CE 0123

# NT1A Pulse Oximeter
# Operating Manual

NEWTECH®

**Dear Customer：**

**Welcome to use NT1A Pulse Oximeter！This manual is mainly designed to offer users the operation guidance and device maintenance information. The manual explains specifications, installation, use, and safety information of the Oximeter. Before use, carefully read this manual so as to use the Oximeter properly.**

**Note:**

**Federal Law (USA) restricts this device to sale by or on the order of a physician.**

**Version information**

**This version is subject to change or upgrade without notice.**

**Version:3.0**

**Issue date: 2015-10-22**

**File's NO.: NT1A-CE-091B**

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## Registration Information

**People's Republic of China Medical Device Manufacturer License: 20010459**

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# Chapter 1 Safety Information

This section contains important safety information related to general use of the NT1A. Other important safety information appears throughout the manual in sections that relate specifically to the precautionary information. Be sure to read all text surrounding all precautionary information.

**Important! Before use, carefully read this manual, accessory direction for use, all precautionary information in boldface type, and specifications.**

| | |
|---|---|
| **Warning:** | **The NT1A is a prescription device and is to be operated by qualified personnel only.** |
| **Warning:** | **Explosion hazard. Do not use the NT1A pulse oximeter in the presence of flammable.** |
| **Warning:** | **He cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.** |
| **Warning:** | **To ensure accurate performance and prevent device failure, do not expose the NT1A to extreme moisture, such as rain.** |

**Caution: The NT1A is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**

| | |
|---|---|
| **Warning:** | **Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, probe application errors, and certain patient conditions.** |

| | |
|---|---|
| **Warning:** | **Do not use the NT1A during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The NT1A may affect the MRI image; the MRI unit may affect the accuracy of oximetry measurements.** |
| **Warning:** | **If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means, and then make sure the Oximeter is functioning correctly.** |
| **Warning:** | **$SpO_2$ measurements may be adversely affected in the presence of high ambient light. Shield the probe area (with a surgical towel, for example) if necessary.** |
| **Warning:** | **Tissue damage can be caused by incorrect application or duration of use of a $SpO_2$ probe. Inspect the probe site as directed in the probe directions for use.** |

**Caution:** **Ambient light, movement, electromagnetic interference, artifacts, dysfunctional hemoglobin, and certain dyes, etc. may be interfering in the pulse oximeter's functions.**

**Caution:** **Do not autoclave, ethylene oxide sterilize. Do not immerse the NT1A in liquid.**

**Caution:** **The Pulse Oximeter does not provide dfib Sync signal so it can not be connected with a defibrillator.**

**Warning: Reposition the probe at least once every 4 hours to allow the patient's skin to respire.**

# Chapter 2 Introduction

## 2.1 Product Introduction

- **Intended use**

The NT1A pulse oximeter is a type of Monitor intended for measurement of pulse oxygen saturation of arterial hemoglobin ($SpO_2$%), and pulse rate. This oximeter can be used on adult, pediatric, and neonatal patients. The measurement is used as reference for diagnosis.

The Pulse Oximeter contains: mainframe and SpO2 probe. The APPLIED PART is SpO2 Probe.

**Caution:** **The NT1A is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**

**Note:** **The NT1A is anti motion, yet measurement can be affected if used under the conditions of strong movements.**

| | |
|---|---|
| **Warning:** | **Do not use the NT1A during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The NT1A may affect the MRI image; The MRI unit may affect the accuracy of oximetry measurements.** |

- **General operating principles and conditions**

The NT1A uses pulse oximetry to measure oxygen saturation in the

blood. Pulse oximetry works by applying a probe to pulsating arteriolar vascular bed, such as a finger. The probe contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement ($SpO_2$).

Because measurement of $SpO_2$ is dependent on light from the probe, excessive ambient light can interfere with this measurement.

| | |
|---|---|
| **Warning:** | **Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, probe application errors, and certain patient conditions.** |

Specific information about ambient environmental conditions, probe application, and patient conditions, is contained throughout this manual.

## 2.2 Description of Controls, Indicators, and Symbols

### 2.2.1 Overview

- **Front views**

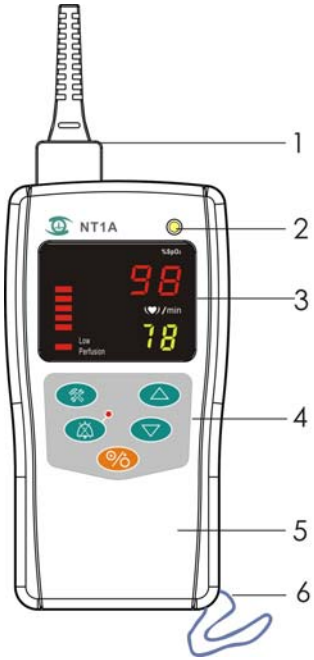



**Figure 2-1：Front View**

1. Probe 2. Power indicator light 3. Display Window
4. Keys 5. Front Panel 6. Wrist Tie

- **Stand**

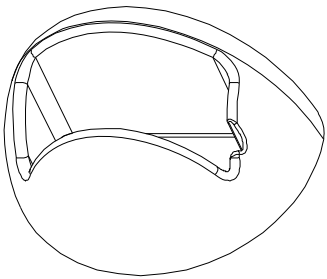


**Figure 2-2：Stand**

- **Rear view**

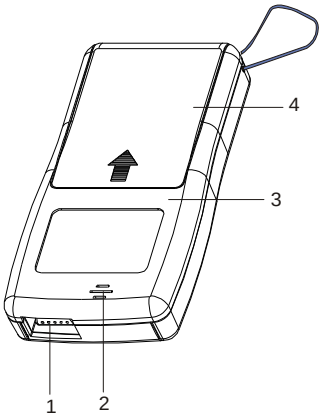



**Figure 2-3: Rear view**

1. Probe Socket 2. Speaker 3. Rear Panel 4. Battery Door

2.2.2 Display


**Figure 2-4：Display View**

- **Symbols**

$SpO_2$%：Percent oxygen saturation ,valid range is 0～100，“———”express invalid value.

/ min: Pulse rate, pulsation number per minute, valid range is

25～250 bpm；“———”Express invalid value.

Low Perfusion：Low perfusion indicator. When the patient pulse strength is low, red LED bar will indicate less than 2.

- **Description of visual indicators and displays**

1. $SpO_2$% display area：Three red digital LED display，when invalid is displayed, “———”will blink by 1Hz frequency；When set up Power Mode, “bat” is displayed；When set up the SPO2 average time, “AVE” is displayed. This area is also used to show error code and software version when it is turned on.

2. PR display area：Three green digital LED display，when invalid is displayed, “———”will blink by 1Hz frequency, when set up power mode or $SpO_2$ average time, current set up is displayed.

3. Pulse Indicator：8-segmant red LED displays current pulse intensity.

**Note: The 8-segmant LED display is not in proportion with pulse strength. It shows the relative pulse strength.**

**Note: If weak pulse indicator is on, all $SpO_2$ and pulse rate measurements may be incorrect. The alarm may be activated.**

**Note: Pulse Indicator is a visual indicator of the patient’s pulse, not in proportion to the pulse volume.**

**The display update period of the NT1A in various operating conditions is 1/60 second.**

- **Description of audible indicators**

The following are audible indicators for which there are no accompanying symbols, keys or visual indicators.

1. Power-On----------One beep
2. Probe disconnected---------2 groups of five-beep every 30 seconds
3. Low voltage---------- 3 beep every 60 seconds
4. Press key----------One beep
5. Pulse volume----------One beep
6. Alarm Tone----------1 group of five-beep/three-beep/one-beep
7. Press key invalid----------One low beep

2.2.3 Keys

**Figure 2-5：Keys**

1. Choice key：
   1.1 Press key (<3s) to switch between, power setting mode and $SpO_2$ average time set-up.
   1.2 In normal working condition, press and hold (>3S) key to enter alarm limits and alarm silence intervals setup.

2 Silence key: This key can control the pulse sound, key's sound and alarm sound in "ON" or "OFF".

2.1 When the silence interval is sets for "15, 30, 60, 90, 120", press the key and the red light is lit, at the same time ,all of the key's sound ,the pulse sound and the alarm sound are "OFF".
Press the silence key again or the interval is "off", the red light is dark, and all of the alarm sound, the key's sound and the

pulse sound are “ON”.

**For example**, if set as 15sec, the red light is lit, all of the alarm sound, the key’s sound and the pulse sound are “OFF”. Press the silence key again or after 15 seconds, the red light is dark and all of the alarm sound, the key’s sound and the pulse sound are “ON”.

2.2 When the silence interval is set as “OFF”, press the silence key then the red light is flash, which can turn off the alarm sound, the key’s sound and the pulse sound. When worse conditions occur, or the patient’s $SpO_2$ or PR changes from no alarm to alarm conditions, all of the alarm sound, the pulse sound and the key’s sound will resume;

2.3 In alarm limit setting，by pressing  for 3 seconds, the default alarm limit for $SpO_2$, and PR will be reset.

3.  Power On/Off key，press the key for 2 seconds to turn the Pulse Oximeter “On or Off”.

4.  Up Key.

4.1 In power setting mode, it is to switch between “All” or “HLF”. All：all-on; HLF：power-save. These are shown at Pulse Rate display area.

4.2 Set $SpO_2$ average time.

4.3 Adjust alarm limit and silence interval time.

4.4 If user keeps this key pressed, the value would scroll fast.

4.5 When the pulse sound takes place, pressing this key can increase the pulse sound volume.

5.  Down Key

Similar functions as Up key.

**Note: when the pulse sound takes place, press this key can decrease the pulse sound volume, until the pulse sound volume is "OFF".**

## 2.3 Description of Function

NT1A Pulse Oximeter's main function:

- Oxygen saturation of arterial hemoglobin measurement;
- Pulse rate measurement;
- Alarm function.

## 2.4 Label


**Meanings of the symbols are:**

 --- Type BF applied part

CE 0123 --- The sign of CE authentication

 --- The sign of reclaiming products

--- Serial number

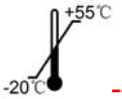


--- Date of Manufacture

 --- Manufacturer

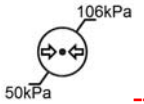
IPX1 --- Drip Proof

 --- Refer to instruction manual



--- Temperature Limit

--- Humidity Limitation



--- Atmospheric pressure limitation

# Chapter 3 Unpacking and Installation

## 3.1 Unpacking

Carefully remove the NT1A and its accessories form the shipping carton. Save the packing materials in case the NT1A must be shipped or stored.

Inspect the equipment for mechanical damage. If yes, please contact your provider promptly.

## 3.2 Installing the batteries

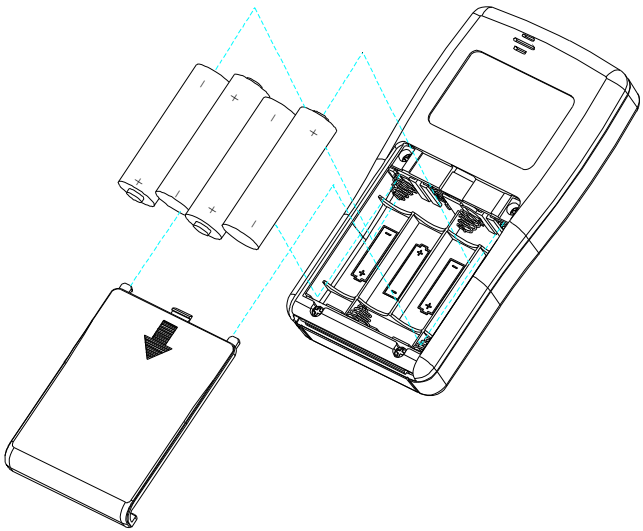


**Figure3-1: Installing Batteries**

1. Refer to figuer1，pull the battery compartment latch downward, toward the bottom of the oximeter, and remove the battery access door.

2. Install four "AA"size batteries, oriented as shown in Figure 3-1. Replace the battery access door.

**Note: Install the negative end of each battery first, compressing the battery terminal spring until the positive terminal clears the positive spring, and pressing the battery downward into place.**

**To remove the batteries, reverse the installation process, removing the positive end of each battery first.**

| |
|---|
| **Warning: Explosion hazard. Do not use the NT1A pulse oximeter in the presence of flammable anesthetics.** |
| **Warning: To ensure patient safety, do not place the Oximeter in any position that might cause it to fall on the patient.** |
| **Warning: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.** |
| **Warning: To ensure accurate performance and prevent device failure, do not expose the NT1A to extreme moisture such as rain.** |

**Caution: Check the batteries periodically for corrosion. Replace batteries if corrosion is present, otherwise damage to the Oximeter may occur.**

**Note: Use 4 alkaline "AA"batteries. Do not use lithium batteries with the NT1A. Lithium batteries will damage the Oximeter. Do not mix alkaline "AA"batteries with rechargeable batteries. When replacing batteries, replace with four (fresh) new batteries. Do not mix used and new batteries.**

| |
|---|
| **Warning：Do not continue using the batteries if found leaking, its outer protective layer broken, or depleted. Dispose according to local regulations.** |

### 3.3 Installing and Using the Probe

| |
|---|
| **Warning：Before use, carefully read the probe directions for use, including all warnings, cautions, and instructions.** |
| **Warning: Do not use a damaged probe. Do not use a probe with exposed optical components.** |
| **Warning: Use only Solaris sensors for $SpO_2$ measurements. Other sensors may cause improper NT1A performance.** |
| **Warning：When there is a troubleshooting in probe, NT1A can not successfully search to pulse.** |

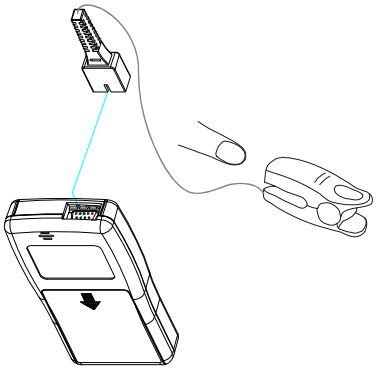


**Figure 3-2：Installing and use the probe**

1. Refer to Figure 3-2, Connect the Oximeter plug to pulse oximeter convex interface.

2. The probe is finger tip oximeter probe. Attach the finger probe with

the light to the patient. Be sure to fully insert the patient's finger into the probe, As following:

1) Use for Finger Sensors, including adult SpO2 probe (S400A) and Pediatric Finger SpO2 Sensor (S400)

Fig. 3-3

Fig. 3-4

Fig.3-5

2) Use for Neonatal Wrap Sensors (W400A/N)

Fig. 3-6

- Biocompatibility Testing

Biocompatibility tests have been conducted on probes in compliance with ISO 10993-1, Biological Evaluation of Medical devices, part 1: Evaluation and Testing. The probes have passed the recommended biocompatibility testing and are therefore, in compliance with ISO 10993-1. These tests include: cell intoxication test, skin stimulation test, and allergy test.

- Performance Considerations

**Warning: Pulse oximetry reading and pulse signal can be affected by certain ambient environmental conditions, probe application errors, and certain patient conditions.**

Inaccurate measurements can be caused by:

- Incorrect application of the probe;
- Placement of the probe on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;

- Ambient light；
- Patient movement.

Loss of pulse signal can occur for the following reasons：

- The probe is too tight；
- A blood pressure cuff is inflated on the same extremity as the one with the probe attached；
- There is arterial occlusion proximal to the probe.

Select an appropriate probe, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the probe. Clean and remove any substances such as nail polish from the application site. Periodically check to see that the probe remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a $SpO_2$ probe. To prevent interference from ambient light, ensure the probe is properly applied, and cover the probe site with opaque material.

**Note: Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.**

If patient movement presents a problem, try one or more of the following remedies to correct the problem.

- Verify that the probe is properly and securely applied.
- Move the probe to a less active site.

**Note: The preceding section pertains to patient and environmental conditions that can be addressed by probe selection and application. For information regarding the**

**impact of other patient and environmental conditions on oximeter performance, see "Performance Considerations" in the Power-On and Use section.**

**Warning: Reposition the probe at least once every 4 hours to allow the patient's skin to respire.**

**Caution: Do not autoclave, ethylene oxide sterilize the device. Clean it with a soft cloth moistened in a mild soap solution and hot water and lightly wipe the surface of the NT1A. If sterilization is required, wipe the probe surfaces with a soft cloth moistened in isopropyl alcohol. Caution, do not allow any liquid to enter any of the NT1A openings.**

# Chapter 4 Power-ON and Use

## 4.1 Basic Operation

| |
|---|
| **Warning: The NT1A is a prescription device and is to be operated by qualified personnel only.** |
| **Warning: Do not lift the oximeter by the probe cable because the cable could disconnect from the oximeter, causing the oximeter to drop on the patient.** |

**Caution: The NT1A is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**

**Important: Prior to using the NT1A, carefully read this manual, accessory direction for use, all precautionary information in boldface type, and all specifications.**

**Note: Before using the NT1A, remove the plastic protective sheet that covers the display. This sheet is only on the display to protect it during shipping. Leaving it on during monitoring could make it difficult to read displayed measurements.**

### 4.1.1 Power-On

1. Install the batteries：The Pulse Oximeter is still power-off. If the batteries were already installed, turn on the NT1A by pressing  key for 2 seconds.

**Caution: If the batteries are insufficient to operate, the power indicator would turn red and blink for three**

**times. Then, NT1A turns itself off if the batteries are still low or installing the batteries fails. This Oximeter may have no response. Please make sure the batteries have enough energy.**

2. If installing the batteries and then power-on is successful, the power indicator light display is green, and will generate “dee”. All displays include：

- All segments of all numeric digits light；
- Pulse indicator；
- Power indicator light；
- Low perfusion indicator.

All display icons stay lit for 1 second.

Make sure that you can hear “dee” sound. If inaudibility occurs, the sound system is damaged, do not continue to use it, contact your provider or manufacturer.

If the sound is low, make sure the holes located on the speaker are not covered. If the volume is still low，do not continue to use the Pulse Oximeter, contact your provider or manufacturer.

Check every display. If any display is not complete, do not continue to use the Pulse Oximeter, contact your provider or manufacturer.

3. During the Power-on, the NT1A automatically conducts a self-test. If the NT1A detects an internal problem, an error tone sounds and the Oximeter displays an Error Code and corresponding number (see Troubleshooting section for error codes). If press key is invalidation, NT1A appears a low voice.

4. If the power-on self-test is normal, the oximeter will display its

software version.

After displaying for approximately 1 second, the Oximeter enters measurement mode.

### 4.1.2 Running Mode

In the normal working condition, there are four modes:

1. If no oximetry probe is inserted, the Pulse Oximeter will turn off automatically in 120 seconds.

2. The oximetry probe has already been inserted, but the probe not attached to the finger, the $SpO_2$% and PR display area has blink"- - -", at the same time, the oximeter will generate lost reminder sound in every 30 seconds. The Pulse Oximeter will be turning itself off automatically if this mode continues in 120 seconds.

3. Pulse search mode: If patient is connected with the probe, the oximeter attempts to search pulse. At the same time, display shows blink"- - -"in $SpO_2$% and PR areas. Normally the search process is approximately 10 seconds. If the pulse search fails, the Pulse Oximeter continues pulse search mode for 120 second.

4. If pulse search is successful, the $SpO_2$% and PR display area will show the patient's $SpO_2$% and PR. Pulse indicator will move with the rhythm of the patient's pulse. Speaker will generate "dee dee" sound with the pulse. The display methods are as follows:

   - $SpO_2$%: percent oxygen saturation;
   - PR: pulse beats per minute (bpm);
   - The frequency of "dee dee" generated by the speaker is closely related to the $SpO_2$%. The higher the $SpO_2$%, the higher the frequency of the tone.

### 4.1.3 Keys Operation

In normal working condition：

- Press  key to turn on or off silencing function.
- Press  key(<3s) to enter power manager setup or $SpO_2$ average time setup.
- Press  key for 2 seconds to turn off the oximeter.
- If press key is invalid, NT1A will sound a one low dee.
- Press and hold  key (>3s) to enter alarm limits and alarm silence intervals setup.

In order to prolong the battery life, the Pulse Oximeter has two power modes：All-on mode and Power-save mode.

In all-on mode, it has no power-save function. More energy could be consumed. In power-save mode, if no key is pressed for 40 seconds, the brightness of the screen will be less; if no key is pressed for 15 minutes, displays will be off automatically. Then if any key is pressed, display will resume.

No matter in all-on mode or in power-save mode, if no patient is connected with the probe and no key is pressed, the Pulse Oximeter will turn itself off automatically in 120 seconds. If the user needs to continue to use it, please press  key for two seconds, the oximeter will be turned on again. When there is not enough power in battery, the oximeter will be turned off by itself too. Please change the batteries in time.

### 4.1.4 Power Mode Setup

In normal working condition, press  once to set power mode. In $SpO_2$ display area “bat” is on. In PR display area “All” and “HLF” are

on. No change is shown in pulse indicator area. "All" indicates all-on mode; "HLF" indicates power-save mode.  or  could be pressed to switch the power modes. After setting, press  twice to exit power-save mode to return to normal mode. Besides, even in all-on mode, if the power is low, the oximeter will switch to power-save mode by itself.

4.1.5 Turn Off

Press  key for 2 seconds to turn off Pulse Oximeter. The device turns off automatically when the batteries are low.

**Warning: To insure the best function, the device should be turned on at least 30 seconds after power-off.**

## 4.2 Average Time Setup

In normal working condition, press  twice to set $SpO_2$ average time. "AVE" will be shown in $SpO_2$ area. In PR area there are three numbers in terms of pulse rate: 4, 8, and 16. Press  or  to select.. After setting, press  once to exit mode setting and return to the normal working situation. If you choose "4" the oximeter is more sensitive, if you choice "16" the measurement is more accurate.

## 4.3 Storage

Remove the batteries from the NT1A before long-term storage, or if the device won't be used for 6 months or more. This protects the device from damage due to batteries leaking acid.

Store the device in its original shipping carton and packing materials to help protect the device from damage during storage.

## 4.4 Environment of Protection

For minimizing risks, discard the used-up batteries and NT1A according to your local government rules, Rosh（2002/95/EC）and WEEE（2002/96/EC）.

## 4.5 Contraindications

The Pulse Oximeter contraindications include the following aspects：

- Excessive patient movement；
- Venous pulsations；
- Intravascular dyes ,such as indocyanine green or ethylene blue；
- Significant levels of dysfunctional haemoglobins;
- Defibrillation.

Ambient environmental conditions and probe application errors can affect pulse oximetry readings. These are discussed in the probe section of this manual and in the probe's directions for use.

The effect of electromagnetic interference on oximetry reading is discussed in the Troubleshooting and Maintenance section of this manual.

# Chapter 5 Alarm Functions

## 5.1 Alarm Type and Level

### 5.1.1 Alarm Type

**Technical alarm:** Technical alarm includes Probe lead-off and low voltage. Its sound is different from physiological alarm. Probe break off is high priority; Low voltage is medium priority.

**Physiological Parameter alarm:** Physiological Parameter alarm includes alarm High/Low limit on both $SpO_2$ and pulse rate. It generates audible alarm sound and visual digit blinking display. The sound can be paused by the operator. The alarm limits can be adjusted and stored. Physiological Parameter alarm level is medium priority.

### 5.1.2 Alarm level:

**High:** When this alarm is on due to the detected data over the pre-set alarm limit by the operator, attention should be given by the doctor, nurse, and the patient himself.

**Medium:** When this alarm is on due to Physiological Parameter alarm is medium priority or low voltage, it may result in inaccurate measurement or malfunction of the device. Attention should be given by the operator.

**Low:** Indicates a common alarm.

## 5.2 Physiological Alarm Limit, Alarm Signal and Alarm Function Testing

### 5.2.1 Physiological Parameter Alarm Limits

The device has alarm default limits. Operator could adjust the alarm limits based on different clinical requirements. The default limit and its adjusting ranges are listed below:

a) $SpO_2$

Alarm High limit range: 30%～100% （default：100%）

Alarm Low limit range: 30%～100% （default：85%）

b) Pulse Rate

Alarm High limit range: 30bpm ～ 250bpm （default: 130bpm）

Alarm Low limit range: 30bpm ～ 250bpm （default: 50bpm）

c) Alarm setting precision should be within testing precision：

$SpO_2$: ±1%, Pulse Rate: ±1 bmp or 2% (take the bigger one)

d) Alarm High limit should not be lower than alarm Low limit.

Please refer to Keys operating instructions to adjust alarm limit and default limit.

| |
|---|
| **Warning: Adjust alarm limits ONLY by authorized personnel.** |
| **Warning: Against alarm limits to extreme values can disable the alarm function.** |

**Warning: Improper alarm limits could delay or void the alarm signals when the patient needs care.**

5.2.2 Physiological Parameter Alarm Signals：

a) Alarm sound

| Identity | High | Medium | Low |
|---|---|---|---|
| Rhythm (One alarm unit) | beep- beep- beep ----beep - beep | beep- beep- beep | beep |
| Alarm unit repeat time Tb(s) | 10 | 15 | 58 |
| Impulse Frequency (Hz) | 2500 | 3000 | 4000 |

b) Visual alarm signal: The digit bars in the display. Flash frequency is 2Hz.

**Warning：The device should be placed within the operator's visible and audible distance (operator's vision should be good, if not, wear eyeglasses). The distance between operator and oximeter should be within 4 meters.**

**Warning：Alarm function may be interfered by ambient light, electromagnetic interference, noise etc.**

### 5.3 Alarm function testing

Set the NT1A $SpO_2$ upper limit as 90% and lower limit as 85%. Turn audio alarm on. Measure the $SpO_2$ on a healthy person's finger. If the display is not within 85% - 90%, the NT1A should sound audio alarm and display visual alarm.

**Note: The NT1A have self-testing function for bio signal alarms. Users should test the alarm functions at least once a year.**

### 5.3.1 Alarm Limit Setup

In the normal mode, press and hold  key for three seconds to enter alarm limit set-up mode, $SpO_2$ display area shows "SPH"（ $SpO_2$ high limit). Press  key to choose parameter setting "SPH" ($SpO_2$ high limit), "SPL" ($SpO_2$ low limit), "PRH" (Pulse Rate high limit), or "PRL" (Pulse Rate low limit). PR display area shows the value of the current parameter setting. Press  or  key to adjust the value. If user keeps the key pressed, the value scrolls fast. Pressing  key for 3 seconds to go back to the normal mode after finishing the settings.

In Alarm limit set-up mode， press and hold  key for 3 seconds, default alarm limits will be re-set.

**Warning: Each time the Oximeter is in use, check alarm limits to ensure that they are appropriately set for the patient being monitored.**

### 5.3.2 Alarm Silence Interval Setup

In the alarm limit setting，continuously press  key，$SpO_2$ display area will show "SPH"→"SPL"→"PRH"→"PRL"→"INT"→"SPH" alternatively，the INT corresponds to the alarm silence intervals，*valid settings are 15sec, 30sec, 60sec, 90sec, 120sec, OFF (Alarm Silence Mode)*. Press  or  key to select. Hold  key for 3 seconds to go back to the normal mode.

When there is no alarm occurrence, press  key to control ON or Off of pulse sound and key sound；when an alarm occurs, press  key to turn off alarm sound, PR sound, and key sound. This key is also for setting up alarm interval function，there are several instances as the following：

- When INT setting as 15sec, 30sec, 60sec, 90sec, 120sec, after this values (e.g. 15 sec. etc.), the silence light will dark; at the same time, all of the pulse sound ,the alarm sound and the key's sound are "ON".

- After alarm silence, press  button one time to open the alarm sound and pulse sound; If it is over the time, press  button one time to keep the silence of the pulse and alarm;

- when INT is setting as "OFF", press  key can turn off the alarm sound ,the key's sound and pulse sound. Until worse alarm condition appears, or patient's $SpO_2$ and PR from no alarm to appears alarm condition, the alarm sound , all of the pulse sound and the key's sound would give back or again press  key, will return the alarm sound, the key's sound and pulse sound;

5.3.3 Resume Default Settings

- To resume all the default settings, press  and  keys simultaneously to turn the device on. The default settings include alarm upper and lower limits, power mode (bat) , average time (AVE) , and alarm silence intervals (INT).

- In normal working mode, press  key once to enter power mode (bat) and average time (AVE) setup. Press and hold  key to resume default settings for power mode (bat) and average time (AVE).

- In normal working mode, press and hold  key to enter alarm limits and alarm silence intervals setup. Press and hold  key to resume default settings for alarm limits and alarm silence intervals.

- When default settings have resumed, NTIA would send out availability sound “de de de ……” until press key is released.

***Attention:*** **If alarm limits are changed from NT1A’s power-on default, a decimal point appears after the displayed value during monitoring or when alarm limits are viewed. The decimal point remains on display until the limit is returned to its default value.**

# Chapter 6 Troubleshooting and Maintenance

| | |
|---|---|
| **Warning:** | **If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the Oximeter is functioning correctly.** |
| **Warning:** | **The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.** |

If you experience a problem while using the NT1A and are unable to correct it, contact qualified service personnel or representative. The NT1A service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

## 6.1 Troubleshooting and Solutions (Refer to Table)

| Problem | Possible Cause | Corrective Action |
|---|---|---|
| No pulse shown on the bar graph. | Probe is disconnected from NT1A;<br>Probe is incorrectly positioned on the patient;<br>Poor patient perfusion;<br>Defective probe. | Check probe connection to the patient and cable to the NT1A;<br>Reposition the probe;<br>Try a new probe or contact your authorized repair center for help. |
| Pulse rate is erratic, intermittent, or incorrect;<br>$SpO_2$% value is erratic, intermittent, or incorrect. | Probe incorrectly positioned;<br>Poor patient perfusion;<br>Patient motion. | Reposition the probe;<br>Patient must remain still to obtain an accurate measurement. |
| NT1A doesn't turn on. | Batteries weak; | Replace the batteries; |

| | | |
|---|---|---|
| | Batteries not installed or batteries incorrectly installed；<br>Internal fuse blown.. | Ensure the batteries are installed correctly；<br>Incorrectly installed batteries may cause an internal fuse to blow．In that case, the NT1A must be sent to an authorized repair center. |
| NT1A turn off unexpectedly. | The NT1A turns itself off automatically two minutes after the probe is removed from the patient or after the probe is disconnected from the NT1A；<br>Batteries are weak or dead. | Connect probe, turn on NT1A again；<br>Replace the batteries. |
| “E01” appears on the Display. | Internal fuse damage. | Contact technical service department. |

## 6.2 Factory Default Settings

NT1A is equipped with factory default settings. To change these settings, refer to instructions in this operating manual.

Default settings

| Value | Settings |
|---|---|
| SpO2 alarm lower limit | 85% |
| SpO2 alarm upper limit | 100% |
| Power mode | ALL |
| Data refresh internal | 8 |
| Alarm silence time internal | OFF |
| Pulse rate alarm lower limit | 50 bpm |
| Pulse rate alarm upper limit | 130bpm |

## 6.3 Obtaining Technical Assistance

For technical information and assistance, or to order parts or a service manual, contact technical service department or your local representative. The service manual includes block diagrams and a parts list required by qualified personnel when servicing the NT1A.

The software version appears on the display screen immediately after the power-on self-test is completed. Write the number down and have it available whenever requesting technical assistance.

The product uses fuses, Details are as follows:Manufacturer : FUZETEC, Model: FSMD160-1812, Specification: 1.6A, 6V.

Product Software version：1.19

## 6.4 Returning NT1A

Contact technical service department or your local representative for shipping instructions including a returned goods authorization number. Remove the batteries before shipping, and unplug the probe. Pack the NT1A in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

## 6.5 Service

**Warning: The cover should be removed only by qualified service personnel. There are no user-service-able parts inside.**

### 6.5.1 Pulse Oximeter

If cleaning is required, wipe the Pulse Oximeter's surfaces with a soft cloth moistened with commercial nonabrasive cleaner. Do not allow

any liquid to enter any of the Pulse Oximeter openings.

| | |
|---|---|
| **Warning:** | **Turn off the Pulse Oximeter before cleaning.** |
| **Warning:** | **Do not autoclave, ethylene oxide sterilize, or immerse the Pulse Oximeter in liquid. If disinfection is required, wipe the Pulse Oximeter's surfaces with a soft cloth moistened with commercial nonabrasive cleaner. Do not allow any liquid to enter any of the Pulse Oximeter's openings.** |
| **Warning:** | **Do not allow any abrasive, instrument, brush and coarse material or touch the Pulse Oximeter's show window.** |
| **Warning:** | **If the pulse oximeter has any exposed internal parts, contact authorized service center. Dispose oximeters according to local regulations.** |

6.5.2 Probe

The probe is the only part touching the patient. Every time the probe is used, it must be cleaned. Refer to the directions for use enclosed with the probe for cleaning directions.

| | |
|---|---|
| **Waring:** | **If $SpO_2$ sensors have any exposed internal parts or wire, contact authorized service center. Dispose $SpO_2$ sensors according to local regulations.** |

## 6.6 Periodic Safety Checks

The following safety checks should be performed every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- Inspect the equipment for mechanical functions (For example：Speaker is working or not； Indicator lamp is working well or not；response of keys is well or not).
- Inspect the safety relevant labels for legibility.
- Verify that the device functions properly as described in this operating manual.

If the oximeter is not functioning properly or fails any of the above tests, do not attempt to repair the oximeter. Please return the oximeter to the manufacturer or to your distributor for any required repairs.

# Chapter 7Appendix

## 7.1 Principles of Measurement

Pulse Oximetry is based on two principles:： Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e. Spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e. plethysmography). A pulse oximeter determines $SpO_2$ by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDS) in the oximetry probe serve as light sources； A photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light. Absorption, the amount of red and infrared light absorbed by blood is related to haemoglobin oxygen saturation. To identify the oxygen saturation of arterial haemoglobin, the Oximeter uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood volume and light absorption increase.

During diastole, blood volume and light absorption reach their lowest point. The Oximeter bases its $SpO_2$ measurements on the difference between maximum and minimum absorption (i.e. Measurements at systole and diastole). Doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of non-pulsatile absorbers such as tissue, bone, and venous blood.

The Pulse Oximeter determines $SpO_2$ and pulse rate by passing two

wavelengths of light, one red and one infrared, through body tissue to a photo detector. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the probe placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissue.

The Pulse Oximeter processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and $SpO_2$) to identify the pulse rate and calculate oxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

## 7.2 Adult Reusable $SpO_2$ Finger Sensor Directions for Use

**Intended Use**

When used with compatible oximeters, this sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation ($SpO_2$) and pulse rate monitoring for patients weighing greater than 40kg.

**Contraindications**

This sensor is contraindicated for use on active patients or for prolonged use.

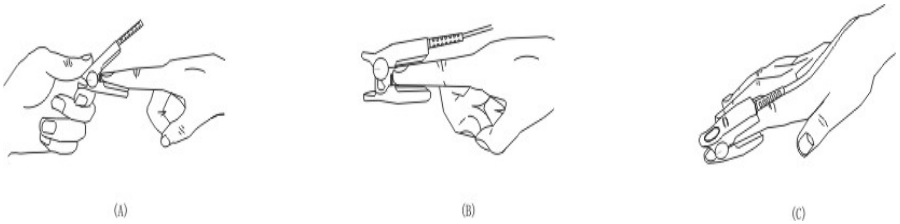
**Instructions for Use**

1. With the upper and lower jaws open, place an index finger evenly on the base of the clip. Push the finger tip against the stop so that it

is over the sensor window (A). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.

**Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.**

2. Spread open the rear tabs of the sensor to provide even force over the length of the pads (B).
3. The sensor should be oriented in such a way that the cable is positioned along the top of the hand (C).
4. Plug the sensor into the oximeter and verify proper operation as described in the oximeter operating manual.
5. Inspect the monitoring site every 4 hours for skin integrity.
6. After use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.




**Caution: Do not sterilize by irradiation steam, or ethylene oxide.**

***Warnings***

1. Some factors may affect the accuracy of saturation measurements. Such factors include：Excessive patient motion,

fingernail polish, use of intravascular dyes, excessive light, poorly per fused finger, extreme finger sizes or improper placement of the sensor.

2. Using the sensor in the presence of bright lights may result in inaccurate measurements.. In such cases, cover the sensor site with an opaque material.
3. The sensor must be moved to a new site at least every 4 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
4. Do not apply tape to secure the sensor in place or to tape it shut; Venous pulsation may lead to inaccurate saturation measurements.
5. Do not use the sensor or other oximetry sensors during MRI scanning.
6. Carefully route cables to reduce the possibility of patient entanglement or strangulation.
7. Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.
8. The surface temperature of this sensor should not be over 41℃. It may burn the patient if it is 41℃.
9. Do not use the sensor if it is damaged.
10. If you have any questions regarding any of this information, contact your local distributor.

***Warranty***

The manufacturer offers a 12-month warranty against manufacturing defects for this product in its undamaged condition.

## 7.3 NT1A Standard Packaging

①Main unit; ② Adult $SpO_2$ finger sensor; ③Wrist Tie; ④Oximeter Base; ⑤ Four dry alkaline batteries

Available $SpO_2$ Sensors for replacement orders

| SN | PN | Description (1.6m cable length) | Icon | Manufacturer |
|---|---|---|---|---|
| 1 | S400A | Adult $SpO_2$ finger sensor |  | Solaris Medical Technology,Inc. |
| 2 | S400P | Pediatric Finger $SpO_2$ Sensor |  | Solaris Medical Technology,Inc. |
| 3 | W400AN | Neonatal Digital $SpO_2$ Wrap sensor |  | Solaris Medical Technology,Inc. |

# Chapter 8 Guarantee

The company offers a 12-month warranty for NT1A Pulse Oximeter from the date of its original purchase to the original purchaser. The company offers a 3-month warranty for $SpO_2$ Probe free of defects from the time of its original purchase.

The warranty does not cover the following:

- The Oximeter series number label is torn off or can not be recognized;
- Damage to the Oximeter resulting from misconnection with other devices;
- Damage to the Oximeter resulting from accidents;
- Changes performed by users without the prior written authorization of the company.

# Chapter 9Technical specification

## 9.1. Performance Index

$SpO_2$%

Measurement Range： 0 ～ 100%;

Measurement Accuracy：at 70% ～ 100% ±3 %

at 0% ～ 69% unspecified

Alarm Upper limit： 30%～100% （default：100%）

Alarm Lower limit： 30%～100% （default：85%）

Permit Error： ±1%

Pulse Rate

Measurement Range： 30 bpm ～ 250 bpm

Measurement Accuracy：1 bpm or ±2%，take the bigger one as standard.

Alarm Upper limit： 30bpm ～ 250bpm （default: 130）

Alarm Lower limit： 30bpm ～ 250bpm （default: 50）

Allowed Error： ±1bpm or ±2% (choose the greater one)

When alarming, screen display data's blink frequency： 2Hz。

Alarm volume：45dB@1 meter，frequency：1000Hz

Delay：＜10 s

**priority**

Alarm sound：high

Reminder sound of pulse oximeter probe lead-off： middle

other reminder sound ： Low

**9.2. Probe Standard type:** Solaris S400A

LED red wavelength： 660nm

LED infrared wavelength： 880~940nm

**9.3. Environmental Requirements**

Working Conditions：

Ambient Temperature：（0 ～ + 40）℃

Relative Humidity Range: ≤95 %, no condensing

Atmospheric Pressure：（70 ～ 106）kPa

Transport/Storage Conditions:

Ambient Temperature：（- 20 ～ +55）℃

Relative Humidity Range: ≤95 %, no condensing

Atmospheric Pressure：（50 ～ 106）kPa

**9.4. Power Requirements**

Four standard “AA”size high energy alkaline batteries are applied on NT1A. The battery life is at least 12 hours.

**9.5. Size and Weight**

Size：130mm(L)×69mm(W)×22mm(H)

Weight (with batteries installed)：195g

(without batteries installed)： 100g

**9.6. The equipment cclassifications**

- Type of Protection：Internally Powered
- Degree of Protection：Type BF
- Enclosure Degree of Protection：IPX1
- Operation Mode： continuous operation

# Chapter10EMCElectro-Magnetic Compatibility）

**Caution: The Oximeter complies with the limits for medical devices to IEC60601-1-2: 2007, EN60601-1-2:2007, Medical Device Directive 93/42/EEC, and this oximeter has been tested for CISPR 11 1 group class A.**

**Guidance and Manufacturer's Declaration-Electromagnetic Emissions**

**For all EQUIPMENT and SYSTEMS**

| **Guidance and manufacturer's declaration-electromagnetic emission** | | |
|---|---|---|
| The *NT1A Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer of the user of the *NT1A Pulse Oximeter* should assure that it is used in such environment. | | |
| **Emission test** | **Compliance** | **Electromagnetic environment-guidance** |
| RF emissions<br>CISPR 11 | Group 1 | The *NT1A 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<br>CISPR 11 | Class B | |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Not applicable | |

## Guidance and manufacture's declaration-electromagnetic immunity

### For all EQUIPMENT and SYSTEMS

| Guidance and manufacturer's declaration-electromagnetic immunity | | | |
|---|---|---|---|
| The *NT1A Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of *NT1A 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 | air±6 kV contact ±8 kV air | air±6 kV contact ±8 kV 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 manufacturer's declaration-electromagnetic immunity-

### For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration-electromagnetic immunity</th></tr>
<tr><td colspan="4">The NT1A Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of NT1A Pulse Oximeter should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF<br>IEC 61000-4-6</td><td>3 Vrms<br>150 kHz to 80 MHz</td><td>3 Vrms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the NT1A Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br><br>$\mathbf{d} = \left[\frac{3.5}{V1}\right]\sqrt{P}$<br><br>$\mathbf{d} = \left[\frac{3.5}{E1}\right]\sqrt{P}$ 80 MHz to 800 MHz<br><br>$\mathbf{d} = \left[\frac{7}{E1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz</td></tr>
<tr><td>Radiated RF<br>IEC 61000-4-3</td><td>3 V/m<br>80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
</table>

| | | | |
|---|---|---|---|
| | | | 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 metres (m).<br><br>Field strengths from fixed RF transmitter as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [b].<br><br>Interference may occur in the vicinity of equipment marked with the following symbol.<br><br>  |

NOTE 1 At 80 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 NT1A Pulse Oximeter is used exceeds the applicable RF compliance level above, the NT1A 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 NT1A Pulse Oximeter.

.b.Over the frequency range 150 kHz to 80MHz. Field strengths should be less than 1 V/m.

**Recommended separation distances between portable and mobile RF**
**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 *NT1A Pulse Oximeter*** | | | |
|---|---|---|---|
| The *NT1A Pulse Oximeter* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *NT1A Pulse Oximeter* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *NT1A 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 $\mathbf{d} = \left[\frac{3.5}{V1}\right]\sqrt{P}$ | 80 MHz to 800 MHZ $\mathbf{d} = \left[\frac{3.5}{E1}\right]\sqrt{P}$ | 800 MHz to 2.5 GHz $\mathbf{d} = \left[\frac{7}{E1}\right]\sqrt{P}$ |
| 0.01 | 0.11 | 0.11 | 0.23 |
| 0.1 | 0.37. | 0.37 | 0.73 |
| 1 | 1.1 | 1.1 | 2.3 |
| 10 | 3.7 | 3.7 | 7.3 |
| 100 | 11 | 11 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

**Note1： At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.**

**Note2： These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (for example, cellular phones, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

The NT1A can generate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source：

- Turn equipment in the vicinity off and on to isolate the offending equipment ；
- Reorient or relocate the other receiving device；
- Increase the separation between the interfering equipment and this equipment.

If assistance is required, contact Technical Service Department or your local representative.