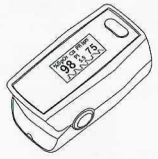
Dr. Odin®

A330N Fingertip Pulse Oximeter

# Operator's Manual



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File No.: A330N-OPE V 1.3 2020/06

| | |
|---|---|
| *Note* | The important information you should know |
| | If a Pulse Oximeter Monitor is not provided with a low SpO2 ALARM CONDITION, a statement to the effect "NoSpO2 Alarms" or Symbol IEC 60417 - 5319 (DB - 2002 - 10) (see IEC 60601 - 1 - 8:2006 +AMD1:2012,TableC.1, Symbol 3). |

* Batch code, Date of manufacturer and Serial No are printed on the label on the battery cover.

*Section 1*

## Safety

### *1.1 Instructions for the Safe Operation and Use of the 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. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
- 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.
- The device should be kept at least 10 minutes from non-working temperature to normal temperature.
- The device is non-sterile and not intended to be sterilized.

### *1.2 Warnings*

***WARNING:*** Although the ME equipment 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 equipment away from sensitive device or contact us.
The portable and mobile RF communication equipment can affect this instrument 's normal operation.

***WARNING:*** EXPLOSION HAZARD — Do not use the 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 causes 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.

***WARNING:*** Don't near active HF surgical equipment and the RF shielded room of an ME system 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.

*Section 2*

## Introduction

### *2.1 General*

This chapter provides a general description of the Pulse Oximeter including:

- Brief device description
- Product features

### *2.2 Indication for use/ intended use*

The 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 in adult patients in clinical institution and home environments.

### *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 for family, hospital (including clinical use in internist/surgery, Anesthesia, pediatrics and etc.) Oxygen Bar, social medical organizations, physical care in sports and etc.

### *2.4 Product Features*

- Lightweight for carrying and Easy-To-Use.
- Manually adjust the direction of interface.
- Color OLED display, simultaneous display for testing value and plethysmography.
- Low Perfusion: 0.3%. (Advanced DSP algorithm can improve measurement accuracy, under the condition of low perfusion.)
- Visual & Sound reminder 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 not be used to measure the child below 3 years as the test result is not guarantee to accurate.

***CAUTION:*** The 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 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 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

***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 decreased electromagnetic immunity of this equipment and result in improper operation.

***WARNING:*** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of theA310 Pulse Oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

***IF ANY:*** a 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 ME EQUIPMENT or ME SYSTEM 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 be used).

***CAUTION:*** Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of 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 |
| LOT | 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 |
| IP22 | 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 |

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.

### *2.5 Expected Service Life*

–The expected service life of the ME equipment;
–The expected service life of parts or accessories shipped with the ME equipment;
– Where the shelf life is less than the expected service life, the shelf life of parts or
Accessories shipped with the ME equipment.

## *Section 3*
## Installation,Setup,and Operation

### *3.1 Description of the Front Panel (as figure 3.1.1)*

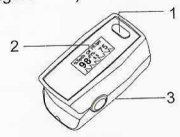


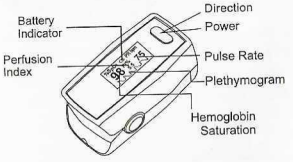

Figure 3.1.1 Parts of front & back panel

Table 3.1.1 Part Definition and Description

| Item | Name | Description |
|---|---|---|
| 1 | Power button | Turn on the machine |
| 2 | OLED Panel | Display the SPO2/PR data & Plethysmogram |
| 3 | Battery Compartment | |

### *3.2.Display*

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




### *3.3 Parameter setting*

When the device is under measuring interface, press the direction button for 1 second in order to enter into menu page (figure 3.3.1 and figure 3.3.2 ). There are two submenus for choice:

#### *3.3.1 Remind Setup*

Press the direction button for 1 second and enter into the Reminder Setup. User can adjust the setting through moving the "*" symbol to the back of the Sound Reminder, Beep, Restore or Brightness.

- Sound Reminder

Press the direction button for 1 second, move the "*" symbol to the back of Sound Reminder, long press the direction button to turn it on/off. (Note: If the measured value exceeds the maximum or minimum value of SPO2 or PR, there will give off sound when sound reminder is turned on.)

- Beep

Press the direction button for 1 second, move the "*" symbol to the back of Beep, long press the direction button to turn it on/off. (Note: When Beep is turned on, the sound emitted during the test indicates the pulse rate sound)

- Restore

When the "*" symbol show behind "Restore", long press the direction button can be changed to "OK", which causes the device to restore factory data setting.

- Demo

Press the direction button for 1 second, move the "*" symbol to the back of Demo, long press the direction button to turn it on/off.

- Brightness

When the "*" symbol show on "Brightness", long press the direction button to change the Brightness value from 1 to 5.

*3.3.2.Limit Value Setting*

When the * symbol show on the Reminder Setup, long press the direction button until enter into the Reminder Limit setup menu (figure 3.3.2). User can press the direction button to select the items. And press the direction button for 1 second to change the data you need.

On the Reminder Limit setup menu page (figure 3.3.2), when the * symbol show behind the "+/-". Press direction button for 1 second to change the "+" to "-" or change the "-" to "+".

When "+" shows on the right side, press the direction button for 1 second, move the "*" after the Spo2 Hi or PR Hi setting, can increase the value to a higher value (until it reaches to the highest.)

When "-" shows on the right side, press the direction button for 1 second, move the "*" after the Spo2 Lo or PR Lo value setting, can reduce the value to a lower value (untill it reaches to the lowest).

| | |
|---|---|
| Operating Environment | Temperature: 5°C to 40°C (41 ℉ to 104 ℉)<br>Humidity:15% to 85% non-condensing<br>Air Pressure: 86Kpa-106Kpa |
| Storage & Transport Environment | Temperature: –25°C to 55°C (-13 ℉-131 ℉)<br>Humidity:15% to 85% non-condensing |
| Dimensions | 63mm×36mm×34mm |
| Weight | 55±2g (including 2 x AAA battery) |
| Accessories | AAA battery----------2 pcs<br>Hang String----------1 pc<br>User manual ----------1 pc |


Figure 3.3.1




Figure 3.3.2

Note:

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

2. The customer can preset the limit value to the 98 or 99 to check whether it is normal for sound reminder 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.

*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 excepted service life.

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

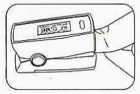
Table 1- Guidance and manufacturer's declaration - electromagnetic emissions

| Emissions test | Compliance |
|---|---|
| RF emissions CISPR 11 | Group 1 |
| RF emissions CISPR 11 | Class B |
| Harmonic emissions IEC 61000-3-2 | Not application |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not application |

*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.

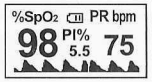


*3.4.3 Read correspondent data from display screen.*

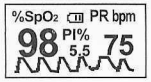
*3.4.4 Display Description of OLED*

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

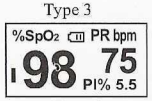
Type 1



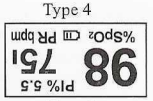

Type 2




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 plethymogram can been regarded as correct if the wave is fluctuated regularly.

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

*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 -25-55℃ and humidity is 15%-93%.
- 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.

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 communica-tions equipment) | 385 | 380–390 | TETRA 400 | Pulse Modulation 18 Hz | 1,8 | 0.3 | 27 |
| | 450 | 430–470 | GMRS 460, FRS 460 | FM±5kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| | 710<br>745<br>780 | 704–787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 0,2 | 0.3 | 9 |
| | 810<br>870<br>930 | 800–960 | GSM 800/ 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 2 | 0.3 | 28 |
| | 1720<br>1845<br>1970 | 1700–1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band1,3,4, 25; UMTS | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| | 2450 | 2400–2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| | 5240<br>5240<br>5785 | 5100–5800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 0,2 | 0.3 | 9 |

### *5.2 Troubleshooting*

Table 5.2.1 troubleshooting

| Problems | Possible Reason | Resolutions |
|---|---|---|
| Oxyhemo-globin or heart rate can not be shown normally | 1. Finger is not plugged correctly.<br>2. Patient's perfusion is too low to be measured. | 1. Retry by plugging the finger<br>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 |
| Oxyhemo-globin or heart rate is shown unstably | 1. Finger might not be plugged deep enough<br>2. Finger is trembling or patient's body is in movement status | 1.Retry by plugging the finger<br>2.Try not to move, let the patient keep calm |
| Oxyhemo-globin or heart rate is abnormal and cause sound reminder | 1. Finger is not plugged correctly.<br>2. Patient's SPO2&PR is abnormal. | 1. Retry by plugging the finger<br>2. go to the hospital for further examination |
| The oximeter can not be powered on | 1. Power of batteries might be inadequate or not be there at all<br>2.Batteries might be installed incorrectly<br>3.The Oximeter might be damaged | 1.Please replace batteries<br>2.Please reinstall the batteries<br>3.Please contact with local customer service center |
| The screen are suddenly off | 1.The product is automa-tically powered off when no signal is detected longer than 16 seconds<br>2.Power quantity of the batteries is exhausted | 1.Normal<br>2.Replace the batteries |

*Section 6*

## Specification

| Name | Pulse Oximeter |
|---|---|
| Model | A330N |
| Anti-electric Shock Type | Internally powered equipment |
| Anti-electric Shock Equipment Degree | Type BF |
| EMC Type | Type B Class I |
| Enclosure Degree of ingress protection | IP22 |
| Internal Power: | 2xAAA 1.5v alkaline battery |
| Power Consumption | Below 45mA |
| Screen | 0.96'OLED |
| SpO2 Display | 35-100% |
| Pulse rate Display | 30-250 BPM |
| PI Display | 0-20% |
| Resolution | SpO2: 1% |
| | Pulse rate: 1BPM |
| | PI: 0.1% |
| Measure Accuracy | SpO2: ±3% (70%-100%)<br>Unspecified (<70%) |
| | PR: ±2BPM |
| | PI 0.1%: (0-1%)<br>1%: (1-20%) |

*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 of whether 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, but at a battery collection station at a recycling site or in a shop.

*Section 9 Certificate of guarantee*

We guarantees the Pulse Oximeter against any manufacturing defect for two years from the date of purchase if it is returned to the dealer from whom it was purchased.

During this period the unit will be repaired or replaced free of charge if the fault is due to defective design or assembly.

This guarantee does not cover any damage or defect caused by improper handling resulting from use that is not in compliance with these instructions or from unauthorized attempts to repair it. Your local dealer cannot declare this manufacturer's guarantee invalid but may expand it by additional guarantees at his discretion and at his own expense.

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