

REMEDY

Use and maintenance book



REF AN-6016 (GIMA 28107)



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Gima S.p.A.

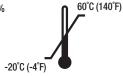
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MODEL AN-6016

Rhinitis Reliever

OPERATION GUIDE

INDEX

1
1
2
2
2
2
3
3
4
4
4
5
5
6
7

INTRODUCTION

Millions of people suffer from allergic rhinitis and / or hayfever. The suffering is often a lot worse in the summer months due the presence of pollen and sufferers can become desperate to relieve the symptoms of their allergies.

The Andon Medical Rhinitis Reliever is an innovative and effective treatment for the relief of those irritating symptoms associated with allergic rhinitis like watery eyes, runny nose and sneezing. It is safe, quick and easy to use and some people may feel an improvement after just a few treatments.

These symptoms above are caused by the body's reaction to allergens. When the body comes into contact with allergens (e.g. pollen, dust pet hair), it produces increased amounts of antibodies which cause certain cells to release histamine. It is histamine that triggers the symptoms of allergic rhinitis and/or hayfever.

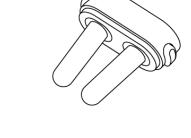
The Andon Medical Rhinitis Reliever works by using phototherapy of two different wavelengths. One wavelength will produce small quantities of heat to promotes increased blood flow and circulation and the second wavelength (red light therapy) suppresses the cells that release histamine and reduces inflammation, thereby relieving the irritating symptoms of allergic rhinitis.

The Andon Medical Rhinitis Reliever can be used alone or alongside your normal allergy medication.

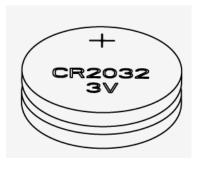
CONTENTS AND DISPLAY INDICATORS



1 Mainframe



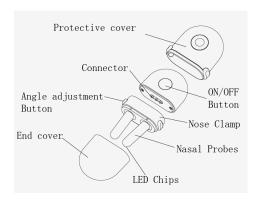
2 Nose Clamp



3 Battery



4 Operation Guide



Note: The pictures in the manual are for reference only.

INTENDED USE

The Rhinitis Reliever is an innovative and effective treatment for the relief of those irritating symptoms associated with allergic rhinitis like watery eyes, runny nose and sneezing.

PACKAGE CONTENTS

- 1 Mainframe
- 1 Operation Guide
- 2 batteries
- 2 Nose Clamp
- 1 Protective cover

CONTRAINDICATION

The device is safe for all people, with the following exceptions or the people who are receiving physiotherapy.

- 1) Keep the device out of the reach of children.
- 2) Not suitable for use with a pacemaker or other implanted medical devices.
- 3) Not suitable for persons with Nasal Polyposis, sensitive skin in the nose or with poor circulation.

PRODUCT DESCRIPTION

The AN-6016 is a battery operated, which works by using phototherapy of two different wavelengths, such as 652 nm (red light) & 940 nm (infrared light). Only one button to turn on or turn off the unit, it is very easy to use and portable.

The AN-6016 corresponds to the below standards:

IEC 60601-1Edition 3.1 2012-08/EN 60601-1:2006/A1:2013 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance).

IEC60601-1-2:2014/EN 60601-1-2:2015(Medical electrical equipment -- Part 1-2: General

requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests).

SPECIFICATIONS

1. Product name: Rhinitis Reliever

2. Model: AN-6016

3. Technology of Treatment: Dual wavelength phototherapy

4. Illuminate Position: Nostrils

5. Wavelengths used: 652 nm & 940 nm

- 6. Classification: Internally powered, Type BF applied part, IP22, No AP or APG, Continuous operation
- 7. Emitting Mode: Continuous Mode
- 8. Light power:3mW-6mW
- 9. Operating Time: Approximately 3 minutes
- 10. Machine size: Approx. 70mm×39mm×17mm
- 11. Weight: Approx. 21g (exclude batteries)
- 12. Power source: batteries: 2 × 3V --- CR2032 alkaline
- 13. Environmental temperature for operation: 15°C 40°C (59°F 104°F)
- 14. Environmental humidity for operation: 30% 85%RH
- 15. Environmental temperature for storage and transport: -20°C 60°C (-4°F 140°F)
- 16. Environmental humidity for storage and transport: 30% 85% RH
- 17. Environmental pressure: 80kPa-105kPa
- 18. Battery life: Approximately 30 uses (3 minutes each use).
- 19. The applied part can arrived maximum temperature 48°C (118.4°F) .

Note: These specifications are subject to change without notice.

NOTICE

- 1. Read all of the information in the operation guide and any other literature in the box before operating the unit.
- 2. Children under 16 must be supervised by an adult when using this product.
- 3. Keep out of reach of children.
- 4. Never look directly at the light, even when using an optical instrument (for example glasses).
- 5. Avoid using the device in the vicinity of flammable or anaesthetic gases.
- 6. Do not use the device if you are connected to, or in the vicinity of high-frequency surgical or industrial equipment.
- 7. Do not use the device in the direct vicinity of short-wave or microwave equipment.
- 8. Only Andon accessories should be used with the uint.
- 9. Information regarding potential electromagnetic or other interference between the Rhinitis Reliever and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the Rhinitis Reliever be kept at least 30 cm away from other wireless devices, such as WLAN

unit, microwave oven, etc. It can't be used near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magneticresonance imaging, where the intensity of EM DISTURBANCES is high.

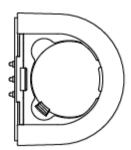
- 10. Please do not share the device with other infective person to avoid cross-infection.
- 11. Please do not knock down, repair, and rebuild it privately.
- 12. Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- 13. If there is unexpected operation or event, please contact the local distributor or the factory.
- 14. Don't twine the cables around you body ,it may cause strangulation.
- 15. Swallowing batteries and/or battery fluid can be extremely dangerous. Keep the batteries and the unit out of the reach of children and disabled persons.
- 16. If you are allergic to plastic, please don't use this device.
- 17. The patient is an intended operator.

SETUP AND OPERATING PROCEDURES

1. BATTERY LOADING

- a. Open battery cover at the back of the device.
- b. Load CR2302 batteries. Please pay attention to polarity.
- c. Close the battery cover.







When the buzzer sounds 5 times in a row, replace all batteries with new ones.

Remove the batteries if the device will not be used for a month or more to avoid relevant damage of battery leakage.

Rechargeable batteries are not suitable for this device.

Please do not mix use new and old batteries or different type of batteries.

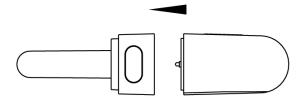
Please do not throw battery into fire.

Avoid getting battery fluids in your eyes,if it happens,immediately rinse with plenty of clean water and contact a physician.

Make sure the battery cover is intact and not damaged before installing the battery.

2. OPERATING INSTRUCTIONS

1) Suction nose clamp to the mainframe.



- 2) Insert the two nasal probes into the nose as far as is comfortably possible.
- 3) Press the ON/OFF button once to turn the unit on. The buzzer sound once and The two wavelengths are activated.
- 4) One treatment cycle lasts for approximately 3 minutes. The unit will automatically turn off after the treatment cycle is over. If you need to turn the unit off during treatment, press the ON/OFF button.
- 5) The Andon Rhinitis Reliever can be used three to four times per day. Allow five to six hours between each treatment.

Note: If you feel any discomfort or pain at any time during treatment, turn the unit off and stop use immediately. Consult your provider for advice.

TROUBLESHOOTING

Problems	Cause	Solution
	Batteries are not installed or low power.	Install or change the batteries as necessary.
Can not turn on the Device	Batteries are not installed correctly.	Check batteries are inserted correctly. Re-insert batteries observing the correct polarity.
	Did not press the "ON/OFF" button	Press the "ON/OFF" button again.
At the sound of the buzzer, the two treatment lights do not light up or one lights up	The nose clamp does not fit properly into the mainframe.	Suction nose clamp to the mainframe again.
Shut off after hearing the buzzer for 5 times	Low battery	Replace with new batteries.

MAINTENANCE

- Remove the batteries if the device will not be used for a month or more to avoid relevant damage of battery leakage.
- 2. This product is not waterproof. Do not clean with any liquid cleaner.
- 3. To clean the unit, use a damp cloth to wipe the surface and nasal probes. Do not allow any liquid to enter the main unit. Do a cleaning after each use is suggested.
- 4. No component can be maintained by user in the device. The circuit diagrams, component part lists, descriptions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairably can be supplied by us.

- 5. The apparatus and the nasal probes can maintain the safety and performance characteristics three years.
- 6. Do not modify this equipment without authorization of the manufacturer.
- 7. No servicing/maintenance while the monitor is in use.
- 8. Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
- 9. The monitor requires 6 hours to warm from the minimum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.
- 10. The monitor requires 6 hours to cool from the maximum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.

EXPLANATION OF SYMBOLS ON UNIT

	<u> </u>		
	Imported by		
†	Type CF applied part, with defibrillation-proof function		
SN	Serial number		
<u></u>	Manufacturer		
	Date of manufacture		
LOT	Lot number		
€	Atmospheric pressure limit		
*	Temperature limit		
Ø	Humidity limit		
C€	Medical Device compliant with Directive 93/42/EEC		
EC REP	Authorized representative in the European community		
	Follow instructions for use		
REF	Product code		
IP22	Covering Protection rate		
	WEEE disposal		

WARRANTY INFORMATION

Only charge the cost of components and transport.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11	Home healthcare environment
	Group 1, Class	
	В	

Table 2 - Enclosure Port

Phenomenon	Basic EMC	Immunity test levels
	standard	Home Healthcare Environment
Electrostatic	IEC 61000-4-2	±8 kV contact
Discharge		±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM	IEC 61000-4-3	10V/m
field		80MHz-2.7GHz
		80% AM at 1kHz
Proximity fields	IEC 61000-4-3	Refer to table 3
from RF wireless		
communications		
equipment		
Rated power	IEC 61000-4-8	30A/m
frequency		50Hz or 60Hz
magnetic fields		

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency	Band	Immunity test levels
(MHz)	(MHz)	Professional healthcare facility
		environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, \pm 5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		

1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		



Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

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