MQ3200

Deluxe Fingertip Pulse Oximeter

USER MANUAL

MEDQUIP drive™

Instructions to User

Dear Users, thank you very much for purchasing our product.
This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. The Manual is written for the current Pulse Oximeter. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.
The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.
Please read the Manual very carefully before using this equipment. These instructions describe the operating procedures to be followed strictly, failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.
Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.
This product is medical device, and can be used repeatedly. Its using life is 3 years.

WARNING:
☞The uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.
☞For the individual patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.
☞The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man, can not stare at the light.
☞Testee can not use enamel or other makeup.
☞Testee's fingernail can not be too long.
☞Please peruse the relative content about the clinical restrictions and caution.
☞This device is not intended for treatment.

1 Safety

1.1 Instructions for Safe Operations

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User's Manual.Only the accessory that appointed or recommendatory by manufacture can be used with this device.
- This product is calibrated before leaving factory.

1.2 Warnings

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the testee measured by MRI and CT.
- The person who is allergic to rubber can not use this device.
- The disposal of scrap instrument and its accessories and packings(including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
- Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.
- Please don't measure this device with function test paper for the device's related information.

1.3 Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- DO NOT operate keys on front panel with sharp materials.
- High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter for instructions of cleaning and disinfection.
- Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60℃.
- As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients' SpO_2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- Do not use the device on infant or neonatal patients.
- The product is suitable for children above four years old and adults(Weight should be between 15kg to 110kg).
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- The waveform is normalized.Please read the measured value when the waveform on screen is equably and steady-going, Here this measured value is optimal value. And the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal useful life for three years since the first electrified use.
- The hanging rope attached the product is made from Non- allergy material, if particular group are sensitive to the hanging rope, stop using it. In addition, pay attention to the use of the hanging rope , do not wear it around the neck avoiding cause harm to the patient.
- The instrument dose not have low-voltage alarm function, it only shows the low-voltage,please change the battery when the battery energy is used out.
- When the parameter is particularly, The instrument dose not have alarm function.Do not use the device in situations where alarms are required.
- Batteries must be removed if the device is going to be stored for more than one month, or else batteries may leak.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

2 Overview

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration. For the purpose of measuring the SpO_2 more easily and accurately, our company developed the Pulse Oximeter. At the same time, the device can measure the pulse rate simultaneously.
The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of SpO_2.

2.1 Classification:

Class II b(MDD93/42/EEC IX Rule 10)
Class II (U.S.FDA)

2.2 Features

- Operation of the product is simple and convenient.
- The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying.
- Power consumption of the product is low and the two originally equipped AAA batteries can be operated continuously for 20 hours.
- The product will automatically be powered off when no signal is in the product within 5 seconds.

2.3 Major Applications and Scope of Application

The Pulse Oximeter can be used to measure human Hemoglobin Saturation and pulse rate through finger, and indicate the pulse intensity by the bar-display. The product is suitable for use in family, hospital(Ordinary sickroom), Oxygen Bar, social medical organizations and also the measure of saturation oxygen and pulse rate.

⚠ **The product is not suitable for use in continuous supervision for patients.**

⚠ **The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.4 Environment Requirements

Storage Environment
a) Temperature :-40℃~+60℃
b) Relative humidity :≤95%
c) Atmospheric pressure :500hPa~1060hPa
Operating Environment
a) Temperature:10℃~40℃
b) Relative Humidity :≤75%
c) Atmospheric pressure:700hPa~1060hPa

3 Principle and Caution

3.1 Principle of Measurement

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

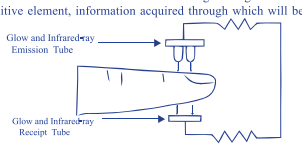

Figure 1. Operating Principle

3.2 Caution

1. The finger should be placed properly (see the attached illustration of this manual ,Figure 5), or else it may cause inaccurate measurement.
2. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
3. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
4. Make sure the optical path is free from any optical obstacles like rubberized fabric.
5. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
6. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
7. Testee can not use enamel or other makeup.

3.3 Clinical Restrictions

1. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.
3. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measure.
4. As the SpO_2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

4 Technical Specifications

1. **Display Format:** OLED Display;
   SpO_2 Measuring Range: 0% - 100%;
   Pulse Rate Measuring Range: 30 bpm - 250 bpm;
   Pulse Wave Display: columniation display and the waveform display.
2. **Power Requirements:** 2 ×1.5V AAA alkaline battery(or using the rechargeable battery instead), adaptable range: 2.6V~3.6V.
3. **Power Consumption:** Smaller than 30mA.
4. **Resolution:** 1% for SpO_2 and 1 bpm for Pulse Rate.
5. **Measurement Accuracy:** ±2% in stage of 70%-100% SpO_2, and meaningless when stage being smaller than 70%. ±2 bpm or±2% (select larger) for Pulse Rate.
6. **Measurement Performance in Weak Filling Condition:** SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).
7. **Resistance to surrounding light:** The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.
8. It is equipped with a function switch. The Oximeter can be powered off in case no finger is the Oximeter within 5 seconds.
9. **Optical Sensor**
   Red light (wavelength is 660nm, 6.65mW)
   Infrared (wavelength is 880nm, 6.75mW)

5 Accessories

- One hanging rope;
- Two batteries (optional);
- One User Manual.

6 Installation

6.1 View of the Front Panel

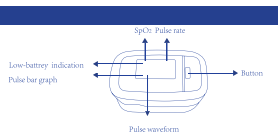

Figure 2. Front View

6.2 Battery

Step 1. Refer to Figure 3. and insert the two AAA size batteries properly in the right direction.
Step 2. Replace the cover.

⚠ **Please take care when you insert the batteries for the improper insertion may damage the device.**

Figure 3. Batteries Installation

6.3 Mounting the Hanging Rope

Step 1. Put the end of the rope through the hole.
Step 2. Put another end of the rope through the first one and then tighten it.

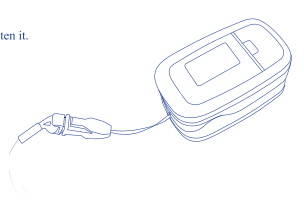

Figure 4. Mounting the hanging rope

7 Operating Guide

7.1 Insert the two batteries properly to the direction, and then replace the cover.
7.2 Open the clip as shown in Figure 5.

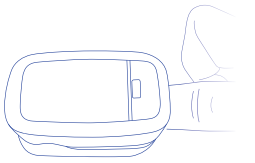

Figure 5. Put finger in position

7.3 Let the patient's finger put into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
7.4 Press the switch button once on front panel.
7.5 Do not shake the finger and keep the patient at ease during the process. Meanwhile, human body is not recommended in movement status.
7.6 Get the information directly from screen display.
7.7 The button has three functions.When the device is power off, pressing the button can open it; When the device is power on, pressing the button shortly can change direction of the screen; When the device is power on, pressing the button long can change brightness of the screen.

⚠ **Fingernails and the luminescent tube should be on the same side.**

8 Repairing and Maintenance

- Please change the batteries when the low-voltage displayed on the screen.
- Please clean the surface of the device before using. Wipe the device with medical alcohol first, and then let it dry in air or clean it by dry clean fabric.
- Using the medical alcohol to disinfect the product after use, prevent from cross infection for next time use.
- Please take out the batteries if the oximeter is not in use for a long time.
- The best storage environment of the device is - 40ºC to 60ºC ambient temperature and not higher than 95% relative humidity.
- Users are advised to calibrate the device termly (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

⚠ **High-pressure sterilization cannot be used on the device.**

⚠ **Do not immerse the device in liquid.**

⚠ **It is recommended that the device should be kept in a dry environment. Humidity may reduce the useful life of the device, or even damage it.**

9 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm
The device can not be turned on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The malfunction of the device.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The display is off suddenly	1. The device will power off automatically when it gets no signal within 5 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

10 Key of Symbols

Symbol	Description
	Type BF
	Warning – See User Manual
%Sp02	The pulse oxygen saturation(%)
PRbpm	Pulse rate (bpm)
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)
	1. no finger inserted 2. An indicator of signal inadequacy
	battery positive electrode
	battery cathode
	1.Power switch 2.change direction of the screen 3.Change brightness of the screen
SN	Serial number
	Alarm inhibit
	WEEE (2002/96/EC)
IP22	Ingress of liquids rank

11 Function Specification

Display Information	Display Mode
The Pulse Oxygen Saturation(SpO_2)	OLED
Pulse Rate(PR)	OLED
Pulse Intensity (bar-graph)	OLED bar-graph display
Pulse wave	OLED
SpO_2 Parameter Specification	
Measuring range	0%~100%, (the resolution is 1%).
Accuracy	70%~100%: ±2% ,Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660nm) Infrared (wavelength is 880nm)
Pulse Parameter Specification	
Measuring range	30bpm~250bpm (the resolution is 1 bpm)
Accuracy	±2bpm or±2% select larger
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 or rechargeable battery	
Battery Useful Life	
Two batteries can work continually for 20 hours	
Dimensions and Weight	
Dimensions	61(L) × 36(W) × 32(H) mm
Weight	About 57g (with the batteries)

Manual de Usuario

ADVERTENCIA:
Puede aparecer una sensación de incomodidad o dolor si se usa el equipo por períodos prolongados; especialmente en el caso de pacientes con problemas de microcirculación. Se recomienda que el sensor no se utilice en el mismo dedo durante más de 2 horas.
En el caso de pacientes especiales debe realizarse una inspección más prudente de la zona sobre la que se hará la medición. El equipo no debe ponerse en contacto con tejido blando o edematoso.
La luz (el infrarrojo es invisible) emitida por el dispositivo es dañina para los ojos, el usuario y el encargado del mantenimiento no debe mirar fijamente a la luz
La persona sujeta a la prueba no debe usar esmalte de uñas u otros cosméticos.
La uña de la persona sujeta a la prueba no debe estar muy crecida.
Por favor lea cuidadosamente el contenido relativo a restricciones clínicas y precauciones.
No está contemplado el uso de este equipo para tratamiento.

1 Resumen

1.1 Aplicaciones Principales y Restricciones de Uso

El producto es adecuado para su uso en hogares, hospitales, bares de oxígeno, tratamiento médico comunitario y medicina deportiva (se aconseja que se emplee antes y después de la actividad deportiva, no durante la misma)

El producto no es adecuado para su uso como herramienta de supervisión continua en pacientes.

Los valores de medición se sobreestimarán si el paciente sufre de intoxicación por monóxido de carbono, no se recomienda emplear el equipo bajo estas circunstancias.

1.2 Parámetros Ambientales
Ambiente de Almacenamiento
a) Temperatura: -40ºC ~ +60ºC
b) Humedad relativa :≤95%
c) Presión atmosférica: 500hPa~1060hPa
Ambiente de Operación
a) Temperatura: 10ºC ~ 40ºC
b) Humedad relativa :≤75%
c) Presión atmosférica: 700hPa~1060hPa

1.3 Seguridad
1.3.1 Advertencias
- Riesgo de explosión – NO USE el oxímetro en un ambiente con gases inflamables, como es el caso, por ejemplo, de algunos agentes anestésicos.
- NO USE el oxímetro cuando se están realizando MRI y CT en la persona sujeta a prueba.
- No rompa la cuerda de soporte, no la coloque en el cuello o el equipo podría romperse debido a una ruptura en la cuerda. La persona alérgica a la cuerda no puede utilizar este equipo.
- La persona alérgica al caucho no puede utilizar este equipo.

1.3.2 Observaciones
- Mantenga el oxímetro alejado del polvo, vibraciones, sustancias corrosivas, materiales explosivos, altas temperaturas y humedad.
- Si el oxímetro se moja, por favor deje de utilizarlo.
- Cuando se transporte de un ambiente frío a un ambiente caluroso o húmedo, por favor no utilizar inmediatamente el equipo.
- NO presione las teclas del panel frontal con materiales punzantes.
- No se debe desinfectar al oxímetro con alta temperatura o vapor a presión alta. Vea el Manual de usuario en el capítulo concerniente a las instrucciones de limpieza y desinfección.
- No sumerja al oxímetro en líquido. Cuando necesite limpiarlo, por favor impregne su superficie con alcohol medicinal utilizando algún material suave. No aplique directamente con un aspersor ningún líquido sobre el equipo.
- Al limpiar el equipo con agua, la temperatura debe ser menor de 60ºC.
- Si los dedos fuesen muy delgados, o estuviesen muy fríos, la medición normal de SpO2 y del pulso del paciente probablemente se vería afectada, por favor asegure el dedo más grueso al sensor (pulgar o dedo medio) a suficiente profundidad.
- No utilice el equipo en niños muy pequeños o en neonatos.
- El equipo es apropiado para su uso en niños mayores de cuatro años y en adultos (el peso debe estar entre 15kg y 110kg).
- Es posible que el equipo no funcione en todos los pacientes. Si no pudiese obtener mediciones estables, por favor deje de utilizarlo.
- Los datos se actualizan con una frecuencia menor a los 5 segundos, esto puede variar según el pulso de los diferentes individuos.
- La onda se encuentra normalizada. Por favor, tome el valor de medición cuando la onda en la pantalla se mantenga con regularidad, es en este momento que el valor de medición es óptimo; la onda en ese momento es la estándar.
- Si apareciesen algunas condiciones anormales en la pantalla durante el proceso de realización de la prueba, retire el dedo y reinsértelo para recobrar el uso normal.
- El equipo tiene un período normal de vida útil de tres años desde el momento del encendido.
- La cuerda de soporte que viene con el equipo está hecha con material no alergénico, si un grupo específico es sensible a la cuerda de soporte, suspenda el uso. Tenga cuidado, además, de no colocar la cuerda de soporte alrededor del cuello PARA evitar causar daños al paciente.
- El instrumento no tiene una función de alarma de bajo voltaje, solo una indicación de bajo voltaje en pantalla, por favor cambie la batería cuando la energía de la misma se agote.
- El equipo no tiene una función de alarma por exceso de uso. No emplee el equipo en situaciones que requieran alarmas.
- Deben removerse las baterías si el equipo se va a almacenar durante más de un mes, de lo contrario, las baterías podrían presentar fugas.
- Un circuito flexible conecta las dos partes del equipo. No tuerza o tire de la conexión.

2 Especificaciones Técnicas

2.1 Funcionamiento
1)Representación del valor de SpO_2
2)Valor del pulso, representación en gráfico de barras
3)Representación de onda
4)Indicación de batería baja: cuando el voltaje es muy bajo para la operación aparece la indicación de capacidad de la batería.
5)Función de apagado automático: El equipo se apagará automáticamente cuando no reciba señal durante 5 segundos.
6)Puede cambiarse el formato de representación en pantalla.

2.2 Parámetros Principales
1) **Medición de SpO_2**
Rango: 0%~100%
Precisión: ±2% en el rango de 70%-100% de SpO2 y no estimable si la medición está por debajo de 70%.
2) **Medición del Pulso**
Rango: 30 bpm - 250 bpm;
Precisión: ±2 lpm or±2% (considere el mayor valor)
3) **Resolución:** 1% para la SpO2 y 1 lpm
4) **Resistencia a la luz ambiental:** La desviación entre el valor medido bajo condiciones de luz artificial o de luz natural interior, con respecto al valor medido en un cuarto oscuro es menor de ±1%.
5) **Voltaje de Operación**: DC 2.6V~3.6V.

3 Instalación

3.1 Vista del Panel Frontal

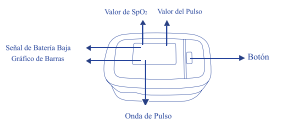

Figura 1 Vista Frontal

3.2 Instalación de la Batería
1) Remítase a la Figura 3 e inserte dos baterías AAA apropiadamente y en la dirección correcta.
2) Vuelva a colocar la cubierta.

Coloque las baterías con cuidado ya que una inserción inapropiada podría dañar el equipo

Figura 2 Instalación de las Baterías

3.3 Montaje de la Cuerda de Soporte

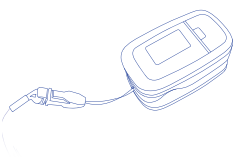

Figura 3 Montaje de la cuerda de soporte

1) Coloque un extremo de la cuerda a través del agujero.
2) Haga pasar el otro extremo de la cuerda a través del primero y ajuste.

3.4 Accesorios
1) Una cuerda de soporte;
2) Dos baterías (opcional);
3) Un Manual de Usuario.

4 Guía de Operación

4.1 Método de Operación
1) Inserte las dos baterías según la dirección correcta y luego recoloque la cubierta.

Por favor coloque las baterías con cuidado ya que una inserción inapropiada podría dañar el equipo.

2)Abra el clip en la posición mostrada en la Figura 6.
3)El dedo del paciente debe reposar en los rebordes de caucho del clip (asegúrese de que el dedo está en la posición correcta) y luego asegure el dedo al clip.

a.Presione una vez el botón en el panel frontal.
b.No mueva el dedo y mantenga al paciente quieto durante el proceso de medición. No se recomienda que el cuerpo del paciente o del sujeto de la prueba esté en movimiento.
4)Recabe la información directamente de la pantalla.
5)Durante el funcionamiento presione brevemente este botón para cambiar la dirección de la pantalla.
6)Durante el funcionamiento mantenga presionando este botón para cambiar el brillo de la pantalla.

Las uñas y el tubo luminiscente deben estar del mismo lado.

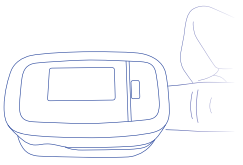

Figura 4 Coloque el dedo en posición

4.2. Precauciones
1) Antes de usar por favor verifique completamente el equipo para asegurar de que pueda trabajar normalmente
2) El dedo debe colocarse adecuadamente (ver la ilustración adjunta en este manual, Figura 6), caso contrario las mediciones pueden resultar imprecisas.
3) El sensor de SpO2 y el conducto receptor fotoeléctrico deben disponerse en tal forma que la arteriola de la persona que se realiza la prueba debe quedar entre ellos.
4) El sensor de SpO_2 no debe emplearse en una ubicación o extremidad conectada a una cánula arterial, ligada a un tensiómetro o que esté recibiendo inyección intravenosa.
5) Asegúrese de que la trayectoria óptica esté libre de cualquier obstáculo óptico como tela recubierta de caucho; de otra forma esto podría producir imprecisiones en la medición de SpO_2 y del pulso.
6) Una excesiva luz ambiental puede afectar el resultado de la medición. Esto incluye lámparas fluorescentes, luces duales de rubí, calefactores infrarrojos, luz directa del sol, etc.
7) Actividades enérgicas por parte de la persona sujeta a la prueba o interferencia electro quirúrgica extrema también podrían afectar la medición.
8) La persona sujeta a la prueba no debe usar esmalte de uñas u otros cosméticos.

4.3 Restricciones Clínicas
1) Como la medida se toma en base al pulso arterial se requiere un flujo de sangre pulsante sustancial en la persona sujeta a la prueba. En caso de una persona con un pulso débil debido a shock, baja temperatura ambiente o corporal, hemorragia importante o empleo de fármacos vasoconstrictores, la onda de SpO_2 (PLETH) disminuirá. En este caso la medición será más sensible a la interferencia.
2) En aquellas personas bajo los efectos de un cantidad importante de fármacos de tinción (tales como azul de metileno, verde índigo y azul índigo ácido) o de carboxihemoglobina (COHb), metahemoglobina (Me+Hb) o hemoglobina tiosalicílica, y en aquellas personas con problemas ictéricos, este equipo podría arrojar resultados inexactos.
3) Fármacos como dopamina, procaína, prilocaína, y butacaína podrían ser también factores importantes que produzcan errores importantes en la medición de SpO2.
4) Ya que el valor de SpO2 sirve como valor de referencia para el diagnóstico de anoxia anémica y anoxia tóxica, algunas pacientes con anemia severa pueden reportar también un buen valor de medición de SpO2.

5 Leyenda de los Símbolos

Símbolo	Descripción
⚠	Advertencia – Vea el Manual de Usuario
$\%SpO_2$	La saturación de oxigeno detectada a través del pulso (%)
PRbpm	Pulso o frecuencia cardiaca (lpm)
▭	El voltaje de la batería es deficiente (reemplace la batería para evitar mediciones inexactas)
+	Ánodo de la batería
▬	Cátodo de la batería
⏻	Botón de encendido/ botón de funciones
IP22	Grado de Protección

6 Especificaciones de Funcionamiento

Información en Pantalla	**Modo de Representación**
Saturación de Oxigeno en Pulso (SpO_2)	Dos dígitos Representación OLED
Pulso (PR)	Tres dígitos Representación OLED
Intensidad del Pulso (gráfico de barras)	Representación en gráfico de barras OLED
Especificación del Parámetro de SpO_2	
Rango de la Medición	0%~100%, (la resolución es 1%).
Precisión	70%~100%: ±2%, Por debajo de 70% no estimable.
Especificación de Parámetro de Pulso	
Rango de la Medición	30bpm~250 lpm (la resolución es de 1 lpm)
Precisión	±2bpm o ±2% considere el mayor valor
Tipo de Seguridad	Equipo alimentado internamente: Tipo BF Equipo en contacto en el cuerpo
Rango de la Intensidad del Pulso	
	Barra de gráficos continua, cuanto más alta se muestre más fuerte es el pulso.
Baterías Requeridas	
2 baterías alcalinas de 1.5 V (tamaño AAA) o baterías recargables	
Vida Útil de la Batería	
2 baterías alcalinas de 1.5 V, 600mAh (tamaño AAA) pueden funcionar durante 32 horas continuas	
Dimensiones y Peso	
Dimensiones	61(L) × 36(A) × 32(H) mm
Peso	Aproximadamente 60 g (incluyendo las baterías)

Appendix

Guidance and manufacture's declaration-electromagnetic emission for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration –electromagnetic emission

The *CMS50D1 Pulse Oximeter* is tended for use in the electromagnetic environment specified below. The customer of the user of the *CMS50D1 Pulse Oximeter* should assure that it isused in such an environment.

Emission test	**compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The *CMS50D1 Pulse Oximeter* uses RF energy only for their internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *CMS50D1 Pulse Oximeter* is suitable for use in all establishments,including domestic establishments 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 emission IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration-electromagnetic immunity

The *CMS50D1 Pulse Oximeter* is intended for use in the electromagnetic environment specified specified below. The the user of *CMS50D1 Pulse Oximeter* should assure that it is used in such an environment.

Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Guidance and manufacture's declaration-electromagnetic immunity for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration-electromagnetic immunity

The *CMS50D1 Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of *CMS50D1 Pulse Oximeter* should assure that it is used in such an environment.

Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Radiated RF ICE 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Portable and mobile RF communication equipment should be used no closer to any part of the *CMS50D1 Pulse Oximeter*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **recommended separation distance** $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.5GHz 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, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80MHz and 800MHz, 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 broadcastcannot 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 CMS50D1 Pulse Oximeter is used exceeds the applicable RF compliance level above, the CMS50D1 Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CMS50D1 Pulse Oximeter.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM for EQUIPMENT or SYSTEM that not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the CMS50D1 Pulse Oximeter

The *CMS50D1 Pulse Oximeter* is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *CMS50D1 Pulse Oximeter* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *CMS50D1 Pulse Oximeter* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150KHz to 80MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	80MHz to 800MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800MHz to 2.5GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80MHz and 800MHz, the separation distance for 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.

Warranty

Your Drive brand product is warranted to be free of defects in materials and workmanship for two years from the original purchase date.

The device was built to exacting standards and carefully inspected prior to shipment. This two year Limited Liability warranty is an expression of our confidence in the materials and workmanship of our products and our assurance to the consumer of years of dependable service. In the event of a defect covered by this warranty, we will at option, repair or replace the device.

This warranty does not cover device failure due to owner misuse or negligence, or normal wear and tear. If you have questions about your Drive device, or this warranty, please contact an authorized Drive Medical provider.

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Manufactured for & distributed by:

Drive Medical
99 Seaview Boulevard
Port Washington, NY 11050

Phone: 1-877-224-0946
Fax: 516-998-4601

www.drivemedical.com

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