ENG

Instructions for use

BW 685 / BW 685 S

Blood and Infusion Warmer

TubeFlow

Tube Warmer

Version 2018-11-25 | 220 – 240 V
40-220-03

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 BW 685 devices with serial number 704500 or higher and for BW 685 S devices with serial number 802300 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 must be immediately removed from service and not used for infusions or transfusions until appropriate investigations have demonstrated that there has been no impairment.
- Unplugging the mains plug is the only safe way to disconnect from the mains power supply. Place the device so that it can easily be disconnected from the mains.
- If the high temperature alarm is triggered, the supply of liquid to the patient must be immediately stopped by disconnecting the connection tube to the patient. The medium being used in the device must no longer be administered to the patient.
- The device may only be fastened to infusion stands, tripods or equipment rails which have sufficient stability and load capacity to support the device.
- The device must only be used in areas in which the electrical installations are in accordance with the standards and regulations in force. To prevent the risk of an electric shock the device shall only be connected to a supply network with protective earth connection.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 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.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The device can be influenced by other devices or equipment nearby or it can influence them. It is subject to special precautions regarding electromagnetic compatibility (EMC). Portable and mobile RF communication equipment can affect medical electrical equipment.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer.
- 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 an authorized service center.
- Only persons and services authorized by BIEGLER shall carry out repairs and modifications on the device.
- Periodic technical safety inspections must be carried out as described in the "Periodic inspections" section.
- No mechanical or electrical modifications shall be made to the components of the warming system.
- The device shall not be set up and operated in direct proximity to devices which generate high levels of excess heat.
- Follow the safety instructions for the media to be heated.

Additional safety instructions for the tube warmer accessory BIEGLER TubeFlow for BW 685 S:

- Only operate the TubeFlow with BW 685 S.
- The BIEGLER TubeFlow may only be clamped to the BIEGLER blood warmer BW 685 S with the fixing clamp according to the diagram in the chapter “Initial operation”.
- Do not bend, cover, warm or cool the BIEGLER TubeFlow. Do not cover the TubeFlow with any cloth or dressing material. Do not expose to direct sunlight or heat radiation. Overheating of the heated liquid or burns to the patient cannot be excluded in the event of non-compliance.
- Do not shorten or damage the BIEGLER TubeFlow.
- Disconnect TubeFlow from BW 685 S only by pulling out the connecting plug but not by unscrewing it.

The BW 685 / BW 685 S / TubeFlow must 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 device has triggered a high temperature alarm that was not caused by external factors.
- 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.

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:

The consumable materials are intended for single use only.

- Only sterile consumables or material specified by BIEGLER or approved by BIEGLER for use with this device may be used in conjunction with the BW 685 / BW 685 S.
- Only use items with intact individual packaging.
- Consumables are only for one-time use (disposable).

  The reuse of disposable products results in possible infection risks for the patient or user. Product contamination may lead to health problems, diseases or death of the patient.
- Do not re-sterilize!

2 DESCRIPTION

2.1 GENERAL DESCRIPTION

The BIEGLER BW 685 / BW 685 S is a warmer for infusions or transfusions and operates on the basis of a continuous flow warmer, where the heat from the heat exchanger is transferred via the extension tubing to the liquid flowing within it.

The groove shape of the heat exchanger allows the use of multiple extension sets, provided that the heating is sufficient for each of the inserted tubes.

The design of the device allows quick and easy installation on all suitable infusion stands and equipment rails.
The preselected temperature after switching on the BW 685 / BW 685 S is 38.5 °C. The temperature can be adjusted between 37 °C and 41 °C in steps of 0.5 °C, and is displayed on an LED panel.

The device features permanent self-test functions with three independent safety shutdowns as well as high temperature alarm and low temperature information signal, thus ensuring safe operation.

The flow rate is neither monitored nor directly controlled by the device, it depends on factors outside the scope of the device.

Optional: The actively heated, reusable silicone profile BIEGLER TubeFlow is available as a warming system for transfusions and infusions between BW 685 S and the patient. The system can be used in all cases in which heating of the transfusion or infusion up to the patient is necessary.

2.2 INTENDED USE

The device is used for warming infusions and transfusions to minimize the risk of hypothermia.

2.3 INDICATION

The blood and infusion warmer BW 685 / BW 685 S is applied in cases where warming of fluids to be infused is necessitated.

2.4 CONTRAINDICATION

The blood and infusion warmer BW 685 / BW 685 S is not able to deliver significant data to use the device as flow rate monitoring or control system. Therefore, the device shall not be used as a substitute for infusion pumps or as medication administration control.

2.5 SCOPE OF DELIVERY

For Blood and Infusion Warmer BW 685 (220 – 240 V)

Qty.	Description	Article No.
1	BW 685 (220 – 240 V)	LB22B2685
1	Instructions for use	

For Blood and Infusion Warmer BW 685 S (220 – 240 V) with TubeFlow

Qty.	Description	Article No.
1	BW 685 S (220 – 240 V)	LB22B4685
1	TubeFlow	LG400TF01
1	Instructions for use	

2.6 CONSUMABLES

Various consumables are available according to requirements.

Description	Length	Article No.
Extension set 35000	350 cm	FP1002001
Extension set 46000	460 cm	FP4600003
Extension set 25000 with bubble trap (not suitable in conjunction with TubeFlow)	460 cm	FP4600001

The optimal and safe heat transfer is only achieved with BIEGLER consumables (or those approved by BIEGLER for this device).

3 INITIAL OPERATION

Observe the directions for use! Handling of this device requires knowledge and adherence to these instructions. The BW 685 / BW 685 S and accessories may only be used by qualified specialized staff. The condition of the patient has to be monitored during the application.

3.1 INITIAL OPERATION OF THE DEVICE

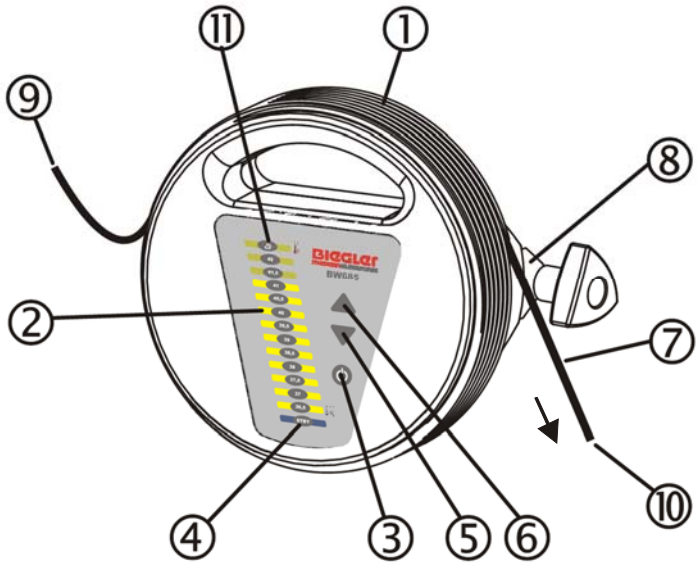


Fig. 1

1 Heat exchanger
2 Temperature scale
3 ON / STANDBY button
4 LED STANDBY
5 Button to reduce the temperature
6 Button to increase the temperature
7 Extension tube
8 Fastening clamp
9 Fluid entry point
10 Fluid exit point
11 Alarm LED
→ Flow direction

Fix the BIEGLER BW 685 / BW 685 S firmly to the infusion stand using the clamps at the back (Fig. 1/8). Only use infusion stands, tripods or equipment rails that are sufficiently stable.

Connect the power cable to the power supply. Before connecting to the mains power supply, check that the voltage specified on the device label matches the mains voltage. The device emits a short beep (control of alarm) and the standby LED (Fig. 1/4) lights up.

If a temperature other than 38.5 °C is desired, this can be preset in Standby mode with the buttons ▲ and ▼ (Fig. 1/5 and Fig. 1/6). If one of the control buttons is pressed, the current default temperature is shown on the display. You can use the ▲ and ▼ buttons to adjust the temperature. The temperature can only be adjusted in Standby mode.

Press the ⏻ button (Fig. 1/3) to start the heating of the BW 685 / BW 685 S. The device performs a self-test of safety-relevant functions, the completion of which is indicated by a short acoustic signal. The BW 685 / BW 685 S reaches the set target temperature within 1 minute. The actual temperature (± 0.5 °C) is indicated on the display.

Select suitable consumables. See the "Consumables" section.

Prepare infusion or transfusion.

Important: The length of the tube between the BW 685 / BW 685 S and the patient must be at least 40 cm, and the tube must not be stretched.

Fig. 2
Position of the tube in the groove of the heat exchanger

Starting from the rear of the heat exchanger, gently pull the extension tube and coil it forwards in a counter-clockwise direction. It is advisable not to increase the distance between the BW 685 / BW 685 S and the patient much beyond 80 cm.

Important: The tube must be completely inserted into the groove (Fig. 2) The flow direction specified in Figure 1 must be complied with.

Check the flow rate constantly during operation.

Optional tube warmer accessory BIEGLER TubeFlow for BW 685 S:

The tube warmer BIEGLER TubeFlow must be inserted with light pressure as indicated in figure 3.2 into the intended fixture (Fig. 3/4) on the BW 685 S. Remove the dust cap from the BW 685 S and attach the connector of the TubeFlow to the socket on the BW 685 S.

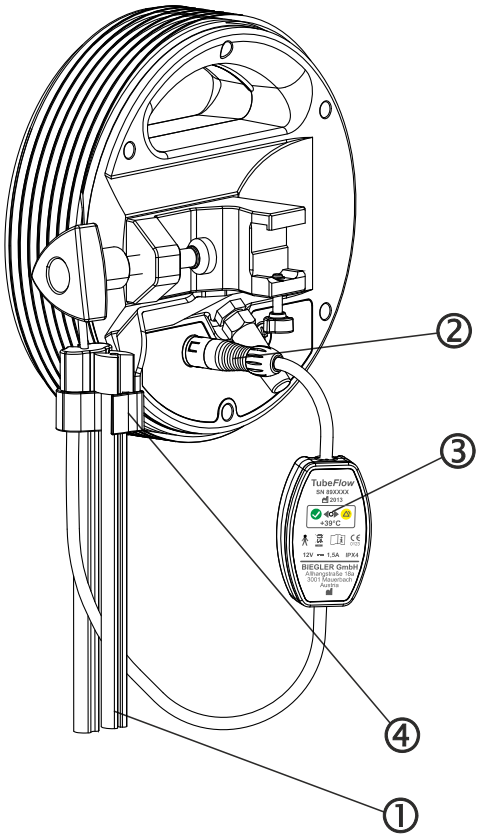


Fig. 3

Fig. 3

1 Tube warmer
2 Connector
3 Control LED (Green – operational / yellow – malfunction)
4 Fixture
5 Heating profile

Fig. 3.1

Insert the transfusion or infusion line with slight pressure into the rules of the heating profile.
Insert the tube over the complete length of the BIEGLER TubeFlow.

Important: Overwarming can result if the full length of the tube warmer is not utilized, thereby possibly harming the medium or patient, since the reference temperature sensor is located at the distal end.

Fig. 3.2

If the TubeFlow is not used there is a special receptacle for the end of the tube.

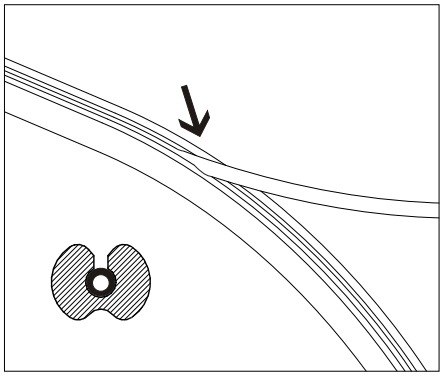


Fig. 3.1

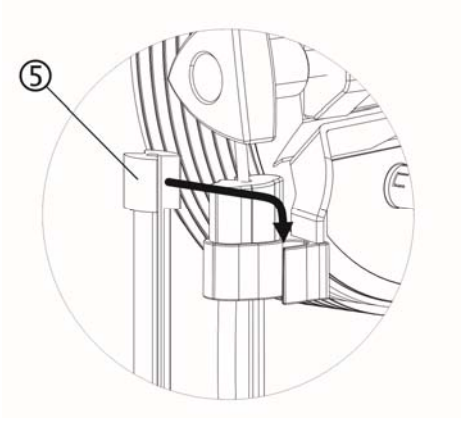


Fig. 3.2

The TubeFlow is activated when the BW 685 S is switched on; this is indicated by a green control LED on the TubeFlow.

- The control LED appears yellow for approx. 1 second after switching on, in order to check the malfunction detection.
- After the test of the malfunction detection, the control LED switches to green, indicating normal operation.
- In the event of a malfunction, the control LED appears yellow.

3.2 ALARMS

The BW 685 / BW 685 S triggers temperature alarms and information signals:

The low temperature information signal is activated when the temperature of the heat exchanger drops below 36.5 °C. The audible low temperature information signal is not active during the first 60 seconds after switch-on.

In the event of a low temperature information signal, i.e. temperatures < 36.5°C, the 36.5 °C LEDs flash and the device emits an information signal every 15 seconds. The low temperature information signal is automatically cancelled after reaching 36.5 °C.

The high temperature alarm is activated when the temperature of the heat exchanger rises above 42 °C. In this case, visual (flashing) and audible (continuous sound) alarm signals are emitted and the heating is switched off. The device can only be restarted and the alarm disengaged once the device has been disconnected from the power supply.

Attention: The temperature alarm can also be triggered by external factors, e.g. exposure to sunlight.
To reset the alarm, the mains plug must be pulled out.

All alarms are alarms of “Low priority” according to EN 60601-1-8.

The alarm system does not have to be verified. The alarm limits cannot be adjusted. The risk management process has found that a shutdown of the alarms is not meaningful, because it is desirable that the error (e. g. high temperature) is detected. Resetting of the alarm is only possible through disconnection of the device from mains. The operator station is in front of the device.

Alarm overview

	Software high temperature alarm	Hardware-high temperature - alarm I	Hardware-high temperature alarm II	Internal fault
Condition	High temperature alarm is triggered when the temperature rises above 42.0 °C	If the temperature rises above 42.5 °C due to a software error, a hardware high temperature alarm is triggered.	If the temperature rises above 45 °C due to a software error, another hardware high temperature alarm is triggered.	Selftest detects an internal fault.
Consequence	The heater is switched off.	The heater is switched off.	The heater is switched off.	The heater is switched off.
Resetting	The alarm can only be reset by pulling out the mains plug.	The alarm can only be reset by pulling out the mains plug.	The alarm can only be reset by pulling out the mains plug. Wait for the temperature switch to cool down.	The alarm can only be reset by pulling out the mains plug.
Visual signal	Yellow top LEDs on	Yellow top LEDs on	Yellow top LEDs on	Yellow top LEDs on + LEDs for error code
Audio signal	Continous tone 3.4 ± 0.5 kHz min. 62 dBA	Continous tone 3.4 ± 0.5 kHz min. 62 dBA	Continous tone 3.4 ± 0.5 kHz min. 62 dBA	Continous tone 3.4 ± 0.5 kHz min. 62 dBA
Priority as per EN 60601-1-8	Low priority	Low priority	Low priority	Low priority

Information signals

	Low temperature information signal
Condition	If the heater temperature is lower than 36.5 °C. The audio low temperature signal is deactivated during the first 60 seconds after switching on.
Consequence	No consequences in relation to the function of the device. (information only)
Resetting	Automatically when the temperature rises above 36.5 °C.
Visual signal	36.5 °C LEDs flash at 1 Hz 50 % duty cycle
Audio signal	1 pulse with 250 ms duration every 15 s frequency: 3.4 ± 0.5 kHz | sound pressure level: min 62 dBA

3.3 SHUTTING DOWN THE DEVICE

After being used for treatment, the device is shut down as follows:

Switch the device to Standby mode with the button ⏻ (Fig. 1/3).

Depressurize the system by switching off any pressure cuffs or infusion pumps used. Empty and disconnect the system as far as possible.

Remove the consumables from the heat exchanger (Fig. 1/1) and from the optional tube warmer if used, and dispose of them according to the applicable local regulations
Disconnect the device from the power supply, and clean and disinfect it as described in the section "Cleaning and disinfection".

3.4 TROUBLESHOOTING

Error	(possible) Cause	Solution
LEDs do not light up	No power supply	Insert the mains plug
No LEDs light up, even though mains plug is inserted and mains voltage available	Device defective	Return device for servicing
Blue LEDs light up, device does not heat	Device is in Standby mode	Press the "ON" button to start the device
Device sounds alarm and does not heat	Internal error	Return device for servicing
<36.5° LEDs flash and device issues short signals in 15 second intervals.	Low temperature information signal has been triggered	The low temperature information signal is automatically cancelled after reaching >36.5 °C.
Alarm LEDs light up, audio alarm (continuous tone)	Device was overheated	Allow device to cool down. If the error occurs again → return device for servicing
Extension tube cannot be inserted into the heating ring	Incorrect diameter of extension tube	Use extension tube according to directions
No connection possibilities for TubeFlow	Unsuitable device model	Suitable device model: BW 685 S
TubeFlow does not heat, even though BW 685 S is switched on	The TubeFlow is poorly connected or not connected at all	Connect the TubeFlow to the BW 685 S
TubeFlow does not heat	BW 685 S is in Standby mode	Press the "ON" button to start the device and thus switch on the TubeFlow

4 MAINTENANCE

The BW 685 / BW 685 S was largely designed as a maintenance-free device. For long-term maintenance of quality and functional safety, the following points have to be observed:

- 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 BW 685 / BW 685 S and the optional tube warmer TubeFlow 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 like Biguacid Liquid, Meliseptol® Foam pure or alcohol-free Schülke acryl-des® shall be used and the manufacturer‘s instructions shall be followed.

The device shall not be disinfected 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. EN 62353) on the BW 685 / BW 685 S and the optional tube warmer TubeFlow 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 results of the periodic inspection must be documented, along with the date, the inspecting agency and the device number.

During the measurements, the heating devices may not be exposed to sunlight, draughts or other conditions which could affect the measurement.

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.

CHECKING THE WARM-UP PERIOD (BW 685 / BW 685 S)

This is the time taken by the BW 685 / BW 685 S to heat up to 38.5 °C from room temperature. If this time is much more than one minute, there is a malfunction.

CHECKING THE CONTROL TEMPERATURE (BW 685 / BW 685 S)

The control temperature is checked on the groove bed of the heat exchanger. The sensor of a suitable contact thermometer (tolerance ± 0.15 °C) is attached here, e.g. with a piece of infusion tube. The examination is carried out at a setting of 38.5 °C. The measured value is read once it has stabilized. The difference must not exceed ± 0.5 °C. If there is a difference of greater than ± 0.5 °C from the control temperature, there is a malfunction.

CHECKING THE LOW TEMPERATURE INFORMATION SIGNAL (BW 685 / BW 685 S)

Preheat the device to 38.5 °C, then disconnect the mains plug. Hold down the ▼ button and reconnect the mains power plug. After the beep, release the ▼ button. Press the ⏻ button. The device is now in an operating mode in which all alarms and signals are active but the heating is switched off. The BW 685 / BW 685 S now slowly cools down. When the temperature drops below the 36.5 °C threshold, the low temperature information signal should trigger.
For reasons of safety, there is a short beep every second in this operating mode, and the STANDBY indicator (Fig. 1/4) flashes. If the low temperature information signal is not triggered, there is a malfunction.

CHECKING THE HIGH TEMPERATURE ALARM (BW 685 / BW 685 S)

Preheat the device to 41 °C and wait for the temperature to stabilize, then disconnect the mains plug. Hold down the ▲ button and reconnect the mains power plug. After the beep, release the ▲ button. Press the ⏻ button. The device now slowly heats up to a target temperature of 42.5 °C. Observe the temperature display carefully. The high temperature alarm should be triggered at a temperature of 42 °C.
For reasons of safety, there is a short beep every second in this operating mode, and the STANDBY indicator (Fig. 1/4) flashes. If the high temperature alarm is not triggered, there is a malfunction.

VISUAL CHECK OF GENERAL CONDITION (BW 685 / BW 685 S)

The device should be checked for mechanical damage (general condition) and for the completeness of the stickers, particularly the device label on the reverse. If there is mechanical damage to the device which could cause risk of injury or impair its functionality, this constitutes a malfunction.

ELECTRICAL SAFETY (BW 685 / BW 685 S)

All relevant electrical safety data should be checked, particularly the earth conductor resistance and leakage current. If a measured value is outside of the specified tolerance, there is a malfunction.

VISUAL CHECK OF GENERAL CONDITION (TubeFlow)

The TubeFlow to be examined must first be subject to a visual check. 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.

CHECKING THE CONTROL TEMPERATURE (TubeFlow)

The temperature check must be performed at an ambient temperature of 22 °C ± 1 °C. During the measurement, the heating device must not be exposed to sunlight, draughts or other conditions which could affect the measurement.

The TubeFlow heating device must be attached in its intended position according to these operating instructions. The head of the TubeFlow is inserted into the fixing clamp. The end of the TubeFlow is inserted into the groove on the fixing clamp. A suitable digital thermometer, as well as a temperature sensor with a diameter of 5 mm, is required for the temperature measurement.

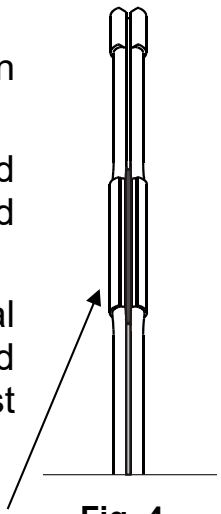
Insert the temperature sensor into the heating profile at the end of the TubeFlow, centrally with respect to the position of the bulge (see **Fig. 4**).

At least 20 cm of the sensor line must be inserted into the heating profile.

Switch the BW 685 S on and check whether the malfunction detection is checked.

Wait for 45 minutes. After this time, the TubeFlow has reached its preset temperature of 39 °C and is evenly heated throughout.

Now connect the temperature sensor to the digital thermometer. The measured temperature value is now entered into the inspection protocol. The measured temperature must be 39 °C ± 1.5 °C.



Temperature sensor

Fig. 4

OVERTEMPERATURE CONTROL (TubeFlow)

An independent temperature sensor is installed in the TubeFlow warmer. The electronic system continuously monitors the sensor. The heating is permanently switched off if a certain predefined temperature is exceeded. In order to examine this overtemperature activation, a calibrated circulation thermostat which can be set to temperatures between 39 °C and 45 °C is required.
Switch the circulation thermostat on. Set a temperature of 40 °C on the circulation thermostat.
Insert the end of the heating profile of the TubeFlow into the water bath of the circulation thermostat, further than the additional insulation.
Start up the TubeFlow. Wait until a temperature of 40 °C has been reached in the circulation thermostat.

Increase the temperature on the circulation thermostat in steps of 0.5 °C, and wait until the set temperature has been reached in the circulation thermostat.
The overtemperature function should be triggered at 42 °C ± 1.5 °C. As soon as the trigger temperature has been reached, the LED on the control unit lights up yellow.
The temperature set on the circulation thermostat when the overtemperature alarm was triggered corresponds to the trigger temperature of the overtemperature protection of the TubeFlow.
If the temperature value is outside of the tolerance range, the TubeFlow must be returned to the manufacturer for recalibration.

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 and its accessories in accordance with the applicable local regulations.

11 ELECTROMAGNETIC COMPLIANCE LEVELS

11.1 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, Class A
Voltage fluctuations and flicker	IEC 61000-3-3, Complies

11.2 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°

12 MANUFACTURER'S DECLARATION

The Blood and Infusion Warmer BW 685 / BW 685 S and the tube warmer TubeFlow, as well as BIEGLER consumables and associated materials (extension tubes) are medical products as defined by Directive 93/42/EEC.

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

CE 0123

13 SYMBOLS

CE 0123 Certifies compliance with the Directive 93/42/EEC


Observe the directions for use


Do not dispose of this product as unsorted municipal waste


Button to increase the temperature setting


Button to decrease the temperature setting


High temperature or device error alarm

IPX4 IP-classification (IEC 60529): IPX4


Degree of prot. against electric shock: Type BF, defibrillation-proof


AC voltage


On / Standby button


Protective earthing


Potential equalization

Serial number


Manufacturer


Date of manufacture


High Temperature


Low Temperature


Humidity limitation


Protect from heat and radioactive sources


Temperature limit


Keep dry


Fragile, handle with care

Catalogue number

Symbols for optional tube warmer TubeFlow


Operation


Malfunction


Direct current

Symbols for accessories

Sterile by ethylene oxide

Designation of the batch


Expiration date


One-time use only

14 OPERATING AND STORAGE CONDITIONS

The blood and infusion warmer BW 685 / BW 685 S shall be used in these environments:

- Medical facilities incl. corporate investigation rooms and family doctors' surgeries
- Hospital bedside (general and intensive care unit)
- Monitoring area

Permissible environmental conditions for the device 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

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

15 TECHNICAL DATA

Device:	Blood and Infusion Warmer
Type designation:	BW 685 / BW 685 S
Operating voltage:	220 V- 240 V | 50/60 Hz
Power consumption:	max. 360W
Supply type:	mains operated
Protection class:	I
Degree of prot. against electric shock:	Type BF, defibrillation-proof
IP-classification (IEC 60529):	IPX4
Classification (93/42/EEC):	IIb according to Rule 9
Operation mode:	Continuous operation
Control temperature:	37 – 41 °C, in 0.5 °C steps
Over temperature switch-off:	42 °C / 42.5 °C / 45°C ± 3 °C
Audio alarm frequency:	3.4 ± 0.5 kHz; sound pr. level: min 62 dBA
Low temp. information signal:	250 ms / 15 s; sound pr. level: min 62 dBA
Max. system pressure:	300 mmHg
Software Version:	8.0
Fuses:	primary 2 x 1.6 AT, sec. 500 mAT
Dimensions:	W x H x D 228 x 228 x 132 mm
Weight of BW 685:	1.9 kg
Weight of BW 685 S:	2.2 kg

(Optional)

Device:	Tube Warmer
Name of model:	TubeFlow
Control temperature:	39 °C
Dimension:	Length 1340 mm

Applied part: venous access (not included) and parts of the consumables.

Fig. 5 Applied part depiction

16 MANUFACTURER

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