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<div><div>Chapter 1 Safety Guide</div><div><div>1.1 Electrical safety</div><div>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 .</div></div><div><div>1.2 Safety information</div><div><div><div>⚠ Warning:</div><div>Information that you should know in order to avoid injury to patients.</div></div><div><div>⚠ Caution:</div><div>Important information that should be emphasized.</div></div></div></div></div>	<div><div><div>⚠ 1.2.1 Warning</div><div><div>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 diagnosis.</div><div>② Before using the device, it should be under normal working condition and operating environment.</div><div>③ The device should be used in a quiet and comfortable environment,not used during exercise.</div><div>④ Ensure that the environment of the device is not disturbed by strong electromagnetic interference sources, such as wireless transmitter, mobile phone, microwave oven, etc.</div><div>⑤ Do not disinfect pulse oximeter with high temperature, high pressure, gas fumigation or liquid immersion.</div><div>⑥ This device is calibrated and maintained by professional technicians.</div><div>⑦ Keep equipment away from children, pets and insects.</div><div>⑧ Only by reading the whole Jane eyre book can you fully understand the meaning of this book.</div><div>⑨ The longest use of a single finger should not exceed 4h, otherwise it will lead to overpressure injury.</div></div></div></div>																																																	
<div><div><div>⑩ Too much ambient light can affect measurement accuracy.Avoid using in strong sunlight and dusty environment.</div><div>⑪ Do not use the instrument when the performance of the instrument changes.</div><div>⑫ Some patients may be allergic after prolonged exposure to the instrument. When allergy occurs, please stop using the instrument immediately.</div><div>⑬ Use the battery recommended by the manufacturer. Use of other batteries may cause heat or damage to the instrument.</div><div>⑭ Do not except the manufacturer shall disassemble or modify the instrument.</div><div>⑮ Do not maintain the instrument when it is in use.</div></div><div><div>1.3 Explanation of symbols</div><table><tr><th>No.</th><th>Symbol</th><th>Explanation</th></tr><tr><td>1</td><td></td><td>BF type applied part</td></tr><tr><td>2</td><td></td><td>Refer to the manual</td></tr><tr><td>3</td><td></td><td>Caution, refer to the attached file</td></tr></table></div></div>	No.	Symbol	Explanation	1		BF type applied part	2		Refer to the manual	3		Caution, refer to the attached file	<div><table><tr><td>4</td><td>SpO2</td><td>Oxygen saturation</td></tr><tr><td>5</td><td>PR</td><td>Pulse rate</td></tr><tr><td>6</td><td></td><td>Disposal of waste electrical and electronic equipment separately(Follow local government regulations and recycling instructions for batteries)</td></tr><tr><td>7</td><td></td><td>No SpO2 Alarms</td></tr><tr><td>8</td><td></td><td>Serial number</td></tr><tr><td>9</td><td></td><td>Enclosure protection class</td></tr><tr><td>10</td><td></td><td>Non-ionizing radiation</td></tr><tr><td>11</td><td></td><td>Date of manufacture</td></tr><tr><td>12</td><td></td><td>Manufacturer</td></tr><tr><td>13</td><td></td><td>On behalf of the European</td></tr><tr><td>14</td><td></td><td>Lifepan</td></tr><tr><td>15</td><td></td><td>power switch</td></tr></table></div>	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		Serial number	9		Enclosure protection class	10		Non-ionizing radiation	11		Date of manufacture	12		Manufacturer	13		On behalf of the European	14		Lifepan	15		power switch	
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<div><div>Chapter 2 Product Overview</div><div><div>2.1 Display</div><div>OLED,LED,TFT,LCD</div></div><div><div>2.2 Product Composition</div><div>It consists of shell, sensor, internal circuit and display screen.</div></div><div><div>2.3 Intended Use</div><div>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.</div></div></div>	<div><div>2.4 Product Features</div><div><div>2.4.1 The product is designed to be light in weight, simple in operation, easy to use and carry.</div><div>2.4.2 True Color high resolution OLED,LED,TTF and LCD.</div><div>2.4.3 It has strong anti-ambient light interference, and low-consumption design.</div><div>2.4.4 It is only used for on-site monitoring and not used for continuous monitoring. It' s suitable for hospitals, clinics, families, oxygen bars, sports centers and so on.</div></div><div><div>2.5 Performance Parameters</div><div><div>Display Type</div><div>OLED,LED,TFT and LCD.</div><div>Oxygen saturation of blood(SpO2)</div><div>Measurement range: 35% ~ 100%</div><div>Resolution: 1%</div><div>Accuracy: Within the range of 90% ~ 100%, tolerance ± 2%; Within the range of 70% ~ 90%, tolerance ± 3%; Less than 70% undefined</div><div>Pulse Rate(PR)</div><div>Measurement range: No less than 30bpm ~ 250bpm</div></div></div></div>																																																	
<div><div>Anti-ambient</div><div>(Real-time pulse rate data after stabilization) Resolution:1bpm Accuracy: ±1% or ±3bpm, large value</div></div> <div><div>Light interference</div><div>The deviation between the Spo2 measured in the room with day lighting Or illumination source and that measured in the darkroom is less than, +1%</div></div> <div><div>Ability</div><div>2x1. 5v, AAA alkaline batteries(It can be used for 1~1.5 hours continuously)</div></div> <div><div>Power supply</div><div>30mA- 80mA</div></div> <div><div>Working current</div><div>OLED,TTF : Digital and waveform display on the same screen,automatic display in four directions.</div></div> <div><div>Direction sensor</div><div>LED,LCD: Manual display in two directions.</div></div> <div><div>Light sensor</div><div>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)</div></div> <div><div>Data update cycle</div><div>No more than 15s(From optical signal to digital signal)</div></div>	<div><div>2.6 Packing list</div><table><tr><th>Description</th><th>Quantity</th></tr><tr><td>Main unit</td><td>1</td></tr><tr><td>Handing rope</td><td>1</td></tr></table></div> <div><div>2.7 Size and Weight</div><div>Length×Width×Height: 58.8×36×34mm Weight: 54g (including batteries)</div></div> <div><div>2.8 Environmental requirements</div><div><div>Working environment</div><div>Temperature：5~40℃ Humidity：≤80%(No condensation) Atmospheric pressure：86~106 kPa</div><div>Storage and transportation condition</div><div>Temperature：-20～55℃ Humidity：≤93%(No condensation) Atmospheric pressure：70~106 kPa</div></div></div>	Description	Quantity	Main unit	1	Handing rope	1																																											
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	⚠ 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 irritation when contacting with human body. 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 standard requirements of IEC 60601-1-8.When abnormal measurements are 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 A) Age for male or female from 18 to 45; B) 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 in the study, and sign the informed consent; E) The volunteers must be in a good state of mood when participating in clinical validation;	
F) Blood pressure values of the volunteers: systolic blood pressure 90~140mmhg,diastolic blood pressure 60~90mmhg; G) Heart Rate of volunteers: 60~100 bpm; H) The first arterial blood gas analysis of volunteers under breathing air: SaO2 ≥ 95%;COHb< 3%, MetHb< 2%, ctHb> 10g/dl; I) The volunteers can have good compliance, and cooperate with the whole test; J) The sample should meet the expected requirements of the clinical trial: Subjects should include both male and female; Adult volunteers should be able to withstand the minimal risk of an agree- ment for controlled blood oxygen test requirement. 2.15 The incompleteness of blood oxygen signals This product adopts normalized waveform. It does not meet the requirement of ISO 80601-2-61.	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 properties of pulse oximetry to determine its validity, so the function tester cannot be used to evaluate the accuracy of the pulse oximetry. 2.17 Product structure introduction Screen Power Battery Signal strength OLED,TFT Electric quantity SpQz + - - - - - PR LED,LCD Signal strength Waveform		
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 negative reverse loading when using batteries, 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 box.Otherwise, 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 4.1 Press the power button on the control Panel to open the pulse oximeter. 4.2 Insert the finger into the rubber finger sleeve. 4.3 After the stable value (approximately 3~4s) is displayed on the screen, 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: ① Screen display can rotate in four directions		