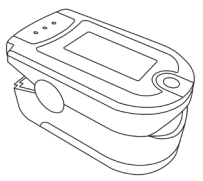
A&D Medical

Pulse Oximeter User Manual

UP-200



INSTRUCTIONS TO USER

Dear Users, thank you very much for purchasing the UP-200 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, product features, functions, specifications, correct methods for: transportation, use, repair, maintenance and storage, 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.

Due to product updates, the specific products you received may not be totally in accordance with the description of this User Manual. We regret any confusion.

This product can be used repeatedly. Its useful life is 3 years.

If you have any questions regarding to the use of this product, please call us at one of the numbers listed at the end of this manual.

WARNING:
- **An uncomfortable or painful feeling may appear if using the oximeter continuously, especially for the microcirculation barrier users. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For individual users, ensure proper placement of the oximeter. The oximeter cannot be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the oximeter is harmful to the eyes, do not stare at the light.**
- **User cannot use enamel or other fingernail polish.**
- **User's fingernail cannot be too long.**
- **Please review the relative content about the clinical restrictions and caution.**
- **This oximeter 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 user's safety and monitoring performance. It is recommended that the oximeter should be inspected at least once a week. When there is obvious damage, stop using the oximeter.
- 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 use the type of accessories included in the package.
- 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 this oximeter if you are allergic to rubber.
- The disposal of the oximeter and its accessories and packaging (including batteries, plastic bags, foam inserts and paper boxes) should follow the local laws and regulations.
- Please check the packing before use to make sure the oximeter and accessories are in accordance with the packing list, or else the oximeter may not work properly.
- Please don't measure this oximeter with a functional tester for the oximeter's related information.
- Warning against servicing and maintenance while the equipment is in use.
- No modification of this equipment is allowed.
- The user is an intended operator.
- The probe of the oximeter is the applied part.

1.3 Attentions
- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, discontinue use.
- Do not use immediately after moving it from a cold environment to warm or humid environment.
- Do not operate buttons on front panel with sharp materials.
- Do not use high temperature or high pressure steam disinfection of the oximeter. Refer to chapter (8) for instructions of cleaning and disinfection.
- Do not immerge the oximeter in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the oximeter directly.
- When cleaning the oximeter with water, the temperature should be lower than 60 °C.
- As to the fingers which are too thin or too cold, it would probably affect the normal measure of the users' SpO_2 and pulse rate, use a larger finger such as thumb or middle finger and place finger deeply into the probe.
- Do not use the oximeter on infant or neonatal users.
- The product is suitable for adults (weight should be between 40 kg to 110 kg).
- The oximeter may not work for all users. 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 the screen is steady. 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 lanyard is made from non-allergy material, if you are sensitive to the lanyard, stop using it. In addition, do not wear it around the neck to avoid harm to the users.
- The oximeter does not have low-voltage alarm function, it only shows the low-voltage. Please change the battery when the battery energy is used up.
- The instrument does not have alarm function. Do not use the device in situations where alarms are required.
- Batteries must be removed if the oximeter is going to be stored for more than one month, or else batteries may leak.
- A flexible circuit connects the two parts of the oximeter. Do not twist or pull on the connection.

1.4 Indication for Use
The Pulse Oximeter is a non-invasive device intended for the spot-check of saturation of arterial hemoglobin(SpO_2) and the pulse rate of adult in home use environments. This oximeter is not intended for continuous monitoring. The device can be used multiple times.Pulse oximeter intended for wellness use.

2 OVERVIEW

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood - the O_2 concentration in the blood. It is an important bio-parameter for respiration. This Pulse Oximeter was developed for the purpose of measuring the SpO_2 more easily and accurately. At the same time, the oximeter can measure the pulse rate.

The Pulse Oximeter features a compact design, low power consumption, and convenient operation. It is only necessary for user to put one finger into a fingertip photoelectric sensor for measurement, and a display screen will directly show measured value of Hemoglobin Saturation.

2.1 Features
- Easy to use
- Easy to view with a display that changes direction automatically.
- Small, lightweight design
- Convenient carrying case.
- Low power consumption – allowing for 20 hours of continuous operation on a new set of batteries.
- Standby mode when no signal is received within 5 seconds.

2.2 Major Applications and Scope of Application
The Pulse Oximeter can be used in measuring pulse oxygen saturation and pulse rate through finger. The product is suitable for family use (It can be used before or after doing sports, and it is not recommended to use the oximeter during sports activity).

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

2.3 Environment Requirements
Storage Environment
a. Temperature: -40°C ~ +60°C
b. Relative humidity: ≤95%
c. Atmospheric pressure: 500hPa ~ 1060hPa

Operating Environment
a. Temperature: 10°C ~ 40°C
b. Relative humidity: ≤75%
c. Atmospheric pressure: 700hPa ~ 1060hPa

3 ACCESSORIES

- 1 Lanyard
- 2 Batteries
- 1 User Manual
- 1 Carrying Case

4 SET UP

4.1 View of the Front Panel

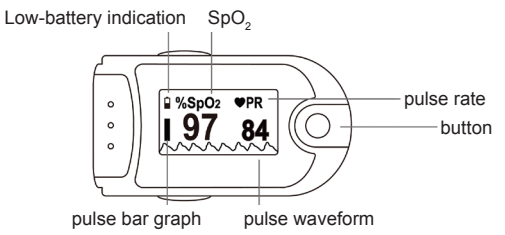


Figure 1: Front View

4.2 Battery
Step 1.Insert the two AAA size batteries in the proper direction (Refer to Figure 2).
Step 2. Put the cover back on.

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

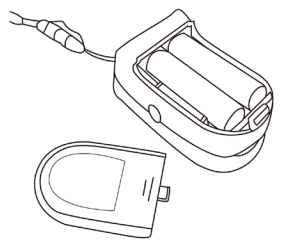


Figure 2: Batteries Installation

4.3 Attaching the lanyard
Step 1. Put the thin loop through the hole on the oximeter.
Step 2. Put the lanyard strap through the thin loop and tighten.

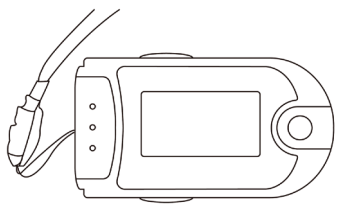


Figure 3: Attaching the Lanyard

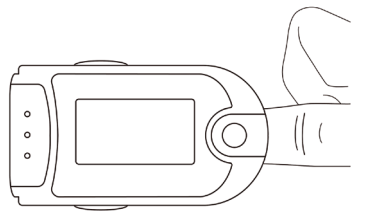


Figure 4: Put Finger in Position

5 USING THE OXIMETER

5.1 Insert the two batteries properly to the direction, and then replace the cover.
5.2 Open the clip as shown in Figure 4.
5.3 Place your finger into the rubber cushions with the nail towards the top of the oximeter, and then clip your finger.
5.4 Press the switch button once on front panel.
5.5 Do not shake your finger and remain still.
5.6 See your results from screen display.
5.7 The button has two functions. When the oximeter is in standby mode, pressing the button can exit it; When the oximeter is in operation status, pressing the button for longer can change brightness of the screen.
5.8 The oximeter changes display direction according to the direction you hold it.

Fingernails and the luminescent tube (emission tube) should be on the same side.

6 PRINCIPLE AND CAUTION

6.1 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.

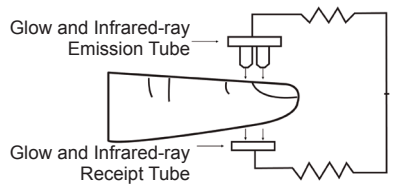


Figure 5: Operating Principle

6.2 Caution
1. The finger should be placed properly (see the attached illustration of this manual, Figure 4), 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 etc.
6. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
7. User cannot use fingernail polish.

6.3 Clinical Restrictions
1. As the measurement 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), carbon monoxide hemoglobin (COHb), methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.
3. Drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also cause inaccurate SpO_2 measurements.
4. As the SpO_2 value serves as a reference value for anemic anoxia and toxic anoxia, some users with serious anemia may report good SpO_2 measurement.

7 TECHNICAL SPECIFICATIONS

1. **Display Format:** LCD Display
   SpO_2 Measurement Range: 0 ~ 100%
   Pulse Rate Measuring Range: 30 bpm ~ 250 bpm
   Pulse Wave Display: bar-graph display and the waveform display.
2. **Power Requirements:** 2 × 1.5 V AAA alkaline battery (or rechargeable battery), adaptable range: 2.6 V ~ 3.6 V.
3. **Power Consumption:** Less than 30 mA.
4. **Resolution:** 1% for SpO_2 and 1 bpm for Pulse Rate.
5. **Measurement Accuracy:**
   SpO2: ±2% for 70% ~ 100%; not applicable if < 70%
   Pulse Rate: ±2 bpm or ±2% (whichever is larger)

Clinical Trial: SpO_2 regression plot & Bland–Altman plot,Refer to Figures 6 and 7.

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, indoor natural light and darkroom is less than ±1%.
8. **It is equipped with a switch function:** The product will enter standby mode when no signal is in the product within 5 seconds.
9. **Optical Sensor**
   Red light (wavelength is 660 nm, 6.65 mW)
   Infrared (wavelength is 905 nm, 6.75 mW)

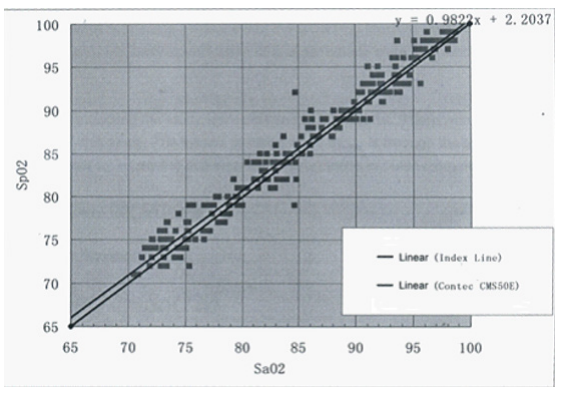


Figure 6: SpO_2 regression plot

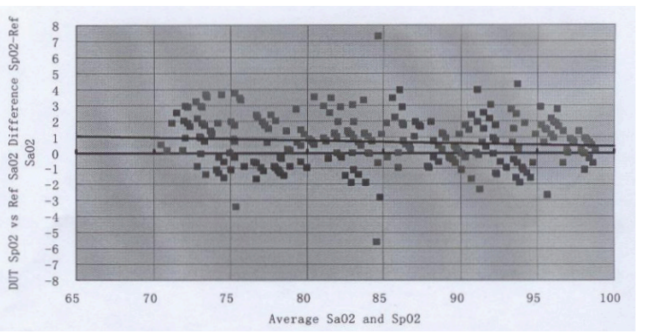


Figure 7: Bland–Altman plot

8 REPAIRING AND MAINTENANCE

- Please change the batteries when low-voltage is displayed on the screen.
- Clean the surface of the oximeter before using. Wipe the oximeter with medical alcohol first, and then let it dry in air.
- Using the medical alcohol to disinfect after use prevents cross infection for next use.
- Please take out the batteries if the oximeter is not used for a long time.
- The oximeter can be transported by ordinary conveyance or according to transport contract. The oximeter can not be transported mixed with toxic, harmful, corrosive material.
- The best storage environment of the oximeter is - 40ºC to 60ºC ambient temperature and not higher than 95% relative humidity.
- There is no need to calibrate the oximeter.

High-pressure sterilization cannot be used on the oximeter.
Do not immerse the oximeter in liquid.
It is recommended that the oximeter should be kept in a dry environment. Humidity may reduce the useful life of the oximeter, or even damage it.

9 TROUBLESHOOTING

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate cannot be displayed normally	1. The finger is not properly positioned. 2. The user's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Go to a hospital for a diagnosis if you are sure the oximeter is working correctly.
The $Sp0_2$ and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking or the user is moving	1. Place the finger properly and try again. 2. Remain still while taking the measurement
The oximeter cannot be turned on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. Malfunction of the oximeter.	1. Change batteries. 2. Reinstall batteries. 3. Please contact customer support.
The display is off suddenly	1. The product will enter standby mode when no signal is in the product within 5 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

10 KEY OF SYMBOLS

Symbol	Description	Symbol	Description
	Type BF		WEEE (2002/96/EC)
	Refer to instruction manual	**IP22**	Ingress of liquids rank
%SpO_2	The pulse oxygen saturation (%)		Manufacturer
PRbpm	Pulse rate (bpm)		Manufacture Date
	Full-voltage		Storage and Transport Temperature limitation
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)		Storage and Transport Humidity limitation
	1. No finger inserted 2. An indicator of signal inadequacy		Storage and Transport Atmospheric pressure limitation
+	Battery positive electrode		This side UP
–	Battery cathode		Fragile, handle with care
	1. Exit standby mode. 2. Change brightness of the screen.		Keep dry
SN	Serial number		Recyclable
	Alarm inhibit		

11 FUNCTION SPECIFICATION

Display Information	Display Mode
The Pulse Oxygen Saturation (SpO_2)	LCD
Pulse Rate (PR)	LCD
Pulse Intensity (bar-graph)	LCD bar-graph display
Pulse Wave	LCD
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 660 nm) Infrared (wavelength is 880 nm)
Pulse Parameter Specification	
Measuring Range	30 bpm ~ 250 bpm (the resolution is 1 bpm)
Accuracy	±2 bpm 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 24 hours	
Dimensions and Weight	
Dimensions	2.3 (L) x 1.3 (W) x 1.3 (H) inch / 59(L) × 33(W) × 32(H) mm
Weight	~ 2 oz / 57 g (with the batteries)

12 APPENDIX

Guidance and manufacture's declaration – electromagnetic emissions for all EQUIPMENT and SYSTEMS

Guidance and Manufacture's Declaration – Electromagnetic Emission		
The *UP-200 Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer of the user of the *UP-200 Pulse Oximeter* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emission CISPR 11	Group 1	The *UP-200 Pulse Oximeter* 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.
RF emission CISPR 11	Class B	The *UP-200 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

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

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
The *UP-200 Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of *UP-200 Pulse Oximeter* should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) 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 floor is covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) 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.

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

Guidance and manufacture's declaration – electromagnetic immunity			
The *UP-200 Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of *UP-200 Pulse Oximeter* should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *UP-200 Pulse Oximeter*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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,[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 80 MHz and 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 *UP-200 Pulse Oximeter* is used exceeds the applicable RF compliance level above, the *UP-200 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 *UP-200 Pulse Oximeter*. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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

Recommended separation distances between portable and mobile RF communications equipment and the UP-100CN			
The *UP-200 Pulse Oximeter* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *UP-200 Pulse Oximeter* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *UP-200 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)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.39	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 distance d 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 80 MHz and 800 MHz, 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.			

13 WARRANTY

Limited Warranty:
A&D Medical ("A&D") warrants to the first purchaser ("You") that the A&D product You purchased (the "Product") will be free from defects in material, workmanship and design for the applicable Warranty Term stated above from the date You purchased the Product under normal use. This Limited Warranty is personal to You and is not transferable. If the Product is defective, then (i) if You are a Consumer, You return the Product to the retailer You purchased it from (if within such retailer's return time frame) or You return it to A&D in accordance with the procedure set forth below, or (ii) if You are NOT a Consumer, You return the Product to A&D in accordance with the procedure set forth below. A&D's warranty obligation is limited to the repair or replacement, at A&D's option, of the defective Product that has been returned by You within the warranty period. Such repair or replacement will be at no charge to You. The repaired or replacement Product is warranted hereunder for the longer of the remainder of the original warranty period or 90 days from the date of shipment of the repaired or replacement Product. If you return the Product for warranty service to A&D, You must return the Product, freight and insurance prepaid, within the warranty period to the address set forth below, together with satisfactory proof of the date of Your purchase (such as a sales receipt or statement of online warranty registration) and a description of the defect. Also please enclose a check for return shipping and insurance of the Product, as provided to you by the customer service representative.

In the United States of America:
2 year warranty
A&D Engineering, Inc.
1756 Automation Parkway
San Jose, CA 95131 U.S.A.
www.andmedical.com
1-888-726-9966

In Canada:
2 year warranty
Auto Control Medical, Inc.
6695 Millcreek Drive, Unit 6 Mississauga,
Ontario, L5N 5R8 Canada
www.lifesourcecanada.com
1-800-461-0991

In Latin America
Please return to your local dealer.

CONTACT INFORMATION

Manufactured by:

Contec Medical Systems Co., Ltd.
No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA

Manufactured for:

A&D Engineering, Inc.
1756 Automation Parkway
San Jose, CA 95131 USA
andmedical.com
1-888-726-9966

Distributed in Canada by:

Auto Control Médical an A&D Company / une compagnie A&D
6695 Millcreek Drive, Unit 6
Mississauga, Ontario
L5N 5R8 Canada
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