

DARAY[®]

HEALTHCARE PRODUCTS



V402+

HANDHELD PULSE OXIMETER & TEMP MONITOR OPERATING MANUAL

GAM.V402+.1009.4

DARAY[®]

HEALTHCARE PRODUCTS

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1. SAFETY

This manual provides the instructions necessary to operate the V402+ SpO2/TEMP patient monitor in accordance with its function and intended use.

NOTE

Adherence to this manual is a requirement for proper performance and correct operation of the V402, and ensures patient and operator safety.

This manual is an integral part of and should always be kept close to the monitor, so that it can be to hand when necessary.

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

Statement

The manufacturer is responsible for safety, reliability and performance of this product only in the condition that:

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

The safety statements presented in this chapter refer to the basic safety information that the operator of the monitor 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.

The following safety terms warning and caution are used throughout this manual to point out hazards and to designate a degree or level of seriousness.

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 product/property damage.

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

1.1 Warnings

- The monitor is intended only as an addition to patient assessment. It must be used in conjunction with clinical signs and symptoms. It is not intended as a device used for treatment purposes.
- The monitor is intended for use only by qualified clinical physicians or well-trained nurses.
- To ensure patient safety, verify this device and accessories can function safely and normally before use.
- When using the monitor together with electrical surgery equipment, the user should pay attention to and guarantee safety of the patient being measured.
- EXPLOSION HAZARD: Do not use the monitor in the presence of flammable anaesthetics, explosive substances, vapours or liquids.
- Do not pull or lift the monitor by its cables. It could lead to falling and consequent patient injury.
- It is not recommended to hang the monitor when transporting patients. Safety hazards may arise from the swinging monitor during the transportation.
- Do not use the monitor and its transducer during MRI (Magnetic Resonance Imaging) scanning because induced currents could potentially cause burns. The monitor can interfere with the proper performance of MRI, and MRI is can interfere with the measurement accuracy of the monitor.
- The monitor and its accessories may be contaminated by micro-organism during transporting, use and storage. Use the recommended methods to sterilise and disinfect the monitor or its accessories when the packing material is damaged, or if it has not been used for a long time.

1.2 Cautions

- The monitor is not a fully sealed device. Keep its surface dry and clean, and prevent any liquid from infiltrating it.
- The device should be positioned appropriately. Keep it from falling, strong vibration or other mechanical damage.
- Do not use mobile phones near where the monitor is operating. Mobile phones may emit electromagnetic radiation which is capable of interfering with the proper performance of the monitor.
- The monitor should only be maintained by personnel approved by our company.
- Before using the monitor on patients, the user should be familiar with its operation.

IMPORTANT

Before use, carefully read this manual, all safety information and specifications.

The monitor is a non-invasive, handheld patient monitor. It operates on AC or rechargeable battery power supply. It is suitable for monitoring adult and child patients. It is widely used in the hospital's operation room, ICU, clinic section office, out-patient department, sickroom, emergency treatment, and the recovery and health care organisations, or in family nursing and in patient transportation.

Parameters measured by the monitor include: arterial oxygen saturation (SpO₂), pulse rate (PR), plethysmogram waveform (PLETH), pulse strength and temperature (TEMP). The monitor measures these parameters through a SpO₂ sensor and a TEMP sensor and displays them on the LCD screen.

The monitor is operated and controlled by the buttons on the front panel. It adopts a monochrome LCD screen in displaying measurements and waveforms, and a dual-colour LED in supplementary status indication. It is also capable of managing measured data and transmitting the patient's trend through the communication socket to a PC for display, observation, saving and printing.

Function structure.

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

2. FUNCTIONS

- The monitor has the following functions:
- Measuring: Intelligent display of SpO₂, PR, PLETH, pulse strength and TEMP.
- Prompting: battery capacity, speaker volume.
- Alarm: judgement of exceeding the limits, Audio and visual alarm.
- Power saving: automatic shutdown when no monitoring.
- Data Managing: data storage, data adding, data deletion, drawing trend waveforms with saved data.
- 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 by a special communication cable.

2.1 Appearance

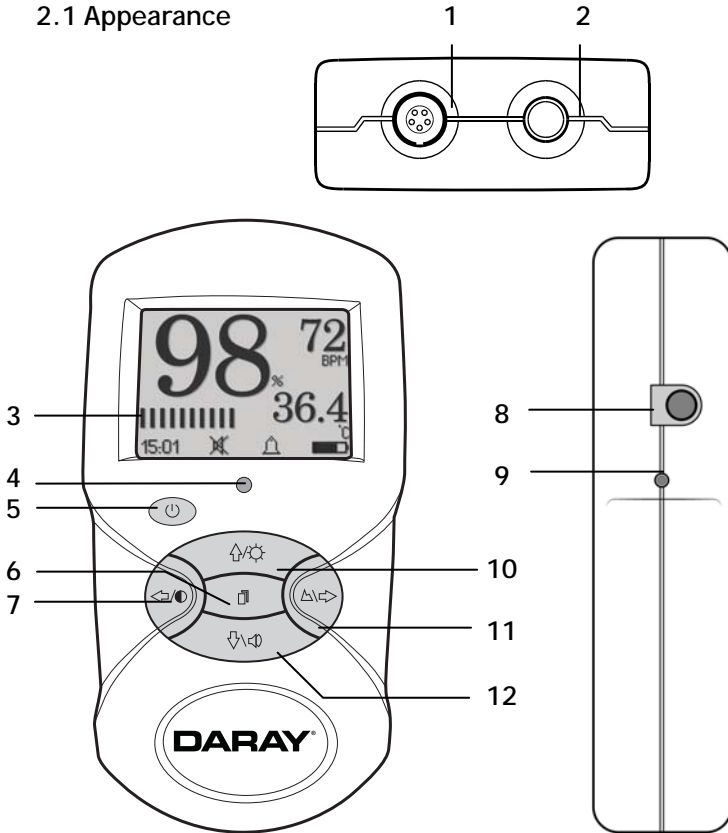


Fig 1

1	SpO2 sensor socket
2	TEMP prove socket
3	LCD display
4	Dual-colour LED: Green = power on. Red flashes with heartbeat
5	Power button
6	Menu button: changes display modes
7	Left arrow/contrast: Adjusts display contrast whilst monitoring or moves cursor left in setup or viewing trend graphs
8	AC power adapter socket
9	PC serial link connector socket
10	Up arrow/backlight: Turns backlight on/off whilst monitoring or moves cursor up in setup or viewing trend graphs
11	Right arrow/graph-view: Change display to graph-view whilst monitoring or moves cursor left in setup or viewing trend graphs
12	Down arrow/mute: Speaker on/off whilst monitoring or moves cursor down in setup or viewing trend graphs

3. INSTALLATION

3.1 Unpacking and Inspection

Please open the package and carefully remove the device and its accessories. Check all materials against the packing list.

- Check the monitor for any mechanical damage.
- Check for damaged wires, sockets and accessories.

Contact supplier immediately if there is any problem.

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

3.2 Connect SpO2 sensor and TEMP Probe

You can connect the SpO2 sensor and TEMP probe to the monitor by simply inserting their connectors to the SpO2 socket on the monitor's top side panel as shown in Fig. 1(1,2).

3.3 Connect AC Power Adaptor

Plug the AC adaptor into the mains and. The adaptor's power indicator LED lights up. Insert the adaptor's connector to the adaptor socket on the monitor's right side as shown in Fig. 1(8).

WARNING: The AC power adaptor supplied is built to special requirements and should only be used with the monitor. Never use other adaptors else the device could be damaged and may result in patient injury.

3.4 Power-on

Press the power button and hold for more than 3 seconds to turn on the monitor. The green LED on the front panel lights up. The LCD screen displays the monitoring mode.

3.5 Computer Data Transfer

The monitor can be connected to a Personal Computer through the serial cable supplied, to transmit patient trend data to the computer for review and saving. The trend waveforms can then also be printed.

Connect the serial cable to the socket on the monitor's right side panel (see Fig 1.9) and the RS232 connector to the PC's serial port.

4. DISPLAY AND OPERATION

The monitor displays three main screens: the monitoring, system setup and trend graphs. The front panel controls operate the monitor on these screens. For more details, please see below and refer to Fig. 1.

4.1 Power On/Off

Press the power button and hold for more than 3 seconds to turn on the monitor. The green LED on the front panel lights up. When the monitor is on, press the power button to turn the monitor off.

NOTE

The monitor is powered either by the built-in rechargeable battery or external AC power supply. If not connected by the external AC power supply and the battery hasn't enough charge, the monitor may not turn on. If this happens, connect the external power supply to charge the battery. The monitor will operate on the battery again after the battery is fully charged. The battery charges automatically whilst connected to the external power supply.

If the SpO₂ sensor and the TEMP cable are disconnected, or if the TEMP cable becomes disconnected and the SpO₂ sensor stays connected but the finger is removed from the sensor, the monitor automatically enters standby mode. In this mode, when the SpO₂ sensor is reconnected and a finger is inserted into the sensor, or the TEMP cable is reconnected, the monitor automatically resumes operation; otherwise the monitor automatically shuts down in 3 minutes.

4.2 Change Display Modes

The LCD initially displays the monitoring screen when the monitor is turned on. When the monitoring screen is displayed, press the menu button once to change to the setup screen. When the setup screen is displayed, press menu button once to change to the trend graphs screen. When the trend graphs screen is displayed, press menu button once to return to the monitoring screen. The menu button repeatedly cycles between the three screen modes in the above sequence.

4.3 Monitoring Screen Display and Operation

The monitoring screen has two forms, parameter monitoring screen and waveform/parameter monitoring screen.

4.3.1 Parameter Screen Display

The LCD displays the parameter monitoring screen. Parameter screen displays measurements of the parameters. The monitor can identify which sensor is connected and then display the appropriate parameter screen automatically. There are four various parameter screens altogether.

SpO2/PR/TEMP Screen

If the SpO2 sensor and the TEMP cable are connected, the LCD screen displays the measurements of SpO2, PR, pulse strength and TEMP, status information and system information (see Fig. 2).

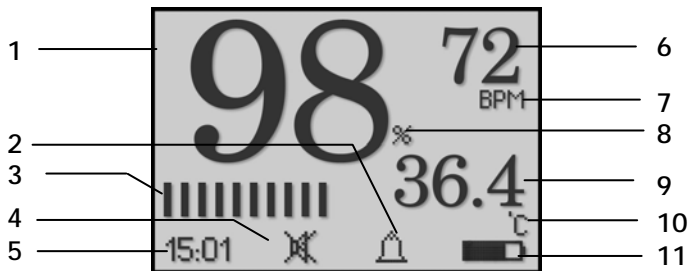


Fig. 2

SpO2 /PR Screen

If only the SpO2 sensor is connected to monitor a patient's SpO2, the LCD screen displays the measurements of SpO2, PR and pulse strength, status information and system information (see Fig. 3).

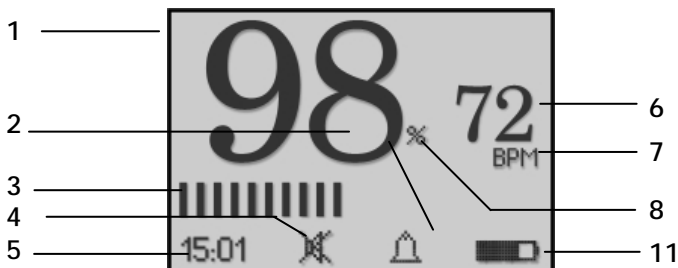


Fig. 3

TEMP Screen

If only the TEMP probe is connected to monitor a patient's TEMP, the LCD screen displays the TEMP measurement; status information and system information (see Fig. 4).

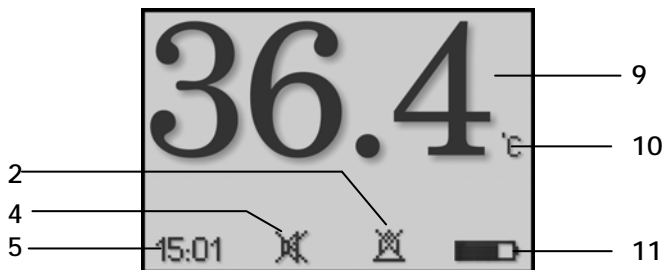


Fig. 4

Non-parameter Screen

As described in section 4.1, when the monitor enters standby mode and no parameter needs to be measured, the LCD screen only displays status information and system information and an animated 'smiley' is displayed (see Fig. 5).

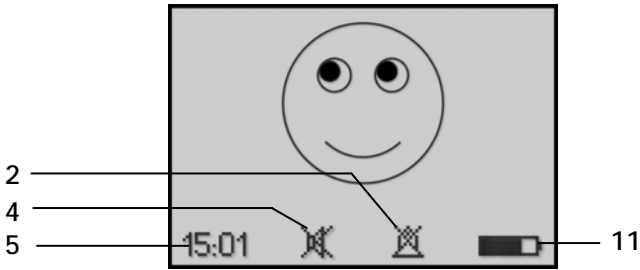


Fig.5

4.3.2 Waveform/parameter screen display

The waveform/parameter screen displays PLETH waveform and measurements of the parameters. (See Fig. 6).

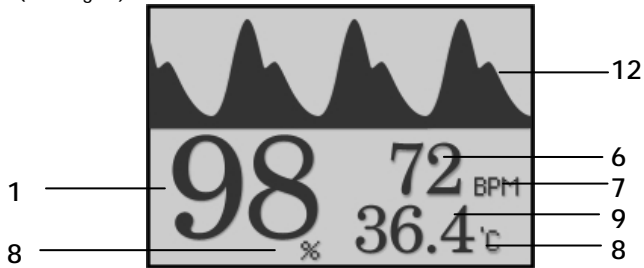


Fig. 6

No	Title	Description
1	SpO2	SpO2 value (refresh: 1/second)
2	Alarm audio	= ON = OFF
3	Pulse strength	Max. 10 segments
4	Pulse audio	= ON = OFF
5	Clock	Displays the current time
6	PR	PR value (refresh: 1/second)
7	BPM	PR unit
8	%	SpO2 unit
9	TEMP	TEMP value (refresh: 1/second)
10	°C	TEMP unit
11	Battery status	Four states indicating battery charge level
12	PLETH	PLETH waveform display (real-time)

Use this table as the key for Figs. 2-6

4.3.4 Button Operation

The four multifunction buttons, Left arrow/Contrast, Waveform/Right arrow, Up arrow/Backlight and Down arrow/Mute, adjust the monitor's functions on the monitoring screen.

Contrast Button

If it is pressed continually, the LCD contrast will increase cyclically.

Waveform Button

If it is pressed, the monitoring screen will switch between parameter screen and waveform screen.

Backlight Button

If it is pressed, the LCD backlight will be turned on or turned off.

Mute Button

It is a 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 sound and alarm sound become silence or audible totally.

4.3.5 Alarm Monitoring 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 set off, the parameter' alarm sound 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 top priority when the speaker is not mute. When there is a alarm whose switch is set on, the speaker sound the alarm sound but not the pulse sound. Only when there is no measurement exceeding its alarm limit or its alarm switch is set off, the speaker sound the pulse sound. The pulse is also indicated by the red colour LED on the front panel no matter whether the pulse sound can be heard. The alarm sound and the pulse sound can be heard no matter which screen is displayed.

The icon of the alarm sound on the 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 OFF status and no sound can be heard. Otherwise the icon shows ON status and the alarm sound will be heard if any parameter's measurement exceeds its alarm limit.

4.4 System Setup Screen Display and Operation

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

4.4.1 Screen Display

The setup items and values are listed in a table on the system setup screen, as shown in Fig. 7

	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 10:40			

Fig. 7

4.4.2 Description of Information Displayed

The meanings of the words and the ranges of the values in Fig. 7 are listed in table 4-2 as follows.

	Upper limit	Lower limit	Alarm	
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	
Alarm sound	0 - 2. Pulse sound has three levels. If set to 0, the alarm sound is silenced and the icon on the monitoring screen also shows OFF (🔇).			
Data output	READY or WAIT			
Data storage	CLEAR or WAIT			
Year 06 - 30	Month 01 - 12	Day 01 - 31	Hour 00 - 23	Minute 00 - 59

4.4.3 Button Operation

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

Left and Right Arrow Buttons

The cursor moves left when the left arrow is pressed and right when the right arrow is pressed. The cursor is indicated by a small black square. It moves to the item which is going to be set up and this item is highlighted.

Up arrow Button

Use the up arrow to increase the values of the alarm sound level or date and time to increase their values using the up arrow. When the values reach their maximum, they return to the minimum and start increasing again.

With the cursor on the alarm on/off positions, press the up button to toggle between ON and OFF.

The Up arrow button is inactive when the cursor is on the DATA OUT and STORAGE items.

Down arrow Button

Use the down arrow to decrease the values of the alarm limit values, alarm sound level or date and time. When the values reach their minimum, they return to the maximum and start decreasing again.

With the cursor on the alarm on/off positions, press the up button to toggle between ON and OFF.

When the Down arrow button is pressed with the cursor on the DATA OUT or STORAGE items, the relevant function is executed. WAIT is displayed instead of READY or CLEAR because the data process takes a short. All buttons are invalid during these processes. WAIT will be replaced by READY or CLEAR when the process is finished.

NOTE

- Incorrectly set time and date interrupts the continuity of the trend time. The date or time should only be adjusted when it is incorrect and should be done immediately after the monitor is powered on.
- Alarm limits setup is very important when monitoring. Avoid setting the upper limits too high or the lower limits too low. For example, the PR upper alarm limit should not be more than 20 bpm higher than the patient's actual PR.

4.5 Trend Waveform Screen Display and Operation

The monitor saves parameter measurements every 2 seconds. The storage area can store 36 hours trend data and the new data will overwrite the oldest data automatically after 36 hours. The saved data will never be lost even if the monitor is powered off. It can be viewed 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.

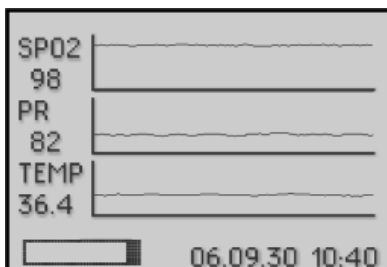


Fig. 8

4.5.2 Description of Information Displayed

No	Description	Remarks
1	SpO2	Arterial oxygen saturation.
2	SpO2 measurement	The current SpO2 measurement indicated by the time indicator.
3	PR	Pulse rate
4	PR measurement	The current PR measurement indicated by the time indicator.
5	TEMP	Temperature
6	TEMP measurement	The current TEMP measurement indicated by the time indicator.
7	SpO2 waveform	SpO2 trend waveform plot - data is stored in memory
8	PR waveform	PR trend waveform drawn plot - data is stored in memory
9	TEMP waveform	TEMP trend waveform drawn plot - data is stored in memory
10	Time indicator	It is the scale indicator of the horizontal axis and the unit indicator of the storage area.
11	Date and time	It shows the moment indicated by the time indicator.
12	Storage area ruler	It shows the total size of the trend data storage area.
13	Page indicator	The data forming one screen trend waveforms (time period of 3 hours) is defined as a page, which corresponding to 90 units of the storage area. The page indicator points out the position of this data segment of this page.
14	Vertical axis	It is the parameter measurement axis. It is divided into 3 segments which is SpO2 axis, PR axis and TEMP axis from top to bottom. The terms on its left side mark the names of these three axes.
15	Horizontal axis	It is the time axis. Its minimum scale is 2 seconds and whole length is 3 hours. The current moment is at the right end of it and time moves forward in the left direction.

NOTE

- Obtaining stable measurements always needs a period of time. When the monitor is powered on or the sensors are connected, the trend data may appear sudden change or transit because of the transition period. The measurements in this period can not be used as diagnostic basis.
- When time indicator points to the time period without monitoring, the displays of measurements and the corresponding times are blank because nothing is saved.

4.5.3 Button Operation

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

Left and Right Arrow Buttons

The left and right arrow buttons move the time indicator left and right in single steps but remains within the current page of data.

Up and Down Arrow Buttons

The up and down arrow buttons move the time indicator 8 steps at a time. When the time indicator is at the far right or left, continual pressing changes the page of data stored in the memory to change forwards or backwards in time.

NOTE: When the time indicator is moved rapidly by the up arrow button or the down arrow button, the movement may be less than 8 steps.

5. SpO2 MONITORING

5.1 Measurement Principle

SpO2 plethysmogram measurement is employed to determine the oxygen saturation of haemoglobin in 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 (the spectro-photometer principle). It measures how much light, sent from one side of the sensor, is transmitted through the patient's 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 4mW.

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 Measurement Steps

Sensor selection for SpO₂ measurement depends on the patient's age. For an adult patient, you should select an adult finger sensor; for a child patient, you can choose either 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 photo-detector is placed in another part.

Please follow the steps and Fig. 9 below to use the adult finger SpO₂ sensor:

1. Insert the sensor's connector to the monitor's SpO₂ socket.
2. Turn on the monitor. The LCD screen will display the parameter monitoring screen.
3. Attach the sensor to an appropriate site on the patient's finger.
4. The readings will be displayed on the LCD screen a moment later.

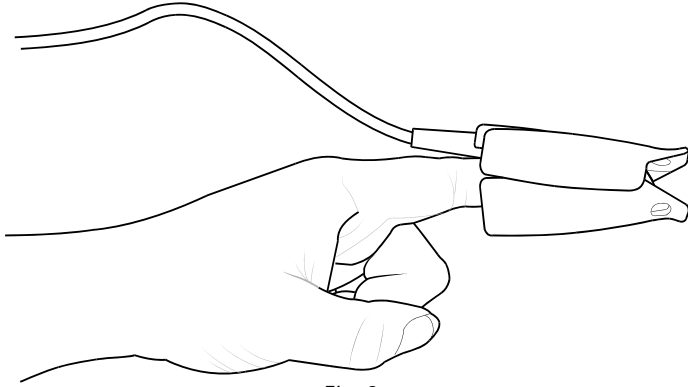


Fig. 9

NOTE

- Make sure to place the SpO₂ sensor on the finger correctly. The LED part of the sensor should be at the backside of the patient hand and the photo-detector part at the inside. Make sure to 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 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;
- 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;
- Intense illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to intense illumination can be corrected by covering the sensor with a dark material);
- Excessive patient motion;
- Venous pulsations;
- SpO₂ is too low;
- Improper sensor installation or incorrect contact position of 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 proximal 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 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 SpO₂ sensor.
- Do not put the sensor on extremities with 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 for proper functions.
- Don't use the monitor to measure patients whose pulse rate is lower than 30bpm, which may cause incorrect results.
- Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check more frequently the sensor placement of child and patient of poor perfusion or immature dermographia by light collimation and proper attaching strictly according to changes of the skin. Check per 2-3 hours the sensor placement 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 crossed 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 precision and fragile. Avoid pressure and knock. Hold the probe and cable carefully and lightly. If not use it, you should 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

6.1 Measurement Principle

The device measures temperature of body surface by taking advantage of the characteristics of the thermal-sensitive resistor located in the temperature probe, whose impedance varies with the body temperature. The monitor measures the impedance of the resistor and then consults a resistance-temperature table stored in the device beforehand. The current temperature is found in the table and displayed on the LCD screen.

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

6.2 Measurement Steps

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

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

NOTE: Because the temperature sensor's impedance varies slowly with the temperature of the body, 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 normal condition before monitoring. **Do not use the TEMP probe once 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 entanglement or strangulation. Cables of electrical surgical equipment should not be wound around that of the TEMP probe.
- If the reading is unreasonable, 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 for proper functions.
- Do not reuse disposable TEMP probes.
- When used on different patients, the monitor is prone to crossed contamination, which should be prevented and controlled by the user. Disinfection is recommended before using the TEMP probe on other patients.

CAUTION: Hold the probe and cable carefully and lightly. If not use it, you should 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.

7. MAINTENANCE

7.1 System Check

7.1.1 Check before Using

Before using the monitor, perform the following steps:

- Check if there is any mechanical damage;
- Check if all the outer cables and accessories are in good condition;
- Check if all the monitoring functions of the monitor can work normally so as to make sure that the monitor is in proper working condition.

In case of any damage, abnormal function, hidden safety danger or exception, do not use the device on patient. Contact the technician in your hospital or the manufacture immediately.

7.1.2 Routine Check

Make sure the 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 leave the device unused for a long time. Otherwise the battery may be damaged because of being thoroughly exhausted.

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 authorized personnel only. Otherwise, equipment failure and possible health hazard may be caused.

7.2 General Cleaning.

Your equipment should be cleaned on a regular basis. When it is polluted by dust, oil, sweat or blood etc. it should be cleaned at once. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning, 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.

Following are 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. How much ppm depends on how much organic matter is on the surface.

CAUTION

- Never use strong solvent, such as acetone.
- ALWAYS dilute the solutions according to the manufacturer's suggestions.
- NEVER use abrasive, erosive cleaners, or cleaners containing acetone.
- NEVER permit fluids 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 any cleaning solution on the equipment.
- ALWAYS wipe off all the cleaning solution with a dry cloth after cleaning and dry the monitor in the air. Never dry the monitor in the violent sunshine or toast it under high temperature.
- If the monitor is polluted by chemical substance, the users should handle it effectively according to the properties of the chemical substance.

The probes and cables may be cleaned with a clean and soft cloth, sponge or cotton swap, dampened with ethanol.

CAUTION: NEVER permit fluids run into the probes and cables. NEVER submerge the probes and cables into any liquid.

WARNING: The cleaning solutions above can only be used for general cleaning. If you use them to control infections, the manufacturer shall assume no responsible for the effectiveness. Please consult your hospital's infection controllers or professionals.

7.3 Disinfection

Disinfection may cause damage to the equipment. We recommend the disinfection are 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.

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

NOTE: ALWAYS dilute the solutions according to the manufacturer's suggestions and adopt 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 all the excess liquids on the equipment surface and accessory surface with a dry cloth.
- Never use EtO and formaldehyde to disinfect.
- Never permit high-pressure and 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 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 SpO2 sensor and TEMP probe, follow local regulations regarding disposal of hospital waste.

8. VITAL SIGNS MONITOR DATA VEIWER

The Vital Signs Monitor Data Veiver (VSDV) software comes with he monitor offering the following functions:

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

Before using VSDV software, you must install it on your PC from the CD.

Instructions on how to you the software can be found in the software's help system.

9. PACKING LIST AND ACCESSORIES

Standard packing list	
Handheld SpO2 /TEMP patient monitor main unit	1 pc
Adult finger SpO2 sensor	1 pc
Surface TEMP probe	1 pc
Vital Signs Monitor Data Veiver software	1 pc
AC power adaptor	1 pc
Communication cable	1 pc
The operator's manual	1 pc
Optional accessory	
Child finger/toe SpO2 sensor	1 pc

CAUTION: Using other accessories may cause damage to the device.

APPENDIX A

General Specifications	
Monitoring Parameters	SpO ₂ , PR, PLETH, Pulse strength, TEMP
Signal sockets	SpO ₂ socket, PR socket, TEMP socket, adaptor socket, PC communication socket

Display screen	
Type	128×64 dot matrix monochrome LCD
Display area	45 × 30mm
Backlight colour	White
LED	Dual-colour LED (red/green)
Size	120 × 63 × 32mm
Weight	300g (not include probes and adaptor)

Features

- PLETH: The monitor can display PLETH waveform
- Intelligent parameter monitoring screen: The monitor automatically selects the parameter measurements to display according to the probes connected to the monitor.
- Audio and visual alarm: The speaker sounds the alarm and the parameter's measurement flashes on the screen.
- Prompting: Icons of battery capacity, pulse sound switch and alarm sound switch.
- Power saving: The monitor will automatic shut down when no monitoring for 3 minutes.
- Trend: The monitor saves parameter measurements every 2 seconds and can store trend data up to 36 hours.
- Data storage: The saved data will never be lost even if the monitor is powered off.
- Communication: Transmitting the patient's trend to a PC for display, observation, saving and printing.

Electrical specifications	
Working Voltage	6.0 - 9.0 V DC

AC power adaptor	
Input	100-240VAC, 50/60Hz, 0.7A
Output	8V DC, 800mA

Internal battery	
Type	2Ah/6V Ni/MH rechargeable battery
Run Time	15-hour continuous operation with a new, fully charged battery (environment temperature is 25°C)
Recharge time	10 hours

Environment Temperature	
Operation	0 - 45 °C
Transportation and storage	-20 - 60 °C

Humidity	
Operation	15 - 95 % (non-condensing)
Transportation and storage	10 - 95 % (non-condensing)

Altitude	
Operation	86 - 106 KPa
Transportation and storage	50 - 106 KPa

Parameter specifications SpO2	
Patient	Adult, child
Range	35 - 100%
Resolution	1%
Accuracy	70 - 99%: ± 2 % 0 - 69%: Unspecified

PR	
Range	30 - 250bpm
Resolution	1bpm
Accuracy	± 2 bpm

TEMP	
Channel	1
Input	Body surface thermal-sensitive resistor temperature sensor
Range	0 - 50°C
Resolution	0.1°C
Accuracy	± 0.2 °C

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:

Freepost Plus RRAS-YGXE-SLBC
Daray Ltd
Marquis Drive
SWADLINCOTE
DE12 6EJ

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Privacy statement: DARAY will not pass on your details to any third party.

PRODUCT:
SERIAL No:

DARAY[®]
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[®]

IMAGNIFY[®]

VitalSignZ[™]

LifeSignZ[™]

BioSignZ[™]

NfuZe[™]

VetZ[™]

The logo for BioProtect features a stylized "B" shape in purple and pink, with a blue sphere inside the curve. The word "BioProtect" is written in blue, with "Antimicrobial protection" in smaller purple text below it. A small "TM" trademark symbol is positioned above the "t".
BioProtect[®]
Antimicrobial protection

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