

CE0123



**GB Instruction manual Pulse Oximeter M70C**

Thank you very much for your confidence in us and congratulations on your purchase! You have acquired a **MedX5** quality product with your purchase. To ensure the best results and long-term satisfaction with your **MedX5** Pulse Oximeter **M70C**, we recommend that you read the following operating and maintenance instructions carefully.

**IMPORTANT INFORMATION! RETAIN FOR FUTURE USE!**

Read the instruction manual carefully before using this device, especially the safety instructions, and keep the instruction manual for future use. Should you give this device to another person, it is vital that you also pass on these instructions for use.

**Explanation of symbols**

**This instruction manual belongs to this device. It contains important information about starting up and operation. Read the instruction manual thoroughly. Non-observance of these instructions can result in serious injury or damage to the device.**

**WARNING**  
These warning notes must be observed to prevent any injury to the user.

**CAUTION**  
These notes must be observed to prevent any damage to the device.

**NOTE**  
These notes give you useful additional information on the installation or operation.

**IPX1** The degree of protection against dripping water

**Classification: Type BF applied part** No SpO<sub>2</sub> alarm

**Manufacturer** Storage conditions

**Date of manufacture** **SN** Serial number

- placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intra-vascular line
- patients suffering from hypotension, severe vasoconstriction, severe anemia, or hypothermia
- cardiac arrest or shock
- false fingernails
- circulatory disorder
- The Pulse Oximeter will **not alert** you if your readings are out of normal range.
- Explosion hazard: Do not use the Pulse Oximeter in an explosive atmosphere.
- The device is not suitable for continuous blood oxygen monitoring.
- In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than 4 hours.
- Operation of the Pulse Oximeter may be affected by the use of an electrosurgical unit (ESU).
- Do not use the Pulse Oximeter in an MRI or CT environment.
- The Pulse Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms advised by a professional physician.
- The device is not intended for sterilization or for cleaning with liquids.
- This equipment is not intended for use during patient transport outside the healthcare facility.
- This equipment should not be used adjacent to or stacked with other equipment.
- The device must not be used with accessories, detachable parts and other materials not described in the instructions for use.
- Please do not attempt to repair the unit yourself in the event of malfunctions. Stop using the device and contact the service centre.
- The materials that contact with the patient's skin have been tested to be in tolerance. In case you should detect skin irritations etc., stop using the device and contact a doctor.
- The swallowing of small parts like packaging bag, battery, battery cover and so on may cause suffocation.

**SAFETY NOTES FOR BATTERIES**

- Do not disassemble batteries!
- Never leave any low battery in the battery compartment since it may leak and cause damage to the unit!
- Increased risk of leakage! Avoid contact with skin, eyes and mucous membranes!
- If battery acid comes in contact with any of these parts, rinse the affected area with copious amounts of fresh water and seek medical attention immediately!
- Insert the batteries correctly, observing the polarity!
- Keep batteries out of children's reach!
- Do not attempt to recharge batteries! **There is a danger of explosion!**
- Do not short circuit! **There is a danger of explosion!**
- Do not throw into a fire! **There is a danger of explosion!**
- Do not throw used batteries into the household refuse; put them in a hazardous waste container or take them to a battery collection point, at the shop where they were purchased

**Items supplied and packaging**

Please check first of all that the device is complete and is not damaged in any way. If in doubt, do not use it and contact the service centre. The following parts are included:

- 1 **MedX5 Pulse Oximeter M70C**
- 2 Batteries (type AAA) 1.5V
- 1 carry bag
- 1 silicone protective cover
- 1 Lanyard
- 1 Instruction manual

The packaging can be reused or recycled. Please dispose properly of any packaging material no longer required. If you notice any transport damage during unpacking, please contact your dealer without delay.

**Device and controls**

- 1 OLED Screen
- 2 Start-button
- 3 Opening for finger
- 4 Battery compartment lid (on rear side of the device)

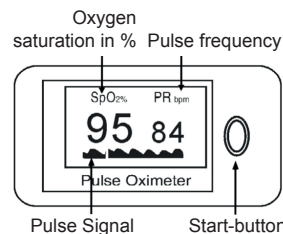
**Insert / change battery**

**Insertion:** You must insert the batteries provided before you can use your unit. The lid of the battery compartment 4 is located on the backside of the unit. Open it, remove it and insert the 2 x AAA type 1.5 V batteries supplied. Ensure correct polarity when inserting (as marked inside the battery compartment). Close the battery compartment.

**Removal:** Replace the batteries when the battery exchange symbol appears in the display. If nothing is displayed the batteries are completely empty and need to be replaced immediately.

**Use**

1. Open the finger opening by pressing the left upper and lower parts of the device together.
2. Place your finger as far as possible into the opening 3 on the right side of the device and release the upper and lower parts.
3. Press the Start-button 2. The OLED-screen will switch on immediately.
4. Keep your finger resp. your whole body still for the reading.  
After a short time, the values for the pulse frequency and the blood oxygen saturation appear on the OLED screen:



5. By repeatedly pressing the Start-button 2 you may switch between 6 different display modes (showing the already explained values in different view modes).
6. Remove your finger. The Pulse Oximeter will power off automatically after approx. 18 seconds.

**What does the measured result mean?**

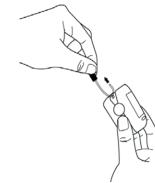
The oxygen saturation (SpO<sub>2</sub>) of the blood is a term referring to the concentration of oxygen attached to human hemoglobin. The normal value lies between 90 and 99 % SpO<sub>2</sub>. A too low value may be an indication for existing diseases like e.g. cardiac defect, problems of the circulatory system, asthma or specific diseases of the lung. A too high value may be caused by a too fast and too deep breathing, what bears the danger of a too low blood carbon dioxide level. The value measured with this device is not suitable in any way to make or confirm a diagnosis - contact your doctor under all circumstances to get a correct diagnosis.

**Adjustement of the display brightness**

The **MedX5 Pulse Oximeter M70C** offers the possibility to adjust the brightness of the display in 5 steps. To do so, press and hold the Start-button 2 (device must be switched on), until the desired brightness level is reached. The current brightness level is displayed on the upper right screen area (e.g. 1, 2, 3, 4 etc.).

**Using the Lanyard**

A Lanyard is included in the scope of delivery of the **MedX5 Pulse Oximeter M70C**. You may attach it to the device by threading the thinner end of the lanyard through the hanging hole on the left side of the device.



**Troubleshooting**

**Error:** SpO<sub>2</sub> and / or pulse frequency values are not displayed resp. are not displayed correctly.  
**Remedying:** Place one of your fingers completely into the finger opening 3 on the backside of the device. Use a new battery. Do not move or speak during the measurement. If still no correct values can be measured, contact the service centre.

**Error:** The device cannot be switched on.

**Remedying:** Remove the old battery and insert a new one. Press the START-button 2. If the device still cannot be switched on, contact the service centre.

**Cleaning and maintenance**

Remove the batteries before cleaning. Never use strong detergents or hard brushes. Clean the unit with a soft cloth, moistened with isopropyl alcohol. Do not let water enter the unit. After cleaning, only use the unit when it is completely dry.

**Disposal**

This product must not be disposed of together with domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substances, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner. Please remove the batteries before disposing of the device. Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop. Consult your municipal authority or your dealer for information about disposal.

**Directives / Norms**

This device is certified in accordance with EC Guidelines and carries the CE symbol (conformity symbol) "CE 0123". The specifications of EU Guideline "93/42/EEC of the Council Directive dated 14 June 1993 concerning medical devices" are met.

**Electromagnetic compatibility:** The device complies with the EN 60601-1-2 standard for electromagnetic compatibility.

**Electromagnetic compatibility - Guidance and manufacturer's declaration**  
*Effective: 19-Jul-2014*

Electromagnetic emissions		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions nach IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601-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 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the thermometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance:</b> d=1.2 √P 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 the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range*. Interference may occur in the vicinity of equipment marked with the following symbol:
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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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter		
The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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	
	80 MHz to 800 MHz d=1.2 √P	800 MHz to 2.5 GHz d=2.3 √P
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334
10	3.6893	7.3786
100	11.6667	23.3334

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated 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 80 MHz and 800 MHz, 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.

**TECHNICAL DATA**

Name and model : **MedX5 Pulse Oximeter M70C**  
 Display system : Digital display (OLED)  
 Power supply : 3 V=, 2 batteries (type LR03, AAA) 1,5V  
 Measuring range : SpO<sub>2</sub> : 70 % - 100 %, Pulse: 25 - 250 beats / min.  
 Accuracy : SpO<sub>2</sub> : ± 1 %, Pulse: (25 - 99) = ± 1; (100 - 250) = ± 1 %  
 Display resolution : SpO<sub>2</sub> : 1 %, Pulse: 1 beat / min.  
 Response time : ø 13 seconds  
 Automatic switch-off : After approx. 18 seconds  
 Operating conditions : +5°C - +40°C, max. 85 % rel. humidity, pressure 700 hPa - 1060 hPa  
 Storage conditions : -20°C - +55°C, max. 93 % rel. humidity, pressure 500 hPa - 1060 hPa  
 Dimensions : approx. 57 x 33 x 30 mm  
 Weight : approx. 54 g

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**Produced for:**

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**ASSIGNED PURPOSE**

The Pulse Oximeter M70C is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate of adult and pediatric patients. It is not suitable for continuous monitoring.

**SAFETY INFORMATION**

- Pulse oximeters are sensitive to motion artefacts. Therefore keep hands still while taking a reading.
- Pulse Oximeters require sufficient blood flow to obtain proper readings. If your hands are cold or you have poor circulation, warm your hands by rubbing them together or use another method before attempting to obtain a reading. A tourniquet, blood pressure cuff or other blood flow hindrances may also result in inaccurate readings.
- **Fingernail polish or acrylic nails obstruct the light transmission and may also result in inaccurate readings.**
- Your finger and the pulse oximeter must be clean for proper reading.
- If a reading is different to obtain, switch to another finger or to the other hand.
- *Inaccurate measurement results may also caused by:*
  - dysfunctional hemoglobin or low hemoglobin
  - the use of intravascular dyes
  - high ambient light
  - excessive patient movement
  - high-frequency electrosurgical interference and defibrillators
  - venous pulsations