
heart sure

Pulse Oximeter
A320

User Manual



File No.: Fingertip-OPE V 1.4 2016/04

Section 1

Safety

1.1 Instructions for the Safe Operation and Use of the Pulse Oximeter

- Do not attempt to service the Pulse Oximeter yourself. Only qualified service personnel should attempt any necessary internal servicing.
- Prolonged use or depending on the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status and correct alignment at least every 2 hours.
- SpO₂ measurements may be adversely affected in the presence of high ambient light. Shield the sensor area if necessary.
- The following will cause interference to the testing accuracy of the Pulse Oximeter:
 - High-frequency electrosurgical equipment.
 - Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
 - Patients with hypotension, severe vasoconstriction, severe anaemia or hypothermia.
 - The patient is in cardiac arrest or is in shock.
 - Fingernail polish or false fingernails may cause inaccurate SpO₂ readings.

1.2 Warnings

WARNING: EXPLOSION HAZARD Do not use the Pulse Oximeter in a flammable atmosphere where concentrations of flammable products exist.

WARNING: Do not throw batteries in fire as this may cause them to explode.

WARNING: Do not attempt to recharge normal dry-cell batteries as they may leak, cause a fire or explode.

WARNING: Do not use the Pulse Oximeter in an MRI or CT environment.

WARNING: Do not modify this equipment without authorisation of the manufacturer.

WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity.

CAUTION: Do not operate the unit if it is damp or wet. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the front-panel switches.








CAUTION: The batteries must be taken out from the battery compartment if the device will not be used for more than 12 months.

CAUTION: The device should only be used if the battery cover is closed.

CAUTION: The batteries must be properly disposed of according to local regulation after their use.

CAUTION: The device should be kept away from children & pets to avoid swallowing.

1.3 Definitions and Symbols

Symbol	Description
	Type BF Equipment
	Batch code [#]
	Date of manufacture [#]
SN	Serial No. [#]
	Information of manufacture, including name and address
	Temperature limitation
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling
	Follow instruction for use
IPX4	Anti-dust & Anti-water class
<i>Warning</i>	The information you should know to protect patients and medical staff from possible injury
<i>Caution</i>	The information you should know to protect the equipment from possible damage
<i>Note</i>	The important information you should know

[#]Batch code, Date of manufacturer and Serial No. are printed on the label on the battery cover

Section 2

Introduction

2.1 General

This chapter provides a general description of the Pulse Oximeter including a brief device description and product features.

2.2 *Brief Device Description*

The Pulse Oximeter is intended for non-invasive spot-check measurements of functional oxygen saturation of arterial haemoglobin (SpO₂). The advanced DSP algorithm[^] can minimize the influence of motion and improve measurement accuracy of low perfusion[^] .

The Pulse Oximeter can be used to measure human oxygen saturation and pulse rate through the finger. The product is suitable for use by individuals and healthcare professionals in multiple situations, including; home, clinical & sporting environments. For example:

- Pre/post-exercise.
- Pre/post-operative conditions.
- Monitoring respiratory conditions.

2.3 *Product Features*

- Measures oxygen saturation (SpO₂) and pulse rate (PR).
- Lightweight & portable.
- Easy to use.
- Manually adjust the direction of interface (6 display modes).
- Dual colour OLED display, simultaneous display for testing value and plethysmograph[^] .
- Low perfusion: 0.2%.
- Anti-shaking technology.
- Visual & sound alarm function.
- Real-time spot-checks.
- Low battery voltage indicator.
- Automatic switch off.
- Standard 2x AAA 1.5V Alkaline batteries will provide more than 20 hours continuous output.

CAUTION: The device cannot be used in children less than 1 year old as the result may not be accurate.

CAUTION: The fingertip Pulse Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

2.3.1 ^ Defintions

^ **DSP algorithm:** Digital signal processor algorithm.

^ **Low perfusion:** In physiology, perfusion is the process of a body delivering blood to a capillary bed in its biological tissue. Under the condition of low perfusion, the measurement of non-invasive saturation of pulse-blood oxygen can be low.

^ **Plethysmograph:** Instrument for measuring changes in volume within an organ or whole body (usually resulting from fluctuations in the amount of blood or air it contains).

Section 3

Installation, Setup and Operation

3.1. Description of the Front Panel (as figure 3.1.1)



Figure 3.1.1
Parts of front & back panel

Table 3.1.1 Part Name and Description

Item	Name	Description
1	Power Button	Turn on/off the machine
2	Direction Button (M)	Direction change & parameter setting within the menu
3	Battery Compartment	Compartment for batteries
4	OLED Panel	Displays the SPO2/PR data & Plethysmograph

3.2 Display

After being switched on, the OLED display is as follows:

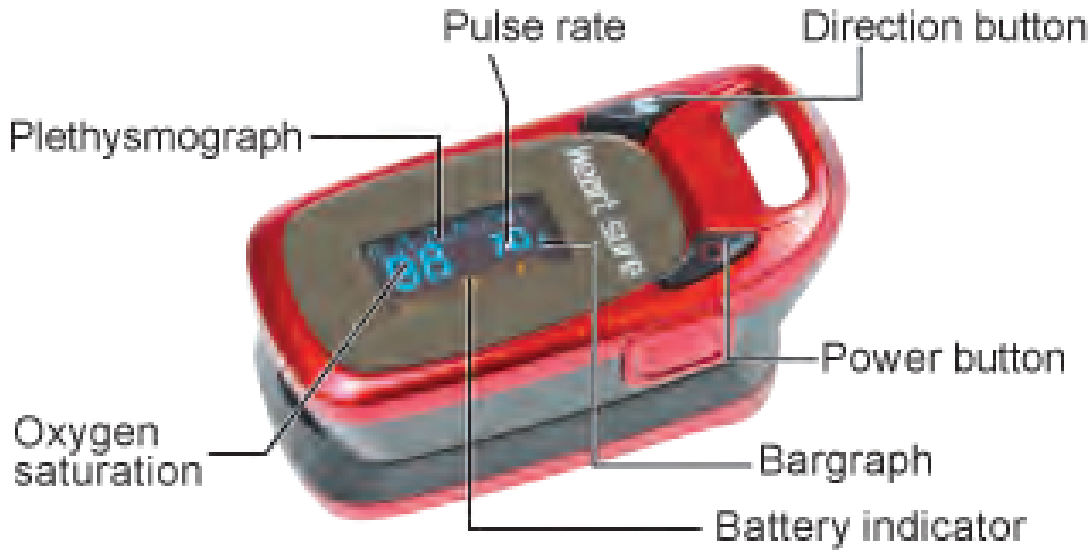
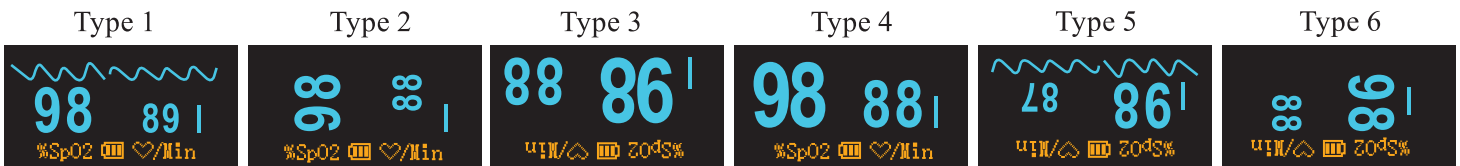


Figure 3.2.1 OLED display

3.2.1 Display Modes

The OLED display can rotate four directions with six different display modes when pressing the direction button (M) as shown below:



3.3 Operation

3.3.1 Install battery

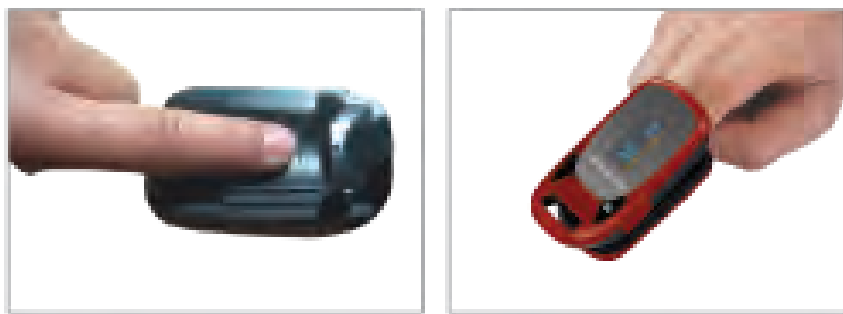
Remove cover & install 2 x AAA batteries into the battery cassette in correct polarities and place cover back on.



3.3.2 Turn the Pulse Oximeter On

Press the power button for 2 seconds to turn the Pulse Oximeter on. Open the clamp, then place one finger into rubber hole of the Pulse Oximeter

(it is best to put the finger as far in as possible) with nail surface upward, then release the clamp to shut.



3.3.3. Read data on the display screen

The data may take a few seconds to appear while a reading is obtained. Only your Healthcare Professional can interpret your individual readings.

3.3.4. Parameter Settings

In the parameter settings menu you can set high/ low alarm values for both SpO2 and PR, as well as turning sound on/off. To access the parameter settings hold down the (M) button for one second.

There are two types of submenus; Alarm Setup and Sounds Setup. To switch between the setups, ensure the * is next to the word Sounds Setup or Alm Setup, then press (M) for one second to switch between menus, as per figures 3.3.1 and 3.3.2.

3.3.4.1. Sounds Setup

Hold down the (M) button for one second to bring up the sound menu as per figure 3.3.1. Press (M) quickly to move down the menu.

To increase parameter values

Press (M) quickly to move down the menu until your * signal appears next to the + / - sign. Then hold down (M) for one second until the + sign appears. This will now increase the value of any parameter in this menu. Quickly press (M) to move to the parameter value you wish to change. Once you have reached the parameter value you want to change, hold down (M) for one second and you will see the value increase. Once you've reached your desired level, release the (M) button.

To decrease parameter values

Press (M) quickly to move down the menu until your * signal appears next to the + / - sign. Then hold down (M) for one second until the - sign appears. This will now decrease the value of any parameter in this menu. Quickly press (M) to move to the parameter value you wish to change. Once you have reached the parameter value you want to change, hold down (M) for one second and you will see the value decrease. Once you've reached your desired level, release the (M) button.

3.3.4.2. Alarm Setup

Hold down the (M) button for one second to bring up alarm menu as per figure 3.3.2. Press (M) quickly to move down the menu.

To turn Alarm or Beep ON

Press (M) quickly to move down the menu until your * signal appears next to the word ALM or Beep. Then hold down (M) for one second until the word *on* appears.

To turn Alarm or Beep OFF

Press (M) quickly to move down the menu until your * signal appears next to the word ALM or Beep. Then hold down (M) for one second until the word *off* appears.

3.3.4.3. To Exit Parameter Settings Menu

Press (M) quickly to move down the menu until your * signal appears next to the word Exit. Then hold down (M) for one second to exit menu.

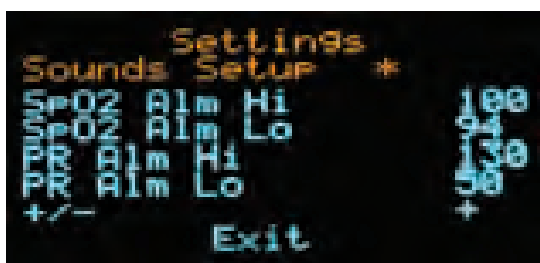


Figure 3.3.1

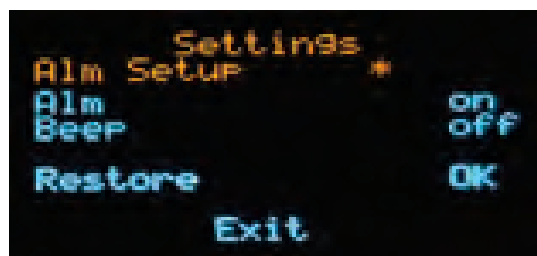


Figure 3.3.2

Note: 1. The alarm sound has a 1 second delay after an incorrect result is detected.

3.4.4 Turn the Pulse Oximeter Off

Press & hold the power button for 2 seconds. Alternatively the device will automatically shut off after approximately 10-15 seconds.

Note: 1. When the battery power is at lowest level, the battery indicator symbol "☐" appears, indicating replacement of battery is required.
2. The plethysmograph can be regarded as correct if the wave is fluctuating constantly.

Section 4

Cleaning and Disinfection

4.1 Cleaning & Disinfection

Switch off the power and take out the batteries before cleaning. Keep the surface of the device clean and free of dust and dirt. Clean the surface (OLED display screen included) of the unit with a soft dry cloth. Disinfect the machine if being used in a clinical setting or by multiple users. To disinfect, use a small amount of 70-75% density medical alcohol on a soft dry cloth to avoid alcohol permeating into the device.

CAUTION: Do not use strong solvent. e.g acetone.

CAUTION: Never use an abrasive such as steel wool or metal polish.

CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquid on the device while cleaning.

CAUTION: Do not leave any cleaning solution on the surface of the device.

Section 5

Troubleshooting and Maintenance

5.1 Maintenance

- Replace the batteries when the battery indicator symbol is low.
- Clean/disinfect surface of the Pulse Oximeter before use.
- Remove the batteries inside the battery cassette if the Pulse Oximeter will not be operated for more than 12 months.
- Store the product in a place where ambient temperature is -10 to 50°C and humidity is 15% to 80%.
- Regularly inspect the device to make sure that no obvious damage exists that will effect the safety and performance of device.

5.2 Troubleshooting

Table 5.2.1 Troubleshooting

Problems	Possible Reason	Resolutions
Oxygen saturation or pulse rate is reading abnormally.	1. Finger is not placed correctly.	1. Retry by placing the finger in the correct position as per instructions.
	2. Patient's perfusion is too low to be measured.	2. Retry the measurement, if still reading abnormally, please consult healthcare professional.
Oxygen saturation or pulse rate is unstable	1. Finger is not placed correctly.	1. Retry by placing the finger in the correct position as per instructions.
	2. Finger is trembling or patient is moving.	2. Ensure patient is not moving during measurement.

Problems	Possible Reason	Resolutions
Oxygen saturation or pulse rate is abnormal and caused alarm to sound.	1. Finger is not placed correctly.	1. Retry by placing the finger in the correct position as per instructions.
	2. Patient's SpO ₂ & PR is abnormal.	2. Please consult healthcare professional.
Pulse Oximeter does not turn on.	1. There maybe inadequate power left in the batteries.	1. Please replace batteries.
	2. Batteries may have been installed incorrectly.	2. Please re-install the batteries.
	3. The Pulse Oximeter may be damaged.	3. Please contact local customer service center.
The device automatically turns off.	1. The product is automatically powered off when no signal is detected longer than approx. 10-15 seconds.	1. This is normal.
	2. There maybe inadequate power left in the batteries.	2. Please replace the batteries.

Section 6

Specifications

Pulse Oximeter Specifications:

Physical Characteristics

Machine

Dimensions : 37mm (W)× 74mm (D) × 38mm (H)

Weight : approx: 50g (including 2×AAA battery)

Retail package

Dimensions: 90mm (W) × 120mm (D) × 67mm (H)

Gross Weight: 175g

Classifications:

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type BF equipment

EMC: Type B class I Mode of operation: Continuous Operation

Enclosure Degree of ingress protection: IPX4[^]

[^] **IPX4** means shell of this product can withstand the water from any direction dropping to the surface.

Power

Internal	2x AAA 1.5V alkaline battery
Power Consumption	Less than 30mA(Normal)

Operation Environmental Condition:

Operating Temperature	5°C to 40°C
Relative Humidity	15% to 80% non-condensing
Air Pressure	86kPa-106kPa
Operating Altitude	0-2000 m

Transportation and Storage Environmental Condition:

Storage Temperature	-10°C to 50°C
Relative Humidity	10% to 80% non-condensing
Air Pressure	60kPa-106kPa
Operating Altitude	0-2000 m

Alarm default value

Parameter	Value
Oxygen Saturation	Upper limit: 100 / Lower limit: 90
Pulse Rate	Upper limit: 130 / Lower limit: 50

Probe LED Specification

	Wave Length	Radiant Power
RED	660±2 nm	1.8 mW
Infra RED	905±2 nm	2.0 mW

Electronics Parameters

Parameter	Value	
Oxygen Saturation Display	35-100%	
Pulse Rate Display	30-250 BPM	
Resolution	Oxygen Saturation	1%
	Pulse Rate	1 BPM
Measure Accuracy	Oxygen Saturation	±2% (70%-100%) unspecified(≤70%)
	Pulse Rate	±2 BPM

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Warranty Information

PRODUCT WARRANTY

This product is warranted to be free of manufacturing defects for 2 years from the date of purchase. This warranty is void if the product is modified or altered is subject to misuse or abuse; damaged in transit; lack of responsible care; is dropped; if damage occurs by reason of failure to follow the written instruction booklet enclosed; or if product repairs are carried out without authority from J.A.Davey Pty Ltd.

We will repair, or at our option replace free of charge, any parts necessary to correct material or workmanship, or replace the entire unit and return to you during the period of the warranty. Otherwise, we will quote for any repair which will be carried out on acceptance of our quotation. The benefits conferred by this warranty are in addition to all other rights and remedies in respect of the product, which the consumer has under the trade practices act and other state or territory laws in Australia and New Zealand.

Our goods come with guarantees that cannot be excluded under the Australian and New Zealand Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

Before you send in your unit for service

Before sending in your unit for service, please take a few minutes to do the following:

- In your user manual, read the troubleshooting section in regards to common problems, possible reasons and resolutions.
- Contact Heart Sure Customer Service. Our staff are trained to assist you with most issues you may experience, without the need to send your product in for service.

Sending in your unit for service

1. Should repair be needed within the warranty period, enclose the tear off section of this warranty card and your proof of purchase receipt. Please ensure all relevant details are completed before sending your unit in for service. Please ensure your contact details are current and include a brief description of the problem you are experiencing together with your proof of purchase.
2. Include the unit with all product components in your package. This is extremely important, as it will assist our repair technicians in making the correct diagnosis of any problems.

**Please return the unit & warranty card
at your cost to:**

IN AUSTRALIA

J.A.Davey Pty Ltd- Heart Sure Repairs
PO Box 84
Port Melbourne
Victoria Australia 3207

IN NEW ZEALAND

BV Medical - Heart Sure Repairs
Unit 7, 110 Mays Road
Onehunga, Auckland, New Zealand, 1061

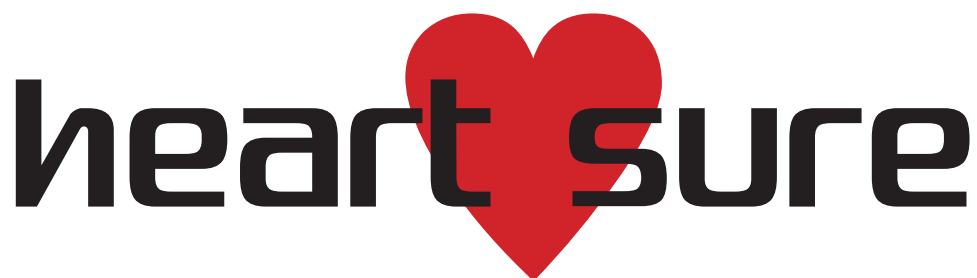
**Should you require any further information
please do not hesitate to contact us by
calling our toll free number:**

IN AUSTRALIA

Free call:
1800 807 464

IN NEW ZEALAND

Free call:
0800 523 583





**PLEASE RETAIN THIS WARRANTY CARD.
RETURN THIS PORTION ONLY WHEN YOU RETURN
YOUR PRODUCT FOR REPAIR UNDER WARRANTY.**

NAME: _____

ADDRESS: _____

POSTCODE: _____

DAYTIME TELEPHONE: _____

EMAIL: _____

MODEL: _____

DATE OF PURCHASE: _____ / _____ / _____

ATTACH PROOF OF PURCHASE

RETAILERS NAME: _____

RETAILERS ADDRESS: _____

_____ RETAILERS POST CODE: _____

BRIEF DESCRIPTION OF PROBLEM YOU ARE EXPERIENCING:

WARRANTY IS VOID UNLESS THE ABOVE INFORMATION IS COMPLETED AND CORRECT.

