



Reg. Numero / Reg. Number	MED 31114	Revisione / Revision	6
Primo rilascio / First issue date	2013-09-18	Valido da / Valid from	2018-09-24
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Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

NUOVA S.B. SYSTEM S.r.l.

Sede Legale e Operativa / Registered and Operational Headquarter:

Via De Vizzi, 90
20092 Cinisello Balsamo, MI - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Disinfettore automatico rapido per lavare, disinfettare, sterilizzare endoscopi termolabili / *Rapid automatic washer-disinfectors for washing, disinfecting, sterilizing thermolabile endoscopes*
Filtri monouso per procedure di disinfezione di dispositivi medici / *Disposable water filters for disinfection procedures of medical devices*
Filtri monouso sterili per procedure di disinfezione di dispositivi medici / *Sterile disposable water filters for disinfection procedures of medical devices*
Sterilizzatrice per endoscopi automatica / *Rapid automatic washer-disinfectors for washing, disinfecting, sterilizing thermolabile endoscopes*

CERTIFICATE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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Rif. rapporto di audit/ *Ref. audit report:* del/dated 22/02/2021

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* del/dated 02/12/2020

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 16:21:35



Organismo Notificato n. 0476
Notified Body nr. 0476





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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Disinfettore automatico rapido per lavare, disinfettare, sterilizzare endoscopi termolabili / *Rapid automatic washer-disinfectors for washing, disinfecting, sterilizing thermolabile endoscopes*

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1107, MDS 7010

Codici / Codes:

Rider EW-50S; Rider EW-60S

Tipologia / Medical Devices:

Filtri monouso per procedure di disinfezione di dispositivi medici / *Disposable water filters for disinfection procedures of medical devices*

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 0108

Marca / Brandname:

SBS

Modello / Model:

WFX C2 ZAABC DDEE

Codici / Codes:

WF1C2-DPSHF2222, WF4C2-DPSHF2210 WF2C2-DPSHF2222, WF2C2-DPSHF2210 WF3C2-DPSHF2222, WF3C2-DPSHF2210 WF4C2-DPSHF2222, WF1C2-DPSHF2210 WFCC2-DPSHF2222, WFCC2-DPSHF2210

CERTIFICATE

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Filtri monouso sterili per procedure di disinfezione di dispositivi medici / Sterile disposable water filters for disinfection procedures of medical devices

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 0108, MDS 7006 Radiation

Marca / Brandname:

SBS

Modello / Model:

WFX C2Y ZAABC DDEE

Codici / Codes:

WF1C2S-DPSHF2222, WF4C2S-DPSHF2210 WF2C2S-DPSHF2222, WF2C2S-DPSHF2210 WF3C2S-DPSHF2222, WF3C2S-DPSHF2210 WF4C2S-DPSHF2222, WF1C2S-DPSHF2210 WFCC2S-DPSHF2222, WFCC2S-DPSHF2210

Tipologia / Medical Devices:

Sterilizzatrice per endoscopi automatica / Rapid automatic washer-disinfectors for washing, disinfecting, sterilizing thermolabile endoscopes

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1107, MDS 7010

Codici / Codes:

GANDY-90 ;GANDY-45

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia. Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey. L'allegato tecnico è parte integrante del presente Certificato./ The technical sheet is an integrating part of this Certificate.

Kiwa Cermet Italia S.p.A.
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Organismo Notificato n. 0476
Notified Body nr. 0476





UniSR
UNIVERSITÀ VITA-SALUTE SAN RAFFAELE

TO WHOM IT MAY CONCERN

According with the studies performed, the following product, manufactured by

Nuova S.B. System S.r.l. Via Margherita dei Vizzi Viganò, 90 - 20092, Cinisello Balsamo (MI)

“GANDY - 45”

fulfills the requirements and therefore the type test of

UNI EN ISO 15883-1:2014

“General requirements, terms and definitions and tests”

UNI EN ISO 15883-4:2019

“Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes”

for cleaning and disinfection of endoscopes in association with the specific

chemicals ECO ZYME and ECOSTERIL-F PLUS

Date: 16/06/2021

Prof. Dr. Massimo Clementi
Professor of Microbiology and Virology
University Vita-Salute San Raffaele, Milan
Director of the Laboratory of Microbiology and Virology
Ospedale San Raffaele, Milan, Italy

TECHNICAL DATA SHEET

Washing and disinfecting machine for endoscopes mod.

Gandy-45

Nuova S.B. System S.r.l.



Review date : 24-05-2021
Rev. N° 0 (05-2021)

Service & Delivery

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1 Abstract

Endoscopic practice is increasingly consolidated and widespread in the clinical routine. Endoscopic instruments must undergo appropriate treatment to ensure the safety and health of patients and healthcare professionals.

The introduction of endoscopes in clinical practice has undoubtedly improved the diagnosis and therapy of many diseases but, as in the case of many other technological innovations, has also led to new health risks linked to both the technical characteristics of the instruments and their conditions of use.

The number of endoscopes carried out each year is constantly growing at national level and not, and progressively the risks to the safety of patients and health professionals are also increasing.

A recent review analysed 50 published studies from 1972 to 2004 and showed that health equipment is a potential vehicle for the transfer of micro-organisms and a significant source of nosocomial infections in the health context (Schabrun, Chipchase, 2006).

In recent years, the endoscopic discipline has found increasing diffusion not only in the diagnostic field but also in the therapeutic field (polypectomy, treatment of esophageal varices, etc.) making it necessary to adopt high-level disinfection procedures of medical devices, and allowing to consolidate scientific knowledge on the most appropriate methods for the treatment of endoscopes in order to prevent the transmission of infections (the so-called reprocessing of endoscopes).



Many reports have been published that have associated endoscopic performance with the onset of infections, but only in a few cases it has been possible to demonstrate a causal association. For example, the association between endoscopic procedure and an infection with HCV or HBV is almost impossible to prove for long incubation times.

Service & Delivery

Transmission of an infection from patient to patient via endoscopes is a rare event and has generally been attributed to the failure to apply appropriate methods of cleaning and disinfection of endoscopes, improper use or inadequate design of washing-disinfection automatic machines, the use of unsuitable disinfectants or in ineffective concentrations, the inadequate storage of endoscopes (Schembre, 2000).

Endoscopes are, according to the classification of E.H. Spaulding - 1977, among the "semi-critical" devices, objects which come into contact with intact mucous membranes and do not normally interrupt the continuity of the body surfaces and should therefore be subjected to high level disinfection. They are medical devices introduced into the human body through natural or not accesses, for diagnostic examinations and/or therapeutic interventions.

Therefore, the endoscopes, especially for digestive use and for bronchoscopy, are considered semi-critical devices and require a high degree of disinfection, usually carried out with chemical disinfectants.



Directive 93/42 on medical devices defines the endoscopes as

“an applied part of electromedical equipment introduced into a patient to provide an internal vision or image for examination, diagnosis and/or therapy”

Depending on their structure, endoscopes are divided into rigid and flexible.

Microorganisms causing infections associated with endoscopic performance can be bacteria, viruses, fungi and helminths. The most frequently isolated micro-organisms in case of infection associated with gastroscopy are *Salmonella spp.* and *Pseudomonas aeruginosa*, while those associated with bronchoscopy are frequently supported by mycobacteria tubercular and mycobacteria atypical (*M. avium*, *xenopy*, *chelonei*) or by *Pseudomonas aeruginosa* and *Serratia marcescens*. There have recently been reports of severe outbreaks of *Pseudomonas spp.* associated with bronchoscopy (Culver et al., 2003).

Service & Delivery

The sources of infection are infected or colonized patients, whether endogenous infections or cross-infections, and the failure of reprocessing endoscopes and accessories. The environment is also an important source of infection, in particular for the quality of the water used for the rinsing of endoscopes in the phase of high level disinfection.

An audit of disinfection practices in Great Britain found a worrying picture since most centres did not follow national guidelines (Schabrun, Chipchase, 2006). In this survey, for example, 43% of the departments did not rinse the bronchoscopes with sterile or filtered water after chemical disinfection, despite numerous reports in the literature attesting to microbial contamination of tap water. Hospitals with specially dedicated endoscopy units and personnel training and training programs had greater tendency to follow standards.

Endoscope reprocessing systems are designed to disinfect or sterilize, using a fully automated system that washes/disinfects the instrument externally and internally.

The washing-disinfecting machines alternate disinfect cycles with rinse. In some cases, it is possible to set the washing and disinfection sequences in terms of time and temperature of the entire cycle following the instructions for the particular disinfectant or detergent. Some models also offer washing or pre-disinfection cycles, multiple rinsing cycles, and air drying cycles.

2 General phases of the endoscopes reprocessing

Below are listed the different stages of reprocessing of endoscopes, to be performed between an endoscopic examination and the following and at the end of the endoscopy session.

1. *Leak Test*
2. *Pre-wash*
3. *Endoscope leak test*
4. *Washing*
5. *Automatic disinfection/sterilization (with or without rinse)*
6. *Rinsing*
7. *Drying*
8. *Purging*
9. *Storage*
10. *Traceability*

In order to have a guarantee of results in reprocessing operations, all the factors influencing the procedures of abatement of the bacterial load must be carefully considered, starting from the adequate preliminary cleaning of the endoscope. A good cleaning has in fact the power to reduce the presence of the present microbial charge by 90%; if, on the contrary, the cleaning and the cleansing are carried out in an inadequate way, they compromise the result of the entire reprocessing process, including the disinfection phase.

It is therefore essential to implement all those procedures and use instruments and equipment for the treatment of endoscopes, in addition to Personal Protection Devices (PPD), which allow to reduce the risk of transmission of infections, following endoscopic investigations, the patient and health care professionals (Nurses and Health Partners of Endoscopic Services and other Operational Units where endoscopic activities are performed).

3 SBS Proposal

Nuova S.B. System S.r.l.



proposes for your specific needs and with the aim of ensuring the safety of your patients and your operators, the

STERILIZERS FOR FLEXIBLE ENDOSCOPES GANDY-45

guarantee reliability, absolute hygiene and effectiveness in the rapid and efficient treatment of your endoscopes.

Produced by: **BIOH Filtrazione S.r.l.**
Manufactured by: **Nuova S.B. System S.r.l.**
Sterilizers for Endoscopes

Prepared and tested **for reprocessing and endoscope recognition of all well-known manufacturers**, such as Fujinon, Olympus, Pentax, Storz, and Wolf, set new standards in terms of production quality and allows **washing, high disinfection and/or low temperature sterilization of the same flexible endoscopes, duodenoscopes, ecoendoscopes, flexible endoscopes for gastric, intestinal, nasal, bronchial endoscopy, etc.**

All machines are extremely durable, easy to clean, with tempered glass door, working perfectly even after many years from their first use, always ensuring high safety standards for patients, operators and endoscopes through the use of advanced technology and high quality standards.

The ideal solution, simple and safe, for the reduction of costs related to nosocomial infections.

3.1 Reduction of management costs

- *A highly innovative design allows a low consumption of chemicals, water and electricity. Special advantages: you can choose whether to use **PERACETIC ACID**, in **single-dose chemical solutions (SINGLE-SHOT)** at each cycle, with concentrations and exposure times that comply with the recent guidelines in the reprocessing of endoscopic probes.*
- *The **Customer Service** is always at your disposal.*
- *Maximum reliability, hygiene and effectiveness in the treatment of your endoscopes.*

3.2 Safety

- *Designed according to UNI EN ISO 15883-1/-4/-5, UNI EN ISO 14937:2009, according to EN 60601-1-Ed. 3, thus ensuring compliance with the highest hygiene standards, with a view to maximum protection for the health of operators and patients.*
- *Risk analysis in accordance with EN ISO 14971.*
- *Equipped with **safety closing mechanism** of the door, able to ensure the safety of the operator preserving him/her from crushing and trauma.*
- ***Medical device** according to Directive 93/42, with **CE Class IIb Marking** according to D. Lgs. 46/97. Compliance with the current security provisions established in D. Lgs. 9 April 2008, n. 81.*
- *Structured to **reduce the movement of contaminated endoscopes**, increasing the safety of staff and patients, and minimizing the possibility of causing damage to endoscopes.*
- *The use of **Bar Code Scanner** Identification System supplied in the standard models identifies not only the operator but also each individual endoscope, significantly reducing the risk of errors during reprocessing and allowing a considerable saving of time.*
- *Effective cleaning of the endoscope channels by our equipment helps prevent microbial growth.*
- *The self-draining design prevents microbial growth that may occur in the presence of residual water.*
- *Self-disinfection program (CHEMICAL OR THERMAL) for the chamber and for the entire washing system.*

3.3 Easy to use

- *The endoscopes are fixed to the machine by means of **connectors**, that guarantee an easy and univocal identification, and attached with adapters of easy grafting, realizing a system in which the number of independent connections is functional (adequate) to the various channels of the endoscopes.*
- *Throughout the process, the **display** informs the operator about the progress of operations and any errors, also ensuring the traceability of the entire disinfection cycle by means of software and/ or print recording system.*
- *The door has a **transparent tempered glass porthole**, with a top opening, allows the operator to view the cleaning process and the treated endoscopes throughout its operation.*
- *Possibility of use on **wheels** to facilitate the movement of the machine.*

The proposed equipment will be new, newly placed on the market and its production will not be ended for the whole duration of the contract. The equipment contains all the latest technical measures, are free of defects due to design, incorrect execution or installation and defects of materials used and meet all the requirements indicated by the Contractor in its documentation.

The equipment will be supplied complete with all the components and accessories necessary for their perfect operation (in relation to the contract stipulated).

The equipment is perfectly manufactured and meets the requirements of safety, robustness, suitability for the type of use, etc. , provided by Community, Italian and regional legislation in force, in compliance with UNI standards as regards dimensional and ergonomic requirements.

4 Features of the high-productivity automatic washing machine for endoscopes GANDY-45

- I **GANDY-45** allows to reprocess **1 flexible endoscope** for each disinfection/sterilization cycle using **single tank**.
- It carries out low temperature washing and high disinfection/sterilization of flexible endoscopes (**5 °C - 40 °C**) in accordance with **UNI EN ISO 15883-1**, and is able to process every **type and brand of endoscope on the market**.
- I A **Temperature Sensor**, placed inside the washing tank, allows to signal, by means of an appropriate alarm, the eventual exceeding of the pre-set temperature limit (**40 °C**) of the disinfection/sterilization liquid, in order to preserve the integrity of the treated flexible endoscopic instruments and maximise the effectiveness of the proposed Chemical Solutions. Higher temperatures could compromise the effectiveness of disinfection/sterilization and also the action of enzymes on organic residues, as well as causing corrosion problems in stainless steel which could be caused by the use of paracetic acid at temperatures above 40 °C.
- I The chemical solution proposed for the disinfection is the **PAA (Peracetic Acid)**; washing and disinfection are carried out by **IMMERSION** and **JET**.
- I **Noise: Maximum Noise of the Device = approx. 50 db** (disinfection with operation of the rotating sprayer arm - Conforming to T.U. 81/2008).
- **Drying of endoscope channels** using sterile air filtered by **0,01 µm** filter.
- I Compact and **ergonomic** design; the small dimensions allow to adapt the washing machine to any type of room and context, without interfering with ordinary hospital activities; possibility to mount wheels for handling equipment; The height of the load compartment is convenient and easy to access for operators; **large tank** allow easy and quick positioning of endoscope (**610x510x180 mm**).
- I Stainless steel 316 metal frame, polymer body covered with an antibacterial solution, internal pipes made of corrosion-resistant polymer material, stainless steel fittings and corrosion-resistant polymer material, tanks of chemicals in HDPE.

Service & Delivery



- | The **"hands-free"** system, consisting of an upper door with automatic opening by means of a button or sensor and a **Barcode Scanning system**, facilitates operator activities, helps prevent errors and saves time, eliminating the risk of hospital infections. It also has an **active door lock during the entire cycle**.
- | Management of countless **different malfunction situations** by means of appropriate different error messages. If an error occurs during the cleaning process, this will be displayed on the "Error message" display and the running program is interrupted. In the case of **"critical" malfunctions** for which the high level disinfection and/or sterilisation conditions are not guaranteed, In addition to stopping the running program, there will also be the **automatic discharge of the liquid contained in the washing tank and an immediate rinsing**, to ensure the integrity of the endoscopic instrument contained in the tank and the safety of any operator who might intervene to remove it. Once the error message has been read and understood by the operator, the same must press the "STOP" button: the program will then return to the boot state.
- | **Simple technology, easy to use and maintenance-management; intuitive and updated operator interface ensures better and quick access and display of parameters for program management.**



Service & Delivery

- Equipped with a **pre-set and programmable automatic self-disinfection cycle**, which allows to sanitize all the components of the equipment (tanks, spraying arms, channels, filters, etc.).
- **Fast and Safe**: every single unit is optimized to ensure a short time of treatment, ensuring a cleaning carried out preserving with extreme care the integrity of your endoscopes. The standard cycle reprocessing time is less than **22 minutes**.
- **“Leak test” throughout the process cycle** and/or independent of the disinfection cycle. With the autonomous "Leak test" program, the sealing of the endoscope can be controlled independently of the washing program



Leak Test of Gandy is in continuous for the whole the cycle duration

At each cycle and for each channel of each treated endoscope, it will be carried out automatically:

- *Leak Test*
 - *Pre-wash*
 - *Endoscope leak test*
 - *Washing*
 - *Automatic disinfection/sterilization (with or without rinse)*
 - *Rinsing*
 - *Drying*
 - *Purging*
 - *drying internal channels endoscope*
- The proposed equipment and its process (temperature, chemicals, pressures, times, etc.) are completely and **totally compatible with all the main brands and types of flexible endoscopes on the market**.
 - **The proposed equipment will be supplied with all the necessary fittings to reprocess all the endoscopes supplied with UU.OO.CC, as well as all accessories, cables, connectors, fittings, software and how much it needs for the proper and safe operation of the reprocessing process.**

Service & Delivery

- The entire proposed process (apparatus, chemicals, programs and times) ensures the achievement of high disinfection/ sterilization of the treated endoscopes. **Low temperature sterilization** is carried out using appropriate sterilizing agent (**ECOSTERIL-F PLUS**) in full compliance with the **UNI EN ISO 14937:2009 Standard**.
- The equipment supplied will be in compliance with EEC Directive 93/42 and with all applicable safety regulations.
- **Complete documentation of the phases and the outcome of the washing by thermal printing (supplied and integrated)**, including details about the cycles of preparation, cleaning, drying, chemical disinfection, the outcome of the leakage test carried out throughout the process cycle, patient, operator and endoscope data.
- The machine is able to keep track of the cycles performed in the history, within which you can see in detail all the data relating to the cycles performed and the **total count of cycles performed**, highlighted in the operator interface.
- **The Barcode Scanning Traceability System allows to uniquely recognize the endoscopes to be treated.**
- The **Barcode Scanner** is used to scan the label of the endoscope and the badge of the operator; therefore the traceability system collects information on equipment, endoscope and operator. The bar code label is glued to the endoscope, made of PVC and therefore resistant to the chemicals used.



- Equipped with **washing system and High Disinfection/ Sterilization Closed Circuit**, including loading and unloading, which ensures the operator to work in a safe environment (gaskets and watertight doors, controlled openings, non-return valves, etc.) containers of chemical products of **different shape** with **different color caps** and an **effective abatement system, which ensures the absence of dangerous fumes** in the environment that houses the equipment through the use of **non-return valves**. The machine is equipped with an **automatic dosing pump** for chemicals liquid. Two flow sensors were installed to monitor the volume of the chemicals liquid dosed. If necessary, the lines of dosing pumps and delivery to detergent containers can be rinsed with the appropriate program. It is also carried out the control of the dosage of chemicals inside the machine.

Service & Delivery

- The machine is equipped with a **disinfectant acid vapour filtration system** consisting of an **activated carbon filter**, which provides purified air for drying the endoscope channel filters. This system ensures the elimination of any emissions of toxic vapours, or potentially harmful to operators, in the surrounding environment, during the cycle and in stand-by conditions.
- Equipped with a **system to block the panel of the washing chamber** to avoid the accidental opening of the chamber during the washing.
- The machine is equipped with **magnetic sensor** that control the rotating sprinkler arm.
- The machine is protected from any water return/reflux by **Non-return Valves**.
- **Water treatment system allows** the discharge of residues in the common sewage system of the hospital.
- The detergent and the sterilizer/ disinfectant used in each cycle are **Single-Shot** and **dosed automatically**, ensuring the use of the correct quantities avoiding unnecessary waste.
- "Disconnected" system of the fluids (Loading/Unloading) allows to avoid return contamination.
- The **containers** with **Detergents** and **Disinfectants**, located outside the machine, are monitored by means of "**low level alarm**" devices, and will have a **volume not exceeding 5 liters**.
- The **Tanks** of Detergents/Disinfectants/Sterilizers are easy to handle, thanks to their packaging, for operators and are placed in a special cabinet with doors equipped with a lock (**controlled access**) and placed in the area below the machine, allow immediate and **simple accessibility** and uniquely identified thanks to the **different color of the sealing cap**.
- The **Detergent** and **Disinfectant** (the plurienzymatic detergent **ECO ZYME**, and the high level disinfectant-sterilizing **ECOSTERIL-F PLUS**), are certified, used not only with tangible results on the washing machines mod. GANDY and compatible with the endoscopes listed above but also effective with the **Biofilm**.
- The machines comply with the current legislation on production and marketing authorisation. The products offered correspond to what is expressly required in terms of composition, unit packaging and intended use. All products carry the code of the register. The label of each product shows in Italian and/or with the following symbols: trade name-measures of the device-intended use and method of use- sterile wording and method of sterilization- single-use marking- CE mark lot number and expiry date - name and business name of the manufacturer, in addition to management and storage warnings.
- The machine is equipped **with automatic instrument leak control (leak test to verify any leakage in the instrument)** which indicates any pressure loss before exposure to water. The

Service & Delivery

control of any existing leaks is carried out before and during the washing process by means of compressed air injected into the sheath of the endoscope through an appropriate adapter, generating an alarm and the consequent automatic shutdown of the disinfection cycle. The endoscope is tested several times during the washing process to check for leaks. Therefore any deterioration of the instrument is established with great rapidity, so as to avoid greater damages and to reduce the costs of successive repairs (constant LEAK TEST in order to avoid infiltrations of liquid in the endoscope).

- I **Single Channel Control**: in the event that a **Channel is blocked or disconnected, acts by means of an alarm specific to the single channel**, generating an error report and interrupting the processing. Each channel is tested during **reprocessing** using sensors so that the **Biofilm** or other possible causes of obstruction are detected and the operator is informed in real time.

- I The connection system has **6 channels, an independent leak detection interface**, which is placed on the side of the decontamination tank to prevent the entry of water from damaging the endoscope.

- In addition to Disinfection/Sterilization, it is also performed the separate phase of Cleansing, Rinsing and Drying completely managed by the machine and without the addition of external Equipment/ Devices. Rinsing with water, at the end of the disinfection/sterilization cycle, effectively removes any trace of dangerous product both inside and outside the endoscope. **All parts of the treated endoscope, internal and external, come into contact with the solutions** of washing, cleansing, Disinfection/ Sterilization, rinsing and drying, during all phases of reprocess according to the time required by the treatment.



Service & Delivery

- Barcode scanning system, integrated thermal printer, 260.6x203.1 mm touch screen control panel, state-of-the-art software.



Thermal Printer

Service & Delivery

```

Hospital name:      XXXX
or N:              XXXX
Cycle N:           XXXX
Program:           XXXX
Tank:              XXXX
Sterilization Date: XXXX
Loading Time:      XXXX
Unloading Time:    XXXX
Duration:          XXXX
Load by:           XXXX
Channel:           XXXX
Endoscope N:      XXXX
Group:             XXXX
Model:             XXXX
Detergent:         XXXX
Disinfectant:     XXXX
Circulating P:    XXXX
Spray rotation:   XXXX
Leak test max:    XXXX
Leak test min:    XXXX
Batch Detergent:  XXXX
Batch Disinfectant: XXXX
Patient:          XXXX

Validated cycle:   XXXX
*****
Phase              Duration (sec.)
Leak Test.         0.1:00
Washing            02:00
Rinsing 1          00:30
Rinsing 2          00:30
Disinfection       05:00
Final Rinsing 1    00:30
Final Rinsing 2    00:30
Drying             00:30
*****
Completed procedure
successfully :      Done
Download by:       XXXX
Allarm:           XXXX

Signature:         XXXX
  
```

Example of reprocessing report (thermal printing)

■ Equipped with:

- **STERILIZATION: 2 Programs.**
- **HIGH-LEVEL DISINFECTION: 11 Programs.**

all selectable and with individually adjustable parameters. Additional functions can be programmed according to specific customer needs.

Washing and disinfecting machine for endoscopes mod. Gandy-45

Cycle Duration Table - Chemicals Used in the different phases of "High Level Disinfection and Sterilization" programs

HIGH LEVEL DISINFECTION programs with ECOSTERIL-F PLUS (First Part)						
Phase	Prog.	Program 1 Standard	Program 2 Standard double wash	Program 3 Advanced	Program 4 Disinfection phase	Program 5 Drying
Leakage Test		40 s	40 s	40 s	40 s	
Pre-wash		Pre-wash (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s	Pre-wash (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s	Pre-wash (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s		
Wash		Wash (300 s) Introduction of Enzymatic Detergent: 40 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 370 s	Wash (300 s) Introduction of Enzymatic Detergent: 40 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 370 s	Wash (450 s) Introduction of Enzymatic Detergent: 40 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 520 s		
Rinse 1		Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s	Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s	Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s		
Rinse 2			Rinse 2 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s	Rinse 2 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s		
Disinfection		PAA Disinfection (300 s) PAA Volume: 70 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 370 s	PAA Disinfection (300 s) PAA Volume: 70 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 370 s	PAA Disinfection (450 s) PAA Volume: 70 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 520 s	PAA Disinfection (360 s) PAA Volume: 70 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 430 s	
Final Rinse 1		Final Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s	Final Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s	Final Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s	Final Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s	
Final Rinse 2			Final Rinse 2 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s	Final Rinse 2 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s	Final Rinse 2 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s	
Drying		Drying (30 s)	Drying (30 s)	Drying (60 s)	Drying (30 s)	Drying (60 s)
Total Time		19 min	22 min	27,5 min	12 min	1 min

HIGH LEVEL DISINFECTION programs with ECOSTERIL-F PLUS (Second Part)							
Phase	Prog.	Program 6 Leak Test	Program 7 Chemical Self-disinf.	Program 8 Thermal Self-disinf.	Program 9 Standard external	Program 10 Customized 1	Program 11 Customized 2
Leakage Test		40 s					
Pre-wash					Pre-wash (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s		
Wash					Wash (300 s) Introduction of Enzymatic Detergent: 40 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 370 s		
Rinse 1					Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s		
Rinse 2							
Disinfection			PAA Disinfection (500 s) PAA Volume: 70 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 570 s	PAA Disinfection (1200 s) PAA Volume: 70 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 1270 s	PAA Disinfection (300 s) PAA Volume: 70 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 370 s		
Final Rinse 1			Final Rinse 1 (150 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s N° process repetitions: 4 Total Process: 1000 s	Final Rinse 1 (100 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s N° process repetitions: 2 Total Process: 400 s	Final Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s		
Final Rinse 2							
Drying							
Total Time		40 s	26 min	28 min	18 min		

STERILIZATION programs with ECOSTERIL-F PLUS			
Phase	Prog.	Program 1 Standard	Program 9 Standard external
Leakage Test		40 s	
Pre-wash		Pre-wash (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s	Pre-wash (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s
Wash		Wash (600 s) Introduction of Enzymatic Detergent: 40 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 670 s	Wash (600 s) Introduction of Enzymatic Detergent: 40 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 670 s
Rinse 1		Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s	Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s
Rinse 2		Rinse 2 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s	Rinse 2 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s
Sterilization		PAA Sterilization (600 s) PAA Volume: 70 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 670 s	PAA Sterilization (600 s) PAA Volume: 70 ml Water Inlet: 40 s Drain Water: 30 s Total Process: 670 s
Final Rinse 1		Final Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s	Final Rinse 1 (20 s) Water Inlet: 40 s Drain Water: 30 s Total Process: 90 s
Final Rinse 2		Final Rinse 2 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s	Final Rinse 2 (20 s) Water Inlet: 40 s Drain Water: 30 s Channels Purge: 30 s Total Process: 120 s
Drying		Drying (30 s)	
Total Time		32 min	31 min

I Advantage of having all the “**smart**” **sensors connectable to a cloud** and therefore remotely viewable, reliable transmission of machine data, process parameters and diagnostic data to the control system. Possibility of extracting the following data from the machine in .csv format, therefore readable by any PC/tablet:

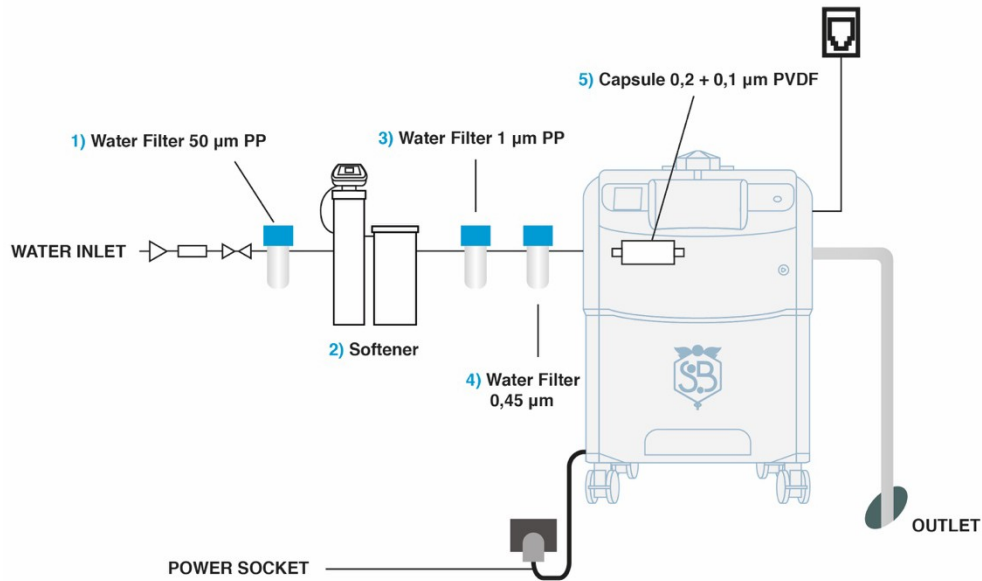
§ HOSPITAL NAME
§ EQUIPMENT SERIAL NUMBER
§ PROGRAM
§ TANK
§ DATE
§ TIME
§ LOAD TIME
§ UNLOAD TIME
§ DURATION
§ DEVICE INSERTED BY
§ USED CHANNELS
§ DEVICE UNLOAD BY
§ NUMBER ENDO
§ GROUP
§ ALARM
§ PATIENT
§ DETERGENT QUANTITY
§ DISINFECTANT QUANTITY
§ CIRCUIT PRESSURE
§ SPRAYER ROTATION
§ LEAK TEST MAX
§ LEAK TEST MIN
§ DETERGENT BATCH
§ DISINFECTANT BATCH

- Possibility of **ONLINE technical intervention service**, for which it is necessary to provide an internet network with a dedicated IP.
- Possibility to **remotely check the functionality of the machine in real time**.



- If necessary and according to verification and agreement between the parties, it will be equipped with a suitable water treatment and supply system, composed as follows:
 - If missing, a suitable **inlet water PRESSURE REGULATOR** will be installed.
 - If a water softener is needed, a first **50 µm (1)** filtering system.
 - **ANY WATER SOFTENER** (in case of excessive water hardness) **(2)** (water softeners are supplied and installed to reduce the degree of hardness of the same water at the inlet of the endoscope-washer in order to preserve the integrity).
 - A **1 µm (3)** pre-filtering system will be installed at the inlet of the endoscope-washer.
 - In line with the pre-filters, **an antibacterial sterile filtering cartridge system for water supply with a 0,45 µm membrane will be installed – ABSOLUTE FILTER in PES CE Class IIb certified as a Medical Device suitable for the production of microbiologically controlled water ready for use for washing and cleaning procedures for medical devices (4).**
 - Then there is **an antibacterial filtering capsule for water supply with a 0,2 µm + 0,1 µm membrane, ABSOLUTE FILTER in PVDF CE certified as a Medical Device suitable for the production of microbiologically controlled water ready for use for washing and cleaning procedures for medical devices (5).** This is done in order to ensure the right pH of the water entering the system and its progressive filtration, able to generate microbiologically sterile water that guarantees an effective and efficient endoscope reprocessing process.

INSTALLATION SHEET ENDOSCOPES-WASHER GANDY-45



- Will be guaranteed training of the staff for the correct use of equipment, under normal and emergency conditions and issued a certificate.



Service & Delivery

- The disinfection cycle in Safe State in case of alarm is interrupted.
- All equipment provided, including primary and secondary packaging material, will be **Latex Free**, as well as consumables. Moreover, the **Washing Room**, as well as the external structure, are built with medical or food grade material, highly resistant not only to **Disinfectant Detergents used but also to the wear**.

In faith
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