prolife

DIGITAL
BLOOD PRESSURE MONITOR

Prolife PA3 Backlight

en Instruction manual

MEDICAL DEVICE NAME

Digital Blood Pressure Monitor Prolife, model **PA3 Backlight**.

MEDICAL DEVICE DESCRIPTION

The Digital Blood Pressure Monitor **Prolife PA3 Backlight** (with integrated date/time display) is a fully automatic, digital blood pressure measuring device for use on the upper arm, which enables very fast and reliable oscillometric measurement of the systolic and diastolic blood pressure as well as the pulse frequency.

The device offers a very high and clinical tested measurement accuracy and has been designed to provide a maximum of user–friendliness.

INTENDED USE

The device is intended for clinical, home and other use.

SCOPE OF APPLICATION

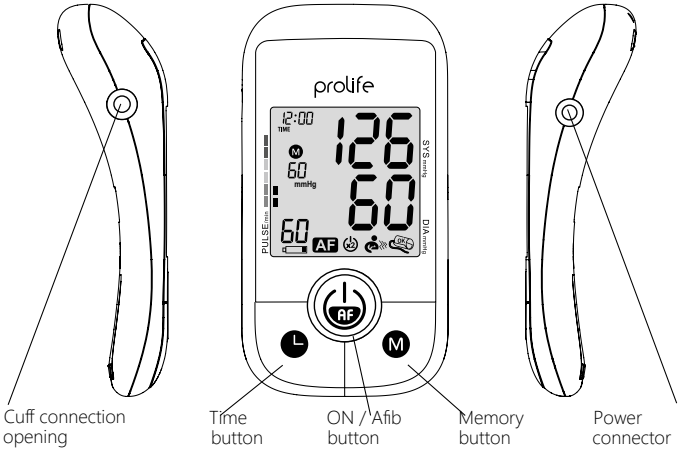
It is used in all areas of medical practice, namely: cardiology, neurology, emergency medical care, andrology, obstetrics and gynecology, anesthesiology and resuscitation, sports medicine, physiotherapy exercises, narcology, neonology, oncology, pediatrics, pulmonology, therapy, physiotherapy, phthisiology, cardiovascular surgery, functional diagnostics, etc.

TECHNICAL SPECIFICATIONS

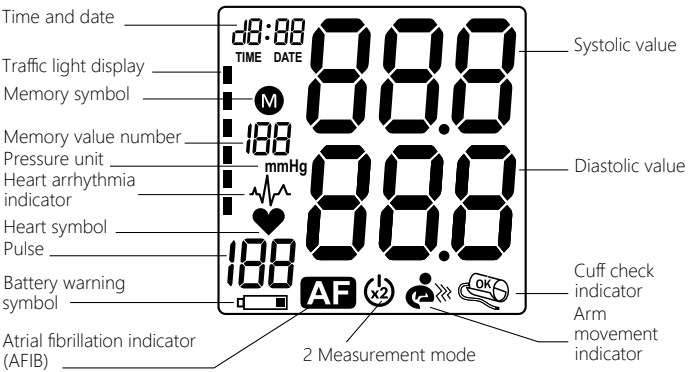
Type	**Digital Blood Pressure Monitor**
Model	**PA3 Backlight**
Measurement Procedure	Oscillometric, corresponding to Korotkoff method: phase I: systolic, phase V: diastolic
Display	Digital
Measuring range	Pressure: 30 to 280 mm Hg (in 1 mm Hg increment); pulse: 40 to 199 beats/minute

Static accuracy	Pressure: ±3mmHg/Pulse: ±5% of reading
Measuring resolution	1 mm Hg
Inflation	Automatic inflation by internal pump
Memory function	199 memories for 1 user (SYS, DIA, Pulse)
Decompression	Constant exhaust valve system
Power source	4–size «AAA» alkaline batteries
Rated voltage	DC 6 V
Operation temperature	5~40 °C/41~104 °F
Operation humidity	15~85% RH maximum
Storage temperature	–10~55 °C/14~131 °F
Storage humidity	10%~95% RH maximum
Dimensions (LxWxH)	172x99x49 (±1,0) mm
Weight (including batteries and cuff)	390 ± 5 g
Cuff pressure display range	0~290 mm Hg
Safety classifications	Type BF equipment
Mode of operation	Continuous operation
Protection against ingress of water	IP22
Accessories	Prolife conic cuff 22-42 cm, Prolife adapter, Prolife bag, 4 «AAA» batteries, instruction manual, warranty card

COMPLETENESS



Display



PUTTING THE DIGITAL BLOOD PRESSURE MONITOR INTO OPERATION

Inserting the batteries

1. Insert the batteries (4 x size AAA 1.5V), thereby observing the indicated polarity.
2. If the battery warning , icon appears in the display, the batteries remain 20% power, they need to be replaced soon.
3. If the battery warning , icon appears in the display, the batteries are empty and must be replaced by new ones.

ATTENTION!

After the battery warning , icon 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.

Reading the set date

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

Setting the time and date

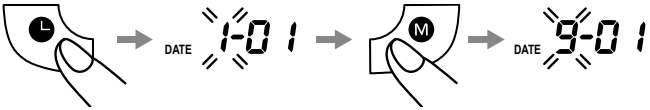
This blood pressure monitor incorporates an integrated clock with date display. This has the advantage, that at each measurement procedure, not only the blood pressure values are stored, but also the exact moment of the measurement.

After new batteries have been inserted, the clock begins to run **TIME** 12:00 and **DATE** 1–01.

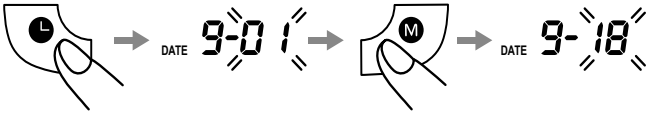
You must then re–enter the date and current time. For this, please proceed as follows.

1. Press the **TIME** button for at least 3 seconds firstly, indicator «Year» will blink. The correct year can be entered by pressing the **MEMORY** button.

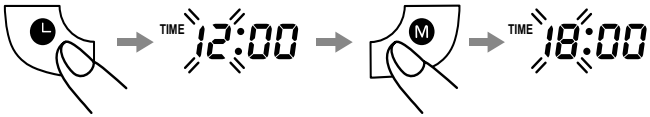
2. Press the **TIME** button again. The display now switches to the current date, during which the first character (month) blinks. The corresponding month can now be entered by pressing the **MEMORY** button.



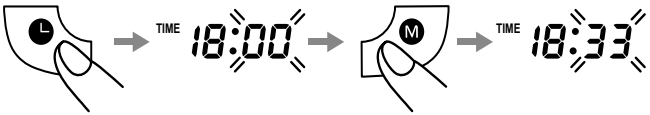
3. Press the **TIME** button again. The last two characters (day) are now blinking. The corresponding day can now be entered by pressing the **MEMORY** button.



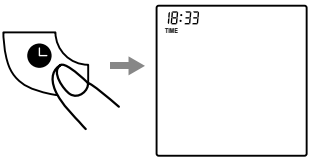
4. Press the **TIME** button again. The display now switches to the current time, during which the first character (Hour) blinks. The corresponding hour can now be entered by pressing the **MEMORY** button.



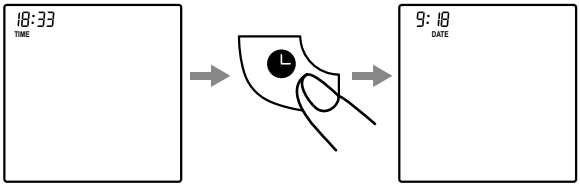
5. Press the **TIME** button again. The last two characters (Minutes) now blink. The exact time can now be entered by pressing the **MEMORY** button.



6. Press the **TIME** button again to complete the setup device. The setting is confirmed and the clock starts running. On the screen the current time is displayed.



7. To view the date, press the **TIME** button.



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.

MEASUREMENT PROCEDURE

Measurement preparation

- 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).
- Try to carry out measurements regularly at the same time of the day, since the blood pressure level changes during the course of the day.

Common sources of error

⚠ NOTE:

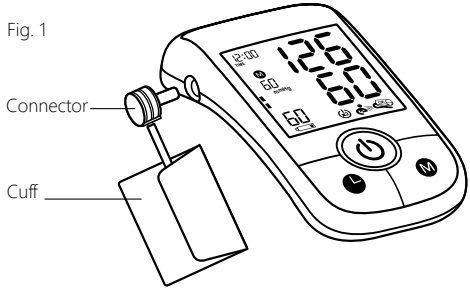
Comparable blood pressure measurements always require the same conditions! In a state of physical and emotional rest.

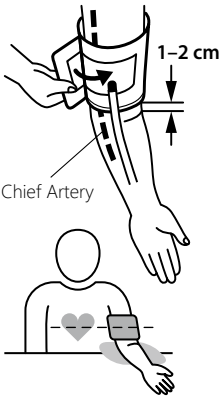
- Take a comfortable position, relax and do not toughen muscles of the arm subject to measurements. If necessary, use a cushion for support.
- The performance of an automatic sphygmomanometer can be influenced by extreme environmental conditions: high or low temperature, humidity, elevation of the measurement point above sea level.
- Prevent deformation and twisting of the cuff tube.
- Improper (loose) fixation of the cuff on the arm causes false measurement values.

Fixation of the cuff

Insert the connector into the cuff connection opening (as shown in Fig. 1) and make sure that the connection is tight.

Fig. 1





1. Fix the cuff with Velcro fastener so that it lies comfortably and fits snugly to your arm. The distance between the edge of the cuff and the middle of the elbow should be about 1~2 cm.
2. Lay the arm on a table, with the palm upwards. The cuff should be at the level of the heart, if necessary place a cushion under the forearm. Ensure support of the arm on a horizontal surface. Stay calm for 2 minutes before measurement.
3. Keep your legs straight and uncrossed, lean on the back of the chair.

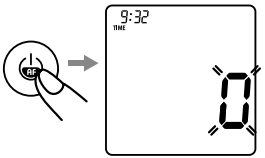
Measuring procedure

Measuring in standard mode

In this mode, an indication of pulse wave arrhythmia is possible.

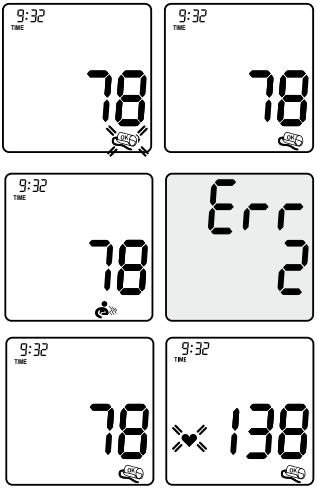
When the cuff is securely fixed, you can start measurement:

1. Press the **ON/OFF** button, the pump begins to inflate the cuff. During this time, the cuff pressure values are continuously displayed.



If the cuff is not firmly fixed and does not fit snugly to the arm, the symbol OK will appear on the display and will flash during the measurement. If the cuff is fixed properly, the symbol OK will appear on the display.

In case of insignificant movement of the arm during the measurement, the symbol , will appear on the display and the measurement will continue, otherwise the display will show the error Err2.



2. When a certain level of pressure in the cuff is reached, the air gradually comes out of it. During measurement, the display shows the cuff pressure values. When the arterial pulse is detected, the heart symbol ♥ begins to flash on the display. After the measurement is completed, the display shows the values of systolic, diastolic pressure and pulse rate.

Example 1: (Fig. 2):
Systole 120,
Diastole 80,
Pulse 70,
and arrhythmia detected,
cuff fit well.

Fig. 2

Example 2: (Fig. 3):
Systole 120,
Diastole 80,
Pulse 70,
and arrhythmia detected,
cuff fit too loose.

Fig. 3

Example 3: (Fig. 4):
Systole 128,
Diastole 86,
Pulse 68,
and a movement detected,
cuff fit well.

Fig. 4

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.

Measuring in AFIB mode (2-measurement mode)

The AFIB mode provides two automatic consecutive measurements, the result is then analyzed and displayed. The blood pressure is a non-constant value and fluctuates over a short period of time, therefore, the result determined in this way is more reliable than one produced by a single measurement.

When the cuff is properly fixed, you can start measurement:

1. Hold the **ON/AFIB** button for more than one second until the symbol ⏻ appears on the display.

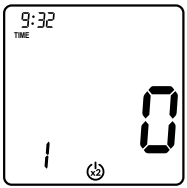
   During measurement a number 1 or 2 is shown on the left-hand side of the display, depending on which of the two consecutive measurements is currently being performed.

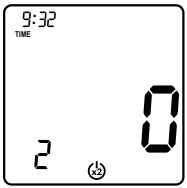
   The interval between measurements is 15 seconds (complies with requirements of «Blood Pressure Monitoring, 2001, 6:145-147» for oscillometric instruments). There is a countdown function.

   The results of the first measurement are not displayed. The blood pressure values will be displayed only after 2 measurements.

   Do not remove the cuff from the arm for the entire duration of the consecutive measurements.

   In some cases, the third measurement can be automatically performed to obtain the exact result.





2. When a certain level of pressure in the cuff is reached, the air gradually comes out of it. During measurement, the display shows the cuff pressure values. When the arterial pulse is detected, the heart symbol begins to flash on the display ♥.

   After the measurement is completed, the display shows the values of systolic, diastolic pressure and pulse rate.

Example 1: (Fig. 5):
Systole 128,
Diastole 86,
Pulse 68,
AFIB detected.

Icon of arrhythmia
and AFIB **AF**
will be appeared arm movement detected and cuff fit too loose detected.

Fig. 5

Example 2: (Fig. 6)
Systole 128,
Diastole 86,
Pulse 68,
arrhythmia detected,
but no AFIB detected.

Arm movement detected and cuff fit well.

Fig. 6

The measurement results are displayed until you switch the device off. If no button is pressed for 3 minutes, the device switches automatically off.

Appearance of the atrial fibrillation indicator for early detection.

This device is able to detect atrial fibrillation (AFIB). This icon **AF** indicates that atrial fibrillation was detected during the measurement. If atrial fibrillation is detected, it is recommended to repeat the measurement again. If the AF symbol appears after repeated measurement, you are advised to wait for one hour and perform the measurement one more time. If the AFIB symbol appears on the display after a pause of 1 hour, you are advised to consult a doctor. If after repeated measurement the AFIB symbol is no longer

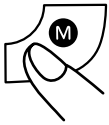
displayed, there is no cause for concern. In this case, it is recommended to measure the pressure the next day. Keep the arm still during measuring to avoid false readings. This device may not detect atrial fibrillation in people with pacemakers or defibrillators.

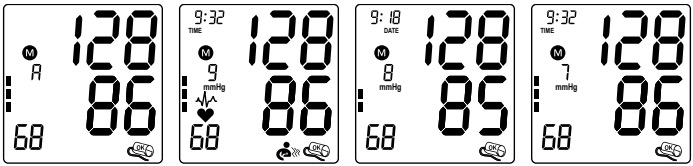
Discontinuing a measurement

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

Memory. Storage and recall of the measurements

The blood pressure monitor automatically stores the 199 last measurement values. By pressing the **MEMORY** button, an average value of the last 3 measurements as well as the last measurement and the further last 198 measurements (MR199,MR198,...,MR1) can be displayed one after the other.





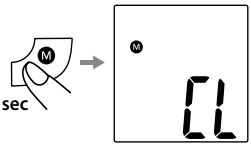
M^A:
average value of the last 3 measurements

M^9:
values of the last measurement

M^8–M^7:
values of the measurement before

Memory. Cancellation of all measurements

Before you delete all readings stored in the memory, make sure you will not need refer to the readings at a later date. You may keep a self-monitoring diary and record data in writing to provide additional information to your doctor.



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. The **«CL»** symbol will start blinking. To permanently clear the memory, press the MEMORY button while the **«CL»** symbol is blinking.

APPEARANCE OF THE HEART ARRHYTHMIA INDICATOR FOR EARLY DETECTION


This symbol indicates that certain pulse irregularities were detected during the measurement.

In most cases, this is no cause for concern (for example, with the so-called respiratory arrhythmia, which is a normal variant). However, if the symbol appears on a regular basis (e.g. several times a week with measurements taken daily), you are advised to inform your doctor.

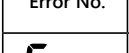
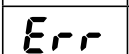
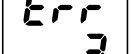
Please show your doctor the following explanation. Information for the doctor on frequent appearance of the Arrhythmia indicator.

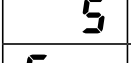
This device is an oscillometric blood pressure monitor that also analyses pulse frequency during measurement. The device is clinically tested. The arrhythmia symbol is displayed after the measurement, if pulse irregularities occur during measurement.

The device does not replace a cardiac examination, but serves to detect rhythm disturbance irregularities at an early stage.

ERROR MESSAGES / MALFUNCTION

If an error occurs during a measurement, the measurement is discontinued and a corresponding error code is displayed.

Error No.	Possible cause(s)
	The device can not determine the value of the pulse
	The influence of external impact on the measurement results. Reason: The arm was moved during the Measurement (Artefact)
	The inflation of the cuff takes too long. The cuff is not correctly seated

	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
	If pressure is over 290 mmHg

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 device does not turn on	Check batteries for correct polarity and if necessary insert correctly Check battery performance and replace if necessary
The device gives an error message several times in succession or the measurement values do not correspond to subjective general condition (too high/low)	Check the positioning of the cuff Measure the blood pressure again in peace and quiet under observance of the details made under point 5
The results of several consecutive measurements vary significantly	Please read and understand «The most common causes of errors» section. Repeat the measurement again, making sure all the rules for its execution are followed. **Note: The blood pressure is a dynamic value and fluctuates continually, therefore, a minor difference in values is acceptable between consecutive measurements**
Blood pressure measured differs from those values measured by the doctor	Keep a self-monitoring diary and show it to your doctor at the next visit. **Note: A patient may experience «white coat syndrome» at the doctor's appointment, so the pressure readings are higher than in a familiar home environment**

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 15 mmHg, and/or you hear irregular pulse tones on several occasions, please consult your doctor.
- The manufacture of the devices takes place according to the terms of the European standard for blood pressure measuring devices (see technical data). If you have any technical problems with the blood pressure monitor, please contact the service center or the manufacturer's representative.
- If you have questions related to the operation of the device and possible malfunctions, please contact the official representative of the manufacturer or the service center.

Any manipulations with the device (opening, mechanical or any other damage) will void all warranty claims.

IMPORTANT INFORMATION ON THE SUBJECT OF BLOOD PRESSURE AND ITS MEASUREMENT

Causes affecting the blood pressure level

The blood pressure level is regulated by a specific region of the brain – vasomotor center. The blood pressure change is subject to the heart force and rate as well as the tone and lumen of blood vessels. Relaxation of the unstriated muscles of the blood vessel walls results in pressure reduction due to the expansion of the lumen of blood vessels.

The blood pressure level changes periodically during cardiac activity: the maximum value (systolic blood pressure value) is observed in the period of blood ejection out of the heart ventricles (systole), the minimum value (diastolic blood pressure value) is observed at the end of the relaxation period (diastole).

The blood pressure values must lie within normal ranges to prevent critical condition of health.

Which values are normal?

The blood pressure is considered to be elevated, if at rest the diastolic pressure level is 90 mmHg or above and/or the systolic pressure level is above 140 mmHg. In this case, please consult your doctor. Maintenance of such pressure levels for a long period of time pose risk to health.

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, please consult your doctor immediately. 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 timely detect deviations from permissible values and take the necessary measures to prevent hypertension and the development of complications. If for medical reasons you have to control your blood pressure, measure it regularly at the same time of the day and keep a self-monitoring diary so that the doctor could evaluate changes in values.

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 blood pressure	Diastolic blood pressure	Measures
Hypotension	lower than 100	lower than 60	Consult your doctor
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». This condition also requires correction, please consult a doctor.

IMPORTANT FACTS ABOUT ATRIAL FIBRILLATION (AFIB)

What is atrial fibrillation (AFIB)? Normal heart functions rhythmically, alternating the phases of contraction and relaxation.

Specialized cardiac muscle cells (so-called cardiac conduction system) generate electrical pulses which make the heart contract by «pushing» the blood into the vessels. Atrial fibrillation occurs in the event of impaired functioning of the cardiac conduction system and the appearance of disorganized electrical signals in the atria, causing their irregular contraction (fibrillation). Atrial fibrillation is the most common form of cardiac arrhythmia or irregular heartbeat. Atrial fibrillation may be asymptomatic, but significantly increases the risk of stroke. This case requires medical supervision.

How does AFIB impact my family or me?

People with AFIB have a five-fold higher risk of getting stroke. Since the chance of having a stroke increases with age, AFIB screening is recommended for people over 65 years and older. Persons aged over 50 with high blood pressure (diagnosed with hypertension), diabetes, cardiac distress and prior stroke also need timely diagnosis of atrial fibrillation. In young people AFIB screening is not recommended as it could generate false positive results and unnecessary anxiety. In addition, young individuals with AFIB have a relatively low risk of getting stroke as compared to elder people. ADVANCE AFIB detection provides a convenient way to screen for AFIB. Knowing your blood pressure and knowing whether you or your family members have AFIB can help reduce the risk of stroke. ADVANCE AFIB detection provides a convenient way to screen for AFIB whilst taking your blood pressure. Risk

factors you can control High blood pressure and AFIB are both considered «controllable» risk factors for strokes. Knowing your blood pressure and knowing whether you have AFIB is the first step in proactive stroke prevention.

INFORMATION PROVIDED BY MANUFACTURER

The **Prolife PA3 Backlight** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Prolife PA3 Backlight** should assure that it is used in such an environment.

Electromagnetic Emissions: (IEC60601–1–2)

Emission Test	**Compliance**	**Electromagnetic Environment**
RF emission CISPR 11	Group 1	The **Prolife PA3 Backlight** uses RF energy only for internal functions. Therefore, this RF emission is extremely weak and there is little chance of it creating any kind of interference whatsoever with nearby electronic equipment
RF emissions CISPR 11	Class B	The **Prolife PA3 Backlight** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000–3–2	Not applicable	
Voltage fluctuations/flicker IEC 61000–3–3	Not applicable	

Electromagnetic Immunity: (IEC60601–1–2)

Immunity test	IEC60601–1–2 test level	Compliance level	Electromagnetic environment–guidance
Electrostatic discharge (ESD) IEC 61000–4–2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electric fast transient/burst IEC 61000–4–4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000–4–5	±1 kV differential mode ±2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000–4–11	<5% UT (95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (95% dip in UT) for 5 sec.	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the upper arm stlye requires continued operation during power mains interruptions, it is recommended that the **Prolife PA3 Backlight** be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000–4–8	3 A/m	Not applicable	Not applicable

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Immunity test	IEC60601–1–2 test level	IEC60601–1–2 test level	Electromagnetic environment – guidance
Conducted RF IEC 61000–4–6 Radiated RF IEC 61000–4–3	3 Vrms 150 kHz to 80 MHz 80% AM (2Hz) 3 Vrms 80 MHz to 2.5 GHz 80% AM (2Hz)	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any partof the **Prolife PA3 Backlight**, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommend separation distance 3 V d=1,2√P 80 Mhz to 800 MHz d = 2.3√p 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to he transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range **b**. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Prolife PA3 Backlight** is used exceeds the applicable RF compliance level above, the **Prolife PA3 Backlight**

should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Prolife PA3 Backlight**.

b. Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the Prolife PA3 Backlight

The **Prolife PA3 Backlight** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Prolife PA3 Backlight** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Prolife PA3 Backlight** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d=1,2√P	80 MHz to 800 MHz d=1,2√P	800 MHz to 2.5 GHz d=2,3√P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CARE AND MAINTENANCE

- Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
- The cuff contains an airtight chamber. Handle it carefully and avoid deformation when twisting or bending.
- Clean the device with a soft, dry cloth. Do not use gasoline and solvents. Gently remove any contaminations from the cuff with a damp cloth and soapy water. Machine washing is prohibited!
- Avoid mechanical and vibration effects on the device. Handle it carefully.
- It is forbidden to open the device housing and perform any other individual manipulations!

WARRANTY

The Digital Blood Pressure Monitor **Prolife PA3 Backlight** has a 10 years warranty from the date of purchase. The warranty does not apply to damage caused by improper handling, accidents, not following the operating instructions or alterations made to the device by third parties.

The warranty is valid only in the presence of a warranty coupon, completed by an official representative, confirming the date of sale and cash receipt. Information on the warranty for consumables, parts and accessories is indicated in the warranty card.

Warranty and free of charge service is not performed when:

- use of the device in violation of the operating instructions;
- in case of damage as a result of deliberate or erroneous actions of the consumer due to improper or negligent treatment;
- the presence of traces of mechanical impact, dents, cracks, chips, etc., on the body of the device, traces of the opening of the casing, disassembly, traces of attempts to repair outside the authorized maintenance center, traces of moisture ingress or aggressive agents, or any other foreign interference in the construction of the device, as well as in other cases of violation by the consumer of the rules for storage, cleaning, transportation and technical operation of the device, provided in the operating instructions;
- penetration of oils, dust, insects, liquids and other foreign objects inside the device.

Precisely follow the instructions to ensure reliable and long–term operation of the device.

If the device does not work properly, contact the seller.

For repair and maintenance, please contact a specialized after–sales service.

The manufacturer reserves the right to make changes in the design of the device.

The information of the date of mass production and the importer is placed on the individual package.

SERVICE LIFE

The service life of the device is 10 years.

BATTERY LIFE

It is used approx. 400 times measurement with 4–size «AAA» alkaline batteries.

SAFETY AND DISPOSAL

Safety and protection

- This device maybe used only for the purpose described in this Instruction manual. The manufacturer cannot be held liable for the damage caused by incorrect application.
- This device 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.
- The cuffs are sensitive and must be handled with care.
- Do not use the device close to strong electromagnetic fields such as mobile telephones or radio installations.
- Do not use the device if you think it is damaged.
- If the device 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 Instruction manual.


Do not allow children to use the device unsupervised: a child may swallow small parts. This device is not a toy and is not intended for games! Keep the appliance out of the reach of children.

- Use only certified accessories, removable parts and materials.

For this device you can use such models of cuffs as:

- Prolife standard cuff 22–32 cm;
- Prolife standard cuff 22–42 cm;
- Prolife conic cuff 22–42 cm.

Device care

Clean the device only with a soft, dry cloth.

Disposal


The symbol on the product or on its packaging indicates that this product is not classified as household waste.

- With proper disposal of the product, you will help to prevent possible negative effects of the device on the environment and human health.
- For the protection of the environment, the appliance must not be disposed of with domestic (household) debris. Disposal must be in accordance with local regulations.
- The device must be disposed of in accordance with the EU Directive 2012/19/EU WEEE (Waste Electrical and Electronic Equipment) for waste electrical and electronic equipment. If you have any questions, please contact the local utility responsible for waste disposal.

REFERENCE TO STANDARDS

The device meets the requirements of the following European standards:

- standard for devices with an arm blood pressure adapter.

Device standard

The device meets the requirements of the European standard for non-invasive blood pressure monitors:

- IEC 60601-1-6:2010+A1:2013/EN 60601-1-6:2010+A1:2015;
- IEC 60601-1:2005+A1:2012/EN 60601-1:2006+A11:2011+A1:2013+12:2014;
- IEC 60601-1-2:2014/EN 60601-1-2:2015;
- IEC/EN 60601-1-11:2015;
- IEC 80601-2-30:2009+A1:2013/EN 80601-2-30:2010+A1:2015.

The device complies with the Medical Device Directive 93/42/EEC.

Manufacturer:

Shenzhen Combei Technology Co., Ltd, 11-5B, No. 105, Huan Guan South Road, Dahe Community, GuanLan, Long Hua New District Shenzhen, People's Republic of China.

Authorized Representative in the EU:

EC REP MedNet EC-REP GmbH, Borkstrasse 10, 48163 Münster, Germany.

Importer in the EU:

SELF CONTROL LTD, 34, Brezovskaya str., 4003 Plovdiv, Bulgaria.

Authorized representative of the manufacturer on the territory of the Republic of Kazakhstan, organization that accepts claims (proposals) for a medical device from consumers on the territory of the Republic of Kazakhstan, organization responsible for post-registration monitoring of the safety of a medical device on the territory of the Republic of Kazakhstan:
"IG Trend" LLP, Republic of Kazakhstan, Almaty, Rayymbek Avenue, No. 169, tel +7 727 339-3474, e-mail: info@igtrend.kz.

For service support on the territory of the Republic of Kazakhstan, please call +7(701) 035 1445 or email: service@igtrend.kz.

Prolife® is the registered trademark by Montex Swiss AG, Tramstrasse 16, CH–9442, Berneck, Switzerland.

REMARK

Symbols	Meaning
CE 0197	The product complies with Directive 93/42/EEC concerning medical products.
	WEEE (Waste Electrical and Electronic Equipment Directive). The symbol on the product or on its packaging indicates that this product is not classified as household waste. To avoid possible harm to the environment and human health, separate such wastes from others and dispose of them in accordance with accepted standards.
	Equipment type BF.
IP22	Ingress protection rating. Leading digit (protection against ingress of solid foreign objects): 2 – protection against ingress of solid objects more than 12 mm in size; fingers or other objects with a maximum length of 80 mm, or solid objects. Second digit (protection against vertically falling water drops): 2 – protection from falling drops, falling objects from above under angle to the vertical of not more than 15° (equipment in normal position).
	Not suitable for children under 3 years. The device is not a toy and is not intended for games.
	Keep dry.
	Attention consult accompanying documents.
	AC/DC adapter.
	Reading Instruction Manual before use.
	European Authorized Representative.
	Manufacturer's name and address.

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