IEM®

Tel-O-Graph BT

Instructions for Use EN

Tel-O-Graph® BT plus
Blood pressure monitor

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician

CE 0044

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1 Introduction

Thank you for choosing the Tel-O-Graph® BT upper-arm blood pressure monitor.

Read this operating manual carefully before use and keep it in a suitable place so that the information is available when required.

The Tel-O-Graph® BT is a fully automated blood pressure and pulse monitor that enables automatic transmission by means of a Bluetooth®.

The Tel-O-Graph® BT can additionally record the pulse wave form of the pulse, and this information is transmitted alongside the blood pressure.

A licence key is and the Hypertension Management Software Client Server software (HMS CS) is required to perform a pulse wave analysis (see HMS CS operating manual). Various forms of pulse wave analysis can be enabled at any time.

The Tel-O-Graph® BT can be integrated in tele-monitoring systems that may involve different products for data transmission and storage. Such products, and the data base used to store and assess the blood pressure readings is not part of the Tel-O-Graph® BT, but is within the responsibility of the care provider/physician that you have allowed to monitor your blood pressure readings. You may not have direct access to the database, and need to contact the care provider/physician, if you have any question related to the stored data.

This operating manual explains the blood pressure monitor and accessories in the order in which you will operate the monitor and also use later.

If you have any questions about our services or products, feel free to contact us.

Pulse Wave Analysis (PWA) is not available in the USA.

1.1 Clinical Validation

The accuracy of the device's measurements has been validated in accordance with ISO 81060-2:2013.

1.2 CE Mark

The Tel-O-Graph® BT meets the requirements of the

- 93/42/EEC (MDD),
- 2014/53/EU (RED),
- 2011/65/EU (RoHS) guidelines

and bears the CE mark.

IEM GmbH hereby declares that the Tel-O-Graph® BT corresponds to the 2014/53/EU (RED) guideline.

The complete text of the EU declaration of conformity is available at the following website address: https://www.iem.de/doc/

1.3 Accessories

Medical accessories

- Blood pressure cuff "S" (Arm circumference:20-24 cm (7.9-9,5 in))
- Blood pressure cuff "M" (Arm circumference: 24-32 cm (9.5-12.6 in))
- Blood pressure cuff "L" (Arm circumference: 32-38 cm (12.6-15.0 in))
- Blood pressure cuff "XL" (Arm circumference: 38-55 cm (15.0-21.7 in)
- HMS CS

General accessories

- Batteries (4x, AA, alkaline)
- USB-Bluetooth®-Adapter
- IEM set pouch

2 Instruction Notes

2.1 Intended Use

The Tel-O-Graph® BT is intended for the measurement of blood pressure and pulse on the upper arm in adults.

The blood pressure monitor is suitable for individuals with an arm circumference of 20-55 cm (7.9-21.7 in) when used with the corresponding monitor cuff size.

The data measured is automatically transmitted.

The Tel-O-Graph® BT with PWA-license additionally records pulse waveform data.

Pulse Wave Analysis (PWA) is not available in the USA.

WARNING

Self-diagnosis and self-treatment on the basis of the results is dangerous!

- Do not undertake any treatment and/or take medication as a result of the measured values without consulting your physician.
- Follow your physician's instructions.

2.2 Improper Use

The blood pressure measuring device must not be used for newborn infants or children under the age of 12, must not be used for surgery, must not be used near a magnetic resonance imaging scanner or other strong magnetic field, and must not be used for monitoring patients within a clinical context or during their transport.

The blood pressure measuring device must be kept out of the reach of unsupervised children and must not be used on people deemed legally incompetent.

It must not be used for any other purpose than the blood pressure measurement procedure described here and must not be used in vehicles or aircraft!

The Tel-O-Graph® BT is not designed to be used on pregnant women or in cases of pre-eclampsia.

Note

- There are currently no clinical studies available on the use of pulse wave analysis in children. Accordingly, there is no confidence interval for persons under the age of 20 years.
- If you are taking medication to alter blood clotting, consult your physician before using the blood pressure monitor.

EN

2.3 Essential Performance

The essential performance features are defined as blood pressure measurement with:

- Error tolerances of the pressure gauge and measurement results within the required limits according to IEC 80601-2-30.
- Maximum change value in blood pressure determination according to IEC 80601-2-30.
- Power delivery (pressure supply to the cuff) within the set limits according to IEC 80601-2-30.
- An error is issued in the event that successful blood pressure measurement is impossible.

The blood pressure monitor does not emit an alarm in the sense of IEC 60601-1-8. The blood pressure monitor is not provided to be used in conjunction with RF surgery monitors or for the clinical monitoring of patients, such as on an intensive care unit.

Basic safety means that the patient cannot be endangered by any automatic device procedure.

In the event of an unclear status or state of the blood pressure monitor, the blood pressure monitor must enter standby mode by the device releasing the air in the cuff. The cuff is not automatically pressurized, to do so, the device must be initiated manually.

3 Safety

This section explains all the safety information for the device.

Read this section carefully before using the blood pressure monitor.

Contact your physician before using the device if you are pregnant, are taking medication to alter blood clotting or if you have been diagnosed with cardiac arrhythmia, coagulation disorders or arteriosclerosis.

3.1 Explanation of the safety symbols

WARNING

Short description of the danger

This warning symbol in connection with the signal word **WARNING** indicates a possible or immediately threatening danger.

Non-adherence may lead to the mild, moderate injuries or to the most severe injuries or death.

ATTENTION

Short description of the danger

This warning symbol, in connection with the signal word **ATTENTION**, indicates possible material damage.

Non-adherence may lead to damage to the products or their accessories.

Note

The signal word **Note** indicates further information about the Tel-O-Graph® BT or its accessories.

External Reference

Indicates reference to external documents in which further information may optionally be found.

3.2 Important patient information

WARNING

Danger as a result of self-diagnosis

- Do not undertake any changes to your treatment and/or take medication due to the measured values without consulting your physician.
- Follow your physician's instructions.

WARNING

Danger of blood flow disruptions as a result of putting on and pumping up a cuff on limbs with an intra-vascular drip or intra-vascular treatment or with an arteriovenous (AV) shunt.

- If you have an intra-vascular drip or arteriovenous (AV) shunt in one of your arms do not place the .cuff at this arm.

WARNING

Danger of tissue bleeding or haematoma.

- When using the blood pressure monitor, make sure it does not impede the blood circulation in your arm.
- If you have sensitive bodily tissue, despite the correct positioning of the cuff, it can still result in tissue bleeding or haematoma.
- If you are taking medication to alter blood clotting or suffer from coagulation disorders, consult your physician before using the blood pressure monitor.

WARNING

Danger of injury as a result of allergic reactions to the cuff material

- In the event of pain or allergic reactions, remove the cuff.
- Pay attention to hygiene concerns.

WARNING

Danger of injury as a result of using unapproved accessories

- Only use accessories approved by the manufacturer and distributed by the trader or manufacturer.
- Read the respective information provided by the manufacturer before using the accessories for the first time.
- Before use, check accessories in relation to the manufacturer specifications.

WARNING

Danger of injury as a result of putting on or pumping up a cuff on an arm on the same side of the body as a mastectomy has been carried out

- Do not apply the Tel-O-Graph® BT cuff to the arm on the side where a mastectomy was performed.

WARNING

Danger of a temporary loss of function of a present electrical medical device as a result of putting on or pumping up a cuff if you are wearing a further electrical medical device for monitoring on the same limb.

- Only apply the Tel-O-Graph® BT cuff if you are not wearing any other medical electrical device on this arm.

WARNING

Danger of fluid occurrence when using the batteries incorrectly

- Liquid that escapes from the batteries due to mishandling can cause skin irritation. If you come into contact with the liquid, rinse it away with plenty of water. If the liquid comes into contact with your eyes, do not rub your eyes but instead immediately rinse them with water for 10 minutes and contact a physician without delay.

WARNING

Danger of blood flow interruptions as a result of steady cuff pressure or too frequent measuring

- Ensure the cuff hose is in the correct position and take care that the cuff hose is not knotted, pinched, kinked or stretched.
- If you notice pain, swelling, reddening or numbness in your arm, around which the cuff is placed, inform your physician. (It is expected that some mild to moderate discomfort may be experienced during a blood pressure measurement.)
- Measurement can be interrupted at any stage by pressing the button. This deflates the cuff and the device can be removed.

WARNING

Danger of strangulation by the cuff hose

- Persons (including children) who are unable to use the blood pressure monitor safely due to their physical, sensory or mental capabilities or their inexperience or lack of knowledge must not use this blood pressure monitor without supervision or instruction by a responsible person.
- The blood pressure monitor may not be used by those with limited mental competencies. (Keep out of reach.)
- Do not wrap the cuff or the cuff hose around your neck!
- The cuff must only be worn on the upper arm!
- Check the correct positioning of the cuff.
- If you notice pain, swelling, reddening or numbness in the arm around which the cuff is placed, inform your physician. (It is expected that some mild to moderate discomfort may be experienced during a blood pressure measurement.)

- Measurement can be interrupted at any stage by pressing the button. This deflates the cuff and the cuff can be removed.

WARNING

Risk of injury if used on patient groups for whom this device is not intended

- The Tel-Graph® BT is not intended for use on women who are pregnant or those with pre-eclampsia.

3.3 Important device instructions

ATTENTION

Equipment failure

- The device must not be used in the vicinity of magnetic resonance imaging apparatus or in the direct proximity of another electrical medical monitor.
- The device is not suitable for simultaneous use with high frequency surgery monitors.
- Do not drop the blood pressure monitor and do not place objects on top of it.
- Do not use the device directly adjacent to other devices or stacked with other devices, as this may result in malfunction. If operation in the manner described above becomes necessary nevertheless, this device and the other devices should be monitored to ensure that they are functioning correctly
- Use of components other than those supplied with the device may result in measurement errors, as other equipment (e.g. transformers and cables) may cause increased electromagnetic interference or have reduced electromagnetic immunity. You should therefore only use genuine IEM accessories.
- The cuff and the hose are made of a material that does not conduct electricity. They thus protect the device against the effects of discharging a defibrillator. In the event of discharging a defibrillator, the device itself must not touch the patient since the device can be damaged as a result of such a discharging and can result in the incorrect value being displayed.

ATTENTION

Warranty

- Do not open the housing of the Tel-O-Graph® BT, otherwise any warranty becomes void.

ATTENTION

Batteries

- Remove the batteries from the battery compartment when they no longer have any charge or if you do not expect to use the blood pressure monitor for a longer period of time.
- Do not throw batteries into fire and never expose them to high temperatures!
- Do not attempt to recharge the batteries. Do not attempt to open or short-circuit the batteries. There is a risk of explosion.

ATTENTION

Electric fields

- Measurements may be faulty if the device is operated in the vicinity of strong electrical fields. Do not operate the blood pressure monitor near:
  - High-voltage power lines
  - Microwave devices
- Portable and mobile RF transmitters, such as mobile phones for example, may affect the blood pressure monitor. Transmission of data via mobile communication networks may be disrupted by other devices, even if those devices comply with the applicable transmission requirements specified by CISPR. You should therefore ensure that the Tel-O-Graph® BT is at least 30 cm (12 inches) from any portable RF communications equipment.

ATTENTION

Fluid damage to the blood pressure monitor

- Liquid must not penetrate the device. If you believe that liquid has penetrated the device during cleaning or use of the blood pressure monitor, the device must no longer be used.
- If the blood pressure monitor is exposed to moisture, switch the blood pressure monitor off and remove the batteries. Immediately inform your healthcare provider/physician.

Note

This blood pressure monitor is intended for use in home healthcare environments and professional healthcare institutions, such as first aid facilities and hospitals.

4 Description of device

4.1 Blood pressure monitor

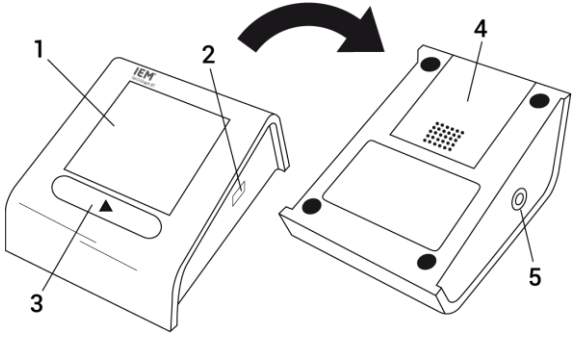


Fig. 1: Blood pressure monitor

1. Display
2. Infrared interface (for service)
3. ▶ - Button
4. Battery cover
5. Air hose socket

4.2 Blood pressure cuff

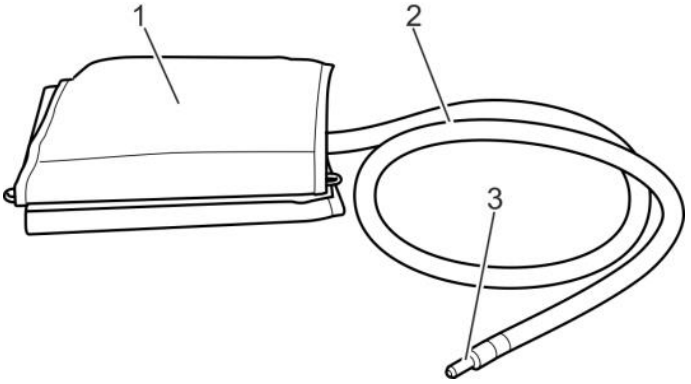


Fig. 2: Blood pressure cuff

1. Blood pressure cuff
2. Air hose
3. Air hose connection

4.3 Display

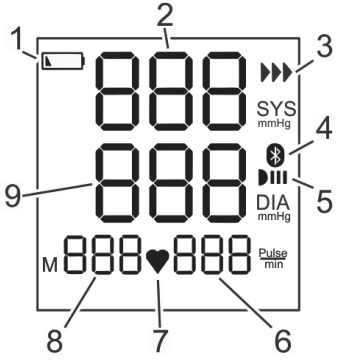


Fig. 3: Display

1. When this appears: Battery empty
2. Display of systolic (upper) value
3. Data transfer
4. Bluetooth®
5. Infrared communication
6. Number of pulse beats per minutes
7. Pulse detected
8. Number of measurement values
9. Display of diastolic (lower) value

4.4 Ambient conditions

ATTENTION

- Extreme temperatures, humidity or air pressure can influence measurement accuracy. Please follow the operating instructions.
- Extreme temperatures, humidity or altitude can affect the performance of the blood pressure monitor. Do not store the device near a fireplace or heating unit and do not expose it to intense sunlight. Do not place the device near a nebuliser or steam generator, as the condensation may damage it.

- Never store the blood pressure monitor outside a temperature range of -25 °C to +70 °C.
- Never use the blood pressure monitor outside a temperature range of +5 °C to +40 °C.
- Only store or use the blood pressure monitor at a relative air humidity (not condensing) of 15 % to 93 %.
- The blood pressure monitor takes approx. 25 minutes to go from the minimum storage temperature of -25 °C to the operating temperature of +5 °C in an ambient temperature of +20 °C.
- The blood pressure monitor takes approx. 25 minutes to go from the maximum storage temperature of +70 °C to the operating temperature of +40 °C in an ambient temperature of +20 °C.

5 Preparing the measurement

5.1 Unpacking

Note

All parts included in delivery package have been properly packed and checked for completeness and functionality. Should the product be incomplete, damaged or defect, please inform your healthcare provider/physician immediately.

WARNING

Risk of strangulation from the cuff hose and blood pressure cuff!

- Keep the blood pressure cuff out of the reach of children!

1. Unpack the entire delivery package and check that everything is present.
2. Inspect the blood pressure monitor to ensure there is no visible damage on the outside. If the blood pressure monitor is damaged, have it repaired before use.
3. Keep the packaging so that it can be safely packaged at a later date.

5.2 Inserting the batteries

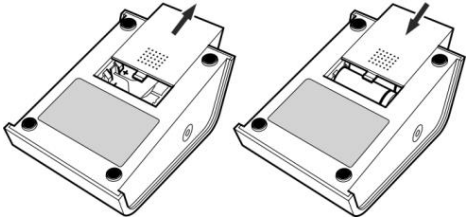


Fig. 4: Opening the battery cover

1. Open the battery cover on the underside of the blood pressure monitor.
2. Insert four batteries (AA, alkaline), with the poles aligned correctly.
3. Close the battery cover.

⇨ The blood pressure monitor switches on automatically, carries out a display test and displays the start screen. (see Fig. 5 and Fig. 6).

Note

- Insert the batteries while holding the blood pressure monitor in your hand.
- Take care not to activate the button on the front!
- By pressing the button when inserting the batteries, you will enter the pressure gauge mode used for servicing purposes. Remove the batteries and insert the batteries again.

WARNING

Make sure that all segments are displayed by the screen. Inform your healthcare provider/physician if the display is damaged.

Fig. 5: Test screen

5.3 Switching the blood pressure monitor on/off

Switching on

Press the (▶) button.

⇨ The display shows the start screen (Fig. 6).

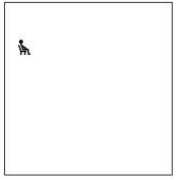


Fig. 6: Start screen

Switching off

The blood pressure monitor switches off automatically after about 5 minutes.

6 Measuring blood pressure and pulse

6.1 Before measuring

- Choose the right cuff size. The blood pressure cuff size is printed on the cuff.
- Avoid eating, smoking or any strenuous activity directly before the measurement. All these factors affect the results. Before measuring your blood pressure, you should relax in a quiet atmosphere for 5 minutes.
- Always measure on the same arm (normally your left).
- Blood pressure changes over the course of the day. Measurements are only comparable when they are measured at the same time of day and under the same circumstances.

6.2 Putting the blood pressure cuff on

WARNING

Risk of injury due to incorrectly connected air hose!

- Do not kink, knot or stretch the air hose.

WARNING

The blood pressure monitor must only be operated with the original blood pressure cuff, since otherwise there is a danger of incorrect measurements or injury!

WARNING

Danger of injury as a result of allergic reactions to the cuff material!

- In the event of pain or allergic reaction, remove the cuff.
- Follow the instructions on cleaning and disinfection (see chapter 9.2)

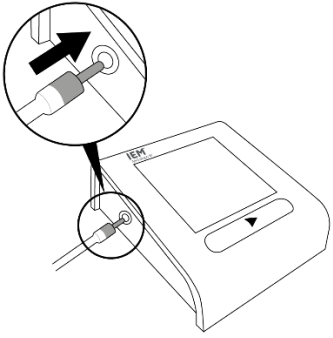


Fig. 7: Insert air hose

1. Insert the air hose connection into the air hose socket on the left side of the blood pressure monitor and place the blood pressure monitor on the table (see fig. 7).
2. Select the correct cuff size. This depends on the upper arm circumference of the person whose blood pressure you will be measuring:

Upper arm circumference	Cuff size
20 – 24 cm (7.9-9.5 in)	S
24 – 32 cm (9.5-12.6 in)	M
32 – 38 cm (12.6-15.0 in)	L
38 – 55 cm (15.0-21.7 in)	XL

Note

To obtain accurate blood pressure and pulse wave readings, it is very important that the correct cuff is used.

3. Uncover your left upper arm.

Note

The blood pressure cuff must be directly against your skin.

4. Insert your left arm into the blood pressure cuff.

Note

Blood pressure cuffs are supplied preassembled. If the cuff is not preassembled, please assemble as follows:

- Spread the cuff out with the Velcro fastening facing downwards.
- One end of the cuff features a clasp. Pass the opposite end of the cuff through the clasp, then fold it back over the clasp so that the two sides of the Velcro fastening meet.

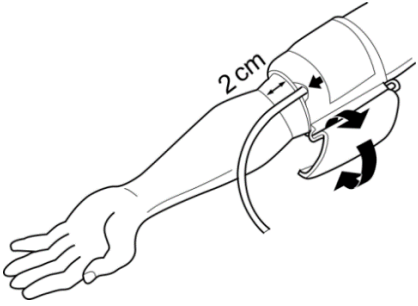


Fig. 8: Correct position of blood pressure cuff

5. Position the blood pressure cuff correctly (see Fig. 8):
   - The hose must run down the middle of the inside of your lower arm towards your middle finger.
   - The lower edge of the cuff must be about 2 cm (0.8 in) above your elbow.
   - The artery marking (arrow above the hose) must be pointing downwards on the middle of the inside of your arm.

6. Once the blood pressure cuff is positioned correctly, fasten the end with the Velcro.

Note

Place the blood pressure cuff so that there is enough room to insert your index and middle fingers between the skin and the material of the blood pressure cuff.

6.3 Correct posture

After positioning the blood pressure cuff, assume the correct posture to take the measurements (Fig. 9).

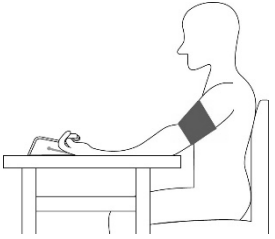


Fig. 9: Correct posture

1. Sit down comfortably on a chair to measure your blood pressure.
2. Place your elbow on a table or a solid surface.
3. Lean back in your chair.
4. Hold your arm so that the blood pressure cuff is at the same height as your heart.
5. Relax your arm and turn the palm of your hand to face upwards.
6. Place your feet flat on the floor and leave your legs uncrossed.

Note

The reading can be affected by the position of the cuff, the patient's correct posture and position, physical exertion or the patient's mental state.

6.4 Measuring

WARNING

Risk of injuries during measurement!

- Do not place the air hose around your neck.
- If you feel any pain during the measurement, stop the measurement.
- Do not place the blood pressure cuff over wounds.

1. Apply the blood pressure cuff and assume the correct posture.
2. Press the (▸) button.

⇨ The display shows the start screen(Fig. 6).

3. Press the (▸) button again to start the measurement.

⇨ The blood pressure monitor will confirm this with a short acoustic signal and briefly displays the display functions. The blood pressure cuff slowly pumps up. The fitting pressure is displayed on the display. After the initial pumping, there is additional pumping. Once the blood pressure monitor detects a pulse, the icon ♥ appears. The reading is taken as the air is let out. The blood pressure monitor confirms the end of the measuring with a short acoustic signal.

Note

Do not talk during the measurement. You can stop the measurement at any time by pressing the (▸) button.

Note

To record the pulse wave, the Tel-O-Graph® BT inflates the cuff to the diastolic blood pressure for approximately 10 seconds after measuring the blood pressure.

⇨ After the measurement, all the air is let out of the blood pressure cuff. The display shows your blood pressure and your pulse rate.

4. Remove the blood pressure cuff.

WARNING

Taking measurements too frequently can result in disruptions to blood flow!

Wait for at least 2 or 3 minutes to give your arteries time to return to their initial state.

6.5 Stopping the measurement

1. If the measurement causes you pain, press the button during the measurement.

⇨ The air is let out of the blood pressure cuff and the measurement is cancelled.

2. Remove the blood pressure cuff.

7 Transferring readings via Bluetooth®

If the blood pressure monitor is configured to transfer readings via Bluetooth®, readings will be sent to the database automatically.

All readings which have not yet been sent to the database will be sent together.

The blood pressure monitor will emit a short beep after transferring readings to confirm that the readings have been transferred successfully.

Note

In the event of problems with data transfer, please see section 12 Error messages. If problems persist, please contact your healthcare provider/physician.

Note

In the event of problems with data transfer, if there are more than 350 readings (15 readings with PWA), any new readings will overwrite the oldest readings.

7.1 Active Pairing (Bluetooth®-Modem)

Note

Pairing requires some basic familiarity with Bluetooth®. If you are not familiar with Bluetooth®, please contact your healthcare provider/physician.

The Bluetooth® connection is preconfigured, but in the event of certain rare faults you may need to create a Bluetooth® connection manually.

To do this:

1. Activate Bluetooth® on the data transfer device (Bluetooth® modem).

Note

Please consult the operating instructions for your device.

The blood pressure monitor should be no more than 10 m from the device, otherwise it may not be possible to establish a data connection.

2. Press the (▸) button.

⇨ The start screen will be displayed (see fig. 6).

3. Press and hold the (▸) button for at least 6 seconds.

⇨ The individual menu options will be displayed.

Note

After 3 seconds, the display will show **bt**; ignore this and hold down the button for another 3 seconds.

After 6 seconds, the menu automatically opens and the display will automatically show the following menu items:

- Passive pairing (PAI P)
- Infrared transmission (Ir)
- Active pairing (PAI A)
- Bluetooth® transmission (bt)
- Delete measured values (c Ir)

4. Wait until [PAI A] and the symbol ✱ are shown on the display.
5. Press the (▸) button.

⇨ The active pairing process will begin and [PAI A] and the symbols ✱ and ▸▸▸ will be shown on the blood pressure monitor display. The data transfer device will be added to the device list automatically.

Note

There should be only one other Bluetooth® device in the surrounding area.

7.2 Passive Pairing (HMS CS)

Note

Pairing requires some basic familiarity with Bluetooth®. If you are not familiar with Bluetooth®, please contact your healthcare provider/physician.

1. Wait until [PAI P] and the symbol are shown on the display.
2. Press the button.

⇨ The passive pairing process will begin and [PAI P] and the symbols and ▸▸▸ will be shown on the blood pressure monitor display.

8 Memory

8.1 Saving readings

The blood pressure monitor can save 350 blood pressure readings and 350 pulse rate readings.

If there are more than 350 readings (15 readings with PWA), the oldest data will be overwritten by the new readings.

Fig. 10: Number of readings

Note

- If a PWA licence key is activated, the storage capacity of the Tel-O-Graph® BT is reduced from 350 to 15 measurements.
- Only readings that have not yet been transferred to the database are saved.

ATTENTION

Data loss

To avoid data loss, contact your healthcare provider/physician before or when the display shows 350 measurements (15 readings with PWA).

The number of readings is shown on the display (Fig. 10).

Note

Previously transmitted data is retained in the database and is not overwritten.

8.2 Delete readings from the device

To clear the memory on your blood pressure monitor, proceed as follows:

1. Press and hold the (▶) button on the blood pressure monitor for about 6 seconds.

⇨ The display shows [PAI P].

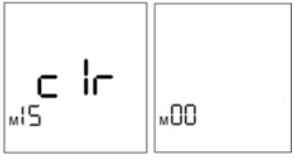


Fig. 11: Delete measurements

Note

After every 3 s, the display automatically shows the next menu item. The sequence is:

- Passive pairing (PAI P)
- Infrared transmission (Ir)
- Active pairing (PAI A)
- Bluetooth® transmission (bt)
- Delete measured values (c Ir)

Note

The Infrared transmission (IR) menu option is intended for service personnel only.

2. Wait until [c Ir] flashes on the display.
3. Press the (▸) button.

⇨ You will hear an acoustic signal and the display will be shown [c Ir] permanently.

4. Press and hold the (▸) button for more than 3 seconds.

⇨ The acoustic signal sounds 3 times and the display shows [M00].

The measurements are deleted. The device returns to standby mode and displays the start screen (see Fig. 6).

9 Cleaning and disinfection

WARNING

- When putting the blood pressure monitor on, there must no longer be any disinfectants on the blood pressure cuff!
- There are patients who have intolerances (e.g. allergies) to disinfectants or its components!

ATTENTION

- Do not immerse the cuff with balloon and blood pressure monitor in disinfectant, water or other liquids!
- If liquid nevertheless penetrates the device, switch it off immediately and send it away to be checked by the manufacturer or healthcare provider/physician!
- Do not open the housing of the Tel-O-Graph® BT, otherwise any warranty becomes void.

Note

Always observe the manufacturer's instructions on the disinfection and cleaning of these products.

9.1 Cleaning

ATTENTION

- To clean, use lukewarm water up to 30 °C at most, to which you can add a mild detergent if necessary. (Never use abrasive or solvent-based detergents as these can damage the surface of the blood pressure monitor and the cuff.)
- Do not use fabric softeners or other additives (e.g. hygiene rinses, textile deodorants). These agents can leave behind residues and damage the material.
- The cuff can be washed in the washing machine up to 30°C using a mild detergent without spin-dry.
- The cuff is not suitable for drying in a dryer.
- The Velcro strip must always be closed before washing.

Cleaning the Tel-O-Graph® BT:

To clean the blood pressure monitor, use a damp cotton wool pad with a mild laundry detergent. Do not use any other cleaning materials.

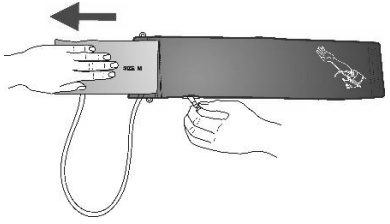
Cleaning the cuff sleeve:

To clean the cuff sleeve, use a mild fabric softener-free laundry detergent and lukewarm water. Do not use any other cleaning materials.

Cleaning the bladder and hose:

The bladder needs to be removed from the cuff sleeve before cleaning. To remove the bladder, pull the end of the cuff out of the clasp and spread the cuff out fully.

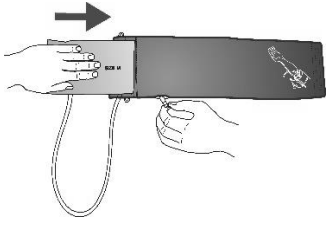
Remove the bladder and hose by pulling the bladder out of the bladder compartment via the slit provided for this purpose on the inside of the cuff.



ATTENTION

- To clean the bladder and hose, use a mild fabric softener-free laundry detergent and lukewarm water. Do not use any other cleaning materials.
- Ensure that no water gets into the bladder or hose.

Once the cuff, hose and bladder are completely dry, spread the cuff sleeve out with the Velcro fastening facing downwards. Insert the bladder into the bladder compartment via the slit provided and thread the hose through the small opening on the inside of the cuff. Ensure there are no folds or creases in the bladder.



ATTENTION

- Ensure that the bladder is the correct size for the cuff sleeve.
- The cuff sleeve size is shown on the outside of the cuff.

9.2 Disinfection

Ask your physician if and when the cuff needs to be disinfected for hygienic reasons.

IEM GmbH has tested the following means for the disinfection:

- Isopropanol (70%)
- Terralin Liquid (Manufacturer: Schülke & Mayr)

When using other disinfectants not checked by IEM GmbH, the user is responsible for the proof of use without damage.

Never use disinfectants which leave residue on the product or which are not suitable for contact with the skin.

To achieve the optimum effect, apply the disinfectant to the cuff for at least five minutes.

Always allow the agents to dry without any residues.

Make sure that any disinfectants used are washed off completely before applying the cuff.

10 Maintenance

The monitor and the cuff are calibrated by the manufacturer for a period of two years. Maintenance (metrological check) must be carried out in accordance with Directive 93/42/EEC every two years at the latest if the device is used professionally. In certain countries, this requirement may be regulated by national laws or regulations.

The metrological check comes at an additional cost and can be carried out in Germany by either **IEM GmbH**, a competent authority or by authorised maintenance services corresponding to the "Medizinprodukte-Betreiber-Verordnung" (Medical Product Operator Regulations).

Other than the metrological check, no further electromagnetic compatibility-related maintenance is required.

11 Disposal

Blood pressure monitor

The symbol on the product or packaging means that this product should not be treated as normal domestic waste, but has to be taken to a recycling point for electric and electronic devices.

You can find out more about this from your local authority, the communal disposal companies or the shop in which you bought the product.

Batteries

Batteries must not be disposed of with domestic waste. As a consumer you are legally bound to return used batteries. You can return your old batteries to official collection points within your community or everywhere batteries of that type are sold.

	Li	Battery contains lithium
	Al	Battery contains alkali
	Mn	Battery contains manganese

12 Error messages

12.1 Blood pressure measurement errors

The blood pressure monitor indicates blood pressure measurement errors and communication errors by emitting 12 short acoustic signals.

Error description	Possible cause	Remedy
Err 1	Arm moved during measurement.	Keep your arm still during the measurement (Chapter 6.3).
	Insufficient valid pulse rate detected.	Put the blood pressure cuff on again (Chapter 6.2).
Err 2	Arm moved during measurement.	Keep your arm still during the measurement (Chapter 6.3).
	The blood pressure cuff is not correctly positioned on your arm.	Check the placement of the blood pressure cuff (Chapter 6.2).
Err 3	Blood pressure beyond the measurement range.	If this notification appears continuously (or repeatedly), it is possible that the blood pressure monitor is not suitable for you. Contact your physician.
	Strong arm movement.	Keep your arm still during the measurement (Chapter 6.3).
Err 4	IR communication error	If this error message is displayed continuously (or repeatedly), contact your healthcare provider/physician or the manufacturer.

Error description	Possible cause	Remedy
Err 5 	Power pack or battery voltage too low.	Change the batteries (Chapter 5.2).
	Battery contacts are corroded.	Clean the battery contacts with a cotton cloth and a little alcohol.
Err 6	Air congestion	Check the blood pressure cuff for air congestion or a kink in the air hose. If there is a kink in the air hose, unkink it, otherwise send the blood pressure monitor to your healthcare provider/physician or the manufacturer.
	Blood pressure cuff incorrectly connected.	Connect the blood pressure cuff to the blood pressure monitor (Chapter 6.2).
	Leak in the blood pressure cuff or air hose	Replace the blood pressure cuff with the air hose.
Err 9	Residual pressure in the blood pressure cuff	Wait until the blood pressure cuff has deflated completely.
Err 10	Internal error	If this error occurs repeatedly, send the blood pressure monitor to your healthcare provider/physician or directly to the manufacturer for checking.
Abr. (Abort)	Measurement cancelled on request	Do not press this button when measuring, unless you want to abort the measuring.

12.2 Communication error

Error description	Possible cause	Remedy
Cod 1	Error during pairing	Repeat the pairing process (Chapter 7.2).
	The data transfer device is switched off	Switch the device on.
Cod 2	No Bluetooth® connection	Check that the data transfer device is switched on. If this error occurs repeatedly, contact your healthcare provider/physician.
Cod 3	Could not send readings	Take another measurement and check whether the readings are transmitted. If this error occurs repeatedly, contact your healthcare provider/physician.
Cod 4	Communication error	If this error occurs repeatedly, contact your healthcare provider/physician.
Cod 5	Invalid target data in EEPROM (memory)	If this error occurs repeatedly, contact your healthcare provider/physician.
Cod 6	Hardware communication error	If this error occurs repeatedly, contact your healthcare provider/physician.
Cod 7	Memory empty	If this error occurs repeatedly, contact your healthcare provider/physician.

13 Technical data and symbols

Technical data

The blood pressure monitor complies with the EMC directives.

The blood pressure cuff and air hose are made of a non-conductive material. This makes the device defibrillator safe.

Specification	Value	Unit
Measuring method	Oscillometric	
Blood pressure measurement range	Systolic 60 to 290 Diastolic 30 to 195	mmHg
Pulse measurement range	30 to 240	1/min
Pressure Accuracy	±2% or ±3 mmHg, whichever is greater	
Memory (without PWA)	350	Measurements
Memory (with PWA)	15	Measurements
Power supply	4-6 VDC (4x NiMH or LR6, AA)	
Dimensions (L x W x H)	151 X 108 X 57	Mm
Weight (without batteries)	334	G
Material (housing)	ABS (acrylonitrile-butadiene-styrene)	
Material (cuff)	Polyester	
IP protection class	20	
Operating temperature	+5 to +40	°C

Specification	Value	Unit
Ambient pressure	700 to 1060	hPa
Transport temperature	-25 to +70	°C
Storage temperature	-25 to +70	°C
Rel. air humidity, not condensing (operation, transport and storage)	15 to 93	%
Battery capacity	c. 500*	Measurements
Data connection	Bluetooth®	
Data transfer	Class 1 Bluetooth®	

*in the case of 2 measurements per day with quality batteries (alkaline)

Symbols

Symbol	Meaning
	4x NiMH or LR6, AA
	Manufacturer
	Date of manufacture YYYY-MM-DD
	Designation of the FCC radio authorisation

Symbol	Meaning
	CE 0044: Labelling of a medical device in accordance with directive 93/42/EEC
	Protect from rain and moisture
	MR unsafe: This product presents hazards in environments where magnetic resonance tomography is performed.
	Comply with the operating manual
	The symbol on the product or packaging means that this product should not be treated as normal domestic waste, but should be taken to a recycling point for electric and electronic devices. You can find out more about this from your local authority, the communal disposal companies or the shop in which you bought the product.
	Device is defibrillator-safe
	The device emits electromagnetic waves.
	This product has a Bluetooth® interface.
	Serial number

14 Warranty and repairs

Warranty information

IEM GmbH provides a two-year warranty on the blood pressure monitor from the date of sale. Proof of the date of sale shall be provided in the form of a properly completed warranty card or an invoice.

Faults due to material or production defects shall be remedied free of charge within the warranty period.

A warranty claim does not result in an extension of the warranty period, neither for the device nor for the replaced components.

The following are excluded from the warranty:

- All damage caused by improper handling, e.g. as a result of failing to comply with the operating manual.
- Damage resulting from maintenance or intervention by the purchaser or unauthorised third parties.
- Transport damage en route from the manufacturer to the consumer or during shipment to customer services
- Accessory parts subject to normal wear and tear (cuff, batteries, etc.)

Liability for direct or indirect consequential damages caused by the device is excluded even in the event that the damage to the device is acknowledged as a warranty case.

Any further claims, irrespective of the cause, are excluded.

IEM GmbH does not grant any warranty on the batteries provided.

ATTENTION

Do not open the casing.

- Once the device is opened, all warranties will lapse.

Repairs

If the device has functional errors, please contact our customer service department who will also inform you about shipping procedures.

15 Manufacturer's EMC guidelines

Electromagnetic interference emissions

The Tel-O-Graph® BT is intended to be operated in the electromagnetic environment specified below. Only use the Tel-O-Graph® BT in such an environment.

Measurements of interference emmisions	Compliance	Electromagnetic environment — guidelines
RF interference emissions according to CISPR 11	Group 1	The Tel-O-Graph® BT uses RF power exclusively for its internal function. Its RF emission is therefore very low and it is unlikely that any neighbouring electronic device will experience any interference.
RF interference emissions according to CISPR 11	Class B	The Tel-O-Graph® BT is suitable for use in facilities other than residential areas and those directly connected to the public supply network which also supplies buildings used for residential purposes.
RF interference emissions according to CISPR 25	Not applicable	
IEC 61000-3-2	Not applicable	
IEC 61000-3-3	Not applicable	

Elektromagnetic immunity

The Tel-O-Graph® BT is intended to be operated in the electromagnetic environment specified below. Only use the Tel-O-Graph® BT in such an environment.

Measurement of interference emissions	Test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	+/- 8kV contact discharge +/- 15kV air discharge	+/- 8kV contact discharge +/- 15kV air discharge	Floors should consist of wood or cement or ceramic tiles. If the floor consists of synthetic materials, relative humidity must be at least 30%.
RF radiated disturbances in accordance with IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Do not use wearable or portable radio equipment closer to the Tel-O-Graph® BT or its cables than the recommended safe distance. The field strength of stationary radio wireless transmitters should be lower than the compliance level at all frequencies, as shown by an on-site examination. Interference is possible in the vicinity of devices bearing the graphic symbol "non-ionising radiation".
IEC 61000-4-4		Not applicable	
IEC 61000-4-5		Not applicable	
IEC 61000-4-6		Not applicable	

Measurement of interference emissions	Test level	Compliance level	Electromagnetic environment – guidelines
Magnetic field at supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	30 A/m	Magnet fields at mains frequency should match the typical values found in business and hospital environments.
IEC 61000-4-11		Not applicable	

Manufacturer's EMC guidelines

The Tel-O-Graph® BT has been tested with the following frequencies:

Measurement of interference emissions	Test level	Compliance level
RF interference emissions according to IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz	380 - 390 MHz 27 V/m; PM 50%; 18 Hz
	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz Sinus) PM; 18 Hz	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz Sinus) PM; 18 Hz
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	704 - 787 MHz 9 V/m; PM 50%; 217 Hz
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	800 - 960 MHz 28 V/m; PM 50%; 18 Hz
	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz
	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz