Dr. Odin® Pulse Oximeter+PI F-26

User Manual



WARRANTY WARRANTY CARD

IMPORTED & MARKETED BY: Passim Medichem Agencies # 186, Ind. Area Phase II, Chandigarh 160 002 # 100, mt. Area in lase it, chantagain 100 Corporate Office:
902, 9th Floor, WallFort House, S.V. Road,
Near Citi Mall, Goregaon (W)
Mumbai-400 662 INDIA
Customer Care No.:
+91-9878785333, 9359490504
(Timings, 20. bt. 7, pp. Mon. to S.t.) (Timing: 9 am to 7 pm, Mon. to Sat.) Website: www.drodin.in

mercare@drodin.in

Production Date: Please see the product labe Use Period: One year Version: V1.0 NO: QR-10-018/03/001 CERIFICATE Date of Preparation: 2018.10

纖纖

out Us

2

Chapter 1 Safety Guide

1.1 Electrical safety

Classified according to the type of protection against electric shock: equipment with internal power supply.

Classified according to the degree of protection against electric shock: BF type Classified according to the degree of protection against harmful liquids: IP22. Classified according to electromagnetic compatibility: Group 1 Class B.

1.2 Safety information

 \bigwedge Warning: Information that you should know in order to avoid injury to

⚠ Caution: Important information that should be emphasized.

- 10 Too much ambient light can affect measurement accuracy. Avoid using in
- Too much an indeed in give a market measurement accuracy. Avoid using it strong sunlight and dusty environment.
 Do not use the instrument when the performance of the instrument changes.
- Some patients may be allergic after prolonged exposure to the instrument. When allergy occurs, please stop using the instrument immediately.
 Use the battery recommended by the manufacturer. Use of other batteries may cause heat or damage to the instrument.
- No one except the manufacturer shall disassemble or modify the instrument.
 Do not maintain the instrument when it is in use.

1.3 Explanation of symbols

No.	Symbol	Explanation	
1	★	BF type applied part	
2	③	Refer to the manual	
3	Δ	Caution, refer to the attached file	

2.4 Product Features

2.5 Performance Parameters

of blood(SpO2)

Pulse Rate(PR)

2.6 Packing list

Description

Handing rope

2.7 Size and Weight

Working environment

Main unit

Length×Width×Height: 58.8×36×34mm Weight: 54g (including batteries)

2.8 Environmental requirements

Date of Revision: NA

① Please do not use the product display information as the only basis for clinical diagnosis and the product is only used as an auxiliary tool in

Email ID: cust

Made in PRC

- Before using the device, it should be under normal working condition
- before using the device, it should be under normal working condition and operating environment.

 The device should be used in a quiet and comfortable environment, not used during exercise.

 Ensure that the environment of the device is not disturbed by strong electromagnetic interference sources, such as wireless transmitter,

- gas fumigation or liquid immersion.
 This device is calibrated and maintained by professional technicians.
 Keep equipment away from children, pets and insects.
 Only by reading the whole Jane eyre book can you fully understand the
- The longest use of a single finger should not exceed 4h, otherwise it will lead to overpressure injury.

4	SpO2	Oxygen saturation
5	PR	Pulse rate
6	*	Disposal of waste electrical and electronic equipment separately(Follow local government regulations and recycling instructions for batteries)
7	⊗	No SpO2 Alarms
8	SN	Serial number
9	IP22	Enclosure protection class
10	((· <u>·</u>))	Non-ionizing radiation
11	اس	Date of manufacture
12		Manufacturer
13	EC REP	On behalf of the European
14	52	Lifenan

2.4.1 The product is designed to be light in weight, simple in operation, easy to

OLED,LED,TFT and LCD. Measurement range: 35% \sim 100% Resolution: 1%

Accuracy: Within the range of 90% ~ 100%, tolerance ± 2%;
Within the range of 70% ~ 90%, tolerance ± 3%;
Less than 70% undefined

Storage and transportation condition

Measurement range: No less than 30bpm ~ 250bpm

use and carry.

2.4.2 True Color high resolution OLED,LED,TFT and LCD.

Chapter 2 Product Overview

2.1 Display

2.2 Product Composition

It consists of shell, sensor, internal circuit and display screen

It can be used under the guidance of the doctor or by the patient himself, by holding it on the finger to measure the blood oxygen saturation and pulse rate. It applies to adults and children. Can be used by different patients, but can only be used by one patient at a time. No contraindications.

Resolution:1bpm Accuracy: ±1% or ±3bpm, large value Anti-ambient Or illumination source and that measured in the darkroom Light interference

(Real-time pulse rate data after stabilization)

Power supply

2x1. 5v, AAA alkaline batteries(It can be used for 1~1.5

Working current Direction sensor

OLED.TFT: Digital and waveform display on the same screen, automatic display in four directions. LED,LCD: Manual display in two directions.

Red light wave length (657nm-663nm 7mW,Low power light in this wavelength range is safe for the human body.) Infrared light (wave length 900nm-910nm 55mW)
No more than 15s(From optical signal to digital signal)

⚠ Caution: The time from extreme storage environment to normal use of the instrument should be no less than 3h.

2.9 Biocompatibility

The product is proved to be non-cytotoxic, non-allergenic and minimal skin

2.10 Conformity Declaration of Blood Oxygen

This product conforms to the standard requirements of ISO 80601-2-61.

2.11 Declaration of no alarm

This product does not have the alarm function and does not conform to the found, consult a doctor or visit the hospital in time.

2.12 The continuous monitoring time in the same position should not exceed 4 hours

2.13 Statement of SPO2 measurement function

The verification of the accuracy of blood oxygen saturation was obtained by a clinical trial comparison with the blood gas analyzer.

2.14 Demographic characteristics of clinical research

- No smoking history/ no history of tobacco addition
- C) No previous history of cardiopulmonary diseases;
 D) The volunteers have the ability to act independently, agree to participate
- E) The volunteers must be in a good state of mood when participating in

2.16 According to ISO 80601-2-61 standards, arterial blood oxygen saturation (SpO2) value depends on the accuracy of the calibration curve of the pulse oximetry is properly reflected pulse oximetry interact with pulse oximetry the organization of the optical properties, functional tester is unable to confirm the SpO2 accuracy calibration curve, also cannot fully evaluate the optical

97 . 67

F) Blood pressure values of the volunteers; systolic blood pressure

- Blood pressure values of the volunteers: systolic blood pressure 90-140mmlg, disabolic blood pressure 60-90mmlg:

 Heart Rate of volunteers: 60-100 bpm;

 The first arterial blood gas analysis of volunteers under breathing air: SaO2 > 59%;COHb

 380 years
 380 which is the standard of the standard of
- J) The sample should meet the expected requirements of the clinical trial:

Adult volunteers should be able to withstand the minimal risk of an agree-

2.15 The incompleteness of blood oxygen signals

This product adopts normalized waveform. It does not meet the requirement

Chapter 3 Battery Installation **3.1** Open the battery cover on the rear panel of the instrument.

3.2 Install two batteries of 1.5V AAA Alkaline correctly in the battery slot according to the positive and negative polarity indication symbol.

3.3 Close the battery cover.

⚠ Caution:

1. Replace the batteries when the batteries

are insufficient.

2. Do not make short-circuit or positive and otherwise it may cause serious damage to the equipment.

3. If the pulse oximeter is not used for a long time, please remove the batteries from the battery boxOtherwise, battery leakage may occur in the battery compartment.

4. After the battery is used, it must be disposed according to local regulations.

Chapter 4 Operation Method

2.17 Product structure introduction

4.1 Press the power button on the control Panel to open the pulse

4.2 Insert the finger into the rubber finger sleeve.



[98] 68

Electric

6

 $\textbf{4.3} \ \, \text{After the stable value (approximately 3-4s) is displayed on the screen,} \\ \text{the monitor data is displayed from the display, and the bar chart shows the pulse intensity.} If numerical flicker is displayed, the signal is insufficient.} \\$

4.4 Screen display can rotate in two or four directions. Here are the options:

Screen display can rotate in four directions automatically. (suitable for OLED,TFT)

When the pulse oximeter is turned on, press the power switch every time, the display rotates 180 degrees. (suitable for LED,LCD)

4.5 After reading the data, remove the finger, and the device will automatically turn off within 15 seconds.

⚠ Caution:

- 1. Ensure that the measured finger is free of lesions.
- Hold fingers correctly and accurately in the direction indicated.

 This pulse oximeter is neither suitable for continuous monitoring nor for the measurement of newborns and infants.
- 4. Do not use this equipment in the presence of flammable anesthetic 5. If the accuracy of equipment measurement is not determined, please first check the patient's vital signs by an alternative method, and then check the
 - oximeter. The inaccurate measurement may be caused by the following factors: Ambient light interference.
- The influence of electromagnetic fields, such as the use of mobile phones nearby.

 4 Blood vessel stains or external coloring products, such as nail polish
- or color skincare products

- If necessary, alcohol can be used for disinfection, before and after
- disinfection should be used clean, soft gauze dipped in water to wipe clean ♠ Caution: Do not use corrosive or abrasive cleaning agents.

Chapter 6 Maintenance and Troubleshooting

Problems

SPO2 or puls rate Are unstable

RF emission EN 55011

Class B

N/A

9

10

11

5.2 Disinfection

- The service life of this equipment is 1 year. In order to ensure the service life
- Please replace the battery when the battery is low.If not in use for a long time, please take out the battery.

 Necessary cleaning or disinfection should be carried out before and after use.
- Regular inspection to make sure that no obvious damage existed to

Possible causes

Fingers may not be in the ght place.
 Fingers tremble or people re in motion.

S Battery power is too low or not installed S Battery is not properly installed Is Instrument may be damaged

ent is intended to be used in the electromagnetic environment specified the purchaser or user of the instrument should guarantee that it is used in

Electromagnetic environment -guidelines The instrument uses RF power only for its internal fu Therefore, its RF emission is low and the possit nterference to nearby electronic devices is minimal.

he instrument is suitable for use in all facilities, including ousehold facilities and public low-voltage power supply etworks directly connected to household homes.

Plug the finger correctly

- (5) Arterial blood is too low to measure, which is caused by shock
- Arterial lood is too low to measure, which is caused by shock, anemia, hypothermia or vasoconstriction.

 Patients with severe smoking may appear instantaneously high in CO, resulting in hemoglobin CO increased.

 Patients with severe jaundice will appear high bilirubin, the metabo lism produced by CO will produce important carboxyl hemoglobin,
- resulting in high SpO2.

 8 The influence of electrical Surgery equipment.

Chapter 5 Cleaning and Disinfection

The product housing and silicone liners can be cleaned and disinfected. Cleaning agent for water, disinfectant for alcohol.

Please shut down and remove the battery before cleaning.
The instrument should be kept clean and free from dust or dirt. Use before and after usable a clean, soft gauze dips in after taking clear water to undertake wiping.

- No flammable substance, overton or lower temperature and humidity existed in operation conditions.

 It is better to preserve the product in a place where ambient temperature
- is -5 40°C and humidity is 15% 85%. It is recommended that the equipment be placed in a dry environment. Damp environment can affect the life of the product and damage it.
- Please stop using the product and comply with local regulations and the recycling instructions for disposal of waste when:

 a. The device does not display properly or cannot be displayed at all.
- b. The device cannot be started (the new battery has been replaced)
- working properly.

6.2 Troubleshooting Chapter 7 Electromagnetic Compatibility Information

Solution

Correctly put your finger and

Replacing the battery
Make sure the battery is
estalled
Contact Service Representat

7.1 Electromagnetic Compatibility

- Caution:
 The instrument conforms to the requirements of IEC 60601-1-2 standard for electromagnetic compatibility.
 The users shall install and use according to the EMC information provided in random file.
 Portable and mobile RF communication equipment may affect the performance of the instrument, avoid strong electromagnetic interference when using, such as close to the mobile phone, microwave oven, etc.
 The guidance and manufacturer's declaration are detailed in the annex.

bursts IEC 61000-4-4

Conducted disturbance induced by RF fields

Vrms 50 kHz to 80

4Hz 30% AM at 1 kHz

The instrument should not be close to or stacked with other equipment. If it must to be close to or stacked, it should be observed and verified to be able to operate normally under its configuration. In addition to the cables sold by the instrument manufacturer as spare parts for internal components, the use of other accessories and cables may result in increased emission or reduced immunity.

9				
Immunity test	IEC 60601 test levels	Applicability levels	electromagnetic environment -guidelines	
electrostatic discharge IEC 61000-4-2	±8 KV contact discharge ±2kV, ±4kV, ±8kV,±15kV Air discharge	±8 kV Contact discharge ±2kV, ±4kV, ±8kV, ±15 kV Air discharge	The ground should be wood, concrete or ceramic tile, if the ground is covered with synthetic materials, the relative humidity should be at least 30%.	
Electrical fast ransients/ oursts EC 61000-4-4	±2kV 100KHz repetition frequency	N/A	/	

Surges IEC 61000-4-5	±1 kV line to line ±2 kV lines to ground	N/A	/
0%UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%UT; 1 cycle and 70%UT;25/30 cycles Single phase; at 0°		N/A	/
Voltage interruptions IEC 61000-4-11 0%UT;250/300 cycle		N/A	/
RATED power frequency magnetic fields IEC 61000-4-8	30A/m	30A/m,50/60Hz	/

Guidelines and manufacturer's statement – Electromagnetic immunity electromagnetic environment -guidelines Portable and mobile RF communications equipment should not be used closer to any part of the instrument than recommended isolation distances, including 3 Vrms 150 kHz to 80 MHz

cables. The distance shall be calculated by a formula corresponding to the frequency of the transmitter. Recommended isolation distance d= $1.2\sqrt{p}$ 80 MHz ~ 2.7 F80 MHz ~ 2.7 GHz

Radiated RF EIM fields EC 61000-4-3	10V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10V/m	In the formula: P— According to the maximum rated output of transmitters provided by transmitter manufacturers, Watt (W) is the unit; d—The recommended isolation distance, Meter(m) is the unit. The field strength of a stationary RF transmitter is determined by surveying (c) the electromagnetic site, and (d) should be lower than the applicability level in each

Note: UT refers to the voltage of the AC network before the test voltage is applied.

a. Stationary transmitter, such as base stations for wireless (cellular/cordless) telephones and ground-based mobile radios, amateur radios, AM and FM radio broadcasts and television broadcasting, are theoretically predicted accurately in the field strength. In order to evaluate the electromagnetic environment of the Stationary RF transmitter, the investigation of the electromagnetic field should be considered. If the measured field strength is higher than the applicable RF conformance level, the instrument should be observed to verify its normal **b.** In the whole frequency range from 150KHz to 80MHz, the field strength

Interference may occur near the device that marks the following symbol Note 1: In the frequency of 80MHz and 800MHz, the higher frequency formula is adopted. Note 2: These guidelines may not be suitable for all situations, where electromagnetit transmission is affected by the absorption and reflection of buildings, objects an

Recommended isolation distance between portable and mobile RF communication devices and instruments

and mobile radio frequency communication equipment (transmitter) and the nstrument as recommended below.				
Rated maximum	Isolation distance for different frequencies of the transmitter/m			
output power of the transmitter/w	150 kHz ~ 80 MHz d = 1.2√P	80 MHz~ 800 MHz d = 1.2√P	800 MHz ~ 2.7 GHz d = 2.3√P	
0.01	N/A	0.12	0.23	
0.1	N/A	0.38	0.73	
1	N/A	1.2	2.3	
10	N/A	3.8	7.3	

For the rated maximum output power of the transmitter not listed in the table above, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency bar, where p is the transmitter manufacturer's maximum output

Note1: In the frequency of 80MHz and 800MHz, the higher frequency Note2: These guidelines may not be suitable for all situations, where

electromagnetic transmission is affected by the absorption and reflection of buildings, objects and bodies.

Chapter8 Warranty and After sales service 8.1 Warranty

13

The instrument can't be maintained by the users themselves. All maintenance and repair processes shall be carried out by the company's accredited technicians. The scope of warranty of this machine covers all equipment failures due to the failure of the device or the production process. During the warranty period, all defective parts can be maintained and replaced free of

8.2 After sales service

If you have any questions regarding use, maintenance, technical parameters and instrument failure, please contact the local distributor or the compan

Warranty Card

	Product information	l
Product Name	Mod	del No.
Serial Number		
Date of purchase	Dist	ributor
	User Information	
Name		
Tel		
Address		
	Maintenance records	5
Date	Maintenance contents	Signature of repairman