

7 Maintenance and cleaning

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

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.

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Instructions for use

Baclyser® ENT



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1 Product

1.1 Product description

The Baclyser® ENT is a CE-marked, inline sterile tap filter* for use between ENT handles and the nozzle attachment to prevent bacterial nosocomial infectious diseases caused by *Pseudomonas aeruginosa*, *Legionella pneumophila*, *Stenotrophomonas maltophilia* or *Staphylococcus aureus* among immunosuppressed and immunocompromised patients.

1.2 Technical data

Size:	L 56 mm x Ø 18 mm	Minimum flowrate:	0.5 l/min at 5 bar, at 25°C
Retention:	7 log steps <i>Brev. dim.</i>	Max. operating pressure:	5 bar at 50°C
Pore size:	0.2 µm	Max. operating temperature:	50°C
Operating time:	4 weeks	Connection:	Luer-Lock
Chlorine resistance*:	≤10 ppm		

1.3 Scope of delivery

- Baclyser® ENT
- 2 Combi Stopper sealing cones
- User instructions

* Sterile filtration: Pathogen retention $\geq 10^7$ *B. diminuta* CFU/cm² filter membrane surface (= 7 log steps).

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

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1.4 Reprocessing

The Baclyser® ENT is a high-quality, CE-labelled single use medical device which can be disposed of with normal recycling waste (plastic).

2 Certificates / Declaration of conformity

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

Extract from the declaration of conformity
Aqua free GmbH, Winsbergring 31, 22525 Hamburg:

The manufacturer declares that its product Baclyser® ENT is a Class I medical device in accordance with point (60) of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of April 5, 2017 on medical devices and Annex VIII to that Regulation.

3 Labelling



Manufacturer label



Individual disposable product label



D/GB Product information material



Medical device label



Do not use if package is damaged

4 Preparation of commissioning and use of product

Please disinfect your hands and wear disposable gloves during filter installation

4.1 Filter installation

- Open the packaging to expose the inlet of the filter
- Leave the filter in its packaging and attach the filter inlet, with a slight twist, to the ENT-water pistol.
- Remove packaging



- Insert the nozzle connection onto the filter outlet with a light twist
- Use only reprocessed nozzles to avoid retrograde contamination



4.2 Filter replacement documentation

- Document the installation date and, with reference to the specified operating time, the next change date

4.3 Cleaning & Handling after use

- Remove the nozzle after treating each patient (after each ear)
- Immediately position the water-pistol with the filter outlet pointing downwards and rinse for some seconds with water
- Attach a new nozzle (reprocessed) to the filter outlet
- Alternatively, for storage (e.g. overnight) seal the filter outlet with a Combi-stopper closing cone



5 Removal of used filter / filter change

Please disinfect your hands and wear disposable gloves before installing the filter

- At the end of the operating time of 4 weeks, dismantle and dispose of the used filter
- Install a new filter (see point 4)

6 Accessories for Baclyser® ENT

- Filter Baclyser® ENT, PU: 1 piece
Item No.: 103574
- Combi-stopper closing cone, PU: 10 pieces
Item No.: 100132
- Short nozzle for ENT-water pistols, extra short (5 cm)
Item No.: 100351
- Splash guard for ENT nozzle, clear
Item No.: 100362