ENG

Instructions for use

autopress-e

automatic pressure controller

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40-203-02

BIEGLER
MEDIZINELEKTRONIK

IMPORTANT

These directions are essential for operating the device. They must therefore be kept in a suitable place near the device, and should be kept with the device if it is given to other users.

For proper and safe use of this device, it is essential that the following warnings and safety instructions, as well as the operating instructions, are read and carefully observed by all users before first using the device.

It is the responsibility of those using the device to fully acquaint themselves with its proper use and operation. If a malfunction is suspected, the device is to be taken out of service immediately and suitable warning signs should be attached to the device to ensure that it is not used before the required service and repair work has been carried out.

Table of Contents

1. Warnings and Safety Instructions

- In the event of any suspected malfunction while in operation, the device should be immediately removed from service.
- Unplugging the mains plug is the only safe way to disconnect from the mains power supply.
- The device may only be fastened to infusion stands, tripods or equipment rails which have sufficient stability and load capacity to support the device.
- Only pressure infusion bags specified by BIEGLER or approved by BIEGLER for use with this device may be used in conjunction with the autopress►e.
- The device must only be used in areas in which the electrical installations are in accordance with the standards and regulations in force.
- The device must not be used in rooms with potential explosion hazard.
- The device must not be immersed in liquids or sterilized with steam or by thermochemical methods.
- All extraneous influences such as electromagnetic waves or high temperatures are to be kept to a minimum.
- Avoid exerting force on the device or its accessories.
- If the device is dropped, damaged due to force, or functions in a way other than described in the operating instructions, stop using the device immediately and return it to the service center.
- Periodic technical safety inspections must be carried out as described in the "Periodic inspections" section.
- Persons and services authorized by BIEGLER must carry out repairs and modifications on the device.
- No mechanical or electrical changes may be made to the components of the device.
- Improper replacement of the lithium battery (other model) would result in an unacceptable risk. The lithium battery may only be replaced by BIEGLER or by authorized BIEGLER personnel.
- Replacement of the lithium accumulator by insufficiently trained personnel can lead to hazards.

- Only infusion bags that are capable of 300 mmHg must be used. Adhere to the instructions for use for this bags.
- The pressure infusion bags must be securely fastened at least 20 cm above the patient to prevent air embolism. Prevent the connecting hose from kinking.
- Always position the autopress►e in such a way that it is easy to operate without obstacles. No other devices or infusion stands shall be positioned shortly before.
- Make sure, that mains plug of the autopress►e is easily reachable to the operator. (The mains plug is used to disconnect the device from mains)
- The automatic pressure controller autopress►e is a class I ME equipment and therefore only intended to be connected to supply mains with protective earth.

The autopress►e may not be used if:

- the housing is damaged or one of the front film layers becomes detached
- the device has been exposed to a hard physical shock (e.g. dropped, hit or shaken)
- the device has been immersed in water
- the mains power cord or plug is damaged
- the device has given someone an electric shock
- the fixing clamp is damaged in such a way that safe clamping to the infusion stand is no longer guaranteed.

The autopress►e may not be used if there is a malfunction:

e. g. display error, no pressure, …

If there is a malfunction, suitable warning signs should be attached to the device to ensure that it is not used until the required service and repair work has been carried out.

Safety instructions for disposable pressure infusion bags:

Disposable consumable materials are intended for single use only. The re-use of products that are intended for single use constitutes a risk of infection for patient or user.

Safety instructions for reusable pressure infusion bags:

Please refer to the instructions for use for reusable pressure infusion bags.

2. Description

2.1 General Description

Description	Article number
autopress►e	LG4000004

The automatic pressure controller autopress►e is used when liquids are to be supplied under constant pressure.

The autopress►e can be used in combination with all BIEGLER Blood- and Infusionwarmers or used as standalone device.

The following single-use pressure infusion bags can be used:

Description	Article number
Pressure Infusion Bag 500 ml	JR2000500
Pressure Infusion Bag 1000 ml	JR2001000
Pressure Infusion Bag 3000 ml	JR2003000

The following reusable pressure cuffs may also be used:

Description	Article number
BIEGLER Reusable Pressure Infusion Bag 500 ml	JR5000500
BIEGLER Reusable Pressure Infusion Bag 1000 ml	JR5001000
BIEGLER Reusable Pressure Infusion Bag 3000 ml	JR5003000

2.2 Scope of Delivery

Quantity	Description
1	autopress►e
2	Pressure Infusion Bag 500 ml
1	Instruction for use

2.3 Intended use

The automatic pressure controller autopress►e is designed for use in IV infusion therapy and for applications where IV infusions or irrigations are to be supplied under constant pressure.

2.4 Indication

The automatic pressure controller autopress►e can be used wherever liquids are to be administered under pressure.

2.5 Contraindication

The automatic pressure controller autopress►e does not provide significant data to use the device as a flow measurement or control system. Therefore, the device must not be used as a replacement for infusion pumps or to control the administration of medication.

The automatic pressure controller autopress►e must not be used for enteral nutrition solutions.

3. Initial Operation

Observe the instructions for use! Handling of this device requires knowledge and adherence to these instructions. The autopress►e and accessories may only be used by physicians, physician assistants or other qualified specialized staff. The condition of the patient has to be monitored during the application.

1. Fix the autopress►e firmly on a stand using the clamps at the back. Only use infusion stands, tripods or equipment rails that are sufficiently stable.
2. Before connecting to the mains power supply, check that the voltage specified on the device label matches the mains voltage.
3. Before you turn on the device, insert the infusion bag or fluid bag into a suitable pressure cuff. Make sure that air has been properly removed from the infusion or flush system before connecting it to the patient.
4. Connect the pressure infusion bag to the Luer-Connector of the autopress►e
5. Switch on the device by pressing the button in the upper right.

Figure 1 - placing the infusion bag

6. Set the desired pressure with the arrow buttons ▲ and ▼. (in steps of 10 mmHg)
7. Start the pressure build-up by pressing the START-buttons ◄ or ► to the corresponding channel.
8. If necessary, the pressure in both channels can be changed by pressing the ▲ and ▼ buttons.
9. By pressing the PAUSE-button ⏸ the pressure in the corresponding channel is released and the channel is vented.

During patient transfer, the device can be disconnected from the mains without switching off. The lithium accumulator provides the power supply for the device and the pressure in the bag is maintained.

Operation:

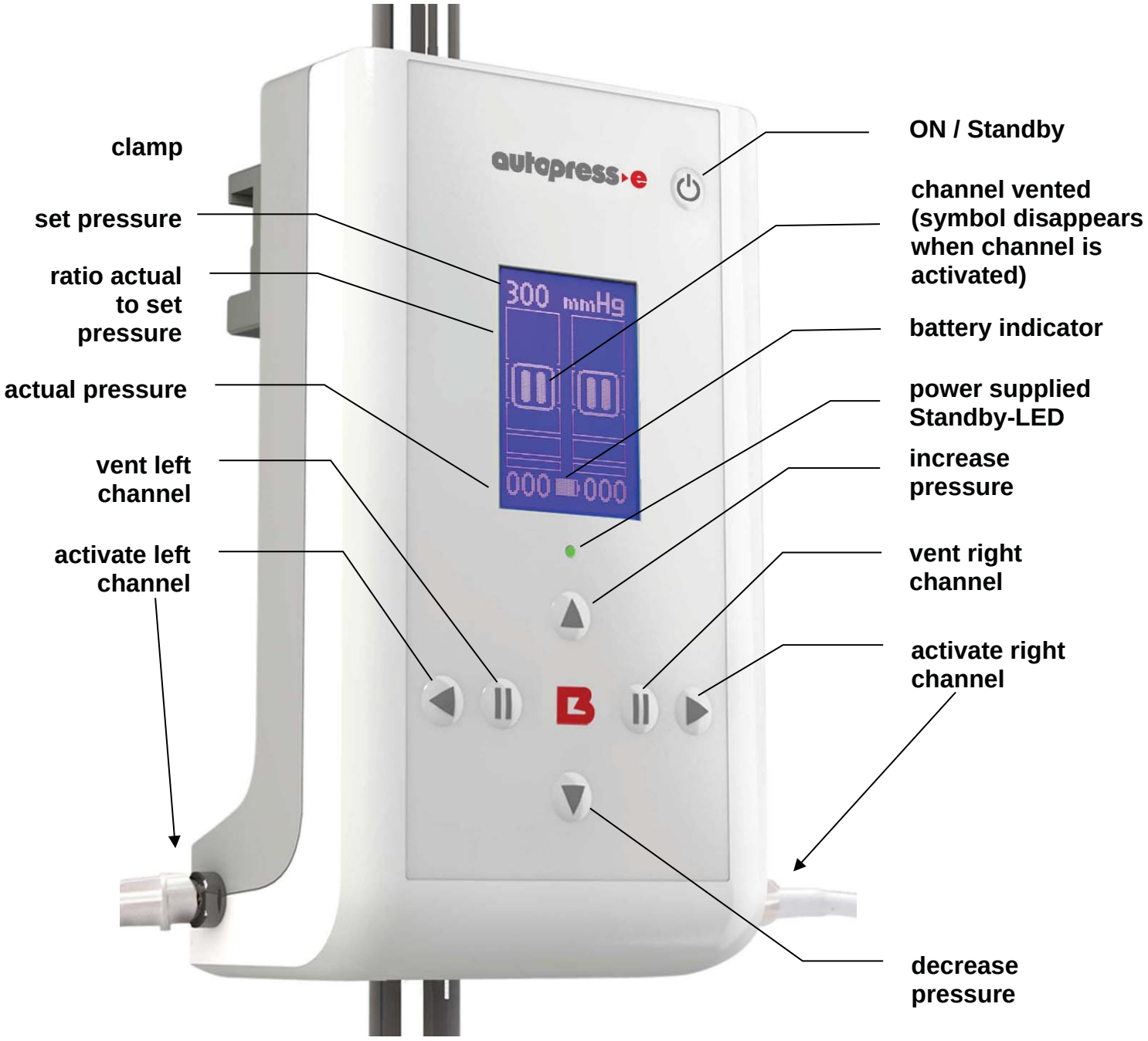

Figure 1 - Operation, Display

4. Maintenance

The autopress►e was largely designed as a maintenance-free device. For long-term maintenance of quality and functional safety, we would like to ask you to observe the following points:

- Always keep the device clean (see the "Cleaning and disinfection" section).
- Periodic technical safety inspections must be carried out as described in the "Periodic inspections" section.

5. Cleaning and Disinfection

Important: Before cleaning or disinfecting, the device must always be disconnected from the mains power supply by pulling the plug.

The device may only be cleaned using a soft cloth with a water-soluble, non-aggressive cleaning agent or a special cleaning agent for plastics.

For the purposes of disinfection, only ready-made alcohol-based disinfectants must be used and the manufacturer ‘s instructions must be followed.

6. Periodic Inspections

The periodic technical safety inspections (according to the local standards in force - e.g. in Austria, EN 62353) on the autopress►e must be carried out at least every 12 months, by persons authorized to carry out such inspections based on their training, knowledge and practical experience. The device cannot be used during inspection. The pressure limitation, as essential performance of the device, is tested during inspection.

- The safety relevant labels on the device and its accessories must be clearly legible.
- The mechanical condition of all components must permit further safe use (housing, power cable, Luer connections).
- The device must not contain any safety-reducing contamination.

The results of the periodic inspection must be documented, along with the date, the inspecting agency and the device number.

Important: If a malfunction is discovered during the periodic inspection, suitable warning signs should be attached to the device to ensure that it is not used before the required service and repair work has been carried out.

7. Manufacturer Liability

The manufacturer and the supplier of the device reject any liability if:

- the device is not used in accordance with the Instructions for use.
- the user is not sufficiently informed about the functioning of the device corresponding with the Instructions for use and the safety instructions
- repairs are not performed exclusively by the manufacturer or by persons and service centers expressly authorized by the manufacturer
- the device is used in places in which the electrical installations do not comply with the applicable national standards, or if the power supply during the period of use of the device is not guaranteed
- original spare parts are not used or the maintenance interval is not adhered to.

8. Warranty Conditions

The manufacturer guarantees that all flaws of material and workmanship which arise within 24 months from the date of purchase will be repaired free of charge.

Claims are only accepted under the following terms:

- The manufacturer and/or supplier is informed immediately of the fault for which the warranty claim is being made.
- The instructions of the manufacturer and/or supplier regarding storage or return of the device are complied with.
- Presentation of a legible copy of the invoice for the device concerned, showing the date of purchase.
- An exact description of the defects or malfunctions identified by the customer.

The manufacturer's warranty will be void if it is found that the maintenance, disinfection and inspection instructions have not been followed according to the operating instructions, the device has been damaged by force or operating error, or has been used in any way contrary to the operating and safety instructions. The warranty will also be void if original BIEGLER materials were not used as replacement parts, or measures for repair were undertaken by persons not authorized by the manufacturer or supplier.

If the manufacturer is required to meet a warranty claim in accordance with these terms, the customer shall bear the costs and risks of transport of the device from and to the place of use.

The manufacturer and/or supplier shall under no circumstances assume liability for slight negligence. The compensation for lost earnings and profits is likewise excluded.

9. Return of Devices

Devices must be carefully cleaned and disinfected before being placed in the original packaging for returning.

If the original packaging is no longer available, the product has to be suitably packaged for the method of dispatch.

10. Disposal

Dispose of the device or its accessories in accordance with local regulations.

Do not dispose of this product
as unsorted municipal waste

11. Symbols

CE 0123 — Compliance with Directive 93/42/EEC	SN — Serial number
 — Consult instructions for use	 — Manufacturer
 — Attention	 — Manufacturing date
 — Defibrillation-proof type CF applied part	
 — ON / Standby	 — AC voltage
 — Activate right channel	 — Increase pressure
 — Activate left channel	 — Decrease pressure
 — Pause button – vent the channel	**IPX4** — Degree of protection against ingress of water - splashing water
 — Temperature limit	 — Humidity limitation
 — Fragile, handle with care	 — Protect from heat and radioactive sources
 — Keep dry	 — Do not dispose of this product as unsorted municipal waste

12. Operating and Storage Conditions

Permissible environmental conditions for transporting and storing the autopress▶e and accessories:

	Transport and storage	Operating
Temperature	10 – 40 °C	10 – 30 °C
Relative humidity	30 – 75 %	30 – 75 %
Ambient pressure	700 – 1060 hPa	700 – 1060 hPa

Values higher or lower than the ranges specified above may cause damage to the device or its accessories.

13. Electromagnetic Compliance Levels

13.1 Emission

Test	Limit
Conducted emission	CISPR 11, Group 1, Class B
Radiated emission	CISPR 11, Group 1, Class B
Harmonic current emissions (IEC 61000-3-2)	IEC 61000-3-2, Class A
Voltage fluctuations and flicker (IEC 61000-3-3)	IEC 61000-3-3, Complies

13.2 Immunity Test Levels

Test	Test level
Electrostatic Discharge (IEC 61000-4-2)	Contact Discharge: ±8 kV Air Discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV
Radiated RF EM filed (IEC 61000-4-3)	80-2700 MHz; 1kHz AM 80 %; 3 V/m

Proximity fields form RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, Pulse Modulation: 18 Hz: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m
Electrical fast transients / bursts (IEC 61000-4-4)	Power lines: 2 kV; 100 kHz repetition frequency Signal lines: 1 kV; 100 kHz repetition frequency
Surges (IEC 61000-4-5)	L-PE and N-PE: 2kV L-N: 1kV
Conducted disturbances inducted by RF fields (IEC 61000-4-6)	0.15-80 MHz; 1kHz AM 80 %; 3 Vrms, 6 Vrms in ISM Band
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz and 60 Hz
Voltage dips / Voltage interruptions (IEC 61000-4-11)	0 % U_T for 0.5 cycle at 8 phase angles 0 % U_T for 1 cycle at 0° 70 % U_T for 25/30 cycles at 0° 0 % U_T for 250/300 cycles at 0°

14. Technical Data

Device:	automatic pressure controller
Type designation:	autopress►e
Operating voltage:	100 – 240 V / 50 – 60 Hz
Power consumption:	max. 36 VA
Supply type:	mains or battery operation
Protection class:	I
Degree of protection against electric shock:	Type CF, defibrillationproof
IP-classification (IEC 60529):	IPX4
Classification (93/42/EEC):	IIa according to Rule 9
Operation mode:	continuous
Pressure range:	0 – 300 mmHg
Accuracy of values displayed:	± 5% of the measured value
Dimensions:	100 x 230 x 180 mm
Weight (device only):	2.3 kg

Battery specification	
Type:	Li-ion battery (Type designation: FB3S1P18650-26)
Charging:	automatically when device is connected to mains
Charging time:	max. 6.5 hours if battery discharged
Mean time to empty battery from full charge:	3 hours @ continuous pumping and 20°C ambient temperature

Applied part: venous access (not included)

Figure 2 – Applied part depiction

15. Manufacturer's Declaration

The autopress►e is a medical product as defined by Directive 93/42/EEC.

This is documented through the CE mark.

Notified Body: TÜV SÜD Product Service GmbH,
Approval Number CE0123

CE 0123

16. Manufacturer

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