

Product Name:	Multi-parameter Patient Monitor
Model:	PM-7000D
Application in COVID-19:	In the general ward and ICU, the Patient Monitor is the necessary equipment for real-time detection of patients' physical signs, and alarms when patients' physical signs have problems. Remote detection can reduce the infection rate of medical staff.
Standard:	CE / ISO 13485
Supply Capability:	2000 pcs / week



PM-7000D

Multi-parameter Patient Monitor



zoncare
CE ISO13485

Wuhan Zoncare Bio-medical Electronics Co.,Ltd.

Add: Zoncare Building, No. 380, High-tech 2nd Road, Eastlake High-tech
Development Zone, Wuhan, Hubei 430206 P. R. China.
Tel: +86-27-8777 0203 Fax: +86-27-8777 0581

Email: info@zoncare.com <http://www.zoncare.com>

© 2019 Wuhan Zoncare Bio-Medical Electronics Co.,Ltd. All rights reserved. Specifications subject to changes
without prior notice.



<http://www.zoncare.com>



A high performance Patient Monitor designed for clinical use

PM-7000D is a product developed based on clinical needs, with accurate parameter measurement performance, simple and superior operation experience, and high-end accessories. When you use it, you fall in love with it.

ECG

iMAC ECG algorithm--Diagnostic level algorithm, which is developed and designed based on professional diagnostic electrocardiograph, is more professional and accurate.

NIBP

Zoncare oscillometry technology, which is closing to Auscultatory method, has more accuracy and repeated measurement consistency. It can accurately detect real blood pressure points, and has a strong resistance to movement and high and low pressure measurement performance.

SpO₂

FASP SpO₂ measurement technology is included in 7000D. It can accurately measure SpO₂, PR and PI Index. SpO₂ can be detected accurately in the range of 40% to 100%, and the PI index can reach 0.057% at the lowest. It has strong anti-interference ability and super low perfusion performance.

PR (Pulse Rate)

PR can be obtained from ECG, SpO₂ or NIBP.

7000D has log management and export function, nurse call function and alarm limit one key setting function. It also has the function of automatic adjustment of pulse tone through the change of SpO₂'s high and low voice. So clinicians can get the changes of vital signs of patients from their hearing.

Massive Storage

2000
NIBP Records

2000
Alarm Events

120 hrs
Graphics Trends

120 hrs
Tabular Trends

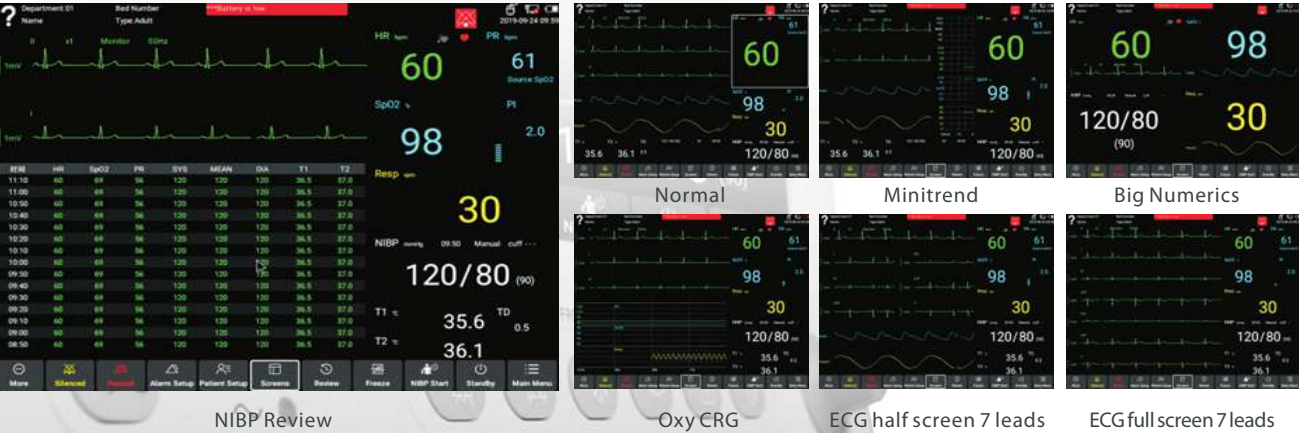
120 mins
Minitrend

8 mins
Oxy CRG

48 hrs
Full Waveform

Seven Display Interface

NIBP Review: 15 history measurements of patients can be compared during normal monitoring.



Accessories

We elaborately selected the materials, extremely attention to every detail of the design, and strive to make you satisfied.



Imported TPU wire, wipe disinfection 2000 remains the same color gold plated electrodes, more stable signal acquisition.



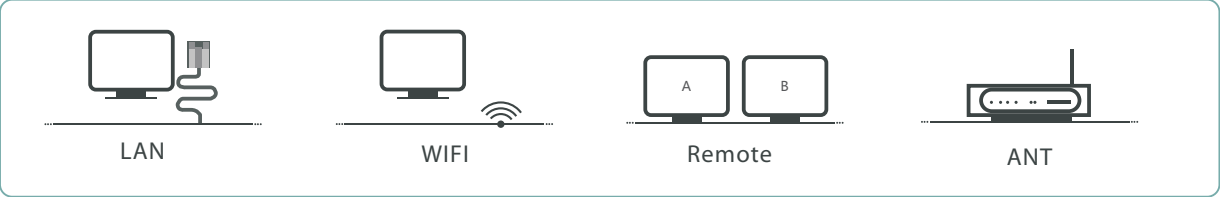
Removable internal capsule design, convenience for wash imported PU fabric, comfortable tactile impression, easy cleaning and disinfection to avoid cross infection.



Shading design, strong resistance to Interference. Improted TPU wire

Multiple Networking Modes

Zoncare provides a super flexible solution for monitoring your patient's status anywhere, anytime, even when you are away from the clinical environment or patients in the ambulance.



Standard Configuration:

ECG, HR (Heart Rate), NIBP, SpO₂, PR (Pulse Rate), Respiration, Dual-TEMP, Lithium Battery

Optional Configuration:

3-channel Recorder, Wall Bracket, Trolley, Battery, Touch Screen, WIFI Module, EtCO₂ Module, IBP Module, Suntech NIBP Module, Masimo SpO₂ Module,

EC Certificate

Full Quality Assurance System

Certificate No.:
9832-2017-CE-RGC-NA-PS rev. 0.0

Project No.:
PRJC-217612-2010-PRC-CHN

Valid until:
25 April 2022

This is to certify that the quality system of:

Wuhan Zoncare Bio-medical Electronics Co., Ltd.

#380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China.

For design, production and final product inspection/testing of:

Multi-Parameter Patient Monitor

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 25 April 2017



For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate

Full Quality Assurance System

Certificate No.:
9832-2017-CE-RGC-NA-PS rev. 0.0

Project No.:
PRJC-217612-2010-PRC-CHN

Valid until:
25 April 2022

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-04-25

Products covered by this Certificate:

Product Description	Product Name	Class
Multi-Parameter Patient Monitor	PM-7000A, PM-7000B, PM-7000C, PM-7000D, PM-7000E, PM-7000F, PM-7000G, PM-7000H, PM-7000M, PM-7000N, PM-7000S	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

#380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China.

EU Representative

Well kang Limited, The Black Church, St. Mary's Place, Dublin 7, Ireland

EC Certificate

Full Quality Assurance System

Certificate No.:
9832-2017-CE-RGC-NA-PS rev. 0.0

Project No.:
PRJC-217612-2010-PRC-CHN

Valid until:
25 April 2022

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate



REGISTRATION NO. 04719Q10000749

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Wuhan Zoncare Bio-medical Electronics Co., Ltd.

Registered Address: #380, High-tech 2nd road, Eastlake high-tech district,
Wuhan, Hubei, P. R. China

Postcode: 430206

Manufacturing Address: #380, High-tech 2nd road, Eastlake high-tech district,
Wuhan, Hubei, P. R. China

Has been assessed and conformed to the following standard(s)
YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, development, manufacturing, and service of Full Digital Colour Doppler Ultrasonic Diagnostic System, All-Digital Ultrasound Diagnostic System, Digital Electrocardiograph, Multi-Parameter Patient Monitor, Infrared Light and Heat-treatment Equipment, i Series All-Digital Ultrasound Diagnostic System, Digital Multi-Channel Electrocardiograph, Holter System, Ambulatory Blood Pressure Monitor, Digital ECG Workstation Software, ECG Data Management System Software, Digital 18-Lead Electrocardiograph.

Date of issue: April 08, 2019

Date of expiry: April 07, 2022

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. Jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: 鄂武汉食药监械出 20200005
Certificate NO.: 鄂武汉食药监械出 20200005

产品名称: 见附件
Product(s): See Attachment

规格型号: 见附件
Model: See Attachment

产品注册或备案凭证号: 见附件
Registration certificate(s): See Attached

生产企业: 武汉中旗生物医疗电子有限公司
Manufacturer: WUHAN ZONCARE BIO-MEDICAL ELECTRONICS CO., LTD

生产企业住所: 武汉东湖新技术开发区高新二路 380 号
Address of manufacturer: #380, HIGH-TECH 2ND ROAD, EASTLAKE HIGH-TECH DISTRICT, WUHAN, HUBEI, P.R. CHINA

生产许可或备案凭证号: 鄂食药监械生产许 20150287 号
Manufacturing License(s): 鄂食药监械生产许 20150287 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至: 2021 年 5 月 30 日
This certification valid until: May 30th 2021

备注:
Remark:



附件（Attachment）

产品名称 Product (s)	注册证号 Registration certificate (s)	规格型号 Model
数字式十八导心电图机 DIGITAL EIGHTEEN CHANNEL ELECTROCARDIOGRAPH	鄂械注准 20182072627	iMAC 18 iMAC 18A iMAC 18B
全数字超声诊断系统 ALL-DIGITAL ULTRASOUND DIAGNOSTIC SYSTEM	鄂械注准 20142231091	ZQ-6600 ZQ-6601 ZQ-6602 ZQ-9900 ZQ-9901 ZQ-9902
全数字超声诊断系统 ALL-DIGITAL ULTRASOUND DIAGNOSTIC SYSTEM	鄂械注准 20202062868	ZONCARE-i70 ZONCARE-i50 ZONCARE-i30
全数字彩色多普勒超声诊断系统 ALL-DIGITAL COLOR DOPPLER ULTRASOUND DIAGNOSTIC SYSTEM	鄂械注准 20142231759	ZONCARE-V3 ZONCARE-V5 ZONCARE-V6 ZONCARE-V7 ZONCARE-V9
全数字彩色多普勒超声诊断系统 ALL-DIGITAL COLOR DOPPLER ULTRASOUND DIAGNOSTIC SYSTEM	鄂械注准 20182062603	ZONCARE-M5pro ZONCARE-M5s ZONCARE-M5
全数字彩色多普勒超声诊断系统 ALL-DIGITAL COLOR DOPPLER ULTRASOUND DIAGNOSTIC SYSTEM	鄂械注准 20182062392	ZONCARE-N7pro ZONCARE-N7s ZONCARE-N7
全数字彩色多普勒超声诊断系统 ALL-DIGITAL COLOR DOPPLER ULTRASOUND DIAGNOSTIC SYSTEM	鄂械注准 20202062865	ZONCARE-P7 ZONCARE-P5 ZONCARE-P3
全数字彩色多普勒超声诊断系统 ALL-DIGITAL COLOR DOPPLER ULTRASOUND DIAGNOSTIC SYSTEM	鄂械注准 20142232001	ZONCARE-S3 ZONCARE-S5 ZONCARE-S6 ZONCARE-S7 ZONCARE-S9

全数字彩色多普勒超声诊断系统 ALL-DIGITAL COLOR DOPPLER ULTRASOUND DIAGNOSTIC SYSTEM	鄂械注准 20192062841	ViV80
多参数监护仪 MULTI-PARAMETER PATIENT MONITOR	鄂械注准 20142211493	PM-7000C PM-7000D PM-7000N PM-7000M PM-7000H
数字式多道心电图机 DIGITAL MULTIPLE CHANNEL ELECTROCARDIOGRAPH	鄂械注准 20202072865	iMAC 120 iMAC 120s iMAC 120pro
十八导心电图机 EIGHTEEN CHANNEL ELECTROCARDIOGRAPH	鄂械注准 20202072866	iMAC 1800 iMAC 1800s iMAC 1800pro
数字式多道心电图机 DIGITAL MULTIPLE CHANNEL ELECTROCARDIOGRAPH	鄂械注准 20202072869	iMAC 1200 iMAC 1200s iMAC 1200pro
数字式多道心电图机 DIGITAL MULTIPLE CHANNEL ELECTROCARDIOGRAPH	鄂械注准 20202072870	U40 U50 U60
数字式多道心电图机 DIGITAL MULTIPLE CHANNEL ELECTROCARDIOGRAPH	鄂械注准 20202072871	iMAC 100 iMAC 100s iMAC 100pro U70 U80 U90
数字式多道心电图机 DIGITAL MULTIPLE CHANNEL ELECTROCARDIOGRAPH	鄂械注准 20202072872	U10 U20 U30 iMAC 300 iMAC 300s iMAC 300pro
数字式多道心电图机 DIGITAL MULTIPLE CHANNEL ELECTROCARDIOGRAPH	鄂械注准 20202072873	iMAC 12 iMAC 12s iMAC 12pro
动态血压监测仪 DYNAMIC BLOOD PRESSURE MONITOR	鄂械注准 20182072604	iE70
动态心电图系统 DYNAMIC ELECTROCARDIOGRAPH SYSTEM	鄂械注准 20162212198	iE90

