

DARAY[®]

HEALTHCARE PRODUCTS



V450/V450T

DESKTOP

PULSE OXIMETER

OPERATION MANUAL

DARAY®

HEALTHCARE PRODUCTS

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Instructions

This manual provides the instructions necessary to operate the Desktop SpO2/TEMP patient monitor (hereinafter called as the monitor). Observance of this manual is a prerequisite for correct use, to ensure patient and operator safety. Temperature function on V450T only.

This manual should always be kept close to the monitor, so that it can easily be referred to when necessary.

Content of this manual is subject to change without prior notice.

Statement

The manufacturer is responsible for the safety, reliability and performance of this product providing the following conditions are adhered to:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by manufacturer authorized personnel; and
- The electrical installation of the relevant room complies with the national and local requirements; and
- This product is used under strict observance of this manual.

1. Safety Information

The operator of the monitor should follow the safety information in this section. There are additional safety statements in other sections, which may be the same as or similar to the following, or specific to the operations.

The following safety terms are used throughout this manual to indicate potential hazards.

Warning:

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

Caution:

Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or damage to equipment.

Note:

Provides application tips or other useful information to ensure that you get the most from your product.

1.1 Warnings

Warnings:

- The monitor is intended only as an accessory in patient assessment. It must be used in conjunction with medical expertise. It is not intended as a device used for treatment purposes.
- The monitor should only be used by qualified clinical physicians or well-trained nurses.
- To ensure patient safety, check the normal operation and safety of this device and accessories before use.
- When using the monitor with electrical surgery equipment, the user should be careful to ensure the safety of the patient.
- **EXPLOSION HAZARD:** Do not use the monitor in the presence of flammable anaesthetics, explosive substances, gases or liquids.
- Do not pull or lift the monitor by its connection cable. This may lead to it falling and causing injury to the patient.
- Do not suspend the monitor when transporting patients. It may swing out during transportation causing safety hazards.
- Do not use the monitor and its transducer during MRI (magnetic resonance imaging) scanning because the induced current could potentially cause burns. The monitor may interfere with MRI performance, and MRI is capable of interfering with the measurement accuracy of the monitor.
- The monitor and its accessories may be contaminated during transport, use and storage. Use the recommended methods to sterilize and disinfect the monitor or its accessories when the packing material is damaged, or it has not been used for a long time.

1.2 Cautions

Cautions:

- Keep its surface dry and clean, and prevent any liquid from infiltrating it.
- The device should be positioned safely. Keep it from falling or other mechanical damage.
- Do not use mobile phones when the monitor is in operation. Mobile phones may emit electromagnetic radiation which is capable of interfering with the performance of the monitor.
- The monitor should only be maintained by DARAY approved personnel
- Before using the monitor on patients, the user should be familiar with its operation.

1.3 Notes

Note:

Important! Before use, read this manual, the safety information and the specifications.

2. General

2.1 Introduction

The monitor is a non-invasive, handheld patient monitor. It operates on AC mains adapter, built in rechargeable battery or regular 1.5v AA batteries (not supplied). It is compact, small, light, easy to use with its integral handle. It is suitable for monitoring adult and child patients.

Parameters measurable include: arterial oxygen saturation (SpO₂), pulse rate (PR), plethysmogram waveform (PLETH), pulse strength and temperature (V450T). The monitor measures parameters using a SpO₂ sensor and a TEMP sensor and displays measurements on the LED screen. The plethysmogram waveform is displayed on the LCD screen.

The monitor operation is controlled by the buttons on the front panel. It is capable of managing measured data and transmitting the patient's trend through the serial port for display, observation, saving and printing.

Function structure

The monitor is composed of the main unit, SpO₂ sensor, TEMP probe (V450T) and AC power adaptor.

2.2 Functions

Functions of the monitor:

- Measurement: Monitoring SpO₂, PR, PLETH, pulse strength and TEMP (V450T).
- Prompts: Battery capacity and speaker volume indicator.
- Alarm: Exceeding limits, audio and visual alarm.
- Power saving: Automatic shutdown when not monitoring.
- Data Managing: Data storage, data adding or deleting, displaying saved trend waveforms.
- Communication: Transmitting the patient's trend data to a PC for display, observation, saving and printing.

For the data display, observation, saving and printing function, you must install the data viewer software in a PC equipped with a printer, and connect the monitor with the PC using the communication cable.

2.3 Appearance

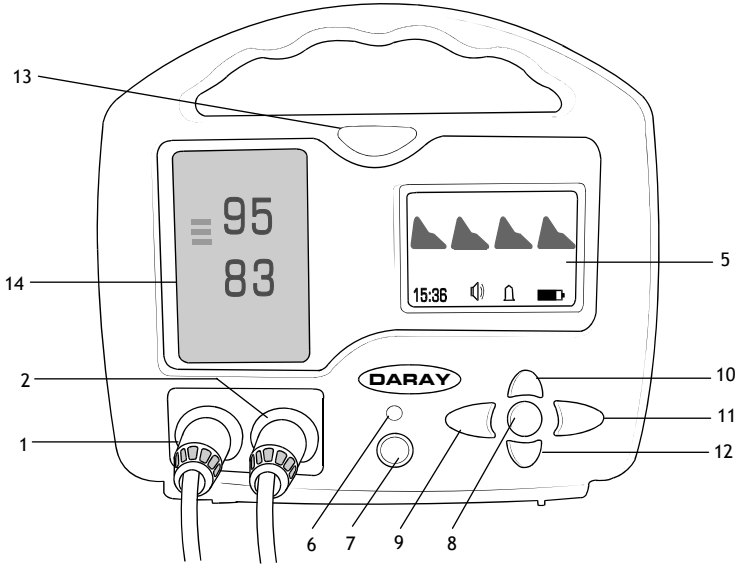


Figure 2-1 Front

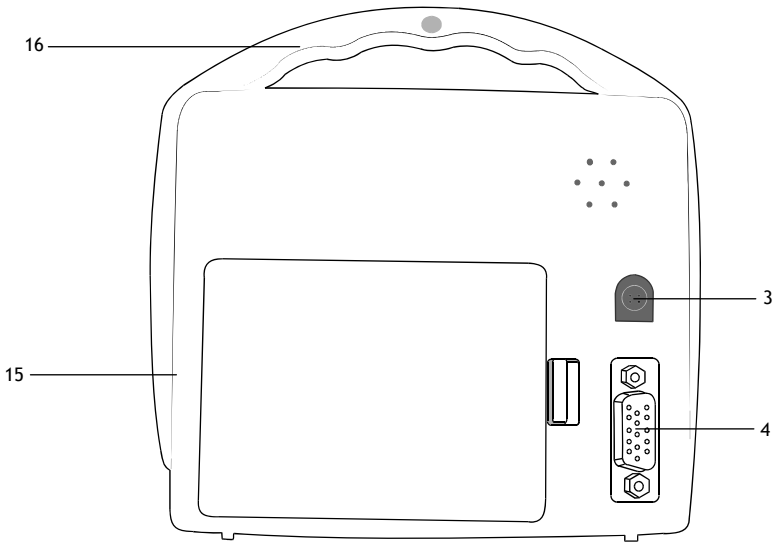


Figure 2-2 Back

Table 2-1 Appearance description

No.	Description	Remarks
1	SpO2 socket	
2	TEMP socket (V450T)	
3	AC power adaptor socket	
4	Serial port	PC serial communication port.
5	LCD	Displays information, as described in section 4.
6	Dual-colour LED	Amber LED, operates on AC power; Green LED, operates on rechargeable battery.
7	Power button	Turns the power on or off.
8	Menu button	Changes the display screen.
9	Left arrow/Contrast button	Adjusts LCD contrast when monitoring and moves cursor to the left when performing setup or observing trend waveforms, as described in section 4.
10	Up arrow button	Used to set the system or to observe trend waveforms, as described in section 4.
11	Right arrow/ backlight button	When monitoring, it switches on or off the backlight. But when performing setup or observing trend waveforms, it is a right arrow button. As described in section 4.
12	Down arrow/Mute button	Turns the speaker on or off when monitoring and moves the cursor down when performing setup or observing trend waveforms, as described in section 4.
13	Homochromy LED	Alarm indicator.
14	LED screen	Displays measurements and pulse strength.
15	Back battery panel	Open to insert or remove the battery.
16	Handle	To handhold the monitor.

Table 2-1 Appearance description

3. Installation

3.1 Unpacking and Inspection

Remove the monitor and accessories carefully from the packaging. Check all items against the packing list.

- Check the monitor for mechanical damage.
- Check exposed wires, sockets and accessories.
- Contact the supplier immediately in the event of a problem.

Warning:

Keep the packaging materials from children's reach.

Note:

Please save the packaging material for future transport and storage. If it is not required it should be disposed in compliance with the local recycling regulations.

3.2 Connect SpO2 Sensor and TEMP (V450T) Probe

Connect the SpO2 sensor and TEMP (V450T) probe to the monitor by inserting their connectors on the monitor's panel. Figure 2-1.

3.3 Connect AC Power Adaptor or Install the Battery

3.3.1 Connect AC Power Adaptor

Insert adaptor's AC connector to the AC power socket in the wall or to the transfer connector. Insert the adaptor's DC connector (on the adaptor's extension cable) to the adaptor socket on the monitor's right side panel. Figure 2-2.

Warning:

The AC power adaptor equipped with the monitor is made according to special requirements and must only be used with the V450/V450T monitor. Never use other adaptors otherwise damage may be caused to the equipment and possible injury to patients.

3.3.2 Install the Battery

The monitor is powered by five batteries. Follow the steps below to install batteries before use:

1. Remove the battery cover door.
2. Place batteries into the slots following the "+" and "-" indicators.
3. Close the battery door.

Caution:

Use AA alkaline or rechargeable batteries. Do not use carbon or poor quality batteries. Remove the batteries if the device is not going to be used for a period of time.

Replace batteries with low charge for new ones; abnormal power supply may lead to damage to equipment or even personnel injuries.

Note:

Battery disposal must be in compliance with the local recycling regulations.

3.4 Power-on

Press the power button for 3 seconds to turn on the monitor. The green LED on the front panel lights up. The LED screen displays the SpO₂/PR/TEMP parameter monitoring interface, and the LCD screen displays the PLETH waveform.

3.5 Connect to a PC

The monitor can be connected to a PC through a serial cable to transmit data to the computer for review and saving. The trend waveforms can also be printed out by a printer connected to the computer.

4. Display and Operation

The LED screen displays the measurements being measured and pulse strength. LCD displays three types of interface; monitoring, system setup and trend waveform, operated by six buttons on the front panel. For button details, please refer to figure 2-1 and table 2-1.

4.1 Power-on and Power-off

Press the power button for 3 seconds to turn the monitor on. The green LED on the front panel lights up. The LED and LCD screen display. To turn the monitor off, press the power button.

Note:

The monitor is powered by the built-in rechargeable battery or external AC power supply. When battery powered, the monitor may not turn on if the charge is low. When this occurs the monitor must be connected to the external power supply to charge the battery. The monitor will operate from the battery when it is fully charged. The monitor can also operate on the external power supply while the battery is charged automatically.

If the SpO2 sensor and the TEMP cable become disconnected, or the TEMP cable becomes disconnected and the SpO2 sensor is connected, but the finger moves away from the sensor, the monitor will automatically enter the standby mode. Under this mode, when the SpO2 sensor is connected and a finger is inserted into the sensor, or the TEMP cable is connected, the monitor will automatically resume the operation mode. Otherwise the monitor will shut down automatically in 3 minutes.

4.2 Change Display

The LCD displays the monitoring screen when the monitor is on. Under this display, press the menu button once to change to the setup screen, when this displays, press the menu button once to change to the trend screen. When the trend screen is displayed, press the menu button once to revert back to the monitoring screen. The menu button changes the screen type cyclically in the above sequence to find the required screen.

4.3 Monitoring Screen

4.3.1 Non-Parameter Screen

As described in section 4.1, when the monitor enters the standby mode and no parameter needs to be measured, the LCD screen displays status and system information only. A face symbol is displayed on the screen instead of measurements. Figure 4-4.

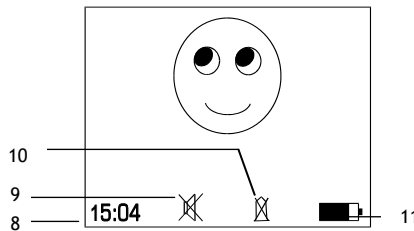






Figure 4-4 Non-parameter screen

4.3.2 Waveform/Parameter Screen Display

The waveform/parameter screen displays PLETH waveform and parameter measurements. Whether the SpO2 sensor and the TEMP (V450T) cable are connected or not, the waveform/parameter screen displays the measurements of SpO2, PR, TEMP (V450T) and PLETH.

4.3.3 Description of Displayed Information

Table 4-1 Description of displayed information on the monitoring screen

No.	Description	Remarks
1	SpO2 measurement	Displays SpO2 value and refreshes every second.
2	%	Unit of SpO2, it prompts SpO2 value on its left-hand side.
3	PR measurement	Displays PR value and is refreshed every second.
4	BPM	Unit of PR and prompts PR value on left-hand side.
5	TEMP measurement	Displays TEMP value and is refreshed every second.
6	°C	Unit of TEMP and prompts TEMP value on its left side.
7	Pulse strength	Displays up to 10 segments to indicate real-time pulse strength.
8	Clock	Displays real-time system time.
9	Pulse sound	 : ON ;  : OFF. Refer to section 4.4 for pulse sound setup.
10	Alarm sound	 : ON ;  : OFF. Refer to section 4.4 for alarm sound
11	Battery capacity	Displays the remaining battery capacity which has four grades, detected every second.
12	PLETH	Displays PLETH waveform in real-time and screen refresh mode.

4.3.4 Button Operation

The three multifunction buttons, Left arrow/Contrast, Right arrow/Backlight, and Down arrow/Mute, adjust the functions on the monitoring screen.

Contrast button

When pressed continually, the LCD contrast will increase cyclically.

Backlight button

When pressed, the LCD backlight will turn on or off.

Mute button

Mute is the main switch of the speaker. No matter what level the pulse sound is and whether every parameter alarm is switched on or off, when it is pressed, pulse and alarm sounds become totally silent.

Note:

If the monitor is powered by 1.5v AA batteries, it is recommended to use the parameters monitoring screen, switch off the backlight and mute the monitor, to save energy.

4.3.5 Alarm Function

When a parameter's measurement exceeds its alarm limit, the monitor can give audio and visual alarms simultaneously. The speaker sounds the alarm and the parameter's measurement flashes on the screen. If the speaker sound is turned off by pressing the Mute button or the parameter alarm switch is off, the parameter alarm will be silenced, but the parameter's measurement still flashes to prompt the alarm. Please refer to section 4.4 for parameter alarm switch setup.

The alarm sound has priority when the speaker is not mute. When an alarm switch is on, the speaker sounds the alarm but not the pulse sound. Only when there is no measurement exceeding its alarm limit or its alarm switch is off, the speaker sounds the pulse sound. The alarm and pulse sound can be heard no matter which screen is displayed.

The alarm sound icon on the waveform monitoring screen reflects the status of all alarm switches. When they are all set off or the speaker is silenced by pressing the Mute button, the icon shows the OFF status and no sound can be heard. Otherwise the icon shows the ON status and the alarm sound will be heard if any parameter's measurement exceeds its alarm limit.

4.4 System Setup Screen

The functions of the alarm limits setup, the system status setup and data management are performed on the LCD setup screen.

4.4.1 Screen Display

The setup items and values are listed in a table on the system setup screen. Figure 4-6.

	UPPER	LOWER	ON/OFF
SPO2	99	92	ON
PR	120	50	ON
TEMP	39.5	34.5	OFF
PULSE	SOUND: 2		
DATA	OUT: READY		
STORAGE:	CLEAR		
2006.09.30 10.38			

*Figure 4-6
System setup screen*

4.4.2 Description of Displayed Information

The meanings of the words and the ranges of the values in figure 4-6 are listed in table 4-2.

Table 4-2 Description of displayed information on the system setup screen

	Upper limit	Lower limit	Alarm switch		
SpO2	85 ~ 100	85 ~ 100	ON or OFF		
PR	40 ~ 250	40 ~ 250	ON or OFF		
TEMP	30.0 ~ 45.0	30.0 ~ 45.0	ON or OFF		
Pulse sound	0-2. Pulse sound has three levels. 0 means the pulse sound is silenced and the icon of the pulse sound on the monitoring screen shows OFF status, as shown in table 4-1.				
Data output	READY or WAIT.				
Data storage area	CLEAR or WAIT.				
	Year 06 ~ 30	Month 01 ~ 12	Day 01 ~ 31	Hour 00 ~ 23	Minute 00 ~ 59

4.4.3 Button Operation of System Setup

The four buttons; Left arrow/Contrast button, Right arrow/Backlight, Up and Down arrows/Mute button, act as arrow buttons on the system setup screen.

Left arrow and Right arrow buttons

The cursor is indicated by a small black square. It moves left when the Left arrow is pressed and right when the Right arrow is pressed. The cursor moves to the items to be set up and the item is inversely displayed.

Up arrow button

When the cursor is on the positions of alarm limit values, pulse sound level or date and time, these values increase if the Up arrow button is pressed. If these values reach the maximum, they will return to the minimum cyclically. When the cursor is on the alarm switch positions, the alarm switch will change between the ON/OFF status if the Up arrow button is pressed. The Up arrow button is invalid when the cursor is on the DATA OUT and STORAGE items positions.

Down arrow button

When the cursor is positioned on alarm limit values, pulse sound level or date and time, their values will decrease if the down arrow button is pressed. If these values reach the minimum, they will return to the maximum cyclically. When the cursor is positioned over the alarm switch, the alarm switch will change between the ON/OFF status if the Down arrow button is pressed. When the cursor is positioned over DATA OUT or STORAGE items and the Down arrow button is pressed, the relevant function is determined to be carried out. WAIT is displayed instead of READY or CLEAR the data process will take a time. All buttons are invalid during this period. The WAIT will be replaced by READY or CLEAR, after the process is finished.

Note:

Avoid adjusting system date and time randomly. Incorrect time saved interrupts the continuity of the trend time. The date or time should only be adjusted when it is inaccurate and should only be changed just after the monitor is powered on.

The set-up of alarm limits is very important when monitoring. Avoid too high, upper limits or too low, lower limits. For example PR upper alarm limit should not be 20 bpm more than the patient's actual PR.

4.5 Trend Waveform Screen Display

The monitor saves parameter measurements every 2 seconds. The storage area can store 36 hours trend data and the new data will replace older versions automatically after 36 hours. Saved data will never be lost even if the monitor is turned off. They can be displayed and observed on the trend screen.

4.5.1 Screen Display

When the LCD appears the trend screen due to the menu button is pressed on the other screen, the monitor draws the parameter trend waveforms on the time-measurement coordinate series. One screen can only display 3 hours data which is defined as a page. The whole storage area is composed of 12 pages. The trend waveforms of one page data is shown in figure 4-7.

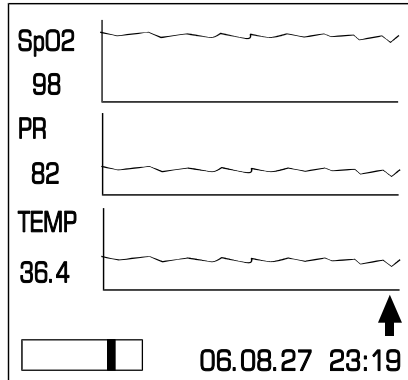


Figure 4-7 Trend waveform screen

4.5.2 Description of Information Displayed

Table 4-3 Description of displayed information on the trend waveform screen

No.	Description	Remarks
(1)	SpO2	The abbreviation of arterial oxygen saturation. It prompts the name of the trend waveform on its right side and the measurement below it.
(2)	SpO2 measurement	SpO2 measurement saved at the moment indicated by the time indicator.
(3)	PR	The abbreviation of pulse rate. It prompts the name of the trend waveform to its right and the measurement below it.
(4)	PR measurement	PR measurement saved at the moment indicated by the time indicator.
(5)	TEMP (V450T)	Abbreviation of temperature. It prompts the name of the trend waveform on its right and the measurement below it.
(6)	TEMP (V450T) measurement	TEMP measurement saved at the moment indicated by the time indicator.
(7)	SpO2 waveform	SpO2 trend waveform drawn dot by dot with the data saved in the data storage area.
(8)	PR waveform	PR trend waveform drawn dot by dot with the data saved in the data storage area.
(9)	TEMP waveform	TEMP trend waveform drawn dot by dot with the data saved in the data storage area.
(10)	Time indicator	The scale indicator of the horizontal axis and the unit indicator of the storage area.
(11)	Date and time	Shows the moment indicated by the time indicator.
(12)	Storage area ruler	Shows the total size of the trend data storage area.
(13)	Page indicator	The trend waveforms data on one screen (time period of 3 hours) is defined as a page, which corresponds to 90 units of the storage area. The page indicator points out the position of this data segment of the page.
(14)	Vertical axis	The parameter measurement axis. It is divided into 3 segments; SpO2 axis, PR axis and TEMP axis from top to bottom. The terms on its left side mark the names of these three axis.
(15)	Horizontal axis	The time axis. Its minimum scale is 2 seconds and whole length is 3 hours. The current moment is to the far right and time moves forward in the left direction.

Note:

Time is needed to obtain accurate measurements. When the monitor is powered on or the sensors are connected, the trend data may not be accurate due to the transition period. The measurements in this period cannot be used as diagnostic basis.

When the time indicator points to the time period without monitoring, the measurement displays and corresponding times are blank because nothing is saved.

4.5.3 Button Operation in Trend Waveform Screen

The four buttons, Left arrow/Contrast button, Right arrow/Backlight, Up arrow and Down arrow/Mute act as arrow buttons on the system setup screen.

Left and Right arrow buttons

These are used to move the time indicator scale by scale along the horizontal axis. The time indicator moves left one scale when the Left arrow is pressed and moves right one scale when the Right arrow is pressed. The Left arrow button is invalid when the time indicator is at the left end and the Right arrow button is invalid when the time indicator is at the right end. The time indicator can point to the data within one page and cannot move pages in the storage area.

Up and down arrow buttons

These are used to move the time indicator rapidly in a step of 8 scales along the horizontal axis. When the time indicator is at the left end, pressing the Up arrow button once triggers the page indicator of the storage area to move left once. When the time indicator is at the right end, pressing the Down arrow button once triggers the page indicator to move right once. The present trend waveforms are cleared and new trend waveforms drawn with the new page data displayed on the screen. The time indicator resets to the right end of the horizontal axis and points to the data at the nearest time on the page. Page movement is carried out cyclically. When the page indicator reaches the left end of the storage area, moving it left again will make it become the first right end page automatically. When the page indicator reaches the right end of the storage area, moving it right again will make it become the first left end page automatically.

Note:

When the time indicator is moved up and down quickly using the button, the time indicator will reach one end of the horizontal axis, it may be in a step less than 8 scales.

5. SpO₂ Monitoring

5.1 Measurement Principle

SpO₂ plethysmogram measurement is used to determine the oxygen saturation of haemoglobin in the arterial blood. The SpO₂/PLETH parameter can also provide a pulse rate signal, pulse strength and a plethysmogram wave.

How the SpO₂ / PLETH Parameter Works

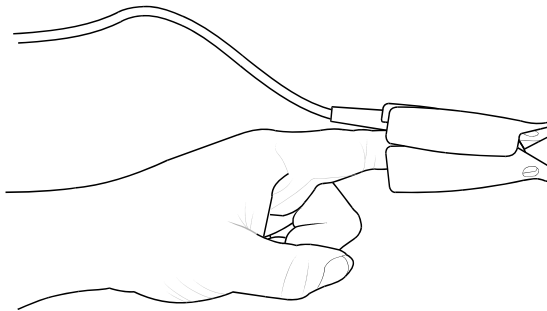
- Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different spectra absorption of haemoglobin and oxyhaemoglobin (called spectrophotometer principle). It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or a toe), to a receiver on the other side.
- The sensor measurement wavelengths are nominally 660nm for the Red LED and 940nm for Infrared LED. Maximum optical power output for LED is 4 mW.
- The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform, pulse rate signal and pulse strength.
- The SpO₂ value, PR value, pulse strength and the PLETH waveform can be displayed on the main screen.
- SpO₂ is a non-invasive measurement of the functional oxygen saturation.

5.2 SpO2 Measurement

Sensor selection for SpO2 measurement depends on the patient's age. For adult, you should choose an adult finger sensor; for a child, you can choose a child hand or toe sensor. The finger SpO2 sensor is a finger clip consisting of two parts. The LEDs are placed in one part and the photodetector is placed in another part.

Please follow these steps and figure 5-1 below to use the adult finger SpO2 sensor:

- Insert the sensor to the SpO2 socket .
- Turn on the monitor. The LED screen will display the parameter monitoring screen and LCD screen display the waveform.
- Attach the sensor to an appropriate site on the patient's finger.
- The measurements will be displayed on the LED screen and the waveform on the LCD screen a minute later.



*Figure 5-1
Placing the adult SpO2 sensor*

Note:

Ensure the SpO2 sensor is placed on the finger correctly. The LED part of the sensor should be to the back of the patient hand and the photodetector part to the inside. Make sure you insert the finger to a suitable depth into the sensor so that 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.

5.3 Measurement Limitations

If the accuracy of any measurement does not seem correct, first check the patient's vital signs by an alternate method. Then check the instrument for correct functioning.

Inaccurate measurements may be caused by:

- Incorrect sensor application or use;
- High-frequency electrical noise, such as noise from electrosurgical apparatus connected to the system;
- Significant levels of dysfunctional haemoglobins (e.g. carboxyhaemoglobin or methemoglobin);
- Significant concentrations of dysfunctional haemoglobin, such as carboxyhaemoglobin and 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 movement;
- Venous pulsations;
- SpO₂ is too low;
- Improper sensor installation or incorrect contact position with the patient;
- 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 SpO₂ sensor attached;
- The patient has hypotension, severe vasoconstriction, severe anaemia, or hypothermia;
- There is arterial occlusion close to the sensor;
- The patient is in cardiac arrest or in shock.

5.4 Precautions

Note:

Do not perform SpO₂ monitoring and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO₂ value.

Warning:

- Check if the sensor cable is in normal condition before monitoring. Do not use the SpO₂ sensor once the package or the sensor is found damaged.
- Remove the SpO₂ sensor from the patient after measurement.
- As with all medical equipment, carefully position cabling to reduce the possibility of patient injury. Cables of electrical surgical equipment should not be wound around the SpO₂ sensor.
- Do not put the sensor on extremities with the arterial catheter or venous syringe.
- If no pulse is found or the reading is unreasonable, first check the patient's condition, and then check the sensor installation and connection with the monitor, finally ask the qualified engineer to check the device and the SpO₂ sensor to ensure proper working order.
- Do not use the monitor to measure patients whose pulse rate is lower than 30bpm, this may cause incorrect results.
- Prolonged and continuous monitoring may increase a change in dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is important to check the sensor more frequently with a child and patient with poor perfusion or immature dermographia by light collimation and positioning correctly according to changes of the skin. Check the sensor placement every 2-3 hours and move it when the skin deteriorates.
- 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.
- Please use the SpO₂ sensor supplied by the monitor or confined to be used by the monitor.
- When used on different patients, the monitor is prone to cross contamination, which should be prevented and controlled by the user. Disinfection is recommended before using the SpO₂ sensor on other patients.

Caution:

SpO₂ sensors are fragile. Avoid from pressure and knocks. Hold the probe and cable carefully. If not in use, coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.

6. TEMP Monitoring (V450T)

6.1 Measurement Principle

The device measures temperature of the body surface by using the thermal-sensitive resistor, located in the temperature probe, the impedance varies with the body temperature. The monitor measures the impedance of the resistor and then consults a resistance-temperature table, previously stored in the device. The current temperature is found in the table and displayed on the LED screen.

The monitor has only one TEMP measurement channel for measuring the body surface temperature of the patient.

6.2 TEMP Measurement

The monitor uses a body surface TEMP probe to measure the patient's body temperature. Disposable or reusable probes can be selected. Please follow the steps below to use the body surface TEMP probe:

- Insert the probe's connector to the monitor's TEMP socket;
- Attach the probe to an appropriate site on the patient's body;
- Turn on the monitor. The LED screen will display the parameter monitoring screen and LCD displays the waveform;
- Wait until the measurement does not change frequently, the stable readings will be displayed on the LED screen.

Note:

Because there is an isolation package outside the thermal-sensitive resistor in the temperature sensor, the impedance varies slowly with the temperature of the body. Therefore an accurate result of temperature measurement is usually obtained after monitoring for more than 5 minutes.

6.3 Precautions

Warning:

- Check if the probe cable is in a safe condition before monitoring. Do not use the TEMP probe if the package or the probe is found damaged.
- Remove the TEMP probe from the patient after measurement.
- As with any medical equipment, carefully route patient cabling to reduce the possibility of patient injury. Cables of electrical surgical equipment should not be wound around the TEMP probe.
- If the reading appears inaccurate, first check the patient's condition, and then check the probe installation and connection with the monitor, finally ask the qualified engineer to check the device and the SpO2 sensor to ensure correct working order.
- Do not reuse disposable TEMP probes.
- When used on different patients the monitor is prone to cross contamination. This should be controlled by the user. Disinfection of the TEMP probe is recommended before using on other patients.

Caution:

Hold the probe and cable carefully and lightly. When not in use, coil up the probe and cable into a loose circle. If the wire inside the cable is pulled tight, it may cause mechanical damage to the probe and the cable.

7. Maintenance

7.1 System Check

7.1.1 Check before Using

Before using the monitor:

- Check if there is any mechanical damage;
- Check outer cables and accessories are in good condition;
- Check if all the monitoring functions work correctly to ensure that the monitor is in proper working order.

In the case of any damage, abnormal function, hidden safety danger or exception, do not use the monitor on the patient.

7.1.2 Routine Check

Ensure qualified service personnel have implemented a complete inspection, including the functional safety check, after the monitor has been used for 6-12 consecutive months, or after monitor servicing or system upgrading. This is to ensure the normal operation of the system.

Store the device with a fully charged battery and charge the battery of the device every 3 months if the device is left unused for a long time.

Warning:

Failure to carry out a satisfactory maintenance schedule may cause equipment failure and possible health hazard.

Safety inspection or maintenance, which requires opening the monitor housing, must be carried out by trained and authorized personnel only. Failure to comply may cause equipment failure and a health hazard.

7.2 General Cleaning

Equipment should be kept clean by cleaning on a regular basis. When polluted by dust, oil, sweat or blood etc. it should be cleaned immediately. Before cleaning the equipment, consult your hospital's regulations for cleaning, disinfecting and sterilizing equipment.

The exterior surfaces of the equipment may be cleaned gently with a clean and soft cloth, sponge or cotton swap, dampened with a non-erosive cleaning solution. Drying off excess cleaning solution before cleaning the equipment is recommended.

Warning:

Power off the monitor and stop charging the battery before cleaning.

Warning:

Use only the cleaning solutions described above for general cleaning. DARAY cannot be held responsible for the effectiveness of the user's infection control. Please consult your hospital's infection controllers or professionals.

Examples of cleaning solutions:

- Diluted soap water
- Diluted formaldehyde (35%-37%)
- Diluted ammonia water
- Hydrogen peroxide (3%)
- Alcohol
- Ethanol (70%)
- Isopropanol (70%)
- Diluted sodium hypochlorite solution (bleaching agent)

Note:

Sodium hypochlorite solution with a concentration of 500ppm (1:100 diluted bleach solution) - 5000ppm (1:10 diluted bleach solution) is very effective. The amount of ppm depends on how much organic matter exists on the surface.

Caution:

- Do not use strong solvent, such as acetone.
- ALWAYS dilute the solutions according to the manufacturer's recommendations.
- NEVER use abrasive, erosive cleaners, or cleaners containing acetone.
- NEVER permit fluids to run into the casing, switches, connectors, or any ventilation openings in the equipment.
- NEVER submerge the equipment into water or any cleaning solution, or pour or spray water or cleaning solution on the equipment.
- ALWAYS wipe off the cleaning solution with a dry cloth after cleaning and dry the monitor naturally in the air. Never dry the monitor in strong sunlight or high temperature.
- If the monitor is polluted by chemical substance, the users should handle it correctly according to the properties of the chemical substance.
- The probes and cables may be cleaned with a clean soft cloth, sponge or cotton swap, dampened with ethanol.
- NEVER permit fluids to run into the probes and cables. NEVER submerge the probes and cables into any liquid.
- For more cleaning information of accessories, refer to the instructions for use of the accessories.

7.3 Disinfection

Disinfection may cause damage to the equipment. We recommend disinfecting is carried out according to the hospital's schedule only when necessary. The equipment should be cleaned prior to disinfection.

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

The probe cables may be disinfected with hydrogen peroxide (3%) or isopropanol (70%). Active reagents are also effective. The connectors cannot be submerged into the above solutions.

Note:

- ALWAYS dilute the solutions according to the manufacturer's suggestions and use a lower concentration if possible.
- NEVER submerge the equipment into water or any solution, or pour water or any solution on the equipment.
- ALWAYS wipe off excess liquids from equipment surfaces and accessories with a dry cloth.
- Never use EtO and formaldehyde to disinfect.
- Never permit high-pressure or high-temperature disinfection of the equipment and accessories.

Warning:

Disinfection may cause damage to the equipment; therefore, when preparing to disinfect the equipment, consult your hospital's infection controllers or professionals.

7.4 Disposal

To avoid contamination or infection to personnel, environment or equipment, ensure 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 the SpO2 sensor and TEMP probe, follow local regulations regarding disposal of hospital waste.

8. SpO2/TEMP Patient Monitor Data Viewer

8.1 STDV Software and its Function

SpO2/TEMP Patient Monitor Data Viewer (SPDV software) is supplied with the monitor. In conjunction with the internal software of the monitor, it has the following functions:

- Download data
- Displaying and previewing data of SpO2, PR and TEMP
- Saving patient data
- Printing patient data

8.2 Download

1. Download the STDV software from the internet or use the STDV disk to install it in your computer, and then open it.
2. Press the “download” to download the data.
3. Connect the computer and monitor by the cable.
4. Switch on the monitor and change to the setup interface, using the right button to “ready”.
5. Press the “start” on the computer to begin download.
6. Press the down arrow button, then the data will be transmitted to the computer.

Note:

Downloading and installation may vary with different operation systems.

9. Packing List and Accessories

Standard Packing List	
SpO2/TEMP patient monitor main unit	1 pc
Adult finger SpO2 sensor	1 pc
TEMP probe (V450T)	1 pc
AC power adaptor	1 pc
Communication cable	1 pc
Operation manual	1 pc
Optional Accessory	
Child finger/toe SpO2 sensor	1 pc

Caution:

Using other accessories may cause damage to the device.

Appendix A Specifications

General

Monitoring Parameters

SpO2

PR

PLETH

Pulse strength

TEMP (V450T)

Connections

SpO2 socket

PR socket

TEMP socket (V450T)

Adaptor socket

PC communication socket

Display screen

Type: 128×64 dot matrix homochromy LCD and Dual-colour LED (red/green)

LCD Display area: 45mm×31mm

LED Display area: 37mm×59mm

LED: Dual-colour LED (red/green) and homochromy LED

Size: 120mm×63mm×32mm

Weight: 300g (does not include probes and adaptor)

Electrical specifications

Working Voltage: 6.0V DC ~ 9.0V DC

AC power adaptor

Input: 100-240VAC, 50/60Hz, 0.7A

Output: 5V DC, 3A

Internal battery

Type: 1.5Ahr/8.4V Li rechargeable battery

Run Time: 15-hour continuous operation with a new, fully charged battery (ambient temperature is 25°C).

Recharge time: 5 hours

Standard 1.5v Batteries

Type: Five pieces of standard 1.5v AA battery or rechargeable battery

Run Time: 7-hour continuous operation with a new battery

(ambient temperature is 25°C).

Environment

Temperature

Operation: 0 °C ~ 45 °C

Transportation and storage: -20 °C ~ 60 °C

Humidity

Operation: 15% - 95% (non-condensing)

Transportation and storage: 10% - 95% (non-condensing)

Altitude

Operation: 86 KPa ~ 106 KPa

Transportation and storage: 50KPa-106 KPa

Parameter Specifications

SpO2

Patient: Adult, child and neonate

Range: 35% - 100%

Resolution: 1%

Accuracy: 70% - 99%: $\pm 2\%$

0% - 69%: Unspecified

PR

Range: 30 bpm ~ 250bpm

Resolution: 1bpm

Accuracy: ± 2 bpm

TEMP (V450T)

Channel: 1

Input: Body surface thermal-sensitive resistor temperature sensor

Range: 0 °C ~ 50 °C

Resolution: 0.1 °C

Accuracy: ± 0.2 °C

Appendix B Units, Symbols and Terms

Table B-1 Units

Unit	Meaning
A	ampere
bpm	beats per minute
°C	centigrade
g	gram
kHz	kilohertz
MHz	megahertz
GHz	Gigahertz
Hz	hertz
k	kilo
kg	kilogram
KPa	kilopascal
m	meter, minute
M	mega
min	minute
mm	millimetres
ms	millisecond
mW	milliwatt
s	second
nm	nanometre
ppm	part per million
V	volt
µA	microampere

Table B-2 Symbols

Symbol	Meaning	Symbol	Meaning
-	minus	<	less than
%	percent	=	equal to
/	per, divide	>	greater than
~	to	±	plus or minus
+	plus	x	multiply

Table B-3 Terms

Abbreviation	Meaning	Abbreviation	Meaning
AC	Alternating current	PC	Personal Computer
D.C.	Direct current	PR	Pulse Rate
ICU	Intensive care unit	PLETH	Plethysmogram
LCD	Liquid Crystal Display	SpO2	Arterial Oxygen Saturation from Pulse Oximeter
LED	Light Emitting Diode	TEMP	Temperature

Returns Policy

IMPORTANT!

Before returning your item, you must call us on 0844 375 9000

We want you to be completely satisfied with your purchase. If you need to return goods purchased from DARAY Ltd, please read the following information carefully.

The DARAY Ltd returns policy provides guidance on when you can return goods we have supplied, and what you can expect from us once you do. To see our detailed returns policy and procedure visit www.daray.co.uk/returns

TYPE OF RETURN	REMEDY
DAMAGED GOODS OR DOA* Goods which are physically damaged on delivery, or which do not function.	We must be notified within 24 hours of receipt.
GOODS DEVELOPING A FAULT Goods which have developed a fault within the warranty period.	Within 14 days of delivery we will replace the item as DOA*. If the fault develops after 14 days, but within the warranty period, we will initiate the returns procedure.
NON WARRANTY Goods which have developed a fault outside the warranty period.	If a fault develops outside the warranty period, we will initiate the returns procedure.
OTHER Any situation which is not covered by the above.	We will try to help, but we cannot normally offer a refund.

*DOA - dead on arrival

For additional clarification, please refer to our terms and conditions at www.daray.co.uk/terms.

In a small number of cases, we may determine that a replacement would not work any better than the original product we supplied. In such cases we will only offer a refund rather than a replacement for qualifying returns.

Replacement bulbs are not eligible for returns, unless they are faulty or damaged.

Spare parts ordered on our website or from supplied part codes are not be eligible for credit. We will accept returns and exchange for the correct item.

If you purchase an item incorrectly you can return it within 14 days and it can be exchanged for another product of equal or high value, excluding transportation charges incurred.

If you send us goods that do not qualify for return, you will invalidate your claim to any refund, and you will be obliged to compensate DARAY Ltd for the cost of return postage and any other reasonable costs incurred processing the goods.

Your statutory rights are not affected.

WARRANTY

TERMS AND CONDITIONS OF WARRANTY

1. To qualify for this warranty you must register on www.daray.co.uk or return to DARAY Ltd (DARAY) the duly completed warranty-registration form accompanying the product.
2. DARAY warrants this product (excluding lamp) against faulty material and workmanship during the period of the warranty. The period of warranty is the period stated on your warranty card and commences on the date of purchase of the product. In the event that the product is not in good working order DARAY will provide, during the warranty period, a free repair service within the United Kingdom. The warranty is subject to proof of purchase being provided; therefore, you should retain your original receipt.
 - 2.1 The repair service consists of the provision of spare parts and/or replacement products (at DARAY's discretion) which will be provided on an exchange basis and will either be new, equivalent to new or reconditioned. All replaced spare parts and products shall become the property of DARAY.
 - 2.2 DARAY's only obligation under this warranty is the provision of the service as set out above.
 - 2.3 All products are returned to DARAY at the customer's cost and risk. Products to be returned should be adequately packed. For the address to send returns to please visit www.daray.co.uk
3. DARAY's arrangements for providing service provided under this warranty may include the use of sub-contractors.
4. This warranty does not cover damage or defects in the Product caused by or resulting from:
 - Wilful neglect or negligence by anyone other than DARAY;
 - Improper use, storage or handling of the product;
 - Use of non-DARAY approved parts (such as replacement lamps) not compatible with the Product;
 - Fire, accident or disaster;
 - Use of non-DARAY modifications other than in accordance with DARAY's instructions;Attachment of fittings and accessories not approved by DARAY;
Repairs, modifications carried out by service personnel not approved by DARAY;
 - Damage caused by chemical corrosion from cleaning agents not approved by DARAY.
 - Failure to use or install the product in accordance with the manufacturer's instructions.
5. Nothing in this warranty shall have the effect of restricting or excluding the liability of DARAY in respect of:
 - a) Death and personal injury caused by the negligence of DARAY, or for fraud;
 - b) Under the Consumer Protection Act 1987 to a person who has suffered damage caused by a defective product or to a dependant or relative of such a person;
 - c) Direct damage to your property caused by the proven negligence of DARAY.
6. This agreement does not give any rights other than those expressly set out above and in particular, DARAY will not be responsible for any loss of income, profits or contracts or any direct or indirect consequential loss, damage caused to or suffered by the purchaser as a direct result of this agreement.
7. This warranty is offered (subject to these terms and conditions) in addition to, and does not affect your statutory rights.
8. DARAY may disclose your details and other personal information to companies within the DARAY group including any subsidiary company or sub contractor of DARAY for the purposes of performing our obligations hereunder.
9. You must not resell outside the UK any products supplied by DARAY and covered by the Export of Goods (Control) Order 1992 (or any law that replaces it) without obtaining all necessary licences. You also agree not to sell the product in the UK if you know or think that the person buying the product intends to export it without getting the necessary licences. You agree to impose similar conditions to these on anyone you sell the product to.
10. These conditions shall in all respect be governed and construed in accordance with English law and the exclusive jurisdiction of the English courts.

DARAY[®] HEALTHCARE PRODUCTS

WARRANTY REGISTRATION
TO VALIDATE YOUR WARRANTY
PLEASE COMPLETE IN BLOCK CAPITALS
AND RETURN IN A WINDOWED DL ENVELOPE
TO OUR FREEPOST ADDRESS

ALTERNATIVELY REGISTER ONLINE AT WWW.DARAY.COM



1 YEAR WARRANTY

NAME:	
COMPANY:	
EMAIL:	
PHONE:	
FAX:	

ADDRESS:

--

PURCHASED FROM:

--

DATE OF PURCHASE:

--

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HEALTHCARE PRODUCTS

ILLUMIN[™]The logo for ILLUMIN features the word "ILLUMIN" in blue, followed by a stylized "S" shape in purple and pink that loops around the end of the word. A small "TM" trademark symbol is positioned above the "S".

MEDISYS[®]

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LifeSignZ[™]

BioSignZ[™]

NfuZe[™]

VetZ[™]

The BioProtect logo features a stylized graphic of a blue and white sphere with a purple arc above it, resembling a protective shield or a globe. To the right of this graphic is the word "BioProtect" in blue, with "Antimicrobial protection" in purple below it. A "TM" trademark symbol is located to the upper right of "BioProtect".
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