North-vision Fingertip Pulse Oximeter Prince-100B

User Manual

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Instructions to User

Dear Users,

Thank you very much for purchasing our product. Please read the manual very carefully before using this device. If you do not follow these instructions may cause measuring abnormality or damage to the oximeter.

The manual is published in English and we have the right to explain the Manual. No part of this manual may be photocopied, reproduced or translated into another language without the permit from North-vision. We reserve the right to improve and amend it at any time without prior notice.

Notes

- The contents contained in this manual are subject to change without notice.
- Information furnished by our company is believed to be accurate and reliable. However, no responsibility is assumed by us for its use, or any infringements of patents or other rights of third parties that may result from its use.

Instructions for Safe Operations

- Check the device to make sure that there is no visible damage that may affect user's safety or measurement performance with regard to sensors and clips. It is recommended that the device should be inspected minimally once a week. When there is obvious damage, stop using the device.
- Necessary maintenance must be performed only by qualified service technicians. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User Manual.

Cautions

- 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 testee is under MRI or CT scanning.

Warnings

- An uncomfortable or painful feeling may appear if using the oximeter continuously on the same place for a long time, especially for poor microcirculation patients. It is recommended that the oximeter should not be applied to the same location for longer than 2 hours. If any abnormal condition is found, please change the position of oximeter.
- DO NOT clip this device on edema or tender tissue. 0 The light (the infrared light is invisible) emitted from the device is harmful to the eyes, so service technician or testee should not stare at the light.
- The local law must be followed when disposing of the device.

Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- The device should be kept out of the reach of children.

- If the oximeter gets wet, please stop using it and do not resume operation until it is dry.
 When it is carried from a cold environment to a warm and humid environment, please do not use it immediately.
- DO NOT operate the button on the front panel with sharp materials.
- DO NOT use high temperature or high pressure steam disinfection on the oximeter. Refer to Chapter 9 for instructions of cleaning and disinfection.

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1 Overview

1.1 Appearance

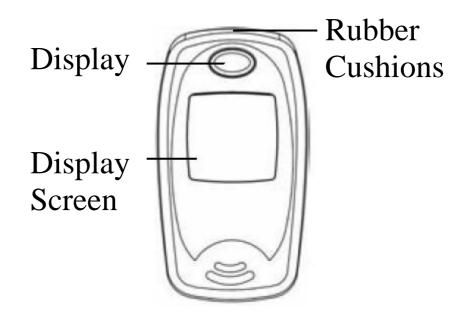
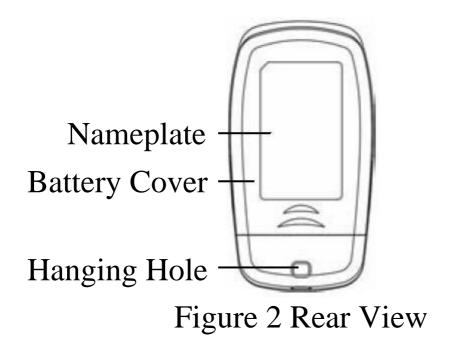


Figure 1 Front View



1.2 Name and Model

Name: Fingertip Pulse Oximeter

Model: Prince-100B

1.3 Feature List

Model Function	Prince-100B
Display screen	OLED
SpO2	
PR	
PI	
Plethysmogram	
Auto on	
Auto off	
Alarm	
Low voltage	$\sqrt{}$
indication	
Multi-directional	$\sqrt{}$
display	

Note: " $\sqrt{}$ " means the oximeter has this function, blank means the oximeter doesn't have this function. "Optional" indicates that this function is optional.

1.4 Applications and Scope

Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO₂) through the testee's body especially on finger. It is designed by using internal (build-in) sensor and applicable for spot-check during no motion and well perfusion condition and can be used in homes, hospitals and clinics. The device is used for adult.

1.5 Key of Symbols

Symbol	Description		
%Spo2	Pulse oxygen saturation		
PR	Pulse rate (beats per minute)		
PI%	Perfusion Index(%)		
≣/■	Pulse intensity bargraph		
421/4	Low battery voltage		
★	With Type BF applied part		
\triangle	Warning — See User Manual		
SN	Serial number		
X	Separate collection for this device.		

2 Battery Installation

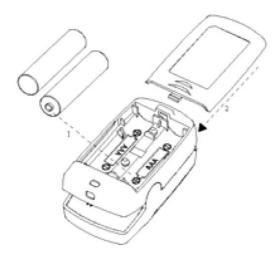


Figure 3 Battery Installation

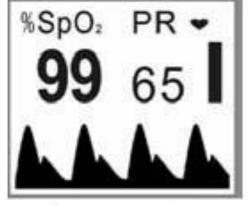
- 1 Refer to Figure 3, insert two AAA size batteries into the battery compartment properly.
- 2 Replace the cover.

⚠ Please make sure that the batteries are correctly installed, or incorrect installation may cause the device not to work.

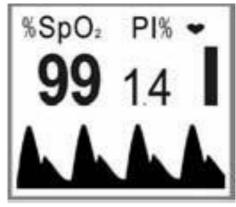
3 Quick Guide to Operation

Step	Operation
	Open the clip and put finger into the
1	rubber cushions of the clip (make sure the
_	finger is in the correct position), and then
	clip the finger.
2	Wait 2 seconds, the oximeter will power
4	on automatically and start to measure.
3	Short time press Display Key to
3	changedisplay direction.
4	Longtime press Display Key to shift the
4	parameter display between PR and PI.
	Remove your finger, the oximeter will
5	poweroff automatically.

4 Display Screen



Default measuring screen



SpO2&PI display screen

5 Instructions for Operation

- The finger should be put in properly and correctly.
- Do not shake the finger. Keep at ease during measurement.
- Do not put wet finger directly into sensor.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
- Do not let anything block the emitting light from device.
- Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
- The orientation-sensor works on the basis of the gravity. A small movable metal ball is built in the orientation-sensor for detecting the orientation of the oximeter. When you want to change the oximeter's display direction, if you move the oximeter too slowly, the movable metal ball will also move slowly because of not enough acceleration. Consequently the response of

orientation detection would be delayed. Please move the oximeter with a bit of force if you want to change the display direction(such as bend/extend your finger quickly), so an acceleration is provided to the orientation-sensor for quick sensing the orientation change.

• Using enamel or other makeup on the nail may affect the accuracy of measurement.

6 Technical Specifications

A. Power supply requirement:

1.5V (AAA size) alkaline battery \times 2

Supply voltage: 3VDC

Operating current: ≤40mA

Operation time:20hrs

B. SpO2 Parameter Specifications

Measuring range: 0%~100%

Accuracy: 70%~100% ±2digits

*NOTE: Arms is defined as root-mean-square value of deviation according to ISO 80601-2-61.

C. Pulse Rate Parameter Specifications

Measuring range: 30bpm~240bpm

D. Perfusion Index(PI) Display

Range: 0.4%~20%

E. Preset alarm limits

SpO2 alarm: Lower limit: 90%

Pulse Rate alarm: Upper limit: 120bpm

Lower limit: 50bpm

F. Audible&visual alarm function

When measuring, if SpO2 value or pulse rate value exceeds the preset alarm limit, the device will alarm automatically and the value which exceeds limit on the screen will flash.

G. Environment requirement

Operating Temperature: 5°C ~40°C

Operating Humidity: 15%~93%

Atmospheric pressure: 700hPa~1060hPa

H. The performance under low perfusion condition

The accuracy of SpO2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6%.

I. Resistance to interference of surrounding light:

The difference between the SpO2 value measured in the condition of indoor natural light and that of

darkroom is less than $\pm 1\%$.

J. Resistance to 50Hz /60Hz interference:

SpO2 and PR are precise which have been tested by BIO-TEK pulse oximeter simulator.

K. Dimensions:

66 mm (L) × 36 mm (W) × 33 mm (H) Net Weight: 60g (including batteries)

L. Classification

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied part.

The degree of protection against harmful ingress of liquids: IP22.

Electro-Magnetic Compatibility: Group I, Class B

7 Accessories

- A. A lanyard
- B. Two batteries
- C. A pouch
- D. An External SpO2 Probe (optional)
- E. A User Manual
- F. Quality Certificate

Note: The accessories are subject to change. Detailed items and quantity see the packing List.

8 Repair and Maintenance

8.1 Maintenance

The life of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please change the batteries when the low-voltage indicator lightens.
- Please clean the surface of the device before using. Wipe the device with alcohol first, and then let it air dry or wipe it dry.

- Please take out the batteries if the oximeter will not be used for a long time.
- The best storage environment of the device is -25°C to 70°C ambient temperature and less than 93% relative humidity.
- The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle. However, if it is necessary to verify its accuracy routinely, the user can do the verification by means of SpO2 simulator, or it can be done by the local third party test house.
- **⚠** High-pressure sterilization cannot be used on the device.
- **⚠** Do not immerse the device in liquid.
- ⚠ It is recommended that the device should be kept in a dry environment. Humidity may reduce the life of the device, or even damage it.

8.2 Cleaning and Disinfecting Instruction

• Surface-clean sensor with a soft cloth by wetting with a solution such as 75% isopropyl alcohol, if low-level disinfection

- is required, use a 1:10 bleach solution.
- Then surface-clean with a cloth saturated with clean water and dry with a clean, soft cloth. Caution: Do not sterilize by irradiation steam, or ethylene oxide. Do not use the sensor if it is damaged.

9 Troubleshooting

Trouble	Possibe Reason	Solution
Display	Maybe the	Please shake the
direction	oximeter is not	oximeter with a
doesn't	used for a long	certain force to
change or	time, the movable	make the
changes	metal ball within	movable metal
insensitively.	the	ball move freely.
	orientation-sensor	If the problem
	can not move	still exists, maybe
	freely.	the
		orientation-sensor
		is not working
		properly. Please
		contact the local
		service center.

Trouble		Possible Reason		Solution
The	1.	The finger is not	1.	Place the
The		Placed far		finger
SpO2 and		enough inside.		correctly
Pulse	2.	The finger is		inside and
Rate		shaking or the		try again.
		patient is moving.	2.	Let the
display instable				patient keep
Ilistable				calm.
	1.	The batteries are	1.	Change
		drained or almost		batteries.
Can not		drained.	2.	Reinstall
turn on	2.	The batteries are		batteries.
the		not inserted	3.	Please
device		properly.		contact the
	3.	The device is		local service
		malfunctioning.		center.
	1.	The device will	1.	Norrnal.
		power off	2.	Change
		automatically		batteries.
No		when it gets no		
display		signal for 8		
		seconds.		
	2.	The batteries are		
		almost drained.		

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