHAMBER	**7**	**23**	A0 temperature reference.	0	99	°C	PASSW.LEV.2
CHAMBER	**7**	**24**	A0 lower temperature limit.	0	99	°C	PASSW.LEV.2
PRINT OUT	**7**	**25**	Horizontal Resolution graphics (pixel/hour).	240	1000	NUM	PASSW.LEV.2
CHAMBER	**7**	**42**	Temperature for the tank cooling.	10	99	°C	PASSW.LEV.2
TEMPERATURE	**7**	**45**	Temperature above set-point for switching off heating elements.	0	10	°C	PASSW.LEV.2
TEMPERATURE	**7**	**46**	Temperature above set-point for switching on heating elements.	0	10	°C	PASSW.LEV.2
DRAINING	**7**	**47**	Drain cooling enabling.	0	1	SEL	PASSW.LEV.2
CHAMBER	**7**	**48**	Chamber cooling enabling.	0	1	SEL	PASSW.LEV.2
PRESSURE	**7**	**49**	Minimum pressure for alarm activation.	0	9,9	BAR	PASSW.LEV.2
PRESSURE	**7**	**50**	Maximum pressure for alarm activation.	0	9,9	BAR	PASSW.LEV.2
CONDUCTIVITY	**7**	**51**	Number of attempts to measure the conductivity of rinsing tank.	0	99	NUM	PASSW.LEV.2
CHEMICALS	**8**	**5**	Chemical product for dosing pump 1; impulse/millilitre (flowmeter).	0	9,999	p/mL	PASSW.LEV.2
CHEMICALS	**8**	**6**	Chemical product for dosing pump 2; impulse/millilitre (flowmeter).	0	9,999	p/mL	PASSW.LEV.2
CHEMICALS	**8**	**9**	Chemical product for dosing pump 1: sec/millilitre (timed control).	0	9,999	s/mL	PASSW.LEV.2
CHEMICALS	**8**	**10**	Chemical product for dosing pump 2: sec/millilitre (timed control).	0	9,999	s/mL	PASSW.LEV.2
CHEMICALS	**8**	**13**	Way of dosing for chemical product 1: 0 = by impulse. 1 = timed.	0	1	SEL	PASSW.LEV.2
CHEMICALS	**8**	**14**	Way of dosing for chemical product 2: 0 = by impulse. 1 = timed.	0	1	SEL	PASSW.LEV.2
CHEMICALS	**8**	**17**	Reference for automatic calibration of chemical flowmeter. If P2.8=YES, the value is once/10 liq.	1 0.03	999 33.77	mL fl.oz	PASSW.LEV.2
WATER	**8**	**27**	Water quantity into the tank.	0	999	L	PASSW.LEV.2

CATEGORY	SECTION	PARAMETER	DESCRIPTION	MIN	MAX	UDM	PASSWORD LEVEL
TEMPERATURE	**8**	**28**	Dosing temperature of dosing pump 1.	0	99	°C	PASSW.LEV.2
TEMPERATURE	**8**	**29**	Dosing temperature of dosing pump 2.	0	99	°C	PASSW.LEV.2
WATER	**8**	**30**	Water quantity into the tank (low level).	0	999	L	PASSW.LEV.2

13.2 Password management

The programmation access and the menu are protected by three password levels:

- **1st level:** *operator password* → it is possible to:
  -access to some parameters
  -access to CLOCK field
  -access to SETTINGS → OPERATOR page
  -access to PROGRAM SELECTION submenu
  -access to CUSTOMER PROGRAM submenu
  -access to DELETE HISTORICAL field

- **2nd level:** *technician password* → it is possible to:
  -access to all parameters
  -access to FLOWMETER field

- **3rd level:** *manufacturer password* → it is possible to:
  -access to STARTING UP AND DISPLAY OF DEVICES
  -access to SETTINGS → PASSWORD page
  -access to UTILITY submenu

The password is made up of from four characters. Every character can be chosen between:

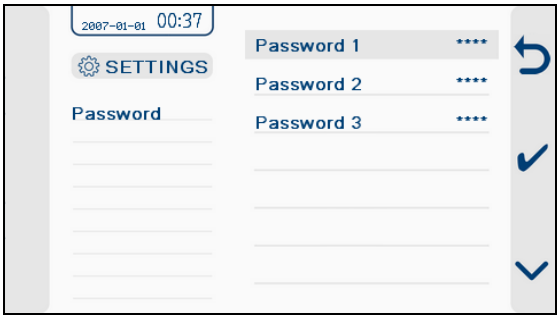
- Number digits: from "**0**" to "**9**";

13.2.1 Password change

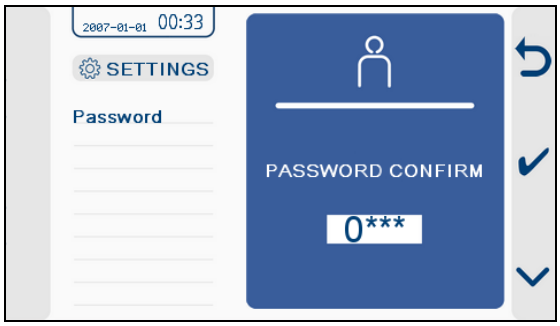
To change the password, follow the procedure:

On the MAIN PAGE (Rif. Par. Control panel –Menù-) select the submenu SETTINGS to access to SETTINGS PAGE.
On the SETTINGS PAGE select the submenu PASSWORD.
A password will be requested → **Insert 3rd level password** for accessing to the page shown on the picture:

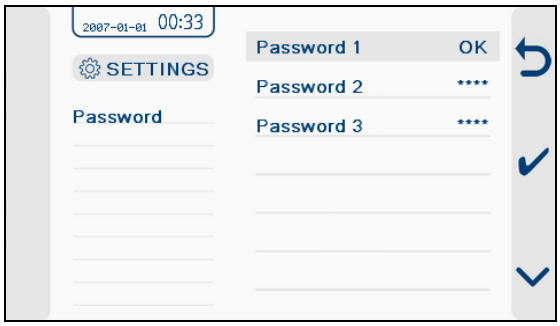
Password 1 → **1st level password**
Password 2 → **2nd level password**
Password 3 → **3rd level password**



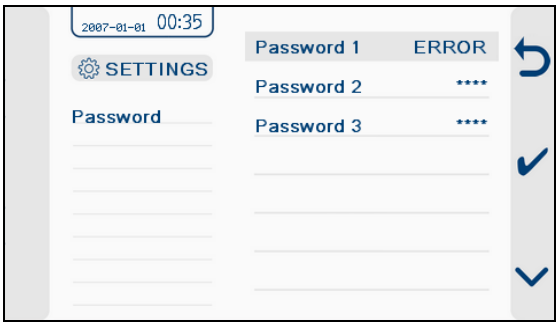
Press on the arrow to scroll the list of passwords.
The selected password will be highlighted in grey.
Press the button in the center to confirm and access to the selected password to modify it.
The new password will be requested.
Insert the new password.
The same password is requested again for confirmation.



To confirm the password, reinsert the same one.
At the end of these operation the password is changed.



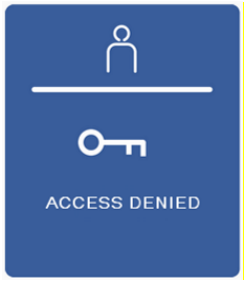
Otherwise, if you insert a different password,
it is not changed.



13.2.2 Recognition password of operator to start programs

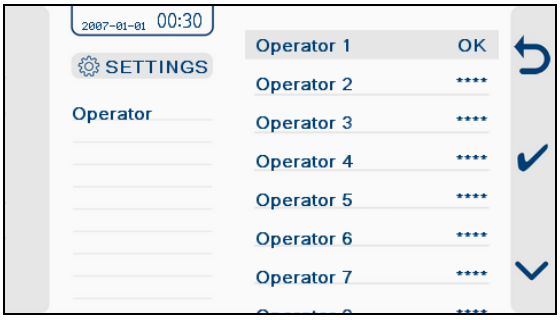
How to activate the recognition password of operator:
To activate/deactivate the recognition password to start programs, set the parameter 1.2 → User recognition (0=disabled, 1=enabled).

If the parameter is set to 0, access to the submenu OPERATORS is not allowed.

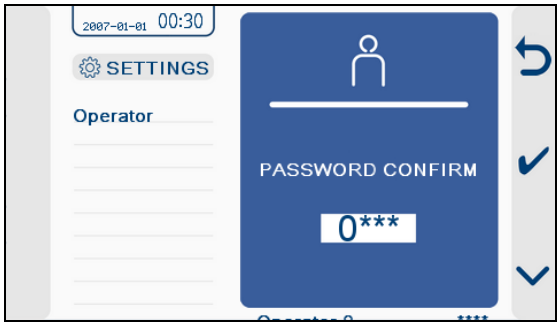


How to set/change the operator password:
To set/change the recognition password to start programs, follow the procedure:

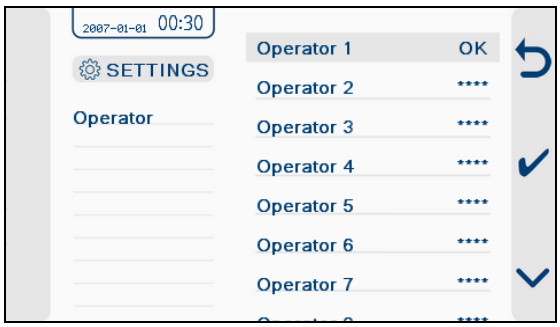
On the MAIN PAGE (Rif. Par. Control panel –Menù-) select the submenu SETTINGS to access to SETTINGS PAGE.
On the SETTINGS PAGE select the submenu OPERATOR.
A password will be requested → **Insert 1st level password** for accessing to the page shown on the picture:

On this page it is possible to set/change the recognition password for each operator.	

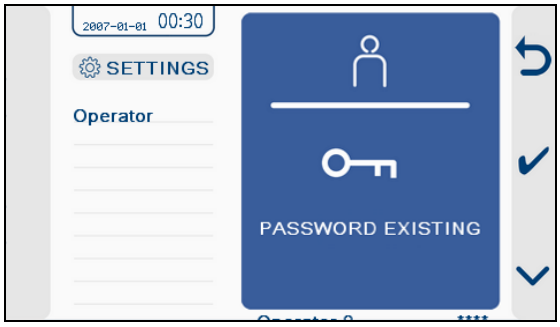
Press on the arrow to scroll the list of operator password.
The selected operator password will be highlighted in grey.
Press the button in the center to confirm and access to the selected operator password to set/modify it.
The new operator password will be requested.
Insert the new operator password.
The same operator password is requested again for confirmation.



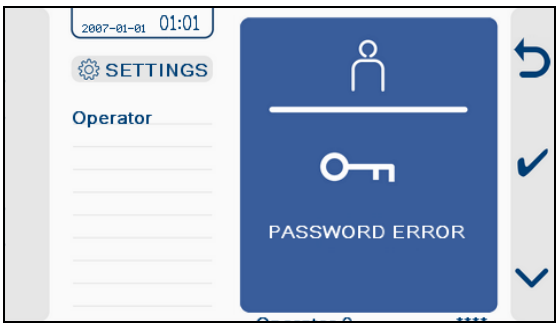
To confirm the operator password, reinsert the same one. At the end of these operation the operator password is set/changed.



In case a password that has already been given to another user is entered, the following pop-up window will appear:

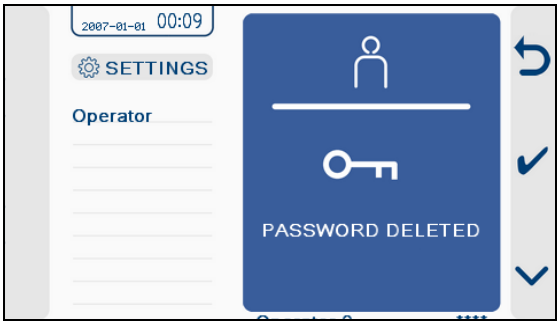


Otherwise, if you insert a different operator password, it is not set/changed.



In order to eliminate a user password, carry out the following procedure:

Press on the arrow to scroll the list of operator password.
The selected operator password will be highlighted in grey.
Press the button in the center to confirm and access to the selected operator password to delete it.
Insert the password 0000.
The same operator password is requested again for confirmation.
Reinsert the same one.
At the end of these operation the operator password is deleted.



Example of password deleted.

14. STARTING UP AND DISPLAY OF DEVICES

It is possible to display the state of the devices.
Enter the menu: **UTILITY → MAINTENANCE → Insert 3rd level password → INPUT STATE**.
Push the confirmation button to access to the inputs list, then through the arrow, scroll the list and select the desired input (the input will be highlighted in grey) and display its status.

Enter the menu: **UTILITY → MAINTENANCE → Insert 3rd level password → OUTPUT STATE**.
Push the confirmation button to access to the output list, then through the arrow scroll the list and select the desired output (the output will be highlighted in grey) and display its status.
In this condition it is possible to enable/disable the output manually as described below:
Pressing the confirm button, the status of the selected output will be highlighted in grey. Using the arrow, set the desired status.

	WARNING
	For input and output's specification see the wiring diagram.

15. CHEMICALS CALIBRATION

Chemical products have different viscosities, so it is recommended to calibrate the dosing system every time you change the type of chemical.
Depending on machine configuration and set parameter (**P8.13 ÷ P8.17**), the chemical dosing can be done by time or impulses (in this case **ONLY** if it presents the flowmeter, ordered as **OPTIONAL**).

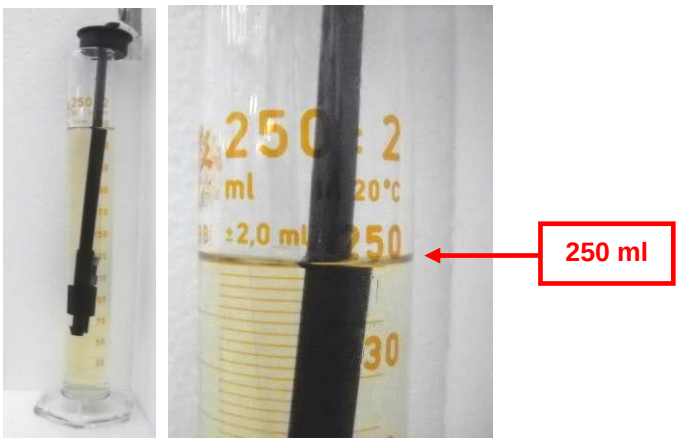
	ATTENTION
	There is a risk of contact with the chemical product, therefore obtain appropriate individual protection gear (gloves for protection from chemical substances, breathing protection masks, goggles etc.) during the execution of operations. **The chemical products are an irritant for the eyes, in case of contact rinse thoroughly with water and consult a doctor. If these products come into contact with the skin, rinse with plenty of water.**

15.1 Timed dosing

In order to do the chemicals calibration, it is necessary to control that the chemical products dosing system is completely filled.
For this calibration's procedure it is necessary to have the stopwatch.

15.1.1 Calibration

Insert the suction lance of the chemical to be calibrated into a ml-graduated cylinder and fill it with the chemical up to 250 ml.



Chemical product

To start the calibration of dosing system it is necessary to activate manually the dosing device.

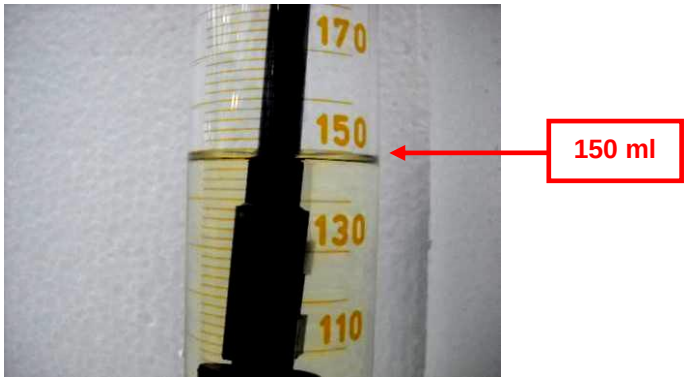
Enter the menu: **UTILITY → MAINTENANCE → Insert 3rd level password → OUTPUT STATE**

Press on the arrow  to scroll the list of devices.

After selecting the output of the device for calibration, activate it as described:

Pressing the confirm button  , the status of the selected output will be highlighted in grey. Use the arrow  to enable the device manually and at same time activate the stopwatch to start measuring the time of dosing.

When the level of chemical product in ml-graduated cylinder has reached 100 ml, deactivate the device and stop the stopwatch.



Chemical product

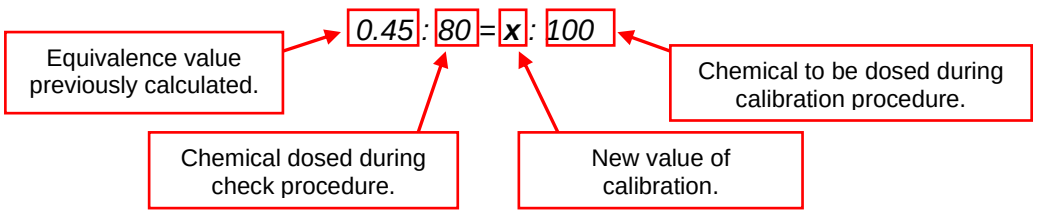
Calculate the value of calibration as the ratio between the time measured by the stopwatch and the amount of chemical product dosed in the cylinder (Ex. 45 sec / 100 ml = 0.45).
Insert the previously calculated value in the relative parameter relative of the doser on the section “EQUIVALENCES”.

15.1.2 Check

After the calibration it is necessary to control the calibration efficacy by the check procedure:

- Activate manually the dosing device and the stopwatch to start measuring the time.
- When the stopwatch reaches the dosing time measured in the previous calibration procedure, deactivate the dosing device.
- Check that the level of product in the ml-graduated cylinder is 100 ml or the same dosed in the previous calibration procedure.
- If the level of dosed product is correct the check procedure is finished and continue the chemical calibration for others dosing devices.
- If not, calculate the new value of the equivalence taking into account the dosage values previously calculated and the amount of chemical dosed.

  Example:



- Insert the new value in the related parameter of the doser on the section “EQUIVALENCES”.
- Control the calibration consistency with a new check procedure.

AFTER THE CHEMICAL CALIBRATION IT IS NECESSARY TO RUN A RINSING CYCLE WITHOUT INSTRUMENTS INSIDE THE CHAMBER.

15.2 Impulsed dosing (Optional)

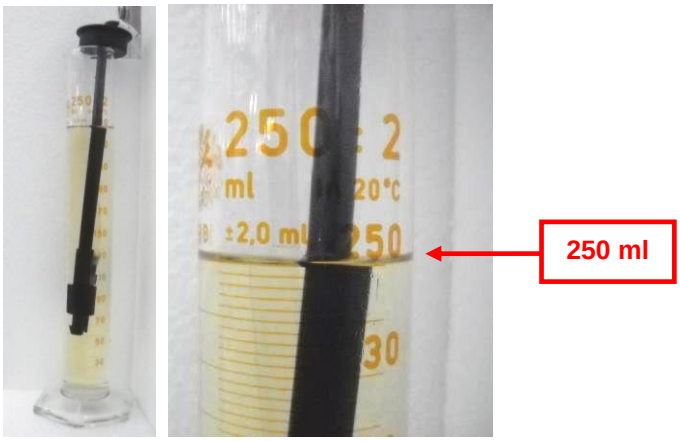
In order to set the flowmeters, it is necessary to control that the chemical products dosing system is completely filled.

15.2.1 Calibration

Enter the menu: **SETTINGS → FLOWMETERS → Insert 2nd level password → CALIBRATION**

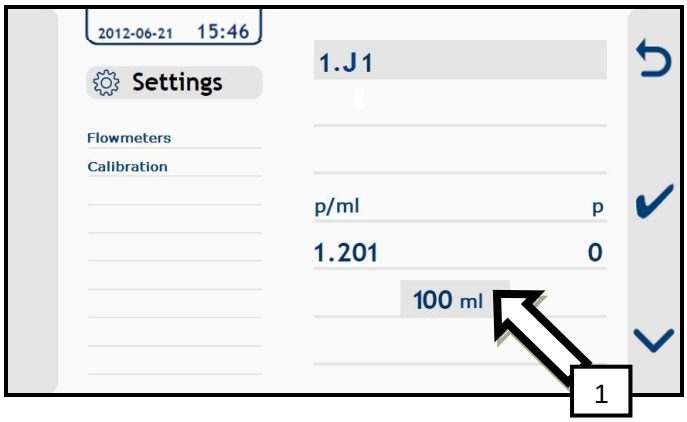
Select the flowmeter that you want to calibrate by using the arrow ✔ (in case the parameter setting does not allow access to the desired flow-meter, a pop-up window will appear, and access will be denied).

Insert the suction lance of the chemical to be calibrated into a ml-graduated cylinder and fill it with the chemical up to 250 ml.



Chemical product

After selecting the flowmeter to calibrate push button ✔ to start the procedure.

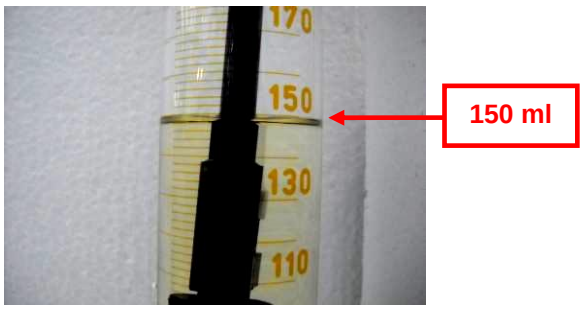


Press button ✔ when the level on the ml-graduated cylinder have reached the displayed quantity (1).

At this point the field (1) will be highlighted in grey. By pressing on the arrow ✔, it is possible adjust the value dosed during the calibration procedure.

To confirm the adjust value, press the button in the center ✔.

If you want to shut off the procedure press button ↩.

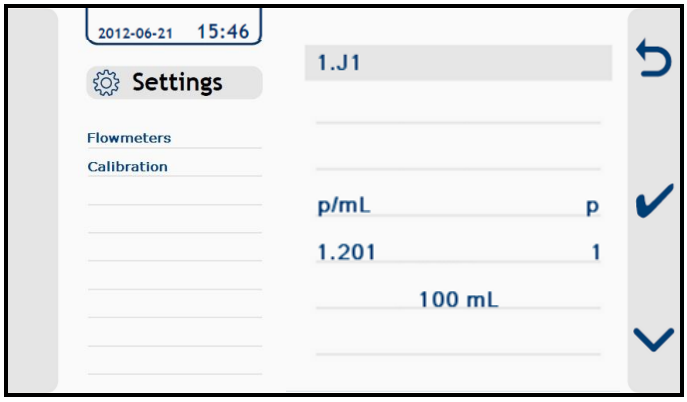


Chemical product

15.2.2 Check

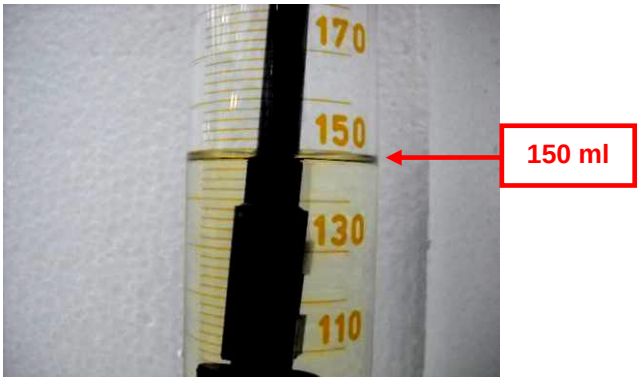
After the calibration it is necessary to control the calibration efficacy by the CHECK procedure.

Enter the menu: **SETTINGS → FLOWMETERS → Insert 2nd level password → CHECK**



Select the chemical flowmeter to check and press button ✔ to begin the calibration verification (in case the parameter setting does not allow access to the desired flow-meter, a pop-up window will appear and access will be denied).

Once finished the dosing, the level of product in the ml-graduated cylinder should be the same of that one shown in the display.



Chemical product

Whether the levels do not correspond, a new calibration must be executed.
The quantity of product to execute the calibration can be changed using 8.17 parameter.

AFTER THE CHEMICAL CALIBRATION IT IS NECESSARY TO RUN A RINSING CYCLE WITHOUT INSTRUMENTS INSIDE THE CHAMBER.

16. CLOCK

- The card has a real-time clock.
- Time readings are also used when recording historical data.

17. PC INTERFACE

The card has a communication channel RS 232.
The channel can be used to access the historical data records and the real time cycle data by setting the communication parameters as follows:

- Baud rate: 2400 bps;
- Handshake: No handshake;
- Data bits: 8 bits;
- Parity: None;
- Stop bits: 1 bit.

To view the data, it is necessary to enable the printer (Set the relative parameter to “YES”).

18. USB PORT

The USB port allows the machine programming and data saving.

18.1 Programming

Insert the USB key on the port and switch OFF and switch ON the control panel board.
On the display it will appear the page shown on the picture:

The page shows the new files installation (delete the existing files and install the new one).

It is possible to program:

- Cycles
- Parameters

18.2 Data saving

On this page it is possible to download from the machine the following information and files:

- Historical
- Parameters
- Program

Insert the USB key on the dedicated port and enter the menu and select the USB menu.

If one of the available fields is selected, but the USB memory stick has not been inserted, a pop-up window will appear to warn that the downloading of data is not possible.

If one of the available fields is selected and the USB memory stick has been correctly inserted, a pop-up window will appear to signal the downloading of the data in progress.
Another pop-up window will appear at the end of the download procedure.

USB - PAGE

FIELD	DESCRIPTION
	Press on the arrow to scroll the list of fields: • Historical • Parameters • Program The selected field will be highlighted in grey. Press the button in the center to download from the machine the selected data.

The cycle and parameter files can be used to program another machine or as back-up of the machine.

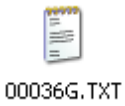
18.3 Data saving during the cycle

To save the data at the end of every washing program, insert the USB key on the dedicated port and follow the procedure:

Start the washing program.

At the end of the cycle the machine creates the file with the samples of temperature and pressure probes with the information of every washing program phases.

To every washing program are associated two files which contain the data structured as below.



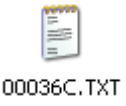
The file *****G.TXT contains:

N.B.: the *****G.TXT will be saved in automatically at the end of the washing program.

```
****************************************
          ****************
End user          :   ****************
Model             :
Machine           :   13146
Work station      :       0
Software          :    7.00
Operator          :
----------------------------------------
B20 PREWASH       Record:          00015
........................................
START:              05/06/13     h: 16:10
```

Information related to machine and operator.

Information related to washing program.



The file *****C.TXT contains:

N.B.: To save the *****C.TXT, insert the key in the dedicated port, enter the menu, select the USB menu and download from the machine the information of historical.

```
****************************************
          ****************
End user          :   ****************
Model             :
Machine           :   13146
Work station      :       0
Software          :    7.00
Operator          :
----------------------------------------
B20 PREWASH       Record:          00015
........................................
START:              05/06/13     h: 16:10

->  chemical load                h: 16:10
     T1=  35.2°C  T2=  35.1°C

->  1: drain                     h: 16:11
     T1=  35.1°C  T2=  35.0°C

->  2: prewashing                h: 16:16
     T1=  24.5°C  T2=  24.5°C

->  3: drain                     h: 16:17
     T1=  24.6°C  T2=  24.6°C

STOP:               05/06/13     h: 16:17
END CYCLE: OK
```

Information related to machine and operator.

Information related to washing program.

Information related to every washing program phase.

19. MAINTENANCE

19.1 General recommendations on maintenance

The intended use of the machine is the washing (with or without ultrasounds) and decontamination (low level disinfection) of surgical instruments, equipment and objects normally used in hospital wards and medical studios.
It is therefore subject to constant contact with aggressive detergents and with contaminated instruments.
For this reason it is necessary to provide some useful instructions for the operators who will be performing maintenance on it.

The maintenance technicians, in normal operating conditions, are not subject to risks if they work safely using suitable means of protection.
In order to work safely the maintenance technician must:

- Carefully comply with the instructions set forth in this manual.
- Use safety devices appropriately and with care, as well as group and individual safety gear provided in the workplace.
- Use special care in making repairs or replacing mechanical parts (e.g. drain pump, etc.) on malfunctioning machines which have not completed the cycle.

Maintenance operations for the machine described in this manual can be divided into "**Routine Maintenance**" and "**Special Maintenance**".

GENERAL GUIDELINES:

MACHINE STATUS
The machine must not be powered electrically and the dedicated safety device must be in the OFF position.
The person performing the task must ensure that there is no-one around the machine during this operation.

SAFETY SYSTEMS TO BE ADOPTED
The operation must be carried out in compliance with standards governing the use of disinfectant substances used (see technical information for the product being used), in compliance with standards concerning contact with parts of the machine which may be contaminated by pathogenic materials and with use of individual protection gear.

19.1.1 Maintenance request

The machine displays the "**MAINTENANCE**" warning after a specified time or after a specified number of working hours according to parameter **(P6.48-P6.49)**. This warning doesn't affect the normal use of machine.
The service technician must do the maintenance operations in the shortest possible time.

To clear the "**MAINTENANCE**" warning, it is necessary to set the parameter **2.13**.

19.2 Procedure for routine maintenance work

Routine maintenance includes all operations aimed at keeping various parts of the machine clean and functional.
They must be performed on a regular basis (see table of routine maintenance tasks) or when considered necessary due to incorrect performance of treatment cycle.

Since these are simple cleaning operations, they are normally performed by the machine operator on his own liability.

19.3 Table of routine maintenance tasks

The following table shows the various routine maintenance tasks, their frequency, which is to perform them and the reference to the specific intervention form.
Each single task is more fully explained in the single reference forms.

Even if the water supply is relatively soft, the high temperature can cause the formation of residues which may create problems with the heating element, compromising the correct treatment cycle and the reaching of the treatment temperature.
For these reasons it is advisable to carry out regular cleaning as described below.

TABLE OF ROUTINE MAINTENANCE TASKS

US 80

MAINTENANCE CHECK LIST

Parts	Step make every.....	months 3	6	9	12	15	18	21	24	Activity	REFERENCE
Tank filters	make every day									Take off filters and cleaning.	M2
Water solenoid filter	make every.....		x		x		x		x	Check, clean and if necessary replace.	M1
Chemical dosing pumps	make every.....		x		x		x		x	Check the inner pipe condition and leaks presence.	M3
Inner pipe and connection pipe of dosing pump	make every.....				x				x	Replace.	M3
Connection pipe of dosing pump	make every.....		x		x		x		x	Check for crushing, initial leaks or hardening.	
Door gasket	make every.....		x		x		x		x	Verify the gasket and replace after 1000 cycles.	
Water heating elements	make every.....				x				x	Check for water leaking from seal.	
Water solenoid valve	make every.....				x				x	Check for any leaks, if necessary remove and clean the membrane seat.	
Drain solenoid valve	make every.....				x				x	Check for any leaks, if necessary remove and clean the membrane seat.	

N.B.: The time frames for execution of the maintenance programme may vary by +/- 15 days from the period indicated in the table.

N.B.:
Routine maintenance tasks must be performed at the intervals set forth in the table.
It is however advisable to carry out single cleaning tasks anytime you feel they may be necessary.

N.B.: In case the machine requires the replacement of one or more components, please refer to the manufacturer's spare part list.

⇨	**It is advisable to carry out a general check-up and to clean the appliance regularly, particularly if the supply water is very hard.**

WARNING:

- Do not clean the machine outside with high pressure water.
- Please contact the retailer that supplies your cleaning products for details of recommended methods and products for sanitizing the machine regularly.

WARNING

IT IS NECESSARY TO MAKE A MAINTENANCE AT REGULAR INTERVALS, THIS MEANS EVERY 3 MONTHS, IN ORDER TO GUARANTEE THE PERFECT FUNCTIONING OF PUMPS DOSING CHEMICAL PRODUCTS.

CLEANING OF WASH TANK DRAIN FILTER		
M2	Worker: **Ac**	Frequency of Intervention: **3 months**
METHOD OF INTERVENTION: clean the tank drain filter in the following manner:		
• Open the wash tank door.		
• Extract the drain filter from the tank. 		
• Clean the drain filter. Remove residues deposited during various cycles. 		
• Replace the clean filter on the tank drain.		

DISINFECTION AND CLEANING OF THE TANK

	Worker: **Ac**	Frequency of Intervention: **Once a week or when it is necessary**

METHOD OF INTERVENTION:

It is advisable to proceed with the disinfection of the machine as described below:
- Open the access door to the tank and check that no equipment or instruments have been left inside.
- Spray a disinfectant product compatible with steel surfaces evenly on the inside of the tank.
- All internal parts must be treated by this operation.

The approved STEELCO product for cleaning and disinfection of the tank is called "STEELCO Surface Cleaner Disinfectant".
N.B.: “Steelco SCD” must be sprayed directly onto a low particle generation cloth that will then be used on all internal surfaces and accessories. Contact time must be 10 minutes. Should this product be sprayed directly onto the surfaces, following a 10-minute contact time, remove the product using the cloth.

ATTENTION

As regards the contact time and the methods of use of the disinfectant used, please comply with the instructions given on the technical data sheet of the product itself.

Always check the compatibility of the chemical product with the materials it will be used on; this information can be found on the technical data sheet of the chemical product used.

The application of the disinfectant inside the chamber must be carried out when the surfaces are cold in order to avoid harmful fumes coming from the product being inhaled.

CLEANING THE EXTERNAL BODY OF THE MACHINE

	Worker: **Ac**	Frequency of Intervention: **daily/weekly**

METHOD OF CLEANING OUTER BODY:

Use a damp cloth to clean the outer body of the machine.
Use only neutral detergents.
Do not use abrasive detergents or solvents and/or thinners of any kind.

METHOD OF CLEANING MARKING LABEL:

Use a damp cloth to clean the marking label surface. Use only water or isopropyl alcohol.
Do not use abrasive detergents or solvents and/or thinners of any kind.

METHOD OF CLEANING CONTROL PANEL:

Clean the control panel using only a soft cloth dampened with a product for the cleaning of plastic materials.

LIMESCALE REMOVAL TREATMENT

	Worker: **Ac**	Frequency of Intervention: **whenever necessary**

MODALITA' DI INTERVENTO:

Use a descaling agent (we recommend vinegar) during an empty washing cycle with cold water (this is usually carried out every week unless the quality of the water requires a daily treatment in order to prevent the build-up of limescale and the blockage of the water jets).
As regards the quantity of the product to use, please comply with the instructions given on the technical data sheet of the product itself.
In case vinegar is used, use a quantity amounting to 100 ml.
The descaling product must be poured into a container of the same size, positioned on an empty loading basket.
Use a washing programme with water at room temperature.

19.4 Procedure for special maintenance work

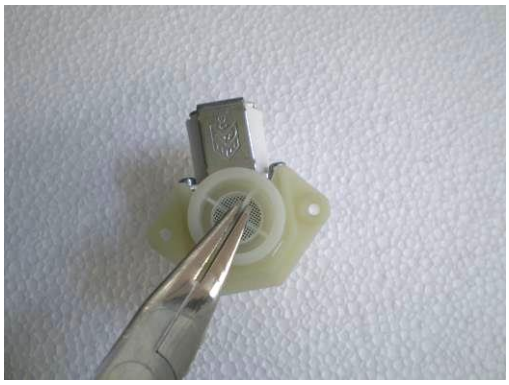
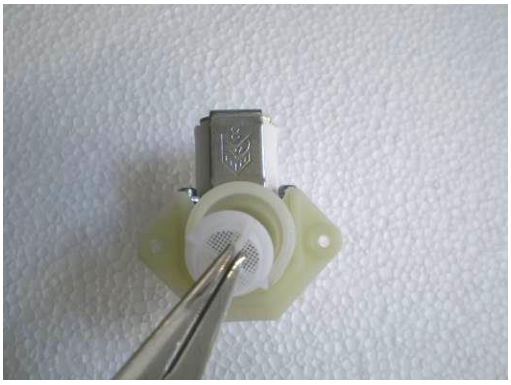
All special maintenance work is to be performed only by qualified, skilled personnel.
A table is shown below which includes possible special maintenance work that may be required.
If your machine should require special maintenance, please contact your retailer/distributor.

19.5 Table of special maintenance

See scheduled maintenance form table.

CLEANING OF COLD EATER INLET FILTERS		
M1	Worker: **Is**	Frequency of Intervention: **6 months**
METHOD OF INTERVENTION: clean (or replace) the filter on the cold water supply tube as described below:		

- Close the water supply tap.
- Loosen and completely unscrew the water supply pipe.
- Remove the filter located inside the water supply pipe fitting and clean it, removing any incrustation or deposits by immersing it in a container of water, or in appropriate lime removal products if required.


REPLACEMENT THE MEMBRANE PIPE OF DISPENSING PUMP

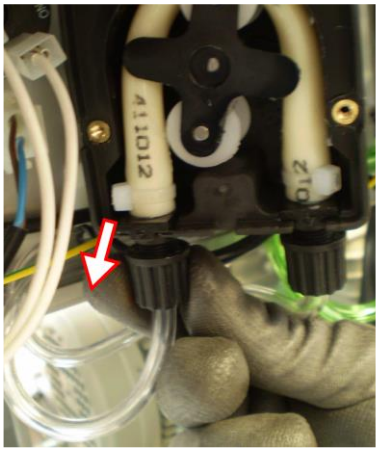
M3 | Worker: **Is** | Frequency of Intervention: **from 3 to 6 months**

METHOD OF INTERVENTION: replace the membrane pipe of dispensing pump for chemical products as described below:

1. Open the closure panel.

2. Access the chemical product pump. Use a tool to remove the protective mask of the rotor.

3. Extract the membrane pipe from the dispensing pump.



4. Turn the rotor manually, clockwise, until the membrane pipe is fully extracted from the dispensing pump.

ATTENTION: the rotor of dispensing pump turns ONLY clockwise !!!

5. Place the membrane pipe in vertical position to help the flow of chemical product from membrane tube to chemical circuit. Do this operation to prevent leakage of chemical product during replacement.

6. Loosen the tube clamps and disconnect the product supply tubes from the membrane pipe attachments.

7. Replace the membrane pipe with another the same type (see the spare part list).

8. Replace the membrane pipe into dispensing pump, manually operating the rotor.

ATTENTION: the rotor of dispensing pump turns ONLY clockwise !!!

9. Replace the protective mask of the rotor.

N.B.: Every 3/6 months, it is advisable to replace the membrane pipe of the dispensing pump.

CLEANING OF DISPENSING PUMP FOR CHEMICAL PRODUCTS		
M3	Worker: **Is**	Frequency of Intervention: **3 months**
METHOD OF INTERVENTION: clean the pump for the dispensing of chemical products as described below:		

- Open the closure panel.
- Access the chemical product pump. Use a tool to remove the protective mask of the rotor.
- Loosen the tube clamps and disconnect the product supply tubes from the membrane tube attachments
- Turn the rotor manually, clockwise, until the membrane tube is fully extracted from the dispensing pump.
- Apply an even layer of silicon grease to the membrane tube you have just removed before re-installing it on the dispensing pump, following the previously described operations in reverse order.

CLEANING OF SAFETY SIGNALS SURFACES		
	Worker: **Is**	Frequency of Intervention: **1 year**
METHOD OF INTERVENTION:		
Clean the safety signals surfaces with water or isopropyl alcohol, using a cloth.		

ASSISTANCE

Should your machine not work properly even after ordinary maintenance has been carried out, contact the Technical Support Centre of reference, describing the fault and giving the machine model and serial numbers.

20. PROBLEMS - CAUSES – SOLUTIONS

20.1 Introduction

This chapter includes possible problems which may occur during machine operation, along with their cause and solution. All components, if not identified by specific figures, are referred to by the attached assembly drawings.
Should the inconveniences continue or take place frequently even after having carried out all the instructions stated in this chapter, please contact the Technical Support Centre of reference.

20.2 Problems – Causes – Solutions

I. MACHINE WILL NOT START:

C. Circuit breaker de-activated.

R. Place it in the "ON" working position.

I. MACHINE DOES NOT REACH SET TEMPERATURE FOR THE SELECTED TREATMENT CYCLE:

C. The heating element is dirty or covered with lime.

R. Clean the heating element.

I. MACHINE DOES NOT PROPERLY RUN TREATMENT CYCLE:

C. Water required for proper treatment does not arrive.

R. Ensure that the water is supplied at the correct pressure and that there are no obstructions.

C. The correct amount of water required for correct treatment cycle does not arrive.

R. Completely close the tap for connection to the plumbing system located upstream from the machine and lean the filter.

I. DETERGENT FILLING PHASE DOES NOT OCCUR CORRECTLY:

C. Chemical dispensing pump not very efficient.

R. Perform the routine maintenance set forth in “Maintenance” chapter.

C. Chemical dispensing pump failed.

R. Contact the Technical Support Centre of reference and request the intervention of an Authorised Technician to perform the repair or the replacement of the pump.

21. DECOMMISSIONING

21.1 Instructions for disassembly of the machine

Please note that the machine may contain contamination from blood and other bodily fluids, pathogens, facultative pathogens, genetically modified material, toxic or carcinogenic substances, heavy metals, etc., and must be decontaminated before disposal.

For environmental and safety reasons, dispose of all process chemical residues in accordance with safety regulations. Wear gloves and protective goggles.

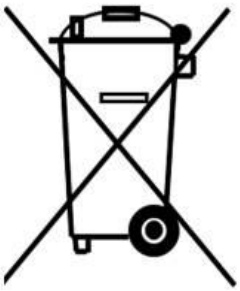
Remove or disable the door lock prior to disposal of the machine, so that children cannot become trapped inside. Then make appropriate arrangements for safe disposal of the machine.

For demolition and subsequent disposal of your machine, proceed as follows:

- Disconnect the machine from the electrical power and water supply, and from the drain.
  With the machine disconnected, check that the water circuit is not pressurized.
- Contact the organization responsible for reporting and certifying machine demolition, in accordance with the laws in the country where the machine is installed.
- Carry out draining, storage and subsequent disposal of substances such as oils and grease which may be in the lubrication tanks in accordance with the law.
- When disassembling the machine, make sure to divide the materials it is made of according to their chemical makeup (iron, aluminium, bronze, plastic, etc.).
- Ensure that the floor where the machine or any parts of it are placed is made of washable materials, non-absorbent, and provided with adequate drainage to protect against accidental oil leaks or rust.
  These drains must carry any leakage to watertight collection containers.
- Cover the machine or parts of it with insulating covers to prevent rain or humidity from damaging the structure through oxidation or rust.

Following the legal requirements where the machine is installed and used, dispose of all materials and substances resulting from its disassembly.

21.2 Machine disposal



- For the dispose of the equipment get through to the manufacturer or distributor.
- Do not dispose of this equipment as miscellaneous solid municipal waste, but arrange to have it collected separately.
- The re-use or correct recycling of the electronic and electrical equipment (AEE) is important in order to protect the environment and the well-being of humans.
- In accordance with European Directive WEEE 2012/19/EC, special collection points are available to which to deliver waste electrical and electronic equipment and the equipment can also be handed over to a distributor at the moment of purchasing a new equivalent type.
- The public administration and producers of electrical and electronic equipment are involved in facilitating the processes of the re-use and recovery of waste electrical and electronic equipment through the organisation of collection activities and the use of appropriate planning arrangements.
- Unauthorized disposal of waste electrical and electronic equipments is punishable by law with the appropriate penalties.