

## Instruction for Use

# ALPRO-BCS Procedural Water Supply System

Independent procedural water supply system for medical and dental treatment devices acc. to standards EN 1717/DIN 1988-100 (protection of the drinking water line)



## EU DECLARATION OF CONFORMITY

Name and address of the manufacturer:

**ALPRO MEDICAL GMBH**  
Mooswiesenstr. 9, 78112 St. Georgen • GERMANY

SRN: DE-MF-000010603

Name of the product:

**ALPRO-BCS (BottleCareSystem)**

REF: REF 8750; included in REF 8757

Basic UDI-DI: ++E25101875000D2

EMDN / CND Code: Z12110180 - INSTRUMENTS FOR DENTAL TREATMENT UNITS - HARDWARE

GMDN Code: n/a

Intended purpose of the product:

Procedural water supply system for medical and dental units.

Risk class of the product: I

Classification rule: 1

Marking of the product:



ALPRO MEDICAL GMBH is manufacturer of the above-mentioned medical device and declares under sole responsibility that this medical device complies with the general safety and performance requirements of Regulation (EU) 2017/745 and that a complete documentation is available.

Applied common specifications: n/a

Conformity assessment procedure:

According to Regulation (EU) 2017/745, Annex IV

The quality assurance system of ALPRO MEDICAL GMBH is certified according to DIN EN ISO 13485:2016.

This declaration of conformity is valid until: 2024-12-31



St. Georgen, 03.01.2022

  
Gerold Reich  
Quality Manager



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## 1. User instructions

Please attend to the following instructions in order to guarantee a trouble-free, economic and safe work.

These instructions for use must always be available in the area of the unit. It must be read and applied by every person who is assigned to work (installation, operation or maintenance) on the unit.

## 2. Symbols used on the product information, labels and instructions for use

	consult instruction for use
	caution, safety-related information
	use-by-date (best before date) YYYY-MM
	batch code XXXXXX (6-digits)
	catalogue number
	serial number
	EEC symbol for finished packs
	Health Industry Bar Code
	CE symbol for medical devices of class I
	CE symbol with identification number of the Notified Body (0123) for medical devices of class IIa, IIb or III
	keep away from sunlight
	spray-cooling
	date of manufacture
	manufacturer, company ALPRO MEDICAL GMBH, St. Georgen
	company logo of ALPRO MEDICAL GMBH, St. Georgen



### 3. Target group

These instructions for use are intended for all users (doctors, dentists and the specialist staff responsible for reprocessing medical devices as well as hygiene specialists) in medical and dental clinics.

### 4. General information on ALPRO-BCS

Set for the procedural water supply system for medical and dental treatment units. The ALPRO-BCS provides an independent water supply of medical and dental treatment devices according to the standards EN 1717/DIN 1988-100 (protection of the drinking water line).

**ALPRO-BCS housing with bottle holder, pressure regulator, air valve with bottle and media hoses (pre-assembled)**



The unit may only be installed by a technician and operated by instructed and trained personnel.

The ALPRO-BCS may only be operated within the specified pressure limits (operating air pressure:  $\leq 3.5$  bar).

Before installing the ALPRO-BCS, a basic cleaning should be carried out with the Biofilm-Removing-Set (BRS®).

For refitting of any treatment unit.

## Field of Application of ALPRO Products with ALPRO-BCS

- Before installing the ALPRO-BCS, a basic cleaning should be carried out with the Biofilm-Removing-Set BRS® (see p. 8)
- Procedural water disinfection with Alpron (see p. 12) or Bilpron (see p. 14)
- Reprocessing the ALPRO-BCS pressure bottle with BC-San 100 (see p. 16)
- Maintenance of the ALPRO-BCS (see p. 18)

## Decontamination of procedural water with Alpron/Bilpron

Bilpron may only be used in suitable equipment and must be rinsed out of the lines after the intended contact time!

- for use on patients, drinking water can be mixed with 1 % Alpron concentrate
- preservation during break times (week-ends, holidays) with Bilpron
- a disinfection of the water lines can be carried out weekly or during rest/break periods (at least 12 hours) or vacation times with Bilpron
- prevention of biofilm formation
- protection against limescale
- no clogging of the instrument tubes and transmission instruments by biofilm or lime
- reduction of repair costs
- increase of functional reliability
- constant quantity of spray water

## Shelf life

The ALPRO-BCS pressure bottle has a shelf life of 9 months. It must be replaced after the expiry date.

## Delivery forms

### REF 8757 ALPRO-BCS StarterSet

- ALPRO-BCS housing
- metal housing upper part with pressure bottle holder and tube connections (completely assembled) for procedural water, 6 mm Ø outside diameter (transparent) and for pressurized air entry 4 mm Ø outside diameter (blue)
- air pressure regulator (preset at 3 bar)
- air valve control (swivelling)
- 2 x ALPRO-BCS pressure bottle, 1.5 L
- riser tube with drip stop
- connection set (to fix the metal housing upper part)
- mounting plate
- 1 L Bilpron
- 10 g BRS® PreCleaner
- 160 g BRS® Remover
- 20 ml BRS® Activator
- instructions for use (BRS® and ALPRO-BCS)
- installation manual ALPRO-BCS
- handover certificate/passport of the device
- 50 ml Alpron sample bottle
- 100 ml BC-San 100
- record of the device



## Approvals\* the following products

\*Tested by well-known dental equipment manufacturers.

Various material and practical tests from well-known dental equipment manufacturers on request



## Accessories

**REF 8775** ALPRO-BCS pressure bottle (1.5 L with riser tube)

**REF 3213** Biofilm-Removing StarterSet\*

- 1 L Bilpron
- 10 g BRS® PreCleaner
- 160 g BRS® Remover
- 20 ml BRS® Activator



**REF 3212** Biofilm-Removing TechnicianSet\*

- 10 x 10 g BRS® PreCleaner
- 10 x 160 g BRS® Remover
- 10 x 20 ml BRS® Activator
- 8 x 1 L Bilpron



**REF 3215** BRS® (Biofilm-Removing-Set)\*

- 12 x 10 g BRS® PreCleaner
- 12 x 160 g BRS® Remover
- 12 x 20 ml BRS® Activator



Application only by qualified medical personnel.

All components\*\* are covered by a warranty of 12 months.

\*\* Pressure bottle and consumables are excluded.

## 5. Basic cleaning with BRS® before installation

(to be carried out only by trained technical staff)

The Biofilm-Removing-Set (BRS®) is used to remove the biofilm in the water lines of the treatment unit.

An application is required for treatment units that have been in operation for more than one year at the time of installation of the ALPRO-BCS (BottleCareSystem) and must be performed by a service technician.

The Biofilm-Removing-Set includes detailed instructions explaining the application step by step.

This action may only be carried out by appropriately trained dental equipment technicians in compliance with the applicable regulations on electrical safety and the drinking water regulations.

**Regulation (EU) 2017/745 Annex I; para. 14.1.**

**If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices.**

**REF 3212** Biofilm-Removing TechnicianSet

can only be obtained through your service technician

- 10 x 10 g BRS® PreCleaner
- 10 x 160 g BRS® Remover
- 10 x 20 ml BRS® Activator
- 8 x 1 L Bilpron



**REF 8593** ALPRO-BRS®-reciprocating plunger type pump

can only be obtained through your service technician

## 6. Operation

1. Fill the included pressure bottle (1.5 l) with drinking water only (according to local drinking water requirements). If necessary install a bacteria filter at the water intake point. It is recommended, in order to maintain the water quality, that an adequate decontamination agent (e. g. Alpron 1 %) is added to the pressure bottle filled with drinking water.
2. Screw the filled pressure bottle into the bottle holder of the ALPRO-BCS.
3. Set the rocker arm at the outside of the ALPRO-BCS to position „I“ = **On**. The pressure bottle is audibly charged with compressed air.
4. As soon as an outlet is “pulled” (e. g. instrument tube) and the foot switch pressed, the procedural water flows from the ALPRO-BCS pressure bottle into the “pulled” instrument tube.
5. When the BCS bottle has to be filled again, **release the BCS bottle in pressurized condition** until you hear air escaping.  
  
**Please note:** This process may be carried out under pressure without any risk, a special forced venting is integrated in the ALPRO-BCS (BottleCareSystem). Then set the **rocker arm** (see point 3) to position „0“ = **OFF**, see SOP.
6. Fill and screw in the ALPRO-BCS pressure bottle (as described under points 1 - 3).
7. To prevent a recontamination during off-time periods (weekends or holidays), we recommend flushing all water lines with Bilpron via the included spare ALPRO-BCS pressure bottle as “break time disinfection”. The empty ALPRO-BCS pressure bottles must be disinfected once a week (e. g. over the weekend) with BC-San 100.





## 7. Product information Alpron

Decontamination of procedural water

**Liquid concentrate for the continuous maintenance of the water quality in procedural water lines (including instruments and tumbler filler) of medical and dental units.**

- concentrate applied at 1% for conservation
- prevents the regrowth of germs
- removes and prevents the formation of algae
- prevents the sedimentation of lime and deposits
- non-corrosive

### Composition

Phenoxyethanol, PHMB (biguanide), EDTA, sodium tosylchloramide  
Contains a source of phenylalanine.

### Efficacy

- bactericidal (EN 13623, test organisms: *klebsiella pneumoniae*, *pseudomonas aeruginosa*) 10 % in 12 hours (disinfection)
- conservation (EuAB 5.1.3, test organisms: *Burkholderia cepacia*, *Enterococcus faecium*, *Legionella pneumophila*, *Pseudomonas aeruginosa*) 1 % for 28 days

### Application

1%

### Expert opinion

HygCen Germany GmbH:

- cytotoxicity test  
DIN EN ISO 10993-5, 2012-11

Dr. Brill + Partner GmbH:

- disinfection EN 13623, 2019-10
- conservation EuAB 5.1.3, 2020-01

Overall expert opinion:

Prof. Dr. rer. nat. Dr. med. habil. Friedrich von Rheinbaben:

- phys. + ecol. compatibility, 2023-02

In special cases expert opinions and approvals may be requested from us.

### Field of Application

Alpron is a concentrate for the continuous decontamination of procedural water and water lines (including instrument tubes and tumbler filler) in all dental units.

### Shelf Life

2 years

### Environment

The contained tensides are biodegradable according to OECD.

The ready-to-use solution is ecologically harmless and completely biodegradable.

### Material compatibility

Very gentle on the material.



## Dosage

### Application with internal disinfection device:

Fill container with undiluted Alpron and ask your service engineer to adjust the disinfection device according to the manufacturer's dilution instruction. (standard = 1%).

### Application with external procedural water supply:

To use an external water supply bottle (e. g. ALPRO-BCS), mix Alpron 1 % (Ratio: 10 ml Alpron and 990 ml drinking water) and connect it to the treatment unit. In case of dosing devices standing aside ask your service engineer to carry out the adjustment.

**Application only by qualified medical personnel with protective clothing.**

## Approvals

Tested by well-known dental equipment manufacturers.

Various material and practical tests from well-known dental equipment manufacturers on request

## Delivery Forms

REF 3183      1 L bottle



CE 0123

## 8. Product information Bilpron

Decontamination of procedural water

### **Solution ready for use for the decontamination and prevention of biofilm formation in procedural water lines of medical and dental units.**

- removes safely and reliably organic as well as inorganic residues such as limestone
- effective against a broad spectrum of germs
- prevents a fast new formation of biofilm
- non-corrosive
- ready for use
- no permanent addition

#### **Composition**

ethylene diamine tetraacetate,  
p-hydroxy benzoic acid ester,  
polyhexamethylenebiguanide.  
Contains a source of phenylalanine.

#### **Efficacy**

Test criteria: with load, room temperature

- bactericidal (EN 13623, test organisms: *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*) in 2 hours
- conservation (EuAB 5.1.3, test organisms: *Burkholderia cepacia*, *Enterococcus faecium*, *Legionella pneumophila*, *Pseudomonas aeruginosa*) for 28 days

#### **Field of application**

When used 1 to 2 times a week in the Weekend-System II (ALPRO) or ALPRO-BCS, as well as other independent medical water supply systems, Bilpron effectively removes organic and inorganic residues in independent medical water supply (including instrument hoses and tumbler fillers).

For disinfection, the ready-to-use solution should act in the procedural water lines for at least 12 hours (overnight) or can be used as a long-term disinfection (holidays) for up to 3 months.

Application only by qualified medical personnel with protective clothing

#### **Expert opinion**

HygCen Germany GmbH:

- cytotoxicity test DIN EN ISO 10993-5, 2015-04

Dr. Brill + Partner GmbH:

- conservation EuAB 5.1.3, 2019-09
- disinfection EN 13623, 2019-08

Overall expert opinion:

Prof. Dr. rer. nat. Dr. med. habil. Friedrich von Rheinbaben:

- biofilm prevention, 2023-03

In special cases expert opinions and approvals may be requested from us.

#### **Shelf Life**

3 years

#### **Environment**

The contained surfactants are biodegradable according to OECD. The solution for use is ecologically harmless.

#### **Compatibility**

Very gentle on materials

## Approvals

Tested by well-known dental equipment manufacturers.

Various material and practical tests from well-known dental equipment manufacturers on request.

## Application

Before starting the application (weekend, holidays or overnight) fill the storing container (tank) with Bilpron (e.g. by use of the Bilpron measuring cup) up to the mark.

Remove transmission instruments from the instrument tubes. Operate the decontamination system according to the operating instructions. Fill each procedural water line (all instrument tubes, tumbler filler and other water supply systems e.g. peripheral devices) with Bilpron until it comes out of the tubes and the tumbler filler (clearly recognizable by the blue colour). Afterwards turn off the treatment unit.

Allow the **Bilpron** to remain in the procedural water lines (minimum 12 hours) until the practice starts to work again.

When the treatment unit is put into operation again turn off the decontamination system and flush all instrument tubes incl. the tumbler filler until clean water comes out.

For further advice, please consult the instructions supplied with the decontamination system.

## Delivery Forms

REF 3181 6 x 1 L bottle in carton

## Accessories

REF 3081 Measuring Cup (500 ml)



CE 0123

## 9. Product information BC-San 100

Decontamination of procedural water

**Solution for the virucidal final disinfection of surfaces of medical devices, such as light guides, polymerisation lamps, heads of intraoral cameras/scanners, as well as for the disinfection/processing of wipe dispenser boxes and pressure bottles (1 – 1.5 L) of stand-alone procedural water supply systems such as the ALPRO-BCS (BottleCareSystem).**

### Composition

Sodium hypochlorite solution with 1 – 2 % active chlorine.

### Efficacy

- |                |         |
|----------------|---------|
| • bactericidal | 10 min. |
| • yeasticidal  | 10 min. |
| • sporicidal   | 10 min. |
| • virucidal    | 5 min.  |

### Application concentrations

Test criteria: clean conditions, room temperature:

- |   |            |
|---|------------|
| • sporicidal (prEN 17126)<br>against <i>Bacillus subtilis</i> | 10 minutes |
| • virucidal (prEN 16777)<br>against Parvo viruses             | 5 minutes  |

### Note:

Pre-disinfection with TB- effective disinfectants.

### Expert opinion

HygCen Germany GmbH:

- EN 16777 (virucidal), 2019-02
- prEN 17126 (sporicidal), 2018-11
- microbicidal, 2018-11

In special cases expert opinions and approvals can be requested from us.

### Application

#### • Virucidal final disinfection

After pre-cleaning and general disinfection (e.g. with **PlastiSept eco Wipes/MinutenWipes**), soak a suitable cellulose wipe with undiluted **BC-San 100**, thoroughly wipe off the surfaces to be disinfected and allow to take effect for at least 5 minutes. Dispose of cellulose wipe after use.

#### • Wipe dispenser boxes

Soak suitable cellulose wipe with undiluted **BC-San 100**, wipe off all inner and outer surfaces of the dispenser box (including lid) and allow to take effect for at least 5 minutes. Dispose of cellulose wipe after use.

#### • Pressure bottles of procedural water supply systems

Fill the content of the bottle (100 ml) of **BC-San 100** into the empty pressure bottle and fill it with drinking water up to the beginning of the screw thread. Leave the solution in the pressure bottle to take effect at least 6 hours (e.g. overnight). During disinfection, keep the filled pressure bottle closed in the processing room **or** attach it to the holder of the procedural water supply system as usual.

**Attention:** Do not apply pressure to the pressure bottle during disinfection!

Application only by qualified medical personnel.

Not suitable for unalloyed metals.

## Restarting

Prior to reconnection the procedural water supply system, dispose of the content of the pressure bottle via the wastewater. For rinsing, fill the disinfected pressure bottle 2 times to 1/3 with drinking water, shake and empty. Afterwards follow the instructions of the manufacturer of the procedural water supply system.

## Shelf Life

2 years

## Delivery Forms

REF 3199      12 x 100 ml bottle  
in a box



CE 0123

## 10. Maintenance

### 10.1. Changing the riser tube on the ALPRO-BCS (BottleCareSystem)

#### Separate the riser tube from the fitting:

The riser tube can only be removed by careful cutting with a knife.

(See figure)

**Please note: If the riser tube is pulled too strongly the plastic thread will be torn out or become leaky (air penetrates into the water system).**



**We recommend changing the riser tube every time the bottle is changed (see point 11), at the latest, after 12 months.**



### 10.2. Operating pressure check (annually by service technician)

The ALPRO-BCS is designed to be connected to a regulated operating air pressure of  $\leq 3.5$  bar (the specific operating pressure requirements of the procedural water must be taken into account and adjusted if necessary).

Note: Annual check by a service technician.

## 11. Hazard and safety information

The ALPRO-BCS pressure bottle has a limited shelf life (see bottle label) and must be replaced afterwards.

The container is under pressure during usage and may burst.

It is recommended to have a regular inspection (once a year) carried out by a service technician to check the extensive functionality of the ALPRO-BCS.

## **12. Troubleshooting**

If faults occur, please contact your service technician.

## **13. Disposal notes**

After disinfection with BC-San 100, the ALPRO-BCS pressure bottle can be disposed of normally (via the dual system).

For final disposal of the unit, please observe the regulations applicable in your country. Other components of the unit and chemicals must be disposed of in accordance with the legal regulations applicable in the country.

Questions about proper disposal can be answered by your dental trader.

## **14. Report incidents**

Please report any incident that may occur in connection with the product to:

**ALPRO MEDICAL GMBH**

E-Mail: [quality@alpro-medical.de](mailto:quality@alpro-medical.de)

Tel.: **+49 7725 9392-0**

and the national authority



Information on processing regarding the workflow and all current work instructions, safety data sheets, instructions for use etc. may be obtained at our website:

**[www.alpro-medical.de](http://www.alpro-medical.de)**

If you have any questions, please do not hesitate to contact us at **[www.alpro-medical.de](http://www.alpro-medical.de)** or by phone **+49 7725 9392-0**. You are also welcome to contact our sales representatives by phone or e-mail.

