

Digital Blood Pressure Monitor

Upper Arm

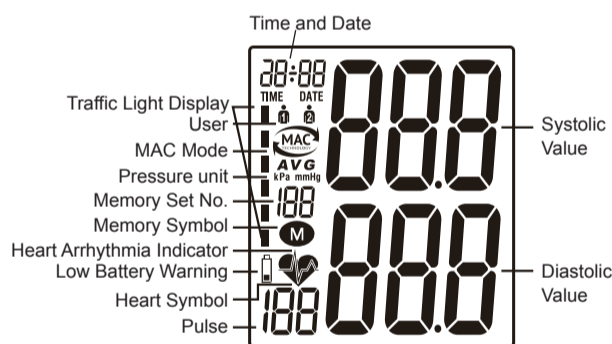
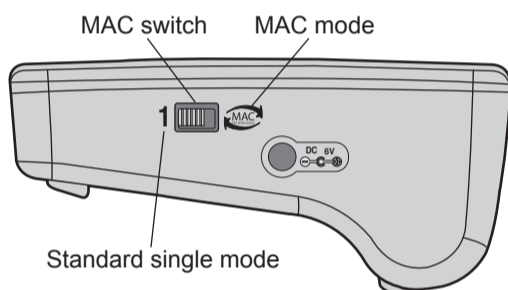
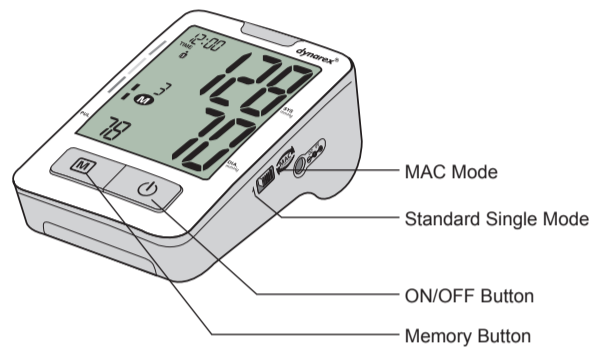
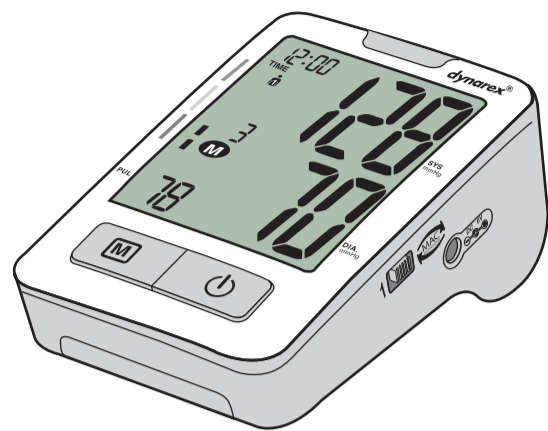


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1. INTRODUCTION

1.1. FEATURES OF THE DIGITAL BLOOD PRESSURE MONITOR

The Digital Blood Pressure Monitor (with integrated time/date display) is a fully automatic, digital blood pressure measuring device for use on the arm, 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 at 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.

1.2. IMPORTANT INFORMATION ABOUT SELF-MEASUREMENT

- Substitution of a different component might result in measurement error.
- Cuff is replaceable only by an original.
- Do not use with neonatal patients.
- It will cause harmful injury to the patient or effect the blood pressure due to connection tubing kinking.
- 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!
- In cases of cardiac irregularity (Arrhythmia), measurements made with this instrument should only be evaluated after consultation with the doctor.

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
Optimum	100-120	60-80	Self-check
Normal	120-130	80-85	Self-check
Slightly High	130-140	85-90	Consult your doctor
Too High	140-160	90-100	Seek medical advice
Far Too High	160-180	100-110	Seek medical advice
Dangerously High	180 and up	110 and up	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. OPERATION

3.1. INSERTING THE BATTERIES

- Insert the batteries (4 x size AA 1.5V), thereby observing the indicated polarity.
- the battery warning appears in the display, the batteries remain 20% power to warn user the batteries will be run out.
- 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 «AA» Long-Life or Alkaline 1.5V Batteries.
- If the Digital Blood Pressure Monitor is left unused for long periods, please remove the batteries from the device.

3. OPERATION (Cont.)

3.2. SETTING DATE/TIME

How to enter to the setting mode:

- after batteries are inserted, the device will automatically enter to the setting mode.
- press and hold "ON/OFF" button for 5 seconds, the device will enter to the setting mode

The setting procedure as follows:



It is essential to set date and time. Otherwise, you will not be able to save your measured value correctly with a date and time.

Use the button to make adjustments.

If you press and hold the button, you can set the values more quickly.

1. Year setting: the year flashes on the display

Choose the desired year with the button and confirm with "ON/OFF" button.



2. Month setting: the month flashes on the display

Choose the desired month with the button and confirm with "ON/OFF" button.



3. Day setting: the day flashes on the display

Choose the desired day with the button and confirm with "ON/OFF" button.



4. Hour setting: the hour flashes on the display

Choose the desired hour with the button and confirm with "ON/OFF" button.



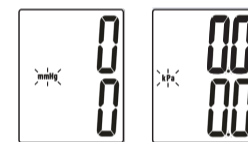
5. Minute setting: the minute flashes on the display

Choose the desired minute with the button and confirm with "ON/OFF" button.



6. Unit setting: the unit "kPa" or "mmHg" flashes on the display

Choose the desired minute with the button and confirm with "ON/OFF" button.



NOTE: the clock will begin to run from 2016-01-01 01:01, and unit in mmHg, if no key is pressed within 20 seconds.

3.3. USER SELECTION

Press and hold the memory button for 2 seconds, flash on the display. Press to choose the desired user.

4. CARRYING OUT A MEASUREMENT

4.1. 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 arm (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.

4.2. COMMON SOURCES OF ERROR

NOTE: 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 arm during 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.
- Avoid compression or restriction of the connection tubing.
- A loose cuff causes false measurement values.
- With repeated measurements, blood accumulates in the respective arm, 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).

4.3. FITTING THE CUFF

Insert air connector into air outlet shown in the photo and please make sure the fitting of the air connector completely and properly to avoid air leakage.



a) The distance between the edge of cuff and the elbow should be approx. 2-3 cm.

b) 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 arm.



c) 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.



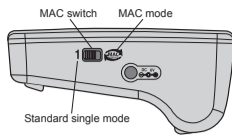
d) Let legs uncrossed, feet flat on the floor, back and arm supported.

4. CARRYING OUT A MEASUREMENT (Cont.)

4.4. MEASURING PROCEDURE

Select the measuring mode: **standard single** or **MAC mode**

This device enables you to select either standard (standard single measurement) or MAC mode (automatic two measurements). To select standard mode, slide the MAC switch on the side of the device downwards to position «1» and to select MAC mode, slide this switch upwards to position «MAC».



In MAC mode: In MAC mode, 2 measurements are automatically taken in succession and the result is then automatically analyzed and displayed. Because blood pressure constantly fluctuates, a result determined in this way is more reliable than one produced by a single measurement.

- After pressing the ON/OFF button, the MAC-symbol appears in the display.
- The bottom, left hand section of the display shows a 1, 2 to indicate which of the 2 measurements is currently being taken. (Fig. 1-2)
- There is a break of 15 seconds between the measurements (15 seconds are adequate according to «Blood Pressure ing, 2001, 6:145-147» for oscillometric instruments). A count down indicates the remaining time.
- The individual results are not displayed. Your blood pressure will only be displayed after all 2 measurements are taken.
- Do not remove the cuff between measurements.
- If one of the individual measurements was questionable, a third one is automatically taken.

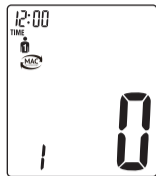


Fig. 1

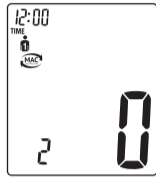


Fig. 2

In the measuring:

After reaching the inflation pressure, the pump stops and the pressure slowly falls away. The cuff-pressure is displayed during the measurement. When the device has detected the pulse, the heart symbol in the display begins to blink. (Fig. 3)



Fig. 3

Measured result:

The measured systolic and diastolic blood pressure values as well as the pulse are now displayed. Example (Fig. 4): Systole 128, Diastole 70, Pulse 80, arrhythmia detected. The measurement results are displayed until you switch the device off. If no button is pressed for 3 minutes, the device switches automatically off



Fig. 4

In standard single mode:

To slide the MAC switch on the side of the device downwards to position «1»

- Press the ON/OFF button, the pump begins to inflate the cuff. In the display, the increasing cuff-pressure is continually displayed.
- After reaching the inflation pressure, the pump stops and the pressure slowly falls away. The cuff- pressure is displayed during the measurement. When the device has detected the pulse, the heart symbol in the display begins to blink.
- The measured systolic and diastolic blood pressure values as well as the pulse are now displayed. Example (Fig. 6): Systole 128, Diastole 70, Pulse 80. The measurement results are displayed until you switch the device off. If no button is pressed for 3 minutes, the device switches automatically off.



Fig. 5



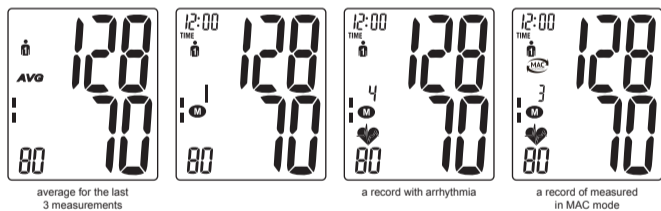
Fig. 6

4.5. 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" power button can be pressed at any time. The device then immediately lowers the cuff-pressure automatically.

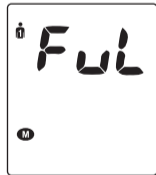
4.6. MEMORY – STORAGE AND RECALL OF THE MEASUREMENTS

The Digital Blood Pressure Monitor automatically stores each of 120 measurement values. By pressing the **M** memory button, to review an average value of the last 3 measurements and all of records. All of 120 measurements (MR1, MR3, ..., MR120) can be displayed (MR1: Values of the last measurement).



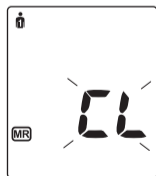
4.7. MEMORY FULL

Pay attention that the maximum memory capacity is not exceeded. When the memory is full, the old values are automatically overwritten with new ones. When memory is full, the display shown 1 second as follows to remind you "memory full".



4.8. 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.



5. ERROR MESSAGES/MALFUNCTIONS (Cont.)

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 observation of the details made under point 5.
Every measurement produces a different value although the instrument functions normally and the values displayed are normal	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.	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. Important thereby is, that comparable measurements always require the same conditions (Quiet conditions)!

If, in spite of observing all these factors, the fluctuations are larger than 15mmHg, and/or you hear irregular pulse tones on several occasions, please consult your doctor.

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 (see technical data) You must consult your specialist dealer or chemist if there are technical problems with the blood pressure instrument. Never attempt to repair the instrument yourself!

Any unauthorized opening of the instrument invalidates all guarantee claims!

6. CARE AND MAINTENANCE, RECALIBRATION

- Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.
- The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of straining through twisting or buckling.
- 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!
- Do not drop the instrument or treat it roughly in any way. avoid strong vibrations.
- Never open the device! Otherwise the manufacturer calibration becomes invalid!

Periodical recalibration

Sensitive measuring devices must from time to time be checked for accuracy. We therefore recommend a periodical inspection of the static pressure display every 2 years. Your specialist dealer would be pleased to provide more extensive information about this.

7. GUARENTEE

The Digital Blood Pressure Monitor is guaranteed for 2 years from date of purchase. The guarantee does not apply to damage caused by improper handling, accidents, not following the operating instructions or alterations made to the instrument by third parties. The guarantee is only valid upon presentation of the guarantee card filled out by the dealer.

8. SERVICE LIFE

5 years

9. BATTERY LIFE

1000 times measurement with 4 AA 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 a choking hazard.
- 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:

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 increment) 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 sets × 2 users (SYS, DIA, Pulse)
Decompression	Constant exhaust valve system
Power Source	4 AA alkaline batteries
Rated Voltage	DC 6.0 V 4.0 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
Storage Humidity	10%~95% RH maximum
Dimensions	128 × 92 × 61 ±1.0 mm
Weight	485 g±5 g (including batteries and cuff)
Cuff Pressure Display Range	0~290 mmHg/0~38.7 kPa
Electrical Shock Protection	Internal power unit
Safety Classifications	Type B equipment
Mode of Operation	Continuous operation
Protection Against Ingress of Water	IP22
Accessories	M-L size Cuff, 4 "AA" batteries, instruction manual

Please be noticed the power adapter is not supplied from the origin, users can buy the adapter in the market which must comply to EN60601-1, EN60601-1-2



13. DECLARATION – ELECTROMAGNETIC EMISSIONS

The Digital Blood Pressure Monitor, Upper Arm, 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, Upper Arm, can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Digital Blood Pressure Monitor, Upper Arm, 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, Upper Arm, 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:



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

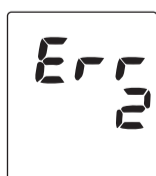
Manufactured for: **Dynarex Corporation**
10 Glenshaw Street • Orangeburg, NY 10962
USA • www.dynarex.com

Made in China

R200618

5. 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: The arm was moved during the Measurement (Artefact).
ERR 3	The inflation of the cuff takes too long. The cuff is not correctly seated.
ERR 5	The measured readings indicated an unacceptable difference between systolic and diastolic pressures. Take another reading following directions carefully. Contact your doctor if you continue to get unusual readings.
ERR 8	Pressure in cuff is over 290mmHg