

Weekend-System II

I. Operating instructions
II. Installation instructions



Further information concerning work steps and standard operating procedures (SOP) can be found on our website: www.alpro-medical.de or can be requested by mail: info@alpro-medical.de or by phone: +49 7725 9392-0.

KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

CE

für das Medizinprodukt Klasse I

for the medical device class I

Weekend-System II

GMDN Code - Term:

40479 - Water purification unit, automatic dosage system for procedural water

Beistellgerät zur Einleitung von Bilpron in die Betriebswasserwege ärztlicher und zahnärztlicher Behandlungseinheiten. Chair-side device for feeding the procedural water lines of medical and dental units with Bilpron.

ALPRO MEDICAL GMBH Mooswiesenstr. 9 78112 St. Georgen • DEUTSCHLAND / GERMANY

ist Hersteller dieses Medizinprodukts und erklärt in alleiniger Verantwortung, dass dieses Medizinprodukt den Grundlegenden Anforderungen der Richtlinie 93/42/EWG entspricht und eine vollständige Dokumentation vorliegt. Das Konformitätsbewertungsverfahren wurde gemäß Anhang VII der Richtlinie 93/42/EWG durchgeführt.

is manufacturer of this medical device and declares under sole responsibility, that this medical device corresponds to the essential requirements of the Directive 93/42/EEC and that a complete documentation exists. The conformity assessment procedure was carried out according to Annex VII of the Directive 93/42/EEC.



Das Qualitätssicherungssystem der ALPRO MEDICAL GMBH ist zertifiziert nach DIN EN ISO 13485:2016 St. Georgen, 18.01.2019

Gerold Reich

Qualitätsbeauftragter/quality manager

The Quality Management System of ALPRO MEDICAL GMBH is certificated in accordance with DIN EN ISO 13485:2016

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I. Operating instructions

These operating instructions must always be available near the device. They have to be read and applied by each person who is instructed to the work at the device (installation, operation or maintenance).

Danger!	This danger symbol describes safety instructions which might lead to endangering of persons in case of non-observance. Apart from the information in these operating instructions, you have to consider the generally applicable safety and accident prevention regulations!
Attention!	This attention symbol identifies any security advice of which the disregard might lead to dangers for the device and its function!
Information	This information symbol identifies particularities of which the observance is necessary for the perfect function of the device!
Fill-level control!	This Fill-level control symbol identifies special parts. When exceeding the max. fill-level, the device might get damaged!

1. Intended use

The Weekend-System II must only be used for the injection of BILPRON into the water pipes of dental treatment units.

The device is designed to be operated only by skilled and qualified personnel and not by the patient.



The Weekend-System II must only be used within the pressure areas indicated (see paragraph "Technical data").

BILPRON must only be used in suitable devices (not in the ALPRON-Tec!) and has to be rinsed out of the lines after the intended time of effect!

2. Operating status of Weekend-Systems II

1. Non-operation

(during the week)

Weekend-System II is swithed off:

- · Tap water flows unhindered
- Tank is not under pressure as the pressure valve closes the way of the air.

2. Injection of BILPRON (on Fridays)

Weekend-System II is switched on:

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

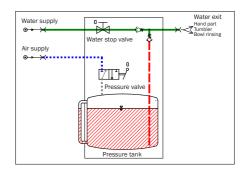
3. Time of effect

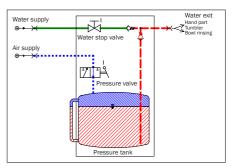
(over the weekend)

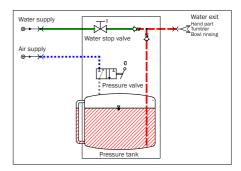
Weekend-System II is switched off again:

- 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.

4. Rinsing/Non-operation (on Mondays)







(same picture as no. 1.)

3. Operation

3.1 Switching the Weekend-System II on and off

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

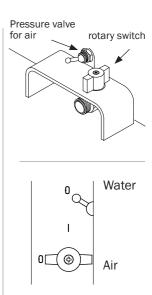
You can switch the compressed air for the tank on and off using the toggle switch of the pressure valve. The compressed air must only be switched on when BILPRON shall be injected into the treatment unit.



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!

Danger The rotary switch for water stop should always be closed in the evening!

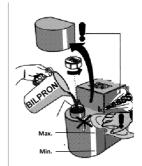
3.2 Filling the tank

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 "O" 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 casingin filter!

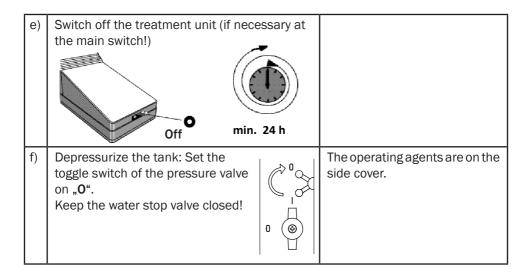
Fill-level control!

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 II!

3.3 Chronological procedure of application

On Fridays" (before work breaks of several days duration resp.): Inject BILPRON

	On Fridays" (before work breaks of several days duration resp.): Inject BILPRON			
	Procedure	Remarks		
a) Danger	Check if enough BILPRON is in the tank: The level indicator at the side has to show a liquid level at "Max."	Filling of the tank: see chapter 3.2		
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".	The operating agents are on the side cover. Decontamination: Set all levers on		
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: 5 x	 You should start with the tumbler filler in order to flood the main lines as soon as possible. Operate the tumbler filler several times. Then continue with the multifunctional syringes and finally rinse the lines with the smallest flow. All instruments which are additionally connected to the dental unit (dental scaler, powder jet devices etc.) have also to be rinsed. If the tank is empty, BILPRON has to be refilled as described in chapter 3.2. 		



"On Mondays" (before work breaks of several days duration resp.): Rinse out BILPRON

	Procedure	Remarks
g)	Switch on the treatment unit: On	
h)	Turn the water on again: Set the waterstop (ball valve) on "O".	The operating agents are on the side cover: Normal operation: Set all levers on 0
i)	Rinse each line until clear water comes out: 1. 10 x 2.	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.
d)		Record the decontamination with BILPRON in the device record book.

4. Maintenance



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

<u>Tank cap</u>

The threads of the tank cap and tank neck should be cleaned from time to time and should be slightly greased with vaseline

Cleaning Please use a clean cloth and cleaning agents free of aldehydes

 $\textbf{and alcohol.} \ \textbf{We recommend PlastiSept eco}, \ \textbf{PlastiSept-Wipes eco}$

or DesNet +.

5. 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 Weekend System II	Possibly the tank has been overfilled
No water flows	Perhaps the water stop is still closed. Open the valve. (see Chapter 3.1)
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.

II Installation instructions

(For qualified technical staff only)

The procedures described below must only be carried out by suitably qualified technicians for dental devices in accordance with the valid instructions for electrical safety and the drinking water decree.

Directive 93/42/EEC for medical devices, 2017/745 annex I; Par. 14.1

If a product is meant for use in combination with other products or equipments, the combination including the connections must be safe and it must not affect the intended performance of the products. Each restriction of use must be stated on the label or in the operating instructions

1. Basic cleaning of the water pipes



The basic cleaning of the water lines with the Biofilm-Removing-Set (BRS®) must not be carried out through the Weekend-System II!

Application of the BIOFILM-REMOVING-SETs (BRS®)

BIOFILM-REMOVING-SET

The Biofilm-Removing-Set (BRS®) serves for the removal of biofilm in the water lines of the treatment unit.

The application is required for treatment units which have been in use for more than one year when the Weekend-System II is installed and must be carried out by a technician. The Biofilm-Removing-Set contains a comprehensive manual in which step-by-step instructions are explained in detail.



Information

All hand and angle parts, instruments for the removal of dental tartar, multifunctional syringes and so on must be removed completely, so that the water lines within these instruments are not blocked due to the cleaning process.

5 L pressure tank system with connection for tube 6/4 REF 8589 For the initial cleaning of the water lines an external pressure tank system must always be used, by means of which the BRS® liquids can be injected into the water lines of the treatment unit with at least 2 bar.

A garden spray device with pump mechanism and pressure storage function in which a tube connection instead of a syringe can be screwed would be very suitable.

2. Installation and connection of the Weekend-System II

2.1 Delivery contents

- Weekend-System II
- · Lead wires
- · Operating instructions
- Device records

2.2 Positioning at the treatment unit

The positioning of Weekend-System II at the treatment unit should be stated in particular cases. The risk of stumbling or obstacle must be excluded.

After installation the Weekend-System II must be accessible easily. In particular, it must be paid attention that the tank can be filled easily.

2.3 Connection at the treatment unit



The Weekend-System II must only be connected by an expert authorized by ALPRO in accordance with the valid instructions for the drinking water decree. In case of interference to the treatment unit, the warranty conditions of the manufacturer have to be followed.

For the connection of the air and water pipes please use the pipes, T-pieces and couplings included in the delivery contents.

a) Water supply

As a rule, the supply is connected with a flexible metal tube (armoured tube included in delivery) directly at the angle valve in the connection box of the treatment unit. It can also be connected behind the lock valve so that the Weekend-System II becomes depressurised when switching off the treatment unit!



If the water pressure in the incoming pipe is higher than 6 bar, an appropriate water pressure regulator must be assembled in front of the Weekend-System II!

b) Water exit

The exit of Weekend-System II has to be connected with the pipe of the treatment unit to the instruments, to the tumbler filler and to the bowl rinsing. If possible, this should be done with a flexible metal tube (included in delivery) which has to be connected directly with the central water supply of the treatment unit.

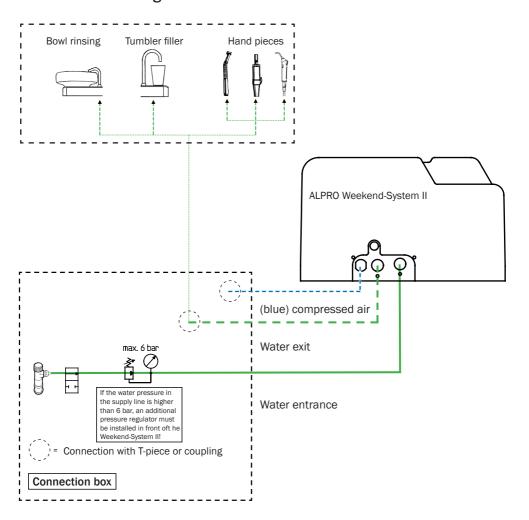
If necessary, the pipes of the treatment unit to the instruments, to the tumbler filler and to the bowl rinsing are to be changed in the way that they are connected together to a common string.

c) Compressed air entrance



The compressed air pipe (blue) of the Weekend-Systems II should be connected into the treatment unit. To do so, the compressed air pipe in the treatment unit must be separated behind the pressure control and a T-piece must be installed. The pressure in this pipe must be at least 2 bar.

2.4 Connection diagram

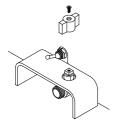


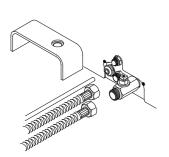
2.5 Instructions for installation

- a) Switch off power supply of the treatment unitt using the main switch!
- b) Close angle valve in the connection box and relieve the water pipe system of the treatment unit of pressure, e.g. by operating the multifunctional syringe.
- c) Fix a position for the Weekend-System II. (see paragraph 2.2)
- d) Seek a suitable entrace into connection box of the treatment unit or prepare it yourself (diameter approx. 30 mm).
- e) Connect the connecting lines of the Weekend-System II to the treatment unit as described in Chapter 2.3 and 2.4.
- f) Unscrew the screw in the turning knob of the water stop and remove the turning knob.
 Remember the position of the turning knob.

Remove the cover!

- g) Fit the pipes for water and compressed air at the Weekend-System II:
- 1. First screw the outgoing pipe on the middle supply.
- 2. Afterwards fit the incoming pipe to the water stop.
- 3. Last insert the plastic tube into the quick coupling.







When installing the device in the practice, secure with a flat wrench (SW 21) when screwing the water tubes to the device in order to prevent the connections in the casing from being damaged.

- h) Fit the cover and the turning knob again. Put the turning knob into the same position as it was before the dismantling (f)!!
- i) Open the angle in the connection box again and switch on the main switch of the treatment unit.

3. Technical data

3.1 Technical values

Operating data

Filling amount: Min: 200 ml, Max: 900 ml

Microfilter: 80 µm (filter F2)

Connection data

Media: Compressed air: without oil, drained and

filtered

Water: filtered (80µm)

Maximum admissible pressures: Air pressure in incoming pipes: 8 bar

Air pressure in the tank: 2 bar

Pressure of incoming water: max. 6 bar

Connection lines: Incoming air pipe: blue PE-/PA-tube

Measures and weight

Measurements width x length x height: 20 cm x 29 cm x 18,5 cm

(without tubes): Weight (empty):

Material:

approx. 2,5 kg

Chassis:

Casing: plastics (ABS)

Tank: plastics (HDPE)

Screwes connections: plastics (POM), brass

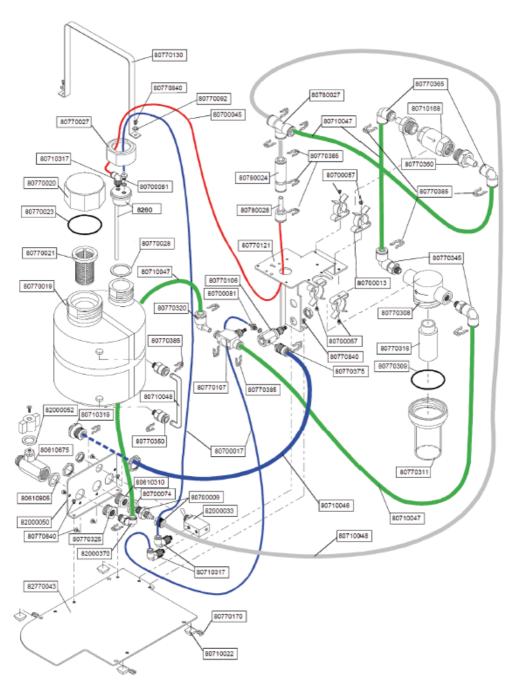
Tubes: polyamide, polyethylene,

high-grade steel

sheet steel, galvanized

3.2 Device diagram

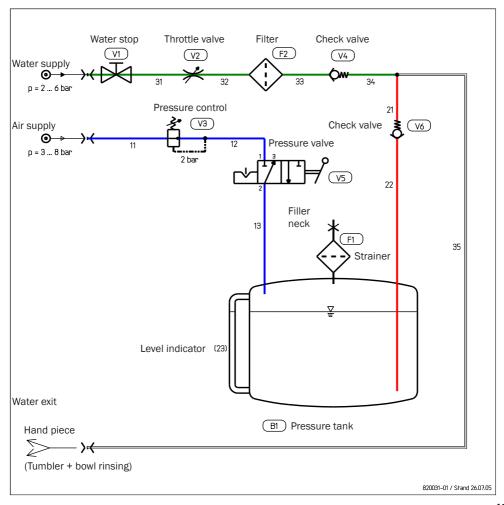
(without housing)



3.3 Spare parts

Article	Art. No.
Tank cap	80770020
Seal for tank cap	80770023
Filter for tank	80770021
Filter element	80770313
Installation kit	8220

3.4 Circuit diagram





Please use our ALPRO information and upgrade system. When registered, you will automatically receive all updated information, standard operating procedures, safety data sheets etc.

Please register under www.alpro-medical.de or by phone under +49 7725 9392-0

In case of any questions, please contact our sales representatives or send us an e-mail.

