

Instruction for Use

Weekend-System II



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:

Weekend-System II

REF: REF 8200; included in REF 5510

Basic UDI-DI: ++E25101820000A8

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

GMDN Code: n/a

Intended purpose of the product:

Chair-side device for feeding the procedural water lines of medical and dental units
with Bilpron.

Risk class of the product: I

Classification rule: 1

Marking of the product: **CE**

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


ALPRO MEDICAL GMBH

St. Georgen, 03.01.2022


Gerold Reich
Quality Manager



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




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II. Operating Manual

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

	Please follow the instruction for use
	Safety related information
	Special features, the observance of which is necessary for the perfect function of the device!
	Use before (date of expiry) YYYY-MM
	Batch number XXXXXX (six-digit)
	Symbol for order number
	Serial number XXXXXX (six-digit)
	Health Industry Bar Code
	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)
	Fill level control symbol If the max. filling level is exceeded, the device may be damaged!
	Do not overfill tank
	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 (physicians, dentists and the specialist personnel responsible for reprocessing medical devices as well as hygiene specialists) in medical and dental facilities.

4. Intended purpose - intended use

4.1. Weekend-System II

Add-on device for the supply of Bilpron into the service water lines of medical and dental treatment units.

4.2. Bilpron StarterSet

Set for basic cleaning and disinfection of procedural waterlines of medical and dental treatment units.

The Weekend System II **may only be used as chair-side device for the supply of BILPRON** into the waterlines of dental treatment units.

The device may only be installed by technicians and operated by instructed and trained specialist personnel. It must not be operated by the patient.



The Weekend System II may only be operated within the pressure areas indicated. (Air pressure in inlet line: 3 – 8 bar; air pressure in the tank: 2 bar; water inlet pressure: 2 – 6 bar).

BILPRON may only be used in devices that are compatible with it and must be removed from the lines after the specified contact time!

5. Application

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

Application is required for treatment units that have been in operation for more than one year at the time of installation of the Weekend System II and must be carried out by a service technician. The biofilm removal set comes with detailed instructions explaining the application step by step.

6. Basic cleaning with BRS[®] before installation

(Exclusively for trained technical personnel)

This activity 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.



The basic cleaning of the waterways with the Biofilm Removing Set (BRS®) must not be carried out with the Weekend System II

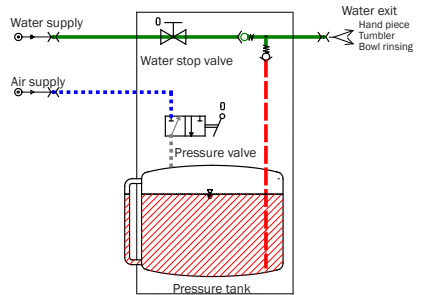
7. Operating states of the Weekend-System II

7.1. Standby mode

(during the week)

Weekend-System II is switched off:

- Tap water flows freely
- Tank is without pressure, the tank pressure valve blocks the air path

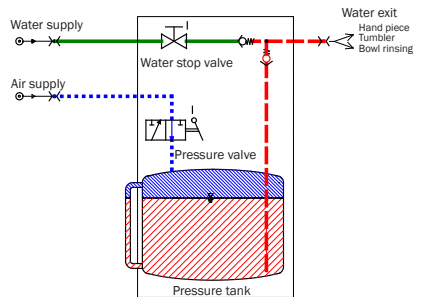


7.2. Injection of BILPRON

(Last working day before the weekend)

Weekend-System II is switched on:

- Tap water is stopped
- Tank is put under pressure
- BILPRON is injected

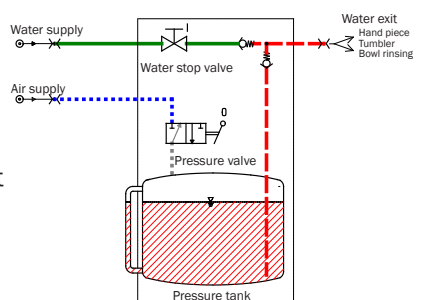


7.3. Time of effect

(during the weekend)

Weekend-System II is switched off again:

- Tap water remains in a stopped position.
- BILPRON still remains in the lines without pressure and has to be rinsed out after the time of effect.



7.4. Rinsing/resting state

(First working day after the weekend)

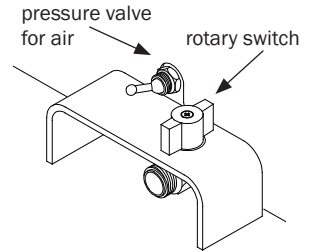
(see picture 1)

8. Operation

8.1. Switching the Weekend System II on and off

The operating agents are on the side of the device, above the cover for the supplies.

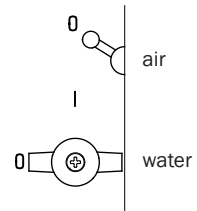
You can switch the compressed air for the tank on and off using the toggle switch of the pressure valve. The compressed air must only be switched on when BILPRON shall be injected into the treatment unit.



Prior to the injection of BILPRON, the procedural water has to be stopped with the rotary switch of the water stop (ball valve).

These operating instructions show the supplies in the top view so that the positions of both switches are visible in a better way.

The required positions for switching on and off are identified by the marks „I“ und „0“ on the cover. In the non-operation of the Weekend-System II all switches have to be at „0“ as shown on the right.



The toggle for compressed air has always to be set on „0“ (pressure release) after having finished the injection of BILPRON!
The rotary switch for water stop should always be closed in the evening!

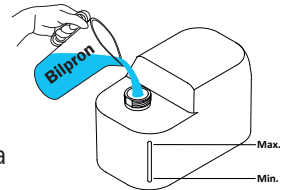
8.2. Filling the tank

When the liquid level in the tank has dropped to „Min.“, the tank has to be refilled again! The level indicator is at the side of the housing.

Only fill the tank up to the marking „Max.“!

The toggle switch of the tank pressure valve has to be set on „0“ after refilling the tank. While opening the tank, you hear a sibilance. This is normal as the compressed air escapes from the tank.

Remove spilt BILPRON immediately with a damp cloth!



Only fill the tank so that the liquid does not cover more than up to the bottom of the casing in filter!



If the fill level is too high, liquid might enter the Weekend-System II via the air-relief valve and might contaminate the inside of Weekend-System III!

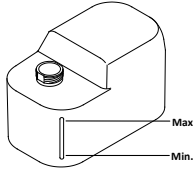
8.3. Timing of use

Before work breaks lasting several days: **Initiate BILPRON.**

Procedure

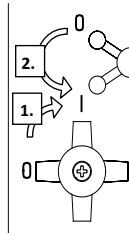
- a) Check if enough BILPRON is in the tank:

The level indicator at the side has to show a liquid level at „Max.“



- b) Switch on Weekend-System II:

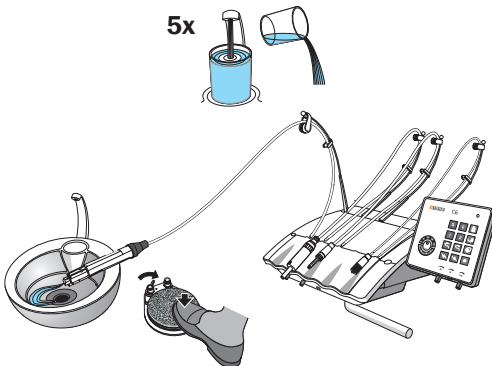
1. First turn off the water:
Set the water stop (ball valve) on „I“.
2. Then pressurize the tank:
Set the toggle switch of the pressure valve on „I“.



- c) Adjust all instruments to maximum flow and remove them:



- d) Each single procedural water line has to be operated as long until the decontamination agent „BILPRON“ visibly comes out as blue solution:



Remarks

Filling of the tank:
see chapter 7.2

The operating agents are on the side cover.

Decontamination:
Set all levers on „I“

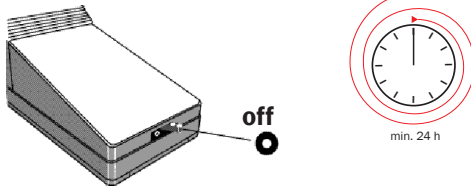


1. You should start with the tumbler filler in order to flood the main lines as soon as possible. Operate the tumbler filler several times.
2. Then continue with the multifunctional syringes and finally rinse the lines with the smallest flow.
3. All instruments which are additionally connected to the dental unit (dental scaler, powder jet devices etc.) have also to be rinsed.
4. If the tank is empty, BILPRON has to be refilled as described in chapter 7.2

Procedure

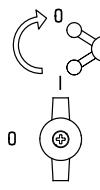
Remarks

- e) Switch off the treatment unit (if necessary at the main switch!)



The operating agents are on the side cover.

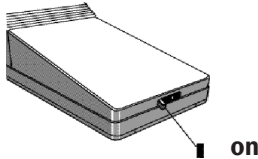
- f) Depressurize the tank: Set the toggle switch of the pressure valve on „0“. Keep the water stop valve closed!



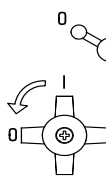
The operating agents are on the side cover.

After work breaks of several days: **rinse out BILPRON**

- g) Switch on the treatment unit:



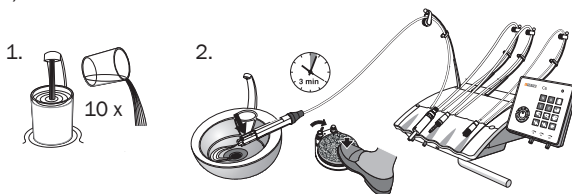
- h) Turn the water on again:
Set the waterstop (ball valve) on „0“.



The operating agents are on the side cover.

Normal operation:
Set all levers on „0“

- i) Rinse each line until clear water comes out:



Start again with the tumbler filler and the multifunctional syringes in order to rinse the main lines as soon as possible. Rinse all instruments one after another for approx. 3 minutes.

- j)



Record the decontamination with BILPRON in the device record book.

9. Maintenance

Filter



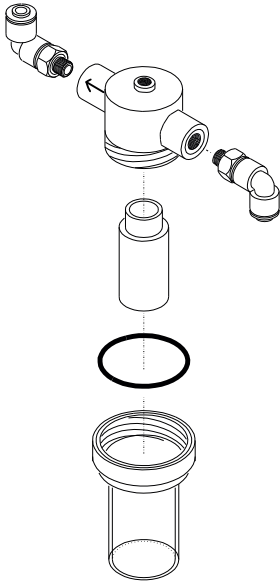
The casing in filter of the water filter should be examined by a dental engineer at least once a year and changed if necessary

Tank cap

1 - 2 times a year, the **thread** on the tank cap and on the tank nozzle including the O-rings must be cleaned and **coated with a little Vaseline** by trained specialist personnel.

Cleaning

Please **use** for this operation a clean cloth and **cleaning agents free of aldehydes and alcohol**. We recommend PlastiSept eco, PlastiSept eco Wipes or DesNet +.



10. Troubleshooting

Before contacting your technical engineer, first please refer to this list of faults. Many possible problems can be solved easily and without the assistance of an engineer.

Problem	Possible cause and solution
Liquid emerges at the bottom of the Weekend-System II	Possibly the tank has been overfilled
No water flows	Perhaps the water stop is still closed. Open the valve (see Chapter 7.1).
Too little water flows	Possibly the filters of the treatment unit and the Weekend-System II have to be cleaned by a dental engineer.
It is difficult to open the tank	Slightly grease the thread in the tank cap with vaseline and do not overtighten the cap on the tank. However, the black sealing ring must be covered at least two thirds.

11. Disposal Notes

Dispose of the device properly.

For final disposal of the device, 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.

Packaging can be recycled.

12. Report Incidents

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

ALPRO MEDICAL GMBH
E-Mail: 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**

If you have any questions, please do not hesitate to contact us at **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.