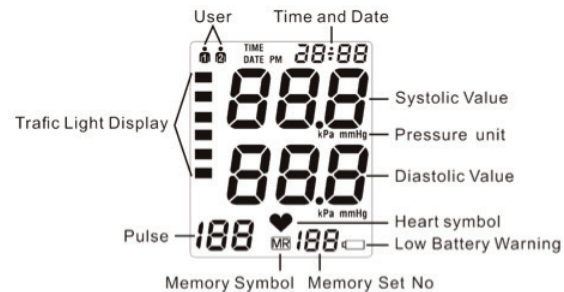


Digital Blood Pressure Monitor

Wrist

Wrist cuff is suitable for wrist circumference of 13.5 to 21 cm

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1. INTRODUCTION

1.1. Features of the Wrist Digital BP Monitor
The blood-pressure monitor Wrist Digital BP Monitor (with integrated time/date display) is a fully automatic, digital blood-pressure measuring device for use on the wrist, which enables very fast and reliable measurement of the systolic and diastolic blood-pressure as well as the pulse frequency by way of the oscillometric method of measuring. The device offers a very high and clinical tested measurement accuracy and has been designed to provide a maximum of user-friendliness. The device is intended for self-use in home.

Before using, please read through this instruction manual carefully and then keep it in a safe place. For further questions on the subject of blood-pressure and its measurement, please contact your doctor.

Attention!

1.2. Important information about self-measurement

- Substitution of a different component might result in measurement error.
- Do not use with neonatal patients.

- Too frequent measurements can cause injury to the patient due to blood flow interference.
- The application of the cuff over a wound can cause further injury.
- The application of the cuff and its pressurization on any limb where intravascular access or therapy, or an arteriovenous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury to the patient.
- Do not let the cuff and its pressurization on the arm on the side of a mastectomy
- The need to check that operation of the automated sphygmomanometer does not result in prolonged impairment of patient blood circulation.
- Not intended to be used together with HF surgical equipment.
- Do not forget: self-measurement means control, not diagnosis or treatment. Unusual values must always be discussed with your doctor. Under no circumstances should you alter the dosages of any drugs prescribed by your doctor.
- The pulse display is not suitable for checking the frequency of heart pacemakers!

Electromagnetic interference

The device contains sensitive electronic components (Microcomputer). Therefore, avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave cookers). These can lead to temporary impairment of the measuring accuracy.

2. BLOOD PRESSURE MEASUREMENT

2.1. How does high/low blood-pressure arise?

The level of blood-pressure is determined in a part of the brain, the so-called circulatory centre, and adapted to the respective situation by way of feedback via the nervous system. To adjust the blood-pressure, the strength and frequency of the heart (Pulse), as well as the width of circulatory blood vessels is altered. The latter is effected by way of fine muscles in the blood-vessel walls. The level of arterial blood-pressure changes periodically during the heart activity: During the «blood ejection» (Systole) the value is maximal (systolic blood-pressure value), at the end of the heart's «rest period» (Diastole) minimal (diastolic blood-pressure value). The blood-pressure values must lie within certain normal ranges in order to prevent particular diseases.

2.2. Which values are normal?

Blood pressure is too high if at rest, the diastolic pressure is above 90 mmHg and/or the systolic blood-pressure is over 160 mmHg. In this case, please consult your doctor immediately. Long-term values at this level endanger your health due to the associated advancing damage to the blood vessels in your body. Should the systolic blood-pressure values lie between 140 mmHg and 160 mmHg and/or the diastolic blood-pressure values lie between 90 mmHg and 100 mmHg, likewise, please consult your doctor. Furthermore, regular self-checks will be necessary.

With blood-pressure values that are too low, i.e. systolic values under 100 mmHg and/or diastolic values under 60 mmHg, likewise, please consult your doctor. Even with normal blood-pressure values, a regular self-check with your blood-pressure monitor is recommended. In this way you can detect possible changes in your values early and react appropriately. If you are undergoing medical treatment to control your blood pressure, please keep a record of the level of your blood pressure by carrying out regular self-measurements at specific times of the day. Show these values to your doctor.

Never use the results of your measurements to alter independently the drug doses prescribed by your doctor.

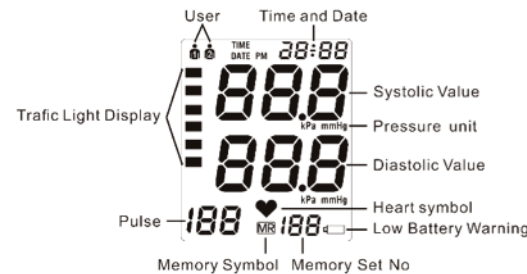
Table for classifying blood-pressure values (unit: mmHg) according to World Health Organization:

Range	Systolic	Diastolic	Measures
	Blood pressure	Blood pressure	
Blood pressure optimum	between 100 and 120	between 60 and 80	Self-check
Blood pressure normal	between 120 and 130	between 80 and 85	Self-check
Blood pressure slightly high	between 130 and 140	between 85 and 90	Consult your doctor
Blood pressure too high	between 140 and 160	Between 90 and 100	Seek medical advice
Blood pressure far too high	between 160 and 180	Between 100 and 110	Seek medical advice
Blood pressure dangerously high	Higher than 180	Higher than 110	Urgently seek medical advice!

Further information

- If your values are mostly standard under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from so-called labile hypertension. Please consult your doctor if you suspect that this might be the case.
- Correctly measured diastolic blood-pressure values above 120mmHg require immediate medical treatment.

3. COMPONENTS



4. OPERATION

4.1. Inserting the batteries

- Insert the batteries (2 × size AAA 1.5V), thereby observing the indicated polarity.
- If the battery warning appears in the display, the batteries are empty and must be replaced by new ones.

Attention! After the battery warning appears, the device is blocked until the batteries have been replaced.

- Please use «AAA» Long-Life or Alkaline 1.5V Batteries. The use of 1.2V Accumulators is not recommended.
- If the blood-pressure monitor is left unused for long periods, please remove the batteries from the device.

4.2. Reading the set date

Please press the TIME button, the date will be shown in the display.

User selection:

This advanced blood pressure monitor allows you to track blood pressure readings for 2 individuals independently.

- Before measurement, make sure you set the unit for the intended user. The unit can track results for 2 individuals. (User 1, User 2)
- Press the TIME button for at least 3 seconds. The display now indicates the set user, during which the set user blink. To confirm, press ON/OFF button.
- Click the MEMORY button to select User
- We suggest the first person to take their pressure to be User 1.

Setting the time, date

This blood-pressure monitor incorporates an integrated clock with date display. This has the advantage, that at each measurement procedure, not only the blood-pressure values are stored, but also the exact moment of the measurement.

After new batteries have been inserted, the clock begins to run from the following setting: 2010-06-20 09:30 O'clock.

You must then re-enter the date and current time. For this, please proceed as follows

- Press the TIME button for at least 3 seconds firstly, user icon blink. Then press TIME button again the display now indicates the set year, during which the four characters blink.

- The correct year can be entered by pressing the MEMORY button

- Press the TIME button again. The display now switches to the current date, during which the first character (month) blinks.

- The corresponding month can now be entered by pressing the MEMORY button.

- Press the TIME button again. The last two characters (day) are now blinking

- The corresponding day can now be entered by pressing the MEMORY button.

- Press the TIME button again. The display now switches to the current time, during which the first character (Hour) blinks

- The corresponding hour can now be entered by pressing the MEMORY button.

- Press the TIME button again. The last two characters (Minutes) now blink.

- The exact time can now be entered by pressing the MEMORY button

- How to select pressure unit, switchable of mmHg and kPa, finished the whole setting process mentioned above, Press the TIME button again, Display "mmHg" blink, To press "MEMORY" button can switch "pressure unit as "mmHg" or "kPa", To press the TIME button selects pressure unit.

12) Now after all settings have been made, press the TIME button once again. The date is briefly displayed and then the time. The input is now confirmed and the clock begins to run.

Further Information

With each press of the button (TIME, MEMORY) one input is made (e.g. switching over from hours to minutes mode, or altering the value by +1).

However, if you keep the respective button depressed, you can switch more quickly to find the desired value respectively.

5. CARRYING OUT A MEASUREMENT

5.1. Before the measurement:

- Avoid eating, smoking as well as all forms of exertion directly before the measurement. All these factors influence the measurement result. Try and find time to relax by sitting in an armchair in a quite atmosphere for about ten minutes before the measurement.
- Measure always on the same wrist (normally left).
- Attempt to carry out the measurements regularly at the same time of day, since the blood-pressure changes during the course of the day.

5.2. Common sources of error:

Comparable blood-pressure measurements always require the same conditions! These are normally always quiet conditions.

- All efforts by the patient to support the arm can increase the blood-pressure. Make sure you are in a comfortable, relaxed position and do not activate any of the muscles in the measurement. Use a cushion for support if necessary.
- The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
- If the wrist artery lies considerably lower (higher) than the heart, an erroneously higher (lower) blood-pressure will be measured! (Each 15 cm difference in height results in a measurement error of 10mmHg!)
- A loose cuff causes false measurement values.
- With repeated measurements, blood accumulates in the respective wrist which can lead to false results. Correctly executed blood-pressure measurements should therefore first be repeated after a 5 minute pause or after the arm has been held up in order to allow the accumulated blood to flow away (after at least 3 minutes).

5.3. Fitting the cuff

- Remove all eventual objects and jewelry (e.g. wristwatch) from the wrist in question. Draw the cuff over the wrist.
- The distance between the cuff and the hand should be approx. 10 mm.
- Secure the cuff with the Velcro fastener, so that it lies comfortably and not too tight, whereby no space should remain between the cuff and the wrist.
- Lay the arm on a table, with the palm upwards. Support the arm a little with a rest (cushion), so that the cuff rests at about the same height as the heart. Take care, that the cuff lies free. Remain so for 2 minutes sitting quietly, before beginning with the measurement.
- Let legs uncrossed, feet flat on the floor, back and arm supported.

5.4. Measuring procedure

After the cuff has been appropriately positioned, the measurement can begin:

- Press the ON/OFF button, the pump begins to inflate the cuff. In the display, the increasing cuff-pressure is continually displayed.

b) After reaching the inflation pressure, the pump stops and the pressure slowly falls away. The cuff-pressure (large characters) is displayed during the measurement. When the device has detected the pulse, the heart symbol in the display begins to blink for every pulse beat.

c) When the measurement has been concluded, The measured systolic and diastolic blood-pressure values as well as the pulse frequency are now displayed. Example (Fig.): Systole 118, Diastole 73, Pulse 75. The measurement results are displayed, until you switch the device off. If no button is pressed for 3 minutes, the device switches automatically off, to save the batteries.

5.5. Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the "ON/OFF" button can be pressed at any time. The device then immediately lowers the cuff-pressure automatically.

5.6. Memory – storage and recall of the measurements

The blood-pressure monitor automatically stores each of the last 120 measurement values. By pressing the MEMORY button, an average value of the last 3 measurements as well as the last measurement (MR1) and the further last 120 measurements (MR2, MR3, ..., MR120) can be displayed one after the other.



(MR1: Values of the last measurement) (MR2-MR120: Values of the measurement before MR1)

5.7. Memory– cancellation of all measurements Attention!
 Before you delete all readings stored in the memory, make sure you will not need refer to the readings at a later date. Keeping a written record is prudent and may provide additional information for your doctor's visit. In order to delete all stored readings, depress the MEMORY button for at least 5 seconds, the display will show the symbol «CL» and then release the button to permanently clear the memory. Press the MEMORY button while «CL» is flashing.



6. ERROR MESSAGES/MALFUNCTIONS

If an error occurs during a measurement, the measurement is discontinued and a corresponding error code is displayed (Example: Error No. 2).



Error No.	Possible cause(s)
ERR 1	No pulse has been detected.
ERR 2	Unnatural pressure impulses influence the measurement result. Reason: hand was moved during the Measurement (Artefact).
ERR 3	1) The inflation takes too long. The cuff is not correctly seated. 2) Positioning Detection error
ERR 5	The measured readings indicated an unacceptable difference between systolic and diastolic pressures. Take another reading following directions carefully. Contact you doctor if you continue to get unusual readings.
ERR 8	Pressure in cuff is over 290mmHg

Other possible malfunctions and their elimination

If problems occur when using the device, the following points should be checked and if necessary, the corresponding measures are to be taken:

Malfunction	Remedy
The display remains empty when the instrument is switched on although the batteries are in place.	1. Check batteries for correct polarity and if necessary insert correctly. 2. If the display is unusual, re-insert batteries or exchange them.
The device frequently fails to measure the blood pressure values, or the values measured are too low (too high).	1. Check the positioning of the cuff. 2. Measure the blood-pressure again in peace and quiet under observance of the details made under point 5.
Every measurement produces a different value although the instrument functions normally and the values displayed are normal	1. Please read the following information and the points listed under «Common sources of error». Repeat the measurement. Please note: Blood pressure fluctuates continually so successive measurements will show some variability.
Blood pressure measured differs from those values measured by the doctor.	1. Record the daily development of the values and consult your doctor. Please note: Individuals visiting their doctor frequently experience anxiety which can result in a higher reading at the doctor than obtained at home under resting conditions.

Further information

The level of blood-pressure is subject to fluctuations even with healthy people. It is important that comparable **measurements always require the same conditions (quiet conditions).**

For licensing, the device has been subjected to strict clinical tests, by which the computer program used to measure the blood-pressure values was tested by experienced specialist doctors in Germany. The same computer program is used in every individual device, and has thus also been clinically tested.

The manufacture of the devices takes place according to the terms of the European standard for blood-pressure measuring devices. You must consult your specialist dealer if there are technical problems with the blood-pressure instrument. **Never attempt to repair the instrument yourself!** Any unauthorised opening of the instrument invalidates all guarantee claims!

7. CARE AND MAINTENANCE, RECALIBRATION

- a) Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.
- b) The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of straining through twisting or buckling.
- c) Clean the device with a soft, dry cloth. Do not use petrol, thinners or similar solvent. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff must not be washed!
- d) Do not drop the instrument or treat it roughly in any way. Avoid strong vibrations.
- e) Never open the device! Otherwise the manufacturer calibration becomes invalid!



8. SERVICE LIFE

5 years

9. BATTERY LIFE

300 times measurement with 2- size "AAA" alkaline Batteries

10. SAFETY, CARE and DISPOSAL



Safety and protection

- This instrument may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for the damage caused by incorrect application.
- This instrument comprise sensitive components and must be treated with caution. Observe the storage and operating condition described in the "Technical specifications" section!
- Protect it from
 - water and moisture
 - extreme temperatures
 - impact and dropping
 - contamination and dust
 - direct sunlight
 - heat and cold
- The cuffs are sensitive and must be handled with care
- Only pump up the cuff once fitted
- Do not use the instrument close to strong electromagnetic fields such as mobile telephones or radio installations
- Do not use the instrument if you think it is damaged or notice anything unusual.
- If the instrument is not going to be used for a prolonged period the batteries should be removed.
- Read the additional safety instructions in the individual sections of this booklet.
- Ensure that children do not use the instrument unsupervised: some parts are small enough to be swallowed
- Must use the recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety
- A warning to remove primary batteries if the instruments is not likely to be used for some time

Instrument care

Clean the instrument only with a soft, dry cloth

Disposal

Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste

11. REFERENCE TO STANDARDS

Device standard: Device corresponds to the requirements of the European standard for

Standard (for arm BPM with adapter)
IEC60601-1-6:2010+A1:2013/ EN60601-1-6:2010+ A1:2015
IEC60601-1:2005+ A1:2012/EN60601-1:2006+ A11:2011+ A1:2013+ A12:2014
IEC60601-1-2:2014/ EN60601-1-2:2015
IEC/EN60601-1-11:2015
IEC80601-2-30:2009+ A1:2013/EN80601-2-30:2010+ A1:2015

The stipulations of the EU-Guidelines 93/42/EEC for Medical Products Class IIa have been fulfilled.

12. TECHNICAL SPECIFICATIONS

Measurement Procedure:	Oscillometric, corresponding to Korotkoff method: Phase I: systolic, Phase V: diastolic
Display:	Digital display
Measuring range	Pressure: 30 to 280 mmHg (in 1 mmHg increments) Pulse: 40 to 199 beats/minute
Static accuracy:	Pressure: ±3 mmHg Pulse: ±5% of reading
Measuring resolution:	1 mmHg
Inflation:	Automatic inflation by internal pump
Memory function:	120 memory × 2 users (SYS, DIA, Pulse)
Decompression:	Constant exhaust valve system
Power source:	2- size "AAA" alkaline Batteries
Rated voltage:	DC 3 V 1.5 W (direct current)
Operation temperature:	5~40°C/41~104°F
Operation humidity:	15%~85% RH maximum
Storage temperature:	-20~55°C/-4~131°F
Cuff size	13.5- 21 cm
Storage humidity:	10%~95%RH maximum
Dimensions:	70 × 65 × 30 ±1.0 mm
Device weight:	129 g ± 5 g (including batteries and cuff)
Batteries weight:	23 g±1.0 g
Storage box weight	57 g±1.0 g
Size of the Sys / Dia digits:	12 mm
Time display:	24 h display
Visible display size:	43.8 × 34 mm
Cuff pressure display range:	0~290 mmHg/0~38.7 kPa
Electrical shock protection:	Internal power unit
Safety classifications:	Type BF equipment
Mode of operation:	Continuous operation
Protection against ingress of water:	IP22
Accessories:	storage case, 2 "AAA" batteries, instruction manual

13. DECLARATION – ELECTROMAGNETIC EMISSIONS

The Digital Blood Pressure Monitor, Wrist, is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Digital Blood Pressure Monitor, Wrist, can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Digital Blood Pressure Monitor, Wrist, and according to the maximum output power of the communications equipment. Please contact Dynarex at QA.Support@-Dynarex.com for more information and manufacturer technical specifications.

Special considerations should be given to proximity of Digital Blood Pressure Monitor, Wrist, and patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electrical interference, or death. Contact Dynarex at QA.Support@Dynarex.com for manufacturer electromagnetic interference technical specifications.

Interference to electronic equipment may occur in the vicinity of devices marked with this symbol:



Manufactured for:
Dynarex Corporation
 10 Glenshaw Street
 Orangeburg, NY 10962
 USA • www.dynarex.com
 Made in China



SYMBOL GLOSSARY
 For an explanation of symbols used in Dynarex packaging, visit dynarex.com/symbols.php