

What is SOLUSCOPE® 3

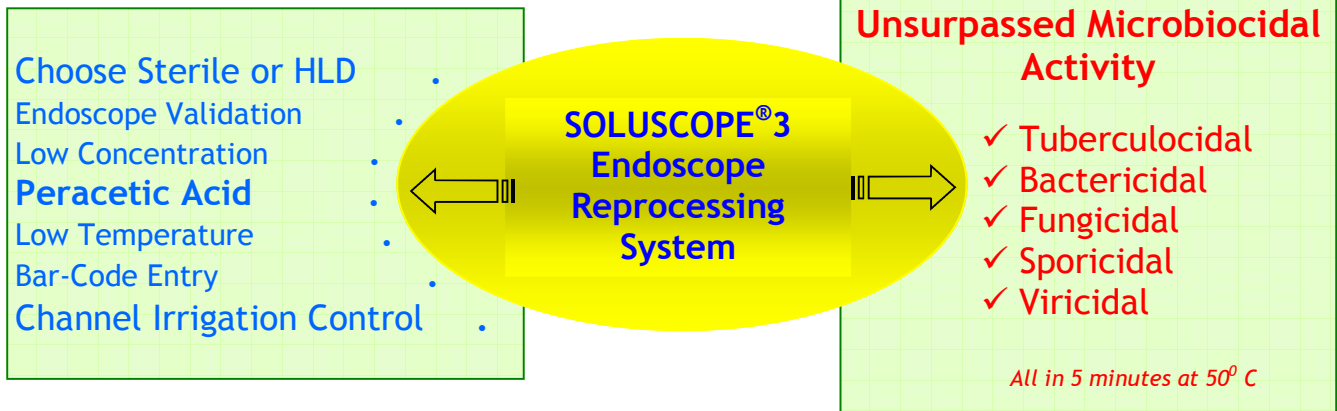
The **SOLUSCOPE 3CC PAA** is not only the pioneering standard for the safe, reliable and hygienic reprocessing of endoscopes, it is also the most effective machine that washes, disinfects / sterilises and dries flexible endoscopes safely after each use, rapidly preparing them for use in the next patient or for storage. The latest reprocessing technology incorporating previous proven and robust engineering from **SOLUSCOPE** Series 2 offers a level of unmatched quality of reprocessing.



THE NEW STANDARD IN REPROCESSING

Soluscope 3 is the latest generation fully automatic endoscopic reprocessor designed to comply with:

- ❖ **The European Standard on washer disinfectors (draft prEN ISO 15888-4)**
- ❖ **The English Health Technical Memorandum HTM 2030**
- ❖ **The new French regulation on prion risk associated with medical devices**
- ❖ **And has Australian TGA Certification for HLD (118778) and STERILIZATION (122580)**



SYSTEM Design & Engineering



At last, **SYSTEM DESIGN** as a concept to eliminate operator error during endoscopic reprocessing. **SOLUSCOPE 3** has been designed to consider the human element so that the same consistent processing steps rigorously and reproducibly carried out by the machine results in a guaranteed **validated process each time, every time**. This reproducible, effective, safe procedure and error monitoring process diminishes the risk of operator error allowing the healthcare worker to focus on their primary objective, **The Patient.**

**EASY ...
 ERROR FREE ...
 OPERATION ...**



From initial hands-free lid operation right through to final product . . .

SOLUSCOPE 3CC PAA is a TGA approved Washer, HLD / Sterilizer able to process up to four flexible endoscopes per hour. After the initial brushing of the endoscopes, all processes associated with washing, disinfecting, alcohol and air drying are conducted in a totally enclosed system without manual intervention.

↩ Here's how it works ↪



Flexibility

The system allows YOU to select between **HLD** or **STERILE** cycles using touch-button controls. Flexible software allows for future changes in regulatory standards should they ever arise.

Decontamination cycles are run when desired.

Water sampling is easily preformed when you nominate.



Lid Design

Simple and elegant, the lid is pneumatically opened using the elbow or back of the hand so that minimal contact is made with the reprocessor, thereby minimising cross-infection potential.



Positive Identification

Optimum traceability is accorded via bar-coded operators and endoscopes that are stored and printed along with each cycle data.



Effortless Tracking System

All data is automatically a printer during the reprocessing cycle. It provides a record of all phases of the **SOLUSCOPE** process, including fault codes, fault errors in the event of cycle failure. Data can also be additionally down-loaded to external PC.



Cycle Verification

The process includes a qualitative chemical indicator that can independently monitor and validate the presence of the active ingredient in **SOLUSCOPE's** chemistry during each cycle



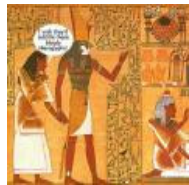


Rapid Turn-around

Cycles are fast and efficient. The extensive cycle programme selection provides you with the fastest reprocessing times of any AER on the market.

Choose from cycles dedicated to:

- Beginning-of-the day **HLD** cycle is completed within 16 minutes and is available for processed endoscopes that have been stored overnight or too long to use within prescribed time intervals according to GENCA Guidelines.
- The standard between-patient **HLD** cycle is completed within 21 minutes.
- The **STERILE** cycle used for bronchoscopes / cystoscopes also takes only 21 minutes.
- End-of-day endoscope cycle (alcohol dry) completed within 23 minutes.



Service cycles

Non-decontamination cycles and service programs are also available. Alcohol dry only, washing only, rinsing only, irrigation flow control mapping and de-scaling are examples of available flexibility for your convenience.



Self-disinfection program

Using the second and different biocide (in this case chlorine tablet), this is under total operator control. Select this option and you can perform this at any convenient time and is completed in 37 minutes. Normally, this cycle is performed at the end-of-day ensuring that the machine and the complete system has been totally decontaminated and is available to you for the beginning of the next list.



Microbiological sampling

You can perform this simple task at a moments notice. Using the automatic sampling device, load it into the system and in less than 5 minutes, the appropriate sample is available for direct testing by the laboratory.



Standards

All programme cycles conform to latest International and Australian Standards and can be reprogrammed for any future development.

Australian Certification for HLD: ATRG 118778
Australian Certification for Sterility: ARTG 122580

Channel Irrigation Flow Control



Flow Control Diagnostics monitors in real time the flow of liquids through the endoscope's channels via flow sensors for each independent channel. It ensures that channels are correctly connected and that no channel is blocked. Continuous flow of liquids ensures that the channels are thoroughly washed, decontaminated,



and flushed and the channels are monitored for flow differentials after every washing, decontamination and rinsing phases. A total of 6 channel irrigation patency tests are carried out on every endoscope, every cycle. If the channel irrigation flow changes during a cycle, the following occurs:

- The reprocessing cycle is interrupted and a message is displayed and printed out warning the user of channel status i.e. blocked or disconnected.
- A decrease in flow indicates that a channel is blocked.
- An increase in flow indicates that the tube has probably not been attached to the endoscope correctly, or has become detached, or there is leakage in the endoscope.
- If an error message is displayed warning that intervention is required by the operator, Soluscope ensures safety by removing all hazardous liquids and then rinsing up to 6 times prior to allowing operator access to the endoscope.

Leak Tester



Permanent Leak Tester

Using its previous proven technology of permanent leak testing, control and monitoring, the system protects your endoscopes from damage and infection control issues.

- Leak tester is automatically activated AND monitored for the entire selected cycle.
- Leak testing must “hold” for 60 seconds prior to any water entering the system.
- The leak tester can detect if the valve on the endoscope has failed to open.
- The leak tester can detect if the leak tester has not been connected.
- The operator is informed of all errors relating to leak testing via audible, displayed and printed messages.

The leak tester thereby identifies potential problems before they are able to cause serious damage to the endoscope. The need for expensive repairs is eliminated by this simple and effective method, since damages due to leakage are the most common cause of costly endoscope repairs.

Endoscope Drying



All air delivered into **SOLUSCOPE** during reprocessing steps or the drying stage, is via an internal air compressor delivering 0.2 micron filtered air.

Normal between-patient drying cycle

Air is pushed through the endoscope channels to deliver a dried, warm endoscope.

For endoscope storage

For the last reprocessing cycle of the day and after preliminary air-drying the endoscope, alcohol is automatically injected into all channels and then additionally





air-dried. Alcohol drying can also be independently requested after a decontamination cycle if a 'scope has not been used.

Endoscope Identification and Documentation



Endoscope recognition is integrated into the **SOLUSCOPE 3**. Each endoscope is bar-coded and is identified at the start of the process by means of a bar-code reader. The operator and the patient can also be additionally identified and a report for each cycle containing all details are printed out or sent to an external computer.

Details on the print-out includes:

- Serial number of the **SOLUSCOPE 3**
- Date and Time
- Name or ID of the person who started the **SOLUSCOPE** cycle
- Type and serial number of the reprocessed endoscope
- All process parameters including:
 - Confirmation of cleaning and biocide injections,
 - Temperature achieved during all phases of the reprocessing,
 - Time of each period of the cycle,
 - Total time taken,
 - Drain times, alcohol injection,
 - Channel irrigation control data,
 - All errors that have occurred,
- AND finally, the report that all reprocessing parameters were correct and that a validated reprocessing result has been achieved.

Rinse Water



Revolutionising decontamination



SOLUSCOPE has been revolutionising decontamination and addressing retro-contamination problems since its conception. During each cycle, PAA is actively purged through the doser to each irrigation channel of the dosing systems and all hydraulic circuitry including the waste drain pipe. Before the end of each cycle, all lines are completely rinsed with filtered water to thoroughly and completely remove all traces of biocide in preparation for the next washing / decontamination cycle.

Three factors come together in ensuring that the chemical and microbial quality of the rinse water does not impair the standard of cleanliness and disinfection of the endoscopes.



- ◆ Just a small concentrations of peracetic acid in the reprocessing cycle has a bacteriocidal effect. Peracetic acid is removed in all rinse phases of the endoscopic reprocessing cycle.
- ◆ Warm water at 45C also exerts a bacteriostatic effect.
- ◆ The use of chlorine for the self-decontamination of the machine system at the end of the day decontaminates all parts of the hydraulic circuit and the capsule water filter.

An effective reduction of water bacteria is achieved and maintained as a direct result of these procedures. Although claimed by many as new and innovative, the use of second biocide, warm water and injecting the biocide onto the final water filter for maintaining bacteriostatic control has long been used and proven in the “previous **SOLUSCOPE 2** Series.



Retro-contamination is effectively banished from modern AER's incorporating **SOLUSCOPE's** design criteria.

Engineering – from Design to Practicality



Using proven and now universally accepted design criteria, **Volumetric Dosage Monitoring, Direct volume control and dual separate higher pressure elevator / auxiliary channel supply**, remains the heart of the system.

Volumetric Dosage Monitoring is critical for “single-shot” chemistries as correct dosage of chemicals is essential in order to achieve the correct concentration of the reprocessing solutions in the AER.

Direct volumetric control guarantees the correct and precise dosage of chemicals and consequently, the correct concentration of the cleaning and disinfection solutions.



Elevator / Auxiliary channel supply for duodenoscopes - Special high-pressure action improves the disinfection of the elevator channel of duodenoscopes

Coupling the volumetric irrigation channel control, leak testing, double monitoring of all parameters makes SOLUSCOPE 3 the most innovative AER in the market.



Easy Installation and cost-saving service solutions

Soluscope 3 is designed for easy installation and service. Following installation, all endoscopes are validated on your AER and logged for future reference. Should future policy dictate reinstallation into new reprocessing rooms, simply unplug, wheel into position and reconnect in new location.



Training Support

We offer comprehensive operator training to ensure that the AER is used to its full potential. Minimising the effect of possible breakdown of your AER comes with the knowledge that factory service technicians are locally available. If required, your technician can also be trained on-site or at the factory further minimising the risk of breakdown.

Service Contracts

Our specialised field service personnel carry out regular and comprehensive testing of your AER. Preventative Maintenance checks are scheduled to ensure maximum availability of the machine and minimises repair costs. The advantages for you are:

- Periodic checks ensure long-term and trouble-free endoscope performance
- Regular professional maintenance and care of instruments saves you money
- Small problems can be identified before they cause major down-time and become major repair costs
- Tips and techniques by experienced service technicians helps the user in becoming familiar with the machine and avoiding potential damage
- Permanent record of all service work is documented and in line with accreditation requirements



Increased Performance down to the last detail



Improved chemicals provide enhanced protection

The new peracetic acid was developed to enhance an efficient process, which offers optimum protection for endoscopy users and service providers. In this process, three new chemicals have been developed which fulfils all the newest European and Australian safety standards. They are easy to use and together with channel irrigation flow control plus bar-coded ID, provides safety to the operator and safety and security to the patient and the Hospital.



Detergent



Peracetic Acid



Activator

- The Biocide is based on peracetic acid (PAA) which works at low concentration, low temperature and low contact time.
- PAA process prevents the formation of biofilms, resulting in increased safety for your patients.
- The characteristics of PAA allow **SOLUSCOPE 3** to be used selectively at 2 different temperatures to obtain HLD or Sterility of flexible endoscopes.
- The Activator solution is buffered in a closed system and injected before the disinfectant to ensure full material compatibility with the endoscope.
- Using process temperatures of 45C or a maximum of 50C considerably reduces the amount of time it takes for the entire reprocessing cycle.
- Fully functional at low temperatures, the PAA process is gentle on your endoscopes.
- A New surfactant-based detergent has been optimised for lower temperatures.
- Soluscope C is an acidic detergent that has been specifically developed to be compatible with both peracetic acid or glutaraldehyde based disinfectants.
- Soluscope C is a bactericidal detergent according to the EN 1040 Standard for its active in-use concentration (0.5%). The test strain organisms *Pseudomonas aeruginosa* and *Staphylococcus aureus* with their log kill reduction results are listed over-page.



Detergent
Soluscope C

Importance of cleaning (manual cleaning with brushing)

No disinfection can be considered adequate without a correct cleaning protocol. Refer to GENCA Endoscopic Cleaning Procedures.

Improper cleaning can easily overwhelm high-level disinfection regardless of subsequent steps. Cleaning is singularly the most critical step and can easily result in a 4 log reduction in microbial contamination or bio-burden.

Since March 2001, the French regulation requires 2 washing steps and successive rinses before the endoscope disinfection, after the first mandatory manual pre-treatment besides the patient's bed.

A good manual cleaning procedure is the only way to limit the biofilm development that can occur between the patient examination and the endoscope disinfection.

The Biofilm

A biofilm may form on any surface exposed to bacteria in an aqueous environment. Only 10% of the natural bacterial population is growing as free cells in suspension ("planktonic cells") in an aqueous medium. Most of bacterial cells are "sessile", i.e. attached to a surface and living within a biofilm. Once bacteria adhere to a surface, cells are able to deeply change their behaviour, building true cells communities well protected behind an excreted slimy coating (the "glycocalyx"). Reducing their exchanges with the outside, these particular cells all together behave as a significantly different organism, and are quite out of reach of disinfectants or antibiotics.

As they are always viable in their planktonic form, sessile cells represent a wide potential source of recontamination when re-dispersed in the environment and are implicated in a significant amount of human infections.

Soluscope C

Soluscope C is an acidic detergent that has been specifically developed to be compatible both with peracetic acid or glutaraldehyde-based disinfectants.

Soluscope C is a bactericidal detergent according to the EN 1040 standard for its active in-use concentration (0.5% v/v) : - **Standards, Strains -Contact time -T° -conditions -Results expressed as log. reduction.**

NF EN 1040 -

Pseudomonas aeruginosa -5 min -20 °C -Distilled water -> **5.32**

Staphylococcus aureus -5 min -20 °C -Distilled water -> **5.18**

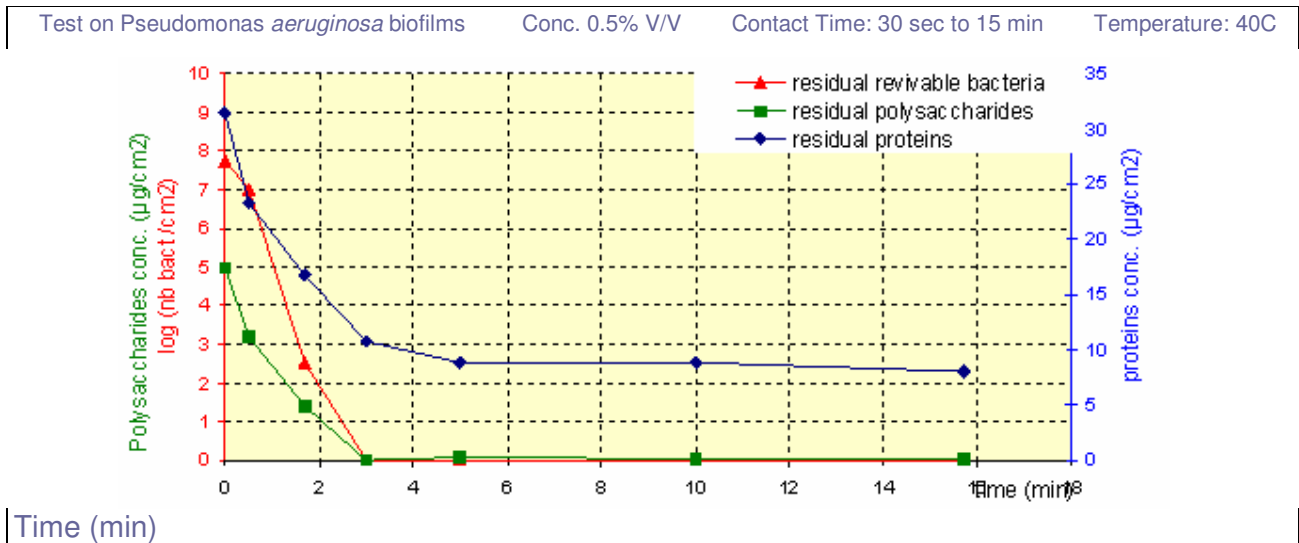
Its singular formulation has been specially tested according to the methodology of the Biotech-Germande laboratory that discriminates between the biocidal efficacy of the detergent (number of viable bacteria) and the cleaning efficacy in terms of organic residuals (proteins and lipopolysaccharides).

Standards, Strains	Contact time	T°	Conditions	Results in log. Reduction
NF EN 1040				
Pseudomonas aeruginosa	5 min	20°C	Distilled water	> 5.32
Staphylococcus aureus	5 min	20°C	Distilled water	> 5.18



The most important function for Soluscope C is its ability to disrupt the biofilm formation, solubilise it and to wash it off. See fig. below:

This test measures the product biocidal efficacy as well as its cleaning efficiency: it quantifies respectively the number of revivable bacteria after cleaning and the reduction of proteins and polysaccharides that are significant of non-revivable bacterial residues.



Its specific formulation has been specially tested according to the methodology of the Biotech-Germade Laboratory that discriminates between the biocidal efficacy of the detergent (number of viable bacteria) and the cleaning efficacy in terms of organic residuals (proteins and lipopolysaccharides).



Peracetic Acid
Soluscope P



Activator
Soluscope A

MEDLORE (Soluscope Company) has marketed a liquid Concentrate such that the PAA (Soluscope P) and the buffering components (Soluscope A) are separated into two containers.

The liquid PAA is stable for 12 months from date of production.

PAA is not a single chemistry as is evidenced by the fact that no two manufacturers produce the same active compound with the same efficacy at the same concentrations and temperature.

Sporicidal efficacy for sterility is achieved in 5 minutes contact time at 1,400ppm and at 50C.

Soluscope is TGA-cleared as a liquid chemical sterilization and HLD processor for medical devices.

The processor automatically dilutes and mixes the concentrates to their final "in-use" neutral concentrations.

In-use concentration of 700ppm PAA at 45°C with a contact time of 5 minutes produces **HLD**.

In-use concentration of 1,400ppm PAA at 50°C with a contact time of 5 minutes produces **STERILITY**.

The total processing cycle including a washing and rinsing phase is approximately 20 minutes and does not exceed temperatures of 50°C during any exposure time. The SOLUSCOPE 3CC using PAA has been available for reprocessing of flexible gastrointestinal endoscopes in Australia since March 2005 and in Europe since March 2003. Instruments processed with 1,400ppm peracetic acid must be handled and stored in a sterile manner upon removal from the SOLUSCOPE 3CC in order to be considered sterile at the point of next use.



Cycle Working Parameters

