

**DPM<sup>TM</sup> | 1**

Pulse Oximeter

Operator's Manual

**mindray**



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## WARNING

- 
- **Federal Law (USA) restricts this device to sale by or on the order of a physician.**
-

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# Contact Information

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# Preface

## Manual Purpose

This manual provides the instructions necessary to operate DPM1 Pulse Oximeter (hereinafter called as DPM1) in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

This manual is an integral part of and should always be kept close to the your DPM1, so that it can be obtained conveniently when necessary.

## Intended Audience

This manual is geared for the clinical medical professionals. Clinical medical professionals are expected to have working knowledge of medical procedures, practices and terminology as required for monitoring patients.

## Version Information

This manual has a version number. This version number changes whenever the manual is updated due to software or technical specification change. Content of this manual is subject to change without prior notice. The version information of this manual is as follows.

Version number	Release date
3.0	2010-04

## Illustrations and Names

All illustrations in this manual are provided as examples only. They may not necessarily accord with the graph, settings or data displayed on your DPM1.

All names appeared in this manual and illustrations are fictive. It is a mere coincidence if the name is the same with yours.

## Conventions

- *Italic* text is used in this manual to quote the referenced chapters or sections.
- The terms warning, and caution are used throughout this manual to point out hazards and to designate a degree or level or seriousness.

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# 1 Safety

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## 1.1 Safety Information

The safety statements presented in this chapter refer to the basic safety information that the operator of DPM1 shall pay attention to and abide by. There are additional safety statements in other chapters or sections, which may be the same as or similar to the followings, or specific to the operations.

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### **WARNING**

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- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**
- 

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### **CAUTION**

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- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**
- 

### **NOTE**

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- **Provides application tips or other useful information to ensure that you get the most from your product.**
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## 1.1.1 Warnings

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### **WARNING**

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- DPM1 is intended for use by qualified clinical physicians or well-trained nurses in hospital.
  - DPM1 is designed for real-time and rapid measurement of the patient's SpO<sub>2</sub>. It is not suitable for long-time continuous patient monitoring. Continual measurement must not exceed 2 hours.
  - DPM1 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. It is not intended as a device used for treatment purposes.
  - To ensure patient safety, verify this device and accessories can function safely and normally before use.
  - **EXPLOSION HAZARD: Do not use DPM1 in the presence of flammable anesthetics, explosive substances, vapors or liquids.**
  - Failure to implement a satisfactory maintenance schedule may cause undue device failure and possible health hazard.
  - When using DPM1 together with the electrical surgery equipment, the user should pay attention to and guarantee safety of the patient being measured.
  - Do not pull or lift DPM1 by its connection cable. That may lead to falling and consequent patient injuries.
  - Magnetic and electrical fields are capable of interfering with the proper performance of DPM1. For this reason make sure that all external devices operated in the vicinity of DPM1 comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
  - DPM1 and its accessories may be contaminated by microorganism during transporting, use and storage. Use the recommended methods to sterilize and disinfect DPM1 or its accessories when the packing material is damaged, or it has not been used for a long time.
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## 1.1.2 Cautions

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### CAUTION

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- Federal Law (USA) restricts this device to sale by or on the order of a physician.
  - The device should be appropriately placed. Keep it from falling, strong vibration or other mechanical damage.
  - To ensure patient safety, use only parts and accessories specified in this manual.
  - DPM1 is a commonly sealed device. Keep its surface dry and clean, and prevent any liquid from infiltrating it.
  - Don't use mobile phones around when DPM1 is in operation.
  - DPM1 should only be maintained by personnel approved by our company.
  - Before using DPM1 on patients, the user should be familiar with its operation.
- 

## 1.1.3 Notes

### NOTE

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- Important! Before use, carefully read this manual, all safety information and specifications.
  - This device is not intended for home use.
-

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## 1.2 Equipment Symbols



Attention!  
Consult accompanying documents (this manual).



Type BF applied part according to IEC 60601-1.



This symbol indicates the socket can connect with the PC through a communication cable.



The following definition of the WEEE label applies to EU member states only.

This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it.

\* For system products, this label may be attached to the main unit only.



Medical equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 NO.601-1.

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# 2 General

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## 2.1 Introduction

DPM1 Pulse Oximeter is a non-invasive, spot-check, oxygen saturation and pulse rate monitor. It operates only on battery power using specified sensors labeled for patients ranging from neonates to adults.

Parameters measured by DPM1 include: arterial oxygen saturation (SpO<sub>2</sub>), pulse rate (PR) and pulse strength. DPM1 measures these parameters through a SpO<sub>2</sub> sensor and displays them on the LCD screen after certain further processing.

DPM1 is operated and controlled by three buttons, which are Power button, Backlight button and Confirm ID button. DPM1 is also capable of managing measured data and transmitting the patient's trend through the dual-purpose socket to a PC for printing.

## 2.2 Contraindications

None

## 2.3 Functions

DPM1 has the following functions:

- Measuring: SpO<sub>2</sub>, PR and pulse strength.
- Prompting: Memory full, ID full, low battery, standby, and technical error etc.
- Power managing: automatic standby, automatic shutdown.
- Data Managing: data storage, data protection, data deletion.
- Data Printing: patient information and trend data.

For the data printing function, you must install the Pulse Oximeter management system in a PC equipped with a printer, and connect DPM1 with the PC by a communication cable. For details, please refer to the *7Pulse Oximeter Management System*

## 2.4 Appearance

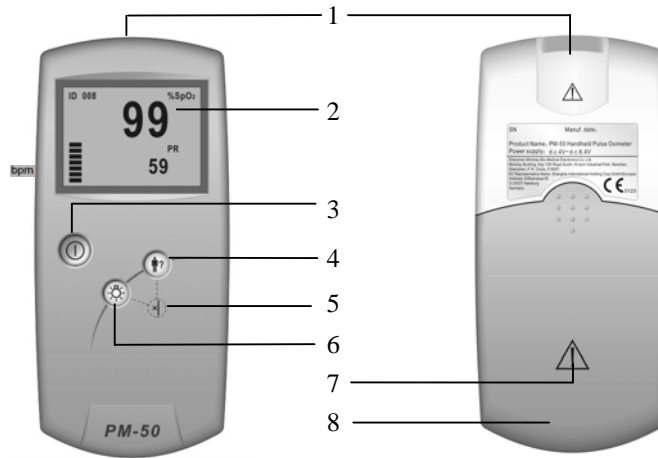


Figure 2-1 Front Panel

Figure 2-2 Back Panel

Table 2-1 Appearance description

No.	Description	Remarks
1	Dual-purpose socket	It connects SpO2 sensor or PC communication cable.
2	LCD	It displays information listed in Table 2-2.
3	Power	It turns on or off the device.
4	Confirm ID	It confirms the patient ID for current measurement.
5	Delete ID	A key combination of 4 and 6.
6	Backlight	It turns on or off the backlight.
7		Caution. Refer to this manual.
8	Battery door	Open it to install or remove batteries.

## 2.5 Displayed Information

The figure below shows information displayed on DPM1's screen.



Figure 2-3 Displayed Information

Table 2-2 Description of displayed information

No.	Description	Remarks
1	ID number	It displays current ID number ranging from 000 to 100
2	ID Full	It appears when ID $\geq$ 95 and blinks when stored ID is being covered by new ID.
3	Memory Full	It appears when previous data is to be covered by new data. Please refer to 5.1.1 Data Storage.
4	Pulse Strength	It can display 7 segments at most to indicate real time pulse strength.
5	SpO2 value	It displays SpO2 value and is refreshed every second.
6	PR value	It displays PR value and is refreshed every second. Unit: bpm (beats/minute)
7	Low battery	It appears only when the battery energy is low.

## 2.6 Button Operation

Three soft buttons are available on DPM1's front panel.



Power



Backlight



Confirm ID

Figure 2-4 Buttons

### 2.6.1 Power Button

- Power-on: Press to turn on the device.
- Power-off: Press and hold for two seconds to turn off the device.

#### NOTE

- **DPM1 is powered by batteries only. Please install batteries before use as described in 3.2 Install Batteries.**
- **In case the SpO<sub>2</sub> cable becomes disconnected or the finger moves away from the sensor, DPM1 will automatically enter the standby mode. Under this mode, when a finger is inserted into the sensor, DPM1 will automatically resume the operation mode. Otherwise, if no finger is inserted in 5 minutes, DPM1 will automatically shut down.**

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## 2.6.2 Backlight Button

- Backlight on: Press the Backlight button to turn on backlight.
- Backlight off: Press the Backlight button to turn off backlight.

## 2.6.3 Confirm ID Button

The Confirm ID button is used to add data. It enables the user to add data, without using a new ID number, to a re-test for the same patient after the sensor is accidentally disconnected.

Refer to section 5.1 Data Management for detailed use of this button.

## 2.6.4 Delete ID Button

The Delete ID button is a key combination of the Backlight button and the Confirm ID button.

Refer to section 5.1 Data Management for detail use of this button.



# 3 Installation

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## 3.1 Unpacking and Inspection

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or our company.

If the packing case is intact, open the package and remove the instrument and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact our Customer Service Department for in case of any problem.

### NOTE

- Please save the packing case and packaging material for future transport and storage.



### WARNING

- Be sure to keep the packaging materials from children's reach.
  - Disposal of the packaging materials shall comply with your local requirements.
- 

## 3.2 Install Batteries

DPM1 is powered by four batteries. Follow the steps below to install batteries before use:

1. Hold DPM1 in one hand.
2. Place the other hand on the battery cover.
3. Push the cover away as Figure 3-1 shows.
4. Place batteries into the slots per the “+” and “-” indications as shown in Figure 3-2.
5. Push back the battery cover.



Figure 3-1

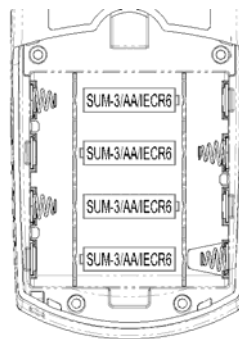


Figure 3-2

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 **CAUTION**

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- To dispose of the batteries, follow local laws for proper disposal.
  - Use AA alkaline batteries or rechargeable batteries. Do not use carbon or poor quality batteries. Remove the batteries if the device is not to be used for a long time.
  - During use, replace batteries of insufficient energy in time with good ones; abnormal power supply may lead to product damages or even personnel injuries.
  - Only the operator can remove the battery cover.
- 

### 3.3 Power-on

Press the Power button to turn on DPM1. The startup interfaces and version information will be displayed, and then the initialization interface of DPM1 as shown in Figure 3-3 will be displayed. After that, DPM1 will automatically switch to the standby mode as shown in Figure 3-4.

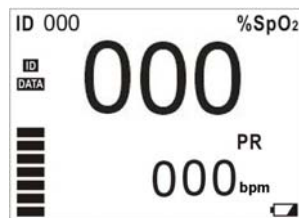


Figure 3-3

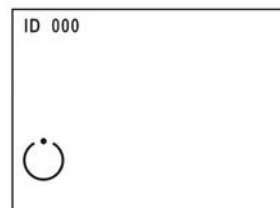


Figure 3-4

### 3.4 Connect SpO<sub>2</sub> Sensor

As show below, you can connect the SpO<sub>2</sub> sensor to DPM1 by simply inserting the sensor's connector to DPM1's dual-purpose socket.



Figure 3-5 Connect SpO<sub>2</sub> sensor

---

## 3.5 Connect Computer

DPM1 can be connected to a Personal Computer through a communication cable to transmit patient's trend to the computer for printing.

Simply connecting one end of the PC communication cable to DPM1's dual-purpose socket and the other end to the PC's serial port.



This symbol will be displayed in the LCD screen indicating that DPM1 has connected with the PC successfully.

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**FOR YOUR NOTES**

# 4 Measurement

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## 4.1 Measuring Principle

SpO<sub>2</sub> monitoring is a non-invasive technique used to measure the amount of oxygenated haemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into electrical signals by the photodetector in the probe. The DPM1 processes the electrical signal and displays on the screen digital values for SpO<sub>2</sub> and pulse rate. The displayed SpO<sub>2</sub> value is of functional saturation.

The sensor measurement wavelengths are nominally 660nm for the red LED and 940nm for infrared LED. The maximum optical power output for LED is 4mW.

## 4.2 Precautions

### NOTE

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- **Do not perform SpO<sub>2</sub> monitoring and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO<sub>2</sub> value.**
  - **A measurement shall last longer than 15 seconds. Otherwise, new data of next measurement can't be added to the same patient.**
  - **DPM1 is not recommended for prolonged monitoring.**
- 

### WARNING

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- **Check if the sensor cable is in normal condition before monitoring. Do not use the SpO<sub>2</sub> sensor once the package or the sensor is found damaged.**
  - **Don't use DPM1 to measure patients whose pulse rate is lower than 25bpm, which may cause incorrect results.**
  - **Remove the SpO<sub>2</sub> sensor from the patient after measurement.**
  - **As with any medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation. Cables of electrical surgical equipment should not be wound around that of the SpO<sub>2</sub> sensor.**
  - **Do not put the sensor on extremities with arterial catheter or venous syringe.**
-

---

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 **WARNING**

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- **If no pulse is found or the reading is unreasonable, first check the patient's condition, and then check the device and the SpO<sub>2</sub> sensor for proper functions.**
  - **Do not reuse disposable SpO<sub>2</sub> sensors.**
  - **Make sure no contamination or scar exists in the site where the sensor is placed. Otherwise, the measured result may be incorrect because the signal received by the sensor is affected.**
  - **When used on different patients, DPM1 is prone to crossed contamination, which should be prevented and controlled by the user. Disinfection is recommended before using the SpO<sub>2</sub> sensor on other patients.**
- 

## 4.3 Measuring Steps

Sensor selection for SpO<sub>2</sub> measurement depends on the patient type. For an adult patient, you can choose a finger SpO<sub>2</sub> sensor; for an infant patient, you can choose a hand or toe sensor. Refer to the following procedure.

### 4.3.1 Adult Measurement

Please follow the steps below to use the adult finger SpO<sub>2</sub> sensor:

1. Insert the sensor's connector to DPM1's dual-purpose socket.
2. Turn on DPM1 to enter the standby mode.
3. Attach the sensor to an appropriate site on the patient.

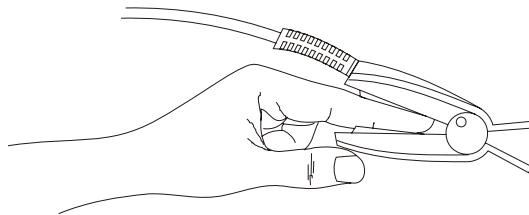


Figure 4-1 placing the adult SpO<sub>2</sub> sensor

4. The readings will be displayed on DPM1's LCD screen a moment later.

### NOTE

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- **Place the SpO<sub>2</sub> sensor cable at the backside of the patient hand. Make sure the fingernail is just opposite to the light emitted from the sensor.**
  - **To acquire accurate results, please read data until the sensor is steadily placed.**
  - **Readings may not be accurate when either the sensor or the patient is moving.**
-

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### 4.3.2 Neonatal Measurement

Please follow the steps below to use the neonatal SpO<sub>2</sub> sensor:

1. Insert the SpO<sub>2</sub> sensor's connector into DPM1's dual-purpose socket.
2. Turn on DPM1 to enter the standby mode.
3. Appropriately place the neonatal SpO<sub>2</sub> sensor.
4. The readings will be displayed on DPM1's LCD screen a moment later.

### 4.3.3 Placing Neonatal SpO<sub>2</sub> Sensor

Neonate SpO<sub>2</sub> sensor consists of a Y-shape SpO<sub>2</sub> sensor and its sheath. Insert the LED and PD ends of the Y-shape SpO<sub>2</sub> sensor respectively into the upper and lower grooves on the sheath (Figure 4-2). The Figure 4-3 shows us the neonate SpO<sub>2</sub> sensor after insertion.

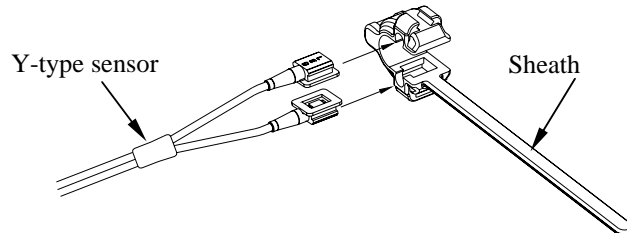


Figure 4-2 Placing Neonatal SpO<sub>2</sub> Sensor 1

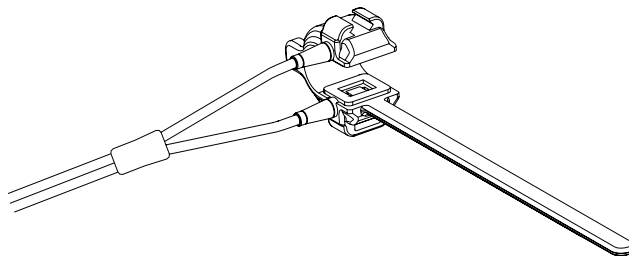


Figure 4-3 Placing Neonatal SpO<sub>2</sub> Sensor 2

Wind the SpO<sub>2</sub> sensor around a hand or foot of a neonate patient. Hold the sensor, pull the belt and fit one of its sides with “V” edge into the “V” groove on the corresponding side of the sheath. Appropriately elongate the belt to about 20mm, and fit the “V” edge of the other side of the belt into the “V” groove of the other side of the sheath. Then, loosen the belt. After the “V” edges of the two sides of the belt fit well into the “V” grooves on the two sides of the sheath, put the belt into the first lock bar to fasten the belt. See Figure 4-4. If the belt is too long, you may put it into the second lock bar. You must position the SpO<sub>2</sub> sensor in this way so as to make the photoelectric component face the correct position. Besides, note not to elongate the belt too much, which may lead to inaccurate measurement and block the blood circulation severely.

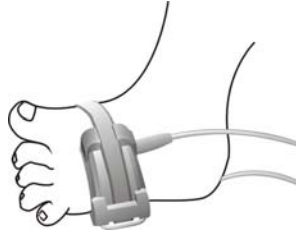


Figure 4-4 Placing Neonatal SpO<sub>2</sub> Sensor 3

## 4.4 Measuring Limitations

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by an alternate method. Then check the instrument for proper function. Inaccurate measurements may be caused by:

- Incorrect sensor application or use;
- Significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin or methemoglobin);
- Intravascular dyes such as indocyanine green or methylene blue;
- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark material);
- Excessive patient motion;
- Venous pulsations;
- Placement of a sensor on the same extremity with a blood pressure cuff, arterial catheter, or intravascular line;

Loss of pulse signal can occur in the following situation:

- The sensor is too tight;
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight;
- A blood pressure cuff is inflated on the same extremity as the one with a SpO<sub>2</sub> sensor attached;
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- There is arterial occlusion proximal to the sensor.
- The patient is in cardiac arrest or in shock.



# 5 Other Functions

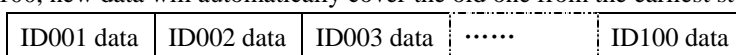
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## 5.1 Data Management

### 5.1.1 Data Storage

DPM1 oximeter has its internal memory to store data. The memory is divided into the ID Data Zone and Trend Data Zone.

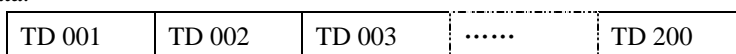
The ID Data Zone is capable of storing 100 patients' ID data at most. When the number exceeds 100, new data will automatically cover the old one from the earliest stored data.



One ID data include:

- Number of the SpO2 and pulse rate values stored to this ID.
- Maximum SPO2 value of this ID.
- Minimum SPO2 value of this ID.
- Average SPO2 value of this ID.
- Maximum PR value of this ID.
- Minimum PR value of this ID.
- Average PR value of this ID.

Trend Data Zone is capable of storing 200 trend data (TD, as shown below) at most. When the number exceeds 200, new data will automatically cover the old data from the earliest stored data.



The first trend data will be stored 15 seconds after the pulse is found. Thereafter one trend data will be stored every 2 minutes. One trend data includes:

- Average SpO2 value within the 2 minutes.
- Average PR value within the 2 minutes.

### NOTE

- **The first trend data are the instant values of SpO2 and PR.**
- **For a patient, his (her) ID data are calculated from all measured trend data of him (her).**
- **Once the trend data of a patient is covered, all trend data of that patient will be deleted, however, the ID data will not be deleted.**

---

## 5.1.2 Data Adding

The previously stored ID number appears on the screen when a finger is inserted into the SpO<sub>2</sub> sensor. It will keep blinking for 8 seconds after the pulse is found.

- Press the Confirm ID button before the ID number stops blinking, DPM1 will set the ID number as current patient ID. The data measured thereafter will be superadded to the previous ID.
- If the user doesn't press the Confirm ID button before the ID number stops blinking, a new ID number, which is the blinking number plus 1, will be set as the current patient ID.

The Confirm ID button is of no use when the current ID number is 000, which will automatically change to 001 when the pulse is found.

## 5.1.3 Data Protection

DPM1 has data protection function. When the power is turned off accidentally during the process of storing a data, DPM1 will evaluate completeness of the last stored data when it is restarted. If the data is complete, it will be validated, otherwise it will be invalidated.

## 5.1.4 Data Deletion

Press the Delete ID button in the standby mode, the message “DELETE ALL?” will be displayed as shown in Figure 5-1.



Figure 5-1

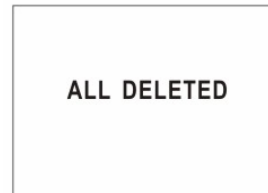


Figure 5-2

- To delete all stored data:

Press the Delete ID button again. As shown in Figure 5-2, the message “ALL DELETED” will be displayed for 2 seconds. Then DPM1 will switch back to the previous standby mode, the ID number restores to “000”, symbols of memory full as well as ID Full disappears.

- Not to delete all stored data:

Don't press the Delete ID button and wait for 10 seconds, the “DELETE ALL?” message will disappear automatically and the previous operation will be cancelled. DPM1 will switch back to the previous mode.

## 5.2 Messages Prompting

DPM1 can display various prompt messages. In Table 5-1, prompt messages as well as their causes and solutions are listed.

Table 5-1 Table of Indications

Message	Cause	Solution
“Low Battery”	Batteries energy lower than 4.0 Voltage.	Replace batteries in time
“Memory Full”	The internal memory is almost full.	Stored data is to be covered. Export data in time.
Blinking “Memory Full”	Memory is full.	Stored data is being covered. Export data in time.
“ID Full”	ID number Stored is greater than 95.	ID data is to be covered. Export data in time.
Blinking “ID Full”	ID data is being covered.	Export data in time.
“Standby”	The device is in standby mode.	None.
“Communication”	The device is in communication mode.	None.
DELETE ALL?	The Delete ID button is pressed.	Refer to 5.1.4 Data Deletion
ALL DELETED	The Delete ID button is pressed again after “DELETE ALL?” appears.	None.

DPM1 can also display technical error messages. In Table 5-2, error messages as well as their causes and solutions are listed.

If the LCD screen can't display anything, it may be damaged or error occurs during system self-test. Please shut down the device (if can't, remove the batteries) and contact our Customer Service.

Table 5-2 Error indications

Error Message	Cause	Solution
Initiate Error	Failed self-test	Shut down the device (if can't, remove the batteries) and contact us for service.
Please Release the Button	Button error	Check for jammed button. If problem remains, contact us for service.
Pulse Not Found Searching...	Pulse not found	Check the patient and alert the doctor.

---

## 5.3 Power Management

### 5.3.1 Battery Detection

DPM1 can detect the battery energy and

- display “Low Battery” message when battery voltage is less than 4.0 V.
- shut down the device automatically when battery voltage is less than 3.85V.

### 5.3.2 Energy Saving

DPM1 can save the energy of the batteries by

- switching to the standby mode automatically when the finger disconnects from the sensor or the sensor disconnects from DPM1.
- shutting down automatically if no finger is inserted into the sensor within 5 minutes under the standby mode.

#### NOTE

- 
- **DPM1 will automatically switch from the standby mode to the normal operation mode when a finger is inserted into the sensor.**
  - **Please refer to 7Pulse Oximeter Management System to learn more functions if your DPM1 has been provided with PMS software.**
-

# 6 Maintenance

---

## 6.1 System Check

Make sure the qualified service personnel have implemented a complete inspection before putting the device into operation, after monitor servicing or system upgrading, or after the monitor has been used for 6-12 consecutive months. This is to ensure the normal operation of the system.

Before using DPM1, perform the following steps.

- Check for any mechanic damages.
- Check for all cables and accessories for damage.
- Check all functions of DPM1 to make sure it is in proper working condition.

In case of any damage or exception, do not use the device. Contact the technician in your hospital or our Customer Service immediately.



### **WARNING**

- **Failure on the part of the responsible hospital or institution employing the use of the monitoring equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazard.**
  - **The safety inspection or maintenance, which requires opening the monitor housing, must be performed by trained and authorize personnel only. Otherwise, equipment failure and possible health hazard may be caused.**
- 

## 6.2 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.

Cleaning agents:

- Mild soap and water
- Quaternary ammonia
- Water/bleach solution (100:1)
- 3 vol% Hydrogen peroxide in water solution
- 70 vol% isopropyl or ethyl alcohol

- 
1. Power off the oximeter.
  2. Wipe the surface and display lens with a cotton swap moistened with a cleaning agent.
  3. Wipe the oximeter case with a soft cloth dampened with a cleaning agent. Do not allow excess liquid to enter the sensor connector.

To avoid damage to the equipment, follow these rules:

- ALWAYS dilute the agents according to the manufacturer's suggestions.
- ALWAYS wipe off excessive cleaning agent with a dry cloth after cleaning.
- NEVER submerge the equipment into water or any cleaning agent, or pour or spray water or any cleaning agent on the equipment.
- NEVER permit fluids run into the casing, switches, connectors, or any ventilation openings in the equipment.
- NEVER use abrasive, erosive cleaners, or cleaners containing acetone.

Failure to follow these rules may erode or fray the casing, or blur lettering on the labels, or cause equipment failures.

For cleaning information of accessories, please refer to the instructions for use of the accessories.

## 6.3 Disinfection

Disinfection may cause damage to the equipment. We recommend the disinfection be contained in the hospital's servicing schedule only when necessary. The equipment should be cleaned prior to disinfection.

Recommended disinfection material: Alcohol based (Ethanol 70%, Isopropanol 70%), and aldehyde based.



### **WARNING**

- **Disinfection may cause damage to the equipment; therefore, when preparing to disinfect the equipment, consult your hospital's infection controllers or professionals.**
  - **The cleaning agents above can only be used for general cleaning. If you use them to control infections, we shall assume no responsible for the effectiveness.**
-

---

## NOTE

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- **Never use EtO and formaldehyde to disinfect.**
  - **Do not autoclave, pressure sterilize, or gas sterilize the oximeter.**
- 

## 6.4 Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect or decontaminate the device appropriately before disposing of it in accordance with your country's law for equipment containing electrical and electronic parts. For SpO<sub>2</sub> sensor, follow local regulations regarding disposal of hospital waste.

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**FOR YOUR NOTES**



# 7 Pulse Oximeter Management System

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The Pulse Oximeter Management System software (PMS software) is developed to realize more functions of DPM1. The PMS software runs in English Windows 98/2000/XP operating system. In conjunction with the internal software of DPM1, the following functions can be realized.

- Outputting data and upgrading internal software.
- Previewing data exported
- Adding patient information
- Printing patient data

## 7.1 Installation and Uninstall

### 7.1.1 Installation

Before you use PMS software, you must first install it in your PC. Take Windows 2000 for example, you can follow the steps below for installation.

1. Insert the installation CD into the CD-ROM.
2. Run the file “Setup.exe” in the installation CD.



Setup.exe

3. Choose your favorite language according to the prompt. Click “OK”, and then click “Next” in the next dialog box.
4. Input the correct serial number, and click “Next” to resume.
5. Select the serial port to connect DPM1 Pulse Oximeter with your PC, and click “Next” to resume.
6. Choose the destination folder where the PMS software is to be installed.
7. Click “Next” and “Finish” according to the prompt.
8. After the installation is completed, a new shortcut icon will appear in the desktop of your computer as shown below.



Pulse  
Oximeter  
Management  
System

9. Double click the icon to run the PMS software.

---

## 7.1.2 Uninstall

To uninstall the PMS software, please follow the steps:

1. Click “Start-Setting-Control Panel”, and double click the icon for “Add/Remove Programs” to open the “Add/Remove Programs” dialog box.
2. Select the “Pulse Oximeter Management System”, and click the “Change/Remove” button. Then following the prompt to uninstall the PMS software.

### NOTE

- The steps above are provided as examples only. They maybe a bit different from your operation if you use other operation system.
- 

## 7.2 Main Interface

Double clicking the shortcut icon for PMS software on the desktop of your computer, the Main Interface of PMS software will be displayed.

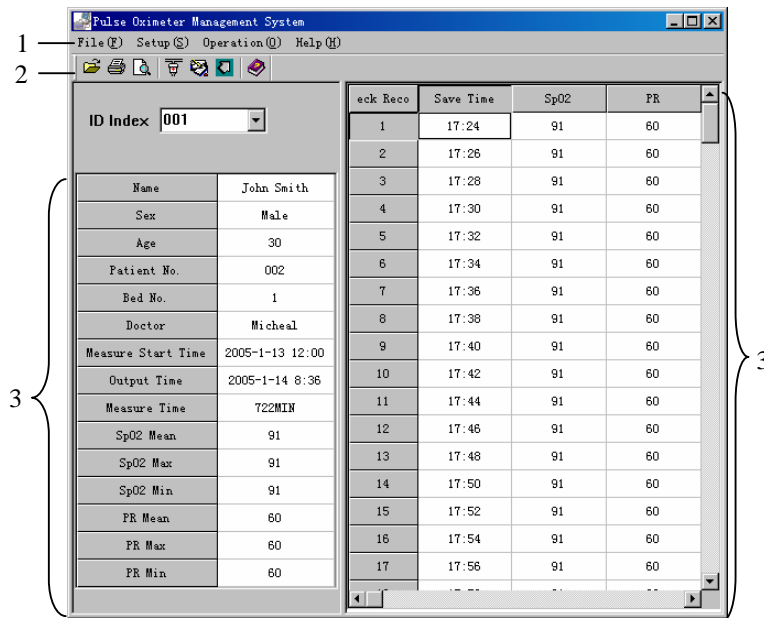


Figure 7-1

1 Menu Bar    2 Tool Bar    3 Data Area

---

## 7.2.1 Menu Bar

In the Menu Bar, four menus are available: <File>, <Setup>, <Operation> and <Help>. See the descriptions below to know the details.

### <File>

Click the <File> menu to see its pull-down menu as shown below.

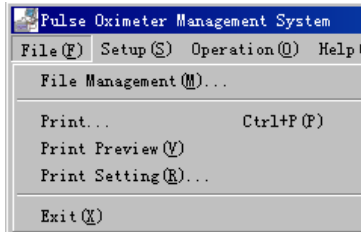


Figure 7-2

There are five submenus:

- <File Management>: Click to open the “File Management” dialog box.
- <Print>: Click to print the current patient data.
- <Print Preview>: Click to preview the data to be printed.
- <Print Setting>: Click to open the “Print Setting” dialog box.
- <Exit>: Click to exit the PMS software.

### <Setup>

Click the <Setup> menu to see its pull-down menu as shown below.

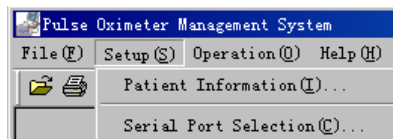
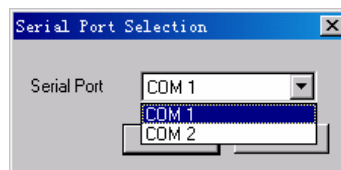


Figure 7-3

There are two submenus:

- <Patient Information>: Click to open the “Modify Patient Information” dialog box.
- <Serial Port Selection>: Click to open the “Serial Port Selection” dialog box.



When you use the Data Output or Software Upgrade function, the default serial port might have been occupied. At this time, you can click the <Serial Port Selection> menu to select other serial port.

<Operation>

Click the <Operation> menu to see its pull-down menu as shown below.

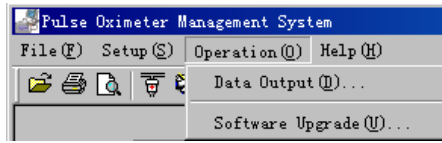


Figure 7-4

There are two submenus:

- <Data Output>: Click to conduct the “Data Output” function.
- <Software Upgrade>: Click to open the “Input Password” dialog box.

<Help>

Click the <Help> menu to see its pull-down menu as shown below.



Figure 7-5

- <Help>: Click to open the “Help” document.
- <About PMS>: Click to show the copyright information.

## NOTE

- When you open the “Help” document, if a dialog box pops up and informs you to install language pack, please select “Never install any language packs”, and then click “Cancel” button.

## 7.2.2 Tool Bar

In the tool bar, you can see the following shortcut icons.



Table 7-1 Shortcut Icons

Icon	Icon Name	Description
	File Management	Equals to <File Management> submenu
	Print	Equals to <Print> submenu
	Print Preview	Equals to <Print Preview> submenu
	Serial Port Selection	Equals to <Serial Port Selection> submenu
	Patient Information	Equals to <Patient Information> submenu
	Data Output	Equals to <Data Output> submenu
	Help	Equals to <Help> submenu

---

## 7.2.3 Data Area

The Data Area displays the data of the current ID. The left part of Data Area is Information Area, and the right part is Patient Data Area.

- Information Area

It displays the patient Name, Sex, Age, and Doctor etc.

- Patient Data Area

It displays the value of measured SpO2, PR, the corresponding Check Record and Save Time of each measurement.

The content in the Information Area can't be directly inputted or changed. Please select <Patient Information> under the <Setup> menu, or click the shortcut icon.

### NOTE

- The data displayed as “---” is invalid.
  - The "(ADD)" appearing beside the check record number is to indicate that the data thereafter are additional ones to this ID.
- 

## 7.3 Functions

Before operate the function hereinafter, please first connect DPM1 with your PC (Refer to *3.5 Connect Computer*), and then double click the shortcut icon on the desktop to run the PMS software.

### 7.3.1 Data Output

PMS software can output the data stored in DPM1 to your PC.

1. Select <Data Output> under the <Operation> menu to start data outputting as shown below. During outputting, you can click exit to cancel the operation.

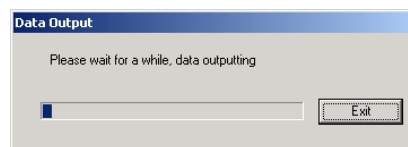


Figure 7-6

2. When data outputting is finished, the following dialog box will pop up.

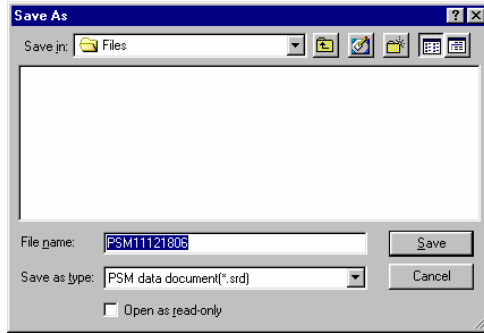


Figure 7-7

3. You can choose the file directory where the data is to be stored, and change the file name.
  - The default file directory is the “Files” folder under the directory where the PMS software is installed.
  - The default file name is “PMS\*\*\*\*\*.srd”, where the “\*\*\*\*\*” represents the current system time. For example, “11091133” means November 9th, 11 o’clock and 33 minute. The hour is 24-hour format.
4. Click “Save” button to save the data. Meanwhile, information and data outputted from DPM1 will be displayed in the Data Area.
5. If error occurs during outputting, the following prompt will pop up.

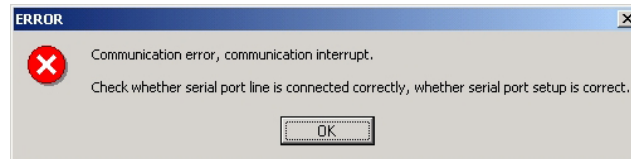


Figure 7-8

When this situation occurs, please check whether the serial port is correctly connected, and try to select another serial port by clicking the <Serial Port Selection> menu.

### 7.3.2 Software Upgrade

With the PMS software, you can upgrade the internal software of DPM1.

1. Click <Software Upgrade> under the <Operation> menu, the “Input Password” dialog box will pop up.



Figure 7-9

2. Input the correct password, and then click the OK button. The “Software Upgrade” dialog box will pop up as shown below.

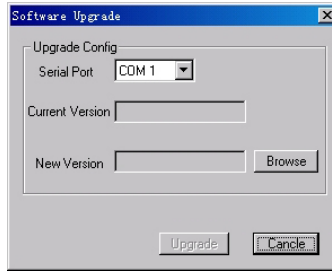


Figure 7-10

3. Select the serial port and click “Browse” to display the dialog box as shown below.

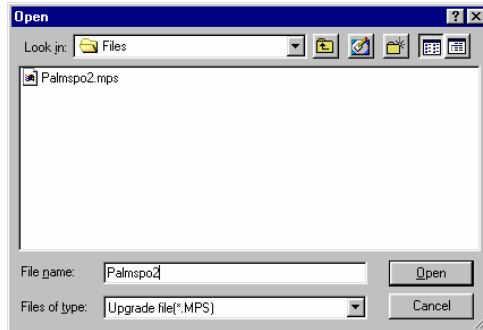


Figure 7-11

4. Select the Upgrade File and click the “Open” button. The version of the Upgrade File will be displayed in Figure 7-10.
5. Click the “Upgrade” button, the system will check the validity and verify version of the Upgrade File. If the Upgrade File is valid, and the current version loaded on the DPM1 Pulse Oximeter is lower than the Upgrade file, the following message will be displayed.

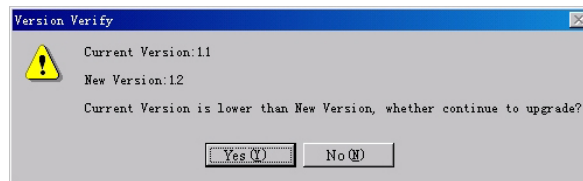


Figure 7-12

6. Click “Yes”, and the system will start to upgrade the software automatically. If you click "Cancel" when the upgrading is in process, the software in the DPM1 will be damaged. You need to upgrade the software again.

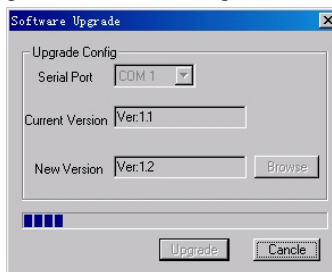


Figure 7-13

- If the version of Upgrade File is lower or the same as that loaded on the DPM1, corresponding different message will be displayed in Figure 7-12. Click “Yes” to continue to upgrade, and “Cancel” to cancel upgrading.
- If the Upgrade File is invalid, the following message will be displayed.

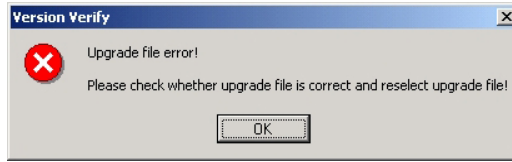


Figure 7-14

7. Click “OK” to finish the upgrading.

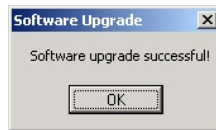


Figure 7-15

### 7.3.3 File Management

File management function helps you to open or delete the data outputted conveniently.

1. Click <File Management> from the <File> menu, the “File Management” dialog box will pop up as shown below.

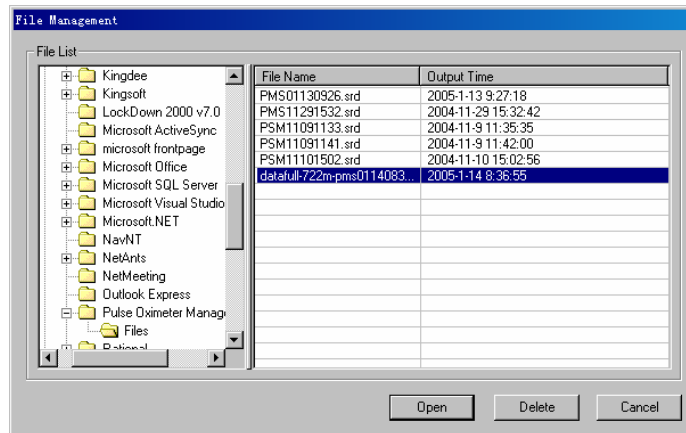


Figure 7-16

2. You can choose the folder where the outputted data is saved in the File List. The Files contained in that folder will be displayed in the right.
3. To open a file, choose a file name and click “Open” button, and then the data contained in the file will be displayed in the Data Area of the Main Interface.
4. To delete a file, choose a file name and click “Delete” button. The data of all patients contained in this file will be deleted. You can’t delete the data of one patient ID contained in the file.



---

### 7.3.4 Modify Patient Information

1. Click <Patient Information> from the <Setup> menu, the “Modify Patient Information” dialog box will pop up.

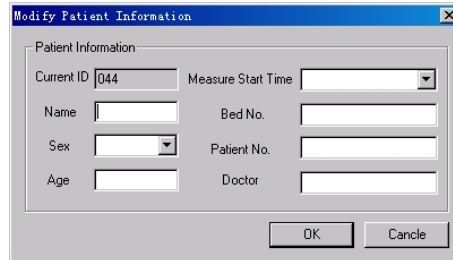


Figure 7-17

2. You can input the following information:
  - Name: 30 characters at maximum.
  - Sex: Male of Female.
  - Age: The age of the patient.
  - Measure Start Time: The displayed format of the time is dependent on the setting of the PC's system. For example, 2004/9/12/15:30, here the hour is 24-hour format.
  - Bed No.: Range from 1 to 65535.
  - Patient No.: 12 characters (English Character or number) at maximum.
  - Doctor: Name of the doctor, 30 characters at maximum.
3. Click “OK”, the dialog box will disappear, and the information inputted will be displayed in the Information Area.
4. Click “Cancel”, the dialog box disappears and no information listed above will be modified.

### 7.3.5 Print Data

1. Click <Print Setting> from the <File> menu to display the dialog box as shown below. You can set the print range of the patient ID.

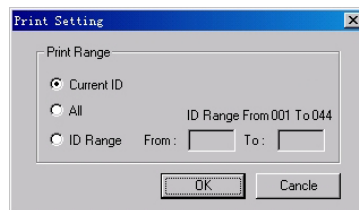


Figure 7-18

2. Click “OK” and set the properties according to the printer your personal computer installed in the pop-up dialog box.
3. Click “OK” to start printing the selected ID data.

4. Before printing, you can select <Print Preview> from the <File> menu to preview the content to be printed, as shown below.

ID001

Name	ABC	Sex	Male
Age	30	Patient No.	100
Bed No.	1	Doctor	ABC
Measure Start Time	Output Time	2004/11/10/09:13	Measure Time 868MIN
SpO2 Mean 99	SpO2 Max 100	SpO2 Min 62	
PR Mean 89	PR Max 90	PR Min 66	
Check Record	Save Time	SpO2	PR
1	+07:52	99	89
2	+07:54	99	89
3	+07:56	99	89

Figure 7-19

5. You can also click <Print> from the <File> menu, and click <OK> button in the pop-up dialog box to start printing.

### 7.3.6 Prompt Message

Error Message	Cause	Solution
Communication Error, communication interrupt	The connection between DPM1 and PC is interrupted.	Restart DPM1, and check the connection between DPM1 and PC.
Upgrade File Error	The upgrade file is invalid	Check the right upgrade file is selected and conduct the upgrade again.
Password Error	The password inputted is incorrect.	Input the correct password or exit the upgrade operation.
Serial Port Error	Other program is using the serial port selected.	Choose another serial port or close the program that using the selected serial port.
Age Input Error	The age inputted is out of the range: 1~255.	Input the age again
Bed No Input Error	The No. inputted is out of the range:1~65535	Input the Bed Number again
Measure Start Time and Output Time are unconformity	The inputted Measure Start Time adds the total measured time is later than the Output Time.	Input the Measure Start Time again.
File not found	The file name you inputted is not available under the current directory.	Select file again
ID Range Error	The inputted ID range is wrong	Input the ID Range again.

# 8 Accessories

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The following SpO<sub>2</sub> sensors are recommended for DPM1 Pulse Oximeter. These sensors are observed with DPM1 Pulse Oximeter.

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 **CAUTION**

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- Using other accessories may cause damage to the device.
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Description	PN
520A Single-patient SpO <sub>2</sub> Sensor (Adult, Disposable)	520A-30-64101
520P Single-patient SpO <sub>2</sub> Sensor (Pediatric, Disposable)	520P-30-64201
520I Single-patient SpO <sub>2</sub> Sensor (Infant, Disposable)	520I-30-64301
512E Adult SpO <sub>2</sub> Sensor (Reusable)	512E-30-90390
512F Adult SpO <sub>2</sub> Sensor (Reusable)	512F-30-28263
512G Pediatric SpO <sub>2</sub> Sensor (Reusable)	512G-30-90607
512H Pediatric SpO <sub>2</sub> Sensor (Reusable)	512H-30-79061
518B Multisite SpO <sub>2</sub> Sensor (Reusable)	518B-30-72107
520N Neonatal SpO <sub>2</sub> Sensor (Disposable)	520N-30-64401

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**FOR YOUR NOTES**

# A Specifications

<b>1. General</b>			
<b>1.1 Basics</b>			
Product Model:	DPM1		
Product Name:	Pulse Oximeter		
Classification:	IIb (According to MDD 93/42EEC directive) II (21CFR 870.2700, 870.2710)		
<b>1.2 Safety Designations</b>			
Safety designations per IEC 60601-1 Standard:			
Type of protection against electric shock:	Internally powered equipment.		
Degree of protection against electric shock:	Type BF		
Mode of operation:	Continuous		
Protection Against Ingress of Liquid's:	Not protected (Ordinary) - IPX0 per IEC60529		
<b>2. Parameter Specifications</b>			
<b>The parameter specifications are applicable to the DPM1 Pulse Oximeter with sensors listed in chapter 8 Accessories.</b>			
<b>2.1 SpO<sub>2</sub></b>			
Range:	0% to 100%		
Resolution:	1%		
Accuracy:	70% to 100%: ±2% (Adult, Pediatric) 70% to 100%: ±3% (Neonate)* 0% to 69%: Unspecified		
*Studies were performed to validate the accuracy of Pulse Oximeter with neonatal SpO <sub>2</sub> sensors by contrast with a CO-Oximeter. Some neonates aged from 1 day to 30 days with a gestation age of 22 weeks to full term were involved in this study. The statistical analysis of data of this study shows the accuracy (Arms) is within the stated accuracy specification. Please see the following table.			
<b>Sensor type</b>	<b>Totally neonates</b>	<b>Data</b>	<b>Arms</b>
518B	97 (51 male & 46 female)	200 pairs	2.38%
520N	122 (65 male & 57 female)	200 pairs	2.88%

The DPM1 Pulse Oximeter with neonatal SpO2 sensors was also validated on adult subjects.	
<b>2.2 PR</b>	
Range:	25 to 254bpm
Resolution:	1bpm
Accuracy:	± 3bpm(For 520N) ± 2bpm(Others)
<b>3. Display and Control</b>	
<b>3.1 Display</b>	
Display Type:	Matrix LCD
Display Area:	Not less than 42mm×35mm.
Back Light:	Blue
Display Information:	SpO <sub>2</sub> , PR, Pulse strength, ID number, Memory Full, ID Full, Low battery, Standby, Communication, Technical error
<b>3.2 Buttons</b>	
Power Button:	Switches on/off the oximeter. The power-on is not delayed and the power-off has a 2 second delay.
Backlight button:	Switches on/off the backlight
ID Confirm button:	Confirms whether use the previous ID for the new measurement.
Backlight button + ID Confirm button	Deletes data
<b>3.3 Power Saving Features</b>	
Refer to 5.3 Power Management	
<b>3.4 Connector</b>	
One dual-purpose socket for connecting SpO2 sensor and communication cable.	
<b>4. Electrical specifications</b>	
Working Voltage:	4.0 to 6.4 VDC
Power Supply:	Batteries
Battery Specifications:	Four Common 1.5V AA alkaline or rechargeable batteries
Shutdown Leakage Current:	< 200uA
Battery Run Time:	15-hour continuous operation with alkaline batteries
Power Consumption	720mW
<b>5. Printing</b>	
Printer	The PC's printer

Paper:	A4
Content:	ID data and trend data
<b>6. Physical Characteristics</b>	
Maximum Size:	65 × 140 × 32mm (W × H × D)
Maximum Weight:	130g (not include battery and sensor)
<b>7. Environment and Safety</b>	
<b>7.1 Temperature</b>	
Operation:	0°C to 50°C
Transportation and storage:	-20°C to 60°C
<b>7.2 Humidity</b>	
Operation:	15% to 95% (noncondensing)
Transportation and storage:	10% to 95% (noncondensing)
<b>7.3 Altitude</b>	
Operation:	-500 to 4,600 m (-1,600 to 15,000 feet)
Transportation and storage:	-500 to 13, 100 m (-1,600 to 43, 000 feet)
<b>7.4 Transportation</b>	
Meets the 1A requirements of the ISTA transportation test procedure.	
<b>7.5 Shock</b>	
Meets all the specifications after being exposed a half sinusoidal pulse that is 15g and 11ms, as required by IEC 68-2-27.	
<b>7.6 Vibration</b>	
After being subjected to sinusoidal or random vibration (see FDA Reviewer Guidance for Pre-market Notification Submission, November 1993 - draft), the oximeter meets all the specifications.	
Sinusoidal vibration:	As required by IEC 68-2-6 1g or 0.07mm, 57-62 Hz crossover frequency 10 - 500Hz, 10 sweep cycles for every axis.
Random vibration:	As required by IEC 68-2-37. 0.02 g <sup>2</sup> /Hz 20 to 500 Hz Low reproducibility. 9 minutes for every axis.
Falling:	Meets the requirements of IEC 60601-1, clause 21.6 and of ECRI PB-296 892, AIII 3.3 (the part against Class III instruments).

Impact:	Meets the requirements of ECRI PB-296 892, AIII 3.2 (the part against Class III instruments).
Spillage and ingress of liquid:	Meets the requirements of IEC 60601-1-1, clause 44.3 and IEC 60601-27, clauses 30 and 34. It also meets the IEC 529 requirements for IPX0 devices.
Surface temperature:	Meets the requirements of IEC 60601-1, clauses 42.1, 42.2 and 42.3. Meets the requirements of FDA Reviewer Guidance for Premarket Notification Submission, November 1993, paragraph i7.
Mechanical stability:	Meets the requirements of IEC 60601-1, clause 24.1.
Incompatibility with external connectors	Meets the requirements of IEC 60601-1, clause 56.3 and of FDA Reviewer Guidance for Premarket Notification Submission November 1993, i2.
Enclosure rigidity and strength	Meets the requirements of IEC 60601-1, clause 21a, 16a and 21b. Meets the requirements of UL 2601-1, clause 55.
Deterioration of heat radiation conditions	Meets the requirements of IEC 60601-1, clause 52.5.5.
Leakage current	Meets the requirements of IEC 60601-1/EN 60601-1, Clause 19.
Dielectric strength	Meets the requirements of IEC 60601-1/EN 60601-1, Clause 20.



# B EMC

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The equipment meets the requirements of IEC 60601-1-2.

## NOTE

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- **The equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
  - **The equipment may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.**
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Table 1

Guidance and MINDRAY DS declaration — electromagnetic emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment — guidance
RF Emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not applicable	

Table 2

<b>Guidance and MINDRAY DS declaration — electromagnetic immunity</b>			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment — guidance</b>
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	Not applicable, the equipment is powered by internal battery.		
Surge IEC 61000-4-5			
Voltage dips, Short interruptions and voltage variation on power supply input lines IEC 61000-4-11			
Power Frequency (50/60 HZ) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3

<b>Guidance and MINDRAY DS declaration — electromagnetic immunity</b>			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment			
<b>Immunity test</b>	<b>IEC 60601 Test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment — guidance</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz ~80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz ~2.5 GHz	3 V/m	
<p>Note — At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note — These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

<sup>b</sup> Over the frequency ranges 150kHz to 80MHz, field strengths should be less than 3V/m.

Table 4

<b>Recommended separation distances between portable and mobile RF communication and the equipment</b>			
The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communication equipment.			
<b>Rated Maximum Output power of Transmitter W (Watts)</b>	<b>Separation Distance According to Frequency of Transmitter M (Meters)</b>		
	150kHz - 80MHz $d = 1.2\sqrt{P}$	80MHz - 800MHz $d = 1.2\sqrt{P}$	800MHz - 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34
For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note — At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
Note — These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



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