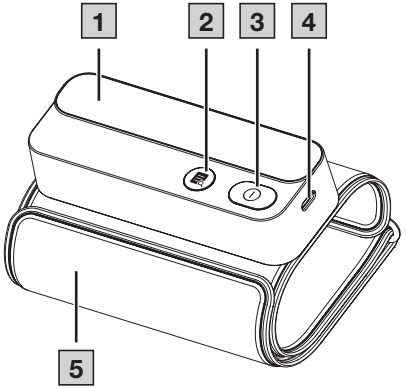
beurer

BM 59

EN Upper arm blood pressure monitor
Instructions for use

CE 0483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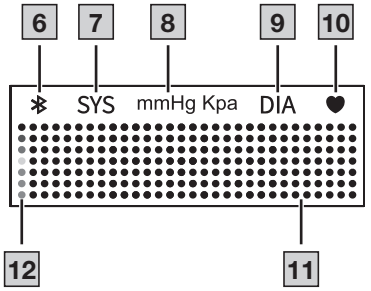
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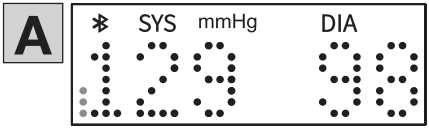
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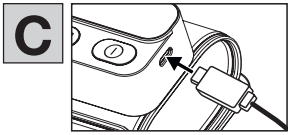
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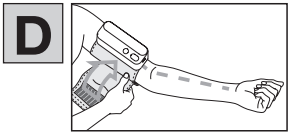
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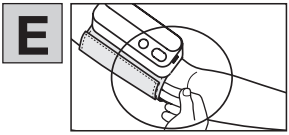
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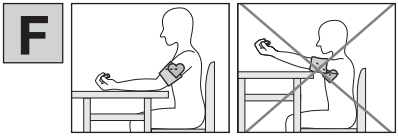
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ENGLISH

Read these instructions for use carefully. Observe the warnings and safety notes. Keep these instructions for use for future reference. Make the instructions for use accessible to other users. If the device is passed on, provide the instructions for use to the next user as well.

CONTENTS

1. INCLUDED IN DELIVERY

Check that the exterior of the cardboard delivery packaging is intact and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed.
If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.

- Upper arm blood pressure monitor
- Upper arm cuff (22 – 42 cm)
- Battery, see chapter “Technical specifications”
- Quick guide
- Instructions for use
- Blood pressure pass
- USB-C cable

2. SIGNS AND SYMBOLS

The following symbols are used on the device, in these instructions for use, on the packaging and on the type plate for the device:

⚠WARNING

Indicates a potentially impending danger. If it is not avoided, there is a risk of death or serious injury.

⚠CAUTION

Indicates a potentially impending danger. If it is not avoided, slight or minor injuries may result.

NOTICE

Indicates a potentially harmful situation. If it is not avoided, the system or something in its vicinity may be damaged.

	**Product information** Note on important information
	**Observe the instructions** Read the instructions before starting work and/or operating devices or machines
	The electronic device must not be disposed of with household waste
	Do not dispose of batteries containing harmful substances with household waste
	Manufacturer
CE	**CE labelling** This product satisfies the requirements of the applicable European and national directives.

	Marking to identify the packaging material. A = material abbreviation, B = material number: 1–7 = plastics, 20–22 = paper and cardboard
	Separate the product and packaging elements and dispose of them in accordance with local regulations.
	Protection class II device
IP22	Device protected against foreign objects ≥ 12.5 mm and against water dripping at an angle
⎓	**Direct current** The device is suitable for use with direct current only
UDI	Unique device identifier (UDI) Identifier for unique product identification
LOT	Batch designation
REF	Item number
SN	Serial number
MD	Medical device
	Type BF applied part
	Temperature range

	Humidity range
	Atmospheric pressure limitation
#	Type number
	Date of manufacture
	Importer symbol
	Protect from rain and keep dry
	Manufacturer in accordance with the Packaging Regulation (PPWR)

3. INTENDED USE

Intended Purpose

The blood pressure monitor (hereinafter, device) is intended for the fully automatic, non-invasive measurement of arterial blood pressure and pulse values on the upper arm.
It is designed for self-measurement by adults in a domestic environment.

Intended Users

The blood pressure measurement is suitable for adult users whose upper arm circumference is within the range printed on the cuff.

Clinical benefits

The user can record their blood pressure and pulse values quickly and easily using the device. The recorded values are classified according to internationally applicable guidelines and evaluated graphically. Furthermore, the device can detect any irregular heart beats that occur during measurement and inform the user via a symbol in the display. The device saves the recorded measurements and can also output average values of previous measurements. The recorded data can provide healthcare service providers with support during the diagnosis and treatment of blood pressure problems, and therefore it plays a part in the long-term monitoring of the user's health.

Indications

In the event of hypertension or hypotension, the user can independently monitor their blood pressure and pulse values at home. However, the user does not need to be suffering from hypertension or arrhythmia in order to use the device.

Contraindications

⚠WARNING

- Do not use the blood pressure monitor on newborns, children or pets.
- Persons with reduced physical, sensory or mental capabilities should be supervised by a person responsible for their safety and receive instructions from that person on how to use the device.
- Do not use the device if you are using electrical implants (e.g. pacemakers).
- Do not use the device if you have metal implants.
- Do not use the cuff on people who have undergone a mastectomy.

- Do not place the cuff over wounds as this may cause further injury.
- Make sure that the cuff is not placed on an arm whose arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular therapy, or an arteriovenous (AV) shunt.
- Do not use the device on people with allergies or sensitive skin.

Undesirable side effects

- Skin irritation
- Negative influence on blood circulation

4. WARNINGS AND SAFETY NOTES

General warnings

⚠ WARNING

- The measurements you take are for your information only – they are not a substitute for a medical examination! Discuss your measured values with your doctor and never make your own medical decisions based on them (e.g. regarding medicine doses).
- The device is only intended for the purpose described in these instructions for use. The manufacturer is not liable for damage resulting from improper or incorrect use.
- Using the blood pressure monitor outside your home environment or while on the move (e.g. while travelling in a car, ambulance or helicopter, or while undertaking physical activity such as playing sport) can influence the measurement accuracy and cause incorrect measurements.
- Cardiovascular diseases may lead to incorrect measurements or have a detrimental effect on measurement accuracy.
- If you have any of the following conditions, it is essential you consult your doctor before using the device: Cardiac arrhythmia, circulatory problems, diabetes, pregnancy, pre-eclampsia, hypotension, chills, shaking.
- Do not use the device at the same time as other medical electrical devices (ME equipment). This could cause the measuring device to malfunction and/or an inaccurate measurement.
- Do not use the device outside of the specified storage and operating conditions. This could lead to incorrect measurements.
- Note that when inflating the cuff, the functions of the limb affected may be impaired.
- Do not perform measurements more frequently than necessary. Due to the restriction of blood flow, some bruising may occur.
- Blood circulation must not be stopped for an unnecessarily long time during the blood pressure measurement. If the device malfunctions, remove the cuff from the arm.
- Place the cuff on the upper arm only. Do not place the cuff on other parts of the body.
- Small parts may present a choking hazard for small children if swallowed. They should therefore always be supervised
- Do not drop, step on or shake the device.
- Do not disassemble the device as this may cause damage, faults and malfunctions.
- To rule out a difference between sides, the measurement should initially be taken on both arms.
- Never operate the device during maintenance work. Maintenance work includes maintenance, inspection and repair.

General precautions

⚠ CAUTION

- The blood pressure monitor is made from precision and electronic components. The accuracy of the measurements and service life of the device depend on its careful handling.
- Protect the device and its mains adapter from impacts, humidity, dirt, major temperature fluctuations and direct sunlight.
- Ensure the device is at room temperature before taking a measurement. If the measuring device has been stored close to the maximum or minimum storage and transport temperatures and is placed in an environment with a temperature of 20 °C, it is recommended that you wait approx. 2 hours before using the measuring device.
- Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.
- Avoid any mechanical restriction, compression or bending of the cuff line.

Notes on handling batteries

⚠ WARNING

- **Risk of explosion! Risk of fire!** Failure to comply with the points mentioned can result in personal injury, overheating, leakage, venting, breakage, explosion, or fire.
- Always use the correct or supplied charging cable/charger/mains adapter for charging.
- Avoid continuous charging or overcharging. Unplug the charger when charging is complete.
- Only use with the battery charger Mains part (EU) (072.78) / Mains part (UK) (072.79).
- Charge the device under supervision, paying attention to any heat generated, deformation, or release of gases. If in doubt, stop charging.
- If the device is not going to be used for a long period of time: Recharge the battery at regular intervals to prevent deep discharge. Deep discharge can permanently reduce capacity and can mean that the battery can no longer be reliably charged.
- If batteries/charging cables/chargers are defective, stop using them and dispose of them properly as soon as possible (see chapter on disposal).
- Do not use modified or damaged batteries/charging cables/chargers.
- Always select the correct battery type.
- Do not throw the device or batteries into a fire.
- Never forcibly discharge, heat, disassemble, open, crush, deform, encapsulate, modify, or knock the device or batteries.
- Never short-circuit batteries or the connections of the battery-powered device.
- Protect the device or batteries from direct sunlight, rain, heat, and water.
- Exposure of batteries to an environment with extremely high temperatures or an extremely low air pressure may result in explosion or leakage of flammable liquids and gases.
- Insert the batteries, taking polarities (+ / -) into account.
- If fluid from a battery comes into contact with your skin or eyes, wash the affected areas with water and seek medical assistance.

NOTICE

- This device contains a battery that may only be replaced by specialist personnel.

- After the device has not been used for a long period of time: Fully charge the battery before reuse.
- Only open the device if the battery needs to be replaced.
- Further information on interchangeability can be found on our website under Service / Instructions for use.

Notes on electromagnetic compatibility

⚠ CAUTION

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The device may not be fully usable in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. If, however, it is necessary to use the device in the manner stated, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of accessories and/or replacement parts other than those specified or provided by the manufacturer of this device could lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.
- Keep portable RF communication devices (including peripheral equipment, such as antenna cables or external antennas) at least 30 cm away from all device parts, including all cables included in delivery.
- Failure to comply with the above can impair the performance of the device.

5. DEVICE DESCRIPTION

The associated drawings are shown on page 2.

1 LED display
2 Memory button
3 START/STOP button
4 Type-C charging port
5 Cuff

Information on the display

6 Symbol for *Bluetooth*® connection
7 Symbol for systolic blood pressure
8 Units of measurement
9 Symbol for diastolic blood pressure
10 Pulse symbol
11 Display of values / Battery level indicator / Cardiac arrhythmia symbol
12 LED risk indicator

6. USAGE

6.1 Initial use

Charging the blood pressure monitor

If 1 appears on the display, you must charge the device. We recommend that you fully charge the device before initial use. Connect the device to a USB power supply using the supplied USB-C cable (see Figure C). Pressing a button will show you the current charge level on the battery level indicator. While the battery is charging, will flash; once the battery is fully charged, will be displayed. The display switches off after

a few seconds. To display the charge level again, briefly press the ⏻.

The device cannot be used whilst it is being charged.

Please connect the device to the “beurer HealthManager Pro” app before taking the first measurement. Follow the instructions in the app on how to integrate it.

6.2 Establishing a *Bluetooth*® connection

- Download the free “beurer HealthManager Pro” app from the Apple App Store or Google Play.

  Click here for the „beurer HealthManager Pro“ app *

- Activate *Bluetooth*® in your smartphone’s settings.
- Start the app.
- Select BM 59 in the app and follow the instructions.

List of system requirements and compatible devices

* This product satisfies the requirements of the applicable European directives.

6.3 Connection to the “beurer HealthManager Pro” app

In order to set the correct time on the device, it must regularly connect to the “beurerHealthManager Pro” app:

- Requirement: *Bluetooth*® connection established (see Section 6.2 Establishing a *Bluetooth*® connection).
- No time on the device: “APP” flashes on the display.
- No successful *Bluetooth*® connection: “NO TIME” is shown in the display.
- *Bluetooth*® connection successful: Time is being synchronized.
- If the process was successful, “TIME” is displayed on the screen.

To skip the time setting, press ⏻. “NO TIME” appears on the display. Please note that any subsequent measurements may appear with an incorrect time in the “beurer HealthManager Pro” app.

6.4 Before the blood pressure measurement

General rules when measuring your own blood pressure

- In order to generate an informative profile of changes in your blood pressure that can be used for comparisons, you should measure your blood pressure regularly and always at the same time of day.
  Measure your blood pressure twice a day: once in the morning after getting up and once in the evening.
- Always perform the measurement when you are sufficiently physically rested. Avoid taking measurements at stressful times.

- Do not take a measurement within 30 minutes of eating, drinking, smoking or exercising.
- Before the initial blood pressure measurement, make sure always to rest for about 5 minutes.
- If you want to take several measurements in succession, always make sure that you leave 5 minutes between each measurement.
- Repeat the measurement if you have doubts about the measured value.

Attaching the cuff

You can measure your blood pressure on either arm. Some deviations between the values in the right and left arm are perfectly normal. Always perform the measurement on the arm with the higher blood pressure values. Consult your doctor about this before starting self-measurement.

- Always measure your blood pressure on the same arm.
- The blood pressure measurement is suitable for adult users whose upper arm circumference is within the range printed on the cuff (22 to 42 cm).
- Before taking the measurement, check the fit using the index mark described below.
- Expose your upper arm. The circulation of the arm must not be hindered by tight clothing or similar.
- The cuff must be placed on the upper arm so that the bottom edge is positioned 2-3 cm above the elbow and over the artery **D**.
  The cuff should be fastened so that two fingers fit under the cuff when it is closed **E**.

Adopting the correct posture

- Sit in a comfortable upright position when taking the blood pressure measurement. Lean back so that your back is supported.
- Place your arm on a surface **F**.
- Place your feet flat on the ground next to one another.
- The cuff must be level with your heart.
- Stay as still as possible during the measurement and do not talk.

6.5 Taking a blood pressure measurement

Requirement: cuff attached, user selected.

Measurement

1. Press ⏻. All display elements are briefly displayed. The cuff inflates itself automatically. The measurement process starts. ♥ is displayed as soon as a pulse is detected.
   To cancel the measurement, press ⏻.
2. Systolic pressure, diastolic pressure **A** and pulse **B** measurements are displayed alternately.
   "Er" is displayed if the measurement could not be performed properly. In this case, please refer to the "Troubleshooting" section.
   If necessary, re-attach the cuff after 1 minute.
   The device switches off automatically after approx. 30 seconds.

6.6 Evaluating the results

General information about blood pressure

- Blood pressure is the force with which the bloodstream presses against the arterial walls. Arterial blood pressure constantly changes in the course of a cardiac cycle.
- Blood pressure is always stated in the form of two values:
  - The highest pressure is the **systolic blood pressure**. This occurs when the heart muscle contracts and blood is pumped into the blood vessels.
  - The lowest pressure is the **diastolic blood pressure**. This occurs when the heart muscle has completely relaxed again and the heart is filling with blood.
- Fluctuations in blood pressure are normal. Even during repeat measurements, there may be considerable differences between the measured values. One-off or irregular measurements therefore do not provide reliable information about the actual blood pressure. Reliable assessment is only possible when you perform the measurement regularly under comparable conditions.

Cardiac arrhythmia

The device can identify heart rhythm abnormalities during the blood pressure measurement. If is displayed after the measurement, this indicates that an irregularity has been detected in your pulse.

Repeat the measurement if is displayed.

When assessing your blood pressure, only use the results that have been recorded without any irregularities in your pulse.

Consult your doctor if is displayed frequently. Only they can determine, through an examination, whether there is an abnormality.

LED risk indicator

Measured blood pressure value range		Classification	Risk indicator colour
Systolic (in mmHg)	**Diastolic** (in mmHg)		
≥ 180	≥ 110	Stage 3 high blood pressure (severe)$_1$	Red
160 – 179	100 – 109	Stage 2 high blood pressure (moderate)$_1$	Orange
140 – 159	90 – 99	Stage 1 high blood pressure (mild)$_1$	Yellow
130 – 139	85 – 89	High normal$_1$	Green
120 – 129	80 – 84	Normal$_1$	Green
< 120	< 80	Optimal$_1$	Green
< 90	< 60	Low blood pressure$_2$	Orange

$_1$Source: WHO, 1999 (World Health Organization)

$_2$Source: National Health Service, 2023

The LED risk indicator **12** indicates which category the recorded blood pressure values fall into. If the measured values are in two different categories (e.g. systolic pressure in the “high normal” range and diastolic pressure in the “normal” range), the LED risk indicator always indicates the higher range – “high normal” in the example described.

Note that these default values are for general guidance only, as individual blood pressures may vary.

Please note that self-measurement at home usually results in values lower than those recorded at a doctor’s surgery. Consult your doctor at regular intervals. Only they are able to give you personal

target values for controlled blood pressure, particularly if you are receiving medical therapy.

Low blood pressure

⚠ WARNING

Low blood pressure (hypotension) can be a health hazard and cause dizziness or fainting. Blood pressure is considered low if systolic and diastolic pressure are below 90/60 mmHG (source: National Health Service, 2023).
Seek medical attention if you suddenly suffer from low blood pressure.

6.7 Transfer of measured values via *Bluetooth*®

- To establish a *Bluetooth*® connection to the "beurer HealthManager Pro" app, follow the instructions under "Establishing a *Bluetooth*® connection".
- To transfer the measured values via *Bluetooth*®, the device connects to the "beurer HealthManager Pro" app. ✱ will flash during this process.
- Once the device has successfully connected to the app, ✱ will be shown permanently on the display.
- Measured values are transferred automatically.

6.8 Displaying and deleting measured values

The results of each successful measurement are stored. If there are more than 240 measurements, the oldest measurements are deleted.
With the device switched off, press 🔍.
Bluetooth® activated ✱: Measurements are transferred automatically.

Individual measured values

1. Press 🔍. All measurements are shown one after the other on the display, starting with the latest measurement. Press 🔍 to return to the previous measurement. Press ⏻ to display the next measurement.
2. To switch the device off again, press and hold ⏻ for 2 seconds.

ⓘ The calculation of the average value and the date and time function are only displayed in the app.

Deleting measured values

1. To delete all of the user's saved measured values, press 🔍 with the device switched off.
2. Press and hold 🔍 for approx. 3 seconds.
   "no" appears on the display. All values are deleted.

7. CLEANING AND MAINTENANCE

- Clean the device and cuff carefully using only a slightly damp cloth.
- Do not use any cleaning solutions or solvents.
- Under no circumstances hold the device or cuff under water, as this can cause liquid to enter and damage the device and cuff.
- If you store the device and cuff, do not place heavy objects on the device and cuff.

8. ACCESSORIES AND/OR REPLACEMENT PARTS

Accessories and/or replacement parts are available at www.beurer.de, under "Service". Please state the corresponding order number.

Designation	Item number and/or order number
USB-C cable	110.046
Mains part (EU)	072.78
Mains part (UK)	072.79

9. TROUBLESHOOTING

Error message	Possible cause	Solution
Er 1	Unable to record a pulse.	Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement.
Er2	The measured blood pressure is outside the measurement range.	
Er3	There is a pneumatic system error. The cuff is not attached correctly.	Repeat the measurement. Ensure that you do not move or speak.
Er4	An error occurred during the measurement.	Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement.
Er5	The inflation pressure is higher than 295 mmHg.	Please take another measurement to check whether the cuff can be correctly inflated.
Er6	There is a system error.	If this error message appears, please contact Customer Services.
Er7	There are problems with the connection between the smartphone/tablet and the app.	Switch off the main unit, close the app and first deactivate *Bluetooth*® on your smartphone/tablet before reactivating the function. Try to establish the connection again.
	Battery is almost empty.	Charge the battery.

10. DISPOSAL

Repairing and disposing of the device

- Do not repair or modify the device yourself. Proper operation can no longer be guaranteed in this case.
- Repairs must only be carried out by Customer Services or authorised retailers. Check the battery first before making a complaint.

- The device must not be disposed of with household waste. Dispose of the device at a suitable local collection or recycling point in your country. Dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment). Please contact the local authorities responsible for waste disposal if you have any questions regarding disposal.

Battery disposal

- The empty, completely discharged batteries must be disposed of in specially designated collection boxes, at recycling points or at electronics retailers. You are legally required to dispose of the batteries.
- The codes below are printed on batteries containing harmful substances:
  - Pb = battery contains lead
  - Cd = battery contains cadmium
  - Hg = battery contains mercury

11. TECHNICAL SPECIFICATIONS

Type	BM 59
Measurement method	Oscillometric, non-invasive blood pressure measurement on the upper arm
Measurement range	Cuff pressure 0–295 mmHg, systolic pressure 57–255 mmHg, diastolic pressure 25–195 mmHg, pulse 40–199 beats/minute
Display accuracy	Systolic pressure ±3 mmHg, diastolic pressure ±3 mmHg, pulse ±5% of the displayed value
Measurement uncertainty	Max. permissible standard deviation according to clinical testing: systolic pressure 8 mmHg, diastolic pressure 8 mmHg
Memory	1 x 240 memory spaces
Dimensions	L 125 mm x W 48 mm x H 28 mm
Weight	Approximately 225 g (with battery and cuff)
Cuff size	22 to 42 cm upper arm circumference
Operating conditions	+5 °C to +40 °C, 15% – 90% relative humidity, 700–1060 hPa ambient pressure
Storage and transport conditions	-20 °C to +55 °C, 10 % – 93% relative humidity (non-condensing)
Power supply	Charge: 5V ⎓ 1A Li-ion rechargeable battery, 3.7 V
Battery life	For approx. 60 measurements depending on blood pressure and inflation pressure levels as well as the number of *Bluetooth*® connections
Product life cycle to be expected	Information on the life cycle of the product can be found at beurer.com
Classification	Internal power supply, IP22 no AP or APG, continuous operation Blood pressure: Application part, type BF

Data transfer via *Bluetooth®* wireless technology	The device uses *Bluetooth®*, Frequency band 2400–24835 MHz, max. transmission power 8 dBm

The serial number is located on the device or in the battery compartment.
We reserve the right to make technical changes to improve and develop the product.

- This device conforms with the European standard EN 60601-1-2 (Group 1, Class B, in accordance with CISPR-11, IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-7, IEC 61000-4-8, IEC 61000-4-11) and is subject to particular precautions with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this device.
- The device complies with Regulation (EU) 2017/745 of the European Parliament and of the Council for medical devices as well as the respective national regulations and the standard IEC 80601-2-30 (Medical electrical equipment Part 2-30 – Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers).
- The accuracy of this blood pressure monitor has been carefully checked and developed with regard to a long useful life. If the device is used for commercial medical purposes, it must be regularly tested for accuracy by appropriate means. Precise instructions for checking accuracy may be requested from the service address.
- We hereby confirm that this product complies with the European RED Directive 2014/53/EU. The CE Declaration of Conformity for this product can be found at: https://www.beurer.com/conformity

12. GUARANTEE/SERVICE

Further information on the guarantee and guarantee conditions can be found in the guarantee leaflet supplied.

Notification of incidents
For users/patients in the European Union and identical regulation systems, the following applies: If during or through use of the product a major incident occurs, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which the user/patient is located.

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