INMED

Pulse Oximeter

Operator's Manual

Model: F-100

Section 1 Safety

1.1 Instructions for Safe Operation and Use of the Inmed F-100 Finger Pulse Oximeter

- Do not attempt to service the Pulse Oximeter. Only qualified service personnel should attempt any needed internal servicing.
- Prolonged use 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 adversely be affected in the presence of high ambient light. Shield the sensor area (with a surgical towel from direct sunlight, for example) if necessary.
- The following reason will cause interference to the testing accuracy of the Inmed F-100 Finger Pulse Oximeter:
-High-frequency electrosurgical equipment.
-Placement of a sensor on an extremity with a blood pressure cuff arterial catheter or intravascular line
-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.
- This device should be kept at least 10 minutes from non-working temperature to normal temperature.
- This device is non-sterile and not intended to be sterilized.

1.2 Inmed F-100 Finger Pulse Oximeter is suitable for home healthcare environment and so on.

WARNING: Although the Inmed F-100 Finger Pulse Oximeter conforms to the intent of the standard EN 60601-1-2 in relation to electromagnetic compatibility, electrical equipment may produce interference. If interference is suspected, move the equipment away from the sensitive device. Portable and mobile RF communication equipment can also affect this device's normal operation.

WARNING: EXPLOSION HAZARD — do not use this Pulse Oximeter 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 fire or even explosion.

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

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

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

WARNING: Don't place near active HF surgical equipment or RF shielded room for magnetic resonance imaging, where the intensity of EM disturbances is high.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or could decrease electromagnetic immunity of this equipment and may result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used not closer than 30cm (12 inches) to any part of the Inmed F-100 Finger Pulse Oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may occur.

IF ANY: List of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

IF ANY: the performance of the Inmed F-100 Finger Pulse Oximeter that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not to be used).

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, flammable materials, 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 should only be used if the battery cover is closed.

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

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

1.3 Definitions and Symbols

SYMBOL	DESCRIPTION
	Type BF Equipment
LOT	Batch code
	Date of manufacture
SN	Serial No.
	Information of the manufacturer, including name and address
	Temperature limitation
	When the end-user wishes to discard this product, it must be sent to separate collection facility for recovery and recycling
	Follow user manual
IP22	Anti-dust & Anti-water class
Warning	Information you should know to protect an individual from any possible injury
Caution	Information you should know to protect the equipment from possible damage
Note	Important information you should know

Section 2 Introduction

2.1 General

This chapter provides a general description of the Inmed F-100 Finger Pulse Oximeter including:

- Brief device description
- Product features

2.2 Indication for use / intended use

Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR), this portable device is indicated for use for adult patients in clinical institution and in home environment.

2.3 Brief Device Description

The 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 Pulse Oximeter can be used to measure human SpO2 and heart rate through finger. The product is suitable to use in homes, hospitals (including clinical use), oxygen bar, social medical organizations physical care, in sports and etc.

2.4 Product Features

- Lightweight and easy-to-use
- Color LED display, simultaneous display for testing value and plethysmograph.
- Low Perfusion: 0.3%. (Advanced DSP algorithm can improve measurement accuracy, under the condition of low perfusion.)
- Visual & sound alarm function
- Real-time spot-checks
- Low Battery voltage indicator
- Automatic switch off
- Standard two AAA 1.5V alkaline battery support more than 20 hours continuous work.

CAUTION: The device cannot be used to measure SpO2 and PR level of children below 3 years old, as the test result would not guarantee to be accurate on them.

CAUTION: 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: The patient is an intended operator and can perform the maintenance of the equipment.

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 SpO2 value (SpO2) of the sensor is compared to the 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 simulator shall be used to assess pulse rate accuracy. 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).

Section 3 Installation, Setup and Operation

3.1 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 the machine
2	LED Panel	Display the SPO2/PR data & Plethysmogram
3	Battery Compartment	

3.2 Display

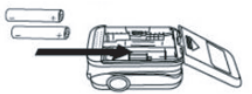
After switching on, the LED display of the Inmed F-100 Finger Pulse Oximeter will look like as shown below:

Figure 3.2.1 LED display

3.3 Operation

3.3.1 Install battery

Install two AAA batteries into the battery cassette in correct polarities then cover it.



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

3.3.2 Turn On the Pulse Oximeter

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

Press power button to turn the Pulse Oximeter on. The Pulse Oximeter will automatically turn off when no finger is placed inside the device for longer than 16 seconds.

3.3.3 Read correspondent data from display screen.

3.3.4 Press the "power" button for 3 seconds to turn on / off, then you'll hear a beep sound

Note: When battery power is at lowest level, the battery capacity indicates symbol of in the LED screen, this reminds the user to replace the battery.

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. Clean the exterior surface LED screen display with a dry and soft cloth, included with the unit. Use 75% density of medical alcohol to clean the surface and use dry fabric with little alcohol to avoid the alcohol from entering into the device.

4.2 Disinfection

Disinfect the machine every use, if used by multiple patients in hospital settings. Use 75% density of medical alcohol to clean the surface contacting with the patient.

CAUTION: Don't use strong solvent. For example: acetone.

CAUTION: Never use with an abrasive material 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 liquid.

CAUTION: Avoid pouring liquid in this device during cleaning.

Section 5 Troubleshooting and Maintenance

5.1 Maintenance

Replace the batteries timely when battery indication is low. Clean the 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 used for a long time.
It is better to preserve the product in a place where ambient temperature is is-25-55°C (-13°F to 131°F) and humidity is 15%-93%.

Do not use in a highly flammable environment and on an extremely low temperature and very humid area.

5.2 Troubleshooting

Table 5.2.1 troubleshooting

Problems	Possible Reason	Resolutions
Oxyhemoglobin or heart rate not shown normally	1. Finger is not plugged correctly. 2. Patient's perfusion is too low to be measured.	1. Retry by plugging the finger 2. Try for few more times to make sure if the device has any problem.
Oxyhemoglobin of heart rate is shown unstably	1. Finger might not be plugged deep enough 2. Finger is trembling or patient's body is moving	1.Retry by plugging the finger 2. Try not to move, let the patient keep calm.
Oxyhemoglobin or heart rate is abnormal, causing sound reminder	1. Finger is not plugged correctly. 2. Patient's SPO2&PR is abnormal.	1. Retry by plugging the finger 2. Go to the hospital for further examination.
The Oximeter does not turn on	1. Power of batteries might be inadequate or none at all 2. Batteries might be installed incorrectly 3.The Oximeter might be damaged	1. Replace the batteries 2. Reinstall the batteries 3. Contact the local customer service center
The screen is suddenly off	1.The product automatically powered off when no signal is detected longer than 16 seconds 2. Power quantity of the batteries is exhausted.	1.Normal 2.Replace the batteries

Section 6 Specification

Name	Inmed Finger Pulse Oximeter
Model	F-100
Anti-electric Shock Type	Internally powered equipment
Anti-electric Shock Equipment Degree	Type BF
EMC Type	Type B Class I
Endosure Degree of ingress protection	IP22
Internal Power:	2xAAA 1.5v alkaline battery
Power Consumption	Below 45mA
Screen	0.96'LED
SpO2 Display	35-100%
Pulse Rate Display	30-250 BPM
Resolution	SpO2: 1%
	Pulse rate: 1BPM
Measurement Accuracy	SpO2 ±3% (70%-100%) Unspecified (<70%)
	PR:±2BPM
Operating Environment	Temperature: 5°C to 40°C (41°F to 104°F) Humidity:15% to 80% non-condensing Air Pressure: 70Kpa-106Kpa
Storage & Transport Environment	Temperature: -25-55°C (-13°F to 131°F) Humidity:15% to 93% non-condensing
Dimensions	62mm×34mm×31mm
Weight	50±2g (including 2 x AAA battery)
Accessories	AAA battery----------2 pcs Hang String----------1 pc User manual----------1 pc

Section 7 Manufacturer's Declaration of the EMC

1.All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.

2.Guidance and manufacturer's declaration -electromagnetic emissions and immunity.

Table 1- Guidance and manufacturer's declaration - electromagnetic emissions

Emission Test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2- Guidance and manufacturer's declaration - Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply line:±2 kV input/output line:±1 kV	Not applicable
Surge IEC 61000-4-5	Line (s) to line(s) :±1 kV. Line (s) to earth:±2 kV. 100 kHz repetition frequency	Not applicable
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz 10 V/m	Not applicable
Radiated RF IEC61000-4-3	80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the AC main voltage prior to application of the test level.		

Table 3- Guidance and manufacturer's declaration - electromagnetic immunity

	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	Immunity Test Level(V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment	385	380–390	TETRA 400	Pulse modulation18 Hz	1,8	0.3	27
	450	430–470	GMRS 460, FRS 460	FM ±5kHz deviation1 kHz sine	2	0.3	28
	710	704–787	LTE Band 13,17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800–960	GSM 800/900,TETRA 800,iDEN 820,CDMA 850,LTE Band 5	Pulse modulation 18 Hz Pulse modulation 217 Hz	2	0.3	28
	870						
	930						
	1720	1700–1990	GSM 1800;CDMA 1900;GSM 1900;DECT;LTE Band1,3,4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400–2570	Bluetooth,WLAN, 802.11 b/g/n, RFID 2450,LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5240						
	5785						

Section 8 Disposal

Observe the applicable regulations when disposing of the pulse oximeter and batteries.

This pulse oximeter must not be disposed of together with domestic waste.

All users are obliged to hand in all electrical or electronic devices, regardless if whether or not they contain toxic substances at a municipal or commercial collection point, so that they can be disposed of in an environmentally acceptable manner.

Please remove the batteries before disposing of the pulse oximeter. Do not dispose of old batteries with your household waste, dispose them instead in a battery collection station at a recycling site or in a shop.

INMED

Product Warranty

NAME:
ADDRESS:
MODEL: **Inmed Finger Pulse Oximeter F-100**
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: 02-8571-1888

https://inmed.com.ph/warranty.php