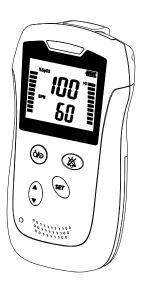# 594810 Hopkins
Handheld Pulse Oximeter
Instructions for Use

Hopkins Medical Products

PRODUCT INFORMATION

Product Name: Hopkins Handheld Pulse Oximeter
Product Model: 594810
Manufactured for: Hopkins Medical Products
Address: 6850 Southbelt Drive
         Caledonia, MI 49316 USA

REVISION HISTORY

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior alarm.
- Revision number: 2.1
- Revision Date: 2/2022

PREFACE

MANUAL PURPOSE

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

INTENDED AUDIENCE

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

ILLUSTRATIONS

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your pulse oximeter.

CONVENTIONS

- *Italic* text is used in this manual to quote the referenced chapters or sections.
- [ ] is used to enclose screen texts.
- → is used to indicate operational procedures.

Contents

1 Safety Information

⚠ WARNING

⚠	**WARNING:** Explosion hazard. Do not use the 594810 in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.
⚠	**WARNING:** Chemicals from a broken LCD display panel are toxic when ingested. Use caution when the 594810 has a broken display panel.
⚠	**WARNING:** Pulse oximetry measurements and pulse signals can be affected by certain environmental conditions, SPO2 sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.
⚠	**WARNING:** The use of accessories, sensors, and cables other than those specified may result in increased emission and/or create invalid readings of the 594810.
⚠	**WARNING:** Failure to cover the sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.
⚠	**WARNING:** Do not silence the audible alarm function or decrease the audible alarm volume if patient safety could be compromised.
⚠	**WARNING:** The 594810 is a prescription device to be operated only by trained personnel.
⚠	**WARNING:** Dispose of batteries in accordance with local ordinances and regulations
⚠	**WARNING:** To ensure patient safety, do not place the 594810 in any position that might cause it to fall on the patient.
⚠	**WARNING:** As with all medical equipment, carefully route patient cables to reduce the possibility of patient entanglement or strangulation.
⚠	**WARNING:** Ensure that the speaker is clear of any obstruction and that the speaker holes are not covered. Failure to do so could result in an inaudiblealarm tone.
⚠	**WARNING:** Disconnect the 594810 and SPO2 sensor from the patient throughout magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.
⚠	**WARNING:** To ensure accurate performance and prevent device failure, do not subject the 594810 to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.
⚠	**WARNING:**Do not use either the 594810, SPO2 sensor, or cables that appear damaged.
⚠	**WARNING:**Do not lift the 594810 by the sensor or extension cable because the cable could disconnect from the 594810 and the 594810 may drop on the patient.

⚠	**WARNING:**The 594810 is not defibrillator-proof. However, it may remain attached to the patient throughout defibrillation or while an electrosurgical unit is in use, but the measurements may be inaccurate throughout the defibrillation and shortly thereafter.
⚠	**WARNING:**Use only the SPO2 sensor and extension cable supplied by Hopkins Medical Products. Do not connect any device other than a Hopkins-approved SPO2 sensor to the sensor connector.
⚠	**WARNING:** The 594810 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the 594810 should be observed to verify normal operation using the configuration in which it is to be used.
⚠	The medical electrical equipment needs to be installed and put into service according to EMC Information
⚠	Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in EMC Information
⚠	The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment
⚠	The equipment should not be used adjacent to or stacked with other equipment, refer to the recommended separation distances provided in EMC Information

⚠ **CAUTION**

⚠	**Caution:**Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
⚠	**Caution:** All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements.

2 Symbols

᎓	Direct Current (DC)
🔆	Attention: Consult accompanying documents (this manual).
⊕↔	Auxiliary output connector
◇—C—◇	Power supply connector
⊗	Alarm silence
SET	Setting button
Ȯ/⊙	Power button
▲	Up button
▼	Down button
�	Date of manufacture
SN	Serial number
▢	Safety Class II equipment
🔲	Type BF applied part, defibrillation protected
IPX1	Resistant to liquid ingress
EC | REP	European community representative
⊠	The following definition of the WEEE label applies to EU member states only.This symbol indicates that this product should not be treated as household waste.
⚠	Caution & warning
Rx only(U.S)	Federal (U.S.) Law restricts this device to sale by or on the order of a physician
⊘STERILE	Non-sterile

3 Introduction

3.1 Working Principle

The Pulse Oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. Skin,bone, tissue, and veins normally absorb a constant amount of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

3. 2 Intended Use

The pulse oximeter is indicated for continuous or spot check monitoring of functional arterial oxygen saturation (SpO2) and pulse rate of adult patients in hospitals and clinics.
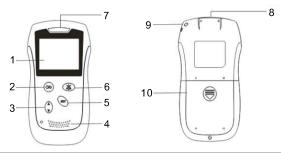
⚠	**WARNING:** Do not make any clinical judgments based solely on the 594810. The 594810 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

3. 3 Included in Package

Quantity	Item
1	594810 pulse oximeter
3	Alkaline "AA" size, 1.5-volt batteries
1	594301 Y-Probe SPO2 sensor
1	Instructions for Use

3.4 Product Description

1	Display screen	2	Power on/off	3	Up/Down
4	Speaker	5	Set	6	Alarm silence
7	Lamp	8	Sensor connector	9	Cord hole
10	Battery door				
NOTE	High level Alarm : the lamp flashes red. Medium level Alarm : the lamp flashes yellow. Low level Alarm : the lamp lights yellow without flashing.				

3.5 Display Screen Elements

1	%SPO2 area of display	2	Measured %SPO2
3	Pulse beats per minute (BPM) area of display	4	Measured BPM
5	Pulse amplitude index signal intensity bar	6	Perfusion index signal intensity bar

4 Battery installation

4.1 Battery Power

The pulse oximeter is designed to operate on three 1.5V alkaline AA batteries.A new set of batteries will provide at least 22 hours of operation.

4. 2 Low battery indicator

The Low Battery indicator displays and flashes on the information area, and a low priority alarm begins to sound when approximately 15 minutes of operation is available. The batteries should be replaced.

⚠	**Caution:** If the 594810 is to be stored for a period of three months or longer, remove the batteries from the device before storage.Warranty is void if batteries are stored in the device.

4. 3 Install the Batteries

1) Turn off power. Pull the battery cover downward, toward the bottom of the 594810, and then remove the battery access door.
2) Install three "AA" size batteries and make sure to orient them correctly.
3) Replace the battery cover.

⚠	WARNING: Dispose of battery in accordance with local ordinances and regulations.
⚠	WARNING: Explosion hazard. Do not use the 594810 in the presence of flammable anesthetics mixed with air, oxygen, or nitrous oxide.
⚠	WARNING: To ensure patient safety, do not place the 594810 in any position that might cause it to fall on the patient.
⚠	WARNING: As with all medical equipment, carefully route patient cables to reduce the possibility of patient entanglement or strangulation.
⚠	WARNING: To ensure accurate performance and prevent device failure, do not expose the 594810 to extreme moisture such as rain.

5 594810 operation

5.1 Introduction

The parameters of the 594810 are preset to factory default values. See Table 2.Table 2 lists the parameters, ranges available, and the factory default values. The parameters may be set on an individual basis, by the clinician, and will remain in effect until the 594810 is turned off.

Table 2: Parameter Ranges

Parameter	Range/selections	Factory defaults
%SpO2 Lower Alarm Limit	85% to 100%	90%
Pulse Rate Upper Alarm Limit	Lower Alarm Limit plus 1 to 250 bpm	90 bpm
Pulse Rate Lower Alarm Limit	30 bpm to Upper Alarm Limit minus 1	40bpm
ON/OFF Alarm	ON or OFF	ON
Patient type	ADU (adult) /PED (pediatric) / NEO (neonate)	Adult
Alarm Volume	1 to 10	5
Pulse Beep Volume	0 to 10	5
Shelf life	5 Years	

5.2 Turn on the 594810

1) Press and hold the Power button to turn on the 594810.

2) The alarm lamp flashes, and then goes out.

3) The system gives a beep and displays the startup screen.

4) The startup screen disappears and the pulse oximeter enters the main screen.

5.3 Set up the 594810

5.3.1 Adjust pulse Beep Volume

1) Press button **[SET]→[VOL]** and press **Up/Down** button to increase or decrease the pulse beep volume, then set the volume between 0 and 10. *Note*：When the pulse beep volume display is shown, the user is able to adjust the volume of the pulse beep tone. Each press of an Up or Down button increases or decr eases the pulse beep volume and increments or decrements by one level.

2) Press power button to return to the main screen.

5.3.2 Select Patient Type

⚠ **WARNING**：Be sure to select correct patient category setting for your patient before measurement. Wrong patient category may result in patient hazard due to pulse rate alarm limits.

1) Press button **[SET]→[PA]** and Press the Up/Down button, select patient type value: ADU(adult), PED(pediatric), NEO(neonate).

PR   PR   PR
ROU PEO NEO

Patient type weight ranges:
Adult, over + 88lb (40Kg)
Pediatric between 33-88lb (15-40Kg)
Neonatal/Infant 2-33lb (1-15Kg)

2) Press power button to return to the main screen.

5.3.3 Set alarm Limit

5.3.3.1 PR High/Low alarm Limit

Press button **[SET]→[BPM H]** or **[BPM L]**and press the Up/Down button, set the PR value between 30 and 250.

Note: The pulse rate alarm limit range is 30 to 250. The upper value of the pulse rate low alarm limit is limited one number lower than the pulse rate upper alarm limit. The pulse rate low alarm limit cannot be set equal to or higher than the pulse rate upper alarm limit. In the same way, the pulse rate upper alarm limit cannot be set equal to or lower than the pulse rate low alarm limit.

5.3.3.2 Set SPO2 Low alarm Limit

Press button **[SET]→[SPO2 L]** and Press the Up/Down button, set the SPO2 value between 85 and 100.
Note: The %SpO2 alarm limit range is 20% to 100%. The upper value of the %SpO2 low alarm limit is limited to the %SpO2 upper alarm limit. The %SpO2 low alarm limit cannot be set equal to or higher than the %SpO2 upper alarm limit. In the same way, the lower value of the %SpO2 upper alarmlimit is limited to the %SpO2 low alarm limit. The %SpO2 upper alarm limit cannot be set equal to or lower than the %SpO2 low alarm limit.

5.3.3.3 Switch ON/OFF alarm Volume

Select **[SET]→[ALn]**, and press the **Up/Down** button, to turn on/off the alarm tone

⚠	**WARNING：** When the alarm sound is switched off, the pulse oximeter will give no audible alarm tones even if a new alarm occurs. Therefore the user should be very careful about whether to switch off the alarm sound or not.
⚠	**WARNING：** Do not rely exclusively on the audible alarm system for patient monitoring. Adjusting volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.

5.3.3.4 Alarm Silence Duration

Press the ⊠ key for 1 second，the ⊠ key will light and the alarm messages remain displayed. The alarm will stay silent until the ⊠ key is pressed again.

⚠	**WARNING：** The 594810 will only keep the last setting. When the 594810 is turned on, user should check whether the current setting meet conditions of patient.

5.3.4 When an Alarm Occurs

When an alarm occurs, observe the following steps to take proper actions:
  1）Check the patient's condition.
  2）Confirm the alarm parameter or alarm category.
  3）Identify the source of the alarm.
  4）Take proper action to eliminate the alarm condition.

5) Make sure the alarm condition is corrected.
For troubleshooting specific alarms, see 5.5.3.

5.3.5 RESET TO DEFAULT
1) Press button **[SET]→[CON]** and Press the Up/Down button, set the value to"SET".
2) Press button **[SET]**.
3) Reset to default value

4)The default values are defined beleow
VOL：05
ALM：on
PA：ADU
BMP H: 90
BMP L: 40
%SPo2: L 90

5.4 SpO2&PR measurement

5.4.1 Place sensor on the finger of patient
1) Select an appropriate SpO2 sensor according to the person category and weight.
2) Wear the sensor into the measurement part of patient.
3) Connect an approved SpO2 sensor or extension cable to the 594810 SpO2 sensor port.

5.4.2 Display description

1	perfusion index signal intensity bar
2	Measured %SPO2
3	Measured BPM
4	Pulse amplitude index signal intensity bar

⚠ **WARNING**

⚠	Use only SpO2 sensors specified in this manual. Follow the SpO2 sensor's instructions for use and adhere to all warnings and cautions.
⚠	When a trend toward deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the person's condition.
⚠	Do not use the pulse oximeter and the SpO2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.
⚠	Reusable sensor must be moved to new site at least every four hours. Because individual skin condition affects the ability of skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
⚠	Do not apply tape to secure the sensor in place or to tape it shut; venous pulsations may lead to inaccurate saturation measurements.
⚠	As with any electrosurgical unit, carefully route patient cabling to avoid entanglement.
⚠	Do not use the SpO2 sensor on a limb with an intravenous infusion or arterial catheter in place.
⚠	Do not use the SpO2 sensor on a limb where the NIBP cuff is applied. This may result in inaccurate SpO2 reading due to blocked blood flow during cuff inflation.
⚠	WARNING: Pulse oximetry readings and pulse signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information.
⚠	Caution: Use only Hopkins-approved sensors and extension cables
	Note: Physiological conditions, medical procedures, or external agents that may interfere with the 594810's ability to detect and display measurements include: ● Dysfunctional hemoglobin ● Arterial dyes ● Low perfusion ● Dark pigment ● Externally applied coloring agents, such as nail polish, dye, or pigmented cream. Inaccurate measurements can be caused by: ● Incorrect application of the sensor ● Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line ● Ambient light

● Prolonged and/or excessive patient movement ● Intravascular dyes or externally applied coloring, such as nail polish or pigmented cream ● failure to cover the sensor site with opaque material in high ambient light conditions Loss-of-pulse signal can occur for the following reasons: ● The sensor is applied too tightly ● A blood pressure cuff is inflated on the same extremity as the one with the sensor attached ● There is arterial occlusion proximal to the sensor ● Poor peripheral perfusion

5.5 Alarms

Alarms triggered by a vital sign that appears abnormal or by technical problems of the Pulse Oximeter, are presented to the user by visual and audible alarm indications.

5.5.1 Alarm Categories

By nature, the pulse oximeter's alarms can be classified into three categories: physiological alarms, technical alarms and prompt messages.

1) Physiological alarms
Physiological alarms, also called patient status alarm, are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition.

2) Technical alarms
Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to improper operation or system problems.

3) Prompt messages
In fact, prompt messages are not alarm messages, which are displayed in the technical alarm area. Apart from the physiological and technical messages, the pulse oximeter will show some messages which indicate the system status.

5.5.2 Alarm Levels

By severity, the pulse oximeter's physiological alarms can be classified into three categories: high level alarms, medium level alarms and low level alarms.

1) High level alarms
Indicate that the patient is in a life threatening situation and an emergency treatment is demanded.

2) Medium level alarms
Indicate that the patient's vital signs appear abnormal and an immediate treatment is required.

3) Low level alarms
   Indicate that the patient's vital signs appear abnormal and an immediate treatment may be required.

5.5.3 Alarm Indicators

When an alarm occurs, the pulse oximeter will indicate it through the following indications:

- Alarm lamp
- Alarm tone
- Alarm message

For different alarm levels, the alarm lamp, alarm tone and alarm messages presented are different.

1) Alarm Lamp
   If a technical or a physiological alarm occurs, the alarm lamp will flash. The flashing color and frequency match the alarm level as follows:
   - High level alarms: the lamp quickly flashes red.
   - Medium level alarms the lamp slowly flashes yellow.
   - Low level alarms: the lamp turns yellow without flashing.

2) Alarm Tones
   When a technical or a physiological alarm occurs, the pulse oximeter presents different alarm tone patterns to match the alarm level:
   - High level alarms: triple + double + triple + double beep.
   - Medium level alarms: triple beep.
   - Low level alarms: single beep.

3) Alarm Messages
   When an alarm occurs, an alarm message will appear in the technical or physiological alarm area. This time lists only the most important physiological and technical alarm messages. In the tables below, "H" means high, "M" means medium and "L" means low. The "Cause and actions" column gives recommendations to instruct you to troubleshoot the problems. If the problem persists, contact your service personnel.

Physiological Alarm Messages

Alarm	Alarm Message	Alarm Level	Cause and actions
SpO2 Too Low	SPO2 reading will flash. Alarm lamp is red and flashing.	H	A measurement has risen above the high alarm limit or fallen below the low alarm limit. Check the patient's condition and check if the appropriate patient type setting is selected.
PR Too High	PR reading will flash. Alarm lamp is red and flashing.	H	
PR Too Low	PR reading will flash. Alarm lamp is red and flashing.	H	
No Pulse	PR and SPO2 reading is " - - ". Alarm lamp is red and flashing.	H	The pulse signal was too weak to be analyzed. Check the patient's condition, SpO2 sensor and measurement site.
Low Perfusion	Alarm lamp stays yellow. The screen will show "Low Perfusion"	L	The pulse signal was weak and please pay attention to sensor location and patient status.
Low signal Quality	Alarm lamp is yellow and flashing. The screen will show "Low Signal Quality"	M	The pulse signal was too weak , Check the patient's condition , SpO2 sensor and measurement site.

Technical Alarm Messages

Alarm	Alarm Message	Alarm Level	Cause and actions
Sensor Off	Alarm lamp is yellow and flashing. The screen will show "OFF"	M	The SpO2 sensor is not applied to the patient or not connected to the pulse oximeter, or there was a fault with the SpO2 sensor, or non-compatible SpO2 sensor was used. Check that the sensor application site and the sensor type are correct, and make sure that the sensor is undamaged. Reconnect the sensor if the sensor is disconnected or use a new sensor if the sensor is damaged, for example, the sensor cable is broken.

*NOTE:*When multiple alarms of different levels occur simultaneously, the pulse oximeter will select the alarm of the highest level and give visual and audible alarm indications accordingly.

5.6 Measurement Limitations

If you doubt the SpO2 measurements, check the patient's vital signs first. Then check the pulse oximeter and SpO2 sensor. The following factors may influence the accuracy of measurements:
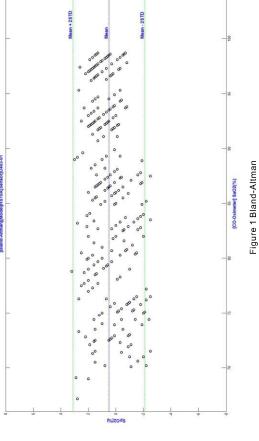
- Ambient light
- Physical movement (person or imposed motion)
- Diagnostic testing
- Low perfusion
- Electromagnetic interference, such as MRI environment
- Electrosurgical units
- Dysfunctional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
- Presence of certain dyes, such as methylene and indigo carmine
- Inappropriate positioning of the SpO2 sensor, or use of incorrect SpO2
- Drop of arterial blood flow to unmeasurable level due to shock, anemia, low temperature or vasoconstrictor.

6 Summary of Spo2 & pulse rate accuracy testing

1) According to ISO80601-2-61, the 300 data pairs (SPO2 VS SaO2) were obtained throughout the hypoxia breathe-down trials in all 12 volunteers.The SpO2 accuracy specification in the range of 70% to 100%,70% to 80%, 80% to 90%, and 90% to 100% is as the following table:

Pulse Oximeter	SPO2 Sensor	Arms			
		100%-70%	100% – 90%	90% - 80%	80% - 70%
594810	Adult	1.3910	1.2555	1.3774	1.5687

2) The data from the hypoxia breathe-down trials for each of the 12 volunteers is summarized in Figures 1&2:
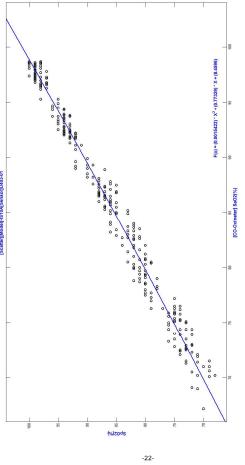
Figure 1 Bland-Altman

Figure 2 Linear Regression

3) The pulse rate accuracy as follows covers the entire pulse rate display range of 30~250bmp and spo2 range of 70~100%.

Pulse Oximeter	Sensor	Arms 25-250	Arms of each level Spo2				
			77% −70%	84% −78%	92% −85%	97% −92%	100% −97%
594810	Adult	1.20	1.17	1.00	0.67	1.33	1.83

The results above suggest that the SPO2 accuracy is within ±2% in range 70-100% and the pulse rate accuracy is less than ±3 in range 25~250 bpm, which meets the requirements of ISO80601-2-61.

7 Maintenance

7.1 Cleaning

⚠️ WARNING: Do not spray, pour, or spill any liquid on the 594810, its accessories, connectors, switches, or openings in the chassis as this may damage the pulse oximeter.

For surface-cleaning and disinfecting follow your institution's procedures or use the steps outlined below:

To surface clean the monitor:
1) Obtain a soft cloth.
2) Dampen the cloth with either a commercial, non-abrasive cleaner or a solution of 70% alcohol in water.
3) Lightly wipe each exterior surface using the dampened soft cloth.

To disinfect the monitor:
1) Saturate a soft cloth or wipe of hospital grade disinfectant (PDI, Cavicide, Sanizide, etc).
2) Lightly wipe each exterior surface using the saturated soft cloth.
Adhere to disinfectant manufacturer guidelines for efficacy and dry time

⚠️ Caution: Before attempting to clean a SpO2 sensor, read the directions for use enclosed with the sensor. Each sensor model has specific cleaning instructions.

7.2 Safety Checks

Before first use, or at least every two years, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the equipment:
- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.
- Inspect all sensor cables for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are used.

- Inspect if the alarm system functions correctly.
- Make sure that the batteries meet the performance requirements.
- Make sure that the pulse oximeter is in good working condition.

In case of any damage or abnormity, do not use the pulse oximeter. Contact your hospital's biomedical engineers or your service personnel immediately.

7.3 Disposal

Dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations. For the disposal of the SpO2 sensor, follow local regulations regarding disposal of hospital waste.

8 Accessories

WARNING

- Use only accessories specified in this manual. Using other accessories may cause damage to the pulse oximeter.
- Disposable accessories are designed for single-person use only. Reuse of them may cause a risk of contamination and affect the measurement accuracy.
- Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
- The SpO2 sensor mentioned in this chapter meet the bio-compatibility requirements and complies with ISO 10993-1, ISO 10993-5 and ISO10993-10 standards.
- Inspect the application site every 2 hours and relocate the sensor for ringer finger again (more frequently if perfusion is poor).
- It should change the measurement part per 2 hours when user continuing using for detecting.
- Do not immerse or wet the sensor.
- Do not lift the 594810 by the sensor cable because it could become disconnected and damage the oximeter.

Pulse Oximeter Probe Sensor Information

Model	Name	Testing position	Intended patient
594403	Reusable Adult Finger Clip SpO2 Sensor	Finger	Adult (≥88lb)
594301	Reusable Neonatal Wrap SpO2 Sensor	Foot, hand or finger	Child or Neonatal/Infant (Weight range)

Adult Finger Sensor Usager

1) Hold the sensor with its opening towards the patient's index or ring finger . The sensor should be oriented in such a way that the sensor side with a fingertip sign is positioned on the top.

2) Insert the patient's index or ring finger into the sensor until the fingernail tip rests against the stop at the end of the sensor. Adjust the finger to be placed evenly on the middle base of the sensor. Direct the cable along the top of the patient's hand.

3) Inspect the sensor site every 2 hours for skin integrity and relocate the sensor every 2 hours according to steps 1-2 .

Neonatal Y-Probe Wrap Sensor Usage

1) Attach the sensor to a well perfused fleshy portion of the infant's hand or foot.
2) Place the sensor to the patient with the light source (LED) on the top of the hand or foot.
3) Secure the sensor with the Hopkins® Adjustable Y-Probe Sensor Latex Free Belt and tighten gently. (Recommended) .
4) Apply a Hopkins® Y-Probe Wrap (#592012) on top to prevent ambient light interference. A secure wrap with the probe sensor centered in the middle of it will minimize any effects from ambient light sources. Other wraps can be used to secure lead wires to minimize the movement of the sensor itself. (Recommended)

IMPORTANT! LED Sensors are light sensitive. Use Hopkins® Y-Probe wrap on top of the Adjustable Y-Probe Sensor with belt to better secure the probe.

Inspect the sensor site every 2 hours for skin integrity and relocate the sensor every 2 hours according to steps 1-4 .

9 Specifications

Environmental specifications	Operating conditions	Storage conditions
Temperature	5 to 40°C(41 to 104°F)	-20 to 60°C(-4 to 140°F)
Relative humidity (non-condensing)	15% to 95%	15% to 95%
Hardware specifications		
Display	Color LCD, 2.4"	
Power indicating lamp	1.lighting green and yellow	
Loudspeaker	1.Gives audible alarm (45 to 85dB) and button tone; Supports Pitch Tone and multi-level volume.	
Alarm indicating lamp	1. lighting red and yellow	
Sensor connector	1.9-pin type D connector	
Power supply connector	1. used to connecting the Charger stand	
Communication port	No	
Data storage	No	
Shelf life	5 Years	
Alkaline batteries		
Quantity	3	
Specification	1.5 V, AA	
Specification	2000 mAh	
Run time	22 hours with SpO2 monitored continuously,audio indicators off and backlight brightness set to minimum using a new,fully charged battery at ambient temperature 25 ℃	
Shutdown delay	Max. 10 minutes after the low battery alarm first occurs	
Measurement specifications		
Spo2		
Display Range	1 to 100%	
Resolution	1%	
Accuracy	70 to 100%: ±2% (measured without motion) 0% to 69%: Unspecified	

PR	
Display Range	25 to 250 bpm
Resolution	1 bpm
Accuracy	25 to 250bpm:±3 bpm (measured without motion)
Refreshing rate	1 s
Physical specifications	
Width × Height × Depth	56×124×30 mm
Max. weight	about 300g (full configuration, including the batteries)

10 EMC information

The device meets the requirements of IEC 60601-1-2:2007.

Guidance and Declaration - Electromagnetic Emissions		
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment - guidance**
Radio frequency (RF) emissions CISPR 11	Group 1	The 594810 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radio frequency (RF) emissions CISPR 11	Class A	The 594810 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions 61000-3-3	Not applicable	

Guidance and Declaration - Electromagnetic Immunity			
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/ burst(EFT) IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines (>3m)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 594810 requires continued operation during power mains interruptions, it is recommended that the 594810 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity		
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity tests	**IEC 60601 test level**	**Compliance level**
Conduced RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	NA
Radiated RF IEC 61000-4-3	3 V/m 80M MHz to 2.5GHz	3 V/m.
Electromagnetic environment - guidance		

Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.Recommended Separation Distance:

$$d = 1.2 \sqrt{P}$$

$$d = 1.2 \sqrt{P} \quad \text{80 MHz to 800 MHz}$$

$$d = 2.3 \sqrt{P} \quad \text{800 MHz to 2,5 GHz}$$

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey , should be less than the compliance level in each frequency rang b.Interference may occur in the vicinity of equipment marked with the symbol

Note 1: From 80 MHz to 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b: Over the frequency range from 150kHz to 80MHz, field strengths should be less than 3V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and The device			
The device is suitable for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.			
Rated Maximum Output power of Transmitter (W)	**Separation Distance (m) Corresponding to Frequency of Transmitter**		
	150k to 80MHz $d = 1.16 \sqrt{P}$	80M to 800MHz $d = 1.16 \sqrt{P}$	800M to 2.5GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *Note 1:* From 80 MHz to 800 MHz, the higher frequency range applies. *Note 2:* These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

11 Warranty

Limited Warranty
Your Hopkins® Handheld Pulse Oximeter is guaranteed for 2 years against manufacturer's defects in material and workmanship for the original purchaser only, from the date of purchase. The warranty does not apply to damage caused by improper handling, accident, not following the operating instructions, normal wear, or alterations made to the instrument.

Battery corrosion is not covered by warranty.
Please remove the batteries during prolonged periods of non-use or storage (longer than 5 days). If a material or manufacturing defect is discovered during the warranty period, Hopkins Medical Products® will repair or replace, at no charge, the device.

Register your product online:
www.hopkinsmedicalproducts.com/registration
For questions or concerns, contact:
customerservice@hopkinsmedical.net
1-800-835-1995

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