INMED

Pulse Oximeter

# Operator's Manual

Model: F-120

*Section 1*

## Safety

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

• Do not attempt to service the Pulse Oximeter. Only qualified service personnel should attempt any needed internal servicing.

• Prolonged use or 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. Keep away from direct sunlight.

The following reason will cause interference to the testing accuracy of the pulse oximeter.

- High-frequency electrosurgical equipment.
- Placement of a sensor on an extremity with a blood pressure cuff arterial catheter, or intravascular line.
- The patient has hypotension severe vasoconstriction severe anemia 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 F120 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

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

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

***WARNING:*** Do not use the pulse oximeter in an MRI or CT environment.

***WARNING:*** Do not modify this equipment without authorization 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 extreme temperature and humidity.

***CAUTION:*** Do not operate the unit if it is damp or wet because of condensation or spills. 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 a long time.

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

***CAUTION:*** The batteries must be proper disposed according to local regulation after their use.

***CAUTION:*** The device should keep away from the children, pets and pests 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 |
| *Warning* | The information you should know to protect patients and medical staff from possible injury |
| *Caution* | The information you should know to protect the equipment from possible damage |
| *Note* | 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:

- Brief device description
- Product features

*2.2 Brief Device Description*

Pulse oximeter, based on all digital technology, is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2). Advanced DSP algorithm* can minimize the influence of motion artifact and improve measurement accuracy of low perfusion*.

The Oximeter can be used to measure human Hemoglobin Saturation and heart rate through finger. The product is suitable for use in family, hospital (including clinical use in internist/surgery, Anesthesia, pediatrics, intensive care and etc.) Oxygen Bar, social medical organizations, physical care in sports and etc.

*2.3 Product Features*

• Lightweight for carrying and Easy-To-Use.

• Manually adjust the direction of interface .

• Color OLED display, simultaneous display for testing value and plethysmogram*.

• Low Perfusion:0.2%. (Advanced DSP algorithm can inprove measurement accuracy, under the condition of low perfusion.)

• Visual & Sound alarm function. Real-time spot-checks.

• Low Battery voltage indicator.

• Automatically switch off.

• Standard two AAA 1.5V Alkaline Battery support more than 20 hours continuous work.

***CAUTION:*** The device can't used to measure the child below 1 year as the result is not guarantee too 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.

***CAUTION:*** A function tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

Clinical testing is used to establish the SpO2 accuracy. The measured arterial hemoglobin saturation value (SpO2) of the sensor is compared to arterial hemoglobin oxygen(SaO2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO2 range of 70 -100%. Accuracy data is calculated using the root-mean-square(Arms value) for all subjects. Only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±Arms of the value measured by a CO-Oximeter.

Pulse rate Accuracy shall be used pulse simulator to assess. The measured pulse rate is compared to the preset pulse rate value in simulator. Accuracy data is calculated using the root-mean-square (Arms value) for all subjects.

***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 is low-accurate.

***Plethysmograph:** is an 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).

**PI (Perfusion Index )** is the ratio of the pulsatile blood flow to the non-pulsatile static blood flow in a patient's peripheral tissue, such as finger tip, toe, or ear lobe. Perfusion index is an indication of the pulse strength at the sensor site.

*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 Definition and Description

| Item | Name | Description |
|---|---|---|
| 1 | Power button | Turn on/off the machine |
| 2 | Direction button | Direction change& Parameter setting in menu |
| 3 | OLED Panel | Display the SPO2/PR data&Plethysmogram |
| 4 | Battery Com-partment | |

*3.2 Display*

After switch on, the OLED display of A320 is as follows:

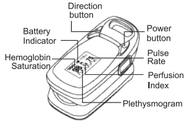



Figure 3.2.1 OLED display

*3.3 Parameter setting*

Press the direction button (“M”) for one second (for 1s), the oximeter will enter into parameter setting. There are two submenu for choice:

When the * signal shown on the Alarm Setup, press “M” for 1s and enter into the Sound Setting menu (figure 3.3.1), press “M” for 1s to turn on/off for the alarm and beep.

When the * signal shown on the Sounds Setup, press “M” for 1s and enter into the Alarm Setting menu(figure 3.3.2), you can press “M” in turn to select the item. And press “M” for 1s to change the data you need.

On the Sounds Setup menu (figure 3.3.1), when the * signal shown on front of the “+/-”, sign “+” on the right side can be changed to “-”, by pressing “M” for 1s, When “-” shows on the right side, press “M” for 1s can increase the SPO2 and PR's highest and lowest alarm value. When “-” shows on the right side, press “M” for 1s can reduce the SPO2 and PR's highest and lowest alarm value.

On the Alarm Setup menu (figure 3.3.2). When the * signal shown on ” Restore”, press “M” for 1s, the right side can be changed to “OK”, which cause the device to restore factory setting data.


Figure3.3.1


Figure 3.3.2

***Note:***

1.The alarm have 1 second delay after the incorrect result being detected.

2. The customer can preset the alarm value to the 98 or 99 to check whether it is normal for alarm setting.

*3.4 Operation*

*3.4.1 Install battery*

Installing two AAA batteries into battery cassette in correct polarities and cover it.

***WARNING:*** Do not attempt to recharge normal alkaline batteries, they may leak and may cause a fire or even explode.

*3.4.2 Turn the Pulse Oximeter on*

Put one of fingers into rubber hole of the Oximeter (it is best to put the finger thoroughly) with nail surface upward, then releasing the clamp.

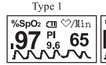
Press power button for 2 seconds to turn the Pulse Oximeter on.

*3.4.3. Read correspondent data from display screen.*

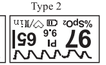
*3.4.4 Display Description of OLED*

The display interface of “OLED” can rotate four directions with six different display modes after pressing the direction button. It is shown as below:

Type 1




Type 2

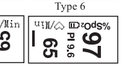



Type 3


Type 4


Type 5


Type 6




***Note:***

1. When battery power is at lowest level, the battery capacity indicates symbol of “ ”in OLED, remind users of replacement of battery.

2. The plethysmogram can been regarded as correct if the wave is fluctuated regularly.

*Section 4*

## Cleaning and Disinfection

*4.1 Cleaning*

Switch off the power and take out the batteries before cleaning. Keep the exterior surface of the device clean and free of dust and dirt. Cleaning exterior surface (OLED display screen included) of the unit with a dry and soft cloth. Use 75% density of medical alcohol to clean the surface and use dry fabric with little alcohol to avoid alcohol permeates into the device.

*4.2 Disinfection*

Disinfecting the machine after using by the patient if multiple patient use the machine in the hospital.

Use 75% density of medical alcohol to clean the surface that contacting with the patient.

***CAUTION:*** Don't use strong solvent. For example, 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 liquids on the device while cleaning.

***CAUTION:*** Don't remain any cleaning solution on the surface of the device.

*Section 5*

## Troubleshooting and Maintenance

*5.1 Maintenance*

• Replace the batteries timely when battery indication is low.Clean surface of the Pulse Oximeter before it is used in diagnosis for patients

• Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.

• It is better to preserve the product in a place where ambient temperature is -10-40℃ and humidity is 10%-80%.

• Regular inspection to make sure that no obvious damage existed to affect the safety and performance of device.

• No flammable substance, overtop or lower temperature and humidity existed in operation conditions.

*5.2 Troubleshooting*

Table 5.2.1 troubleshooting

| Problems | Possible Reason | Resolutions |
|---|---|---|
| Oxyhemoglobin or heart rate can not be shown normally | 1.Finger is not inserted correctly. 2.Patient's perfusion is too low to be measured. | 1.Retry by inserting the finger 2.Try some more times, If you can make sure about no problem existing in the product, Please go to a hospital timely for exact diagnosis |
| Oxyhemoglobin or heart rate is shown unstable | 1. Finger might not be inserted deep enough 2. Finger is trembling or patient's body is in movement status | 1.Retry by inserting the finger 2.Try not to move, Let the patient keep calm. |
| The screen are suddenly off | 1 The product is automatically powered off when no signal is detected longer than 8 seconds 2.Power quantity of the batteries is exhausted. | 1. Normal 2. Replace the batteries |

*Section 6*

## Specification

Pulse Oximeter Specifications:

Physical Characteristics

Machine:

Dimensions

–74 mm (L) x 37mm (W) x 38mm (D)

Weight

– approx: 55 g

（including 2 xAAA battery）

Outer box:

Dimensions

–490mm (L) X370mm (W) X240mm (H)

Gross Weight: 9.7 kg

Classification ：

Anti-electric Shock Type : Internally powered equipment

Anti-electric Shock Degree : Type BF equipment

EMC : Type B

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 | 2xAAA 1.5v Alkaline battery |
| Power Consumption | Smaller than 30mA (Normal) |

Environmental

| | |
|---|---|
| Operating Temperature | 5°C to 40°C |
| Storage Temperature | －10°C to 50°C |
| Relative Humidity | 15% to 80% non-condensing |
| Air Pressure | 86Kpa-106Kpa |
| Operating Attitude | 0-2000 m |

Alarm default value

| Parameter | Value |
|---|---|
| Hemoglobin saturation | Upper limit: 100/ bottom limit:90 |
| Pulse rate | Upper limit: 130 / bottom 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 |
|---|---|---|
| Hemoglobin saturation display | | 35-100% |
| Pulse rate Display | | 30-250 BPM |
| Resolution | Hemoglobin Saturation | 1% |
| | Pulse rate | 1 BPM |
| Measure Accuracy | Hemoglobin Saturation | ±3% (70%-100%) unspecified(<70%) |
| | Pulse rate | ±1 BPM |

INMED

## Product Warranty

| |
|---|
| NAME: |
| ADDRESS: |
| MODEL: Inmed FInger Pulse Oximeter F-120 |
| PURCHASED FROM: |
| DATE OF PURCHASE: |
| REGISTRATION DATE: |

Inmed Corporation warrants this product to be free from defects in material or workmanship within the specified warranty period under normal use. If fault is found, please return the equipment to the store where product was purchased. Inmed Corporation will repair or replace any defective part free of charge subject to the terms and conditions stated herein.

*For service, the unit is to be returned freight prepaid to:*

**Inmed Corporation**

5 Calle Industria, Bagumbayan,
Quezon City, 1110, Philippines
Tel: 02.571.1888 | Fax: 02.571.9812

**Please register your unit online at www.inmed.com.ph**