

GETINGE

GETINGE POKA-YOKE AER
A SAFER WAY TO REPROCESS
ENDOSCOPES



POKA-YOKE MEANS “ERROR-PROOFING”

As the use of endoscopes increases, so does the frequency of infections linked to endoscope reprocessing.

This is indeed an area where “zero tolerance” towards cross-contamination must be maintained. And at Getinge, we’re convinced that there’s only one way to do this.

Think SYSTEM, not PRODUCT.

And ask yourself: how can our routines ensure that things are always done in the right way? With emphasis on “always”?

The Japanese word poka-yoke stands for a concept aiming to make errors impossible. When we designed our new AER, Automated Endoscope Reprocessor, we applied poka-yoke thinking.

We built it into the product, and into the workflow around the product. We applied a system approach, in the way that we always do at Getinge – the way of thinking that has made us the world leader in disinfection and sterilization.

Let us introduce the Getinge POKA-YOKE AER – a more comprehensive approach to infection control in endoscope reprocessing.



SO, WHAT'S SO SPECIAL ABOUT THE POKA-YOKE AER?

Here's a crash course:



Thanks to the unique lid design, you can have a dirty-to-clean workflow even if your reprocessing room is small. This is important in reducing cross-contamination risks.



Hands-free operation, both on loading and un-loading sides, means that you don't have to touch any panels or buttons with dirty hands. Open the AER with the foot pedal, let the RFID choose the right cycle and the AER starts automatically.



Unique handling of chemicals. The APERLAN disinfectant bottles can only be placed in one way – the right one. The machine will also pierce and inject them, so there's no operator exposure whatsoever.



Optimum traceability is built-in. Thanks to RFID tags, info on operators and endoscopes is automatically stored and printed along with the cycle data. And the Getinge software helps manage all data.



The cycles are fast and efficient for all flexible endoscopes. In fact, no other AER can run such an extensive program, conforming to national and international regulations, so quickly.



To secure maximum infection control, one must consider the whole workflow. That's why we offer not only an endoscope reprocessor, but a complete reprocessing system.



MODERN INFECTION CONTROL – THERE’S ALWAYS TWO SIDES TO IT

DIRTY SIDE

Modern infection control is based on the barrier principle, a clear separation of dirty and clean areas.

However, in a smaller endoscopy clinic, this might be difficult to achieve. Double-door AERs are usually designed for larger departments, with many endoscopes and lots of space.

The two-way lid – a smart solution

The POKA-YOKE AER solves the problem by featuring a lid that allows loading and unloading from opposite sides.



CLEAN SIDE



Manual pre-treatment is performed on the dirty side, drying and storage on the clean side. In this way, disinfected endoscopes never have to be handled in the same area as dirty ones. The design of the AER creates a barrier between dirty and clean areas, reducing the risk of cross-contamination.

On the next page, you'll see an example of how the POKA-YOKE AER functions as the core of a complete hygienic system, ensuring maximum hygiene safety even where space is limited.



A SYSTEM APPROACH BASED ON YOUR EVERYDAY REALITY



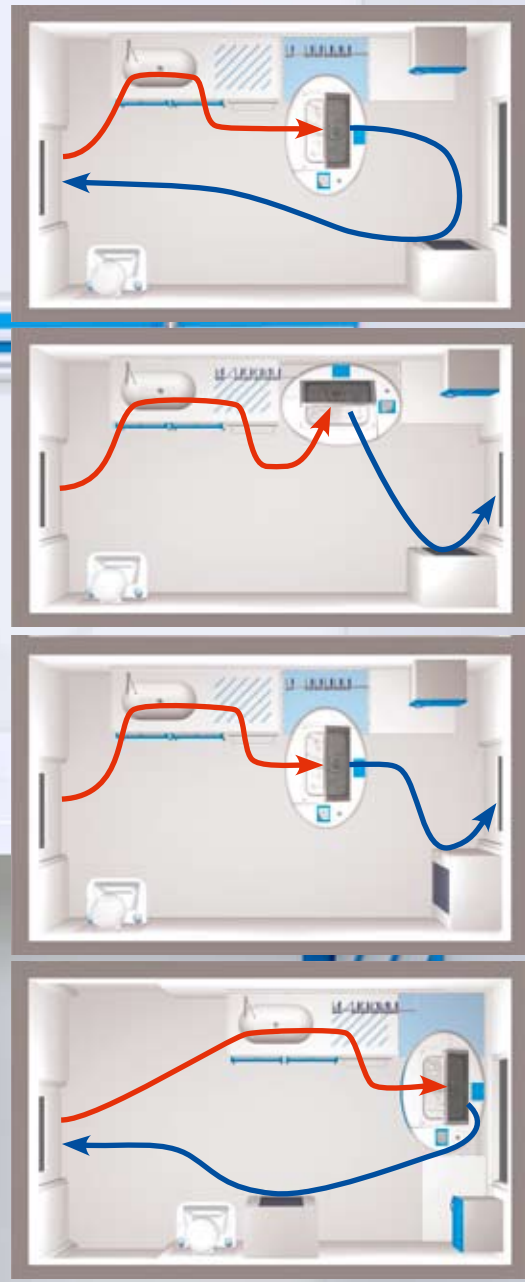
Getinge's world leadership in sterilization and disinfection is based on our extensive knowledge of everyday experience in clinics and hospitals.

As we see it, product excellence is never enough. To ensure maximum infection control, you need to consider the whole workflow. That's why not only do we offer an endoscope reprocessor, but also a complete reprocessing system including accessories which have been carefully thought through to make things both simple and secure.

Manual cleaning

Initial manual cleaning and flushing channels is performed in the procedure room while the endoscope is still connected.

When the endoscope has been brought into the reprocessing room, manual cleaning continues. Here you will need sinks, spray guns, automated water tap, preparation area, shelf for brushes, waste bin etc.



There are various ways of positioning the POKA-YOKE AER in the reprocessing room.

Automated reprocessing

Ideally, the AER is placed out from the wall, by a special wall-mounted work bench to function as a semi-divider of the room. However, there are several options for positioning that enable a hygienic workflow – see examples to the right.

Shelves for endoscope connectors and adaptors and a stand for a flipchart are examples of accessories that are conveniently close to the AER.

Drying and storage

When the reprocessing cycle is completed, the endoscope is unloaded on the clean side.

In this area you may need a storage cabinet for sterile goods, a printer for process data, a wall-mounted work bench for final assembly of the endoscope, and an endoscope storage cabinet.

For details on all accessories, see pages 20-21.

LOAD, START AND UNLOAD WITHOUT TOUCHING

Infection control is about seeing the whole picture, and as far as possible, ensuring the risk of human errors is eliminated.

For example: avoiding the situation where a nurse touches a handle, panel, start-button or barcode reader after holding a dirty endoscope, leaving micro-organisms waiting to be picked up when unloading the clean endoscope?

The answer is: touch-free operation.



The first part is basic: a foot pedal

After the manual pre-cleaning, the operator presses the pedal to open the machine. No need to touch any handles or buttons.

After reprocessing, the lid can only be opened with the pedal on the opposite, clean side – unless the AER has been configured to open towards one side only, which is also possible. (And in which case touch-free handling is even more important!)



Then, the best part: RFID identification and automatic start

When the operator has placed the endoscope into the AER, its RFID tag is automatically identified by the machine's RFID antenna (RFID = Radio-Frequency Identification). The operator also has a RFID tag for automatic user identification.

When the foot pedal is pressed, the POKA-YOKE AER will close the lid and automatically choose the right cycle for the endoscope, based on the RFID tag information, and start.

Smooth, simple and failsafe

This procedure has several benefits.

Firstly, it is easy and saves time for the operator. No data to be entered, just load the endoscope and press the pedal.

Secondly, it reduces the risk of human errors. Only the cycle that is right for the loaded endoscope can be used. The machine cannot be started or unloaded without storing the correct user information.

Thirdly, it reduces the risk of cross-contamination. No buttons to be touched to open or close the lid, select cycle, enter user information, start the machine or unload the clean endoscope.

It couldn't be simpler – or safer.





EVERYTHING DOCUMENTED – WITHOUT YOU HAVING TO LIFT A FINGER

As a clinic using endoscopes, the responsibility is yours to ensure that important procedure data is collected and stored. Therefore, you'll need an AER with a fail-safe traceability system.

Ideally, an AER would collect data automatically and therefore eliminate risks of human error when entering ID information. It would also store all information automatically, in a way that makes it easy to find exactly what you're looking for, should you ever need it. It would keep track of absolutely everything – from cycle numbers, endoscopes, users, surgeons and patient IDs to alarm histories and number of processes per endoscopes.

With an AER like that, you can really relax and focus on providing quality care, spending less on time consuming paperwork. Exactly like you get with the POKA-YOKE AER.



The RFID tags ensure automatic data collection

Both endoscope and operator are automatically identified, so the correct ID information is always collected. The control system records the cycle number, date, endoscope ID, type of cycle, user ID, cycle start and stop time.



LEVEL 1: Poka-Yoke Log saves all data for you

There are three traceability software packages available for you to choose from. The LEVEL 1 package includes Poka-Yoke Log – a Getinge software package for easy storage and management of all data on a PC. All cycle parameters, alarms, endoscope numbers and user IDs are automatically documented. All information is easy to search, read and print!



A compact, easy to load printer is also available where Poka-Yoke Log Software cannot be used. Printer ticket contains traceability information.

LEVEL 2: Patient ID and easy ordering procedures

The LEVEL 2 software package also adds patient ID documentation, which is a legal requirement in many areas of the world. Date, cycle, endoscope, user, alarm number and patient ID can be easily searched directly on the screen of the computer, making things even simpler. In addition, this traceability package supports direct ordering of consumables with pdf order forms that can be automatically generated and sent via fax or internet. You can forget checking stock-levels – the machine takes care of that for you.

LEVEL 3: Extended traceability and E-services

Our top-of-the-range option in the Poka-Yoke software includes all of Levels 1 and 2 and a number of additional features such as extended search functions for cross-searching on all data, surgeon/physician ID and reports on previous/next patient IDs etc. The software provides follow-up reports on the number of processes, number of processes per endoscope, reported errors etc and will notify you when it's time for endoscope maintenance. It will also keep track of when the AER needs preventive maintenance, which then can be automatically ordered and even performed through an online connection. Could it get any easier?

Poka-Yoke software solutions:

	LEVEL 1	LEVEL 2	LEVEL 3
Cycle documentation	✓	✓	✓
Endoscope serial no	✓	✓	✓
RFID tag no	✓	✓	✓
User ID	✓	✓	✓
Screen search for date & cycle	✓	✓	✓
Patient ID		✓	✓
Screen search for endoscope, user, alarm no & patient ID		✓	✓
Automatic ordering of consumables		✓	✓
Patient ID reg. possible with scanner			✓
Extended functions for cross-searching			✓
Surgeon/physician ID			✓
Reports patient IDs			✓
Follow-up reports (processes/scope etc)			✓
Triggers for maintenance of endoscope			✓
Triggers automatic preventive maintenance			✓

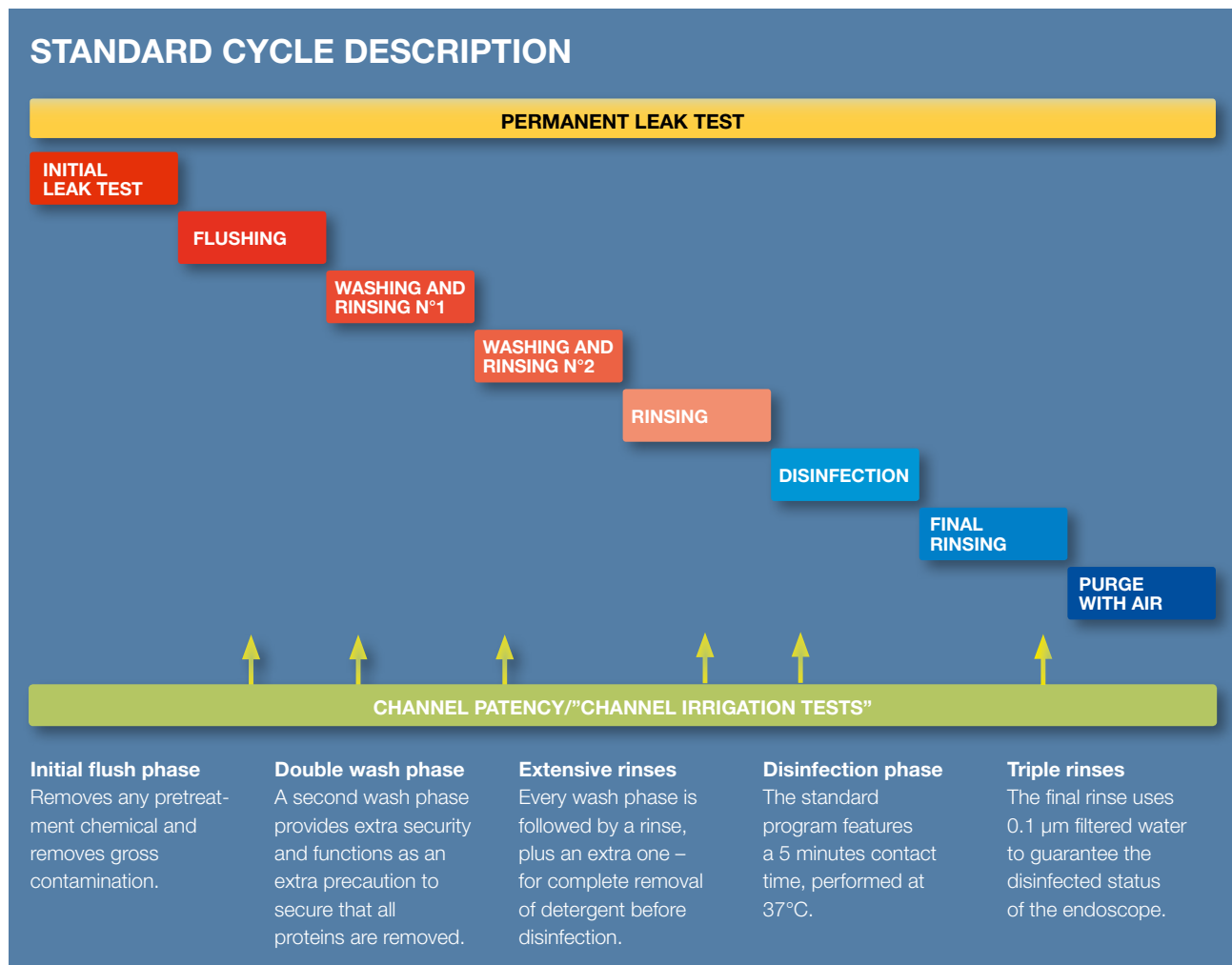
Software solutions under development.

A MORE COMPREHENSIVE PROGRAM – IN A SHORTER TIME

When it comes to endoscope reprocessing, it is better to be on the safe side and take some extra precautions. It's certainly better if the washing/disinfection process sometimes exceeds the need – rather than the other way round.

That's why we think that you will appreciate the comprehensiveness of the POKA-YOKE's standard program. It features double washes, continuous leak tests, five flow tests and three final rinses. It's been designed to meet all regulations, including the ones in countries where demands have increased following the emergence of prion diseases.

No other machine can complete so many phases in such a short time.



Special program for clean endoscopes – saves time

A shorter 15 minute disinfection cycle is available for processed endoscopes that have been stored too long to use without renewed reprocessing. To be used according to local regulations.

Programmable thermal self-disinfection program

The self-disinfection program uses thermal disinfection to reduce risk of cross-contamination. By pre-setting the program for automatic start, you know that the AER is always ready for use the minute you need it.



There are four rotating nozzles to deliver the washing, disinfection and rinse solutions a high pressure in the chamber and on the exterior of the endoscopes.



Every endoscope channel is individually connected to one of the six available internal connections, in order to clean and disinfect the internal channels of the endoscope.



Cycle status and time left – an LED panel gives you information at a glance.



The POKA-YOKE AER features a unique holder, that makes it easier to load the endoscope. By putting some space between the bottom of the chamber and the endoscope, the holder also ensures that the disinfectant comes in contact with all external surfaces of the endoscope.

UNIQUE SAFETY FEATURE: THE CVL-SYSTEM

This is something that no other AER can offer you. It's called CVL (Channel irrigation Verification Library) and it's a bit complicated – but very smart:

1. The first four times an endoscope is reprocessed, the POKA-YOKE AER automatically checks the pressure of each channel six times – and stores the values.
2. These 24 measures mean that every individual channel in the endoscope has its own pattern value for reference.
3. What's more, the AER also has a database with all the preset values for minimum flow that are specified by the manufacturers for different kinds of scopes.
4. During operation, the POKA-YOKE AER automatically compares the flow of each channel of each endoscope with A) the pattern value of the specific endoscope; and B) the required values set by the manufacturer.
5. If there's a significant deviation of the pressure compared to the reference values, the AER notices it. You can set the AER to either just make note of the deviation to assess when going through the reports and to trigger a clear warning so that the cycle can be stopped.

This way, you know that continuous safety is always assured.

The CVL system will warn you if deviation in flow are noticed inside the channels, when an endoscope channel is blocked or disconnected. The CVL functions as a quality assurance, letting you feel confident that everything works as it should on a day-to-day basis.



EASY TO USE WITH ALL KINDS OF FLEXIBLE ENDOSCOPES

Naturally, manufacturers of flexible endoscopes often recommend their preferred brand of AERs. It's understandable that they want to make sure that the function of their products is not compromised by repro-processors whose performance they have no control over.

But let us put it this way: We're not an endoscope manufacturer but Getinge Infection Control Group know a thing or two about safe reprocessing. Being the world leader in disinfection and sterilization, it is even tempting to claim that we know more about it than anyone.

So both you and the manufacturer of your endoscopes can rest assured – whatever the type or brand, the POKA-YOKE AER is tested to provide full compatibility and efficacy.

Tested for all kinds of endoscopes

Getinge POKA-YOKE AER is developed for and extensively tested with all types and brands of flexible endoscopes. It handles scopes for upper and lower GI endoscopy, cystoscopy*, hysteroscopy*, bronchoscopy and rhinolaryngoscopy.

Easy to connect any type of endoscope

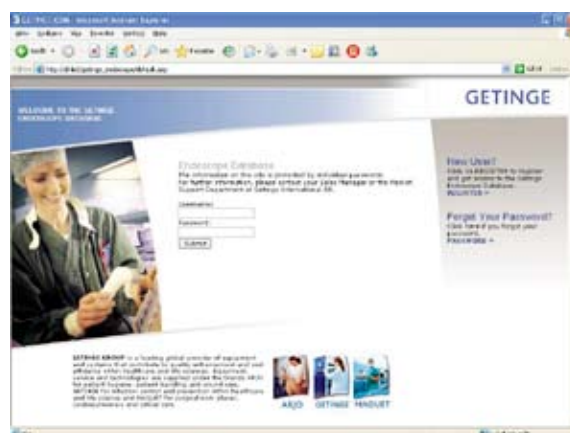
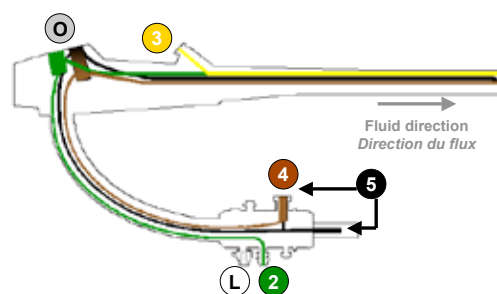
The POKA-YOKE AER identifies the endoscope and displays help for the operator on the screen. Also each tube for the connection of internal channels has a different colour to make correct connection easy.

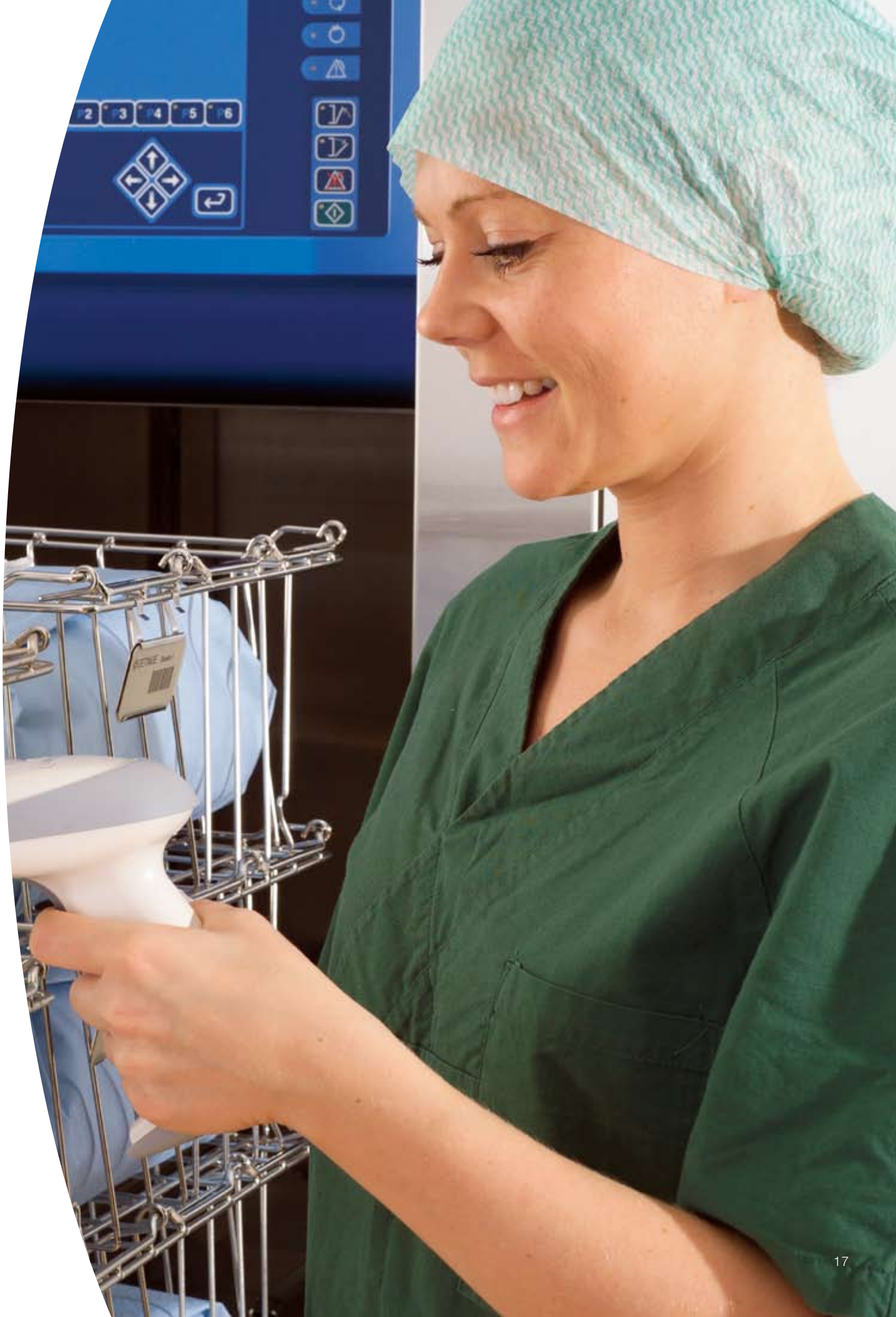
Connector database on the web for POKA-YOKE users

As a POKA-YOKE user, you get access to a dedicated POKA-YOKE customer area through the address www.getingepokayoke.com. Here you will find information about use, technical features and an easy-to-navigate endoscope connection database. This gives you quick and constant access to updated connection information. Customized endoscope connection kits are available for each endoscope model – in visual, easy-to-grasp presentation formats.

* Tested according to local regulations.

Getinge Poka-Yoke family 09 GPY-OLY-F09		
#	Channel function	Reference
2	Suction Channel	GPY-SU-01
3	Biopsy channel	GPY-B-03
4	Water channel	GPY-WA-02
5	Air channel	
L	Leakage test	GPY-L-03
O	Channel separator	LFC-S-01





A SAFER WAY TO HANDLE CHEMICALS

As we see it, the performance of a machine is defined not only by how well it does its job in general, but also by its interaction with the operator.

We want to make every machine as easy and safe to use as possible. This is fundamental to us at Getinge.

When it comes to the POKA-YOKE AER, we made it extra easy to use in everyday work. But we've also simplified changing detergent and disinfectant bottles.

We have made it easier – and much safer. We have made it impossible to make errors – and minimised any exposure to chemicals.

High-efficiency detergent

The Getinge Poka-Yoke DLC is an alkaline type detergent with well-documented efficiency for protein and biofilm removal. The 3 litre bottles last for 30 cycles, allowing about one week operation without need to change the detergent bottle.

APERLAN for best disinfection efficacy

The disinfectant used is the peracetic acid-based APERLAN Poka-Yoke, delivered in two separate 4,5 litre bottles – Agent A and Agent B. The two agents are mixed inside of the machine and last for about 70–80 cycles. The APERLAN is used as single shot, i.e. it is not recycled/reused.

The disinfectant bottles can only be placed in one way – the right way.

Since the bottles of Agent A and B have different shapes, they can only be positioned in the place allocated for them. No room for human errors.

The bottles don't have to be opened

The bottles of Agent A and B are pierced inside the machine. This means that the operator will not be exposed to any possible health-hazardous chemicals. The safety for the operator is increased and there are no chemical fumes in the reprocessing room.

Warning when bottle levels are low

The level of detergent and disinfectant is constantly monitored by the control system and can be displayed on the operator screen. The system warns if levels are low – no risk of running out of chemicals during a cycle.



The POKA-YOKE AER features a built-in storage space for the detergent and the disinfectant bottles.

The large double door makes it easy to access the bottles and replace them.



ACCESSORIES FOR A FULLY EQUIPPED REPROCESSING ROOM

Getinge offers everything you need to ensure the best possible hygienic workflow in your reprocessing room. Here are examples of the accessories available. For more information and layout suggestions for your reprocessing room, please visit www.getingepokayoke.com.



1. Pre-treatment unit

For manual pre-treatment of endoscopes before the process. Made of gentle composite material.



2. Chemical storage trolley

For storage of 2+2 disinfectant bottles and 3 DLC-detergent bottles. The trolley is also lockable to the pre-treatment unit for safe storage.



3. Waste trolley

For general waste such as gloves, brushes etc, this trolley is positioned under the pre-treatment unit for easy access. Foot-pedal opening.



4. U-shaped transfer table

Serves as a barrier between the dirty and clean sides. It has the same shape as the Poka-Yoke AER and is made of gentle composite material.



5. Wall rail

Made of sturdy extruded aluminium, the wall-rail serves as a multi-purpose holder. Can be used to hold/conceal wiring, cords etc.

6. Chart holder

Mounted on the wall-rail, the swivel chart holder keeps instructions for use/manual pre-cleaning etc close at hand.



7. Connector holder system

Also mounted on the wall-rail, the connector holder transfers clean connectors back to the dirty side for storage and re-use. The connectors are safely and hygienically transferred in a practical disposable plastic bag.



8. Printer holder

The printer holder gives easy access to print-outs once the process is finished. Mounted on the wall-rail.



9. Clean table

The clean table serves as a worktop for assembly of processed flexible endoscopes. Made of gentle composite material.

EASY INSTALLATION AND COST-SAVING SERVICE SOLUTIONS



The Getinge POKA-YOKE AER is designed to be very easy to install and service. Putting it in place and connecting to water, drain and electricity is quick and easy.

Choice of unloading mode can be made at installation, by selection in the software for either same-side unloading or opposite side unloading. This setting can also be easily changed later, for example if a new reprocessing room layout will allow the dirty-to-clean workflow that wasn't possible at installation.



All the training support you may need

We offer operator training to ensure that the AER can be optimally utilized to its full potential. To prevent breakdowns and minimize the risk for undesired downtime, there is also training available for your technician at the unit. The training sessions can be held either at your facility or at the Lancer/Getinge Academy.

Preventive maintenance and validation packages

We also offer a range of preventive maintenance service contracts as well as validation and training packages which can be tailored to your own requirements:

- Installation to agreed services
- Commissioning
- Installation & Operational Testing (IOT) validation to EN ISO 15883-1
- Performance Qualification (PQ) validation testing to EN ISO 15883-1
- Servicing and service contracts
- Quarterly testing to EN ISO 15883-1
- Annual revalidation testing to EN ISO 15883-1
- Revalidation to EN ISO 15883-1
- Repeat validation to EN ISO 15883-1



CONFORMS TO ALL NORMS AND STANDARDS – AND

Manufactured to the highest standards

Thorough experience and well-established expertise are prerequisites for reliable production of AERs. The Getinge POKA-YOKE AER is manufactured at our Centre of Excellence for endoscope reprocessing in Toulouse, France, which has been manufacturing automated endoscope reprocessors since 1993. The new assembly line for the POKA-YOKE AER has been built according to lean manufacturing principles.

Proven, scientifically tested technology

The POKA-YOKE includes proven, scientifically tested technology on endoscope channel irrigation systems/alarms, regulation and monitoring of cycle parameters, chemical combination efficacy/compatibility – and much more.

Getinge POKA-YOKE AER conforms to the following norms among others:

- European Machine and Medical Device directives
- EN ISO 15883-1
- PrEN ISO 15883-4
- HTM2030, C32 (UK)
- DGS 138, Guide CTIN 11/2003 (France).

Endoscope compatibility testing

The Biotech-Germande laboratory conducted during 2004 an extensive testing of endoscope compatibility, where endoscope materials and parts were exposed to the maximum dosing of disinfectant possible in the POKA-YOKE AER and showed no deterioration.

Endoscope connection

All different connection kits and methods for every endoscope brand and model have been listed and successfully tested.

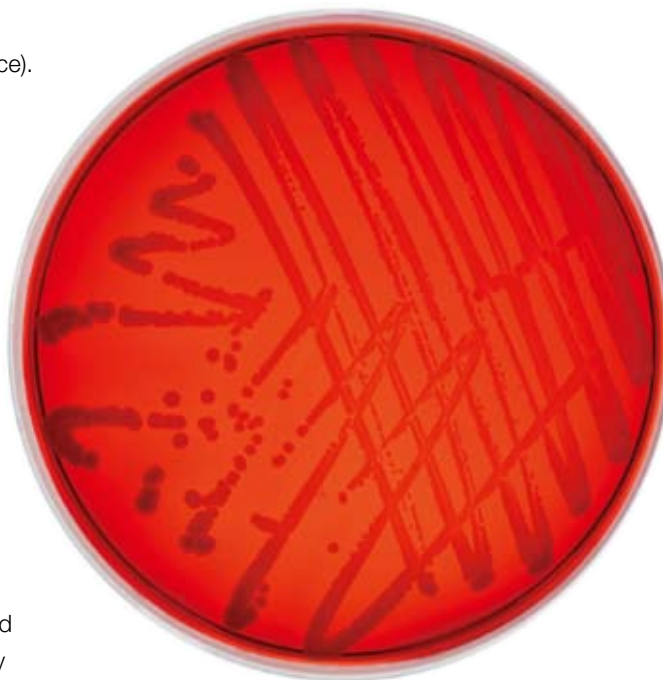
Scientific efficacy testing

These tests were also performed by the Biotech-Germande laboratory. The tests included:

- Biocidal activity of the APERLAN Poka-Yoke
- Bactericidal, fungicidal, mycobactericidal, virucidal, sporicidal according to EN standards on disinfectants
- Bactericidal and sporicidal activity of the disinfectant according to EN ISO 15883-4
- Cleaning efficacy tests according to EN ISO 15883-4
- Endoscope disinfection cycle efficacy tests according to EN ISO 15883-4
- Self disinfection cycle efficacy tests according to EN ISO 15883-4 (including water treatment unit)

Functional testing

The Getinge POKA-YOKE AER has also been through many factory validation tests. Seven prototypes have been tested, as well as the first serial units.



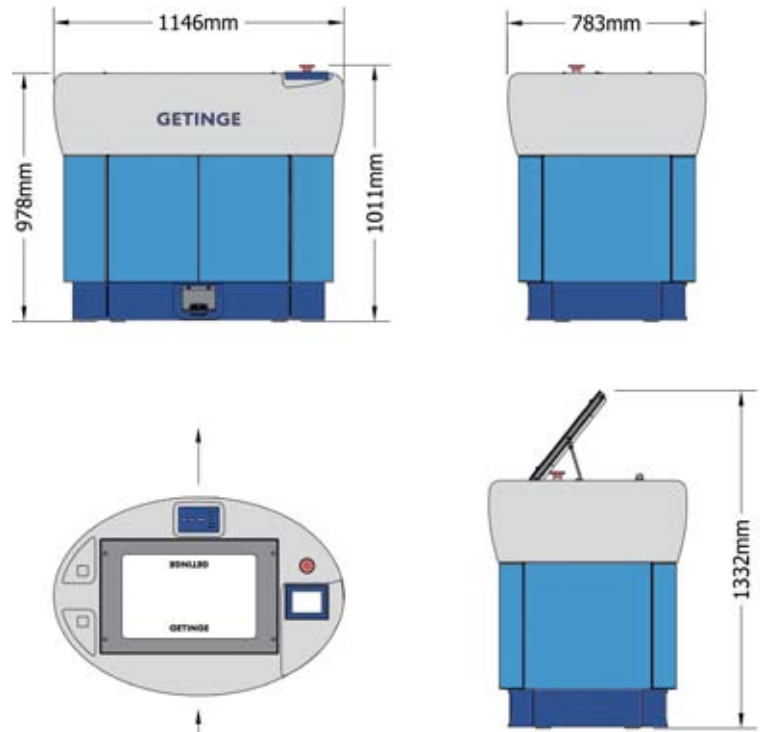
THOROUGHLY TESTED IN EVERY WAY



Our Centre of Excellence for endoscope reprocessing in Toulouse, France.



TECHNICAL DATA



GETINGE POKA-YOKE AER:

✓=standard O=Optional

GENERAL FEATURES:		CONNECTION OF UTILITIES/DEMAND	
Number of endoscopes:	1	Electrical connections	230V +/-10%
Compatibility to all endoscopes according to EN ISO 15883-1 and prEN ISO 15883-4	✓	Electrical consumption	26A/ph
Blue-tinted glass lid, can open to both sides	✓	Water supply	To national guidelines and requirements. Minimum softened water <7 DH.
SPRAYING- & CVL SYSTEM		Incoming water filter 0,1 µm	✓
4 rotating nozzles 360°	✓	Water consumption per cycle phase:	3.25 litres
6 internal channel connections, colour coded	✓	HEPA filter for incoming air	✓
CVL system	✓	Weight	150 kgs
MACHINE DISINFECTION		CONTROL/VALIDATION/TRACEABILITY	
Thermal disinfection cycle	✓	Industrial PLC system (Programmable Logic Controller)	✓
ENDOSCOPE DISINFECTION CYCLES		Printer	✓
Permanent leak test	✓	Program for identification of endoscopes and CVL identification	✓
Max number of channel irrigation tests during full cycle	6	RFID identification of endoscope	✓
Working temperature	37°C	RFID identification of user	✓
Automatic mixing of disinfectant inside machine	✓	Automatic dosing of detergent	✓
Standard time of contact with disinfectant	5 min	Automatic dosing of disinfectant	✓
Adjustable final air blowing time	✓	Independent cycle parameters monitoring system	✓
CONSUMABLES		Cycle documentation system	under development
Disinfectant Aerialan Poka-Yoke, Agent A	4,5 litres, box of 2 bottles	Ethernet, IP address for Remote	✓
Disinfectant Aerialan Poka-Yoke, Agent B	4,5 litres, box of 2 bottles	DELIVERABLES	
Detergent Getinge Poka-Yoke DLC	3 litres, box of 1 bottle	Endoscope RFID-tags	3 pcs
		User RFID-tags	2 pcs
		Machine disinfection-tag Ao 600	✓
		Machine disinfection-tag Ao 3000	✓
		User manual	✓
		Service manual	✓



Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.

GETINGE

Getinge Infection Control
PO Box 69, SE-310 44 Getinge, Sweden
Phone: +46 35 15 55 00
Fax: +46 35 18 14 50
info@getinge.com www.getinge.com

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