

## 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

	Use before (date of expiry) YYYY-MM
	Batch number XXXXXX (six-digit)
	Please follow the instruction for use
	EEC symbol for finished packs
	CE symbol for Medical Devices of class I
	CE symbol with Notified Body (0123) for Medical Devices of class IIa, IIb or III (see declaration of conformity)
	Symbol for order number
	Serial number
	Health Industry Bar Code
	Information on safety
	Manufacturer, Company ALPRO MEDICAL GMBH, St. Georgen
	Date of manufacture
	Keep away from sunlight
	Pictogram for decontamination of procedural water
	Pictogram for spray cooling
	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®.

## Field of Application

For refitting of any treatment unit.

## Areas 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)

## Procedural Water Disinfection 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) 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

## Durability

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

## Approvals

Approvals can be obtained from us in special cases.

To be carried out only by technical staff.



REF 3179-N Bilpron StarterSet

## Form of Delivery

### 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
- Drawings
- 1 L Bilpron
- 10 g BRS® PreCleaner
- 160 g BRS® Remover
- 20 ml BRS® Activator
- Instructions for use
- 50 ml Alpron sample bottle
- 100 ml BC-San 100



## Accessories

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

**REF 8774** ALPRO-BCS housing (for refitting)

**REF 3179-N** Bilpron StarterSet

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

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

\* Pressure bottle and consumables are excluded



REF 8775  
REF 8774



ALPRO-BCS pressure bottle  
ALPRO-BCS housing

## 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 3204-N Biofilm-Removing-Set (BRS®)  
(can only be obtained through your  
service technician)



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 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 pressure bottles. Then set the **rocker arm** (see point 3) to position „0“ = **OFF**, see SOP.

6. Fill and screw in the BCS 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 pressure bottle as “break time disinfection”. The empty BCS-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 1% or ready for use for disinfection
- 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

### Efficacy

- bactericidal\*
- yeasticidal\*

\*as concentrate

### Application

1% or as concentrate for shock disinfection/sanitation

### Clinical Data

- Dr. F. H. H. Brill, Hamburg, disinfection
- EN 13623, Pharm. Eur. 5.1.3, 2019-05
- Institute Heppeler, Lörrach, phys. + ecolog. compatibility, 1997-10
- Prof. Dr. H.-P. Werner, HygCen, Schwerin, cytotoxicity test 2012-11

In special cases clinical data 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 for use solution is ecologically harmless.

### Compatibility

Very good compatibility with materials.

### Dosage

Application with internal disinfection device:

Fill dosing container with undiluted Alpron and ask your service engineer to adjust the required dosage (standard = 1 %).

Application with external dosage device:

Mix Alpron with external procedural water (e.g. in ALPRO-BCS) at 1 % (Ratio: 10 ml Alpron for 990 ml procedural water) and connect it to the treatment unit. In case of chair-side dosage devices, ask your service engineer to carry out the adjustment.

## Approvals

Tested by well-known dental equipment manufacturers.

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

## Delivery Forms

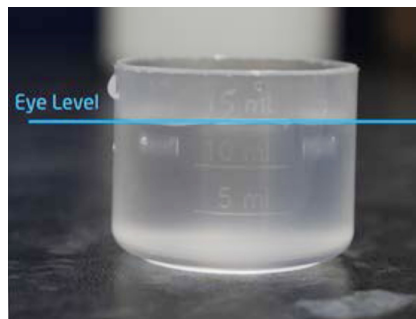
REF 3183      1 L bottle



**Alpron**

CE 0123

**Use only by qualified medical personnel with appropriate protective clothing.**



## 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**

- bactericidal/fungicidal
- removes and prevents lime and algae formation

#### **Field of application**

- Solution ready for use for the application in the Weekend-System II (ALPRO) or ALPRO-BCS as well as other autarkic medical water supply systems once to twice a week. Bilpron effectively removes organic and anorganic residues in water lines (including instrument tubes and tumbler filler).
- Contact time in the treatment unit for disinfection at least 12 hours (overnight) or as long-term disinfection up to 3 months (holidays) possible.

#### **Clinical Data**

- Institute Niedermann, Überlingen, screening test bactericidal, fungicidal effect, 2014-05 (according to DGHM surface disinfection)
- Prof. Dr. H.-P. Werner, HygGen, Schwerin, cytotoxicity test, 2012-12
- Dr. F.H.H. Brill, preserving, EuAB 5.1.3, 2019-09, quantitative suspension test according to DIN EN 13623, 2019-08

**In special cases clinical data and approvals may be requested from us.**

#### **Shelf Life**

2 years

#### **Environment**

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

#### **Approvals**

Approved for pause/long-term disinfection amongst others by Chirana-Dental, Heka Dental, Planmeca, Ritter, Dentsply Sirona, Takara Belmont, TGA, EMS, NSK, Ultradent.

#### **Application**

Before starting the application (weekend, holidays or overnight) fill the tank with Bilpron up to the mark (e.g. by Bilpron measuring cup). Remove transmission instruments from the instrument tubes. Activate the decontamination system according to manufacturer's instructions. Fill each water line (all instrument tubes, tumbler filler and other water supplies e.g.

peripheral devices) with Bilpron until it comes out of the various outlets (recognizable by the blue colour). Afterwards turn off the treatment unit.

Allow Bilpron to remain in the procedural water lines until the practice starts to work again (for at least 12 hours.)

### Delivery Forms

- REF 3181 6 x 1 L bottle in carton
- REF 3179-N Bilpron StarterSet
- REF 3179-PM Bilpron StarterSet 3 (PM)

### Accessories

- REF 3081 Measuring Cup (500 ml)

After restarting the treatment unit, turn off the decontamination system and flush all flooded procedural water lines until clear water comes out.

For further information see the instruction manual of the decontamination system.

Application only by qualified personnel with adequate protective clothing.



## 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 cylinders (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

- sporicidal
- virucidal

### Application Concentrations

Test criteria: low contamination, room temperature:

- sporicidal (prEN 17126)  
against Bacillus subtilis 10 minutes
- virucidal (prEN 16777)  
against Parvo viruses 5 minutes

### Note:

Pre-disinfection with TB- effective disinfectants

### Application

**1. 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 the surfaces to be disinfected and allow to take effect for at least 5 minutes.

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

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



## Attention

Do not put pressure on the pressure cylinder during the disinfection!



## Reconnection

Prior to reconnecting the procedural water supply system, discard the contents of the pressure bottle via the waste water. Then fill the disinfected pressure bottle 1/3 full with drinking water, shake it and empty it. Repeat this procedure once. Then follow the manufacturer's instructions for the procedural water supply system.

## Shelf Life

2 years

## Delivery Forms

REF 3199 12 x 100 ml bottle  
in cardboard box

## Clinical Data

- Prof. Dr. H.-P. Werner, HygCen, Schwerin, virucidal prEN 16777, 2018-11, sporicidal prEN 17126, 2018-11, microbicidal 2018-11

In special cases clinical data and approvals may be requested from us.



Application only by qualified medical personnel wearing protective clothing!  
Not suitable for unalloyed metals.

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.

## **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 the preparation with regard to the work steps and all current work instructions, safety data sheets, instructions for use etc. can be found on 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.