Pulse Oximeter User Manual

UP-100CN

LIFE SOURCE® A&D Medical

A&D Medical

ACM AUTO CONTROL MÉDICAL An A&D Company

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Distributed in Canda by/Distribué au Canada par:
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INSTRUCTIONS TO USER

Dear users, thank you very much for purchasing the Pulse Oximeter.
This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.
The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.
Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.
This product is medical device, which can be used repeatedly.

WARNING:
- **Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier users. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the special users, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not stare at the light.**
- **User cannot use with fingernail polish.**
- **User's fingernail cannot be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

1 SAFETY

1.1 Instructions for Safe Operations
- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect user's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User's Manual. Only the accessory that appointed or recommendatory by manufacture can be used with this device.
- This product is calibrated before leaving factory.

1.2 Warnings
- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the user measured by MRI and CT.
- Persons allergic to rubber can not use this device.
- The disposal of scrap instrument and its accessories and packings (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
- Please check the packing before use to make sure the device and accessories are in accordance with the packing list, or else the device may have the possibility of working abnormally.
- Please don't measure this device with function test paper for the device's related information.

1.3 Attentions
- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- DO NOT operate keys on front panel with sharp materials.
- High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter for instructions of cleaning and disinfection.
- Do not submerge oximeter in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60ºC.
- Fingers which are too thin or too cold, are likely to affect the normal measure of the users' SpO2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- Do not use the device on infant or neonatal users.
- The product is suitable for children above four years old and adults (Weight should be between 15kg to 110kg).
- The device may not work for all users. If you are unable to achieve stable readings, discontinue use.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- Please read the measured value when the waveform on screen is equably and steady-going, This measured value is optimal value. And the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal useful life for three years from first use.
- The lanyard attached to the product is made from Non-allergy material, if there is a sensitivity to the lanyard, stop using it. In addition, pay attention to the use of the lanyard, do not wear it around the neck avoiding harm to the user.
- The instrument does not have low-voltage alarm function, it only shows the low-voltage, please change the battery when the battery energy is used up.
- Do not use this device if alarms are required.This device does not have audible alarms.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

2 OVERVIEW

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so-called the O2 concentration in the blood. It is an important bio-parameter for the respiration. For the purpose of measuring the SpO2 more easily and accurately, our company developed the Pulse Oximeter. At the same time, the device can measure the pulse rate simultaneously.
The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for user to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of Hemoglobin Saturation.

2.1 Classification:
Class 3 (SCHEDULE 1 rule 10)

2.2 Features
a. Operation of the product is simple and convenient.
b. The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying.
c. Low power consumption.

2.3 Major Applications and Scope of Application
The Pulse Oximeter is a non-invasive device intended for the spot-check or continuous monitoring of oxygen saturation of arterial hemoglobin (Sp02) and the pulse rate of adult users through the finger in home and hospital environments (including clinical use in internal medicine, surgery, anesthesia, and intensive care). The are not intended for single use and out-of-hospital transport use.
⚠ **The product is not suitable for use in continuous supervision for users.**
⚠ **The problem of overrating would emerge when the user is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.4 Environment Requirements
Storage Environment
a. Temperature: -40°C ~ +60°C
b. Relative humidity: ≤95%
c. Atmospheric pressure: 500hPa ~ 1060hPa

Operating Environment
a. Temperature: 10°C ~ 40°C
b. Relative humidity: ≤75%
c. Atmospheric pressure: 700hPa ~ 1060hPa

3 PRINCIPLE OF MEASUREMENT

Principle of the Oximeter: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO2) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

3.1 Clinical Restrictions
a. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
b. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO2 determination by this monitor may be inaccurate.
c. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO2 measure.
d. As the SpO2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some users with serious anemia may also report good SpO2 measurement.

4 TECHNICAL SPECIFICATIONS

4.1 Main Performance
a. SpO2 value display
b. Pulse rate value display, bar graph display
c. Low battery indication:when the voltage is too low to work,low battery indication appears.
d. The product will automatically be powered off.

4.2 Main Parameters
a. **Measurement of SpO2**
Measurement Range: 0 ~ 100%
Accuracy: 70 ~ 100%, ±2%; 0 ~ 69%,unspecified
b. **Measurement of pulse rate**
Measurement Range: 30 bpm ~ 250 bpm
Accuracy: ±2 bpm or ±2% (select larger)
c. **Power Requirements**
2 ×1.5V AAA alkaline battery, adaptable range: 2.6V ~ 3.6V.
d. **Power Consumption**
Smaller than 25 mA.
e. **Resolution**
SpO2: 1%, Pulse rate: 1bpm.
f. **Measurement Performance in Weak Filling Condition:**
SpO2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).
g. **Resistance to surrounding light:**
The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.
h. **Power supply requirement:** 2.6V DC ~ 3.6V DC.
i. **Optical Sensor**
Red light (wavelength is 660nm, 6.65mW)
Infrared (wavelength is 905nm, 6.75mW)

5 ACCESSORIES
- One lanyard
- Two batteries
- One case

6 INSTALLATION

6.1 View of the Front Panel

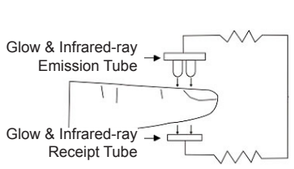

Figure 1: Operating Principle

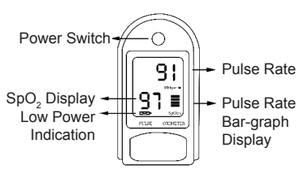

Figure 2: Front View

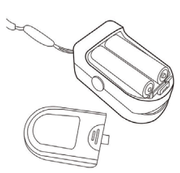

Figure 3: Batteries Installation

Figure 4: Put finger in position

6.2 Battery Installation
a. Refer to Figure 3. and insert the two AAA size batteries in the right direction.
b. Replace the cover.

⚠ **Please take care when you insert the batteries for the improper insertion may damage the device.**

6.3 Attaching the lanyard
a. Put the end of the lanyard through the hole.
b. Put another end of the lanyard through the first one and then tighten it.

7 OPERATING GUIDE

a. Open the clip
b. Put the user's finger into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger as shown in figure 4.
c. Press the switch button once on front panel.
d. Do not shake the finger and keep the user at ease during the process. Keep body still during measurement process.
e. Get the information directly from screen display.
f. Press button, and the device is reset.

⚠ **Fingernails and the emission tube should be on the same side.**

8 MAINTENANCE ,TRANSPORTATION AND STORAGE

8.1 Cleaning and Disinfecting
After cleaning the device, wipe the surface of device with ethanol and-air dry (or clean with a clean, dry cloth).

8.2 Maintenance
a. Please change the batteries when the low-voltage ( ) displayed on the screen.
b. Please take out the batteries if the oximeter is not in use for a long time.
c. Device does not require calibration.

8.3 Transportation and Storage
a. The device cannot be transported mixed with toxic, harmful, corrosive material.
b. The best storage environment of the device is - 40ºC to +60ºC ambient temperature and not higher than 95% relative humidity, and in a room with no corrosive material and good ventilation.

9 TROUBLESHOOTING

Trouble	Possible Reason	Solution
The SpO2 and Pulse Rate cannot be displayed normally	1. The finger is not properly positioned. 2. The user's SpO2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The Sp02 and Pulse Rate is not stable	1. The finger is not placed inside deep enough. 2. The finger is shaking or the user is moving	1. Place the finger properly and try again. 2.Stay calm, quiet and still during measurement
The device can't be turned on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The malfunction of the device.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The display is off suddenly	1. The device is damaged. 2. The batteries are almost drained.	1. Please contact the local service center. 2. Change batteries.

10 KEY OF SYMBOLS

Symbol	Description	Symbol	Description
	Refer to instruction manual	+	Battery positive electrode
SpO2%	The pulse oxygen saturation (%)	−	Battery cathode
PRbpm	Pulse rate (bpm)		1. 1. No finger inserted 2. An indicator of signal inadequacy
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)		Power switch
	Type BF		Alarm inhibit
SN	Serial number		WEEE (2002/96/EC)
IP22	Ingress of liquids rank	CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
EC REP	European Representative		

11 FUNCTION SPECIFICATION

Display Information	**Display Mode**
The Pulse Oxygen Saturation(SpO_2)	Digital LED display
Pulse Rate(PR)	Digital LED display
Pulse Intensity (bar-graph)	Digital bar-graph display
SpO2 Parameter Specification	
Measuring Range	0% ~ 100%, (the resolution is 1%).
Accuracy	70% ~ 100%:±2% ,Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660nm) Infrared (wavelength is 880nm)
Pulse Parameter Specification	
Measuring Range	30bpm ~ 250bpm (the resolution is 1 bpm)
Accuracy	±2bpm or ±2% select larger
Safety Type	Interior Battery, BF Type
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 or rechargeable battery	
Battery Useful Life	
Two batteries can work continually for 24 hours	
Dimensions and Weight	
Dimensions	58.5(L) × 31(W) × 32 (H) mm
Weight	About 52g (with the batteries)

12 APPENDIX

Guidance and manufacture's declaration – electromagnetic emissions for all EQUIPMENT and SYSTEMS

Guidance and Manufacture's Declaration – Electromagnetic Emission		
The UP-100CN is intended for use in the electromagnetic environment specified below. The customer of the user of the UP-100CN should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emission CISPR 11	Group 1	The UP-100CN 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 emission CISPR 11	Class B	The UP-100CN 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacture's declaration – electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
The UP-100CN is intended for use in the electromagnetic environment specified below. The customer or the user of UP-100CN 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 floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	N/A	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% U_T** (>95% dip in U_T) for 0.5 cycle **40% U^T** (60% dip in U_T) for 5 cycles **70% U_T** (30% dip in U_T) for 25 cycles **<5% U_T** (>95% dip in U_T) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the UP-100CN requires continued operation during power mains interruptions, it is recommended that the UP-100CN be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) 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.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The UP-100CN is intended for use in the electromagnetic environment specified below. The customer or the user of UP-100CN 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 UP-100CN, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 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 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 UP-100CN is used exceeds the applicable RF compliance level above, the UP-100CN should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the UP-100CN.
[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 EQUIPMENT or SYSTEM for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the UP-100CN			
The UP-100CN is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the UP-100CN can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UP-100CN 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 $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.39	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.			