

Installation Manual (for technicians) **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



St. Georgen, 03.01.2022

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I. Installation Manual

(Exclusively for trained technical personnel)

The activities described below may only be carried out by dental equipment technicians who have been specially trained and in compliance with the applicable regulations on electrical safety and the drinking water regulations.

Regulation (EU) 2017/745 Annex I; para 14.1 Where a device is intended to be used in combination with other devices or equipment, the combination, including the connections, shall be safe and shall not impair the intended performance of the devices.

1. Basic Cleaning of the Water Lines

(exclusively for trained service technician)



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

BIOFILM-REMOVING-SET

Application of the Biofilm-Removing-Set (BRS®)

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 carried out by a service technician.

The Biofilm-Removing-Set comes with detailed instructions explaining the application step by step. Completely remove all handpieces and contraangles, ultrasonic handpieces, multifunctional syringes, etc., so that the water lines in these instruments are not clogged by the cleaning process.



5-litre pressure tank system with connection for hose 6 mm/4 mm REF 8593

For basic cleaning of the water lines always use an external pressure tank system from which the BRS® solutions are pumped into the waterways of the treatment unit at a pressure of at least 2 bar. For optimum results when using the BRS®, we recommend the use of the ALPRO-BRS® reciprocating plunger type pump (REF 8593) and the readymade canister.

2. Installation and Connection of the Weekend-Systems II

2.1. Form of delivery

- Weekend-System II
- Connection cables
- Installation manual (for technical personnel)
- Operating manual
- Device passport and handover protocol

2.2. Positioning on 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 to 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

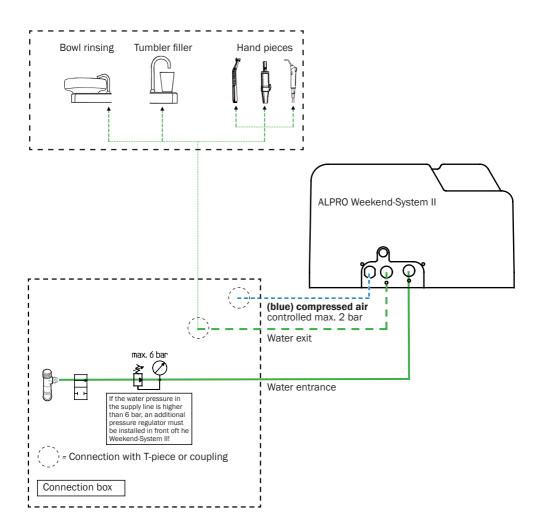
The exit of Weekend-System II has to be connected with the pipe of the treatment unit to the instruments, to the tumbler filler and to the bowl rinsing. If possible, this should be done with a flexible metal tube (included in delivery) which has to be connected directly with the central water supply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

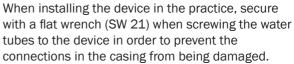
2.4. Connection Diagram



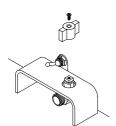
2.5. Instructions for installation

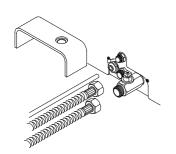
Before installation, a basic cleaning should be carried out (see chapter 1. page 4)

- a) Switch off power supply of the treatment unit 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 chapter 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 stopn 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.
 - Afterwards fit the incoming pipe to the water stop.
 - 3. Last insert the plastic tube into the quick coupling.



- 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.









For warranty and quality reasons according to ISO 13485:2016 - 7.5.3, we kindly ask you to fill in the device passport including the protocol and return a copy to us as the manufacturer. Thank you very much!

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 (80 µm)

Maximum admissible pressures: Air pressure in incoming pipes: max. 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

(without tubes): width x length x height: 20 cm x 29 cm x 18.5 cm

Weight (empty): approx. 2.5 kg

Material

Chassis: sheet steel, galvanized

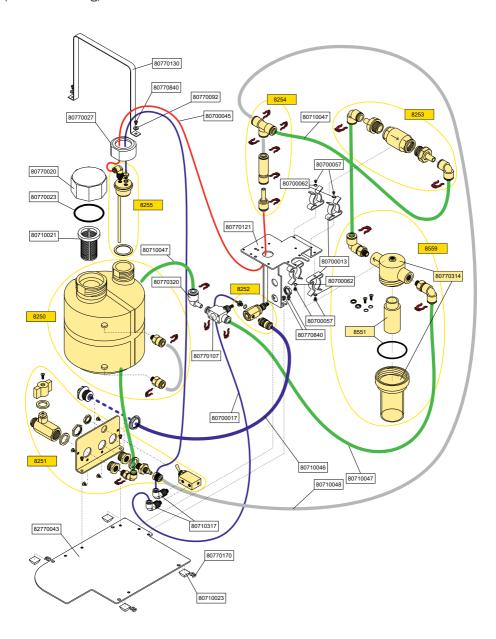
Casing: acrylonitrile butadiene styrene copolymer (ABS)

Tank: high-density polyethylene (HDPE)
Screwes connections: Polyoxymethylene (POM), brass

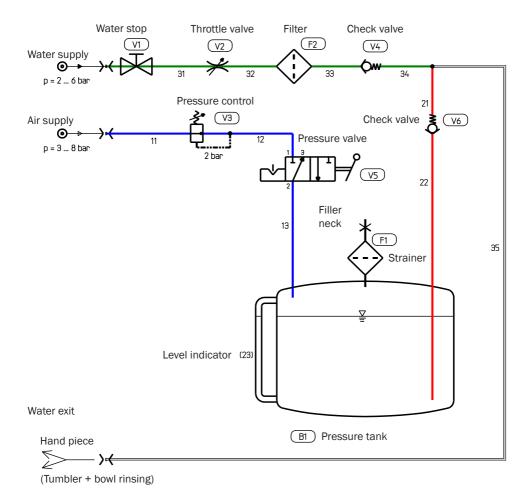
Tubes: polyamide, polyethylene, high-grade steel

3.2. Device Diagram

(without housing)



3.3. Circuit Diagram



3.4. Spare parts

REF 8220	Installation kit	
REF 8250 Pressure tank assembly		
REF 8251 Water/air supply assembly		
REF 8252 Pressure regulator assembly		
REF 8253	Socket check valve assembly	
REF 8254	Assembly group check valve	
REF 8255	Assembly riser tube/tank	
REF 8551	Spare part water filter Note: When changing the filter element, also change the sealing ring	
REF 8559	Conversion set water filter	

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

[]i	Please follow the instruction for use	
<u> </u>	Safety related information	
3	Special features, the observance of which is necessary for the perfect function of the device!	
	Use before (date of expiry) YYYY-MM	
LOT	Batch number XXXXXX (six-digit)	
REF	Symbol for order number	
SN	Serial number XXXXXX (six-digit)	
HIBC	Health Industry Bar Code	
C€	CE symbol for Medical Devices of class I	
€ 0123	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!	
Ž i i mix	Do not overfill tank	
	Date of manufacture	
•••	Manufacturer, Company ALPRO MEDICAL GMBH, St. Georgen	
ALPRO MEDICAL GMBH	Company logo of ALPRO MEDICAL GMBH, St. Georgen	

3. Target Group

Trained technical staff.

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

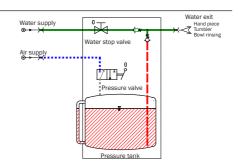
7. Operating states of the Weekend-System II

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

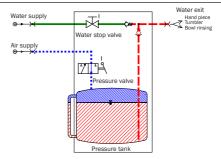


7.2. Injection of BILPRON

(Last working day before the weekend)

Weekend-System II is switched on:

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

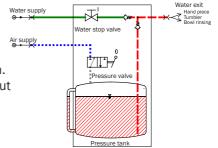


7.3. Time of effect

(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

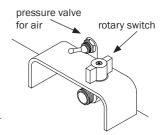
8.1. Switching the Weekend System II on and off

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 com-pressed air must only be switched on when BILPRON shall be injected into the treatment unit.

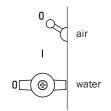


Prior to the injection of BILPRON, the <u>procedural</u> water has to be stopped with the rotary switch of the water stop (ball valve).



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 "O" on the cover. In the non-operation of the Weekend-System II all switches have to be at "O" 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!

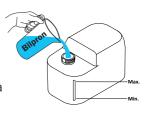
The rotary switch for water stop should always be closed in the evening!

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 casingin 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 II!

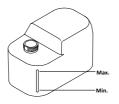
8.3. Timing of use

Before work breaks lasting several days: Initiate BILPRON.

Procedure

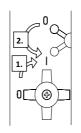
Remarks

a) 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 7.2

- 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.

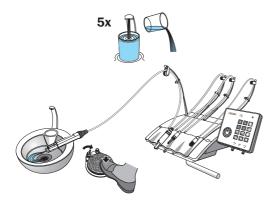


c) Adjust all instruments to maximum flow and remove them:



Procedure

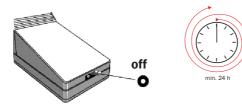
 d) Each single procedural water line has to be operated as long until the decontamination agent "BILPRON" visibly comes out as blue solution;



Remarks

- 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

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



The operating agents are on the side cover.

Procedure

Remarks

f) Depressurize the tank: Set the toggle switch of the pressure valve on "O".
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:



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 "O"

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



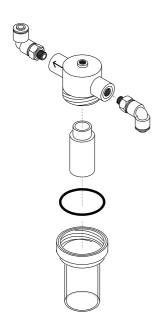
The casingin filter of the water filter should be examined by a dental engineer at least once a year and changed if necessary

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 Possibly the tank has been overfilled	
Liquid emerges at the bottom of the Weekend-System II		
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 thedevice, 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:

and the national authority

ALPRO MEDICAL GMBH

E-Mail: quality@alpro-medical.de

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





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.