ENG

Instructions for use

autopress

automatic pressure controller

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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.

This manual is valid for devices with serial number 381000 or higher.

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.

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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.
- 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 centre.
- 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.

- 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 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 is easily reachable to the operator. (The mains plug is used to disconnect the device from mains)
- The automatic pressure controller autopress is a class I ME equipment and therefore only intended to be connected to supply mains with protective earth.

The autopress 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 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 consumable materials:

Consumables are only for one-time use (disposable). The reuse of disposable products results in possible infection risks for the patient or user.

2. DESCRIPTION

2.1 GENERAL DISCRIPTION

Description	Article number
autopress	LG4000003

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

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

Only the following single-use pressure infusion bags can be used:

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

2.2 SCOPE OF DELIVERY

Quantity	Description
1	autopress
2	BIEGLER Pressure Infusion Bag 500 ml
1	Instructions for use

3. INITIAL OPERATION

Observe the instructions for use! Handling of this device requires knowledge and adherence to these instructions. The autopress *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 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 switching on the device place the infusion bag in an appropriate pressure infusion bag and then connect the infusion to the patient.
4. Connect the pressure infusion bag to the Luer-Connector of the autopress
5. Switch on the device by pressing the button in the upper right. ⏻
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.

Figure 1 - placing the infusion bag

If the patient has to be moved the device can be unplugged without switching off – the pressure is maintained.

Operation:

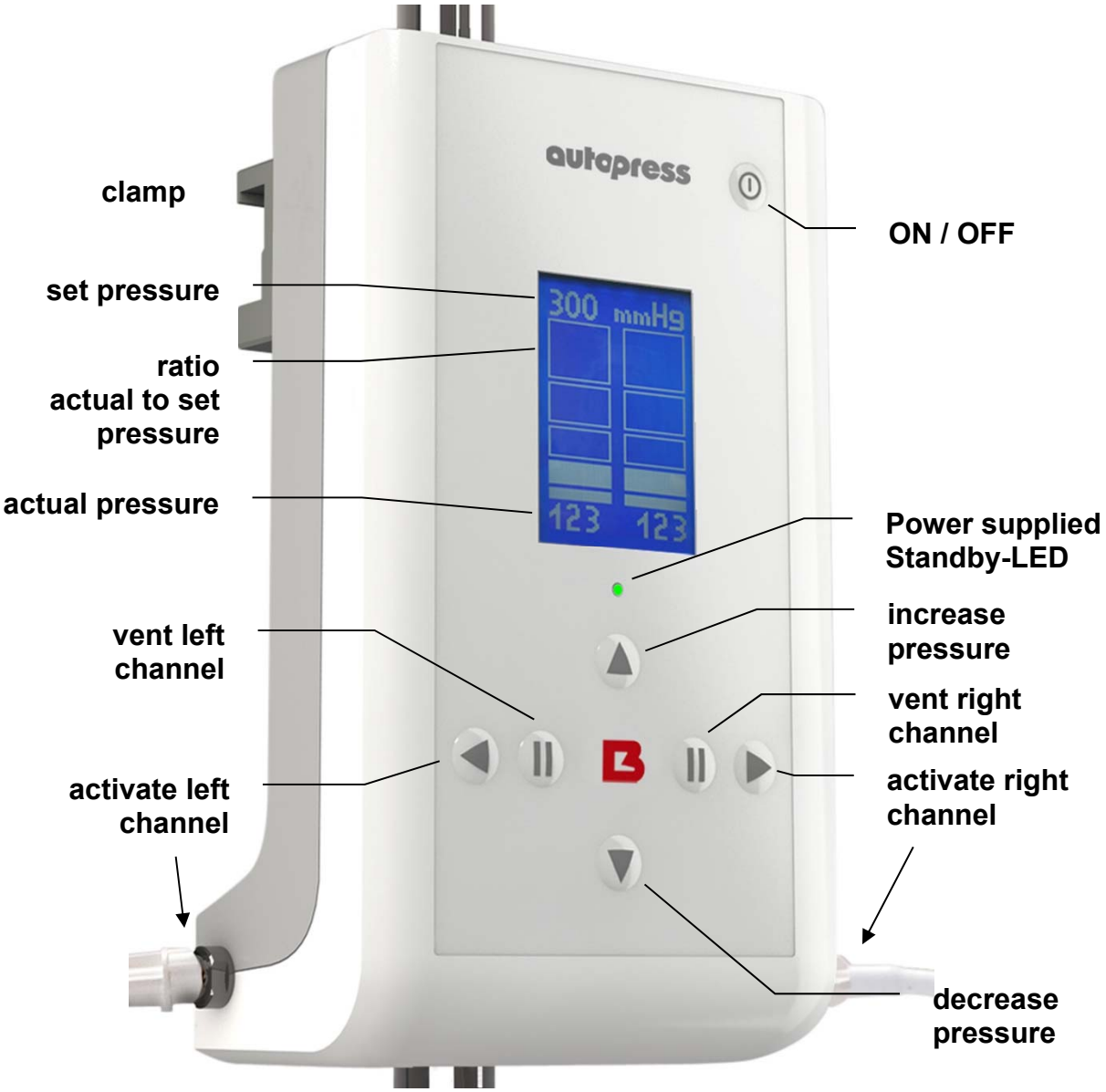

Figure 2 - Operation, Display

4. MAINTENANCE

The autopress 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 spray disinfectants (e.g. Meliseptol Foam pure, BRAUN) must be used and the manufacturer‘s instructions must be followed.

Do not disinfect the device with steam (i.e. in autoclaves), hot air or thermochemical cleaning solutions.

6. PERIODIC INSPECTIONS

The periodic technical safety inspections (according to the local standards in force - e.g. in Austria, EN 62353) on the **autopress** 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 device should be checked for mechanical damage (general condition) and for the completeness of the device label.

Furthermore, the device must not display any contamination or corrosion which could impair safety, particularly in the area of the plug connector.

If there is mechanical damage to the device which could cause risk of injury or impair its functionality, this constitutes a malfunction.

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 directions for use.
- the user is not sufficiently informed about the functioning of the device corresponding with the directions 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 at the end of its expected service life and its accessories in accordance with the applicable local regulations.

Do not dispose of this product
as unsorted municipal waste

11. SYMBOLS

CE 0123 compliance with Directive 93/42/EEC

 Consult instructions for use

 Attention, consult accompanying documents

 Defibrillation-proof type CF applied part

 On / OFF

 activate right channel

 activate left channel

 pause button – vent the channel

LOT Batch code

 Latex free

 Fragile, handle with care

 Keep dry

 Do not dispose of this product as unsorted municipal waste

SN Serial number

REF Catalogue number

 Manufacturer

 manufacturing date

 AC voltage

 increase pressure

 decrease pressure

IPX4 Degree of protection against ingress of water - splashing water

 Use by

 Humidity limitation

 Temperature limit

 Protect from heat and radioactive sources

EC REP authorized in the European Community

12. OPERATING AND STORAGE CONDITIONS

Permissible environmental conditions for transporting and storing the **autopress** 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. EMC TABLES

Table 1

Guidelines and manufacturer's declaration – electromagnetic emissions		
The **autopress** is intended for use in the environment specified below. The customer or the user of the **autopress** should ensure that it is used in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment - guidelines**
RF emissions acc. to CISPR 11	Group 1	The **autopress** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions acc. to CISPR 11	Class B	The **autopress** is suitable for use in all establishments, including domestic establishments and those directly connected to the public power supply network that also supplies buildings used for domestic purposes.
Emission of harmonics according to IEC 61000-3-2	Class A	
Emission of harmonics according to IEC 61000-3-3	Compliant	

Table 2

Guidelines and manufacturer's declaration – electromagnetic interference resistance The **autopress** is intended for use in the electro-magnetic environment specified below. The customer or the user of the **autopress** should assure that it is used in such an environment.			
Interference resistance test	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment - guideline**
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Fast transient /electrical bursts acc. to IEC 61000-4-4	± 2 kV 100kHz repetition frequency	± 2 kV 100kHz repetition frequency	The mains power supply quality should be that of a typical commercial or hospital environment.
Surges as per IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The mains power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations of the supply voltage acc. to IEC 61000-4-11	< 5 % U_T (> 95 % fall in U_T) for ½ period 40 % U_T (60 % fall in U_T) for 5 periods 70 % U_T (30 % fall in U_T) for 25 periods < 5 % U_T (> 95 % fall in U_T) for 5 s	< 5 % U_T (> 95 % fall in U_T) for ½ period 40 % U_T (60 % fall in U_T) for 5 periods 70 % U_T (30 % fall in U_T) for 25 periods < 5 % U_T (> 95 % fall in U_T) for 5 s	The mains power supply quality should be that of a typical commercial or hospital environment. If the user of the **autopress** requires continued operation even in the case of power supply interruptions it is recommended to connect the **autopress** to an uninterruptible power source or a battery.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at this power frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Table 4

<table>
<tr><td colspan="4">Guidelines and manufacturer's declaration – electromagnetic interference resistance
The autopress is intended for use in the electro-magnetic environment specified below. The customer or the user of the autopress should ensure that it is used in such an environment.</td></tr>
<tr><td>Interference resistance test</td><td>IEC 60601-test level</td><td>Compliance level</td><td>Electromagnetic environment - guidelines</td></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the autopress, including cables, than the recommended protection distance calculated from the equation applicable to the frequency of the transmitter:

Recommended protection distance:</td></tr>
<tr><td>Conducted RF disturbance variables acc. to
IEC 61000-4-6</td><td>3 V_{eff}
150 kHz to 80 MHz</td><td>→ $V1$ in V</td><td>$d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$</td></tr>
<tr><td>Radiated RF disturbance variables according to IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>→ $E1$ in V/m</td><td>$d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$ for 80 MHz to 800 MHz</td></tr>
<tr><td></td><td></td><td></td><td>$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ for 800 MHz to 2.5 GHz</td></tr>
<tr><td></td><td></td><td></td><td rowspan="3">Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended protection distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from stationary transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment resulting from stationary RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the autopress is used exceeds the applicable RF compliance level above, the autopress should be observed to verify normal operation. If abnormal performance characteristics are observed, additional measures may be necessary, such as reorienting or relocating the autopress.</td></tr>
<tr><td colspan="4">[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.</td></tr>
</table>

Table 6

Recommended safety distances between portable and mobile RF telecommunications devices and the autopress			
The **autopress** is intended for use in an electromagnetic environment in which radiated RF disturbance variables are controlled. The customer or user of the **autopress** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **autopress** as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Protection distance according to transmitter frequency m**		
	150 kHz to 80 MHz $d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$	**80 MHz to 800 MHz** $d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left(\frac{7}{E1}\right) * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended distance can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

14. TECHNICAL DATA

Device:	automatic pressure controller
Type designation:	autopress
Operating voltage:	100 – 240 Vac / 50 – 60 Hz
Power consumption:	max. 36 VA
Supply type:	mains 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):	2.1 kg

Applied part: venous access (not included)

Figure 3 – Applied part depiction

15. MANUFACTURER'S DECLARATION

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

This is documented through the CE mark.
Notified Body: TÜV SÜD Product Service, Approval Number CE0123

16. MANUFACTURER

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