



## Adult Mask - Instructions for Use

**Model:** ReDe Mask Adult  
**Part Number:** RDM-001-000001-0

### Indications for Use

The ReDe Mask is indicated for use by healthcare professionals in healthcare facility procedural areas and recovery rooms as an adjunct to monitor breathing in adult patients who are sedated for a diagnostic or therapeutic procedure. The ReDe Mask measures the time period between the current and previous exhalation and illuminates a colored light during the exhalation that reflects the interval of time between breaths. If the interval is less than 7.5 seconds, the green light illuminates during exhalation; if the interval is greater than 7.5 seconds but up to 20 seconds, the yellow light illuminates during exhalation; and if the interval between breaths is 20 seconds or longer, the red light flashes continuously. The ReDe Mask is only to be used when supplemental oxygen is provided by the facemask. The ReDe Mask is not a standalone device and is only to be used as an adjunct to pulse oximetry.

### Principle of Operation

The ReDe Mask is designed to detect breathing events (cycles of inhalation followed by exhalation) by measuring temperature changes in the immediate vicinity of a patient's nose and/or mouth. Exhalations produce a temperature warming as expired air exits the mouth and nose, while inhalations result in a temperature cooling as ambient air and supplied oxygen enter the mask. The overall pattern is thus one of repeating periods of a warming and a cooling phase with every breath. The rate of warming and cooling, that is, the slope of the temperature change (degrees C per unit time) depends on the vigor with which the patient is breathing, which can range from very shallow breathing (small slope values) to vigorous breaths (large slope values). The ReDe Mask's breath detection algorithms are based on continuously measuring the warming and cooling slopes coupled with real-time analysis to determine the changeover point from negative slope (inhalation phase) to positive slope (exhalation phase). It is the detection of *inflection points* in the slope (negative to positive) that yield the elapsed time period between successive breaths. With each new breath the elapsed time between inflection points is used to determine which LED to illuminate.

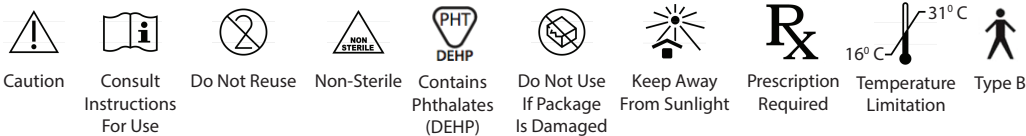
### Calculation of Instantaneous Breathing Rate

The breathing rate is the inverse of the period as measured by the ReDe Mask. Dividing the period into 60 seconds yields the instantaneous breathing rate as breaths per minute (BPM) for that breath. A period of 20 seconds is 3 BPM. A period of 7.5 seconds is 8 BPM. Use this information to help translate the colored light indications into meaningful instantaneous breathing rate information as follows. Note that the red light only flashes at a constant 4 Hz to alert that the calculated instantaneous breathing rate is less than 3 BPM.

### Warnings

- The ReDe Mask is not intended to replace capnography during moderate to deep sedation, or any other time that capnography is indicated for monitoring ventilation.
- The ReDe Mask is not a standalone device and is only to be used as an adjunct to pulse oximetry.
- The ReDe Mask should not be used in the MRI suite.
- The ReDe Mask should not be used by healthcare providers with color blindness.
- Do not obstruct visibility of the ReDe Mask. Bedside proximity and line of sight must be maintained to visualize the light illuminations.
- Do not place the ReDe Mask into any solution or attempt to clean it with any solutions and do not place the ReDe Mask in an autoclave or a Steris. Doing so will damage the electronic circuit and cause the ReDe Mask to malfunction.
- The ReDe Mask is for single use only; it must be discarded after use and must not be re-used. Reuse may cause cross infection.
- The ReDe Mask requires a prescription.
- The ReDe Mask may be put in the trash unless specific Restrictions of Hazardous Substances (RoHS) regulate otherwise.
- Breathing response rate: 0 to 45 breaths per minute
- Tidal volume: 100 to 500 ml
- Working oxygen gas flow rate: 1 to 6 liters per minute
- Ambient operating temperature: 16° to 31° C (61° to 88° F)
- Humidity: 50% RH
- Storage temperature: -20° to 55° C (-4° to 131° F)
- Battery life: Max - 8 hours
- Battery: Not replaceable
- Shelf life: 1 year from date of manufacture

### Symbols



### Applied Parts: Mask and Mask Tubing

1. Attach distal end of the oxygen line to the oxygen source. Adjust liter flow as prescribed.
2. Center the ReDe Mask over the mouth and nose of the patient while stretching the elastic strap behind the patient's head.
3. Crimp the metal band over the patient's nose so the mask conforms to the nose and the edges of the mask do not contact the patient's eyes.
4. Slide the power switch to the ON position. All indicator lights will rapidly blink three times to indicate that it is working correctly.

## How to Interpret the Indicator Lights (Maintain a Line of Sight to the Lights)

**IMPORTANT - If the power-on sequence of Green-Yellow-Red lights, which repeats three times, is not immediately displayed when turning on the switch, the ReDe Mask should not be used. Note the occurrence of other non-normal or error conditions as listed below.**

NORMAL USAGE		
Indicator Light	Pattern	Status
Green-Yellow-Red	Three repetitions	Normal startup sequence when unit is powered on.
Green	Illumination on each breath	Current breath interval is less than 7.5 seconds.
Yellow	Illumination on each breath	Current breath interval is greater than 7.5 seconds but up to 20 seconds.
Red	Rapid flashing	Current breath interval is 20 seconds or longer.

The following table indicates how to interpret the lights under non-normal or error conditions.

NON-NORMAL or ERROR CONDITIONS		
Indicator Light	Pattern	Status
Green-Yellow-Red	Simultaneous flashing of all lights	Unit is nearing expiration and will shut down in 15 minutes.
Red-Yellow-Green	Slow sequential R-Y-G flashes	Unit has expired. Discard and replace unit.
Yellow-Green	Rapid sequential flashing of yellow and green light immediately after startup	Firmware has failed validation. Discard and replace unit.
Green-Red	Simultaneous flashing of green and red light	Either temporary out-of-range for thermistor temperature or broken thermistor. Out-of-range will self-correct if/when thermistor comes back into range. Broken thermistor requires you to discard and replace unit.

## Troubleshooting the ReDe Mask

If the monitoring module of the ReDe Mask should stop functioning within 8 hours of use, the following actions should be taken:


1. Confirm that the device power switch is in the "ON" position.
  - a. If not in the "ON" position, move the power switch to the "ON" position and verify that the device continues to work. The ReDe Mask may have been inadvertently turned OFF.
2. Confirm that the ReDe Mask has not been used for over 8 hours.
  - a. If the device has been used for over 8 hours, the working life of the ReDe Mask has expired. Discard ReDe Mask and replace with a new unit.
3. Turn the power switch to the "OFF" position, wait 5 seconds then turn the power switch to the "ON" position.

## Standards Compliance

IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012

- Internally powered ME equipment
- Type B applied part
- Continuous operation

IEC 60601-1-2:2007

- Class B, Group 1 RF Emissions
- Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
- Interference may occur in the vicinity of equipment marked with the following symbol: 

## Manufacturer's Declarations

### Guidance and Manufacturer's Declaration – Electromagnetic Emission – for all EQUIPMENT AND SYSTEMS


Guidance and Manufacturer's Declaration – Electromagnetic Emission		
The RDM-001-000001-0 ReDe Mask Adult is intended for use in the electromagnetic environment specified below. The customer or the user of RDM-001-000001-0 ReDe Mask Adult should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The RDM-001-000001-0 ReDe Mask Adult 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 Emissions CISPR 11	Class B	The RDM-001-000001-0 ReDe Mask Adult 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 Manufacturer's Declaration – Electromagnetic Immunity – for all EQUIPMENT AND SYSTEMS**

<b>Guidance and Manufacturer's Declaration – Electromagnetic Immunity</b>			
The RDM-001-000001-0 ReDe Mask Adult is intended for use in the electromagnetic environment specified below. The customer or the user of the RDM-001-000001-0 ReDe Mask Adult 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 floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles < 5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RDM-001-000001-0 ReDe Mask Adult requires continued operation during power mains interruptions, it is recommended that the RDM-001-000001-0 ReDe Mask Adult be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) 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.
NOTE: U <sub>T</sub> is the a. c. mains voltage prior to application of the test level.			

**Guidance and Manufacturer's Declaration – Electromagnetic Emission – for all EQUIPMENT AND SYSTEMS that are not LIFE SUPPORTING**

<b>Guidance and Manufacturer's Declaration – Electromagnetic Immunity</b>			
The RDM-001-000001-0 ReDe Mask Adult is intended for use in the electromagnetic environment specified below. The customer or the user of the RDM-001-000001-0 ReDe Mask Adult should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the RDM-001-000001-0 ReDe Mask Adult, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[ \frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$  where <i>p</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in

			<p>metres (m).<sup>b</sup></p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> 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 RDM-001-000001-0 ReDe Mask Adult is used exceeds the applicable RF compliance level above, the RDM-001-000001-0 ReDe Mask Adult should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

**Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE SUPPORTING**

<b>Recommended separation distances between portable and mobile RF communications equipment and the RDM-001-000001-0 ReDe Mask Adult</b>			
The RDM-001-000001-0 ReDe Mask Adult is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RDM-001-000001-0 ReDe Mask Adult can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RDM-001-000001-0 ReDe Mask Adult as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter  W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	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	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	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.			
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.			



## Manufacturer



TereoPneuma  
13223 Black Mountain Rd  
Ste 1-224  
San Diego CA 92129  
USA  
Tel 858 842 5036  
Fax 858 842 5037

## Warranty

TereoPneuma warrants the ReDe Mask against faulty materials or manufacturing defects for a period of one (1) year from the date of purchase. Warranty applicable only if purchased from an authorized distributor. TEREOPNEUMA DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

## Service

United States TereoPneuma  
13223 Black Mountain Rd  
Ste 1-224  
San Diego CA 92129  
USA

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