

7 Maintenance and cleaning

The Germlyser® G requires no maintenance within the specified operating time. The outside of the filter can be cleaned using common surface disinfectants.

When replacing the Germlyser® G, a small amount of unfiltered water will flow out. Over time, this will lead to deposits on and in the adapters. Aqua free recommends replacement of the adapters after a period of use every 6 to 12 months.

In the case of a deviation from the specifications or a damage to the packaging, the product should be returned to Aqua free, along with a Defect Report (form available to download on the service page of the Aqua free website www.aqua-free.com).

8 Storage

The Germlyser® filter must be properly stored in a dry and hygienic environment at a temperature between 10 and 50°C.

9 Return

The Germlyser® reusable filters must be sent back to Aqua free within the agreed time for reprocessing (form downloads at the service page under www.aqua-free.com).

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Instructions for use

Germlyser® G



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1 Product

1.1 Product description

The Germlyser® G is a CE-marked, point-of-use, sterile filter for manual final rinsing of endoscopes to prevent bacterial nosocomial infectious diseases caused by *Pseudomonas aeruginosa*, *Legionella pneumophila*, *Stenotrophomonas maltophilia* or *Staphylococcus aureus* among immunosuppressed and immunocompromised patients. To achieve this intended use, a specific combination of retention of these bacteria in the filter membrane structure and specific measurements to prevent retrograde contamination with these bacteria on the filter outlet, are necessary.

1.2 Technical data

Size:	L 77 mm x Ø 55 mm	Flow rate:	Adjustable up to 6 l/min at 5 bar, at 25°C
Retention*:	7 log steps <i>Brev. dim.</i>	Max. operating pressure****:	5 bar at 60°C
Pore size:	0.2 µm	Max. operating temperature:	60°C (at 70°C < 10 min. over operating time)
Operating time**:	4 weeks	Connection:	Quick-release coupling
Chlorine resistance***:	<10 ppm		

* Measured in accordance with the international ASTM F838-15a standard - Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration

** The operating time can be increased up to 8 weeks if sufficient hygienic measures exist and an adequate hygiene plan is carried out. We recommend monitoring by appropriate clinical microbiological testing.

*** Continuous dosage of ≤ 10 ppm over operating time; short-term (1h) high dosage (400,000 ppm) for chemical disinfection.

**** The Germlyser® G is not suitable for connection to low-pressure systems (e.g. boilers)

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1.3 Scope of delivery

- Germlyser® G
- Transport box
- Cable tie for product return and box fastener
- Zip lock bag for used filter
- Information material, sticker for filter

1.4 Reprocessing

The Germlyser® G is a high-quality, reusable **CE**-labelled medical device that is made available to the customer at a fixed rental rate. Reprocessing is carried out exclusively by Aqua free.

2 Certificates / Declaration of conformity

The company Aqua free GmbH is certified according to DIN EN ISO 13485. The Germlyser® filters are **CE**-labelled medical devices.

**Extract from the declaration of conformity
Aqua free GmbH, Winsberg 31, DE-22525 Hamburg:**

The manufacturer declares for the product Germlyser® G to Annex IX of the directive 93/42 EWG on medical devices and medical products of Class I the conformity with the basic requirements of Annex I of the council directive 97/42 EEC of the European communities.

3 Labelling



Manufacturer label



Individual product label



D/GB Product information material



Medical device label



Do not use if package is damaged



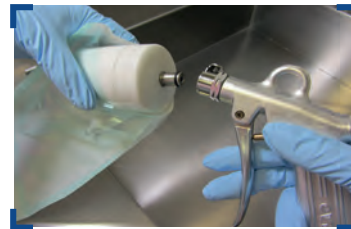
Non-sterile

4 Preparation of commissioning and use of product

Please disinfect your hands and wear disposable gloves during filter installation

4.1 Filter installation on spray-pistol

- Open the packaging on the adapter side of the filter
- Wet the seal with a commercial disinfectant (for easy and safe installation)
- Leave the filter in its packaging and insert it into the quick-release coupling of the spray-pistol with a slight turning movement until the filter audibly engages
- Align the filter and remove packaging
- Open water supply and test the leak tightness of installation and the water flow

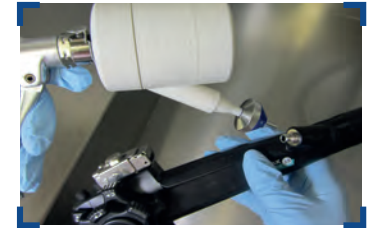


4.2 Filter replacement documentation

- Note the date of next filter replacement on the sticker and place it on the filter in an easily visible position – but **not** on the barcode

4.3 Filter handling

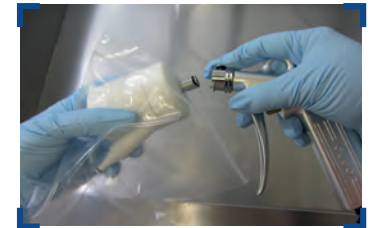
- Hold the filter outlet for flushing into the endoscope channel, use appropriate purging accessories
- Do not submerge the filter into the wash water and avoid contamination by splashing
- Daily, wipe down the filter outlet with a common surface disinfectant



5 Removal of used filter / filter change

Please disinfect your hands and wear disposable gloves during filter installation

- Place zip lock bag over the filter, loosen the coupling and pull off the filter
- Place the filter into the provided transport box
- Equip the transport box with protective foil for safe transport
- Close transport box with cable ties
- Install a new filter (see point 4)



6 Accessories for Germlyser® G

- Spray-pistol with integrated quick-release-coupling and hose of 2 m length
Item No.: 100233
- Extension hose with integrated quick-release coupling, 1.5 m length
Item No.: 100363
- Purge for endoscope channels with Luer-lock
Item No.: 100360
- Purge for endoscope channels
Item No.: 100361