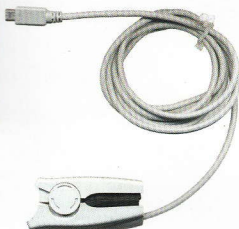


Made in China

Patient Monitor

User Manual



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1. Preface

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual includes information on all the functions of PM60A as well as the specific operating methods, and also we gathered together some most common questions with detailed answers.

Please read the specification carefully before using this product to smooth your usage.

Thanks for using PM60A patient monitor products and look forward to your valuable suggestions and advice.

1.1 Caution

Before using the equipment, please pay attention to the following security and validity:

- The system should be used under doctors' guidance.
- The reliability of the product depends on whether the users operation is in total accordance with the manual's guidance or not.

⚠ Warning: system errors may arise if non-proper accessories are replaced; and therefore, any maintenance men who haven't been

trained by our company or normal maintenance organization should not try to maintain this system.

1.2 Manipulator Obligation



Caution: please read the user manual carefully before usage.

Obligations of the manufacturer.

1. Our company is responsible for solving the software or hardware problems within one year's warranty period, problems which are caused by improper use are excluded.
2. Our company is responsible for the necessary training on users.
3. Our company is responsible for updating the software for free and maintenance for life
4. Our company is responsible for free maintenance on hardware within one year's warranty period.
5. Our company is not responsible for the damages which are caused by improper use or non-appointed accessories.

per use or non-appointed accessories.

1.1 Caution

Before using the equipment, please pay attention to the following security and validity.

- The system should be used under doctors' guidance.
- The reliability of the product depends on whether the user's operation is in total accordance with the manual's guidance or not.
- ⚠ Warning: system errors may arise if non-proper accessories are equipped, and moreover, any maintenance men who haven't been

caused by

2.The Basics

2.1 Introduction

2.1.1 Intended Use

The patient monitor is intended for continuously monitoring, spot checking, displaying and storing oxygen saturation and pulse rate of single adult, pediatrics and neonatal patient in hospital, emergency treatment and patient transport as well as in home care environment.

WARNING

This patient monitor is intended for use only by clinical professionals or under their guidance. Anyone unauthorized or untrained must not perform any operation on it.

2.1.2 Contraindications

None.

2.1.3 Components

This patient monitor consists of a main unit and an SpO₂ sensor.

2.2 Features:

Regular Check Mode and Continuous Monitoring Mode

SpO₂ data analysis

Data Graph and Trend Table Review : 24 hours data review , 50 latest alarm review, 96 hours trend Table review

Full screen touch operation

Big capacity SD card case storage

Sync with PC based Software (WinXP and WinVista)

3.Main Technical Index

3.1 Performance Specifications

Display: 3.5" Color TFT

Resolution: 320 x 240

Display Mode: Standard face, Waveform face, Display
Direction adjustable

Indicator: Power indicator light, Alarm sound, pulse tone

Interface: One dual-purpose socket for connecting SpO₂
sensors and communication cables

Power Supply: DC 5V, <300mA

Battery: Built-in Li-Polymer, 6 hours for charging, 7
hours for continuous working.
12 hours for standby mode 3.7v,1900mah

Trend Graph/Table: Resolution from 1s, 5s, 10s,30s,1min,and
so on. Storage of latest 96 hours trend data.
Second is the unit.

History: Storage of latest 10000 case history by SD card.
Permit to review momentarily.

Alarm: Adjustable High and Low limits. Three level
audible and visual alarm , latest 50 alarm
information and waveform displays 8 seconds
which 4 seconds are before a certain time when
the alarm is turned on and 4 seconds are after
appointed time when the alarm is turned on.

Wave: Storage of 24 hours waveform, and only the real-time stored patients have waveform.

3.2 Technical specifications

Safety

Meet the requirement of IEC60601 series

Type of Protection: Class II with internal electric power supply

Degree of Protection: BF

Dimension and Weight

Dimension: 92(W)x82(H)x22(D)mm

Weight: 136g(with battery)

Operation Environment:

Temperature: 0 °C ~ +40 °C

Humidity: 15% ~ 95%

Storage Environment:

Temperature: -20 °C ~ +60 °C

Humidity: 10% ~ 95%

Patient Range

Neonate ,Pediatrics and Adult

3.3 SpO₂

Measurement Range: 0 ~ 100%

Resolution: 1%

Accuracy: ± 2%(70%~100%, Adult/Pediatrics, non-motion)
± 3%(70%~100%, Neonate,

non-motion)

0% ~ 69% unspecified

Alarm Range: 0% ~ 100%

Refreshing Rate: 1s

Pulse Rate:

Measurement Range: 30~ 250 bpm

Resolution: 1bpm

Accuracy: ± 3 bpm (non-motion)

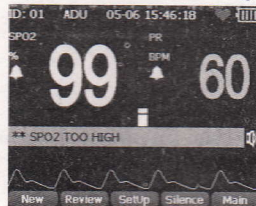
Alarm Range: 25 ~ 250 bpm

Refreshing Rate: 1s

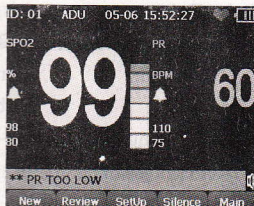
4.Function Instructions

4.1 Main Interface

The system enters the main interface automatically after power on , please check the following charts for reference:



Model 4-1-1 main1

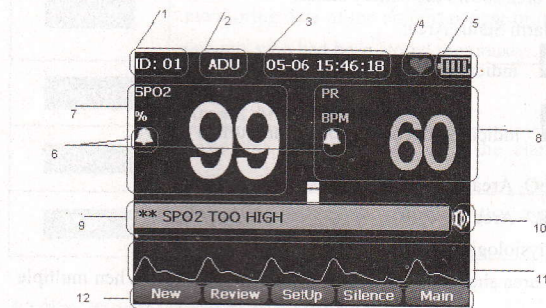


Model 4-1-2 main2

Notice :

Model 4-1-1 displays the waveform, Model 4-1-2 doesn't display the waveform.

4.1.1 Introduce the composing Parts as follows:



Model 4-1-3 Main

1. Patient ID Area:

This area shows the ID number of the patient that is under current monitoring.




2. Patient type Area:

This area shows the patient type.

Patients are classified as adult, pediatrics and neonate.

3. System Time Area.

4. Heart Rate Area:

Click the  button can shield the sound of heart. The  button and the  button flicker alternately after the sounds are turned off .

5. Battery symbol Area:

This area shows the battery status.

6. Alarm Status Area:



indicates that alarm sounds are turned on;



indicates that alarm sounds are turned off.

7. SpO₂ Area .

8. PR Area .

9. Physiological Alarm Area:

This area shows the physiological alarm message. When multiple messages come, they will be displayed circularly.

10. Physiological Alarm Status Area:



Click the button to pause or reactivate the alarm sound.



indicates that alarm sounds are paused.

11. Waveform Area:

This area displays SpO₂ real time waveform.

12. Function button Area

Function button:

Functions as follows:

	Enter the new patient case history menu. Patient's case history can be stored for 10,000 items at maximum.
--	---

	Enter the data review menu. Review the monitoring data of the current patient or the patients who had been stored previously.
	Enter the system setup menu. Amend the system setup.
	Press this button to turn off the alarm sound.
	Press this button to return to the main menu.

4.2 New Patient Information Interface

Click the “ New” button of the main interface to enter the New patient case history interface. New Patient information interface which is shown as following:

New Patient

Name Jack Height 170 cm

Sex MALE Weight 70 kg

Pat ADU

Blood B

OK Cancel

Model 4-2-1 New Patient

Users can set up and store the personal information of the patient

that is under current monitoring. After the patient information is stored, it will return to the main menu. The “ **New** ” button change into the “ **Save** ” button. Then click the button to store the information into SD card.

4.3 Data Review Interface

4.3.1 Data Review Interface

Click the “ **Review** ” button of the main interface to enter the patient data review interface. Data review interface which is shown as following:

Model 4-3-1 Data Review

Users can review the monitoring data of the current patient or the patients who had been stored previously by selecting "Patient ID". Review includes 4 kinds: "TrendTable", "TrendGraph", "AlarmReview", "WaveReview", which are shown as following:

Notice:

The “ wave review “ function is only available for the current patient, but is not available for previous patients; By clicking Show Stat. Item ,users can choose whether to show statistic in the TrendTable or not.

And the item is only applicable for TrendTable.

Menu : Functions listed in the chart below:

Patient ID	Select the Patient ID that is needed to review
Review Type	Select the category that is needed to review
Resolution	Review Resolution only be applicable for "TrendTable" and "TrendGraph" .
Start Time	Set up the starting time of review

4.3.2 TrendTable Interface

TrendTable Interface which is shown as following:

ID: 1	Max	Ave	Min
SpO2(%):	99	99	99
PR(bmp):	60	60	60
TrendTable			
TIME	SPO2	PR	
2008-05-06 15:54:58	99	60	
2008-05-06 15:54:57	99	60	
2008-05-06 15:54:56	99	60	
2008-05-06 15:54:55	99	60	
2008-05-06 15:54:54	99	60	

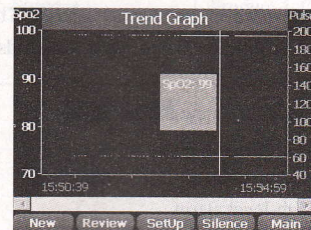
Model 4-3-2 TrendTable

The detailed information of the key as following:

Max :	The maximum of the Parameter data in the logical range
Min:	The minimum of the Parameter data in the logical range
Ave:	The average of the Parameter data in the logical range

4.3.3 TrendGraph Interface

TrendGraph Interface which is shown as following:



Model 4-3-3 TrendGraph

4.3.3.1.

Press the screen to display the parameter value of SpO2 and PR at a certain time.

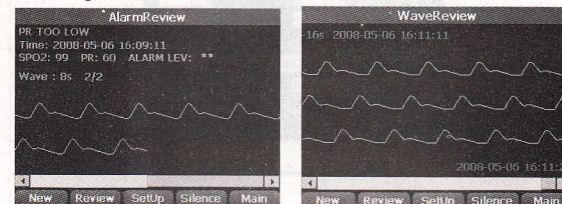
4.3.3.2. The analysis result can be displayed in the TrendGraph.

You can set the analysis parameters in the "System Setup" Menu.

4.3.4 AlarmReview and WaveReview

4.3.5 Interface

AlarmReview and WaveReview Interface which is shown as following:



Model 4-3-4 AlarmReview and WaveReview

In the AlarmReview waveform display district, The waveforms displayed are before 4 seconds and after 4 seconds of the alarm event.

This alarm symbol includes the following items:

“ * ” : low-level alarm

“ * * ” : mid-level alarm

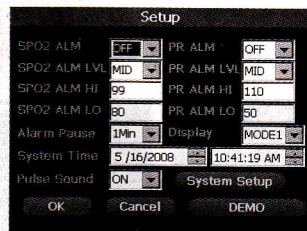
“ * * * ” : high-level alarm

The waveforms can be displayed for 16 seconds at maximum in every screen.

4.4 Set up Interface

4.4.1 Set up Interface

Click the “**Setup**” button of the main interface to enter the Setup interface. Setup interface which is shown as following:



Model 4-4-1 Setup

Instruction:

Monitoring setting and producer setting Options as follows:

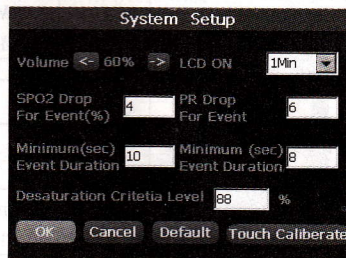
Item	Purpose	Producer setting	Choosing scope
SpO2 ALM	Turn on/off SpO2 alarm	OFF	OFF ON
SpO2 ALM LVL	SpO2 alarm level	MID	LOW, MID, HIGH
SpO2 ALM HI	SpO2 alarm high-level	99	0----100
SpO2 ALM LO	SpO2 alarm low-level	80	
PR ALM	Turn on/off PR alarm	OFF	OFF ON
PR ALM LVL	PR alarm level	MID	LOW, MID, HIGH
PR ALM HI	PR alarm high-level	110	0----300
PR ALM LO	PR alarm low-level	50	
Alarm Pause	Alarm Pause Time	1MIN	1Min,2Min,3Min,Always
Display	Display mode	Model	Model1, Model2
System Time	Set system time		

System Setup	Enter system setup menu		
Pulse Sound	Turn on/off pulse sound		OFF ON
Demo	Enter Demo mode		

NOTICE: If the time is changed, users should restart the apparatus by hand to ensure the accuracy of the data storage time.

4.4.2 System Setup

Click the “**System Setup**” button of the Setup menu to enter the System Setup menu interface. System Setup menu interface which is shown as following:



Model 4-4-2 System Setup

4.4.2.1.

Users can set system sounds and overtime of the backdrop lighting .

4.4.2.2.

SpO2 Parameters

Drop for Event (%): value, in %, to qualify as an SpO2 (Desaturation) Event.

Minimum Event Duration (sec): value, in seconds, of SpO2 decrease that qualifies as an SpO2 (desaturation) event.

Desaturation Criteria Level (%): value, in %, below which the SpO2 level must drop to be classified in a special category of statistics. This threshold is indicated on the SpO2 graph by a red dotted line.

Pulse Rate Parameters

Rate Change For Event (bpm): value, in beats per minute, to qualify as a pulse rate event.

Minimum Event Duration (sec): value, in seconds, of pulse rate change to qualify as a pulse rate event.

4.4.2.3.

Click “OK” to set new analysis parameters or click “Cancel” to leave them unchanged.

All setting will turn back to manufacturer's setting when Click “**Default**” button.

5. Maintenance and Cleaning

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.

We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.

Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

- Always dilute according to the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not allow liquid to enter the case.

Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

WARNING

- **Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the equipment.**

CAUTION

- **If you spill liquid on the equipment or accessories, contact us or your service personnel.**

NOTE:

- **To clean or disinfect reusable accessories, refer to the instructions delivered with the accessories.**

5.1 Safety Checks

Before every use, or after your patient monitor has been used for 6 to 12 months, or whenever your patient monitor is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.
- Inspect all power cords for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Inspect if the alarm system functions correctly.
- Make sure that the batteries meet the performance requirements.
- Make sure that the patient monitor is in good working condition.

In case of any damage or abnormality, do not use the patient monitor. Contact your hospital's biomedical engineers or your service personnel immediately.

5.2 Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

- Mild soap (diluted)
- Ammonia (diluted)
- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

1. Shut down the patient monitor and disconnect it from the power line.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry your equipment in a ventilated, cool place.

5.3 Disinfecting

Disinfection may cause damage to the equipment and is therefore not recommended for this patient monitor unless otherwise indicated in your hospital's servicing schedule.

Clean the patient monitor before disinfecting it.

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.

CAUTION

- **Never use EtO or formaldehyde for disinfection.**

5.4 Disposal

Dispose of the patient monitor in accordance with local environment and waste disposal regulations. For the disposal of SpO₂ sensor, follow local regulations regarding disposal of hospital waste.

6. Appendix

6.1. Alarm Characters Specification:

Finger Out

SpO₂ Sensor OFF

Battery Too Low

SpO₂ Too High

SpO₂ Too Low

PR Too High

PR Too Low

6.2. Usual Metrical Range:

SpO₂ 1-99

PR 1-250

