



# 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



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 Warsaw, 27/04/2020

Anna  
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 Wyroba

Elektronicznie  
 podpisany przez Anna  
 Małgorzata Wyroba  
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 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



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Anna  
 Małgorzata  
 Wyroba

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

**Mgr Anna Wyroba**  
 Vice-President



# EC CERTIFICATE

## Soluscope SAS

100 rue du Fauge  
ZI Les Paluds  
13400 AUBAGNE – FRANCE

## Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

**The design, manufacture of washer-disinfectors for endoscopes or TEE probes, disinfectant and cleaning solutions, consumables and accessories**

Device Classification:

**IIb**

Device Descriptions:

**Washer-disinfectors for endoscopes or TEE probes, disinfectant and cleaning solutions, consumables and accessories**

Model Type:

**See Attachment 1**

Manufacturing/Off Sites located at:

199, Avenue de Jouques  
ZI Les Paluds, 13400 Aubagne  
France

**We hereby declare that an examination of the full quality assurance system has been carried out per report 11756157, following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 2 attachments listing model numbers.**

File Number	A14025	Cycle Start Date	07 September 2017
Certificate No.	537.170907	Effective Date	07 September 2017
		Expiry Date	06 September 2022

Authorised by

**Deborah Stubbs**  
Certification Reviewer

For and on Behalf of UL International (UK) Ltd

**Notified Body**

**0843**



# EC CERTIFICATE

## Soluscope SAS

100 rue du Fauge  
ZI Les Paluds  
13400 AUBAGNE – FRANCE

### Attachment 1 of 2

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Flexible Endoscope washer/disinfectors	SOLUSCOPE SERIE 4 PA	SL-V4-PA used with Soluscope CLN and Soluscope PAA	IIb	35628 (endoscopes washer/disinfectors)
		SL-V4-SA-PA used with Soluscope CLN and Soluscope PAA	IIb	
		SL-V4-RO-PA used with Soluscope CLN and Soluscope PAA	IIb	
	SOLUSCOPE SERIE ENT	SL-ENT used with Soluscope C+ and Soluscope P and its additive Soluscope A	IIb	
	SOLUSCOPE SERIE 3	SL-V3-GTA used with Soluscope C+ and Soluscope D	IIb	
		SL-V3-PA used with Soluscope C+ and Soluscope P and its additive Soluscope A	IIb	
SOLUSCOPE SPRINT	SL-V3-PA-G used with Soluscope C+ and Soluscope P and its additive Soluscope A	IIb		

File Number A14025  
Certificate No. 537.170907

Cycle Start Date 07 September 2017  
Effective Date 07 September 2017  
Expiry Date 06 September 2022

Authorised by

**Deborah Stubbs**  
Certification Reviewer  
For and on Behalf of UL International (UK) Ltd

**Notified Body**

**0843**



# EC CERTIFICATE

## Soluscope SAS

100 rue du Fauge  
ZI Les Paluds  
13400 AUBAGNE – FRANCE

### Attachment 2 of 2

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
	SOLUSCOPE SERIE 1	SL-V1-PA used with Soluscope EZ or Soluscope NW and Soluscope PA	IIb	35628 (for endoscopes washer/disinfector)
		SL-V1-GTA used with Soluscope EZ or Soluscope NW and Soluscope GTA	IIb	
		SL-V1-120-PA used with Soluscope EZ or Soluscope NW and Soluscope PA	IIb	
		SL-V1-120-GTA used with Soluscope EZ or Soluscope NW and Soluscope GTA	IIb	
		SL-V1-OPA used with Soluscope EZ or Soluscope NW and Soluscope OPA	IIb	
		SL-V1-120-OPA used with Soluscope EZ or Soluscope NW and Soluscope OPA	IIb	
<b>TEE probes washer/disinfectors</b>	SOLUSCOPE SERIE TEE	SL-TEE used with Soluscope C+ and Soluscope P and its additive Soluscope A	IIb	61673 (TEE probes washer-disinfector)

File Number A14025  
Certificate No. 537.170907

Cycle Start Date 07 September 2017  
Effective Date 07 September 2017  
Expiry Date 06 September 2022

Authorised by

**Deborah Stubbs**  
Certification Reviewer  
For and on Behalf of UL International (UK) Ltd

**Notified Body**  
**0843**



# CERTIFICATE OF REGISTRATION

## Soluscope SAS

100 rue du Fauge  
ZI Les Paluds  
Aubagne 13400 FRANCE

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

**ISO 13485:2016**

**EN ISO 13485:2016**

The design, manufacture and servicing of endoscope and TEE probes reproprocessors. The design and manufacture of disinfectant and cleaning solutions, consumables and accessories. The design, manufacture and servicing of drying and storage cabinets for flexible endoscopes. The provision of technical support for endoscope and TEE probe reprocessing. The installation and servicing of sterilizers intended for rigid endoscopes and surgical instruments.

Certificate with Addendum(s) totals 2 pages.



Authorized by

**Deborah Jennings-Conner**  
Global Regulatory Director  
Life and Health Sciences, UL LLC



Check Certificate  
Status: [here](#)

File Number A14025  
Certificate Number 2407.200907  
Initial Issue Date January 18, 2020

Cycle Start September 7, 2021  
Effective Date September 7, 2021  
Expiry Date March 6, 2022

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.



UL LLC  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA



**Compilation of all tests performed on Soluscope Serie 4 - PAA to demonstrate compliance with  
NF EN ISO 15883-1: 2006 and 15883-4:2009**

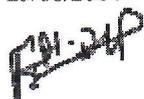
Description of test	Requirement clause	Test clause	Test code	Result
<b>EN ISO 15883-1:2006</b>				
Temperature control :				
Rate of rise	4.1.4	6.8.2	Not applicable RE-SO2-10-04-019-0	PASS
Flushing stage	4.2.2	6.8.2		
Over-temperature cut-out	5.8.3	6.8.5		
Chemical disinfection				
Chamber walls and load carrier	4.3.2	6.8.2	RE-SO2-10-04-019-0	PASS
Load	4.3.3	6.8.3		
Fluid emission				
Chamber leak proof	5.1.7, 5.1.8	6.5.3	RE-SO2-11-09-078-1	PASS
Doors and interlocks				
Cycle start	5.4.1.8	6.3.1	RE-SO2-11-09-075-3	PASS
Loading/unloading	5.4.3.1	6.3.4		
	5.4.3.3	6.3.3		
	5.4.1.4	6.3.4		
On fault condition	5.4.1.5	6.3.5		
	5.22	6.3.6		
Door interlock	5.4.3.2	6.3.7		
Process residual	4.4.1 4.4.2	6.10.4	RE-SO2-11-10-084-2	PASS
Chemical dosing				
Accuracy and repeatability	5.7.5	6.9.1	RE-SO2-11-09-083-3	PASS
Low level indicator	5.7.6	6.9.2		
Water quality	4.4.1	6.4.2	RE-SO2-11-09-085-3	PASS
Rinse water	4.4.2, 4.4.3	6.4.2		
	4.2.1.2	6.4.3		
Prior to OQ and PQ	8.2 b)	6.4.3		
Volume per stage	8.2 b)	6.4.4		
Pipework				
Dead volume	5.5.1.2	6.5.1	RE-SO2-11-09-079-1	PASS
Free draining	4.1.7	6.5.2		
	5.1.10	6.5.2		
	5.3.1.1 a)	6.5.4		
	5.5.1.1	6.5.5		

This test report should not be reproduced, or entirely, without the written authorization of Biotech Germande



Description of test	Requirement clause	Test clause	Test code	Results
<b>NF EN ISO 15883-4:2009</b>				
Leak test failure alarm	4.2.3	6.5	RE-SO2-11-07-049-0	PASS
Leak test	4.2.5	6.5	RE-SO2-11-07-049-0	PASS
Cleaning efficacy	4.3.5	6.11	2033.SOL.12 (annex F) C.002.MED.00.126.2.m (annex R)	PASS
In vitro disinfectant efficacy	4.4.2	6.12.2	SP-SO2-11-06-025-0	PASS
Disinfection efficacy	4.4.1	6.12.6.1	C.002.MED.00.127.m	PASS
Efficacy of the complete cycle	4.1.3	Annex B	C.002.MED.00.128.1.m 2039.SOL.12 (with pretreatment)	PASS
Temperature of disinfection stage	4.4.3	6.9	RE-SO2-10-04-019-0	PASS
Disinfection of liquid transport system	4.8.5	6.12.5	C.002.MED.00.129.m	PASS
Self-disinfection test	4.8.7	6.12.3.1	C.002.MED.00.130.m	PASS
Disinfection of water treatment equipment	4.5.2	6.12.4	C.002.MED.00.131.m	PASS
Channels non-obstruction test	5.2.2.1	6.6	RE-SO2-11-06-037-1	PASS
Channels non connected test	5.2.2.2	6.7	RE-SO2-11-06-040-1	PASS
Temperature throughout process	5.4.2 5.4.3	6.9.1	RE-SO2-10-04-019-0	PASS
Minimum process temperature test	5.4.4	6.9.2	RE-SO2-10-04-019-0	PASS
Leak-test non-connection test	4.2.4 4.2.5	6.5.2.4	RE-SO2-11-07-050-0	PASS

Christine AH-DIP  
 Study Manager  
 25/06/2014



Lionel PINEAU  
 Managing director  
 25/06/2014



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# SERIE4

The logo for Soluscope, featuring the word "Soluscope" in white text on a dark blue rectangular background. The background has a yellow-orange shape extending from the bottom right corner, resembling a stylized bracket or a graphic element.

**Soluscope**

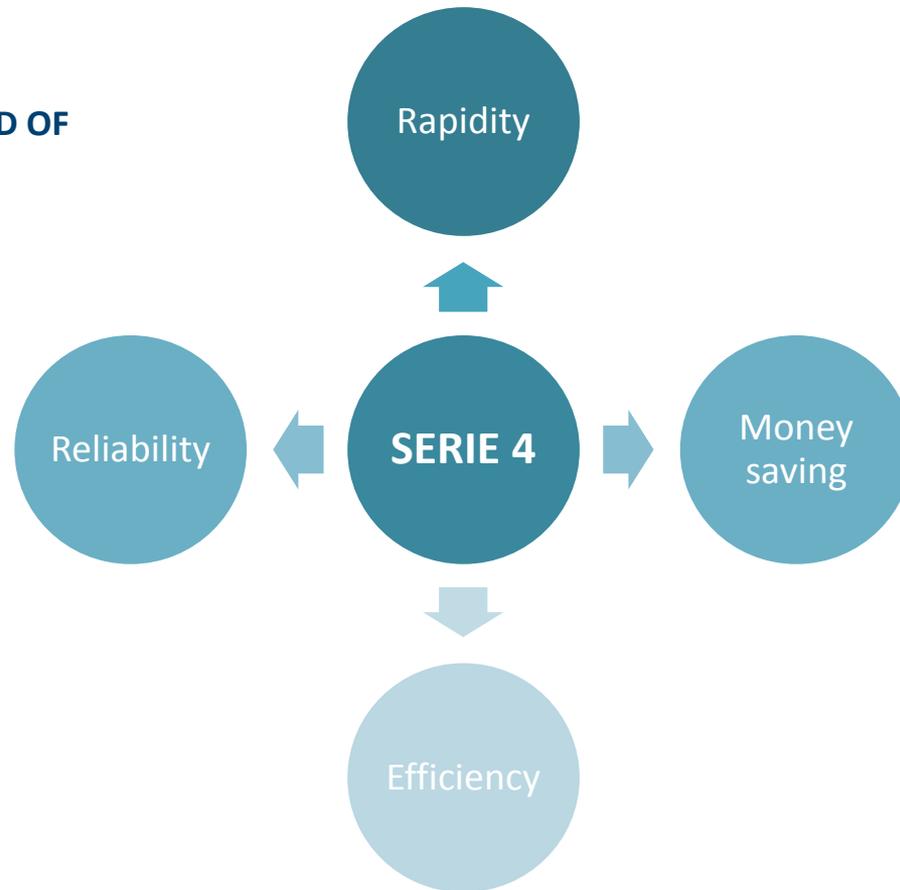
**Rapid Reliable Efficient**  
**Soluscope Serie 4**

PA Version

# SERIE 4

## 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



# SERIE 4



an Intuitive  
device



an Integrated  
process



an Innovative  
concept

# SERIE4

Power at your fingertips

## AN INTUITIVE DEVICE

# SERIE 4

## 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



# SERIE 4

## 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



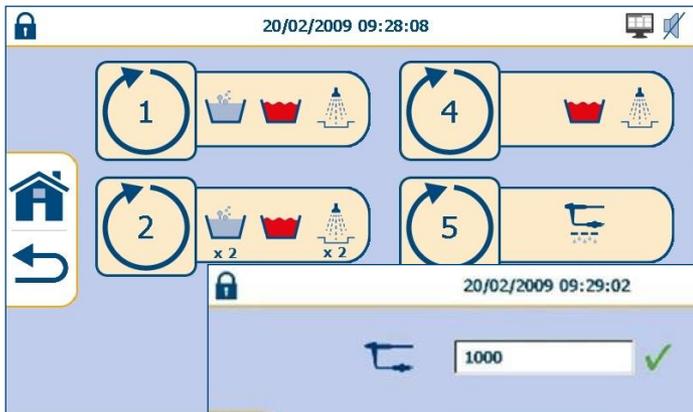
Endoscope  
cycles

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

# SERIE4

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... )
- A single bowl for all endoscope types

### 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



# SERIE 4

## AN INTEGRATED PROCESS

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

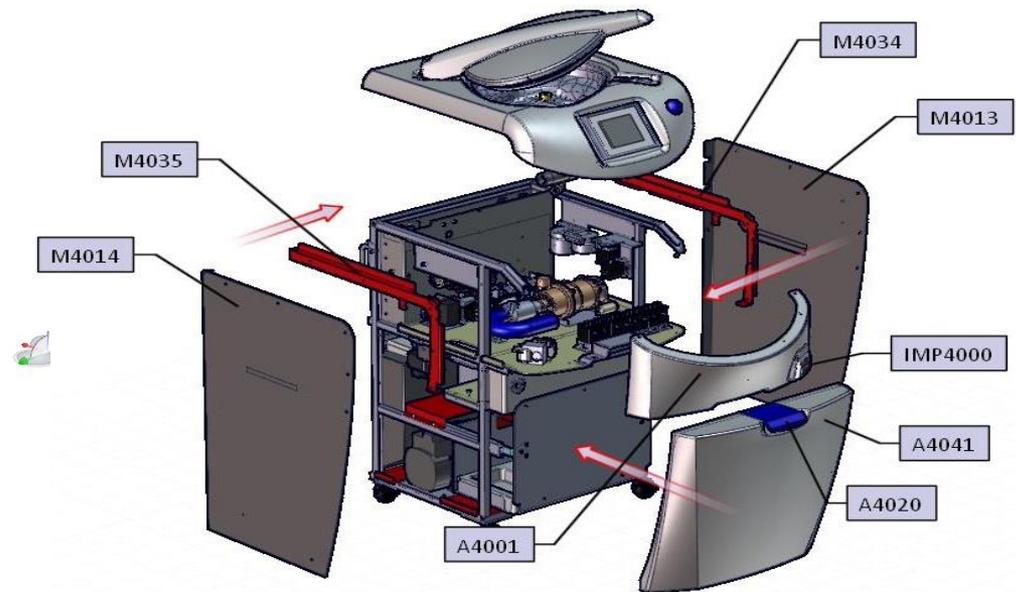
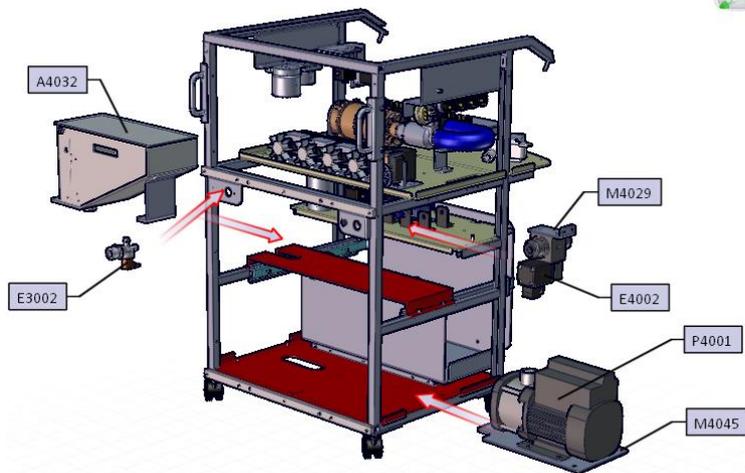


# SERIE 4

## 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 : 0.2 $\mu$ m terminal filter and 3 pre-filters (0.2 $\mu$ m, 1 $\mu$ m, 5 $\mu$ m)
- 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



# SERIE4

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

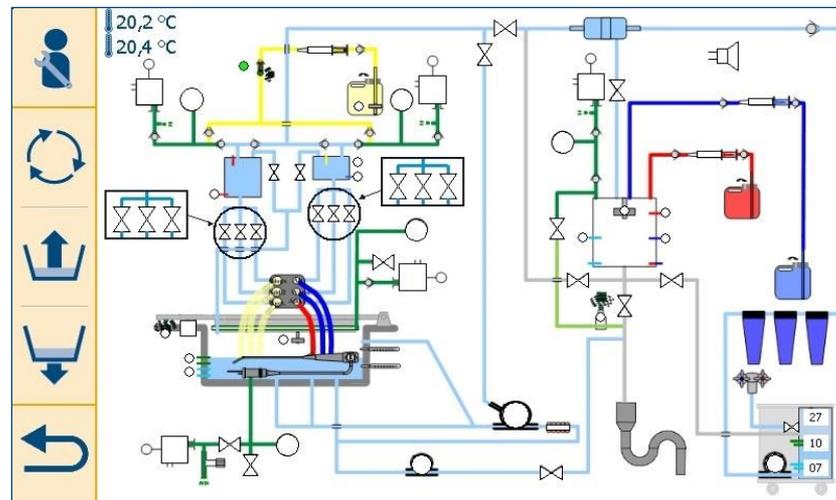


# SERIE 4

## 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

# SERIE4

The drill down

## DEVICE SPECIFICATIONS

# SERIE 4

## ENDOSCOPE CYCLES

Cycle 1	Cycle 2	Cycle 4	Cycle 5	Cycle 11
<i>Simple cleaning HLD</i>	<i>Double cleaning HLD</i>	<i>Disinfection without cleaning</i>	<i>Purging</i>	<i>Rinse</i>
Leak Test	Leak Test	Leak Test	Purging	Rinse
Pre-rinse	Pre-rinse	Pre-rinse	2 min	8 min, 15l water
Cleaning	Cleaning	Disinfection		
Rinse	Rinse	Rinse		
Disinfection	Cleaning	Purging		
Rinse	Rinse	15 min, 30l water		
Purging	Disinfection			
16-17 min, 45l water	Rinse			
	Purging			
	20-21 min, 50l water			

# SERIE 4

## 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

# SERIE 4

## CHEMISTRY CONSUMPTION

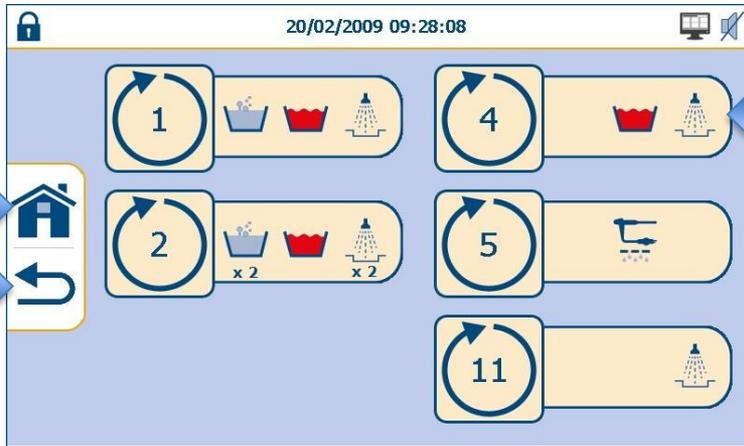
CYCLE 1 (standard cycle cleaning / disinfection)	SL-V3-PA	SL-V3-GTA	SL-V4-PA
Detergent (ml)	50 ± 5	50 ± 5	52.5 ± 2.5
Disinfectant (ml)	133 ± 6	110 ± 5	84 ± 4
Anticorrosive (ml)	133 ± 6	0	0

CYCLE 6 (self-disinfection cycle)	SL-V3-PA	SL-V3-GTA	SL-V4-PA
Detergent (ml)	0	0	0
Disinfectant (ml)	266 ± 12	0	168 ± 8
Anticorrosive (ml)	266 ± 12	0	0

# SERIE4

## CYCLES

Back to main menu  
Back to previous page



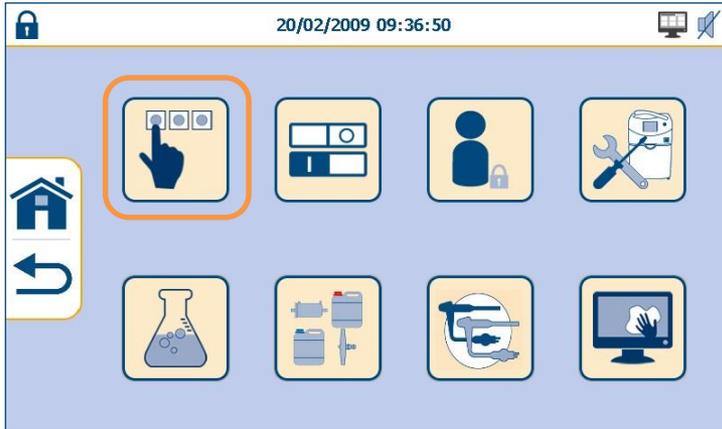
Icon you can click for action

Details  
Stop



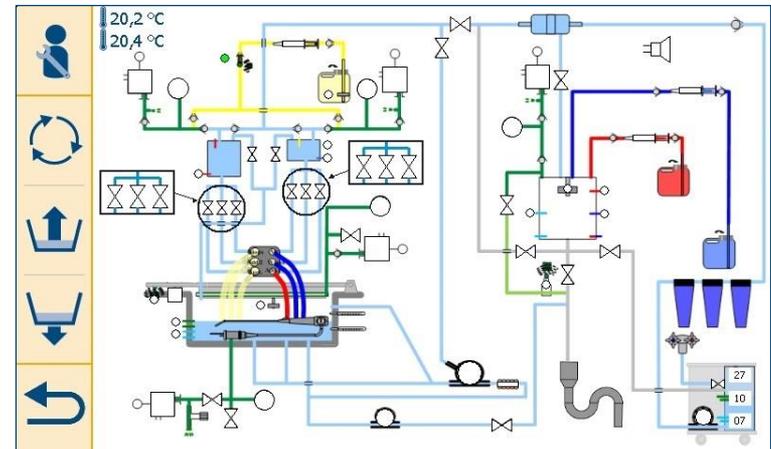
# SERIE 4

## SETTINGS



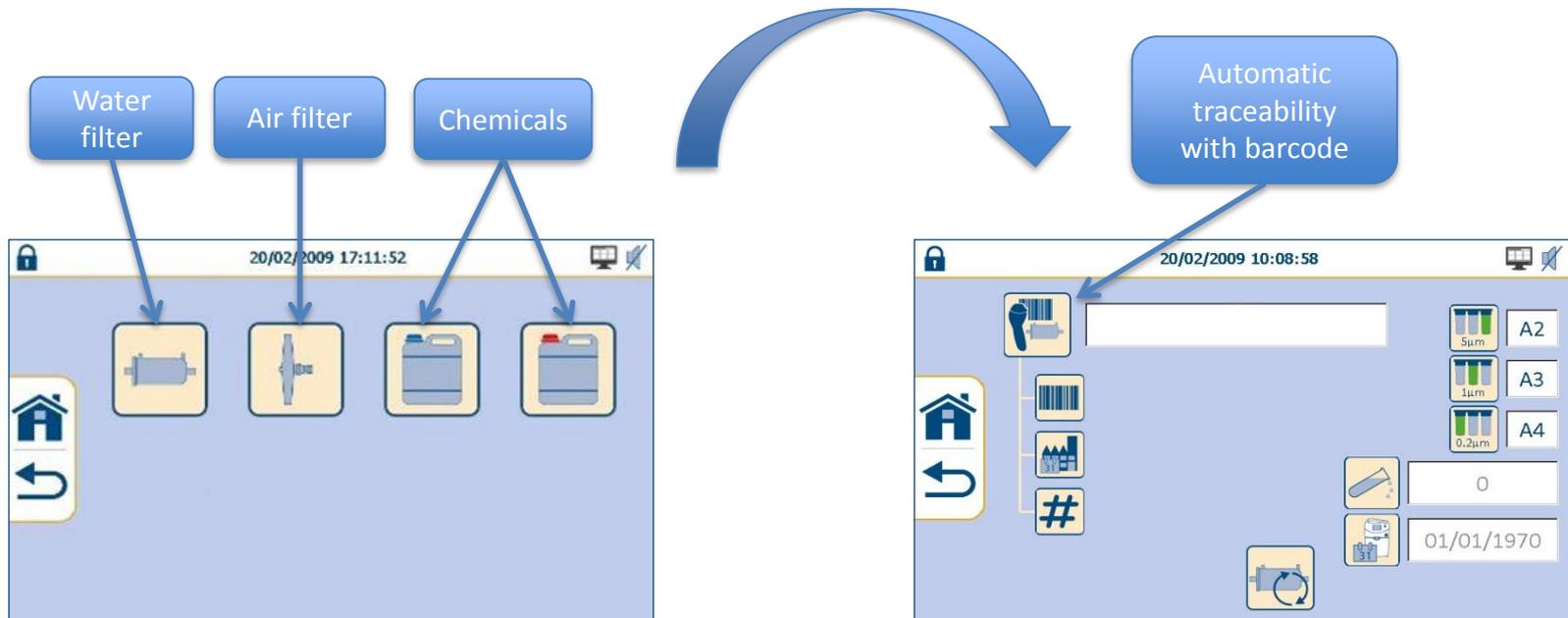
Easy access to servicing mode

More visual  
Different points of test



# SERIE 4

## 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

# SERIE 4

## 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

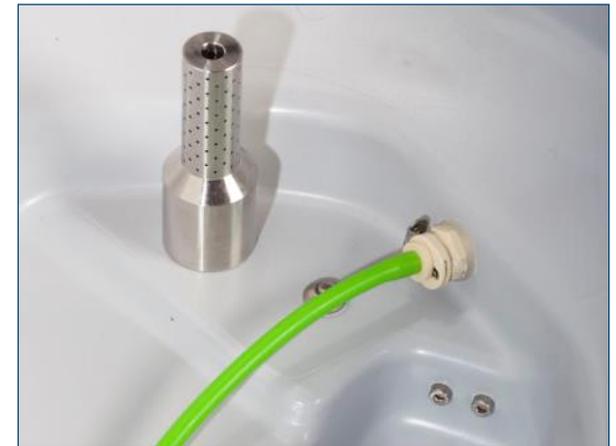


# SERIE 4

## 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

#### Replacement frequency:

- connectors – after 1000 cycles of use or every 2 years at the latest
- O-ring seals – every 3 months



# SERIE 4

<https://pro.soluscope.com>

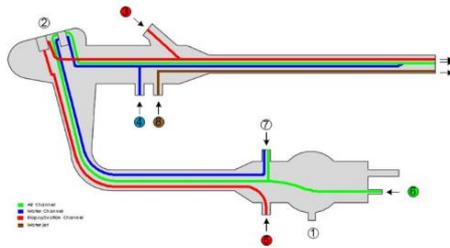


Fujifilm | EC-400HL

Soluscope



## Information



Type



Colonoscope

Group

05

Options



HD



Video



Zoom

Visualize the qualifications

S3F-E | SERIE 3 | DSC8000 | SERIE 4

Visualize in PDF format Add to cart Visualize the cart

Leak test



SL-TO-F

Blocker/Separator



WF-B

Biopsy/Suction



WF-BAL

Air/Water



WF-AW

Additional channel



WF-S

S2F-E | SERIE 1 | DSC8000

Visualize in PDF format Add to cart Visualize the cart

Leak test



SL-TO-F

Blocker/Separator



SL-FUJI-3N

Biopsy/Suction



SL-S1-F

Air/Water



SL-W1-F

AW option



SL-W5

# SERIE 4

## 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)

Soluscope SAS : 100, rue du Fauge – Z.I. Les Paluds - 13400 Aubagne - France  
Tel : +33 (0)4 91 83 21 22 • Fax : +33 (0)4 91 83 21 10 • E-mail : [info@soluscope.com](mailto:info@soluscope.com)

# SERIE 4

THANK YOU ...



## EC MANUFACTURER'S DECLARATION OF CONFORMITY

Déclaration de conformité CE du Fabricant

## FULL QUALITY ASSURANCE SYSTEM

Système complet d'Assurance de Qualité

Manufacturer's Name Nom du Fabricant	SOLUSCOPE SAS	
Address / Adresse	100, Rue du Fauge – Z.I. Les Paluds – 13400 AUBAGNE - FRANCE	
Designation / Désignation	SOLUSCOPE SERIE 4 PA	
Product References Références du produit	SL-V4-PA ; SL-V4-SA-PA ; SL-V4-RO-PA	
Classification of the Medical Device Classe du Dispositif Médical	Class IIb Classe IIb	Annex IX, Rule No. 15 Annexe IX, Règle n° 15
Medical Device type Type de Dispositif médical	Washer-disinfector Laveur-désinfecteur	
Scope of Application Domaine d'Application	Flexible endoscope reprocessing, to be used exclusively with SOLUSCOPE CLN and SOLUSCOPE PAA chemicals, according to the user manual Nettoyage et désinfection des endoscopes souples, à utiliser exclusivement avec les produits SOLUSCOPE CLN et SOLUSCOPE PAA, conformément au manuel d'utilisation	
GMDN Code & Term Code & Désignation GMDN	35012	Endoscope washer/disinfector
Quality Management System according to ISO 9001: 2015 EN ISO 13485: 2016	Certificate No. 1789.210122 Certificate No. 2407.210122	Certificate Expiry: September 6, 2021 Certificate Expiry: September 6, 2021
Notified Body - CE Marking Organisme Notifié – Marquage CE	1434	Polish Centre for Testing and Certification
CE Marking Marquage CE	Certificate No. 1434-MDD-141/2020	Certificate Expiry: 06 Sept 2022

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, March 03, 2021

Christian AFFRE  
C.E.O.  
Président


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

# SERIE 4

rapid, reliable, efficient



**Soluscope**

CE  
1434

# SERIE 4



an  
**Intuitive**  
machine



*The power at your fingertips*

#### A NEW GENERATION OF INTERFACE

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

#### A SINGLE BOWL, ANY ENDOSCOPE

The newly designed bowl can house any type and brand of flexible endoscopes, including ultrasound models.

#### STRAIGHTFORWARD MONITORING OF INFORMATION FOR GUARANTEED TRACEABILITY

Embedded traceability system includes barcode reader, printer and local data storage.

#### REDUCED MANIPULATION

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

CE MARK / ISO 15883 - 1&4 compliant



an  
**Integrated**  
concept

*Uniting the most effective systems  
for improved performance*

**A COMPACT AND MOBILE DESIGN**

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

**A RELIABLE AND ROBUST DESIGN**

A double check system with alarm verifies all critical parameters to ensure constant performance. The *Soluscope* continuous leak test prevents endoscope damage.

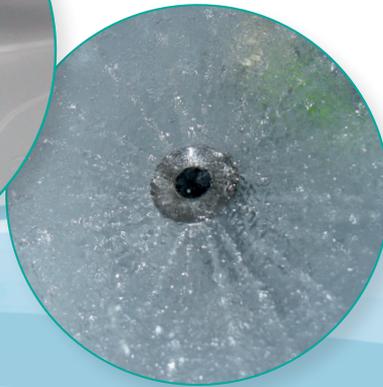


automated endoscope reprocessor



an

# Innovative process



## *Soluscope's cutting edge technology*

### A UNIQUE AND PATENTED DUAL WASH TECHNIQUE

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

### NEW CHEMISTRY

Better results are attained whilst using less water and chemistry. A new all-in-one disinfectant has been developed with improved efficacy to reduce the contact time to 3 minutes.

### GREATER EFFICACY WHILST USING LESS

Being conscious of time, money and the environment, the *Serie 4 PA* reprocesses endoscopes faster at a reduced cost per cycle. Lower chemical and water consumption for reduced global costs.

### ACCURACY AND REPRODUCIBILITY

The patented volumetric channel control monitors each individual channel. The *Serie 4 PA* complies with international standards, and provides safety for the patient, operator and endoscope.



# Chemistry

## THE NEW GENERATION OF CHEMISTRY

Dedicated single shot chemistry delivers proven safety and compatibility with all endoscope brands.

## CONCENTRATED FORMULA HAS BEEN ADAPTED SPECIFICALLY FOR THE SERIE 4 PA

The *Soluscope CLN* cleaner works actively against biofilm and proteins. Does not foam. The all-in-one concentrated peracetic acid based stabilized disinfectant *Soluscope PAA* ensures a High Level Disinfection of your endoscope every time.

## OPTIMIZED CONTACT TIME, TEMPERATURE AND DOSAGE

*Soluscope PAA* has a 3-minute contact time with your endoscope. A minimum chemical dose provided for every cycle at a moderate temperature helps preserving your endoscope.



# Connectors

A unique *Soluscope* offer of compatible connectors is based on over 25 years of collecting data on endoscopes. *Soluscope* connectors are standard use in all our devices.

They ensure an effective, safe and proven link between all *Soluscope* equipment and endoscopes.



# A complete solution to optimize your organization

## TRANSPORT

*Soluscope Trolley* is designed to dispatch endoscopes from treatment to examination room.

The specific trays equipped with transparent lids safely store the endoscopes during transportation.

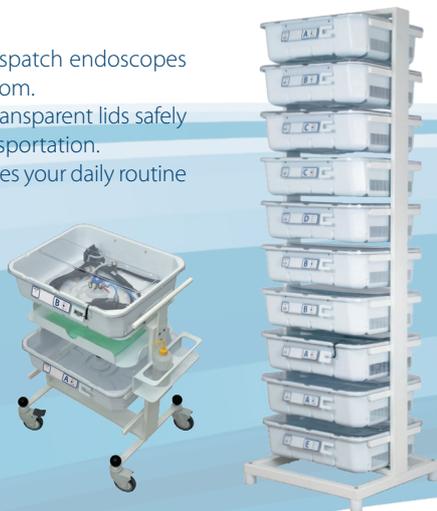
*Soluscope transport solution* facilitates your daily routine in a safe manner.

## STORAGE

*Soluscope Rack* can store up to 10 trays in a reduced space.

## SERVICES

After-sales service, maintenance and training are designed to get the best of your device.



## TECHNICAL SPECIFICATIONS

Capacity per cycle	1 endoscope, processing by flooding-immersion
Reprocessing cycle time	16 minutes (cycle 1)
Reprocessing temperature	35 to 40°C
Contact time / disinfection	3 minutes
Traceability	Barcode reader - Printer - Memory Card - IT Soluscope (option)
Electrical connection	1 x 220-240V with 30 mA differential power breaker
Electrical frequency	50 or 60 Hz
Water input	Tap water
Water pressure	< 4 bars (58 psi) with pressure reducer
Water flow rate	4 L / min minimum
Water hardness	10 to 30 TH (100 to 300 mg / L CaCO <sub>3</sub> )
Water pH	6.5 to 9
Fouling index	< 3
RO water	on request
Dimensions (W x D x H)	63.8 x 122 x 159.2 cm (open lid and drawer) 63.8 x 87.5 x 109.6 cm (closed lid and drawer)
Weight (empty)	107 Kg
Weight (full)	135 Kg

# Data management solution

The *Serie 4 PA* is compatible with the global traceability software solution *IT Soluscope* which provides access to your endoscope data base in real time allowing data management.



Soluscope  
REGISTERED TO ISO  
9001:2015 AND 13485:2016  
FILE NUMBER A14025



## SOLUSCOPE COMPLETE SOLUTION

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*Soluscope* products are compliant with *European and international standards*, and are *CE marked*. *ISO 9001 version 2015 and ISO 13485 version 2016 certified*, *Soluscope* is continuously committed to satisfying its clients' rigorous demands.

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