

DARAY[®]

HEALTHCARE PRODUCTS



V203

HANDHELD PULSE OXIMETER & TEMPERATURE MONITOR OPERATING MANUAL

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1. WARNINGS

- Read and understand this manual before using the product.
- The monitor is intended only to assist with patient assessment and it must be used in conjunction with expert clinical diagnosis. It is not intended as a treatment device.
- The monitor is intended for use by qualified and trained staff only.
- To ensure patient safety, check the function of the monitor and its sensors before use.
- SpO2 sensors are fragile precision instruments - please treat them accordingly.
- Take extra care when using the monitor with electrical surgery equipment.
- **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 sensors' cables which may become disconnected allowing the monitor to fall onto the patient or the floor.
- Do not allow the monitor to swing freely when transporting patients, to avoid accidental damage.
- Do not use the monitor or its sensors during MRI (magnetic resonance imaging) scanning because induced currents could cause burns. The monitor and MRI equipment can interfere with each other.
- The monitor and its accessories may be contaminated by bacteria during transporting, 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 long periods.
- Do not perform SpO2 monitoring and NIBP measurements on the same arm simultaneously - obstruction of blood flow during NIBP measurements may adversely affect the SpO2 reading.
- Do not put the sensors on the same extremity as any arterial catheter or venous syringe.
- As with any medical equipment, carefully position sensor cables to avoid danger to the patient.
- Separate cables from other electrical surgical equipment as far as practical from the V203 sensor cables.
- 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 and the monitor's battery state.
- Do not use the monitor to measure patients whose pulse rate is lower than 3bpm which is outside the equipment's specification.
- Do not allow prolonged and continuous monitoring which may damage the patient, especially small children.
- Do not place the sensor over scar tissue.
- Remove nail varnish, plasters, etc from the finger inserted into the sensor.
- Remove the sensors from the patient after monitoring is completed.
- The monitor is not waterproof. Keep its surface dry and clean, and prevent any liquid from entering it.
- Ensure the monitor cannot fall over during use, and that it is not subjected to mechanical vibration or shock.
- Do not permit mobile phones to be used near to the monitor.
- The monitor should only be maintained by personnel approved by the manufacturer.

2. INTRODUCTION

2.1 General

The V203 is a non-invasive, handheld pulse oximeter and temperature monitor powered by 3 x 1.5V AA alkaline or rechargeable batteries; DARAY supplies rechargeable batteries and a charger with the product. It is compact, light and simple to use for monitoring adult, paediatric, infant and neonatal patients.

The monitor measures and displays arterial oxygen saturation (SpO₂), pulse rate (PR), plethysmogram waveform (PLETH), pulse strength and temperature (TEMP). The monitor measures these parameters via 2 sensors, processes the signals and shows the results on clear LED displays. Battery state is also displayed, and the unit shuts down to save battery life if it is not used for 3 minutes. The device can store up to 36 hours of data which may be downloaded to a PC for trend analysis.

User-set audio and visual alarms are featured, and the monitor is operated and controlled by the buttons on its front panel.

2.2 SpO₂ Measurement principles

SpO₂ measurement determines the oxygen saturation of haemoglobin in the arterial blood. The V203 displays SpO₂ as a %, pulse rate, pulse strength and a plethysmogram wave (PLETH).

Arterial oxygen saturation is measured by a technique called pulse oximetry which is a continuous, non-invasive method based on the different spectra absorption of haemoglobin and oxyhaemoglobin. This spectrophotometer principle measures how much light from a red and an infrared LED source 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 source wavelengths are nominally 940nm for the red LED and 660nm for infrared, whilst the power output of each source is nominally 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. The sensor detects the pulse and gives an output from which the PLETH waveform, pulse rate signal and pulse strength can be derived.

2.3 TEMP Measurement principles

The temperature-measuring probe employs a thermal-sensitive device, the resistance of which varies with temperature. The monitor measures the resistance of the sensor and then uses a table to relate the resistance to temperature. This information is processed so it can be displayed.

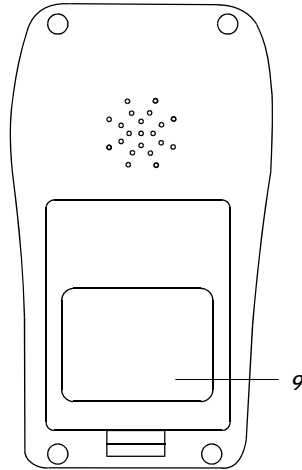
2.4 Controls and displays

General

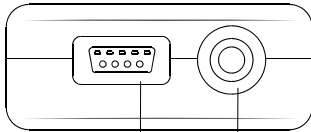
The V203 has 3 different displays: monitoring screen, system-setup screen and trend-waveform screen. The 6 buttons on the front panel operate the monitor in conjunction with these screens.



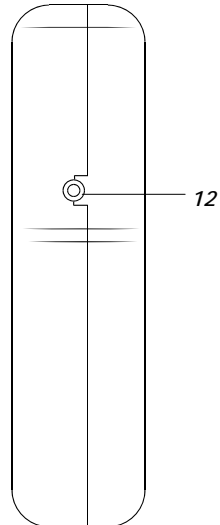
Front panel



Rear panel



Top Panel



Right side panel

No.	Description	Remarks
1	LCD screen	See below for details
2	Battery-state indicator	Flashes in time with pulse rate. Red indicates low battery power.
3	On/Off button	
4	Menu button	Toggles displays between monitoring, setup, and trend/waveform screens
5	Left arrow/contrast button	Press and hold to adjust display contrast in steps. Moves cursor left during trend waveform setup and playback
6	Up arrow/backlight button	Turns display light on and off and moves cursor up during trend waveform setup and playback
7	Right arrow/PLETH button	Changes display to PLETH and moves cursor to the right during trend waveform setup and playback
8	Down arrow/mute button	Turns speaker on and off and moves cursor down during trend waveform setup and playback
9	Battery compartment	
10	SpO2 sensor connector	
11	TEMP sensor connector	
12	PC interface cable socket	

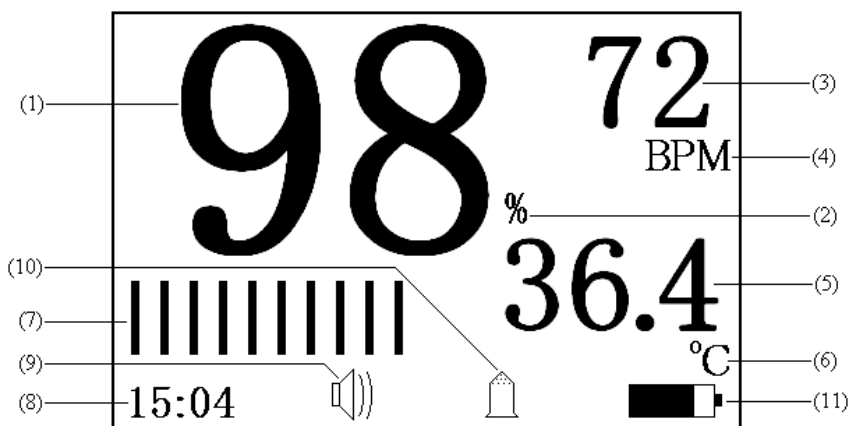
Displays

The monitoring screen has 2 functions: parameter monitoring and waveform/parameter monitoring. The parameter monitoring screen is displayed when the monitor is turned on. The monitor detects which sensor is connected and then displays the appropriate parameter screen automatically.

There are 4 parameter screens:

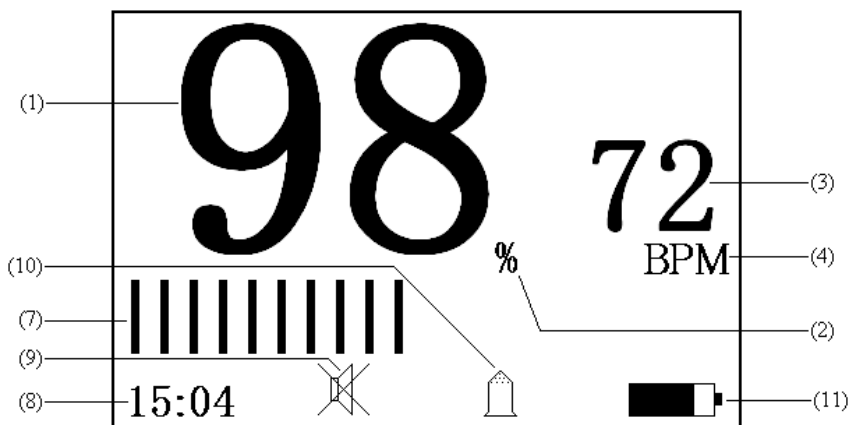
SpO2/PR/TEMP screen

If the SpO2 and TEMP sensors are both connected, the displays contain the full amount of information.



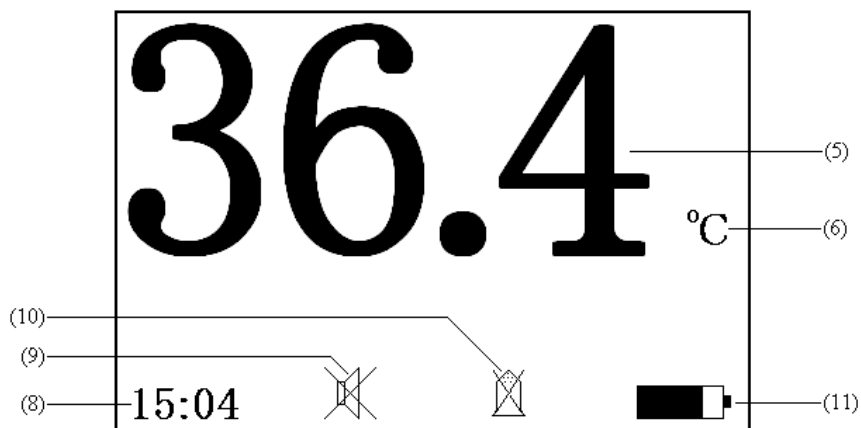
If the SpO2 and TEMP sensors become disconnected, or if the SpO2 sensor does not fit correctly over a finger, the monitor will automatically enter a standby mode. When the sensors are connected, the monitor will resume its operation mode as long as this is within 3 minutes, otherwise it will automatically shut down to save battery power.

SpO2/PR screen



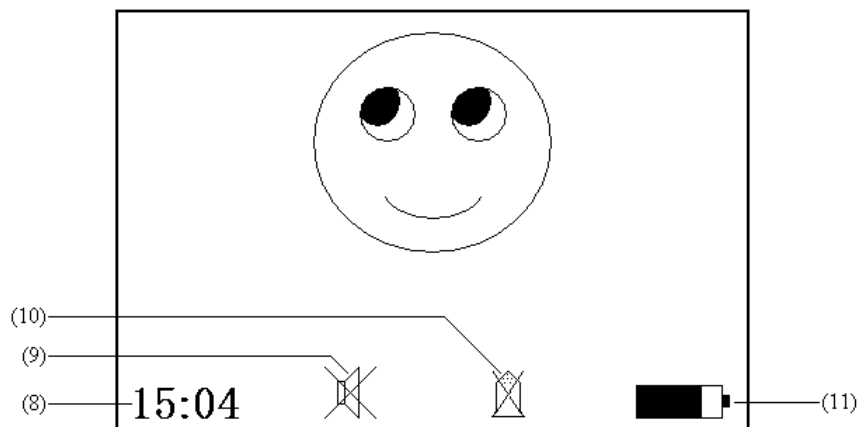
If the SpO2 sensor only is connected, the TEMP display is omitted.

TEMP screen



Screen display when the TEMP probe only is connected.

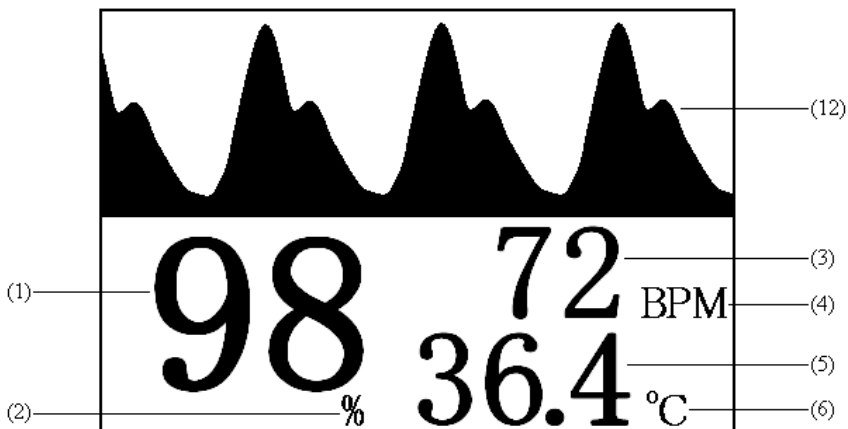
Non-parameter screen







Screen display when the monitor enters its standby mode.

Waveform/Parameter monitoring display

The waveform/parameter screen displays the PLETH waveform as well as measurements of SpO₂, PR and TEMP.



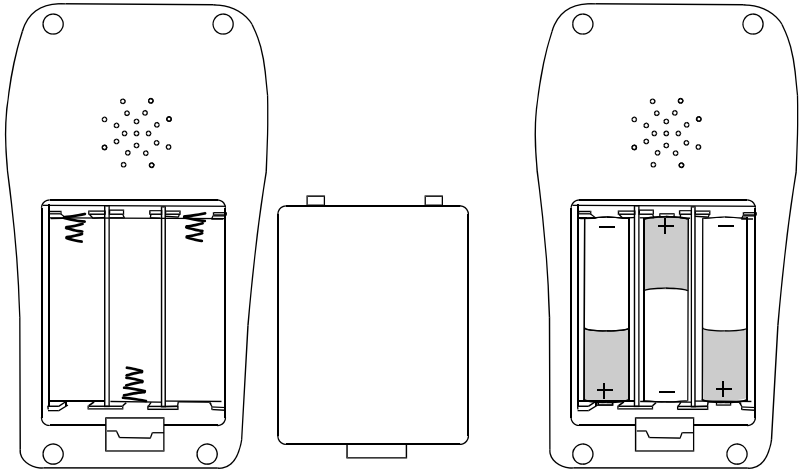
Displayed Information on the monitoring screens.

No.	Description	Remarks
1/2	SpO ₂ measurement	SpO ₂ value as %, refreshed every second.
3/4	PR measurement	PR value in BPM, refreshed every second.
5/6	TEMP measurement	TEMP value in deg C, refreshed every second.
7	Pulse strength	1 - 10 segments proportional to pulse strength.
8	Time clock	
9	Pulse sound	 : ON;  : OFF.
10	Alarm sound	 : ON;  : OFF.
11	Battery power	Remaining battery power displayed in quarters and detected every second.
12	PLETH	PLETH waveform in real-time and screen refresh mode.

3. ASSEMBLY

The monitor is powered by 3 x AA batteries installed as follows:

- 1 Open and remove the battery compartment lid by pushing the catch upwards.
- 2 Fit the batteries, ensuring they are inserted the correct way round as shown.
- 3 Refit the battery compartment lid by inserting the 2 tongues and clicking down the catch.



Battery compartment cover

Caution

- Use only AA alkaline batteries or rechargeable batteries. Do not use poor quality batteries.
- Fully charge rechargeable batteries before use.
- Remove the batteries if the device is not to be used for long periods.
- Weak battery charge may cause inaccurate readings.

Dispose of flat batteries correctly.

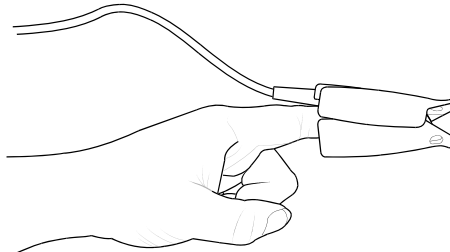
Plug the sensors into the sockets on the monitor's top panel.

4. OPERATION

4.1 Advice on SpO₂ sensors

Sensor selection for SpO₂ measurement depends on the patient's age and body site. For an adult patient, a finger sensor is usually best; for a paediatric patient, a soft-tip sensor is appropriate; for an infant or a neonate, a wrap sensor is easiest. The finger sensor can be placed on a toe, and the wrap sensor can be placed on a hand or foot.

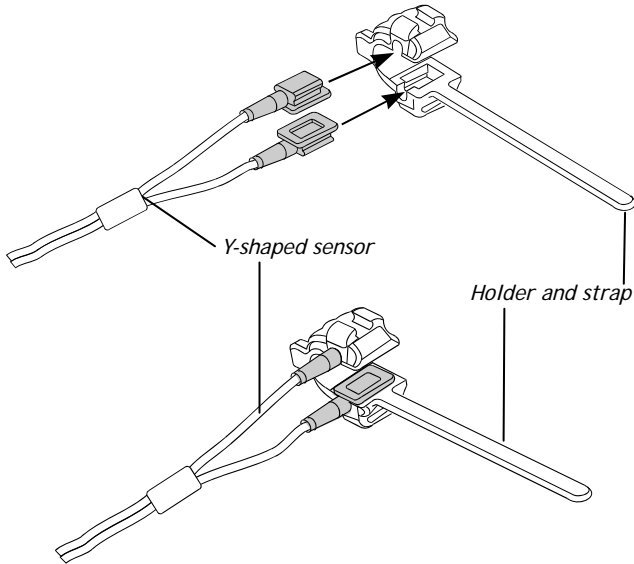
The adult finger SpO₂ sensor is a finger clip consisting of 2 parts. The red and infrared LEDs are located in one half and the photo detector in the other. The icon on the sensor represents the fingernail and the sensor should be placed over the fingertip with the icon lying over the nail.



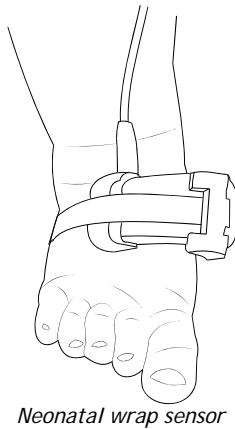
Adult finger SpO₂ sensor

Readings may not be accurate when either the sensor or the patient is moving.

The neonatal wrap sensor consists of a Y-shaped SpO₂ sensor and its holder. The Y-shaped sensor has the LEDs in one part and the photo detector in the other. Insert the 2 ends of the Y-shaped sensor respectively into the holder's upper and lower grooves.



Fit the sensor around the patient's hand or foot and hold it in place using the strap. The sensor must be positioned directly opposite the detector. Do not over tighten the strap and restrict the patient's blood flow.



NOTE

If the applied tissue site is too thin, the measurements may be inaccurate.

Do not use the monitor on animals whose pulse rate is greater than 250bpm which is beyond the specified accurate range of the device.

If the accuracy of any measurement does not seem realistic, first check the patient's vital signs using an alternative method. Then check the V203's battery state and that it is correctly connected.

Inaccurate measurements may be caused by:

- Incorrect sensor fitment
- Placement of a sensor on the same extremity with a blood pressure cuff, arterial catheter, or intravascular line
- High-frequency electrical noise, such as may be generated by nearby electrosurgical equipment
- Significant concentrations of dysfunctional haemoglobin, such as carboxyhaemoglobin and methemoglobin
- Intravascular dyes such as indocyanine green or methylene blue
- Exposure to high-intensity illumination, such as surgical lights (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight
- Excessive patient motion
- Venous pulsations
- Actual SpO₂ level is too low to register

4.2 Using the monitor

To turn on the monitor, press and hold the power button for more than 3 seconds. Press and hold the button again to turn the monitor off. Turn on the screen to display the monitor. Pressing the menu button toggles through the 3 different displays.

NOTE: to save battery life, it is recommended to select the parameter monitoring screen, and switch off the backlight and speaker when they are not needed.

Fit the required sensors to the patient. The monitor takes a few seconds to read, process and display the data from the sensors, a stable TEMP reading may take up to 5 minutes.

4.3 Alarms

Upper and lower limit alarms can be set for SpO₂, PR and TEMP; the alarms are set using the set-up mode, as described in the 4.4 system setup section. When a parameter's measurement exceeds its alarm limit, the monitor can give audio and visual alarms simultaneously, regardless of which display screen is selected. If the speaker is turned off or a parameter's alarm is selected 'off', the parameter's measurement display flashes to alert the user.

The alarm sound overrides the PR 'beat' when the speaker is switched on; the green LED on the front panel continues to flash at the PR 'beat'. The alarm-sound icon on the monitoring screen reflects the status of all alarm switches: when they are all set off or the speaker is silenced, the icon displays its 'OFF' status and no sound can be heard. Otherwise the icon displays its 'ON' status and the alarm sound will be heard if any parameter's measurement exceeds its alarm limit.

4.4 System setup

Alarm limits, system status and data management are managed via the set-up screen. Select the set-up screen by toggling the menu button.

	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		
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	Upper Limit Range	Lower Limit Range	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, 1, 2. 0 = muted, 1 = lower level, 2 = higher.		
Data output	READY or WAIT.		
Data storage area	CLEAR or WAIT.		

The 4 multifunction buttons; Left/Contrast, Right/Waveform, Up/Backlight and Down/Mute act as directional navigation of the system set-up screen.

Alarm Set-Up

Move the cursor, a small black square, using the left/right arrow buttons until it is over the alarm range to be set. Set the required value using the up/down buttons.

Place the cursor over the alarm on/off cell and select the required status using the up button.

Set alarm limits; the PR upper alarm limit should not be 20 bpm more than the patient's actual PR.

Pulse-Sound Level

Move the cursor until it is over the pulse-sound level number. Set the required level using the up/down buttons.

Data Output and Data Storage Area

Move the cursor until it is over the parameter to be set, then use the down button to select the required status. A 'WAIT' message will be displayed whilst the data process clears and all buttons will be inoperative during this period.

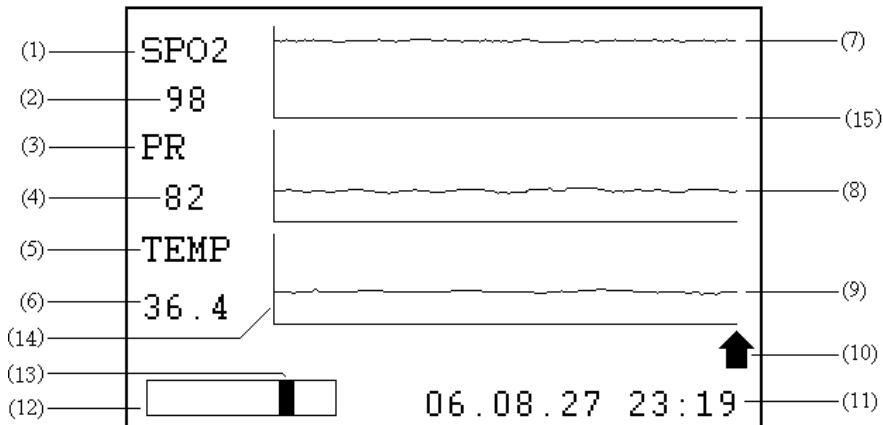
DATE and TIME

Move the cursor over the parameter to be set then use the up/down button to set the correct year, month, etc.

The date and time are best reset just after the monitor is first switched on. **To avoid confusing the trend calculations, do not reset the date and time unless necessary.**

4.5 Trend waveform display and operation

The monitor saves parameter measurements every 2 seconds. The non-volatile memory can store 36 hours of trend data. After 36 hours, new data overwrites the old. Trend data can be displayed and observed on the trend waveform screen which shows 3 hours' data per 'page' and therefore produces 12 'pages' to cover the full 36 hours. Select the trend waveform screen using the menu button.







Description of displayed information on the trend waveform screen

No.	Description	Remarks
1/2	SpO2 measurement	Instantaneous
3/4	PR measurement	Instantaneous
5/6	TEMP measurement	Instantaneous
7	SpO2 waveform	
8	PR waveform	
9	TEMP waveform	
10	Time indicator	Indicates the horizontal-axis scale and the memory units
11	Date and time	
12	Memory space	Displays how much memory is filled. One 'page', containing 3 hours of data, takes 90 units of memory space.
13	Page indicator	
14	Vertical axis	
15	Horizontal axis	The time axis. Minimum scale is 2 seconds. Total length is 3 hours

CAUTION: It takes time before the trend information is statistically valid, and diagnoses should not be drawn from short-term trend lines.

Button Operation

There are 4 multifunction buttons, which act as arrow keys.

 Up arrow/Backlight	The up arrow is used to move the time indicator in steps of 8 along the horizontal axis. When the time indicator is at the far left, pressing the up arrow once triggers the page indicator of the storage area to move left. The present trend waveforms are cleared and new trend waveforms are drawn from the new data page. The time indicator resets to the far right of the horizontal axis and points to the nearest data on the page.
 Down arrow/Mute	The down arrow is used to move the time indicator in steps of 8 along the horizontal axis. When the time indicator is at the far right, pressing the down arrow button triggers the page indicator of the storage area to move right. The present trend waveforms are cleared and new trend waveforms are drawn from the new data page. The time indicator resets to the far right of the horizontal axis and points to the nearest data on the page.
 Left arrow/Contrast	The left arrow is used to move the time indicator step by step along the horizontal axis. The left arrow is inoperative when the time indicator is at the far left end of the scale.
 Waveform/Right arrow	The right arrow is used to move the time indicator step by step along the horizontal axis. The right arrow is inoperative when the time indicator is at the far right end of the scale.

Page selection is cyclical, i.e. when the page indicator reaches the far left of the storage area, moving it further to the left will select the first right page, and vice versa when the page indicator reaches the far right of the storage area.

The time indicator can point to the data within one page and cannot move pages in the storage area.

CAUTION: pressing the Up or Down arrow buttons too quickly may cause the time indicator to jump in steps of less than 8 scales.

4.6 PC connection

The monitor can be connected to a PC's serial port by plugging in an interface cable into PC interface socket (see page 6, right side panel, item 12).

Software is supplied on a CD-ROM to enable trend and patient data to be downloaded, reviewed on the PC, and printed.

5. MAINTENANCE

5.1 Pre-use check

Before using the monitor:

- Check the monitor, sensors and sensor cables for any mechanical damage.
- Check the battery, and replace, if required.
- Check the monitor on yourself.
- Do not use the monitor, if you have any doubt over its serviceability.

CAUTION

Remove the batteries if the monitor is not used for long periods.

5.2 Periodic servicing and recalibration

Before using ensure the device has been serviced and recalibrated in accordance with your organisation's policies and procedures.

WARNING

- Failure to implement an adequate maintenance policy may jeopardise equipment and patient safety.
- Any maintenance which requires opening the monitor housing must be undertaken by trained and authorized personnel only.

5.3 Cleaning

CAUTION

- Power down the monitor before cleaning.
- Never use strong solvents, such as acetone.
- Dilute the solution in accordance with the manufacturer's recommendations.
- NEVER use abrasives.
- NEVER permit fluids to enter the casing or connectors.
- NEVER submerge the equipment, or pour or spray any cleaning solution onto the equipment.
- Always wipe off all the cleaning solution with a dry cloth and allow the monitor to dry naturally.

The V203 should be regularly cleaned by wiping with a soft, lint-free cloth dipped in diluted sodium hypochlorite and then wiped dry.

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

5.4 Disinfecting

CAUTIONS

- Obtain experts' advice before starting disinfecting.
- Always dilute chemicals in accordance with their manufacturer's recommendations and use the lowest effective concentration possible.
- NEVER submerge the equipment, or allow liquid to enter it.
- Always wipe off liquids as quickly as possible using a dry, soft cloth.
- NEVER use ETO and formaldehyde to disinfect.
- NEVER permit high-pressure or high-temperature sterilization of the monitor or its accessories.

Disinfection may cause damage to the equipment and should only be used when absolutely necessary. The equipment should be cleaned prior to disinfecting.

Recommended disinfectants are 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. **Do not submerge electrical connections.**

5.5 Disposal

Disinfect or decontaminate the device appropriately before disposing of it in accordance with your local regulations regarding the disposal of electronic equipment and hospital waste.

6. PACKING LIST AND ACCESSORIES

Standard Packing List	
Handheld monitor	1 pc
Surface TEMP sensor	1 pc
PC interface cable	1 pc
Operator's manual	1 pc

Optional Sensors	
Paediatric soft tip SpO2 sensor	
Neonatal/infant wrap SpO2 sensor	
Adult finger SpO2 sensor	
Finger clip SpO2 sensor	

CAUTION

Using non-manufacturer supplied accessories may cause damage.

7. SPECIFICATIONS

Monitoring parameters	SpO ₂ , pulse rate (PR), PLETH, Pulse strength, TEMP
Patient range	Adult, paediatric, infant, neonatal
Auto-power shut down:	After 3 minutes with no use
PC input:	RS232 serial
Trends:	Updates every 2 seconds. Stores up to 36 hours of SpO ₂ , PR and TEMP data. Non-volatile memory

SpO₂

Range:	35 ~99%
Resolution:	1 %
Accuracy:	±2 % (70 ~ 99%), unspecified (0 ~ 69%)

PR

Range:	30 ~250bpm
Resolution:	1bpm
Accuracy:	±2bpm

TEMP

TEMP:	Single channel
Input:	Body-surface, thermistor sensor
Range:	0 ~ 50°C
Resolution:	0.1°C
Accuracy:	±0.2°C

Display

Displays:	128x64 dot matrix monochrome LCD. 45x30mm display area. Selectable white backlight. Red/green LEDs. Automatic selection of display format
Pulse strength/ Battery-state indicator:	10 segment bar-graph red LED
Battery serviceability indicator:	Green and red LEDs

Alarm

Alarms:	Audio and visual, user-settable for SpO ₂ , PR and TEMP, upper and lower limits
Volume control:	3 levels: mute, soft and louder

Battery

Battery type:	3x 1.5V AA alkaline or rechargeable batteries
Run time:	7-hours continuous operation with new or fully-charged batteries (@25°C)
Working voltage:	DC 2.8V~DC 5.4V

Size and weight

Size:	72 (W) × 130 (H) × 34 (D) mm
Weight:	145g (less sensors and batteries)

Environmental

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

8. 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.

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