Veroval[®]

8 38/38 #38:88

BPU 26

EN Upper arm blood pressure monitor

Dear custome Thank you for choosing a HARTMANN blood pressure monitor. The Veroval® BPU 26 is a quality product intended for fully automatic blood pressure measurement on the upper arm of adults and is suitable for clinical and domestic use. $Requiring \ no \ preliminary \ settings, this \ blood \ pressure \ monitor \ easily \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ inflates \ for \ simple, \ quick \ and \ automatically \ and \ automatically \ inflates \ and \ automatically \ aut$ reliable measurement of the systolic and diastolic blood pressure and the pulse rate.

The monitor also indicates if it detects an irregular heartbeat.

The blood pressure monitor can be connected to a smartphone or tablet via $\textit{Bluetooth}^{\,\circ}$. On the smartphone/tablet you can evaluate the measured values using the Veroval® medi.connect app. We wish you the best of health.

Please read these instructions for use carefully before handling the device the first time. Correctly measuring your blood pressure depends on an appropriate handling of the device. These instructions for use are designed to teach you each step in taking your own blood pressure measurements using the Veroval® BPU 26. You will be given important and useful hints to ensure that you obtain reliable results for your personal blood pressure profile. Use the monitor in accordance with the information provided in the instructions for use. Please store these instructions carefully and ensure other users can access them. Check the packaging for any damage and that the contents are complete.

Package contents: · Blood pressure monito

- · Universal upper arm cuff 4 x 1.5 V AA batteries
- Storage bag Instructions for use with warranty certificate
- 1. Device and display description
- **Blood pressure monitor** 1 Extra large LCD display
- 2 START/STOP button 3 Memory button for User 1
- 4 Memory button for User 2
- 5 Cuff connector socket 6 Battery compartment 7 Mains socket
- Cuff 8 Cuff with application instructions
- 9 Size indicator to correctly fit cuff 10 Cuff plug
- 11 Cuff tube
- Display 12 Systolic blood pressure 13 Diastolic blood pressure 14 Pulse rate
- 15 Flashes when the device is measuring and the pulse rate is detected 16 Irregular heartbeat symbol 17 Measurement OK/cuff fit check & resting indicator symbols
- 18 Atrial fibrillation (AFIB) 19 Average value (A), morning (AM), evening (PM)/memory space number
- 20 User memory 21 Battery symbol
- 22 Traffic light system for your values/progress bar 23 Bluetooth®symbol
- 24 Date and time display

2. Important information Signs and symbols



MD Medical Device



Manufacturer

Country of manufacture

Date of manufacture

LOT Batch code

REF Catalogue number SN Serial numbe

Type number

Caution: Safety note indicating possible damage to the device/accessory or a risk of injury or damage to health

Temperature limit **Humidity limitation**

† Protection against electric shock (type BF)

(

UDI Unique Device Identifier Distributor

EC REP

Authorised representative in the European Community (EC) CH REP Authorised representative in Switzerland

mporte

Direct current

Protected against solid objects with a diameter of ≥12.5 mm and against vertically falling drops of IP21

Ø Symbol for the marking of electrical and electronic equipment

Cardboard recycling code



Dispose of packaging in an environmentally responsible way



The fully automatic blood pressure monitor Veroval® BPU 26 is intended for clinical and home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm.

The use of the device does not require a specific knowledge or professional ability Intended user

The patient is the intended operator, except in case of patients that require special assistance. Patient population

Adults whose upper arm circumference is within the range indicated on the cuff.

· Only use the monitor to take blood pressure measurements on the upper arm. Do not place the cuff on other areas of

• Only use the supplied cuff or an original replacement cuff. The measured values may otherwise be incorrect. · If measured values are questionable, repeat the measurement.

- Do not leave the monitor unattended near small children or persons who cannot operate it themselves. There is a risk of strangulation if the cuff tube becomes wrapped around the neck. Swallowing small parts that have detached from the device can also result in suffocation.
- Do not under any circumstances carry out blood pressure measurements on newborns, babies or toddlers. Do not use the monitor for diagnosis in clinical situations where the patient is in immediate danger.
- Please note that the pressure build-up in the cuff can lead to temporary disruption of medical devices being used at the same time on the same arm. The function of the arm on which the cuff is placed may become impaired during inflation
- If you are carrying out the measurement on another person, please ensure that using the blood pressure monitor does not have a lasting negative effect on the blood circulation. People with restricted physical, sensory or mental skills should be supervised by a person responsible for their
- safety and receive instructions from this person on how to use the device. Taking measurements too often within a short time period as well as maintaining continuous cuff pressure can
- disrupt the blood circulation and cause injuries. Please take a break between measurements and do not bend or fold the air tube. If the monitor malfunctions, remove the cuff from the arm.
- Always consult your doctor about if and when the blood pressure monitor can be used by pre-eclampsia
- patients during pregnancy. Always consult your doctor about if and when the blood pressure monitor can be used by persons who have had
- a mastectomy or lymph node clearance.
- If a possible allergic skin reaction occurs on the arm where the cuff is used, discontinue its use and consult a
- Do not use the blood pressure monitor together with a high frequency surgical device.
- The device is not intended for use in vehicles (e.g. ambulances) or helicopters.

/ Contraindications

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- Please do not place the cuff over a wound as this may cause further injuries. • If an intravenous treatment is being carried out or a venous catheter is inserted in the arm, blood pressure
- measurements can lead to injury. Never use the cuff on the arm to which these conditions apply. If you are prone to hematoma, do not put on a cuff nor carry out a blood pressure measurement. • Do not use the blood pressure monitor in the absence of a full arm.
- Important instructions for self-measurements

- Even minor changes in internal and external factors (e.g. deep breathing, stimulants, talking, excitement, $environmental\ factors)\ can \ lead\ to\ fluctuations\ in\ blood\ pressure.\ This\ explains\ why\ deviating\ values\ are\ often$ measured at the doctor or pharmacist. Measurement results fundamentally depend on the measurement location and the position of the patient (sitting,
- standing, reclining). They are also influenced by e.g. physical activity and physiological preconditions of the patient. For comparable values, carry out the measurement in the same location and in the same position.
- Cardiovascular disease can result in erroneous readings or lower the accuracy of the measurement. The accuracy may also be affected if you have very low blood pressure, diabetes, circulatory disorders and arrhythmias and chills or

\diagup Consult your doctor before measuring your own blood pressure if ...

- you are pregnant. Blood pressure may vary during pregnancy. Regular blood pressure monitoring is particularly important if you have high blood pressure because elevated values may affect foetal development. Always check with
- your doctor if and when you should measure your own blood pressure, especially if you suffer from pre-eclampsia. you have diabetes, liver function disorders or narrowing of blood vessels (e.g. arteriosclerosis, peripheral arterial disease) as these may cause anomalous values.
- you have certain blood disorders (e.g. haemophilia) or severe circulatory disorders or are taking blood-thinning medication
- you are on dialysis or taking anticoagulant medication (anticoagulants), platelet aggregation inhibitors or steroids. • you wear a pacemaker, which may cause anomalous values. The blood pressure monitor itself does not affect a
- pacemaker. Please note that the pulse rate displayed is not suitable for checking the frequency of pacemakers. you tend to bruise easily and/or are sensitive to pressure pain.
- $you \, suffer from \, severe \, heart \, rhythm \, disorders \, or \, cardiac \, arrhythmias. \, Due \, to \, the \, oscillometric \, measurement \, method \, is a constant of the contract of the contrac$ used, incorrect measured values may be obtained in some cases or it may not be possible to measure blood pressure. • these symbols Ω and/or Ω appear often, it may indicate heart rhythm disorders. Please consult your doctor in that case. Severe heart rhythm disorders or atrial fibrillation may sometimes produce false measurements or reduce the measurement accuracy. Please discuss with your doctor whether taking your own blood pressure is appropriate
- the readings taken by you are for your information only they are not a substitute for a medical examination. Discuss your measured values with your doctor and never make a medical decision based on these measurements (e.g.
- medications and their dosages). taking your own blood pressure is not a substitute for medical treatment. Do not interpret your measured values yourself and do not use them for self-prescribed treatment. Take readings based on the instructions of your doctor and trust his or her diagnosis. Take medication only as prescribed by your doctor and do not alter the dose on your own accord. Discuss with your doctor the appropriate time to measure your blood pressure

An irregular heartbeat is present when the heart rhythm deviates by more than 25 % from the median heart rhythm. The contraction of the heart muscle is stimulated by electrical signals. A disorder of these electrical signals is called an arrhythmia. This may be due to a genetic predisposition, stress, age, lack of sleep, exhaustion or similar factors. A doctor can establish whether an irregular heartbeat is the result of an

Heart rhythm disorders are disturbances of the normal rate or rhythm of the heartbeat. A distinction should be made between mild and severe heart rhythm disorders. This can only be determined by a special examination carried out by a

Power supply (batteries, power supply unit)

- Observe the polarity labels plus (+) and minus (-). Only use high-quality batteries (see specification in Chapter 13 'Technical data'). If you use low-quality batteries, we
- can no longer guarantee the specified number of measurements Never mix old and new batteries or batteries from different manufacturers.
- Remove flat batteries immediately. Replace batteries if the battery symbol remains illuminated.
- Always replace all the batteries at the same time.
- If you do not intend to use the monitor for a longer period of time, you should remove the batteries to prevent
- If you use the monitor with the power supply unit, position the monitor so that you can disconnect the power supply

Information about batteries Choking hazard

- Small children could swallow batteries and suffocate on them. Keep the packaging, batteries and the monitor
- Do not throw batteries into a fire. Batteries must not be charged or short-circuited. • If a battery has leaked, wear protective gloves and clean the battery compartment with a dry cloth. If liquid from a battery cell comes into contact with skin or eyes, clean the affected area with water and seek medical
- Protect batteries from excessive heat. Do not disassemble, open or crush batteries.

! Safety information concerning the device

- This blood pressure monitor is not waterproof. This blood pressure monitor is made of high-quality electronic precision components. The accuracy of the measured
- values and the lifetime of the device depend on careful handling. Protect the device from violent shaking, hitting or vibrations and do not let it drop on the ground.
- Do not bend or fold the cuff excessively. Never open the device. The device must not be modified or dismantled, and must not be repaired by the user. Repairs
- may only be carried out by authorised specialists. Do not inflate the cuff when it is not properly applied to the upper arm.
- Use the device only with the approved upper arm cuff. The device may otherwise sustain external or internal damage. The cuff tube may only be removed from the unit by pulling on the corresponding connector plug. Never pull on the
- tube itself. • Do not expose the device to extreme temperatures, humidity, dust or direct sunlight as this may cause it to
- malfunction
- Keep the packaging, batteries and device out of reach of children. Protect the device and cuff against contact with pets and pests in order to avoid damage.
- Please comply with the storage and operating conditions defined in Chapter 13 ´Technical data`. Storing or using the device outside the specified temperature and humidity range can affect the accuracy of the measurement or the function of the device.
- If the device was not stored within the minimum/maximum permissible storage conditions, a waiting period of at least 2 hours must be observed before using it under the specified operating conditions (Chapter 13 'Technical data')
- or an ambient temperature of approx. 20 °C. Do not use the device in explosive environments with inflammable gases or concentrated oxygen.

Instructions regarding electromagnetic compatibility

manufacturer or the customer service (contact details see Chapter 12).

Instructions for the measurement function check

- The device is suitable for use in all environments listed in these instructions for use, including domestic
- It may only be possible to use the device to a limited extent 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. However, if it is necessary to use the device in the manner described above, this device and the other
- devices must be monitored to ensure that they are working properly. The use of accessories other than those specified or provided by the manufacturer of this device may result in increased electromagnetic emissions or a decrease in the device's electromagnetic immunity and lead to faulty
- Failure to comply with the above can impair the performance characteristics of the device. Do not use the device near strong electromagnetic fields and keep it away from radio equipment and mobile phones.
- Portable and mobile high-frequency and communication devices, such as telephones and mobile phones, can impair the functionality of this electronic medical device. Therefore keep a minimum distance of 30 cm. Further documentation in accordance with the electromagnetic compatibility standard can be requested from the

Every Veroval® device has been carefully tested by HARTMANN for measurement accuracy and has been developed with a view to a long service life. We recommend carrying out a metrological check every 2 years for devices in professional use, for example, in pharmacies, medical practices or hospitals. Please also observe the national regulations specified by the legislator. Metrological checks may only be carried out by the competent authorities or authorised maintenance providers against cost reimbursement.

Disposal information
This product (monitor and cuff) is subject to the European Directive 2012/19/EU on Waste Electrical and Electronic Equipment and is marked accordingly. Never dispose of electronic equipment in your household waste. Please the proper disposal. This protects the environment and

The batteries comply with the European Directive 2013/56/EU. To protect our environment, empty batteries

must not be disposed of in household waste. Please comply with the relevant waste disposal regulations or use public

collection points, recycling points or electronic retailers.

- 3. Blood pressure information Two values must be measured to determine blood pressure:
- Systolic (upper) blood pressure, which is produced when the heart contracts and pumps blood into the blood yessels. Diastolic (lower) blood pressure, which is produced when the heart is expanded and fills with blood again.

Blood pressure values are displayed in mmHg. For improved assessment of the results, a traffic light system is located on the left side of the Veroval® BPU 26 which is a direct result indicator, making it easier to categorise the measured value. The World Health Organisation (WHO) and the $European\ Society\ of\ Cardiology\ (ESC)\ \&\ European\ Society\ of\ Hypertension\ (ESH)\ have\ developed\ the\ following\ summary$ for classifying blood pressure values:

Results indicator	Evaluation	Systolic pressure		Diastolic pressure
Red	Grade 3 hypertension	above 179 mmHg	and/or	above 109 mmHg
Orange	Grade 2 hypertension	160 — 179 mmHg	and/or	100 – 109 mmHg
Yellow	Grade 1 hypertension	140 – 159 mmHg	and/or	90 – 99 mmHg
Green	High normal	130 — 139 mmHg	and/or	85 – 89 mmHg
Green	Normal	120 — 129 mmHg	and/or	80 – 84 mmHg
Green	Optimal	up to 119 mmHg	and	up to 79 mmHq

Classification of blood pressure taken in practice and definition of hypertension grade (source: 2018 ESC/ESH guidelines)

- Established hypertension (high blood pressure) is defined as having a systolic value of at least 140 mmHg and/or a diastolic value of at least 90 mmHg. In general, low blood pressure (hypotension) is defined as a systolic value below 105 mmHg and a diastolic value of 60 mmHg. However, the threshold between normal and low blood pressure (hypotension) is not as accurately specified as the threshold for high blood pressure (hypertension). Hypotension may be associated with symptoms such as dizziness, fatigue, tendency to faint, visual disturbances or high pulse rate. In order to ensure that hypotension or the corresponding symptoms are not attendant symptoms of serious illness, a doctor should be
- Constantly elevated blood pressure significantly increases the right of consequences of high blood pressure, e.g. heart attack, stroke and organ damage, are the most common consequences of high blood pressure, e.g. heart attack, stroke and organ damage, are the most common consequences of high blood pressure, e.g. heart attack, stroke and organ damage, are the most common consequences of high blood pressure, e.g. heart attack, stroke and organ damage, are the most common consequences of high blood pressure, e.g. heart attack, stroke and organ damage, are the most common consequences of high blood pressure, e.g. heart attack, stroke and organ damage, are the most common consequences of high blood pressure, e.g. heart attack, stroke and organ damage, are the most common consequences of high blood pressure, e.g. heart attack, stroke and organ damage, are the most common consequences of high blood pressure, e.g. heart attack, stroke and organ damage, are the most common consequences of high blood pressure at the stroke organ consequences of high blood pressure at the stroke organ consequences of high blood pressure at the stroke organ consequences of high blood pressure at the stroke organ consequences or Constantly elevated blood pressure significantly increases the risk of developing other disorders. Physical causes of death worldwide. Daily blood pressure monitoring is therefore an important measure that can help to protect you from these risks. You should discuss this with your doctor, especially if you have frequently elevated or borderline blood pressure values (see Chapter 3 'Blood pressure information'). The Veroval® medi. connect app lets you share your readings easily with your doctor by email or as a print-out; (see chapter 7 'Transferring measured values via *Bluetooth*® to the Veroval® medi.connect app'). Your doctor will initiate appropriate measures.

4. Preparing the measurement

START/STOP button ①.

confirm using the START/STOP button ①.

consulted in case of doubt.

- Inserting/changing the batteries - Open the battery cover on the bottom of the device. Insert the batteries (see Chapter 13 ´Technical data'). Ensure correct polarity (+ and –) when inserting the batteries. Close the battery lid. 12 hor 24 h flash on the display. Set the date and time as described below.
- If the 'Change battery' symbol and 'LO' are permanently illuminated, blood pressure can no longer be measured and you need to replace all the batteries.

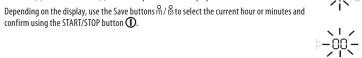
Setting the date, time and *Bluetooth*® It is very important that you set the date and time correctly. This is the only way to save your measured values It is very important trial you set the date and time conseas. This is also important for correctly using all the correctly, with the date and time, for subsequent retrieval. This is also important for correctly using all the memory and analysis functions. We recommend activating automatic Bluetooth® data transfer if you want to use the

• To switch to settings, reinsert the batteries or press the START/STOP button ① for 5 seconds. Proceed as follows:

The hour format flashes on the display. Select the desired hour format using the Save buttons \widehat{n}/\widehat{n} and confirm using the

The display shows the year (a), the month (b) and the day (c). Depending on the display, use the Save buttons n / n to select the year, the month or the day and confirm using the START/STOP button ①.

If the 12-hour format is selected, the month is displayed before the day. The hour (d) and the minutes (e) flash in sequence on the display.



Use the memory button ក្តា or ក្តា to select whether a<u>u</u>tomatic *Bluetooth*® data transfer is activated (Bluetooth* symbol and $\Box \Box$ is displayed, $\Box \neg$ is flashing) or deactivated (Bluetooth* symbol and bb is displayed, OFF is flashing) and confirm with the START/STOP button ①



The device switches off automatically once all data has been set.

The measured values will remain in the memory when the batteries are changed. The date and time settings will also be caused.

5. Measuring your blood pressure

The 10 golden rules of blood pressure measurement Many factors play a role in blood pressure measurement. These ten general rules help you to correctly carry out the



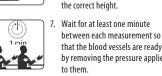
3. Do not measure when you have a strong urge to urinate. A full bladder can increase blood pressure by about 10 mmHq.



completely bare upper arm and in a comfortable upright seated position. The blood circulation must not be constricted by a rolled-up sleeve, for example . Please do not talk or move when

measuring your blood pressure.

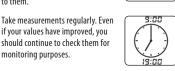
Talking increases values by about



that the blood vessels are ready, by removing the pressure applied Take measurements regularly. Even if your values have improved, you

monitoring purposes

If you are using a wrist monitor.



10. Always take measurements at the same time of day. Because a person has about 100,000 different blood pressure values every day, individua measurements are not meaningful. Only regular measurements taken at the same time each day over a longer period of time give a meaningful assessment of blood pressure values

Applying the blood pressure monitor

• Before applying the cuff, insert the cuff socket into the connector socket on the left side of the device. • Do not mechanically constrict, compress or bend the sleeve tube.

• Blood pressure must be measured on a bare upper arm. If the cuff is completely open, thread the end of the cuff through the metal ring to form a loop. Position the cuff on the upper arm so that the lower edge is $2-3\,\mathrm{cm}$ above the crook of the arm and above the artery. The tube points to the centre of the palm



Now bend your arm slightly, grasp the free end of the cuff, wrap it firmly round your arm and close the hook-and-loop

Make sure the tube is not bent or damaged. Important: It is essential that the cuff is correctly applied to obtain correct measurements. The cuff included with \$(1)\$ and \$(2)\$ is a second of the cuff ofthe device is a universal cuff for upper arm circumferences of 22 to 42 cm. The white arrow must point to an area

The cuff should fit firmly but not tightly. You should be able to insert two fingers between the arm and the cuff.

This innovative Veroval® device with Comfort Air Technology ensures comfortable measurement. The individual inflation pressure is determined independently for each measurement and depends on the corresponding systolic blood pressure value. This allows for more comfortable upper arm measurements.

Carrying out the measurement

Starting the measurement

• You should take your blood pressure in a quiet place, in a relaxed and comfortable seated position.

- arm. Over the long term, the arm giving higher readings should be used for blood pressure monitoring. However, if there is a very clear difference between readings on either arm, you need to check with your doctor which arm youshould use for the measurement.
- · Always measure on the same arm and place your forearm in a relaxed position on a support. • We recommend that you measure your blood pressure while sitting with your back against the back of the chair. Place $both\ feet\ flat\ on\ the\ floor\ next\ to\ each\ other.\ Do\ not\ cross\ your\ legs.\ Relax\ your\ forearm\ and\ hand\ with\ your\ palm$

The Veroval® BPU 26 offers you two measurement methods. Depending on the situation and your preference, you can choose between resultantiant. reference, you can choose between regular single measurement (standard mode) or fully automatic

- that is created. Press the START/STOP button ① . The appearance of all display segments, followed by the time and date, indicates that the device is carrying out an automated check and is ready for use. Check the display segments for completion (see Chapter 1 ´Device and display description`). • After about 0.5 seconds the cuff inflates automatically. If this inflation pressure is insufficient or if interference is
- If the cuff has been applied firmly enough on the arm, the cuff symbol \approx appears on the display. If the cuff is not applied firmly enough, the cuff symbol $\stackrel{\star}{\approx}$ or the error message 'E3' appear on the display. The measured values can be questionable, therefore you can stop the measurement by pressing the START/STOP button ① OR repeat the measurement following the instructions as described above in 'Applying the blood pressure monitor'. Please also note
- the information in Chapter 8 'Explanation of error messages'. There is no clinical data how the measurement is influenced if the cuff is not applied firmly enough. Please make sure that the cuff fits firmly and repeat the measurement.

- As the cuff pressure is released, the heart symbol flashes \bigcirc and the dropping pressure in the cuff is shown on the
- After the measurement is complete, the systolic and diastolic blood pressure as well as the pulse rate are shown simultaneously.



- **₹**}~87 - The resting indicator symbol \mathscr{R} only appears on the display if the user was sufficiently relaxed during the measurement. If the Veroval® BPU 26 device identifies any evidence of agitation, the following symbol will be
- displayed *. Therefore, please follow the 10 golden rules (see Chapter 5 'Measuring your blood pressure') and repeat the measurement. The complete 'Measurement OK' symbol \mathbb{R}^2 only appears on the display if the cuff has been applied firmly enough and if the user was sufficiently relaxed during the measurement. $% \label{eq:control_eq} % \label{eq$
- blood pressure, we recommend that your doctor checks your heart rhythm. In addition to the measured values, the time, date, the associated user memory \vec{n} or \vec{n} are shown. While the result of the measurement is displayed, you can assign the values to the corresponding user memory by pressing the \mathring{n} or \mathring{a} button. This assignment can be made for 10 seconds if *Bluetooth** transfer is activated in the device settings. After this time the device starts the *Bluetooth** data transfer automatically. If you do not assign the values to the corresponding

- In expert mode, three blood pressure measurements are automatically taken in succession and the average value of the three measurements is displayed at the end.
- To start the fully automatic multiple measurement, press and hold the START/STOP button ① for 2 seconds until '-3-' appears in the display. The info at the top left of the display shows you which of the measurements is currently running. The results of the
- individual measurements are not displayed. • The time interval between the measurements is 60 seconds and is shown in the display as a countdown.
- The complete 'Measurement OK' symbol Appears on the display if during all three measurements the cuff has been applied firmly enough and if the user was sufficiently relaxed during the measurement.

eliable blood pressure values for your personal health care and individual blood pressure monitoring. Automatic *Bluetooth®* data transfer after measurement

monitor now attempts to connect to the Veroval® medi.connect app for approx. 2 minutes. The Veroval® medi.connect

As soon as a connection is established, all measurement data is automatically transferred to the app. During transmission the *Bluetooth®* symbol **3** is displayed permanently and the results indicator on the left of the display runs from bottom to top.



- The measurement will not be saved if the power supply is interrupted before the device is switched off.
- measurement process is interrupted and cuff pressure is automatically released.

6. Memory function

- The Veroval® BPU 26 stores up to 100 measurements in each user memory. The most recent measurement is always saved together with the date and time in memory slot no. 1 and all older saved values are moved up one memory slot.
- Once all memory slots are occupied, the oldest value is deleted. The device has two memory buttons, $\stackrel{\circ}{n}$ and $\stackrel{\circ}{n}$, that are used to record the measurement results for two separate users. A represents the measured values for the first user, a represents the measured values for the second user. After the measurement is finished, you can assign the measured value to the respective person by pressing nand කි. This
- assignment can be made for 10 seconds. If you do not assign them, the measured value is automatically stored in the user memory that is currently displayed. • The time of the measurement is also saved, along with each of the blood pressure values, to enable the morning and
 - evening averages to be determined. The time saved in the device must therefore be set correctly to the actual time (see Chapter 4, section ´Setting the date, time and $\textit{Bluetooth}^{\circledast}$).
- Veroval® BPU 26 features the following measurement data storage functions (corresponding to the guidelines of the European Society of Hypertension (ESH)):
- Individual measured value memory
- Average value of the evening values
- differentiates between measurements taken in the morning and those taken in the evening. This distinction is medically relevant because blood pressure changes over the course of the day. With this information, your doctor is more likely to identify the right treatment for you if you should need medicinal
- The memory recall is activated by pressing the $\stackrel{\circ}{n}$ or $\stackrel{\circ}{n}$ button with the device switched off. For values saved in the first user memory button, press the ର୍ଜି button, for the second user memory press the ର୍ଜି memory button. - If automatic data transfer is activated, the *Bluetooth* වී flashes on the display. The blood pressure monitor now attempts to connect to the Veroval® medi.connect app for approx. 2 minutes. The Veroval® medi.connect app must be active to allow data transfers. As soon as a connection is established, all measurement data is automatically transferred to the app. During transmission the Bluetooth® symbol 3 is displayed permanently and the results

Average values

• After selecting the respective user memory, the corresponding symbol $\stackrel{\circ}{\cap}$ or $\stackrel{\circ}{\cap}$ and $\stackrel{\circ}{\cap}$? appear on the display. The average value of all the data stored for the particular user memory is displayed.





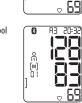
• If there is no morning or evening value for the past 7 days in the memory, dashes will be



• In order to distinguish a single measurement from a multiple measurement, the R3 symbol

• By pressing the n button again (or the n button if you are in user memory 2), all memory

values can be retrieved one after the other, starting with the most recently measured



during the measurement.

 If an irregular heartbeat and/or atrial fibrillation was detected during measurement, that information and/or arrial fibrillation was detected during measurement, that information of an and/or arrived from the device's memory along with the systolic and diastolic blood pressure readings, pulse rate, time, date and year.

The symbols 🕮 or 🕅 are also saved together with the individual measured value if they were displayed

You can cancel the memory recall at any time by pressing the START/STOP button \bigcirc . Otherwise, the device will switch off automatically after a few seconds.

are now deleted. If you release the button early, no data will be deleted.

With a few clicks, all results can be printed or sent to the doctor via email.

Deleting saved readings All data saved for each user can be deleted separately for user memory \hat{n} and user memory \hat{n} . To do so, press the button of the corresponding user memory ($\stackrel{\sim}{n}$ or $\stackrel{\sim}{n}$). The average 'A' value will then appear on the display.

Press and hold the user memory button for 5 seconds. 'CL 00' appears on the display. All data in the selected user m

7. Transferring measured values via *Bluetooth*° to the Veroval® medi.connect app You can use the Veroval® BPU 26 with your smartphone or tablet. You can transfer your data to your smartphone/tablet quickly and easily via Bluetooth® using the Veroval® medi.connect app.

Within the app, you can select different time periods and automatically receive perfectly prepared charts of your values.

· Apple iOS 10 and higher Android 5.0 and higher Android and iOS devices have subtle differences in their electronic components which can affect functionality, such as Bluetooth® connectivity. Due to the variation between device manufacturers,

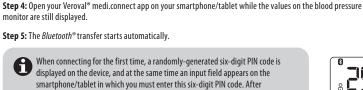
Download and install the Veroval® medi.connect app • To be able to use the Veroval® BPU 26 with the app, you must download the app and install it on your smartphone or

 Install the app by following the step-by-step instructions in the Veroval® medi.connect app. Connect the Veroval® BPU 26 to the app **Step 1:** Make sure that you activated *Bluetooth** on the blood pressure monitor (see Chapter 4, section 'Bluetooth*').

Step 3: Perform a blood pressure measurement (see or Step 3: Data transfer at a later point: Chapter 5 'Measuring your blood pressure'). The result Go to memory mode (see Chapter 6, section 'User is shown in the display and the *Bluetooth** symbol

Step 2: Make sure that you activated *Bluetooth*® on your smartphone/tablet and that you have installed the Veroval®

flashes. Do not switch off the blood pressure monitor



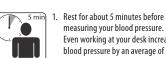
Monitor cannot be Batteries are missing, inserted incorrectly Check the batteries. If necessary, replace with four new identical batteries Power supply unit not correctly connected Plug the power supply unit into the or faulty. connector socket on the side of the Cuff will not inflate The cuff connector plug is incorrectly Check the connection between the cuff positioned in the connector socket of the connector plug and socket. Wrong cuff type connected. Verify that only an approved Veroval® cuff and connector are being used. Pulse could not be detected correctly. Check that the cuff has been positioned E correctly. Do not talk or move during E2 Check that the cuff has been positioned Systolic or diastolic blood pressure could not be detected. correctly. Do not talk or move during E3 Apply the cuff so that two fingers fit The cuff was applied too firmly or too loosely or the cuff is defective. between the cuff and the upper arm. The air tube is not correctly connected to the monitor. Check that the connector plug is correctly positioned. If this error occurs frequently, you should use a new EH Error during measurement. the measurement again (see Chanter 5 'Measuring your blood pressure'). Inflation pressure is higher than

Please rest for at least 1 minute, then take Please rest for at least 1 minute, then take the measurement again (see Chapter 5 300 mmHg. 'Measuring your blood pressure').

The data could not be sent via Bluetooth®. The batteries are almost empty. Replace batteries.

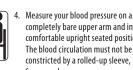
The Bluetooth® symbol

and b is shown in the display.



measuring your blood pressure. Even working at your desk increases blood pressure by an average of about 6 mmHg systolic and 5 mmHg





. Do not consume any nicotine or

caffeine up to one hour before

















within the sizing scale. If it is outside the range, it is not possible to guarantee a correct measurement result

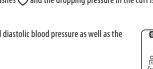
Measurement can be taken on the right or left arm. We recommend you perform the measurement on the left upper

facing upwards on a support and make sure the cuff is at the height of your heart. • Do not measure your blood pressure after taking a bath or playing sports. • Do not eat, drink or exercise for at least 30 minutes before the measurement. Please wait for at least one minute between two measurements.

multiple measurement (expert mode). Standard mode (Single measurement) • Start a measurement only after applying the cuff because the cuff may otherwise be damaged by the excess pressure

experienced during measurement, the device will increase pressure to the appropriate higher pressure value in increments of 40 mmHg. During inflation, the results indicator on the left of the display also increases at the same

 $\stackrel{igl|}{}$ Do not speak or move for the duration of the measurement.



If irregular heartbeat and/or atrial fibrillation <u>was</u> detected during the measurement, the display will show the heart symbol $\bigcap_{i=1}^{\infty}$ and/or the symbol for AFIB [aab]. However, the measurement may also have been disrupted by body

user memory, the measured values are automatically stored in the user memory shown on the display. You can use the results indicator on the left of the display to classify your measurement result (see table in Chapter 3 Expert Mode (Multiple Measurement)

While the countdown is running, keep the cuff attached and remain seated at rest. • After the last measurement, the final result is displayed. In addition, the $R\exists$ symbol and the date are displayed alternately at the top in the expert mode. This indicates that the value is calculated from the average of three

If automatic Bluetooth® data transfer is activated, the Bluetooth® symbol 🛭 flashes on the display. The blood pressure app must be active to allow data transfers.

If you press the START/STOP button $oldsymbol{0}$ in the meantime, the transfer is cancelled and the Once all data has been transferred successfully, the result indicators are displayed

• To switch off the device, press the START/STOP button ①, otherwise the device will automatically switch off after 2

The expert mode was developed in accordance with the recommendations of the international hypertension societies and the latest scientific for the commendations.

permanently and the device switches off. If a connection to the app cannot be established after 2 minutes, the *Bluetooth** symbol \mathfrak{g} goes off and the blood pressure monitor switches off automatically after 5 seconds.

If you wish to stop the measurement for any reason, simply press the START/STOP button ①. The inflation or

movement or speaking. It is best to repeat the measurement. If you see these symbols regularly when measuring your

hypertension societies and the latest scientific findings. With regular use, it provides even better and more

medi.connect app.

If your smartphone or tablet has a protective cover, remove it to ensure that there is no interference during the transfer. The Veroval® medi.connect app is not intended for medical or commercial use and is no medical device in accordance with The values displayed are purely for visualisation purposes and must not be used as a basis for therapeutic treatments. The software is not part of a diagnostic-medical system. 8. Explanation of error messages Possible causes Remedy

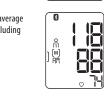
88 A system error has occurred. message appears.

Proceed as described in Chapter 7 Transferring measured values via Bluetooth® to the Veroval® medi.connect

 Average value of all measured blood pressure values per user Average value of the morning values Veroval® BPU 26 follows the recommendations of the European Society of Hypertension (ESH) and differentiates between measurements taken in all treatment for high blood pressure.

indicator on the left of the display runs from bottom to top. If you press the START/STOP button (1) in the meantime, the transfer is cancelled and the device turns off. Once all data has been transferred successfully, the result indicators are displayed permanently and the device automatically switches off after 30 seconds.

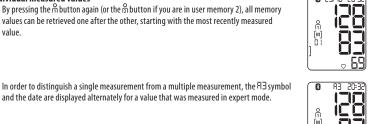
• By pressing the n button again (or the n button if you are in user memory 2), the average values for all morning measurements 'All' (00:00 to 11:59) for the past 7 days (including the current day) appear.



• By pressing the h button again (or the h button if you are in user memory 2) the average values for all evening measurements 'Pil' (12:00 to 23:59) taken on the last 7 days (including the current day) appear.



shown on the display instead of the morning or evening average values. If no values at all are stored in the memory, then dashes will also be displayed instead of the overall average





Individual measured values

Even if the power supply is interrupted, e.g. when changing the batteries, the stored values will still be

Compatible devices $\label{thm:connect} \begin{tabular}{ll} \hline The Veroval @medi.connect app is designed and optimized for iOS and Android smartphones and tablets that support $(A_{\rm connect})$ and $(A_{\rm connect})$ a$ Bluetooth® 4.0 and run the following operating systems:

 $\bullet \quad \text{Download the Veroval} \\ ^{\circ} \text{ medi.connect app from the Apple App Store or Google Play Store. You can also download} \\$ the app from our website www.veroval.info. To avoid lengthy download times and any associated costs, it is recommended to use a WiFi connection for the download.

memory'). Select the desired user memory.

Contact customer service if this error

HARTMANN cannot guarantee optimal performance of the Veroval® medi.connect app across all available A detailed list of compatible devices is available on our website at www.veroval.info.

successfully entering the code, the device will be connected to your smartphone/

Error

25.08.22 15:09

• Switch the device off if an error symbol appears. Check for all possible causes and follow the 10 golden rules (Chapter 5 'Measuring your blood pressure') as well as the instructions for self-measurement from Chapter 2 'Important information'.

• Relax for one minute and then take the measurement again.

9. Monitor maintenance

• Only use a soft, damp cloth to clean the device. Please do not use thinner, alcohol, detergents or solvents. • The cuff can be cleaned carefully using a slightly damp cloth and mild soap solution. Do not completely immerse the

cuff in water. It is recommended to clean and disinfect the cuff regularly or after each use, especially when used by several users, to prevent infection. The cuff should be disinfected, particularly on the inside, by wiping with a disinfectant. Use a disinfectant that is compatible with the cuff materials, e.g. 75 % ethanol or isopropyl alcohol. To protect from

external influences, keep the device, the cuff and these instructions in the storage bag. • If you store a device and cuff, do not place any heavy objects on the device and the cuff. Remove the batteries.

 $\bullet \quad \text{To ensure the accuracy of the measurement, please use only original accessories from HARTMANN, such as the} \\$ Veroval® power supply unit (model number: 925 391), which can be ordered from your pharmacist or medical specialist.

• Mains power mode: On the back of the unit is a connector socket for the adapter for mains operation (output 6V DC/600 mA). Only use the Veroval® power supply unit. The warranty covering the function and measuring

accuracy of the monitor cannot be assumed otherwise. $\bullet \quad \text{For more information, please visit www.veroval.info}.$

11. Warranty conditions

• We offer a 3-year warranty for this high-quality blood pressure monitor from the purchase date and in accordance with the conditions listed below.

• Warranty claims must be made during the warranty period. The purchase date must be documented by an

appropriately completed and stamped warranty certificate or proof of purchase. • Within the warranty period, HARTMANN will replace or repair free of charge any faulty device components caused by

material faults or manufacturing errors. This does not extend the warranty period.

• For local warranty conditions, please consult the local warranty certificate. • This device is solely intended for the purpose stated in these instructions for use.

 The manufacturer is not liable for damage or injuries resulting from improper handling, use or unauthorized
interference. Accessory parts that are subject to wear and tear (batteries, cuffs, etc.) are excluded from the warranty. Claims for compensation are limited to the value of the product; compensation for consequential damage or injury is expressly excluded.

• In warranty cases, please send the monitor with cuff and, if applicable, the power supply unit, together with the fully $completed\ and\ stamped\ warranty\ certificate\ or\ purchase\ receipt\ directly\ or\ via\ your\ dealer\ to\ the\ Customer\ Services$ department of your country.

12. Contact information for customer enquiries

ZA – HARTMANN South Africa

Epsom Avenue, Northriding, 2169 Johannesburg

www.veroval.info

Tel. +27 860 4278 6266 phzahelpdesk@hartmann.info

If necessary, please contact us at the relevant address listed at the end of the instructions for any questions regarding initial startup, use and maintenance of the device, or to report an unexpected operating malfunction or incident. For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, $please\ report\ it\ to\ the\ manufacturer\ and/or\ its\ authorized\ representative\ and\ to\ your\ national\ authority.$

 $Vigilance\ contact\ point\ for\ Europe:\ www.ec.europa.eu/growth/sectors/medical-devices/contacts/$

Model	Veroval® BPU 26		
Туре	GCE609		
Measuring method	Oscillometric		
Display range	0-300 mmHg		
Measuring range	Systolic (SYS): 50–280 mmHg Diastolic (DIA): 30–200 mmHg Pulse: 40–199 pulse beats per minute Displaying of correct values outside the measuring range cannot be guaranteed.		
Display unit	1 mmHg		
Technical measurement accuracy	Cuff pressure: ±3 mmHg Pulse: ±5 % of the displayed pulse rate		
Clinical measuring accuracy	Complies with the requirements of IEC 80601-2-30; Korotkoff validation method: Phase I (SYS), Phase V (DIA)		
Operating mode	Continuous mode		
Nominal voltage	DC 6V		
Power supply	4 x 1.5 V alkaline manganese (AA/LR06) batteries or optional Veroval® power supply unit		
Expected service life	20,000 measurements		
Battery capacity	Approx. 800 measurements		
Protection against electric shock	Medical-electrical equipment with internal power supply (only when batteries are used); applied part: type BF		
Protection against harmful ingress of water or solid materials	IP21		
Inflation pressure	Comfort Air Technology: Individual inflation pressure depends on systolic blood pressure		
Automatic switch-off function	2 minutes after measurement/otherwise 30 sec.		
Cuff	Veroval® cuff for BPU 26, cuff for arm circumference of 22 to 42 cm Model number: 30602		
Memory capacity	2×100 measurements with average of all measurements and morning/evening average of the last 7 days		
Operating conditions	Ambient temperature: $+10$ °C to $+40$ °C Relative humidity: <90 %, non-condensing Air pressure: 800 hPa -1050 hPa		
Storage/transport conditions	Ambient temperature: -20 °C to +55 °C Relative humidity: <90 %, non-condensing		
Serial number	On the rating label		
Reference to standards	IEC 60601-1; IEC 60601-1-2 (In accordance with CISPR11, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8)		
Weight	Approx. 220 g (without batteries)		
Dimensions	134(L) x 91(W) x 48(H) mm		
Data transfer	2400 MHz - 2483.5 MHz frequency band		
	Transmission power: +5 dBm		
	The blood pressure monitor used <i>Bluetooth</i> * low energy technology compatible		

Power supply unit:

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Model no.	LXCP12-006060BEH	
Input	100-240V~, 50-60Hz, 0.5A max	
Output	6V DC, 600mA	
Manufacturer	Globalcare Medical Technology Co., Ltd.	
Protection	The device is double-insulated and has a primary fuse which disconnects the monitor from the mains in the event of a fault. Make sure you have removed the batteries from the battery compartment before connecting the power supply unit.	
♦-©- ♦	Polarity of the DC voltage connection	
	Protective insulation / Protection Class 2	
Housing and protective covers	The power supply unit housing protects against touching parts that can carry a current (fingers, needles, test hooks). The user must not touch the patient and the outlet plug of the AC / DC power supply unit at the same time.	

Legal requirements and guidelines
The Veroval® BPU 26 conforms with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, as well as the respective national provisions, and bears the CE mark. • The device complies with international standard IEC 80601-2-30 (Medical electrical equipment Part 2-30: Particular

requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers). $\bullet \quad \text{This product is subject to special precautionary measures with regard to electromagnetic compatibility.}$

 Beyond statutory requirements, the device has been clinically validated by the ESH-IP2 Protocol of the European Society of Hypertension (ESH) and the protocol of the German society of hypertension (DHL).
 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 under: www.veroval.info

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mark of Apple Inc., registered in the U.S. and other countries. Google Play and the Google Play logo are trademarks of Google LLC.

Android is a trademark of Google LLC. Date of revision of the text: 2022-08-11, Version 1





EC REP Donawa Lifescience Piazza Albania, 10 00153 Rome, Italy www.donawa.comCH REP Camara and Partners Sàrl
Route de St Cergue 14

1260 Nyon, Switzerland



HARTMANN connect (8) Veroval[®] Warranty certificate compact + Upper arm blood pressure monitor Purchase date Serial number (see rating label) Reason for complain Dealer's stamp **%**

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