World Health Organization

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Anexa 4

Achiziție Dispozitiv de spălare și dezinfectare automată a instrumentelor chirurgicale 200 l

Lista cerințelor și specificațiilor

Dispozitiv de spălare și dezinfectare automată a instrumentelor chirurgicale 200 litri					
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	Dispozitiv de spălare și dezinfectare automată a instrumentelor chirurgicale 200 litri		**MODEL: DS610/2 SL G2 Producător: Steelco S.p.a. Țara: Italia**	
CARACTERISTICI TEHNICE și CARACTERISTICI FIZICE					
2	CAPACITATE	Volumul camerei de spălare (convențional 200l), dreptunghiular, orizontală cu încărcare frontală (min. 8 coșuri DIN)	min. 190l-240l max.	DA 255 l sau 12 cosuri DIN	pag. 2 din DS 610 SL G2 Data Sheet
3	CADRU, CORP, CAMERA DE SPALA	Versiunea cu uși duble (de trecere)	da	DA	pag. 3 din DS 610 SL G2 Data Sheet
		Camera de spalare din otel inoxidabil AISI 316L	da	DA AISI 316 L sau DIN 1.4404	pag. 3 din DS 610 SL G2 Data Sheet
		Față din oțel inoxidabil AISI 304L, capace laterale	da	DA AISI 304 sau DIN 1.4301	pag. 3 din DS 610 SL G2 Data Sheet
		țevile și fitingurile sunt fabricate din oțel inoxidabil 316L	da	DA AISI 316 L sau DIN 1.4404	pag. 3 din DS 610 SL G2 Data Sheet
		Ușă complet automată cu sticlă dublă călită.	da	DA automată sau motorizată	pag. 3 din DS 610 SL G2 Data Sheet
		Brațe rotative pentru jetul de apă în interiorul camerei	minim 2, sau pe fiecare nivel de rack	DA 2 inclusă in standart si deja in dependeta de cos pot fi difertite	pag. 3 din DS 610 SL G2 Data Sheet
		Min. 2 pompe dozatoare de detergent și dezinfectant	da	DA inclus 2 pompe	pag. 4 din DS 610 SL G2 Data Sheet

		Ventilator motor de uscare, min. 150 m3/h	da	DA 155m3/h	pag. 4 din DS 610 SL G2 Data Sheet
		Pompa de apa, integrată	da	DA	pag. 4 din DS 610 SL G2 Data Sheet
		Prize de apă pentru apa rece, caldă și distilată	da	DA	pag. 3 din DS 610 SL G2 Data Sheet
		Spațiu de stocare integrat pentru dezinfectant și detergent	da	DA	pag. 4 din DS 610 SL G2 Data Sheet
		Dacă apare o pană de curent, ușa poate fi deschisă manual. Este prevăzut un dispozitiv de blocare a ușii e pentru a preveni contaminarea încrucișată	da	DA	pag. 26 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2
4	CICLU	Proces de spălare și dezinfecție complet automat, controlat de microprocesor	da	DA	pag. 4 din DS 610 SL G2 Data
		minim 5 programe prestabilite din fabrică	≥ 5 programe	DA 15 programe predifinite	pag. 49 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2
		minim10 programe care pot fi programate de utilizator	≥ 15 programe în total	DA 50 programe care pot fi create in total 65 prgame	pag. 4 din DS 610 SL G2 Data Sheet
		Interval de temperatură 15-95 ºC	da	DA maximul este indicat pina la 93°C dar protocolul si temperatura poate fi setat conforam standartelor nationale vezi protocolaele din manualul de utilizare	pag. 3 din DS 610 SL G2 Data Sheet pag. 49 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2
		Monitorizarea temperaturii cu min. 3 senzori electronici de temperatură de înaltă precizie	da	DA se foloseste o tehnologie mai precisă două microprocesoare separta verifică temperatură după se face media care nu permite o deviere de zecimi din temperatură	pag. 4 din DS 610 SL G2 Data Sheet
		Sistem dublu de incalzire: cu abur si electric	da	DA	pag. 4,6 din DS 610 SL G2 Data Sheet
		Ciclurile minime furnizate de mașina de spălare și dezinfectare trebuie să includă: prespălare, curățare, clătire intermediară, dezinfecție termică/clătire finală, uscare.	da	Da	pag. 5 din DS 610 SL G2 Data Sheet
		mașinile de spălare și dezinfectare ar trebui să aibă un ciclu validat	da	DA	
		Ecranul va afișa: indicarea ciclului, mesaj text și reprezentări grafice ale procesului, temperatura apei, timpul rămas, numărul programului	da	DA	pag. 36 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2 - *Paragraful 8. CONTROL PANEL*

		Trebuie să aibă un mod de service pentru testarea de întreținere preventivă și pentru a facilita depanarea. Program de diagnosticare de service încorporat pentru a permite calibrarea sistemului și verificarea operațiunilor componentelor.	da	DA	pag.59 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2 - *Paragraful 11.6.3. Maintenance*
5	SIGURANȚĂ	Protecție împotriva temperaturii excesive	da	DA	pag.71 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2
		Alarme: pană de curent, eșec ciclului de dezinfecție	da	DA	pag.61 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2
		Sistem intern de condensare a aburului, care reduce cantitatea de abur în timpul uscării și previne scurgerea aburului	da	DA	pag.7 din DS 610 SL G2 Data Sheet
		Iluminarea interioara a camerei	da	DA	pag.5 din DS 610 SL G2 Data Sheet
		Butoanele de oprire de siguranță, unul pe partea de încărcare și unul pe partea de descărcare, oprește automat toată activitatea unității atunci când este apăsat.	da	DA	pag.19 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2
		Ușile trebuie să fie izolate termic pentru a preveni ca temperatura suprafeței să prezinte un potențial pericol pentru operatori	da	DA	pag.3 din DS 610 SL G2 Data Sheet
		Ușile se blochează pentru a preveni deschiderea ambelor părți	da	DA	pag.3 din DS 610 SL G2 Data Sheet
		Este da să dispună opțiunea de măsurare a conductibilității apei în timpul clătirii finale	da	DA	pag.7 din DS 610 SL G2 Data
		Controlul nivelului apei prin senzor de nivel și protecție la supraplin	da	DA	pag.4 din DS 610 SL G2 Data Sheet
6	AER	Aerul folosit la mașina de spălat fără ulei (adică nu trebuie să aibă mai mult de 0,5 mg de ulei pe metru cub de aer liber măsurat la 1013 mbar și 20ºC; vezi ISO 554); filtrat la o eficiență de cel puțin 95% atunci când este testat. lipsit de bacterii	da	DA denumit si air medical	
		Filtru HEPA Clasa H14, încorporat, destinat sistemului de uscare forțată cu aer.	da	DA aerul merge prin HEPA filtru H14 efecienta 99,99 % (EN 1822)	pag. 4 din DS 610 SL G2 Data Sheet
		Sistem „deschis” pentru utilizarea detergenților și dezinfectanților, mașinile de spălare și dezinfectare trebuie să fie deschise pentru a utiliza diferiți detergenți și chimicale, nu doar de la un singur producător	da	DA	pag. 8 din DS 610 SL G2 Data Sheet
		Loc special integrat pentru chimicale și detergenți	da	DA	pag. 4 din DS 610 SL G2 Data Sheet
		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	pag. 157 din Service Manual PLW 7111, LAB 610 G2, DS 600 G2, DS 610 G2, DS 610 SL G2

7	Cerințe pentru detergenți, aditivi și compatibilitate cu alți aditivi chimici	Și detergenții și aditivii utilizați ar trebui să fie compatibili cu alte substanțe chimice utilizate în aceeași etapă a procesului, cât și, în măsura în care este posibil, cu cele utilizate în etapele precedente și ulterioare, pentru a minimiza efectul negativ la intercalare. Agenții de curățare utilizați în mașinile de spălare și dezinfectare ar trebui să fie: lichizi (pentru a facilita distribuirea precisă); neabraziv; spumare redusă; supus ușor la clătire; biodegradabili. Detergenții nu trebuie să conțină: agenți de colorare artificiali; înălbitori optici; parfumuri; halogenuri la o concentrație în utilizare mai mare de 120 mg/L; săpunuri grase, glicerină sau lanolină; reziduu toxic.	da	DA find un sistem de tip deschis ramine la preferinta utilizatorului tipul de dezinfectat unica necesitate este necesara sa fie de tip lighită.	
8	PREPARAREA APEI ȘI CALITATEA	Duritate totală: < 3 °d (< 0,5 mmol CaO/L) Conținut total de sare: < 500 mg/l Conținut de clor: < 100 mg/l Valoare pH: 5-8	compatibil cu mașina de spălat	DA	pag. 20 din Service Manual PLW 7111, LAB 610 G2, DS 600 G2, DS 610 G2, DS 610 SL G2
		încălzire electrică integrată a apei	da	DA	pag. 4 din DS 610 SL G2 Data Sheet - *EEX*
CARACTERISTICI ELECTRICE					
9	CARACTERISTICI ELECTRICE	380V, 50 Hz, 3 faza	da	DA	pag. 3 din DS 610 SL G2 Data Sheet -380/415 V 3 faze
Caracteristici electronice					
10	Caracteristici electronice	Panouri cu ecran multicolor de minim 5" dintr-o parte cu butoane sau opțiune de ecran tactil	da	DA 5 Inch	pag. 4 din DS 610 SL G2 Data Sheet
		Niveluri de acces la meniul de service prin parole/ coduri de acces. Toate parolele/codurile de acces vor fi puse la dispoziția personalului tehnic la momentul predării-primirii dispozitivului	da	DA	pag. 4 din DS 610 SL G2 Data Sheet
		Testul de diagnosticare permite verificarea sistemului	da	DA	
		Senzor de nivel pentru controlul detergenților și dezinfectanților	da	DA	pag. 4 din DS 610 SL G2 Data Sheet
		Conexiune RS232 pentru acțiuni tehnice	da	DA comunicare pentru service se face prin USB si RJ 45 este mult mi autilizat si mai accesibil	pag. 4 din DS 610 SL G2 Data Sheet
		mașinile de dezinfectare sunt controlate de un dispozitiv logic programabil electronic (PLC) care acoperă performanța ciclului, controlul parametrilor și verificarea siguranței procesului	da	DA	pag. 14 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2

		Memorie internă pentru stocarea a minim 500 de cicluri	da	DA pina la 100.000 cilcluri	pag. 4 din DS 610 SL G2 Data Sheet
ACCESORII, CONSUMABILE, PIESE DE SCHIMB, ALTE COMPONENTE					
11	Accesorii/ piese de schimb	Kit de întreținere pentru min. 2 ani	min. 2 ani	DA inclus	
		Raft multifuncțional cu 2 niveluri minm. Folosit pentru a ține tăvile de instrumente încărcate în timpul procesării de decontaminare	da	DA 4 nivle PN: C1811	pag. 28 din Operation Instruction DS 600 EZ, 600, 610, 610 SL - G2
		Trebuie să includă un detergent și un dezinfectant pentru minim 100 de cicluri de spălare, inclusiv cicluri de testare.	da	DA inclus	
		Hârtie de imprimantă 10 buc	min. 10 buc.	DA inclus	
		Imprimantă de date integrată (hârtia utilizată pe imprimantă trebuie să aibă dimensiuni universale utilizate în alte unități)	1	DA inclus	pag. 7 din DS 610 SL G2 Data Sheet
		Sistem de încărcare (cărucior/troleu), dimensiune ajustată la modelul oferit	2 cărucioare	DA inclus	T641 Fixed height transfer trolley - din broshura
		Compresor de aer (fara ulei), numai pentru modelele care folosesc aer comprimat	da	DA inclus	
INSTRUIRE, INSTALARE SI UTILIZARE					
12	Transport	Furnizorul trebuie să includă transportul până la unitatea medicală finală	da	DA inclus	
13	Instalare	Furnizorul trebuie să efectueze verificările de instalare, siguranță și funcționare înainte de predare. Trebuie asigurată instruirea utilizatorilor și a tehnicienilor.	da	DA inclus	
		Supape de presiune pentru apă și pompe de evacuare a apei în canalizare, dacă este cazul	da	DA inclus	
		Traseul de electricitate și canalizare a punctelor de racordare, va fi asigurat de beneficiar (confom recomandărilor producătorului)	va fi asigurat de beneficiar	DA inclus	
GARANȚIE ȘI ÎNTREȚINERE					
14	Garanție și deservire completă (inclusiv piese de schimb)	minim 24 de luni	da	DA 24 luni	
DOCUMENTAȚIE					
15	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 inclus	
SIGURANȚĂ ȘI STANDARDE					
16	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. EN ISO 15223 6. EN ISO 14001	toate certificatele trebuie prezentate în copii cu ștampila de confirmare	DA	CE este in acord comun cu MDR (2017/745/EU), standartul care devine valabil pentru Europa, este aplicabil EN ISO 15883-1/-2/-5. pag. 2 din DS 610 SL G2 Data Sheet si Certificatea Atasate

DS 610 SL G2

Surgical instrument washer disinfector

The DS 610 G2 range of medium capacity – 12 DIN – washer disinfectors offer flexible and scalable solutions to meet the reprocessing needs of mid-sized clinics and CSSDs. The washer disinfectors are foreseen to be installed in barrier or as freestanding devices.

This range of devices offers a complete washing and thermal disinfection treatment and are equipped with an efficient hot air-drying system which ensures after disinfection a perfect drying of all instruments and tubes thanks to the accurate distribution of the air on all the chamber zones and on the washing cart levels.

Fast cycle configurations allow for shorter cycle times with a great improvement of working efficiency and a consequent reduction of energy consumption.

The different applications are performed by using dedicated washing carts and accessories: surgical instruments, MIS instruments, anesthesia instruments, ophthalmology instruments, dental instruments, containers, OP rubber shoes, baby bottles, laboratory glassware…

DS 610 G2 can also be equipped with Power Pulse technology. Power Pulse Cleaning (PPC) allows to reduce or totally skip manual pre-treatment in the cleaning process of complex narrow lumen surgical instruments. PPC involves the pulsing of medical grade air pressure bursts during channel flushing for generating a strong front wave and water turbulence along lumen walls improving mechanical cleaning action of lumens, joins and junctions. PPC also improves instrument drying by triggering air pulses during the drying phase.

The Flexible Loading System allows preparation of instruments in single modules and a facilitated loading of the wash cart, improving safety and ergonomics. A wide range of modules is available, including one specifically designed to have the Power Pulse.

The DS 610 G2 range is completed with fixed or variable height loading trolleys or automatic systems where applicable.

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Versions

Model name	Door opening	Overall dimensions			Chamber dimensions		
		W	H	D	W	H	D
DS 610 SL G2		650 mm 25.59”	1940 mm 76.38” 2395* mm 94.29”	700 mm 27.56”	570 mm 22.44”	728 mm 28.66”	614 mm 24.17”

*Read the “Steam condenser” paragraph in the “Option features” section

Technical features

Washing capacity

- 12 DIN baskets 480x250x50
- 5 ISO baskets 485x344x50
- 6 SPRI baskets
- 2 DIN container 250x600x300

Usable chamber volume

- DS 610 G2: 253 l (55.65 gal US)
- DS 610 SL G2: 255 l (56.09 gal US)

Water consumption

12-22 l according to cycle phase and type of load

Noise

<70 dB(A)

Standard compliances

Medical device marked CE with notified body code no. 0051, according to MDR (2017/745/EU) and applicable standards such as EN ISO 15883-1/-2/-5.

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Construction

Frame

- Frame made of stainless steel AISI 304 (DIN 1.4301)
- Panels made of stainless steel AISI 304 (DIN 1.4301) brush finishing

Doors

- Doors made of double HST temperate glass with inside frame made of stainless steel AISI 316L. A silicone foam gasket ensures the perfect sealing of the door system with the washing chamber

Washing chamber

- Washing chamber, washing arms, pre-heating tanks and water filters made of high quality stainless steel AISI 316 L (DIN 1.4404) polish finishing
- Self-cleaning sump with rounded edges to avoid dirty deposit and bacterial growth

Components

- All the critical components are made of stainless steel or material resistant to aggressive chemicals

Thermal insulation

- High quality thermal insulation to minimize energy loss

Standard features

Door

- Motorized sliding down glass door with safety device. The glass door grants total visual monitoring of the process and is made of double HST (High Shock Tested) tempered glass
- The device is equipped with a safety lock system which is activated during all the cycle time to protect the operator against any inconvenience and to prevent any misuse of the device
- In the double door pass through version, doors are interlocked to avoid simultaneous opening

Washing chamber

- Washing chamber system is constructed without angles therefore removing breeding ground for germs
- The self-cleaning sump, built with rounded edges, allows a very fast drainage phase, and improves the water recirculation system during the treatment
- Two levels water filtering system to capture residue and preventing their re-circulation to grant excellent washing results

Device main switch

- Disconnects the machine from the electrical utilities
- Located inside the technical area in the bottom part of the machine

Water connections

- Connections available for cold water, warm water, and demi water

Washing system

- 2 washing spray arms are installed on the top and bottom of the washing chamber to grant an efficient water and air distribution inside the chamber
- Easy disassembling washing arms for cleaning and maintenance
- Up to five more washing arms in the available wash carts
- The device permits the automatic and direct connection to the washing cart hydraulic circuit. This allows the water distribution through rotating arms and/or injection systems dedicated to the treatment of hollow instruments
- Washing and drying injection system on the same circuit
- The device is equipped with a variable speed washing pump with a max flow rate of 700 l/min (184.92 gal.US/min)
- Pump power 750 W
- Pressure switch on washing circuit
- Thermal disinfection achieved by raising the DI water temperature up to 93°C (200°F) and holding it for a selected time which can be set in accordance with end user specific requirement and different countries law protocols
- Thermal disinfection phase can be managed either with temperature/holding time or by setting the A_0 target
- Identification of the wash cart type for the automatic assignation of cycle program

Heating configuration

- EEX (Electrically heated water recirculation, Electrically heated drying)
- Multi-frequency 380/415V range 3 phase + N, 50Hz or 60Hz

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Filter system

- Water filter on inlet water solenoid valves protecting the device from incoming water debris
- Two-stage filtration of the water recirculation system to protect recirculation and drain pumps from debris
- Filters can be easily removed for cleaning

Process water volume control

- Flowmeters monitor water volume loaded in the sump

Chemical dosage system

- The device is equipped with two maintenance free dosing pumps under complete micro-processor control with the possibility to customize the quantity of liquid dosed. Additional chemical dosing pumps are available as option
- Double control of the chemical dispensing system with time-dosing and volume check through flow meters
- Chemical product quantity check with minimum level alarm

Chemical storage

- Large storage on bottom basement to place up to three chemical containers of 5 lt. (1.32 gal US) each. Chemical storage is accessible through a removable panel
- UL version has limited room

Water recirculation heating system

- 8.4 kW (three 2.8 kW elements) electric heating elements in the sump providing heating up to 93°C (200°F)
- Electric thermostat

Temperature control system

- Temperature check by means of 2 PT1000 independent probes
- Temperature probes monitor the device cycle temperature. Temperature measures are also documented parameters of the disinfection phase. During the cycle, the delta temperature between the probes is monitored by two independent microprocessors which stop the cycle in case of discrepancy higher than 2° C

Gravity drain

- The device is standard foreseen for gravity drain, drain pump is available as option

Forced hot air drying with HEPA filter

- Forced hot air-drying system for a perfect distribution on all the washing chamber, washing cart levels and/or washing cart injectors for MIC and anesthesia instruments applications
- ISO coarse pre-filter
- Electrical heating element of 4 kW
- Heating elements provide up to 130°C (184°F) air
- Blower flow rate up to 155 m^3/h (5473.77 ft^3/h), 550 W of power
- HEPA filter H14 grade with global efficiency M.P.P.S. 99,995% (EN 1822)
- HEPA filter H14 is placed after the heating elements and the blower avoiding any source of contamination from the blowing system

Microprocessor control system

- The device is controlled by a microprocessor for total checking and displaying cycle phase parameters. An independent monitoring microprocessor checks temperature and chemical dosing parameters
- Cycle phase and process residual time are highlighted on the HMI
- Possibility to memorize 65 different cycles programs
- 5 levels of password to protect the system and the access to new programs
- Up to 100.000 historical cycle data storage

System control panel

- Color touchscreen 7” LCD display on loading and unloading side

System monitoring

- Acoustic and visual alarms to control each single washing cycle
- A minimum water level sensor is placed at the lowest position of the chamber sump to check for water presence. A pressure switch in the pump checks for water pressure presence
- USB port for historical cycle data, machine parameters and washing programs download and upload

Wi-Fi & Ethernet connection

Floor anchoring

- The machine is foreseen to be floor anchored. See details in the GA drawings

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Spill detection monitor

- Placed within the washer base tray, allows spill detection alarm activation

Light inside the chamber

- A white LED light allows clear visibility of the machine load

Device plinth on rollers

- For easy service and installation

Automatic loading/unloading

- Only available for the sliding door version

Programming and cycle operation

The user can create customized programs to meet specific needs. Listed are various phases that can be programmed and repeated into various combinations.

- **Pre-Wash** – User can define the length of the wash cycle, detergent dosing and select between cold, hot and DI water or mix two sources
- **Wash** – User can define the length of the wash cycle, detergent dosing and dosing temperature, temperature of the water and select between cold, hot and DI water or mix two sources
- **Rinse** – User can select the length of the rinse, the presence and the amount of neutralizer, temperature of the water and select between cold, hot and DI water or mix two sources
- **Thermal disinfection** – User can define the length of the DI water rinse, temperature of the water up to 93°C (200°F) presence and amount of rinse aid. Thermal disinfection phase can be managed either with temperature/holding time or by setting the A_0 target
- **Drying** – Programmable between low speed and high-speed drying and up to a temperature of 130°C (284°F). Operation time of the steam condenser

Pass through function

- The purpose of the operation is to allow the passage of clean baskets from the unloading to the loading environment, through the machine itself (the passage can be repeated several times). This function is available until a new cycle is started

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Option features

Heating configuration

Steam heating

- Steam heating configuration option converts all the heating systems to steam-to-water: water recirculation system, pre-heating tank. Drying heating remains electrically heated

Mixed heating

- Mixed heating configuration option converts all the heating systems to mixed heating (a software parameter activates either the steam or electrical heating systems): water recirculation system, pre-heating tank. Drying heating remains electrically heated

Structural machine configuration

Three color light inside the chamber

- Light color according to device status:
  White = on cycle
  Green = cycle completed
  Red = in alarm

Machine connections

Kiwa Watermark Certification

- Water backflow prevention safety certificate for devices to be installed in The Netherlands

Built-in water softener

- Positioned below the chamber
- Only softens the cold water feeding the sump

Built-in pressure booster pump for demi-water

- Provides proper water pressure for demineralized water supply

Drain water cooling system

Drain pump

- Independently operated drain pump for efficient pumping out water waste

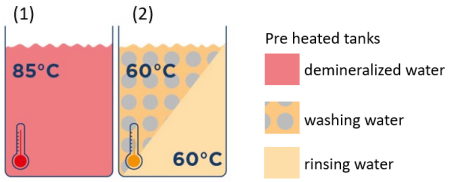
Built-in 2-way drain

- It allows to drain water after each cycle phase either to main drain or to an external secondary tank for reuse. It requires drain pump option. it reduces storage space for chemicals to 2 x 5 liters canisters

Hydraulic configuration

Pre-heating tanks

- The machine can be equipped with up to two tanks for the pre-heating of thermal-disinfection and/or washing phase water
- 6 kW electrical heating elements (each tank)
- Pre-heating tanks are connected directly with the washing chamber through large valves thus allowing a reduction of the water loading time and of the whole cycle



- The pre-heated demineralized water tank (1) (85°C standard set) allows radically reduced thermal-disinfection process time and consequently total cycle time. This pre-heating tank also includes an additional dedicated DI water inlet controlled by a solenoid valve
- The pre-heated hot water washing tank (2) (60°C standard set) allows to reduce washing process time and consequently total cycle time while the machine is performing the washing phase the washing tank (2) is filled with rinsing water and pre-heated. Saving heating time in the washing chamber avoids also cool down thus reducing energy loss
- The functions and the heating temperatures of the pre-heating tanks can be varied to best suit the customer's procedures
- Pre-heating tanks can be self-disinfected and self-emptied. Disinfection and emptying can also be programmed with auto-start
- Tank heating system (electrical, steam or mixed) is in accordance with the main heating configuration of the device

Steam condenser

- Prevents the emission of vapors entering the washing area. Temperature set is programmable from 0°C to 93°C (32°F – 200°F)
- Steam condenser is fed by cold water. Water and condensate are drained
- Steam condenser is within the standard height of the device. It brings the total height of the

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machine to 2395 mm only when it is combined with two pre-heating tanks or with one pre-heating tank and Power Pulse Cleaning

Steam condenser with heat recovery

- Prevents the emission of vapors entering the washing area. Temperature set is programmable from 0°C to 93°C (32°F – 200°F)
- Steam condenser is fed by DI water. DI water heats up by exchanging energy and feeds the DI water pre-heating. Condensate goes to drain
- Requires at least one pre-heating tank
- This option brings the total height of the machine to 2395 mm
- Not compatible with DI water fed by pressure booster pump

Power Pulse Cleaning

- Power Pulse Cleaning (PPC) allows to reduce or totally skip manual pre-treatment in the cleaning process of complex narrow lumen surgical instruments. PPC involves the pulsing of medical grade air pressure bursts during channel flushing for generating a strong front wave and water turbulence along lumen walls improving mechanical cleaning action of lumens, joins and junctions. PPC also improves instrument drying by triggering air pulses during the drying phase
- Requires compressed medical air
- Increases washing efficacy on hollow instruments

Drying options

Humidity sensor

- It measures the relative humidity present in the washing chamber and allows to reduce the drying phase time as soon as the reference value set in the parameter is reached

Chemical dosing

Additional chemical dosing pumps and dosing control

- Additional 3rd and 4th maintenance free dosing pumps for chemical products with minimum level alarm

Process quality

Washing arm rotation monitoring

Analogue pressure transducer

- To monitor water pressure values in the washing circuit

Conductivity sensor

- Accurate measuring of the conductivity value during the final rinse. Water conductivity data are also included in the cycle report

Sampling water test port

Control options

Printer

- For validating washing phases with detailed information
- Plus2 printer is integrated on the top panel

Free contacts

- Up to three free contacts to allow the control of external devices simultaneously with the control of machine components
- UL version limited to one free contact

Further options

External floor anchoring kit

- Suitable for anchoring the machine in case for anti-seismic compliance. Anti-seismic documentation is not included. Due to external encumbrance, floor anchoring kit is not compatible with zero-gap installation of two or more devices side by side. For detailed information always refer to General Arrangement drawing (GA) document

Electrical connection

- Electrical power consumption data are available on General Arrangement (G.A.) documentation
- Multi frequency electrical voltages in 50Hz and 60Hz

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Racks and carts

A large variety of basket trays, injector racks, net baskets for: surgical instruments, MIS instruments, anesthesia instruments, ophthalmology instruments, OP rubber shoes, containers, baby bottles…

Chemical products

A large selection of cleaning chemicals is available

Validation support documentation and services

Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) testing available upon request

Required utilities

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

Hot water, Cold Water, DI Water

Drain Connection

Steam feed
(when config. requires)

Steam condensate return
(when config. requires)

Exhaust air connection

Medical air
(when config. requires)

Electrical requirements

- Total power: 10,1 kW (standard machine)
- 380/415V 3~+N/50Hz (standard machine)
- other electrical connections are available to match electrical requirements of installation site
- UL components version available

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Steelco

Miele Group Member

Operating instructions

DS 600 EZ G2
DS 600 G2
DS 610 G2
DS 610 SL G2

CE 0051

Read the operating instructions carefully before installing and using the machine. This will help protect users from personal injury and help prevent damage to the machine.

en -UK

Contents

1. GENERAL RULES

The washer-disinfector is generally referred to as “the machine” in these operating instructions. Reprocessable instruments and utensils are referred to as “load items” if they are not more specifically defined.

1.1 Limits of 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 operator must comply with all instructions set forth in the operating instructions, most notably:

- ► Always consider the intended use of the machine
- ► Always carry out the required maintenance work
- ► Use of the machine should be limited to persons who have been properly trained and instructed on use of the machine
- ► Use only original spare parts

Any modifications, adaptation or other which may be made to machines subsequently placed on the market do not oblige the manufacturer to intervene on previously supplied machines, or to consider the machine and related user manual lacking and inadequate.

The operating instructions on the following pages are designed to guarantee the longevity and functionality of your machine.

The instructions in this manual do not replace, but rather supplement the employer requirements in order to adhere to current health and safety legislation.

The machine is covered by a 15-month warranty starting from the time of shipment.

1.2 Validity, contents and storage

It is very 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 owner or user in order that they can become acquainted with its operation and the relative warnings.

Read the instructions carefully before installing and using the machine.

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

In order to prevent possible accidents to persons or property due to incorrect translation of the instructions, the client must:

- ► not perform operations or manoeuvres with the machine in case of doubt or uncertainty regarding the operation to be performed
- ► ask the Steelco after-sales service for clarifications on the instruction.

2. PRODUCT INFORMATION

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

Main differences between the 4 available versions

DS 600 EZ G2	Small chamber version – simplified version with stainless steel control panel
DS 600 G2	Small chamber version – hinged door – manual movement
DS 610 G2	Big chamber version – hinged door – manual movement
DS 610 SL G2	Big chamber version – sliding door – automatic movement

2.1 Appropriate use

These machines can be used to clean, rinse, disinfect (through thermal disinfection), reprocessable medical devices in healthcare facilities such as (dental) practices, hospital CSSDs, and outpatient operating centres. Reprocessable medical devices include invasive and non-invasive medical devices.
For this purpose, the information provided by the manufacturers of the medical devices (EN ISO 17664) and the manufacturers of the process chemicals must also be observed.

Information note: The ISO 17664 standard: 2004 defines the responsibility of the manufacturer of the reusable medical instrument in providing all the instructions for its proper reprocessing and maintenance after outpatient use. This is the information for the correct preparation, cleaning, disinfection, drying, packaging, control, testing, sterilisation, and storage phases. If medical devices have been used and exposed to compromised blood or tissues, before each use/reuse with human patients, these devices must necessarily be reprocessed in accordance with the instrument manufacturer's guidelines, in compliance with international and local standards, and in accordance with good hospital practices. Thermal disinfection washing devices perform a partial function in the overall reprocessing of reusable medical devices.
This washing and disinfection device is therefore not intended to be used for terminal disinfection or sterilisation.

2.1.1 Fields of application

- Private practice doctors
- Hospitals
- Dentistry practices
- Clinics
- Hospital CSSDs
- Healthcare facilities

Reprocessing conditions must be suitable for the load and type of soiling. Process chemicals must be suitable for the type of soiling.
The use of a suitable load carrier (basket, module, insert, etc.) is important to ensure adequate reprocessing of the load.
The machine can be qualified for process validation.

The machine fulfils the requirements of the EU Machinery Directive 2006/42/EC.

WARNING

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

Inappropriate use can lead to personal injury and damage to property.

Steelco cannot be held liable for damage caused by improper or incorrect use or operation of the machine.

2.2 Safety instructions and warnings

This machine complies with all statutory safety requirements. Inappropriate use can lead to personal injury and damage to property.
Read the operating instructions carefully before using this machine. This will prevent both personal injury and damage to the machine.
Keep these instructions in a safe place where they are accessible to users at all times.

2.2.1 Appropriate use

- Use of the machine is only approved for the applications stated in the operating instructions. Alterations or conversion of the machine, or its use for purposes other than those intended, are not permitted and could be dangerous.
- The cleaning and disinfection processes are only designed for reprocessing medical devices include invasive and non-invasive medical devices, which are designated as re-processable by the manufacturer. The information provided by the manufacturer of the load items must be observed.

- ► Steelco cannot be held liable for damage caused by improper or incorrect use or operation of the machine.
- ► This machine is intended for indoor use only.

2.2.2 Risk of injury

Please pay attention to the following notes to avoid injury

- ► The machine may only be installed, commissioned, repaired, and maintained by the Customer Service Department or a suitably qualified service technician. A service contract is recommended to ensure full compliance with GLP guidelines. Incorrect repairs can cause considerable danger to users.
- ► Do not install the machine in areas where there is any risk of explosion or freezing conditions.
- ► To reduce the risk of water damage, the area around the machine should be limited to furniture and fittings designed for use in commercial environments.
- ► Some of the metal parts pose a risk of injury or cutting. Wear cut-resistant protective gloves when transporting and setting up the machine.
- ► The electrical safety of the machine can only be guaranteed when it is correctly earthed. It is essential that this standard safety requirement be observed and regularly tested. In case of doubt, have the electrical installation inspected by a qualified electrician. Steelco cannot be held liable for the consequences of an inadequate earthing system (e.g. electric shock).
- ► A damaged or leaking machine can pose a threat to your safety. Always switch off a damaged or leaking machine immediately and contact the Customer Service Department.
- ► Machine operators must be instructed on how to use the machine and receive regular training. Untrained personnel must not be allowed to access the machine or its controls.
- ► Use only process chemicals which have been approved by their manufacturer for the relevant application. The manufacturer of the process chemicals is liable for any negative influences on the material of the load and the machine.
- ► Take care when using process chemicals. Some chemicals may be caustic, irritating and toxic. The relevant safety regulations and safety data sheets issued by the process chemical manufacturers must be observed. Wear gloves and protective goggles.

  The machine is designed for use only with water and appropriate process chemicals. The use of organic solvents or inflammable liquids is not permitted. This could cause an explosion or damage rubber or plastic components in the machine and cause liquids to leak out.
- ► The water in the wash chamber must not be used as drinking water.
- ► Do not lift the machine by its protruding parts such as the door handle or the opened service flap as these could be damaged or torn off.
- ► Do not sit or lean on the opened door. This could cause the machine to topple over and be damaged, or cause personal injury.
- ► Be careful when arranging items with sharp, pointed ends. Position them in the machine in such a way as to avoid injuring yourself or others.
- ► Broken glass can result in serious injury when loading or unloading. Broken glass items must not be processed in the machine.
- ► Please be aware that the machine may be operating at high temperatures. Deactivating the lock to open the door can result in a risk of burning or scalding, or contact with corrosive substances. Where disinfectant is in use, there is also a risk of inhaling toxic vapours.
- ► Should personnel accidentally come into contact with toxic vapours or process chemicals, follow the emergency instructions given in the manufacturer's safety data sheets.
- ► Load carriers such as baskets, mobile units and inserts must be allowed to cool down before they are unloaded. Any remaining water in the containers could still be very hot. Empty this water into the wash chamber before removing items.
- ► Never clean the machine or nearby with a water hose or a pressure washer.
- ► The machine must be disconnected from the power supply before any maintenance or repair works are carried out.

2.2.3 Quality assurance

The following points should be observed to assist in maintaining quality standards when reprocessing reprocessable medical devices include invasive and non-invasive medical devices, and to avoid damage to the loads being cleaned.

- ► Only authorised personnel may interrupt a program in exceptional circumstances.
- ► It is the responsibility of the operator to demonstrably ensure reprocessing standards in routine operation. Process results must be inspected and documented on a regular basis.
- ► For thermal disinfection, use temperatures and temperature holding times to achieve the required infection prophylaxis in accordance with current health and safety regulations.
- ► Only reprocess undamaged and suitable items. When washing plastic items, ensure they are thermally resistant. Nickel-plated and aluminium items require special procedures and are not generally suitable for machine reprocessing. Ferrous materials that can rust or corrode must not be introduced into the wash chamber as wash items or soiled items.
- ► Under certain circumstances, process chemicals may damage the machine. Users are urged to follow the recommendations issued by the manufacturers of process chemicals. Contact Steelco in the event of damage and any suspicion of material incompatibility.
- ► Cleaning agents containing chlorine can damage the elastomers of the machine. If cleaning agents containing chlorine must be used, a maximum temperature of 70 °C in the “Main wash” program blocks is recommended (see program chart).
- ► Abrasive substances should not be introduced into the machine as these could damage mechanical components in the water circuit. Any abrasive residue on the load must be completely removed before reprocessing.
- ► During pre-treatments with cleaning or disinfecting agents, certain types of stains and the interaction of certain process chemicals can create foam. Foam can have an adverse effect on the disinfection and cleaning result.
- ► Reprocessing should not result in foam being discharged from the chamber. Foam discharge can compromise the machine's operation.
- ► The process used must be monitored on a regular basis by the operator to check foaming levels.
- ► Even when a process chemical, e.g. detergent, is recommended, Steelco takes no responsibility for the effect of such chemicals on the load items. Please note that changes in product formulation, storage conditions, etc., which are not announced by manufacturers of process chemicals may impair the quality of cleaning results.
- ► Always follow the relevant manufacturer's instructions on the storage and disposal of process chemicals.
- ► In critical applications where very stringent requirements have to be met, it is strongly recommended that all relevant factors for the process, such as detergents, water quality, etc., be discussed with Customer Service Department.
- ► If the cleaning result is subject to particularly stringent requirements (e.g. chemical analysis), quality control should be regularly carried out by the operator to ensure the required standards of cleanliness are achieved.
- ► Load carriers such as mobile units, baskets and inserts which hold the load must be used only as intended.
  Lumened items must be thoroughly cleaned, internally and externally.
- ► Secure small and light items with covering nets or place them in a mesh tray for small items, so that they do not block the spray arms.
- ► Empty any containers or utensils before loading them.
- ► The amount of residual solvents on items going into the wash chamber should be minimal. There should be no more than a trace of any solvents with a flash point below 21 °C.
- ► Chloride solutions, in particular hydrochloric acid, or ferrous materials subject to rust or corrosion must not be placed in the chamber.
- ► Ensure that solutions containing chlorides or hydrochloric acid do not come into contact with the stainless steel outer casing of the machine in order to avoid any damage due to corrosion.

- ► After any plumbing work, the water pipework to the machine will need to be vented. If this is not done, the machine's components may be damaged.
- ► Follow the installation instructions in the installation plan and service manual.
- ► If an accident occurs while using the device, notify the manufacturer and the competent authorities.

2.2.4 Using components

- ► Only use genuine original spare parts and components suitable for their intended application. Model designations are available from Steelco.
- ► Only use Steelco load carriers, such as mobile units, baskets, modules, and inserts. Using mobile units, baskets and inserts made by other manufacturers or making modifications to Steelco components can result in unsatisfactory cleaning and a poor disinfection result. Any resulting damage would not be covered by the warranty.

2.2.5 Disposing of your old appliance

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 residue in accordance with safety regulations. Wear gloves and protective goggles.

Make the door lock inoperable, so that children cannot accidentally shut themselves in. Then make appropriate arrangements for safe disposal of the machine.

Old electrical and electronic appliances often contain valuable materials. However, they also contain harmful substances which were essential for their correct functioning and safety. These could be hazardous to human health and to the environment if disposed of with general waste or if handled incorrectly. Please do not, therefore, dispose of your old appliance with general waste.

Make use of local waste collection/recycling centres for electrical and electronic devices. Consult your dealer if necessary. National legislation may require the deletion of personal data saved on the machine before disposal. Please ensure that your old appliance poses no risk to children while being stored prior to disposal.

2.2.6 Warning signs

To inform operating personnel of their obligations and to warn of residual risks, the machine is equipped with safety labels in accordance with the relevant legislation (Directive 92/58 EEC).

General warning signs

Caution!
Danger of electric shock!

Caution!
Observe the operating instructions!

Caution!
Hot surfaces!

The health and safety risk assessment carried out on-site, as well as the evaluation of residual risks, determines the safety equipment which the supervisor must provide for the user.

Steelco cannot be held liable for damage or injury caused by non-compliance with the safety instructions and warnings.

2.3 Technical data

	DS 600 G2 ***DS 600 G2 EZ***	***DS 610 G2*** ***DS 610 SL G2***
Dimensions	External W x D x H 650 mm x 700 mm x 1820 mm	External W x D x H 650 mm x 700 mm x 1940 mm
Weight	Net weight: 320 kg Max during operation: 412 kg	Net weight: 355 kg Max during operation: 455 kg
Average sound pressure level	< 70 dB(A)	
Protection rating (according to IEC 60529)	IP00	
Backflow preventer (according to EN 1717)	AB – Air gap not limited	
Operation	Temperature range +5 to +35 °C Relative humidity range Max 80% (5 ÷ 31°C); 80…50% (31…35°C) Maximum altitude: 2000 m (special device settings are available for higher altitudes)	
Ambient lighting requirements	500 … 1500 lux	
Installation site air exchange requirements	min 10 air exchanges / hour	
Electrical connection	See the device's data plate	
Storage and transportation conditions	-5 ... +50 C 20 % to 90 % non-condensing Ventilation: Non-influencing air exchange (only required if any supplied containers of chemical products are installed).	

Overvoltage category (according to IEC EN 60664)	II
Pollution level according to EN 61010	II
Equipment Class (according to CISPR 11)	A
Equipment Group (according to CISPR 11)	1
Control system data	Microcontroller: STM32F767BGT6 (*) CPU: Core: Arm® 32-bit Cortex®-M7 (216MHz max) Internal RAM: 512 KB Internal FLASH: 1MB External program flash: 64Mb External data flash: 256Mb External SDRAM: 16MB

WARNING

Any use of the machine not within the recommended ambient conditions is forbidden.

Inappropriate ambient conditions can damage the machine.

The machine is certified according to EN 61326 for electromagnetic compatibility. If the device is exposed to an electromagnetic field out of the range for which it is certified, it can be damaged, or its functionality cannot be guaranteed.

In case of exposure to conditions not within the recommended ones, contact technical assistance for a general check of the device.

2.4 Recommendation for proper operation

- ► The user must supervise the machine during operation.
- ► Before starting the cycle, the operator must always check that the water filters are in the well and properly positioned.
- ► To prevent contact with contaminated material, appropriate personal protective equipment must be worn during reprocessing.
- ► Do not reprocess items containing substances which, in accordance with current legislation, must not be discharged into the sewage system. These substances must be disposed of separately.
- ► Follow the manufacturer’s instructions, as well as national requirements and guidelines relating to the machine-based reprocessing of loaded items.
- ► The machine is designed for use with water and process chemicals.
- ► Check that the type of chemical product is suitable for the specifications of the wash program used.
- ► Do not use powder cleaning agents.
- ► Do not use domestic detergents.
- ► Components which are not approved by the manufacturer may compromise reprocessing results as well as user safety.
- ► The user must carry out a general check-up and clean the appliance regularly as indicated in the maintenance instructions.
- ► Visually check the load for cleanliness.
- ► The on-site stopcock must be easily accessible so that the inlet can be turned off when not in use.
- ► If the new machine appears to be damaged, contact your dealer before installation.

- ► Any modifications to the electrical and hydraulic systems, which are necessary in order to install the machine, must be carried out by qualified and authorised persons only.
- ► The user is forbidden to carry out any repairs.
- ► If the machine shows an alarm that cannot be easily solved, technical assistance must be contacted.
- ► If the machine is not working properly, contact technical assistance.
- ► Technical assistance on this machine must only be carried out by qualified and authorised service partners.

ATTENTION: chemical products are irritating to the eyes, in case of contact wash abundantly with water and consult a doctor; in case of contact with the skin, wash with plenty of water.

The manufacturer declines any liability for accidents to persons or property arising from failure to comply with the above-mentioned rules. Failure to comply with the rules results in the immediate and total cancellation of the warranty.

2.5 Training

Instructions for use of the machine will be provided by the Steelco Customer Service Department or an authorised service technician during machine commissioning.

It is the duty of the responsible body to ensure that users are sufficiently trained and instructed.

The responsible body must record and archive the training sessions, including evidence that the contents have been understood.

2.5.1 User profiles

User profiles are identified as follows:

SUPERVISOR	**Senior service technician:** Special machine settings can only be made by the Customer Service Department, such as the installation of new functions.
MAINTENANCE ENGINEER	**Service technician:** The machine may only be installed, commissioned, repaired and maintained by the Customer Service Department or an authorised service technician.
DEPARTMENT MANAGER	**Responsible for the machine in the workplace:** More advanced tasks, e.g. interrupting or cancelling a program, require more detailed knowledge of machine reprocessing of medical devices include invasive and non-invasive medical devices. Alterations or adaptations of the machine, e.g. to accessories used or on-site conditions, require additional specific knowledge of the machine. Validation processes assume specialist knowledge about machine reprocessing of reprocessable medical devices including invasive and non-invasive medical devices, the processes involved and applicable standards and legislation.
OPERATOR	**User:** Users must be instructed on operating and loading the machine, and receive regular training to guarantee safe daily use. They must have knowledge of machine reprocessing of instruments and utensils.

2.6 Residual risks

The OPERATOR, in normal operating conditions, is not exposed to risks if they work safely, using the appropriate means of protection.

In order to operate safely, the operator must:

- ► Carefully comply with the instructions set forth in this manual.
- ► Use safety devices appropriately and with care, and the group and individual safety gear provided in the workplace.
- ► Personally take action or report to responsible staff in the event of deficiencies in the aforementioned devices and means, as well as any hazardous conditions of which they may become aware, taking immediate action in urgent cases within their scope of responsibility and ability, to eliminate or reduce the deficiencies or hazards.

The washer disinfector is nonetheless considered to have some residual risks. Below is a list of the appropriate measures to be taken for each phase or significant action of work:

PHASE	**BASKET LOADING**
RISK	Bruising and cutting of the upper limbs, caused by accidental contact due to a fall or impact against tools and objects and instruments, mainly during basket handling operations.
MEASURE	Enable only trained personnel with the necessary equipment for this type of operation (e.g. baskets with protections, transport trolleys) and appropriate clothing and PPE (e.g. protective overalls and gloves).
PHASE	**DOSING OF DETERGENTS/CHEMICAL ADDITIVES**
RISK	Contact of body parts with washing chemicals.
MEASURE	Assign staff that is trained and equipped with appropriate clothing and PPE. Wear safety clothing, gloves and goggles and comply with the safety instructions set out by the manufacturer of the chemical products.
FIRST AID MEASURE	► Remove/immediately remove clothes that have been contaminated or soaked with the product. ► If the substances come into contact with the skin, wash off the affected areas immediately and rinse with water.
RISK	Inhaling of washing chemical vapours.
MEASURE	Assign staff that is trained and equipped with appropriate clothing and PPE. Comply with the safety requirements specified by the manufacturer of the chemicals, and if foreseen, wear a suitable protective mask to protect the airways.
RISK	Accidental release of washing chemicals.
MEASURE	Do not disperse the concentrated chemical into drains or directly on surfaces; Collect any spilled fluid with absorbent material (e.g., sand, earth, sawdust); Rinse the residual chemical with plenty of water.
	IN CASE OF CONTACT WITH THE BODY OR RELEASE OF CHEMICAL PRODUCTS, ALWAYS REFER TO THE SAFETY MEASURES INDICATED IN THE PRODUCT DATA SHEET.
PHASE	**DAMAGE TO THE DEVICE**
RISK	Use of inappropriate components, detergents, washing processes.

MEASURE	Use suitable components that do not damage the surface of the device and check its integrity. Use the chemical product in the quantity and manner prescribed by the manufacturer and follow instructions regarding the compatibility of the material.
PHASE	**INCORRECT CONNECTION OF CHEMICAL PRODUCTS**
RISK	Use of the incorrect chemical for the process when changing the chemical tank.
MEASURE	Use of a colour code for the chemical caps to help the operator when replacing the chemicals.

2.7 Table of symbols

Symbols applied to the machine

	Electrical shock risk
	Warning: hot surface
	Manufacturer
	Date of manufacture
	Warning! See the accompanying documentation for important cautionary notices, such as warnings and precautions.
	Consult the user instructions
	Earth terminal
	CE mark issued by the notified body: 0051 identifies IMQ Indicated 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 configuration/specifications required by the customers. The machine configuration requested by the customer is in line with the configuration reported inside the technical documentation “DT-8051520DSXX2A” and in the DD-8051520DSXX2A medical device description document.
REP	Local authorized representative for Switzerland

	Local authorized representative
	Indicate the number of the product model. Indicated on the serial number label
	Indicate the unique number of the device Indicated on the serial number label

3. MACHINE DESCRIPTION

❶ Control panel

❷ USB port

❸ Door

❹ Chamber - *access to chamber filters and washing arms*

❺ Main switch (behind maintenance flap)

❻ Technical area panel - *access to chemical & air filters area*

❼ Printer

❽ Emergency switch

DOOR OPENING/CLOSING BUTTONS (automatic version)

The **automatic door version** is equipped with a key switch to open/close the door on the load side, which can be used in the event of a failure that blocks all machine operation.

EMERGENCY BUTTONS (automatic version)

The **automatic door version** is equipped with emergency buttons, of the non-automatic reset type:

- ► No. 1 emergency button located on the loading side.
- ► No. 1 emergency button located on the unloading side (in case of machine with pass-through door).

The red emergency button is marked with the indication "**EMERGENCY**", it is located in an easily accessible position, but sufficiently protected from accidental operations.

4. INSTALLATION

4.1 Water connection

4.1.1 Water quality

The quality of the water used in all stages of cleaning is essential in achieving good results.

- The water must be compatible with the material of which the machine is made.
- The water must be compatible with process chemicals.
- The water must be compatible with process requirements for the various stages of the process.

In order to achieve good reprocessing results, the machine requires a supply of soft water with a low calcium content. Hard water causes the build-up of calcium deposits on the load and in the machine.

Water with a hardness level higher than 0.7 mmol/l (7 °fH – French scale or 4 °dH – German scale) must be softened. This automatically occurs during a program sequence on machines with a built-in water softener (ex works option). The water softener must be set to the exact hardness of the water supply.

The water softener must be reactivated at regular intervals. This requires the use of special reactivation salt. Reactivation is carried out automatically during a program sequence.

Softened water must be provided on-site for machines without a built-in water softener.

The maximum allowed water hardness is 65 °fH or 36 °dH.

Note: The water hardness is set by the Customer Service Department.

Water from the chamber is not suitable for drinking.

4.1.2 Requirements

- ► The machine must be connected to the water supply in strict accordance with local regulations
- ► The water used must comply with European regulations for drinking water quality, as a minimum. If the water supply has a high iron content, there is a danger of corrosion on the items being cleaned in the machine, as well as the machine itself. If the chloride content of the water exceeds 100 mg/l, the risk of corrosion on the load in the machine will be further increased.
- ► Use only the hoses supplied with the machine
- ► Do not shorten the hoses supplied with the machine
- ► The **minimum flow pressure** for cold water, hot water and DI water connections is 40 kPa
- ► If the **steam condenser** is installed, the minimum pressure required is 200 kPa
- ► The **recommended flow pressure** is ≥ 200 kPa for the cold and hot water connections and ≥ 200 kPa for the DI water connection in order to avoid excessively long water intake times and to guarantee the best performance of the steam condenser (if installed)
- ► The **maximum permissible static water pressure** is 600 kPa
- ► A booster pump is required for the DI water connection if the flow pressure is below 40 kPa
- ► If the machine is equipped with a booster pump, but the pressure on the demineralised water tap is higher than 100 kPa, disconnect the booster pump, otherwise the component could be seriously damaged
- ► If the pressure is higher than 600 kPa (8 bar), a pressure reducer must be installed
- ► If the water pressure is not within the specified range, contact the Customer Service Department or an authorised service technician for advice.

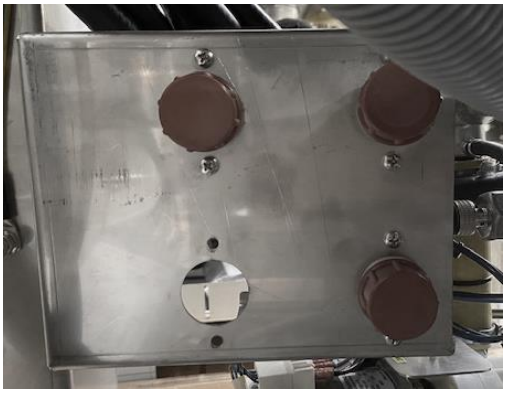
► A stopcock valve with a ¾” male threaded union must be provided on-site. The valve should be easily accessible, since the water supply should be shut off whenever the machine is not in use.

⚠	Do not overtighten the threaded unions on the hoses.

Information:

► The anti-return water system is already installed inside the appliance in accordance with the IEC 61770 standard.

► If no hot or DI water supply is available, the **red** or **white** coded inlet valves should be closed with a cap supplied with the machine.



The hot or demi water absence must be set in the machine settings: in this case the machine automatically fills cold water instead of the non-connected water type. In this case, the non used water hoses do not need to be assembled.

If no cold water supply is available, or the hardness of the water is higher than specified in the installation plan, and the machine is not equipped with a water softener, the **blue** coded inlet valve should be closed with a cap supplied with the machine.

The water absence needs to be set in the machine settings, in order to allow the machine to automatically fill the alternative water.

► Non-compliance with the above conditions shall render the warranty invalid.

⚠	When the machine is not in operation, always close the stopcocks.

4.1.3 Built-in softener

The purpose of the built-in softener is to reduce the quantity of limescale contained in the supply water used for washing and thermal disinfection. The instrument washer, if fed with particularly hard water, quickly degenerates, compromising its functionality and service life.
To keep the resins that perform the descaling activity active, they must be regenerated as described in the table.

For machines equipped with this device, the value corresponding to the water hardness must be set at the time of installation, as follows:

WATER HARDNESS (°fH)	WATER HARDNESS (°dH)	PARAMETER SETTING
7 - 15	**4 - 8**	6
16 - 30	**9 - 17**	4
31 - 50	**18 - 28**	2
51 - 65	29 - 37	1

4.2 Electrical connection

Only qualified, skilled personnel may connect the machine to the power supply

- ► It is recommended that the machine be connected to the mains electrical supply via a suitably rated plug and socket compliant with all local and national standards.
- ► The machine must only be operated with the voltage, frequency and fuse rating shown on the data plate.
- ► The electrical connection must be made according to the technical regulations in force.
- ► The power supply voltage must not differ from its nominal value by more than ±10 %.
- ► The frequency of the power supply must not differ from its nominal value by more than 1 %.
- ► The electrical safety of the machine can only be guaranteed when it is correctly earthed. Equipotential bonding is required.
- ► Make sure that the electrical systems are properly 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 systems), placed on the lower technical area, on the solenoid valve bracket

- ► The machine is equipped with a power cable
- ► Machines that are permanently connected (without a plug) must be connected via a power switch with all-pole isolation. The power switch must be designed to operate at the rated current.
- ► For increased safety, it is recommended to protect the machine with a suitable residual current device (RCD) with a trip current of 30 mA (DIN VDE 0664)
- ► The installed safety device must be equipped with fuses according to the specification indicated in the Installation plan and Wiring diagram
- ► The machine should be disconnected from the power supply when not used for long periods of time.
- ► The electrical connection and fuse rating must comply with local and national regulations.

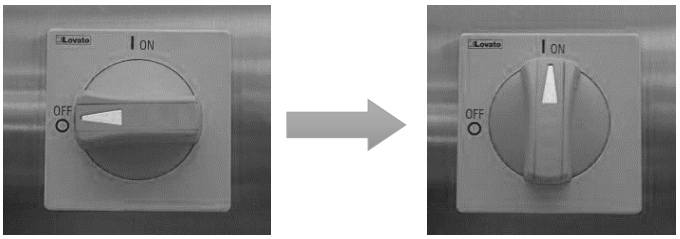
Please refer to the installation plan provided.

5. OPERATIONS

5.1 Powering on

To turn on the machine, follow the steps below:

► Activate the main switch located in the technical area behind the lower door.



► Once the switch is activated, the control panel automatically starts.
► *Take note of any fault or warning messages on the display when starting the machine.*

5.2 Check warnings and fill level

Check that no warnings are active on the display, in particular regarding low-level chemical products or the lack of salt, and if necessary, replace the container and fill the salt box operating as described in this manual.

⚠	Take care when using process chemicals. Some agents may be corrosive and irritating. The relevant safety regulations and safety data sheets issued by the process chemical manufacturers must be observed. Wear protective gloves and goggles.

5.3 Opening and closing the door

The door is made of high-strength tempered glass. A particular manufacturing test (HST) certifies its integrity and robustness.
The thermal dispersion of the glass has been contained thanks to the use of a special material with a low dispersion coefficient.
Nevertheless, particular attention is recommended during use, due to the danger of burns.

⚠	**ATTENTION** ► During normal use, be careful not to sharply strike the glass door, as there is a risk of breakage. ► Slowly insert the basket inside the wash chamber to avoid the risk of breaking the glass door ► Place the load in the basket in such a way that it does not protrude, avoiding striking the glass door. ► Before opening the door, make sure that the opening area is free from obstructions.

5.3.1 Manual door version

Use the handle to open and close the door.
The door is automatically locked after the cycle starts by means of a door lock and cannot be opened for the entire duration of the cycle.

To open the door during cleaning, the cycle must be interrupted, remembering that:
► The material inside the machine may be very hot.
► It will subsequently be necessary to repeat the complete wash cycle.

ATTENTION

Always use the handle to close the door.
Do not place your fingers between the door and the washing chamber, as there may be a risk of crushing

5.4 Emergency door release

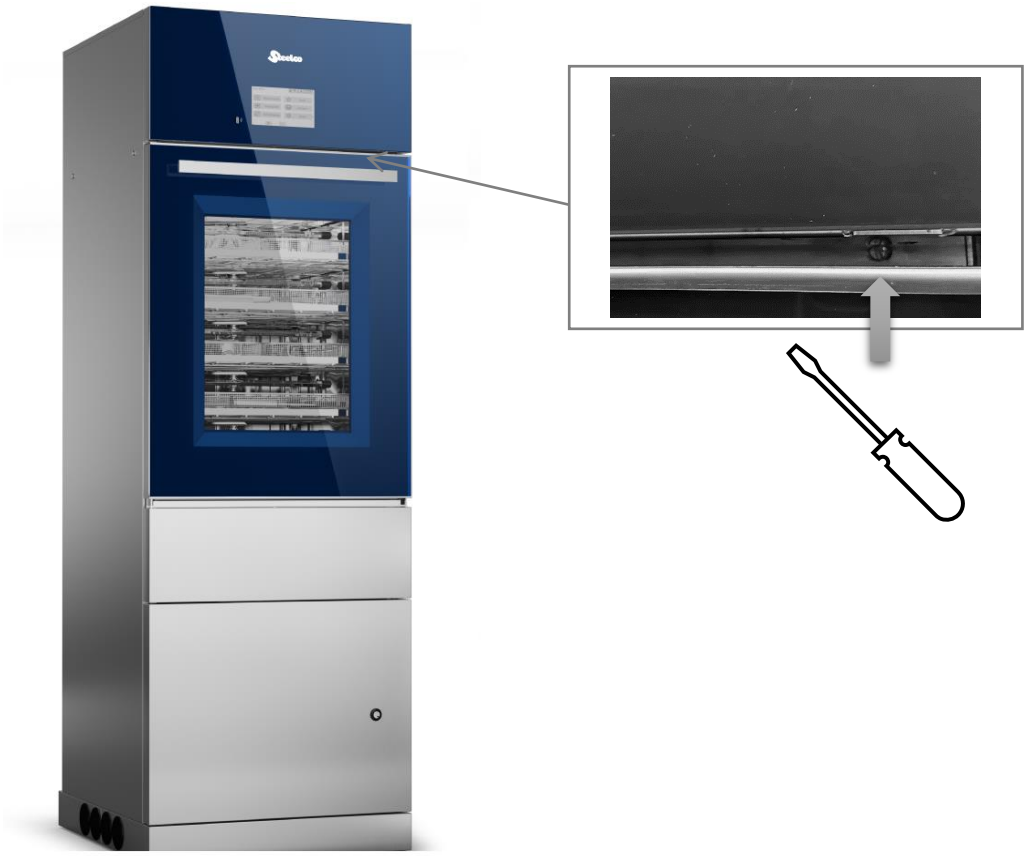
The emergency release may only be used when it is no longer possible to open the door normally, e.g. in the event of a power outage.

If the emergency release is operated during a program sequence, hot water and process chemicals can escape.

The load, the load carrier and the wash chamber may be very hot.
Danger of scalding, burning and chemical burns. Where disinfecting agents are used, there is also a danger of inhaling toxic fumes.

In the **manual door version**, an emergency door release system is available in case of a power failure. There is a hole above the upper right of the door (see picture).

- ► Insert a screwdriver and unscrew the screw of the door lock
- ► Open the door
- ► When the power is restored, an alarm will appear on the display to advise that the door has been manually unlocked
- ► Reset the alarm and the machine will automatically unlock the door. Tighten the screw of the door lock to restore regular door operation.



ATTENTION

In the **automatic door version**, the machine is equipped with a key switch to open/close the door on the load side, which can be used in the event of a fault that blocks all machine operation.

The door is only moved if the red emergency button is activated!

The emergency switch can only be reset by authorised technical personnel equipped with the appropriate key.

ATTENTION

A cycle that has been interrupted due to a power failure, with subsequent manual opening of the door, must be considered failed.
The cycle must be run again.

5.5 Preparation

ATTENTION:
Before placing the instruments in the washer, remove the composite material, such as cement and amalgam, as defined by the instrument manufacturer.

- ► Follow the manufacturer's instructions for reprocessing.
- ► Make sure that the items are suitable for reprocessing in a thermal washer-disinfection machine and check their compatibility with the chemicals used during the wash programs.
- ► Carefully place the items into the load carriers.
- ► Make sure that load items are not shielded or concealed by other items.
- ► Position the load items in such a way that fluids can drain off freely.
- ► Tall or heavy items should be placed towards the middle of the basket if possible to facilitate washing.
- ► Make sure that the items do not block the spray arms and that the arms can turn freely.
- ► Distribute the load evenly across the baskets.
- ► The mobile units, baskets, modules and inserts holding the load must be used only as intended.
- ► Empty any containers or utensils before loading them.
- ► Take apart any items that can be dismantled in accordance with the manufacturer's instructions, and process the individual parts separately from each other.
- ► Do not place items to be cleaned inside other items where they may be concealed. Do not place items so close together that cleaning is hampered.
- ► Arrange the load so that the water can access all surfaces.
- ► Small items and micro components must only be processed in special inserts, mesh trays with lids or mesh inserts.
- ► Plastic items must be thermally resistant.

Injector connections that are not in use must be closed using the caps provided. New caps are available from Steelco.

The maximum load permitted for each cycle is 50 Kg (baskets included).

NEVER USE THE MACHINE WITHOUT THE BASKETS!
Non-compliance can cause dangerous water leaks from the door.

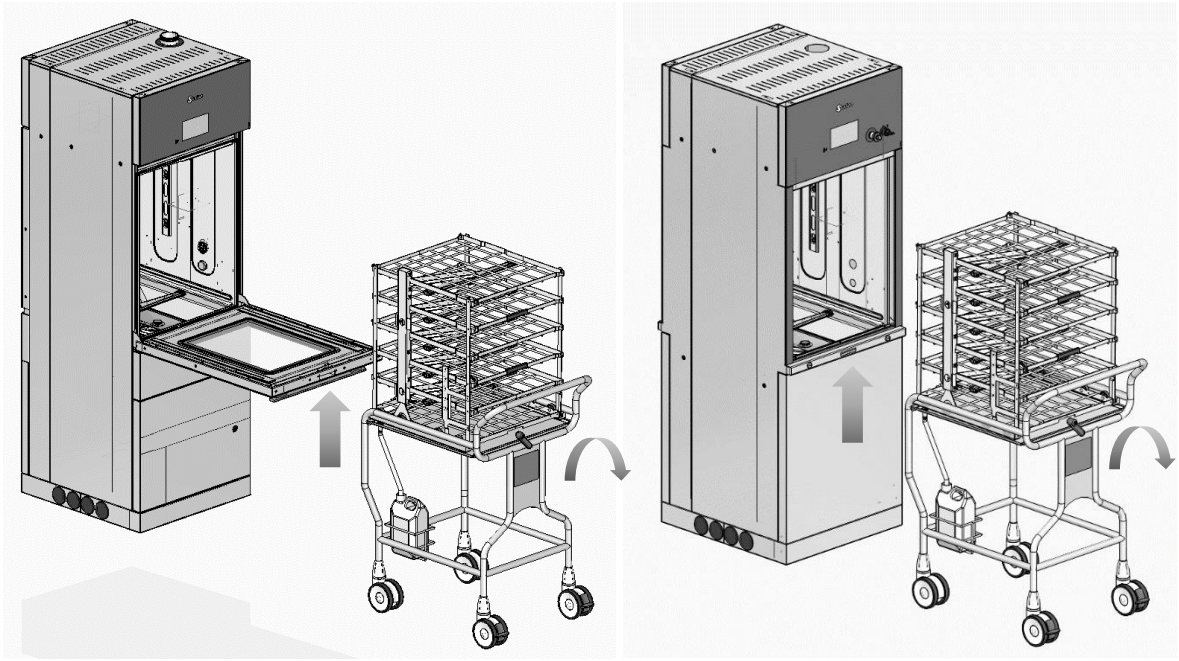
	Do not insert solid dirt (excrements, toilet paper, ...). This could block the machine's drainage system.

Before starting to use the machine, make sure that all the routine maintenance tasks have been carried out. Check the spray arm rotation.

The list below provides examples of load carriers and inserts which may be used when reprocessing medical devices include invasive and non-invasive medical devices.

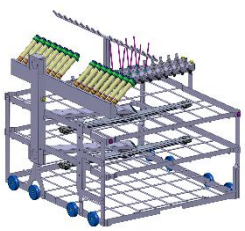
Other accessories are available from Steelco.

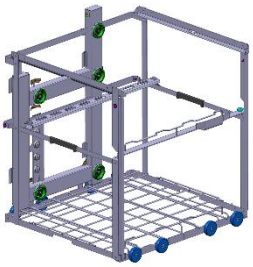
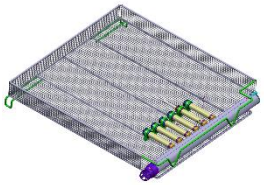
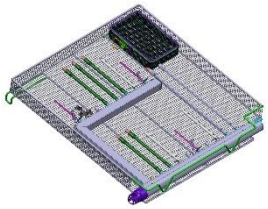
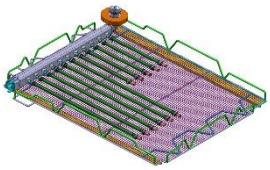
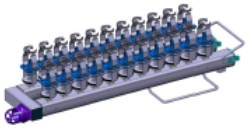
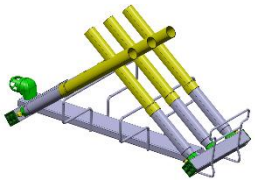
To transfer the basket to the machine, a trolley is available:

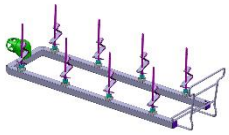
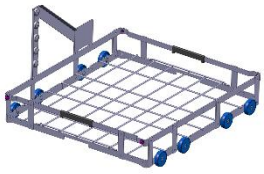
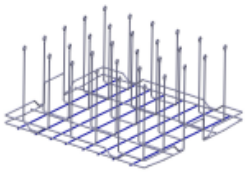
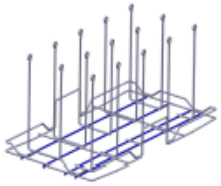


To hook the trolley to the machine for the transfer, it is necessary to reach the door (manual door version) or the trolley coupling (automatic door version) and rotate the handle.

CODE	PICTURE	DESCRIPTION	DS 600 EZ G2	DS 600 G2	DS 610 G2	D DS 610 SL
C1801		Surgical instruments basket: 6 levels basket	-	-	•	•

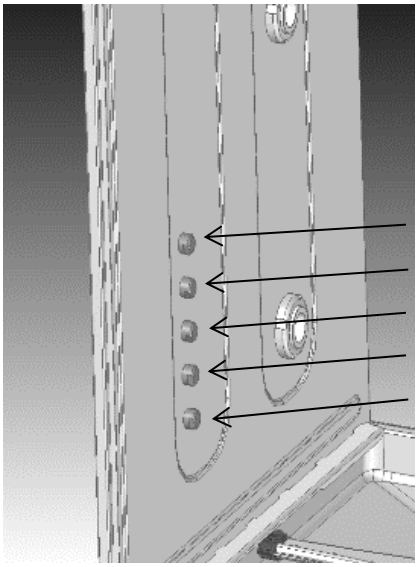
CODE	PICTURE	DESCRIPTION	DS 600 EZ G2	DS 600 G2	DS 610 G2	D DS 610 SL
C1802		Modular baskets: basket for multiple purposes. With the additional modules can treat from surgical instruments to microsurgery instruments	-	-	•	•
C1803		Surgical instruments baskets: 5 levels basket	-	-	•	•
C1810		Surgical instruments baskets: 3 levels basket	-	-	•	•
C1811		Surgical instruments baskets: 4 levels basket	-	-	•	•
C1812		Surgical instruments baskets: 5 levels basket	-	-	•	•
C1813		*Microsurgery instruments basket*	-	-	•	•

CODE	PICTURE	DESCRIPTION	DS 600 EZ G2	DS 600 G2	DS 610 G2	D DS 610 SL
C1819		*Modular basket: with the additional modules allow the treatment of several type of instruments, from dental instrument to orthopaedic instruments*	-	-	•	•
C1805		*Module for hollow instruments connection*	•	•	•	•
C1806		*Module for long hollow instruments connection*	•	•	•	•
C1808		*Module for hollow instruments connection*	•	•	•	•
C1809		*Module for hollow instruments connection and special connection to the power pulse system*	•	•	•	•
C1804		*Module for surgical and orthopaedic instruments treatment*	•	•	•	•
C1816		*Module for dental instruments*	•	•	•	•
C1817		*Module for orthopaedic instruments*	•	•	•	•

CODE	PICTURE	DESCRIPTION	DS 600 EZ G2	DS 600 G2	DS 610 G2	D DS 610 SL
C1820		*Module for anaesthesia equipment*	•	•	•	•
C1821		*Module for hollow instruments connection and special surgical and anaesthesia instruments*	•	•	•	•
C1822		*Basic basket for shoes and container modules*	•	•	•	•
C1823		*Module for 2 containers*	-	-	•	•
C1824		*Module for 3 containers*	-	-	•	•
C1825		*Module for 50 shoes*	•	•	•	•
C1826		*Module for 15 shoes with number lower or equal to 45*	•	•	•	•
C1828		*Module for shoes with number over 46*	•	•	•	•

The machine is equipped with an automatic system to check the correct positioning of the basket inside the wash chamber; in case of incorrect positioning, the wash cycle start functions are inhibited.

The machine is equipped with a system to recognise the type of basket positioned in the chamber. The activation of a particular wash cycle can be automatically combined if the basket recognition setting is activated.
On the left side of the machine, inside the wash chamber, there are 5 basket recognition sensors.
The table below explains the code corresponding to the position of magnets (“I” indicates the presence of a magnet)



CODE	POS. 1	POS. 2	POS. 3	POS. 4	POS. 5
00	--	--	--	--	--
01	I	0	0	0	I
02	0	I	0	0	I
03	I	I	0	0	0
04	0	0	I	0	I
05	I	0	I	0	0
06	0	I	I	0	0
07	I	I	I	0	I
08	0	0	0	I	I
09	I	0	0	I	0
10	0	I	0	I	0
11	I	I	0	I	I
12	0	0	I	I	0
13	I	0	I	I	I
14	0	I	I	I	I
15	I	I	I	I	0

5.6 Checks after a program

- ► Visually check the load for cleanliness.
- ► Are all lumened instruments still attached to the appropriate nozzles?
- ► Are the lumens free from obstructions?

Any items that have been disconnected during reprocessing or which are found not to be sufficiently cleaned, must be reprocessed again

6. CHEMICAL PRODUCT CONTAINER REPLACEMENT

Replace an empty container as follows:

- ► Have a new container with process chemicals ready.
- ► Open the door in the plinth of the machine.
- ► Remove the siphon and place it on a chemical-resistant and easy-to-clean surface.
- ► Insert the siphon into the new container.
- ► Place the container in the plinth of the machine.
- ► Close the door in the plinth.
- ► Start the appropriate program to vent the DOS pump.

ATTENTION

- ► The chemical that is used can be dangerous if touched or inhaled.
- ► Stock the chemical products following the instructions in the safety data sheets.
- ► Only use process chemicals specifically designed for use in the machine and follow the chemical manufacturer's instructions.
- ► Take care when using process chemicals. Some agents may be corrosive and irritating. The relevant safety regulations and safety data sheets issued by the process chemical manufacturers must be observed. Wear protective gloves and goggles.
- ► The chemical compartment in the plinth of the machine is accessed using a key. The compartment may only be accessed by authorised personnel.

6.1 Recommendation

Use only chemical products that are appropriate for the reprocessed load and the machine. The manufacturer recommends the products indicated in the table below for good compatibility of the material with the device. In case of uncertainty, please contact the manufacturer of the load, process chemicals or machine.

Each chemical dispensing system is combined with a label that identifies the number of the dispenser. Depending on the type of chemicals used, a coloured tube and its cap are installed.
As the pre-set cycles in the machine refer to a dedicated dosing system (DOS 1-4) of the recommended chemicals, it is necessary to check the correspondence of the cycles (ref. Chapter 7) with the chemicals selected by the user.
Make sure that each specific chemical canister matches the correct dosing system (DOS 1-4).

ATTENTION

If chemicals are used other than those recommended, check that the set dosage corresponds with the indicated dosage in the technical data sheets of the products used for each cycle, and modify it if necessary.

The colours used to identify the chemicals are as follows:

DOS 1	**BLUE**	Installed ex-factory. Alkaline, acid, enzymatic, or neutral detergent	e.g. ProCare Med 10 A ProCare Med 10 MA ProCare Med 10 EN
DOS 2	**GREEN**	Optional pump (Retrofit Kit) Lubricant or rinse aid	e.g. ProCare Med 60 LUB

			ProCare Med 40
DOS 3	**RED**	Installed ex-factory. Acid detergent or neutraliser	e.g. ProCare Med 30 C ProCare Med 30 P
DOS 4	**BLACK**	Optional pump (Retrofit Kit) Disinfectant	e.g. ProCare Med 20 CD

ATTENTION

To ensure the correct treatment of objects, the use of specific products is recommended.
If necessary, ask the dealer or manufacturer for advice.

7. REFILLING THE SALT

For reactivation of the water softener, use only appropriate salt.

Alternatively use special, coarse-grained dishwasher salt or other pure evaporated salt for reactivation. Never use any other kind of salt, e.g. table salt, animal feed salt or de-icing salt. Other salts may contain insoluble additives which can impair the functionality of the water softener.

The following prompt reminds the user to refill the salt container: “salt loading needed”. This warning will appear at the beginning of each cycle for three times to remind the needs of a salt refilling, then will be automatically canceled.

The container for dishwasher salt is located in the base of the wash chamber inside the machine.

- ► Open the door.
- ► Remove the load carrier.
- ► Unscrew the plastic cap on the container.
- ► Fill the funnel with salt.
- ► Raise the funnel by the handle and place it on the container.
- ► Release the handle. The salt then passes from the funnel into the container.
- ► Repeat the process until the container is visibly full.

The supply container contains approx. 800 g of salt.

The container must always be completely filled. If filled to less than full, the water softening capacity is reduced and limescale may be deposited on the load and on wash chamber surfaces.

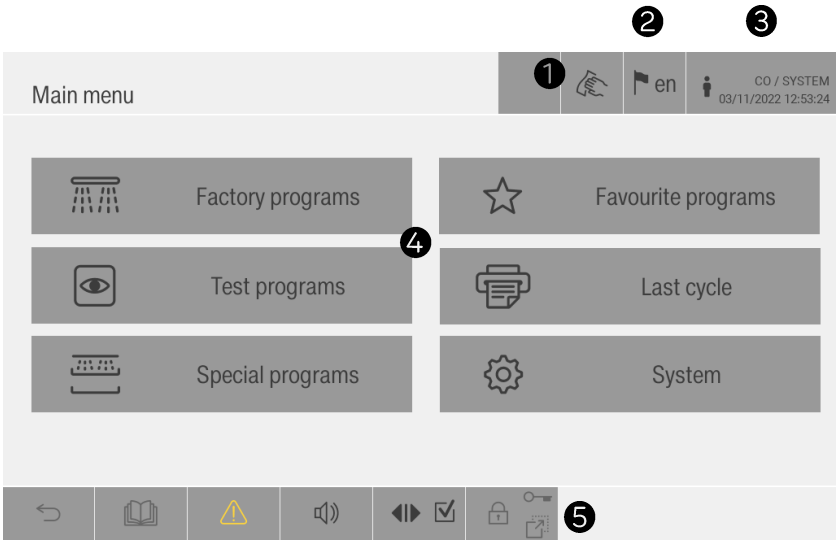
- ► Refit the plastic cap on the salt container and screw it in tightly.
- ► Place the load carrier in the machine.
- ► Start the “Rinse” program.

Always run the “Rinse” program after refilling the salt. This removes and dissolves any spilled salt and brine. Excess salt and brine which has overflowed can cause corrosion damage if not rinsed away.

During reactivation, the following symbol appears on the display:  .

8. CONTROL PANEL

8.1 Control panel – loading side



❶ Header
❷ Display language selection
❸ Current user
❹ Buttons to call up sub-menu
Cycle selection
Last cycle information menu
Settings menu
❺ Footer

Symbols	Button Description / Function
Factory program	Opens the list of ex-factory programs
Test program	Opens the list of test programs
Special program	Opens the list of special or customised programs
Favourite programs	Opens the list of programs saved as favourites, choose between Factory and Special programs
Last cycle	Opens a sub-menu with all the information about the last cycle run
System	Opens a sub-menu with the settings, adjustment and utility functions

8.1.1 Symbols on the header

BUTTON	DESCRIPTION
	Cycle running (GREEN)
	Cycle in alarm (RED)
	The current program has been interrupted, so the cycle needs to be repeated (YELLOW)
 END	Program completed successfully (GREEN)
 END	Program ended, but there was a program interruption (YELLOW)
 END	Program not completed successfully (RED)
	If manual mode is activated, the symbol is displayed at the top of the display (YELLOW)
	Regeneration active (YELLOW)
	Display cleaning button (Freezes the display for 30s to allow display cleaning)

8.1.2 Symbols on the footer

BUTTON	DESCRIPTION
	Backward button
	Main menu button
	Alarms active icon
	Warnings active icon
	Acoustic signal enabled
	Acoustic signal disabled
	Open door. Only closure is possible.
	Closed door. Only opening is possible.
	Door not closed. It is possible to open and close the door.
	Door locked.
	Door opening (yellow flashing).
	Door closing (yellow flashing).
	Door enabled.
	Door disabled because the unloading door is enabled.

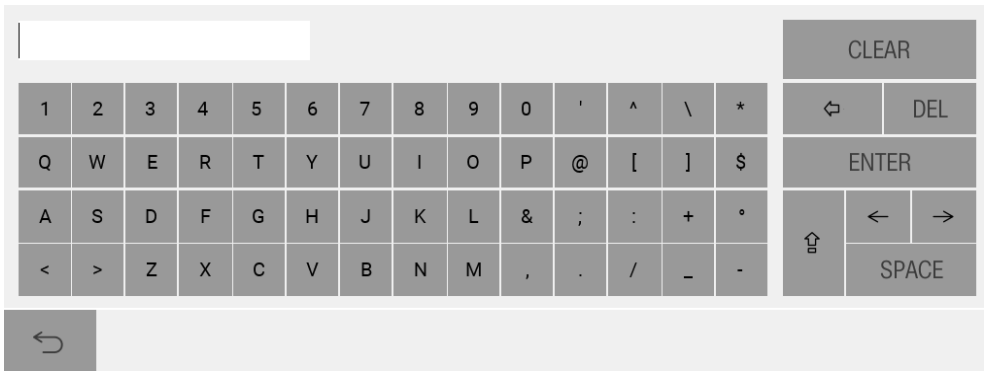
	Door disabled due to program running.
	Door disabled due to alarm.
	Door locked due to high chamber temperature

8.1.3 Keyboards

There are 2 available types of keyboards used to enter data, numbers, alphanumeric data and passwords.

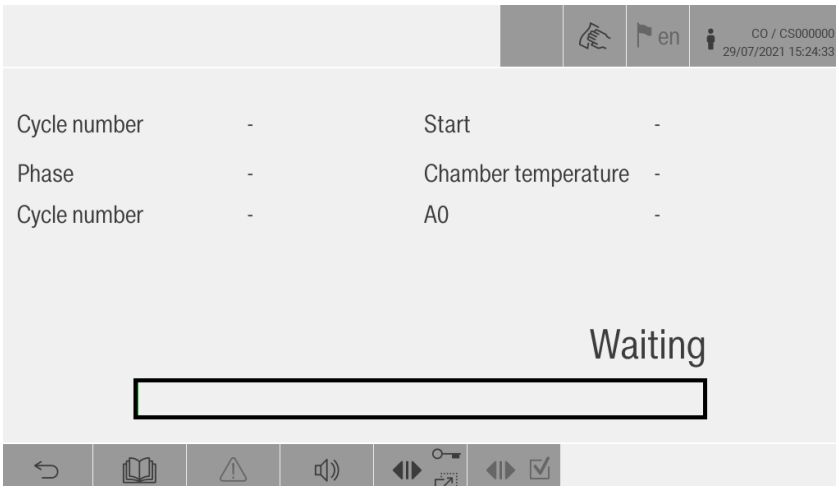
Numeric keyboard

Alphanumeric and password input keyboard



8.2 Control panel – unloading side

When the machine is waiting for a cycle start, the following screen appears.



If the icon is pressed the following page will appear:

By selecting the CYCLE button it is possible to return to the previously shown cycle page.

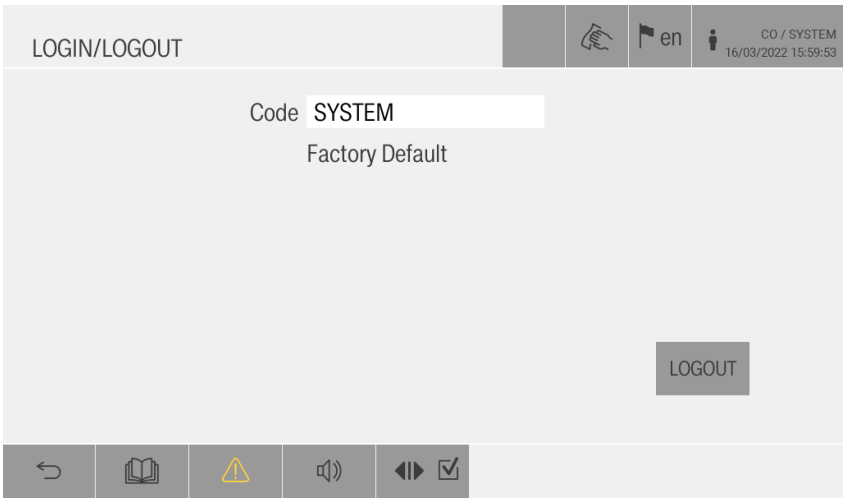
9. CYCLE MANAGEMENT

9.1 Operator login

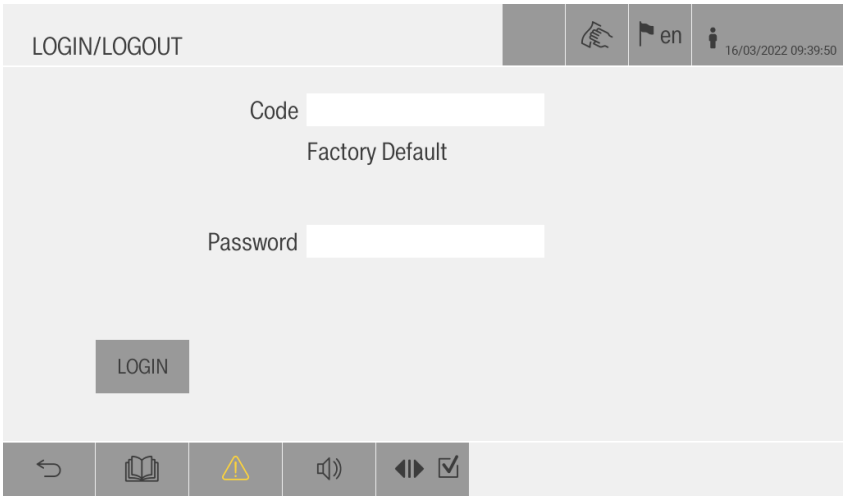
The operator must log in to be able to execute every operation on the display. Depending on the operator's level of authorisation, elements of the menu may be hidden.

To log in, press the  icon in the header.

If another operator is already logged in, the LOGOUT button must be pressed.



When the icon is pressed again, the following page will appear:



Insert the code and the password, then press LOGIN.
The operator code will appear at the top right of the display over the date and time.

ATTENTION

When an operator logs in for the first time, a password change is requested.
After the password change it will be necessary to LOG IN again.

9.2 Change language

To change the language, press the language icon in the header and the following screen will appear.

The language can be selected and confirmed using the ✓ key.

9.3 Cycle start

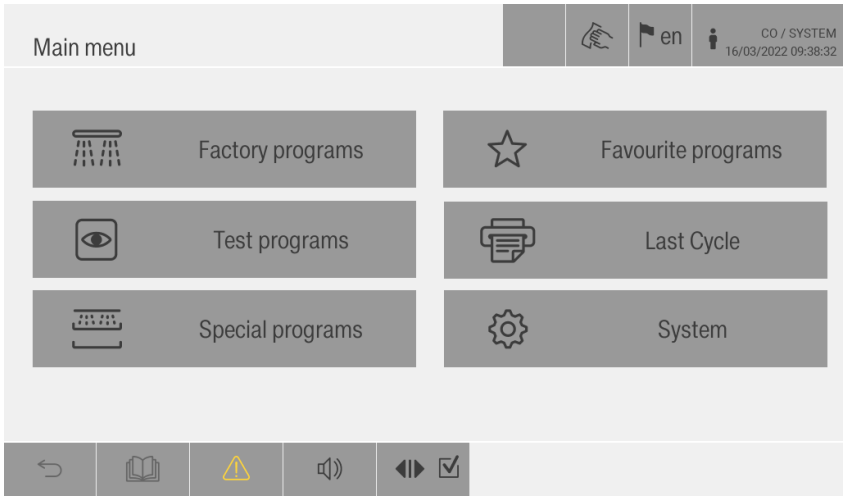
The start of a cycle can be set in two ways:

- ► Manually selecting the cycle
- ► Using the BASKET recognition

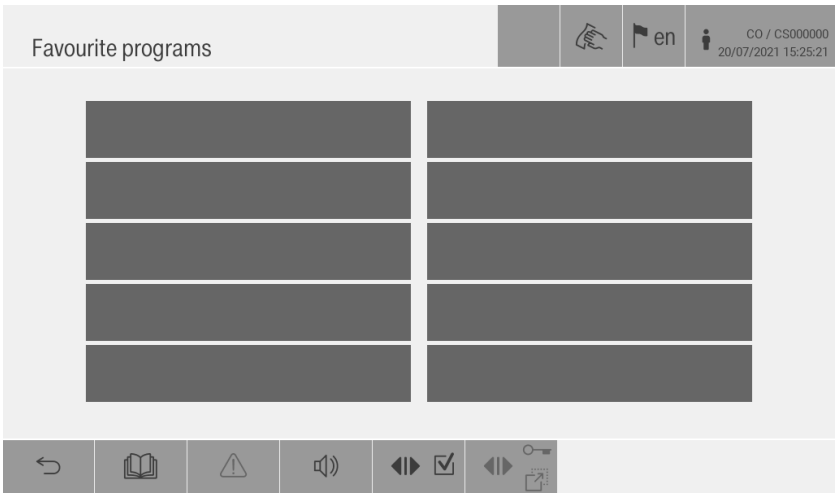
This setting can only be made by a trained technician with supervisor access.

9.3.1 Cycle start: standard version

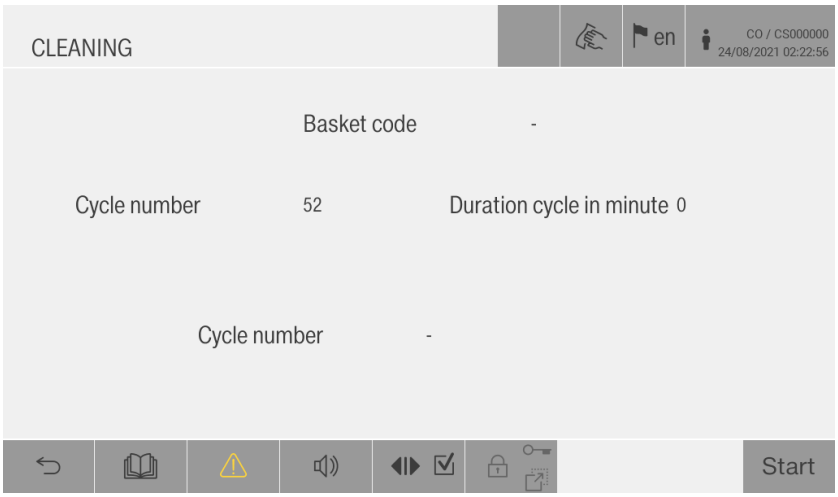
If the parameter for the AUTOMATIC CYCLE START is set to NO (SYSTEM → SETTING → WORK 3) With the machine ON, the main menu appears, and the cycle menu must be selected, choosing between FACTORY PROGRAMS, FAVOURITE PROGRAMS and SPECIAL PROGRAMS.



Select the cycle to be run from the list

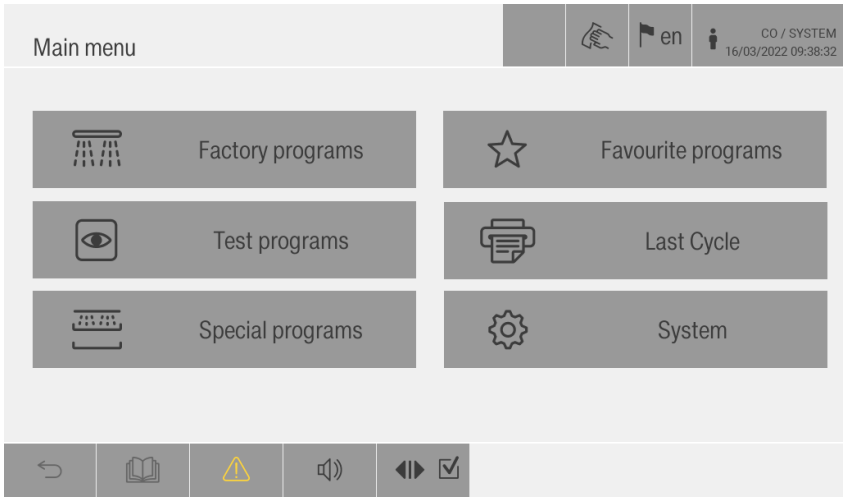


Then press the START button at the bottom of the screen **twice**

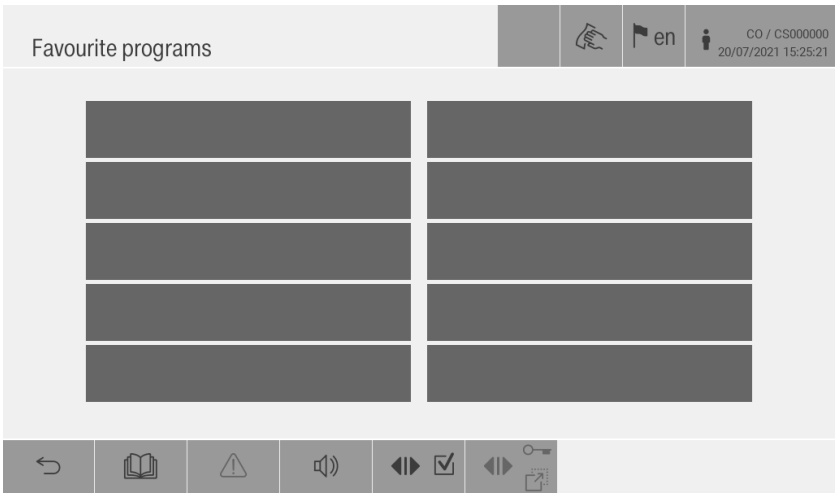


9.3.2 Cycle start: automatic version

If the parameter for the AUTOMATIC CYCLE START is set to YES (SYSTEM → SETTING → WORK 3) The procedure is the same as in the previous section.



Select the cycle to be run and the cycle will automatically start.

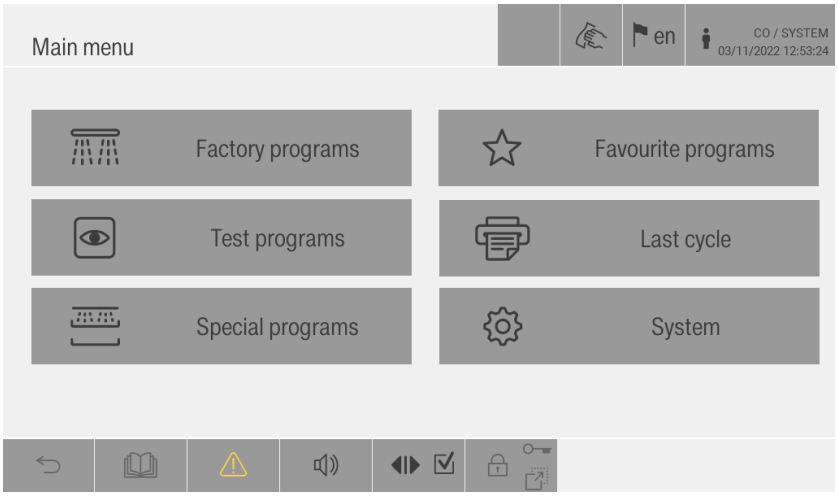


9.3.3 Cycle start: barcode reader

If the barcode reader is installed on the machine, and the CYCLE SELECTION is set to BASKET RECOGNITION, it is necessary to scan the code on the basket.
The list of the enabled program will be displayed and, according to the cycle start setting, it will be possible to select and start the cycle.

9.4 Reset procedure

In the event of an alarm, a red cross appears at the bottom of the display.

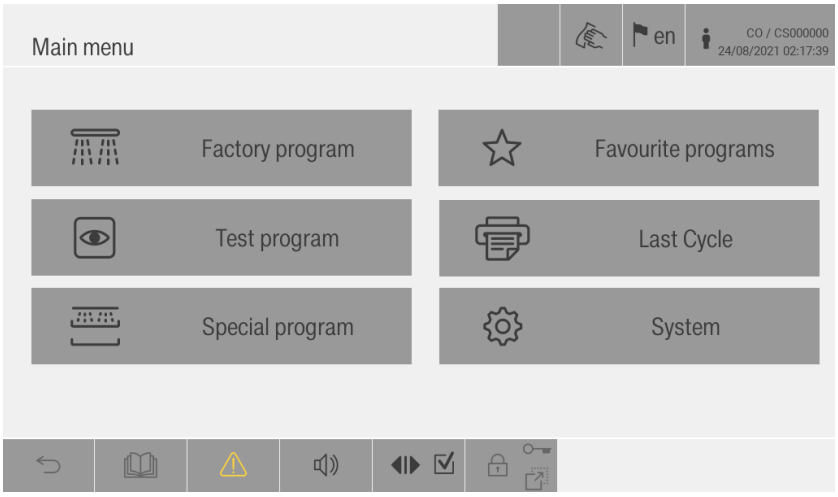


Press the red cross and a screen with the alarm code will be displayed.

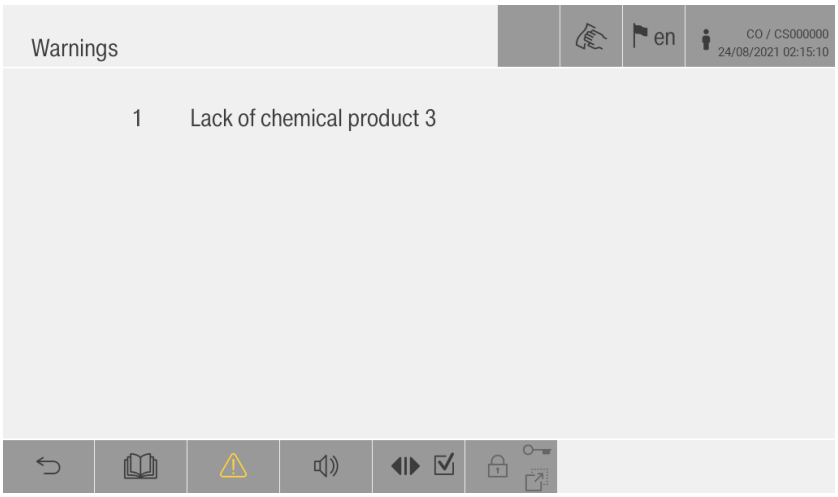
Solve the problem and press the RESET button. The machine resumes the cycle or goes into stand-by mode.

9.5 Alerts

In the event of a warning, a yellow triangle ⚠ appears on the footer of the display.

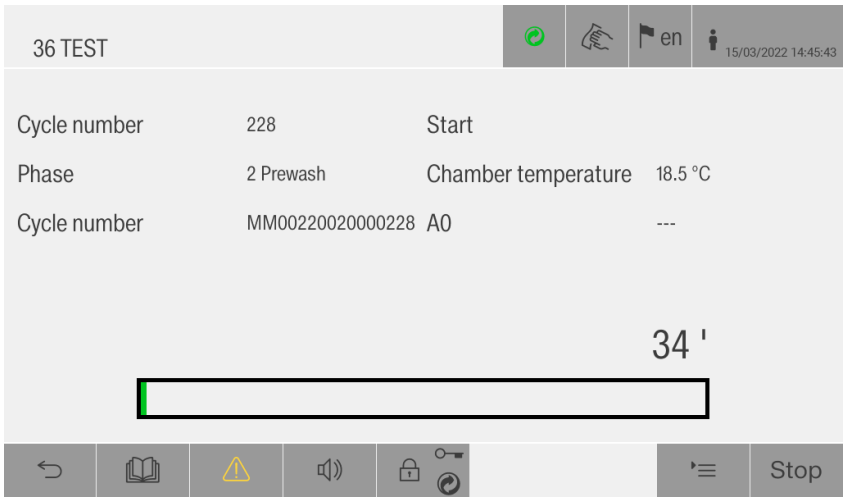


Press the yellow triangle and a screen with the warning code will be displayed.

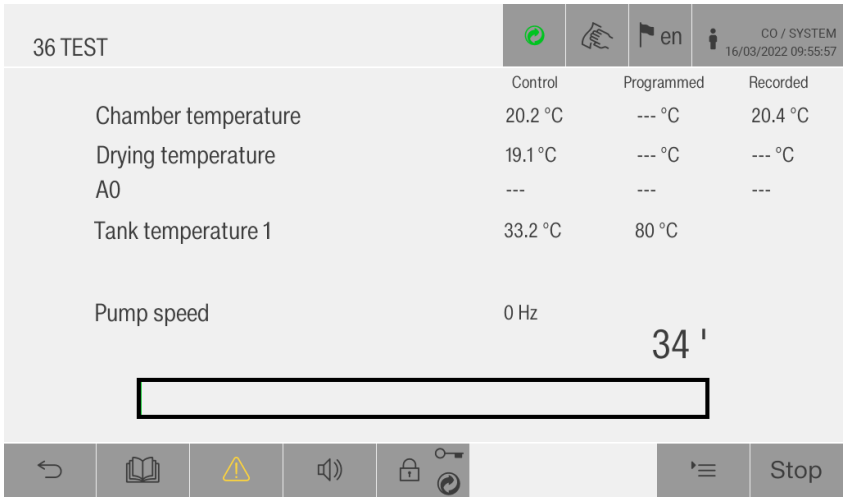


9.6 Cycle screens

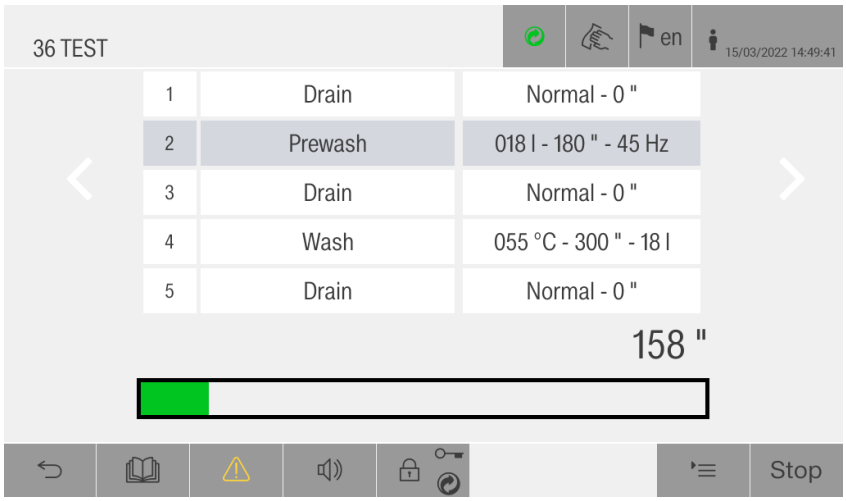
During the wash cycle, various information can be viewed.
The main page after the start of the cycle is the following:



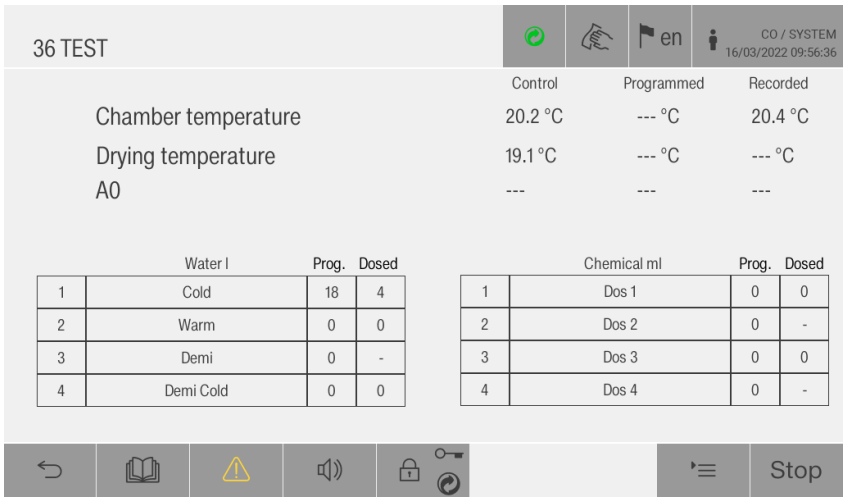
By pressing the ☰ button on the footer, the view can be changed and other information can be seen



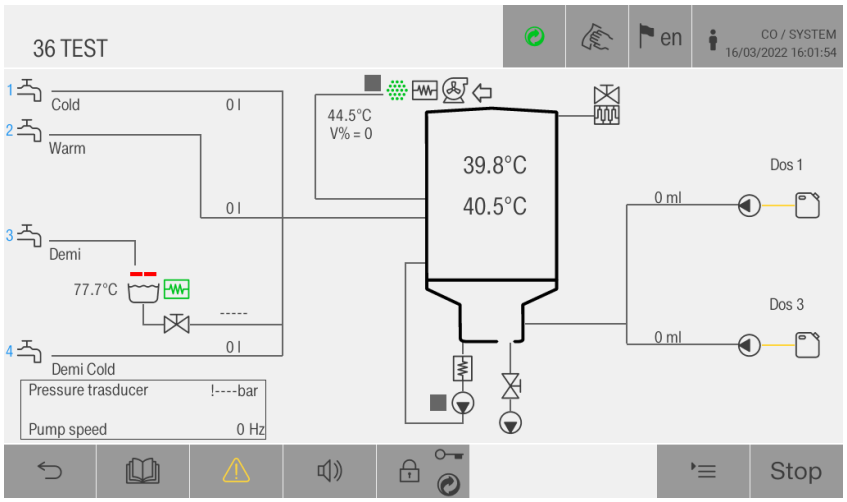
Second page: temperature information and remaining time



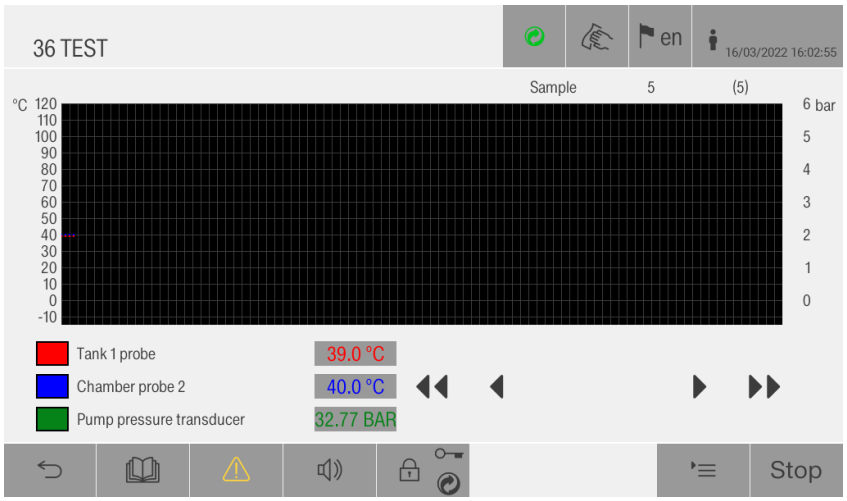
Third page: cycle information and remaining time of the running phase



Fourth page: consumption data and temperature information



Fifth page: synoptic



Sixth page: sensors trend

10. WASH PROGRAMS

The machine in your possession can be used with various wash programs depending on requirements; in particular, the following options are available:

Program	A_0 value	Use
SurgiPro	3000	Cycle dedicated to surgical instruments
AnesPro	3000	Cycle dedicated to anaesthesia equipment
ContainPro	600	Cycle dedicated to containers for instrument transport
MicroPro	3000	Cycle dedicated to microsurgical instruments
RoboPro	3000	Cycle dedicated to robotic instruments such as DaVinci or CMR Versius
OphthaPro	3000	Cycle dedicated to ophthalmology instruments
OrthoPro	3000	Cycle dedicated to orthopaedic instruments
ShoesPro	600	Cycle dedicated to OP shoes
ChemPro	--	Cycle dedicated to the treatment of thermolabile instruments and objects
BabyPro	600	Cycle dedicated to baby bottles
Rinse	--	Cycle dedicated to service operation or salt replacement rinse
Drain	--	Service cycle
Drying	--	Cycle dedicated to the drying phase only
Refresh	--	Cycle dedicated to refreshing instruments
Self-cleaning	600	Cycle dedicated to tank and chamber disinfection before a maintenance intervention, or to be periodically run to clean the chamber and circuits

10.1 Program blocks

- **Drain:** drains water from the chamber
- **Prewash:** the prewash is used to remove coarse dirt and foaming substances.
- **Wash:** depending on the load, washing usually occurs at temperatures of 45°C - 93°C, adding the necessary detergent (chemicals)
- **Rinse:**
  - Intermediate rinse: rinse-off and neutralisation of process chemicals from the previous phases
  - Final rinse: demineralised water should preferably be used, if available, to avoid deposits on the load and to reduce process chemical residue.
- **Drying:** sufficient drying reduces the risk of corrosion caused by residual moisture on the load.
- **Tank disinfection:** used in special cycles for the periodical disinfection of the tanks and chamber to avoid bioburden growth on the surfaces of the tanks and chamber, such as hydraulic circuits

10.2 Program overview

No.	Program name	Prewash	Main wash	Wash	Rinse	Final rinse	Drying
1	SurgiPro	CW – 22 l 50 Hz 180”	WW – 22 l Dos1- 6 ml/l 55°C - 300”		CDW – 20 l 120”	DW – 20 l 90°C – 300”	120” – 900” 120°C
2	AnesPro	CW – 24 l 50 Hz 120”	WW – 25 l Dos1- 6 ml/l 55°C - 300”		CDW – 20 l 120”	DW – 20 l 90°C – 300”	120” – 900” 100°C
3	ContainPro		WW – 20 l Dos1- 6 ml/l 45°C - 180”		CDW – 18 l 60”	DW – 20 l 90°C – 60”	120” – 900” 120°C
4	MicroPro	CW – 22 l 50 Hz 180”	WW – 24 l Dos1- 6 ml/l 55°C - 300”		CDW – 20 l 120”	DW – 20 l 90°C – 300”	120” – 900” 120°C
5	RoboPro	CW – 22 l 50 Hz 180”	WW – 24 l Dos1- 6 ml/l 40°C - 300”	WW – 24 l Dos1- 6 ml/l 55°C - 300”	CDW – 20 l 120”	DW – 20 l 90°C – 300”	120” – 900” 120°C
6	OphthaPro	CW – 24 l 50 Hz 120”	WW – 24 l Dos1- 6 ml/l 55°C - 300”		CDW – 20 l 120”	DW – 20 l 90°C – 300”	120” – 900” 120°C
7	OrthoPro	CW – 22 l 50 Hz 180”	WW – 22 l Dos1- 6 ml/l 55°C - 300”		CDW – 20 l 120”	DW – 20 l 90°C – 300”	120” – 900” 120°C
8	ShoesPro	CW – 20 l 50 Hz 60”	WW – 20 l Dos1- 6 ml/l 45°C - 180”		CDW – 18 l 60”	DW – 20 l 80°C – 60”	120” – 900” 100°C
9	ChemPro						
10	BabyPro	CW – 22 l 50 Hz 60”	WW – 22 l Dos1- 6 ml/l 45°C - 180”		CDW – 18 l 60”	DW – 20 l 90°C – 60”	120” – 900” 120°C
11	Rinse				CDW – 20 l 60”		
12	Drain						
13	Drying						120” – 900” 120°C
14	Refresh	CDW – 22 l Dos1- 7 ml/l 55°C - 900”	CW – 22 l 50 Hz 120”	CDW – 22 l Dos3- 3 ml/l 50°C - 600”	CDW – 22 l 50 Hz 120”	DW – 20 l 80°C – 120”	120” – 600” 110°C
15	Self-cleaning					DW – 20 l 90°C – 60”	

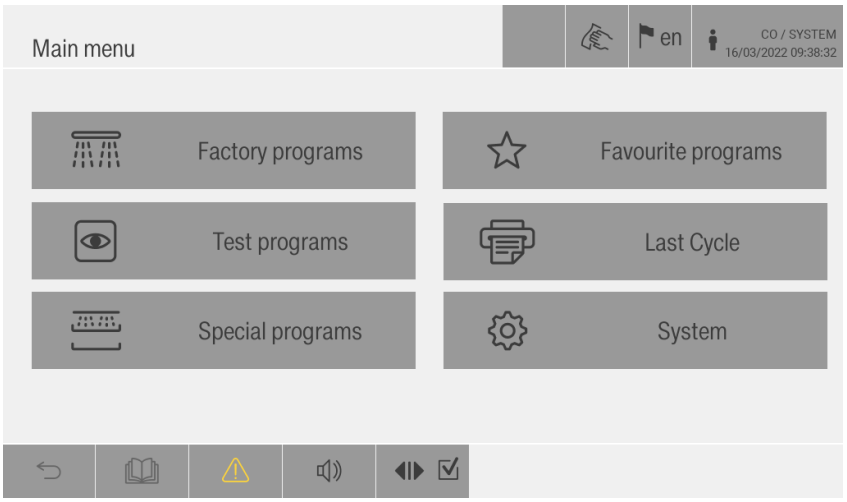
CW = cold water
WW = warm water
CDW = cold demi water
DW = demineralised water

DOS 1 = Detergent
DOS 2 = optional (retrofit kit required)
DOS 3 = Neutraliser
DOS 4 = (retrofit kit required)

11. MENU

11.1 Main Menu

The main menu allows access to the settings menu, archives, machine status and cycle selection menu. Depending on the authorisation level of the logged operator, the following menu can be completely or partially accessed.



11.2 Factory programs

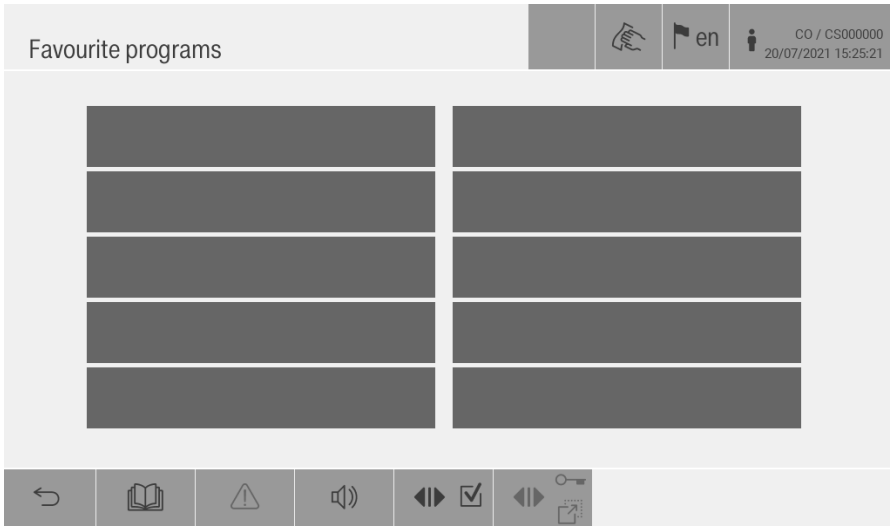
This menu is dedicated to the selection of the manufacturer programs, to start a wash cycle:

11.3 Special programs

This menu is dedicated to the selection of the customer programs, to start a wash cycle:

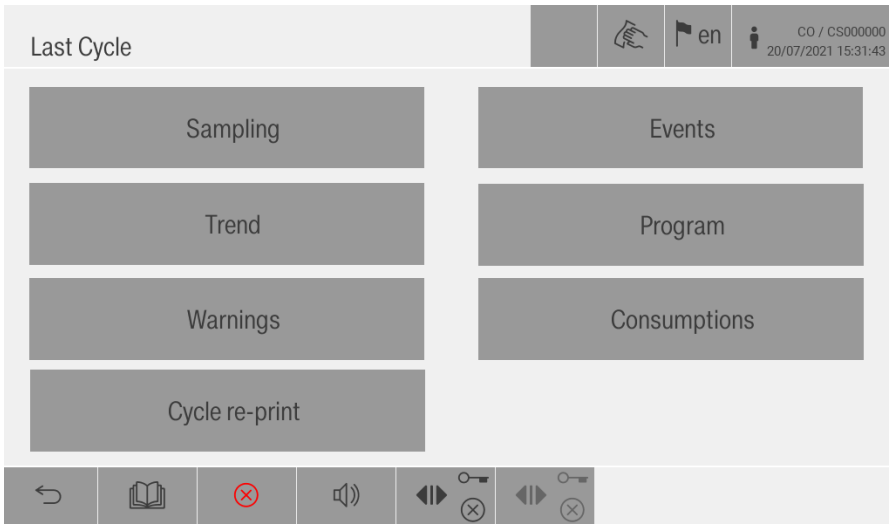
11.4 Favourite programs

In this menu it is possible to save the most used programs, to facilitate the operator when selecting the wash cycle:



11.5 Last cycle

This page allows viewing of the data of the last program run.



From this page it is possible to open the various dedicated pages to view the samples, events, graph, program specifications, warnings and consumption relative to the last program run.

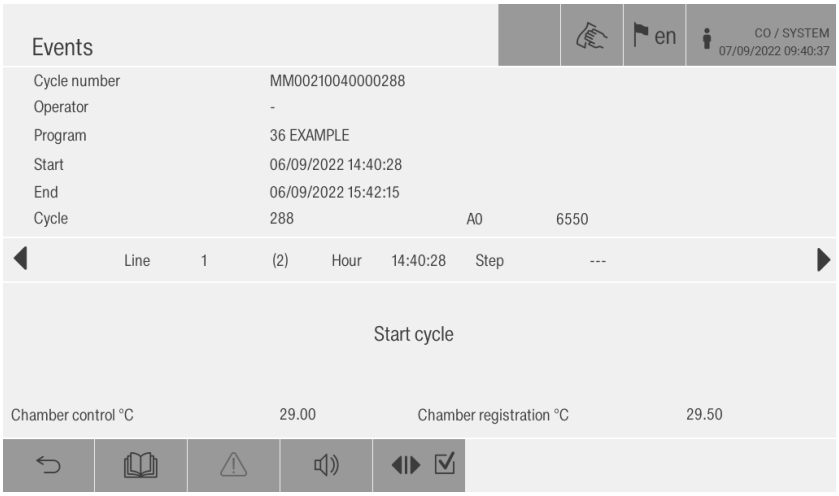
If a printer is installed, it is also possible to reprint the entire report, or the desired data from the various pages.

11.5.1 Sampling

The different pages can be scrolled to view all the temperatures:

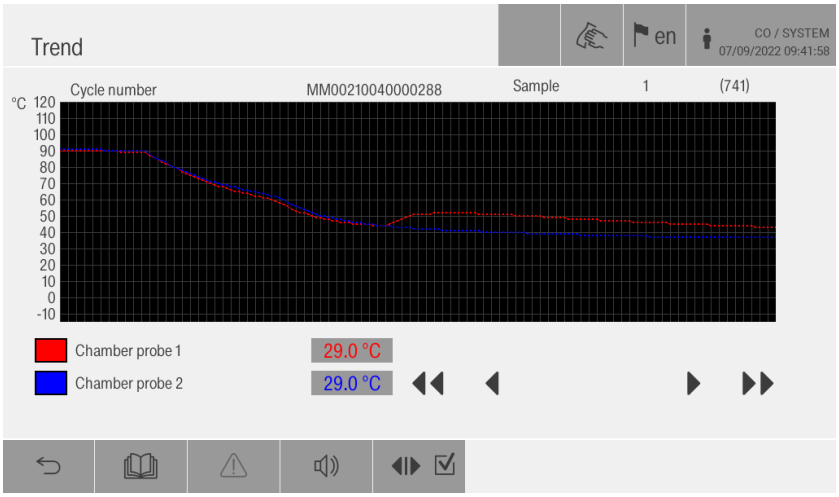
11.5.2 Events

The different pages can be scrolled to view all the steps executed during the cycle:



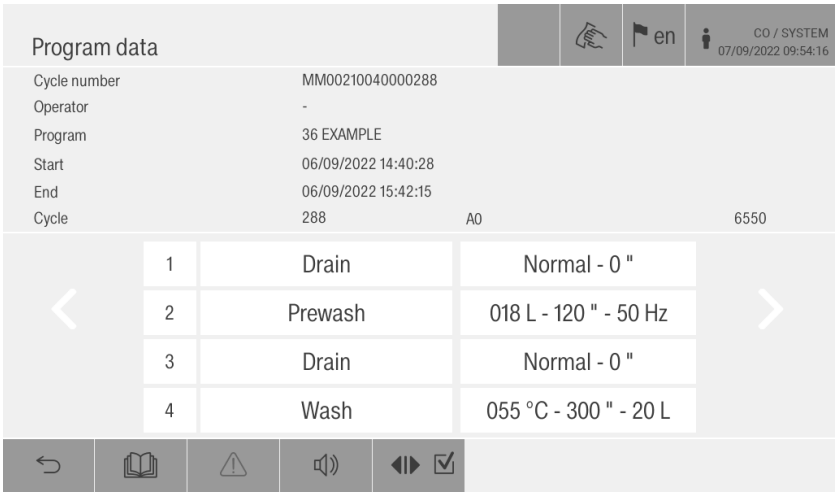
11.5.3 Trend

Displays the sensors trend:



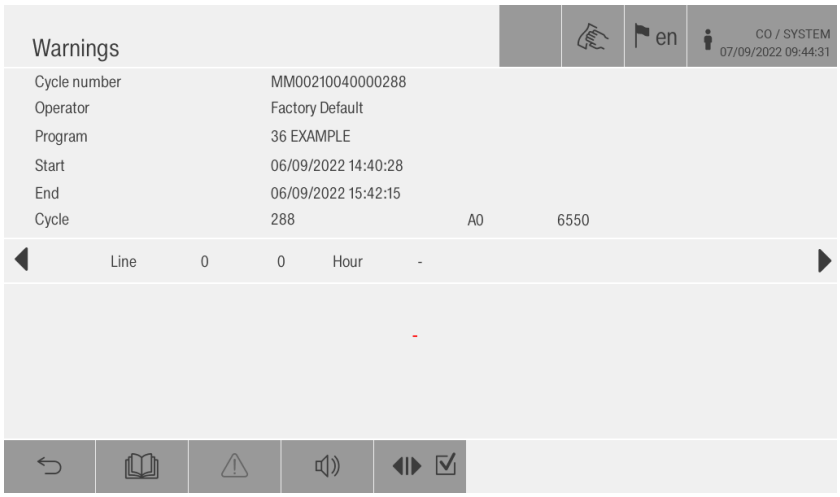
11.5.4 Program data

Displays the cycle parameters:



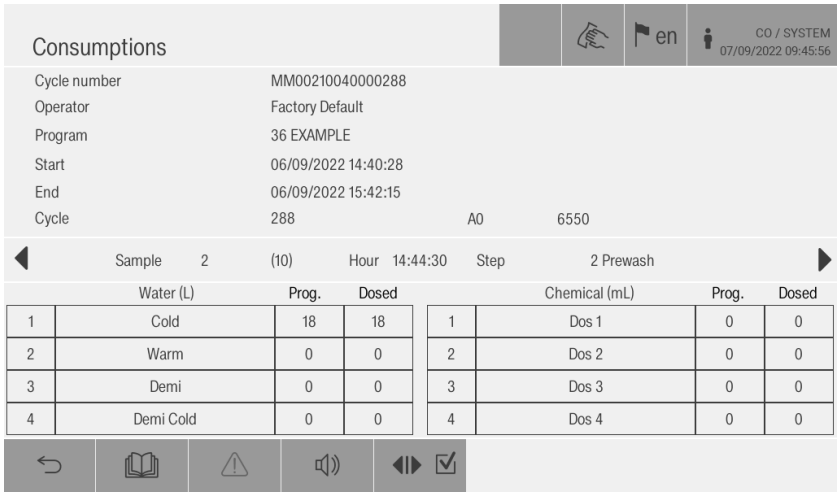
11.5.5 Warnings

The different pages can be scrolled to view all the warnings and alarms that occurred during the cycle:



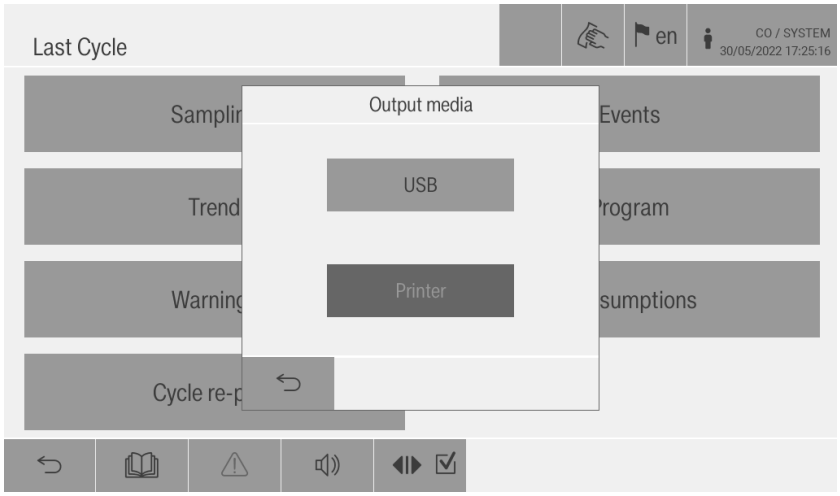
11.5.6 Consumption

Displays the water and chemical product consumption data for each stage of the cycle:



11.5.7 Cycle re-print

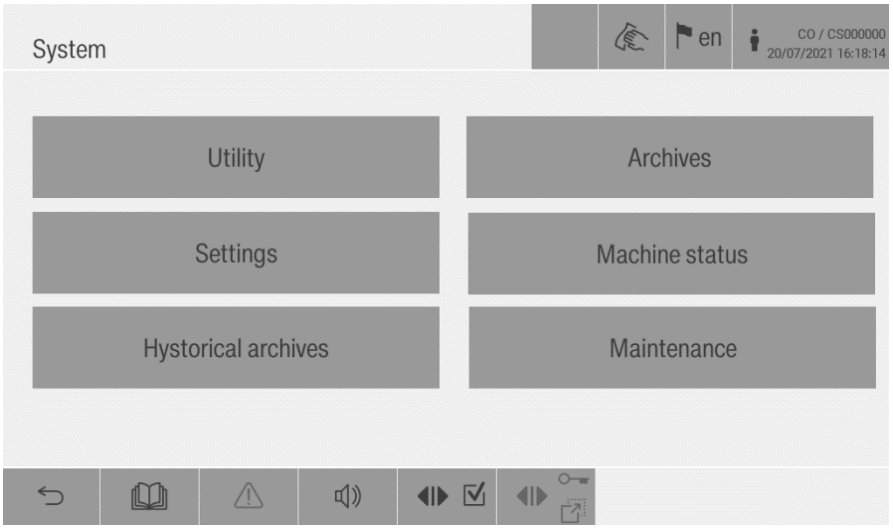
Allows printing of the sampling, cycle setting, and events of the last cycle on a USB or printer:



11.6 System

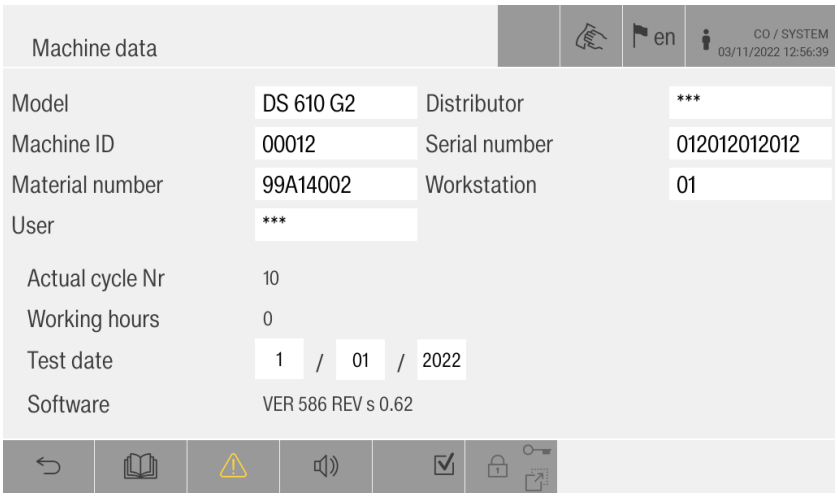
This menu allows access to several other menus:

- ► Utility: machine backup and recovery, automatic cycle repetition, machine data, heating selection (in case of mixed heated machines)
- ► Archives: storage and settings of program settings
- ► Settings: machine set-up
- ► Machine status: check and activation of input/output
- ► Historical archives: to consult the servicing log, events, cycles, etc.
- ► Maintenance: execution of maintenance and adjustment operations



11.6.1 Utility

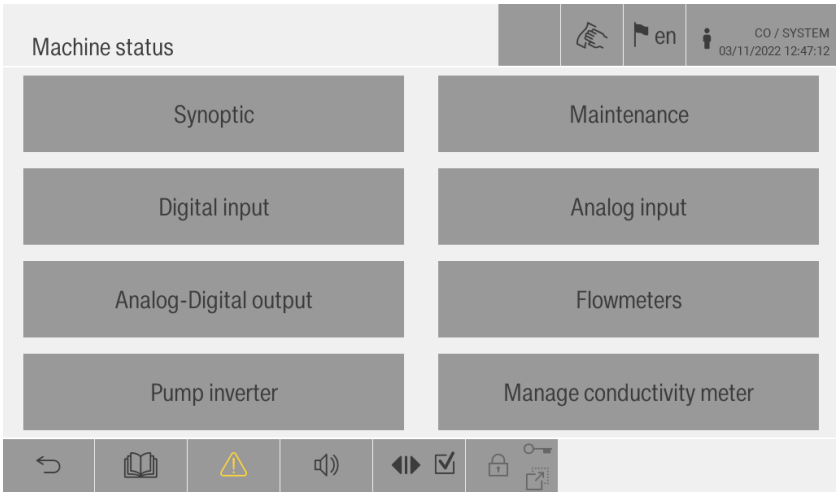
Machine data: to view the main machine data including the name, serial number, test date and user



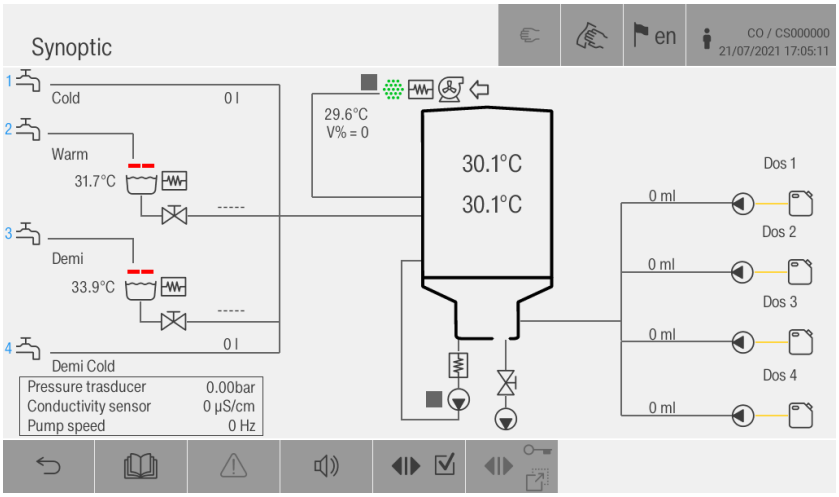
11.6.2 Machine status

In this menu it is possible to check the machine's digital input and output.

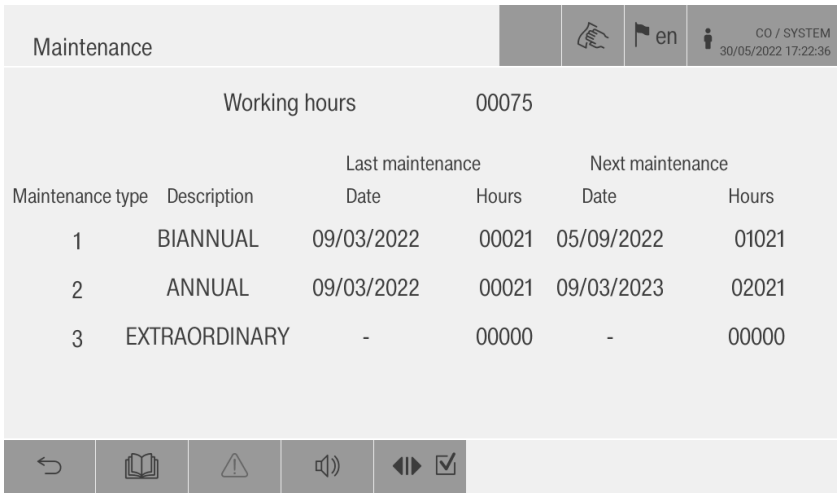
If the machine is running a cycle, this menu is hidden.



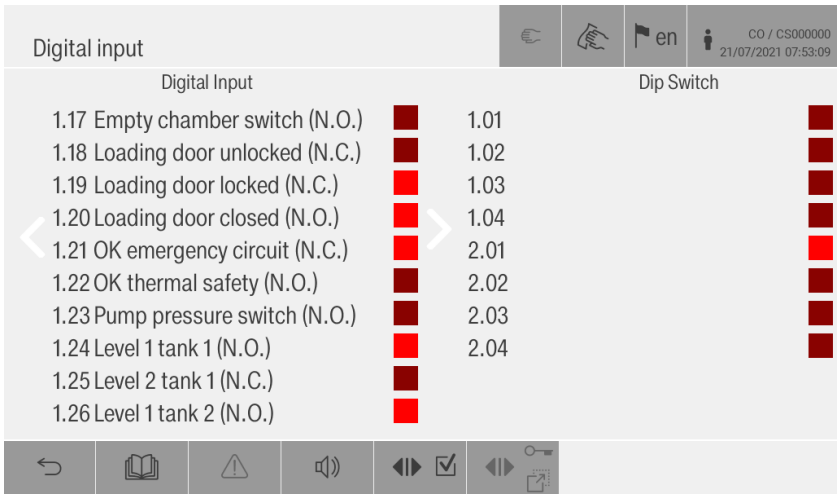
Synoptic: allows checking and activation of the devices directly from the image. The component turns green when active, grey when disabled, and red if in alarm.

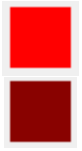


Maintenance: displays the maintenance status



Digital input: displays the digital input status

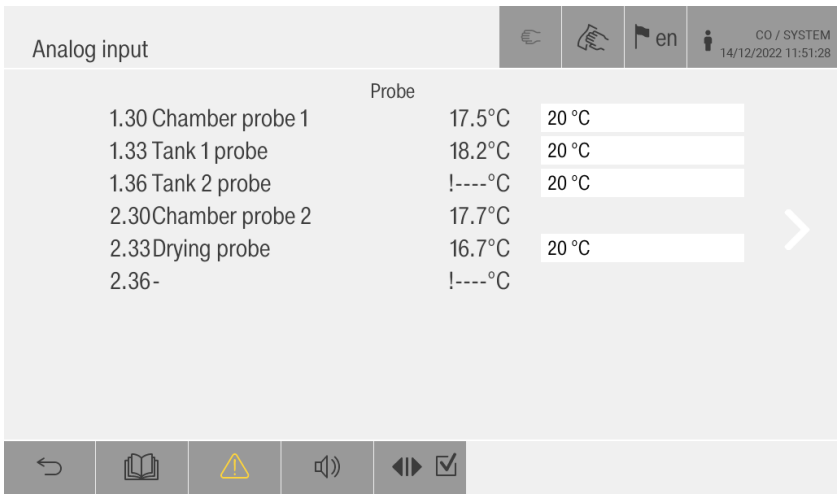




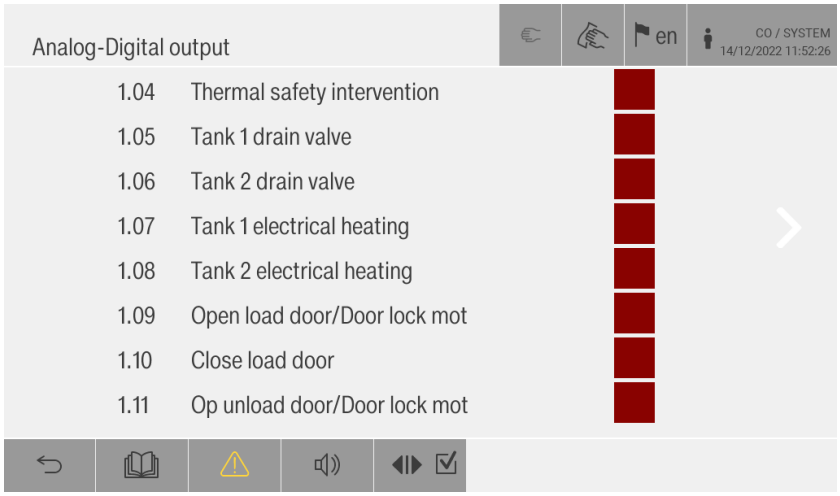
Input ON

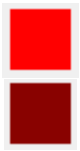
Input OFF

Analogue input: displays the status and value measured from the analogue input by the probes and pressure transducers



Analogue-Digital output: displays and allows changes to the digital output status.
To activate the digital output, it is sufficient to press on the red square on the right side of the output description.

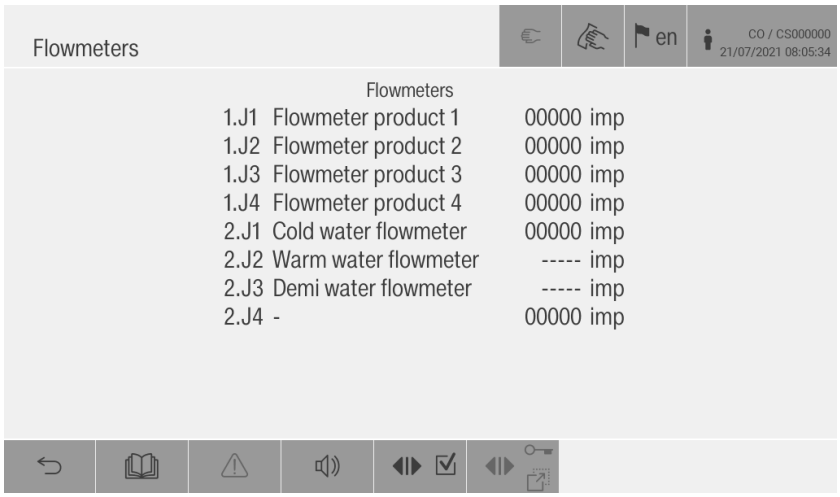




Output active

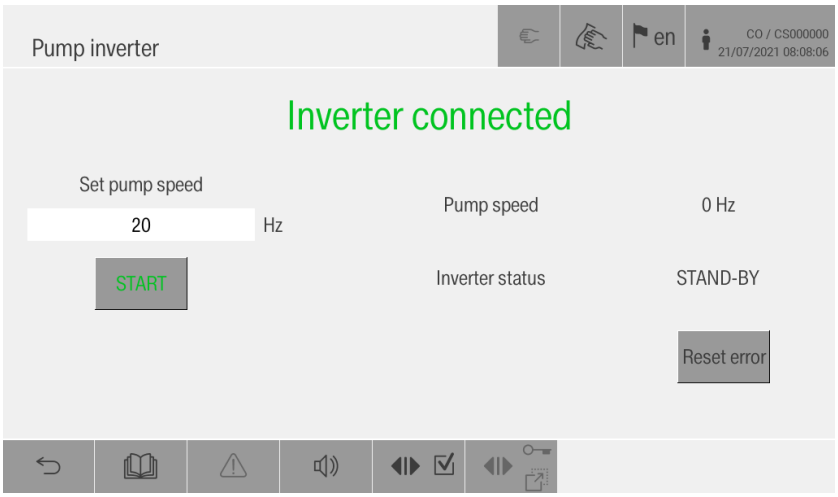
Output not active

Flowmeters: displays the status and value measured from the water and chemical flowmeters

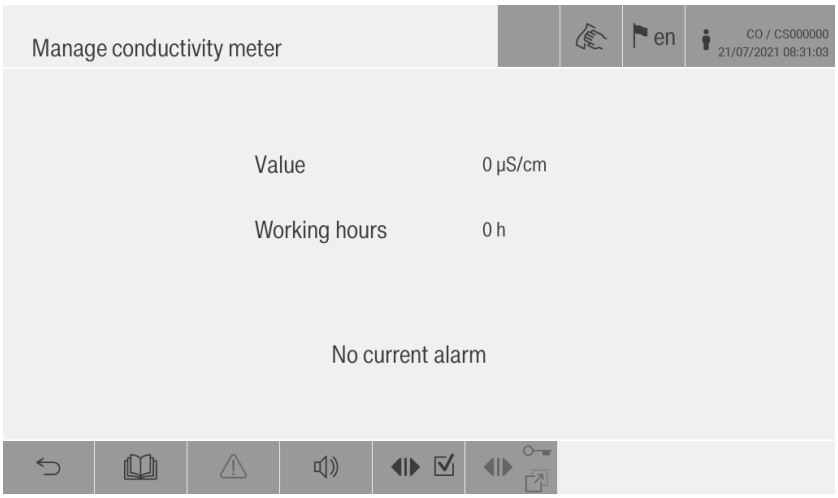


Pump inverter: allows manual control of pump activation when the inverter is installed.
To activate the pump inverter, the manual control must be activated.

⚠	To manually activate the pump inverter, the door must be closed and locked, the chamber must be filled with water and there must be no alarms displayed on the management page below



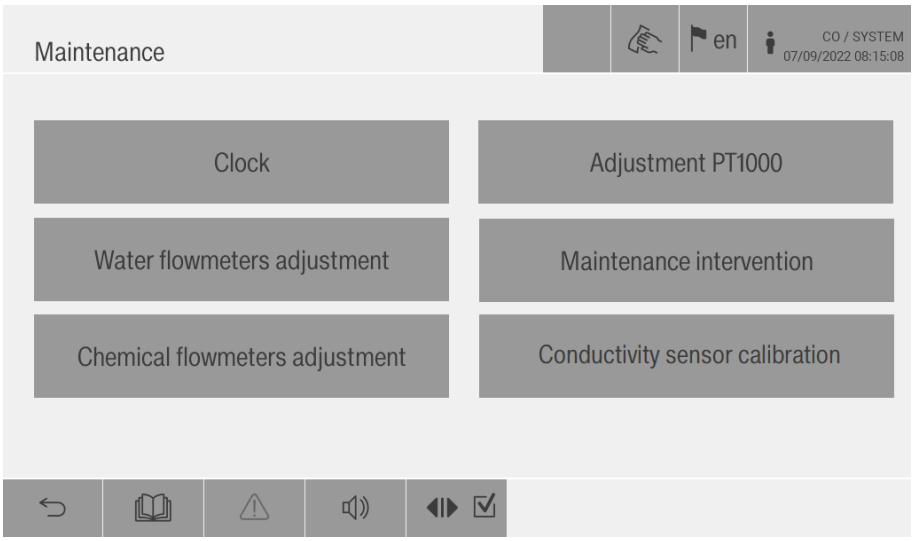
Conductometer: displays the status of the conductometer, presence of alarms, and value measured by the probe.



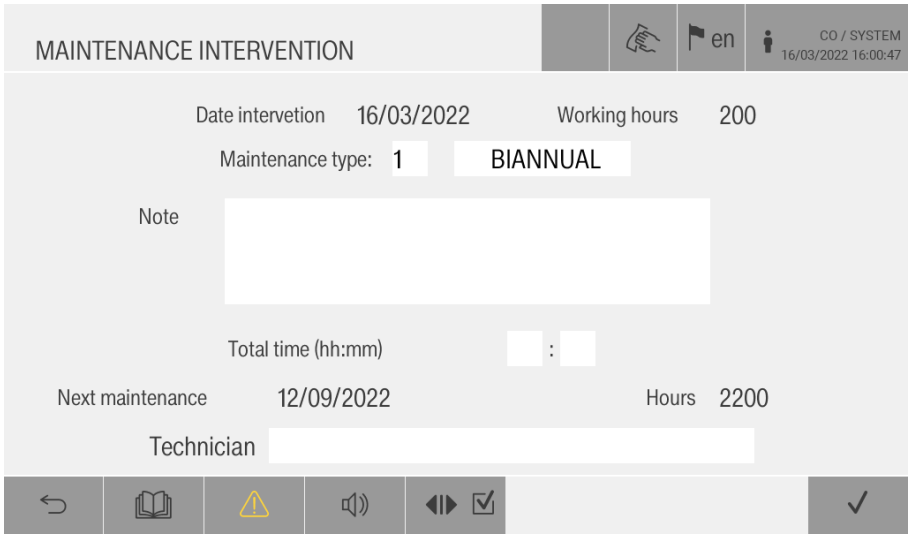
11.6.3 Maintenance

This menu allows the execution and registration of routine maintenance.

	For user level 1 and 2, only the following menus can be accessed: - Clock - Maintenance intervention



Maintenance intervention: this menu is used to record maintenance interventions



The date is automatically filled based on the clock.
The type of maintenance must be selected (only BIANNUAL can be selected for user level 1 and 2), including a description of the activity carried out.
Then fill in the time required to complete the activity and the name of the technician or operator who performed the maintenance.
The next maintenance interval will be automatically reset.

12. ALARM MESSAGES

12.1 Description of alarms

During operation, every machine error is notified through an alarm message and relative acoustic signal.
An alarm that occurs during machine operation is signalled by a red cross on the display and a message.
The alarm remains active until the problem is solved and the message is reset, as explained in the related section.

12.2 List of alarms

Some of the potential alarms can be solved and reset by the operator.
For other alarms, a service technician must intervene.
For safe access to the chamber and technical area, please refer to the “Maintenance” section.

The person in charge of alarm resolution is indicated in the following table according to the legend below.

OP: operator
S: service technician

M: manual door version
A: automatic door version

No.	Message displayed	Door version	Description	Responsible for alarm resolution
1	**Power failure**		Signals that the electrical power supply was interrupted during a cycle, once the power is restored	OP
2	**Loading door open during cycle**	**M**	Side loading door opened and/or unlocked during the cycle in progress	S
3	**Unloading door open during cycle**	**M**	Side unloading door opened and/or unlocked during the cycle in progress	S
4	**Loading door open & locked**	**M**	Side loading door is open and locked (inconsistency)	S
5	**Unloading door open & locked**	**M**	Unloading side door is open and locked (inconsistency)	S
6	**Door status discrepancy**	**M**	The 2 doors are in an inadmissible configuration (they may both be open, because both unlocked and/or open). Or since one of the doors is with door lock motorisation off, the status of the 2 locking and unlocking limit switches is incompatible.	OP
7	**Loading door locking failure**	**M**	Triggered in the following possible situations (side loading door): **a)** the door was not locked within the time defined by the parameter **b)** the door was opened when it had	S

			started locking	
8	**Unloading door locking failure**	**M**	Triggered in the following possible situations (sterile side door): **a)** the door was not locked within the time defined by the parameter **b)** the door was opened when it had started locking	S
9	**Loading door unlocking failure**	**M**	The loading door was not unlocked within the time defined by the parameter	S
10	**Unloading door unlocking failure**	**M**	The sterile door was not unlocked within the time defined by the parameter	S
2	**Loading door opening failure**	**A**	The door opening motor 1 (loading side) is continuously on, longer than the time defined by the parameter	S
3	**Unloading door closing failure**	**A**	The door opening motor 2 (unloading side) is continuously on, longer than the time defined by the parameter	S
4	**Loading door closing failure**	**A**	The door closing motor 1 (loading side) is continuously on, longer than the time defined by the parameter	S
5	**Unloading door closing failure**	**A**	The door closing motor 2 (unloading side) is continuously on, longer than the time defined by the parameter	S
6	**Door status discrepancy**	**A**	The doors are in an inadmissible configuration (both not closed).	S
7	**Loading door open during cycle**	**A**	During the cycle, door 1 (loading side) is open.	S
8	**Unloading door open during cycle**	**A**	During the cycle, door 2 (unloading side) is open.	S
9	**Loading door limit switch discrepancy**	**A**	Door 1 (loading side): with the door opening limit switch active, the closing limit switch is also active.	S
10	**Unload.door limit switch discrepancy**	**A**	Door 2 (unloading side): with the door opening limit switch active, the closing limit switch is also active.	S
11	**No cold water**		The cold water wash tank supply was not completed (no new water flowmeter pulse for longer than the time defined by the parameter).	S

12	**No warm water**		The warm water wash tank supply was not completed (no new water flowmeter pulse for longer than the time defined by the parameter). In the configuration with tank 2 present, it indicates that the water 2 supply in the tank or the water 2 discharge from the tank to the wash tank was not completed within the maximum time defined by the parameter (level control).	S
13	**No demi water**		The demineralised water wash tank supply was not completed (no new water flowmeter pulse for longer than the time defined by the parameter). In the configuration with tank 1 present, it indicates that the water 1 supply in the tank or the water 1 discharge from the tank to the wash tank was not completed within the maximum time defined by the parameter (level control).	S
17	**Chemical DOS1 lack**		The product associated with the dosage unit 1 (detergent) is finished (if enabled as an alarm by the parameter). Diagnostics based on (with dosing pump active): - pressure switch disabled if time-based dosage (1.5 s reading delay); - no new pulse for longer than the time defined by the parameter if dosage by flowmeter.	OP
18	**Chemical DOS2 lack**		The product associated with the dosage unit 2 (neutralising agent) is finished (if enabled as an alarm by the parameter). Diagnostics based on (with dosing pump active): - pressure switch disabled if time-based dosage (1.5 s reading delay); - no new pulse for longer than the time defined by the parameter if dosage by flowmeter.	OP
19	**Chemical DOS3 lack**		The product associated with the dosage unit 3 (lubricant) is finished (if enabled as an alarm by the parameter). Diagnostics based on (with dosing pump active): - pressure switch disabled if time-based dosage (1.5 s reading delay); - no new pulse for longer than the time defined by the parameter if dosage by flowmeter.	OP

20	**Chemical DOS4 lack**		The product associated with the dosage unit 4 (soda ash) is finished (if enabled as an alarm by the parameter). Diagnostics based on (with dosing pump active): - pressure switch disabled if time-based dosage (1.5 s reading delay); - no new pulse for longer than the time defined by the parameter if dosage by flowmeter.	OP
23	**Drain failure**		Triggered if the drainage solenoid valve is open for longer than the set limit, if the wash tank level is still active (wash tank not emptied);	S
24	**Fan failure**		Diagnostics active if the delay parameter is not zero, for the following situations: - the fan pressure switch is inactive, having sent a command to turn the fan on at maximum speed; - the fan pressure switch is active, having sent a command to turn the fan off. The pressure switch reading is subject to the delay defined by the parameter	S
25	**Minimum drying temperature not reached**		The air temperature never reached the minimum limit defined by the parameter during drying with electric heating (or does not reach the drying set point when the latter has a value lower than the one defined by the parameter).	S
26	**Prewash temperature too high**		The wash tank temperature has risen above the maximum limit defined by the parameter during the prewash phase.	OP
27	**Chamber temperature too high**		The temperature in the wash tank exceeds the limit 102°C (operating limit to protect against overheating).	S
28	**Drying temperature too high**		The air temperature exceeds the limit 162°C (operating limit to protect against overheating).	S
29	**Tank 1 temperature too high**		In the configuration with tank 1 present, the air temperature in tank 1 exceeds the limit 100°C (operating limit to protect against overheating).	S
30	**Chamber probe 1 failure**		Fault in wash tank temperature probe 1 (regulation probe)	S
31	**Chamber probe 2 failure**		Fault in wash tank temperature probe 2 (redundancy probe).	S
32	**Drying probe failure**		Fault in air temperature probe (drying probe).	S
33	**Tank 1 probe failure**		In the configuration with tank 1 present, temperature probe fault in tank 1.	S

34	**Chamb. probes temperature discrepancy**		Triggered when the parameter relating to the control is set to YES, only during the treatment phase and if all the following conditions are satisfied: a) the wash tank temperature is greater than the limit set by the parameter b) the wash tank probe 2 differs from probe 1 by an absolute value greater than the maximum limit set by the parameter; c) the heating element in the wash tank is inactive (the heating elements in the wash tank are off or steam heating is inactive);	S
36	**Unloading side panel not connected**		Lack of communication with the keyboard on the unloading door side (on Can Bus serial)	S
37	**CAN serial connection failure**		Lack of communication on the serial (Can Bus) connecting the master keyboard with the slave base boards.	S
39	**No chamber heating**		During the electrical heating of the wash tank (wash tank resistance on) the temperature increased by less than 1°C during the time set by the parameter.	S
40	**No tank 2 heating**		In the configuration with tank 2 present, during the electrical heating of tank 2, the temperature of tank 2 increased by less than 1°C during the time set by the parameter.	S
41	**No tank 1 heating**		In the configuration with tank 1 present, during the electrical heating of tank 1, the temperature of tank 1 increased by less than 1°C during the time set by the parameter.	S
42	**Thermal protection intervention**		The thermal safety input is disabled with the safety contactor command on, or is active with the safety contactor command off (1.5 s reading delay).	S
46	**Wash pump pressure switch failure**		Diagnostics active if parameter = YES. The pressure switch of the wash impeller pump is disabled with the pump command on, or is active with the pump command off (diagnostics with the pump command on is bypassed during water supply and active draining). It intervenes with a reading delay as defined by the parameter.	S
47	**Chemical flowmeter 1 failure**		The flowmeter for the chemical additive 1 (detergent) signals surplus pulses above the limit defined by the parameter, with the dosing pump	S

			command off.	
48	**Chemical flowmeter 2 failure**		The flowmeter for the chemical additive 2 (neutralising agent) signals surplus pulses above the limit defined by the parameter, with the dosing pump command off.	S
49	**Chemical flowmeter 3 failure**		The flowmeter for the chemical additive 3 (lubricant) signals surplus pulses above the limit defined by the parameter, with the dosing pump command off.	S
50	**Chemical flowmeter 4 failure**		The flowmeter for the chemical additive 4 (soda ash) signals surplus pulses above the limit defined by the parameter, with the dosing pump command off.	S
51	**Cold water flowmeter failure**		The flowmeter for the cold water signals surplus pulses above the limit defined by the parameter, with the water solenoid valve command closed.	S
52	**Warm water flowmeter failure**		The flowmeter for the warm water signals surplus pulses above the limit defined by the parameter, with the water solenoid valve command closed.	S
53	**Demi water flowmeter failure**		The flowmeter for the demineralised water signals surplus pulses above the limit defined by the parameter, with the water solenoid valve command closed.	S
54	**Hepa filter obstructed**		The air filter of the drying fan is clogged (5.0 s reading delay).	S
55	**Conductometer failure**		Electrical conductivity sensor error (Ex, with x = 1,..., 6) - E1: generic error - E2: measurement above the maximum limit - E3: measurement below the minimum limit - E4: sensor in short circuit - E7: Max limit for reset reached - E8: Conductometer status discrepancy - E9: MieleBus plug-in not recognised	S
56	**Conductivity too high**		The conductivity value exceeds the maximum limit set by the phase parameter. Conductivity is monitored in the prewash/treatment phase, during which the "conductivity" phase parameter is enabled, 15” after the following activities: - Wait time from completion of conductometer start-up - Water filling into the chamber	S

			complete - Chemical filling complete - Wash pump running from 15” after completion of water and chemical filling - The conductometer measurement is active from 20” When the conductivity check has a negative outcome, the phase is repeated, draining the water first. The alarm occurs after 3 consecutive fails.	
57	**Washing arm speed too low**		En: failure of sensor “n”. The speed is lower than the minimum limit in these conditions: a) With “program selection = BASKET / BOTH” and parameter “Washing arm sensors = YES” b) Washing arm “n” is present for the basket in the chamber c) The pump is active from 20”	**S**
58	**No chamber heating**		During steam heating of the chamber the temperature did not increase by 1°C within the time set by the parameter	**S**
59	**No tank 1 heating**		With tank 1 present, during steam heating the temperature did not increase by 1°C within the time set by the parameter	**S**
60	**Failure on thermoregulation**		In the treatment phase, the thermoregulation timeout (equal to 30 min), which starts as soon as the temperature in the wash tank reaches the set point + 0.5°C (with the water supply complete and any gradual chamber cooling concluded), has expired. Notifies an undefined situation of permanence in the phase for the following possible reasons: a) temperature fluctuations above/below the set point due to a structural defect in the flue. b) incorrect chemical input temperature setting (> thermoregulation set point)	S

61	**Washing arm speed too high**		En: failure of sensor “n”. The speed is higher than the maximum limit in these conditions: a) With “program selection = BASKET / BOTH” and parameter “Washing arm sensors = YES” b) Washing arm “n” is present for the basket in the chamber c) The pump is active from 20” If the washing arm “n” is absent the alarm is shown regardless with speed > 4 rpm to identify a possible error on the washing arms setting	**S**
67	**Door manually unlocked**		During a power failure with the cycle running, the loading door was manually unlocked	**OP**
68	**Emergency intervention**		Emergency button activation (the digital input to which it is connected is open).	S
69	**Humidity sensor failure**		Failure of the humidity sensor	**S**
70	**Water below tank drain level**		During a prewash, wash or rinse phase after water filling, before the pump starts, the minimum level sensor in the chamber was not activated	**S**
74	**Tank 2 temperature too high**		In the configuration with tank 2 present, the air temperature in tank 2 exceeds the limit 100°C (operating limit to protect against overheating).	S
75	**Tank 2 probe failure**		In the configuration with tank 2 present, temperature probe fault in tank 2.	S
77	**Tank 2 limit switch failure**		In the configuration with tank 2 present, it is triggered in one of the following conditions. a) Inconsistent level switches: in tank 2 the lower maximum level (N.A.) is open and the upper maximum level (N.C.) is open (Diagnostics generated without any delay). b) Timeout for level switch transition: in tank 2, the maximum transition time between the lower and upper filling levels (and vice versa) during the supply/drainage of the tank water has elapsed.	S
78	**Tank 1 limit switch failure**		In the configuration with tank 1 present, it is triggered in one of the following conditions. a) Inconsistent level switches: in tank 1 the lower maximum level (N.A.) is open and the upper maximum level	S

			(N.C.) is open (Diagnostics generated without any delay). b) Timeout for level switch transition: in tank 1, the maximum transition time between the lower and upper filling levels (and vice versa) during the supply/drainage of the tank water has elapsed.	
83	**No tank 2 heating**		In the configuration with tank 2 present, during the electrical heating of tank 2, the temperature of tank 2 increased by less than 1°C during the time set by the parameter.	S
85	**No cold demi water**		The type 4 water wash tank supply was not completed (no new water flowmeter pulse for longer than the time set by the parameter).	S
86	**Cold demi water flowmeter failure**		The flowmeter for the type 4 water signals surplus pulses above the limit set by the parameter, with the water solenoid valve command closed.	S
91	**DOS1 dosing failure**		In the chemical dosage configuration with time control and flowmeter redundancy, for the dosage into the wash tank of the chemical product from dosage unit 1 there was a difference in absolute value between the time-measured value and the flowmeter-measured value, greater than the maximum percentage error (with respect to the programmed quantity of chemical) set in the specific configuration parameter	S
92	**DOS2 dosing failure**		In the chemical dosage configuration with time control and flowmeter redundancy, for the dosage into the wash tank of the chemical product from dosage unit 2 there was a difference in absolute value between the time-measured value and the flowmeter-measured value, greater than the maximum percentage error (with respect to the programmed quantity of chemical) set in the specific configuration parameter	S
93	**DOS3 dosing failure**		In the chemical dosage configuration with time control and flowmeter redundancy, for the dosage into the wash tank of the chemical product from dosage unit 3 there was a difference in absolute value between the time-measured value and the flowmeter-measured value, greater than the maximum percentage error (with respect to the programmed quantity of chemical) set in the specific configuration parameter	S

94	**DOS4 dosing failure**		In the chemical dosage configuration with time control and flowmeter redundancy, for the dosage into the wash tank of the chemical product from dosage unit 4 there was a difference in absolute value between the time-measured value and the flowmeter-measured value, greater than the maximum percentage error (with respect to the programmed quantity of chemical) set in the specific configuration parameter	S
97	**Water leakage**		The water leakage sensor is activated for longer than the time set by the parameter	**S**
98	**Pump inverter communicatio n failure**		Diagnostics active if wash pump with ECS inverter Timeout on the RS485 communication serial between the keyboard and the wash pump inverter	S
99	**Pump inverter alarm**		Diagnostics active if wash pump with ECS inverter The wash pump inverter is in a state of alarm. The sub-code "Ex" or "Ax" is displayed: "Ex" indicates the active error code, "Ax" the specific active alarm code for the inverter (see inverter specification), with x number > 0	S
100	**Inverter operating error**		Frequency inverter failure (communication of status from the inverter not valid)	**S**
101	**Timeout PP valve ON**		Diagnostics active if Power Pulse configured (P58> 0) The piston forward valve has been active for longer than the maximum allowed time defined by the parameter	S
102	**Timeout PP valve OFF**		Diagnostics active if Power Pulse configured The piston reverse valve has been active for longer than the maximum allowed time defined by the parameter	S
103	**Piston failure during cycle PP**		Diagnostics active if Power Pulse configured During the cycle enabled with the Power Pulse the forward limit switch of the piston has become disabled (piston displaced or limit switch faulty)	S
104	**Limit switch discrepancy PP**		Diagnostics active if Power Pulse configured The piston forward and reverse limit switches are both active.	S
105	**Compressed air lacking PP**		Diagnostics active if Power Pulse configured with the compressed air valve command open, the air pressure switch is disabled (0 = diagnostic disabled)	S

106	**Compressed air too high PP**		Diagnostics active if Power Pulse configured with the compressed air valve command open, the air pressure switch is disabled (0 = diagnostic disabled)	S
107	**Leakage in tank 1**		With tank 1 drain valve closed the tank level 2 is deactivated and the water filling is complete for a time less than “Max waiting time between levels on tank”. With this parameter set to 0 the diagnostic is disabled.	**S**
108	**Leakage in tank 2**		With tank **2** drain valve closed the tank level 2 is deactivated and the water filling is complete for a time less than “Max waiting time between levels on tank”. With this parameter set to 0 the diagnostic is disabled.	**S**
110	**Air pressure transducer PP failure**		With power pulse set to YES, failure on power pulse pressure transducer	**S**
111	**Washing arms sensor communicatio n**		One serial connection failure: - E1: failure on RS485 connection with washing arms sensor board - E2: failure on the CAN chain with slave board 1	**S**

12.3 List of warnings

Message displayed	Description	Responsible for warning resolution
Pump pressure transducer failure	Pressure transducer enabled by parameters but error on the sensor signal	S
Drainage in progress	Drainage in progress – it is necessary to wait until drainage is complete	OP
Certificates not valid	Machine certificates not valid – they must be updated	**S**
Empty program	The program cannot be used because it is empty	**S**
Warning – hot material!!	The cycle finished with the temperature in the chamber over 65 °C – be careful when removing the load	**OP**
A door is open	One door must be closed	**OP**
Wait	No operations can be carried out because another is ongoing	**OP**
Close door	The door must be closed to start the cycle	**OP**
Salt loading required	Salt loading is required to ensure the correct regeneration of the softener circuit	**OP**
Print in progress	Print in progress – it is necessary to wait for the print to complete before starting another cycle	**OP**

Cooling in progress	The temperature in the chamber is too high – chamber cooling is ongoing – this step must be completed before the load can be accessed	**OP**
Lack of chemical DOS1	The chemical product connected to dosing pump 1 in the canister is finished – to avoid an alarm during the next cycle it is advisable to replace the canister	**OP**
Lack of chemical DOS2	The chemical product connected to dosing pump 2 in the canister is finished – to avoid an alarm during the next cycle it is advisable to replace the canister	**OP**
Lack of chemical DOS3	The chemical product connected to dosing pump 3 in the canister is finished – to avoid an alarm during the next cycle it is advisable to replace the canister	**OP**
Lack of chemical DOS4	The chemical product connected to dosing pump 4 in the canister is finished – to avoid an alarm during the next cycle it is advisable to replace the canister	**OP**
Main board communication error	There is no communication between the display and the main board	**S**
No basket	The machine is unable to recognise the basket. - The code on the basket is wrong Or - A basket sensor is not working	**OP**
Maintenance overdue	The maintenance interval has elapsed – new maintenance is needed – the description of the required maintenance is provided in the warning	**OP / S**

13. CONNECTIVITY

13.1 USB

There is a USB port on the loading side next to the control panel, which allows:

- ► saving of historical data
- ► saving of cycle data during execution, instead of printing

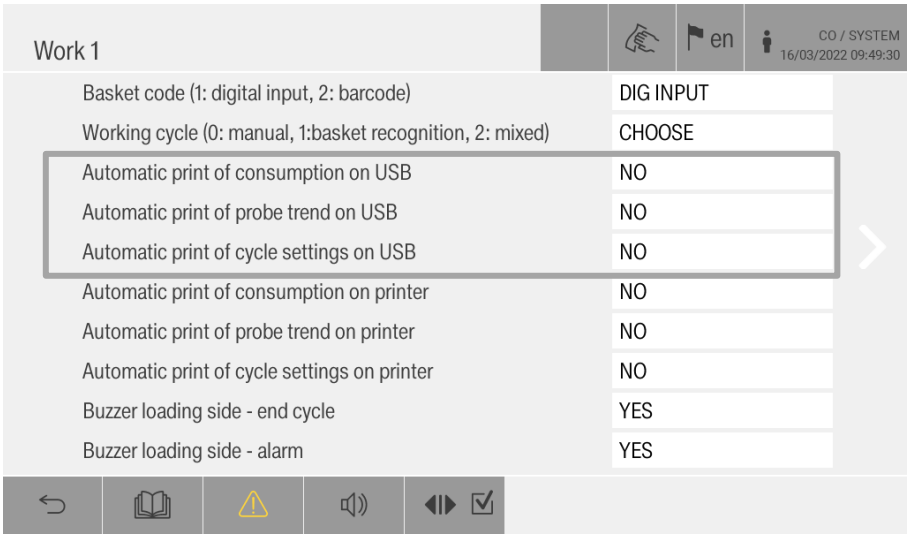
13.1.1 USB requirements

The USB needs to be formatted in FAT format.
The capacity of the USB must be maximum 32GB.

Only for SELV connections to external devices compliant with IEC 60950-1 or IEC 62368

13.1.2 Wash cycle print on USB

When running a cycle, it is possible to save the cycle settings, consumption data, and sensor values, using the USB.
If the USB is inserted and the following parameters on WORK data (page 1) are set to YES,



3 files will be saved during each cycle:

PRT00157	Cycle execution data
SET00157	Cycle settings data
TMP00157	Probe sampling data

Each one is saved as a TXT file.

13.1.3 Saving historical data on USB

With a USB it is also possible to save all historical data regarding:

- ► Operator accesses
- ► Alarms
- ► Events
- ► Maintenance intervention

Each one is saved as a TXT file.

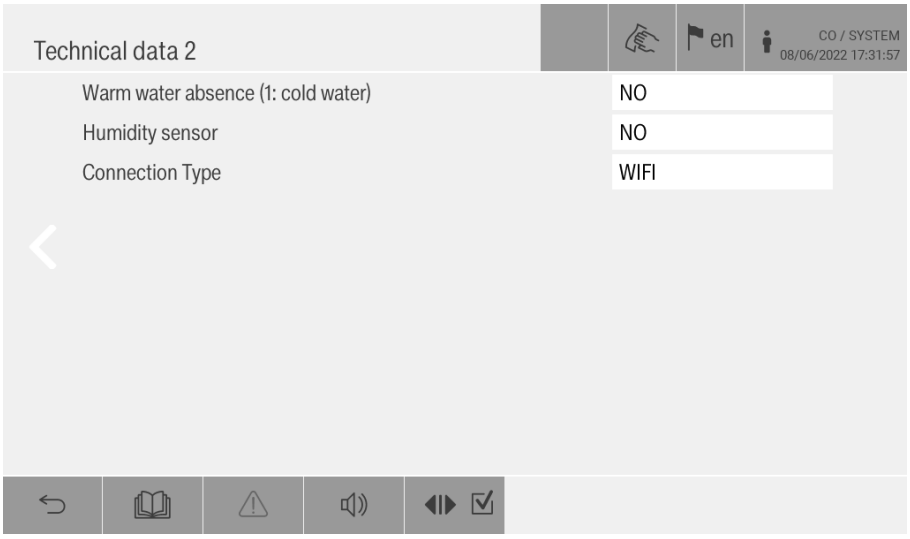
13.2 Network connection

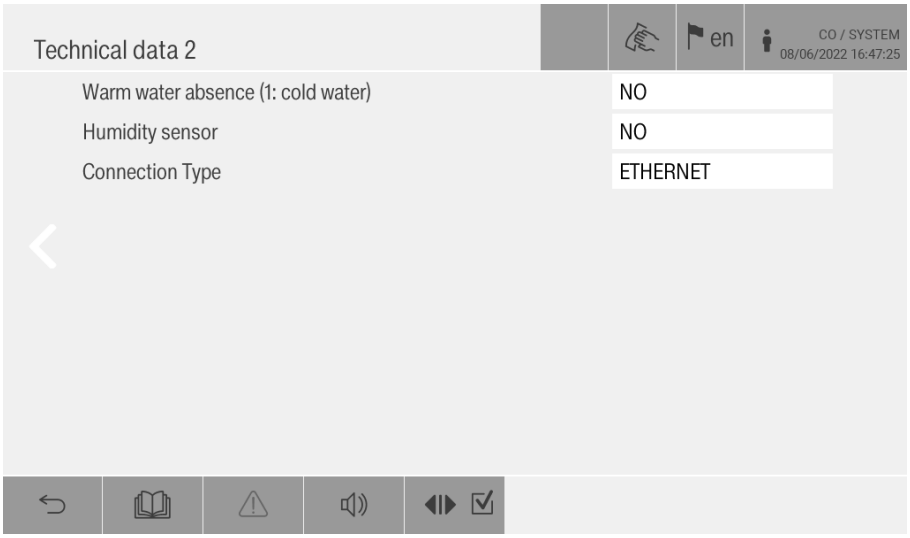
The washer disinfector can be integrated into an internal network via an Ethernet or WiFi interface.

Only the systems required for machine access via a web interface and for the documentation of reprocessing results (e.g., a PC on which the documentation software is installed) may be operated on this network.

1. The machine should be operated only in a separate network segment which meets one of the following requirements:
   – it is physically separated from other network segments
   – access to the segment is restricted by a firewall or a router which has been configured accordingly
2. Limit access to this separate network segment to persons requiring access in the course of their work.
3. Use strong passwords to protect access to systems that are connected to the machine.
4. Configure the Ethernet interface.

The type of connection can be defined in the SETTINGS menu, under TECHNICAL DATA 2, choosing between WiFi and Ethernet.





The UTILITY menu contains the NETWORK SETTING menu where the IP address or the DHCP function can be set.
If the machine is connected using WiFi, the SSID section is also active to connect the machine to an existing network.

When the networking functions are activated and the device is connected to the Internet, the device sends the following data to the Cloud:

- ► Device serial number
- ► Device model and technical features
- ► Device status
- ► Information about the software status of the device

Initially, this data cannot be assigned to a specific user and is not permanently saved. Data cannot be permanently saved or assigned to a specific user until after the device is linked to a user.
Data transmission and processing are governed by strict security standards.

Settings in the machine, e.g., parameters for disinfection or dispensing process chemicals, may be changed as a result of unauthorized access via the network.
Under no circumstances should it be possible to access the machine via the Internet or other public or unsecured networks, either directly or indirectly (e.g., using port forwarding)!

13.2.1 Ethernet connection

There is an Ethernet port on the rear part of the control panel. This port allows connection to the traceability system or to the Cloud platform.

The connection to these systems using the Ethernet port can only be made by trained technicians.
The connected external devices need to be compliant with IEC 60950-1 or IEC 62368-1.
The cable used must be CAT5 or higher.

13.2.2 WiFi connection

The machine is also equipped with a WiFi connection allowing the device to be connected to the traceability system or the Cloud platform.

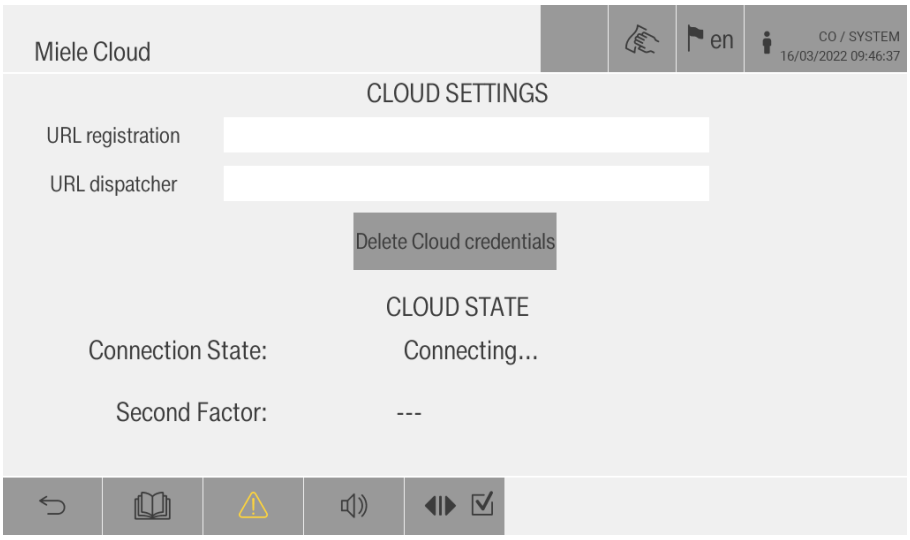
The connection to these systems using WiFi can only be made by trained technicians.

The WiFi connection must be made according to 802.11b/g/n.

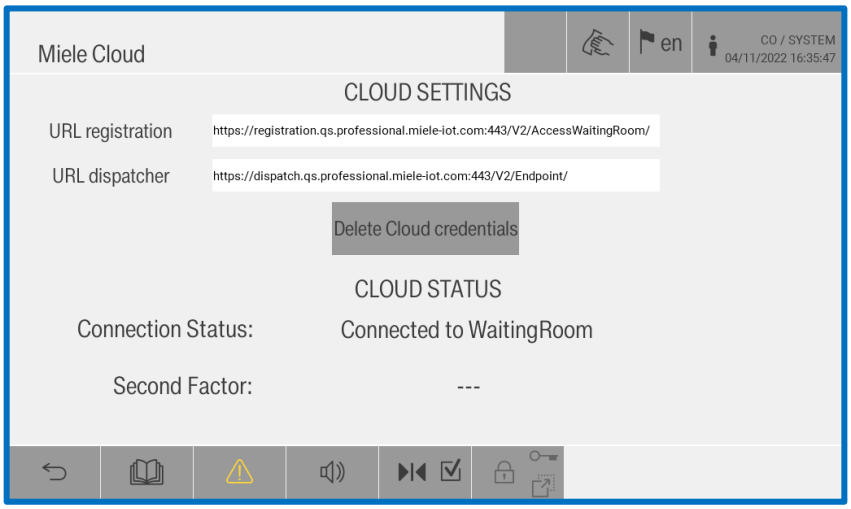
13.3 Cloud

The washer disinfector can be connected to a cloud called Cloud.
The settings needed for access are inserted in the following page in the UTILITY menu.

The connection to the Cloud page is possible with both Wi-Fi and Ethernet connection enabled.



The machine automatically connects to the Cloud platform when switched on, if the machine is connected to a network. The URL registration and URL dispatcher fields are automatically filled.
The technician must run the start-up procedure on the Cloud page in order to record and identify the machine.



Connection Status:
When the machine tries to access the Miele Cloud, on the Connection State field “Connected to WaitingRoom” is displayed.
As soon as the technician gains access, the machine status will automatically change to “Connecting…” and then “Connected to Miele Prof Cloud”.

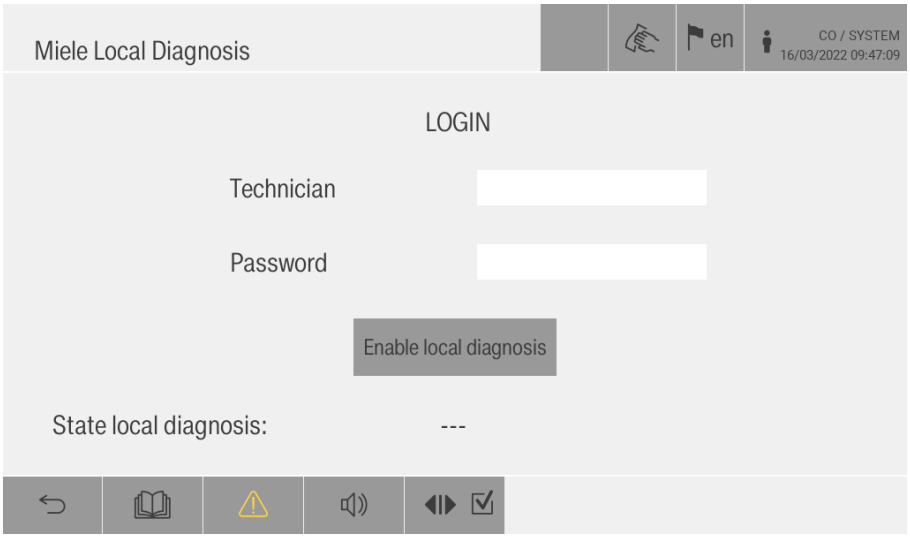
The “Second Factor” field will then be filled by the system.

In case of an error, the writing “Connection error” will be shown.

When the machine is connected to the WiFi network and the connection is lost, the machine is able to reconnect automatically as soon as the connection is restored

13.4 Miele Local Diagnosis

If the machine needs to be connected directly to the diagnostic tool, the technician needs to log in via this page with the Username and Password defined by the manufacturer.



When the data has been entered, the machine connects automatically to the tool.
After the connection has been established, the machine is able to exchange the data and status of the machine, to help the technician during the diagnostic operations.

It is not necessary to set an IP address, because the machine has a unique address dedicated to this specific tool.

14. MAINTENANCE

14.1 General recommendations on maintenance

Maintenance for the machine described in this manual can be divided into routine maintenance and special maintenance.

The operators and 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 operator and maintenance technician must:

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

14.1.1 Machine status

The machine must be completely switched off. The person responsible for said task must ensure that the safety of other people nearby is not compromised. The main switch must be in the OFF position.

14.1.2 Safety systems

The machine should only be operated in compliance with valid standards and regulations concerning the use of disinfectants (cf. data sheets for individual products). Rules concerning contact with machine parts potentially contaminated with pathogens also apply. Personal protective gear must be worn.

14.1.3 Procedure

If possible, run a disinfection program for the wash chamber. Open the wash chamber door and wipe with a suitable disinfectant.
Wipe all internal parts as well as any baskets and their contents.
Leave the disinfectant to act for the required amount of time (see the product data sheet or safety data sheet for the disinfectant in question).
When performing maintenance on parts of the machine which have not been reached by the disinfectant, take appropriate precautions and use suitable safety gear.

14.1.4 Decontamination procedures

Before making repairs or replacing mechanical parts (e.g. drain pump, heating elements, etc.) in cases where disinfection has not been completed, the disinfection procedure must first be carried out in order to eliminate any pathogenic residue.

14.1.5 Machine status verification

After a maintenance intervention, to check if the machine is working properly, run a cycle to check that all its functions have been restored.

14.2 Maintenance reminder

The machine displays a maintenance reminder, with a description of the elapsed interventions, after a specified time or specified number of operating hours. This warning does not affect normal use of the machine.

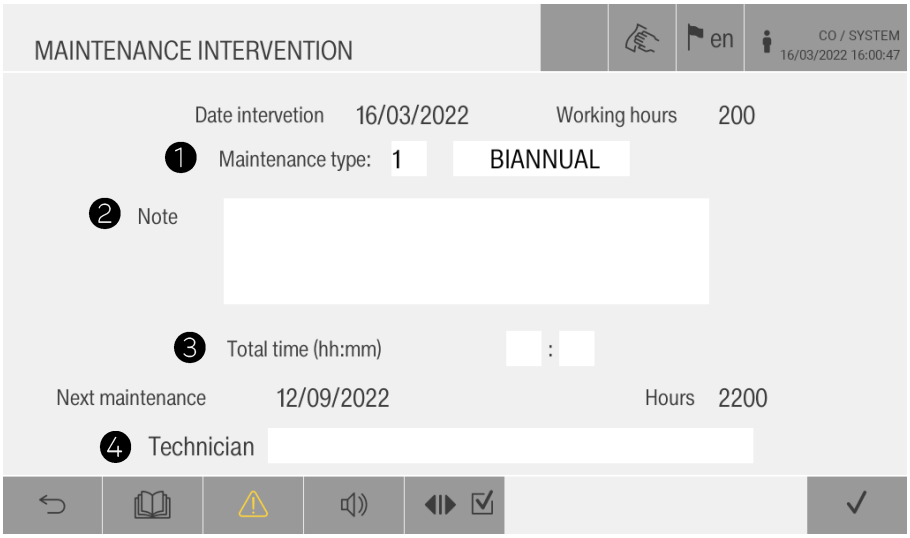
Any due maintenance must be carried out in the shortest possible time.

To clear the maintenance warning, proceed as follows:

1. Carry out the maintenance intervention on the machine as described in the procedures below and according to the table.
2. From the MAIN MENU, open the SYSTEM menu:

SYSTEM → MAINTENANCE → MAINTENANCE INTERVENTION

3. Select the type of maintenance at point ❶, provide a description of the intervention at point ❷, insert the time needed at point ❸ and the name of the operator at point ❹.
   Once filled in, confirm and save the intervention with the button ✓.



14.3 Routine maintenance

Routine maintenance includes all work aimed at keeping various parts of the machine clean and functional. Such work must be performed on a regular basis or when it is considered necessary. Since these are simple cleaning tasks, they are normally performed by the machine operators at their own risk. The following table shows the various routine maintenance tasks, their frequency and who is to perform them. Each task is described in more detail on the following pages.
Routine maintenance tasks must be performed at the intervals set forth in the table.
It is however advisable to carry out single cleaning tasks whenever necessary.

A PM kit (Preventive maintenance kit) is available for routine maintenance activities, containing all parts necessary for the works.
The available codes for these machine models are:

PM KIT code	**Description**	**Compatible with**
PM710006A13	Biannual PM kit	DS 600 EZ – DS 600 – DS 610 – DS 610 SL

TABLE OF ROUTINE MAINTENANCE TASKS

Component	***Responsibility***	***Maintenance interval***	***Activity***	***Ref***
Chamber filters: *- sump filter* *- surface filter*	OP	EVERY DAY	Remove the filters and clean them under running water and if necessary, use a brush	M1
Washing arms	OP	EVERY WEEK	Check the correct rotation of the washing arms Remove the washing arms and clean them under running water	M2

Disinfection and cleaning of wash chamber	OP	EVERY WEEK	Disinfection of the chamber, basket, and hydraulic circuit	M3
Cleaning of external panels	OP	EVERY WEEK	Disinfection of the machine's external surfaces	M4
Drying pre-filter	OP	EVERY 6 MONTHS	Replace	M5
Cleaning of wash chamber temperature probes	OP	EVERY 6 MONTHS	Cleaning of temperature probes to remove dirt and limescale	M6
Limescale removal treatment	OP	WHEN NECESSARY	Removal of limescale deposits from the chamber	M7

OP: operator

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 whenever deemed necessary.

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

Particular attention should be paid to the heating element and thermostat probe

Even if the supply water is soft, the high operating temperatures may cause limescale to build up.
Apart from damaging the resistors, limescale can also clog the nozzles, in which case the correct tank temperature for thermal-disinfection may not be reached.

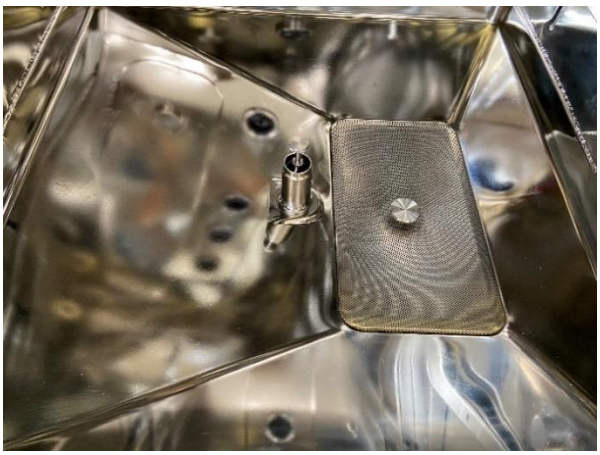
WARNING:
- ► Do not clean the machine outside with pressurised water.
- ► Contact your trusted supplier of cleaning products for details concerning the recommended methods and products for regular sanitisation of the machine.

CHAMBER FILTERS and CLEANLINESS of float switch		
Reference: **M1**	Responsibility: **OP**	Frequency**: EVERY DAY**

Follow the instructions below:

- ► Open the wash chamber door and extract the basket
- ► Extract the filter from the chamber and the filter from the sump.
- ► Check if the float switch moves freely and clean it if necessary.

  To clean the level switch, remove the clips on the top and remove the float. Clean the float with running water and the central part with a cloth. Then reassemble the float switch.

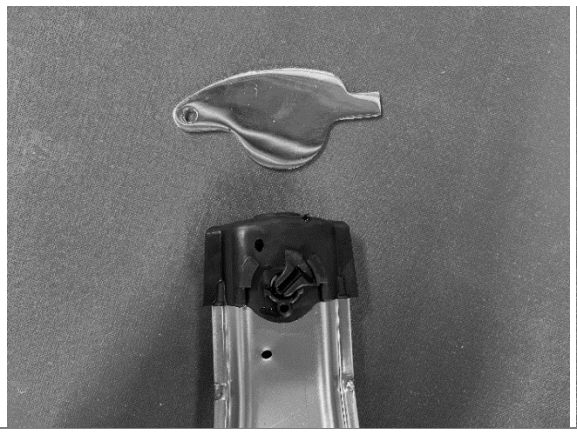


- ► Clean the filters under running water. Remove any residue with a soft brush if necessary.
- ► Remove and clean any deposits and encrustations from the wash chamber drain.
- ► Place both filters in their original position

CLEANING THE WASHING ARMS		
Reference: **M2**	Responsibility: **OP**	Frequency**: EVERY WEEK**

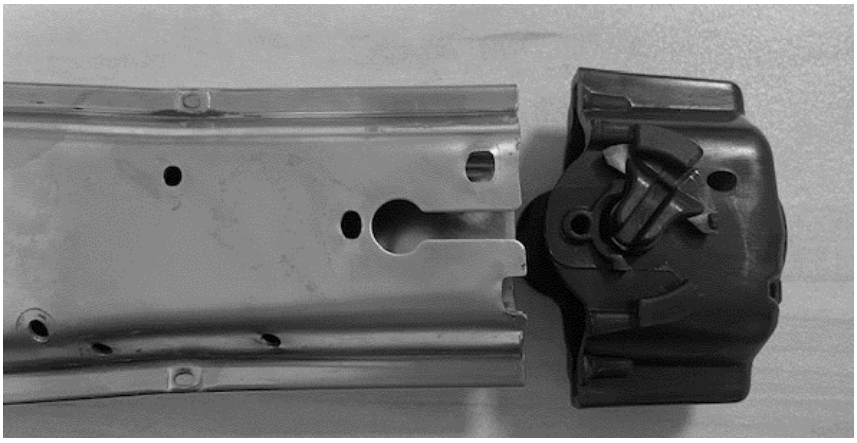
Follow the instructions below:

- ► Open the wash chamber door and extract the basket
- ► Unscrew the lock pin of the machine and basket washing arms



► Unscrew the pin from the washing arm end cap

► Remove the end cap and wash the washing arms under running water **and brush them with a soft brush if necessary**

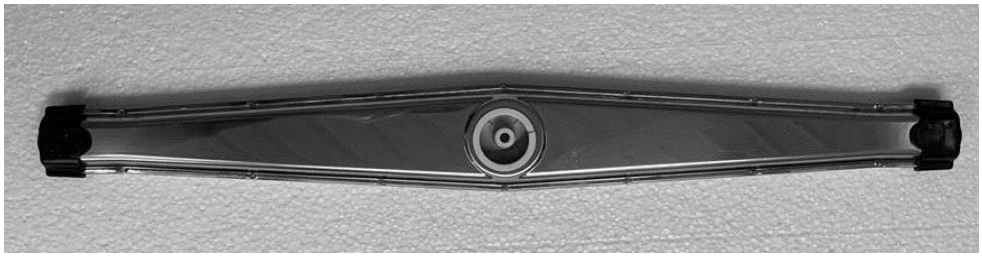


► Assemble the end cap and fasten the pin

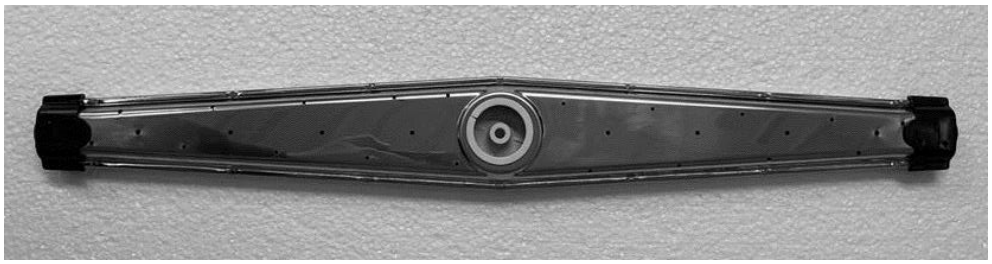
► Screw the washing arms back into their original position, making sure not to mix up the machine and basket washing arms

To identify the machine washing arm, check the holes:

- **MACHINE WASHING ARM: no holes on the rear part**



- **BASKET WASHING ARM: holes on the rear part**



DISINFECTION AND CLEANING OF WASH CHAMBER		
Reference: **M3**	Responsibility: **OP**	Frequency**: EVERY WEEK**

Follow the instructions below:

Run an empty wash cycle with a basket inside to carry out the thermal-disinfection process inside the wash chamber. This will guarantee the complete disinfection of the wash chamber, basket, and hydraulic circuits.

If it is not possible to run an empty wash cycle, it is advisable to proceed with the disinfection of the machine as described below:

- ► Open the access door to the chamber and check that no equipment, trays, or instruments have been left in the washing basket.
- ► Inside the wash chamber, evenly spray a disinfectant compatible for use on stainless steel surfaces, and which contains the following active ingredients:
    - ▹ quaternary ammonium salts
      or
    - ▹ chlorhexidine digluconate – ammonium chloride – isopropyl or ethyl alcohol
- ► All internal accessible parts must be treated in accordance with this procedure.

- ► As regards the contact time and methods of use of the disinfectant used, follow the instructions provided in 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 in the technical data sheet of the chemical product used
- ► The disinfectant must be applied in the chamber when the surfaces are cold to avoid the inhalation of harmful fumes released by the product.

CLEANING THE EXTERNAL PANELS OF THE MACHINE

Reference: **M4**	Responsibility: **OP**	Frequency**: EVERY WEEK**

Follow the instructions below:

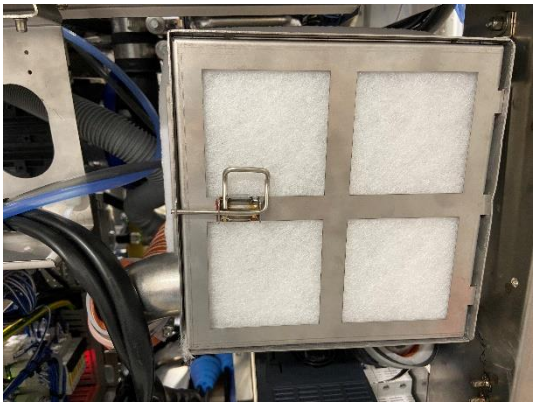
- ► Spray a disinfectant which is compatible for use on stainless steel surfaces, and which contains the following active ingredients:
    - ▹ quaternary ammonium salts
      or
    - ▹ chlorhexidine digluconate – ammonium chloride – isopropyl or ethyl alcohol

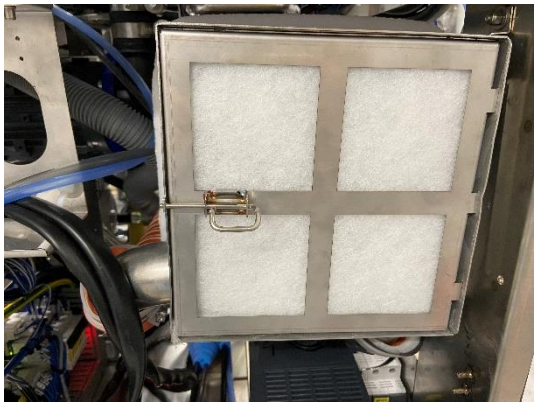
- ► As regards the contact time and methods of use of the disinfectant used, follow the instructions provided in the technical data sheet of the product itself
- ► Always check the compatibility of the chemical product with the materials it will be used on; this information can be found in the technical data sheet of the chemical product used
- ► The disinfectant must be applied in the chamber when the surfaces are cold to avoid the inhalation of harmful fumes released by the product.

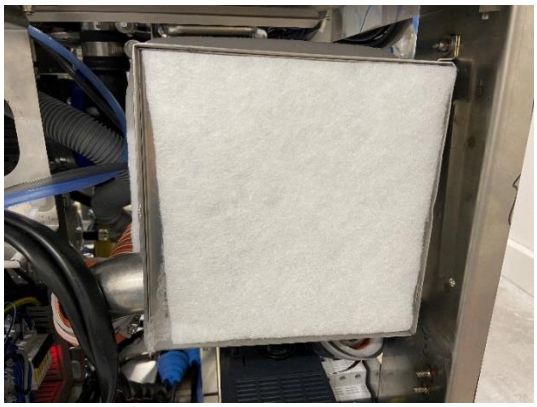
PRE-FILTERS REPLACEMENT		
Reference: **M5**	Responsibility: **OP**	Frequency**: EVERY 6 MONTHS**

Follow the instructions below:

- ► Open the lower technical area door where chemical products are placed
- ► Open the **bracket with the handle**
- ► Remove the bracket and extract the filter







- ► Replace the filter and fix it in the original position
- ► Place the bracket with the handle in position and fix it with the handle

CLEANING THE WASH CHAMBER TEMPERATURE PROBES		
Reference: **M6**	Responsibility: **OP**	Frequency**: EVERY 6 MONTHS**

Follow the instructions below:

- ► Open the wash chamber door and extract the basket
- ► Check the chamber temperature probes (on top of the chamber on the left side) and remove any deposits or limescale using a damp cloth and an appropriate detergent.

Take care not to damage or move the probe

LIMESCALE REMOVAL TREATMENT		
Reference: **M7**	Responsibility: **OP**	Frequency**: WHEN NECESSARY**

Follow the instructions below:

Use a descaling agent (we recommend vinegar) during an empty wash cycle with cold water (this is usually carried out every week unless a properly configured water softener is used, either built-in to the machine or provided on-site).

As regards the quantity of product to use, follow the instructions provided in the technical data sheet of the product itself. If vinegar is used, use 0.5 litres.

The descaling product must be poured into a container of the same size, positioned on an empty loading basket.

Use a wash program with water at room temperature, without activating the drying cycle.

Even if the feed water only contains a small amount of limescale, high temperatures can generate the formation of limescale residue. This, as well as problems potentially affecting the heating element, may cause the blockage of the nozzles, jeopardising the correct washing process and preventing the ideal disinfection temperature from being reached in the tank

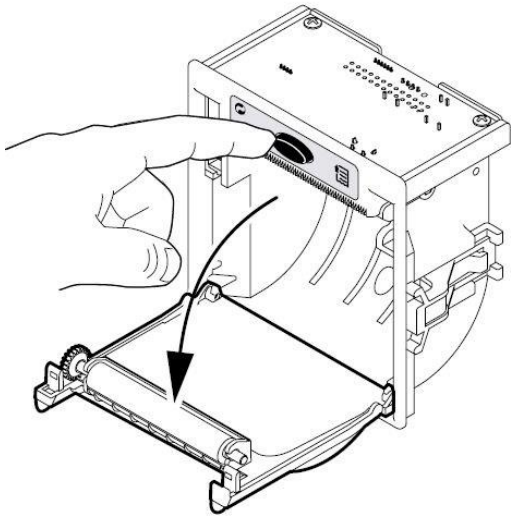
14.4 Drying air filtration

The machines are equipped standard with an air filter (class 5) in accordance with EN 779, and a HEPA H14 filter in accordance with EN 1822.
The class 5 air filter can be replaced by a trained operator or technician in charge of the installed machine.
The HEPA filter must be replaced during annual maintenance by a service technician.

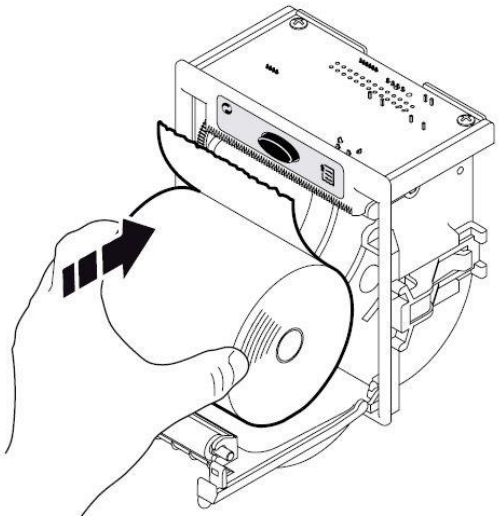
14.5 Changing the paper roll on printer

To change the paper roll, proceed as follow:

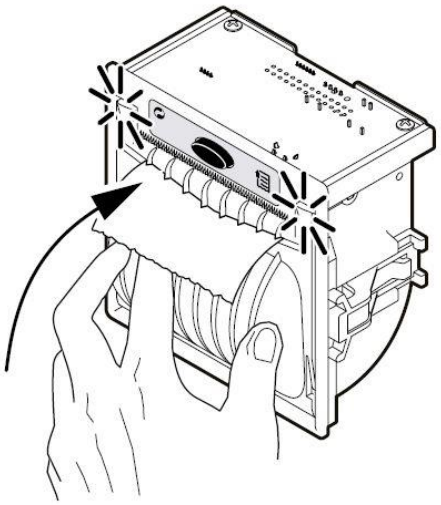
1. Press the OPEN key to open the printer cover



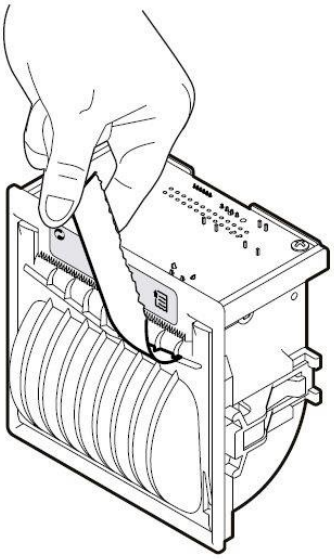
2. Remove the old plastic roll
3. Place the paper roll making sure it unrolls in the proper direction



4. Take out the paper and close the cover



5. Tear off the exceeding paper using the jagged edge



15. Problems – Causes – Remedies

15.1 Introduction

This chapter includes possible problems that may occur during machine operation, along with their causes and remedies. If the problems persist or regularly occur even after following the instructions in this chapter, please contact the Customer Service Department.

15.2 Problem (P) – Cause (C) - Remedy (R)

P. MACHINE DOES NOT START:
C. Circuit breaker deactivated.
R. Check the power supply.

P. WASH PROGRAM DOES NOT START:
C. Door not closed correctly.
R. Check door closure.
C. Lack of process chemicals.
R. Replace the chemical container and select “Fill DOSx”

P: MACHINE DOES NOT REACH SET TEMPERATURE FOR THE SELECTED PROGRAM:
C. Deposits on thermostat probe in wash chamber.
R. Clean the thermostat probe in the wash chamber as described under “Maintenance”.

P. MACHINE DOES NOT RUN THE WASH PROGRAM PROPERLY:
C. Nozzles are clogged by deposits or limescale.
R. Clean the nozzles or spray arms as described under “Maintenance”.
C. Lack of water.
R. Ensure sufficient water pressure and remove blockages.
C. Insufficient water supply for the relevant program.
R. Shut off the water supply and clean the inlet filters (SERVICE).

P. INCORRECT DISPENSING:
C. Chemical dispenser pump is not working properly.
R. Perform routine maintenance and contact the Customer Service Department or an authorised and trained service technician.

P: MACHINE DOES NOT DRY:
C. Air filter of drying system is dirty or clogged.
R. Contact the Customer Service Department to replace the filter.
C. The fan of the drying system does not work.
R. Contact the Customer Service Department or an authorised and trained service technician.

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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*

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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

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

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

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Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

IAF: 19,18,29

MS N° 0005MS

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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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ANNEX No.

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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

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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
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.SEE3-2**
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
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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
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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
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: 19

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
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Building trust together.

Certificate

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

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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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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

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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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

SGQ N° 005 A

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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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

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, 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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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

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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: 18

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. **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
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
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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, 18

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. **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
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

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

IMQ
Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

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THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

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
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	2006-05-05	2021-03-25	2024-04-22

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

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IAF: 19, 18

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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

IQNet Partners*:
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IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
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* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com