

# SERIE4

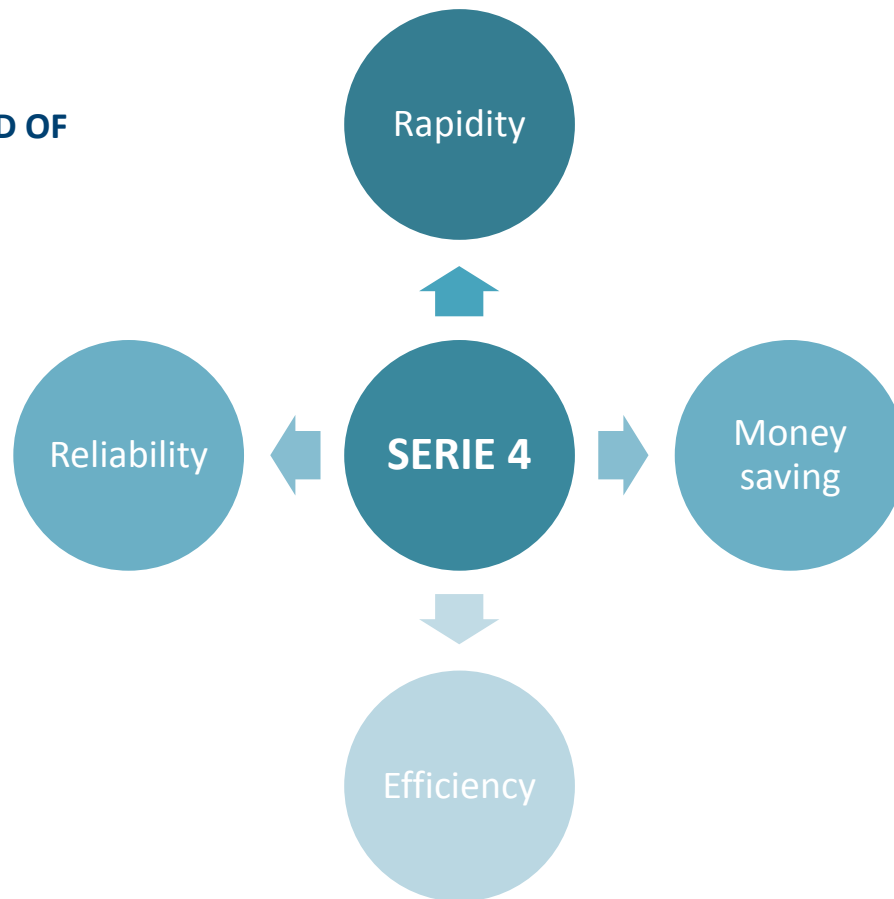


## Rapid Reliable Efficient Soluscope Serie 4

PA Version

## DEVICE INTRODUCTION

A PERFECT BLEND OF



# SERIE 4

## RAPID

- **Complete cycle 1 in 16 minutes**

## RELIABLE

- New patented irrigation system
- Complete self-disinfection cycle
- Less water / less chemistry

## EFFICIENT

- New components
- Improved complete water treatment system
- **Self-disinfection cycle**
- **ISO15883-1/4** compliant / CE MARK



- Double check of critical parameters
- Patented channel controls
- **Continuous leak test**



# SERIE4



an Intuitive  
device



an Integrated  
process



an Innovative  
concept

# SERIE4

Power at your fingertips

## AN INTUITIVE DEVICE

# SERIE4

## AN INTUITIVE DEVICE

### TOUCH SCREEN

- **Large 7" screen**
- New intuitive and graphical user interface
- Controls all Serie 4 functions

### TRACEABILITY

- Simple integrated data management
- IT Soluscope

### CONNECTORS

- **6 endoscope channels**
- 1 leak test



# SERIE4

## AN INTUITIVE DEVICE

A REACTIVE SCREEN FOR SIMPLE ACCESS TO ALL FUNCTIONS

HMI => « what you see is what you get »

It is fast and simple to use the machine



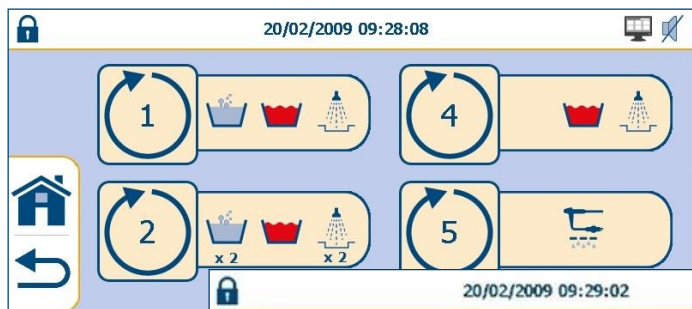
Endoscope  
cycles

Machine  
cycles

Settings

# SERIE 4

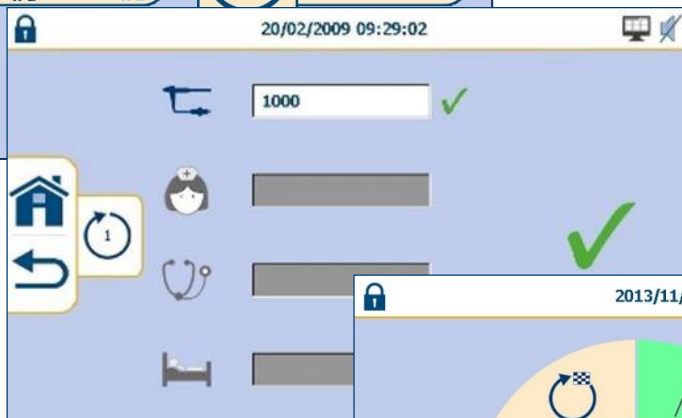
## AN INTUITIVE DEVICE



Click on cycle 1

A Simple “click” to access

- Endoscope cycles
- Machine cycles
- Settings



Confirmation request depending on settings



Cycle is launched

Uniting the most effective systems for improved performance

## **AN INTEGRATED PROCESS**

# SERIE 4

## AN INTEGRATED PROCESS

### A NEW ERGONOMIC DESIGN

- All elements embedded (filters, printer... )

### COMPACT SIZE

- Small footprint
- Can be set up side by side
- Dimensions : WxDxH: 63.8 x 87.5 x 109.6 (closed lid)

### ROBUST COMPONENTS

- New more powerful pump
- New more resistant valve
- Stainless steel connector
- **Bigger tank capacity (up to 10L)**



# SERIE4

## AN INTEGRATED PROCESS

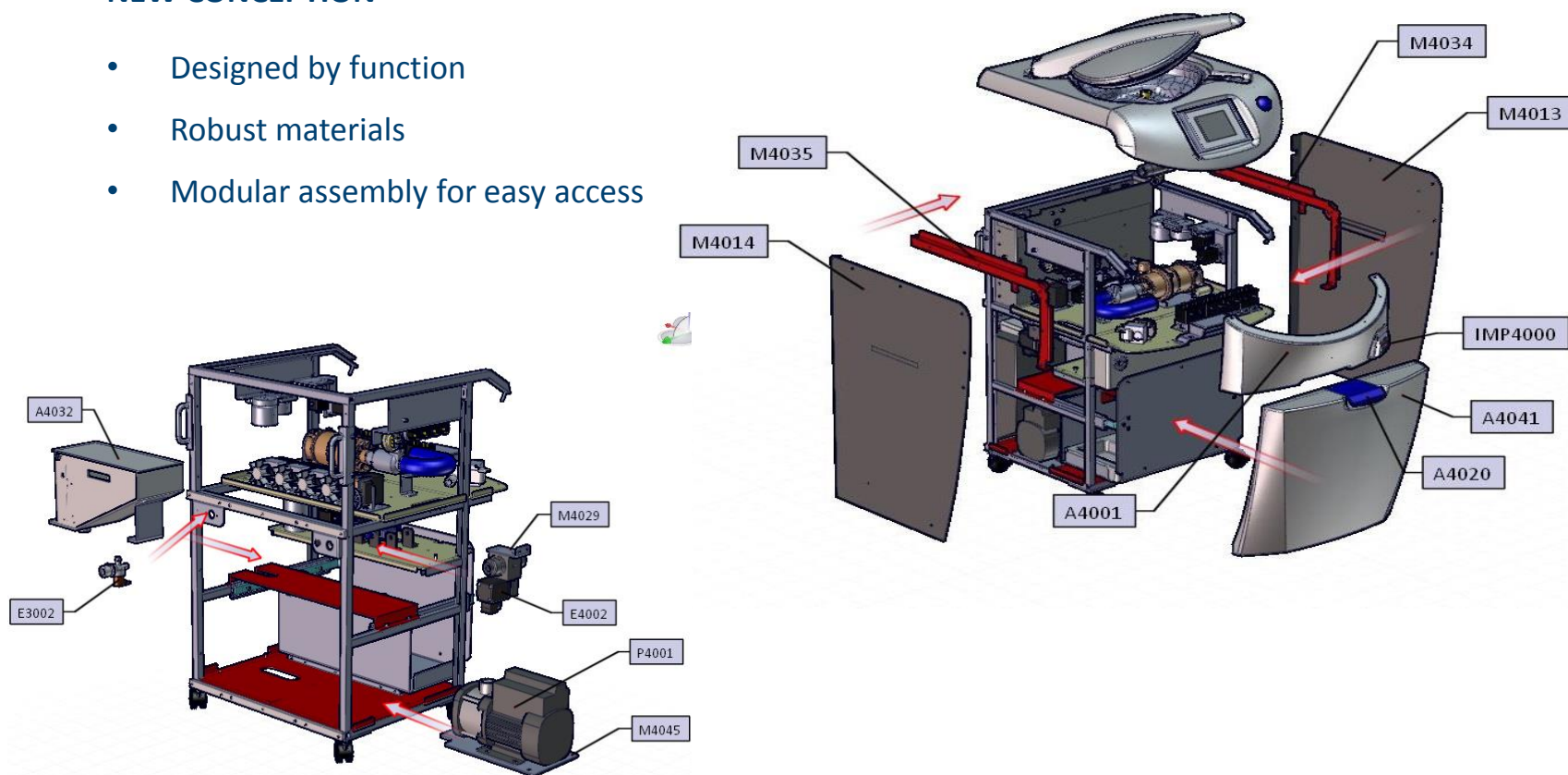
- Robust and resistant materials  
(smooth design, colour stable over time)
- Easy to clean



## AN INTEGRATED PROCESS

### NEW CONCEPTION

- Designed by function
- Robust materials
- Modular assembly for easy access



# SERIE 4

## AN INTEGRATED PROCESS

### NEW FILTRATION SYSTEM

- **Water treatment : 0.2µm terminal filter and 3 pre-filters (0.2µm, 1µm, 5µm)**
- **Air filter in the drawer: HEPA**

### IMPROVED SAFETY AND PROTECTION

- Chemical bottles housed in the drawer

### EMBEDDED TRACEABILITY

- Printer
- Barcode reader
- Network connection



# SERIE 4

## AN INTEGRATED PROCESS

### EASY TO INSTALL

- « Plug and play » concept:
  - Power cable
  - Water IN/OUT
  - Barcode scanner USB port
  - ON/OFF button
- Can replace a Soluscope Serie 3 AER with no installation changes
- **On wheels, can be moved easily**



Soluscope's cutting edge technology

## AN INNOVATIVE CONCEPT

# SERIE4

## AN INNOVATIVE CONCEPT

- Dual wash technology
- New chemistry
  - CLN: detergent
  - PAA: disinfectant
- **Volumetric control of individual channels for obstruction and disconnection detection**
- **Continuous leak test**



# / SERIE 4

## AN INNOVATIVE CONCEPT

### DUAL WASH TECHNOLOGY

- A unique technique
- A patented spray system
  - 2 multi-directional water jets
- Water pressure creates a mechanical cleaning action in conjunction with a cross cleaning effect for more effective removal of bio-matter
- Improved efficacy



# SERIE 4

## AN INNOVATIVE CONCEPT

### NEW CHEMISTRY

- **Single shot**
- Excellent efficacy
- Safety for the operator and the endoscope
- Using less to bring you more (half consumption of water and chemistry)
- **Less contact time: more efficiency**
- **Less product: more efficiency**
- **Less bottles: more safety**



# SERIE 4

## AN INNOVATIVE CONCEPT

### SIMPLIFICATION OF THE OPERATING PROCEDURE

#### Soluscope CLN:

- A detergent with proven efficacy
- A detergent specific to the Soluscope Serie 4
- Compatible with multidirectional jets (non foaming)
- Original formula
- Validated high level performance



#### Soluscope PAA:

- A new generation of **peracetic acid** disinfectant
- No need for anticorrosive additive
- **Efficacy obtained at 900 ppm, 3 min, 40°C**
- Performance tests
  - ✓ *in vitro*
  - ✓ *simulated-use*



# / SERIE 4

## AN INNOVATIVE CONCEPT

### SOLUSCOPE CLN: A NEW HIGHLY EFFICIENT CLEANER

- Fights actively against biofilm
- **Operates at 35°C**
- 5l bottles
- Color code bottle
- New safer and very efficient plunger
- Shelf life: 36 months



# / SERIE 4

## AN INNOVATIVE CONCEPT

### SOLUSCOPE PAA: NEW FORMULA ALL-IN-ONE HIGH LEVEL DISINFECTANT

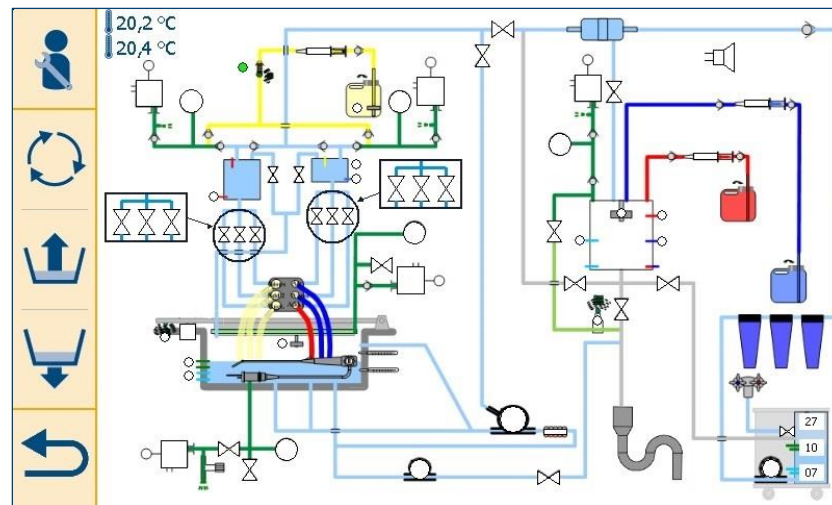
- No mixing required, single bottle
- Cost effective with minimal dosage and a 5% concentrated formula
- Improved efficacy: **3 min** contact time & active at 40°C / 900ppm
- Less corrosive to endoscopes, connectors and reprocessor
- Safe for the endoscope: compatibility test run on 1000 cycles
- New safer and very efficient plunger



## AN INNOVATIVE CONCEPT

### VOLUMETRIC CHANNEL CONTROL SYSTEM

- Patented
- Ensures that every endoscope channel is free from blockages and well connected
- Monitors time to empty a constant volume of solution



# / SERIE 4

## AN INNOVATIVE CONCEPT

### CONTINUOUS LEAK TEST

- Overpressure inside the endoscope
- Measures any changes in pressure
- Prevents water from entering the endoscope



# SERIE4

## AN INNOVATIVE CONCEPT



### Safer for the user

- Less manipulation with less product
- More protection

### Safer for the endoscopes

- More integrity protection
- Less product & short contact time

### Safer for the patient

- More traceability and control

The drill down

## DEVICE SPECIFICATIONS

# SERIE 4

## ENDOSCOPE CYCLES

Cycle 1
<i>Simple cleaning HLD</i>
Leak Test
Pre-rinse
Cleaning
Rinse
Disinfection
Rinse
<b>Purging</b>
<b>16-17 min, 45l water</b>

Cycle 2
<i>Double cleaning HLD</i>
Leak Test
Pre-rinse
<b>Cleaning</b>
Rinse
<b>Cleaning</b>
Rinse
Disinfection
Rinse
<b>Purging</b>
<b>20-21 min, 50l water</b>

Cycle 4
<i>Disinfection without cleaning</i>
Leak Test
Pre-rinse
Disinfection
Rinse
Purging
15 min, 30l water

Cycle 5
<i>Purging</i>
Purging
2 min

Cycle 11
<i>Rinse</i>
Rinse
8 min, 15l water

## MACHINE CYCLES

### Cycle 6

#### *Self-Disinfection*

Break tank disinfection

Filtration system disinfection

Machine disinfection

Hourly recirculation of machine lines until rinsing is activated

Delayed rinse, launched by the user

Purging

40 min, 35l water

### Cycle 10

#### *Seal Inflation*

Inflation of lid seal for inspection

### Cycle 12

#### *Prion Inactivation*

Disinfection with a 2% chlorine solution

Rinse

Purging

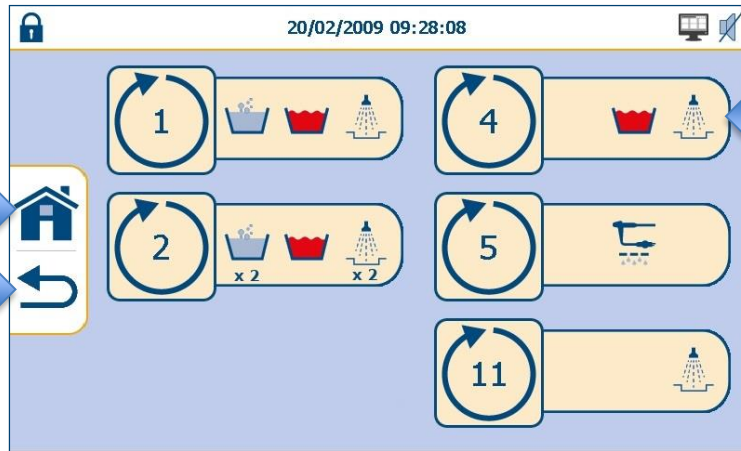
80 min, 60l water

# SERIE4

## CYCLES

Back to main menu

Back to previous page



Icon you can click for action

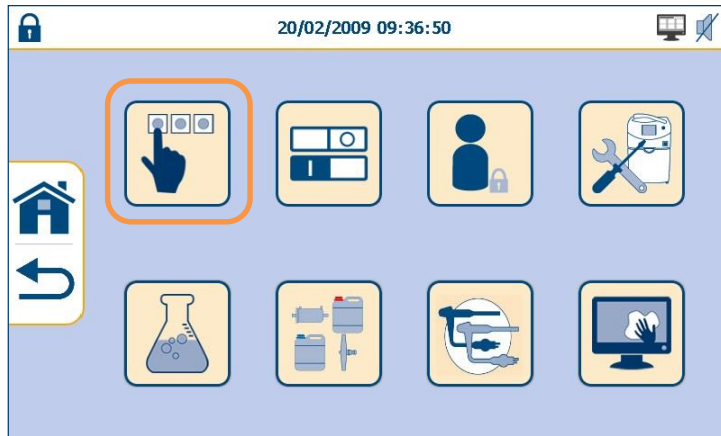
Details

Stop



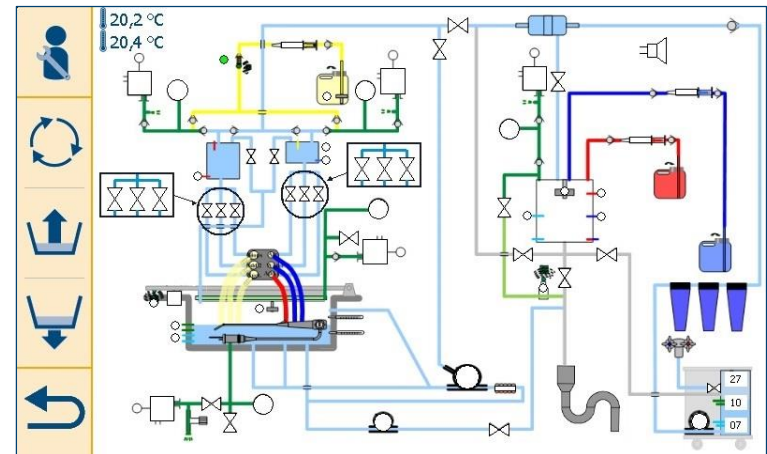
# SERIE 4

## SETTINGS



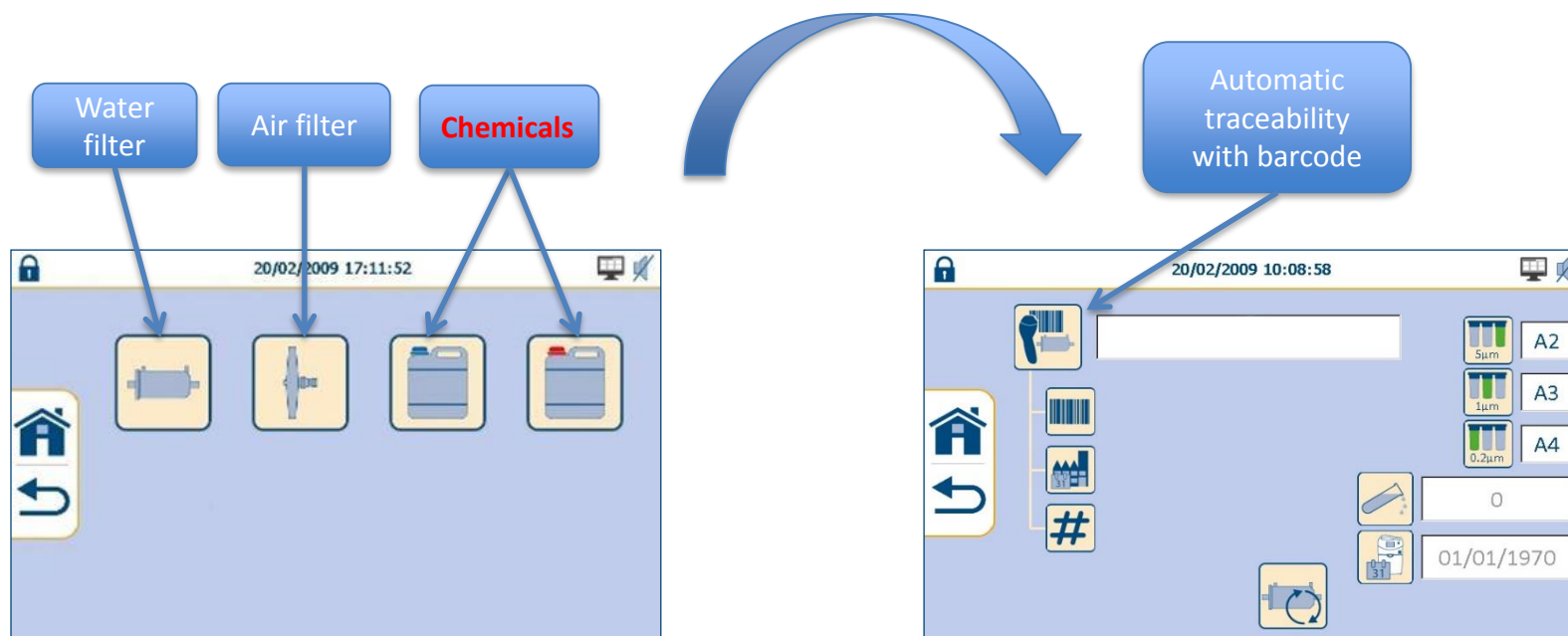
Easy access to servicing mode

More visual  
Different points of test



# SERIE4

## CONSUMABLES MANAGEMENT



# SERIE4

## SERVICES

### SERVICES AND INSTALLATION

- Installation and validation upon delivery

### 2 YEARS WARRANTY

### PREVENTIVE MAINTENANCE

- Every 4000 cycles or 2 years (whichever comes first)
- Aim to identify and prevent any potential high cost damage
- Replaced parts list

### TRAINING

- For operator
- For technician

# SERIE4

## FILTERS

### WATER FILTRATION

- 5 µm, 1µm and 0.2µm prefilters
- A terminal 0.2µm stage ensures no contaminants in the water supply
- Full tracking capability by barcode
- Must be changed every 3 months or 1000 cycles (all at the same time for the best efficiency)

### AIR FILTER

- To be changed every month to ensure the efficiency of the air purge

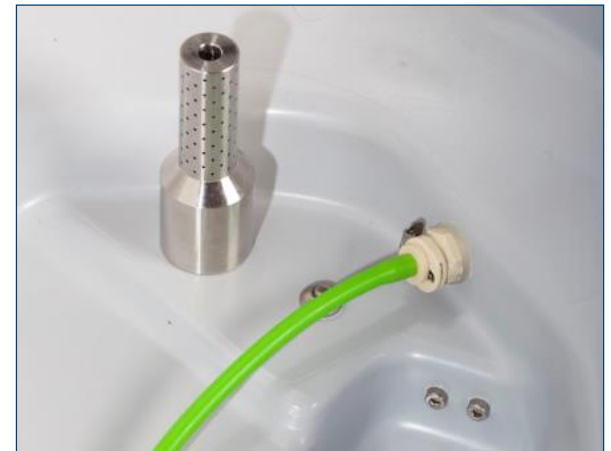


# SERIE4

## HYGIENE



- New materials robust and color stable over time
- Smooth so easy to clean
- Painted steel on sides and back
- PVC bowl



# SERIE 4

## CONNECTORS

### 20 YEARS OF DATA

- Connectors available for the major market brands: **Fujifilm, Olympus, Pentax, Storz, Vision Science, Wolf, Endochoice...**
- **Over 1500 endoscope models registered**
- Connectors database: <https://pro.soluscope.com>
  - Simple system to access information regarding which connectors to be used for your endoscope reprocessing and storage,
  - How to attach them, and general information
  - An extensive choice, access details are provided with the purchase of Soluscope products



## TRACEABILITY

- Internal memory
- All data stored in local SD card (replaced every 2 years or 4000 cycles during maintenance)
- Embedded printer
- All data on the printout
- IT Soluscope compatible

Ticket: 19

Hosp.: SOLUS  
Dept.: R&D  
Soluscope: Serie 4 PA21581  
PLC version : V1.7.4  
CYCLE 1 / CYCLE COUNTER : 19  
Start time: 14/11/2014 17:28:24  
Input operator : OPE  
Patient : Patient  
Doctor : DOC  
Endoscope : 1000 SN1000  
Water filter 5 µm: A2  
Water filter 1 µm: A3  
Water filter 0.2 µm: A4  
Terminal water filter: A1040714.L0000358  
Air filter ID: B110071313/02122  
ID Soluscope CLN : C2040414S09401Q  
ID Soluscope PAA : C1010714S191805F  
Time to inflate endoscope: 5.71 s

Output operator : OPE

14/11/2014 17:50:56  
Cycle complete and valid : 0h 22min 33s

# SERIE 4

## SOLUSCOPE COMPLETE SOLUTION



Soluscope proposes a complete solution for flexible endoscope reprocessing.

It offers products for every step of the reprocessing cycle.  
Each part is certified , easy to use and effective in order to reduce your daily workload.



[www.soluscope.com](http://www.soluscope.com)

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# **SERIE4**

**THANK YOU ...**





**SERIE 4 - RAPID, RELIABLE, EFFICIENT**

# The **power** at your **fingertips**

Using cutting edge technologies  
for improved performances.

## **WORKFLOW OPTIMISATION**

The Soluscope Serie 4 PA offers fast reprocessing cycles to adapt your organization to growing endoscopy activity.

## **A UNIQUE AND PATENTED DUAL WASH TECHNOLOGY**

Semi-immersion bathes the endoscope, whilst the shower adds mechanical cleaning action.

Better results using less water and chemistry for reduced global costs.

## **LIQUID CHEMICAL STERILANT (LCS) CYCLE**

The LCS cycle achieves higher level of efficacy against bacterial endospores (compared to high level disinfection) for challenging cases. Cycle efficacy has been tested based on ISO 14937 protocol.



# User-centered design

## Advanced ergonomics for fast adoption.

### SMART AND EASY-TO-USE INTERFACE

The Soluscope Serie 4 PA brings the benefit of an intuitive and graphic interface for fast adoption and quick use. The large and comfortable 7" touch screen enables easy access to all cycles and machine parameters.

### AN INTEGRATED CONCEPT

The Soluscope Serie 4 PA is easy to install. All the elements (chemistry, filters, traceability, barcode reader) are integrated and allow easy access for maintenance.



### TURNKEY ELECTRONIC TRACEABILITY AND DATA MANAGEMENT

The Soluscope Serie 4 PA includes barcode reader, printer and local data storage.

It is compatible with our EP-Digital suite for electronic traceability, real-time monitoring of endoscope inventory and enables microbiological samplings and services records.



### MINIMISED HANDLING TO REDUCE CROSS-CONTAMINATION RISKS

Dedicated connectors reduce the need for endoscope handling and subsequently the risk of contamination.



### A RELIABLE AND REPRODUCIBLE PROCESS

A double check system with alarm verifies all critical parameters to ensure constant performance.

A continuous leak test checks sheath integrity to guarantee endoscope safety during the whole process.

A patented volumetric channel control monitors each individual channel.

# Highest standards to ensure **patient safety**

CE MARK / ISO 15883 -  
1 & 4 compliant.

## PROVEN SAFETY

Proven and tested according to EN ISO 15883-4:2018, Soluscope Serie 4 PA in combination with its dedicated, specifically designed chemistry, is compatible with a large range of flexible endoscopes.

## CONNECTORS

Compatible with all Soluscope equipments, the connector stays hooked to the endoscope during the entire reprocessing journey, from pre-cleaning to storage.

This link ensures both connector and endoscope are at the same level of hygiene and provides an efficient and safe process before use on a patient.



## SOLUSCOPE PAA

- Peracetic acid-based disinfectant
- Broad spectrum antimicrobial activity
- Compatible with a large range of flexible endoscopes



## SOLUSCOPE CLN

- pH neutral detergent
- Proven efficacy against biofilm and proteins
- Non foaming

"Ecolab provides  
a complete  
solution  
for flexible  
endoscope  
reprocessing"





## THE ECOLAB SOLUTION

Ecolab provides a complete solution for flexible endoscope reprocessing.

It offers products for every step of the reprocessing cycle.

Each part is certified, easy to use and effective in order to reduce your daily load.



Non-contractual pictures - Soluscope reserves the right to make any changes to the specifications given in this document without notice or obligation.



**SOLUSCOPE SAS**  
(An Ecolab Company)  
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Z.I Les Paluds - 13400  
Aubagne - France

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Switzerland

**ECOLAB®**  
[www.ecolab.com](http://www.ecolab.com)

**Soluscope**  
[www.soluscope.com](http://www.soluscope.com)



# CERTIFICATE

**EC Certificate No. 1434-MDD-141/2020**  
**Full Quality Assurance System**  
**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**Soluscope SAS**  
**100 rue du Fauge**  
**ZI Les Paluds**  
**Aubagne 13400 FRANCE**

for the design, manufacture and final inspection of medical devices, class: **Class IIb**

**Washer-disinfectors for endoscopes or TEE probes,  
disinfectants and cleaners, consumables and accessories**

*The list of medical devices covered by this certificate is provided in the Annexes 1 and 2*

**complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)**  
**implemented into Polish law, as evidenced by the audit conducted by the PCBC**

Validity of the Certificate: from **27.04.2020** to **06.09.2022**

The date of issue of the Certificate: **27.04.2020**

The date of the first issue of the Certificate: **26.04.2019**



Issued under the Contract No. MD-15/2020  
Application No: 850/2019  
Certificate bears the qualified signature.  
Warsaw, 27/04/2020  
Module **H2/3/4/5**  
FBM-26\_E\_8

Anna  
Małgorzata  
Wyroba

**Mgr Anna Wyroba**  
**Vice-President**

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.04.27  
17:13:08 +02'00'



## ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-141/2020**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Flexible Endoscope washer/disinfectors	SOLUSCOPE SERIE 1	SL-V1-PA used with Soluscope EZ or Soluscope NW and Soluscope PA
		SL-V1-120-PA used with Soluscope EZ or Soluscope NW and Soluscope PA
		SL-V1-GTA used with Soluscope EZ or Soluscope NW and Soluscope GTA
		SL-V1-120-GTA used with Soluscope EZ or Soluscope NW and Soluscope GTA
		SL-V1-OPA used with Soluscope EZ or Soluscope NW and Soluscope OPA
		SL-V1-120-OPA used with Soluscope EZ or Soluscope NW and Soluscope OPA
		SL-V1-AL-PA used with Soluscope EZ or Soluscope NW and Soluscope PA
		SL-V1-AL-GTA used with Soluscope EZ or Soluscope NW and Soluscope GTA
		SL-V1-AL-OPA used with Soluscope EZ or Soluscope NW and Soluscope OPA
	SOLUSCOPE SERIE 3	SL-V3-PA used with Soluscope C+ or Soluscope CLN+ and Soluscope P and its additive Soluscope A



Issued under the Contract No. MD-15/2020  
Application No: 850/2019  
Certificate bears the qualified signature.  
Warsaw, 27/04/2020

Anna  
Małgorzata  
Wyroba

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.04.27  
17:15:21 +02'00'

**Mgr Anna Wyroba**  
Vice-President



## ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-141/2020**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Flexible Endoscope washer/disinfectors	SOLUSCOPE SERIE 3	SL-V3-GTA used with Soluscope C+ or Soluscope CLN + and Soluscope D
	SOLUSCOPE SERIE 4 PA	SL-V4-PA used with Soluscope CLN and Soluscope PAA
		SL-V4-SA-PA used with Soluscope CLN and Soluscope PAA
		SL-V4-RO-PA used with Soluscope CLN and Soluscope PAA
	SOLUSCOPE SERIE ENT	SL-ENT used with Soluscope C+ and Soluscope P and its additive Soluscope A
	SOLUSCOPE SPRINT	SL-V3-PA-G used with Soluscope C+ or Soluscope CLN+ and Soluscope P and its additive Soluscope A
	SOLUSCOPE SPRINT PT	SL-V3-PA-G-PT used with Soluscope C+ or Soluscope CLN+ and Soluscope P and its additive Soluscope A
		SL-V3-PA-PT used with Soluscope C+ or Soluscope CLN+ and Soluscope P and its additive Soluscope A
TEE probes washer/disinfectors	SOLUSCOPE SERIE TEE	SL-TEE used with Soluscope C+ and Soluscope P and its additive Soluscope A



Issued under the Contract No. MD-15/2020  
Application No: 850/2019  
Certificate bears the qualified signature.  
Warsaw, 27/04/2020

Anna  
Małgorzata  
Wyroba

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.04.27  
17:17:02 +02'00'

**Mgr Anna Wyroba**  
Vice-President

# EC MANUFACTURER'S DECLARATION OF CONFORMITY

Déclaration de conformité CE du Fabricant

## FULL QUALITY ASSURANCE SYSTEM

Système complet d'Assurance de Qualité

<b>Manufacturer's Name</b> Nom du Fabricant	<b>SOLUSCOPE SAS</b>	
<b>Address / Adresse</b>	<b>100, Rue du Fauge – Z.I. Les Paluds – 13400 AUBAGNE - FRANCE</b>	
<b>Designation / Désignation</b>	<b>SOLUSCOPE SERIE 4 PA</b>	
<b>Product References</b> Références du produit	<b>SL-V4-PA ; SL-V4-SA-PA ; SL-V4-RO-PA</b>	
<b>Classification of the Medical Device</b> Classe du Dispositif Médical	<b>Class IIb</b> Classe IIb	<b>Annex IX, Rule No. 15</b> Annexe IX, Règle n° 15
<b>Medical Device type</b> Type de Dispositif médical	<b>Washer-disinfector</b> Laveur-désinfecteur	
<b>Scope of Application</b> Domaine d'Application	<b>Flexible endoscope reprocessing, to be used exclusively with SOLUSCOPE CLN and SOLUSCOPE PAA chemicals, according to the user manual</b> Nettoyage et désinfection des endoscopes souples, à utiliser exclusivement avec les produits SOLUSCOPE CLN et SOLUSCOPE PAA, conformément au manuel d'utilisation	
<b>GMDN Code &amp; Term</b> Code & Désignation GMDN	<b>35012</b>	<b>Endoscope washer/disinfector</b>
<b>Quality Management System according to</b> <b>ISO 9001: 2015</b> <b>EN ISO 13485: 2016</b>	<b>Certificate No. 1789.210723</b> <b>Certificate No. 2407.210723</b>	<b>Certificate Expiry: September 6, 2022</b> <b>Certificate Expiry: September 6, 2022</b>
<b>Notified Body - CE Marking</b> Organisme Notifié – Marquage CE	<b>1434</b>	<b>Polish Centre for Testing and Certification</b>
<b>CE Marking</b> Marquage CE	<b>Certificate No. 1434-MDD-420/2021</b>	<b>Certificate Expiry: 26/05/2024</b>

I undersigned, Christian AFFRE, C.E.O. of SOLUSCOPE SAS, declare that the above-mentioned device complies with the relevant provisions according to the European Directive 93/42/EEC concerning Medical Devices as amended, Annex II (with exemption of section 4), as transposed in the French decree N° 2009-482 of 28<sup>th</sup> April 2009; and particularly, fulfils the Essential Requirements according to the Annex I; consequently, the CE mark is affixed on the above cited device.

*Je soussigné, Christian AFFRE, Président de SOLUSCOPE SAS, déclare que le dispositif médical décrit ci-dessus est conforme aux dispositions qui le concernent selon l'Annexe II (à l'exception du point 4) de la Directive Européenne 93/42/CEE amendée relative aux Dispositifs Médicaux, transposée en droit français dans le décret N° 2009-482 du 28/04/2009; et en particulier, satisfait aux Exigences Essentielles de l'Annexe I; en conséquence la marque CE est apposée sur ce dispositif médical.*

Aubagne, 02/08/2021

Christian AFFRE  
C.E.O.

Président

[www.soluscope.com](http://www.soluscope.com)

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Soluscope SAS au capital de 11 700 000 € • Code APE 3250 A • RCS Marseille 490918075 • N° TVA intracommunautaire FR 36490918075  
Siret 49091807500048 • Organisme de formation enregistré sous le numéro 93131375813 auprès du préfet de la région Provence-Alpes-Côte d'Azur

Compilation of all tests performed on  
SOLUSCOPE SERIE 4 PA using SOLUSCOPE PAA, and SOLUSCOPE CLN  
to demonstrate compliance with EN ISO 15883-4:2018

Note: Compliance with ISO 15883-1 requirements was not verified

Description of test	Requirement clause	Test clause	Test reference	Results
<b>EN ISO 15883-4:2018</b>				
Leak test failure alarm	4.2.3	6.5.3.3	-	Not performed
Leak test connector	4.2.4 4.2.5	6.5.3.4	-	Not performed
Over-pressurization prevention	4.2.4 d)	6.5.3.2	-	Not performed
Cleaning efficacy	4.3.5	6.11 6.11.3.2 a)	2830.SOL.19 Cleaning Annex F V2	Pass
		6.11.3.2 b)	Report 2830.SOL.19 Cleaning Surrogate Annex I.V2	Pass <sup>(a)</sup>
		6.11.3.2 c)	Rapport 2830.SOL.19 Cleaning Endoscope Annexe R V3	Pass : performed on endoscope type test groups provided by the manufacturer <sup>(b)</sup>
			Report 2830.SOL.19 Cleaning Endoscope Annex I V2	Pass : performed on endoscope type test groups provided by the manufacturer <sup>(b)</sup>
In vitro disinfectant efficacy	4.4.2.2	6.12.2	-	Not performed
Disinfection efficacy	4.4.2.5	6.12.6.1	Rapport 2829.SOL.19 Désinfection.V2	Pass <sup>(a)</sup>
Efficacy of the complete cycle	4.1.3	Annex B	Rapport 2844.SOL.19 Complete cycle.V4	Pass : performed on endoscope type test groups provided by the manufacturer <sup>(b)</sup>
		Annex I	Rapport	Pass <sup>(a)</sup>

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		(ISO/TS 15883-5:2005)	2844.SOL.19 Complete cycle surrogate.V3	
Final rinse water treatment - quality	4.5.2	-	-	Not Performed
Final rinse water quality	4.5.2 4.9.2.3 a) 4.9.2.3 b)	6.3	-	Not Performed
Drying	4.7	6.8	-	Not performed
Disinfection of liquid transport system	4.8.5	6.12.5.1	Rapport final 2828.SOL.19 Annexes D and 2828.SOL.19.C1	Pass
Self-disinfection test	4.8.7	6.12.3.1	Rapport final 2828.SOL.19.C2 AD Annexe F	Pass
Water treatment equipment	4.9.2.2	6.12.4.1	2944 Serie 4 K12 RAPPORT FINAL	Pass
Channel non-obstruction test	5.2.2.1	6.6	-	Not performed
Channels non connected test	5.2.2.2	6.7	-	Not performed
Temperature throughout process	4.4.3 5.4.2 5.4.3	6.9	-	Not performed
Minimum process temperature test	5.4.4	6.9.2	-	Not performed
Dosing system	5.7	6.10	-	Not applicable
General information	Not applicable	Not applicable	-	Not applicable

(a) Definition of the worst case surrogate. Internal document SZ-LDE-20-12-002-0 and Test report 2803.SOL.19 and 2803.SOL.19.C1.V5: Evaluation of the effect of channel diameter and length on the process efficacy of a disinfection cycle (cycle 4) of an endoscope washer/disinfector (SOLUSCOPE Serie 4 PA) according to the revised version of ISO 15883-4, annex H.

(b) Definition of endoscope type test groups. Internal document SZ-LDE-20-12-001-0

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Study Manager

Date: 01/12/2022



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