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IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential Performance

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Address ..... :	Northeast 3/4/5 Floor, C1 Block, No.9 Changyang Road, West Tahiu Lake, International Medical Industrial Park, 213145, Changzhou, Jiangsu, P.R. China

Test specification:

Standard ..... :	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure ..... :	CB Scheme
Non-standard test method……..:	None

Test Report Form No. ..... :	IEC60601_1K
Test Report Form Originator ..... :	UL(US)
Master TRF ..... :	2015-11

General disclaimer:

The test results presented in this report relate only to the object tested.

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Test item description ..... : Trade Mark ..... : Manufacturer ..... : Model/Type reference ..... : Ratings ..... :	**Mesh Nebulizer** Changzhou Zhengyuan Medical Technology Co., Ltd. **YS37** DC 3V(2"AA" Alkaline Battery) Or AC adapter(input: 100 ~240V,50/60Hz; Output: DC3 ~ 5V,1~2A)	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
[X] **CB Testing Laboratory**:	Electrosuisse	
Testing location/ address :	Luppmenstrasse 1, 8320 Fehraltorf SWITZERLAND	
[ ] **Associated CB Testing Laboratory:**		
Testing location/ address ..... :		
Tested by (name, function, signature) ..... :	Regis Juillerat Project engineer	
Approved by (name, function, signature) ..... :	Karim Badr Project engineer	

Electromagnetic Compatibility Information

Guidance and manufacturer’ s declaration - electromagnetic emission		
The YS37 Mesh Nebulizer is intended for use in the electromagnetic environment specified below . The customer or the user of YS37 Mesh Nebulizer should assure that it is used in such an enviroment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR11	Group 1	The YS37 Mesh Nebulizer 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 CISPR11	Class B	
Harmonic emissions IEC61000-3-2	N/A	The YS37 Mesh Nebulizer 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.
Voltage fluctuations/flicker emissions IEC61000-3-3	N/A	

Guidance and manufacturer's declaration -electromagnetic immunity			
The YS37 Mesh Nebulizer is intended for use in the electromagnetic environment specified below . The customer or the user of YS37 Mesh Nebulizer should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC61000-4-2	±8KV contact ±15KV air	±8KV contact ±15KV air	Floor 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 IEC61000-4-4	±2KV for power supply lines ±1KV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC610000-4-5	±1KV differential mode ±2KV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips ,short interruption and voltage variations on power supply input lines IEC61000-4-11	＜5%UT, (＞95% dip in U_T) for 0.5cycle 40%U_T, (60% dip in U_T) For 5 cycels 70%U_T, （30% dip in U_T） For 25 cycles ＜5%U_T, (＞95% dip in U_T) For 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the YS35 Mesh Nebulizer requires continued operation during power mains interruptions, it is recommended that the YS35 Mesh Nebulizer be powered from an uninterruptible power supply or a battery
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration -electromagnetic immunity			
The YS37 Mesh Nebulizer is intended for use in the electromagnetic environment specified below . The customer or the user of YS37 Mesh Nebulizer should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC610000-4-6	3V/m 150kHz to 80MHz	N/A	Portable and mobile RFcommunications equipment should be used no closer to any part of the YS35 Mesh Nebulizer,including cables,than the recommended separation distance calculate from the equation applicable to the frequency of the transmitter Recommended Separation Distance $d=[\frac{3.5}{V1}]\sqrt{P}$ $d=[\frac{3.5}{E1}]\sqrt{P}$ 80 MHz~800 MHz $d=[\frac{7}{E1}]\sqrt{P}$ 800 MHz~2.5 GHz Where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RFtransmitters , as determined by an electromagnetic site survey, should be less than the compliance
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.7GHz	3V/m	

			level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80MHz and 800MHz, the higher frequency range applies NOTE2 These guidelines may not apply in all situations. Electromagnetic 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 cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to the YS37 Mesh Nebulizer is used exceeds the applicable RF compliance level above, the YS37 Mesh Nebulizer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting the YS37 Mesh Nebulizer. b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

Recommended separation distance between

Portable and mobile RF communications equipment and the YS37Mesh Nebulizer

The YS37 Mesh Nebulizer is intended for use in an electromagnetic environment in which Radiated RF disturbances are controlled. The customer or the user of the YS37 Mesh Nebulizer can help prevent electromagnetic interference by maintaining a minimum distance between portable an mobile RF communications equipment (transmitters) and the YS37 Mesh Nebulizer as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**		
	150KH～80MHz $d=[\frac{3.5}{V1}]\sqrt{P}$	80 MHz～800 MHz $d=[\frac{3.5}{E1}]\sqrt{P}$	800MHz～2.5 GHz $d=[\frac{7}{E1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0..38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	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 equuation applicable to the frequency of the transmitter, where P is the maximmum output power rating of the transmitter in wats (w) according to transmitter manufacturer.

NOTE1 At 80Mhz and 800MHz,the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Product Specification

Name	Mesh Nebulizer
Model	YS37
Dimensions	45mm(L) * 45mm (W) * 115mm(H)
Power Source	DC 3V(2”AA” Alkaline Battery) Or AC adapter(input: 100 ~240V,50/60Hz; Output: DC3 ~ 5V,1~2A)
Safety Grade	BF
Power Consumption	Approx. 1.5W
Vibration Frequency	120KHz±10%
Nebulization Rate	>0.2ml/min
Medicine Temperature	<41°C
Working Voice	<50dB
Particle Size	5μm±25%
Medicine Capacity	8ml maximum, 05ml minimum
Battery Life	Nebulize continuously approximately an hour and a half The device can be used for approximately 4 days if operating for 20 minutes a day by 2 “AA” Alkaline Battery
Guarantee Time	Main Unit 12 Months (medicine bottle not included); Medicine Bottle 3 Months
Operating Temperature	Environmental Temp: 10 °C ~ 40°C, Relative Humidity <80%R.H., not in Coagulation situation Air Pressure: (70.0 ~ 106.0) kPa
Storage Temperature	Environmental temperature: -20 °C ~ 55°C Relative Humidity <80%R.H. Air Pressure: (70.0 ~ 106.0) kPa
Accessory	Adult Mask, Child Mask, Mouth Piece, Lithium Battery (Option), Instruction Manual, Certification, Warranty Card, Carry Pouch

Guidance and manufacturer's

Item	Applied standard	Result
Emission Measurement		
Radiated emission	IEC 60601-1-2:2014 CISPR11:2009+A1:2010	PASS
Conducted disturbance	IEC 60601-1-2:2014 CISPR11:2009+A1:2010	Not applicable
Harmonic current emission (harmonic)	IEC 60601-1-2:2014 IEC 61000-3-2:2005+A1:2008+A2:2009	Not applicable
Voltage fluctuations & Flicker (Flicker)	IEC 60601-1-2:2014 IEC 61000-3-3:2013	Not applicable
Immunity Measurement		
Electrostatic discharge	IEC 60601-1-2:2014 IEC 61000-4-2:2008	PASS
RF field strength susceptibility	IEC 60601-1-2:2014 IEC 61000-4-3:2006+A1:2007+A2:2010	PASS
Electrical fast transients/burst test	IEC 60601-1-2:2014 IEC 61000-4-4:2012	Not applicable
Surges test	IEC 60601-1-2:2014 IEC 61000-4-5:2005	Not applicable
Conducted susceptibility test	IEC 60601-1-2:2014 IEC 61000-4-6:2013	Not applicable
Power-frequency magnetic Field susceptibility test	IEC 60601-1-2:2014 IEC 61000-4-8:2009	PASS
Voltage dips and interruptions test	IEC 60601-1-2:2014 IEC 61000-4-11:2004	Not applicable

Declaration-electromagnetic emissions

Contact information

Manufacturer Information:

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